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Anhang 4-G1: Zusatzanalysen, TULIP-1, TULIP-2, TULIP-1+TULIP-2, MUSE, TULIP-1+TULIP-2+MUSE, ITT-Population, nur in Deutschland zugelassene Medikamente

Contents

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Subject disposition and summary of treatment exposure
Full analysis set

		Anifrolumab 300mg (N=127)	Placebo (N=125)
Patients who completed the study		105 (82.7)	98 (78.4)
Patients withdrawn from the study		22 (17.3)	27 (21.6)
WITHDRAWAL BY SUBJECT		9 (7.1)	12 (9.6)
ADVERSE EVENT		8 (6.3)	3 (2.4)
LACK OF EFFICACY		3 (2.4)	6 (4.8)
OTHER		1 (0.8)	2 (1.6)
CONDITION UNDER INVESTIGATION WORSENED		1 (0.8)	1 (0.8)
LOST TO FOLLOW-UP		0	2 (1.6)
SEVERE NON-COMPLIANCE TO PROTOCOL		0	0
Duration of study (weeks)	n (missing)	127 (0)	125 (0)
	Mean (SD)	50.5 (11.28)	50.1 (11.44)
	Median	52.4	52.3
	Min, Max	0, 70	5, 70
Patients who completed investigational product		104 (81.9)	97 (77.6)
Patients discontinued investigational product		23 (18.1)	28 (22.4)
Withdrawal By Subject		10 (7.9)	10 (8.0)
Adverse Event		8 (6.3)	6 (4.8)
Lack Of Efficacy		2 (1.6)	6 (4.8)
Condition Under Investigation Worsened		1 (0.8)	4 (3.2)
Severe Non-Compliance To Protocol		0	1 (0.8)
Other		2 (1.6)	0
Lost To Follow-Up		0	1 (0.8)
Duration of exposure (weeks)	n (missing)	127 (0)	125 (0)
	Mean (SD)	46.7 (13.39)	46.5 (12.72)
	Median	52.1	52.1
	Min, Max	4, 55	4, 54
Number of Infusions	n (missing)	127 (0)	125 (0)
	Mean (SD)	11.3 (3.32)	11.4 (3.26)
	Median	13.0	13.0
	Min, Max	1, 13	1, 13
Subjects enrolled to the LTE study		89 (70.1)	83 (66.4)

Duration of study defined as time from randomization until end of participation date.
Duration of exposure defined as difference of date of first exposure to treatment and date of last exposure to treatment + 28 days.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Demographic and baseline characteristics
Full analysis set

		Anifrolumab 300mg (N=127)	Placebo (N=125)	Total (N=252)
Age	n (missing)	127 (0)	125 (0)	252 (0)
	Mean (SD)	41.9 (11.74)	40.7 (11.95)	41.3 (11.84)
	Median	40.0	41.0	40.0
	Min, Max	19, 68	20, 69	19, 69
Age subgroups (%)	<= 65	122 (96.1)	123 (98.4)	245 (97.2)
	> 65	5 (3.9)	2 (1.6)	7 (2.8)
Sex (%)	female	115 (90.6)	117 (93.6)	232 (92.1)
	male	12 (9.4)	8 (6.4)	20 (7.9)
Race (%)	American Indian or Alaska Native	0	1 (0.8)	1 (0.4)
	Asian	7 (5.5)	3 (2.4)	10 (4.0)
	Black or African American	22 (17.3)	14 (11.2)	36 (14.3)
	Other	13 (10.2)	11 (8.8)	24 (9.5)
	White	85 (66.9)	96 (76.8)	181 (71.8)
Ethnicity (%)	Hispanic/Latino	23 (18.1)	24 (19.2)	47 (18.7)
	Non-hispanic/Latino	104 (81.9)	101 (80.8)	205 (81.3)
Geographic region (%)	Asia Pacific	6 (4.7)	2 (1.6)	8 (3.2)
	Europe	47 (37.0)	56 (44.8)	103 (40.9)
	Latin America	18 (14.2)	18 (14.4)	36 (14.3)
	North America	53 (41.7)	46 (36.8)	99 (39.3)
	Rest Of World	3 (2.4)	3 (2.4)	6 (2.4)
Geographic region subgroup (%)	EU	47 (37.0)	56 (44.8)	103 (40.9)
	non-EU	80 (63.0)	69 (55.2)	149 (59.1)
Height (cm)	n (missing)	127 (0)	125 (0)	252 (0)
	Mean (SD)	163.31 (7.648)	162.81 (8.202)	163.06 (7.916)
	Median	163.00	162.60	162.60
	Min, Max	145.0, 183.0	140.0, 195.0	140.0, 195.0
Weight (cm)	n (missing)	127 (0)	125 (0)	252 (0)
	Mean (SD)	76.86 (20.429)	74.18 (18.006)	75.53 (19.274)
	Median	73.00	70.00	71.40
	Min, Max	42.0, 132.7	42.2, 138.0	42.0, 138.0
BMI (kg/m^2)	n (missing)	127 (0)	125 (0)	252 (0)
	Mean (SD)	28.73 (7.051)	28.07 (7.006)	28.40 (7.023)
	Median	27.74	26.40	26.89
	Min, Max	16.0, 47.2	17.2, 57.5	16.0, 57.5
BMI subgroup (%)	<=28 kg/m2	67 (52.8)	73 (58.4)	140 (55.6)
	>28 kg/m2	60 (47.2)	52 (41.6)	112 (44.4)

[a] Asia Pacific: Australia, New Zealand, South Korea, Taiwan. Europe: Germany, Hungary, Italy, Poland, Romania, Ukraine, United Kingdom. Latin America: Argentinia, Brazil, Chile, Colombia, Peru. Rest of World: Israel.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SLE disease characteristics
Full analysis set

		Anifrolumab 300mg (N=127)	Placebo (N=125)	Total (N=252)
SLEDAI-2K score at screening	n (missing)	127 (0)	125 (0)	252 (0)
	Mean (SD)	11.2 (3.62)	11.0 (3.32)	11.1 (3.47)
	Median	10.0	10.0	10.0
	Min, Max	6, 25	6, 24	6, 25
SLEDAI-2K score at screening, categorisation (%)	< 10 points	39 (30.7)	37 (29.6)	76 (30.2)
	>= 10 points	88 (69.3)	88 (70.4)	176 (69.8)
Clinical SLEDAI-2K score at screening	n (missing)	127 (0)	125 (0)	252 (0)
	Mean (SD)	8.7 (2.80)	8.5 (2.29)	8.6 (2.55)
	Median	8.0	8.0	8.0
	Min, Max	4, 20	4, 16	4, 20
SLEDAI-2K score at baseline	n (missing)	127 (0)	125 (0)	252 (0)
	Mean (SD)	11.2 (3.86)	11.3 (3.37)	11.2 (3.62)
	Median	10.0	10.0	10.0
	Min, Max	4, 32	6, 23	4, 32
SLEDAI-2K score at baseline, categorisation (%)	< 10 points	38 (29.9)	35 (28.0)	73 (29.0)
	>= 10 points	89 (70.1)	90 (72.0)	179 (71.0)
Clinical SLEDAI-2K score at baseline	n (missing)	127 (0)	125 (0)	252 (0)
	Mean (SD)	8.8 (2.75)	8.8 (2.49)	8.8 (2.62)
	Median	8.0	8.0	8.0
	Min, Max	4, 20	4, 18	4, 20
Total Organ Score CNS	n (missing)	127 (0)	125 (0)	252 (0)
	Mean (SD)	0.1 (0.71)	0.1 (0.72)	0.1 (0.71)
	Median	0.0	0.0	0.0
	Min, Max	0, 8	0, 8	0, 8
Total Organ Score CVS and Respiratory	n (missing)	127 (0)	125 (0)	252 (0)
	Mean (SD)	0.2 (0.54)	0.1 (0.55)	0.1 (0.55)
	Median	0.0	0.0	0.0
	Min, Max	0, 2	0, 4	0, 4
Total Organ Score Hematological	n (missing)	127 (0)	125 (0)	252 (0)
	Mean (SD)	0.1 (0.33)	0.1 (0.33)	0.1 (0.33)
	Median	0.0	0.0	0.0
	Min, Max	0, 1	0, 2	0, 2
Total Organ Score Immunology	n (missing)	127 (0)	125 (0)	252 (0)
	Mean (SD)	1.9 (1.64)	1.9 (1.64)	1.9 (1.64)
	Median	2.0	2.0	2.0
	Min, Max	0, 4	0, 4	0, 4
Total Organ Score Mucocutaneous	n (missing)	127 (0)	125 (0)	252 (0)
	Mean (SD)	4.2 (1.56)	4.0 (1.59)	4.1 (1.57)
	Median	4.0	4.0	4.0
	Min, Max	0, 6	0, 6	0, 6
Total Organ Score Musculoskeletal	n (missing)	127 (0)	125 (0)	252 (0)
	Mean (SD)	3.7 (1.19)	4.0 (0.95)	3.8 (1.09)
	Median	4.0	4.0	4.0
	Min, Max	0, 8	0, 8	0, 8
Total Organ Score Renal	n (missing)	127 (0)	125 (0)	252 (0)
	Mean (SD)	0.4 (1.58)	0.4 (1.70)	0.4 (1.64)
	Median	0.0	0.0	0.0
	Min, Max	0, 12	0, 12	0, 12

Baseline is defined as the last measurement prior to randomisation and dose administration on Day 1.
Only subjects with baseline positive anti-dsDNA and abnormal complement level, respectively, are included in the summary statistics for the respective variables.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SLE disease characteristics
Full analysis set

		Anifrolumab 300mg (N=127)	Placebo (N=125)	Total (N=252)
Total Organ Score Vascular	n (missing)	127 (0)	125 (0)	252 (0)
	Mean (SD)	0.8 (2.35)	0.7 (2.28)	0.7 (2.31)
	Median	0.0	0.0	0.0
	Min, Max	0, 8	0, 8	0, 8
Adjudication Scoring (BILAG) at baseline Overall (%)	At least one A	64 (50.4)	61 (48.8)	125 (49.6)
	No A and <2Bs	4 (3.1)	10 (8.0)	14 (5.6)
	No A and at least 2 Bs	59 (46.5)	54 (43.2)	113 (44.8)
Adjudication Scoring (BILAG) at baseline Constitutional (%)	A	1 (0.8)	0	1 (0.4)
	B	6 (4.7)	7 (5.6)	13 (5.2)
	C, D or E	120 (94.5)	118 (94.4)	238 (94.4)
Adjudication Scoring (BILAG) at baseline Mucocutaneous (%)	A	39 (30.7)	27 (21.6)	66 (26.2)
	B	74 (58.3)	79 (63.2)	153 (60.7)
	C, D or E	14 (11.0)	19 (15.2)	33 (13.1)
Adjudication Scoring (BILAG) at baseline Neuropsychiatric (%)	B	5 (3.9)	2 (1.6)	7 (2.8)
	C, D or E	122 (96.1)	123 (98.4)	245 (97.2)
Adjudication Scoring (BILAG) at baseline Musculoskeletal (%)	A	37 (29.1)	43 (34.4)	80 (31.7)
	B	74 (58.3)	73 (58.4)	147 (58.3)
	C, D or E	16 (12.6)	9 (7.2)	25 (9.9)
Adjudication Scoring (BILAG) at baseline Cardiorespiratory (%)	A	1 (0.8)	1 (0.8)	2 (0.8)
	B	9 (7.1)	4 (3.2)	13 (5.2)
	C, D or E	117 (92.1)	120 (96.0)	237 (94.0)
Adjudication Scoring (BILAG) at baseline Gastrointestinal (%)	B	0	1 (0.8)	1 (0.4)
	C, D or E	127 (100.0)	124 (99.2)	251 (99.6)
Adjudication Scoring (BILAG) at baseline Ophthalmic (%)	A	1 (0.8)	0	1 (0.4)
	C, D or E	126 (99.2)	125 (100.0)	251 (99.6)
Adjudication Scoring (BILAG) at baseline Renal (%)	A	0	1 (0.8)	1 (0.4)
	B	10 (7.9)	8 (6.4)	18 (7.1)
	C, D or E	117 (92.1)	116 (92.8)	233 (92.5)
Adjudication Scoring (BILAG) at baseline Haematological (%)	B	1 (0.8)	1 (0.8)	2 (0.8)
	C, D or E	126 (99.2)	124 (99.2)	250 (99.2)
BILAG-2004 global score at baseline	n (missing)	127 (0)	125 (0)	252 (0)
	Mean (SD)	19.6 (5.87)	18.9 (5.28)	19.3 (5.58)
	Median	17.0	18.0	17.5
	Min, Max	2, 40	4, 33	2, 40
Physician Global Assessment (PGA) score at baseline	n (missing)	127 (0)	125 (0)	252 (0)
	Mean (SD)	1.9 (0.40)	1.8 (0.35)	1.9 (0.38)
	Median	2.0	1.9	1.9
	Min, Max	1, 3	1, 3	1, 3
CLASI activity score at baseline	n (missing)	127 (0)	125 (0)	252 (0)
	Mean (SD)	8.9 (7.74)	8.1 (6.39)	8.5 (7.10)
	Median	7.0	6.0	6.0
	Min, Max	0, 41	0, 35	0, 41
CLASI activity score at baseline, categorisation 1 (%)	0	4 (3.1)	4 (3.2)	8 (3.2)
	> 0	123 (96.9)	121 (96.8)	244 (96.8)
CLASI activity score at baseline, categorisation 2 (%)	<10	87 (68.5)	85 (68.0)	172 (68.3)

Baseline is defined as the last measurement prior to randomisation and dose administration on Day 1.
Only subjects with baseline positive anti-dsDNA and abnormal complement level, respectively, are included in the summary statistics for the respective variables.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SLE disease characteristics
Full analysis set

		Anifrolumab 300mg (N=127)	Placebo (N=125)	Total (N=252)
CLASI activity score at baseline, categorisation 2 (%)	>=10	40 (31.5)	40 (32.0)	80 (31.7)
CLASI damage score at baseline	n (missing)	127 (0)	125 (0)	252 (0)
	Mean (SD)	1.9 (3.68)	1.9 (4.62)	1.9 (4.16)
	Median	0.0	0.0	0.0
	Min, Max	0, 16	0, 35	0, 35
CLASI damage score at baseline, categorisation 1 (%)	0	82 (64.6)	83 (66.4)	165 (65.5)
	> 0	45 (35.4)	42 (33.6)	87 (34.5)
CLASI damage score at baseline, categorisation 2 (%)	<10	119 (93.7)	118 (94.4)	237 (94.0)
	>=10	8 (6.3)	7 (5.6)	15 (6.0)
Tender Joint Count at Baseline	n (missing)	127 (0)	125 (0)	252 (0)
	Mean (SD)	11.2 (7.32)	10.5 (7.09)	10.9 (7.20)
	Median	9.0	10.0	10.0
	Min, Max	0, 28	0, 28	0, 28
Tender Joint Count at Baseline, categorisation (%)	0	9 (7.1)	5 (4.0)	14 (5.6)
	> 0	118 (92.9)	120 (96.0)	238 (94.4)
Swollen Joint Count at Baseline	n (missing)	127 (0)	125 (0)	252 (0)
	Mean (SD)	7.3 (5.62)	7.0 (4.89)	7.2 (5.26)
	Median	6.0	6.0	6.0
	Min, Max	0, 25	0, 23	0, 25
Swollen Joint Count at Baseline, categorisation (%)	0	12 (9.4)	10 (8.0)	22 (8.7)
	> 0	115 (90.6)	115 (92.0)	230 (91.3)
Active Joint Count at Baseline	n (missing)	127 (0)	125 (0)	252 (0)
	Mean (SD)	7.0 (5.59)	6.2 (4.44)	6.6 (5.06)
	Median	6.0	6.0	6.0
	Min, Max	0, 25	0, 23	0, 25
Active Joint Count at Baseline, categorisation (%)	0	13 (10.2)	11 (8.8)	24 (9.5)
	> 0	114 (89.8)	114 (91.2)	228 (90.5)
SDI global score at baseline	n (missing)	126 (1)	123 (2)	249 (3)
	Mean (SD)	0.6 (1.11)	0.7 (1.05)	0.7 (1.08)
	Median	0.0	0.0	0.0
	Min, Max	0, 5	0, 5	0, 5
SDI global score at baseline, categorisation (%)	0 (no damage)	86 (67.7)	72 (57.6)	158 (62.7)
	>=1 (damage)	40 (31.5)	51 (40.8)	91 (36.1)
	Missing	1 (0.8)	2 (1.6)	3 (1.2)
Time from initial SLE diagnosis to randomisation (months)	n (missing)	127 (0)	125 (0)	252 (0)
	Mean (SD)	111.8 (96.81)	103.8 (93.28)	107.9 (94.97)
	Median	85.0	76.0	82.0
	Min, Max	0, 450	4, 503	0, 503
Cushingoid features (%)	Any Cushingoid Feature	44 (34.6)	46 (36.8)	90 (35.7)
	Moon Face	22 (17.3)	26 (20.8)	48 (19.0)
	Buffalo Hump	10 (7.9)	9 (7.2)	19 (7.5)
	Purple or Violaceous Striae	12 (9.4)	7 (5.6)	19 (7.5)
	Central Obesity	18 (14.2)	21 (16.8)	39 (15.5)
	Hirsutisim	5 (3.9)	4 (3.2)	9 (3.6)
	Acne	6 (4.7)	5 (4.0)	11 (4.4)
	Easy Bruising	26 (20.5)	16 (12.8)	42 (16.7)
	Fragile Skin	16 (12.6)	13 (10.4)	29 (11.5)

Baseline is defined as the last measurement prior to randomisation and dose administration on Day 1.
Only subjects with baseline positive anti-dsDNA and abnormal complement level, respectively, are included in the summary statistics for the respective variables.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SLE disease characteristics
Full analysis set

		Anifrolumab 300mg (N=127)	Placebo (N=125)	Total (N=252)
Results of 4-gene Type 1 Interferon (IFN) test (%)	High	105 (82.7)	101 (80.8)	206 (81.7)
	Low	22 (17.3)	24 (19.2)	46 (18.3)
Anti-dsDNA levels at baseline	n (missing)	56 (0)	55 (0)	111 (0)
	Mean (SD)	164.9 (326.14)	250.1 (615.86)	207.1 (491.13)
	Median	57.3	53.2	53.5
	Min, Max	15, 1808	17, 3790	15, 3790
Anti-dsDNA levels at baseline, categorisation (%)	Negative	71 (55.9)	70 (56.0)	141 (56.0)
	Positive	56 (44.1)	55 (44.0)	111 (44.0)
ANA (%)	Abnormal (titre >= 1:80)	114 (89.8)	114 (91.2)	228 (90.5)
	Normal (titre < 1:80)	9 (7.1)	8 (6.4)	17 (6.7)
	Missing	4 (3.1)	3 (2.4)	7 (2.8)
Complement C3 level at baseline	n (missing)	44 (0)	46 (0)	90 (0)
	Mean (SD)	0.66 (0.161)	0.71 (0.140)	0.69 (0.151)
	Median	0.69	0.73	0.71
	Min, Max	0.2, 0.9	0.4, 0.9	0.2, 0.9
Complement C3 level at baseline, categorisation (%)	Abnormal	44 (34.6)	46 (36.8)	90 (35.7)
	Normal	83 (65.4)	79 (63.2)	162 (64.3)
Complement C4 level at baseline	n (missing)	24 (0)	29 (0)	53 (0)
	Mean (SD)	0.07 (0.017)	0.07 (0.013)	0.07 (0.015)
	Median	0.07	0.07	0.07
	Min, Max	0.1, 0.1	0.1, 0.1	0.1, 0.1
Complement C4 level at baseline, categorisation (%)	Abnormal	24 (18.9)	29 (23.2)	53 (21.0)
	Normal	103 (81.1)	96 (76.8)	199 (79.0)
Complement CH50 level at baseline	n (missing)	16 (0)	12 (0)	28 (0)
	Mean (SD)	34.25 (25.494)	50.58 (28.701)	41.25 (27.648)
	Median	28.50	57.50	37.50
	Min, Max	5.0, 86.0	5.0, 90.0	5.0, 90.0
Complement CH50 level at baseline, categorisation (%)	Abnormal	16 (12.6)	12 (9.6)	28 (11.1)
	Normal	111 (87.4)	113 (90.4)	224 (88.9)

Baseline is defined as the last measurement prior to randomisation and dose administration on Day 1.
Only subjects with baseline positive anti-dsDNA and abnormal complement level, respectively, are included in the summary statistics for the respective variables.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Observation times for Efficacy endpoints
Full analysis set

		Anifrolumab 300mg (N=127)	Placebo (N=125)
SRI4: Observation time (weeks)	n (missing)	127 (0)	125 (0)
	Mean (SD)	48.4 (10.77)	48.4 (10.72)
	Median	52.1	52.1
	Min, Max	0, 54	5, 54
CLASI activity score: Observation time (weeks)	n (missing)	127 (0)	125 (0)
	Mean (SD)	48.4 (10.71)	48.4 (10.72)
	Median	52.1	52.1
	Min, Max	0, 54	5, 54
CLASI damage score: Observation time (weeks)	n (missing)	127 (0)	125 (0)
	Mean (SD)	48.4 (10.71)	48.4 (10.72)
	Median	52.1	52.1
	Min, Max	0, 54	5, 54
BICLA: Observation time (weeks)	n (missing)	127 (0)	125 (0)
	Mean (SD)	48.4 (10.71)	48.4 (10.72)
	Median	52.1	52.1
	Min, Max	0, 54	5, 54
SLEDAI-2K Total Score: Observation time (weeks)	n (missing)	127 (0)	125 (0)
	Mean (SD)	48.1 (11.10)	47.7 (11.75)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
PGA: Observation time (weeks)	n (missing)	127 (0)	125 (0)
	Mean (SD)	48.3 (11.20)	48.4 (10.73)
	Median	52.1	52.1
	Min, Max	0, 54	5, 54
BILAG Global Score: Observation time (weeks)	n (missing)	127 (0)	125 (0)
	Mean (SD)	48.2 (11.10)	48.3 (10.71)
	Median	52.1	52.1
	Min, Max	0, 54	5, 54
Tender Joint Count: Observation time (weeks)	n (missing)	127 (0)	125 (0)
	Mean (SD)	48.4 (10.76)	48.4 (10.74)
	Median	52.1	52.1
	Min, Max	0, 54	5, 54
Swollen Joint Count: Observation time (weeks)	n (missing)	127 (0)	125 (0)
	Mean (SD)	48.4 (10.76)	48.4 (10.74)
	Median	52.1	52.1
	Min, Max	0, 54	5, 54
FACIT-F Total Score: Observation time (weeks)	n (missing)	127 (0)	125 (0)
	Mean (SD)	48.1 (11.44)	48.0 (11.17)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
SF-36 v2.0 Acute - Mental Component Score: Observation time (weeks)	n (missing)	127 (0)	125 (0)
	Mean (SD)	47.4 (13.04)	47.4 (12.16)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
SF-36 v2.0 Acute - Physical Component Score: Observation time (weeks)	n (missing)	127 (0)	125 (0)
	Mean (SD)	47.4 (13.04)	47.4 (12.16)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
EQ-5D VAS Score: Observation time (weeks)	n (missing)	127 (0)	125 (0)

Observation duration defined as time from randomization until last non-missing assessment after randomization. Subjects without assessment are censored at day 1.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Observation times for Efficacy endpoints
Full analysis set

		Anifrolumab 300mg (N=127)	Placebo (N=125)
EQ-5D VAS Score: Observation time (weeks)	Mean (SD)	45.4 (14.75)	46.4 (13.41)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
SDI Global Score: Observation time (weeks)	n (missing)	127 (0)	125 (0)
	Mean (SD)	42.5 (18.23)	45.3 (15.37)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
PtGA: Observation time (weeks)	n (missing)	127 (0)	125 (0)
	Mean (SD)	47.8 (11.83)	47.4 (11.96)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54

Observation duration defined as time from randomization until last non-missing assessment after randomization. Subjects without assessment are censored at day 1.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 4	Number of subjects with events, n (%)	12 (9.4)	11 (8.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.12 (0.52, 2.42)	
	p-value	0.7644	
	Odds Ratio (95% CI)	1.14 (0.47, 2.76)	
	p-value	0.7640	
	Risk Difference (95% CI)	1.08 (-5.94, 8.09)	
	p-value	0.7638	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.07 (0.49, 2.34)	
	p-value	0.8581	
	Odds Ratio (95% CI)	1.08 (0.46, 2.55)	
	p-value	0.8581	
	Risk Difference (95% CI)	0.65 (-6.46, 7.76)	
	p-value	0.8580	
	CMH approach		
	Response rate	9.6	8.7
	Difference in response rates (95% CI)	0.99 (-7.76, 9.73)	
	p-value	0.8248	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 8	Number of subjects with events, n (%)	26 (20.5)	17 (13.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.51 (0.88, 2.60)	
	p-value	0.1326	
	Odds Ratio (95% CI)	1.70 (0.85, 3.37)	
	p-value	0.1319	
	Risk Difference (95% CI)	7.08 (-2.02, 16.19)	
	p-value	0.1274	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.51 (0.86, 2.63)	
	p-value	0.1517	
	Odds Ratio (95% CI)	1.64 (0.84, 3.19)	
	p-value	0.1494	
	Risk Difference (95% CI)	6.87 (-2.37, 16.11)	
	p-value	0.1449	
	CMH approach		
	Response rate	20.8	13.6
	Difference in response rates (95% CI)	7.16 (-2.90, 17.21)	
	p-value	0.1630	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 12	Number of subjects with events, n (%)	47 (37.0)	32 (25.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.45 (1.00, 2.09)	
	p-value	0.0478	
	Odds Ratio (95% CI)	1.76 (1.01, 3.06)	
	p-value	0.0462	
	Risk Difference (95% CI)	11.55 (0.36, 22.75)	
	p-value	0.0431	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.45 (0.99, 2.10)	
	p-value	0.0542	
	Odds Ratio (95% CI)	1.71 (1.00, 2.93)	
	p-value	0.0520	
	Risk Difference (95% CI)	11.41 (0.05, 22.77)	
	p-value	0.0490	
	CMH approach		
	Response rate	37.2	25.5
	Difference in response rates (95% CI)	11.70 (0.29, 23.11)	
	p-value	0.0444	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 16	Number of subjects with events, n (%)	54 (42.5)	48 (38.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.11 (0.83, 1.50)	
	p-value	0.4713	
	Odds Ratio (95% CI)	1.20 (0.73, 1.99)	
	p-value	0.4755	
	Risk Difference (95% CI)	4.45 (-7.75, 16.66)	
	p-value	0.4747	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.11 (0.82, 1.50)	
	p-value	0.5060	
	Odds Ratio (95% CI)	1.19 (0.72, 1.96)	
	p-value	0.5055	
	Risk Difference (95% CI)	4.12 (-7.99, 16.23)	
	p-value	0.5049	
	CMH approach		
	Response rate	42.7	38.6
	Difference in response rates (95% CI)	4.08 (-8.02, 16.18)	
	p-value	0.5087	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 20	Number of subjects with events, n (%)	62 (48.8)	56 (44.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.08 (0.83, 1.40)	
	p-value	0.5554	
	Odds Ratio (95% CI)	1.16 (0.70, 1.92)	
	p-value	0.5588	
	Risk Difference (95% CI)	3.68 (-8.65, 16.01)	
	p-value	0.5583	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.09 (0.84, 1.42)	
	p-value	0.5232	
	Odds Ratio (95% CI)	1.18 (0.72, 1.93)	
	p-value	0.5228	
	Risk Difference (95% CI)	4.02 (-8.29, 16.33)	
	p-value	0.5223	
	CMH approach		
	Response rate	48.7	44.8
	Difference in response rates (95% CI)	3.91 (-8.28, 16.09)	
	p-value	0.5298	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 24	Number of subjects with events, n (%)	63 (49.6)	59 (47.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.04 (0.81, 1.34)	
	p-value	0.7609	
	Odds Ratio (95% CI)	1.08 (0.66, 1.76)	
	p-value	0.7646	
	Risk Difference (95% CI)	1.93 (-10.69, 14.55)	
	p-value	0.7644	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.05 (0.81, 1.36)	
	p-value	0.7025	
	Odds Ratio (95% CI)	1.10 (0.67, 1.81)	
	p-value	0.7024	
	Risk Difference (95% CI)	2.41 (-9.93, 14.74)	
	p-value	0.7023	
	CMH approach		
	Response rate	49.6	47.3
	Difference in response rates (95% CI)	2.23 (-9.92, 14.39)	
	p-value	0.7190	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 28	Number of subjects with events, n (%)	66 (52.0)	62 (49.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.03 (0.81, 1.31)	
	p-value	0.7868	
	Odds Ratio (95% CI)	1.07 (0.65, 1.75)	
	p-value	0.7893	
	Risk Difference (95% CI)	1.70 (-10.79, 14.20)	
	p-value	0.7893	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.05 (0.82, 1.34)	
	p-value	0.7071	
	Odds Ratio (95% CI)	1.10 (0.67, 1.80)	
	p-value	0.7069	
	Risk Difference (95% CI)	2.37 (-9.97, 14.71)	
	p-value	0.7068	
	CMH approach		
	Response rate	51.8	49.8
	Difference in response rates (95% CI)	2.05 (-10.22, 14.33)	
	p-value	0.7429	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 32	Number of subjects with events, n (%)	66 (52.0)	60 (48.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.07 (0.84, 1.36)	
	p-value	0.5955	
	Odds Ratio (95% CI)	1.14 (0.70, 1.87)	
	p-value	0.5999	
	Risk Difference (95% CI)	3.35 (-9.17, 15.87)	
	p-value	0.5997	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.08 (0.85, 1.39)	
	p-value	0.5293	
	Odds Ratio (95% CI)	1.17 (0.72, 1.92)	
	p-value	0.5288	
	Risk Difference (95% CI)	3.97 (-8.37, 16.31)	
	p-value	0.5284	
	CMH approach		
	Response rate	51.7	48.3
	Difference in response rates (95% CI)	3.33 (-8.86, 15.52)	
	p-value	0.5924	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 36	Number of subjects with events, n (%)	67 (52.8)	61 (48.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.07 (0.84, 1.37)	
	p-value	0.5596	
	Odds Ratio (95% CI)	1.16 (0.71, 1.90)	
	p-value	0.5621	
	Risk Difference (95% CI)	3.69 (-8.77, 16.14)	
	p-value	0.5618	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.08 (0.85, 1.38)	
	p-value	0.5305	
	Odds Ratio (95% CI)	1.17 (0.71, 1.92)	
	p-value	0.5301	
	Risk Difference (95% CI)	3.96 (-8.38, 16.29)	
	p-value	0.5297	
	CMH approach		
	Response rate	52.3	49.0
	Difference in response rates (95% CI)	3.30 (-8.92, 15.52)	
	p-value	0.5965	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 40	Number of subjects with events, n (%)	67 (52.8)	60 (48.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.10 (0.86, 1.40)	
	p-value	0.4500	
	Odds Ratio (95% CI)	1.21 (0.74, 1.99)	
	p-value	0.4530	
	Risk Difference (95% CI)	4.75 (-7.64, 17.15)	
	p-value	0.4523	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.10 (0.86, 1.41)	
	p-value	0.4511	
	Odds Ratio (95% CI)	1.21 (0.74, 1.98)	
	p-value	0.4504	
	Risk Difference (95% CI)	4.76 (-7.58, 17.09)	
	p-value	0.4498	
	CMH approach		
	Response rate	52.4	48.1
	Difference in response rates (95% CI)	4.28 (-7.95, 16.51)	
	p-value	0.4931	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 44	Number of subjects with events, n (%)	66 (52.0)	55 (44.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.17 (0.91, 1.51)	
	p-value	0.2214	
	Odds Ratio (95% CI)	1.35 (0.83, 2.22)	
	p-value	0.2283	
	Risk Difference (95% CI)	7.72 (-4.78, 20.22)	
	p-value	0.2262	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.18 (0.91, 1.53)	
	p-value	0.2078	
	Odds Ratio (95% CI)	1.38 (0.84, 2.26)	
	p-value	0.2060	
	Risk Difference (95% CI)	7.97 (-4.33, 20.27)	
	p-value	0.2041	
	CMH approach		
	Response rate	52.0	44.4
	Difference in response rates (95% CI)	7.64 (-4.55, 19.83)	
	p-value	0.2192	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 48	Number of subjects with events, n (%)	66 (52.0)	52 (41.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.25 (0.96, 1.62)	
	p-value	0.0953	
	Odds Ratio (95% CI)	1.53 (0.93, 2.54)	
	p-value	0.0969	
	Risk Difference (95% CI)	10.46 (-1.78, 22.70)	
	p-value	0.0940	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.25 (0.96, 1.63)	
	p-value	0.1019	
	Odds Ratio (95% CI)	1.52 (0.92, 2.50)	
	p-value	0.0997	
	Risk Difference (95% CI)	10.37 (-1.89, 22.62)	
	p-value	0.0972	
	CMH approach		
	Response rate	51.8	41.8
	Difference in response rates (95% CI)	10.01 (-2.19, 22.21)	
	p-value	0.1077	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 52	Number of subjects with events, n (%)	65 (51.2)	55 (44.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.16 (0.90, 1.50)	
	p-value	0.2608	
	Odds Ratio (95% CI)	1.32 (0.81, 2.18)	
	p-value	0.2669	
	Risk Difference (95% CI)	7.08 (-5.36, 19.52)	
	p-value	0.2647	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.16 (0.90, 1.51)	
	p-value	0.2557	
	Odds Ratio (95% CI)	1.33 (0.81, 2.19)	
	p-value	0.2542	
	Risk Difference (95% CI)	7.18 (-5.12, 19.48)	
	p-value	0.2525	
	CMH approach		
	Response rate	51.0	44.2
	Difference in response rates (95% CI)	6.74 (-5.51, 18.98)	
	p-value	0.2807	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.7321
< 10 points	21/ 39 (53.8)	53.8	16/ 37 (43.2)	43.2	1.25 (0.78, 1.99)	0.3602	10.60 (-11.77, 32.98)	0.3531	
>= 10 points	44/ 88 (50.0)	49.9	39/ 88 (44.3)	44.6	1.13 (0.82, 1.54)	0.4513	5.30 (-9.27, 19.87)	0.4759	
OCS dose at baseline									0.1573
<10 mg/day	28/ 57 (49.1)	49.4	27/ 52 (51.9)	51.9	0.95 (0.65, 1.37)	0.7701	-2.49 (-21.01, 16.02)	0.7917	
>=10 mg/day	37/ 70 (52.9)	53.3	28/ 73 (38.4)	38.5	1.38 (0.96, 1.99)	0.0854	14.77 (-1.42, 30.97)	0.0737	
Result of type I IFN gene signature test									0.3916
LOW	9/ 22 (40.9)	40.9	11/ 24 (45.8)	45.8	0.89 (0.46, 1.73)	0.7374	-4.92 (-33.64, 23.79)	0.7368	
HIGH	56/105 (53.3)	53.2	44/101 (43.6)	43.9	1.22 (0.92, 1.63)	0.1643	9.35 (-4.19, 22.89)	0.1759	
Age (years)									0.0518
<= 65	63/122 (51.6)	51.5	53/123 (43.1)	43.2	1.20 (0.92, 1.56)	0.1822	8.30 (-4.15, 20.74)	0.1914	
> 65	2/ 5 (40.0)	40.0	2/ 2 (100.0)	100.0	0.40 (0.14, 1.17)	0.0943	-60.00 (-138.52, 18.52)	0.1342	
Sex									0.2818
male	5/ 12 (41.7)	41.7	1/ 8 (12.5)	12.5	3.33 (0.47, 23.47)	0.2267	29.17 (-11.92, 70.25)	0.1641	
female	60/115 (52.2)	51.8	54/117 (46.2)	46.4	1.13 (0.87, 1.47)	0.3600	5.32 (-7.45, 18.09)	0.4142	
Race									0.3122
White	44/ 85 (51.8)	51.7	45/ 96 (46.9)	47.6	1.10 (0.82, 1.48)	0.5108	4.10 (-10.39, 18.59)	0.5794	
Black or African American	10/ 22 (45.5)	45.5	6/ 14 (42.9)	42.9	1.06 (0.50, 2.26)	0.8792	2.60 (-30.74, 35.94)	0.8786	
Asian	3/ 7 (42.9)	42.9	2/ 3 (66.7)	66.7	0.64 (0.20, 2.07)	0.4597	-23.81 (-90.87, 43.25)	0.4865	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	8/ 13 (61.5)	61.5	2/ 11 (18.2)	18.2	3.38 (0.90, 12.74)	0.0714	43.36 (5.96, 80.76)	0.0231	
Ethnicity									0.5176
Hispanic/Latino	11/ 23 (47.8)	47.8	8/ 24 (33.3)	33.3	1.43 (0.71, 2.91)	0.3181	14.49 (-13.52, 42.50)	0.3105	
Non-hispanic/Latino	54/104 (51.9)	51.3	47/101 (46.5)	47.1	1.12 (0.84, 1.48)	0.4417	4.17 (-9.53, 17.87)	0.5506	
Geographic region									0.8900
EU	32/ 47 (68.1)	68.1	31/ 56 (55.4)	55.4	1.23 (0.91, 1.67)	0.1850	12.73 (-6.02, 31.47)	0.1833	
non-EU	33/ 80 (41.3)	41.2	24/ 69 (34.8)	34.8	1.19 (0.78, 1.80)	0.4213	6.43 (-9.29, 22.15)	0.4226	
Onset of disease									0.3678
Paediatric	1/ 8 (12.5)	12.5	2/ 7 (28.6)	28.6	0.44 (0.05, 3.85)	0.4564	-16.07 (-62.66, 30.51)	0.4989	
Adult	64/119 (53.8)	53.6	53/118 (44.9)	45.1	1.20 (0.92, 1.55)	0.1747	8.53 (-4.08, 21.14)	0.1850	
ADA result									0.6768
Negative	57/111 (51.4)	50.9	50/112 (44.6)	45.2	1.15 (0.87, 1.51)	0.3174	5.69 (-7.31, 18.69)	0.3910	
Positive (At any time)	8/ 15 (53.3)	53.3	5/ 13 (38.5)	38.5	1.39 (0.60, 3.20)	0.4428	14.87 (-21.93, 51.67)	0.4283	
BMI (kg/m2) at enrolment									0.5711
< 30	40/ 74 (54.1)	54.7	38/ 87 (43.7)	44.2	1.24 (0.90, 1.70)	0.1888	10.45 (-4.76, 25.66)	0.1782	
>= 30	25/ 53 (47.2)	48.1	17/ 38 (44.7)	45.1	1.05 (0.67, 1.66)	0.8191	2.92 (-17.31, 23.15)	0.7772	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) - individual components at week 52 (Full analysis set)
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
>=4 point reduction in SLEDAI-2k [a]	66 (52.0)	55 (44.0)
No discontinuation of IP	104 (81.9)	97 (77.6)
No use of medication beyond protocol allowed threshold	101 (79.5)	90 (72.0)
No worsening of BILAG [a]	87 (68.5)	72 (57.6)
No worsening of PGA [a]	86 (67.7)	74 (59.2)

[a] Subjects who discontinued IP or used medications beyond protocol allowed threshold are considered non-responders and not included in this category.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate at week 52 sensitivity analysis, multiple imputation
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 52	Number of subjects with events, n (%)	64 (50.7)	55 (43.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.16 (0.90, 1.50)	
	p-value	0.2605	
	Odds Ratio (95% CI)	1.33 (0.81, 2.18)	
	p-value	0.2673	
	Risk Difference (95% CI)	7.14 (-5.41, 19.69)	
	p-value	0.2648	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.16 (0.89, 1.51)	
	p-value	0.2666	
	Odds Ratio (95% CI)	1.33 (0.81, 2.19)	
	p-value	0.2651	
	Risk Difference (95% CI)	7.05 (-5.31, 19.41)	
	p-value	0.2635	

For each outcome and visit, 100 imputations were generated by randomised treatment group. Each imputed dataset was analysed separately, and the single estimates are combined using PROC MIANALYZE. The estimated number of responders and non-responders are rounded to an integer. Therefore, there might be slight mismatches between number of subjects and corresponding percentage.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (8) response rate at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=122)	Placebo (N=120)
Week 52	Number of subjects with events, n (%)	37 (30.3)	18 (15.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	2.00 (1.22, 3.29)	
	p-value	0.0063	
	Odds Ratio (95% CI)	2.40 (1.28, 4.47)	
	p-value	0.0060	
	Risk Difference (95% CI)	15.45 (4.84, 26.06)	
	p-value	0.0043	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	2.02 (1.22, 3.35)	
	p-value	0.0062	
	Odds Ratio (95% CI)	2.47 (1.31, 4.64)	
	p-value	0.0051	
	Risk Difference (95% CI)	15.33 (4.97, 25.69)	
	p-value	0.0037	
	CMH approach		
	Response rate	30.4	15.0
	Difference in response rates (95% CI)	15.39 (4.42, 26.36)	
	p-value	0.0059	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (8) response rate at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=122) n/ N (%)	Response rate	Placebo (N=120) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9266
< 10 points	9/ 34 (26.5)	26.5	4/ 32 (12.5)	12.5	2.12 (0.72, 6.20)	0.1710	13.97 (-6.01, 33.95)	0.1705	
>= 10 points	28/ 88 (31.8)	32.0	14/ 88 (15.9)	16.0	2.00 (1.13, 3.53)	0.0170	16.06 (3.12, 29.00)	0.0150	
OCS dose at baseline									0.0467
<10 mg/day	13/ 55 (23.6)	24.0	10/ 48 (20.8)	20.9	1.13 (0.55, 2.35)	0.7339	3.04 (-14.17, 20.26)	0.7289	
>=10 mg/day	24/ 67 (35.8)	36.0	8/ 72 (11.1)	11.4	3.22 (1.56, 6.67)	0.0016	24.63 (10.08, 39.18)	0.0009	
Result of type I IFN gene signature test									0.5731
LOW	4/ 22 (18.2)	18.2	3/ 23 (13.0)	13.0	1.39 (0.35, 5.53)	0.6367	5.14 (-18.57, 28.84)	0.6710	
HIGH	33/100 (33.0)	33.2	15/ 97 (15.5)	15.5	2.13 (1.24, 3.67)	0.0062	17.74 (5.40, 30.07)	0.0048	
Age (years)									0.0847
<= 65	37/117 (31.6)	31.6	17/118 (14.4)	14.4	2.20 (1.31, 3.67)	0.0027	17.21 (6.03, 28.39)	0.0025	
> 65	0/ 5 (0.0)	0.0	1/ 2 (50.0)	50.0	0.17 (0.01, 2.98)	0.2235	-50.00 (-128.29, 28.29)	0.2107	
Sex									0.4554
male	4/ 12 (33.3)	33.3	0/ 7 (0.0)	0.0	5.54 (0.34, 89.80)	0.2285	33.33 (-6.25, 72.91)	0.0988	
female	33/110 (30.0)	30.1	18/113 (15.9)	16.0	1.88 (1.13, 3.14)	0.0151	14.09 (2.58, 25.60)	0.0164	
Race									0.5198
White	22/ 82 (26.8)	27.0	15/ 92 (16.3)	16.1	1.65 (0.92, 2.95)	0.0951	10.92 (-1.94, 23.79)	0.0961	
Black or African American	6/ 21 (28.6)	28.6	3/ 14 (21.4)	21.4	1.33 (0.40, 4.47)	0.6411	7.14 (-23.66, 37.94)	0.6494	
Asian	2/ 6 (33.3)	33.3	0/ 2 (0.0)	0.0	2.14 (0.14, 32.48)	0.5827	33.33 (-42.86, 109.52)	0.3912	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	7/ 13 (53.8)	53.8	0/ 11 (0.0)	0.0	12.86 (0.82, 202.52)	0.0694	53.85 (20.09, 87.61)	0.0018	
Ethnicity									0.0943
Hispanic/Latino	8/ 23 (34.8)	34.8	0/ 24 (0.0)	0.0	17.71 (1.08, 290.23)	0.0440	34.78 (12.52, 57.05)	0.0022	
Non-hispanic/Latino	29/ 99 (29.3)	29.1	18/ 96 (18.8)	18.8	1.56 (0.93, 2.62)	0.0906	10.30 (-2.06, 22.66)	0.1023	
Geographic region									0.7996
EU	18/ 43 (41.9)	41.9	10/ 54 (18.5)	18.5	2.26 (1.17, 4.38)	0.0156	23.34 (5.04, 41.65)	0.0125	
non-EU	19/ 79 (24.1)	24.0	8/ 66 (12.1)	12.1	1.98 (0.93, 4.24)	0.0767	11.98 (-1.42, 25.39)	0.0797	
Onset of disease									0.8511
Paediatric	1/ 8 (12.5)	12.5	0/ 7 (0.0)	0.0	2.67 (0.13, 56.63)	0.5293	12.50 (-28.93, 53.93)	0.5543	
Adult	36/114 (31.6)	31.8	18/113 (15.9)	15.9	1.98 (1.20, 3.28)	0.0076	15.88 (4.39, 27.36)	0.0067	
ADA result									0.6376
Negative	32/107 (29.9)	30.0	15/107 (14.0)	14.1	2.13 (1.23, 3.70)	0.0071	15.94 (4.27, 27.60)	0.0074	
Positive (At any time)	5/ 14 (35.7)	35.7	3/ 13 (23.1)	23.1	1.55 (0.46, 5.22)	0.4815	12.64 (-22.94, 48.21)	0.4863	
BMI (kg/m2) at enrolment									0.7399
< 30	24/ 71 (33.8)	34.1	14/ 82 (17.1)	17.0	1.98 (1.11, 3.53)	0.0204	17.09 (2.83, 31.36)	0.0188	
>= 30	13/ 51 (25.5)	26.0	4/ 38 (10.5)	10.7	2.42 (0.86, 6.84)	0.0952	15.27 (-2.70, 33.24)	0.0958	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=4 reduction in SLEDAI-2K at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 52	Number of subjects with events, n (%)	66 (52.0)	55 (44.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.17 (0.91, 1.51)	
	p-value	0.2175	
	Odds Ratio (95% CI)	1.36 (0.83, 2.24)	
	p-value	0.2228	
	Risk Difference (95% CI)	7.77 (-4.66, 20.21)	
	p-value	0.2204	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.18 (0.91, 1.53)	
	p-value	0.2078	
	Odds Ratio (95% CI)	1.38 (0.84, 2.26)	
	p-value	0.2060	
	Risk Difference (95% CI)	7.97 (-4.33, 20.27)	
	p-value	0.2041	
	CMH approach		
	Response rate	51.6	44.2
	Difference in response rates (95% CI)	7.43 (-4.81, 19.67)	
	p-value	0.2342	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=4 reduction in SLEDAI-2K at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.6098
< 10 points	22/ 39 (56.4)	56.4	16/ 37 (43.2)	43.2	1.30 (0.82, 2.07)	0.2583	13.17 (-9.16, 35.50)	0.2478	
>= 10 points	44/ 88 (50.0)	49.9	39/ 88 (44.3)	44.6	1.13 (0.82, 1.54)	0.4513	5.30 (-9.27, 19.87)	0.4759	
OCS dose at baseline									0.1280
<10 mg/day	28/ 57 (49.1)	49.4	27/ 52 (51.9)	51.9	0.95 (0.65, 1.37)	0.7701	-2.49 (-21.01, 16.02)	0.7917	
>=10 mg/day	38/ 70 (54.3)	54.5	28/ 73 (38.4)	38.5	1.42 (0.99, 2.03)	0.0598	16.00 (-0.18, 32.18)	0.0526	
Result of type I IFN gene signature test									0.3651
LOW	9/ 22 (40.9)	40.9	11/ 24 (45.8)	45.8	0.89 (0.46, 1.73)	0.7374	-4.92 (-33.64, 23.79)	0.7368	
HIGH	57/105 (54.3)	54.0	44/101 (43.6)	43.9	1.25 (0.94, 1.65)	0.1275	10.19 (-3.34, 23.72)	0.1398	
Age (years)									0.0485
<= 65	64/122 (52.5)	52.2	53/123 (43.1)	43.2	1.22 (0.93, 1.59)	0.1443	8.98 (-3.46, 21.41)	0.1573	
> 65	2/ 5 (40.0)	40.0	2/ 2 (100.0)	100.0	0.40 (0.14, 1.17)	0.0943	-60.00 (-138.52, 18.52)	0.1342	
Sex									0.2892
male	5/ 12 (41.7)	41.7	1/ 8 (12.5)	12.5	3.33 (0.47, 23.47)	0.2267	29.17 (-11.92, 70.25)	0.1641	
female	61/115 (53.0)	52.5	54/117 (46.2)	46.4	1.15 (0.89, 1.49)	0.2952	6.09 (-6.67, 18.85)	0.3495	
Race									0.3139
White	44/ 85 (51.8)	51.7	45/ 96 (46.9)	47.6	1.10 (0.82, 1.48)	0.5108	4.10 (-10.39, 18.59)	0.5794	
Black or African American	11/ 22 (50.0)	50.0	6/ 14 (42.9)	42.9	1.17 (0.56, 2.43)	0.6811	7.14 (-26.23, 40.52)	0.6749	
Asian	3/ 7 (42.9)	42.9	2/ 3 (66.7)	66.7	0.64 (0.20, 2.07)	0.4597	-23.81 (-90.87, 43.25)	0.4865	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	8/ 13 (61.5)	61.5	2/ 11 (18.2)	18.2	3.38 (0.90, 12.74)	0.0714	43.36 (5.96, 80.76)	0.0231	
Ethnicity									0.5482
Hispanic/Latino	11/ 23 (47.8)	47.8	8/ 24 (33.3)	33.3	1.43 (0.71, 2.91)	0.3181	14.49 (-13.52, 42.50)	0.3105	
Non-hispanic/Latino	55/104 (52.9)	52.0	47/101 (46.5)	47.1	1.14 (0.86, 1.50)	0.3650	4.95 (-8.74, 18.64)	0.4787	
Geographic region									0.9800
EU	32/ 47 (68.1)	68.1	31/ 56 (55.4)	55.4	1.23 (0.91, 1.67)	0.1850	12.73 (-6.02, 31.47)	0.1833	
non-EU	34/ 80 (42.5)	42.6	24/ 69 (34.8)	34.8	1.22 (0.81, 1.84)	0.3399	7.78 (-7.96, 23.53)	0.3325	
Onset of disease									0.3604
Paediatric	1/ 8 (12.5)	12.5	2/ 7 (28.6)	28.6	0.44 (0.05, 3.85)	0.4564	-16.07 (-62.66, 30.51)	0.4989	
Adult	65/119 (54.6)	54.4	53/118 (44.9)	45.1	1.22 (0.94, 1.57)	0.1377	9.28 (-3.32, 21.88)	0.1487	
ADA result									0.7052
Negative	58/111 (52.3)	51.6	50/112 (44.6)	45.2	1.17 (0.89, 1.54)	0.2573	6.43 (-6.56, 19.42)	0.3322	
Positive (At any time)	8/ 15 (53.3)	53.3	5/ 13 (38.5)	38.5	1.39 (0.60, 3.20)	0.4428	14.87 (-21.93, 51.67)	0.4283	
BMI (kg/m2) at enrolment									0.6658
< 30	40/ 74 (54.1)	54.7	38/ 87 (43.7)	44.2	1.24 (0.90, 1.70)	0.1888	10.45 (-4.76, 25.66)	0.1782	
>= 30	26/ 53 (49.1)	50.1	17/ 38 (44.7)	45.1	1.10 (0.70, 1.72)	0.6863	4.95 (-15.14, 25.04)	0.6291	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=8 reduction in SLEDAI-2K at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 52	Number of subjects with events, n (%)	37 (29.1)	18 (14.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	2.01 (1.22, 3.32)	
	p-value	0.0062	
	Odds Ratio (95% CI)	2.40 (1.29, 4.48)	
	p-value	0.0058	
	Risk Difference (95% CI)	14.94 (4.71, 25.17)	
	p-value	0.0042	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	2.02 (1.22, 3.36)	
	p-value	0.0064	
	Odds Ratio (95% CI)	2.44 (1.30, 4.58)	
	p-value	0.0054	
	Risk Difference (95% CI)	14.73 (4.72, 24.75)	
	p-value	0.0039	
	CMH approach		
	Response rate	29.3	14.4
	Difference in response rates (95% CI)	14.90 (4.26, 25.55)	
	p-value	0.0061	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=8 reduction in SLEDAI-2K at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9172
< 10 points	9/ 39 (23.1)	23.1	4/ 37 (10.8)	10.8	2.13 (0.72, 6.34)	0.1721	12.27 (-5.54, 30.08)	0.1771	
>= 10 points	28/ 88 (31.8)	32.0	14/ 88 (15.9)	16.0	2.00 (1.13, 3.53)	0.0170	16.06 (3.12, 29.00)	0.0150	
OCS dose at baseline									0.0662
<10 mg/day	13/ 57 (22.8)	23.0	10/ 52 (19.2)	19.3	1.19 (0.57, 2.47)	0.6487	3.68 (-12.78, 20.13)	0.6615	
>=10 mg/day	24/ 70 (34.3)	34.8	8/ 73 (11.0)	11.2	3.13 (1.51, 6.49)	0.0022	23.60 (9.35, 37.85)	0.0012	
Result of type I IFN gene signature test									0.6206
LOW	4/ 22 (18.2)	18.2	3/ 24 (12.5)	12.5	1.45 (0.37, 5.79)	0.5948	5.68 (-17.66, 29.02)	0.6333	
HIGH	33/105 (31.4)	31.7	15/101 (14.9)	14.8	2.12 (1.23, 3.65)	0.0071	16.97 (5.03, 28.90)	0.0053	
Age (years)									0.0848
<= 65	37/122 (30.3)	30.5	17/123 (13.8)	13.8	2.19 (1.31, 3.68)	0.0029	16.66 (5.80, 27.51)	0.0026	
> 65	0/ 5 (0.0)	0.0	1/ 2 (50.0)	50.0	0.17 (0.01, 2.98)	0.2235	-50.00 (-128.29, 28.29)	0.2107	
Sex									0.4056
male	4/ 12 (33.3)	33.3	0/ 8 (0.0)	0.0	6.23 (0.38, 101.99)	0.1996	33.33 (-4.31, 70.98)	0.0827	
female	33/115 (28.7)	28.8	18/117 (15.4)	15.4	1.87 (1.12, 3.12)	0.0173	13.42 (2.23, 24.61)	0.0188	
Race									0.4999
White	22/ 85 (25.9)	26.2	15/ 96 (15.6)	15.7	1.66 (0.92, 2.98)	0.0924	10.52 (-2.34, 23.38)	0.1089	
Black or African American	6/ 22 (27.3)	27.3	3/ 14 (21.4)	21.4	1.27 (0.38, 4.28)	0.6968	5.84 (-24.53, 36.22)	0.7061	
Asian	2/ 7 (28.6)	28.6	0/ 3 (0.0)	0.0	2.50 (0.15, 40.67)	0.5196	28.57 (-33.74, 90.89)	0.3688	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	7/ 13 (53.8)	53.8	0/ 11 (0.0)	0.0	12.86 (0.82, 202.52)	0.0694	53.85 (20.09, 87.61)	0.0018	
Ethnicity									0.0946
Hispanic/Latino	8/ 23 (34.8)	34.8	0/ 24 (0.0)	0.0	17.71 (1.08, 290.23)	0.0440	34.78 (12.52, 57.05)	0.0022	
Non-hispanic/Latino	29/104 (27.9)	28.0	18/101 (17.8)	18.1	1.56 (0.93, 2.63)	0.0919	9.92 (-2.29, 22.13)	0.1115	
Geographic region									0.9292
EU	18/ 47 (38.3)	38.3	10/ 56 (17.9)	17.9	2.14 (1.10, 4.19)	0.0253	20.44 (2.99, 37.89)	0.0217	
non-EU	19/ 80 (23.8)	23.6	8/ 69 (11.6)	11.5	2.05 (0.96, 4.38)	0.0647	12.14 (-0.97, 25.25)	0.0696	
Onset of disease									0.8514
Paediatric	1/ 8 (12.5)	12.5	0/ 7 (0.0)	0.0	2.67 (0.13, 56.63)	0.5293	12.50 (-28.93, 53.93)	0.5543	
Adult	36/119 (30.3)	30.5	18/118 (15.3)	15.2	1.98 (1.20, 3.29)	0.0079	15.33 (4.21, 26.45)	0.0069	
ADA result									0.5605
Negative	32/111 (28.8)	29.1	15/112 (13.4)	13.3	2.15 (1.24, 3.75)	0.0067	15.76 (4.44, 27.07)	0.0064	
Positive (At any time)	5/ 15 (33.3)	33.3	3/ 13 (23.1)	23.1	1.44 (0.42, 4.91)	0.5558	10.26 (-24.52, 45.03)	0.5632	
BMI (kg/m2) at enrolment									0.8114
< 30	24/ 74 (32.4)	32.7	14/ 87 (16.1)	15.9	2.02 (1.13, 3.61)	0.0182	16.82 (3.10, 30.54)	0.0163	
>= 30	13/ 53 (24.5)	24.7	4/ 38 (10.5)	10.6	2.33 (0.82, 6.59)	0.1110	14.07 (-3.61, 31.75)	0.1188	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
No worsening in BILAG-2004 (>=1A or >=2B compared to BL) at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 52	Number of subjects with events, n (%)	87 (68.5)	72 (57.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.19 (0.99, 1.44)	
	p-value	0.0652	
	Odds Ratio (95% CI)	1.64 (0.97, 2.78)	
	p-value	0.0664	
	Risk Difference (95% CI)	11.09 (-0.63, 22.81)	
	p-value	0.0636	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.19 (0.98, 1.44)	
	p-value	0.0754	
	Odds Ratio (95% CI)	1.60 (0.96, 2.68)	
	p-value	0.0737	
	Risk Difference (95% CI)	10.90 (-0.94, 22.75)	
	p-value	0.0712	
	CMH approach		
	Response rate	68.3	57.8
	Difference in response rates (95% CI)	10.46 (-1.42, 22.34)	
	p-value	0.0843	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
No worsening in BILAG-2004 (>=1A or >=2B compared to BL) at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Anifrolumab 300mg (N=127) Response rate	Placebo (N=125) n/ N (%)	Placebo (N=125) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9581
< 10 points	29/ 39 (74.4)	74.4	23/ 37 (62.2)	62.2	1.20 (0.88, 1.63)	0.2599	12.20 (-8.90, 33.30)	0.2572	
>= 10 points	58/ 88 (65.9)	65.6	49/ 88 (55.7)	56.0	1.18 (0.93, 1.50)	0.1675	9.57 (-4.69, 23.84)	0.1882	
OCS dose at baseline									0.8531
<10 mg/day	42/ 57 (73.7)	73.8	33/ 52 (63.5)	63.4	1.16 (0.90, 1.50)	0.2567	10.37 (-7.39, 28.12)	0.2524	
>=10 mg/day	45/ 70 (64.3)	64.5	39/ 73 (53.4)	53.1	1.20 (0.91, 1.59)	0.1893	11.42 (-4.63, 27.47)	0.1633	
Result of type I IFN gene signature test									0.6195
LOW	16/ 22 (72.7)	72.7	16/ 24 (66.7)	66.7	1.09 (0.74, 1.60)	0.6548	6.06 (-21.13, 33.25)	0.6622	
HIGH	71/105 (67.6)	67.3	56/101 (55.4)	55.8	1.22 (0.98, 1.52)	0.0760	11.45 (-1.75, 24.65)	0.0892	
Age (years)									0.1011
<= 65	83/122 (68.0)	67.9	70/123 (56.9)	57.0	1.20 (0.98, 1.45)	0.0744	10.94 (-1.16, 23.04)	0.0763	
> 65	4/ 5 (80.0)	80.0	2/ 2 (100.0)	100.0	0.80 (0.52, 1.24)	0.3183	-20.00 (-97.30, 57.30)	0.6121	
Sex									0.1073
male	8/ 12 (66.7)	66.7	1/ 8 (12.5)	12.5	5.33 (0.82, 34.83)	0.0804	54.17 (13.54, 94.79)	0.0090	
female	79/115 (68.7)	68.4	71/117 (60.7)	60.9	1.13 (0.94, 1.37)	0.2033	7.41 (-4.96, 19.78)	0.2402	
Race									0.0743
White	60/ 85 (70.6)	70.0	59/ 96 (61.5)	62.0	1.15 (0.93, 1.42)	0.1952	7.99 (-6.05, 22.04)	0.2645	
Black or African American	13/ 22 (59.1)	59.1	8/ 14 (57.1)	57.1	1.03 (0.58, 1.83)	0.9085	1.95 (-31.27, 35.17)	0.9085	
Asian	5/ 7 (71.4)	71.4	3/ 3 (100.0)	100.0	0.71 (0.45, 1.14)	0.1593	-28.57 (-90.89, 33.74)	0.3688	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	9/ 13 (69.2)	69.2	2/ 11 (18.2)	18.2	3.81 (1.03, 14.04)	0.0446	51.05 (14.20, 87.90)	0.0066	
Ethnicity									0.2799
Hispanic/Latino	15/ 23 (65.2)	65.2	10/ 24 (41.7)	41.7	1.57 (0.89, 2.74)	0.1166	23.55 (-4.40, 51.51)	0.0987	
Non-hispanic/Latino	72/104 (69.2)	68.5	62/101 (61.4)	61.6	1.13 (0.92, 1.38)	0.2406	6.90 (-6.37, 20.16)	0.3081	
Geographic region									0.4499
EU	37/ 47 (78.7)	78.7	39/ 56 (69.6)	69.6	1.13 (0.90, 1.42)	0.2921	9.08 (-8.11, 26.27)	0.3005	
non-EU	50/ 80 (62.5)	62.7	33/ 69 (47.8)	47.6	1.31 (0.97, 1.76)	0.0797	15.11 (-0.64, 30.86)	0.0601	
Onset of disease									0.6145
Paediatric	3/ 8 (37.5)	37.5	3/ 7 (42.9)	42.9	0.88 (0.25, 3.02)	0.8325	-5.36 (-55.63, 44.92)	0.8346	
Adult	84/119 (70.6)	70.4	69/118 (58.5)	58.7	1.21 (1.00, 1.46)	0.0537	11.70 (-0.46, 23.86)	0.0592	
ADA result									0.9154
Negative	77/111 (69.4)	68.8	65/112 (58.0)	58.6	1.20 (0.98, 1.46)	0.0807	10.25 (-2.41, 22.91)	0.1124	
Positive (At any time)	10/ 15 (66.7)	66.7	7/ 13 (53.8)	53.8	1.24 (0.67, 2.30)	0.4979	12.82 (-23.68, 49.32)	0.4912	
BMI (kg/m2) at enrolment									0.3246
< 30	52/ 74 (70.3)	70.6	48/ 87 (55.2)	55.3	1.27 (1.00, 1.62)	0.0487	15.24 (0.49, 29.99)	0.0429	
>= 30	35/ 53 (66.0)	66.8	24/ 38 (63.2)	63.4	1.05 (0.77, 1.43)	0.7782	3.44 (-16.33, 23.20)	0.7332	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Maintained OCS Reduction at week 52 (for subjects with baseline OCS >=10 mg/day)
Full analysis set

Timepoint		Anifrolumab 300mg (N=70)	Placebo (N=73)
Week 52	Number of subjects with events, n (%)	38 (54.3)	24 (32.9)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.73 (1.18, 2.54)	
	p-value	0.0049	
	Odds Ratio (95% CI)	2.91 (1.40, 6.03)	
	p-value	0.0041	
	Risk Difference (95% CI)	23.28 (8.19, 38.36)	
	p-value	0.0025	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.65 (1.12, 2.44)	
	p-value	0.0122	
	Odds Ratio (95% CI)	2.42 (1.23, 4.78)	
	p-value	0.0105	
	Risk Difference (95% CI)	21.41 (5.52, 37.29)	
	p-value	0.0083	
	CMH approach		
	Response rate	55.0	31.9
	Difference in response rates (95% CI)	23.12 (7.51, 38.73)	
	p-value	0.0037	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Maintained OCS Reduction at week 52 (for subjects with baseline OCS >=10 mg/day) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=70) n/ N (%)	Response rate	Placebo (N=73) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8676
< 10 points	11/ 20 (55.0)	55.0	6/ 17 (35.3)	35.3	1.56 (0.73, 3.32)	0.2501	19.71 (-12.07, 51.48)	0.2242	
>= 10 points	27/ 50 (54.0)	54.0	18/ 56 (32.1)	32.1	1.68 (1.06, 2.66)	0.0266	21.86 (3.32, 40.39)	0.0208	
OCS dose at baseline									NE
>=10 mg/day	38/ 70 (54.3)	55.0	24/ 73 (32.9)	31.9	1.65 (1.12, 2.44)	0.0122	23.12 (7.51, 38.73)	0.0037	
Result of type I IFN gene signature test									0.2848
LOW	7/ 8 (87.5)	87.5	8/ 12 (66.7)	66.7	1.31 (0.81, 2.12)	0.2650	20.83 (-19.79, 61.46)	0.3149	
HIGH	31/ 62 (50.0)	49.9	16/ 61 (26.2)	26.4	1.91 (1.17, 3.11)	0.0097	23.48 (6.58, 40.37)	0.0065	
Age (years)									0.2086
<= 65	38/ 69 (55.1)	55.1	23/ 72 (31.9)	31.9	1.72 (1.16, 2.57)	0.0074	23.13 (7.14, 39.12)	0.0046	
> 65	0/ 1 (0.0)	0.0	1/ 1 (100.0)	100.0	0.33 (0.03, 4.19)	0.3948	-100.00 (-235.79, 35.79)	0.1489	
Sex									0.2470
male	5/ 9 (55.6)	55.6	0/ 6 (0.0)	0.0	7.70 (0.50, 117.97)	0.1427	55.56 (9.89, 101.22)	0.0171	
female	33/ 61 (54.1)	54.1	24/ 67 (35.8)	35.8	1.51 (1.02, 2.24)	0.0409	18.28 (1.26, 35.29)	0.0353	
Race									0.0935
White	21/ 39 (53.8)	53.8	20/ 57 (35.1)	35.1	1.53 (0.97, 2.42)	0.0664	18.76 (-1.25, 38.77)	0.0662	
Black or African American	8/ 16 (50.0)	50.0	1/ 6 (16.7)	16.7	3.00 (0.47, 19.18)	0.2458	33.33 (-10.77, 77.43)	0.1385	
Asian	3/ 4 (75.0)	75.0	2/ 2 (100.0)	100.0	0.75 (0.43, 1.32)	0.3190	-25.00 (-105.74, 55.74)	0.5439	
Other	6/ 11 (54.5)	54.5	1/ 8 (12.5)	12.5	4.36 (0.65, 29.50)	0.1308	42.05 (-0.02, 84.11)	0.0501	
Ethnicity									0.7233
Hispanic/Latino	5/ 14 (35.7)	35.7	2/ 12 (16.7)	16.7	2.14 (0.50, 9.11)	0.3020	19.05 (-16.34, 54.44)	0.2915	
Non-hispanic/Latino	33/ 56 (58.9)	58.9	22/ 61 (36.1)	36.1	1.63 (1.10, 2.44)	0.0160	22.86 (5.16, 40.57)	0.0114	
Geographic region									0.3821
EU	20/ 31 (64.5)	64.5	18/ 43 (41.9)	41.9	1.54 (0.99, 2.39)	0.0531	22.66 (0.12, 45.19)	0.0488	
non-EU	18/ 39 (46.2)	46.2	6/ 30 (20.0)	20.0	2.31 (1.05, 5.09)	0.0385	26.15 (4.35, 47.96)	0.0187	
Onset of disease									0.6643
Paediatric	3/ 6 (50.0)	50.0	1/ 5 (20.0)	20.0	2.50 (0.36, 17.17)	0.3514	30.00 (-27.51, 87.51)	0.3066	
Adult	35/ 64 (54.7)	54.7	23/ 68 (33.8)	33.8	1.62 (1.08, 2.41)	0.0187	20.86 (4.22, 37.51)	0.0140	
ADA result									0.5129
Negative	34/ 59 (57.6)	57.6	23/ 65 (35.4)	35.4	1.63 (1.10, 2.42)	0.0154	22.24 (5.04, 39.45)	0.0113	
Positive (At any time)	4/ 10 (40.0)	40.0	1/ 8 (12.5)	12.5	3.20 (0.44, 23.28)	0.2506	27.50 (-15.41, 70.41)	0.2091	
BMI (kg/m2) at enrolment									0.9301
< 30	26/ 45 (57.8)	57.8	19/ 56 (33.9)	33.9	1.70 (1.09, 2.65)	0.0184	23.85 (4.74, 42.96)	0.0144	
>= 30	12/ 25 (48.0)	48.0	5/ 17 (29.4)	29.4	1.63 (0.70, 3.79)	0.2542	18.59 (-11.17, 48.35)	0.2209	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=50% Reduction in CLASI activity score at week 52 (for subjects with baseline CLASI activity score >=10)
Full analysis set

Timepoint		Anifrolumab 300mg (N=40)	Placebo (N=40)
Week 52	Number of subjects with events, n (%)	24 (60.0)	20 (50.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.16 (0.79, 1.70)	
	p-value	0.4461	
	Odds Ratio (95% CI)	1.43 (0.56, 3.61)	
	p-value	0.4517	
	Risk Difference (95% CI)	8.25 (-13.21, 29.70)	
	p-value	0.4512	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.20 (0.80, 1.79)	
	p-value	0.3718	
	Odds Ratio (95% CI)	1.50 (0.62, 3.64)	
	p-value	0.3695	
	Risk Difference (95% CI)	10.00 (-11.69, 31.69)	
	p-value	0.3663	
	CMH approach		
	Response rate	60.0	50.0
	Difference in response rates (95% CI)	10.00 (-11.73, 31.73)	
	p-value	0.3671	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=50% Reduction in CLASI activity score at week 52 (for subjects with baseline CLASI activity score >=10) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=40) n/ N (%)	Response rate	Placebo (N=40) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.7311
< 10 points	6/ 8 (75.0)	75.0	5/ 9 (55.6)	55.6	1.35 (0.66, 2.74)	0.4062	19.44 (-26.68, 65.57)	0.4087	
>= 10 points	18/ 32 (56.3)	56.3	15/ 31 (48.4)	48.4	1.16 (0.72, 1.87)	0.5343	7.86 (-16.75, 32.48)	0.5313	
OCS dose at baseline									0.4474
<10 mg/day	9/ 14 (64.3)	64.3	6/ 14 (42.9)	42.9	1.50 (0.73, 3.08)	0.2697	21.43 (-15.04, 57.89)	0.2494	
>=10 mg/day	15/ 26 (57.7)	57.7	14/ 26 (53.8)	53.8	1.07 (0.66, 1.74)	0.7803	3.85 (-23.18, 30.87)	0.7803	
Result of type I IFN gene signature test									0.1994
LOW	5/ 7 (71.4)	71.4	6/ 7 (85.7)	85.7	0.83 (0.48, 1.46)	0.5217	-14.29 (-62.85, 34.28)	0.5642	
HIGH	19/ 33 (57.6)	57.6	14/ 33 (42.4)	42.4	1.36 (0.83, 2.22)	0.2254	15.15 (-8.75, 39.06)	0.2141	
Age (years)									NE
<= 65	23/ 39 (59.0)	59.0	19/ 39 (48.7)	48.7	1.21 (0.80, 1.83)	0.3669	10.26 (-11.79, 32.30)	0.3618	
> 65	1/ 1 (100.0)	100.0	1/ 1 (100.0)	100.0	NE		0.00 (-135.79, 135.79)	1.0000	
Sex									0.3705
male	2/ 4 (50.0)	50.0	0/ 3 (0.0)	0.0	4.00 (0.26, 61.76)	0.3208	50.00 (-20.81, 120.81)	0.1664	
female	22/ 36 (61.1)	61.1	20/ 37 (54.1)	54.1	1.13 (0.76, 1.68)	0.5428	7.06 (-15.62, 29.73)	0.5419	
Race									0.1978
White	17/ 29 (58.6)	58.6	18/ 36 (50.0)	50.0	1.17 (0.75, 1.83)	0.4860	8.62 (-15.68, 32.92)	0.4868	
Black or African American	3/ 6 (50.0)		0		NE		NE		
Asian	3/ 4 (75.0)	75.0	1/ 1 (100.0)	100.0	0.75 (0.43, 1.32)	0.3190	-25.00 (-132.10, 82.10)	0.6473	
Other	1/ 1 (100.0)	100.0	1/ 3 (33.3)	33.3	3.00 (0.61, 14.86)	0.1785	66.67 (-44.49, 177.82)	0.2398	
Ethnicity									0.4632
Hispanic/Latino	0/ 4 (0.0)	0.0	1/ 5 (20.0)	20.0	0.40 (0.02, 7.82)	0.5457	-20.00 (-79.23, 39.23)	0.5081	
Non-hispanic/Latino	24/ 36 (66.7)	66.7	19/ 35 (54.3)	54.3	1.23 (0.84, 1.80)	0.2916	12.38 (-10.32, 35.09)	0.2852	
Geographic region									0.4968
EU	14/ 19 (73.7)	73.7	14/ 21 (66.7)	66.7	1.11 (0.74, 1.66)	0.6278	7.02 (-22.13, 36.16)	0.6370	
non-EU	10/ 21 (47.6)	47.6	6/ 19 (31.6)	31.6	1.51 (0.68, 3.35)	0.3140	16.04 (-14.21, 46.29)	0.2987	
Onset of disease									0.8218
Paediatric	2/ 4 (50.0)	50.0	1/ 2 (50.0)	50.0	1.00 (0.18, 5.46)	1.0000	0.00 (-84.87, 84.87)	1.0000	
Adult	22/ 36 (61.1)	61.1	19/ 38 (50.0)	50.0	1.22 (0.81, 1.84)	0.3387	11.11 (-11.45, 33.67)	0.3343	
ADA result									0.3043
Negative	23/ 35 (65.7)	65.7	19/ 38 (50.0)	50.0	1.31 (0.88, 1.96)	0.1783	15.71 (-6.76, 38.19)	0.1706	
Positive (At any time)	1/ 5 (20.0)	20.0	1/ 2 (50.0)	50.0	0.40 (0.04, 3.74)	0.4216	-30.00 (-110.68, 50.68)	0.4661	
BMI (kg/m2) at enrolment									0.5565
< 30	17/ 25 (68.0)	68.0	13/ 25 (52.0)	52.0	1.31 (0.82, 2.08)	0.2559	16.00 (-11.03, 43.03)	0.2460	
>= 30	7/ 15 (46.7)	46.7	7/ 15 (46.7)	46.7	1.00 (0.47, 2.15)	1.0000	0.00 (-35.73, 35.73)	1.0000	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 4	Number of subjects with events, n (%)	31 (24.4)	19 (15.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.55 (0.93, 2.58)	
	p-value	0.0917	
	Odds Ratio (95% CI)	1.72 (0.91, 3.23)	
	p-value	0.0924	
	Risk Difference (95% CI)	8.66 (-1.27, 18.60)	
	p-value	0.0875	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.61 (0.96, 2.69)	
	p-value	0.0714	
	Odds Ratio (95% CI)	1.80 (0.96, 3.40)	
	p-value	0.0689	
	Risk Difference (95% CI)	9.21 (-0.56, 18.98)	
	p-value	0.0646	
	CMH approach		
	Response rate	24.2	15.4
	Difference in response rates (95% CI)	8.83 (-1.58, 19.24)	
	p-value	0.0964	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 8	Number of subjects with events, n (%)	48 (37.8)	30 (24.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.56 (1.08, 2.27)	
	p-value	0.0188	
	Odds Ratio (95% CI)	1.91 (1.11, 3.30)	
	p-value	0.0202	
	Risk Difference (95% CI)	13.90 (2.46, 25.35)	
	p-value	0.0173	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.57 (1.07, 2.31)	
	p-value	0.0203	
	Odds Ratio (95% CI)	1.92 (1.12, 3.32)	
	p-value	0.0186	
	Risk Difference (95% CI)	13.80 (2.52, 25.07)	
	p-value	0.0165	
	CMH approach		
	Response rate	37.6	24.3
	Difference in response rates (95% CI)	13.36 (1.99, 24.73)	
	p-value	0.0213	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 12	Number of subjects with events, n (%)	52 (40.9)	37 (29.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.38 (0.99, 1.93)	
	p-value	0.0582	
	Odds Ratio (95% CI)	1.65 (0.98, 2.78)	
	p-value	0.0599	
	Risk Difference (95% CI)	11.55 (-0.33, 23.43)	
	p-value	0.0568	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.38 (0.98, 1.95)	
	p-value	0.0627	
	Odds Ratio (95% CI)	1.65 (0.98, 2.78)	
	p-value	0.0604	
	Risk Difference (95% CI)	11.34 (-0.37, 23.06)	
	p-value	0.0576	
	CMH approach		
	Response rate	40.9	30.0
	Difference in response rates (95% CI)	10.96 (-0.73, 22.66)	
	p-value	0.0662	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 16	Number of subjects with events, n (%)	58 (45.7)	40 (32.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.42 (1.03, 1.95)	
	p-value	0.0340	
	Odds Ratio (95% CI)	1.74 (1.05, 2.90)	
	p-value	0.0325	
	Risk Difference (95% CI)	13.44 (1.28, 25.60)	
	p-value	0.0303	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.43 (1.04, 1.96)	
	p-value	0.0285	
	Odds Ratio (95% CI)	1.79 (1.07, 2.98)	
	p-value	0.0267	
	Risk Difference (95% CI)	13.67 (1.76, 25.58)	
	p-value	0.0245	
	CMH approach		
	Response rate	45.2	32.1
	Difference in response rates (95% CI)	13.07 (1.24, 24.91)	
	p-value	0.0304	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 20	Number of subjects with events, n (%)	57 (44.9)	46 (36.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.22 (0.90, 1.65)	
	p-value	0.1973	
	Odds Ratio (95% CI)	1.39 (0.84, 2.30)	
	p-value	0.1982	
	Risk Difference (95% CI)	8.11 (-4.18, 20.39)	
	p-value	0.1958	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.22 (0.90, 1.65)	
	p-value	0.1944	
	Odds Ratio (95% CI)	1.40 (0.84, 2.32)	
	p-value	0.1925	
	Risk Difference (95% CI)	8.08 (-4.01, 20.18)	
	p-value	0.1903	
	CMH approach		
	Response rate	44.7	36.8
	Difference in response rates (95% CI)	7.93 (-4.17, 20.02)	
	p-value	0.1989	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 24	Number of subjects with events, n (%)	61 (48.0)	49 (39.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.24 (0.93, 1.65)	
	p-value	0.1376	
	Odds Ratio (95% CI)	1.45 (0.88, 2.39)	
	p-value	0.1399	
	Risk Difference (95% CI)	9.46 (-2.98, 21.90)	
	p-value	0.1361	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.23 (0.92, 1.63)	
	p-value	0.1602	
	Odds Ratio (95% CI)	1.43 (0.87, 2.36)	
	p-value	0.1581	
	Risk Difference (95% CI)	8.83 (-3.36, 21.03)	
	p-value	0.1558	
	CMH approach		
	Response rate	47.7	39.0
	Difference in response rates (95% CI)	8.68 (-3.45, 20.81)	
	p-value	0.1608	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 28	Number of subjects with events, n (%)	60 (47.2)	52 (41.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.12 (0.85, 1.48)	
	p-value	0.4247	
	Odds Ratio (95% CI)	1.22 (0.74, 2.01)	
	p-value	0.4279	
	Risk Difference (95% CI)	5.04 (-7.41, 17.50)	
	p-value	0.4274	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.14 (0.86, 1.50)	
	p-value	0.3686	
	Odds Ratio (95% CI)	1.26 (0.76, 2.07)	
	p-value	0.3676	
	Risk Difference (95% CI)	5.64 (-6.61, 17.89)	
	p-value	0.3665	
	CMH approach		
	Response rate	46.9	41.8
	Difference in response rates (95% CI)	5.05 (-7.07, 17.17)	
	p-value	0.4139	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 32	Number of subjects with events, n (%)	64 (50.4)	54 (43.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.16 (0.89, 1.50)	
	p-value	0.2681	
	Odds Ratio (95% CI)	1.32 (0.80, 2.17)	
	p-value	0.2729	
	Risk Difference (95% CI)	6.98 (-5.46, 19.43)	
	p-value	0.2713	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.17 (0.90, 1.52)	
	p-value	0.2545	
	Odds Ratio (95% CI)	1.34 (0.81, 2.19)	
	p-value	0.2529	
	Risk Difference (95% CI)	7.19 (-5.10, 19.48)	
	p-value	0.2513	
	CMH approach		
	Response rate	50.1	43.4
	Difference in response rates (95% CI)	6.68 (-5.53, 18.88)	
	p-value	0.2837	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 36	Number of subjects with events, n (%)	65 (51.2)	53 (42.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.20 (0.93, 1.56)	
	p-value	0.1649	
	Odds Ratio (95% CI)	1.41 (0.86, 2.31)	
	p-value	0.1708	
	Risk Difference (95% CI)	8.81 (-3.71, 21.32)	
	p-value	0.1680	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.21 (0.93, 1.57)	
	p-value	0.1650	
	Odds Ratio (95% CI)	1.42 (0.87, 2.34)	
	p-value	0.1630	
	Risk Difference (95% CI)	8.78 (-3.49, 21.05)	
	p-value	0.1608	
	CMH approach		
	Response rate	50.8	42.7
	Difference in response rates (95% CI)	8.12 (-4.06, 20.30)	
	p-value	0.1911	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 40	Number of subjects with events, n (%)	62 (48.8)	48 (38.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.26 (0.95, 1.66)	
	p-value	0.1069	
	Odds Ratio (95% CI)	1.51 (0.91, 2.51)	
	p-value	0.1105	
	Risk Difference (95% CI)	10.03 (-2.18, 22.23)	
	p-value	0.1073	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.27 (0.96, 1.69)	
	p-value	0.0983	
	Odds Ratio (95% CI)	1.53 (0.93, 2.53)	
	p-value	0.0961	
	Risk Difference (95% CI)	10.42 (-1.76, 22.60)	
	p-value	0.0935	
	CMH approach		
	Response rate	48.2	38.8
	Difference in response rates (95% CI)	9.47 (-2.51, 21.44)	
	p-value	0.1212	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 44	Number of subjects with events, n (%)	62 (48.8)	43 (34.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.41 (1.05, 1.90)	
	p-value	0.0239	
	Odds Ratio (95% CI)	1.78 (1.08, 2.93)	
	p-value	0.0248	
	Risk Difference (95% CI)	14.41 (2.05, 26.76)	
	p-value	0.0223	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.42 (1.05, 1.92)	
	p-value	0.0224	
	Odds Ratio (95% CI)	1.82 (1.10, 3.02)	
	p-value	0.0208	
	Risk Difference (95% CI)	14.42 (2.38, 26.46)	
	p-value	0.0189	
	CMH approach		
	Response rate	48.5	34.5
	Difference in response rates (95% CI)	13.98 (2.05, 25.90)	
	p-value	0.0217	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 48	Number of subjects with events, n (%)	61 (48.0)	39 (31.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.52 (1.12, 2.08)	
	p-value	0.0077	
	Odds Ratio (95% CI)	2.03 (1.21, 3.40)	
	p-value	0.0075	
	Risk Difference (95% CI)	16.70 (4.73, 28.67)	
	p-value	0.0062	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.54 (1.12, 2.11)	
	p-value	0.0076	
	Odds Ratio (95% CI)	2.04 (1.22, 3.41)	
	p-value	0.0066	
	Risk Difference (95% CI)	16.83 (4.94, 28.73)	
	p-value	0.0055	
	CMH approach		
	Response rate	47.6	31.6
	Difference in response rates (95% CI)	15.99 (4.10, 27.87)	
	p-value	0.0084	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 52	Number of subjects with events, n (%)	64 (50.4)	41 (32.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.53 (1.14, 2.06)	
	p-value	0.0047	
	Odds Ratio (95% CI)	2.10 (1.26, 3.52)	
	p-value	0.0047	
	Risk Difference (95% CI)	17.83 (5.79, 29.86)	
	p-value	0.0037	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.54 (1.13, 2.08)	
	p-value	0.0057	
	Odds Ratio (95% CI)	2.08 (1.25, 3.47)	
	p-value	0.0049	
	Risk Difference (95% CI)	17.59 (5.62, 29.57)	
	p-value	0.0040	
	CMH approach		
	Response rate	50.0	33.3
	Difference in response rates (95% CI)	16.79 (4.86, 28.73)	
	p-value	0.0058	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.5495
< 10 points	23/ 39 (59.0)	59.0	16/ 37 (43.2)	43.2	1.36 (0.87, 2.14)	0.1790	15.73 (-6.53, 37.99)	0.1660	
>= 10 points	41/ 88 (46.6)	46.6	25/ 88 (28.4)	28.7	1.64 (1.10, 2.45)	0.0154	17.89 (3.79, 32.00)	0.0129	
OCS dose at baseline									0.3328
<10 mg/day	27/ 57 (47.4)	47.5	19/ 52 (36.5)	36.5	1.30 (0.83, 2.03)	0.2590	10.98 (-7.51, 29.48)	0.2444	
>=10 mg/day	37/ 70 (52.9)	52.6	22/ 73 (30.1)	30.5	1.75 (1.16, 2.65)	0.0077	22.04 (6.43, 37.65)	0.0057	
Result of type I IFN gene signature test									0.4573
LOW	10/ 22 (45.5)	45.5	9/ 24 (37.5)	37.5	1.21 (0.61, 2.42)	0.5848	7.95 (-20.61, 36.52)	0.5852	
HIGH	54/105 (51.4)	51.1	32/101 (31.7)	32.3	1.62 (1.15, 2.28)	0.0054	18.77 (5.63, 31.91)	0.0051	
Age (years)									0.9408
<= 65	60/122 (49.2)	48.7	40/123 (32.5)	32.9	1.51 (1.11, 2.07)	0.0094	15.79 (3.68, 27.91)	0.0106	
> 65	4/ 5 (80.0)	80.0	1/ 2 (50.0)	50.0	1.60 (0.37, 6.85)	0.5262	30.00 (-50.68, 110.68)	0.4661	
Sex									0.3145
male	6/ 12 (50.0)	50.0	1/ 8 (12.5)	12.5	4.00 (0.59, 27.25)	0.1567	37.50 (-3.74, 78.74)	0.0747	
female	58/115 (50.4)	50.0	40/117 (34.2)	34.7	1.48 (1.08, 2.01)	0.0139	15.34 (2.84, 27.83)	0.0162	
Race									0.6287
White	42/ 85 (49.4)	49.6	33/ 96 (34.4)	34.6	1.44 (1.01, 2.04)	0.0423	15.05 (0.80, 29.31)	0.0385	
Black or African American	12/ 22 (54.5)	54.5	6/ 14 (42.9)	42.9	1.27 (0.62, 2.60)	0.5086	11.69 (-21.65, 45.03)	0.4920	
Asian	4/ 7 (57.1)	57.1	1/ 3 (33.3)	33.3	1.71 (0.31, 9.61)	0.5401	23.81 (-43.25, 90.87)	0.4865	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	6/ 13 (46.2)	46.2	1/ 11 (9.1)	9.1	5.08 (0.72, 36.00)	0.1040	37.06 (1.08, 73.05)	0.0435	
Ethnicity									0.9570
Hispanic/Latino	9/ 23 (39.1)	39.1	6/ 24 (25.0)	25.0	1.57 (0.66, 3.70)	0.3074	14.13 (-12.89, 41.15)	0.3053	
Non-hispanic/Latino	55/104 (52.9)	52.1	35/101 (34.7)	35.5	1.53 (1.10, 2.11)	0.0104	16.56 (3.17, 29.95)	0.0154	
Geographic region									0.8675
EU	30/ 47 (63.8)	63.8	22/ 56 (39.3)	39.3	1.62 (1.10, 2.40)	0.0148	24.54 (5.68, 43.40)	0.0108	
non-EU	34/ 80 (42.5)	42.6	19/ 69 (27.5)	27.3	1.54 (0.97, 2.44)	0.0644	15.26 (0.03, 30.48)	0.0496	
Onset of disease									0.8280
Paediatric	3/ 8 (37.5)	37.5	2/ 7 (28.6)	28.6	1.31 (0.30, 5.73)	0.7176	8.93 (-40.44, 58.29)	0.7230	
Adult	61/119 (51.3)	51.1	39/118 (33.1)	33.5	1.55 (1.14, 2.12)	0.0057	17.60 (5.24, 29.96)	0.0053	
ADA result									0.8483
Negative	58/111 (52.3)	51.6	38/112 (33.9)	34.8	1.54 (1.13, 2.11)	0.0070	16.84 (4.06, 29.62)	0.0098	
Positive (At any time)	6/ 15 (40.0)	40.0	3/ 13 (23.1)	23.1	1.73 (0.54, 5.59)	0.3569	16.92 (-18.26, 52.11)	0.3458	
BMI (kg/m2) at enrolment									0.2198
< 30	39/ 74 (52.7)	52.7	26/ 87 (29.9)	30.8	1.76 (1.20, 2.60)	0.0041	21.90 (7.08, 36.72)	0.0038	
>= 30	25/ 53 (47.2)	47.9	15/ 38 (39.5)	39.7	1.19 (0.74, 1.94)	0.4725	8.26 (-12.02, 28.53)	0.4247	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA - individual components at week 52 (Full analysis set)
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
BILAG improvement [a]	64 (50.4)	42 (33.6)
No discontinuation of IP	104 (81.9)	97 (77.6)
No use of medication beyond protocol allowed threshold	101 (79.5)	90 (72.0)
No worsening of PGA [a]	86 (67.7)	74 (59.2)
No worsening of SLEDAI-2K [a]	89 (70.1)	71 (56.8)

[a] Subjects who discontinued IP or used medications beyond protocol allowed threshold are considered non-responders and not included in this category.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate at week 52 sensitivity analysis, multiple imputation
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 52	Number of subjects with events, n (%)	63 (49.8)	41 (33.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.51 (1.12, 2.03)	
	p-value	0.0071	
	Odds Ratio (95% CI)	2.03 (1.21, 3.41)	
	p-value	0.0073	
	Risk Difference (95% CI)	17.08 (4.92, 29.24)	
	p-value	0.0059	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.51 (1.11, 2.05)	
	p-value	0.0083	
	Odds Ratio (95% CI)	2.02 (1.21, 3.37)	
	p-value	0.0073	
	Risk Difference (95% CI)	16.85 (4.80, 28.90)	
	p-value	0.0061	

For each outcome and visit, 100 imputations were generated by randomised treatment group. Each imputed dataset was analysed separately, and the single estimates are combined using PROC MIANALYZE. The estimated number of responders and non-responders are rounded to an integer. Therefore, there might be slight mismatches between number of subjects and corresponding percentage.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Change from baseline in PGA VAS < 0.3 at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 52	Number of subjects with events, n (%)	86 (67.7)	74 (59.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.15 (0.96, 1.38)	
	p-value	0.1409	
	Odds Ratio (95% CI)	1.48 (0.88, 2.50)	
	p-value	0.1436	
	Risk Difference (95% CI)	8.84 (-2.93, 20.60)	
	p-value	0.1409	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.14 (0.95, 1.38)	
	p-value	0.1627	
	Odds Ratio (95% CI)	1.45 (0.86, 2.42)	
	p-value	0.1610	
	Risk Difference (95% CI)	8.52 (-3.33, 20.36)	
	p-value	0.1588	
	CMH approach		
	Response rate	67.6	59.3
	Difference in response rates (95% CI)	8.23 (-3.67, 20.14)	
	p-value	0.1753	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Change from baseline in PGA VAS < 0.3 at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9389
< 10 points	28/ 39 (71.8)	71.8	23/ 37 (62.2)	62.2	1.15 (0.84, 1.59)	0.3764	9.63 (-11.69, 30.96)	0.3760	
>= 10 points	58/ 88 (65.9)	65.6	51/ 88 (58.0)	58.2	1.14 (0.90, 1.44)	0.2791	7.37 (-6.90, 21.65)	0.3113	
OCS dose at baseline									0.8473
<10 mg/day	42/ 57 (73.7)	73.8	33/ 52 (63.5)	63.4	1.16 (0.90, 1.50)	0.2567	10.37 (-7.39, 28.12)	0.2524	
>=10 mg/day	44/ 70 (62.9)	63.3	41/ 73 (56.2)	55.8	1.12 (0.85, 1.47)	0.4157	7.46 (-8.65, 23.57)	0.3642	
Result of type I IFN gene signature test									0.7808
LOW	16/ 22 (72.7)	72.7	16/ 24 (66.7)	66.7	1.09 (0.74, 1.60)	0.6548	6.06 (-21.13, 33.25)	0.6622	
HIGH	70/105 (66.7)	66.4	58/101 (57.4)	57.7	1.16 (0.94, 1.44)	0.1750	8.72 (-4.52, 21.95)	0.1967	
Age (years)									0.1393
<= 65	82/122 (67.2)	67.2	72/123 (58.5)	58.6	1.15 (0.95, 1.39)	0.1617	8.67 (-3.45, 20.79)	0.1609	
> 65	4/ 5 (80.0)	80.0	2/ 2 (100.0)	100.0	0.80 (0.52, 1.24)	0.3183	-20.00 (-97.30, 57.30)	0.6121	
Sex									0.1759
male	8/ 12 (66.7)	66.7	2/ 8 (25.0)	25.0	2.67 (0.75, 9.45)	0.1286	41.67 (-0.96, 84.30)	0.0554	
female	78/115 (67.8)	67.6	72/117 (61.5)	61.8	1.10 (0.91, 1.33)	0.3174	5.83 (-6.56, 18.22)	0.3565	
Race									0.0809
White	60/ 85 (70.6)	70.0	61/ 96 (63.5)	63.9	1.11 (0.91, 1.36)	0.3133	6.12 (-7.90, 20.15)	0.3921	
Black or African American	12/ 22 (54.5)	54.5	8/ 14 (57.1)	57.1	0.95 (0.53, 1.73)	0.8777	-2.60 (-35.94, 30.74)	0.8786	
Asian	5/ 7 (71.4)	71.4	3/ 3 (100.0)	100.0	0.71 (0.45, 1.14)	0.1593	-28.57 (-90.89, 33.74)	0.3688	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	9/ 13 (69.2)	69.2	2/ 11 (18.2)	18.2	3.81 (1.03, 14.04)	0.0446	51.05 (14.20, 87.90)	0.0066	
Ethnicity									0.2175
Hispanic/Latino	15/ 23 (65.2)	65.2	10/ 24 (41.7)	41.7	1.57 (0.89, 2.74)	0.1166	23.55 (-4.40, 51.51)	0.0987	
Non-hispanic/Latino	71/104 (68.3)	67.7	64/101 (63.4)	63.5	1.08 (0.88, 1.31)	0.4604	4.27 (-8.99, 17.54)	0.5278	
Geographic region									0.3568
EU	37/ 47 (78.7)	78.7	41/ 56 (73.2)	73.2	1.08 (0.87, 1.34)	0.5127	5.51 (-11.41, 22.43)	0.5234	
non-EU	49/ 80 (61.3)	61.4	33/ 69 (47.8)	47.6	1.28 (0.95, 1.73)	0.1082	13.76 (-2.05, 29.56)	0.0880	
Onset of disease									0.6597
Paediatric	3/ 8 (37.5)	37.5	3/ 7 (42.9)	42.9	0.88 (0.25, 3.02)	0.8325	-5.36 (-55.63, 44.92)	0.8346	
Adult	83/119 (69.7)	69.7	71/118 (60.2)	60.4	1.16 (0.96, 1.40)	0.1247	9.34 (-2.83, 21.51)	0.1327	
ADA result									0.8123
Negative	76/111 (68.5)	68.1	67/112 (59.8)	60.2	1.14 (0.94, 1.39)	0.1801	7.87 (-4.82, 20.55)	0.2242	
Positive (At any time)	10/ 15 (66.7)	66.7	7/ 13 (53.8)	53.8	1.24 (0.67, 2.30)	0.4979	12.82 (-23.68, 49.32)	0.4912	
BMI (kg/m2) at enrolment									0.2112
< 30	52/ 74 (70.3)	70.6	49/ 87 (56.3)	56.5	1.25 (0.98, 1.58)	0.0674	14.09 (-0.67, 28.85)	0.0613	
>= 30	34/ 53 (64.2)	64.8	25/ 38 (65.8)	66.1	0.98 (0.72, 1.32)	0.8713	-1.31 (-21.05, 18.43)	0.8966	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Change from baseline in PGA VAS < 0.45 at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 52	Number of subjects with events, n (%)	88 (69.3)	74 (59.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.17 (0.98, 1.41)	
	p-value	0.0840	
	Odds Ratio (95% CI)	1.59 (0.94, 2.70)	
	p-value	0.0856	
	Risk Difference (95% CI)	10.36 (-1.34, 22.07)	
	p-value	0.0827	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.17 (0.97, 1.41)	
	p-value	0.0971	
	Odds Ratio (95% CI)	1.56 (0.93, 2.61)	
	p-value	0.0954	
	Risk Difference (95% CI)	10.09 (-1.68, 21.86)	
	p-value	0.0929	
	CMH approach		
	Response rate	69.1	59.3
	Difference in response rates (95% CI)	9.74 (-2.13, 21.61)	
	p-value	0.1076	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Change from baseline in PGA VAS < 0.45 at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8657
< 10 points	29/ 39 (74.4)	74.4	23/ 37 (62.2)	62.2	1.20 (0.88, 1.63)	0.2599	12.20 (-8.90, 33.30)	0.2572	
>= 10 points	59/ 88 (67.0)	66.8	51/ 88 (58.0)	58.2	1.16 (0.92, 1.46)	0.2153	8.55 (-5.70, 22.79)	0.2396	
OCS dose at baseline									0.9675
<10 mg/day	42/ 57 (73.7)	73.8	33/ 52 (63.5)	63.4	1.16 (0.90, 1.50)	0.2567	10.37 (-7.39, 28.12)	0.2524	
>=10 mg/day	46/ 70 (65.7)	65.9	41/ 73 (56.2)	55.8	1.17 (0.90, 1.52)	0.2437	10.14 (-5.89, 26.17)	0.2150	
Result of type I IFN gene signature test									0.6849
LOW	16/ 22 (72.7)	72.7	16/ 24 (66.7)	66.7	1.09 (0.74, 1.60)	0.6548	6.06 (-21.13, 33.25)	0.6622	
HIGH	72/105 (68.6)	68.3	58/101 (57.4)	57.7	1.19 (0.97, 1.48)	0.1011	10.57 (-2.62, 23.76)	0.1163	
Age (years)									0.1140
<= 65	84/122 (68.9)	68.8	72/123 (58.5)	58.6	1.18 (0.97, 1.42)	0.0953	10.20 (-1.89, 22.28)	0.0982	
> 65	4/ 5 (80.0)	80.0	2/ 2 (100.0)	100.0	0.80 (0.52, 1.24)	0.3183	-20.00 (-97.30, 57.30)	0.6121	
Sex									0.1884
male	8/ 12 (66.7)	66.7	2/ 8 (25.0)	25.0	2.67 (0.75, 9.45)	0.1286	41.67 (-0.96, 84.30)	0.0554	
female	80/115 (69.6)	69.3	72/117 (61.5)	61.8	1.13 (0.94, 1.36)	0.1999	7.52 (-4.83, 19.86)	0.2327	
Race									0.0610
White	60/ 85 (70.6)	70.0	61/ 96 (63.5)	63.9	1.11 (0.91, 1.36)	0.3133	6.12 (-7.90, 20.15)	0.3921	
Black or African American	13/ 22 (59.1)	59.1	8/ 14 (57.1)	57.1	1.03 (0.58, 1.83)	0.9085	1.95 (-31.27, 35.17)	0.9085	
Asian	5/ 7 (71.4)	71.4	3/ 3 (100.0)	100.0	0.71 (0.45, 1.14)	0.1593	-28.57 (-90.89, 33.74)	0.3688	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	10/ 13 (76.9)	76.9	2/ 11 (18.2)	18.2	4.23 (1.17, 15.35)	0.0282	58.74 (22.74, 94.75)	0.0014	
Ethnicity									0.1514
Hispanic/Latino	16/ 23 (69.6)	69.6	10/ 24 (41.7)	41.7	1.67 (0.97, 2.88)	0.0653	27.90 (0.27, 55.52)	0.0478	
Non-hispanic/Latino	72/104 (69.2)	68.5	64/101 (63.4)	63.5	1.09 (0.90, 1.33)	0.3760	5.05 (-8.19, 18.29)	0.4549	
Geographic region									0.2522
EU	37/ 47 (78.7)	78.7	41/ 56 (73.2)	73.2	1.08 (0.87, 1.34)	0.5127	5.51 (-11.41, 22.43)	0.5234	
non-EU	51/ 80 (63.8)	63.9	33/ 69 (47.8)	47.6	1.33 (0.99, 1.79)	0.0576	16.32 (0.59, 32.06)	0.0421	
Onset of disease									0.6328
Paediatric	3/ 8 (37.5)	37.5	3/ 7 (42.9)	42.9	0.88 (0.25, 3.02)	0.8325	-5.36 (-55.63, 44.92)	0.8346	
Adult	85/119 (71.4)	71.3	71/118 (60.2)	60.4	1.19 (0.99, 1.43)	0.0701	10.98 (-1.16, 23.11)	0.0762	
ADA result									0.8735
Negative	78/111 (70.3)	69.8	67/112 (59.8)	60.2	1.17 (0.97, 1.43)	0.1041	9.59 (-3.05, 22.23)	0.1371	
Positive (At any time)	10/ 15 (66.7)	66.7	7/ 13 (53.8)	53.8	1.24 (0.67, 2.30)	0.4979	12.82 (-23.68, 49.32)	0.4912	
BMI (kg/m2) at enrolment									0.3264
< 30	52/ 74 (70.3)	70.6	49/ 87 (56.3)	56.5	1.25 (0.98, 1.58)	0.0674	14.09 (-0.67, 28.85)	0.0613	
>= 30	36/ 53 (67.9)	68.7	25/ 38 (65.8)	66.1	1.03 (0.77, 1.39)	0.8317	2.53 (-17.04, 22.10)	0.7999	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Constitutional
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 52	Number of subjects with events, n (%)	1 (0.8)	0 (0.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	NE	
	p-value		
	Odds Ratio (95% CI)	NE	
	p-value		
	Risk Difference (95% CI)	0.62 (-0.75, 2.00)	
	p-value	0.3747	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	2.95 (0.12, 71.81)	
	p-value	0.5060	
	Odds Ratio (95% CI)	2.98 (0.12, 73.76)	
	p-value	0.5055	
	Risk Difference (95% CI)	0.79 (-0.75, 2.32)	
	p-value	0.3154	
	CMH approach		
	Response rate	0.8	0.0
	Difference in response rates (95% CI)	0.83 (-5.48, 7.14)	
	p-value	0.7965	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Constitutional - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE		0.00 (-9.58, 9.58)	1.0000	
>= 10 points	1/ 88 (1.1)	1.1	0/ 88 (0.0)	0.0	3.00 (0.12, 72.65)	0.4993	1.10 (-6.02, 8.22)	0.7618	
OCS dose at baseline									NE
<10 mg/day	1/ 57 (1.8)	1.7	0/ 52 (0.0)	0.0	2.74 (0.11, 65.85)	0.5341	1.70 (-9.28, 12.67)	0.7618	
>=10 mg/day	0/ 70 (0.0)	0.0	0/ 73 (0.0)	0.0	NE		0.00 (-8.22, 8.22)	1.0000	
Result of type I IFN gene signature test									NE
LOW	1/ 22 (4.5)	4.5	0/ 24 (0.0)	0.0	3.26 (0.14, 76.10)	0.4621	4.55 (-12.32, 21.41)	0.5973	
HIGH	0/105 (0.0)	0.0	0/101 (0.0)	0.0	NE		0.00 (-6.74, 6.74)	1.0000	
Age (years)									NE
<= 65	1/122 (0.8)	0.9	0/123 (0.0)	0.0	3.02 (0.12, 73.52)	0.4966	0.90 (-5.59, 7.39)	0.7861	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE		0.00 (-74.81, 74.81)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE		0.00 (-31.89, 31.89)	1.0000	
female	1/115 (0.9)	0.9	0/117 (0.0)	0.0	3.05 (0.13, 74.15)	0.4931	0.93 (-5.88, 7.74)	0.7898	
Race									NE
White	1/ 85 (1.2)	1.1	0/ 96 (0.0)	0.0	3.38 (0.14, 81.97)	0.4535	1.12 (-7.42, 9.66)	0.7969	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE		0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-26.65, 26.65)	1.0000	
Ethnicity									NE
Hispanic/Latino	1/ 23 (4.3)	4.3	0/ 24 (0.0)	0.0	3.13 (0.13, 73.01)	0.4785	4.35 (-12.12, 20.81)	0.6048	
Non-hispanic/Latino	0/104 (0.0)	0.0	0/101 (0.0)	0.0	NE		0.00 (-7.49, 7.49)	1.0000	
Geographic region									NE
EU	0/ 47 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-7.27, 7.27)	1.0000	
non-EU	1/ 80 (1.3)	1.2	0/ 69 (0.0)	0.0	2.59 (0.11, 62.63)	0.5577	1.22 (-7.12, 9.56)	0.7740	
Onset of disease									NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE		0.00 (-38.51, 38.51)	1.0000	
Adult	1/119 (0.8)	0.8	0/118 (0.0)	0.0	2.98 (0.12, 72.30)	0.5030	0.85 (-5.81, 7.50)	0.8031	
ADA result									NE
Negative	1/111 (0.9)	0.9	0/112 (0.0)	0.0	3.03 (0.12, 73.51)	0.4962	0.95 (-6.14, 8.03)	0.7937	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/ 74 (0.0)	0.0	0/ 87 (0.0)	0.0	NE		0.00 (-7.46, 7.46)	1.0000	
>= 30	1/ 53 (1.9)	1.9	0/ 38 (0.0)	0.0	2.17 (0.09, 51.79)	0.6330	1.85 (-11.30, 15.01)	0.7826	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Mucocutaneous
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 52	Number of subjects with events, n (%)	30 (23.6)	46 (36.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.65 (0.44, 0.95)	
	p-value	0.0261	
	Odds Ratio (95% CI)	0.53 (0.30, 0.92)	
	p-value	0.0243	
	Risk Difference (95% CI)	-13.02 (-24.18, -1.86)	
	p-value	0.0222	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.64 (0.44, 0.95)	
	p-value	0.0251	
	Odds Ratio (95% CI)	0.53 (0.31, 0.92)	
	p-value	0.0235	
	Risk Difference (95% CI)	-13.18 (-24.41, -1.95)	
	p-value	0.0214	
	CMH approach		
	Response rate	23.9	36.7
	Difference in response rates (95% CI)	-12.85 (-24.34, -1.36)	
	p-value	0.0284	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Mucocutaneous - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9601
< 10 points	8/ 39 (20.5)	20.5	12/ 37 (32.4)	32.4	0.63 (0.29, 1.37)	0.2456	-11.92 (-32.15, 8.31)	0.2482	
>= 10 points	22/ 88 (25.0)	24.8	34/ 88 (38.6)	38.6	0.65 (0.41, 1.01)	0.0566	-13.77 (-27.54, 0.01)	0.0501	
OCS dose at baseline									0.3198
<10 mg/day	15/ 57 (26.3)	26.3	17/ 52 (32.7)	32.5	0.80 (0.45, 1.44)	0.4663	-6.25 (-23.84, 11.33)	0.4859	
>=10 mg/day	15/ 70 (21.4)	22.4	29/ 73 (39.7)	39.2	0.54 (0.32, 0.92)	0.0225	-16.81 (-31.91, -1.70)	0.0292	
Result of type I IFN gene signature test									0.1472
LOW	8/ 22 (36.4)	36.4	8/ 24 (33.3)	33.3	1.09 (0.49, 2.41)	0.8293	3.03 (-24.91, 30.97)	0.8317	
HIGH	22/105 (21.0)	21.1	38/101 (37.6)	37.5	0.56 (0.36, 0.87)	0.0105	-16.40 (-29.00, -3.81)	0.0107	
Age (years)									0.5632
<= 65	29/122 (23.8)	24.3	46/123 (37.4)	37.4	0.64 (0.43, 0.94)	0.0233	-13.08 (-24.76, -1.39)	0.0283	
> 65	1/ 5 (20.0)	20.0	0/ 2 (0.0)	0.0	1.50 (0.08, 26.86)	0.7830	20.00 (-57.30, 97.30)	0.6121	
Sex									0.0833
male	0/ 12 (0.0)	0.0	5/ 8 (62.5)	62.5	0.06 (0.00, 1.00)	0.0502	-62.50 (-101.45, -23.55)	0.0017	
female	30/115 (26.1)	26.4	41/117 (35.0)	34.9	0.74 (0.50, 1.10)	0.1424	-8.56 (-20.63, 3.51)	0.1648	
Race									0.6488
White	24/ 85 (28.2)	27.7	37/ 96 (38.5)	39.0	0.73 (0.48, 1.12)	0.1491	-11.30 (-25.22, 2.62)	0.1116	
Black or African American	1/ 22 (4.5)	4.5	3/ 14 (21.4)	21.4	0.21 (0.02, 1.84)	0.1598	-16.88 (-43.88, 10.11)	0.2203	
Asian	2/ 7 (28.6)	28.6	2/ 3 (66.7)	66.7	0.43 (0.10, 1.77)	0.2417	-38.10 (-104.47, 28.28)	0.2606	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	3/ 13 (23.1)	23.1	4/ 11 (36.4)	36.4	0.63 (0.18, 2.24)	0.4805	-13.29 (-51.39, 24.81)	0.4943	
Ethnicity									0.5279
Hispanic/Latino	7/ 23 (30.4)	30.4	9/ 24 (37.5)	37.5	0.81 (0.36, 1.82)	0.6114	-7.07 (-34.50, 20.37)	0.6138	
Non-hispanic/Latino	23/104 (22.1)	22.2	37/101 (36.6)	36.3	0.60 (0.39, 0.94)	0.0254	-14.16 (-26.89, -1.43)	0.0292	
Geographic region									0.9907
EU	12/ 47 (25.5)	25.5	22/ 56 (39.3)	39.3	0.65 (0.36, 1.17)	0.1501	-13.75 (-31.85, 4.34)	0.1363	
non-EU	18/ 80 (22.5)	22.4	24/ 69 (34.8)	34.9	0.65 (0.38, 1.09)	0.1002	-12.47 (-27.30, 2.36)	0.0992	
Onset of disease									0.4302
Paediatric	1/ 8 (12.5)	12.5	3/ 7 (42.9)	42.9	0.29 (0.04, 2.21)	0.2326	-30.36 (-77.91, 17.19)	0.2108	
Adult	29/119 (24.4)	24.4	43/118 (36.4)	36.3	0.67 (0.45, 0.99)	0.0465	-11.86 (-23.71, -0.00)	0.0499	
ADA result									0.3583
Negative	26/111 (23.4)	23.6	43/112 (38.4)	38.3	0.61 (0.40, 0.92)	0.0182	-14.69 (-26.97, -2.40)	0.0191	
Positive (At any time)	4/ 15 (26.7)	26.7	3/ 13 (23.1)	23.1	1.16 (0.32, 4.24)	0.8274	3.59 (-30.57, 37.75)	0.8368	
BMI (kg/m2) at enrolment									0.0535
< 30	13/ 74 (17.6)	18.0	34/ 87 (39.1)	39.3	0.45 (0.26, 0.79)	0.0051	-21.24 (-35.23, -7.25)	0.0029	
>= 30	17/ 53 (32.1)	31.9	12/ 38 (31.6)	31.6	1.02 (0.55, 1.87)	0.9600	0.27 (-19.66, 20.19)	0.9791	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Neuropsychiatric
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 52	Number of subjects with events, n (%)	3 (2.4)	0 (0.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	NE	
	p-value		
	Odds Ratio (95% CI)	NE	
	p-value		
	Risk Difference (95% CI)	2.23 (-0.36, 4.81)	
	p-value	0.0911	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	6.89 (0.36, 132.04)	
	p-value	0.2002	
	Odds Ratio (95% CI)	7.06 (0.36, 138.03)	
	p-value	0.1978	
	Risk Difference (95% CI)	2.36 (-0.28, 5.00)	
	p-value	0.0796	
	CMH approach		
	Response rate	2.4	0.0
	Difference in response rates (95% CI)	2.42 (-4.19, 9.03)	
	p-value	0.4731	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Neuropsychiatric - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE		0.00 (-9.58, 9.58)	1.0000	
>= 10 points	3/ 88 (3.4)	3.4	0/ 88 (0.0)	0.0	7.00 (0.37, 133.55)	0.1958	3.37 (-4.27, 11.01)	0.3876	
OCS dose at baseline									0.8653
<10 mg/day	2/ 57 (3.5)	3.5	0/ 52 (0.0)	0.0	4.57 (0.22, 93.01)	0.3231	3.47 (-7.90, 14.84)	0.5501	
>=10 mg/day	1/ 70 (1.4)	1.5	0/ 73 (0.0)	0.0	3.13 (0.13, 75.49)	0.4828	1.46 (-7.16, 10.08)	0.7402	
Result of type I IFN gene signature test									0.8614
LOW	1/ 22 (4.5)	4.5	0/ 24 (0.0)	0.0	3.26 (0.14, 76.10)	0.4621	4.55 (-12.32, 21.41)	0.5973	
HIGH	2/105 (1.9)	1.9	0/101 (0.0)	0.0	4.81 (0.23, 99.00)	0.3086	1.94 (-5.21, 9.09)	0.5944	
Age (years)									NE
<= 65	3/122 (2.5)	2.6	0/123 (0.0)	0.0	7.06 (0.37, 135.19)	0.1946	2.57 (-4.24, 9.37)	0.4595	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE		0.00 (-74.81, 74.81)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE		0.00 (-31.89, 31.89)	1.0000	
female	3/115 (2.6)	2.7	0/117 (0.0)	0.0	7.12 (0.37, 136.33)	0.1925	2.67 (-4.46, 9.81)	0.4624	
Race									0.7225
White	2/ 85 (2.4)	2.2	0/ 96 (0.0)	0.0	5.64 (0.27, 115.85)	0.2620	2.21 (-6.50, 10.93)	0.6186	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE		0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	1/ 13 (7.7)	7.7	0/ 11 (0.0)	0.0	2.57 (0.12, 57.44)	0.5512	7.69 (-21.17, 36.55)	0.6014	
Ethnicity									0.8431
Hispanic/Latino	1/ 23 (4.3)	4.3	0/ 24 (0.0)	0.0	3.13 (0.13, 73.01)	0.4785	4.35 (-12.12, 20.81)	0.6048	
Non-hispanic/Latino	2/104 (1.9)	1.9	0/101 (0.0)	0.0	4.86 (0.24, 99.94)	0.3057	1.91 (-5.89, 9.71)	0.6312	
Geographic region									0.9312
EU	1/ 47 (2.1)	2.1	0/ 56 (0.0)	0.0	3.56 (0.15, 85.45)	0.4332	2.13 (-6.08, 10.33)	0.6114	
non-EU	2/ 80 (2.5)	2.4	0/ 69 (0.0)	0.0	4.32 (0.21, 88.50)	0.3421	2.44 (-6.18, 11.05)	0.5794	
Onset of disease									NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE		0.00 (-38.51, 38.51)	1.0000	
Adult	3/119 (2.5)	2.6	0/118 (0.0)	0.0	6.94 (0.36, 132.94)	0.1983	2.58 (-4.40, 9.55)	0.4689	
ADA result									NE
Negative	3/111 (2.7)	2.8	0/112 (0.0)	0.0	7.06 (0.37, 135.16)	0.1943	2.79 (-4.63, 10.22)	0.4607	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/ 74 (0.0)	0.0	0/ 87 (0.0)	0.0	NE		0.00 (-7.46, 7.46)	1.0000	
>= 30	3/ 53 (5.7)	5.5	0/ 38 (0.0)	0.0	5.06 (0.27, 95.10)	0.2791	5.47 (-8.31, 19.26)	0.4365	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Musculoskeletal
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 52	Number of subjects with events, n (%)	24 (18.9)	23 (18.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.01 (0.60, 1.71)	
	p-value	0.9638	
	Odds Ratio (95% CI)	1.02 (0.53, 1.93)	
	p-value	0.9636	
	Risk Difference (95% CI)	0.22 (-9.38, 9.83)	
	p-value	0.9636	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.03 (0.61, 1.72)	
	p-value	0.9192	
	Odds Ratio (95% CI)	1.03 (0.55, 1.95)	
	p-value	0.9192	
	Risk Difference (95% CI)	0.50 (-9.12, 10.12)	
	p-value	0.9192	
	CMH approach		
	Response rate	19.0	18.5
	Difference in response rates (95% CI)	0.49 (-9.70, 10.67)	
	p-value	0.9255	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Musculoskeletal - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8316
< 10 points	8/ 39 (20.5)	20.5	8/ 37 (21.6)	21.6	0.95 (0.40, 2.27)	0.9057	-1.11 (-20.27, 18.06)	0.9097	
>= 10 points	16/ 88 (18.2)	17.9	15/ 88 (17.0)	17.1	1.07 (0.56, 2.02)	0.8432	0.74 (-11.00, 12.47)	0.9021	
OCS dose at baseline									0.1333
<10 mg/day	16/ 57 (28.1)	27.9	10/ 52 (19.2)	19.2	1.46 (0.73, 2.92)	0.2861	8.72 (-7.94, 25.38)	0.3049	
>=10 mg/day	8/ 70 (11.4)	11.7	13/ 73 (17.8)	17.8	0.64 (0.28, 1.45)	0.2876	-6.09 (-18.85, 6.67)	0.3494	
Result of type I IFN gene signature test									0.2186
LOW	8/ 22 (36.4)	36.4	5/ 24 (20.8)	20.8	1.75 (0.67, 4.54)	0.2534	15.53 (-11.18, 42.24)	0.2544	
HIGH	16/105 (15.2)	15.1	18/101 (17.8)	18.0	0.86 (0.46, 1.58)	0.6180	-2.88 (-13.82, 8.06)	0.6061	
Age (years)									0.7905
<= 65	23/122 (18.9)	19.1	23/123 (18.7)	18.8	1.01 (0.60, 1.70)	0.9755	0.31 (-10.07, 10.69)	0.9533	
> 65	1/ 5 (20.0)	20.0	0/ 2 (0.0)	0.0	1.50 (0.08, 26.86)	0.7830	20.00 (-57.30, 97.30)	0.6121	
Sex									0.4011
male	2/ 12 (16.7)	16.7	0/ 8 (0.0)	0.0	3.46 (0.19, 63.86)	0.4038	16.67 (-18.93, 52.26)	0.3588	
female	22/115 (19.1)	19.2	23/117 (19.7)	19.8	0.97 (0.58, 1.64)	0.9191	-0.60 (-11.34, 10.15)	0.9136	
Race									0.0683
White	19/ 85 (22.4)	21.8	15/ 96 (15.6)	15.7	1.43 (0.78, 2.63)	0.2505	6.05 (-6.38, 18.47)	0.3402	
Black or African American	2/ 22 (9.1)	9.1	3/ 14 (21.4)	21.4	0.42 (0.08, 2.23)	0.3111	-12.34 (-40.23, 15.55)	0.3859	
Asian	2/ 7 (28.6)	28.6	3/ 3 (100.0)	100.0	0.29 (0.09, 0.92)	0.0361	-71.43 (-133.74, -9.11)	0.0247	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	1/ 13 (7.7)	7.7	2/ 11 (18.2)	18.2	0.42 (0.04, 4.06)	0.4561	-10.49 (-43.84, 22.86)	0.5376	
Ethnicity									0.4160
Hispanic/Latino	3/ 23 (13.0)	13.0	5/ 24 (20.8)	20.8	0.63 (0.17, 2.33)	0.4843	-7.79 (-31.29, 15.71)	0.5158	
Non-hispanic/Latino	21/104 (20.2)	20.6	18/101 (17.8)	17.6	1.13 (0.64, 2.00)	0.6659	3.00 (-8.59, 14.60)	0.6118	
Geographic region									0.6530
EU	7/ 47 (14.9)	14.9	7/ 56 (12.5)	12.5	1.19 (0.45, 3.15)	0.7242	2.39 (-11.97, 16.75)	0.7439	
non-EU	17/ 80 (21.3)	21.4	16/ 69 (23.2)	23.0	0.92 (0.50, 1.67)	0.7762	-1.61 (-15.34, 12.11)	0.8179	
Onset of disease									0.8996
Paediatric	1/ 8 (12.5)	12.5	1/ 7 (14.3)	14.3	0.88 (0.07, 11.54)	0.9192	-1.79 (-46.38, 42.81)	0.9374	
Adult	23/119 (19.3)	19.2	22/118 (18.6)	18.8	1.04 (0.61, 1.75)	0.8933	0.45 (-10.13, 11.03)	0.9333	
ADA result									0.1132
Negative	21/111 (18.9)	18.9	17/112 (15.2)	15.2	1.25 (0.70, 2.23)	0.4590	3.76 (-6.92, 14.43)	0.4901	
Positive (At any time)	3/ 15 (20.0)	20.0	6/ 13 (46.2)	46.2	0.43 (0.13, 1.40)	0.1613	-26.15 (-61.26, 8.96)	0.1443	
BMI (kg/m2) at enrolment									0.9205
< 30	12/ 74 (16.2)	15.7	14/ 87 (16.1)	15.9	1.01 (0.50, 2.04)	0.9830	-0.19 (-12.47, 12.09)	0.9756	
>= 30	12/ 53 (22.6)	22.5	9/ 38 (23.7)	23.5	0.96 (0.45, 2.04)	0.9072	-1.03 (-19.37, 17.31)	0.9120	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Cardiorespiratory
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 52	Number of subjects with events, n (%)	3 (2.4)	0 (0.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	NE	
	p-value		
	Odds Ratio (95% CI)	NE	
	p-value		
	Risk Difference (95% CI)	2.39 (-0.28, 5.05)	
	p-value	0.0797	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	6.89 (0.36, 132.04)	
	p-value	0.2002	
	Odds Ratio (95% CI)	7.06 (0.36, 138.03)	
	p-value	0.1978	
	Risk Difference (95% CI)	2.36 (-0.28, 5.00)	
	p-value	0.0796	
	CMH approach		
	Response rate	2.4	0.0
	Difference in response rates (95% CI)	2.43 (-4.14, 9.00)	
	p-value	0.4689	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Cardiorespiratory - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE		0.00 (-9.58, 9.58)	1.0000	
>= 10 points	3/ 88 (3.4)	3.3	0/ 88 (0.0)	0.0	7.00 (0.37, 133.55)	0.1958	3.30 (-4.22, 10.81)	0.3900	
OCS dose at baseline									0.8653
<10 mg/day	2/ 57 (3.5)	3.5	0/ 52 (0.0)	0.0	4.57 (0.22, 93.01)	0.3231	3.47 (-7.90, 14.84)	0.5501	
>=10 mg/day	1/ 70 (1.4)	1.7	0/ 73 (0.0)	0.0	3.13 (0.13, 75.49)	0.4828	1.70 (-6.78, 10.17)	0.6951	
Result of type I IFN gene signature test									0.7764
LOW	2/ 22 (9.1)	9.1	0/ 24 (0.0)	0.0	5.43 (0.28, 107.33)	0.2660	9.09 (-9.17, 27.35)	0.3292	
HIGH	1/105 (1.0)	0.9	0/101 (0.0)	0.0	2.89 (0.12, 70.05)	0.5147	0.94 (-5.99, 7.86)	0.7908	
Age (years)									NE
<= 65	3/122 (2.5)	2.6	0/123 (0.0)	0.0	7.06 (0.37, 135.19)	0.1946	2.62 (-4.15, 9.39)	0.4481	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE		0.00 (-74.81, 74.81)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE		0.00 (-31.89, 31.89)	1.0000	
female	3/115 (2.6)	2.7	0/117 (0.0)	0.0	7.12 (0.37, 136.33)	0.1925	2.68 (-4.40, 9.77)	0.4581	
Race									NE
White	3/ 85 (3.5)	3.3	0/ 96 (0.0)	0.0	7.90 (0.41, 150.69)	0.1697	3.34 (-5.54, 12.22)	0.4616	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE		0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-26.65, 26.65)	1.0000	
Ethnicity									0.8431
Hispanic/Latino	1/ 23 (4.3)	4.3	0/ 24 (0.0)	0.0	3.13 (0.13, 73.01)	0.4785	4.35 (-12.12, 20.81)	0.6048	
Non-hispanic/Latino	2/104 (1.9)	2.2	0/101 (0.0)	0.0	4.86 (0.24, 99.94)	0.3057	2.18 (-5.67, 10.02)	0.5863	
Geographic region									0.9312
EU	1/ 47 (2.1)	2.1	0/ 56 (0.0)	0.0	3.56 (0.15, 85.45)	0.4332	2.13 (-6.08, 10.33)	0.6114	
non-EU	2/ 80 (2.5)	2.4	0/ 69 (0.0)	0.0	4.32 (0.21, 88.50)	0.3421	2.44 (-6.18, 11.05)	0.5794	
Onset of disease									NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE		0.00 (-38.51, 38.51)	1.0000	
Adult	3/119 (2.5)	2.5	0/118 (0.0)	0.0	6.94 (0.36, 132.94)	0.1983	2.54 (-4.38, 9.46)	0.4723	
ADA result									NE
Negative	3/111 (2.7)	2.8	0/112 (0.0)	0.0	7.06 (0.37, 135.16)	0.1943	2.75 (-4.61, 10.12)	0.4635	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment									0.6559
< 30	2/ 74 (2.7)	2.9	0/ 87 (0.0)	0.0	5.87 (0.29, 120.30)	0.2510	2.95 (-5.16, 11.05)	0.4764	
>= 30	1/ 53 (1.9)	1.9	0/ 38 (0.0)	0.0	2.17 (0.09, 51.79)	0.6330	1.85 (-11.30, 15.01)	0.7826	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Gastrointestinal
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 52	Number of subjects with events, n (%)	0 (0.0)	1 (0.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.00 (NE, NE)	
	p-value	NE	
	Odds Ratio (95% CI)	0.00 (NE, NE)	
	p-value	NE	
	Risk Difference (95% CI)	-0.78 (-2.33, 0.77)	
	p-value	0.3254	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.33 (0.01, 7.98)	
	p-value	0.4937	
	Odds Ratio (95% CI)	0.33 (0.01, 8.07)	
	p-value	0.4932	
	Risk Difference (95% CI)	-0.80 (-2.36, 0.76)	
	p-value	0.3154	
	CMH approach		
	Response rate	0.0	0.8
	Difference in response rates (95% CI)	-0.77 (-7.09, 5.55)	
	p-value	0.8112	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Gastrointestinal - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE		0.00 (-9.58, 9.58)	1.0000	
>= 10 points	0/ 88 (0.0)	0.0	1/ 88 (1.1)	1.1	0.33 (0.01, 8.07)	0.4993	-1.10 (-8.30, 6.09)	0.7643	
OCS dose at baseline									NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE		0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	0/ 70 (0.0)	0.0	1/ 73 (1.4)	1.4	0.35 (0.01, 8.39)	0.5152	-1.37 (-9.94, 7.21)	0.7547	
Result of type I IFN gene signature test									NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-15.17, 15.17)	1.0000	
HIGH	0/105 (0.0)	0.0	1/101 (1.0)	0.9	0.32 (0.01, 7.78)	0.4847	-0.94 (-7.89, 6.01)	0.7903	
Age (years)									NE
<= 65	0/122 (0.0)	0.0	1/123 (0.8)	0.8	0.34 (0.01, 8.17)	0.5030	-0.79 (-7.29, 5.70)	0.8105	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE		0.00 (-74.81, 74.81)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE		0.00 (-31.89, 31.89)	1.0000	
female	0/115 (0.0)	0.0	1/117 (0.9)	0.8	0.34 (0.01, 8.24)	0.5064	-0.81 (-7.62, 5.99)	0.8147	
Race									NE
White	0/ 85 (0.0)	0.0	1/ 96 (1.0)	0.9	0.38 (0.02, 9.11)	0.5475	-0.93 (-9.44, 7.57)	0.8296	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE		0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-26.65, 26.65)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	0/104 (0.0)	0.0	1/101 (1.0)	0.9	0.32 (0.01, 7.86)	0.4883	-0.92 (-8.59, 6.74)	0.8132	
Geographic region									NE
EU	0/ 47 (0.0)	0.0	1/ 56 (1.8)	1.8	0.40 (0.02, 9.49)	0.5676	-1.79 (-9.75, 6.18)	0.6602	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE		0.00 (-8.12, 8.12)	1.0000	
Onset of disease									NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE		0.00 (-38.51, 38.51)	1.0000	
Adult	0/119 (0.0)	0.0	1/118 (0.8)	0.8	0.33 (0.01, 8.03)	0.4965	-0.81 (-7.47, 5.86)	0.8125	
ADA result									NE
Negative	0/111 (0.0)	0.0	1/112 (0.9)	0.8	0.34 (0.01, 8.17)	0.5031	-0.82 (-7.89, 6.25)	0.8193	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/ 74 (0.0)	0.0	1/ 87 (1.1)	1.2	0.39 (0.02, 9.46)	0.5636	-1.15 (-8.90, 6.60)	0.7706	
>= 30	0/ 53 (0.0)	0.0	0/ 38 (0.0)	0.0	NE		0.00 (-12.88, 12.88)	1.0000	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Ophthalmic
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 52	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	NE	
	p-value		
	Odds Ratio (95% CI)	NE	
	p-value		
	Risk Difference (95% CI)	NE	
	p-value		
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	NE	
	p-value		
	Odds Ratio (95% CI)	NE	
	p-value		
	Risk Difference (95% CI)	NE	
	p-value		
	CMH approach		
	Response rate	0.0	0.0
	Difference in response rates (95% CI)	0.00 (-6.17, 6.17)	
	p-value	1.0000	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Ophthalmic - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-9.58, 9.58)	1.0000	
>= 10 points	0/ 88 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	0/ 70 (0.0)	0.0	0/ 73 (0.0)	0.0	NE	0.00 (-8.22, 8.22)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-15.17, 15.17)	1.0000	
HIGH	0/105 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-6.74, 6.74)	1.0000	
Age (years)								NE
<= 65	0/122 (0.0)	0.0	0/123 (0.0)	0.0	NE	0.00 (-6.34, 6.34)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE	0.00 (-74.81, 74.81)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE	0.00 (-31.89, 31.89)	1.0000	
female	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-6.65, 6.65)	1.0000	
Race								NE
White	0/ 85 (0.0)	0.0	0/ 96 (0.0)	0.0	NE	0.00 (-8.35, 8.35)	1.0000	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE	0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-26.65, 26.65)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	0/104 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-7.49, 7.49)	1.0000	
Geographic region								NE
EU	0/ 47 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-7.27, 7.27)	1.0000	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-8.12, 8.12)	1.0000	
Onset of disease								NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE	0.00 (-38.51, 38.51)	1.0000	
Adult	0/119 (0.0)	0.0	0/118 (0.0)	0.0	NE	0.00 (-6.51, 6.51)	1.0000	
ADA result								NE
Negative	0/111 (0.0)	0.0	0/112 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 74 (0.0)	0.0	0/ 87 (0.0)	0.0	NE	0.00 (-7.46, 7.46)	1.0000	
>= 30	0/ 53 (0.0)	0.0	0/ 38 (0.0)	0.0	NE	0.00 (-12.88, 12.88)	1.0000	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Renal
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 52	Number of subjects with events, n (%)	5 (3.9)	7 (5.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.75 (0.25, 2.25)	
	p-value	0.6094	
	Odds Ratio (95% CI)	0.73 (0.22, 2.45)	
	p-value	0.6068	
	Risk Difference (95% CI)	-1.35 (-6.49, 3.79)	
	p-value	0.6060	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.70 (0.23, 2.16)	
	p-value	0.5378	
	Odds Ratio (95% CI)	0.69 (0.21, 2.24)	
	p-value	0.5374	
	Risk Difference (95% CI)	-1.66 (-6.92, 3.60)	
	p-value	0.5356	
	CMH approach		
	Response rate	4.1	5.4
	Difference in response rates (95% CI)	-1.34 (-9.04, 6.36)	
	p-value	0.7329	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Renal - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Anifrolumab 300mg (N=127) Response rate	Placebo (N=125) n/ N (%)	Placebo (N=125) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE		0.00 (-9.58, 9.58)	1.0000	
>= 10 points	5/ 88 (5.7)	5.8	7/ 88 (8.0)	7.7	0.71 (0.24, 2.17)	0.5521	-1.92 (-11.47, 7.64)	0.6943	
OCS dose at baseline									0.3779
<10 mg/day	1/ 57 (1.8)	1.8	0/ 52 (0.0)	0.0	2.74 (0.11, 65.85)	0.5341	1.77 (-9.32, 12.86)	0.7547	
>=10 mg/day	4/ 70 (5.7)	5.8	7/ 73 (9.6)	9.6	0.60 (0.18, 1.95)	0.3915	-3.74 (-15.11, 7.63)	0.5194	
Result of type I IFN gene signature test									NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-15.17, 15.17)	1.0000	
HIGH	5/105 (4.8)	5.0	7/101 (6.9)	6.6	0.69 (0.23, 2.09)	0.5093	-1.64 (-10.43, 7.15)	0.7145	
Age (years)									NE
<= 65	5/122 (4.1)	4.2	7/123 (5.7)	5.6	0.72 (0.23, 2.21)	0.5656	-1.35 (-9.28, 6.58)	0.7384	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE		0.00 (-74.81, 74.81)	1.0000	
Sex									0.9907
male	1/ 12 (8.3)	8.3	1/ 8 (12.5)	12.5	0.67 (0.05, 9.19)	0.7620	-4.17 (-41.42, 33.09)	0.8265	
female	4/115 (3.5)	3.6	6/117 (5.1)	4.9	0.68 (0.20, 2.34)	0.5390	-1.30 (-9.33, 6.74)	0.7518	
Race									0.2849
White	3/ 85 (3.5)	3.9	4/ 96 (4.2)	3.7	0.85 (0.20, 3.68)	0.8246	0.19 (-9.42, 9.79)	0.9696	
Black or African American	2/ 22 (9.1)	9.1	0/ 14 (0.0)	0.0	3.26 (0.17, 63.30)	0.4347	9.09 (-13.23, 31.41)	0.4248	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 13 (0.0)	0.0	3/ 11 (27.3)	27.3	0.12 (0.01, 2.14)	0.1503	-27.27 (-60.18, 5.63)	0.1043	
Ethnicity									0.1960
Hispanic/Latino	0/ 23 (0.0)	0.0	3/ 24 (12.5)	12.5	0.15 (0.01, 2.73)	0.1994	-12.50 (-31.19, 6.19)	0.1899	
Non-hispanic/Latino	5/104 (4.8)	5.0	4/101 (4.0)	3.7	1.21 (0.34, 4.39)	0.7676	1.35 (-7.59, 10.29)	0.7674	
Geographic region									0.7044
EU	3/ 47 (6.4)	6.4	4/ 56 (7.1)	7.1	0.89 (0.21, 3.79)	0.8788	-0.76 (-12.34, 10.82)	0.8976	
non-EU	2/ 80 (2.5)	2.4	3/ 69 (4.3)	4.5	0.58 (0.10, 3.34)	0.5377	-2.05 (-11.74, 7.64)	0.6790	
Onset of disease									0.7299
Paediatric	2/ 8 (25.0)	25.0	2/ 7 (28.6)	28.6	0.88 (0.16, 4.68)	0.8760	-3.57 (-51.91, 44.77)	0.8849	
Adult	3/119 (2.5)	2.7	5/118 (4.2)	4.0	0.59 (0.15, 2.43)	0.4700	-1.38 (-9.04, 6.28)	0.7246	
ADA result									0.3627
Negative	3/111 (2.7)	2.8	6/112 (5.4)	4.9	0.50 (0.13, 1.97)	0.3244	-2.11 (-10.29, 6.06)	0.6129	
Positive (At any time)	2/ 15 (13.3)	13.3	1/ 13 (7.7)	7.7	1.73 (0.18, 16.99)	0.6367	5.64 (-23.60, 34.88)	0.7054	
BMI (kg/m2) at enrolment									0.2203
< 30	2/ 74 (2.7)	2.7	6/ 87 (6.9)	6.9	0.39 (0.08, 1.88)	0.2422	-4.18 (-13.74, 5.38)	0.3914	
>= 30	3/ 53 (5.7)	5.4	1/ 38 (2.6)	2.7	2.15 (0.23, 19.89)	0.4998	2.72 (-11.68, 17.11)	0.7115	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Haematological
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 52	Number of subjects with events, n (%)	1 (0.8)	0 (0.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	NE	
	p-value		
	Odds Ratio (95% CI)	NE	
	p-value		
	Risk Difference (95% CI)	0.78 (-0.76, 2.31)	
	p-value	0.3214	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	2.95 (0.12, 71.81)	
	p-value	0.5060	
	Odds Ratio (95% CI)	2.98 (0.12, 73.76)	
	p-value	0.5055	
	Risk Difference (95% CI)	0.79 (-0.75, 2.32)	
	p-value	0.3154	
	CMH approach		
	Response rate	0.8	0.0
	Difference in response rates (95% CI)	0.77 (-5.51, 7.05)	
	p-value	0.8099	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Haematological - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	1/ 39 (2.6)	2.6	0/ 37 (0.0)	0.0	2.85 (0.12, 67.83)	0.5172	2.56 (-8.02, 13.15)	0.6350	
>= 10 points	0/ 88 (0.0)	0.0	0/ 88 (0.0)	0.0	NE		0.00 (-6.92, 6.92)	1.0000	
OCS dose at baseline									NE
<10 mg/day	1/ 57 (1.8)	1.8	0/ 52 (0.0)	0.0	2.74 (0.11, 65.85)	0.5341	1.78 (-9.25, 12.81)	0.7517	
>=10 mg/day	0/ 70 (0.0)	0.0	0/ 73 (0.0)	0.0	NE		0.00 (-8.22, 8.22)	1.0000	
Result of type I IFN gene signature test									NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-15.17, 15.17)	1.0000	
HIGH	1/105 (1.0)	0.9	0/101 (0.0)	0.0	2.89 (0.12, 70.05)	0.5147	0.94 (-5.95, 7.84)	0.7886	
Age (years)									NE
<= 65	1/122 (0.8)	0.8	0/123 (0.0)	0.0	3.02 (0.12, 73.52)	0.4966	0.79 (-5.66, 7.25)	0.8093	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE		0.00 (-74.81, 74.81)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE		0.00 (-31.89, 31.89)	1.0000	
female	1/115 (0.9)	0.8	0/117 (0.0)	0.0	3.05 (0.13, 74.15)	0.4931	0.84 (-5.93, 7.60)	0.8087	
Race									NE
White	1/ 85 (1.2)	1.0	0/ 96 (0.0)	0.0	3.38 (0.14, 81.97)	0.4535	1.02 (-7.46, 9.50)	0.8136	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE		0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-26.65, 26.65)	1.0000	
Ethnicity									NE
Hispanic/Latino	1/ 23 (4.3)	4.3	0/ 24 (0.0)	0.0	3.13 (0.13, 73.01)	0.4785	4.35 (-12.12, 20.81)	0.6048	
Non-hispanic/Latino	0/104 (0.0)	0.0	0/101 (0.0)	0.0	NE		0.00 (-7.49, 7.49)	1.0000	
Geographic region									NE
EU	0/ 47 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-7.27, 7.27)	1.0000	
non-EU	1/ 80 (1.3)	1.4	0/ 69 (0.0)	0.0	2.59 (0.11, 62.63)	0.5577	1.35 (-7.05, 9.76)	0.7525	
Onset of disease									NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE		0.00 (-38.51, 38.51)	1.0000	
Adult	1/119 (0.8)	0.8	0/118 (0.0)	0.0	2.98 (0.12, 72.30)	0.5030	0.79 (-5.83, 7.41)	0.8151	
ADA result									NE
Negative	1/111 (0.9)	0.9	0/112 (0.0)	0.0	3.03 (0.12, 73.51)	0.4962	0.87 (-6.16, 7.90)	0.8084	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/ 74 (0.0)	0.0	0/ 87 (0.0)	0.0	NE		0.00 (-7.46, 7.46)	1.0000	
>= 30	1/ 53 (1.9)	2.0	0/ 38 (0.0)	0.0	2.17 (0.09, 51.79)	0.6330	2.03 (-11.22, 15.27)	0.7640	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Major clinical response at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 52	Number of subjects with events, n (%)	30 (23.6)	23 (18.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.28 (0.79, 2.08)	
	p-value	0.3121	
	Odds Ratio (95% CI)	1.38 (0.74, 2.55)	
	p-value	0.3102	
	Risk Difference (95% CI)	5.22 (-4.83, 15.27)	
	p-value	0.3084	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.28 (0.79, 2.08)	
	p-value	0.3115	
	Odds Ratio (95% CI)	1.37 (0.75, 2.52)	
	p-value	0.3102	
	Risk Difference (95% CI)	5.22 (-4.81, 15.26)	
	p-value	0.3078	
	CMH approach		
	Response rate	23.1	18.5
	Difference in response rates (95% CI)	4.68 (-5.86, 15.22)	
	p-value	0.3841	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Major clinical response at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.6636
< 10 points	11/ 39 (28.2)	28.2	7/ 37 (18.9)	18.9	1.49 (0.65, 3.43)	0.3480	9.29 (-10.35, 28.92)	0.3540	
>= 10 points	19/ 88 (21.6)	21.6	16/ 88 (18.2)	18.2	1.19 (0.65, 2.15)	0.5718	3.43 (-9.05, 15.91)	0.5900	
OCS dose at baseline									0.8475
<10 mg/day	12/ 57 (21.1)	21.2	9/ 52 (17.3)	17.3	1.22 (0.56, 2.65)	0.6218	3.88 (-12.29, 20.05)	0.6384	
>=10 mg/day	18/ 70 (25.7)	24.8	14/ 73 (19.2)	19.4	1.34 (0.72, 2.48)	0.3513	5.48 (-8.79, 19.75)	0.4516	
Result of type I IFN gene signature test									0.2642
LOW	2/ 22 (9.1)	9.1	4/ 24 (16.7)	16.7	0.55 (0.11, 2.69)	0.4566	-7.58 (-29.86, 14.71)	0.5053	
HIGH	28/105 (26.7)	26.3	19/101 (18.8)	18.9	1.42 (0.85, 2.37)	0.1838	7.42 (-4.48, 19.32)	0.2214	
Age (years)									0.1576
<= 65	30/122 (24.6)	24.0	22/123 (17.9)	17.8	1.37 (0.84, 2.24)	0.2028	6.13 (-4.60, 16.87)	0.2629	
> 65	0/ 5 (0.0)	0.0	1/ 2 (50.0)	50.0	0.17 (0.01, 2.98)	0.2235	-50.00 (-128.29, 28.29)	0.2107	
Sex									0.2435
male	4/ 12 (33.3)	33.3	0/ 8 (0.0)	0.0	6.23 (0.38, 101.99)	0.1996	33.33 (-4.31, 70.98)	0.0827	
female	26/115 (22.6)	21.9	23/117 (19.7)	19.7	1.15 (0.70, 1.89)	0.5825	2.16 (-8.77, 13.09)	0.6980	
Race									0.8289
White	21/ 85 (24.7)	25.4	17/ 96 (17.7)	17.3	1.40 (0.79, 2.46)	0.2513	8.12 (-4.52, 20.76)	0.2081	
Black or African American	6/ 22 (27.3)	27.3	4/ 14 (28.6)	28.6	0.95 (0.33, 2.79)	0.9323	-1.30 (-32.63, 30.03)	0.9353	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	3/ 13 (23.1)	23.1	2/ 11 (18.2)	18.2	1.27 (0.26, 6.28)	0.7701	4.90 (-31.11, 40.90)	0.7899	
Ethnicity									0.0597
Hispanic/Latino	2/ 23 (8.7)	8.7	6/ 24 (25.0)	25.0	0.35 (0.08, 1.55)	0.1661	-16.30 (-39.49, 6.88)	0.1681	
Non-hispanic/Latino	28/104 (26.9)	25.6	17/101 (16.8)	17.0	1.60 (0.94, 2.74)	0.0864	8.61 (-3.23, 20.45)	0.1539	
Geographic region									0.1187
EU	19/ 47 (40.4)	40.4	12/ 56 (21.4)	21.4	1.89 (1.03, 3.47)	0.0414	19.00 (1.09, 36.90)	0.0376	
non-EU	11/ 80 (13.8)	13.6	11/ 69 (15.9)	16.0	0.86 (0.40, 1.87)	0.7070	-2.33 (-15.16, 10.49)	0.7213	
Onset of disease									0.6313
Paediatric	1/ 8 (12.5)	12.5	0/ 7 (0.0)	0.0	2.67 (0.13, 56.63)	0.5293	12.50 (-28.93, 53.93)	0.5543	
Adult	29/119 (24.4)	24.1	23/118 (19.5)	19.5	1.25 (0.77, 2.03)	0.3661	4.56 (-6.43, 15.55)	0.4158	
ADA result									0.6901
Negative	26/111 (23.4)	22.7	21/112 (18.8)	18.8	1.25 (0.75, 2.08)	0.3939	3.94 (-7.36, 15.24)	0.4941	
Positive (At any time)	4/ 15 (26.7)	26.7	2/ 13 (15.4)	15.4	1.73 (0.38, 7.98)	0.4800	11.28 (-21.66, 44.22)	0.5020	
BMI (kg/m2) at enrolment									0.7943
< 30	18/ 74 (24.3)	24.1	17/ 87 (19.5)	19.3	1.24 (0.69, 2.24)	0.4638	4.77 (-8.72, 18.26)	0.4882	
>= 30	12/ 53 (22.6)	23.1	6/ 38 (15.8)	15.9	1.43 (0.59, 3.48)	0.4258	7.22 (-10.83, 25.27)	0.4329	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Partial clinical response at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 52	Number of subjects with events, n (%)	61 (48.0)	54 (43.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.12 (0.86, 1.46)	
	p-value	0.4126	
	Odds Ratio (95% CI)	1.23 (0.75, 2.02)	
	p-value	0.4165	
	Risk Difference (95% CI)	5.16 (-7.25, 17.56)	
	p-value	0.4152	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.11 (0.85, 1.46)	
	p-value	0.4423	
	Odds Ratio (95% CI)	1.22 (0.74, 2.00)	
	p-value	0.4415	
	Risk Difference (95% CI)	4.83 (-7.45, 17.12)	
	p-value	0.4408	
	CMH approach		
	Response rate	47.6	43.3
	Difference in response rates (95% CI)	4.35 (-7.87, 16.56)	
	p-value	0.4853	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Partial clinical response at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.6196
< 10 points	23/ 39 (59.0)	59.0	18/ 37 (48.6)	48.6	1.21 (0.79, 1.85)	0.3714	10.33 (-12.02, 32.67)	0.3650	
>= 10 points	38/ 88 (43.2)	43.4	36/ 88 (40.9)	41.0	1.06 (0.75, 1.49)	0.7602	2.32 (-12.18, 16.82)	0.7539	
OCS dose at baseline									0.0726
<10 mg/day	25/ 57 (43.9)	44.0	27/ 52 (51.9)	52.0	0.84 (0.57, 1.25)	0.4003	-7.95 (-26.61, 10.70)	0.4034	
>=10 mg/day	36/ 70 (51.4)	50.6	27/ 73 (37.0)	37.1	1.39 (0.95, 2.03)	0.0859	13.50 (-2.71, 29.71)	0.1026	
Result of type I IFN gene signature test									0.1778
LOW	7/ 22 (31.8)	31.8	11/ 24 (45.8)	45.8	0.69 (0.33, 1.47)	0.3406	-14.02 (-42.18, 14.15)	0.3294	
HIGH	54/105 (51.4)	51.1	43/101 (42.6)	42.7	1.21 (0.90, 1.62)	0.2063	8.46 (-5.10, 22.01)	0.2214	
Age (years)									0.9172
<= 65	58/122 (47.5)	46.8	53/123 (43.1)	43.0	1.10 (0.84, 1.45)	0.4846	3.87 (-8.49, 16.22)	0.5395	
> 65	3/ 5 (60.0)	60.0	1/ 2 (50.0)	50.0	1.20 (0.25, 5.71)	0.8188	10.00 (-71.85, 91.85)	0.8107	
Sex									0.1236
male	7/ 12 (58.3)	58.3	1/ 8 (12.5)	12.5	4.67 (0.70, 31.04)	0.1110	45.83 (4.75, 86.92)	0.0288	
female	54/115 (47.0)	46.5	53/117 (45.3)	45.4	1.04 (0.78, 1.37)	0.8001	1.10 (-11.63, 13.84)	0.8654	
Race									0.3580
White	37/ 85 (43.5)	43.9	41/ 96 (42.7)	43.4	1.02 (0.73, 1.42)	0.9113	0.57 (-13.81, 14.95)	0.9383	
Black or African American	10/ 22 (45.5)	45.5	8/ 14 (57.1)	57.1	0.80 (0.42, 1.52)	0.4864	-11.69 (-45.03, 21.65)	0.4920	
Asian	5/ 7 (71.4)	71.4	0/ 3 (0.0)	0.0	5.50 (0.39, 76.65)	0.2047	71.43 (9.11, 133.74)	0.0247	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	9/ 13 (69.2)	69.2	5/ 11 (45.5)	45.5	1.52 (0.73, 3.20)	0.2663	23.78 (-15.52, 63.07)	0.2356	
Ethnicity									0.3833
Hispanic/Latino	10/ 23 (43.5)	43.5	12/ 24 (50.0)	50.0	0.87 (0.47, 1.61)	0.6556	-6.52 (-35.03, 21.98)	0.6538	
Non-hispanic/Latino	51/104 (49.0)	48.2	42/101 (41.6)	41.7	1.18 (0.87, 1.60)	0.2862	6.53 (-7.07, 20.14)	0.3467	
Geographic region									0.1705
EU	29/ 47 (61.7)	61.7	25/ 56 (44.6)	44.6	1.38 (0.96, 2.00)	0.0852	17.06 (-2.04, 36.15)	0.0799	
non-EU	32/ 80 (40.0)	40.1	29/ 69 (42.0)	42.1	0.95 (0.65, 1.40)	0.8015	-1.97 (-17.84, 13.90)	0.8080	
Onset of disease									0.9294
Paediatric	4/ 8 (50.0)	50.0	3/ 7 (42.9)	42.9	1.17 (0.39, 3.51)	0.7837	7.14 (-43.46, 57.75)	0.7821	
Adult	57/119 (47.9)	47.6	51/118 (43.2)	43.4	1.11 (0.84, 1.47)	0.4704	4.28 (-8.33, 16.88)	0.5059	
ADA result									0.1401
Negative	54/111 (48.6)	48.0	52/112 (46.4)	46.6	1.05 (0.80, 1.38)	0.7400	1.44 (-11.56, 14.44)	0.8282	
Positive (At any time)	7/ 15 (46.7)	46.7	2/ 13 (15.4)	15.4	3.03 (0.76, 12.12)	0.1163	31.28 (-2.93, 65.49)	0.0731	
BMI (kg/m2) at enrolment									0.1114
< 30	39/ 74 (52.7)	52.3	35/ 87 (40.2)	40.4	1.31 (0.94, 1.83)	0.1140	11.94 (-3.36, 27.24)	0.1262	
>= 30	22/ 53 (41.5)	42.2	19/ 38 (50.0)	50.3	0.83 (0.53, 1.30)	0.4184	-8.16 (-28.53, 12.21)	0.4323	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=50% Joint reduction at week 52 (for subjects with at least 6 tender joints and swollen joints at baseline)
Full analysis set

Timepoint		Anifrolumab 300mg (N=67)	Placebo (N=67)
Week 52	Number of subjects with events, n (%)	37 (55.2)	30 (44.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.24 (0.90, 1.70)	
	p-value	0.1935	
	Odds Ratio (95% CI)	1.59 (0.78, 3.24)	
	p-value	0.2068	
	Risk Difference (95% CI)	10.88 (-5.86, 27.61)	
	p-value	0.2027	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.23 (0.88, 1.74)	
	p-value	0.2299	
	Odds Ratio (95% CI)	1.52 (0.77, 3.01)	
	p-value	0.2274	
	Risk Difference (95% CI)	10.45 (-6.39, 27.29)	
	p-value	0.2240	
	CMH approach		
	Response rate	54.4	45.6
	Difference in response rates (95% CI)	8.78 (-8.10, 25.66)	
	p-value	0.3080	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=50% Joint reduction at week 52 (for subjects with at least 6 tender joints and swollen joints at baseline) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=67) n/ N (%)	Response rate	Placebo (N=67) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.4616
< 10 points	15/ 23 (65.2)	65.2	8/ 18 (44.4)	44.4	1.47 (0.81, 2.66)	0.2077	20.77 (-9.54, 51.08)	0.1792	
>= 10 points	22/ 44 (50.0)	51.7	22/ 49 (44.9)	44.4	1.11 (0.73, 1.71)	0.6224	7.30 (-12.85, 27.45)	0.4777	
OCS dose at baseline									0.9917
<10 mg/day	16/ 28 (57.1)	57.1	13/ 28 (46.4)	46.4	1.23 (0.74, 2.05)	0.4259	10.71 (-15.35, 36.78)	0.4204	
>=10 mg/day	21/ 39 (53.8)	53.8	17/ 39 (43.6)	43.6	1.24 (0.78, 1.96)	0.3683	10.26 (-11.83, 32.35)	0.3628	
Result of type I IFN gene signature test									0.6210
LOW	7/ 14 (50.0)	50.0	5/ 15 (33.3)	33.3	1.50 (0.62, 3.64)	0.3702	16.67 (-19.14, 52.47)	0.3616	
HIGH	30/ 53 (56.6)	55.6	25/ 52 (48.1)	49.1	1.18 (0.81, 1.70)	0.3844	6.56 (-12.58, 25.70)	0.5017	
Age (years)									0.1339
<= 65	34/ 63 (54.0)	52.7	28/ 65 (43.1)	44.2	1.25 (0.87, 1.80)	0.2206	8.54 (-8.81, 25.88)	0.3347	
> 65	3/ 4 (75.0)	75.0	2/ 2 (100.0)	100.0	0.75 (0.43, 1.32)	0.3190	-25.00 (-105.74, 55.74)	0.5439	
Sex									0.5024
male	3/ 6 (50.0)	50.0	0/ 2 (0.0)	0.0	3.00 (0.21, 41.89)	0.4141	50.00 (-26.61, 126.61)	0.2008	
female	34/ 61 (55.7)	54.6	30/ 65 (46.2)	47.0	1.21 (0.86, 1.71)	0.2836	7.64 (-9.77, 25.05)	0.3899	
Race									0.3772
White	24/ 43 (55.8)	56.0	26/ 56 (46.4)	46.3	1.20 (0.82, 1.77)	0.3513	9.67 (-10.08, 29.43)	0.3372	
Black or African American	6/ 14 (42.9)	42.9	2/ 5 (40.0)	40.0	1.07 (0.31, 3.67)	0.9126	2.86 (-47.88, 53.60)	0.9121	
Asian	1/ 2 (50.0)	50.0	1/ 1 (100.0)	100.0	0.50 (0.13, 2.00)	0.3270	-50.00 (-168.41, 68.41)	0.4079	
Other	6/ 8 (75.0)	75.0	1/ 5 (20.0)	20.0	3.75 (0.62, 22.64)	0.1497	55.00 (2.33, 107.67)	0.0407	
Ethnicity									0.3324
Hispanic/Latino	8/ 13 (61.5)	61.5	4/ 12 (33.3)	33.3	1.85 (0.74, 4.58)	0.1858	28.21 (-10.08, 66.49)	0.1488	
Non-hispanic/Latino	29/ 54 (53.7)	52.5	26/ 55 (47.3)	47.9	1.14 (0.78, 1.65)	0.5029	4.63 (-14.42, 23.69)	0.6336	
Geographic region									0.5512
EU	15/ 22 (68.2)	68.2	17/ 29 (58.6)	58.6	1.16 (0.77, 1.77)	0.4790	9.56 (-17.25, 36.37)	0.4846	
non-EU	22/ 45 (48.9)	48.0	13/ 38 (34.2)	34.5	1.43 (0.84, 2.43)	0.1889	13.48 (-7.69, 34.64)	0.2121	
Onset of disease									0.4741
Paediatric	2/ 4 (50.0)	50.0	1/ 5 (20.0)	20.0	2.50 (0.34, 18.63)	0.3712	30.00 (-34.10, 94.10)	0.3590	
Adult	35/ 63 (55.6)	54.9	29/ 62 (46.8)	47.3	1.19 (0.84, 1.68)	0.3289	7.67 (-9.89, 25.22)	0.3922	
ADA result									0.5524
Negative	33/ 57 (57.9)	57.0	29/ 62 (46.8)	47.4	1.24 (0.88, 1.75)	0.2266	9.53 (-8.31, 27.36)	0.2950	
Positive (At any time)	4/ 9 (44.4)	44.4	1/ 5 (20.0)	20.0	2.22 (0.33, 14.84)	0.4099	24.44 (-28.17, 77.06)	0.3625	
BMI (kg/m2) at enrolment									0.0289
< 30	23/ 34 (67.6)	67.6	18/ 45 (40.0)	40.0	1.69 (1.10, 2.59)	0.0158	27.65 (6.19, 49.11)	0.0116	
>= 30	14/ 33 (42.4)	42.4	12/ 22 (54.5)	54.5	0.78 (0.45, 1.35)	0.3713	-12.12 (-38.95, 14.71)	0.3758	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=50% Joint reduction at week 52 (for subjects with at least 8 tender joints and swollen joints at baseline)
Full analysis set

Timepoint		Anifrolumab 300mg (N=48)	Placebo (N=46)
Week 52	Number of subjects with events, n (%)	26 (54.2)	18 (39.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.45 (0.99, 2.12)	
	p-value	0.0577	
	Odds Ratio (95% CI)	2.40 (0.93, 6.20)	
	p-value	0.0701	
	Risk Difference (95% CI)	18.32 (-0.78, 37.43)	
	p-value	0.0601	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.38 (0.89, 2.16)	
	p-value	0.1517	
	Odds Ratio (95% CI)	1.84 (0.81, 4.18)	
	p-value	0.1457	
	Risk Difference (95% CI)	15.04 (-4.90, 34.98)	
	p-value	0.1394	
	CMH approach		
	Response rate	53.4	39.8
	Difference in response rates (95% CI)	13.58 (-6.13, 33.30)	
	p-value	0.1769	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=50% Joint reduction at week 52 (for subjects with at least 8 tender joints and swollen joints at baseline) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=48) n/ N (%)	Response rate	Placebo (N=46) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.6459
< 10 points	11/ 16 (68.8)	68.8	7/ 16 (43.8)	43.8	1.57 (0.82, 3.00)	0.1705	25.00 (-8.77, 58.77)	0.1468	
>= 10 points	15/ 32 (46.9)	46.9	11/ 30 (36.7)	36.7	1.28 (0.70, 2.32)	0.4206	10.21 (-14.32, 34.74)	0.4146	
OCS dose at baseline									0.7084
<10 mg/day	11/ 19 (57.9)	57.9	6/ 16 (37.5)	37.5	1.54 (0.74, 3.23)	0.2499	20.39 (-12.36, 53.15)	0.2224	
>=10 mg/day	15/ 29 (51.7)	51.7	12/ 30 (40.0)	40.0	1.29 (0.74, 2.27)	0.3699	11.72 (-13.59, 37.04)	0.3641	
Result of type I IFN gene signature test									0.5769
LOW	6/ 12 (50.0)	50.0	3/ 11 (27.3)	27.3	1.83 (0.60, 5.61)	0.2882	22.73 (-16.98, 62.43)	0.2619	
HIGH	20/ 36 (55.6)	54.5	15/ 35 (42.9)	43.9	1.30 (0.80, 2.10)	0.2907	10.61 (-12.11, 33.32)	0.3600	
Age (years)									0.1560
<= 65	25/ 46 (54.3)	53.2	17/ 45 (37.8)	38.8	1.44 (0.91, 2.28)	0.1205	14.41 (-5.72, 34.53)	0.1607	
> 65	1/ 2 (50.0)	50.0	1/ 1 (100.0)	100.0	0.50 (0.13, 2.00)	0.3270	-50.00 (-168.41, 68.41)	0.4079	
Sex									0.6646
male	2/ 5 (40.0)	40.0	0/ 2 (0.0)	0.0	2.50 (0.17, 37.26)	0.5062	40.00 (-38.52, 118.52)	0.3181	
female	24/ 43 (55.8)	55.0	18/ 44 (40.9)	41.6	1.36 (0.88, 2.13)	0.1699	13.46 (-7.03, 33.94)	0.1979	
Race									0.6633
White	19/ 32 (59.4)	60.5	16/ 38 (42.1)	41.5	1.41 (0.88, 2.26)	0.1520	19.03 (-4.12, 42.18)	0.1072	
Black or African American	5/ 13 (38.5)	38.5	1/ 4 (25.0)	25.0	1.54 (0.25, 9.60)	0.6448	13.46 (-41.00, 67.93)	0.6281	
Asian	0		1/ 1 (100.0)		NE		NE		
Other	2/ 3 (66.7)	66.7	0/ 3 (0.0)	0.0	5.00 (0.34, 74.52)	0.2430	66.67 (-9.16, 142.49)	0.0848	
Ethnicity									0.8750
Hispanic/Latino	4/ 8 (50.0)	50.0	3/ 9 (33.3)	33.3	1.50 (0.47, 4.76)	0.4914	16.67 (-30.35, 63.68)	0.4872	
Non-hispanic/Latino	22/ 40 (55.0)	53.3	15/ 37 (40.5)	41.6	1.36 (0.84, 2.19)	0.2134	11.65 (-10.66, 33.95)	0.3062	
Geographic region									0.6783
EU	11/ 14 (78.6)	78.6	10/ 17 (58.8)	58.8	1.34 (0.82, 2.16)	0.2399	19.75 (-13.48, 52.97)	0.2440	
non-EU	15/ 34 (44.1)	44.1	8/ 29 (27.6)	27.6	1.60 (0.79, 3.22)	0.1890	16.53 (-7.11, 40.18)	0.1706	
Onset of disease									0.8594
Paediatric	1/ 3 (33.3)	33.3	1/ 5 (20.0)	20.0	1.67 (0.16, 17.89)	0.6732	13.33 (-56.26, 82.93)	0.7073	
Adult	25/ 45 (55.6)	55.1	17/ 41 (41.5)	41.8	1.34 (0.86, 2.10)	0.2004	13.27 (-7.58, 34.11)	0.2124	
ADA result									0.7885
Negative	23/ 39 (59.0)	58.4	17/ 41 (41.5)	41.6	1.42 (0.91, 2.23)	0.1233	16.87 (-4.33, 38.08)	0.1188	
Positive (At any time)	3/ 8 (37.5)	37.5	1/ 5 (20.0)	20.0	1.88 (0.26, 13.42)	0.5313	17.50 (-36.11, 71.11)	0.5223	
BMI (kg/m2) at enrolment									0.0352
< 30	14/ 21 (66.7)	66.7	9/ 29 (31.0)	31.0	2.15 (1.15, 4.00)	0.0158	35.63 (8.88, 62.39)	0.0090	
>= 30	12/ 27 (44.4)	44.4	9/ 17 (52.9)	52.9	0.84 (0.45, 1.55)	0.5774	-8.50 (-38.76, 21.77)	0.5822	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Low Disease Activity State at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 52	Number of subjects with events, n (%)	35 (27.6)	23 (18.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.48 (0.93, 2.35)	
	p-value	0.0942	
	Odds Ratio (95% CI)	1.67 (0.92, 3.04)	
	p-value	0.0941	
	Risk Difference (95% CI)	9.01 (-1.39, 19.41)	
	p-value	0.0897	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.50 (0.94, 2.38)	
	p-value	0.0883	
	Odds Ratio (95% CI)	1.69 (0.93, 3.06)	
	p-value	0.0859	
	Risk Difference (95% CI)	9.16 (-1.16, 19.48)	
	p-value	0.0820	
	CMH approach		
	Response rate	27.4	18.6
	Difference in response rates (95% CI)	8.84 (-1.90, 19.59)	
	p-value	0.1067	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Low Disease Activity State at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.3562
< 10 points	12/ 39 (30.8)	30.8	10/ 37 (27.0)	27.0	1.14 (0.56, 2.31)	0.7198	3.74 (-17.02, 24.51)	0.7239	
>= 10 points	23/ 88 (26.1)	26.1	13/ 88 (14.8)	15.0	1.77 (0.96, 3.26)	0.0679	11.14 (-1.28, 23.56)	0.0788	
OCS dose at baseline									0.2335
<10 mg/day	16/ 57 (28.1)	28.1	13/ 52 (25.0)	25.0	1.12 (0.60, 2.10)	0.7177	3.16 (-14.10, 20.41)	0.7199	
>=10 mg/day	19/ 70 (27.1)	27.0	10/ 73 (13.7)	13.7	1.98 (0.99, 3.96)	0.0528	13.35 (-0.46, 27.16)	0.0582	
Result of type I IFN gene signature test									0.2928
LOW	5/ 22 (22.7)	22.7	6/ 24 (25.0)	25.0	0.91 (0.32, 2.56)	0.8569	-2.27 (-28.16, 23.62)	0.8634	
HIGH	30/105 (28.6)	28.5	17/101 (16.8)	17.2	1.70 (1.00, 2.88)	0.0498	11.33 (-0.47, 23.13)	0.0599	
Age (years)									NE
<= 65	35/122 (28.7)	28.6	23/123 (18.7)	18.9	1.53 (0.97, 2.44)	0.0698	9.74 (-1.25, 20.72)	0.0823	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE		0.00 (-74.81, 74.81)	1.0000	
Sex									0.7820
male	3/ 12 (25.0)	25.0	1/ 8 (12.5)	12.5	2.00 (0.25, 15.99)	0.5134	12.50 (-27.35, 52.35)	0.5387	
female	32/115 (27.8)	27.5	22/117 (18.8)	19.1	1.48 (0.92, 2.39)	0.1080	8.49 (-2.78, 19.77)	0.1397	
Race									0.6824
White	23/ 85 (27.1)	26.9	20/ 96 (20.8)	21.5	1.30 (0.77, 2.19)	0.3275	5.33 (-7.72, 18.38)	0.4230	
Black or African American	7/ 22 (31.8)	31.8	3/ 14 (21.4)	21.4	1.48 (0.46, 4.81)	0.5096	10.39 (-20.36, 41.14)	0.5079	
Asian	1/ 7 (14.3)	14.3	0/ 3 (0.0)	0.0	1.50 (0.08, 29.15)	0.7888	14.29 (-46.56, 75.13)	0.6454	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	4/ 13 (30.8)	30.8	0/ 11 (0.0)	0.0	7.71 (0.46, 129.18)	0.1553	30.77 (-2.07, 63.61)	0.0663	
Ethnicity									0.1884
Hispanic/Latino	7/ 23 (30.4)	30.4	2/ 24 (8.3)	8.3	3.65 (0.85, 15.78)	0.0828	22.10 (-1.71, 45.92)	0.0689	
Non-hispanic/Latino	28/104 (26.9)	26.2	21/101 (20.8)	21.3	1.29 (0.79, 2.12)	0.3063	4.93 (-7.22, 17.08)	0.4265	
Geographic region									0.4591
EU	17/ 47 (36.2)	36.2	15/ 56 (26.8)	26.8	1.35 (0.76, 2.40)	0.3067	9.38 (-8.79, 27.56)	0.3115	
non-EU	18/ 80 (22.5)	22.6	8/ 69 (11.6)	11.4	1.94 (0.90, 4.18)	0.0907	11.21 (-1.70, 24.13)	0.0889	
Onset of disease									0.2890
Paediatric	0/ 8 (0.0)	0.0	1/ 7 (14.3)	14.3	0.30 (0.01, 6.29)	0.4353	-14.29 (-56.18, 27.61)	0.5040	
Adult	35/119 (29.4)	29.3	22/118 (18.6)	18.9	1.58 (0.99, 2.52)	0.0565	10.41 (-0.81, 21.63)	0.0690	
ADA result									0.2306
Negative	31/111 (27.9)	27.7	23/112 (20.5)	21.1	1.36 (0.85, 2.18)	0.2009	6.62 (-5.04, 18.28)	0.2660	
Positive (At any time)	4/ 15 (26.7)	26.7	0/ 13 (0.0)	0.0	7.88 (0.46, 133.76)	0.1533	26.67 (-2.66, 55.99)	0.0747	
BMI (kg/m2) at enrolment									0.4273
< 30	22/ 74 (29.7)	30.0	15/ 87 (17.2)	17.8	1.72 (0.97, 3.08)	0.0649	12.20 (-1.34, 25.74)	0.0774	
>= 30	13/ 53 (24.5)	24.9	8/ 38 (21.1)	21.2	1.17 (0.54, 2.53)	0.6995	3.76 (-14.89, 22.42)	0.6924	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Mental Component Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 52	Number of subjects with events, n (%)	36 (28.3)	28 (22.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.30 (0.85, 2.00)	
	p-value	0.2248	
	Odds Ratio (95% CI)	1.43 (0.80, 2.53)	
	p-value	0.2254	
	Risk Difference (95% CI)	6.74 (-4.07, 17.55)	
	p-value	0.2217	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.27 (0.83, 1.94)	
	p-value	0.2806	
	Odds Ratio (95% CI)	1.37 (0.77, 2.43)	
	p-value	0.2791	
	Risk Difference (95% CI)	5.95 (-4.77, 16.66)	
	p-value	0.2768	
	CMH approach		
	Response rate	28.1	22.5
	Difference in response rates (95% CI)	5.65 (-5.31, 16.61)	
	p-value	0.3126	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Mental Component Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8741
< 10 points	14/ 39 (35.9)	35.9	11/ 37 (29.7)	29.7	1.21 (0.63, 2.31)	0.5692	6.17 (-15.16, 27.50)	0.5709	
>= 10 points	22/ 88 (25.0)	25.1	17/ 88 (19.3)	19.6	1.29 (0.74, 2.26)	0.3666	5.49 (-7.26, 18.24)	0.3990	
OCS dose at baseline									0.1847
<10 mg/day	14/ 57 (24.6)	24.6	14/ 52 (26.9)	26.7	0.91 (0.48, 1.73)	0.7780	-2.14 (-19.11, 14.84)	0.8050	
>=10 mg/day	22/ 70 (31.4)	31.2	14/ 73 (19.2)	18.2	1.64 (0.91, 2.94)	0.0976	12.97 (-1.28, 27.22)	0.0745	
Result of type I IFN gene signature test									0.4700
LOW	6/ 22 (27.3)	27.3	7/ 24 (29.2)	29.2	0.94 (0.37, 2.36)	0.8868	-1.89 (-28.75, 24.96)	0.8901	
HIGH	30/105 (28.6)	28.3	21/101 (20.8)	21.0	1.37 (0.85, 2.23)	0.2001	7.33 (-4.66, 19.32)	0.2307	
Age (years)									0.3081
<= 65	35/122 (28.7)	28.3	27/123 (22.0)	21.8	1.31 (0.85, 2.02)	0.2279	6.56 (-4.53, 17.65)	0.2463	
> 65	1/ 5 (20.0)	20.0	1/ 2 (50.0)	50.0	0.40 (0.04, 3.74)	0.4216	-30.00 (-110.68, 50.68)	0.4661	
Sex									0.3404
male	3/ 12 (25.0)	25.0	0/ 8 (0.0)	0.0	4.85 (0.28, 82.84)	0.2759	25.00 (-11.81, 61.81)	0.1831	
female	33/115 (28.7)	28.5	28/117 (23.9)	24.1	1.20 (0.78, 1.85)	0.4111	4.39 (-7.19, 15.97)	0.4572	
Race									0.5024
White	25/ 85 (29.4)	29.7	20/ 96 (20.8)	21.6	1.41 (0.85, 2.35)	0.1854	8.16 (-5.19, 21.51)	0.2311	
Black or African American	8/ 22 (36.4)	36.4	7/ 14 (50.0)	50.0	0.73 (0.34, 1.56)	0.4125	-13.64 (-46.79, 19.52)	0.4202	
Asian	2/ 7 (28.6)	28.6	1/ 3 (33.3)	33.3	0.86 (0.12, 6.23)	0.8789	-4.76 (-71.14, 61.61)	0.8882	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	1/ 13 (7.7)	7.7	0/ 11 (0.0)	0.0	2.57 (0.12, 57.44)	0.5512	7.69 (-21.17, 36.55)	0.6014	
Ethnicity									0.7524
Hispanic/Latino	4/ 23 (17.4)	17.4	4/ 24 (16.7)	16.7	1.04 (0.30, 3.69)	0.9473	0.72 (-22.90, 24.35)	0.9521	
Non-hispanic/Latino	32/104 (30.8)	30.3	24/101 (23.8)	23.5	1.29 (0.82, 2.04)	0.2635	6.77 (-5.66, 19.20)	0.2860	
Geographic region									0.8742
EU	17/ 47 (36.2)	36.2	15/ 56 (26.8)	26.8	1.35 (0.76, 2.40)	0.3067	9.38 (-8.79, 27.56)	0.3115	
non-EU	19/ 80 (23.8)	23.9	13/ 69 (18.8)	18.4	1.26 (0.67, 2.36)	0.4696	5.53 (-8.15, 19.20)	0.4284	
Onset of disease									0.7656
Paediatric	2/ 8 (25.0)	25.0	1/ 7 (14.3)	14.3	1.75 (0.20, 15.41)	0.6142	10.71 (-35.71, 57.14)	0.6510	
Adult	34/119 (28.6)	28.5	27/118 (22.9)	23.2	1.25 (0.81, 1.93)	0.3185	5.35 (-6.06, 16.77)	0.3580	
ADA result									0.2806
Negative	33/111 (29.7)	29.2	24/112 (21.4)	21.7	1.39 (0.88, 2.19)	0.1590	7.55 (-4.25, 19.35)	0.2097	
Positive (At any time)	3/ 15 (20.0)	20.0	4/ 13 (30.8)	30.8	0.65 (0.18, 2.38)	0.5159	-10.77 (-45.00, 23.46)	0.5374	
BMI (kg/m2) at enrolment									0.1332
< 30	22/ 74 (29.7)	30.2	16/ 87 (18.4)	18.0	1.62 (0.92, 2.84)	0.0954	12.23 (-1.39, 25.85)	0.0785	
>= 30	14/ 53 (26.4)	27.0	12/ 38 (31.6)	31.2	0.84 (0.44, 1.60)	0.5896	-4.24 (-23.62, 15.14)	0.6683	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Physical Component Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 52	Number of subjects with events, n (%)	42 (33.1)	36 (28.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.18 (0.82, 1.71)	
	p-value	0.3685	
	Odds Ratio (95% CI)	1.28 (0.75, 2.19)	
	p-value	0.3716	
	Risk Difference (95% CI)	5.26 (-6.24, 16.76)	
	p-value	0.3699	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.15 (0.79, 1.66)	
	p-value	0.4643	
	Odds Ratio (95% CI)	1.22 (0.72, 2.09)	
	p-value	0.4637	
	Risk Difference (95% CI)	4.27 (-7.13, 15.67)	
	p-value	0.4628	
	CMH approach		
	Response rate	33.0	28.7
	Difference in response rates (95% CI)	4.25 (-7.37, 15.87)	
	p-value	0.4736	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Physical Component Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.0241
< 10 points	16/ 39 (41.0)	41.0	6/ 37 (16.2)	16.2	2.53 (1.11, 5.76)	0.0272	24.81 (4.74, 44.88)	0.0154	
>= 10 points	26/ 88 (29.5)	29.6	30/ 88 (34.1)	34.3	0.87 (0.56, 1.34)	0.5183	-4.67 (-18.61, 9.26)	0.5112	
OCS dose at baseline									0.9370
<10 mg/day	18/ 57 (31.6)	31.7	14/ 52 (26.9)	26.8	1.17 (0.65, 2.11)	0.5954	4.85 (-12.66, 22.37)	0.5871	
>=10 mg/day	24/ 70 (34.3)	34.5	22/ 73 (30.1)	29.6	1.14 (0.71, 1.83)	0.5959	4.95 (-10.56, 20.46)	0.5316	
Result of type I IFN gene signature test									0.8994
LOW	7/ 22 (31.8)	31.8	7/ 24 (29.2)	29.2	1.09 (0.46, 2.61)	0.8452	2.65 (-24.63, 29.93)	0.8489	
HIGH	35/105 (33.3)	33.2	29/101 (28.7)	28.6	1.16 (0.77, 1.75)	0.4750	4.61 (-8.23, 17.45)	0.4821	
Age (years)									0.3490
<= 65	41/122 (33.6)	33.5	35/123 (28.5)	28.2	1.18 (0.81, 1.72)	0.3847	5.29 (-6.50, 17.07)	0.3793	
> 65	1/ 5 (20.0)	20.0	1/ 2 (50.0)	50.0	0.40 (0.04, 3.74)	0.4216	-30.00 (-110.68, 50.68)	0.4661	
Sex									0.5745
male	5/ 12 (41.7)	41.7	2/ 8 (25.0)	25.0	1.67 (0.42, 6.59)	0.4663	16.67 (-26.40, 59.73)	0.4482	
female	37/115 (32.2)	31.9	34/117 (29.1)	29.0	1.11 (0.75, 1.63)	0.6071	2.94 (-9.12, 14.99)	0.6330	
Race									0.5323
White	31/ 85 (36.5)	36.9	32/ 96 (33.3)	33.2	1.09 (0.73, 1.63)	0.6582	3.67 (-10.42, 17.76)	0.6099	
Black or African American	4/ 22 (18.2)	18.2	3/ 14 (21.4)	21.4	0.85 (0.22, 3.24)	0.8099	-3.25 (-32.58, 26.09)	0.8283	
Asian	2/ 7 (28.6)	28.6	0/ 3 (0.0)	0.0	2.50 (0.15, 40.67)	0.5196	28.57 (-33.74, 90.89)	0.3688	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	5/ 13 (38.5)	38.5	1/ 11 (9.1)	9.1	4.23 (0.58, 30.99)	0.1557	29.37 (-6.33, 65.07)	0.1069	
Ethnicity									0.3973
Hispanic/Latino	8/ 23 (34.8)	34.8	5/ 24 (20.8)	20.8	1.67 (0.64, 4.36)	0.2953	13.95 (-12.31, 40.21)	0.2978	
Non-hispanic/Latino	34/104 (32.7)	32.7	31/101 (30.7)	30.5	1.07 (0.71, 1.59)	0.7586	2.15 (-10.91, 15.21)	0.7469	
Geographic region									0.3146
EU	22/ 47 (46.8)	46.8	25/ 56 (44.6)	44.6	1.05 (0.69, 1.60)	0.8258	2.17 (-17.16, 21.49)	0.8261	
non-EU	20/ 80 (25.0)	25.1	11/ 69 (15.9)	15.8	1.57 (0.81, 3.04)	0.1825	9.31 (-4.37, 23.00)	0.1823	
Onset of disease									NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE		0.00 (-38.51, 38.51)	1.0000	
Adult	42/119 (35.3)	35.1	36/118 (30.5)	30.4	1.16 (0.80, 1.67)	0.4341	4.77 (-7.36, 16.90)	0.4410	
ADA result									0.5923
Negative	38/111 (34.2)	34.2	34/112 (30.4)	30.4	1.13 (0.77, 1.65)	0.5364	3.75 (-8.76, 16.26)	0.5563	
Positive (At any time)	4/ 15 (26.7)	26.7	2/ 13 (15.4)	15.4	1.73 (0.38, 7.98)	0.4800	11.28 (-21.66, 44.22)	0.5020	
BMI (kg/m2) at enrolment									0.7597
< 30	27/ 74 (36.5)	36.7	26/ 87 (29.9)	29.7	1.22 (0.79, 1.90)	0.3744	6.96 (-7.89, 21.82)	0.3580	
>= 30	15/ 53 (28.3)	29.1	10/ 38 (26.3)	26.6	1.08 (0.54, 2.13)	0.8346	2.43 (-16.65, 21.52)	0.8028	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - General Health Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 52	Number of subjects with events, n (%)	25 (19.7)	17 (13.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.50 (0.85, 2.67)	
	p-value	0.1637	
	Odds Ratio (95% CI)	1.62 (0.82, 3.20)	
	p-value	0.1621	
	Risk Difference (95% CI)	6.67 (-2.55, 15.89)	
	p-value	0.1561	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.45 (0.82, 2.55)	
	p-value	0.1992	
	Odds Ratio (95% CI)	1.56 (0.79, 3.05)	
	p-value	0.1971	
	Risk Difference (95% CI)	6.09 (-3.08, 15.25)	
	p-value	0.1930	
	CMH approach		
	Response rate	19.6	13.5
	Difference in response rates (95% CI)	6.05 (-3.95, 16.05)	
	p-value	0.2359	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - General Health Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.1982
< 10 points	9/ 39 (23.1)	23.1	3/ 37 (8.1)	8.1	2.85 (0.83, 9.71)	0.0947	14.97 (-2.31, 32.25)	0.0896	
>= 10 points	16/ 88 (18.2)	18.2	14/ 88 (15.9)	16.1	1.14 (0.59, 2.20)	0.6888	2.06 (-9.81, 13.93)	0.7340	
OCS dose at baseline									0.9750
<10 mg/day	11/ 57 (19.3)	19.3	7/ 52 (13.5)	13.4	1.43 (0.60, 3.42)	0.4171	5.93 (-9.72, 21.58)	0.4579	
>=10 mg/day	14/ 70 (20.0)	20.0	10/ 73 (13.7)	13.0	1.46 (0.69, 3.07)	0.3177	7.00 (-6.11, 20.11)	0.2955	
Result of type I IFN gene signature test									0.3402
LOW	4/ 22 (18.2)	18.2	5/ 24 (20.8)	20.8	0.87 (0.27, 2.84)	0.8212	-2.65 (-27.35, 22.05)	0.8334	
HIGH	21/105 (20.0)	19.9	12/101 (11.9)	11.9	1.68 (0.87, 3.24)	0.1189	8.00 (-2.93, 18.92)	0.1514	
Age (years)									0.9721
<= 65	24/122 (19.7)	19.5	17/123 (13.8)	13.6	1.42 (0.81, 2.51)	0.2237	5.88 (-4.30, 16.05)	0.2576	
> 65	1/ 5 (20.0)	20.0	0/ 2 (0.0)	0.0	1.50 (0.08, 26.86)	0.7830	20.00 (-57.30, 97.30)	0.6121	
Sex									0.5429
male	2/ 12 (16.7)	16.7	0/ 8 (0.0)	0.0	3.46 (0.19, 63.86)	0.4038	16.67 (-18.93, 52.26)	0.3588	
female	23/115 (20.0)	19.8	17/117 (14.5)	14.4	1.38 (0.78, 2.44)	0.2733	5.33 (-5.23, 15.90)	0.3223	
Race									0.6541
White	17/ 85 (20.0)	19.8	13/ 96 (13.5)	13.8	1.48 (0.76, 2.86)	0.2472	6.02 (-6.22, 18.25)	0.3352	
Black or African American	3/ 22 (13.6)	13.6	3/ 14 (21.4)	21.4	0.64 (0.15, 2.72)	0.5421	-7.79 (-36.46, 20.87)	0.5942	
Asian	2/ 7 (28.6)	28.6	0/ 3 (0.0)	0.0	2.50 (0.15, 40.67)	0.5196	28.57 (-33.74, 90.89)	0.3688	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	3/ 13 (23.1)	23.1	1/ 11 (9.1)	9.1	2.54 (0.31, 21.06)	0.3882	13.99 (-20.25, 48.22)	0.4233	
Ethnicity									0.2578
Hispanic/Latino	6/ 23 (26.1)	26.1	2/ 24 (8.3)	8.3	3.13 (0.70, 13.95)	0.1345	17.75 (-5.58, 41.08)	0.1358	
Non-hispanic/Latino	19/104 (18.3)	18.0	15/101 (14.9)	14.8	1.23 (0.66, 2.28)	0.5120	3.17 (-8.15, 14.48)	0.5834	
Geographic region									0.1977
EU	11/ 47 (23.4)	23.4	12/ 56 (21.4)	21.4	1.09 (0.53, 2.24)	0.8104	1.98 (-14.70, 18.65)	0.8163	
non-EU	14/ 80 (17.5)	17.4	5/ 69 (7.2)	7.3	2.42 (0.92, 6.36)	0.0745	10.12 (-1.99, 22.24)	0.1016	
Onset of disease									NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE		0.00 (-38.51, 38.51)	1.0000	
Adult	25/119 (21.0)	20.9	17/118 (14.4)	14.4	1.46 (0.83, 2.56)	0.1876	6.53 (-4.00, 17.06)	0.2241	
ADA result									0.8836
Negative	22/111 (19.8)	19.6	15/112 (13.4)	13.4	1.48 (0.81, 2.70)	0.2015	6.25 (-4.53, 17.02)	0.2558	
Positive (At any time)	3/ 15 (20.0)	20.0	2/ 13 (15.4)	15.4	1.30 (0.26, 6.62)	0.7521	4.62 (-27.45, 36.68)	0.7779	
BMI (kg/m2) at enrolment									0.5540
< 30	17/ 74 (23.0)	22.9	12/ 87 (13.8)	13.4	1.67 (0.85, 3.26)	0.1361	9.56 (-3.21, 22.34)	0.1424	
>= 30	8/ 53 (15.1)	15.2	5/ 38 (13.2)	13.3	1.15 (0.41, 3.24)	0.7952	1.90 (-15.33, 19.13)	0.8286	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Mental Health Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 52	Number of subjects with events, n (%)	33 (26.0)	17 (13.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	2.02 (1.18, 3.43)	
	p-value	0.0099	
	Odds Ratio (95% CI)	2.43 (1.25, 4.72)	
	p-value	0.0091	
	Risk Difference (95% CI)	13.36 (3.71, 23.00)	
	p-value	0.0066	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.91 (1.12, 3.25)	
	p-value	0.0168	
	Odds Ratio (95% CI)	2.23 (1.17, 4.26)	
	p-value	0.0151	
	Risk Difference (95% CI)	12.38 (2.67, 22.09)	
	p-value	0.0124	
	CMH approach		
	Response rate	25.7	13.5
	Difference in response rates (95% CI)	12.24 (1.93, 22.54)	
	p-value	0.0199	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Mental Health Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.2584
< 10 points	13/ 39 (33.3)	33.3	4/ 37 (10.8)	10.8	3.08 (1.10, 8.61)	0.0315	22.52 (3.72, 41.32)	0.0189	
>= 10 points	20/ 88 (22.7)	22.7	13/ 88 (14.8)	15.0	1.54 (0.82, 2.90)	0.1820	7.70 (-4.41, 19.80)	0.2126	
OCS dose at baseline									0.9410
<10 mg/day	15/ 57 (26.3)	26.5	7/ 52 (13.5)	13.4	1.95 (0.87, 4.41)	0.1068	13.11 (-2.98, 29.19)	0.1102	
>=10 mg/day	18/ 70 (25.7)	25.8	10/ 73 (13.7)	12.7	1.88 (0.93, 3.78)	0.0779	13.07 (-0.33, 26.47)	0.0559	
Result of type I IFN gene signature test									0.0584
LOW	4/ 22 (18.2)	18.2	6/ 24 (25.0)	25.0	0.73 (0.24, 2.24)	0.5791	-6.82 (-32.05, 18.41)	0.5964	
HIGH	29/105 (27.6)	27.4	11/101 (10.9)	10.9	2.54 (1.34, 4.80)	0.0043	16.50 (5.22, 27.77)	0.0041	
Age (years)									0.8751
<= 65	32/122 (26.2)	25.9	17/123 (13.8)	13.6	1.90 (1.11, 3.23)	0.0183	12.33 (1.85, 22.80)	0.0210	
> 65	1/ 5 (20.0)	20.0	0/ 2 (0.0)	0.0	1.50 (0.08, 26.86)	0.7830	20.00 (-57.30, 97.30)	0.6121	
Sex									0.6800
male	2/ 12 (16.7)	16.7	0/ 8 (0.0)	0.0	3.46 (0.19, 63.86)	0.4038	16.67 (-18.93, 52.26)	0.3588	
female	31/115 (27.0)	26.7	17/117 (14.5)	14.4	1.86 (1.09, 3.16)	0.0229	12.27 (1.33, 23.20)	0.0279	
Race									0.7992
White	22/ 85 (25.9)	25.7	12/ 96 (12.5)	12.8	2.07 (1.09, 3.93)	0.0258	12.92 (0.45, 25.38)	0.0423	
Black or African American	8/ 22 (36.4)	36.4	4/ 14 (28.6)	28.6	1.27 (0.47, 3.45)	0.6350	7.79 (-24.19, 39.78)	0.6330	
Asian	2/ 7 (28.6)	28.6	0/ 3 (0.0)	0.0	2.50 (0.15, 40.67)	0.5196	28.57 (-33.74, 90.89)	0.3688	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	1/ 13 (7.7)	7.7	1/ 11 (9.1)	9.1	0.85 (0.06, 12.01)	0.9018	-1.40 (-32.83, 30.04)	0.9305	
Ethnicity									0.3979
Hispanic/Latino	3/ 23 (13.0)	13.0	3/ 24 (12.5)	12.5	1.04 (0.23, 4.65)	0.9555	0.54 (-21.52, 22.61)	0.9615	
Non-hispanic/Latino	30/104 (28.8)	28.3	14/101 (13.9)	13.6	2.08 (1.17, 3.69)	0.0121	14.73 (3.05, 26.40)	0.0134	
Geographic region									0.4061
EU	15/ 47 (31.9)	31.9	11/ 56 (19.6)	19.6	1.62 (0.83, 3.19)	0.1585	12.27 (-4.99, 29.54)	0.1636	
non-EU	18/ 80 (22.5)	22.8	6/ 69 (8.7)	8.7	2.59 (1.09, 6.15)	0.0314	14.18 (1.50, 26.86)	0.0284	
Onset of disease									0.9350
Paediatric	2/ 8 (25.0)	25.0	1/ 7 (14.3)	14.3	1.75 (0.20, 15.41)	0.6142	10.71 (-35.71, 57.14)	0.6510	
Adult	31/119 (26.1)	26.0	16/118 (13.6)	13.6	1.92 (1.11, 3.32)	0.0193	12.42 (1.69, 23.14)	0.0233	
ADA result									0.8868
Negative	29/111 (26.1)	25.7	15/112 (13.4)	13.4	1.95 (1.11, 3.43)	0.0205	12.28 (1.24, 23.32)	0.0292	
Positive (At any time)	4/ 15 (26.7)	26.7	2/ 13 (15.4)	15.4	1.73 (0.38, 7.98)	0.4800	11.28 (-21.66, 44.22)	0.5020	
BMI (kg/m2) at enrolment									0.2056
< 30	21/ 74 (28.4)	28.6	10/ 87 (11.5)	10.7	2.47 (1.24, 4.90)	0.0098	17.92 (5.02, 30.83)	0.0065	
>= 30	12/ 53 (22.6)	23.3	7/ 38 (18.4)	18.3	1.23 (0.53, 2.83)	0.6278	5.02 (-13.10, 23.15)	0.5868	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Physical Functioning Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 52	Number of subjects with events, n (%)	31 (24.4)	29 (23.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.10 (0.71, 1.71)	
	p-value	0.6787	
	Odds Ratio (95% CI)	1.13 (0.63, 2.04)	
	p-value	0.6792	
	Risk Difference (95% CI)	2.22 (-8.29, 12.73)	
	p-value	0.6787	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.05 (0.68, 1.64)	
	p-value	0.8217	
	Odds Ratio (95% CI)	1.07 (0.60, 1.91)	
	p-value	0.8217	
	Risk Difference (95% CI)	1.21 (-9.31, 11.72)	
	p-value	0.8216	
	CMH approach		
	Response rate	24.4	22.9
	Difference in response rates (95% CI)	1.47 (-9.50, 12.44)	
	p-value	0.7929	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Physical Functioning Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.2735
< 10 points	9/ 39 (23.1)	23.1	5/ 37 (13.5)	13.5	1.71 (0.63, 4.63)	0.2925	9.56 (-8.73, 27.85)	0.3054	
>= 10 points	22/ 88 (25.0)	25.0	24/ 88 (27.3)	27.3	0.92 (0.56, 1.51)	0.7317	-2.37 (-15.63, 10.90)	0.7265	
OCS dose at baseline									0.4781
<10 mg/day	13/ 57 (22.8)	22.9	9/ 52 (17.3)	17.3	1.32 (0.61, 2.82)	0.4780	5.57 (-10.76, 21.91)	0.5035	
>=10 mg/day	18/ 70 (25.7)	26.0	20/ 73 (27.4)	26.4	0.94 (0.54, 1.62)	0.8199	-0.36 (-15.15, 14.42)	0.9615	
Result of type I IFN gene signature test									0.3122
LOW	5/ 22 (22.7)	22.7	8/ 24 (33.3)	33.3	0.68 (0.26, 1.77)	0.4323	-10.61 (-37.27, 16.06)	0.4356	
HIGH	26/105 (24.8)	24.8	21/101 (20.8)	20.6	1.19 (0.72, 1.98)	0.4985	4.17 (-7.86, 16.20)	0.4967	
Age (years)									0.3930
<= 65	30/122 (24.6)	24.6	28/123 (22.8)	22.2	1.08 (0.69, 1.69)	0.7368	2.35 (-8.75, 13.44)	0.6782	
> 65	1/ 5 (20.0)	20.0	1/ 2 (50.0)	50.0	0.40 (0.04, 3.74)	0.4216	-30.00 (-110.68, 50.68)	0.4661	
Sex									0.5337
male	3/ 12 (25.0)	25.0	1/ 8 (12.5)	12.5	2.00 (0.25, 15.99)	0.5134	12.50 (-27.35, 52.35)	0.5387	
female	28/115 (24.3)	24.3	28/117 (23.9)	23.6	1.02 (0.64, 1.61)	0.9410	0.69 (-10.81, 12.18)	0.9069	
Race									0.9252
White	23/ 85 (27.1)	27.6	24/ 96 (25.0)	24.6	1.08 (0.66, 1.77)	0.7525	2.97 (-10.39, 16.32)	0.6633	
Black or African American	5/ 22 (22.7)	22.7	4/ 14 (28.6)	28.6	0.80 (0.26, 2.47)	0.6917	-5.84 (-36.72, 25.03)	0.7106	
Asian	1/ 7 (14.3)	14.3	0/ 3 (0.0)	0.0	1.50 (0.08, 29.15)	0.7888	14.29 (-46.56, 75.13)	0.6454	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	2/ 13 (15.4)	15.4	1/ 11 (9.1)	9.1	1.69 (0.18, 16.25)	0.6485	6.29 (-26.73, 39.32)	0.7087	
Ethnicity									0.6584
Hispanic/Latino	3/ 23 (13.0)	13.0	4/ 24 (16.7)	16.7	0.78 (0.20, 3.12)	0.7284	-3.62 (-26.46, 19.21)	0.7558	
Non-hispanic/Latino	28/104 (26.9)	26.5	25/101 (24.8)	24.0	1.09 (0.68, 1.73)	0.7229	2.51 (-9.93, 14.95)	0.6926	
Geographic region									0.3574
EU	17/ 47 (36.2)	36.2	21/ 56 (37.5)	37.5	0.96 (0.58, 1.60)	0.8893	-1.33 (-20.12, 17.46)	0.8897	
non-EU	14/ 80 (17.5)	17.3	8/ 69 (11.6)	11.6	1.51 (0.67, 3.38)	0.3172	5.67 (-6.85, 18.19)	0.3747	
Onset of disease									NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE		0.00 (-38.51, 38.51)	1.0000	
Adult	31/119 (26.1)	26.1	29/118 (24.6)	24.4	1.06 (0.68, 1.64)	0.7942	1.75 (-9.74, 13.25)	0.7652	
ADA result									0.4398
Negative	29/111 (26.1)	26.2	26/112 (23.2)	22.9	1.13 (0.71, 1.78)	0.6144	3.32 (-8.53, 15.18)	0.5828	
Positive (At any time)	2/ 15 (13.3)	13.3	3/ 13 (23.1)	23.1	0.58 (0.11, 2.94)	0.5089	-9.74 (-41.98, 22.49)	0.5536	
BMI (kg/m2) at enrolment									0.7047
< 30	19/ 74 (25.7)	26.4	22/ 87 (25.3)	24.7	1.02 (0.60, 1.72)	0.9550	1.77 (-12.17, 15.70)	0.8039	
>= 30	12/ 53 (22.6)	23.1	7/ 38 (18.4)	18.7	1.23 (0.53, 2.83)	0.6278	4.41 (-13.91, 22.73)	0.6370	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Role Emotional Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 52	Number of subjects with events, n (%)	31 (24.4)	20 (16.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.61 (0.98, 2.63)	
	p-value	0.0591	
	Odds Ratio (95% CI)	1.86 (0.97, 3.56)	
	p-value	0.0597	
	Risk Difference (95% CI)	9.52 (-0.18, 19.23)	
	p-value	0.0545	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.53 (0.92, 2.53)	
	p-value	0.1011	
	Odds Ratio (95% CI)	1.70 (0.91, 3.17)	
	p-value	0.0987	
	Risk Difference (95% CI)	8.41 (-1.45, 18.26)	
	p-value	0.0944	
	CMH approach		
	Response rate	24.6	16.0
	Difference in response rates (95% CI)	8.64 (-1.82, 19.10)	
	p-value	0.1055	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Role Emotional Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.5506
< 10 points	9/ 39 (23.1)	23.1	7/ 37 (18.9)	18.9	1.22 (0.51, 2.94)	0.6579	4.16 (-14.96, 23.27)	0.6699	
>= 10 points	22/ 88 (25.0)	25.0	13/ 88 (14.8)	15.0	1.69 (0.91, 3.14)	0.0956	9.96 (-2.37, 22.30)	0.1133	
OCS dose at baseline									0.5245
<10 mg/day	14/ 57 (24.6)	24.7	10/ 52 (19.2)	19.1	1.28 (0.62, 2.62)	0.5049	5.54 (-11.05, 22.13)	0.5129	
>=10 mg/day	17/ 70 (24.3)	25.3	10/ 73 (13.7)	12.7	1.77 (0.87, 3.60)	0.1134	12.55 (-0.76, 25.86)	0.0645	
Result of type I IFN gene signature test									0.4350
LOW	6/ 22 (27.3)	27.3	6/ 24 (25.0)	25.0	1.09 (0.41, 2.89)	0.8608	2.27 (-24.16, 28.70)	0.8662	
HIGH	25/105 (23.8)	24.0	14/101 (13.9)	14.0	1.72 (0.95, 3.11)	0.0745	10.06 (-1.29, 21.41)	0.0823	
Age (years)									0.2379
<= 65	30/122 (24.6)	24.9	19/123 (15.4)	15.1	1.59 (0.95, 2.67)	0.0781	9.79 (-0.77, 20.36)	0.0693	
> 65	1/ 5 (20.0)	20.0	1/ 2 (50.0)	50.0	0.40 (0.04, 3.74)	0.4216	-30.00 (-110.68, 50.68)	0.4661	
Sex									0.5721
male	2/ 12 (16.7)	16.7	0/ 8 (0.0)	0.0	3.46 (0.19, 63.86)	0.4038	16.67 (-18.93, 52.26)	0.3588	
female	29/115 (25.2)	25.3	20/117 (17.1)	17.1	1.48 (0.89, 2.45)	0.1338	8.22 (-2.86, 19.29)	0.1459	
Race									0.3521
White	23/ 85 (27.1)	27.0	15/ 96 (15.6)	16.2	1.73 (0.97, 3.10)	0.0641	10.88 (-2.04, 23.79)	0.0990	
Black or African American	5/ 22 (22.7)	22.7	5/ 14 (35.7)	35.7	0.64 (0.22, 1.81)	0.3956	-12.99 (-44.54, 18.57)	0.4198	
Asian	1/ 7 (14.3)	14.3	0/ 3 (0.0)	0.0	1.50 (0.08, 29.15)	0.7888	14.29 (-46.56, 75.13)	0.6454	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	2/ 13 (15.4)	15.4	0/ 11 (0.0)	0.0	4.29 (0.23, 80.81)	0.3314	15.38 (-15.20, 45.97)	0.3241	
Ethnicity									0.6756
Hispanic/Latino	4/ 23 (17.4)	17.4	2/ 24 (8.3)	8.3	2.09 (0.42, 10.32)	0.3669	9.06 (-12.96, 31.07)	0.4200	
Non-hispanic/Latino	27/104 (26.0)	26.1	18/101 (17.8)	17.8	1.46 (0.86, 2.47)	0.1640	8.33 (-3.67, 20.33)	0.1735	
Geographic region									0.7165
EU	16/ 47 (34.0)	34.0	11/ 56 (19.6)	19.6	1.73 (0.89, 3.36)	0.1038	14.40 (-3.01, 31.81)	0.1050	
non-EU	15/ 80 (18.8)	18.5	9/ 69 (13.0)	12.7	1.44 (0.67, 3.08)	0.3500	5.81 (-6.80, 18.42)	0.3663	
Onset of disease									0.6646
Paediatric	1/ 8 (12.5)	12.5	1/ 7 (14.3)	14.3	0.88 (0.07, 11.54)	0.9192	-1.79 (-46.38, 42.81)	0.9374	
Adult	30/119 (25.2)	25.4	19/118 (16.1)	16.2	1.57 (0.94, 2.62)	0.0881	9.13 (-1.76, 20.02)	0.1005	
ADA result									0.1658
Negative	28/111 (25.2)	25.5	16/112 (14.3)	14.4	1.77 (1.01, 3.08)	0.0448	11.01 (-0.17, 22.19)	0.0535	
Positive (At any time)	3/ 15 (20.0)	20.0	4/ 13 (30.8)	30.8	0.65 (0.18, 2.38)	0.5159	-10.77 (-45.00, 23.46)	0.5374	
BMI (kg/m2) at enrolment									0.4733
< 30	17/ 74 (23.0)	23.9	15/ 87 (17.2)	16.6	1.33 (0.72, 2.48)	0.3652	7.26 (-5.81, 20.34)	0.2761	
>= 30	14/ 53 (26.4)	26.8	5/ 38 (13.2)	12.9	2.01 (0.79, 5.10)	0.1429	13.90 (-3.97, 31.77)	0.1274	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

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SF-36 v2.0 Acute response rate at week 52 - Role Physical Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 52	Number of subjects with events, n (%)	49 (38.6)	35 (28.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.46 (1.02, 2.09)	
	p-value	0.0372	
	Odds Ratio (95% CI)	1.79 (1.04, 3.09)	
	p-value	0.0357	
	Risk Difference (95% CI)	12.49 (1.08, 23.89)	
	p-value	0.0320	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.38 (0.96, 1.97)	
	p-value	0.0781	
	Odds Ratio (95% CI)	1.62 (0.95, 2.74)	
	p-value	0.0757	
	Risk Difference (95% CI)	10.58 (-0.98, 22.14)	
	p-value	0.0728	
	CMH approach		
	Response rate	38.7	27.7
	Difference in response rates (95% CI)	11.01 (-0.70, 22.73)	
	p-value	0.0655	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Role Physical Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8256
< 10 points	14/ 39 (35.9)	35.9	9/ 37 (24.3)	24.3	1.48 (0.73, 2.99)	0.2802	11.57 (-9.26, 32.40)	0.2762	
>= 10 points	35/ 88 (39.8)	39.8	26/ 88 (29.5)	29.6	1.35 (0.89, 2.03)	0.1579	10.14 (-3.97, 24.26)	0.1590	
OCS dose at baseline									0.4118
<10 mg/day	22/ 57 (38.6)	38.7	12/ 52 (23.1)	23.0	1.67 (0.92, 3.03)	0.0900	15.67 (-1.96, 33.29)	0.0815	
>=10 mg/day	27/ 70 (38.6)	39.2	23/ 73 (31.5)	30.0	1.22 (0.78, 1.92)	0.3774	9.14 (-6.36, 24.63)	0.2480	
Result of type I IFN gene signature test									0.1662
LOW	8/ 22 (36.4)	36.4	10/ 24 (41.7)	41.7	0.87 (0.42, 1.81)	0.7139	-5.30 (-33.68, 23.07)	0.7142	
HIGH	41/105 (39.0)	39.2	25/101 (24.8)	24.6	1.58 (1.04, 2.39)	0.0316	14.66 (1.81, 27.51)	0.0254	
Age (years)									0.2718
<= 65	48/122 (39.3)	39.6	34/123 (27.6)	27.0	1.42 (0.99, 2.04)	0.0553	12.56 (0.70, 24.41)	0.0379	
> 65	1/ 5 (20.0)	20.0	1/ 2 (50.0)	50.0	0.40 (0.04, 3.74)	0.4216	-30.00 (-110.68, 50.68)	0.4661	
Sex									0.5588
male	6/ 12 (50.0)	50.0	2/ 8 (25.0)	25.0	2.00 (0.53, 7.54)	0.3059	25.00 (-18.21, 68.21)	0.2568	
female	43/115 (37.4)	37.3	33/117 (28.2)	27.8	1.33 (0.91, 1.93)	0.1390	9.50 (-2.69, 21.68)	0.1267	
Race									0.8158
White	36/ 85 (42.4)	42.6	31/ 96 (32.3)	32.5	1.31 (0.90, 1.92)	0.1633	10.08 (-4.20, 24.36)	0.1667	
Black or African American	8/ 22 (36.4)	36.4	3/ 14 (21.4)	21.4	1.70 (0.54, 5.33)	0.3654	14.94 (-16.11, 45.98)	0.3457	
Asian	1/ 7 (14.3)	14.3	0/ 3 (0.0)	0.0	1.50 (0.08, 29.15)	0.7888	14.29 (-46.56, 75.13)	0.6454	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	4/ 13 (30.8)	30.8	1/ 11 (9.1)	9.1	3.38 (0.44, 26.00)	0.2412	21.68 (-13.44, 56.80)	0.2264	
Ethnicity									0.2483
Hispanic/Latino	6/ 23 (26.1)	26.1	2/ 24 (8.3)	8.3	3.13 (0.70, 13.95)	0.1345	17.75 (-5.58, 41.08)	0.1358	
Non-hispanic/Latino	43/104 (41.3)	41.6	33/101 (32.7)	32.3	1.27 (0.88, 1.82)	0.2020	9.27 (-4.06, 22.59)	0.1729	
Geographic region									0.1304
EU	26/ 47 (55.3)	55.3	26/ 56 (46.4)	46.4	1.19 (0.81, 1.74)	0.3674	8.89 (-10.43, 28.21)	0.3670	
non-EU	23/ 80 (28.8)	28.5	9/ 69 (13.0)	13.0	2.20 (1.09, 4.44)	0.0269	15.54 (2.03, 29.05)	0.0242	
Onset of disease									0.8281
Paediatric	2/ 8 (25.0)	25.0	1/ 7 (14.3)	14.3	1.75 (0.20, 15.41)	0.6142	10.71 (-35.71, 57.14)	0.6510	
Adult	47/119 (39.5)	39.7	34/118 (28.8)	28.6	1.37 (0.96, 1.97)	0.0863	11.11 (-1.04, 23.26)	0.0732	
ADA result									0.6952
Negative	43/111 (38.7)	39.0	32/112 (28.6)	28.3	1.36 (0.93, 1.97)	0.1114	10.74 (-1.83, 23.31)	0.0940	
Positive (At any time)	6/ 15 (40.0)	40.0	3/ 13 (23.1)	23.1	1.73 (0.54, 5.59)	0.3569	16.92 (-18.26, 52.11)	0.3458	
BMI (kg/m2) at enrolment									0.5296
< 30	30/ 74 (40.5)	41.3	27/ 87 (31.0)	30.4	1.31 (0.86, 1.98)	0.2096	10.89 (-3.82, 25.61)	0.1467	
>= 30	19/ 53 (35.8)	36.6	8/ 38 (21.1)	21.4	1.70 (0.83, 3.47)	0.1436	15.19 (-3.78, 34.16)	0.1166	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

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SF-36 v2.0 Acute response rate at week 52 - Social Functioning Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 52	Number of subjects with events, n (%)	30 (23.6)	24 (19.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.27 (0.79, 2.06)	
	p-value	0.3265	
	Odds Ratio (95% CI)	1.35 (0.74, 2.47)	
	p-value	0.3272	
	Risk Difference (95% CI)	5.16 (-5.11, 15.44)	
	p-value	0.3248	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.23 (0.76, 1.98)	
	p-value	0.3940	
	Odds Ratio (95% CI)	1.30 (0.71, 2.38)	
	p-value	0.3930	
	Risk Difference (95% CI)	4.42 (-5.69, 14.53)	
	p-value	0.3914	
	CMH approach		
	Response rate	23.6	19.2
	Difference in response rates (95% CI)	4.31 (-6.34, 14.96)	
	p-value	0.4278	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

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SF-36 v2.0 Acute response rate at week 52 - Social Functioning Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.4046
< 10 points	12/ 39 (30.8)	30.8	7/ 37 (18.9)	18.9	1.63 (0.72, 3.68)	0.2430	11.85 (-8.00, 31.70)	0.2420	
>= 10 points	18/ 88 (20.5)	20.6	17/ 88 (19.3)	19.6	1.06 (0.58, 1.92)	0.8502	1.02 (-11.40, 13.45)	0.8718	
OCS dose at baseline									0.4493
<10 mg/day	12/ 57 (21.1)	21.1	11/ 52 (21.2)	21.0	1.00 (0.48, 2.06)	0.9897	0.02 (-16.45, 16.49)	0.9980	
>=10 mg/day	18/ 70 (25.7)	25.6	13/ 73 (17.8)	17.1	1.44 (0.77, 2.72)	0.2557	8.50 (-5.48, 22.48)	0.2335	
Result of type I IFN gene signature test									0.5186
LOW	5/ 22 (22.7)	22.7	6/ 24 (25.0)	25.0	0.91 (0.32, 2.56)	0.8569	-2.27 (-28.16, 23.62)	0.8634	
HIGH	25/105 (23.8)	23.7	18/101 (17.8)	18.0	1.34 (0.78, 2.29)	0.2938	5.78 (-5.90, 17.46)	0.3318	
Age (years)									0.3217
<= 65	29/122 (23.8)	23.6	23/123 (18.7)	18.5	1.27 (0.78, 2.07)	0.3338	5.10 (-5.67, 15.86)	0.3536	
> 65	1/ 5 (20.0)	20.0	1/ 2 (50.0)	50.0	0.40 (0.04, 3.74)	0.4216	-30.00 (-110.68, 50.68)	0.4661	
Sex									0.3260
male	3/ 12 (25.0)	25.0	0/ 8 (0.0)	0.0	4.85 (0.28, 82.84)	0.2759	25.00 (-11.81, 61.81)	0.1831	
female	27/115 (23.5)	23.3	24/117 (20.5)	20.6	1.14 (0.70, 1.86)	0.5860	2.69 (-8.52, 13.90)	0.6381	
Race									0.3760
White	23/ 85 (27.1)	27.7	18/ 96 (18.8)	19.3	1.44 (0.84, 2.48)	0.1858	8.39 (-4.73, 21.52)	0.2102	
Black or African American	6/ 22 (27.3)	27.3	5/ 14 (35.7)	35.7	0.76 (0.29, 2.03)	0.5895	-8.44 (-40.44, 23.56)	0.6051	
Asian	1/ 7 (14.3)	14.3	1/ 3 (33.3)	33.3	0.43 (0.04, 4.82)	0.4925	-19.05 (-84.04, 45.95)	0.5657	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-26.65, 26.65)	1.0000	
Ethnicity									0.2385
Hispanic/Latino	1/ 23 (4.3)	4.3	3/ 24 (12.5)	12.5	0.35 (0.04, 3.11)	0.3445	-8.15 (-28.15, 11.84)	0.4242	
Non-hispanic/Latino	29/104 (27.9)	28.2	21/101 (20.8)	20.7	1.34 (0.82, 2.19)	0.2407	7.49 (-4.85, 19.83)	0.2343	
Geographic region									0.8059
EU	16/ 47 (34.0)	34.0	14/ 56 (25.0)	25.0	1.36 (0.74, 2.49)	0.3160	9.04 (-8.87, 26.95)	0.3224	
non-EU	14/ 80 (17.5)	17.6	10/ 69 (14.5)	14.3	1.21 (0.57, 2.54)	0.6198	3.23 (-9.71, 16.17)	0.6247	
Onset of disease									0.7898
Paediatric	1/ 8 (12.5)	12.5	1/ 7 (14.3)	14.3	0.88 (0.07, 11.54)	0.9192	-1.79 (-46.38, 42.81)	0.9374	
Adult	29/119 (24.4)	24.4	23/118 (19.5)	19.6	1.25 (0.77, 2.03)	0.3661	4.73 (-6.38, 15.84)	0.4038	
ADA result									0.1501
Negative	28/111 (25.2)	25.1	20/112 (17.9)	18.1	1.41 (0.85, 2.35)	0.1845	6.97 (-4.48, 18.41)	0.2330	
Positive (At any time)	2/ 15 (13.3)	13.3	4/ 13 (30.8)	30.8	0.43 (0.09, 1.99)	0.2829	-17.44 (-50.61, 15.74)	0.3029	
BMI (kg/m2) at enrolment									0.6095
< 30	17/ 74 (23.0)	22.9	15/ 87 (17.2)	17.2	1.33 (0.72, 2.48)	0.3652	5.73 (-7.38, 18.84)	0.3917	
>= 30	13/ 53 (24.5)	24.8	9/ 38 (23.7)	23.9	1.04 (0.49, 2.17)	0.9262	0.83 (-18.19, 19.85)	0.9318	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Bodily Pain Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 52	Number of subjects with events, n (%)	35 (27.6)	31 (24.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.13 (0.75, 1.71)	
	p-value	0.5570	
	Odds Ratio (95% CI)	1.18 (0.67, 2.09)	
	p-value	0.5591	
	Risk Difference (95% CI)	3.25 (-7.63, 14.12)	
	p-value	0.5585	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.11 (0.73, 1.68)	
	p-value	0.6188	
	Odds Ratio (95% CI)	1.15 (0.66, 2.02)	
	p-value	0.6186	
	Risk Difference (95% CI)	2.76 (-8.09, 13.61)	
	p-value	0.6182	
	CMH approach		
	Response rate	27.3	24.9
	Difference in response rates (95% CI)	2.39 (-8.70, 13.47)	
	p-value	0.6730	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Bodily Pain Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.0762
< 10 points	17/ 39 (43.6)	43.6	9/ 37 (24.3)	24.3	1.79 (0.92, 3.51)	0.0885	19.27 (-1.87, 40.40)	0.0740	
>= 10 points	18/ 88 (20.5)	20.5	22/ 88 (25.0)	25.2	0.82 (0.47, 1.42)	0.4732	-4.71 (-17.56, 8.14)	0.4726	
OCS dose at baseline									0.4016
<10 mg/day	15/ 57 (26.3)	26.4	15/ 52 (28.8)	28.8	0.91 (0.50, 1.68)	0.7677	-2.41 (-19.68, 14.86)	0.7845	
>=10 mg/day	20/ 70 (28.6)	28.2	16/ 73 (21.9)	21.6	1.30 (0.74, 2.30)	0.3618	6.61 (-7.92, 21.15)	0.3727	
Result of type I IFN gene signature test									0.6805
LOW	6/ 22 (27.3)	27.3	7/ 24 (29.2)	29.2	0.94 (0.37, 2.36)	0.8868	-1.89 (-28.75, 24.96)	0.8901	
HIGH	29/105 (27.6)	27.3	24/101 (23.8)	23.9	1.16 (0.73, 1.85)	0.5277	3.34 (-8.81, 15.50)	0.5899	
Age (years)									0.3657
<= 65	34/122 (27.9)	27.4	30/123 (24.4)	24.3	1.14 (0.75, 1.74)	0.5360	3.13 (-8.09, 14.36)	0.5843	
> 65	1/ 5 (20.0)	20.0	1/ 2 (50.0)	50.0	0.40 (0.04, 3.74)	0.4216	-30.00 (-110.68, 50.68)	0.4661	
Sex									0.5469
male	2/ 12 (16.7)	16.7	2/ 8 (25.0)	25.0	0.67 (0.12, 3.81)	0.6486	-8.33 (-49.17, 32.50)	0.6892	
female	33/115 (28.7)	28.3	29/117 (24.8)	24.9	1.16 (0.76, 1.78)	0.5018	3.37 (-8.24, 14.98)	0.5696	
Race									0.9740
White	26/ 85 (30.6)	30.6	27/ 96 (28.1)	28.6	1.09 (0.69, 1.71)	0.7162	2.02 (-11.63, 15.67)	0.7719	
Black or African American	6/ 22 (27.3)	27.3	3/ 14 (21.4)	21.4	1.27 (0.38, 4.28)	0.6968	5.84 (-24.53, 36.22)	0.7061	
Asian	1/ 7 (14.3)	14.3	0/ 3 (0.0)	0.0	1.50 (0.08, 29.15)	0.7888	14.29 (-46.56, 75.13)	0.6454	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	2/ 13 (15.4)	15.4	1/ 11 (9.1)	9.1	1.69 (0.18, 16.25)	0.6485	6.29 (-26.73, 39.32)	0.7087	
Ethnicity									0.8316
Hispanic/Latino	7/ 23 (30.4)	30.4	6/ 24 (25.0)	25.0	1.22 (0.48, 3.08)	0.6779	5.43 (-20.98, 31.85)	0.6868	
Non-hispanic/Latino	28/104 (26.9)	26.8	25/101 (24.8)	24.6	1.09 (0.68, 1.73)	0.7229	2.22 (-10.26, 14.70)	0.7273	
Geographic region									0.6520
EU	17/ 47 (36.2)	36.2	19/ 56 (33.9)	33.9	1.07 (0.63, 1.81)	0.8120	2.24 (-16.39, 20.87)	0.8136	
non-EU	18/ 80 (22.5)	23.0	12/ 69 (17.4)	17.0	1.29 (0.67, 2.49)	0.4413	5.94 (-7.44, 19.32)	0.3840	
Onset of disease									0.5686
Paediatric	1/ 8 (12.5)	12.5	0/ 7 (0.0)	0.0	2.67 (0.13, 56.63)	0.5293	12.50 (-28.93, 53.93)	0.5543	
Adult	34/119 (28.6)	28.2	31/118 (26.3)	26.4	1.09 (0.72, 1.65)	0.6917	1.76 (-9.82, 13.35)	0.7655	
ADA result									0.7057
Negative	32/111 (28.8)	28.3	28/112 (25.0)	25.2	1.15 (0.75, 1.78)	0.5199	3.07 (-8.89, 15.03)	0.6151	
Positive (At any time)	3/ 15 (20.0)	20.0	3/ 13 (23.1)	23.1	0.87 (0.21, 3.58)	0.8432	-3.08 (-36.39, 30.24)	0.8564	
BMI (kg/m2) at enrolment									0.9271
< 30	20/ 74 (27.0)	27.1	21/ 87 (24.1)	23.9	1.12 (0.66, 1.90)	0.6748	3.15 (-10.80, 17.09)	0.6584	
>= 30	15/ 53 (28.3)	29.3	10/ 38 (26.3)	26.2	1.08 (0.54, 2.13)	0.8346	3.05 (-15.97, 22.06)	0.7535	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Vitality Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 52	Number of subjects with events, n (%)	38 (29.9)	27 (21.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.42 (0.92, 2.20)	
	p-value	0.1159	
	Odds Ratio (95% CI)	1.59 (0.90, 2.84)	
	p-value	0.1120	
	Risk Difference (95% CI)	8.86 (-1.94, 19.66)	
	p-value	0.1077	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.39 (0.90, 2.12)	
	p-value	0.1348	
	Odds Ratio (95% CI)	1.55 (0.88, 2.74)	
	p-value	0.1325	
	Risk Difference (95% CI)	8.32 (-2.42, 19.07)	
	p-value	0.1291	
	CMH approach		
	Response rate	29.7	21.6
	Difference in response rates (95% CI)	8.16 (-2.90, 19.22)	
	p-value	0.1484	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Vitality Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.2814
< 10 points	16/ 39 (41.0)	41.0	8/ 37 (21.6)	21.6	1.90 (0.92, 3.90)	0.0811	19.40 (-1.36, 40.17)	0.0670	
>= 10 points	22/ 88 (25.0)	25.1	19/ 88 (21.6)	21.8	1.16 (0.68, 1.98)	0.5933	3.29 (-9.67, 16.26)	0.6187	
OCS dose at baseline									0.6786
<10 mg/day	17/ 57 (29.8)	29.8	10/ 52 (19.2)	19.2	1.55 (0.78, 3.08)	0.2091	10.56 (-6.29, 27.42)	0.2194	
>=10 mg/day	21/ 70 (30.0)	29.5	17/ 73 (23.3)	22.5	1.29 (0.74, 2.23)	0.3659	6.94 (-7.67, 21.55)	0.3519	
Result of type I IFN gene signature test									0.3163
LOW	7/ 22 (31.8)	31.8	8/ 24 (33.3)	33.3	0.95 (0.41, 2.20)	0.9129	-1.52 (-29.13, 26.10)	0.9144	
HIGH	31/105 (29.5)	29.3	19/101 (18.8)	18.9	1.57 (0.95, 2.59)	0.0781	10.32 (-1.72, 22.37)	0.0931	
Age (years)									0.2715
<= 65	37/122 (30.3)	30.0	26/123 (21.1)	20.8	1.43 (0.93, 2.22)	0.1035	9.17 (-2.04, 20.38)	0.1088	
> 65	1/ 5 (20.0)	20.0	1/ 2 (50.0)	50.0	0.40 (0.04, 3.74)	0.4216	-30.00 (-110.68, 50.68)	0.4661	
Sex									0.5059
male	4/ 12 (33.3)	33.3	1/ 8 (12.5)	12.5	2.67 (0.36, 19.71)	0.3365	20.83 (-19.79, 61.46)	0.3149	
female	34/115 (29.6)	29.3	26/117 (22.2)	22.2	1.33 (0.86, 2.07)	0.2045	7.08 (-4.45, 18.61)	0.2291	
Race									0.7752
White	29/ 85 (34.1)	34.5	22/ 96 (22.9)	23.0	1.49 (0.93, 2.38)	0.0977	11.44 (-2.18, 25.06)	0.0997	
Black or African American	8/ 22 (36.4)	36.4	4/ 14 (28.6)	28.6	1.27 (0.47, 3.45)	0.6350	7.79 (-24.19, 39.78)	0.6330	
Asian	1/ 7 (14.3)	14.3	0/ 3 (0.0)	0.0	1.50 (0.08, 29.15)	0.7888	14.29 (-46.56, 75.13)	0.6454	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 13 (0.0)	0.0	1/ 11 (9.1)	9.1	0.29 (0.01, 6.38)	0.4293	-9.09 (-38.51, 20.33)	0.5447	
Ethnicity									0.3917
Hispanic/Latino	3/ 23 (13.0)	13.0	4/ 24 (16.7)	16.7	0.78 (0.20, 3.12)	0.7284	-3.62 (-26.46, 19.21)	0.7558	
Non-hispanic/Latino	35/104 (33.7)	33.4	23/101 (22.8)	22.6	1.48 (0.94, 2.32)	0.0884	10.84 (-1.78, 23.47)	0.0924	
Geographic region									0.4823
EU	18/ 47 (38.3)	38.3	17/ 56 (30.4)	30.4	1.26 (0.74, 2.16)	0.3969	7.94 (-10.59, 26.47)	0.4009	
non-EU	20/ 80 (25.0)	25.3	10/ 69 (14.5)	14.6	1.73 (0.87, 3.43)	0.1200	10.68 (-2.77, 24.13)	0.1195	
Onset of disease									0.7202
Paediatric	1/ 8 (12.5)	12.5	1/ 7 (14.3)	14.3	0.88 (0.07, 11.54)	0.9192	-1.79 (-46.38, 42.81)	0.9374	
Adult	37/119 (31.1)	30.9	26/118 (22.0)	22.1	1.41 (0.92, 2.17)	0.1183	8.80 (-2.74, 20.33)	0.1350	
ADA result									0.9231
Negative	35/111 (31.5)	31.2	25/112 (22.3)	22.4	1.41 (0.91, 2.20)	0.1247	8.72 (-3.27, 20.70)	0.1540	
Positive (At any time)	3/ 15 (20.0)	20.0	2/ 13 (15.4)	15.4	1.30 (0.26, 6.62)	0.7521	4.62 (-27.45, 36.68)	0.7779	
BMI (kg/m2) at enrolment									0.5657
< 30	20/ 74 (27.0)	27.3	19/ 87 (21.8)	21.2	1.24 (0.72, 2.14)	0.4443	6.03 (-7.70, 19.76)	0.3892	
>= 30	18/ 53 (34.0)	34.7	8/ 38 (21.1)	21.2	1.61 (0.78, 3.32)	0.1937	13.52 (-5.52, 32.55)	0.1641	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
C-SSRS Suicidal ideation or behaviour
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
On-treatment/Follow-Up	Number of subjects with events, n (%)	2 (1.6)	0 (0.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	NE	
	p-value		
	Odds Ratio (95% CI)	NE	
	p-value		
	Risk Difference (95% CI)	1.54 (-0.61, 3.70)	
	p-value	0.1606	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	4.92 (0.24, 101.50)	
	p-value	0.3020	
	Odds Ratio (95% CI)	5.00 (0.24, 105.20)	
	p-value	0.3005	
	Risk Difference (95% CI)	1.57 (-0.59, 3.74)	
	p-value	0.1540	
	CMH approach		
	Response rate	1.5	0.0
	Difference in response rates (95% CI)	1.53 (-4.89, 7.95)	
	p-value	0.6401	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
C-SSRS Suicidal ideation or behaviour - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE		0.00 (-9.58, 9.58)	1.0000	
>= 10 points	2/ 88 (2.3)	2.2	0/ 88 (0.0)	0.0	5.00 (0.24, 102.67)	0.2966	2.19 (-5.18, 9.56)	0.5608	
OCS dose at baseline									NE
<10 mg/day	2/ 57 (3.5)	3.5	0/ 52 (0.0)	0.0	4.57 (0.22, 93.01)	0.3231	3.54 (-7.91, 14.99)	0.5449	
>=10 mg/day	0/ 70 (0.0)	0.0	0/ 73 (0.0)	0.0	NE		0.00 (-8.22, 8.22)	1.0000	
Result of type I IFN gene signature test									NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-15.17, 15.17)	1.0000	
HIGH	2/105 (1.9)	1.9	0/101 (0.0)	0.0	4.81 (0.23, 99.00)	0.3086	1.87 (-5.21, 8.96)	0.6042	
Age (years)									NE
<= 65	2/122 (1.6)	1.6	0/123 (0.0)	0.0	5.04 (0.24, 103.92)	0.2948	1.64 (-4.97, 8.25)	0.6264	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE		0.00 (-74.81, 74.81)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE		0.00 (-31.89, 31.89)	1.0000	
female	2/115 (1.7)	1.7	0/117 (0.0)	0.0	5.09 (0.25, 104.80)	0.2920	1.66 (-5.26, 8.58)	0.6378	
Race									0.8102
White	1/ 85 (1.2)	1.1	0/ 96 (0.0)	0.0	3.38 (0.14, 81.97)	0.4535	1.09 (-7.44, 9.63)	0.8018	
Black or African American	1/ 22 (4.5)	4.5	0/ 14 (0.0)	0.0	1.96 (0.09, 44.92)	0.6747	4.55 (-16.65, 25.74)	0.6742	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-26.65, 26.65)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	2/104 (1.9)	1.6	0/101 (0.0)	0.0	4.86 (0.24, 99.94)	0.3057	1.64 (-6.08, 9.36)	0.6767	
Geographic region									NE
EU	0/ 47 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-7.27, 7.27)	1.0000	
non-EU	2/ 80 (2.5)	2.4	0/ 69 (0.0)	0.0	4.32 (0.21, 88.50)	0.3421	2.43 (-6.24, 11.09)	0.5829	
Onset of disease									0.9613
Paediatric	1/ 8 (12.5)	12.5	0/ 7 (0.0)	0.0	2.67 (0.13, 56.63)	0.5293	12.50 (-28.93, 53.93)	0.5543	
Adult	1/119 (0.8)	0.8	0/118 (0.0)	0.0	2.98 (0.12, 72.30)	0.5030	0.85 (-5.81, 7.51)	0.8033	
ADA result									NE
Negative	2/111 (1.8)	1.7	0/112 (0.0)	0.0	5.04 (0.24, 103.90)	0.2944	1.73 (-5.46, 8.92)	0.6374	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/ 74 (0.0)	0.0	0/ 87 (0.0)	0.0	NE		0.00 (-7.46, 7.46)	1.0000	
>= 30	2/ 53 (3.8)	3.6	0/ 38 (0.0)	0.0	3.61 (0.18, 73.14)	0.4028	3.62 (-9.90, 17.15)	0.5997	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Modified SELENA Flare Index based flares - mild/moderate flare
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
at least once during study	Number of subjects with events, n (%)	36 (28.3)	37 (29.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.97 (0.66, 1.44)	
	p-value	0.8987	
	Odds Ratio (95% CI)	0.97 (0.56, 1.66)	
	p-value	0.8985	
	Risk Difference (95% CI)	-0.74 (-12.06, 10.59)	
	p-value	0.8985	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.96 (0.65, 1.41)	
	p-value	0.8264	
	Odds Ratio (95% CI)	0.94 (0.55, 1.62)	
	p-value	0.8264	
	Risk Difference (95% CI)	-1.25 (-12.46, 9.95)	
	p-value	0.8264	
	CMH approach		
	Response rate	28.5	29.5
	Difference in response rates (95% CI)	-0.99 (-12.45, 10.48)	
	p-value	0.8662	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Modified SELENA Flare Index based flares - mild/moderate flare - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.3799
< 10 points	12/ 39 (30.8)	30.8	9/ 37 (24.3)	24.3	1.26 (0.60, 2.65)	0.5325	6.44 (-14.05, 26.94)	0.5377	
>= 10 points	24/ 88 (27.3)	27.3	28/ 88 (31.8)	31.8	0.86 (0.54, 1.36)	0.5097	-4.42 (-18.14, 9.30)	0.5276	
OCS dose at baseline									0.3620
<10 mg/day	16/ 57 (28.1)	28.0	12/ 52 (23.1)	23.0	1.22 (0.64, 2.32)	0.5531	4.97 (-11.99, 21.94)	0.5657	
>=10 mg/day	20/ 70 (28.6)	28.9	25/ 73 (34.2)	33.9	0.83 (0.51, 1.36)	0.4669	-4.99 (-20.52, 10.54)	0.5290	
Result of type I IFN gene signature test									0.4939
LOW	8/ 22 (36.4)	36.4	7/ 24 (29.2)	29.2	1.25 (0.54, 2.87)	0.6039	7.20 (-20.41, 34.81)	0.6094	
HIGH	28/105 (26.7)	26.8	30/101 (29.7)	29.6	0.90 (0.58, 1.39)	0.6283	-2.82 (-15.41, 9.78)	0.6613	
Age (years)									0.7604
<= 65	35/122 (28.7)	28.9	37/123 (30.1)	30.0	0.95 (0.65, 1.41)	0.8109	-1.12 (-12.80, 10.56)	0.8505	
> 65	1/ 5 (20.0)	20.0	0/ 2 (0.0)	0.0	1.50 (0.08, 26.86)	0.7830	20.00 (-57.30, 97.30)	0.6121	
Sex									0.6661
male	2/ 12 (16.7)	16.7	2/ 8 (25.0)	25.0	0.67 (0.12, 3.81)	0.6486	-8.33 (-49.17, 32.50)	0.6892	
female	34/115 (29.6)	29.8	35/117 (29.9)	29.8	0.99 (0.67, 1.47)	0.9536	-0.03 (-12.04, 11.98)	0.9964	
Race									0.7048
White	22/ 85 (25.9)	25.8	28/ 96 (29.2)	28.9	0.89 (0.55, 1.43)	0.6228	-3.12 (-16.65, 10.42)	0.6518	
Black or African American	10/ 22 (45.5)	45.5	5/ 14 (35.7)	35.7	1.27 (0.55, 2.94)	0.5730	9.74 (-23.21, 42.70)	0.5624	
Asian	3/ 7 (42.9)	42.9	2/ 3 (66.7)	66.7	0.64 (0.20, 2.07)	0.4597	-23.81 (-90.87, 43.25)	0.4865	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	1/ 13 (7.7)	7.7	2/ 11 (18.2)	18.2	0.42 (0.04, 4.06)	0.4561	-10.49 (-43.84, 22.86)	0.5376	
Ethnicity									0.5510
Hispanic/Latino	4/ 23 (17.4)	17.4	6/ 24 (25.0)	25.0	0.70 (0.23, 2.15)	0.5285	-7.61 (-32.41, 17.20)	0.5477	
Non-hispanic/Latino	32/104 (30.8)	31.3	31/101 (30.7)	30.8	1.00 (0.66, 1.51)	0.9906	0.53 (-12.47, 13.52)	0.9365	
Geographic region									0.3115
EU	7/ 47 (14.9)	14.9	13/ 56 (23.2)	23.2	0.64 (0.28, 1.48)	0.2964	-8.32 (-24.05, 7.41)	0.2998	
non-EU	29/ 80 (36.3)	36.1	24/ 69 (34.8)	35.2	1.04 (0.67, 1.61)	0.8522	0.89 (-14.56, 16.34)	0.9099	
Onset of disease									0.3641
Paediatric	4/ 8 (50.0)	50.0	2/ 7 (28.6)	28.6	1.75 (0.45, 6.82)	0.4203	21.43 (-28.27, 71.13)	0.3981	
Adult	32/119 (26.9)	26.8	35/118 (29.7)	29.5	0.91 (0.60, 1.36)	0.6361	-2.72 (-14.42, 8.98)	0.6487	
ADA result									0.0744
Negative	34/111 (30.6)	30.9	31/112 (27.7)	27.4	1.11 (0.73, 1.67)	0.6280	3.49 (-8.74, 15.73)	0.5758	
Positive (At any time)	2/ 15 (13.3)	13.3	6/ 13 (46.2)	46.2	0.29 (0.07, 1.19)	0.0860	-32.82 (-66.91, 1.27)	0.0591	
BMI (kg/m2) at enrolment									0.1593
< 30	15/ 74 (20.3)	20.4	25/ 87 (28.7)	28.5	0.71 (0.40, 1.24)	0.2220	-8.14 (-21.97, 5.68)	0.2482	
>= 30	21/ 53 (39.6)	39.8	12/ 38 (31.6)	32.1	1.25 (0.71, 2.23)	0.4385	7.73 (-12.19, 27.65)	0.4470	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Modified SELENA Flare Index based flares - severe flare
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
at least once during study	Number of subjects with events, n (%)	2 (1.6)	7 (5.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.29 (0.07, 1.33)	
	p-value	0.1116	
	Odds Ratio (95% CI)	0.27 (0.05, 1.35)	
	p-value	0.1114	
	Risk Difference (95% CI)	-3.97 (-8.56, 0.61)	
	p-value	0.0896	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.28 (0.06, 1.33)	
	p-value	0.1091	
	Odds Ratio (95% CI)	0.27 (0.05, 1.32)	
	p-value	0.1066	
	Risk Difference (95% CI)	-4.03 (-8.60, 0.55)	
	p-value	0.0847	
	CMH approach		
	Response rate	1.6	5.6
	Difference in response rates (95% CI)	-3.94 (-11.32, 3.44)	
	p-value	0.2958	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Modified SELENA Flare Index based flares - severe flare - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Anifrolumab 300mg (N=127) Response rate	Placebo (N=125) n/ N (%)	Placebo (N=125) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9773
< 10 points	0/ 39 (0.0)	0.0	1/ 37 (2.7)	2.7	0.32 (0.01, 7.54)	0.4771	-2.70 (-13.38, 7.98)	0.6199	
>= 10 points	2/ 88 (2.3)	2.3	6/ 88 (6.8)	6.7	0.33 (0.07, 1.61)	0.1710	-4.34 (-13.17, 4.50)	0.3358	
OCS dose at baseline									0.9418
<10 mg/day	0/ 57 (0.0)	0.0	1/ 52 (1.9)	1.9	0.30 (0.01, 7.32)	0.4636	-1.91 (-13.06, 9.24)	0.7370	
>=10 mg/day	2/ 70 (2.9)	2.9	6/ 73 (8.2)	8.4	0.35 (0.07, 1.66)	0.1861	-5.52 (-16.17, 5.13)	0.3097	
Result of type I IFN gene signature test									NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-15.17, 15.17)	1.0000	
HIGH	2/105 (1.9)	2.0	7/101 (6.9)	6.8	0.27 (0.06, 1.29)	0.1019	-4.82 (-13.19, 3.55)	0.2592	
Age (years)									NE
<= 65	2/122 (1.6)	1.7	7/123 (5.7)	5.8	0.29 (0.06, 1.36)	0.1159	-4.06 (-11.65, 3.52)	0.2941	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE		0.00 (-74.81, 74.81)	1.0000	
Sex									0.9299
male	1/ 12 (8.3)	8.3	3/ 8 (37.5)	37.5	0.22 (0.03, 1.78)	0.1562	-29.17 (-69.85, 11.51)	0.1599	
female	1/115 (0.9)	0.9	4/117 (3.4)	3.3	0.25 (0.03, 2.24)	0.2176	-2.42 (-9.84, 4.99)	0.5218	
Race									0.8037
White	1/ 85 (1.2)	1.3	4/ 96 (4.2)	3.7	0.28 (0.03, 2.48)	0.2538	-2.39 (-11.53, 6.74)	0.6078	
Black or African American	1/ 22 (4.5)	4.5	1/ 14 (7.1)	7.1	0.64 (0.04, 9.37)	0.7419	-2.60 (-26.25, 21.05)	0.8296	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 13 (0.0)	0.0	2/ 11 (18.2)	18.2	0.17 (0.01, 3.23)	0.2392	-18.18 (-49.64, 13.28)	0.2573	
Ethnicity									0.5396
Hispanic/Latino	1/ 23 (4.3)	4.3	2/ 24 (8.3)	8.3	0.52 (0.05, 5.37)	0.5844	-3.99 (-22.98, 15.01)	0.6810	
Non-hispanic/Latino	1/104 (1.0)	1.1	5/101 (5.0)	4.9	0.19 (0.02, 1.63)	0.1315	-3.85 (-12.31, 4.62)	0.3731	
Geographic region									0.8303
EU	0/ 47 (0.0)	0.0	2/ 56 (3.6)	3.6	0.24 (0.01, 4.83)	0.3495	-3.57 (-12.14, 5.00)	0.4142	
non-EU	2/ 80 (2.5)	2.4	5/ 69 (7.2)	7.3	0.35 (0.07, 1.72)	0.1946	-4.89 (-15.09, 5.31)	0.3475	
Onset of disease									0.9503
Paediatric	0/ 8 (0.0)	0.0	1/ 7 (14.3)	14.3	0.30 (0.01, 6.29)	0.4353	-14.29 (-56.18, 27.61)	0.5040	
Adult	2/119 (1.7)	1.8	6/118 (5.1)	5.0	0.33 (0.07, 1.60)	0.1696	-3.24 (-10.89, 4.41)	0.4062	
ADA result									0.6265
Negative	2/111 (1.8)	2.0	5/112 (4.5)	4.5	0.40 (0.08, 2.04)	0.2719	-2.52 (-10.53, 5.49)	0.5377	
Positive (At any time)	0/ 15 (0.0)	0.0	2/ 13 (15.4)	15.4	0.17 (0.01, 3.34)	0.2469	-15.38 (-43.19, 12.42)	0.2781	
BMI (kg/m2) at enrolment									0.7874
< 30	2/ 74 (2.7)	2.7	6/ 87 (6.9)	6.9	0.39 (0.08, 1.88)	0.2422	-4.18 (-13.74, 5.38)	0.3914	
>= 30	0/ 53 (0.0)	0.0	1/ 38 (2.6)	2.5	0.24 (0.01, 5.75)	0.3792	-2.50 (-15.87, 10.88)	0.7144	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Modified SELENA Flare Index based flares - mild/moderate or severe flare
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
at least once during study	Number of subjects with events, n (%)	36 (28.3)	42 (33.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.86 (0.59, 1.25)	
	p-value	0.4170	
	Odds Ratio (95% CI)	0.80 (0.47, 1.37)	
	p-value	0.4154	
	Risk Difference (95% CI)	-4.81 (-16.38, 6.75)	
	p-value	0.4148	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.84 (0.58, 1.22)	
	p-value	0.3683	
	Odds Ratio (95% CI)	0.78 (0.46, 1.34)	
	p-value	0.3675	
	Risk Difference (95% CI)	-5.25 (-16.66, 6.15)	
	p-value	0.3665	
	CMH approach		
	Response rate	28.5	33.6
	Difference in response rates (95% CI)	-5.03 (-16.61, 6.56)	
	p-value	0.3951	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Modified SELENA Flare Index based flares - mild/moderate or severe flare - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.3264
< 10 points	12/ 39 (30.8)	30.8	10/ 37 (27.0)	27.0	1.14 (0.56, 2.31)	0.7198	3.74 (-17.02, 24.51)	0.7239	
>= 10 points	24/ 88 (27.3)	27.3	32/ 88 (36.4)	36.2	0.75 (0.48, 1.16)	0.1991	-8.91 (-22.79, 4.98)	0.2086	
OCS dose at baseline									0.2642
<10 mg/day	16/ 57 (28.1)	28.0	13/ 52 (25.0)	24.9	1.12 (0.60, 2.10)	0.7177	3.06 (-14.00, 20.13)	0.7250	
>=10 mg/day	20/ 70 (28.6)	28.9	29/ 73 (39.7)	39.6	0.72 (0.45, 1.15)	0.1655	-10.69 (-26.44, 5.06)	0.1833	
Result of type I IFN gene signature test									0.3097
LOW	8/ 22 (36.4)	36.4	7/ 24 (29.2)	29.2	1.25 (0.54, 2.87)	0.6039	7.20 (-20.41, 34.81)	0.6094	
HIGH	28/105 (26.7)	26.8	35/101 (34.7)	34.6	0.77 (0.51, 1.17)	0.2161	-7.76 (-20.52, 5.00)	0.2332	
Age (years)									0.6961
<= 65	35/122 (28.7)	28.9	42/123 (34.1)	34.2	0.84 (0.58, 1.22)	0.3590	-5.29 (-17.09, 6.51)	0.3795	
> 65	1/ 5 (20.0)	20.0	0/ 2 (0.0)	0.0	1.50 (0.08, 26.86)	0.7830	20.00 (-57.30, 97.30)	0.6121	
Sex									0.1872
male	2/ 12 (16.7)	16.7	4/ 8 (50.0)	50.0	0.33 (0.08, 1.41)	0.1355	-33.33 (-75.77, 9.10)	0.1237	
female	34/115 (29.6)	29.8	38/117 (32.5)	32.3	0.91 (0.62, 1.34)	0.6319	-2.55 (-14.65, 9.54)	0.6788	
Race									0.4030
White	22/ 85 (25.9)	25.8	31/ 96 (32.3)	31.7	0.80 (0.51, 1.27)	0.3478	-5.88 (-19.51, 7.74)	0.3974	
Black or African American	10/ 22 (45.5)	45.5	5/ 14 (35.7)	35.7	1.27 (0.55, 2.94)	0.5730	9.74 (-23.21, 42.70)	0.5624	
Asian	3/ 7 (42.9)	42.9	2/ 3 (66.7)	66.7	0.64 (0.20, 2.07)	0.4597	-23.81 (-90.87, 43.25)	0.4865	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	1/ 13 (7.7)	7.7	4/ 11 (36.4)	36.4	0.21 (0.03, 1.63)	0.1354	-28.67 (-64.27, 6.93)	0.1145	
Ethnicity									0.3298
Hispanic/Latino	4/ 23 (17.4)	17.4	8/ 24 (33.3)	33.3	0.52 (0.18, 1.50)	0.2269	-15.94 (-41.56, 9.67)	0.2225	
Non-hispanic/Latino	32/104 (30.8)	31.3	34/101 (33.7)	33.9	0.91 (0.61, 1.36)	0.6576	-2.53 (-15.61, 10.56)	0.7051	
Geographic region									0.3860
EU	7/ 47 (14.9)	14.9	14/ 56 (25.0)	25.0	0.60 (0.26, 1.35)	0.2159	-10.11 (-26.01, 5.80)	0.2129	
non-EU	29/ 80 (36.3)	36.1	28/ 69 (40.6)	41.0	0.89 (0.59, 1.34)	0.5873	-4.93 (-20.47, 10.60)	0.5336	
Onset of disease									0.5455
Paediatric	4/ 8 (50.0)	50.0	3/ 7 (42.9)	42.9	1.17 (0.39, 3.51)	0.7837	7.14 (-43.46, 57.75)	0.7821	
Adult	32/119 (26.9)	26.8	39/118 (33.1)	32.9	0.81 (0.55, 1.20)	0.3025	-6.12 (-17.92, 5.68)	0.3093	
ADA result									0.0610
Negative	34/111 (30.6)	30.9	35/112 (31.3)	31.0	0.98 (0.66, 1.45)	0.9203	-0.17 (-12.53, 12.19)	0.9785	
Positive (At any time)	2/ 15 (13.3)	13.3	7/ 13 (53.8)	53.8	0.25 (0.06, 0.99)	0.0482	-40.51 (-74.60, -6.43)	0.0198	
BMI (kg/m2) at enrolment									0.1023
< 30	15/ 74 (20.3)	20.4	29/ 87 (33.3)	33.1	0.61 (0.35, 1.04)	0.0715	-12.76 (-26.82, 1.30)	0.0753	
>= 30	21/ 53 (39.6)	39.8	13/ 38 (34.2)	34.6	1.16 (0.67, 2.01)	0.6021	5.23 (-14.90, 25.37)	0.6106	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score Improvement >=15% (of maxmimum value =40)
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
at least once during study	Number of subjects with events, n (%)	107 (84.3)	97 (77.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.09 (0.97, 1.23)	
	p-value	0.1660	
	Odds Ratio (95% CI)	1.58 (0.83, 3.02)	
	p-value	0.1675	
	Risk Difference (95% CI)	6.82 (-2.79, 16.43)	
	p-value	0.1644	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.09 (0.96, 1.22)	
	p-value	0.1811	
	Odds Ratio (95% CI)	1.54 (0.82, 2.92)	
	p-value	0.1806	
	Risk Difference (95% CI)	6.65 (-3.02, 16.32)	
	p-value	0.1777	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score Improvement >=15% (of maxmimum value =40) at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 52	Number of subjects with events, n (%)	75 (59.1)	58 (46.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.28 (1.02, 1.61)	
	p-value	0.0342	
	Odds Ratio (95% CI)	1.73 (1.04, 2.88)	
	p-value	0.0360	
	Risk Difference (95% CI)	13.21 (1.07, 25.36)	
	p-value	0.0329	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.27 (1.00, 1.61)	
	p-value	0.0467	
	Odds Ratio (95% CI)	1.67 (1.01, 2.74)	
	p-value	0.0448	
	Risk Difference (95% CI)	12.66 (0.43, 24.88)	
	p-value	0.0425	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (5) response rate at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 52	Number of subjects with events, n (%)	57 (44.9)	41 (32.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.37 (1.00, 1.87)	
	p-value	0.0512	
	Odds Ratio (95% CI)	1.66 (1.00, 2.76)	
	p-value	0.0523	
	Risk Difference (95% CI)	12.20 (0.04, 24.35)	
	p-value	0.0492	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.37 (1.00, 1.88)	
	p-value	0.0521	
	Odds Ratio (95% CI)	1.67 (1.00, 2.78)	
	p-value	0.0499	
	Risk Difference (95% CI)	12.08 (0.14, 24.02)	
	p-value	0.0473	
	CMH approach		
	Response rate	44.8	33.0
	Difference in response rates (95% CI)	11.83 (-0.15, 23.81)	
	p-value	0.0530	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (6) response rate at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 52	Number of subjects with events, n (%)	55 (43.3)	41 (32.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.32 (0.96, 1.82)	
	p-value	0.0847	
	Odds Ratio (95% CI)	1.56 (0.94, 2.59)	
	p-value	0.0872	
	Risk Difference (95% CI)	10.73 (-1.43, 22.89)	
	p-value	0.0838	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.32 (0.96, 1.82)	
	p-value	0.0890	
	Odds Ratio (95% CI)	1.57 (0.94, 2.61)	
	p-value	0.0867	
	Risk Difference (95% CI)	10.51 (-1.41, 22.42)	
	p-value	0.0840	
	CMH approach		
	Response rate	43.3	33.0
	Difference in response rates (95% CI)	10.37 (-1.60, 22.35)	
	p-value	0.0896	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (7) response rate at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=122)	Placebo (N=121)
Week 52	Number of subjects with events, n (%)	38 (31.1)	19 (15.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.95 (1.20, 3.16)	
	p-value	0.0068	
	Odds Ratio (95% CI)	2.35 (1.27, 4.34)	
	p-value	0.0064	
	Risk Difference (95% CI)	15.40 (4.69, 26.11)	
	p-value	0.0048	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.98 (1.22, 3.24)	
	p-value	0.0061	
	Odds Ratio (95% CI)	2.43 (1.30, 4.52)	
	p-value	0.0052	
	Risk Difference (95% CI)	15.45 (4.98, 25.91)	
	p-value	0.0038	
	CMH approach		
	Response rate	31.2	15.8
	Difference in response rates (95% CI)	15.36 (4.34, 26.38)	
	p-value	0.0063	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate sensitivity analysis using modified BILAG at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 52	Number of subjects with events, n (%)	67 (52.8)	45 (36.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.47 (1.11, 1.94)	
	p-value	0.0072	
	Odds Ratio (95% CI)	2.01 (1.21, 3.36)	
	p-value	0.0073	
	Risk Difference (95% CI)	17.01 (4.89, 29.13)	
	p-value	0.0059	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.47 (1.10, 1.95)	
	p-value	0.0088	
	Odds Ratio (95% CI)	1.99 (1.20, 3.29)	
	p-value	0.0077	
	Risk Difference (95% CI)	16.76 (4.66, 28.85)	
	p-value	0.0066	
	CMH approach		
	Response rate	52.5	36.4
	Difference in response rates (95% CI)	16.11 (4.13, 28.09)	
	p-value	0.0084	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate sensitivity analysis excluding subjects with no BILAG A or B or PGA VAS score >2.7 at baseline at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=126)	Placebo (N=124)
Week 52	Number of subjects with events, n (%)	63 (50.0)	41 (33.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.52 (1.13, 2.05)	
	p-value	0.0060	
	Odds Ratio (95% CI)	2.06 (1.23, 3.45)	
	p-value	0.0060	
	Risk Difference (95% CI)	17.40 (5.30, 29.50)	
	p-value	0.0048	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.51 (1.11, 2.05)	
	p-value	0.0079	
	Odds Ratio (95% CI)	2.02 (1.21, 3.38)	
	p-value	0.0069	
	Risk Difference (95% CI)	16.94 (4.90, 28.97)	
	p-value	0.0058	
	CMH approach		
	Response rate	49.8	33.4
	Difference in response rates (95% CI)	16.36 (4.37, 28.35)	
	p-value	0.0075	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate sensitivity analysis excluding criterion of no restricted medications at week 52
Full analysis set

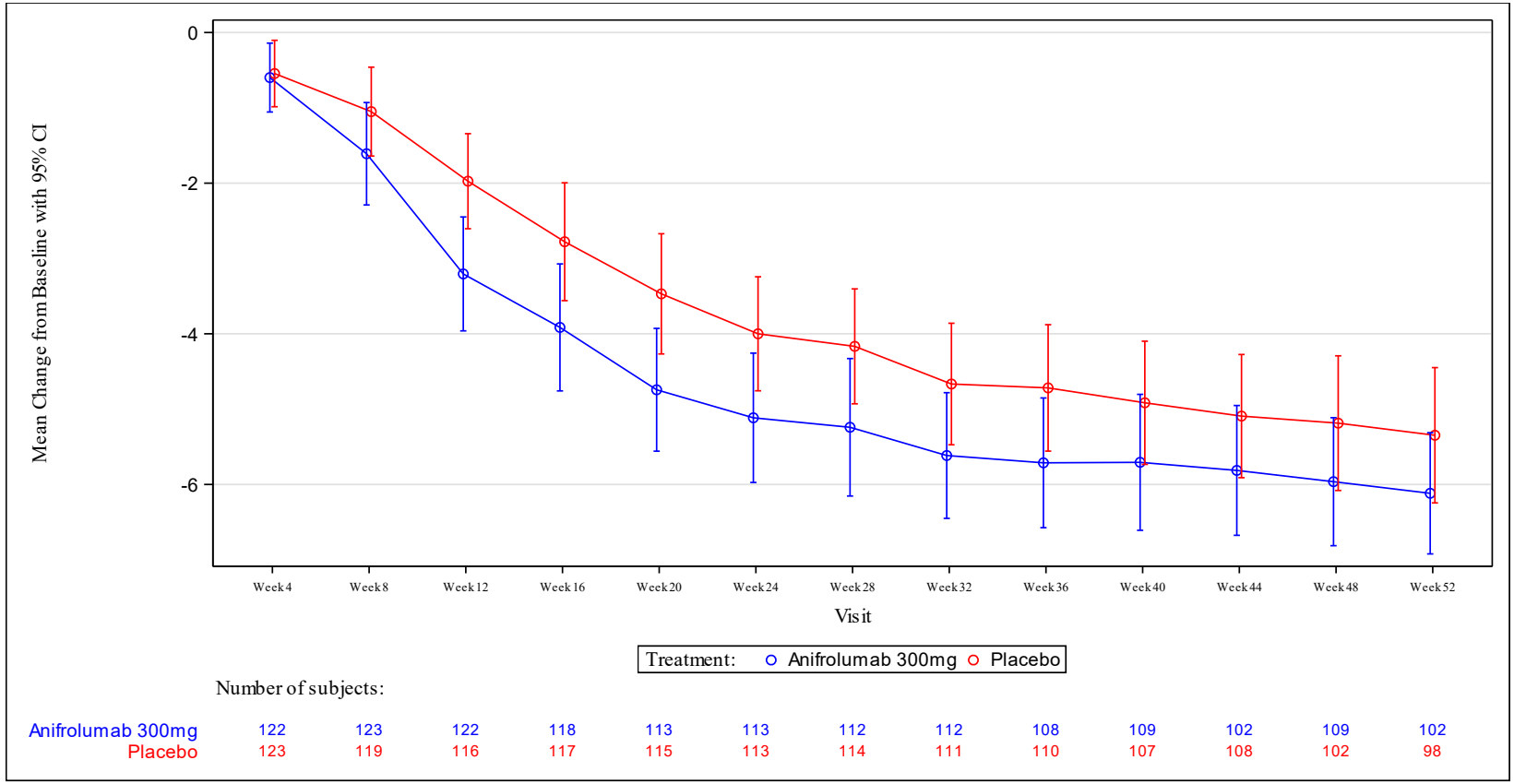
Timepoint		Anifrolumab 300mg (N=127)	Placebo (N=125)
Week 52	Number of subjects with events, n (%)	73 (57.5)	54 (43.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.33 (1.04, 1.69)	
	p-value	0.0245	
	Odds Ratio (95% CI)	1.75 (1.07, 2.88)	
	p-value	0.0260	
	Risk Difference (95% CI)	14.39 (1.91, 26.87)	
	p-value	0.0238	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.33 (1.04, 1.71)	
	p-value	0.0255	
	Odds Ratio (95% CI)	1.78 (1.08, 2.93)	
	p-value	0.0239	
	Risk Difference (95% CI)	14.28 (2.06, 26.50)	
	p-value	0.0220	
	CMH approach		
	Response rate	57.3	43.7
	Difference in response rates (95% CI)	13.60 (1.48, 25.71)	
	p-value	0.0278	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - SLEDAI-2K Total Score
Full analysis set

	Anifrolumab 300mg (N=127)				Placebo (N=125)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	127	11.28 (3.84)	0	-	125	11.35 (3.49)	0	-
Week 4	122	10.73 (3.45)	122	-0.60 (2.55)	123	10.71 (3.48)	123	-0.54 (2.47)
Week 8	123	9.72 (4.18)	123	-1.61 (3.81)	119	10.24 (3.90)	119	-1.05 (3.25)
Week 12	122	8.11 (4.09)	122	-3.20 (4.22)	116	9.25 (4.09)	116	-1.97 (3.43)
Week 16	118	7.47 (4.52)	118	-3.92 (4.62)	117	8.49 (4.65)	117	-2.78 (4.27)
Week 20	113	6.35 (4.06)	113	-4.74 (4.37)	115	7.76 (4.29)	115	-3.47 (4.32)
Week 24	113	6.35 (4.30)	113	-5.12 (4.61)	113	7.22 (3.90)	113	-4.00 (4.06)
Week 28	112	6.23 (4.76)	112	-5.24 (4.87)	114	7.13 (4.03)	114	-4.17 (4.11)
Week 32	112	5.78 (4.21)	112	-5.62 (4.46)	111	6.67 (4.04)	111	-4.67 (4.29)
Week 36	108	5.73 (4.47)	108	-5.71 (4.51)	110	6.53 (3.96)	110	-4.72 (4.44)
Week 40	109	5.70 (4.40)	109	-5.71 (4.75)	107	6.16 (4.18)	107	-4.92 (4.27)
Week 44	102	5.50 (4.47)	102	-5.81 (4.39)	108	6.10 (4.25)	108	-5.09 (4.29)
Week 48	109	5.47 (4.16)	109	-5.96 (4.48)	102	5.97 (4.12)	102	-5.19 (4.55)
Week 52	102	5.35 (3.79)	102	-6.12 (4.10)	98	5.73 (4.01)	98	-5.35 (4.48)

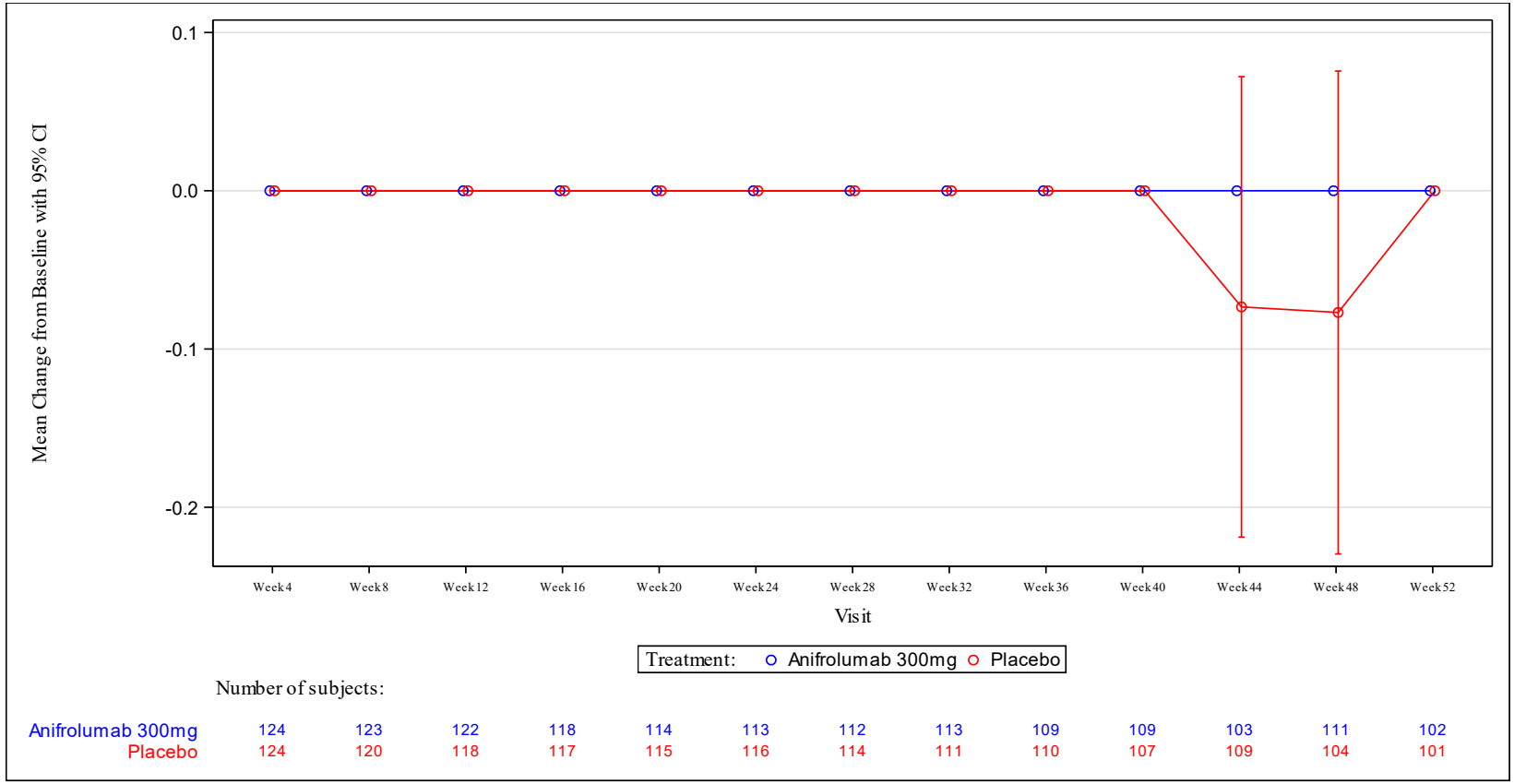
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - SLEDAI-2K Total Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score CNS
Full analysis set

	Anifrolumab 300mg (N=127)				Placebo (N=125)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	127	0.06 (0.71)	0	-	125	0.06 (0.72)	0	-
Week 4	124	0.06 (0.72)	124	0.00 (0.00)	124	0.06 (0.72)	124	0.00 (0.00)
Week 8	123	0.07 (0.72)	123	0.00 (0.00)	120	0.07 (0.73)	120	0.00 (0.00)
Week 12	122	0.07 (0.72)	122	0.00 (0.00)	118	0.07 (0.74)	118	0.00 (0.00)
Week 16	118	0.07 (0.74)	118	0.00 (0.00)	117	0.07 (0.74)	117	0.00 (0.00)
Week 20	114	0.07 (0.75)	114	0.00 (0.00)	115	0.07 (0.75)	115	0.00 (0.00)
Week 24	113	0.07 (0.75)	113	0.00 (0.00)	116	0.07 (0.74)	116	0.00 (0.00)
Week 28	112	0.07 (0.76)	112	0.00 (0.00)	114	0.07 (0.75)	114	0.00 (0.00)
Week 32	113	0.07 (0.75)	113	0.00 (0.00)	111	0.00 (0.00)	111	0.00 (0.00)
Week 36	109	0.07 (0.77)	109	0.00 (0.00)	110	0.07 (0.76)	110	0.00 (0.00)
Week 40	109	0.00 (0.00)	109	0.00 (0.00)	107	0.07 (0.77)	107	0.00 (0.00)
Week 44	103	0.08 (0.79)	103	0.00 (0.00)	109	0.00 (0.00)	109	-0.07 (0.77)
Week 48	111	0.07 (0.76)	111	0.00 (0.00)	104	0.00 (0.00)	104	-0.08 (0.78)
Week 52	102	0.08 (0.79)	102	0.00 (0.00)	101	0.00 (0.00)	101	0.00 (0.00)

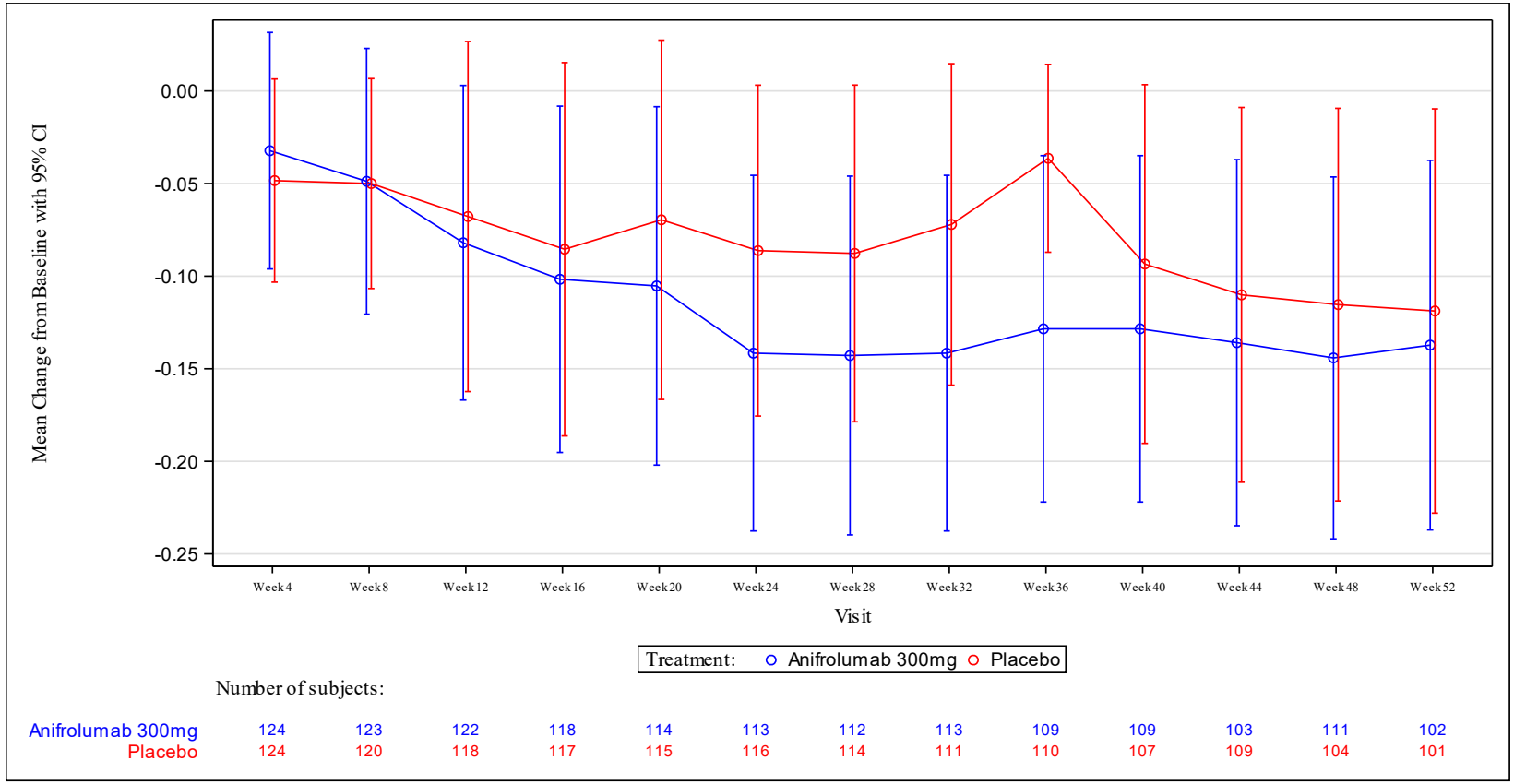
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Total Organ Score CNS
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score CVS and Respiratory
Full analysis set

	Anifrolumab 300mg (N=127)				Placebo (N=125)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	127	0.16 (0.54)	0	-	125	0.13 (0.55)	0	-
Week 4	124	0.13 (0.49)	124	-0.03 (0.36)	124	0.08 (0.40)	124	-0.05 (0.31)
Week 8	123	0.11 (0.47)	123	-0.05 (0.40)	120	0.05 (0.31)	120	-0.05 (0.31)
Week 12	122	0.08 (0.40)	122	-0.08 (0.47)	118	0.05 (0.32)	118	-0.07 (0.52)
Week 16	118	0.07 (0.36)	118	-0.10 (0.51)	117	0.02 (0.18)	117	-0.09 (0.55)
Week 20	114	0.05 (0.32)	114	-0.11 (0.52)	115	0.03 (0.26)	115	-0.07 (0.53)
Week 24	113	0.04 (0.26)	113	-0.14 (0.52)	116	0.02 (0.19)	116	-0.09 (0.49)
Week 28	112	0.04 (0.27)	112	-0.14 (0.52)	114	0.02 (0.19)	114	-0.09 (0.49)
Week 32	113	0.04 (0.26)	113	-0.14 (0.52)	111	0.04 (0.27)	111	-0.07 (0.46)
Week 36	109	0.06 (0.33)	109	-0.13 (0.49)	110	0.02 (0.19)	110	-0.04 (0.27)
Week 40	109	0.06 (0.33)	109	-0.13 (0.49)	107	0.00 (0.00)	107	-0.09 (0.51)
Week 44	103	0.04 (0.28)	103	-0.14 (0.51)	109	0.00 (0.00)	109	-0.11 (0.53)
Week 48	111	0.04 (0.27)	111	-0.14 (0.52)	104	0.00 (0.00)	104	-0.12 (0.55)
Week 52	102	0.04 (0.28)	102	-0.14 (0.51)	101	0.00 (0.00)	101	-0.12 (0.55)

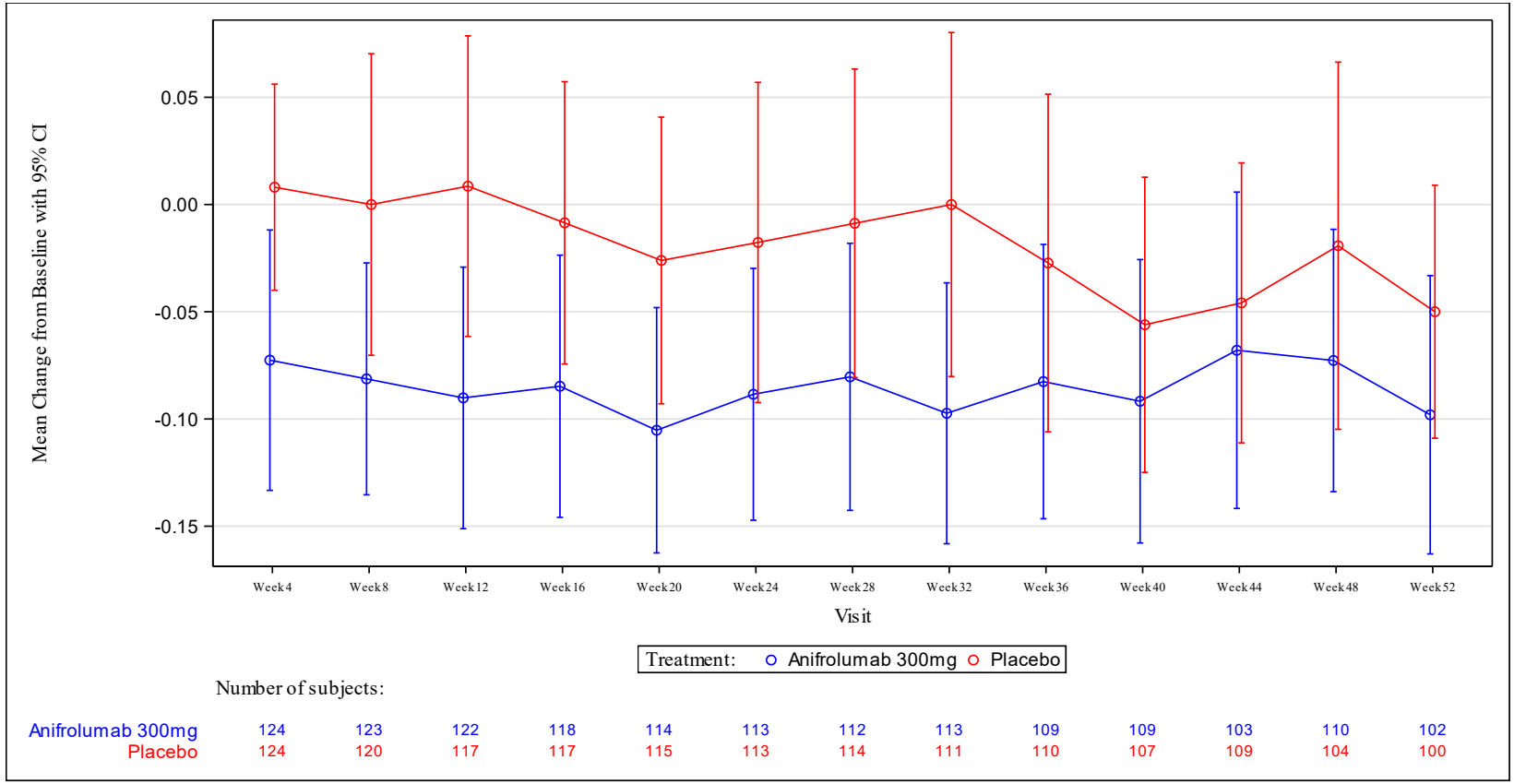
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Total Organ Score CVS and Respiratory
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score Hematological
Full analysis set

	Anifrolumab 300mg (N=127)				Placebo (N=125)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	127	0.13 (0.33)	0	-	125	0.10 (0.33)	0	-
Week 4	124	0.06 (0.23)	124	-0.07 (0.34)	124	0.11 (0.34)	124	0.01 (0.27)
Week 8	123	0.04 (0.20)	123	-0.08 (0.30)	120	0.09 (0.29)	120	0.00 (0.39)
Week 12	122	0.03 (0.18)	122	-0.09 (0.34)	117	0.11 (0.34)	117	0.01 (0.38)
Week 16	118	0.03 (0.18)	118	-0.08 (0.34)	117	0.09 (0.29)	117	-0.01 (0.36)
Week 20	114	0.03 (0.16)	114	-0.11 (0.31)	115	0.07 (0.29)	115	-0.03 (0.36)
Week 24	113	0.04 (0.19)	113	-0.09 (0.32)	113	0.07 (0.29)	113	-0.02 (0.40)
Week 28	112	0.04 (0.19)	112	-0.08 (0.33)	114	0.10 (0.30)	114	-0.01 (0.39)
Week 32	113	0.03 (0.16)	113	-0.10 (0.33)	111	0.09 (0.32)	111	0.00 (0.43)
Week 36	109	0.03 (0.16)	109	-0.08 (0.34)	110	0.07 (0.29)	110	-0.03 (0.42)
Week 40	109	0.03 (0.16)	109	-0.09 (0.35)	107	0.05 (0.21)	107	-0.06 (0.36)
Week 44	103	0.05 (0.22)	103	-0.07 (0.38)	109	0.06 (0.25)	109	-0.05 (0.34)
Week 48	110	0.04 (0.19)	110	-0.07 (0.32)	104	0.07 (0.35)	104	-0.02 (0.44)
Week 52	102	0.02 (0.14)	102	-0.10 (0.33)	100	0.04 (0.20)	100	-0.05 (0.30)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Total Organ Score Hematological
Full analysis set



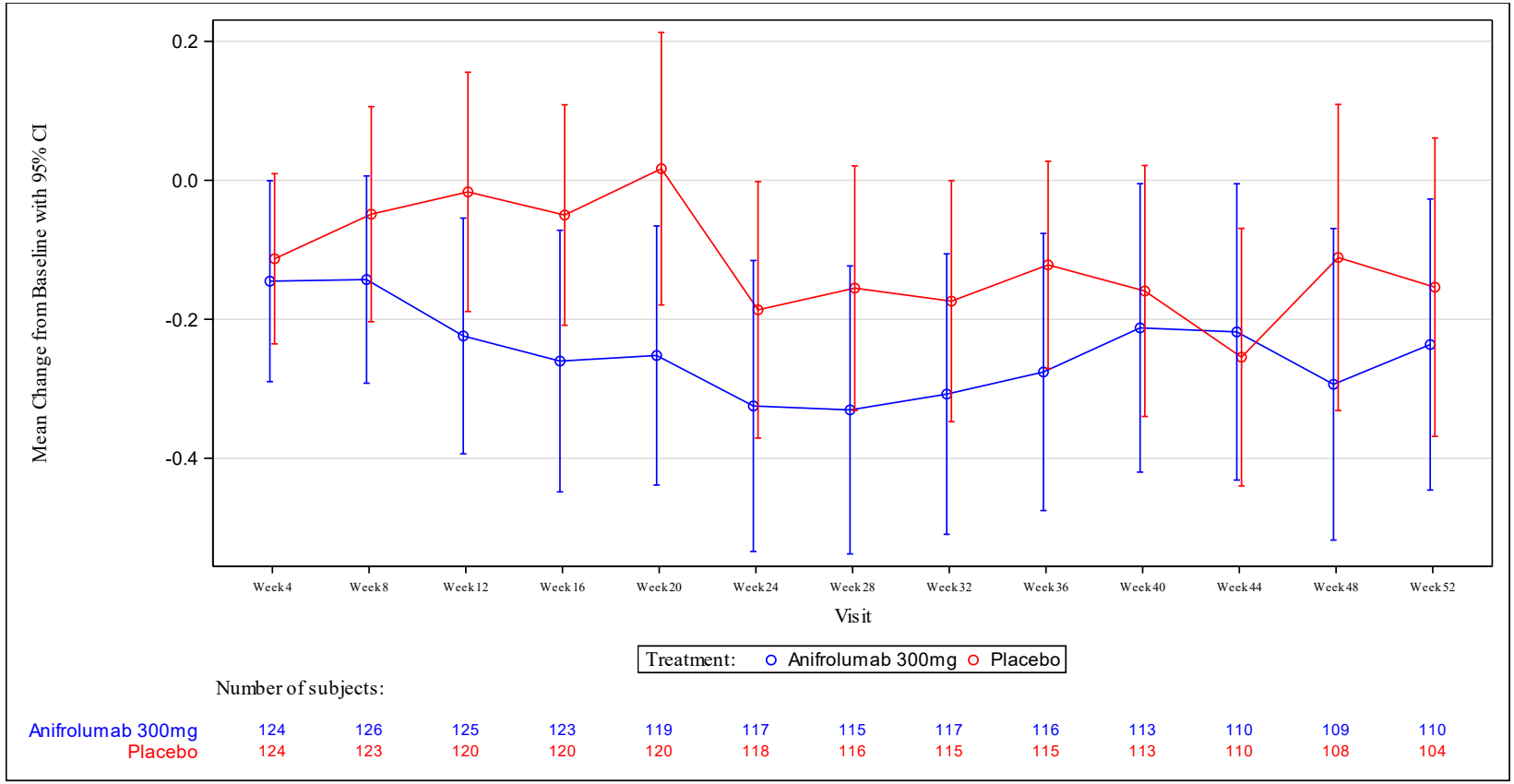
Number of subjects:

	Week 4	Week 8	Week 12	Week 16	Week 20	Week 24	Week 28	Week 32	Week 36	Week 40	Week 44	Week 48	Week 52
Anifrolumab 300mg	124	123	122	118	114	113	112	113	109	109	103	110	102
Placebo	124	120	117	117	115	113	114	111	110	107	109	104	100

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score Immunology
Full analysis set

	Anifrolumab 300mg (N=127)				Placebo (N=125)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	127	1.86 (1.64)	0	-	125	1.94 (1.64)	0	-
Week 4	124	1.73 (1.64)	124	-0.15 (0.81)	124	1.81 (1.58)	124	-0.11 (0.69)
Week 8	126	1.71 (1.59)	126	-0.14 (0.85)	123	1.89 (1.61)	123	-0.05 (0.87)
Week 12	125	1.63 (1.57)	125	-0.22 (0.96)	120	1.83 (1.52)	120	-0.02 (0.95)
Week 16	123	1.59 (1.68)	123	-0.26 (1.05)	120	1.83 (1.61)	120	-0.05 (0.88)
Week 20	119	1.61 (1.59)	119	-0.25 (1.03)	120	1.90 (1.66)	120	0.02 (1.08)
Week 24	117	1.54 (1.61)	117	-0.32 (1.14)	118	1.71 (1.60)	118	-0.19 (1.01)
Week 28	115	1.51 (1.60)	115	-0.33 (1.12)	116	1.76 (1.67)	116	-0.16 (0.96)
Week 32	117	1.52 (1.65)	117	-0.31 (1.10)	115	1.72 (1.56)	115	-0.17 (0.94)
Week 36	116	1.57 (1.56)	116	-0.28 (1.08)	115	1.77 (1.63)	115	-0.12 (0.81)
Week 40	113	1.66 (1.69)	113	-0.21 (1.11)	113	1.72 (1.60)	113	-0.16 (0.97)
Week 44	110	1.69 (1.63)	110	-0.22 (1.13)	110	1.62 (1.59)	110	-0.25 (0.98)
Week 48	109	1.63 (1.59)	109	-0.29 (1.18)	108	1.76 (1.54)	108	-0.11 (1.15)
Week 52	110	1.67 (1.66)	110	-0.24 (1.11)	104	1.75 (1.57)	104	-0.15 (1.10)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Total Organ Score Immunology
Full analysis set



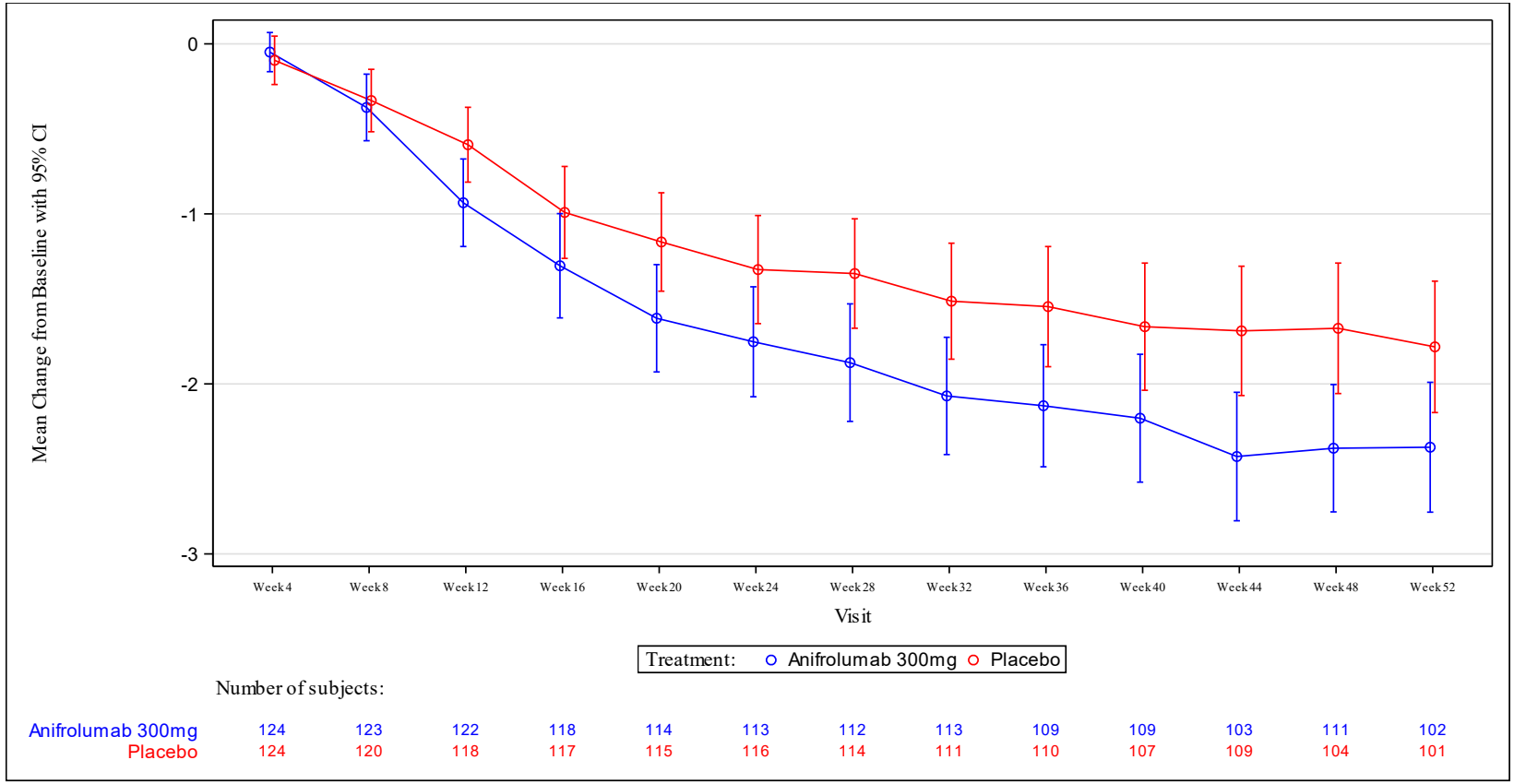
Number of subjects:

	Week 4	Week 8	Week 12	Week 16	Week 20	Week 24	Week 28	Week 32	Week 36	Week 40	Week 44	Week 48	Week 52
Anifrolumab 300mg	124	126	125	123	119	117	115	117	116	113	110	109	110
Placebo	124	123	120	120	120	118	116	115	115	113	110	108	104

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score Mucocutaneous
Full analysis set

	Anifrolumab 300mg (N=127)				Placebo (N=125)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	127	4.22 (1.56)	0	-	125	4.00 (1.59)	0	-
Week 4	124	4.23 (1.53)	124	-0.05 (0.65)	124	3.90 (1.57)	124	-0.10 (0.80)
Week 8	123	3.90 (1.55)	123	-0.37 (1.10)	120	3.72 (1.52)	120	-0.33 (1.02)
Week 12	122	3.33 (1.74)	122	-0.93 (1.44)	118	3.37 (1.67)	118	-0.59 (1.21)
Week 16	118	3.00 (1.86)	118	-1.31 (1.68)	117	3.03 (1.71)	117	-0.99 (1.48)
Week 20	114	2.68 (1.88)	114	-1.61 (1.70)	115	2.89 (1.66)	115	-1.17 (1.57)
Week 24	113	2.58 (1.90)	113	-1.75 (1.73)	116	2.78 (1.66)	116	-1.33 (1.73)
Week 28	112	2.45 (1.93)	112	-1.88 (1.85)	114	2.72 (1.69)	114	-1.35 (1.73)
Week 32	113	2.34 (1.85)	113	-2.07 (1.85)	111	2.59 (1.68)	111	-1.51 (1.81)
Week 36	109	2.18 (1.90)	109	-2.13 (1.89)	110	2.51 (1.72)	110	-1.55 (1.87)
Week 40	109	2.06 (1.89)	109	-2.20 (1.98)	107	2.32 (1.76)	107	-1.66 (1.95)
Week 44	103	1.84 (1.79)	103	-2.43 (1.93)	109	2.33 (1.80)	109	-1.69 (2.00)
Week 48	111	1.91 (1.84)	111	-2.38 (1.99)	104	2.31 (1.71)	104	-1.67 (1.97)
Week 52	102	1.92 (1.80)	102	-2.37 (1.94)	101	2.20 (1.66)	101	-1.78 (1.96)

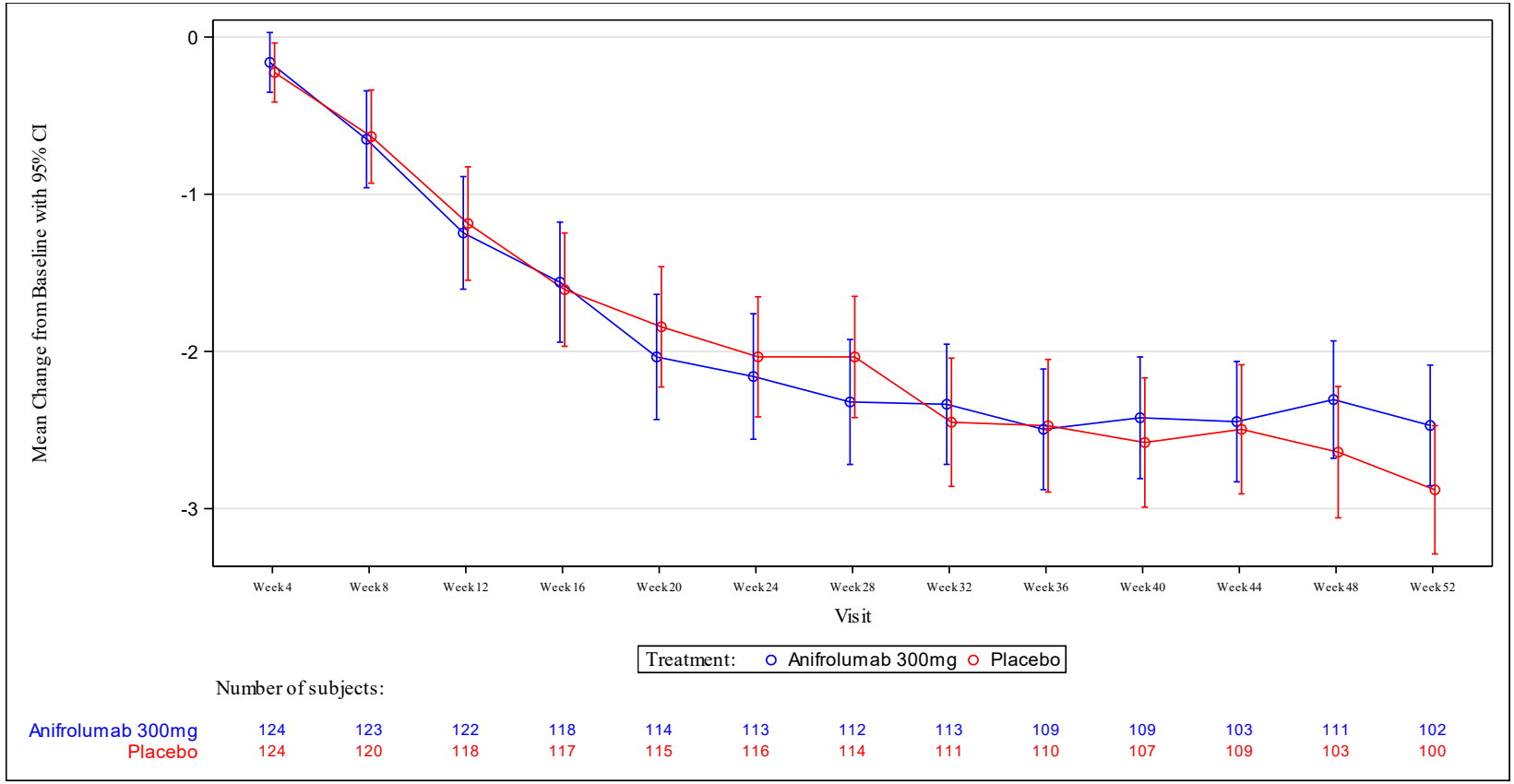
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Total Organ Score Mucocutaneous
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score Musculoskeletal
Full analysis set

	Anifrolumab 300mg (N=127)				Placebo (N=125)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	127	3.69 (1.19)	0	-	125	3.97 (0.95)	0	-
Week 4	124	3.52 (1.31)	124	-0.16 (1.07)	124	3.74 (1.22)	124	-0.23 (1.06)
Week 8	123	3.02 (1.72)	123	-0.65 (1.73)	120	3.33 (1.58)	120	-0.63 (1.64)
Week 12	122	2.46 (1.95)	122	-1.25 (2.00)	118	2.78 (1.92)	118	-1.19 (1.98)
Week 16	118	2.10 (2.07)	118	-1.56 (2.09)	117	2.39 (2.04)	117	-1.61 (1.97)
Week 20	114	1.61 (2.04)	114	-2.04 (2.14)	115	2.12 (2.07)	115	-1.84 (2.07)
Week 24	113	1.52 (2.02)	113	-2.16 (2.14)	116	1.93 (2.08)	116	-2.03 (2.08)
Week 28	112	1.39 (1.99)	112	-2.32 (2.12)	114	1.93 (2.08)	114	-2.04 (2.08)
Week 32	113	1.31 (1.89)	113	-2.34 (2.05)	111	1.51 (2.02)	111	-2.45 (2.17)
Week 36	109	1.14 (1.81)	109	-2.50 (2.02)	110	1.49 (2.09)	110	-2.47 (2.23)
Week 40	109	1.21 (1.85)	109	-2.42 (2.04)	107	1.38 (1.99)	107	-2.58 (2.15)
Week 44	103	1.13 (1.81)	103	-2.45 (1.96)	109	1.47 (2.01)	109	-2.50 (2.16)
Week 48	111	1.33 (1.89)	111	-2.31 (1.99)	103	1.32 (1.97)	103	-2.64 (2.14)
Week 52	102	1.22 (1.85)	102	-2.47 (1.95)	100	1.08 (1.87)	100	-2.88 (2.06)

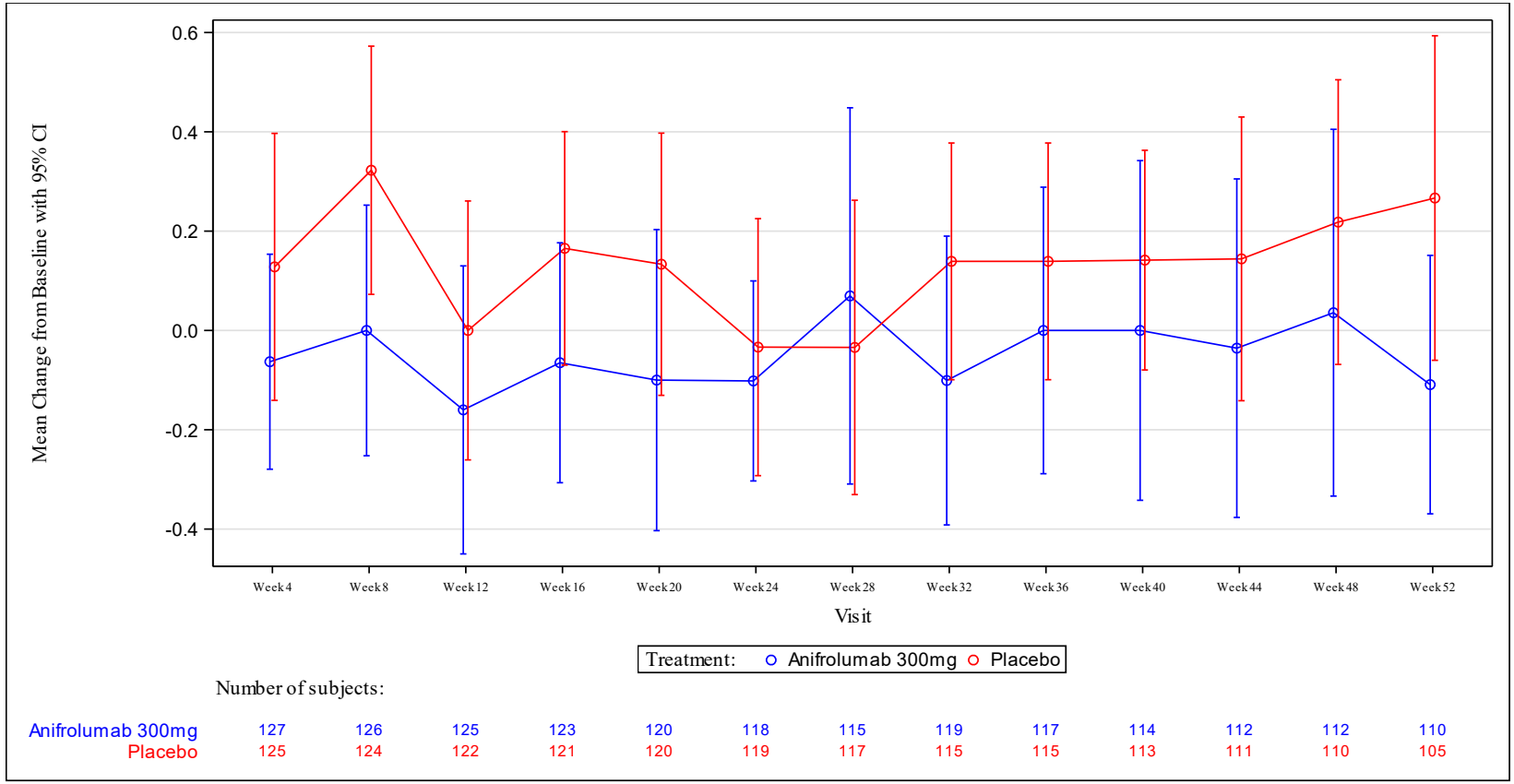
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Total Organ Score Musculoskeletal
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score Renal
Full analysis set

	Anifrolumab 300mg (N=127)				Placebo (N=125)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	127	0.41 (1.58)	0	-	125	0.45 (1.70)	0	-
Week 4	127	0.35 (1.34)	127	-0.06 (1.23)	125	0.58 (2.14)	125	0.13 (1.52)
Week 8	126	0.41 (1.59)	126	0.00 (1.43)	124	0.77 (2.37)	124	0.32 (1.41)
Week 12	125	0.26 (1.22)	125	-0.16 (1.64)	122	0.36 (1.45)	122	0.00 (1.45)
Week 16	123	0.36 (1.36)	123	-0.07 (1.35)	121	0.53 (1.93)	121	0.17 (1.31)
Week 20	120	0.30 (1.29)	120	-0.10 (1.68)	120	0.50 (1.91)	120	0.13 (1.46)
Week 24	118	0.27 (1.01)	118	-0.10 (1.10)	119	0.37 (1.38)	119	-0.03 (1.43)
Week 28	115	0.42 (1.86)	115	0.07 (2.05)	117	0.38 (1.48)	117	-0.03 (1.62)
Week 32	119	0.27 (1.25)	119	-0.10 (1.60)	115	0.45 (1.57)	115	0.14 (1.29)
Week 36	117	0.38 (1.48)	117	0.00 (1.58)	115	0.45 (1.57)	115	0.14 (1.29)
Week 40	114	0.39 (1.59)	114	0.00 (1.84)	113	0.46 (1.75)	113	0.14 (1.19)
Week 44	112	0.36 (1.57)	112	-0.04 (1.82)	111	0.47 (2.00)	111	0.14 (1.52)
Week 48	112	0.43 (1.73)	112	0.04 (1.97)	110	0.55 (2.06)	110	0.22 (1.52)
Week 52	110	0.29 (1.40)	110	-0.11 (1.38)	105	0.53 (2.01)	105	0.27 (1.69)

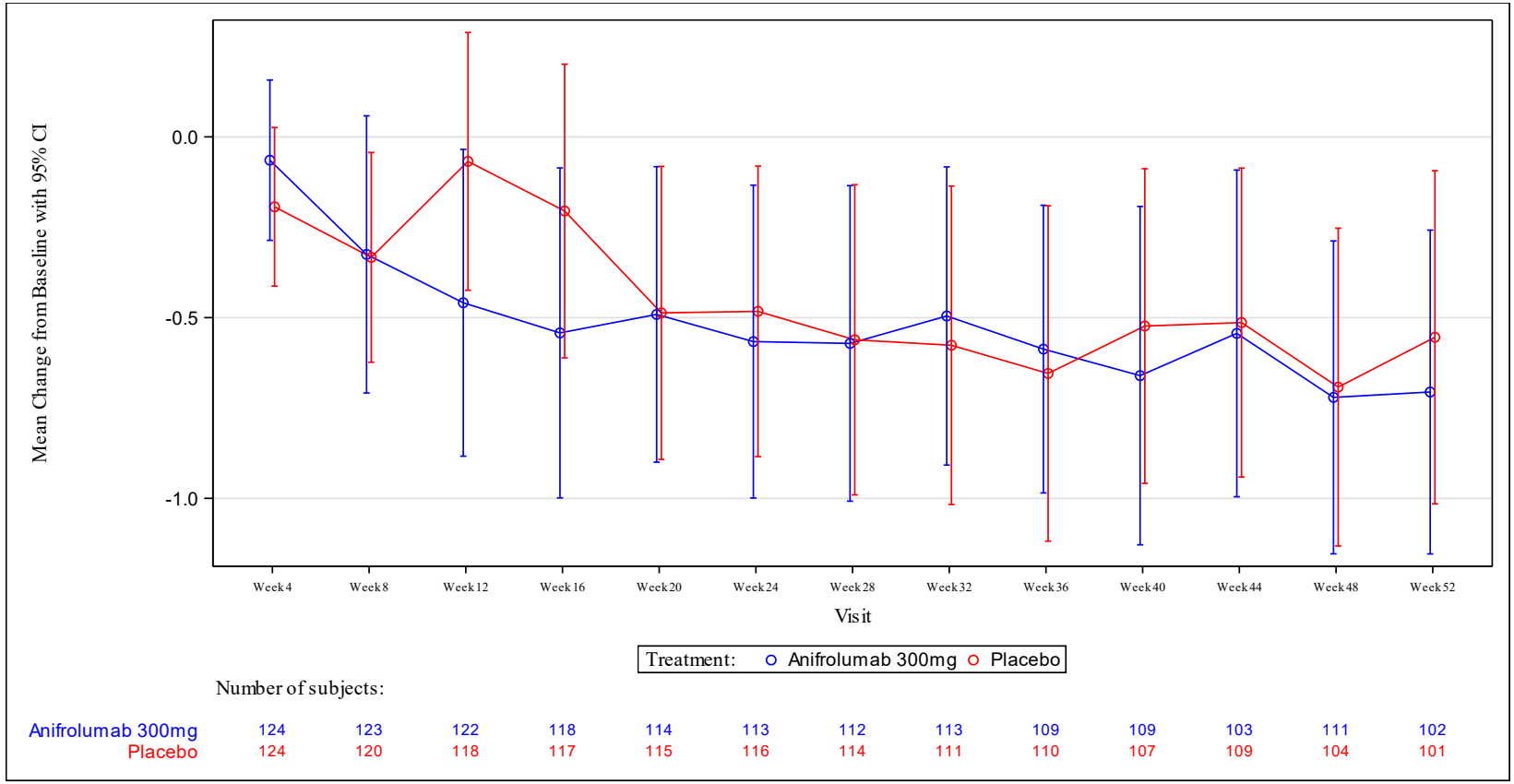
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Total Organ Score Renal
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score Vascular
Full analysis set

	Anifrolumab 300mg (N=127)				Placebo (N=125)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	127	0.76 (2.35)	0	-	125	0.70 (2.28)	0	-
Week 4	124	0.71 (2.28)	124	-0.06 (1.25)	124	0.52 (1.97)	124	-0.19 (1.23)
Week 8	123	0.46 (1.86)	123	-0.33 (2.15)	120	0.40 (1.75)	120	-0.33 (1.61)
Week 12	122	0.26 (1.43)	122	-0.46 (2.37)	118	0.61 (2.13)	118	-0.07 (1.96)
Week 16	118	0.27 (1.45)	118	-0.54 (2.50)	117	0.48 (1.91)	117	-0.21 (2.22)
Week 20	114	0.21 (1.29)	114	-0.49 (2.20)	115	0.28 (1.47)	115	-0.49 (2.19)
Week 24	113	0.28 (1.48)	113	-0.57 (2.32)	116	0.21 (1.28)	116	-0.48 (2.18)
Week 28	112	0.29 (1.49)	112	-0.57 (2.33)	114	0.21 (1.29)	114	-0.56 (2.31)
Week 32	113	0.28 (1.48)	113	-0.50 (2.21)	111	0.22 (1.30)	111	-0.58 (2.34)
Week 36	109	0.22 (1.31)	109	-0.59 (2.10)	110	0.15 (1.07)	110	-0.65 (2.45)
Week 40	109	0.22 (1.31)	109	-0.66 (2.47)	107	0.15 (1.09)	107	-0.52 (2.27)
Week 44	103	0.23 (1.35)	103	-0.54 (2.31)	109	0.15 (1.08)	109	-0.51 (2.25)
Week 48	111	0.14 (1.07)	111	-0.72 (2.30)	104	0.08 (0.78)	104	-0.69 (2.26)
Week 52	102	0.08 (0.79)	102	-0.71 (2.28)	101	0.16 (1.12)	101	-0.55 (2.33)

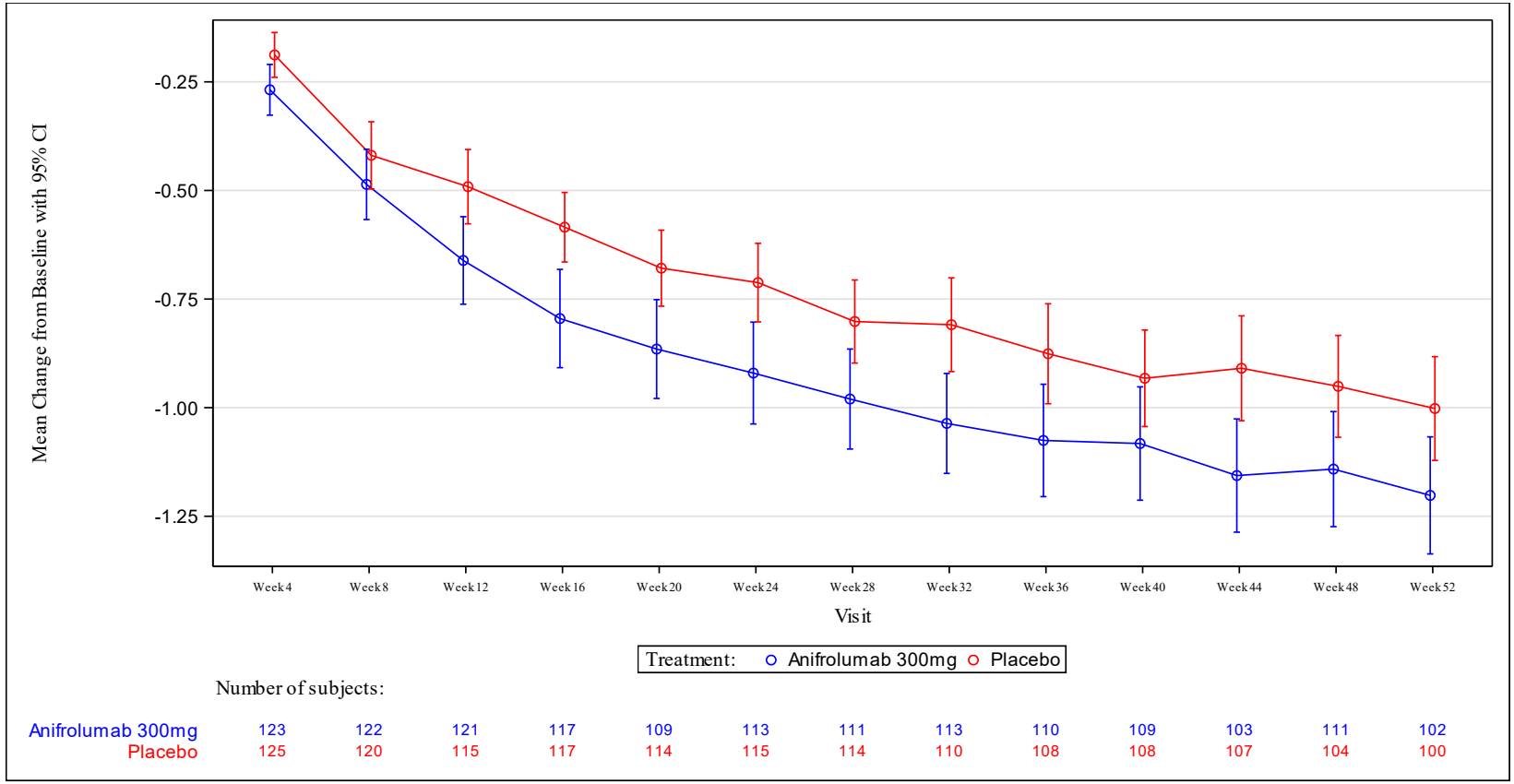
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Total Organ Score Vascular
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - PGA
Full analysis set

	Anifrolumab 300mg (N=127)				Placebo (N=125)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	127	1.88 (0.40)	0	-	125	1.84 (0.35)	0	-
Week 4	123	1.61 (0.52)	123	-0.27 (0.33)	125	1.65 (0.43)	125	-0.19 (0.29)
Week 8	122	1.39 (0.53)	122	-0.49 (0.45)	120	1.43 (0.51)	120	-0.42 (0.43)
Week 12	121	1.21 (0.56)	121	-0.66 (0.56)	115	1.36 (0.52)	115	-0.49 (0.46)
Week 16	117	1.08 (0.62)	117	-0.79 (0.62)	117	1.26 (0.49)	117	-0.58 (0.44)
Week 20	109	1.01 (0.62)	109	-0.87 (0.60)	114	1.17 (0.50)	114	-0.68 (0.47)
Week 24	113	0.95 (0.64)	113	-0.92 (0.63)	115	1.12 (0.51)	115	-0.71 (0.49)
Week 28	111	0.89 (0.63)	111	-0.98 (0.61)	114	1.04 (0.52)	114	-0.80 (0.52)
Week 32	113	0.84 (0.60)	113	-1.04 (0.62)	110	1.03 (0.57)	110	-0.81 (0.57)
Week 36	110	0.80 (0.61)	110	-1.08 (0.68)	108	0.95 (0.57)	108	-0.88 (0.60)
Week 40	109	0.80 (0.60)	109	-1.08 (0.69)	108	0.90 (0.54)	108	-0.93 (0.58)
Week 44	103	0.71 (0.56)	103	-1.16 (0.67)	107	0.95 (0.58)	107	-0.91 (0.63)
Week 48	111	0.72 (0.59)	111	-1.14 (0.70)	104	0.89 (0.57)	104	-0.95 (0.60)
Week 52	102	0.65 (0.56)	102	-1.20 (0.69)	100	0.84 (0.56)	100	-1.00 (0.60)

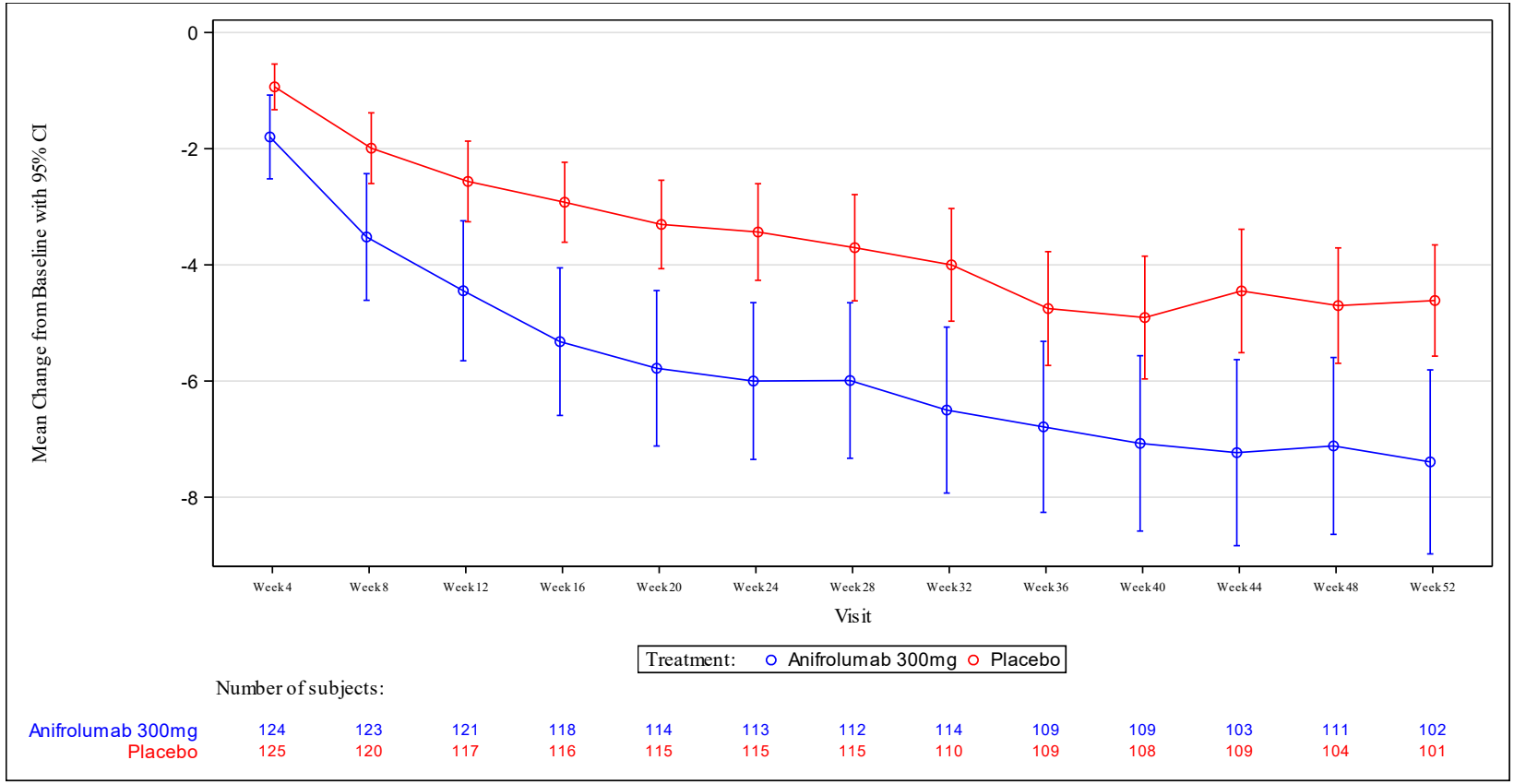
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - PGA
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - CLASI Total Activity Score
Full analysis set

	Anifrolumab 300mg (N=127)				Placebo (N=125)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	127	8.87 (7.74)	0	-	125	8.09 (6.39)	0	-
Week 4	124	7.20 (6.31)	124	-1.80 (4.06)	125	7.15 (5.92)	125	-0.94 (2.22)
Week 8	123	5.50 (4.65)	123	-3.52 (6.11)	120	6.26 (6.07)	120	-1.99 (3.37)
Week 12	121	4.50 (4.40)	121	-4.45 (6.69)	117	5.71 (5.88)	117	-2.56 (3.79)
Week 16	118	3.92 (3.93)	118	-5.32 (6.97)	116	5.07 (4.92)	116	-2.92 (3.74)
Week 20	114	3.44 (3.57)	114	-5.78 (7.21)	115	5.07 (5.63)	115	-3.30 (4.12)
Week 24	113	3.15 (3.62)	113	-6.00 (7.24)	115	4.97 (6.21)	115	-3.43 (4.50)
Week 28	112	2.89 (3.25)	112	-5.99 (7.15)	115	4.74 (5.88)	115	-3.70 (4.95)
Week 32	114	2.82 (3.30)	114	-6.50 (7.70)	110	4.46 (5.39)	110	-4.00 (5.13)
Week 36	109	2.46 (3.11)	109	-6.79 (7.75)	109	3.75 (4.22)	109	-4.75 (5.16)
Week 40	109	2.28 (2.97)	109	-7.07 (7.95)	108	3.68 (4.32)	108	-4.91 (5.54)
Week 44	103	2.17 (2.95)	103	-7.23 (8.19)	109	3.84 (5.21)	109	-4.45 (5.60)
Week 48	111	2.18 (2.77)	111	-7.12 (8.09)	104	3.63 (4.71)	104	-4.70 (5.11)
Week 52	102	2.09 (2.88)	102	-7.39 (8.06)	101	3.59 (4.92)	101	-4.61 (4.85)

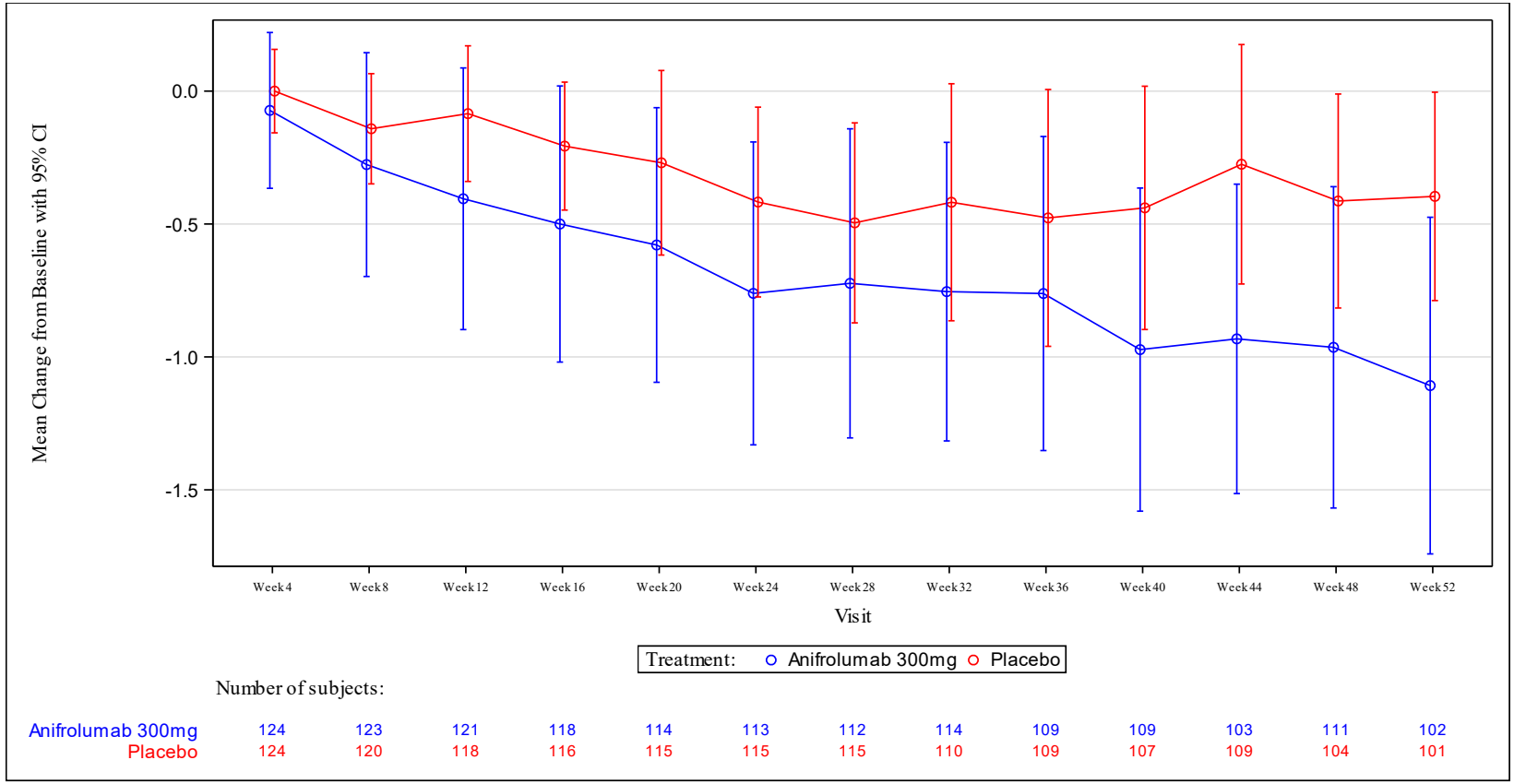
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - CLASI Total Activity Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - CLASI Total Damage Score
Full analysis set

	Anifrolumab 300mg (N=127)				Placebo (N=125)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	127	1.87 (3.68)	0	-	125	1.94 (4.62)	0	-
Week 4	124	1.83 (3.62)	124	-0.07 (1.65)	124	1.90 (4.60)	124	0.00 (0.88)
Week 8	123	1.63 (3.19)	123	-0.28 (2.36)	120	1.88 (4.56)	120	-0.14 (1.15)
Week 12	121	1.45 (3.04)	121	-0.40 (2.73)	118	1.93 (4.76)	118	-0.08 (1.40)
Week 16	118	1.49 (3.04)	118	-0.50 (2.85)	116	1.66 (4.36)	116	-0.21 (1.31)
Week 20	114	1.28 (2.36)	114	-0.58 (2.78)	115	1.77 (4.49)	115	-0.27 (1.88)
Week 24	113	1.09 (2.17)	113	-0.76 (3.06)	115	1.62 (4.02)	115	-0.42 (1.93)
Week 28	112	1.06 (2.16)	112	-0.72 (3.11)	115	1.53 (3.90)	115	-0.50 (2.04)
Week 32	114	1.11 (2.12)	114	-0.75 (3.03)	110	1.54 (3.89)	110	-0.42 (2.36)
Week 36	109	1.02 (2.00)	109	-0.76 (3.11)	109	1.58 (3.73)	109	-0.48 (2.54)
Week 40	109	0.93 (1.94)	109	-0.97 (3.20)	107	1.50 (3.80)	107	-0.44 (2.39)
Week 44	103	1.07 (2.12)	103	-0.93 (2.98)	109	1.56 (3.82)	109	-0.28 (2.37)
Week 48	111	0.94 (1.84)	111	-0.96 (3.21)	104	1.52 (3.68)	104	-0.41 (2.07)
Week 52	102	0.90 (1.85)	102	-1.11 (3.22)	101	1.39 (3.59)	101	-0.40 (1.99)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - CLASI Total Damage Score
Full analysis set



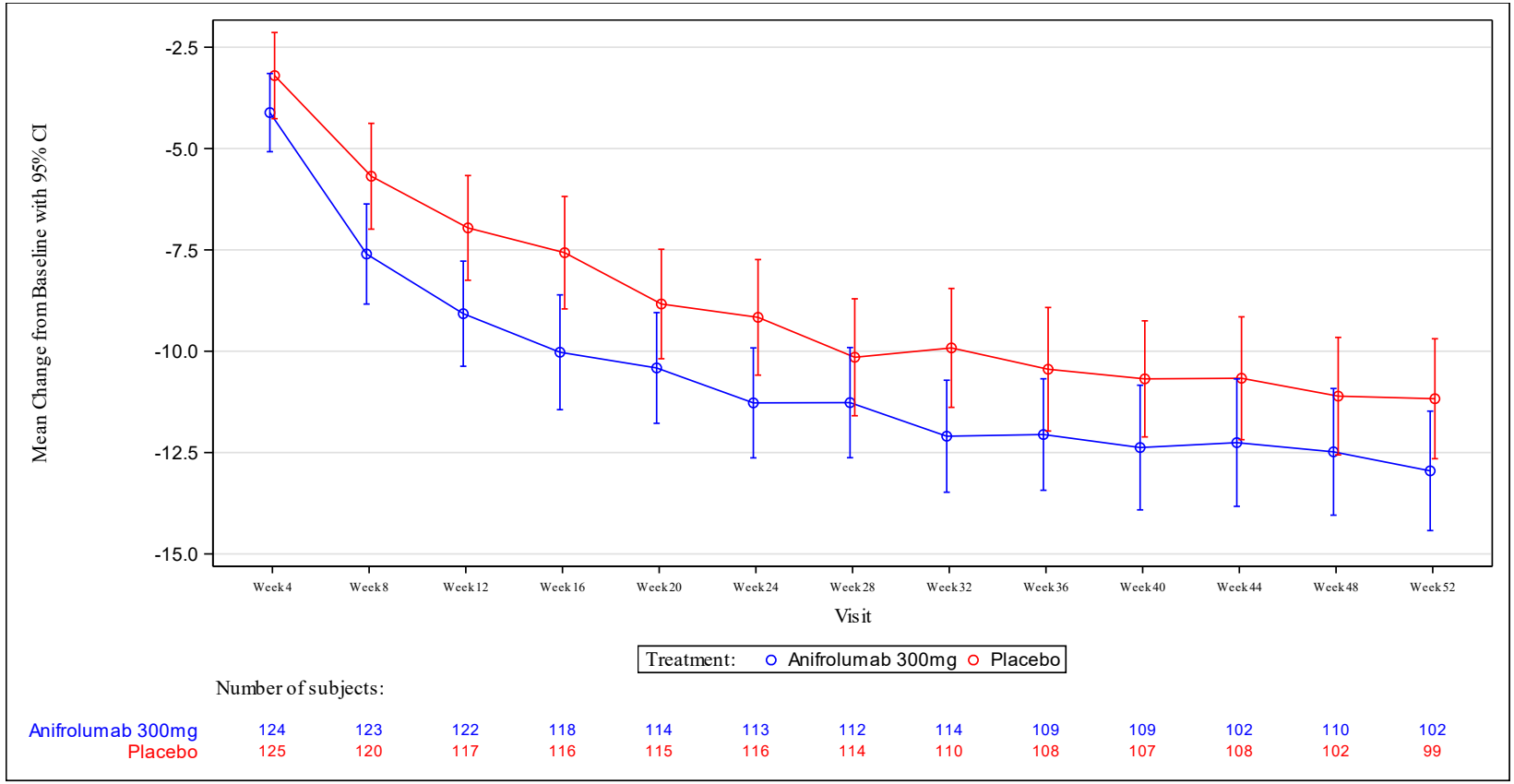
Number of subjects:

	Week 4	Week 8	Week 12	Week 16	Week 20	Week 24	Week 28	Week 32	Week 36	Week 40	Week 44	Week 48	Week 52
Anifrolumab 300mg	124	123	121	118	114	113	112	114	109	109	103	111	102
Placebo	124	120	118	116	115	115	115	110	109	107	109	104	101

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - BILAG Global Score
Full analysis set

	Anifrolumab 300mg (N=127)				Placebo (N=125)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	127	19.57 (5.87)	0	-	125	18.93 (5.28)	0	-
Week 4	124	15.35 (7.49)	124	-4.11 (5.42)	125	15.73 (6.17)	125	-3.20 (6.01)
Week 8	123	11.85 (7.88)	123	-7.60 (6.92)	120	13.23 (7.18)	120	-5.68 (7.22)
Week 12	122	10.37 (7.92)	122	-9.07 (7.24)	117	12.03 (6.79)	117	-6.96 (7.06)
Week 16	118	9.47 (8.46)	118	-10.03 (7.77)	116	11.50 (7.33)	116	-7.57 (7.54)
Week 20	114	8.96 (7.95)	114	-10.41 (7.36)	115	10.10 (6.96)	115	-8.83 (7.31)
Week 24	113	8.27 (8.00)	113	-11.27 (7.28)	116	9.78 (7.01)	116	-9.16 (7.75)
Week 28	112	8.23 (7.85)	112	-11.27 (7.26)	114	8.85 (7.04)	114	-10.15 (7.77)
Week 32	114	7.41 (7.46)	114	-12.10 (7.45)	110	9.05 (7.18)	110	-9.92 (7.76)
Week 36	109	7.51 (7.70)	109	-12.06 (7.24)	108	8.27 (6.86)	108	-10.44 (7.99)
Week 40	109	7.12 (7.89)	109	-12.38 (8.10)	107	8.28 (6.58)	107	-10.68 (7.47)
Week 44	102	7.14 (8.08)	102	-12.25 (8.00)	108	8.36 (6.69)	108	-10.67 (7.94)
Week 48	110	6.88 (7.88)	110	-12.48 (8.27)	102	7.89 (6.33)	102	-11.11 (7.38)
Week 52	102	6.54 (7.31)	102	-12.95 (7.50)	99	7.70 (6.12)	99	-11.17 (7.42)

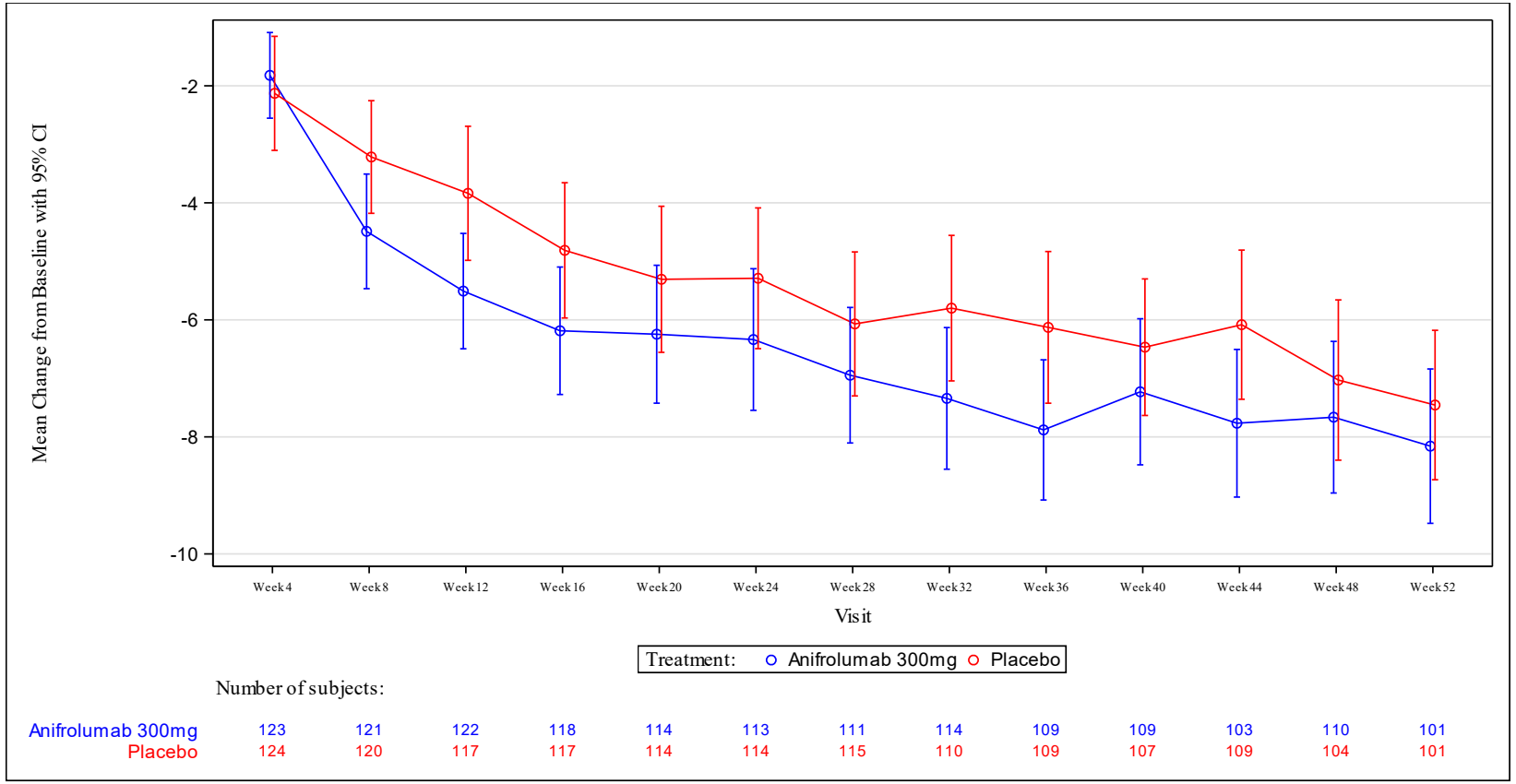
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - BILAG Global Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Tender Joint Count
Full analysis set

	Anifrolumab 300mg (N=127)				Placebo (N=125)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	127	11.17 (7.32)	0	-	125	10.54 (7.09)	0	-
Week 4	123	9.28 (7.76)	123	-1.82 (4.10)	124	8.44 (6.91)	124	-2.13 (5.48)
Week 8	121	6.82 (7.17)	121	-4.49 (5.44)	120	7.38 (6.89)	120	-3.22 (5.33)
Week 12	122	5.68 (6.93)	122	-5.51 (5.50)	117	6.63 (7.30)	117	-3.84 (6.26)
Week 16	118	4.95 (7.04)	118	-6.19 (5.97)	117	5.85 (6.50)	117	-4.81 (6.31)
Week 20	114	4.72 (7.32)	114	-6.25 (6.35)	114	5.14 (6.69)	114	-5.31 (6.73)
Week 24	113	4.84 (7.45)	113	-6.34 (6.49)	114	4.90 (6.75)	114	-5.29 (6.48)
Week 28	111	4.20 (6.51)	111	-6.95 (6.16)	115	4.32 (6.40)	115	-6.07 (6.66)
Week 32	114	3.89 (6.21)	114	-7.34 (6.52)	110	4.46 (6.72)	110	-5.80 (6.58)
Week 36	109	3.29 (6.04)	109	-7.88 (6.31)	109	4.27 (6.92)	109	-6.13 (6.83)
Week 40	109	3.63 (6.55)	109	-7.23 (6.57)	107	3.77 (5.59)	107	-6.47 (6.09)
Week 44	103	2.84 (5.04)	103	-7.77 (6.46)	109	3.93 (6.29)	109	-6.08 (6.72)
Week 48	110	3.39 (5.72)	110	-7.66 (6.86)	104	3.34 (5.33)	104	-7.03 (7.04)
Week 52	101	3.12 (5.76)	101	-8.16 (6.68)	101	2.67 (4.81)	101	-7.46 (6.47)

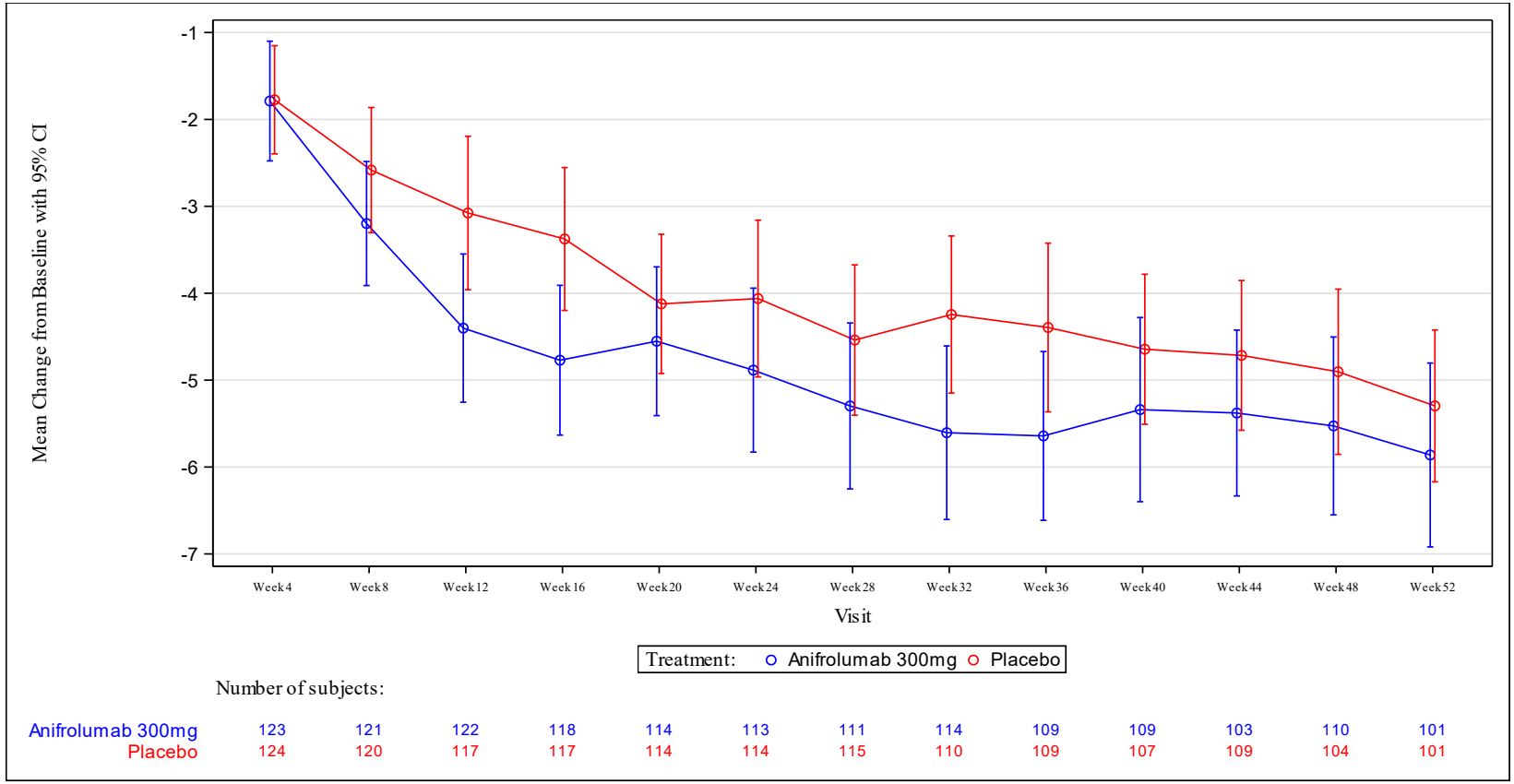
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Tender Joint Count
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Swollen Joint Count
Full analysis set

	Anifrolumab 300mg (N=127)				Placebo (N=125)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	127	7.31 (5.62)	0	-	125	6.99 (4.89)	0	-
Week 4	123	5.44 (5.46)	123	-1.79 (3.86)	124	5.25 (5.17)	124	-1.77 (3.50)
Week 8	121	4.12 (4.86)	121	-3.20 (3.97)	120	4.40 (4.71)	120	-2.58 (3.99)
Week 12	122	2.96 (4.00)	122	-4.40 (4.76)	117	3.77 (5.05)	117	-3.08 (4.82)
Week 16	118	2.56 (4.01)	118	-4.77 (4.73)	117	3.73 (4.72)	117	-3.38 (4.49)
Week 20	114	2.44 (4.37)	114	-4.55 (4.61)	114	2.86 (4.19)	114	-4.12 (4.32)
Week 24	113	2.44 (4.52)	113	-4.88 (5.06)	114	2.69 (4.19)	114	-4.06 (4.86)
Week 28	111	2.07 (3.84)	111	-5.30 (5.08)	115	2.44 (3.93)	115	-4.54 (4.68)
Week 32	114	1.63 (3.02)	114	-5.61 (5.38)	110	2.62 (4.14)	110	-4.25 (4.78)
Week 36	109	1.73 (3.26)	109	-5.64 (5.11)	109	2.51 (4.48)	109	-4.39 (5.11)
Week 40	109	1.93 (3.98)	109	-5.34 (5.58)	107	2.05 (3.13)	107	-4.64 (4.50)
Week 44	103	1.54 (2.84)	103	-5.38 (4.88)	109	2.12 (3.27)	109	-4.72 (4.54)
Week 48	110	1.69 (3.16)	110	-5.53 (5.42)	104	1.92 (3.56)	104	-4.90 (4.89)
Week 52	101	1.46 (2.85)	101	-5.86 (5.36)	101	1.57 (2.70)	101	-5.30 (4.42)

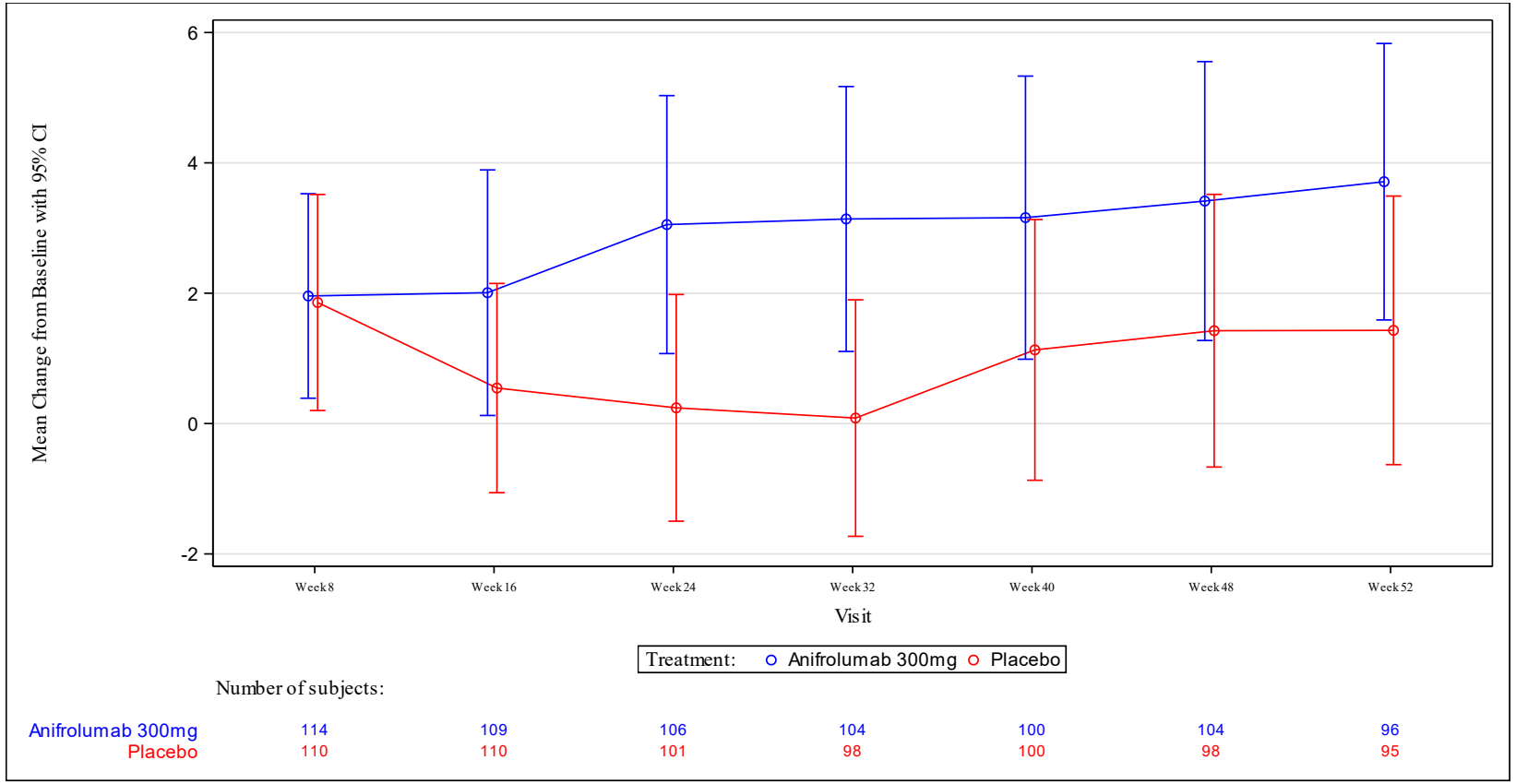
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Swollen Joint Count
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Mental Component Score
Full analysis set

	Anifrolumab 300mg (N=127)				Placebo (N=125)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	123	42.89 (11.67)	0	-	118	45.11 (11.52)	0	-
Week 8	115	44.89 (11.63)	114	1.96 (8.45)	117	46.44 (10.81)	110	1.86 (8.77)
Week 16	111	44.82 (11.75)	109	2.01 (9.92)	116	45.25 (10.78)	110	0.54 (8.49)
Week 24	110	45.10 (12.57)	106	3.05 (10.28)	107	44.76 (10.43)	101	0.24 (8.81)
Week 32	108	45.11 (11.42)	104	3.14 (10.45)	103	44.74 (10.35)	98	0.08 (9.05)
Week 40	104	45.52 (11.42)	100	3.16 (10.95)	105	46.14 (11.14)	100	1.13 (10.08)
Week 48	108	45.44 (11.19)	104	3.41 (11.00)	101	46.53 (10.44)	98	1.42 (10.43)
Week 52	100	46.05 (10.93)	96	3.71 (10.47)	99	46.42 (11.22)	95	1.43 (10.11)

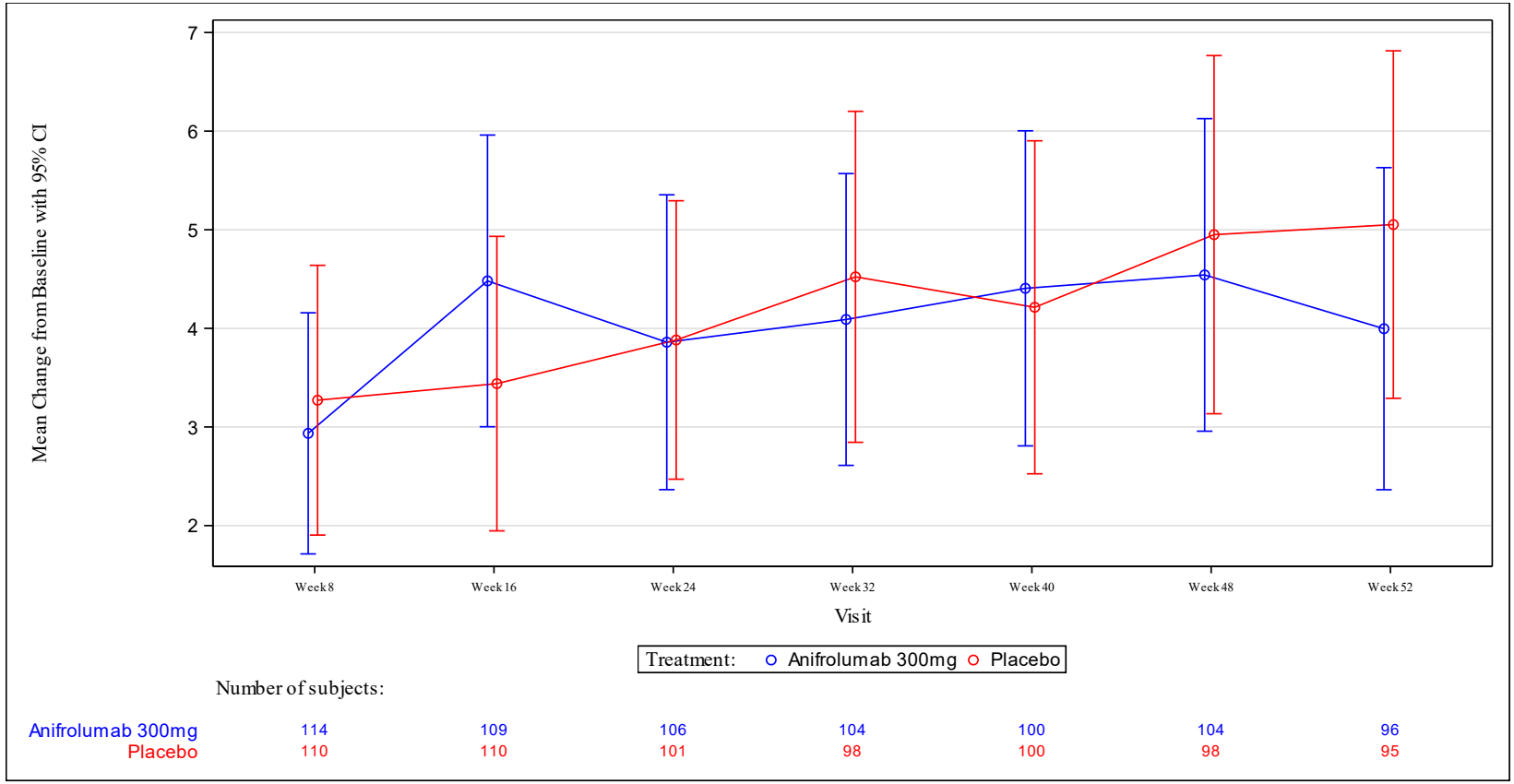
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Mental Component Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Physical Component Score
Full analysis set

	Anifrolumab 300mg (N=127)				Placebo (N=125)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	123	37.45 (9.10)	0	-	118	37.64 (8.79)	0	-
Week 8	115	40.69 (8.74)	114	2.94 (6.59)	117	40.55 (8.34)	110	3.27 (7.24)
Week 16	111	42.47 (10.04)	109	4.48 (7.79)	116	40.93 (9.13)	110	3.44 (7.90)
Week 24	110	41.66 (9.92)	106	3.86 (7.76)	107	41.81 (8.72)	101	3.88 (7.15)
Week 32	108	41.79 (9.62)	104	4.09 (7.61)	103	42.51 (9.02)	98	4.52 (8.37)
Week 40	104	42.53 (9.84)	100	4.41 (8.05)	105	41.58 (9.83)	100	4.21 (8.51)
Week 48	108	42.34 (10.42)	104	4.54 (8.15)	101	42.49 (10.05)	98	4.95 (9.06)
Week 52	100	41.83 (9.79)	96	4.00 (8.06)	99	42.81 (9.48)	95	5.05 (8.65)

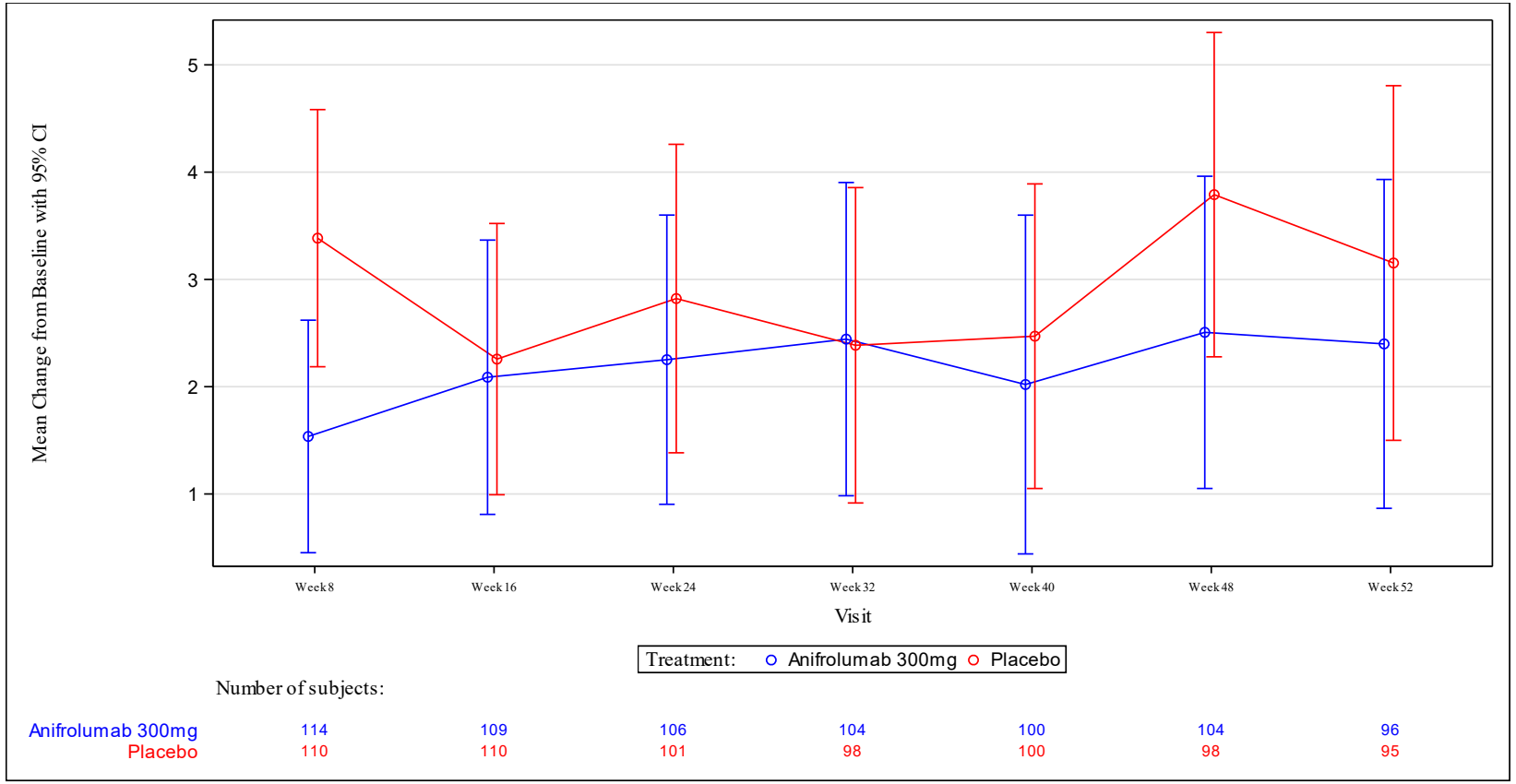
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Physical Component Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute General Health Score
Full analysis set

	Anifrolumab 300mg (N=127)				Placebo (N=125)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	123	37.89 (7.84)	0	-	118	39.40 (8.12)	0	-
Week 8	115	39.65 (8.02)	114	1.54 (5.84)	117	42.34 (8.33)	110	3.38 (6.34)
Week 16	111	40.48 (9.07)	109	2.09 (6.73)	116	41.29 (8.45)	110	2.26 (6.69)
Week 24	110	39.99 (9.74)	106	2.25 (7.00)	107	42.30 (8.57)	101	2.82 (7.28)
Week 32	108	40.32 (9.57)	104	2.44 (7.51)	103	42.16 (8.72)	98	2.39 (7.33)
Week 40	104	40.45 (9.50)	100	2.02 (7.96)	105	42.12 (9.02)	100	2.47 (7.15)
Week 48	108	40.33 (9.51)	104	2.51 (7.48)	101	43.52 (9.23)	98	3.79 (7.54)
Week 52	100	40.13 (9.08)	96	2.40 (7.56)	99	43.32 (9.09)	95	3.15 (8.11)

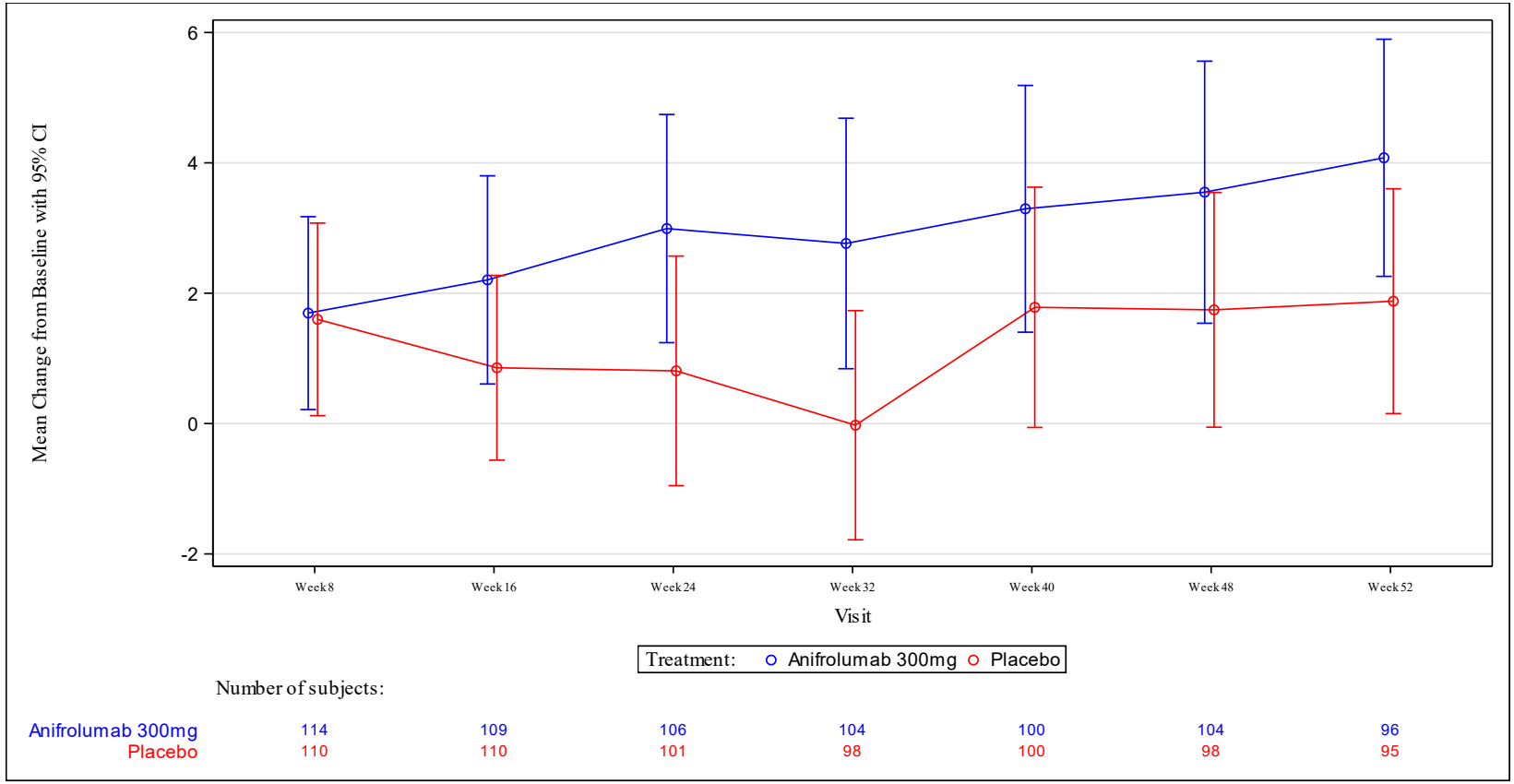
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute General Health Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Mental Health Score
Full analysis set

	Anifrolumab 300mg (N=127)				Placebo (N=125)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	123	43.14 (10.97)	0	-	118	44.72 (10.49)	0	-
Week 8	115	44.88 (10.72)	114	1.69 (7.97)	117	46.11 (9.69)	110	1.60 (7.82)
Week 16	111	45.35 (11.47)	109	2.20 (8.41)	116	45.27 (10.40)	110	0.86 (7.50)
Week 24	110	45.44 (11.88)	106	2.99 (9.09)	107	44.98 (9.85)	101	0.81 (8.92)
Week 32	108	45.19 (10.79)	104	2.76 (9.88)	103	44.39 (9.28)	98	-0.03 (8.77)
Week 40	104	46.14 (10.17)	100	3.30 (9.54)	105	46.32 (10.14)	100	1.78 (9.29)
Week 48	108	45.90 (10.03)	104	3.55 (10.34)	101	46.12 (9.98)	98	1.74 (8.98)
Week 52	100	46.47 (10.18)	96	4.08 (8.98)	99	46.33 (10.16)	95	1.88 (8.47)

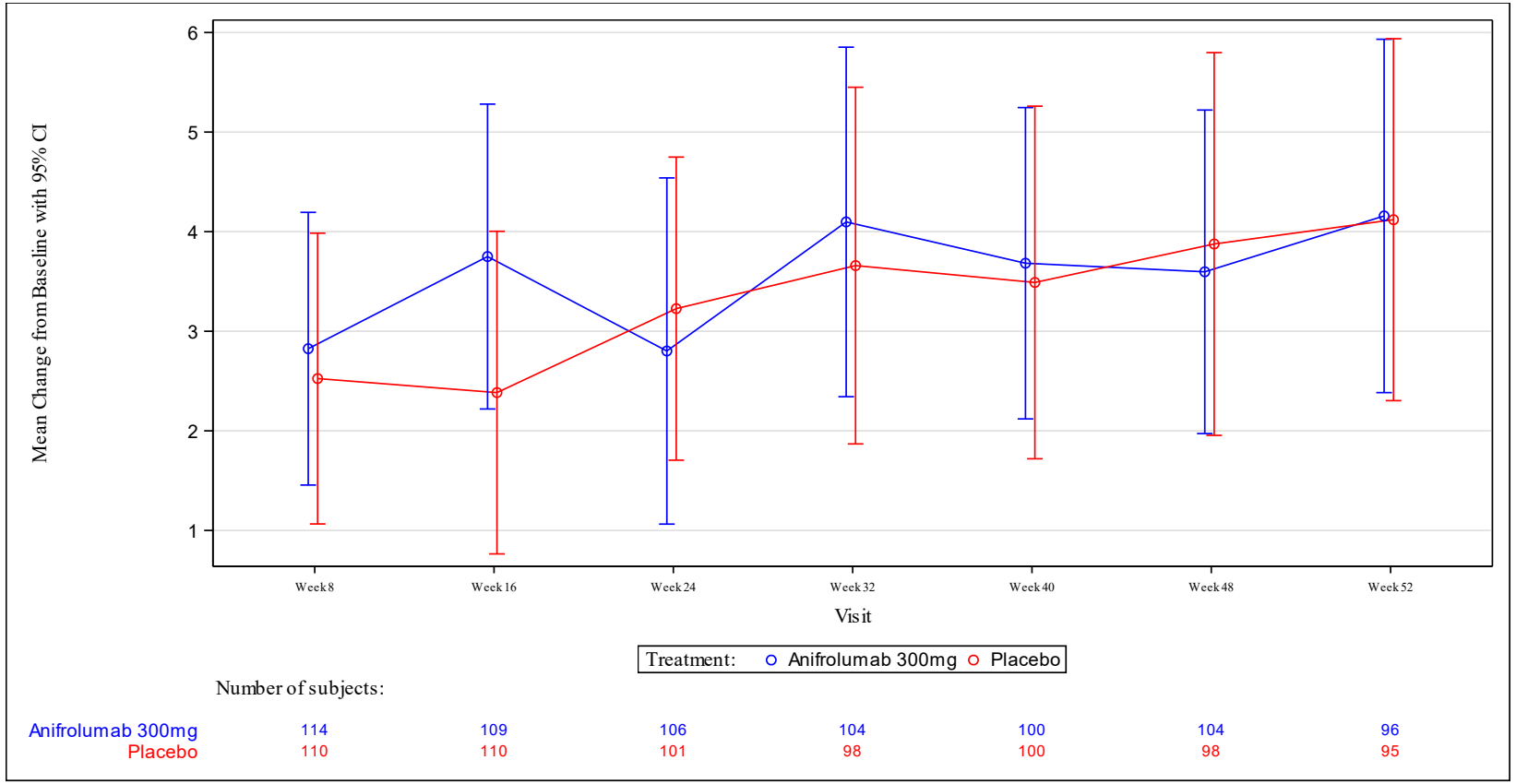
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Mental Health Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Physical Functioning Score
Full analysis set

	Anifrolumab 300mg (N=127)				Placebo (N=125)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	123	39.08 (10.24)	0	-	118	39.24 (9.08)	0	-
Week 8	115	42.40 (9.88)	114	2.82 (7.38)	117	41.51 (8.78)	110	2.52 (7.73)
Week 16	111	43.30 (10.42)	109	3.75 (8.06)	116	41.60 (9.94)	110	2.38 (8.57)
Week 24	110	42.32 (10.97)	106	2.80 (9.03)	107	42.73 (9.54)	101	3.23 (7.71)
Week 32	108	43.35 (10.30)	104	4.10 (9.02)	103	43.10 (9.47)	98	3.66 (8.93)
Week 40	104	43.45 (10.60)	100	3.68 (7.88)	105	42.26 (10.53)	100	3.49 (8.92)
Week 48	108	43.04 (10.73)	104	3.60 (8.35)	101	42.82 (11.01)	98	3.88 (9.59)
Week 52	100	43.83 (9.87)	96	4.16 (8.76)	99	43.36 (10.13)	95	4.12 (8.92)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Physical Functioning Score
Full analysis set



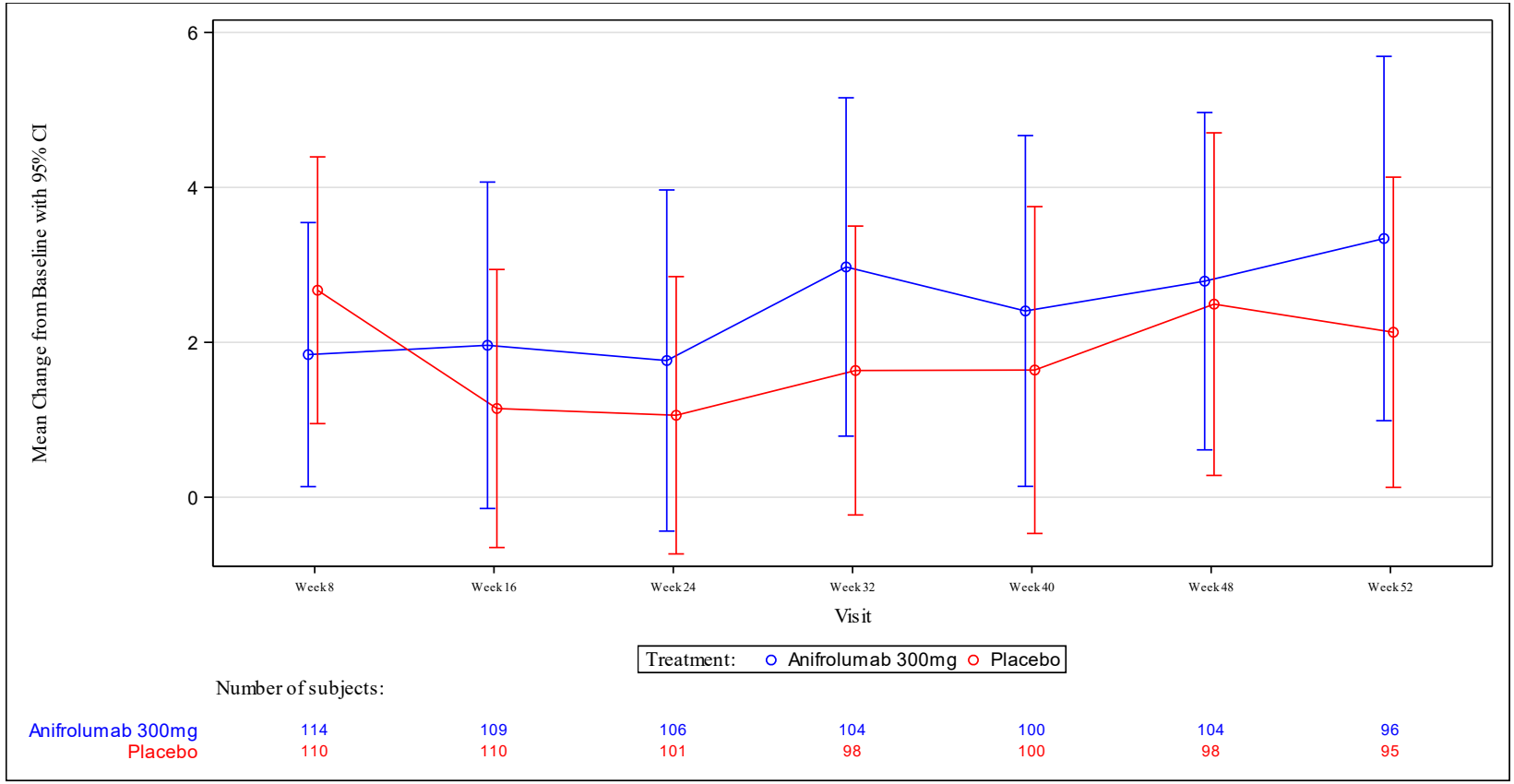
Number of subjects:

	Week 8	Week 16	Week 24	Week 32	Week 40	Week 48	Week 52
Anifrolumab 300mg	114	109	106	104	100	104	96
Placebo	110	110	101	98	100	98	95

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Role Emotional Score
Full analysis set

	Anifrolumab 300mg (N=127)				Placebo (N=125)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	123	40.59 (12.40)	0	-	118	41.34 (11.17)	0	-
Week 8	115	42.63 (12.66)	114	1.84 (9.19)	117	43.01 (11.40)	110	2.67 (9.11)
Week 16	111	42.54 (12.04)	109	1.96 (11.10)	116	41.98 (11.77)	110	1.15 (9.50)
Week 24	110	42.04 (13.49)	106	1.76 (11.43)	107	41.87 (10.81)	101	1.06 (9.07)
Week 32	108	42.88 (11.77)	104	2.97 (11.23)	103	42.34 (11.70)	98	1.64 (9.30)
Week 40	104	42.79 (11.80)	100	2.40 (11.41)	105	42.88 (11.94)	100	1.64 (10.63)
Week 48	108	42.81 (11.82)	104	2.79 (11.20)	101	43.70 (11.18)	98	2.49 (11.03)
Week 52	100	43.77 (11.25)	96	3.34 (11.61)	99	43.61 (11.39)	95	2.13 (9.83)

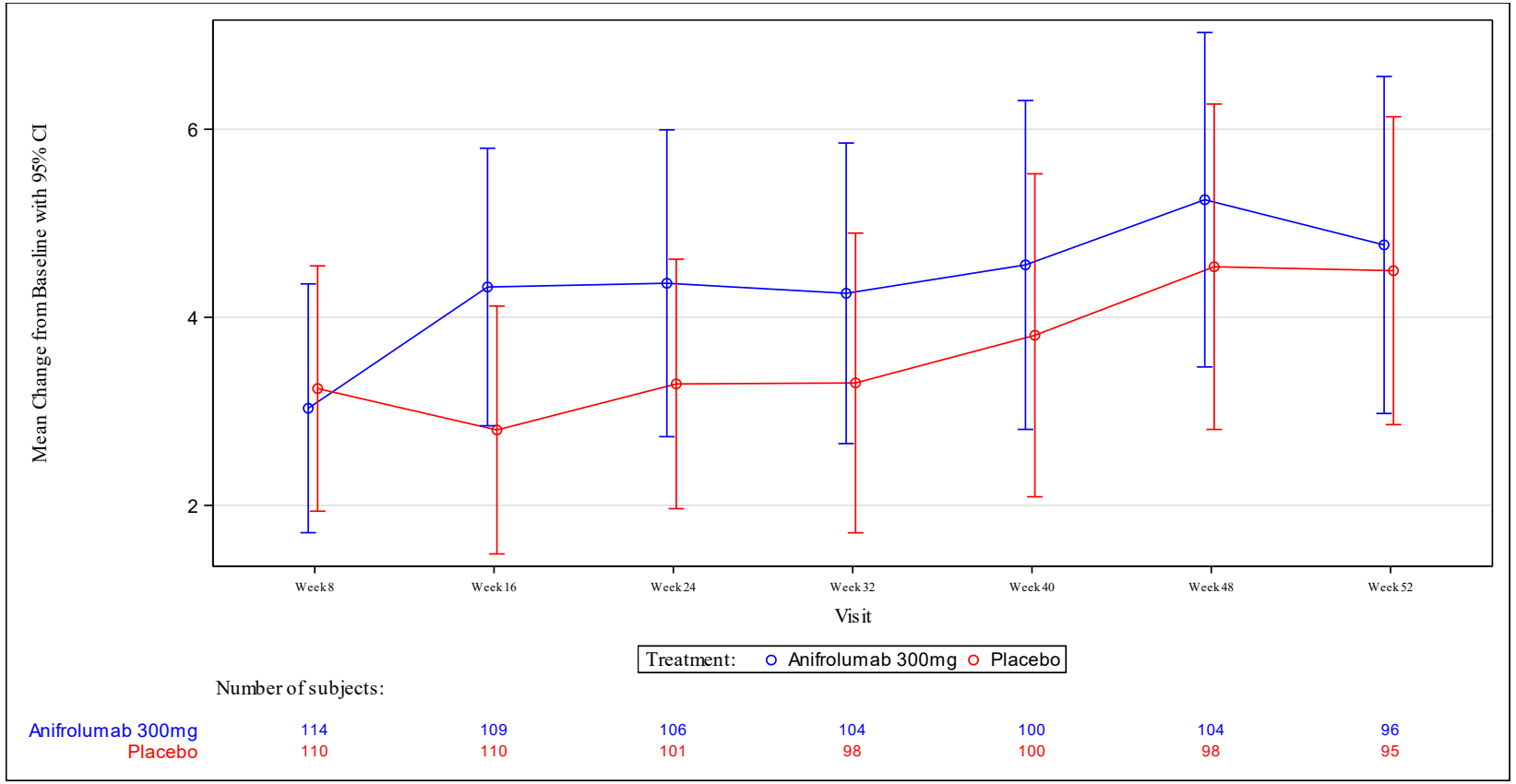
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Role Emotional Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Role Physical Score
Full analysis set

	Anifrolumab 300mg (N=127)				Placebo (N=125)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	123	37.59 (9.62)	0	-	118	37.77 (7.69)	0	-
Week 8	115	40.77 (9.49)	114	3.03 (7.13)	117	40.67 (8.01)	110	3.24 (6.90)
Week 16	111	42.12 (10.05)	109	4.32 (7.77)	116	40.46 (8.87)	110	2.80 (6.97)
Week 24	110	41.95 (10.50)	106	4.36 (8.47)	107	41.05 (8.77)	101	3.29 (6.72)
Week 32	108	41.48 (9.37)	104	4.26 (8.22)	103	41.37 (8.76)	98	3.30 (7.95)
Week 40	104	42.13 (9.29)	100	4.56 (8.81)	105	41.71 (9.18)	100	3.81 (8.65)
Week 48	108	42.56 (9.85)	104	5.25 (9.14)	101	42.34 (9.54)	98	4.54 (8.63)
Week 52	100	42.02 (9.76)	96	4.77 (8.85)	99	42.62 (8.77)	95	4.50 (8.03)

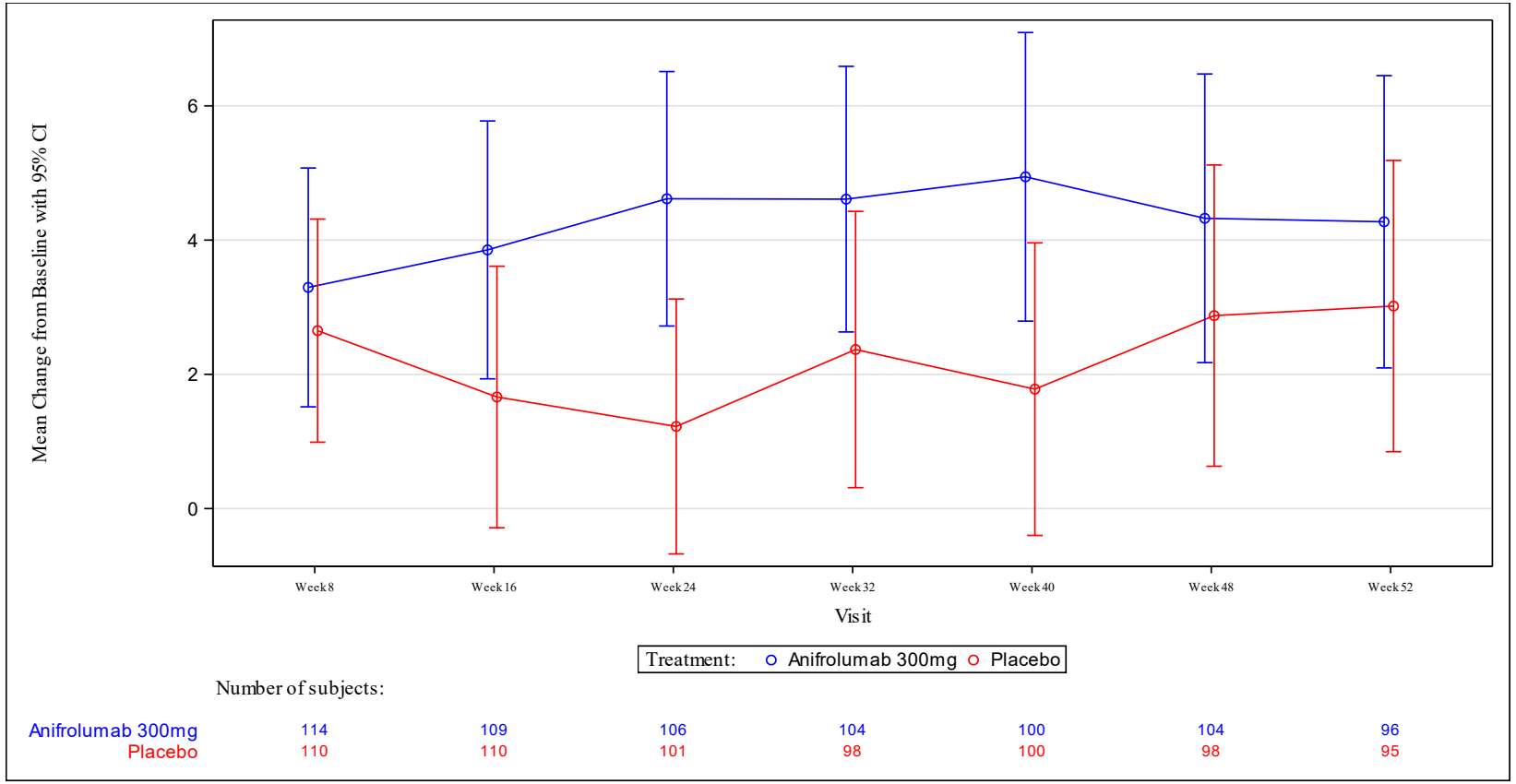
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Role Physical Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Social Functioning Score
Full analysis set

	Anifrolumab 300mg (N=127)				Placebo (N=125)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	123	39.22 (10.98)	0	-	118	41.11 (10.11)	0	-
Week 8	115	42.81 (10.89)	114	3.30 (9.59)	117	43.39 (9.78)	110	2.65 (8.80)
Week 16	111	43.29 (10.41)	109	3.85 (10.12)	116	42.55 (9.09)	110	1.66 (10.31)
Week 24	110	43.26 (10.67)	106	4.62 (9.84)	107	42.28 (9.85)	101	1.22 (9.62)
Week 32	108	43.01 (10.34)	104	4.61 (10.17)	103	43.16 (9.90)	98	2.37 (10.27)
Week 40	104	43.95 (10.59)	100	4.94 (10.84)	105	42.48 (10.10)	100	1.78 (10.98)
Week 48	108	42.96 (10.92)	104	4.32 (11.06)	101	44.11 (9.47)	98	2.87 (11.20)
Week 52	100	43.34 (10.57)	96	4.27 (10.75)	99	43.86 (9.28)	95	3.02 (10.65)

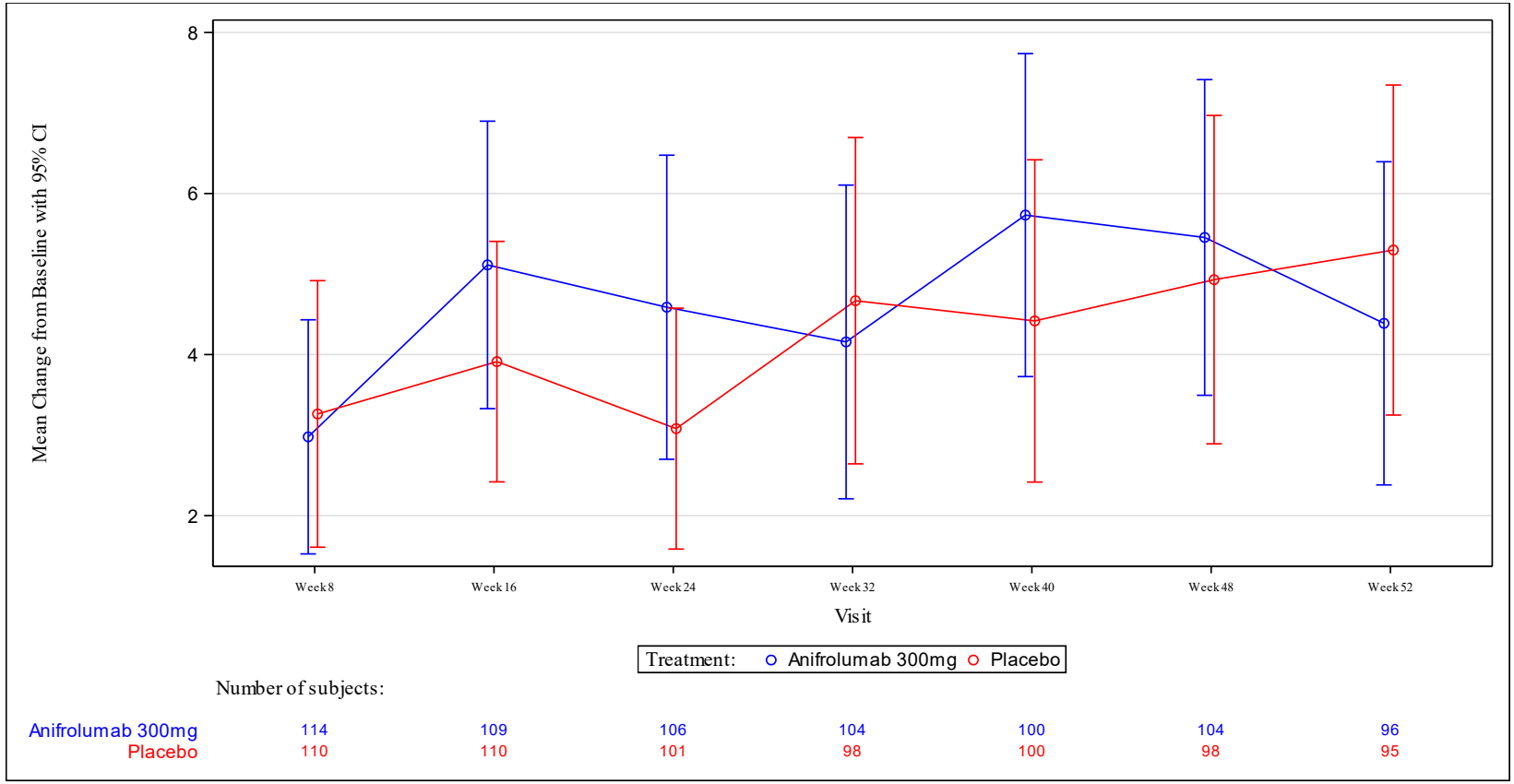
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Social Functioning Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Bodily Pain Score
Full analysis set

	Anifrolumab 300mg (N=127)				Placebo (N=125)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	123	38.41 (8.84)	0	-	118	38.74 (9.12)	0	-
Week 8	115	41.50 (9.51)	114	2.98 (7.84)	117	41.21 (8.56)	110	3.26 (8.76)
Week 16	111	43.97 (10.32)	109	5.11 (9.40)	116	42.13 (8.95)	110	3.91 (7.90)
Week 24	110	43.01 (10.70)	106	4.59 (9.81)	107	41.62 (8.67)	101	3.08 (7.58)
Week 32	108	42.65 (10.39)	104	4.16 (10.02)	103	42.95 (9.80)	98	4.67 (10.11)
Week 40	104	44.66 (10.15)	100	5.73 (10.11)	105	42.40 (9.08)	100	4.42 (10.09)
Week 48	108	43.93 (10.88)	104	5.45 (10.08)	101	43.11 (9.65)	98	4.93 (10.17)
Week 52	100	43.11 (9.74)	96	4.39 (9.90)	99	43.31 (8.83)	95	5.30 (10.06)

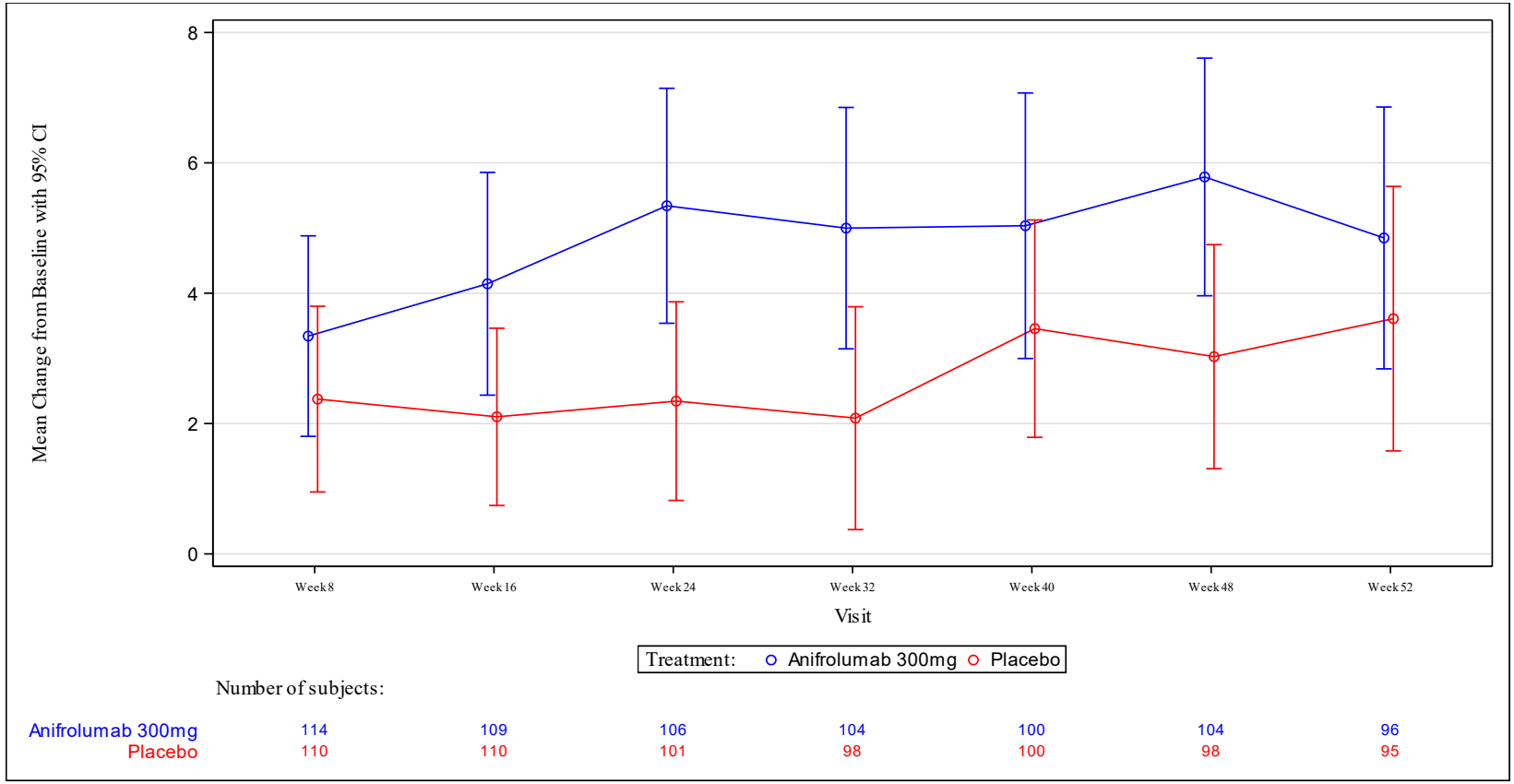
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Bodily Pain Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Vitality Score
Full analysis set

	Anifrolumab 300mg (N=127)				Placebo (N=125)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	123	40.87 (9.08)	0	-	118	43.94 (8.88)	0	-
Week 8	115	44.18 (9.64)	114	3.34 (8.29)	117	45.98 (9.34)	110	2.38 (7.54)
Week 16	111	45.22 (10.52)	109	4.14 (9.00)	116	45.85 (9.59)	110	2.10 (7.19)
Week 24	110	45.69 (10.72)	106	5.34 (9.36)	107	46.13 (9.61)	101	2.34 (7.72)
Week 32	108	45.61 (9.88)	104	5.00 (9.52)	103	46.45 (9.49)	98	2.08 (8.53)
Week 40	104	45.75 (10.91)	100	5.04 (10.27)	105	47.35 (9.86)	100	3.46 (8.40)
Week 48	108	46.54 (10.98)	104	5.78 (9.37)	101	47.32 (9.93)	98	3.03 (8.57)
Week 52	100	45.85 (10.05)	96	4.85 (9.91)	99	47.60 (10.28)	95	3.61 (9.96)

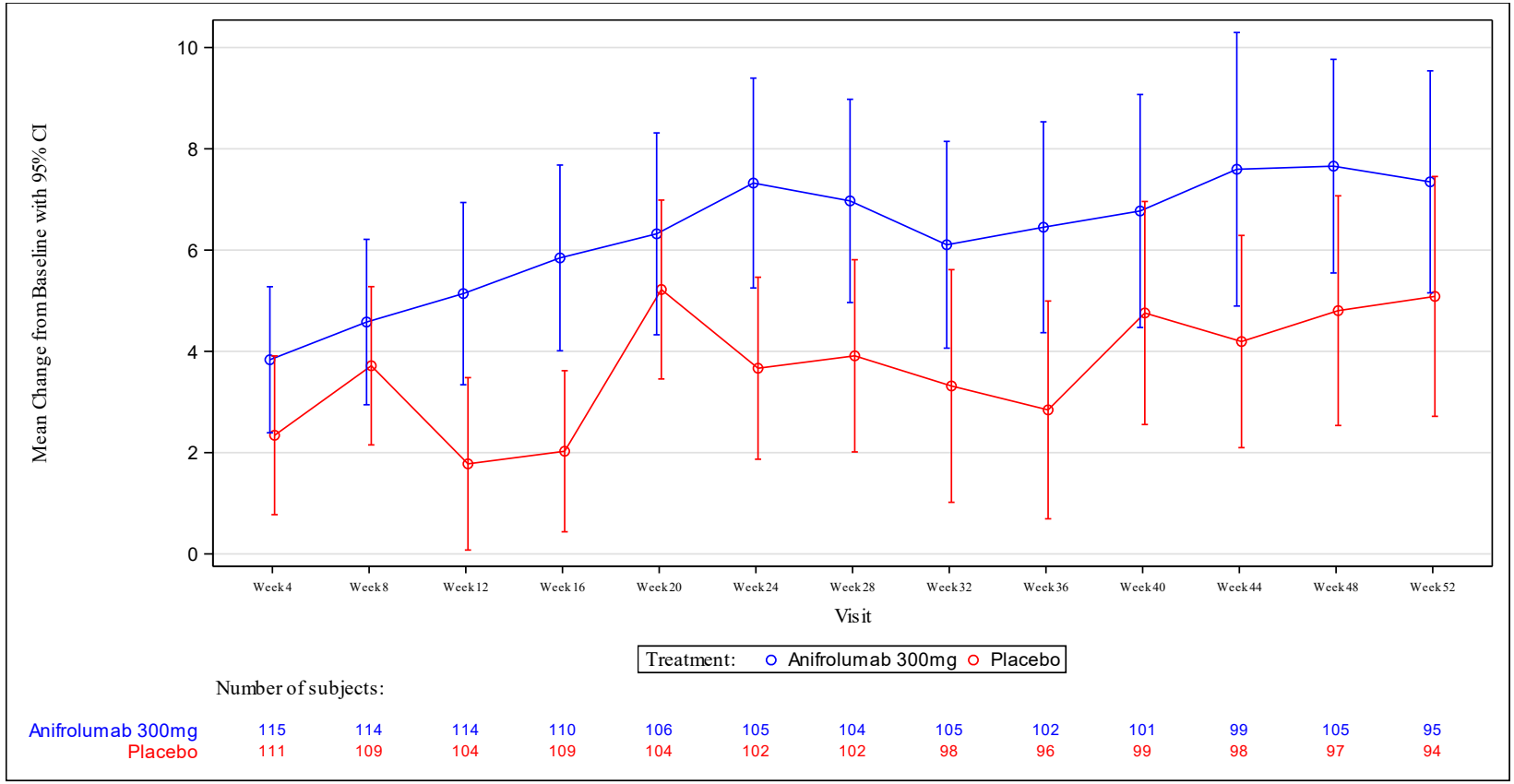
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Vitality Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - FACIT-F Total Score
Full analysis set

	Anifrolumab 300mg (N=127)				Placebo (N=125)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	122	24.54 (11.77)	0	-	117	27.25 (11.54)	0	-
Week 4	118	28.12 (11.50)	115	3.83 (7.81)	117	28.46 (12.51)	111	2.34 (8.33)
Week 8	116	29.25 (11.61)	114	4.58 (8.80)	117	30.46 (11.87)	109	3.72 (8.23)
Week 12	116	29.30 (13.50)	114	5.14 (9.70)	112	29.17 (12.92)	104	1.78 (8.75)
Week 16	113	30.91 (12.32)	110	5.85 (9.70)	116	29.26 (12.73)	109	2.03 (8.38)
Week 20	109	31.12 (12.92)	106	6.32 (10.35)	112	32.56 (11.81)	104	5.22 (9.08)
Week 24	110	31.32 (13.41)	105	7.32 (10.71)	109	30.61 (12.82)	102	3.67 (9.15)
Week 28	108	32.10 (12.77)	104	6.97 (10.32)	109	31.28 (12.03)	102	3.91 (9.66)
Week 32	110	30.15 (12.81)	105	6.10 (10.55)	104	31.35 (12.98)	98	3.32 (11.46)
Week 36	107	30.83 (12.97)	102	6.45 (10.60)	101	31.02 (13.77)	96	2.84 (10.61)
Week 40	106	31.22 (12.47)	101	6.77 (11.65)	106	31.98 (13.18)	99	4.76 (11.04)
Week 44	102	32.26 (14.50)	99	7.60 (13.54)	103	31.92 (12.56)	98	4.19 (10.45)
Week 48	110	32.07 (13.08)	105	7.66 (10.90)	102	32.86 (12.53)	97	4.80 (11.25)
Week 52	100	31.72 (12.73)	95	7.35 (10.76)	99	32.87 (12.76)	94	5.09 (11.56)

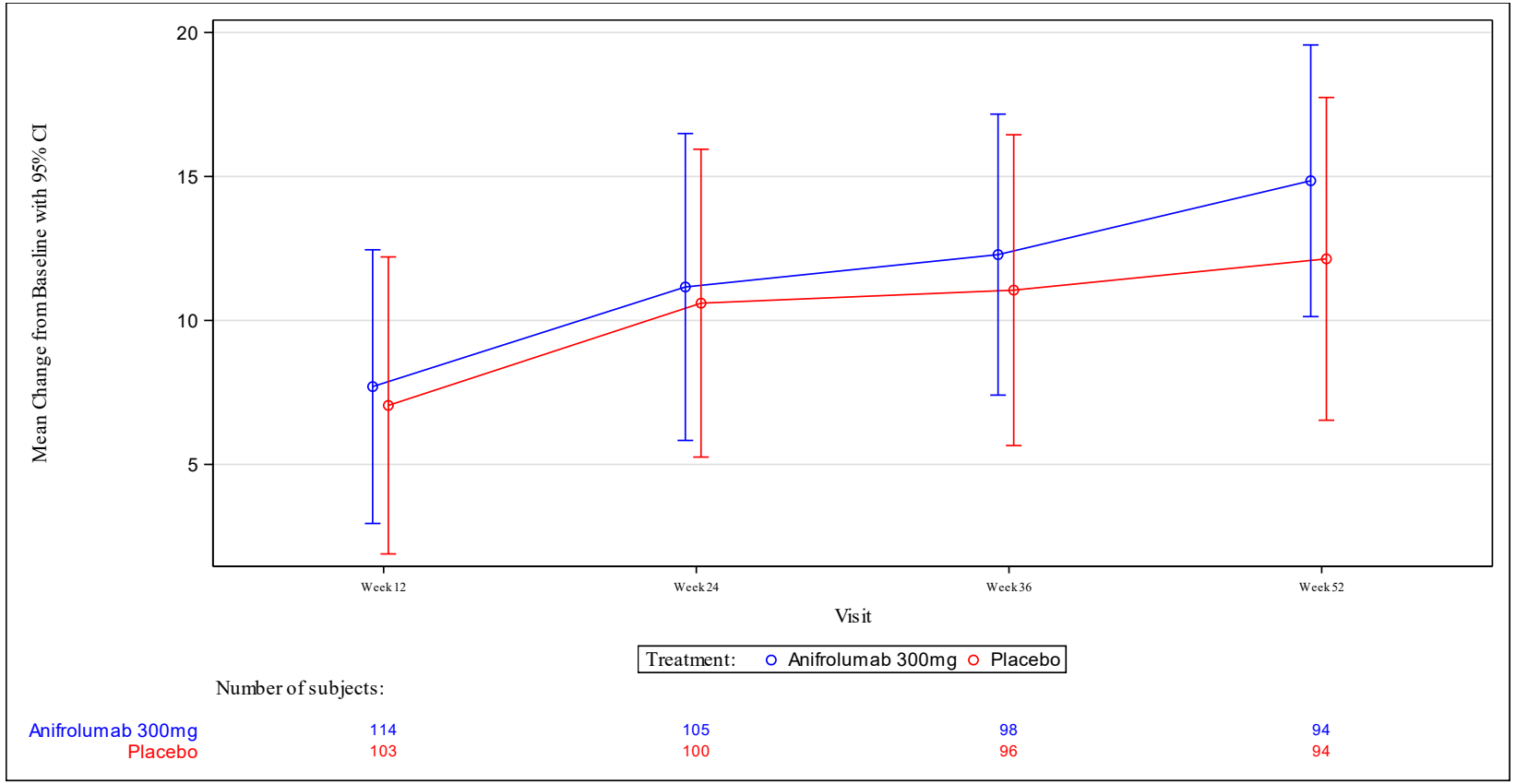
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - FACIT-F Total Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - EQ VAS Score
Full analysis set

	Anifrolumab 300mg (N=127)				Placebo (N=125)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	122	54.55 (20.06)	0	-	117	52.64 (22.04)	0	-
Week 12	116	61.45 (21.87)	114	7.70 (25.61)	111	59.10 (20.04)	103	7.05 (26.39)
Week 24	110	64.28 (22.09)	105	11.16 (27.54)	107	62.80 (20.27)	100	10.60 (26.94)
Week 36	103	65.11 (20.58)	98	12.29 (24.34)	100	64.88 (22.41)	96	11.05 (26.63)
Week 52	99	67.31 (19.31)	94	14.85 (23.03)	99	65.05 (21.57)	94	12.14 (27.36)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - EQ VAS Score
Full analysis set



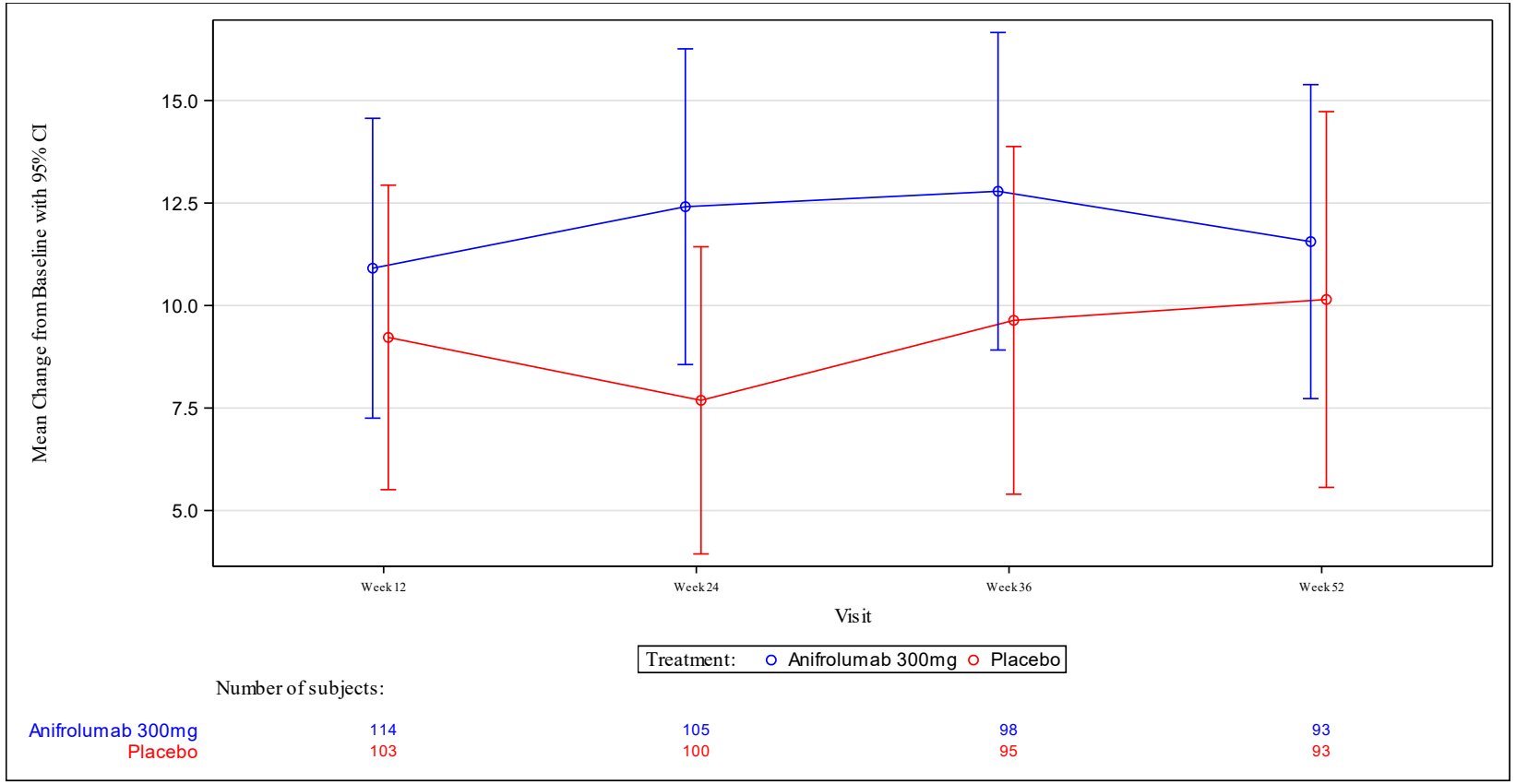
Number of subjects:

	Week 12	Week 24	Week 36	Week 52
Anifrolumab 300mg	114	105	98	94
Placebo	103	100	96	94

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Physical Health domain score
Full analysis set

	Anifrolumab 300mg (N=127)				Placebo (N=125)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	122	52.26 (24.42)	0	-	117	54.14 (24.20)	0	-
Week 12	116	62.31 (26.38)	114	10.91 (19.71)	111	62.33 (23.75)	103	9.22 (19.00)
Week 24	110	63.61 (26.73)	105	12.41 (19.89)	107	62.15 (23.60)	100	7.69 (18.88)
Week 36	103	64.44 (25.32)	98	12.79 (19.32)	99	64.52 (23.96)	95	9.64 (20.82)
Week 52	98	64.06 (26.24)	93	11.56 (18.60)	98	63.87 (24.46)	93	10.15 (22.25)

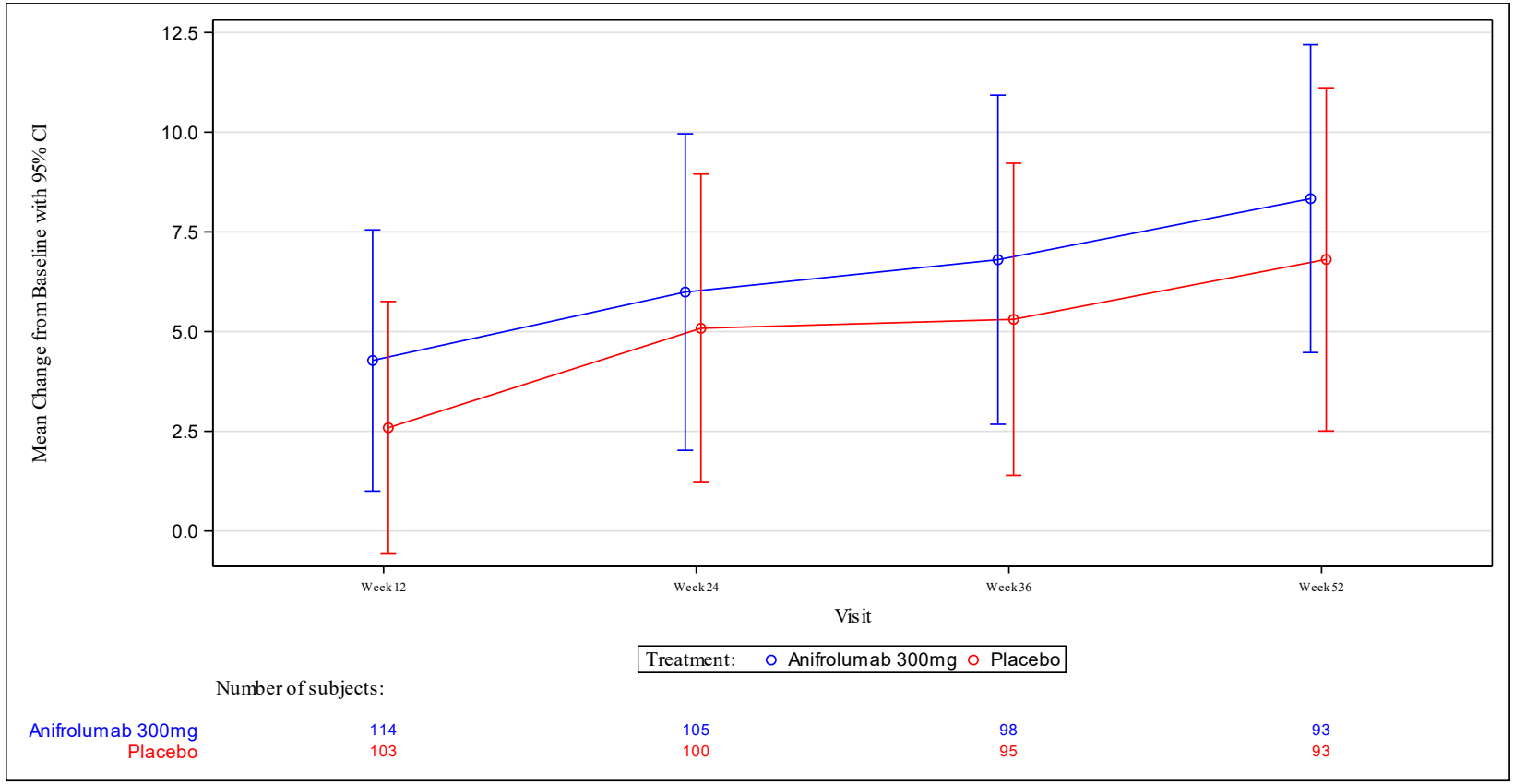
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Lupus QoL Physical Health domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Emotional Health domain score
Full analysis set

	Anifrolumab 300mg (N=127)				Placebo (N=125)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	122	66.22 (24.89)	0	-	117	66.88 (25.82)	0	-
Week 12	116	69.40 (23.77)	114	4.28 (17.65)	111	69.37 (23.91)	103	2.59 (16.19)
Week 24	110	71.78 (25.18)	105	5.99 (20.50)	107	71.22 (23.30)	100	5.08 (19.49)
Week 36	103	71.80 (24.36)	98	6.80 (20.58)	99	73.95 (21.83)	95	5.31 (19.21)
Week 52	98	73.55 (23.30)	93	8.33 (18.73)	98	75.13 (21.72)	93	6.81 (20.89)

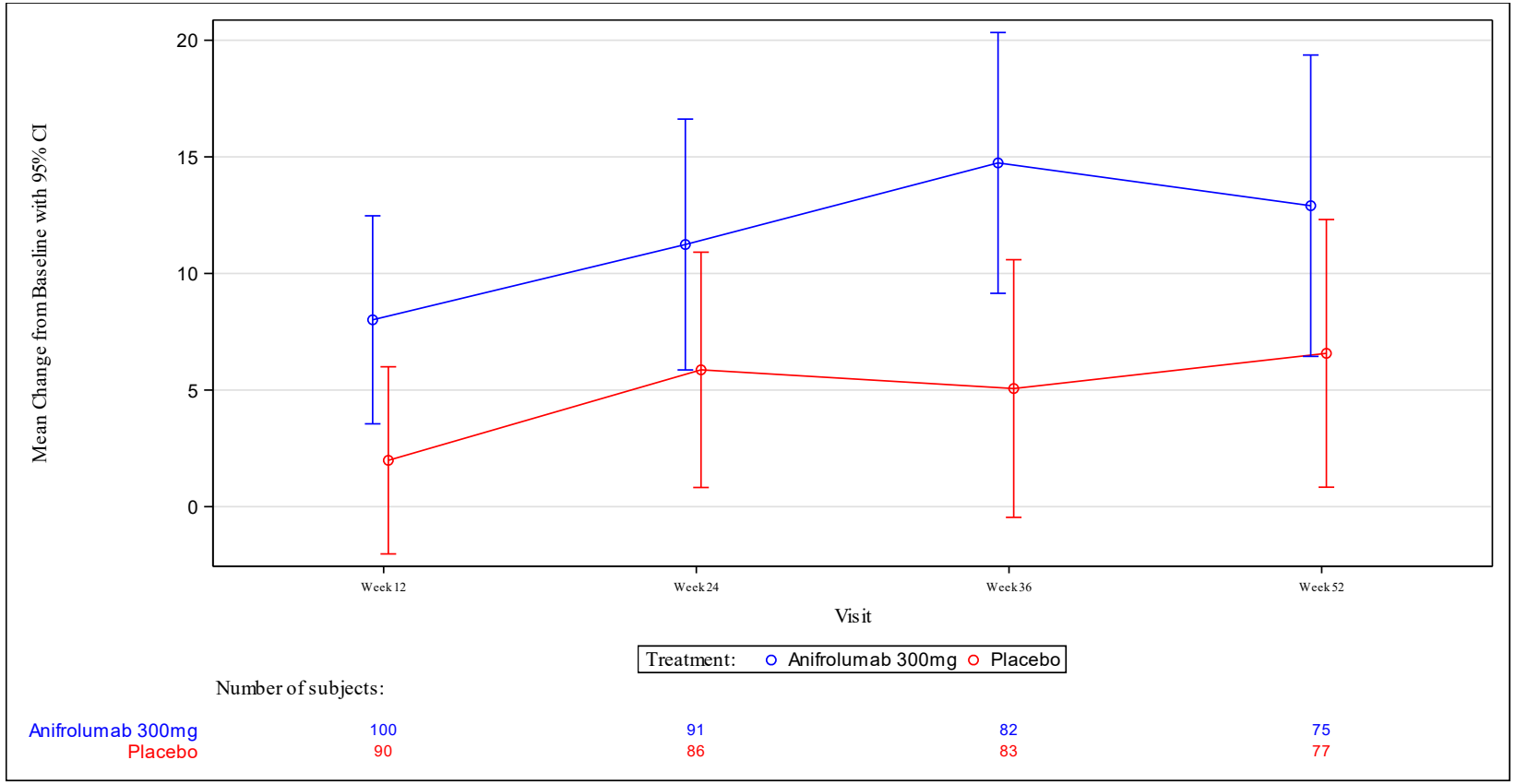
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Lupus QoL Emotional Health domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Body Image domain score
Full analysis set

	Anifrolumab 300mg (N=127)				Placebo (N=125)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	114	58.43 (28.30)	0	-	108	63.43 (27.60)	0	-
Week 12	106	64.56 (26.88)	100	8.01 (22.48)	99	65.03 (25.94)	90	1.99 (19.16)
Week 24	101	67.80 (27.28)	91	11.24 (25.82)	96	67.44 (26.81)	86	5.87 (23.53)
Week 36	92	70.79 (26.29)	82	14.74 (25.45)	91	70.15 (25.02)	83	5.07 (25.30)
Week 52	84	67.91 (24.77)	75	12.91 (28.08)	85	69.28 (25.40)	77	6.57 (25.29)

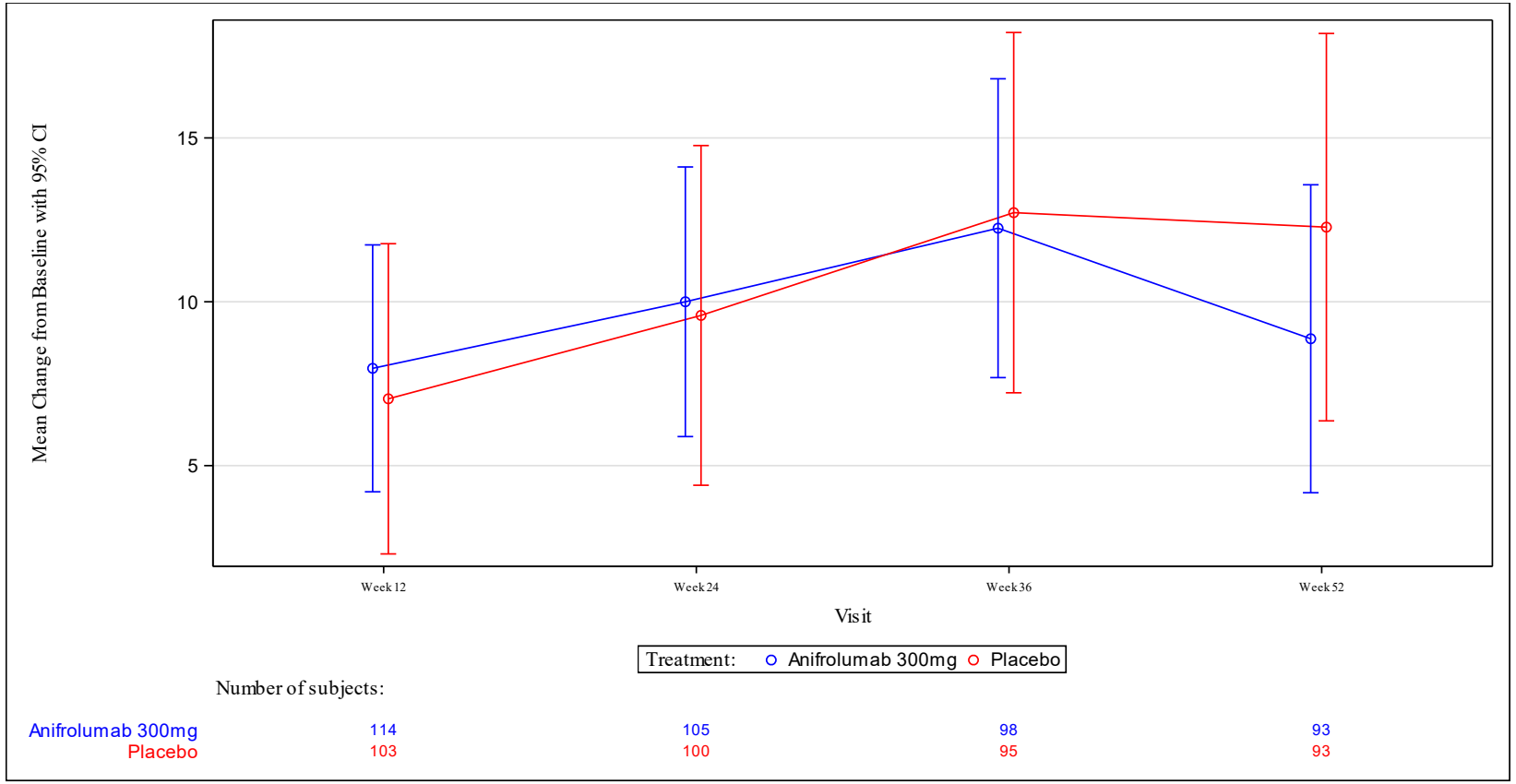
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Lupus QoL Body Image domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Burden to Others domain score
Full analysis set

	Anifrolumab 300mg (N=127)				Placebo (N=125)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	122	52.94 (30.99)	0	-	117	51.28 (31.71)	0	-
Week 12	116	58.91 (31.23)	114	7.97 (20.30)	111	59.23 (28.05)	103	7.04 (24.22)
Week 24	110	61.21 (31.78)	105	10.00 (21.26)	107	60.05 (28.45)	100	9.58 (26.12)
Week 36	103	63.83 (31.56)	98	12.24 (22.74)	99	65.82 (27.70)	95	12.72 (26.99)
Week 52	98	60.88 (31.58)	93	8.87 (22.82)	98	65.99 (27.01)	93	12.28 (28.70)

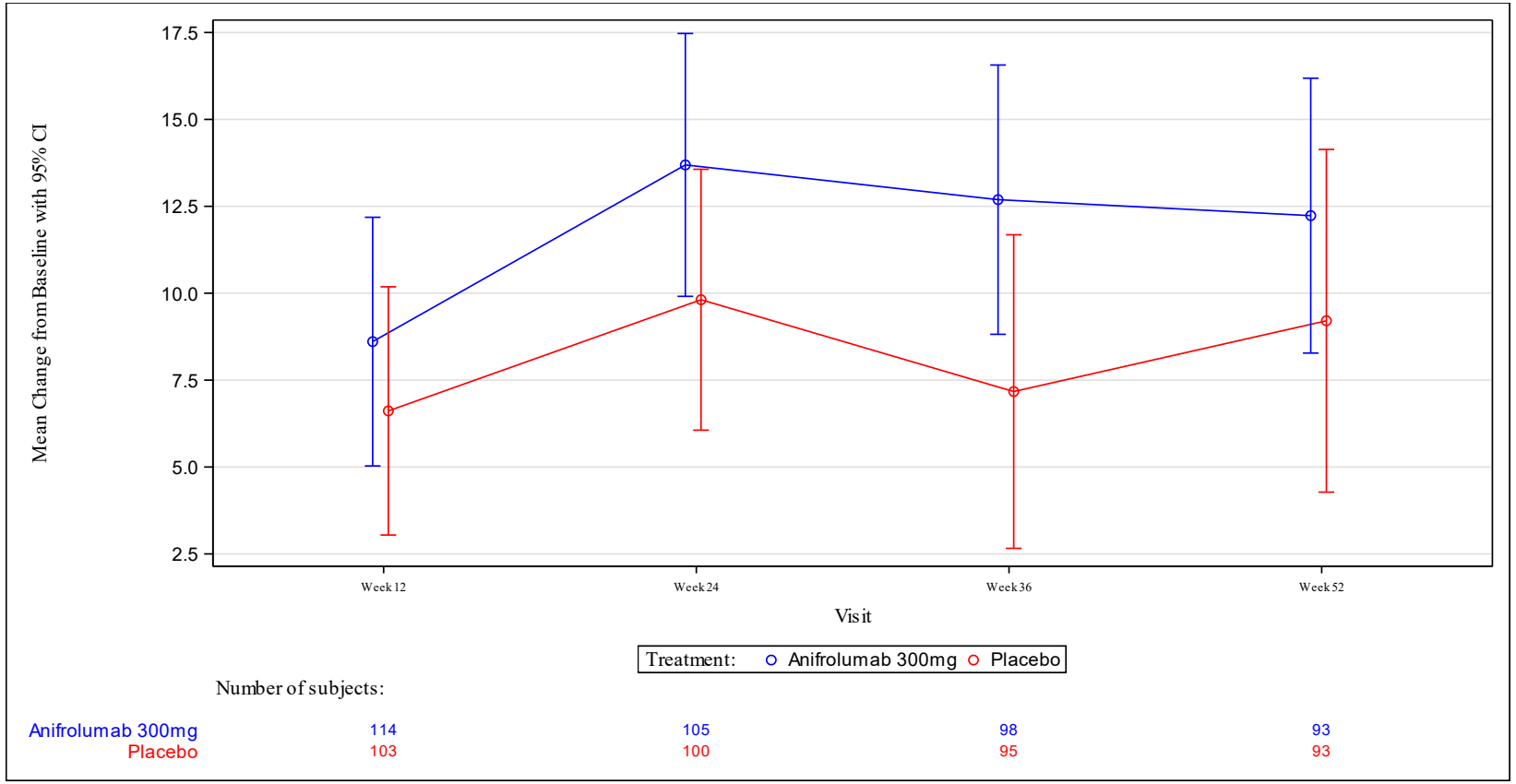
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Lupus QoL Burden to Others domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Fatigue domain score
Full analysis set

	Anifrolumab 300mg (N=127)				Placebo (N=125)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	122	47.08 (25.45)	0	-	117	49.68 (25.64)	0	-
Week 12	116	54.42 (27.50)	114	8.61 (19.28)	111	56.42 (26.78)	103	6.61 (18.27)
Week 24	110	58.92 (27.87)	105	13.69 (19.54)	107	59.40 (26.76)	100	9.81 (18.91)
Week 36	103	59.04 (27.75)	98	12.69 (19.32)	99	59.41 (26.75)	95	7.17 (22.14)
Week 52	98	58.35 (29.22)	93	12.23 (19.20)	98	60.33 (26.10)	93	9.21 (23.93)

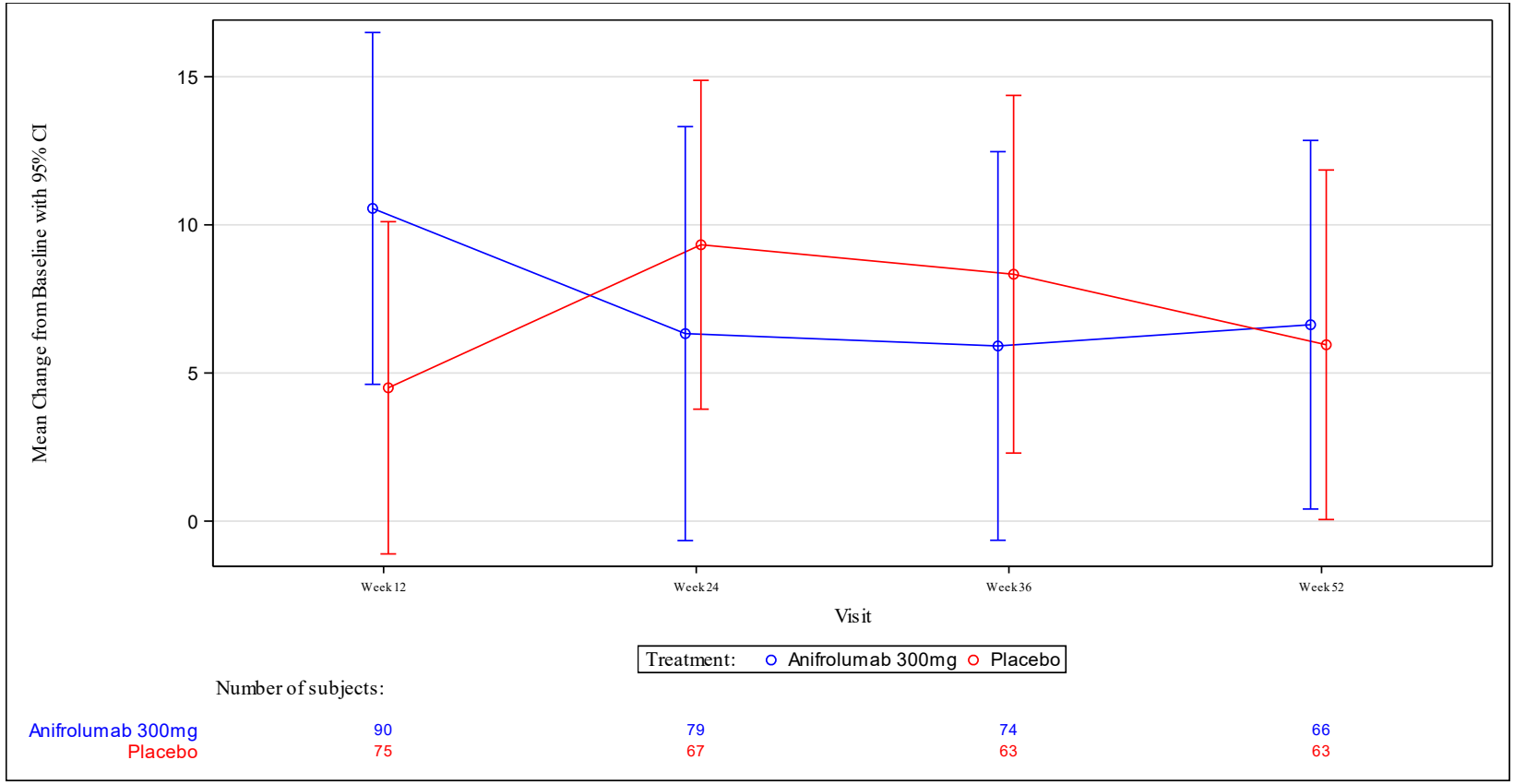
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Lupus QoL Fatigue domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Intimate Relationships domain score
Full analysis set

	Anifrolumab 300mg (N=127)				Placebo (N=125)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	106	52.95 (32.53)	0	-	98	59.82 (27.94)	0	-
Week 12	100	64.38 (31.70)	90	10.56 (28.35)	84	62.95 (30.28)	75	4.50 (24.37)
Week 24	89	61.52 (31.43)	79	6.33 (31.19)	76	67.11 (28.71)	67	9.33 (22.75)
Week 36	83	63.25 (32.51)	74	5.91 (28.31)	70	68.39 (28.21)	63	8.33 (23.97)
Week 52	78	66.19 (30.69)	66	6.63 (25.31)	69	66.49 (30.35)	63	5.95 (23.42)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Lupus QoL Intimate Relationships domain score
Full analysis set

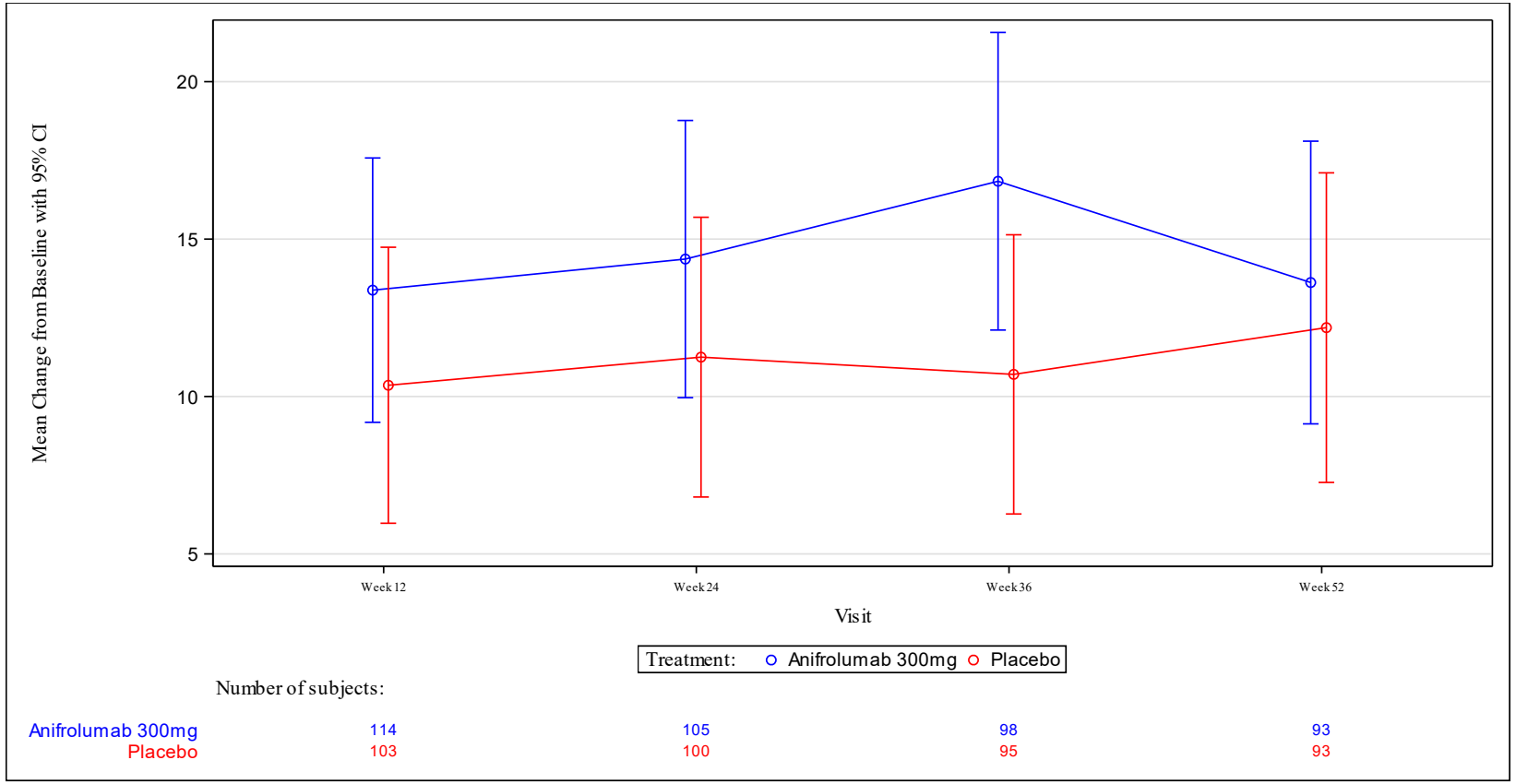


Number of subjects:				
Anifrolumab 300mg	90	79	74	66
Placebo	75	67	63	63

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Pain domain score
Full analysis set

	Anifrolumab 300mg (N=127)				Placebo (N=125)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	122	51.78 (27.24)	0	-	117	52.92 (27.05)	0	-
Week 12	116	63.94 (28.48)	114	13.38 (22.63)	111	62.39 (27.93)	103	10.36 (22.43)
Week 24	110	65.30 (27.71)	105	14.37 (22.75)	107	63.94 (27.18)	100	11.25 (22.39)
Week 36	103	68.37 (26.87)	98	16.84 (23.57)	99	64.56 (27.78)	95	10.70 (21.77)
Week 52	98	66.75 (27.51)	93	13.62 (21.80)	98	65.90 (26.38)	93	12.19 (23.87)

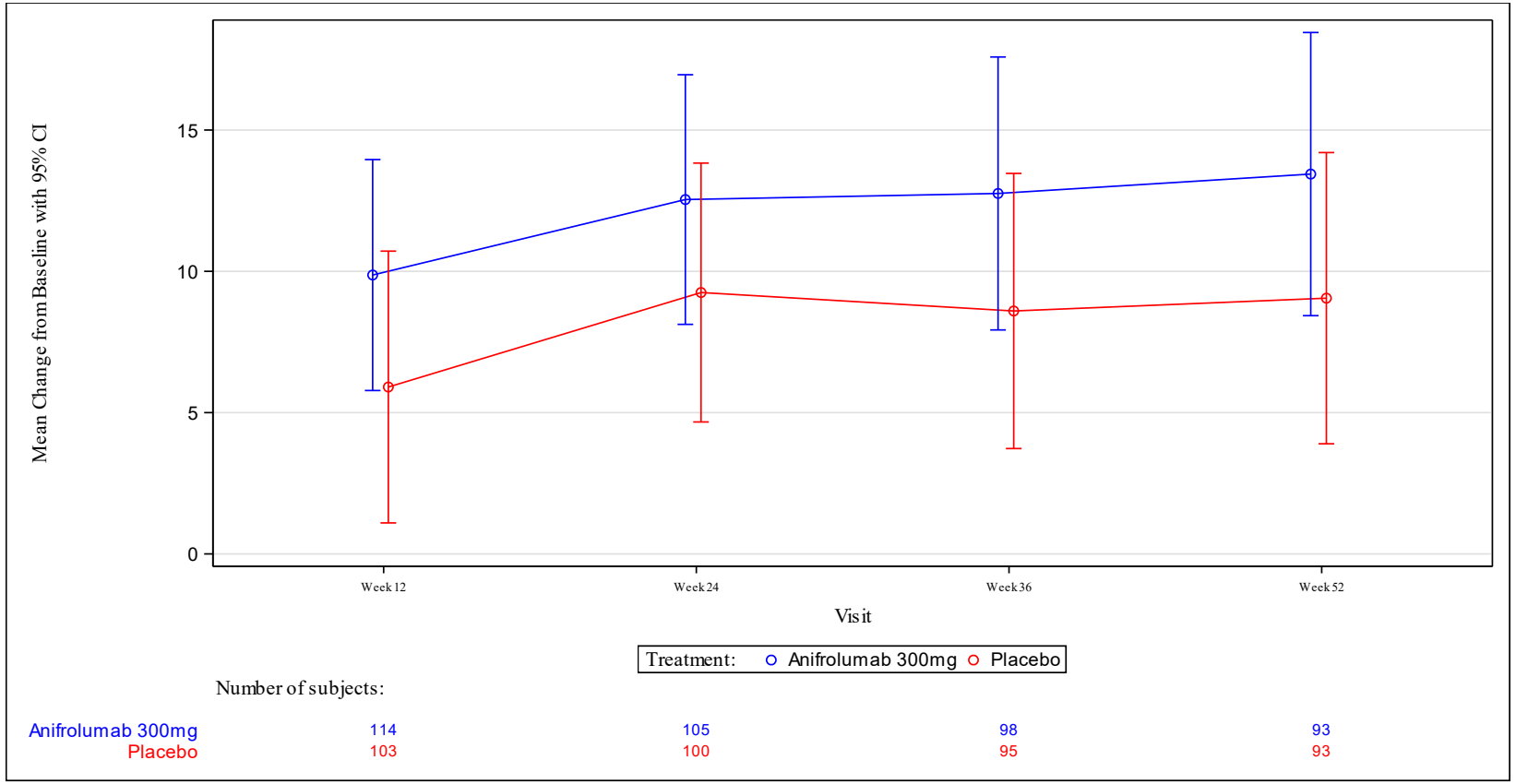
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Lupus QoL Pain domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Planning domain score
Full analysis set

	Anifrolumab 300mg (N=127)				Placebo (N=125)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	122	56.35 (29.85)	0	-	117	58.12 (29.53)	0	-
Week 12	116	64.58 (29.22)	114	9.87 (22.02)	111	63.81 (28.04)	103	5.91 (24.61)
Week 24	110	67.35 (28.98)	105	12.54 (22.83)	107	66.51 (28.18)	100	9.25 (23.09)
Week 36	103	67.96 (28.77)	98	12.76 (24.09)	99	68.77 (27.49)	95	8.60 (23.90)
Week 52	98	67.69 (29.46)	93	13.44 (24.33)	98	67.94 (27.14)	93	9.05 (25.02)

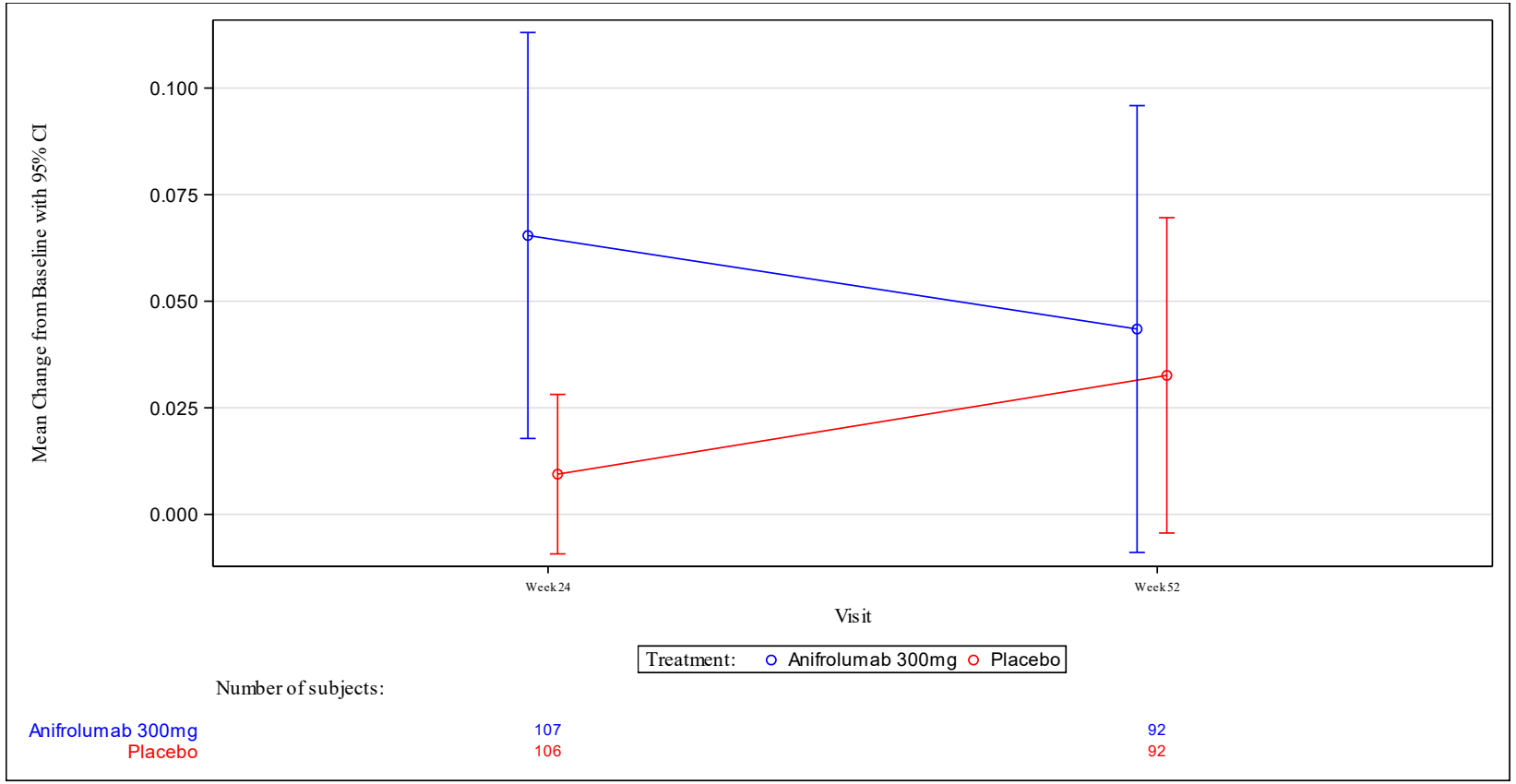
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Lupus QoL Planning domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - SDI Global Score
Full analysis set

	Anifrolumab 300mg (N=127)				Placebo (N=125)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	121	0.62 (1.13)	0	-	117	0.72 (1.05)	0	-
Week 24	109	0.67 (1.13)	107	0.07 (0.25)	110	0.75 (1.10)	106	0.01 (0.10)
Week 52	95	0.66 (1.10)	92	0.04 (0.25)	100	0.70 (1.05)	92	0.03 (0.18)

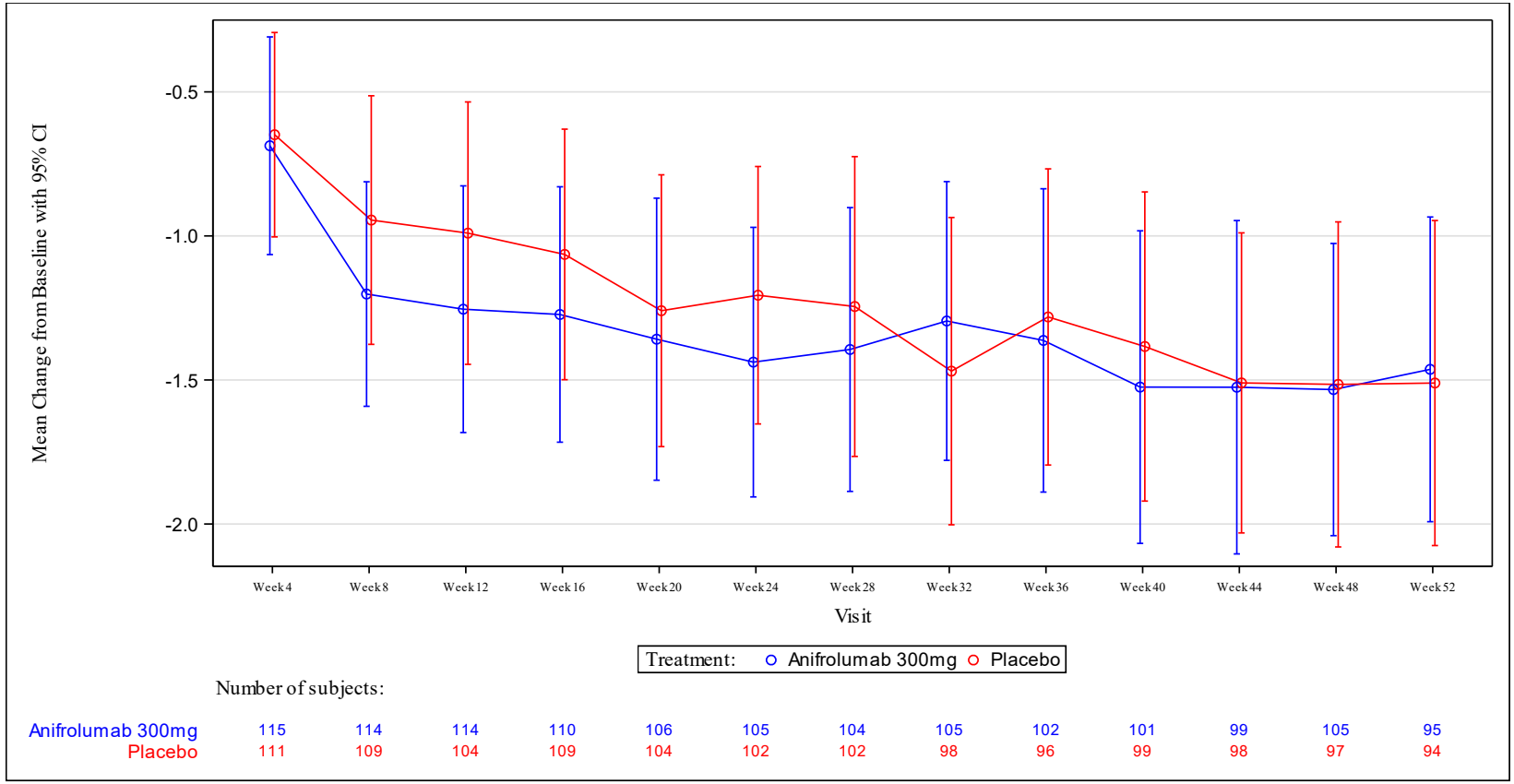
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - SDI Global Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - NRS Score
Full analysis set

	Anifrolumab 300mg (N=127)				Placebo (N=125)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	122	5.63 (2.51)	0	-	117	5.55 (2.34)	0	-
Week 4	118	5.03 (2.45)	115	-0.69 (2.04)	117	5.10 (2.61)	111	-0.65 (1.89)
Week 8	116	4.43 (2.53)	114	-1.20 (2.10)	117	4.82 (2.52)	109	-0.94 (2.27)
Week 12	116	4.38 (2.71)	114	-1.25 (2.31)	112	4.65 (2.62)	104	-0.99 (2.34)
Week 16	113	4.19 (2.68)	110	-1.27 (2.35)	116	4.63 (2.44)	109	-1.06 (2.29)
Week 20	109	4.10 (2.73)	106	-1.36 (2.54)	112	4.40 (2.46)	104	-1.26 (2.43)
Week 24	110	4.10 (2.67)	105	-1.44 (2.42)	109	4.50 (2.54)	102	-1.21 (2.27)
Week 28	108	4.06 (2.71)	104	-1.39 (2.53)	109	4.46 (2.59)	102	-1.25 (2.65)
Week 32	110	4.35 (2.60)	105	-1.30 (2.50)	104	4.18 (2.66)	98	-1.47 (2.66)
Week 36	107	4.13 (2.62)	102	-1.36 (2.68)	101	4.29 (2.58)	96	-1.28 (2.54)
Week 40	106	3.93 (2.67)	101	-1.52 (2.75)	106	4.37 (2.67)	99	-1.38 (2.69)
Week 44	102	3.88 (2.72)	99	-1.53 (2.90)	103	4.22 (2.64)	98	-1.51 (2.60)
Week 48	110	4.00 (2.72)	105	-1.53 (2.62)	102	4.10 (2.79)	97	-1.52 (2.80)
Week 52	100	4.03 (2.61)	95	-1.46 (2.60)	99	4.11 (2.71)	94	-1.51 (2.75)

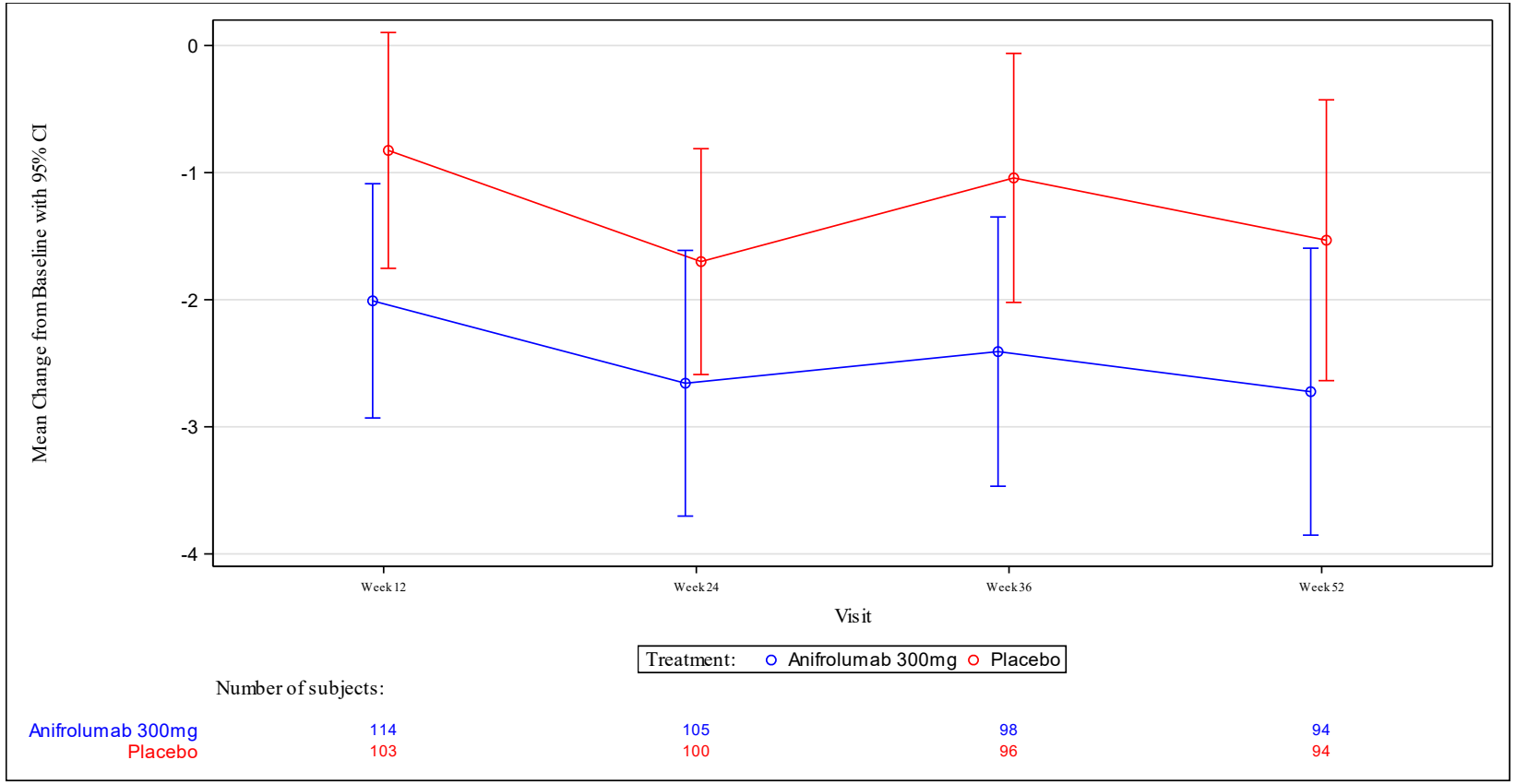
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - NRS Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - PHQ-8 Total Score
Full analysis set

	Anifrolumab 300mg (N=127)				Placebo (N=125)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	122	10.16 (6.30)	0	-	117	8.90 (5.96)	0	-
Week 12	116	8.54 (6.45)	114	-2.01 (4.97)	111	7.88 (6.08)	103	-0.83 (4.75)
Week 24	110	7.84 (6.04)	105	-2.66 (5.40)	107	7.59 (5.92)	100	-1.70 (4.48)
Week 36	103	8.27 (5.92)	98	-2.41 (5.28)	100	7.52 (6.01)	96	-1.04 (4.83)
Week 52	99	7.74 (5.96)	94	-2.72 (5.51)	99	7.07 (5.94)	94	-1.53 (5.39)

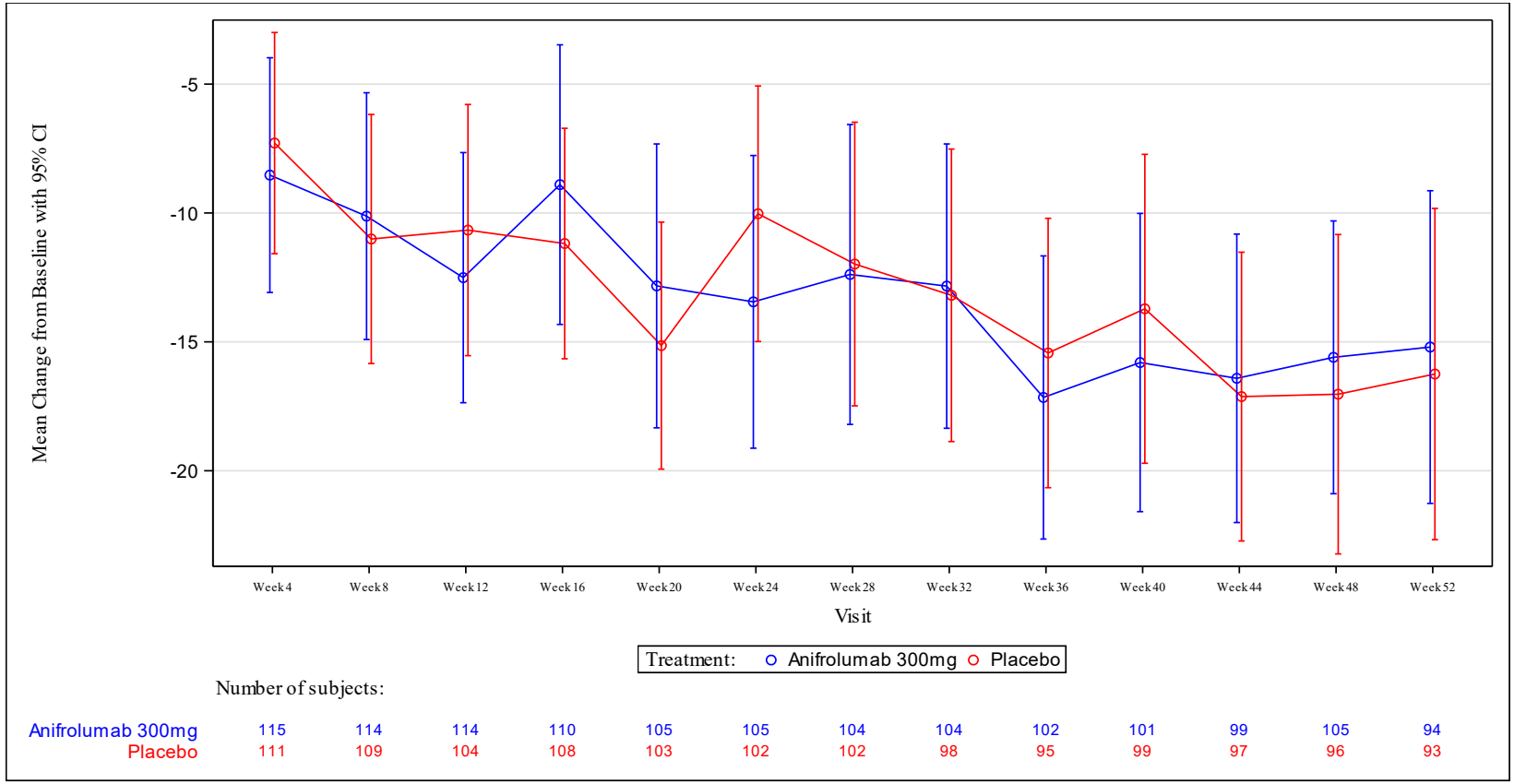
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - PHQ-8 Total Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - PtGA
Full analysis set

	Anifrolumab 300mg (N=127)				Placebo (N=125)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	122	56.06 (21.46)	0	-	117	54.49 (20.98)	0	-
Week 4	118	47.46 (21.23)	115	-8.53 (24.65)	117	48.89 (22.76)	111	-7.29 (22.81)
Week 8	116	45.66 (24.75)	114	-10.12 (25.80)	117	45.67 (22.66)	109	-11.01 (25.45)
Week 12	116	43.53 (24.09)	114	-12.51 (26.15)	112	45.23 (24.24)	104	-10.66 (25.05)
Week 16	113	46.59 (26.77)	110	-8.90 (28.70)	115	43.86 (24.02)	108	-11.19 (23.44)
Week 20	108	42.14 (26.26)	105	-12.83 (28.46)	110	39.58 (23.58)	103	-15.15 (24.51)
Week 24	110	42.95 (26.40)	105	-13.45 (29.34)	109	45.39 (25.12)	102	-10.03 (25.24)
Week 28	108	42.80 (26.00)	104	-12.38 (29.92)	109	42.30 (24.55)	102	-11.98 (28.01)
Week 32	109	43.20 (25.10)	104	-12.84 (28.36)	104	41.22 (25.45)	98	-13.19 (28.30)
Week 36	107	39.14 (23.77)	102	-17.16 (27.96)	100	37.51 (24.68)	95	-15.43 (25.65)
Week 40	106	40.61 (24.97)	101	-15.80 (29.30)	105	41.29 (26.81)	99	-13.72 (30.04)
Week 44	102	39.18 (24.68)	99	-16.41 (28.05)	102	38.46 (25.67)	97	-17.12 (27.79)
Week 48	110	39.92 (25.12)	105	-15.60 (27.34)	101	38.08 (26.00)	96	-17.03 (30.58)
Week 52	99	41.36 (26.40)	94	-15.20 (29.61)	98	39.91 (27.29)	93	-16.25 (31.20)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - PtGA
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SLEDAI-2K Total Score
Full analysis set

Visit	Anifrolumab 300mg (N=127) N	Anifrolumab 300mg (N=127) LSMean (SE)	Placebo (N=125) N	Placebo (N=125) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-0.68 (0.25)		-0.67 (0.25)	-0.00 (0.30)	(-0.59, 0.58)	0.9888			
Week 8		-1.71 (0.33)		-1.26 (0.33)	-0.44 (0.42)	(-1.27, 0.39)	0.2971			
Week 12		-3.35 (0.35)		-2.22 (0.35)	-1.13 (0.45)	(-2.02, -0.23)	0.0137			
Week 16		-3.98 (0.40)		-2.98 (0.40)	-1.00 (0.53)	(-2.04, 0.04)	0.0592			
Week 20		-4.82 (0.40)		-3.60 (0.40)	-1.22 (0.52)	(-2.26, -0.19)	0.0202			
Week 24		-5.01 (0.38)		-4.25 (0.39)	-0.76 (0.51)	(-1.76, 0.24)	0.1355			
Week 28		-5.17 (0.40)		-4.33 (0.41)	-0.84 (0.54)	(-1.90, 0.22)	0.1214			
Week 32		-5.64 (0.39)		-4.73 (0.39)	-0.92 (0.51)	(-1.93, 0.10)	0.0762			
Week 36		-5.68 (0.40)		-4.85 (0.40)	-0.84 (0.53)	(-1.88, 0.21)	0.1149			
Week 40		-5.49 (0.41)		-5.10 (0.41)	-0.38 (0.54)	(-1.46, 0.69)	0.4821			
Week 44		-5.69 (0.41)		-5.25 (0.41)	-0.44 (0.54)	(-1.50, 0.63)	0.4205			
Week 48		-5.68 (0.41)		-5.18 (0.42)	-0.50 (0.55)	(-1.59, 0.59)	0.3665			
Week 52		-5.99 (0.39)		-5.40 (0.39)	-0.59 (0.51)	(-1.59, 0.42)	0.2526			
OVERALL	126	-4.53 (0.32)	124	-3.83 (0.32)	-0.70 (0.40)	(-1.49, 0.10)	0.0860	-0.20 (0.13)	(-0.44, 0.05)	0.1236

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SLEDAI-2K Total Score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											0.7646
< 10 points	38	-3.81 (0.39)	37	-3.25 (0.39)	-0.56 (0.53)	(-1.62, 0.50)	0.2956	-0.23 (0.23)	(-0.69, 0.22)	0.3148	
>= 10 points	88	-4.53 (0.41)	87	-3.74 (0.42)	-0.79 (0.53)	(-1.84, 0.27)	0.1421	-0.20 (0.15)	(-0.50, 0.09)	0.1799	
OCS dose at baseline											0.0976
<10 mg/day	57	-3.86 (0.37)	52	-3.91 (0.39)	0.04 (0.51)	(-0.97, 1.06)	0.9315	0.02 (0.19)	(-0.36, 0.39)	0.9351	
>=10 mg/day	69	-4.97 (0.51)	72	-3.70 (0.50)	-1.27 (0.60)	(-2.46, -0.07)	0.0382	-0.30 (0.17)	(-0.63, 0.04)	0.0806	
Result of type I IFN gene signature test											0.3886
LOW	22	-3.17 (0.55)	24	-3.10 (0.51)	-0.07 (0.74)	(-1.57, 1.43)	0.9245	-0.03 (0.30)	(-0.61, 0.55)	0.9260	
HIGH	104	-4.95 (0.34)	100	-4.13 (0.35)	-0.83 (0.47)	(-1.74, 0.09)	0.0775	-0.24 (0.14)	(-0.51, 0.04)	0.0908	
Age (years)											NE
<= 65	121	-4.60 (0.33)	122	-3.81 (0.33)	-0.79 (0.41)	(-1.60, 0.03)	0.0574	-0.22 (0.13)	(-0.47, 0.04)	0.0933	
> 65	5	NE	2	NE	NE	NE		NE	NE		
Sex											NE
male	12	NE	7	NE	NE	NE		NE	NE		
female	114	-4.34 (0.33)	117	-3.92 (0.32)	-0.42 (0.41)	(-1.23, 0.39)	0.3059	-0.12 (0.13)	(-0.38, 0.14)	0.3594	
Race											NE
White	85	-3.98 (0.37)	95	-3.74 (0.35)	-0.24 (0.47)	(-1.16, 0.69)	0.6165	-0.07 (0.15)	(-0.36, 0.22)	0.6458	
Black or African American	21	-5.64 (0.83)	14	-4.37 (0.89)	-1.27 (1.17)	(-3.65, 1.10)	0.2830	-0.34 (0.35)	(-1.03, 0.34)	0.3226	
Asian	7	NE	3	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	NE	NE	NE		NE	NE		
Other	13	NE	11	NE	NE	NE		NE	NE		
Ethnicity											0.6742
Hispanic/Latino	23	-4.99 (0.84)	24	-3.89 (0.87)	-1.10 (1.01)	(-3.15, 0.95)	0.2843	-0.26 (0.29)	(-0.84, 0.31)	0.3739	
Non-hispanic/Latino	103	-4.49 (0.34)	100	-3.85 (0.34)	-0.64 (0.44)	(-1.50, 0.23)	0.1498	-0.19 (0.14)	(-0.46, 0.09)	0.1879	
Geographic region											0.2757
EU	47	-5.13 (0.53)	55	-3.81 (0.51)	-1.32 (0.65)	(-2.61, -0.03)	0.0453	-0.35 (0.20)	(-0.74, 0.04)	0.0789	
non-EU	79	-4.11 (0.40)	69	-3.70 (0.42)	-0.41 (0.52)	(-1.45, 0.63)	0.4361	-0.12 (0.16)	(-0.44, 0.21)	0.4833	
Onset of disease											NE
Paediatric	8	NE	7	NE	NE	NE		NE	NE		
Adult	118	-4.36 (0.32)	117	-3.80 (0.32)	-0.57 (0.41)	(-1.36, 0.23)	0.1650	-0.16 (0.13)	(-0.42, 0.09)	0.2119	
ADA result											0.1549
Negative	111	-4.53 (0.32)	111	-3.87 (0.33)	-0.66 (0.42)	(-1.49, 0.16)	0.1151	-0.19 (0.13)	(-0.46, 0.07)	0.1525	
Positive (At any time)	15	-5.38 (1.08)	13	-2.55 (1.10)	-2.83 (1.46)	(-5.91, 0.25)	0.0694	-0.67 (0.39)	(-1.44, 0.10)	0.0861	
BMI (kg/m2) at enrolment											0.3729
< 30	73	-4.85 (0.46)	86	-3.85 (0.43)	-0.99 (0.53)	(-2.03, 0.05)	0.0620	-0.25 (0.16)	(-0.56, 0.07)	0.1206	
>= 30	53	-4.04 (0.45)	38	-3.80 (0.52)	-0.24 (0.66)	(-1.55, 1.07)	0.7176	-0.07 (0.21)	(-0.49, 0.34)	0.7308	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score CNS
Full analysis set

Visit	Anifrolumab 300mg (N=127) N	Anifrolumab 300mg (N=127) LSMean (SE)	Placebo (N=125) N	Placebo (N=125) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		NE		NE	NE	NE				
Week 8		NE		NE	NE	NE				
Week 12		NE		NE	NE	NE				
Week 16		NE		NE	NE	NE				
Week 20		NE		NE	NE	NE				
Week 24		NE		NE	NE	NE				
Week 28		NE		NE	NE	NE				
Week 32		NE		NE	NE	NE				
Week 36		NE		NE	NE	NE				
Week 40		NE		NE	NE	NE				
Week 44		NE		NE	NE	NE				
Week 48		NE		NE	NE	NE				
Week 52		NE		NE	NE	NE				
OVERALL	126	NE	125	NE	NE	NE		NE	NE	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score CNS - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) N	LSMean (SE)	Placebo (N=125) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											NE
< 10 points	38	NE	37	NE	NE	NE		NE	NE		
>= 10 points	88	NE	88	NE	NE	NE		NE	NE		
OCS dose at baseline											NE
<10 mg/day	57	NE	52	NE	NE	NE		NE	NE		
>=10 mg/day	69	NE	73	NE	NE	NE		NE	NE		
Result of type I IFN gene signature test											NE
LOW	22	NE	24	NE	NE	NE		NE	NE		
HIGH	104	NE	101	NE	NE	NE		NE	NE		
Age (years)											NE
<= 65	121	NE	123	NE	NE	NE		NE	NE		
> 65	5	NE	2	NE	NE	NE		NE	NE		
Sex											NE
male	12	NE	8	NE	NE	NE		NE	NE		
female	114	NE	117	NE	NE	NE		NE	NE		
Race											NE
White	85	NE	96	NE	NE	NE		NE	NE		
Black or African American	21	NE	14	NE	NE	NE		NE	NE		
Asian	7	NE	3	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	NE	NE	NE		NE	NE		
Other	13	NE	11	NE	NE	NE		NE	NE		
Ethnicity											NE
Hispanic/Latino	23	NE	24	NE	NE	NE		NE	NE		
Non-hispanic/Latino	103	NE	101	NE	NE	NE		NE	NE		
Geographic region											NE
EU	47	NE	56	NE	NE	NE		NE	NE		
non-EU	79	NE	69	NE	NE	NE		NE	NE		
Onset of disease											NE
Paediatric	8	NE	7	NE	NE	NE		NE	NE		
Adult	118	NE	118	NE	NE	NE		NE	NE		
ADA result											NE
Negative	111	NE	112	NE	NE	NE		NE	NE		
Positive (At any time)	15	NE	13	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											NE
< 30	73	NE	87	NE	NE	NE		NE	NE		
>= 30	53	NE	38	NE	NE	NE		NE	NE		

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score CVS and Respiratory
Full analysis set

Visit	Anifrolumab 300mg (N=127) N	Anifrolumab 300mg (N=127) LSMean (SE)	Placebo (N=125) N	Placebo (N=125) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		NE		NE	NE	NE				
Week 8		NE		NE	NE	NE				
Week 12		NE		NE	NE	NE				
Week 16		NE		NE	NE	NE				
Week 20		NE		NE	NE	NE				
Week 24		NE		NE	NE	NE				
Week 28		NE		NE	NE	NE				
Week 32		NE		NE	NE	NE				
Week 36		NE		NE	NE	NE				
Week 40		NE		NE	NE	NE				
Week 44		NE		NE	NE	NE				
Week 48		NE		NE	NE	NE				
Week 52		NE		NE	NE	NE				
OVERALL	126	NE	125	NE	NE	NE		NE	NE	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score CVS and Respiratory - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											NE
< 10 points	38	NE	37	NE	NE	NE		NE	NE		
>= 10 points	88	NE	88	NE	NE	NE		NE	NE		
OCS dose at baseline											NE
<10 mg/day	57	NE	52	NE	NE	NE		NE	NE		
>=10 mg/day	69	NE	73	NE	NE	NE		NE	NE		
Result of type I IFN gene signature test											NE
LOW	22	NE	24	NE	NE	NE		NE	NE		
HIGH	104	NE	101	NE	NE	NE		NE	NE		
Age (years)											NE
<= 65	121	NE	123	NE	NE	NE		NE	NE		
> 65	5	NE	2	NE	NE	NE		NE	NE		
Sex											NE
male	12	NE	8	NE	NE	NE		NE	NE		
female	114	NE	117	NE	NE	NE		NE	NE		
Race											NE
White	85	NE	96	NE	NE	NE		NE	NE		
Black or African American	21	NE	14	NE	NE	NE		NE	NE		
Asian	7	NE	3	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	NE	NE	NE		NE	NE		
Other	13	NE	11	NE	NE	NE		NE	NE		
Ethnicity											NE
Hispanic/Latino	23	NE	24	NE	NE	NE		NE	NE		
Non-hispanic/Latino	103	NE	101	NE	NE	NE		NE	NE		
Geographic region											NE
EU	47	NE	56	NE	NE	NE		NE	NE		
non-EU	79	NE	69	NE	NE	NE		NE	NE		
Onset of disease											NE
Paediatric	8	NE	7	NE	NE	NE		NE	NE		
Adult	118	NE	118	NE	NE	NE		NE	NE		
ADA result											NE
Negative	111	NE	112	NE	NE	NE		NE	NE		
Positive (At any time)	15	NE	13	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											NE
< 30	73	NE	87	NE	NE	NE		NE	NE		
>= 30	53	NE	38	NE	NE	NE		NE	NE		

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score Hematological
Full analysis set

	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-0.07 (0.02)		-0.01 (0.02)	-0.06 (0.03)	(-0.13, 0.00)	0.0632			
Week 8		-0.09 (0.02)		-0.03 (0.02)	-0.06 (0.03)	(-0.12, 0.00)	0.0652			
Week 12		-0.10 (0.02)		-0.01 (0.02)	-0.08 (0.03)	(-0.15, -0.02)	0.0140			
Week 16		-0.09 (0.02)		-0.02 (0.02)	-0.06 (0.03)	(-0.13, -0.00)	0.0407			
Week 20		-0.10 (0.02)		-0.05 (0.02)	-0.05 (0.03)	(-0.11, 0.00)	0.0638			
Week 24		-0.09 (0.02)		-0.04 (0.02)	-0.05 (0.03)	(-0.11, 0.02)	0.1400			
Week 28		-0.09 (0.02)		-0.03 (0.02)	-0.06 (0.03)	(-0.12, 0.00)	0.0605			
Week 32		-0.10 (0.02)		-0.03 (0.02)	-0.07 (0.03)	(-0.13, -0.00)	0.0474			
Week 36		-0.08 (0.02)		-0.05 (0.02)	-0.03 (0.03)	(-0.09, 0.03)	0.3532			
Week 40		-0.09 (0.02)		-0.08 (0.02)	-0.01 (0.03)	(-0.06, 0.04)	0.5968			
Week 44		-0.07 (0.02)		-0.06 (0.02)	-0.01 (0.03)	(-0.07, 0.05)	0.7255			
Week 48		-0.08 (0.03)		-0.05 (0.03)	-0.03 (0.04)	(-0.10, 0.04)	0.4231			
Week 52		-0.11 (0.02)		-0.08 (0.02)	-0.03 (0.02)	(-0.07, 0.02)	0.2741			
OVERALL	126	-0.09 (0.01)	125	-0.04 (0.01)	-0.05 (0.02)	(-0.08, -0.01)	0.0114	-0.28 (0.13)	(-0.53, -0.03)	0.0270

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score Hematological - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											NE
< 10 points	38	NE	37	NE	NE	NE		NE	NE		
>= 10 points	88	-0.10 (0.02)	88	-0.06 (0.02)	-0.03 (0.02)	(-0.08, 0.02)	0.1875	-0.18 (0.15)	(-0.47, 0.12)	0.2399	
OCS dose at baseline											NE
<10 mg/day	57	NE	52	NE	NE	NE		NE	NE		
>=10 mg/day	69	-0.10 (0.02)	73	-0.04 (0.02)	-0.06 (0.03)	(-0.12, -0.01)	0.0181	-0.34 (0.17)	(-0.67, -0.00)	0.0474	
Result of type I IFN gene signature test											NE
LOW	22	NE	24	NE	NE	NE		NE	NE		
HIGH	104	-0.08 (0.02)	101	-0.03 (0.02)	-0.05 (0.02)	(-0.09, -0.01)	0.0226	-0.31 (0.14)	(-0.58, -0.03)	0.0291	
Age (years)											NE
<= 65	121	-0.09 (0.02)	123	-0.05 (0.02)	-0.05 (0.02)	(-0.08, -0.01)	0.0117	-0.28 (0.13)	(-0.53, -0.03)	0.0302	
> 65	5	NE	2	NE	NE	NE		NE	NE		
Sex											NE
male	12	NE	8	NE	NE	NE		NE	NE		
female	114	-0.09 (0.02)	117	-0.05 (0.02)	-0.04 (0.02)	(-0.08, -0.01)	0.0256	-0.26 (0.13)	(-0.52, -0.00)	0.0491	
Race											NE
White	85	-0.06 (0.02)	96	-0.03 (0.02)	-0.03 (0.02)	(-0.07, 0.01)	0.1119	-0.22 (0.15)	(-0.51, 0.08)	0.1497	
Black or African American	21	NE	14	NE	NE	NE		NE	NE		
Asian	7	NE	3	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	NE	NE	NE		NE	NE		
Other	13	NE	11	NE	NE	NE		NE	NE		
Ethnicity											NE
Hispanic/Latino	23	NE	24	NE	NE	NE		NE	NE		
Non-hispanic/Latino	103	-0.08 (0.01)	101	-0.05 (0.01)	-0.04 (0.02)	(-0.07, -0.00)	0.0457	-0.25 (0.14)	(-0.53, 0.03)	0.0749	
Geographic region											0.2301
EU	47	-0.08 (0.02)	56	-0.01 (0.02)	-0.07 (0.03)	(-0.12, -0.02)	0.0059	-0.45 (0.20)	(-0.84, -0.06)	0.0251	
non-EU	79	-0.08 (0.02)	69	-0.05 (0.02)	-0.03 (0.03)	(-0.08, 0.02)	0.2907	-0.16 (0.17)	(-0.48, 0.16)	0.3323	
Onset of disease											NE
Paediatric	8	NE	7	NE	NE	NE		NE	NE		
Adult	118	-0.09 (0.01)	118	-0.04 (0.01)	-0.06 (0.02)	(-0.09, -0.02)	0.0010	-0.38 (0.13)	(-0.63, -0.12)	0.0042	
ADA result											NE
Negative	111	-0.08 (0.02)	112	-0.03 (0.02)	-0.05 (0.02)	(-0.09, -0.02)	0.0054	-0.34 (0.13)	(-0.60, -0.07)	0.0126	
Positive (At any time)	15	NE	13	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											NE
< 30	73	-0.12 (0.02)	87	-0.06 (0.02)	-0.06 (0.03)	(-0.11, -0.01)	0.0311	-0.28 (0.16)	(-0.60, 0.03)	0.0765	
>= 30	53	NE	38	NE	NE	NE		NE	NE		

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score Immunology
Full analysis set

	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-0.17 (0.08)		-0.13 (0.08)	-0.04 (0.09)	(-0.22, 0.15)	0.6909			
Week 8		-0.18 (0.09)		-0.07 (0.08)	-0.11 (0.10)	(-0.31, 0.10)	0.2962			
Week 12		-0.27 (0.09)		-0.04 (0.09)	-0.23 (0.11)	(-0.46, -0.01)	0.0410			
Week 16		-0.30 (0.10)		-0.07 (0.10)	-0.24 (0.12)	(-0.47, 0.00)	0.0514			
Week 20		-0.29 (0.10)		-0.00 (0.10)	-0.29 (0.13)	(-0.54, -0.03)	0.0275			
Week 24		-0.37 (0.10)		-0.20 (0.10)	-0.16 (0.13)	(-0.42, 0.10)	0.2153			
Week 28		-0.38 (0.10)		-0.17 (0.10)	-0.21 (0.13)	(-0.46, 0.04)	0.1045			
Week 32		-0.34 (0.10)		-0.19 (0.10)	-0.15 (0.13)	(-0.39, 0.10)	0.2456			
Week 36		-0.30 (0.10)		-0.14 (0.09)	-0.16 (0.12)	(-0.40, 0.07)	0.1694			
Week 40		-0.22 (0.10)		-0.18 (0.10)	-0.04 (0.13)	(-0.30, 0.22)	0.7569			
Week 44		-0.23 (0.10)		-0.27 (0.10)	0.04 (0.13)	(-0.22, 0.30)	0.7621			
Week 48		-0.30 (0.11)		-0.12 (0.11)	-0.18 (0.15)	(-0.46, 0.11)	0.2252			
Week 52		-0.25 (0.11)		-0.15 (0.11)	-0.10 (0.14)	(-0.37, 0.17)	0.4823			
OVERALL	126	-0.28 (0.08)	125	-0.13 (0.08)	-0.14 (0.09)	(-0.32, 0.03)	0.1080	-0.17 (0.13)	(-0.42, 0.08)	0.1858

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score Immunology - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											0.9993
< 10 points	38	-0.05 (0.07)	37	0.09 (0.07)	-0.14 (0.09)	(-0.32, 0.03)	0.1112	-0.35 (0.23)	(-0.80, 0.11)	0.1376	
>= 10 points	88	-0.35 (0.10)	88	-0.21 (0.10)	-0.14 (0.12)	(-0.38, 0.09)	0.2263	-0.16 (0.15)	(-0.45, 0.14)	0.3023	
OCS dose at baseline											0.1098
<10 mg/day	57	-0.09 (0.08)	52	-0.09 (0.08)	-0.00 (0.10)	(-0.20, 0.20)	0.9979	-0.00 (0.19)	(-0.38, 0.38)	0.9981	
>=10 mg/day	69	-0.42 (0.13)	73	-0.15 (0.12)	-0.27 (0.14)	(-0.54, -0.00)	0.0461	-0.25 (0.17)	(-0.58, 0.08)	0.1315	
Result of type I IFN gene signature test											0.1208
LOW	22	-0.25 (0.11)	24	0.11 (0.10)	-0.37 (0.14)	(-0.66, -0.08)	0.0144	-0.73 (0.31)	(-1.33, -0.13)	0.0173	
HIGH	104	-0.26 (0.08)	101	-0.16 (0.08)	-0.09 (0.10)	(-0.30, 0.11)	0.3790	-0.12 (0.14)	(-0.39, 0.16)	0.4103	
Age (years)											NE
<= 65	121	-0.28 (0.08)	123	-0.14 (0.08)	-0.15 (0.09)	(-0.32, 0.03)	0.1115	-0.16 (0.13)	(-0.42, 0.09)	0.1991	
> 65	5	NE	2	NE	NE	NE		NE	NE		
Sex											NE
male	12	NE	8	NE	NE	NE		NE	NE		
female	114	-0.27 (0.08)	117	-0.11 (0.08)	-0.16 (0.09)	(-0.34, 0.02)	0.0727	-0.20 (0.13)	(-0.45, 0.06)	0.1374	
Race											NE
White	85	-0.14 (0.08)	96	-0.17 (0.08)	0.03 (0.10)	(-0.16, 0.22)	0.7581	0.04 (0.15)	(-0.25, 0.33)	0.7939	
Black or African American	21	-0.51 (0.16)	14	-0.16 (0.15)	-0.35 (0.21)	(-0.78, 0.08)	0.1085	-0.50 (0.35)	(-1.18, 0.19)	0.1580	
Asian	7	NE	3	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	NE	NE	NE		NE	NE		
Other	13	NE	11	NE	NE	NE		NE	NE		
Ethnicity											0.5713
Hispanic/Latino	23	-0.29 (0.26)	24	0.02 (0.27)	-0.30 (0.31)	(-0.93, 0.33)	0.3391	-0.23 (0.29)	(-0.80, 0.34)	0.4320	
Non-hispanic/Latino	103	-0.24 (0.08)	101	-0.12 (0.08)	-0.12 (0.09)	(-0.29, 0.06)	0.1908	-0.15 (0.14)	(-0.43, 0.12)	0.2766	
Geographic region											0.3848
EU	47	-0.22 (0.14)	56	-0.18 (0.13)	-0.04 (0.14)	(-0.31, 0.23)	0.7832	-0.04 (0.20)	(-0.43, 0.35)	0.8437	
non-EU	79	-0.26 (0.09)	69	-0.07 (0.10)	-0.20 (0.12)	(-0.43, 0.04)	0.1025	-0.23 (0.17)	(-0.56, 0.09)	0.1570	
Onset of disease											NE
Paediatric	8	NE	7	NE	NE	NE		NE	NE		
Adult	118	-0.28 (0.08)	118	-0.13 (0.08)	-0.15 (0.09)	(-0.33, 0.03)	0.1097	-0.17 (0.13)	(-0.43, 0.08)	0.1886	
ADA result											NE
Negative	111	-0.27 (0.08)	112	-0.12 (0.08)	-0.16 (0.10)	(-0.35, 0.03)	0.0988	-0.19 (0.13)	(-0.45, 0.08)	0.1656	
Positive (At any time)	15	NE	13	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.8723
< 30	73	-0.35 (0.12)	87	-0.21 (0.11)	-0.14 (0.12)	(-0.39, 0.10)	0.2453	-0.14 (0.16)	(-0.45, 0.17)	0.3851	
>= 30	53	-0.17 (0.08)	38	-0.05 (0.09)	-0.12 (0.12)	(-0.35, 0.11)	0.3201	-0.19 (0.21)	(-0.61, 0.23)	0.3665	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score Mucocutaneous
Full analysis set

	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		0.02 (0.08)		-0.08 (0.07)	0.10 (0.09)	(-0.08, 0.28)	0.2585			
Week 8		-0.30 (0.10)		-0.34 (0.10)	0.04 (0.13)	(-0.21, 0.30)	0.7494			
Week 12		-0.85 (0.12)		-0.62 (0.12)	-0.23 (0.16)	(-0.55, 0.09)	0.1550			
Week 16		-1.23 (0.14)		-1.02 (0.14)	-0.21 (0.19)	(-0.59, 0.17)	0.2727			
Week 20		-1.55 (0.15)		-1.16 (0.15)	-0.38 (0.20)	(-0.78, 0.01)	0.0569			
Week 24		-1.65 (0.15)		-1.30 (0.15)	-0.35 (0.21)	(-0.76, 0.07)	0.1012			
Week 28		-1.78 (0.16)		-1.38 (0.16)	-0.40 (0.22)	(-0.84, 0.04)	0.0725			
Week 32		-1.97 (0.16)		-1.51 (0.16)	-0.46 (0.22)	(-0.90, -0.02)	0.0393			
Week 36		-2.05 (0.17)		-1.56 (0.17)	-0.49 (0.23)	(-0.94, -0.03)	0.0353			
Week 40		-2.08 (0.18)		-1.70 (0.18)	-0.39 (0.24)	(-0.86, 0.09)	0.1134			
Week 44		-2.20 (0.18)		-1.71 (0.18)	-0.50 (0.24)	(-0.98, -0.02)	0.0431			
Week 48		-2.22 (0.18)		-1.72 (0.18)	-0.49 (0.25)	(-0.98, 0.00)	0.0508			
Week 52		-2.27 (0.17)		-1.78 (0.17)	-0.49 (0.24)	(-0.96, -0.02)	0.0422			
OVERALL	126	-1.55 (0.12)	125	-1.22 (0.12)	-0.33 (0.16)	(-0.65, -0.00)	0.0469	-0.24 (0.13)	(-0.49, 0.01)	0.0598

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score Mucocutaneous - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) N	LSMean (SE)	Placebo (N=125) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.7097
< 10 points	38	-1.53 (0.23)	37	-1.09 (0.23)	-0.44 (0.31)	(-1.06, 0.19)	0.1705	-0.30 (0.23)	(-0.76, 0.15)	0.1909	
>= 10 points	88	-1.55 (0.14)	88	-1.25 (0.14)	-0.30 (0.19)	(-0.68, 0.08)	0.1246	-0.22 (0.15)	(-0.52, 0.07)	0.1429	
OCS dose at baseline											0.0640
<10 mg/day	57	-1.36 (0.18)	52	-1.34 (0.19)	-0.02 (0.25)	(-0.52, 0.48)	0.9356	-0.01 (0.19)	(-0.39, 0.36)	0.9385	
>=10 mg/day	69	-1.74 (0.16)	73	-1.11 (0.16)	-0.63 (0.22)	(-1.06, -0.21)	0.0040	-0.46 (0.17)	(-0.79, -0.13)	0.0068	
Result of type I IFN gene signature test											0.8853
LOW	22	-1.46 (0.26)	24	-1.09 (0.24)	-0.38 (0.35)	(-1.09, 0.34)	0.2937	-0.31 (0.30)	(-0.89, 0.27)	0.2987	
HIGH	104	-1.65 (0.13)	101	-1.34 (0.14)	-0.32 (0.19)	(-0.69, 0.05)	0.0917	-0.23 (0.14)	(-0.51, 0.04)	0.0975	
Age (years)											NE
<= 65	121	-1.56 (0.13)	123	-1.22 (0.12)	-0.34 (0.17)	(-0.67, -0.01)	0.0432	-0.24 (0.13)	(-0.50, 0.01)	0.0570	
> 65	5	NE	2	NE	NE	NE		NE	NE		
Sex											NE
male	12	NE	8	NE	NE	NE		NE	NE		
female	114	-1.50 (0.13)	117	-1.27 (0.13)	-0.22 (0.17)	(-0.56, 0.11)	0.1886	-0.16 (0.13)	(-0.42, 0.09)	0.2122	
Race											NE
White	85	-1.47 (0.15)	96	-1.17 (0.15)	-0.29 (0.20)	(-0.69, 0.11)	0.1494	-0.21 (0.15)	(-0.50, 0.09)	0.1690	
Black or African American	21	-1.78 (0.32)	14	-1.74 (0.33)	-0.04 (0.43)	(-0.93, 0.85)	0.9311	-0.03 (0.35)	(-0.70, 0.65)	0.9386	
Asian	7	NE	3	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	NE	NE	NE		NE	NE		
Other	13	-1.41 (0.38)	11	-0.30 (0.41)	-1.11 (0.42)	(-1.99, -0.22)	0.0165	-0.79 (0.43)	(-1.63, 0.05)	0.0644	
Ethnicity											0.4897
Hispanic/Latino	23	-1.44 (0.32)	24	-1.39 (0.33)	-0.05 (0.41)	(-0.88, 0.79)	0.9104	-0.03 (0.29)	(-0.60, 0.54)	0.9204	
Non-hispanic/Latino	103	-1.61 (0.13)	101	-1.25 (0.13)	-0.36 (0.18)	(-0.71, -0.00)	0.0493	-0.26 (0.14)	(-0.54, 0.01)	0.0603	
Geographic region											0.1650
EU	47	-1.78 (0.20)	56	-1.12 (0.18)	-0.66 (0.26)	(-1.18, -0.14)	0.0143	-0.48 (0.20)	(-0.87, -0.09)	0.0170	
non-EU	79	-1.42 (0.16)	69	-1.23 (0.17)	-0.19 (0.22)	(-0.62, 0.25)	0.3974	-0.13 (0.16)	(-0.45, 0.19)	0.4251	
Onset of disease											NE
Paediatric	8	NE	7	NE	NE	NE		NE	NE		
Adult	118	-1.55 (0.13)	118	-1.20 (0.13)	-0.35 (0.17)	(-0.68, -0.02)	0.0377	-0.26 (0.13)	(-0.51, -0.00)	0.0495	
ADA result											NE
Negative	111	-1.56 (0.13)	112	-1.19 (0.13)	-0.38 (0.17)	(-0.72, -0.03)	0.0316	-0.28 (0.13)	(-0.54, -0.01)	0.0408	
Positive (At any time)	15	NE	13	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.4207
< 30	73	-1.69 (0.15)	87	-1.23 (0.14)	-0.46 (0.19)	(-0.84, -0.07)	0.0197	-0.34 (0.16)	(-0.66, -0.03)	0.0312	
>= 30	53	-1.33 (0.20)	38	-1.16 (0.23)	-0.17 (0.30)	(-0.77, 0.43)	0.5769	-0.11 (0.21)	(-0.53, 0.30)	0.5912	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score Musculoskeletal
Full analysis set

Visit	Anifrolumab 300mg (N=127) N	Anifrolumab 300mg (N=127) LSMean (SE)	Placebo (N=125) N	Placebo (N=125) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-0.09 (0.11)		-0.02 (0.11)	-0.06 (0.13)	(-0.32, 0.19)	0.6281			
Week 8		-0.57 (0.15)		-0.45 (0.15)	-0.12 (0.20)	(-0.52, 0.28)	0.5624			
Week 12		-1.16 (0.18)		-1.00 (0.18)	-0.16 (0.24)	(-0.64, 0.32)	0.5142			
Week 16		-1.48 (0.19)		-1.44 (0.19)	-0.03 (0.25)	(-0.53, 0.46)	0.8926			
Week 20		-1.93 (0.19)		-1.66 (0.19)	-0.27 (0.26)	(-0.78, 0.24)	0.2983			
Week 24		-2.05 (0.19)		-1.84 (0.19)	-0.21 (0.26)	(-0.72, 0.30)	0.4229			
Week 28		-2.17 (0.19)		-1.87 (0.19)	-0.30 (0.26)	(-0.81, 0.21)	0.2407			
Week 32		-2.36 (0.19)		-2.22 (0.19)	-0.14 (0.26)	(-0.65, 0.36)	0.5776			
Week 36		-2.44 (0.19)		-2.27 (0.19)	-0.17 (0.26)	(-0.68, 0.34)	0.5100			
Week 40		-2.27 (0.19)		-2.30 (0.19)	0.03 (0.26)	(-0.48, 0.54)	0.9094			
Week 44		-2.31 (0.19)		-2.28 (0.19)	-0.03 (0.26)	(-0.53, 0.48)	0.9182			
Week 48		-2.19 (0.19)		-2.42 (0.19)	0.23 (0.25)	(-0.27, 0.73)	0.3709			
Week 52		-2.39 (0.19)		-2.58 (0.19)	0.18 (0.25)	(-0.31, 0.68)	0.4678			
OVERALL	126	-1.80 (0.14)	125	-1.72 (0.14)	-0.08 (0.19)	(-0.45, 0.28)	0.6628	-0.05 (0.13)	(-0.30, 0.20)	0.6875

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score Musculoskeletal - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											0.7493
< 10 points	38	-1.85 (0.26)	37	-1.86 (0.26)	0.01 (0.36)	(-0.70, 0.72)	0.9676	0.01 (0.23)	(-0.44, 0.46)	0.9688	
>= 10 points	88	-1.78 (0.17)	88	-1.66 (0.17)	-0.12 (0.22)	(-0.55, 0.32)	0.5892	-0.08 (0.15)	(-0.37, 0.22)	0.6184	
OCS dose at baseline											0.8563
<10 mg/day	57	-1.85 (0.20)	52	-1.77 (0.21)	-0.08 (0.28)	(-0.64, 0.48)	0.7893	-0.05 (0.19)	(-0.43, 0.33)	0.7963	
>=10 mg/day	69	-1.83 (0.20)	73	-1.68 (0.19)	-0.14 (0.24)	(-0.62, 0.34)	0.5560	-0.09 (0.17)	(-0.41, 0.24)	0.6101	
Result of type I IFN gene signature test											NE
LOW	22	NE	24	NE	NE	NE		NE	NE		
HIGH	104	-2.05 (0.15)	101	-1.89 (0.15)	-0.16 (0.21)	(-0.57, 0.24)	0.4346	-0.11 (0.14)	(-0.38, 0.17)	0.4470	
Age (years)											NE
<= 65	121	-1.82 (0.15)	123	-1.70 (0.15)	-0.12 (0.19)	(-0.49, 0.26)	0.5370	-0.07 (0.13)	(-0.32, 0.18)	0.5738	
> 65	5	NE	2	NE	NE	NE		NE	NE		
Sex											NE
male	12	NE	8	NE	NE	NE		NE	NE		
female	114	-1.80 (0.15)	117	-1.69 (0.15)	-0.11 (0.19)	(-0.49, 0.28)	0.5820	-0.07 (0.13)	(-0.32, 0.19)	0.6115	
Race											NE
White	85	-1.80 (0.17)	96	-1.89 (0.16)	0.09 (0.22)	(-0.35, 0.54)	0.6767	0.06 (0.15)	(-0.23, 0.35)	0.6900	
Black or African American	21	NE	14	NE	NE	NE		NE	NE		
Asian	7	NE	3	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	NE	NE	NE		NE	NE		
Other	13	NE	11	NE	NE	NE		NE	NE		
Ethnicity											0.3737
Hispanic/Latino	23	-2.05 (0.37)	24	-1.59 (0.41)	-0.45 (0.44)	(-1.34, 0.43)	0.3088	-0.23 (0.29)	(-0.81, 0.34)	0.4264	
Non-hispanic/Latino	103	-1.75 (0.16)	101	-1.73 (0.16)	-0.02 (0.21)	(-0.43, 0.39)	0.9219	-0.01 (0.14)	(-0.29, 0.26)	0.9272	
Geographic region											0.9140
EU	47	-2.24 (0.22)	56	-2.12 (0.21)	-0.12 (0.28)	(-0.68, 0.44)	0.6769	-0.08 (0.20)	(-0.46, 0.31)	0.6994	
non-EU	79	-1.55 (0.18)	69	-1.47 (0.19)	-0.08 (0.25)	(-0.57, 0.41)	0.7556	-0.05 (0.16)	(-0.37, 0.28)	0.7749	
Onset of disease											NE
Paediatric	8	NE	7	NE	NE	NE		NE	NE		
Adult	118	-1.87 (0.15)	118	-1.71 (0.15)	-0.15 (0.19)	(-0.53, 0.22)	0.4169	-0.10 (0.13)	(-0.35, 0.16)	0.4559	
ADA result											NE
Negative	111	-1.80 (0.15)	112	-1.84 (0.15)	0.04 (0.20)	(-0.35, 0.42)	0.8416	0.02 (0.13)	(-0.24, 0.29)	0.8535	
Positive (At any time)	15	NE	13	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.3294
< 30	73	-1.97 (0.19)	87	-1.72 (0.17)	-0.25 (0.22)	(-0.69, 0.20)	0.2734	-0.15 (0.16)	(-0.46, 0.16)	0.3415	
>= 30	53	-1.58 (0.22)	38	-1.72 (0.26)	0.14 (0.33)	(-0.51, 0.80)	0.6658	0.09 (0.21)	(-0.33, 0.51)	0.6759	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score Renal
Full analysis set

	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-0.10 (0.13)		0.10 (0.13)	-0.21 (0.17)	(-0.54, 0.13)	0.2216			
Week 8		-0.04 (0.14)		0.30 (0.14)	-0.34 (0.19)	(-0.71, 0.03)	0.0753			
Week 12		-0.20 (0.12)		-0.07 (0.12)	-0.13 (0.16)	(-0.44, 0.18)	0.4159			
Week 16		-0.10 (0.13)		0.10 (0.13)	-0.20 (0.16)	(-0.52, 0.11)	0.2080			
Week 20		-0.13 (0.14)		0.04 (0.14)	-0.17 (0.18)	(-0.53, 0.18)	0.3424			
Week 24		-0.12 (0.10)		-0.06 (0.10)	-0.06 (0.13)	(-0.32, 0.19)	0.6275			
Week 28		0.04 (0.16)		-0.04 (0.16)	0.08 (0.21)	(-0.33, 0.50)	0.6982			
Week 32		-0.11 (0.13)		0.06 (0.13)	-0.17 (0.17)	(-0.51, 0.16)	0.3140			
Week 36		-0.01 (0.13)		0.07 (0.13)	-0.08 (0.18)	(-0.43, 0.27)	0.6503			
Week 40		-0.01 (0.14)		0.05 (0.15)	-0.05 (0.19)	(-0.43, 0.33)	0.7828			
Week 44		-0.03 (0.16)		0.05 (0.16)	-0.08 (0.21)	(-0.50, 0.33)	0.6874			
Week 48		0.04 (0.16)		0.13 (0.17)	-0.09 (0.22)	(-0.53, 0.34)	0.6712			
Week 52		-0.09 (0.15)		0.27 (0.15)	-0.37 (0.21)	(-0.77, 0.04)	0.0766			
OVERALL	127	-0.07 (0.11)	125	0.08 (0.11)	-0.14 (0.15)	(-0.43, 0.14)	0.3230	-0.11 (0.13)	(-0.36, 0.14)	0.3745

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score Renal - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) N	LSMean (SE)	Placebo (N=125) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											NE
< 10 points	39	NE	37	NE	NE	NE		NE	NE		
>= 10 points	88	-0.05 (0.16)	88	0.19 (0.16)	-0.24 (0.20)	(-0.64, 0.17)	0.2471	-0.16 (0.15)	(-0.46, 0.14)	0.2916	
OCS dose at baseline											NE
<10 mg/day	57	NE	52	NE	NE	NE		NE	NE		
>=10 mg/day	70	-0.03 (0.21)	73	0.16 (0.20)	-0.19 (0.26)	(-0.69, 0.32)	0.4691	-0.10 (0.17)	(-0.43, 0.22)	0.5326	
Result of type I IFN gene signature test											NE
LOW	22	NE	24	NE	NE	NE		NE	NE		
HIGH	105	-0.05 (0.13)	101	0.13 (0.13)	-0.18 (0.18)	(-0.54, 0.17)	0.3096	-0.14 (0.14)	(-0.41, 0.14)	0.3256	
Age (years)											NE
<= 65	122	-0.07 (0.12)	123	0.07 (0.12)	-0.15 (0.15)	(-0.44, 0.15)	0.3311	-0.11 (0.13)	(-0.36, 0.14)	0.3889	
> 65	5	NE	2	NE	NE	NE		NE	NE		
Sex											NE
male	12	NE	8	NE	NE	NE		NE	NE		
female	115	-0.05 (0.12)	117	0.10 (0.11)	-0.15 (0.15)	(-0.44, 0.14)	0.3173	-0.12 (0.13)	(-0.38, 0.14)	0.3580	
Race											NE
White	85	NE	96	NE	NE	NE		NE	NE		
Black or African American	22	NE	14	NE	NE	NE		NE	NE		
Asian	7	NE	3	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	NE	NE	NE		NE	NE		
Other	13	NE	11	NE	NE	NE		NE	NE		
Ethnicity											NE
Hispanic/Latino	23	NE	24	NE	NE	NE		NE	NE		
Non-hispanic/Latino	104	-0.06 (0.13)	101	0.05 (0.13)	-0.11 (0.17)	(-0.44, 0.21)	0.4918	-0.09 (0.14)	(-0.36, 0.19)	0.5292	
Geographic region											NE
EU	47	NE	56	NE	NE	NE		NE	NE		
non-EU	80	0.07 (0.11)	69	0.05 (0.12)	0.01 (0.16)	(-0.30, 0.33)	0.9303	0.01 (0.16)	(-0.31, 0.34)	0.9316	
Onset of disease											NE
Paediatric	8	NE	7	NE	NE	NE		NE	NE		
Adult	119	-0.00 (0.11)	118	0.03 (0.11)	-0.04 (0.14)	(-0.31, 0.24)	0.7976	-0.03 (0.13)	(-0.29, 0.22)	0.8149	
ADA result											NE
Negative	111	-0.04 (0.09)	112	0.03 (0.09)	-0.06 (0.12)	(-0.30, 0.17)	0.5854	-0.07 (0.13)	(-0.33, 0.20)	0.6221	
Positive (At any time)	15	NE	13	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											NE
< 30	74	0.05 (0.16)	87	0.22 (0.15)	-0.16 (0.19)	(-0.53, 0.21)	0.3830	-0.12 (0.16)	(-0.43, 0.19)	0.4596	
>= 30	53	NE	38	NE	NE	NE		NE	NE		

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score Vascular
Full analysis set

Visit	Anifrolumab 300mg (N=127) N	Anifrolumab 300mg (N=127) LSMean (SE)	Placebo (N=125) N	Placebo (N=125) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		NE		NE	NE	NE				
Week 8		NE		NE	NE	NE				
Week 12		NE		NE	NE	NE				
Week 16		NE		NE	NE	NE				
Week 20		NE		NE	NE	NE				
Week 24		NE		NE	NE	NE				
Week 28		NE		NE	NE	NE				
Week 32		NE		NE	NE	NE				
Week 36		NE		NE	NE	NE				
Week 40		NE		NE	NE	NE				
Week 44		NE		NE	NE	NE				
Week 48		NE		NE	NE	NE				
Week 52		NE		NE	NE	NE				
OVERALL	126	NE	125	NE	NE	NE		NE	NE	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score Vascular - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											NE
< 10 points	38	NE	37	NE	NE	NE		NE	NE		
>= 10 points	88	NE	88	NE	NE	NE		NE	NE		
OCS dose at baseline											NE
<10 mg/day	57	NE	52	NE	NE	NE		NE	NE		
>=10 mg/day	69	NE	73	NE	NE	NE		NE	NE		
Result of type I IFN gene signature test											NE
LOW	22	NE	24	NE	NE	NE		NE	NE		
HIGH	104	NE	101	NE	NE	NE		NE	NE		
Age (years)											NE
<= 65	121	NE	123	NE	NE	NE		NE	NE		
> 65	5	NE	2	NE	NE	NE		NE	NE		
Sex											NE
male	12	NE	8	NE	NE	NE		NE	NE		
female	114	NE	117	NE	NE	NE		NE	NE		
Race											NE
White	85	NE	96	NE	NE	NE		NE	NE		
Black or African American	21	NE	14	NE	NE	NE		NE	NE		
Asian	7	NE	3	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	NE	NE	NE		NE	NE		
Other	13	NE	11	NE	NE	NE		NE	NE		
Ethnicity											NE
Hispanic/Latino	23	NE	24	NE	NE	NE		NE	NE		
Non-hispanic/Latino	103	NE	101	NE	NE	NE		NE	NE		
Geographic region											NE
EU	47	NE	56	NE	NE	NE		NE	NE		
non-EU	79	NE	69	NE	NE	NE		NE	NE		
Onset of disease											NE
Paediatric	8	NE	7	NE	NE	NE		NE	NE		
Adult	118	NE	118	NE	NE	NE		NE	NE		
ADA result											NE
Negative	111	NE	112	NE	NE	NE		NE	NE		
Positive (At any time)	15	NE	13	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											NE
< 30	73	NE	87	NE	NE	NE		NE	NE		
>= 30	53	NE	38	NE	NE	NE		NE	NE		

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - PGA
Full analysis set

	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-0.25 (0.03)		-0.18 (0.03)	-0.07 (0.04)	(-0.15, 0.01)	0.0704			
Week 8		-0.46 (0.04)		-0.41 (0.04)	-0.05 (0.05)	(-0.16, 0.05)	0.3272			
Week 12		-0.64 (0.05)		-0.48 (0.05)	-0.16 (0.06)	(-0.28, -0.04)	0.0116			
Week 16		-0.77 (0.05)		-0.58 (0.05)	-0.19 (0.07)	(-0.32, -0.06)	0.0041			
Week 20		-0.84 (0.05)		-0.67 (0.05)	-0.17 (0.07)	(-0.31, -0.04)	0.0122			
Week 24		-0.89 (0.05)		-0.70 (0.05)	-0.18 (0.07)	(-0.32, -0.04)	0.0114			
Week 28		-0.95 (0.05)		-0.79 (0.05)	-0.16 (0.07)	(-0.30, -0.01)	0.0320			
Week 32		-1.00 (0.06)		-0.80 (0.06)	-0.21 (0.07)	(-0.35, -0.06)	0.0060			
Week 36		-1.02 (0.06)		-0.86 (0.06)	-0.16 (0.08)	(-0.32, -0.00)	0.0476			
Week 40		-1.00 (0.06)		-0.91 (0.06)	-0.09 (0.08)	(-0.25, 0.08)	0.2935			
Week 44		-1.05 (0.06)		-0.88 (0.06)	-0.18 (0.08)	(-0.34, -0.01)	0.0372			
Week 48		-1.07 (0.06)		-0.91 (0.06)	-0.17 (0.08)	(-0.33, 0.00)	0.0505			
Week 52		-1.14 (0.06)		-0.95 (0.06)	-0.19 (0.09)	(-0.36, -0.02)	0.0289			
OVERALL	126	-0.85 (0.04)	125	-0.70 (0.04)	-0.15 (0.06)	(-0.27, -0.04)	0.0093	-0.30 (0.13)	(-0.55, -0.05)	0.0168

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - PGA - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) N	LSMean (SE)	Placebo (N=125) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.3656
< 10 points	38	-0.91 (0.08)	37	-0.68 (0.08)	-0.23 (0.10)	(-0.43, -0.03)	0.0242	-0.48 (0.23)	(-0.94, -0.02)	0.0395	
>= 10 points	88	-0.80 (0.05)	88	-0.68 (0.05)	-0.12 (0.07)	(-0.26, 0.02)	0.0952	-0.24 (0.15)	(-0.53, 0.06)	0.1187	
OCS dose at baseline											0.2749
<10 mg/day	57	-0.73 (0.06)	52	-0.64 (0.06)	-0.09 (0.08)	(-0.25, 0.07)	0.2788	-0.20 (0.19)	(-0.57, 0.18)	0.3092	
>=10 mg/day	69	-0.97 (0.07)	73	-0.75 (0.06)	-0.22 (0.08)	(-0.38, -0.06)	0.0086	-0.40 (0.17)	(-0.73, -0.07)	0.0190	
Result of type I IFN gene signature test											0.6735
LOW	22	-0.76 (0.08)	24	-0.64 (0.08)	-0.12 (0.11)	(-0.34, 0.11)	0.3172	-0.29 (0.30)	(-0.87, 0.29)	0.3313	
HIGH	104	-0.92 (0.05)	101	-0.75 (0.05)	-0.17 (0.07)	(-0.30, -0.04)	0.0108	-0.35 (0.14)	(-0.63, -0.07)	0.0129	
Age (years)											NE
<= 65	121	-0.85 (0.05)	123	-0.70 (0.05)	-0.15 (0.06)	(-0.27, -0.03)	0.0118	-0.29 (0.13)	(-0.55, -0.04)	0.0222	
> 65	5	NE	2	NE	NE	NE		NE	NE		
Sex											NE
male	12	NE	8	NE	NE	NE		NE	NE		
female	114	-0.84 (0.05)	117	-0.70 (0.05)	-0.14 (0.06)	(-0.26, -0.02)	0.0275	-0.27 (0.13)	(-0.53, -0.01)	0.0420	
Race											NE
White	85	-0.78 (0.05)	96	-0.72 (0.05)	-0.06 (0.07)	(-0.19, 0.07)	0.3760	-0.12 (0.15)	(-0.41, 0.17)	0.4133	
Black or African American	21	-1.21 (0.13)	14	-0.74 (0.12)	-0.47 (0.16)	(-0.81, -0.14)	0.0078	-0.87 (0.36)	(-1.58, -0.16)	0.0168	
Asian	7	NE	3	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	NE	NE	NE		NE	NE		
Other	13	NE	11	NE	NE	NE		NE	NE		
Ethnicity											NE
Hispanic/Latino	23	NE	24	NE	NE	NE		NE	NE		
Non-hispanic/Latino	103	-0.87 (0.05)	101	-0.70 (0.05)	-0.17 (0.06)	(-0.29, -0.04)	0.0089	-0.34 (0.14)	(-0.62, -0.06)	0.0157	
Geographic region											0.6928
EU	47	-0.93 (0.07)	56	-0.74 (0.07)	-0.19 (0.09)	(-0.36, -0.02)	0.0305	-0.38 (0.20)	(-0.77, 0.01)	0.0570	
non-EU	79	-0.80 (0.06)	69	-0.66 (0.06)	-0.14 (0.08)	(-0.30, 0.01)	0.0722	-0.28 (0.17)	(-0.60, 0.05)	0.0960	
Onset of disease											NE
Paediatric	8	NE	7	NE	NE	NE		NE	NE		
Adult	118	-0.85 (0.05)	118	-0.71 (0.05)	-0.14 (0.06)	(-0.26, -0.02)	0.0199	-0.28 (0.13)	(-0.54, -0.02)	0.0328	
ADA result											NE
Negative	111	-0.84 (0.05)	112	-0.70 (0.05)	-0.14 (0.06)	(-0.26, -0.02)	0.0239	-0.28 (0.13)	(-0.54, -0.02)	0.0368	
Positive (At any time)	15	NE	13	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.2306
< 30	73	-0.88 (0.06)	87	-0.67 (0.05)	-0.21 (0.07)	(-0.35, -0.07)	0.0030	-0.42 (0.16)	(-0.73, -0.11)	0.0088	
>= 30	53	-0.80 (0.07)	38	-0.74 (0.08)	-0.06 (0.10)	(-0.27, 0.14)	0.5433	-0.12 (0.21)	(-0.54, 0.30)	0.5667	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - CLASI Total Activity Score
Full analysis set

	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-1.59 (0.31)		-1.12 (0.31)	-0.47 (0.39)	(-1.24, 0.30)	0.2278			
Week 8		-3.29 (0.36)		-2.18 (0.36)	-1.11 (0.47)	(-2.03, -0.19)	0.0185			
Week 12		-4.26 (0.38)		-2.72 (0.38)	-1.53 (0.50)	(-2.51, -0.56)	0.0022			
Week 16		-4.93 (0.37)		-3.19 (0.37)	-1.74 (0.49)	(-2.70, -0.78)	0.0004			
Week 20		-5.30 (0.39)		-3.44 (0.39)	-1.86 (0.51)	(-2.86, -0.85)	0.0004			
Week 24		-5.57 (0.43)		-3.45 (0.43)	-2.12 (0.57)	(-3.25, -1.00)	0.0003			
Week 28		-5.87 (0.43)		-3.81 (0.43)	-2.05 (0.57)	(-3.18, -0.92)	0.0004			
Week 32		-6.01 (0.43)		-4.15 (0.43)	-1.87 (0.57)	(-2.99, -0.74)	0.0013			
Week 36		-6.34 (0.42)		-4.62 (0.42)	-1.72 (0.56)	(-2.82, -0.62)	0.0023			
Week 40		-6.43 (0.44)		-4.69 (0.44)	-1.74 (0.58)	(-2.89, -0.59)	0.0033			
Week 44		-6.43 (0.46)		-4.53 (0.46)	-1.90 (0.61)	(-3.11, -0.69)	0.0023			
Week 48		-6.50 (0.44)		-4.74 (0.45)	-1.76 (0.59)	(-2.93, -0.58)	0.0035			
Week 52		-6.58 (0.45)		-4.70 (0.45)	-1.88 (0.60)	(-3.07, -0.69)	0.0021			
OVERALL	126	-5.31 (0.35)	125	-3.64 (0.35)	-1.67 (0.45)	(-2.56, -0.78)	0.0003	-0.42 (0.13)	(-0.67, -0.17)	0.0009

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - CLASI Total Activity Score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											0.0576
< 10 points	38	-4.04 (0.44)	37	-3.45 (0.42)	-0.60 (0.57)	(-1.75, 0.56)	0.3032	-0.22 (0.23)	(-0.68, 0.23)	0.3342	
>= 10 points	88	-5.68 (0.45)	88	-3.52 (0.46)	-2.16 (0.59)	(-3.33, -0.99)	0.0004	-0.51 (0.15)	(-0.81, -0.21)	0.0010	
OCS dose at baseline											0.0128
<10 mg/day	57	-3.85 (0.40)	52	-3.45 (0.42)	-0.41 (0.55)	(-1.51, 0.69)	0.4610	-0.13 (0.19)	(-0.51, 0.24)	0.4866	
>=10 mg/day	69	-6.26 (0.54)	73	-3.71 (0.53)	-2.55 (0.66)	(-3.87, -1.24)	0.0002	-0.56 (0.17)	(-0.90, -0.23)	0.0010	
Result of type I IFN gene signature test											NE
LOW	22	NE	24	NE	NE	NE		NE	NE		
HIGH	104	-5.86 (0.38)	101	-3.85 (0.40)	-2.01 (0.54)	(-3.07, -0.95)	0.0003	-0.51 (0.14)	(-0.79, -0.23)	0.0004	
Age (years)											NE
<= 65	121	-5.27 (0.37)	123	-3.60 (0.36)	-1.67 (0.46)	(-2.59, -0.75)	0.0004	-0.41 (0.13)	(-0.67, -0.16)	0.0014	
> 65	5	NE	2	NE	NE	NE		NE	NE		
Sex											NE
male	12	NE	8	NE	NE	NE		NE	NE		
female	114	-4.88 (0.35)	117	-3.50 (0.35)	-1.37 (0.45)	(-2.26, -0.49)	0.0025	-0.36 (0.13)	(-0.62, -0.10)	0.0062	
Race											NE
White	85	-4.94 (0.41)	96	-3.88 (0.39)	-1.06 (0.53)	(-2.10, -0.02)	0.0452	-0.28 (0.15)	(-0.57, 0.02)	0.0638	
Black or African American	21	-4.84 (0.71)	14	-5.48 (0.63)	0.64 (0.87)	(-1.46, 2.74)	0.4885	0.21 (0.35)	(-0.47, 0.89)	0.5384	
Asian	7	NE	3	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	1.50 (0.00)	NE	NE		NE	NE		
Other	13	NE	11	NE	NE	NE		NE	NE		
Ethnicity											NE
Hispanic/Latino	23	NE	24	NE	NE	NE		NE	NE		
Non-hispanic/Latino	103	-5.94 (0.40)	101	-4.01 (0.41)	-1.93 (0.53)	(-2.98, -0.89)	0.0004	-0.47 (0.14)	(-0.75, -0.19)	0.0009	
Geographic region											0.3622
EU	47	-6.60 (0.67)	56	-4.32 (0.64)	-2.28 (0.84)	(-3.95, -0.61)	0.0081	-0.48 (0.20)	(-0.88, -0.09)	0.0164	
non-EU	79	-4.74 (0.38)	69	-3.34 (0.40)	-1.40 (0.49)	(-2.38, -0.42)	0.0055	-0.42 (0.17)	(-0.74, -0.09)	0.0124	
Onset of disease											NE
Paediatric	8	NE	7	NE	NE	NE		NE	NE		
Adult	118	-5.04 (0.35)	118	-3.51 (0.35)	-1.53 (0.45)	(-2.42, -0.65)	0.0008	-0.40 (0.13)	(-0.66, -0.14)	0.0022	
ADA result											NE
Negative	111	-5.49 (0.37)	112	-3.80 (0.37)	-1.70 (0.48)	(-2.64, -0.75)	0.0005	-0.43 (0.14)	(-0.70, -0.17)	0.0013	
Positive (At any time)	15	NE	13	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.0475
< 30	73	-5.90 (0.48)	87	-3.54 (0.45)	-2.35 (0.57)	(-3.48, -1.22)	<.0001	-0.56 (0.16)	(-0.88, -0.25)	0.0005	
>= 30	53	-4.23 (0.51)	38	-3.74 (0.59)	-0.49 (0.75)	(-1.99, 1.01)	0.5130	-0.13 (0.21)	(-0.55, 0.29)	0.5356	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - CLASI Total Damage Score
Full analysis set

	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-0.16 (0.14)		-0.08 (0.14)	-0.08 (0.17)	(-0.41, 0.25)	0.6354			
Week 8		-0.36 (0.17)		-0.21 (0.17)	-0.15 (0.22)	(-0.58, 0.28)	0.4924			
Week 12		-0.50 (0.20)		-0.15 (0.20)	-0.35 (0.26)	(-0.85, 0.16)	0.1810			
Week 16		-0.56 (0.20)		-0.27 (0.20)	-0.29 (0.27)	(-0.82, 0.24)	0.2814			
Week 20		-0.53 (0.22)		-0.32 (0.21)	-0.21 (0.29)	(-0.77, 0.36)	0.4735			
Week 24		-0.73 (0.22)		-0.48 (0.22)	-0.25 (0.30)	(-0.84, 0.33)	0.3993			
Week 28		-0.72 (0.23)		-0.56 (0.23)	-0.16 (0.30)	(-0.76, 0.43)	0.5894			
Week 32		-0.74 (0.24)		-0.48 (0.24)	-0.26 (0.32)	(-0.89, 0.38)	0.4249			
Week 36		-0.78 (0.25)		-0.43 (0.25)	-0.35 (0.34)	(-1.01, 0.32)	0.3063			
Week 40		-0.96 (0.25)		-0.43 (0.25)	-0.53 (0.34)	(-1.19, 0.14)	0.1213			
Week 44		-0.94 (0.24)		-0.45 (0.24)	-0.48 (0.32)	(-1.12, 0.15)	0.1363			
Week 48		-0.95 (0.25)		-0.46 (0.25)	-0.49 (0.33)	(-1.15, 0.17)	0.1452			
Week 52		-1.00 (0.24)		-0.46 (0.25)	-0.54 (0.33)	(-1.19, 0.12)	0.1072			
OVERALL	126	-0.69 (0.20)	125	-0.37 (0.20)	-0.32 (0.26)	(-0.83, 0.19)	0.2215	-0.14 (0.13)	(-0.39, 0.10)	0.2556

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - CLASI Total Damage Score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											NE
< 10 points	38	NE	37	NE	NE	NE		NE	NE		
>= 10 points	88	-0.53 (0.24)	88	-0.38 (0.25)	-0.14 (0.34)	(-0.81, 0.53)	0.6727	-0.06 (0.15)	(-0.36, 0.23)	0.6824	
OCS dose at baseline											NE
<10 mg/day	57	NE	52	NE	NE	NE		NE	NE		
>=10 mg/day	69	NE	73	NE	NE	NE		NE	NE		
Result of type I IFN gene signature test											NE
LOW	22	NE	24	NE	NE	NE		NE	NE		
HIGH	104	NE	101	NE	NE	NE		NE	NE		
Age (years)											NE
<= 65	121	-0.68 (0.20)	123	-0.35 (0.20)	-0.33 (0.26)	(-0.85, 0.18)	0.2054	-0.15 (0.13)	(-0.40, 0.10)	0.2452	
> 65	5	NE	2	NE	NE	NE		NE	NE		
Sex											NE
male	12	NE	8	NE	NE	NE		NE	NE		
female	114	-0.64 (0.20)	117	-0.43 (0.20)	-0.21 (0.26)	(-0.72, 0.30)	0.4221	-0.10 (0.13)	(-0.36, 0.16)	0.4576	
Race											NE
White	85	-0.61 (0.22)	96	-0.42 (0.21)	-0.19 (0.28)	(-0.75, 0.37)	0.5101	-0.09 (0.15)	(-0.38, 0.20)	0.5448	
Black or African American	21	NE	14	NE	NE	NE		NE	NE		
Asian	7	NE	3	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	NE	NE	NE		NE	NE		
Other	13	NE	11	NE	NE	NE		NE	NE		
Ethnicity											NE
Hispanic/Latino	23	NE	24	NE	NE	NE		NE	NE		
Non-hispanic/Latino	103	-0.81 (0.21)	101	-0.39 (0.21)	-0.42 (0.27)	(-0.97, 0.12)	0.1239	-0.20 (0.14)	(-0.48, 0.07)	0.1512	
Geographic region											NE
EU	47	NE	56	NE	NE	NE		NE	NE		
non-EU	79	NE	69	NE	NE	NE		NE	NE		
Onset of disease											NE
Paediatric	8	NE	7	NE	NE	NE		NE	NE		
Adult	118	-0.56 (0.20)	118	-0.29 (0.20)	-0.26 (0.26)	(-0.77, 0.24)	0.3065	-0.12 (0.13)	(-0.38, 0.13)	0.3409	
ADA result											NE
Negative	111	-0.81 (0.20)	112	-0.36 (0.20)	-0.45 (0.27)	(-0.98, 0.08)	0.0946	-0.21 (0.13)	(-0.47, 0.05)	0.1164	
Positive (At any time)	15	NE	13	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											NE
< 30	73	NE	87	NE	NE	NE		NE	NE		
>= 30	53	NE	38	NE	NE	NE		NE	NE		

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - BILAG Global Score
Full analysis set

	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-3.78 (0.58)		-3.14 (0.57)	-0.64 (0.71)	(-2.04, 0.75)	0.3654			
Week 8		-7.33 (0.68)		-5.60 (0.68)	-1.73 (0.87)	(-3.44, -0.02)	0.0473			
Week 12		-8.79 (0.67)		-6.85 (0.67)	-1.94 (0.86)	(-3.63, -0.26)	0.0242			
Week 16		-9.71 (0.72)		-7.46 (0.72)	-2.25 (0.93)	(-4.09, -0.41)	0.0168			
Week 20		-10.04 (0.70)		-8.66 (0.70)	-1.39 (0.90)	(-3.16, 0.39)	0.1256			
Week 24		-10.77 (0.71)		-9.11 (0.71)	-1.66 (0.92)	(-3.47, 0.15)	0.0718			
Week 28		-10.92 (0.71)		-9.95 (0.70)	-0.96 (0.91)	(-2.76, 0.84)	0.2930			
Week 32		-11.55 (0.70)		-9.87 (0.71)	-1.69 (0.91)	(-3.48, 0.11)	0.0654			
Week 36		-11.51 (0.71)		-10.31 (0.71)	-1.19 (0.92)	(-3.00, 0.62)	0.1948			
Week 40		-11.54 (0.73)		-10.35 (0.72)	-1.19 (0.94)	(-3.05, 0.66)	0.2063			
Week 44		-11.47 (0.75)		-10.22 (0.74)	-1.24 (0.98)	(-3.17, 0.68)	0.2040			
Week 48		-11.64 (0.75)		-10.53 (0.75)	-1.11 (0.98)	(-3.05, 0.83)	0.2594			
Week 52		-12.12 (0.71)		-10.59 (0.71)	-1.53 (0.92)	(-3.35, 0.29)	0.0982			
OVERALL	126	-10.09 (0.58)	125	-8.66 (0.58)	-1.43 (0.71)	(-2.83, -0.02)	0.0470	-0.22 (0.13)	(-0.47, 0.03)	0.0840

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - BILAG Global Score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											0.5961
< 10 points	38	-10.17 (0.82)	37	-8.14 (0.79)	-2.03 (1.04)	(-4.10, 0.03)	0.0537	-0.41 (0.23)	(-0.86, 0.05)	0.0815	
>= 10 points	88	-9.62 (0.74)	88	-8.32 (0.74)	-1.29 (0.93)	(-3.14, 0.55)	0.1671	-0.19 (0.15)	(-0.48, 0.11)	0.2195	
OCS dose at baseline											0.2561
<10 mg/day	57	-9.39 (0.79)	52	-8.87 (0.82)	-0.52 (1.05)	(-2.60, 1.55)	0.6174	-0.09 (0.19)	(-0.46, 0.29)	0.6480	
>=10 mg/day	69	-10.66 (0.87)	73	-8.51 (0.82)	-2.15 (0.98)	(-4.08, -0.22)	0.0294	-0.30 (0.17)	(-0.63, 0.03)	0.0749	
Result of type I IFN gene signature test											0.0232
LOW	22	-8.28 (1.19)	24	-10.12 (1.11)	1.84 (1.59)	(-1.36, 5.04)	0.2530	0.33 (0.30)	(-0.25, 0.91)	0.2686	
HIGH	104	-10.97 (0.57)	101	-8.79 (0.59)	-2.18 (0.78)	(-3.73, -0.63)	0.0060	-0.37 (0.14)	(-0.65, -0.09)	0.0087	
Age (years)											NE
<= 65	121	-10.11 (0.61)	123	-8.68 (0.60)	-1.43 (0.73)	(-2.88, 0.01)	0.0519	-0.21 (0.13)	(-0.47, 0.04)	0.0964	
> 65	5	NE	2	NE	NE	NE		NE	NE		
Sex											NE
male	12	NE	8	NE	NE	NE		NE	NE		
female	114	-9.87 (0.62)	117	-8.76 (0.60)	-1.10 (0.75)	(-2.59, 0.38)	0.1438	-0.17 (0.13)	(-0.43, 0.09)	0.2010	
Race											NE
White	85	-9.98 (0.70)	96	-9.19 (0.67)	-0.80 (0.86)	(-2.50, 0.91)	0.3582	-0.12 (0.15)	(-0.41, 0.17)	0.4153	
Black or African American	21	-12.12 (1.21)	14	-9.07 (1.03)	-3.05 (1.51)	(-6.11, 0.01)	0.0505	-0.60 (0.35)	(-1.29, 0.09)	0.0889	
Asian	7	NE	3	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	NE	NE	NE		NE	NE		
Other	13	NE	11	NE	NE	NE		NE	NE		
Ethnicity											0.7027
Hispanic/Latino	23	-7.34 (1.53)	24	-6.50 (1.65)	-0.84 (1.85)	(-4.59, 2.91)	0.6513	-0.11 (0.29)	(-0.68, 0.47)	0.7138	
Non-hispanic/Latino	103	-10.49 (0.64)	101	-8.88 (0.62)	-1.61 (0.79)	(-3.17, -0.05)	0.0426	-0.25 (0.14)	(-0.53, 0.02)	0.0730	
Geographic region											0.7212
EU	47	-11.57 (1.05)	56	-9.75 (1.00)	-1.82 (1.16)	(-4.13, 0.49)	0.1203	-0.25 (0.20)	(-0.64, 0.14)	0.2141	
non-EU	79	-9.32 (0.71)	69	-8.03 (0.74)	-1.29 (0.92)	(-3.11, 0.52)	0.1607	-0.21 (0.17)	(-0.53, 0.12)	0.2121	
Onset of disease											NE
Paediatric	8	NE	7	NE	NE	NE		NE	NE		
Adult	118	-10.11 (0.60)	118	-8.69 (0.60)	-1.42 (0.74)	(-2.87, 0.04)	0.0560	-0.22 (0.13)	(-0.47, 0.04)	0.0958	
ADA result											0.3706
Negative	111	-9.96 (0.61)	112	-8.85 (0.60)	-1.11 (0.76)	(-2.60, 0.38)	0.1439	-0.17 (0.13)	(-0.44, 0.09)	0.1975	
Positive (At any time)	15	-8.29 (1.52)	13	-5.38 (1.54)	-2.91 (1.86)	(-6.76, 0.95)	0.1320	-0.49 (0.39)	(-1.25, 0.26)	0.2023	
BMI (kg/m2) at enrolment											0.7479
< 30	73	-10.10 (0.81)	87	-8.41 (0.75)	-1.69 (0.89)	(-3.45, 0.07)	0.0598	-0.24 (0.16)	(-0.55, 0.07)	0.1282	
>= 30	53	-10.30 (0.87)	38	-9.11 (1.00)	-1.20 (1.23)	(-3.65, 1.25)	0.3337	-0.19 (0.21)	(-0.61, 0.23)	0.3738	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Tender Joint Count
Full analysis set

Visit	Anifrolumab 300mg (N=127) N	Anifrolumab 300mg (N=127) LSMean (SE)	Placebo (N=125) N	Placebo (N=125) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-1.19 (0.48)		-1.65 (0.48)	0.46 (0.60)	(-0.73, 1.65)	0.4483			
Week 8		-3.75 (0.49)		-2.73 (0.49)	-1.02 (0.62)	(-2.25, 0.20)	0.1008			
Week 12		-4.72 (0.53)		-3.43 (0.53)	-1.29 (0.68)	(-2.63, 0.05)	0.0593			
Week 16		-5.53 (0.52)		-4.41 (0.52)	-1.12 (0.67)	(-2.45, 0.20)	0.0966			
Week 20		-5.74 (0.56)		-4.83 (0.56)	-0.92 (0.73)	(-2.36, 0.53)	0.2140			
Week 24		-5.64 (0.57)		-4.97 (0.57)	-0.67 (0.75)	(-2.15, 0.81)	0.3740			
Week 28		-6.18 (0.54)		-5.65 (0.53)	-0.53 (0.69)	(-1.89, 0.84)	0.4483			
Week 32		-6.64 (0.54)		-5.30 (0.54)	-1.34 (0.71)	(-2.74, 0.05)	0.0584			
Week 36		-7.04 (0.55)		-5.62 (0.54)	-1.42 (0.71)	(-2.82, -0.02)	0.0471			
Week 40		-6.57 (0.53)		-5.98 (0.53)	-0.59 (0.69)	(-1.94, 0.76)	0.3917			
Week 44		-7.00 (0.55)		-5.67 (0.55)	-1.33 (0.72)	(-2.74, 0.09)	0.0656			
Week 48		-6.91 (0.55)		-6.35 (0.56)	-0.56 (0.73)	(-1.99, 0.88)	0.4452			
Week 52		-7.29 (0.51)		-6.81 (0.51)	-0.48 (0.66)	(-1.78, 0.82)	0.4681			
OVERALL	126	-5.71 (0.43)	125	-4.88 (0.42)	-0.83 (0.52)	(-1.86, 0.20)	0.1121	-0.17 (0.13)	(-0.42, 0.07)	0.1695

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Tender Joint Count - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) N	LSMean (SE)	Placebo (N=125) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.8520
< 10 points	38	-6.26 (0.81)	37	-5.59 (0.78)	-0.67 (1.04)	(-2.74, 1.40)	0.5210	-0.14 (0.23)	(-0.59, 0.32)	0.5560	
>= 10 points	88	-5.04 (0.49)	88	-4.15 (0.49)	-0.89 (0.61)	(-2.10, 0.31)	0.1436	-0.19 (0.15)	(-0.49, 0.10)	0.1974	
OCS dose at baseline											0.6456
<10 mg/day	57	-5.56 (0.58)	52	-4.45 (0.60)	-1.11 (0.76)	(-2.61, 0.40)	0.1475	-0.25 (0.19)	(-0.63, 0.13)	0.1911	
>=10 mg/day	69	-6.22 (0.61)	73	-5.59 (0.58)	-0.63 (0.70)	(-2.02, 0.76)	0.3709	-0.12 (0.17)	(-0.45, 0.20)	0.4573	
Result of type I IFN gene signature test											NE
LOW	22	NE	24	NE	NE	NE		NE	NE		
HIGH	104	-6.40 (0.40)	101	-5.80 (0.42)	-0.60 (0.56)	(-1.70, 0.49)	0.2799	-0.14 (0.14)	(-0.42, 0.13)	0.3022	
Age (years)											NE
<= 65	121	-5.49 (0.45)	123	-4.68 (0.43)	-0.81 (0.53)	(-1.85, 0.23)	0.1253	-0.17 (0.13)	(-0.42, 0.08)	0.1934	
> 65	5	NE	2	NE	NE	NE		NE	NE		
Sex											NE
male	12	NE	8	NE	NE	NE		NE	NE		
female	114	-5.66 (0.45)	117	-5.04 (0.44)	-0.62 (0.54)	(-1.69, 0.45)	0.2530	-0.13 (0.13)	(-0.39, 0.13)	0.3243	
Race											NE
White	85	-6.13 (0.49)	96	-5.32 (0.47)	-0.81 (0.60)	(-2.00, 0.37)	0.1786	-0.18 (0.15)	(-0.47, 0.11)	0.2322	
Black or African American	21	-6.07 (1.80)	14	-3.70 (1.51)	-2.37 (2.12)	(-6.68, 1.94)	0.2715	-0.32 (0.35)	(-1.00, 0.37)	0.3640	
Asian	7	NE	3	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	-17.00 (0.00)	NE	NE		NE	NE		
Other	13	NE	11	NE	NE	NE		NE	NE		
Ethnicity											NE
Hispanic/Latino	23	NE	24	NE	NE	NE		NE	NE		
Non-hispanic/Latino	103	-5.75 (0.48)	101	-4.89 (0.47)	-0.85 (0.59)	(-2.01, 0.30)	0.1474	-0.18 (0.14)	(-0.45, 0.10)	0.2047	
Geographic region											0.6244
EU	47	-5.89 (0.60)	56	-5.30 (0.57)	-0.60 (0.64)	(-1.88, 0.68)	0.3565	-0.14 (0.20)	(-0.53, 0.25)	0.4754	
non-EU	79	-5.60 (0.58)	69	-4.52 (0.61)	-1.08 (0.75)	(-2.57, 0.41)	0.1529	-0.21 (0.17)	(-0.53, 0.11)	0.2054	
Onset of disease											NE
Paediatric	8	NE	7	NE	NE	NE		NE	NE		
Adult	118	-5.86 (0.44)	118	-4.82 (0.44)	-1.04 (0.53)	(-2.09, 0.01)	0.0521	-0.22 (0.13)	(-0.47, 0.04)	0.0940	
ADA result											NE
Negative	111	-5.63 (0.44)	112	-5.28 (0.43)	-0.35 (0.54)	(-1.42, 0.72)	0.5247	-0.07 (0.13)	(-0.34, 0.19)	0.5766	
Positive (At any time)	15	NE	13	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.7042
< 30	73	-5.31 (0.54)	87	-4.25 (0.49)	-1.07 (0.60)	(-2.25, 0.12)	0.0784	-0.23 (0.16)	(-0.54, 0.08)	0.1473	
>= 30	53	-6.75 (0.74)	38	-6.13 (0.84)	-0.62 (1.02)	(-2.65, 1.42)	0.5483	-0.12 (0.21)	(-0.53, 0.30)	0.5880	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Swollen Joint Count
Full analysis set

Visit	Anifrolumab 300mg (N=127) N	Anifrolumab 300mg (N=127) LSMean (SE)	Placebo (N=125) N	Placebo (N=125) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-1.57 (0.38)		-1.67 (0.38)	0.10 (0.50)	(-0.89, 1.09)	0.8459			
Week 8		-2.90 (0.36)		-2.49 (0.35)	-0.41 (0.46)	(-1.32, 0.49)	0.3665			
Week 12		-4.01 (0.38)		-3.03 (0.38)	-0.98 (0.50)	(-1.97, 0.01)	0.0513			
Week 16		-4.34 (0.36)		-3.22 (0.36)	-1.12 (0.47)	(-2.05, -0.19)	0.0183			
Week 20		-4.37 (0.36)		-3.91 (0.36)	-0.46 (0.46)	(-1.38, 0.45)	0.3220			
Week 24		-4.43 (0.39)		-4.04 (0.38)	-0.39 (0.50)	(-1.39, 0.60)	0.4375			
Week 28		-4.76 (0.36)		-4.29 (0.35)	-0.47 (0.46)	(-1.37, 0.44)	0.3093			
Week 32		-5.35 (0.34)		-4.11 (0.35)	-1.25 (0.44)	(-2.12, -0.37)	0.0053			
Week 36		-5.18 (0.37)		-4.24 (0.37)	-0.94 (0.48)	(-1.88, 0.00)	0.0510			
Week 40		-4.92 (0.36)		-4.53 (0.36)	-0.40 (0.46)	(-1.31, 0.52)	0.3921			
Week 44		-5.13 (0.32)		-4.56 (0.31)	-0.56 (0.40)	(-1.35, 0.22)	0.1595			
Week 48		-5.23 (0.35)		-4.75 (0.35)	-0.48 (0.45)	(-1.37, 0.41)	0.2923			
Week 52		-5.43 (0.30)		-5.00 (0.30)	-0.42 (0.38)	(-1.17, 0.32)	0.2660			
OVERALL	126	-4.43 (0.28)	125	-3.83 (0.28)	-0.60 (0.34)	(-1.27, 0.07)	0.0798	-0.19 (0.13)	(-0.44, 0.06)	0.1328

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Swollen Joint Count - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) N	LSMean (SE)	Placebo (N=125) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.5592
< 10 points	38	-4.40 (0.55)	37	-3.45 (0.53)	-0.95 (0.70)	(-2.36, 0.45)	0.1801	-0.29 (0.23)	(-0.74, 0.17)	0.2177	
>= 10 points	88	-4.40 (0.32)	88	-3.92 (0.33)	-0.48 (0.40)	(-1.27, 0.31)	0.2314	-0.16 (0.15)	(-0.45, 0.14)	0.2957	
OCS dose at baseline											0.2966
<10 mg/day	57	-4.24 (0.35)	52	-4.01 (0.37)	-0.23 (0.47)	(-1.15, 0.69)	0.6211	-0.09 (0.19)	(-0.46, 0.29)	0.6538	
>=10 mg/day	69	-4.55 (0.41)	73	-3.62 (0.40)	-0.93 (0.48)	(-1.89, 0.03)	0.0562	-0.27 (0.17)	(-0.60, 0.06)	0.1085	
Result of type I IFN gene signature test											NE
LOW	22	NE	24	NE	NE	NE		NE	NE		
HIGH	104	-4.47 (0.28)	101	-3.99 (0.29)	-0.49 (0.38)	(-1.24, 0.26)	0.2034	-0.17 (0.14)	(-0.44, 0.10)	0.2244	
Age (years)											NE
<= 65	121	-4.42 (0.30)	123	-3.77 (0.29)	-0.65 (0.35)	(-1.34, 0.03)	0.0620	-0.20 (0.13)	(-0.45, 0.05)	0.1158	
> 65	5	NE	2	NE	NE	NE		NE	NE		
Sex											NE
male	12	NE	8	NE	NE	NE		NE	NE		
female	114	-4.31 (0.29)	117	-3.85 (0.29)	-0.47 (0.35)	(-1.16, 0.23)	0.1905	-0.15 (0.13)	(-0.41, 0.11)	0.2600	
Race											NE
White	85	-4.47 (0.32)	96	-3.94 (0.31)	-0.53 (0.40)	(-1.31, 0.25)	0.1808	-0.18 (0.15)	(-0.47, 0.11)	0.2302	
Black or African American	21	-4.80 (0.93)	14	-4.08 (0.87)	-0.72 (1.18)	(-3.14, 1.71)	0.5496	-0.18 (0.35)	(-0.86, 0.50)	0.6026	
Asian	7	NE	3	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	NE	NE	NE		NE	NE		
Other	13	NE	11	NE	NE	NE		NE	NE		
Ethnicity											0.9927
Hispanic/Latino	23	-5.11 (0.68)	24	-4.53 (0.77)	-0.58 (0.77)	(-2.14, 0.98)	0.4560	-0.16 (0.29)	(-0.73, 0.41)	0.5816	
Non-hispanic/Latino	103	-4.30 (0.31)	101	-3.73 (0.31)	-0.57 (0.38)	(-1.33, 0.19)	0.1389	-0.18 (0.14)	(-0.46, 0.09)	0.1936	
Geographic region											0.6738
EU	47	-4.32 (0.32)	56	-3.80 (0.30)	-0.52 (0.38)	(-1.27, 0.23)	0.1704	-0.23 (0.20)	(-0.62, 0.16)	0.2463	
non-EU	79	-4.55 (0.39)	69	-3.77 (0.41)	-0.78 (0.50)	(-1.77, 0.20)	0.1178	-0.22 (0.17)	(-0.55, 0.10)	0.1735	
Onset of disease											NE
Paediatric	8	NE	7	NE	NE	NE		NE	NE		
Adult	118	-4.49 (0.29)	118	-3.68 (0.29)	-0.80 (0.35)	(-1.49, -0.12)	0.0220	-0.26 (0.13)	(-0.51, 0.00)	0.0503	
ADA result											NE
Negative	111	-4.36 (0.30)	112	-3.98 (0.30)	-0.37 (0.37)	(-1.10, 0.35)	0.3102	-0.12 (0.13)	(-0.38, 0.14)	0.3743	
Positive (At any time)	15	NE	13	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.5656
< 30	73	-4.55 (0.36)	87	-3.72 (0.33)	-0.83 (0.42)	(-1.67, 0.01)	0.0538	-0.26 (0.16)	(-0.58, 0.05)	0.0971	
>= 30	53	-4.79 (0.45)	38	-4.40 (0.51)	-0.39 (0.63)	(-1.64, 0.86)	0.5375	-0.12 (0.21)	(-0.54, 0.30)	0.5723	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Mental Component Score
Full analysis set

	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 8		1.29 (0.84)		2.04 (0.84)	-0.75 (1.05)	(-2.82, 1.32)	0.4764			
Week 16		0.97 (0.91)		0.64 (0.89)	0.33 (1.14)	(-1.93, 2.58)	0.7762			
Week 24		1.89 (0.92)		0.43 (0.92)	1.46 (1.18)	(-0.86, 3.78)	0.2157			
Week 32		2.12 (0.92)		-0.03 (0.92)	2.15 (1.17)	(-0.16, 4.46)	0.0678			
Week 40		1.62 (1.00)		1.23 (0.99)	0.39 (1.29)	(-2.15, 2.93)	0.7615			
Week 48		2.35 (0.98)		1.62 (0.99)	0.73 (1.28)	(-1.79, 3.24)	0.5703			
Week 52		2.56 (0.98)		1.68 (0.98)	0.87 (1.27)	(-1.64, 3.38)	0.4942			
OVERALL	119	1.83 (0.77)	116	1.09 (0.76)	0.74 (0.92)	(-1.07, 2.55)	0.4223	0.09 (0.13)	(-0.17, 0.35)	0.4937

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Mental Component Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) N	LSMean (SE)	Placebo (N=125) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.4167
< 10 points	34	2.29 (1.22)	36	0.46 (1.15)	1.83 (1.52)	(-1.21, 4.86)	0.2341	0.26 (0.24)	(-0.21, 0.73)	0.2835	
>= 10 points	85	1.67 (0.93)	80	1.39 (0.95)	0.28 (1.15)	(-2.00, 2.55)	0.8102	0.03 (0.16)	(-0.27, 0.34)	0.8358	
OCS dose at baseline											0.7670
<10 mg/day	53	1.63 (1.10)	47	0.52 (1.17)	1.10 (1.46)	(-1.81, 4.01)	0.4535	0.14 (0.20)	(-0.26, 0.53)	0.4949	
>=10 mg/day	66	1.93 (1.11)	69	1.38 (1.04)	0.54 (1.20)	(-1.82, 2.91)	0.6511	0.06 (0.17)	(-0.28, 0.40)	0.7221	
Result of type I IFN gene signature test											0.5530
LOW	21	2.93 (1.37)	23	1.12 (1.25)	1.81 (1.81)	(-1.87, 5.48)	0.3250	0.29 (0.30)	(-0.30, 0.89)	0.3393	
HIGH	98	1.98 (0.77)	93	1.42 (0.79)	0.56 (1.05)	(-1.51, 2.64)	0.5934	0.07 (0.14)	(-0.21, 0.36)	0.6123	
Age (years)											NE
<= 65	114	1.77 (0.81)	115	1.06 (0.78)	0.71 (0.94)	(-1.15, 2.56)	0.4531	0.08 (0.13)	(-0.18, 0.34)	0.5295	
> 65	5	NE	1	NE	NE	NE		NE	NE		
Sex											0.7356
male	12	2.63 (1.45)	8	2.67 (1.80)	-0.03 (2.02)	(-4.62, 4.56)	0.9871	-0.01 (0.46)	(-0.90, 0.89)	0.9889	
female	107	1.62 (0.83)	108	0.90 (0.80)	0.73 (0.99)	(-1.23, 2.68)	0.4643	0.09 (0.14)	(-0.18, 0.35)	0.5306	
Race											NE
White	81	1.97 (0.86)	87	0.70 (0.83)	1.26 (1.06)	(-0.83, 3.36)	0.2342	0.16 (0.15)	(-0.14, 0.47)	0.2935	
Black or African American	19	6.08 (3.28)	14	1.50 (2.42)	4.59 (3.49)	(-2.57, 11.75)	0.1996	0.36 (0.36)	(-0.34, 1.06)	0.3092	
Asian	7	NE	3	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	NE	NE	NE		NE	NE		
Other	12	0.50 (2.83)	11	5.04 (3.05)	-4.54 (2.55)	(-9.87, 0.78)	0.0901	-0.44 (0.42)	(-1.27, 0.39)	0.2989	
Ethnicity											0.0851
Hispanic/Latino	22	0.94 (1.67)	23	3.37 (1.89)	-2.44 (1.93)	(-6.34, 1.47)	0.2146	-0.28 (0.30)	(-0.87, 0.31)	0.3471	
Non-hispanic/Latino	97	2.24 (0.87)	93	0.89 (0.84)	1.35 (1.05)	(-0.72, 3.42)	0.2001	0.16 (0.15)	(-0.12, 0.45)	0.2657	
Geographic region											0.9138
EU	45	3.39 (1.32)	52	2.62 (1.22)	0.77 (1.39)	(-1.99, 3.53)	0.5811	0.09 (0.20)	(-0.31, 0.49)	0.6707	
non-EU	74	0.69 (0.96)	64	0.12 (1.01)	0.57 (1.23)	(-1.86, 3.00)	0.6433	0.07 (0.17)	(-0.27, 0.40)	0.6839	
Onset of disease											NE
Paediatric	7	NE	6	NE	NE	NE		NE	NE		
Adult	112	1.71 (0.78)	110	0.90 (0.78)	0.81 (0.94)	(-1.05, 2.67)	0.3905	0.10 (0.13)	(-0.17, 0.36)	0.4646	
ADA result											0.9201
Negative	105	1.46 (0.81)	103	0.74 (0.81)	0.71 (0.99)	(-1.24, 2.67)	0.4724	0.09 (0.14)	(-0.19, 0.36)	0.5344	
Positive (At any time)	14	4.02 (2.72)	13	3.56 (2.67)	0.45 (2.43)	(-4.59, 5.50)	0.8541	0.04 (0.39)	(-0.71, 0.80)	0.9087	
BMI (kg/m2) at enrolment											0.3402
< 30	70	1.37 (1.02)	80	1.35 (0.93)	0.02 (1.08)	(-2.12, 2.15)	0.9875	0.00 (0.16)	(-0.32, 0.32)	0.9903	
>= 30	49	1.47 (1.25)	36	-0.51 (1.40)	1.98 (1.75)	(-1.51, 5.47)	0.2620	0.23 (0.22)	(-0.20, 0.66)	0.3004	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Physical Component Score
Full analysis set

	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 8		1.71 (0.68)		1.98 (0.67)	-0.27 (0.81)	(-1.88, 1.33)	0.7371			
Week 16		3.39 (0.78)		2.03 (0.77)	1.37 (0.97)	(-0.55, 3.28)	0.1606			
Week 24		2.86 (0.77)		2.85 (0.77)	0.01 (0.97)	(-1.90, 1.91)	0.9952			
Week 32		2.97 (0.77)		3.25 (0.77)	-0.28 (0.96)	(-2.18, 1.61)	0.7684			
Week 40		3.21 (0.81)		2.77 (0.81)	0.44 (1.03)	(-1.60, 2.48)	0.6703			
Week 48		3.21 (0.83)		3.40 (0.83)	-0.19 (1.07)	(-2.30, 1.92)	0.8594			
Week 52		2.89 (0.80)		3.39 (0.80)	-0.50 (1.02)	(-2.50, 1.51)	0.6270			
OVERALL	119	2.89 (0.68)	116	2.81 (0.68)	0.08 (0.82)	(-1.54, 1.70)	0.9211	0.01 (0.13)	(-0.24, 0.27)	0.9327

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Physical Component Score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											0.0419
< 10 points	34	3.51 (1.04)	36	1.05 (0.97)	2.46 (1.26)	(-0.06, 4.98)	0.0555	0.41 (0.24)	(-0.06, 0.88)	0.0893	
>= 10 points	85	3.07 (0.82)	80	3.92 (0.84)	-0.84 (1.02)	(-2.86, 1.17)	0.4109	-0.11 (0.16)	(-0.42, 0.19)	0.4772	
OCS dose at baseline											0.5972
<10 mg/day	53	2.24 (0.82)	47	2.70 (0.86)	-0.46 (1.09)	(-2.63, 1.71)	0.6742	-0.08 (0.20)	(-0.47, 0.32)	0.7023	
>=10 mg/day	66	3.36 (1.08)	69	2.97 (1.02)	0.39 (1.17)	(-1.94, 2.71)	0.7423	0.04 (0.17)	(-0.29, 0.38)	0.7954	
Result of type I IFN gene signature test											0.0276
LOW	21	1.02 (1.17)	23	4.14 (1.05)	-3.13 (1.56)	(-6.27, 0.02)	0.0511	-0.59 (0.31)	(-1.20, 0.01)	0.0557	
HIGH	98	4.12 (0.69)	93	3.24 (0.71)	0.88 (0.94)	(-0.98, 2.74)	0.3511	0.13 (0.14)	(-0.16, 0.41)	0.3767	
Age (years)											NE
<= 65	114	3.02 (0.71)	115	2.72 (0.68)	0.30 (0.83)	(-1.34, 1.94)	0.7197	0.04 (0.13)	(-0.22, 0.30)	0.7632	
> 65	5	NE	1	NE	NE	NE		NE	NE		
Sex											0.1023
male	12	1.75 (2.07)	8	-3.23 (2.57)	4.98 (3.11)	(-1.73, 11.70)	0.1327	0.66 (0.47)	(-0.26, 1.59)	0.1595	
female	107	2.81 (0.73)	108	3.11 (0.71)	-0.29 (0.88)	(-2.02, 1.43)	0.7379	-0.04 (0.14)	(-0.31, 0.23)	0.7743	
Race											NE
White	81	2.75 (0.80)	87	3.21 (0.77)	-0.46 (1.00)	(-2.44, 1.51)	0.6437	-0.06 (0.15)	(-0.37, 0.24)	0.6790	
Black or African American	19	6.62 (2.16)	14	2.39 (1.71)	4.22 (2.39)	(-0.68, 9.12)	0.0884	0.50 (0.36)	(-0.20, 1.20)	0.1649	
Asian	7	NE	3	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	NE	NE	NE		NE	NE		
Other	12	NE	11	NE	NE	NE		NE	NE		
Ethnicity											0.7219
Hispanic/Latino	22	2.15 (1.55)	23	1.58 (1.76)	0.57 (1.80)	(-3.07, 4.20)	0.7553	0.07 (0.30)	(-0.51, 0.66)	0.8135	
Non-hispanic/Latino	97	2.96 (0.77)	93	3.12 (0.75)	-0.16 (0.93)	(-2.00, 1.69)	0.8667	-0.02 (0.15)	(-0.31, 0.26)	0.8843	
Geographic region											0.2733
EU	45	3.87 (1.23)	52	4.62 (1.15)	-0.75 (1.33)	(-3.40, 1.89)	0.5729	-0.09 (0.20)	(-0.49, 0.31)	0.6578	
non-EU	74	2.74 (0.76)	64	1.70 (0.79)	1.04 (0.96)	(-0.85, 2.93)	0.2776	0.16 (0.17)	(-0.17, 0.50)	0.3445	
Onset of disease											NE
Paediatric	7	NE	6	NE	NE	NE		NE	NE		
Adult	112	3.12 (0.70)	110	2.92 (0.69)	0.20 (0.84)	(-1.46, 1.86)	0.8121	0.03 (0.13)	(-0.24, 0.29)	0.8388	
ADA result											0.0325
Negative	105	2.55 (0.73)	103	3.03 (0.72)	-0.48 (0.89)	(-2.24, 1.28)	0.5908	-0.06 (0.14)	(-0.34, 0.21)	0.6403	
Positive (At any time)	14	8.80 (2.27)	13	4.72 (2.22)	4.08 (1.94)	(0.08, 8.09)	0.0460	0.48 (0.39)	(-0.29, 1.25)	0.2208	
BMI (kg/m2) at enrolment											0.2155
< 30	70	2.85 (0.88)	80	3.27 (0.81)	-0.42 (0.93)	(-2.26, 1.43)	0.6547	-0.06 (0.16)	(-0.38, 0.26)	0.7278	
>= 30	49	3.63 (1.11)	36	1.79 (1.25)	1.83 (1.56)	(-1.27, 4.94)	0.2434	0.24 (0.22)	(-0.19, 0.67)	0.2813	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute General Health Score
Full analysis set

	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 8		0.40 (0.62)		2.50 (0.61)	-2.10 (0.75)	(-3.58, -0.62)	0.0055			
Week 16		1.12 (0.68)		1.35 (0.67)	-0.23 (0.85)	(-1.90, 1.44)	0.7841			
Week 24		0.94 (0.71)		2.16 (0.71)	-1.22 (0.90)	(-3.00, 0.56)	0.1768			
Week 32		1.19 (0.74)		1.79 (0.73)	-0.60 (0.94)	(-2.46, 1.25)	0.5215			
Week 40		1.00 (0.76)		1.80 (0.75)	-0.80 (0.97)	(-2.71, 1.12)	0.4144			
Week 48		1.20 (0.76)		2.99 (0.76)	-1.80 (0.98)	(-3.72, 0.13)	0.0679			
Week 52		1.31 (0.79)		2.51 (0.78)	-1.20 (1.02)	(-3.21, 0.80)	0.2371			
OVERALL	119	1.02 (0.63)	116	2.16 (0.62)	-1.14 (0.77)	(-2.65, 0.37)	0.1393	-0.17 (0.13)	(-0.42, 0.09)	0.2022

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute General Health Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) N	LSMean (SE)	Placebo (N=125) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.3803
< 10 points	34	0.90 (1.06)	36	0.92 (1.00)	-0.02 (1.30)	(-2.60, 2.57)	0.9900	-0.00 (0.24)	(-0.47, 0.47)	0.9912	
>= 10 points	85	1.29 (0.77)	80	2.73 (0.77)	-1.43 (0.96)	(-3.33, 0.47)	0.1386	-0.20 (0.16)	(-0.51, 0.10)	0.1916	
OCS dose at baseline											0.9352
<10 mg/day	53	0.87 (0.92)	47	2.01 (0.95)	-1.13 (1.21)	(-3.54, 1.27)	0.3509	-0.17 (0.20)	(-0.56, 0.22)	0.3965	
>=10 mg/day	66	1.10 (0.91)	69	2.36 (0.85)	-1.26 (1.01)	(-3.25, 0.73)	0.2118	-0.17 (0.17)	(-0.51, 0.16)	0.3121	
Result of type I IFN gene signature test											0.1537
LOW	21	-0.12 (1.41)	23	3.38 (1.29)	-3.50 (1.88)	(-7.30, 0.30)	0.0700	-0.54 (0.31)	(-1.15, 0.06)	0.0779	
HIGH	98	2.02 (0.61)	93	2.58 (0.63)	-0.56 (0.84)	(-2.21, 1.08)	0.5001	-0.09 (0.14)	(-0.38, 0.19)	0.5207	
Age (years)											NE
<= 65	114	1.06 (0.66)	115	2.19 (0.63)	-1.13 (0.78)	(-2.66, 0.39)	0.1450	-0.16 (0.13)	(-0.42, 0.10)	0.2162	
> 65	5	NE	1	NE	NE	NE		NE	NE		
Sex											0.5353
male	12	0.86 (1.59)	8	0.80 (1.91)	0.06 (1.95)	(-4.41, 4.53)	0.9751	0.01 (0.46)	(-0.88, 0.91)	0.9808	
female	107	1.05 (0.69)	108	2.31 (0.66)	-1.25 (0.83)	(-2.88, 0.38)	0.1314	-0.18 (0.14)	(-0.45, 0.09)	0.1907	
Race											NE
White	81	0.50 (0.77)	87	1.88 (0.74)	-1.38 (0.96)	(-3.29, 0.52)	0.1529	-0.20 (0.15)	(-0.50, 0.10)	0.1987	
Black or African American	19	1.62 (1.87)	14	3.12 (1.50)	-1.51 (2.10)	(-5.82, 2.80)	0.4794	-0.20 (0.35)	(-0.90, 0.49)	0.5635	
Asian	7	NE	3	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	NE	NE	NE		NE	NE		
Other	12	3.78 (3.09)	11	5.36 (3.41)	-1.59 (2.22)	(-6.23, 3.06)	0.4830	-0.14 (0.42)	(-0.96, 0.68)	0.7396	
Ethnicity											0.4026
Hispanic/Latino	22	2.58 (1.42)	23	2.46 (1.60)	0.12 (1.65)	(-3.21, 3.45)	0.9412	0.02 (0.30)	(-0.57, 0.60)	0.9553	
Non-hispanic/Latino	97	0.59 (0.72)	93	2.03 (0.69)	-1.44 (0.88)	(-3.17, 0.29)	0.1019	-0.21 (0.15)	(-0.49, 0.08)	0.1516	
Geographic region											0.6721
EU	45	1.48 (1.20)	52	3.24 (1.11)	-1.76 (1.34)	(-4.42, 0.89)	0.1898	-0.22 (0.20)	(-0.62, 0.18)	0.2862	
non-EU	74	0.80 (0.74)	64	1.88 (0.77)	-1.07 (0.94)	(-2.93, 0.79)	0.2556	-0.17 (0.17)	(-0.51, 0.16)	0.3169	
Onset of disease											NE
Paediatric	7	NE	6	NE	NE	NE		NE	NE		
Adult	112	1.03 (0.65)	110	2.28 (0.65)	-1.25 (0.80)	(-2.82, 0.32)	0.1184	-0.18 (0.13)	(-0.45, 0.08)	0.1770	
ADA result											0.1020
Negative	105	0.48 (0.66)	103	2.11 (0.65)	-1.63 (0.81)	(-3.23, -0.02)	0.0467	-0.24 (0.14)	(-0.52, 0.03)	0.0802	
Positive (At any time)	14	7.69 (2.05)	13	5.89 (2.05)	1.80 (1.93)	(-2.19, 5.79)	0.3610	0.23 (0.39)	(-0.53, 0.99)	0.5489	
BMI (kg/m2) at enrolment											0.8342
< 30	70	1.73 (0.89)	80	2.63 (0.81)	-0.90 (0.97)	(-2.83, 1.02)	0.3561	-0.12 (0.16)	(-0.44, 0.20)	0.4558	
>= 30	49	0.09 (0.91)	36	1.33 (1.03)	-1.24 (1.28)	(-3.78, 1.31)	0.3358	-0.20 (0.22)	(-0.63, 0.24)	0.3753	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Mental Health Score
Full analysis set

	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 8		0.99 (0.76)		1.64 (0.76)	-0.65 (0.95)	(-2.53, 1.23)	0.4953			
Week 16		1.27 (0.81)		0.81 (0.80)	0.45 (1.02)	(-1.56, 2.47)	0.6585			
Week 24		1.84 (0.85)		0.67 (0.85)	1.18 (1.10)	(-1.00, 3.35)	0.2874			
Week 32		1.83 (0.86)		-0.30 (0.87)	2.13 (1.12)	(-0.07, 4.34)	0.0577			
Week 40		1.99 (0.87)		1.62 (0.87)	0.37 (1.13)	(-1.87, 2.60)	0.7462			
Week 48		2.51 (0.88)		1.64 (0.88)	0.87 (1.15)	(-1.39, 3.13)	0.4492			
Week 52		2.85 (0.85)		1.79 (0.85)	1.06 (1.10)	(-1.10, 3.22)	0.3341			
OVERALL	119	1.90 (0.67)	116	1.12 (0.66)	0.77 (0.80)	(-0.80, 2.35)	0.3348	0.11 (0.13)	(-0.15, 0.36)	0.4112

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Mental Health Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) N	LSMean (SE)	Placebo (N=125) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.1823
< 10 points	34	2.63 (1.05)	36	0.33 (0.99)	2.30 (1.29)	(-0.29, 4.88)	0.0808	0.38 (0.24)	(-0.10, 0.85)	0.1192	
>= 10 points	85	1.58 (0.81)	80	1.46 (0.83)	0.12 (1.00)	(-1.86, 2.09)	0.9080	0.02 (0.16)	(-0.29, 0.32)	0.9206	
OCS dose at baseline											0.3559
<10 mg/day	53	1.83 (0.94)	47	0.06 (1.00)	1.77 (1.25)	(-0.72, 4.26)	0.1616	0.26 (0.20)	(-0.14, 0.65)	0.2041	
>=10 mg/day	66	1.92 (0.96)	69	1.66 (0.90)	0.26 (1.05)	(-1.81, 2.33)	0.8035	0.03 (0.17)	(-0.30, 0.37)	0.8438	
Result of type I IFN gene signature test											0.6641
LOW	21	1.55 (1.16)	23	0.19 (1.06)	1.36 (1.54)	(-1.80, 4.52)	0.3856	0.26 (0.30)	(-0.34, 0.85)	0.3975	
HIGH	98	2.50 (0.68)	93	1.92 (0.70)	0.58 (0.93)	(-1.25, 2.41)	0.5337	0.09 (0.14)	(-0.20, 0.37)	0.5554	
Age (years)											NE
<= 65	114	1.95 (0.70)	115	1.17 (0.67)	0.78 (0.81)	(-0.82, 2.39)	0.3370	0.11 (0.13)	(-0.15, 0.37)	0.4218	
> 65	5	NE	1	NE	NE	NE		NE	NE		
Sex											0.2777
male	12	2.41 (1.28)	8	3.41 (1.51)	-1.00 (1.49)	(-4.21, 2.21)	0.5152	-0.22 (0.46)	(-1.12, 0.68)	0.6324	
female	107	1.91 (0.72)	108	1.03 (0.70)	0.87 (0.86)	(-0.83, 2.58)	0.3120	0.12 (0.14)	(-0.15, 0.39)	0.3868	
Race											NE
White	81	2.04 (0.77)	87	0.89 (0.74)	1.15 (0.94)	(-0.71, 3.01)	0.2234	0.17 (0.15)	(-0.14, 0.47)	0.2820	
Black or African American	19	4.78 (2.41)	14	0.72 (1.92)	4.06 (2.73)	(-1.55, 9.68)	0.1491	0.43 (0.36)	(-0.27, 1.13)	0.2299	
Asian	7	NE	3	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	2.48 (0.00)	NE	NE		NE	NE		
Other	12	-0.79 (2.19)	11	3.25 (2.32)	-4.04 (2.31)	(-8.93, 0.84)	0.0984	-0.51 (0.43)	(-1.34, 0.32)	0.2303	
Ethnicity											0.2058
Hispanic/Latino	22	1.57 (1.69)	23	3.11 (1.91)	-1.55 (1.94)	(-5.46, 2.37)	0.4297	-0.18 (0.30)	(-0.76, 0.41)	0.5535	
Non-hispanic/Latino	97	2.20 (0.73)	93	1.04 (0.71)	1.15 (0.89)	(-0.61, 2.91)	0.1981	0.16 (0.15)	(-0.12, 0.45)	0.2635	
Geographic region											0.7612
EU	45	3.53 (1.19)	52	2.94 (1.11)	0.59 (1.25)	(-1.89, 3.08)	0.6362	0.07 (0.20)	(-0.33, 0.47)	0.7180	
non-EU	74	0.77 (0.80)	64	-0.32 (0.85)	1.09 (1.03)	(-0.95, 3.12)	0.2940	0.16 (0.17)	(-0.18, 0.49)	0.3566	
Onset of disease											NE
Paediatric	7	NE	6	NE	NE	NE		NE	NE		
Adult	112	1.85 (0.69)	110	0.93 (0.69)	0.92 (0.83)	(-0.70, 2.55)	0.2647	0.13 (0.13)	(-0.14, 0.39)	0.3429	
ADA result											0.9417
Negative	105	1.53 (0.70)	103	0.86 (0.70)	0.67 (0.86)	(-1.02, 2.36)	0.4341	0.09 (0.14)	(-0.18, 0.37)	0.4992	
Positive (At any time)	14	4.37 (2.32)	13	3.87 (2.32)	0.50 (2.24)	(-4.15, 5.14)	0.8268	0.06 (0.39)	(-0.70, 0.81)	0.8839	
BMI (kg/m2) at enrolment											0.1232
< 30	70	1.41 (0.91)	80	1.58 (0.84)	-0.17 (0.97)	(-2.08, 1.74)	0.8602	-0.02 (0.16)	(-0.34, 0.30)	0.8906	
>= 30	49	1.69 (1.04)	36	-0.84 (1.17)	2.53 (1.46)	(-0.38, 5.43)	0.0873	0.35 (0.22)	(-0.09, 0.78)	0.1160	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Physical Functioning Score
Full analysis set

	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 8		1.66 (0.74)		1.29 (0.74)	0.36 (0.90)	(-1.41, 2.13)	0.6861			
Week 16		2.51 (0.82)		1.13 (0.81)	1.38 (1.02)	(-0.63, 3.39)	0.1778			
Week 24		1.69 (0.85)		2.17 (0.85)	-0.48 (1.08)	(-2.61, 1.66)	0.6593			
Week 32		2.88 (0.84)		2.20 (0.84)	0.68 (1.06)	(-1.41, 2.77)	0.5226			
Week 40		2.26 (0.85)		2.06 (0.84)	0.20 (1.07)	(-1.91, 2.31)	0.8531			
Week 48		2.32 (0.88)		2.25 (0.88)	0.07 (1.13)	(-2.15, 2.30)	0.9483			
Week 52		2.97 (0.86)		2.50 (0.86)	0.46 (1.09)	(-1.69, 2.61)	0.6720			
OVERALL	119	2.33 (0.73)	116	1.94 (0.73)	0.38 (0.88)	(-1.36, 2.12)	0.6646	0.05 (0.13)	(-0.21, 0.30)	0.7115

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Physical Functioning Score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											0.0514
< 10 points	34	2.32 (1.17)	36	-0.55 (1.10)	2.87 (1.42)	(0.03, 5.70)	0.0473	0.42 (0.24)	(-0.05, 0.90)	0.0799	
>= 10 points	85	2.94 (0.88)	80	3.56 (0.90)	-0.62 (1.10)	(-2.79, 1.54)	0.5699	-0.08 (0.16)	(-0.38, 0.23)	0.6229	
OCS dose at baseline											0.8521
<10 mg/day	53	2.02 (0.89)	47	1.85 (0.93)	0.18 (1.17)	(-2.14, 2.49)	0.8802	0.03 (0.20)	(-0.37, 0.42)	0.8916	
>=10 mg/day	66	2.41 (1.16)	69	1.91 (1.09)	0.50 (1.26)	(-2.00, 3.00)	0.6950	0.05 (0.17)	(-0.28, 0.39)	0.7562	
Result of type I IFN gene signature test											0.0550
LOW	21	0.18 (1.24)	23	2.72 (1.09)	-2.54 (1.64)	(-5.85, 0.77)	0.1284	-0.46 (0.31)	(-1.06, 0.14)	0.1347	
HIGH	98	3.57 (0.75)	93	2.42 (0.77)	1.16 (1.02)	(-0.85, 3.16)	0.2571	0.16 (0.14)	(-0.13, 0.44)	0.2826	
Age (years)											NE
<= 65	114	2.33 (0.76)	115	1.77 (0.73)	0.56 (0.89)	(-1.20, 2.31)	0.5314	0.07 (0.13)	(-0.19, 0.33)	0.5992	
> 65	5	NE	1	NE	NE	NE		NE	NE		
Sex											0.1614
male	12	2.02 (2.17)	8	-1.76 (2.60)	3.78 (2.45)	(-1.52, 9.07)	0.1474	0.49 (0.46)	(-0.43, 1.40)	0.2962	
female	107	2.26 (0.79)	108	2.16 (0.76)	0.10 (0.94)	(-1.76, 1.95)	0.9194	0.01 (0.14)	(-0.26, 0.28)	0.9310	
Race											NE
White	81	2.62 (0.84)	87	2.48 (0.81)	0.13 (1.04)	(-1.91, 2.18)	0.8968	0.02 (0.15)	(-0.28, 0.32)	0.9087	
Black or African American	19	6.68 (2.79)	14	1.53 (2.13)	5.16 (2.96)	(-0.91, 11.22)	0.0924	0.47 (0.36)	(-0.23, 1.18)	0.1849	
Asian	7	NE	3	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	NE	NE	NE		NE	NE		
Other	12	-6.84 (3.61)	11	-6.62 (3.86)	-0.22 (3.51)	(-7.64, 7.20)	0.9513	-0.02 (0.42)	(-0.83, 0.80)	0.9683	
Ethnicity											0.7618
Hispanic/Latino	22	0.89 (1.77)	23	1.18 (2.00)	-0.29 (2.15)	(-4.62, 4.04)	0.8929	-0.03 (0.30)	(-0.62, 0.55)	0.9150	
Non-hispanic/Latino	97	2.65 (0.82)	93	2.23 (0.80)	0.43 (0.99)	(-1.54, 2.39)	0.6686	0.05 (0.15)	(-0.23, 0.34)	0.7115	
Geographic region											0.3322
EU	45	4.01 (1.25)	52	4.16 (1.17)	-0.15 (1.32)	(-2.77, 2.47)	0.9089	-0.02 (0.20)	(-0.42, 0.38)	0.9302	
non-EU	74	1.79 (0.84)	64	0.30 (0.88)	1.50 (1.07)	(-0.62, 3.61)	0.1647	0.21 (0.17)	(-0.13, 0.54)	0.2237	
Onset of disease											NE
Paediatric	7	NE	6	NE	NE	NE		NE	NE		
Adult	112	2.56 (0.74)	110	2.02 (0.74)	0.54 (0.90)	(-1.23, 2.31)	0.5490	0.07 (0.13)	(-0.19, 0.33)	0.6072	
ADA result											0.0597
Negative	105	2.02 (0.77)	103	2.18 (0.77)	-0.16 (0.95)	(-2.03, 1.72)	0.8687	-0.02 (0.14)	(-0.29, 0.25)	0.8857	
Positive (At any time)	14	8.93 (2.63)	13	4.25 (2.56)	4.68 (2.39)	(-0.28, 9.63)	0.0630	0.48 (0.39)	(-0.29, 1.24)	0.2248	
BMI (kg/m2) at enrolment											0.1238
< 30	70	1.77 (0.96)	80	2.19 (0.89)	-0.42 (1.02)	(-2.44, 1.61)	0.6852	-0.05 (0.16)	(-0.37, 0.27)	0.7522	
>= 30	49	3.47 (1.18)	36	0.90 (1.33)	2.57 (1.65)	(-0.71, 5.85)	0.1230	0.31 (0.22)	(-0.12, 0.75)	0.1576	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Role Emotional Score
Full analysis set

	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 8		1.23 (0.91)		2.14 (0.91)	-0.91 (1.14)	(-3.15, 1.33)	0.4255			
Week 16		0.97 (0.99)		0.66 (0.98)	0.31 (1.26)	(-2.17, 2.80)	0.8030			
Week 24		0.89 (1.00)		0.78 (1.00)	0.11 (1.28)	(-2.42, 2.63)	0.9343			
Week 32		2.09 (0.99)		0.84 (0.99)	1.25 (1.26)	(-1.23, 3.73)	0.3221			
Week 40		1.01 (1.06)		1.23 (1.05)	-0.22 (1.37)	(-2.92, 2.48)	0.8736			
Week 48		1.91 (1.04)		2.16 (1.04)	-0.25 (1.34)	(-2.89, 2.39)	0.8527			
Week 52		2.34 (1.03)		1.89 (1.02)	0.45 (1.32)	(-2.15, 3.06)	0.7319			
OVERALL	119	1.49 (0.81)	116	1.39 (0.80)	0.11 (0.97)	(-1.80, 2.01)	0.9118	0.01 (0.13)	(-0.24, 0.27)	0.9253

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Role Emotional Score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											0.4402
< 10 points	34	1.13 (1.37)	36	-0.21 (1.32)	1.34 (1.73)	(-2.11, 4.80)	0.4408	0.17 (0.24)	(-0.30, 0.64)	0.4858	
>= 10 points	85	1.94 (0.96)	80	2.22 (0.98)	-0.28 (1.18)	(-2.61, 2.06)	0.8159	-0.03 (0.16)	(-0.34, 0.27)	0.8418	
OCS dose at baseline											0.5618
<10 mg/day	53	1.61 (1.17)	47	0.81 (1.24)	0.79 (1.54)	(-2.27, 3.85)	0.6087	0.09 (0.20)	(-0.30, 0.49)	0.6451	
>=10 mg/day	66	1.43 (1.16)	69	1.78 (1.09)	-0.36 (1.24)	(-2.82, 2.11)	0.7743	-0.04 (0.17)	(-0.38, 0.30)	0.8229	
Result of type I IFN gene signature test											0.7670
LOW	21	1.98 (1.54)	23	2.34 (1.40)	-0.36 (2.03)	(-4.46, 3.75)	0.8619	-0.05 (0.30)	(-0.64, 0.54)	0.8666	
HIGH	98	1.79 (0.80)	93	1.47 (0.83)	0.33 (1.09)	(-1.83, 2.48)	0.7650	0.04 (0.14)	(-0.24, 0.32)	0.7777	
Age (years)											NE
<= 65	114	1.35 (0.85)	115	1.22 (0.82)	0.13 (0.98)	(-1.81, 2.07)	0.8972	0.01 (0.13)	(-0.24, 0.27)	0.9144	
> 65	5	NE	1	NE	NE	NE		NE	NE		
Sex											0.8685
male	12	6.58 (2.74)	8	6.19 (3.22)	0.39 (2.94)	(-6.15, 6.93)	0.8974	0.04 (0.46)	(-0.85, 0.93)	0.9304	
female	107	1.17 (0.86)	108	1.30 (0.84)	-0.13 (1.03)	(-2.15, 1.90)	0.9017	-0.01 (0.14)	(-0.28, 0.25)	0.9162	
Race											NE
White	81	1.69 (0.87)	87	0.93 (0.84)	0.76 (1.07)	(-1.36, 2.88)	0.4818	0.10 (0.15)	(-0.21, 0.40)	0.5352	
Black or African American	19	5.34 (3.84)	14	2.31 (3.01)	3.03 (4.18)	(-5.52, 11.59)	0.4737	0.20 (0.35)	(-0.49, 0.89)	0.5689	
Asian	7	NE	3	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	NE	NE	NE		NE	NE		
Other	12	-4.44 (3.93)	11	1.02 (4.30)	-5.47 (2.94)	(-11.62, 0.69)	0.0787	-0.38 (0.42)	(-1.21, 0.45)	0.3700	
Ethnicity											0.2045
Hispanic/Latino	22	0.87 (1.82)	23	3.40 (2.06)	-2.53 (2.11)	(-6.79, 1.73)	0.2363	-0.27 (0.30)	(-0.86, 0.32)	0.3688	
Non-hispanic/Latino	97	1.66 (0.91)	93	1.18 (0.88)	0.48 (1.10)	(-1.68, 2.64)	0.6625	0.05 (0.15)	(-0.23, 0.34)	0.7070	
Geographic region											0.7232
EU	45	3.26 (1.22)	52	2.71 (1.14)	0.55 (1.29)	(-2.01, 3.12)	0.6700	0.07 (0.20)	(-0.33, 0.47)	0.7429	
non-EU	74	0.46 (1.08)	64	0.57 (1.13)	-0.12 (1.37)	(-2.83, 2.60)	0.9331	-0.01 (0.17)	(-0.35, 0.32)	0.9418	
Onset of disease											NE
Paediatric	7	NE	6	NE	NE	NE		NE	NE		
Adult	112	1.43 (0.83)	110	1.32 (0.83)	0.12 (1.00)	(-1.85, 2.08)	0.9070	0.01 (0.13)	(-0.25, 0.28)	0.9213	
ADA result											0.6754
Negative	105	1.06 (0.86)	103	1.10 (0.85)	-0.04 (1.05)	(-2.11, 2.03)	0.9707	-0.00 (0.14)	(-0.28, 0.27)	0.9748	
Positive (At any time)	14	4.48 (3.11)	13	3.32 (3.05)	1.16 (2.66)	(-4.37, 6.69)	0.6676	0.10 (0.39)	(-0.66, 0.85)	0.7969	
BMI (kg/m2) at enrolment											0.4168
< 30	70	0.88 (1.00)	80	1.34 (0.93)	-0.46 (1.06)	(-2.56, 1.64)	0.6673	-0.05 (0.16)	(-0.38, 0.27)	0.7390	
>= 30	49	1.16 (1.39)	36	-0.17 (1.55)	1.34 (1.94)	(-2.52, 5.19)	0.4923	0.14 (0.22)	(-0.29, 0.57)	0.5293	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Role Physical Score
Full analysis set

	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 8		2.07 (0.70)		2.38 (0.70)	-0.30 (0.86)	(-1.99, 1.38)	0.7233			
Week 16		3.36 (0.76)		1.71 (0.75)	1.65 (0.95)	(-0.22, 3.52)	0.0834			
Week 24		3.63 (0.79)		2.58 (0.79)	1.05 (1.00)	(-0.92, 3.01)	0.2946			
Week 32		3.21 (0.79)		2.48 (0.79)	0.73 (0.99)	(-1.23, 2.69)	0.4664			
Week 40		2.98 (0.85)		2.73 (0.85)	0.24 (1.09)	(-1.91, 2.39)	0.8226			
Week 48		3.95 (0.85)		3.40 (0.85)	0.56 (1.09)	(-1.60, 2.71)	0.6101			
Week 52		3.43 (0.82)		3.30 (0.82)	0.13 (1.04)	(-1.93, 2.19)	0.9005			
OVERALL	119	3.23 (0.69)	116	2.65 (0.68)	0.58 (0.83)	(-1.06, 2.22)	0.4862	0.08 (0.13)	(-0.18, 0.33)	0.5516

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Role Physical Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) N	LSMean (SE)	Placebo (N=125) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.3364
< 10 points	34	3.23 (1.10)	36	1.44 (1.04)	1.79 (1.38)	(-0.96, 4.54)	0.1986	0.28 (0.24)	(-0.19, 0.75)	0.2443	
>= 10 points	85	3.66 (0.83)	80	3.52 (0.85)	0.14 (1.03)	(-1.89, 2.16)	0.8941	0.02 (0.16)	(-0.29, 0.32)	0.9088	
OCS dose at baseline											0.3694
<10 mg/day	53	2.07 (0.96)	47	2.34 (1.01)	-0.27 (1.28)	(-2.81, 2.27)	0.8342	-0.04 (0.20)	(-0.43, 0.35)	0.8489	
>=10 mg/day	66	4.15 (1.01)	69	2.91 (0.95)	1.24 (1.09)	(-0.92, 3.39)	0.2572	0.15 (0.17)	(-0.18, 0.49)	0.3738	
Result of type I IFN gene signature test											0.0718
LOW	21	2.17 (1.03)	23	3.97 (0.91)	-1.81 (1.36)	(-4.56, 0.94)	0.1914	-0.39 (0.30)	(-0.99, 0.21)	0.2004	
HIGH	98	4.17 (0.71)	93	2.96 (0.73)	1.20 (0.97)	(-0.72, 3.12)	0.2185	0.17 (0.15)	(-0.11, 0.45)	0.2428	
Age (years)											NE
<= 65	114	3.41 (0.72)	115	2.61 (0.69)	0.80 (0.84)	(-0.86, 2.46)	0.3431	0.11 (0.13)	(-0.15, 0.36)	0.4258	
> 65	5	NE	1	NE	NE	NE		NE	NE		
Sex											0.2689
male	12	7.13 (1.38)	8	4.29 (1.79)	2.85 (2.23)	(-1.90, 7.59)	0.2213	0.56 (0.47)	(-0.36, 1.47)	0.2330	
female	107	3.00 (0.74)	108	2.81 (0.71)	0.19 (0.88)	(-1.55, 1.93)	0.8293	0.03 (0.14)	(-0.24, 0.29)	0.8532	
Race											NE
White	81	3.31 (0.78)	87	2.80 (0.75)	0.50 (0.97)	(-1.41, 2.42)	0.6038	0.07 (0.15)	(-0.23, 0.37)	0.6436	
Black or African American	19	6.24 (2.37)	14	2.28 (1.85)	3.97 (2.59)	(-1.33, 9.26)	0.1361	0.43 (0.36)	(-0.27, 1.13)	0.2319	
Asian	7	NE	3	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	NE	NE	NE		NE	NE		
Other	12	6.77 (3.29)	11	10.33 (3.79)	-3.56 (2.71)	(-9.26, 2.15)	0.2062	-0.29 (0.42)	(-1.11, 0.54)	0.4951	
Ethnicity											0.7139
Hispanic/Latino	22	1.35 (1.76)	23	1.47 (2.01)	-0.12 (2.04)	(-4.24, 4.01)	0.9546	-0.01 (0.30)	(-0.60, 0.57)	0.9659	
Non-hispanic/Latino	97	3.75 (0.76)	93	3.04 (0.74)	0.71 (0.93)	(-1.13, 2.54)	0.4500	0.10 (0.15)	(-0.19, 0.38)	0.5102	
Geographic region											0.6979
EU	45	4.80 (1.16)	52	4.39 (1.10)	0.41 (1.25)	(-2.08, 2.89)	0.7462	0.05 (0.20)	(-0.35, 0.45)	0.8015	
non-EU	74	2.55 (0.85)	64	1.50 (0.89)	1.05 (1.08)	(-1.09, 3.19)	0.3348	0.14 (0.17)	(-0.19, 0.48)	0.3975	
Onset of disease											NE
Paediatric	7	NE	6	NE	NE	NE		NE	NE		
Adult	112	3.46 (0.71)	110	2.70 (0.71)	0.76 (0.86)	(-0.94, 2.46)	0.3794	0.10 (0.13)	(-0.16, 0.36)	0.4514	
ADA result											0.1467
Negative	105	2.84 (0.74)	103	2.60 (0.73)	0.24 (0.91)	(-1.55, 2.03)	0.7923	0.03 (0.14)	(-0.24, 0.30)	0.8189	
Positive (At any time)	14	7.85 (2.07)	13	4.65 (2.09)	3.20 (1.82)	(-0.58, 6.97)	0.0931	0.41 (0.39)	(-0.36, 1.17)	0.2979	
BMI (kg/m2) at enrolment											0.2000
< 30	70	3.34 (0.84)	80	3.40 (0.79)	-0.06 (0.91)	(-1.86, 1.73)	0.9443	-0.01 (0.16)	(-0.33, 0.31)	0.9563	
>= 30	49	3.39 (1.16)	36	1.07 (1.30)	2.32 (1.62)	(-0.91, 5.55)	0.1570	0.29 (0.22)	(-0.14, 0.72)	0.1920	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Social Functioning Score
Full analysis set

	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 8		2.30 (0.87)		2.54 (0.87)	-0.24 (1.09)	(-2.38, 1.90)	0.8251			
Week 16		2.57 (0.92)		1.37 (0.90)	1.20 (1.16)	(-1.07, 3.48)	0.2989			
Week 24		3.33 (0.92)		1.36 (0.92)	1.97 (1.16)	(-0.32, 4.26)	0.0912			
Week 32		3.27 (0.93)		1.99 (0.93)	1.29 (1.19)	(-1.05, 3.62)	0.2801			
Week 40		3.11 (0.99)		1.26 (0.99)	1.86 (1.28)	(-0.67, 4.38)	0.1483			
Week 48		2.83 (0.98)		2.37 (0.98)	0.46 (1.26)	(-2.03, 2.95)	0.7139			
Week 52		2.75 (0.97)		2.58 (0.96)	0.18 (1.24)	(-2.27, 2.63)	0.8867			
OVERALL	119	2.88 (0.78)	116	1.92 (0.77)	0.96 (0.93)	(-0.88, 2.80)	0.3046	0.11 (0.13)	(-0.14, 0.37)	0.3818

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Social Functioning Score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											0.3075
< 10 points	34	2.65 (1.31)	36	0.28 (1.23)	2.37 (1.62)	(-0.87, 5.61)	0.1481	0.31 (0.24)	(-0.16, 0.79)	0.1930	
>= 10 points	85	3.31 (0.93)	80	2.96 (0.95)	0.35 (1.15)	(-1.92, 2.61)	0.7622	0.04 (0.16)	(-0.26, 0.35)	0.7943	
OCS dose at baseline											0.4297
<10 mg/day	53	2.03 (1.09)	47	1.90 (1.14)	0.13 (1.43)	(-2.72, 2.97)	0.9297	0.02 (0.20)	(-0.38, 0.41)	0.9365	
>=10 mg/day	66	3.60 (1.15)	69	1.98 (1.07)	1.62 (1.24)	(-0.83, 4.07)	0.1927	0.18 (0.17)	(-0.16, 0.51)	0.3055	
Result of type I IFN gene signature test											0.4855
LOW	21	2.73 (1.39)	23	2.81 (1.26)	-0.08 (1.87)	(-3.88, 3.71)	0.9648	-0.01 (0.30)	(-0.60, 0.58)	0.9653	
HIGH	98	3.48 (0.78)	93	2.06 (0.81)	1.42 (1.07)	(-0.69, 3.52)	0.1856	0.18 (0.15)	(-0.10, 0.47)	0.2101	
Age (years)											NE
<= 65	114	2.89 (0.82)	115	1.89 (0.78)	1.00 (0.95)	(-0.87, 2.87)	0.2938	0.12 (0.13)	(-0.14, 0.38)	0.3794	
> 65	5	NE	1	NE	NE	NE		NE	NE		
Sex											0.5115
male	12	5.84 (1.54)	8	3.77 (1.86)	2.08 (1.81)	(-1.84, 5.99)	0.2721	0.37 (0.46)	(-0.53, 1.28)	0.4171	
female	107	2.60 (0.84)	108	1.88 (0.81)	0.72 (1.00)	(-1.26, 2.70)	0.4747	0.08 (0.14)	(-0.18, 0.35)	0.5402	
Race											NE
White	81	2.92 (0.90)	87	2.06 (0.87)	0.86 (1.11)	(-1.33, 3.05)	0.4399	0.11 (0.15)	(-0.20, 0.41)	0.4951	
Black or African American	19	11.90 (3.04)	14	3.10 (2.35)	8.80 (3.33)	(1.87, 15.72)	0.0153	0.74 (0.37)	(0.03, 1.46)	0.0424	
Asian	7	NE	3	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	NE	NE	NE		NE	NE		
Other	12	-1.13 (5.37)	11	0.77 (5.87)	-1.90 (3.19)	(-8.65, 4.85)	0.5595	-0.10 (0.42)	(-0.92, 0.72)	0.8174	
Ethnicity											0.3628
Hispanic/Latino	22	0.50 (1.67)	23	1.04 (1.89)	-0.54 (1.92)	(-4.42, 3.34)	0.7789	-0.06 (0.30)	(-0.65, 0.52)	0.8332	
Non-hispanic/Latino	97	3.55 (0.90)	93	2.08 (0.87)	1.47 (1.09)	(-0.68, 3.61)	0.1792	0.17 (0.15)	(-0.12, 0.45)	0.2430	
Geographic region											0.7857
EU	45	4.83 (1.30)	52	4.11 (1.22)	0.72 (1.38)	(-2.02, 3.47)	0.6028	0.08 (0.20)	(-0.32, 0.48)	0.6886	
non-EU	74	1.88 (0.97)	64	0.66 (1.01)	1.22 (1.23)	(-1.20, 3.65)	0.3206	0.15 (0.17)	(-0.19, 0.48)	0.3855	
Onset of disease											NE
Paediatric	7	NE	6	NE	NE	NE		NE	NE		
Adult	112	2.86 (0.80)	110	1.69 (0.79)	1.16 (0.96)	(-0.73, 3.06)	0.2278	0.14 (0.13)	(-0.13, 0.40)	0.3040	
ADA result											0.3273
Negative	105	2.53 (0.84)	103	1.80 (0.84)	0.72 (1.03)	(-1.31, 2.75)	0.4836	0.08 (0.14)	(-0.19, 0.36)	0.5443	
Positive (At any time)	14	6.54 (2.15)	13	3.77 (2.08)	2.76 (1.81)	(-1.01, 6.53)	0.1422	0.34 (0.39)	(-0.42, 1.10)	0.3764	
BMI (kg/m2) at enrolment											0.4953
< 30	70	2.84 (0.99)	80	2.38 (0.91)	0.46 (1.05)	(-1.61, 2.53)	0.6630	0.06 (0.16)	(-0.27, 0.38)	0.7349	
>= 30	49	3.13 (1.35)	36	1.20 (1.51)	1.93 (1.89)	(-1.83, 5.68)	0.3097	0.21 (0.22)	(-0.23, 0.64)	0.3504	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Bodily Pain Score
Full analysis set

	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 8		1.75 (0.79)		2.01 (0.79)	-0.26 (0.98)	(-2.19, 1.67)	0.7873			
Week 16		4.01 (0.83)		2.65 (0.82)	1.36 (1.05)	(-0.71, 3.42)	0.1964			
Week 24		3.44 (0.86)		2.26 (0.86)	1.17 (1.10)	(-0.99, 3.33)	0.2863			
Week 32		3.06 (0.93)		3.19 (0.94)	-0.13 (1.21)	(-2.51, 2.26)	0.9172			
Week 40		4.67 (0.93)		3.01 (0.92)	1.67 (1.20)	(-0.69, 4.03)	0.1655			
Week 48		4.12 (0.94)		3.63 (0.95)	0.50 (1.23)	(-1.92, 2.91)	0.6859			
Week 52		3.34 (0.92)		3.78 (0.91)	-0.43 (1.18)	(-2.76, 1.89)	0.7137			
OVERALL	119	3.49 (0.71)	116	2.93 (0.70)	0.55 (0.85)	(-1.13, 2.23)	0.5175	0.07 (0.13)	(-0.18, 0.33)	0.5826

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Bodily Pain Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) N	LSMean (SE)	Placebo (N=125) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.0098
< 10 points	34	5.21 (1.13)	36	1.40 (1.04)	3.81 (1.36)	(1.08, 6.54)	0.0070	0.59 (0.24)	(0.11, 1.07)	0.0163	
>= 10 points	85	3.15 (0.85)	80	3.78 (0.87)	-0.64 (1.05)	(-2.71, 1.44)	0.5445	-0.08 (0.16)	(-0.39, 0.22)	0.6021	
OCS dose at baseline											0.4443
<10 mg/day	53	3.34 (0.87)	47	2.04 (0.91)	1.30 (1.14)	(-0.97, 3.57)	0.2570	0.21 (0.20)	(-0.19, 0.60)	0.3048	
>=10 mg/day	66	3.59 (1.12)	69	3.57 (1.06)	0.02 (1.22)	(-2.39, 2.44)	0.9845	0.00 (0.17)	(-0.33, 0.34)	0.9877	
Result of type I IFN gene signature test											0.1772
LOW	21	1.97 (1.13)	23	3.39 (1.02)	-1.43 (1.49)	(-4.45, 1.60)	0.3458	-0.28 (0.30)	(-0.87, 0.32)	0.3593	
HIGH	98	4.69 (0.73)	93	3.70 (0.75)	0.99 (0.99)	(-0.96, 2.95)	0.3180	0.14 (0.14)	(-0.15, 0.42)	0.3448	
Age (years)											NE
<= 65	114	3.68 (0.74)	115	2.91 (0.71)	0.77 (0.86)	(-0.93, 2.47)	0.3728	0.10 (0.13)	(-0.16, 0.36)	0.4571	
> 65	5	NE	1	NE	NE	NE		NE	NE		
Sex											0.3510
male	12	5.32 (2.51)	8	2.41 (3.09)	2.91 (2.68)	(-3.01, 8.83)	0.3023	0.32 (0.46)	(-0.58, 1.22)	0.4870	
female	107	3.38 (0.76)	108	3.11 (0.73)	0.27 (0.90)	(-1.52, 2.05)	0.7688	0.03 (0.14)	(-0.23, 0.30)	0.8017	
Race											NE
White	81	3.28 (0.85)	87	3.19 (0.82)	0.09 (1.05)	(-1.98, 2.16)	0.9311	0.01 (0.15)	(-0.29, 0.31)	0.9386	
Black or African American	19	7.17 (2.39)	14	3.12 (1.85)	4.05 (2.62)	(-1.32, 9.43)	0.1334	0.43 (0.36)	(-0.27, 1.13)	0.2246	
Asian	7	NE	3	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	-7.51 (0.00)	NE	NE		NE	NE		
Other	12	NE	11	NE	NE	NE		NE	NE		
Ethnicity											0.8675
Hispanic/Latino	22	3.36 (1.63)	23	2.62 (1.87)	0.74 (1.87)	(-3.04, 4.51)	0.6951	0.09 (0.30)	(-0.50, 0.67)	0.7710	
Non-hispanic/Latino	97	3.49 (0.81)	93	3.10 (0.78)	0.39 (0.98)	(-1.54, 2.31)	0.6935	0.05 (0.15)	(-0.23, 0.33)	0.7330	
Geographic region											0.2322
EU	45	4.34 (1.34)	52	4.72 (1.27)	-0.38 (1.43)	(-3.22, 2.46)	0.7916	-0.04 (0.20)	(-0.44, 0.36)	0.8388	
non-EU	74	3.04 (0.79)	64	1.34 (0.82)	1.70 (0.99)	(-0.26, 3.66)	0.0894	0.25 (0.17)	(-0.08, 0.59)	0.1400	
Onset of disease											NE
Paediatric	7	NE	6	NE	NE	NE		NE	NE		
Adult	112	3.57 (0.73)	110	2.87 (0.73)	0.70 (0.88)	(-1.04, 2.44)	0.4285	0.09 (0.13)	(-0.17, 0.35)	0.5008	
ADA result											0.2367
Negative	105	3.13 (0.75)	103	2.97 (0.74)	0.15 (0.91)	(-1.64, 1.95)	0.8652	0.02 (0.14)	(-0.25, 0.29)	0.8838	
Positive (At any time)	14	8.76 (2.94)	13	5.17 (2.90)	3.58 (2.75)	(-2.16, 9.32)	0.2075	0.32 (0.39)	(-0.44, 1.08)	0.4048	
BMI (kg/m2) at enrolment											0.1768
< 30	70	2.90 (0.96)	80	3.03 (0.90)	-0.13 (1.02)	(-2.15, 1.89)	0.8992	-0.02 (0.16)	(-0.34, 0.30)	0.9221	
>= 30	49	4.42 (1.09)	36	2.08 (1.22)	2.34 (1.52)	(-0.68, 5.37)	0.1273	0.31 (0.22)	(-0.12, 0.74)	0.1619	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Vitality Score
Full analysis set

	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 8		1.77 (0.80)		1.86 (0.78)	-0.09 (0.98)	(-2.01, 1.84)	0.9299			
Week 16		2.63 (0.84)		1.46 (0.81)	1.16 (1.04)	(-0.88, 3.21)	0.2641			
Week 24		3.64 (0.87)		1.92 (0.85)	1.73 (1.10)	(-0.43, 3.89)	0.1166			
Week 32		3.40 (0.89)		1.46 (0.87)	1.94 (1.13)	(-0.29, 4.16)	0.0873			
Week 40		3.13 (0.93)		2.83 (0.91)	0.30 (1.19)	(-2.05, 2.65)	0.8020			
Week 48		4.11 (0.92)		2.63 (0.91)	1.48 (1.19)	(-0.85, 3.82)	0.2125			
Week 52		3.68 (0.98)		3.07 (0.96)	0.61 (1.27)	(-1.88, 3.10)	0.6306			
OVERALL	119	3.19 (0.75)	116	2.18 (0.72)	1.02 (0.90)	(-0.75, 2.79)	0.2576	0.13 (0.13)	(-0.13, 0.38)	0.3308

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Vitality Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) N	LSMean (SE)	Placebo (N=125) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.0392
< 10 points	34	4.85 (1.29)	36	0.95 (1.17)	3.90 (1.58)	(0.75, 7.05)	0.0161	0.53 (0.24)	(0.05, 1.01)	0.0291	
>= 10 points	85	2.88 (0.88)	80	2.94 (0.89)	-0.06 (1.09)	(-2.22, 2.10)	0.9566	-0.01 (0.16)	(-0.31, 0.30)	0.9623	
OCS dose at baseline											0.5004
<10 mg/day	53	2.74 (1.05)	47	2.53 (1.08)	0.21 (1.38)	(-2.53, 2.95)	0.8806	0.03 (0.20)	(-0.37, 0.42)	0.8916	
>=10 mg/day	66	3.48 (1.09)	69	2.05 (1.00)	1.43 (1.18)	(-0.90, 3.77)	0.2273	0.17 (0.17)	(-0.17, 0.50)	0.3356	
Result of type I IFN gene signature test											0.6680
LOW	21	3.91 (1.42)	23	3.61 (1.28)	0.30 (1.89)	(-3.53, 4.13)	0.8746	0.05 (0.30)	(-0.54, 0.64)	0.8769	
HIGH	98	3.73 (0.74)	93	2.50 (0.76)	1.22 (1.02)	(-0.78, 3.23)	0.2308	0.17 (0.15)	(-0.12, 0.45)	0.2527	
Age (years)											NE
<= 65	114	3.31 (0.79)	115	2.15 (0.74)	1.16 (0.92)	(-0.65, 2.97)	0.2072	0.14 (0.13)	(-0.12, 0.40)	0.2853	
> 65	5	NE	1	NE	NE	NE		NE	NE		
Sex											0.1841
male	12	6.31 (2.13)	8	2.11 (2.47)	4.20 (2.40)	(-0.97, 9.36)	0.1028	0.56 (0.47)	(-0.36, 1.47)	0.2340	
female	107	2.93 (0.81)	108	2.16 (0.76)	0.77 (0.96)	(-1.13, 2.66)	0.4265	0.09 (0.14)	(-0.17, 0.36)	0.4925	
Race											NE
White	81	3.25 (0.89)	87	2.12 (0.83)	1.13 (1.09)	(-1.03, 3.28)	0.3029	0.14 (0.15)	(-0.16, 0.45)	0.3566	
Black or African American	19	11.23 (2.10)	14	3.74 (1.64)	7.50 (2.30)	(2.63, 12.36)	0.0047	0.91 (0.37)	(0.18, 1.64)	0.0142	
Asian	7	NE	3	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	NE	NE	NE		NE	NE		
Other	12	3.39 (3.83)	11	7.47 (4.48)	-4.08 (2.85)	(-10.10, 1.94)	0.1706	-0.28 (0.42)	(-1.10, 0.54)	0.5048	
Ethnicity											0.1554
Hispanic/Latino	22	2.33 (1.66)	23	3.96 (1.91)	-1.63 (1.96)	(-5.59, 2.34)	0.4121	-0.19 (0.30)	(-0.77, 0.40)	0.5306	
Non-hispanic/Latino	97	3.53 (0.86)	93	2.00 (0.80)	1.53 (1.04)	(-0.52, 3.58)	0.1429	0.19 (0.15)	(-0.10, 0.47)	0.1977	
Geographic region											0.4708
EU	45	3.88 (1.35)	52	3.66 (1.24)	0.21 (1.43)	(-2.62, 3.05)	0.8808	0.02 (0.20)	(-0.38, 0.42)	0.9072	
non-EU	74	3.15 (0.90)	64	1.62 (0.92)	1.54 (1.14)	(-0.73, 3.80)	0.1821	0.20 (0.17)	(-0.13, 0.54)	0.2380	
Onset of disease											NE
Paediatric	7	NE	6	NE	NE	NE		NE	NE		
Adult	112	3.20 (0.78)	110	2.23 (0.75)	0.97 (0.93)	(-0.86, 2.80)	0.2981	0.12 (0.13)	(-0.14, 0.38)	0.3719	
ADA result											0.5346
Negative	105	2.85 (0.80)	103	2.13 (0.77)	0.73 (0.98)	(-1.20, 2.65)	0.4578	0.09 (0.14)	(-0.18, 0.36)	0.5173	
Positive (At any time)	14	5.49 (2.84)	13	3.02 (2.81)	2.47 (2.63)	(-3.03, 7.97)	0.3597	0.23 (0.39)	(-0.53, 0.99)	0.5505	
BMI (kg/m2) at enrolment											0.0672
< 30	70	2.62 (1.04)	80	2.64 (0.95)	-0.03 (1.10)	(-2.21, 2.16)	0.9815	-0.00 (0.16)	(-0.32, 0.32)	0.9854	
>= 30	49	4.21 (1.12)	36	0.74 (1.22)	3.47 (1.56)	(0.37, 6.58)	0.0288	0.45 (0.22)	(0.02, 0.89)	0.0422	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - FACIT-F Total Score
Full analysis set

Visit	Anifrolumab 300mg (N=127) N	Anifrolumab 300mg (N=127) LSMean (SE)	Placebo (N=125) N	Placebo (N=125) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		2.16 (0.81)		1.49 (0.79)	0.67 (0.99)	(-1.27, 2.62)	0.4963			
Week 8		2.96 (0.83)		2.82 (0.82)	0.14 (1.04)	(-1.91, 2.19)	0.8950			
Week 12		3.61 (0.93)		1.06 (0.93)	2.55 (1.20)	(0.18, 4.92)	0.0350			
Week 16		4.42 (0.90)		1.11 (0.89)	3.32 (1.15)	(1.06, 5.58)	0.0042			
Week 20		4.61 (0.96)		4.46 (0.94)	0.15 (1.23)	(-2.27, 2.57)	0.9024			
Week 24		5.54 (0.98)		2.89 (0.97)	2.65 (1.26)	(0.16, 5.15)	0.0368			
Week 28		5.50 (0.98)		3.22 (0.97)	2.28 (1.27)	(-0.23, 4.79)	0.0747			
Week 32		4.40 (1.04)		2.87 (1.04)	1.53 (1.37)	(-1.17, 4.24)	0.2650			
Week 36		4.34 (1.07)		2.12 (1.07)	2.22 (1.41)	(-0.56, 5.00)	0.1176			
Week 40		4.47 (1.09)		3.82 (1.09)	0.64 (1.45)	(-2.21, 3.49)	0.6570			
Week 44		5.32 (1.18)		3.24 (1.18)	2.08 (1.58)	(-1.04, 5.20)	0.1904			
Week 48		5.69 (1.06)		3.86 (1.06)	1.83 (1.40)	(-0.93, 4.58)	0.1931			
Week 52		5.63 (1.09)		3.91 (1.09)	1.72 (1.44)	(-1.13, 4.57)	0.2359			
OVERALL	121	4.51 (0.83)	116	2.84 (0.82)	1.68 (1.03)	(-0.35, 3.70)	0.1050	0.19 (0.13)	(-0.07, 0.44)	0.1526

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - FACIT-F Total Score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											0.2848
< 10 points	36	4.86 (1.46)	36	1.47 (1.37)	3.39 (1.82)	(-0.25, 7.03)	0.0676	0.40 (0.24)	(-0.07, 0.86)	0.0971	
>= 10 points	85	4.91 (0.98)	80	3.89 (1.00)	1.02 (1.25)	(-1.46, 3.50)	0.4164	0.11 (0.16)	(-0.19, 0.42)	0.4675	
OCS dose at baseline											0.9621
<10 mg/day	53	4.47 (1.16)	46	2.60 (1.21)	1.86 (1.58)	(-1.27, 5.00)	0.2409	0.22 (0.20)	(-0.17, 0.62)	0.2729	
>=10 mg/day	68	4.76 (1.21)	70	2.99 (1.14)	1.76 (1.37)	(-0.94, 4.47)	0.1991	0.18 (0.17)	(-0.15, 0.51)	0.2913	
Result of type I IFN gene signature test											0.1995
LOW	21	4.49 (1.86)	23	5.61 (1.69)	-1.11 (2.47)	(-6.11, 3.89)	0.6548	-0.13 (0.30)	(-0.72, 0.46)	0.6635	
HIGH	100	5.10 (0.81)	93	2.73 (0.84)	2.37 (1.13)	(0.15, 4.60)	0.0369	0.29 (0.14)	(0.01, 0.58)	0.0443	
Age (years)											NE
<= 65	116	4.62 (0.87)	115	2.79 (0.84)	1.83 (1.05)	(-0.25, 3.91)	0.0836	0.20 (0.13)	(-0.06, 0.46)	0.1315	
> 65	5	NE	1	NE	NE	NE		NE	NE		
Sex											NE
male	12	NE	8	NE	NE	NE		NE	NE		
female	109	4.62 (0.90)	108	3.13 (0.87)	1.49 (1.11)	(-0.70, 3.69)	0.1813	0.16 (0.14)	(-0.11, 0.43)	0.2358	
Race											NE
White	81	4.26 (0.98)	88	2.56 (0.93)	1.70 (1.24)	(-0.74, 4.14)	0.1716	0.19 (0.15)	(-0.11, 0.50)	0.2112	
Black or African American	20	NE	13	NE	NE	NE		NE	NE		
Asian	7	NE	3	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	-0.50 (0.00)	NE	NE		NE	NE		
Other	13	NE	11	NE	NE	NE		NE	NE		
Ethnicity											0.8495
Hispanic/Latino	23	2.08 (1.88)	23	0.18 (2.08)	1.90 (2.20)	(-2.55, 6.34)	0.3944	0.20 (0.30)	(-0.38, 0.78)	0.5071	
Non-hispanic/Latino	98	5.17 (0.92)	93	3.75 (0.90)	1.42 (1.16)	(-0.86, 3.70)	0.2196	0.16 (0.14)	(-0.12, 0.44)	0.2720	
Geographic region											0.2345
EU	46	5.94 (1.27)	53	5.29 (1.19)	0.65 (1.41)	(-2.16, 3.46)	0.6484	0.07 (0.20)	(-0.32, 0.47)	0.7128	
non-EU	75	3.88 (1.07)	63	0.87 (1.11)	3.01 (1.39)	(0.25, 5.77)	0.0329	0.33 (0.17)	(-0.01, 0.67)	0.0547	
Onset of disease											NE
Paediatric	7	NE	6	NE	NE	NE		NE	NE		
Adult	114	4.73 (0.85)	110	2.94 (0.84)	1.79 (1.06)	(-0.29, 3.88)	0.0911	0.20 (0.13)	(-0.06, 0.46)	0.1351	
ADA result											0.9987
Negative	106	4.11 (0.89)	103	2.45 (0.87)	1.66 (1.12)	(-0.55, 3.88)	0.1403	0.18 (0.14)	(-0.09, 0.45)	0.1864	
Positive (At any time)	15	0.28 (4.11)	13	-1.37 (4.25)	1.66 (4.15)	(-8.25, 11.56)	0.7023	0.10 (0.38)	(-0.64, 0.85)	0.7865	
BMI (kg/m2) at enrolment											0.3213
< 30	72	3.89 (1.07)	80	3.00 (0.98)	0.89 (1.18)	(-1.44, 3.22)	0.4508	0.10 (0.16)	(-0.22, 0.42)	0.5408	
>= 30	49	5.30 (1.38)	36	2.13 (1.55)	3.17 (1.97)	(-0.75, 7.09)	0.1118	0.33 (0.22)	(-0.10, 0.76)	0.1356	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - EQ VAS Score
Full analysis set

	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 12		5.77 (2.13)		3.92 (2.16)	1.86 (2.71)	(-3.48, 7.19)	0.4936			
Week 24		8.28 (2.23)		8.18 (2.24)	0.10 (2.83)	(-5.48, 5.68)	0.9725			
Week 36		9.26 (2.24)		8.46 (2.22)	0.80 (2.84)	(-4.79, 6.40)	0.7776			
Week 52		11.94 (2.23)		8.61 (2.19)	3.33 (2.80)	(-2.20, 8.86)	0.2360			
OVERALL	116	8.81 (1.84)	113	7.29 (1.82)	1.52 (2.19)	(-2.79, 5.83)	0.4870	0.08 (0.13)	(-0.18, 0.34)	0.5576

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - EQ VAS Score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											0.4301
< 10 points	34	8.26 (3.14)	34	4.00 (2.92)	4.26 (3.83)	(-3.41, 11.92)	0.2713	0.24 (0.24)	(-0.24, 0.72)	0.3285	
>= 10 points	82	9.94 (2.18)	79	9.37 (2.23)	0.57 (2.67)	(-4.70, 5.84)	0.8309	0.03 (0.16)	(-0.28, 0.34)	0.8553	
OCS dose at baseline											0.7774
<10 mg/day	52	6.56 (2.79)	45	5.96 (2.89)	0.60 (3.61)	(-6.57, 7.76)	0.8690	0.03 (0.20)	(-0.37, 0.43)	0.8831	
>=10 mg/day	64	9.81 (2.50)	68	7.94 (2.35)	1.87 (2.71)	(-3.49, 7.23)	0.4907	0.09 (0.17)	(-0.25, 0.44)	0.5875	
Result of type I IFN gene signature test											0.2677
LOW	21	1.44 (3.64)	23	4.74 (3.30)	-3.29 (4.78)	(-12.98, 6.39)	0.4950	-0.20 (0.30)	(-0.79, 0.39)	0.5106	
HIGH	95	12.23 (1.81)	90	9.57 (1.87)	2.66 (2.45)	(-2.18, 7.50)	0.2797	0.15 (0.15)	(-0.14, 0.44)	0.3084	
Age (years)											NE
<= 65	111	9.40 (1.92)	112	7.43 (1.85)	1.97 (2.22)	(-2.40, 6.34)	0.3754	0.10 (0.13)	(-0.16, 0.36)	0.4622	
> 65	5	NE	1	NE	NE	NE		NE	NE		
Sex											0.2244
male	12	11.27 (7.51)	8	-0.02 (9.21)	11.29 (8.56)	(-7.28, 29.86)	0.2108	0.42 (0.46)	(-0.49, 1.32)	0.3690	
female	104	8.16 (1.95)	105	7.63 (1.88)	0.53 (2.29)	(-4.00, 5.05)	0.8192	0.03 (0.14)	(-0.24, 0.30)	0.8465	
Race											NE
White	78	8.80 (2.19)	86	8.40 (2.10)	0.40 (2.64)	(-4.83, 5.62)	0.8803	0.02 (0.16)	(-0.29, 0.33)	0.8959	
Black or African American	19	14.42 (4.05)	13	6.99 (3.35)	7.42 (4.87)	(-2.56, 17.41)	0.1387	0.46 (0.37)	(-0.25, 1.18)	0.2056	
Asian	7	NE	3	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	0	NE	NE	NE		NE	NE		
Other	12	6.83 (12.02)	11	-2.74 (13.95)	9.57 (9.53)	(-10.43, 29.56)	0.3284	0.21 (0.42)	(-0.61, 1.03)	0.6160	
Ethnicity											0.3983
Hispanic/Latino	21	8.27 (5.15)	23	2.76 (5.70)	5.51 (5.87)	(-6.37, 17.38)	0.3541	0.21 (0.30)	(-0.38, 0.80)	0.4858	
Non-hispanic/Latino	95	8.70 (1.99)	90	8.54 (1.93)	0.16 (2.38)	(-4.55, 4.86)	0.9481	0.01 (0.15)	(-0.28, 0.30)	0.9555	
Geographic region											0.2724
EU	45	14.52 (3.09)	52	15.34 (2.92)	-0.82 (3.28)	(-7.33, 5.69)	0.8029	-0.04 (0.20)	(-0.44, 0.36)	0.8483	
non-EU	71	5.01 (2.29)	61	1.03 (2.39)	3.98 (2.90)	(-1.76, 9.72)	0.1721	0.21 (0.18)	(-0.13, 0.55)	0.2343	
Onset of disease											NE
Paediatric	6	NE	6	NE	NE	NE		NE	NE		
Adult	110	8.61 (1.90)	107	7.07 (1.90)	1.54 (2.27)	(-2.93, 6.01)	0.4982	0.08 (0.14)	(-0.19, 0.34)	0.5680	
ADA result											0.3710
Negative	101	8.42 (1.94)	100	7.58 (1.91)	0.83 (2.34)	(-3.79, 5.46)	0.7221	0.04 (0.14)	(-0.23, 0.32)	0.7601	
Positive (At any time)	15	25.77 (7.51)	13	18.66 (7.52)	7.10 (6.61)	(-6.63, 20.84)	0.2943	0.24 (0.38)	(-0.50, 0.99)	0.5202	
BMI (kg/m2) at enrolment											0.9819
< 30	69	10.27 (2.61)	78	8.32 (2.44)	1.94 (2.77)	(-3.53, 7.41)	0.4839	0.09 (0.17)	(-0.23, 0.41)	0.5884	
>= 30	47	6.08 (2.63)	35	4.24 (2.90)	1.84 (3.62)	(-5.37, 9.05)	0.6127	0.10 (0.22)	(-0.33, 0.54)	0.6441	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Lupus QoL Physical Health domain score
Full analysis set

	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 12		8.85 (1.95)		7.93 (1.96)	0.92 (2.41)	(-3.82, 5.67)	0.7023			
Week 24		9.22 (2.04)		7.06 (2.03)	2.16 (2.53)	(-2.83, 7.16)	0.3940			
Week 36		9.28 (2.08)		7.93 (2.06)	1.35 (2.59)	(-3.76, 6.45)	0.6028			
Week 52		8.71 (2.14)		7.86 (2.11)	0.84 (2.68)	(-4.43, 6.12)	0.7526			
OVERALL	116	9.02 (1.84)	113	7.70 (1.82)	1.32 (2.20)	(-3.01, 5.65)	0.5484	0.07 (0.13)	(-0.19, 0.33)	0.6115

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Lupus QoL Physical Health domain score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											0.1499
< 10 points	34	8.57 (2.83)	34	2.81 (2.63)	5.75 (3.45)	(-1.14, 12.65)	0.1003	0.36 (0.24)	(-0.12, 0.84)	0.1441	
>= 10 points	82	10.36 (2.25)	79	10.96 (2.29)	-0.60 (2.76)	(-6.05, 4.85)	0.8275	-0.03 (0.16)	(-0.34, 0.28)	0.8519	
OCS dose at baseline											0.9698
<10 mg/day	52	7.84 (2.42)	45	6.25 (2.52)	1.59 (3.17)	(-4.71, 7.88)	0.6178	0.09 (0.20)	(-0.31, 0.49)	0.6539	
>=10 mg/day	64	10.00 (2.81)	68	8.59 (2.65)	1.42 (3.04)	(-4.60, 7.44)	0.6413	0.06 (0.17)	(-0.28, 0.41)	0.7144	
Result of type I IFN gene signature test											0.1120
LOW	21	5.66 (3.58)	23	11.60 (3.19)	-5.94 (4.74)	(-15.56, 3.68)	0.2182	-0.37 (0.30)	(-0.97, 0.23)	0.2263	
HIGH	95	10.19 (1.81)	90	7.64 (1.88)	2.55 (2.47)	(-2.32, 7.42)	0.3031	0.14 (0.15)	(-0.15, 0.43)	0.3316	
Age (years)											NE
<= 65	111	10.07 (1.93)	112	8.09 (1.85)	1.98 (2.23)	(-2.41, 6.38)	0.3752	0.10 (0.13)	(-0.16, 0.36)	0.4607	
> 65	5	NE	1	NE	NE	NE		NE	NE		
Sex											0.1099
male	12	7.36 (5.31)	8	-4.48 (6.39)	11.84 (6.87)	(-2.87, 26.55)	0.1064	0.62 (0.47)	(-0.30, 1.54)	0.1859	
female	104	8.42 (1.97)	105	8.19 (1.90)	0.24 (2.33)	(-4.36, 4.83)	0.9197	0.01 (0.14)	(-0.26, 0.28)	0.9317	
Race											0.3074
White	78	8.46 (2.20)	86	6.25 (2.11)	2.21 (2.69)	(-3.10, 7.52)	0.4126	0.11 (0.16)	(-0.19, 0.42)	0.4715	
Black or African American	19	18.68 (5.61)	13	14.96 (4.87)	3.72 (6.68)	(-9.94, 17.38)	0.5816	0.17 (0.36)	(-0.54, 0.87)	0.6469	
Asian	7	8.96 (10.29)	3	-8.40 (15.68)	17.37 (18.78)	(-28.69, 63.43)	0.3910	0.58 (0.71)	(-0.81, 1.97)	0.4167	
American Indian or Alaska Native	0	NE	0	NE	NE	NE		NE	NE		
Other	12	8.86 (8.35)	11	17.22 (9.58)	-8.36 (5.95)	(-20.99, 4.27)	0.1794	-0.27 (0.42)	(-1.09, 0.56)	0.5265	
Ethnicity											0.5718
Hispanic/Latino	21	5.25 (4.14)	23	6.85 (4.59)	-1.60 (4.87)	(-11.49, 8.29)	0.7442	-0.08 (0.30)	(-0.67, 0.52)	0.8007	
Non-hispanic/Latino	95	9.57 (2.10)	90	8.07 (2.02)	1.50 (2.52)	(-3.48, 6.48)	0.5533	0.08 (0.15)	(-0.21, 0.36)	0.6096	
Geographic region											0.8630
EU	45	14.08 (2.93)	52	11.75 (2.77)	2.33 (3.12)	(-3.88, 8.53)	0.4581	0.12 (0.20)	(-0.28, 0.52)	0.5677	
non-EU	71	6.44 (2.19)	61	4.83 (2.27)	1.61 (2.77)	(-3.89, 7.10)	0.5638	0.09 (0.17)	(-0.25, 0.43)	0.6141	
Onset of disease											0.1156
Paediatric	6	-16.13 (12.79)	6	1.25 (10.64)	-17.38 (11.96)	(-45.74, 10.98)	0.1901	-0.56 (0.59)	(-1.72, 0.61)	0.3485	
Adult	110	9.07 (1.91)	107	7.30 (1.90)	1.78 (2.28)	(-2.72, 6.28)	0.4368	0.09 (0.14)	(-0.18, 0.36)	0.5103	
ADA result											0.7184
Negative	101	8.66 (1.98)	100	7.58 (1.95)	1.07 (2.40)	(-3.67, 5.82)	0.6557	0.05 (0.14)	(-0.22, 0.33)	0.6998	
Positive (At any time)	15	23.26 (6.03)	13	19.95 (6.29)	3.31 (5.72)	(-8.59, 15.21)	0.5689	0.14 (0.38)	(-0.60, 0.88)	0.7133	
BMI (kg/m2) at enrolment											0.4890
< 30	69	11.60 (2.25)	78	8.77 (2.10)	2.82 (2.40)	(-1.92, 7.57)	0.2416	0.15 (0.17)	(-0.17, 0.48)	0.3612	
>= 30	47	6.22 (3.27)	35	6.95 (3.64)	-0.73 (4.53)	(-9.76, 8.31)	0.8733	-0.03 (0.22)	(-0.47, 0.41)	0.8838	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Lupus QoL Emotional Health domain score
Full analysis set

Visit	Anifrolumab 300mg (N=127) N	LSMean (SE)	Placebo (N=125) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 12		1.97 (1.66)		1.35 (1.69)	0.61 (2.08)	(-3.50, 4.72)	0.7685			
Week 24		3.51 (1.88)		3.60 (1.89)	-0.09 (2.40)	(-4.83, 4.65)	0.9703			
Week 36		4.41 (1.92)		4.08 (1.91)	0.33 (2.46)	(-4.53, 5.18)	0.8940			
Week 52		6.11 (1.90)		5.64 (1.87)	0.47 (2.40)	(-4.27, 5.21)	0.8455			
OVERALL	116	4.00 (1.54)	113	3.67 (1.52)	0.33 (1.84)	(-3.30, 3.96)	0.8576	0.02 (0.13)	(-0.24, 0.28)	0.8789

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Lupus QoL Emotional Health domain score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											0.2878
< 10 points	34	4.43 (2.12)	34	1.59 (1.98)	2.85 (2.62)	(-2.39, 8.09)	0.2810	0.24 (0.24)	(-0.24, 0.71)	0.3340	
>= 10 points	82	4.50 (1.90)	79	5.39 (1.95)	-0.89 (2.35)	(-5.53, 3.75)	0.7055	-0.05 (0.16)	(-0.36, 0.26)	0.7453	
OCS dose at baseline											0.8004
<10 mg/day	52	2.77 (2.21)	45	1.79 (2.34)	0.98 (2.91)	(-4.80, 6.77)	0.7371	0.06 (0.20)	(-0.34, 0.46)	0.7626	
>=10 mg/day	64	4.79 (2.22)	68	4.77 (2.10)	0.02 (2.42)	(-4.77, 4.82)	0.9925	0.00 (0.17)	(-0.34, 0.34)	0.9941	
Result of type I IFN gene signature test											0.3714
LOW	21	1.04 (2.85)	23	3.88 (2.57)	-2.84 (3.74)	(-10.43, 4.76)	0.4529	-0.22 (0.30)	(-0.81, 0.37)	0.4685	
HIGH	95	5.99 (1.55)	90	4.99 (1.60)	1.00 (2.11)	(-3.17, 5.17)	0.6368	0.07 (0.15)	(-0.22, 0.35)	0.6553	
Age (years)											NE
<= 65	111	3.75 (1.62)	112	3.57 (1.56)	0.18 (1.88)	(-3.52, 3.89)	0.9225	0.01 (0.13)	(-0.25, 0.27)	0.9353	
> 65	5	NE	1	NE	NE	NE		NE	NE		
Sex											0.2896
male	12	4.26 (3.39)	8	-0.28 (4.54)	4.54 (4.19)	(-4.43, 13.51)	0.2967	0.36 (0.46)	(-0.55, 1.26)	0.4388	
female	104	3.67 (1.66)	105	4.04 (1.60)	-0.37 (1.98)	(-4.27, 3.53)	0.8518	-0.02 (0.14)	(-0.29, 0.25)	0.8732	
Race											0.4875
White	78	4.78 (1.68)	86	2.65 (1.61)	2.13 (2.04)	(-1.91, 6.17)	0.2995	0.14 (0.16)	(-0.16, 0.45)	0.3634	
Black or African American	19	8.58 (6.13)	13	7.14 (4.97)	1.44 (7.06)	(-13.17, 16.05)	0.8401	0.06 (0.36)	(-0.65, 0.77)	0.8686	
Asian	7	2.48 (5.92)	3	-4.49 (9.42)	6.98 (10.92)	(-22.91, 36.86)	0.5566	0.40 (0.70)	(-0.97, 1.77)	0.5695	
American Indian or Alaska Native	0	NE	0	NE	NE	NE		NE	NE		
Other	12	3.46 (11.47)	11	12.17 (12.30)	-8.71 (7.07)	(-23.57, 6.15)	0.2338	-0.21 (0.42)	(-1.03, 0.61)	0.6184	
Ethnicity											0.1330
Hispanic/Latino	21	2.63 (4.17)	23	8.85 (4.67)	-6.22 (4.88)	(-16.09, 3.66)	0.2102	-0.29 (0.30)	(-0.89, 0.30)	0.3362	
Non-hispanic/Latino	95	4.30 (1.65)	90	2.61 (1.61)	1.70 (1.99)	(-2.23, 5.63)	0.3953	0.11 (0.15)	(-0.18, 0.40)	0.4641	
Geographic region											0.8017
EU	45	9.08 (2.00)	52	7.73 (1.90)	1.35 (2.14)	(-2.90, 5.59)	0.5303	0.10 (0.20)	(-0.30, 0.50)	0.6287	
non-EU	71	1.04 (2.08)	61	0.55 (2.17)	0.49 (2.66)	(-4.78, 5.76)	0.8544	0.03 (0.17)	(-0.31, 0.37)	0.8717	
Onset of disease											0.7887
Paediatric	6	10.43 (16.60)	6	6.33 (12.27)	4.09 (12.91)	(-26.05, 34.24)	0.7600	0.11 (0.58)	(-1.03, 1.24)	0.8550	
Adult	110	3.96 (1.56)	107	3.36 (1.56)	0.60 (1.88)	(-3.11, 4.30)	0.7515	0.04 (0.14)	(-0.23, 0.30)	0.7883	
ADA result											0.1321
Negative	101	4.21 (1.61)	100	2.89 (1.60)	1.33 (1.97)	(-2.56, 5.21)	0.5014	0.08 (0.14)	(-0.19, 0.36)	0.5606	
Positive (At any time)	15	2.17 (7.49)	13	11.17 (8.39)	-9.00 (6.57)	(-22.92, 4.92)	0.1894	-0.30 (0.38)	(-1.04, 0.45)	0.4386	
BMI (kg/m2) at enrolment											0.2675
< 30	69	4.17 (1.96)	78	5.46 (1.83)	-1.29 (2.07)	(-5.39, 2.80)	0.5335	-0.08 (0.17)	(-0.40, 0.24)	0.6306	
>= 30	47	2.88 (2.71)	35	-0.60 (2.99)	3.48 (3.77)	(-4.04, 11.00)	0.3597	0.19 (0.22)	(-0.25, 0.63)	0.3978	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Lupus QoL Body Image domain score
Full analysis set

	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 12		5.53 (2.10)		2.27 (2.17)	3.27 (2.65)	(-1.95, 8.49)	0.2183			
Week 24		8.70 (2.40)		4.44 (2.44)	4.26 (3.09)	(-1.83, 10.35)	0.1692			
Week 36		9.58 (2.51)		6.00 (2.52)	3.57 (3.24)	(-2.83, 9.97)	0.2724			
Week 52		9.01 (2.55)		6.33 (2.53)	2.69 (3.27)	(-3.76, 9.13)	0.4120			
OVERALL	107	8.21 (2.07)	104	4.76 (2.08)	3.45 (2.54)	(-1.57, 8.46)	0.1768	0.16 (0.14)	(-0.11, 0.43)	0.2429

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Lupus QoL Body Image domain score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											0.3566
< 10 points	33	3.88 (2.98)	31	4.59 (2.95)	-0.71 (3.77)	(-8.24, 6.83)	0.8521	-0.04 (0.25)	(-0.53, 0.45)	0.8683	
>= 10 points	74	9.72 (2.51)	73	5.85 (2.58)	3.87 (3.24)	(-2.52, 10.27)	0.2331	0.18 (0.17)	(-0.15, 0.50)	0.2851	
OCS dose at baseline											0.3214
<10 mg/day	49	3.30 (2.80)	40	2.84 (3.01)	0.46 (3.81)	(-7.12, 8.04)	0.9044	0.02 (0.21)	(-0.39, 0.44)	0.9122	
>=10 mg/day	58	11.81 (3.12)	64	6.25 (2.96)	5.56 (3.46)	(-1.29, 12.41)	0.1104	0.23 (0.18)	(-0.12, 0.59)	0.1999	
Result of type I IFN gene signature test											0.0896
LOW	21	1.85 (3.96)	21	7.05 (3.79)	-5.20 (5.32)	(-16.00, 5.59)	0.3348	-0.29 (0.31)	(-0.90, 0.32)	0.3542	
HIGH	86	10.97 (2.09)	83	5.90 (2.17)	5.07 (2.89)	(-0.62, 10.77)	0.0806	0.26 (0.15)	(-0.05, 0.56)	0.0955	
Age (years)											NE
<= 65	103	8.61 (2.18)	103	4.95 (2.14)	3.65 (2.60)	(-1.47, 8.77)	0.1610	0.17 (0.14)	(-0.11, 0.44)	0.2341	
> 65	4	NE	1	NE	NE	NE		NE	NE		
Sex											0.1338
male	10	13.90 (5.25)	7	0.36 (6.86)	13.54 (7.17)	(-2.24, 29.32)	0.0857	0.75 (0.51)	(-0.26, 1.75)	0.1469	
female	97	7.24 (2.19)	97	5.18 (2.15)	2.07 (2.67)	(-3.20, 7.33)	0.4397	0.10 (0.14)	(-0.19, 0.38)	0.5029	
Race											NE
White	72	9.13 (2.30)	80	3.40 (2.21)	5.73 (2.85)	(0.10, 11.36)	0.0461	0.29 (0.16)	(-0.03, 0.61)	0.0756	
Black or African American	17	19.56 (7.79)	11	13.73 (5.83)	5.83 (8.55)	(-11.88, 23.53)	0.5022	0.20 (0.39)	(-0.56, 0.96)	0.6011	
Asian	6	NE	3	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	0	NE	NE	NE		NE	NE		
Other	12	-19.46 (9.77)	10	-8.22 (9.80)	-11.23 (7.14)	(-26.27, 3.80)	0.1336	-0.33 (0.43)	(-1.18, 0.51)	0.4425	
Ethnicity											0.2241
Hispanic/Latino	19	4.35 (4.65)	22	7.09 (4.99)	-2.74 (5.51)	(-13.92, 8.44)	0.6217	-0.12 (0.31)	(-0.74, 0.49)	0.6967	
Non-hispanic/Latino	88	9.53 (2.36)	82	4.69 (2.36)	4.84 (2.92)	(-0.93, 10.61)	0.0995	0.22 (0.15)	(-0.08, 0.52)	0.1505	
Geographic region											0.1997
EU	41	17.49 (3.44)	47	10.20 (3.38)	7.30 (3.75)	(-0.15, 14.75)	0.0547	0.32 (0.22)	(-0.10, 0.74)	0.1373	
non-EU	66	3.84 (2.44)	57	2.87 (2.57)	0.98 (3.21)	(-5.38, 7.33)	0.7616	0.05 (0.18)	(-0.31, 0.40)	0.7846	
Onset of disease											NE
Paediatric	6	NE	6	NE	NE	NE		NE	NE		
Adult	101	7.63 (2.03)	98	4.79 (2.07)	2.85 (2.52)	(-2.12, 7.81)	0.2593	0.14 (0.14)	(-0.14, 0.42)	0.3288	
ADA result											0.6261
Negative	95	8.47 (2.21)	92	4.30 (2.25)	4.17 (2.76)	(-1.28, 9.61)	0.1331	0.19 (0.15)	(-0.09, 0.48)	0.1888	
Positive (At any time)	12	10.23 (7.60)	12	9.45 (7.61)	0.78 (6.37)	(-12.71, 14.27)	0.9039	0.03 (0.41)	(-0.77, 0.83)	0.9441	
BMI (kg/m2) at enrolment											0.9557
< 30	64	9.06 (2.87)	73	6.21 (2.74)	2.85 (3.26)	(-3.58, 9.29)	0.3822	0.12 (0.17)	(-0.21, 0.46)	0.4754	
>= 30	43	7.32 (3.11)	31	4.16 (3.57)	3.16 (4.41)	(-5.64, 11.96)	0.4761	0.15 (0.24)	(-0.31, 0.62)	0.5116	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Lupus QoL Burden to Others domain score
Full analysis set

	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 12		8.15 (2.16)		7.86 (2.20)	0.28 (2.72)	(-5.09, 5.65)	0.9177			
Week 24		10.46 (2.30)		9.24 (2.31)	1.23 (2.91)	(-4.51, 6.96)	0.6743			
Week 36		11.69 (2.43)		12.29 (2.42)	-0.61 (3.11)	(-6.75, 5.53)	0.8457			
Week 52		9.47 (2.51)		12.62 (2.47)	-3.15 (3.20)	(-9.46, 3.16)	0.3259			
OVERALL	116	9.94 (1.97)	113	10.50 (1.95)	-0.56 (2.36)	(-5.21, 4.09)	0.8117	-0.03 (0.13)	(-0.29, 0.23)	0.8397

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Lupus QoL Burden to Others domain score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											0.5682
< 10 points	34	9.45 (2.64)	34	8.30 (2.48)	1.14 (3.24)	(-5.34, 7.63)	0.7253	0.08 (0.24)	(-0.40, 0.55)	0.7547	
>= 10 points	82	10.68 (2.46)	79	12.07 (2.52)	-1.39 (3.04)	(-7.39, 4.61)	0.6476	-0.06 (0.16)	(-0.37, 0.25)	0.6943	
OCS dose at baseline											0.3346
<10 mg/day	52	7.16 (2.46)	45	10.32 (2.56)	-3.15 (3.20)	(-9.51, 3.21)	0.3275	-0.18 (0.20)	(-0.58, 0.22)	0.3803	
>=10 mg/day	64	11.88 (3.07)	68	10.56 (2.90)	1.32 (3.35)	(-5.31, 7.94)	0.6948	0.05 (0.17)	(-0.29, 0.40)	0.7563	
Result of type I IFN gene signature test											0.8565
LOW	21	13.13 (3.75)	23	13.13 (3.34)	-0.00 (4.92)	(-9.97, 9.96)	0.9995	-0.00 (0.30)	(-0.59, 0.59)	0.9995	
HIGH	95	7.68 (1.96)	90	8.69 (2.02)	-1.01 (2.67)	(-6.27, 4.25)	0.7040	-0.05 (0.15)	(-0.34, 0.24)	0.7200	
Age (years)											NE
<= 65	111	9.31 (2.07)	112	10.32 (1.99)	-1.01 (2.40)	(-5.74, 3.73)	0.6753	-0.05 (0.13)	(-0.31, 0.22)	0.7263	
> 65	5	NE	1	NE	NE	NE		NE	NE		
Sex											0.8819
male	12	13.99 (4.52)	8	15.78 (5.58)	-1.79 (5.73)	(-14.03, 10.45)	0.7596	-0.11 (0.46)	(-1.00, 0.79)	0.8115	
female	104	9.55 (2.11)	105	10.40 (2.04)	-0.86 (2.52)	(-5.82, 4.11)	0.7339	-0.04 (0.14)	(-0.31, 0.23)	0.7714	
Race											NE
White	78	10.58 (2.31)	86	9.63 (2.21)	0.95 (2.81)	(-4.60, 6.51)	0.7345	0.05 (0.16)	(-0.26, 0.35)	0.7663	
Black or African American	19	12.31 (6.08)	13	12.58 (5.40)	-0.27 (7.41)	(-15.47, 14.92)	0.9709	-0.01 (0.36)	(-0.72, 0.69)	0.9754	
Asian	7	NE	3	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	0	NE	NE	NE		NE	NE		
Other	12	11.86 (11.77)	11	24.63 (13.56)	-12.77 (7.98)	(-29.60, 4.06)	0.1279	-0.29 (0.42)	(-1.11, 0.54)	0.4938	
Ethnicity											0.0148
Hispanic/Latino	21	5.55 (4.35)	23	17.50 (4.77)	-11.95 (5.03)	(-22.12, -1.77)	0.0227	-0.54 (0.31)	(-1.15, 0.06)	0.0769	
Non-hispanic/Latino	95	10.85 (2.23)	90	8.90 (2.17)	1.95 (2.69)	(-3.36, 7.26)	0.4697	0.09 (0.15)	(-0.20, 0.38)	0.5334	
Geographic region											0.8753
EU	45	13.71 (3.20)	52	13.24 (3.05)	0.47 (3.49)	(-6.46, 7.40)	0.8931	0.02 (0.20)	(-0.38, 0.42)	0.9162	
non-EU	71	8.44 (2.37)	61	8.70 (2.46)	-0.26 (3.03)	(-6.25, 5.74)	0.9330	-0.01 (0.17)	(-0.36, 0.33)	0.9410	
Onset of disease											0.4822
Paediatric	6	14.07 (17.64)	6	4.16 (14.73)	9.91 (14.79)	(-24.98, 44.80)	0.5240	0.23 (0.58)	(-0.91, 1.37)	0.6920	
Adult	110	9.87 (2.02)	107	10.49 (2.01)	-0.62 (2.42)	(-5.40, 4.16)	0.7982	-0.03 (0.14)	(-0.30, 0.24)	0.8281	
ADA result											0.5248
Negative	101	10.38 (2.15)	100	10.43 (2.13)	-0.05 (2.61)	(-5.20, 5.11)	0.9859	-0.00 (0.14)	(-0.28, 0.27)	0.9878	
Positive (At any time)	15	9.26 (4.64)	13	12.88 (4.85)	-3.61 (4.96)	(-13.94, 6.71)	0.4746	-0.20 (0.38)	(-0.94, 0.55)	0.6026	
BMI (kg/m2) at enrolment											0.4358
< 30	69	7.99 (2.78)	78	9.91 (2.61)	-1.92 (2.97)	(-7.79, 3.95)	0.5189	-0.08 (0.17)	(-0.41, 0.24)	0.6165	
>= 30	47	12.21 (2.83)	35	10.31 (3.09)	1.91 (3.91)	(-5.89, 9.71)	0.6274	0.10 (0.22)	(-0.34, 0.54)	0.6547	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Lupus QoL Fatigue domain score
Full analysis set

	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 12		5.54 (1.95)		5.06 (1.95)	0.48 (2.39)	(-4.23, 5.20)	0.8404			
Week 24		9.91 (2.02)		7.94 (2.01)	1.97 (2.49)	(-2.93, 6.87)	0.4286			
Week 36		8.34 (2.18)		6.03 (2.16)	2.32 (2.75)	(-3.10, 7.73)	0.3999			
Week 52		8.62 (2.30)		7.19 (2.27)	1.43 (2.92)	(-4.32, 7.17)	0.6252			
OVERALL	116	8.10 (1.87)	113	6.55 (1.84)	1.55 (2.23)	(-2.84, 5.94)	0.4874	0.08 (0.13)	(-0.18, 0.34)	0.5562

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Lupus QoL Fatigue domain score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) N	LSMean (SE)	Placebo (N=125) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.7796
< 10 points	34	6.28 (3.29)	34	5.79 (3.09)	0.49 (4.03)	(-7.57, 8.55)	0.9039	0.03 (0.24)	(-0.45, 0.50)	0.9149	
>= 10 points	82	9.48 (2.21)	79	7.64 (2.24)	1.85 (2.71)	(-3.50, 7.20)	0.4963	0.09 (0.16)	(-0.22, 0.40)	0.5588	
OCS dose at baseline											0.7257
<10 mg/day	52	9.53 (2.29)	45	6.99 (2.37)	2.54 (3.00)	(-3.42, 8.49)	0.3994	0.15 (0.20)	(-0.24, 0.55)	0.4473	
>=10 mg/day	64	6.67 (2.91)	68	5.66 (2.75)	1.01 (3.17)	(-5.27, 7.28)	0.7512	0.04 (0.17)	(-0.30, 0.38)	0.8025	
Result of type I IFN gene signature test											0.1957
LOW	21	5.73 (4.20)	23	10.51 (3.76)	-4.78 (5.52)	(-15.97, 6.42)	0.3926	-0.25 (0.30)	(-0.85, 0.34)	0.4059	
HIGH	95	10.32 (1.77)	90	7.30 (1.83)	3.02 (2.41)	(-1.74, 7.78)	0.2126	0.17 (0.15)	(-0.12, 0.46)	0.2392	
Age (years)											NE
<= 65	111	8.58 (1.95)	112	6.73 (1.87)	1.85 (2.26)	(-2.60, 6.30)	0.4127	0.09 (0.13)	(-0.17, 0.35)	0.4946	
> 65	5	NE	1	NE	NE	NE		NE	NE		
Sex											0.0367
male	12	10.85 (4.60)	8	-1.98 (5.80)	12.83 (5.53)	(0.96, 24.69)	0.0360	0.76 (0.48)	(-0.17, 1.69)	0.1092	
female	104	7.25 (2.00)	105	7.00 (1.92)	0.25 (2.37)	(-4.42, 4.92)	0.9145	0.01 (0.14)	(-0.26, 0.28)	0.9271	
Race											NE
White	78	9.33 (2.17)	86	6.43 (2.07)	2.90 (2.63)	(-2.29, 8.10)	0.2712	0.15 (0.16)	(-0.16, 0.46)	0.3352	
Black or African American	19	2.24 (6.07)	13	10.82 (4.98)	-8.58 (6.88)	(-22.70, 5.53)	0.2228	-0.36 (0.36)	(-1.07, 0.35)	0.3254	
Asian	7	NE	3	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	0	NE	NE	NE		NE	NE		
Other	12	3.23 (9.16)	11	6.41 (9.72)	-3.19 (6.95)	(-17.94, 11.57)	0.6529	-0.10 (0.42)	(-0.91, 0.72)	0.8182	
Ethnicity											0.7177
Hispanic/Latino	21	8.78 (4.60)	23	5.51 (5.09)	3.27 (5.33)	(-7.53, 14.06)	0.5435	0.14 (0.30)	(-0.45, 0.73)	0.6427	
Non-hispanic/Latino	95	7.78 (2.09)	90	6.64 (2.02)	1.14 (2.51)	(-3.82, 6.09)	0.6510	0.06 (0.15)	(-0.23, 0.35)	0.6969	
Geographic region											0.9442
EU	45	14.43 (2.68)	52	12.55 (2.52)	1.87 (2.84)	(-3.77, 7.52)	0.5115	0.10 (0.20)	(-0.30, 0.50)	0.6145	
non-EU	71	4.89 (2.35)	61	2.73 (2.44)	2.16 (2.99)	(-3.75, 8.07)	0.4707	0.11 (0.17)	(-0.23, 0.45)	0.5269	
Onset of disease											0.4574
Paediatric	6	21.34 (25.12)	6	6.09 (19.33)	15.25 (18.35)	(-28.61, 59.11)	0.4348	0.26 (0.58)	(-0.88, 1.39)	0.6589	
Adult	110	8.06 (1.90)	107	6.55 (1.88)	1.51 (2.27)	(-2.98, 5.99)	0.5084	0.08 (0.14)	(-0.19, 0.34)	0.5752	
ADA result											0.7726
Negative	101	7.48 (2.01)	100	6.27 (1.98)	1.21 (2.44)	(-3.61, 6.03)	0.6207	0.06 (0.14)	(-0.22, 0.34)	0.6694	
Positive (At any time)	15	14.27 (6.39)	13	11.39 (6.46)	2.88 (5.25)	(-8.14, 13.91)	0.5894	0.12 (0.38)	(-0.63, 0.86)	0.7593	
BMI (kg/m2) at enrolment											0.9408
< 30	69	9.17 (2.34)	78	7.41 (2.17)	1.77 (2.48)	(-3.14, 6.67)	0.4783	0.09 (0.17)	(-0.23, 0.42)	0.5819	
>= 30	47	7.54 (3.23)	35	6.15 (3.60)	1.38 (4.49)	(-7.57, 10.34)	0.7590	0.06 (0.22)	(-0.37, 0.50)	0.7781	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Lupus QoL Intimate Relationships domain score
Full analysis set

	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 12		6.23 (2.82)		3.31 (2.95)	2.93 (3.69)	(-4.36, 10.21)	0.4289			
Week 24		2.67 (3.04)		8.97 (3.16)	-6.30 (4.03)	(-14.26, 1.66)	0.1201			
Week 36		3.87 (2.99)		6.64 (3.09)	-2.76 (3.93)	(-10.53, 5.00)	0.4834			
Week 52		4.16 (3.05)		4.07 (3.05)	0.09 (3.92)	(-7.66, 7.83)	0.9825			
OVERALL	94	4.23 (2.49)	91	5.75 (2.50)	-1.51 (3.06)	(-7.55, 4.53)	0.6218	-0.06 (0.15)	(-0.35, 0.23)	0.6695

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Lupus QoL Intimate Relationships domain score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) N	LSMean (SE)	Placebo (N=125) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.9658
< 10 points	26	0.92 (4.54)	28	2.65 (4.23)	-1.73 (5.52)	(-12.84, 9.39)	0.7559	-0.07 (0.27)	(-0.61, 0.46)	0.7836	
>= 10 points	68	6.78 (2.77)	63	8.80 (3.00)	-2.01 (3.70)	(-9.35, 5.32)	0.5877	-0.09 (0.17)	(-0.43, 0.26)	0.6235	
OCS dose at baseline											0.3187
<10 mg/day	42	3.65 (3.39)	32	1.48 (3.74)	2.17 (4.70)	(-7.24, 11.58)	0.6462	0.10 (0.23)	(-0.36, 0.56)	0.6720	
>=10 mg/day	52	4.16 (3.77)	59	8.25 (3.52)	-4.09 (4.16)	(-12.34, 4.16)	0.3276	-0.15 (0.19)	(-0.52, 0.22)	0.4311	
Result of type I IFN gene signature test											0.1750
LOW	19	-2.24 (5.34)	20	7.72 (4.72)	-9.96 (6.94)	(-24.11, 4.20)	0.1613	-0.44 (0.32)	(-1.08, 0.20)	0.1758	
HIGH	75	7.47 (2.50)	71	6.92 (2.64)	0.55 (3.45)	(-6.28, 7.38)	0.8736	0.02 (0.17)	(-0.30, 0.35)	0.8803	
Age (years)											NE
<= 65	92	3.57 (2.54)	91	5.51 (2.51)	-1.94 (3.08)	(-8.02, 4.13)	0.5283	-0.08 (0.15)	(-0.37, 0.21)	0.5879	
> 65	2	NE	0	NE	NE	NE		NE	NE		
Sex											NE
male	8	NE	6	NE	NE	NE		NE	NE		
female	86	3.73 (2.70)	85	5.93 (2.65)	-2.19 (3.27)	(-8.66, 4.27)	0.5032	-0.09 (0.15)	(-0.39, 0.21)	0.5641	
Race											NE
White	66	6.33 (2.86)	71	5.21 (2.83)	1.12 (3.56)	(-5.92, 8.16)	0.7532	0.05 (0.17)	(-0.29, 0.38)	0.7819	
Black or African American	15	6.67 (11.66)	11	7.00 (8.31)	-0.33 (13.21)	(-27.91, 27.26)	0.9806	-0.01 (0.40)	(-0.79, 0.77)	0.9837	
Asian	4	NE	3	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	0	NE	NE	NE		NE	NE		
Other	9	-21.01 (12.53)	6	-5.03 (15.00)	-15.98 (10.59)	(-40.28, 8.33)	0.1689	-0.40 (0.53)	(-1.45, 0.64)	0.4499	
Ethnicity											0.1254
Hispanic/Latino	16	-4.62 (5.97)	15	7.12 (6.96)	-11.74 (7.16)	(-26.48, 3.00)	0.1134	-0.45 (0.36)	(-1.16, 0.26)	0.2169	
Non-hispanic/Latino	78	6.00 (2.80)	76	5.55 (2.75)	0.45 (3.47)	(-6.42, 7.32)	0.8973	0.02 (0.16)	(-0.30, 0.33)	0.9094	
Geographic region											0.7241
EU	36	13.99 (3.82)	43	16.63 (3.82)	-2.64 (4.27)	(-11.16, 5.88)	0.5387	-0.11 (0.23)	(-0.55, 0.33)	0.6320	
non-EU	58	-0.01 (3.08)	48	0.56 (3.23)	-0.57 (4.00)	(-8.51, 7.36)	0.8863	-0.02 (0.20)	(-0.41, 0.36)	0.8989	
Onset of disease											NE
Paediatric	4	NE	4	NE	NE	NE		NE	NE		
Adult	90	4.29 (2.55)	87	4.76 (2.56)	-0.47 (3.12)	(-6.64, 5.70)	0.8812	-0.02 (0.15)	(-0.31, 0.28)	0.8975	
ADA result											0.4858
Negative	83	4.57 (2.64)	82	5.85 (2.65)	-1.28 (3.28)	(-7.76, 5.19)	0.6959	-0.05 (0.16)	(-0.36, 0.25)	0.7330	
Positive (At any time)	11	-4.21 (8.69)	9	3.81 (9.48)	-8.03 (9.10)	(-27.49, 11.44)	0.3923	-0.27 (0.45)	(-1.15, 0.62)	0.5527	
BMI (kg/m2) at enrolment											0.0489
< 30	53	2.08 (3.07)	62	8.34 (2.89)	-6.26 (3.49)	(-13.20, 0.68)	0.0763	-0.28 (0.19)	(-0.64, 0.09)	0.1425	
>= 30	41	8.47 (4.25)	29	1.19 (4.83)	7.28 (5.92)	(-4.55, 19.12)	0.2233	0.27 (0.24)	(-0.21, 0.75)	0.2687	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Lupus QoL Pain domain score
Full analysis set

	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 12		11.57 (2.26)		8.81 (2.28)	2.77 (2.81)	(-2.77, 8.30)	0.3262			
Week 24		11.62 (2.30)		10.37 (2.29)	1.25 (2.84)	(-4.35, 6.85)	0.6602			
Week 36		13.95 (2.33)		9.97 (2.31)	3.98 (2.89)	(-1.72, 9.68)	0.1705			
Week 52		11.86 (2.37)		10.49 (2.34)	1.37 (2.94)	(-4.44, 7.17)	0.6426			
OVERALL	116	12.25 (2.07)	113	9.91 (2.04)	2.34 (2.45)	(-2.49, 7.17)	0.3405	0.11 (0.13)	(-0.15, 0.37)	0.4224

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Lupus QoL Pain domain score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											0.0828
< 10 points	34	12.58 (3.46)	34	3.99 (3.22)	8.59 (4.22)	(0.15, 17.04)	0.0462	0.44 (0.25)	(-0.05, 0.92)	0.0760	
>= 10 points	82	13.04 (2.43)	79	13.39 (2.48)	-0.35 (2.97)	(-6.21, 5.50)	0.9050	-0.02 (0.16)	(-0.33, 0.29)	0.9190	
OCS dose at baseline											0.9560
<10 mg/day	52	11.86 (3.01)	45	9.37 (3.13)	2.49 (3.90)	(-5.26, 10.24)	0.5254	0.12 (0.20)	(-0.28, 0.51)	0.5711	
>=10 mg/day	64	12.54 (2.94)	68	10.33 (2.77)	2.21 (3.18)	(-4.09, 8.51)	0.4884	0.09 (0.17)	(-0.25, 0.44)	0.5864	
Result of type I IFN gene signature test											0.3187
LOW	21	12.00 (3.92)	23	14.62 (3.53)	-2.63 (5.15)	(-13.05, 7.80)	0.6129	-0.15 (0.30)	(-0.74, 0.44)	0.6244	
HIGH	95	12.44 (2.04)	90	9.24 (2.11)	3.20 (2.77)	(-2.27, 8.68)	0.2496	0.16 (0.15)	(-0.13, 0.45)	0.2784	
Age (years)											NE
<= 65	111	13.08 (2.17)	112	10.20 (2.08)	2.89 (2.49)	(-2.02, 7.80)	0.2479	0.13 (0.13)	(-0.13, 0.39)	0.3393	
> 65	5	NE	1	NE	NE	NE		NE	NE		
Sex											0.0995
male	12	11.12 (5.26)	8	-0.98 (6.41)	12.09 (6.01)	(-0.75, 24.94)	0.0631	0.64 (0.47)	(-0.28, 1.56)	0.1753	
female	104	12.00 (2.23)	105	10.70 (2.15)	1.29 (2.62)	(-3.88, 6.47)	0.6225	0.06 (0.14)	(-0.21, 0.33)	0.6772	
Race											NE
White	78	11.87 (2.41)	86	9.03 (2.29)	2.83 (2.91)	(-2.91, 8.58)	0.3317	0.13 (0.16)	(-0.17, 0.44)	0.3971	
Black or African American	19	17.38 (6.50)	13	15.17 (5.59)	2.21 (7.62)	(-13.41, 17.84)	0.7738	0.08 (0.36)	(-0.62, 0.79)	0.8136	
Asian	7	NE	3	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	0	NE	NE	NE		NE	NE		
Other	12	7.79 (12.13)	11	9.01 (14.60)	-1.22 (8.91)	(-20.17, 17.73)	0.8927	-0.03 (0.42)	(-0.84, 0.79)	0.9502	
Ethnicity											0.8936
Hispanic/Latino	21	14.01 (5.37)	23	12.59 (6.16)	1.42 (6.34)	(-11.44, 14.29)	0.8237	0.05 (0.30)	(-0.54, 0.64)	0.8653	
Non-hispanic/Latino	95	11.83 (2.27)	90	9.48 (2.19)	2.35 (2.72)	(-3.01, 7.71)	0.3889	0.11 (0.15)	(-0.18, 0.40)	0.4603	
Geographic region											0.4851
EU	45	15.56 (2.90)	52	14.69 (2.73)	0.88 (3.08)	(-5.25, 7.00)	0.7769	0.04 (0.20)	(-0.35, 0.44)	0.8277	
non-EU	71	11.09 (2.58)	61	7.08 (2.69)	4.01 (3.26)	(-2.44, 10.45)	0.2212	0.19 (0.17)	(-0.16, 0.53)	0.2876	
Onset of disease											NE
Paediatric	6	NE	6	NE	NE	NE		NE	NE		
Adult	110	12.69 (2.14)	107	9.71 (2.13)	2.99 (2.54)	(-2.02, 7.99)	0.2408	0.13 (0.14)	(-0.13, 0.40)	0.3244	
ADA result											0.5908
Negative	101	11.74 (2.16)	100	9.89 (2.13)	1.84 (2.61)	(-3.31, 6.99)	0.4812	0.09 (0.14)	(-0.19, 0.36)	0.5456	
Positive (At any time)	15	27.74 (9.51)	13	21.30 (9.62)	6.44 (8.15)	(-10.63, 23.51)	0.4390	0.17 (0.38)	(-0.57, 0.92)	0.6461	
BMI (kg/m2) at enrolment											0.9786
< 30	69	12.77 (2.63)	78	10.26 (2.44)	2.52 (2.78)	(-2.97, 8.01)	0.3659	0.12 (0.17)	(-0.21, 0.44)	0.4849	
>= 30	47	11.79 (3.42)	35	9.13 (3.81)	2.67 (4.72)	(-6.75, 12.08)	0.5741	0.11 (0.22)	(-0.32, 0.55)	0.6082	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Lupus QoL Planning domain score
Full analysis set

	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 12		7.21 (2.22)		4.65 (2.25)	2.57 (2.79)	(-2.93, 8.06)	0.3583			
Week 24		9.45 (2.21)		7.96 (2.20)	1.49 (2.73)	(-3.89, 6.87)	0.5853			
Week 36		9.13 (2.32)		7.10 (2.31)	2.03 (2.91)	(-3.71, 7.76)	0.4866			
Week 52		9.09 (2.43)		6.45 (2.41)	2.64 (3.08)	(-3.42, 8.70)	0.3917			
OVERALL	116	8.72 (2.02)	113	6.54 (2.00)	2.18 (2.41)	(-2.58, 6.94)	0.3674	0.10 (0.13)	(-0.16, 0.36)	0.4449

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Lupus QoL Planning domain score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											0.2153
< 10 points	34	8.41 (3.33)	34	1.94 (3.09)	6.47 (4.01)	(-1.55, 14.50)	0.1120	0.34 (0.24)	(-0.14, 0.82)	0.1621	
>= 10 points	82	10.48 (2.40)	79	10.19 (2.46)	0.29 (2.96)	(-5.56, 6.15)	0.9219	0.01 (0.16)	(-0.30, 0.32)	0.9327	
OCS dose at baseline											0.4942
<10 mg/day	52	7.11 (2.82)	45	2.93 (2.96)	4.18 (3.69)	(-3.16, 11.52)	0.2608	0.21 (0.20)	(-0.19, 0.61)	0.3126	
>=10 mg/day	64	10.14 (2.97)	68	9.30 (2.79)	0.84 (3.20)	(-5.50, 7.18)	0.7939	0.04 (0.17)	(-0.31, 0.38)	0.8378	
Result of type I IFN gene signature test											0.0280
LOW	21	3.63 (4.25)	23	12.57 (3.79)	-8.95 (5.58)	(-20.28, 2.39)	0.1181	-0.47 (0.31)	(-1.07, 0.13)	0.1273	
HIGH	95	10.71 (1.95)	90	6.07 (2.03)	4.64 (2.66)	(-0.60, 9.88)	0.0823	0.24 (0.15)	(-0.05, 0.53)	0.1016	
Age (years)											NE
<= 65	111	8.41 (2.12)	112	6.35 (2.04)	2.06 (2.46)	(-2.78, 6.90)	0.4027	0.09 (0.13)	(-0.17, 0.36)	0.4856	
> 65	5	NE	1	NE	NE	NE		NE	NE		
Sex											0.3413
male	12	8.29 (6.26)	8	-0.49 (7.39)	8.78 (7.54)	(-7.27, 24.83)	0.2621	0.39 (0.46)	(-0.51, 1.30)	0.3943	
female	104	8.13 (2.15)	105	6.92 (2.08)	1.21 (2.55)	(-3.82, 6.24)	0.6366	0.06 (0.14)	(-0.22, 0.33)	0.6873	
Race											NE
White	78	9.16 (2.34)	86	5.54 (2.25)	3.62 (2.85)	(-2.02, 9.26)	0.2067	0.17 (0.16)	(-0.13, 0.48)	0.2682	
Black or African American	19	20.27 (6.13)	13	12.77 (5.19)	7.50 (7.11)	(-7.09, 22.09)	0.3010	0.31 (0.36)	(-0.40, 1.02)	0.3970	
Asian	7	NE	3	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	0	NE	NE	NE		NE	NE		
Other	12	0.97 (10.41)	11	5.29 (11.50)	-4.32 (7.36)	(-19.83, 11.19)	0.5647	-0.11 (0.42)	(-0.93, 0.71)	0.7880	
Ethnicity											0.9389
Hispanic/Latino	21	6.63 (5.44)	23	3.90 (6.15)	2.74 (6.30)	(-10.03, 15.50)	0.6662	0.10 (0.30)	(-0.49, 0.69)	0.7453	
Non-hispanic/Latino	95	9.16 (2.21)	90	6.94 (2.14)	2.21 (2.67)	(-3.05, 7.47)	0.4074	0.11 (0.15)	(-0.18, 0.39)	0.4744	
Geographic region											0.6630
EU	45	15.60 (2.88)	52	14.42 (2.71)	1.18 (3.10)	(-4.98, 7.33)	0.7051	0.06 (0.20)	(-0.34, 0.46)	0.7681	
non-EU	71	5.27 (2.57)	61	2.14 (2.68)	3.13 (3.26)	(-3.31, 9.58)	0.3377	0.15 (0.17)	(-0.20, 0.49)	0.4032	
Onset of disease											0.9671
Paediatric	6	12.34 (14.13)	6	10.06 (11.49)	2.28 (11.45)	(-24.66, 29.22)	0.8477	0.07 (0.58)	(-1.07, 1.20)	0.9081	
Adult	110	8.56 (2.09)	107	5.80 (2.09)	2.76 (2.51)	(-2.19, 7.71)	0.2722	0.13 (0.14)	(-0.14, 0.39)	0.3517	
ADA result											0.5064
Negative	101	8.92 (2.17)	100	6.23 (2.15)	2.69 (2.64)	(-2.52, 7.91)	0.3100	0.12 (0.14)	(-0.15, 0.40)	0.3805	
Positive (At any time)	15	9.63 (7.58)	13	11.83 (7.81)	-2.19 (6.86)	(-16.51, 12.13)	0.7526	-0.07 (0.38)	(-0.82, 0.67)	0.8454	
BMI (kg/m2) at enrolment											0.4469
< 30	69	8.76 (2.73)	78	7.57 (2.56)	1.19 (2.92)	(-4.58, 6.96)	0.6838	0.05 (0.17)	(-0.27, 0.38)	0.7516	
>= 30	47	9.49 (3.13)	35	4.34 (3.45)	5.15 (4.31)	(-3.44, 13.74)	0.2362	0.24 (0.22)	(-0.20, 0.68)	0.2791	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SDI Global Score
Full analysis set

	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 24		0.06 (0.02)		0.01 (0.02)	0.05 (0.03)	(0.00, 0.10)	0.0334			
Week 52		0.05 (0.03)		0.03 (0.03)	0.02 (0.03)	(-0.04, 0.08)	0.5202			
OVERALL	109	0.06 (0.02)	109	0.02 (0.02)	0.04 (0.03)	(-0.02, 0.09)	0.1682	0.16 (0.14)	(-0.11, 0.42)	0.2485

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SDI Global Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) N	LSMean (SE)	Placebo (N=125) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											NE
< 10 points	32	NE	31	NE	NE	NE		NE	NE		
>= 10 points	77	0.01 (0.02)	78	0.02 (0.02)	-0.00 (0.03)	(-0.06, 0.05)	0.8595	-0.02 (0.16)	(-0.34, 0.29)	0.8775	
OCS dose at baseline											0.3714
<10 mg/day	53	0.08 (0.03)	44	0.02 (0.03)	0.07 (0.04)	(-0.02, 0.15)	0.1096	0.29 (0.21)	(-0.11, 0.69)	0.1583	
>=10 mg/day	56	0.03 (0.03)	65	0.01 (0.03)	0.02 (0.04)	(-0.05, 0.09)	0.6300	0.07 (0.18)	(-0.29, 0.43)	0.7055	
Result of type I IFN gene signature test											NE
LOW	18	NE	19	NE	NE	NE		NE	NE		
HIGH	91	0.09 (0.02)	90	0.04 (0.02)	0.04 (0.03)	(-0.02, 0.11)	0.1915	0.18 (0.15)	(-0.11, 0.48)	0.2156	
Age (years)											NE
<= 65	106	0.06 (0.02)	107	0.02 (0.02)	0.04 (0.03)	(-0.02, 0.09)	0.1628	0.16 (0.14)	(-0.11, 0.43)	0.2470	
> 65	3	NE	2	NE	NE	NE		NE	NE		
Sex											NE
male	11	NE	8	NE	NE	NE		NE	NE		
female	98	0.06 (0.03)	101	0.02 (0.02)	0.04 (0.03)	(-0.01, 0.10)	0.1443	0.17 (0.14)	(-0.10, 0.45)	0.2207	
Race											NE
White	75	0.05 (0.02)	82	0.01 (0.02)	0.04 (0.03)	(-0.02, 0.09)	0.2266	0.17 (0.16)	(-0.15, 0.48)	0.2999	
Black or African American	15	NE	14	NE	NE	NE		NE	NE		
Asian	7	0.19 (0.21)	2	0.04 (0.48)	0.15 (0.50)	(-1.25, 1.55)	0.7862	0.22 (0.80)	(-1.35, 1.80)	0.7818	
American Indian or Alaska Native	0	NE	0	NE	NE	NE		NE	NE		
Other	12	NE	11	NE	NE	NE		NE	NE		
Ethnicity											0.5148
Hispanic/Latino	19	0.08 (0.06)	21	-0.00 (0.07)	0.08 (0.07)	(-0.07, 0.23)	0.2637	0.28 (0.32)	(-0.34, 0.91)	0.3729	
Non-hispanic/Latino	90	0.05 (0.02)	88	0.01 (0.02)	0.03 (0.03)	(-0.03, 0.09)	0.2734	0.14 (0.15)	(-0.16, 0.43)	0.3558	
Geographic region											0.7508
EU	45	0.07 (0.04)	50	0.02 (0.03)	0.05 (0.04)	(-0.02, 0.13)	0.1855	0.21 (0.21)	(-0.19, 0.62)	0.3007	
non-EU	64	0.05 (0.03)	59	0.01 (0.03)	0.03 (0.04)	(-0.04, 0.11)	0.3976	0.13 (0.18)	(-0.22, 0.49)	0.4652	
Onset of disease											NE
Paediatric	5	NE	4	NE	NE	NE		NE	NE		
Adult	104	0.06 (0.02)	105	0.02 (0.02)	0.04 (0.03)	(-0.02, 0.10)	0.1651	0.16 (0.14)	(-0.11, 0.43)	0.2448	
ADA result											NE
Negative	97	0.05 (0.02)	98	0.02 (0.02)	0.03 (0.03)	(-0.02, 0.09)	0.2676	0.13 (0.14)	(-0.15, 0.42)	0.3469	
Positive (At any time)	12	NE	11	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											NE
< 30	65	0.04 (0.03)	76	0.03 (0.02)	0.02 (0.03)	(-0.04, 0.07)	0.5656	0.08 (0.17)	(-0.25, 0.41)	0.6408	
>= 30	44	NE	33	NE	NE	NE		NE	NE		

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - NRS Score
Full analysis set

Visit	Anifrolumab 300mg (N=127) N	Anifrolumab 300mg (N=127) LSMean (SE)	Placebo (N=125) N	Placebo (N=125) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-0.27 (0.19)		-0.28 (0.19)	0.01 (0.24)	(-0.45, 0.48)	0.9608			
Week 8		-0.79 (0.21)		-0.54 (0.21)	-0.25 (0.26)	(-0.76, 0.27)	0.3449			
Week 12		-0.91 (0.22)		-0.56 (0.22)	-0.35 (0.28)	(-0.90, 0.20)	0.2106			
Week 16		-0.92 (0.22)		-0.68 (0.22)	-0.24 (0.28)	(-0.79, 0.31)	0.3844			
Week 20		-0.95 (0.23)		-0.85 (0.23)	-0.10 (0.30)	(-0.69, 0.49)	0.7445			
Week 24		-1.08 (0.22)		-0.79 (0.22)	-0.29 (0.28)	(-0.85, 0.27)	0.3149			
Week 28		-1.08 (0.24)		-0.84 (0.24)	-0.23 (0.31)	(-0.85, 0.38)	0.4510			
Week 32		-0.90 (0.23)		-1.08 (0.24)	0.18 (0.31)	(-0.43, 0.78)	0.5646			
Week 36		-1.01 (0.24)		-0.88 (0.24)	-0.13 (0.32)	(-0.76, 0.49)	0.6740			
Week 40		-1.11 (0.25)		-0.92 (0.25)	-0.19 (0.33)	(-0.85, 0.47)	0.5685			
Week 44		-1.14 (0.25)		-1.04 (0.25)	-0.10 (0.33)	(-0.75, 0.55)	0.7687			
Week 48		-1.13 (0.25)		-1.06 (0.25)	-0.08 (0.33)	(-0.73, 0.57)	0.8186			
Week 52		-1.05 (0.25)		-1.02 (0.25)	-0.03 (0.33)	(-0.67, 0.62)	0.9335			
OVERALL	121	-0.95 (0.19)	116	-0.81 (0.19)	-0.14 (0.23)	(-0.59, 0.32)	0.5507	-0.07 (0.13)	(-0.32, 0.19)	0.6055

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - NRS Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) N	LSMean (SE)	Placebo (N=125) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.0498
< 10 points	36	-1.26 (0.32)	36	-0.47 (0.29)	-0.79 (0.39)	(-1.56, -0.02)	0.0439	-0.43 (0.24)	(-0.89, 0.04)	0.0735	
>= 10 points	85	-0.89 (0.23)	80	-1.04 (0.23)	0.15 (0.29)	(-0.42, 0.72)	0.5980	0.07 (0.16)	(-0.23, 0.38)	0.6422	
OCS dose at baseline											0.7584
<10 mg/day	53	-0.95 (0.25)	46	-0.71 (0.26)	-0.24 (0.34)	(-0.90, 0.43)	0.4848	-0.13 (0.20)	(-0.52, 0.27)	0.5221	
>=10 mg/day	68	-0.99 (0.29)	70	-0.90 (0.28)	-0.09 (0.32)	(-0.73, 0.55)	0.7758	-0.04 (0.17)	(-0.37, 0.29)	0.8189	
Result of type I IFN gene signature test											0.1030
LOW	21	-0.51 (0.36)	23	-1.08 (0.33)	0.57 (0.48)	(-0.39, 1.54)	0.2347	0.35 (0.30)	(-0.25, 0.95)	0.2485	
HIGH	100	-1.39 (0.19)	93	-1.08 (0.20)	-0.31 (0.26)	(-0.83, 0.21)	0.2376	-0.16 (0.14)	(-0.45, 0.12)	0.2607	
Age (years)											NE
<= 65	116	-0.98 (0.20)	115	-0.79 (0.19)	-0.19 (0.23)	(-0.65, 0.27)	0.4242	-0.09 (0.13)	(-0.35, 0.17)	0.4954	
> 65	5	NE	1	NE	NE	NE		NE	NE		
Sex											NE
male	12	NE	8	NE	NE	NE		NE	NE		
female	109	-0.97 (0.21)	108	-0.85 (0.20)	-0.12 (0.25)	(-0.61, 0.37)	0.6293	-0.06 (0.14)	(-0.32, 0.21)	0.6753	
Race											NE
White	81	-0.87 (0.23)	88	-0.83 (0.22)	-0.05 (0.28)	(-0.60, 0.51)	0.8664	-0.02 (0.15)	(-0.32, 0.28)	0.8806	
Black or African American	20	-1.29 (0.54)	13	-0.70 (0.49)	-0.59 (0.67)	(-1.97, 0.78)	0.3847	-0.26 (0.36)	(-0.96, 0.44)	0.4622	
Asian	7	NE	3	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	NE	NE	NE		NE	NE		
Other	13	NE	11	NE	NE	NE		NE	NE		
Ethnicity											0.8565
Hispanic/Latino	23	-0.93 (0.42)	23	-0.93 (0.48)	0.00 (0.47)	(-0.96, 0.96)	1.0000	0.00 (0.29)	(-0.58, 0.58)	1.0000	
Non-hispanic/Latino	98	-0.95 (0.21)	93	-0.85 (0.21)	-0.10 (0.27)	(-0.62, 0.42)	0.7116	-0.05 (0.14)	(-0.33, 0.24)	0.7450	
Geographic region											0.4762
EU	46	-1.33 (0.34)	53	-1.28 (0.33)	-0.05 (0.38)	(-0.80, 0.70)	0.8928	-0.02 (0.20)	(-0.42, 0.37)	0.9161	
non-EU	75	-0.88 (0.21)	63	-0.50 (0.22)	-0.38 (0.27)	(-0.93, 0.16)	0.1667	-0.21 (0.17)	(-0.55, 0.13)	0.2197	
Onset of disease											NE
Paediatric	7	NE	6	NE	NE	NE		NE	NE		
Adult	114	-0.98 (0.19)	110	-0.87 (0.20)	-0.11 (0.24)	(-0.58, 0.36)	0.6446	-0.05 (0.13)	(-0.32, 0.21)	0.6893	
ADA result											0.4307
Negative	106	-0.81 (0.19)	103	-0.73 (0.19)	-0.08 (0.24)	(-0.55, 0.40)	0.7550	-0.04 (0.14)	(-0.31, 0.23)	0.7828	
Positive (At any time)	15	-2.81 (0.88)	13	-2.12 (0.91)	-0.70 (0.75)	(-2.24, 0.85)	0.3616	-0.20 (0.38)	(-0.95, 0.54)	0.5972	
BMI (kg/m2) at enrolment											0.1387
< 30	72	-0.86 (0.26)	80	-0.92 (0.25)	0.07 (0.29)	(-0.50, 0.63)	0.8195	0.03 (0.16)	(-0.29, 0.35)	0.8575	
>= 30	49	-1.11 (0.27)	36	-0.47 (0.31)	-0.65 (0.39)	(-1.42, 0.12)	0.0986	-0.34 (0.22)	(-0.77, 0.09)	0.1251	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - PHQ-8 Total Score
Full analysis set

	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 12		-1.27 (0.49)		-0.80 (0.49)	-0.47 (0.61)	(-1.68, 0.74)	0.4420			
Week 24		-1.87 (0.48)		-1.45 (0.48)	-0.42 (0.60)	(-1.61, 0.77)	0.4883			
Week 36		-1.49 (0.51)		-1.21 (0.50)	-0.27 (0.64)	(-1.53, 0.99)	0.6704			
Week 52		-2.13 (0.55)		-1.51 (0.54)	-0.62 (0.70)	(-2.00, 0.76)	0.3782			
OVERALL	116	-1.69 (0.43)	113	-1.24 (0.42)	-0.45 (0.51)	(-1.45, 0.56)	0.3846	-0.10 (0.13)	(-0.36, 0.16)	0.4607

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - PHQ-8 Total Score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											0.1424
< 10 points	34	-1.80 (0.76)	34	-0.26 (0.71)	-1.54 (0.93)	(-3.39, 0.31)	0.1005	-0.36 (0.24)	(-0.84, 0.12)	0.1442	
>= 10 points	82	-1.91 (0.50)	79	-2.00 (0.51)	0.09 (0.62)	(-1.13, 1.31)	0.8862	0.02 (0.16)	(-0.29, 0.33)	0.9016	
OCS dose at baseline											0.5205
<10 mg/day	52	-1.36 (0.61)	45	-1.29 (0.64)	-0.07 (0.81)	(-1.67, 1.54)	0.9351	-0.01 (0.20)	(-0.41, 0.38)	0.9415	
>=10 mg/day	64	-2.06 (0.62)	68	-1.32 (0.58)	-0.74 (0.67)	(-2.07, 0.59)	0.2726	-0.15 (0.17)	(-0.49, 0.19)	0.3887	
Result of type I IFN gene signature test											0.5901
LOW	21	-1.70 (0.87)	23	-1.82 (0.78)	0.12 (1.14)	(-2.21, 2.44)	0.9183	0.03 (0.30)	(-0.56, 0.62)	0.9207	
HIGH	95	-1.82 (0.42)	90	-1.25 (0.44)	-0.57 (0.57)	(-1.71, 0.56)	0.3211	-0.14 (0.15)	(-0.43, 0.15)	0.3480	
Age (years)											NE
<= 65	111	-1.62 (0.45)	112	-1.17 (0.43)	-0.46 (0.52)	(-1.49, 0.58)	0.3843	-0.10 (0.13)	(-0.36, 0.17)	0.4674	
> 65	5	NE	1	NE	NE	NE		NE	NE		
Sex											0.3283
male	12	0.15 (0.89)	8	1.75 (1.12)	-1.60 (1.21)	(-4.24, 1.04)	0.2107	-0.49 (0.46)	(-1.40, 0.42)	0.2903	
female	104	-1.64 (0.46)	105	-1.34 (0.44)	-0.30 (0.55)	(-1.38, 0.78)	0.5806	-0.07 (0.14)	(-0.34, 0.21)	0.6368	
Race											0.2450
White	78	-1.47 (0.48)	86	-1.08 (0.46)	-0.39 (0.58)	(-1.54, 0.76)	0.5037	-0.09 (0.16)	(-0.40, 0.22)	0.5592	
Black or African American	19	-4.19 (1.61)	13	-2.80 (1.27)	-1.39 (1.81)	(-5.11, 2.33)	0.4500	-0.22 (0.36)	(-0.93, 0.49)	0.5419	
Asian	7	-2.11 (1.31)	3	1.71 (2.16)	-3.82 (2.64)	(-11.32, 3.68)	0.2254	-0.98 (0.74)	(-2.44, 0.48)	0.1898	
American Indian or Alaska Native	0	NE	0	NE	NE	NE		NE	NE		
Other	12	-1.94 (2.06)	11	-3.61 (2.21)	1.67 (1.39)	(-1.28, 4.62)	0.2478	0.22 (0.42)	(-0.60, 1.04)	0.5947	
Ethnicity											0.1564
Hispanic/Latino	21	-0.73 (1.07)	23	-2.02 (1.20)	1.29 (1.25)	(-1.23, 3.81)	0.3062	0.24 (0.30)	(-0.36, 0.83)	0.4348	
Non-hispanic/Latino	95	-1.86 (0.47)	90	-1.21 (0.45)	-0.65 (0.57)	(-1.77, 0.47)	0.2548	-0.14 (0.15)	(-0.43, 0.14)	0.3264	
Geographic region											0.6206
EU	45	-2.42 (0.64)	52	-2.18 (0.60)	-0.24 (0.68)	(-1.58, 1.11)	0.7258	-0.05 (0.20)	(-0.45, 0.34)	0.7884	
non-EU	71	-1.49 (0.57)	61	-0.76 (0.59)	-0.73 (0.73)	(-2.17, 0.71)	0.3171	-0.15 (0.17)	(-0.50, 0.19)	0.3776	
Onset of disease											0.1388
Paediatric	6	-4.86 (3.01)	6	-0.07 (2.39)	-4.79 (2.96)	(-11.62, 2.04)	0.1442	-0.67 (0.60)	(-1.84, 0.51)	0.2682	
Adult	110	-1.63 (0.44)	107	-1.29 (0.44)	-0.34 (0.53)	(-1.38, 0.69)	0.5148	-0.08 (0.14)	(-0.34, 0.19)	0.5803	
ADA result											0.1911
Negative	101	-1.57 (0.46)	100	-0.99 (0.46)	-0.59 (0.56)	(-1.70, 0.52)	0.2984	-0.13 (0.14)	(-0.40, 0.15)	0.3683	
Positive (At any time)	15	-4.99 (1.29)	13	-5.96 (1.37)	0.98 (1.06)	(-1.20, 3.15)	0.3638	0.19 (0.38)	(-0.55, 0.94)	0.6159	
BMI (kg/m2) at enrolment											0.8076
< 30	69	-1.82 (0.54)	78	-1.50 (0.50)	-0.32 (0.58)	(-1.45, 0.82)	0.5850	-0.07 (0.17)	(-0.39, 0.25)	0.6708	
>= 30	47	-1.39 (0.73)	35	-0.79 (0.81)	-0.60 (1.02)	(-2.63, 1.43)	0.5575	-0.12 (0.22)	(-0.56, 0.32)	0.5899	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - PtGA
Full analysis set

Visit	Anifrolumab 300mg (N=127) N	Anifrolumab 300mg (N=127) LSMean (SE)	Placebo (N=125) N	Placebo (N=125) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-5.44 (2.10)		-5.29 (2.09)	-0.15 (2.62)	(-5.32, 5.01)	0.9533			
Week 8		-7.34 (2.26)		-8.65 (2.27)	1.31 (2.88)	(-4.37, 6.98)	0.6505			
Week 12		-9.79 (2.30)		-7.79 (2.33)	-2.00 (2.97)	(-7.85, 3.85)	0.5012			
Week 16		-6.26 (2.40)		-9.02 (2.39)	2.77 (3.09)	(-3.33, 8.86)	0.3723			
Week 20		-9.01 (2.43)		-12.27 (2.43)	3.26 (3.15)	(-2.95, 9.46)	0.3022			
Week 24		-9.79 (2.54)		-8.10 (2.55)	-1.69 (3.32)	(-8.24, 4.85)	0.6101			
Week 28		-8.72 (2.57)		-9.42 (2.57)	0.70 (3.36)	(-5.93, 7.33)	0.8353			
Week 32		-9.11 (2.50)		-10.96 (2.53)	1.85 (3.28)	(-4.61, 8.31)	0.5736			
Week 36		-13.91 (2.43)		-12.85 (2.45)	-1.06 (3.16)	(-7.29, 5.16)	0.7367			
Week 40		-10.86 (2.66)		-10.54 (2.67)	-0.32 (3.51)	(-7.23, 6.59)	0.9273			
Week 44		-12.44 (2.49)		-14.01 (2.50)	1.57 (3.25)	(-4.83, 7.98)	0.6285			
Week 48		-11.65 (2.58)		-12.91 (2.62)	1.26 (3.40)	(-5.45, 7.97)	0.7114			
Week 52		-11.28 (2.78)		-12.07 (2.79)	0.79 (3.69)	(-6.48, 8.06)	0.8312			
OVERALL	121	-9.66 (1.93)	116	-10.30 (1.92)	0.64 (2.34)	(-3.98, 5.25)	0.7864	0.03 (0.13)	(-0.22, 0.28)	0.8159

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - PtGA - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=127)		Placebo (N=125)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											0.0838
< 10 points	36	-11.53 (3.29)	36	-6.10 (3.10)	-5.42 (4.07)	(-13.54, 2.70)	0.1869	-0.28 (0.24)	(-0.74, 0.18)	0.2381	
>= 10 points	85	-9.92 (2.29)	80	-13.10 (2.36)	3.18 (2.87)	(-2.49, 8.85)	0.2693	0.15 (0.16)	(-0.16, 0.46)	0.3364	
OCS dose at baseline											0.4156
<10 mg/day	53	-7.47 (2.59)	46	-10.47 (2.71)	3.00 (3.41)	(-3.78, 9.78)	0.3819	0.16 (0.20)	(-0.24, 0.56)	0.4290	
>=10 mg/day	68	-10.99 (2.91)	70	-10.17 (2.76)	-0.82 (3.22)	(-7.19, 5.55)	0.7991	-0.03 (0.17)	(-0.37, 0.30)	0.8385	
Result of type I IFN gene signature test											0.0283
LOW	21	-1.41 (3.57)	23	-12.02 (3.30)	10.61 (4.76)	(0.97, 20.24)	0.0318	0.65 (0.31)	(0.04, 1.26)	0.0367	
HIGH	100	-13.70 (1.94)	93	-12.34 (2.01)	-1.36 (2.66)	(-6.60, 3.89)	0.6104	-0.07 (0.14)	(-0.35, 0.21)	0.6280	
Age (years)											NE
<= 65	116	-9.67 (2.02)	115	-9.98 (1.95)	0.31 (2.38)	(-4.38, 5.00)	0.8967	0.01 (0.13)	(-0.24, 0.27)	0.9126	
> 65	5	NE	1	NE	NE	NE		NE	NE		
Sex											NE
male	12	NE	8	NE	NE	NE		NE	NE		
female	109	-9.36 (2.05)	108	-10.80 (2.00)	1.44 (2.47)	(-3.43, 6.31)	0.5606	0.07 (0.14)	(-0.20, 0.33)	0.6163	
Race											NE
White	81	-8.65 (2.36)	88	-11.88 (2.28)	3.23 (2.91)	(-2.51, 8.98)	0.2679	0.15 (0.15)	(-0.15, 0.45)	0.3276	
Black or African American	20	NE	13	NE	NE	NE		NE	NE		
Asian	7	NE	3	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	18.00 (0.00)	NE	NE		NE	NE		
Other	13	NE	11	NE	NE	NE		NE	NE		
Ethnicity											0.6565
Hispanic/Latino	23	-6.43 (4.10)	23	-9.53 (4.65)	3.10 (4.76)	(-6.50, 12.70)	0.5179	0.14 (0.30)	(-0.43, 0.72)	0.6235	
Non-hispanic/Latino	98	-10.34 (2.20)	93	-11.01 (2.16)	0.67 (2.70)	(-4.66, 6.00)	0.8047	0.03 (0.14)	(-0.25, 0.32)	0.8291	
Geographic region											0.3484
EU	46	-17.48 (3.41)	53	-19.77 (3.24)	2.29 (3.65)	(-4.95, 9.54)	0.5307	0.10 (0.20)	(-0.30, 0.49)	0.6287	
non-EU	75	-6.81 (2.26)	63	-4.74 (2.36)	-2.07 (2.89)	(-7.79, 3.65)	0.4757	-0.11 (0.17)	(-0.44, 0.23)	0.5303	
Onset of disease											NE
Paediatric	7	NE	6	NE	NE	NE		NE	NE		
Adult	114	-9.60 (1.97)	110	-10.28 (1.98)	0.68 (2.40)	(-4.06, 5.42)	0.7772	0.03 (0.13)	(-0.23, 0.29)	0.8079	
ADA result											0.7228
Negative	106	-9.23 (2.06)	103	-10.75 (2.05)	1.52 (2.55)	(-3.50, 6.54)	0.5523	0.07 (0.14)	(-0.20, 0.34)	0.6039	
Positive (At any time)	15	-20.77 (4.46)	13	-20.18 (4.65)	-0.59 (5.36)	(-11.65, 10.47)	0.9132	-0.03 (0.38)	(-0.78, 0.71)	0.9292	
BMI (kg/m2) at enrolment											0.1408
< 30	72	-10.28 (2.61)	80	-12.90 (2.45)	2.63 (2.81)	(-2.94, 8.19)	0.3522	0.12 (0.16)	(-0.20, 0.44)	0.4651	
>= 30	49	-9.26 (2.94)	36	-4.59 (3.28)	-4.67 (4.08)	(-12.79, 3.45)	0.2554	-0.23 (0.22)	(-0.66, 0.20)	0.2986	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SLEDAI-2K Total Score
Full analysis set

Visit	Anifrolumab 300mg (N=127) n/ N#	Anifrolumab 300mg (N=127) Compliance	Placebo (N=125) n/ N#	Placebo (N=125) Compliance
Baseline	127/ 127	100.0%	125/ 125	100.0%
Week 4	122/ 127	96.06%	123/ 125	98.40%
Week 8	123/ 127	96.85%	119/ 125	95.20%
Week 12	122/ 126	96.83%	116/ 125	92.80%
Week 16	118/ 126	93.65%	117/ 125	93.60%
Week 20	113/ 126	89.68%	115/ 125	92.00%
Week 24	113/ 126	89.68%	113/ 125	90.40%
Week 28	112/ 126	88.89%	114/ 125	91.20%
Week 32	112/ 126	88.89%	111/ 125	88.80%
Week 36	108/ 126	85.71%	110/ 125	88.00%
Week 40	109/ 126	86.51%	107/ 124	86.29%
Week 44	102/ 126	80.95%	108/ 124	87.10%
Week 48	109/ 126	86.51%	102/ 124	82.26%
Week 52	102/ 126	80.95%	98/ 124	79.03%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - PGA
Full analysis set

Visit	Anifrolumab 300mg (N=127) n/ N#	Anifrolumab 300mg (N=127) Compliance	Placebo (N=125) n/ N#	Placebo (N=125) Compliance
Baseline	127/ 127	100.0%	125/ 125	100.0%
Week 4	123/ 127	96.85%	125/ 125	100.0%
Week 8	122/ 127	96.06%	120/ 125	96.00%
Week 12	121/ 126	96.03%	115/ 125	92.00%
Week 16	117/ 126	92.86%	117/ 125	93.60%
Week 20	109/ 126	86.51%	114/ 125	91.20%
Week 24	113/ 126	89.68%	115/ 125	92.00%
Week 28	111/ 126	88.10%	114/ 125	91.20%
Week 32	113/ 126	89.68%	110/ 125	88.00%
Week 36	110/ 126	87.30%	108/ 125	86.40%
Week 40	109/ 126	86.51%	108/ 124	87.10%
Week 44	103/ 126	81.75%	107/ 124	86.29%
Week 48	111/ 126	88.10%	104/ 124	83.87%
Week 52	102/ 126	80.95%	100/ 124	80.65%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - CLASI Total Activity Score
Full analysis set

Visit	Anifrolumab 300mg (N=127) n/ N#	Anifrolumab 300mg (N=127) Compliance	Placebo (N=125) n/ N#	Placebo (N=125) Compliance
Baseline	127/ 127	100.0%	125/ 125	100.0%
Week 4	124/ 127	97.64%	125/ 125	100.0%
Week 8	123/ 127	96.85%	120/ 125	96.00%
Week 12	121/ 126	96.03%	117/ 125	93.60%
Week 16	118/ 126	93.65%	116/ 125	92.80%
Week 20	114/ 126	90.48%	115/ 125	92.00%
Week 24	113/ 126	89.68%	115/ 125	92.00%
Week 28	112/ 126	88.89%	115/ 125	92.00%
Week 32	114/ 126	90.48%	110/ 125	88.00%
Week 36	109/ 126	86.51%	109/ 125	87.20%
Week 40	109/ 126	86.51%	108/ 124	87.10%
Week 44	103/ 126	81.75%	109/ 124	87.90%
Week 48	111/ 126	88.10%	104/ 124	83.87%
Week 52	102/ 126	80.95%	101/ 124	81.45%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - CLASI Total Damage Score
Full analysis set

Visit	Anifrolumab 300mg (N=127) n/ N#	Anifrolumab 300mg (N=127) Compliance	Placebo (N=125) n/ N#	Placebo (N=125) Compliance
Baseline	127/ 127	100.0%	125/ 125	100.0%
Week 4	124/ 127	97.64%	124/ 125	99.20%
Week 8	123/ 127	96.85%	120/ 125	96.00%
Week 12	121/ 126	96.03%	118/ 125	94.40%
Week 16	118/ 126	93.65%	116/ 125	92.80%
Week 20	114/ 126	90.48%	115/ 125	92.00%
Week 24	113/ 126	89.68%	115/ 125	92.00%
Week 28	112/ 126	88.89%	115/ 125	92.00%
Week 32	114/ 126	90.48%	110/ 125	88.00%
Week 36	109/ 126	86.51%	109/ 125	87.20%
Week 40	109/ 126	86.51%	107/ 124	86.29%
Week 44	103/ 126	81.75%	109/ 124	87.90%
Week 48	111/ 126	88.10%	104/ 124	83.87%
Week 52	102/ 126	80.95%	101/ 124	81.45%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - BILAG Global Score
Full analysis set

Visit	Anifrolumab 300mg (N=127) n/ N#	Anifrolumab 300mg (N=127) Compliance	Placebo (N=125) n/ N#	Placebo (N=125) Compliance
Baseline	127/ 127	100.0%	125/ 125	100.0%
Week 4	124/ 127	97.64%	125/ 125	100.0%
Week 8	123/ 127	96.85%	120/ 125	96.00%
Week 12	122/ 126	96.83%	117/ 125	93.60%
Week 16	118/ 126	93.65%	116/ 125	92.80%
Week 20	114/ 126	90.48%	115/ 125	92.00%
Week 24	113/ 126	89.68%	116/ 125	92.80%
Week 28	112/ 126	88.89%	114/ 125	91.20%
Week 32	114/ 126	90.48%	110/ 125	88.00%
Week 36	109/ 126	86.51%	108/ 125	86.40%
Week 40	109/ 126	86.51%	107/ 124	86.29%
Week 44	102/ 126	80.95%	108/ 124	87.10%
Week 48	110/ 126	87.30%	102/ 124	82.26%
Week 52	102/ 126	80.95%	99/ 124	79.84%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Tender Joint Count
Full analysis set

Visit	Anifrolumab 300mg (N=127) n/ N#	Anifrolumab 300mg (N=127) Compliance	Placebo (N=125) n/ N#	Placebo (N=125) Compliance
Baseline	127/ 127	100.0%	125/ 125	100.0%
Week 4	123/ 127	96.85%	124/ 125	99.20%
Week 8	121/ 127	95.28%	120/ 125	96.00%
Week 12	122/ 126	96.83%	117/ 125	93.60%
Week 16	118/ 126	93.65%	117/ 125	93.60%
Week 20	114/ 126	90.48%	114/ 125	91.20%
Week 24	113/ 126	89.68%	114/ 125	91.20%
Week 28	111/ 126	88.10%	115/ 125	92.00%
Week 32	114/ 126	90.48%	110/ 125	88.00%
Week 36	109/ 126	86.51%	109/ 125	87.20%
Week 40	109/ 126	86.51%	107/ 124	86.29%
Week 44	103/ 126	81.75%	109/ 124	87.90%
Week 48	110/ 126	87.30%	104/ 124	83.87%
Week 52	101/ 126	80.16%	101/ 124	81.45%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Swollen Joint Count
Full analysis set

Visit	Anifrolumab 300mg (N=127) n/ N#	Anifrolumab 300mg (N=127) Compliance	Placebo (N=125) n/ N#	Placebo (N=125) Compliance
Baseline	127/ 127	100.0%	125/ 125	100.0%
Week 4	123/ 127	96.85%	124/ 125	99.20%
Week 8	121/ 127	95.28%	120/ 125	96.00%
Week 12	122/ 126	96.83%	117/ 125	93.60%
Week 16	118/ 126	93.65%	117/ 125	93.60%
Week 20	114/ 126	90.48%	114/ 125	91.20%
Week 24	113/ 126	89.68%	114/ 125	91.20%
Week 28	111/ 126	88.10%	115/ 125	92.00%
Week 32	114/ 126	90.48%	110/ 125	88.00%
Week 36	109/ 126	86.51%	109/ 125	87.20%
Week 40	109/ 126	86.51%	107/ 124	86.29%
Week 44	103/ 126	81.75%	109/ 124	87.90%
Week 48	110/ 126	87.30%	104/ 124	83.87%
Week 52	101/ 126	80.16%	101/ 124	81.45%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute Mental Component Score
Full analysis set

Visit	Anifrolumab 300mg (N=127) n/ N#	Anifrolumab 300mg (N=127) Compliance	Placebo (N=125) n/ N#	Placebo (N=125) Compliance
Baseline	123/ 127	96.85%	118/ 125	94.40%
Week 8	115/ 127	90.55%	117/ 125	93.60%
Week 16	111/ 126	88.10%	116/ 125	92.80%
Week 24	110/ 126	87.30%	107/ 125	85.60%
Week 32	108/ 126	85.71%	103/ 125	82.40%
Week 40	104/ 126	82.54%	105/ 124	84.68%
Week 48	108/ 126	85.71%	101/ 124	81.45%
Week 52	100/ 126	79.37%	99/ 124	79.84%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute Physical Component Score
Full analysis set

Visit	Anifrolumab 300mg (N=127) n/ N#	Anifrolumab 300mg (N=127) Compliance	Placebo (N=125) n/ N#	Placebo (N=125) Compliance
Baseline	123/ 127	96.85%	118/ 125	94.40%
Week 8	115/ 127	90.55%	117/ 125	93.60%
Week 16	111/ 126	88.10%	116/ 125	92.80%
Week 24	110/ 126	87.30%	107/ 125	85.60%
Week 32	108/ 126	85.71%	103/ 125	82.40%
Week 40	104/ 126	82.54%	105/ 124	84.68%
Week 48	108/ 126	85.71%	101/ 124	81.45%
Week 52	100/ 126	79.37%	99/ 124	79.84%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute General Health Score
Full analysis set

Visit	Anifrolumab 300mg (N=127) n/ N#	Anifrolumab 300mg (N=127) Compliance	Placebo (N=125) n/ N#	Placebo (N=125) Compliance
Baseline	123/ 127	96.85%	118/ 125	94.40%
Week 8	115/ 127	90.55%	117/ 125	93.60%
Week 16	111/ 126	88.10%	116/ 125	92.80%
Week 24	110/ 126	87.30%	107/ 125	85.60%
Week 32	108/ 126	85.71%	103/ 125	82.40%
Week 40	104/ 126	82.54%	105/ 124	84.68%
Week 48	108/ 126	85.71%	101/ 124	81.45%
Week 52	100/ 126	79.37%	99/ 124	79.84%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute Mental Health Score
Full analysis set

Visit	Anifrolumab 300mg (N=127) n/ N#	Anifrolumab 300mg (N=127) Compliance	Placebo (N=125) n/ N#	Placebo (N=125) Compliance
Baseline	123/ 127	96.85%	118/ 125	94.40%
Week 8	115/ 127	90.55%	117/ 125	93.60%
Week 16	111/ 126	88.10%	116/ 125	92.80%
Week 24	110/ 126	87.30%	107/ 125	85.60%
Week 32	108/ 126	85.71%	103/ 125	82.40%
Week 40	104/ 126	82.54%	105/ 124	84.68%
Week 48	108/ 126	85.71%	101/ 124	81.45%
Week 52	100/ 126	79.37%	99/ 124	79.84%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute Physical Functioning Score
Full analysis set

Visit	Anifrolumab 300mg (N=127) n/ N#	Anifrolumab 300mg (N=127) Compliance	Placebo (N=125) n/ N#	Placebo (N=125) Compliance
Baseline	123/ 127	96.85%	118/ 125	94.40%
Week 8	115/ 127	90.55%	117/ 125	93.60%
Week 16	111/ 126	88.10%	116/ 125	92.80%
Week 24	110/ 126	87.30%	107/ 125	85.60%
Week 32	108/ 126	85.71%	103/ 125	82.40%
Week 40	104/ 126	82.54%	105/ 124	84.68%
Week 48	108/ 126	85.71%	101/ 124	81.45%
Week 52	100/ 126	79.37%	99/ 124	79.84%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute Role Emotional Score
Full analysis set

Visit	Anifrolumab 300mg (N=127) n/ N#	Anifrolumab 300mg (N=127) Compliance	Placebo (N=125) n/ N#	Placebo (N=125) Compliance
Baseline	123/ 127	96.85%	118/ 125	94.40%
Week 8	115/ 127	90.55%	117/ 125	93.60%
Week 16	111/ 126	88.10%	116/ 125	92.80%
Week 24	110/ 126	87.30%	107/ 125	85.60%
Week 32	108/ 126	85.71%	103/ 125	82.40%
Week 40	104/ 126	82.54%	105/ 124	84.68%
Week 48	108/ 126	85.71%	101/ 124	81.45%
Week 52	100/ 126	79.37%	99/ 124	79.84%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute Role Physical Score
Full analysis set

Visit	Anifrolumab 300mg (N=127) n/ N#	Anifrolumab 300mg (N=127) Compliance	Placebo (N=125) n/ N#	Placebo (N=125) Compliance
Baseline	123/ 127	96.85%	118/ 125	94.40%
Week 8	115/ 127	90.55%	117/ 125	93.60%
Week 16	111/ 126	88.10%	116/ 125	92.80%
Week 24	110/ 126	87.30%	107/ 125	85.60%
Week 32	108/ 126	85.71%	103/ 125	82.40%
Week 40	104/ 126	82.54%	105/ 124	84.68%
Week 48	108/ 126	85.71%	101/ 124	81.45%
Week 52	100/ 126	79.37%	99/ 124	79.84%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute Social Functioning Score
Full analysis set

Visit	Anifrolumab 300mg (N=127) n/ N#	Anifrolumab 300mg (N=127) Compliance	Placebo (N=125) n/ N#	Placebo (N=125) Compliance
Baseline	123/ 127	96.85%	118/ 125	94.40%
Week 8	115/ 127	90.55%	117/ 125	93.60%
Week 16	111/ 126	88.10%	116/ 125	92.80%
Week 24	110/ 126	87.30%	107/ 125	85.60%
Week 32	108/ 126	85.71%	103/ 125	82.40%
Week 40	104/ 126	82.54%	105/ 124	84.68%
Week 48	108/ 126	85.71%	101/ 124	81.45%
Week 52	100/ 126	79.37%	99/ 124	79.84%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute Bodily Pain Score
Full analysis set

Visit	Anifrolumab 300mg (N=127) n/ N#	Anifrolumab 300mg (N=127) Compliance	Placebo (N=125) n/ N#	Placebo (N=125) Compliance
Baseline	123/ 127	96.85%	118/ 125	94.40%
Week 8	115/ 127	90.55%	117/ 125	93.60%
Week 16	111/ 126	88.10%	116/ 125	92.80%
Week 24	110/ 126	87.30%	107/ 125	85.60%
Week 32	108/ 126	85.71%	103/ 125	82.40%
Week 40	104/ 126	82.54%	105/ 124	84.68%
Week 48	108/ 126	85.71%	101/ 124	81.45%
Week 52	100/ 126	79.37%	99/ 124	79.84%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute Vitality Score
Full analysis set

Visit	Anifrolumab 300mg (N=127) n/ N#	Anifrolumab 300mg (N=127) Compliance	Placebo (N=125) n/ N#	Placebo (N=125) Compliance
Baseline	123/ 127	96.85%	118/ 125	94.40%
Week 8	115/ 127	90.55%	117/ 125	93.60%
Week 16	111/ 126	88.10%	116/ 125	92.80%
Week 24	110/ 126	87.30%	107/ 125	85.60%
Week 32	108/ 126	85.71%	103/ 125	82.40%
Week 40	104/ 126	82.54%	105/ 124	84.68%
Week 48	108/ 126	85.71%	101/ 124	81.45%
Week 52	100/ 126	79.37%	99/ 124	79.84%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - FACIT-F Total Score
Full analysis set

Visit	Anifrolumab 300mg (N=127) n/ N#	Anifrolumab 300mg (N=127) Compliance	Placebo (N=125) n/ N#	Placebo (N=125) Compliance
Baseline	122/ 127	96.06%	117/ 125	93.60%
Week 4	118/ 127	92.91%	117/ 125	93.60%
Week 8	116/ 127	91.34%	117/ 125	93.60%
Week 12	116/ 126	92.06%	112/ 125	89.60%
Week 16	113/ 126	89.68%	116/ 125	92.80%
Week 20	109/ 126	86.51%	112/ 125	89.60%
Week 24	110/ 126	87.30%	109/ 125	87.20%
Week 28	108/ 126	85.71%	109/ 125	87.20%
Week 32	110/ 126	87.30%	104/ 125	83.20%
Week 36	107/ 126	84.92%	101/ 125	80.80%
Week 40	106/ 126	84.13%	106/ 124	85.48%
Week 44	102/ 126	80.95%	103/ 124	83.06%
Week 48	110/ 126	87.30%	102/ 124	82.26%
Week 52	100/ 126	79.37%	99/ 124	79.84%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - EQ VAS Score
Full analysis set

Visit	Anifrolumab 300mg (N=127) n/ N#	Anifrolumab 300mg (N=127) Compliance	Placebo (N=125) n/ N#	Placebo (N=125) Compliance
Baseline	122/ 127	96.06%	117/ 125	93.60%
Week 12	116/ 126	92.06%	111/ 125	88.80%
Week 24	110/ 126	87.30%	107/ 125	85.60%
Week 36	103/ 126	81.75%	100/ 125	80.00%
Week 52	99/ 126	78.57%	99/ 124	79.84%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Lupus QoL Physical Health domain score
Full analysis set

Visit	Anifrolumab 300mg (N=127) n/ N#	Anifrolumab 300mg (N=127) Compliance	Placebo (N=125) n/ N#	Placebo (N=125) Compliance
Baseline	122/ 127	96.06%	117/ 125	93.60%
Week 12	116/ 126	92.06%	111/ 125	88.80%
Week 24	110/ 126	87.30%	107/ 125	85.60%
Week 36	103/ 126	81.75%	99/ 125	79.20%
Week 52	98/ 126	77.78%	98/ 124	79.03%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Lupus QoL Emotional Health domain score
Full analysis set

	Anifrolumab 300mg (N=127)		Placebo (N=125)	
Visit	n/ N#	Compliance	n/ N#	Compliance
Baseline	122/ 127	96.06%	117/ 125	93.60%
Week 12	116/ 126	92.06%	111/ 125	88.80%
Week 24	110/ 126	87.30%	107/ 125	85.60%
Week 36	103/ 126	81.75%	99/ 125	79.20%
Week 52	98/ 126	77.78%	98/ 124	79.03%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Lupus QoL Body Image domain score
Full analysis set

Visit	Anifrolumab 300mg (N=127) n/ N#	Anifrolumab 300mg (N=127) Compliance	Placebo (N=125) n/ N#	Placebo (N=125) Compliance
Baseline	114/ 127	89.76%	108/ 125	86.40%
Week 12	106/ 126	84.13%	99/ 125	79.20%
Week 24	101/ 126	80.16%	96/ 125	76.80%
Week 36	92/ 126	73.02%	91/ 125	72.80%
Week 52	84/ 126	66.67%	85/ 124	68.55%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Lupus QoL Burden to Others domain score
Full analysis set

Visit	Anifrolumab 300mg (N=127) n/ N#	Anifrolumab 300mg (N=127) Compliance	Placebo (N=125) n/ N#	Placebo (N=125) Compliance
Baseline	122/ 127	96.06%	117/ 125	93.60%
Week 12	116/ 126	92.06%	111/ 125	88.80%
Week 24	110/ 126	87.30%	107/ 125	85.60%
Week 36	103/ 126	81.75%	99/ 125	79.20%
Week 52	98/ 126	77.78%	98/ 124	79.03%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Lupus QoL Fatigue domain score
Full analysis set

Visit	Anifrolumab 300mg (N=127) n/ N#	Anifrolumab 300mg (N=127) Compliance	Placebo (N=125) n/ N#	Placebo (N=125) Compliance
Baseline	122/ 127	96.06%	117/ 125	93.60%
Week 12	116/ 126	92.06%	111/ 125	88.80%
Week 24	110/ 126	87.30%	107/ 125	85.60%
Week 36	103/ 126	81.75%	99/ 125	79.20%
Week 52	98/ 126	77.78%	98/ 124	79.03%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Lupus QoL Intimate Relationships domain score
Full analysis set

Visit	Anifrolumab 300mg (N=127) n/ N#	Anifrolumab 300mg (N=127) Compliance	Placebo (N=125) n/ N#	Placebo (N=125) Compliance
Baseline	106/ 127	83.46%	98/ 125	78.40%
Week 12	100/ 126	79.37%	84/ 125	67.20%
Week 24	89/ 126	70.63%	76/ 125	60.80%
Week 36	83/ 126	65.87%	70/ 125	56.00%
Week 52	78/ 126	61.90%	69/ 124	55.65%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Lupus QoL Pain domain score
Full analysis set

Visit	Anifrolumab 300mg (N=127) n/ N#	Anifrolumab 300mg (N=127) Compliance	Placebo (N=125) n/ N#	Placebo (N=125) Compliance
Baseline	122/ 127	96.06%	117/ 125	93.60%
Week 12	116/ 126	92.06%	111/ 125	88.80%
Week 24	110/ 126	87.30%	107/ 125	85.60%
Week 36	103/ 126	81.75%	99/ 125	79.20%
Week 52	98/ 126	77.78%	98/ 124	79.03%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Lupus QoL Planning domain score
Full analysis set

Visit	Anifrolumab 300mg (N=127) n/ N#	Anifrolumab 300mg (N=127) Compliance	Placebo (N=125) n/ N#	Placebo (N=125) Compliance
Baseline	122/ 127	96.06%	117/ 125	93.60%
Week 12	116/ 126	92.06%	111/ 125	88.80%
Week 24	110/ 126	87.30%	107/ 125	85.60%
Week 36	103/ 126	81.75%	99/ 125	79.20%
Week 52	98/ 126	77.78%	98/ 124	79.03%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SDI Global Score
Full analysis set

Visit	Anifrolumab 300mg (N=127) n/ N#	Anifrolumab 300mg (N=127) Compliance	Placebo (N=125) n/ N#	Placebo (N=125) Compliance
Baseline	121/ 127	95.28%	117/ 125	93.60%
Week 24	109/ 126	86.51%	110/ 125	88.00%
Week 52	95/ 126	75.40%	100/ 124	80.65%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - NRS Score
Full analysis set

Visit	Anifrolumab 300mg (N=127) n/ N#	Anifrolumab 300mg (N=127) Compliance	Placebo (N=125) n/ N#	Placebo (N=125) Compliance
Baseline	122/ 127	96.06%	117/ 125	93.60%
Week 4	118/ 127	92.91%	117/ 125	93.60%
Week 8	116/ 127	91.34%	117/ 125	93.60%
Week 12	116/ 126	92.06%	112/ 125	89.60%
Week 16	113/ 126	89.68%	116/ 125	92.80%
Week 20	109/ 126	86.51%	112/ 125	89.60%
Week 24	110/ 126	87.30%	109/ 125	87.20%
Week 28	108/ 126	85.71%	109/ 125	87.20%
Week 32	110/ 126	87.30%	104/ 125	83.20%
Week 36	107/ 126	84.92%	101/ 125	80.80%
Week 40	106/ 126	84.13%	106/ 124	85.48%
Week 44	102/ 126	80.95%	103/ 124	83.06%
Week 48	110/ 126	87.30%	102/ 124	82.26%
Week 52	100/ 126	79.37%	99/ 124	79.84%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - PHQ-8 Total Score
Full analysis set

Visit	Anifrolumab 300mg (N=127) n/ N#	Anifrolumab 300mg (N=127) Compliance	Placebo (N=125) n/ N#	Placebo (N=125) Compliance
Baseline	122/ 127	96.06%	117/ 125	93.60%
Week 12	116/ 126	92.06%	111/ 125	88.80%
Week 24	110/ 126	87.30%	107/ 125	85.60%
Week 36	103/ 126	81.75%	100/ 125	80.00%
Week 52	99/ 126	78.57%	99/ 124	79.84%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - PtGA
Full analysis set

Visit	Anifrolumab 300mg (N=127) n/ N#	Anifrolumab 300mg (N=127) Compliance	Placebo (N=125) n/ N#	Placebo (N=125) Compliance
Baseline	122/ 127	96.06%	117/ 125	93.60%
Week 4	118/ 127	92.91%	117/ 125	93.60%
Week 8	116/ 127	91.34%	117/ 125	93.60%
Week 12	116/ 126	92.06%	112/ 125	89.60%
Week 16	113/ 126	89.68%	115/ 125	92.00%
Week 20	108/ 126	85.71%	110/ 125	88.00%
Week 24	110/ 126	87.30%	109/ 125	87.20%
Week 28	108/ 126	85.71%	109/ 125	87.20%
Week 32	109/ 126	86.51%	104/ 125	83.20%
Week 36	107/ 126	84.92%	100/ 125	80.00%
Week 40	106/ 126	84.13%	105/ 124	84.68%
Week 44	102/ 126	80.95%	102/ 124	82.26%
Week 48	110/ 126	87.30%	101/ 124	81.45%
Week 52	99/ 126	78.57%	98/ 124	79.03%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Flare rate through Week 52
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) Number of flares	Anifrolumab 300mg (N=127) Total Follow-up time (years)	Anifrolumab 300mg (N=127) Annual rate (SE)	Placebo (N=125) Number of flares	Placebo (N=125) Total Follow-up time (years)	Placebo (N=125) Annual rate (SE)	Rate ratio (95% CI)	p-Value	Interaction p-Value
Overall	62	117.87	0.44 (0.18)	86	115.96	0.62 (0.17)	0.71 (0.48, 1.05)	0.0844	
SLEDAI-2K score at screening									0.6325
< 10 points	9	34.90	NE	15	33.40	NE	NE		
>= 10 points	53	82.97	0.68 (0.19)	71	82.55	0.92 (0.18)	0.73 (0.47, 1.15)	0.1807	
OCS dose at baseline									0.7255
<10 mg/day	26	54.32	0.41 (0.27)	30	48.90	0.53 (0.27)	0.78 (0.41, 1.46)	0.4291	
>=10 mg/day	36	63.55	0.48 (0.25)	56	67.06	0.72 (0.23)	0.67 (0.41, 1.11)	0.1194	
Result of type I IFN gene signature test									0.0930
LOW	17	21.03	0.59 (0.34)	13	23.06	0.42 (0.35)	1.42 (0.65, 3.13)	0.3817	
HIGH	45	96.83	0.39 (0.19)	73	92.90	0.65 (0.17)	0.60 (0.38, 0.93)	0.0239	
Age (years)									0.4978
<= 65	60	113.05	0.43 (0.19)	83	114.04	0.60 (0.18)	0.73 (0.49, 1.08)	0.1148	
> 65	2	4.82	NE	3	1.92	NE	NE		
Sex									0.1292
male	4	11.83	0.00 (958.28)	10	7.32	0.00 (958.28)	0.28 (0.09, 0.91)	0.0338	
female	58	106.04	0.47 (0.19)	76	108.64	0.61 (0.18)	0.78 (0.51, 1.18)	0.2358	
Race									0.1857
White	40	79.60	0.41 (0.21)	67	88.67	0.60 (0.19)	0.68 (0.44, 1.05)	0.0834	
Black or African American	14	19.40	0.58 (0.53)	6	13.38	0.44 (0.51)	1.32 (0.38, 4.65)	0.6608	
Asian	5	6.93	0.48 (0.63)	1	2.98	0.32 (1.03)	1.50 (0.16, 14.16)	0.7243	
American Indian or Alaska Native	0		NE	0	0.16	NE	NE		
Other	3	11.93	NE	12	10.77	NE	NE		
Ethnicity									0.3996
Hispanic/Latino	9	20.32	0.27 (0.57)	21	23.15	0.48 (0.59)	0.56 (0.20, 1.58)	0.2715	
Non-hispanic/Latino	53	97.55	0.48 (0.19)	65	92.80	0.62 (0.18)	0.78 (0.51, 1.19)	0.2425	
Geographic region									0.4331
EU	15	45.71	0.21 (0.39)	34	51.81	0.40 (0.35)	0.54 (0.27, 1.08)	0.0798	
non-EU	47	72.16	0.56 (0.21)	52	64.14	0.74 (0.20)	0.75 (0.47, 1.20)	0.2327	
Onset of disease									0.6991
Paediatric	5	6.94	NE	5	6.43	NE	NE		
Adult	57	110.93	0.44 (0.19)	81	109.53	0.64 (0.18)	0.69 (0.45, 1.04)	0.0785	
ADA result									0.1375
Negative	56	104.31	0.47 (0.19)	71	103.99	0.59 (0.18)	0.79 (0.52, 1.20)	0.2743	
Positive (At any time)	6	13.56	0.15 (0.82)	15	11.97	0.55 (0.66)	0.27 (0.10, 0.78)	0.0152	
BMI (kg/m2) at enrolment									0.1293
< 30	33	69.16	0.46 (0.25)	68	80.04	0.81 (0.21)	0.56 (0.34, 0.92)	0.0229	
>= 30	29	48.70	0.43 (0.27)	18	35.91	0.40 (0.31)	1.09 (0.55, 2.14)	0.8084	

Rates and rate ratio from negative binomial regression model with factors for treatment group and the stratification factors. The logarithm (to base e) of the follow-up time is used as an offset variable in the model to adjust for subjects having different exposure times.
p-Value for interaction from same negative binomial regression model with additional factors for subgroup and subgroup*treatment interaction.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Flare rate through Week 52 using modified BILAG
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) Number of flares	Anifrolumab 300mg (N=127) Total Follow-up time (years)	Anifrolumab 300mg (N=127) Annual rate (SE)	Placebo (N=125) Number of flares	Placebo (N=125) Total Follow-up time (years)	Placebo (N=125) Annual rate (SE)	Rate ratio (95% CI)	p-Value	Interaction p-Value
Overall	36	117.87	0.20 (0.25)	66	115.96	0.37 (0.23)	0.54 (0.33, 0.87)	0.0119	

Rates and rate ratio from negative binomial regression model with factors for treatment group and the stratification factors. The logarithm (to base e) of the follow-up time is used as an offset variable in the model to adjust for subjects having different exposure times.
p-Value for interaction from same negative binomial regression model with additional factors for subgroup and subgroup*treatment interaction.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Flare rate through Week 52 while on treatment
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) Number of flares	Anifrolumab 300mg (N=127) Total Follow-up time (years)	Anifrolumab 300mg (N=127) Annual rate (SE)	Placebo (N=125) Number of flares	Placebo (N=125) Total Follow-up time (years)	Placebo (N=125) Annual rate (SE)	Rate ratio (95% CI)	p-Value	Interaction p-Value
Overall	55	113.76	0.41 (0.19)	77	111.48	0.58 (0.18)	0.70 (0.47, 1.05)	0.0843	

Rates and rate ratio from negative binomial regression model with factors for treatment group and the stratification factors. The logarithm (to base e) of the follow-up time is used as an offset variable in the model to adjust for subjects having different exposure times.
p-Value for interaction from same negative binomial regression model with additional factors for subgroup and subgroup*treatment interaction.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Flare rate through Week 52 sensitivity analysis, multiple imputation and negative binomial regression model
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) Number of flares	Anifrolumab 300mg (N=127) Total Follow-up time (years)	Anifrolumab 300mg (N=127) Annual rate (SE)	Placebo (N=125) Number of flares	Placebo (N=125) Total Follow-up time (years)	Placebo (N=125) Annual rate (SE)	Rate ratio (95% CI)	p-Value
Overall	67	127.30	0.44 (0.00)	94	125.55	0.62 (0.00)	0.71 (0.48, 1.05)	0.0821

The number of flares after withdrawal from study is imputed conditional upon the observed number of flares prior to the withdrawal, a post-withdrawal model assumption, the baseline covariates included in the main analysis model and the time the subject would have remained in the study if not withdrawn (ie, date of first administration of IP + 364 days â€“ date of withdrawal). This analysis is repeated multiple times and the results combined using Rubinâ€™s formula. Full details are given in SAP
Rates and rate ratio from negative binomial regression model with factors for treatment group and the stratification factors. The logarithm (to base e) of the follow-up time is used as an offset variable in the model to adjust for subjects having different exposure times.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Flare rate through Week 52 sensitivity analysis, tipping point analysis
Full analysis set

Shift (log(Delta A)) for Anifrolumab 300 mg	Shift (log(Delta P)) for Placebo						
	0	-0.25	-0.5	-0.75	-1	-1.25	-1.5
0	0.0756	0.0830	0.0892	0.0943	0.0985	0.1018	0.1045
0.25	0.0822	0.0902	0.0968	0.1022	0.1066	0.1102	0.1130
0.5	0.0916	0.1002	0.1073	0.1132	0.1180	0.1218	0.1249
0.75	0.1049	0.1144	0.1223	0.1289	0.1341	0.1383	0.1417
1	0.1243	0.1352	0.1442	0.1515	0.1575	0.1622	0.1660
1.25	0.1536	0.1663	0.1768	0.1853	0.1921	0.1976	0.2020
1.5	0.1987	0.2139	0.2264	0.2365	0.2447	0.2511	0.2562

The response variable in the model is the number of flares up to Week 52/EDV. The model includes covariates of treatment group, and the stratification factors (SLEDAI-2K Score at Screening (<10 points vs >= 10 points), Week 0 OCS dose (<10 mg/day vs >=10 mg/day prednisone or equivalent) and Type 1 IFN test result at screening (high vs low)).
The logarithm (to base e) of the follow-up time is used as an offset variable in the model to adjust for subjects having different exposure times.
P-values of this analysis are presented.
For the scenario in the upper left corner, missing at random analysis is performed, where for each subject the rate after withdrawal y1 is assumed to be the same as their rate before withdrawal y2, which itself is calculated based on their randomised treatment group and baseline covariates. For the other scenarios, the same analyses are performed with the rate after withdrawal modified to be Deltay2 (Delta P and Delta A for placebo and anifrolumab 300 mg, respectively).

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Overall Survival
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	1 (0.8)	1 (0.8)
Number of censored subjects, n (%)	126 (99.2)	124 (99.2)
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Anifrolumab 300mg vs. Placebo (adjusted)		
Hazard Ratio (95% CI)	0.92 (0.06, 14.74)	
p-value	0.9624	
Analysis Anifrolumab 300mg vs. Placebo (unadjusted)		
Hazard Ratio (95% CI)	0.98 (0.06, 15.73)	
p-value	0.9907	

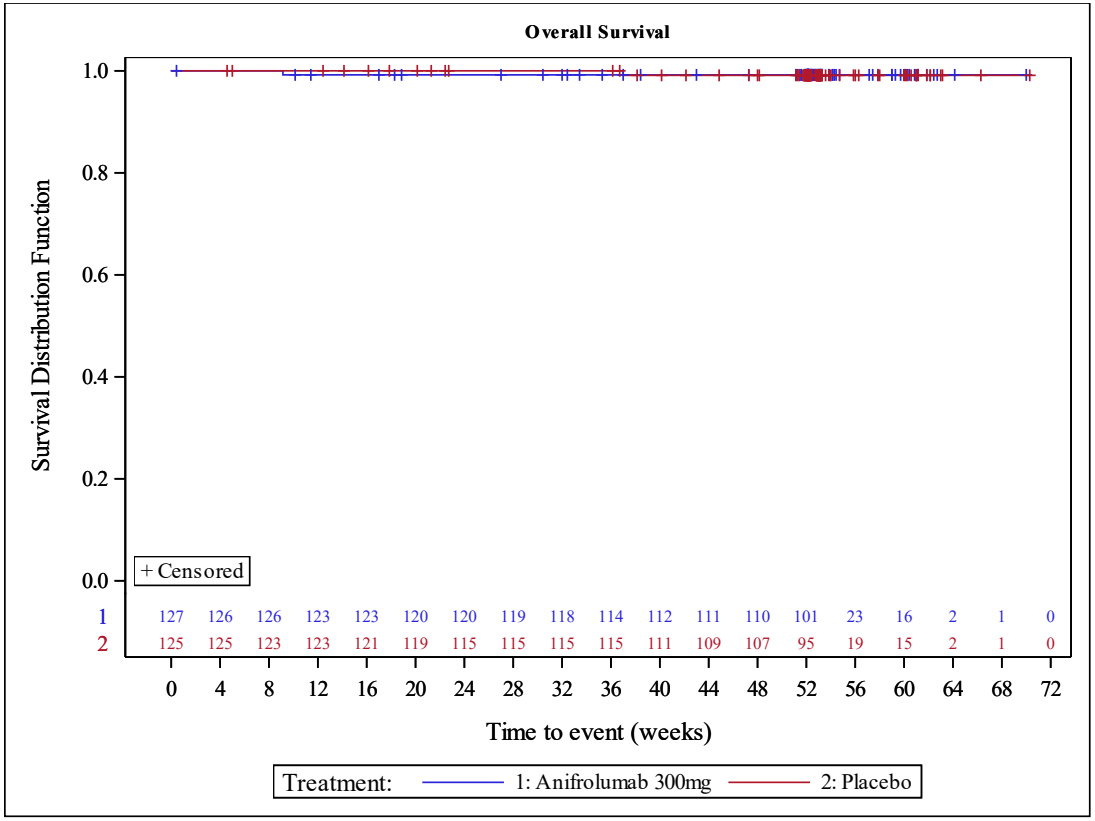
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model. Adjusted analysis also includes stratification factors in the model.
Two-sided log rank test used.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Overall Survival - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Anifrolumab 300mg (N=127) Median (95% CI)	Placebo (N=125) n/ N (%)	Placebo (N=125) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening							0.9983
< 10 points	1/ 39 (2.6)	NE (NE, NE)	0/ 37 (0.0)	NE (NE, NE)	NE		
>= 10 points	0/ 88 (0.0)	NE (NE, NE)	1/ 88 (1.1)	NE (NE, NE)	NE		
OCS dose at baseline							1.0000
<10 mg/day	0/ 57 (0.0)	NE (NE, NE)	0/ 52 (0.0)	NE (NE, NE)	NE		
>=10 mg/day	1/ 70 (1.4)	NE (NE, NE)	1/ 73 (1.4)	NE (NE, NE)	0.92 (0.06, 14.74)	0.9624	
Result of type I IFN gene signature test							1.0000
LOW	0/ 22 (0.0)	NE (NE, NE)	0/ 24 (0.0)	NE (NE, NE)	NE		
HIGH	1/105 (1.0)	NE (NE, NE)	1/101 (1.0)	NE (NE, NE)	0.92 (0.06, 14.74)	0.9624	
Age (years)							0.9996
<= 65	1/122 (0.8)	NE (NE, NE)	1/123 (0.8)	NE (NE, NE)	0.88 (0.05, 14.17)	0.9400	
> 65	0/ 5 (0.0)	NE (NE, NE)	0/ 2 (0.0)	NE (NE, NE)	NE		
Sex							1.0000
male	0/ 12 (0.0)	NE (NE, NE)	0/ 8 (0.0)	NE (NE, NE)	NE		
female	1/115 (0.9)	NE (NE, NE)	1/117 (0.9)	NE (NE, NE)	0.98 (0.06, 15.73)	0.9964	
Race							1.0000
White	0/ 85 (0.0)	NE (NE, NE)	0/ 96 (0.0)	NE (NE, NE)	NE		
Black or African American	0/ 22 (0.0)	NE (NE, NE)	1/ 14 (7.1)	NE (NE, NE)	NE		
Asian	0/ 7 (0.0)	NE (NE, NE)	0/ 3 (0.0)	NE (NE, NE)	NE		
American Indian or Alaska Native	0	NE (NE, NE)	0/ 1 (0.0)	NE (NE, NE)	NE		
Other	1/ 13 (7.7)	NE (NE, NE)	0/ 11 (0.0)	NE (NE, NE)	NE		
Ethnicity							0.9992
Hispanic/Latino	1/ 23 (4.3)	NE (NE, NE)	0/ 24 (0.0)	NE (NE, NE)	NE		
Non-hispanic/Latino	0/104 (0.0)	NE (NE, NE)	1/101 (1.0)	NE (NE, NE)	NE		
Geographic region							1.0000
EU	0/ 47 (0.0)	NE (NE, NE)	0/ 56 (0.0)	NE (NE, NE)	NE		
non-EU	1/ 80 (1.3)	NE (NE, NE)	1/ 69 (1.4)	NE (NE, NE)	0.95 (0.06, 15.41)	0.9918	
Onset of disease							1.0000
Paediatric	0/ 8 (0.0)	NE (NE, NE)	0/ 7 (0.0)	NE (NE, NE)	NE		
Adult	1/119 (0.8)	NE (NE, NE)	1/118 (0.8)	NE (NE, NE)	0.95 (0.06, 15.25)	0.9791	
ADA result							1.0000
Negative	1/111 (0.9)	NE (NE, NE)	1/112 (0.9)	NE (NE, NE)	0.89 (0.05, 14.59)	0.9523	
Positive (At any time)	0/ 15 (0.0)	NE (NE, NE)	0/ 13 (0.0)	NE (NE, NE)	NE		
BMI (kg/m2) at enrolment							0.9981
< 30	1/ 74 (1.4)	NE (NE, NE)	0/ 87 (0.0)	NE (NE, NE)	NE		
>= 30	0/ 53 (0.0)	NE (NE, NE)	1/ 38 (2.6)	NE (NE, NE)	NE		

Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of Overall Survival
Full analysis set



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Time to first Flare
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	39 (30.7)	55 (44.0)
Number of censored subjects, n (%)	88 (69.3)	70 (56.0)
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	36.00 (16.86, 53.71)	20.00 (12.00, 28.57)
Median (95% CI)	NE (53.71, NE)	NE (36.00, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Anifrolumab 300mg vs. Placebo (adjusted)		
Hazard Ratio (95% CI)	0.62 (0.41, 0.93)	
p-value	0.0213	
Analysis Anifrolumab 300mg vs. Placebo (unadjusted)		
Hazard Ratio (95% CI)	0.61 (0.41, 0.93)	
p-value	0.0190	

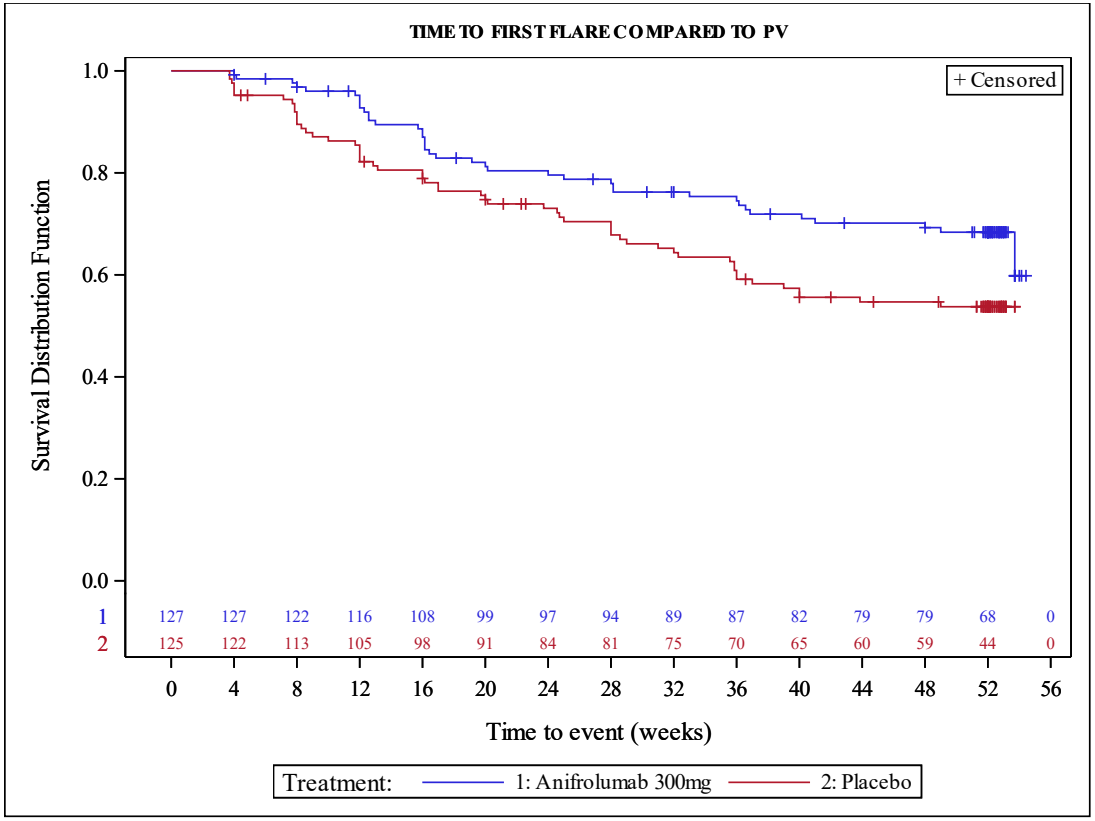
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model. Adjusted analysis also includes stratification factors in the model.
Two-sided log rank test used.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Time to first Flare - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Anifrolumab 300mg (N=127) Median (95% CI)	Placebo (N=125) n/ N (%)	Placebo (N=125) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening							0.7427
< 10 points	8/ 39 (20.5)	NE (53.71, NE)	13/ 37 (35.1)	NE (36.00, NE)	0.48 (0.19, 1.22)	0.1200	
>= 10 points	31/ 88 (35.2)	NE (NE, NE)	42/ 88 (47.7)	NE (29.00, NE)	0.65 (0.41, 1.03)	0.0742	
OCS dose at baseline							0.1277
<10 mg/day	19/ 57 (33.3)	NE (NE, NE)	18/ 52 (34.6)	NE (39.00, NE)	0.90 (0.47, 1.73)	0.7519	
>=10 mg/day	20/ 70 (28.6)	NE (53.71, NE)	37/ 73 (50.7)	40.00 (25.00, NE)	0.47 (0.27, 0.82)	0.0066	
Result of type I IFN gene signature test							0.1227
LOW	10/ 22 (45.5)	NE (16.14, NE)	10/ 24 (41.7)	NE (28.57, NE)	1.21 (0.50, 2.95)	0.6240	
HIGH	29/105 (27.6)	NE (53.71, NE)	45/101 (44.6)	NE (35.86, NE)	0.52 (0.33, 0.84)	0.0046	
Age (years)							0.7778
<= 65	37/122 (30.3)	NE (53.71, NE)	54/123 (43.9)	NE (36.00, NE)	0.60 (0.40, 0.92)	0.0178	
> 65	2/ 5 (40.0)	NE (12.00, NE)	1/ 2 (50.0)	NE (19.71, NE)	0.89 (0.00,)	<.0001	
Sex							0.4385
male	4/ 12 (33.3)	NE (12.00, NE)	5/ 8 (62.5)	24.71 (4.00, NE)	0.40 (0.10, 1.65)	0.0447	
female	35/115 (30.4)	NE (53.71, NE)	50/117 (42.7)	NE (39.00, NE)	0.65 (0.42, 1.00)	0.0567	
Race							0.5636
White	27/ 85 (31.8)	NE (53.71, NE)	44/ 96 (45.8)	NE (35.86, NE)	0.59 (0.36, 0.96)	0.0358	
Black or African American	7/ 22 (31.8)	NE (28.14, NE)	5/ 14 (35.7)	NE (28.57, NE)	0.91 (0.22, 3.69)	0.7428	
Asian	3/ 7 (42.9)	NE (8.00, NE)	1/ 3 (33.3)	NE (31.00, NE)	1.03 (0.09, 12.21)	0.7822	
American Indian or Alaska Native	0	NE (NE, NE)	0/ 1 (0.0)	NE (NE, NE)	NE		
Other	2/ 13 (15.4)	NE (12.29, NE)	5/ 11 (45.5)	NE (8.57, NE)	0.37 (0.07, 1.91)	0.2112	
Ethnicity							0.3752
Hispanic/Latino	8/ 23 (34.8)	NE (25.00, NE)	9/ 24 (37.5)	NE (28.00, NE)	0.98 (0.38, 2.58)	0.9997	
Non-hispanic/Latino	31/104 (29.8)	NE (53.71, NE)	46/101 (45.5)	NE (36.00, NE)	0.57 (0.36, 0.90)	0.0122	
Geographic region							0.1752
EU	9/ 47 (19.1)	NE (53.71, NE)	23/ 56 (41.1)	NE (36.00, NE)	0.34 (0.15, 0.78)	0.0098	
non-EU	30/ 80 (37.5)	NE (48.00, NE)	32/ 69 (46.4)	NE (32.00, NE)	0.73 (0.44, 1.20)	0.2158	
Onset of disease							0.9768
Paediatric	4/ 8 (50.0)	36.00 (12.00, NE)	4/ 7 (57.1)	43.86 (3.71, NE)	0.14 (0.02, 0.96)	0.0849	
Adult	35/119 (29.4)	NE (53.71, NE)	51/118 (43.2)	NE (36.00, NE)	0.61 (0.40, 0.94)	0.0258	
ADA result							0.4408
Negative	34/111 (30.6)	NE (53.71, NE)	47/112 (42.0)	NE (37.00, NE)	0.65 (0.42, 1.01)	0.0458	
Positive (At any time)	5/ 15 (33.3)	NE (12.00, NE)	8/ 13 (61.5)	35.86 (8.00, NE)	0.31 (0.09, 1.05)	0.0782	
BMI (kg/m2) at enrolment							0.3827
< 30	22/ 74 (29.7)	53.71 (53.71, NE)	41/ 87 (47.1)	NE (35.57, NE)	0.54 (0.32, 0.92)	0.0240	
>= 30	17/ 53 (32.1)	NE (NE, NE)	14/ 38 (36.8)	NE (32.29, NE)	0.79 (0.39, 1.61)	0.5637	

Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of Time to first Flare
Full analysis set



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Time to sustained BICLA response up to week 52
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	64 (50.4)	41 (32.8)
Number of censored subjects, n (%)	63 (49.6)	84 (67.2)
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	16.00 (12.00, 24.00)	32.14 (20.86, 51.57)
Median (95% CI)	48.14 (35.71, 52.00)	NE (53.00, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Anifrolumab 300mg vs. Placebo (adjusted)		
Hazard Ratio (95% CI)	1.95 (1.32, 2.90)	
p-value	0.0005	
Analysis Anifrolumab 300mg vs. Placebo (unadjusted)		
Hazard Ratio (95% CI)	1.90 (1.28, 2.82)	
p-value	0.0011	

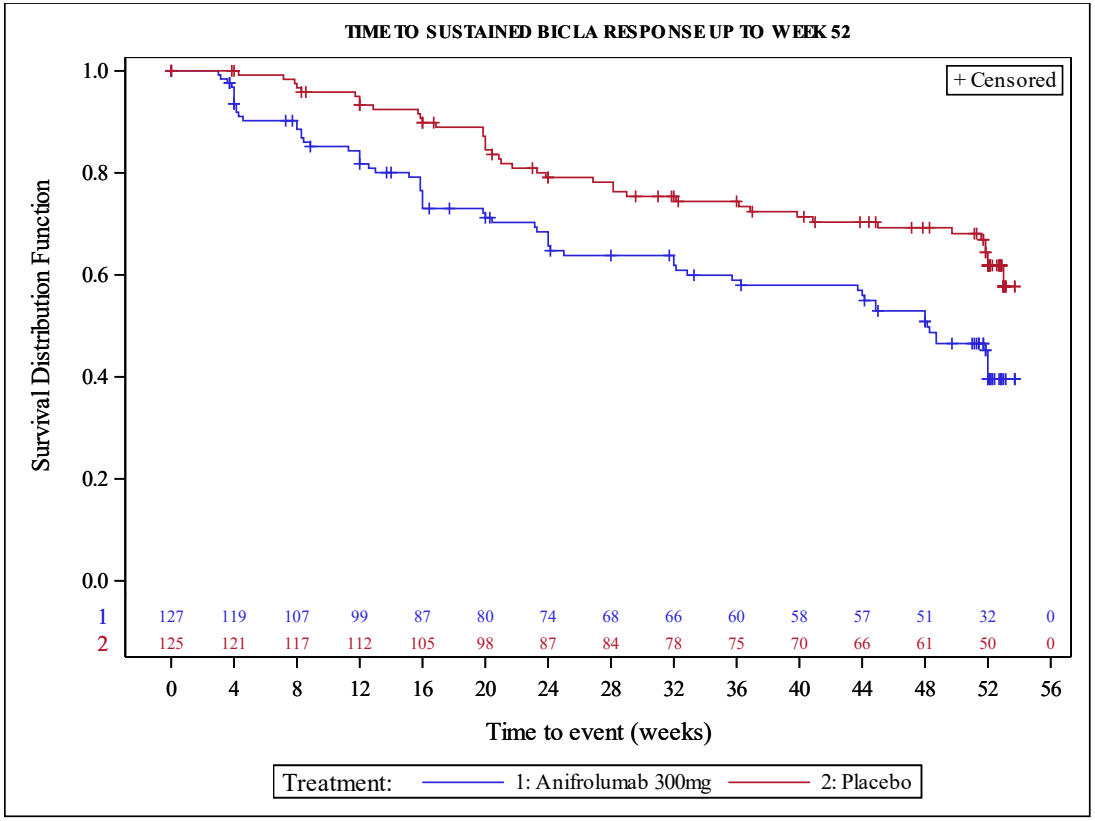
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model. Adjusted analysis also includes stratification factors in the model.
Two-sided log rank test used.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Time to sustained BICLA response up to week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Anifrolumab 300mg (N=127) Median (95% CI)	Placebo (N=125) n/ N (%)	Placebo (N=125) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening							0.8793
< 10 points	23/ 39 (59.0)	32.00 (16.00, 52.00)	16/ 37 (43.2)	53.00 (39.86, NE)	1.91 (1.00, 3.63)	0.0322	
>= 10 points	41/ 88 (46.6)	51.86 (44.00, NE)	25/ 88 (28.4)	NE (NE, NE)	1.95 (1.18, 3.22)	0.0061	
OCS dose at baseline							0.2368
<10 mg/day	27/ 57 (47.4)	52.00 (32.00, NE)	19/ 52 (36.5)	53.00 (49.71, NE)	1.50 (0.83, 2.69)	0.1298	
>=10 mg/day	37/ 70 (52.9)	48.00 (24.00, 52.00)	22/ 73 (30.1)	NE (52.00, NE)	2.36 (1.39, 4.02)	0.0009	
Result of type I IFN gene signature test							0.5094
LOW	10/ 22 (45.5)	48.14 (25.00, NE)	9/ 24 (37.5)	NE (28.14, NE)	1.53 (0.61, 3.86)	0.3360	
HIGH	54/105 (51.4)	48.00 (32.00, 52.00)	32/101 (31.7)	NE (53.00, NE)	2.06 (1.33, 3.20)	0.0007	
Age (years)							0.6032
<= 65	60/122 (49.2)	48.29 (36.29, NE)	40/123 (32.5)	NE (53.00, NE)	1.94 (1.29, 2.90)	0.0008	
> 65	4/ 5 (80.0)	32.00 (15.86, 52.00)	1/ 2 (50.0)	NE (8.29, NE)	0.00 (0.00,)	<.0001	
Sex							0.3667
male	6/ 12 (50.0)	NE (4.00, NE)	1/ 8 (12.5)	NE (28.14, NE)	4.66 (0.55, 39.63)	0.1812	
female	58/115 (50.4)	48.14 (35.71, 52.00)	40/117 (34.2)	NE (53.00, NE)	1.89 (1.26, 2.83)	0.0017	
Race							0.6747
White	42/ 85 (49.4)	51.86 (25.00, NE)	33/ 96 (34.4)	NE (52.00, NE)	1.97 (1.23, 3.15)	0.0024	
Black or African American	12/ 22 (54.5)	48.00 (20.00, NE)	6/ 14 (42.9)	49.71 (20.00, NE)	2.74 (0.80, 9.37)	0.3183	
Asian	4/ 7 (57.1)	44.86 (4.00, NE)	1/ 3 (33.3)	NE (51.57, NE)	5.63 (0.41, 77.70)	0.0906	
American Indian or Alaska Native	0	NE (NE, NE)	0/ 1 (0.0)	NE (NE, NE)	NE		
Other	6/ 13 (46.2)	48.29 (8.43, NE)	1/ 11 (9.1)	NE (NE, NE)	7.33 (0.87, 61.46)	0.0259	
Ethnicity							0.8624
Hispanic/Latino	9/ 23 (39.1)	52.00 (25.00, NE)	6/ 24 (25.0)	NE (51.86, NE)	1.75 (0.59, 5.17)	0.2197	
Non-hispanic/Latino	55/104 (52.9)	48.00 (32.00, 52.00)	35/101 (34.7)	NE (52.00, NE)	2.00 (1.30, 3.07)	0.0013	
Geographic region							0.7848
EU	30/ 47 (63.8)	24.14 (15.14, 51.86)	22/ 56 (39.3)	53.00 (36.14, NE)	2.05 (1.17, 3.58)	0.0077	
non-EU	34/ 80 (42.5)	52.00 (44.86, NE)	19/ 69 (27.5)	NE (52.00, NE)	1.90 (1.08, 3.35)	0.0160	
Onset of disease							0.8917
Paediatric	3/ 8 (37.5)	48.00 (3.00, NE)	2/ 7 (28.6)	NE (23.86, NE)	3.38 (0.30, 38.23)	0.1362	
Adult	61/119 (51.3)	48.14 (32.86, 52.00)	39/118 (33.1)	NE (53.00, NE)	1.94 (1.30, 2.91)	0.0006	
ADA result							0.8134
Negative	58/111 (52.3)	48.14 (32.86, 52.00)	38/112 (33.9)	NE (52.00, NE)	1.95 (1.29, 2.95)	0.0012	
Positive (At any time)	6/ 15 (40.0)	NE (12.00, NE)	3/ 13 (23.1)	NE (16.86, NE)	2.30 (0.54, 9.86)	0.2622	
BMI (kg/m2) at enrolment							0.7299
< 30	39/ 74 (52.7)	44.86 (32.00, 52.00)	26/ 87 (29.9)	NE (53.00, NE)	2.04 (1.24, 3.37)	0.0028	
>= 30	25/ 53 (47.2)	52.00 (24.14, NE)	15/ 38 (39.5)	NE (51.57, NE)	1.72 (0.89, 3.35)	0.0823	

Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of Time to sustained BICLA response up to week 52
Full analysis set



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Time to OCS Reduction <=7.5 mg/day (for subjects with baseline OCS >=10 mg/day)
Full analysis set

	Anifrolumab 300mg (N=70)	Placebo (N=73)
Number of subjects with events, n (%)	48 (68.6)	39 (53.4)
Number of censored subjects, n (%)	22 (31.4)	34 (46.6)
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	13.00 (11.43, 16.29)	15.00 (10.86, 20.14)
Median (95% CI)	21.14 (16.29, 24.29)	28.00 (20.29, NE)
75%-ile (95% CI)	40.29 (24.29, NE)	NE (NE, NE)
Analysis Anifrolumab 300mg vs. Placebo (adjusted)		
Hazard Ratio (95% CI)	1.62 (1.06, 2.48)	
p-value	0.0360	
Analysis Anifrolumab 300mg vs. Placebo (unadjusted)		
Hazard Ratio (95% CI)	1.57 (1.03, 2.40)	
p-value	0.0360	

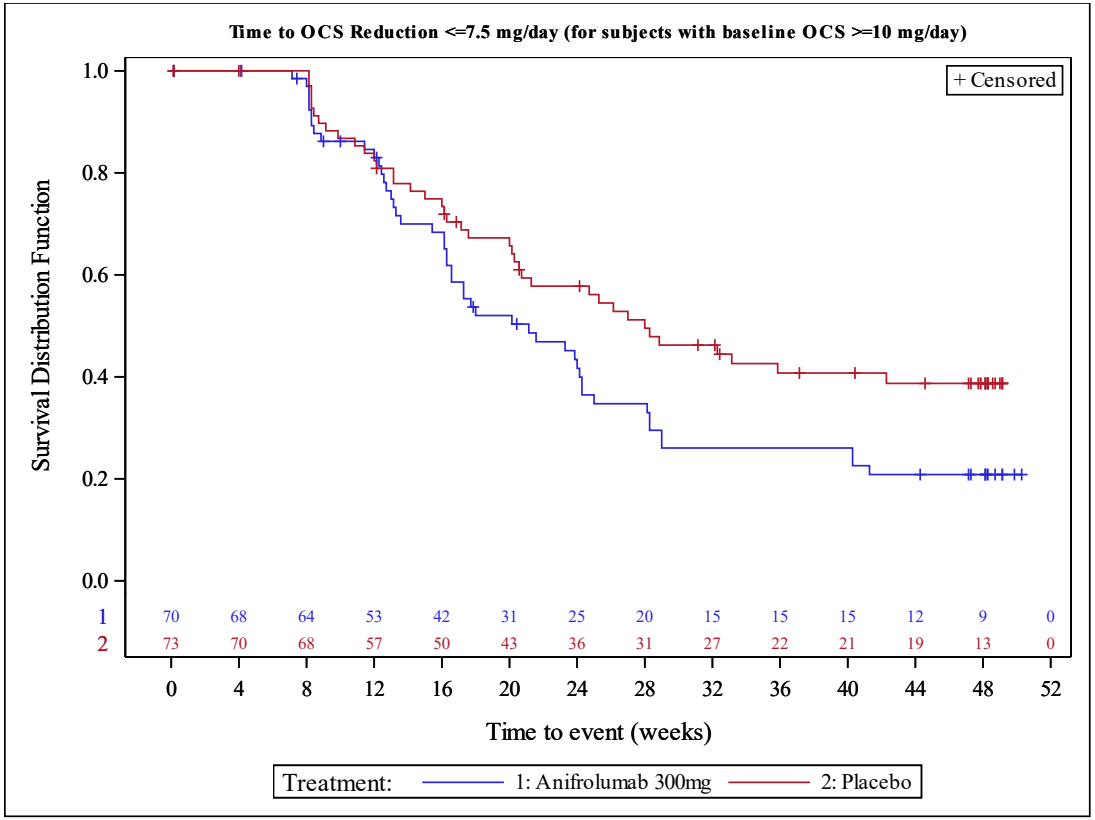
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model. Adjusted analysis also includes stratification factors in the model.
Two-sided log rank test used.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Time to OCS Reduction <=7.5 mg/day (for subjects with baseline OCS >=10 mg/day) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=70) n/ N (%)	Anifrolumab 300mg (N=70) Median (95% CI)	Placebo (N=73) n/ N (%)	Placebo (N=73) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening							0.6540
< 10 points	14/ 20 (70.0)	28.29 (12.43, 29.00)	9/ 17 (52.9)	28.29 (20.14, NE)	2.33 (0.94, 5.79)	0.0722	
>= 10 points	34/ 50 (68.0)	17.71 (15.43, 24.00)	30/ 56 (53.6)	26.14 (17.14, NE)	1.48 (0.91, 2.43)	0.1651	
OCS dose at baseline							NE
>=10 mg/day	48/ 70 (68.6)	21.14 (16.29, 24.29)	39/ 73 (53.4)	28.00 (20.29, NE)	1.62 (1.06, 2.48)	0.0360	
Result of type I IFN gene signature test							0.5651
LOW	7/ 8 (87.5)	21.36 (8.14, 40.29)	10/ 12 (83.3)	23.00 (9.86, 35.86)	1.30 (0.47, 3.57)	0.8545	
HIGH	41/ 62 (66.1)	21.14 (16.14, 24.29)	29/ 61 (47.5)	32.29 (20.29, NE)	1.70 (1.06, 2.75)	0.0270	
Age (years)							0.9815
<= 65	48/ 69 (69.6)	20.14 (16.29, 24.29)	38/ 72 (52.8)	28.29 (20.57, NE)	1.68 (1.10, 2.58)	0.0221	
> 65	0/ 1 (0.0)	NE (NE, NE)	1/ 1 (100.0)	20.29 (NE, NE)	NE		
Sex							0.0450
male	9/ 9 (100.0)	16.14 (7.14, 24.14)	2/ 6 (33.3)	NE (28.29, NE)	32.55 (2.40, 441.87)	0.0080	
female	39/ 61 (63.9)	21.57 (16.57, 28.14)	37/ 67 (55.2)	26.14 (20.00, NE)	1.36 (0.87, 2.14)	0.2228	
Race							0.0589
White	25/ 39 (64.1)	23.29 (16.14, 25.00)	29/ 57 (50.9)	28.86 (20.14, NE)	1.43 (0.83, 2.45)	0.3700	
Black or African American	11/ 16 (68.8)	28.14 (8.14, 41.29)	4/ 6 (66.7)	26.64 (10.86, NE)	1.35 (0.42, 4.34)	0.3516	
Asian	3/ 4 (75.0)	26.14 (21.14, NE)	2/ 2 (100.0)	14.07 (12.00, 16.14)	0.00 (0.00,)	0.0389	
Other	9/ 11 (81.8)	13.14 (8.14, 16.57)	4/ 8 (50.0)	NE (15.00, NE)	4.75 (1.34, 16.78)	0.0213	
Ethnicity							0.1285
Hispanic/Latino	9/ 14 (64.3)	16.57 (8.43, 17.29)	6/ 12 (50.0)	NE (15.00, NE)	3.36 (1.07, 10.59)	0.0374	
Non-hispanic/Latino	39/ 56 (69.6)	23.29 (16.29, 28.29)	33/ 61 (54.1)	28.00 (17.57, 42.29)	1.42 (0.89, 2.26)	0.2349	
Geographic region							0.4959
EU	23/ 31 (74.2)	21.57 (15.43, 25.00)	24/ 43 (55.8)	21.29 (16.29, 35.86)	1.38 (0.76, 2.51)	0.4169	
non-EU	25/ 39 (64.1)	18.00 (13.57, 28.29)	15/ 30 (50.0)	28.29 (20.29, NE)	1.89 (0.99, 3.62)	0.0247	
Onset of disease							0.6687
Paediatric	4/ 6 (66.7)	28.29 (12.57, 40.29)	2/ 5 (40.0)	26.14 (20.14, NE)	0.89 (0.10, 8.37)	0.6949	
Adult	44/ 64 (68.8)	18.00 (16.14, 24.29)	37/ 68 (54.4)	28.00 (20.00, NE)	1.57 (1.01, 2.43)	0.0510	
ADA result							0.0379
Negative	41/ 59 (69.5)	23.29 (16.57, 25.00)	38/ 65 (58.5)	25.29 (17.57, 33.14)	1.35 (0.87, 2.11)	0.2472	
Positive (At any time)	7/ 10 (70.0)	16.29 (7.14, NE)	1/ 8 (12.5)	NE (35.86, NE)	NE		
BMI (kg/m2) at enrolment							0.4370
< 30	34/ 45 (75.6)	17.71 (16.14, 24.00)	29/ 56 (51.8)	27.00 (20.00, NE)	1.86 (1.12, 3.07)	0.0147	
>= 30	14/ 25 (56.0)	24.29 (13.57, NE)	10/ 17 (58.8)	33.14 (12.14, NE)	1.27 (0.56, 2.89)	0.5809	

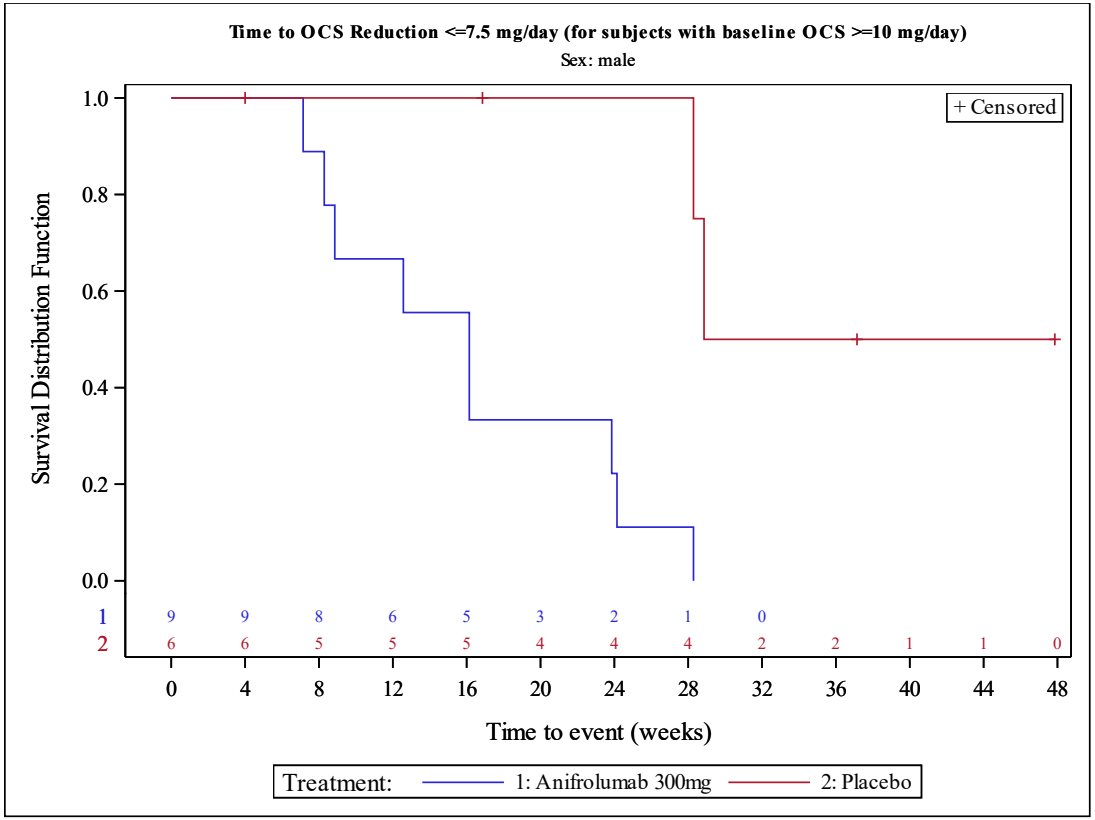
Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of Time to OCS Reduction <=7.5 mg/day (for subjects with baseline OCS >=10 mg/day)
Full analysis set



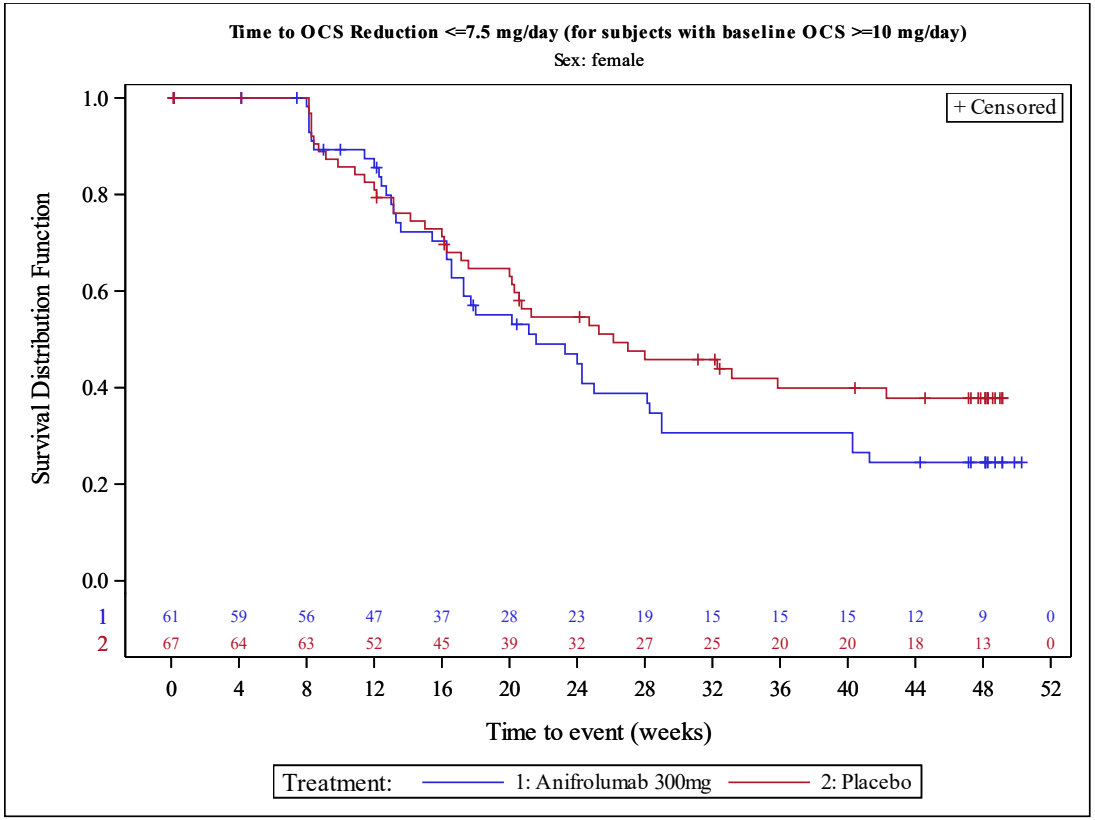
Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of Time to OCS Reduction <=7.5 mg/day (for subjects with baseline OCS >=10 mg/day)
Full analysis set



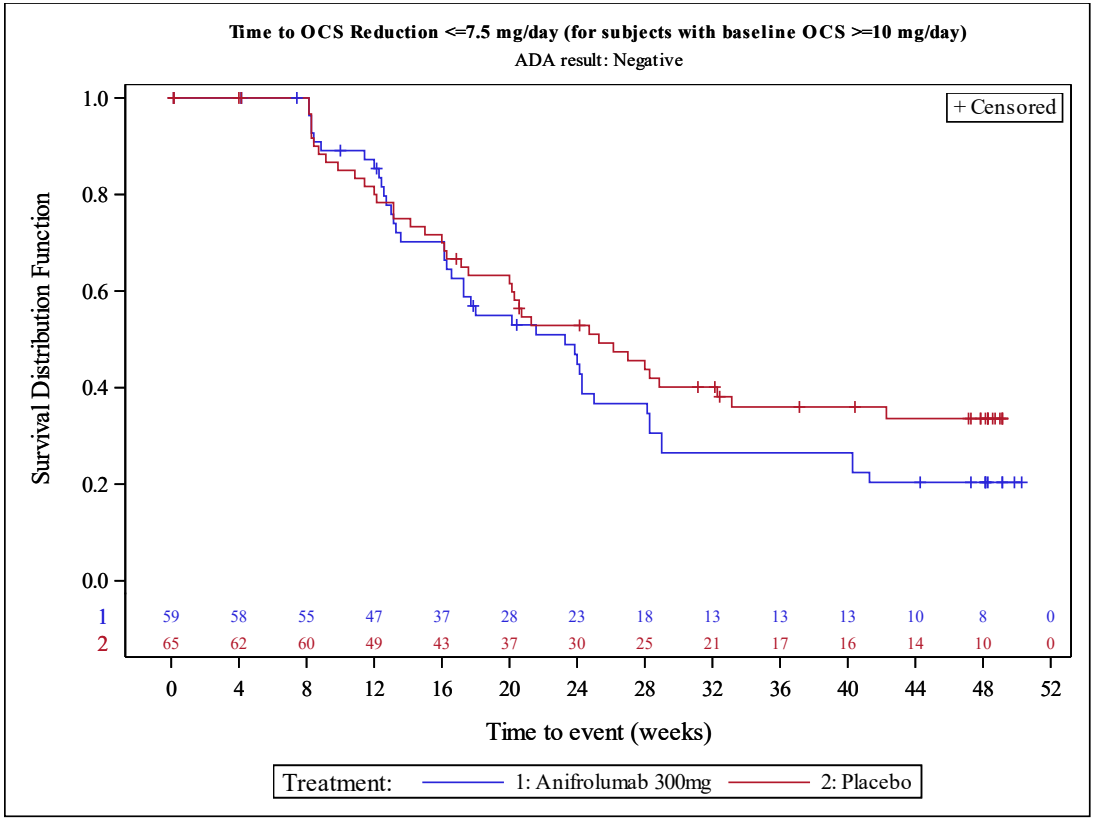
Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of Time to OCS Reduction <=7.5 mg/day (for subjects with baseline OCS >=10 mg/day)
Full analysis set



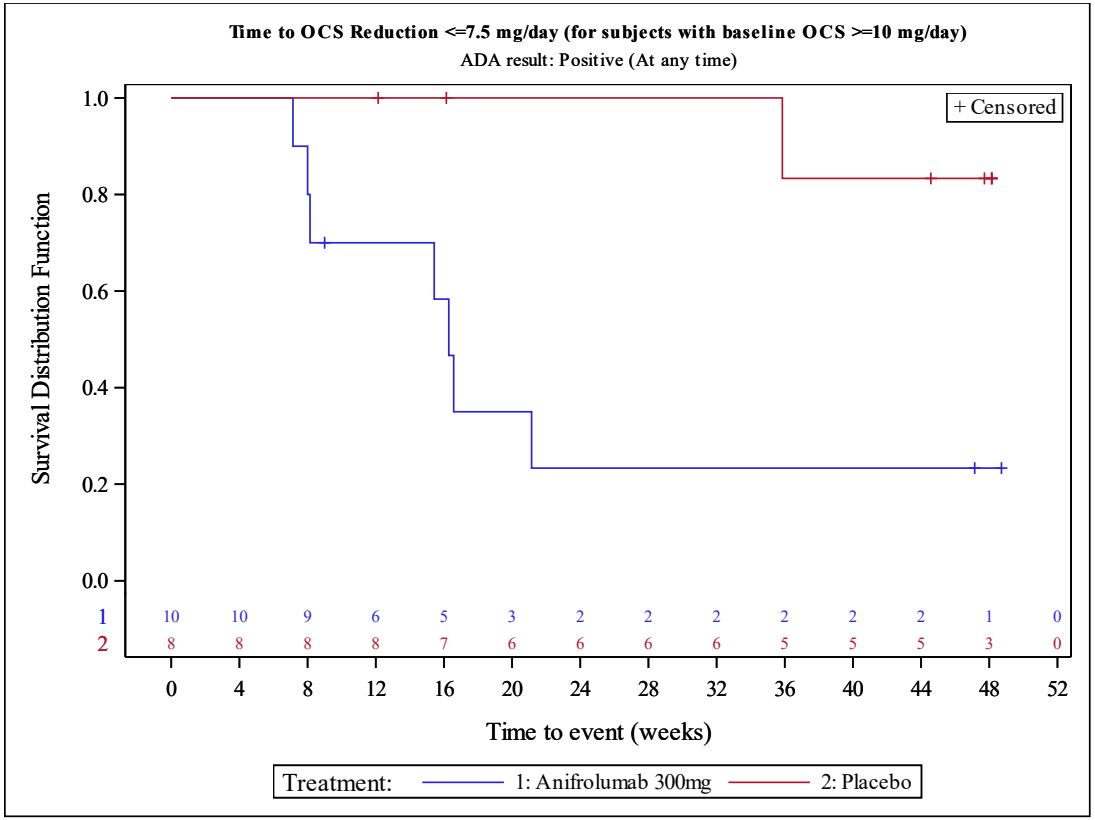
Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of Time to OCS Reduction <=7.5 mg/day (for subjects with baseline OCS >=10 mg/day)
Full analysis set



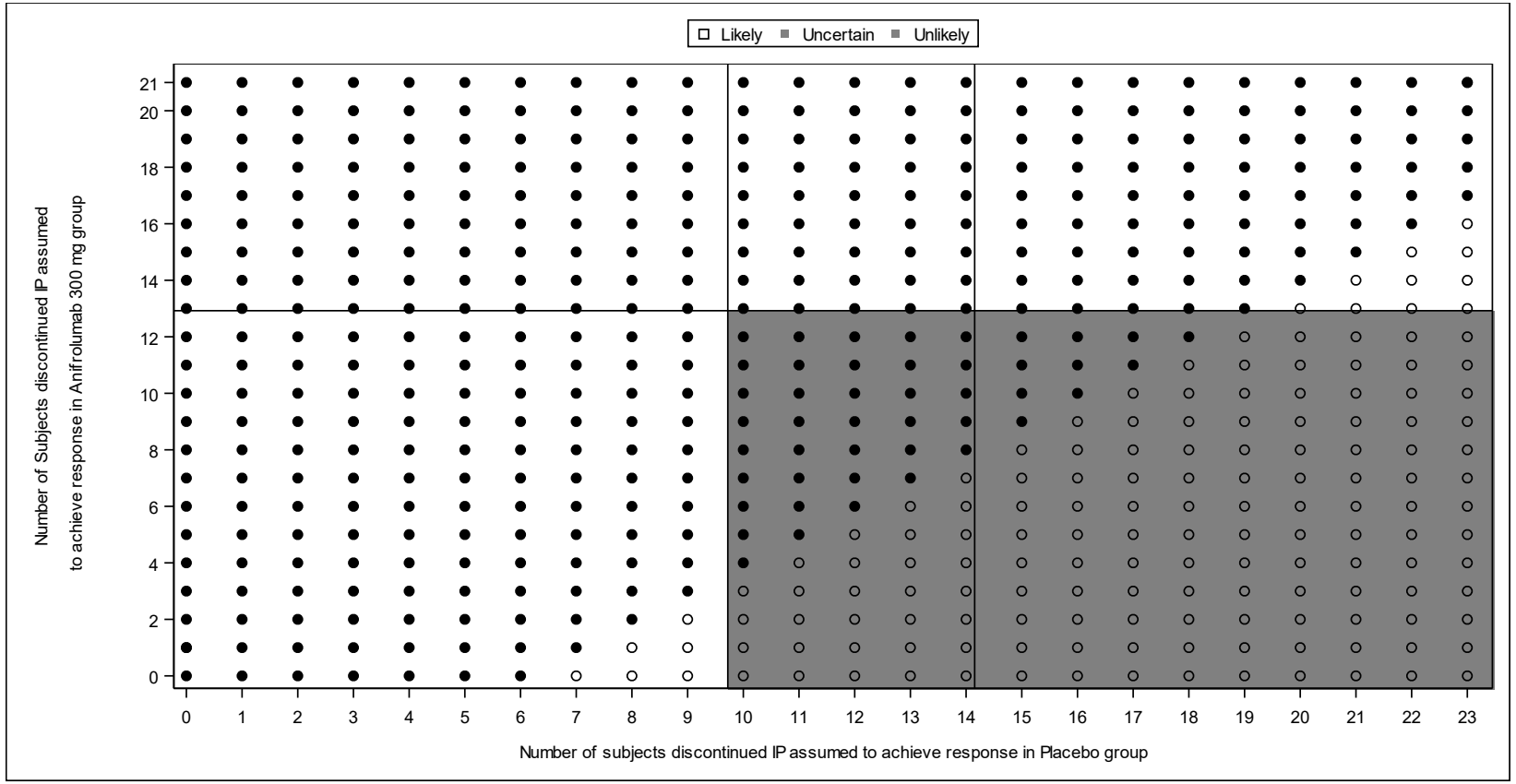
Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of Time to OCS Reduction <=7.5 mg/day (for subjects with baseline OCS >=10 mg/day)
Full analysis set



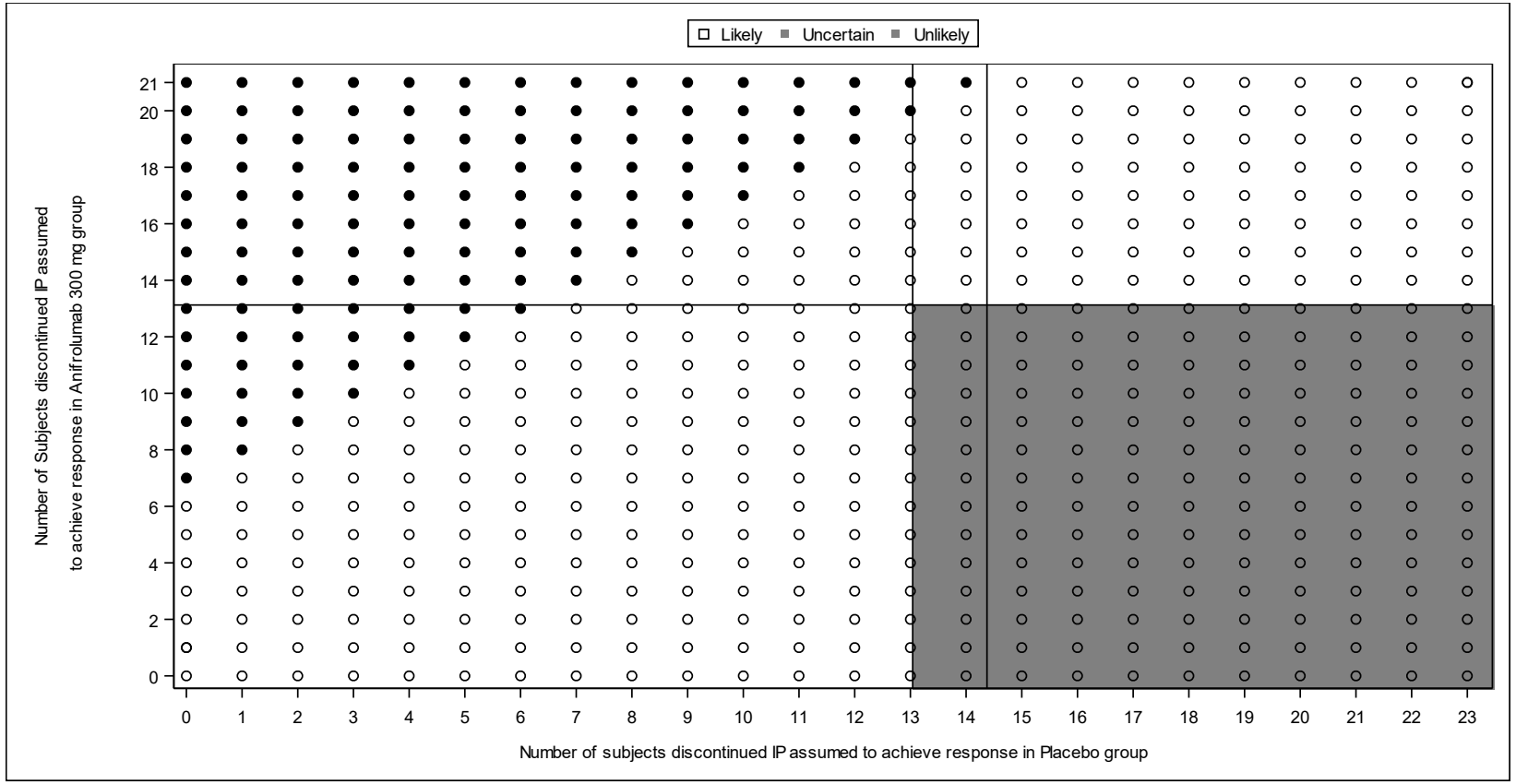
Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Plot of BICLA response rate sensitivity analysis at week 52, tipping point analysis
Full analysis set



Subjects with permanent discontinuation of IP are taken as non-responders at the bottom left grid. A certain number of such subjects from both groups are altered to be responders, while the numbers for both groups are as stated in both axes.
For each scenario, Pearson`s chi-squared test is used to compare the proportion of subjects achieving response at Week 52. The dots are presenting the results: filled = p-value <0.05, open = p-value >=0.05.
The three colors area indicate the tipping point area: white=likely, bright grey=uncertain, darker grey=Unlikely.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Plot of SRI (4) response rate sensitivity analysis at week 52, tipping point analysis
Full analysis set



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For each scenario, Pearson`s chi-squared test is used to compare the proportion of subjects achieving response at Week 52. The dots are presenting the results: filled = p-value <0.05, open = p-value >=0.05.
The three colors area indicate the tipping point area: white=likely, bright grey=uncertain, darker grey=Unlikely.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
OCS dose increases and cumulative OCS dose until week 52
Full analysis set

		Anifrolumab 300mg (N=127)	Placebo (N=125)	Total (N=252)
Number of dose increases (%)	0	87 (68.5)	79 (63.2)	166 (65.9)
	1	28 (22.0)	22 (17.6)	50 (19.8)
	2	5 (3.9)	11 (8.8)	16 (6.3)
	>2	7 (5.5)	13 (10.4)	20 (7.9)
Cumulative OCS Dose (mg/day)	n (missing)	127 (0)	125 (0)	252 (0)
	Mean (SD)	2577.9 (3576.35)	2734.1 (2045.23)	2655.3 (2914.31)
	Median	2009.0	2385.0	2200.0
	Min, Max	0, 35466	0, 9000	0, 35466
AUC up to Week 52 (mg/day)	n (missing)	127 (0)	125 (0)	252 (0)
	Mean (SD)	2788.0 (3589.70)	3006.2 (2100.85)	2896.3 (2942.96)
	Median	2311.9	2824.1	2616.9
	Min, Max	0, 35369	0, 8854	0, 35369

Subjects without any documented dose value regarded as missing values for calculation of cumulative dose and AUC.
AUC defines the cumulative dose normalized for a period of 52 weeks.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	114 (89.8)	94 (75.2)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.19 (1.06, 1.34)	
p-value	0.0029	
Odds Ratio (95% CI)	2.89 (1.43, 5.84)	
p-value	0.0031	
Risk Difference (95% CI)	14.56 (5.34, 23.79)	
p-value	0.0020	
CMH approach		
Response rate	89.9	75.5
Difference in response rates (95% CI)	14.34 (4.33, 24.35)	
p-value	0.0050	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.3123
< 10 points	36/ 39 (92.3)	93.1	31/ 37 (83.8)	84.8	1.10 (0.93, 1.30)	0.2590	8.28 (-9.51, 26.08)	0.3617	
>= 10 points	78/ 88 (88.6)	88.6	63/ 88 (71.6)	71.6	1.24 (1.06, 1.44)	0.0057	16.95 (4.63, 29.26)	0.0070	
OCS dose at baseline									0.8257
<10 mg/day	54/ 57 (94.7)	94.7	42/ 52 (80.8)	80.7	1.17 (1.01, 1.36)	0.0323	14.00 (-0.61, 28.60)	0.0603	
>=10 mg/day	60/ 70 (85.7)	85.9	52/ 73 (71.2)	72.0	1.20 (1.01, 1.43)	0.0375	13.88 (-0.11, 27.86)	0.0518	
Result of type I IFN gene signature test									0.1781
LOW	21/ 22 (95.5)	95.5	16/ 24 (66.7)	66.7	1.43 (1.06, 1.93)	0.0179	28.79 (5.43, 52.15)	0.0157	
HIGH	93/105 (88.6)	88.6	78/101 (77.2)	77.5	1.15 (1.01, 1.30)	0.0333	11.11 (0.02, 22.19)	0.0495	
Age (years)									0.0767
<= 65	110/122 (90.2)	90.3	92/123 (74.8)	75.2	1.21 (1.07, 1.36)	0.0019	15.10 (4.95, 25.24)	0.0035	
> 65	4/ 5 (80.0)	80.0	2/ 2 (100.0)	100.0	0.80 (0.52, 1.24)	0.3183	-20.00 (-97.30, 57.30)	0.6121	
Sex									0.7102
male	10/ 12 (83.3)	83.3	5/ 8 (62.5)	62.5	1.33 (0.74, 2.41)	0.3420	20.83 (-21.21, 62.87)	0.3314	
female	104/115 (90.4)	90.6	89/117 (76.1)	76.4	1.19 (1.06, 1.34)	0.0040	14.22 (3.86, 24.59)	0.0072	
Race									0.4238
White	76/ 85 (89.4)	88.8	70/ 96 (72.9)	73.5	1.23 (1.06, 1.41)	0.0049	15.24 (2.93, 27.54)	0.0152	
Black or African American	19/ 22 (86.4)	86.4	12/ 14 (85.7)	85.7	1.01 (0.77, 1.32)	0.9564	0.65 (-26.65, 27.95)	0.9628	
Asian	7/ 7 (100.0)	100.0	3/ 3 (100.0)	100.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		1/ 1 (100.0)		NE		NE		
Other	12/ 13 (92.3)	92.3	8/ 11 (72.7)	72.7	1.27 (0.86, 1.88)	0.2362	19.58 (-15.14, 54.30)	0.2690	
Ethnicity									0.4109
Hispanic/Latino	21/ 23 (91.3)	91.3	20/ 24 (83.3)	83.3	1.10 (0.88, 1.36)	0.4134	7.97 (-13.94, 29.89)	0.4759	
Non-hispanic/Latino	93/104 (89.4)	89.7	74/101 (73.3)	74.0	1.22 (1.07, 1.40)	0.0038	15.68 (4.28, 27.09)	0.0070	
Geographic region									0.0425
EU	39/ 47 (83.0)	83.0	33/ 56 (58.9)	58.9	1.41 (1.09, 1.82)	0.0083	24.05 (6.86, 41.24)	0.0061	
non-EU	75/ 80 (93.8)	93.8	61/ 69 (88.4)	88.1	1.06 (0.96, 1.17)	0.2616	5.69 (-5.57, 16.95)	0.3220	
Onset of disease									0.8877
Paediatric	8/ 8 (100.0)	100.0	6/ 7 (85.7)	85.7	1.17 (0.86, 1.58)	0.3178	14.29 (-27.61, 56.18)	0.5040	
Adult	106/119 (89.1)	89.0	88/118 (74.6)	74.9	1.19 (1.06, 1.35)	0.0045	14.16 (3.70, 24.63)	0.0080	
ADA result									0.7012
Negative	101/111 (91.0)	91.1	84/112 (75.0)	75.5	1.21 (1.07, 1.37)	0.0019	15.60 (4.93, 26.27)	0.0042	
Positive (At any time)	13/ 15 (86.7)	86.7	10/ 13 (76.9)	76.9	1.13 (0.79, 1.61)	0.5136	9.74 (-22.49, 41.98)	0.5536	
BMI (kg/m2) at enrolment									0.3098
< 30	65/ 74 (87.8)	88.0	62/ 87 (71.3)	71.8	1.23 (1.05, 1.44)	0.0095	16.19 (3.33, 29.05)	0.0136	
>= 30	49/ 53 (92.5)	92.8	32/ 38 (84.2)	84.0	1.10 (0.94, 1.29)	0.2458	8.71 (-7.65, 25.08)	0.2968	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Serious Adverse Event
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	15 (11.8)	24 (19.2)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.62 (0.34, 1.12)	
p-value	0.1101	
Odds Ratio (95% CI)	0.56 (0.28, 1.13)	
p-value	0.1079	
Risk Difference (95% CI)	-7.39 (-16.29, 1.51)	
p-value	0.1036	
CMH approach		
Response rate	11.9	19.2
Difference in response rates (95% CI)	-7.23 (-17.09, 2.63)	
p-value	0.1506	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Serious Adverse Event - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.7957
< 10 points	4/ 39 (10.3)	11.0	7/ 37 (18.9)	18.9	0.54 (0.17, 1.70)	0.2938	-7.83 (-26.53, 10.86)	0.4115	
>= 10 points	11/ 88 (12.5)	12.5	17/ 88 (19.3)	19.3	0.65 (0.32, 1.30)	0.2219	-6.80 (-18.51, 4.90)	0.2548	
OCS dose at baseline									0.8693
<10 mg/day	7/ 57 (12.3)	12.1	11/ 52 (21.2)	21.3	0.58 (0.24, 1.39)	0.2205	-9.24 (-24.49, 6.00)	0.2346	
>=10 mg/day	8/ 70 (11.4)	11.4	13/ 73 (17.8)	18.5	0.64 (0.28, 1.45)	0.2876	-7.04 (-20.11, 6.03)	0.2912	
Result of type I IFN gene signature test									0.2504
LOW	5/ 22 (22.7)	22.7	5/ 24 (20.8)	20.8	1.09 (0.36, 3.27)	0.8764	1.89 (-23.48, 27.26)	0.8837	
HIGH	10/105 (9.5)	9.5	19/101 (18.8)	18.8	0.51 (0.25, 1.04)	0.0622	-9.27 (-19.92, 1.38)	0.0879	
Age (years)									0.2823
<= 65	13/122 (10.7)	10.8	24/123 (19.5)	19.5	0.55 (0.29, 1.02)	0.0585	-8.77 (-18.73, 1.20)	0.0846	
> 65	2/ 5 (40.0)	40.0	0/ 2 (0.0)	0.0	2.50 (0.17, 37.26)	0.5062	40.00 (-38.52, 118.52)	0.3181	
Sex									0.2887
male	0/ 12 (0.0)	0.0	2/ 8 (25.0)	25.0	0.14 (0.01, 2.55)	0.1837	-25.00 (-62.65, 12.65)	0.1931	
female	15/115 (13.0)	13.3	22/117 (18.8)	18.6	0.69 (0.38, 1.27)	0.2351	-5.33 (-15.73, 5.08)	0.3157	
Race									0.4151
White	11/ 85 (12.9)	13.1	16/ 96 (16.7)	16.8	0.78 (0.38, 1.58)	0.4849	-3.75 (-15.64, 8.14)	0.5365	
Black or African American	2/ 22 (9.1)	9.1	5/ 14 (35.7)	35.7	0.25 (0.06, 1.14)	0.0732	-26.62 (-56.28, 3.03)	0.0785	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	2/ 13 (15.4)	15.4	3/ 11 (27.3)	27.3	0.56 (0.11, 2.79)	0.4828	-11.89 (-48.05, 24.27)	0.5194	
Ethnicity									0.9368
Hispanic/Latino	4/ 23 (17.4)	17.4	7/ 24 (29.2)	29.2	0.60 (0.20, 1.77)	0.3513	-11.78 (-37.03, 13.48)	0.3608	
Non-hispanic/Latino	11/104 (10.6)	11.0	17/101 (16.8)	17.2	0.63 (0.31, 1.27)	0.1979	-6.23 (-17.17, 4.71)	0.2645	
Geographic region									0.7917
EU	4/ 47 (8.5)	8.5	9/ 56 (16.1)	16.1	0.53 (0.17, 1.61)	0.2626	-7.56 (-21.26, 6.13)	0.2792	
non-EU	11/ 80 (13.8)	13.5	15/ 69 (21.7)	21.9	0.63 (0.31, 1.28)	0.2049	-8.41 (-21.71, 4.90)	0.2157	
Onset of disease									0.2680
Paediatric	1/ 8 (12.5)	12.5	4/ 7 (57.1)	57.1	0.22 (0.03, 1.53)	0.1251	-44.64 (-92.19, 2.91)	0.0657	
Adult	14/119 (11.8)	11.8	20/118 (16.9)	16.9	0.69 (0.37, 1.31)	0.2588	-5.13 (-15.13, 4.87)	0.3146	
ADA result									0.2827
Negative	14/111 (12.6)	12.7	20/112 (17.9)	18.0	0.71 (0.38, 1.33)	0.2798	-5.27 (-15.83, 5.28)	0.3277	
Positive (At any time)	1/ 15 (6.7)	6.7	4/ 13 (30.8)	30.8	0.22 (0.03, 1.70)	0.1459	-24.10 (-55.97, 7.76)	0.1382	
BMI (kg/m2) at enrolment									0.9841
< 30	9/ 74 (12.2)	12.2	17/ 87 (19.5)	19.7	0.62 (0.30, 1.31)	0.2130	-7.57 (-19.93, 4.78)	0.2298	
>= 30	6/ 53 (11.3)	11.0	7/ 38 (18.4)	18.7	0.61 (0.22, 1.68)	0.3437	-7.68 (-24.77, 9.41)	0.3783	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Severe Adverse Event
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	14 (11.0)	16 (12.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.86 (0.44, 1.69)	
p-value	0.6637	
Odds Ratio (95% CI)	0.84 (0.39, 1.81)	
p-value	0.6636	
Risk Difference (95% CI)	-1.78 (-9.77, 6.22)	
p-value	0.6633	
CMH approach		
Response rate	11.2	12.7
Difference in response rates (95% CI)	-1.50 (-10.81, 7.81)	
p-value	0.7528	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Severe Adverse Event - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.7591
< 10 points	3/ 39 (7.7)	7.5	4/ 37 (10.8)	11.0	0.71 (0.17, 2.97)	0.6404	-3.47 (-21.23, 14.29)	0.7021	
>= 10 points	11/ 88 (12.5)	12.7	12/ 88 (13.6)	13.5	0.92 (0.43, 1.97)	0.8231	-0.83 (-12.03, 10.37)	0.8847	
OCS dose at baseline									0.7686
<10 mg/day	5/ 57 (8.8)	8.7	6/ 52 (11.5)	11.7	0.76 (0.25, 2.34)	0.6332	-2.94 (-16.88, 11.01)	0.6797	
>=10 mg/day	9/ 70 (12.9)	12.9	10/ 73 (13.7)	14.1	0.94 (0.41, 2.17)	0.8822	-1.25 (-14.17, 11.67)	0.8498	
Result of type I IFN gene signature test									0.8322
LOW	2/ 22 (9.1)	9.1	3/ 24 (12.5)	12.5	0.73 (0.13, 3.95)	0.7124	-3.41 (-24.91, 18.09)	0.7559	
HIGH	12/105 (11.4)	11.7	13/101 (12.9)	12.8	0.89 (0.43, 1.85)	0.7514	-1.07 (-11.40, 9.26)	0.8394	
Age (years)									NE
<= 65	14/122 (11.5)	11.7	16/123 (13.0)	13.0	0.88 (0.45, 1.73)	0.7147	-1.33 (-10.88, 8.22)	0.7847	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE		0.00 (-74.81, 74.81)	1.0000	
Sex									0.8400
male	1/ 12 (8.3)	8.3	1/ 8 (12.5)	12.5	0.67 (0.05, 9.19)	0.7620	-4.17 (-41.42, 33.09)	0.8265	
female	13/115 (11.3)	11.5	15/117 (12.8)	12.6	0.88 (0.44, 1.77)	0.7233	-1.03 (-10.84, 8.78)	0.8365	
Race									0.1279
White	10/ 85 (11.8)	12.2	8/ 96 (8.3)	8.0	1.41 (0.58, 3.41)	0.4438	4.21 (-6.87, 15.30)	0.4561	
Black or African American	3/ 22 (13.6)	13.6	6/ 14 (42.9)	42.9	0.32 (0.09, 1.07)	0.0643	-29.22 (-60.02, 1.58)	0.0630	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	1/ 13 (7.7)	7.7	2/ 11 (18.2)	18.2	0.42 (0.04, 4.06)	0.4561	-10.49 (-43.84, 22.86)	0.5376	
Ethnicity									0.8733
Hispanic/Latino	3/ 23 (13.0)	13.0	4/ 24 (16.7)	16.7	0.78 (0.20, 3.12)	0.7284	-3.62 (-26.46, 19.21)	0.7558	
Non-hispanic/Latino	11/104 (10.6)	11.3	12/101 (11.9)	12.2	0.89 (0.41, 1.92)	0.7675	-0.84 (-11.44, 9.76)	0.8767	
Geographic region									0.2946
EU	4/ 47 (8.5)	8.5	3/ 56 (5.4)	5.4	1.59 (0.37, 6.74)	0.5303	3.15 (-8.56, 14.87)	0.5978	
non-EU	10/ 80 (12.5)	12.6	13/ 69 (18.8)	18.9	0.66 (0.31, 1.42)	0.2893	-6.38 (-19.38, 6.62)	0.3364	
Onset of disease									0.2644
Paediatric	1/ 8 (12.5)	12.5	3/ 7 (42.9)	42.9	0.29 (0.04, 2.21)	0.2326	-30.36 (-77.91, 17.19)	0.2108	
Adult	13/119 (10.9)	11.1	13/118 (11.0)	11.0	0.99 (0.48, 2.05)	0.9818	0.06 (-9.41, 9.53)	0.9900	
ADA result									0.1711
Negative	12/111 (10.8)	11.3	11/112 (9.8)	9.8	1.10 (0.51, 2.39)	0.8082	1.46 (-8.31, 11.22)	0.7701	
Positive (At any time)	2/ 15 (13.3)	13.3	5/ 13 (38.5)	38.5	0.35 (0.08, 1.50)	0.1555	-25.13 (-58.91, 8.66)	0.1449	
BMI (kg/m2) at enrolment									0.2546
< 30	8/ 74 (10.8)	10.8	8/ 87 (9.2)	9.2	1.18 (0.46, 2.98)	0.7330	1.56 (-9.64, 12.77)	0.7846	
>= 30	6/ 53 (11.3)	11.4	8/ 38 (21.1)	21.2	0.54 (0.20, 1.42)	0.2114	-9.83 (-27.50, 7.85)	0.2758	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Non-Severe Adverse Event
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	112 (88.2)	92 (73.6)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.20 (1.06, 1.35)	
p-value	0.0039	
Odds Ratio (95% CI)	2.68 (1.37, 5.23)	
p-value	0.0039	
Risk Difference (95% CI)	14.59 (5.04, 24.14)	
p-value	0.0028	
CMH approach		
Response rate	88.4	74.0
Difference in response rates (95% CI)	14.37 (4.17, 24.57)	
p-value	0.0058	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Non-Severe Adverse Event - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.1773
< 10 points	35/ 39 (89.7)	90.7	31/ 37 (83.8)	84.8	1.07 (0.90, 1.28)	0.4469	5.97 (-12.05, 23.98)	0.5163	
>= 10 points	77/ 88 (87.5)	87.4	61/ 88 (69.3)	69.4	1.26 (1.08, 1.48)	0.0043	17.97 (5.41, 30.54)	0.0051	
OCS dose at baseline									0.7997
<10 mg/day	54/ 57 (94.7)	94.7	42/ 52 (80.8)	80.7	1.17 (1.01, 1.36)	0.0323	14.00 (-0.61, 28.60)	0.0603	
>=10 mg/day	58/ 70 (82.9)	83.2	50/ 73 (68.5)	69.3	1.21 (1.00, 1.46)	0.0478	13.93 (-0.47, 28.32)	0.0579	
Result of type I IFN gene signature test									0.1911
LOW	21/ 22 (95.5)	95.5	16/ 24 (66.7)	66.7	1.43 (1.06, 1.93)	0.0179	28.79 (5.43, 52.15)	0.0157	
HIGH	91/105 (86.7)	86.8	76/101 (75.2)	75.6	1.15 (1.01, 1.32)	0.0398	11.14 (-0.19, 22.48)	0.0539	
Age (years)									0.0752
<= 65	108/122 (88.5)	88.8	90/123 (73.2)	73.6	1.21 (1.07, 1.37)	0.0027	15.16 (4.83, 25.49)	0.0040	
> 65	4/ 5 (80.0)	80.0	2/ 2 (100.0)	100.0	0.80 (0.52, 1.24)	0.3183	-20.00 (-97.30, 57.30)	0.6121	
Sex									0.7189
male	10/ 12 (83.3)	83.3	5/ 8 (62.5)	62.5	1.33 (0.74, 2.41)	0.3420	20.83 (-21.21, 62.87)	0.3314	
female	102/115 (88.7)	88.9	87/117 (74.4)	74.8	1.19 (1.05, 1.35)	0.0056	14.16 (3.58, 24.74)	0.0087	
Race									0.4044
White	75/ 85 (88.2)	87.5	68/ 96 (70.8)	71.7	1.25 (1.07, 1.45)	0.0041	15.80 (3.32, 28.27)	0.0131	
Black or African American	19/ 22 (86.4)	86.4	12/ 14 (85.7)	85.7	1.01 (0.77, 1.32)	0.9564	0.65 (-26.65, 27.95)	0.9628	
Asian	7/ 7 (100.0)	100.0	3/ 3 (100.0)	100.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		1/ 1 (100.0)		NE		NE		
Other	11/ 13 (84.6)	84.6	8/ 11 (72.7)	72.7	1.16 (0.76, 1.79)	0.4899	11.89 (-24.27, 48.05)	0.5194	
Ethnicity									0.2216
Hispanic/Latino	20/ 23 (87.0)	87.0	20/ 24 (83.3)	83.3	1.04 (0.82, 1.33)	0.7269	3.62 (-19.21, 26.46)	0.7558	
Non-hispanic/Latino	92/104 (88.5)	88.6	72/101 (71.3)	72.1	1.24 (1.08, 1.43)	0.0029	16.48 (4.90, 28.05)	0.0053	
Geographic region									0.0257
EU	38/ 47 (80.9)	80.9	31/ 56 (55.4)	55.4	1.46 (1.11, 1.92)	0.0066	25.49 (7.94, 43.05)	0.0044	
non-EU	74/ 80 (92.5)	92.4	61/ 69 (88.4)	88.1	1.05 (0.94, 1.16)	0.4017	4.34 (-7.11, 15.78)	0.4575	
Onset of disease									0.5017
Paediatric	8/ 8 (100.0)	100.0	5/ 7 (71.4)	71.4	1.40 (0.88, 2.24)	0.1593	28.57 (-15.44, 72.58)	0.2032	
Adult	104/119 (87.4)	87.4	87/118 (73.7)	74.1	1.19 (1.04, 1.35)	0.0089	13.33 (2.71, 23.95)	0.0139	
ADA result									0.8583
Negative	99/111 (89.2)	89.3	83/112 (74.1)	74.6	1.20 (1.06, 1.37)	0.0043	14.70 (3.85, 25.56)	0.0079	
Positive (At any time)	13/ 15 (86.7)	86.7	9/ 13 (69.2)	69.2	1.25 (0.83, 1.89)	0.2867	17.44 (-15.74, 50.61)	0.3029	
BMI (kg/m2) at enrolment									0.3218
< 30	63/ 74 (85.1)	85.5	60/ 87 (69.0)	69.5	1.23 (1.04, 1.46)	0.0152	15.95 (2.71, 29.18)	0.0182	
>= 30	49/ 53 (92.5)	92.8	32/ 38 (84.2)	84.0	1.10 (0.94, 1.29)	0.2458	8.71 (-7.65, 25.08)	0.2968	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event leading to discontinuation of study drug
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	8 (6.3)	6 (4.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.31 (0.47, 3.67)	
p-value	0.6048	
Odds Ratio (95% CI)	1.33 (0.45, 3.96)	
p-value	0.6045	
Risk Difference (95% CI)	1.50 (-4.15, 7.15)	
p-value	0.6029	
CMH approach		
Response rate	6.2	4.7
Difference in response rates (95% CI)	1.49 (-6.34, 9.32)	
p-value	0.7090	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event leading to discontinuation of study drug - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.2219
< 10 points	4/ 39 (10.3)	10.4	1/ 37 (2.7)	2.8	3.79 (0.44, 32.40)	0.2229	7.67 (-9.15, 24.48)	0.3714	
>= 10 points	4/ 88 (4.5)	4.5	5/ 88 (5.7)	5.6	0.80 (0.22, 2.88)	0.7328	-1.04 (-10.04, 7.96)	0.8205	
OCS dose at baseline									0.9649
<10 mg/day	3/ 57 (5.3)	5.2	2/ 52 (3.8)	3.8	1.37 (0.24, 7.87)	0.7253	1.44 (-11.00, 13.87)	0.8207	
>=10 mg/day	5/ 70 (7.1)	7.1	4/ 73 (5.5)	5.5	1.30 (0.36, 4.66)	0.6832	1.59 (-9.09, 12.27)	0.7702	
Result of type I IFN gene signature test									0.2857
LOW	2/ 22 (9.1)	9.1	0/ 24 (0.0)	0.0	5.43 (0.28, 107.33)	0.2660	9.09 (-9.17, 27.35)	0.3292	
HIGH	6/105 (5.7)	5.6	6/101 (5.9)	5.8	0.96 (0.32, 2.88)	0.9447	-0.21 (-8.88, 8.46)	0.9623	
Age (years)									0.8768
<= 65	7/122 (5.7)	5.6	6/123 (4.9)	4.8	1.18 (0.41, 3.40)	0.7644	0.72 (-7.21, 8.66)	0.8585	
> 65	1/ 5 (20.0)	20.0	0/ 2 (0.0)	0.0	1.50 (0.08, 26.86)	0.7830	20.00 (-57.30, 97.30)	0.6121	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE		0.00 (-31.89, 31.89)	1.0000	
female	8/115 (7.0)	6.9	6/117 (5.1)	5.0	1.36 (0.49, 3.79)	0.5605	1.84 (-6.58, 10.27)	0.6680	
Race									0.6956
White	5/ 85 (5.9)	6.0	3/ 96 (3.1)	3.3	1.88 (0.46, 7.64)	0.3763	2.68 (-7.05, 12.42)	0.5893	
Black or African American	1/ 22 (4.5)	4.5	1/ 14 (7.1)	7.1	0.64 (0.04, 9.37)	0.7419	-2.60 (-26.25, 21.05)	0.8296	
Asian	1/ 7 (14.3)	14.3	0/ 3 (0.0)	0.0	1.50 (0.08, 29.15)	0.7888	14.29 (-46.56, 75.13)	0.6454	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	1/ 13 (7.7)	7.7	2/ 11 (18.2)	18.2	0.42 (0.04, 4.06)	0.4561	-10.49 (-43.84, 22.86)	0.5376	
Ethnicity									0.0549
Hispanic/Latino	1/ 23 (4.3)	4.3	4/ 24 (16.7)	16.7	0.26 (0.03, 2.16)	0.2131	-12.32 (-33.16, 8.52)	0.2467	
Non-hispanic/Latino	7/104 (6.7)	6.9	2/101 (2.0)	1.8	3.40 (0.72, 15.97)	0.1212	5.03 (-3.82, 13.88)	0.2655	
Geographic region									0.2709
EU	3/ 47 (6.4)	6.4	1/ 56 (1.8)	1.8	3.57 (0.38, 33.23)	0.2628	4.60 (-5.64, 14.84)	0.3789	
non-EU	5/ 80 (6.3)	6.4	5/ 69 (7.2)	7.3	0.86 (0.26, 2.86)	0.8086	-0.96 (-11.75, 9.82)	0.8611	
Onset of disease									0.1288
Paediatric	0/ 8 (0.0)	0.0	2/ 7 (28.6)	28.6	0.18 (0.01, 3.18)	0.2403	-28.57 (-72.58, 15.44)	0.2032	
Adult	8/119 (6.7)	6.6	4/118 (3.4)	3.3	1.98 (0.61, 6.41)	0.2526	3.34 (-4.68, 11.36)	0.4148	
ADA result									0.6187
Negative	6/111 (5.4)	5.2	4/112 (3.6)	3.5	1.51 (0.44, 5.22)	0.5116	1.68 (-6.55, 9.92)	0.6887	
Positive (At any time)	2/ 15 (13.3)	13.3	2/ 13 (15.4)	15.4	0.87 (0.14, 5.32)	0.8771	-2.05 (-32.99, 28.89)	0.8966	
BMI (kg/m2) at enrolment									0.9903
< 30	6/ 74 (8.1)	8.0	5/ 87 (5.7)	6.0	1.41 (0.45, 4.44)	0.5560	2.10 (-8.09, 12.28)	0.6867	
>= 30	2/ 53 (3.8)	3.9	1/ 38 (2.6)	2.7	1.43 (0.13, 15.25)	0.7651	1.17 (-12.96, 15.29)	0.8716	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Serious Adverse Event leading to discontinuation of study drug
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	4 (3.1)	4 (3.2)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.98 (0.25, 3.85)	
p-value	0.9818	
Odds Ratio (95% CI)	0.98 (0.24, 4.02)	
p-value	0.9818	
Risk Difference (95% CI)	-0.05 (-4.38, 4.28)	
p-value	0.9818	
CMH approach		
Response rate	3.0	3.1
Difference in response rates (95% CI)	-0.11 (-7.23, 7.02)	
p-value	0.9768	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Serious Adverse Event leading to discontinuation of study drug - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.0778
< 10 points	3/ 39 (7.7)	7.8	0/ 37 (0.0)	0.0	6.65 (0.36, 124.51)	0.2050	7.84 (-7.98, 23.66)	0.3314	
>= 10 points	1/ 88 (1.1)	1.1	4/ 88 (4.5)	4.4	0.25 (0.03, 2.19)	0.2108	-3.31 (-11.42, 4.80)	0.4238	
OCS dose at baseline									0.4823
<10 mg/day	1/ 57 (1.8)	1.8	0/ 52 (0.0)	0.0	2.74 (0.11, 65.85)	0.5341	1.77 (-9.32, 12.86)	0.7547	
>=10 mg/day	3/ 70 (4.3)	4.1	4/ 73 (5.5)	5.5	0.78 (0.18, 3.37)	0.7416	-1.32 (-11.37, 8.72)	0.7961	
Result of type I IFN gene signature test									0.3951
LOW	1/ 22 (4.5)	4.5	0/ 24 (0.0)	0.0	3.26 (0.14, 76.10)	0.4621	4.55 (-12.32, 21.41)	0.5973	
HIGH	3/105 (2.9)	2.6	4/101 (4.0)	3.8	0.72 (0.17, 3.14)	0.6637	-1.15 (-9.00, 6.71)	0.7750	
Age (years)									0.6787
<= 65	3/122 (2.5)	2.2	4/123 (3.3)	3.2	0.76 (0.17, 3.31)	0.7105	-1.00 (-8.18, 6.19)	0.7854	
> 65	1/ 5 (20.0)	20.0	0/ 2 (0.0)	0.0	1.50 (0.08, 26.86)	0.7830	20.00 (-57.30, 97.30)	0.6121	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE		0.00 (-31.89, 31.89)	1.0000	
female	4/115 (3.5)	3.3	4/117 (3.4)	3.3	1.02 (0.26, 3.97)	0.9802	0.04 (-7.61, 7.69)	0.9914	
Race									0.2793
White	3/ 85 (3.5)	3.6	1/ 96 (1.0)	0.9	3.39 (0.36, 31.96)	0.2865	2.63 (-6.39, 11.64)	0.5683	
Black or African American	0/ 22 (0.0)	0.0	1/ 14 (7.1)	7.1	0.22 (0.01, 4.99)	0.3399	-7.14 (-29.62, 15.33)	0.5333	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	1/ 13 (7.7)	7.7	2/ 11 (18.2)	18.2	0.42 (0.04, 4.06)	0.4561	-10.49 (-43.84, 22.86)	0.5376	
Ethnicity									0.4916
Hispanic/Latino	1/ 23 (4.3)	4.3	2/ 24 (8.3)	8.3	0.52 (0.05, 5.37)	0.5844	-3.99 (-22.98, 15.01)	0.6810	
Non-hispanic/Latino	3/104 (2.9)	2.7	2/101 (2.0)	1.8	1.46 (0.25, 8.54)	0.6767	0.84 (-7.36, 9.04)	0.8415	
Geographic region									0.8412
EU	1/ 47 (2.1)	2.1	1/ 56 (1.8)	1.8	1.19 (0.08, 18.54)	0.9004	0.34 (-8.48, 9.16)	0.9394	
non-EU	3/ 80 (3.8)	3.8	3/ 69 (4.3)	4.5	0.86 (0.18, 4.14)	0.8533	-0.69 (-10.57, 9.20)	0.8918	
Onset of disease									0.3876
Paediatric	0/ 8 (0.0)	0.0	1/ 7 (14.3)	14.3	0.30 (0.01, 6.29)	0.4353	-14.29 (-56.18, 27.61)	0.5040	
Adult	4/119 (3.4)	3.2	3/118 (2.5)	2.4	1.32 (0.30, 5.78)	0.7106	0.78 (-6.60, 8.16)	0.8367	
ADA result									0.1579
Negative	4/111 (3.6)	3.3	2/112 (1.8)	1.6	2.02 (0.38, 10.79)	0.4119	1.64 (-6.02, 9.29)	0.6756	
Positive (At any time)	0/ 15 (0.0)	0.0	2/ 13 (15.4)	15.4	0.17 (0.01, 3.34)	0.2469	-15.38 (-43.19, 12.42)	0.2781	
BMI (kg/m2) at enrolment									0.7589
< 30	3/ 74 (4.1)	3.7	3/ 87 (3.4)	3.5	1.18 (0.24, 5.65)	0.8399	0.27 (-8.70, 9.25)	0.9522	
>= 30	1/ 53 (1.9)	1.9	1/ 38 (2.6)	2.7	0.72 (0.05, 11.11)	0.8119	-0.86 (-14.65, 12.92)	0.9022	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with Adverse Event leading to death
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	1 (0.8)	1 (0.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.98 (0.06, 15.56)	
p-value	0.9910	
Odds Ratio (95% CI)	0.98 (0.06, 15.91)	
p-value	0.9910	
Risk Difference (95% CI)	-0.01 (-2.20, 2.18)	
p-value	0.9910	
CMH approach		
Response rate	0.7	0.8
Difference in response rates (95% CI)	-0.08 (-6.49, 6.33)	
p-value	0.9804	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with Adverse Event leading to death - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.3494
< 10 points	1/ 39 (2.6)	2.3	0/ 37 (0.0)	0.0	2.85 (0.12, 67.83)	0.5172	2.32 (-12.76, 17.39)	0.7633	
>= 10 points	0/ 88 (0.0)	0.0	1/ 88 (1.1)	1.1	0.33 (0.01, 8.07)	0.4993	-1.10 (-8.30, 6.09)	0.7643	
OCS dose at baseline									NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE		0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	1/ 70 (1.4)	1.2	1/ 73 (1.4)	1.4	1.04 (0.07, 16.35)	0.9762	-0.14 (-8.92, 8.64)	0.9746	
Result of type I IFN gene signature test									NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-15.17, 15.17)	1.0000	
HIGH	1/105 (1.0)	0.8	1/101 (1.0)	0.9	0.96 (0.06, 15.17)	0.9780	-0.10 (-7.17, 6.97)	0.9782	
Age (years)									NE
<= 65	1/122 (0.8)	0.7	1/123 (0.8)	0.8	1.01 (0.06, 15.94)	0.9954	-0.12 (-6.69, 6.46)	0.9727	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE		0.00 (-74.81, 74.81)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE		0.00 (-31.89, 31.89)	1.0000	
female	1/115 (0.9)	0.8	1/117 (0.9)	0.8	1.02 (0.06, 16.07)	0.9902	-0.04 (-6.94, 6.86)	0.9900	
Race									0.2725
White	0/ 85 (0.0)	0.0	0/ 96 (0.0)	0.0	NE		0.00 (-8.35, 8.35)	1.0000	
Black or African American	0/ 22 (0.0)	0.0	1/ 14 (7.1)	7.1	0.22 (0.01, 4.99)	0.3399	-7.14 (-29.62, 15.33)	0.5333	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	1/ 13 (7.7)	7.7	0/ 11 (0.0)	0.0	2.57 (0.12, 57.44)	0.5512	7.69 (-21.17, 36.55)	0.6014	
Ethnicity									0.3216
Hispanic/Latino	1/ 23 (4.3)	4.3	0/ 24 (0.0)	0.0	3.13 (0.13, 73.01)	0.4785	4.35 (-12.12, 20.81)	0.6048	
Non-hispanic/Latino	0/104 (0.0)	0.0	1/101 (1.0)	0.9	0.32 (0.01, 7.86)	0.4883	-0.92 (-8.59, 6.74)	0.8132	
Geographic region									NE
EU	0/ 47 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-7.27, 7.27)	1.0000	
non-EU	1/ 80 (1.3)	1.4	1/ 69 (1.4)	1.5	0.86 (0.05, 13.53)	0.9161	-0.14 (-8.93, 8.65)	0.9753	
Onset of disease									NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE		0.00 (-38.51, 38.51)	1.0000	
Adult	1/119 (0.8)	0.8	1/118 (0.8)	0.8	0.99 (0.06, 15.67)	0.9952	-0.05 (-6.82, 6.71)	0.9874	
ADA result									NE
Negative	1/111 (0.9)	0.7	1/112 (0.9)	0.8	1.01 (0.06, 15.93)	0.9949	-0.09 (-7.24, 7.07)	0.9809	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment									0.2424
< 30	1/ 74 (1.4)	1.2	0/ 87 (0.0)	0.0	3.52 (0.15, 85.13)	0.4388	1.18 (-6.50, 8.86)	0.7628	
>= 30	0/ 53 (0.0)	0.0	1/ 38 (2.6)	2.7	0.24 (0.01, 5.75)	0.3792	-2.72 (-16.24, 10.81)	0.6939	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Anaphylaxis
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.17, 6.17)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Anaphylaxis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Anifrolumab 300mg (N=127) Response rate	Placebo (N=125) n/ N (%)	Placebo (N=125) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Analysis Anifrolumab 300mg vs. Placebo Difference in response rates (95% CI)	Analysis Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-14.65, 14.65)	1.0000	
>= 10 points	0/ 88 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	0/ 70 (0.0)	0.0	0/ 73 (0.0)	0.0	NE	0.00 (-8.22, 8.22)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-15.17, 15.17)	1.0000	
HIGH	0/105 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-6.74, 6.74)	1.0000	
Age (years)								NE
<= 65	0/122 (0.0)	0.0	0/123 (0.0)	0.0	NE	0.00 (-6.34, 6.34)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE	0.00 (-74.81, 74.81)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE	0.00 (-31.89, 31.89)	1.0000	
female	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-6.65, 6.65)	1.0000	
Race								NE
White	0/ 85 (0.0)	0.0	0/ 96 (0.0)	0.0	NE	0.00 (-8.35, 8.35)	1.0000	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE	0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-26.65, 26.65)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	0/104 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-7.49, 7.49)	1.0000	
Geographic region								NE
EU	0/ 47 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-7.27, 7.27)	1.0000	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-8.12, 8.12)	1.0000	
Onset of disease								NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE	0.00 (-38.51, 38.51)	1.0000	
Adult	0/119 (0.0)	0.0	0/118 (0.0)	0.0	NE	0.00 (-6.51, 6.51)	1.0000	
ADA result								NE
Negative	0/111 (0.0)	0.0	0/112 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 74 (0.0)	0.0	0/ 87 (0.0)	0.0	NE	0.00 (-7.46, 7.46)	1.0000	
>= 30	0/ 53 (0.0)	0.0	0/ 38 (0.0)	0.0	NE	0.00 (-12.88, 12.88)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Anaphylaxis
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.17, 6.17)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Anaphylaxis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-14.65, 14.65)	1.0000	
>= 10 points	0/ 88 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	0/ 70 (0.0)	0.0	0/ 73 (0.0)	0.0	NE	0.00 (-8.22, 8.22)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-15.17, 15.17)	1.0000	
HIGH	0/105 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-6.74, 6.74)	1.0000	
Age (years)								NE
<= 65	0/122 (0.0)	0.0	0/123 (0.0)	0.0	NE	0.00 (-6.34, 6.34)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE	0.00 (-74.81, 74.81)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE	0.00 (-31.89, 31.89)	1.0000	
female	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-6.65, 6.65)	1.0000	
Race								NE
White	0/ 85 (0.0)	0.0	0/ 96 (0.0)	0.0	NE	0.00 (-8.35, 8.35)	1.0000	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE	0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-26.65, 26.65)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	0/104 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-7.49, 7.49)	1.0000	
Geographic region								NE
EU	0/ 47 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-7.27, 7.27)	1.0000	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-8.12, 8.12)	1.0000	
Onset of disease								NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE	0.00 (-38.51, 38.51)	1.0000	
Adult	0/119 (0.0)	0.0	0/118 (0.0)	0.0	NE	0.00 (-6.51, 6.51)	1.0000	
ADA result								NE
Negative	0/111 (0.0)	0.0	0/112 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 74 (0.0)	0.0	0/ 87 (0.0)	0.0	NE	0.00 (-7.46, 7.46)	1.0000	
>= 30	0/ 53 (0.0)	0.0	0/ 38 (0.0)	0.0	NE	0.00 (-12.88, 12.88)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Anaphylaxis
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.17, 6.17)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Anaphylaxis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-14.65, 14.65)	1.0000	
>= 10 points	0/ 88 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	0/ 70 (0.0)	0.0	0/ 73 (0.0)	0.0	NE	0.00 (-8.22, 8.22)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-15.17, 15.17)	1.0000	
HIGH	0/105 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-6.74, 6.74)	1.0000	
Age (years)								NE
<= 65	0/122 (0.0)	0.0	0/123 (0.0)	0.0	NE	0.00 (-6.34, 6.34)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE	0.00 (-74.81, 74.81)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE	0.00 (-31.89, 31.89)	1.0000	
female	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-6.65, 6.65)	1.0000	
Race								NE
White	0/ 85 (0.0)	0.0	0/ 96 (0.0)	0.0	NE	0.00 (-8.35, 8.35)	1.0000	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE	0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-26.65, 26.65)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	0/104 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-7.49, 7.49)	1.0000	
Geographic region								NE
EU	0/ 47 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-7.27, 7.27)	1.0000	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-8.12, 8.12)	1.0000	
Onset of disease								NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE	0.00 (-38.51, 38.51)	1.0000	
Adult	0/119 (0.0)	0.0	0/118 (0.0)	0.0	NE	0.00 (-6.51, 6.51)	1.0000	
ADA result								NE
Negative	0/111 (0.0)	0.0	0/112 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 74 (0.0)	0.0	0/ 87 (0.0)	0.0	NE	0.00 (-7.46, 7.46)	1.0000	
>= 30	0/ 53 (0.0)	0.0	0/ 38 (0.0)	0.0	NE	0.00 (-12.88, 12.88)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Anaphylaxis
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.17, 6.17)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Anaphylaxis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-14.65, 14.65)	1.0000	
>= 10 points	0/ 88 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	0/ 70 (0.0)	0.0	0/ 73 (0.0)	0.0	NE	0.00 (-8.22, 8.22)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-15.17, 15.17)	1.0000	
HIGH	0/105 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-6.74, 6.74)	1.0000	
Age (years)								NE
<= 65	0/122 (0.0)	0.0	0/123 (0.0)	0.0	NE	0.00 (-6.34, 6.34)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE	0.00 (-74.81, 74.81)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE	0.00 (-31.89, 31.89)	1.0000	
female	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-6.65, 6.65)	1.0000	
Race								NE
White	0/ 85 (0.0)	0.0	0/ 96 (0.0)	0.0	NE	0.00 (-8.35, 8.35)	1.0000	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE	0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-26.65, 26.65)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	0/104 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-7.49, 7.49)	1.0000	
Geographic region								NE
EU	0/ 47 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-7.27, 7.27)	1.0000	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-8.12, 8.12)	1.0000	
Onset of disease								NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE	0.00 (-38.51, 38.51)	1.0000	
Adult	0/119 (0.0)	0.0	0/118 (0.0)	0.0	NE	0.00 (-6.51, 6.51)	1.0000	
ADA result								NE
Negative	0/111 (0.0)	0.0	0/112 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 74 (0.0)	0.0	0/ 87 (0.0)	0.0	NE	0.00 (-7.46, 7.46)	1.0000	
>= 30	0/ 53 (0.0)	0.0	0/ 38 (0.0)	0.0	NE	0.00 (-12.88, 12.88)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	5 (3.9)	2 (1.6)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	2.46 (0.49, 12.45)	
p-value	0.2763	
Odds Ratio (95% CI)	2.52 (0.48, 13.24)	
p-value	0.2747	
Risk Difference (95% CI)	2.34 (-1.70, 6.37)	
p-value	0.2563	
CMH approach		
Response rate	4.0	1.6
Difference in response rates (95% CI)	2.42 (-4.69, 9.52)	
p-value	0.5046	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.4193
< 10 points	1/ 39 (2.6)	2.6	1/ 37 (2.7)	2.8	0.95 (0.06, 14.62)	0.9699	-0.17 (-15.89, 15.54)	0.9828	
>= 10 points	4/ 88 (4.5)	4.5	1/ 88 (1.1)	1.1	4.00 (0.46, 35.08)	0.2108	3.44 (-4.71, 11.60)	0.4079	
OCS dose at baseline									0.8703
<10 mg/day	3/ 57 (5.3)	5.2	1/ 52 (1.9)	1.9	2.74 (0.29, 25.50)	0.3766	3.35 (-8.68, 15.37)	0.5853	
>=10 mg/day	2/ 70 (2.9)	2.9	1/ 73 (1.4)	1.4	2.09 (0.19, 22.49)	0.5446	1.55 (-7.76, 10.86)	0.7444	
Result of type I IFN gene signature test									0.7719
LOW	1/ 22 (4.5)	4.5	0/ 24 (0.0)	0.0	3.26 (0.14, 76.10)	0.4621	4.55 (-12.32, 21.41)	0.5973	
HIGH	4/105 (3.8)	3.9	2/101 (2.0)	1.9	1.92 (0.36, 10.27)	0.4440	1.94 (-5.89, 9.78)	0.6269	
Age (years)									NE
<= 65	5/122 (4.1)	4.2	2/123 (1.6)	1.6	2.52 (0.50, 12.74)	0.2635	2.57 (-4.75, 9.88)	0.4916	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE		0.00 (-74.81, 74.81)	1.0000	
Sex									0.6379
male	2/ 12 (16.7)	16.7	0/ 8 (0.0)	0.0	3.46 (0.19, 63.86)	0.4038	16.67 (-18.93, 52.26)	0.3588	
female	3/115 (2.6)	2.7	2/117 (1.7)	1.7	1.53 (0.26, 8.96)	0.6398	0.97 (-6.40, 8.34)	0.7964	
Race									0.9426
White	4/ 85 (4.7)	4.5	2/ 96 (2.1)	2.2	2.26 (0.42, 12.02)	0.3395	2.38 (-7.00, 11.77)	0.6184	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE		0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	1/ 13 (7.7)	7.7	0/ 11 (0.0)	0.0	2.57 (0.12, 57.44)	0.5512	7.69 (-21.17, 36.55)	0.6014	
Ethnicity									NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	5/104 (4.8)	5.0	2/101 (2.0)	1.9	2.43 (0.48, 12.23)	0.2822	3.10 (-5.51, 11.70)	0.4803	
Geographic region									0.9605
EU	2/ 47 (4.3)	4.3	1/ 56 (1.8)	1.8	2.38 (0.22, 25.46)	0.4725	2.47 (-7.10, 12.04)	0.6132	
non-EU	3/ 80 (3.8)	3.8	1/ 69 (1.4)	1.4	2.59 (0.28, 24.31)	0.4055	2.44 (-6.70, 11.57)	0.6013	
Onset of disease									0.8678
Paediatric	1/ 8 (12.5)	12.5	0/ 7 (0.0)	0.0	2.67 (0.13, 56.63)	0.5293	12.50 (-28.93, 53.93)	0.5543	
Adult	4/119 (3.4)	3.4	2/118 (1.7)	1.7	1.98 (0.37, 10.62)	0.4239	1.66 (-5.68, 9.00)	0.6580	
ADA result									NE
Negative	5/111 (4.5)	4.6	2/112 (1.8)	1.8	2.52 (0.50, 12.73)	0.2626	2.89 (-5.08, 10.85)	0.4775	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment									0.2915
< 30	4/ 74 (5.4)	5.7	1/ 87 (1.1)	1.2	4.70 (0.54, 41.16)	0.1619	4.53 (-4.49, 13.55)	0.3249	
>= 30	1/ 53 (1.9)	2.0	1/ 38 (2.6)	2.5	0.72 (0.05, 11.11)	0.8119	-0.47 (-14.19, 13.26)	0.9467	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.17, 6.17)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-14.65, 14.65)	1.0000	
>= 10 points	0/ 88 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	0/ 70 (0.0)	0.0	0/ 73 (0.0)	0.0	NE	0.00 (-8.22, 8.22)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-15.17, 15.17)	1.0000	
HIGH	0/105 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-6.74, 6.74)	1.0000	
Age (years)								NE
<= 65	0/122 (0.0)	0.0	0/123 (0.0)	0.0	NE	0.00 (-6.34, 6.34)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE	0.00 (-74.81, 74.81)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE	0.00 (-31.89, 31.89)	1.0000	
female	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-6.65, 6.65)	1.0000	
Race								NE
White	0/ 85 (0.0)	0.0	0/ 96 (0.0)	0.0	NE	0.00 (-8.35, 8.35)	1.0000	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE	0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-26.65, 26.65)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	0/104 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-7.49, 7.49)	1.0000	
Geographic region								NE
EU	0/ 47 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-7.27, 7.27)	1.0000	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-8.12, 8.12)	1.0000	
Onset of disease								NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE	0.00 (-38.51, 38.51)	1.0000	
Adult	0/119 (0.0)	0.0	0/118 (0.0)	0.0	NE	0.00 (-6.51, 6.51)	1.0000	
ADA result								NE
Negative	0/111 (0.0)	0.0	0/112 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 74 (0.0)	0.0	0/ 87 (0.0)	0.0	NE	0.00 (-7.46, 7.46)	1.0000	
>= 30	0/ 53 (0.0)	0.0	0/ 38 (0.0)	0.0	NE	0.00 (-12.88, 12.88)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.17, 6.17)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-14.65, 14.65)	1.0000	
>= 10 points	0/ 88 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	0/ 70 (0.0)	0.0	0/ 73 (0.0)	0.0	NE	0.00 (-8.22, 8.22)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-15.17, 15.17)	1.0000	
HIGH	0/105 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-6.74, 6.74)	1.0000	
Age (years)								NE
<= 65	0/122 (0.0)	0.0	0/123 (0.0)	0.0	NE	0.00 (-6.34, 6.34)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE	0.00 (-74.81, 74.81)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE	0.00 (-31.89, 31.89)	1.0000	
female	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-6.65, 6.65)	1.0000	
Race								NE
White	0/ 85 (0.0)	0.0	0/ 96 (0.0)	0.0	NE	0.00 (-8.35, 8.35)	1.0000	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE	0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-26.65, 26.65)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	0/104 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-7.49, 7.49)	1.0000	
Geographic region								NE
EU	0/ 47 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-7.27, 7.27)	1.0000	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-8.12, 8.12)	1.0000	
Onset of disease								NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE	0.00 (-38.51, 38.51)	1.0000	
Adult	0/119 (0.0)	0.0	0/118 (0.0)	0.0	NE	0.00 (-6.51, 6.51)	1.0000	
ADA result								NE
Negative	0/111 (0.0)	0.0	0/112 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 74 (0.0)	0.0	0/ 87 (0.0)	0.0	NE	0.00 (-7.46, 7.46)	1.0000	
>= 30	0/ 53 (0.0)	0.0	0/ 38 (0.0)	0.0	NE	0.00 (-12.88, 12.88)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	5 (3.9)	2 (1.6)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	2.46 (0.49, 12.45)	
p-value	0.2763	
Odds Ratio (95% CI)	2.52 (0.48, 13.24)	
p-value	0.2747	
Risk Difference (95% CI)	2.34 (-1.70, 6.37)	
p-value	0.2563	
CMH approach		
Response rate	4.0	1.6
Difference in response rates (95% CI)	2.42 (-4.69, 9.52)	
p-value	0.5046	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.4193
< 10 points	1/ 39 (2.6)	2.6	1/ 37 (2.7)	2.8	0.95 (0.06, 14.62)	0.9699	-0.17 (-15.89, 15.54)	0.9828	
>= 10 points	4/ 88 (4.5)	4.5	1/ 88 (1.1)	1.1	4.00 (0.46, 35.08)	0.2108	3.44 (-4.71, 11.60)	0.4079	
OCS dose at baseline									0.8703
<10 mg/day	3/ 57 (5.3)	5.2	1/ 52 (1.9)	1.9	2.74 (0.29, 25.50)	0.3766	3.35 (-8.68, 15.37)	0.5853	
>=10 mg/day	2/ 70 (2.9)	2.9	1/ 73 (1.4)	1.4	2.09 (0.19, 22.49)	0.5446	1.55 (-7.76, 10.86)	0.7444	
Result of type I IFN gene signature test									0.7719
LOW	1/ 22 (4.5)	4.5	0/ 24 (0.0)	0.0	3.26 (0.14, 76.10)	0.4621	4.55 (-12.32, 21.41)	0.5973	
HIGH	4/105 (3.8)	3.9	2/101 (2.0)	1.9	1.92 (0.36, 10.27)	0.4440	1.94 (-5.89, 9.78)	0.6269	
Age (years)									NE
<= 65	5/122 (4.1)	4.2	2/123 (1.6)	1.6	2.52 (0.50, 12.74)	0.2635	2.57 (-4.75, 9.88)	0.4916	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE		0.00 (-74.81, 74.81)	1.0000	
Sex									0.6379
male	2/ 12 (16.7)	16.7	0/ 8 (0.0)	0.0	3.46 (0.19, 63.86)	0.4038	16.67 (-18.93, 52.26)	0.3588	
female	3/115 (2.6)	2.7	2/117 (1.7)	1.7	1.53 (0.26, 8.96)	0.6398	0.97 (-6.40, 8.34)	0.7964	
Race									0.9426
White	4/ 85 (4.7)	4.5	2/ 96 (2.1)	2.2	2.26 (0.42, 12.02)	0.3395	2.38 (-7.00, 11.77)	0.6184	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE		0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	1/ 13 (7.7)	7.7	0/ 11 (0.0)	0.0	2.57 (0.12, 57.44)	0.5512	7.69 (-21.17, 36.55)	0.6014	
Ethnicity									NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	5/104 (4.8)	5.0	2/101 (2.0)	1.9	2.43 (0.48, 12.23)	0.2822	3.10 (-5.51, 11.70)	0.4803	
Geographic region									0.9605
EU	2/ 47 (4.3)	4.3	1/ 56 (1.8)	1.8	2.38 (0.22, 25.46)	0.4725	2.47 (-7.10, 12.04)	0.6132	
non-EU	3/ 80 (3.8)	3.8	1/ 69 (1.4)	1.4	2.59 (0.28, 24.31)	0.4055	2.44 (-6.70, 11.57)	0.6013	
Onset of disease									0.8678
Paediatric	1/ 8 (12.5)	12.5	0/ 7 (0.0)	0.0	2.67 (0.13, 56.63)	0.5293	12.50 (-28.93, 53.93)	0.5543	
Adult	4/119 (3.4)	3.4	2/118 (1.7)	1.7	1.98 (0.37, 10.62)	0.4239	1.66 (-5.68, 9.00)	0.6580	
ADA result									NE
Negative	5/111 (4.5)	4.6	2/112 (1.8)	1.8	2.52 (0.50, 12.73)	0.2626	2.89 (-5.08, 10.85)	0.4775	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment									0.2915
< 30	4/ 74 (5.4)	5.7	1/ 87 (1.1)	1.2	4.70 (0.54, 41.16)	0.1619	4.53 (-4.49, 13.55)	0.3249	
>= 30	1/ 53 (1.9)	2.0	1/ 38 (2.6)	2.5	0.72 (0.05, 11.11)	0.8119	-0.47 (-14.19, 13.26)	0.9467	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Herpes Zoster leading to discontinuation of study drug
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.17, 6.17)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Herpes Zoster leading to discontinuation of study drug - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-14.65, 14.65)	1.0000	
>= 10 points	0/ 88 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	0/ 70 (0.0)	0.0	0/ 73 (0.0)	0.0	NE	0.00 (-8.22, 8.22)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-15.17, 15.17)	1.0000	
HIGH	0/105 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-6.74, 6.74)	1.0000	
Age (years)								NE
<= 65	0/122 (0.0)	0.0	0/123 (0.0)	0.0	NE	0.00 (-6.34, 6.34)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE	0.00 (-74.81, 74.81)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE	0.00 (-31.89, 31.89)	1.0000	
female	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-6.65, 6.65)	1.0000	
Race								NE
White	0/ 85 (0.0)	0.0	0/ 96 (0.0)	0.0	NE	0.00 (-8.35, 8.35)	1.0000	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE	0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-26.65, 26.65)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	0/104 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-7.49, 7.49)	1.0000	
Geographic region								NE
EU	0/ 47 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-7.27, 7.27)	1.0000	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-8.12, 8.12)	1.0000	
Onset of disease								NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE	0.00 (-38.51, 38.51)	1.0000	
Adult	0/119 (0.0)	0.0	0/118 (0.0)	0.0	NE	0.00 (-6.51, 6.51)	1.0000	
ADA result								NE
Negative	0/111 (0.0)	0.0	0/112 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 74 (0.0)	0.0	0/ 87 (0.0)	0.0	NE	0.00 (-7.46, 7.46)	1.0000	
>= 30	0/ 53 (0.0)	0.0	0/ 38 (0.0)	0.0	NE	0.00 (-12.88, 12.88)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Hypersensitivity
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	8 (6.3)	2 (1.6)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.94 (0.85, 18.18)	
p-value	0.0791	
Odds Ratio (95% CI)	4.13 (0.86, 19.87)	
p-value	0.0764	
Risk Difference (95% CI)	4.70 (-0.06, 9.46)	
p-value	0.0532	
CMH approach		
Response rate	6.5	1.6
Difference in response rates (95% CI)	4.87 (-2.41, 12.15)	
p-value	0.1899	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Hypersensitivity - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Anifrolumab 300mg (N=127) Response rate	Placebo (N=125) n/ N (%)	Placebo (N=125) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9730
< 10 points	4/ 39 (10.3)	11.6	1/ 37 (2.7)	2.8	3.79 (0.44, 32.40)	0.2229	8.83 (-7.88, 25.54)	0.3005	
>= 10 points	4/ 88 (4.5)	4.4	1/ 88 (1.1)	1.1	4.00 (0.46, 35.08)	0.2108	3.30 (-4.60, 11.20)	0.4135	
OCS dose at baseline									0.5497
<10 mg/day	6/ 57 (10.5)	10.4	1/ 52 (1.9)	1.9	5.47 (0.68, 43.96)	0.1098	8.52 (-4.15, 21.19)	0.1873	
>=10 mg/day	2/ 70 (2.9)	3.4	1/ 73 (1.4)	1.4	2.09 (0.19, 22.49)	0.5446	2.02 (-6.97, 11.02)	0.6593	
Result of type I IFN gene signature test									0.2153
LOW	5/ 22 (22.7)	22.7	0/ 24 (0.0)	0.0	11.96 (0.70, 204.47)	0.0867	22.73 (1.52, 43.93)	0.0357	
HIGH	3/105 (2.9)	2.8	2/101 (2.0)	1.9	1.44 (0.25, 8.46)	0.6845	0.87 (-6.67, 8.41)	0.8203	
Age (years)									0.9051
<= 65	6/122 (4.9)	5.1	2/123 (1.6)	1.6	3.02 (0.62, 14.69)	0.1699	3.47 (-3.86, 10.79)	0.3540	
> 65	2/ 5 (40.0)	40.0	0/ 2 (0.0)	0.0	2.50 (0.17, 37.26)	0.5062	40.00 (-38.52, 118.52)	0.3181	
Sex									0.1655
male	1/ 12 (8.3)	8.3	1/ 8 (12.5)	12.5	0.67 (0.05, 9.19)	0.7620	-4.17 (-41.42, 33.09)	0.8265	
female	7/115 (6.1)	6.2	1/117 (0.9)	0.8	7.12 (0.89, 56.97)	0.0643	5.39 (-2.25, 13.04)	0.1667	
Race									NE
White	8/ 85 (9.4)	8.7	2/ 96 (2.1)	2.2	4.52 (0.99, 20.69)	0.0521	6.58 (-3.13, 16.30)	0.1843	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE		0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-26.65, 26.65)	1.0000	
Ethnicity									0.9626
Hispanic/Latino	1/ 23 (4.3)	4.3	0/ 24 (0.0)	0.0	3.13 (0.13, 73.01)	0.4785	4.35 (-12.12, 20.81)	0.6048	
Non-hispanic/Latino	7/104 (6.7)	7.2	2/101 (2.0)	1.9	3.40 (0.72, 15.97)	0.1212	5.24 (-3.46, 13.95)	0.2379	
Geographic region									0.4297
EU	3/ 47 (6.4)	6.4	0/ 56 (0.0)	0.0	8.31 (0.44, 156.96)	0.1578	6.38 (-3.33, 16.10)	0.1978	
non-EU	5/ 80 (6.3)	6.2	2/ 69 (2.9)	2.8	2.16 (0.43, 10.76)	0.3490	3.39 (-6.27, 13.06)	0.4912	
Onset of disease									NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE		0.00 (-38.51, 38.51)	1.0000	
Adult	8/119 (6.7)	6.7	2/118 (1.7)	1.7	3.97 (0.86, 18.29)	0.0772	4.95 (-2.70, 12.59)	0.2047	
ADA result									NE
Negative	8/111 (7.2)	7.3	2/112 (1.8)	1.8	4.04 (0.88, 18.58)	0.0733	5.57 (-2.56, 13.70)	0.1792	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment									0.7078
< 30	2/ 74 (2.7)	3.2	1/ 87 (1.1)	1.3	2.35 (0.22, 25.42)	0.4814	1.81 (-6.36, 9.98)	0.6637	
>= 30	6/ 53 (11.3)	11.4	1/ 38 (2.6)	2.7	4.30 (0.54, 34.28)	0.1683	8.71 (-6.37, 23.79)	0.2576	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Hypersensitivity
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.17, 6.17)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Hypersensitivity - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-14.65, 14.65)	1.0000	
>= 10 points	0/ 88 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	0/ 70 (0.0)	0.0	0/ 73 (0.0)	0.0	NE	0.00 (-8.22, 8.22)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-15.17, 15.17)	1.0000	
HIGH	0/105 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-6.74, 6.74)	1.0000	
Age (years)								NE
<= 65	0/122 (0.0)	0.0	0/123 (0.0)	0.0	NE	0.00 (-6.34, 6.34)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE	0.00 (-74.81, 74.81)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE	0.00 (-31.89, 31.89)	1.0000	
female	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-6.65, 6.65)	1.0000	
Race								NE
White	0/ 85 (0.0)	0.0	0/ 96 (0.0)	0.0	NE	0.00 (-8.35, 8.35)	1.0000	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE	0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-26.65, 26.65)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	0/104 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-7.49, 7.49)	1.0000	
Geographic region								NE
EU	0/ 47 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-7.27, 7.27)	1.0000	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-8.12, 8.12)	1.0000	
Onset of disease								NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE	0.00 (-38.51, 38.51)	1.0000	
Adult	0/119 (0.0)	0.0	0/118 (0.0)	0.0	NE	0.00 (-6.51, 6.51)	1.0000	
ADA result								NE
Negative	0/111 (0.0)	0.0	0/112 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 74 (0.0)	0.0	0/ 87 (0.0)	0.0	NE	0.00 (-7.46, 7.46)	1.0000	
>= 30	0/ 53 (0.0)	0.0	0/ 38 (0.0)	0.0	NE	0.00 (-12.88, 12.88)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Hypersensitivity
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.17, 6.17)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Hypersensitivity - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-14.65, 14.65)	1.0000	
>= 10 points	0/ 88 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	0/ 70 (0.0)	0.0	0/ 73 (0.0)	0.0	NE	0.00 (-8.22, 8.22)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-15.17, 15.17)	1.0000	
HIGH	0/105 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-6.74, 6.74)	1.0000	
Age (years)								NE
<= 65	0/122 (0.0)	0.0	0/123 (0.0)	0.0	NE	0.00 (-6.34, 6.34)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE	0.00 (-74.81, 74.81)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE	0.00 (-31.89, 31.89)	1.0000	
female	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-6.65, 6.65)	1.0000	
Race								NE
White	0/ 85 (0.0)	0.0	0/ 96 (0.0)	0.0	NE	0.00 (-8.35, 8.35)	1.0000	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE	0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-26.65, 26.65)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	0/104 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-7.49, 7.49)	1.0000	
Geographic region								NE
EU	0/ 47 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-7.27, 7.27)	1.0000	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-8.12, 8.12)	1.0000	
Onset of disease								NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE	0.00 (-38.51, 38.51)	1.0000	
Adult	0/119 (0.0)	0.0	0/118 (0.0)	0.0	NE	0.00 (-6.51, 6.51)	1.0000	
ADA result								NE
Negative	0/111 (0.0)	0.0	0/112 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 74 (0.0)	0.0	0/ 87 (0.0)	0.0	NE	0.00 (-7.46, 7.46)	1.0000	
>= 30	0/ 53 (0.0)	0.0	0/ 38 (0.0)	0.0	NE	0.00 (-12.88, 12.88)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Hypersensitivity
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	8 (6.3)	2 (1.6)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.94 (0.85, 18.18)	
p-value	0.0791	
Odds Ratio (95% CI)	4.13 (0.86, 19.87)	
p-value	0.0764	
Risk Difference (95% CI)	4.70 (-0.06, 9.46)	
p-value	0.0532	
CMH approach		
Response rate	6.5	1.6
Difference in response rates (95% CI)	4.87 (-2.41, 12.15)	
p-value	0.1899	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Hypersensitivity - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9730
< 10 points	4/ 39 (10.3)	11.6	1/ 37 (2.7)	2.8	3.79 (0.44, 32.40)	0.2229	8.83 (-7.88, 25.54)	0.3005	
>= 10 points	4/ 88 (4.5)	4.4	1/ 88 (1.1)	1.1	4.00 (0.46, 35.08)	0.2108	3.30 (-4.60, 11.20)	0.4135	
OCS dose at baseline									0.5497
<10 mg/day	6/ 57 (10.5)	10.4	1/ 52 (1.9)	1.9	5.47 (0.68, 43.96)	0.1098	8.52 (-4.15, 21.19)	0.1873	
>=10 mg/day	2/ 70 (2.9)	3.4	1/ 73 (1.4)	1.4	2.09 (0.19, 22.49)	0.5446	2.02 (-6.97, 11.02)	0.6593	
Result of type I IFN gene signature test									0.2153
LOW	5/ 22 (22.7)	22.7	0/ 24 (0.0)	0.0	11.96 (0.70, 204.47)	0.0867	22.73 (1.52, 43.93)	0.0357	
HIGH	3/105 (2.9)	2.8	2/101 (2.0)	1.9	1.44 (0.25, 8.46)	0.6845	0.87 (-6.67, 8.41)	0.8203	
Age (years)									0.9051
<= 65	6/122 (4.9)	5.1	2/123 (1.6)	1.6	3.02 (0.62, 14.69)	0.1699	3.47 (-3.86, 10.79)	0.3540	
> 65	2/ 5 (40.0)	40.0	0/ 2 (0.0)	0.0	2.50 (0.17, 37.26)	0.5062	40.00 (-38.52, 118.52)	0.3181	
Sex									0.1655
male	1/ 12 (8.3)	8.3	1/ 8 (12.5)	12.5	0.67 (0.05, 9.19)	0.7620	-4.17 (-41.42, 33.09)	0.8265	
female	7/115 (6.1)	6.2	1/117 (0.9)	0.8	7.12 (0.89, 56.97)	0.0643	5.39 (-2.25, 13.04)	0.1667	
Race									NE
White	8/ 85 (9.4)	8.7	2/ 96 (2.1)	2.2	4.52 (0.99, 20.69)	0.0521	6.58 (-3.13, 16.30)	0.1843	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE		0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-26.65, 26.65)	1.0000	
Ethnicity									0.9626
Hispanic/Latino	1/ 23 (4.3)	4.3	0/ 24 (0.0)	0.0	3.13 (0.13, 73.01)	0.4785	4.35 (-12.12, 20.81)	0.6048	
Non-hispanic/Latino	7/104 (6.7)	7.2	2/101 (2.0)	1.9	3.40 (0.72, 15.97)	0.1212	5.24 (-3.46, 13.95)	0.2379	
Geographic region									0.4297
EU	3/ 47 (6.4)	6.4	0/ 56 (0.0)	0.0	8.31 (0.44, 156.96)	0.1578	6.38 (-3.33, 16.10)	0.1978	
non-EU	5/ 80 (6.3)	6.2	2/ 69 (2.9)	2.8	2.16 (0.43, 10.76)	0.3490	3.39 (-6.27, 13.06)	0.4912	
Onset of disease									NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE		0.00 (-38.51, 38.51)	1.0000	
Adult	8/119 (6.7)	6.7	2/118 (1.7)	1.7	3.97 (0.86, 18.29)	0.0772	4.95 (-2.70, 12.59)	0.2047	
ADA result									NE
Negative	8/111 (7.2)	7.3	2/112 (1.8)	1.8	4.04 (0.88, 18.58)	0.0733	5.57 (-2.56, 13.70)	0.1792	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment									0.7078
< 30	2/ 74 (2.7)	3.2	1/ 87 (1.1)	1.3	2.35 (0.22, 25.42)	0.4814	1.81 (-6.36, 9.98)	0.6637	
>= 30	6/ 53 (11.3)	11.4	1/ 38 (2.6)	2.7	4.30 (0.54, 34.28)	0.1683	8.71 (-6.37, 23.79)	0.2576	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Influenza
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	1 (0.8)	1 (0.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.98 (0.06, 15.56)	
p-value	0.9910	
Odds Ratio (95% CI)	0.98 (0.06, 15.91)	
p-value	0.9910	
Risk Difference (95% CI)	-0.01 (-2.20, 2.18)	
p-value	0.9910	
CMH approach		
Response rate	0.8	0.8
Difference in response rates (95% CI)	0.07 (-6.37, 6.51)	
p-value	0.9832	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.3269
< 10 points	0/ 39 (0.0)	0.0	1/ 37 (2.7)	2.1	0.32 (0.01, 7.54)	0.4771	-2.14 (-17.04, 12.76)	0.7785	
>= 10 points	1/ 88 (1.1)	1.1	0/ 88 (0.0)	0.0	3.00 (0.12, 72.65)	0.4993	1.10 (-6.02, 8.22)	0.7618	
OCS dose at baseline									0.3682
<10 mg/day	1/ 57 (1.8)	1.7	0/ 52 (0.0)	0.0	2.74 (0.11, 65.85)	0.5341	1.70 (-9.28, 12.67)	0.7618	
>=10 mg/day	0/ 70 (0.0)	0.0	1/ 73 (1.4)	1.1	0.35 (0.01, 8.39)	0.5152	-1.13 (-9.50, 7.24)	0.7913	
Result of type I IFN gene signature test									NE
LOW	1/ 22 (4.5)	4.5	1/ 24 (4.2)	4.2	1.09 (0.07, 16.41)	0.9498	0.38 (-17.82, 18.58)	0.9675	
HIGH	0/105 (0.0)	0.0	0/101 (0.0)	0.0	NE		0.00 (-6.74, 6.74)	1.0000	
Age (years)									NE
<= 65	1/122 (0.8)	0.9	1/123 (0.8)	0.7	1.01 (0.06, 15.94)	0.9954	0.16 (-6.45, 6.76)	0.9630	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE		0.00 (-74.81, 74.81)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE		0.00 (-31.89, 31.89)	1.0000	
female	1/115 (0.9)	0.9	1/117 (0.9)	0.8	1.02 (0.06, 16.07)	0.9902	0.12 (-6.81, 7.06)	0.9728	
Race									0.2287
White	1/ 85 (1.2)	1.1	0/ 96 (0.0)	0.0	3.38 (0.14, 81.97)	0.4535	1.12 (-7.42, 9.66)	0.7969	
Black or African American	0/ 22 (0.0)	0.0	1/ 14 (7.1)	7.1	0.22 (0.01, 4.99)	0.3399	-7.14 (-29.62, 15.33)	0.5333	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-26.65, 26.65)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	1/104 (1.0)	1.1	1/101 (1.0)	0.9	0.97 (0.06, 15.32)	0.9834	0.20 (-7.62, 8.01)	0.9604	
Geographic region									0.2732
EU	1/ 47 (2.1)	2.1	0/ 56 (0.0)	0.0	3.56 (0.15, 85.45)	0.4332	2.13 (-6.08, 10.33)	0.6114	
non-EU	0/ 80 (0.0)	0.0	1/ 69 (1.4)	1.5	0.29 (0.01, 6.96)	0.4437	-1.48 (-9.89, 6.93)	0.7296	
Onset of disease									NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE		0.00 (-38.51, 38.51)	1.0000	
Adult	1/119 (0.8)	0.8	1/118 (0.8)	0.8	0.99 (0.06, 15.67)	0.9952	0.00 (-6.79, 6.79)	1.0000	
ADA result									NE
Negative	1/111 (0.9)	0.9	1/112 (0.9)	0.9	1.01 (0.06, 15.93)	0.9949	0.08 (-7.14, 7.30)	0.9822	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment									0.2424
< 30	1/ 74 (1.4)	1.6	0/ 87 (0.0)	0.0	3.52 (0.15, 85.13)	0.4388	1.58 (-6.15, 9.30)	0.6893	
>= 30	0/ 53 (0.0)	0.0	1/ 38 (2.6)	2.7	0.24 (0.01, 5.75)	0.3792	-2.67 (-16.00, 10.65)	0.6941	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Influenza
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.17, 6.17)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Anifrolumab 300mg (N=127) Response rate	Placebo (N=125) n/ N (%)	Placebo (N=125) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Analysis Anifrolumab 300mg vs. Placebo Difference in response rates (95% CI)	Analysis Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-14.65, 14.65)	1.0000	
>= 10 points	0/ 88 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	0/ 70 (0.0)	0.0	0/ 73 (0.0)	0.0	NE	0.00 (-8.22, 8.22)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-15.17, 15.17)	1.0000	
HIGH	0/105 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-6.74, 6.74)	1.0000	
Age (years)								NE
<= 65	0/122 (0.0)	0.0	0/123 (0.0)	0.0	NE	0.00 (-6.34, 6.34)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE	0.00 (-74.81, 74.81)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE	0.00 (-31.89, 31.89)	1.0000	
female	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-6.65, 6.65)	1.0000	
Race								NE
White	0/ 85 (0.0)	0.0	0/ 96 (0.0)	0.0	NE	0.00 (-8.35, 8.35)	1.0000	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE	0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-26.65, 26.65)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	0/104 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-7.49, 7.49)	1.0000	
Geographic region								NE
EU	0/ 47 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-7.27, 7.27)	1.0000	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-8.12, 8.12)	1.0000	
Onset of disease								NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE	0.00 (-38.51, 38.51)	1.0000	
Adult	0/119 (0.0)	0.0	0/118 (0.0)	0.0	NE	0.00 (-6.51, 6.51)	1.0000	
ADA result								NE
Negative	0/111 (0.0)	0.0	0/112 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 74 (0.0)	0.0	0/ 87 (0.0)	0.0	NE	0.00 (-7.46, 7.46)	1.0000	
>= 30	0/ 53 (0.0)	0.0	0/ 38 (0.0)	0.0	NE	0.00 (-12.88, 12.88)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Influenza
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.17, 6.17)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Anifrolumab 300mg (N=127) Response rate	Placebo (N=125) n/ N (%)	Placebo (N=125) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Analysis Anifrolumab 300mg vs. Placebo Difference in response rates (95% CI)	Analysis Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-14.65, 14.65)	1.0000	
>= 10 points	0/ 88 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	0/ 70 (0.0)	0.0	0/ 73 (0.0)	0.0	NE	0.00 (-8.22, 8.22)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-15.17, 15.17)	1.0000	
HIGH	0/105 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-6.74, 6.74)	1.0000	
Age (years)								NE
<= 65	0/122 (0.0)	0.0	0/123 (0.0)	0.0	NE	0.00 (-6.34, 6.34)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE	0.00 (-74.81, 74.81)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE	0.00 (-31.89, 31.89)	1.0000	
female	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-6.65, 6.65)	1.0000	
Race								NE
White	0/ 85 (0.0)	0.0	0/ 96 (0.0)	0.0	NE	0.00 (-8.35, 8.35)	1.0000	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE	0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-26.65, 26.65)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	0/104 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-7.49, 7.49)	1.0000	
Geographic region								NE
EU	0/ 47 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-7.27, 7.27)	1.0000	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-8.12, 8.12)	1.0000	
Onset of disease								NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE	0.00 (-38.51, 38.51)	1.0000	
Adult	0/119 (0.0)	0.0	0/118 (0.0)	0.0	NE	0.00 (-6.51, 6.51)	1.0000	
ADA result								NE
Negative	0/111 (0.0)	0.0	0/112 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 74 (0.0)	0.0	0/ 87 (0.0)	0.0	NE	0.00 (-7.46, 7.46)	1.0000	
>= 30	0/ 53 (0.0)	0.0	0/ 38 (0.0)	0.0	NE	0.00 (-12.88, 12.88)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Influenza
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	1 (0.8)	1 (0.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.98 (0.06, 15.56)	
p-value	0.9910	
Odds Ratio (95% CI)	0.98 (0.06, 15.91)	
p-value	0.9910	
Risk Difference (95% CI)	-0.01 (-2.20, 2.18)	
p-value	0.9910	
CMH approach		
Response rate	0.8	0.8
Difference in response rates (95% CI)	0.07 (-6.37, 6.51)	
p-value	0.9832	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.3269
< 10 points	0/ 39 (0.0)	0.0	1/ 37 (2.7)	2.1	0.32 (0.01, 7.54)	0.4771	-2.14 (-17.04, 12.76)	0.7785	
>= 10 points	1/ 88 (1.1)	1.1	0/ 88 (0.0)	0.0	3.00 (0.12, 72.65)	0.4993	1.10 (-6.02, 8.22)	0.7618	
OCS dose at baseline									0.3682
<10 mg/day	1/ 57 (1.8)	1.7	0/ 52 (0.0)	0.0	2.74 (0.11, 65.85)	0.5341	1.70 (-9.28, 12.67)	0.7618	
>=10 mg/day	0/ 70 (0.0)	0.0	1/ 73 (1.4)	1.1	0.35 (0.01, 8.39)	0.5152	-1.13 (-9.50, 7.24)	0.7913	
Result of type I IFN gene signature test									NE
LOW	1/ 22 (4.5)	4.5	1/ 24 (4.2)	4.2	1.09 (0.07, 16.41)	0.9498	0.38 (-17.82, 18.58)	0.9675	
HIGH	0/105 (0.0)	0.0	0/101 (0.0)	0.0	NE		0.00 (-6.74, 6.74)	1.0000	
Age (years)									NE
<= 65	1/122 (0.8)	0.9	1/123 (0.8)	0.7	1.01 (0.06, 15.94)	0.9954	0.16 (-6.45, 6.76)	0.9630	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE		0.00 (-74.81, 74.81)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE		0.00 (-31.89, 31.89)	1.0000	
female	1/115 (0.9)	0.9	1/117 (0.9)	0.8	1.02 (0.06, 16.07)	0.9902	0.12 (-6.81, 7.06)	0.9728	
Race									0.2287
White	1/ 85 (1.2)	1.1	0/ 96 (0.0)	0.0	3.38 (0.14, 81.97)	0.4535	1.12 (-7.42, 9.66)	0.7969	
Black or African American	0/ 22 (0.0)	0.0	1/ 14 (7.1)	7.1	0.22 (0.01, 4.99)	0.3399	-7.14 (-29.62, 15.33)	0.5333	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-26.65, 26.65)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	1/104 (1.0)	1.1	1/101 (1.0)	0.9	0.97 (0.06, 15.32)	0.9834	0.20 (-7.62, 8.01)	0.9604	
Geographic region									0.2732
EU	1/ 47 (2.1)	2.1	0/ 56 (0.0)	0.0	3.56 (0.15, 85.45)	0.4332	2.13 (-6.08, 10.33)	0.6114	
non-EU	0/ 80 (0.0)	0.0	1/ 69 (1.4)	1.5	0.29 (0.01, 6.96)	0.4437	-1.48 (-9.89, 6.93)	0.7296	
Onset of disease									NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE		0.00 (-38.51, 38.51)	1.0000	
Adult	1/119 (0.8)	0.8	1/118 (0.8)	0.8	0.99 (0.06, 15.67)	0.9952	0.00 (-6.79, 6.79)	1.0000	
ADA result									NE
Negative	1/111 (0.9)	0.9	1/112 (0.9)	0.9	1.01 (0.06, 15.93)	0.9949	0.08 (-7.14, 7.30)	0.9822	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment									0.2424
< 30	1/ 74 (1.4)	1.6	0/ 87 (0.0)	0.0	3.52 (0.15, 85.13)	0.4388	1.58 (-6.15, 9.30)	0.6893	
>= 30	0/ 53 (0.0)	0.0	1/ 38 (2.6)	2.7	0.24 (0.01, 5.75)	0.3792	-2.67 (-16.00, 10.65)	0.6941	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - MACE
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.17, 6.17)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - MACE - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-14.65, 14.65)	1.0000	
>= 10 points	0/ 88 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	0/ 70 (0.0)	0.0	0/ 73 (0.0)	0.0	NE	0.00 (-8.22, 8.22)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-15.17, 15.17)	1.0000	
HIGH	0/105 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-6.74, 6.74)	1.0000	
Age (years)								NE
<= 65	0/122 (0.0)	0.0	0/123 (0.0)	0.0	NE	0.00 (-6.34, 6.34)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE	0.00 (-74.81, 74.81)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE	0.00 (-31.89, 31.89)	1.0000	
female	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-6.65, 6.65)	1.0000	
Race								NE
White	0/ 85 (0.0)	0.0	0/ 96 (0.0)	0.0	NE	0.00 (-8.35, 8.35)	1.0000	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE	0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-26.65, 26.65)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	0/104 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-7.49, 7.49)	1.0000	
Geographic region								NE
EU	0/ 47 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-7.27, 7.27)	1.0000	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-8.12, 8.12)	1.0000	
Onset of disease								NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE	0.00 (-38.51, 38.51)	1.0000	
Adult	0/119 (0.0)	0.0	0/118 (0.0)	0.0	NE	0.00 (-6.51, 6.51)	1.0000	
ADA result								NE
Negative	0/111 (0.0)	0.0	0/112 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 74 (0.0)	0.0	0/ 87 (0.0)	0.0	NE	0.00 (-7.46, 7.46)	1.0000	
>= 30	0/ 53 (0.0)	0.0	0/ 38 (0.0)	0.0	NE	0.00 (-12.88, 12.88)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious MACE
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.17, 6.17)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious MACE - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-14.65, 14.65)	1.0000	
>= 10 points	0/ 88 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	0/ 70 (0.0)	0.0	0/ 73 (0.0)	0.0	NE	0.00 (-8.22, 8.22)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-15.17, 15.17)	1.0000	
HIGH	0/105 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-6.74, 6.74)	1.0000	
Age (years)								NE
<= 65	0/122 (0.0)	0.0	0/123 (0.0)	0.0	NE	0.00 (-6.34, 6.34)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE	0.00 (-74.81, 74.81)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE	0.00 (-31.89, 31.89)	1.0000	
female	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-6.65, 6.65)	1.0000	
Race								NE
White	0/ 85 (0.0)	0.0	0/ 96 (0.0)	0.0	NE	0.00 (-8.35, 8.35)	1.0000	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE	0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-26.65, 26.65)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	0/104 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-7.49, 7.49)	1.0000	
Geographic region								NE
EU	0/ 47 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-7.27, 7.27)	1.0000	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-8.12, 8.12)	1.0000	
Onset of disease								NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE	0.00 (-38.51, 38.51)	1.0000	
Adult	0/119 (0.0)	0.0	0/118 (0.0)	0.0	NE	0.00 (-6.51, 6.51)	1.0000	
ADA result								NE
Negative	0/111 (0.0)	0.0	0/112 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 74 (0.0)	0.0	0/ 87 (0.0)	0.0	NE	0.00 (-7.46, 7.46)	1.0000	
>= 30	0/ 53 (0.0)	0.0	0/ 38 (0.0)	0.0	NE	0.00 (-12.88, 12.88)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe MACE
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.17, 6.17)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe MACE - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=127)		Placebo (N=125)		Analysis Anifrolumab 300mg vs. Placebo			Interaction
Level	n/ N (%)	Response rate	n/ N (%)	Response rate	Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-14.65, 14.65)	1.0000	
>= 10 points	0/ 88 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	0/ 70 (0.0)	0.0	0/ 73 (0.0)	0.0	NE	0.00 (-8.22, 8.22)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-15.17, 15.17)	1.0000	
HIGH	0/105 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-6.74, 6.74)	1.0000	
Age (years)								NE
<= 65	0/122 (0.0)	0.0	0/123 (0.0)	0.0	NE	0.00 (-6.34, 6.34)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE	0.00 (-74.81, 74.81)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE	0.00 (-31.89, 31.89)	1.0000	
female	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-6.65, 6.65)	1.0000	
Race								NE
White	0/ 85 (0.0)	0.0	0/ 96 (0.0)	0.0	NE	0.00 (-8.35, 8.35)	1.0000	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE	0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-26.65, 26.65)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	0/104 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-7.49, 7.49)	1.0000	
Geographic region								NE
EU	0/ 47 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-7.27, 7.27)	1.0000	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-8.12, 8.12)	1.0000	
Onset of disease								NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE	0.00 (-38.51, 38.51)	1.0000	
Adult	0/119 (0.0)	0.0	0/118 (0.0)	0.0	NE	0.00 (-6.51, 6.51)	1.0000	
ADA result								NE
Negative	0/111 (0.0)	0.0	0/112 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 74 (0.0)	0.0	0/ 87 (0.0)	0.0	NE	0.00 (-7.46, 7.46)	1.0000	
>= 30	0/ 53 (0.0)	0.0	0/ 38 (0.0)	0.0	NE	0.00 (-12.88, 12.88)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe MACE
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.17, 6.17)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe MACE - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-14.65, 14.65)	1.0000	
>= 10 points	0/ 88 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	0/ 70 (0.0)	0.0	0/ 73 (0.0)	0.0	NE	0.00 (-8.22, 8.22)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-15.17, 15.17)	1.0000	
HIGH	0/105 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-6.74, 6.74)	1.0000	
Age (years)								NE
<= 65	0/122 (0.0)	0.0	0/123 (0.0)	0.0	NE	0.00 (-6.34, 6.34)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE	0.00 (-74.81, 74.81)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE	0.00 (-31.89, 31.89)	1.0000	
female	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-6.65, 6.65)	1.0000	
Race								NE
White	0/ 85 (0.0)	0.0	0/ 96 (0.0)	0.0	NE	0.00 (-8.35, 8.35)	1.0000	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE	0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-26.65, 26.65)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	0/104 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-7.49, 7.49)	1.0000	
Geographic region								NE
EU	0/ 47 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-7.27, 7.27)	1.0000	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-8.12, 8.12)	1.0000	
Onset of disease								NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE	0.00 (-38.51, 38.51)	1.0000	
Adult	0/119 (0.0)	0.0	0/118 (0.0)	0.0	NE	0.00 (-6.51, 6.51)	1.0000	
ADA result								NE
Negative	0/111 (0.0)	0.0	0/112 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 74 (0.0)	0.0	0/ 87 (0.0)	0.0	NE	0.00 (-7.46, 7.46)	1.0000	
>= 30	0/ 53 (0.0)	0.0	0/ 38 (0.0)	0.0	NE	0.00 (-12.88, 12.88)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	4 (3.1)	7 (5.6)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.56 (0.17, 1.87)	
p-value	0.3486	
Odds Ratio (95% CI)	0.55 (0.16, 1.92)	
p-value	0.3475	
Risk Difference (95% CI)	-2.45 (-7.50, 2.60)	
p-value	0.3413	
CMH approach		
Response rate	3.2	5.4
Difference in response rates (95% CI)	-2.26 (-9.79, 5.28)	
p-value	0.5568	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.6808
< 10 points	1/ 39 (2.6)	2.3	1/ 37 (2.7)	2.1	0.95 (0.06, 14.62)	0.9699	0.18 (-15.14, 15.50)	0.9818	
>= 10 points	3/ 88 (3.4)	3.4	6/ 88 (6.8)	6.8	0.50 (0.13, 1.94)	0.3157	-3.38 (-12.27, 5.50)	0.4554	
OCS dose at baseline									0.9006
<10 mg/day	2/ 57 (3.5)	3.4	3/ 52 (5.8)	5.9	0.61 (0.11, 3.50)	0.5774	-2.48 (-14.72, 9.77)	0.6918	
>=10 mg/day	2/ 70 (2.9)	2.7	4/ 73 (5.5)	5.5	0.52 (0.10, 2.76)	0.4435	-2.79 (-12.80, 7.23)	0.5856	
Result of type I IFN gene signature test									0.4090
LOW	2/ 22 (9.1)	9.1	2/ 24 (8.3)	8.3	1.09 (0.17, 7.10)	0.9274	0.76 (-19.82, 21.33)	0.9425	
HIGH	2/105 (1.9)	1.9	5/101 (5.0)	4.8	0.38 (0.08, 1.94)	0.2470	-2.93 (-10.92, 5.06)	0.4718	
Age (years)									NE
<= 65	4/122 (3.3)	3.3	7/123 (5.7)	5.5	0.58 (0.17, 1.92)	0.3688	-2.16 (-9.88, 5.56)	0.5834	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE		0.00 (-74.81, 74.81)	1.0000	
Sex									0.5251
male	0/ 12 (0.0)	0.0	1/ 8 (12.5)	12.5	0.23 (0.01, 5.05)	0.3517	-12.50 (-47.86, 22.86)	0.4884	
female	4/115 (3.5)	3.5	6/117 (5.1)	4.9	0.68 (0.20, 2.34)	0.5390	-1.33 (-9.28, 6.63)	0.7441	
Race									0.8293
White	2/ 85 (2.4)	2.2	3/ 96 (3.1)	3.4	0.75 (0.13, 4.40)	0.7527	-1.15 (-10.38, 8.08)	0.8070	
Black or African American	1/ 22 (4.5)	4.5	2/ 14 (14.3)	14.3	0.32 (0.03, 3.19)	0.3302	-9.74 (-35.28, 15.80)	0.4548	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	1/ 13 (7.7)	7.7	2/ 11 (18.2)	18.2	0.42 (0.04, 4.06)	0.4561	-10.49 (-43.84, 22.86)	0.5376	
Ethnicity									0.3288
Hispanic/Latino	1/ 23 (4.3)	4.3	4/ 24 (16.7)	16.7	0.26 (0.03, 2.16)	0.2131	-12.32 (-33.16, 8.52)	0.2467	
Non-hispanic/Latino	3/104 (2.9)	3.2	3/101 (3.0)	2.7	0.97 (0.20, 4.70)	0.9710	0.50 (-8.00, 8.99)	0.9090	
Geographic region									0.8298
EU	0/ 47 (0.0)	0.0	1/ 56 (1.8)	1.8	0.40 (0.02, 9.49)	0.5676	-1.79 (-9.75, 6.18)	0.6602	
non-EU	4/ 80 (5.0)	5.0	6/ 69 (8.7)	8.9	0.58 (0.17, 1.95)	0.3754	-3.93 (-14.71, 6.85)	0.4748	
Onset of disease									0.6334
Paediatric	0/ 8 (0.0)	0.0	1/ 7 (14.3)	14.3	0.30 (0.01, 6.29)	0.4353	-14.29 (-56.18, 27.61)	0.5040	
Adult	4/119 (3.4)	3.3	6/118 (5.1)	5.0	0.66 (0.19, 2.28)	0.5127	-1.63 (-9.45, 6.19)	0.6830	
ADA result									0.8069
Negative	3/111 (2.7)	2.6	5/112 (4.5)	4.3	0.61 (0.15, 2.47)	0.4845	-1.69 (-9.68, 6.30)	0.6783	
Positive (At any time)	1/ 15 (6.7)	6.7	2/ 13 (15.4)	15.4	0.43 (0.04, 4.25)	0.4727	-8.72 (-38.25, 20.82)	0.5629	
BMI (kg/m2) at enrolment									0.3703
< 30	2/ 74 (2.7)	2.6	6/ 87 (6.9)	6.5	0.39 (0.08, 1.88)	0.2422	-3.95 (-13.19, 5.28)	0.4016	
>= 30	2/ 53 (3.8)	3.7	1/ 38 (2.6)	2.7	1.43 (0.13, 15.25)	0.7651	0.99 (-13.01, 14.99)	0.8900	

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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

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D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Non-opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
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p-value	0.3486	
Odds Ratio (95% CI)	0.55 (0.16, 1.92)	
p-value	0.3475	
Risk Difference (95% CI)	-2.45 (-7.50, 2.60)	
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CMH approach		
Response rate	3.2	5.4
Difference in response rates (95% CI)	-2.26 (-9.79, 5.28)	
p-value	0.5568	

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D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Non-opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.6808
< 10 points	1/ 39 (2.6)	2.3	1/ 37 (2.7)	2.1	0.95 (0.06, 14.62)	0.9699	0.18 (-15.14, 15.50)	0.9818	
>= 10 points	3/ 88 (3.4)	3.4	6/ 88 (6.8)	6.8	0.50 (0.13, 1.94)	0.3157	-3.38 (-12.27, 5.50)	0.4554	
OCS dose at baseline									0.9006
<10 mg/day	2/ 57 (3.5)	3.4	3/ 52 (5.8)	5.9	0.61 (0.11, 3.50)	0.5774	-2.48 (-14.72, 9.77)	0.6918	
>=10 mg/day	2/ 70 (2.9)	2.7	4/ 73 (5.5)	5.5	0.52 (0.10, 2.76)	0.4435	-2.79 (-12.80, 7.23)	0.5856	
Result of type I IFN gene signature test									0.4090
LOW	2/ 22 (9.1)	9.1	2/ 24 (8.3)	8.3	1.09 (0.17, 7.10)	0.9274	0.76 (-19.82, 21.33)	0.9425	
HIGH	2/105 (1.9)	1.9	5/101 (5.0)	4.8	0.38 (0.08, 1.94)	0.2470	-2.93 (-10.92, 5.06)	0.4718	
Age (years)									NE
<= 65	4/122 (3.3)	3.3	7/123 (5.7)	5.5	0.58 (0.17, 1.92)	0.3688	-2.16 (-9.88, 5.56)	0.5834	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE		0.00 (-74.81, 74.81)	1.0000	
Sex									0.5251
male	0/ 12 (0.0)	0.0	1/ 8 (12.5)	12.5	0.23 (0.01, 5.05)	0.3517	-12.50 (-47.86, 22.86)	0.4884	
female	4/115 (3.5)	3.5	6/117 (5.1)	4.9	0.68 (0.20, 2.34)	0.5390	-1.33 (-9.28, 6.63)	0.7441	
Race									0.8293
White	2/ 85 (2.4)	2.2	3/ 96 (3.1)	3.4	0.75 (0.13, 4.40)	0.7527	-1.15 (-10.38, 8.08)	0.8070	
Black or African American	1/ 22 (4.5)	4.5	2/ 14 (14.3)	14.3	0.32 (0.03, 3.19)	0.3302	-9.74 (-35.28, 15.80)	0.4548	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	1/ 13 (7.7)	7.7	2/ 11 (18.2)	18.2	0.42 (0.04, 4.06)	0.4561	-10.49 (-43.84, 22.86)	0.5376	
Ethnicity									0.3288
Hispanic/Latino	1/ 23 (4.3)	4.3	4/ 24 (16.7)	16.7	0.26 (0.03, 2.16)	0.2131	-12.32 (-33.16, 8.52)	0.2467	
Non-hispanic/Latino	3/104 (2.9)	3.2	3/101 (3.0)	2.7	0.97 (0.20, 4.70)	0.9710	0.50 (-8.00, 8.99)	0.9090	
Geographic region									0.8298
EU	0/ 47 (0.0)	0.0	1/ 56 (1.8)	1.8	0.40 (0.02, 9.49)	0.5676	-1.79 (-9.75, 6.18)	0.6602	
non-EU	4/ 80 (5.0)	5.0	6/ 69 (8.7)	8.9	0.58 (0.17, 1.95)	0.3754	-3.93 (-14.71, 6.85)	0.4748	
Onset of disease									0.6334
Paediatric	0/ 8 (0.0)	0.0	1/ 7 (14.3)	14.3	0.30 (0.01, 6.29)	0.4353	-14.29 (-56.18, 27.61)	0.5040	
Adult	4/119 (3.4)	3.3	6/118 (5.1)	5.0	0.66 (0.19, 2.28)	0.5127	-1.63 (-9.45, 6.19)	0.6830	
ADA result									0.8069
Negative	3/111 (2.7)	2.6	5/112 (4.5)	4.3	0.61 (0.15, 2.47)	0.4845	-1.69 (-9.68, 6.30)	0.6783	
Positive (At any time)	1/ 15 (6.7)	6.7	2/ 13 (15.4)	15.4	0.43 (0.04, 4.25)	0.4727	-8.72 (-38.25, 20.82)	0.5629	
BMI (kg/m2) at enrolment									0.3703
< 30	2/ 74 (2.7)	2.6	6/ 87 (6.9)	6.5	0.39 (0.08, 1.88)	0.2422	-3.95 (-13.19, 5.28)	0.4016	
>= 30	2/ 53 (3.8)	3.7	1/ 38 (2.6)	2.7	1.43 (0.13, 15.25)	0.7651	0.99 (-13.01, 14.99)	0.8900	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Non-opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	4 (3.1)	4 (3.2)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.98 (0.25, 3.85)	
p-value	0.9818	
Odds Ratio (95% CI)	0.98 (0.24, 4.02)	
p-value	0.9818	
Risk Difference (95% CI)	-0.05 (-4.38, 4.28)	
p-value	0.9818	
CMH approach		
Response rate	3.2	3.1
Difference in response rates (95% CI)	0.10 (-7.10, 7.30)	
p-value	0.9782	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Non-opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.4538
< 10 points	1/ 39 (2.6)	2.3	0/ 37 (0.0)	0.0	2.85 (0.12, 67.83)	0.5172	2.32 (-12.76, 17.39)	0.7633	
>= 10 points	3/ 88 (3.4)	3.4	4/ 88 (4.5)	4.5	0.75 (0.17, 3.25)	0.7008	-1.10 (-9.57, 7.37)	0.7989	
OCS dose at baseline									0.5218
<10 mg/day	2/ 57 (3.5)	3.4	1/ 52 (1.9)	2.0	1.82 (0.17, 19.53)	0.6191	1.41 (-10.14, 12.97)	0.8103	
>=10 mg/day	2/ 70 (2.9)	2.7	3/ 73 (4.1)	4.1	0.70 (0.12, 4.04)	0.6854	-1.42 (-11.17, 8.33)	0.7755	
Result of type I IFN gene signature test									0.4119
LOW	2/ 22 (9.1)	9.1	1/ 24 (4.2)	4.2	2.18 (0.21, 22.42)	0.5116	4.92 (-14.58, 24.43)	0.6207	
HIGH	2/105 (1.9)	1.9	3/101 (3.0)	2.8	0.64 (0.11, 3.76)	0.6224	-0.98 (-8.63, 6.67)	0.8021	
Age (years)									NE
<= 65	4/122 (3.3)	3.3	4/123 (3.3)	3.1	1.01 (0.26, 3.94)	0.9906	0.20 (-7.19, 7.59)	0.9579	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE		0.00 (-74.81, 74.81)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE		0.00 (-31.89, 31.89)	1.0000	
female	4/115 (3.5)	3.5	4/117 (3.4)	3.2	1.02 (0.26, 3.97)	0.9802	0.29 (-7.45, 8.04)	0.9408	
Race									0.5109
White	2/ 85 (2.4)	2.2	1/ 96 (1.0)	1.1	2.26 (0.21, 24.47)	0.5027	1.12 (-7.77, 10.01)	0.8047	
Black or African American	1/ 22 (4.5)	4.5	2/ 14 (14.3)	14.3	0.32 (0.03, 3.19)	0.3302	-9.74 (-35.28, 15.80)	0.4548	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	1/ 13 (7.7)	7.7	1/ 11 (9.1)	9.1	0.85 (0.06, 12.01)	0.9018	-1.40 (-32.83, 30.04)	0.9305	
Ethnicity									0.4916
Hispanic/Latino	1/ 23 (4.3)	4.3	2/ 24 (8.3)	8.3	0.52 (0.05, 5.37)	0.5844	-3.99 (-22.98, 15.01)	0.6810	
Non-hispanic/Latino	3/104 (2.9)	3.2	2/101 (2.0)	1.8	1.46 (0.25, 8.54)	0.6767	1.39 (-6.98, 9.76)	0.7455	
Geographic region									NE
EU	0/ 47 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-7.27, 7.27)	1.0000	
non-EU	4/ 80 (5.0)	5.0	4/ 69 (5.8)	6.0	0.86 (0.22, 3.32)	0.8297	-0.95 (-11.22, 9.32)	0.8565	
Onset of disease									NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE		0.00 (-38.51, 38.51)	1.0000	
Adult	4/119 (3.4)	3.3	4/118 (3.4)	3.3	0.99 (0.25, 3.87)	0.9903	0.06 (-7.52, 7.64)	0.9869	
ADA result									0.3961
Negative	3/111 (2.7)	2.6	2/112 (1.8)	1.7	1.51 (0.26, 8.88)	0.6463	0.94 (-6.65, 8.53)	0.8082	
Positive (At any time)	1/ 15 (6.7)	6.7	2/ 13 (15.4)	15.4	0.43 (0.04, 4.25)	0.4727	-8.72 (-38.25, 20.82)	0.5629	
BMI (kg/m2) at enrolment									0.6880
< 30	2/ 74 (2.7)	2.6	3/ 87 (3.4)	3.3	0.78 (0.13, 4.57)	0.7864	-0.70 (-9.39, 7.99)	0.8745	
>= 30	2/ 53 (3.8)	3.7	1/ 38 (2.6)	2.7	1.43 (0.13, 15.25)	0.7651	0.99 (-13.01, 14.99)	0.8900	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Non-opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	0 (0.0)	4 (3.2)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.11 (0.01, 2.01)	
p-value	0.1363	
Odds Ratio (95% CI)	0.11 (0.01, 1.99)	
p-value	0.1334	
Risk Difference (95% CI)	-3.20 (-6.29, -0.11)	
p-value	0.0421	
CMH approach		
Response rate	0.0	3.1
Difference in response rates (95% CI)	-3.13 (-9.85, 3.59)	
p-value	0.3617	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Non-opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Anifrolumab 300mg (N=127) Response rate	Placebo (N=125) n/ N (%)	Placebo (N=125) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.7186
< 10 points	0/ 39 (0.0)	0.0	1/ 37 (2.7)	2.1	0.32 (0.01, 7.54)	0.4771	-2.14 (-17.04, 12.76)	0.7785	
>= 10 points	0/ 88 (0.0)	0.0	3/ 88 (3.4)	3.4	0.14 (0.01, 2.73)	0.1958	-3.38 (-11.09, 4.32)	0.3892	
OCS dose at baseline									0.9518
<10 mg/day	0/ 57 (0.0)	0.0	2/ 52 (3.8)	3.9	0.18 (0.01, 3.72)	0.2690	-3.89 (-15.38, 7.60)	0.5069	
>=10 mg/day	0/ 70 (0.0)	0.0	2/ 73 (2.7)	2.7	0.21 (0.01, 4.27)	0.3087	-2.73 (-11.64, 6.17)	0.5473	
Result of type I IFN gene signature test									0.6599
LOW	0/ 22 (0.0)	0.0	1/ 24 (4.2)	4.2	0.36 (0.02, 8.46)	0.5276	-4.17 (-20.81, 12.48)	0.6237	
HIGH	0/105 (0.0)	0.0	3/101 (3.0)	2.9	0.14 (0.01, 2.63)	0.1875	-2.90 (-10.24, 4.44)	0.4389	
Age (years)									NE
<= 65	0/122 (0.0)	0.0	4/123 (3.3)	3.2	0.11 (0.01, 2.06)	0.1405	-3.15 (-10.04, 3.73)	0.3696	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE		0.00 (-74.81, 74.81)	1.0000	
Sex									0.8319
male	0/ 12 (0.0)	0.0	1/ 8 (12.5)	12.5	0.23 (0.01, 5.05)	0.3517	-12.50 (-47.86, 22.86)	0.4884	
female	0/115 (0.0)	0.0	3/117 (2.6)	2.4	0.15 (0.01, 2.78)	0.2003	-2.43 (-9.50, 4.64)	0.5002	
Race									0.8984
White	0/ 85 (0.0)	0.0	2/ 96 (2.1)	2.3	0.23 (0.01, 4.63)	0.3342	-2.27 (-11.00, 6.46)	0.6101	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE		0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 13 (0.0)	0.0	2/ 11 (18.2)	18.2	0.17 (0.01, 3.23)	0.2392	-18.18 (-49.64, 13.28)	0.2573	
Ethnicity									0.7241
Hispanic/Latino	0/ 23 (0.0)	0.0	3/ 24 (12.5)	12.5	0.15 (0.01, 2.73)	0.1994	-12.50 (-31.19, 6.19)	0.1899	
Non-hispanic/Latino	0/104 (0.0)	0.0	1/101 (1.0)	0.9	0.32 (0.01, 7.86)	0.4883	-0.89 (-8.52, 6.74)	0.8189	
Geographic region									0.5982
EU	0/ 47 (0.0)	0.0	1/ 56 (1.8)	1.8	0.40 (0.02, 9.49)	0.5676	-1.79 (-9.75, 6.18)	0.6602	
non-EU	0/ 80 (0.0)	0.0	3/ 69 (4.3)	4.5	0.12 (0.01, 2.35)	0.1640	-4.47 (-13.69, 4.74)	0.3413	
Onset of disease									0.7336
Paediatric	0/ 8 (0.0)	0.0	1/ 7 (14.3)	14.3	0.30 (0.01, 6.29)	0.4353	-14.29 (-56.18, 27.61)	0.5040	
Adult	0/119 (0.0)	0.0	3/118 (2.5)	2.5	0.14 (0.01, 2.71)	0.1945	-2.50 (-9.45, 4.45)	0.4809	
ADA result									0.7477
Negative	0/111 (0.0)	0.0	3/112 (2.7)	2.6	0.14 (0.01, 2.76)	0.1984	-2.63 (-10.00, 4.74)	0.4842	
Positive (At any time)	0/ 15 (0.0)	0.0	1/ 13 (7.7)	7.7	0.29 (0.01, 6.60)	0.4388	-7.69 (-33.59, 18.20)	0.5604	
BMI (kg/m2) at enrolment									NE
< 30	0/ 74 (0.0)	0.0	4/ 87 (4.6)	4.4	0.13 (0.01, 2.38)	0.1693	-4.40 (-12.79, 3.98)	0.3033	
>= 30	0/ 53 (0.0)	0.0	0/ 38 (0.0)	0.0	NE		0.00 (-12.88, 12.88)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	1 (0.8)	1 (0.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.98 (0.06, 15.56)	
p-value	0.9910	
Odds Ratio (95% CI)	0.98 (0.06, 15.91)	
p-value	0.9910	
Risk Difference (95% CI)	-0.01 (-2.20, 2.18)	
p-value	0.9910	
CMH approach		
Response rate	0.8	0.8
Difference in response rates (95% CI)	-0.00 (-6.49, 6.48)	
p-value	0.9988	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE		0.00 (-14.65, 14.65)	1.0000	
>= 10 points	1/ 88 (1.1)	1.2	1/ 88 (1.1)	1.2	1.00 (0.06, 15.74)	1.0000	-0.01 (-7.50, 7.48)	0.9985	
OCS dose at baseline									0.3104
<10 mg/day	0/ 57 (0.0)	0.0	1/ 52 (1.9)	1.9	0.30 (0.01, 7.32)	0.4636	-1.91 (-13.06, 9.24)	0.7370	
>=10 mg/day	1/ 70 (1.4)	1.5	0/ 73 (0.0)	0.0	3.13 (0.13, 75.49)	0.4828	1.46 (-7.16, 10.08)	0.7402	
Result of type I IFN gene signature test									NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-15.17, 15.17)	1.0000	
HIGH	1/105 (1.0)	1.0	1/101 (1.0)	1.0	0.96 (0.06, 15.17)	0.9780	-0.01 (-7.18, 7.17)	0.9987	
Age (years)									NE
<= 65	1/122 (0.8)	0.8	1/123 (0.8)	0.8	1.01 (0.06, 15.94)	0.9954	0.03 (-6.63, 6.68)	0.9938	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE		0.00 (-74.81, 74.81)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE		0.00 (-31.89, 31.89)	1.0000	
female	1/115 (0.9)	0.9	1/117 (0.9)	0.9	1.02 (0.06, 16.07)	0.9902	0.02 (-6.98, 7.02)	0.9961	
Race									0.3804
White	0/ 85 (0.0)	0.0	0/ 96 (0.0)	0.0	NE		0.00 (-8.35, 8.35)	1.0000	
Black or African American	0/ 22 (0.0)	0.0	1/ 14 (7.1)	7.1	0.22 (0.01, 4.99)	0.3399	-7.14 (-29.62, 15.33)	0.5333	
Asian	1/ 7 (14.3)	14.3	0/ 3 (0.0)	0.0	1.50 (0.08, 29.15)	0.7888	14.29 (-46.56, 75.13)	0.6454	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-26.65, 26.65)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	1/104 (1.0)	1.1	1/101 (1.0)	1.2	0.97 (0.06, 15.32)	0.9834	-0.10 (-8.02, 7.81)	0.9796	
Geographic region									NE
EU	0/ 47 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-7.27, 7.27)	1.0000	
non-EU	1/ 80 (1.3)	1.2	1/ 69 (1.4)	1.5	0.86 (0.05, 13.53)	0.9161	-0.28 (-9.07, 8.52)	0.9507	
Onset of disease									NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE		0.00 (-38.51, 38.51)	1.0000	
Adult	1/119 (0.8)	0.9	1/118 (0.8)	0.8	0.99 (0.06, 15.67)	0.9952	0.04 (-6.80, 6.88)	0.9910	
ADA result									0.3040
Negative	1/111 (0.9)	1.0	0/112 (0.0)	0.0	3.03 (0.12, 73.51)	0.4962	0.98 (-6.14, 8.11)	0.7866	
Positive (At any time)	0/ 15 (0.0)	0.0	1/ 13 (7.7)	7.7	0.29 (0.01, 6.60)	0.4388	-7.69 (-33.59, 18.20)	0.5604	
BMI (kg/m2) at enrolment									0.2424
< 30	1/ 74 (1.4)	1.4	0/ 87 (0.0)	0.0	3.52 (0.15, 85.13)	0.4388	1.37 (-6.48, 9.22)	0.7326	
>= 30	0/ 53 (0.0)	0.0	1/ 38 (2.6)	2.7	0.24 (0.01, 5.75)	0.3792	-2.72 (-16.24, 10.81)	0.6939	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	0 (0.0)	1 (0.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.33 (0.01, 7.98)	
p-value	0.4937	
Odds Ratio (95% CI)	0.33 (0.01, 8.07)	
p-value	0.4932	
Risk Difference (95% CI)	-0.80 (-2.36, 0.76)	
p-value	0.3154	
CMH approach		
Response rate	0.0	0.8
Difference in response rates (95% CI)	-0.83 (-7.15, 5.49)	
p-value	0.7976	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE		0.00 (-14.65, 14.65)	1.0000	
>= 10 points	0/ 88 (0.0)	0.0	1/ 88 (1.1)	1.2	0.33 (0.01, 8.07)	0.4993	-1.18 (-8.37, 6.01)	0.7475	
OCS dose at baseline									NE
<10 mg/day	0/ 57 (0.0)	0.0	1/ 52 (1.9)	1.9	0.30 (0.01, 7.32)	0.4636	-1.91 (-13.06, 9.24)	0.7370	
>=10 mg/day	0/ 70 (0.0)	0.0	0/ 73 (0.0)	0.0	NE		0.00 (-8.22, 8.22)	1.0000	
Result of type I IFN gene signature test									NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-15.17, 15.17)	1.0000	
HIGH	0/105 (0.0)	0.0	1/101 (1.0)	1.0	0.32 (0.01, 7.78)	0.4847	-1.01 (-7.96, 5.94)	0.7753	
Age (years)									NE
<= 65	0/122 (0.0)	0.0	1/123 (0.8)	0.8	0.34 (0.01, 8.17)	0.5030	-0.82 (-7.30, 5.66)	0.8039	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE		0.00 (-74.81, 74.81)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE		0.00 (-31.89, 31.89)	1.0000	
female	0/115 (0.0)	0.0	1/117 (0.9)	0.9	0.34 (0.01, 8.24)	0.5064	-0.90 (-7.71, 5.91)	0.7956	
Race									NE
White	0/ 85 (0.0)	0.0	0/ 96 (0.0)	0.0	NE		0.00 (-8.35, 8.35)	1.0000	
Black or African American	0/ 22 (0.0)	0.0	1/ 14 (7.1)	7.1	0.22 (0.01, 4.99)	0.3399	-7.14 (-29.62, 15.33)	0.5333	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-26.65, 26.65)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	0/104 (0.0)	0.0	1/101 (1.0)	1.2	0.32 (0.01, 7.86)	0.4883	-1.16 (-8.86, 6.54)	0.7680	
Geographic region									NE
EU	0/ 47 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-7.27, 7.27)	1.0000	
non-EU	0/ 80 (0.0)	0.0	1/ 69 (1.4)	1.5	0.29 (0.01, 6.96)	0.4437	-1.49 (-10.02, 7.03)	0.7318	
Onset of disease									NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE		0.00 (-38.51, 38.51)	1.0000	
Adult	0/119 (0.0)	0.0	1/118 (0.8)	0.8	0.33 (0.01, 8.03)	0.4965	-0.85 (-7.51, 5.81)	0.8033	
ADA result									NE
Negative	0/111 (0.0)	0.0	0/112 (0.0)	0.0	NE		0.00 (-6.92, 6.92)	1.0000	
Positive (At any time)	0/ 15 (0.0)	0.0	1/ 13 (7.7)	7.7	0.29 (0.01, 6.60)	0.4388	-7.69 (-33.59, 18.20)	0.5604	
BMI (kg/m2) at enrolment									NE
< 30	0/ 74 (0.0)	0.0	0/ 87 (0.0)	0.0	NE		0.00 (-7.46, 7.46)	1.0000	
>= 30	0/ 53 (0.0)	0.0	1/ 38 (2.6)	2.7	0.24 (0.01, 5.75)	0.3792	-2.72 (-16.24, 10.81)	0.6939	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	0 (0.0)	1 (0.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.33 (0.01, 7.98)	
p-value	0.4937	
Odds Ratio (95% CI)	0.33 (0.01, 8.07)	
p-value	0.4932	
Risk Difference (95% CI)	-0.80 (-2.36, 0.76)	
p-value	0.3154	
CMH approach		
Response rate	0.0	0.8
Difference in response rates (95% CI)	-0.83 (-7.15, 5.49)	
p-value	0.7976	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Opportunistic infection - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=127)		Placebo (N=125)		Analysis Anifrolumab 300mg vs. Placebo			Interaction
Level	n/ N (%)	Response rate	n/ N (%)	Response rate	Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE		0.00 (-14.65, 14.65)	1.0000	
>= 10 points	0/ 88 (0.0)	0.0	1/ 88 (1.1)	1.2	0.33 (0.01, 8.07)	0.4993	-1.18 (-8.37, 6.01)	0.7475	
OCS dose at baseline									NE
<10 mg/day	0/ 57 (0.0)	0.0	1/ 52 (1.9)	1.9	0.30 (0.01, 7.32)	0.4636	-1.91 (-13.06, 9.24)	0.7370	
>=10 mg/day	0/ 70 (0.0)	0.0	0/ 73 (0.0)	0.0	NE		0.00 (-8.22, 8.22)	1.0000	
Result of type I IFN gene signature test									NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-15.17, 15.17)	1.0000	
HIGH	0/105 (0.0)	0.0	1/101 (1.0)	1.0	0.32 (0.01, 7.78)	0.4847	-1.01 (-7.96, 5.94)	0.7753	
Age (years)									NE
<= 65	0/122 (0.0)	0.0	1/123 (0.8)	0.8	0.34 (0.01, 8.17)	0.5030	-0.82 (-7.30, 5.66)	0.8039	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE		0.00 (-74.81, 74.81)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE		0.00 (-31.89, 31.89)	1.0000	
female	0/115 (0.0)	0.0	1/117 (0.9)	0.9	0.34 (0.01, 8.24)	0.5064	-0.90 (-7.71, 5.91)	0.7956	
Race									NE
White	0/ 85 (0.0)	0.0	0/ 96 (0.0)	0.0	NE		0.00 (-8.35, 8.35)	1.0000	
Black or African American	0/ 22 (0.0)	0.0	1/ 14 (7.1)	7.1	0.22 (0.01, 4.99)	0.3399	-7.14 (-29.62, 15.33)	0.5333	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-26.65, 26.65)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	0/104 (0.0)	0.0	1/101 (1.0)	1.2	0.32 (0.01, 7.86)	0.4883	-1.16 (-8.86, 6.54)	0.7680	
Geographic region									NE
EU	0/ 47 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-7.27, 7.27)	1.0000	
non-EU	0/ 80 (0.0)	0.0	1/ 69 (1.4)	1.5	0.29 (0.01, 6.96)	0.4437	-1.49 (-10.02, 7.03)	0.7318	
Onset of disease									NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE		0.00 (-38.51, 38.51)	1.0000	
Adult	0/119 (0.0)	0.0	1/118 (0.8)	0.8	0.33 (0.01, 8.03)	0.4965	-0.85 (-7.51, 5.81)	0.8033	
ADA result									NE
Negative	0/111 (0.0)	0.0	0/112 (0.0)	0.0	NE		0.00 (-6.92, 6.92)	1.0000	
Positive (At any time)	0/ 15 (0.0)	0.0	1/ 13 (7.7)	7.7	0.29 (0.01, 6.60)	0.4388	-7.69 (-33.59, 18.20)	0.5604	
BMI (kg/m2) at enrolment									NE
< 30	0/ 74 (0.0)	0.0	0/ 87 (0.0)	0.0	NE		0.00 (-7.46, 7.46)	1.0000	
>= 30	0/ 53 (0.0)	0.0	1/ 38 (2.6)	2.7	0.24 (0.01, 5.75)	0.3792	-2.72 (-16.24, 10.81)	0.6939	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	1 (0.8)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	2.95 (0.12, 71.81)	
p-value	0.5060	
Odds Ratio (95% CI)	2.98 (0.12, 73.76)	
p-value	0.5055	
Risk Difference (95% CI)	0.79 (-0.75, 2.32)	
p-value	0.3154	
CMH approach		
Response rate	0.8	0.0
Difference in response rates (95% CI)	0.82 (-5.52, 7.16)	
p-value	0.7994	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE		0.00 (-14.65, 14.65)	1.0000	
>= 10 points	1/ 88 (1.1)	1.2	0/ 88 (0.0)	0.0	3.00 (0.12, 72.65)	0.4993	1.17 (-6.05, 8.40)	0.7502	
OCS dose at baseline									NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE		0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	1/ 70 (1.4)	1.5	0/ 73 (0.0)	0.0	3.13 (0.13, 75.49)	0.4828	1.46 (-7.16, 10.08)	0.7402	
Result of type I IFN gene signature test									NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-15.17, 15.17)	1.0000	
HIGH	1/105 (1.0)	1.0	0/101 (0.0)	0.0	2.89 (0.12, 70.05)	0.5147	1.01 (-5.97, 7.98)	0.7775	
Age (years)									NE
<= 65	1/122 (0.8)	0.8	0/123 (0.0)	0.0	3.02 (0.12, 73.52)	0.4966	0.85 (-5.67, 7.36)	0.7987	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE		0.00 (-74.81, 74.81)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE		0.00 (-31.89, 31.89)	1.0000	
female	1/115 (0.9)	0.9	0/117 (0.0)	0.0	3.05 (0.13, 74.15)	0.4931	0.92 (-5.92, 7.76)	0.7926	
Race									NE
White	0/ 85 (0.0)	0.0	0/ 96 (0.0)	0.0	NE		0.00 (-8.35, 8.35)	1.0000	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE		0.00 (-19.87, 19.87)	1.0000	
Asian	1/ 7 (14.3)	14.3	0/ 3 (0.0)	0.0	1.50 (0.08, 29.15)	0.7888	14.29 (-46.56, 75.13)	0.6454	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-26.65, 26.65)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	1/104 (1.0)	1.1	0/101 (0.0)	0.0	2.91 (0.12, 70.71)	0.5109	1.06 (-6.66, 8.77)	0.7884	
Geographic region									NE
EU	0/ 47 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-7.27, 7.27)	1.0000	
non-EU	1/ 80 (1.3)	1.2	0/ 69 (0.0)	0.0	2.59 (0.11, 62.63)	0.5577	1.21 (-7.19, 9.62)	0.7771	
Onset of disease									NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE		0.00 (-38.51, 38.51)	1.0000	
Adult	1/119 (0.8)	0.9	0/118 (0.0)	0.0	2.98 (0.12, 72.30)	0.5030	0.89 (-5.81, 7.58)	0.7954	
ADA result									NE
Negative	1/111 (0.9)	1.0	0/112 (0.0)	0.0	3.03 (0.12, 73.51)	0.4962	0.98 (-6.14, 8.11)	0.7866	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	1/ 74 (1.4)	1.4	0/ 87 (0.0)	0.0	3.52 (0.15, 85.13)	0.4388	1.37 (-6.48, 9.22)	0.7326	
>= 30	0/ 53 (0.0)	0.0	0/ 38 (0.0)	0.0	NE		0.00 (-12.88, 12.88)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	0 (0.0)	2 (1.6)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.20 (0.01, 4.06)	
p-value	0.2926	
Odds Ratio (95% CI)	0.19 (0.01, 4.08)	
p-value	0.2910	
Risk Difference (95% CI)	-1.60 (-3.80, 0.60)	
p-value	0.1540	
CMH approach		
Response rate	0.0	1.6
Difference in response rates (95% CI)	-1.59 (-8.03, 4.85)	
p-value	0.6279	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9822
< 10 points	0/ 39 (0.0)	0.0	1/ 37 (2.7)	2.8	0.32 (0.01, 7.54)	0.4771	-2.76 (-17.98, 12.46)	0.7223	
>= 10 points	0/ 88 (0.0)	0.0	1/ 88 (1.1)	1.1	0.33 (0.01, 8.07)	0.4993	-1.10 (-8.30, 6.09)	0.7643	
OCS dose at baseline									0.9543
<10 mg/day	0/ 57 (0.0)	0.0	1/ 52 (1.9)	1.9	0.30 (0.01, 7.32)	0.4636	-1.90 (-12.96, 9.16)	0.7365	
>=10 mg/day	0/ 70 (0.0)	0.0	1/ 73 (1.4)	1.4	0.35 (0.01, 8.39)	0.5152	-1.37 (-9.94, 7.21)	0.7547	
Result of type I IFN gene signature test									NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-15.17, 15.17)	1.0000	
HIGH	0/105 (0.0)	0.0	2/101 (2.0)	1.9	0.19 (0.01, 3.96)	0.2855	-1.95 (-9.06, 5.16)	0.5912	
Age (years)									NE
<= 65	0/122 (0.0)	0.0	2/123 (1.6)	1.6	0.20 (0.01, 4.16)	0.2997	-1.64 (-8.26, 4.98)	0.6267	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE		0.00 (-74.81, 74.81)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE		0.00 (-31.89, 31.89)	1.0000	
female	0/115 (0.0)	0.0	2/117 (1.7)	1.7	0.20 (0.01, 4.19)	0.3023	-1.71 (-8.64, 5.22)	0.6288	
Race									NE
White	0/ 85 (0.0)	0.0	2/ 96 (2.1)	2.2	0.23 (0.01, 4.63)	0.3342	-2.16 (-10.82, 6.51)	0.6254	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE		0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-26.65, 26.65)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	0/104 (0.0)	0.0	2/101 (2.0)	1.9	0.19 (0.01, 4.00)	0.2883	-1.91 (-9.71, 5.88)	0.6304	
Geographic region									NE
EU	0/ 47 (0.0)	0.0	2/ 56 (3.6)	3.6	0.24 (0.01, 4.83)	0.3495	-3.57 (-12.14, 5.00)	0.4142	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE		0.00 (-8.12, 8.12)	1.0000	
Onset of disease									NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE		0.00 (-38.51, 38.51)	1.0000	
Adult	0/119 (0.0)	0.0	2/118 (1.7)	1.7	0.20 (0.01, 4.09)	0.2947	-1.71 (-8.51, 5.09)	0.6221	
ADA result									NE
Negative	0/111 (0.0)	0.0	2/112 (1.8)	1.8	0.20 (0.01, 4.16)	0.2997	-1.76 (-8.96, 5.44)	0.6315	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment									0.8325
< 30	0/ 74 (0.0)	0.0	1/ 87 (1.1)	1.3	0.39 (0.02, 9.46)	0.5636	-1.34 (-9.06, 6.38)	0.7339	
>= 30	0/ 53 (0.0)	0.0	1/ 38 (2.6)	2.7	0.24 (0.01, 5.75)	0.3792	-2.72 (-16.24, 10.81)	0.6939	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.17, 6.17)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Anifrolumab 300mg (N=127) Response rate	Placebo (N=125) n/ N (%)	Placebo (N=125) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Analysis Anifrolumab 300mg vs. Placebo Difference in response rates (95% CI)	Analysis Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-14.65, 14.65)	1.0000	
>= 10 points	0/ 88 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	0/ 70 (0.0)	0.0	0/ 73 (0.0)	0.0	NE	0.00 (-8.22, 8.22)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-15.17, 15.17)	1.0000	
HIGH	0/105 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-6.74, 6.74)	1.0000	
Age (years)								NE
<= 65	0/122 (0.0)	0.0	0/123 (0.0)	0.0	NE	0.00 (-6.34, 6.34)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE	0.00 (-74.81, 74.81)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE	0.00 (-31.89, 31.89)	1.0000	
female	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-6.65, 6.65)	1.0000	
Race								NE
White	0/ 85 (0.0)	0.0	0/ 96 (0.0)	0.0	NE	0.00 (-8.35, 8.35)	1.0000	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE	0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-26.65, 26.65)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	0/104 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-7.49, 7.49)	1.0000	
Geographic region								NE
EU	0/ 47 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-7.27, 7.27)	1.0000	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-8.12, 8.12)	1.0000	
Onset of disease								NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE	0.00 (-38.51, 38.51)	1.0000	
Adult	0/119 (0.0)	0.0	0/118 (0.0)	0.0	NE	0.00 (-6.51, 6.51)	1.0000	
ADA result								NE
Negative	0/111 (0.0)	0.0	0/112 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 74 (0.0)	0.0	0/ 87 (0.0)	0.0	NE	0.00 (-7.46, 7.46)	1.0000	
>= 30	0/ 53 (0.0)	0.0	0/ 38 (0.0)	0.0	NE	0.00 (-12.88, 12.88)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.17, 6.17)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-14.65, 14.65)	1.0000	
>= 10 points	0/ 88 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	0/ 70 (0.0)	0.0	0/ 73 (0.0)	0.0	NE	0.00 (-8.22, 8.22)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-15.17, 15.17)	1.0000	
HIGH	0/105 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-6.74, 6.74)	1.0000	
Age (years)								NE
<= 65	0/122 (0.0)	0.0	0/123 (0.0)	0.0	NE	0.00 (-6.34, 6.34)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE	0.00 (-74.81, 74.81)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE	0.00 (-31.89, 31.89)	1.0000	
female	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-6.65, 6.65)	1.0000	
Race								NE
White	0/ 85 (0.0)	0.0	0/ 96 (0.0)	0.0	NE	0.00 (-8.35, 8.35)	1.0000	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE	0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-26.65, 26.65)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	0/104 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-7.49, 7.49)	1.0000	
Geographic region								NE
EU	0/ 47 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-7.27, 7.27)	1.0000	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-8.12, 8.12)	1.0000	
Onset of disease								NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE	0.00 (-38.51, 38.51)	1.0000	
Adult	0/119 (0.0)	0.0	0/118 (0.0)	0.0	NE	0.00 (-6.51, 6.51)	1.0000	
ADA result								NE
Negative	0/111 (0.0)	0.0	0/112 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 74 (0.0)	0.0	0/ 87 (0.0)	0.0	NE	0.00 (-7.46, 7.46)	1.0000	
>= 30	0/ 53 (0.0)	0.0	0/ 38 (0.0)	0.0	NE	0.00 (-12.88, 12.88)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	0 (0.0)	2 (1.6)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.20 (0.01, 4.06)	
p-value	0.2926	
Odds Ratio (95% CI)	0.19 (0.01, 4.08)	
p-value	0.2910	
Risk Difference (95% CI)	-1.60 (-3.80, 0.60)	
p-value	0.1540	
CMH approach		
Response rate	0.0	1.6
Difference in response rates (95% CI)	-1.59 (-8.03, 4.85)	
p-value	0.6279	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Anifrolumab 300mg (N=127) Response rate	Placebo (N=125) n/ N (%)	Placebo (N=125) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9822
< 10 points	0/ 39 (0.0)	0.0	1/ 37 (2.7)	2.8	0.32 (0.01, 7.54)	0.4771	-2.76 (-17.98, 12.46)	0.7223	
>= 10 points	0/ 88 (0.0)	0.0	1/ 88 (1.1)	1.1	0.33 (0.01, 8.07)	0.4993	-1.10 (-8.30, 6.09)	0.7643	
OCS dose at baseline									0.9543
<10 mg/day	0/ 57 (0.0)	0.0	1/ 52 (1.9)	1.9	0.30 (0.01, 7.32)	0.4636	-1.90 (-12.96, 9.16)	0.7365	
>=10 mg/day	0/ 70 (0.0)	0.0	1/ 73 (1.4)	1.4	0.35 (0.01, 8.39)	0.5152	-1.37 (-9.94, 7.21)	0.7547	
Result of type I IFN gene signature test									NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-15.17, 15.17)	1.0000	
HIGH	0/105 (0.0)	0.0	2/101 (2.0)	1.9	0.19 (0.01, 3.96)	0.2855	-1.95 (-9.06, 5.16)	0.5912	
Age (years)									NE
<= 65	0/122 (0.0)	0.0	2/123 (1.6)	1.6	0.20 (0.01, 4.16)	0.2997	-1.64 (-8.26, 4.98)	0.6267	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE		0.00 (-74.81, 74.81)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE		0.00 (-31.89, 31.89)	1.0000	
female	0/115 (0.0)	0.0	2/117 (1.7)	1.7	0.20 (0.01, 4.19)	0.3023	-1.71 (-8.64, 5.22)	0.6288	
Race									NE
White	0/ 85 (0.0)	0.0	2/ 96 (2.1)	2.2	0.23 (0.01, 4.63)	0.3342	-2.16 (-10.82, 6.51)	0.6254	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE		0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-26.65, 26.65)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	0/104 (0.0)	0.0	2/101 (2.0)	1.9	0.19 (0.01, 4.00)	0.2883	-1.91 (-9.71, 5.88)	0.6304	
Geographic region									NE
EU	0/ 47 (0.0)	0.0	2/ 56 (3.6)	3.6	0.24 (0.01, 4.83)	0.3495	-3.57 (-12.14, 5.00)	0.4142	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE		0.00 (-8.12, 8.12)	1.0000	
Onset of disease									NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE		0.00 (-38.51, 38.51)	1.0000	
Adult	0/119 (0.0)	0.0	2/118 (1.7)	1.7	0.20 (0.01, 4.09)	0.2947	-1.71 (-8.51, 5.09)	0.6221	
ADA result									NE
Negative	0/111 (0.0)	0.0	2/112 (1.8)	1.8	0.20 (0.01, 4.16)	0.2997	-1.76 (-8.96, 5.44)	0.6315	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment									0.8325
< 30	0/ 74 (0.0)	0.0	1/ 87 (1.1)	1.3	0.39 (0.02, 9.46)	0.5636	-1.34 (-9.06, 6.38)	0.7339	
>= 30	0/ 53 (0.0)	0.0	1/ 38 (2.6)	2.7	0.24 (0.01, 5.75)	0.3792	-2.72 (-16.24, 10.81)	0.6939	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Vasculitis
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.17, 6.17)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Anifrolumab 300mg (N=127) Response rate	Placebo (N=125) n/ N (%)	Placebo (N=125) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Analysis Anifrolumab 300mg vs. Placebo Difference in response rates (95% CI)	Analysis Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-14.65, 14.65)	1.0000	
>= 10 points	0/ 88 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	0/ 70 (0.0)	0.0	0/ 73 (0.0)	0.0	NE	0.00 (-8.22, 8.22)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-15.17, 15.17)	1.0000	
HIGH	0/105 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-6.74, 6.74)	1.0000	
Age (years)								NE
<= 65	0/122 (0.0)	0.0	0/123 (0.0)	0.0	NE	0.00 (-6.34, 6.34)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE	0.00 (-74.81, 74.81)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE	0.00 (-31.89, 31.89)	1.0000	
female	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-6.65, 6.65)	1.0000	
Race								NE
White	0/ 85 (0.0)	0.0	0/ 96 (0.0)	0.0	NE	0.00 (-8.35, 8.35)	1.0000	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE	0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-26.65, 26.65)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	0/104 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-7.49, 7.49)	1.0000	
Geographic region								NE
EU	0/ 47 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-7.27, 7.27)	1.0000	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-8.12, 8.12)	1.0000	
Onset of disease								NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE	0.00 (-38.51, 38.51)	1.0000	
Adult	0/119 (0.0)	0.0	0/118 (0.0)	0.0	NE	0.00 (-6.51, 6.51)	1.0000	
ADA result								NE
Negative	0/111 (0.0)	0.0	0/112 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 74 (0.0)	0.0	0/ 87 (0.0)	0.0	NE	0.00 (-7.46, 7.46)	1.0000	
>= 30	0/ 53 (0.0)	0.0	0/ 38 (0.0)	0.0	NE	0.00 (-12.88, 12.88)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Vasculitis
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.17, 6.17)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Anifrolumab 300mg (N=127) Response rate	Placebo (N=125) n/ N (%)	Placebo (N=125) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Analysis Anifrolumab 300mg vs. Placebo Difference in response rates (95% CI)	Analysis Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-14.65, 14.65)	1.0000	
>= 10 points	0/ 88 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	0/ 70 (0.0)	0.0	0/ 73 (0.0)	0.0	NE	0.00 (-8.22, 8.22)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-15.17, 15.17)	1.0000	
HIGH	0/105 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-6.74, 6.74)	1.0000	
Age (years)								NE
<= 65	0/122 (0.0)	0.0	0/123 (0.0)	0.0	NE	0.00 (-6.34, 6.34)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE	0.00 (-74.81, 74.81)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE	0.00 (-31.89, 31.89)	1.0000	
female	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-6.65, 6.65)	1.0000	
Race								NE
White	0/ 85 (0.0)	0.0	0/ 96 (0.0)	0.0	NE	0.00 (-8.35, 8.35)	1.0000	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE	0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-26.65, 26.65)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	0/104 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-7.49, 7.49)	1.0000	
Geographic region								NE
EU	0/ 47 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-7.27, 7.27)	1.0000	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-8.12, 8.12)	1.0000	
Onset of disease								NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE	0.00 (-38.51, 38.51)	1.0000	
Adult	0/119 (0.0)	0.0	0/118 (0.0)	0.0	NE	0.00 (-6.51, 6.51)	1.0000	
ADA result								NE
Negative	0/111 (0.0)	0.0	0/112 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 74 (0.0)	0.0	0/ 87 (0.0)	0.0	NE	0.00 (-7.46, 7.46)	1.0000	
>= 30	0/ 53 (0.0)	0.0	0/ 38 (0.0)	0.0	NE	0.00 (-12.88, 12.88)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Vasculitis
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.17, 6.17)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Anifrolumab 300mg (N=127) Response rate	Placebo (N=125) n/ N (%)	Placebo (N=125) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Analysis Anifrolumab 300mg vs. Placebo Difference in response rates (95% CI)	Analysis Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-14.65, 14.65)	1.0000	
>= 10 points	0/ 88 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	0/ 70 (0.0)	0.0	0/ 73 (0.0)	0.0	NE	0.00 (-8.22, 8.22)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-15.17, 15.17)	1.0000	
HIGH	0/105 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-6.74, 6.74)	1.0000	
Age (years)								NE
<= 65	0/122 (0.0)	0.0	0/123 (0.0)	0.0	NE	0.00 (-6.34, 6.34)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE	0.00 (-74.81, 74.81)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE	0.00 (-31.89, 31.89)	1.0000	
female	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-6.65, 6.65)	1.0000	
Race								NE
White	0/ 85 (0.0)	0.0	0/ 96 (0.0)	0.0	NE	0.00 (-8.35, 8.35)	1.0000	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE	0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-26.65, 26.65)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	0/104 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-7.49, 7.49)	1.0000	
Geographic region								NE
EU	0/ 47 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-7.27, 7.27)	1.0000	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-8.12, 8.12)	1.0000	
Onset of disease								NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE	0.00 (-38.51, 38.51)	1.0000	
Adult	0/119 (0.0)	0.0	0/118 (0.0)	0.0	NE	0.00 (-6.51, 6.51)	1.0000	
ADA result								NE
Negative	0/111 (0.0)	0.0	0/112 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 74 (0.0)	0.0	0/ 87 (0.0)	0.0	NE	0.00 (-7.46, 7.46)	1.0000	
>= 30	0/ 53 (0.0)	0.0	0/ 38 (0.0)	0.0	NE	0.00 (-12.88, 12.88)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Vasculitis
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.17, 6.17)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-14.65, 14.65)	1.0000	
>= 10 points	0/ 88 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	0/ 70 (0.0)	0.0	0/ 73 (0.0)	0.0	NE	0.00 (-8.22, 8.22)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-15.17, 15.17)	1.0000	
HIGH	0/105 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-6.74, 6.74)	1.0000	
Age (years)								NE
<= 65	0/122 (0.0)	0.0	0/123 (0.0)	0.0	NE	0.00 (-6.34, 6.34)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE	0.00 (-74.81, 74.81)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE	0.00 (-31.89, 31.89)	1.0000	
female	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-6.65, 6.65)	1.0000	
Race								NE
White	0/ 85 (0.0)	0.0	0/ 96 (0.0)	0.0	NE	0.00 (-8.35, 8.35)	1.0000	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE	0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-26.65, 26.65)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	0/104 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-7.49, 7.49)	1.0000	
Geographic region								NE
EU	0/ 47 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-7.27, 7.27)	1.0000	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-8.12, 8.12)	1.0000	
Onset of disease								NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE	0.00 (-38.51, 38.51)	1.0000	
Adult	0/119 (0.0)	0.0	0/118 (0.0)	0.0	NE	0.00 (-6.51, 6.51)	1.0000	
ADA result								NE
Negative	0/111 (0.0)	0.0	0/112 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 74 (0.0)	0.0	0/ 87 (0.0)	0.0	NE	0.00 (-7.46, 7.46)	1.0000	
>= 30	0/ 53 (0.0)	0.0	0/ 38 (0.0)	0.0	NE	0.00 (-12.88, 12.88)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Malignancy
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	1 (0.8)	1 (0.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.98 (0.06, 15.56)	
p-value	0.9910	
Odds Ratio (95% CI)	0.98 (0.06, 15.91)	
p-value	0.9910	
Risk Difference (95% CI)	-0.01 (-2.20, 2.18)	
p-value	0.9910	
CMH approach		
Response rate	0.7	0.8
Difference in response rates (95% CI)	-0.08 (-6.49, 6.33)	
p-value	0.9804	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.3494
< 10 points	1/ 39 (2.6)	2.3	0/ 37 (0.0)	0.0	2.85 (0.12, 67.83)	0.5172	2.32 (-12.76, 17.39)	0.7633	
>= 10 points	0/ 88 (0.0)	0.0	1/ 88 (1.1)	1.1	0.33 (0.01, 8.07)	0.4993	-1.10 (-8.30, 6.09)	0.7643	
OCS dose at baseline									NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE		0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	1/ 70 (1.4)	1.2	1/ 73 (1.4)	1.4	1.04 (0.07, 16.35)	0.9762	-0.14 (-8.92, 8.64)	0.9746	
Result of type I IFN gene signature test									NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-15.17, 15.17)	1.0000	
HIGH	1/105 (1.0)	0.8	1/101 (1.0)	0.9	0.96 (0.06, 15.17)	0.9780	-0.10 (-7.17, 6.97)	0.9782	
Age (years)									NE
<= 65	1/122 (0.8)	0.7	1/123 (0.8)	0.8	1.01 (0.06, 15.94)	0.9954	-0.12 (-6.69, 6.46)	0.9727	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE		0.00 (-74.81, 74.81)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE		0.00 (-31.89, 31.89)	1.0000	
female	1/115 (0.9)	0.8	1/117 (0.9)	0.8	1.02 (0.06, 16.07)	0.9902	-0.04 (-6.94, 6.86)	0.9900	
Race									NE
White	1/ 85 (1.2)	1.3	1/ 96 (1.0)	0.9	1.13 (0.07, 17.78)	0.9310	0.41 (-8.26, 9.08)	0.9259	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE		0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-26.65, 26.65)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	1/104 (1.0)	0.8	1/101 (1.0)	0.9	0.97 (0.06, 15.32)	0.9834	-0.15 (-7.90, 7.60)	0.9699	
Geographic region									NE
EU	1/ 47 (2.1)	2.1	1/ 56 (1.8)	1.8	1.19 (0.08, 18.54)	0.9004	0.34 (-8.48, 9.16)	0.9394	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE		0.00 (-8.12, 8.12)	1.0000	
Onset of disease									NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE		0.00 (-38.51, 38.51)	1.0000	
Adult	1/119 (0.8)	0.8	1/118 (0.8)	0.8	0.99 (0.06, 15.67)	0.9952	-0.05 (-6.82, 6.71)	0.9874	
ADA result									NE
Negative	1/111 (0.9)	0.7	1/112 (0.9)	0.8	1.01 (0.06, 15.93)	0.9949	-0.09 (-7.24, 7.07)	0.9809	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	1/ 74 (1.4)	1.2	1/ 87 (1.1)	1.2	1.18 (0.07, 18.47)	0.9083	0.03 (-7.93, 7.99)	0.9942	
>= 30	0/ 53 (0.0)	0.0	0/ 38 (0.0)	0.0	NE		0.00 (-12.88, 12.88)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Malignancy
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	1 (0.8)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	2.95 (0.12, 71.81)	
p-value	0.5060	
Odds Ratio (95% CI)	2.98 (0.12, 73.76)	
p-value	0.5055	
Risk Difference (95% CI)	0.79 (-0.75, 2.32)	
p-value	0.3154	
CMH approach		
Response rate	0.7	0.0
Difference in response rates (95% CI)	0.69 (-5.57, 6.95)	
p-value	0.8289	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Anifrolumab 300mg (N=127) Response rate	Placebo (N=125) n/ N (%)	Placebo (N=125) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	1/ 39 (2.6)	2.3	0/ 37 (0.0)	0.0	2.85 (0.12, 67.83)	0.5172	2.32 (-12.76, 17.39)	0.7633	
>= 10 points	0/ 88 (0.0)	0.0	0/ 88 (0.0)	0.0	NE		0.00 (-6.92, 6.92)	1.0000	
OCS dose at baseline									NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE		0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	1/ 70 (1.4)	1.2	0/ 73 (0.0)	0.0	3.13 (0.13, 75.49)	0.4828	1.22 (-7.21, 9.66)	0.7760	
Result of type I IFN gene signature test									NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-15.17, 15.17)	1.0000	
HIGH	1/105 (1.0)	0.8	0/101 (0.0)	0.0	2.89 (0.12, 70.05)	0.5147	0.84 (-6.02, 7.71)	0.8095	
Age (years)									NE
<= 65	1/122 (0.8)	0.7	0/123 (0.0)	0.0	3.02 (0.12, 73.52)	0.4966	0.68 (-5.74, 7.10)	0.8358	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE		0.00 (-74.81, 74.81)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE		0.00 (-31.89, 31.89)	1.0000	
female	1/115 (0.9)	0.8	0/117 (0.0)	0.0	3.05 (0.13, 74.15)	0.4931	0.77 (-5.98, 7.52)	0.8231	
Race									NE
White	1/ 85 (1.2)	1.3	0/ 96 (0.0)	0.0	3.38 (0.14, 81.97)	0.4535	1.35 (-7.17, 9.86)	0.7567	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE		0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-26.65, 26.65)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	1/104 (1.0)	0.8	0/101 (0.0)	0.0	2.91 (0.12, 70.71)	0.5109	0.77 (-6.80, 8.35)	0.8411	
Geographic region									NE
EU	1/ 47 (2.1)	2.1	0/ 56 (0.0)	0.0	3.56 (0.15, 85.45)	0.4332	2.13 (-6.08, 10.33)	0.6114	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE		0.00 (-8.12, 8.12)	1.0000	
Onset of disease									NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE		0.00 (-38.51, 38.51)	1.0000	
Adult	1/119 (0.8)	0.8	0/118 (0.0)	0.0	2.98 (0.12, 72.30)	0.5030	0.75 (-5.85, 7.36)	0.8234	
ADA result									NE
Negative	1/111 (0.9)	0.7	0/112 (0.0)	0.0	3.03 (0.12, 73.51)	0.4962	0.74 (-6.27, 7.74)	0.8368	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	1/ 74 (1.4)	1.2	0/ 87 (0.0)	0.0	3.52 (0.15, 85.13)	0.4388	1.18 (-6.50, 8.86)	0.7628	
>= 30	0/ 53 (0.0)	0.0	0/ 38 (0.0)	0.0	NE		0.00 (-12.88, 12.88)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Malignancy
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.17, 6.17)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Anifrolumab 300mg (N=127) Response rate	Placebo (N=125) n/ N (%)	Placebo (N=125) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Analysis Anifrolumab 300mg vs. Placebo Difference in response rates (95% CI)	Analysis Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-14.65, 14.65)	1.0000	
>= 10 points	0/ 88 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	0/ 70 (0.0)	0.0	0/ 73 (0.0)	0.0	NE	0.00 (-8.22, 8.22)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-15.17, 15.17)	1.0000	
HIGH	0/105 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-6.74, 6.74)	1.0000	
Age (years)								NE
<= 65	0/122 (0.0)	0.0	0/123 (0.0)	0.0	NE	0.00 (-6.34, 6.34)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE	0.00 (-74.81, 74.81)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE	0.00 (-31.89, 31.89)	1.0000	
female	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-6.65, 6.65)	1.0000	
Race								NE
White	0/ 85 (0.0)	0.0	0/ 96 (0.0)	0.0	NE	0.00 (-8.35, 8.35)	1.0000	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE	0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-26.65, 26.65)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	0/104 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-7.49, 7.49)	1.0000	
Geographic region								NE
EU	0/ 47 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-7.27, 7.27)	1.0000	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-8.12, 8.12)	1.0000	
Onset of disease								NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE	0.00 (-38.51, 38.51)	1.0000	
Adult	0/119 (0.0)	0.0	0/118 (0.0)	0.0	NE	0.00 (-6.51, 6.51)	1.0000	
ADA result								NE
Negative	0/111 (0.0)	0.0	0/112 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 74 (0.0)	0.0	0/ 87 (0.0)	0.0	NE	0.00 (-7.46, 7.46)	1.0000	
>= 30	0/ 53 (0.0)	0.0	0/ 38 (0.0)	0.0	NE	0.00 (-12.88, 12.88)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Malignancy
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	1 (0.8)	1 (0.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.98 (0.06, 15.56)	
p-value	0.9910	
Odds Ratio (95% CI)	0.98 (0.06, 15.91)	
p-value	0.9910	
Risk Difference (95% CI)	-0.01 (-2.20, 2.18)	
p-value	0.9910	
CMH approach		
Response rate	0.7	0.8
Difference in response rates (95% CI)	-0.08 (-6.49, 6.33)	
p-value	0.9804	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.3494
< 10 points	1/ 39 (2.6)	2.3	0/ 37 (0.0)	0.0	2.85 (0.12, 67.83)	0.5172	2.32 (-12.76, 17.39)	0.7633	
>= 10 points	0/ 88 (0.0)	0.0	1/ 88 (1.1)	1.1	0.33 (0.01, 8.07)	0.4993	-1.10 (-8.30, 6.09)	0.7643	
OCS dose at baseline									NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE		0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	1/ 70 (1.4)	1.2	1/ 73 (1.4)	1.4	1.04 (0.07, 16.35)	0.9762	-0.14 (-8.92, 8.64)	0.9746	
Result of type I IFN gene signature test									NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-15.17, 15.17)	1.0000	
HIGH	1/105 (1.0)	0.8	1/101 (1.0)	0.9	0.96 (0.06, 15.17)	0.9780	-0.10 (-7.17, 6.97)	0.9782	
Age (years)									NE
<= 65	1/122 (0.8)	0.7	1/123 (0.8)	0.8	1.01 (0.06, 15.94)	0.9954	-0.12 (-6.69, 6.46)	0.9727	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE		0.00 (-74.81, 74.81)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE		0.00 (-31.89, 31.89)	1.0000	
female	1/115 (0.9)	0.8	1/117 (0.9)	0.8	1.02 (0.06, 16.07)	0.9902	-0.04 (-6.94, 6.86)	0.9900	
Race									NE
White	1/ 85 (1.2)	1.3	1/ 96 (1.0)	0.9	1.13 (0.07, 17.78)	0.9310	0.41 (-8.26, 9.08)	0.9259	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE		0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-26.65, 26.65)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	1/104 (1.0)	0.8	1/101 (1.0)	0.9	0.97 (0.06, 15.32)	0.9834	-0.15 (-7.90, 7.60)	0.9699	
Geographic region									NE
EU	1/ 47 (2.1)	2.1	1/ 56 (1.8)	1.8	1.19 (0.08, 18.54)	0.9004	0.34 (-8.48, 9.16)	0.9394	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE		0.00 (-8.12, 8.12)	1.0000	
Onset of disease									NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE		0.00 (-38.51, 38.51)	1.0000	
Adult	1/119 (0.8)	0.8	1/118 (0.8)	0.8	0.99 (0.06, 15.67)	0.9952	-0.05 (-6.82, 6.71)	0.9874	
ADA result									NE
Negative	1/111 (0.9)	0.7	1/112 (0.9)	0.8	1.01 (0.06, 15.93)	0.9949	-0.09 (-7.24, 7.07)	0.9809	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	1/ 74 (1.4)	1.2	1/ 87 (1.1)	1.2	1.18 (0.07, 18.47)	0.9083	0.03 (-7.93, 7.99)	0.9942	
>= 30	0/ 53 (0.0)	0.0	0/ 38 (0.0)	0.0	NE		0.00 (-12.88, 12.88)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of SOCs Cardiac disorders and/or Vascular disorders
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	5 (3.9)	17 (13.6)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.29 (0.11, 0.76)	
p-value	0.0119	
Odds Ratio (95% CI)	0.26 (0.09, 0.73)	
p-value	0.0105	
Risk Difference (95% CI)	-9.66 (-16.56, -2.77)	
p-value	0.0060	
CMH approach		
Response rate	4.0	13.6
Difference in response rates (95% CI)	-9.55 (-18.10, -1.01)	
p-value	0.0285	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of SOCs Cardiac disorders and/or Vascular disorders - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.4891
< 10 points	2/ 39 (5.1)	5.2	4/ 37 (10.8)	11.6	0.47 (0.09, 2.44)	0.3718	-6.40 (-24.00, 11.20)	0.4759	
>= 10 points	3/ 88 (3.4)	3.4	13/ 88 (14.8)	14.5	0.23 (0.07, 0.78)	0.0185	-11.10 (-21.15, -1.05)	0.0305	
OCS dose at baseline									0.7430
<10 mg/day	2/ 57 (3.5)	3.6	5/ 52 (9.6)	9.6	0.36 (0.07, 1.80)	0.2158	-6.04 (-19.07, 6.99)	0.3637	
>=10 mg/day	3/ 70 (4.3)	4.6	12/ 73 (16.4)	16.9	0.26 (0.08, 0.88)	0.0311	-12.26 (-24.23, -0.29)	0.0446	
Result of type I IFN gene signature test									0.3086
LOW	1/ 22 (4.5)	4.5	1/ 24 (4.2)	4.2	1.09 (0.07, 16.41)	0.9498	0.38 (-17.82, 18.58)	0.9675	
HIGH	4/105 (3.8)	3.9	16/101 (15.8)	15.7	0.24 (0.08, 0.69)	0.0085	-11.78 (-21.41, -2.14)	0.0166	
Age (years)									NE
<= 65	5/122 (4.1)	4.2	17/123 (13.8)	13.9	0.30 (0.11, 0.78)	0.0136	-9.77 (-18.54, -0.99)	0.0292	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE		0.00 (-74.81, 74.81)	1.0000	
Sex									0.5048
male	1/ 12 (8.3)	8.3	1/ 8 (12.5)	12.5	0.67 (0.05, 9.19)	0.7620	-4.17 (-41.42, 33.09)	0.8265	
female	4/115 (3.5)	3.5	16/117 (13.7)	13.5	0.25 (0.09, 0.74)	0.0118	-9.99 (-18.91, -1.06)	0.0283	
Race									0.7053
White	4/ 85 (4.7)	4.8	13/ 96 (13.5)	13.1	0.35 (0.12, 1.03)	0.0555	-8.30 (-18.94, 2.34)	0.1264	
Black or African American	1/ 22 (4.5)	4.5	1/ 14 (7.1)	7.1	0.64 (0.04, 9.37)	0.7419	-2.60 (-26.25, 21.05)	0.8296	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 13 (0.0)	0.0	3/ 11 (27.3)	27.3	0.12 (0.01, 2.14)	0.1503	-27.27 (-60.18, 5.63)	0.1043	
Ethnicity									0.5498
Hispanic/Latino	1/ 23 (4.3)	4.3	6/ 24 (25.0)	25.0	0.17 (0.02, 1.34)	0.0926	-20.65 (-42.82, 1.52)	0.0679	
Non-hispanic/Latino	4/104 (3.8)	4.2	11/101 (10.9)	10.8	0.35 (0.12, 1.07)	0.0664	-6.60 (-16.15, 2.94)	0.1751	
Geographic region									0.4276
EU	1/ 47 (2.1)	2.1	8/ 56 (14.3)	14.3	0.15 (0.02, 1.15)	0.0676	-12.16 (-24.01, -0.30)	0.0444	
non-EU	4/ 80 (5.0)	5.1	9/ 69 (13.0)	13.1	0.38 (0.12, 1.19)	0.0972	-7.99 (-19.43, 3.44)	0.1705	
Onset of disease									0.6898
Paediatric	0/ 8 (0.0)	0.0	2/ 7 (28.6)	28.6	0.18 (0.01, 3.18)	0.2403	-28.57 (-72.58, 15.44)	0.2032	
Adult	5/119 (4.2)	4.2	15/118 (12.7)	12.6	0.33 (0.12, 0.88)	0.0268	-8.39 (-17.19, 0.42)	0.0618	
ADA result									0.1527
Negative	4/111 (3.6)	3.8	17/112 (15.2)	15.0	0.24 (0.08, 0.68)	0.0077	-11.22 (-20.60, -1.85)	0.0190	
Positive (At any time)	1/ 15 (6.7)	6.7	0/ 13 (0.0)	0.0	2.63 (0.12, 59.40)	0.5442	6.67 (-18.77, 32.11)	0.6075	
BMI (kg/m2) at enrolment									0.0534
< 30	0/ 74 (0.0)	0.0	13/ 87 (14.9)	15.3	0.04 (0.00, 0.72)	0.0285	-15.34 (-25.43, -5.25)	0.0029	
>= 30	5/ 53 (9.4)	9.5	4/ 38 (10.5)	10.6	0.90 (0.26, 3.12)	0.8633	-1.11 (-17.39, 15.16)	0.8933	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Time to first Onset of Herpes Zoster (on-treatment)
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	5 (3.9)	2 (1.6)
Number of censored subjects, n (%)	122 (96.1)	123 (98.4)
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Anifrolumab 300mg vs. Placebo (adjusted)		
Hazard Ratio (95% CI)	2.42 (0.47, 12.49)	
p-value	0.2923	
Analysis Anifrolumab 300mg vs. Placebo (unadjusted)		
Hazard Ratio (95% CI)	2.48 (0.48, 12.76)	
p-value	0.2623	

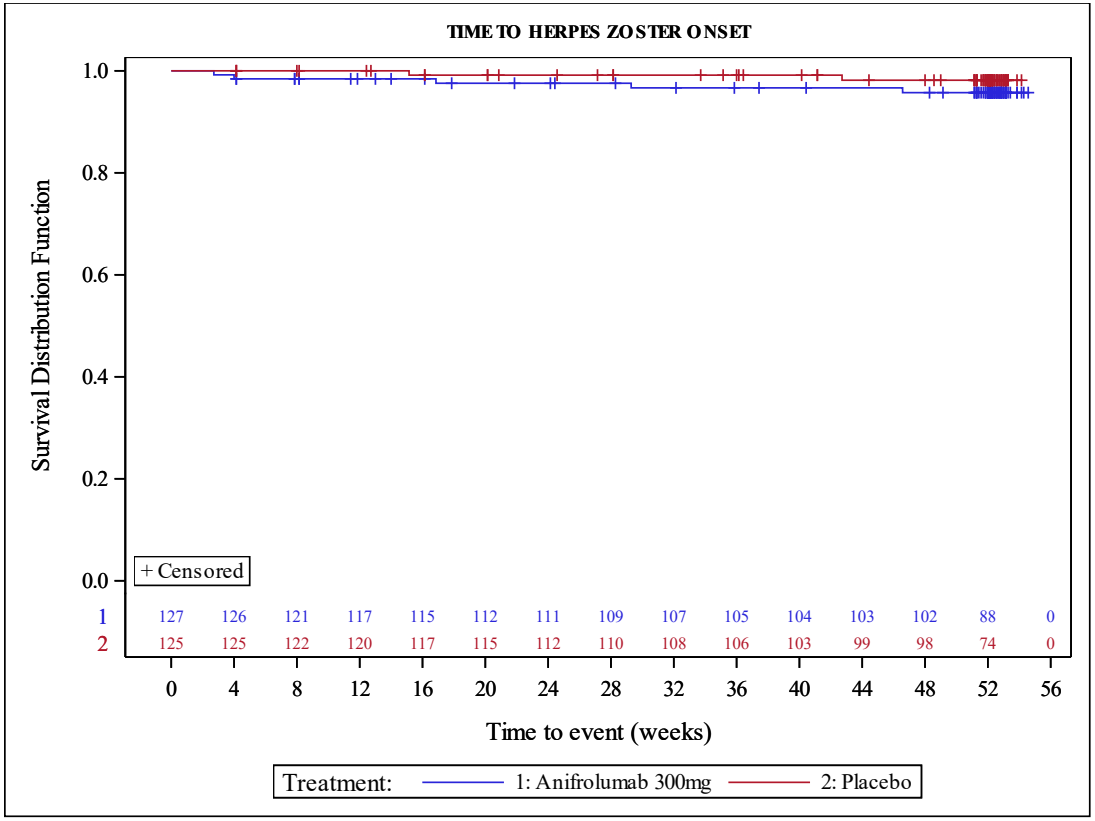
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model. Adjusted analysis also includes stratification factors in the model.
Two-sided log rank test used.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Time to first Onset of Herpes Zoster (on-treatment) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Anifrolumab 300mg (N=127) Median (95% CI)	Placebo (N=125) n/ N (%)	Placebo (N=125) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening							0.4387
< 10 points	1/ 39 (2.6)	NE (NE, NE)	1/ 37 (2.7)	NE (NE, NE)	0.97 (0.06, 15.49)	0.9818	
>= 10 points	4/ 88 (4.5)	NE (NE, NE)	1/ 88 (1.1)	NE (NE, NE)	4.06 (0.45, 36.46)	0.2070	
OCS dose at baseline							0.8572
<10 mg/day	3/ 57 (5.3)	NE (NE, NE)	1/ 52 (1.9)	NE (NE, NE)	2.86 (0.30, 27.58)	0.3849	
>=10 mg/day	2/ 70 (2.9)	NE (NE, NE)	1/ 73 (1.4)	NE (NE, NE)	2.07 (0.19, 22.84)	0.5449	
Result of type I IFN gene signature test							0.9948
LOW	1/ 22 (4.5)	NE (NE, NE)	0/ 24 (0.0)	NE (NE, NE)	NE		
HIGH	4/105 (3.8)	NE (NE, NE)	2/101 (2.0)	NE (NE, NE)	1.89 (0.35, 10.30)	0.4246	
Age (years)							0.9998
<= 65	5/122 (4.1)	NE (NE, NE)	2/123 (1.6)	NE (NE, NE)	2.49 (0.48, 12.87)	0.2972	
> 65	0/ 5 (0.0)	NE (NE, NE)	0/ 2 (0.0)	NE (NE, NE)	NE		
Sex							0.9951
male	2/ 12 (16.7)	NE (46.57, NE)	0/ 8 (0.0)	NE (NE, NE)	NE		
female	3/115 (2.6)	NE (NE, NE)	2/117 (1.7)	NE (NE, NE)	1.53 (0.25, 9.18)	0.6680	
Race							1.0000
White	4/ 85 (4.7)	NE (NE, NE)	2/ 96 (2.1)	NE (NE, NE)	2.13 (0.39, 11.74)	0.4194	
Black or African American	0/ 22 (0.0)	NE (NE, NE)	0/ 14 (0.0)	NE (NE, NE)	NE		
Asian	0/ 7 (0.0)	NE (NE, NE)	0/ 3 (0.0)	NE (NE, NE)	NE		
American Indian or Alaska Native	0	NE (NE, NE)	0/ 1 (0.0)	NE (NE, NE)	NE		
Other	1/ 13 (7.7)	NE (NE, NE)	0/ 11 (0.0)	NE (NE, NE)	NE		
Ethnicity							0.9998
Hispanic/Latino	0/ 23 (0.0)	NE (NE, NE)	0/ 24 (0.0)	NE (NE, NE)	NE		
Non-hispanic/Latino	5/104 (4.8)	NE (NE, NE)	2/101 (2.0)	NE (NE, NE)	2.29 (0.44, 11.86)	0.2968	
Geographic region							0.8833
EU	2/ 47 (4.3)	NE (NE, NE)	1/ 56 (1.8)	NE (NE, NE)	2.76 (0.25, 30.55)	0.3866	
non-EU	3/ 80 (3.8)	NE (NE, NE)	1/ 69 (1.4)	NE (NE, NE)	2.99 (0.31, 28.89)	0.3679	
Onset of disease							0.9950
Paediatric	1/ 8 (12.5)	NE (46.57, NE)	0/ 7 (0.0)	NE (NE, NE)	NE		
Adult	4/119 (3.4)	NE (NE, NE)	2/118 (1.7)	NE (NE, NE)	1.95 (0.36, 10.65)	0.4718	
ADA result							0.9998
Negative	5/111 (4.5)	NE (NE, NE)	2/112 (1.8)	NE (NE, NE)	2.45 (0.47, 12.67)	0.2687	
Positive (At any time)	0/ 15 (0.0)	NE (NE, NE)	0/ 13 (0.0)	NE (NE, NE)	NE		
BMI (kg/m2) at enrolment							0.3274
< 30	4/ 74 (5.4)	NE (NE, NE)	1/ 87 (1.1)	NE (NE, NE)	5.07 (0.56, 45.88)	0.1085	
>= 30	1/ 53 (1.9)	NE (NE, NE)	1/ 38 (2.6)	NE (NE, NE)	0.90 (0.06, 14.51)	0.9435	

Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of Time to first Onset of Herpes Zoster (on-treatment)
Full analysis set



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Time to first Onset of non-opportunistic serious infection (on-treatment)
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	4 (3.1)	5 (4.0)
Number of censored subjects, n (%)	123 (96.9)	120 (96.0)
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Anifrolumab 300mg vs. Placebo (adjusted)		
Hazard Ratio (95% CI)	0.77 (0.21, 2.90)	
p-value	0.5546	
Analysis Anifrolumab 300mg vs. Placebo (unadjusted)		
Hazard Ratio (95% CI)	0.76 (0.21, 2.85)	
p-value	0.6876	

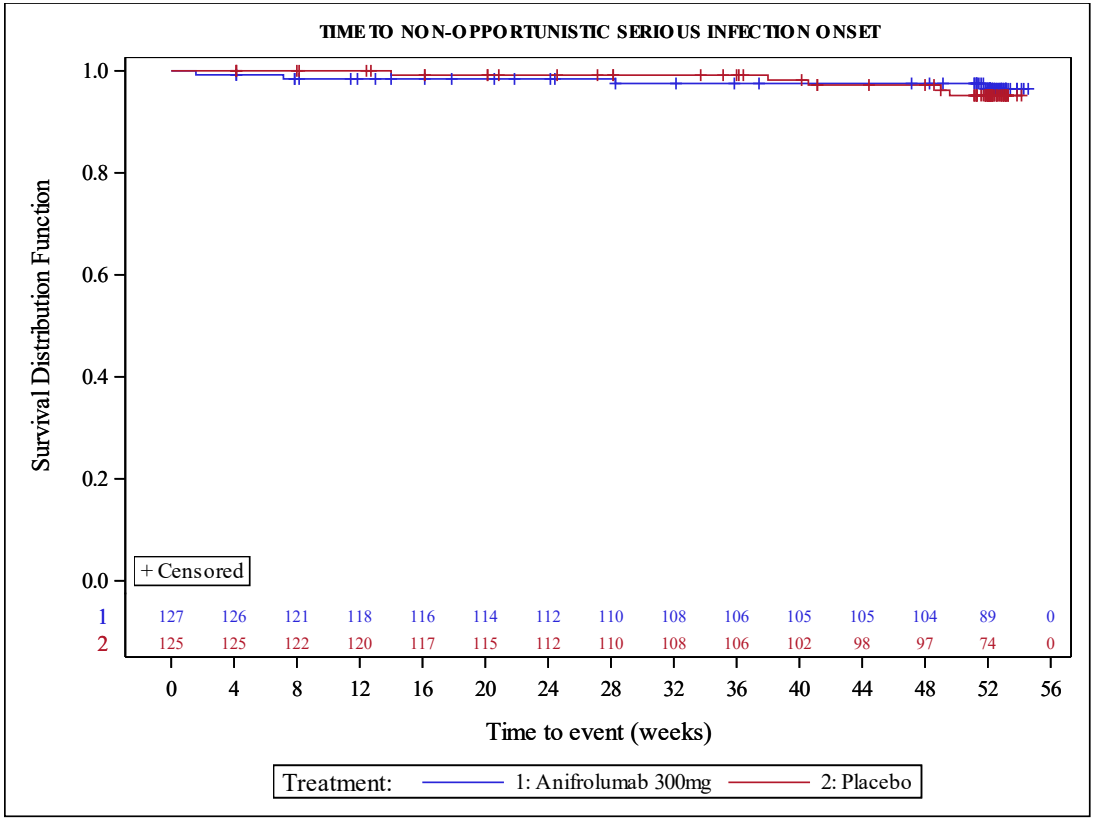
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model. Adjusted analysis also includes stratification factors in the model.
Two-sided log rank test used.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Time to first Onset of non-opportunistic serious infection (on-treatment) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Anifrolumab 300mg (N=127) Median (95% CI)	Placebo (N=125) n/ N (%)	Placebo (N=125) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening							0.8233
< 10 points	1/ 39 (2.6)	NE (NE, NE)	1/ 37 (2.7)	NE (NE, NE)	1.09 (0.07, 17.77)	0.8236	
>= 10 points	3/ 88 (3.4)	NE (NE, NE)	4/ 88 (4.5)	NE (NE, NE)	0.71 (0.16, 3.18)	0.5820	
OCS dose at baseline							0.5953
<10 mg/day	2/ 57 (3.5)	NE (NE, NE)	3/ 52 (5.8)	NE (NE, NE)	0.55 (0.09, 3.31)	0.4554	
>=10 mg/day	2/ 70 (2.9)	NE (NE, NE)	2/ 73 (2.7)	NE (NE, NE)	0.96 (0.13, 6.83)	0.9564	
Result of type I IFN gene signature test							0.7002
LOW	2/ 22 (9.1)	NE (NE, NE)	2/ 24 (8.3)	NE (NE, NE)	0.81 (0.11, 5.79)	0.7573	
HIGH	2/105 (1.9)	NE (NE, NE)	3/101 (3.0)	NE (NE, NE)	0.64 (0.11, 3.82)	0.6062	
Age (years)							1.0000
<= 65	4/122 (3.3)	NE (NE, NE)	5/123 (4.1)	NE (NE, NE)	0.80 (0.21, 2.99)	0.6382	
> 65	0/ 5 (0.0)	NE (NE, NE)	0/ 2 (0.0)	NE (NE, NE)	NE		
Sex							0.9943
male	0/ 12 (0.0)	NE (NE, NE)	1/ 8 (12.5)	NE (38.00, NE)	NE		
female	4/115 (3.5)	NE (NE, NE)	4/117 (3.4)	NE (NE, NE)	1.06 (0.26, 4.26)	0.9046	
Race							0.9890
White	2/ 85 (2.4)	NE (NE, NE)	3/ 96 (3.1)	NE (NE, NE)	0.48 (0.08, 2.88)	0.3909	
Black or African American	1/ 22 (4.5)	NE (NE, NE)	1/ 14 (7.1)	NE (49.57, NE)	0.34 (0.02, 5.46)	0.4229	
Asian	0/ 7 (0.0)	NE (NE, NE)	0/ 3 (0.0)	NE (NE, NE)	NE		
American Indian or Alaska Native	0	NE (NE, NE)	0/ 1 (0.0)	NE (NE, NE)	NE		
Other	1/ 13 (7.7)	NE (NE, NE)	1/ 11 (9.1)	NE (40.57, NE)	0.71 (0.04, 11.79)	0.6622	
Ethnicity							0.2332
Hispanic/Latino	1/ 23 (4.3)	NE (NE, NE)	3/ 24 (12.5)	NE (NE, NE)	0.29 (0.03, 3.21)	0.4702	
Non-hispanic/Latino	3/104 (2.9)	NE (NE, NE)	2/101 (2.0)	NE (NE, NE)	1.50 (0.24, 9.19)	0.6922	
Geographic region							0.9928
EU	0/ 47 (0.0)	NE (NE, NE)	1/ 56 (1.8)	NE (NE, NE)	NE		
non-EU	4/ 80 (5.0)	NE (NE, NE)	4/ 69 (5.8)	NE (NE, NE)	0.75 (0.19, 3.04)	0.7052	
Onset of disease							0.9937
Paediatric	0/ 8 (0.0)	NE (NE, NE)	1/ 7 (14.3)	NE (40.57, NE)	NE		
Adult	4/119 (3.4)	NE (NE, NE)	4/118 (3.4)	NE (NE, NE)	0.92 (0.23, 3.71)	0.7325	
ADA result							0.8724
Negative	3/111 (2.7)	NE (NE, NE)	4/112 (3.6)	NE (NE, NE)	0.71 (0.16, 3.19)	0.4953	
Positive (At any time)	1/ 15 (6.7)	NE (NE, NE)	1/ 13 (7.7)	NE (49.57, NE)	0.43 (0.03, 7.04)	0.5430	
BMI (kg/m2) at enrolment							0.9925
< 30	2/ 74 (2.7)	NE (NE, NE)	5/ 87 (5.7)	NE (NE, NE)	0.47 (0.09, 2.45)	0.3833	
>= 30	2/ 53 (3.8)	NE (NE, NE)	0/ 38 (0.0)	NE (NE, NE)	NE		

Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of Time to first Onset of non-opportunistic serious infection (on-treatment)
Full analysis set



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=127)	Placebo (N=125)
SOC: Gastrointestinal disorders	Number of subjects with events, n (%)	29 (22.8)	29 (23.2)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.98 (0.63, 1.55)	
	p-value	0.9451	
	Odds Ratio (95% CI)	0.98 (0.54, 1.76)	
	p-value	0.9451	
	Risk Difference (95% CI)	-0.37 (-10.76, 10.03)	
	p-value	0.9451	
	CMH approach		
	Response rate	22.9	23.7
	Difference in response rates (95% CI)	-0.84 (-11.45, 9.77)	
	p-value	0.8769	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=127)	Placebo (N=125)
SOC: General disorders and administration site conditions	Number of subjects with events, n (%)	17 (13.4)	12 (9.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.39 (0.69, 2.80)	
	p-value	0.3495	
	Odds Ratio (95% CI)	1.46 (0.66, 3.19)	
	p-value	0.3484	
	Risk Difference (95% CI)	3.79 (-4.07, 11.64)	
	p-value	0.3450	
	CMH approach		
	Response rate	13.3	9.8
	Difference in response rates (95% CI)	3.50 (-5.59, 12.60)	
	p-value	0.4504	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=127)	Placebo (N=125)
SOC: Immune system disorders	Number of subjects with events, n (%)	10 (7.9)	4 (3.2)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	2.46 (0.79, 7.64)	
	p-value	0.1193	
	Odds Ratio (95% CI)	2.59 (0.79, 8.47)	
	p-value	0.1168	
	Risk Difference (95% CI)	4.67 (-0.94, 10.28)	
	p-value	0.1024	
	CMH approach		
	Response rate	8.0	3.2
	Difference in response rates (95% CI)	4.80 (-2.96, 12.56)	
	p-value	0.2253	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=127)	Placebo (N=125)
SOC: Infections and infestations	Number of subjects with events, n (%)	96 (75.6)	73 (58.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.29 (1.08, 1.55)	
	p-value	0.0045	
	Odds Ratio (95% CI)	2.21 (1.29, 3.78)	
	p-value	0.0040	
	Risk Difference (95% CI)	17.19 (5.77, 28.61)	
	p-value	0.0032	
	CMH approach		
	Response rate	75.4	58.7
	Difference in response rates (95% CI)	16.71 (5.11, 28.32)	
	p-value	0.0048	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=127)	Placebo (N=125)
SOC: Infections and infestations, PT: Bronchitis	Number of subjects with events, n (%)	11 (8.7)	6 (4.8)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.80 (0.69, 4.73)	
	p-value	0.2299	
	Odds Ratio (95% CI)	1.88 (0.67, 5.25)	
	p-value	0.2280	
	Risk Difference (95% CI)	3.86 (-2.30, 10.02)	
	p-value	0.2194	
	CMH approach		
	Response rate	8.8	5.1
	Difference in response rates (95% CI)	3.72 (-4.33, 11.77)	
	p-value	0.3651	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=127)	Placebo (N=125)
SOC: Infections and infestations, PT: Nasopharyngitis	Number of subjects with events, n (%)	28 (22.0)	19 (15.2)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.45 (0.86, 2.46)	
	p-value	0.1671	
	Odds Ratio (95% CI)	1.58 (0.83, 3.00)	
	p-value	0.1650	
	Risk Difference (95% CI)	6.85 (-2.72, 16.42)	
	p-value	0.1608	
	CMH approach		
	Response rate	22.4	15.1
	Difference in response rates (95% CI)	7.27 (-3.01, 17.56)	
	p-value	0.1659	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=127)	Placebo (N=125)
SOC: Infections and infestations, PT: Pharyngitis	Number of subjects with events, n (%)	9 (7.1)	11 (8.8)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.81 (0.35, 1.88)	
	p-value	0.6157	
	Odds Ratio (95% CI)	0.79 (0.32, 1.98)	
	p-value	0.6155	
	Risk Difference (95% CI)	-1.71 (-8.39, 4.96)	
	p-value	0.6150	
	CMH approach		
	Response rate	7.2	9.1
	Difference in response rates (95% CI)	-1.87 (-10.26, 6.52)	
	p-value	0.6616	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=127)	Placebo (N=125)
SOC: Infections and infestations, PT: Upper respiratory tract infection	Number of subjects with events, n (%)	14 (11.0)	11 (8.8)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.25 (0.59, 2.65)	
	p-value	0.5561	
	Odds Ratio (95% CI)	1.28 (0.56, 2.95)	
	p-value	0.5557	
	Risk Difference (95% CI)	2.22 (-5.15, 9.59)	
	p-value	0.5543	
	CMH approach		
	Response rate	10.8	9.1
	Difference in response rates (95% CI)	1.69 (-6.99, 10.36)	
	p-value	0.7032	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=127)	Placebo (N=125)
SOC: Infections and infestations, PT: Urinary tract infection	Number of subjects with events, n (%)	13 (10.2)	20 (16.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.64 (0.33, 1.23)	
	p-value	0.1801	
	Odds Ratio (95% CI)	0.60 (0.28, 1.26)	
	p-value	0.1782	
	Risk Difference (95% CI)	-5.76 (-14.08, 2.55)	
	p-value	0.1741	
	CMH approach		
	Response rate	10.2	15.8
	Difference in response rates (95% CI)	-5.62 (-15.06, 3.82)	
	p-value	0.2434	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=127)	Placebo (N=125)
SOC: Injury, poisoning and procedural complications	Number of subjects with events, n (%)	27 (21.3)	22 (17.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.21 (0.73, 2.00)	
	p-value	0.4642	
	Odds Ratio (95% CI)	1.26 (0.68, 2.37)	
	p-value	0.4635	
	Risk Difference (95% CI)	3.66 (-6.10, 13.42)	
	p-value	0.4622	
	CMH approach		
	Response rate	21.3	18.1
	Difference in response rates (95% CI)	3.21 (-7.00, 13.43)	
	p-value	0.5378	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=127)	Placebo (N=125)
SOC: Metabolism and nutrition disorders	Number of subjects with events, n (%)	7 (5.5)	10 (8.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.69 (0.27, 1.75)	
	p-value	0.4342	
	Odds Ratio (95% CI)	0.67 (0.25, 1.82)	
	p-value	0.4335	
	Risk Difference (95% CI)	-2.49 (-8.68, 3.71)	
	p-value	0.4311	
	CMH approach		
	Response rate	5.5	8.1
	Difference in response rates (95% CI)	-2.55 (-10.70, 5.59)	
	p-value	0.5393	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=127)	Placebo (N=125)
SOC: Musculoskeletal and connective tissue disorders	Number of subjects with events, n (%)	29 (22.8)	29 (23.2)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.98 (0.63, 1.55)	
	p-value	0.9451	
	Odds Ratio (95% CI)	0.98 (0.54, 1.76)	
	p-value	0.9451	
	Risk Difference (95% CI)	-0.37 (-10.76, 10.03)	
	p-value	0.9451	
	CMH approach		
	Response rate	22.9	23.5
	Difference in response rates (95% CI)	-0.54 (-11.38, 10.31)	
	p-value	0.9229	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=127)	Placebo (N=125)
SOC: Nervous system disorders	Number of subjects with events, n (%)	27 (21.3)	20 (16.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.33 (0.79, 2.24)	
	p-value	0.2867	
	Odds Ratio (95% CI)	1.42 (0.75, 2.69)	
	p-value	0.2852	
	Risk Difference (95% CI)	5.26 (-4.33, 14.85)	
	p-value	0.2823	
	CMH approach		
	Response rate	20.9	16.1
	Difference in response rates (95% CI)	4.79 (-5.26, 14.84)	
	p-value	0.3500	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

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D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=127)	Placebo (N=125)
SOC: Nervous system disorders, PT: Headache	Number of subjects with events, n (%)	11 (8.7)	12 (9.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.90 (0.41, 1.97)	
	p-value	0.7960	
	Odds Ratio (95% CI)	0.89 (0.38, 2.11)	
	p-value	0.7960	
	Risk Difference (95% CI)	-0.94 (-8.05, 6.17)	
	p-value	0.7959	
	CMH approach		
	Response rate	8.5	9.6
	Difference in response rates (95% CI)	-1.16 (-9.69, 7.37)	
	p-value	0.7899	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=127)	Placebo (N=125)
SOC: Psychiatric disorders	Number of subjects with events, n (%)	11 (8.7)	13 (10.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.83 (0.39, 1.79)	
	p-value	0.6389	
	Odds Ratio (95% CI)	0.82 (0.35, 1.90)	
	p-value	0.6387	
	Risk Difference (95% CI)	-1.74 (-8.99, 5.51)	
	p-value	0.6384	
	CMH approach		
	Response rate	8.6	10.5
	Difference in response rates (95% CI)	-1.95 (-10.69, 6.78)	
	p-value	0.6609	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=127)	Placebo (N=125)
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with events, n (%)	25 (19.7)	14 (11.2)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.76 (0.96, 3.22)	
	p-value	0.0681	
	Odds Ratio (95% CI)	1.94 (0.96, 3.94)	
	p-value	0.0656	
	Risk Difference (95% CI)	8.49 (-0.37, 17.34)	
	p-value	0.0603	
	CMH approach		
	Response rate	19.5	11.2
	Difference in response rates (95% CI)	8.32 (-1.46, 18.09)	
	p-value	0.0954	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=127)	Placebo (N=125)
SOC: Respiratory, thoracic and mediastinal disorders, PT: Cough	Number of subjects with events, n (%)	11 (8.7)	5 (4.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	2.17 (0.77, 6.05)	
	p-value	0.1407	
	Odds Ratio (95% CI)	2.28 (0.77, 6.75)	
	p-value	0.1383	
	Risk Difference (95% CI)	4.66 (-1.32, 10.64)	
	p-value	0.1264	
	CMH approach		
	Response rate	8.5	4.0
	Difference in response rates (95% CI)	4.50 (-3.47, 12.46)	
	p-value	0.2684	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=127)	Placebo (N=125)
SOC: Skin and subcutaneous tissue disorders	Number of subjects with events, n (%)	19 (15.0)	13 (10.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.44 (0.74, 2.79)	
	p-value	0.2808	
	Odds Ratio (95% CI)	1.52 (0.71, 3.22)	
	p-value	0.2793	
	Risk Difference (95% CI)	4.56 (-3.63, 12.75)	
	p-value	0.2752	
	CMH approach		
	Response rate	15.0	10.4
	Difference in response rates (95% CI)	4.52 (-4.80, 13.84)	
	p-value	0.3417	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=127)	Placebo (N=125)
SOC: Vascular disorders	Number of subjects with events, n (%)	3 (2.4)	10 (8.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.30 (0.08, 1.05)	
	p-value	0.0590	
	Odds Ratio (95% CI)	0.28 (0.07, 1.04)	
	p-value	0.0565	
	Risk Difference (95% CI)	-5.64 (-11.08, -0.20)	
	p-value	0.0422	
	CMH approach		
	Response rate	2.4	7.9
	Difference in response rates (95% CI)	-5.51 (-13.22, 2.20)	
	p-value	0.1616	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations	SLEDAI-2K score at screening									0.6031
	< 10 points	32/ 39 (82.1)	83.0	25/ 37 (67.6)	68.9	1.21 (0.93, 1.59)	0.1542	14.06 (-6.32, 34.44)	0.1764	
	>= 10 points	64/ 88 (72.7)	72.6	48/ 88 (54.5)	54.6	1.33 (1.06, 1.68)	0.0141	17.95 (3.83, 32.07)	0.0127	
	OCS dose at baseline									0.8903
	<10 mg/day	46/ 57 (80.7)	80.7	33/ 52 (63.5)	63.4	1.27 (1.00, 1.62)	0.0518	17.33 (0.14, 34.53)	0.0482	
	>=10 mg/day	50/ 70 (71.4)	71.3	40/ 73 (54.8)	55.4	1.30 (1.01, 1.68)	0.0421	15.93 (0.10, 31.75)	0.0486	
	Result of type I IFN gene signature test									0.6228
	LOW	17/ 22 (77.3)	77.3	13/ 24 (54.2)	54.2	1.43 (0.93, 2.20)	0.1071	23.11 (-4.13, 50.34)	0.0963	
	HIGH	79/105 (75.2)	75.0	60/101 (59.4)	59.7	1.27 (1.04, 1.54)	0.0176	15.28 (2.45, 28.11)	0.0196	
	Age (years)									0.7718
	<= 65	92/122 (75.4)	75.3	72/123 (58.5)	58.9	1.29 (1.08, 1.54)	0.0058	16.38 (4.59, 28.17)	0.0065	
	> 65	4/ 5 (80.0)	80.0	1/ 2 (50.0)	50.0	1.60 (0.37, 6.85)	0.5262	30.00 (-50.68, 110.68)	0.4661	
	Sex									0.2339
	male	10/ 12 (83.3)	83.3	3/ 8 (37.5)	37.5	2.22 (0.88, 5.63)	0.0923	45.83 (3.79, 87.87)	0.0326	
	female	86/115 (74.8)	74.6	70/117 (59.8)	60.1	1.25 (1.04, 1.50)	0.0166	14.48 (2.36, 26.60)	0.0192	
	Race									0.2008
	White	62/ 85 (72.9)	72.2	53/ 96 (55.2)	56.0	1.32 (1.06, 1.65)	0.0139	16.20 (2.24, 30.16)	0.0229	
	Black or African American	16/ 22 (72.7)	72.7	11/ 14 (78.6)	78.6	0.93 (0.64, 1.35)	0.6859	-5.84 (-36.22, 24.53)	0.7061	
	Asian	7/ 7 (100.0)	100.0	3/ 3 (100.0)	100.0	NE		0.00 (-58.56, 58.56)	1.0000	
	American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
	Other	11/ 13 (84.6)	84.6	6/ 11 (54.5)	54.5	1.55 (0.86, 2.79)	0.1427	30.07 (-7.36, 67.50)	0.1153	
	Ethnicity									0.3140
	Hispanic/Latino	18/ 23 (78.3)	78.3	17/ 24 (70.8)	70.8	1.10 (0.79, 1.54)	0.5597	7.43 (-18.45, 33.31)	0.5738	
	Non-hispanic/Latino	78/104 (75.0)	74.4	56/101 (55.4)	56.1	1.35 (1.10, 1.66)	0.0042	18.30 (5.23, 31.38)	0.0061	
	Geographic region									0.0572
	EU	33/ 47 (70.2)	70.2	24/ 56 (42.9)	42.9	1.64 (1.15, 2.34)	0.0064	27.36 (8.80, 45.91)	0.0039	
	non-EU	63/ 80 (78.8)	78.8	49/ 69 (71.0)	70.6	1.11 (0.92, 1.34)	0.2834	8.15 (-6.31, 22.61)	0.2694	
	Onset of disease									0.1602
	Paediatric	8/ 8 (100.0)	100.0	3/ 7 (42.9)	42.9	2.33 (0.99, 5.49)	0.0522	57.14 (12.11, 102.17)	0.0129	
	Adult	88/119 (73.9)	73.8	70/118 (59.3)	59.8	1.25 (1.04, 1.50)	0.0186	14.00 (1.98, 26.03)	0.0225	
	ADA result									0.8550
	Negative	86/111 (77.5)	77.2	66/112 (58.9)	59.3	1.31 (1.09, 1.58)	0.0036	17.85 (5.52, 30.19)	0.0046	
	Positive (At any time)	10/ 15 (66.7)	66.7	7/ 13 (53.8)	53.8	1.24 (0.67, 2.30)	0.4979	12.82 (-23.68, 49.32)	0.4912	
	BMI (kg/m2) at enrolment									0.3289
	< 30	56/ 74 (75.7)	75.5	48/ 87 (55.2)	55.5	1.37 (1.09, 1.73)	0.0069	19.95 (5.41, 34.49)	0.0072	
	>= 30	40/ 53 (75.5)	75.7	25/ 38 (65.8)	65.6	1.15 (0.87, 1.51)	0.3294	10.17 (-9.25, 29.59)	0.3046	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Serious Adverse Events by SOC, PT (incidence in either arm >= 5% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=127)	Placebo (N=125)
SOC: Infections and infestations	Number of subjects with events, n (%)	4 (3.1)	9 (7.2)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.44 (0.14, 1.38)	
	p-value	0.1594	
	Odds Ratio (95% CI)	0.42 (0.13, 1.40)	
	p-value	0.1572	
	Risk Difference (95% CI)	-4.05 (-9.51, 1.40)	
	p-value	0.1456	
	CMH approach		
	Response rate	3.1	7.0
	Difference in response rates (95% CI)	-3.91 (-11.63, 3.81)	
	p-value	0.3205	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Serious Adverse Events by SOC, PT (incidence in either arm >= 5% or >=10 patients) - Subgroup analysis
Full analysis set

- NO OBSERVATIONS FOR THIS ANALYSIS -

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Severe (Grade >=3) by SOC, PT (incidence in either arm >= 5% or >=10 patients)
Full analysis set

- NO OBSERVATIONS FOR THIS ANALYSIS -

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Severe (Grade >=3) by SOC, PT (incidence in either arm >= 5% or >=10 patients) - Subgroup analysis
Full analysis set

- NO OBSERVATIONS FOR THIS ANALYSIS -

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event (on-treatment)
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	114 (89.8)	93 (74.4)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.21 (1.07, 1.36)	
p-value	0.0019	
Odds Ratio (95% CI)	3.02 (1.50, 6.08)	
p-value	0.0020	
Risk Difference (95% CI)	15.36 (6.07, 24.65)	
p-value	0.0012	
CMH approach		
Response rate	89.9	74.6
Difference in response rates (95% CI)	15.24 (5.17, 25.31)	
p-value	0.0030	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event (on-treatment) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.4846
< 10 points	36/ 39 (92.3)	93.1	30/ 37 (81.1)	81.7	1.14 (0.95, 1.36)	0.1582	11.31 (-6.84, 29.46)	0.2219	
>= 10 points	78/ 88 (88.6)	88.6	63/ 88 (71.6)	71.6	1.24 (1.06, 1.44)	0.0057	16.95 (4.63, 29.26)	0.0070	
OCS dose at baseline									0.7023
<10 mg/day	54/ 57 (94.7)	94.7	42/ 52 (80.8)	80.7	1.17 (1.01, 1.36)	0.0323	14.00 (-0.61, 28.60)	0.0603	
>=10 mg/day	60/ 70 (85.7)	85.9	51/ 73 (69.9)	70.4	1.23 (1.03, 1.47)	0.0247	15.48 (1.37, 29.58)	0.0315	
Result of type I IFN gene signature test									0.2060
LOW	21/ 22 (95.5)	95.5	16/ 24 (66.7)	66.7	1.43 (1.06, 1.93)	0.0179	28.79 (5.43, 52.15)	0.0157	
HIGH	93/105 (88.6)	88.6	77/101 (76.2)	76.4	1.16 (1.02, 1.32)	0.0224	12.21 (1.05, 23.37)	0.0320	
Age (years)									0.0694
<= 65	110/122 (90.2)	90.3	91/123 (74.0)	74.3	1.22 (1.08, 1.37)	0.0012	16.06 (5.86, 26.26)	0.0020	
> 65	4/ 5 (80.0)	80.0	2/ 2 (100.0)	100.0	0.80 (0.52, 1.24)	0.3183	-20.00 (-97.30, 57.30)	0.6121	
Sex									0.7378
male	10/ 12 (83.3)	83.3	5/ 8 (62.5)	62.5	1.33 (0.74, 2.41)	0.3420	20.83 (-21.21, 62.87)	0.3314	
female	104/115 (90.4)	90.6	88/117 (75.2)	75.4	1.20 (1.07, 1.36)	0.0026	15.18 (4.76, 25.60)	0.0043	
Race									0.3848
White	76/ 85 (89.4)	88.8	69/ 96 (71.9)	72.6	1.24 (1.08, 1.44)	0.0032	16.13 (3.79, 28.48)	0.0104	
Black or African American	19/ 22 (86.4)	86.4	12/ 14 (85.7)	85.7	1.01 (0.77, 1.32)	0.9564	0.65 (-26.65, 27.95)	0.9628	
Asian	7/ 7 (100.0)	100.0	3/ 3 (100.0)	100.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		1/ 1 (100.0)		NE		NE		
Other	12/ 13 (92.3)	92.3	8/ 11 (72.7)	72.7	1.27 (0.86, 1.88)	0.2362	19.58 (-15.14, 54.30)	0.2690	
Ethnicity									0.3571
Hispanic/Latino	21/ 23 (91.3)	91.3	20/ 24 (83.3)	83.3	1.10 (0.88, 1.36)	0.4134	7.97 (-13.94, 29.89)	0.4759	
Non-hispanic/Latino	93/104 (89.4)	89.7	73/101 (72.3)	72.8	1.24 (1.08, 1.42)	0.0024	16.89 (5.44, 28.35)	0.0039	
Geographic region									0.0281
EU	39/ 47 (83.0)	83.0	32/ 56 (57.1)	57.1	1.45 (1.12, 1.89)	0.0051	25.84 (8.59, 43.08)	0.0033	
non-EU	75/ 80 (93.8)	93.8	61/ 69 (88.4)	88.1	1.06 (0.96, 1.17)	0.2616	5.69 (-5.57, 16.95)	0.3220	
Onset of disease									0.8342
Paediatric	8/ 8 (100.0)	100.0	6/ 7 (85.7)	85.7	1.17 (0.86, 1.58)	0.3178	14.29 (-27.61, 56.18)	0.5040	
Adult	106/119 (89.1)	89.0	87/118 (73.7)	73.9	1.21 (1.07, 1.37)	0.0030	15.10 (4.59, 25.62)	0.0049	
ADA result									0.6564
Negative	101/111 (91.0)	91.1	83/112 (74.1)	74.4	1.23 (1.08, 1.39)	0.0012	16.67 (5.94, 27.40)	0.0023	
Positive (At any time)	13/ 15 (86.7)	86.7	10/ 13 (76.9)	76.9	1.13 (0.79, 1.61)	0.5136	9.74 (-22.49, 41.98)	0.5536	
BMI (kg/m2) at enrolment									0.2515
< 30	65/ 74 (87.8)	88.0	61/ 87 (70.1)	70.5	1.25 (1.07, 1.47)	0.0062	17.53 (4.56, 30.50)	0.0081	
>= 30	49/ 53 (92.5)	92.8	32/ 38 (84.2)	84.0	1.10 (0.94, 1.29)	0.2458	8.71 (-7.65, 25.08)	0.2968	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Serious Adverse Event (on-treatment)
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	14 (11.0)	20 (16.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.69 (0.36, 1.30)	
p-value	0.2515	
Odds Ratio (95% CI)	0.65 (0.31, 1.35)	
p-value	0.2500	
Risk Difference (95% CI)	-4.98 (-13.40, 3.45)	
p-value	0.2470	
CMH approach		
Response rate	11.1	16.0
Difference in response rates (95% CI)	-4.87 (-14.37, 4.63)	
p-value	0.3152	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Serious Adverse Event (on-treatment) - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=127)		Placebo (N=125)		Analysis Anifrolumab 300mg vs. Placebo				Interaction
Level	n/ N (%)	Response rate	n/ N (%)	Response rate	Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	p-Value
SLEDAI-2K score at screening									0.8601
< 10 points	4/ 39 (10.3)	11.0	5/ 37 (13.5)	13.4	0.76 (0.22, 2.61)	0.6617	-2.32 (-20.15, 15.52)	0.7991	
>= 10 points	10/ 88 (11.4)	11.3	15/ 88 (17.0)	17.1	0.67 (0.32, 1.40)	0.2852	-5.77 (-17.11, 5.56)	0.3181	
OCS dose at baseline									0.9181
<10 mg/day	7/ 57 (12.3)	12.1	9/ 52 (17.3)	17.5	0.71 (0.28, 1.77)	0.4616	-5.45 (-20.19, 9.30)	0.4690	
>=10 mg/day	7/ 70 (10.0)	10.0	11/ 73 (15.1)	15.7	0.66 (0.27, 1.61)	0.3661	-5.76 (-18.32, 6.79)	0.3684	
Result of type I IFN gene signature test									0.3537
LOW	5/ 22 (22.7)	22.7	5/ 24 (20.8)	20.8	1.09 (0.36, 3.27)	0.8764	1.89 (-23.48, 27.26)	0.8837	
HIGH	9/105 (8.6)	8.5	15/101 (14.9)	14.9	0.58 (0.26, 1.26)	0.1672	-6.38 (-16.53, 3.76)	0.2177	
Age (years)									0.3177
<= 65	12/122 (9.8)	9.9	20/123 (16.3)	16.2	0.60 (0.31, 1.18)	0.1417	-6.33 (-15.92, 3.25)	0.1954	
> 65	2/ 5 (40.0)	40.0	0/ 2 (0.0)	0.0	2.50 (0.17, 37.26)	0.5062	40.00 (-38.52, 118.52)	0.3181	
Sex									0.2526
male	0/ 12 (0.0)	0.0	2/ 8 (25.0)	25.0	0.14 (0.01, 2.55)	0.1837	-25.00 (-62.65, 12.65)	0.1931	
female	14/115 (12.2)	12.3	18/117 (15.4)	15.2	0.79 (0.41, 1.51)	0.4798	-2.83 (-12.85, 7.20)	0.5806	
Race									0.5600
White	10/ 85 (11.8)	11.8	14/ 96 (14.6)	14.4	0.81 (0.38, 1.72)	0.5782	-2.61 (-14.13, 8.91)	0.6570	
Black or African American	2/ 22 (9.1)	9.1	4/ 14 (28.6)	28.6	0.32 (0.07, 1.51)	0.1501	-19.48 (-48.41, 9.45)	0.1869	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	2/ 13 (15.4)	15.4	2/ 11 (18.2)	18.2	0.85 (0.14, 5.06)	0.8547	-2.80 (-37.65, 32.05)	0.8750	
Ethnicity									0.8664
Hispanic/Latino	3/ 23 (13.0)	13.0	5/ 24 (20.8)	20.8	0.63 (0.17, 2.33)	0.4843	-7.79 (-31.29, 15.71)	0.5158	
Non-hispanic/Latino	11/104 (10.6)	11.0	15/101 (14.9)	15.3	0.71 (0.34, 1.48)	0.3610	-4.31 (-15.08, 6.45)	0.4321	
Geographic region									0.7891
EU	4/ 47 (8.5)	8.5	8/ 56 (14.3)	14.3	0.60 (0.19, 1.86)	0.3715	-5.78 (-19.20, 7.65)	0.3990	
non-EU	10/ 80 (12.5)	12.3	12/ 69 (17.4)	17.6	0.72 (0.33, 1.56)	0.4036	-5.29 (-18.03, 7.46)	0.4163	
Onset of disease									0.2057
Paediatric	0/ 8 (0.0)	0.0	3/ 7 (42.9)	42.9	0.13 (0.01, 2.10)	0.1494	-42.86 (-87.89, 2.17)	0.0621	
Adult	14/119 (11.8)	11.8	17/118 (14.4)	14.4	0.82 (0.42, 1.58)	0.5474	-2.62 (-12.38, 7.15)	0.5996	
ADA result									0.2298
Negative	13/111 (11.7)	11.7	16/112 (14.3)	14.5	0.82 (0.41, 1.62)	0.5687	-2.73 (-12.86, 7.39)	0.5967	
Positive (At any time)	1/ 15 (6.7)	6.7	4/ 13 (30.8)	30.8	0.22 (0.03, 1.70)	0.1459	-24.10 (-55.97, 7.76)	0.1382	
BMI (kg/m2) at enrolment									0.9235
< 30	8/ 74 (10.8)	10.8	14/ 87 (16.1)	15.9	0.67 (0.30, 1.51)	0.3367	-5.11 (-16.93, 6.72)	0.3972	
>= 30	6/ 53 (11.3)	11.0	6/ 38 (15.8)	16.0	0.72 (0.25, 2.05)	0.5354	-4.97 (-21.76, 11.82)	0.5620	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Severe Adverse Event (on-treatment)
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	12 (9.4)	14 (11.2)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.84 (0.41, 1.75)	
p-value	0.6482	
Odds Ratio (95% CI)	0.83 (0.37, 1.87)	
p-value	0.6481	
Risk Difference (95% CI)	-1.75 (-9.26, 5.76)	
p-value	0.6478	
CMH approach		
Response rate	9.6	11.2
Difference in response rates (95% CI)	-1.54 (-10.53, 7.45)	
p-value	0.7367	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Severe Adverse Event (on-treatment) - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=127)		Placebo (N=125)		Analysis Anifrolumab 300mg vs. Placebo				Interaction
Level	n/ N (%)	Response rate	n/ N (%)	Response rate	Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	p-Value
SLEDAI-2K score at screening									0.7817
< 10 points	3/ 39 (7.7)	7.5	4/ 37 (10.8)	11.0	0.71 (0.17, 2.97)	0.6404	-3.47 (-21.23, 14.29)	0.7021	
>= 10 points	9/ 88 (10.2)	10.4	10/ 88 (11.4)	11.3	0.90 (0.38, 2.11)	0.8082	-0.89 (-11.54, 9.75)	0.8692	
OCS dose at baseline									0.4870
<10 mg/day	4/ 57 (7.0)	7.0	6/ 52 (11.5)	11.7	0.61 (0.18, 2.04)	0.4198	-4.71 (-18.33, 8.92)	0.4985	
>=10 mg/day	8/ 70 (11.4)	11.4	8/ 73 (11.0)	11.4	1.04 (0.41, 2.63)	0.9290	0.03 (-12.37, 12.43)	0.9966	
Result of type I IFN gene signature test									0.8474
LOW	2/ 22 (9.1)	9.1	3/ 24 (12.5)	12.5	0.73 (0.13, 3.95)	0.7124	-3.41 (-24.91, 18.09)	0.7559	
HIGH	10/105 (9.5)	9.8	11/101 (10.9)	10.9	0.87 (0.39, 1.97)	0.7460	-1.12 (-11.02, 8.77)	0.8237	
Age (years)									NE
<= 65	12/122 (9.8)	10.0	14/123 (11.4)	11.4	0.86 (0.42, 1.79)	0.6948	-1.41 (-10.62, 7.80)	0.7640	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE		0.00 (-74.81, 74.81)	1.0000	
Sex									0.8545
male	1/ 12 (8.3)	8.3	1/ 8 (12.5)	12.5	0.67 (0.05, 9.19)	0.7620	-4.17 (-41.42, 33.09)	0.8265	
female	11/115 (9.6)	9.8	13/117 (11.1)	11.0	0.86 (0.40, 1.84)	0.6995	-1.15 (-10.62, 8.31)	0.8110	
Race									0.4005
White	8/ 85 (9.4)	9.8	8/ 96 (8.3)	8.0	1.13 (0.44, 2.88)	0.7987	1.81 (-9.01, 12.63)	0.7426	
Black or African American	3/ 22 (13.6)	13.6	5/ 14 (35.7)	35.7	0.38 (0.11, 1.35)	0.1357	-22.08 (-52.46, 8.31)	0.1544	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	1/ 13 (7.7)	7.7	1/ 11 (9.1)	9.1	0.85 (0.06, 12.01)	0.9018	-1.40 (-32.83, 30.04)	0.9305	
Ethnicity									0.8037
Hispanic/Latino	2/ 23 (8.7)	8.7	3/ 24 (12.5)	12.5	0.70 (0.13, 3.79)	0.6748	-3.80 (-24.91, 17.30)	0.7239	
Non-hispanic/Latino	10/104 (9.6)	10.5	11/101 (10.9)	11.2	0.88 (0.39, 1.99)	0.7635	-0.74 (-11.15, 9.68)	0.8899	
Geographic region									0.5588
EU	3/ 47 (6.4)	6.4	3/ 56 (5.4)	5.4	1.19 (0.25, 5.63)	0.8250	1.03 (-10.14, 12.19)	0.8571	
non-EU	9/ 80 (11.3)	11.4	11/ 69 (15.9)	16.0	0.71 (0.31, 1.60)	0.4047	-4.61 (-17.11, 7.89)	0.4700	
Onset of disease									0.1493
Paediatric	0/ 8 (0.0)	0.0	3/ 7 (42.9)	42.9	0.13 (0.01, 2.10)	0.1494	-42.86 (-87.89, 2.17)	0.0621	
Adult	12/119 (10.1)	10.2	11/118 (9.3)	9.4	1.08 (0.50, 2.35)	0.8430	0.83 (-8.36, 10.01)	0.8598	
ADA result									0.3412
Negative	10/111 (9.0)	9.4	10/112 (8.9)	9.0	1.01 (0.44, 2.33)	0.9832	0.43 (-9.04, 9.90)	0.9289	
Positive (At any time)	2/ 15 (13.3)	13.3	4/ 13 (30.8)	30.8	0.43 (0.09, 1.99)	0.2829	-17.44 (-50.61, 15.74)	0.3029	
BMI (kg/m2) at enrolment									0.2661
< 30	7/ 74 (9.5)	9.4	7/ 87 (8.0)	8.1	1.18 (0.43, 3.20)	0.7513	1.35 (-9.49, 12.19)	0.8077	
>= 30	5/ 53 (9.4)	9.6	7/ 38 (18.4)	18.5	0.51 (0.18, 1.49)	0.2200	-8.92 (-26.07, 8.23)	0.3079	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Non-Severe Adverse Event (on-treatment)
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	111 (87.4)	91 (72.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.20 (1.06, 1.36)	
p-value	0.0044	
Odds Ratio (95% CI)	2.59 (1.35, 4.99)	
p-value	0.0044	
Risk Difference (95% CI)	14.60 (4.90, 24.31)	
p-value	0.0032	
CMH approach		
Response rate	87.6	73.1
Difference in response rates (95% CI)	14.50 (4.18, 24.82)	
p-value	0.0059	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Non-Severe Adverse Event (on-treatment) - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=127)		Placebo (N=125)		Analysis Anifrolumab 300mg vs. Placebo				Interaction
Level	n/ N (%)	Response rate	n/ N (%)	Response rate	Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	p-Value
SLEDAI-2K score at screening									0.2149
< 10 points	34/ 39 (87.2)	88.1	30/ 37 (81.1)	81.7	1.08 (0.88, 1.31)	0.4700	6.41 (-12.37, 25.19)	0.5036	
>= 10 points	77/ 88 (87.5)	87.4	61/ 88 (69.3)	69.4	1.26 (1.08, 1.48)	0.0043	17.97 (5.41, 30.54)	0.0051	
OCS dose at baseline									0.5760
<10 mg/day	53/ 57 (93.0)	92.9	42/ 52 (80.8)	80.7	1.15 (0.99, 1.34)	0.0668	12.22 (-2.63, 27.06)	0.1069	
>=10 mg/day	58/ 70 (82.9)	83.2	49/ 73 (67.1)	67.7	1.23 (1.02, 1.50)	0.0322	15.53 (1.01, 30.04)	0.0360	
Result of type I IFN gene signature test									0.1980
LOW	21/ 22 (95.5)	95.5	16/ 24 (66.7)	66.7	1.43 (1.06, 1.93)	0.0179	28.79 (5.43, 52.15)	0.0157	
HIGH	90/105 (85.7)	85.8	75/101 (74.3)	74.5	1.15 (1.00, 1.33)	0.0429	11.30 (-0.19, 22.80)	0.0539	
Age (years)									0.0745
<= 65	107/122 (87.7)	88.0	89/123 (72.4)	72.7	1.21 (1.07, 1.38)	0.0032	15.33 (4.87, 25.79)	0.0041	
> 65	4/ 5 (80.0)	80.0	2/ 2 (100.0)	100.0	0.80 (0.52, 1.24)	0.3183	-20.00 (-97.30, 57.30)	0.6121	
Sex									0.7233
male	10/ 12 (83.3)	83.3	5/ 8 (62.5)	62.5	1.33 (0.74, 2.41)	0.3420	20.83 (-21.21, 62.87)	0.3314	
female	101/115 (87.8)	88.1	86/117 (73.5)	73.8	1.19 (1.05, 1.36)	0.0065	14.29 (3.58, 25.00)	0.0089	
Race									0.2440
White	75/ 85 (88.2)	87.5	67/ 96 (69.8)	70.8	1.26 (1.09, 1.47)	0.0026	16.70 (4.18, 29.21)	0.0089	
Black or African American	18/ 22 (81.8)	81.8	12/ 14 (85.7)	85.7	0.95 (0.71, 1.28)	0.7538	-3.90 (-31.90, 24.11)	0.7851	
Asian	7/ 7 (100.0)	100.0	3/ 3 (100.0)	100.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		1/ 1 (100.0)		NE		NE		
Other	11/ 13 (84.6)	84.6	8/ 11 (72.7)	72.7	1.16 (0.76, 1.79)	0.4899	11.89 (-24.27, 48.05)	0.5194	
Ethnicity									0.2171
Hispanic/Latino	20/ 23 (87.0)	87.0	20/ 24 (83.3)	83.3	1.04 (0.82, 1.33)	0.7269	3.62 (-19.21, 26.46)	0.7558	
Non-hispanic/Latino	91/104 (87.5)	87.6	71/101 (70.3)	70.9	1.24 (1.08, 1.44)	0.0033	16.69 (4.98, 28.41)	0.0052	
Geographic region									0.0134
EU	38/ 47 (80.9)	80.9	30/ 56 (53.6)	53.6	1.51 (1.14, 2.00)	0.0041	27.28 (9.70, 44.86)	0.0024	
non-EU	73/ 80 (91.3)	91.1	61/ 69 (88.4)	88.1	1.03 (0.93, 1.15)	0.5695	2.99 (-8.62, 14.59)	0.6140	
Onset of disease									0.5074
Paediatric	8/ 8 (100.0)	100.0	5/ 7 (71.4)	71.4	1.40 (0.88, 2.24)	0.1593	28.57 (-15.44, 72.58)	0.2032	
Adult	103/119 (86.6)	86.6	86/118 (72.9)	73.1	1.19 (1.04, 1.35)	0.0100	13.48 (2.74, 24.22)	0.0139	
ADA result									0.8222
Negative	99/111 (89.2)	89.3	82/112 (73.2)	73.6	1.22 (1.07, 1.39)	0.0028	15.77 (4.86, 26.69)	0.0046	
Positive (At any time)	12/ 15 (80.0)	80.0	9/ 13 (69.2)	69.2	1.16 (0.74, 1.80)	0.5214	10.77 (-23.46, 45.00)	0.5374	
BMI (kg/m2) at enrolment									0.2022
< 30	63/ 74 (85.1)	85.5	59/ 87 (67.8)	68.2	1.26 (1.06, 1.49)	0.0101	17.29 (3.94, 30.63)	0.0111	
>= 30	48/ 53 (90.6)	90.7	32/ 38 (84.2)	84.0	1.08 (0.91, 1.27)	0.3811	6.68 (-9.97, 23.34)	0.4316	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event leading to discontinuation of study drug (on-treatment)
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	8 (6.3)	4 (3.2)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.97 (0.61, 6.37)	
p-value	0.2584	
Odds Ratio (95% CI)	2.03 (0.60, 6.93)	
p-value	0.2567	
Risk Difference (95% CI)	3.10 (-2.13, 8.33)	
p-value	0.2456	
CMH approach		
Response rate	6.2	3.2
Difference in response rates (95% CI)	3.03 (-4.58, 10.64)	
p-value	0.4349	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event leading to discontinuation of study drug (on-treatment) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.4302
< 10 points	4/ 39 (10.3)	10.4	1/ 37 (2.7)	2.8	3.79 (0.44, 32.40)	0.2229	7.67 (-9.15, 24.48)	0.3714	
>= 10 points	4/ 88 (4.5)	4.5	3/ 88 (3.4)	3.4	1.33 (0.31, 5.78)	0.7008	1.16 (-7.44, 9.76)	0.7915	
OCS dose at baseline									0.5948
<10 mg/day	3/ 57 (5.3)	5.2	2/ 52 (3.8)	3.8	1.37 (0.24, 7.87)	0.7253	1.44 (-11.00, 13.87)	0.8207	
>=10 mg/day	5/ 70 (7.1)	7.1	2/ 73 (2.7)	2.7	2.61 (0.52, 13.00)	0.2424	4.33 (-5.84, 14.50)	0.4044	
Result of type I IFN gene signature test									0.4208
LOW	2/ 22 (9.1)	9.1	0/ 24 (0.0)	0.0	5.43 (0.28, 107.33)	0.2660	9.09 (-9.17, 27.35)	0.3292	
HIGH	6/105 (5.7)	5.6	4/101 (4.0)	3.9	1.44 (0.42, 4.96)	0.5608	1.68 (-6.69, 10.05)	0.6946	
Age (years)									0.9189
<= 65	7/122 (5.7)	5.6	4/123 (3.3)	3.3	1.76 (0.53, 5.87)	0.3548	2.31 (-5.39, 10.02)	0.5567	
> 65	1/ 5 (20.0)	20.0	0/ 2 (0.0)	0.0	1.50 (0.08, 26.86)	0.7830	20.00 (-57.30, 97.30)	0.6121	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE		0.00 (-31.89, 31.89)	1.0000	
female	8/115 (7.0)	6.9	4/117 (3.4)	3.4	2.03 (0.63, 6.57)	0.2350	3.47 (-4.73, 11.67)	0.4070	
Race									0.9618
White	5/ 85 (5.9)	6.0	3/ 96 (3.1)	3.3	1.88 (0.46, 7.64)	0.3763	2.68 (-7.05, 12.42)	0.5893	
Black or African American	1/ 22 (4.5)	4.5	0/ 14 (0.0)	0.0	1.96 (0.09, 44.92)	0.6747	4.55 (-16.65, 25.74)	0.6742	
Asian	1/ 7 (14.3)	14.3	0/ 3 (0.0)	0.0	1.50 (0.08, 29.15)	0.7888	14.29 (-46.56, 75.13)	0.6454	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	1/ 13 (7.7)	7.7	1/ 11 (9.1)	9.1	0.85 (0.06, 12.01)	0.9018	-1.40 (-32.83, 30.04)	0.9305	
Ethnicity									0.0536
Hispanic/Latino	1/ 23 (4.3)	4.3	3/ 24 (12.5)	12.5	0.35 (0.04, 3.11)	0.3445	-8.15 (-28.15, 11.84)	0.4242	
Non-hispanic/Latino	7/104 (6.7)	6.9	1/101 (1.0)	0.9	6.80 (0.85, 54.27)	0.0706	5.95 (-2.76, 14.66)	0.1803	
Geographic region									0.4972
EU	3/ 47 (6.4)	6.4	1/ 56 (1.8)	1.8	3.57 (0.38, 33.23)	0.2628	4.60 (-5.64, 14.84)	0.3789	
non-EU	5/ 80 (6.3)	6.4	3/ 69 (4.3)	4.3	1.44 (0.36, 5.80)	0.6100	2.02 (-8.23, 12.26)	0.6993	
Onset of disease									0.0622
Paediatric	0/ 8 (0.0)	0.0	2/ 7 (28.6)	28.6	0.18 (0.01, 3.18)	0.2403	-28.57 (-72.58, 15.44)	0.2032	
Adult	8/119 (6.7)	6.6	2/118 (1.7)	1.7	3.97 (0.86, 18.29)	0.0772	4.95 (-2.83, 12.73)	0.2122	
ADA result									0.3080
Negative	6/111 (5.4)	5.2	2/112 (1.8)	1.9	3.03 (0.62, 14.68)	0.1691	3.33 (-4.65, 11.31)	0.4132	
Positive (At any time)	2/ 15 (13.3)	13.3	2/ 13 (15.4)	15.4	0.87 (0.14, 5.32)	0.8771	-2.05 (-32.99, 28.89)	0.8966	
BMI (kg/m2) at enrolment									0.6655
< 30	6/ 74 (8.1)	8.0	4/ 87 (4.6)	4.8	1.76 (0.52, 6.01)	0.3647	3.25 (-6.74, 13.24)	0.5239	
>= 30	2/ 53 (3.8)	3.9	0/ 38 (0.0)	0.0	3.61 (0.18, 73.14)	0.4028	3.88 (-9.63, 17.39)	0.5734	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Serious Adverse Event leading to discontinuation of study drug (on-treatment)
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	4 (3.1)	2 (1.6)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.97 (0.37, 10.55)	
p-value	0.4293	
Odds Ratio (95% CI)	2.00 (0.36, 11.12)	
p-value	0.4285	
Risk Difference (95% CI)	1.55 (-2.20, 5.30)	
p-value	0.4180	
CMH approach		
Response rate	3.0	1.5
Difference in response rates (95% CI)	1.44 (-5.45, 8.32)	
p-value	0.6826	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Serious Adverse Event leading to discontinuation of study drug (on-treatment) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.1792
< 10 points	3/ 39 (7.7)	7.8	0/ 37 (0.0)	0.0	6.65 (0.36, 124.51)	0.2050	7.84 (-7.98, 23.66)	0.3314	
>= 10 points	1/ 88 (1.1)	1.1	2/ 88 (2.3)	2.2	0.50 (0.05, 5.41)	0.5685	-1.11 (-8.78, 6.56)	0.7771	
OCS dose at baseline									0.7621
<10 mg/day	1/ 57 (1.8)	1.8	0/ 52 (0.0)	0.0	2.74 (0.11, 65.85)	0.5341	1.77 (-9.32, 12.86)	0.7547	
>=10 mg/day	3/ 70 (4.3)	4.1	2/ 73 (2.7)	2.7	1.56 (0.27, 9.08)	0.6181	1.41 (-8.09, 10.91)	0.7712	
Result of type I IFN gene signature test									0.6582
LOW	1/ 22 (4.5)	4.5	0/ 24 (0.0)	0.0	3.26 (0.14, 76.10)	0.4621	4.55 (-12.32, 21.41)	0.5973	
HIGH	3/105 (2.9)	2.6	2/101 (2.0)	1.9	1.44 (0.25, 8.46)	0.6845	0.74 (-6.79, 8.27)	0.8472	
Age (years)									0.9962
<= 65	3/122 (2.5)	2.2	2/123 (1.6)	1.6	1.51 (0.26, 8.89)	0.6472	0.59 (-6.34, 7.52)	0.8673	
> 65	1/ 5 (20.0)	20.0	0/ 2 (0.0)	0.0	1.50 (0.08, 26.86)	0.7830	20.00 (-57.30, 97.30)	0.6121	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE		0.00 (-31.89, 31.89)	1.0000	
female	4/115 (3.5)	3.3	2/117 (1.7)	1.6	2.03 (0.38, 10.89)	0.4066	1.67 (-5.74, 9.07)	0.6586	
Race									0.4339
White	3/ 85 (3.5)	3.6	1/ 96 (1.0)	0.9	3.39 (0.36, 31.96)	0.2865	2.63 (-6.39, 11.64)	0.5683	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE		0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	1/ 13 (7.7)	7.7	1/ 11 (9.1)	9.1	0.85 (0.06, 12.01)	0.9018	-1.40 (-32.83, 30.04)	0.9305	
Ethnicity									0.5677
Hispanic/Latino	1/ 23 (4.3)	4.3	1/ 24 (4.2)	4.2	1.04 (0.07, 15.72)	0.9755	0.18 (-17.65, 18.02)	0.9841	
Non-hispanic/Latino	3/104 (2.9)	2.7	1/101 (1.0)	0.9	2.91 (0.31, 27.55)	0.3509	1.76 (-6.29, 9.81)	0.6680	
Geographic region									0.6679
EU	1/ 47 (2.1)	2.1	1/ 56 (1.8)	1.8	1.19 (0.08, 18.54)	0.9004	0.34 (-8.48, 9.16)	0.9394	
non-EU	3/ 80 (3.8)	3.8	1/ 69 (1.4)	1.5	2.59 (0.28, 24.31)	0.4055	2.30 (-6.95, 11.54)	0.6264	
Onset of disease									0.1753
Paediatric	0/ 8 (0.0)	0.0	1/ 7 (14.3)	14.3	0.30 (0.01, 6.29)	0.4353	-14.29 (-56.18, 27.61)	0.5040	
Adult	4/119 (3.4)	3.2	1/118 (0.8)	0.8	3.97 (0.45, 34.96)	0.2147	2.39 (-4.73, 9.51)	0.5104	
ADA result									0.0618
Negative	4/111 (3.6)	3.3	0/112 (0.0)	0.0	9.08 (0.49, 166.69)	0.1373	3.28 (-4.10, 10.67)	0.3835	
Positive (At any time)	0/ 15 (0.0)	0.0	2/ 13 (15.4)	15.4	0.17 (0.01, 3.34)	0.2469	-15.38 (-43.19, 12.42)	0.2781	
BMI (kg/m2) at enrolment									0.9115
< 30	3/ 74 (4.1)	3.7	2/ 87 (2.3)	2.3	1.76 (0.30, 10.27)	0.5280	1.43 (-7.32, 10.17)	0.7490	
>= 30	1/ 53 (1.9)	1.9	0/ 38 (0.0)	0.0	2.17 (0.09, 51.79)	0.6330	1.85 (-11.30, 15.01)	0.7826	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with Adverse Event leading to death (on-treatment)
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	1 (0.8)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	2.95 (0.12, 71.81)	
p-value	0.5060	
Odds Ratio (95% CI)	2.98 (0.12, 73.76)	
p-value	0.5055	
Risk Difference (95% CI)	0.79 (-0.75, 2.32)	
p-value	0.3154	
CMH approach		
Response rate	0.7	0.0
Difference in response rates (95% CI)	0.69 (-5.57, 6.95)	
p-value	0.8289	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with Adverse Event leading to death (on-treatment) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	1/ 39 (2.6)	2.3	0/ 37 (0.0)	0.0	2.85 (0.12, 67.83)	0.5172	2.32 (-12.76, 17.39)	0.7633	
>= 10 points	0/ 88 (0.0)	0.0	0/ 88 (0.0)	0.0	NE		0.00 (-6.92, 6.92)	1.0000	
OCS dose at baseline									NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE		0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	1/ 70 (1.4)	1.2	0/ 73 (0.0)	0.0	3.13 (0.13, 75.49)	0.4828	1.22 (-7.21, 9.66)	0.7760	
Result of type I IFN gene signature test									NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-15.17, 15.17)	1.0000	
HIGH	1/105 (1.0)	0.8	0/101 (0.0)	0.0	2.89 (0.12, 70.05)	0.5147	0.84 (-6.02, 7.71)	0.8095	
Age (years)									NE
<= 65	1/122 (0.8)	0.7	0/123 (0.0)	0.0	3.02 (0.12, 73.52)	0.4966	0.68 (-5.74, 7.10)	0.8358	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE		0.00 (-74.81, 74.81)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE		0.00 (-31.89, 31.89)	1.0000	
female	1/115 (0.9)	0.8	0/117 (0.0)	0.0	3.05 (0.13, 74.15)	0.4931	0.77 (-5.98, 7.52)	0.8231	
Race									NE
White	0/ 85 (0.0)	0.0	0/ 96 (0.0)	0.0	NE		0.00 (-8.35, 8.35)	1.0000	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE		0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	1/ 13 (7.7)	7.7	0/ 11 (0.0)	0.0	2.57 (0.12, 57.44)	0.5512	7.69 (-21.17, 36.55)	0.6014	
Ethnicity									NE
Hispanic/Latino	1/ 23 (4.3)	4.3	0/ 24 (0.0)	0.0	3.13 (0.13, 73.01)	0.4785	4.35 (-12.12, 20.81)	0.6048	
Non-hispanic/Latino	0/104 (0.0)	0.0	0/101 (0.0)	0.0	NE		0.00 (-7.49, 7.49)	1.0000	
Geographic region									NE
EU	0/ 47 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-7.27, 7.27)	1.0000	
non-EU	1/ 80 (1.3)	1.4	0/ 69 (0.0)	0.0	2.59 (0.11, 62.63)	0.5577	1.35 (-7.05, 9.76)	0.7525	
Onset of disease									NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE		0.00 (-38.51, 38.51)	1.0000	
Adult	1/119 (0.8)	0.8	0/118 (0.0)	0.0	2.98 (0.12, 72.30)	0.5030	0.75 (-5.85, 7.36)	0.8234	
ADA result									NE
Negative	1/111 (0.9)	0.7	0/112 (0.0)	0.0	3.03 (0.12, 73.51)	0.4962	0.74 (-6.27, 7.74)	0.8368	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	1/ 74 (1.4)	1.2	0/ 87 (0.0)	0.0	3.52 (0.15, 85.13)	0.4388	1.18 (-6.50, 8.86)	0.7628	
>= 30	0/ 53 (0.0)	0.0	0/ 38 (0.0)	0.0	NE		0.00 (-12.88, 12.88)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	5 (3.9)	2 (1.6)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	2.46 (0.49, 12.45)	
p-value	0.2763	
Odds Ratio (95% CI)	2.52 (0.48, 13.24)	
p-value	0.2747	
Risk Difference (95% CI)	2.34 (-1.70, 6.37)	
p-value	0.2563	
CMH approach		
Response rate	4.0	1.6
Difference in response rates (95% CI)	2.42 (-4.69, 9.52)	
p-value	0.5046	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Anifrolumab 300mg (N=127) Response rate	Placebo (N=125) n/ N (%)	Placebo (N=125) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.4193
< 10 points	1/ 39 (2.6)	2.6	1/ 37 (2.7)	2.8	0.95 (0.06, 14.62)	0.9699	-0.17 (-15.89, 15.54)	0.9828	
>= 10 points	4/ 88 (4.5)	4.5	1/ 88 (1.1)	1.1	4.00 (0.46, 35.08)	0.2108	3.44 (-4.71, 11.60)	0.4079	
OCS dose at baseline									0.8703
<10 mg/day	3/ 57 (5.3)	5.2	1/ 52 (1.9)	1.9	2.74 (0.29, 25.50)	0.3766	3.35 (-8.68, 15.37)	0.5853	
>=10 mg/day	2/ 70 (2.9)	2.9	1/ 73 (1.4)	1.4	2.09 (0.19, 22.49)	0.5446	1.55 (-7.76, 10.86)	0.7444	
Result of type I IFN gene signature test									0.7719
LOW	1/ 22 (4.5)	4.5	0/ 24 (0.0)	0.0	3.26 (0.14, 76.10)	0.4621	4.55 (-12.32, 21.41)	0.5973	
HIGH	4/105 (3.8)	3.9	2/101 (2.0)	1.9	1.92 (0.36, 10.27)	0.4440	1.94 (-5.89, 9.78)	0.6269	
Age (years)									NE
<= 65	5/122 (4.1)	4.2	2/123 (1.6)	1.6	2.52 (0.50, 12.74)	0.2635	2.57 (-4.75, 9.88)	0.4916	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE		0.00 (-74.81, 74.81)	1.0000	
Sex									0.6379
male	2/ 12 (16.7)	16.7	0/ 8 (0.0)	0.0	3.46 (0.19, 63.86)	0.4038	16.67 (-18.93, 52.26)	0.3588	
female	3/115 (2.6)	2.7	2/117 (1.7)	1.7	1.53 (0.26, 8.96)	0.6398	0.97 (-6.40, 8.34)	0.7964	
Race									0.9426
White	4/ 85 (4.7)	4.5	2/ 96 (2.1)	2.2	2.26 (0.42, 12.02)	0.3395	2.38 (-7.00, 11.77)	0.6184	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE		0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	1/ 13 (7.7)	7.7	0/ 11 (0.0)	0.0	2.57 (0.12, 57.44)	0.5512	7.69 (-21.17, 36.55)	0.6014	
Ethnicity									NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	5/104 (4.8)	5.0	2/101 (2.0)	1.9	2.43 (0.48, 12.23)	0.2822	3.10 (-5.51, 11.70)	0.4803	
Geographic region									0.9605
EU	2/ 47 (4.3)	4.3	1/ 56 (1.8)	1.8	2.38 (0.22, 25.46)	0.4725	2.47 (-7.10, 12.04)	0.6132	
non-EU	3/ 80 (3.8)	3.8	1/ 69 (1.4)	1.4	2.59 (0.28, 24.31)	0.4055	2.44 (-6.70, 11.57)	0.6013	
Onset of disease									0.8678
Paediatric	1/ 8 (12.5)	12.5	0/ 7 (0.0)	0.0	2.67 (0.13, 56.63)	0.5293	12.50 (-28.93, 53.93)	0.5543	
Adult	4/119 (3.4)	3.4	2/118 (1.7)	1.7	1.98 (0.37, 10.62)	0.4239	1.66 (-5.68, 9.00)	0.6580	
ADA result									NE
Negative	5/111 (4.5)	4.6	2/112 (1.8)	1.8	2.52 (0.50, 12.73)	0.2626	2.89 (-5.08, 10.85)	0.4775	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment									0.2915
< 30	4/ 74 (5.4)	5.7	1/ 87 (1.1)	1.2	4.70 (0.54, 41.16)	0.1619	4.53 (-4.49, 13.55)	0.3249	
>= 30	1/ 53 (1.9)	2.0	1/ 38 (2.6)	2.5	0.72 (0.05, 11.11)	0.8119	-0.47 (-14.19, 13.26)	0.9467	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Serious Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.17, 6.17)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Serious Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-14.65, 14.65)	1.0000	
>= 10 points	0/ 88 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	0/ 70 (0.0)	0.0	0/ 73 (0.0)	0.0	NE	0.00 (-8.22, 8.22)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-15.17, 15.17)	1.0000	
HIGH	0/105 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-6.74, 6.74)	1.0000	
Age (years)								NE
<= 65	0/122 (0.0)	0.0	0/123 (0.0)	0.0	NE	0.00 (-6.34, 6.34)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE	0.00 (-74.81, 74.81)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE	0.00 (-31.89, 31.89)	1.0000	
female	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-6.65, 6.65)	1.0000	
Race								NE
White	0/ 85 (0.0)	0.0	0/ 96 (0.0)	0.0	NE	0.00 (-8.35, 8.35)	1.0000	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE	0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-26.65, 26.65)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	0/104 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-7.49, 7.49)	1.0000	
Geographic region								NE
EU	0/ 47 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-7.27, 7.27)	1.0000	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-8.12, 8.12)	1.0000	
Onset of disease								NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE	0.00 (-38.51, 38.51)	1.0000	
Adult	0/119 (0.0)	0.0	0/118 (0.0)	0.0	NE	0.00 (-6.51, 6.51)	1.0000	
ADA result								NE
Negative	0/111 (0.0)	0.0	0/112 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 74 (0.0)	0.0	0/ 87 (0.0)	0.0	NE	0.00 (-7.46, 7.46)	1.0000	
>= 30	0/ 53 (0.0)	0.0	0/ 38 (0.0)	0.0	NE	0.00 (-12.88, 12.88)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Severe Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.17, 6.17)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Severe Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Anifrolumab 300mg (N=127) Response rate	Placebo (N=125) n/ N (%)	Placebo (N=125) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Analysis Anifrolumab 300mg vs. Placebo Difference in response rates (95% CI)	Analysis Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-14.65, 14.65)	1.0000	
>= 10 points	0/ 88 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	0/ 70 (0.0)	0.0	0/ 73 (0.0)	0.0	NE	0.00 (-8.22, 8.22)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-15.17, 15.17)	1.0000	
HIGH	0/105 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-6.74, 6.74)	1.0000	
Age (years)								NE
<= 65	0/122 (0.0)	0.0	0/123 (0.0)	0.0	NE	0.00 (-6.34, 6.34)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE	0.00 (-74.81, 74.81)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE	0.00 (-31.89, 31.89)	1.0000	
female	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-6.65, 6.65)	1.0000	
Race								NE
White	0/ 85 (0.0)	0.0	0/ 96 (0.0)	0.0	NE	0.00 (-8.35, 8.35)	1.0000	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE	0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-26.65, 26.65)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	0/104 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-7.49, 7.49)	1.0000	
Geographic region								NE
EU	0/ 47 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-7.27, 7.27)	1.0000	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-8.12, 8.12)	1.0000	
Onset of disease								NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE	0.00 (-38.51, 38.51)	1.0000	
Adult	0/119 (0.0)	0.0	0/118 (0.0)	0.0	NE	0.00 (-6.51, 6.51)	1.0000	
ADA result								NE
Negative	0/111 (0.0)	0.0	0/112 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 74 (0.0)	0.0	0/ 87 (0.0)	0.0	NE	0.00 (-7.46, 7.46)	1.0000	
>= 30	0/ 53 (0.0)	0.0	0/ 38 (0.0)	0.0	NE	0.00 (-12.88, 12.88)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Non-Severe Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	5 (3.9)	2 (1.6)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	2.46 (0.49, 12.45)	
p-value	0.2763	
Odds Ratio (95% CI)	2.52 (0.48, 13.24)	
p-value	0.2747	
Risk Difference (95% CI)	2.34 (-1.70, 6.37)	
p-value	0.2563	
CMH approach		
Response rate	4.0	1.6
Difference in response rates (95% CI)	2.42 (-4.69, 9.52)	
p-value	0.5046	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Non-Severe Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.4193
< 10 points	1/ 39 (2.6)	2.6	1/ 37 (2.7)	2.8	0.95 (0.06, 14.62)	0.9699	-0.17 (-15.89, 15.54)	0.9828	
>= 10 points	4/ 88 (4.5)	4.5	1/ 88 (1.1)	1.1	4.00 (0.46, 35.08)	0.2108	3.44 (-4.71, 11.60)	0.4079	
OCS dose at baseline									0.8703
<10 mg/day	3/ 57 (5.3)	5.2	1/ 52 (1.9)	1.9	2.74 (0.29, 25.50)	0.3766	3.35 (-8.68, 15.37)	0.5853	
>=10 mg/day	2/ 70 (2.9)	2.9	1/ 73 (1.4)	1.4	2.09 (0.19, 22.49)	0.5446	1.55 (-7.76, 10.86)	0.7444	
Result of type I IFN gene signature test									0.7719
LOW	1/ 22 (4.5)	4.5	0/ 24 (0.0)	0.0	3.26 (0.14, 76.10)	0.4621	4.55 (-12.32, 21.41)	0.5973	
HIGH	4/105 (3.8)	3.9	2/101 (2.0)	1.9	1.92 (0.36, 10.27)	0.4440	1.94 (-5.89, 9.78)	0.6269	
Age (years)									NE
<= 65	5/122 (4.1)	4.2	2/123 (1.6)	1.6	2.52 (0.50, 12.74)	0.2635	2.57 (-4.75, 9.88)	0.4916	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE		0.00 (-74.81, 74.81)	1.0000	
Sex									0.6379
male	2/ 12 (16.7)	16.7	0/ 8 (0.0)	0.0	3.46 (0.19, 63.86)	0.4038	16.67 (-18.93, 52.26)	0.3588	
female	3/115 (2.6)	2.7	2/117 (1.7)	1.7	1.53 (0.26, 8.96)	0.6398	0.97 (-6.40, 8.34)	0.7964	
Race									0.9426
White	4/ 85 (4.7)	4.5	2/ 96 (2.1)	2.2	2.26 (0.42, 12.02)	0.3395	2.38 (-7.00, 11.77)	0.6184	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE		0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	1/ 13 (7.7)	7.7	0/ 11 (0.0)	0.0	2.57 (0.12, 57.44)	0.5512	7.69 (-21.17, 36.55)	0.6014	
Ethnicity									NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	5/104 (4.8)	5.0	2/101 (2.0)	1.9	2.43 (0.48, 12.23)	0.2822	3.10 (-5.51, 11.70)	0.4803	
Geographic region									0.9605
EU	2/ 47 (4.3)	4.3	1/ 56 (1.8)	1.8	2.38 (0.22, 25.46)	0.4725	2.47 (-7.10, 12.04)	0.6132	
non-EU	3/ 80 (3.8)	3.8	1/ 69 (1.4)	1.4	2.59 (0.28, 24.31)	0.4055	2.44 (-6.70, 11.57)	0.6013	
Onset of disease									0.8678
Paediatric	1/ 8 (12.5)	12.5	0/ 7 (0.0)	0.0	2.67 (0.13, 56.63)	0.5293	12.50 (-28.93, 53.93)	0.5543	
Adult	4/119 (3.4)	3.4	2/118 (1.7)	1.7	1.98 (0.37, 10.62)	0.4239	1.66 (-5.68, 9.00)	0.6580	
ADA result									NE
Negative	5/111 (4.5)	4.6	2/112 (1.8)	1.8	2.52 (0.50, 12.73)	0.2626	2.89 (-5.08, 10.85)	0.4775	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment									0.2915
< 30	4/ 74 (5.4)	5.7	1/ 87 (1.1)	1.2	4.70 (0.54, 41.16)	0.1619	4.53 (-4.49, 13.55)	0.3249	
>= 30	1/ 53 (1.9)	2.0	1/ 38 (2.6)	2.5	0.72 (0.05, 11.11)	0.8119	-0.47 (-14.19, 13.26)	0.9467	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Herpes Zoster leading to discontinuation of study drug
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.17, 6.17)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Herpes Zoster leading to discontinuation of study drug - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Anifrolumab 300mg (N=127) Response rate	Placebo (N=125) n/ N (%)	Placebo (N=125) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Analysis Anifrolumab 300mg vs. Placebo Difference in response rates (95% CI)	Analysis Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-14.65, 14.65)	1.0000	
>= 10 points	0/ 88 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	0/ 70 (0.0)	0.0	0/ 73 (0.0)	0.0	NE	0.00 (-8.22, 8.22)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-15.17, 15.17)	1.0000	
HIGH	0/105 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-6.74, 6.74)	1.0000	
Age (years)								NE
<= 65	0/122 (0.0)	0.0	0/123 (0.0)	0.0	NE	0.00 (-6.34, 6.34)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE	0.00 (-74.81, 74.81)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE	0.00 (-31.89, 31.89)	1.0000	
female	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-6.65, 6.65)	1.0000	
Race								NE
White	0/ 85 (0.0)	0.0	0/ 96 (0.0)	0.0	NE	0.00 (-8.35, 8.35)	1.0000	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE	0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-26.65, 26.65)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	0/104 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-7.49, 7.49)	1.0000	
Geographic region								NE
EU	0/ 47 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-7.27, 7.27)	1.0000	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-8.12, 8.12)	1.0000	
Onset of disease								NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE	0.00 (-38.51, 38.51)	1.0000	
Adult	0/119 (0.0)	0.0	0/118 (0.0)	0.0	NE	0.00 (-6.51, 6.51)	1.0000	
ADA result								NE
Negative	0/111 (0.0)	0.0	0/112 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 74 (0.0)	0.0	0/ 87 (0.0)	0.0	NE	0.00 (-7.46, 7.46)	1.0000	
>= 30	0/ 53 (0.0)	0.0	0/ 38 (0.0)	0.0	NE	0.00 (-12.88, 12.88)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Influenza
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	1 (0.8)	1 (0.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.98 (0.06, 15.56)	
p-value	0.9910	
Odds Ratio (95% CI)	0.98 (0.06, 15.91)	
p-value	0.9910	
Risk Difference (95% CI)	-0.01 (-2.20, 2.18)	
p-value	0.9910	
CMH approach		
Response rate	0.8	0.8
Difference in response rates (95% CI)	0.07 (-6.37, 6.51)	
p-value	0.9832	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.3269
< 10 points	0/ 39 (0.0)	0.0	1/ 37 (2.7)	2.1	0.32 (0.01, 7.54)	0.4771	-2.14 (-17.04, 12.76)	0.7785	
>= 10 points	1/ 88 (1.1)	1.1	0/ 88 (0.0)	0.0	3.00 (0.12, 72.65)	0.4993	1.10 (-6.02, 8.22)	0.7618	
OCS dose at baseline									0.3682
<10 mg/day	1/ 57 (1.8)	1.7	0/ 52 (0.0)	0.0	2.74 (0.11, 65.85)	0.5341	1.70 (-9.28, 12.67)	0.7618	
>=10 mg/day	0/ 70 (0.0)	0.0	1/ 73 (1.4)	1.1	0.35 (0.01, 8.39)	0.5152	-1.13 (-9.50, 7.24)	0.7913	
Result of type I IFN gene signature test									NE
LOW	1/ 22 (4.5)	4.5	1/ 24 (4.2)	4.2	1.09 (0.07, 16.41)	0.9498	0.38 (-17.82, 18.58)	0.9675	
HIGH	0/105 (0.0)	0.0	0/101 (0.0)	0.0	NE		0.00 (-6.74, 6.74)	1.0000	
Age (years)									NE
<= 65	1/122 (0.8)	0.9	1/123 (0.8)	0.7	1.01 (0.06, 15.94)	0.9954	0.16 (-6.45, 6.76)	0.9630	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE		0.00 (-74.81, 74.81)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE		0.00 (-31.89, 31.89)	1.0000	
female	1/115 (0.9)	0.9	1/117 (0.9)	0.8	1.02 (0.06, 16.07)	0.9902	0.12 (-6.81, 7.06)	0.9728	
Race									0.2287
White	1/ 85 (1.2)	1.1	0/ 96 (0.0)	0.0	3.38 (0.14, 81.97)	0.4535	1.12 (-7.42, 9.66)	0.7969	
Black or African American	0/ 22 (0.0)	0.0	1/ 14 (7.1)	7.1	0.22 (0.01, 4.99)	0.3399	-7.14 (-29.62, 15.33)	0.5333	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-26.65, 26.65)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	1/104 (1.0)	1.1	1/101 (1.0)	0.9	0.97 (0.06, 15.32)	0.9834	0.20 (-7.62, 8.01)	0.9604	
Geographic region									0.2732
EU	1/ 47 (2.1)	2.1	0/ 56 (0.0)	0.0	3.56 (0.15, 85.45)	0.4332	2.13 (-6.08, 10.33)	0.6114	
non-EU	0/ 80 (0.0)	0.0	1/ 69 (1.4)	1.5	0.29 (0.01, 6.96)	0.4437	-1.48 (-9.89, 6.93)	0.7296	
Onset of disease									NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE		0.00 (-38.51, 38.51)	1.0000	
Adult	1/119 (0.8)	0.8	1/118 (0.8)	0.8	0.99 (0.06, 15.67)	0.9952	0.00 (-6.79, 6.79)	1.0000	
ADA result									NE
Negative	1/111 (0.9)	0.9	1/112 (0.9)	0.9	1.01 (0.06, 15.93)	0.9949	0.08 (-7.14, 7.30)	0.9822	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment									0.2424
< 30	1/ 74 (1.4)	1.6	0/ 87 (0.0)	0.0	3.52 (0.15, 85.13)	0.4388	1.58 (-6.15, 9.30)	0.6893	
>= 30	0/ 53 (0.0)	0.0	1/ 38 (2.6)	2.7	0.24 (0.01, 5.75)	0.3792	-2.67 (-16.00, 10.65)	0.6941	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Serious Influenza
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.17, 6.17)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Serious Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-14.65, 14.65)	1.0000	
>= 10 points	0/ 88 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	0/ 70 (0.0)	0.0	0/ 73 (0.0)	0.0	NE	0.00 (-8.22, 8.22)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-15.17, 15.17)	1.0000	
HIGH	0/105 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-6.74, 6.74)	1.0000	
Age (years)								NE
<= 65	0/122 (0.0)	0.0	0/123 (0.0)	0.0	NE	0.00 (-6.34, 6.34)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE	0.00 (-74.81, 74.81)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE	0.00 (-31.89, 31.89)	1.0000	
female	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-6.65, 6.65)	1.0000	
Race								NE
White	0/ 85 (0.0)	0.0	0/ 96 (0.0)	0.0	NE	0.00 (-8.35, 8.35)	1.0000	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE	0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-26.65, 26.65)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	0/104 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-7.49, 7.49)	1.0000	
Geographic region								NE
EU	0/ 47 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-7.27, 7.27)	1.0000	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-8.12, 8.12)	1.0000	
Onset of disease								NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE	0.00 (-38.51, 38.51)	1.0000	
Adult	0/119 (0.0)	0.0	0/118 (0.0)	0.0	NE	0.00 (-6.51, 6.51)	1.0000	
ADA result								NE
Negative	0/111 (0.0)	0.0	0/112 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 74 (0.0)	0.0	0/ 87 (0.0)	0.0	NE	0.00 (-7.46, 7.46)	1.0000	
>= 30	0/ 53 (0.0)	0.0	0/ 38 (0.0)	0.0	NE	0.00 (-12.88, 12.88)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Severe Influenza
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.17, 6.17)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Severe Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-14.65, 14.65)	1.0000	
>= 10 points	0/ 88 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	0/ 70 (0.0)	0.0	0/ 73 (0.0)	0.0	NE	0.00 (-8.22, 8.22)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-15.17, 15.17)	1.0000	
HIGH	0/105 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-6.74, 6.74)	1.0000	
Age (years)								NE
<= 65	0/122 (0.0)	0.0	0/123 (0.0)	0.0	NE	0.00 (-6.34, 6.34)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE	0.00 (-74.81, 74.81)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE	0.00 (-31.89, 31.89)	1.0000	
female	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-6.65, 6.65)	1.0000	
Race								NE
White	0/ 85 (0.0)	0.0	0/ 96 (0.0)	0.0	NE	0.00 (-8.35, 8.35)	1.0000	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE	0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-26.65, 26.65)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	0/104 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-7.49, 7.49)	1.0000	
Geographic region								NE
EU	0/ 47 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-7.27, 7.27)	1.0000	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-8.12, 8.12)	1.0000	
Onset of disease								NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE	0.00 (-38.51, 38.51)	1.0000	
Adult	0/119 (0.0)	0.0	0/118 (0.0)	0.0	NE	0.00 (-6.51, 6.51)	1.0000	
ADA result								NE
Negative	0/111 (0.0)	0.0	0/112 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 74 (0.0)	0.0	0/ 87 (0.0)	0.0	NE	0.00 (-7.46, 7.46)	1.0000	
>= 30	0/ 53 (0.0)	0.0	0/ 38 (0.0)	0.0	NE	0.00 (-12.88, 12.88)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Non-Severe Influenza
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	1 (0.8)	1 (0.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.98 (0.06, 15.56)	
p-value	0.9910	
Odds Ratio (95% CI)	0.98 (0.06, 15.91)	
p-value	0.9910	
Risk Difference (95% CI)	-0.01 (-2.20, 2.18)	
p-value	0.9910	
CMH approach		
Response rate	0.8	0.8
Difference in response rates (95% CI)	0.07 (-6.37, 6.51)	
p-value	0.9832	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Non-Severe Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.3269
< 10 points	0/ 39 (0.0)	0.0	1/ 37 (2.7)	2.1	0.32 (0.01, 7.54)	0.4771	-2.14 (-17.04, 12.76)	0.7785	
>= 10 points	1/ 88 (1.1)	1.1	0/ 88 (0.0)	0.0	3.00 (0.12, 72.65)	0.4993	1.10 (-6.02, 8.22)	0.7618	
OCS dose at baseline									0.3682
<10 mg/day	1/ 57 (1.8)	1.7	0/ 52 (0.0)	0.0	2.74 (0.11, 65.85)	0.5341	1.70 (-9.28, 12.67)	0.7618	
>=10 mg/day	0/ 70 (0.0)	0.0	1/ 73 (1.4)	1.1	0.35 (0.01, 8.39)	0.5152	-1.13 (-9.50, 7.24)	0.7913	
Result of type I IFN gene signature test									NE
LOW	1/ 22 (4.5)	4.5	1/ 24 (4.2)	4.2	1.09 (0.07, 16.41)	0.9498	0.38 (-17.82, 18.58)	0.9675	
HIGH	0/105 (0.0)	0.0	0/101 (0.0)	0.0	NE		0.00 (-6.74, 6.74)	1.0000	
Age (years)									NE
<= 65	1/122 (0.8)	0.9	1/123 (0.8)	0.7	1.01 (0.06, 15.94)	0.9954	0.16 (-6.45, 6.76)	0.9630	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE		0.00 (-74.81, 74.81)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE		0.00 (-31.89, 31.89)	1.0000	
female	1/115 (0.9)	0.9	1/117 (0.9)	0.8	1.02 (0.06, 16.07)	0.9902	0.12 (-6.81, 7.06)	0.9728	
Race									0.2287
White	1/ 85 (1.2)	1.1	0/ 96 (0.0)	0.0	3.38 (0.14, 81.97)	0.4535	1.12 (-7.42, 9.66)	0.7969	
Black or African American	0/ 22 (0.0)	0.0	1/ 14 (7.1)	7.1	0.22 (0.01, 4.99)	0.3399	-7.14 (-29.62, 15.33)	0.5333	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-26.65, 26.65)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	1/104 (1.0)	1.1	1/101 (1.0)	0.9	0.97 (0.06, 15.32)	0.9834	0.20 (-7.62, 8.01)	0.9604	
Geographic region									0.2732
EU	1/ 47 (2.1)	2.1	0/ 56 (0.0)	0.0	3.56 (0.15, 85.45)	0.4332	2.13 (-6.08, 10.33)	0.6114	
non-EU	0/ 80 (0.0)	0.0	1/ 69 (1.4)	1.5	0.29 (0.01, 6.96)	0.4437	-1.48 (-9.89, 6.93)	0.7296	
Onset of disease									NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE		0.00 (-38.51, 38.51)	1.0000	
Adult	1/119 (0.8)	0.8	1/118 (0.8)	0.8	0.99 (0.06, 15.67)	0.9952	0.00 (-6.79, 6.79)	1.0000	
ADA result									NE
Negative	1/111 (0.9)	0.9	1/112 (0.9)	0.9	1.01 (0.06, 15.93)	0.9949	0.08 (-7.14, 7.30)	0.9822	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment									0.2424
< 30	1/ 74 (1.4)	1.6	0/ 87 (0.0)	0.0	3.52 (0.15, 85.13)	0.4388	1.58 (-6.15, 9.30)	0.6893	
>= 30	0/ 53 (0.0)	0.0	1/ 38 (2.6)	2.7	0.24 (0.01, 5.75)	0.3792	-2.67 (-16.00, 10.65)	0.6941	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	0 (0.0)	1 (0.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.33 (0.01, 7.98)	
p-value	0.4937	
Odds Ratio (95% CI)	0.33 (0.01, 8.07)	
p-value	0.4932	
Risk Difference (95% CI)	-0.80 (-2.36, 0.76)	
p-value	0.3154	
CMH approach		
Response rate	0.0	0.8
Difference in response rates (95% CI)	-0.77 (-7.09, 5.55)	
p-value	0.8112	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE		0.00 (-14.65, 14.65)	1.0000	
>= 10 points	0/ 88 (0.0)	0.0	1/ 88 (1.1)	1.1	0.33 (0.01, 8.07)	0.4993	-1.10 (-8.30, 6.09)	0.7643	
OCS dose at baseline									NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE		0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	0/ 70 (0.0)	0.0	1/ 73 (1.4)	1.4	0.35 (0.01, 8.39)	0.5152	-1.37 (-9.94, 7.21)	0.7547	
Result of type I IFN gene signature test									NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-15.17, 15.17)	1.0000	
HIGH	0/105 (0.0)	0.0	1/101 (1.0)	0.9	0.32 (0.01, 7.78)	0.4847	-0.94 (-7.89, 6.01)	0.7903	
Age (years)									NE
<= 65	0/122 (0.0)	0.0	1/123 (0.8)	0.8	0.34 (0.01, 8.17)	0.5030	-0.79 (-7.29, 5.70)	0.8105	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE		0.00 (-74.81, 74.81)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE		0.00 (-31.89, 31.89)	1.0000	
female	0/115 (0.0)	0.0	1/117 (0.9)	0.8	0.34 (0.01, 8.24)	0.5064	-0.81 (-7.62, 5.99)	0.8147	
Race									NE
White	0/ 85 (0.0)	0.0	1/ 96 (1.0)	0.9	0.38 (0.02, 9.11)	0.5475	-0.93 (-9.44, 7.57)	0.8296	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE		0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-26.65, 26.65)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	0/104 (0.0)	0.0	1/101 (1.0)	0.9	0.32 (0.01, 7.86)	0.4883	-0.92 (-8.59, 6.74)	0.8132	
Geographic region									NE
EU	0/ 47 (0.0)	0.0	1/ 56 (1.8)	1.8	0.40 (0.02, 9.49)	0.5676	-1.79 (-9.75, 6.18)	0.6602	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE		0.00 (-8.12, 8.12)	1.0000	
Onset of disease									NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE		0.00 (-38.51, 38.51)	1.0000	
Adult	0/119 (0.0)	0.0	1/118 (0.8)	0.8	0.33 (0.01, 8.03)	0.4965	-0.81 (-7.47, 5.86)	0.8125	
ADA result									NE
Negative	0/111 (0.0)	0.0	1/112 (0.9)	0.8	0.34 (0.01, 8.17)	0.5031	-0.82 (-7.89, 6.25)	0.8193	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/ 74 (0.0)	0.0	0/ 87 (0.0)	0.0	NE		0.00 (-7.46, 7.46)	1.0000	
>= 30	0/ 53 (0.0)	0.0	1/ 38 (2.6)	2.7	0.24 (0.01, 5.75)	0.3792	-2.72 (-16.24, 10.81)	0.6939	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Serious Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.17, 6.17)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Serious Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=127)		Placebo (N=125)		Analysis Anifrolumab 300mg vs. Placebo			Interaction
Level	n/ N (%)	Response rate	n/ N (%)	Response rate	Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-14.65, 14.65)	1.0000	
>= 10 points	0/ 88 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	0/ 70 (0.0)	0.0	0/ 73 (0.0)	0.0	NE	0.00 (-8.22, 8.22)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-15.17, 15.17)	1.0000	
HIGH	0/105 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-6.74, 6.74)	1.0000	
Age (years)								NE
<= 65	0/122 (0.0)	0.0	0/123 (0.0)	0.0	NE	0.00 (-6.34, 6.34)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE	0.00 (-74.81, 74.81)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE	0.00 (-31.89, 31.89)	1.0000	
female	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-6.65, 6.65)	1.0000	
Race								NE
White	0/ 85 (0.0)	0.0	0/ 96 (0.0)	0.0	NE	0.00 (-8.35, 8.35)	1.0000	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE	0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-26.65, 26.65)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	0/104 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-7.49, 7.49)	1.0000	
Geographic region								NE
EU	0/ 47 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-7.27, 7.27)	1.0000	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-8.12, 8.12)	1.0000	
Onset of disease								NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE	0.00 (-38.51, 38.51)	1.0000	
Adult	0/119 (0.0)	0.0	0/118 (0.0)	0.0	NE	0.00 (-6.51, 6.51)	1.0000	
ADA result								NE
Negative	0/111 (0.0)	0.0	0/112 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 74 (0.0)	0.0	0/ 87 (0.0)	0.0	NE	0.00 (-7.46, 7.46)	1.0000	
>= 30	0/ 53 (0.0)	0.0	0/ 38 (0.0)	0.0	NE	0.00 (-12.88, 12.88)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Severe Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.17, 6.17)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Severe Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-14.65, 14.65)	1.0000	
>= 10 points	0/ 88 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	0/ 70 (0.0)	0.0	0/ 73 (0.0)	0.0	NE	0.00 (-8.22, 8.22)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-15.17, 15.17)	1.0000	
HIGH	0/105 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-6.74, 6.74)	1.0000	
Age (years)								NE
<= 65	0/122 (0.0)	0.0	0/123 (0.0)	0.0	NE	0.00 (-6.34, 6.34)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE	0.00 (-74.81, 74.81)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE	0.00 (-31.89, 31.89)	1.0000	
female	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-6.65, 6.65)	1.0000	
Race								NE
White	0/ 85 (0.0)	0.0	0/ 96 (0.0)	0.0	NE	0.00 (-8.35, 8.35)	1.0000	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE	0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-26.65, 26.65)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	0/104 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-7.49, 7.49)	1.0000	
Geographic region								NE
EU	0/ 47 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-7.27, 7.27)	1.0000	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-8.12, 8.12)	1.0000	
Onset of disease								NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE	0.00 (-38.51, 38.51)	1.0000	
Adult	0/119 (0.0)	0.0	0/118 (0.0)	0.0	NE	0.00 (-6.51, 6.51)	1.0000	
ADA result								NE
Negative	0/111 (0.0)	0.0	0/112 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 74 (0.0)	0.0	0/ 87 (0.0)	0.0	NE	0.00 (-7.46, 7.46)	1.0000	
>= 30	0/ 53 (0.0)	0.0	0/ 38 (0.0)	0.0	NE	0.00 (-12.88, 12.88)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Non-Severe Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	0 (0.0)	1 (0.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.33 (0.01, 7.98)	
p-value	0.4937	
Odds Ratio (95% CI)	0.33 (0.01, 8.07)	
p-value	0.4932	
Risk Difference (95% CI)	-0.80 (-2.36, 0.76)	
p-value	0.3154	
CMH approach		
Response rate	0.0	0.8
Difference in response rates (95% CI)	-0.77 (-7.09, 5.55)	
p-value	0.8112	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Non-Severe Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=127)		Placebo (N=125)		Analysis Anifrolumab 300mg vs. Placebo				Interaction
Level	n/ N (%)	Response rate	n/ N (%)	Response rate	Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE		0.00 (-14.65, 14.65)	1.0000	
>= 10 points	0/ 88 (0.0)	0.0	1/ 88 (1.1)	1.1	0.33 (0.01, 8.07)	0.4993	-1.10 (-8.30, 6.09)	0.7643	
OCS dose at baseline									NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE		0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	0/ 70 (0.0)	0.0	1/ 73 (1.4)	1.4	0.35 (0.01, 8.39)	0.5152	-1.37 (-9.94, 7.21)	0.7547	
Result of type I IFN gene signature test									NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-15.17, 15.17)	1.0000	
HIGH	0/105 (0.0)	0.0	1/101 (1.0)	0.9	0.32 (0.01, 7.78)	0.4847	-0.94 (-7.89, 6.01)	0.7903	
Age (years)									NE
<= 65	0/122 (0.0)	0.0	1/123 (0.8)	0.8	0.34 (0.01, 8.17)	0.5030	-0.79 (-7.29, 5.70)	0.8105	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE		0.00 (-74.81, 74.81)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE		0.00 (-31.89, 31.89)	1.0000	
female	0/115 (0.0)	0.0	1/117 (0.9)	0.8	0.34 (0.01, 8.24)	0.5064	-0.81 (-7.62, 5.99)	0.8147	
Race									NE
White	0/ 85 (0.0)	0.0	1/ 96 (1.0)	0.9	0.38 (0.02, 9.11)	0.5475	-0.93 (-9.44, 7.57)	0.8296	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE		0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-26.65, 26.65)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	0/104 (0.0)	0.0	1/101 (1.0)	0.9	0.32 (0.01, 7.86)	0.4883	-0.92 (-8.59, 6.74)	0.8132	
Geographic region									NE
EU	0/ 47 (0.0)	0.0	1/ 56 (1.8)	1.8	0.40 (0.02, 9.49)	0.5676	-1.79 (-9.75, 6.18)	0.6602	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE		0.00 (-8.12, 8.12)	1.0000	
Onset of disease									NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE		0.00 (-38.51, 38.51)	1.0000	
Adult	0/119 (0.0)	0.0	1/118 (0.8)	0.8	0.33 (0.01, 8.03)	0.4965	-0.81 (-7.47, 5.86)	0.8125	
ADA result									NE
Negative	0/111 (0.0)	0.0	1/112 (0.9)	0.8	0.34 (0.01, 8.17)	0.5031	-0.82 (-7.89, 6.25)	0.8193	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/ 74 (0.0)	0.0	0/ 87 (0.0)	0.0	NE		0.00 (-7.46, 7.46)	1.0000	
>= 30	0/ 53 (0.0)	0.0	1/ 38 (2.6)	2.7	0.24 (0.01, 5.75)	0.3792	-2.72 (-16.24, 10.81)	0.6939	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Vasculitis
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.17, 6.17)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-14.65, 14.65)	1.0000	
>= 10 points	0/ 88 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	0/ 70 (0.0)	0.0	0/ 73 (0.0)	0.0	NE	0.00 (-8.22, 8.22)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-15.17, 15.17)	1.0000	
HIGH	0/105 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-6.74, 6.74)	1.0000	
Age (years)								NE
<= 65	0/122 (0.0)	0.0	0/123 (0.0)	0.0	NE	0.00 (-6.34, 6.34)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE	0.00 (-74.81, 74.81)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE	0.00 (-31.89, 31.89)	1.0000	
female	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-6.65, 6.65)	1.0000	
Race								NE
White	0/ 85 (0.0)	0.0	0/ 96 (0.0)	0.0	NE	0.00 (-8.35, 8.35)	1.0000	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE	0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-26.65, 26.65)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	0/104 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-7.49, 7.49)	1.0000	
Geographic region								NE
EU	0/ 47 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-7.27, 7.27)	1.0000	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-8.12, 8.12)	1.0000	
Onset of disease								NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE	0.00 (-38.51, 38.51)	1.0000	
Adult	0/119 (0.0)	0.0	0/118 (0.0)	0.0	NE	0.00 (-6.51, 6.51)	1.0000	
ADA result								NE
Negative	0/111 (0.0)	0.0	0/112 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 74 (0.0)	0.0	0/ 87 (0.0)	0.0	NE	0.00 (-7.46, 7.46)	1.0000	
>= 30	0/ 53 (0.0)	0.0	0/ 38 (0.0)	0.0	NE	0.00 (-12.88, 12.88)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Serious Vasculitis
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.17, 6.17)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Serious Vasculitis - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=127)		Placebo (N=125)		Analysis Anifrolumab 300mg vs. Placebo			Interaction
Level	n/ N (%)	Response rate	n/ N (%)	Response rate	Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-14.65, 14.65)	1.0000	
>= 10 points	0/ 88 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	0/ 70 (0.0)	0.0	0/ 73 (0.0)	0.0	NE	0.00 (-8.22, 8.22)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-15.17, 15.17)	1.0000	
HIGH	0/105 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-6.74, 6.74)	1.0000	
Age (years)								NE
<= 65	0/122 (0.0)	0.0	0/123 (0.0)	0.0	NE	0.00 (-6.34, 6.34)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE	0.00 (-74.81, 74.81)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE	0.00 (-31.89, 31.89)	1.0000	
female	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-6.65, 6.65)	1.0000	
Race								NE
White	0/ 85 (0.0)	0.0	0/ 96 (0.0)	0.0	NE	0.00 (-8.35, 8.35)	1.0000	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE	0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-26.65, 26.65)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	0/104 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-7.49, 7.49)	1.0000	
Geographic region								NE
EU	0/ 47 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-7.27, 7.27)	1.0000	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-8.12, 8.12)	1.0000	
Onset of disease								NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE	0.00 (-38.51, 38.51)	1.0000	
Adult	0/119 (0.0)	0.0	0/118 (0.0)	0.0	NE	0.00 (-6.51, 6.51)	1.0000	
ADA result								NE
Negative	0/111 (0.0)	0.0	0/112 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 74 (0.0)	0.0	0/ 87 (0.0)	0.0	NE	0.00 (-7.46, 7.46)	1.0000	
>= 30	0/ 53 (0.0)	0.0	0/ 38 (0.0)	0.0	NE	0.00 (-12.88, 12.88)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Severe Vasculitis
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.17, 6.17)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Severe Vasculitis - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=127)		Placebo (N=125)		Analysis Anifrolumab 300mg vs. Placebo			Interaction
Level	n/ N (%)	Response rate	n/ N (%)	Response rate	Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-14.65, 14.65)	1.0000	
>= 10 points	0/ 88 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	0/ 70 (0.0)	0.0	0/ 73 (0.0)	0.0	NE	0.00 (-8.22, 8.22)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-15.17, 15.17)	1.0000	
HIGH	0/105 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-6.74, 6.74)	1.0000	
Age (years)								NE
<= 65	0/122 (0.0)	0.0	0/123 (0.0)	0.0	NE	0.00 (-6.34, 6.34)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE	0.00 (-74.81, 74.81)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE	0.00 (-31.89, 31.89)	1.0000	
female	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-6.65, 6.65)	1.0000	
Race								NE
White	0/ 85 (0.0)	0.0	0/ 96 (0.0)	0.0	NE	0.00 (-8.35, 8.35)	1.0000	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE	0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-26.65, 26.65)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	0/104 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-7.49, 7.49)	1.0000	
Geographic region								NE
EU	0/ 47 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-7.27, 7.27)	1.0000	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-8.12, 8.12)	1.0000	
Onset of disease								NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE	0.00 (-38.51, 38.51)	1.0000	
Adult	0/119 (0.0)	0.0	0/118 (0.0)	0.0	NE	0.00 (-6.51, 6.51)	1.0000	
ADA result								NE
Negative	0/111 (0.0)	0.0	0/112 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 74 (0.0)	0.0	0/ 87 (0.0)	0.0	NE	0.00 (-7.46, 7.46)	1.0000	
>= 30	0/ 53 (0.0)	0.0	0/ 38 (0.0)	0.0	NE	0.00 (-12.88, 12.88)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Non-Severe Vasculitis
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.17, 6.17)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Non-Severe Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-14.65, 14.65)	1.0000	
>= 10 points	0/ 88 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	0/ 70 (0.0)	0.0	0/ 73 (0.0)	0.0	NE	0.00 (-8.22, 8.22)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-15.17, 15.17)	1.0000	
HIGH	0/105 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-6.74, 6.74)	1.0000	
Age (years)								NE
<= 65	0/122 (0.0)	0.0	0/123 (0.0)	0.0	NE	0.00 (-6.34, 6.34)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE	0.00 (-74.81, 74.81)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE	0.00 (-31.89, 31.89)	1.0000	
female	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-6.65, 6.65)	1.0000	
Race								NE
White	0/ 85 (0.0)	0.0	0/ 96 (0.0)	0.0	NE	0.00 (-8.35, 8.35)	1.0000	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE	0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-26.65, 26.65)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	0/104 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-7.49, 7.49)	1.0000	
Geographic region								NE
EU	0/ 47 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-7.27, 7.27)	1.0000	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-8.12, 8.12)	1.0000	
Onset of disease								NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE	0.00 (-38.51, 38.51)	1.0000	
Adult	0/119 (0.0)	0.0	0/118 (0.0)	0.0	NE	0.00 (-6.51, 6.51)	1.0000	
ADA result								NE
Negative	0/111 (0.0)	0.0	0/112 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 74 (0.0)	0.0	0/ 87 (0.0)	0.0	NE	0.00 (-7.46, 7.46)	1.0000	
>= 30	0/ 53 (0.0)	0.0	0/ 38 (0.0)	0.0	NE	0.00 (-12.88, 12.88)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Malignancy
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	1 (0.8)	1 (0.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.98 (0.06, 15.56)	
p-value	0.9910	
Odds Ratio (95% CI)	0.98 (0.06, 15.91)	
p-value	0.9910	
Risk Difference (95% CI)	-0.01 (-2.20, 2.18)	
p-value	0.9910	
CMH approach		
Response rate	0.7	0.8
Difference in response rates (95% CI)	-0.08 (-6.49, 6.33)	
p-value	0.9804	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.3494
< 10 points	1/ 39 (2.6)	2.3	0/ 37 (0.0)	0.0	2.85 (0.12, 67.83)	0.5172	2.32 (-12.76, 17.39)	0.7633	
>= 10 points	0/ 88 (0.0)	0.0	1/ 88 (1.1)	1.1	0.33 (0.01, 8.07)	0.4993	-1.10 (-8.30, 6.09)	0.7643	
OCS dose at baseline									NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE		0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	1/ 70 (1.4)	1.2	1/ 73 (1.4)	1.4	1.04 (0.07, 16.35)	0.9762	-0.14 (-8.92, 8.64)	0.9746	
Result of type I IFN gene signature test									NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-15.17, 15.17)	1.0000	
HIGH	1/105 (1.0)	0.8	1/101 (1.0)	0.9	0.96 (0.06, 15.17)	0.9780	-0.10 (-7.17, 6.97)	0.9782	
Age (years)									NE
<= 65	1/122 (0.8)	0.7	1/123 (0.8)	0.8	1.01 (0.06, 15.94)	0.9954	-0.12 (-6.69, 6.46)	0.9727	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE		0.00 (-74.81, 74.81)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE		0.00 (-31.89, 31.89)	1.0000	
female	1/115 (0.9)	0.8	1/117 (0.9)	0.8	1.02 (0.06, 16.07)	0.9902	-0.04 (-6.94, 6.86)	0.9900	
Race									NE
White	1/ 85 (1.2)	1.3	1/ 96 (1.0)	0.9	1.13 (0.07, 17.78)	0.9310	0.41 (-8.26, 9.08)	0.9259	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE		0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-26.65, 26.65)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	1/104 (1.0)	0.8	1/101 (1.0)	0.9	0.97 (0.06, 15.32)	0.9834	-0.15 (-7.90, 7.60)	0.9699	
Geographic region									NE
EU	1/ 47 (2.1)	2.1	1/ 56 (1.8)	1.8	1.19 (0.08, 18.54)	0.9004	0.34 (-8.48, 9.16)	0.9394	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE		0.00 (-8.12, 8.12)	1.0000	
Onset of disease									NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE		0.00 (-38.51, 38.51)	1.0000	
Adult	1/119 (0.8)	0.8	1/118 (0.8)	0.8	0.99 (0.06, 15.67)	0.9952	-0.05 (-6.82, 6.71)	0.9874	
ADA result									NE
Negative	1/111 (0.9)	0.7	1/112 (0.9)	0.8	1.01 (0.06, 15.93)	0.9949	-0.09 (-7.24, 7.07)	0.9809	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	1/ 74 (1.4)	1.2	1/ 87 (1.1)	1.2	1.18 (0.07, 18.47)	0.9083	0.03 (-7.93, 7.99)	0.9942	
>= 30	0/ 53 (0.0)	0.0	0/ 38 (0.0)	0.0	NE		0.00 (-12.88, 12.88)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Serious Malignancy
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	1 (0.8)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	2.95 (0.12, 71.81)	
p-value	0.5060	
Odds Ratio (95% CI)	2.98 (0.12, 73.76)	
p-value	0.5055	
Risk Difference (95% CI)	0.79 (-0.75, 2.32)	
p-value	0.3154	
CMH approach		
Response rate	0.7	0.0
Difference in response rates (95% CI)	0.69 (-5.57, 6.95)	
p-value	0.8289	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Serious Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	1/ 39 (2.6)	2.3	0/ 37 (0.0)	0.0	2.85 (0.12, 67.83)	0.5172	2.32 (-12.76, 17.39)	0.7633	
>= 10 points	0/ 88 (0.0)	0.0	0/ 88 (0.0)	0.0	NE		0.00 (-6.92, 6.92)	1.0000	
OCS dose at baseline									NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE		0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	1/ 70 (1.4)	1.2	0/ 73 (0.0)	0.0	3.13 (0.13, 75.49)	0.4828	1.22 (-7.21, 9.66)	0.7760	
Result of type I IFN gene signature test									NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-15.17, 15.17)	1.0000	
HIGH	1/105 (1.0)	0.8	0/101 (0.0)	0.0	2.89 (0.12, 70.05)	0.5147	0.84 (-6.02, 7.71)	0.8095	
Age (years)									NE
<= 65	1/122 (0.8)	0.7	0/123 (0.0)	0.0	3.02 (0.12, 73.52)	0.4966	0.68 (-5.74, 7.10)	0.8358	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE		0.00 (-74.81, 74.81)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE		0.00 (-31.89, 31.89)	1.0000	
female	1/115 (0.9)	0.8	0/117 (0.0)	0.0	3.05 (0.13, 74.15)	0.4931	0.77 (-5.98, 7.52)	0.8231	
Race									NE
White	1/ 85 (1.2)	1.3	0/ 96 (0.0)	0.0	3.38 (0.14, 81.97)	0.4535	1.35 (-7.17, 9.86)	0.7567	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE		0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-26.65, 26.65)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	1/104 (1.0)	0.8	0/101 (0.0)	0.0	2.91 (0.12, 70.71)	0.5109	0.77 (-6.80, 8.35)	0.8411	
Geographic region									NE
EU	1/ 47 (2.1)	2.1	0/ 56 (0.0)	0.0	3.56 (0.15, 85.45)	0.4332	2.13 (-6.08, 10.33)	0.6114	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE		0.00 (-8.12, 8.12)	1.0000	
Onset of disease									NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE		0.00 (-38.51, 38.51)	1.0000	
Adult	1/119 (0.8)	0.8	0/118 (0.0)	0.0	2.98 (0.12, 72.30)	0.5030	0.75 (-5.85, 7.36)	0.8234	
ADA result									NE
Negative	1/111 (0.9)	0.7	0/112 (0.0)	0.0	3.03 (0.12, 73.51)	0.4962	0.74 (-6.27, 7.74)	0.8368	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	1/ 74 (1.4)	1.2	0/ 87 (0.0)	0.0	3.52 (0.15, 85.13)	0.4388	1.18 (-6.50, 8.86)	0.7628	
>= 30	0/ 53 (0.0)	0.0	0/ 38 (0.0)	0.0	NE		0.00 (-12.88, 12.88)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Severe Malignancy
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.17, 6.17)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Severe Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Anifrolumab 300mg (N=127) Response rate	Placebo (N=125) n/ N (%)	Placebo (N=125) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Analysis Anifrolumab 300mg vs. Placebo Difference in response rates (95% CI)	Analysis Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 39 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-14.65, 14.65)	1.0000	
>= 10 points	0/ 88 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	0/ 70 (0.0)	0.0	0/ 73 (0.0)	0.0	NE	0.00 (-8.22, 8.22)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-15.17, 15.17)	1.0000	
HIGH	0/105 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-6.74, 6.74)	1.0000	
Age (years)								NE
<= 65	0/122 (0.0)	0.0	0/123 (0.0)	0.0	NE	0.00 (-6.34, 6.34)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE	0.00 (-74.81, 74.81)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE	0.00 (-31.89, 31.89)	1.0000	
female	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-6.65, 6.65)	1.0000	
Race								NE
White	0/ 85 (0.0)	0.0	0/ 96 (0.0)	0.0	NE	0.00 (-8.35, 8.35)	1.0000	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE	0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-26.65, 26.65)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	0/104 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-7.49, 7.49)	1.0000	
Geographic region								NE
EU	0/ 47 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-7.27, 7.27)	1.0000	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-8.12, 8.12)	1.0000	
Onset of disease								NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE	0.00 (-38.51, 38.51)	1.0000	
Adult	0/119 (0.0)	0.0	0/118 (0.0)	0.0	NE	0.00 (-6.51, 6.51)	1.0000	
ADA result								NE
Negative	0/111 (0.0)	0.0	0/112 (0.0)	0.0	NE	0.00 (-6.92, 6.92)	1.0000	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 74 (0.0)	0.0	0/ 87 (0.0)	0.0	NE	0.00 (-7.46, 7.46)	1.0000	
>= 30	0/ 53 (0.0)	0.0	0/ 38 (0.0)	0.0	NE	0.00 (-12.88, 12.88)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Non-Severe Malignancy
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	1 (0.8)	1 (0.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.98 (0.06, 15.56)	
p-value	0.9910	
Odds Ratio (95% CI)	0.98 (0.06, 15.91)	
p-value	0.9910	
Risk Difference (95% CI)	-0.01 (-2.20, 2.18)	
p-value	0.9910	
CMH approach		
Response rate	0.7	0.8
Difference in response rates (95% CI)	-0.08 (-6.49, 6.33)	
p-value	0.9804	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Non-Severe Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.3494
< 10 points	1/ 39 (2.6)	2.3	0/ 37 (0.0)	0.0	2.85 (0.12, 67.83)	0.5172	2.32 (-12.76, 17.39)	0.7633	
>= 10 points	0/ 88 (0.0)	0.0	1/ 88 (1.1)	1.1	0.33 (0.01, 8.07)	0.4993	-1.10 (-8.30, 6.09)	0.7643	
OCS dose at baseline									NE
<10 mg/day	0/ 57 (0.0)	0.0	0/ 52 (0.0)	0.0	NE		0.00 (-10.69, 10.69)	1.0000	
>=10 mg/day	1/ 70 (1.4)	1.2	1/ 73 (1.4)	1.4	1.04 (0.07, 16.35)	0.9762	-0.14 (-8.92, 8.64)	0.9746	
Result of type I IFN gene signature test									NE
LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-15.17, 15.17)	1.0000	
HIGH	1/105 (1.0)	0.8	1/101 (1.0)	0.9	0.96 (0.06, 15.17)	0.9780	-0.10 (-7.17, 6.97)	0.9782	
Age (years)									NE
<= 65	1/122 (0.8)	0.7	1/123 (0.8)	0.8	1.01 (0.06, 15.94)	0.9954	-0.12 (-6.69, 6.46)	0.9727	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE		0.00 (-74.81, 74.81)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE		0.00 (-31.89, 31.89)	1.0000	
female	1/115 (0.9)	0.8	1/117 (0.9)	0.8	1.02 (0.06, 16.07)	0.9902	-0.04 (-6.94, 6.86)	0.9900	
Race									NE
White	1/ 85 (1.2)	1.3	1/ 96 (1.0)	0.9	1.13 (0.07, 17.78)	0.9310	0.41 (-8.26, 9.08)	0.9259	
Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE		0.00 (-19.87, 19.87)	1.0000	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 13 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-26.65, 26.65)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
Non-hispanic/Latino	1/104 (1.0)	0.8	1/101 (1.0)	0.9	0.97 (0.06, 15.32)	0.9834	-0.15 (-7.90, 7.60)	0.9699	
Geographic region									NE
EU	1/ 47 (2.1)	2.1	1/ 56 (1.8)	1.8	1.19 (0.08, 18.54)	0.9004	0.34 (-8.48, 9.16)	0.9394	
non-EU	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE		0.00 (-8.12, 8.12)	1.0000	
Onset of disease									NE
Paediatric	0/ 8 (0.0)	0.0	0/ 7 (0.0)	0.0	NE		0.00 (-38.51, 38.51)	1.0000	
Adult	1/119 (0.8)	0.8	1/118 (0.8)	0.8	0.99 (0.06, 15.67)	0.9952	-0.05 (-6.82, 6.71)	0.9874	
ADA result									NE
Negative	1/111 (0.9)	0.7	1/112 (0.9)	0.8	1.01 (0.06, 15.93)	0.9949	-0.09 (-7.24, 7.07)	0.9809	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	1/ 74 (1.4)	1.2	1/ 87 (1.1)	1.2	1.18 (0.07, 18.47)	0.9083	0.03 (-7.93, 7.99)	0.9942	
>= 30	0/ 53 (0.0)	0.0	0/ 38 (0.0)	0.0	NE		0.00 (-12.88, 12.88)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of SOCs Cardiac disorders and/or Vascular disorders (on-treatment)
Full analysis set

	Anifrolumab 300mg (N=127)	Placebo (N=125)
Number of subjects with events, n (%)	2 (1.6)	16 (12.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.12 (0.03, 0.52)	
p-value	0.0046	
Odds Ratio (95% CI)	0.11 (0.02, 0.48)	
p-value	0.0036	
Risk Difference (95% CI)	-11.23 (-17.47, -4.98)	
p-value	0.0004	
CMH approach		
Response rate	1.6	12.7
Difference in response rates (95% CI)	-11.10 (-19.31, -2.90)	
p-value	0.0080	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of SOCs Cardiac disorders and/or Vascular disorders (on-treatment) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9401
< 10 points	0/ 39 (0.0)	0.0	3/ 37 (8.1)	8.8	0.14 (0.01, 2.54)	0.1815	-8.82 (-25.14, 7.51)	0.2898	
>= 10 points	2/ 88 (2.3)	2.3	13/ 88 (14.8)	14.5	0.15 (0.04, 0.66)	0.0119	-12.20 (-22.11, -2.29)	0.0159	
OCS dose at baseline									0.7454
<10 mg/day	0/ 57 (0.0)	0.0	4/ 52 (7.7)	7.7	0.10 (0.01, 1.84)	0.1219	-7.70 (-19.92, 4.52)	0.2167	
>=10 mg/day	2/ 70 (2.9)	2.9	12/ 73 (16.4)	16.9	0.17 (0.04, 0.75)	0.0189	-13.96 (-25.74, -2.17)	0.0203	
Result of type I IFN gene signature test									0.5572
LOW	0/ 22 (0.0)	0.0	1/ 24 (4.2)	4.2	0.36 (0.02, 8.46)	0.5276	-4.17 (-20.81, 12.48)	0.6237	
HIGH	2/105 (1.9)	2.0	15/101 (14.9)	14.7	0.13 (0.03, 0.55)	0.0055	-12.66 (-21.99, -3.33)	0.0078	
Age (years)									NE
<= 65	2/122 (1.6)	1.7	16/123 (13.0)	13.1	0.13 (0.03, 0.54)	0.0051	-11.41 (-19.83, -2.99)	0.0079	
> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE		0.00 (-74.81, 74.81)	1.0000	
Sex									0.7601
male	0/ 12 (0.0)	0.0	1/ 8 (12.5)	12.5	0.23 (0.01, 5.05)	0.3517	-12.50 (-47.86, 22.86)	0.4884	
female	2/115 (1.7)	1.8	15/117 (12.8)	12.6	0.14 (0.03, 0.58)	0.0070	-10.76 (-19.44, -2.09)	0.0150	
Race									0.9575
White	2/ 85 (2.4)	2.6	12/ 96 (12.5)	11.8	0.19 (0.04, 0.82)	0.0258	-9.22 (-19.51, 1.08)	0.0793	
Black or African American	0/ 22 (0.0)	0.0	1/ 14 (7.1)	7.1	0.22 (0.01, 4.99)	0.3399	-7.14 (-29.62, 15.33)	0.5333	
Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 13 (0.0)	0.0	3/ 11 (27.3)	27.3	0.12 (0.01, 2.14)	0.1503	-27.27 (-60.18, 5.63)	0.1043	
Ethnicity									0.7031
Hispanic/Latino	0/ 23 (0.0)	0.0	5/ 24 (20.8)	20.8	0.09 (0.01, 1.62)	0.1038	-20.83 (-41.20, -0.47)	0.0449	
Non-hispanic/Latino	2/104 (1.9)	2.1	11/101 (10.9)	10.8	0.18 (0.04, 0.78)	0.0218	-8.68 (-17.96, 0.60)	0.0668	
Geographic region									0.8269
EU	1/ 47 (2.1)	2.1	8/ 56 (14.3)	14.3	0.15 (0.02, 1.15)	0.0676	-12.16 (-24.01, -0.30)	0.0444	
non-EU	1/ 80 (1.3)	1.2	8/ 69 (11.6)	11.8	0.11 (0.01, 0.84)	0.0335	-10.57 (-21.26, 0.12)	0.0526	
Onset of disease									0.6402
Paediatric	0/ 8 (0.0)	0.0	1/ 7 (14.3)	14.3	0.30 (0.01, 6.29)	0.4353	-14.29 (-56.18, 27.61)	0.5040	
Adult	2/119 (1.7)	1.8	15/118 (12.7)	12.6	0.13 (0.03, 0.57)	0.0064	-10.81 (-19.35, -2.27)	0.0131	
ADA result									NE
Negative	2/111 (1.8)	2.0	16/112 (14.3)	14.1	0.13 (0.03, 0.54)	0.0050	-12.10 (-21.18, -3.02)	0.0090	
Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
BMI (kg/m2) at enrolment									0.2210
< 30	0/ 74 (0.0)	0.0	12/ 87 (13.8)	14.0	0.05 (0.00, 0.78)	0.0329	-14.00 (-23.95, -4.06)	0.0058	
>= 30	2/ 53 (3.8)	3.6	4/ 38 (10.5)	10.6	0.36 (0.07, 1.86)	0.2217	-7.02 (-22.52, 8.47)	0.3742	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=127)	Placebo (N=125)
SOC: Gastrointestinal disorders	Number of subjects with events, n (%)	28 (22.0)	28 (22.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.98 (0.62, 1.56)	
	p-value	0.9463	
	Odds Ratio (95% CI)	0.98 (0.54, 1.77)	
	p-value	0.9463	
	Risk Difference (95% CI)	-0.35 (-10.62, 9.91)	
	p-value	0.9463	
	CMH approach		
	Response rate	22.1	22.9
	Difference in response rates (95% CI)	-0.79 (-11.36, 9.79)	
	p-value	0.8840	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=127)	Placebo (N=125)
SOC: General disorders and administration site conditions	Number of subjects with events, n (%)	17 (13.4)	12 (9.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.39 (0.69, 2.80)	
	p-value	0.3495	
	Odds Ratio (95% CI)	1.46 (0.66, 3.19)	
	p-value	0.3484	
	Risk Difference (95% CI)	3.79 (-4.07, 11.64)	
	p-value	0.3450	
	CMH approach		
	Response rate	13.3	9.8
	Difference in response rates (95% CI)	3.50 (-5.59, 12.60)	
	p-value	0.4504	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=127)	Placebo (N=125)
SOC: Immune system disorders	Number of subjects with events, n (%)	10 (7.9)	4 (3.2)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	2.46 (0.79, 7.64)	
	p-value	0.1193	
	Odds Ratio (95% CI)	2.59 (0.79, 8.47)	
	p-value	0.1168	
	Risk Difference (95% CI)	4.67 (-0.94, 10.28)	
	p-value	0.1024	
	CMH approach		
	Response rate	8.0	3.2
	Difference in response rates (95% CI)	4.80 (-2.96, 12.56)	
	p-value	0.2253	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=127)	Placebo (N=125)
SOC: Infections and infestations	Number of subjects with events, n (%)	95 (74.8)	72 (57.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.30 (1.08, 1.56)	
	p-value	0.0047	
	Odds Ratio (95% CI)	2.19 (1.28, 3.73)	
	p-value	0.0042	
	Risk Difference (95% CI)	17.20 (5.71, 28.70)	
	p-value	0.0033	
	CMH approach		
	Response rate	74.6	57.8
	Difference in response rates (95% CI)	16.78 (5.11, 28.45)	
	p-value	0.0048	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=127)	Placebo (N=125)
SOC: Infections and infestations, PT: Bronchitis	Number of subjects with events, n (%)	11 (8.7)	6 (4.8)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.80 (0.69, 4.73)	
	p-value	0.2299	
	Odds Ratio (95% CI)	1.88 (0.67, 5.25)	
	p-value	0.2280	
	Risk Difference (95% CI)	3.86 (-2.30, 10.02)	
	p-value	0.2194	
	CMH approach		
	Response rate	8.8	5.1
	Difference in response rates (95% CI)	3.72 (-4.33, 11.77)	
	p-value	0.3651	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=127)	Placebo (N=125)
SOC: Infections and infestations, PT: Nasopharyngitis	Number of subjects with events, n (%)	28 (22.0)	17 (13.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.62 (0.94, 2.81)	
	p-value	0.0850	
	Odds Ratio (95% CI)	1.80 (0.93, 3.48)	
	p-value	0.0825	
	Risk Difference (95% CI)	8.45 (-0.94, 17.83)	
	p-value	0.0777	
	CMH approach		
	Response rate	22.4	13.6
	Difference in response rates (95% CI)	8.81 (-1.37, 19.00)	
	p-value	0.0898	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=127)	Placebo (N=125)
SOC: Infections and infestations, PT: Pharyngitis	Number of subjects with events, n (%)	9 (7.1)	11 (8.8)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.81 (0.35, 1.88)	
	p-value	0.6157	
	Odds Ratio (95% CI)	0.79 (0.32, 1.98)	
	p-value	0.6155	
	Risk Difference (95% CI)	-1.71 (-8.39, 4.96)	
	p-value	0.6150	
	CMH approach		
	Response rate	7.2	9.1
	Difference in response rates (95% CI)	-1.87 (-10.26, 6.52)	
	p-value	0.6616	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=127)	Placebo (N=125)
SOC: Infections and infestations, PT: Upper respiratory tract infection	Number of subjects with events, n (%)	14 (11.0)	10 (8.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.38 (0.64, 2.99)	
	p-value	0.4163	
	Odds Ratio (95% CI)	1.42 (0.61, 3.34)	
	p-value	0.4154	
	Risk Difference (95% CI)	3.02 (-4.21, 10.25)	
	p-value	0.4125	
	CMH approach		
	Response rate	10.8	8.2
	Difference in response rates (95% CI)	2.59 (-6.02, 11.20)	
	p-value	0.5556	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=127)	Placebo (N=125)
SOC: Infections and infestations, PT: Urinary tract infection	Number of subjects with events, n (%)	12 (9.4)	19 (15.2)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.62 (0.32, 1.23)	
	p-value	0.1701	
	Odds Ratio (95% CI)	0.58 (0.27, 1.26)	
	p-value	0.1681	
	Risk Difference (95% CI)	-5.75 (-13.84, 2.34)	
	p-value	0.1637	
	CMH approach		
	Response rate	9.4	15.1
	Difference in response rates (95% CI)	-5.67 (-14.94, 3.60)	
	p-value	0.2308	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=127)	Placebo (N=125)
SOC: Injury, poisoning and procedural complications	Number of subjects with events, n (%)	25 (19.7)	22 (17.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.12 (0.67, 1.88)	
	p-value	0.6712	
	Odds Ratio (95% CI)	1.15 (0.61, 2.17)	
	p-value	0.6711	
	Risk Difference (95% CI)	2.09 (-7.53, 11.70)	
	p-value	0.6707	
	CMH approach		
	Response rate	19.7	18.1
	Difference in response rates (95% CI)	1.62 (-8.51, 11.75)	
	p-value	0.7540	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=127)	Placebo (N=125)
SOC: Metabolism and nutrition disorders	Number of subjects with events, n (%)	7 (5.5)	10 (8.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.69 (0.27, 1.75)	
	p-value	0.4342	
	Odds Ratio (95% CI)	0.67 (0.25, 1.82)	
	p-value	0.4335	
	Risk Difference (95% CI)	-2.49 (-8.68, 3.71)	
	p-value	0.4311	
	CMH approach		
	Response rate	5.5	8.1
	Difference in response rates (95% CI)	-2.55 (-10.70, 5.59)	
	p-value	0.5393	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=127)	Placebo (N=125)
SOC: Musculoskeletal and connective tissue disorders	Number of subjects with events, n (%)	27 (21.3)	27 (21.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.98 (0.61, 1.58)	
	p-value	0.9475	
	Odds Ratio (95% CI)	0.98 (0.54, 1.79)	
	p-value	0.9475	
	Risk Difference (95% CI)	-0.34 (-10.47, 9.79)	
	p-value	0.9475	
	CMH approach		
	Response rate	21.4	21.9
	Difference in response rates (95% CI)	-0.51 (-11.14, 10.12)	
	p-value	0.9256	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=127)	Placebo (N=125)
SOC: Nervous system disorders	Number of subjects with events, n (%)	27 (21.3)	16 (12.8)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.66 (0.94, 2.93)	
	p-value	0.0794	
	Odds Ratio (95% CI)	1.84 (0.94, 3.61)	
	p-value	0.0769	
	Risk Difference (95% CI)	8.46 (-0.76, 17.68)	
	p-value	0.0720	
	CMH approach		
	Response rate	20.9	12.8
	Difference in response rates (95% CI)	8.06 (-1.74, 17.86)	
	p-value	0.1071	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=127)	Placebo (N=125)
SOC: Nervous system disorders, PT: Headache	Number of subjects with events, n (%)	11 (8.7)	10 (8.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.08 (0.48, 2.46)	
	p-value	0.8494	
	Odds Ratio (95% CI)	1.09 (0.45, 2.67)	
	p-value	0.8494	
	Risk Difference (95% CI)	0.66 (-6.16, 7.48)	
	p-value	0.8493	
	CMH approach		
	Response rate	8.5	8.0
	Difference in response rates (95% CI)	0.43 (-7.94, 8.81)	
	p-value	0.9192	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=127)	Placebo (N=125)
SOC: Psychiatric disorders	Number of subjects with events, n (%)	11 (8.7)	13 (10.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.83 (0.39, 1.79)	
	p-value	0.6389	
	Odds Ratio (95% CI)	0.82 (0.35, 1.90)	
	p-value	0.6387	
	Risk Difference (95% CI)	-1.74 (-8.99, 5.51)	
	p-value	0.6384	
	CMH approach		
	Response rate	8.6	10.5
	Difference in response rates (95% CI)	-1.95 (-10.69, 6.78)	
	p-value	0.6609	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=127)	Placebo (N=125)
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with events, n (%)	25 (19.7)	14 (11.2)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.76 (0.96, 3.22)	
	p-value	0.0681	
	Odds Ratio (95% CI)	1.94 (0.96, 3.94)	
	p-value	0.0656	
	Risk Difference (95% CI)	8.49 (-0.37, 17.34)	
	p-value	0.0603	
	CMH approach		
	Response rate	19.5	11.2
	Difference in response rates (95% CI)	8.32 (-1.46, 18.09)	
	p-value	0.0954	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=127)	Placebo (N=125)
SOC: Respiratory, thoracic and mediastinal disorders, PT: Cough	Number of subjects with events, n (%)	11 (8.7)	5 (4.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	2.17 (0.77, 6.05)	
	p-value	0.1407	
	Odds Ratio (95% CI)	2.28 (0.77, 6.75)	
	p-value	0.1383	
	Risk Difference (95% CI)	4.66 (-1.32, 10.64)	
	p-value	0.1264	
	CMH approach		
	Response rate	8.5	4.0
	Difference in response rates (95% CI)	4.50 (-3.47, 12.46)	
	p-value	0.2684	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=127)	Placebo (N=125)
SOC: Skin and subcutaneous tissue disorders	Number of subjects with events, n (%)	19 (15.0)	13 (10.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.44 (0.74, 2.79)	
	p-value	0.2808	
	Odds Ratio (95% CI)	1.52 (0.71, 3.22)	
	p-value	0.2793	
	Risk Difference (95% CI)	4.56 (-3.63, 12.75)	
	p-value	0.2752	
	CMH approach		
	Response rate	15.0	10.4
	Difference in response rates (95% CI)	4.52 (-4.80, 13.84)	
	p-value	0.3417	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=127)	Placebo (N=125)
SOC: Vascular disorders	Number of subjects with events, n (%)	1 (0.8)	10 (8.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.10 (0.01, 0.76)	
	p-value	0.0260	
	Odds Ratio (95% CI)	0.09 (0.01, 0.72)	
	p-value	0.0235	
	Risk Difference (95% CI)	-7.21 (-12.21, -2.21)	
	p-value	0.0047	
	CMH approach		
	Response rate	0.8	7.9
	Difference in response rates (95% CI)	-7.05 (-14.59, 0.50)	
	p-value	0.0671	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations	SLEDAI-2K score									0.8419
	< 10 points	32/ 39 (82.1)	83.0	24/ 37 (64.9)	65.9	1.26 (0.96, 1.67)	0.0986	17.09 (-3.45, 37.63)	0.1030	
	>= 10 points	63/ 88 (71.6)	71.5	48/ 88 (54.5)	54.6	1.31 (1.04, 1.65)	0.0214	16.85 (2.69, 31.00)	0.0196	
	OCS dose									0.6933
	<10 mg/day	45/ 57 (78.9)	79.0	33/ 52 (63.5)	63.4	1.24 (0.97, 1.59)	0.0819	15.64 (-1.66, 32.93)	0.0764	
	>=10 mg/day	50/ 70 (71.4)	71.3	39/ 73 (53.4)	53.8	1.34 (1.03, 1.73)	0.0288	17.53 (1.65, 33.41)	0.0305	
	Result of type I IFN gene signature test									0.8679
	LOW	16/ 22 (72.7)	72.7	13/ 24 (54.2)	54.2	1.34 (0.86, 2.10)	0.1976	18.56 (-9.19, 46.31)	0.1899	
	HIGH	79/105 (75.2)	75.0	59/101 (58.4)	58.6	1.29 (1.06, 1.57)	0.0121	16.38 (3.52, 29.25)	0.0125	
	Age (years)									0.7750
	<= 65	91/122 (74.6)	74.4	71/123 (57.7)	57.9	1.29 (1.08, 1.55)	0.0061	16.44 (4.59, 28.29)	0.0065	
	> 65	4/ 5 (80.0)	80.0	1/ 2 (50.0)	50.0	1.60 (0.37, 6.85)	0.5262	30.00 (-50.68, 110.68)	0.4661	
	Sex									0.2364
	male	10/ 12 (83.3)	83.3	3/ 8 (37.5)	37.5	2.22 (0.88, 5.63)	0.0923	45.83 (3.79, 87.87)	0.0326	
	female	85/115 (73.9)	73.7	69/117 (59.0)	59.2	1.25 (1.04, 1.51)	0.0174	14.52 (2.34, 26.69)	0.0195	
	Race									0.1996
	White	61/ 85 (71.8)	71.1	52/ 96 (54.2)	55.1	1.32 (1.06, 1.66)	0.0152	15.98 (1.95, 30.01)	0.0256	
	Black or African American	16/ 22 (72.7)	72.7	11/ 14 (78.6)	78.6	0.93 (0.64, 1.35)	0.6859	-5.84 (-36.22, 24.53)	0.7061	
	Asian	7/ 7 (100.0)	100.0	3/ 3 (100.0)	100.0	NE		0.00 (-58.56, 58.56)	1.0000	
	American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
	Other	11/ 13 (84.6)	84.6	6/ 11 (54.5)	54.5	1.55 (0.86, 2.79)	0.1427	30.07 (-7.36, 67.50)	0.1153	
	Ethnicity									0.3048
	Hispanic/Latino	18/ 23 (78.3)	78.3	17/ 24 (70.8)	70.8	1.10 (0.79, 1.54)	0.5597	7.43 (-18.45, 33.31)	0.5738	
	Non-hispanic/Latino	77/104 (74.0)	73.3	55/101 (54.5)	54.9	1.36 (1.10, 1.68)	0.0044	18.42 (5.26, 31.57)	0.0061	
	Geographic region									0.0328
	EU	33/ 47 (70.2)	70.2	23/ 56 (41.1)	41.1	1.71 (1.19, 2.46)	0.0040	29.14 (10.63, 47.65)	0.0020	
	non-EU	62/ 80 (77.5)	77.6	49/ 69 (71.0)	70.6	1.09 (0.90, 1.32)	0.3710	6.93 (-7.61, 21.46)	0.3504	
	Onset of disease									0.1625
	Paediatric	8/ 8 (100.0)	100.0	3/ 7 (42.9)	42.9	2.33 (0.99, 5.49)	0.0522	57.14 (12.11, 102.17)	0.0129	
	Adult	87/119 (73.1)	72.9	69/118 (58.5)	58.8	1.25 (1.04, 1.51)	0.0193	14.10 (2.00, 26.20)	0.0224	
	ADA result									0.8467
	Negative	85/111 (76.6)	76.2	65/112 (58.0)	58.2	1.32 (1.09, 1.59)	0.0039	17.98 (5.58, 30.38)	0.0045	
	Positive (At any time)	10/ 15 (66.7)	66.7	7/ 13 (53.8)	53.8	1.24 (0.67, 2.30)	0.4979	12.82 (-23.68, 49.32)	0.4912	
	BMI (kg/m2)									0.2262
	< 30	56/ 74 (75.7)	75.5	47/ 87 (54.0)	54.2	1.40 (1.11, 1.77)	0.0046	21.29 (6.69, 35.89)	0.0043	
	>= 30	39/ 53 (73.6)	73.9	25/ 38 (65.8)	65.6	1.12 (0.85, 1.48)	0.4337	8.32 (-11.22, 27.86)	0.4040	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=127) n/ N (%)	Response rate	Placebo (N=125) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SOC: Vascular disorders	SLEDAI-2K score									0.5863
	< 10 points	0/ 39 (0.0)	0.0	1/ 37 (2.7)	2.8	0.32 (0.01, 7.54)	0.4771	-2.76 (-17.98, 12.46)	0.7223	
	>= 10 points	1/ 88 (1.1)	1.2	9/ 88 (10.2)	10.1	0.11 (0.01, 0.86)	0.0352	-8.90 (-18.02, 0.23)	0.0561	
	OCS dose									0.9426
	<10 mg/day	0/ 57 (0.0)	0.0	3/ 52 (5.8)	5.7	0.13 (0.01, 2.47)	0.1746	-5.72 (-17.61, 6.18)	0.3460	
	>=10 mg/day	1/ 70 (1.4)	1.5	7/ 73 (9.6)	9.6	0.15 (0.02, 1.18)	0.0714	-8.11 (-18.64, 2.42)	0.1311	
	Result of type I IFN gene signature test									NE
	LOW	0/ 22 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-15.17, 15.17)	1.0000	
	HIGH	1/105 (1.0)	1.0	10/101 (9.9)	9.6	0.10 (0.01, 0.74)	0.0243	-8.62 (-17.21, -0.04)	0.0490	
	Age (years)									NE
	<= 65	1/122 (0.8)	0.8	10/123 (8.1)	8.1	0.10 (0.01, 0.78)	0.0275	-7.20 (-14.94, 0.54)	0.0682	
	> 65	0/ 5 (0.0)	0.0	0/ 2 (0.0)	0.0	NE		0.00 (-74.81, 74.81)	1.0000	
	Sex									NE
	male	0/ 12 (0.0)	0.0	0/ 8 (0.0)	0.0	NE		0.00 (-31.89, 31.89)	1.0000	
	female	1/115 (0.9)	0.9	10/117 (8.5)	8.4	0.10 (0.01, 0.78)	0.0281	-7.47 (-15.55, 0.61)	0.0699	
	Race									0.8784
	White	1/ 85 (1.2)	1.3	7/ 96 (7.3)	7.0	0.16 (0.02, 1.28)	0.0849	-5.74 (-15.33, 3.85)	0.2409	
	Black or African American	0/ 22 (0.0)	0.0	0/ 14 (0.0)	0.0	NE		0.00 (-19.87, 19.87)	1.0000	
	Asian	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
	American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
	Other	0/ 13 (0.0)	0.0	3/ 11 (27.3)	27.3	0.12 (0.01, 2.14)	0.1503	-27.27 (-60.18, 5.63)	0.1043	
	Ethnicity									0.8533
	Hispanic/Latino	0/ 23 (0.0)	0.0	4/ 24 (16.7)	16.7	0.12 (0.01, 2.04)	0.1405	-16.67 (-36.26, 2.93)	0.0955	
	Non-hispanic/Latino	1/104 (1.0)	1.1	6/101 (5.9)	5.6	0.16 (0.02, 1.32)	0.0891	-4.55 (-13.12, 4.01)	0.2973	
	Geographic region									0.5423
	EU	1/ 47 (2.1)	2.1	5/ 56 (8.9)	8.9	0.24 (0.03, 1.97)	0.1831	-6.80 (-17.57, 3.97)	0.2157	
	non-EU	0/ 80 (0.0)	0.0	5/ 69 (7.2)	7.5	0.08 (0.00, 1.40)	0.0831	-7.46 (-17.23, 2.32)	0.1348	
	Onset of disease									0.5982
	Paediatric	0/ 8 (0.0)	0.0	1/ 7 (14.3)	14.3	0.30 (0.01, 6.29)	0.4353	-14.29 (-56.18, 27.61)	0.5040	
	Adult	1/119 (0.8)	0.9	9/118 (7.6)	7.4	0.11 (0.01, 0.86)	0.0350	-6.55 (-14.38, 1.28)	0.1011	
	ADA result									NE
	Negative	1/111 (0.9)	1.0	10/112 (8.9)	8.6	0.10 (0.01, 0.78)	0.0275	-7.61 (-15.96, 0.75)	0.0744	
	Positive (At any time)	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
	BMI (kg/m2)									0.3817
	< 30	0/ 74 (0.0)	0.0	8/ 87 (9.2)	9.4	0.07 (0.00, 1.18)	0.0646	-9.41 (-18.74, -0.08)	0.0481	
	>= 30	1/ 53 (1.9)	1.8	2/ 38 (5.3)	5.4	0.36 (0.03, 3.81)	0.3950	-3.62 (-17.99, 10.75)	0.6214	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Serious Adverse Events by SOC, PT (incidence in either arm >= 5% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=127)	Placebo (N=125)
SOC: Infections and infestations	Number of subjects with events, n (%)	4 (3.1)	7 (5.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.56 (0.17, 1.87)	
	p-value	0.3486	
	Odds Ratio (95% CI)	0.55 (0.16, 1.92)	
	p-value	0.3475	
	Risk Difference (95% CI)	-2.45 (-7.50, 2.60)	
	p-value	0.3413	
	CMH approach		
	Response rate	3.1	5.5
	Difference in response rates (95% CI)	-2.37 (-9.88, 5.13)	
	p-value	0.5358	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Serious Adverse Events by SOC, PT (incidence in either arm >= 5% or >=10 patients) (on-treatment) - Subgroup analysis
Full analysis set

- NO OBSERVATIONS FOR THIS ANALYSIS -

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Severe (Grade >=3) by SOC, PT (incidence in either arm >= 5% or >=10 patients) (on-treatment)
Full analysis set

- NO OBSERVATIONS FOR THIS ANALYSIS -

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Severe (Grade >=3) by SOC, PT (incidence in either arm >= 5% or >=10 patients) (on-treatment) - Subgroup analysis
Full analysis set

- NO OBSERVATIONS FOR THIS ANALYSIS -

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Subject disposition and summary of treatment exposure
Full analysis set

		Anifrolumab 300mg (N=119)	Placebo (N=121)
Patients who completed the study		102 (85.7)	87 (71.9)
Patients withdrawn from the study		17 (14.3)	34 (28.1)
WITHDRAWAL BY SUBJECT		10 (8.4)	17 (14.0)
ADVERSE EVENT		1 (0.8)	6 (5.0)
OTHER		4 (3.4)	3 (2.5)
LACK OF EFFICACY		1 (0.8)	4 (3.3)
CONDITION UNDER INVESTIGATION WORSENED		1 (0.8)	1 (0.8)
LOST TO FOLLOW-UP		0	2 (1.7)
SEVERE NON-COMPLIANCE TO PROTOCOL		0	1 (0.8)
Duration of study (weeks)	n (missing)	119 (0)	121 (0)
	Mean (SD)	51.2 (10.61)	49.0 (12.49)
	Median	52.3	52.3
	Min, Max	11, 68	3, 64
Patients who completed investigational product		101 (84.9)	83 (68.6)
Patients discontinued investigational product		18 (15.1)	38 (31.4)
Withdrawal By Subject		5 (4.2)	14 (11.6)
Adverse Event		3 (2.5)	11 (9.1)
Lack Of Efficacy		2 (1.7)	7 (5.8)
Other		5 (4.2)	2 (1.7)
Condition Under Investigation Worsened		2 (1.7)	1 (0.8)
Lost To Follow-Up		1 (0.8)	2 (1.7)
Severe Non-Compliance To Protocol		0	1 (0.8)
Duration of exposure (weeks)	n (missing)	119 (0)	121 (0)
	Mean (SD)	48.4 (10.71)	43.6 (14.95)
	Median	52.1	52.1
	Min, Max	4, 57	4, 56
Number of Infusions	n (missing)	119 (0)	121 (0)
	Mean (SD)	11.8 (2.67)	10.5 (3.65)
	Median	13.0	13.0
	Min, Max	1, 13	1, 13
Subjects enrolled to the LTE study		84 (70.6)	65 (53.7)

Duration of study defined as time from randomization until end of participation date.
Duration of exposure defined as difference of date of first exposure to treatment and date of last exposure to treatment + 28 days.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Demographic and baseline characteristics
Full analysis set

		Anifrolumab 300mg (N=119)	Placebo (N=121)	Total (N=240)
Age	n (missing)	119 (0)	121 (0)	240 (0)
	Mean (SD)	43.8 (11.69)	41.0 (11.13)	42.4 (11.47)
	Median	45.0	42.0	43.0
	Min, Max	18, 68	19, 66	18, 68
Age subgroups (%)	<= 65	117 (98.3)	120 (99.2)	237 (98.8)
	> 65	2 (1.7)	1 (0.8)	3 (1.3)
Sex (%)	female	108 (90.8)	109 (90.1)	217 (90.4)
	male	11 (9.2)	12 (9.9)	23 (9.6)
Race (%)	Asian	17 (14.3)	16 (13.2)	33 (13.8)
	Black or African American	11 (9.2)	18 (14.9)	29 (12.1)
	Other	8 (6.7)	6 (5.0)	14 (5.8)
	White	75 (63.0)	78 (64.5)	153 (63.8)
	Missing	8 (6.7)	3 (2.5)	11 (4.6)
Ethnicity (%)	Hispanic/Latino	27 (22.7)	32 (26.4)	59 (24.6)
	Non-hispanic/Latino	84 (70.6)	86 (71.1)	170 (70.8)
	Missing	8 (6.7)	3 (2.5)	11 (4.6)
Geographic region (%)	Asia Pacific	15 (12.6)	14 (11.6)	29 (12.1)
	Europe	45 (37.8)	33 (27.3)	78 (32.5)
	Latin America	15 (12.6)	14 (11.6)	29 (12.1)
	North America	42 (35.3)	54 (44.6)	96 (40.0)
	Rest Of World	2 (1.7)	6 (5.0)	8 (3.3)
Geographic region subgroup (%)	EU	45 (37.8)	33 (27.3)	78 (32.5)
	non-EU	74 (62.2)	88 (72.7)	162 (67.5)
Height (cm)	n (missing)	119 (0)	121 (0)	240 (0)
	Mean (SD)	163.09 (8.718)	163.97 (7.767)	163.53 (8.247)
	Median	162.10	164.00	163.00
	Min, Max	145.0, 198.0	148.0, 188.0	145.0, 198.0
Weight (cm)	n (missing)	119 (0)	121 (0)	240 (0)
	Mean (SD)	72.11 (19.592)	72.11 (18.540)	72.11 (19.029)
	Median	67.70	67.80	67.75
	Min, Max	44.0, 130.8	45.0, 134.5	44.0, 134.5
BMI (kg/m^2)	n (missing)	119 (0)	121 (0)	240 (0)
	Mean (SD)	27.05 (6.866)	26.82 (6.732)	26.94 (6.785)
	Median	25.11	25.22	25.16
	Min, Max	16.7, 49.8	17.5, 51.8	16.7, 51.8
BMI subgroup (%)	<=28 kg/m2	75 (63.0)	77 (63.6)	152 (63.3)
	>28 kg/m2	44 (37.0)	44 (36.4)	88 (36.7)

[a] Asia Pacific: Australia, New Zealand, South Korea, Taiwan. Europe: Germany, Hungary, Italy, Poland, Romania, Ukraine, United Kingdom. Latin America: Argentinia, Brazil, Chile, Colombia, Peru. Rest of World: Israel.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SLE disease characteristics
Full analysis set

		Anifrolumab 300mg (N=119)	Placebo (N=121)	Total (N=240)
SLEDAI-2K score at screening	n (missing)	119 (0)	121 (0)	240 (0)
	Mean (SD)	11.5 (4.16)	11.2 (3.47)	11.4 (3.82)
	Median	10.0	10.0	10.0
	Min, Max	6, 24	6, 24	6, 24
SLEDAI-2K score at screening, categorisation (%)	< 10 points	41 (34.5)	32 (26.4)	73 (30.4)
	>= 10 points	78 (65.5)	89 (73.6)	167 (69.6)
Clinical SLEDAI-2K score at screening	n (missing)	119 (0)	121 (0)	240 (0)
	Mean (SD)	8.7 (3.27)	8.7 (2.94)	8.7 (3.10)
	Median	8.0	8.0	8.0
	Min, Max	4, 18	4, 18	4, 18
SLEDAI-2K score at baseline	n (missing)	119 (0)	121 (0)	240 (0)
	Mean (SD)	11.3 (3.70)	11.5 (3.93)	11.4 (3.81)
	Median	10.0	10.0	10.0
	Min, Max	6, 22	4, 26	4, 26
SLEDAI-2K score at baseline, categorisation (%)	< 10 points	40 (33.6)	34 (28.1)	74 (30.8)
	>= 10 points	79 (66.4)	87 (71.9)	166 (69.2)
Clinical SLEDAI-2K score at baseline	n (missing)	119 (0)	121 (0)	240 (0)
	Mean (SD)	8.8 (3.17)	9.0 (2.88)	8.9 (3.02)
	Median	8.0	8.0	8.0
	Min, Max	4, 18	4, 18	4, 18
Total Organ Score CNS	n (missing)	119 (0)	121 (0)	240 (0)
	Mean (SD)	0.0 (0.00)	0.1 (0.73)	0.0 (0.52)
	Median	0.0	0.0	0.0
	Min, Max	0, 0	0, 8	0, 8
Total Organ Score CVS and Respiratory	n (missing)	119 (0)	121 (0)	240 (0)
	Mean (SD)	0.1 (0.44)	0.2 (0.55)	0.1 (0.50)
	Median	0.0	0.0	0.0
	Min, Max	0, 2	0, 2	0, 2
Total Organ Score Hematological	n (missing)	119 (0)	121 (0)	240 (0)
	Mean (SD)	0.2 (0.41)	0.1 (0.38)	0.2 (0.40)
	Median	0.0	0.0	0.0
	Min, Max	0, 2	0, 2	0, 2
Total Organ Score Immunology	n (missing)	119 (0)	121 (0)	240 (0)
	Mean (SD)	2.1 (1.58)	1.8 (1.63)	1.9 (1.61)
	Median	2.0	2.0	2.0
	Min, Max	0, 4	0, 4	0, 4
Total Organ Score Mucocutaneous	n (missing)	119 (0)	121 (0)	240 (0)
	Mean (SD)	3.8 (1.61)	3.9 (1.63)	3.9 (1.62)
	Median	4.0	4.0	4.0
	Min, Max	0, 6	0, 6	0, 6
Total Organ Score Musculoskeletal	n (missing)	119 (0)	121 (0)	240 (0)
	Mean (SD)	3.7 (1.13)	3.9 (1.15)	3.8 (1.14)
	Median	4.0	4.0	4.0
	Min, Max	0, 8	0, 8	0, 8
Total Organ Score Renal	n (missing)	119 (0)	121 (0)	240 (0)
	Mean (SD)	0.3 (1.29)	0.5 (1.78)	0.4 (1.56)
	Median	0.0	0.0	0.0
	Min, Max	0, 8	0, 12	0, 12

Baseline is defined as the last measurement prior to randomisation and dose administration on Day 1.
Only subjects with baseline positive anti-dsDNA and abnormal complement level, respectively, are included in the summary statistics for the respective variables.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SLE disease characteristics
Full analysis set

		Anifrolumab 300mg (N=119)	Placebo (N=121)	Total (N=240)
Total Organ Score Vascular	n (missing)	119 (0)	121 (0)	240 (0)
	Mean (SD)	1.1 (2.74)	1.0 (2.65)	1.0 (2.69)
	Median	0.0	0.0	0.0
	Min, Max	0, 8	0, 8	0, 8
Adjudication Scoring (BILAG) at baseline Overall (%)	At least one A	43 (36.1)	62 (51.2)	105 (43.8)
	No A and <2Bs	7 (5.9)	7 (5.8)	14 (5.8)
	No A and at least 2 Bs	69 (58.0)	52 (43.0)	121 (50.4)
Adjudication Scoring (BILAG) at baseline Constitutional (%)	B	8 (6.7)	4 (3.3)	12 (5.0)
	C, D or E	111 (93.3)	117 (96.7)	228 (95.0)
Adjudication Scoring (BILAG) at baseline Mucocutaneous (%)	A	14 (11.8)	29 (24.0)	43 (17.9)
	B	89 (74.8)	72 (59.5)	161 (67.1)
	C, D or E	16 (13.4)	20 (16.5)	36 (15.0)
Adjudication Scoring (BILAG) at baseline Neuropsychiatric (%)	B	0	2 (1.7)	2 (0.8)
	C, D or E	119 (100.0)	119 (98.3)	238 (99.2)
Adjudication Scoring (BILAG) at baseline Musculoskeletal (%)	A	31 (26.1)	34 (28.1)	65 (27.1)
	B	72 (60.5)	73 (60.3)	145 (60.4)
	C, D or E	16 (13.4)	14 (11.6)	30 (12.5)
Adjudication Scoring (BILAG) at baseline Cardiorespiratory (%)	A	1 (0.8)	1 (0.8)	2 (0.8)
	B	4 (3.4)	9 (7.4)	13 (5.4)
	C, D or E	114 (95.8)	111 (91.7)	225 (93.8)
Adjudication Scoring (BILAG) at baseline Gastrointestinal (%)	B	0	1 (0.8)	1 (0.4)
	C, D or E	119 (100.0)	120 (99.2)	239 (99.6)
Adjudication Scoring (BILAG) at baseline Ophthalmic (%)	B	0	1 (0.8)	1 (0.4)
	C, D or E	119 (100.0)	120 (99.2)	239 (99.6)
Adjudication Scoring (BILAG) at baseline Renal (%)	A	1 (0.8)	3 (2.5)	4 (1.7)
	B	6 (5.0)	8 (6.6)	14 (5.8)
	C, D or E	112 (94.1)	110 (90.9)	222 (92.5)
Adjudication Scoring (BILAG) at baseline Haematological (%)	C, D or E	119 (100.0)	121 (100.0)	240 (100.0)
BILAG-2004 global score at baseline	n (missing)	119 (0)	121 (0)	240 (0)
	Mean (SD)	17.6 (4.38)	18.7 (5.07)	18.2 (4.76)
	Median	17.0	17.0	17.0
	Min, Max	3, 33	9, 33	3, 33
Physician Global Assessment (PGA) score at baseline	n (missing)	119 (0)	121 (0)	240 (0)
	Mean (SD)	1.7 (0.42)	1.8 (0.41)	1.7 (0.41)
	Median	1.6	1.7	1.7
	Min, Max	1, 3	1, 3	1, 3
CLASI activity score at baseline	n (missing)	119 (0)	121 (0)	240 (0)
	Mean (SD)	7.2 (7.07)	8.0 (8.37)	7.6 (7.75)
	Median	5.0	6.0	5.5
	Min, Max	0, 51	0, 52	0, 52
CLASI activity score at baseline, categorisation 1 (%)	0	4 (3.4)	10 (8.3)	14 (5.8)
	> 0	115 (96.6)	111 (91.7)	226 (94.2)
CLASI activity score at baseline, categorisation 2 (%)	<10	94 (79.0)	91 (75.2)	185 (77.1)
	>=10	25 (21.0)	30 (24.8)	55 (22.9)

Baseline is defined as the last measurement prior to randomisation and dose administration on Day 1.
Only subjects with baseline positive anti-dsDNA and abnormal complement level, respectively, are included in the summary statistics for the respective variables.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SLE disease characteristics
Full analysis set

		Anifrolumab 300mg (N=119)	Placebo (N=121)	Total (N=240)
CLASI damage score at baseline	n (missing)	119 (0)	121 (0)	240 (0)
	Mean (SD)	1.6 (3.54)	1.9 (4.49)	1.7 (4.04)
	Median	0.0	0.0	0.0
	Min, Max	0, 23	0, 33	0, 33
CLASI damage score at baseline, categorisation 1 (%)	0	82 (68.9)	80 (66.1)	162 (67.5)
	> 0	37 (31.1)	41 (33.9)	78 (32.5)
CLASI damage score at baseline, categorisation 2 (%)	<10	114 (95.8)	116 (95.9)	230 (95.8)
	>=10	5 (4.2)	5 (4.1)	10 (4.2)
Tender Joint Count at Baseline	n (missing)	119 (0)	121 (0)	240 (0)
	Mean (SD)	8.7 (7.44)	11.2 (7.88)	10.0 (7.76)
	Median	7.0	10.0	8.0
	Min, Max	0, 28	0, 28	0, 28
Tender Joint Count at Baseline, categorisation (%)	0	11 (9.2)	5 (4.1)	16 (6.7)
	> 0	108 (90.8)	116 (95.9)	224 (93.3)
Swollen Joint Count at Baseline	n (missing)	119 (0)	121 (0)	240 (0)
	Mean (SD)	6.1 (5.91)	7.3 (6.44)	6.7 (6.21)
	Median	5.0	5.0	5.0
	Min, Max	0, 28	0, 25	0, 28
Swollen Joint Count at Baseline, categorisation (%)	0	14 (11.8)	12 (9.9)	26 (10.8)
	> 0	105 (88.2)	109 (90.1)	214 (89.2)
Active Joint Count at Baseline	n (missing)	119 (0)	121 (0)	240 (0)
	Mean (SD)	5.4 (5.88)	7.0 (6.40)	6.2 (6.18)
	Median	4.0	5.0	4.0
	Min, Max	0, 28	0, 25	0, 28
Active Joint Count at Baseline, categorisation (%)	0	16 (13.4)	12 (9.9)	28 (11.7)
	> 0	103 (86.6)	109 (90.1)	212 (88.3)
SDI global score at baseline	n (missing)	119 (0)	121 (0)	240 (0)
	Mean (SD)	0.4 (0.79)	0.5 (0.73)	0.4 (0.76)
	Median	0.0	0.0	0.0
	Min, Max	0, 4	0, 3	0, 4
SDI global score at baseline, categorisation (%)	0 (no damage)	84 (70.6)	80 (66.1)	164 (68.3)
	>=1 (damage)	35 (29.4)	41 (33.9)	76 (31.7)
Time from initial SLE diagnosis to randomisation (months)	n (missing)	119 (0)	121 (0)	240 (0)
	Mean (SD)	139.1 (112.87)	99.9 (89.99)	119.3 (103.65)
	Median	120.0	73.0	88.5
	Min, Max	6, 493	6, 397	6, 493
Cushingoid features (%)	Any Cushingoid Feature	30 (25.2)	36 (29.8)	66 (27.5)
	Moon Face	20 (16.8)	21 (17.4)	41 (17.1)
	Buffalo Hump	9 (7.6)	3 (2.5)	12 (5.0)
	Purple or Violaceous Striae	9 (7.6)	10 (8.3)	19 (7.9)
	Central Obesity	15 (12.6)	14 (11.6)	29 (12.1)
	Hirsutisim	9 (7.6)	3 (2.5)	12 (5.0)
	Acne	8 (6.7)	5 (4.1)	13 (5.4)
	Easy Bruising	10 (8.4)	12 (9.9)	22 (9.2)
	Fragile Skin	6 (5.0)	12 (9.9)	18 (7.5)
Results of 4-gene Type 1 Interferon (IFN) test (%)	High	96 (80.7)	97 (80.2)	193 (80.4)
	Low	23 (19.3)	24 (19.8)	47 (19.6)

Baseline is defined as the last measurement prior to randomisation and dose administration on Day 1.
Only subjects with baseline positive anti-dsDNA and abnormal complement level, respectively, are included in the summary statistics for the respective variables.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SLE disease characteristics
Full analysis set

		Anifrolumab 300mg (N=119)	Placebo (N=121)	Total (N=240)
Anti-dsDNA levels at baseline	n (missing)	59 (0)	47 (0)	106 (0)
	Mean (SD)	89.1 (158.21)	202.8 (594.05)	139.5 (414.31)
	Median	40.1	46.4	43.3
	Min, Max	16, 1094	16, 3790	16, 3790
Anti-dsDNA levels at baseline, categorisation (%)	Negative	60 (50.4)	74 (61.2)	134 (55.8)
	Positive	59 (49.6)	47 (38.8)	106 (44.2)
ANA (%)	Abnormal (titre >= 1:80)	102 (85.7)	108 (89.3)	210 (87.5)
	Normal (titre < 1:80)	9 (7.6)	8 (6.6)	17 (7.1)
	Missing	8 (6.7)	5 (4.1)	13 (5.4)
Complement C3 level at baseline	n (missing)	48 (0)	45 (0)	93 (0)
	Mean (SD)	0.72 (0.139)	0.67 (0.143)	0.69 (0.142)
	Median	0.75	0.68	0.71
	Min, Max	0.3, 0.9	0.4, 0.9	0.3, 0.9
Complement C3 level at baseline, categorisation (%)	Abnormal	48 (40.3)	45 (37.2)	93 (38.8)
	Normal	71 (59.7)	76 (62.8)	147 (61.3)
Complement C4 level at baseline	n (missing)	30 (0)	27 (0)	57 (0)
	Mean (SD)	0.08 (0.015)	0.07 (0.015)	0.08 (0.015)
	Median	0.08	0.07	0.07
	Min, Max	0.1, 0.1	0.1, 0.1	0.1, 0.1
Complement C4 level at baseline, categorisation (%)	Abnormal	30 (25.2)	27 (22.3)	57 (23.8)
	Normal	89 (74.8)	94 (77.7)	183 (76.3)
Complement CH50 level at baseline	n (missing)	7 (0)	9 (0)	16 (0)
	Mean (SD)	51.43 (29.613)	47.89 (29.298)	49.44 (28.493)
	Median	43.00	45.00	44.00
	Min, Max	11.0, 89.0	5.0, 85.0	5.0, 89.0
Complement CH50 level at baseline, categorisation (%)	Abnormal	7 (5.9)	9 (7.4)	16 (6.7)
	Normal	112 (94.1)	112 (92.6)	224 (93.3)

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Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Observation times for Efficacy endpoints
Full analysis set

		Anifrolumab 300mg (N=119)	Placebo (N=121)
SRI4: Observation time (weeks)	n (missing)	119 (0)	121 (0)
	Mean (SD)	49.0 (9.61)	46.6 (12.41)
	Median	52.1	52.1
	Min, Max	11, 54	0, 54
CLASI activity score: Observation time (weeks)	n (missing)	119 (0)	121 (0)
	Mean (SD)	49.0 (9.62)	46.6 (12.41)
	Median	52.1	52.1
	Min, Max	11, 54	0, 54
CLASI damage score: Observation time (weeks)	n (missing)	119 (0)	121 (0)
	Mean (SD)	49.0 (9.62)	46.6 (12.41)
	Median	52.1	52.1
	Min, Max	11, 54	0, 54
BICLA: Observation time (weeks)	n (missing)	119 (0)	121 (0)
	Mean (SD)	49.0 (9.61)	46.6 (12.38)
	Median	52.1	52.1
	Min, Max	11, 54	0, 54
SLEDAI-2K Total Score: Observation time (weeks)	n (missing)	119 (0)	121 (0)
	Mean (SD)	48.7 (9.60)	46.1 (12.67)
	Median	52.1	52.1
	Min, Max	11, 54	0, 54
PGA: Observation time (weeks)	n (missing)	119 (0)	121 (0)
	Mean (SD)	49.0 (9.62)	46.6 (12.38)
	Median	52.1	52.1
	Min, Max	11, 54	0, 54
BILAG Global Score: Observation time (weeks)	n (missing)	119 (0)	121 (0)
	Mean (SD)	49.0 (9.62)	46.6 (12.40)
	Median	52.1	52.1
	Min, Max	11, 54	0, 54
Tender Joint Count: Observation time (weeks)	n (missing)	119 (0)	121 (0)
	Mean (SD)	49.0 (9.62)	46.6 (12.41)
	Median	52.1	52.1
	Min, Max	11, 54	0, 54
Swollen Joint Count: Observation time (weeks)	n (missing)	119 (0)	121 (0)
	Mean (SD)	49.0 (9.62)	46.6 (12.41)
	Median	52.1	52.1
	Min, Max	11, 54	0, 54
FACIT-F Total Score: Observation time (weeks)	n (missing)	119 (0)	121 (0)
	Mean (SD)	48.8 (9.59)	45.7 (13.22)
	Median	52.1	52.1
	Min, Max	11, 54	0, 54
SF-36 v2.0 Acute - Mental Component Score: Observation time (weeks)	n (missing)	119 (0)	121 (0)
	Mean (SD)	48.5 (10.78)	44.8 (14.45)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
SF-36 v2.0 Acute - Physical Component Score: Observation time (weeks)	n (missing)	119 (0)	121 (0)
	Mean (SD)	48.5 (10.78)	44.8 (14.45)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
EQ-5D VAS Score: Observation time (weeks)	n (missing)	119 (0)	121 (0)

Observation duration defined as time from randomization until last non-missing assessment after randomization. Subjects without assessment are censored at day 1.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Observation times for Efficacy endpoints
Full analysis set

		Anifrolumab 300mg (N=119)	Placebo (N=121)
EQ-5D VAS Score: Observation time (weeks)	Mean (SD)	46.7 (11.87)	42.8 (15.58)
	Median	52.1	52.1
	Min, Max	11, 54	0, 54
SDI Global Score: Observation time (weeks)	n (missing)	119 (0)	121 (0)
	Mean (SD)	45.6 (15.55)	42.1 (17.91)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
PtGA: Observation time (weeks)	n (missing)	119 (0)	121 (0)
	Mean (SD)	48.5 (10.47)	45.0 (13.83)
	Median	52.1	52.1
	Min, Max	4, 54	0, 54

Observation duration defined as time from randomization until last non-missing assessment after randomization. Subjects without assessment are censored at day 1.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 4	Number of subjects with events, n (%)	11 (9.2)	10 (8.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.31 (0.55, 3.10)	
	p-value	0.5405	
	Odds Ratio (95% CI)	1.35 (0.53, 3.43)	
	p-value	0.5305	
	Risk Difference (95% CI)	2.26 (-4.79, 9.30)	
	p-value	0.5299	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.12 (0.49, 2.53)	
	p-value	0.7885	
	Odds Ratio (95% CI)	1.13 (0.46, 2.77)	
	p-value	0.7885	
	Risk Difference (95% CI)	0.98 (-6.17, 8.13)	
	p-value	0.7884	
	CMH approach		
	Response rate	9.5	7.6
	Difference in response rates (95% CI)	1.94 (-6.96, 10.83)	
	p-value	0.6698	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 8	Number of subjects with events, n (%)	40 (33.6)	28 (23.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.50 (0.99, 2.28)	
	p-value	0.0546	
	Odds Ratio (95% CI)	1.80 (1.00, 3.24)	
	p-value	0.0505	
	Risk Difference (95% CI)	11.34 (0.14, 22.54)	
	p-value	0.0473	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.45 (0.96, 2.19)	
	p-value	0.0753	
	Odds Ratio (95% CI)	1.68 (0.95, 2.97)	
	p-value	0.0731	
	Risk Difference (95% CI)	10.47 (-0.86, 21.81)	
	p-value	0.0702	
	CMH approach		
	Response rate	33.5	22.4
	Difference in response rates (95% CI)	11.14 (-0.36, 22.64)	
	p-value	0.0577	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 12	Number of subjects with events, n (%)	58 (48.7)	39 (32.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.57 (1.13, 2.17)	
	p-value	0.0065	
	Odds Ratio (95% CI)	2.15 (1.25, 3.70)	
	p-value	0.0054	
	Risk Difference (95% CI)	17.77 (5.60, 29.94)	
	p-value	0.0042	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.51 (1.10, 2.08)	
	p-value	0.0106	
	Odds Ratio (95% CI)	2.00 (1.18, 3.38)	
	p-value	0.0096	
	Risk Difference (95% CI)	16.51 (4.26, 28.76)	
	p-value	0.0082	
	CMH approach		
	Response rate	48.6	32.0
	Difference in response rates (95% CI)	16.62 (4.32, 28.93)	
	p-value	0.0081	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 16	Number of subjects with events, n (%)	58 (48.7)	44 (36.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.39 (1.02, 1.88)	
	p-value	0.0347	
	Odds Ratio (95% CI)	1.78 (1.05, 3.02)	
	p-value	0.0327	
	Risk Difference (95% CI)	13.73 (1.34, 26.12)	
	p-value	0.0298	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.34 (0.99, 1.81)	
	p-value	0.0550	
	Odds Ratio (95% CI)	1.66 (0.99, 2.79)	
	p-value	0.0532	
	Risk Difference (95% CI)	12.38 (-0.04, 24.79)	
	p-value	0.0507	
	CMH approach		
	Response rate	49.1	35.8
	Difference in response rates (95% CI)	13.29 (0.96, 25.62)	
	p-value	0.0346	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 20	Number of subjects with events, n (%)	63 (52.9)	53 (43.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.21 (0.93, 1.59)	
	p-value	0.1577	
	Odds Ratio (95% CI)	1.46 (0.87, 2.44)	
	p-value	0.1532	
	Risk Difference (95% CI)	9.29 (-3.38, 21.96)	
	p-value	0.1506	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.21 (0.93, 1.57)	
	p-value	0.1586	
	Odds Ratio (95% CI)	1.44 (0.87, 2.40)	
	p-value	0.1572	
	Risk Difference (95% CI)	9.14 (-3.45, 21.73)	
	p-value	0.1549	
	CMH approach		
	Response rate	52.9	43.5
	Difference in response rates (95% CI)	9.42 (-3.21, 22.05)	
	p-value	0.1437	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 24	Number of subjects with events, n (%)	67 (56.3)	50 (41.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.37 (1.04, 1.79)	
	p-value	0.0233	
	Odds Ratio (95% CI)	1.86 (1.10, 3.15)	
	p-value	0.0207	
	Risk Difference (95% CI)	14.97 (2.50, 27.44)	
	p-value	0.0186	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.36 (1.05, 1.78)	
	p-value	0.0221	
	Odds Ratio (95% CI)	1.83 (1.10, 3.05)	
	p-value	0.0207	
	Risk Difference (95% CI)	14.98 (2.47, 27.49)	
	p-value	0.0189	
	CMH approach		
	Response rate	55.9	40.7
	Difference in response rates (95% CI)	15.20 (2.79, 27.61)	
	p-value	0.0164	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 28	Number of subjects with events, n (%)	67 (56.3)	53 (43.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.30 (1.00, 1.70)	
	p-value	0.0533	
	Odds Ratio (95% CI)	1.68 (1.00, 2.81)	
	p-value	0.0483	
	Risk Difference (95% CI)	12.96 (0.26, 25.67)	
	p-value	0.0456	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.29 (0.99, 1.66)	
	p-value	0.0550	
	Odds Ratio (95% CI)	1.65 (0.99, 2.75)	
	p-value	0.0534	
	Risk Difference (95% CI)	12.50 (-0.05, 25.05)	
	p-value	0.0510	
	CMH approach		
	Response rate	56.0	43.0
	Difference in response rates (95% CI)	13.06 (0.49, 25.64)	
	p-value	0.0417	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 32	Number of subjects with events, n (%)	68 (57.1)	53 (43.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.32 (1.01, 1.73)	
	p-value	0.0409	
	Odds Ratio (95% CI)	1.73 (1.03, 2.89)	
	p-value	0.0367	
	Risk Difference (95% CI)	13.76 (1.03, 26.49)	
	p-value	0.0341	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.30 (1.01, 1.68)	
	p-value	0.0409	
	Odds Ratio (95% CI)	1.71 (1.03, 2.85)	
	p-value	0.0393	
	Risk Difference (95% CI)	13.34 (0.80, 25.88)	
	p-value	0.0370	
	CMH approach		
	Response rate	56.9	42.9
	Difference in response rates (95% CI)	14.04 (1.51, 26.56)	
	p-value	0.0280	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 36	Number of subjects with events, n (%)	67 (56.3)	49 (40.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.41 (1.06, 1.87)	
	p-value	0.0174	
	Odds Ratio (95% CI)	1.90 (1.13, 3.17)	
	p-value	0.0146	
	Risk Difference (95% CI)	16.19 (3.44, 28.93)	
	p-value	0.0128	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.39 (1.06, 1.82)	
	p-value	0.0159	
	Odds Ratio (95% CI)	1.89 (1.13, 3.16)	
	p-value	0.0147	
	Risk Difference (95% CI)	15.81 (3.32, 28.29)	
	p-value	0.0131	
	CMH approach		
	Response rate	55.9	39.8
	Difference in response rates (95% CI)	16.11 (3.57, 28.64)	
	p-value	0.0118	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 40	Number of subjects with events, n (%)	65 (54.6)	44 (36.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.51 (1.12, 2.04)	
	p-value	0.0071	
	Odds Ratio (95% CI)	2.09 (1.24, 3.51)	
	p-value	0.0055	
	Risk Difference (95% CI)	18.27 (5.66, 30.88)	
	p-value	0.0045	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.50 (1.13, 2.00)	
	p-value	0.0055	
	Odds Ratio (95% CI)	2.11 (1.26, 3.53)	
	p-value	0.0047	
	Risk Difference (95% CI)	18.26 (5.87, 30.65)	
	p-value	0.0039	
	CMH approach		
	Response rate	53.9	35.7
	Difference in response rates (95% CI)	18.14 (5.76, 30.52)	
	p-value	0.0041	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 44	Number of subjects with events, n (%)	65 (54.6)	48 (39.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.40 (1.05, 1.88)	
	p-value	0.0239	
	Odds Ratio (95% CI)	1.84 (1.10, 3.08)	
	p-value	0.0199	
	Risk Difference (95% CI)	15.40 (2.67, 28.14)	
	p-value	0.0178	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.38 (1.05, 1.81)	
	p-value	0.0222	
	Odds Ratio (95% CI)	1.83 (1.10, 3.06)	
	p-value	0.0208	
	Risk Difference (95% CI)	14.95 (2.46, 27.44)	
	p-value	0.0190	
	CMH approach		
	Response rate	53.7	38.7
	Difference in response rates (95% CI)	14.96 (2.56, 27.36)	
	p-value	0.0180	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 48	Number of subjects with events, n (%)	62 (52.1)	51 (42.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.25 (0.94, 1.66)	
	p-value	0.1217	
	Odds Ratio (95% CI)	1.52 (0.91, 2.55)	
	p-value	0.1132	
	Risk Difference (95% CI)	10.32 (-2.35, 22.99)	
	p-value	0.1104	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.24 (0.94, 1.62)	
	p-value	0.1248	
	Odds Ratio (95% CI)	1.49 (0.90, 2.48)	
	p-value	0.1231	
	Risk Difference (95% CI)	9.95 (-2.62, 22.52)	
	p-value	0.1207	
	CMH approach		
	Response rate	51.7	41.4
	Difference in response rates (95% CI)	10.28 (-2.28, 22.83)	
	p-value	0.1086	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 52	Number of subjects with events, n (%)	61 (51.3)	45 (37.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.36 (1.01, 1.84)	
	p-value	0.0452	
	Odds Ratio (95% CI)	1.72 (1.02, 2.89)	
	p-value	0.0406	
	Risk Difference (95% CI)	13.33 (0.70, 25.96)	
	p-value	0.0386	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.38 (1.03, 1.84)	
	p-value	0.0303	
	Odds Ratio (95% CI)	1.78 (1.06, 2.97)	
	p-value	0.0288	
	Risk Difference (95% CI)	14.07 (1.63, 26.51)	
	p-value	0.0267	
	CMH approach		
	Response rate	50.4	37.0
	Difference in response rates (95% CI)	13.43 (0.97, 25.89)	
	p-value	0.0347	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9275
< 10 points	20/ 41 (48.8)	48.3	11/ 32 (34.4)	34.5	1.42 (0.80, 2.52)	0.2307	13.89 (-8.89, 36.68)	0.2320	
>= 10 points	41/ 78 (52.6)	51.6	34/ 89 (38.2)	38.2	1.38 (0.98, 1.93)	0.0643	13.45 (-1.48, 28.38)	0.0775	
OCS dose at baseline									0.4393
<10 mg/day	26/ 58 (44.8)	44.0	24/ 65 (36.9)	36.9	1.21 (0.79, 1.86)	0.3734	7.09 (-10.36, 24.54)	0.4257	
>=10 mg/day	35/ 61 (57.4)	57.4	21/ 56 (37.5)	37.5	1.53 (1.02, 2.29)	0.0378	19.88 (2.08, 37.67)	0.0286	
Result of type I IFN gene signature test									0.5307
LOW	11/ 23 (47.8)	47.8	10/ 24 (41.7)	41.7	1.15 (0.61, 2.17)	0.6716	6.16 (-22.28, 34.60)	0.6712	
HIGH	50/ 96 (52.1)	51.1	35/ 97 (36.1)	35.9	1.44 (1.04, 2.00)	0.0278	15.23 (1.36, 29.09)	0.0313	
Age (years)									0.7802
<= 65	60/117 (51.3)	50.5	45/120 (37.5)	37.3	1.37 (1.02, 1.83)	0.0349	13.24 (0.72, 25.76)	0.0383	
> 65	1/ 2 (50.0)	50.0	0/ 1 (0.0)	0.0	2.00 (0.14, 28.42)	0.6087	50.00 (-68.41, 168.41)	0.4079	
Sex									0.1551
male	8/ 11 (72.7)	72.7	9/ 12 (75.0)	75.0	0.97 (0.60, 1.58)	0.9015	-2.27 (-40.53, 35.99)	0.9073	
female	53/108 (49.1)	48.4	36/109 (33.0)	33.0	1.49 (1.07, 2.07)	0.0184	15.41 (2.44, 28.38)	0.0199	
Race									0.5798
White	40/ 75 (53.3)	53.5	33/ 78 (42.3)	42.2	1.26 (0.90, 1.76)	0.1749	11.33 (-4.46, 27.12)	0.1596	
Black or African American	5/ 11 (45.5)	45.5	6/ 18 (33.3)	33.3	1.36 (0.54, 3.42)	0.5086	12.12 (-24.80, 49.04)	0.5199	
Asian	8/ 17 (47.1)	47.1	3/ 16 (18.8)	18.8	2.51 (0.80, 7.83)	0.1129	28.31 (-3.53, 60.15)	0.0814	
Other	4/ 8 (50.0)	50.0	1/ 6 (16.7)	16.7	3.00 (0.44, 20.44)	0.2618	33.33 (-17.11, 83.78)	0.1953	
Ethnicity									0.6783
Hispanic/Latino	14/ 27 (51.9)	51.9	13/ 32 (40.6)	40.6	1.28 (0.73, 2.22)	0.3885	11.23 (-14.21, 36.66)	0.3870	
Non-hispanic/Latino	43/ 84 (51.2)	51.5	30/ 86 (34.9)	34.4	1.47 (1.03, 2.10)	0.0349	17.10 (2.39, 31.81)	0.0227	
Geographic region									0.3952
EU	28/ 45 (62.2)	62.2	18/ 33 (54.5)	54.5	1.14 (0.78, 1.68)	0.5035	7.68 (-14.50, 29.85)	0.4975	
non-EU	33/ 74 (44.6)	44.6	27/ 88 (30.7)	30.4	1.45 (0.97, 2.18)	0.0696	14.15 (-0.92, 29.22)	0.0657	
Onset of disease									0.3116
Paediatric	5/ 11 (45.5)	45.5	0/ 5 (0.0)	0.0	5.50 (0.36, 83.84)	0.2200	45.45 (-1.42, 92.33)	0.0573	
Adult	56/108 (51.9)	51.5	45/116 (38.8)	38.6	1.34 (1.00, 1.79)	0.0515	12.91 (0.02, 25.81)	0.0497	
ADA result									0.4385
Negative	59/115 (51.3)	50.2	43/111 (38.7)	38.7	1.32 (0.99, 1.78)	0.0611	11.53 (-1.36, 24.42)	0.0795	
Positive (At any time)	2/ 4 (50.0)	50.0	2/ 10 (20.0)	20.0	2.50 (0.51, 12.14)	0.2557	30.00 (-26.43, 86.43)	0.2975	
BMI (kg/m2) at enrolment									0.8610
< 30	47/ 85 (55.3)	55.6	35/ 89 (39.3)	39.6	1.41 (1.02, 1.94)	0.0375	16.05 (1.44, 30.65)	0.0313	
>= 30	14/ 34 (41.2)	41.2	10/ 32 (31.3)	31.3	1.32 (0.69, 2.53)	0.4072	9.93 (-13.36, 33.21)	0.4034	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.5265
All negative/normal	16/ 38 (42.1)	42.8	20/ 56 (35.7)	35.3	1.18 (0.71, 1.97)	0.5288	7.46 (-13.02, 27.94)	0.4752	
At least one positive/abnormal	45/ 81 (55.6)	55.6	25/ 65 (38.5)	38.5	1.44 (1.00, 2.08)	0.0477	17.09 (1.03, 33.16)	0.0370	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) - individual components at week 52 (Full analysis set)
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
>=4 point reduction in SLEDAI-2k [a]	61 (51.3)	46 (38.0)
No discontinuation of IP	101 (84.9)	83 (68.6)
No use of medication beyond protocol allowed threshold	94 (79.0)	84 (69.4)
No worsening of BILAG [a]	80 (67.2)	60 (49.6)
No worsening of PGA [a]	78 (65.5)	60 (49.6)

[a] Subjects who discontinued IP or used medications beyond protocol allowed threshold are considered non-responders and not included in this category.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate at week 52 sensitivity analysis, multiple imputation
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 52	Number of subjects with events, n (%)	61 (51.3)	45 (36.9)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.37 (1.01, 1.86)	
	p-value	0.0431	
	Odds Ratio (95% CI)	1.74 (1.03, 2.94)	
	p-value	0.0386	
	Risk Difference (95% CI)	13.62 (0.85, 26.39)	
	p-value	0.0366	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.39 (1.03, 1.86)	
	p-value	0.0291	
	Odds Ratio (95% CI)	1.80 (1.07, 3.03)	
	p-value	0.0276	
	Risk Difference (95% CI)	14.33 (1.76, 26.91)	
	p-value	0.0255	

For each outcome and visit, 100 imputations were generated by randomised treatment group. Each imputed dataset was analysed separately, and the single estimates are combined using PROC MIANALYZE. The estimated number of responders and non-responders are rounded to an integer. Therefore, there might be slight mismatches between number of subjects and corresponding percentage.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (8) response rate at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=109)	Placebo (N=112)
Week 52	Number of subjects with events, n (%)	31 (28.4)	17 (15.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.92 (1.12, 3.29)	
	p-value	0.0177	
	Odds Ratio (95% CI)	2.29 (1.17, 4.48)	
	p-value	0.0160	
	Risk Difference (95% CI)	13.84 (2.87, 24.82)	
	p-value	0.0135	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.87 (1.10, 3.18)	
	p-value	0.0201	
	Odds Ratio (95% CI)	2.22 (1.14, 4.31)	
	p-value	0.0183	
	Risk Difference (95% CI)	13.26 (2.50, 24.03)	
	p-value	0.0158	
	CMH approach		
	Response rate	28.9	15.1
	Difference in response rates (95% CI)	13.79 (2.54, 25.04)	
	p-value	0.0163	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (8) response rate at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=109) n/ N (%)	Response rate	Placebo (N=112) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.2987
< 10 points	4/ 31 (12.9)	12.9	3/ 23 (13.0)	13.0	0.99 (0.24, 4.00)	0.9879	-0.14 (-20.83, 20.55)	0.9894	
>= 10 points	27/ 78 (34.6)	33.9	14/ 89 (15.7)	15.8	2.20 (1.25, 3.89)	0.0066	18.10 (4.65, 31.55)	0.0084	
OCS dose at baseline									0.1255
<10 mg/day	10/ 52 (19.2)	19.8	10/ 60 (16.7)	16.8	1.15 (0.52, 2.55)	0.7239	3.08 (-12.94, 19.10)	0.7063	
>=10 mg/day	21/ 57 (36.8)	36.8	7/ 52 (13.5)	13.5	2.74 (1.27, 5.90)	0.0102	23.38 (7.32, 39.44)	0.0043	
Result of type I IFN gene signature test									0.3683
LOW	3/ 20 (15.0)	15.0	3/ 20 (15.0)	15.0	1.00 (0.23, 4.37)	1.0000	0.00 (-25.17, 25.17)	1.0000	
HIGH	28/ 89 (31.5)	31.9	14/ 92 (15.2)	15.1	2.07 (1.17, 3.66)	0.0128	16.85 (4.29, 29.42)	0.0086	
Age (years)									NE
<= 65	31/107 (29.0)	29.4	17/111 (15.3)	15.2	1.89 (1.12, 3.21)	0.0181	14.15 (2.77, 25.52)	0.0148	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									0.5877
male	3/ 9 (33.3)	33.3	3/ 12 (25.0)	25.0	1.33 (0.35, 5.13)	0.6755	8.33 (-32.87, 49.54)	0.6918	
female	28/100 (28.0)	28.2	14/100 (14.0)	14.0	2.00 (1.12, 3.57)	0.0189	14.28 (2.64, 25.92)	0.0162	
Race									0.5266
White	18/ 69 (26.1)	26.5	11/ 72 (15.3)	14.8	1.71 (0.87, 3.35)	0.1195	11.71 (-2.56, 25.99)	0.1077	
Black or African American	2/ 9 (22.2)	22.2	3/ 15 (20.0)	20.0	1.11 (0.23, 5.43)	0.8965	2.22 (-35.27, 39.72)	0.9075	
Asian	7/ 16 (43.8)	43.8	1/ 16 (6.3)	6.3	7.00 (0.97, 50.57)	0.0538	37.50 (7.49, 67.51)	0.0143	
Other	3/ 8 (37.5)	37.5	1/ 6 (16.7)	16.7	2.25 (0.30, 16.63)	0.4269	20.83 (-29.28, 70.95)	0.4152	
Ethnicity									0.3906
Hispanic/Latino	7/ 23 (30.4)	30.4	6/ 28 (21.4)	21.4	1.42 (0.55, 3.64)	0.4647	9.01 (-16.06, 34.07)	0.4813	
Non-hispanic/Latino	23/ 79 (29.1)	29.6	10/ 81 (12.3)	12.2	2.36 (1.20, 4.63)	0.0127	17.37 (4.16, 30.59)	0.0100	
Geographic region									0.4628
EU	15/ 43 (34.9)	34.9	8/ 33 (24.2)	24.2	1.44 (0.69, 2.98)	0.3275	10.64 (-10.24, 31.52)	0.3178	
non-EU	16/ 66 (24.2)	25.2	9/ 79 (11.4)	11.3	2.13 (1.01, 4.50)	0.0480	13.89 (0.26, 27.52)	0.0457	
Onset of disease									0.6467
Paediatric	3/ 11 (27.3)	27.3	0/ 5 (0.0)	0.0	3.50 (0.21, 57.35)	0.3799	27.27 (-18.60, 73.14)	0.2439	
Adult	28/ 98 (28.6)	29.0	17/107 (15.9)	15.8	1.80 (1.05, 3.08)	0.0321	13.28 (1.48, 25.07)	0.0274	
ADA result									0.3462
Negative	29/105 (27.6)	27.9	16/102 (15.7)	15.6	1.76 (1.02, 3.04)	0.0423	12.30 (0.69, 23.91)	0.0379	
Positive (At any time)	2/ 4 (50.0)	50.0	1/ 10 (10.0)	10.0	5.00 (0.61, 40.91)	0.1334	40.00 (-15.21, 95.21)	0.1556	
BMI (kg/m2) at enrolment									0.7197
< 30	25/ 81 (30.9)	31.4	13/ 83 (15.7)	15.5	1.97 (1.09, 3.58)	0.0258	15.87 (2.45, 29.29)	0.0205	
>= 30	6/ 28 (21.4)	21.4	4/ 29 (13.8)	13.8	1.55 (0.49, 4.92)	0.4542	7.64 (-13.68, 28.95)	0.4826	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.1210
All negative/normal	4/ 29 (13.8)	13.7	8/ 49 (16.3)	16.4	0.84 (0.28, 2.56)	0.7657	-2.68 (-21.56, 16.19)	0.7806	
At least one positive/abnormal	27/ 80 (33.8)	33.8	9/ 63 (14.3)	14.3	2.36 (1.20, 4.66)	0.0130	19.46 (5.60, 33.33)	0.0059	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=4 reduction in SLEDAI-2K at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 52	Number of subjects with events, n (%)	61 (51.3)	46 (38.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.33 (0.99, 1.80)	
	p-value	0.0587	
	Odds Ratio (95% CI)	1.66 (0.99, 2.79)	
	p-value	0.0533	
	Risk Difference (95% CI)	12.61 (-0.06, 25.28)	
	p-value	0.0511	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.35 (1.01, 1.80)	
	p-value	0.0413	
	Odds Ratio (95% CI)	1.71 (1.03, 2.87)	
	p-value	0.0397	
	Risk Difference (95% CI)	13.24 (0.78, 25.71)	
	p-value	0.0374	
	CMH approach		
	Response rate	50.4	37.7
	Difference in response rates (95% CI)	12.72 (0.24, 25.19)	
	p-value	0.0458	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=4 reduction in SLEDAI-2K at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8594
< 10 points	20/ 41 (48.8)	48.3	11/ 32 (34.4)	34.5	1.42 (0.80, 2.52)	0.2307	13.89 (-8.89, 36.68)	0.2320	
>= 10 points	41/ 78 (52.6)	51.6	35/ 89 (39.3)	39.2	1.34 (0.96, 1.87)	0.0879	12.43 (-2.53, 27.38)	0.1034	
OCS dose at baseline									0.3583
<10 mg/day	26/ 58 (44.8)	44.0	25/ 65 (38.5)	38.3	1.17 (0.77, 1.77)	0.4744	5.70 (-11.79, 23.18)	0.5230	
>=10 mg/day	35/ 61 (57.4)	57.4	21/ 56 (37.5)	37.5	1.53 (1.02, 2.29)	0.0378	19.88 (2.08, 37.67)	0.0286	
Result of type I IFN gene signature test									0.5813
LOW	11/ 23 (47.8)	47.8	10/ 24 (41.7)	41.7	1.15 (0.61, 2.17)	0.6716	6.16 (-22.28, 34.60)	0.6712	
HIGH	50/ 96 (52.1)	51.1	36/ 97 (37.1)	36.7	1.40 (1.02, 1.94)	0.0394	14.34 (0.46, 28.22)	0.0429	
Age (years)									0.7678
<= 65	60/117 (51.3)	50.5	46/120 (38.3)	38.0	1.34 (1.00, 1.78)	0.0473	12.51 (-0.03, 25.04)	0.0505	
> 65	1/ 2 (50.0)	50.0	0/ 1 (0.0)	0.0	2.00 (0.14, 28.42)	0.6087	50.00 (-68.41, 168.41)	0.4079	
Sex									0.1815
male	8/ 11 (72.7)	72.7	9/ 12 (75.0)	75.0	0.97 (0.60, 1.58)	0.9015	-2.27 (-40.53, 35.99)	0.9073	
female	53/108 (49.1)	48.4	37/109 (33.9)	33.8	1.45 (1.04, 2.00)	0.0261	14.59 (1.60, 27.59)	0.0277	
Race									0.5447
White	40/ 75 (53.3)	53.5	34/ 78 (43.6)	43.5	1.22 (0.88, 1.70)	0.2301	10.07 (-5.73, 25.87)	0.2118	
Black or African American	5/ 11 (45.5)	45.5	6/ 18 (33.3)	33.3	1.36 (0.54, 3.42)	0.5086	12.12 (-24.80, 49.04)	0.5199	
Asian	8/ 17 (47.1)	47.1	3/ 16 (18.8)	18.8	2.51 (0.80, 7.83)	0.1129	28.31 (-3.53, 60.15)	0.0814	
Other	4/ 8 (50.0)	50.0	1/ 6 (16.7)	16.7	3.00 (0.44, 20.44)	0.2618	33.33 (-17.11, 83.78)	0.1953	
Ethnicity									0.7498
Hispanic/Latino	14/ 27 (51.9)	51.9	13/ 32 (40.6)	40.6	1.28 (0.73, 2.22)	0.3885	11.23 (-14.21, 36.66)	0.3870	
Non-hispanic/Latino	43/ 84 (51.2)	51.5	31/ 86 (36.0)	35.5	1.42 (1.00, 2.02)	0.0498	15.97 (1.23, 30.72)	0.0337	
Geographic region									0.2895
EU	28/ 45 (62.2)	62.2	19/ 33 (57.6)	57.6	1.08 (0.75, 1.57)	0.6818	4.65 (-17.45, 26.75)	0.6803	
non-EU	33/ 74 (44.6)	44.6	27/ 88 (30.7)	30.4	1.45 (0.97, 2.18)	0.0696	14.15 (-0.92, 29.22)	0.0657	
Onset of disease									0.3040
Paediatric	5/ 11 (45.5)	45.5	0/ 5 (0.0)	0.0	5.50 (0.36, 83.84)	0.2200	45.45 (-1.42, 92.33)	0.0573	
Adult	56/108 (51.9)	51.5	46/116 (39.7)	39.3	1.31 (0.98, 1.75)	0.0688	12.14 (-0.77, 25.05)	0.0652	
ADA result									0.4219
Negative	59/115 (51.3)	50.2	44/111 (39.6)	39.5	1.29 (0.97, 1.73)	0.0818	10.75 (-2.16, 23.65)	0.1026	
Positive (At any time)	2/ 4 (50.0)	50.0	2/ 10 (20.0)	20.0	2.50 (0.51, 12.14)	0.2557	30.00 (-26.43, 86.43)	0.2975	
BMI (kg/m2) at enrolment									0.9208
< 30	47/ 85 (55.3)	55.6	36/ 89 (40.4)	40.7	1.37 (1.00, 1.88)	0.0528	14.96 (0.33, 29.59)	0.0451	
>= 30	14/ 34 (41.2)	41.2	10/ 32 (31.3)	31.3	1.32 (0.69, 2.53)	0.4072	9.93 (-13.36, 33.21)	0.4034	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.6066
All negative/normal	16/ 38 (42.1)	42.8	20/ 56 (35.7)	35.3	1.18 (0.71, 1.97)	0.5288	7.46 (-13.02, 27.94)	0.4752	
At least one positive/abnormal	45/ 81 (55.6)	55.6	26/ 65 (40.0)	40.0	1.39 (0.97, 1.98)	0.0704	15.56 (-0.56, 31.67)	0.0585	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=8 reduction in SLEDAI-2K at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 52	Number of subjects with events, n (%)	31 (26.1)	17 (14.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.94 (1.13, 3.32)	
	p-value	0.0164	
	Odds Ratio (95% CI)	2.31 (1.18, 4.51)	
	p-value	0.0143	
	Risk Difference (95% CI)	12.83 (2.80, 22.86)	
	p-value	0.0121	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.85 (1.09, 3.16)	
	p-value	0.0236	
	Odds Ratio (95% CI)	2.16 (1.12, 4.15)	
	p-value	0.0218	
	Risk Difference (95% CI)	12.00 (1.97, 22.03)	
	p-value	0.0190	
	CMH approach		
	Response rate	26.0	13.7
	Difference in response rates (95% CI)	12.30 (1.61, 22.99)	
	p-value	0.0242	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=8 reduction in SLEDAI-2K at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.3385
< 10 points	4/ 41 (9.8)	9.3	3/ 32 (9.4)	8.8	1.04 (0.25, 4.32)	0.9563	0.46 (-17.72, 18.65)	0.9602	
>= 10 points	27/ 78 (34.6)	33.9	14/ 89 (15.7)	15.8	2.20 (1.25, 3.89)	0.0066	18.10 (4.65, 31.55)	0.0084	
OCS dose at baseline									0.1140
<10 mg/day	10/ 58 (17.2)	18.0	10/ 65 (15.4)	15.3	1.12 (0.50, 2.50)	0.7806	2.75 (-12.07, 17.57)	0.7158	
>=10 mg/day	21/ 61 (34.4)	34.4	7/ 56 (12.5)	12.5	2.75 (1.27, 5.98)	0.0104	21.93 (6.71, 37.14)	0.0047	
Result of type I IFN gene signature test									0.4187
LOW	3/ 23 (13.0)	13.0	3/ 24 (12.5)	12.5	1.04 (0.23, 4.65)	0.9555	0.54 (-21.52, 22.61)	0.9615	
HIGH	28/ 96 (29.2)	29.2	14/ 97 (14.4)	14.0	2.02 (1.14, 3.60)	0.0167	15.21 (3.04, 27.38)	0.0143	
Age (years)									NE
<= 65	31/117 (26.5)	26.5	17/120 (14.2)	13.8	1.87 (1.10, 3.19)	0.0215	12.66 (1.87, 23.44)	0.0215	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									0.4195
male	3/ 11 (27.3)	27.3	3/ 12 (25.0)	25.0	1.09 (0.28, 4.32)	0.9013	2.27 (-35.99, 40.53)	0.9073	
female	28/108 (25.9)	25.5	14/109 (12.8)	12.6	2.02 (1.13, 3.62)	0.0184	12.98 (1.90, 24.06)	0.0217	
Race									0.5560
White	18/ 75 (24.0)	24.5	11/ 78 (14.1)	13.6	1.70 (0.86, 3.36)	0.1253	10.93 (-2.42, 24.29)	0.1086	
Black or African American	2/ 11 (18.2)	18.2	3/ 18 (16.7)	16.7	1.09 (0.21, 5.54)	0.9164	1.52 (-31.01, 34.04)	0.9272	
Asian	7/ 17 (41.2)	41.2	1/ 16 (6.3)	6.3	6.59 (0.91, 47.76)	0.0621	34.93 (5.61, 64.24)	0.0195	
Other	3/ 8 (37.5)	37.5	1/ 6 (16.7)	16.7	2.25 (0.30, 16.63)	0.4269	20.83 (-29.28, 70.95)	0.4152	
Ethnicity									0.3757
Hispanic/Latino	7/ 27 (25.9)	25.9	6/ 32 (18.8)	18.8	1.38 (0.53, 3.62)	0.5094	7.18 (-15.20, 29.55)	0.5296	
Non-hispanic/Latino	23/ 84 (27.4)	27.9	10/ 86 (11.6)	11.5	2.35 (1.19, 4.64)	0.0134	16.45 (3.84, 29.05)	0.0105	
Geographic region									0.4227
EU	15/ 45 (33.3)	33.3	8/ 33 (24.2)	24.2	1.38 (0.66, 2.86)	0.3933	9.09 (-11.48, 29.66)	0.3863	
non-EU	16/ 74 (21.6)	22.6	9/ 88 (10.2)	10.0	2.11 (0.99, 4.50)	0.0522	12.58 (0.20, 24.96)	0.0463	
Onset of disease									0.6387
Paediatric	3/ 11 (27.3)	27.3	0/ 5 (0.0)	0.0	3.50 (0.21, 57.35)	0.3799	27.27 (-18.60, 73.14)	0.2439	
Adult	28/108 (25.9)	26.2	17/116 (14.7)	14.3	1.77 (1.03, 3.04)	0.0394	11.86 (0.72, 23.00)	0.0369	
ADA result									0.3436
Negative	29/115 (25.2)	25.0	16/111 (14.4)	14.3	1.75 (1.01, 3.04)	0.0470	10.69 (-0.37, 21.75)	0.0582	
Positive (At any time)	2/ 4 (50.0)	50.0	1/ 10 (10.0)	10.0	5.00 (0.61, 40.91)	0.1334	40.00 (-15.21, 95.21)	0.1556	
BMI (kg/m2) at enrolment									0.5966
< 30	25/ 85 (29.4)	29.8	13/ 89 (14.6)	14.6	2.01 (1.10, 3.67)	0.0224	15.26 (2.47, 28.05)	0.0193	
>= 30	6/ 34 (17.6)	17.6	4/ 32 (12.5)	12.5	1.41 (0.44, 4.55)	0.5633	5.15 (-13.68, 23.98)	0.5921	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.0780
All negative/normal	4/ 38 (10.5)	11.1	8/ 56 (14.3)	14.1	0.74 (0.24, 2.27)	0.5955	-3.04 (-19.80, 13.72)	0.7225	
At least one positive/abnormal	27/ 81 (33.3)	33.3	9/ 65 (13.8)	13.8	2.41 (1.22, 4.75)	0.0113	19.49 (5.86, 33.12)	0.0051	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
No worsening in BILAG-2004 (>=1A or >=2B compared to BL) at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 52	Number of subjects with events, n (%)	80 (67.2)	60 (49.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.33 (1.06, 1.68)	
	p-value	0.0148	
	Odds Ratio (95% CI)	1.93 (1.15, 3.24)	
	p-value	0.0131	
	Risk Difference (95% CI)	16.46 (3.75, 29.17)	
	p-value	0.0112	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.36 (1.09, 1.69)	
	p-value	0.0065	
	Odds Ratio (95% CI)	2.09 (1.24, 3.52)	
	p-value	0.0059	
	Risk Difference (95% CI)	17.64 (5.37, 29.91)	
	p-value	0.0048	
	CMH approach		
	Response rate	66.1	49.5
	Difference in response rates (95% CI)	16.62 (4.25, 28.99)	
	p-value	0.0085	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
No worsening in BILAG-2004 (>=1A or >=2B compared to BL) at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9453
< 10 points	29/ 41 (70.7)	70.2	17/ 32 (53.1)	52.4	1.33 (0.91, 1.95)	0.1402	17.88 (-4.62, 40.37)	0.1194	
>= 10 points	51/ 78 (65.4)	64.9	43/ 89 (48.3)	48.6	1.35 (1.03, 1.77)	0.0274	16.36 (1.58, 31.14)	0.0300	
OCS dose at baseline									0.7070
<10 mg/day	37/ 58 (63.8)	62.2	32/ 65 (49.2)	49.1	1.30 (0.95, 1.77)	0.1057	13.10 (-4.23, 30.42)	0.1384	
>=10 mg/day	43/ 61 (70.5)	70.5	28/ 56 (50.0)	50.0	1.41 (1.04, 1.92)	0.0289	20.49 (3.01, 37.97)	0.0216	
Result of type I IFN gene signature test									0.4450
LOW	17/ 23 (73.9)	73.9	11/ 24 (45.8)	45.8	1.61 (0.98, 2.65)	0.0601	28.08 (0.76, 55.40)	0.0440	
HIGH	63/ 96 (65.6)	64.2	49/ 97 (50.5)	50.4	1.30 (1.02, 1.66)	0.0359	13.78 (-0.09, 27.66)	0.0515	
Age (years)									0.7725
<= 65	79/117 (67.5)	66.5	60/120 (50.0)	49.9	1.35 (1.09, 1.68)	0.0071	16.60 (4.18, 29.03)	0.0088	
> 65	1/ 2 (50.0)	50.0	0/ 1 (0.0)	0.0	2.00 (0.14, 28.42)	0.6087	50.00 (-68.41, 168.41)	0.4079	
Sex									0.3143
male	9/ 11 (81.8)	81.8	9/ 12 (75.0)	75.0	1.09 (0.71, 1.68)	0.6912	6.82 (-30.20, 43.84)	0.7181	
female	71/108 (65.7)	64.9	51/109 (46.8)	46.7	1.41 (1.10, 1.79)	0.0059	18.20 (5.14, 31.27)	0.0063	
Race									0.7143
White	54/ 75 (72.0)	72.1	40/ 78 (51.3)	51.3	1.40 (1.08, 1.82)	0.0100	20.87 (5.58, 36.16)	0.0075	
Black or African American	6/ 11 (54.5)	54.5	10/ 18 (55.6)	55.6	0.98 (0.50, 1.94)	0.9578	-1.01 (-38.40, 36.38)	0.9578	
Asian	11/ 17 (64.7)	64.7	6/ 16 (37.5)	37.5	1.73 (0.84, 3.56)	0.1394	27.21 (-6.10, 60.51)	0.1094	
Other	4/ 8 (50.0)	50.0	2/ 6 (33.3)	33.3	1.50 (0.40, 5.65)	0.5492	16.67 (-35.65, 68.98)	0.5324	
Ethnicity									0.9625
Hispanic/Latino	16/ 27 (59.3)	59.3	14/ 32 (43.8)	43.8	1.35 (0.82, 2.24)	0.2363	15.51 (-9.85, 40.86)	0.2306	
Non-hispanic/Latino	59/ 84 (70.2)	70.0	44/ 86 (51.2)	51.2	1.37 (1.07, 1.76)	0.0126	18.78 (4.18, 33.38)	0.0117	
Geographic region									0.2623
EU	34/ 45 (75.6)	75.6	22/ 33 (66.7)	66.7	1.13 (0.85, 1.52)	0.4024	8.89 (-11.89, 29.67)	0.4017	
non-EU	46/ 74 (62.2)	61.6	38/ 88 (43.2)	43.5	1.44 (1.07, 1.94)	0.0167	18.12 (2.84, 33.40)	0.0201	
Onset of disease									0.4543
Paediatric	6/ 11 (54.5)	54.5	1/ 5 (20.0)	20.0	2.73 (0.44, 17.07)	0.2837	34.55 (-16.21, 85.30)	0.1822	
Adult	74/108 (68.5)	67.8	59/116 (50.9)	50.7	1.35 (1.08, 1.68)	0.0079	17.05 (4.33, 29.77)	0.0086	
ADA result									0.4206
Negative	78/115 (67.8)	66.5	58/111 (52.3)	52.4	1.30 (1.04, 1.61)	0.0189	14.11 (1.41, 26.82)	0.0295	
Positive (At any time)	2/ 4 (50.0)	50.0	2/ 10 (20.0)	20.0	2.50 (0.51, 12.14)	0.2557	30.00 (-26.43, 86.43)	0.2975	
BMI (kg/m2) at enrolment									0.7658
< 30	61/ 85 (71.8)	71.8	46/ 89 (51.7)	51.7	1.39 (1.09, 1.77)	0.0076	20.04 (5.76, 34.32)	0.0059	
>= 30	19/ 34 (55.9)	55.9	14/ 32 (43.8)	43.8	1.28 (0.78, 2.09)	0.3310	12.13 (-11.86, 36.13)	0.3217	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.6207
All negative/normal	25/ 38 (65.8)	65.2	29/ 56 (51.8)	51.8	1.27 (0.90, 1.79)	0.1692	13.42 (-7.05, 33.89)	0.1987	
At least one positive/abnormal	55/ 81 (67.9)	67.9	31/ 65 (47.7)	47.7	1.42 (1.06, 1.91)	0.0191	20.21 (4.33, 36.09)	0.0126	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Maintained OCS Reduction at week 52 (for subjects with baseline OCS >=10 mg/day)
Full analysis set

Timepoint		Anifrolumab 300mg (N=61)	Placebo (N=56)
Week 52	Number of subjects with events, n (%)	32 (52.5)	14 (25.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	2.03 (1.20, 3.43)	
	p-value	0.0087	
	Odds Ratio (95% CI)	3.04 (1.38, 6.69)	
	p-value	0.0057	
	Risk Difference (95% CI)	26.03 (8.65, 43.41)	
	p-value	0.0033	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	2.10 (1.26, 3.50)	
	p-value	0.0046	
	Odds Ratio (95% CI)	3.31 (1.51, 7.27)	
	p-value	0.0028	
	Risk Difference (95% CI)	27.46 (10.56, 44.36)	
	p-value	0.0015	
	CMH approach		
	Response rate	52.5	25.0
	Difference in response rates (95% CI)	27.46 (10.39, 44.52)	
	p-value	0.0016	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Maintained OCS Reduction at week 52 (for subjects with baseline OCS >=10 mg/day) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=61) n/ N (%)	Response rate	Placebo (N=56) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8944
< 10 points	10/ 18 (55.6)	55.6	3/ 12 (25.0)	25.0	2.22 (0.77, 6.44)	0.1411	30.56 (-4.33, 65.44)	0.0860	
>= 10 points	22/ 43 (51.2)	51.2	11/ 44 (25.0)	25.0	2.05 (1.14, 3.69)	0.0172	26.16 (6.27, 46.05)	0.0099	
OCS dose at baseline									NE
>=10 mg/day	32/ 61 (52.5)	52.5	14/ 56 (25.0)	25.0	2.10 (1.26, 3.50)	0.0046	27.46 (10.39, 44.52)	0.0016	
Result of type I IFN gene signature test									0.4344
LOW	1/ 5 (20.0)	20.0	2/ 9 (22.2)	22.2	0.90 (0.11, 7.63)	0.9230	-2.22 (-53.37, 48.93)	0.9321	
HIGH	31/ 56 (55.4)	54.9	12/ 47 (25.5)	25.3	2.17 (1.26, 3.73)	0.0051	29.60 (11.14, 48.06)	0.0017	
Age (years)									NE
<= 65	32/ 60 (53.3)	53.3	14/ 56 (25.0)	25.0	2.13 (1.28, 3.56)	0.0037	28.33 (11.20, 45.47)	0.0012	
> 65	0/ 1 (0.0)		0		NE		NE		
Sex									0.9982
male	5/ 6 (83.3)	83.3	2/ 5 (40.0)	40.0	2.08 (0.67, 6.46)	0.2036	43.33 (-13.60, 100.27)	0.1358	
female	27/ 55 (49.1)	49.1	12/ 51 (23.5)	23.5	2.09 (1.19, 3.66)	0.0105	25.56 (7.74, 43.38)	0.0049	
Race									0.0331
White	21/ 38 (55.3)	55.3	10/ 44 (22.7)	22.7	2.43 (1.31, 4.50)	0.0047	32.54 (12.19, 52.89)	0.0017	
Black or African American	1/ 4 (25.0)	25.0	2/ 6 (33.3)	33.3	0.75 (0.10, 5.77)	0.7822	-8.33 (-69.88, 53.21)	0.7907	
Asian	5/ 10 (50.0)	50.0	1/ 4 (25.0)	25.0	2.00 (0.33, 12.18)	0.4522	25.00 (-31.67, 81.67)	0.3872	
Other	2/ 5 (40.0)	40.0	1/ 1 (100.0)	100.0	0.40 (0.14, 1.17)	0.0943	-60.00 (-165.43, 45.43)	0.2647	
Ethnicity									0.7762
Hispanic/Latino	8/ 17 (47.1)	47.1	5/ 19 (26.3)	26.3	1.79 (0.72, 4.42)	0.2085	20.74 (-10.75, 52.23)	0.1967	
Non-hispanic/Latino	21/ 40 (52.5)	52.5	9/ 36 (25.0)	25.0	2.10 (1.11, 3.97)	0.0226	27.50 (6.23, 48.77)	0.0113	
Geographic region									0.6005
EU	17/ 26 (65.4)	65.4	6/ 22 (27.3)	27.3	2.40 (1.15, 5.01)	0.0201	38.11 (11.37, 64.85)	0.0052	
non-EU	15/ 35 (42.9)	42.9	8/ 34 (23.5)	23.5	1.82 (0.89, 3.73)	0.1010	19.33 (-2.78, 41.44)	0.0867	
Onset of disease									0.7931
Paediatric	5/ 9 (55.6)	55.6	1/ 3 (33.3)	33.3	1.67 (0.30, 9.16)	0.5567	22.22 (-42.56, 87.00)	0.5014	
Adult	27/ 52 (51.9)	51.9	13/ 53 (24.5)	24.5	2.12 (1.23, 3.63)	0.0065	27.39 (9.37, 45.42)	0.0029	
ADA result									0.9975
Negative	31/ 57 (54.4)	54.4	13/ 48 (27.1)	27.1	2.01 (1.19, 3.38)	0.0088	27.30 (9.09, 45.51)	0.0033	
Positive (At any time)	1/ 4 (25.0)	25.0	1/ 8 (12.5)	12.5	2.00 (0.16, 24.33)	0.5866	12.50 (-43.64, 68.64)	0.6625	
BMI (kg/m2) at enrolment									0.4261
< 30	27/ 45 (60.0)	60.0	11/ 43 (25.6)	25.6	2.35 (1.34, 4.12)	0.0030	34.42 (14.80, 54.04)	0.0006	
>= 30	5/ 16 (31.3)	31.3	3/ 13 (23.1)	23.1	1.35 (0.40, 4.63)	0.6290	8.17 (-25.88, 42.23)	0.6381	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.8716
All negative/normal	9/ 17 (52.9)	52.9	5/ 21 (23.8)	23.8	2.22 (0.92, 5.40)	0.0773	29.13 (-1.40, 59.67)	0.0615	
At least one positive/abnormal	23/ 44 (52.3)	52.3	9/ 35 (25.7)	25.7	2.03 (1.08, 3.82)	0.0273	26.56 (5.58, 47.54)	0.0131	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=50% Reduction in CLASI activity score at week 52 (for subjects with baseline CLASI activity score >=10)
Full analysis set

Timepoint		Anifrolumab 300mg (N=25)	Placebo (N=30)
Week 52	Number of subjects with events, n (%)	15 (60.0)	15 (50.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.17 (0.73, 1.87)	
	p-value	0.5239	
	Odds Ratio (95% CI)	1.47 (0.46, 4.65)	
	p-value	0.5164	
	Risk Difference (95% CI)	8.34 (-16.79, 33.48)	
	p-value	0.5154	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.20 (0.74, 1.94)	
	p-value	0.4567	
	Odds Ratio (95% CI)	1.50 (0.51, 4.39)	
	p-value	0.4591	
	Risk Difference (95% CI)	10.00 (-16.25, 36.25)	
	p-value	0.4552	
	CMH approach		
	Response rate	60.0	50.0
	Difference in response rates (95% CI)	10.00 (-16.32, 36.32)	
	p-value	0.4565	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=50% Reduction in CLASI activity score at week 52 (for subjects with baseline CLASI activity score >=10) - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=25)		Placebo (N=30)		Analysis Anifrolumab 300mg vs. Placebo				Interaction
Level	n/ N (%)	Response rate	n/ N (%)	Response rate	Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	p-Value
SLEDAI-2K score at screening									0.7768
< 10 points	2/ 4 (50.0)	50.0	2/ 4 (50.0)	50.0	1.00 (0.25, 4.00)	1.0000	0.00 (-69.30, 69.30)	1.0000	
>= 10 points	13/ 21 (61.9)	61.9	13/ 26 (50.0)	50.0	1.24 (0.74, 2.06)	0.4120	11.90 (-16.53, 40.34)	0.4118	
OCS dose at baseline									0.6805
<10 mg/day	5/ 8 (62.5)	62.5	4/ 9 (44.4)	44.4	1.41 (0.57, 3.48)	0.4610	18.06 (-29.14, 65.26)	0.4534	
>=10 mg/day	10/ 17 (58.8)	58.8	11/ 21 (52.4)	52.4	1.12 (0.64, 1.99)	0.6898	6.44 (-25.34, 38.22)	0.6911	
Result of type I IFN gene signature test									0.6170
LOW	1/ 2 (50.0)	50.0	3/ 5 (60.0)	60.0	0.83 (0.18, 3.96)	0.8188	-10.00 (-91.85, 71.85)	0.8107	
HIGH	14/ 23 (60.9)	60.9	12/ 25 (48.0)	48.0	1.27 (0.75, 2.14)	0.3736	12.87 (-15.18, 40.92)	0.3686	
Age (years)									NE
<= 65	15/ 25 (60.0)	60.0	15/ 30 (50.0)	50.0	1.20 (0.74, 1.94)	0.4567	10.00 (-16.32, 36.32)	0.4565	
Sex									0.3509
male	1/ 3 (33.3)	33.3	3/ 5 (60.0)	60.0	0.56 (0.10, 3.21)	0.5111	-26.67 (-97.61, 44.28)	0.4613	
female	14/ 22 (63.6)	63.6	12/ 25 (48.0)	48.0	1.33 (0.79, 2.22)	0.2841	15.64 (-12.59, 43.87)	0.2777	
Race									0.2369
White	12/ 19 (63.2)	63.2	12/ 20 (60.0)	60.0	1.05 (0.64, 1.73)	0.8394	3.16 (-27.64, 33.95)	0.8407	
Black or African American	0/ 1 (0.0)	0.0	1/ 3 (33.3)	33.3	0.67 (0.04, 10.05)	0.7696	-33.33 (-144.49, 77.82)	0.5567	
Asian	3/ 3 (100.0)	100.0	0/ 5 (0.0)	0.0	10.50 (0.72, 153.07)	0.0854	100.00 (37.22, 162.78)	0.0018	
Other	0/ 1 (0.0)		0		NE		NE		
Ethnicity									0.9854
Hispanic/Latino	2/ 3 (66.7)	66.7	2/ 4 (50.0)	50.0	1.33 (0.38, 4.72)	0.6558	16.67 (-57.74, 91.08)	0.6607	
Non-hispanic/Latino	13/ 21 (61.9)	61.9	11/ 24 (45.8)	45.8	1.35 (0.78, 2.34)	0.2835	16.07 (-12.86, 45.00)	0.2763	
Geographic region									0.1455
EU	7/ 12 (58.3)	58.3	9/ 13 (69.2)	69.2	0.84 (0.46, 1.54)	0.5758	-10.90 (-49.14, 27.35)	0.5765	
non-EU	8/ 13 (61.5)	61.5	6/ 17 (35.3)	35.3	1.74 (0.80, 3.78)	0.1592	26.24 (-9.09, 61.58)	0.1455	
Onset of disease									0.5055
Paediatric	0/ 1 (0.0)	0.0	1/ 2 (50.0)	50.0	0.50 (0.04, 7.10)	0.6087	-50.00 (-168.41, 68.41)	0.4079	
Adult	15/ 24 (62.5)	62.5	14/ 28 (50.0)	50.0	1.25 (0.77, 2.03)	0.3651	12.50 (-14.42, 39.42)	0.3628	
ADA result									NE
Negative	15/ 24 (62.5)	62.5	15/ 28 (53.6)	53.6	1.17 (0.73, 1.85)	0.5146	8.93 (-17.97, 35.83)	0.5153	
Positive (At any time)	0/ 1 (0.0)	0.0	0/ 2 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
BMI (kg/m2) at enrolment									0.4934
< 30	12/ 20 (60.0)	60.0	11/ 24 (45.8)	45.8	1.31 (0.75, 2.30)	0.3486	14.17 (-15.24, 43.58)	0.3451	
>= 30	3/ 5 (60.0)	60.0	4/ 6 (66.7)	66.7	0.90 (0.36, 2.24)	0.8209	-6.67 (-65.26, 51.93)	0.8235	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.5923
All negative/normal	3/ 4 (75.0)	75.0	6/ 12 (50.0)	50.0	1.50 (0.67, 3.34)	0.3206	25.00 (-30.24, 80.24)	0.3750	
At least one positive/abnormal	12/ 21 (57.1)	57.1	9/ 18 (50.0)	50.0	1.14 (0.63, 2.07)	0.6585	7.14 (-24.23, 38.52)	0.6554	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 4	Number of subjects with events, n (%)	31 (26.1)	24 (19.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.29 (0.80, 2.08)	
	p-value	0.2912	
	Odds Ratio (95% CI)	1.40 (0.75, 2.58)	
	p-value	0.2880	
	Risk Difference (95% CI)	5.83 (-4.88, 16.54)	
	p-value	0.2860	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.31 (0.82, 2.10)	
	p-value	0.2546	
	Odds Ratio (95% CI)	1.42 (0.78, 2.61)	
	p-value	0.2532	
	Risk Difference (95% CI)	6.22 (-4.40, 16.83)	
	p-value	0.2511	
	CMH approach		
	Response rate	25.9	20.1
	Difference in response rates (95% CI)	5.85 (-5.25, 16.94)	
	p-value	0.3018	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 8	Number of subjects with events, n (%)	42 (35.3)	24 (19.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.77 (1.14, 2.74)	
	p-value	0.0109	
	Odds Ratio (95% CI)	2.21 (1.22, 4.01)	
	p-value	0.0092	
	Risk Difference (95% CI)	15.23 (4.05, 26.40)	
	p-value	0.0076	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.78 (1.15, 2.74)	
	p-value	0.0091	
	Odds Ratio (95% CI)	2.20 (1.23, 3.95)	
	p-value	0.0080	
	Risk Difference (95% CI)	15.46 (4.31, 26.60)	
	p-value	0.0066	
	CMH approach		
	Response rate	35.1	19.3
	Difference in response rates (95% CI)	15.88 (4.43, 27.33)	
	p-value	0.0066	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 12	Number of subjects with events, n (%)	48 (40.3)	34 (28.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.40 (0.97, 2.03)	
	p-value	0.0712	
	Odds Ratio (95% CI)	1.66 (0.96, 2.87)	
	p-value	0.0671	
	Risk Difference (95% CI)	11.36 (-0.69, 23.42)	
	p-value	0.0647	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.44 (1.00, 2.06)	
	p-value	0.0485	
	Odds Ratio (95% CI)	1.73 (1.01, 2.97)	
	p-value	0.0466	
	Risk Difference (95% CI)	12.24 (0.33, 24.15)	
	p-value	0.0440	
	CMH approach		
	Response rate	39.6	28.5
	Difference in response rates (95% CI)	11.09 (-1.01, 23.19)	
	p-value	0.0724	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 16	Number of subjects with events, n (%)	51 (42.9)	38 (31.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.34 (0.94, 1.91)	
	p-value	0.1054	
	Odds Ratio (95% CI)	1.57 (0.92, 2.67)	
	p-value	0.0966	
	Risk Difference (95% CI)	10.51 (-1.83, 22.84)	
	p-value	0.0950	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.36 (0.98, 1.91)	
	p-value	0.0691	
	Odds Ratio (95% CI)	1.64 (0.97, 2.78)	
	p-value	0.0671	
	Risk Difference (95% CI)	11.45 (-0.69, 23.59)	
	p-value	0.0645	
	CMH approach		
	Response rate	42.0	31.1
	Difference in response rates (95% CI)	10.90 (-1.30, 23.09)	
	p-value	0.0799	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 20	Number of subjects with events, n (%)	51 (42.9)	39 (32.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.30 (0.92, 1.85)	
	p-value	0.1403	
	Odds Ratio (95% CI)	1.50 (0.89, 2.54)	
	p-value	0.1309	
	Risk Difference (95% CI)	9.64 (-2.81, 22.08)	
	p-value	0.1291	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.33 (0.95, 1.85)	
	p-value	0.0919	
	Odds Ratio (95% CI)	1.58 (0.93, 2.67)	
	p-value	0.0899	
	Risk Difference (95% CI)	10.63 (-1.56, 22.81)	
	p-value	0.0873	
	CMH approach		
	Response rate	42.1	31.8
	Difference in response rates (95% CI)	10.35 (-1.89, 22.60)	
	p-value	0.0974	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 24	Number of subjects with events, n (%)	60 (50.4)	33 (27.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.84 (1.28, 2.63)	
	p-value	0.0009	
	Odds Ratio (95% CI)	2.59 (1.51, 4.45)	
	p-value	0.0005	
	Risk Difference (95% CI)	22.39 (10.16, 34.62)	
	p-value	0.0003	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.85 (1.31, 2.60)	
	p-value	0.0004	
	Odds Ratio (95% CI)	2.71 (1.58, 4.64)	
	p-value	0.0003	
	Risk Difference (95% CI)	23.15 (11.16, 35.13)	
	p-value	0.0002	
	CMH approach		
	Response rate	50.0	27.0
	Difference in response rates (95% CI)	22.99 (10.81, 35.17)	
	p-value	0.0002	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 28	Number of subjects with events, n (%)	55 (46.2)	36 (29.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.54 (1.09, 2.20)	
	p-value	0.0157	
	Odds Ratio (95% CI)	1.96 (1.15, 3.34)	
	p-value	0.0129	
	Risk Difference (95% CI)	15.94 (3.59, 28.29)	
	p-value	0.0114	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.55 (1.11, 2.17)	
	p-value	0.0101	
	Odds Ratio (95% CI)	2.03 (1.19, 3.45)	
	p-value	0.0090	
	Risk Difference (95% CI)	16.47 (4.36, 28.57)	
	p-value	0.0077	
	CMH approach		
	Response rate	45.9	29.6
	Difference in response rates (95% CI)	16.30 (4.03, 28.58)	
	p-value	0.0092	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 32	Number of subjects with events, n (%)	54 (45.4)	34 (28.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.58 (1.09, 2.28)	
	p-value	0.0159	
	Odds Ratio (95% CI)	2.00 (1.16, 3.42)	
	p-value	0.0119	
	Risk Difference (95% CI)	15.88 (3.67, 28.09)	
	p-value	0.0108	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.61 (1.14, 2.28)	
	p-value	0.0067	
	Odds Ratio (95% CI)	2.13 (1.24, 3.63)	
	p-value	0.0058	
	Risk Difference (95% CI)	17.28 (5.27, 29.29)	
	p-value	0.0048	
	CMH approach		
	Response rate	44.3	27.9
	Difference in response rates (95% CI)	16.39 (4.28, 28.51)	
	p-value	0.0080	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 36	Number of subjects with events, n (%)	51 (42.9)	34 (28.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.50 (1.04, 2.18)	
	p-value	0.0313	
	Odds Ratio (95% CI)	1.85 (1.07, 3.18)	
	p-value	0.0265	
	Risk Difference (95% CI)	13.91 (1.77, 26.04)	
	p-value	0.0247	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.53 (1.07, 2.17)	
	p-value	0.0189	
	Odds Ratio (95% CI)	1.92 (1.12, 3.29)	
	p-value	0.0175	
	Risk Difference (95% CI)	14.76 (2.79, 26.72)	
	p-value	0.0156	
	CMH approach		
	Response rate	42.3	28.0
	Difference in response rates (95% CI)	14.28 (2.13, 26.44)	
	p-value	0.0213	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 40	Number of subjects with events, n (%)	46 (38.7)	34 (28.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.33 (0.90, 1.96)	
	p-value	0.1462	
	Odds Ratio (95% CI)	1.51 (0.88, 2.61)	
	p-value	0.1354	
	Risk Difference (95% CI)	9.23 (-2.84, 21.30)	
	p-value	0.1338	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.38 (0.96, 1.98)	
	p-value	0.0859	
	Odds Ratio (95% CI)	1.61 (0.94, 2.77)	
	p-value	0.0838	
	Risk Difference (95% CI)	10.56 (-1.30, 22.42)	
	p-value	0.0811	
	CMH approach		
	Response rate	37.6	28.1
	Difference in response rates (95% CI)	9.49 (-2.52, 21.49)	
	p-value	0.1215	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 44	Number of subjects with events, n (%)	48 (40.3)	41 (33.9)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.15 (0.81, 1.64)	
	p-value	0.4330	
	Odds Ratio (95% CI)	1.24 (0.73, 2.10)	
	p-value	0.4213	
	Risk Difference (95% CI)	5.09 (-7.32, 17.50)	
	p-value	0.4213	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.19 (0.85, 1.66)	
	p-value	0.3023	
	Odds Ratio (95% CI)	1.32 (0.78, 2.23)	
	p-value	0.3013	
	Risk Difference (95% CI)	6.45 (-5.75, 18.65)	
	p-value	0.2999	
	CMH approach		
	Response rate	39.2	33.7
	Difference in response rates (95% CI)	5.55 (-6.71, 17.80)	
	p-value	0.3748	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 48	Number of subjects with events, n (%)	50 (42.0)	41 (33.9)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.20 (0.86, 1.69)	
	p-value	0.2771	
	Odds Ratio (95% CI)	1.35 (0.79, 2.29)	
	p-value	0.2702	
	Risk Difference (95% CI)	6.95 (-5.38, 19.28)	
	p-value	0.2694	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.24 (0.89, 1.72)	
	p-value	0.1964	
	Odds Ratio (95% CI)	1.41 (0.84, 2.39)	
	p-value	0.1948	
	Risk Difference (95% CI)	8.13 (-4.11, 20.37)	
	p-value	0.1928	
	CMH approach		
	Response rate	41.3	34.0
	Difference in response rates (95% CI)	7.29 (-4.98, 19.56)	
	p-value	0.2441	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 52	Number of subjects with events, n (%)	51 (42.9)	37 (30.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.31 (0.93, 1.86)	
	p-value	0.1259	
	Odds Ratio (95% CI)	1.54 (0.90, 2.63)	
	p-value	0.1183	
	Risk Difference (95% CI)	9.74 (-2.45, 21.92)	
	p-value	0.1175	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.40 (1.00, 1.97)	
	p-value	0.0512	
	Odds Ratio (95% CI)	1.70 (1.00, 2.89)	
	p-value	0.0492	
	Risk Difference (95% CI)	12.28 (0.18, 24.38)	
	p-value	0.0467	
	CMH approach		
	Response rate	41.7	31.1
	Difference in response rates (95% CI)	10.62 (-1.60, 22.84)	
	p-value	0.0884	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.5706
< 10 points	22/ 41 (53.7)	52.3	11/ 32 (34.4)	34.5	1.56 (0.89, 2.72)	0.1170	17.81 (-4.81, 40.43)	0.1227	
>= 10 points	29/ 78 (37.2)	36.7	26/ 89 (29.2)	30.0	1.27 (0.83, 1.96)	0.2755	6.71 (-7.82, 21.24)	0.3654	
OCS dose at baseline									0.6349
<10 mg/day	23/ 58 (39.7)	38.9	17/ 65 (26.2)	26.7	1.52 (0.90, 2.54)	0.1148	12.19 (-4.66, 29.03)	0.1562	
>=10 mg/day	28/ 61 (45.9)	45.9	20/ 56 (35.7)	35.7	1.29 (0.82, 2.00)	0.2686	10.19 (-7.58, 27.96)	0.2612	
Result of type I IFN gene signature test									0.6117
LOW	9/ 23 (39.1)	39.1	8/ 24 (33.3)	33.3	1.17 (0.55, 2.51)	0.6798	5.80 (-21.96, 33.56)	0.6823	
HIGH	42/ 96 (43.8)	42.3	29/ 97 (29.9)	30.5	1.46 (1.00, 2.14)	0.0495	11.81 (-1.79, 25.41)	0.0888	
Age (years)									NE
<= 65	51/117 (43.6)	42.4	37/120 (30.8)	31.2	1.41 (1.01, 1.98)	0.0447	11.21 (-1.10, 23.51)	0.0743	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									0.5044
male	6/ 11 (54.5)	54.5	6/ 12 (50.0)	50.0	1.09 (0.50, 2.38)	0.8273	4.55 (-36.31, 45.40)	0.8274	
female	45/108 (41.7)	40.8	31/109 (28.4)	28.7	1.47 (1.01, 2.13)	0.0443	12.04 (-0.73, 24.80)	0.0646	
Race									0.6531
White	30/ 75 (40.0)	39.3	25/ 78 (32.1)	32.3	1.25 (0.82, 1.91)	0.3078	7.00 (-8.36, 22.36)	0.3718	
Black or African American	5/ 11 (45.5)	45.5	7/ 18 (38.9)	38.9	1.17 (0.49, 2.79)	0.7248	6.57 (-30.65, 43.78)	0.7295	
Asian	8/ 17 (47.1)	47.1	3/ 16 (18.8)	18.8	2.51 (0.80, 7.83)	0.1129	28.31 (-3.53, 60.15)	0.0814	
Other	3/ 8 (37.5)	37.5	1/ 6 (16.7)	16.7	2.25 (0.30, 16.63)	0.4269	20.83 (-29.28, 70.95)	0.4152	
Ethnicity									0.4764
Hispanic/Latino	14/ 27 (51.9)	51.9	10/ 32 (31.3)	31.3	1.66 (0.88, 3.11)	0.1149	20.60 (-4.34, 45.54)	0.1055	
Non-hispanic/Latino	32/ 84 (38.1)	37.8	26/ 86 (30.2)	29.9	1.26 (0.83, 1.92)	0.2820	7.88 (-6.48, 22.24)	0.2819	
Geographic region									0.1152
EU	20/ 45 (44.4)	44.4	15/ 33 (45.5)	45.5	0.98 (0.60, 1.61)	0.9293	-1.01 (-23.38, 21.36)	0.9295	
non-EU	31/ 74 (41.9)	41.3	22/ 88 (25.0)	25.1	1.68 (1.07, 2.63)	0.0247	16.28 (1.60, 30.95)	0.0298	
Onset of disease									0.6030
Paediatric	5/ 11 (45.5)	45.5	1/ 5 (20.0)	20.0	2.27 (0.35, 14.73)	0.3892	25.45 (-25.30, 76.21)	0.3257	
Adult	46/108 (42.6)	41.8	36/116 (31.0)	31.3	1.37 (0.97, 1.94)	0.0751	10.50 (-2.17, 23.17)	0.1044	
ADA result									0.4561
Negative	49/115 (42.6)	41.3	35/111 (31.5)	32.2	1.35 (0.96, 1.91)	0.0887	9.08 (-3.51, 21.68)	0.1575	
Positive (At any time)	2/ 4 (50.0)	50.0	2/ 10 (20.0)	20.0	2.50 (0.51, 12.14)	0.2557	30.00 (-26.43, 86.43)	0.2975	
BMI (kg/m2) at enrolment									0.7172
< 30	39/ 85 (45.9)	46.2	28/ 89 (31.5)	31.6	1.46 (0.99, 2.14)	0.0540	14.61 (0.26, 28.97)	0.0460	
>= 30	12/ 34 (35.3)	35.3	9/ 32 (28.1)	28.1	1.25 (0.61, 2.57)	0.5347	7.17 (-15.58, 29.92)	0.5368	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.1524
All negative/normal	14/ 38 (36.8)	36.8	20/ 56 (35.7)	35.1	1.03 (0.60, 1.78)	0.9109	1.68 (-18.56, 21.92)	0.8708	
At least one positive/abnormal	37/ 81 (45.7)	45.7	17/ 65 (26.2)	26.2	1.75 (1.09, 2.80)	0.0207	19.53 (4.17, 34.88)	0.0127	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA - individual components at week 52 (Full analysis set)
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
BILAG improvement [a]	52 (43.7)	38 (31.4)
No discontinuation of IP	101 (84.9)	83 (68.6)
No use of medication beyond protocol allowed threshold	94 (79.0)	84 (69.4)
No worsening of PGA [a]	78 (65.5)	60 (49.6)
No worsening of SLEDAI-2K [a]	78 (65.5)	60 (49.6)

[a] Subjects who discontinued IP or used medications beyond protocol allowed threshold are considered non-responders and not included in this category.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate at week 52 sensitivity analysis, multiple imputation
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 52	Number of subjects with events, n (%)	51 (42.9)	37 (30.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.31 (0.92, 1.85)	
	p-value	0.1354	
	Odds Ratio (95% CI)	1.53 (0.89, 2.63)	
	p-value	0.1276	
	Risk Difference (95% CI)	9.59 (-2.72, 21.90)	
	p-value	0.1269	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.40 (0.99, 1.97)	
	p-value	0.0549	
	Odds Ratio (95% CI)	1.70 (0.99, 2.90)	
	p-value	0.0531	
	Risk Difference (95% CI)	12.20 (-0.03, 24.43)	
	p-value	0.0506	

For each outcome and visit, 100 imputations were generated by randomised treatment group. Each imputed dataset was analysed separately, and the single estimates are combined using PROC MIANALYZE. The estimated number of responders and non-responders are rounded to an integer. Therefore, there might be slight mismatches between number of subjects and corresponding percentage.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Change from baseline in PGA VAS < 0.3 at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 52	Number of subjects with events, n (%)	78 (65.5)	60 (49.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.29 (1.02, 1.63)	
	p-value	0.0322	
	Odds Ratio (95% CI)	1.77 (1.06, 2.96)	
	p-value	0.0294	
	Risk Difference (95% CI)	14.44 (1.66, 27.22)	
	p-value	0.0268	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.32 (1.06, 1.65)	
	p-value	0.0137	
	Odds Ratio (95% CI)	1.93 (1.15, 3.25)	
	p-value	0.0128	
	Risk Difference (95% CI)	15.96 (3.62, 28.30)	
	p-value	0.0112	
	CMH approach		
	Response rate	64.4	49.6
	Difference in response rates (95% CI)	14.76 (2.37, 27.16)	
	p-value	0.0195	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Change from baseline in PGA VAS < 0.3 at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8957
< 10 points	28/ 41 (68.3)	67.0	17/ 32 (53.1)	52.4	1.29 (0.87, 1.89)	0.2029	14.67 (-7.95, 37.28)	0.2036	
>= 10 points	50/ 78 (64.1)	63.5	43/ 89 (48.3)	48.8	1.33 (1.01, 1.74)	0.0413	14.72 (-0.14, 29.58)	0.0522	
OCS dose at baseline									0.7479
<10 mg/day	35/ 58 (60.3)	58.9	31/ 65 (47.7)	47.7	1.27 (0.91, 1.76)	0.1612	11.19 (-6.21, 28.59)	0.2075	
>=10 mg/day	43/ 61 (70.5)	70.5	29/ 56 (51.8)	51.8	1.36 (1.01, 1.84)	0.0442	18.71 (1.23, 36.18)	0.0359	
Result of type I IFN gene signature test									0.3817
LOW	17/ 23 (73.9)	73.9	11/ 24 (45.8)	45.8	1.61 (0.98, 2.65)	0.0601	28.08 (0.76, 55.40)	0.0440	
HIGH	61/ 96 (63.5)	62.1	49/ 97 (50.5)	50.6	1.26 (0.98, 1.61)	0.0704	11.47 (-2.43, 25.37)	0.1058	
Age (years)									0.7581
<= 65	77/117 (65.8)	64.7	60/120 (50.0)	50.0	1.32 (1.05, 1.64)	0.0150	14.75 (2.30, 27.20)	0.0202	
> 65	1/ 2 (50.0)	50.0	0/ 1 (0.0)	0.0	2.00 (0.14, 28.42)	0.6087	50.00 (-68.41, 168.41)	0.4079	
Sex									0.3736
male	9/ 11 (81.8)	81.8	9/ 12 (75.0)	75.0	1.09 (0.71, 1.68)	0.6912	6.82 (-30.20, 43.84)	0.7181	
female	69/108 (63.9)	63.0	51/109 (46.8)	46.9	1.37 (1.07, 1.75)	0.0128	16.09 (3.01, 29.18)	0.0159	
Race									0.5472
White	53/ 75 (70.7)	71.1	40/ 78 (51.3)	51.3	1.38 (1.06, 1.79)	0.0160	19.83 (4.51, 35.15)	0.0112	
Black or African American	5/ 11 (45.5)	45.5	10/ 18 (55.6)	55.6	0.82 (0.38, 1.76)	0.6086	-10.10 (-47.49, 27.29)	0.5965	
Asian	11/ 17 (64.7)	64.7	6/ 16 (37.5)	37.5	1.73 (0.84, 3.56)	0.1394	27.21 (-6.10, 60.51)	0.1094	
Other	4/ 8 (50.0)	50.0	2/ 6 (33.3)	33.3	1.50 (0.40, 5.65)	0.5492	16.67 (-35.65, 68.98)	0.5324	
Ethnicity									0.7237
Hispanic/Latino	17/ 27 (63.0)	63.0	14/ 32 (43.8)	43.8	1.44 (0.88, 2.34)	0.1436	19.21 (-5.97, 44.39)	0.1348	
Non-hispanic/Latino	56/ 84 (66.7)	66.7	44/ 86 (51.2)	51.2	1.30 (1.01, 1.68)	0.0427	15.49 (0.77, 30.22)	0.0392	
Geographic region									0.4275
EU	33/ 45 (73.3)	73.3	21/ 33 (63.6)	63.6	1.15 (0.84, 1.57)	0.3735	9.70 (-11.47, 30.86)	0.3692	
non-EU	45/ 74 (60.8)	60.7	39/ 88 (44.3)	44.5	1.37 (1.02, 1.85)	0.0369	16.22 (0.93, 31.51)	0.0376	
Onset of disease									0.4370
Paediatric	6/ 11 (54.5)	54.5	1/ 5 (20.0)	20.0	2.73 (0.44, 17.07)	0.2837	34.55 (-16.21, 85.30)	0.1822	
Adult	72/108 (66.7)	66.0	59/116 (50.9)	50.8	1.31 (1.05, 1.64)	0.0175	15.13 (2.39, 27.87)	0.0199	
ADA result									0.4026
Negative	76/115 (66.1)	64.7	58/111 (52.3)	52.6	1.26 (1.01, 1.58)	0.0371	12.11 (-0.60, 24.82)	0.0618	
Positive (At any time)	2/ 4 (50.0)	50.0	2/ 10 (20.0)	20.0	2.50 (0.51, 12.14)	0.2557	30.00 (-26.43, 86.43)	0.2975	
BMI (kg/m2) at enrolment									0.6721
< 30	60/ 85 (70.6)	70.6	46/ 89 (51.7)	51.7	1.37 (1.07, 1.74)	0.0120	18.86 (4.50, 33.22)	0.0101	
>= 30	18/ 34 (52.9)	52.9	14/ 32 (43.8)	43.8	1.21 (0.73, 2.00)	0.4590	9.19 (-14.85, 33.23)	0.4537	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.3863
All negative/normal	24/ 38 (63.2)	63.7	30/ 56 (53.6)	53.3	1.18 (0.84, 1.66)	0.3484	10.33 (-10.12, 30.78)	0.3223	
At least one positive/abnormal	54/ 81 (66.7)	66.7	30/ 65 (46.2)	46.2	1.44 (1.07, 1.96)	0.0179	20.51 (4.59, 36.44)	0.0116	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Change from baseline in PGA VAS < 0.45 at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 52	Number of subjects with events, n (%)	78 (65.5)	63 (52.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.23 (0.98, 1.54)	
	p-value	0.0728	
	Odds Ratio (95% CI)	1.62 (0.96, 2.71)	
	p-value	0.0683	
	Risk Difference (95% CI)	11.98 (-0.75, 24.72)	
	p-value	0.0652	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.26 (1.02, 1.56)	
	p-value	0.0358	
	Odds Ratio (95% CI)	1.75 (1.04, 2.95)	
	p-value	0.0346	
	Risk Difference (95% CI)	13.48 (1.15, 25.81)	
	p-value	0.0322	
	CMH approach		
	Response rate	64.4	52.1
	Difference in response rates (95% CI)	12.35 (-0.04, 24.74)	
	p-value	0.0507	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Change from baseline in PGA VAS < 0.45 at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8802
< 10 points	28/ 41 (68.3)	67.0	17/ 32 (53.1)	52.4	1.29 (0.87, 1.89)	0.2029	14.67 (-7.95, 37.28)	0.2036	
>= 10 points	50/ 78 (64.1)	63.5	46/ 89 (51.7)	52.1	1.24 (0.96, 1.61)	0.1054	11.41 (-3.45, 26.27)	0.1324	
OCS dose at baseline									0.6445
<10 mg/day	35/ 58 (60.3)	58.9	33/ 65 (50.8)	50.9	1.19 (0.87, 1.63)	0.2862	8.00 (-9.44, 25.43)	0.3688	
>=10 mg/day	43/ 61 (70.5)	70.5	30/ 56 (53.6)	53.6	1.32 (0.98, 1.76)	0.0663	16.92 (-0.54, 34.38)	0.0575	
Result of type I IFN gene signature test									0.4537
LOW	17/ 23 (73.9)	73.9	12/ 24 (50.0)	50.0	1.48 (0.93, 2.36)	0.1016	23.91 (-3.44, 51.27)	0.0867	
HIGH	61/ 96 (63.5)	62.1	51/ 97 (52.6)	52.6	1.21 (0.95, 1.54)	0.1254	9.49 (-4.40, 23.38)	0.1807	
Age (years)									0.7309
<= 65	77/117 (65.8)	64.7	63/120 (52.5)	52.4	1.25 (1.01, 1.55)	0.0389	12.33 (-0.12, 24.77)	0.0522	
> 65	1/ 2 (50.0)	50.0	0/ 1 (0.0)	0.0	2.00 (0.14, 28.42)	0.6087	50.00 (-68.41, 168.41)	0.4079	
Sex									0.5035
male	9/ 11 (81.8)	81.8	9/ 12 (75.0)	75.0	1.09 (0.71, 1.68)	0.6912	6.82 (-30.20, 43.84)	0.7181	
female	69/108 (63.9)	63.0	54/109 (49.5)	49.6	1.29 (1.02, 1.63)	0.0352	13.41 (0.30, 26.51)	0.0449	
Race									0.5697
White	53/ 75 (70.7)	71.1	43/ 78 (55.1)	54.9	1.28 (1.00, 1.64)	0.0494	16.15 (0.88, 31.42)	0.0382	
Black or African American	5/ 11 (45.5)	45.5	10/ 18 (55.6)	55.6	0.82 (0.38, 1.76)	0.6086	-10.10 (-47.49, 27.29)	0.5965	
Asian	11/ 17 (64.7)	64.7	6/ 16 (37.5)	37.5	1.73 (0.84, 3.56)	0.1394	27.21 (-6.10, 60.51)	0.1094	
Other	4/ 8 (50.0)	50.0	2/ 6 (33.3)	33.3	1.50 (0.40, 5.65)	0.5492	16.67 (-35.65, 68.98)	0.5324	
Ethnicity									0.7822
Hispanic/Latino	17/ 27 (63.0)	63.0	15/ 32 (46.9)	46.9	1.34 (0.84, 2.15)	0.2173	16.09 (-9.15, 41.32)	0.2114	
Non-hispanic/Latino	56/ 84 (66.7)	66.7	46/ 86 (53.5)	53.5	1.25 (0.97, 1.60)	0.0823	13.26 (-1.46, 27.98)	0.0775	
Geographic region									0.4199
EU	33/ 45 (73.3)	73.3	22/ 33 (66.7)	66.7	1.10 (0.82, 1.48)	0.5318	6.67 (-14.30, 27.63)	0.5331	
non-EU	45/ 74 (60.8)	60.7	41/ 88 (46.6)	46.7	1.31 (0.98, 1.74)	0.0708	14.04 (-1.28, 29.36)	0.0726	
Onset of disease									0.9068
Paediatric	6/ 11 (54.5)	54.5	2/ 5 (40.0)	40.0	1.36 (0.41, 4.53)	0.6129	14.55 (-38.05, 67.14)	0.5878	
Adult	72/108 (66.7)	66.0	61/116 (52.6)	52.5	1.27 (1.02, 1.58)	0.0331	13.50 (0.75, 26.24)	0.0379	
ADA result									0.6598
Negative	76/115 (66.1)	64.7	60/111 (54.1)	54.3	1.22 (0.99, 1.52)	0.0679	10.45 (-2.27, 23.16)	0.1073	
Positive (At any time)	2/ 4 (50.0)	50.0	3/ 10 (30.0)	30.0	1.67 (0.43, 6.51)	0.4625	20.00 (-37.30, 77.30)	0.4939	
BMI (kg/m2) at enrolment									0.3863
< 30	60/ 85 (70.6)	70.6	47/ 89 (52.8)	52.8	1.34 (1.05, 1.70)	0.0176	17.77 (3.42, 32.13)	0.0152	
>= 30	18/ 34 (52.9)	52.9	16/ 32 (50.0)	50.0	1.06 (0.66, 1.69)	0.8114	2.94 (-21.18, 27.06)	0.8111	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.4515
All negative/normal	24/ 38 (63.2)	63.7	31/ 56 (55.4)	55.0	1.14 (0.81, 1.60)	0.4447	8.61 (-11.85, 29.08)	0.4093	
At least one positive/abnormal	54/ 81 (66.7)	66.7	32/ 65 (49.2)	49.2	1.35 (1.01, 1.81)	0.0411	17.44 (1.49, 33.38)	0.0321	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Constitutional
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 52	Number of subjects with events, n (%)	1 (0.8)	2 (1.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.83 (0.10, 6.98)	
	p-value	0.8636	
	Odds Ratio (95% CI)	0.83 (0.09, 8.08)	
	p-value	0.8722	
	Risk Difference (95% CI)	-0.24 (-3.18, 2.69)	
	p-value	0.8700	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.51 (0.05, 5.53)	
	p-value	0.5786	
	Odds Ratio (95% CI)	0.50 (0.05, 5.64)	
	p-value	0.5782	
	Risk Difference (95% CI)	-0.81 (-3.61, 1.99)	
	p-value	0.5698	
	CMH approach		
	Response rate	0.9	1.4
	Difference in response rates (95% CI)	-0.56 (-7.44, 6.31)	
	p-value	0.8726	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Constitutional - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-15.48, 15.48)	1.0000	
>= 10 points	1/ 78 (1.3)	1.4	2/ 89 (2.2)	2.0	0.57 (0.05, 6.17)	0.6441	-0.65 (-8.65, 7.36)	0.8739	
OCS dose at baseline									0.2613
<10 mg/day	0/ 58 (0.0)	0.0	2/ 65 (3.1)	2.8	0.22 (0.01, 4.57)	0.3305	-2.79 (-13.07, 7.50)	0.5956	
>=10 mg/day	1/ 61 (1.6)	1.6	0/ 56 (0.0)	0.0	2.76 (0.11, 66.34)	0.5318	1.64 (-5.42, 8.70)	0.6490	
Result of type I IFN gene signature test									0.2190
LOW	1/ 23 (4.3)	4.3	0/ 24 (0.0)	0.0	3.13 (0.13, 73.01)	0.4785	4.35 (-12.12, 20.81)	0.6048	
HIGH	0/ 96 (0.0)	0.0	2/ 97 (2.1)	1.8	0.20 (0.01, 4.15)	0.2999	-1.78 (-9.32, 5.77)	0.6443	
Age (years)									NE
<= 65	1/117 (0.9)	0.9	2/120 (1.7)	1.5	0.51 (0.05, 5.58)	0.5834	-0.57 (-7.53, 6.38)	0.8717	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-27.45, 27.45)	1.0000	
female	1/108 (0.9)	1.0	2/109 (1.8)	1.6	0.50 (0.05, 5.48)	0.5742	-0.65 (-8.17, 6.86)	0.8649	
Race									NE
White	1/ 75 (1.3)	1.5	2/ 78 (2.6)	2.5	0.52 (0.05, 5.62)	0.5901	-1.03 (-9.86, 7.81)	0.8199	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE		0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE		0.00 (-41.13, 41.13)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	1/ 84 (1.2)	1.3	2/ 86 (2.3)	2.3	0.51 (0.05, 5.54)	0.5816	-1.00 (-8.90, 6.91)	0.8051	
Geographic region									0.1544
EU	0/ 45 (0.0)	0.0	2/ 33 (6.1)	6.1	0.15 (0.01, 2.98)	0.2123	-6.06 (-18.13, 6.01)	0.3250	
non-EU	1/ 74 (1.4)	1.4	0/ 88 (0.0)	0.0	3.56 (0.15, 86.11)	0.4347	1.40 (-6.51, 9.31)	0.7290	
Onset of disease									0.3743
Paediatric	0/ 11 (0.0)	0.0	1/ 5 (20.0)	20.0	0.17 (0.01, 3.51)	0.2491	-20.00 (-65.94, 25.94)	0.3936	
Adult	1/108 (0.9)	0.9	1/116 (0.9)	0.8	1.07 (0.07, 16.96)	0.9595	0.17 (-7.01, 7.36)	0.9625	
ADA result									NE
Negative	1/115 (0.9)	0.9	2/111 (1.8)	1.6	0.48 (0.04, 5.25)	0.5496	-0.65 (-7.92, 6.63)	0.8615	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE		0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	1/ 85 (1.2)	1.0	2/ 89 (2.2)	2.2	0.52 (0.05, 5.67)	0.5944	-1.14 (-8.78, 6.50)	0.7694	
>= 30	0/ 34 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-10.92, 10.92)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.8159
All negative/normal	0/ 38 (0.0)	0.0	1/ 56 (1.8)	1.5	0.49 (0.02, 11.65)	0.6571	-1.55 (-14.81, 11.72)	0.8193	
At least one positive/abnormal	1/ 81 (1.2)	1.2	1/ 65 (1.5)	1.5	0.80 (0.05, 12.58)	0.8755	-0.30 (-6.69, 6.08)	0.9256	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Mucocutaneous
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 52	Number of subjects with events, n (%)	34 (28.6)	37 (30.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.97 (0.65, 1.44)	
	p-value	0.8790	
	Odds Ratio (95% CI)	0.96 (0.54, 1.68)	
	p-value	0.8784	
	Risk Difference (95% CI)	-0.91 (-12.53, 10.72)	
	p-value	0.8784	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.93 (0.63, 1.38)	
	p-value	0.7335	
	Odds Ratio (95% CI)	0.91 (0.52, 1.58)	
	p-value	0.7334	
	Risk Difference (95% CI)	-2.01 (-13.55, 9.54)	
	p-value	0.7333	
	CMH approach		
	Response rate	28.3	30.0
	Difference in response rates (95% CI)	-1.68 (-13.49, 10.13)	
	p-value	0.7801	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Mucocutaneous - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.6819
< 10 points	10/ 41 (24.4)	24.5	7/ 32 (21.9)	21.1	1.11 (0.48, 2.60)	0.8014	3.33 (-17.63, 24.29)	0.7552	
>= 10 points	24/ 78 (30.8)	31.1	30/ 89 (33.7)	33.6	0.91 (0.59, 1.42)	0.6861	-2.53 (-16.75, 11.69)	0.7276	
OCS dose at baseline									0.6357
<10 mg/day	16/ 58 (27.6)	27.1	21/ 65 (32.3)	31.9	0.85 (0.49, 1.47)	0.5703	-4.85 (-21.43, 11.73)	0.5661	
>=10 mg/day	18/ 61 (29.5)	29.5	16/ 56 (28.6)	28.6	1.03 (0.59, 1.82)	0.9113	0.94 (-15.74, 17.62)	0.9123	
Result of type I IFN gene signature test									0.5230
LOW	8/ 23 (34.8)	34.8	7/ 24 (29.2)	29.2	1.19 (0.52, 2.76)	0.6804	5.62 (-21.56, 32.79)	0.6855	
HIGH	26/ 96 (27.1)	26.7	30/ 97 (30.9)	30.2	0.88 (0.56, 1.36)	0.5570	-3.49 (-16.59, 9.62)	0.6020	
Age (years)									0.3907
<= 65	33/117 (28.2)	27.9	36/120 (30.0)	29.5	0.94 (0.63, 1.40)	0.7612	-1.55 (-13.40, 10.31)	0.7984	
> 65	1/ 2 (50.0)	50.0	1/ 1 (100.0)	100.0	0.50 (0.13, 2.00)	0.3270	-50.00 (-168.41, 68.41)	0.4079	
Sex									0.8867
male	4/ 11 (36.4)	36.4	5/ 12 (41.7)	41.7	0.87 (0.31, 2.44)	0.7955	-5.30 (-45.63, 35.02)	0.7966	
female	30/108 (27.8)	27.7	32/109 (29.4)	28.9	0.95 (0.62, 1.44)	0.7968	-1.22 (-13.58, 11.15)	0.8470	
Race									0.7794
White	26/ 75 (34.7)	34.9	24/ 78 (30.8)	29.9	1.13 (0.71, 1.78)	0.6077	5.04 (-9.94, 20.01)	0.5097	
Black or African American	2/ 11 (18.2)	18.2	4/ 18 (22.2)	22.2	0.82 (0.18, 3.75)	0.7962	-4.04 (-37.30, 29.22)	0.8118	
Asian	5/ 17 (29.4)	29.4	7/ 16 (43.8)	43.8	0.67 (0.27, 1.69)	0.3988	-14.34 (-47.45, 18.77)	0.3960	
Other	1/ 8 (12.5)	12.5	1/ 6 (16.7)	16.7	0.75 (0.06, 9.72)	0.8258	-4.17 (-51.55, 43.21)	0.8632	
Ethnicity									0.7368
Hispanic/Latino	5/ 27 (18.5)	18.5	7/ 32 (21.9)	21.9	0.85 (0.30, 2.36)	0.7506	-3.36 (-25.12, 18.41)	0.7625	
Non-hispanic/Latino	29/ 84 (34.5)	34.5	29/ 86 (33.7)	33.5	1.02 (0.67, 1.55)	0.9121	1.06 (-13.33, 15.45)	0.8857	
Geographic region									0.6659
EU	12/ 45 (26.7)	26.7	8/ 33 (24.2)	24.2	1.10 (0.51, 2.38)	0.8092	2.42 (-17.67, 22.52)	0.8131	
non-EU	22/ 74 (29.7)	29.1	29/ 88 (33.0)	32.4	0.90 (0.57, 1.43)	0.6608	-3.30 (-17.77, 11.17)	0.6550	
Onset of disease									0.6633
Paediatric	3/ 11 (27.3)	27.3	2/ 5 (40.0)	40.0	0.68 (0.16, 2.89)	0.6030	-12.73 (-64.43, 38.97)	0.6295	
Adult	31/108 (28.7)	28.3	35/116 (30.2)	29.6	0.95 (0.63, 1.43)	0.8097	-1.27 (-13.43, 10.89)	0.8379	
ADA result									0.9080
Negative	33/115 (28.7)	28.5	34/111 (30.6)	30.2	0.94 (0.63, 1.40)	0.7502	-1.66 (-13.91, 10.58)	0.7899	
Positive (At any time)	1/ 4 (25.0)	25.0	3/ 10 (30.0)	30.0	0.83 (0.12, 5.82)	0.8541	-5.00 (-60.97, 50.97)	0.8610	
BMI (kg/m2) at enrolment									0.9699
< 30	23/ 85 (27.1)	26.8	26/ 89 (29.2)	29.0	0.93 (0.58, 1.49)	0.7523	-2.28 (-15.91, 11.35)	0.7429	
>= 30	11/ 34 (32.4)	32.4	11/ 32 (34.4)	34.4	0.94 (0.48, 1.86)	0.8617	-2.02 (-25.07, 21.03)	0.8635	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.9919
All negative/normal	10/ 38 (26.3)	25.4	16/ 56 (28.6)	28.0	0.92 (0.47, 1.81)	0.8110	-2.56 (-21.80, 16.68)	0.7942	
At least one positive/abnormal	24/ 81 (29.6)	29.6	21/ 65 (32.3)	32.3	0.92 (0.56, 1.49)	0.7273	-2.68 (-17.91, 12.55)	0.7304	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Neuropsychiatric
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 52	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	NE	
	p-value		
	Odds Ratio (95% CI)	NE	
	p-value		
	Risk Difference (95% CI)	NE	
	p-value		
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	NE	
	p-value		
	Odds Ratio (95% CI)	NE	
	p-value		
	Risk Difference (95% CI)	NE	
	p-value		
	CMH approach		
	Response rate	0.0	0.0
	Difference in response rates (95% CI)	0.00 (-6.50, 6.50)	
	p-value	1.0000	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Neuropsychiatric - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.48, 15.48)	1.0000	
>= 10 points	0/ 78 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-7.36, 7.36)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 58 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-9.71, 9.71)	1.0000	
>=10 mg/day	0/ 61 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-6.39, 6.39)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	0/ 97 (0.0)	0.0	NE	0.00 (-7.23, 7.23)	1.0000	
Age (years)								NE
<= 65	0/117 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.57, 6.57)	1.0000	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-116.14, 116.14)	1.0000	
Sex								NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	0/109 (0.0)	0.0	NE	0.00 (-7.09, 7.09)	1.0000	
Race								NE
White	0/ 75 (0.0)	0.0	0/ 78 (0.0)	0.0	NE	0.00 (-7.93, 7.93)	1.0000	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE	0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE	0.00 (-41.13, 41.13)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	0/ 86 (0.0)	0.0	NE	0.00 (-7.13, 7.13)	1.0000	
Geographic region								NE
EU	0/ 45 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-9.64, 9.64)	1.0000	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-7.62, 7.62)	1.0000	
Onset of disease								NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
Adult	0/108 (0.0)	0.0	0/116 (0.0)	0.0	NE	0.00 (-6.89, 6.89)	1.0000	
ADA result								NE
Negative	0/115 (0.0)	0.0	0/111 (0.0)	0.0	NE	0.00 (-6.86, 6.86)	1.0000	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE	0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 85 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-6.95, 6.95)	1.0000	
>= 30	0/ 34 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-10.92, 10.92)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	0/ 81 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-5.25, 5.25)	1.0000	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Musculoskeletal
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 52	Number of subjects with events, n (%)	23 (19.3)	21 (17.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.16 (0.67, 2.00)	
	p-value	0.6031	
	Odds Ratio (95% CI)	1.19 (0.62, 2.31)	
	p-value	0.6022	
	Risk Difference (95% CI)	2.65 (-7.29, 12.58)	
	p-value	0.6015	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.11 (0.65, 1.90)	
	p-value	0.6932	
	Odds Ratio (95% CI)	1.14 (0.59, 2.20)	
	p-value	0.6931	
	Risk Difference (95% CI)	1.97 (-7.82, 11.76)	
	p-value	0.6930	
	CMH approach		
	Response rate	19.4	17.1
	Difference in response rates (95% CI)	2.24 (-8.25, 12.73)	
	p-value	0.6755	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Musculoskeletal - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.3787
< 10 points	7/ 41 (17.1)	16.9	7/ 32 (21.9)	20.3	0.78 (0.30, 2.00)	0.6054	-3.40 (-23.32, 16.52)	0.7383	
>= 10 points	16/ 78 (20.5)	20.8	14/ 89 (15.7)	15.5	1.30 (0.68, 2.50)	0.4232	5.26 (-7.29, 17.80)	0.4114	
OCS dose at baseline									0.3059
<10 mg/day	11/ 58 (19.0)	18.8	14/ 65 (21.5)	21.5	0.88 (0.43, 1.78)	0.7239	-2.61 (-17.69, 12.47)	0.7347	
>=10 mg/day	12/ 61 (19.7)	19.7	7/ 56 (12.5)	12.5	1.57 (0.67, 3.71)	0.3006	7.17 (-6.75, 21.10)	0.3127	
Result of type I IFN gene signature test									0.1298
LOW	6/ 23 (26.1)	26.1	2/ 24 (8.3)	8.3	3.13 (0.70, 13.95)	0.1345	17.75 (-5.58, 41.08)	0.1358	
HIGH	17/ 96 (17.7)	17.7	19/ 97 (19.6)	19.3	0.90 (0.50, 1.63)	0.7377	-1.60 (-13.34, 10.15)	0.7900	
Age (years)									NE
<= 65	23/117 (19.7)	19.7	21/120 (17.5)	17.3	1.12 (0.66, 1.92)	0.6695	2.41 (-8.19, 13.01)	0.6558	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									0.4674
male	0/ 11 (0.0)	0.0	1/ 12 (8.3)	8.3	0.36 (0.02, 8.04)	0.5200	-8.33 (-38.19, 21.52)	0.5843	
female	23/108 (21.3)	21.4	20/109 (18.3)	18.1	1.16 (0.68, 1.99)	0.5866	3.29 (-8.02, 14.59)	0.5687	
Race									0.5838
White	17/ 75 (22.7)	23.3	13/ 78 (16.7)	16.6	1.36 (0.71, 2.60)	0.3530	6.79 (-6.86, 20.44)	0.3296	
Black or African American	1/ 11 (9.1)	9.1	4/ 18 (22.2)	22.2	0.41 (0.05, 3.21)	0.3948	-13.13 (-44.47, 18.21)	0.4115	
Asian	3/ 17 (17.6)	17.6	4/ 16 (25.0)	25.0	0.71 (0.19, 2.67)	0.6083	-7.35 (-37.59, 22.88)	0.6336	
Other	1/ 8 (12.5)	12.5	0/ 6 (0.0)	0.0	2.33 (0.11, 48.99)	0.5854	12.50 (-31.37, 56.37)	0.5765	
Ethnicity									0.5091
Hispanic/Latino	4/ 27 (14.8)	14.8	6/ 32 (18.8)	18.8	0.79 (0.25, 2.51)	0.6898	-3.94 (-24.66, 16.79)	0.7098	
Non-hispanic/Latino	18/ 84 (21.4)	21.5	15/ 86 (17.4)	18.5	1.23 (0.66, 2.27)	0.5123	3.06 (-9.37, 15.48)	0.6299	
Geographic region									0.2539
EU	7/ 45 (15.6)	15.6	2/ 33 (6.1)	6.1	2.57 (0.57, 11.57)	0.2199	9.49 (-6.00, 24.99)	0.2299	
non-EU	16/ 74 (21.6)	21.7	19/ 88 (21.6)	22.3	1.00 (0.56, 1.80)	0.9962	-0.62 (-14.09, 12.86)	0.9287	
Onset of disease									0.5713
Paediatric	2/ 11 (18.2)	18.2	0/ 5 (0.0)	0.0	2.50 (0.14, 44.26)	0.5320	18.18 (-26.66, 63.02)	0.4268	
Adult	21/108 (19.4)	19.3	21/116 (18.1)	18.0	1.07 (0.62, 1.85)	0.7972	1.32 (-9.61, 12.26)	0.8125	
ADA result									0.2308
Negative	22/115 (19.1)	19.2	21/111 (18.9)	18.7	1.01 (0.59, 1.73)	0.9677	0.46 (-10.51, 11.43)	0.9345	
Positive (At any time)	1/ 4 (25.0)	25.0	0/ 10 (0.0)	0.0	6.60 (0.32, 135.38)	0.2208	25.00 (-27.17, 77.17)	0.3476	
BMI (kg/m2) at enrolment									0.4312
< 30	16/ 85 (18.8)	18.5	13/ 89 (14.6)	14.4	1.29 (0.66, 2.52)	0.4573	4.11 (-7.63, 15.86)	0.4927	
>= 30	7/ 34 (20.6)	20.6	8/ 32 (25.0)	25.0	0.82 (0.34, 2.01)	0.6697	-4.41 (-25.51, 16.68)	0.6819	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.3551
All negative/normal	9/ 38 (23.7)	24.0	14/ 56 (25.0)	26.0	0.95 (0.46, 1.96)	0.8844	-1.94 (-20.99, 17.11)	0.8420	
At least one positive/abnormal	14/ 81 (17.3)	17.3	7/ 65 (10.8)	10.8	1.60 (0.69, 3.74)	0.2734	6.51 (-5.30, 18.33)	0.2797	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Cardiorespiratory
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 52	Number of subjects with events, n (%)	1 (0.8)	0 (0.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	NE	
	p-value		
	Odds Ratio (95% CI)	NE	
	p-value		
	Risk Difference (95% CI)	0.98 (-0.81, 2.78)	
	p-value	0.2811	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	3.05 (0.13, 74.13)	
	p-value	0.4933	
	Odds Ratio (95% CI)	3.08 (0.12, 76.26)	
	p-value	0.4928	
	Risk Difference (95% CI)	0.84 (-0.80, 2.48)	
	p-value	0.3153	
	CMH approach		
	Response rate	1.0	0.0
	Difference in response rates (95% CI)	0.98 (-5.73, 7.68)	
	p-value	0.7753	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Cardiorespiratory - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-15.48, 15.48)	1.0000	
>= 10 points	1/ 78 (1.3)	1.4	0/ 89 (0.0)	0.0	3.42 (0.14, 82.71)	0.4497	1.40 (-6.32, 9.13)	0.7217	
OCS dose at baseline									NE
<10 mg/day	1/ 58 (1.7)	1.9	0/ 65 (0.0)	0.0	3.36 (0.14, 80.80)	0.4557	1.91 (-8.32, 12.13)	0.7145	
>=10 mg/day	0/ 61 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-6.39, 6.39)	1.0000	
Result of type I IFN gene signature test									NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
HIGH	1/ 96 (1.0)	1.2	0/ 97 (0.0)	0.0	3.03 (0.13, 73.49)	0.4954	1.22 (-6.29, 8.73)	0.7507	
Age (years)									NE
<= 65	1/117 (0.9)	1.0	0/120 (0.0)	0.0	3.08 (0.13, 74.76)	0.4900	0.98 (-5.79, 7.74)	0.7775	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-27.45, 27.45)	1.0000	
female	1/108 (0.9)	1.1	0/109 (0.0)	0.0	3.03 (0.12, 73.51)	0.4961	1.05 (-6.25, 8.35)	0.7779	
Race									NE
White	1/ 75 (1.3)	1.4	0/ 78 (0.0)	0.0	3.12 (0.13, 75.37)	0.4840	1.39 (-6.91, 9.68)	0.7434	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE		0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE		0.00 (-41.13, 41.13)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	1/ 84 (1.2)	1.2	0/ 86 (0.0)	0.0	3.07 (0.13, 74.33)	0.4902	1.24 (-6.23, 8.71)	0.7445	
Geographic region									NE
EU	1/ 45 (2.2)	2.2	0/ 33 (0.0)	0.0	2.22 (0.09, 52.78)	0.6224	2.22 (-8.20, 12.64)	0.6760	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE		0.00 (-7.62, 7.62)	1.0000	
Onset of disease									NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
Adult	1/108 (0.9)	1.0	0/116 (0.0)	0.0	3.22 (0.13, 78.21)	0.4724	1.03 (-6.07, 8.14)	0.7755	
ADA result									NE
Negative	1/115 (0.9)	1.0	0/111 (0.0)	0.0	2.90 (0.12, 70.36)	0.5135	1.01 (-6.06, 8.08)	0.7785	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE		0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	1/ 85 (1.2)	1.2	0/ 89 (0.0)	0.0	3.14 (0.13, 76.02)	0.4817	1.22 (-6.06, 8.50)	0.7429	
>= 30	0/ 34 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-10.92, 10.92)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	1/ 81 (1.2)	1.2	0/ 65 (0.0)	0.0	2.41 (0.10, 58.31)	0.5874	1.23 (-4.49, 6.96)	0.6726	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Gastrointestinal
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 52	Number of subjects with events, n (%)	0 (0.0)	1 (0.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.00 (NE, NE)	
	p-value	NE	
	Odds Ratio (95% CI)	0.00 (NE, NE)	
	p-value	NE	
	Risk Difference (95% CI)	-0.85 (-2.51, 0.81)	
	p-value	0.3136	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.34 (0.01, 8.24)	
	p-value	0.5062	
	Odds Ratio (95% CI)	0.34 (0.01, 8.33)	
	p-value	0.5057	
	Risk Difference (95% CI)	-0.83 (-2.44, 0.79)	
	p-value	0.3153	
	CMH approach		
	Response rate	0.0	0.8
	Difference in response rates (95% CI)	-0.84 (-7.46, 5.77)	
	p-value	0.8024	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Gastrointestinal - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 41 (0.0)	0.0	1/ 32 (3.1)	2.8	0.26 (0.01, 6.22)	0.4072	-2.81 (-18.81, 13.19)	0.7307	
>= 10 points	0/ 78 (0.0)	0.0	0/ 89 (0.0)	0.0	NE		0.00 (-7.36, 7.36)	1.0000	
OCS dose at baseline									NE
<10 mg/day	0/ 58 (0.0)	0.0	1/ 65 (1.5)	1.7	0.37 (0.02, 8.98)	0.5433	-1.65 (-11.65, 8.35)	0.7463	
>=10 mg/day	0/ 61 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-6.39, 6.39)	1.0000	
Result of type I IFN gene signature test									NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	1/ 97 (1.0)	1.1	0.34 (0.01, 8.17)	0.5035	-1.05 (-8.44, 6.33)	0.7799	
Age (years)									NE
<= 65	0/117 (0.0)	0.0	1/120 (0.8)	0.9	0.34 (0.01, 8.31)	0.5096	-0.85 (-7.54, 5.83)	0.8022	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	1/109 (0.9)	0.9	0.34 (0.01, 8.17)	0.5032	-0.89 (-8.10, 6.31)	0.8078	
Race									NE
White	0/ 75 (0.0)	0.0	0/ 78 (0.0)	0.0	NE		0.00 (-7.93, 7.93)	1.0000	
Black or African American	0/ 11 (0.0)	0.0	1/ 18 (5.6)	5.6	0.53 (0.02, 11.93)	0.6879	-5.56 (-31.15, 20.04)	0.6705	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE		0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE		0.00 (-41.13, 41.13)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	1/ 86 (1.2)	1.4	0.34 (0.01, 8.26)	0.5084	-1.35 (-8.76, 6.06)	0.7204	
Geographic region									NE
EU	0/ 45 (0.0)	0.0	0/ 33 (0.0)	0.0	NE		0.00 (-9.64, 9.64)	1.0000	
non-EU	0/ 74 (0.0)	0.0	1/ 88 (1.1)	1.4	0.40 (0.02, 9.57)	0.5683	-1.40 (-9.31, 6.51)	0.7290	
Onset of disease									NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
Adult	0/108 (0.0)	0.0	1/116 (0.9)	0.9	0.36 (0.01, 8.69)	0.5277	-0.90 (-7.92, 6.11)	0.8012	
ADA result									NE
Negative	0/115 (0.0)	0.0	1/111 (0.9)	0.9	0.32 (0.01, 7.82)	0.4861	-0.90 (-7.88, 6.09)	0.8009	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE		0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/ 85 (0.0)	0.0	1/ 89 (1.1)	1.1	0.35 (0.01, 8.45)	0.5172	-1.12 (-8.30, 6.05)	0.7587	
>= 30	0/ 34 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-10.92, 10.92)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									NE
All negative/normal	0/ 38 (0.0)	0.0	1/ 56 (1.8)	2.3	0.49 (0.02, 11.65)	0.6571	-2.34 (-15.79, 11.11)	0.7327	
At least one positive/abnormal	0/ 81 (0.0)	0.0	0/ 65 (0.0)	0.0	NE		0.00 (-5.25, 5.25)	1.0000	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Ophthalmic
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 52	Number of subjects with events, n (%)	0 (0.0)	1 (0.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.00 (NE, NE)	
	p-value	NE	
	Odds Ratio (95% CI)	0.00 (NE, NE)	
	p-value	NE	
	Risk Difference (95% CI)	-0.72 (-2.24, 0.81)	
	p-value	0.3553	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.34 (0.01, 8.24)	
	p-value	0.5062	
	Odds Ratio (95% CI)	0.34 (0.01, 8.33)	
	p-value	0.5057	
	Risk Difference (95% CI)	-0.83 (-2.44, 0.79)	
	p-value	0.3153	
	CMH approach		
	Response rate	0.0	0.7
	Difference in response rates (95% CI)	-0.71 (-7.33, 5.91)	
	p-value	0.8329	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Ophthalmic - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-15.48, 15.48)	1.0000	
>= 10 points	0/ 78 (0.0)	0.0	1/ 89 (1.1)	1.0	0.38 (0.02, 9.19)	0.5514	-1.02 (-8.60, 6.55)	0.7909	
OCS dose at baseline									NE
<10 mg/day	0/ 58 (0.0)	0.0	1/ 65 (1.5)	1.4	0.37 (0.02, 8.98)	0.5433	-1.39 (-11.40, 8.62)	0.7851	
>=10 mg/day	0/ 61 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-6.39, 6.39)	1.0000	
Result of type I IFN gene signature test									NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	1/ 97 (1.0)	0.9	0.34 (0.01, 8.17)	0.5035	-0.89 (-8.28, 6.50)	0.8138	
Age (years)									NE
<= 65	0/117 (0.0)	0.0	1/120 (0.8)	0.7	0.34 (0.01, 8.31)	0.5096	-0.73 (-7.42, 5.96)	0.8302	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	1/109 (0.9)	0.8	0.34 (0.01, 8.17)	0.5032	-0.81 (-8.04, 6.41)	0.8254	
Race									NE
White	0/ 75 (0.0)	0.0	1/ 78 (1.3)	1.3	0.35 (0.01, 8.37)	0.5143	-1.27 (-9.51, 6.98)	0.7635	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE		0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE		0.00 (-41.13, 41.13)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	1/ 86 (1.2)	1.1	0.34 (0.01, 8.26)	0.5084	-1.13 (-8.54, 6.29)	0.7658	
Geographic region									NE
EU	0/ 45 (0.0)	0.0	1/ 33 (3.0)	3.0	0.25 (0.01, 5.86)	0.3864	-3.03 (-13.99, 7.93)	0.5879	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE		0.00 (-7.62, 7.62)	1.0000	
Onset of disease									NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
Adult	0/108 (0.0)	0.0	1/116 (0.9)	0.8	0.36 (0.01, 8.69)	0.5277	-0.77 (-7.79, 6.25)	0.8302	
ADA result									NE
Negative	0/115 (0.0)	0.0	1/111 (0.9)	0.8	0.32 (0.01, 7.82)	0.4861	-0.78 (-7.78, 6.21)	0.8265	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE		0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/ 85 (0.0)	0.0	1/ 89 (1.1)	1.1	0.35 (0.01, 8.45)	0.5172	-1.09 (-8.31, 6.13)	0.7677	
>= 30	0/ 34 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-10.92, 10.92)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	0/ 81 (0.0)	0.0	1/ 65 (1.5)	1.5	0.27 (0.01, 6.48)	0.4180	-1.54 (-7.49, 4.42)	0.6127	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Renal
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 52	Number of subjects with events, n (%)	4 (3.4)	7 (5.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.60 (0.18, 2.00)	
	p-value	0.4093	
	Odds Ratio (95% CI)	0.58 (0.16, 2.10)	
	p-value	0.4056	
	Risk Difference (95% CI)	-2.26 (-7.49, 2.98)	
	p-value	0.3988	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.58 (0.17, 1.93)	
	p-value	0.3760	
	Odds Ratio (95% CI)	0.57 (0.16, 1.99)	
	p-value	0.3749	
	Risk Difference (95% CI)	-2.42 (-7.70, 2.85)	
	p-value	0.3675	
	CMH approach		
	Response rate	3.4	5.6
	Difference in response rates (95% CI)	-2.24 (-10.22, 5.75)	
	p-value	0.5830	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Renal - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-15.48, 15.48)	1.0000	
>= 10 points	4/ 78 (5.1)	4.9	7/ 89 (7.9)	8.1	0.65 (0.20, 2.14)	0.4813	-3.22 (-13.14, 6.71)	0.5255	
OCS dose at baseline									0.6530
<10 mg/day	1/ 58 (1.7)	1.9	3/ 65 (4.6)	4.2	0.37 (0.04, 3.49)	0.3879	-2.27 (-13.28, 8.74)	0.6862	
>=10 mg/day	3/ 61 (4.9)	4.9	4/ 56 (7.1)	7.1	0.69 (0.16, 2.94)	0.6145	-2.22 (-12.54, 8.09)	0.6726	
Result of type I IFN gene signature test									NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
HIGH	4/ 96 (4.2)	4.3	7/ 97 (7.2)	7.0	0.58 (0.17, 1.91)	0.3679	-2.79 (-12.04, 6.46)	0.5547	
Age (years)									NE
<= 65	4/117 (3.4)	3.5	7/120 (5.8)	5.7	0.59 (0.18, 1.95)	0.3836	-2.23 (-10.29, 5.83)	0.5876	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									0.4209
male	0/ 11 (0.0)	0.0	2/ 12 (16.7)	16.7	0.22 (0.01, 4.07)	0.3068	-16.67 (-48.35, 15.02)	0.3025	
female	4/108 (3.7)	3.7	5/109 (4.6)	4.8	0.81 (0.22, 2.93)	0.7447	-1.07 (-9.57, 7.43)	0.8056	
Race									0.2429
White	1/ 75 (1.3)	1.4	4/ 78 (5.1)	5.1	0.26 (0.03, 2.27)	0.2234	-3.68 (-13.05, 5.70)	0.4421	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	2/ 16 (12.5)	12.5	0.19 (0.01, 3.66)	0.2703	-12.50 (-36.56, 11.56)	0.3085	
Other	3/ 8 (37.5)	37.5	1/ 6 (16.7)	16.7	2.25 (0.30, 16.63)	0.4269	20.83 (-29.28, 70.95)	0.4152	
Ethnicity									0.2566
Hispanic/Latino	3/ 27 (11.1)	11.1	3/ 32 (9.4)	9.4	1.19 (0.26, 5.40)	0.8262	1.74 (-16.60, 20.07)	0.8527	
Non-hispanic/Latino	1/ 84 (1.2)	1.2	4/ 86 (4.7)	4.5	0.26 (0.03, 2.24)	0.2185	-3.26 (-11.72, 5.19)	0.4489	
Geographic region									0.5004
EU	0/ 45 (0.0)	0.0	1/ 33 (3.0)	3.0	0.25 (0.01, 5.86)	0.3864	-3.03 (-13.99, 7.93)	0.5879	
non-EU	4/ 74 (5.4)	5.8	6/ 88 (6.8)	6.4	0.79 (0.23, 2.70)	0.7107	-0.56 (-10.65, 9.53)	0.9135	
Onset of disease									0.4942
Paediatric	2/ 11 (18.2)	18.2	1/ 5 (20.0)	20.0	0.91 (0.11, 7.84)	0.9309	-1.82 (-50.71, 47.07)	0.9419	
Adult	2/108 (1.9)	1.8	6/116 (5.2)	5.0	0.36 (0.07, 1.74)	0.2022	-3.14 (-11.14, 4.86)	0.4418	
ADA result									0.7242
Negative	4/115 (3.5)	3.4	5/111 (4.5)	4.3	0.77 (0.21, 2.80)	0.6941	-0.89 (-9.04, 7.26)	0.8304	
Positive (At any time)	0/ 4 (0.0)	0.0	2/ 10 (20.0)	20.0	0.44 (0.03, 7.58)	0.5719	-20.00 (-70.84, 30.84)	0.4407	
BMI (kg/m2) at enrolment									0.1287
< 30	3/ 85 (3.5)	3.7	2/ 89 (2.2)	2.2	1.57 (0.27, 9.17)	0.6160	1.48 (-6.87, 9.83)	0.7282	
>= 30	1/ 34 (2.9)	2.9	5/ 32 (15.6)	15.6	0.19 (0.02, 1.53)	0.1177	-12.68 (-29.12, 3.75)	0.1304	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.7613
All negative/normal	1/ 38 (2.6)	3.0	2/ 56 (3.6)	3.1	0.74 (0.07, 7.84)	0.8002	-0.12 (-14.28, 14.04)	0.9869	
At least one positive/abnormal	3/ 81 (3.7)	3.7	5/ 65 (7.7)	7.7	0.48 (0.12, 1.94)	0.3040	-3.99 (-12.94, 4.96)	0.3825	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Haematological
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 52	Number of subjects with events, n (%)	1 (0.8)	0 (0.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	NE	
	p-value		
	Odds Ratio (95% CI)	NE	
	p-value		
	Risk Difference (95% CI)	0.85 (-0.82, 2.52)	
	p-value	0.3168	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	3.05 (0.13, 74.13)	
	p-value	0.4933	
	Odds Ratio (95% CI)	3.08 (0.12, 76.26)	
	p-value	0.4928	
	Risk Difference (95% CI)	0.84 (-0.80, 2.48)	
	p-value	0.3153	
	CMH approach		
	Response rate	0.8	0.0
	Difference in response rates (95% CI)	0.84 (-5.77, 7.46)	
	p-value	0.8024	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Haematological - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	1/ 41 (2.4)	2.8	0/ 32 (0.0)	0.0	2.36 (0.10, 56.00)	0.5958	2.81 (-13.19, 18.81)	0.7307	
>= 10 points	0/ 78 (0.0)	0.0	0/ 89 (0.0)	0.0	NE		0.00 (-7.36, 7.36)	1.0000	
OCS dose at baseline									NE
<10 mg/day	1/ 58 (1.7)	1.7	0/ 65 (0.0)	0.0	3.36 (0.14, 80.80)	0.4557	1.65 (-8.35, 11.65)	0.7463	
>=10 mg/day	0/ 61 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-6.39, 6.39)	1.0000	
Result of type I IFN gene signature test									NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
HIGH	1/ 96 (1.0)	1.1	0/ 97 (0.0)	0.0	3.03 (0.13, 73.49)	0.4954	1.05 (-6.33, 8.44)	0.7799	
Age (years)									NE
<= 65	1/117 (0.9)	0.9	0/120 (0.0)	0.0	3.08 (0.13, 74.76)	0.4900	0.85 (-5.83, 7.54)	0.8022	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-27.45, 27.45)	1.0000	
female	1/108 (0.9)	1.0	0/109 (0.0)	0.0	3.03 (0.12, 73.51)	0.4961	0.97 (-6.25, 8.19)	0.7926	
Race									NE
White	0/ 75 (0.0)	0.0	0/ 78 (0.0)	0.0	NE		0.00 (-7.93, 7.93)	1.0000	
Black or African American	1/ 11 (9.1)	9.1	0/ 18 (0.0)	0.0	4.75 (0.21, 107.35)	0.3274	9.09 (-18.02, 36.20)	0.5111	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE		0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE		0.00 (-41.13, 41.13)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	1/ 84 (1.2)	1.0	0/ 86 (0.0)	0.0	3.07 (0.13, 74.33)	0.4902	1.01 (-6.29, 8.32)	0.7855	
Geographic region									NE
EU	0/ 45 (0.0)	0.0	0/ 33 (0.0)	0.0	NE		0.00 (-9.64, 9.64)	1.0000	
non-EU	1/ 74 (1.4)	1.1	0/ 88 (0.0)	0.0	3.56 (0.15, 86.11)	0.4347	1.12 (-6.71, 8.94)	0.7794	
Onset of disease									NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
Adult	1/108 (0.9)	0.9	0/116 (0.0)	0.0	3.22 (0.13, 78.21)	0.4724	0.90 (-6.11, 7.92)	0.8012	
ADA result									NE
Negative	1/115 (0.9)	0.9	0/111 (0.0)	0.0	2.90 (0.12, 70.36)	0.5135	0.90 (-6.09, 7.88)	0.8009	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE		0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/ 85 (0.0)	0.0	0/ 89 (0.0)	0.0	NE		0.00 (-6.95, 6.95)	1.0000	
>= 30	1/ 34 (2.9)	2.9	0/ 32 (0.0)	0.0	2.83 (0.12, 67.01)	0.5197	2.94 (-9.11, 14.99)	0.6323	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									NE
All negative/normal	1/ 38 (2.6)	2.2	0/ 56 (0.0)	0.0	4.38 (0.18, 104.87)	0.3615	2.18 (-11.23, 15.58)	0.7503	
At least one positive/abnormal	0/ 81 (0.0)	0.0	0/ 65 (0.0)	0.0	NE		0.00 (-5.25, 5.25)	1.0000	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Major clinical response at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 52	Number of subjects with events, n (%)	25 (21.0)	10 (8.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	2.38 (1.20, 4.73)	
	p-value	0.0132	
	Odds Ratio (95% CI)	2.84 (1.27, 6.34)	
	p-value	0.0110	
	Risk Difference (95% CI)	11.78 (3.04, 20.52)	
	p-value	0.0083	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	2.54 (1.28, 5.06)	
	p-value	0.0079	
	Odds Ratio (95% CI)	2.95 (1.35, 6.46)	
	p-value	0.0067	
	Risk Difference (95% CI)	12.74 (3.93, 21.56)	
	p-value	0.0046	
	CMH approach		
	Response rate	20.8	8.3
	Difference in response rates (95% CI)	12.53 (2.72, 22.34)	
	p-value	0.0123	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Major clinical response at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.6655
< 10 points	13/ 41 (31.7)	31.0	5/ 32 (15.6)	15.1	2.03 (0.81, 5.10)	0.1325	15.93 (-4.95, 36.81)	0.1347	
>= 10 points	12/ 78 (15.4)	15.9	5/ 89 (5.6)	5.6	2.74 (1.01, 7.43)	0.0479	10.30 (-0.73, 21.33)	0.0672	
OCS dose at baseline									0.7495
<10 mg/day	15/ 58 (25.9)	25.8	7/ 65 (10.8)	10.9	2.40 (1.05, 5.48)	0.0373	14.88 (-0.03, 29.80)	0.0505	
>=10 mg/day	10/ 61 (16.4)	16.4	3/ 56 (5.4)	5.4	3.06 (0.89, 10.56)	0.0767	11.04 (-1.10, 23.17)	0.0746	
Result of type I IFN gene signature test									0.4517
LOW	5/ 23 (21.7)	21.7	1/ 24 (4.2)	4.2	5.22 (0.66, 41.32)	0.1177	17.57 (-4.20, 39.34)	0.1136	
HIGH	20/ 96 (20.8)	20.6	9/ 97 (9.3)	9.3	2.25 (1.08, 4.68)	0.0309	11.28 (0.29, 22.27)	0.0442	
Age (years)									NE
<= 65	25/117 (21.4)	21.1	10/120 (8.3)	8.4	2.56 (1.29, 5.10)	0.0073	12.74 (2.83, 22.65)	0.0118	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									0.8899
male	2/ 11 (18.2)	18.2	1/ 12 (8.3)	8.3	2.18 (0.23, 20.84)	0.4980	9.85 (-24.37, 44.06)	0.5726	
female	23/108 (21.3)	21.1	9/109 (8.3)	8.1	2.58 (1.25, 5.32)	0.0102	12.96 (2.65, 23.26)	0.0137	
Race									0.8688
White	14/ 75 (18.7)	18.3	5/ 78 (6.4)	6.9	2.91 (1.10, 7.69)	0.0309	11.37 (-0.59, 23.32)	0.0624	
Black or African American	3/ 11 (27.3)	27.3	2/ 18 (11.1)	11.1	2.45 (0.48, 12.46)	0.2786	16.16 (-16.91, 49.23)	0.3381	
Asian	3/ 17 (17.6)	17.6	2/ 16 (12.5)	12.5	1.41 (0.27, 7.38)	0.6828	5.15 (-23.03, 33.33)	0.7203	
Other	2/ 8 (25.0)	25.0	1/ 6 (16.7)	16.7	1.50 (0.17, 12.94)	0.7122	8.33 (-40.77, 57.44)	0.7394	
Ethnicity									0.5690
Hispanic/Latino	8/ 27 (29.6)	29.6	3/ 32 (9.4)	9.4	3.16 (0.93, 10.75)	0.0654	20.25 (-1.06, 41.57)	0.0626	
Non-hispanic/Latino	14/ 84 (16.7)	16.5	7/ 86 (8.1)	8.6	2.05 (0.87, 4.82)	0.1008	7.96 (-3.23, 19.15)	0.1634	
Geographic region									0.7798
EU	9/ 45 (20.0)	20.0	3/ 33 (9.1)	9.1	2.20 (0.64, 7.50)	0.2079	10.91 (-5.96, 27.78)	0.2051	
non-EU	16/ 74 (21.6)	21.7	7/ 88 (8.0)	8.2	2.72 (1.18, 6.25)	0.0186	13.53 (1.26, 25.81)	0.0306	
Onset of disease									0.7894
Paediatric	3/ 11 (27.3)	27.3	0/ 5 (0.0)	0.0	3.50 (0.21, 57.35)	0.3799	27.27 (-18.60, 73.14)	0.2439	
Adult	22/108 (20.4)	20.4	10/116 (8.6)	8.7	2.36 (1.17, 4.76)	0.0161	11.70 (1.43, 21.96)	0.0255	
ADA result									0.2844
Negative	23/115 (20.0)	20.1	10/111 (9.0)	9.0	2.22 (1.11, 4.45)	0.0245	11.03 (0.84, 21.22)	0.0339	
Positive (At any time)	2/ 4 (50.0)	50.0	0/ 10 (0.0)	0.0	11.00 (0.64, 189.48)	0.0987	50.00 (-3.58, 103.58)	0.0674	
BMI (kg/m2) at enrolment									0.9046
< 30	20/ 85 (23.5)	23.6	8/ 89 (9.0)	9.0	2.62 (1.22, 5.62)	0.0136	14.58 (2.89, 26.27)	0.0145	
>= 30	5/ 34 (14.7)	14.7	2/ 32 (6.3)	6.3	2.35 (0.49, 11.28)	0.2846	8.46 (-8.53, 25.44)	0.3291	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.7211
All negative/normal	8/ 38 (21.1)	20.9	4/ 56 (7.1)	7.9	2.95 (0.95, 9.10)	0.0602	12.95 (-4.35, 30.24)	0.1424	
At least one positive/abnormal	17/ 81 (21.0)	21.0	6/ 65 (9.2)	9.2	2.27 (0.95, 5.44)	0.0647	11.76 (-0.20, 23.71)	0.0539	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Partial clinical response at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 52	Number of subjects with events, n (%)	58 (48.7)	46 (38.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.29 (0.95, 1.75)	
	p-value	0.0996	
	Odds Ratio (95% CI)	1.56 (0.93, 2.62)	
	p-value	0.0939	
	Risk Difference (95% CI)	10.89 (-1.74, 23.51)	
	p-value	0.0910	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.28 (0.96, 1.72)	
	p-value	0.0962	
	Odds Ratio (95% CI)	1.55 (0.93, 2.59)	
	p-value	0.0944	
	Risk Difference (95% CI)	10.72 (-1.75, 23.19)	
	p-value	0.0919	
	CMH approach		
	Response rate	48.4	37.9
	Difference in response rates (95% CI)	10.53 (-1.98, 23.05)	
	p-value	0.0990	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Partial clinical response at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8518
< 10 points	22/ 41 (53.7)	53.6	13/ 32 (40.6)	40.1	1.32 (0.80, 2.19)	0.2814	13.49 (-9.49, 36.48)	0.2500	
>= 10 points	36/ 78 (46.2)	46.3	33/ 89 (37.1)	36.7	1.24 (0.87, 1.79)	0.2353	9.58 (-5.38, 24.54)	0.2093	
OCS dose at baseline									0.7535
<10 mg/day	30/ 58 (51.7)	51.0	25/ 65 (38.5)	38.8	1.34 (0.91, 2.00)	0.1420	12.15 (-5.41, 29.71)	0.1752	
>=10 mg/day	28/ 61 (45.9)	45.9	21/ 56 (37.5)	37.5	1.22 (0.79, 1.89)	0.3615	8.40 (-9.45, 26.25)	0.3563	
Result of type I IFN gene signature test									0.4195
LOW	12/ 23 (52.2)	52.2	12/ 24 (50.0)	50.0	1.04 (0.60, 1.83)	0.8815	2.17 (-26.41, 30.76)	0.8815	
HIGH	46/ 96 (47.9)	47.5	34/ 97 (35.1)	34.9	1.37 (0.97, 1.92)	0.0731	12.60 (-1.32, 26.52)	0.0760	
Age (years)									0.7393
<= 65	57/117 (48.7)	48.4	46/120 (38.3)	38.1	1.27 (0.95, 1.70)	0.1092	10.26 (-2.34, 22.86)	0.1106	
> 65	1/ 2 (50.0)	50.0	0/ 1 (0.0)	0.0	2.00 (0.14, 28.42)	0.6087	50.00 (-68.41, 168.41)	0.4079	
Sex									0.9782
male	7/ 11 (63.6)	63.6	6/ 12 (50.0)	50.0	1.27 (0.62, 2.62)	0.5120	13.64 (-26.84, 54.11)	0.5091	
female	51/108 (47.2)	47.1	40/109 (36.7)	36.4	1.29 (0.94, 1.77)	0.1191	10.73 (-2.34, 23.79)	0.1077	
Race									0.2974
White	35/ 75 (46.7)	46.7	35/ 78 (44.9)	44.2	1.04 (0.74, 1.47)	0.8237	2.46 (-13.37, 18.30)	0.7604	
Black or African American	5/ 11 (45.5)	45.5	3/ 18 (16.7)	16.7	2.73 (0.81, 9.23)	0.1067	28.79 (-6.48, 64.06)	0.1097	
Asian	8/ 17 (47.1)	47.1	4/ 16 (25.0)	25.0	1.88 (0.70, 5.05)	0.2092	22.06 (-10.62, 54.74)	0.1858	
Other	5/ 8 (62.5)	62.5	2/ 6 (33.3)	33.3	1.88 (0.54, 6.56)	0.3253	29.17 (-22.83, 81.16)	0.2716	
Ethnicity									0.5881
Hispanic/Latino	16/ 27 (59.3)	59.3	13/ 32 (40.6)	40.6	1.46 (0.86, 2.46)	0.1569	18.63 (-6.63, 43.90)	0.1483	
Non-hispanic/Latino	37/ 84 (44.0)	43.8	31/ 86 (36.0)	36.2	1.22 (0.84, 1.77)	0.2891	7.63 (-7.09, 22.36)	0.3095	
Geographic region									0.1810
EU	24/ 45 (53.3)	53.3	18/ 33 (54.5)	54.5	0.98 (0.65, 1.48)	0.9153	-1.21 (-23.61, 21.19)	0.9155	
non-EU	34/ 74 (45.9)	46.0	28/ 88 (31.8)	31.9	1.44 (0.97, 2.14)	0.0670	14.09 (-1.03, 29.22)	0.0678	
Onset of disease									0.2268
Paediatric	6/ 11 (54.5)	54.5	0/ 5 (0.0)	0.0	6.50 (0.43, 97.14)	0.1749	54.55 (7.67, 101.42)	0.0226	
Adult	52/108 (48.1)	48.1	46/116 (39.7)	39.5	1.21 (0.90, 1.64)	0.2016	8.52 (-4.47, 21.51)	0.1984	
ADA result									0.6919
Negative	56/115 (48.7)	48.4	43/111 (38.7)	38.5	1.26 (0.93, 1.70)	0.1349	9.92 (-3.01, 22.85)	0.1328	
Positive (At any time)	2/ 4 (50.0)	50.0	3/ 10 (30.0)	30.0	1.67 (0.43, 6.51)	0.4625	20.00 (-37.30, 77.30)	0.4939	
BMI (kg/m2) at enrolment									0.4982
< 30	43/ 85 (50.6)	50.6	33/ 89 (37.1)	37.5	1.36 (0.97, 1.92)	0.0755	13.05 (-1.55, 27.66)	0.0798	
>= 30	15/ 34 (44.1)	44.1	13/ 32 (40.6)	40.6	1.09 (0.62, 1.91)	0.7746	3.49 (-20.41, 27.39)	0.7745	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.6891
All negative/normal	20/ 38 (52.6)	52.9	24/ 56 (42.9)	42.6	1.23 (0.80, 1.88)	0.3458	10.27 (-10.45, 31.00)	0.3313	
At least one positive/abnormal	38/ 81 (46.9)	46.9	22/ 65 (33.8)	33.8	1.39 (0.92, 2.09)	0.1198	13.07 (-2.81, 28.95)	0.1068	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=50% Joint reduction at week 52 (for subjects with at least 6 tender joints and swollen joints at baseline)
Full analysis set

Timepoint		Anifrolumab 300mg (N=43)	Placebo (N=59)
Week 52	Number of subjects with events, n (%)	16 (37.2)	21 (35.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.98 (0.58, 1.66)	
	p-value	0.9542	
	Odds Ratio (95% CI)	0.98 (0.42, 2.26)	
	p-value	0.9540	
	Risk Difference (95% CI)	-0.56 (-19.55, 18.43)	
	p-value	0.9540	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.05 (0.62, 1.76)	
	p-value	0.8666	
	Odds Ratio (95% CI)	1.07 (0.47, 2.43)	
	p-value	0.8669	
	Risk Difference (95% CI)	1.62 (-17.30, 20.54)	
	p-value	0.8670	
	CMH approach		
	Response rate	37.3	35.9
	Difference in response rates (95% CI)	1.39 (-17.78, 20.55)	
	p-value	0.8873	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=50% Joint reduction at week 52 (for subjects with at least 6 tender joints and swollen joints at baseline) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=43) n/ N (%)	Response rate	Placebo (N=59) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.4929
< 10 points	6/ 16 (37.5)	37.5	7/ 15 (46.7)	46.7	0.80 (0.35, 1.85)	0.6066	-9.17 (-44.02, 25.69)	0.6062	
>= 10 points	10/ 27 (37.0)	37.0	14/ 44 (31.8)	31.8	1.16 (0.60, 2.24)	0.6495	5.22 (-17.84, 28.27)	0.6573	
OCS dose at baseline									0.6670
<10 mg/day	6/ 22 (27.3)	27.3	9/ 30 (30.0)	30.0	0.91 (0.38, 2.18)	0.8308	-2.73 (-28.27, 22.81)	0.8342	
>=10 mg/day	10/ 21 (47.6)	47.6	12/ 29 (41.4)	41.4	1.15 (0.62, 2.15)	0.6589	6.24 (-21.69, 34.17)	0.6615	
Result of type I IFN gene signature test									0.3415
LOW	4/ 9 (44.4)	44.4	3/ 12 (25.0)	25.0	1.78 (0.52, 6.04)	0.3562	19.44 (-22.37, 61.26)	0.3621	
HIGH	12/ 34 (35.3)	35.4	18/ 47 (38.3)	38.8	0.92 (0.51, 1.65)	0.7833	-3.35 (-24.91, 18.21)	0.7605	
Age (years)									NE
<= 65	16/ 43 (37.2)	37.3	21/ 58 (36.2)	36.5	1.03 (0.61, 1.72)	0.9176	0.81 (-18.43, 20.06)	0.9340	
> 65	0		0/ 1 (0.0)		NE		NE		
Sex									0.4512
male	0/ 1 (0.0)	0.0	3/ 5 (60.0)	60.0	0.43 (0.04, 5.19)	0.5055	-60.00 (-165.43, 45.43)	0.2647	
female	16/ 42 (38.1)	38.3	18/ 54 (33.3)	34.0	1.14 (0.67, 1.96)	0.6275	4.26 (-15.33, 23.84)	0.6702	
Race									0.7111
White	11/ 30 (36.7)	36.7	17/ 42 (40.5)	40.5	0.91 (0.50, 1.64)	0.7453	-3.81 (-26.70, 19.08)	0.7443	
Black or African American	1/ 3 (33.3)	33.3	3/ 9 (33.3)	33.3	1.00 (0.16, 6.35)	1.0000	0.00 (-64.39, 64.39)	1.0000	
Asian	1/ 3 (33.3)	33.3	0/ 4 (0.0)	0.0	3.75 (0.20, 69.40)	0.3747	33.33 (-36.93, 103.59)	0.3524	
Other	0/ 3 (0.0)	0.0	1/ 3 (33.3)	33.3	0.33 (0.02, 5.97)	0.4554	-33.33 (-109.16, 42.49)	0.3889	
Ethnicity									0.7166
Hispanic/Latino	3/ 11 (27.3)	27.3	3/ 13 (23.1)	23.1	1.18 (0.30, 4.72)	0.8130	4.20 (-33.08, 41.47)	0.8254	
Non-hispanic/Latino	10/ 28 (35.7)	35.7	18/ 45 (40.0)	40.0	0.89 (0.48, 1.65)	0.7168	-4.29 (-27.26, 18.69)	0.7146	
Geographic region									0.7041
EU	9/ 14 (64.3)	64.3	9/ 15 (60.0)	60.0	1.07 (0.61, 1.89)	0.8120	4.29 (-31.44, 40.01)	0.8141	
non-EU	7/ 29 (24.1)	24.1	12/ 44 (27.3)	27.3	0.89 (0.40, 1.98)	0.7664	-3.13 (-24.18, 17.92)	0.7704	
Onset of disease									0.4425
Paediatric	1/ 2 (50.0)	50.0	0/ 2 (0.0)	0.0	3.00 (0.19, 47.96)	0.4373	50.00 (-45.24, 145.24)	0.3035	
Adult	15/ 41 (36.6)	36.6	21/ 57 (36.8)	37.1	0.99 (0.59, 1.68)	0.9793	-0.45 (-20.05, 19.14)	0.9637	
ADA result									0.8726
Negative	16/ 42 (38.1)	38.1	20/ 55 (36.4)	36.5	1.05 (0.62, 1.76)	0.8609	1.66 (-17.98, 21.29)	0.8686	
Positive (At any time)	0/ 1 (0.0)	0.0	1/ 4 (25.0)	25.0	0.83 (0.05, 13.02)	0.8966	-25.00 (-132.10, 82.10)	0.6473	
BMI (kg/m2) at enrolment									0.5026
< 30	12/ 31 (38.7)	38.7	15/ 45 (33.3)	33.3	1.16 (0.63, 2.13)	0.6285	5.38 (-16.78, 27.53)	0.6343	
>= 30	4/ 12 (33.3)	33.3	6/ 14 (42.9)	42.9	0.78 (0.29, 2.12)	0.6234	-9.52 (-47.31, 28.26)	0.6213	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.6172
All negative/normal	6/ 17 (35.3)	35.3	12/ 31 (38.7)	38.7	0.91 (0.42, 1.99)	0.8168	-3.42 (-32.23, 25.40)	0.8163	
At least one positive/abnormal	10/ 26 (38.5)	38.5	9/ 28 (32.1)	32.1	1.20 (0.58, 2.47)	0.6277	6.32 (-19.45, 32.09)	0.6308	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=50% Joint reduction at week 52 (for subjects with at least 8 tender joints and swollen joints at baseline)
Full analysis set

Timepoint		Anifrolumab 300mg (N=24)	Placebo (N=47)
Week 52	Number of subjects with events, n (%)	7 (29.2)	14 (29.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.83 (0.37, 1.83)	
	p-value	0.6361	
	Odds Ratio (95% CI)	0.75 (0.23, 2.44)	
	p-value	0.6269	
	Risk Difference (95% CI)	-5.66 (-27.94, 16.61)	
	p-value	0.6183	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.98 (0.46, 2.10)	
	p-value	0.9568	
	Odds Ratio (95% CI)	0.97 (0.33, 2.86)	
	p-value	0.9568	
	Risk Difference (95% CI)	-0.62 (-23.02, 21.78)	
	p-value	0.9567	
	CMH approach		
	Response rate	29.2	29.8
	Difference in response rates (95% CI)	-0.62 (-23.54, 22.29)	
	p-value	0.9577	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=50% Joint reduction at week 52 (for subjects with at least 8 tender joints and swollen joints at baseline) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=24) n/ N (%)	Response rate	Placebo (N=47) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9716
< 10 points	4/ 11 (36.4)	36.4	5/ 12 (41.7)	41.7	0.87 (0.31, 2.44)	0.7955	-5.30 (-45.63, 35.02)	0.7966	
>= 10 points	3/ 13 (23.1)	23.1	9/ 35 (25.7)	25.7	0.90 (0.29, 2.81)	0.8525	-2.64 (-31.55, 26.27)	0.8581	
OCS dose at baseline									0.8147
<10 mg/day	2/ 11 (18.2)	18.2	5/ 23 (21.7)	21.7	0.84 (0.19, 3.65)	0.8122	-3.56 (-35.24, 28.12)	0.8258	
>=10 mg/day	5/ 13 (38.5)	38.5	9/ 24 (37.5)	37.5	1.03 (0.43, 2.42)	0.9540	0.96 (-32.17, 34.09)	0.9546	
Result of type I IFN gene signature test									0.3609
LOW	2/ 7 (28.6)	28.6	1/ 9 (11.1)	11.1	2.57 (0.29, 22.93)	0.3975	17.46 (-27.57, 62.49)	0.4473	
HIGH	5/ 17 (29.4)	29.4	13/ 38 (34.2)	34.2	0.86 (0.36, 2.03)	0.7300	-4.80 (-31.90, 22.30)	0.7285	
Age (years)									NE
<= 65	7/ 24 (29.2)	29.2	14/ 46 (30.4)	30.4	0.96 (0.45, 2.05)	0.9128	-1.27 (-24.31, 21.77)	0.9141	
> 65	0		0/ 1 (0.0)		NE		NE		
Sex									0.3093
male	0/ 1 (0.0)	0.0	2/ 2 (100.0)	100.0	0.30 (0.03, 3.49)	0.3361	-100.00 (-216.14, 16.14)	0.0915	
female	7/ 23 (30.4)	30.4	12/ 45 (26.7)	26.7	1.14 (0.52, 2.50)	0.7415	3.77 (-19.59, 27.12)	0.7518	
Race									0.6201
White	5/ 17 (29.4)	29.4	12/ 35 (34.3)	34.3	0.86 (0.36, 2.04)	0.7290	-4.87 (-32.35, 22.60)	0.7280	
Black or African American	0/ 1 (0.0)	0.0	2/ 6 (33.3)	33.3	0.70 (0.05, 9.41)	0.7879	-33.33 (-137.04, 70.38)	0.5287	
Asian	1/ 3 (33.3)	33.3	0/ 4 (0.0)	0.0	3.75 (0.20, 69.40)	0.3747	33.33 (-36.93, 103.59)	0.3524	
Other	0/ 2 (0.0)	0.0	0/ 2 (0.0)	0.0	NE		0.00 (-92.39, 92.39)	1.0000	
Ethnicity									0.4108
Hispanic/Latino	3/ 9 (33.3)	33.3	2/ 9 (22.2)	22.2	1.50 (0.32, 6.94)	0.6040	11.11 (-32.70, 54.92)	0.6191	
Non-hispanic/Latino	3/ 14 (21.4)	21.4	12/ 38 (31.6)	31.6	0.68 (0.22, 2.05)	0.4923	-10.15 (-37.99, 17.69)	0.4749	
Geographic region									0.7101
EU	3/ 4 (75.0)	75.0	7/ 12 (58.3)	58.3	1.29 (0.61, 2.70)	0.5061	16.67 (-38.46, 71.79)	0.5535	
non-EU	4/ 20 (20.0)	20.0	7/ 35 (20.0)	20.0	1.00 (0.33, 3.00)	1.0000	0.00 (-23.56, 23.56)	1.0000	
Onset of disease									NE
Paediatric	0		0/ 2 (0.0)		NE		NE		
Adult	7/ 24 (29.2)	29.2	14/ 45 (31.1)	31.1	0.94 (0.44, 2.00)	0.8678	-1.94 (-25.11, 21.23)	0.8694	
ADA result									NE
Negative	7/ 24 (29.2)	29.2	13/ 44 (29.5)	29.5	0.99 (0.46, 2.14)	0.9739	-0.38 (-23.55, 22.79)	0.9744	
Positive (At any time)	0		1/ 3 (33.3)		NE		NE		
BMI (kg/m2) at enrolment									0.3501
< 30	6/ 17 (35.3)	35.3	11/ 38 (28.9)	28.9	1.22 (0.54, 2.75)	0.6331	6.35 (-21.02, 33.71)	0.6494	
>= 30	1/ 7 (14.3)	14.3	3/ 9 (33.3)	33.3	0.43 (0.06, 3.28)	0.4148	-19.05 (-64.86, 26.76)	0.4151	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.9570
All negative/normal	4/ 12 (33.3)	33.3	8/ 24 (33.3)	33.3	1.00 (0.38, 2.66)	1.0000	0.00 (-33.43, 33.43)	1.0000	
At least one positive/abnormal	3/ 12 (25.0)	25.0	6/ 23 (26.1)	26.1	0.96 (0.29, 3.17)	0.9445	-1.09 (-33.27, 31.10)	0.9472	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Low Disease Activity State at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 52	Number of subjects with events, n (%)	26 (21.8)	16 (13.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.58 (0.88, 2.84)	
	p-value	0.1228	
	Odds Ratio (95% CI)	1.75 (0.87, 3.54)	
	p-value	0.1173	
	Risk Difference (95% CI)	7.73 (-1.81, 17.27)	
	p-value	0.1122	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.65 (0.94, 2.92)	
	p-value	0.0837	
	Odds Ratio (95% CI)	1.83 (0.93, 3.63)	
	p-value	0.0813	
	Risk Difference (95% CI)	8.63 (-0.94, 18.19)	
	p-value	0.0772	
	CMH approach		
	Response rate	21.5	13.2
	Difference in response rates (95% CI)	8.26 (-2.05, 18.58)	
	p-value	0.1163	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Low Disease Activity State at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.2283
< 10 points	11/ 41 (26.8)	26.7	8/ 32 (25.0)	24.7	1.07 (0.49, 2.35)	0.8600	1.98 (-19.30, 23.25)	0.8555	
>= 10 points	15/ 78 (19.2)	18.9	8/ 89 (9.0)	8.7	2.14 (0.96, 4.77)	0.0632	10.24 (-1.38, 21.86)	0.0841	
OCS dose at baseline									0.6006
<10 mg/day	13/ 58 (22.4)	21.6	10/ 65 (15.4)	16.3	1.46 (0.69, 3.07)	0.3219	5.26 (-9.62, 20.14)	0.4887	
>=10 mg/day	13/ 61 (21.3)	21.3	6/ 56 (10.7)	10.7	1.99 (0.81, 4.88)	0.1328	10.60 (-3.23, 24.42)	0.1329	
Result of type I IFN gene signature test									0.1275
LOW	6/ 23 (26.1)	26.1	7/ 24 (29.2)	29.2	0.89 (0.35, 2.26)	0.8138	-3.08 (-29.49, 23.33)	0.8192	
HIGH	20/ 96 (20.8)	20.4	9/ 97 (9.3)	9.3	2.25 (1.08, 4.68)	0.0309	11.07 (-0.01, 22.15)	0.0503	
Age (years)									0.8729
<= 65	25/117 (21.4)	21.0	16/120 (13.3)	13.3	1.60 (0.90, 2.84)	0.1070	7.75 (-2.61, 18.11)	0.1424	
> 65	1/ 2 (50.0)	50.0	0/ 1 (0.0)	0.0	2.00 (0.14, 28.42)	0.6087	50.00 (-68.41, 168.41)	0.4079	
Sex									0.3175
male	4/ 11 (36.4)	36.4	1/ 12 (8.3)	8.3	4.36 (0.57, 33.32)	0.1555	28.03 (-8.38, 64.44)	0.1313	
female	22/108 (20.4)	20.5	15/109 (13.8)	13.6	1.48 (0.81, 2.70)	0.2001	6.91 (-4.02, 17.83)	0.2153	
Race									0.7732
White	15/ 75 (20.0)	19.8	8/ 78 (10.3)	9.9	1.95 (0.88, 4.33)	0.1007	9.90 (-2.47, 22.27)	0.1169	
Black or African American	3/ 11 (27.3)	27.3	5/ 18 (27.8)	27.8	0.98 (0.29, 3.32)	0.9765	-0.51 (-35.71, 34.69)	0.9776	
Asian	5/ 17 (29.4)	29.4	2/ 16 (12.5)	12.5	2.35 (0.53, 10.45)	0.2607	16.91 (-12.86, 46.68)	0.2655	
Other	1/ 8 (12.5)	12.5	0/ 6 (0.0)	0.0	2.33 (0.11, 48.99)	0.5854	12.50 (-31.37, 56.37)	0.5765	
Ethnicity									0.6929
Hispanic/Latino	6/ 27 (22.2)	22.2	5/ 32 (15.6)	15.6	1.42 (0.49, 4.15)	0.5191	6.60 (-14.86, 28.06)	0.5468	
Non-hispanic/Latino	18/ 84 (21.4)	21.5	10/ 86 (11.6)	11.4	1.84 (0.90, 3.76)	0.0925	10.10 (-1.81, 22.00)	0.0964	
Geographic region									0.7879
EU	10/ 45 (22.2)	22.2	5/ 33 (15.2)	15.2	1.47 (0.55, 3.89)	0.4414	7.07 (-11.27, 25.41)	0.4499	
non-EU	16/ 74 (21.6)	21.3	11/ 88 (12.5)	13.0	1.73 (0.86, 3.49)	0.1264	8.33 (-4.14, 20.80)	0.1903	
Onset of disease									0.7689
Paediatric	2/ 11 (18.2)	18.2	0/ 5 (0.0)	0.0	2.50 (0.14, 44.26)	0.5320	18.18 (-26.66, 63.02)	0.4268	
Adult	24/108 (22.2)	21.9	16/116 (13.8)	13.9	1.61 (0.91, 2.87)	0.1045	8.02 (-2.79, 18.83)	0.1458	
ADA result									0.5992
Negative	26/115 (22.6)	22.1	15/111 (13.5)	13.2	1.67 (0.94, 2.99)	0.0818	8.96 (-1.74, 19.66)	0.1008	
Positive (At any time)	0/ 4 (0.0)	0.0	1/ 10 (10.0)	10.0	0.73 (0.04, 15.04)	0.8405	-10.00 (-59.47, 39.47)	0.6920	
BMI (kg/m2) at enrolment									0.7825
< 30	18/ 85 (21.2)	21.2	12/ 89 (13.5)	13.9	1.57 (0.81, 3.06)	0.1848	7.30 (-4.70, 19.31)	0.2330	
>= 30	8/ 34 (23.5)	23.5	4/ 32 (12.5)	12.5	1.88 (0.63, 5.65)	0.2592	11.03 (-8.61, 30.67)	0.2711	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.0502
All negative/normal	8/ 38 (21.1)	21.4	12/ 56 (21.4)	21.2	0.98 (0.44, 2.17)	0.9652	0.19 (-17.84, 18.23)	0.9831	
At least one positive/abnormal	18/ 81 (22.2)	22.2	4/ 65 (6.2)	6.2	3.61 (1.29, 10.15)	0.0148	16.07 (4.57, 27.57)	0.0062	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Mental Component Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 52	Number of subjects with events, n (%)	30 (25.2)	27 (22.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.08 (0.66, 1.77)	
	p-value	0.7702	
	Odds Ratio (95% CI)	1.10 (0.60, 2.00)	
	p-value	0.7631	
	Risk Difference (95% CI)	1.67 (-9.19, 12.53)	
	p-value	0.7633	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.13 (0.72, 1.78)	
	p-value	0.5985	
	Odds Ratio (95% CI)	1.17 (0.65, 2.13)	
	p-value	0.5983	
	Risk Difference (95% CI)	2.90 (-7.87, 13.66)	
	p-value	0.5980	
	CMH approach		
	Response rate	23.7	22.0
	Difference in response rates (95% CI)	1.75 (-9.20, 12.71)	
	p-value	0.7535	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Mental Component Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.0240
< 10 points	16/ 41 (39.0)	38.6	5/ 32 (15.6)	15.7	2.50 (1.02, 6.09)	0.0442	22.82 (1.54, 44.09)	0.0356	
>= 10 points	14/ 78 (17.9)	17.0	22/ 89 (24.7)	24.2	0.73 (0.40, 1.32)	0.2935	-7.17 (-19.96, 5.62)	0.2720	
OCS dose at baseline									0.1324
<10 mg/day	11/ 58 (19.0)	18.1	16/ 65 (24.6)	24.4	0.77 (0.39, 1.52)	0.4531	-6.36 (-21.47, 8.75)	0.4094	
>=10 mg/day	19/ 61 (31.1)	31.1	11/ 56 (19.6)	19.6	1.59 (0.83, 3.03)	0.1632	11.50 (-4.44, 27.45)	0.1572	
Result of type I IFN gene signature test									0.3516
LOW	4/ 23 (17.4)	17.4	6/ 24 (25.0)	25.0	0.70 (0.23, 2.15)	0.5285	-7.61 (-32.41, 17.20)	0.5477	
HIGH	26/ 96 (27.1)	25.3	21/ 97 (21.6)	21.2	1.25 (0.76, 2.06)	0.3810	4.07 (-8.14, 16.28)	0.5134	
Age (years)									0.6643
<= 65	29/117 (24.8)	23.3	27/120 (22.5)	22.2	1.10 (0.70, 1.74)	0.6789	1.13 (-9.86, 12.12)	0.8402	
> 65	1/ 2 (50.0)	50.0	0/ 1 (0.0)	0.0	2.00 (0.14, 28.42)	0.6087	50.00 (-68.41, 168.41)	0.4079	
Sex									0.9571
male	3/ 11 (27.3)	27.3	3/ 12 (25.0)	25.0	1.09 (0.28, 4.32)	0.9013	2.27 (-35.99, 40.53)	0.9073	
female	27/108 (25.0)	23.7	24/109 (22.0)	21.9	1.14 (0.70, 1.84)	0.6049	1.76 (-9.84, 13.36)	0.7659	
Race									0.7956
White	19/ 75 (25.3)	24.3	21/ 78 (26.9)	26.7	0.94 (0.55, 1.60)	0.8231	-2.39 (-16.68, 11.90)	0.7432	
Black or African American	3/ 11 (27.3)	27.3	4/ 18 (22.2)	22.2	1.23 (0.34, 4.48)	0.7567	5.05 (-29.58, 39.68)	0.7750	
Asian	4/ 17 (23.5)	23.5	2/ 16 (12.5)	12.5	1.88 (0.40, 8.90)	0.4250	11.03 (-18.04, 40.10)	0.4572	
Other	1/ 8 (12.5)	12.5	0/ 6 (0.0)	0.0	2.33 (0.11, 48.99)	0.5854	12.50 (-31.37, 56.37)	0.5765	
Ethnicity									0.3309
Hispanic/Latino	9/ 27 (33.3)	33.3	7/ 32 (21.9)	21.9	1.52 (0.65, 3.55)	0.3283	11.46 (-12.01, 34.93)	0.3386	
Non-hispanic/Latino	18/ 84 (21.4)	20.8	20/ 86 (23.3)	22.9	0.92 (0.53, 1.62)	0.7751	-2.14 (-15.10, 10.82)	0.7462	
Geographic region									0.7383
EU	11/ 45 (24.4)	24.4	8/ 33 (24.2)	24.2	1.01 (0.46, 2.23)	0.9836	0.20 (-19.70, 20.10)	0.9841	
non-EU	19/ 74 (25.7)	24.1	19/ 88 (21.6)	21.8	1.19 (0.68, 2.07)	0.5411	2.35 (-10.98, 15.68)	0.7298	
Onset of disease									0.4141
Paediatric	3/ 11 (27.3)	27.3	0/ 5 (0.0)	0.0	3.50 (0.21, 57.35)	0.3799	27.27 (-18.60, 73.14)	0.2439	
Adult	27/108 (25.0)	23.8	27/116 (23.3)	23.0	1.07 (0.67, 1.71)	0.7631	0.85 (-10.58, 12.28)	0.8840	
ADA result									0.9201
Negative	29/115 (25.2)	23.5	25/111 (22.5)	22.2	1.12 (0.70, 1.79)	0.6353	1.31 (-10.01, 12.62)	0.8211	
Positive (At any time)	1/ 4 (25.0)	25.0	2/ 10 (20.0)	20.0	1.25 (0.15, 10.23)	0.8352	5.00 (-50.09, 60.09)	0.8588	
BMI (kg/m2) at enrolment									0.6224
< 30	22/ 85 (25.9)	26.3	19/ 89 (21.3)	21.3	1.21 (0.71, 2.07)	0.4822	4.94 (-7.98, 17.85)	0.4536	
>= 30	8/ 34 (23.5)	23.5	8/ 32 (25.0)	25.0	0.94 (0.40, 2.21)	0.8892	-1.47 (-22.92, 19.98)	0.8931	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.0325
All negative/normal	14/ 38 (36.8)	34.9	10/ 56 (17.9)	16.9	2.06 (1.03, 4.15)	0.0423	17.99 (-0.75, 36.72)	0.0599	
At least one positive/abnormal	16/ 81 (19.8)	19.8	17/ 65 (26.2)	26.2	0.76 (0.41, 1.38)	0.3589	-6.40 (-20.44, 7.64)	0.3715	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Physical Component Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 52	Number of subjects with events, n (%)	33 (27.7)	30 (24.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.07 (0.70, 1.63)	
	p-value	0.7607	
	Odds Ratio (95% CI)	1.09 (0.61, 1.96)	
	p-value	0.7613	
	Risk Difference (95% CI)	1.74 (-9.48, 12.96)	
	p-value	0.7613	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.12 (0.73, 1.71)	
	p-value	0.6054	
	Odds Ratio (95% CI)	1.16 (0.65, 2.07)	
	p-value	0.6052	
	Risk Difference (95% CI)	2.94 (-8.19, 14.07)	
	p-value	0.6050	
	CMH approach		
	Response rate	27.6	25.3
	Difference in response rates (95% CI)	2.34 (-9.24, 13.92)	
	p-value	0.6917	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Physical Component Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.6077
< 10 points	12/ 41 (29.3)	29.1	7/ 32 (21.9)	22.2	1.34 (0.60, 3.01)	0.4808	6.95 (-14.43, 28.32)	0.5242	
>= 10 points	21/ 78 (26.9)	26.6	23/ 89 (25.8)	26.9	1.04 (0.63, 1.73)	0.8743	-0.26 (-14.12, 13.60)	0.9706	
OCS dose at baseline									0.2158
<10 mg/day	16/ 58 (27.6)	26.9	12/ 65 (18.5)	18.9	1.49 (0.77, 2.89)	0.2326	8.05 (-7.65, 23.74)	0.3150	
>=10 mg/day	17/ 61 (27.9)	27.9	18/ 56 (32.1)	32.1	0.87 (0.50, 1.51)	0.6142	-4.27 (-21.09, 12.54)	0.6183	
Result of type I IFN gene signature test									0.5895
LOW	8/ 23 (34.8)	34.8	6/ 24 (25.0)	25.0	1.39 (0.57, 3.39)	0.4674	9.78 (-16.98, 36.54)	0.4737	
HIGH	25/ 96 (26.0)	25.8	24/ 97 (24.7)	25.3	1.05 (0.65, 1.71)	0.8357	0.50 (-12.33, 13.34)	0.9388	
Age (years)									0.6600
<= 65	32/117 (27.4)	27.3	30/120 (25.0)	25.4	1.09 (0.71, 1.68)	0.6808	1.89 (-9.76, 13.53)	0.7507	
> 65	1/ 2 (50.0)	50.0	0/ 1 (0.0)	0.0	2.00 (0.14, 28.42)	0.6087	50.00 (-68.41, 168.41)	0.4079	
Sex									0.1664
male	2/ 11 (18.2)	18.2	5/ 12 (41.7)	41.7	0.44 (0.11, 1.81)	0.2528	-23.48 (-61.83, 14.87)	0.2300	
female	31/108 (28.7)	28.6	25/109 (22.9)	23.2	1.25 (0.79, 1.97)	0.3336	5.37 (-6.82, 17.57)	0.3877	
Race									0.7571
White	22/ 75 (29.3)	30.5	23/ 78 (29.5)	29.1	0.99 (0.61, 1.63)	0.9833	1.44 (-13.49, 16.36)	0.8505	
Black or African American	3/ 11 (27.3)	27.3	4/ 18 (22.2)	22.2	1.23 (0.34, 4.48)	0.7567	5.05 (-29.58, 39.68)	0.7750	
Asian	2/ 17 (11.8)	11.8	1/ 16 (6.3)	6.3	1.88 (0.19, 18.80)	0.5901	5.51 (-20.07, 31.10)	0.6727	
Other	1/ 8 (12.5)	12.5	2/ 6 (33.3)	33.3	0.38 (0.04, 3.23)	0.3722	-20.83 (-70.20, 28.53)	0.4082	
Ethnicity									0.6390
Hispanic/Latino	8/ 27 (29.6)	29.6	11/ 32 (34.4)	34.4	0.86 (0.41, 1.83)	0.6990	-4.75 (-28.99, 19.50)	0.7013	
Non-hispanic/Latino	20/ 84 (23.8)	24.2	19/ 86 (22.1)	22.0	1.08 (0.62, 1.87)	0.7902	2.20 (-11.10, 15.49)	0.7459	
Geographic region									0.3126
EU	16/ 45 (35.6)	35.6	8/ 33 (24.2)	24.2	1.47 (0.71, 3.01)	0.2972	11.31 (-9.37, 32.00)	0.2838	
non-EU	17/ 74 (23.0)	23.0	22/ 88 (25.0)	24.6	0.92 (0.53, 1.60)	0.7641	-1.57 (-15.24, 12.11)	0.8224	
Onset of disease									0.4969
Paediatric	3/ 11 (27.3)	27.3	2/ 5 (40.0)	40.0	0.68 (0.16, 2.89)	0.6030	-12.73 (-64.43, 38.97)	0.6295	
Adult	30/108 (27.8)	27.8	28/116 (24.1)	24.3	1.15 (0.74, 1.79)	0.5347	3.49 (-8.47, 15.46)	0.5674	
ADA result									0.7554
Negative	32/115 (27.8)	27.6	27/111 (24.3)	25.0	1.14 (0.74, 1.78)	0.5498	2.62 (-9.28, 14.52)	0.6658	
Positive (At any time)	1/ 4 (25.0)	25.0	3/ 10 (30.0)	30.0	0.83 (0.12, 5.82)	0.8541	-5.00 (-60.97, 50.97)	0.8610	
BMI (kg/m2) at enrolment									0.6149
< 30	24/ 85 (28.2)	28.2	21/ 89 (23.6)	23.3	1.20 (0.72, 1.98)	0.4856	4.86 (-8.57, 18.29)	0.4784	
>= 30	9/ 34 (26.5)	26.5	9/ 32 (28.1)	28.1	0.94 (0.43, 2.07)	0.8801	-1.65 (-23.72, 20.42)	0.8832	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.0517
All negative/normal	8/ 38 (21.1)	21.4	18/ 56 (32.1)	31.1	0.65 (0.32, 1.35)	0.2519	-9.71 (-28.36, 8.94)	0.3073	
At least one positive/abnormal	25/ 81 (30.9)	30.9	12/ 65 (18.5)	18.5	1.67 (0.91, 3.06)	0.0965	12.40 (-1.68, 26.49)	0.0844	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - General Health Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 52	Number of subjects with events, n (%)	18 (15.1)	7 (5.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	2.96 (1.16, 7.56)	
	p-value	0.0236	
	Odds Ratio (95% CI)	3.22 (1.23, 8.44)	
	p-value	0.0175	
	Risk Difference (95% CI)	9.68 (2.11, 17.24)	
	p-value	0.0122	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	2.61 (1.13, 6.03)	
	p-value	0.0242	
	Odds Ratio (95% CI)	2.90 (1.16, 7.23)	
	p-value	0.0222	
	Risk Difference (95% CI)	9.34 (1.68, 17.01)	
	p-value	0.0169	
	CMH approach		
	Response rate	15.0	5.5
	Difference in response rates (95% CI)	9.47 (0.21, 18.73)	
	p-value	0.0449	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - General Health Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.2133
< 10 points	7/ 41 (17.1)	16.5	0/ 32 (0.0)	0.0	11.79 (0.70, 198.95)	0.0871	16.52 (-1.15, 34.18)	0.0669	
>= 10 points	11/ 78 (14.1)	14.0	7/ 89 (7.9)	7.7	1.79 (0.73, 4.40)	0.2023	6.37 (-4.69, 17.43)	0.2592	
OCS dose at baseline									0.5708
<10 mg/day	9/ 58 (15.5)	15.3	3/ 65 (4.6)	4.2	3.36 (0.96, 11.83)	0.0588	11.11 (-1.96, 24.18)	0.0958	
>=10 mg/day	9/ 61 (14.8)	14.8	4/ 56 (7.1)	7.1	2.07 (0.67, 6.33)	0.2045	7.61 (-4.65, 19.87)	0.2236	
Result of type I IFN gene signature test									0.7505
LOW	4/ 23 (17.4)	17.4	2/ 24 (8.3)	8.3	2.09 (0.42, 10.32)	0.3669	9.06 (-12.96, 31.07)	0.4200	
HIGH	14/ 96 (14.6)	14.4	5/ 97 (5.2)	4.9	2.83 (1.06, 7.55)	0.0378	9.57 (-0.61, 19.75)	0.0654	
Age (years)									0.8772
<= 65	17/117 (14.5)	14.4	7/120 (5.8)	5.6	2.49 (1.07, 5.78)	0.0338	8.81 (-0.47, 18.08)	0.0627	
> 65	1/ 2 (50.0)	50.0	0/ 1 (0.0)	0.0	2.00 (0.14, 28.42)	0.6087	50.00 (-68.41, 168.41)	0.4079	
Sex									0.4991
male	1/ 11 (9.1)	9.1	1/ 12 (8.3)	8.3	1.09 (0.08, 15.41)	0.9487	0.76 (-31.59, 33.11)	0.9634	
female	17/108 (15.7)	15.6	6/109 (5.5)	5.4	2.86 (1.17, 6.98)	0.0209	10.27 (0.40, 20.15)	0.0415	
Race									0.9272
White	12/ 75 (16.0)	16.3	6/ 78 (7.7)	7.4	2.08 (0.82, 5.26)	0.1216	8.95 (-3.00, 20.89)	0.1421	
Black or African American	1/ 11 (9.1)	9.1	1/ 18 (5.6)	5.6	1.64 (0.11, 23.59)	0.7176	3.54 (-24.93, 32.00)	0.8077	
Asian	2/ 17 (11.8)	11.8	0/ 16 (0.0)	0.0	4.72 (0.24, 91.41)	0.3045	11.76 (-11.99, 35.52)	0.3318	
Other	2/ 8 (25.0)	25.0	0/ 6 (0.0)	0.0	3.89 (0.22, 68.67)	0.3539	25.00 (-20.73, 70.73)	0.2840	
Ethnicity									0.1119
Hispanic/Latino	8/ 27 (29.6)	29.6	1/ 32 (3.1)	3.1	9.48 (1.26, 71.10)	0.0287	26.50 (6.44, 46.57)	0.0096	
Non-hispanic/Latino	9/ 84 (10.7)	10.7	6/ 86 (7.0)	6.7	1.54 (0.57, 4.13)	0.3949	3.99 (-6.36, 14.35)	0.4497	
Geographic region									0.5816
EU	5/ 45 (11.1)	11.1	2/ 33 (6.1)	6.1	1.83 (0.38, 8.87)	0.4513	5.05 (-9.67, 19.77)	0.5014	
non-EU	13/ 74 (17.6)	17.7	5/ 88 (5.7)	5.3	3.09 (1.16, 8.27)	0.0246	12.36 (0.89, 23.83)	0.0346	
Onset of disease									0.9905
Paediatric	2/ 11 (18.2)	18.2	0/ 5 (0.0)	0.0	2.50 (0.14, 44.26)	0.5320	18.18 (-26.66, 63.02)	0.4268	
Adult	16/108 (14.8)	14.9	7/116 (6.0)	5.8	2.46 (1.05, 5.74)	0.0381	9.07 (-0.63, 18.77)	0.0669	
ADA result									0.5176
Negative	17/115 (14.8)	14.6	7/111 (6.3)	6.1	2.34 (1.01, 5.43)	0.0470	8.54 (-1.09, 18.17)	0.0822	
Positive (At any time)	1/ 4 (25.0)	25.0	0/ 10 (0.0)	0.0	6.60 (0.32, 135.38)	0.2208	25.00 (-27.17, 77.17)	0.3476	
BMI (kg/m2) at enrolment									0.8774
< 30	13/ 85 (15.3)	15.4	5/ 89 (5.6)	5.6	2.72 (1.01, 7.31)	0.0469	9.75 (-0.89, 20.38)	0.0725	
>= 30	5/ 34 (14.7)	14.7	2/ 32 (6.3)	6.3	2.35 (0.49, 11.28)	0.2846	8.46 (-8.53, 25.44)	0.3291	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.8166
All negative/normal	6/ 38 (15.8)	16.7	3/ 56 (5.4)	4.8	2.95 (0.78, 11.07)	0.1094	11.90 (-4.59, 28.39)	0.1571	
At least one positive/abnormal	12/ 81 (14.8)	14.8	4/ 65 (6.2)	6.2	2.41 (0.81, 7.11)	0.1120	8.66 (-1.93, 19.25)	0.1090	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Mental Health Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 52	Number of subjects with events, n (%)	24 (20.2)	17 (14.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.37 (0.74, 2.54)	
	p-value	0.3183	
	Odds Ratio (95% CI)	1.43 (0.72, 2.84)	
	p-value	0.3016	
	Risk Difference (95% CI)	5.08 (-4.54, 14.69)	
	p-value	0.3008	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.44 (0.81, 2.53)	
	p-value	0.2118	
	Odds Ratio (95% CI)	1.55 (0.78, 3.05)	
	p-value	0.2100	
	Risk Difference (95% CI)	6.12 (-3.38, 15.62)	
	p-value	0.2070	
	CMH approach		
	Response rate	19.0	13.7
	Difference in response rates (95% CI)	5.25 (-4.85, 15.35)	
	p-value	0.3086	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Mental Health Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.0151
< 10 points	14/ 41 (34.1)	34.0	2/ 32 (6.3)	6.0	5.46 (1.34, 22.32)	0.0181	27.97 (8.14, 47.81)	0.0057	
>= 10 points	10/ 78 (12.8)	12.4	15/ 89 (16.9)	17.0	0.76 (0.36, 1.59)	0.4689	-4.66 (-16.60, 7.29)	0.4448	
OCS dose at baseline									0.6624
<10 mg/day	10/ 58 (17.2)	16.6	9/ 65 (13.8)	13.6	1.25 (0.54, 2.85)	0.6037	2.96 (-11.07, 17.00)	0.6789	
>=10 mg/day	14/ 61 (23.0)	23.0	8/ 56 (14.3)	14.3	1.61 (0.73, 3.54)	0.2391	8.67 (-5.90, 23.23)	0.2436	
Result of type I IFN gene signature test									0.6508
LOW	3/ 23 (13.0)	13.0	3/ 24 (12.5)	12.5	1.04 (0.23, 4.65)	0.9555	0.54 (-21.52, 22.61)	0.9615	
HIGH	21/ 96 (21.9)	20.5	14/ 97 (14.4)	14.0	1.52 (0.82, 2.80)	0.1848	6.41 (-4.95, 17.77)	0.2685	
Age (years)									NE
<= 65	24/117 (20.5)	19.3	17/120 (14.2)	13.8	1.45 (0.82, 2.55)	0.2005	5.48 (-4.72, 15.69)	0.2923	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									0.5922
male	4/ 11 (36.4)	36.4	4/ 12 (33.3)	33.3	1.09 (0.36, 3.34)	0.8788	3.03 (-36.82, 42.89)	0.8815	
female	20/108 (18.5)	17.7	13/109 (11.9)	11.8	1.55 (0.81, 2.96)	0.1816	5.88 (-4.65, 16.42)	0.2735	
Race									0.8644
White	15/ 75 (20.0)	18.3	13/ 78 (16.7)	16.2	1.20 (0.61, 2.35)	0.5947	2.06 (-10.64, 14.76)	0.7506	
Black or African American	2/ 11 (18.2)	18.2	3/ 18 (16.7)	16.7	1.09 (0.21, 5.54)	0.9164	1.52 (-31.01, 34.04)	0.9272	
Asian	3/ 17 (17.6)	17.6	1/ 16 (6.3)	6.3	2.82 (0.33, 24.43)	0.3458	11.40 (-15.36, 38.16)	0.4038	
Other	1/ 8 (12.5)	12.5	0/ 6 (0.0)	0.0	2.33 (0.11, 48.99)	0.5854	12.50 (-31.37, 56.37)	0.5765	
Ethnicity									0.8714
Hispanic/Latino	6/ 27 (22.2)	22.2	5/ 32 (15.6)	15.6	1.42 (0.49, 4.15)	0.5191	6.60 (-14.86, 28.06)	0.5468	
Non-hispanic/Latino	15/ 84 (17.9)	17.1	12/ 86 (14.0)	13.7	1.28 (0.64, 2.57)	0.4879	3.34 (-8.43, 15.11)	0.5779	
Geographic region									0.9279
EU	10/ 45 (22.2)	22.2	5/ 33 (15.2)	15.2	1.47 (0.55, 3.89)	0.4414	7.07 (-11.27, 25.41)	0.4499	
non-EU	14/ 74 (18.9)	17.6	12/ 88 (13.6)	13.2	1.39 (0.68, 2.81)	0.3636	4.36 (-7.67, 16.39)	0.4772	
Onset of disease									0.6947
Paediatric	2/ 11 (18.2)	18.2	0/ 5 (0.0)	0.0	2.50 (0.14, 44.26)	0.5320	18.18 (-26.66, 63.02)	0.4268	
Adult	22/108 (20.4)	19.4	17/116 (14.7)	14.3	1.39 (0.78, 2.47)	0.2626	5.08 (-5.50, 15.66)	0.3468	
ADA result									0.6552
Negative	23/115 (20.0)	18.7	16/111 (14.4)	14.4	1.39 (0.78, 2.48)	0.2703	4.32 (-6.16, 14.79)	0.4194	
Positive (At any time)	1/ 4 (25.0)	25.0	1/ 10 (10.0)	10.0	2.50 (0.20, 31.00)	0.4756	15.00 (-38.83, 68.83)	0.5850	
BMI (kg/m2) at enrolment									0.8517
< 30	17/ 85 (20.0)	20.2	12/ 89 (13.5)	13.2	1.48 (0.75, 2.92)	0.2534	6.97 (-4.69, 18.63)	0.2413	
>= 30	7/ 34 (20.6)	20.6	5/ 32 (15.6)	15.6	1.32 (0.47, 3.73)	0.6036	4.96 (-14.84, 24.77)	0.6233	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.5018
All negative/normal	10/ 38 (26.3)	23.2	8/ 56 (14.3)	13.5	1.84 (0.80, 4.24)	0.1508	9.69 (-7.42, 26.79)	0.2670	
At least one positive/abnormal	14/ 81 (17.3)	17.3	9/ 65 (13.8)	13.8	1.25 (0.58, 2.70)	0.5730	3.44 (-8.88, 15.75)	0.5843	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Physical Functioning Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 52	Number of subjects with events, n (%)	28 (23.5)	25 (20.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.08 (0.66, 1.77)	
	p-value	0.7467	
	Odds Ratio (95% CI)	1.11 (0.60, 2.06)	
	p-value	0.7434	
	Risk Difference (95% CI)	1.76 (-8.79, 12.31)	
	p-value	0.7433	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.14 (0.71, 1.83)	
	p-value	0.5927	
	Odds Ratio (95% CI)	1.18 (0.64, 2.18)	
	p-value	0.5925	
	Risk Difference (95% CI)	2.87 (-7.63, 13.36)	
	p-value	0.5922	
	CMH approach		
	Response rate	23.0	20.6
	Difference in response rates (95% CI)	2.37 (-8.65, 13.39)	
	p-value	0.6735	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Physical Functioning Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.1644
< 10 points	11/ 41 (26.8)	26.5	4/ 32 (12.5)	12.4	2.15 (0.75, 6.11)	0.1527	14.02 (-6.05, 34.08)	0.1709	
>= 10 points	17/ 78 (21.8)	21.5	21/ 89 (23.6)	24.4	0.92 (0.53, 1.62)	0.7821	-2.88 (-16.22, 10.46)	0.6722	
OCS dose at baseline									0.5428
<10 mg/day	13/ 58 (22.4)	21.6	11/ 65 (16.9)	17.2	1.32 (0.64, 2.72)	0.4447	4.38 (-10.68, 19.44)	0.5686	
>=10 mg/day	15/ 61 (24.6)	24.6	14/ 56 (25.0)	25.0	0.98 (0.52, 1.85)	0.9591	-0.41 (-16.40, 15.58)	0.9599	
Result of type I IFN gene signature test									0.8411
LOW	6/ 23 (26.1)	26.1	6/ 24 (25.0)	25.0	1.04 (0.39, 2.77)	0.9319	1.09 (-24.89, 27.07)	0.9346	
HIGH	22/ 96 (22.9)	22.2	19/ 97 (19.6)	19.5	1.17 (0.68, 2.02)	0.5725	2.69 (-9.47, 14.84)	0.6648	
Age (years)									0.6676
<= 65	27/117 (23.1)	22.5	25/120 (20.8)	20.7	1.11 (0.68, 1.79)	0.6767	1.86 (-9.21, 12.93)	0.7423	
> 65	1/ 2 (50.0)	50.0	0/ 1 (0.0)	0.0	2.00 (0.14, 28.42)	0.6087	50.00 (-68.41, 168.41)	0.4079	
Sex									0.5791
male	4/ 11 (36.4)	36.4	5/ 12 (41.7)	41.7	0.87 (0.31, 2.44)	0.7955	-5.30 (-45.63, 35.02)	0.7966	
female	24/108 (22.2)	21.8	20/109 (18.3)	18.1	1.21 (0.71, 2.06)	0.4791	3.73 (-7.74, 15.21)	0.5238	
Race									0.9208
White	21/ 75 (28.0)	27.5	20/ 78 (25.6)	24.9	1.09 (0.65, 1.84)	0.7420	2.57 (-11.88, 17.03)	0.7269	
Black or African American	1/ 11 (9.1)	9.1	3/ 18 (16.7)	16.7	0.55 (0.06, 4.61)	0.5780	-7.58 (-38.13, 22.98)	0.6270	
Asian	1/ 17 (5.9)	5.9	1/ 16 (6.3)	6.3	0.94 (0.06, 13.82)	0.9647	-0.37 (-24.51, 23.77)	0.9762	
Other	2/ 8 (25.0)	25.0	1/ 6 (16.7)	16.7	1.50 (0.17, 12.94)	0.7122	8.33 (-40.77, 57.44)	0.7394	
Ethnicity									0.9504
Hispanic/Latino	8/ 27 (29.6)	29.6	9/ 32 (28.1)	28.1	1.05 (0.47, 2.35)	0.8988	1.50 (-22.28, 25.29)	0.9013	
Non-hispanic/Latino	17/ 84 (20.2)	20.2	16/ 86 (18.6)	18.2	1.09 (0.59, 2.01)	0.7878	2.06 (-10.57, 14.70)	0.7489	
Geographic region									0.2402
EU	15/ 45 (33.3)	33.3	7/ 33 (21.2)	21.2	1.57 (0.72, 3.42)	0.2540	12.12 (-8.07, 32.31)	0.2394	
non-EU	13/ 74 (17.6)	17.3	18/ 88 (20.5)	19.4	0.86 (0.45, 1.63)	0.6428	-2.01 (-14.70, 10.68)	0.7558	
Onset of disease									0.8267
Paediatric	2/ 11 (18.2)	18.2	1/ 5 (20.0)	20.0	0.91 (0.11, 7.84)	0.9309	-1.82 (-50.71, 47.07)	0.9419	
Adult	26/108 (24.1)	23.7	24/116 (20.7)	20.5	1.16 (0.71, 1.90)	0.5437	3.27 (-8.20, 14.74)	0.5762	
ADA result									0.5238
Negative	27/115 (23.5)	22.8	24/111 (21.6)	22.0	1.09 (0.67, 1.76)	0.7387	0.83 (-10.59, 12.25)	0.8869	
Positive (At any time)	1/ 4 (25.0)	25.0	1/ 10 (10.0)	10.0	2.50 (0.20, 31.00)	0.4756	15.00 (-38.83, 68.83)	0.5850	
BMI (kg/m2) at enrolment									0.2502
< 30	23/ 85 (27.1)	27.2	18/ 89 (20.2)	20.0	1.34 (0.78, 2.30)	0.2911	7.27 (-5.74, 20.29)	0.2735	
>= 30	5/ 34 (14.7)	14.7	7/ 32 (21.9)	21.9	0.67 (0.24, 1.90)	0.4548	-7.17 (-27.04, 12.70)	0.4795	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.2839
All negative/normal	9/ 38 (23.7)	23.1	15/ 56 (26.8)	24.8	0.88 (0.43, 1.81)	0.7364	-1.76 (-20.42, 16.89)	0.8530	
At least one positive/abnormal	19/ 81 (23.5)	23.5	10/ 65 (15.4)	15.4	1.52 (0.76, 3.05)	0.2327	8.07 (-5.09, 21.23)	0.2292	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Role Emotional Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 52	Number of subjects with events, n (%)	30 (25.2)	25 (20.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.17 (0.72, 1.91)	
	p-value	0.5168	
	Odds Ratio (95% CI)	1.23 (0.66, 2.28)	
	p-value	0.5083	
	Risk Difference (95% CI)	3.58 (-7.03, 14.18)	
	p-value	0.5085	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.22 (0.77, 1.95)	
	p-value	0.4032	
	Odds Ratio (95% CI)	1.29 (0.71, 2.37)	
	p-value	0.4025	
	Risk Difference (95% CI)	4.55 (-6.08, 15.17)	
	p-value	0.4014	
	CMH approach		
	Response rate	24.0	20.7
	Difference in response rates (95% CI)	3.33 (-7.52, 14.18)	
	p-value	0.5480	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Role Emotional Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.0472
< 10 points	17/ 41 (41.5)	42.0	6/ 32 (18.8)	18.6	2.21 (0.99, 4.96)	0.0541	23.46 (1.89, 45.04)	0.0331	
>= 10 points	13/ 78 (16.7)	16.1	19/ 89 (21.3)	21.1	0.78 (0.41, 1.48)	0.4459	-5.03 (-17.55, 7.50)	0.4315	
OCS dose at baseline									0.5192
<10 mg/day	13/ 58 (22.4)	21.4	14/ 65 (21.5)	21.9	1.04 (0.53, 2.03)	0.9068	-0.53 (-15.47, 14.41)	0.9446	
>=10 mg/day	17/ 61 (27.9)	27.9	11/ 56 (19.6)	19.6	1.42 (0.73, 2.76)	0.3033	8.23 (-7.48, 23.93)	0.3047	
Result of type I IFN gene signature test									0.4751
LOW	5/ 23 (21.7)	21.7	6/ 24 (25.0)	25.0	0.87 (0.31, 2.46)	0.7922	-3.26 (-28.71, 22.18)	0.8017	
HIGH	25/ 96 (26.0)	24.6	19/ 97 (19.6)	19.6	1.33 (0.79, 2.25)	0.2882	4.96 (-7.03, 16.94)	0.4176	
Age (years)									0.7056
<= 65	29/117 (24.8)	23.6	25/120 (20.8)	20.8	1.19 (0.74, 1.90)	0.4691	2.75 (-8.15, 13.65)	0.6207	
> 65	1/ 2 (50.0)	50.0	0/ 1 (0.0)	0.0	2.00 (0.14, 28.42)	0.6087	50.00 (-68.41, 168.41)	0.4079	
Sex									0.8648
male	3/ 11 (27.3)	27.3	3/ 12 (25.0)	25.0	1.09 (0.28, 4.32)	0.9013	2.27 (-35.99, 40.53)	0.9073	
female	27/108 (25.0)	24.1	22/109 (20.2)	20.4	1.24 (0.75, 2.03)	0.3978	3.73 (-7.77, 15.23)	0.5246	
Race									0.6836
White	22/ 75 (29.3)	27.9	18/ 78 (23.1)	22.9	1.27 (0.74, 2.17)	0.3806	5.00 (-9.17, 19.16)	0.4893	
Black or African American	2/ 11 (18.2)	18.2	5/ 18 (27.8)	27.8	0.65 (0.15, 2.81)	0.5689	-9.60 (-43.45, 24.26)	0.5785	
Asian	1/ 17 (5.9)	5.9	2/ 16 (12.5)	12.5	0.47 (0.05, 4.70)	0.5209	-6.62 (-32.32, 19.09)	0.6139	
Other	1/ 8 (12.5)	12.5	0/ 6 (0.0)	0.0	2.33 (0.11, 48.99)	0.5854	12.50 (-31.37, 56.37)	0.5765	
Ethnicity									0.8643
Hispanic/Latino	8/ 27 (29.6)	29.6	8/ 32 (25.0)	25.0	1.19 (0.51, 2.73)	0.6902	4.63 (-18.86, 28.12)	0.6993	
Non-hispanic/Latino	18/ 84 (21.4)	20.6	17/ 86 (19.8)	19.5	1.08 (0.60, 1.96)	0.7889	1.03 (-11.56, 13.62)	0.8728	
Geographic region									0.7802
EU	14/ 45 (31.1)	31.1	8/ 33 (24.2)	24.2	1.28 (0.61, 2.70)	0.5108	6.87 (-13.56, 27.30)	0.5099	
non-EU	16/ 74 (21.6)	20.4	17/ 88 (19.3)	20.0	1.12 (0.61, 2.06)	0.7168	0.39 (-12.45, 13.23)	0.9523	
Onset of disease									0.3284
Paediatric	4/ 11 (36.4)	36.4	0/ 5 (0.0)	0.0	4.50 (0.29, 70.57)	0.2842	36.36 (-10.18, 82.90)	0.1257	
Adult	26/108 (24.1)	23.2	25/116 (21.6)	21.6	1.12 (0.69, 1.81)	0.6529	1.67 (-9.63, 12.96)	0.7726	
ADA result									0.3708
Negative	28/115 (24.3)	23.3	23/111 (20.7)	20.7	1.18 (0.72, 1.91)	0.5154	2.55 (-8.65, 13.75)	0.6557	
Positive (At any time)	2/ 4 (50.0)	50.0	2/ 10 (20.0)	20.0	2.50 (0.51, 12.14)	0.2557	30.00 (-26.43, 86.43)	0.2975	
BMI (kg/m2) at enrolment									0.7785
< 30	20/ 85 (23.5)	23.7	18/ 89 (20.2)	20.3	1.16 (0.66, 2.04)	0.5984	3.37 (-9.18, 15.91)	0.5990	
>= 30	10/ 34 (29.4)	29.4	7/ 32 (21.9)	21.9	1.34 (0.58, 3.10)	0.4879	7.54 (-14.12, 29.20)	0.4953	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.1986
All negative/normal	11/ 38 (28.9)	26.8	9/ 56 (16.1)	15.4	1.80 (0.83, 3.92)	0.1386	11.41 (-6.65, 29.47)	0.2157	
At least one positive/abnormal	19/ 81 (23.5)	23.5	16/ 65 (24.6)	24.6	0.95 (0.53, 1.70)	0.8705	-1.16 (-15.38, 13.06)	0.8731	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Role Physical Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 52	Number of subjects with events, n (%)	42 (35.3)	27 (22.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.50 (0.99, 2.27)	
	p-value	0.0531	
	Odds Ratio (95% CI)	1.77 (1.00, 3.15)	
	p-value	0.0513	
	Risk Difference (95% CI)	11.58 (0.09, 23.08)	
	p-value	0.0483	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.58 (1.05, 2.39)	
	p-value	0.0292	
	Odds Ratio (95% CI)	1.90 (1.07, 3.36)	
	p-value	0.0273	
	Risk Difference (95% CI)	12.98 (1.63, 24.33)	
	p-value	0.0250	
	CMH approach		
	Response rate	34.8	22.8
	Difference in response rates (95% CI)	11.97 (0.36, 23.58)	
	p-value	0.0432	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Role Physical Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.1124
< 10 points	18/ 41 (43.9)	44.4	5/ 32 (15.6)	15.5	2.81 (1.17, 6.75)	0.0209	28.93 (7.57, 50.29)	0.0079	
>= 10 points	24/ 78 (30.8)	30.8	22/ 89 (24.7)	25.9	1.24 (0.76, 2.04)	0.3833	4.97 (-8.95, 18.89)	0.4844	
OCS dose at baseline									0.1166
<10 mg/day	22/ 58 (37.9)	36.9	11/ 65 (16.9)	17.9	2.24 (1.19, 4.21)	0.0122	19.04 (3.15, 34.94)	0.0189	
>=10 mg/day	20/ 61 (32.8)	32.8	16/ 56 (28.6)	28.6	1.15 (0.66, 1.99)	0.6227	4.22 (-12.67, 21.10)	0.6246	
Result of type I IFN gene signature test									0.9771
LOW	9/ 23 (39.1)	39.1	6/ 24 (25.0)	25.0	1.57 (0.66, 3.70)	0.3074	14.13 (-12.89, 41.15)	0.3053	
HIGH	33/ 96 (34.4)	33.7	21/ 97 (21.6)	22.3	1.59 (0.99, 2.54)	0.0532	11.44 (-1.41, 24.28)	0.0809	
Age (years)									0.8552
<= 65	41/117 (35.0)	34.5	27/120 (22.5)	22.9	1.56 (1.03, 2.36)	0.0358	11.66 (-0.02, 23.33)	0.0504	
> 65	1/ 2 (50.0)	50.0	0/ 1 (0.0)	0.0	2.00 (0.14, 28.42)	0.6087	50.00 (-68.41, 168.41)	0.4079	
Sex									0.1171
male	3/ 11 (27.3)	27.3	5/ 12 (41.7)	41.7	0.65 (0.20, 2.12)	0.4794	-14.39 (-53.94, 25.15)	0.4756	
female	39/108 (36.1)	35.9	22/109 (20.2)	20.5	1.79 (1.14, 2.81)	0.0112	15.40 (3.17, 27.64)	0.0136	
Race									0.5151
White	27/ 75 (36.0)	35.4	21/ 78 (26.9)	26.7	1.34 (0.83, 2.15)	0.2297	8.71 (-6.24, 23.66)	0.2535	
Black or African American	3/ 11 (27.3)	27.3	5/ 18 (27.8)	27.8	0.98 (0.29, 3.32)	0.9765	-0.51 (-35.71, 34.69)	0.9776	
Asian	5/ 17 (29.4)	29.4	0/ 16 (0.0)	0.0	10.39 (0.62, 173.97)	0.1035	29.41 (2.61, 56.21)	0.0315	
Other	2/ 8 (25.0)	25.0	1/ 6 (16.7)	16.7	1.50 (0.17, 12.94)	0.7122	8.33 (-40.77, 57.44)	0.7394	
Ethnicity									0.4154
Hispanic/Latino	6/ 27 (22.2)	22.2	7/ 32 (21.9)	21.9	1.02 (0.39, 2.66)	0.9744	0.35 (-21.96, 22.65)	0.9757	
Non-hispanic/Latino	31/ 84 (36.9)	36.5	20/ 86 (23.3)	22.9	1.59 (0.99, 2.55)	0.0567	13.63 (-0.28, 27.54)	0.0548	
Geographic region									0.7901
EU	20/ 45 (44.4)	44.4	9/ 33 (27.3)	27.3	1.63 (0.85, 3.11)	0.1383	17.17 (-4.14, 38.49)	0.1144	
non-EU	22/ 74 (29.7)	28.6	18/ 88 (20.5)	20.1	1.45 (0.85, 2.50)	0.1753	8.56 (-5.01, 22.12)	0.2163	
Onset of disease									0.8730
Paediatric	3/ 11 (27.3)	27.3	1/ 5 (20.0)	20.0	1.36 (0.18, 10.09)	0.7613	7.27 (-42.56, 57.11)	0.7748	
Adult	39/108 (36.1)	35.7	26/116 (22.4)	22.6	1.61 (1.06, 2.46)	0.0265	13.03 (0.99, 25.06)	0.0339	
ADA result									0.3743
Negative	42/115 (36.5)	35.9	25/111 (22.5)	23.3	1.62 (1.06, 2.47)	0.0244	12.63 (0.70, 24.57)	0.0380	
Positive (At any time)	0/ 4 (0.0)	0.0	2/ 10 (20.0)	20.0	0.44 (0.03, 7.58)	0.5719	-20.00 (-70.84, 30.84)	0.4407	
BMI (kg/m2) at enrolment									0.2129
< 30	32/ 85 (37.6)	37.5	18/ 89 (20.2)	20.2	1.86 (1.13, 3.05)	0.0139	17.37 (3.87, 30.86)	0.0116	
>= 30	10/ 34 (29.4)	29.4	9/ 32 (28.1)	28.1	1.05 (0.49, 2.24)	0.9082	1.29 (-21.05, 23.62)	0.9101	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.6338
All negative/normal	15/ 38 (39.5)	38.4	15/ 56 (26.8)	25.6	1.47 (0.82, 2.65)	0.1941	12.72 (-7.02, 32.47)	0.2066	
At least one positive/abnormal	27/ 81 (33.3)	33.3	12/ 65 (18.5)	18.5	1.81 (0.99, 3.28)	0.0522	14.87 (0.65, 29.09)	0.0404	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Social Functioning Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 52	Number of subjects with events, n (%)	25 (21.0)	18 (14.9)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.37 (0.75, 2.51)	
	p-value	0.3106	
	Odds Ratio (95% CI)	1.44 (0.73, 2.81)	
	p-value	0.2924	
	Risk Difference (95% CI)	5.26 (-4.52, 15.03)	
	p-value	0.2918	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.41 (0.81, 2.45)	
	p-value	0.2191	
	Odds Ratio (95% CI)	1.52 (0.78, 2.97)	
	p-value	0.2174	
	Risk Difference (95% CI)	6.13 (-3.55, 15.82)	
	p-value	0.2145	
	CMH approach		
	Response rate	19.5	14.4
	Difference in response rates (95% CI)	5.11 (-4.95, 15.16)	
	p-value	0.3195	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Social Functioning Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.0102
< 10 points	16/ 41 (39.0)	38.6	3/ 32 (9.4)	9.1	4.16 (1.33, 13.06)	0.0145	29.48 (9.01, 49.96)	0.0048	
>= 10 points	9/ 78 (11.5)	11.0	15/ 89 (16.9)	16.3	0.68 (0.32, 1.48)	0.3338	-5.35 (-16.87, 6.17)	0.3627	
OCS dose at baseline									0.0735
<10 mg/day	9/ 58 (15.5)	14.7	12/ 65 (18.5)	18.0	0.84 (0.38, 1.85)	0.6658	-3.38 (-17.51, 10.75)	0.6391	
>=10 mg/day	16/ 61 (26.2)	26.2	6/ 56 (10.7)	10.7	2.45 (1.03, 5.82)	0.0426	15.52 (1.18, 29.85)	0.0338	
Result of type I IFN gene signature test									0.9828
LOW	4/ 23 (17.4)	17.4	3/ 24 (12.5)	12.5	1.39 (0.35, 5.55)	0.6399	4.89 (-17.99, 27.77)	0.6752	
HIGH	21/ 96 (21.9)	20.0	15/ 97 (15.5)	14.9	1.41 (0.78, 2.58)	0.2568	5.16 (-6.03, 16.35)	0.3662	
Age (years)									0.7835
<= 65	24/117 (20.5)	19.0	18/120 (15.0)	14.6	1.37 (0.78, 2.38)	0.2695	4.42 (-5.67, 14.52)	0.3904	
> 65	1/ 2 (50.0)	50.0	0/ 1 (0.0)	0.0	2.00 (0.14, 28.42)	0.6087	50.00 (-68.41, 168.41)	0.4079	
Sex									0.3835
male	2/ 11 (18.2)	18.2	3/ 12 (25.0)	25.0	0.73 (0.15, 3.57)	0.6949	-6.82 (-43.84, 30.20)	0.7181	
female	23/108 (21.3)	20.1	15/109 (13.8)	13.3	1.55 (0.85, 2.80)	0.1493	6.73 (-3.91, 17.36)	0.2150	
Race									0.6831
White	17/ 75 (22.7)	21.2	15/ 78 (19.2)	19.3	1.18 (0.64, 2.19)	0.6020	1.85 (-11.50, 15.20)	0.7860	
Black or African American	2/ 11 (18.2)	18.2	3/ 18 (16.7)	16.7	1.09 (0.21, 5.54)	0.9164	1.52 (-31.01, 34.04)	0.9272	
Asian	3/ 17 (17.6)	17.6	0/ 16 (0.0)	0.0	6.61 (0.37, 118.73)	0.1999	17.65 (-7.37, 42.67)	0.1668	
Other	1/ 8 (12.5)	12.5	0/ 6 (0.0)	0.0	2.33 (0.11, 48.99)	0.5854	12.50 (-31.37, 56.37)	0.5765	
Ethnicity									0.4957
Hispanic/Latino	9/ 27 (33.3)	33.3	6/ 32 (18.8)	18.8	1.78 (0.72, 4.36)	0.2087	14.58 (-8.51, 37.67)	0.2158	
Non-hispanic/Latino	14/ 84 (16.7)	15.8	12/ 86 (14.0)	13.9	1.19 (0.59, 2.43)	0.6238	1.87 (-9.76, 13.51)	0.7524	
Geographic region									0.4540
EU	7/ 45 (15.6)	15.6	5/ 33 (15.2)	15.2	1.03 (0.36, 2.95)	0.9610	0.40 (-17.10, 17.91)	0.9639	
non-EU	18/ 74 (24.3)	22.6	13/ 88 (14.8)	14.6	1.65 (0.87, 3.13)	0.1284	8.00 (-4.46, 20.46)	0.2084	
Onset of disease									0.6881
Paediatric	2/ 11 (18.2)	18.2	0/ 5 (0.0)	0.0	2.50 (0.14, 44.26)	0.5320	18.18 (-26.66, 63.02)	0.4268	
Adult	23/108 (21.3)	20.0	18/116 (15.5)	15.1	1.37 (0.79, 2.40)	0.2664	4.91 (-5.65, 15.47)	0.3623	
ADA result									0.6448
Negative	24/115 (20.9)	19.2	17/111 (15.3)	14.7	1.36 (0.78, 2.39)	0.2822	4.59 (-5.79, 14.98)	0.3859	
Positive (At any time)	1/ 4 (25.0)	25.0	1/ 10 (10.0)	10.0	2.50 (0.20, 31.00)	0.4756	15.00 (-38.83, 68.83)	0.5850	
BMI (kg/m2) at enrolment									0.0845
< 30	19/ 85 (22.4)	22.6	10/ 89 (11.2)	11.1	1.99 (0.98, 4.03)	0.0561	11.52 (-0.09, 23.13)	0.0518	
>= 30	6/ 34 (17.6)	17.6	8/ 32 (25.0)	25.0	0.71 (0.28, 1.81)	0.4686	-7.35 (-28.06, 13.35)	0.4864	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.9707
All negative/normal	10/ 38 (26.3)	24.6	10/ 56 (17.9)	17.4	1.47 (0.68, 3.19)	0.3259	7.22 (-11.02, 25.47)	0.4378	
At least one positive/abnormal	15/ 81 (18.5)	18.5	8/ 65 (12.3)	12.3	1.50 (0.68, 3.33)	0.3130	6.21 (-6.00, 18.42)	0.3188	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Bodily Pain Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 52	Number of subjects with events, n (%)	29 (24.4)	27 (22.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.07 (0.68, 1.69)	
	p-value	0.7708	
	Odds Ratio (95% CI)	1.09 (0.60, 2.00)	
	p-value	0.7718	
	Risk Difference (95% CI)	1.60 (-9.22, 12.41)	
	p-value	0.7719	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.09 (0.69, 1.73)	
	p-value	0.7067	
	Odds Ratio (95% CI)	1.12 (0.62, 2.04)	
	p-value	0.7066	
	Risk Difference (95% CI)	2.06 (-8.65, 12.76)	
	p-value	0.7066	
	CMH approach		
	Response rate	24.5	22.5
	Difference in response rates (95% CI)	2.00 (-9.30, 13.30)	
	p-value	0.7285	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Bodily Pain Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.5243
< 10 points	12/ 41 (29.3)	30.2	7/ 32 (21.9)	21.8	1.34 (0.60, 3.01)	0.4808	8.40 (-13.13, 29.93)	0.4445	
>= 10 points	17/ 78 (21.8)	21.7	20/ 89 (22.5)	22.9	0.97 (0.55, 1.72)	0.9163	-1.14 (-14.51, 12.23)	0.8672	
OCS dose at baseline									0.4786
<10 mg/day	16/ 58 (27.6)	27.2	14/ 65 (21.5)	21.9	1.28 (0.69, 2.39)	0.4368	5.30 (-10.66, 21.27)	0.5150	
>=10 mg/day	13/ 61 (21.3)	21.3	13/ 56 (23.2)	23.2	0.92 (0.47, 1.81)	0.8047	-1.90 (-17.41, 13.60)	0.8099	
Result of type I IFN gene signature test									0.7737
LOW	6/ 23 (26.1)	26.1	5/ 24 (20.8)	20.8	1.25 (0.44, 3.54)	0.6717	5.25 (-20.21, 30.72)	0.6859	
HIGH	23/ 96 (24.0)	24.1	22/ 97 (22.7)	22.9	1.06 (0.63, 1.76)	0.8338	1.20 (-11.41, 13.81)	0.8524	
Age (years)									0.6459
<= 65	28/117 (23.9)	24.0	27/120 (22.5)	22.6	1.06 (0.67, 1.69)	0.7941	1.40 (-9.96, 12.75)	0.8092	
> 65	1/ 2 (50.0)	50.0	0/ 1 (0.0)	0.0	2.00 (0.14, 28.42)	0.6087	50.00 (-68.41, 168.41)	0.4079	
Sex									0.0893
male	1/ 11 (9.1)	9.1	5/ 12 (41.7)	41.7	0.22 (0.03, 1.59)	0.1328	-32.58 (-69.27, 4.12)	0.0819	
female	28/108 (25.9)	26.0	22/109 (20.2)	20.5	1.28 (0.79, 2.10)	0.3175	5.58 (-6.27, 17.43)	0.3559	
Race									0.9128
White	20/ 75 (26.7)	26.9	19/ 78 (24.4)	23.8	1.09 (0.64, 1.88)	0.7434	3.14 (-11.25, 17.54)	0.6687	
Black or African American	2/ 11 (18.2)	18.2	4/ 18 (22.2)	22.2	0.82 (0.18, 3.75)	0.7962	-4.04 (-37.30, 29.22)	0.8118	
Asian	2/ 17 (11.8)	11.8	3/ 16 (18.8)	18.8	0.63 (0.12, 3.28)	0.5807	-6.99 (-35.24, 21.27)	0.6281	
Other	1/ 8 (12.5)	12.5	1/ 6 (16.7)	16.7	0.75 (0.06, 9.72)	0.8258	-4.17 (-51.55, 43.21)	0.8632	
Ethnicity									0.8661
Hispanic/Latino	8/ 27 (29.6)	29.6	9/ 32 (28.1)	28.1	1.05 (0.47, 2.35)	0.8988	1.50 (-22.28, 25.29)	0.9013	
Non-hispanic/Latino	17/ 84 (20.2)	20.2	18/ 86 (20.9)	20.9	0.97 (0.54, 1.75)	0.9112	-0.66 (-13.57, 12.25)	0.9202	
Geographic region									0.1540
EU	13/ 45 (28.9)	28.9	5/ 33 (15.2)	15.2	1.91 (0.75, 4.82)	0.1731	13.74 (-5.23, 32.71)	0.1558	
non-EU	16/ 74 (21.6)	21.9	22/ 88 (25.0)	25.3	0.86 (0.49, 1.52)	0.6145	-3.36 (-17.00, 10.29)	0.6299	
Onset of disease									0.3995
Paediatric	3/ 11 (27.3)	27.3	0/ 5 (0.0)	0.0	3.50 (0.21, 57.35)	0.3799	27.27 (-18.60, 73.14)	0.2439	
Adult	26/108 (24.1)	24.3	27/116 (23.3)	23.4	1.03 (0.65, 1.66)	0.8883	0.89 (-10.85, 12.62)	0.8823	
ADA result									0.8949
Negative	28/115 (24.3)	24.5	25/111 (22.5)	22.8	1.08 (0.67, 1.73)	0.7463	1.68 (-10.01, 13.36)	0.7786	
Positive (At any time)	1/ 4 (25.0)	25.0	2/ 10 (20.0)	20.0	1.25 (0.15, 10.23)	0.8352	5.00 (-50.09, 60.09)	0.8588	
BMI (kg/m2) at enrolment									0.4784
< 30	21/ 85 (24.7)	24.9	22/ 89 (24.7)	24.7	1.00 (0.59, 1.68)	0.9984	0.19 (-13.15, 13.53)	0.9778	
>= 30	8/ 34 (23.5)	23.5	5/ 32 (15.6)	15.6	1.51 (0.55, 4.13)	0.4259	7.90 (-12.27, 28.08)	0.4426	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.6882
All negative/normal	11/ 38 (28.9)	28.7	13/ 56 (23.2)	22.2	1.25 (0.63, 2.48)	0.5302	6.48 (-12.38, 25.34)	0.5008	
At least one positive/abnormal	18/ 81 (22.2)	22.2	14/ 65 (21.5)	21.5	1.03 (0.56, 1.91)	0.9210	0.68 (-13.12, 14.49)	0.9227	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Vitality Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 52	Number of subjects with events, n (%)	24 (20.2)	19 (15.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.26 (0.71, 2.23)	
	p-value	0.4274	
	Odds Ratio (95% CI)	1.32 (0.67, 2.58)	
	p-value	0.4209	
	Risk Difference (95% CI)	4.03 (-5.76, 13.83)	
	p-value	0.4196	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.28 (0.74, 2.22)	
	p-value	0.3690	
	Odds Ratio (95% CI)	1.36 (0.70, 2.63)	
	p-value	0.3681	
	Risk Difference (95% CI)	4.47 (-5.23, 14.16)	
	p-value	0.3667	
	CMH approach		
	Response rate	19.8	15.5
	Difference in response rates (95% CI)	4.25 (-6.22, 14.72)	
	p-value	0.4261	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Vitality Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.4207
< 10 points	11/ 41 (26.8)	26.9	5/ 32 (15.6)	15.5	1.72 (0.66, 4.44)	0.2650	11.36 (-9.37, 32.09)	0.2827	
>= 10 points	13/ 78 (16.7)	16.6	14/ 89 (15.7)	15.5	1.06 (0.53, 2.11)	0.8697	1.05 (-11.21, 13.31)	0.8664	
OCS dose at baseline									0.8323
<10 mg/day	12/ 58 (20.7)	20.6	11/ 65 (16.9)	17.1	1.22 (0.58, 2.56)	0.5933	3.59 (-11.53, 18.70)	0.6418	
>=10 mg/day	12/ 61 (19.7)	19.7	8/ 56 (14.3)	14.3	1.38 (0.61, 3.12)	0.4432	5.39 (-8.82, 19.59)	0.4573	
Result of type I IFN gene signature test									0.2317
LOW	3/ 23 (13.0)	13.0	5/ 24 (20.8)	20.8	0.63 (0.17, 2.33)	0.4843	-7.79 (-31.29, 15.71)	0.5158	
HIGH	21/ 96 (21.9)	21.4	14/ 97 (14.4)	14.2	1.52 (0.82, 2.80)	0.1848	7.23 (-4.47, 18.93)	0.2257	
Age (years)									0.7303
<= 65	23/117 (19.7)	19.2	19/120 (15.8)	15.6	1.24 (0.72, 2.16)	0.4421	3.57 (-6.92, 14.06)	0.5053	
> 65	1/ 2 (50.0)	50.0	0/ 1 (0.0)	0.0	2.00 (0.14, 28.42)	0.6087	50.00 (-68.41, 168.41)	0.4079	
Sex									0.4552
male	2/ 11 (18.2)	18.2	3/ 12 (25.0)	25.0	0.73 (0.15, 3.57)	0.6949	-6.82 (-43.84, 30.20)	0.7181	
female	22/108 (20.4)	20.0	16/109 (14.7)	14.5	1.39 (0.77, 2.49)	0.2734	5.51 (-5.49, 16.52)	0.3263	
Race									0.9572
White	17/ 75 (22.7)	22.2	14/ 78 (17.9)	17.9	1.26 (0.67, 2.38)	0.4695	4.27 (-9.31, 17.84)	0.5378	
Black or African American	3/ 11 (27.3)	27.3	3/ 18 (16.7)	16.7	1.64 (0.40, 6.73)	0.4947	10.61 (-23.32, 44.53)	0.5400	
Asian	2/ 17 (11.8)	11.8	1/ 16 (6.3)	6.3	1.88 (0.19, 18.80)	0.5901	5.51 (-20.07, 31.10)	0.6727	
Other	1/ 8 (12.5)	12.5	0/ 6 (0.0)	0.0	2.33 (0.11, 48.99)	0.5854	12.50 (-31.37, 56.37)	0.5765	
Ethnicity									0.3854
Hispanic/Latino	7/ 27 (25.9)	25.9	4/ 32 (12.5)	12.5	2.07 (0.68, 6.34)	0.2004	13.43 (-8.02, 34.87)	0.2198	
Non-hispanic/Latino	16/ 84 (19.0)	18.5	14/ 86 (16.3)	15.9	1.17 (0.61, 2.24)	0.6364	2.59 (-9.59, 14.77)	0.6770	
Geographic region									0.5876
EU	7/ 45 (15.6)	15.6	5/ 33 (15.2)	15.2	1.03 (0.36, 2.95)	0.9610	0.40 (-17.10, 17.91)	0.9639	
non-EU	17/ 74 (23.0)	22.2	14/ 88 (15.9)	15.4	1.44 (0.76, 2.73)	0.2577	6.82 (-6.07, 19.71)	0.2995	
Onset of disease									0.6401
Paediatric	2/ 11 (18.2)	18.2	0/ 5 (0.0)	0.0	2.50 (0.14, 44.26)	0.5320	18.18 (-26.66, 63.02)	0.4268	
Adult	22/108 (20.4)	20.1	19/116 (16.4)	16.2	1.24 (0.71, 2.17)	0.4413	3.88 (-7.10, 14.85)	0.4886	
ADA result									0.2691
Negative	23/115 (20.0)	19.5	19/111 (17.1)	17.0	1.17 (0.67, 2.02)	0.5783	2.55 (-8.38, 13.48)	0.6476	
Positive (At any time)	1/ 4 (25.0)	25.0	0/ 10 (0.0)	0.0	6.60 (0.32, 135.38)	0.2208	25.00 (-27.17, 77.17)	0.3476	
BMI (kg/m2) at enrolment									0.2700
< 30	18/ 85 (21.2)	21.5	12/ 89 (13.5)	13.3	1.57 (0.81, 3.06)	0.1848	8.19 (-3.87, 20.25)	0.1832	
>= 30	6/ 34 (17.6)	17.6	7/ 32 (21.9)	21.9	0.81 (0.30, 2.14)	0.6668	-4.23 (-24.55, 16.09)	0.6834	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.9332
All negative/normal	10/ 38 (26.3)	27.0	11/ 56 (19.6)	19.3	1.34 (0.63, 2.84)	0.4452	7.73 (-11.11, 26.57)	0.4211	
At least one positive/abnormal	14/ 81 (17.3)	17.3	8/ 65 (12.3)	12.3	1.40 (0.63, 3.14)	0.4084	4.98 (-7.09, 17.05)	0.4191	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
C-SSRS Suicidal ideation or behaviour
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
On-treatment/Follow-Up	Number of subjects with events, n (%)	3 (2.5)	5 (4.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.72 (0.15, 3.35)	
	p-value	0.6709	
	Odds Ratio (95% CI)	0.71 (0.15, 3.27)	
	p-value	0.6568	
	Risk Difference (95% CI)	-0.99 (-5.32, 3.34)	
	p-value	0.6547	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.61 (0.15, 2.50)	
	p-value	0.4918	
	Odds Ratio (95% CI)	0.60 (0.14, 2.57)	
	p-value	0.4912	
	Risk Difference (95% CI)	-1.61 (-6.14, 2.92)	
	p-value	0.4856	
	CMH approach		
	Response rate	2.5	4.1
	Difference in response rates (95% CI)	-1.62 (-9.14, 5.90)	
	p-value	0.6731	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
C-SSRS Suicidal ideation or behaviour - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8479
< 10 points	1/ 41 (2.4)	2.8	1/ 32 (3.1)	2.8	0.78 (0.05, 12.00)	0.8589	0.00 (-16.50, 16.50)	1.0000	
>= 10 points	2/ 78 (2.6)	2.3	4/ 89 (4.5)	4.3	0.57 (0.11, 3.03)	0.5101	-2.01 (-10.66, 6.64)	0.6492	
OCS dose at baseline									0.9533
<10 mg/day	1/ 58 (1.7)	1.7	2/ 65 (3.1)	3.0	0.56 (0.05, 6.02)	0.6325	-1.39 (-11.95, 9.17)	0.7960	
>=10 mg/day	2/ 61 (3.3)	3.3	3/ 56 (5.4)	5.4	0.61 (0.11, 3.53)	0.5828	-2.08 (-11.50, 7.34)	0.6655	
Result of type I IFN gene signature test									0.3591
LOW	0/ 23 (0.0)	0.0	2/ 24 (8.3)	8.3	0.21 (0.01, 4.12)	0.3029	-8.33 (-25.96, 9.29)	0.3540	
HIGH	3/ 96 (3.1)	3.1	3/ 97 (3.1)	3.0	1.01 (0.21, 4.88)	0.9897	0.04 (-8.27, 8.35)	0.9922	
Age (years)									NE
<= 65	3/117 (2.6)	2.5	5/120 (4.2)	4.1	0.62 (0.15, 2.52)	0.4993	-1.58 (-9.18, 6.02)	0.6837	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-27.45, 27.45)	1.0000	
female	3/108 (2.8)	2.7	5/109 (4.6)	4.5	0.61 (0.15, 2.47)	0.4845	-1.75 (-9.94, 6.45)	0.6765	
Race									0.3187
White	3/ 75 (4.0)	3.8	3/ 78 (3.8)	3.6	1.04 (0.22, 4.99)	0.9609	0.26 (-9.16, 9.67)	0.9577	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	2/ 16 (12.5)	12.5	0.19 (0.01, 3.66)	0.2703	-12.50 (-36.56, 11.56)	0.3085	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE		0.00 (-41.13, 41.13)	1.0000	
Ethnicity									0.3947
Hispanic/Latino	0/ 27 (0.0)	0.0	2/ 32 (6.3)	6.3	0.24 (0.01, 4.71)	0.3442	-6.25 (-20.55, 8.05)	0.3916	
Non-hispanic/Latino	3/ 84 (3.6)	3.5	3/ 86 (3.5)	3.6	1.02 (0.21, 4.93)	0.9766	-0.09 (-8.71, 8.53)	0.9833	
Geographic region									0.3961
EU	1/ 45 (2.2)	2.2	0/ 33 (0.0)	0.0	2.22 (0.09, 52.78)	0.6224	2.22 (-8.20, 12.64)	0.6760	
non-EU	2/ 74 (2.7)	2.6	5/ 88 (5.7)	5.8	0.48 (0.10, 2.38)	0.3658	-3.19 (-12.43, 6.06)	0.4990	
Onset of disease									NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
Adult	3/108 (2.8)	2.7	5/116 (4.3)	4.3	0.64 (0.16, 2.63)	0.5406	-1.55 (-9.53, 6.43)	0.7033	
ADA result									NE
Negative	3/115 (2.6)	2.5	5/111 (4.5)	4.4	0.58 (0.14, 2.37)	0.4468	-1.92 (-9.85, 6.02)	0.6362	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE		0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment									0.7194
< 30	2/ 85 (2.4)	2.4	4/ 89 (4.5)	4.6	0.52 (0.10, 2.78)	0.4478	-2.17 (-10.58, 6.24)	0.6128	
>= 30	1/ 34 (2.9)	2.9	1/ 32 (3.1)	3.1	0.94 (0.06, 14.42)	0.9653	-0.18 (-13.37, 13.00)	0.9782	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.0366
All negative/normal	3/ 38 (7.9)	8.1	1/ 56 (1.8)	1.7	4.42 (0.48, 40.93)	0.1905	6.41 (-8.44, 21.26)	0.3975	
At least one positive/abnormal	0/ 81 (0.0)	0.0	4/ 65 (6.2)	6.2	0.09 (0.00, 1.63)	0.1032	-6.15 (-13.76, 1.45)	0.1127	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Modified SELENA Flare Index based flares - mild/moderate flare
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
at least once during study	Number of subjects with events, n (%)	37 (31.1)	47 (38.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.80 (0.56, 1.15)	
	p-value	0.2210	
	Odds Ratio (95% CI)	0.71 (0.42, 1.22)	
	p-value	0.2164	
	Risk Difference (95% CI)	-7.78 (-20.04, 4.48)	
	p-value	0.2138	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.80 (0.56, 1.13)	
	p-value	0.2108	
	Odds Ratio (95% CI)	0.71 (0.42, 1.21)	
	p-value	0.2089	
	Risk Difference (95% CI)	-7.75 (-19.77, 4.27)	
	p-value	0.2065	
	CMH approach		
	Response rate	30.5	38.3
	Difference in response rates (95% CI)	-7.74 (-19.79, 4.30)	
	p-value	0.2078	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Modified SELENA Flare Index based flares - mild/moderate flare - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.0526
< 10 points	17/ 41 (41.5)	41.4	10/ 32 (31.3)	31.6	1.33 (0.71, 2.49)	0.3787	9.73 (-12.71, 32.16)	0.3955	
>= 10 points	20/ 78 (25.6)	25.9	37/ 89 (41.6)	41.7	0.62 (0.39, 0.97)	0.0358	-15.77 (-30.16, -1.38)	0.0317	
OCS dose at baseline									0.9607
<10 mg/day	18/ 58 (31.0)	31.2	25/ 65 (38.5)	37.2	0.81 (0.49, 1.32)	0.3924	-6.05 (-22.93, 10.83)	0.4824	
>=10 mg/day	19/ 61 (31.1)	31.1	22/ 56 (39.3)	39.3	0.79 (0.48, 1.30)	0.3582	-8.14 (-25.53, 9.25)	0.3590	
Result of type I IFN gene signature test									0.7947
LOW	6/ 23 (26.1)	26.1	7/ 24 (29.2)	29.2	0.89 (0.35, 2.26)	0.8138	-3.08 (-29.49, 23.33)	0.8192	
HIGH	31/ 96 (32.3)	31.6	40/ 97 (41.2)	40.5	0.78 (0.54, 1.14)	0.2008	-8.90 (-22.43, 4.64)	0.1976	
Age (years)									0.3368
<= 65	37/117 (31.6)	31.0	46/120 (38.3)	37.9	0.82 (0.58, 1.17)	0.2813	-6.88 (-19.02, 5.26)	0.2665	
> 65	0/ 2 (0.0)	0.0	1/ 1 (100.0)	100.0	0.22 (0.02, 3.16)	0.2666	-100.00 (-216.14, 16.14)	0.0915	
Sex									0.3804
male	2/ 11 (18.2)	18.2	5/ 12 (41.7)	41.7	0.44 (0.11, 1.81)	0.2528	-23.48 (-61.83, 14.87)	0.2300	
female	35/108 (32.4)	31.8	42/109 (38.5)	38.1	0.84 (0.59, 1.21)	0.3475	-6.37 (-19.08, 6.34)	0.3262	
Race									0.4431
White	20/ 75 (26.7)	25.4	30/ 78 (38.5)	38.3	0.69 (0.43, 1.11)	0.1256	-12.84 (-27.59, 1.90)	0.0877	
Black or African American	5/ 11 (45.5)	45.5	5/ 18 (27.8)	27.8	1.64 (0.61, 4.39)	0.3280	17.68 (-18.82, 54.18)	0.3425	
Asian	6/ 17 (35.3)	35.3	8/ 16 (50.0)	50.0	0.71 (0.31, 1.59)	0.3987	-14.71 (-48.37, 18.96)	0.3919	
Other	3/ 8 (37.5)	37.5	2/ 6 (33.3)	33.3	1.13 (0.27, 4.76)	0.8729	4.17 (-47.83, 56.16)	0.8752	
Ethnicity									0.8422
Hispanic/Latino	9/ 27 (33.3)	33.3	14/ 32 (43.8)	43.8	0.76 (0.39, 1.48)	0.4211	-10.42 (-35.36, 14.53)	0.4130	
Non-hispanic/Latino	25/ 84 (29.8)	29.1	31/ 86 (36.0)	35.7	0.83 (0.54, 1.27)	0.3854	-6.68 (-20.83, 7.47)	0.3547	
Geographic region									0.1116
EU	8/ 45 (17.8)	17.8	12/ 33 (36.4)	36.4	0.49 (0.23, 1.06)	0.0698	-18.59 (-38.90, 1.72)	0.0729	
non-EU	29/ 74 (39.2)	37.9	35/ 88 (39.8)	38.2	0.99 (0.67, 1.45)	0.9397	-0.34 (-15.04, 14.37)	0.9643	
Onset of disease									0.6191
Paediatric	4/ 11 (36.4)	36.4	3/ 5 (60.0)	60.0	0.61 (0.21, 1.75)	0.3544	-23.64 (-75.94, 28.66)	0.3757	
Adult	33/108 (30.6)	30.0	44/116 (37.9)	37.5	0.81 (0.56, 1.16)	0.2488	-7.46 (-19.87, 4.95)	0.2387	
ADA result									0.9848
Negative	35/115 (30.4)	30.0	41/111 (36.9)	36.5	0.82 (0.57, 1.19)	0.3024	-6.43 (-18.81, 5.96)	0.3091	
Positive (At any time)	2/ 4 (50.0)	50.0	6/ 10 (60.0)	60.0	0.83 (0.28, 2.51)	0.7459	-10.00 (-67.81, 47.81)	0.7346	
BMI (kg/m2) at enrolment									0.6670
< 30	23/ 85 (27.1)	26.6	32/ 89 (36.0)	35.2	0.75 (0.48, 1.18)	0.2114	-8.59 (-22.14, 4.97)	0.2144	
>= 30	14/ 34 (41.2)	41.2	15/ 32 (46.9)	46.9	0.88 (0.51, 1.52)	0.6414	-5.70 (-29.67, 18.27)	0.6413	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.7229
All negative/normal	11/ 38 (28.9)	28.4	19/ 56 (33.9)	33.0	0.85 (0.46, 1.58)	0.6145	-4.56 (-24.23, 15.10)	0.6493	
At least one positive/abnormal	26/ 81 (32.1)	32.1	28/ 65 (43.1)	43.1	0.75 (0.49, 1.14)	0.1723	-10.98 (-26.79, 4.83)	0.1736	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Modified SELENA Flare Index based flares - severe flare
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
at least once during study	Number of subjects with events, n (%)	3 (2.5)	6 (5.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.54 (0.14, 2.07)	
	p-value	0.3671	
	Odds Ratio (95% CI)	0.53 (0.13, 2.14)	
	p-value	0.3719	
	Risk Difference (95% CI)	-2.28 (-7.18, 2.62)	
	p-value	0.3622	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.51 (0.13, 1.99)	
	p-value	0.3305	
	Odds Ratio (95% CI)	0.50 (0.12, 2.03)	
	p-value	0.3292	
	Risk Difference (95% CI)	-2.44 (-7.22, 2.35)	
	p-value	0.3180	
	CMH approach		
	Response rate	2.6	5.2
	Difference in response rates (95% CI)	-2.58 (-10.35, 5.19)	
	p-value	0.5156	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Modified SELENA Flare Index based flares - severe flare - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Anifrolumab 300mg (N=119) Response rate	Placebo (N=121) n/ N (%)	Placebo (N=121) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.7403
< 10 points	1/ 41 (2.4)	2.8	1/ 32 (3.1)	3.5	0.78 (0.05, 12.00)	0.8589	-0.65 (-17.29, 16.00)	0.9391	
>= 10 points	2/ 78 (2.6)	2.6	5/ 89 (5.6)	5.8	0.46 (0.09, 2.29)	0.3401	-3.27 (-12.39, 5.85)	0.4828	
OCS dose at baseline									0.1231
<10 mg/day	2/ 58 (3.4)	3.6	1/ 65 (1.5)	1.4	2.24 (0.21, 24.08)	0.5052	2.17 (-8.61, 12.94)	0.6935	
>=10 mg/day	1/ 61 (1.6)	1.6	5/ 56 (8.9)	8.9	0.18 (0.02, 1.52)	0.1165	-7.29 (-17.21, 2.63)	0.1498	
Result of type I IFN gene signature test									0.7515
LOW	0/ 23 (0.0)	0.0	1/ 24 (4.2)	4.2	0.35 (0.01, 8.11)	0.5106	-4.17 (-20.53, 12.19)	0.6177	
HIGH	3/ 96 (3.1)	3.3	5/ 97 (5.2)	5.5	0.61 (0.15, 2.47)	0.4845	-2.18 (-10.99, 6.62)	0.6269	
Age (years)									NE
<= 65	3/117 (2.6)	2.7	6/120 (5.0)	5.2	0.51 (0.13, 2.00)	0.3366	-2.57 (-10.41, 5.27)	0.5208	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									0.2016
male	1/ 11 (9.1)	9.1	0/ 12 (0.0)	0.0	3.25 (0.15, 72.36)	0.4566	9.09 (-21.06, 39.24)	0.5545	
female	2/108 (1.9)	1.9	6/109 (5.5)	5.8	0.34 (0.07, 1.63)	0.1760	-3.86 (-12.22, 4.49)	0.3650	
Race									0.6943
White	1/ 75 (1.3)	1.0	4/ 78 (5.1)	4.9	0.26 (0.03, 2.27)	0.2234	-3.90 (-13.03, 5.23)	0.4025	
Black or African American	0/ 11 (0.0)	0.0	1/ 18 (5.6)	5.6	0.53 (0.02, 11.93)	0.6879	-5.56 (-31.15, 20.04)	0.6705	
Asian	1/ 17 (5.9)	5.9	1/ 16 (6.3)	6.3	0.94 (0.06, 13.82)	0.9647	-0.37 (-24.51, 23.77)	0.9762	
Other	1/ 8 (12.5)	12.5	0/ 6 (0.0)	0.0	2.33 (0.11, 48.99)	0.5854	12.50 (-31.37, 56.37)	0.5765	
Ethnicity									0.7042
Hispanic/Latino	1/ 27 (3.7)	3.7	3/ 32 (9.4)	9.4	0.40 (0.04, 3.58)	0.4090	-5.67 (-22.04, 10.70)	0.4971	
Non-hispanic/Latino	2/ 84 (2.4)	2.3	3/ 86 (3.5)	3.6	0.68 (0.12, 3.98)	0.6713	-1.35 (-9.75, 7.05)	0.7529	
Geographic region									0.5474
EU	0/ 45 (0.0)	0.0	1/ 33 (3.0)	3.0	0.25 (0.01, 5.86)	0.3864	-3.03 (-13.99, 7.93)	0.5879	
non-EU	3/ 74 (4.1)	4.0	5/ 88 (5.7)	5.7	0.71 (0.18, 2.89)	0.6359	-1.68 (-11.27, 7.92)	0.7319	
Onset of disease									NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
Adult	3/108 (2.8)	2.9	6/116 (5.2)	5.3	0.54 (0.14, 2.09)	0.3706	-2.50 (-10.68, 5.69)	0.5503	
ADA result									0.7608
Negative	3/115 (2.6)	2.7	4/111 (3.6)	3.8	0.72 (0.17, 3.16)	0.6675	-1.07 (-8.97, 6.82)	0.7897	
Positive (At any time)	0/ 4 (0.0)	0.0	2/ 10 (20.0)	20.0	0.44 (0.03, 7.58)	0.5719	-20.00 (-70.84, 30.84)	0.4407	
BMI (kg/m2) at enrolment									0.2261
< 30	3/ 85 (3.5)	3.6	3/ 89 (3.4)	3.3	1.05 (0.22, 5.05)	0.9543	0.32 (-8.16, 8.80)	0.9410	
>= 30	0/ 34 (0.0)	0.0	3/ 32 (9.4)	9.4	0.13 (0.01, 2.51)	0.1791	-9.38 (-23.51, 4.76)	0.1937	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.2463
All negative/normal	0/ 38 (0.0)	0.0	4/ 56 (7.1)	7.2	0.16 (0.01, 2.93)	0.2182	-7.15 (-21.31, 7.01)	0.3223	
At least one positive/abnormal	3/ 81 (3.7)	3.7	2/ 65 (3.1)	3.1	1.20 (0.21, 6.99)	0.8363	0.63 (-7.02, 8.28)	0.8724	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Modified SELENA Flare Index based flares - mild/moderate or severe flare
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
at least once during study	Number of subjects with events, n (%)	39 (32.8)	50 (41.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.79 (0.56, 1.11)	
	p-value	0.1693	
	Odds Ratio (95% CI)	0.69 (0.41, 1.17)	
	p-value	0.1666	
	Risk Difference (95% CI)	-8.79 (-21.17, 3.58)	
	p-value	0.1637	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.79 (0.57, 1.11)	
	p-value	0.1733	
	Odds Ratio (95% CI)	0.69 (0.41, 1.17)	
	p-value	0.1711	
	Risk Difference (95% CI)	-8.55 (-20.72, 3.62)	
	p-value	0.1686	
	CMH approach		
	Response rate	32.3	41.1
	Difference in response rates (95% CI)	-8.75 (-20.93, 3.43)	
	p-value	0.1591	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Modified SELENA Flare Index based flares - mild/moderate or severe flare - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.0946
< 10 points	17/ 41 (41.5)	41.4	11/ 32 (34.4)	35.1	1.21 (0.66, 2.20)	0.5411	6.27 (-16.32, 28.86)	0.5866	
>= 10 points	22/ 78 (28.2)	28.5	39/ 89 (43.8)	44.2	0.64 (0.42, 0.98)	0.0422	-15.72 (-30.30, -1.15)	0.0344	
OCS dose at baseline									0.6632
<10 mg/day	19/ 58 (32.8)	33.1	25/ 65 (38.5)	37.2	0.85 (0.53, 1.38)	0.5124	-4.14 (-21.13, 12.85)	0.6330	
>=10 mg/day	20/ 61 (32.8)	32.8	25/ 56 (44.6)	44.6	0.73 (0.46, 1.17)	0.1911	-11.86 (-29.48, 5.77)	0.1875	
Result of type I IFN gene signature test									0.7784
LOW	6/ 23 (26.1)	26.1	7/ 24 (29.2)	29.2	0.89 (0.35, 2.26)	0.8138	-3.08 (-29.49, 23.33)	0.8192	
HIGH	33/ 96 (34.4)	33.9	43/ 97 (44.3)	44.0	0.78 (0.54, 1.11)	0.1604	-10.15 (-23.87, 3.56)	0.1468	
Age (years)									0.3404
<= 65	39/117 (33.3)	32.8	49/120 (40.8)	40.7	0.82 (0.58, 1.14)	0.2347	-7.88 (-20.15, 4.39)	0.2082	
> 65	0/ 2 (0.0)	0.0	1/ 1 (100.0)	100.0	0.22 (0.02, 3.16)	0.2666	-100.00 (-216.14, 16.14)	0.0915	
Sex									0.3889
male	2/ 11 (18.2)	18.2	5/ 12 (41.7)	41.7	0.44 (0.11, 1.81)	0.2528	-23.48 (-61.83, 14.87)	0.2300	
female	37/108 (34.3)	33.7	45/109 (41.3)	41.3	0.83 (0.59, 1.17)	0.2880	-7.54 (-20.39, 5.31)	0.2500	
Race									0.4294
White	20/ 75 (26.7)	25.4	31/ 78 (39.7)	39.6	0.67 (0.42, 1.07)	0.0921	-14.11 (-28.86, 0.65)	0.0609	
Black or African American	5/ 11 (45.5)	45.5	6/ 18 (33.3)	33.3	1.36 (0.54, 3.42)	0.5086	12.12 (-24.80, 49.04)	0.5199	
Asian	7/ 17 (41.2)	41.2	9/ 16 (56.3)	56.3	0.73 (0.36, 1.49)	0.3917	-15.07 (-48.95, 18.80)	0.3832	
Other	4/ 8 (50.0)	50.0	2/ 6 (33.3)	33.3	1.50 (0.40, 5.65)	0.5492	16.67 (-35.65, 68.98)	0.5324	
Ethnicity									0.9565
Hispanic/Latino	10/ 27 (37.0)	37.0	15/ 32 (46.9)	46.9	0.79 (0.43, 1.46)	0.4526	-9.84 (-35.07, 15.40)	0.4448	
Non-hispanic/Latino	26/ 84 (31.0)	30.3	33/ 86 (38.4)	38.2	0.81 (0.53, 1.22)	0.3123	-7.92 (-22.25, 6.40)	0.2785	
Geographic region									0.1154
EU	8/ 45 (17.8)	17.8	12/ 33 (36.4)	36.4	0.49 (0.23, 1.06)	0.0698	-18.59 (-38.90, 1.72)	0.0729	
non-EU	31/ 74 (41.9)	40.8	38/ 88 (43.2)	41.7	0.97 (0.68, 1.39)	0.8688	-0.95 (-15.89, 13.99)	0.9007	
Onset of disease									0.6262
Paediatric	4/ 11 (36.4)	36.4	3/ 5 (60.0)	60.0	0.61 (0.21, 1.75)	0.3544	-23.64 (-75.94, 28.66)	0.3757	
Adult	35/108 (32.4)	32.0	47/116 (40.5)	40.3	0.80 (0.56, 1.14)	0.2116	-8.34 (-20.88, 4.21)	0.1927	
ADA result									0.7915
Negative	37/115 (32.2)	31.9	43/111 (38.7)	38.6	0.83 (0.58, 1.18)	0.3036	-6.74 (-19.25, 5.78)	0.2914	
Positive (At any time)	2/ 4 (50.0)	50.0	7/ 10 (70.0)	70.0	0.71 (0.25, 2.06)	0.5341	-20.00 (-77.30, 37.30)	0.4939	
BMI (kg/m2) at enrolment									0.8457
< 30	25/ 85 (29.4)	29.1	34/ 89 (38.2)	37.4	0.77 (0.50, 1.17)	0.2248	-8.36 (-22.18, 5.46)	0.2359	
>= 30	14/ 34 (41.2)	41.2	16/ 32 (50.0)	50.0	0.82 (0.48, 1.40)	0.4732	-8.82 (-32.81, 15.17)	0.4710	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.9920
All negative/normal	11/ 38 (28.9)	28.4	21/ 56 (37.5)	36.8	0.77 (0.42, 1.41)	0.3994	-8.45 (-28.30, 11.40)	0.4039	
At least one positive/abnormal	28/ 81 (34.6)	34.6	29/ 65 (44.6)	44.6	0.77 (0.52, 1.16)	0.2157	-10.05 (-26.00, 5.91)	0.2171	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score Improvement >=15% (of maxmimum value =33)
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
at least once during study	Number of subjects with events, n (%)	108 (90.8)	98 (81.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.12 (1.01, 1.24)	
	p-value	0.0351	
	Odds Ratio (95% CI)	2.28 (1.05, 4.97)	
	p-value	0.0374	
	Risk Difference (95% CI)	9.71 (0.88, 18.55)	
	p-value	0.0312	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.12 (1.01, 1.24)	
	p-value	0.0313	
	Odds Ratio (95% CI)	2.30 (1.07, 4.97)	
	p-value	0.0333	
	Risk Difference (95% CI)	9.76 (1.05, 18.48)	
	p-value	0.0281	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score Improvement >=15% (of maxmimum value =33) at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 52	Number of subjects with events, n (%)	65 (54.6)	51 (42.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.27 (0.97, 1.68)	
	p-value	0.0871	
	Odds Ratio (95% CI)	1.58 (0.95, 2.63)	
	p-value	0.0809	
	Risk Difference (95% CI)	11.48 (-1.32, 24.29)	
	p-value	0.0788	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.30 (0.99, 1.69)	
	p-value	0.0555	
	Odds Ratio (95% CI)	1.65 (0.99, 2.75)	
	p-value	0.0538	
	Risk Difference (95% CI)	12.47 (-0.07, 25.02)	
	p-value	0.0514	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (5) response rate at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=120)
Week 52	Number of subjects with events, n (%)	47 (39.5)	31 (25.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.54 (1.05, 2.27)	
	p-value	0.0266	
	Odds Ratio (95% CI)	1.92 (1.09, 3.39)	
	p-value	0.0232	
	Risk Difference (95% CI)	13.77 (2.05, 25.49)	
	p-value	0.0213	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.53 (1.05, 2.23)	
	p-value	0.0269	
	Odds Ratio (95% CI)	1.87 (1.08, 3.25)	
	p-value	0.0251	
	Risk Difference (95% CI)	13.66 (1.89, 25.43)	
	p-value	0.0229	
	CMH approach		
	Response rate	39.2	25.7
	Difference in response rates (95% CI)	13.50 (1.54, 25.45)	
	p-value	0.0269	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (6) response rate at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=120)
Week 52	Number of subjects with events, n (%)	47 (39.5)	28 (23.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.70 (1.14, 2.54)	
	p-value	0.0093	
	Odds Ratio (95% CI)	2.19 (1.23, 3.90)	
	p-value	0.0075	
	Risk Difference (95% CI)	16.11 (4.55, 27.68)	
	p-value	0.0063	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.69 (1.14, 2.51)	
	p-value	0.0087	
	Odds Ratio (95% CI)	2.14 (1.22, 3.76)	
	p-value	0.0076	
	Risk Difference (95% CI)	16.16 (4.57, 27.76)	
	p-value	0.0063	
	CMH approach		
	Response rate	39.2	23.4
	Difference in response rates (95% CI)	15.81 (3.98, 27.65)	
	p-value	0.0088	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (7) response rate at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=109)	Placebo (N=113)
Week 52	Number of subjects with events, n (%)	33 (30.3)	17 (15.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	2.06 (1.22, 3.50)	
	p-value	0.0073	
	Odds Ratio (95% CI)	2.53 (1.30, 4.94)	
	p-value	0.0063	
	Risk Difference (95% CI)	15.89 (4.85, 26.94)	
	p-value	0.0048	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	2.01 (1.19, 3.39)	
	p-value	0.0087	
	Odds Ratio (95% CI)	2.45 (1.27, 4.73)	
	p-value	0.0075	
	Risk Difference (95% CI)	15.23 (4.38, 26.09)	
	p-value	0.0060	
	CMH approach		
	Response rate	30.7	14.9
	Difference in response rates (95% CI)	15.76 (4.48, 27.03)	
	p-value	0.0062	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate sensitivity analysis using modified BILAG at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 52	Number of subjects with events, n (%)	56 (47.1)	40 (33.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.35 (0.97, 1.87)	
	p-value	0.0715	
	Odds Ratio (95% CI)	1.64 (0.97, 2.79)	
	p-value	0.0652	
	Risk Difference (95% CI)	11.74 (-0.68, 24.15)	
	p-value	0.0639	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.42 (1.04, 1.95)	
	p-value	0.0291	
	Odds Ratio (95% CI)	1.80 (1.07, 3.04)	
	p-value	0.0275	
	Risk Difference (95% CI)	14.00 (1.73, 26.28)	
	p-value	0.0254	
	CMH approach		
	Response rate	46.0	33.4
	Difference in response rates (95% CI)	12.62 (0.24, 25.00)	
	p-value	0.0456	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate sensitivity analysis excluding subjects with no BILAG A or B or PGA VAS score >2.7 at baseline at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=117)	Placebo (N=121)
Week 52	Number of subjects with events, n (%)	51 (43.6)	37 (30.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.33 (0.94, 1.89)	
	p-value	0.1034	
	Odds Ratio (95% CI)	1.58 (0.92, 2.71)	
	p-value	0.0965	
	Risk Difference (95% CI)	10.44 (-1.84, 22.71)	
	p-value	0.0956	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.43 (1.02, 2.00)	
	p-value	0.0401	
	Odds Ratio (95% CI)	1.75 (1.03, 2.99)	
	p-value	0.0384	
	Risk Difference (95% CI)	13.01 (0.84, 25.18)	
	p-value	0.0361	
	CMH approach		
	Response rate	42.4	31.1
	Difference in response rates (95% CI)	11.32 (-0.98, 23.62)	
	p-value	0.0712	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate sensitivity analysis excluding criterion of no restricted medications at week 52
Full analysis set

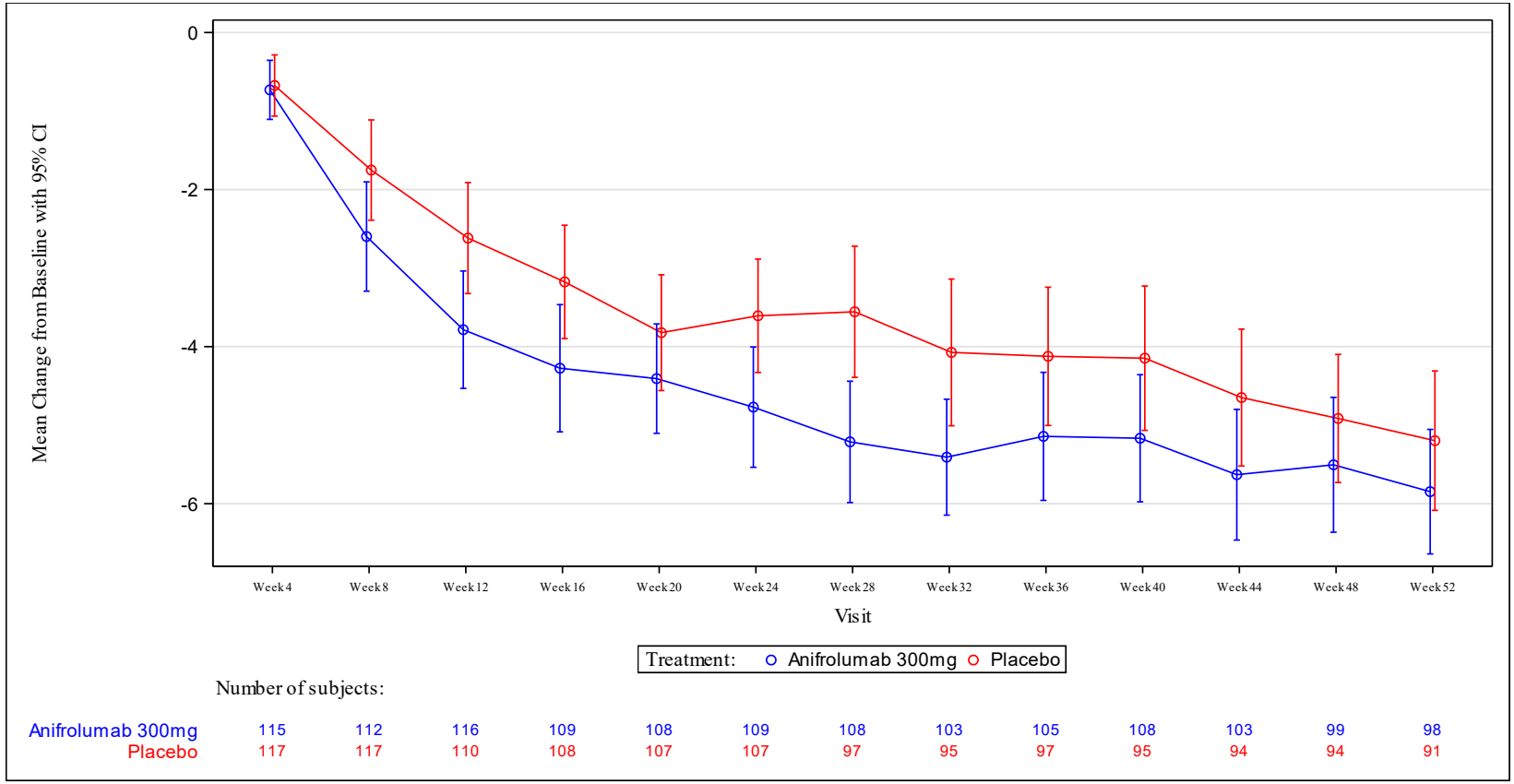
Timepoint		Anifrolumab 300mg (N=119)	Placebo (N=121)
Week 52	Number of subjects with events, n (%)	60 (50.4)	47 (38.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.25 (0.93, 1.68)	
	p-value	0.1408	
	Odds Ratio (95% CI)	1.49 (0.89, 2.50)	
	p-value	0.1337	
	Risk Difference (95% CI)	9.71 (-2.94, 22.35)	
	p-value	0.1324	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.30 (0.98, 1.73)	
	p-value	0.0737	
	Odds Ratio (95% CI)	1.60 (0.96, 2.67)	
	p-value	0.0719	
	Risk Difference (95% CI)	11.58 (-0.92, 24.07)	
	p-value	0.0694	
	CMH approach		
	Response rate	49.8	39.1
	Difference in response rates (95% CI)	10.77 (-1.79, 23.34)	
	p-value	0.0929	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - SLEDAI-2K Total Score
Full analysis set

	Anifrolumab 300mg (N=119)				Placebo (N=121)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	119	11.31 (3.70)	0	-	121	11.49 (3.93)	0	-
Week 4	115	10.63 (3.89)	115	-0.73 (2.04)	117	10.74 (3.97)	117	-0.68 (2.13)
Week 8	112	8.77 (4.30)	112	-2.60 (3.72)	117	9.73 (4.32)	117	-1.75 (3.49)
Week 12	116	7.54 (3.95)	116	-3.78 (4.06)	110	8.85 (3.95)	110	-2.62 (3.74)
Week 16	109	6.83 (3.76)	109	-4.28 (4.27)	108	8.22 (3.94)	108	-3.18 (3.78)
Week 20	108	6.72 (3.58)	108	-4.41 (3.65)	107	7.62 (3.87)	107	-3.82 (3.85)
Week 24	109	6.37 (3.66)	109	-4.77 (4.04)	107	7.79 (3.81)	107	-3.61 (3.77)
Week 28	108	5.95 (3.46)	108	-5.21 (4.05)	97	7.67 (3.92)	97	-3.56 (4.14)
Week 32	103	5.90 (3.59)	103	-5.41 (3.78)	95	7.36 (4.40)	95	-4.07 (4.59)
Week 36	105	5.94 (3.83)	105	-5.14 (4.21)	97	7.27 (4.38)	97	-4.12 (4.37)
Week 40	108	5.91 (3.70)	108	-5.17 (4.24)	95	7.17 (4.41)	95	-4.15 (4.51)
Week 44	103	5.40 (3.45)	103	-5.63 (4.26)	94	6.56 (3.76)	94	-4.65 (4.25)
Week 48	99	5.49 (3.81)	99	-5.51 (4.31)	94	6.39 (3.74)	94	-4.91 (3.98)
Week 52	98	5.04 (3.26)	98	-5.85 (3.95)	91	6.24 (3.81)	91	-5.20 (4.26)

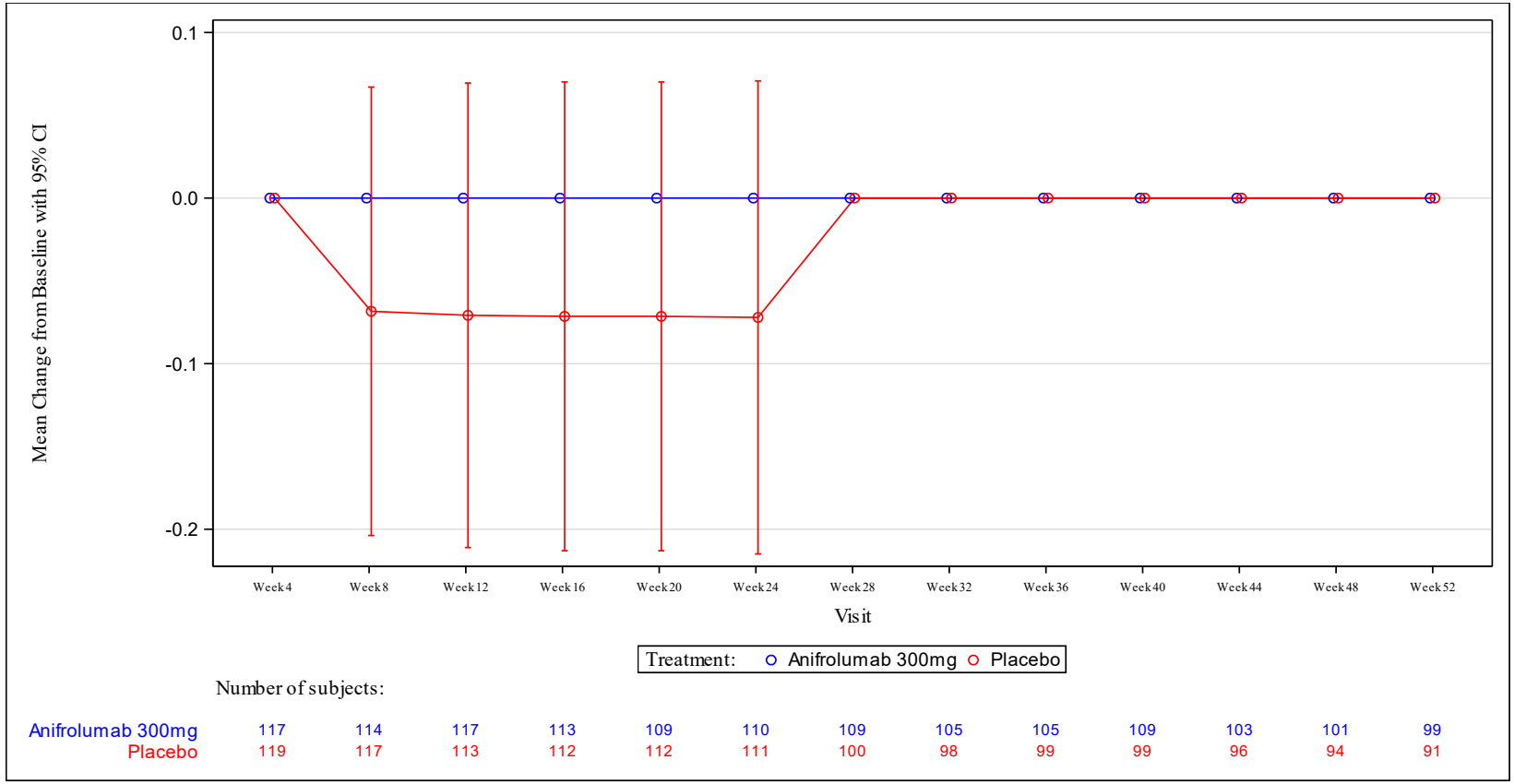
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - SLEDAI-2K Total Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score CNS
Full analysis set

	Anifrolumab 300mg (N=119)				Placebo (N=121)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	119	0.00 (0.00)	0	-	121	0.07 (0.73)	0	-
Week 4	117	0.00 (0.00)	117	0.00 (0.00)	119	0.07 (0.73)	119	0.00 (0.00)
Week 8	114	0.00 (0.00)	114	0.00 (0.00)	117	0.00 (0.00)	117	-0.07 (0.74)
Week 12	117	0.00 (0.00)	117	0.00 (0.00)	113	0.00 (0.00)	113	-0.07 (0.75)
Week 16	113	0.00 (0.00)	113	0.00 (0.00)	112	0.00 (0.00)	112	-0.07 (0.76)
Week 20	109	0.00 (0.00)	109	0.00 (0.00)	112	0.00 (0.00)	112	-0.07 (0.76)
Week 24	110	0.00 (0.00)	110	0.00 (0.00)	111	0.00 (0.00)	111	-0.07 (0.76)
Week 28	109	0.00 (0.00)	109	0.00 (0.00)	100	0.00 (0.00)	100	0.00 (0.00)
Week 32	105	0.00 (0.00)	105	0.00 (0.00)	98	0.00 (0.00)	98	0.00 (0.00)
Week 36	105	0.00 (0.00)	105	0.00 (0.00)	99	0.00 (0.00)	99	0.00 (0.00)
Week 40	109	0.00 (0.00)	109	0.00 (0.00)	99	0.00 (0.00)	99	0.00 (0.00)
Week 44	103	0.00 (0.00)	103	0.00 (0.00)	96	0.00 (0.00)	96	0.00 (0.00)
Week 48	101	0.00 (0.00)	101	0.00 (0.00)	94	0.00 (0.00)	94	0.00 (0.00)
Week 52	99	0.00 (0.00)	99	0.00 (0.00)	91	0.00 (0.00)	91	0.00 (0.00)

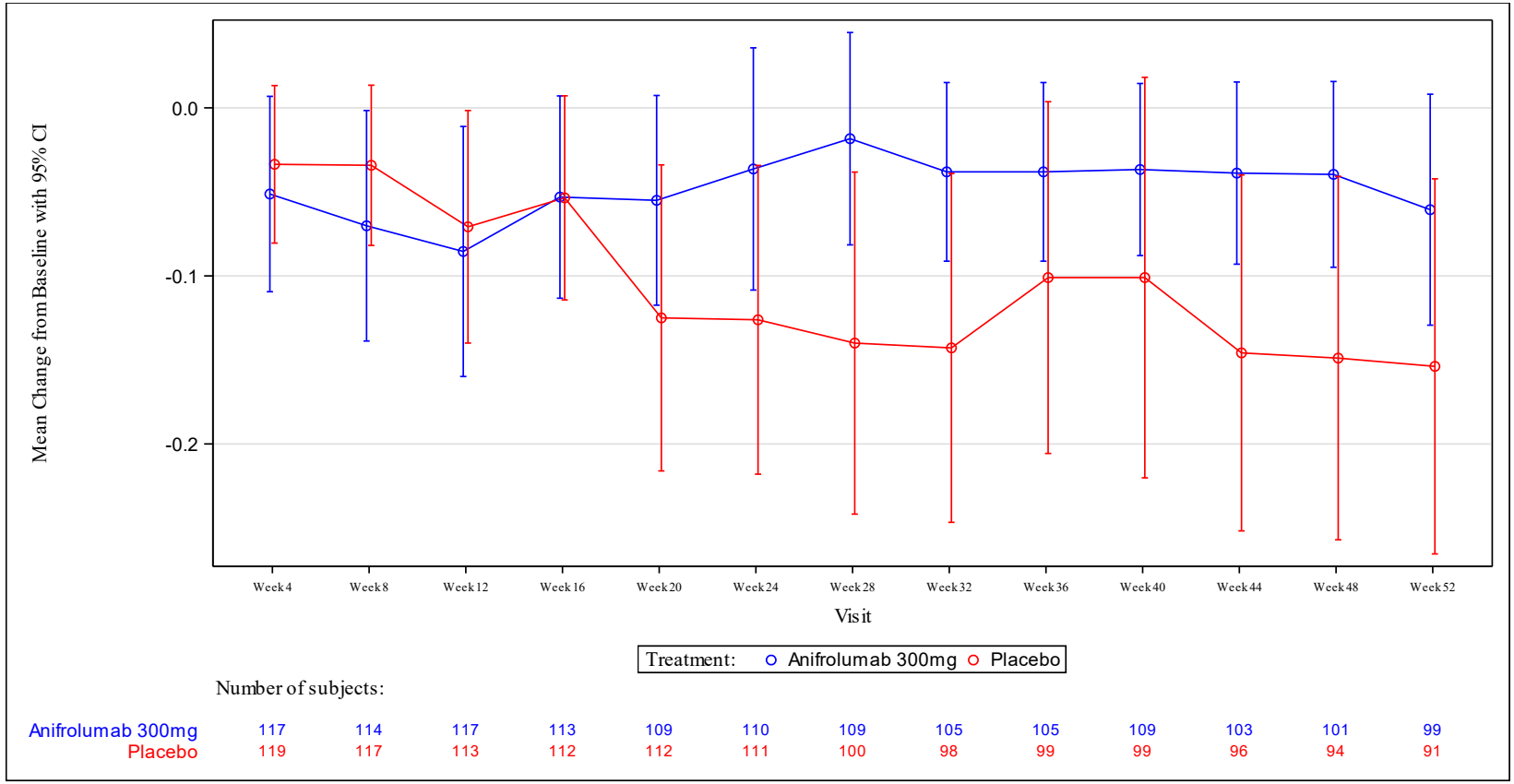
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Total Organ Score CNS
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score CVS and Respiratory
Full analysis set

	Anifrolumab 300mg (N=119)				Placebo (N=121)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	119	0.10 (0.44)	0	-	121	0.17 (0.55)	0	-
Week 4	117	0.05 (0.32)	117	-0.05 (0.32)	119	0.12 (0.47)	119	-0.03 (0.26)
Week 8	114	0.04 (0.26)	114	-0.07 (0.37)	117	0.12 (0.48)	117	-0.03 (0.26)
Week 12	117	0.00 (0.00)	117	-0.09 (0.41)	113	0.09 (0.41)	113	-0.07 (0.37)
Week 16	113	0.02 (0.19)	113	-0.05 (0.32)	112	0.07 (0.37)	112	-0.05 (0.32)
Week 20	109	0.02 (0.19)	109	-0.06 (0.33)	112	0.02 (0.19)	112	-0.13 (0.49)
Week 24	110	0.02 (0.19)	110	-0.04 (0.38)	111	0.02 (0.19)	111	-0.13 (0.49)
Week 28	109	0.04 (0.27)	109	-0.02 (0.33)	100	0.02 (0.20)	100	-0.14 (0.51)
Week 32	105	0.00 (0.00)	105	-0.04 (0.27)	98	0.00 (0.00)	98	-0.14 (0.52)
Week 36	105	0.02 (0.20)	105	-0.04 (0.27)	99	0.04 (0.28)	99	-0.10 (0.52)
Week 40	109	0.02 (0.19)	109	-0.04 (0.27)	99	0.06 (0.34)	99	-0.10 (0.60)
Week 44	103	0.02 (0.20)	103	-0.04 (0.28)	96	0.00 (0.00)	96	-0.15 (0.52)
Week 48	101	0.02 (0.20)	101	-0.04 (0.28)	94	0.00 (0.00)	94	-0.15 (0.53)
Week 52	99	0.00 (0.00)	99	-0.06 (0.34)	91	0.00 (0.00)	91	-0.15 (0.54)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Total Organ Score CVS and Respiratory
Full analysis set



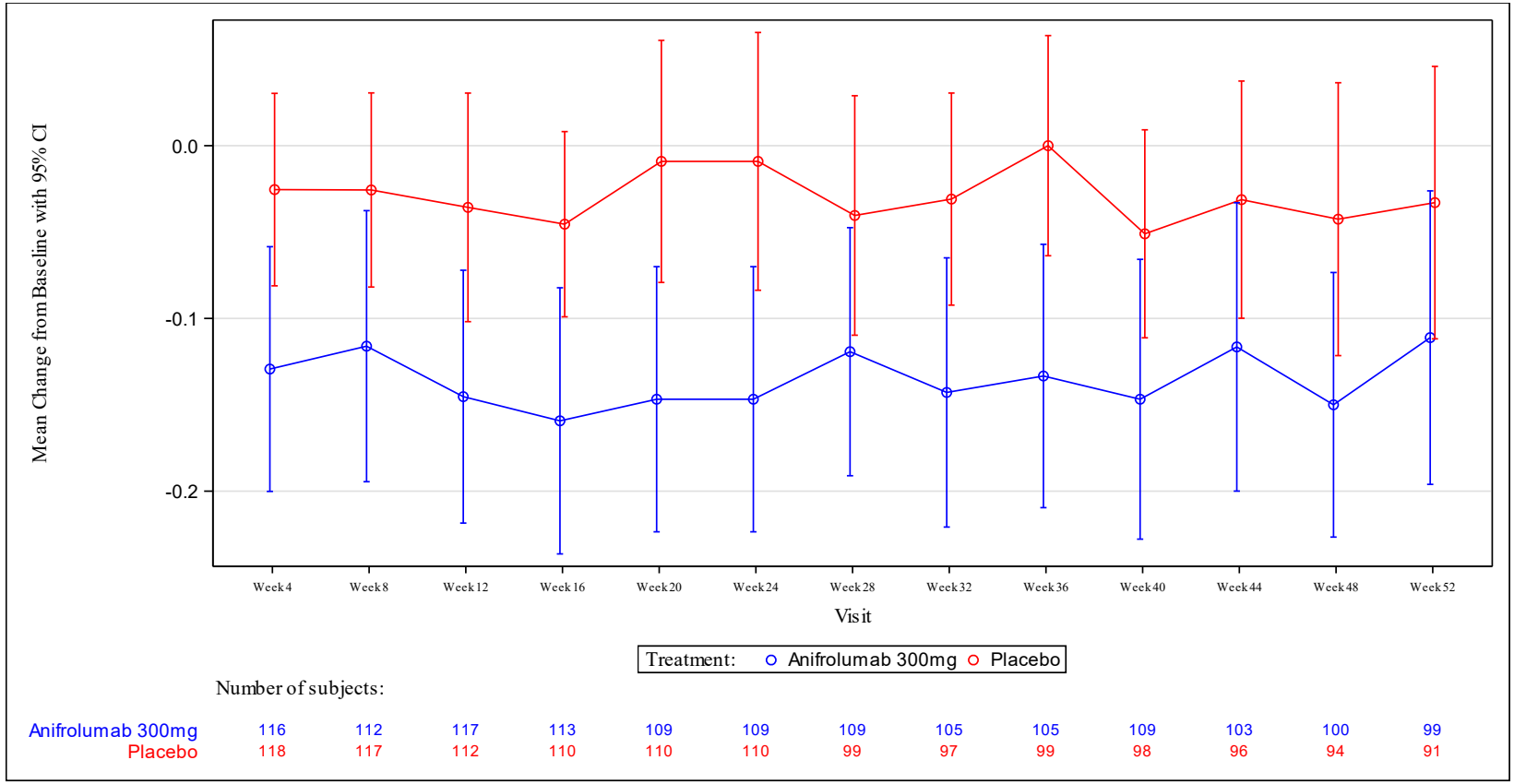
Number of subjects:

	Week 4	Week 8	Week 12	Week 16	Week 20	Week 24	Week 28	Week 32	Week 36	Week 40	Week 44	Week 48	Week 52
Anifrolumab 300mg	117	114	117	113	109	110	109	105	105	109	103	101	99
Placebo	119	117	113	112	112	111	100	98	99	99	96	94	91

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score Hematological
Full analysis set

	Anifrolumab 300mg (N=119)				Placebo (N=121)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	119	0.18 (0.41)	0	-	121	0.15 (0.38)	0	-
Week 4	116	0.06 (0.24)	116	-0.13 (0.39)	118	0.12 (0.35)	118	-0.03 (0.31)
Week 8	112	0.07 (0.26)	112	-0.12 (0.42)	117	0.12 (0.33)	117	-0.03 (0.31)
Week 12	117	0.04 (0.20)	117	-0.15 (0.40)	112	0.10 (0.35)	112	-0.04 (0.35)
Week 16	113	0.04 (0.19)	113	-0.16 (0.41)	110	0.07 (0.26)	110	-0.05 (0.28)
Week 20	109	0.04 (0.19)	109	-0.15 (0.40)	110	0.14 (0.39)	110	-0.01 (0.37)
Week 24	109	0.04 (0.19)	109	-0.15 (0.40)	110	0.14 (0.37)	110	-0.01 (0.39)
Week 28	109	0.06 (0.25)	109	-0.12 (0.38)	99	0.12 (0.36)	99	-0.04 (0.35)
Week 32	105	0.06 (0.23)	105	-0.14 (0.40)	97	0.11 (0.35)	97	-0.03 (0.30)
Week 36	105	0.04 (0.19)	105	-0.13 (0.39)	99	0.14 (0.38)	99	0.00 (0.32)
Week 40	109	0.04 (0.19)	109	-0.15 (0.43)	98	0.09 (0.32)	98	-0.05 (0.30)
Week 44	103	0.06 (0.24)	103	-0.12 (0.43)	96	0.10 (0.34)	96	-0.03 (0.34)
Week 48	100	0.04 (0.20)	100	-0.15 (0.39)	94	0.12 (0.35)	94	-0.04 (0.39)
Week 52	99	0.08 (0.27)	99	-0.11 (0.43)	91	0.13 (0.37)	91	-0.03 (0.38)

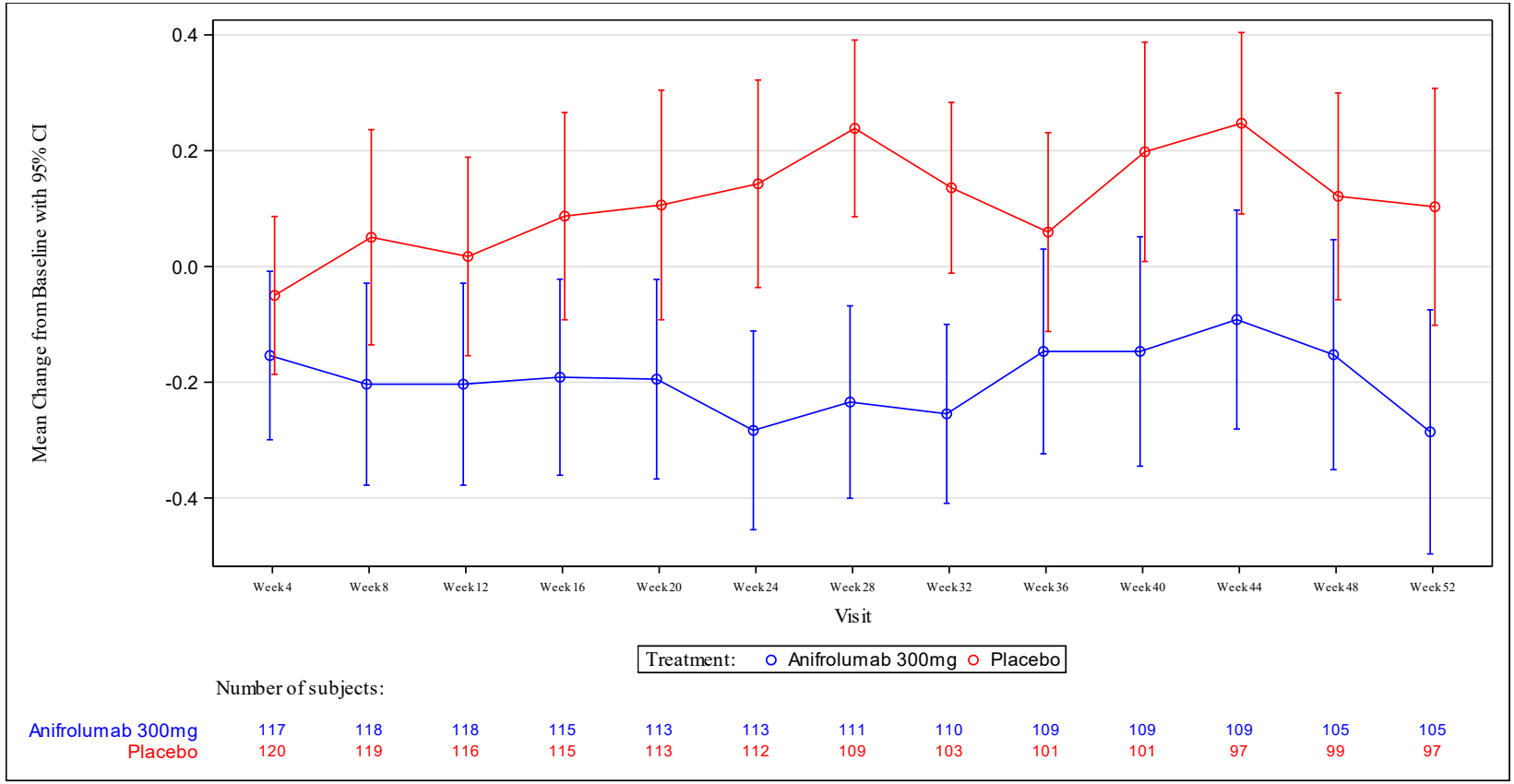
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Total Organ Score Hematological
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score Immunology
Full analysis set

	Anifrolumab 300mg (N=119)				Placebo (N=121)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	119	2.07 (1.58)	0	-	121	1.79 (1.63)	0	-
Week 4	117	1.90 (1.51)	117	-0.15 (0.79)	120	1.72 (1.58)	120	-0.05 (0.75)
Week 8	118	1.86 (1.52)	118	-0.20 (0.96)	119	1.82 (1.65)	119	0.05 (1.02)
Week 12	118	1.86 (1.50)	118	-0.20 (0.96)	116	1.81 (1.63)	116	0.02 (0.93)
Week 16	115	1.86 (1.52)	115	-0.19 (0.92)	115	1.88 (1.70)	115	0.09 (0.97)
Week 20	113	1.91 (1.54)	113	-0.19 (0.92)	113	1.89 (1.69)	113	0.11 (1.06)
Week 24	113	1.81 (1.51)	113	-0.28 (0.92)	112	1.91 (1.66)	112	0.14 (0.96)
Week 28	111	1.86 (1.49)	111	-0.23 (0.88)	109	2.02 (1.67)	109	0.24 (0.80)
Week 32	110	1.80 (1.51)	110	-0.25 (0.82)	103	1.86 (1.62)	103	0.14 (0.75)
Week 36	109	1.89 (1.51)	109	-0.15 (0.93)	101	1.78 (1.62)	101	0.06 (0.87)
Week 40	109	1.93 (1.46)	109	-0.15 (1.04)	101	1.92 (1.60)	101	0.20 (0.96)
Week 44	109	1.98 (1.58)	109	-0.09 (1.00)	97	2.00 (1.66)	97	0.25 (0.78)
Week 48	105	1.92 (1.52)	105	-0.15 (1.03)	99	1.88 (1.69)	99	0.12 (0.90)
Week 52	105	1.77 (1.53)	105	-0.29 (1.09)	97	1.88 (1.63)	97	0.10 (1.02)

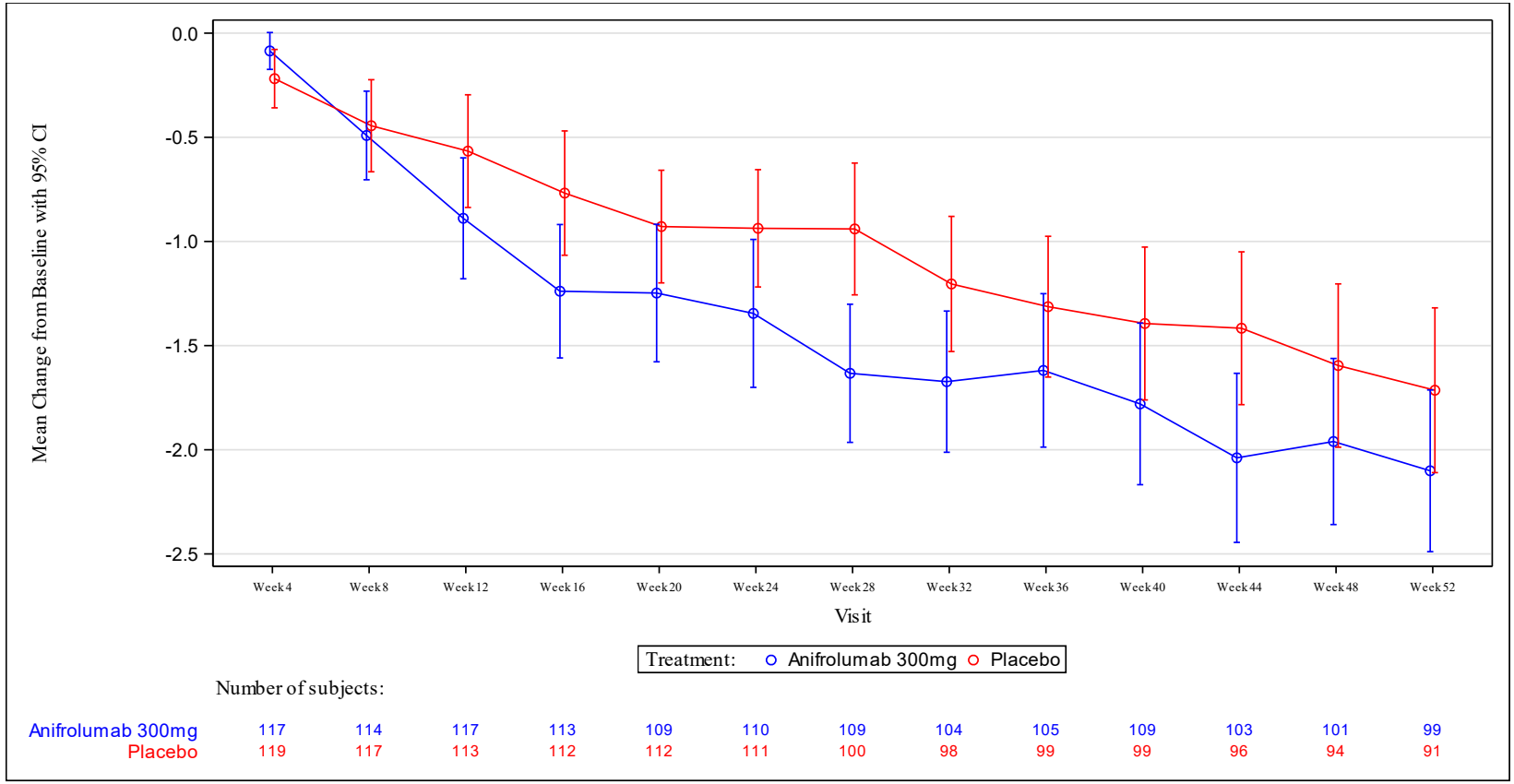
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Total Organ Score Immunology
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score Mucocutaneous
Full analysis set

	Anifrolumab 300mg (N=119)				Placebo (N=121)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	119	3.85 (1.61)	0	-	121	3.93 (1.63)	0	-
Week 4	117	3.76 (1.58)	117	-0.09 (0.48)	119	3.70 (1.68)	119	-0.22 (0.77)
Week 8	114	3.32 (1.61)	114	-0.49 (1.15)	117	3.45 (1.79)	117	-0.44 (1.21)
Week 12	117	2.96 (1.75)	117	-0.89 (1.59)	113	3.31 (1.87)	113	-0.57 (1.45)
Week 16	113	2.62 (1.67)	113	-1.24 (1.72)	112	3.14 (1.89)	112	-0.77 (1.59)
Week 20	109	2.61 (1.62)	109	-1.25 (1.74)	112	2.98 (1.72)	112	-0.93 (1.44)
Week 24	110	2.55 (1.65)	110	-1.35 (1.88)	111	2.97 (1.70)	111	-0.94 (1.50)
Week 28	109	2.22 (1.47)	109	-1.63 (1.75)	100	2.96 (1.74)	100	-0.94 (1.59)
Week 32	104	2.15 (1.52)	104	-1.67 (1.74)	98	2.65 (1.81)	98	-1.20 (1.62)
Week 36	105	2.19 (1.70)	105	-1.62 (1.90)	99	2.57 (1.81)	99	-1.31 (1.69)
Week 40	109	2.06 (1.67)	109	-1.78 (2.04)	99	2.46 (1.76)	99	-1.39 (1.84)
Week 44	103	1.81 (1.65)	103	-2.04 (2.08)	96	2.44 (1.77)	96	-1.42 (1.81)
Week 48	101	1.84 (1.59)	101	-1.96 (2.02)	94	2.32 (1.77)	94	-1.60 (1.91)
Week 52	99	1.70 (1.57)	99	-2.10 (1.95)	91	2.18 (1.78)	91	-1.71 (1.90)

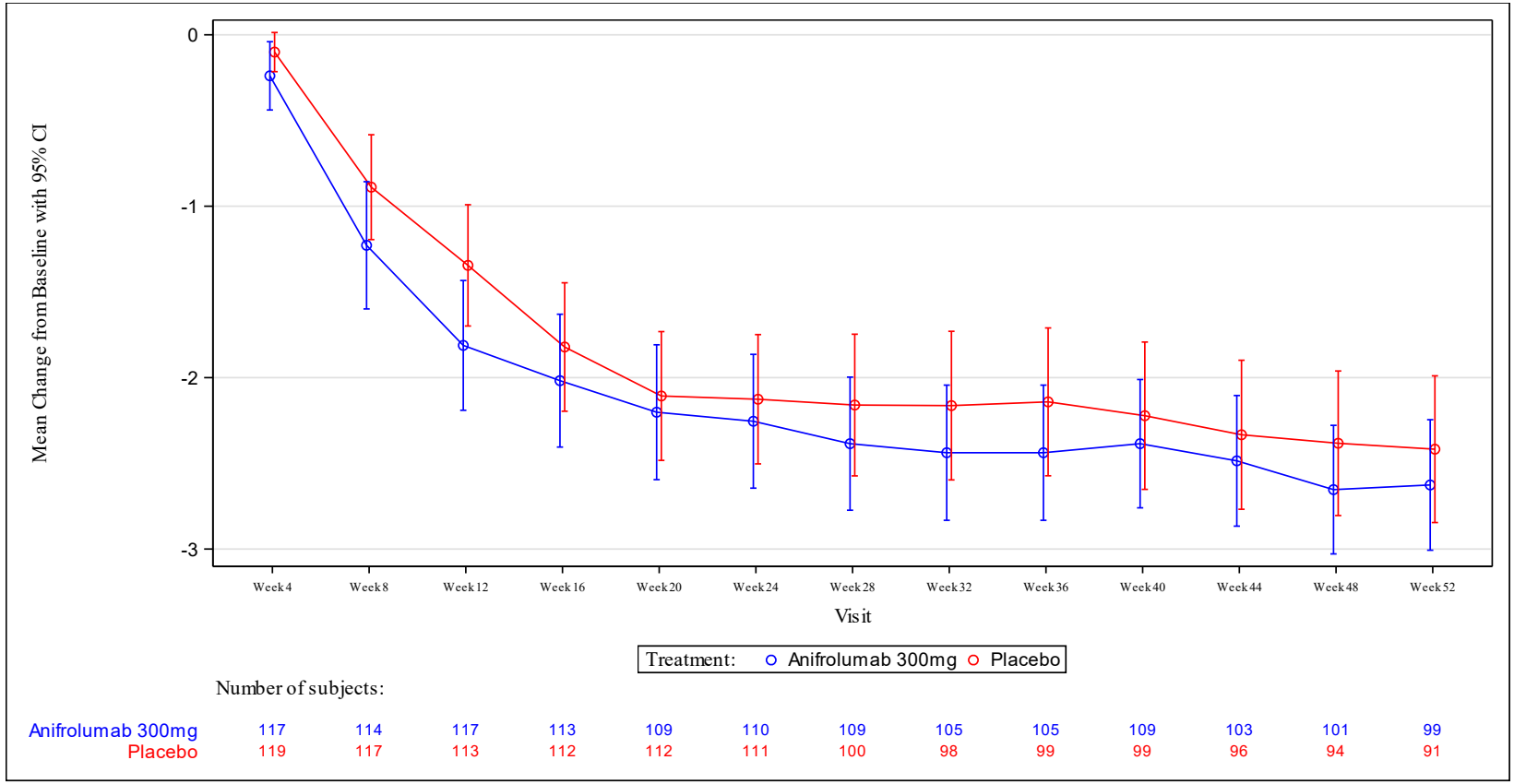
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Total Organ Score Mucocutaneous
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score Musculoskeletal
Full analysis set

	Anifrolumab 300mg (N=119)				Placebo (N=121)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	119	3.73 (1.13)	0	-	121	3.87 (1.15)	0	-
Week 4	117	3.49 (1.44)	117	-0.24 (1.09)	119	3.76 (1.31)	119	-0.10 (0.63)
Week 8	114	2.49 (1.95)	114	-1.23 (2.00)	117	2.97 (1.98)	117	-0.89 (1.67)
Week 12	117	1.91 (2.01)	117	-1.81 (2.07)	113	2.55 (2.14)	113	-1.35 (1.90)
Week 16	113	1.70 (1.99)	113	-2.02 (2.08)	112	2.04 (2.15)	112	-1.82 (2.00)
Week 20	109	1.50 (1.95)	109	-2.20 (2.07)	112	1.75 (2.13)	112	-2.11 (2.01)
Week 24	110	1.45 (1.93)	110	-2.25 (2.07)	111	1.77 (2.14)	111	-2.13 (2.01)
Week 28	109	1.32 (1.89)	109	-2.39 (2.05)	100	1.72 (2.07)	100	-2.16 (2.08)
Week 32	105	1.26 (1.87)	105	-2.44 (2.04)	98	1.71 (2.07)	98	-2.16 (2.16)
Week 36	105	1.30 (1.88)	105	-2.44 (2.04)	99	1.78 (2.15)	99	-2.14 (2.16)
Week 40	109	1.32 (1.89)	109	-2.39 (1.97)	99	1.70 (2.15)	99	-2.22 (2.15)
Week 44	103	1.24 (1.86)	103	-2.49 (1.95)	96	1.58 (2.13)	96	-2.33 (2.15)
Week 48	101	1.07 (1.78)	101	-2.65 (1.90)	94	1.53 (2.12)	94	-2.38 (2.06)
Week 52	99	1.05 (1.77)	99	-2.63 (1.91)	91	1.49 (2.12)	91	-2.42 (2.06)

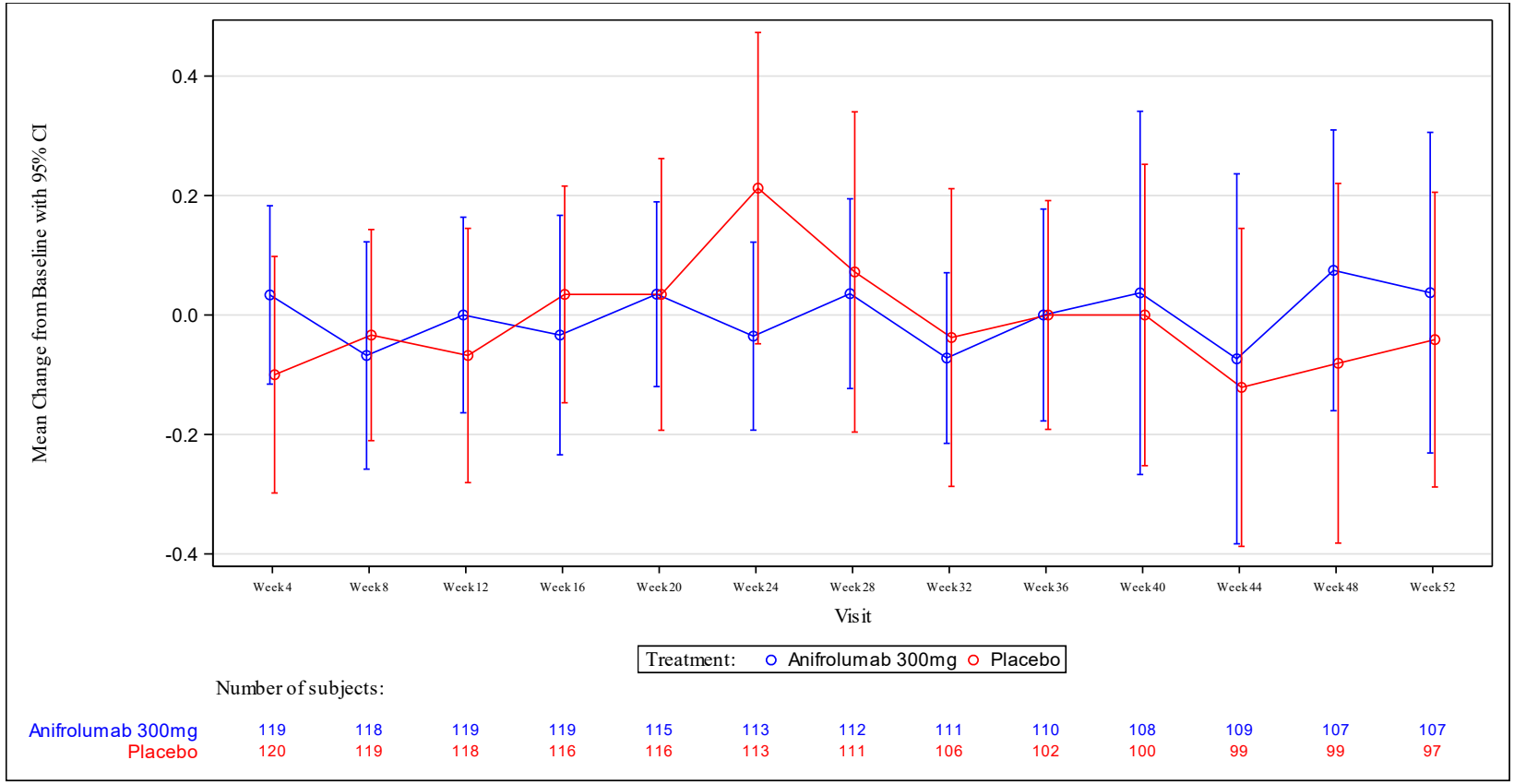
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Total Organ Score Musculoskeletal
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score Renal
Full analysis set

	Anifrolumab 300mg (N=119)				Placebo (N=121)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	119	0.30 (1.29)	0	-	121	0.53 (1.78)	0	-
Week 4	119	0.34 (1.43)	119	0.03 (0.82)	120	0.43 (1.70)	120	-0.10 (1.10)
Week 8	118	0.24 (1.31)	118	-0.07 (1.04)	119	0.50 (1.69)	119	-0.03 (0.97)
Week 12	119	0.30 (1.49)	119	0.00 (0.90)	118	0.47 (1.40)	118	-0.07 (1.17)
Week 16	119	0.27 (1.35)	119	-0.03 (1.10)	116	0.48 (1.60)	116	0.03 (0.99)
Week 20	115	0.28 (1.37)	115	0.03 (0.84)	116	0.48 (1.51)	116	0.03 (1.24)
Week 24	113	0.21 (0.90)	113	-0.04 (0.84)	113	0.67 (2.20)	113	0.21 (1.40)
Week 28	112	0.29 (1.39)	112	0.04 (0.85)	111	0.54 (1.91)	111	0.07 (1.43)
Week 32	111	0.18 (0.83)	111	-0.07 (0.76)	106	0.42 (1.65)	106	-0.04 (1.29)
Week 36	110	0.25 (1.12)	110	0.00 (0.94)	102	0.47 (1.52)	102	0.00 (0.97)
Week 40	108	0.22 (1.32)	108	0.04 (1.59)	100	0.48 (1.64)	100	0.00 (1.27)
Week 44	109	0.18 (1.26)	109	-0.07 (1.63)	99	0.28 (1.18)	99	-0.12 (1.33)
Week 48	107	0.30 (1.52)	107	0.07 (1.23)	99	0.32 (1.48)	99	-0.08 (1.51)
Week 52	107	0.26 (1.38)	107	0.04 (1.40)	97	0.37 (1.30)	97	-0.04 (1.22)

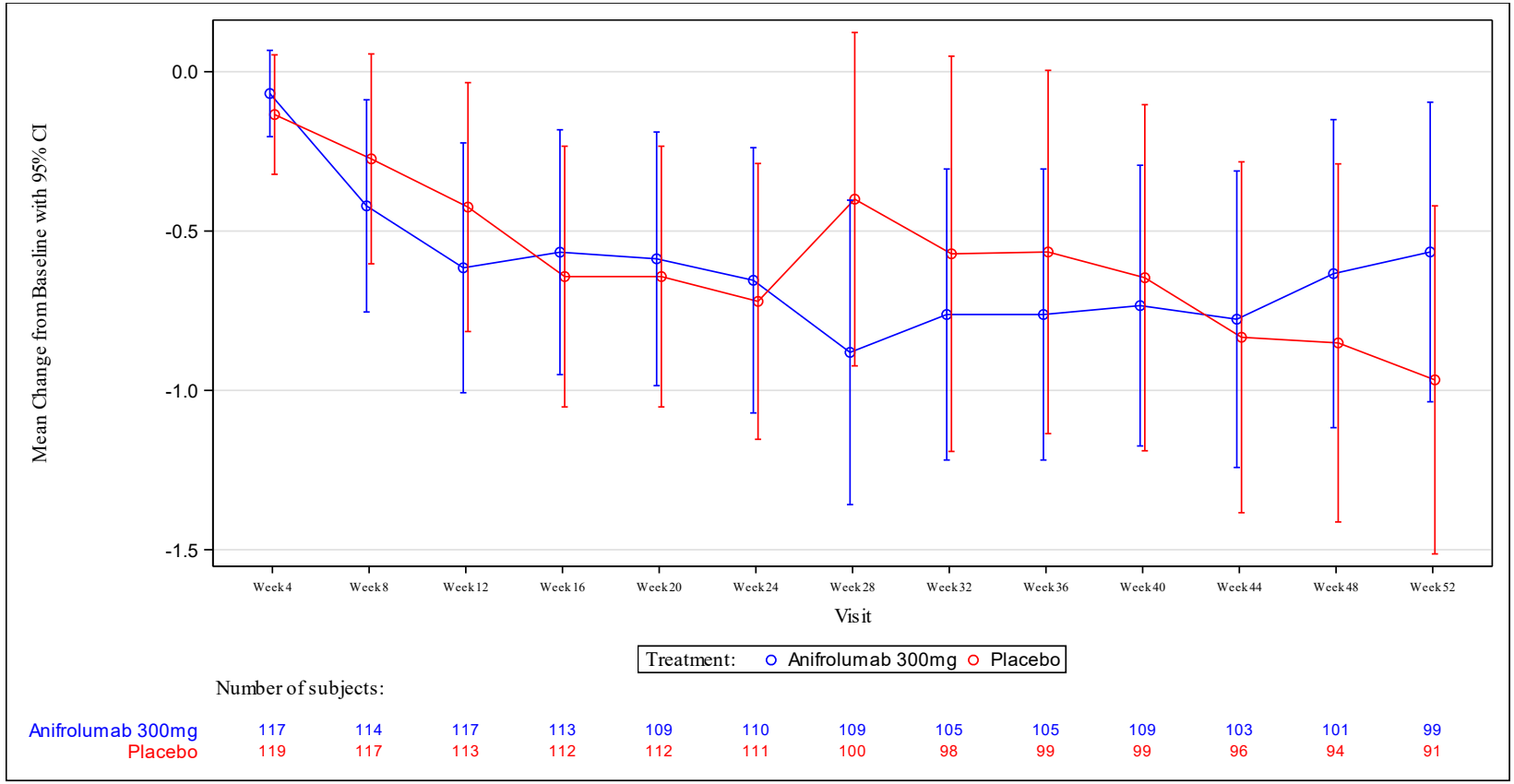
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Total Organ Score Renal
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score Vascular
Full analysis set

	Anifrolumab 300mg (N=119)				Placebo (N=121)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	119	1.08 (2.74)	0	-	121	0.99 (2.65)	0	-
Week 4	117	1.03 (2.69)	117	-0.07 (0.74)	119	0.87 (2.51)	119	-0.13 (1.03)
Week 8	114	0.70 (2.27)	114	-0.42 (1.79)	117	0.75 (2.34)	117	-0.27 (1.80)
Week 12	117	0.48 (1.91)	117	-0.62 (2.14)	113	0.57 (2.06)	113	-0.42 (2.10)
Week 16	113	0.42 (1.80)	113	-0.57 (2.06)	112	0.43 (1.81)	112	-0.64 (2.18)
Week 20	109	0.37 (1.68)	109	-0.59 (2.10)	112	0.36 (1.66)	112	-0.64 (2.18)
Week 24	110	0.36 (1.67)	110	-0.65 (2.20)	111	0.22 (1.30)	111	-0.72 (2.30)
Week 28	109	0.15 (1.08)	109	-0.88 (2.52)	100	0.56 (2.05)	100	-0.40 (2.64)
Week 32	105	0.38 (1.71)	105	-0.76 (2.36)	98	0.49 (1.93)	98	-0.57 (3.09)
Week 36	105	0.30 (1.54)	105	-0.76 (2.36)	99	0.48 (1.92)	99	-0.57 (2.86)
Week 40	109	0.29 (1.51)	109	-0.73 (2.32)	99	0.40 (1.76)	99	-0.65 (2.72)
Week 44	103	0.16 (1.11)	103	-0.78 (2.38)	96	0.17 (1.15)	96	-0.83 (2.72)
Week 48	101	0.32 (1.57)	101	-0.63 (2.45)	94	0.26 (1.41)	94	-0.85 (2.74)
Week 52	99	0.24 (1.38)	99	-0.57 (2.36)	91	0.18 (1.18)	91	-0.97 (2.62)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Total Organ Score Vascular
Full analysis set



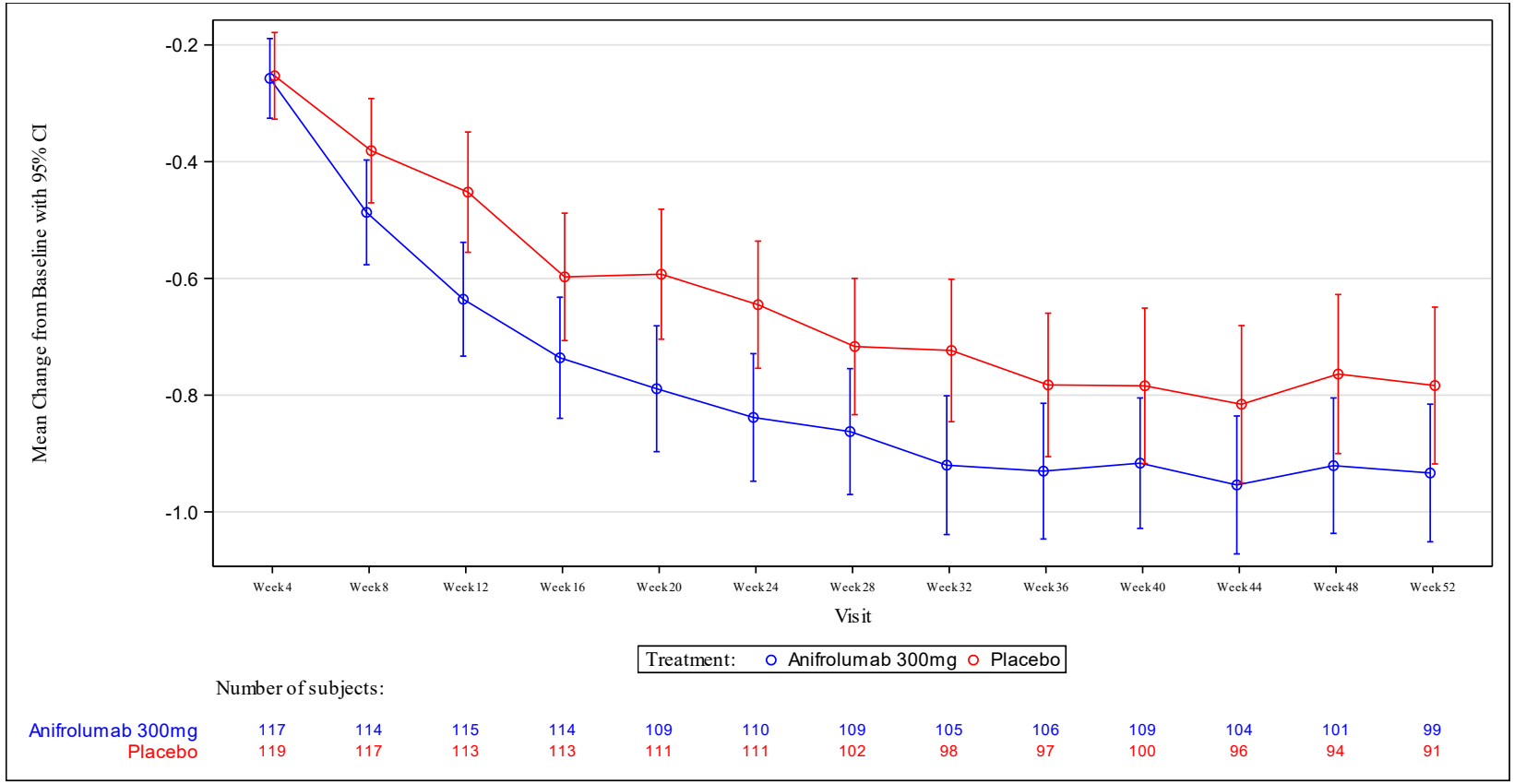
Number of subjects:

	Week 4	Week 8	Week 12	Week 16	Week 20	Week 24	Week 28	Week 32	Week 36	Week 40	Week 44	Week 48	Week 52
Anifrolumab 300mg	117	114	117	113	109	110	109	105	105	109	103	101	99
Placebo	119	117	113	112	112	111	100	98	99	99	96	94	91

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - PGA
Full analysis set

	Anifrolumab 300mg (N=119)				Placebo (N=121)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	119	1.65 (0.42)	0	-	121	1.76 (0.41)	0	-
Week 4	117	1.39 (0.49)	117	-0.26 (0.37)	119	1.51 (0.49)	119	-0.25 (0.41)
Week 8	114	1.14 (0.52)	114	-0.49 (0.48)	117	1.38 (0.54)	117	-0.38 (0.49)
Week 12	115	1.02 (0.55)	115	-0.64 (0.53)	113	1.32 (0.53)	113	-0.45 (0.55)
Week 16	114	0.92 (0.56)	114	-0.74 (0.56)	113	1.16 (0.52)	113	-0.60 (0.59)
Week 20	109	0.85 (0.52)	109	-0.79 (0.57)	111	1.18 (0.56)	111	-0.59 (0.59)
Week 24	110	0.81 (0.54)	110	-0.84 (0.58)	111	1.12 (0.53)	111	-0.65 (0.58)
Week 28	109	0.79 (0.55)	109	-0.86 (0.57)	102	1.05 (0.53)	102	-0.72 (0.59)
Week 32	105	0.74 (0.55)	105	-0.92 (0.61)	98	1.05 (0.58)	98	-0.72 (0.61)
Week 36	106	0.73 (0.58)	106	-0.93 (0.60)	97	0.99 (0.56)	97	-0.78 (0.61)
Week 40	109	0.74 (0.59)	109	-0.92 (0.59)	100	0.98 (0.56)	100	-0.78 (0.67)
Week 44	104	0.67 (0.55)	104	-0.95 (0.61)	96	0.95 (0.55)	96	-0.82 (0.67)
Week 48	101	0.73 (0.56)	101	-0.92 (0.59)	94	0.98 (0.57)	94	-0.76 (0.67)
Week 52	99	0.68 (0.55)	99	-0.93 (0.59)	91	0.96 (0.57)	91	-0.78 (0.65)

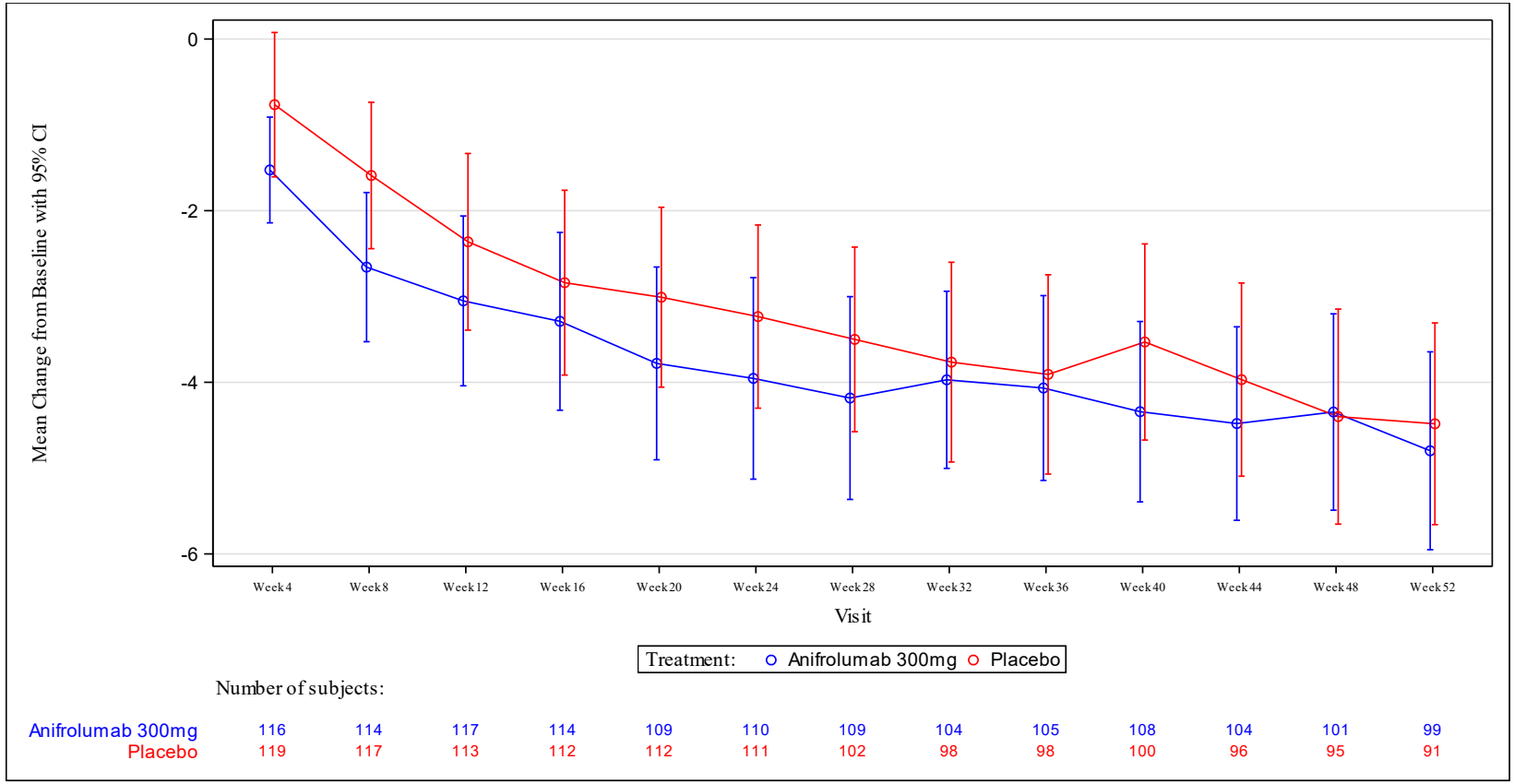
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - PGA
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - CLASI Total Activity Score
Full analysis set

	Anifrolumab 300mg (N=119)				Placebo (N=121)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	119	7.17 (7.07)	0	-	121	7.99 (8.37)	0	-
Week 4	116	5.64 (5.17)	116	-1.53 (3.35)	119	7.27 (8.35)	119	-0.76 (4.63)
Week 8	114	4.48 (4.15)	114	-2.66 (4.68)	117	6.46 (8.13)	117	-1.59 (4.66)
Week 12	117	4.18 (4.21)	117	-3.05 (5.40)	113	5.81 (7.58)	113	-2.36 (5.52)
Week 16	114	4.02 (4.10)	114	-3.29 (5.58)	112	5.38 (7.32)	112	-2.84 (5.75)
Week 20	109	3.50 (3.44)	109	-3.78 (5.92)	112	5.21 (7.30)	112	-3.01 (5.60)
Week 24	110	3.44 (3.71)	110	-3.95 (6.21)	111	5.01 (7.27)	111	-3.23 (5.67)
Week 28	109	3.19 (3.68)	109	-4.18 (6.22)	102	4.49 (6.86)	102	-3.50 (5.48)
Week 32	104	2.97 (3.40)	104	-3.97 (5.31)	98	4.66 (7.69)	98	-3.77 (5.81)
Week 36	105	2.92 (3.36)	105	-4.07 (5.56)	98	4.64 (7.65)	98	-3.91 (5.79)
Week 40	108	2.64 (3.20)	108	-4.34 (5.51)	100	4.80 (7.95)	100	-3.53 (5.76)
Week 44	104	2.84 (4.44)	104	-4.48 (5.80)	96	4.57 (7.41)	96	-3.97 (5.56)
Week 48	101	2.53 (3.27)	101	-4.35 (5.80)	95	4.18 (7.02)	95	-4.40 (6.15)
Week 52	99	2.60 (4.38)	99	-4.80 (5.78)	91	4.29 (7.06)	91	-4.48 (5.64)

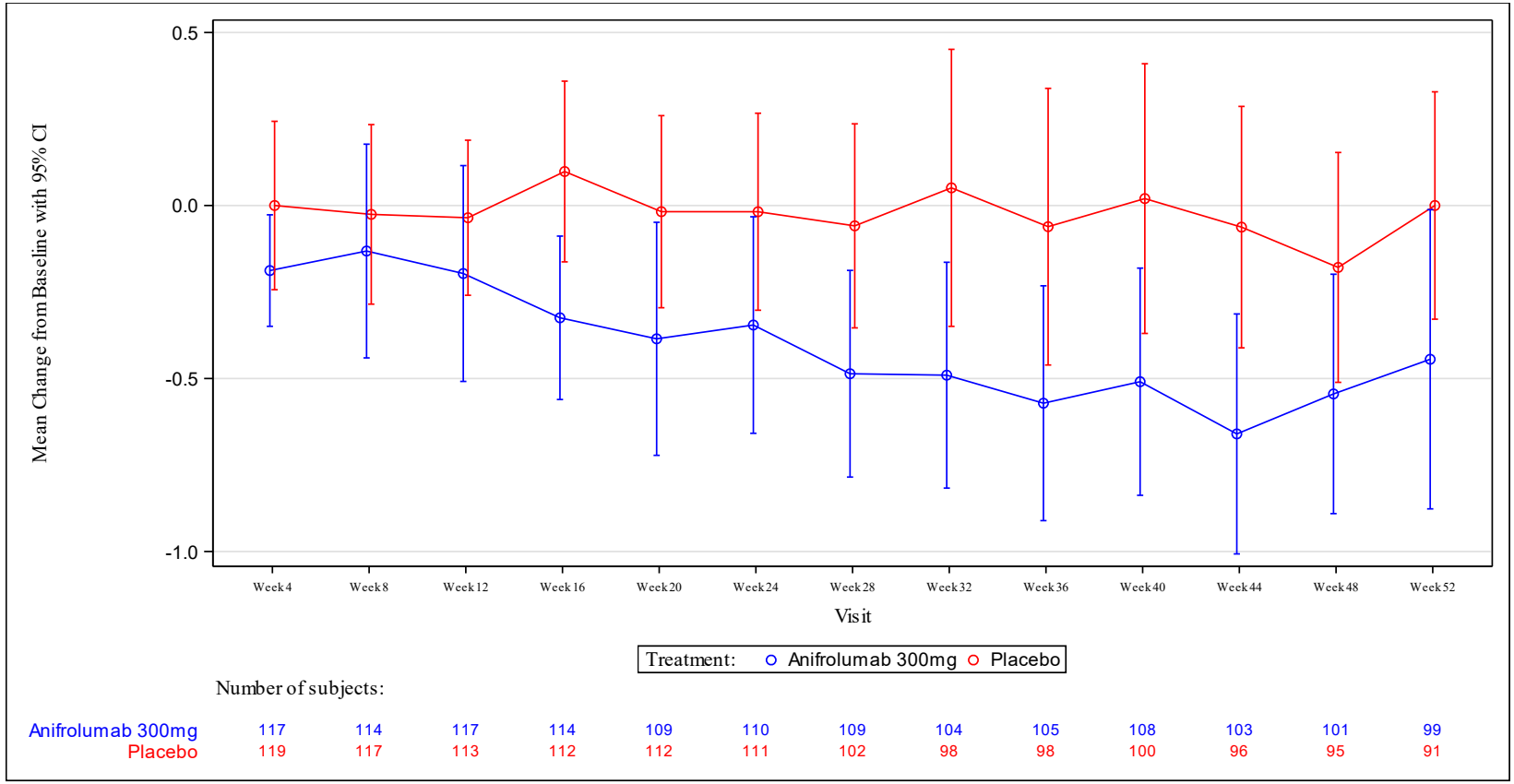
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - CLASI Total Activity Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - CLASI Total Damage Score
Full analysis set

	Anifrolumab 300mg (N=119)				Placebo (N=121)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	119	1.55 (3.54)	0	-	121	1.90 (4.49)	0	-
Week 4	117	1.31 (3.26)	117	-0.19 (0.88)	119	1.89 (4.59)	119	0.00 (1.34)
Week 8	114	1.40 (3.51)	114	-0.13 (1.66)	117	1.86 (4.60)	117	-0.03 (1.42)
Week 12	117	1.37 (3.41)	117	-0.20 (1.70)	113	1.85 (4.57)	113	-0.04 (1.20)
Week 16	114	1.21 (2.92)	114	-0.32 (1.27)	112	2.01 (4.81)	112	0.10 (1.39)
Week 20	109	1.26 (2.89)	109	-0.39 (1.77)	112	1.79 (4.77)	112	-0.02 (1.48)
Week 24	110	1.25 (2.91)	110	-0.35 (1.66)	111	1.85 (4.61)	111	-0.02 (1.51)
Week 28	109	1.16 (2.72)	109	-0.49 (1.57)	102	1.68 (4.45)	102	-0.06 (1.50)
Week 32	104	1.08 (2.61)	104	-0.49 (1.68)	98	1.92 (4.74)	98	0.05 (2.00)
Week 36	105	1.01 (2.39)	105	-0.57 (1.75)	98	1.81 (4.59)	98	-0.06 (1.99)
Week 40	108	1.04 (2.59)	108	-0.51 (1.72)	100	1.71 (4.52)	100	0.02 (1.96)
Week 44	103	0.92 (2.48)	103	-0.66 (1.77)	96	1.67 (4.50)	96	-0.06 (1.72)
Week 48	101	0.98 (2.56)	101	-0.54 (1.75)	95	1.56 (4.46)	95	-0.18 (1.63)
Week 52	99	1.24 (3.48)	99	-0.44 (2.17)	91	1.76 (4.62)	91	0.00 (1.58)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - CLASI Total Damage Score
Full analysis set



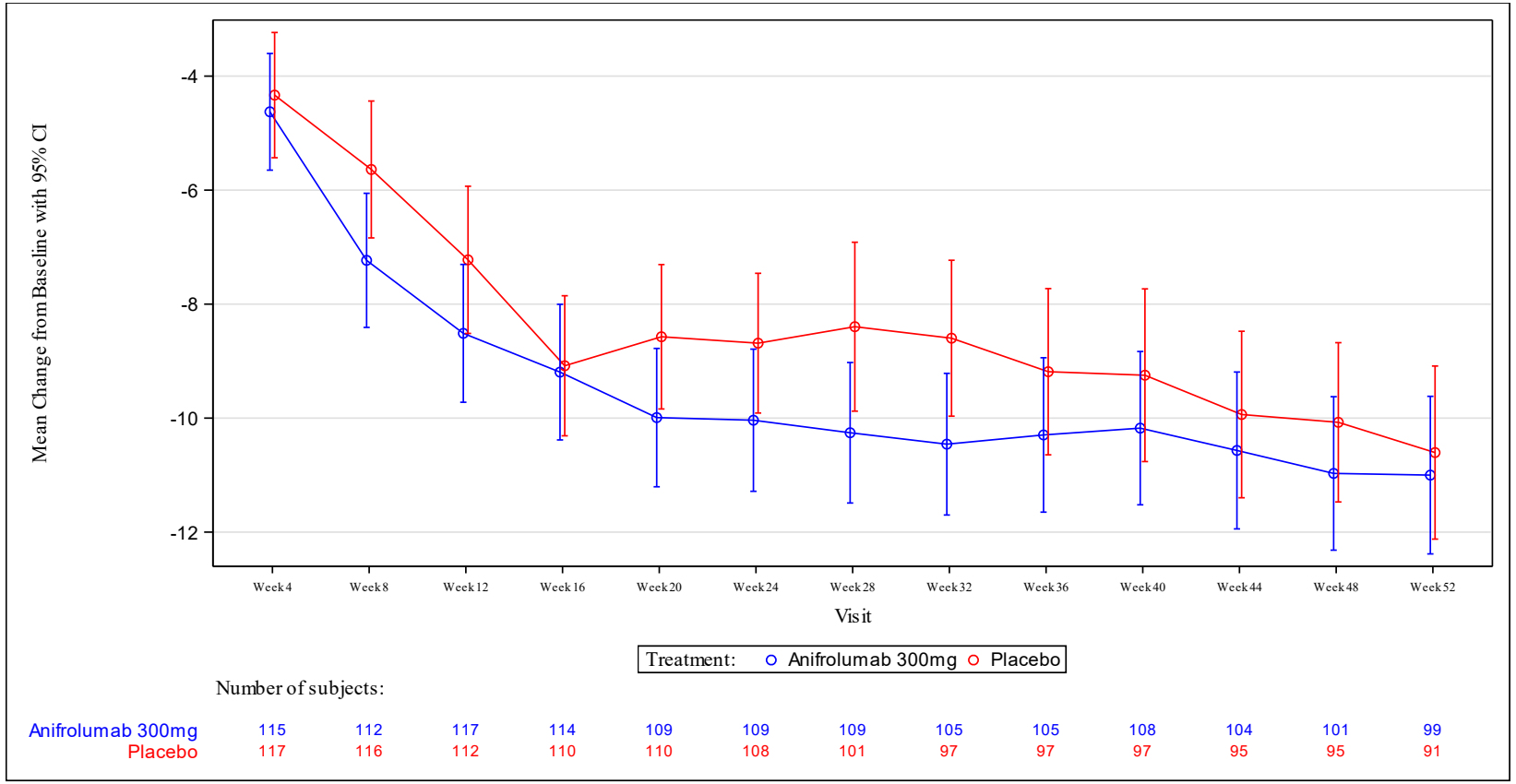
Number of subjects:

	Week 4	Week 8	Week 12	Week 16	Week 20	Week 24	Week 28	Week 32	Week 36	Week 40	Week 44	Week 48	Week 52
Anifrolumab 300mg	117	114	117	114	109	110	109	104	105	108	103	101	99
Placebo	119	117	113	112	112	111	102	98	98	100	96	95	91

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - BILAG Global Score
Full analysis set

	Anifrolumab 300mg (N=119)				Placebo (N=121)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	119	17.61 (4.38)	0	-	121	18.69 (5.07)	0	-
Week 4	115	12.90 (6.53)	115	-4.63 (5.54)	117	14.29 (6.58)	117	-4.33 (6.00)
Week 8	112	10.15 (6.49)	112	-7.23 (6.28)	116	13.08 (7.10)	116	-5.64 (6.53)
Week 12	117	9.01 (6.75)	117	-8.51 (6.60)	112	11.50 (6.37)	112	-7.22 (6.89)
Week 16	114	8.38 (6.42)	114	-9.19 (6.41)	110	9.56 (6.40)	110	-9.08 (6.50)
Week 20	109	7.58 (5.92)	109	-9.99 (6.39)	110	9.94 (6.52)	110	-8.57 (6.70)
Week 24	109	7.56 (6.12)	109	-10.04 (6.57)	108	10.02 (6.57)	108	-8.69 (6.43)
Week 28	109	7.26 (6.19)	109	-10.26 (6.49)	101	10.07 (6.91)	101	-8.40 (7.51)
Week 32	105	6.83 (6.32)	105	-10.46 (6.42)	97	10.03 (6.98)	97	-8.60 (6.78)
Week 36	105	7.27 (6.38)	105	-10.30 (7.00)	97	9.47 (7.43)	97	-9.19 (7.23)
Week 40	108	7.39 (6.60)	108	-10.18 (7.05)	97	9.24 (7.52)	97	-9.25 (7.52)
Week 44	104	6.88 (6.25)	104	-10.57 (7.08)	95	8.51 (6.80)	95	-9.94 (7.17)
Week 48	101	6.60 (6.31)	101	-10.97 (6.82)	95	8.19 (6.82)	95	-10.07 (6.86)
Week 52	99	6.40 (6.64)	99	-11.00 (6.93)	91	7.91 (6.98)	91	-10.60 (7.29)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - BILAG Global Score
Full analysis set



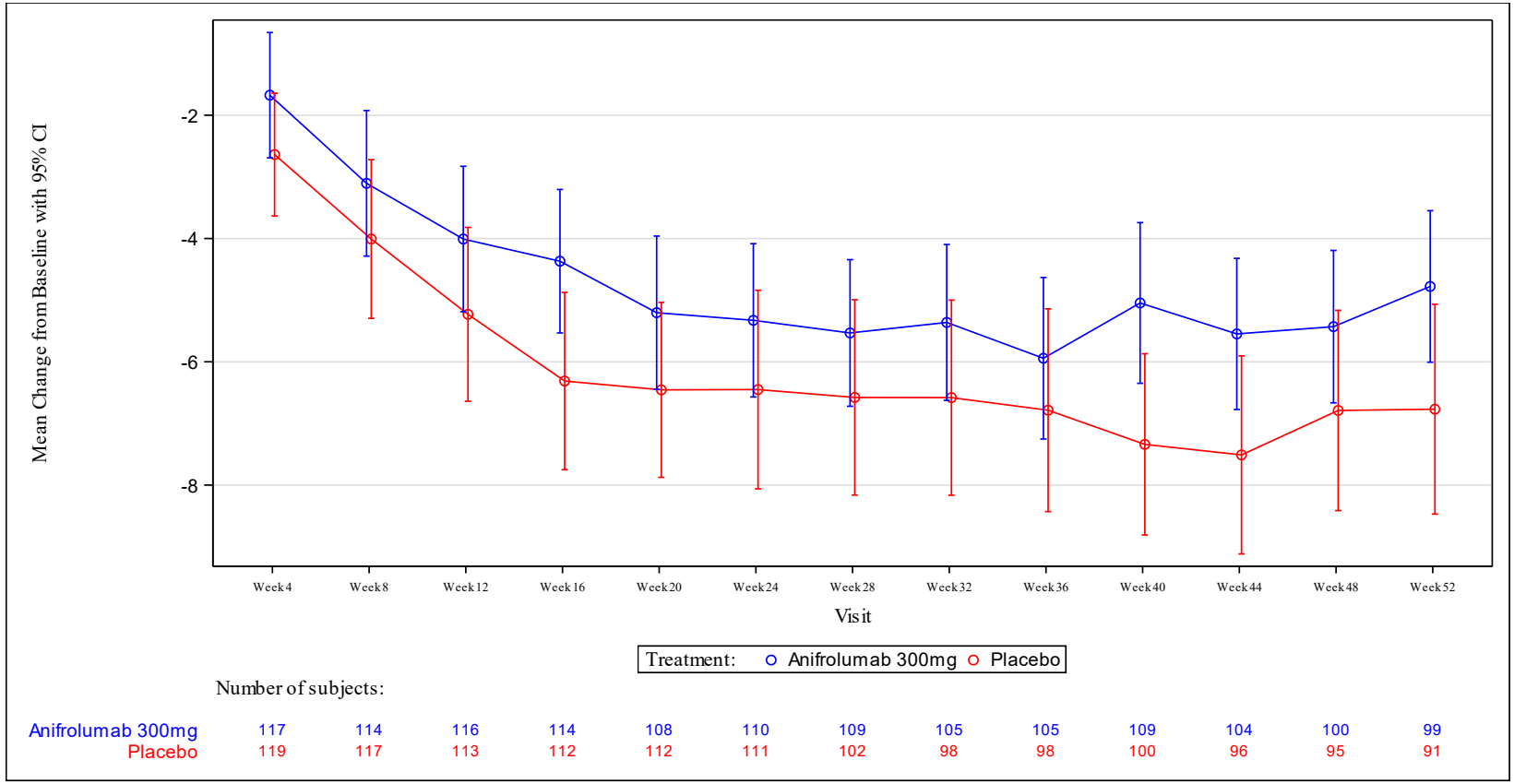
Number of subjects:

	Week 4	Week 8	Week 12	Week 16	Week 20	Week 24	Week 28	Week 32	Week 36	Week 40	Week 44	Week 48	Week 52
Anifrolumab 300mg	115	112	117	114	109	109	109	105	105	108	104	101	99
Placebo	117	116	112	110	110	108	101	97	97	97	95	95	91

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Tender Joint Count
Full analysis set

	Anifrolumab 300mg (N=119)				Placebo (N=121)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	119	8.66 (7.44)	0	-	121	11.24 (7.88)	0	-
Week 4	117	6.82 (7.57)	117	-1.68 (5.55)	119	8.60 (7.97)	119	-2.64 (5.48)
Week 8	114	5.20 (6.76)	114	-3.11 (6.36)	117	7.26 (7.44)	117	-4.01 (7.03)
Week 12	116	4.34 (6.63)	116	-4.01 (6.42)	113	6.19 (6.81)	113	-5.23 (7.57)
Week 16	114	4.17 (6.48)	114	-4.37 (6.27)	112	4.75 (6.23)	112	-6.31 (7.68)
Week 20	108	3.35 (5.72)	108	-5.20 (6.52)	112	4.71 (6.09)	112	-6.46 (7.58)
Week 24	110	3.42 (5.79)	110	-5.33 (6.58)	111	4.77 (6.45)	111	-6.45 (8.56)
Week 28	109	3.06 (5.77)	109	-5.53 (6.26)	102	4.36 (5.96)	102	-6.58 (8.07)
Week 32	105	2.84 (5.49)	105	-5.36 (6.53)	98	4.46 (6.26)	98	-6.58 (7.89)
Week 36	105	2.70 (5.44)	105	-5.94 (6.77)	98	4.12 (5.62)	98	-6.79 (8.20)
Week 40	109	3.55 (6.73)	109	-5.05 (6.87)	100	3.61 (5.12)	100	-7.34 (7.41)
Week 44	104	2.88 (5.63)	104	-5.55 (6.30)	96	3.51 (5.39)	96	-7.51 (7.93)
Week 48	100	3.43 (6.67)	100	-5.43 (6.23)	95	4.19 (6.34)	95	-6.79 (7.97)
Week 52	99	3.22 (6.20)	99	-4.78 (6.16)	91	3.95 (5.41)	91	-6.77 (8.17)

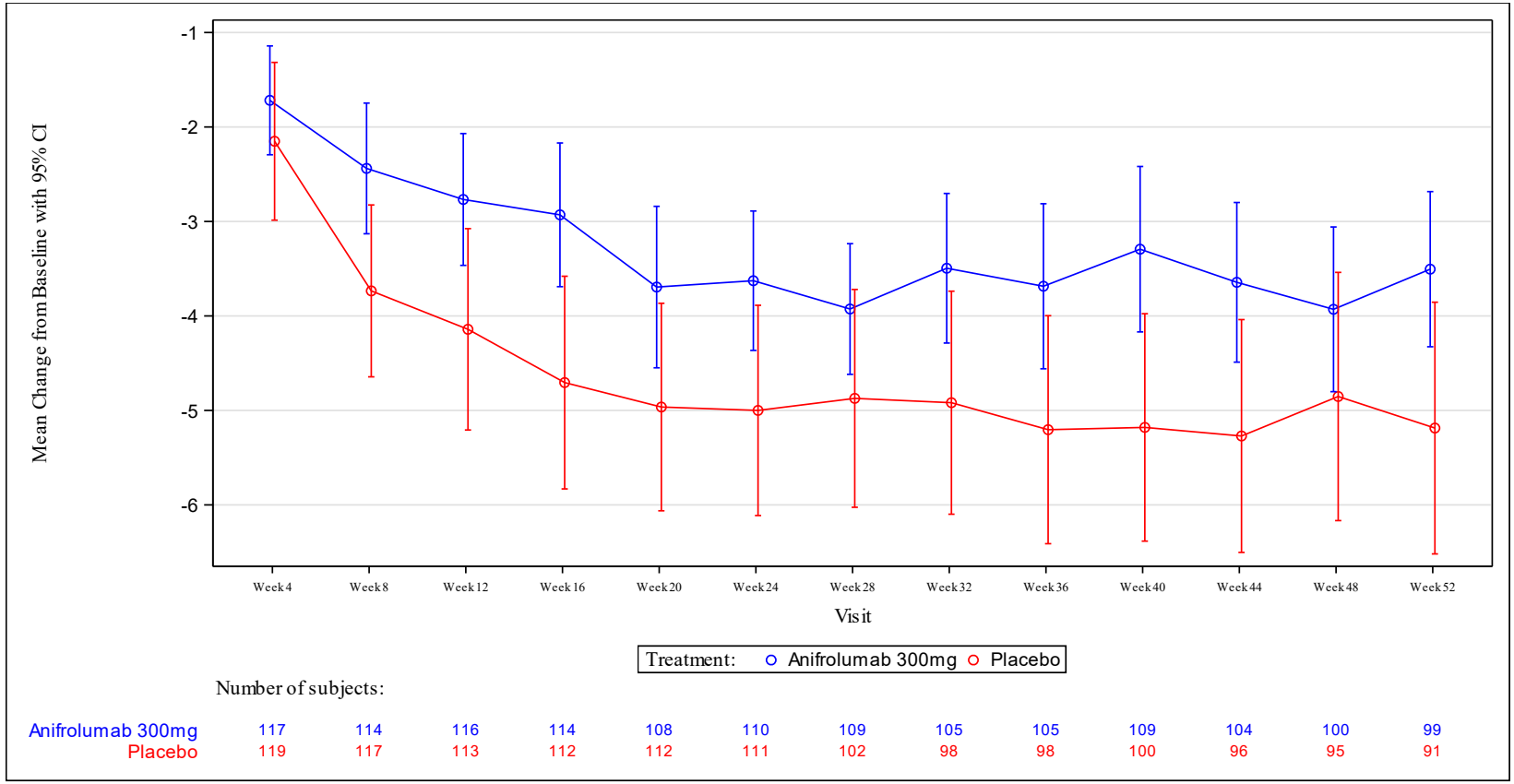
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Tender Joint Count
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Swollen Joint Count
Full analysis set

	Anifrolumab 300mg (N=119)				Placebo (N=121)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	119	6.08 (5.91)	0	-	121	7.31 (6.44)	0	-
Week 4	117	4.22 (5.97)	117	-1.72 (3.15)	119	5.08 (5.85)	119	-2.15 (4.60)
Week 8	114	3.22 (5.51)	114	-2.44 (3.73)	117	3.54 (5.07)	117	-3.74 (4.97)
Week 12	116	3.01 (5.84)	116	-2.77 (3.79)	113	3.25 (4.80)	113	-4.14 (5.72)
Week 16	114	2.88 (5.68)	114	-2.93 (4.10)	112	2.28 (3.90)	112	-4.71 (6.01)
Week 20	108	2.17 (4.95)	108	-3.69 (4.48)	112	2.36 (4.16)	112	-4.96 (5.86)
Week 24	110	2.35 (4.96)	110	-3.63 (3.90)	111	2.27 (4.36)	111	-5.00 (5.91)
Week 28	109	2.02 (4.63)	109	-3.93 (3.64)	102	2.27 (4.12)	102	-4.87 (5.87)
Week 32	105	1.97 (4.85)	105	-3.50 (4.09)	98	2.28 (4.44)	98	-4.92 (5.89)
Week 36	105	2.22 (5.31)	105	-3.69 (4.51)	98	1.95 (3.68)	98	-5.20 (6.02)
Week 40	109	2.63 (6.19)	109	-3.29 (4.61)	100	2.09 (4.13)	100	-5.18 (6.07)
Week 44	104	2.03 (4.96)	104	-3.64 (4.34)	96	1.91 (4.07)	96	-5.27 (6.08)
Week 48	100	2.20 (5.45)	100	-3.93 (4.39)	95	2.34 (4.85)	95	-4.85 (6.45)
Week 52	99	1.88 (4.63)	99	-3.51 (4.12)	91	2.02 (3.90)	91	-5.19 (6.40)

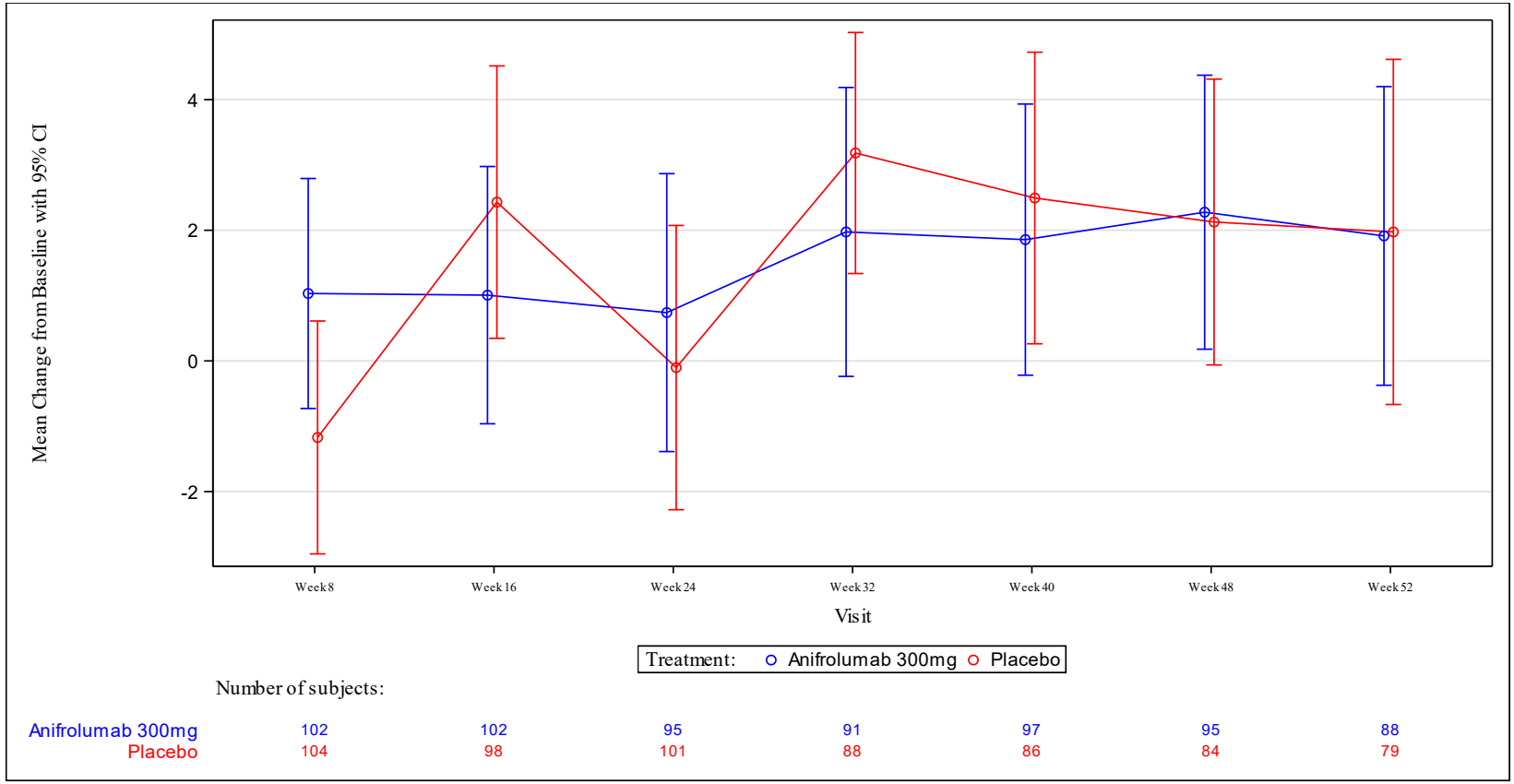
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Swollen Joint Count
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Mental Component Score
Full analysis set

	Anifrolumab 300mg (N=119)				Placebo (N=121)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	113	44.89 (11.81)	0	-	114	41.94 (10.85)	0	-
Week 8	107	45.95 (11.89)	102	1.03 (8.96)	107	40.92 (10.79)	104	-1.17 (9.17)
Week 16	108	45.73 (11.22)	102	1.01 (10.02)	102	44.48 (11.20)	98	2.43 (10.40)
Week 24	101	46.05 (12.30)	95	0.74 (10.44)	107	42.44 (12.25)	101	-0.10 (11.02)
Week 32	97	47.14 (11.16)	91	1.97 (10.62)	91	44.72 (10.60)	88	3.18 (8.71)
Week 40	103	46.51 (11.22)	97	1.86 (10.30)	90	43.62 (10.54)	86	2.49 (10.41)
Week 48	100	46.79 (11.15)	95	2.28 (10.29)	87	43.28 (9.92)	84	2.13 (10.08)
Week 52	94	46.30 (12.20)	88	1.91 (10.79)	82	43.23 (10.99)	79	1.97 (11.79)

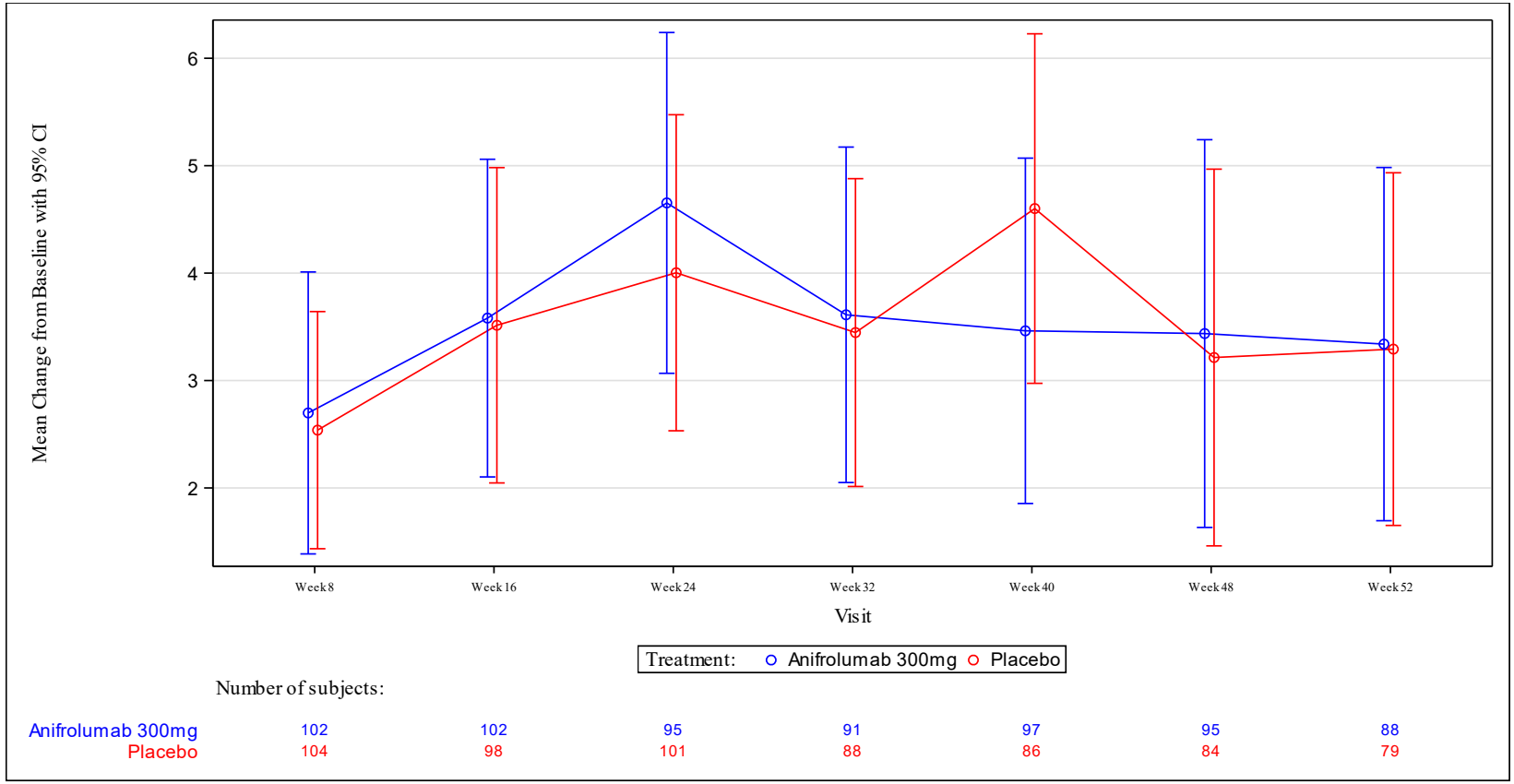
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Mental Component Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Physical Component Score
Full analysis set

	Anifrolumab 300mg (N=119)				Placebo (N=121)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	113	39.25 (8.24)	0	-	114	37.38 (9.75)	0	-
Week 8	107	42.34 (8.70)	102	2.70 (6.68)	107	40.34 (9.24)	104	2.54 (5.68)
Week 16	108	42.75 (8.75)	102	3.58 (7.53)	102	41.09 (9.11)	98	3.51 (7.32)
Week 24	101	44.50 (9.01)	95	4.65 (7.79)	107	41.75 (8.51)	101	4.00 (7.45)
Week 32	97	43.27 (8.67)	91	3.61 (7.50)	91	41.21 (8.19)	88	3.45 (6.76)
Week 40	103	43.25 (9.12)	97	3.46 (7.98)	90	42.42 (8.68)	86	4.60 (7.59)
Week 48	100	43.31 (9.41)	95	3.44 (8.86)	87	41.19 (8.98)	84	3.21 (8.08)
Week 52	94	43.62 (9.03)	88	3.34 (7.76)	82	42.03 (8.25)	79	3.29 (7.33)

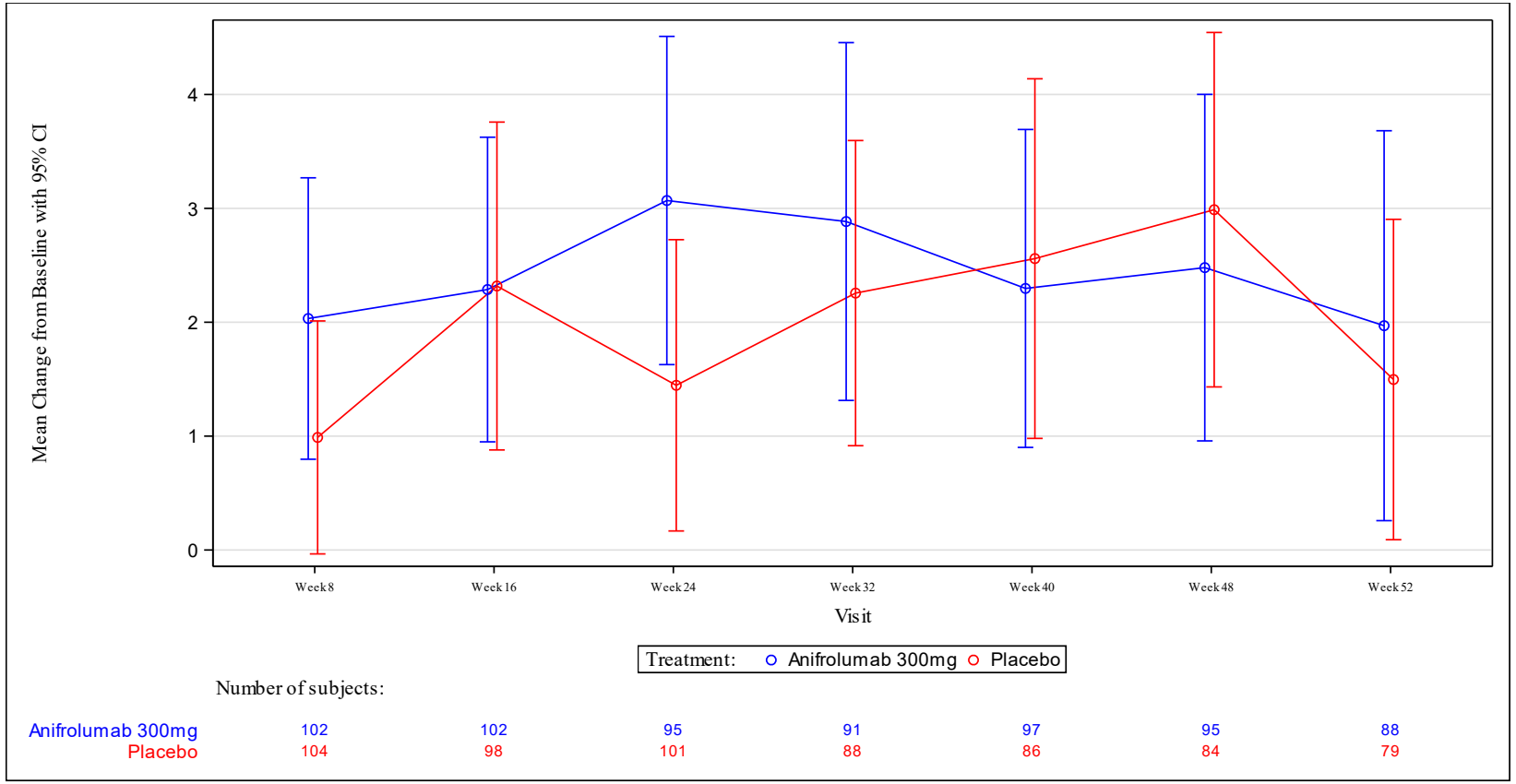
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Physical Component Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute General Health Score
Full analysis set

	Anifrolumab 300mg (N=119)				Placebo (N=121)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	113	39.25 (7.64)	0	-	114	38.18 (7.91)	0	-
Week 8	107	41.61 (8.40)	102	2.03 (6.29)	107	39.52 (7.47)	104	0.99 (5.26)
Week 16	108	41.48 (8.86)	102	2.29 (6.81)	102	40.65 (8.09)	98	2.32 (7.18)
Week 24	101	42.48 (9.29)	95	3.07 (7.07)	107	40.49 (7.98)	101	1.45 (6.48)
Week 32	97	42.04 (8.87)	91	2.88 (7.54)	91	40.64 (8.27)	88	2.26 (6.32)
Week 40	103	41.87 (8.21)	97	2.30 (6.93)	90	40.91 (8.29)	86	2.56 (7.36)
Week 48	100	41.83 (8.98)	95	2.48 (7.47)	87	41.47 (8.13)	84	2.99 (7.17)
Week 52	94	41.65 (9.89)	88	1.97 (8.08)	82	40.64 (8.50)	79	1.50 (6.28)

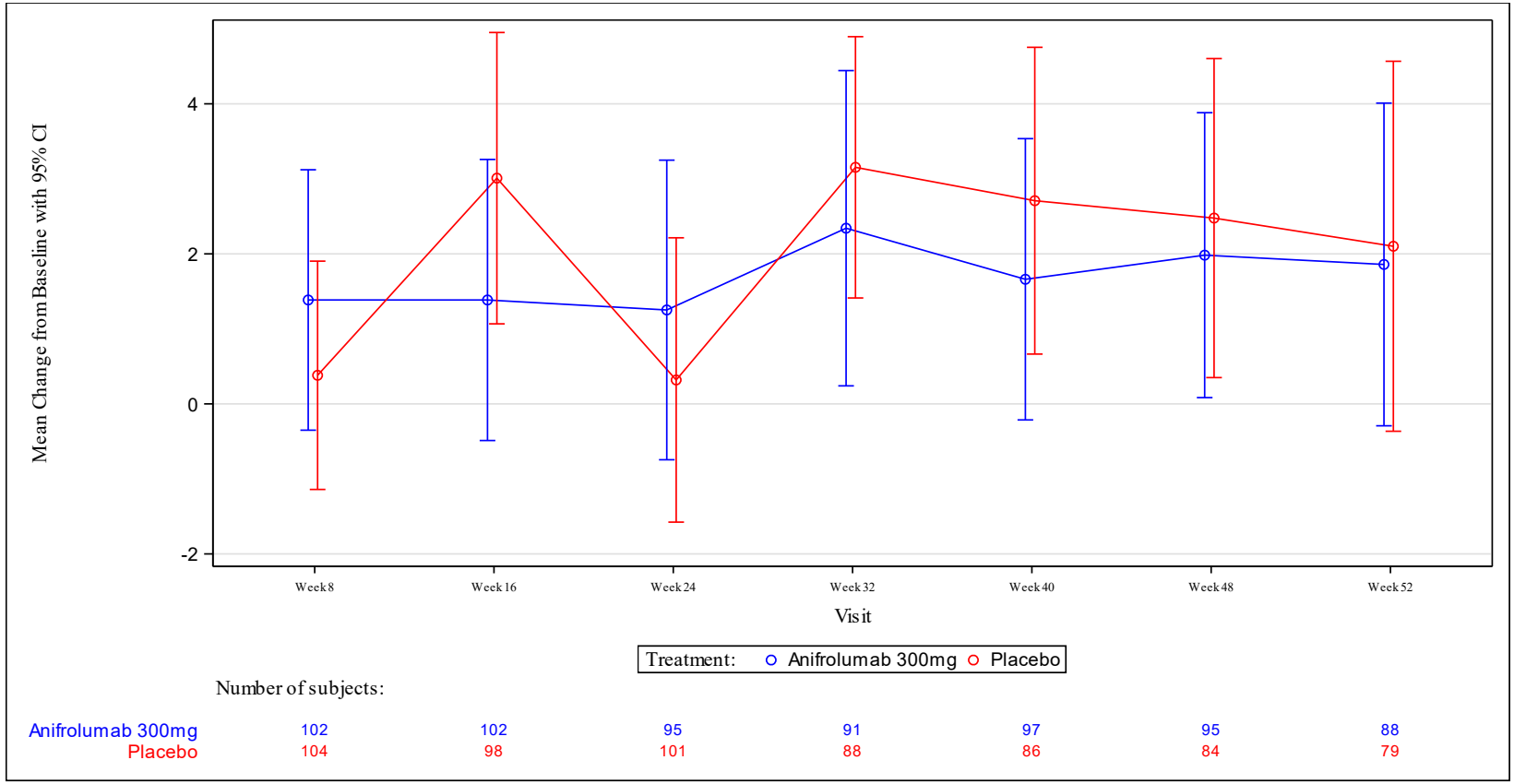
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute General Health Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Mental Health Score
Full analysis set

	Anifrolumab 300mg (N=119)				Placebo (N=121)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	113	45.00 (10.39)	0	-	114	42.57 (10.34)	0	-
Week 8	107	46.30 (10.83)	102	1.39 (8.84)	107	43.09 (9.88)	104	0.38 (7.83)
Week 16	108	46.18 (10.48)	102	1.39 (9.54)	102	45.50 (10.56)	98	3.01 (9.69)
Week 24	101	46.61 (11.41)	95	1.25 (9.80)	107	43.57 (10.52)	101	0.32 (9.60)
Week 32	97	47.43 (10.50)	91	2.34 (10.09)	91	45.60 (10.55)	88	3.15 (8.22)
Week 40	103	46.49 (10.25)	97	1.66 (9.30)	90	44.56 (10.02)	86	2.71 (9.54)
Week 48	100	46.77 (9.97)	95	1.98 (9.32)	87	44.56 (10.53)	84	2.48 (9.80)
Week 52	94	46.52 (10.93)	88	1.86 (10.15)	82	44.64 (10.44)	79	2.10 (11.01)

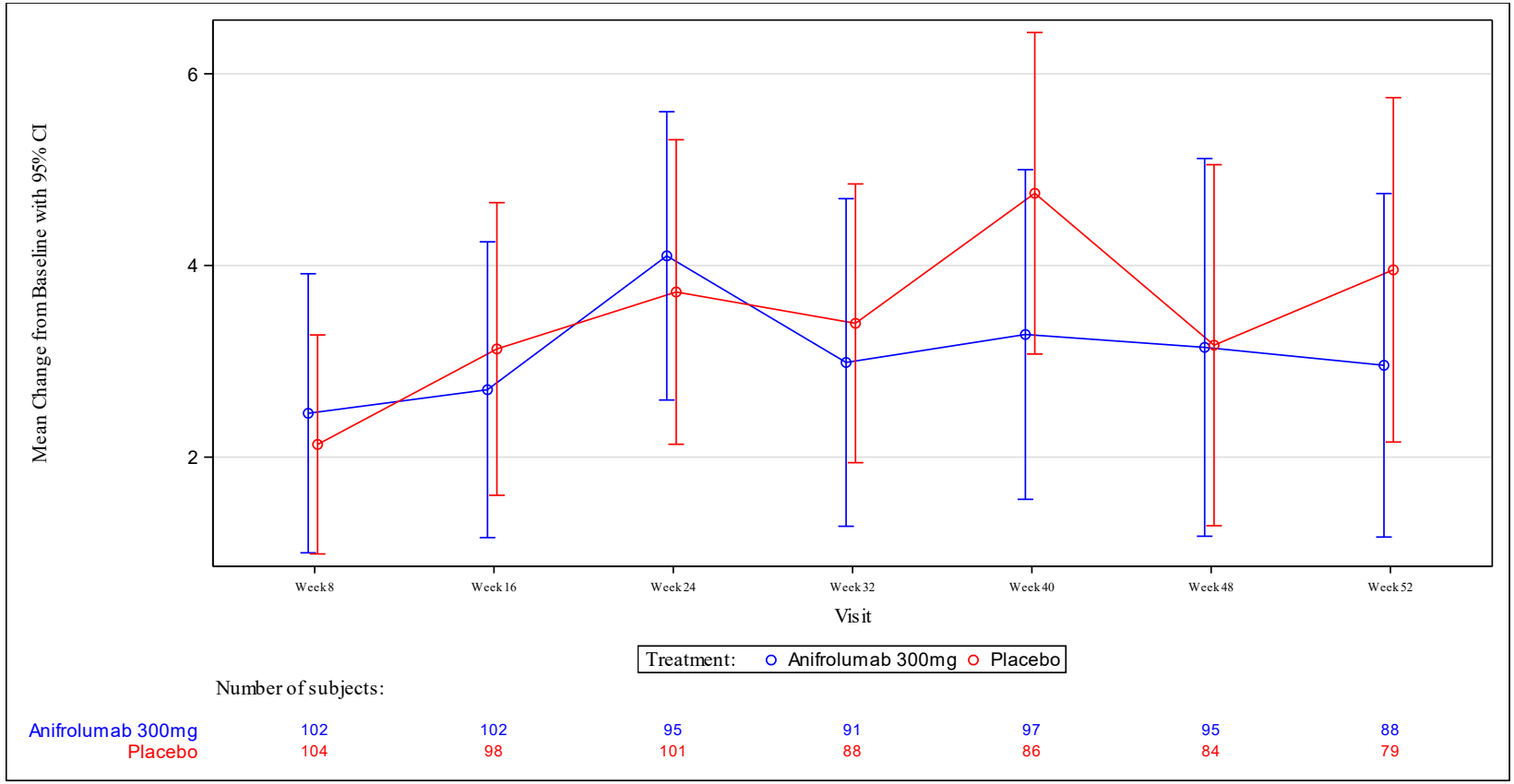
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Mental Health Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Physical Functioning Score
Full analysis set

	Anifrolumab 300mg (N=119)				Placebo (N=121)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	113	41.04 (9.45)	0	-	114	38.16 (10.91)	0	-
Week 8	107	43.63 (9.51)	102	2.46 (7.41)	107	40.83 (10.22)	104	2.13 (5.87)
Week 16	108	43.60 (9.67)	102	2.70 (7.86)	102	41.45 (9.71)	98	3.13 (7.62)
Week 24	101	45.64 (9.69)	95	4.10 (7.38)	107	42.13 (9.79)	101	3.72 (8.05)
Week 32	97	44.45 (10.01)	91	2.99 (8.21)	91	41.93 (9.58)	88	3.40 (6.86)
Week 40	103	44.34 (10.11)	97	3.28 (8.53)	90	42.81 (10.01)	86	4.75 (7.82)
Week 48	100	44.65 (9.50)	95	3.15 (9.67)	87	41.50 (10.19)	84	3.17 (8.68)
Week 52	94	44.73 (9.66)	88	2.96 (8.46)	82	43.08 (9.85)	79	3.95 (8.02)

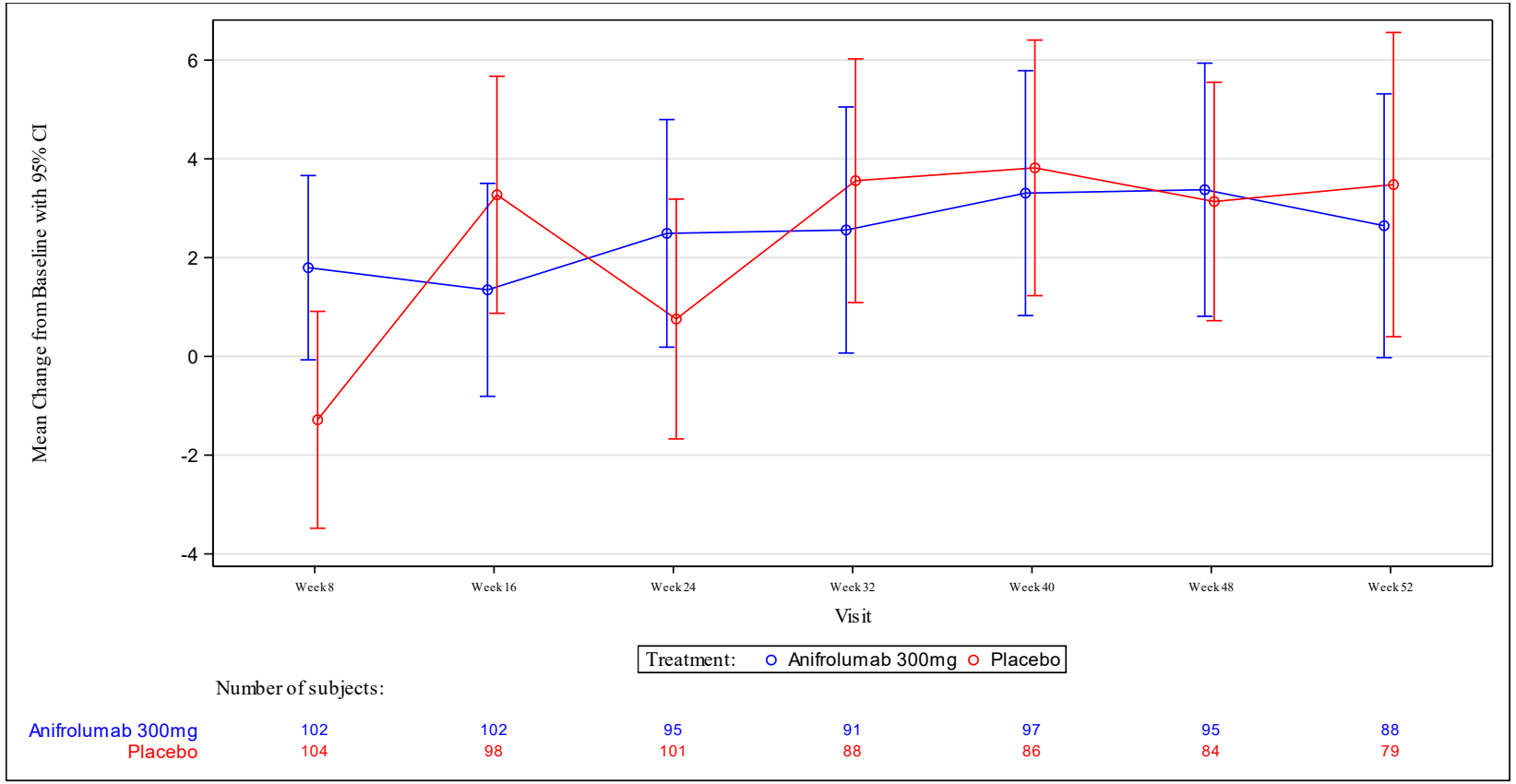
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Physical Functioning Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Role Emotional Score
Full analysis set

	Anifrolumab 300mg (N=119)				Placebo (N=121)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	113	41.22 (13.32)	0	-	114	38.03 (12.53)	0	-
Week 8	107	42.87 (12.69)	102	1.80 (9.50)	107	36.95 (11.93)	104	-1.28 (11.29)
Week 16	108	42.81 (12.15)	102	1.35 (10.98)	102	41.49 (12.40)	98	3.27 (11.97)
Week 24	101	43.92 (12.36)	95	2.49 (11.31)	107	39.16 (13.66)	101	0.76 (12.30)
Week 32	97	44.07 (11.58)	91	2.56 (11.96)	91	41.21 (12.03)	88	3.56 (11.64)
Week 40	103	43.93 (12.08)	97	3.31 (12.30)	90	40.97 (11.95)	86	3.82 (12.07)
Week 48	100	43.62 (12.12)	95	3.37 (12.58)	87	40.24 (10.88)	84	3.14 (11.12)
Week 52	94	43.62 (12.38)	88	2.65 (12.60)	82	40.42 (12.27)	79	3.48 (13.75)

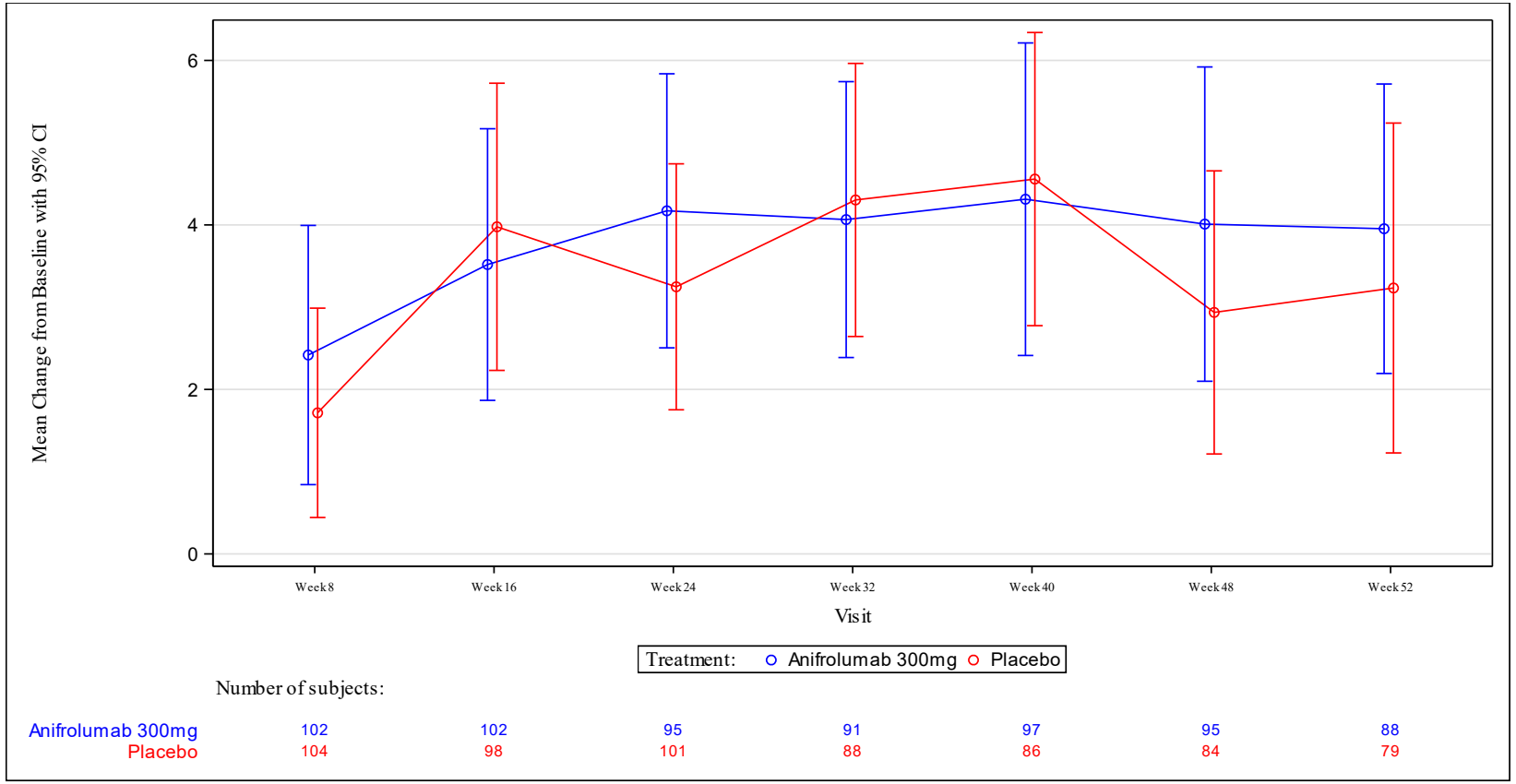
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Role Emotional Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Role Physical Score
Full analysis set

	Anifrolumab 300mg (N=119)				Placebo (N=121)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	113	38.79 (9.71)	0	-	114	36.69 (8.98)	0	-
Week 8	107	41.48 (9.34)	102	2.42 (8.02)	107	38.64 (8.75)	104	1.72 (6.54)
Week 16	108	42.54 (9.50)	102	3.52 (8.41)	102	40.78 (9.40)	98	3.98 (8.71)
Week 24	101	43.52 (9.09)	95	4.17 (8.18)	107	40.06 (8.62)	101	3.25 (7.57)
Week 32	97	43.30 (9.38)	91	4.06 (8.05)	91	41.08 (8.57)	88	4.30 (7.83)
Week 40	103	43.25 (9.41)	97	4.31 (9.43)	90	41.27 (8.77)	86	4.56 (8.31)
Week 48	100	42.90 (10.16)	95	4.01 (9.38)	87	39.71 (8.94)	84	2.94 (7.93)
Week 52	94	43.18 (8.92)	88	3.95 (8.31)	82	40.55 (8.90)	79	3.23 (8.95)

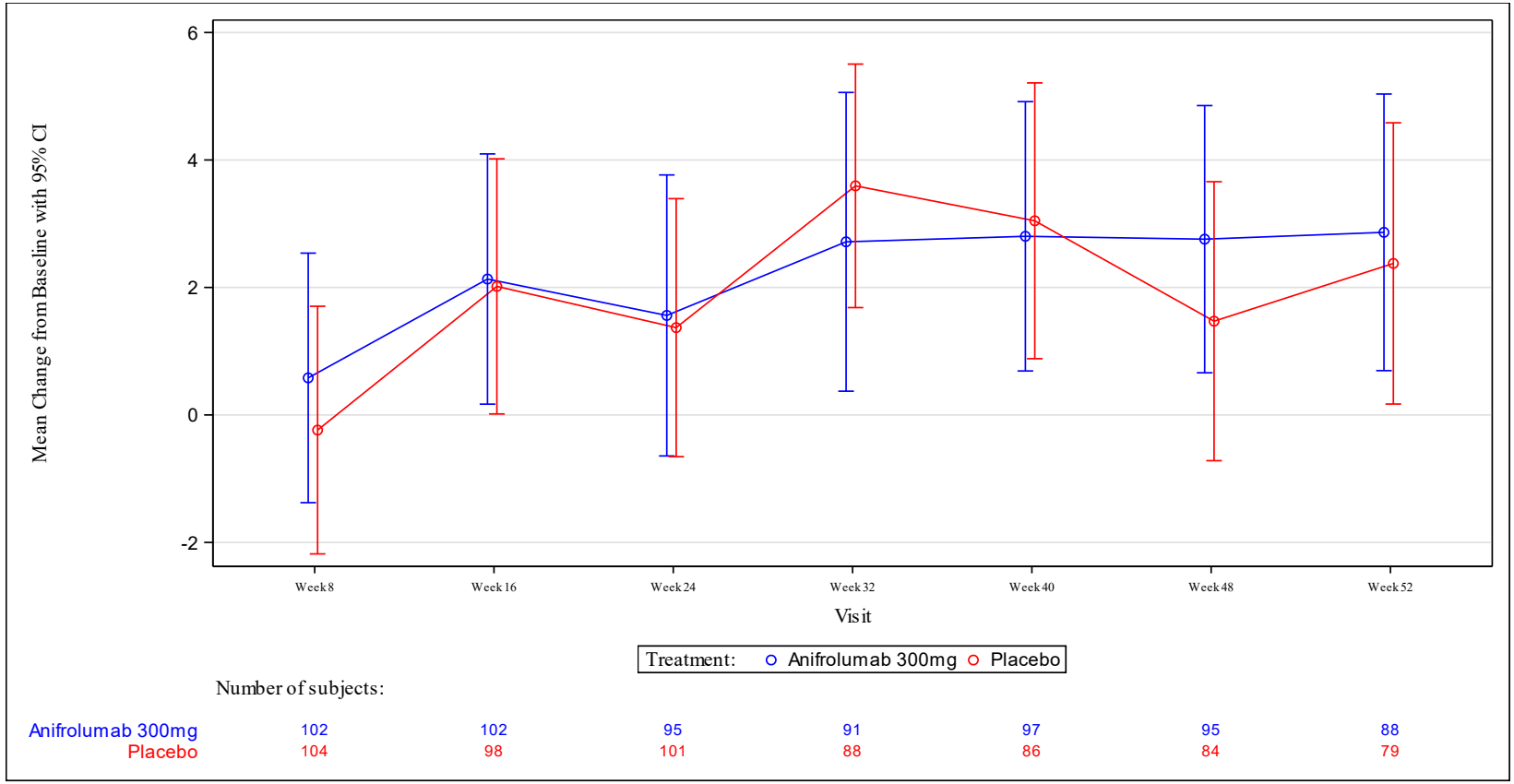
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Role Physical Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Social Functioning Score
Full analysis set

	Anifrolumab 300mg (N=119)				Placebo (N=121)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	113	42.92 (10.47)	0	-	114	39.70 (9.66)	0	-
Week 8	107	43.90 (10.00)	102	0.58 (9.97)	107	39.79 (10.74)	104	-0.24 (9.99)
Week 16	108	44.43 (10.17)	102	2.13 (9.99)	102	41.81 (9.48)	98	2.02 (9.98)
Week 24	101	45.14 (10.59)	95	1.56 (10.82)	107	41.17 (10.64)	101	1.37 (10.25)
Week 32	97	46.24 (10.30)	91	2.72 (11.25)	91	42.51 (9.71)	88	3.59 (9.01)
Week 40	103	45.70 (9.52)	97	2.80 (10.48)	90	41.97 (9.50)	86	3.05 (10.09)
Week 48	100	46.11 (9.33)	95	2.76 (10.29)	87	40.38 (9.84)	84	1.47 (10.08)
Week 52	94	45.54 (10.58)	88	2.86 (10.24)	82	41.91 (9.82)	79	2.38 (9.85)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Social Functioning Score
Full analysis set



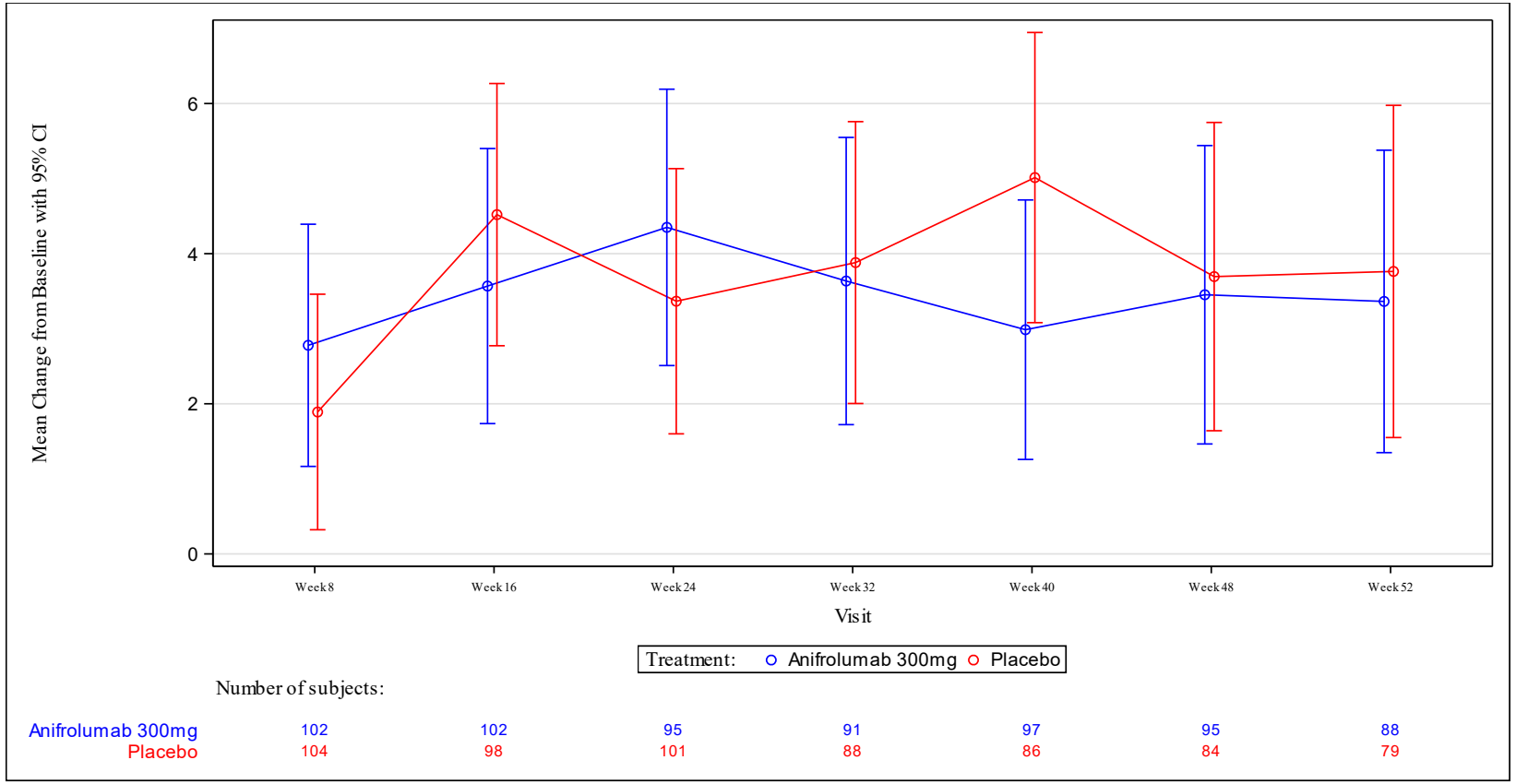
Number of subjects:

	Week 8	Week 16	Week 24	Week 32	Week 40	Week 48	Week 52
Anifrolumab 300mg	102	102	95	91	97	95	88
Placebo	104	98	101	88	86	84	79

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Bodily Pain Score
Full analysis set

	Anifrolumab 300mg (N=119)				Placebo (N=121)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	113	40.57 (7.91)	0	-	114	38.27 (8.73)	0	-
Week 8	107	43.67 (8.90)	102	2.78 (8.21)	107	40.40 (9.58)	104	1.89 (8.07)
Week 16	108	43.88 (9.44)	102	3.57 (9.33)	102	42.98 (9.37)	98	4.52 (8.71)
Week 24	101	45.69 (9.53)	95	4.35 (9.04)	107	42.25 (9.83)	101	3.37 (8.95)
Week 32	97	44.72 (9.20)	91	3.64 (9.19)	91	42.23 (8.78)	88	3.88 (8.86)
Week 40	103	44.25 (8.58)	97	2.99 (8.58)	90	43.55 (8.75)	86	5.01 (9.01)
Week 48	100	44.37 (9.85)	95	3.45 (9.76)	87	42.29 (9.61)	84	3.69 (9.46)
Week 52	94	44.94 (9.89)	88	3.36 (9.51)	82	42.76 (9.46)	79	3.76 (9.88)

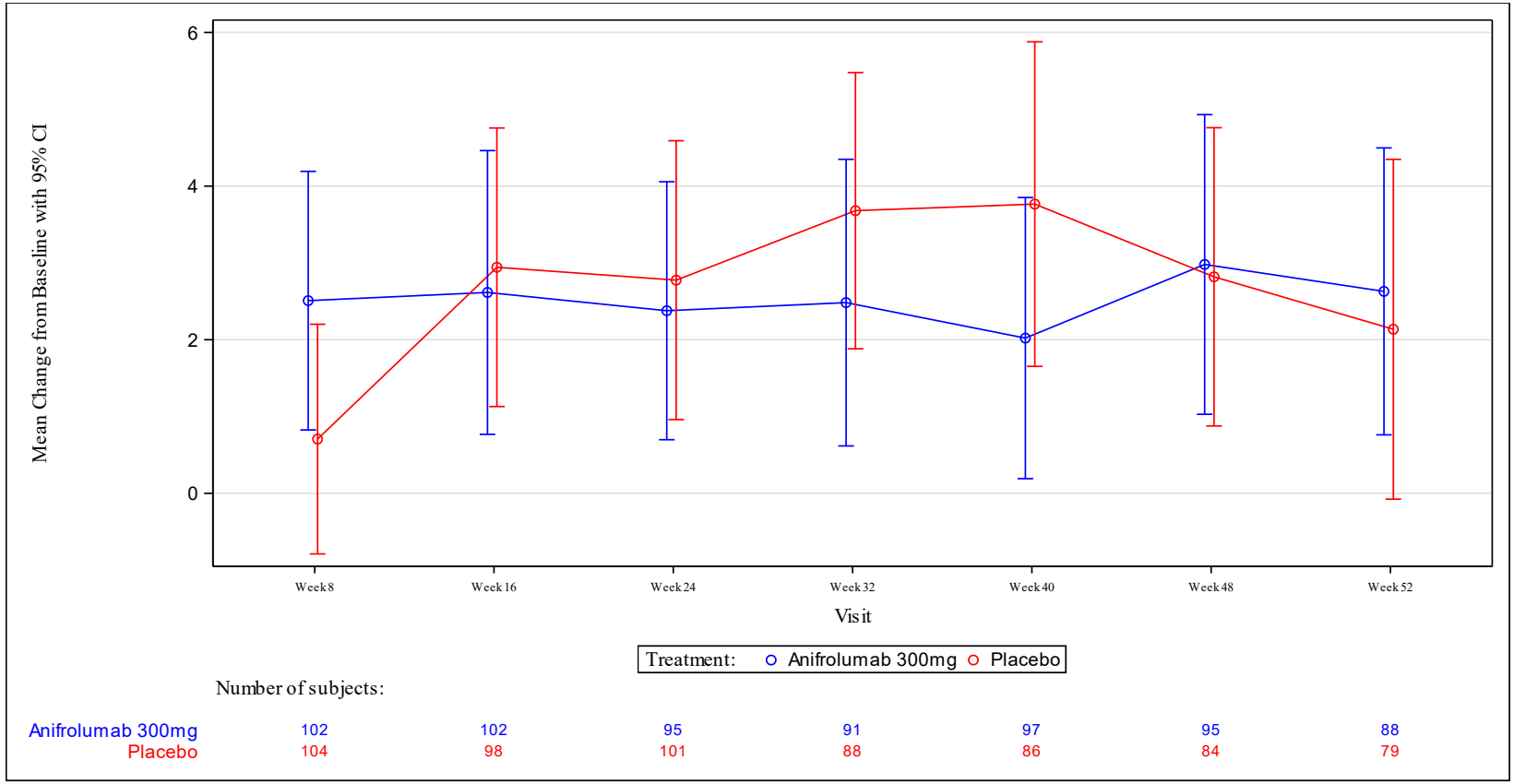
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Bodily Pain Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Vitality Score
Full analysis set

	Anifrolumab 300mg (N=119)				Placebo (N=121)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	113	43.67 (10.05)	0	-	114	40.74 (8.64)	0	-
Week 8	107	46.66 (9.83)	102	2.51 (8.57)	107	41.86 (8.62)	104	0.71 (7.69)
Week 16	108	46.09 (10.26)	102	2.62 (9.40)	102	44.15 (8.85)	98	2.94 (9.05)
Week 24	101	47.05 (10.03)	95	2.38 (8.24)	107	44.48 (9.85)	101	2.78 (9.20)
Week 32	97	46.73 (9.94)	91	2.48 (8.96)	91	45.01 (9.04)	88	3.68 (8.49)
Week 40	103	46.56 (9.62)	97	2.02 (9.08)	90	45.08 (9.71)	86	3.77 (9.85)
Week 48	100	47.43 (9.49)	95	2.98 (9.58)	87	44.22 (9.31)	84	2.82 (8.95)
Week 52	94	46.94 (10.16)	88	2.63 (8.82)	82	43.89 (9.54)	79	2.14 (9.88)

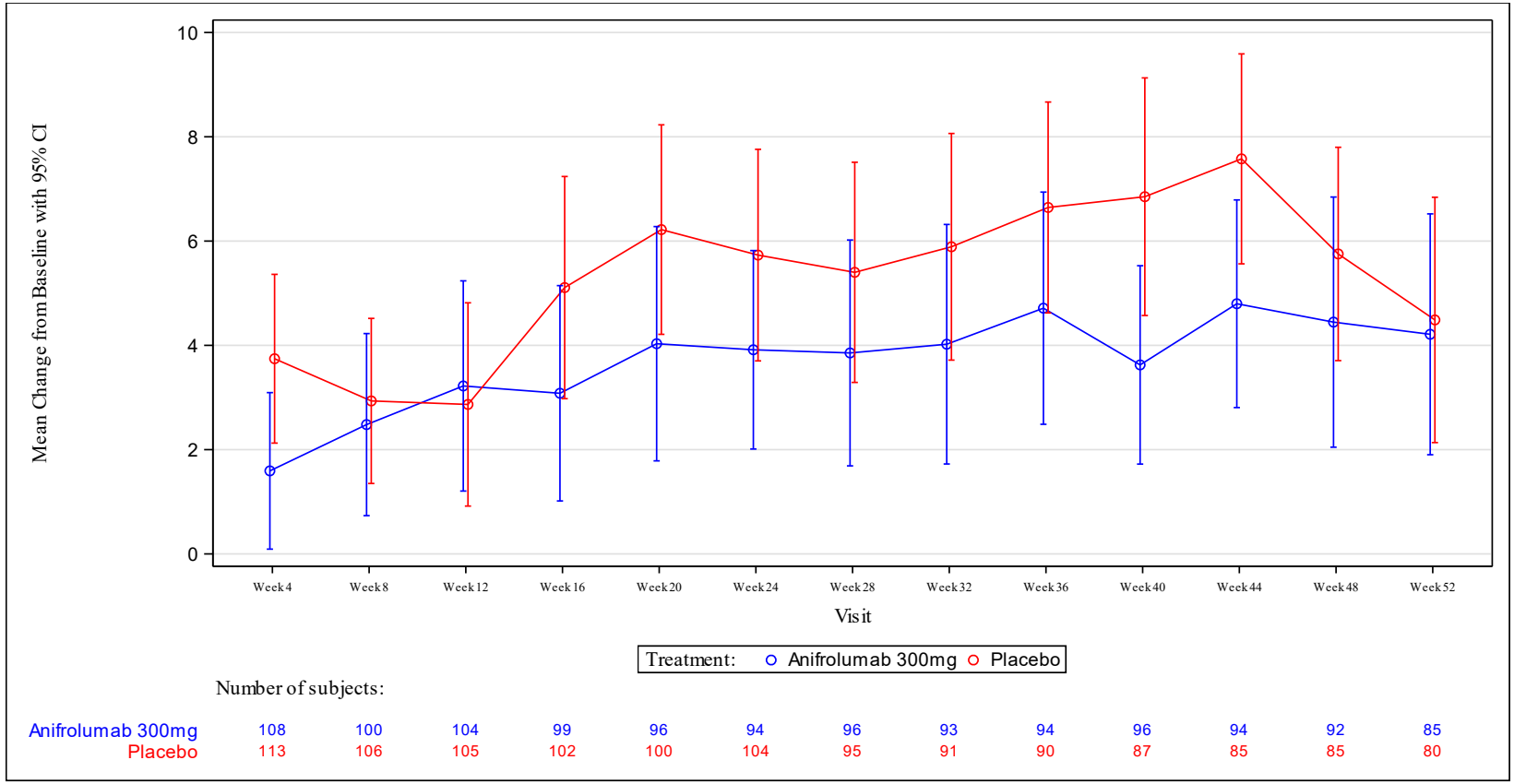
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Vitality Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - FACIT-F Total Score
Full analysis set

	Anifrolumab 300mg (N=119)				Placebo (N=121)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	110	28.32 (12.24)	0	-	116	23.38 (10.69)	0	-
Week 4	113	29.58 (11.66)	108	1.59 (7.87)	116	27.10 (10.54)	113	3.74 (8.68)
Week 8	107	31.64 (11.88)	100	2.48 (8.80)	109	26.44 (10.92)	106	2.93 (8.22)
Week 12	113	32.12 (12.21)	104	3.22 (10.36)	108	26.22 (11.82)	105	2.87 (10.07)
Week 16	108	31.38 (12.08)	99	3.08 (10.35)	104	28.20 (11.39)	102	5.11 (10.85)
Week 20	105	32.83 (11.66)	96	4.03 (11.09)	104	30.56 (10.87)	100	6.22 (10.13)
Week 24	103	33.28 (11.72)	94	3.91 (9.29)	108	29.17 (12.10)	104	5.73 (10.43)
Week 28	105	32.89 (11.16)	96	3.85 (10.69)	99	29.43 (11.35)	95	5.40 (10.36)
Week 32	101	33.13 (11.88)	93	4.02 (11.15)	94	29.82 (11.53)	91	5.89 (10.44)
Week 36	103	33.58 (11.92)	94	4.71 (10.87)	93	29.87 (10.81)	90	6.64 (9.66)
Week 40	105	33.02 (11.23)	96	3.63 (9.39)	90	30.33 (11.07)	87	6.85 (10.69)
Week 44	103	33.82 (11.15)	94	4.80 (9.72)	87	30.87 (10.51)	85	7.58 (9.33)
Week 48	100	33.80 (11.81)	92	4.45 (11.58)	89	29.34 (11.17)	85	5.75 (9.48)
Week 52	94	33.32 (11.90)	85	4.21 (10.71)	83	28.73 (11.55)	80	4.49 (10.57)

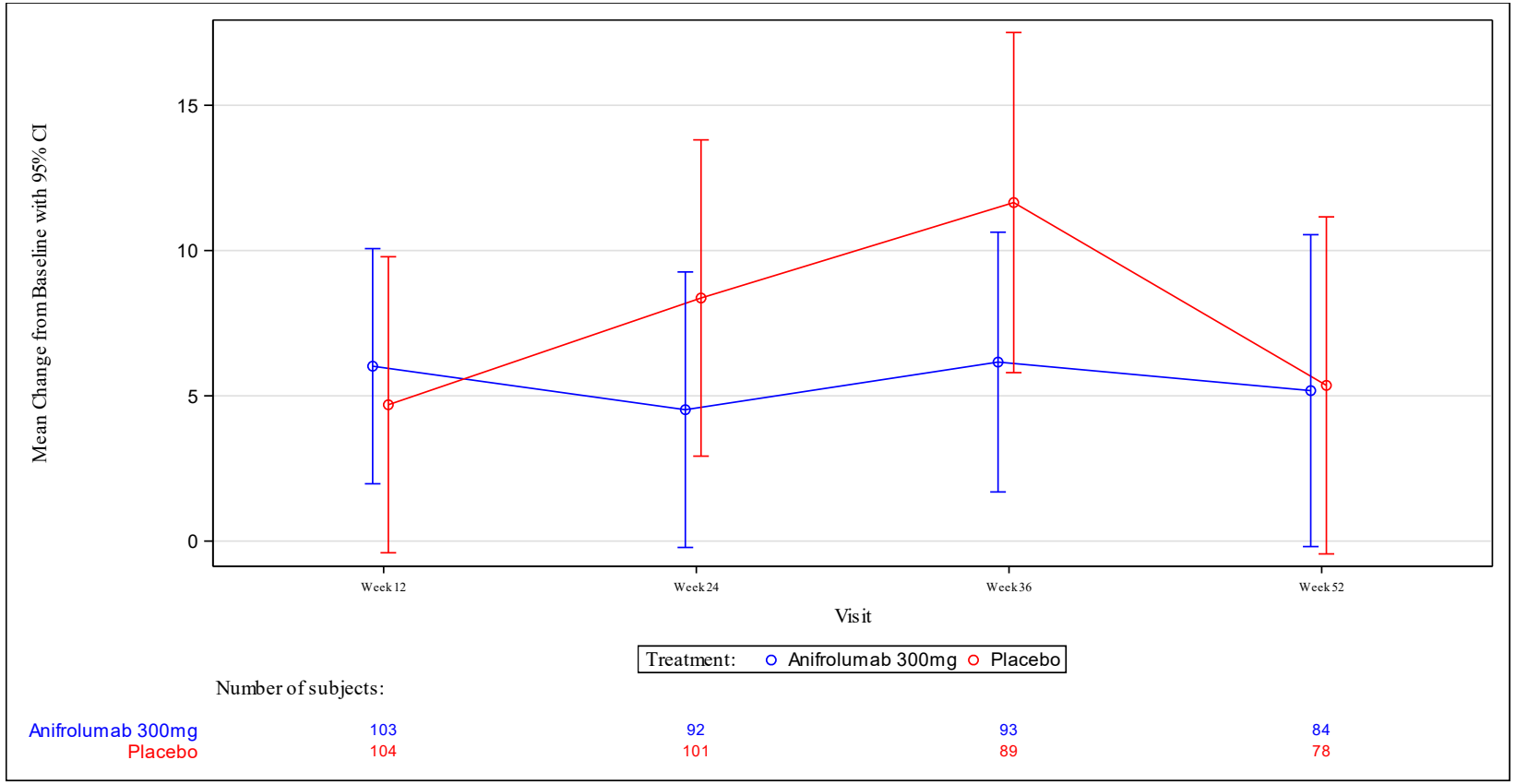
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - FACIT-F Total Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - EQ VAS Score
Full analysis set

	Anifrolumab 300mg (N=119)				Placebo (N=121)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	110	60.74 (19.34)	0	-	116	53.60 (21.84)	0	-
Week 12	112	66.13 (21.07)	103	6.02 (20.70)	107	58.93 (20.48)	104	4.69 (26.20)
Week 24	101	65.97 (20.11)	92	4.52 (22.89)	105	63.10 (20.80)	101	8.37 (27.57)
Week 36	102	67.81 (20.48)	93	6.16 (21.70)	92	65.38 (21.83)	89	11.65 (27.79)
Week 52	93	67.29 (20.62)	84	5.18 (24.73)	81	61.04 (21.89)	78	5.36 (25.73)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - EQ VAS Score
Full analysis set



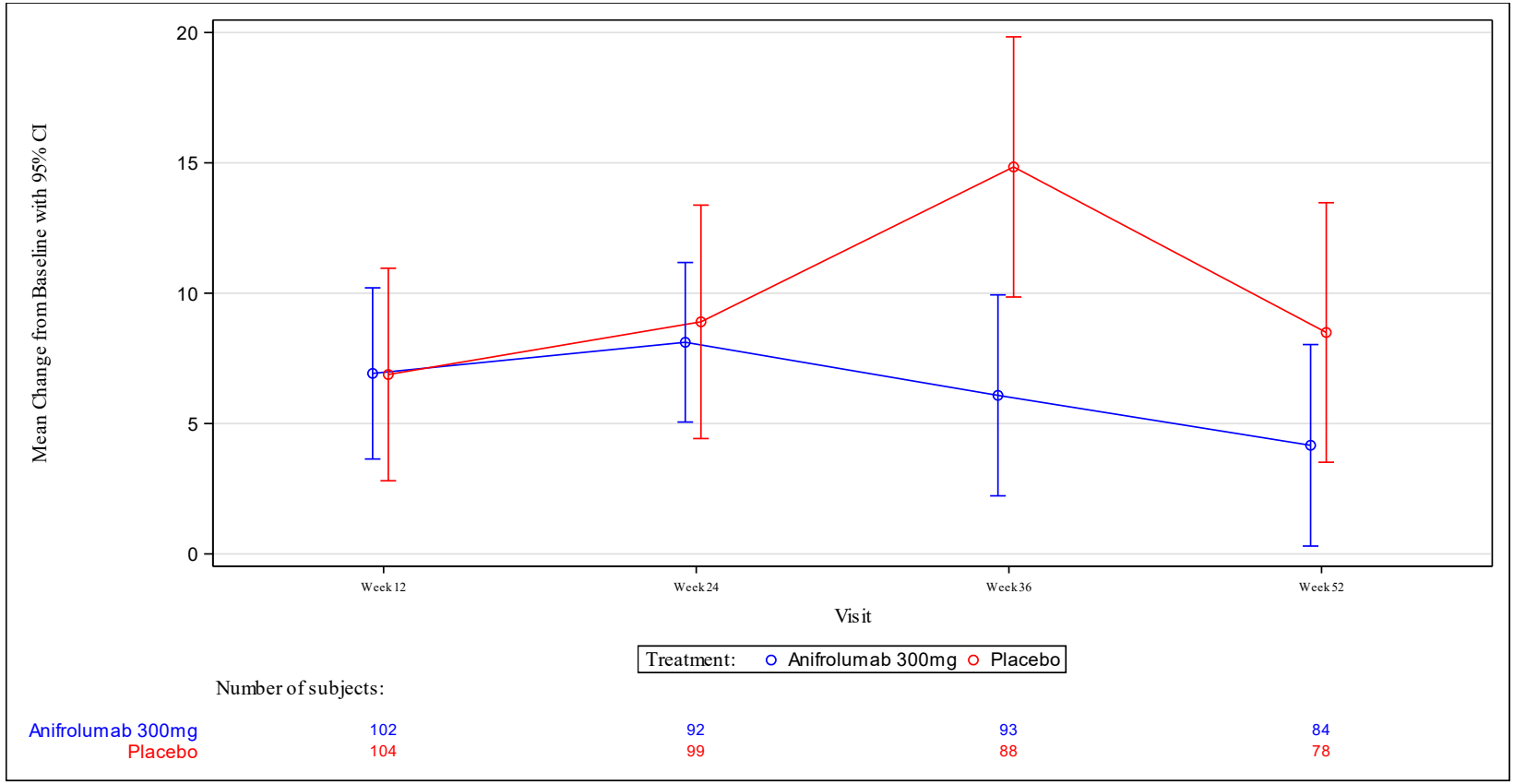
Number of subjects:

	Week 12	Week 24	Week 36	Week 52
Anifrolumab 300mg	103	92	93	84
Placebo	104	101	89	78

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Physical Health domain score
Full analysis set

	Anifrolumab 300mg (N=119)				Placebo (N=121)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	110	60.60 (24.73)	0	-	116	51.35 (25.51)	0	-
Week 12	111	69.12 (24.50)	102	6.92 (16.71)	107	58.38 (26.33)	104	6.88 (20.96)
Week 24	101	70.08 (24.01)	92	8.12 (14.78)	103	60.65 (24.13)	99	8.90 (22.44)
Week 36	102	67.62 (24.11)	93	6.08 (18.71)	91	65.52 (22.90)	88	14.84 (23.55)
Week 52	93	67.51 (23.86)	84	4.17 (17.81)	81	62.85 (22.34)	78	8.49 (22.07)

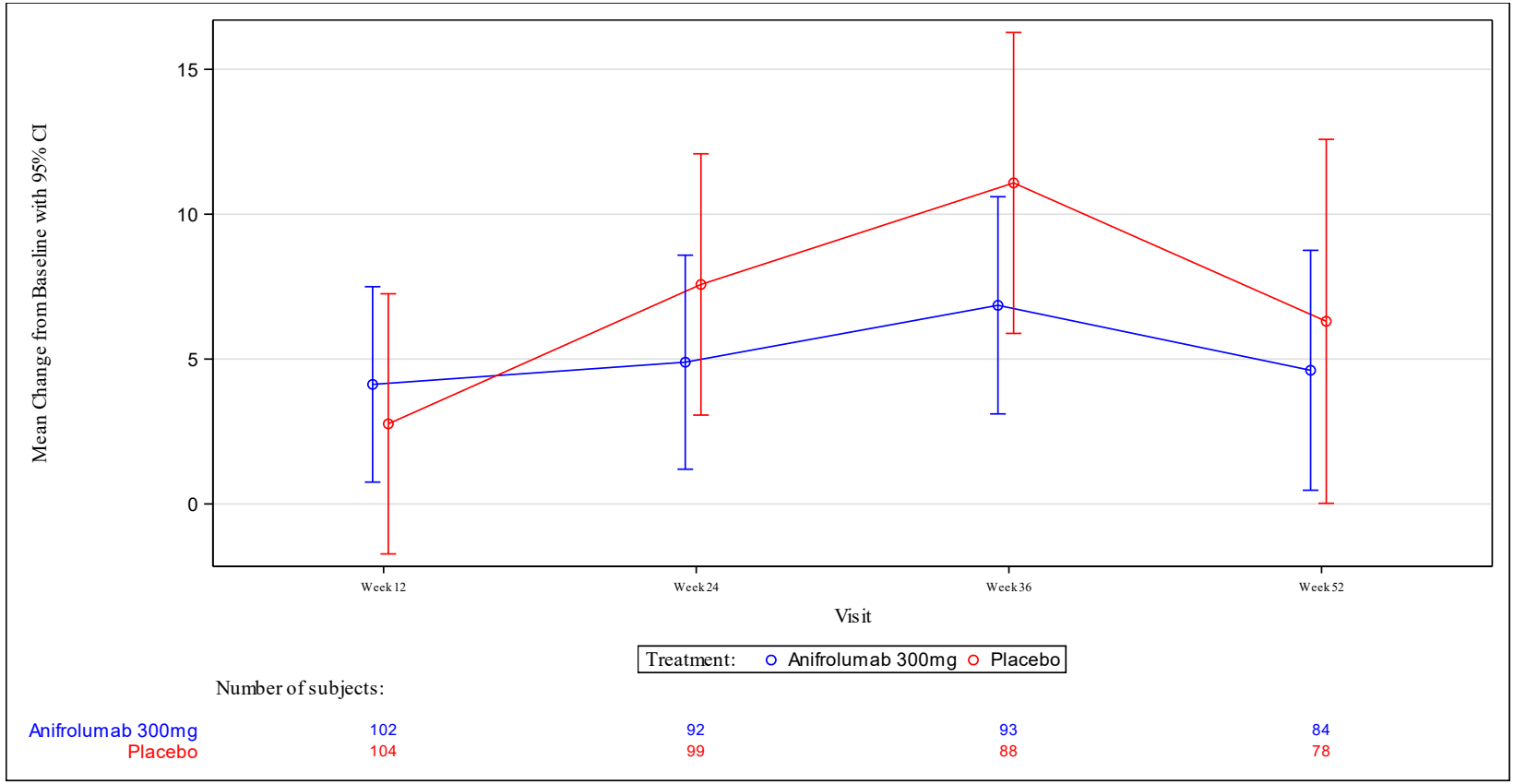
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Lupus QoL Physical Health domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Emotional Health domain score
Full analysis set

	Anifrolumab 300mg (N=119)				Placebo (N=121)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	110	70.15 (22.99)	0	-	116	61.49 (25.98)	0	-
Week 12	111	74.62 (23.22)	102	4.13 (17.17)	107	64.72 (24.79)	104	2.76 (23.08)
Week 24	101	76.32 (21.06)	92	4.89 (17.83)	103	69.30 (24.72)	99	7.58 (22.61)
Week 36	102	76.96 (18.83)	93	6.86 (18.20)	91	73.08 (22.37)	88	11.08 (24.51)
Week 52	93	76.03 (22.00)	84	4.61 (19.08)	81	70.27 (24.76)	78	6.30 (27.86)

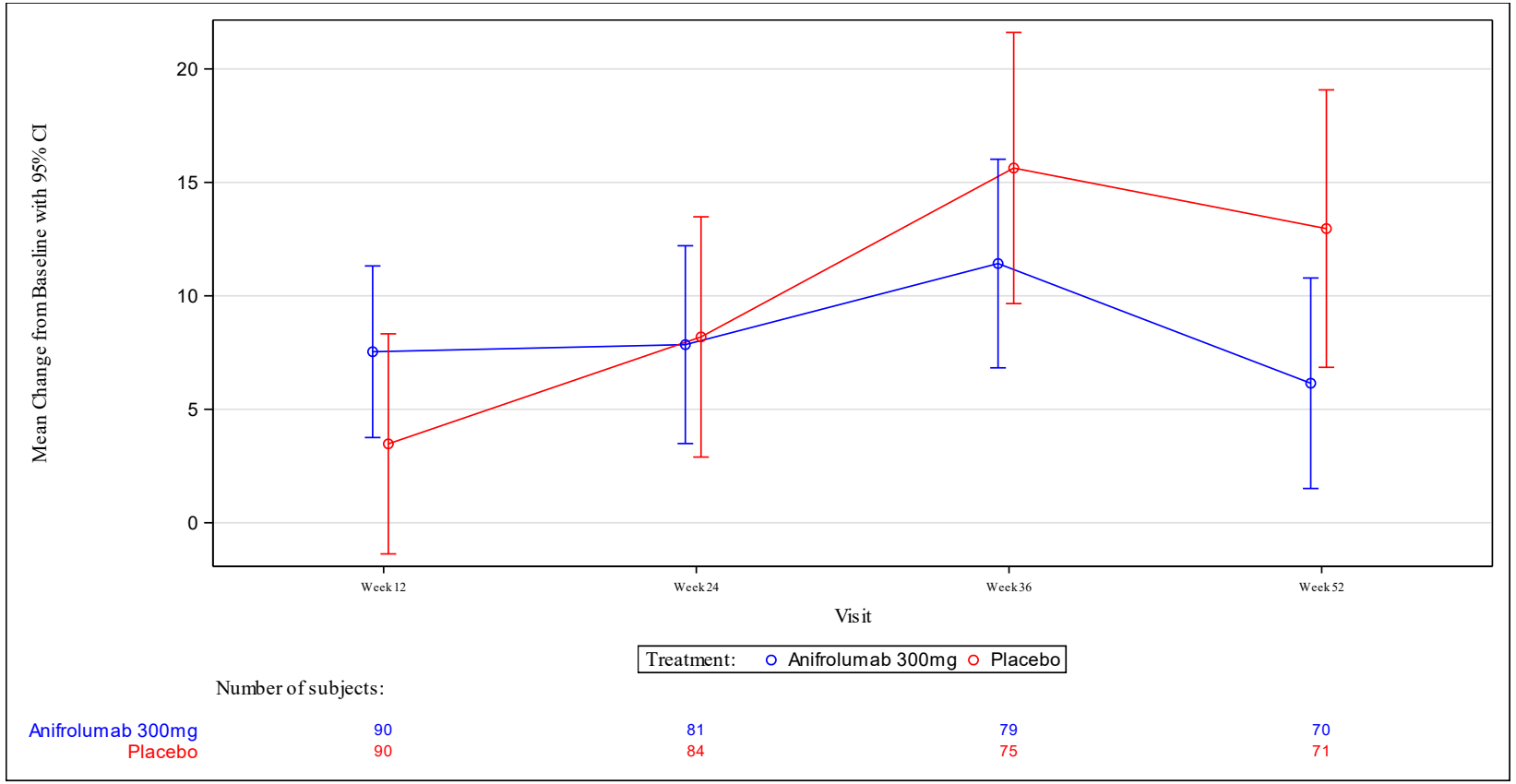
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Lupus QoL Emotional Health domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Body Image domain score
Full analysis set

	Anifrolumab 300mg (N=119)				Placebo (N=121)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	104	63.47 (30.98)	0	-	108	58.97 (28.84)	0	-
Week 12	100	71.37 (26.99)	90	7.54 (18.05)	97	61.67 (27.01)	90	3.48 (23.16)
Week 24	89	72.05 (27.56)	81	7.85 (19.71)	92	65.35 (26.45)	84	8.19 (24.40)
Week 36	87	73.59 (24.81)	79	11.42 (20.52)	81	70.61 (24.27)	75	15.63 (25.96)
Week 52	81	72.36 (29.13)	70	6.15 (19.45)	76	71.46 (27.04)	71	12.96 (25.83)

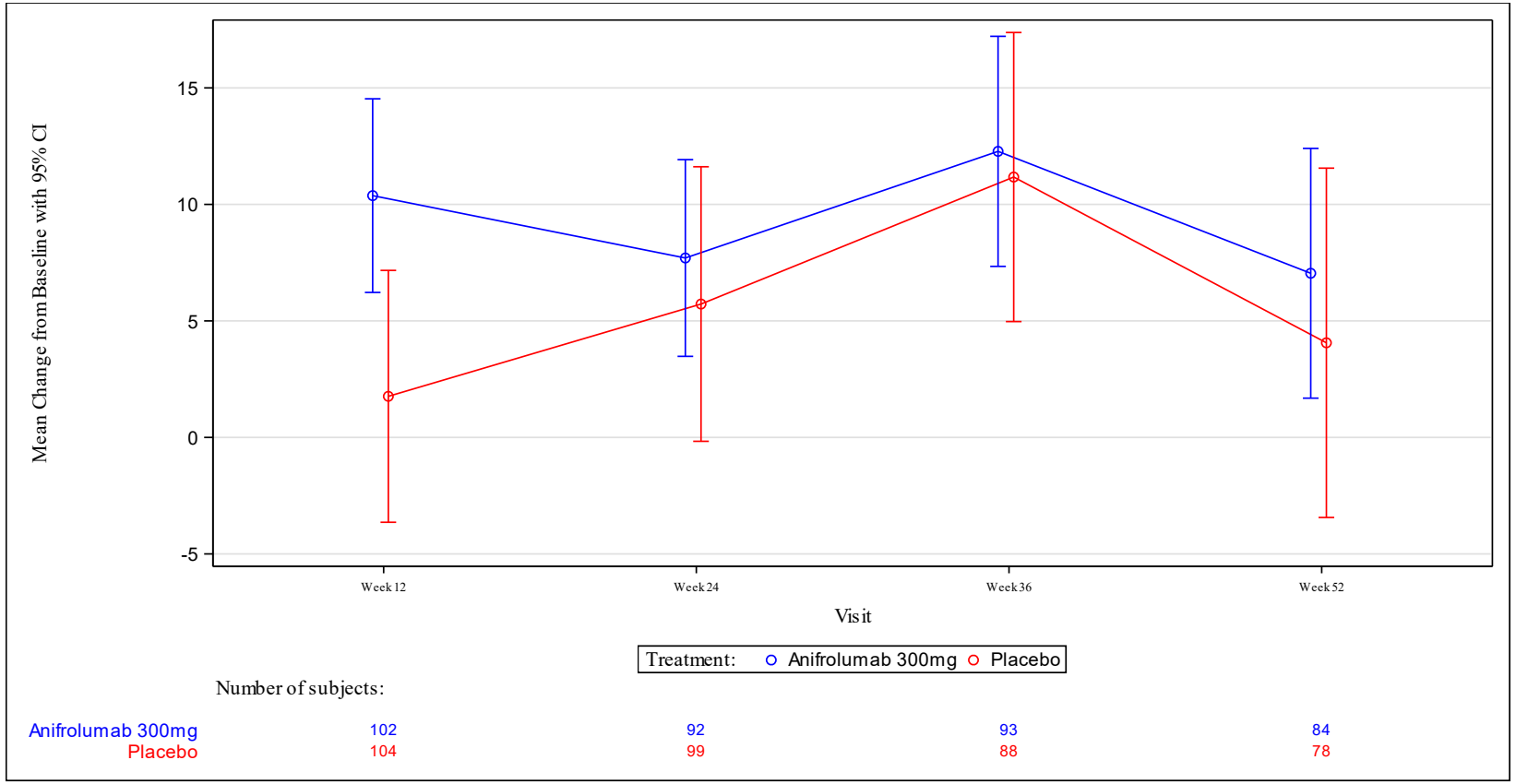
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Lupus QoL Body Image domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Burden to Others domain score
Full analysis set

	Anifrolumab 300mg (N=119)				Placebo (N=121)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	110	58.79 (30.05)	0	-	116	50.36 (30.28)	0	-
Week 12	111	69.29 (27.50)	102	10.38 (21.16)	107	52.41 (30.31)	104	1.76 (27.79)
Week 24	101	67.16 (30.25)	92	7.70 (20.38)	103	55.74 (31.81)	99	5.72 (29.54)
Week 36	102	69.20 (26.71)	93	12.28 (23.97)	91	62.09 (27.73)	88	11.17 (29.28)
Week 52	93	66.85 (28.71)	84	7.04 (24.70)	81	55.14 (32.13)	78	4.06 (33.25)

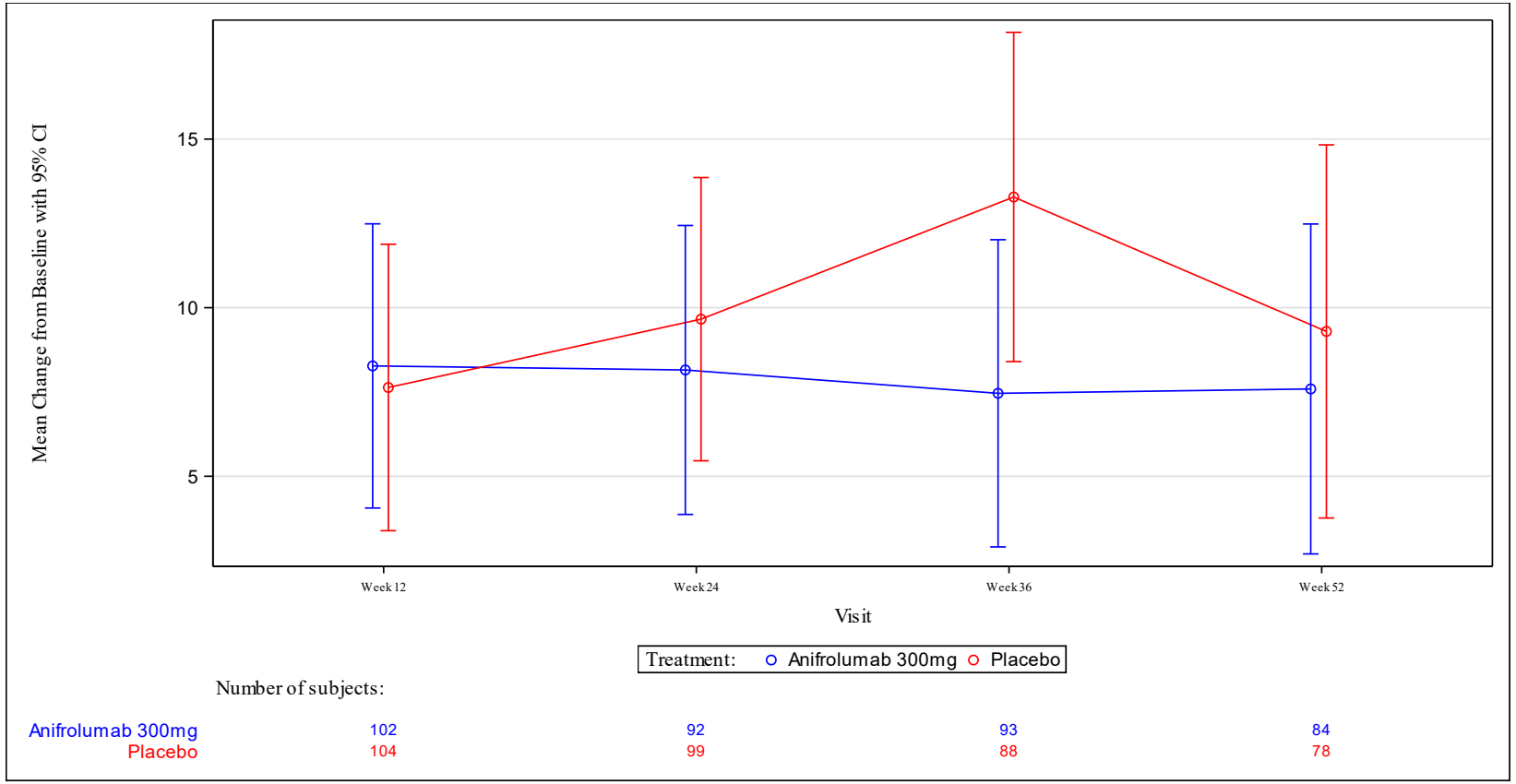
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Lupus QoL Burden to Others domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Fatigue domain score
Full analysis set

	Anifrolumab 300mg (N=119)				Placebo (N=121)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	110	52.27 (28.13)	0	-	116	43.80 (25.41)	0	-
Week 12	111	61.88 (26.12)	102	8.27 (21.46)	107	51.81 (25.71)	104	7.63 (21.84)
Week 24	101	63.24 (25.50)	92	8.15 (20.69)	103	54.55 (25.47)	99	9.66 (21.06)
Week 36	102	61.52 (25.03)	93	7.46 (22.12)	91	57.28 (24.26)	88	13.28 (23.03)
Week 52	93	62.43 (25.96)	84	7.59 (22.55)	81	55.17 (26.12)	78	9.29 (24.54)

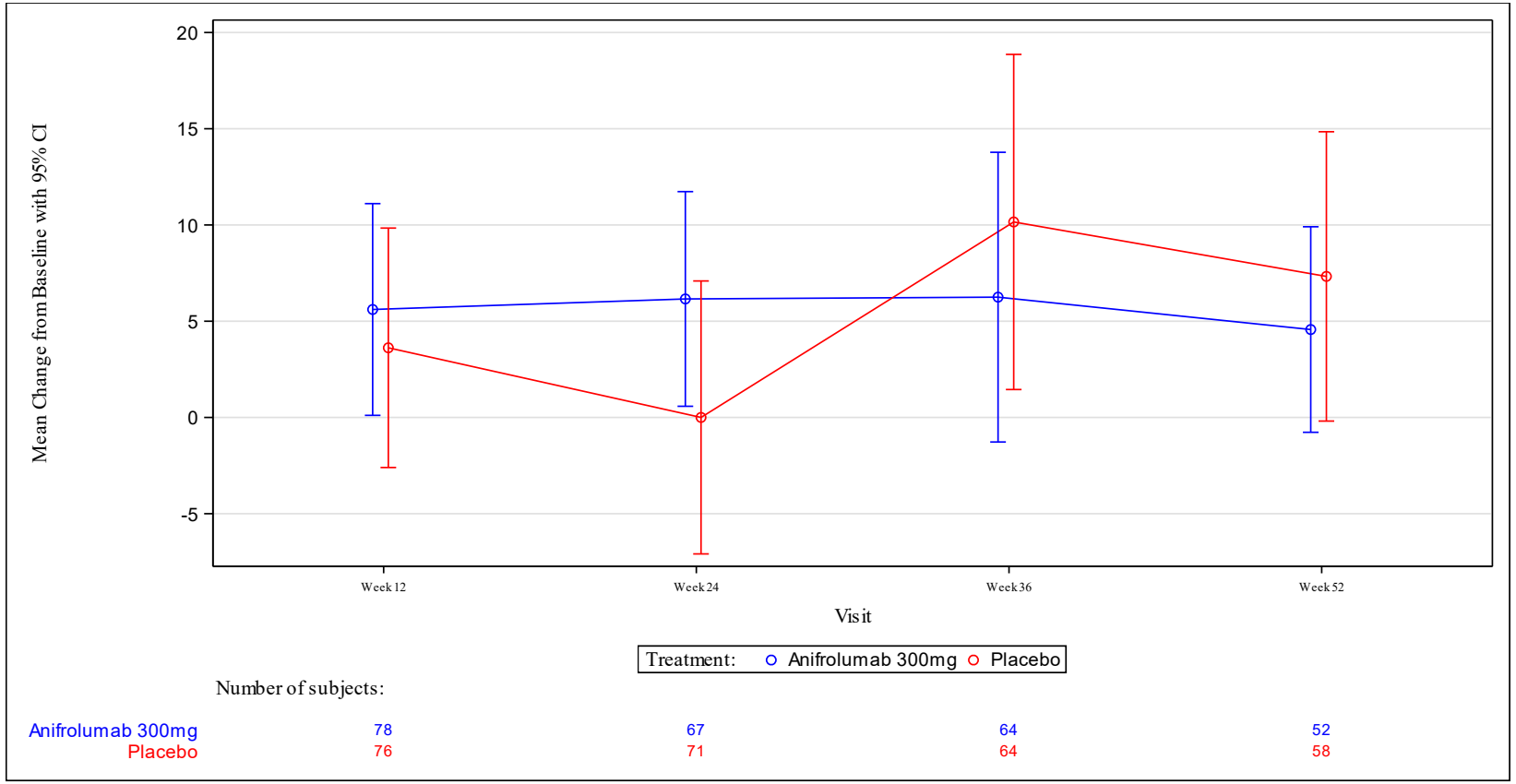
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Lupus QoL Fatigue domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Intimate Relationships domain score
Full analysis set

	Anifrolumab 300mg (N=119)				Placebo (N=121)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	89	58.15 (32.65)	0	-	94	57.45 (29.86)	0	-
Week 12	89	65.45 (31.76)	78	5.61 (24.40)	89	59.97 (31.99)	76	3.62 (27.22)
Week 24	76	66.94 (33.58)	67	6.16 (22.86)	77	58.28 (31.84)	71	0.00 (29.96)
Week 36	77	66.40 (32.46)	64	6.25 (30.13)	68	67.46 (28.91)	64	10.16 (34.85)
Week 52	62	66.33 (32.06)	52	4.57 (19.18)	63	65.87 (28.42)	58	7.33 (28.58)

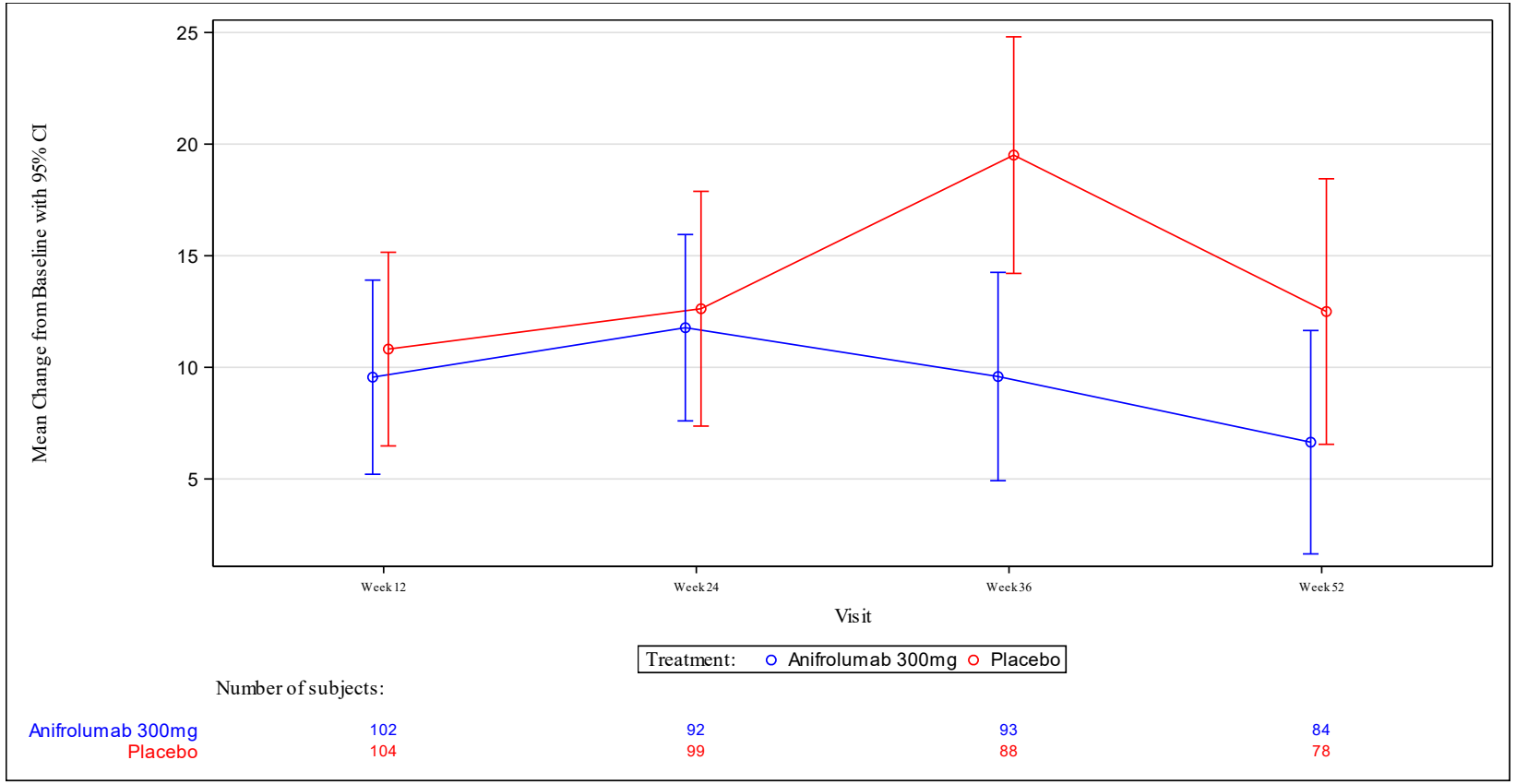
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Lupus QoL Intimate Relationships domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Pain domain score
Full analysis set

	Anifrolumab 300mg (N=119)				Placebo (N=121)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	110	59.85 (28.38)	0	-	116	48.42 (29.30)	0	-
Week 12	111	70.35 (26.13)	102	9.56 (22.14)	107	59.89 (26.82)	104	10.82 (22.30)
Week 24	101	72.77 (24.15)	92	11.78 (20.15)	103	60.76 (28.36)	99	12.63 (26.36)
Week 36	102	69.93 (24.66)	93	9.59 (22.65)	91	66.48 (25.40)	88	19.51 (25.01)
Week 52	93	70.52 (22.44)	84	6.65 (23.06)	81	63.68 (24.73)	78	12.50 (26.38)

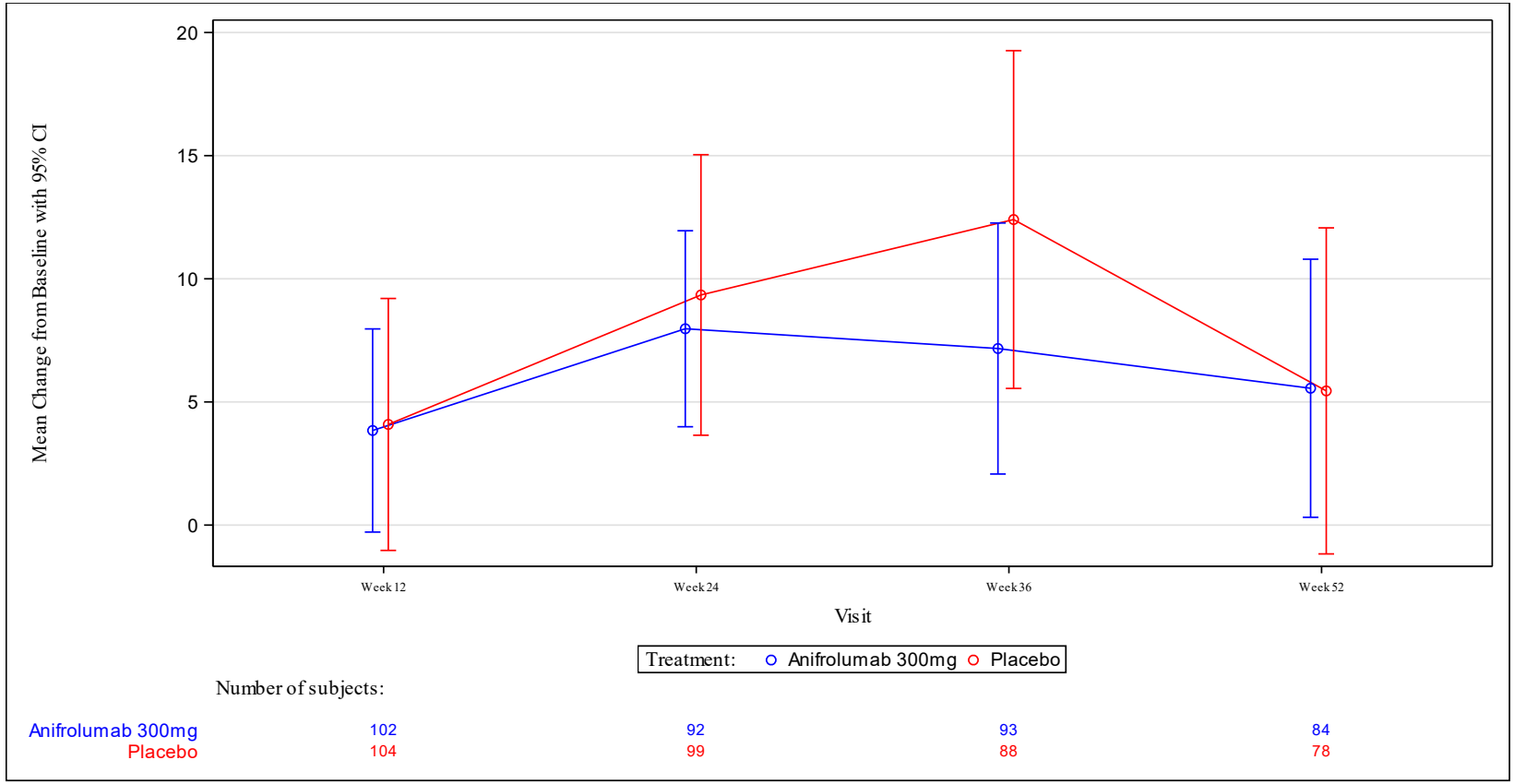
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Lupus QoL Pain domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Planning domain score
Full analysis set

	Anifrolumab 300mg (N=119)				Placebo (N=121)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	110	65.68 (28.21)	0	-	116	55.46 (30.64)	0	-
Week 12	111	70.27 (28.15)	102	3.84 (21.00)	107	60.12 (29.56)	104	4.09 (26.30)
Week 24	101	75.25 (26.42)	92	7.97 (19.22)	103	64.40 (28.85)	99	9.34 (28.55)
Week 36	102	72.71 (26.38)	93	7.17 (24.74)	91	67.67 (27.10)	88	12.41 (32.36)
Week 52	93	72.85 (26.58)	84	5.56 (24.14)	81	64.61 (27.28)	78	5.45 (29.36)

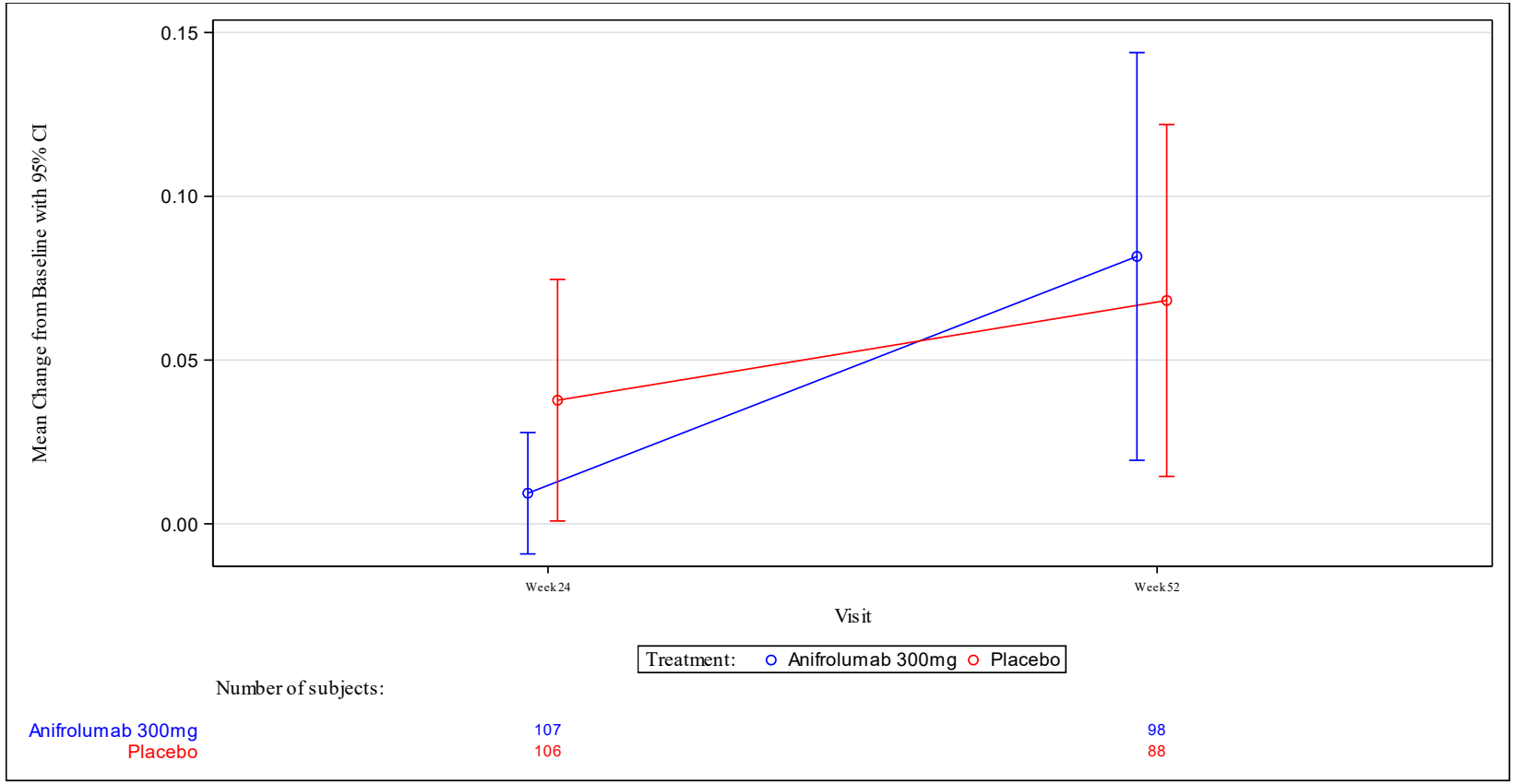
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Lupus QoL Planning domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - SDI Global Score
Full analysis set

	Anifrolumab 300mg (N=119)				Placebo (N=121)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	119	0.44 (0.79)	0	-	121	0.45 (0.73)	0	-
Week 24	107	0.47 (0.82)	107	0.01 (0.10)	106	0.46 (0.82)	106	0.04 (0.19)
Week 52	98	0.57 (0.89)	98	0.08 (0.31)	88	0.44 (0.74)	88	0.07 (0.25)

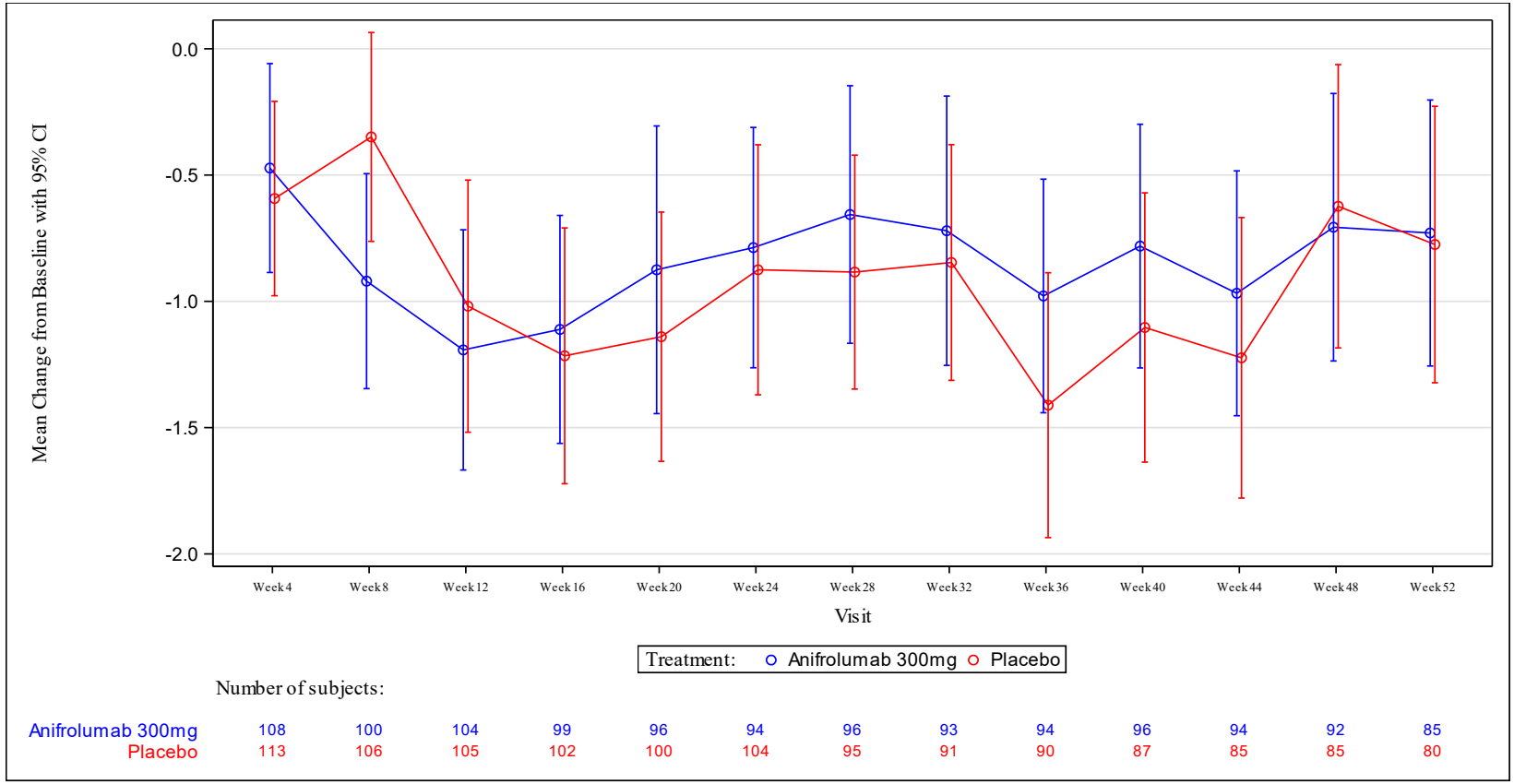
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - SDI Global Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - NRS Score
Full analysis set

	Anifrolumab 300mg (N=119)				Placebo (N=121)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	110	4.97 (2.31)	0	-	116	5.64 (2.55)	0	-
Week 4	113	4.50 (2.42)	108	-0.47 (2.17)	116	5.03 (2.57)	113	-0.59 (2.06)
Week 8	107	3.98 (2.56)	100	-0.92 (2.14)	109	5.29 (2.71)	106	-0.35 (2.15)
Week 12	113	3.78 (2.59)	104	-1.19 (2.45)	108	4.63 (2.68)	105	-1.02 (2.58)
Week 16	108	3.87 (2.41)	99	-1.11 (2.26)	104	4.46 (2.53)	102	-1.22 (2.58)
Week 20	105	4.00 (2.57)	96	-0.88 (2.81)	104	4.43 (2.63)	100	-1.14 (2.49)
Week 24	103	3.89 (2.51)	94	-0.79 (2.32)	108	4.71 (2.65)	104	-0.88 (2.55)
Week 28	105	4.10 (2.60)	96	-0.66 (2.52)	99	4.57 (2.63)	95	-0.88 (2.27)
Week 32	101	4.07 (2.46)	93	-0.72 (2.59)	94	4.67 (2.62)	91	-0.85 (2.24)
Week 36	103	3.91 (2.59)	94	-0.98 (2.26)	93	4.22 (2.41)	90	-1.41 (2.50)
Week 40	105	3.94 (2.41)	96	-0.78 (2.38)	90	4.47 (2.66)	87	-1.10 (2.50)
Week 44	103	3.83 (2.43)	94	-0.97 (2.37)	87	4.36 (2.52)	85	-1.22 (2.57)
Week 48	100	4.11 (2.53)	92	-0.71 (2.56)	89	4.79 (2.65)	85	-0.62 (2.60)
Week 52	94	3.89 (2.48)	85	-0.73 (2.44)	83	4.66 (2.68)	80	-0.78 (2.46)

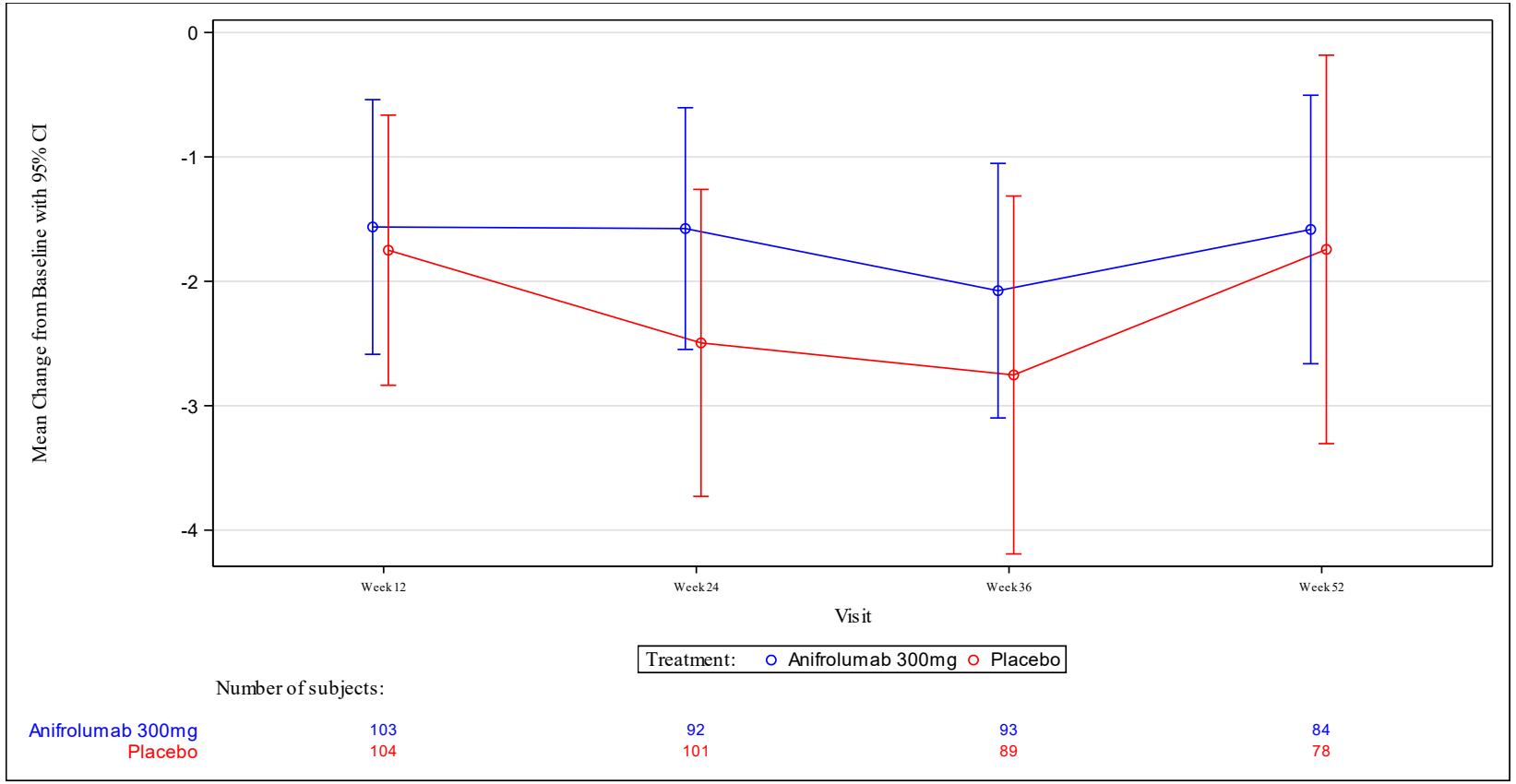
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - NRS Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - PHQ-8 Total Score
Full analysis set

	Anifrolumab 300mg (N=119)				Placebo (N=121)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	110	8.55 (5.98)	0	-	116	10.75 (5.98)	0	-
Week 12	112	6.82 (5.61)	103	-1.56 (5.24)	107	8.96 (5.48)	104	-1.75 (5.58)
Week 24	101	6.68 (5.43)	92	-1.58 (4.69)	105	8.27 (5.74)	101	-2.50 (6.25)
Week 36	102	6.37 (5.39)	93	-2.08 (4.97)	92	8.12 (5.55)	89	-2.75 (6.83)
Week 52	93	6.59 (5.39)	84	-1.58 (4.97)	81	8.73 (5.80)	78	-1.74 (6.92)

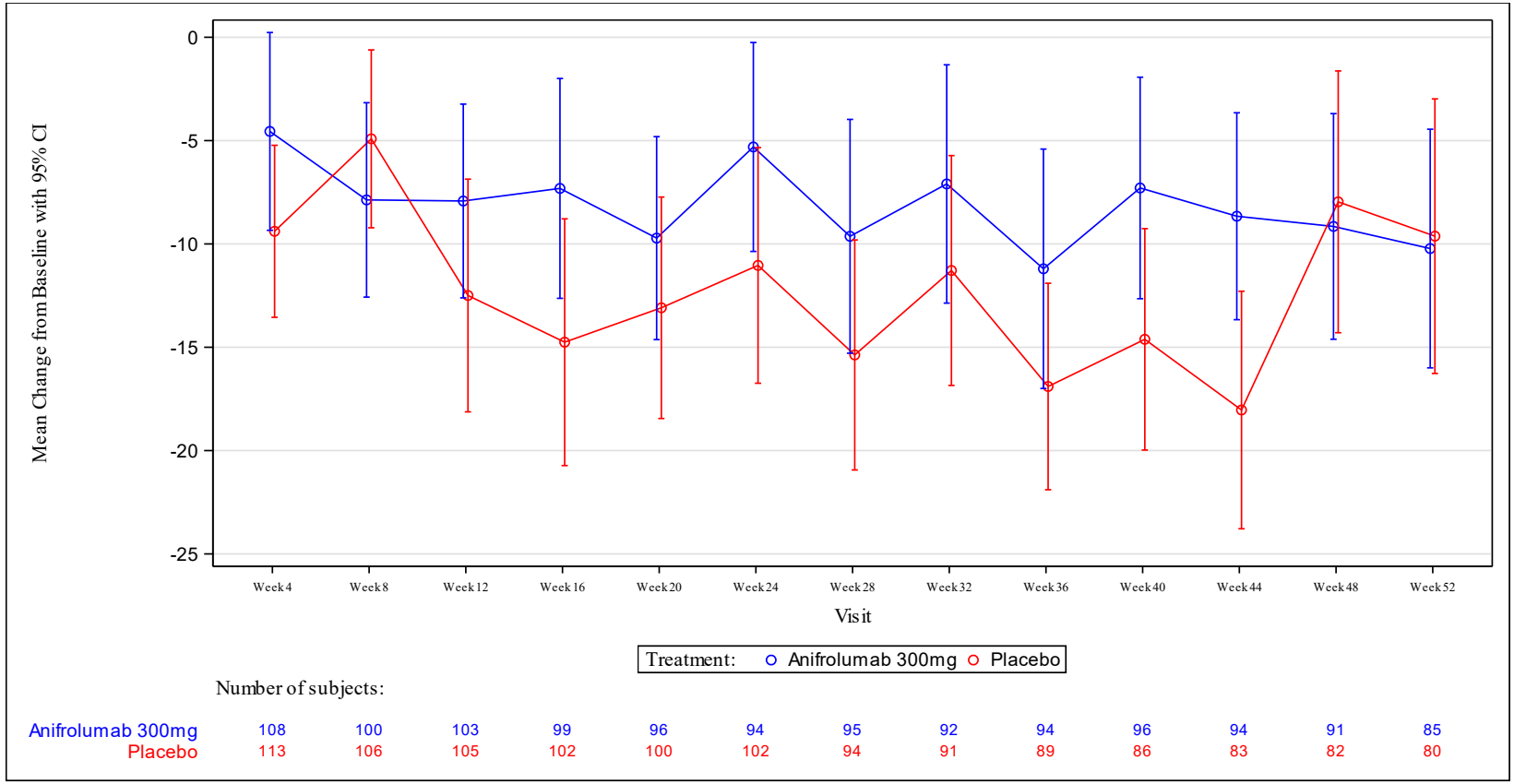
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - PHQ-8 Total Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - PtGA
Full analysis set

	Anifrolumab 300mg (N=119)				Placebo (N=121)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	110	49.83 (21.08)	0	-	116	59.28 (22.07)	0	-
Week 4	113	45.70 (22.98)	108	-4.56 (25.09)	116	49.19 (23.14)	113	-9.39 (22.33)
Week 8	107	41.78 (23.04)	100	-7.87 (23.70)	109	54.03 (22.35)	106	-4.92 (22.35)
Week 12	112	41.52 (23.90)	103	-7.92 (23.98)	108	47.81 (24.74)	105	-12.50 (29.09)
Week 16	108	42.53 (23.56)	99	-7.31 (26.67)	104	44.83 (24.56)	102	-14.75 (30.39)
Week 20	105	39.44 (22.73)	96	-9.72 (24.24)	104	45.36 (24.62)	100	-13.09 (27.00)
Week 24	103	41.89 (25.33)	94	-5.31 (24.68)	106	48.19 (24.98)	102	-11.04 (29.03)
Week 28	104	40.28 (23.84)	95	-9.63 (27.77)	98	42.53 (23.36)	94	-15.37 (27.17)
Week 32	100	42.15 (25.13)	92	-7.10 (27.84)	94	45.36 (24.66)	91	-11.29 (26.70)
Week 36	103	39.09 (24.31)	94	-11.20 (28.28)	92	41.36 (22.34)	89	-16.90 (23.72)
Week 40	105	41.41 (24.50)	96	-7.29 (26.45)	89	44.98 (23.19)	86	-14.62 (24.99)
Week 44	103	40.48 (22.84)	94	-8.66 (24.44)	85	41.27 (22.90)	83	-18.04 (26.32)
Week 48	99	41.08 (24.29)	91	-9.15 (26.21)	86	48.35 (25.62)	82	-7.96 (28.83)
Week 52	94	39.15 (24.43)	85	-10.22 (26.77)	83	47.16 (25.34)	80	-9.63 (29.85)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - PtGA
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SLEDAI-2K Total Score
Full analysis set

Visit	Anifrolumab 300mg (N=119) N	LSMean (SE)	Placebo (N=121) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-0.73 (0.22)		-0.69 (0.23)	-0.04 (0.27)	(-0.58, 0.50)	0.8875			
Week 8		-2.60 (0.34)		-1.73 (0.34)	-0.87 (0.45)	(-1.76, 0.01)	0.0520			
Week 12		-3.75 (0.35)		-2.65 (0.36)	-1.10 (0.47)	(-2.04, -0.17)	0.0209			
Week 16		-4.37 (0.36)		-3.25 (0.36)	-1.12 (0.48)	(-2.08, -0.17)	0.0211			
Week 20		-4.46 (0.34)		-3.77 (0.34)	-0.69 (0.45)	(-1.58, 0.20)	0.1291			
Week 24		-4.98 (0.35)		-3.57 (0.36)	-1.40 (0.48)	(-2.34, -0.47)	0.0035			
Week 28		-5.35 (0.38)		-3.60 (0.39)	-1.76 (0.52)	(-2.78, -0.74)	0.0008			
Week 32		-5.35 (0.38)		-3.89 (0.39)	-1.46 (0.52)	(-2.49, -0.43)	0.0056			
Week 36		-5.32 (0.39)		-4.00 (0.40)	-1.33 (0.54)	(-2.39, -0.26)	0.0148			
Week 40		-5.37 (0.40)		-3.98 (0.41)	-1.39 (0.55)	(-2.48, -0.30)	0.0125			
Week 44		-5.60 (0.39)		-4.43 (0.40)	-1.17 (0.53)	(-2.22, -0.12)	0.0289			
Week 48		-5.64 (0.38)		-4.63 (0.40)	-1.01 (0.53)	(-2.05, 0.03)	0.0571			
Week 52		-5.85 (0.39)		-4.91 (0.40)	-0.95 (0.53)	(-2.00, 0.10)	0.0769			
OVERALL	119	-4.57 (0.28)	119	-3.47 (0.29)	-1.10 (0.38)	(-1.84, -0.36)	0.0038	-0.35 (0.13)	(-0.61, -0.09)	0.0075

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SLEDAI-2K Total Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) N	LSMean (SE)	Placebo (N=121) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.5855
< 10 points	41	-3.09 (0.35)	32	-2.21 (0.40)	-0.88 (0.51)	(-1.91, 0.15)	0.0928	-0.39 (0.24)	(-0.86, 0.08)	0.1017	
>= 10 points	78	-5.20 (0.38)	87	-3.94 (0.36)	-1.26 (0.48)	(-2.21, -0.31)	0.0097	-0.37 (0.16)	(-0.68, -0.06)	0.0187	
OCS dose at baseline											0.0495
<10 mg/day	58	-4.01 (0.36)	64	-3.61 (0.35)	-0.40 (0.48)	(-1.36, 0.55)	0.4064	-0.14 (0.18)	(-0.50, 0.21)	0.4289	
>=10 mg/day	61	-5.29 (0.46)	55	-3.42 (0.47)	-1.87 (0.57)	(-3.01, -0.73)	0.0016	-0.52 (0.19)	(-0.89, -0.15)	0.0059	
Result of type I IFN gene signature test											0.0493
LOW	23	-3.31 (0.54)	24	-3.56 (0.53)	0.25 (0.75)	(-1.28, 1.78)	0.7412	0.09 (0.29)	(-0.48, 0.67)	0.7454	
HIGH	96	-4.92 (0.31)	95	-3.47 (0.32)	-1.45 (0.43)	(-2.30, -0.60)	0.0009	-0.47 (0.15)	(-0.76, -0.18)	0.0014	
Age (years)											NE
<= 65	117	-4.58 (0.29)	118	-3.45 (0.29)	-1.14 (0.38)	(-1.88, -0.39)	0.0030	-0.36 (0.13)	(-0.62, -0.10)	0.0063	
> 65	2	NE	1	NE	NE	NE		NE	NE		
Sex											0.5468
male	11	-4.61 (0.76)	12	-2.83 (0.79)	-1.77 (0.96)	(-3.80, 0.25)	0.0821	-0.65 (0.43)	(-1.49, 0.19)	0.1305	
female	108	-4.54 (0.31)	107	-3.40 (0.31)	-1.14 (0.41)	(-1.95, -0.34)	0.0054	-0.35 (0.14)	(-0.62, -0.09)	0.0098	
Race											NE
White	75	-4.29 (0.34)	77	-3.57 (0.34)	-0.72 (0.45)	(-1.61, 0.18)	0.1168	-0.24 (0.16)	(-0.56, 0.08)	0.1427	
Black or African American	11	NE	18	NE	NE	NE		NE	NE		
Asian	17	-7.19 (1.13)	16	-3.91 (1.02)	-3.28 (1.07)	(-5.49, -1.08)	0.0050	-0.73 (0.36)	(-1.44, -0.02)	0.0436	
Other	8	NE	5	NE	NE	NE		NE	NE		
Ethnicity											0.7459
Hispanic/Latino	27	-5.15 (0.60)	32	-3.78 (0.58)	-1.37 (0.81)	(-3.00, 0.26)	0.0974	-0.42 (0.26)	(-0.94, 0.10)	0.1098	
Non-hispanic/Latino	84	-4.39 (0.34)	84	-3.32 (0.34)	-1.07 (0.43)	(-1.92, -0.22)	0.0141	-0.34 (0.16)	(-0.65, -0.04)	0.0276	
Geographic region											0.0388
EU	45	-5.02 (0.50)	32	-5.15 (0.57)	0.13 (0.61)	(-1.09, 1.35)	0.8310	0.04 (0.23)	(-0.41, 0.49)	0.8650	
non-EU	74	-4.36 (0.35)	87	-2.92 (0.34)	-1.44 (0.46)	(-2.35, -0.54)	0.0020	-0.47 (0.16)	(-0.78, -0.15)	0.0035	
Onset of disease											NE
Paediatric	11	NE	5	NE	NE	NE		NE	NE		
Adult	108	-4.54 (0.29)	114	-3.43 (0.29)	-1.11 (0.39)	(-1.87, -0.35)	0.0044	-0.36 (0.14)	(-0.63, -0.10)	0.0075	
ADA result											NE
Negative	115	-4.46 (0.28)	109	-3.52 (0.29)	-0.94 (0.38)	(-1.68, -0.20)	0.0135	-0.31 (0.13)	(-0.57, -0.04)	0.0223	
Positive (At any time)	4	NE	10	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.3362
< 30	85	-4.97 (0.36)	87	-3.64 (0.37)	-1.34 (0.47)	(-2.26, -0.41)	0.0051	-0.40 (0.15)	(-0.70, -0.09)	0.0103	
>= 30	34	-3.50 (0.47)	32	-2.93 (0.47)	-0.58 (0.63)	(-1.85, 0.69)	0.3655	-0.21 (0.25)	(-0.69, 0.27)	0.3935	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.3065
All negative/normal	38	-3.72 (0.44)	55	-3.08 (0.37)	-0.64 (0.56)	(-1.76, 0.48)	0.2575	-0.23 (0.21)	(-0.65, 0.18)	0.2702	
At least one positive/abnormal	81	-5.05 (0.39)	64	-3.65 (0.45)	-1.41 (0.50)	(-2.39, -0.42)	0.0055	-0.40 (0.17)	(-0.73, -0.06)	0.0192	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score CNS
Full analysis set

Visit	Anifrolumab 300mg (N=119) N	LSMean (SE)	Placebo (N=121) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		NE		NE	NE	NE				
Week 8		NE		NE	NE	NE				
Week 12		NE		NE	NE	NE				
Week 16		NE		NE	NE	NE				
Week 20		NE		NE	NE	NE				
Week 24		NE		NE	NE	NE				
Week 28		NE		NE	NE	NE				
Week 32		NE		NE	NE	NE				
Week 36		NE		NE	NE	NE				
Week 40		NE		NE	NE	NE				
Week 44		NE		NE	NE	NE				
Week 48		NE		NE	NE	NE				
Week 52		NE		NE	NE	NE				
OVERALL	119	NE	119	NE	NE	NE		NE	NE	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score CNS - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) N	LSMean (SE)	Placebo (N=121) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											NE
< 10 points	41	NE	32	NE	NE	NE		NE	NE		
>= 10 points	78	NE	87	NE	NE	NE		NE	NE		
OCS dose at baseline											NE
<10 mg/day	58	NE	64	NE	NE	NE		NE	NE		
>=10 mg/day	61	NE	55	NE	NE	NE		NE	NE		
Result of type I IFN gene signature test											NE
LOW	23	NE	24	NE	NE	NE		NE	NE		
HIGH	96	NE	95	NE	NE	NE		NE	NE		
Age (years)											NE
<= 65	117	NE	118	NE	NE	NE		NE	NE		
> 65	2	NE	1	NE	NE	NE		NE	NE		
Sex											NE
male	11	NE	12	NE	NE	NE		NE	NE		
female	108	NE	107	NE	NE	NE		NE	NE		
Race											NE
White	75	NE	77	NE	NE	NE		NE	NE		
Black or African American	11	NE	18	NE	NE	NE		NE	NE		
Asian	17	NE	16	NE	NE	NE		NE	NE		
Other	8	NE	5	NE	NE	NE		NE	NE		
Ethnicity											NE
Hispanic/Latino	27	NE	32	NE	NE	NE		NE	NE		
Non-hispanic/Latino	84	NE	84	NE	NE	NE		NE	NE		
Geographic region											NE
EU	45	NE	32	NE	NE	NE		NE	NE		
non-EU	74	NE	87	NE	NE	NE		NE	NE		
Onset of disease											NE
Paediatric	11	NE	5	NE	NE	NE		NE	NE		
Adult	108	NE	114	NE	NE	NE		NE	NE		
ADA result											NE
Negative	115	NE	109	NE	NE	NE		NE	NE		
Positive (At any time)	4	NE	10	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											NE
< 30	85	NE	87	NE	NE	NE		NE	NE		
>= 30	34	NE	32	NE	NE	NE		NE	NE		
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											NE
All negative/normal	38	NE	55	NE	NE	NE		NE	NE		
At least one positive/abnormal	81	NE	64	NE	NE	NE		NE	NE		

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score CVS and Respiratory
Full analysis set

Visit	Anifrolumab 300mg (N=119) N	Anifrolumab 300mg (N=119) LSMean (SE)	Placebo (N=121) N	Placebo (N=121) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		NE		NE	NE	NE				
Week 8		NE		NE	NE	NE				
Week 12		NE		NE	NE	NE				
Week 16		NE		NE	NE	NE				
Week 20		NE		NE	NE	NE				
Week 24		NE		NE	NE	NE				
Week 28		NE		NE	NE	NE				
Week 32		NE		NE	NE	NE				
Week 36		NE		NE	NE	NE				
Week 40		NE		NE	NE	NE				
Week 44		NE		NE	NE	NE				
Week 48		NE		NE	NE	NE				
Week 52		NE		NE	NE	NE				
OVERALL	119	NE	119	NE	NE	NE		NE	NE	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score CVS and Respiratory - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) N	LSMean (SE)	Placebo (N=121) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											NE
< 10 points	41	NE	32	NE	NE	NE		NE	NE		
>= 10 points	78	NE	87	NE	NE	NE		NE	NE		
OCS dose at baseline											NE
<10 mg/day	58	NE	64	NE	NE	NE		NE	NE		
>=10 mg/day	61	NE	55	NE	NE	NE		NE	NE		
Result of type I IFN gene signature test											NE
LOW	23	NE	24	NE	NE	NE		NE	NE		
HIGH	96	NE	95	NE	NE	NE		NE	NE		
Age (years)											NE
<= 65	117	NE	118	NE	NE	NE		NE	NE		
> 65	2	NE	1	NE	NE	NE		NE	NE		
Sex											NE
male	11	NE	12	NE	NE	NE		NE	NE		
female	108	NE	107	NE	NE	NE		NE	NE		
Race											NE
White	75	NE	77	NE	NE	NE		NE	NE		
Black or African American	11	NE	18	NE	NE	NE		NE	NE		
Asian	17	NE	16	NE	NE	NE		NE	NE		
Other	8	NE	5	NE	NE	NE		NE	NE		
Ethnicity											NE
Hispanic/Latino	27	NE	32	NE	NE	NE		NE	NE		
Non-hispanic/Latino	84	NE	84	NE	NE	NE		NE	NE		
Geographic region											NE
EU	45	NE	32	NE	NE	NE		NE	NE		
non-EU	74	NE	87	NE	NE	NE		NE	NE		
Onset of disease											NE
Paediatric	11	NE	5	NE	NE	NE		NE	NE		
Adult	108	NE	114	NE	NE	NE		NE	NE		
ADA result											NE
Negative	115	NE	109	NE	NE	NE		NE	NE		
Positive (At any time)	4	NE	10	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											NE
< 30	85	NE	87	NE	NE	NE		NE	NE		
>= 30	34	NE	32	NE	NE	NE		NE	NE		
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											NE
All negative/normal	38	NE	55	NE	NE	NE		NE	NE		
At least one positive/abnormal	81	NE	64	NE	NE	NE		NE	NE		

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score Hematological
Full analysis set

Visit	Anifrolumab 300mg (N=119) N	Anifrolumab 300mg (N=119) LSMean (SE)	Placebo (N=121) N	Placebo (N=121) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-0.11 (0.03)		-0.05 (0.03)	-0.06 (0.03)	(-0.13, 0.01)	0.0829			
Week 8		-0.11 (0.03)		-0.05 (0.03)	-0.06 (0.03)	(-0.13, 0.01)	0.0768			
Week 12		-0.14 (0.03)		-0.07 (0.03)	-0.07 (0.03)	(-0.13, 0.00)	0.0536			
Week 16		-0.15 (0.02)		-0.09 (0.02)	-0.06 (0.03)	(-0.12, -0.01)	0.0267			
Week 20		-0.14 (0.03)		-0.03 (0.03)	-0.11 (0.04)	(-0.18, -0.03)	0.0046			
Week 24		-0.14 (0.03)		-0.03 (0.03)	-0.11 (0.04)	(-0.18, -0.03)	0.0042			
Week 28		-0.12 (0.03)		-0.06 (0.03)	-0.06 (0.04)	(-0.13, 0.01)	0.1150			
Week 32		-0.13 (0.03)		-0.06 (0.03)	-0.07 (0.03)	(-0.14, -0.01)	0.0318			
Week 36		-0.14 (0.03)		-0.04 (0.03)	-0.11 (0.03)	(-0.18, -0.04)	0.0025			
Week 40		-0.15 (0.02)		-0.08 (0.03)	-0.07 (0.03)	(-0.13, -0.00)	0.0370			
Week 44		-0.12 (0.03)		-0.07 (0.03)	-0.05 (0.04)	(-0.12, 0.02)	0.1541			
Week 48		-0.14 (0.03)		-0.06 (0.03)	-0.08 (0.04)	(-0.15, -0.01)	0.0197			
Week 52		-0.10 (0.03)		-0.06 (0.03)	-0.04 (0.04)	(-0.12, 0.04)	0.3030			
OVERALL	119	-0.13 (0.02)	119	-0.06 (0.02)	-0.07 (0.02)	(-0.12, -0.03)	0.0027	-0.34 (0.13)	(-0.60, -0.09)	0.0090

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score Hematological - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) N	LSMean (SE)	Placebo (N=121) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											NE
< 10 points	41	NE	32	NE	NE	NE		NE	NE		
>= 10 points	78	-0.14 (0.03)	87	-0.06 (0.02)	-0.08 (0.03)	(-0.14, -0.02)	0.0126	-0.34 (0.16)	(-0.64, -0.03)	0.0321	
OCS dose at baseline											0.3117
<10 mg/day	58	-0.10 (0.03)	64	-0.02 (0.03)	-0.08 (0.04)	(-0.15, -0.01)	0.0232	-0.40 (0.18)	(-0.76, -0.04)	0.0297	
>=10 mg/day	61	-0.14 (0.03)	55	-0.11 (0.02)	-0.04 (0.03)	(-0.09, 0.02)	0.1860	-0.19 (0.19)	(-0.56, 0.17)	0.3044	
Result of type I IFN gene signature test											NE
LOW	23	NE	24	NE	NE	NE		NE	NE		
HIGH	96	-0.14 (0.02)	95	-0.05 (0.02)	-0.09 (0.03)	(-0.14, -0.03)	0.0035	-0.40 (0.15)	(-0.69, -0.12)	0.0056	
Age (years)											NE
<= 65	117	-0.13 (0.02)	118	-0.06 (0.02)	-0.07 (0.02)	(-0.12, -0.03)	0.0027	-0.34 (0.13)	(-0.60, -0.09)	0.0091	
> 65	2	NE	1	NE	NE	NE		NE	NE		
Sex											NE
male	11	NE	12	NE	NE	NE		NE	NE		
female	108	-0.13 (0.02)	107	-0.06 (0.02)	-0.07 (0.03)	(-0.12, -0.02)	0.0065	-0.33 (0.14)	(-0.60, -0.06)	0.0167	
Race											NE
White	75	-0.06 (0.02)	77	-0.03 (0.02)	-0.03 (0.02)	(-0.07, 0.02)	0.2302	-0.18 (0.16)	(-0.49, 0.14)	0.2789	
Black or African American	11	NE	18	NE	NE	NE		NE	NE		
Asian	17	NE	16	NE	NE	NE		NE	NE		
Other	8	NE	5	NE	NE	NE		NE	NE		
Ethnicity											NE
Hispanic/Latino	27	NE	32	NE	NE	NE		NE	NE		
Non-hispanic/Latino	84	-0.15 (0.02)	84	-0.06 (0.02)	-0.09 (0.03)	(-0.14, -0.03)	0.0023	-0.41 (0.16)	(-0.72, -0.11)	0.0084	
Geographic region											NE
EU	45	NE	32	NE	NE	NE		NE	NE		
non-EU	74	-0.13 (0.03)	87	-0.04 (0.02)	-0.09 (0.03)	(-0.15, -0.03)	0.0059	-0.39 (0.16)	(-0.71, -0.08)	0.0139	
Onset of disease											NE
Paediatric	11	NE	5	NE	NE	NE		NE	NE		
Adult	108	-0.11 (0.02)	114	-0.05 (0.02)	-0.06 (0.02)	(-0.11, -0.02)	0.0102	-0.31 (0.14)	(-0.57, -0.04)	0.0237	
ADA result											NE
Negative	115	-0.13 (0.02)	109	-0.04 (0.02)	-0.08 (0.02)	(-0.13, -0.04)	0.0008	-0.40 (0.14)	(-0.66, -0.13)	0.0033	
Positive (At any time)	4	NE	10	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											NE
< 30	85	-0.16 (0.03)	87	-0.06 (0.03)	-0.10 (0.03)	(-0.16, -0.04)	0.0018	-0.40 (0.15)	(-0.70, -0.10)	0.0097	
>= 30	34	NE	32	NE	NE	NE		NE	NE		
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											NE
All negative/normal	38	NE	55	NE	NE	NE		NE	NE		
At least one positive/abnormal	81	-0.20 (0.03)	64	-0.06 (0.03)	-0.13 (0.03)	(-0.20, -0.07)	0.0002	-0.49 (0.17)	(-0.82, -0.15)	0.0041	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score Immunology
Full analysis set

	Anifrolumab 300mg (N=119)		Placebo (N=121)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-0.15 (0.07)		-0.11 (0.08)	-0.04 (0.10)	(-0.22, 0.15)	0.7153			
Week 8		-0.20 (0.09)		-0.01 (0.09)	-0.19 (0.12)	(-0.43, 0.05)	0.1202			
Week 12		-0.20 (0.09)		-0.05 (0.09)	-0.16 (0.12)	(-0.39, 0.07)	0.1767			
Week 16		-0.17 (0.09)		0.02 (0.09)	-0.19 (0.12)	(-0.42, 0.04)	0.1099			
Week 20		-0.17 (0.09)		0.02 (0.10)	-0.19 (0.13)	(-0.43, 0.06)	0.1396			
Week 24		-0.30 (0.09)		0.06 (0.09)	-0.36 (0.12)	(-0.59, -0.13)	0.0024			
Week 28		-0.25 (0.08)		0.17 (0.08)	-0.42 (0.11)	(-0.63, -0.21)	0.0001			
Week 32		-0.28 (0.08)		0.06 (0.08)	-0.35 (0.10)	(-0.55, -0.15)	0.0009			
Week 36		-0.18 (0.09)		-0.01 (0.09)	-0.17 (0.12)	(-0.40, 0.06)	0.1402			
Week 40		-0.16 (0.09)		0.12 (0.10)	-0.28 (0.13)	(-0.53, -0.04)	0.0256			
Week 44		-0.11 (0.09)		0.18 (0.09)	-0.29 (0.12)	(-0.52, -0.06)	0.0153			
Week 48		-0.14 (0.10)		0.07 (0.10)	-0.22 (0.13)	(-0.48, 0.04)	0.0995			
Week 52		-0.29 (0.10)		0.04 (0.11)	-0.33 (0.14)	(-0.61, -0.05)	0.0228			
OVERALL	119	-0.20 (0.07)	121	0.04 (0.07)	-0.24 (0.08)	(-0.41, -0.08)	0.0039	-0.33 (0.13)	(-0.58, -0.07)	0.0118

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score Immunology - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) N	LSMean (SE)	Placebo (N=121) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.8514
< 10 points	41	-0.20 (0.10)	32	0.06 (0.11)	-0.26 (0.14)	(-0.54, 0.02)	0.0678	-0.41 (0.24)	(-0.88, 0.05)	0.0821	
>= 10 points	78	-0.14 (0.09)	89	0.09 (0.09)	-0.23 (0.10)	(-0.43, -0.02)	0.0290	-0.29 (0.16)	(-0.59, 0.02)	0.0672	
OCS dose at baseline											0.4949
<10 mg/day	58	-0.10 (0.07)	65	0.11 (0.07)	-0.20 (0.10)	(-0.40, -0.01)	0.0415	-0.35 (0.18)	(-0.70, 0.01)	0.0558	
>=10 mg/day	61	-0.36 (0.13)	56	-0.04 (0.13)	-0.32 (0.14)	(-0.60, -0.04)	0.0252	-0.32 (0.19)	(-0.68, 0.05)	0.0865	
Result of type I IFN gene signature test											0.4430
LOW	23	-0.08 (0.11)	24	0.07 (0.11)	-0.15 (0.16)	(-0.47, 0.17)	0.3420	-0.28 (0.29)	(-0.85, 0.30)	0.3433	
HIGH	96	-0.23 (0.07)	97	0.06 (0.07)	-0.30 (0.10)	(-0.49, -0.10)	0.0027	-0.41 (0.15)	(-0.70, -0.13)	0.0045	
Age (years)											NE
<= 65	117	-0.19 (0.07)	120	0.05 (0.07)	-0.24 (0.08)	(-0.40, -0.07)	0.0048	-0.32 (0.13)	(-0.58, -0.07)	0.0134	
> 65	2	NE	1	NE	NE	NE		NE	NE		
Sex											NE
male	11	NE	12	NE	NE	NE		NE	NE		
female	108	-0.19 (0.07)	109	0.08 (0.07)	-0.27 (0.09)	(-0.45, -0.09)	0.0028	-0.36 (0.14)	(-0.63, -0.09)	0.0083	
Race											NE
White	75	-0.23 (0.09)	78	0.04 (0.09)	-0.27 (0.11)	(-0.49, -0.05)	0.0146	-0.35 (0.16)	(-0.67, -0.03)	0.0320	
Black or African American	11	-0.22 (0.25)	18	-0.36 (0.25)	0.14 (0.30)	(-0.49, 0.76)	0.6511	0.13 (0.38)	(-0.62, 0.89)	0.7251	
Asian	17	NE	16	NE	NE	NE		NE	NE		
Other	8	NE	6	NE	NE	NE		NE	NE		
Ethnicity											0.1431
Hispanic/Latino	27	-0.15 (0.11)	32	-0.11 (0.11)	-0.05 (0.15)	(-0.34, 0.25)	0.7520	-0.08 (0.26)	(-0.59, 0.44)	0.7725	
Non-hispanic/Latino	84	-0.27 (0.09)	86	0.04 (0.09)	-0.31 (0.11)	(-0.52, -0.10)	0.0038	-0.39 (0.15)	(-0.69, -0.08)	0.0128	
Geographic region											0.9876
EU	45	-0.23 (0.14)	33	0.03 (0.17)	-0.26 (0.17)	(-0.61, 0.08)	0.1318	-0.27 (0.23)	(-0.72, 0.18)	0.2400	
non-EU	74	-0.21 (0.08)	88	0.05 (0.08)	-0.26 (0.10)	(-0.45, -0.07)	0.0081	-0.38 (0.16)	(-0.69, -0.07)	0.0178	
Onset of disease											NE
Paediatric	11	NE	5	NE	NE	NE		NE	NE		
Adult	108	-0.17 (0.07)	116	0.03 (0.07)	-0.20 (0.08)	(-0.37, -0.04)	0.0152	-0.29 (0.13)	(-0.55, -0.02)	0.0331	
ADA result											NE
Negative	115	-0.16 (0.07)	111	0.03 (0.07)	-0.19 (0.09)	(-0.36, -0.02)	0.0255	-0.26 (0.13)	(-0.53, -0.00)	0.0488	
Positive (At any time)	4	NE	10	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.1382
< 30	85	-0.23 (0.08)	89	0.10 (0.09)	-0.33 (0.10)	(-0.53, -0.12)	0.0017	-0.40 (0.15)	(-0.70, -0.10)	0.0091	
>= 30	34	-0.09 (0.10)	32	-0.01 (0.10)	-0.08 (0.13)	(-0.34, 0.18)	0.5434	-0.14 (0.25)	(-0.62, 0.34)	0.5677	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.3408
All negative/normal	38	0.08 (0.09)	56	0.25 (0.08)	-0.18 (0.12)	(-0.41, 0.05)	0.1320	-0.30 (0.21)	(-0.72, 0.11)	0.1496	
At least one positive/abnormal	81	-0.35 (0.10)	65	-0.02 (0.12)	-0.33 (0.11)	(-0.55, -0.11)	0.0040	-0.36 (0.17)	(-0.69, -0.03)	0.0315	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score Mucocutaneous
Full analysis set

Visit	Anifrolumab 300mg (N=119) N	LSMean (SE)	Placebo (N=121) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-0.10 (0.07)		-0.23 (0.07)	0.12 (0.08)	(-0.04, 0.29)	0.1420			
Week 8		-0.52 (0.11)		-0.47 (0.11)	-0.06 (0.15)	(-0.35, 0.24)	0.7076			
Week 12		-0.89 (0.14)		-0.61 (0.14)	-0.28 (0.19)	(-0.66, 0.10)	0.1439			
Week 16		-1.26 (0.15)		-0.80 (0.15)	-0.46 (0.21)	(-0.87, -0.05)	0.0264			
Week 20		-1.26 (0.14)		-0.90 (0.14)	-0.36 (0.20)	(-0.75, 0.03)	0.0719			
Week 24		-1.41 (0.16)		-0.94 (0.16)	-0.47 (0.22)	(-0.89, -0.05)	0.0299			
Week 28		-1.67 (0.15)		-0.93 (0.16)	-0.74 (0.21)	(-1.16, -0.32)	0.0006			
Week 32		-1.71 (0.15)		-1.16 (0.16)	-0.55 (0.21)	(-0.97, -0.13)	0.0102			
Week 36		-1.73 (0.17)		-1.28 (0.17)	-0.45 (0.24)	(-0.92, 0.01)	0.0556			
Week 40		-1.84 (0.18)		-1.36 (0.18)	-0.49 (0.25)	(-0.98, 0.01)	0.0543			
Week 44		-2.05 (0.18)		-1.43 (0.18)	-0.62 (0.25)	(-1.12, -0.13)	0.0138			
Week 48		-2.05 (0.18)		-1.54 (0.18)	-0.51 (0.25)	(-1.01, -0.01)	0.0449			
Week 52		-2.17 (0.18)		-1.70 (0.18)	-0.47 (0.25)	(-0.96, 0.03)	0.0629			
OVERALL	119	-1.44 (0.12)	119	-1.03 (0.13)	-0.41 (0.17)	(-0.75, -0.08)	0.0166	-0.30 (0.13)	(-0.56, -0.04)	0.0215

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score Mucocutaneous - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) N	LSMean (SE)	Placebo (N=121) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.5086
< 10 points	41	-0.95 (0.20)	32	-0.67 (0.22)	-0.29 (0.29)	(-0.88, 0.30)	0.3324	-0.23 (0.24)	(-0.69, 0.24)	0.3415	
>= 10 points	78	-1.70 (0.16)	87	-1.17 (0.15)	-0.53 (0.21)	(-0.94, -0.11)	0.0126	-0.37 (0.16)	(-0.68, -0.06)	0.0185	
OCS dose at baseline											0.0079
<10 mg/day	58	-1.10 (0.17)	64	-1.10 (0.16)	0.00 (0.23)	(-0.45, 0.45)	0.9972	0.00 (0.18)	(-0.35, 0.36)	0.9973	
>=10 mg/day	61	-1.86 (0.19)	55	-0.95 (0.20)	-0.91 (0.25)	(-1.41, -0.40)	0.0005	-0.60 (0.19)	(-0.97, -0.23)	0.0016	
Result of type I IFN gene signature test											0.4572
LOW	23	-1.21 (0.25)	24	-1.02 (0.24)	-0.19 (0.34)	(-0.88, 0.50)	0.5828	-0.16 (0.29)	(-0.73, 0.42)	0.5942	
HIGH	96	-1.50 (0.14)	95	-1.02 (0.14)	-0.48 (0.20)	(-0.87, -0.09)	0.0158	-0.35 (0.15)	(-0.63, -0.06)	0.0175	
Age (years)											NE
<= 65	117	-1.44 (0.12)	118	-0.99 (0.12)	-0.44 (0.17)	(-0.78, -0.11)	0.0091	-0.33 (0.13)	(-0.59, -0.07)	0.0125	
> 65	2	NE	1	NE	NE	NE		NE	NE		
Sex											NE
male	11	NE	12	NE	NE	NE		NE	NE		
female	108	-1.43 (0.13)	107	-1.04 (0.13)	-0.39 (0.18)	(-0.75, -0.04)	0.0295	-0.29 (0.14)	(-0.56, -0.02)	0.0360	
Race											NE
White	75	-1.51 (0.15)	77	-1.18 (0.15)	-0.33 (0.21)	(-0.74, 0.08)	0.1183	-0.24 (0.16)	(-0.56, 0.08)	0.1343	
Black or African American	11	NE	18	NE	NE	NE		NE	NE		
Asian	17	-1.30 (0.37)	16	-0.38 (0.34)	-0.92 (0.39)	(-1.72, -0.11)	0.0284	-0.61 (0.36)	(-1.31, 0.09)	0.0859	
Other	8	NE	5	NE	NE	NE		NE	NE		
Ethnicity											0.3050
Hispanic/Latino	27	-1.95 (0.26)	32	-1.19 (0.25)	-0.75 (0.35)	(-1.45, -0.05)	0.0364	-0.54 (0.27)	(-1.06, -0.02)	0.0421	
Non-hispanic/Latino	84	-1.31 (0.15)	84	-0.97 (0.15)	-0.34 (0.20)	(-0.73, 0.05)	0.0859	-0.25 (0.15)	(-0.56, 0.05)	0.1039	
Geographic region											0.3214
EU	45	-1.64 (0.20)	32	-1.50 (0.24)	-0.14 (0.30)	(-0.74, 0.46)	0.6364	-0.10 (0.23)	(-0.56, 0.35)	0.6563	
non-EU	74	-1.39 (0.16)	87	-0.88 (0.15)	-0.50 (0.21)	(-0.91, -0.09)	0.0161	-0.37 (0.16)	(-0.68, -0.06)	0.0205	
Onset of disease											NE
Paediatric	11	NE	5	NE	NE	NE		NE	NE		
Adult	108	-1.37 (0.13)	114	-1.03 (0.13)	-0.34 (0.17)	(-0.68, 0.00)	0.0519	-0.25 (0.13)	(-0.52, 0.01)	0.0617	
ADA result											NE
Negative	115	-1.42 (0.13)	109	-1.07 (0.13)	-0.35 (0.18)	(-0.70, 0.00)	0.0520	-0.25 (0.13)	(-0.51, 0.01)	0.0606	
Positive (At any time)	4	NE	10	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.1468
< 30	85	-1.61 (0.14)	87	-1.01 (0.15)	-0.59 (0.19)	(-0.98, -0.21)	0.0026	-0.44 (0.15)	(-0.74, -0.14)	0.0045	
>= 30	34	-1.11 (0.26)	32	-1.12 (0.26)	0.01 (0.37)	(-0.73, 0.74)	0.9834	0.01 (0.25)	(-0.48, 0.49)	0.9837	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.0517
All negative/normal	38	-1.16 (0.23)	55	-1.19 (0.19)	0.03 (0.29)	(-0.56, 0.62)	0.9177	0.02 (0.21)	(-0.39, 0.43)	0.9191	
At least one positive/abnormal	81	-1.55 (0.15)	64	-0.88 (0.18)	-0.67 (0.21)	(-1.09, -0.26)	0.0018	-0.48 (0.17)	(-0.81, -0.15)	0.0045	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score Musculoskeletal
Full analysis set

	Anifrolumab 300mg (N=119)		Placebo (N=121)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-0.18 (0.09)		-0.00 (0.09)	-0.18 (0.12)	(-0.40, 0.05)	0.1273			
Week 8		-1.12 (0.17)		-0.78 (0.17)	-0.33 (0.24)	(-0.80, 0.13)	0.1579			
Week 12		-1.73 (0.19)		-1.26 (0.19)	-0.47 (0.26)	(-0.98, 0.03)	0.0670			
Week 16		-1.93 (0.19)		-1.69 (0.19)	-0.24 (0.26)	(-0.76, 0.28)	0.3607			
Week 20		-2.11 (0.19)		-2.01 (0.19)	-0.10 (0.26)	(-0.62, 0.42)	0.7072			
Week 24		-2.22 (0.19)		-1.97 (0.19)	-0.25 (0.27)	(-0.77, 0.27)	0.3463			
Week 28		-2.36 (0.19)		-2.10 (0.20)	-0.26 (0.27)	(-0.79, 0.27)	0.3318			
Week 32		-2.27 (0.20)		-1.99 (0.20)	-0.28 (0.28)	(-0.83, 0.27)	0.3214			
Week 36		-2.38 (0.20)		-2.02 (0.20)	-0.36 (0.28)	(-0.91, 0.18)	0.1893			
Week 40		-2.32 (0.20)		-2.04 (0.20)	-0.29 (0.27)	(-0.83, 0.25)	0.2959			
Week 44		-2.37 (0.19)		-2.12 (0.20)	-0.25 (0.27)	(-0.78, 0.29)	0.3641			
Week 48		-2.54 (0.19)		-2.17 (0.20)	-0.37 (0.26)	(-0.89, 0.15)	0.1642			
Week 52		-2.48 (0.19)		-2.31 (0.20)	-0.17 (0.27)	(-0.70, 0.35)	0.5183			
OVERALL	119	-2.00 (0.14)	119	-1.73 (0.14)	-0.27 (0.19)	(-0.65, 0.11)	0.1563	-0.17 (0.13)	(-0.43, 0.08)	0.1805

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score Musculoskeletal - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) N	LSMean (SE)	Placebo (N=121) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.9710
< 10 points	41	-1.80 (0.23)	32	-1.52 (0.26)	-0.28 (0.34)	(-0.96, 0.41)	0.4261	-0.19 (0.24)	(-0.65, 0.28)	0.4311	
>= 10 points	78	-2.09 (0.19)	87	-1.83 (0.18)	-0.26 (0.24)	(-0.72, 0.20)	0.2709	-0.16 (0.16)	(-0.46, 0.15)	0.3137	
OCS dose at baseline											0.5328
<10 mg/day	58	-2.05 (0.19)	64	-1.88 (0.19)	-0.16 (0.26)	(-0.68, 0.35)	0.5350	-0.11 (0.18)	(-0.46, 0.25)	0.5499	
>=10 mg/day	61	-2.01 (0.22)	55	-1.60 (0.23)	-0.40 (0.29)	(-0.98, 0.17)	0.1666	-0.23 (0.19)	(-0.60, 0.13)	0.2099	
Result of type I IFN gene signature test											0.3067
LOW	23	-1.86 (0.29)	24	-1.98 (0.28)	0.12 (0.40)	(-0.70, 0.93)	0.7751	0.08 (0.29)	(-0.49, 0.65)	0.7787	
HIGH	96	-2.09 (0.16)	95	-1.74 (0.16)	-0.35 (0.22)	(-0.78, 0.08)	0.1087	-0.23 (0.15)	(-0.51, 0.06)	0.1176	
Age (years)											NE
<= 65	117	-2.01 (0.14)	118	-1.72 (0.15)	-0.29 (0.19)	(-0.67, 0.09)	0.1313	-0.19 (0.13)	(-0.44, 0.07)	0.1547	
> 65	2	NE	1	NE	NE	NE		NE	NE		
Sex											NE
male	11	NE	12	NE	NE	NE		NE	NE		
female	108	-1.93 (0.15)	107	-1.65 (0.15)	-0.28 (0.20)	(-0.68, 0.12)	0.1677	-0.18 (0.14)	(-0.45, 0.09)	0.1906	
Race											NE
White	75	-2.01 (0.18)	77	-1.68 (0.18)	-0.33 (0.25)	(-0.81, 0.16)	0.1902	-0.21 (0.16)	(-0.53, 0.11)	0.2004	
Black or African American	11	NE	18	NE	NE	NE		NE	NE		
Asian	17	NE	16	NE	NE	NE		NE	NE		
Other	8	NE	5	NE	NE	NE		NE	NE		
Ethnicity											0.5905
Hispanic/Latino	27	-2.04 (0.28)	32	-1.63 (0.27)	-0.42 (0.37)	(-1.17, 0.33)	0.2713	-0.28 (0.26)	(-0.79, 0.24)	0.2906	
Non-hispanic/Latino	84	-1.92 (0.18)	84	-1.74 (0.18)	-0.18 (0.24)	(-0.64, 0.29)	0.4495	-0.11 (0.15)	(-0.41, 0.19)	0.4770	
Geographic region											0.2606
EU	45	-2.19 (0.22)	32	-2.28 (0.25)	0.10 (0.30)	(-0.50, 0.69)	0.7475	0.07 (0.23)	(-0.39, 0.52)	0.7763	
non-EU	74	-1.83 (0.18)	87	-1.49 (0.17)	-0.33 (0.24)	(-0.81, 0.14)	0.1691	-0.21 (0.16)	(-0.52, 0.10)	0.1896	
Onset of disease											NE
Paediatric	11	NE	5	NE	NE	NE		NE	NE		
Adult	108	-2.05 (0.15)	114	-1.75 (0.15)	-0.29 (0.20)	(-0.69, 0.10)	0.1449	-0.19 (0.13)	(-0.45, 0.08)	0.1647	
ADA result											NE
Negative	115	-2.00 (0.15)	109	-1.70 (0.15)	-0.30 (0.20)	(-0.70, 0.10)	0.1364	-0.19 (0.13)	(-0.45, 0.07)	0.1582	
Positive (At any time)	4	NE	10	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.4012
< 30	85	-2.01 (0.17)	87	-1.83 (0.18)	-0.18 (0.23)	(-0.63, 0.28)	0.4427	-0.11 (0.15)	(-0.41, 0.19)	0.4798	
>= 30	34	-1.94 (0.26)	32	-1.41 (0.25)	-0.53 (0.35)	(-1.24, 0.18)	0.1389	-0.36 (0.25)	(-0.84, 0.13)	0.1501	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.1013
All negative/normal	38	-2.29 (0.26)	55	-1.59 (0.22)	-0.70 (0.33)	(-1.36, -0.04)	0.0385	-0.43 (0.21)	(-0.85, -0.02)	0.0421	
At least one positive/abnormal	81	-1.91 (0.18)	64	-1.88 (0.21)	-0.03 (0.24)	(-0.50, 0.44)	0.9015	-0.02 (0.17)	(-0.35, 0.31)	0.9160	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score Renal
Full analysis set

Visit	Anifrolumab 300mg (N=119) N	LSMean (SE)	Placebo (N=121) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		0.02 (0.09)		-0.07 (0.09)	0.08 (0.12)	(-0.15, 0.32)	0.4793			
Week 8		-0.08 (0.09)		0.00 (0.09)	-0.08 (0.12)	(-0.32, 0.16)	0.4925			
Week 12		-0.02 (0.09)		-0.01 (0.09)	-0.00 (0.12)	(-0.25, 0.24)	0.9973			
Week 16		-0.05 (0.10)		0.05 (0.10)	-0.10 (0.14)	(-0.37, 0.17)	0.4633			
Week 20		-0.01 (0.10)		0.04 (0.10)	-0.05 (0.14)	(-0.32, 0.23)	0.7405			
Week 24		-0.07 (0.11)		0.21 (0.11)	-0.29 (0.15)	(-0.59, 0.02)	0.0649			
Week 28		-0.01 (0.11)		0.08 (0.11)	-0.09 (0.16)	(-0.39, 0.22)	0.5714			
Week 32		-0.11 (0.11)		0.04 (0.11)	-0.15 (0.15)	(-0.45, 0.15)	0.3271			
Week 36		-0.04 (0.11)		0.08 (0.11)	-0.12 (0.14)	(-0.41, 0.17)	0.4104			
Week 40		-0.03 (0.14)		0.09 (0.14)	-0.12 (0.20)	(-0.51, 0.27)	0.5514			
Week 44		-0.11 (0.14)		0.00 (0.14)	-0.11 (0.20)	(-0.50, 0.28)	0.5820			
Week 48		0.01 (0.14)		-0.15 (0.14)	0.16 (0.19)	(-0.21, 0.54)	0.3945			
Week 52		-0.01 (0.13)		-0.07 (0.13)	0.06 (0.18)	(-0.29, 0.41)	0.7344			
OVERALL	119	-0.04 (0.08)	121	0.02 (0.08)	-0.06 (0.11)	(-0.27, 0.15)	0.5740	-0.07 (0.13)	(-0.32, 0.18)	0.5978

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score Renal - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) N	LSMean (SE)	Placebo (N=121) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											NE
< 10 points	41	NE	32	NE	NE	NE		NE	NE		
>= 10 points	78	-0.10 (0.12)	89	0.02 (0.12)	-0.12 (0.15)	(-0.42, 0.18)	0.4266	-0.11 (0.16)	(-0.41, 0.19)	0.4807	
OCS dose at baseline											NE
<10 mg/day	58	NE	65	NE	NE	NE		NE	NE		
>=10 mg/day	61	NE	56	NE	NE	NE		NE	NE		
Result of type I IFN gene signature test											NE
LOW	23	NE	24	NE	NE	NE		NE	NE		
HIGH	96	-0.06 (0.09)	97	0.02 (0.10)	-0.08 (0.13)	(-0.34, 0.18)	0.5572	-0.08 (0.14)	(-0.36, 0.20)	0.5668	
Age (years)											NE
<= 65	117	-0.04 (0.08)	120	0.02 (0.08)	-0.06 (0.11)	(-0.28, 0.16)	0.5787	-0.07 (0.13)	(-0.32, 0.19)	0.6029	
> 65	2	NE	1	NE	NE	NE		NE	NE		
Sex											NE
male	11	NE	12	NE	NE	NE		NE	NE		
female	108	-0.05 (0.08)	109	0.05 (0.08)	-0.10 (0.11)	(-0.31, 0.11)	0.3549	-0.12 (0.14)	(-0.39, 0.15)	0.3772	
Race											NE
White	75	NE	78	NE	NE	NE		NE	NE		
Black or African American	11	NE	18	NE	NE	NE		NE	NE		
Asian	17	NE	16	NE	NE	NE		NE	NE		
Other	8	NE	6	NE	NE	NE		NE	NE		
Ethnicity											NE
Hispanic/Latino	27	NE	32	NE	NE	NE		NE	NE		
Non-hispanic/Latino	84	-0.02 (0.08)	86	0.03 (0.08)	-0.05 (0.11)	(-0.27, 0.16)	0.6266	-0.07 (0.15)	(-0.37, 0.23)	0.6393	
Geographic region											NE
EU	45	NE	33	NE	NE	NE		NE	NE		
non-EU	74	-0.02 (0.10)	88	-0.02 (0.10)	-0.00 (0.14)	(-0.28, 0.28)	0.9951	-0.00 (0.16)	(-0.31, 0.31)	0.9953	
Onset of disease											NE
Paediatric	11	NE	5	NE	NE	NE		NE	NE		
Adult	108	-0.06 (0.09)	116	0.02 (0.09)	-0.08 (0.12)	(-0.32, 0.16)	0.5215	-0.08 (0.13)	(-0.34, 0.18)	0.5389	
ADA result											NE
Negative	115	-0.03 (0.07)	111	-0.04 (0.07)	0.02 (0.09)	(-0.17, 0.20)	0.8678	0.02 (0.13)	(-0.24, 0.28)	0.8719	
Positive (At any time)	4	NE	10	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											NE
< 30	85	-0.06 (0.09)	89	0.07 (0.09)	-0.13 (0.12)	(-0.38, 0.11)	0.2906	-0.16 (0.15)	(-0.45, 0.14)	0.3026	
>= 30	34	NE	32	NE	NE	NE		NE	NE		
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											NE
All negative/normal	38	NE	56	NE	NE	NE		NE	NE		
At least one positive/abnormal	81	-0.08 (0.15)	65	0.09 (0.18)	-0.17 (0.21)	(-0.59, 0.25)	0.4249	-0.12 (0.17)	(-0.45, 0.21)	0.4754	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score Vascular
Full analysis set

Visit	Anifrolumab 300mg (N=119) N	Anifrolumab 300mg (N=119) LSMean (SE)	Placebo (N=121) N	Placebo (N=121) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		NE		NE	NE	NE				
Week 8		NE		NE	NE	NE				
Week 12		NE		NE	NE	NE				
Week 16		NE		NE	NE	NE				
Week 20		NE		NE	NE	NE				
Week 24		NE		NE	NE	NE				
Week 28		NE		NE	NE	NE				
Week 32		NE		NE	NE	NE				
Week 36		NE		NE	NE	NE				
Week 40		NE		NE	NE	NE				
Week 44		NE		NE	NE	NE				
Week 48		NE		NE	NE	NE				
Week 52		NE		NE	NE	NE				
OVERALL	119	NE	119	NE	NE	NE		NE	NE	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score Vascular - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) N	LSMean (SE)	Placebo (N=121) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											NE
< 10 points	41	NE	32	NE	NE	NE		NE	NE		
>= 10 points	78	NE	87	NE	NE	NE		NE	NE		
OCS dose at baseline											NE
<10 mg/day	58	NE	64	NE	NE	NE		NE	NE		
>=10 mg/day	61	NE	55	NE	NE	NE		NE	NE		
Result of type I IFN gene signature test											NE
LOW	23	NE	24	NE	NE	NE		NE	NE		
HIGH	96	NE	95	NE	NE	NE		NE	NE		
Age (years)											NE
<= 65	117	NE	118	NE	NE	NE		NE	NE		
> 65	2	NE	1	NE	NE	NE		NE	NE		
Sex											NE
male	11	NE	12	NE	NE	NE		NE	NE		
female	108	NE	107	NE	NE	NE		NE	NE		
Race											NE
White	75	NE	77	NE	NE	NE		NE	NE		
Black or African American	11	NE	18	NE	NE	NE		NE	NE		
Asian	17	NE	16	NE	NE	NE		NE	NE		
Other	8	NE	5	NE	NE	NE		NE	NE		
Ethnicity											NE
Hispanic/Latino	27	NE	32	NE	NE	NE		NE	NE		
Non-hispanic/Latino	84	NE	84	NE	NE	NE		NE	NE		
Geographic region											NE
EU	45	NE	32	NE	NE	NE		NE	NE		
non-EU	74	NE	87	NE	NE	NE		NE	NE		
Onset of disease											NE
Paediatric	11	NE	5	NE	NE	NE		NE	NE		
Adult	108	NE	114	NE	NE	NE		NE	NE		
ADA result											NE
Negative	115	NE	109	NE	NE	NE		NE	NE		
Positive (At any time)	4	NE	10	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											NE
< 30	85	NE	87	NE	NE	NE		NE	NE		
>= 30	34	NE	32	NE	NE	NE		NE	NE		
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											NE
All negative/normal	38	NE	55	NE	NE	NE		NE	NE		
At least one positive/abnormal	81	NE	64	NE	NE	NE		NE	NE		

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - PGA
Full analysis set

	Anifrolumab 300mg (N=119)		Placebo (N=121)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-0.27 (0.04)		-0.23 (0.04)	-0.04 (0.05)	(-0.14, 0.06)	0.4725			
Week 8		-0.49 (0.05)		-0.35 (0.05)	-0.14 (0.06)	(-0.26, -0.02)	0.0246			
Week 12		-0.64 (0.05)		-0.41 (0.05)	-0.23 (0.07)	(-0.36, -0.10)	0.0007			
Week 16		-0.75 (0.05)		-0.57 (0.05)	-0.18 (0.07)	(-0.31, -0.04)	0.0120			
Week 20		-0.78 (0.05)		-0.54 (0.05)	-0.25 (0.07)	(-0.39, -0.11)	0.0006			
Week 24		-0.86 (0.05)		-0.60 (0.05)	-0.25 (0.07)	(-0.39, -0.12)	0.0003			
Week 28		-0.88 (0.05)		-0.64 (0.06)	-0.24 (0.07)	(-0.39, -0.10)	0.0009			
Week 32		-0.90 (0.06)		-0.66 (0.06)	-0.24 (0.08)	(-0.39, -0.09)	0.0017			
Week 36		-0.94 (0.06)		-0.71 (0.06)	-0.23 (0.08)	(-0.38, -0.08)	0.0031			
Week 40		-0.92 (0.06)		-0.71 (0.06)	-0.21 (0.08)	(-0.37, -0.05)	0.0084			
Week 44		-0.94 (0.06)		-0.72 (0.06)	-0.23 (0.08)	(-0.39, -0.07)	0.0055			
Week 48		-0.91 (0.06)		-0.69 (0.06)	-0.22 (0.08)	(-0.38, -0.06)	0.0073			
Week 52		-0.92 (0.06)		-0.73 (0.06)	-0.19 (0.08)	(-0.35, -0.04)	0.0167			
OVERALL	119	-0.79 (0.04)	119	-0.58 (0.05)	-0.20 (0.06)	(-0.32, -0.09)	0.0004	-0.42 (0.13)	(-0.67, -0.16)	0.0015

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - PGA - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) N	LSMean (SE)	Placebo (N=121) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.1131
< 10 points	41	-0.71 (0.08)	32	-0.67 (0.09)	-0.04 (0.12)	(-0.28, 0.19)	0.7043	-0.09 (0.24)	(-0.55, 0.38)	0.7169	
>= 10 points	78	-0.82 (0.05)	87	-0.56 (0.05)	-0.26 (0.07)	(-0.39, -0.13)	0.0001	-0.54 (0.16)	(-0.85, -0.23)	0.0007	
OCS dose at baseline											0.7527
<10 mg/day	58	-0.72 (0.06)	64	-0.55 (0.06)	-0.17 (0.08)	(-0.32, -0.01)	0.0324	-0.37 (0.18)	(-0.73, -0.01)	0.0427	
>=10 mg/day	61	-0.84 (0.07)	55	-0.63 (0.07)	-0.21 (0.09)	(-0.38, -0.03)	0.0187	-0.36 (0.19)	(-0.73, 0.01)	0.0543	
Result of type I IFN gene signature test											0.4335
LOW	23	-0.71 (0.08)	24	-0.59 (0.08)	-0.12 (0.11)	(-0.34, 0.10)	0.2670	-0.31 (0.29)	(-0.89, 0.26)	0.2876	
HIGH	96	-0.81 (0.05)	95	-0.59 (0.05)	-0.22 (0.07)	(-0.35, -0.09)	0.0009	-0.47 (0.15)	(-0.76, -0.18)	0.0014	
Age (years)											NE
<= 65	117	-0.79 (0.04)	118	-0.58 (0.05)	-0.21 (0.06)	(-0.32, -0.10)	0.0003	-0.43 (0.13)	(-0.69, -0.17)	0.0012	
> 65	2	NE	1	NE	NE	NE		NE	NE		
Sex											0.1181
male	11	-0.89 (0.17)	12	-1.00 (0.18)	0.11 (0.21)	(-0.33, 0.56)	0.5976	0.19 (0.42)	(-0.63, 1.01)	0.6566	
female	108	-0.78 (0.05)	107	-0.55 (0.05)	-0.23 (0.06)	(-0.35, -0.11)	0.0001	-0.48 (0.14)	(-0.75, -0.21)	0.0005	
Race											NE
White	75	-0.79 (0.05)	77	-0.62 (0.05)	-0.17 (0.07)	(-0.31, -0.04)	0.0125	-0.38 (0.16)	(-0.70, -0.06)	0.0210	
Black or African American	11	NE	18	NE	NE	NE		NE	NE		
Asian	17	-0.96 (0.18)	16	-0.44 (0.16)	-0.52 (0.16)	(-0.85, -0.18)	0.0036	-0.74 (0.36)	(-1.45, -0.03)	0.0408	
Other	8	NE	5	NE	NE	NE		NE	NE		
Ethnicity											0.2871
Hispanic/Latino	27	-0.90 (0.08)	32	-0.60 (0.08)	-0.31 (0.11)	(-0.53, -0.09)	0.0075	-0.67 (0.27)	(-1.20, -0.15)	0.0124	
Non-hispanic/Latino	84	-0.72 (0.05)	84	-0.55 (0.05)	-0.17 (0.07)	(-0.30, -0.04)	0.0110	-0.36 (0.16)	(-0.66, -0.05)	0.0217	
Geographic region											0.2503
EU	45	-0.88 (0.08)	32	-0.77 (0.08)	-0.11 (0.09)	(-0.29, 0.06)	0.2052	-0.23 (0.23)	(-0.68, 0.23)	0.3287	
non-EU	74	-0.76 (0.06)	87	-0.52 (0.05)	-0.24 (0.07)	(-0.39, -0.10)	0.0011	-0.48 (0.16)	(-0.80, -0.17)	0.0025	
Onset of disease											NE
Paediatric	11	NE	5	NE	NE	NE		NE	NE		
Adult	108	-0.79 (0.04)	114	-0.61 (0.04)	-0.18 (0.06)	(-0.29, -0.07)	0.0018	-0.39 (0.14)	(-0.65, -0.12)	0.0043	
ADA result											NE
Negative	115	-0.78 (0.04)	109	-0.59 (0.05)	-0.20 (0.06)	(-0.31, -0.08)	0.0010	-0.41 (0.14)	(-0.67, -0.14)	0.0025	
Positive (At any time)	4	NE	10	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.6980
< 30	85	-0.75 (0.05)	87	-0.56 (0.06)	-0.18 (0.07)	(-0.32, -0.05)	0.0088	-0.35 (0.15)	(-0.65, -0.05)	0.0219	
>= 30	34	-0.82 (0.08)	32	-0.58 (0.08)	-0.23 (0.11)	(-0.46, -0.00)	0.0461	-0.48 (0.25)	(-0.97, 0.01)	0.0552	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.1441
All negative/normal	38	-0.76 (0.08)	55	-0.67 (0.07)	-0.10 (0.10)	(-0.30, 0.10)	0.3312	-0.20 (0.21)	(-0.62, 0.21)	0.3425	
At least one positive/abnormal	81	-0.80 (0.06)	64	-0.53 (0.07)	-0.28 (0.07)	(-0.42, -0.14)	0.0002	-0.48 (0.17)	(-0.82, -0.15)	0.0044	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - CLASI Total Activity Score
Full analysis set

	Anifrolumab 300mg (N=119)		Placebo (N=121)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-1.41 (0.37)		-0.42 (0.38)	-0.99 (0.48)	(-1.94, -0.04)	0.0402			
Week 8		-2.54 (0.38)		-1.23 (0.39)	-1.32 (0.50)	(-2.30, -0.33)	0.0088			
Week 12		-2.91 (0.42)		-1.96 (0.43)	-0.96 (0.56)	(-2.06, 0.14)	0.0882			
Week 16		-3.16 (0.44)		-2.29 (0.44)	-0.87 (0.58)	(-2.02, 0.27)	0.1355			
Week 20		-3.55 (0.45)		-2.33 (0.45)	-1.23 (0.59)	(-2.40, -0.06)	0.0400			
Week 24		-3.85 (0.46)		-2.55 (0.46)	-1.30 (0.61)	(-2.51, -0.09)	0.0349			
Week 28		-3.97 (0.44)		-3.04 (0.45)	-0.93 (0.59)	(-2.09, 0.23)	0.1155			
Week 32		-4.12 (0.44)		-2.91 (0.45)	-1.20 (0.59)	(-2.37, -0.04)	0.0428			
Week 36		-4.16 (0.45)		-3.09 (0.45)	-1.07 (0.60)	(-2.25, 0.10)	0.0732			
Week 40		-4.37 (0.45)		-2.89 (0.46)	-1.48 (0.61)	(-2.68, -0.28)	0.0156			
Week 44		-4.29 (0.43)		-3.30 (0.44)	-0.99 (0.58)	(-2.13, 0.14)	0.0861			
Week 48		-4.32 (0.45)		-3.67 (0.46)	-0.65 (0.60)	(-1.85, 0.54)	0.2798			
Week 52		-4.56 (0.41)		-3.74 (0.43)	-0.82 (0.55)	(-1.91, 0.27)	0.1385			
OVERALL	119	-3.63 (0.38)	119	-2.57 (0.39)	-1.06 (0.49)	(-2.03, -0.09)	0.0320	-0.25 (0.13)	(-0.51, 0.00)	0.0511

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - CLASI Total Activity Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) N	LSMean (SE)	Placebo (N=121) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.5258
< 10 points	41	-3.25 (0.46)	32	-2.70 (0.52)	-0.55 (0.67)	(-1.91, 0.81)	0.4207	-0.18 (0.24)	(-0.65, 0.28)	0.4350	
>= 10 points	78	-3.68 (0.53)	87	-2.54 (0.50)	-1.14 (0.65)	(-2.42, 0.14)	0.0810	-0.24 (0.16)	(-0.55, 0.06)	0.1210	
OCS dose at baseline											NE
<10 mg/day	58	NE	64	NE	NE	NE		NE	NE		
>=10 mg/day	61	-3.96 (0.56)	55	-2.45 (0.56)	-1.51 (0.67)	(-2.83, -0.19)	0.0255	-0.35 (0.19)	(-0.72, 0.02)	0.0616	
Result of type I IFN gene signature test											NE
LOW	23	NE	24	NE	NE	NE		NE	NE		
HIGH	96	-4.26 (0.44)	95	-2.98 (0.45)	-1.28 (0.60)	(-2.47, -0.09)	0.0353	-0.30 (0.15)	(-0.58, -0.01)	0.0420	
Age (years)											NE
<= 65	117	-3.62 (0.39)	118	-2.53 (0.39)	-1.08 (0.50)	(-2.06, -0.10)	0.0303	-0.26 (0.13)	(-0.51, -0.00)	0.0493	
> 65	2	NE	1	NE	NE	NE		NE	NE		
Sex											0.3397
male	11	-2.41 (2.30)	12	-4.28 (2.28)	1.87 (3.11)	(-4.60, 8.34)	0.5535	0.23 (0.42)	(-0.59, 1.05)	0.5791	
female	108	-3.65 (0.33)	107	-2.53 (0.34)	-1.12 (0.43)	(-1.98, -0.27)	0.0105	-0.32 (0.14)	(-0.59, -0.05)	0.0192	
Race											NE
White	75	-3.64 (0.36)	77	-3.01 (0.36)	-0.63 (0.46)	(-1.53, 0.28)	0.1723	-0.20 (0.16)	(-0.52, 0.12)	0.2198	
Black or African American	11	NE	18	NE	NE	NE		NE	NE		
Asian	17	NE	16	NE	NE	NE		NE	NE		
Other	8	NE	5	NE	NE	NE		NE	NE		
Ethnicity											0.7444
Hispanic/Latino	27	-3.41 (0.71)	32	-2.11 (0.67)	-1.30 (0.96)	(-3.25, 0.65)	0.1837	-0.34 (0.26)	(-0.86, 0.18)	0.1956	
Non-hispanic/Latino	84	-3.54 (0.44)	84	-2.60 (0.45)	-0.94 (0.58)	(-2.09, 0.21)	0.1097	-0.23 (0.15)	(-0.53, 0.07)	0.1392	
Geographic region											0.0046
EU	45	-3.58 (0.53)	32	-4.32 (0.61)	0.74 (0.71)	(-0.68, 2.16)	0.3024	0.21 (0.23)	(-0.25, 0.66)	0.3724	
non-EU	74	-3.68 (0.51)	87	-1.70 (0.49)	-1.99 (0.65)	(-3.27, -0.71)	0.0026	-0.44 (0.16)	(-0.76, -0.13)	0.0055	
Onset of disease											NE
Paediatric	11	NE	5	NE	NE	NE		NE	NE		
Adult	108	-3.65 (0.41)	114	-2.58 (0.40)	-1.07 (0.53)	(-2.11, -0.03)	0.0430	-0.25 (0.13)	(-0.51, 0.01)	0.0636	
ADA result											NE
Negative	115	-3.58 (0.38)	109	-2.80 (0.39)	-0.78 (0.50)	(-1.76, 0.20)	0.1184	-0.19 (0.13)	(-0.45, 0.07)	0.1563	
Positive (At any time)	4	NE	10	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.0261
< 30	85	-4.09 (0.52)	87	-2.48 (0.53)	-1.61 (0.65)	(-2.89, -0.34)	0.0138	-0.33 (0.15)	(-0.63, -0.03)	0.0313	
>= 30	34	-2.45 (0.45)	32	-2.84 (0.45)	0.39 (0.62)	(-0.86, 1.63)	0.5389	0.15 (0.25)	(-0.34, 0.63)	0.5517	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.0291
All negative/normal	38	-2.80 (0.44)	55	-2.86 (0.37)	0.06 (0.56)	(-1.06, 1.17)	0.9191	0.02 (0.21)	(-0.39, 0.43)	0.9211	
At least one positive/abnormal	81	-4.21 (0.62)	64	-2.19 (0.72)	-2.01 (0.76)	(-3.53, -0.49)	0.0099	-0.35 (0.17)	(-0.68, -0.02)	0.0357	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - CLASI Total Damage Score
Full analysis set

	Anifrolumab 300mg (N=119)		Placebo (N=121)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-0.16 (0.12)		0.03 (0.12)	-0.19 (0.15)	(-0.47, 0.10)	0.2083			
Week 8		-0.08 (0.15)		0.00 (0.15)	-0.09 (0.20)	(-0.48, 0.31)	0.6652			
Week 12		-0.17 (0.14)		-0.01 (0.14)	-0.17 (0.19)	(-0.54, 0.20)	0.3698			
Week 16		-0.32 (0.13)		0.12 (0.13)	-0.44 (0.17)	(-0.77, -0.11)	0.0098			
Week 20		-0.33 (0.16)		-0.02 (0.16)	-0.31 (0.21)	(-0.72, 0.11)	0.1478			
Week 24		-0.39 (0.16)		0.02 (0.16)	-0.41 (0.21)	(-0.81, 0.00)	0.0504			
Week 28		-0.44 (0.15)		-0.05 (0.15)	-0.39 (0.20)	(-0.78, -0.01)	0.0459			
Week 32		-0.47 (0.17)		0.02 (0.17)	-0.48 (0.23)	(-0.93, -0.04)	0.0331			
Week 36		-0.49 (0.17)		-0.09 (0.18)	-0.40 (0.23)	(-0.86, 0.06)	0.0854			
Week 40		-0.43 (0.17)		-0.03 (0.18)	-0.41 (0.23)	(-0.87, 0.05)	0.0825			
Week 44		-0.51 (0.17)		-0.12 (0.18)	-0.39 (0.23)	(-0.85, 0.07)	0.0982			
Week 48		-0.42 (0.17)		-0.17 (0.18)	-0.25 (0.23)	(-0.71, 0.20)	0.2758			
Week 52		-0.39 (0.19)		-0.16 (0.19)	-0.22 (0.26)	(-0.74, 0.29)	0.3883			
OVERALL	119	-0.35 (0.14)	119	-0.04 (0.14)	-0.32 (0.18)	(-0.66, 0.03)	0.0699	-0.21 (0.13)	(-0.47, 0.04)	0.0991

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - CLASI Total Damage Score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=119)		Placebo (N=121)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											NE
< 10 points	41	NE	32	NE	NE	NE		NE	NE		
>= 10 points	78	NE	87	NE	NE	NE		NE	NE		
OCS dose at baseline											NE
<10 mg/day	58	NE	64	NE	NE	NE		NE	NE		
>=10 mg/day	61	NE	55	NE	NE	NE		NE	NE		
Result of type I IFN gene signature test											NE
LOW	23	NE	24	NE	NE	NE		NE	NE		
HIGH	96	-0.38 (0.15)	95	-0.07 (0.15)	-0.30 (0.20)	(-0.70, 0.10)	0.1357	-0.21 (0.15)	(-0.49, 0.08)	0.1521	
Age (years)											NE
<= 65	117	NE	118	NE	NE	NE		NE	NE		
> 65	2	NE	1	NE	NE	NE		NE	NE		
Sex											NE
male	11	NE	12	NE	NE	NE		NE	NE		
female	108	-0.32 (0.14)	107	-0.03 (0.14)	-0.29 (0.18)	(-0.65, 0.07)	0.1098	-0.20 (0.14)	(-0.47, 0.07)	0.1451	
Race											NE
White	75	-0.51 (0.13)	77	-0.12 (0.13)	-0.39 (0.18)	(-0.74, -0.03)	0.0323	-0.34 (0.16)	(-0.66, -0.02)	0.0390	
Black or African American	11	NE	18	NE	NE	NE		NE	NE		
Asian	17	NE	16	NE	NE	NE		NE	NE		
Other	8	NE	5	NE	NE	NE		NE	NE		
Ethnicity											NE
Hispanic/Latino	27	NE	32	NE	NE	NE		NE	NE		
Non-hispanic/Latino	84	NE	84	NE	NE	NE		NE	NE		
Geographic region											NE
EU	45	-0.49 (0.21)	32	-0.05 (0.24)	-0.44 (0.30)	(-1.03, 0.15)	0.1413	-0.31 (0.23)	(-0.77, 0.14)	0.1795	
non-EU	74	NE	87	NE	NE	NE		NE	NE		
Onset of disease											NE
Paediatric	11	NE	5	NE	NE	NE		NE	NE		
Adult	108	-0.38 (0.14)	114	-0.05 (0.14)	-0.33 (0.19)	(-0.70, 0.04)	0.0773	-0.22 (0.13)	(-0.48, 0.05)	0.1061	
ADA result											NE
Negative	115	-0.30 (0.13)	109	-0.15 (0.13)	-0.15 (0.17)	(-0.49, 0.18)	0.3668	-0.11 (0.13)	(-0.37, 0.15)	0.4140	
Positive (At any time)	4	NE	10	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											NE
< 30	85	NE	87	NE	NE	NE		NE	NE		
>= 30	34	NE	32	NE	NE	NE		NE	NE		
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											NE
All negative/normal	38	-0.15 (0.16)	55	-0.02 (0.13)	-0.13 (0.20)	(-0.53, 0.27)	0.5129	-0.13 (0.21)	(-0.55, 0.28)	0.5241	
At least one positive/abnormal	81	NE	64	NE	NE	NE		NE	NE		

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - BILAG Global Score
Full analysis set

Visit	Anifrolumab 300mg (N=119) N	LSMean (SE)	Placebo (N=121) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-4.78 (0.58)		-4.08 (0.58)	-0.70 (0.75)	(-2.17, 0.78)	0.3533			
Week 8		-7.47 (0.62)		-5.45 (0.62)	-2.01 (0.81)	(-3.61, -0.41)	0.0138			
Week 12		-8.64 (0.63)		-7.08 (0.64)	-1.56 (0.83)	(-3.19, 0.07)	0.0599			
Week 16		-9.56 (0.61)		-8.92 (0.62)	-0.64 (0.79)	(-2.20, 0.92)	0.4217			
Week 20		-10.12 (0.61)		-8.29 (0.62)	-1.83 (0.80)	(-3.41, -0.25)	0.0235			
Week 24		-10.45 (0.62)		-8.10 (0.63)	-2.35 (0.81)	(-3.96, -0.75)	0.0042			
Week 28		-10.50 (0.65)		-8.12 (0.67)	-2.38 (0.87)	(-4.10, -0.67)	0.0065			
Week 32		-10.72 (0.64)		-8.01 (0.66)	-2.71 (0.85)	(-4.39, -1.03)	0.0017			
Week 36		-10.58 (0.68)		-8.80 (0.70)	-1.78 (0.91)	(-3.58, 0.02)	0.0524			
Week 40		-10.34 (0.69)		-8.83 (0.71)	-1.51 (0.93)	(-3.33, 0.32)	0.1060			
Week 44		-10.74 (0.67)		-9.35 (0.69)	-1.39 (0.90)	(-3.16, 0.38)	0.1228			
Week 48		-11.01 (0.66)		-9.49 (0.69)	-1.52 (0.89)	(-3.27, 0.24)	0.0904			
Week 52		-11.11 (0.68)		-10.24 (0.71)	-0.87 (0.92)	(-2.69, 0.95)	0.3467			
OVERALL	119	-9.69 (0.51)	119	-8.06 (0.52)	-1.63 (0.64)	(-2.89, -0.38)	0.0109	-0.29 (0.13)	(-0.55, -0.04)	0.0249

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - BILAG Global Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) N	LSMean (SE)	Placebo (N=121) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.5530
< 10 points	41	-9.54 (0.79)	32	-8.50 (0.90)	-1.04 (1.12)	(-3.27, 1.19)	0.3563	-0.20 (0.24)	(-0.67, 0.26)	0.3917	
>= 10 points	78	-9.56 (0.67)	87	-7.71 (0.63)	-1.85 (0.78)	(-3.39, -0.30)	0.0193	-0.31 (0.16)	(-0.62, -0.01)	0.0462	
OCS dose at baseline											0.7709
<10 mg/day	58	-9.61 (0.65)	64	-8.17 (0.65)	-1.44 (0.87)	(-3.16, 0.28)	0.0990	-0.28 (0.18)	(-0.64, 0.07)	0.1208	
>=10 mg/day	61	-9.88 (0.90)	55	-8.06 (0.87)	-1.82 (0.95)	(-3.70, 0.06)	0.0577	-0.27 (0.19)	(-0.63, 0.10)	0.1543	
Result of type I IFN gene signature test											0.5598
LOW	23	-9.43 (0.98)	24	-8.55 (0.92)	-0.88 (1.29)	(-3.49, 1.72)	0.4974	-0.19 (0.29)	(-0.76, 0.38)	0.5192	
HIGH	96	-9.72 (0.54)	95	-7.97 (0.55)	-1.75 (0.74)	(-3.21, -0.29)	0.0189	-0.33 (0.15)	(-0.61, -0.04)	0.0251	
Age (years)											NE
<= 65	117	-9.77 (0.51)	118	-8.09 (0.52)	-1.68 (0.64)	(-2.95, -0.41)	0.0095	-0.30 (0.13)	(-0.56, -0.04)	0.0226	
> 65	2	NE	1	NE	NE	NE		NE	NE		
Sex											0.7597
male	11	-7.17 (1.66)	12	-6.07 (1.92)	-1.10 (1.92)	(-5.09, 2.88)	0.5716	-0.17 (0.42)	(-0.99, 0.65)	0.6788	
female	108	-9.84 (0.54)	107	-8.12 (0.54)	-1.72 (0.68)	(-3.06, -0.39)	0.0115	-0.31 (0.14)	(-0.58, -0.04)	0.0251	
Race											NE
White	75	-9.24 (0.64)	77	-8.40 (0.64)	-0.84 (0.82)	(-2.45, 0.78)	0.3069	-0.15 (0.16)	(-0.47, 0.17)	0.3595	
Black or African American	11	-9.73 (2.13)	18	-7.44 (2.16)	-2.29 (2.45)	(-7.46, 2.88)	0.3632	-0.26 (0.38)	(-1.02, 0.49)	0.4935	
Asian	17	-12.70 (1.75)	16	-9.19 (1.60)	-3.51 (1.68)	(-6.94, -0.09)	0.0448	-0.50 (0.35)	(-1.20, 0.19)	0.1571	
Other	8	NE	5	NE	NE	NE		NE	NE		
Ethnicity											0.1634
Hispanic/Latino	27	-11.12 (1.01)	32	-7.88 (1.00)	-3.25 (1.32)	(-5.89, -0.61)	0.0168	-0.59 (0.27)	(-1.11, -0.06)	0.0284	
Non-hispanic/Latino	84	-8.95 (0.61)	84	-7.81 (0.61)	-1.14 (0.75)	(-2.62, 0.33)	0.1280	-0.20 (0.15)	(-0.51, 0.10)	0.1897	
Geographic region											0.0416
EU	45	-10.54 (0.87)	32	-10.80 (0.96)	0.26 (0.96)	(-1.66, 2.18)	0.7875	0.05 (0.23)	(-0.41, 0.50)	0.8437	
non-EU	74	-9.41 (0.63)	87	-7.12 (0.61)	-2.29 (0.80)	(-3.86, -0.71)	0.0047	-0.41 (0.16)	(-0.72, -0.09)	0.0109	
Onset of disease											NE
Paediatric	11	NE	5	NE	NE	NE		NE	NE		
Adult	108	-9.67 (0.53)	114	-8.09 (0.53)	-1.58 (0.66)	(-2.88, -0.28)	0.0174	-0.28 (0.13)	(-0.55, -0.02)	0.0352	
ADA result											NE
Negative	115	-9.62 (0.52)	109	-8.13 (0.53)	-1.49 (0.66)	(-2.79, -0.19)	0.0244	-0.27 (0.13)	(-0.53, -0.01)	0.0457	
Positive (At any time)	4	NE	10	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.9061
< 30	85	-10.15 (0.62)	87	-8.53 (0.65)	-1.62 (0.75)	(-3.09, -0.15)	0.0313	-0.27 (0.15)	(-0.58, 0.03)	0.0730	
>= 30	34	-8.50 (0.95)	32	-7.06 (0.95)	-1.44 (1.31)	(-4.06, 1.18)	0.2746	-0.26 (0.25)	(-0.75, 0.22)	0.2914	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.9971
All negative/normal	38	-9.42 (0.91)	55	-7.74 (0.76)	-1.67 (1.15)	(-3.96, 0.62)	0.1499	-0.29 (0.21)	(-0.71, 0.12)	0.1643	
At least one positive/abnormal	81	-9.97 (0.72)	64	-8.30 (0.83)	-1.67 (0.79)	(-3.22, -0.11)	0.0357	-0.25 (0.17)	(-0.58, 0.08)	0.1311	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Tender Joint Count
Full analysis set

Visit	Anifrolumab 300mg (N=119) N	Anifrolumab 300mg (N=119) LSMean (SE)	Placebo (N=121) N	Placebo (N=121) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-1.81 (0.54)		-1.67 (0.55)	-0.14 (0.71)	(-1.53, 1.26)	0.8477			
Week 8		-3.14 (0.58)		-3.05 (0.59)	-0.09 (0.76)	(-1.59, 1.41)	0.9023			
Week 12		-3.98 (0.58)		-4.14 (0.59)	0.16 (0.77)	(-1.36, 1.67)	0.8392			
Week 16		-4.51 (0.56)		-5.44 (0.57)	0.92 (0.74)	(-0.53, 2.38)	0.2120			
Week 20		-5.17 (0.55)		-5.40 (0.56)	0.23 (0.72)	(-1.20, 1.65)	0.7521			
Week 24		-5.29 (0.59)		-5.31 (0.60)	0.03 (0.78)	(-1.52, 1.57)	0.9741			
Week 28		-5.55 (0.56)		-5.74 (0.57)	0.18 (0.74)	(-1.27, 1.63)	0.8040			
Week 32		-5.26 (0.57)		-5.41 (0.59)	0.15 (0.76)	(-1.35, 1.64)	0.8469			
Week 36		-5.86 (0.56)		-5.85 (0.58)	-0.02 (0.74)	(-1.48, 1.45)	0.9831			
Week 40		-5.07 (0.56)		-6.30 (0.59)	1.23 (0.75)	(-0.25, 2.70)	0.1019			
Week 44		-5.57 (0.55)		-6.34 (0.57)	0.77 (0.72)	(-0.66, 2.20)	0.2878			
Week 48		-5.27 (0.59)		-5.60 (0.61)	0.32 (0.78)	(-1.22, 1.87)	0.6801			
Week 52		-4.83 (0.60)		-5.98 (0.62)	1.15 (0.80)	(-0.43, 2.73)	0.1540			
OVERALL	119	-4.72 (0.45)	119	-5.09 (0.47)	0.38 (0.57)	(-0.76, 1.51)	0.5131	0.07 (0.13)	(-0.18, 0.33)	0.5672

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Tender Joint Count - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) N	LSMean (SE)	Placebo (N=121) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.6667
< 10 points	41	-4.56 (0.82)	32	-5.27 (0.93)	0.71 (1.18)	(-1.65, 3.07)	0.5497	0.13 (0.24)	(-0.33, 0.60)	0.5706	
>= 10 points	78	-4.60 (0.55)	87	-4.73 (0.53)	0.13 (0.64)	(-1.14, 1.41)	0.8392	0.03 (0.16)	(-0.28, 0.33)	0.8635	
OCS dose at baseline											0.1774
<10 mg/day	58	-3.94 (0.60)	64	-4.87 (0.62)	0.93 (0.81)	(-0.67, 2.54)	0.2519	0.19 (0.18)	(-0.16, 0.55)	0.2837	
>=10 mg/day	61	-6.40 (0.72)	55	-5.85 (0.69)	-0.55 (0.74)	(-2.01, 0.92)	0.4618	-0.10 (0.19)	(-0.47, 0.26)	0.5863	
Result of type I IFN gene signature test											NE
LOW	23	NE	24	NE	NE	NE		NE	NE		
HIGH	96	-5.32 (0.44)	95	-5.60 (0.46)	0.28 (0.62)	(-0.94, 1.50)	0.6494	0.06 (0.14)	(-0.22, 0.35)	0.6626	
Age (years)											NE
<= 65	117	-4.76 (0.46)	118	-5.11 (0.47)	0.35 (0.58)	(-0.79, 1.49)	0.5441	0.07 (0.13)	(-0.19, 0.32)	0.5971	
> 65	2	NE	1	NE	NE	NE		NE	NE		
Sex											NE
male	11	NE	12	NE	NE	NE		NE	NE		
female	108	-4.84 (0.49)	107	-5.25 (0.50)	0.41 (0.62)	(-0.82, 1.63)	0.5132	0.08 (0.14)	(-0.19, 0.35)	0.5626	
Race											NE
White	75	-5.35 (0.57)	77	-6.26 (0.58)	0.91 (0.72)	(-0.52, 2.34)	0.2115	0.18 (0.16)	(-0.14, 0.50)	0.2657	
Black or African American	11	-3.82 (2.50)	18	-4.77 (2.32)	0.96 (2.68)	(-4.57, 6.48)	0.7248	0.10 (0.38)	(-0.65, 0.85)	0.7944	
Asian	17	NE	16	NE	NE	NE		NE	NE		
Other	8	NE	5	NE	NE	NE		NE	NE		
Ethnicity											0.4309
Hispanic/Latino	27	-5.15 (0.99)	32	-5.01 (0.97)	-0.14 (1.28)	(-2.73, 2.45)	0.9163	-0.03 (0.26)	(-0.54, 0.49)	0.9234	
Non-hispanic/Latino	84	-4.53 (0.56)	84	-5.54 (0.57)	1.02 (0.70)	(-0.36, 2.40)	0.1481	0.20 (0.15)	(-0.11, 0.50)	0.2063	
Geographic region											0.4484
EU	45	-6.28 (0.49)	32	-6.29 (0.55)	0.01 (0.60)	(-1.19, 1.20)	0.9873	0.00 (0.23)	(-0.45, 0.46)	0.9899	
non-EU	74	-4.15 (0.60)	87	-4.90 (0.60)	0.75 (0.77)	(-0.77, 2.27)	0.3325	0.14 (0.16)	(-0.17, 0.45)	0.3845	
Onset of disease											NE
Paediatric	11	NE	5	NE	NE	NE		NE	NE		
Adult	108	-4.99 (0.48)	114	-5.27 (0.48)	0.28 (0.60)	(-0.91, 1.47)	0.6450	0.05 (0.13)	(-0.21, 0.32)	0.6845	
ADA result											NE
Negative	115	-4.68 (0.46)	109	-4.99 (0.49)	0.31 (0.60)	(-0.86, 1.49)	0.6013	0.06 (0.13)	(-0.20, 0.32)	0.6455	
Positive (At any time)	4	NE	10	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.5003
< 30	85	-5.10 (0.52)	87	-5.12 (0.56)	0.03 (0.64)	(-1.24, 1.29)	0.9663	0.01 (0.15)	(-0.29, 0.30)	0.9718	
>= 30	34	-4.03 (0.92)	32	-5.01 (0.90)	0.97 (1.25)	(-1.52, 3.47)	0.4387	0.18 (0.25)	(-0.30, 0.67)	0.4567	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.5798
All negative/normal	38	-5.73 (0.88)	55	-5.61 (0.74)	-0.13 (1.11)	(-2.33, 2.08)	0.9081	-0.02 (0.21)	(-0.44, 0.39)	0.9118	
At least one positive/abnormal	81	-4.34 (0.54)	64	-4.91 (0.64)	0.57 (0.62)	(-0.65, 1.80)	0.3543	0.11 (0.17)	(-0.21, 0.44)	0.4953	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Swollen Joint Count
Full analysis set

Visit	Anifrolumab 300mg (N=119) N	Anifrolumab 300mg (N=119) LSMean (SE)	Placebo (N=121) N	Placebo (N=121) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-1.91 (0.39)		-1.90 (0.39)	-0.01 (0.50)	(-1.00, 0.98)	0.9892			
Week 8		-2.52 (0.40)		-3.47 (0.40)	0.95 (0.52)	(-0.07, 1.97)	0.0674			
Week 12		-2.87 (0.42)		-3.85 (0.43)	0.98 (0.55)	(-0.10, 2.07)	0.0759			
Week 16		-3.19 (0.41)		-4.43 (0.42)	1.25 (0.55)	(0.17, 2.32)	0.0236			
Week 20		-3.85 (0.40)		-4.53 (0.41)	0.68 (0.53)	(-0.36, 1.72)	0.2003			
Week 24		-3.80 (0.40)		-4.56 (0.40)	0.76 (0.52)	(-0.26, 1.78)	0.1447			
Week 28		-4.06 (0.38)		-4.57 (0.39)	0.51 (0.49)	(-0.45, 1.47)	0.2985			
Week 32		-3.63 (0.41)		-4.53 (0.42)	0.91 (0.54)	(-0.16, 1.98)	0.0963			
Week 36		-3.78 (0.41)		-4.74 (0.42)	0.95 (0.54)	(-0.11, 2.02)	0.0785			
Week 40		-3.44 (0.44)		-4.73 (0.46)	1.29 (0.59)	(0.12, 2.46)	0.0303			
Week 44		-3.84 (0.42)		-4.55 (0.44)	0.71 (0.57)	(-0.40, 1.82)	0.2103			
Week 48		-3.93 (0.44)		-4.26 (0.46)	0.33 (0.60)	(-0.85, 1.51)	0.5823			
Week 52		-3.56 (0.44)		-4.65 (0.46)	1.09 (0.59)	(-0.07, 2.25)	0.0659			
OVERALL	119	-3.41 (0.33)	119	-4.21 (0.34)	0.80 (0.42)	(-0.02, 1.62)	0.0561	0.22 (0.13)	(-0.04, 0.47)	0.0936

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Swollen Joint Count - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) N	LSMean (SE)	Placebo (N=121) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.8653
< 10 points	41	-3.89 (0.69)	32	-4.86 (0.78)	0.97 (0.98)	(-0.99, 2.93)	0.3264	0.22 (0.24)	(-0.25, 0.68)	0.3600	
>= 10 points	78	-3.05 (0.36)	87	-3.84 (0.35)	0.79 (0.43)	(-0.06, 1.64)	0.0681	0.25 (0.16)	(-0.06, 0.55)	0.1167	
OCS dose at baseline											0.8261
<10 mg/day	58	-3.25 (0.45)	64	-3.90 (0.45)	0.65 (0.60)	(-0.54, 1.84)	0.2809	0.18 (0.18)	(-0.17, 0.54)	0.3139	
>=10 mg/day	61	-4.01 (0.48)	55	-4.49 (0.46)	0.48 (0.51)	(-0.53, 1.49)	0.3518	0.13 (0.19)	(-0.23, 0.50)	0.4800	
Result of type I IFN gene signature test											0.9075
LOW	23	-3.16 (0.73)	24	-4.08 (0.70)	0.92 (0.98)	(-1.07, 2.91)	0.3567	0.26 (0.29)	(-0.31, 0.84)	0.3736	
HIGH	96	-3.44 (0.35)	95	-4.23 (0.36)	0.79 (0.48)	(-0.16, 1.74)	0.1030	0.23 (0.15)	(-0.06, 0.51)	0.1195	
Age (years)											NE
<= 65	117	-3.47 (0.33)	118	-4.23 (0.34)	0.76 (0.42)	(-0.06, 1.59)	0.0699	0.21 (0.13)	(-0.05, 0.46)	0.1124	
> 65	2	NE	1	NE	NE	NE		NE	NE		
Sex											NE
male	11	NE	12	NE	NE	NE		NE	NE		
female	108	-3.50 (0.35)	107	-4.25 (0.36)	0.75 (0.45)	(-0.13, 1.63)	0.0959	0.20 (0.14)	(-0.07, 0.47)	0.1401	
Race											NE
White	75	-3.56 (0.42)	77	-5.03 (0.42)	1.47 (0.54)	(0.41, 2.53)	0.0068	0.40 (0.16)	(0.08, 0.72)	0.0152	
Black or African American	11	NE	18	NE	NE	NE		NE	NE		
Asian	17	NE	16	NE	NE	NE		NE	NE		
Other	8	NE	5	NE	NE	NE		NE	NE		
Ethnicity											0.7720
Hispanic/Latino	27	-2.82 (0.86)	32	-4.12 (0.83)	1.30 (1.11)	(-0.93, 3.54)	0.2469	0.28 (0.26)	(-0.24, 0.79)	0.2870	
Non-hispanic/Latino	84	-3.46 (0.37)	84	-4.42 (0.38)	0.95 (0.48)	(0.00, 1.90)	0.0494	0.27 (0.16)	(-0.03, 0.58)	0.0771	
Geographic region											0.7390
EU	45	-4.10 (0.33)	32	-4.67 (0.37)	0.57 (0.38)	(-0.19, 1.32)	0.1391	0.26 (0.23)	(-0.19, 0.72)	0.2590	
non-EU	74	-3.24 (0.44)	87	-4.03 (0.43)	0.79 (0.55)	(-0.30, 1.88)	0.1548	0.20 (0.16)	(-0.11, 0.51)	0.2062	
Onset of disease											NE
Paediatric	11	NE	5	NE	NE	NE		NE	NE		
Adult	108	-3.56 (0.35)	114	-4.32 (0.35)	0.76 (0.44)	(-0.11, 1.63)	0.0849	0.21 (0.13)	(-0.06, 0.47)	0.1278	
ADA result											NE
Negative	115	-3.41 (0.33)	109	-4.12 (0.35)	0.72 (0.43)	(-0.14, 1.57)	0.0992	0.20 (0.13)	(-0.07, 0.46)	0.1426	
Positive (At any time)	4	NE	10	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.9442
< 30	85	-3.29 (0.40)	87	-3.91 (0.42)	0.62 (0.49)	(-0.34, 1.58)	0.2047	0.16 (0.15)	(-0.14, 0.46)	0.2889	
>= 30	34	-3.36 (0.61)	32	-4.05 (0.60)	0.69 (0.82)	(-0.96, 2.33)	0.4068	0.20 (0.25)	(-0.29, 0.68)	0.4284	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.6909
All negative/normal	38	-3.66 (0.59)	55	-4.53 (0.49)	0.88 (0.74)	(-0.60, 2.35)	0.2415	0.24 (0.21)	(-0.18, 0.65)	0.2576	
At least one positive/abnormal	81	-3.61 (0.43)	64	-4.14 (0.51)	0.52 (0.49)	(-0.46, 1.50)	0.2938	0.13 (0.17)	(-0.20, 0.46)	0.4362	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Mental Component Score
Full analysis set

	Anifrolumab 300mg (N=119)		Placebo (N=121)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 8		2.21 (0.91)		-0.99 (0.92)	3.20 (1.18)	(0.88, 5.52)	0.0071			
Week 16		1.80 (0.95)		2.40 (0.98)	-0.60 (1.25)	(-3.07, 1.86)	0.6308			
Week 24		1.83 (1.08)		0.09 (1.08)	1.73 (1.42)	(-1.07, 4.54)	0.2240			
Week 32		2.99 (0.97)		2.50 (1.00)	0.50 (1.28)	(-2.02, 3.02)	0.6984			
Week 40		2.93 (0.96)		2.25 (1.02)	0.67 (1.28)	(-1.85, 3.20)	0.5991			
Week 48		2.97 (0.96)		1.30 (1.03)	1.66 (1.29)	(-0.88, 4.21)	0.1985			
Week 52		2.77 (1.07)		1.40 (1.12)	1.36 (1.44)	(-1.48, 4.21)	0.3449			
OVERALL	112	2.50 (0.78)	110	1.28 (0.82)	1.22 (0.99)	(-0.72, 3.16)	0.2173	0.14 (0.13)	(-0.12, 0.41)	0.2836

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Mental Component Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) N	LSMean (SE)	Placebo (N=121) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.0285
< 10 points	40	5.47 (1.25)	30	1.05 (1.47)	4.42 (1.79)	(0.84, 8.01)	0.0164	0.55 (0.25)	(0.07, 1.03)	0.0258	
>= 10 points	72	0.34 (1.02)	80	0.61 (0.97)	-0.27 (1.17)	(-2.59, 2.04)	0.8167	-0.03 (0.16)	(-0.35, 0.29)	0.8478	
OCS dose at baseline											0.7190
<10 mg/day	58	2.87 (0.97)	61	2.00 (1.03)	0.87 (1.31)	(-1.73, 3.47)	0.5095	0.11 (0.18)	(-0.25, 0.47)	0.5415	
>=10 mg/day	54	2.15 (1.41)	49	0.55 (1.36)	1.60 (1.55)	(-1.48, 4.68)	0.3044	0.16 (0.20)	(-0.23, 0.55)	0.4203	
Result of type I IFN gene signature test											0.6272
LOW	22	3.24 (1.88)	22	3.21 (1.75)	0.03 (2.55)	(-5.12, 5.18)	0.9903	0.00 (0.30)	(-0.59, 0.59)	0.9904	
HIGH	90	2.11 (0.80)	88	0.73 (0.83)	1.38 (1.10)	(-0.79, 3.54)	0.2112	0.18 (0.15)	(-0.12, 0.47)	0.2338	
Age (years)											NE
<= 65	110	2.29 (0.79)	110	1.22 (0.82)	1.07 (0.99)	(-0.87, 3.02)	0.2785	0.13 (0.13)	(-0.14, 0.39)	0.3483	
> 65	2	NE	0	NE	NE	NE		NE	NE		
Sex											0.9656
male	10	7.25 (5.28)	12	6.31 (7.38)	0.95 (4.12)	(-7.76, 9.65)	0.8214	0.04 (0.43)	(-0.80, 0.88)	0.9231	
female	102	2.08 (0.79)	98	0.95 (0.82)	1.13 (1.00)	(-0.84, 3.10)	0.2604	0.14 (0.14)	(-0.14, 0.42)	0.3217	
Race											NE
White	70	3.27 (1.07)	70	2.78 (1.08)	0.49 (1.35)	(-2.18, 3.16)	0.7156	0.05 (0.17)	(-0.28, 0.39)	0.7474	
Black or African American	10	2.52 (2.52)	17	1.04 (2.42)	1.48 (3.14)	(-4.97, 7.93)	0.6419	0.15 (0.40)	(-0.63, 0.94)	0.6997	
Asian	16	-3.30 (2.10)	16	-9.03 (2.14)	5.74 (2.07)	(1.50, 9.97)	0.0096	0.66 (0.36)	(-0.06, 1.37)	0.0708	
Other	8	NE	5	NE	NE	NE		NE	NE		
Ethnicity											0.9380
Hispanic/Latino	27	4.23 (1.65)	31	3.50 (1.62)	0.73 (2.18)	(-3.65, 5.12)	0.7378	0.08 (0.26)	(-0.43, 0.60)	0.7543	
Non-hispanic/Latino	77	1.32 (0.97)	77	0.40 (1.00)	0.93 (1.16)	(-1.36, 3.21)	0.4246	0.11 (0.16)	(-0.21, 0.42)	0.5072	
Geographic region											0.6166
EU	41	1.90 (1.37)	28	1.10 (1.56)	0.80 (1.61)	(-2.42, 4.02)	0.6218	0.09 (0.25)	(-0.39, 0.57)	0.7069	
non-EU	71	2.58 (0.98)	82	0.76 (0.98)	1.82 (1.25)	(-0.65, 4.29)	0.1474	0.21 (0.16)	(-0.11, 0.53)	0.1965	
Onset of disease											NE
Paediatric	9	NE	4	NE	NE	NE		NE	NE		
Adult	103	2.56 (0.83)	106	1.31 (0.84)	1.25 (1.03)	(-0.79, 3.29)	0.2293	0.15 (0.14)	(-0.13, 0.42)	0.2936	
ADA result											NE
Negative	108	2.47 (0.80)	101	1.30 (0.84)	1.16 (1.02)	(-0.84, 3.16)	0.2540	0.14 (0.14)	(-0.13, 0.41)	0.3184	
Positive (At any time)	4	NE	9	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.7968
< 30	79	1.79 (0.97)	79	0.71 (1.04)	1.08 (1.17)	(-1.23, 3.39)	0.3562	0.12 (0.16)	(-0.19, 0.43)	0.4497	
>= 30	33	3.53 (1.32)	31	1.89 (1.29)	1.63 (1.80)	(-1.97, 5.23)	0.3672	0.22 (0.25)	(-0.27, 0.71)	0.3849	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.2853
All negative/normal	37	4.15 (1.13)	52	1.48 (0.97)	2.67 (1.43)	(-0.18, 5.51)	0.0655	0.38 (0.22)	(-0.04, 0.81)	0.0792	
At least one positive/abnormal	75	1.64 (1.24)	58	1.10 (1.46)	0.55 (1.38)	(-2.19, 3.28)	0.6932	0.05 (0.17)	(-0.29, 0.39)	0.7754	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Physical Component Score
Full analysis set

	Anifrolumab 300mg (N=119)		Placebo (N=121)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 8		2.68 (0.63)		2.02 (0.65)	0.67 (0.81)	(-0.93, 2.26)	0.4105			
Week 16		3.46 (0.70)		2.98 (0.73)	0.48 (0.92)	(-1.33, 2.29)	0.6008			
Week 24		4.54 (0.72)		3.38 (0.73)	1.16 (0.94)	(-0.68, 3.01)	0.2144			
Week 32		3.38 (0.70)		3.06 (0.72)	0.33 (0.91)	(-1.47, 2.13)	0.7190			
Week 40		3.45 (0.74)		4.09 (0.78)	-0.63 (0.99)	(-2.58, 1.32)	0.5230			
Week 48		3.35 (0.80)		2.71 (0.85)	0.64 (1.09)	(-1.51, 2.79)	0.5582			
Week 52		3.19 (0.73)		3.02 (0.78)	0.16 (0.98)	(-1.77, 2.10)	0.8681			
OVERALL	112	3.44 (0.58)	110	3.04 (0.61)	0.40 (0.73)	(-1.04, 1.84)	0.5823	0.06 (0.13)	(-0.20, 0.33)	0.6343

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Physical Component Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) N	LSMean (SE)	Placebo (N=121) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.9995
< 10 points	40	3.36 (0.91)	30	2.94 (1.11)	0.42 (1.34)	(-2.25, 3.09)	0.7535	0.07 (0.24)	(-0.40, 0.54)	0.7702	
>= 10 points	72	3.61 (0.78)	80	3.19 (0.74)	0.42 (0.89)	(-1.34, 2.18)	0.6385	0.06 (0.16)	(-0.26, 0.38)	0.6980	
OCS dose at baseline											0.2711
<10 mg/day	58	3.45 (0.70)	61	2.38 (0.74)	1.08 (0.94)	(-0.79, 2.95)	0.2570	0.19 (0.18)	(-0.17, 0.55)	0.2952	
>=10 mg/day	54	2.91 (1.12)	49	3.51 (1.07)	-0.60 (1.20)	(-2.98, 1.77)	0.6157	-0.08 (0.20)	(-0.46, 0.31)	0.7000	
Result of type I IFN gene signature test											0.6594
LOW	22	3.17 (1.28)	22	3.54 (1.18)	-0.37 (1.69)	(-3.80, 3.05)	0.8262	-0.06 (0.30)	(-0.65, 0.53)	0.8333	
HIGH	90	3.59 (0.60)	88	3.13 (0.63)	0.46 (0.83)	(-1.18, 2.09)	0.5834	0.08 (0.15)	(-0.22, 0.37)	0.6016	
Age (years)											NE
<= 65	110	3.38 (0.59)	110	2.98 (0.61)	0.40 (0.73)	(-1.04, 1.85)	0.5852	0.06 (0.13)	(-0.20, 0.33)	0.6383	
> 65	2	NE	0	NE	NE	NE		NE	NE		
Sex											0.0020
male	10	3.11 (2.58)	12	9.78 (3.05)	-6.66 (2.40)	(-11.77, -1.56)	0.0137	-0.67 (0.44)	(-1.54, 0.20)	0.1291	
female	102	3.74 (0.58)	98	2.64 (0.61)	1.10 (0.75)	(-0.37, 2.58)	0.1408	0.18 (0.14)	(-0.09, 0.46)	0.1952	
Race											NE
White	70	3.36 (0.68)	70	4.20 (0.71)	-0.83 (0.88)	(-2.57, 0.91)	0.3462	-0.14 (0.17)	(-0.47, 0.19)	0.4016	
Black or African American	10	4.89 (2.01)	17	3.67 (1.98)	1.22 (2.29)	(-3.54, 5.97)	0.6009	0.16 (0.40)	(-0.63, 0.94)	0.6957	
Asian	16	1.29 (2.21)	16	-1.60 (2.08)	2.89 (1.97)	(-1.13, 6.91)	0.1526	0.33 (0.36)	(-0.37, 1.03)	0.3574	
Other	8	NE	5	NE	NE	NE		NE	NE		
Ethnicity											0.2713
Hispanic/Latino	27	4.05 (1.15)	31	2.62 (1.11)	1.43 (1.51)	(-1.61, 4.46)	0.3491	0.23 (0.26)	(-0.29, 0.75)	0.3816	
Non-hispanic/Latino	77	2.66 (0.70)	77	3.14 (0.73)	-0.48 (0.85)	(-2.17, 1.21)	0.5740	-0.08 (0.16)	(-0.39, 0.24)	0.6353	
Geographic region											0.2109
EU	41	3.99 (1.16)	28	5.13 (1.30)	-1.14 (1.36)	(-3.85, 1.57)	0.4042	-0.16 (0.25)	(-0.64, 0.32)	0.5243	
non-EU	71	3.42 (0.70)	82	2.52 (0.72)	0.90 (0.90)	(-0.88, 2.68)	0.3205	0.14 (0.16)	(-0.17, 0.46)	0.3765	
Onset of disease											NE
Paediatric	9	NE	4	NE	NE	NE		NE	NE		
Adult	103	3.24 (0.57)	106	3.01 (0.59)	0.23 (0.72)	(-1.18, 1.65)	0.7467	0.04 (0.14)	(-0.23, 0.31)	0.7782	
ADA result											NE
Negative	108	3.40 (0.59)	101	3.01 (0.63)	0.39 (0.76)	(-1.10, 1.88)	0.6069	0.06 (0.14)	(-0.21, 0.33)	0.6537	
Positive (At any time)	4	NE	9	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.5928
< 30	79	3.27 (0.73)	79	2.88 (0.78)	0.39 (0.89)	(-1.36, 2.14)	0.6618	0.06 (0.16)	(-0.25, 0.37)	0.7182	
>= 30	33	4.60 (0.97)	31	3.36 (0.97)	1.24 (1.32)	(-1.41, 3.88)	0.3522	0.22 (0.25)	(-0.27, 0.71)	0.3745	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.0728
All negative/normal	37	2.63 (0.94)	52	4.00 (0.82)	-1.37 (1.21)	(-3.78, 1.03)	0.2597	-0.23 (0.22)	(-0.66, 0.19)	0.2793	
At least one positive/abnormal	75	3.92 (0.87)	58	2.54 (1.01)	1.38 (0.95)	(-0.49, 3.25)	0.1467	0.18 (0.18)	(-0.16, 0.52)	0.3043	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute General Health Score
Full analysis set

	Anifrolumab 300mg (N=119)		Placebo (N=121)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 8		2.24 (0.60)		1.06 (0.61)	1.18 (0.76)	(-0.32, 2.67)	0.1221			
Week 16		2.34 (0.69)		2.29 (0.71)	0.05 (0.90)	(-1.72, 1.83)	0.9519			
Week 24		3.11 (0.70)		1.62 (0.71)	1.49 (0.91)	(-0.30, 3.29)	0.1029			
Week 32		2.72 (0.74)		2.22 (0.76)	0.50 (0.98)	(-1.42, 2.43)	0.6063			
Week 40		2.77 (0.71)		2.41 (0.75)	0.36 (0.95)	(-1.52, 2.24)	0.7057			
Week 48		2.64 (0.74)		2.74 (0.78)	-0.10 (1.00)	(-2.07, 1.87)	0.9241			
Week 52		2.47 (0.77)		1.56 (0.81)	0.91 (1.03)	(-1.13, 2.95)	0.3804			
OVERALL	112	2.61 (0.59)	110	1.98 (0.61)	0.63 (0.75)	(-0.84, 2.10)	0.4011	0.10 (0.13)	(-0.16, 0.36)	0.4620

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute General Health Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) N	LSMean (SE)	Placebo (N=121) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.4077
< 10 points	40	3.69 (0.83)	30	2.24 (0.99)	1.45 (1.20)	(-0.94, 3.84)	0.2289	0.27 (0.24)	(-0.21, 0.75)	0.2653	
>= 10 points	72	1.89 (0.81)	80	1.70 (0.77)	0.19 (0.95)	(-1.70, 2.07)	0.8448	0.03 (0.16)	(-0.29, 0.35)	0.8676	
OCS dose at baseline											0.2658
<10 mg/day	58	3.21 (0.78)	61	1.84 (0.81)	1.36 (1.06)	(-0.73, 3.46)	0.2002	0.22 (0.18)	(-0.14, 0.58)	0.2302	
>=10 mg/day	54	1.88 (1.02)	49	2.22 (0.98)	-0.33 (1.10)	(-2.52, 1.85)	0.7617	-0.05 (0.20)	(-0.43, 0.34)	0.8153	
Result of type I IFN gene signature test											0.1518
LOW	22	2.31 (1.37)	22	4.06 (1.28)	-1.75 (1.83)	(-5.44, 1.94)	0.3443	-0.28 (0.30)	(-0.87, 0.32)	0.3627	
HIGH	90	2.64 (0.60)	88	1.51 (0.63)	1.13 (0.83)	(-0.51, 2.77)	0.1769	0.19 (0.15)	(-0.10, 0.49)	0.1981	
Age (years)											NE
<= 65	110	2.61 (0.60)	110	1.99 (0.62)	0.62 (0.75)	(-0.87, 2.10)	0.4129	0.10 (0.13)	(-0.17, 0.36)	0.4751	
> 65	2	NE	0	NE	NE	NE		NE	NE		
Sex											0.0179
male	10	3.28 (2.17)	12	7.31 (2.28)	-4.03 (2.04)	(-8.33, 0.26)	0.0640	-0.52 (0.44)	(-1.38, 0.33)	0.2326	
female	102	2.82 (0.62)	98	1.67 (0.64)	1.15 (0.79)	(-0.42, 2.71)	0.1495	0.18 (0.14)	(-0.10, 0.46)	0.2015	
Race											NE
White	70	2.65 (0.70)	70	3.07 (0.72)	-0.42 (0.91)	(-2.21, 1.37)	0.6446	-0.07 (0.17)	(-0.40, 0.26)	0.6786	
Black or African American	10	4.94 (2.08)	17	1.98 (1.94)	2.97 (2.44)	(-2.13, 8.06)	0.2388	0.38 (0.40)	(-0.41, 1.17)	0.3419	
Asian	16	2.53 (2.44)	16	1.49 (2.37)	1.03 (2.52)	(-4.11, 6.17)	0.6853	0.10 (0.35)	(-0.59, 0.80)	0.7675	
Other	8	NE	5	NE	NE	NE		NE	NE		
Ethnicity											0.0450
Hispanic/Latino	27	5.02 (1.08)	31	2.00 (1.05)	3.02 (1.40)	(0.21, 5.83)	0.0357	0.52 (0.27)	(-0.01, 1.04)	0.0527	
Non-hispanic/Latino	77	1.65 (0.73)	77	1.97 (0.75)	-0.32 (0.90)	(-2.09, 1.46)	0.7253	-0.05 (0.16)	(-0.36, 0.27)	0.7648	
Geographic region											0.0519
EU	41	2.22 (1.03)	28	3.66 (1.16)	-1.43 (1.23)	(-3.90, 1.03)	0.2492	-0.22 (0.25)	(-0.70, 0.26)	0.3691	
non-EU	71	3.07 (0.74)	82	1.49 (0.74)	1.58 (0.94)	(-0.28, 3.44)	0.0948	0.24 (0.16)	(-0.08, 0.56)	0.1355	
Onset of disease											NE
Paediatric	9	NE	4	NE	NE	NE		NE	NE		
Adult	103	2.43 (0.61)	106	2.04 (0.62)	0.39 (0.77)	(-1.13, 1.91)	0.6155	0.06 (0.14)	(-0.21, 0.33)	0.6581	
ADA result											NE
Negative	108	2.45 (0.60)	101	2.07 (0.64)	0.37 (0.78)	(-1.16, 1.91)	0.6302	0.06 (0.14)	(-0.21, 0.33)	0.6707	
Positive (At any time)	4	NE	9	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.5683
< 30	79	2.12 (0.74)	79	1.89 (0.78)	0.23 (0.92)	(-1.58, 2.04)	0.8022	0.03 (0.16)	(-0.28, 0.35)	0.8312	
>= 30	33	3.73 (0.97)	31	2.60 (0.96)	1.13 (1.29)	(-1.45, 3.72)	0.3834	0.21 (0.25)	(-0.29, 0.70)	0.4128	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.9981
All negative/normal	37	3.17 (0.86)	52	2.46 (0.74)	0.71 (1.10)	(-1.47, 2.89)	0.5186	0.13 (0.22)	(-0.29, 0.55)	0.5369	
At least one positive/abnormal	75	2.93 (0.92)	58	2.22 (1.07)	0.71 (1.04)	(-1.36, 2.77)	0.5001	0.09 (0.17)	(-0.26, 0.43)	0.6175	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Mental Health Score
Full analysis set

	Anifrolumab 300mg (N=119)		Placebo (N=121)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 8		2.59 (0.84)		0.80 (0.85)	1.79 (1.07)	(-0.33, 3.91)	0.0973			
Week 16		2.28 (0.90)		3.17 (0.93)	-0.89 (1.18)	(-3.23, 1.44)	0.4520			
Week 24		2.30 (0.97)		0.90 (0.97)	1.40 (1.27)	(-1.11, 3.90)	0.2733			
Week 32		3.48 (0.94)		2.97 (0.97)	0.51 (1.24)	(-1.94, 2.96)	0.6838			
Week 40		2.86 (0.87)		2.88 (0.93)	-0.02 (1.16)	(-2.32, 2.27)	0.9851			
Week 48		2.86 (0.93)		2.27 (0.99)	0.58 (1.26)	(-1.89, 3.06)	0.6428			
Week 52		2.94 (1.00)		2.29 (1.05)	0.65 (1.36)	(-2.02, 3.32)	0.6315			
OVERALL	112	2.76 (0.73)	110	2.18 (0.76)	0.57 (0.92)	(-1.24, 2.38)	0.5334	0.07 (0.13)	(-0.19, 0.34)	0.5883

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Mental Health Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) N	LSMean (SE)	Placebo (N=121) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.2038
< 10 points	40	5.13 (1.20)	30	2.72 (1.42)	2.41 (1.72)	(-1.02, 5.84)	0.1650	0.31 (0.24)	(-0.16, 0.79)	0.2001	
>= 10 points	72	1.01 (0.94)	80	1.19 (0.90)	-0.17 (1.09)	(-2.33, 1.99)	0.8735	-0.02 (0.16)	(-0.34, 0.30)	0.8940	
OCS dose at baseline											0.9935
<10 mg/day	58	3.08 (0.92)	61	2.61 (0.98)	0.47 (1.25)	(-2.00, 2.95)	0.7044	0.06 (0.18)	(-0.30, 0.42)	0.7258	
>=10 mg/day	54	2.37 (1.28)	49	1.88 (1.23)	0.49 (1.42)	(-2.34, 3.32)	0.7313	0.05 (0.20)	(-0.33, 0.44)	0.7852	
Result of type I IFN gene signature test											0.4275
LOW	22	3.05 (1.59)	22	4.09 (1.45)	-1.04 (2.14)	(-5.38, 3.30)	0.6295	-0.14 (0.30)	(-0.74, 0.45)	0.6345	
HIGH	90	2.04 (0.76)	88	1.19 (0.79)	0.85 (1.05)	(-1.22, 2.91)	0.4180	0.12 (0.15)	(-0.18, 0.41)	0.4410	
Age (years)											NE
<= 65	110	2.63 (0.74)	110	2.15 (0.76)	0.48 (0.92)	(-1.34, 2.30)	0.6032	0.06 (0.13)	(-0.20, 0.33)	0.6528	
> 65	2	NE	0	NE	NE	NE		NE	NE		
Sex											0.9959
male	10	2.52 (5.51)	12	1.97 (7.26)	0.56 (3.76)	(-7.47, 8.59)	0.8841	0.02 (0.43)	(-0.81, 0.86)	0.9546	
female	102	2.29 (0.71)	98	1.71 (0.74)	0.58 (0.91)	(-1.21, 2.37)	0.5247	0.08 (0.14)	(-0.20, 0.36)	0.5750	
Race											NE
White	70	3.13 (1.02)	70	3.28 (1.04)	-0.15 (1.30)	(-2.71, 2.42)	0.9109	-0.02 (0.17)	(-0.35, 0.31)	0.9209	
Black or African American	10	3.46 (2.13)	17	1.36 (2.04)	2.10 (2.62)	(-3.30, 7.50)	0.4316	0.26 (0.40)	(-0.53, 1.04)	0.5179	
Asian	16	-1.55 (2.13)	16	-7.53 (2.08)	5.98 (1.84)	(2.20, 9.75)	0.0030	0.69 (0.37)	(-0.02, 1.41)	0.0582	
Other	8	NE	5	NE	NE	NE		NE	NE		
Ethnicity											0.4097
Hispanic/Latino	27	3.50 (1.61)	31	5.04 (1.57)	-1.54 (2.16)	(-5.89, 2.80)	0.4786	-0.18 (0.26)	(-0.69, 0.34)	0.5003	
Non-hispanic/Latino	77	1.90 (0.89)	77	1.46 (0.91)	0.44 (1.06)	(-1.65, 2.53)	0.6771	0.06 (0.16)	(-0.26, 0.37)	0.7295	
Geographic region											0.5924
EU	41	2.71 (1.23)	28	2.63 (1.41)	0.08 (1.47)	(-2.85, 3.01)	0.9588	0.01 (0.25)	(-0.47, 0.49)	0.9682	
non-EU	71	2.60 (0.93)	82	1.51 (0.93)	1.08 (1.18)	(-1.25, 3.41)	0.3595	0.13 (0.16)	(-0.19, 0.45)	0.4148	
Onset of disease											NE
Paediatric	9	NE	4	NE	NE	NE		NE	NE		
Adult	103	3.00 (0.76)	106	2.31 (0.77)	0.68 (0.94)	(-1.18, 2.55)	0.4694	0.09 (0.14)	(-0.18, 0.36)	0.5285	
ADA result											NE
Negative	108	2.85 (0.73)	101	2.25 (0.78)	0.60 (0.94)	(-1.25, 2.44)	0.5238	0.08 (0.14)	(-0.19, 0.35)	0.5777	
Positive (At any time)	4	NE	9	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.9700
< 30	79	2.61 (0.91)	79	2.15 (0.97)	0.46 (1.08)	(-1.67, 2.60)	0.6686	0.06 (0.16)	(-0.26, 0.37)	0.7278	
>= 30	33	2.54 (1.24)	31	2.00 (1.23)	0.54 (1.72)	(-2.90, 3.98)	0.7543	0.08 (0.25)	(-0.41, 0.57)	0.7604	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.7940
All negative/normal	37	3.53 (1.03)	52	2.63 (0.89)	0.90 (1.31)	(-1.71, 3.51)	0.4932	0.14 (0.22)	(-0.28, 0.56)	0.5125	
At least one positive/abnormal	75	2.19 (1.17)	58	1.77 (1.37)	0.42 (1.29)	(-2.13, 2.98)	0.7448	0.04 (0.17)	(-0.30, 0.38)	0.8151	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Physical Functioning Score
Full analysis set

	Anifrolumab 300mg (N=119)		Placebo (N=121)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 8		2.64 (0.68)		1.57 (0.70)	1.07 (0.87)	(-0.64, 2.77)	0.2191			
Week 16		2.78 (0.74)		2.60 (0.76)	0.18 (0.96)	(-1.71, 2.07)	0.8512			
Week 24		4.11 (0.75)		3.18 (0.76)	0.93 (0.97)	(-0.99, 2.84)	0.3407			
Week 32		3.01 (0.76)		2.78 (0.79)	0.23 (1.00)	(-1.75, 2.20)	0.8219			
Week 40		3.34 (0.78)		3.92 (0.82)	-0.57 (1.04)	(-2.62, 1.47)	0.5805			
Week 48		3.23 (0.86)		2.38 (0.91)	0.84 (1.17)	(-1.47, 3.15)	0.4737			
Week 52		3.02 (0.81)		3.35 (0.85)	-0.33 (1.09)	(-2.48, 1.81)	0.7609			
OVERALL	112	3.16 (0.64)	110	2.83 (0.67)	0.33 (0.80)	(-1.25, 1.92)	0.6787	0.05 (0.13)	(-0.21, 0.31)	0.7180

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Physical Functioning Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) N	LSMean (SE)	Placebo (N=121) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.3503
< 10 points	40	4.28 (0.96)	30	2.88 (1.16)	1.39 (1.41)	(-1.43, 4.22)	0.3276	0.22 (0.24)	(-0.25, 0.70)	0.3577	
>= 10 points	72	2.52 (0.87)	80	2.74 (0.82)	-0.22 (1.00)	(-2.20, 1.76)	0.8238	-0.03 (0.16)	(-0.35, 0.29)	0.8527	
OCS dose at baseline											0.6476
<10 mg/day	58	3.35 (0.72)	61	2.61 (0.76)	0.74 (0.98)	(-1.20, 2.68)	0.4487	0.13 (0.18)	(-0.23, 0.49)	0.4828	
>=10 mg/day	54	3.16 (1.26)	49	3.19 (1.21)	-0.03 (1.38)	(-2.77, 2.71)	0.9826	-0.00 (0.20)	(-0.39, 0.38)	0.9863	
Result of type I IFN gene signature test											0.4597
LOW	22	4.63 (1.62)	22	2.80 (1.48)	1.83 (2.17)	(-2.56, 6.22)	0.4038	0.25 (0.30)	(-0.35, 0.84)	0.4157	
HIGH	90	3.00 (0.64)	88	2.90 (0.67)	0.10 (0.88)	(-1.64, 1.84)	0.9092	0.02 (0.15)	(-0.28, 0.31)	0.9133	
Age (years)											NE
<= 65	110	3.06 (0.64)	110	2.73 (0.67)	0.33 (0.80)	(-1.26, 1.91)	0.6853	0.05 (0.13)	(-0.22, 0.31)	0.7249	
> 65	2	NE	0	NE	NE	NE		NE	NE		
Sex											0.1183
male	10	5.15 (2.81)	12	8.67 (3.33)	-3.52 (2.62)	(-9.03, 2.00)	0.1967	-0.32 (0.43)	(-1.17, 0.52)	0.4523	
female	102	3.24 (0.64)	98	2.46 (0.68)	0.78 (0.83)	(-0.85, 2.41)	0.3487	0.12 (0.14)	(-0.16, 0.39)	0.4072	
Race											NE
White	70	3.49 (0.80)	70	4.26 (0.83)	-0.78 (1.04)	(-2.84, 1.28)	0.4564	-0.11 (0.17)	(-0.44, 0.22)	0.5030	
Black or African American	10	3.31 (2.58)	17	4.17 (2.56)	-0.86 (3.08)	(-7.26, 5.55)	0.7836	-0.09 (0.40)	(-0.87, 0.70)	0.8308	
Asian	16	-1.04 (1.83)	16	-4.56 (1.79)	3.52 (1.64)	(0.16, 6.89)	0.0408	0.47 (0.36)	(-0.23, 1.18)	0.1867	
Other	8	NE	5	NE	NE	NE		NE	NE		
Ethnicity											0.9790
Hispanic/Latino	27	3.45 (1.34)	31	3.48 (1.27)	-0.02 (1.76)	(-3.54, 3.50)	0.9906	-0.00 (0.26)	(-0.52, 0.51)	0.9911	
Non-hispanic/Latino	77	2.45 (0.76)	77	2.53 (0.79)	-0.07 (0.92)	(-1.89, 1.75)	0.9367	-0.01 (0.16)	(-0.33, 0.31)	0.9469	
Geographic region											0.5250
EU	41	5.13 (1.31)	28	5.88 (1.47)	-0.75 (1.54)	(-3.83, 2.33)	0.6290	-0.09 (0.25)	(-0.57, 0.39)	0.7114	
non-EU	71	2.49 (0.75)	82	2.08 (0.76)	0.41 (0.97)	(-1.50, 2.31)	0.6733	0.06 (0.16)	(-0.26, 0.38)	0.7046	
Onset of disease											NE
Paediatric	9	NE	4	NE	NE	NE		NE	NE		
Adult	103	3.23 (0.63)	106	2.82 (0.65)	0.41 (0.80)	(-1.16, 1.98)	0.6090	0.06 (0.14)	(-0.21, 0.33)	0.6546	
ADA result											NE
Negative	108	3.26 (0.65)	101	2.75 (0.69)	0.51 (0.83)	(-1.12, 2.14)	0.5361	0.08 (0.14)	(-0.20, 0.35)	0.5877	
Positive (At any time)	4	NE	9	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.5906
< 30	79	2.87 (0.75)	79	2.45 (0.80)	0.43 (0.91)	(-1.36, 2.22)	0.6361	0.06 (0.16)	(-0.25, 0.37)	0.6981	
>= 30	33	4.50 (1.32)	31	2.98 (1.31)	1.52 (1.82)	(-2.12, 5.17)	0.4064	0.20 (0.25)	(-0.29, 0.69)	0.4197	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.5542
All negative/normal	37	3.39 (1.08)	52	3.66 (0.93)	-0.27 (1.40)	(-3.06, 2.52)	0.8470	-0.04 (0.22)	(-0.46, 0.38)	0.8514	
At least one positive/abnormal	75	2.93 (0.94)	58	2.17 (1.09)	0.76 (1.03)	(-1.28, 2.79)	0.4627	0.09 (0.17)	(-0.25, 0.43)	0.5992	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Role Emotional Score
Full analysis set

	Anifrolumab 300mg (N=119)		Placebo (N=121)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 8		2.84 (1.00)		-1.40 (1.01)	4.24 (1.28)	(1.71, 6.77)	0.0011			
Week 16		2.32 (1.04)		3.01 (1.08)	-0.69 (1.37)	(-3.39, 2.01)	0.6155			
Week 24		3.44 (1.14)		0.61 (1.14)	2.83 (1.50)	(-0.13, 5.79)	0.0605			
Week 32		3.42 (1.08)		2.74 (1.12)	0.68 (1.43)	(-2.15, 3.50)	0.6363			
Week 40		4.04 (1.09)		3.01 (1.15)	1.04 (1.47)	(-1.86, 3.93)	0.4816			
Week 48		3.86 (1.07)		1.64 (1.14)	2.22 (1.43)	(-0.61, 5.05)	0.1226			
Week 52		3.38 (1.17)		2.20 (1.23)	1.18 (1.58)	(-1.94, 4.30)	0.4563			
OVERALL	112	3.33 (0.86)	110	1.69 (0.89)	1.64 (1.08)	(-0.48, 3.77)	0.1285	0.18 (0.13)	(-0.09, 0.44)	0.1863

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Role Emotional Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) N	LSMean (SE)	Placebo (N=121) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.0028
< 10 points	40	6.79 (1.26)	30	0.58 (1.49)	6.21 (1.81)	(2.61, 9.82)	0.0010	0.76 (0.25)	(0.27, 1.25)	0.0023	
>= 10 points	72	1.00 (1.14)	80	1.45 (1.08)	-0.45 (1.30)	(-3.02, 2.13)	0.7329	-0.05 (0.16)	(-0.36, 0.27)	0.7776	
OCS dose at baseline											0.6024
<10 mg/day	58	4.16 (1.05)	61	3.06 (1.11)	1.10 (1.43)	(-1.74, 3.93)	0.4445	0.13 (0.18)	(-0.23, 0.49)	0.4779	
>=10 mg/day	54	2.20 (1.59)	49	-0.05 (1.51)	2.26 (1.70)	(-1.13, 5.64)	0.1888	0.20 (0.20)	(-0.19, 0.59)	0.3117	
Result of type I IFN gene signature test											0.8058
LOW	22	3.80 (2.11)	22	2.92 (1.97)	0.87 (2.82)	(-4.84, 6.58)	0.7583	0.09 (0.30)	(-0.50, 0.68)	0.7661	
HIGH	90	3.08 (0.85)	88	1.46 (0.89)	1.62 (1.18)	(-0.70, 3.94)	0.1688	0.20 (0.15)	(-0.10, 0.49)	0.1894	
Age (years)											NE
<= 65	110	3.19 (0.87)	110	1.64 (0.90)	1.55 (1.08)	(-0.58, 3.69)	0.1529	0.17 (0.14)	(-0.10, 0.43)	0.2160	
> 65	2	NE	0	NE	NE	NE		NE	NE		
Sex											0.3207
male	10	11.35 (3.63)	12	12.86 (5.06)	-1.51 (3.06)	(-8.00, 4.98)	0.6278	-0.10 (0.43)	(-0.94, 0.74)	0.8221	
female	102	3.25 (0.90)	98	1.52 (0.94)	1.73 (1.15)	(-0.53, 4.00)	0.1333	0.19 (0.14)	(-0.09, 0.47)	0.1856	
Race											NE
White	70	4.15 (1.12)	70	3.65 (1.14)	0.50 (1.42)	(-2.30, 3.31)	0.7235	0.05 (0.17)	(-0.28, 0.38)	0.7545	
Black or African American	10	3.18 (3.17)	17	0.65 (3.22)	2.53 (4.15)	(-6.02, 11.08)	0.5479	0.20 (0.40)	(-0.58, 0.98)	0.6150	
Asian	16	-2.24 (2.14)	16	-7.29 (2.52)	5.06 (2.73)	(-0.49, 10.61)	0.0728	0.53 (0.36)	(-0.18, 1.23)	0.1439	
Other	8	NE	5	NE	NE	NE		NE	NE		
Ethnicity											0.8350
Hispanic/Latino	27	5.06 (1.73)	31	3.41 (1.70)	1.65 (2.27)	(-2.91, 6.20)	0.4709	0.18 (0.26)	(-0.34, 0.69)	0.5058	
Non-hispanic/Latino	77	2.02 (1.06)	77	0.92 (1.09)	1.11 (1.27)	(-1.41, 3.62)	0.3859	0.12 (0.16)	(-0.20, 0.43)	0.4691	
Geographic region											0.8585
EU	41	3.15 (1.46)	28	1.41 (1.65)	1.74 (1.71)	(-1.69, 5.16)	0.3142	0.19 (0.25)	(-0.29, 0.67)	0.4429	
non-EU	71	3.33 (1.09)	82	1.20 (1.10)	2.13 (1.39)	(-0.62, 4.88)	0.1274	0.22 (0.16)	(-0.10, 0.54)	0.1744	
Onset of disease											NE
Paediatric	9	NE	4	NE	NE	NE		NE	NE		
Adult	103	3.12 (0.90)	106	1.68 (0.92)	1.44 (1.13)	(-0.78, 3.66)	0.2027	0.15 (0.14)	(-0.12, 0.43)	0.2655	
ADA result											NE
Negative	108	3.13 (0.87)	101	1.52 (0.92)	1.61 (1.12)	(-0.59, 3.81)	0.1509	0.17 (0.14)	(-0.10, 0.45)	0.2086	
Positive (At any time)	4	NE	9	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.1635
< 30	79	2.30 (1.02)	79	1.58 (1.09)	0.73 (1.24)	(-1.72, 3.17)	0.5581	0.08 (0.16)	(-0.23, 0.39)	0.6277	
>= 30	33	5.87 (1.60)	31	1.66 (1.59)	4.22 (2.18)	(-0.14, 8.58)	0.0578	0.46 (0.25)	(-0.04, 0.96)	0.0692	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.1219
All negative/normal	37	4.82 (1.40)	52	1.12 (1.20)	3.70 (1.77)	(0.18, 7.22)	0.0398	0.43 (0.22)	(0.00, 0.85)	0.0497	
At least one positive/abnormal	75	2.77 (1.28)	58	2.59 (1.51)	0.19 (1.42)	(-2.63, 3.00)	0.8965	0.02 (0.17)	(-0.33, 0.36)	0.9255	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Role Physical Score
Full analysis set

	Anifrolumab 300mg (N=119)		Placebo (N=121)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 8		2.96 (0.70)		1.52 (0.72)	1.44 (0.89)	(-0.33, 3.20)	0.1101			
Week 16		3.84 (0.80)		3.58 (0.83)	0.26 (1.06)	(-1.82, 2.34)	0.8042			
Week 24		4.59 (0.75)		2.95 (0.76)	1.64 (0.97)	(-0.28, 3.55)	0.0933			
Week 32		4.31 (0.78)		4.10 (0.80)	0.21 (1.02)	(-1.80, 2.23)	0.8355			
Week 40		4.52 (0.81)		4.17 (0.86)	0.35 (1.09)	(-1.81, 2.50)	0.7514			
Week 48		4.14 (0.83)		2.31 (0.89)	1.82 (1.13)	(-0.41, 4.06)	0.1086			
Week 52		3.99 (0.81)		3.10 (0.86)	0.89 (1.09)	(-1.26, 3.04)	0.4163			
OVERALL	112	4.05 (0.62)	110	3.11 (0.65)	0.94 (0.77)	(-0.58, 2.47)	0.2239	0.14 (0.13)	(-0.12, 0.40)	0.2943

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Role Physical Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) N	LSMean (SE)	Placebo (N=121) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.3191
< 10 points	40	5.06 (0.99)	30	2.83 (1.20)	2.23 (1.45)	(-0.66, 5.12)	0.1276	0.34 (0.24)	(-0.13, 0.82)	0.1573	
>= 10 points	72	3.01 (0.81)	80	2.49 (0.77)	0.52 (0.93)	(-1.31, 2.35)	0.5748	0.08 (0.16)	(-0.24, 0.39)	0.6424	
OCS dose at baseline											0.8771
<10 mg/day	58	3.78 (0.76)	61	2.85 (0.80)	0.93 (1.02)	(-1.09, 2.95)	0.3652	0.15 (0.18)	(-0.21, 0.51)	0.4043	
>=10 mg/day	54	3.57 (1.15)	49	2.89 (1.12)	0.68 (1.25)	(-1.80, 3.16)	0.5890	0.08 (0.20)	(-0.30, 0.47)	0.6767	
Result of type I IFN gene signature test											0.5229
LOW	22	3.36 (1.38)	22	3.66 (1.27)	-0.30 (1.83)	(-4.00, 3.40)	0.8698	-0.05 (0.30)	(-0.64, 0.54)	0.8743	
HIGH	90	4.07 (0.63)	88	3.08 (0.66)	0.99 (0.87)	(-0.72, 2.71)	0.2545	0.16 (0.15)	(-0.13, 0.46)	0.2779	
Age (years)											NE
<= 65	110	3.89 (0.63)	110	3.05 (0.65)	0.84 (0.78)	(-0.70, 2.37)	0.2836	0.12 (0.13)	(-0.14, 0.39)	0.3566	
> 65	2	NE	0	NE	NE	NE		NE	NE		
Sex											0.2382
male	10	6.27 (3.00)	12	8.85 (4.31)	-2.58 (3.37)	(-10.00, 4.84)	0.4606	-0.19 (0.43)	(-1.04, 0.65)	0.6516	
female	102	4.19 (0.63)	98	2.68 (0.66)	1.51 (0.80)	(-0.07, 3.09)	0.0611	0.23 (0.14)	(-0.05, 0.51)	0.1006	
Race											NE
White	70	3.77 (0.75)	70	3.97 (0.77)	-0.20 (0.95)	(-2.08, 1.68)	0.8337	-0.03 (0.17)	(-0.36, 0.30)	0.8534	
Black or African American	10	4.59 (1.91)	17	4.75 (1.91)	-0.15 (2.42)	(-5.16, 4.85)	0.9500	-0.02 (0.40)	(-0.80, 0.76)	0.9590	
Asian	16	2.14 (2.14)	16	-5.52 (2.04)	7.67 (1.90)	(3.77, 11.57)	0.0004	0.89 (0.37)	(0.16, 1.62)	0.0168	
Other	8	NE	5	NE	NE	NE		NE	NE		
Ethnicity											0.7345
Hispanic/Latino	27	4.62 (1.29)	31	3.40 (1.29)	1.23 (1.76)	(-2.30, 4.75)	0.4884	0.17 (0.26)	(-0.34, 0.69)	0.5108	
Non-hispanic/Latino	77	3.23 (0.75)	77	2.68 (0.78)	0.56 (0.91)	(-1.24, 2.35)	0.5411	0.08 (0.16)	(-0.23, 0.40)	0.6103	
Geographic region											0.2863
EU	41	3.27 (1.15)	28	3.86 (1.30)	-0.59 (1.38)	(-3.35, 2.18)	0.6723	-0.08 (0.25)	(-0.56, 0.40)	0.7406	
non-EU	71	4.13 (0.76)	82	2.91 (0.79)	1.22 (0.99)	(-0.73, 3.17)	0.2168	0.18 (0.16)	(-0.14, 0.50)	0.2719	
Onset of disease											0.4912
Paediatric	9	9.64 (7.54)	4	17.56 (15.61)	-7.92 (12.70)	(-60.20, 44.35)	0.5937	-0.29 (0.60)	(-1.48, 0.89)	0.6293	
Adult	103	3.92 (0.63)	106	3.08 (0.65)	0.83 (0.79)	(-0.72, 2.39)	0.2908	0.13 (0.14)	(-0.14, 0.40)	0.3610	
ADA result											NE
Negative	108	4.06 (0.63)	101	3.03 (0.68)	1.02 (0.81)	(-0.57, 2.61)	0.2056	0.15 (0.14)	(-0.12, 0.42)	0.2717	
Positive (At any time)	4	NE	9	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.9378
< 30	79	3.92 (0.77)	79	2.80 (0.82)	1.12 (0.93)	(-0.71, 2.94)	0.2294	0.16 (0.16)	(-0.16, 0.47)	0.3262	
>= 30	33	4.26 (1.05)	31	3.00 (1.08)	1.25 (1.47)	(-1.69, 4.19)	0.3972	0.21 (0.25)	(-0.29, 0.70)	0.4118	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.4703
All negative/normal	37	3.41 (1.07)	52	3.37 (0.93)	0.04 (1.37)	(-2.68, 2.76)	0.9772	0.01 (0.22)	(-0.42, 0.43)	0.9782	
At least one positive/abnormal	75	4.43 (0.89)	58	3.17 (1.05)	1.25 (0.98)	(-0.68, 3.18)	0.2025	0.16 (0.18)	(-0.18, 0.50)	0.3651	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Social Functioning Score
Full analysis set

	Anifrolumab 300mg (N=119)		Placebo (N=121)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 8		1.26 (0.95)		-1.02 (0.97)	2.28 (1.25)	(-0.17, 4.74)	0.0683			
Week 16		2.23 (0.91)		0.93 (0.94)	1.30 (1.19)	(-1.03, 3.64)	0.2728			
Week 24		2.34 (1.01)		0.31 (1.02)	2.03 (1.33)	(-0.60, 4.65)	0.1294			
Week 32		3.23 (0.99)		1.69 (1.02)	1.54 (1.31)	(-1.04, 4.13)	0.2405			
Week 40		3.36 (0.93)		1.75 (0.99)	1.61 (1.25)	(-0.85, 4.07)	0.1987			
Week 48		3.32 (0.94)		-0.10 (1.01)	3.43 (1.26)	(0.95, 5.91)	0.0070			
Week 52		3.08 (0.98)		1.08 (1.04)	1.99 (1.32)	(-0.60, 4.59)	0.1316			
OVERALL	112	2.69 (0.75)	110	0.66 (0.79)	2.03 (0.94)	(0.17, 3.88)	0.0321	0.25 (0.13)	(-0.01, 0.51)	0.0642

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Social Functioning Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) N	LSMean (SE)	Placebo (N=121) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.0133
< 10 points	40	5.65 (1.19)	30	0.27 (1.42)	5.38 (1.70)	(1.97, 8.78)	0.0025	0.70 (0.25)	(0.21, 1.19)	0.0051	
>= 10 points	72	0.89 (0.96)	80	0.54 (0.92)	0.35 (1.10)	(-1.82, 2.53)	0.7486	0.04 (0.16)	(-0.28, 0.36)	0.7912	
OCS dose at baseline											0.8939
<10 mg/day	58	2.54 (0.90)	61	0.64 (0.96)	1.90 (1.22)	(-0.53, 4.32)	0.1237	0.26 (0.18)	(-0.10, 0.62)	0.1541	
>=10 mg/day	54	2.63 (1.42)	49	0.48 (1.36)	2.16 (1.50)	(-0.82, 5.13)	0.1539	0.21 (0.20)	(-0.17, 0.60)	0.2790	
Result of type I IFN gene signature test											0.5008
LOW	22	3.41 (1.80)	22	0.00 (1.67)	3.40 (2.40)	(-1.47, 8.28)	0.1647	0.41 (0.30)	(-0.19, 1.01)	0.1779	
HIGH	90	2.83 (0.76)	88	1.18 (0.80)	1.64 (1.05)	(-0.43, 3.72)	0.1202	0.22 (0.15)	(-0.07, 0.52)	0.1386	
Age (years)											NE
<= 65	110	2.31 (0.75)	110	0.54 (0.78)	1.77 (0.93)	(-0.07, 3.61)	0.0591	0.22 (0.14)	(-0.05, 0.48)	0.1044	
> 65	2	NE	0	NE	NE	NE		NE	NE		
Sex											0.5651
male	10	5.98 (3.57)	12	5.75 (5.46)	0.23 (3.55)	(-7.19, 7.65)	0.9498	0.01 (0.43)	(-0.83, 0.85)	0.9745	
female	102	2.54 (0.77)	98	0.20 (0.80)	2.34 (0.97)	(0.43, 4.25)	0.0168	0.30 (0.14)	(0.02, 0.58)	0.0362	
Race											NE
White	70	2.82 (0.96)	70	1.82 (0.99)	1.00 (1.22)	(-1.41, 3.41)	0.4138	0.12 (0.17)	(-0.21, 0.45)	0.4717	
Black or African American	10	4.04 (2.66)	17	2.99 (2.55)	1.05 (3.17)	(-5.49, 7.59)	0.7429	0.10 (0.40)	(-0.68, 0.89)	0.7944	
Asian	16	-2.25 (2.05)	16	-10.54 (1.98)	8.29 (1.88)	(4.44, 12.13)	0.0001	1.00 (0.38)	(0.26, 1.74)	0.0080	
Other	8	NE	5	NE	NE	NE		NE	NE		
Ethnicity											0.5066
Hispanic/Latino	27	5.28 (1.58)	31	2.15 (1.57)	3.13 (2.14)	(-1.17, 7.42)	0.1504	0.36 (0.27)	(-0.16, 0.88)	0.1724	
Non-hispanic/Latino	77	1.04 (0.91)	77	-0.50 (0.94)	1.53 (1.08)	(-0.60, 3.67)	0.1577	0.19 (0.16)	(-0.13, 0.51)	0.2432	
Geographic region											0.5572
EU	41	2.27 (1.44)	28	0.98 (1.62)	1.29 (1.63)	(-1.98, 4.56)	0.4343	0.14 (0.25)	(-0.34, 0.62)	0.5626	
non-EU	71	2.92 (0.92)	82	0.45 (0.93)	2.47 (1.17)	(0.15, 4.78)	0.0370	0.30 (0.16)	(-0.02, 0.62)	0.0633	
Onset of disease											NE
Paediatric	9	NE	4	NE	NE	NE		NE	NE		
Adult	103	2.63 (0.78)	106	0.54 (0.80)	2.10 (0.97)	(0.18, 4.01)	0.0319	0.26 (0.14)	(-0.01, 0.53)	0.0629	
ADA result											NE
Negative	108	2.66 (0.77)	101	0.57 (0.82)	2.08 (0.98)	(0.15, 4.02)	0.0346	0.26 (0.14)	(-0.02, 0.53)	0.0659	
Positive (At any time)	4	NE	9	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.7582
< 30	79	1.99 (0.93)	79	-0.32 (1.00)	2.30 (1.11)	(0.11, 4.50)	0.0399	0.27 (0.16)	(-0.05, 0.58)	0.0951	
>= 30	33	4.16 (1.32)	31	2.51 (1.28)	1.65 (1.81)	(-1.97, 5.27)	0.3649	0.22 (0.25)	(-0.27, 0.71)	0.3769	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.7586
All negative/normal	37	3.90 (1.26)	52	1.50 (1.08)	2.40 (1.60)	(-0.79, 5.60)	0.1386	0.31 (0.22)	(-0.12, 0.73)	0.1568	
At least one positive/abnormal	75	2.67 (1.10)	58	0.89 (1.30)	1.78 (1.21)	(-0.61, 4.18)	0.1428	0.18 (0.18)	(-0.16, 0.53)	0.2973	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Bodily Pain Score
Full analysis set

	Anifrolumab 300mg (N=119)		Placebo (N=121)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 8		3.01 (0.81)		1.16 (0.83)	1.86 (1.05)	(-0.22, 3.93)	0.0794			
Week 16		3.63 (0.87)		3.69 (0.89)	-0.06 (1.14)	(-2.31, 2.19)	0.9590			
Week 24		4.59 (0.89)		2.61 (0.90)	1.98 (1.16)	(-0.31, 4.27)	0.0904			
Week 32		3.69 (0.88)		2.98 (0.91)	0.71 (1.17)	(-1.60, 3.02)	0.5451			
Week 40		3.30 (0.82)		4.42 (0.88)	-1.12 (1.09)	(-3.27, 1.03)	0.3064			
Week 48		3.61 (0.93)		2.87 (0.99)	0.74 (1.27)	(-1.76, 3.23)	0.5604			
Week 52		3.28 (0.95)		3.10 (1.00)	0.18 (1.29)	(-2.36, 2.72)	0.8873			
OVERALL	112	3.59 (0.68)	110	2.98 (0.71)	0.61 (0.85)	(-1.07, 2.29)	0.4726	0.08 (0.13)	(-0.18, 0.35)	0.5358

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Bodily Pain Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) N	LSMean (SE)	Placebo (N=121) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.6502
< 10 points	40	3.72 (1.09)	30	2.48 (1.31)	1.25 (1.57)	(-1.89, 4.38)	0.4300	0.18 (0.24)	(-0.30, 0.65)	0.4679	
>= 10 points	72	3.67 (0.89)	80	3.28 (0.85)	0.40 (1.02)	(-1.62, 2.41)	0.6969	0.05 (0.16)	(-0.27, 0.37)	0.7485	
OCS dose at baseline											0.5056
<10 mg/day	58	3.99 (0.78)	61	3.01 (0.83)	0.98 (1.06)	(-1.12, 3.09)	0.3555	0.16 (0.18)	(-0.20, 0.52)	0.3935	
>=10 mg/day	54	2.59 (1.34)	49	2.79 (1.27)	-0.20 (1.43)	(-3.05, 2.64)	0.8878	-0.02 (0.20)	(-0.41, 0.37)	0.9138	
Result of type I IFN gene signature test											0.7150
LOW	22	4.21 (1.41)	22	4.27 (1.24)	-0.06 (1.82)	(-3.74, 3.62)	0.9748	-0.01 (0.30)	(-0.60, 0.58)	0.9759	
HIGH	90	3.59 (0.70)	88	2.90 (0.74)	0.70 (0.97)	(-1.23, 2.62)	0.4762	0.10 (0.15)	(-0.19, 0.40)	0.4972	
Age (years)											NE
<= 65	110	3.57 (0.69)	110	2.96 (0.72)	0.61 (0.86)	(-1.08, 2.30)	0.4774	0.08 (0.13)	(-0.18, 0.35)	0.5420	
> 65	2	NE	0	NE	NE	NE		NE	NE		
Sex											0.0688
male	10	5.15 (3.75)	12	10.50 (4.95)	-5.34 (3.42)	(-12.67, 1.98)	0.1401	-0.34 (0.43)	(-1.19, 0.50)	0.4278	
female	102	3.78 (0.70)	98	2.70 (0.73)	1.09 (0.89)	(-0.67, 2.84)	0.2242	0.15 (0.14)	(-0.13, 0.43)	0.2869	
Race											NE
White	70	3.54 (0.77)	70	4.07 (0.79)	-0.53 (0.98)	(-2.46, 1.41)	0.5919	-0.08 (0.17)	(-0.41, 0.25)	0.6348	
Black or African American	10	5.56 (2.67)	17	4.37 (2.57)	1.19 (3.20)	(-5.45, 7.83)	0.7139	0.12 (0.40)	(-0.66, 0.90)	0.7695	
Asian	16	-0.36 (2.71)	16	-3.26 (2.53)	2.90 (2.46)	(-2.14, 7.95)	0.2480	0.27 (0.36)	(-0.43, 0.97)	0.4477	
Other	8	NE	5	NE	NE	NE		NE	NE		
Ethnicity											0.0224
Hispanic/Latino	27	5.58 (1.23)	31	2.08 (1.21)	3.50 (1.63)	(0.23, 6.76)	0.0362	0.52 (0.27)	(-0.00, 1.05)	0.0504	
Non-hispanic/Latino	77	2.17 (0.80)	77	2.99 (0.83)	-0.82 (0.96)	(-2.72, 1.09)	0.3974	-0.11 (0.16)	(-0.43, 0.20)	0.4794	
Geographic region											0.2241
EU	41	3.41 (1.40)	28	4.25 (1.59)	-0.85 (1.61)	(-4.07, 2.38)	0.6009	-0.10 (0.25)	(-0.58, 0.38)	0.6961	
non-EU	71	3.84 (0.80)	82	2.37 (0.82)	1.47 (1.02)	(-0.55, 3.50)	0.1517	0.21 (0.16)	(-0.11, 0.53)	0.2030	
Onset of disease											NE
Paediatric	9	NE	4	NE	NE	NE		NE	NE		
Adult	103	3.13 (0.65)	106	3.02 (0.66)	0.11 (0.81)	(-1.48, 1.70)	0.8902	0.02 (0.14)	(-0.25, 0.29)	0.9047	
ADA result											NE
Negative	108	3.44 (0.69)	101	2.95 (0.73)	0.49 (0.88)	(-1.24, 2.22)	0.5755	0.07 (0.14)	(-0.20, 0.34)	0.6264	
Positive (At any time)	4	NE	9	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.1177
< 30	79	3.23 (0.86)	79	3.31 (0.92)	-0.08 (1.02)	(-2.10, 1.95)	0.9393	-0.01 (0.16)	(-0.32, 0.30)	0.9506	
>= 30	33	5.08 (1.16)	31	2.21 (1.15)	2.87 (1.58)	(-0.30, 6.05)	0.0750	0.43 (0.25)	(-0.06, 0.93)	0.0867	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.0826
All negative/normal	37	2.74 (1.12)	52	4.15 (0.96)	-1.41 (1.42)	(-4.24, 1.41)	0.3230	-0.20 (0.22)	(-0.63, 0.22)	0.3441	
At least one positive/abnormal	75	3.93 (1.02)	58	2.21 (1.20)	1.71 (1.11)	(-0.48, 3.90)	0.1240	0.19 (0.18)	(-0.15, 0.53)	0.2798	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Vitality Score
Full analysis set

	Anifrolumab 300mg (N=119)		Placebo (N=121)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 8		3.25 (0.77)		0.19 (0.79)	3.06 (1.00)	(1.09, 5.02)	0.0025			
Week 16		2.76 (0.84)		2.52 (0.87)	0.24 (1.12)	(-1.96, 2.44)	0.8283			
Week 24		3.08 (0.86)		2.18 (0.87)	0.90 (1.13)	(-1.33, 3.12)	0.4282			
Week 32		3.01 (0.86)		3.12 (0.89)	-0.11 (1.14)	(-2.36, 2.14)	0.9252			
Week 40		2.82 (0.87)		3.42 (0.94)	-0.60 (1.19)	(-2.94, 1.74)	0.6122			
Week 48		3.46 (0.89)		2.26 (0.95)	1.20 (1.21)	(-1.18, 3.59)	0.3208			
Week 52		3.09 (0.91)		1.81 (0.97)	1.28 (1.24)	(-1.16, 3.73)	0.3021			
OVERALL	112	3.07 (0.66)	110	2.21 (0.70)	0.85 (0.83)	(-0.79, 2.49)	0.3065	0.12 (0.13)	(-0.14, 0.38)	0.3764

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Vitality Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) N	LSMean (SE)	Placebo (N=121) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.7751
< 10 points	40	3.56 (1.06)	30	2.37 (1.27)	1.20 (1.53)	(-1.87, 4.26)	0.4388	0.17 (0.24)	(-0.30, 0.65)	0.4736	
>= 10 points	72	2.34 (0.87)	80	1.66 (0.84)	0.67 (1.00)	(-1.31, 2.65)	0.5039	0.09 (0.16)	(-0.23, 0.41)	0.5822	
OCS dose at baseline											0.8309
<10 mg/day	58	2.60 (0.85)	61	1.48 (0.90)	1.12 (1.16)	(-1.17, 3.41)	0.3339	0.16 (0.18)	(-0.20, 0.52)	0.3702	
>=10 mg/day	54	3.76 (1.18)	49	3.00 (1.15)	0.76 (1.26)	(-1.75, 3.26)	0.5503	0.09 (0.20)	(-0.30, 0.48)	0.6495	
Result of type I IFN gene signature test											0.4678
LOW	22	3.82 (1.81)	22	4.61 (1.76)	-0.79 (2.62)	(-6.07, 4.49)	0.7633	-0.09 (0.30)	(-0.68, 0.50)	0.7579	
HIGH	90	2.93 (0.65)	88	1.72 (0.68)	1.22 (0.90)	(-0.55, 2.98)	0.1764	0.19 (0.15)	(-0.10, 0.49)	0.1986	
Age (years)											NE
<= 65	110	2.92 (0.67)	110	2.11 (0.70)	0.81 (0.83)	(-0.83, 2.45)	0.3297	0.11 (0.13)	(-0.15, 0.38)	0.4014	
> 65	2	NE	0	NE	NE	NE		NE	NE		
Sex											0.4883
male	10	8.38 (3.44)	12	9.67 (4.54)	-1.29 (3.19)	(-8.62, 6.04)	0.6964	-0.09 (0.43)	(-0.93, 0.75)	0.8332	
female	102	2.89 (0.69)	98	1.89 (0.73)	1.01 (0.88)	(-0.74, 2.75)	0.2565	0.14 (0.14)	(-0.14, 0.42)	0.3184	
Race											NE
White	70	4.08 (0.82)	70	4.51 (0.84)	-0.43 (1.05)	(-2.50, 1.64)	0.6807	-0.06 (0.17)	(-0.39, 0.27)	0.7147	
Black or African American	10	3.08 (2.37)	17	2.69 (2.38)	0.39 (2.80)	(-5.41, 6.19)	0.8897	0.04 (0.40)	(-0.74, 0.82)	0.9160	
Asian	16	-1.97 (2.40)	16	-7.08 (2.25)	5.12 (2.16)	(0.68, 9.55)	0.0254	0.54 (0.36)	(-0.17, 1.24)	0.1366	
Other	8	NE	5	NE	NE	NE		NE	NE		
Ethnicity											0.1396
Hispanic/Latino	27	4.86 (1.32)	31	2.01 (1.30)	2.85 (1.78)	(-0.72, 6.41)	0.1149	0.40 (0.27)	(-0.12, 0.92)	0.1355	
Non-hispanic/Latino	77	1.94 (0.84)	77	2.11 (0.87)	-0.17 (1.01)	(-2.16, 1.82)	0.8663	-0.02 (0.16)	(-0.34, 0.29)	0.8889	
Geographic region											0.0373
EU	41	3.02 (1.21)	28	4.71 (1.38)	-1.70 (1.40)	(-4.49, 1.10)	0.2296	-0.22 (0.25)	(-0.70, 0.26)	0.3665	
non-EU	71	3.05 (0.80)	82	1.14 (0.81)	1.91 (1.03)	(-0.11, 3.94)	0.0640	0.27 (0.16)	(-0.05, 0.59)	0.0983	
Onset of disease											NE
Paediatric	9	NE	4	NE	NE	NE		NE	NE		
Adult	103	3.08 (0.68)	106	2.27 (0.70)	0.81 (0.86)	(-0.88, 2.50)	0.3457	0.11 (0.14)	(-0.16, 0.38)	0.4123	
ADA result											NE
Negative	108	3.04 (0.67)	101	2.39 (0.72)	0.65 (0.86)	(-1.04, 2.34)	0.4481	0.09 (0.14)	(-0.18, 0.36)	0.5079	
Positive (At any time)	4	NE	9	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.5401
< 30	79	2.45 (0.83)	79	1.11 (0.90)	1.34 (1.00)	(-0.63, 3.32)	0.1806	0.17 (0.16)	(-0.14, 0.49)	0.2758	
>= 30	33	4.65 (1.07)	31	4.39 (1.06)	0.26 (1.47)	(-2.68, 3.19)	0.8615	0.04 (0.25)	(-0.45, 0.53)	0.8663	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.5065
All negative/normal	37	4.33 (1.09)	52	3.95 (0.94)	0.38 (1.39)	(-2.38, 3.14)	0.7851	0.06 (0.22)	(-0.37, 0.48)	0.7946	
At least one positive/abnormal	75	2.33 (0.94)	58	0.79 (1.11)	1.54 (1.05)	(-0.55, 3.62)	0.1471	0.18 (0.18)	(-0.16, 0.53)	0.2911	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - FACIT-F Total Score
Full analysis set

	Anifrolumab 300mg (N=119)		Placebo (N=121)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		2.05 (0.83)		2.76 (0.83)	-0.72 (1.05)	(-2.79, 1.35)	0.4962			
Week 8		3.01 (0.86)		1.74 (0.86)	1.27 (1.09)	(-0.89, 3.42)	0.2477			
Week 12		3.76 (0.97)		1.73 (0.98)	2.03 (1.28)	(-0.50, 4.56)	0.1146			
Week 16		3.45 (0.99)		3.62 (1.00)	-0.17 (1.31)	(-2.74, 2.41)	0.8985			
Week 20		4.53 (0.99)		5.43 (0.99)	-0.90 (1.30)	(-3.47, 1.67)	0.4897			
Week 24		4.69 (1.00)		4.10 (0.98)	0.60 (1.30)	(-1.97, 3.16)	0.6477			
Week 28		4.74 (1.01)		4.73 (1.02)	0.01 (1.34)	(-2.64, 2.66)	0.9931			
Week 32		4.01 (1.07)		4.86 (1.08)	-0.85 (1.43)	(-3.67, 1.96)	0.5506			
Week 36		5.17 (0.99)		4.83 (1.02)	0.34 (1.32)	(-2.26, 2.94)	0.7961			
Week 40		4.52 (0.99)		5.99 (1.02)	-1.47 (1.32)	(-4.07, 1.13)	0.2653			
Week 44		5.05 (0.92)		6.17 (0.96)	-1.12 (1.22)	(-3.53, 1.29)	0.3591			
Week 48		4.47 (1.06)		4.34 (1.09)	0.12 (1.43)	(-2.69, 2.94)	0.9308			
Week 52		4.24 (1.06)		3.41 (1.09)	0.83 (1.43)	(-1.99, 3.65)	0.5620			
OVERALL	110	4.13 (0.77)	114	4.13 (0.79)	-0.00 (0.97)	(-1.92, 1.91)	0.9978	-0.00 (0.13)	(-0.26, 0.26)	0.9981

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - FACIT-F Total Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) N	LSMean (SE)	Placebo (N=121) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.3474
< 10 points	37	5.12 (1.21)	31	3.70 (1.36)	1.42 (1.70)	(-1.99, 4.82)	0.4081	0.19 (0.24)	(-0.29, 0.67)	0.4422	
>= 10 points	73	2.89 (1.01)	83	3.43 (0.96)	-0.54 (1.20)	(-2.91, 1.83)	0.6541	-0.06 (0.16)	(-0.38, 0.25)	0.7011	
OCS dose at baseline											0.4649
<10 mg/day	56	4.70 (0.95)	61	4.09 (0.97)	0.61 (1.27)	(-1.92, 3.13)	0.6339	0.08 (0.19)	(-0.28, 0.44)	0.6577	
>=10 mg/day	54	2.84 (1.40)	53	3.67 (1.31)	-0.84 (1.51)	(-3.84, 2.16)	0.5813	-0.08 (0.19)	(-0.46, 0.30)	0.6648	
Result of type I IFN gene signature test											0.4489
LOW	21	3.73 (1.84)	22	5.81 (1.62)	-2.08 (2.48)	(-7.10, 2.95)	0.4081	-0.25 (0.31)	(-0.85, 0.35)	0.4074	
HIGH	89	4.11 (0.80)	92	4.13 (0.81)	-0.02 (1.09)	(-2.17, 2.12)	0.9827	-0.00 (0.15)	(-0.29, 0.29)	0.9834	
Age (years)											NE
<= 65	109	4.11 (0.78)	114	4.13 (0.79)	-0.02 (0.98)	(-1.95, 1.90)	0.9826	-0.00 (0.13)	(-0.27, 0.26)	0.9847	
> 65	1	NE	0	NE	NE	NE		NE	NE		
Sex											NE
male	10	NE	12	NE	NE	NE		NE	NE		
female	100	3.90 (0.81)	102	3.64 (0.82)	0.26 (1.03)	(-1.76, 2.28)	0.7996	0.03 (0.14)	(-0.24, 0.31)	0.8213	
Race											NE
White	69	4.28 (1.02)	74	5.39 (1.01)	-1.12 (1.29)	(-3.67, 1.44)	0.3888	-0.13 (0.17)	(-0.46, 0.20)	0.4391	
Black or African American	11	NE	17	NE	NE	NE		NE	NE		
Asian	16	4.08 (2.01)	16	-3.10 (2.04)	7.19 (2.05)	(3.02, 11.36)	0.0013	0.86 (0.37)	(0.14, 1.59)	0.0201	
Other	8	NE	5	NE	NE	NE		NE	NE		
Ethnicity											0.2491
Hispanic/Latino	26	5.37 (1.86)	32	2.93 (1.77)	2.44 (2.45)	(-2.47, 7.35)	0.3236	0.25 (0.27)	(-0.27, 0.77)	0.3534	
Non-hispanic/Latino	78	3.55 (0.89)	80	4.20 (0.91)	-0.65 (1.09)	(-2.80, 1.50)	0.5522	-0.08 (0.16)	(-0.39, 0.23)	0.6115	
Geographic region											0.0795
EU	39	2.76 (1.22)	31	5.04 (1.33)	-2.27 (1.47)	(-5.21, 0.66)	0.1264	-0.30 (0.24)	(-0.77, 0.18)	0.2175	
non-EU	71	4.69 (0.98)	83	3.59 (0.97)	1.10 (1.25)	(-1.36, 3.57)	0.3786	0.13 (0.16)	(-0.19, 0.45)	0.4292	
Onset of disease											NE
Paediatric	8	NE	4	NE	NE	NE		NE	NE		
Adult	102	4.22 (0.79)	110	4.11 (0.79)	0.11 (0.99)	(-1.83, 2.06)	0.9093	0.01 (0.14)	(-0.26, 0.28)	0.9202	
ADA result											NE
Negative	106	4.03 (0.76)	105	4.37 (0.79)	-0.34 (0.97)	(-2.26, 1.57)	0.7243	-0.04 (0.14)	(-0.31, 0.23)	0.7551	
Positive (At any time)	4	NE	9	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.6787
< 30	79	3.61 (0.96)	83	3.83 (1.00)	-0.22 (1.17)	(-2.52, 2.09)	0.8531	-0.02 (0.16)	(-0.33, 0.28)	0.8771	
>= 30	31	5.61 (1.38)	31	4.92 (1.30)	0.69 (1.84)	(-3.00, 4.37)	0.7106	0.09 (0.25)	(-0.41, 0.59)	0.7206	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.4721
All negative/normal	36	4.07 (1.28)	53	4.98 (1.05)	-0.91 (1.60)	(-4.09, 2.27)	0.5714	-0.12 (0.22)	(-0.54, 0.31)	0.5860	
At least one positive/abnormal	74	3.85 (1.14)	61	3.29 (1.32)	0.56 (1.27)	(-1.96, 3.08)	0.6601	0.06 (0.17)	(-0.28, 0.39)	0.7474	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - EQ VAS Score
Full analysis set

	Anifrolumab 300mg (N=119)		Placebo (N=121)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 12		6.60 (2.06)		0.71 (2.08)	5.89 (2.64)	(0.68, 11.10)	0.0270			
Week 24		4.66 (2.25)		4.29 (2.23)	0.37 (2.89)	(-5.33, 6.08)	0.8980			
Week 36		7.52 (2.24)		7.10 (2.31)	0.42 (2.95)	(-5.39, 6.23)	0.8872			
Week 52		6.56 (2.32)		2.16 (2.43)	4.40 (3.10)	(-1.72, 10.52)	0.1575			
OVERALL	110	6.34 (1.76)	111	3.57 (1.81)	2.77 (2.17)	(-1.51, 7.05)	0.2032	0.15 (0.13)	(-0.12, 0.41)	0.2746

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - EQ VAS Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) N	LSMean (SE)	Placebo (N=121) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.8396
< 10 points	37	9.76 (3.06)	31	6.54 (3.45)	3.22 (4.32)	(-5.43, 11.86)	0.4596	0.17 (0.24)	(-0.31, 0.65)	0.4898	
>= 10 points	73	3.62 (2.23)	80	1.41 (2.12)	2.20 (2.53)	(-2.80, 7.21)	0.3855	0.12 (0.16)	(-0.20, 0.43)	0.4761	
OCS dose at baseline											0.5560
<10 mg/day	56	7.22 (2.22)	59	5.88 (2.31)	1.34 (2.97)	(-4.55, 7.23)	0.6536	0.08 (0.19)	(-0.29, 0.44)	0.6786	
>=10 mg/day	54	4.72 (3.15)	52	0.77 (2.98)	3.95 (3.29)	(-2.58, 10.47)	0.2327	0.18 (0.19)	(-0.21, 0.56)	0.3676	
Result of type I IFN gene signature test											0.0876
LOW	21	2.86 (3.48)	22	7.36 (3.19)	-4.51 (4.57)	(-13.76, 4.75)	0.3307	-0.29 (0.31)	(-0.89, 0.31)	0.3502	
HIGH	89	8.61 (1.82)	89	4.24 (1.86)	4.38 (2.48)	(-0.51, 9.26)	0.0790	0.25 (0.15)	(-0.04, 0.55)	0.0959	
Age (years)											NE
<= 65	109	6.42 (1.76)	111	3.50 (1.81)	2.92 (2.17)	(-1.37, 7.20)	0.1810	0.16 (0.14)	(-0.11, 0.42)	0.2502	
> 65	1	NE	0	NE	NE	NE		NE	NE		
Sex											0.6990
male	10	-9.64 (7.88)	12	-9.71 (9.40)	0.07 (7.45)	(-15.70, 15.84)	0.9928	0.00 (0.43)	(-0.84, 0.84)	0.9958	
female	100	7.91 (1.84)	99	4.82 (1.88)	3.08 (2.31)	(-1.47, 7.64)	0.1830	0.17 (0.14)	(-0.11, 0.44)	0.2439	
Race											0.0003
White	69	5.19 (2.01)	72	8.53 (2.03)	-3.33 (2.52)	(-8.32, 1.65)	0.1880	-0.20 (0.17)	(-0.53, 0.14)	0.2464	
Black or African American	11	10.87 (5.98)	17	1.37 (6.19)	9.50 (6.99)	(-5.00, 24.01)	0.1878	0.39 (0.39)	(-0.37, 1.16)	0.3155	
Asian	16	4.77 (6.72)	15	-18.69 (6.14)	23.46 (6.03)	(11.07, 35.84)	0.0006	0.90 (0.38)	(0.15, 1.64)	0.0180	
Other	8	17.08 (8.79)	5	3.43 (16.03)	13.65 (13.93)	(-19.02, 46.32)	0.3585	0.43 (0.58)	(-0.70, 1.57)	0.4548	
Ethnicity											0.8030
Hispanic/Latino	26	8.57 (3.14)	32	5.80 (3.02)	2.77 (3.91)	(-5.09, 10.63)	0.4814	0.16 (0.26)	(-0.35, 0.68)	0.5333	
Non-hispanic/Latino	78	3.43 (2.15)	77	1.83 (2.22)	1.60 (2.61)	(-3.56, 6.76)	0.5408	0.08 (0.16)	(-0.23, 0.40)	0.6065	
Geographic region											0.0534
EU	39	4.76 (3.23)	29	7.83 (3.61)	-3.07 (3.78)	(-10.64, 4.50)	0.4204	-0.15 (0.25)	(-0.63, 0.33)	0.5337	
non-EU	71	6.96 (2.11)	82	1.13 (2.10)	5.83 (2.63)	(0.63, 11.02)	0.0281	0.31 (0.16)	(-0.01, 0.63)	0.0540	
Onset of disease											0.0462
Paediatric	8	16.08 (5.99)	4	-4.92 (9.10)	21.01 (9.31)	(-0.11, 42.12)	0.0509	1.12 (0.67)	(-0.20, 2.44)	0.0964	
Adult	102	5.56 (1.82)	107	3.65 (1.84)	1.91 (2.23)	(-2.49, 6.32)	0.3931	0.10 (0.14)	(-0.17, 0.37)	0.4618	
ADA result											0.0004
Negative	106	5.39 (1.77)	102	3.47 (1.85)	1.92 (2.21)	(-2.44, 6.29)	0.3859	0.10 (0.14)	(-0.17, 0.38)	0.4540	
Positive (At any time)	4	52.53 (10.03)	9	14.77 (5.78)	37.76 (9.89)	(16.05, 59.47)	0.0027	1.94 (0.75)	(0.46, 3.42)	0.0101	
BMI (kg/m2) at enrolment											0.2619
< 30	79	5.42 (2.22)	81	1.50 (2.35)	3.92 (2.63)	(-1.28, 9.12)	0.1384	0.19 (0.16)	(-0.12, 0.50)	0.2290	
>= 30	31	6.10 (3.03)	30	7.57 (2.89)	-1.46 (4.01)	(-9.53, 6.60)	0.7169	-0.09 (0.26)	(-0.59, 0.41)	0.7301	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.0221
All negative/normal	36	5.11 (2.92)	52	8.47 (2.42)	-3.37 (3.66)	(-10.64, 3.91)	0.3599	-0.19 (0.22)	(-0.62, 0.24)	0.3798	
At least one positive/abnormal	74	7.87 (2.56)	59	0.76 (2.96)	7.11 (2.75)	(1.66, 12.56)	0.0110	0.32 (0.18)	(-0.03, 0.66)	0.0716	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Lupus QoL Physical Health domain score
Full analysis set

	Anifrolumab 300mg (N=119)		Placebo (N=121)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 12		9.29 (1.94)		5.45 (1.97)	3.84 (2.48)	(-1.05, 8.73)	0.1230			
Week 24		10.31 (1.94)		8.11 (1.97)	2.20 (2.46)	(-2.66, 7.05)	0.3732			
Week 36		8.10 (2.02)		12.74 (2.12)	-4.65 (2.64)	(-9.85, 0.55)	0.0795			
Week 52		5.75 (2.08)		8.69 (2.19)	-2.93 (2.74)	(-8.35, 2.48)	0.2866			
OVERALL	109	8.36 (1.71)	111	8.75 (1.78)	-0.39 (2.12)	(-4.57, 3.79)	0.8558	-0.02 (0.13)	(-0.29, 0.24)	0.8760

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Lupus QoL Physical Health domain score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=119)		Placebo (N=121)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											0.1616
< 10 points	37	9.88 (2.84)	31	14.87 (3.23)	-4.99 (4.07)	(-13.13, 3.15)	0.2248	-0.28 (0.24)	(-0.76, 0.20)	0.2519	
>= 10 points	72	7.39 (2.18)	80	5.71 (2.10)	1.68 (2.48)	(-3.22, 6.58)	0.4990	0.09 (0.16)	(-0.23, 0.41)	0.5809	
OCS dose at baseline											0.7483
<10 mg/day	56	7.19 (1.91)	59	8.47 (2.01)	-1.28 (2.57)	(-6.37, 3.81)	0.6189	-0.09 (0.19)	(-0.45, 0.28)	0.6472	
>=10 mg/day	53	7.90 (3.36)	52	7.75 (3.24)	0.14 (3.62)	(-7.04, 7.33)	0.9684	0.01 (0.20)	(-0.38, 0.39)	0.9756	
Result of type I IFN gene signature test											0.5784
LOW	21	7.60 (3.61)	22	10.86 (3.21)	-3.27 (4.78)	(-12.97, 6.44)	0.4991	-0.20 (0.31)	(-0.80, 0.40)	0.5069	
HIGH	88	8.10 (1.78)	89	8.39 (1.83)	-0.29 (2.42)	(-5.07, 4.49)	0.9059	-0.02 (0.15)	(-0.31, 0.28)	0.9109	
Age (years)											NE
<= 65	108	8.35 (1.71)	111	8.73 (1.78)	-0.38 (2.13)	(-4.57, 3.82)	0.8602	-0.02 (0.14)	(-0.29, 0.24)	0.8797	
> 65	1	NE	0	NE	NE	NE		NE	NE		
Sex											0.3069
male	10	13.27 (7.47)	12	21.06 (11.43)	-7.79 (7.64)	(-23.95, 8.37)	0.3227	-0.22 (0.43)	(-1.07, 0.62)	0.6013	
female	99	8.33 (1.78)	99	7.98 (1.84)	0.34 (2.24)	(-4.07, 4.76)	0.8779	0.02 (0.14)	(-0.26, 0.30)	0.8932	
Race											0.0361
White	69	8.36 (2.19)	72	11.67 (2.22)	-3.31 (2.75)	(-8.75, 2.13)	0.2304	-0.18 (0.17)	(-0.51, 0.15)	0.2919	
Black or African American	10	16.15 (7.11)	17	11.41 (7.19)	4.75 (8.25)	(-12.38, 21.88)	0.5710	0.17 (0.40)	(-0.61, 0.95)	0.6728	
Asian	16	0.66 (4.61)	15	-11.40 (4.74)	12.07 (4.58)	(2.66, 21.47)	0.0138	0.64 (0.37)	(-0.09, 1.36)	0.0839	
Other	8	10.81 (5.82)	5	11.48 (8.85)	-0.67 (8.15)	(-19.45, 18.11)	0.9368	-0.03 (0.57)	(-1.15, 1.08)	0.9511	
Ethnicity											0.7875
Hispanic/Latino	26	11.06 (3.90)	32	10.51 (3.77)	0.54 (5.31)	(-10.10, 11.19)	0.9186	0.03 (0.26)	(-0.49, 0.54)	0.9217	
Non-hispanic/Latino	77	6.24 (1.98)	77	7.26 (2.04)	-1.02 (2.35)	(-5.68, 3.64)	0.6655	-0.06 (0.16)	(-0.37, 0.26)	0.7213	
Geographic region											0.0961
EU	39	5.87 (3.27)	29	12.74 (3.56)	-6.86 (3.74)	(-14.34, 0.62)	0.0716	-0.34 (0.25)	(-0.83, 0.14)	0.1676	
non-EU	70	8.88 (2.03)	82	8.16 (2.09)	0.73 (2.61)	(-4.44, 5.90)	0.7806	0.04 (0.16)	(-0.28, 0.36)	0.8053	
Onset of disease											0.6123
Paediatric	8	-0.34 (10.07)	4	8.05 (20.48)	-8.39 (16.31)	(-47.00, 30.21)	0.6228	-0.24 (0.62)	(-1.44, 0.97)	0.7004	
Adult	101	8.79 (1.77)	107	8.84 (1.80)	-0.05 (2.18)	(-4.36, 4.26)	0.9814	-0.00 (0.14)	(-0.27, 0.27)	0.9840	
ADA result											NE
Negative	105	8.36 (1.72)	102	9.30 (1.82)	-0.94 (2.17)	(-5.23, 3.35)	0.6661	-0.05 (0.14)	(-0.32, 0.22)	0.7087	
Positive (At any time)	4	NE	9	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.5963
< 30	78	7.82 (2.00)	81	8.47 (2.15)	-0.65 (2.37)	(-5.34, 4.04)	0.7844	-0.03 (0.16)	(-0.35, 0.28)	0.8256	
>= 30	31	10.42 (3.56)	30	8.25 (3.40)	2.17 (4.76)	(-7.40, 11.74)	0.6509	0.11 (0.26)	(-0.39, 0.61)	0.6641	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.2321
All negative/normal	36	5.48 (2.96)	52	10.05 (2.49)	-4.57 (3.73)	(-12.00, 2.86)	0.2244	-0.25 (0.22)	(-0.68, 0.17)	0.2442	
At least one positive/abnormal	73	10.30 (2.47)	59	9.38 (2.90)	0.92 (2.68)	(-4.38, 6.22)	0.7323	0.04 (0.18)	(-0.30, 0.39)	0.8094	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Lupus QoL Emotional Health domain score
Full analysis set

	Anifrolumab 300mg (N=119)		Placebo (N=121)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 12		5.71 (1.99)		0.77 (2.00)	4.94 (2.55)	(-0.08, 9.96)	0.0536			
Week 24		7.01 (1.99)		5.74 (1.99)	1.28 (2.53)	(-3.70, 6.25)	0.6141			
Week 36		8.06 (1.92)		8.87 (2.00)	-0.80 (2.47)	(-5.67, 4.07)	0.7454			
Week 52		6.64 (2.34)		5.93 (2.42)	0.72 (3.13)	(-5.46, 6.90)	0.8191			
OVERALL	109	6.86 (1.73)	111	5.32 (1.78)	1.53 (2.15)	(-2.71, 5.78)	0.4773	0.08 (0.13)	(-0.18, 0.35)	0.5388

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Lupus QoL Emotional Health domain score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) N	LSMean (SE)	Placebo (N=121) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.9640
< 10 points	37	10.30 (2.92)	31	8.79 (3.31)	1.51 (4.16)	(-6.81, 9.83)	0.7176	0.08 (0.24)	(-0.39, 0.56)	0.7341	
>= 10 points	72	4.69 (2.23)	80	2.96 (2.12)	1.73 (2.54)	(-3.30, 6.76)	0.4973	0.09 (0.16)	(-0.23, 0.41)	0.5756	
OCS dose at baseline											0.9334
<10 mg/day	56	6.38 (1.97)	59	5.30 (2.05)	1.08 (2.65)	(-4.18, 6.33)	0.6849	0.07 (0.19)	(-0.30, 0.44)	0.7067	
>=10 mg/day	53	7.54 (3.38)	52	6.08 (3.19)	1.45 (3.59)	(-5.67, 8.58)	0.6869	0.06 (0.20)	(-0.32, 0.44)	0.7565	
Result of type I IFN gene signature test											0.9389
LOW	21	7.00 (3.79)	22	5.00 (3.49)	1.99 (5.16)	(-8.45, 12.44)	0.7013	0.12 (0.31)	(-0.48, 0.71)	0.7040	
HIGH	88	7.64 (1.79)	89	6.09 (1.83)	1.56 (2.44)	(-3.25, 6.37)	0.5238	0.09 (0.15)	(-0.20, 0.39)	0.5456	
Age (years)											NE
<= 65	108	6.82 (1.74)	111	5.35 (1.78)	1.48 (2.16)	(-2.78, 5.73)	0.4942	0.08 (0.14)	(-0.19, 0.34)	0.5544	
> 65	1	NE	0	NE	NE	NE		NE	NE		
Sex											0.8256
male	10	2.08 (6.75)	12	-1.49 (9.82)	3.57 (6.99)	(-11.09, 18.22)	0.6158	0.12 (0.43)	(-0.72, 0.96)	0.7826	
female	99	6.75 (1.77)	99	4.80 (1.80)	1.95 (2.22)	(-2.43, 6.33)	0.3810	0.11 (0.14)	(-0.17, 0.39)	0.4416	
Race											0.4324
White	69	7.39 (2.32)	72	6.64 (2.32)	0.75 (2.91)	(-5.01, 6.51)	0.7964	0.04 (0.17)	(-0.29, 0.37)	0.8197	
Black or African American	10	14.88 (6.02)	17	13.88 (5.97)	1.00 (7.17)	(-13.89, 15.89)	0.8900	0.04 (0.40)	(-0.74, 0.82)	0.9147	
Asian	16	-11.72 (4.36)	15	-13.44 (4.49)	1.72 (4.55)	(-7.63, 11.07)	0.7088	0.10 (0.36)	(-0.61, 0.80)	0.7892	
Other	8	3.36 (5.10)	5	-11.81 (8.93)	15.17 (8.26)	(-3.42, 33.75)	0.0983	0.85 (0.60)	(-0.34, 2.03)	0.1606	
Ethnicity											0.8199
Hispanic/Latino	26	8.87 (3.69)	32	8.99 (3.54)	-0.11 (4.88)	(-9.89, 9.67)	0.9816	-0.01 (0.26)	(-0.52, 0.51)	0.9827	
Non-hispanic/Latino	77	5.50 (2.12)	77	4.37 (2.15)	1.14 (2.53)	(-3.86, 6.14)	0.6534	0.06 (0.16)	(-0.26, 0.38)	0.7075	
Geographic region											0.8653
EU	39	8.69 (3.35)	29	7.85 (3.70)	0.84 (3.92)	(-7.02, 8.70)	0.8313	0.04 (0.25)	(-0.44, 0.52)	0.8688	
non-EU	70	5.53 (2.04)	82	3.90 (2.03)	1.64 (2.56)	(-3.43, 6.70)	0.5245	0.09 (0.16)	(-0.23, 0.41)	0.5735	
Onset of disease											0.8729
Paediatric	8	5.12 (10.01)	4	1.49 (14.23)	3.63 (10.65)	(-21.07, 28.33)	0.7425	0.12 (0.61)	(-1.08, 1.32)	0.8472	
Adult	101	7.50 (1.78)	107	5.61 (1.79)	1.89 (2.20)	(-2.44, 6.22)	0.3909	0.10 (0.14)	(-0.17, 0.38)	0.4566	
ADA result											NE
Negative	105	6.99 (1.75)	102	5.65 (1.82)	1.34 (2.20)	(-2.99, 5.68)	0.5414	0.07 (0.14)	(-0.20, 0.35)	0.5948	
Positive (At any time)	4	NE	9	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.7754
< 30	78	4.89 (2.15)	81	2.46 (2.26)	2.43 (2.55)	(-2.61, 7.46)	0.3427	0.12 (0.16)	(-0.19, 0.43)	0.4399	
>= 30	31	11.03 (3.04)	30	9.99 (2.88)	1.05 (4.10)	(-7.19, 9.28)	0.7991	0.06 (0.26)	(-0.44, 0.57)	0.8051	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.6110
All negative/normal	36	7.67 (2.72)	52	7.38 (2.27)	0.29 (3.41)	(-6.50, 7.09)	0.9314	0.02 (0.22)	(-0.41, 0.44)	0.9343	
At least one positive/abnormal	73	6.67 (2.68)	59	4.10 (3.12)	2.58 (2.91)	(-3.18, 8.33)	0.3778	0.11 (0.18)	(-0.23, 0.45)	0.5315	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Lupus QoL Body Image domain score
Full analysis set

	Anifrolumab 300mg (N=119)		Placebo (N=121)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 12		8.93 (2.19)		2.90 (2.19)	6.02 (2.76)	(0.57, 11.48)	0.0306			
Week 24		10.52 (2.36)		7.47 (2.37)	3.05 (3.02)	(-2.92, 9.01)	0.3150			
Week 36		13.06 (2.28)		13.11 (2.36)	-0.05 (2.93)	(-5.83, 5.73)	0.9862			
Week 52		9.44 (2.66)		10.98 (2.69)	-1.54 (3.49)	(-8.43, 5.34)	0.6588			
OVERALL	102	10.48 (1.92)	103	8.62 (1.96)	1.87 (2.34)	(-2.74, 6.48)	0.4252	0.09 (0.14)	(-0.18, 0.37)	0.4979

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Lupus QoL Body Image domain score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) N	LSMean (SE)	Placebo (N=121) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.7737
< 10 points	34	9.13 (2.77)	29	6.18 (3.14)	2.95 (3.82)	(-4.69, 10.59)	0.4428	0.18 (0.25)	(-0.32, 0.67)	0.4853	
>= 10 points	68	11.90 (2.64)	74	10.34 (2.48)	1.56 (2.97)	(-4.32, 7.44)	0.6005	0.07 (0.17)	(-0.26, 0.40)	0.6684	
OCS dose at baseline											0.7712
<10 mg/day	52	11.28 (2.02)	55	9.76 (2.11)	1.52 (2.69)	(-3.83, 6.86)	0.5748	0.10 (0.19)	(-0.28, 0.48)	0.6072	
>=10 mg/day	50	9.31 (3.97)	48	6.37 (3.70)	2.94 (4.11)	(-5.22, 11.11)	0.4754	0.11 (0.20)	(-0.29, 0.50)	0.5913	
Result of type I IFN gene signature test											0.9271
LOW	19	8.90 (4.22)	20	7.90 (3.91)	1.00 (5.87)	(-10.92, 12.93)	0.8654	0.05 (0.32)	(-0.57, 0.68)	0.8644	
HIGH	83	10.32 (1.97)	83	8.73 (1.98)	1.59 (2.64)	(-3.63, 6.81)	0.5482	0.09 (0.16)	(-0.22, 0.39)	0.5706	
Age (years)											NE
<= 65	101	10.47 (1.93)	103	8.65 (1.96)	1.82 (2.34)	(-2.81, 6.44)	0.4388	0.09 (0.14)	(-0.18, 0.37)	0.5105	
> 65	1	NE	0	NE	NE	NE		NE	NE		
Sex											0.5452
male	10	18.50 (5.30)	12	12.33 (6.59)	6.17 (5.99)	(-6.85, 19.18)	0.3229	0.29 (0.43)	(-0.55, 1.14)	0.4979	
female	92	10.85 (2.05)	91	8.61 (2.08)	2.24 (2.53)	(-2.75, 7.22)	0.3776	0.11 (0.15)	(-0.18, 0.40)	0.4467	
Race											NE
White	66	10.35 (2.39)	65	7.94 (2.50)	2.42 (3.04)	(-3.61, 8.44)	0.4289	0.12 (0.17)	(-0.22, 0.46)	0.4884	
Black or African American	10	12.20 (7.05)	17	14.53 (7.15)	-2.33 (8.29)	(-19.52, 14.87)	0.7816	-0.08 (0.40)	(-0.86, 0.70)	0.8346	
Asian	13	-6.96 (6.58)	14	6.43 (5.80)	-13.39 (6.45)	(-26.79, 0.01)	0.0501	-0.57 (0.39)	(-1.35, 0.20)	0.1466	
Other	8	NE	5	NE	NE	NE		NE	NE		
Ethnicity											0.5764
Hispanic/Latino	25	11.48 (3.68)	29	7.91 (3.78)	3.58 (4.73)	(-5.95, 13.10)	0.4537	0.18 (0.27)	(-0.36, 0.72)	0.5086	
Non-hispanic/Latino	72	9.02 (2.39)	72	8.53 (2.41)	0.49 (2.85)	(-5.15, 6.13)	0.8641	0.02 (0.17)	(-0.30, 0.35)	0.8860	
Geographic region											0.7319
EU	37	9.60 (3.61)	26	9.37 (3.86)	0.23 (4.07)	(-7.95, 8.41)	0.9551	0.01 (0.26)	(-0.49, 0.51)	0.9663	
non-EU	65	10.00 (2.31)	77	8.07 (2.29)	1.93 (2.85)	(-3.71, 7.57)	0.4988	0.10 (0.17)	(-0.23, 0.43)	0.5565	
Onset of disease											NE
Paediatric	8	NE	4	NE	NE	NE		NE	NE		
Adult	94	11.67 (1.95)	99	9.14 (1.95)	2.53 (2.36)	(-2.13, 7.18)	0.2856	0.13 (0.14)	(-0.15, 0.41)	0.3625	
ADA result											NE
Negative	98	10.74 (1.94)	94	8.64 (2.00)	2.10 (2.39)	(-2.62, 6.81)	0.3809	0.11 (0.14)	(-0.17, 0.39)	0.4530	
Positive (At any time)	4	NE	9	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.4963
< 30	71	10.07 (2.43)	74	7.06 (2.51)	3.01 (2.82)	(-2.57, 8.59)	0.2882	0.14 (0.17)	(-0.18, 0.47)	0.3932	
>= 30	31	11.43 (3.30)	29	11.94 (3.23)	-0.51 (4.33)	(-9.21, 8.20)	0.9072	-0.03 (0.26)	(-0.53, 0.48)	0.9137	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.9453
All negative/normal	34	10.67 (3.09)	49	8.10 (2.60)	2.57 (3.87)	(-5.14, 10.28)	0.5088	0.14 (0.22)	(-0.30, 0.58)	0.5305	
At least one positive/abnormal	68	11.93 (2.99)	54	9.70 (3.36)	2.23 (3.08)	(-3.88, 8.34)	0.4713	0.09 (0.18)	(-0.27, 0.45)	0.6222	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Lupus QoL Burden to Others domain score
Full analysis set

	Anifrolumab 300mg (N=119)		Placebo (N=121)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 12		12.87 (2.43)		0.50 (2.44)	12.37 (3.08)	(6.29, 18.45)	<.0001			
Week 24		10.32 (2.59)		4.59 (2.58)	5.73 (3.30)	(-0.77, 12.24)	0.0839			
Week 36		14.03 (2.50)		11.10 (2.60)	2.93 (3.23)	(-3.45, 9.30)	0.3664			
Week 52		9.39 (2.90)		3.77 (2.99)	5.62 (3.86)	(-1.99, 13.23)	0.1466			
OVERALL	109	11.65 (2.20)	111	4.99 (2.25)	6.66 (2.73)	(1.29, 12.04)	0.0154	0.28 (0.14)	(0.02, 0.55)	0.0361

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Lupus QoL Burden to Others domain score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) N	LSMean (SE)	Placebo (N=121) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.7829
< 10 points	37	11.08 (3.21)	31	3.32 (3.65)	7.75 (4.54)	(-1.31, 16.82)	0.0924	0.39 (0.25)	(-0.10, 0.87)	0.1169	
>= 10 points	72	11.92 (2.99)	80	5.73 (2.85)	6.19 (3.42)	(-0.58, 12.95)	0.0726	0.24 (0.16)	(-0.08, 0.56)	0.1377	
OCS dose at baseline											0.9967
<10 mg/day	56	11.19 (2.40)	59	4.78 (2.49)	6.41 (3.24)	(-0.00, 12.82)	0.0500	0.34 (0.19)	(-0.03, 0.71)	0.0679	
>=10 mg/day	53	11.98 (4.39)	52	5.54 (4.16)	6.43 (4.60)	(-2.70, 15.57)	0.1654	0.21 (0.20)	(-0.18, 0.59)	0.2922	
Result of type I IFN gene signature test											0.1979
LOW	21	10.39 (4.92)	22	11.39 (4.61)	-1.00 (6.67)	(-14.50, 12.50)	0.8816	-0.04 (0.31)	(-0.64, 0.55)	0.8841	
HIGH	88	10.76 (2.23)	89	2.34 (2.26)	8.42 (3.01)	(2.48, 14.36)	0.0057	0.40 (0.15)	(0.10, 0.69)	0.0089	
Age (years)											NE
<= 65	108	11.55 (2.21)	111	5.02 (2.25)	6.52 (2.73)	(1.14, 11.91)	0.0178	0.28 (0.14)	(0.01, 0.54)	0.0403	
> 65	1	NE	0	NE	NE	NE		NE	NE		
Sex											0.3013
male	10	22.77 (7.76)	12	23.90 (9.59)	-1.14 (7.88)	(-17.92, 15.65)	0.8872	-0.04 (0.43)	(-0.88, 0.80)	0.9313	
female	99	10.92 (2.29)	99	3.39 (2.34)	7.53 (2.87)	(1.87, 13.19)	0.0094	0.33 (0.14)	(0.05, 0.61)	0.0226	
Race											0.3073
White	69	11.41 (2.89)	72	7.72 (2.89)	3.69 (3.62)	(-3.48, 10.85)	0.3108	0.15 (0.17)	(-0.18, 0.48)	0.3701	
Black or African American	10	18.40 (9.06)	17	13.23 (8.37)	5.17 (10.32)	(-16.24, 26.58)	0.6214	0.15 (0.40)	(-0.63, 0.94)	0.6993	
Asian	16	11.46 (6.44)	15	-6.12 (6.59)	17.58 (6.40)	(4.13, 31.02)	0.0132	0.67 (0.37)	(-0.06, 1.39)	0.0717	
Other	8	19.22 (12.77)	5	14.51 (22.97)	4.71 (21.15)	(-48.57, 57.99)	0.8320	0.10 (0.57)	(-1.01, 1.22)	0.8559	
Ethnicity											0.6397
Hispanic/Latino	26	17.90 (5.01)	32	8.46 (4.63)	9.44 (6.44)	(-3.47, 22.34)	0.1485	0.36 (0.27)	(-0.16, 0.88)	0.1772	
Non-hispanic/Latino	77	10.41 (2.63)	77	4.33 (2.68)	6.08 (3.14)	(-0.12, 12.28)	0.0545	0.26 (0.16)	(-0.06, 0.58)	0.1085	
Geographic region											0.2122
EU	39	9.66 (3.47)	29	8.01 (3.87)	1.65 (4.45)	(-7.26, 10.56)	0.7124	0.08 (0.25)	(-0.40, 0.56)	0.7556	
non-EU	70	12.53 (2.67)	82	3.94 (2.65)	8.59 (3.33)	(2.00, 15.17)	0.0110	0.37 (0.16)	(0.05, 0.69)	0.0253	
Onset of disease											0.5552
Paediatric	8	-7.31 (13.18)	4	-26.23 (18.23)	18.92 (20.09)	(-30.70, 68.54)	0.3840	0.47 (0.62)	(-0.75, 1.69)	0.4494	
Adult	101	12.04 (2.27)	107	5.08 (2.28)	6.95 (2.80)	(1.43, 12.48)	0.0139	0.30 (0.14)	(0.03, 0.57)	0.0324	
ADA result											NE
Negative	105	11.45 (2.24)	102	5.81 (2.32)	5.64 (2.82)	(0.09, 11.19)	0.0465	0.24 (0.14)	(-0.03, 0.52)	0.0822	
Positive (At any time)	4	NE	9	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.4070
< 30	78	8.77 (2.69)	81	0.88 (2.84)	7.89 (3.21)	(1.56, 14.23)	0.0150	0.32 (0.16)	(0.01, 0.63)	0.0464	
>= 30	31	15.23 (3.95)	30	12.40 (3.74)	2.83 (5.20)	(-7.59, 13.24)	0.5886	0.13 (0.26)	(-0.37, 0.63)	0.6086	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.1795
All negative/normal	36	11.34 (3.45)	52	8.74 (2.91)	2.60 (4.32)	(-5.99, 11.20)	0.5485	0.12 (0.22)	(-0.30, 0.55)	0.5691	
At least one positive/abnormal	73	10.13 (3.36)	59	-0.06 (3.84)	10.19 (3.64)	(2.98, 17.40)	0.0060	0.35 (0.18)	(0.00, 0.69)	0.0482	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Lupus QoL Fatigue domain score
Full analysis set

	Anifrolumab 300mg (N=119)		Placebo (N=121)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 12		9.51 (2.14)		5.07 (2.16)	4.45 (2.73)	(-0.94, 9.83)	0.1049			
Week 24		9.74 (2.10)		7.61 (2.10)	2.13 (2.64)	(-3.07, 7.32)	0.4202			
Week 36		8.98 (2.18)		10.48 (2.26)	-1.50 (2.82)	(-7.06, 4.07)	0.5965			
Week 52		9.42 (2.45)		8.56 (2.56)	0.87 (3.26)	(-5.57, 7.31)	0.7911			
OVERALL	109	9.41 (1.87)	111	7.93 (1.92)	1.49 (2.31)	(-3.07, 6.04)	0.5213	0.07 (0.13)	(-0.19, 0.34)	0.5818

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Lupus QoL Fatigue domain score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) N	LSMean (SE)	Placebo (N=121) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.7345
< 10 points	37	9.23 (2.89)	31	8.88 (3.27)	0.36 (4.04)	(-7.72, 8.43)	0.9298	0.02 (0.24)	(-0.46, 0.50)	0.9352	
>= 10 points	72	8.84 (2.50)	80	6.80 (2.39)	2.04 (2.86)	(-3.62, 7.69)	0.4780	0.10 (0.16)	(-0.22, 0.41)	0.5584	
OCS dose at baseline											0.5942
<10 mg/day	56	9.40 (2.16)	59	6.77 (2.25)	2.63 (2.91)	(-3.14, 8.40)	0.3690	0.16 (0.19)	(-0.21, 0.52)	0.4039	
>=10 mg/day	53	8.71 (3.68)	52	8.61 (3.46)	0.10 (3.75)	(-7.35, 7.54)	0.9797	0.00 (0.20)	(-0.38, 0.39)	0.9850	
Result of type I IFN gene signature test											0.8580
LOW	21	8.09 (4.58)	22	7.63 (4.24)	0.46 (6.24)	(-12.17, 13.09)	0.9416	0.02 (0.31)	(-0.58, 0.62)	0.9421	
HIGH	88	9.80 (1.89)	89	8.13 (1.93)	1.67 (2.56)	(-3.38, 6.72)	0.5154	0.09 (0.15)	(-0.20, 0.39)	0.5391	
Age (years)											NE
<= 65	108	9.23 (1.87)	111	7.98 (1.92)	1.25 (2.31)	(-3.31, 5.81)	0.5887	0.06 (0.14)	(-0.20, 0.33)	0.6421	
> 65	1	NE	0	NE	NE	NE		NE	NE		
Sex											0.1050
male	10	5.21 (6.26)	12	14.47 (8.17)	-9.26 (6.75)	(-23.41, 4.89)	0.1866	-0.36 (0.43)	(-1.21, 0.49)	0.4068	
female	99	10.24 (2.00)	99	7.83 (2.04)	2.41 (2.49)	(-2.51, 7.33)	0.3349	0.12 (0.14)	(-0.16, 0.40)	0.4002	
Race											0.2782
White	69	9.86 (2.42)	72	10.35 (2.43)	-0.49 (3.03)	(-6.49, 5.51)	0.8714	-0.02 (0.17)	(-0.35, 0.31)	0.8867	
Black or African American	10	21.97 (7.57)	17	10.35 (7.38)	11.62 (8.55)	(-6.17, 29.41)	0.1887	0.40 (0.40)	(-0.39, 1.19)	0.3225	
Asian	16	-1.13 (5.35)	15	-10.40 (5.10)	9.28 (5.31)	(-1.60, 20.15)	0.0916	0.44 (0.36)	(-0.28, 1.15)	0.2289	
Other	8	6.07 (5.03)	5	6.23 (8.29)	-0.16 (7.89)	(-18.43, 18.11)	0.9846	-0.01 (0.57)	(-1.13, 1.11)	0.9871	
Ethnicity											0.8964
Hispanic/Latino	26	12.02 (3.85)	32	10.02 (3.73)	2.00 (4.99)	(-8.01, 12.02)	0.6903	0.10 (0.26)	(-0.42, 0.61)	0.7149	
Non-hispanic/Latino	77	7.48 (2.31)	77	6.22 (2.35)	1.26 (2.76)	(-4.19, 6.71)	0.6486	0.06 (0.16)	(-0.25, 0.38)	0.7036	
Geographic region											0.1692
EU	39	7.49 (3.50)	29	10.91 (3.85)	-3.42 (4.05)	(-11.54, 4.70)	0.4023	-0.16 (0.25)	(-0.64, 0.32)	0.5197	
non-EU	70	10.22 (2.28)	82	6.82 (2.28)	3.40 (2.86)	(-2.26, 9.06)	0.2367	0.17 (0.16)	(-0.15, 0.49)	0.2979	
Onset of disease											0.4387
Paediatric	8	3.20 (7.77)	4	-7.13 (12.17)	10.33 (11.34)	(-15.50, 36.17)	0.3870	0.42 (0.62)	(-0.80, 1.64)	0.4990	
Adult	101	9.90 (1.93)	107	8.54 (1.95)	1.36 (2.37)	(-3.32, 6.04)	0.5667	0.07 (0.14)	(-0.20, 0.34)	0.6213	
ADA result											NE
Negative	105	9.43 (1.86)	102	8.34 (1.93)	1.10 (2.33)	(-3.50, 5.69)	0.6385	0.06 (0.14)	(-0.22, 0.33)	0.6836	
Positive (At any time)	4	NE	9	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.6122
< 30	78	7.84 (2.17)	81	4.96 (2.29)	2.88 (2.57)	(-2.20, 7.96)	0.2651	0.14 (0.16)	(-0.17, 0.46)	0.3649	
>= 30	31	12.39 (3.75)	30	12.37 (3.58)	0.02 (5.02)	(-10.05, 10.08)	0.9970	0.00 (0.26)	(-0.50, 0.50)	0.9972	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.2578
All negative/normal	36	7.15 (3.07)	52	9.34 (2.58)	-2.19 (3.85)	(-9.84, 5.47)	0.5710	-0.12 (0.22)	(-0.54, 0.31)	0.5894	
At least one positive/abnormal	73	8.76 (2.78)	59	5.44 (3.21)	3.32 (2.99)	(-2.59, 9.23)	0.2680	0.14 (0.18)	(-0.21, 0.48)	0.4356	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Lupus QoL Intimate Relationships domain score
Full analysis set

	Anifrolumab 300mg (N=119)		Placebo (N=121)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 12		5.68 (3.00)		3.41 (3.02)	2.27 (3.92)	(-5.47, 10.01)	0.5630			
Week 24		7.26 (3.14)		0.17 (3.13)	7.09 (4.08)	(-0.97, 15.15)	0.0842			
Week 36		6.00 (3.60)		8.14 (3.62)	-2.14 (4.78)	(-11.59, 7.30)	0.6543			
Week 52		4.59 (3.27)		6.53 (3.25)	-1.94 (4.23)	(-10.32, 6.44)	0.6474			
OVERALL	86	5.88 (2.58)	89	4.56 (2.61)	1.32 (3.23)	(-5.05, 7.69)	0.6832	0.05 (0.15)	(-0.24, 0.35)	0.7208

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Lupus QoL Intimate Relationships domain score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) N	LSMean (SE)	Placebo (N=121) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.8980
< 10 points	30	5.17 (4.88)	25	4.36 (5.43)	0.81 (6.95)	(-13.20, 14.81)	0.9079	0.03 (0.27)	(-0.50, 0.56)	0.9130	
>= 10 points	56	7.17 (3.18)	64	5.36 (3.01)	1.82 (3.65)	(-5.42, 9.06)	0.6202	0.08 (0.18)	(-0.28, 0.43)	0.6808	
OCS dose at baseline											0.0549
<10 mg/day	45	5.20 (3.20)	47	9.44 (3.21)	-4.25 (4.31)	(-12.83, 4.33)	0.3279	-0.19 (0.21)	(-0.60, 0.22)	0.3544	
>=10 mg/day	41	5.16 (4.71)	42	-3.15 (4.52)	8.32 (4.92)	(-1.50, 18.14)	0.0955	0.28 (0.22)	(-0.16, 0.71)	0.2088	
Result of type I IFN gene signature test											0.7945
LOW	19	1.53 (6.54)	19	2.54 (5.83)	-1.01 (8.42)	(-18.16, 16.15)	0.9057	-0.04 (0.32)	(-0.67, 0.60)	0.9106	
HIGH	67	6.27 (2.70)	70	4.89 (2.70)	1.38 (3.59)	(-5.72, 8.48)	0.7015	0.06 (0.17)	(-0.27, 0.40)	0.7196	
Age (years)											NE
<= 65	86	5.88 (2.58)	89	4.56 (2.61)	1.32 (3.23)	(-5.05, 7.69)	0.6832	0.05 (0.15)	(-0.24, 0.35)	0.7208	
> 65	0	NE	0	NE	NE	NE		NE	NE		
Sex											0.8838
male	9	8.84 (5.57)	11	6.36 (6.35)	2.48 (4.99)	(-8.18, 13.14)	0.6269	0.12 (0.45)	(-0.76, 1.01)	0.7840	
female	77	6.10 (2.81)	78	4.52 (2.83)	1.58 (3.56)	(-5.46, 8.63)	0.6576	0.06 (0.16)	(-0.25, 0.38)	0.6933	
Race											NE
White	59	7.69 (3.02)	60	7.20 (3.03)	0.49 (3.84)	(-7.14, 8.11)	0.8998	0.02 (0.18)	(-0.34, 0.38)	0.9104	
Black or African American	9	12.39 (9.29)	14	10.43 (8.66)	1.95 (10.74)	(-20.66, 24.57)	0.8578	0.06 (0.43)	(-0.78, 0.90)	0.8861	
Asian	7	NE	9	NE	NE	NE		NE	NE		
Other	6	NE	5	NE	NE	NE		NE	NE		
Ethnicity											0.7458
Hispanic/Latino	22	4.12 (5.07)	25	4.61 (4.93)	-0.48 (6.24)	(-13.13, 12.16)	0.9387	-0.02 (0.29)	(-0.59, 0.55)	0.9466	
Non-hispanic/Latino	59	7.09 (3.18)	63	5.19 (3.12)	1.90 (3.89)	(-5.80, 9.61)	0.6257	0.08 (0.18)	(-0.28, 0.43)	0.6717	
Geographic region											0.7372
EU	32	8.76 (4.84)	23	9.24 (5.56)	-0.48 (6.06)	(-12.71, 11.74)	0.9368	-0.02 (0.27)	(-0.55, 0.52)	0.9487	
non-EU	54	5.76 (3.23)	66	3.80 (3.09)	1.96 (4.01)	(-6.00, 9.91)	0.6270	0.08 (0.18)	(-0.28, 0.44)	0.6657	
Onset of disease											NE
Paediatric	6	NE	2	NE	NE	NE		NE	NE		
Adult	80	5.49 (2.69)	87	4.77 (2.67)	0.73 (3.35)	(-5.89, 7.34)	0.8284	0.03 (0.15)	(-0.27, 0.33)	0.8489	
ADA result											NE
Negative	83	5.78 (2.66)	84	4.93 (2.70)	0.85 (3.35)	(-5.77, 7.46)	0.8009	0.03 (0.15)	(-0.27, 0.34)	0.8241	
Positive (At any time)	3	NE	5	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.9363
< 30	61	1.66 (3.23)	62	0.21 (3.29)	1.45 (3.93)	(-6.33, 9.23)	0.7127	0.06 (0.18)	(-0.30, 0.41)	0.7550	
>= 30	25	11.45 (4.50)	27	10.57 (4.37)	0.89 (5.86)	(-10.93, 12.70)	0.8805	0.04 (0.28)	(-0.51, 0.58)	0.8894	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.4794
All negative/normal	29	6.84 (5.14)	43	8.36 (4.27)	-1.52 (6.37)	(-14.25, 11.21)	0.8121	-0.05 (0.24)	(-0.53, 0.42)	0.8223	
At least one positive/abnormal	57	4.90 (3.08)	46	1.26 (3.51)	3.63 (3.54)	(-3.40, 10.67)	0.3073	0.15 (0.20)	(-0.24, 0.54)	0.4399	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Lupus QoL Pain domain score
Full analysis set

	Anifrolumab 300mg (N=119)		Placebo (N=121)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 12		12.68 (2.12)		9.01 (2.16)	3.67 (2.73)	(-1.71, 9.05)	0.1799			
Week 24		14.32 (2.23)		10.85 (2.26)	3.47 (2.88)	(-2.21, 9.15)	0.2297			
Week 36		12.51 (2.16)		17.24 (2.28)	-4.73 (2.83)	(-10.31, 0.84)	0.0958			
Week 52		10.37 (2.31)		12.96 (2.45)	-2.58 (3.10)	(-8.69, 3.53)	0.4053			
OVERALL	109	12.47 (1.79)	111	12.51 (1.88)	-0.04 (2.24)	(-4.45, 4.36)	0.9844	-0.00 (0.13)	(-0.27, 0.26)	0.9866

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Lupus QoL Pain domain score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) N	LSMean (SE)	Placebo (N=121) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.3410
< 10 points	37	11.99 (2.86)	31	15.19 (3.27)	-3.20 (4.06)	(-11.33, 4.93)	0.4339	-0.18 (0.24)	(-0.66, 0.30)	0.4657	
>= 10 points	72	12.74 (2.36)	80	11.29 (2.31)	1.45 (2.71)	(-3.91, 6.80)	0.5940	0.07 (0.16)	(-0.25, 0.39)	0.6630	
OCS dose at baseline											0.5529
<10 mg/day	56	13.20 (1.93)	59	14.38 (2.03)	-1.18 (2.59)	(-6.32, 3.96)	0.6504	-0.08 (0.19)	(-0.44, 0.29)	0.6769	
>=10 mg/day	53	10.53 (3.66)	52	8.91 (3.54)	1.62 (3.93)	(-6.19, 9.42)	0.6818	0.06 (0.20)	(-0.32, 0.44)	0.7527	
Result of type I IFN gene signature test											0.9153
LOW	21	17.76 (3.80)	22	18.42 (3.39)	-0.66 (4.93)	(-10.65, 9.33)	0.8941	-0.04 (0.31)	(-0.64, 0.56)	0.8984	
HIGH	88	9.98 (1.85)	89	10.05 (1.90)	-0.07 (2.52)	(-5.05, 4.91)	0.9772	-0.00 (0.15)	(-0.30, 0.29)	0.9784	
Age (years)											NE
<= 65	108	12.38 (1.80)	111	12.54 (1.89)	-0.16 (2.24)	(-4.58, 4.25)	0.9419	-0.01 (0.14)	(-0.27, 0.26)	0.9502	
> 65	1	NE	0	NE	NE	NE		NE	NE		
Sex											0.4190
male	10	3.83 (6.53)	12	9.03 (9.10)	-5.20 (6.83)	(-19.57, 9.18)	0.4570	-0.18 (0.43)	(-1.03, 0.66)	0.6682	
female	99	13.24 (1.90)	99	12.58 (1.98)	0.66 (2.40)	(-4.08, 5.39)	0.7846	0.03 (0.14)	(-0.24, 0.31)	0.8114	
Race											0.0838
White	69	11.11 (2.27)	72	15.78 (2.33)	-4.67 (2.89)	(-10.38, 1.04)	0.1080	-0.24 (0.17)	(-0.57, 0.09)	0.1555	
Black or African American	10	26.56 (6.85)	17	18.90 (6.82)	7.66 (8.20)	(-9.36, 24.68)	0.3604	0.29 (0.40)	(-0.50, 1.07)	0.4757	
Asian	16	-4.39 (4.53)	15	-12.41 (4.67)	8.02 (4.61)	(-1.46, 17.50)	0.0939	0.43 (0.36)	(-0.28, 1.15)	0.2359	
Other	8	21.57 (11.10)	5	15.34 (20.57)	6.22 (16.22)	(-31.70, 44.15)	0.7119	0.15 (0.57)	(-0.96, 1.27)	0.7862	
Ethnicity											0.5552
Hispanic/Latino	26	12.11 (3.60)	32	15.83 (3.51)	-3.72 (4.90)	(-13.54, 6.10)	0.4512	-0.19 (0.26)	(-0.71, 0.33)	0.4701	
Non-hispanic/Latino	77	10.52 (2.22)	77	10.95 (2.31)	-0.43 (2.66)	(-5.68, 4.82)	0.8714	-0.02 (0.16)	(-0.34, 0.29)	0.8936	
Geographic region											0.5720
EU	39	9.26 (3.25)	29	12.61 (3.53)	-3.35 (3.72)	(-10.81, 4.10)	0.3713	-0.17 (0.25)	(-0.65, 0.31)	0.4945	
non-EU	70	12.52 (2.12)	82	13.26 (2.19)	-0.75 (2.73)	(-6.14, 4.65)	0.7854	-0.04 (0.16)	(-0.36, 0.28)	0.8098	
Onset of disease											0.6348
Paediatric	8	-0.97 (16.39)	4	-13.00 (33.15)	12.02 (25.63)	(-50.90, 74.94)	0.6558	0.21 (0.61)	(-1.00, 1.41)	0.7339	
Adult	101	12.43 (1.84)	107	12.63 (1.89)	-0.20 (2.27)	(-4.68, 4.29)	0.9309	-0.01 (0.14)	(-0.28, 0.26)	0.9405	
ADA result											NE
Negative	105	12.69 (1.83)	102	12.86 (1.94)	-0.17 (2.31)	(-4.73, 4.38)	0.9404	-0.01 (0.14)	(-0.28, 0.26)	0.9484	
Positive (At any time)	4	NE	9	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.8966
< 30	78	10.00 (2.17)	81	9.60 (2.36)	0.40 (2.58)	(-4.69, 5.49)	0.8773	0.02 (0.16)	(-0.29, 0.33)	0.9018	
>= 30	31	17.61 (3.83)	30	17.96 (3.56)	-0.35 (5.17)	(-10.74, 10.03)	0.9459	-0.02 (0.26)	(-0.52, 0.48)	0.9470	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.0529
All negative/normal	36	10.80 (2.97)	52	16.67 (2.50)	-5.87 (3.74)	(-13.33, 1.58)	0.1207	-0.32 (0.22)	(-0.75, 0.10)	0.1373	
At least one positive/abnormal	73	12.24 (2.67)	59	8.95 (3.16)	3.29 (2.90)	(-2.44, 9.03)	0.2583	0.14 (0.18)	(-0.20, 0.48)	0.4267	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Lupus QoL Planning domain score
Full analysis set

	Anifrolumab 300mg (N=119)		Placebo (N=121)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 12		6.66 (2.38)		2.74 (2.41)	3.92 (3.04)	(-2.07, 9.90)	0.1988			
Week 24		10.79 (2.39)		7.96 (2.42)	2.83 (3.03)	(-3.15, 8.81)	0.3521			
Week 36		9.28 (2.63)		11.30 (2.75)	-2.02 (3.47)	(-8.86, 4.83)	0.5617			
Week 52		7.67 (2.65)		7.09 (2.78)	0.58 (3.52)	(-6.36, 7.52)	0.8690			
OVERALL	109	8.60 (2.11)	111	7.27 (2.19)	1.33 (2.63)	(-3.85, 6.51)	0.6142	0.06 (0.13)	(-0.21, 0.32)	0.6643

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Lupus QoL Planning domain score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) N	LSMean (SE)	Placebo (N=121) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.1984
< 10 points	37	8.53 (3.41)	31	12.18 (3.88)	-3.65 (4.86)	(-13.38, 6.07)	0.4557	-0.17 (0.24)	(-0.65, 0.31)	0.4839	
>= 10 points	72	8.90 (2.72)	80	5.11 (2.62)	3.79 (3.14)	(-2.41, 10.00)	0.2289	0.16 (0.16)	(-0.16, 0.48)	0.3192	
OCS dose at baseline											0.7921
<10 mg/day	56	9.58 (2.44)	59	8.21 (2.54)	1.37 (3.27)	(-5.11, 7.85)	0.6762	0.07 (0.19)	(-0.29, 0.44)	0.7000	
>=10 mg/day	53	8.11 (4.05)	52	5.31 (3.95)	2.81 (4.36)	(-5.85, 11.46)	0.5214	0.10 (0.20)	(-0.29, 0.48)	0.6229	
Result of type I IFN gene signature test											0.7574
LOW	21	12.58 (5.25)	22	13.10 (4.75)	-0.52 (7.03)	(-14.77, 13.74)	0.9416	-0.02 (0.31)	(-0.62, 0.58)	0.9426	
HIGH	88	7.70 (2.12)	89	5.88 (2.17)	1.83 (2.88)	(-3.86, 7.51)	0.5264	0.09 (0.15)	(-0.20, 0.39)	0.5485	
Age (years)											NE
<= 65	108	8.41 (2.11)	111	7.33 (2.19)	1.08 (2.63)	(-4.10, 6.25)	0.6822	0.05 (0.14)	(-0.22, 0.31)	0.7242	
> 65	1	NE	0	NE	NE	NE		NE	NE		
Sex											0.3416
male	10	17.92 (8.08)	12	7.67 (10.99)	10.25 (8.61)	(-8.49, 29.00)	0.2567	0.30 (0.43)	(-0.55, 1.14)	0.4884	
female	99	8.14 (2.17)	99	6.49 (2.25)	1.65 (2.75)	(-3.77, 7.08)	0.5479	0.07 (0.14)	(-0.20, 0.35)	0.5988	
Race											0.1057
White	69	10.03 (2.75)	72	11.50 (2.79)	-1.48 (3.51)	(-8.41, 5.46)	0.6741	-0.06 (0.17)	(-0.39, 0.27)	0.7081	
Black or African American	10	10.51 (7.96)	17	7.12 (8.21)	3.39 (9.09)	(-15.48, 22.27)	0.7127	0.11 (0.40)	(-0.68, 0.89)	0.7902	
Asian	16	-5.79 (6.25)	15	-20.06 (6.40)	14.27 (6.02)	(1.90, 26.63)	0.0254	0.56 (0.37)	(-0.16, 1.28)	0.1287	
Other	8	-14.28 (17.72)	5	12.64 (28.92)	-26.92 (29.22)	(-121.22, 67.38)	0.4265	-0.45 (0.58)	(-1.58, 0.69)	0.4394	
Ethnicity											0.6343
Hispanic/Latino	26	11.69 (4.40)	32	8.04 (4.18)	3.65 (5.91)	(-8.19, 15.48)	0.5394	0.16 (0.26)	(-0.36, 0.67)	0.5561	
Non-hispanic/Latino	77	6.67 (2.60)	77	6.20 (2.68)	0.47 (3.12)	(-5.70, 6.64)	0.8806	0.02 (0.16)	(-0.30, 0.34)	0.9004	
Geographic region											0.1161
EU	39	11.91 (3.84)	29	17.35 (4.25)	-5.44 (4.54)	(-14.54, 3.65)	0.2357	-0.23 (0.25)	(-0.71, 0.25)	0.3527	
non-EU	70	7.11 (2.50)	82	3.86 (2.54)	3.25 (3.17)	(-3.00, 9.51)	0.3056	0.15 (0.16)	(-0.17, 0.47)	0.3678	
Onset of disease											0.5206
Paediatric	8	-6.80 (16.36)	4	7.18 (30.16)	-13.98 (24.34)	(-73.29, 45.33)	0.5862	-0.25 (0.62)	(-1.46, 0.95)	0.6804	
Adult	101	9.59 (2.15)	107	7.84 (2.18)	1.75 (2.65)	(-3.48, 6.98)	0.5108	0.08 (0.14)	(-0.19, 0.35)	0.5704	
ADA result											NE
Negative	105	8.88 (2.13)	102	7.87 (2.24)	1.00 (2.69)	(-4.31, 6.32)	0.7098	0.04 (0.14)	(-0.23, 0.32)	0.7462	
Positive (At any time)	4	NE	9	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.3757
< 30	78	8.06 (2.62)	81	4.98 (2.79)	3.08 (3.09)	(-3.02, 9.18)	0.3201	0.13 (0.16)	(-0.18, 0.44)	0.4245	
>= 30	31	9.54 (3.91)	30	11.88 (3.65)	-2.34 (5.29)	(-12.96, 8.27)	0.6595	-0.11 (0.26)	(-0.61, 0.39)	0.6662	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.1450
All negative/normal	36	6.74 (3.31)	52	10.47 (2.81)	-3.73 (4.19)	(-12.09, 4.62)	0.3760	-0.18 (0.22)	(-0.61, 0.24)	0.3963	
At least one positive/abnormal	73	9.13 (3.27)	59	4.89 (3.83)	4.24 (3.52)	(-2.72, 11.20)	0.2301	0.15 (0.18)	(-0.20, 0.49)	0.4005	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SDI Global Score
Full analysis set

	Anifrolumab 300mg (N=119)		Placebo (N=121)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 24		0.00 (0.02)		0.03 (0.02)	-0.03 (0.02)	(-0.07, 0.01)	0.1464			
Week 52		0.08 (0.03)		0.07 (0.03)	0.01 (0.04)	(-0.07, 0.09)	0.8314			
OVERALL	110	0.04 (0.02)	108	0.05 (0.02)	-0.01 (0.03)	(-0.06, 0.04)	0.7037	-0.05 (0.14)	(-0.31, 0.22)	0.7298

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SDI Global Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) N	LSMean (SE)	Placebo (N=121) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											NE
< 10 points	39	NE	29	NE	NE	NE		NE	NE		
>= 10 points	71	0.02 (0.03)	79	0.05 (0.03)	-0.03 (0.03)	(-0.10, 0.03)	0.2672	-0.15 (0.16)	(-0.47, 0.17)	0.3609	
OCS dose at baseline											0.1299
<10 mg/day	54	0.05 (0.02)	59	0.02 (0.02)	0.03 (0.03)	(-0.04, 0.10)	0.4117	0.15 (0.19)	(-0.22, 0.52)	0.4232	
>=10 mg/day	56	0.01 (0.04)	49	0.07 (0.04)	-0.05 (0.04)	(-0.14, 0.03)	0.2024	-0.19 (0.20)	(-0.57, 0.20)	0.3384	
Result of type I IFN gene signature test											NE
LOW	21	NE	20	NE	NE	NE		NE	NE		
HIGH	89	0.03 (0.02)	88	0.06 (0.02)	-0.03 (0.03)	(-0.09, 0.03)	0.2985	-0.15 (0.15)	(-0.44, 0.15)	0.3194	
Age (years)											NE
<= 65	109	0.04 (0.02)	107	0.04 (0.02)	-0.00 (0.03)	(-0.05, 0.05)	0.9405	-0.01 (0.14)	(-0.28, 0.26)	0.9456	
> 65	1	NE	1	NE	NE	NE		NE	NE		
Sex											NE
male	10	NE	12	NE	NE	NE		NE	NE		
female	100	0.04 (0.02)	96	0.04 (0.02)	-0.00 (0.03)	(-0.06, 0.06)	0.9673	-0.01 (0.14)	(-0.29, 0.27)	0.9699	
Race											NE
White	71	0.05 (0.02)	67	0.03 (0.03)	0.02 (0.03)	(-0.04, 0.09)	0.5154	0.10 (0.17)	(-0.23, 0.44)	0.5417	
Black or African American	10	0.08 (0.08)	18	0.11 (0.07)	-0.03 (0.09)	(-0.22, 0.16)	0.7306	-0.11 (0.39)	(-0.88, 0.67)	0.7833	
Asian	15	NE	15	NE	NE	NE		NE	NE		
Other	8	NE	5	NE	NE	NE		NE	NE		
Ethnicity											0.8742
Hispanic/Latino	25	0.05 (0.05)	29	0.05 (0.05)	-0.00 (0.06)	(-0.13, 0.12)	0.9903	-0.00 (0.27)	(-0.54, 0.53)	0.9907	
Non-hispanic/Latino	79	0.04 (0.02)	76	0.05 (0.03)	-0.01 (0.03)	(-0.07, 0.05)	0.7076	-0.05 (0.16)	(-0.37, 0.26)	0.7426	
Geographic region											0.5402
EU	41	0.05 (0.04)	29	0.03 (0.05)	0.01 (0.05)	(-0.09, 0.12)	0.7859	0.05 (0.24)	(-0.42, 0.53)	0.8252	
non-EU	69	0.03 (0.02)	79	0.05 (0.02)	-0.02 (0.03)	(-0.09, 0.04)	0.4657	-0.11 (0.16)	(-0.43, 0.21)	0.4988	
Onset of disease											NE
Paediatric	11	NE	5	NE	NE	NE		NE	NE		
Adult	99	0.03 (0.02)	103	0.05 (0.02)	-0.02 (0.03)	(-0.07, 0.04)	0.5261	-0.08 (0.14)	(-0.36, 0.19)	0.5642	
ADA result											NE
Negative	106	0.04 (0.02)	98	0.05 (0.02)	-0.01 (0.03)	(-0.07, 0.04)	0.6329	-0.06 (0.14)	(-0.34, 0.21)	0.6623	
Positive (At any time)	4	NE	10	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.1934
< 30	79	0.03 (0.02)	78	0.06 (0.03)	-0.03 (0.03)	(-0.09, 0.03)	0.2707	-0.15 (0.16)	(-0.46, 0.16)	0.3427	
>= 30	31	0.07 (0.04)	30	0.02 (0.04)	0.05 (0.06)	(-0.06, 0.16)	0.3799	0.22 (0.26)	(-0.28, 0.72)	0.3948	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.4820
All negative/normal	35	0.03 (0.03)	50	0.02 (0.03)	0.01 (0.04)	(-0.07, 0.09)	0.8371	0.04 (0.22)	(-0.39, 0.48)	0.8415	
At least one positive/abnormal	75	0.04 (0.03)	58	0.07 (0.04)	-0.03 (0.04)	(-0.10, 0.04)	0.4152	-0.11 (0.17)	(-0.45, 0.23)	0.5255	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - NRS Score
Full analysis set

Visit	Anifrolumab 300mg (N=119) N	Anifrolumab 300mg (N=119) LSMean (SE)	Placebo (N=121) N	Placebo (N=121) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-0.59 (0.21)		-0.48 (0.21)	-0.11 (0.26)	(-0.63, 0.41)	0.6735			
Week 8		-1.01 (0.22)		-0.16 (0.22)	-0.86 (0.28)	(-1.41, -0.30)	0.0025			
Week 12		-1.29 (0.23)		-0.82 (0.24)	-0.47 (0.31)	(-1.07, 0.14)	0.1317			
Week 16		-1.20 (0.23)		-1.06 (0.23)	-0.14 (0.30)	(-0.74, 0.45)	0.6305			
Week 20		-0.95 (0.25)		-1.06 (0.25)	0.11 (0.33)	(-0.54, 0.75)	0.7388			
Week 24		-0.97 (0.23)		-0.68 (0.23)	-0.30 (0.30)	(-0.90, 0.30)	0.3280			
Week 28		-0.91 (0.24)		-0.92 (0.24)	0.00 (0.32)	(-0.62, 0.63)	0.9888			
Week 32		-0.79 (0.24)		-0.81 (0.25)	0.02 (0.32)	(-0.62, 0.65)	0.9614			
Week 36		-1.19 (0.23)		-1.22 (0.24)	0.03 (0.31)	(-0.57, 0.63)	0.9246			
Week 40		-0.97 (0.24)		-1.08 (0.24)	0.11 (0.32)	(-0.51, 0.73)	0.7262			
Week 44		-1.06 (0.23)		-1.16 (0.24)	0.10 (0.31)	(-0.52, 0.71)	0.7573			
Week 48		-0.85 (0.25)		-0.71 (0.26)	-0.15 (0.33)	(-0.80, 0.51)	0.6633			
Week 52		-0.76 (0.25)		-0.74 (0.25)	-0.01 (0.33)	(-0.66, 0.64)	0.9687			
OVERALL	110	-0.97 (0.18)	114	-0.84 (0.18)	-0.13 (0.22)	(-0.56, 0.31)	0.5612	-0.07 (0.13)	(-0.33, 0.19)	0.6150

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - NRS Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) N	LSMean (SE)	Placebo (N=121) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.9973
< 10 points	37	-0.98 (0.30)	31	-0.87 (0.34)	-0.11 (0.43)	(-0.97, 0.74)	0.7951	-0.06 (0.24)	(-0.54, 0.42)	0.8097	
>= 10 points	73	-0.97 (0.23)	83	-0.86 (0.21)	-0.11 (0.26)	(-0.63, 0.41)	0.6756	-0.06 (0.16)	(-0.37, 0.26)	0.7261	
OCS dose at baseline											0.0817
<10 mg/day	56	-1.16 (0.21)	61	-0.67 (0.22)	-0.49 (0.28)	(-1.05, 0.07)	0.0829	-0.30 (0.19)	(-0.66, 0.07)	0.1113	
>=10 mg/day	54	-0.75 (0.34)	53	-1.05 (0.32)	0.30 (0.36)	(-0.41, 1.01)	0.4040	0.12 (0.19)	(-0.25, 0.50)	0.5196	
Result of type I IFN gene signature test											0.2832
LOW	21	-0.83 (0.40)	22	-1.27 (0.36)	0.45 (0.52)	(-0.62, 1.52)	0.3991	0.25 (0.31)	(-0.35, 0.85)	0.4128	
HIGH	89	-0.92 (0.18)	92	-0.75 (0.19)	-0.17 (0.25)	(-0.67, 0.32)	0.4854	-0.10 (0.15)	(-0.39, 0.19)	0.5082	
Age (years)											NE
<= 65	109	-0.96 (0.18)	114	-0.84 (0.18)	-0.13 (0.22)	(-0.56, 0.31)	0.5704	-0.07 (0.13)	(-0.33, 0.20)	0.6231	
> 65	1	NE	0	NE	NE	NE		NE	NE		
Sex											0.1913
male	10	-2.61 (0.80)	12	-3.59 (0.88)	0.99 (0.87)	(-0.93, 2.90)	0.2814	0.33 (0.43)	(-0.51, 1.18)	0.4382	
female	100	-1.02 (0.19)	102	-0.82 (0.19)	-0.19 (0.24)	(-0.66, 0.27)	0.4154	-0.10 (0.14)	(-0.38, 0.17)	0.4724	
Race											NE
White	69	-1.16 (0.21)	74	-1.02 (0.21)	-0.13 (0.27)	(-0.66, 0.39)	0.6180	-0.07 (0.17)	(-0.40, 0.25)	0.6604	
Black or African American	11	-0.70 (0.65)	17	-1.92 (0.57)	1.22 (0.82)	(-0.48, 2.92)	0.1491	0.52 (0.39)	(-0.25, 1.30)	0.1847	
Asian	16	NE	16	NE	NE	NE		NE	NE		
Other	8	NE	5	NE	NE	NE		NE	NE		
Ethnicity											0.0020
Hispanic/Latino	26	-1.94 (0.35)	32	-0.72 (0.33)	-1.23 (0.44)	(-2.11, -0.34)	0.0076	-0.66 (0.27)	(-1.20, -0.13)	0.0146	
Non-hispanic/Latino	78	-0.55 (0.21)	80	-0.89 (0.21)	0.34 (0.25)	(-0.16, 0.85)	0.1770	0.18 (0.16)	(-0.13, 0.50)	0.2473	
Geographic region											0.0036
EU	39	-0.63 (0.33)	31	-1.40 (0.36)	0.77 (0.37)	(0.02, 1.52)	0.0446	0.38 (0.24)	(-0.10, 0.85)	0.1221	
non-EU	71	-1.14 (0.21)	83	-0.57 (0.21)	-0.57 (0.27)	(-1.10, -0.04)	0.0353	-0.31 (0.16)	(-0.62, 0.01)	0.0603	
Onset of disease											NE
Paediatric	8	NE	4	NE	NE	NE		NE	NE		
Adult	102	-0.94 (0.18)	110	-0.89 (0.18)	-0.05 (0.22)	(-0.49, 0.39)	0.8112	-0.03 (0.14)	(-0.30, 0.24)	0.8354	
ADA result											NE
Negative	106	-0.94 (0.18)	105	-0.87 (0.19)	-0.07 (0.23)	(-0.52, 0.38)	0.7505	-0.04 (0.14)	(-0.31, 0.23)	0.7814	
Positive (At any time)	4	NE	9	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.0502
< 30	79	-0.87 (0.22)	83	-0.92 (0.23)	0.05 (0.26)	(-0.47, 0.57)	0.8498	0.02 (0.16)	(-0.28, 0.33)	0.8762	
>= 30	31	-1.41 (0.34)	31	-0.41 (0.33)	-1.00 (0.46)	(-1.93, -0.07)	0.0362	-0.53 (0.26)	(-1.04, -0.02)	0.0406	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.5879
All negative/normal	36	-0.95 (0.30)	53	-0.99 (0.24)	0.05 (0.37)	(-0.69, 0.78)	0.9001	0.03 (0.22)	(-0.40, 0.45)	0.9045	
At least one positive/abnormal	74	-0.89 (0.26)	61	-0.68 (0.31)	-0.21 (0.29)	(-0.77, 0.36)	0.4708	-0.09 (0.17)	(-0.43, 0.25)	0.6099	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - PHQ-8 Total Score
Full analysis set

Visit	Anifrolumab 300mg (N=119) N	LSMean (SE)	Placebo (N=121) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 12		-2.16 (0.50)		-1.26 (0.50)	-0.90 (0.63)	(-2.14, 0.35)	0.1571			
Week 24		-2.09 (0.53)		-1.88 (0.53)	-0.21 (0.68)	(-1.54, 1.13)	0.7581			
Week 36		-2.67 (0.54)		-2.07 (0.55)	-0.60 (0.69)	(-1.96, 0.77)	0.3909			
Week 52		-2.24 (0.57)		-1.45 (0.59)	-0.79 (0.75)	(-2.27, 0.68)	0.2907			
OVERALL	110	-2.29 (0.46)	111	-1.67 (0.47)	-0.62 (0.57)	(-1.74, 0.49)	0.2719	-0.13 (0.13)	(-0.39, 0.14)	0.3435

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - PHQ-8 Total Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) N	LSMean (SE)	Placebo (N=121) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.7298
< 10 points	37	-2.83 (0.62)	31	-1.89 (0.69)	-0.93 (0.86)	(-2.65, 0.78)	0.2805	-0.24 (0.24)	(-0.72, 0.24)	0.3214	
>= 10 points	73	-1.80 (0.63)	80	-1.26 (0.60)	-0.55 (0.73)	(-1.99, 0.90)	0.4556	-0.10 (0.16)	(-0.42, 0.22)	0.5347	
OCS dose at baseline											0.4735
<10 mg/day	56	-2.50 (0.57)	59	-1.55 (0.60)	-0.95 (0.77)	(-2.47, 0.57)	0.2187	-0.21 (0.19)	(-0.58, 0.15)	0.2573	
>=10 mg/day	54	-1.69 (0.84)	52	-1.58 (0.77)	-0.11 (0.89)	(-1.87, 1.65)	0.9034	-0.02 (0.19)	(-0.40, 0.36)	0.9252	
Result of type I IFN gene signature test											0.9599
LOW	21	-2.68 (1.10)	22	-2.10 (0.94)	-0.58 (1.46)	(-3.54, 2.37)	0.6913	-0.12 (0.31)	(-0.72, 0.48)	0.6913	
HIGH	89	-2.23 (0.47)	89	-1.57 (0.48)	-0.66 (0.64)	(-1.92, 0.59)	0.2982	-0.15 (0.15)	(-0.44, 0.15)	0.3248	
Age (years)											NE
<= 65	109	-2.29 (0.46)	111	-1.67 (0.47)	-0.61 (0.57)	(-1.73, 0.50)	0.2808	-0.13 (0.13)	(-0.39, 0.14)	0.3524	
> 65	1	NE	0	NE	NE	NE		NE	NE		
Sex											0.5480
male	10	-0.92 (1.58)	12	0.94 (2.14)	-1.86 (1.68)	(-5.36, 1.64)	0.2802	-0.28 (0.43)	(-1.12, 0.57)	0.5183	
female	100	-2.24 (0.48)	99	-1.45 (0.49)	-0.79 (0.60)	(-1.97, 0.39)	0.1882	-0.16 (0.14)	(-0.44, 0.11)	0.2489	
Race											0.0562
White	69	-1.92 (0.63)	72	-2.29 (0.62)	0.37 (0.79)	(-1.19, 1.92)	0.6410	0.07 (0.17)	(-0.26, 0.40)	0.6787	
Black or African American	11	-5.63 (1.48)	17	-3.65 (1.50)	-1.98 (1.83)	(-5.76, 1.80)	0.2894	-0.34 (0.39)	(-1.10, 0.43)	0.3890	
Asian	16	0.20 (1.18)	15	3.53 (1.12)	-3.33 (1.13)	(-5.65, -1.01)	0.0066	-0.71 (0.37)	(-1.44, 0.02)	0.0550	
Other	8	-2.75 (1.87)	5	-1.27 (3.87)	-1.48 (3.44)	(-9.54, 6.59)	0.6804	-0.20 (0.57)	(-1.33, 0.92)	0.7203	
Ethnicity											0.5830
Hispanic/Latino	26	-2.42 (1.07)	32	-1.44 (1.00)	-0.99 (1.37)	(-3.73, 1.76)	0.4740	-0.17 (0.26)	(-0.69, 0.34)	0.5092	
Non-hispanic/Latino	78	-1.86 (0.52)	77	-1.70 (0.53)	-0.16 (0.63)	(-1.40, 1.08)	0.7977	-0.03 (0.16)	(-0.35, 0.28)	0.8302	
Geographic region											0.2900
EU	39	-2.65 (0.71)	29	-2.86 (0.79)	0.21 (0.83)	(-1.45, 1.87)	0.7992	0.05 (0.25)	(-0.43, 0.53)	0.8449	
non-EU	71	-1.95 (0.58)	82	-1.00 (0.58)	-0.95 (0.73)	(-2.39, 0.48)	0.1915	-0.19 (0.16)	(-0.51, 0.13)	0.2478	
Onset of disease											0.8841
Paediatric	8	-1.02 (2.65)	4	0.22 (5.33)	-1.24 (4.14)	(-11.04, 8.56)	0.7730	-0.13 (0.61)	(-1.34, 1.07)	0.8273	
Adult	102	-2.30 (0.47)	107	-1.67 (0.47)	-0.63 (0.58)	(-1.78, 0.52)	0.2793	-0.13 (0.14)	(-0.40, 0.14)	0.3489	
ADA result											0.6484
Negative	106	-2.32 (0.47)	102	-1.76 (0.48)	-0.56 (0.58)	(-1.71, 0.59)	0.3378	-0.12 (0.14)	(-0.39, 0.16)	0.4043	
Positive (At any time)	4	-2.47 (3.53)	9	-0.32 (2.63)	-2.15 (3.44)	(-9.98, 5.68)	0.5478	-0.26 (0.60)	(-1.44, 0.92)	0.6663	
BMI (kg/m2) at enrolment											0.9368
< 30	79	-1.91 (0.53)	81	-1.06 (0.56)	-0.85 (0.62)	(-2.09, 0.38)	0.1741	-0.17 (0.16)	(-0.49, 0.14)	0.2705	
>= 30	31	-2.88 (0.92)	30	-2.13 (0.88)	-0.74 (1.24)	(-3.23, 1.74)	0.5521	-0.15 (0.26)	(-0.65, 0.36)	0.5652	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.3819
All negative/normal	36	-2.13 (0.80)	52	-2.15 (0.66)	0.01 (1.00)	(-1.98, 2.01)	0.9891	0.00 (0.22)	(-0.42, 0.43)	0.9894	
At least one positive/abnormal	74	-2.22 (0.65)	59	-1.16 (0.75)	-1.06 (0.70)	(-2.44, 0.33)	0.1330	-0.19 (0.17)	(-0.53, 0.16)	0.2902	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - PtGA
Full analysis set

Visit	Anifrolumab 300mg (N=119) N	Anifrolumab 300mg (N=119) LSMean (SE)	Placebo (N=121) N	Placebo (N=121) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-7.52 (2.18)		-7.05 (2.19)	-0.47 (2.83)	(-6.05, 5.12)	0.8690			
Week 8		-9.98 (2.18)		-2.25 (2.18)	-7.72 (2.82)	(-13.29, -2.16)	0.0068			
Week 12		-10.89 (2.41)		-8.62 (2.43)	-2.27 (3.20)	(-8.58, 4.05)	0.4803			
Week 16		-10.15 (2.49)		-10.99 (2.50)	0.83 (3.31)	(-5.69, 7.36)	0.8013			
Week 20		-12.18 (2.37)		-10.97 (2.38)	-1.21 (3.13)	(-7.37, 4.95)	0.6986			
Week 24		-8.81 (2.54)		-6.99 (2.51)	-1.82 (3.35)	(-8.42, 4.77)	0.5861			
Week 28		-12.48 (2.48)		-13.34 (2.52)	0.87 (3.31)	(-5.66, 7.39)	0.7938			
Week 32		-8.83 (2.58)		-9.96 (2.62)	1.14 (3.46)	(-5.68, 7.96)	0.7425			
Week 36		-13.95 (2.36)		-14.13 (2.44)	0.18 (3.16)	(-6.06, 6.41)	0.9558			
Week 40		-9.97 (2.40)		-11.72 (2.51)	1.75 (3.24)	(-4.64, 8.14)	0.5898			
Week 44		-10.73 (2.31)		-15.13 (2.43)	4.40 (3.12)	(-1.74, 10.55)	0.1593			
Week 48		-10.73 (2.57)		-6.58 (2.69)	-4.15 (3.50)	(-11.06, 2.76)	0.2374			
Week 52		-11.00 (2.63)		-7.46 (2.71)	-3.55 (3.57)	(-10.58, 3.49)	0.3215			
OVERALL	110	-10.56 (1.76)	114	-9.63 (1.81)	-0.93 (2.20)	(-5.25, 3.40)	0.6739	-0.05 (0.13)	(-0.31, 0.21)	0.7150

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - PtGA - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) N	LSMean (SE)	Placebo (N=121) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.7546
< 10 points	37	-8.98 (2.78)	31	-6.77 (3.27)	-2.21 (4.00)	(-10.23, 5.80)	0.5823	-0.13 (0.24)	(-0.60, 0.35)	0.6076	
>= 10 points	73	-10.83 (2.27)	83	-10.11 (2.16)	-0.72 (2.64)	(-5.92, 4.49)	0.7861	-0.04 (0.16)	(-0.35, 0.28)	0.8201	
OCS dose at baseline											0.5460
<10 mg/day	56	-9.49 (2.16)	61	-7.78 (2.25)	-1.71 (2.90)	(-7.47, 4.04)	0.5562	-0.10 (0.19)	(-0.46, 0.26)	0.5868	
>=10 mg/day	54	-11.71 (3.26)	53	-12.76 (3.10)	1.05 (3.53)	(-5.96, 8.06)	0.7676	0.04 (0.19)	(-0.33, 0.42)	0.8175	
Result of type I IFN gene signature test											0.4047
LOW	21	-12.12 (4.15)	22	-15.44 (3.72)	3.32 (5.87)	(-8.52, 15.16)	0.5749	0.18 (0.31)	(-0.42, 0.78)	0.5593	
HIGH	89	-9.75 (1.83)	92	-7.77 (1.83)	-1.99 (2.47)	(-6.86, 2.88)	0.4215	-0.11 (0.15)	(-0.41, 0.18)	0.4452	
Age (years)											NE
<= 65	109	-10.59 (1.76)	114	-9.65 (1.81)	-0.94 (2.20)	(-5.28, 3.40)	0.6687	-0.05 (0.13)	(-0.31, 0.21)	0.7103	
> 65	1	NE	0	NE	NE	NE		NE	NE		
Sex											0.2114
male	10	-14.46 (5.48)	12	-20.98 (7.55)	6.52 (6.43)	(-7.31, 20.35)	0.3286	0.28 (0.43)	(-0.57, 1.12)	0.5197	
female	100	-10.62 (1.85)	102	-8.59 (1.89)	-2.04 (2.34)	(-6.66, 2.58)	0.3852	-0.11 (0.14)	(-0.38, 0.17)	0.4443	
Race											NE
White	69	-12.12 (2.26)	74	-12.71 (2.27)	0.59 (2.85)	(-5.05, 6.23)	0.8356	0.03 (0.17)	(-0.30, 0.36)	0.8539	
Black or African American	11	NE	17	NE	NE	NE		NE	NE		
Asian	16	-8.54 (7.28)	16	6.69 (6.91)	-15.23 (6.66)	(-29.09, -1.37)	0.0328	-0.52 (0.36)	(-1.23, 0.18)	0.1466	
Other	8	NE	5	NE	NE	NE		NE	NE		
Ethnicity											0.0074
Hispanic/Latino	26	-21.19 (3.77)	32	-9.26 (3.68)	-11.93 (4.75)	(-21.50, -2.36)	0.0158	-0.58 (0.27)	(-1.11, -0.06)	0.0304	
Non-hispanic/Latino	78	-6.59 (2.04)	80	-9.03 (2.10)	2.44 (2.50)	(-2.50, 7.38)	0.3300	0.13 (0.16)	(-0.18, 0.44)	0.4075	
Geographic region											0.0006
EU	39	-8.00 (2.88)	31	-17.34 (3.16)	9.34 (3.40)	(2.53, 16.15)	0.0081	0.52 (0.24)	(0.04, 1.00)	0.0341	
non-EU	71	-11.38 (2.14)	83	-5.84 (2.15)	-5.54 (2.70)	(-10.88, -0.19)	0.0423	-0.29 (0.16)	(-0.61, 0.03)	0.0729	
Onset of disease											NE
Paediatric	8	NE	4	NE	NE	NE		NE	NE		
Adult	102	-10.53 (1.82)	110	-9.93 (1.84)	-0.60 (2.26)	(-5.05, 3.86)	0.7913	-0.03 (0.14)	(-0.30, 0.24)	0.8181	
ADA result											NE
Negative	106	-10.36 (1.78)	105	-9.56 (1.85)	-0.80 (2.24)	(-5.22, 3.62)	0.7225	-0.04 (0.14)	(-0.31, 0.23)	0.7569	
Positive (At any time)	4	NE	9	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.0568
< 30	79	-8.96 (2.20)	83	-10.43 (2.31)	1.48 (2.67)	(-3.81, 6.76)	0.5818	0.07 (0.16)	(-0.24, 0.38)	0.6460	
>= 30	31	-14.80 (2.99)	31	-7.17 (2.87)	-7.64 (3.97)	(-15.58, 0.31)	0.0592	-0.46 (0.26)	(-0.97, 0.04)	0.0728	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.9789
All negative/normal	36	-13.41 (2.89)	53	-12.51 (2.43)	-0.90 (3.64)	(-8.14, 6.34)	0.8049	-0.05 (0.22)	(-0.47, 0.37)	0.8136	
At least one positive/abnormal	74	-7.24 (2.57)	61	-6.22 (2.96)	-1.02 (2.84)	(-6.65, 4.60)	0.7196	-0.05 (0.17)	(-0.38, 0.29)	0.7944	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SLEDAI-2K Total Score
Full analysis set

Visit	Anifrolumab 300mg (N=119) n/ N#	Anifrolumab 300mg (N=119) Compliance	Placebo (N=121) n/ N#	Placebo (N=121) Compliance
Baseline	119/ 119	100.0%	121/ 121	100.0%
Week 4	115/ 119	96.64%	117/ 121	96.69%
Week 8	112/ 119	94.12%	117/ 121	96.69%
Week 12	116/ 119	97.48%	110/ 121	90.91%
Week 16	109/ 119	91.60%	108/ 121	89.26%
Week 20	108/ 119	90.76%	107/ 121	88.43%
Week 24	109/ 119	91.60%	107/ 121	88.43%
Week 28	108/ 119	90.76%	97/ 121	80.17%
Week 32	103/ 119	86.55%	95/ 121	78.51%
Week 36	105/ 119	88.24%	97/ 121	80.17%
Week 40	108/ 119	90.76%	95/ 121	78.51%
Week 44	103/ 119	86.55%	94/ 121	77.69%
Week 48	99/ 119	83.19%	94/ 121	77.69%
Week 52	98/ 119	82.35%	91/ 121	75.21%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - PGA
Full analysis set

Visit	Anifrolumab 300mg (N=119) n/ N#	Anifrolumab 300mg (N=119) Compliance	Placebo (N=121) n/ N#	Placebo (N=121) Compliance
Baseline	119/ 119	100.0%	121/ 121	100.0%
Week 4	117/ 119	98.32%	119/ 121	98.35%
Week 8	114/ 119	95.80%	117/ 121	96.69%
Week 12	115/ 119	96.64%	113/ 121	93.39%
Week 16	114/ 119	95.80%	113/ 121	93.39%
Week 20	109/ 119	91.60%	111/ 121	91.74%
Week 24	110/ 119	92.44%	111/ 121	91.74%
Week 28	109/ 119	91.60%	102/ 121	84.30%
Week 32	105/ 119	88.24%	98/ 121	80.99%
Week 36	106/ 119	89.08%	97/ 121	80.17%
Week 40	109/ 119	91.60%	100/ 121	82.64%
Week 44	104/ 119	87.39%	96/ 121	79.34%
Week 48	101/ 119	84.87%	94/ 121	77.69%
Week 52	99/ 119	83.19%	91/ 121	75.21%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - CLASI Total Activity Score
Full analysis set

Visit	Anifrolumab 300mg (N=119) n/ N#	Anifrolumab 300mg (N=119) Compliance	Placebo (N=121) n/ N#	Placebo (N=121) Compliance
Baseline	119/ 119	100.0%	121/ 121	100.0%
Week 4	116/ 119	97.48%	119/ 121	98.35%
Week 8	114/ 119	95.80%	117/ 121	96.69%
Week 12	117/ 119	98.32%	113/ 121	93.39%
Week 16	114/ 119	95.80%	112/ 121	92.56%
Week 20	109/ 119	91.60%	112/ 121	92.56%
Week 24	110/ 119	92.44%	111/ 121	91.74%
Week 28	109/ 119	91.60%	102/ 121	84.30%
Week 32	104/ 119	87.39%	98/ 121	80.99%
Week 36	105/ 119	88.24%	98/ 121	80.99%
Week 40	108/ 119	90.76%	100/ 121	82.64%
Week 44	104/ 119	87.39%	96/ 121	79.34%
Week 48	101/ 119	84.87%	95/ 121	78.51%
Week 52	99/ 119	83.19%	91/ 121	75.21%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - CLASI Total Damage Score
Full analysis set

Visit	Anifrolumab 300mg (N=119) n/ N#	Anifrolumab 300mg (N=119) Compliance	Placebo (N=121) n/ N#	Placebo (N=121) Compliance
Baseline	119/ 119	100.0%	121/ 121	100.0%
Week 4	117/ 119	98.32%	119/ 121	98.35%
Week 8	114/ 119	95.80%	117/ 121	96.69%
Week 12	117/ 119	98.32%	113/ 121	93.39%
Week 16	114/ 119	95.80%	112/ 121	92.56%
Week 20	109/ 119	91.60%	112/ 121	92.56%
Week 24	110/ 119	92.44%	111/ 121	91.74%
Week 28	109/ 119	91.60%	102/ 121	84.30%
Week 32	104/ 119	87.39%	98/ 121	80.99%
Week 36	105/ 119	88.24%	98/ 121	80.99%
Week 40	108/ 119	90.76%	100/ 121	82.64%
Week 44	103/ 119	86.55%	96/ 121	79.34%
Week 48	101/ 119	84.87%	95/ 121	78.51%
Week 52	99/ 119	83.19%	91/ 121	75.21%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - BILAG Global Score
Full analysis set

Visit	Anifrolumab 300mg (N=119) n/ N#	Anifrolumab 300mg (N=119) Compliance	Placebo (N=121) n/ N#	Placebo (N=121) Compliance
Baseline	119/ 119	100.0%	121/ 121	100.0%
Week 4	115/ 119	96.64%	117/ 121	96.69%
Week 8	112/ 119	94.12%	116/ 121	95.87%
Week 12	117/ 119	98.32%	112/ 121	92.56%
Week 16	114/ 119	95.80%	110/ 121	90.91%
Week 20	109/ 119	91.60%	110/ 121	90.91%
Week 24	109/ 119	91.60%	108/ 121	89.26%
Week 28	109/ 119	91.60%	101/ 121	83.47%
Week 32	105/ 119	88.24%	97/ 121	80.17%
Week 36	105/ 119	88.24%	97/ 121	80.17%
Week 40	108/ 119	90.76%	97/ 121	80.17%
Week 44	104/ 119	87.39%	95/ 121	78.51%
Week 48	101/ 119	84.87%	95/ 121	78.51%
Week 52	99/ 119	83.19%	91/ 121	75.21%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Tender Joint Count
Full analysis set

Visit	Anifrolumab 300mg (N=119) n/ N#	Anifrolumab 300mg (N=119) Compliance	Placebo (N=121) n/ N#	Placebo (N=121) Compliance
Baseline	119/ 119	100.0%	121/ 121	100.0%
Week 4	117/ 119	98.32%	119/ 121	98.35%
Week 8	114/ 119	95.80%	117/ 121	96.69%
Week 12	116/ 119	97.48%	113/ 121	93.39%
Week 16	114/ 119	95.80%	112/ 121	92.56%
Week 20	108/ 119	90.76%	112/ 121	92.56%
Week 24	110/ 119	92.44%	111/ 121	91.74%
Week 28	109/ 119	91.60%	102/ 121	84.30%
Week 32	105/ 119	88.24%	98/ 121	80.99%
Week 36	105/ 119	88.24%	98/ 121	80.99%
Week 40	109/ 119	91.60%	100/ 121	82.64%
Week 44	104/ 119	87.39%	96/ 121	79.34%
Week 48	100/ 119	84.03%	95/ 121	78.51%
Week 52	99/ 119	83.19%	91/ 121	75.21%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Swollen Joint Count
Full analysis set

Visit	Anifrolumab 300mg (N=119) n/ N#	Anifrolumab 300mg (N=119) Compliance	Placebo (N=121) n/ N#	Placebo (N=121) Compliance
Baseline	119/ 119	100.0%	121/ 121	100.0%
Week 4	117/ 119	98.32%	119/ 121	98.35%
Week 8	114/ 119	95.80%	117/ 121	96.69%
Week 12	116/ 119	97.48%	113/ 121	93.39%
Week 16	114/ 119	95.80%	112/ 121	92.56%
Week 20	108/ 119	90.76%	112/ 121	92.56%
Week 24	110/ 119	92.44%	111/ 121	91.74%
Week 28	109/ 119	91.60%	102/ 121	84.30%
Week 32	105/ 119	88.24%	98/ 121	80.99%
Week 36	105/ 119	88.24%	98/ 121	80.99%
Week 40	109/ 119	91.60%	100/ 121	82.64%
Week 44	104/ 119	87.39%	96/ 121	79.34%
Week 48	100/ 119	84.03%	95/ 121	78.51%
Week 52	99/ 119	83.19%	91/ 121	75.21%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute Mental Component Score
Full analysis set

Visit	Anifrolumab 300mg (N=119) n/ N#	Anifrolumab 300mg (N=119) Compliance	Placebo (N=121) n/ N#	Placebo (N=121) Compliance
Baseline	113/ 119	94.96%	114/ 121	94.21%
Week 8	107/ 119	89.92%	107/ 121	88.43%
Week 16	108/ 119	90.76%	102/ 121	84.30%
Week 24	101/ 119	84.87%	107/ 121	88.43%
Week 32	97/ 119	81.51%	91/ 121	75.21%
Week 40	103/ 119	86.55%	90/ 121	74.38%
Week 48	100/ 119	84.03%	87/ 121	71.90%
Week 52	94/ 119	78.99%	82/ 121	67.77%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute Physical Component Score
Full analysis set

Visit	Anifrolumab 300mg (N=119) n/ N#	Anifrolumab 300mg (N=119) Compliance	Placebo (N=121) n/ N#	Placebo (N=121) Compliance
Baseline	113/ 119	94.96%	114/ 121	94.21%
Week 8	107/ 119	89.92%	107/ 121	88.43%
Week 16	108/ 119	90.76%	102/ 121	84.30%
Week 24	101/ 119	84.87%	107/ 121	88.43%
Week 32	97/ 119	81.51%	91/ 121	75.21%
Week 40	103/ 119	86.55%	90/ 121	74.38%
Week 48	100/ 119	84.03%	87/ 121	71.90%
Week 52	94/ 119	78.99%	82/ 121	67.77%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute General Health Score
Full analysis set

Visit	Anifrolumab 300mg (N=119) n/ N#	Anifrolumab 300mg (N=119) Compliance	Placebo (N=121) n/ N#	Placebo (N=121) Compliance
Baseline	113/ 119	94.96%	114/ 121	94.21%
Week 8	107/ 119	89.92%	107/ 121	88.43%
Week 16	108/ 119	90.76%	102/ 121	84.30%
Week 24	101/ 119	84.87%	107/ 121	88.43%
Week 32	97/ 119	81.51%	91/ 121	75.21%
Week 40	103/ 119	86.55%	90/ 121	74.38%
Week 48	100/ 119	84.03%	87/ 121	71.90%
Week 52	94/ 119	78.99%	82/ 121	67.77%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute Mental Health Score
Full analysis set

Visit	Anifrolumab 300mg (N=119) n/ N#	Anifrolumab 300mg (N=119) Compliance	Placebo (N=121) n/ N#	Placebo (N=121) Compliance
Baseline	113/ 119	94.96%	114/ 121	94.21%
Week 8	107/ 119	89.92%	107/ 121	88.43%
Week 16	108/ 119	90.76%	102/ 121	84.30%
Week 24	101/ 119	84.87%	107/ 121	88.43%
Week 32	97/ 119	81.51%	91/ 121	75.21%
Week 40	103/ 119	86.55%	90/ 121	74.38%
Week 48	100/ 119	84.03%	87/ 121	71.90%
Week 52	94/ 119	78.99%	82/ 121	67.77%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute Physical Functioning Score
Full analysis set

Visit	Anifrolumab 300mg (N=119) n/ N#	Anifrolumab 300mg (N=119) Compliance	Placebo (N=121) n/ N#	Placebo (N=121) Compliance
Baseline	113/ 119	94.96%	114/ 121	94.21%
Week 8	107/ 119	89.92%	107/ 121	88.43%
Week 16	108/ 119	90.76%	102/ 121	84.30%
Week 24	101/ 119	84.87%	107/ 121	88.43%
Week 32	97/ 119	81.51%	91/ 121	75.21%
Week 40	103/ 119	86.55%	90/ 121	74.38%
Week 48	100/ 119	84.03%	87/ 121	71.90%
Week 52	94/ 119	78.99%	82/ 121	67.77%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute Role Emotional Score
Full analysis set

Visit	Anifrolumab 300mg (N=119) n/ N#	Anifrolumab 300mg (N=119) Compliance	Placebo (N=121) n/ N#	Placebo (N=121) Compliance
Baseline	113/ 119	94.96%	114/ 121	94.21%
Week 8	107/ 119	89.92%	107/ 121	88.43%
Week 16	108/ 119	90.76%	102/ 121	84.30%
Week 24	101/ 119	84.87%	107/ 121	88.43%
Week 32	97/ 119	81.51%	91/ 121	75.21%
Week 40	103/ 119	86.55%	90/ 121	74.38%
Week 48	100/ 119	84.03%	87/ 121	71.90%
Week 52	94/ 119	78.99%	82/ 121	67.77%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute Role Physical Score
Full analysis set

Visit	Anifrolumab 300mg (N=119) n/ N#	Anifrolumab 300mg (N=119) Compliance	Placebo (N=121) n/ N#	Placebo (N=121) Compliance
Baseline	113/ 119	94.96%	114/ 121	94.21%
Week 8	107/ 119	89.92%	107/ 121	88.43%
Week 16	108/ 119	90.76%	102/ 121	84.30%
Week 24	101/ 119	84.87%	107/ 121	88.43%
Week 32	97/ 119	81.51%	91/ 121	75.21%
Week 40	103/ 119	86.55%	90/ 121	74.38%
Week 48	100/ 119	84.03%	87/ 121	71.90%
Week 52	94/ 119	78.99%	82/ 121	67.77%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute Social Functioning Score
Full analysis set

Visit	Anifrolumab 300mg (N=119) n/ N#	Anifrolumab 300mg (N=119) Compliance	Placebo (N=121) n/ N#	Placebo (N=121) Compliance
Baseline	113/ 119	94.96%	114/ 121	94.21%
Week 8	107/ 119	89.92%	107/ 121	88.43%
Week 16	108/ 119	90.76%	102/ 121	84.30%
Week 24	101/ 119	84.87%	107/ 121	88.43%
Week 32	97/ 119	81.51%	91/ 121	75.21%
Week 40	103/ 119	86.55%	90/ 121	74.38%
Week 48	100/ 119	84.03%	87/ 121	71.90%
Week 52	94/ 119	78.99%	82/ 121	67.77%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute Bodily Pain Score
Full analysis set

Visit	Anifrolumab 300mg (N=119) n/ N#	Anifrolumab 300mg (N=119) Compliance	Placebo (N=121) n/ N#	Placebo (N=121) Compliance
Baseline	113/ 119	94.96%	114/ 121	94.21%
Week 8	107/ 119	89.92%	107/ 121	88.43%
Week 16	108/ 119	90.76%	102/ 121	84.30%
Week 24	101/ 119	84.87%	107/ 121	88.43%
Week 32	97/ 119	81.51%	91/ 121	75.21%
Week 40	103/ 119	86.55%	90/ 121	74.38%
Week 48	100/ 119	84.03%	87/ 121	71.90%
Week 52	94/ 119	78.99%	82/ 121	67.77%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute Vitality Score
Full analysis set

Visit	Anifrolumab 300mg (N=119) n/ N#	Anifrolumab 300mg (N=119) Compliance	Placebo (N=121) n/ N#	Placebo (N=121) Compliance
Baseline	113/ 119	94.96%	114/ 121	94.21%
Week 8	107/ 119	89.92%	107/ 121	88.43%
Week 16	108/ 119	90.76%	102/ 121	84.30%
Week 24	101/ 119	84.87%	107/ 121	88.43%
Week 32	97/ 119	81.51%	91/ 121	75.21%
Week 40	103/ 119	86.55%	90/ 121	74.38%
Week 48	100/ 119	84.03%	87/ 121	71.90%
Week 52	94/ 119	78.99%	82/ 121	67.77%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - FACIT-F Total Score
Full analysis set

Visit	Anifrolumab 300mg (N=119) n/ N#	Anifrolumab 300mg (N=119) Compliance	Placebo (N=121) n/ N#	Placebo (N=121) Compliance
Baseline	110/ 119	92.44%	116/ 121	95.87%
Week 4	113/ 119	94.96%	116/ 121	95.87%
Week 8	107/ 119	89.92%	109/ 121	90.08%
Week 12	113/ 119	94.96%	108/ 121	89.26%
Week 16	108/ 119	90.76%	104/ 121	85.95%
Week 20	105/ 119	88.24%	104/ 121	85.95%
Week 24	103/ 119	86.55%	108/ 121	89.26%
Week 28	105/ 119	88.24%	99/ 121	81.82%
Week 32	101/ 119	84.87%	94/ 121	77.69%
Week 36	103/ 119	86.55%	93/ 121	76.86%
Week 40	105/ 119	88.24%	90/ 121	74.38%
Week 44	103/ 119	86.55%	87/ 121	71.90%
Week 48	100/ 119	84.03%	89/ 121	73.55%
Week 52	94/ 119	78.99%	83/ 121	68.60%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - EQ VAS Score
Full analysis set

Visit	Anifrolumab 300mg (N=119) n/ N#	Anifrolumab 300mg (N=119) Compliance	Placebo (N=121) n/ N#	Placebo (N=121) Compliance
Baseline	110/ 119	92.44%	116/ 121	95.87%
Week 12	112/ 119	94.12%	107/ 121	88.43%
Week 24	101/ 119	84.87%	105/ 121	86.78%
Week 36	102/ 119	85.71%	92/ 121	76.03%
Week 52	93/ 119	78.15%	81/ 121	66.94%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Lupus QoL Physical Health domain score
Full analysis set

Visit	Anifrolumab 300mg (N=119) n/ N#	Anifrolumab 300mg (N=119) Compliance	Placebo (N=121) n/ N#	Placebo (N=121) Compliance
Baseline	110/ 119	92.44%	116/ 121	95.87%
Week 12	111/ 119	93.28%	107/ 121	88.43%
Week 24	101/ 119	84.87%	103/ 121	85.12%
Week 36	102/ 119	85.71%	91/ 121	75.21%
Week 52	93/ 119	78.15%	81/ 121	66.94%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Lupus QoL Emotional Health domain score
Full analysis set

Visit	Anifrolumab 300mg (N=119) n/ N#	Anifrolumab 300mg (N=119) Compliance	Placebo (N=121) n/ N#	Placebo (N=121) Compliance
Baseline	110/ 119	92.44%	116/ 121	95.87%
Week 12	111/ 119	93.28%	107/ 121	88.43%
Week 24	101/ 119	84.87%	103/ 121	85.12%
Week 36	102/ 119	85.71%	91/ 121	75.21%
Week 52	93/ 119	78.15%	81/ 121	66.94%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Lupus QoL Body Image domain score
Full analysis set

Visit	Anifrolumab 300mg (N=119) n/ N#	Anifrolumab 300mg (N=119) Compliance	Placebo (N=121) n/ N#	Placebo (N=121) Compliance
Baseline	104/ 119	87.39%	108/ 121	89.26%
Week 12	100/ 119	84.03%	97/ 121	80.17%
Week 24	89/ 119	74.79%	92/ 121	76.03%
Week 36	87/ 119	73.11%	81/ 121	66.94%
Week 52	81/ 119	68.07%	76/ 121	62.81%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Lupus QoL Burden to Others domain score
Full analysis set

Visit	Anifrolumab 300mg (N=119) n/ N#	Anifrolumab 300mg (N=119) Compliance	Placebo (N=121) n/ N#	Placebo (N=121) Compliance
Baseline	110/ 119	92.44%	116/ 121	95.87%
Week 12	111/ 119	93.28%	107/ 121	88.43%
Week 24	101/ 119	84.87%	103/ 121	85.12%
Week 36	102/ 119	85.71%	91/ 121	75.21%
Week 52	93/ 119	78.15%	81/ 121	66.94%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Lupus QoL Fatigue domain score
Full analysis set

Visit	Anifrolumab 300mg (N=119) n/ N#	Anifrolumab 300mg (N=119) Compliance	Placebo (N=121) n/ N#	Placebo (N=121) Compliance
Baseline	110/ 119	92.44%	116/ 121	95.87%
Week 12	111/ 119	93.28%	107/ 121	88.43%
Week 24	101/ 119	84.87%	103/ 121	85.12%
Week 36	102/ 119	85.71%	91/ 121	75.21%
Week 52	93/ 119	78.15%	81/ 121	66.94%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Lupus QoL Intimate Relationships domain score
Full analysis set

Visit	Anifrolumab 300mg (N=119) n/ N#	Anifrolumab 300mg (N=119) Compliance	Placebo (N=121) n/ N#	Placebo (N=121) Compliance
Baseline	89/ 119	74.79%	94/ 121	77.69%
Week 12	89/ 119	74.79%	89/ 121	73.55%
Week 24	76/ 119	63.87%	77/ 121	63.64%
Week 36	77/ 119	64.71%	68/ 121	56.20%
Week 52	62/ 119	52.10%	63/ 121	52.07%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Lupus QoL Pain domain score
Full analysis set

Visit	Anifrolumab 300mg (N=119) n/ N#	Anifrolumab 300mg (N=119) Compliance	Placebo (N=121) n/ N#	Placebo (N=121) Compliance
Baseline	110/ 119	92.44%	116/ 121	95.87%
Week 12	111/ 119	93.28%	107/ 121	88.43%
Week 24	101/ 119	84.87%	103/ 121	85.12%
Week 36	102/ 119	85.71%	91/ 121	75.21%
Week 52	93/ 119	78.15%	81/ 121	66.94%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Lupus QoL Planning domain score
Full analysis set

Visit	Anifrolumab 300mg (N=119) n/ N#	Anifrolumab 300mg (N=119) Compliance	Placebo (N=121) n/ N#	Placebo (N=121) Compliance
Baseline	110/ 119	92.44%	116/ 121	95.87%
Week 12	111/ 119	93.28%	107/ 121	88.43%
Week 24	101/ 119	84.87%	103/ 121	85.12%
Week 36	102/ 119	85.71%	91/ 121	75.21%
Week 52	93/ 119	78.15%	81/ 121	66.94%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SDI Global Score
Full analysis set

Visit	Anifrolumab 300mg (N=119) n/ N#	Anifrolumab 300mg (N=119) Compliance	Placebo (N=121) n/ N#	Placebo (N=121) Compliance
Baseline	119/ 119	100.0%	121/ 121	100.0%
Week 24	107/ 119	89.92%	106/ 121	87.60%
Week 52	98/ 119	82.35%	88/ 121	72.73%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - NRS Score
Full analysis set

Visit	Anifrolumab 300mg (N=119) n/ N#	Anifrolumab 300mg (N=119) Compliance	Placebo (N=121) n/ N#	Placebo (N=121) Compliance
Baseline	110/ 119	92.44%	116/ 121	95.87%
Week 4	113/ 119	94.96%	116/ 121	95.87%
Week 8	107/ 119	89.92%	109/ 121	90.08%
Week 12	113/ 119	94.96%	108/ 121	89.26%
Week 16	108/ 119	90.76%	104/ 121	85.95%
Week 20	105/ 119	88.24%	104/ 121	85.95%
Week 24	103/ 119	86.55%	108/ 121	89.26%
Week 28	105/ 119	88.24%	99/ 121	81.82%
Week 32	101/ 119	84.87%	94/ 121	77.69%
Week 36	103/ 119	86.55%	93/ 121	76.86%
Week 40	105/ 119	88.24%	90/ 121	74.38%
Week 44	103/ 119	86.55%	87/ 121	71.90%
Week 48	100/ 119	84.03%	89/ 121	73.55%
Week 52	94/ 119	78.99%	83/ 121	68.60%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - PHQ-8 Total Score
Full analysis set

Visit	Anifrolumab 300mg (N=119) n/ N#	Anifrolumab 300mg (N=119) Compliance	Placebo (N=121) n/ N#	Placebo (N=121) Compliance
Baseline	110/ 119	92.44%	116/ 121	95.87%
Week 12	112/ 119	94.12%	107/ 121	88.43%
Week 24	101/ 119	84.87%	105/ 121	86.78%
Week 36	102/ 119	85.71%	92/ 121	76.03%
Week 52	93/ 119	78.15%	81/ 121	66.94%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - PtGA
Full analysis set

Visit	Anifrolumab 300mg (N=119) n/ N#	Anifrolumab 300mg (N=119) Compliance	Placebo (N=121) n/ N#	Placebo (N=121) Compliance
Baseline	110/ 119	92.44%	116/ 121	95.87%
Week 4	113/ 119	94.96%	116/ 121	95.87%
Week 8	107/ 119	89.92%	109/ 121	90.08%
Week 12	112/ 119	94.12%	108/ 121	89.26%
Week 16	108/ 119	90.76%	104/ 121	85.95%
Week 20	105/ 119	88.24%	104/ 121	85.95%
Week 24	103/ 119	86.55%	106/ 121	87.60%
Week 28	104/ 119	87.39%	98/ 121	80.99%
Week 32	100/ 119	84.03%	94/ 121	77.69%
Week 36	103/ 119	86.55%	92/ 121	76.03%
Week 40	105/ 119	88.24%	89/ 121	73.55%
Week 44	103/ 119	86.55%	85/ 121	70.25%
Week 48	99/ 119	83.19%	86/ 121	71.07%
Week 52	94/ 119	78.99%	83/ 121	68.60%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Flare rate through Week 52
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) Number of flares	Anifrolumab 300mg (N=119) Total Follow-up time (years)	Anifrolumab 300mg (N=119) Annual rate (SE)	Placebo (N=121) Number of flares	Placebo (N=121) Total Follow-up time (years)	Placebo (N=121) Annual rate (SE)	Rate ratio (95% CI)	p-Value	Interaction p-Value
Overall	47	111.84	0.37 (0.20)	73	108.08	0.60 (0.19)	0.62 (0.40, 0.96)	0.0334	
SLEDAI-2K score at screening									0.0905
< 10 points	19	39.44	0.49 (0.27)	12	29.46	0.43 (0.32)	1.12 (0.52, 2.42)	0.7659	
>= 10 points	28	72.39	0.33 (0.27)	61	78.62	0.68 (0.23)	0.49 (0.29, 0.84)	0.0097	
OCS dose at baseline									0.0989
<10 mg/day	24	54.19	0.42 (0.26)	31	59.77	0.46 (0.26)	0.92 (0.48, 1.78)	0.8046	
>=10 mg/day	23	57.64	0.28 (0.36)	42	48.30	0.67 (0.31)	0.42 (0.23, 0.75)	0.0037	
Result of type I IFN gene signature test									0.0961
LOW	10	21.79	0.44 (0.49)	7	20.62	0.33 (0.48)	1.31 (0.37, 4.64)	0.6710	
HIGH	37	90.05	0.38 (0.20)	66	87.45	0.73 (0.17)	0.53 (0.33, 0.84)	0.0076	
Age (years)									0.2053
<= 65	47	110.48	0.38 (0.20)	71	107.06	0.60 (0.19)	0.64 (0.41, 0.99)	0.0458	
> 65	0	1.36	NE	2	1.02	NE	NE		
Sex									0.6892
male	4	10.23	NE	10	12.07	NE	NE		
female	43	101.61	0.38 (0.21)	63	96.01	0.59 (0.20)	0.65 (0.41, 1.04)	0.0738	
Race									0.1262
White	30	72.03	0.35 (0.24)	43	67.85	0.54 (0.23)	0.65 (0.38, 1.11)	0.1137	
Black or African American	8	9.54	0.98 (0.48)	12	17.68	0.87 (0.44)	1.13 (0.37, 3.40)	0.8336	
Asian	3	15.64	NE	14	14.57	NE	NE		
Other	4	7.94	0.00 (7104.14)	3	4.93	0.00 (7104.14)	1.80 (0.15, 21.16)	0.6399	
Ethnicity									0.5849
Hispanic/Latino	11	25.68	0.26 (0.44)	24	28.79	0.55 (0.36)	0.47 (0.21, 1.04)	0.0614	
Non-hispanic/Latino	34	79.47	0.40 (0.24)	48	76.24	0.59 (0.23)	0.68 (0.40, 1.17)	0.1643	
Geographic region									0.8589
EU	12	42.16	0.21 (0.44)	12	29.64	0.29 (0.47)	0.70 (0.31, 1.58)	0.3919	
non-EU	35	69.68	0.46 (0.22)	61	78.43	0.72 (0.20)	0.64 (0.39, 1.05)	0.0764	
Onset of disease									0.7758
Paediatric	9	11.03	NE	9	5.05	NE	NE		
Adult	38	100.81	0.32 (0.21)	64	103.03	0.54 (0.20)	0.60 (0.38, 0.96)	0.0313	
ADA result									0.1498
Negative	46	107.77	0.39 (0.20)	59	99.18	0.55 (0.20)	0.71 (0.45, 1.12)	0.1428	
Positive (At any time)	1	4.07	NE	14	8.90	NE	NE		
BMI (kg/m2) at enrolment									0.5655
< 30	25	80.56	0.30 (0.27)	44	77.65	0.58 (0.27)	0.53 (0.29, 0.97)	0.0395	
>= 30	22	31.27	NE	29	30.43	NE	NE		
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.0651
All negative/normal	18	35.89	0.49 (0.28)	24	51.19	0.42 (0.26)	1.16 (0.58, 2.33)	0.6794	
At least one positive/abnormal	29	75.94	0.38 (0.28)	49	56.88	0.88 (0.31)	0.43 (0.25, 0.76)	0.0036	

Rates and rate ratio from negative binomial regression model with factors for treatment group and the stratification factors. The logarithm (to base e) of the follow-up time is used as an offset variable in the model to adjust for subjects having different exposure times.
p-Value for interaction from same negative binomial regression model with additional factors for subgroup and subgroup*treatment interaction.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Flare rate through Week 52 using modified BILAG
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) Number of flares	Anifrolumab 300mg (N=119) Total Follow-up time (years)	Anifrolumab 300mg (N=119) Annual rate (SE)	Placebo (N=121) Number of flares	Placebo (N=121) Total Follow-up time (years)	Placebo (N=121) Annual rate (SE)	Rate ratio (95% CI)	p-Value	Interaction p-Value
Overall	36	111.84	0.28 (0.22)	61	108.08	0.48 (0.21)	0.57 (0.35, 0.93)	0.0236	

Rates and rate ratio from negative binomial regression model with factors for treatment group and the stratification factors. The logarithm (to base e) of the follow-up time is used as an offset variable in the model to adjust for subjects having different exposure times.
p-Value for interaction from same negative binomial regression model with additional factors for subgroup and subgroup*treatment interaction.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Flare rate through Week 52 while on treatment
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) Number of flares	Anifrolumab 300mg (N=119) Total Follow-up time (years)	Anifrolumab 300mg (N=119) Annual rate (SE)	Placebo (N=121) Number of flares	Placebo (N=121) Total Follow-up time (years)	Placebo (N=121) Annual rate (SE)	Rate ratio (95% CI)	p-Value	Interaction p-Value
Overall	44	110.33	0.35 (0.21)	64	101.21	0.55 (0.21)	0.63 (0.39, 1.01)	0.0555	

Rates and rate ratio from negative binomial regression model with factors for treatment group and the stratification factors. The logarithm (to base e) of the follow-up time is used as an offset variable in the model to adjust for subjects having different exposure times.
p-Value for interaction from same negative binomial regression model with additional factors for subgroup and subgroup*treatment interaction.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Flare rate through Week 52 sensitivity analysis, multiple imputation and negative binomial regression model
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) Number of flares	Anifrolumab 300mg (N=119) Total Follow-up time (years)	Anifrolumab 300mg (N=119) Annual rate (SE)	Placebo (N=121) Number of flares	Placebo (N=121) Total Follow-up time (years)	Placebo (N=121) Annual rate (SE)	Rate ratio (95% CI)	p-Value
Overall	50	119.24	0.37 (0.00)	84	121.21	0.60 (0.01)	0.62 (0.40, 0.97)	0.0343

The number of flares after withdrawal from study is imputed conditional upon the observed number of flares prior to the withdrawal, a post-withdrawal model assumption, the baseline covariates included in the main analysis model and the time the subject would have remained in the study if not withdrawn (ie, date of first administration of IP + 364 days â€“ date of withdrawal). This analysis is repeated multiple times and the results combined using Rubinâ€™s formula. Full details are given in SAP
Rates and rate ratio from negative binomial regression model with factors for treatment group and the stratification factors. The logarithm (to base e) of the follow-up time is used as an offset variable in the model to adjust for subjects having different exposure times.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Flare rate through Week 52 sensitivity analysis, tipping point analysis
Full analysis set

Shift (log(Delta A)) for Anifrolumab 300 mg	Shift (log(Delta P)) for Placebo						
	0	-0.25	-0.5	-0.75	-1	-1.25	-1.5
0	0.0422	0.0489	0.0549	0.0599	0.0642	0.0677	NE
0.25	0.0449	0.0520	0.0582	0.0636	0.0680	0.0717	0.0747
0.5	0.0488	0.0563	0.0630	0.0686	0.0734	0.0773	0.0805
0.75	0.0542	0.0625	0.0697	0.0759	0.0810	0.0852	0.0886
1	0.0622	0.0714	0.0795	0.0863	0.0920	0.0966	0.1004
1.25	0.0742	0.0849	0.0941	0.1019	0.1083	0.1136	0.1179
1.5	0.0929	0.1056	0.1165	0.1257	0.1333	0.1395	0.1445

The response variable in the model is the number of flares up to Week 52/EDV. The model includes covariates of treatment group, and the stratification factors (SLEDAI-2K Score at Screening (<10 points vs >= 10 points), Week 0 OCS dose (<10 mg/day vs >=10 mg/day prednisone or equivalent) and Type 1 IFN test result at screening (high vs low)).
The logarithm (to base e) of the follow-up time is used as an offset variable in the model to adjust for subjects having different exposure times.
P-values of this analysis are presented.
For the scenario in the upper left corner, missing at random analysis is performed, where for each subject the rate after withdrawal y1 is assumed to be the same as their rate before withdrawal y2, which itself is calculated based on their randomised treatment group and baseline covariates. For the other scenarios, the same analyses are performed with the rate after withdrawal modified to be Deltay2 (Delta P and Delta A for placebo and anifrolumab 300 mg, respectively).

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Overall Survival
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	119 (100.0)	121 (100.0)
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Anifrolumab 300mg vs. Placebo (adjusted)		
Hazard Ratio (95% CI)	NE	
p-value		
Analysis Anifrolumab 300mg vs. Placebo (unadjusted)		
Hazard Ratio (95% CI)	NE	
p-value		

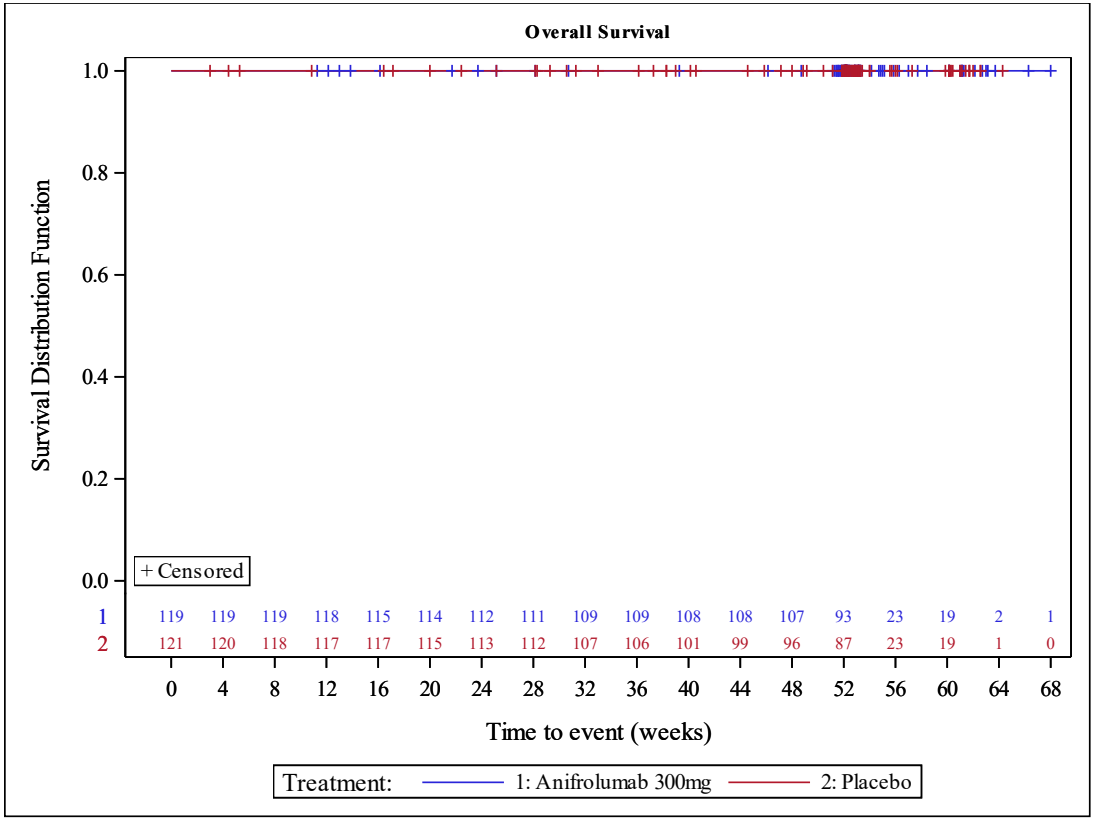
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model. Adjusted analysis also includes stratification factors in the model.
Two-sided log rank test used.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Overall Survival - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Anifrolumab 300mg (N=119) Median (95% CI)	Placebo (N=121) n/ N (%)	Placebo (N=121) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening							NE
< 10 points	0/ 41 (0.0)	NE (NE, NE)	0/ 32 (0.0)	NE (NE, NE)	NE		
>= 10 points	0/ 78 (0.0)	NE (NE, NE)	0/ 89 (0.0)	NE (NE, NE)	NE		
OCS dose at baseline							NE
<10 mg/day	0/ 58 (0.0)	NE (NE, NE)	0/ 65 (0.0)	NE (NE, NE)	NE		
>=10 mg/day	0/ 61 (0.0)	NE (NE, NE)	0/ 56 (0.0)	NE (NE, NE)	NE		
Result of type I IFN gene signature test							NE
LOW	0/ 23 (0.0)	NE (NE, NE)	0/ 24 (0.0)	NE (NE, NE)	NE		
HIGH	0/ 96 (0.0)	NE (NE, NE)	0/ 97 (0.0)	NE (NE, NE)	NE		
Age (years)							NE
<= 65	0/117 (0.0)	NE (NE, NE)	0/120 (0.0)	NE (NE, NE)	NE		
> 65	0/ 2 (0.0)	NE (NE, NE)	0/ 1 (0.0)	NE (NE, NE)	NE		
Sex							NE
male	0/ 11 (0.0)	NE (NE, NE)	0/ 12 (0.0)	NE (NE, NE)	NE		
female	0/108 (0.0)	NE (NE, NE)	0/109 (0.0)	NE (NE, NE)	NE		
Race							NE
White	0/ 75 (0.0)	NE (NE, NE)	0/ 78 (0.0)	NE (NE, NE)	NE		
Black or African American	0/ 11 (0.0)	NE (NE, NE)	0/ 18 (0.0)	NE (NE, NE)	NE		
Asian	0/ 17 (0.0)	NE (NE, NE)	0/ 16 (0.0)	NE (NE, NE)	NE		
Other	0/ 8 (0.0)	NE (NE, NE)	0/ 6 (0.0)	NE (NE, NE)	NE		
Ethnicity							NE
Hispanic/Latino	0/ 27 (0.0)	NE (NE, NE)	0/ 32 (0.0)	NE (NE, NE)	NE		
Non-hispanic/Latino	0/ 84 (0.0)	NE (NE, NE)	0/ 86 (0.0)	NE (NE, NE)	NE		
Geographic region							NE
EU	0/ 45 (0.0)	NE (NE, NE)	0/ 33 (0.0)	NE (NE, NE)	NE		
non-EU	0/ 74 (0.0)	NE (NE, NE)	0/ 88 (0.0)	NE (NE, NE)	NE		
Onset of disease							NE
Paediatric	0/ 11 (0.0)	NE (NE, NE)	0/ 5 (0.0)	NE (NE, NE)	NE		
Adult	0/108 (0.0)	NE (NE, NE)	0/116 (0.0)	NE (NE, NE)	NE		
ADA result							NE
Negative	0/115 (0.0)	NE (NE, NE)	0/111 (0.0)	NE (NE, NE)	NE		
Positive (At any time)	0/ 4 (0.0)	NE (NE, NE)	0/ 10 (0.0)	NE (NE, NE)	NE		
BMI (kg/m2) at enrolment							NE
< 30	0/ 85 (0.0)	NE (NE, NE)	0/ 89 (0.0)	NE (NE, NE)	NE		
>= 30	0/ 34 (0.0)	NE (NE, NE)	0/ 32 (0.0)	NE (NE, NE)	NE		
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group							NE
All negative/normal	0/ 38 (0.0)	NE (NE, NE)	0/ 56 (0.0)	NE (NE, NE)	NE		
At least one positive/abnormal	0/ 81 (0.0)	NE (NE, NE)	0/ 65 (0.0)	NE (NE, NE)	NE		

Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of Overall Survival
Full analysis set



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Time to first Flare
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	33 (27.7)	46 (38.0)
Number of censored subjects, n (%)	86 (72.3)	75 (62.0)
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	39.57 (31.14, NE)	20.14 (16.00, 32.57)
Median (95% CI)	NE (NE, NE)	NE (52.29, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Anifrolumab 300mg vs. Placebo (adjusted)		
Hazard Ratio (95% CI)	0.61 (0.39, 0.96)	
p-value	0.0405	
Analysis Anifrolumab 300mg vs. Placebo (unadjusted)		
Hazard Ratio (95% CI)	0.64 (0.41, 1.00)	
p-value	0.0516	

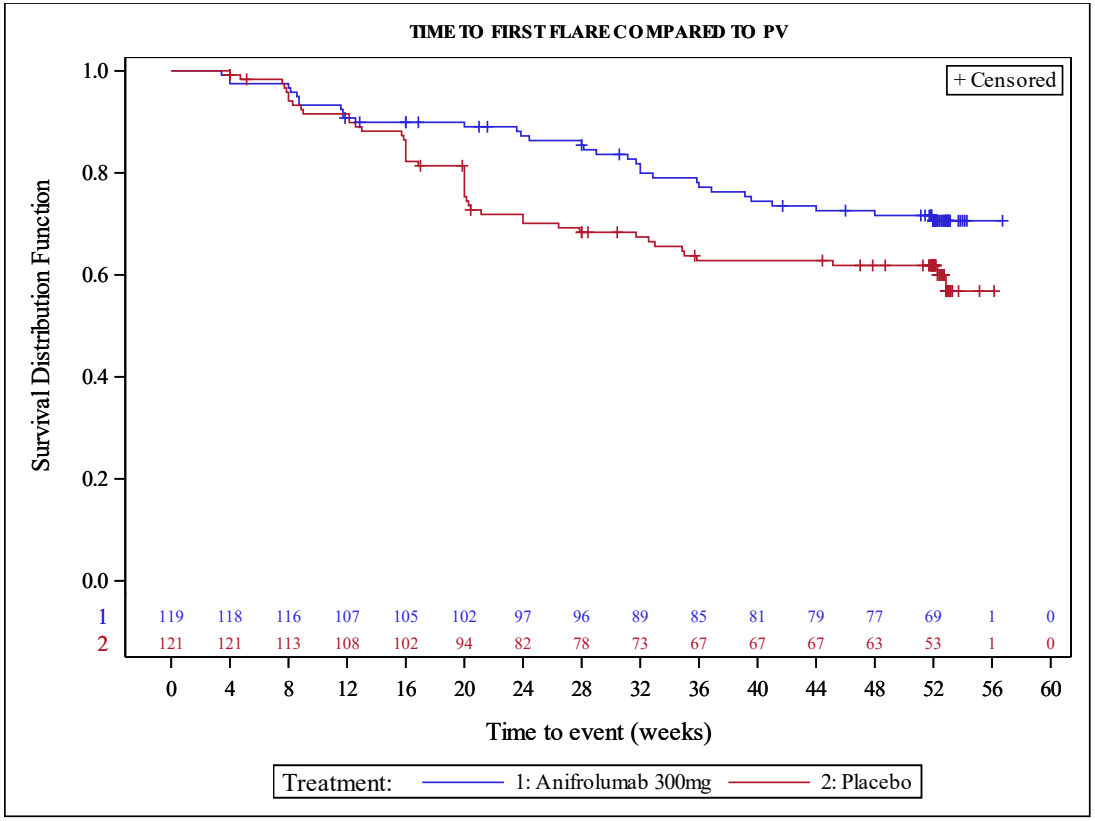
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model. Adjusted analysis also includes stratification factors in the model.
Two-sided log rank test used.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Time to first Flare - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Anifrolumab 300mg (N=119) Median (95% CI)	Placebo (N=121) n/ N (%)	Placebo (N=121) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening							0.1611
< 10 points	14/ 41 (34.1)	NE (48.00, NE)	10/ 32 (31.3)	NE (24.00, NE)	0.92 (0.40, 2.10)	0.9120	
>= 10 points	19/ 78 (24.4)	NE (NE, NE)	36/ 89 (40.4)	NE (35.86, NE)	0.50 (0.29, 0.88)	0.0185	
OCS dose at baseline							0.1563
<10 mg/day	16/ 58 (27.6)	NE (NE, NE)	20/ 65 (30.8)	NE (52.86, NE)	0.89 (0.46, 1.73)	0.7322	
>=10 mg/day	17/ 61 (27.9)	NE (NE, NE)	26/ 56 (46.4)	NE (21.14, NE)	0.45 (0.24, 0.84)	0.0127	
Result of type I IFN gene signature test							0.5771
LOW	5/ 23 (21.7)	NE (NE, NE)	6/ 24 (25.0)	NE (52.29, NE)	0.84 (0.25, 2.87)	0.8449	
HIGH	28/ 96 (29.2)	NE (NE, NE)	40/ 97 (41.2)	NE (33.00, NE)	0.58 (0.36, 0.95)	0.0333	
Age (years)							0.9835
<= 65	33/117 (28.2)	NE (NE, NE)	45/120 (37.5)	NE (52.86, NE)	0.63 (0.40, 0.99)	0.0555	
> 65	0/ 2 (0.0)	NE (NE, NE)	1/ 1 (100.0)	8.00 (NE, NE)	NE		
Sex							0.8344
male	3/ 11 (27.3)	NE (20.00, NE)	6/ 12 (50.0)	52.86 (12.57, NE)	0.20 (0.03, 1.32)	0.1459	
female	30/108 (27.8)	NE (NE, NE)	40/109 (36.7)	NE (52.29, NE)	0.63 (0.39, 1.02)	0.0608	
Race							0.3505
White	21/ 75 (28.0)	NE (NE, NE)	30/ 78 (38.5)	NE (35.86, NE)	0.57 (0.32, 1.01)	0.0743	
Black or African American	5/ 11 (45.5)	NE (11.71, NE)	7/ 18 (38.9)	NE (20.43, NE)	1.30 (0.40, 4.20)	0.6237	
Asian	3/ 17 (17.6)	NE (NE, NE)	6/ 16 (37.5)	NE (16.86, NE)	0.14 (0.02, 0.82)	0.0630	
Other	2/ 8 (25.0)	NE (8.57, NE)	2/ 6 (33.3)	NE (8.29, NE)	1.18 (0.14, 10.13)	0.9257	
Ethnicity							0.1373
Hispanic/Latino	6/ 27 (22.2)	NE (NE, NE)	16/ 32 (50.0)	35.86 (20.00, NE)	0.31 (0.12, 0.81)	0.0298	
Non-hispanic/Latino	25/ 84 (29.8)	NE (NE, NE)	29/ 86 (33.7)	NE (NE, NE)	0.77 (0.45, 1.32)	0.3027	
Geographic region							0.5432
EU	10/ 45 (22.2)	NE (NE, NE)	9/ 33 (27.3)	NE (52.86, NE)	0.81 (0.33, 2.01)	0.5405	
non-EU	23/ 74 (31.1)	NE (NE, NE)	37/ 88 (42.0)	NE (35.00, NE)	0.56 (0.33, 0.95)	0.0472	
Onset of disease							0.1319
Paediatric	4/ 11 (36.4)	NE (11.71, NE)	4/ 5 (80.0)	20.00 (4.00, NE)	0.18 (0.03, 1.21)	0.1382	
Adult	29/108 (26.9)	NE (NE, NE)	42/116 (36.2)	NE (52.86, NE)	0.64 (0.40, 1.02)	0.0703	
ADA result							0.1414
Negative	32/115 (27.8)	NE (NE, NE)	39/111 (35.1)	NE (52.86, NE)	0.70 (0.44, 1.12)	0.1527	
Positive (At any time)	1/ 4 (25.0)	NE (36.00, NE)	7/ 10 (70.0)	16.00 (4.00, NE)	0.18 (0.02, 1.55)	0.1231	
BMI (kg/m2) at enrolment							0.9798
< 30	19/ 85 (22.4)	NE (NE, NE)	28/ 89 (31.5)	NE (52.86, NE)	0.60 (0.33, 1.08)	0.1075	
>= 30	14/ 34 (41.2)	NE (31.71, NE)	18/ 32 (56.3)	40.50 (20.00, NE)	0.50 (0.23, 1.07)	0.0552	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group							0.3788
All negative/normal	11/ 38 (28.9)	NE (NE, NE)	19/ 56 (33.9)	NE (52.29, NE)	0.87 (0.41, 1.86)	0.6794	
At least one positive/abnormal	22/ 81 (27.2)	NE (NE, NE)	27/ 65 (41.5)	52.86 (31.71, NE)	0.51 (0.28, 0.90)	0.0208	

Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of Time to first Flare
Full analysis set



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Time to sustained BICLA response up to week 52
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	51 (42.9)	37 (30.6)
Number of censored subjects, n (%)	68 (57.1)	84 (69.4)
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	27.86 (16.00, 41.00)	44.00 (33.00, 48.86)
Median (95% CI)	53.00 (49.00, NE)	53.00 (52.00, NE)
75%-ile (95% CI)	NE (53.14, NE)	NE (NE, NE)
Analysis Anifrolumab 300mg vs. Placebo (adjusted)		
Hazard Ratio (95% CI)	1.27 (0.83, 1.95)	
p-value	0.3634	
Analysis Anifrolumab 300mg vs. Placebo (unadjusted)		
Hazard Ratio (95% CI)	1.35 (0.88, 2.06)	
p-value	0.1641	

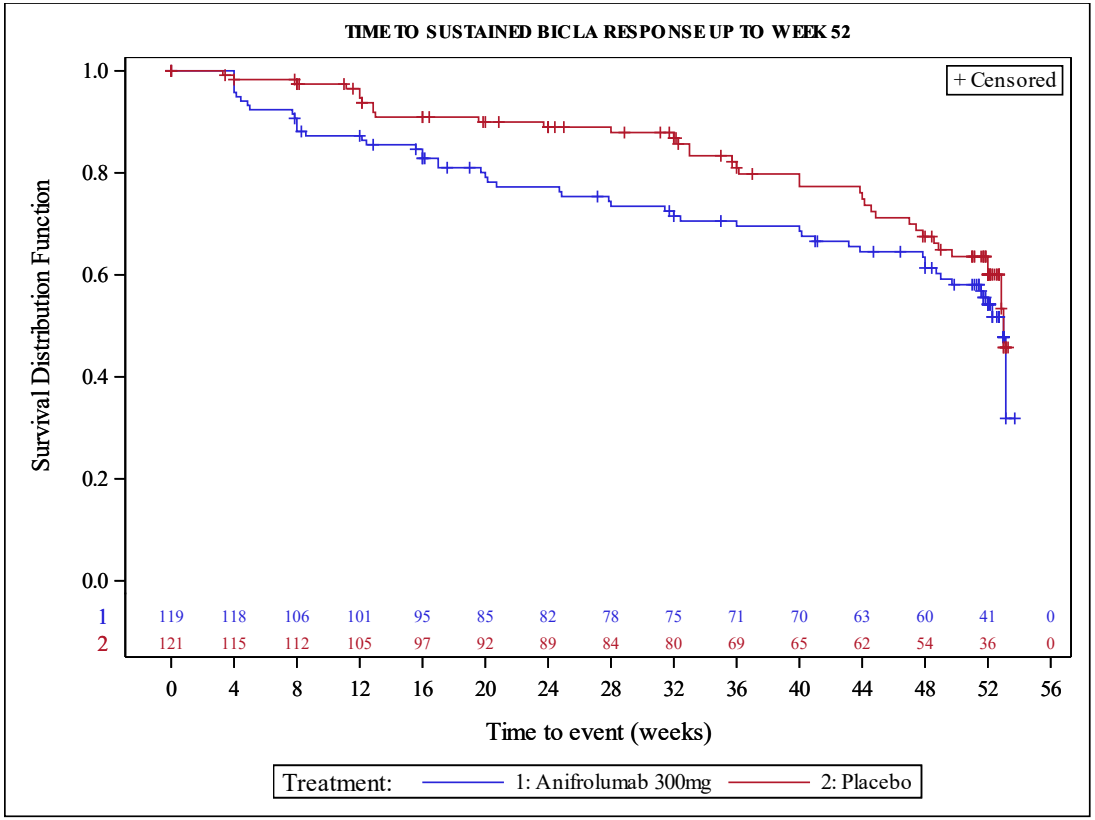
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model. Adjusted analysis also includes stratification factors in the model.
Two-sided log rank test used.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Time to sustained BICLA response up to week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Anifrolumab 300mg (N=119) Median (95% CI)	Placebo (N=121) n/ N (%)	Placebo (N=121) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening							0.5690
< 10 points	22/ 41 (53.7)	49.71 (32.00, NE)	11/ 32 (34.4)	NE (36.14, NE)	1.50 (0.72, 3.11)	0.2767	
>= 10 points	29/ 78 (37.2)	53.14 (52.00, NE)	26/ 89 (29.2)	53.00 (52.00, NE)	1.14 (0.67, 1.95)	0.7573	
OCS dose at baseline							0.4280
<10 mg/day	23/ 58 (39.7)	NE (48.00, NE)	17/ 65 (26.2)	NE (53.00, NE)	1.46 (0.77, 2.76)	0.2274	
>=10 mg/day	28/ 61 (45.9)	53.00 (43.14, NE)	20/ 56 (35.7)	52.86 (47.00, NE)	1.01 (0.56, 1.80)	0.9007	
Result of type I IFN gene signature test							0.5775
LOW	9/ 23 (39.1)	NE (20.71, NE)	8/ 24 (33.3)	47.86 (35.71, NE)	0.90 (0.34, 2.38)	0.9356	
HIGH	42/ 96 (43.8)	53.00 (48.71, NE)	29/ 97 (29.9)	53.00 (52.00, NE)	1.30 (0.80, 2.10)	0.2937	
Age (years)							0.9995
<= 65	51/117 (43.6)	53.00 (48.71, NE)	37/120 (30.8)	53.00 (52.00, NE)	1.28 (0.83, 1.96)	0.3379	
> 65	0/ 2 (0.0)	NE (NE, NE)	0/ 1 (0.0)	NE (NE, NE)	NE		
Sex							0.5882
male	6/ 11 (54.5)	51.71 (5.00, NE)	6/ 12 (50.0)	NE (12.86, NE)	1.08 (0.31, 3.83)	0.8188	
female	45/108 (41.7)	53.00 (48.00, NE)	31/109 (28.4)	53.00 (52.00, NE)	1.33 (0.84, 2.11)	0.2776	
Race							0.5087
White	30/ 75 (40.0)	53.14 (51.71, NE)	25/ 78 (32.1)	53.00 (48.57, NE)	0.94 (0.54, 1.62)	0.5527	
Black or African American	5/ 11 (45.5)	48.00 (4.00, NE)	7/ 18 (38.9)	52.86 (36.00, NE)	2.40 (0.62, 9.26)	0.2182	
Asian	8/ 17 (47.1)	47.86 (20.00, NE)	3/ 16 (18.8)	NE (40.00, NE)	2.25 (0.52, 9.84)	0.4555	
Other	3/ 8 (37.5)	NE (4.14, NE)	1/ 6 (16.7)	NE (12.86, NE)	0.00 (0.00,)	0.0253	
Ethnicity							0.3294
Hispanic/Latino	14/ 27 (51.9)	49.71 (16.00, NE)	10/ 32 (31.3)	NE (43.86, NE)	1.64 (0.70, 3.82)	0.3221	
Non-hispanic/Latino	32/ 84 (38.1)	53.14 (52.00, NE)	26/ 86 (30.2)	52.86 (52.00, NE)	1.02 (0.61, 1.73)	0.9346	
Geographic region							0.1633
EU	20/ 45 (44.4)	53.00 (48.00, NE)	15/ 33 (45.5)	52.00 (36.14, NE)	0.80 (0.40, 1.60)	0.2097	
non-EU	31/ 74 (41.9)	NE (43.86, NE)	22/ 88 (25.0)	NE (52.86, NE)	1.63 (0.93, 2.85)	0.0878	
Onset of disease							0.4473
Paediatric	5/ 11 (45.5)	49.00 (4.00, NE)	1/ 5 (20.0)	NE (44.86, NE)	1.72 (0.18, 16.69)	0.6768	
Adult	46/108 (42.6)	53.00 (48.71, NE)	36/116 (31.0)	53.00 (52.00, NE)	1.24 (0.80, 1.92)	0.4213	
ADA result							0.8031
Negative	49/115 (42.6)	53.00 (49.00, NE)	35/111 (31.5)	52.86 (52.00, NE)	1.23 (0.79, 1.90)	0.5620	
Positive (At any time)	2/ 4 (50.0)	NE (17.00, NE)	2/ 10 (20.0)	NE (28.00, NE)	1.70 (0.11, 26.34)	0.7505	
BMI (kg/m2) at enrolment							0.9270
< 30	39/ 85 (45.9)	52.29 (47.86, NE)	28/ 89 (31.5)	53.00 (49.71, NE)	1.26 (0.77, 2.07)	0.3898	
>= 30	12/ 34 (35.3)	NE (43.86, NE)	9/ 32 (28.1)	NE (44.86, NE)	1.16 (0.45, 2.97)	0.7640	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group							0.0781
All negative/normal	14/ 38 (36.8)	NE (48.00, NE)	20/ 56 (35.7)	52.86 (44.57, NE)	0.80 (0.39, 1.64)	0.5646	
At least one positive/abnormal	37/ 81 (45.7)	52.29 (41.00, NE)	17/ 65 (26.2)	53.00 (52.00, NE)	1.65 (0.92, 2.96)	0.1052	

Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of Time to sustained BICLA response up to week 52
Full analysis set



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Time to OCS Reduction <=7.5 mg/day (for subjects with baseline OCS >=10 mg/day)
Full analysis set

	Anifrolumab 300mg (N=61)	Placebo (N=56)
Number of subjects with events, n (%)	40 (65.6)	26 (46.4)
Number of censored subjects, n (%)	21 (34.4)	30 (53.6)
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	12.43 (9.00, 20.14)	17.14 (12.29, 24.14)
Median (95% CI)	24.57 (20.71, 33.29)	29.14 (21.29, NE)
75%-ile (95% CI)	NE (29.57, NE)	NE (48.29, NE)
Analysis Anifrolumab 300mg vs. Placebo (adjusted)		
Hazard Ratio (95% CI)	1.43 (0.87, 2.35)	
p-value	0.1298	
Analysis Anifrolumab 300mg vs. Placebo (unadjusted)		
Hazard Ratio (95% CI)	1.42 (0.87, 2.33)	
p-value	0.1568	

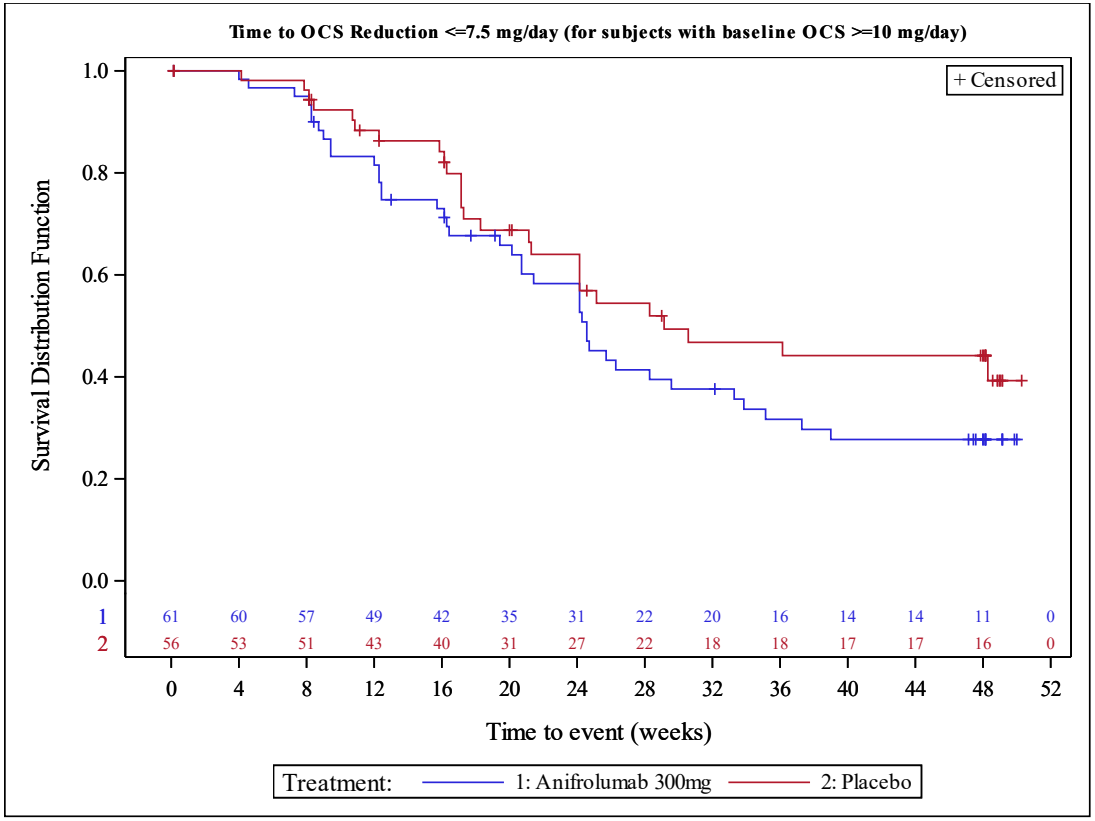
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model. Adjusted analysis also includes stratification factors in the model.
Two-sided log rank test used.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Time to OCS Reduction <=7.5 mg/day (for subjects with baseline OCS >=10 mg/day) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=61) n/ N (%)	Anifrolumab 300mg (N=61) Median (95% CI)	Placebo (N=56) n/ N (%)	Placebo (N=56) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening							0.1966
< 10 points	13/ 18 (72.2)	24.14 (16.14, 26.29)	4/ 12 (33.3)	NE (17.14, NE)	2.71 (0.87, 8.51)	0.0941	
>= 10 points	27/ 43 (62.8)	24.71 (20.14, 37.29)	22/ 44 (50.0)	28.29 (18.29, NE)	1.20 (0.68, 2.10)	0.4399	
OCS dose at baseline							NE
>=10 mg/day	40/ 61 (65.6)	24.57 (20.71, 33.29)	26/ 56 (46.4)	29.14 (21.29, NE)	1.43 (0.87, 2.35)	0.1298	
Result of type I IFN gene signature test							0.1209
LOW	2/ 5 (40.0)	39.00 (24.14, NE)	6/ 9 (66.7)	17.14 (16.29, 48.29)	0.48 (0.09, 2.60)	0.4374	
HIGH	38/ 56 (67.9)	24.29 (19.43, 29.57)	20/ 47 (42.6)	36.14 (24.14, NE)	1.66 (0.97, 2.86)	0.0649	
Age (years)							NE
<= 65	40/ 60 (66.7)	24.57 (20.14, 29.57)	26/ 56 (46.4)	29.14 (21.29, NE)	1.45 (0.88, 2.37)	0.1194	
> 65	0/ 1 (0.0)	NE (NE, NE)	0	NE (NE, NE)	NE		
Sex							0.2151
male	5/ 6 (83.3)	18.50 (8.14, NE)	2/ 5 (40.0)	NE (16.14, NE)	4.95 (0.90, 27.25)	0.0976	
female	35/ 55 (63.6)	24.57 (20.71, 33.86)	24/ 51 (47.1)	29.14 (21.14, NE)	1.31 (0.78, 2.23)	0.2619	
Race							0.8541
White	26/ 38 (68.4)	24.14 (16.14, 33.86)	20/ 44 (45.5)	29.14 (17.29, NE)	1.46 (0.82, 2.62)	0.2242	
Black or African American	1/ 4 (25.0)	NE (24.14, NE)	3/ 6 (50.0)	NE (24.14, NE)	NE		
Asian	7/ 10 (70.0)	24.43 (7.29, NE)	1/ 4 (25.0)	NE (17.14, NE)	1.43 (0.14, 15.06)	1.0000	
Other	3/ 5 (60.0)	35.14 (12.43, NE)	1/ 1 (100.0)	28.29 (NE, NE)	0.51 (0.05, 5.74)	0.5826	
Ethnicity							0.3543
Hispanic/Latino	11/ 17 (64.7)	20.14 (8.71, NE)	11/ 19 (57.9)	24.14 (16.14, 29.14)	1.14 (0.48, 2.68)	0.6182	
Non-hispanic/Latino	26/ 40 (65.0)	24.57 (20.71, 33.86)	14/ 36 (38.9)	48.29 (24.14, NE)	1.79 (0.93, 3.44)	0.0662	
Geographic region							0.8976
EU	19/ 26 (73.1)	24.14 (16.29, 28.29)	11/ 22 (50.0)	30.57 (12.29, NE)	1.35 (0.63, 2.90)	0.4538	
non-EU	21/ 35 (60.0)	24.57 (15.71, NE)	15/ 34 (44.1)	29.14 (24.14, NE)	1.31 (0.67, 2.56)	0.4786	
Onset of disease							0.7019
Paediatric	7/ 9 (77.8)	24.71 (8.71, 33.86)	2/ 3 (66.7)	36.14 (25.14, NE)	2.23 (0.41, 11.97)	0.4406	
Adult	33/ 52 (63.5)	24.29 (20.14, 33.29)	24/ 53 (45.3)	29.14 (21.14, NE)	1.37 (0.81, 2.32)	0.2035	
ADA result							0.1039
Negative	38/ 57 (66.7)	24.29 (20.14, 28.29)	21/ 48 (43.8)	36.14 (21.29, NE)	1.67 (0.98, 2.86)	0.0474	
Positive (At any time)	2/ 4 (50.0)	NE (9.43, NE)	5/ 8 (62.5)	24.14 (4.14, NE)	0.20 (0.02, 2.03)	0.2885	
BMI (kg/m2) at enrolment							0.0221
< 30	32/ 45 (71.1)	24.14 (20.14, 28.29)	16/ 43 (37.2)	NE (21.14, NE)	1.94 (1.06, 3.56)	0.0248	
>= 30	8/ 16 (50.0)	37.29 (8.14, NE)	10/ 13 (76.9)	24.14 (10.71, 36.14)	0.32 (0.11, 0.96)	0.0178	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group							0.0784
All negative/normal	13/ 17 (76.5)	20.14 (9.00, 24.57)	9/ 21 (42.9)	48.29 (17.14, NE)	2.97 (1.18, 7.46)	0.0257	
At least one positive/abnormal	27/ 44 (61.4)	26.29 (21.43, 39.00)	17/ 35 (48.6)	28.29 (17.29, NE)	1.07 (0.58, 1.98)	0.7468	

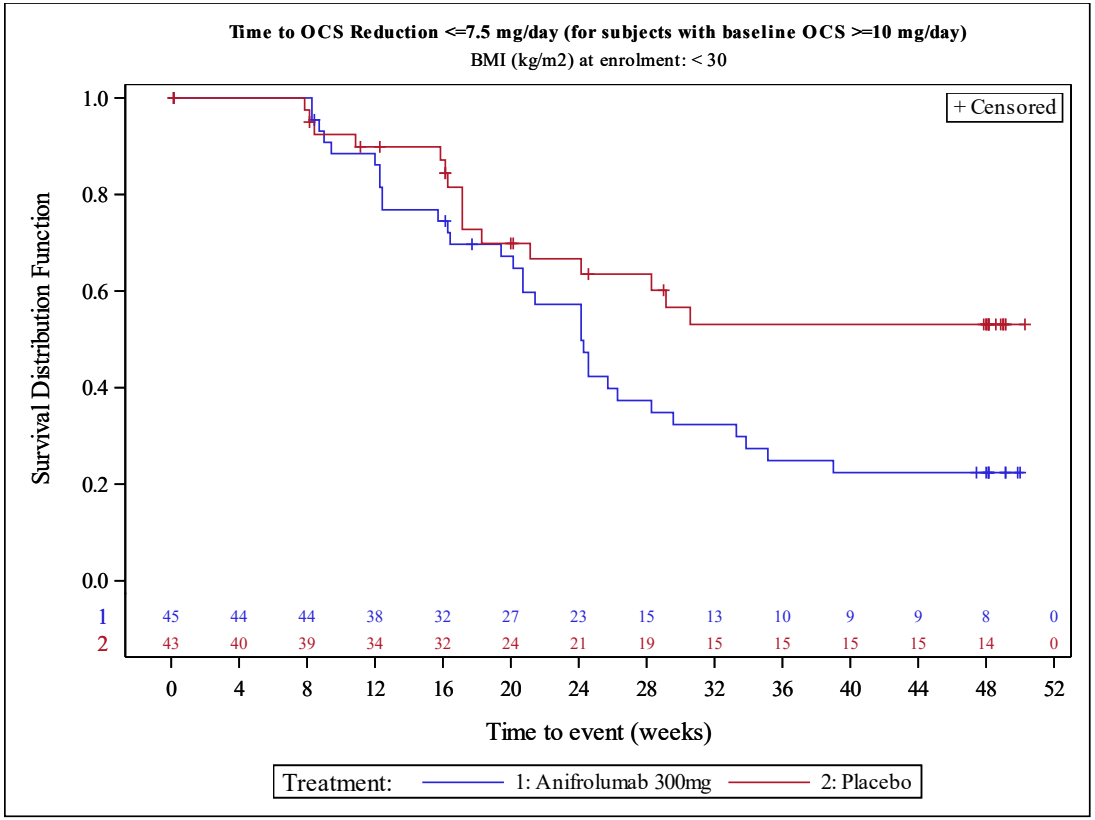
Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of Time to OCS Reduction <=7.5 mg/day (for subjects with baseline OCS >=10 mg/day)
Full analysis set



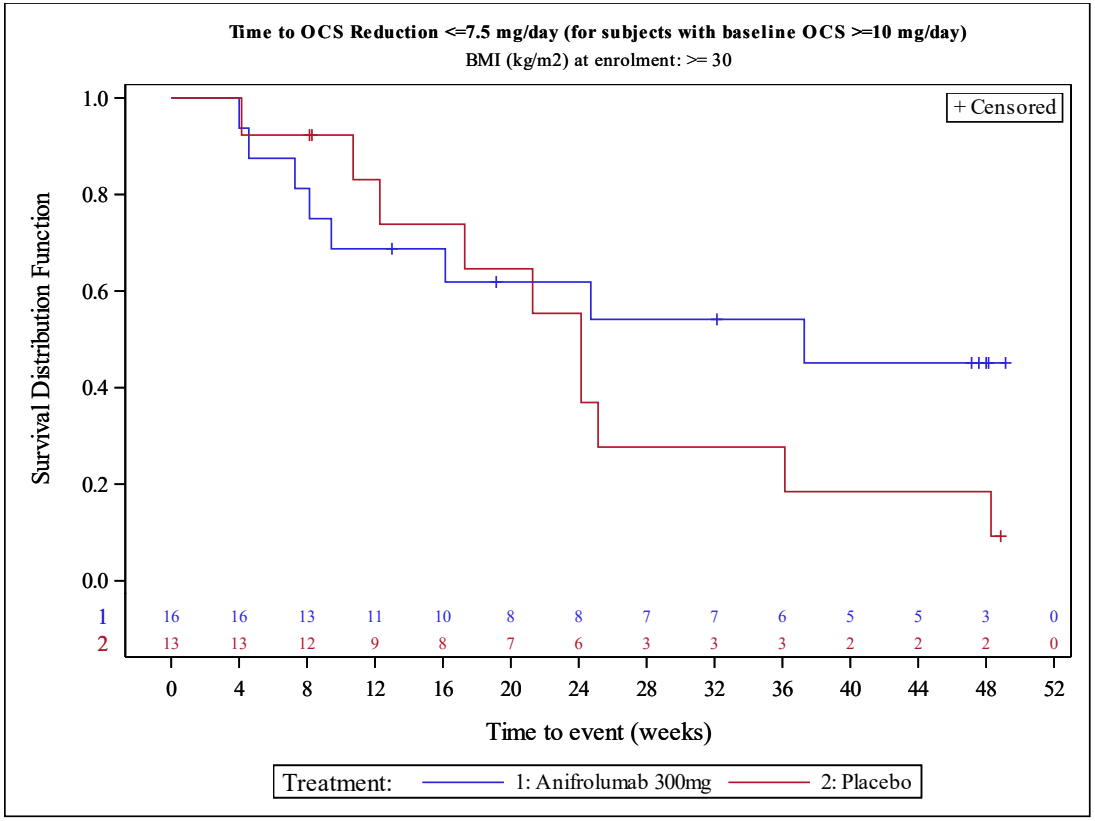
Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of Time to OCS Reduction <=7.5 mg/day (for subjects with baseline OCS >=10 mg/day)
Full analysis set



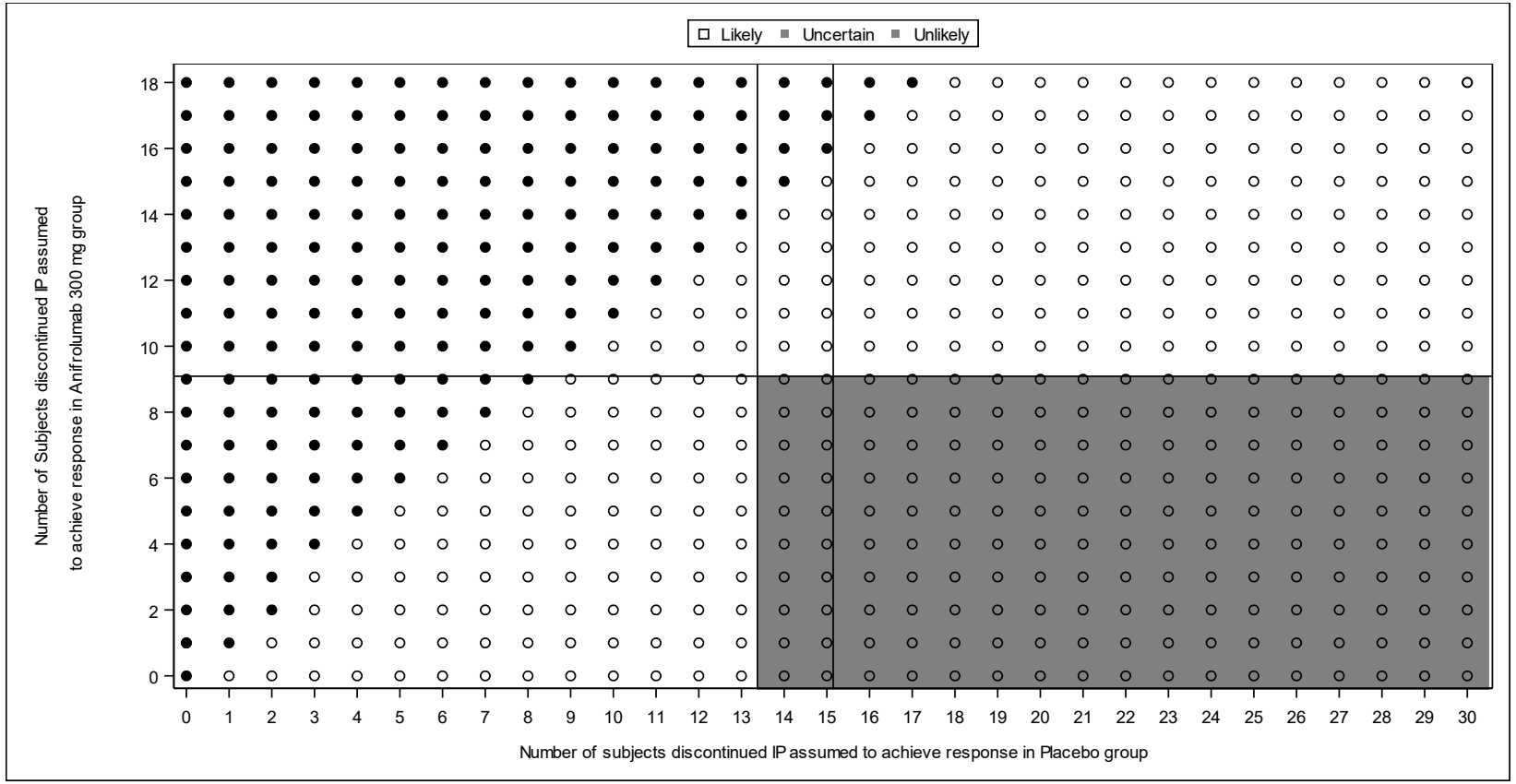
Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of Time to OCS Reduction <=7.5 mg/day (for subjects with baseline OCS >=10 mg/day)
Full analysis set



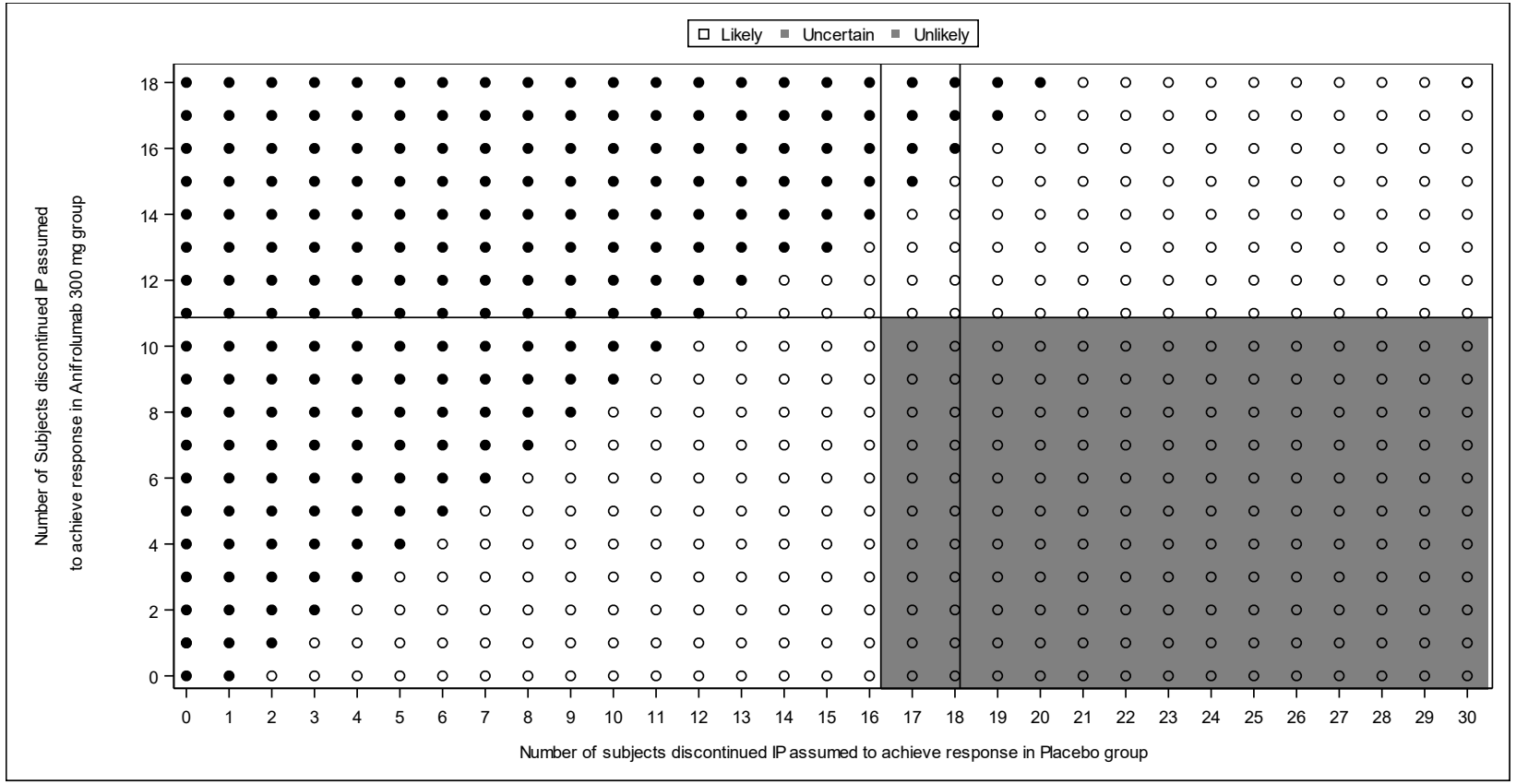
Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Plot of BICLA response rate sensitivity analysis at week 52, tipping point analysis
Full analysis set



Subjects with permanent discontinuation of IP are taken as non-responders at the bottom left grid. A certain number of such subjects from both groups are altered to be responders, while the numbers for both groups are as stated in both axes.
For each scenario, Pearson`s chi-squared test is used to compare the proportion of subjects achieving response at Week 52. The dots are presenting the results: filled = p-value <0.05, open = p-value >=0.05.
The three colors area indicate the tipping point area: white=likely, bright grey=uncertain, darker grey=Unlikely.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Plot of SRI (4) response rate sensitivity analysis at week 52, tipping point analysis
Full analysis set



Subjects with permanent discontinuation of IP are taken as non-responders at the bottom left grid. A certain number of such subjects from both groups are altered to be responders, while the numbers for both groups are as stated in both axes.
For each scenario, Pearson`s chi-squared test is used to compare the proportion of subjects achieving response at Week 52. The dots are presenting the results: filled = p-value <0.05, open = p-value >=0.05.
The three colors area indicate the tipping point area: white=likely, bright grey=uncertain, darker grey=Unlikely.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
OCS dose increases and cumulative OCS dose until week 52
Full analysis set

		Anifrolumab 300mg (N=119)	Placebo (N=121)	Total (N=240)
Number of dose increases (%)	0	90 (75.6)	74 (61.2)	164 (68.3)
	1	18 (15.1)	23 (19.0)	41 (17.1)
	2	9 (7.6)	12 (9.9)	21 (8.8)
	>2	2 (1.7)	12 (9.9)	14 (5.8)
Cumulative OCS Dose (mg/day)	n (missing)	119 (0)	121 (0)	240 (0)
	Mean (SD)	2299.4 (1684.61)	2556.6 (1989.95)	2429.1 (1845.53)
	Median	2277.5	2370.0	2283.8
	Min, Max	0, 9075	0, 9188	0, 9188
AUC up to Week 52 (mg/day)	n (missing)	119 (0)	121 (0)	240 (0)
	Mean (SD)	2465.8 (1948.58)	2916.5 (2262.65)	2693.1 (2120.41)
	Median	2327.4	2730.0	2443.1
	Min, Max	0, 13265	0, 10920	0, 13265

Subjects without any documented dose value regarded as missing values for calculation of cumulative dose and AUC.
AUC defines the cumulative dose normalized for a period of 52 weeks.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	105 (88.2)	104 (86.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.03 (0.93, 1.13)	
p-value	0.5977	
Odds Ratio (95% CI)	1.23 (0.57, 2.62)	
p-value	0.5981	
Risk Difference (95% CI)	2.28 (-6.19, 10.76)	
p-value	0.5973	
CMH approach		
Response rate	88.3	85.2
Difference in response rates (95% CI)	3.10 (-6.72, 12.92)	
p-value	0.5364	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.3472
< 10 points	38/ 41 (92.7)	93.3	27/ 32 (84.4)	83.6	1.10 (0.92, 1.30)	0.2849	9.66 (-9.14, 28.47)	0.3138	
>= 10 points	67/ 78 (85.9)	85.7	77/ 89 (86.5)	86.0	0.99 (0.88, 1.12)	0.9079	-0.29 (-12.03, 11.45)	0.9617	
OCS dose at baseline									0.2084
<10 mg/day	53/ 58 (91.4)	91.3	61/ 65 (93.8)	93.8	0.97 (0.88, 1.08)	0.6038	-2.49 (-15.03, 10.05)	0.6972	
>=10 mg/day	52/ 61 (85.2)	84.4	43/ 56 (76.8)	77.1	1.11 (0.93, 1.33)	0.2494	7.33 (-7.96, 22.63)	0.3473	
Result of type I IFN gene signature test									0.7648
LOW	19/ 23 (82.6)	82.6	20/ 24 (83.3)	83.3	0.99 (0.76, 1.28)	0.9473	-0.72 (-24.35, 22.90)	0.9521	
HIGH	86/ 96 (89.6)	89.7	84/ 97 (86.6)	85.6	1.03 (0.93, 1.15)	0.5223	4.04 (-6.72, 14.81)	0.4617	
Age (years)									0.3043
<= 65	104/117 (88.9)	88.9	103/120 (85.8)	85.1	1.04 (0.94, 1.14)	0.4792	3.74 (-6.08, 13.57)	0.4554	
> 65	1/ 2 (50.0)	50.0	1/ 1 (100.0)	100.0	0.50 (0.13, 2.00)	0.3270	-50.00 (-168.41, 68.41)	0.4079	
Sex									0.4438
male	8/ 11 (72.7)	72.7	10/ 12 (83.3)	83.3	0.87 (0.56, 1.36)	0.5457	-10.61 (-47.70, 26.49)	0.5753	
female	97/108 (89.8)	89.9	94/109 (86.2)	85.7	1.04 (0.94, 1.15)	0.4177	4.11 (-6.14, 14.36)	0.4318	
Race									0.6124
White	64/ 75 (85.3)	85.0	65/ 78 (83.3)	83.3	1.02 (0.89, 1.17)	0.7336	1.63 (-11.12, 14.39)	0.8020	
Black or African American	9/ 11 (81.8)	81.8	14/ 18 (77.8)	77.8	1.05 (0.72, 1.53)	0.7897	4.04 (-29.22, 37.30)	0.8118	
Asian	16/ 17 (94.1)	94.1	16/ 16 (100.0)	100.0	0.94 (0.84, 1.06)	0.3174	-5.88 (-28.08, 16.32)	0.6035	
Other	8/ 8 (100.0)	100.0	6/ 6 (100.0)	100.0	NE		0.00 (-41.13, 41.13)	1.0000	
Ethnicity									0.3205
Hispanic/Latino	26/ 27 (96.3)	96.3	28/ 32 (87.5)	87.5	1.10 (0.95, 1.28)	0.2119	8.80 (-8.27, 25.86)	0.3123	
Non-hispanic/Latino	71/ 84 (84.5)	84.0	73/ 86 (84.9)	85.0	1.00 (0.88, 1.13)	0.9480	-0.95 (-12.83, 10.94)	0.8759	
Geographic region									0.6533
EU	37/ 45 (82.2)	82.2	25/ 33 (75.8)	75.8	1.09 (0.86, 1.37)	0.4965	6.46 (-12.73, 25.65)	0.5091	
non-EU	68/ 74 (91.9)	91.7	79/ 88 (89.8)	89.3	1.02 (0.93, 1.13)	0.6399	2.35 (-8.66, 13.35)	0.6757	
Onset of disease									0.2486
Paediatric	10/ 11 (90.9)	90.9	5/ 5 (100.0)	100.0	0.91 (0.75, 1.10)	0.3175	-9.09 (-52.53, 34.34)	0.6817	
Adult	95/108 (88.0)	88.0	99/116 (85.3)	84.7	1.03 (0.93, 1.14)	0.5643	3.23 (-7.02, 13.48)	0.5369	
ADA result									NE
Negative	101/115 (87.8)	87.9	94/111 (84.7)	83.7	1.04 (0.93, 1.15)	0.4939	4.28 (-6.02, 14.58)	0.4153	
Positive (At any time)	4/ 4 (100.0)	100.0	10/ 10 (100.0)	100.0	NE		0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment									0.8262
< 30	75/ 85 (88.2)	88.4	77/ 89 (86.5)	86.5	1.02 (0.91, 1.14)	0.7328	1.90 (-9.20, 13.00)	0.7370	
>= 30	30/ 34 (88.2)	88.2	27/ 32 (84.4)	84.4	1.05 (0.86, 1.27)	0.6498	3.86 (-14.53, 22.25)	0.6808	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.8002
All negative/normal	34/ 38 (89.5)	89.9	48/ 56 (85.7)	84.9	1.04 (0.90, 1.22)	0.5817	4.97 (-11.81, 21.74)	0.5616	
At least one positive/abnormal	71/ 81 (87.7)	87.7	56/ 65 (86.2)	86.2	1.02 (0.90, 1.16)	0.7902	1.50 (-10.19, 13.19)	0.8014	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Serious Adverse Event
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	10 (8.4)	28 (23.1)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.36 (0.18, 0.71)	
p-value	0.0033	
Odds Ratio (95% CI)	0.30 (0.14, 0.66)	
p-value	0.0026	
Risk Difference (95% CI)	-14.74 (-23.75, -5.72)	
p-value	0.0014	
CMH approach		
Response rate	8.6	22.7
Difference in response rates (95% CI)	-14.02 (-24.03, -4.01)	
p-value	0.0060	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Serious Adverse Event - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9923
< 10 points	1/ 41 (2.4)	2.8	2/ 32 (6.3)	6.3	0.39 (0.04, 4.11)	0.4336	-3.46 (-20.59, 13.67)	0.6923	
>= 10 points	9/ 78 (11.5)	11.2	26/ 89 (29.2)	29.7	0.39 (0.20, 0.79)	0.0087	-18.51 (-31.26, -5.76)	0.0044	
OCS dose at baseline									0.9286
<10 mg/day	4/ 58 (6.9)	7.4	13/ 65 (20.0)	18.4	0.34 (0.12, 1.00)	0.0497	-10.99 (-24.52, 2.54)	0.1115	
>=10 mg/day	6/ 61 (9.8)	10.1	15/ 56 (26.8)	27.0	0.37 (0.15, 0.88)	0.0248	-16.94 (-32.42, -1.45)	0.0320	
Result of type I IFN gene signature test									0.9637
LOW	0/ 23 (0.0)	0.0	1/ 24 (4.2)	4.2	0.35 (0.01, 8.11)	0.5106	-4.17 (-20.53, 12.19)	0.6177	
HIGH	10/ 96 (10.4)	10.8	27/ 97 (27.8)	27.2	0.37 (0.19, 0.73)	0.0040	-16.46 (-28.27, -4.64)	0.0063	
Age (years)									NE
<= 65	10/117 (8.5)	8.8	28/120 (23.3)	22.9	0.37 (0.19, 0.72)	0.0036	-14.13 (-24.23, -4.03)	0.0061	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									0.2022
male	2/ 11 (18.2)	18.2	2/ 12 (16.7)	16.7	1.09 (0.18, 6.48)	0.9237	1.52 (-34.31, 37.34)	0.9339	
female	8/108 (7.4)	7.5	26/109 (23.9)	23.7	0.31 (0.15, 0.66)	0.0021	-16.22 (-26.75, -5.69)	0.0025	
Race									0.6559
White	7/ 75 (9.3)	9.4	16/ 78 (20.5)	20.5	0.46 (0.20, 1.04)	0.0629	-11.12 (-23.61, 1.38)	0.0811	
Black or African American	0/ 11 (0.0)	0.0	4/ 18 (22.2)	22.2	0.18 (0.01, 2.98)	0.2290	-22.22 (-50.98, 6.53)	0.1299	
Asian	1/ 17 (5.9)	5.9	5/ 16 (31.3)	31.3	0.19 (0.02, 1.44)	0.1078	-25.37 (-54.05, 3.32)	0.0831	
Other	0/ 8 (0.0)	0.0	3/ 6 (50.0)	50.0	0.11 (0.01, 1.82)	0.1232	-50.00 (-97.62, -2.38)	0.0396	
Ethnicity									0.1292
Hispanic/Latino	0/ 27 (0.0)	0.0	11/ 32 (34.4)	34.4	0.05 (0.00, 0.83)	0.0366	-34.38 (-53.42, -15.33)	0.0004	
Non-hispanic/Latino	8/ 84 (9.5)	9.7	17/ 86 (19.8)	19.4	0.48 (0.22, 1.06)	0.0682	-9.67 (-21.31, 1.97)	0.1033	
Geographic region									0.0578
EU	6/ 45 (13.3)	13.3	5/ 33 (15.2)	15.2	0.88 (0.29, 2.64)	0.8196	-1.82 (-19.00, 15.36)	0.8357	
non-EU	4/ 74 (5.4)	5.5	23/ 88 (26.1)	25.2	0.21 (0.07, 0.57)	0.0024	-19.69 (-31.40, -7.97)	0.0010	
Onset of disease									0.5743
Paediatric	3/ 11 (27.3)	27.3	3/ 5 (60.0)	60.0	0.45 (0.14, 1.51)	0.1984	-32.73 (-84.43, 18.97)	0.2147	
Adult	7/108 (6.5)	6.6	25/116 (21.6)	21.2	0.30 (0.14, 0.67)	0.0031	-14.52 (-24.59, -4.45)	0.0047	
ADA result									0.4996
Negative	10/115 (8.7)	8.8	22/111 (19.8)	19.3	0.44 (0.22, 0.88)	0.0212	-10.51 (-20.71, -0.31)	0.0435	
Positive (At any time)	0/ 4 (0.0)	0.0	6/ 10 (60.0)	60.0	0.17 (0.01, 2.46)	0.1931	-60.00 (-112.36, -7.64)	0.0247	
BMI (kg/m2) at enrolment									0.7817
< 30	7/ 85 (8.2)	8.5	19/ 89 (21.3)	20.7	0.39 (0.17, 0.87)	0.0218	-12.22 (-23.59, -0.85)	0.0351	
>= 30	3/ 34 (8.8)	8.8	9/ 32 (28.1)	28.1	0.31 (0.09, 1.06)	0.0613	-19.30 (-38.89, 0.29)	0.0535	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.0317
All negative/normal	5/ 38 (13.2)	14.1	8/ 56 (14.3)	13.3	0.92 (0.33, 2.60)	0.8767	0.74 (-16.13, 17.60)	0.9319	
At least one positive/abnormal	5/ 81 (6.2)	6.2	20/ 65 (30.8)	30.8	0.20 (0.08, 0.51)	0.0007	-24.60 (-37.41, -11.78)	0.0002	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Severe Adverse Event
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	4 (3.4)	10 (8.3)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.41 (0.13, 1.26)	
p-value	0.1192	
Odds Ratio (95% CI)	0.39 (0.12, 1.27)	
p-value	0.1165	
Risk Difference (95% CI)	-4.90 (-10.78, 0.98)	
p-value	0.1021	
CMH approach		
Response rate	3.3	8.3
Difference in response rates (95% CI)	-5.03 (-13.27, 3.22)	
p-value	0.2320	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Severe Adverse Event - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9464
< 10 points	1/ 41 (2.4)	2.4	2/ 32 (6.3)	5.6	0.39 (0.04, 4.11)	0.4336	-3.21 (-19.98, 13.55)	0.7074	
>= 10 points	3/ 78 (3.8)	3.5	8/ 89 (9.0)	9.4	0.43 (0.12, 1.56)	0.1977	-5.88 (-15.69, 3.93)	0.2398	
OCS dose at baseline									0.7036
<10 mg/day	1/ 58 (1.7)	1.5	4/ 65 (6.2)	6.1	0.28 (0.03, 2.44)	0.2488	-4.59 (-15.61, 6.44)	0.4150	
>=10 mg/day	3/ 61 (4.9)	5.0	6/ 56 (10.7)	10.3	0.46 (0.12, 1.75)	0.2539	-5.29 (-18.27, 7.68)	0.4240	
Result of type I IFN gene signature test									0.4596
LOW	1/ 23 (4.3)	4.3	1/ 24 (4.2)	4.2	1.04 (0.07, 15.72)	0.9755	0.18 (-17.65, 18.02)	0.9841	
HIGH	3/ 96 (3.1)	3.0	9/ 97 (9.3)	9.4	0.34 (0.09, 1.21)	0.0946	-6.32 (-15.61, 2.97)	0.1827	
Age (years)									NE
<= 65	4/117 (3.4)	3.4	10/120 (8.3)	8.4	0.41 (0.13, 1.27)	0.1227	-4.99 (-13.32, 3.34)	0.2408	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									0.8978
male	0/ 11 (0.0)	0.0	1/ 12 (8.3)	8.3	0.36 (0.02, 8.04)	0.5200	-8.33 (-38.19, 21.52)	0.5843	
female	4/108 (3.7)	3.6	9/109 (8.3)	8.2	0.45 (0.14, 1.41)	0.1708	-4.63 (-13.51, 4.24)	0.3058	
Race									0.5342
White	1/ 75 (1.3)	1.4	8/ 78 (10.3)	10.3	0.13 (0.02, 1.01)	0.0516	-8.96 (-19.18, 1.25)	0.0854	
Black or African American	0/ 11 (0.0)	0.0	1/ 18 (5.6)	5.6	0.53 (0.02, 11.93)	0.6879	-5.56 (-31.15, 20.04)	0.6705	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE		0.00 (-20.27, 20.27)	1.0000	
Other	1/ 8 (12.5)	12.5	1/ 6 (16.7)	16.7	0.75 (0.06, 9.72)	0.8258	-4.17 (-51.55, 43.21)	0.8632	
Ethnicity									0.6499
Hispanic/Latino	1/ 27 (3.7)	3.7	7/ 32 (21.9)	21.9	0.17 (0.02, 1.29)	0.0867	-18.17 (-36.86, 0.52)	0.0568	
Non-hispanic/Latino	1/ 84 (1.2)	1.2	3/ 86 (3.5)	3.8	0.34 (0.04, 3.22)	0.3475	-2.59 (-10.81, 5.62)	0.5365	
Geographic region									0.0675
EU	3/ 45 (6.7)	6.7	1/ 33 (3.0)	3.0	2.20 (0.24, 20.22)	0.4860	3.64 (-9.21, 16.48)	0.5789	
non-EU	1/ 74 (1.4)	1.5	9/ 88 (10.2)	10.0	0.13 (0.02, 1.02)	0.0521	-8.50 (-18.24, 1.24)	0.0872	
Onset of disease									0.6559
Paediatric	1/ 11 (9.1)	9.1	2/ 5 (40.0)	40.0	0.23 (0.03, 1.96)	0.1778	-30.91 (-80.46, 18.65)	0.2215	
Adult	3/108 (2.8)	2.8	8/116 (6.9)	7.0	0.40 (0.11, 1.48)	0.1706	-4.21 (-12.59, 4.16)	0.3238	
ADA result									0.9531
Negative	4/115 (3.5)	3.3	8/111 (7.2)	7.2	0.48 (0.15, 1.56)	0.2229	-3.87 (-12.34, 4.60)	0.3704	
Positive (At any time)	0/ 4 (0.0)	0.0	2/ 10 (20.0)	20.0	0.44 (0.03, 7.58)	0.5719	-20.00 (-70.84, 30.84)	0.4407	
BMI (kg/m2) at enrolment									0.7958
< 30	2/ 85 (2.4)	2.3	6/ 89 (6.7)	6.6	0.35 (0.07, 1.68)	0.1895	-4.35 (-13.09, 4.39)	0.3292	
>= 30	2/ 34 (5.9)	5.9	4/ 32 (12.5)	12.5	0.47 (0.09, 2.40)	0.3639	-6.62 (-23.14, 9.91)	0.4326	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.9475
All negative/normal	1/ 38 (2.6)	3.0	4/ 56 (7.1)	7.9	0.37 (0.04, 3.17)	0.3632	-4.98 (-19.89, 9.94)	0.5132	
At least one positive/abnormal	3/ 81 (3.7)	3.7	6/ 65 (9.2)	9.2	0.40 (0.10, 1.54)	0.1839	-5.53 (-14.85, 3.79)	0.2450	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Non-Severe Adverse Event
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	105 (88.2)	103 (85.1)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.04 (0.94, 1.14)	
p-value	0.4784	
Odds Ratio (95% CI)	1.31 (0.62, 2.77)	
p-value	0.4792	
Risk Difference (95% CI)	3.11 (-5.47, 11.70)	
p-value	0.4775	
CMH approach		
Response rate	88.3	84.3
Difference in response rates (95% CI)	3.98 (-5.92, 13.87)	
p-value	0.4310	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Non-Severe Adverse Event - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.4165
< 10 points	38/ 41 (92.7)	93.3	27/ 32 (84.4)	83.6	1.10 (0.92, 1.30)	0.2849	9.66 (-9.14, 28.47)	0.3138	
>= 10 points	67/ 78 (85.9)	85.7	76/ 89 (85.4)	84.8	1.01 (0.89, 1.14)	0.9261	0.97 (-10.89, 12.84)	0.8722	
OCS dose at baseline									0.1478
<10 mg/day	53/ 58 (91.4)	91.3	61/ 65 (93.8)	93.8	0.97 (0.88, 1.08)	0.6038	-2.49 (-15.03, 10.05)	0.6972	
>=10 mg/day	52/ 61 (85.2)	84.4	42/ 56 (75.0)	75.3	1.14 (0.95, 1.37)	0.1720	9.15 (-6.34, 24.64)	0.2471	
Result of type I IFN gene signature test									0.7025
LOW	19/ 23 (82.6)	82.6	20/ 24 (83.3)	83.3	0.99 (0.76, 1.28)	0.9473	-0.72 (-24.35, 22.90)	0.9521	
HIGH	86/ 96 (89.6)	89.7	83/ 97 (85.6)	84.5	1.05 (0.94, 1.16)	0.3984	5.14 (-5.73, 16.01)	0.3543	
Age (years)									0.2979
<= 65	104/117 (88.9)	88.9	102/120 (85.0)	84.2	1.05 (0.95, 1.15)	0.3746	4.62 (-5.28, 14.51)	0.3604	
> 65	1/ 2 (50.0)	50.0	1/ 1 (100.0)	100.0	0.50 (0.13, 2.00)	0.3270	-50.00 (-168.41, 68.41)	0.4079	
Sex									0.4172
male	8/ 11 (72.7)	72.7	10/ 12 (83.3)	83.3	0.87 (0.56, 1.36)	0.5457	-10.61 (-47.70, 26.49)	0.5753	
female	97/108 (89.8)	89.9	93/109 (85.3)	84.8	1.05 (0.95, 1.16)	0.3167	5.10 (-5.24, 15.44)	0.3339	
Race									0.5319
White	64/ 75 (85.3)	85.0	64/ 78 (82.1)	82.1	1.04 (0.90, 1.20)	0.5827	2.90 (-9.99, 15.79)	0.6596	
Black or African American	9/ 11 (81.8)	81.8	14/ 18 (77.8)	77.8	1.05 (0.72, 1.53)	0.7897	4.04 (-29.22, 37.30)	0.8118	
Asian	16/ 17 (94.1)	94.1	16/ 16 (100.0)	100.0	0.94 (0.84, 1.06)	0.3174	-5.88 (-28.08, 16.32)	0.6035	
Other	8/ 8 (100.0)	100.0	6/ 6 (100.0)	100.0	NE		0.00 (-41.13, 41.13)	1.0000	
Ethnicity									0.2026
Hispanic/Latino	26/ 27 (96.3)	96.3	27/ 32 (84.4)	84.4	1.14 (0.97, 1.35)	0.1196	11.92 (-5.75, 29.60)	0.1862	
Non-hispanic/Latino	71/ 84 (84.5)	84.0	73/ 86 (84.9)	85.0	1.00 (0.88, 1.13)	0.9480	-0.95 (-12.83, 10.94)	0.8759	
Geographic region									0.7265
EU	37/ 45 (82.2)	82.2	25/ 33 (75.8)	75.8	1.09 (0.86, 1.37)	0.4965	6.46 (-12.73, 25.65)	0.5091	
non-EU	68/ 74 (91.9)	91.7	78/ 88 (88.6)	88.3	1.04 (0.94, 1.15)	0.4834	3.41 (-7.73, 14.56)	0.5485	
Onset of disease									0.2144
Paediatric	10/ 11 (90.9)	90.9	5/ 5 (100.0)	100.0	0.91 (0.75, 1.10)	0.3175	-9.09 (-52.53, 34.34)	0.6817	
Adult	95/108 (88.0)	88.0	98/116 (84.5)	83.9	1.04 (0.94, 1.16)	0.4496	4.12 (-6.20, 14.43)	0.4340	
ADA result									NE
Negative	101/115 (87.8)	87.9	93/111 (83.8)	82.7	1.05 (0.94, 1.17)	0.3856	5.27 (-5.11, 15.65)	0.3194	
Positive (At any time)	4/ 4 (100.0)	100.0	10/ 10 (100.0)	100.0	NE		0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment									0.9168
< 30	75/ 85 (88.2)	88.4	76/ 89 (85.4)	85.4	1.03 (0.92, 1.16)	0.5795	2.99 (-8.24, 14.22)	0.6017	
>= 30	30/ 34 (88.2)	88.2	27/ 32 (84.4)	84.4	1.05 (0.86, 1.27)	0.6498	3.86 (-14.53, 22.25)	0.6808	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.9409
All negative/normal	34/ 38 (89.5)	89.9	48/ 56 (85.7)	84.9	1.04 (0.90, 1.22)	0.5817	4.97 (-11.81, 21.74)	0.5616	
At least one positive/abnormal	71/ 81 (87.7)	87.7	55/ 65 (84.6)	84.6	1.04 (0.91, 1.18)	0.6003	3.04 (-8.89, 14.97)	0.6177	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event leading to discontinuation of study drug
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	3 (2.5)	11 (9.1)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.28 (0.08, 0.97)	
p-value	0.0445	
Odds Ratio (95% CI)	0.26 (0.07, 0.95)	
p-value	0.0419	
Risk Difference (95% CI)	-6.57 (-12.42, -0.72)	
p-value	0.0276	
CMH approach		
Response rate	2.6	9.2
Difference in response rates (95% CI)	-6.52 (-14.83, 1.80)	
p-value	0.1244	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event leading to discontinuation of study drug - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.5951
< 10 points	0/ 41 (0.0)	0.0	2/ 32 (6.3)	6.4	0.16 (0.01, 3.16)	0.2269	-6.42 (-22.83, 9.98)	0.4429	
>= 10 points	3/ 78 (3.8)	4.0	9/ 89 (10.1)	10.6	0.38 (0.11, 1.36)	0.1360	-6.67 (-16.73, 3.39)	0.1935	
OCS dose at baseline									0.8165
<10 mg/day	1/ 58 (1.7)	1.9	5/ 65 (7.7)	8.2	0.22 (0.03, 1.86)	0.1663	-6.28 (-17.88, 5.32)	0.2889	
>=10 mg/day	2/ 61 (3.3)	3.9	6/ 56 (10.7)	10.9	0.31 (0.06, 1.45)	0.1365	-6.97 (-19.69, 5.74)	0.2825	
Result of type I IFN gene signature test									0.8142
LOW	1/ 23 (4.3)	4.3	3/ 24 (12.5)	12.5	0.35 (0.04, 3.11)	0.3445	-8.15 (-28.15, 11.84)	0.4242	
HIGH	2/ 96 (2.1)	2.2	8/ 97 (8.2)	8.3	0.25 (0.06, 1.16)	0.0767	-6.11 (-15.23, 3.00)	0.1887	
Age (years)									NE
<= 65	3/117 (2.6)	2.7	11/120 (9.2)	9.2	0.28 (0.08, 0.98)	0.0459	-6.47 (-14.85, 1.90)	0.1299	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-27.45, 27.45)	1.0000	
female	3/108 (2.8)	2.9	11/109 (10.1)	10.2	0.28 (0.08, 0.96)	0.0429	-7.30 (-16.36, 1.76)	0.1143	
Race									0.6935
White	2/ 75 (2.7)	2.9	8/ 78 (10.3)	9.8	0.26 (0.06, 1.18)	0.0817	-6.88 (-17.19, 3.44)	0.1915	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	3/ 16 (18.8)	18.8	0.13 (0.01, 2.42)	0.1740	-18.75 (-44.14, 6.64)	0.1479	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE		0.00 (-41.13, 41.13)	1.0000	
Ethnicity									0.6416
Hispanic/Latino	1/ 27 (3.7)	3.7	4/ 32 (12.5)	12.5	0.30 (0.04, 2.49)	0.2632	-8.80 (-25.86, 8.27)	0.3123	
Non-hispanic/Latino	1/ 84 (1.2)	1.2	7/ 86 (8.1)	7.9	0.15 (0.02, 1.16)	0.0692	-6.61 (-15.58, 2.36)	0.1484	
Geographic region									0.8184
EU	1/ 45 (2.2)	2.2	2/ 33 (6.1)	6.1	0.37 (0.03, 3.88)	0.4043	-3.84 (-16.54, 8.86)	0.5536	
non-EU	2/ 74 (2.7)	2.9	9/ 88 (10.2)	9.7	0.26 (0.06, 1.19)	0.0822	-6.88 (-16.75, 2.99)	0.1719	
Onset of disease									0.2384
Paediatric	1/ 11 (9.1)	9.1	0/ 5 (0.0)	0.0	1.50 (0.07, 31.57)	0.7942	9.09 (-34.34, 52.53)	0.6817	
Adult	2/108 (1.9)	1.9	11/116 (9.5)	9.4	0.20 (0.04, 0.86)	0.0310	-7.59 (-16.15, 0.96)	0.0820	
ADA result									0.8442
Negative	3/115 (2.6)	2.7	9/111 (8.1)	8.2	0.32 (0.09, 1.16)	0.0826	-5.42 (-14.01, 3.17)	0.2161	
Positive (At any time)	0/ 4 (0.0)	0.0	2/ 10 (20.0)	20.0	0.44 (0.03, 7.58)	0.5719	-20.00 (-70.84, 30.84)	0.4407	
BMI (kg/m2) at enrolment									0.7111
< 30	3/ 85 (3.5)	3.5	9/ 89 (10.1)	10.2	0.35 (0.10, 1.25)	0.1049	-6.69 (-16.21, 2.82)	0.1680	
>= 30	0/ 34 (0.0)	0.0	2/ 32 (6.3)	6.3	0.19 (0.01, 3.78)	0.2756	-6.25 (-19.47, 6.97)	0.3543	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.0966
All negative/normal	2/ 38 (5.3)	5.9	3/ 56 (5.4)	5.0	0.98 (0.17, 5.60)	0.9841	0.97 (-13.96, 15.91)	0.8985	
At least one positive/abnormal	1/ 81 (1.2)	1.2	8/ 65 (12.3)	12.3	0.10 (0.01, 0.78)	0.0281	-11.07 (-20.53, -1.62)	0.0217	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Serious Adverse Event leading to discontinuation of study drug
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	1 (0.8)	6 (5.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.17 (0.02, 1.39)	
p-value	0.0979	
Odds Ratio (95% CI)	0.16 (0.02, 1.37)	
p-value	0.0948	
Risk Difference (95% CI)	-4.12 (-8.32, 0.08)	
p-value	0.0547	
CMH approach		
Response rate	1.0	5.3
Difference in response rates (95% CI)	-4.29 (-11.84, 3.26)	
p-value	0.2659	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Serious Adverse Event leading to discontinuation of study drug - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-15.48, 15.48)	1.0000	
>= 10 points	1/ 78 (1.3)	1.4	6/ 89 (6.7)	7.6	0.19 (0.02, 1.55)	0.1205	-6.17 (-15.37, 3.04)	0.1892	
OCS dose at baseline									0.0767
<10 mg/day	1/ 58 (1.7)	1.9	0/ 65 (0.0)	0.0	3.36 (0.14, 80.80)	0.4557	1.91 (-8.32, 12.13)	0.7145	
>=10 mg/day	0/ 61 (0.0)	0.0	6/ 56 (10.7)	10.9	0.07 (0.00, 1.23)	0.0689	-10.90 (-23.07, 1.27)	0.0792	
Result of type I IFN gene signature test									NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
HIGH	1/ 96 (1.0)	1.2	6/ 97 (6.2)	6.6	0.17 (0.02, 1.37)	0.0961	-5.35 (-14.02, 3.33)	0.2269	
Age (years)									NE
<= 65	1/117 (0.9)	1.0	6/120 (5.0)	5.3	0.17 (0.02, 1.40)	0.0995	-4.28 (-11.89, 3.33)	0.2699	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-27.45, 27.45)	1.0000	
female	1/108 (0.9)	1.1	6/109 (5.5)	5.9	0.17 (0.02, 1.37)	0.0962	-4.86 (-13.09, 3.38)	0.2475	
Race									0.8300
White	1/ 75 (1.3)	1.4	5/ 78 (6.4)	6.3	0.21 (0.02, 1.74)	0.1473	-4.94 (-14.54, 4.65)	0.3128	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	1/ 16 (6.3)	6.3	0.31 (0.01, 7.21)	0.4694	-6.25 (-28.63, 16.13)	0.5841	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE		0.00 (-41.13, 41.13)	1.0000	
Ethnicity									0.7069
Hispanic/Latino	0/ 27 (0.0)	0.0	3/ 32 (9.4)	9.4	0.17 (0.01, 3.12)	0.2318	-9.38 (-24.52, 5.77)	0.2251	
Non-hispanic/Latino	1/ 84 (1.2)	1.2	3/ 86 (3.5)	3.4	0.34 (0.04, 3.22)	0.3475	-2.14 (-10.37, 6.09)	0.6106	
Geographic region									0.7117
EU	0/ 45 (0.0)	0.0	2/ 33 (6.1)	6.1	0.15 (0.01, 2.98)	0.2123	-6.06 (-18.13, 6.01)	0.3250	
non-EU	1/ 74 (1.4)	1.5	4/ 88 (4.5)	4.3	0.30 (0.03, 2.60)	0.2731	-2.80 (-11.65, 6.06)	0.5358	
Onset of disease									0.1742
Paediatric	1/ 11 (9.1)	9.1	0/ 5 (0.0)	0.0	1.50 (0.07, 31.57)	0.7942	9.09 (-34.34, 52.53)	0.6817	
Adult	0/108 (0.0)	0.0	6/116 (5.2)	5.3	0.08 (0.00, 1.45)	0.0879	-5.33 (-13.04, 2.39)	0.1759	
ADA result									0.7424
Negative	1/115 (0.9)	1.0	4/111 (3.6)	4.0	0.24 (0.03, 2.13)	0.2003	-2.94 (-10.71, 4.82)	0.4573	
Positive (At any time)	0/ 4 (0.0)	0.0	2/ 10 (20.0)	20.0	0.44 (0.03, 7.58)	0.5719	-20.00 (-70.84, 30.84)	0.4407	
BMI (kg/m2) at enrolment									0.8347
< 30	1/ 85 (1.2)	1.2	5/ 89 (5.6)	5.4	0.21 (0.02, 1.76)	0.1496	-4.22 (-12.66, 4.21)	0.3263	
>= 30	0/ 34 (0.0)	0.0	1/ 32 (3.1)	3.1	0.31 (0.01, 7.45)	0.4735	-3.13 (-15.29, 9.04)	0.6147	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.1386
All negative/normal	1/ 38 (2.6)	3.0	1/ 56 (1.8)	1.5	1.47 (0.10, 22.85)	0.7816	1.43 (-12.51, 15.37)	0.8409	
At least one positive/abnormal	0/ 81 (0.0)	0.0	5/ 65 (7.7)	7.7	0.07 (0.00, 1.30)	0.0748	-7.69 (-15.74, 0.36)	0.0610	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with Adverse Event leading to death
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.50, 6.50)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with Adverse Event leading to death - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.48, 15.48)	1.0000	
>= 10 points	0/ 78 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-7.36, 7.36)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 58 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-9.71, 9.71)	1.0000	
>=10 mg/day	0/ 61 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.81, 9.81)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	0/ 97 (0.0)	0.0	NE	0.00 (-7.23, 7.23)	1.0000	
Age (years)								NE
<= 65	0/117 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.57, 6.57)	1.0000	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-116.14, 116.14)	1.0000	
Sex								NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	0/109 (0.0)	0.0	NE	0.00 (-7.09, 7.09)	1.0000	
Race								NE
White	0/ 75 (0.0)	0.0	0/ 78 (0.0)	0.0	NE	0.00 (-7.93, 7.93)	1.0000	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE	0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE	0.00 (-41.13, 41.13)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	0/ 86 (0.0)	0.0	NE	0.00 (-7.13, 7.13)	1.0000	
Geographic region								NE
EU	0/ 45 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-9.64, 9.64)	1.0000	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-7.62, 7.62)	1.0000	
Onset of disease								NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
Adult	0/108 (0.0)	0.0	0/116 (0.0)	0.0	NE	0.00 (-6.89, 6.89)	1.0000	
ADA result								NE
Negative	0/115 (0.0)	0.0	0/111 (0.0)	0.0	NE	0.00 (-6.86, 6.86)	1.0000	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE	0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 85 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-6.95, 6.95)	1.0000	
>= 30	0/ 34 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-10.92, 10.92)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	0/ 81 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-5.25, 5.25)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Anaphylaxis
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.50, 6.50)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Anaphylaxis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.48, 15.48)	1.0000	
>= 10 points	0/ 78 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-7.36, 7.36)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 58 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-9.71, 9.71)	1.0000	
>=10 mg/day	0/ 61 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.81, 9.81)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	0/ 97 (0.0)	0.0	NE	0.00 (-7.23, 7.23)	1.0000	
Age (years)								NE
<= 65	0/117 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.57, 6.57)	1.0000	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-116.14, 116.14)	1.0000	
Sex								NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	0/109 (0.0)	0.0	NE	0.00 (-7.09, 7.09)	1.0000	
Race								NE
White	0/ 75 (0.0)	0.0	0/ 78 (0.0)	0.0	NE	0.00 (-7.93, 7.93)	1.0000	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE	0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE	0.00 (-41.13, 41.13)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	0/ 86 (0.0)	0.0	NE	0.00 (-7.13, 7.13)	1.0000	
Geographic region								NE
EU	0/ 45 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-9.64, 9.64)	1.0000	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-7.62, 7.62)	1.0000	
Onset of disease								NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
Adult	0/108 (0.0)	0.0	0/116 (0.0)	0.0	NE	0.00 (-6.89, 6.89)	1.0000	
ADA result								NE
Negative	0/115 (0.0)	0.0	0/111 (0.0)	0.0	NE	0.00 (-6.86, 6.86)	1.0000	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE	0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 85 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-6.95, 6.95)	1.0000	
>= 30	0/ 34 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-10.92, 10.92)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	0/ 81 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-5.25, 5.25)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Anaphylaxis
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.50, 6.50)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Anaphylaxis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.48, 15.48)	1.0000	
>= 10 points	0/ 78 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-7.36, 7.36)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 58 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-9.71, 9.71)	1.0000	
>=10 mg/day	0/ 61 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.81, 9.81)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	0/ 97 (0.0)	0.0	NE	0.00 (-7.23, 7.23)	1.0000	
Age (years)								NE
<= 65	0/117 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.57, 6.57)	1.0000	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-116.14, 116.14)	1.0000	
Sex								NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	0/109 (0.0)	0.0	NE	0.00 (-7.09, 7.09)	1.0000	
Race								NE
White	0/ 75 (0.0)	0.0	0/ 78 (0.0)	0.0	NE	0.00 (-7.93, 7.93)	1.0000	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE	0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE	0.00 (-41.13, 41.13)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	0/ 86 (0.0)	0.0	NE	0.00 (-7.13, 7.13)	1.0000	
Geographic region								NE
EU	0/ 45 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-9.64, 9.64)	1.0000	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-7.62, 7.62)	1.0000	
Onset of disease								NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
Adult	0/108 (0.0)	0.0	0/116 (0.0)	0.0	NE	0.00 (-6.89, 6.89)	1.0000	
ADA result								NE
Negative	0/115 (0.0)	0.0	0/111 (0.0)	0.0	NE	0.00 (-6.86, 6.86)	1.0000	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE	0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 85 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-6.95, 6.95)	1.0000	
>= 30	0/ 34 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-10.92, 10.92)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	0/ 81 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-5.25, 5.25)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Anaphylaxis
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.50, 6.50)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Anaphylaxis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.48, 15.48)	1.0000	
>= 10 points	0/ 78 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-7.36, 7.36)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 58 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-9.71, 9.71)	1.0000	
>=10 mg/day	0/ 61 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.81, 9.81)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	0/ 97 (0.0)	0.0	NE	0.00 (-7.23, 7.23)	1.0000	
Age (years)								NE
<= 65	0/117 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.57, 6.57)	1.0000	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-116.14, 116.14)	1.0000	
Sex								NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	0/109 (0.0)	0.0	NE	0.00 (-7.09, 7.09)	1.0000	
Race								NE
White	0/ 75 (0.0)	0.0	0/ 78 (0.0)	0.0	NE	0.00 (-7.93, 7.93)	1.0000	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE	0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE	0.00 (-41.13, 41.13)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	0/ 86 (0.0)	0.0	NE	0.00 (-7.13, 7.13)	1.0000	
Geographic region								NE
EU	0/ 45 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-9.64, 9.64)	1.0000	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-7.62, 7.62)	1.0000	
Onset of disease								NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
Adult	0/108 (0.0)	0.0	0/116 (0.0)	0.0	NE	0.00 (-6.89, 6.89)	1.0000	
ADA result								NE
Negative	0/115 (0.0)	0.0	0/111 (0.0)	0.0	NE	0.00 (-6.86, 6.86)	1.0000	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE	0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 85 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-6.95, 6.95)	1.0000	
>= 30	0/ 34 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-10.92, 10.92)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	0/ 81 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-5.25, 5.25)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Anaphylaxis
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.50, 6.50)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Anaphylaxis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.48, 15.48)	1.0000	
>= 10 points	0/ 78 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-7.36, 7.36)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 58 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-9.71, 9.71)	1.0000	
>=10 mg/day	0/ 61 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.81, 9.81)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	0/ 97 (0.0)	0.0	NE	0.00 (-7.23, 7.23)	1.0000	
Age (years)								NE
<= 65	0/117 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.57, 6.57)	1.0000	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-116.14, 116.14)	1.0000	
Sex								NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	0/109 (0.0)	0.0	NE	0.00 (-7.09, 7.09)	1.0000	
Race								NE
White	0/ 75 (0.0)	0.0	0/ 78 (0.0)	0.0	NE	0.00 (-7.93, 7.93)	1.0000	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE	0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE	0.00 (-41.13, 41.13)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	0/ 86 (0.0)	0.0	NE	0.00 (-7.13, 7.13)	1.0000	
Geographic region								NE
EU	0/ 45 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-9.64, 9.64)	1.0000	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-7.62, 7.62)	1.0000	
Onset of disease								NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
Adult	0/108 (0.0)	0.0	0/116 (0.0)	0.0	NE	0.00 (-6.89, 6.89)	1.0000	
ADA result								NE
Negative	0/115 (0.0)	0.0	0/111 (0.0)	0.0	NE	0.00 (-6.86, 6.86)	1.0000	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE	0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 85 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-6.95, 6.95)	1.0000	
>= 30	0/ 34 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-10.92, 10.92)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	0/ 81 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-5.25, 5.25)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	8 (6.7)	3 (2.5)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	2.71 (0.74, 9.97)	
p-value	0.1334	
Odds Ratio (95% CI)	2.83 (0.73, 10.96)	
p-value	0.1309	
Risk Difference (95% CI)	4.24 (-1.04, 9.53)	
p-value	0.1155	
CMH approach		
Response rate	6.9	2.6
Difference in response rates (95% CI)	4.34 (-3.73, 12.41)	
p-value	0.2916	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9445
< 10 points	1/ 41 (2.4)	2.4	0/ 32 (0.0)	0.0	2.36 (0.10, 56.00)	0.5958	2.41 (-13.44, 18.25)	0.7658	
>= 10 points	7/ 78 (9.0)	8.9	3/ 89 (3.4)	3.6	2.66 (0.71, 9.95)	0.1453	5.33 (-4.46, 15.12)	0.2862	
OCS dose at baseline									0.5209
<10 mg/day	4/ 58 (6.9)	6.8	1/ 65 (1.5)	1.8	4.48 (0.52, 38.97)	0.1739	5.02 (-6.45, 16.49)	0.3911	
>=10 mg/day	4/ 61 (6.6)	6.7	2/ 56 (3.6)	3.6	1.84 (0.35, 9.64)	0.4726	3.09 (-9.08, 15.26)	0.6188	
Result of type I IFN gene signature test									0.7948
LOW	2/ 23 (8.7)	8.7	1/ 24 (4.2)	4.2	2.09 (0.20, 21.48)	0.5362	4.53 (-14.55, 23.61)	0.6417	
HIGH	6/ 96 (6.3)	6.5	2/ 97 (2.1)	2.2	3.03 (0.63, 14.65)	0.1676	4.29 (-4.59, 13.18)	0.3437	
Age (years)									NE
<= 65	8/117 (6.8)	7.1	3/120 (2.5)	2.6	2.74 (0.74, 10.06)	0.1299	4.49 (-3.66, 12.64)	0.2802	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									0.8516
male	1/ 11 (9.1)	9.1	0/ 12 (0.0)	0.0	3.25 (0.15, 72.36)	0.4566	9.09 (-21.06, 39.24)	0.5545	
female	7/108 (6.5)	6.7	3/109 (2.8)	2.9	2.35 (0.63, 8.87)	0.2055	3.82 (-4.83, 12.48)	0.3866	
Race									0.8083
White	3/ 75 (4.0)	4.3	2/ 78 (2.6)	2.4	1.56 (0.27, 9.08)	0.6206	1.86 (-7.53, 11.26)	0.6973	
Black or African American	0/ 11 (0.0)	0.0	1/ 18 (5.6)	5.6	0.53 (0.02, 11.93)	0.6879	-5.56 (-31.15, 20.04)	0.6705	
Asian	1/ 17 (5.9)	5.9	0/ 16 (0.0)	0.0	2.83 (0.12, 64.89)	0.5145	5.88 (-16.32, 28.08)	0.6035	
Other	2/ 8 (25.0)	25.0	0/ 6 (0.0)	0.0	3.89 (0.22, 68.67)	0.3539	25.00 (-20.73, 70.73)	0.2840	
Ethnicity									0.5600
Hispanic/Latino	3/ 27 (11.1)	11.1	1/ 32 (3.1)	3.1	3.56 (0.39, 32.23)	0.2594	7.99 (-8.87, 24.84)	0.3531	
Non-hispanic/Latino	3/ 84 (3.6)	3.7	2/ 86 (2.3)	2.2	1.54 (0.26, 8.96)	0.6336	1.50 (-6.93, 9.94)	0.7266	
Geographic region									0.7931
EU	2/ 45 (4.4)	4.4	0/ 33 (0.0)	0.0	3.70 (0.18, 74.51)	0.3937	4.44 (-6.67, 15.56)	0.4332	
non-EU	6/ 74 (8.1)	8.7	3/ 88 (3.4)	3.2	2.38 (0.62, 9.18)	0.2088	5.43 (-4.67, 15.52)	0.2920	
Onset of disease									0.9255
Paediatric	2/ 11 (18.2)	18.2	0/ 5 (0.0)	0.0	2.50 (0.14, 44.26)	0.5320	18.18 (-26.66, 63.02)	0.4268	
Adult	6/108 (5.6)	5.8	3/116 (2.6)	2.6	2.15 (0.55, 8.38)	0.2708	3.14 (-5.17, 11.45)	0.4587	
ADA result									0.8418
Negative	7/115 (6.1)	6.3	2/111 (1.8)	1.9	3.38 (0.72, 15.91)	0.1236	4.42 (-3.80, 12.64)	0.2922	
Positive (At any time)	1/ 4 (25.0)	25.0	1/ 10 (10.0)	10.0	2.50 (0.20, 31.00)	0.4756	15.00 (-38.83, 68.83)	0.5850	
BMI (kg/m2) at enrolment									0.3479
< 30	5/ 85 (5.9)	5.9	1/ 89 (1.1)	1.1	5.24 (0.62, 43.89)	0.1270	4.82 (-3.70, 13.35)	0.2674	
>= 30	3/ 34 (8.8)	8.8	2/ 32 (6.3)	6.3	1.41 (0.25, 7.91)	0.6948	2.57 (-13.16, 18.31)	0.7486	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.6875
All negative/normal	1/ 38 (2.6)	2.8	1/ 56 (1.8)	1.7	1.47 (0.10, 22.85)	0.7816	1.09 (-12.74, 14.93)	0.8772	
At least one positive/abnormal	7/ 81 (8.6)	8.6	2/ 65 (3.1)	3.1	2.81 (0.60, 13.06)	0.1879	5.57 (-3.22, 14.35)	0.2144	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.50, 6.50)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.48, 15.48)	1.0000	
>= 10 points	0/ 78 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-7.36, 7.36)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 58 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-9.71, 9.71)	1.0000	
>=10 mg/day	0/ 61 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.81, 9.81)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	0/ 97 (0.0)	0.0	NE	0.00 (-7.23, 7.23)	1.0000	
Age (years)								NE
<= 65	0/117 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.57, 6.57)	1.0000	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-116.14, 116.14)	1.0000	
Sex								NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	0/109 (0.0)	0.0	NE	0.00 (-7.09, 7.09)	1.0000	
Race								NE
White	0/ 75 (0.0)	0.0	0/ 78 (0.0)	0.0	NE	0.00 (-7.93, 7.93)	1.0000	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE	0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE	0.00 (-41.13, 41.13)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	0/ 86 (0.0)	0.0	NE	0.00 (-7.13, 7.13)	1.0000	
Geographic region								NE
EU	0/ 45 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-9.64, 9.64)	1.0000	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-7.62, 7.62)	1.0000	
Onset of disease								NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
Adult	0/108 (0.0)	0.0	0/116 (0.0)	0.0	NE	0.00 (-6.89, 6.89)	1.0000	
ADA result								NE
Negative	0/115 (0.0)	0.0	0/111 (0.0)	0.0	NE	0.00 (-6.86, 6.86)	1.0000	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE	0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 85 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-6.95, 6.95)	1.0000	
>= 30	0/ 34 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-10.92, 10.92)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	0/ 81 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-5.25, 5.25)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.50, 6.50)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.48, 15.48)	1.0000	
>= 10 points	0/ 78 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-7.36, 7.36)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 58 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-9.71, 9.71)	1.0000	
>=10 mg/day	0/ 61 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.81, 9.81)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	0/ 97 (0.0)	0.0	NE	0.00 (-7.23, 7.23)	1.0000	
Age (years)								NE
<= 65	0/117 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.57, 6.57)	1.0000	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-116.14, 116.14)	1.0000	
Sex								NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	0/109 (0.0)	0.0	NE	0.00 (-7.09, 7.09)	1.0000	
Race								NE
White	0/ 75 (0.0)	0.0	0/ 78 (0.0)	0.0	NE	0.00 (-7.93, 7.93)	1.0000	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE	0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE	0.00 (-41.13, 41.13)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	0/ 86 (0.0)	0.0	NE	0.00 (-7.13, 7.13)	1.0000	
Geographic region								NE
EU	0/ 45 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-9.64, 9.64)	1.0000	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-7.62, 7.62)	1.0000	
Onset of disease								NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
Adult	0/108 (0.0)	0.0	0/116 (0.0)	0.0	NE	0.00 (-6.89, 6.89)	1.0000	
ADA result								NE
Negative	0/115 (0.0)	0.0	0/111 (0.0)	0.0	NE	0.00 (-6.86, 6.86)	1.0000	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE	0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 85 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-6.95, 6.95)	1.0000	
>= 30	0/ 34 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-10.92, 10.92)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	0/ 81 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-5.25, 5.25)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	8 (6.7)	3 (2.5)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	2.71 (0.74, 9.97)	
p-value	0.1334	
Odds Ratio (95% CI)	2.83 (0.73, 10.96)	
p-value	0.1309	
Risk Difference (95% CI)	4.24 (-1.04, 9.53)	
p-value	0.1155	
CMH approach		
Response rate	6.9	2.6
Difference in response rates (95% CI)	4.34 (-3.73, 12.41)	
p-value	0.2916	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9445
< 10 points	1/ 41 (2.4)	2.4	0/ 32 (0.0)	0.0	2.36 (0.10, 56.00)	0.5958	2.41 (-13.44, 18.25)	0.7658	
>= 10 points	7/ 78 (9.0)	8.9	3/ 89 (3.4)	3.6	2.66 (0.71, 9.95)	0.1453	5.33 (-4.46, 15.12)	0.2862	
OCS dose at baseline									0.5209
<10 mg/day	4/ 58 (6.9)	6.8	1/ 65 (1.5)	1.8	4.48 (0.52, 38.97)	0.1739	5.02 (-6.45, 16.49)	0.3911	
>=10 mg/day	4/ 61 (6.6)	6.7	2/ 56 (3.6)	3.6	1.84 (0.35, 9.64)	0.4726	3.09 (-9.08, 15.26)	0.6188	
Result of type I IFN gene signature test									0.7948
LOW	2/ 23 (8.7)	8.7	1/ 24 (4.2)	4.2	2.09 (0.20, 21.48)	0.5362	4.53 (-14.55, 23.61)	0.6417	
HIGH	6/ 96 (6.3)	6.5	2/ 97 (2.1)	2.2	3.03 (0.63, 14.65)	0.1676	4.29 (-4.59, 13.18)	0.3437	
Age (years)									NE
<= 65	8/117 (6.8)	7.1	3/120 (2.5)	2.6	2.74 (0.74, 10.06)	0.1299	4.49 (-3.66, 12.64)	0.2802	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									0.8516
male	1/ 11 (9.1)	9.1	0/ 12 (0.0)	0.0	3.25 (0.15, 72.36)	0.4566	9.09 (-21.06, 39.24)	0.5545	
female	7/108 (6.5)	6.7	3/109 (2.8)	2.9	2.35 (0.63, 8.87)	0.2055	3.82 (-4.83, 12.48)	0.3866	
Race									0.8083
White	3/ 75 (4.0)	4.3	2/ 78 (2.6)	2.4	1.56 (0.27, 9.08)	0.6206	1.86 (-7.53, 11.26)	0.6973	
Black or African American	0/ 11 (0.0)	0.0	1/ 18 (5.6)	5.6	0.53 (0.02, 11.93)	0.6879	-5.56 (-31.15, 20.04)	0.6705	
Asian	1/ 17 (5.9)	5.9	0/ 16 (0.0)	0.0	2.83 (0.12, 64.89)	0.5145	5.88 (-16.32, 28.08)	0.6035	
Other	2/ 8 (25.0)	25.0	0/ 6 (0.0)	0.0	3.89 (0.22, 68.67)	0.3539	25.00 (-20.73, 70.73)	0.2840	
Ethnicity									0.5600
Hispanic/Latino	3/ 27 (11.1)	11.1	1/ 32 (3.1)	3.1	3.56 (0.39, 32.23)	0.2594	7.99 (-8.87, 24.84)	0.3531	
Non-hispanic/Latino	3/ 84 (3.6)	3.7	2/ 86 (2.3)	2.2	1.54 (0.26, 8.96)	0.6336	1.50 (-6.93, 9.94)	0.7266	
Geographic region									0.7931
EU	2/ 45 (4.4)	4.4	0/ 33 (0.0)	0.0	3.70 (0.18, 74.51)	0.3937	4.44 (-6.67, 15.56)	0.4332	
non-EU	6/ 74 (8.1)	8.7	3/ 88 (3.4)	3.2	2.38 (0.62, 9.18)	0.2088	5.43 (-4.67, 15.52)	0.2920	
Onset of disease									0.9255
Paediatric	2/ 11 (18.2)	18.2	0/ 5 (0.0)	0.0	2.50 (0.14, 44.26)	0.5320	18.18 (-26.66, 63.02)	0.4268	
Adult	6/108 (5.6)	5.8	3/116 (2.6)	2.6	2.15 (0.55, 8.38)	0.2708	3.14 (-5.17, 11.45)	0.4587	
ADA result									0.8418
Negative	7/115 (6.1)	6.3	2/111 (1.8)	1.9	3.38 (0.72, 15.91)	0.1236	4.42 (-3.80, 12.64)	0.2922	
Positive (At any time)	1/ 4 (25.0)	25.0	1/ 10 (10.0)	10.0	2.50 (0.20, 31.00)	0.4756	15.00 (-38.83, 68.83)	0.5850	
BMI (kg/m2) at enrolment									0.3479
< 30	5/ 85 (5.9)	5.9	1/ 89 (1.1)	1.1	5.24 (0.62, 43.89)	0.1270	4.82 (-3.70, 13.35)	0.2674	
>= 30	3/ 34 (8.8)	8.8	2/ 32 (6.3)	6.3	1.41 (0.25, 7.91)	0.6948	2.57 (-13.16, 18.31)	0.7486	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.6875
All negative/normal	1/ 38 (2.6)	2.8	1/ 56 (1.8)	1.7	1.47 (0.10, 22.85)	0.7816	1.09 (-12.74, 14.93)	0.8772	
At least one positive/abnormal	7/ 81 (8.6)	8.6	2/ 65 (3.1)	3.1	2.81 (0.60, 13.06)	0.1879	5.57 (-3.22, 14.35)	0.2144	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Herpes Zoster leading to discontinuation of study drug
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.50, 6.50)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Herpes Zoster leading to discontinuation of study drug - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.48, 15.48)	1.0000	
>= 10 points	0/ 78 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-7.36, 7.36)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 58 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-9.71, 9.71)	1.0000	
>=10 mg/day	0/ 61 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.81, 9.81)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	0/ 97 (0.0)	0.0	NE	0.00 (-7.23, 7.23)	1.0000	
Age (years)								NE
<= 65	0/117 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.57, 6.57)	1.0000	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-116.14, 116.14)	1.0000	
Sex								NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	0/109 (0.0)	0.0	NE	0.00 (-7.09, 7.09)	1.0000	
Race								NE
White	0/ 75 (0.0)	0.0	0/ 78 (0.0)	0.0	NE	0.00 (-7.93, 7.93)	1.0000	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE	0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE	0.00 (-41.13, 41.13)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	0/ 86 (0.0)	0.0	NE	0.00 (-7.13, 7.13)	1.0000	
Geographic region								NE
EU	0/ 45 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-9.64, 9.64)	1.0000	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-7.62, 7.62)	1.0000	
Onset of disease								NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
Adult	0/108 (0.0)	0.0	0/116 (0.0)	0.0	NE	0.00 (-6.89, 6.89)	1.0000	
ADA result								NE
Negative	0/115 (0.0)	0.0	0/111 (0.0)	0.0	NE	0.00 (-6.86, 6.86)	1.0000	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE	0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 85 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-6.95, 6.95)	1.0000	
>= 30	0/ 34 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-10.92, 10.92)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	0/ 81 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-5.25, 5.25)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Hypersensitivity
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	2 (1.7)	1 (0.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	2.03 (0.19, 22.13)	
p-value	0.5600	
Odds Ratio (95% CI)	2.05 (0.18, 22.93)	
p-value	0.5597	
Risk Difference (95% CI)	0.85 (-1.96, 3.67)	
p-value	0.5523	
CMH approach		
Response rate	1.5	0.7
Difference in response rates (95% CI)	0.75 (-6.09, 7.59)	
p-value	0.8302	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Hypersensitivity - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.7348
< 10 points	1/ 41 (2.4)	2.2	0/ 32 (0.0)	0.0	2.36 (0.10, 56.00)	0.5958	2.16 (-13.66, 17.98)	0.7889	
>= 10 points	1/ 78 (1.3)	1.2	1/ 89 (1.1)	1.0	1.14 (0.07, 17.94)	0.9252	0.14 (-7.70, 7.99)	0.9716	
OCS dose at baseline									0.2613
<10 mg/day	0/ 58 (0.0)	0.0	1/ 65 (1.5)	1.4	0.37 (0.02, 8.98)	0.5433	-1.39 (-11.40, 8.62)	0.7851	
>=10 mg/day	2/ 61 (3.3)	3.0	0/ 56 (0.0)	0.0	4.60 (0.23, 93.72)	0.3214	3.03 (-7.42, 13.47)	0.5702	
Result of type I IFN gene signature test									NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
HIGH	2/ 96 (2.1)	1.8	1/ 97 (1.0)	0.9	2.02 (0.19, 21.92)	0.5630	0.93 (-6.77, 8.64)	0.8122	
Age (years)									NE
<= 65	2/117 (1.7)	1.5	1/120 (0.8)	0.7	2.05 (0.19, 22.32)	0.5552	0.76 (-6.16, 7.68)	0.8303	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-27.45, 27.45)	1.0000	
female	2/108 (1.9)	1.6	1/109 (0.9)	0.8	2.02 (0.19, 21.93)	0.5639	0.79 (-6.67, 8.26)	0.8347	
Race									0.3143
White	1/ 75 (1.3)	1.0	0/ 78 (0.0)	0.0	3.12 (0.13, 75.37)	0.4840	1.04 (-7.05, 9.13)	0.8007	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	1/ 16 (6.3)	6.3	0.31 (0.01, 7.21)	0.4694	-6.25 (-28.63, 16.13)	0.5841	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE		0.00 (-41.13, 41.13)	1.0000	
Ethnicity									0.3072
Hispanic/Latino	1/ 27 (3.7)	3.7	0/ 32 (0.0)	0.0	3.54 (0.15, 83.40)	0.4336	3.70 (-9.98, 17.39)	0.5959	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	1/ 86 (1.2)	1.1	0.34 (0.01, 8.26)	0.5084	-1.13 (-8.54, 6.29)	0.7658	
Geographic region									0.7712
EU	1/ 45 (2.2)	2.2	0/ 33 (0.0)	0.0	2.22 (0.09, 52.78)	0.6224	2.22 (-8.20, 12.64)	0.6760	
non-EU	1/ 74 (1.4)	1.1	1/ 88 (1.1)	1.1	1.19 (0.08, 18.69)	0.9019	0.06 (-8.00, 8.11)	0.9891	
Onset of disease									0.8735
Paediatric	1/ 11 (9.1)	9.1	0/ 5 (0.0)	0.0	1.50 (0.07, 31.57)	0.7942	9.09 (-34.34, 52.53)	0.6817	
Adult	1/108 (0.9)	0.8	1/116 (0.9)	0.8	1.07 (0.07, 16.96)	0.9595	-0.02 (-7.13, 7.09)	0.9962	
ADA result									NE
Negative	2/115 (1.7)	1.5	1/111 (0.9)	0.8	1.93 (0.18, 20.99)	0.5890	0.68 (-6.52, 7.88)	0.8535	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE		0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment									0.2435
< 30	0/ 85 (0.0)	0.0	1/ 89 (1.1)	1.1	0.35 (0.01, 8.45)	0.5172	-1.09 (-8.31, 6.13)	0.7677	
>= 30	2/ 34 (5.9)	5.9	0/ 32 (0.0)	0.0	4.71 (0.23, 94.58)	0.3109	5.88 (-7.13, 18.90)	0.3757	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.4283
All negative/normal	1/ 38 (2.6)	2.2	0/ 56 (0.0)	0.0	4.38 (0.18, 104.87)	0.3615	2.18 (-11.23, 15.58)	0.7503	
At least one positive/abnormal	1/ 81 (1.2)	1.2	1/ 65 (1.5)	1.5	0.80 (0.05, 12.58)	0.8755	-0.30 (-6.69, 6.08)	0.9256	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Hypersensitivity
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	1 (0.8)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.05 (0.13, 74.13)	
p-value	0.4933	
Odds Ratio (95% CI)	3.08 (0.12, 76.26)	
p-value	0.4928	
Risk Difference (95% CI)	0.84 (-0.80, 2.48)	
p-value	0.3153	
CMH approach		
Response rate	0.8	0.0
Difference in response rates (95% CI)	0.81 (-5.84, 7.47)	
p-value	0.8112	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Hypersensitivity - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-15.48, 15.48)	1.0000	
>= 10 points	1/ 78 (1.3)	1.2	0/ 89 (0.0)	0.0	3.42 (0.14, 82.71)	0.4497	1.17 (-6.47, 8.81)	0.7647	
OCS dose at baseline									NE
<10 mg/day	0/ 58 (0.0)	0.0	0/ 65 (0.0)	0.0	NE		0.00 (-9.71, 9.71)	1.0000	
>=10 mg/day	1/ 61 (1.6)	1.7	0/ 56 (0.0)	0.0	2.76 (0.11, 66.34)	0.5318	1.68 (-8.56, 11.93)	0.7478	
Result of type I IFN gene signature test									NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
HIGH	1/ 96 (1.0)	1.0	0/ 97 (0.0)	0.0	3.03 (0.13, 73.49)	0.4954	1.01 (-6.43, 8.46)	0.7899	
Age (years)									NE
<= 65	1/117 (0.9)	0.8	0/120 (0.0)	0.0	3.08 (0.13, 74.76)	0.4900	0.83 (-5.90, 7.56)	0.8086	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-27.45, 27.45)	1.0000	
female	1/108 (0.9)	0.9	0/109 (0.0)	0.0	3.03 (0.12, 73.51)	0.4961	0.88 (-6.38, 8.13)	0.8124	
Race									NE
White	0/ 75 (0.0)	0.0	0/ 78 (0.0)	0.0	NE		0.00 (-7.93, 7.93)	1.0000	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE		0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE		0.00 (-41.13, 41.13)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	0/ 86 (0.0)	0.0	NE		0.00 (-7.13, 7.13)	1.0000	
Geographic region									NE
EU	1/ 45 (2.2)	2.2	0/ 33 (0.0)	0.0	2.22 (0.09, 52.78)	0.6224	2.22 (-8.20, 12.64)	0.6760	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE		0.00 (-7.62, 7.62)	1.0000	
Onset of disease									NE
Paediatric	1/ 11 (9.1)	9.1	0/ 5 (0.0)	0.0	1.50 (0.07, 31.57)	0.7942	9.09 (-34.34, 52.53)	0.6817	
Adult	0/108 (0.0)	0.0	0/116 (0.0)	0.0	NE		0.00 (-6.89, 6.89)	1.0000	
ADA result									NE
Negative	1/115 (0.9)	0.8	0/111 (0.0)	0.0	2.90 (0.12, 70.36)	0.5135	0.81 (-6.20, 7.81)	0.8213	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE		0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/ 85 (0.0)	0.0	0/ 89 (0.0)	0.0	NE		0.00 (-6.95, 6.95)	1.0000	
>= 30	1/ 34 (2.9)	2.9	0/ 32 (0.0)	0.0	2.83 (0.12, 67.01)	0.5197	2.94 (-9.11, 14.99)	0.6323	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	1/ 81 (1.2)	1.2	0/ 65 (0.0)	0.0	2.41 (0.10, 58.31)	0.5874	1.23 (-4.49, 6.96)	0.6726	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Hypersensitivity
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.50, 6.50)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Hypersensitivity - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.48, 15.48)	1.0000	
>= 10 points	0/ 78 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-7.36, 7.36)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 58 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-9.71, 9.71)	1.0000	
>=10 mg/day	0/ 61 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.81, 9.81)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	0/ 97 (0.0)	0.0	NE	0.00 (-7.23, 7.23)	1.0000	
Age (years)								NE
<= 65	0/117 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.57, 6.57)	1.0000	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-116.14, 116.14)	1.0000	
Sex								NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	0/109 (0.0)	0.0	NE	0.00 (-7.09, 7.09)	1.0000	
Race								NE
White	0/ 75 (0.0)	0.0	0/ 78 (0.0)	0.0	NE	0.00 (-7.93, 7.93)	1.0000	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE	0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE	0.00 (-41.13, 41.13)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	0/ 86 (0.0)	0.0	NE	0.00 (-7.13, 7.13)	1.0000	
Geographic region								NE
EU	0/ 45 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-9.64, 9.64)	1.0000	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-7.62, 7.62)	1.0000	
Onset of disease								NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
Adult	0/108 (0.0)	0.0	0/116 (0.0)	0.0	NE	0.00 (-6.89, 6.89)	1.0000	
ADA result								NE
Negative	0/115 (0.0)	0.0	0/111 (0.0)	0.0	NE	0.00 (-6.86, 6.86)	1.0000	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE	0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 85 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-6.95, 6.95)	1.0000	
>= 30	0/ 34 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-10.92, 10.92)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	0/ 81 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-5.25, 5.25)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Hypersensitivity
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	2 (1.7)	1 (0.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	2.03 (0.19, 22.13)	
p-value	0.5600	
Odds Ratio (95% CI)	2.05 (0.18, 22.93)	
p-value	0.5597	
Risk Difference (95% CI)	0.85 (-1.96, 3.67)	
p-value	0.5523	
CMH approach		
Response rate	1.5	0.7
Difference in response rates (95% CI)	0.75 (-6.09, 7.59)	
p-value	0.8302	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Hypersensitivity - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.7348
< 10 points	1/ 41 (2.4)	2.2	0/ 32 (0.0)	0.0	2.36 (0.10, 56.00)	0.5958	2.16 (-13.66, 17.98)	0.7889	
>= 10 points	1/ 78 (1.3)	1.2	1/ 89 (1.1)	1.0	1.14 (0.07, 17.94)	0.9252	0.14 (-7.70, 7.99)	0.9716	
OCS dose at baseline									0.2613
<10 mg/day	0/ 58 (0.0)	0.0	1/ 65 (1.5)	1.4	0.37 (0.02, 8.98)	0.5433	-1.39 (-11.40, 8.62)	0.7851	
>=10 mg/day	2/ 61 (3.3)	3.0	0/ 56 (0.0)	0.0	4.60 (0.23, 93.72)	0.3214	3.03 (-7.42, 13.47)	0.5702	
Result of type I IFN gene signature test									NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
HIGH	2/ 96 (2.1)	1.8	1/ 97 (1.0)	0.9	2.02 (0.19, 21.92)	0.5630	0.93 (-6.77, 8.64)	0.8122	
Age (years)									NE
<= 65	2/117 (1.7)	1.5	1/120 (0.8)	0.7	2.05 (0.19, 22.32)	0.5552	0.76 (-6.16, 7.68)	0.8303	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-27.45, 27.45)	1.0000	
female	2/108 (1.9)	1.6	1/109 (0.9)	0.8	2.02 (0.19, 21.93)	0.5639	0.79 (-6.67, 8.26)	0.8347	
Race									0.3143
White	1/ 75 (1.3)	1.0	0/ 78 (0.0)	0.0	3.12 (0.13, 75.37)	0.4840	1.04 (-7.05, 9.13)	0.8007	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	1/ 16 (6.3)	6.3	0.31 (0.01, 7.21)	0.4694	-6.25 (-28.63, 16.13)	0.5841	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE		0.00 (-41.13, 41.13)	1.0000	
Ethnicity									0.3072
Hispanic/Latino	1/ 27 (3.7)	3.7	0/ 32 (0.0)	0.0	3.54 (0.15, 83.40)	0.4336	3.70 (-9.98, 17.39)	0.5959	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	1/ 86 (1.2)	1.1	0.34 (0.01, 8.26)	0.5084	-1.13 (-8.54, 6.29)	0.7658	
Geographic region									0.7712
EU	1/ 45 (2.2)	2.2	0/ 33 (0.0)	0.0	2.22 (0.09, 52.78)	0.6224	2.22 (-8.20, 12.64)	0.6760	
non-EU	1/ 74 (1.4)	1.1	1/ 88 (1.1)	1.1	1.19 (0.08, 18.69)	0.9019	0.06 (-8.00, 8.11)	0.9891	
Onset of disease									0.8735
Paediatric	1/ 11 (9.1)	9.1	0/ 5 (0.0)	0.0	1.50 (0.07, 31.57)	0.7942	9.09 (-34.34, 52.53)	0.6817	
Adult	1/108 (0.9)	0.8	1/116 (0.9)	0.8	1.07 (0.07, 16.96)	0.9595	-0.02 (-7.13, 7.09)	0.9962	
ADA result									NE
Negative	2/115 (1.7)	1.5	1/111 (0.9)	0.8	1.93 (0.18, 20.99)	0.5890	0.68 (-6.52, 7.88)	0.8535	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE		0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment									0.2435
< 30	0/ 85 (0.0)	0.0	1/ 89 (1.1)	1.1	0.35 (0.01, 8.45)	0.5172	-1.09 (-8.31, 6.13)	0.7677	
>= 30	2/ 34 (5.9)	5.9	0/ 32 (0.0)	0.0	4.71 (0.23, 94.58)	0.3109	5.88 (-7.13, 18.90)	0.3757	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.4283
All negative/normal	1/ 38 (2.6)	2.2	0/ 56 (0.0)	0.0	4.38 (0.18, 104.87)	0.3615	2.18 (-11.23, 15.58)	0.7503	
At least one positive/abnormal	1/ 81 (1.2)	1.2	1/ 65 (1.5)	1.5	0.80 (0.05, 12.58)	0.8755	-0.30 (-6.69, 6.08)	0.9256	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Influenza
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	3 (2.5)	6 (5.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.51 (0.13, 1.99)	
p-value	0.3305	
Odds Ratio (95% CI)	0.50 (0.12, 2.03)	
p-value	0.3292	
Risk Difference (95% CI)	-2.44 (-7.22, 2.35)	
p-value	0.3180	
CMH approach		
Response rate	2.3	4.4
Difference in response rates (95% CI)	-2.08 (-9.53, 5.36)	
p-value	0.5835	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.2349
< 10 points	2/ 41 (4.9)	5.0	1/ 32 (3.1)	3.2	1.56 (0.15, 16.46)	0.7110	1.76 (-15.08, 18.60)	0.8377	
>= 10 points	1/ 78 (1.3)	1.2	5/ 89 (5.6)	5.1	0.23 (0.03, 1.91)	0.1730	-3.96 (-12.47, 4.56)	0.3628	
OCS dose at baseline									0.0869
<10 mg/day	1/ 58 (1.7)	1.7	6/ 65 (9.2)	8.8	0.19 (0.02, 1.51)	0.1151	-7.11 (-18.67, 4.44)	0.2274	
>=10 mg/day	2/ 61 (3.3)	3.0	0/ 56 (0.0)	0.0	4.60 (0.23, 93.72)	0.3214	3.03 (-7.42, 13.47)	0.5702	
Result of type I IFN gene signature test									0.7515
LOW	0/ 23 (0.0)	0.0	1/ 24 (4.2)	4.2	0.35 (0.01, 8.11)	0.5106	-4.17 (-20.53, 12.19)	0.6177	
HIGH	3/ 96 (3.1)	2.9	5/ 97 (5.2)	4.4	0.61 (0.15, 2.47)	0.4845	-1.57 (-9.93, 6.79)	0.7133	
Age (years)									NE
<= 65	3/117 (2.6)	2.3	6/120 (5.0)	4.5	0.51 (0.13, 2.00)	0.3366	-2.13 (-9.67, 5.40)	0.5787	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									0.7662
male	0/ 11 (0.0)	0.0	1/ 12 (8.3)	8.3	0.36 (0.02, 8.04)	0.5200	-8.33 (-38.19, 21.52)	0.5843	
female	3/108 (2.8)	2.6	5/109 (4.6)	4.1	0.61 (0.15, 2.47)	0.4845	-1.57 (-9.61, 6.48)	0.7029	
Race									0.9812
White	1/ 75 (1.3)	1.0	2/ 78 (2.6)	2.5	0.52 (0.05, 5.62)	0.5901	-1.49 (-10.17, 7.19)	0.7367	
Black or African American	0/ 11 (0.0)	0.0	1/ 18 (5.6)	5.6	0.53 (0.02, 11.93)	0.6879	-5.56 (-31.15, 20.04)	0.6705	
Asian	0/ 17 (0.0)	0.0	1/ 16 (6.3)	6.3	0.31 (0.01, 7.21)	0.4694	-6.25 (-28.63, 16.13)	0.5841	
Other	1/ 8 (12.5)	12.5	1/ 6 (16.7)	16.7	0.75 (0.06, 9.72)	0.8258	-4.17 (-51.55, 43.21)	0.8632	
Ethnicity									0.3884
Hispanic/Latino	1/ 27 (3.7)	3.7	1/ 32 (3.1)	3.1	1.19 (0.08, 18.06)	0.9027	0.58 (-14.12, 15.28)	0.9385	
Non-hispanic/Latino	1/ 84 (1.2)	1.0	4/ 86 (4.7)	4.5	0.26 (0.03, 2.24)	0.2185	-3.47 (-11.74, 4.79)	0.4099	
Geographic region									0.7429
EU	1/ 45 (2.2)	2.2	2/ 33 (6.1)	6.1	0.37 (0.03, 3.88)	0.4043	-3.84 (-16.54, 8.86)	0.5536	
non-EU	2/ 74 (2.7)	2.6	4/ 88 (4.5)	4.3	0.59 (0.11, 3.16)	0.5415	-1.73 (-10.76, 7.29)	0.7066	
Onset of disease									NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
Adult	3/108 (2.8)	2.6	6/116 (5.2)	4.7	0.54 (0.14, 2.09)	0.3706	-2.14 (-10.06, 5.79)	0.5971	
ADA result									0.8896
Negative	3/115 (2.6)	2.4	5/111 (4.5)	4.0	0.58 (0.14, 2.37)	0.4468	-1.65 (-9.43, 6.13)	0.6775	
Positive (At any time)	0/ 4 (0.0)	0.0	1/ 10 (10.0)	10.0	0.73 (0.04, 15.04)	0.8405	-10.00 (-59.47, 39.47)	0.6920	
BMI (kg/m2) at enrolment									0.4023
< 30	3/ 85 (3.5)	3.6	4/ 89 (4.5)	4.4	0.79 (0.18, 3.41)	0.7468	-0.77 (-9.39, 7.85)	0.8614	
>= 30	0/ 34 (0.0)	0.0	2/ 32 (6.3)	6.3	0.19 (0.01, 3.78)	0.2756	-6.25 (-19.47, 6.97)	0.3543	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.1766
All negative/normal	2/ 38 (5.3)	5.2	2/ 56 (3.6)	3.3	1.47 (0.22, 10.01)	0.6916	1.89 (-12.66, 16.44)	0.7991	
At least one positive/abnormal	1/ 81 (1.2)	1.2	4/ 65 (6.2)	6.2	0.20 (0.02, 1.75)	0.1462	-4.92 (-12.86, 3.02)	0.2247	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Influenza
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	0 (0.0)	1 (0.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.34 (0.01, 8.24)	
p-value	0.5062	
Odds Ratio (95% CI)	0.34 (0.01, 8.33)	
p-value	0.5057	
Risk Difference (95% CI)	-0.83 (-2.44, 0.79)	
p-value	0.3153	
CMH approach		
Response rate	0.0	0.7
Difference in response rates (95% CI)	-0.71 (-7.33, 5.91)	
p-value	0.8329	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-15.48, 15.48)	1.0000	
>= 10 points	0/ 78 (0.0)	0.0	1/ 89 (1.1)	1.0	0.38 (0.02, 9.19)	0.5514	-1.02 (-8.60, 6.55)	0.7909	
OCS dose at baseline									NE
<10 mg/day	0/ 58 (0.0)	0.0	1/ 65 (1.5)	1.4	0.37 (0.02, 8.98)	0.5433	-1.39 (-11.40, 8.62)	0.7851	
>=10 mg/day	0/ 61 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-9.81, 9.81)	1.0000	
Result of type I IFN gene signature test									NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	1/ 97 (1.0)	0.9	0.34 (0.01, 8.17)	0.5035	-0.89 (-8.28, 6.50)	0.8138	
Age (years)									NE
<= 65	0/117 (0.0)	0.0	1/120 (0.8)	0.7	0.34 (0.01, 8.31)	0.5096	-0.73 (-7.42, 5.96)	0.8302	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	1/109 (0.9)	0.8	0.34 (0.01, 8.17)	0.5032	-0.81 (-8.04, 6.41)	0.8254	
Race									NE
White	0/ 75 (0.0)	0.0	1/ 78 (1.3)	1.3	0.35 (0.01, 8.37)	0.5143	-1.27 (-9.51, 6.98)	0.7635	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE		0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE		0.00 (-41.13, 41.13)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	1/ 86 (1.2)	1.1	0.34 (0.01, 8.26)	0.5084	-1.13 (-8.54, 6.29)	0.7658	
Geographic region									NE
EU	0/ 45 (0.0)	0.0	0/ 33 (0.0)	0.0	NE		0.00 (-9.64, 9.64)	1.0000	
non-EU	0/ 74 (0.0)	0.0	1/ 88 (1.1)	1.1	0.40 (0.02, 9.57)	0.5683	-1.06 (-8.92, 6.80)	0.7910	
Onset of disease									NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
Adult	0/108 (0.0)	0.0	1/116 (0.9)	0.8	0.36 (0.01, 8.69)	0.5277	-0.77 (-7.79, 6.25)	0.8302	
ADA result									NE
Negative	0/115 (0.0)	0.0	1/111 (0.9)	0.8	0.32 (0.01, 7.82)	0.4861	-0.78 (-7.78, 6.21)	0.8265	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE		0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/ 85 (0.0)	0.0	0/ 89 (0.0)	0.0	NE		0.00 (-6.95, 6.95)	1.0000	
>= 30	0/ 34 (0.0)	0.0	1/ 32 (3.1)	3.1	0.31 (0.01, 7.45)	0.4735	-3.13 (-15.29, 9.04)	0.6147	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	0/ 81 (0.0)	0.0	1/ 65 (1.5)	1.5	0.27 (0.01, 6.48)	0.4180	-1.54 (-7.49, 4.42)	0.6127	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Influenza
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	0 (0.0)	1 (0.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.34 (0.01, 8.24)	
p-value	0.5062	
Odds Ratio (95% CI)	0.34 (0.01, 8.33)	
p-value	0.5057	
Risk Difference (95% CI)	-0.83 (-2.44, 0.79)	
p-value	0.3153	
CMH approach		
Response rate	0.0	0.7
Difference in response rates (95% CI)	-0.71 (-7.33, 5.91)	
p-value	0.8329	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-15.48, 15.48)	1.0000	
>= 10 points	0/ 78 (0.0)	0.0	1/ 89 (1.1)	1.0	0.38 (0.02, 9.19)	0.5514	-1.02 (-8.60, 6.55)	0.7909	
OCS dose at baseline									NE
<10 mg/day	0/ 58 (0.0)	0.0	1/ 65 (1.5)	1.4	0.37 (0.02, 8.98)	0.5433	-1.39 (-11.40, 8.62)	0.7851	
>=10 mg/day	0/ 61 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-9.81, 9.81)	1.0000	
Result of type I IFN gene signature test									NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	1/ 97 (1.0)	0.9	0.34 (0.01, 8.17)	0.5035	-0.89 (-8.28, 6.50)	0.8138	
Age (years)									NE
<= 65	0/117 (0.0)	0.0	1/120 (0.8)	0.7	0.34 (0.01, 8.31)	0.5096	-0.73 (-7.42, 5.96)	0.8302	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	1/109 (0.9)	0.8	0.34 (0.01, 8.17)	0.5032	-0.81 (-8.04, 6.41)	0.8254	
Race									NE
White	0/ 75 (0.0)	0.0	1/ 78 (1.3)	1.3	0.35 (0.01, 8.37)	0.5143	-1.27 (-9.51, 6.98)	0.7635	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE		0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE		0.00 (-41.13, 41.13)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	1/ 86 (1.2)	1.1	0.34 (0.01, 8.26)	0.5084	-1.13 (-8.54, 6.29)	0.7658	
Geographic region									NE
EU	0/ 45 (0.0)	0.0	0/ 33 (0.0)	0.0	NE		0.00 (-9.64, 9.64)	1.0000	
non-EU	0/ 74 (0.0)	0.0	1/ 88 (1.1)	1.1	0.40 (0.02, 9.57)	0.5683	-1.06 (-8.92, 6.80)	0.7910	
Onset of disease									NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
Adult	0/108 (0.0)	0.0	1/116 (0.9)	0.8	0.36 (0.01, 8.69)	0.5277	-0.77 (-7.79, 6.25)	0.8302	
ADA result									NE
Negative	0/115 (0.0)	0.0	1/111 (0.9)	0.8	0.32 (0.01, 7.82)	0.4861	-0.78 (-7.78, 6.21)	0.8265	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE		0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/ 85 (0.0)	0.0	0/ 89 (0.0)	0.0	NE		0.00 (-6.95, 6.95)	1.0000	
>= 30	0/ 34 (0.0)	0.0	1/ 32 (3.1)	3.1	0.31 (0.01, 7.45)	0.4735	-3.13 (-15.29, 9.04)	0.6147	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	0/ 81 (0.0)	0.0	1/ 65 (1.5)	1.5	0.27 (0.01, 6.48)	0.4180	-1.54 (-7.49, 4.42)	0.6127	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Influenza
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	3 (2.5)	5 (4.1)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.61 (0.15, 2.50)	
p-value	0.4918	
Odds Ratio (95% CI)	0.60 (0.14, 2.57)	
p-value	0.4912	
Risk Difference (95% CI)	-1.61 (-6.14, 2.92)	
p-value	0.4856	
CMH approach		
Response rate	2.3	3.7
Difference in response rates (95% CI)	-1.37 (-8.74, 5.99)	
p-value	0.7153	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.2983
< 10 points	2/ 41 (4.9)	5.0	1/ 32 (3.1)	3.2	1.56 (0.15, 16.46)	0.7110	1.76 (-15.08, 18.60)	0.8377	
>= 10 points	1/ 78 (1.3)	1.2	4/ 89 (4.5)	4.1	0.29 (0.03, 2.50)	0.2573	-2.93 (-11.30, 5.44)	0.4926	
OCS dose at baseline									0.1081
<10 mg/day	1/ 58 (1.7)	1.7	5/ 65 (7.7)	7.4	0.22 (0.03, 1.86)	0.1663	-5.72 (-17.07, 5.63)	0.3232	
>=10 mg/day	2/ 61 (3.3)	3.0	0/ 56 (0.0)	0.0	4.60 (0.23, 93.72)	0.3214	3.03 (-7.42, 13.47)	0.5702	
Result of type I IFN gene signature test									0.6600
LOW	0/ 23 (0.0)	0.0	1/ 24 (4.2)	4.2	0.35 (0.01, 8.11)	0.5106	-4.17 (-20.53, 12.19)	0.6177	
HIGH	3/ 96 (3.1)	2.9	4/ 97 (4.1)	3.6	0.76 (0.17, 3.30)	0.7116	-0.68 (-8.93, 7.57)	0.8718	
Age (years)									NE
<= 65	3/117 (2.6)	2.3	5/120 (4.2)	3.7	0.62 (0.15, 2.52)	0.4993	-1.40 (-8.85, 6.05)	0.7122	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									0.6728
male	0/ 11 (0.0)	0.0	1/ 12 (8.3)	8.3	0.36 (0.02, 8.04)	0.5200	-8.33 (-38.19, 21.52)	0.5843	
female	3/108 (2.8)	2.6	4/109 (3.7)	3.3	0.76 (0.17, 3.30)	0.7110	-0.75 (-8.70, 7.19)	0.8528	
Race									0.9512
White	1/ 75 (1.3)	1.0	1/ 78 (1.3)	1.3	1.04 (0.07, 16.33)	0.9777	-0.22 (-8.62, 8.17)	0.9583	
Black or African American	0/ 11 (0.0)	0.0	1/ 18 (5.6)	5.6	0.53 (0.02, 11.93)	0.6879	-5.56 (-31.15, 20.04)	0.6705	
Asian	0/ 17 (0.0)	0.0	1/ 16 (6.3)	6.3	0.31 (0.01, 7.21)	0.4694	-6.25 (-28.63, 16.13)	0.5841	
Other	1/ 8 (12.5)	12.5	1/ 6 (16.7)	16.7	0.75 (0.06, 9.72)	0.8258	-4.17 (-51.55, 43.21)	0.8632	
Ethnicity									0.4893
Hispanic/Latino	1/ 27 (3.7)	3.7	1/ 32 (3.1)	3.1	1.19 (0.08, 18.06)	0.9027	0.58 (-14.12, 15.28)	0.9385	
Non-hispanic/Latino	1/ 84 (1.2)	1.0	3/ 86 (3.5)	3.4	0.34 (0.04, 3.22)	0.3475	-2.35 (-10.38, 5.68)	0.5665	
Geographic region									0.6077
EU	1/ 45 (2.2)	2.2	2/ 33 (6.1)	6.1	0.37 (0.03, 3.88)	0.4043	-3.84 (-16.54, 8.86)	0.5536	
non-EU	2/ 74 (2.7)	2.6	3/ 88 (3.4)	3.2	0.79 (0.14, 4.62)	0.7962	-0.67 (-9.51, 8.17)	0.8817	
Onset of disease									NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
Adult	3/108 (2.8)	2.6	5/116 (4.3)	3.9	0.64 (0.16, 2.63)	0.5406	-1.37 (-9.20, 6.47)	0.7322	
ADA result									0.9940
Negative	3/115 (2.6)	2.4	4/111 (3.6)	3.2	0.72 (0.17, 3.16)	0.6675	-0.87 (-8.55, 6.81)	0.8247	
Positive (At any time)	0/ 4 (0.0)	0.0	1/ 10 (10.0)	10.0	0.73 (0.04, 15.04)	0.8405	-10.00 (-59.47, 39.47)	0.6920	
BMI (kg/m2) at enrolment									0.6069
< 30	3/ 85 (3.5)	3.6	4/ 89 (4.5)	4.4	0.79 (0.18, 3.41)	0.7468	-0.77 (-9.39, 7.85)	0.8614	
>= 30	0/ 34 (0.0)	0.0	1/ 32 (3.1)	3.1	0.31 (0.01, 7.45)	0.4735	-3.13 (-15.29, 9.04)	0.6147	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.2565
All negative/normal	2/ 38 (5.3)	5.2	2/ 56 (3.6)	3.3	1.47 (0.22, 10.01)	0.6916	1.89 (-12.66, 16.44)	0.7991	
At least one positive/abnormal	1/ 81 (1.2)	1.2	3/ 65 (4.6)	4.6	0.27 (0.03, 2.51)	0.2485	-3.38 (-10.86, 4.09)	0.3753	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - MACE
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	1 (0.8)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.05 (0.13, 74.13)	
p-value	0.4933	
Odds Ratio (95% CI)	3.08 (0.12, 76.26)	
p-value	0.4928	
Risk Difference (95% CI)	0.84 (-0.80, 2.48)	
p-value	0.3153	
CMH approach		
Response rate	0.8	0.0
Difference in response rates (95% CI)	0.81 (-5.84, 7.47)	
p-value	0.8112	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - MACE - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-15.48, 15.48)	1.0000	
>= 10 points	1/ 78 (1.3)	1.2	0/ 89 (0.0)	0.0	3.42 (0.14, 82.71)	0.4497	1.17 (-6.47, 8.81)	0.7647	
OCS dose at baseline									NE
<10 mg/day	0/ 58 (0.0)	0.0	0/ 65 (0.0)	0.0	NE		0.00 (-9.71, 9.71)	1.0000	
>=10 mg/day	1/ 61 (1.6)	1.7	0/ 56 (0.0)	0.0	2.76 (0.11, 66.34)	0.5318	1.68 (-8.56, 11.93)	0.7478	
Result of type I IFN gene signature test									NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
HIGH	1/ 96 (1.0)	1.0	0/ 97 (0.0)	0.0	3.03 (0.13, 73.49)	0.4954	1.01 (-6.43, 8.46)	0.7899	
Age (years)									NE
<= 65	1/117 (0.9)	0.8	0/120 (0.0)	0.0	3.08 (0.13, 74.76)	0.4900	0.83 (-5.90, 7.56)	0.8086	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-27.45, 27.45)	1.0000	
female	1/108 (0.9)	0.9	0/109 (0.0)	0.0	3.03 (0.12, 73.51)	0.4961	0.88 (-6.38, 8.13)	0.8124	
Race									NE
White	1/ 75 (1.3)	1.4	0/ 78 (0.0)	0.0	3.12 (0.13, 75.37)	0.4840	1.39 (-6.91, 9.68)	0.7434	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE		0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE		0.00 (-41.13, 41.13)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	1/ 84 (1.2)	1.2	0/ 86 (0.0)	0.0	3.07 (0.13, 74.33)	0.4902	1.24 (-6.23, 8.71)	0.7445	
Geographic region									NE
EU	1/ 45 (2.2)	2.2	0/ 33 (0.0)	0.0	2.22 (0.09, 52.78)	0.6224	2.22 (-8.20, 12.64)	0.6760	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE		0.00 (-7.62, 7.62)	1.0000	
Onset of disease									NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
Adult	1/108 (0.9)	0.9	0/116 (0.0)	0.0	3.22 (0.13, 78.21)	0.4724	0.91 (-6.16, 7.99)	0.7999	
ADA result									NE
Negative	1/115 (0.9)	0.8	0/111 (0.0)	0.0	2.90 (0.12, 70.36)	0.5135	0.81 (-6.20, 7.81)	0.8213	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE		0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/ 85 (0.0)	0.0	0/ 89 (0.0)	0.0	NE		0.00 (-6.95, 6.95)	1.0000	
>= 30	1/ 34 (2.9)	2.9	0/ 32 (0.0)	0.0	2.83 (0.12, 67.01)	0.5197	2.94 (-9.11, 14.99)	0.6323	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	1/ 81 (1.2)	1.2	0/ 65 (0.0)	0.0	2.41 (0.10, 58.31)	0.5874	1.23 (-4.49, 6.96)	0.6726	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious MACE
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	1 (0.8)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.05 (0.13, 74.13)	
p-value	0.4933	
Odds Ratio (95% CI)	3.08 (0.12, 76.26)	
p-value	0.4928	
Risk Difference (95% CI)	0.84 (-0.80, 2.48)	
p-value	0.3153	
CMH approach		
Response rate	0.8	0.0
Difference in response rates (95% CI)	0.81 (-5.84, 7.47)	
p-value	0.8112	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious MACE - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-15.48, 15.48)	1.0000	
>= 10 points	1/ 78 (1.3)	1.2	0/ 89 (0.0)	0.0	3.42 (0.14, 82.71)	0.4497	1.17 (-6.47, 8.81)	0.7647	
OCS dose at baseline									NE
<10 mg/day	0/ 58 (0.0)	0.0	0/ 65 (0.0)	0.0	NE		0.00 (-9.71, 9.71)	1.0000	
>=10 mg/day	1/ 61 (1.6)	1.7	0/ 56 (0.0)	0.0	2.76 (0.11, 66.34)	0.5318	1.68 (-8.56, 11.93)	0.7478	
Result of type I IFN gene signature test									NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
HIGH	1/ 96 (1.0)	1.0	0/ 97 (0.0)	0.0	3.03 (0.13, 73.49)	0.4954	1.01 (-6.43, 8.46)	0.7899	
Age (years)									NE
<= 65	1/117 (0.9)	0.8	0/120 (0.0)	0.0	3.08 (0.13, 74.76)	0.4900	0.83 (-5.90, 7.56)	0.8086	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-27.45, 27.45)	1.0000	
female	1/108 (0.9)	0.9	0/109 (0.0)	0.0	3.03 (0.12, 73.51)	0.4961	0.88 (-6.38, 8.13)	0.8124	
Race									NE
White	1/ 75 (1.3)	1.4	0/ 78 (0.0)	0.0	3.12 (0.13, 75.37)	0.4840	1.39 (-6.91, 9.68)	0.7434	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE		0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE		0.00 (-41.13, 41.13)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	1/ 84 (1.2)	1.2	0/ 86 (0.0)	0.0	3.07 (0.13, 74.33)	0.4902	1.24 (-6.23, 8.71)	0.7445	
Geographic region									NE
EU	1/ 45 (2.2)	2.2	0/ 33 (0.0)	0.0	2.22 (0.09, 52.78)	0.6224	2.22 (-8.20, 12.64)	0.6760	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE		0.00 (-7.62, 7.62)	1.0000	
Onset of disease									NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
Adult	1/108 (0.9)	0.9	0/116 (0.0)	0.0	3.22 (0.13, 78.21)	0.4724	0.91 (-6.16, 7.99)	0.7999	
ADA result									NE
Negative	1/115 (0.9)	0.8	0/111 (0.0)	0.0	2.90 (0.12, 70.36)	0.5135	0.81 (-6.20, 7.81)	0.8213	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE		0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/ 85 (0.0)	0.0	0/ 89 (0.0)	0.0	NE		0.00 (-6.95, 6.95)	1.0000	
>= 30	1/ 34 (2.9)	2.9	0/ 32 (0.0)	0.0	2.83 (0.12, 67.01)	0.5197	2.94 (-9.11, 14.99)	0.6323	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	1/ 81 (1.2)	1.2	0/ 65 (0.0)	0.0	2.41 (0.10, 58.31)	0.5874	1.23 (-4.49, 6.96)	0.6726	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe MACE
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	1 (0.8)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.05 (0.13, 74.13)	
p-value	0.4933	
Odds Ratio (95% CI)	3.08 (0.12, 76.26)	
p-value	0.4928	
Risk Difference (95% CI)	0.84 (-0.80, 2.48)	
p-value	0.3153	
CMH approach		
Response rate	0.8	0.0
Difference in response rates (95% CI)	0.81 (-5.84, 7.47)	
p-value	0.8112	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe MACE - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-15.48, 15.48)	1.0000	
>= 10 points	1/ 78 (1.3)	1.2	0/ 89 (0.0)	0.0	3.42 (0.14, 82.71)	0.4497	1.17 (-6.47, 8.81)	0.7647	
OCS dose at baseline									NE
<10 mg/day	0/ 58 (0.0)	0.0	0/ 65 (0.0)	0.0	NE		0.00 (-9.71, 9.71)	1.0000	
>=10 mg/day	1/ 61 (1.6)	1.7	0/ 56 (0.0)	0.0	2.76 (0.11, 66.34)	0.5318	1.68 (-8.56, 11.93)	0.7478	
Result of type I IFN gene signature test									NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
HIGH	1/ 96 (1.0)	1.0	0/ 97 (0.0)	0.0	3.03 (0.13, 73.49)	0.4954	1.01 (-6.43, 8.46)	0.7899	
Age (years)									NE
<= 65	1/117 (0.9)	0.8	0/120 (0.0)	0.0	3.08 (0.13, 74.76)	0.4900	0.83 (-5.90, 7.56)	0.8086	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-27.45, 27.45)	1.0000	
female	1/108 (0.9)	0.9	0/109 (0.0)	0.0	3.03 (0.12, 73.51)	0.4961	0.88 (-6.38, 8.13)	0.8124	
Race									NE
White	1/ 75 (1.3)	1.4	0/ 78 (0.0)	0.0	3.12 (0.13, 75.37)	0.4840	1.39 (-6.91, 9.68)	0.7434	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE		0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE		0.00 (-41.13, 41.13)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	1/ 84 (1.2)	1.2	0/ 86 (0.0)	0.0	3.07 (0.13, 74.33)	0.4902	1.24 (-6.23, 8.71)	0.7445	
Geographic region									NE
EU	1/ 45 (2.2)	2.2	0/ 33 (0.0)	0.0	2.22 (0.09, 52.78)	0.6224	2.22 (-8.20, 12.64)	0.6760	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE		0.00 (-7.62, 7.62)	1.0000	
Onset of disease									NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
Adult	1/108 (0.9)	0.9	0/116 (0.0)	0.0	3.22 (0.13, 78.21)	0.4724	0.91 (-6.16, 7.99)	0.7999	
ADA result									NE
Negative	1/115 (0.9)	0.8	0/111 (0.0)	0.0	2.90 (0.12, 70.36)	0.5135	0.81 (-6.20, 7.81)	0.8213	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE		0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/ 85 (0.0)	0.0	0/ 89 (0.0)	0.0	NE		0.00 (-6.95, 6.95)	1.0000	
>= 30	1/ 34 (2.9)	2.9	0/ 32 (0.0)	0.0	2.83 (0.12, 67.01)	0.5197	2.94 (-9.11, 14.99)	0.6323	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	1/ 81 (1.2)	1.2	0/ 65 (0.0)	0.0	2.41 (0.10, 58.31)	0.5874	1.23 (-4.49, 6.96)	0.6726	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe MACE
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.50, 6.50)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe MACE - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.48, 15.48)	1.0000	
>= 10 points	0/ 78 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-7.36, 7.36)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 58 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-9.71, 9.71)	1.0000	
>=10 mg/day	0/ 61 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.81, 9.81)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	0/ 97 (0.0)	0.0	NE	0.00 (-7.23, 7.23)	1.0000	
Age (years)								NE
<= 65	0/117 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.57, 6.57)	1.0000	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-116.14, 116.14)	1.0000	
Sex								NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	0/109 (0.0)	0.0	NE	0.00 (-7.09, 7.09)	1.0000	
Race								NE
White	0/ 75 (0.0)	0.0	0/ 78 (0.0)	0.0	NE	0.00 (-7.93, 7.93)	1.0000	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE	0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE	0.00 (-41.13, 41.13)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	0/ 86 (0.0)	0.0	NE	0.00 (-7.13, 7.13)	1.0000	
Geographic region								NE
EU	0/ 45 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-9.64, 9.64)	1.0000	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-7.62, 7.62)	1.0000	
Onset of disease								NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
Adult	0/108 (0.0)	0.0	0/116 (0.0)	0.0	NE	0.00 (-6.89, 6.89)	1.0000	
ADA result								NE
Negative	0/115 (0.0)	0.0	0/111 (0.0)	0.0	NE	0.00 (-6.86, 6.86)	1.0000	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE	0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 85 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-6.95, 6.95)	1.0000	
>= 30	0/ 34 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-10.92, 10.92)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	0/ 81 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-5.25, 5.25)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	2 (1.7)	8 (6.6)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.25 (0.06, 1.17)	
p-value	0.0791	
Odds Ratio (95% CI)	0.24 (0.05, 1.16)	
p-value	0.0762	
Risk Difference (95% CI)	-4.93 (-9.92, 0.06)	
p-value	0.0529	
CMH approach		
Response rate	1.8	6.7
Difference in response rates (95% CI)	-4.90 (-12.76, 2.97)	
p-value	0.2222	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9031
< 10 points	0/ 41 (0.0)	0.0	1/ 32 (3.1)	3.5	0.26 (0.01, 6.22)	0.4072	-3.46 (-19.60, 12.69)	0.6746	
>= 10 points	2/ 78 (2.6)	2.6	7/ 89 (7.9)	8.1	0.33 (0.07, 1.52)	0.1542	-5.55 (-15.07, 3.98)	0.2535	
OCS dose at baseline									0.6511
<10 mg/day	1/ 58 (1.7)	1.9	3/ 65 (4.6)	4.2	0.37 (0.04, 3.49)	0.3879	-2.27 (-13.28, 8.74)	0.6862	
>=10 mg/day	1/ 61 (1.6)	1.7	5/ 56 (8.9)	9.4	0.18 (0.02, 1.52)	0.1165	-7.74 (-19.99, 4.51)	0.2155	
Result of type I IFN gene signature test									NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
HIGH	2/ 96 (2.1)	2.2	8/ 97 (8.2)	8.3	0.25 (0.06, 1.16)	0.0767	-6.11 (-15.20, 2.99)	0.1880	
Age (years)									NE
<= 65	2/117 (1.7)	1.8	8/120 (6.7)	6.8	0.26 (0.06, 1.18)	0.0809	-4.95 (-12.89, 2.99)	0.2222	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-27.45, 27.45)	1.0000	
female	2/108 (1.9)	1.9	8/109 (7.3)	7.5	0.25 (0.05, 1.16)	0.0770	-5.58 (-14.16, 2.99)	0.2018	
Race									0.8747
White	2/ 75 (2.7)	2.8	5/ 78 (6.4)	6.7	0.42 (0.08, 2.08)	0.2853	-3.90 (-13.82, 6.02)	0.4411	
Black or African American	0/ 11 (0.0)	0.0	1/ 18 (5.6)	5.6	0.53 (0.02, 11.93)	0.6879	-5.56 (-31.15, 20.04)	0.6705	
Asian	0/ 17 (0.0)	0.0	2/ 16 (12.5)	12.5	0.19 (0.01, 3.66)	0.2703	-12.50 (-36.56, 11.56)	0.3085	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE		0.00 (-41.13, 41.13)	1.0000	
Ethnicity									0.6015
Hispanic/Latino	0/ 27 (0.0)	0.0	3/ 32 (9.4)	9.4	0.17 (0.01, 3.12)	0.2318	-9.38 (-24.52, 5.77)	0.2251	
Non-hispanic/Latino	2/ 84 (2.4)	2.5	5/ 86 (5.8)	5.6	0.41 (0.08, 2.05)	0.2777	-3.15 (-12.08, 5.78)	0.4892	
Geographic region									0.5684
EU	0/ 45 (0.0)	0.0	2/ 33 (6.1)	6.1	0.15 (0.01, 2.98)	0.2123	-6.06 (-18.13, 6.01)	0.3250	
non-EU	2/ 74 (2.7)	2.9	6/ 88 (6.8)	6.7	0.40 (0.08, 1.91)	0.2481	-3.80 (-13.40, 5.79)	0.4373	
Onset of disease									0.5189
Paediatric	1/ 11 (9.1)	9.1	1/ 5 (20.0)	20.0	0.45 (0.04, 5.89)	0.5464	-10.91 (-58.51, 36.69)	0.6533	
Adult	1/108 (0.9)	0.9	7/116 (6.0)	6.0	0.15 (0.02, 1.23)	0.0772	-5.11 (-13.08, 2.87)	0.2096	
ADA result									0.8999
Negative	2/115 (1.7)	1.8	5/111 (4.5)	4.5	0.39 (0.08, 1.95)	0.2493	-2.71 (-10.68, 5.26)	0.5049	
Positive (At any time)	0/ 4 (0.0)	0.0	3/ 10 (30.0)	30.0	0.31 (0.02, 5.01)	0.4125	-30.00 (-81.79, 21.79)	0.2563	
BMI (kg/m2) at enrolment									0.7962
< 30	1/ 85 (1.2)	1.2	5/ 89 (5.6)	5.4	0.21 (0.02, 1.76)	0.1496	-4.22 (-12.66, 4.21)	0.3263	
>= 30	1/ 34 (2.9)	2.9	3/ 32 (9.4)	9.4	0.31 (0.03, 2.86)	0.3041	-6.43 (-21.46, 8.59)	0.4013	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.0710
All negative/normal	2/ 38 (5.3)	5.9	2/ 56 (3.6)	3.1	1.47 (0.22, 10.01)	0.6916	2.86 (-11.83, 17.54)	0.7032	
At least one positive/abnormal	0/ 81 (0.0)	0.0	6/ 65 (9.2)	9.2	0.06 (0.00, 1.08)	0.0564	-9.23 (-17.68, -0.78)	0.0324	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Non-opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	2 (1.7)	8 (6.6)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.25 (0.06, 1.17)	
p-value	0.0791	
Odds Ratio (95% CI)	0.24 (0.05, 1.16)	
p-value	0.0762	
Risk Difference (95% CI)	-4.93 (-9.92, 0.06)	
p-value	0.0529	
CMH approach		
Response rate	1.8	6.7
Difference in response rates (95% CI)	-4.90 (-12.76, 2.97)	
p-value	0.2222	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Non-opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9031
< 10 points	0/ 41 (0.0)	0.0	1/ 32 (3.1)	3.5	0.26 (0.01, 6.22)	0.4072	-3.46 (-19.60, 12.69)	0.6746	
>= 10 points	2/ 78 (2.6)	2.6	7/ 89 (7.9)	8.1	0.33 (0.07, 1.52)	0.1542	-5.55 (-15.07, 3.98)	0.2535	
OCS dose at baseline									0.6511
<10 mg/day	1/ 58 (1.7)	1.9	3/ 65 (4.6)	4.2	0.37 (0.04, 3.49)	0.3879	-2.27 (-13.28, 8.74)	0.6862	
>=10 mg/day	1/ 61 (1.6)	1.7	5/ 56 (8.9)	9.4	0.18 (0.02, 1.52)	0.1165	-7.74 (-19.99, 4.51)	0.2155	
Result of type I IFN gene signature test									NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
HIGH	2/ 96 (2.1)	2.2	8/ 97 (8.2)	8.3	0.25 (0.06, 1.16)	0.0767	-6.11 (-15.20, 2.99)	0.1880	
Age (years)									NE
<= 65	2/117 (1.7)	1.8	8/120 (6.7)	6.8	0.26 (0.06, 1.18)	0.0809	-4.95 (-12.89, 2.99)	0.2222	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-27.45, 27.45)	1.0000	
female	2/108 (1.9)	1.9	8/109 (7.3)	7.5	0.25 (0.05, 1.16)	0.0770	-5.58 (-14.16, 2.99)	0.2018	
Race									0.8747
White	2/ 75 (2.7)	2.8	5/ 78 (6.4)	6.7	0.42 (0.08, 2.08)	0.2853	-3.90 (-13.82, 6.02)	0.4411	
Black or African American	0/ 11 (0.0)	0.0	1/ 18 (5.6)	5.6	0.53 (0.02, 11.93)	0.6879	-5.56 (-31.15, 20.04)	0.6705	
Asian	0/ 17 (0.0)	0.0	2/ 16 (12.5)	12.5	0.19 (0.01, 3.66)	0.2703	-12.50 (-36.56, 11.56)	0.3085	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE		0.00 (-41.13, 41.13)	1.0000	
Ethnicity									0.6015
Hispanic/Latino	0/ 27 (0.0)	0.0	3/ 32 (9.4)	9.4	0.17 (0.01, 3.12)	0.2318	-9.38 (-24.52, 5.77)	0.2251	
Non-hispanic/Latino	2/ 84 (2.4)	2.5	5/ 86 (5.8)	5.6	0.41 (0.08, 2.05)	0.2777	-3.15 (-12.08, 5.78)	0.4892	
Geographic region									0.5684
EU	0/ 45 (0.0)	0.0	2/ 33 (6.1)	6.1	0.15 (0.01, 2.98)	0.2123	-6.06 (-18.13, 6.01)	0.3250	
non-EU	2/ 74 (2.7)	2.9	6/ 88 (6.8)	6.7	0.40 (0.08, 1.91)	0.2481	-3.80 (-13.40, 5.79)	0.4373	
Onset of disease									0.5189
Paediatric	1/ 11 (9.1)	9.1	1/ 5 (20.0)	20.0	0.45 (0.04, 5.89)	0.5464	-10.91 (-58.51, 36.69)	0.6533	
Adult	1/108 (0.9)	0.9	7/116 (6.0)	6.0	0.15 (0.02, 1.23)	0.0772	-5.11 (-13.08, 2.87)	0.2096	
ADA result									0.8999
Negative	2/115 (1.7)	1.8	5/111 (4.5)	4.5	0.39 (0.08, 1.95)	0.2493	-2.71 (-10.68, 5.26)	0.5049	
Positive (At any time)	0/ 4 (0.0)	0.0	3/ 10 (30.0)	30.0	0.31 (0.02, 5.01)	0.4125	-30.00 (-81.79, 21.79)	0.2563	
BMI (kg/m2) at enrolment									0.7962
< 30	1/ 85 (1.2)	1.2	5/ 89 (5.6)	5.4	0.21 (0.02, 1.76)	0.1496	-4.22 (-12.66, 4.21)	0.3263	
>= 30	1/ 34 (2.9)	2.9	3/ 32 (9.4)	9.4	0.31 (0.03, 2.86)	0.3041	-6.43 (-21.46, 8.59)	0.4013	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.0710
All negative/normal	2/ 38 (5.3)	5.9	2/ 56 (3.6)	3.1	1.47 (0.22, 10.01)	0.6916	2.86 (-11.83, 17.54)	0.7032	
At least one positive/abnormal	0/ 81 (0.0)	0.0	6/ 65 (9.2)	9.2	0.06 (0.00, 1.08)	0.0564	-9.23 (-17.68, -0.78)	0.0324	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Non-opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	0 (0.0)	1 (0.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.34 (0.01, 8.24)	
p-value	0.5062	
Odds Ratio (95% CI)	0.34 (0.01, 8.33)	
p-value	0.5057	
Risk Difference (95% CI)	-0.83 (-2.44, 0.79)	
p-value	0.3153	
CMH approach		
Response rate	0.0	0.9
Difference in response rates (95% CI)	-0.88 (-7.55, 5.80)	
p-value	0.7968	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Non-opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-15.48, 15.48)	1.0000	
>= 10 points	0/ 78 (0.0)	0.0	1/ 89 (1.1)	1.3	0.38 (0.02, 9.19)	0.5514	-1.26 (-8.94, 6.42)	0.7475	
OCS dose at baseline									NE
<10 mg/day	0/ 58 (0.0)	0.0	0/ 65 (0.0)	0.0	NE		0.00 (-9.71, 9.71)	1.0000	
>=10 mg/day	0/ 61 (0.0)	0.0	1/ 56 (1.8)	1.8	0.31 (0.01, 7.37)	0.4661	-1.82 (-12.13, 8.49)	0.7297	
Result of type I IFN gene signature test									NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	1/ 97 (1.0)	1.1	0.34 (0.01, 8.17)	0.5035	-1.09 (-8.57, 6.38)	0.7742	
Age (years)									NE
<= 65	0/117 (0.0)	0.0	1/120 (0.8)	0.9	0.34 (0.01, 8.31)	0.5096	-0.88 (-7.62, 5.87)	0.7989	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	1/109 (0.9)	1.0	0.34 (0.01, 8.17)	0.5032	-0.98 (-8.28, 6.31)	0.7912	
Race									NE
White	0/ 75 (0.0)	0.0	1/ 78 (1.3)	1.3	0.35 (0.01, 8.37)	0.5143	-1.27 (-9.51, 6.98)	0.7635	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE		0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE		0.00 (-41.13, 41.13)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 27 (0.0)	0.0	1/ 32 (3.1)	3.1	0.39 (0.02, 9.27)	0.5623	-3.13 (-16.45, 10.20)	0.6458	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	0/ 86 (0.0)	0.0	NE		0.00 (-7.13, 7.13)	1.0000	
Geographic region									NE
EU	0/ 45 (0.0)	0.0	0/ 33 (0.0)	0.0	NE		0.00 (-9.64, 9.64)	1.0000	
non-EU	0/ 74 (0.0)	0.0	1/ 88 (1.1)	1.1	0.40 (0.02, 9.57)	0.5683	-1.06 (-8.92, 6.80)	0.7910	
Onset of disease									NE
Paediatric	0/ 11 (0.0)	0.0	1/ 5 (20.0)	20.0	0.17 (0.01, 3.51)	0.2491	-20.00 (-65.94, 25.94)	0.3936	
Adult	0/108 (0.0)	0.0	0/116 (0.0)	0.0	NE		0.00 (-6.89, 6.89)	1.0000	
ADA result									NE
Negative	0/115 (0.0)	0.0	0/111 (0.0)	0.0	NE		0.00 (-6.86, 6.86)	1.0000	
Positive (At any time)	0/ 4 (0.0)	0.0	1/ 10 (10.0)	10.0	0.73 (0.04, 15.04)	0.8405	-10.00 (-59.47, 39.47)	0.6920	
BMI (kg/m2) at enrolment									NE
< 30	0/ 85 (0.0)	0.0	0/ 89 (0.0)	0.0	NE		0.00 (-6.95, 6.95)	1.0000	
>= 30	0/ 34 (0.0)	0.0	1/ 32 (3.1)	3.1	0.31 (0.01, 7.45)	0.4735	-3.13 (-15.29, 9.04)	0.6147	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	0/ 81 (0.0)	0.0	1/ 65 (1.5)	1.5	0.27 (0.01, 6.48)	0.4180	-1.54 (-7.49, 4.42)	0.6127	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Non-opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	2 (1.7)	7 (5.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.29 (0.06, 1.37)	
p-value	0.1183	
Odds Ratio (95% CI)	0.28 (0.06, 1.37)	
p-value	0.1155	
Risk Difference (95% CI)	-4.10 (-8.86, 0.65)	
p-value	0.0909	
CMH approach		
Response rate	1.8	5.8
Difference in response rates (95% CI)	-4.02 (-11.76, 3.72)	
p-value	0.3086	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Non-opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8362
< 10 points	0/ 41 (0.0)	0.0	1/ 32 (3.1)	3.5	0.26 (0.01, 6.22)	0.4072	-3.46 (-19.60, 12.69)	0.6746	
>= 10 points	2/ 78 (2.6)	2.6	6/ 89 (6.7)	6.9	0.38 (0.08, 1.83)	0.2279	-4.29 (-13.60, 5.02)	0.3667	
OCS dose at baseline									0.7588
<10 mg/day	1/ 58 (1.7)	1.9	3/ 65 (4.6)	4.2	0.37 (0.04, 3.49)	0.3879	-2.27 (-13.28, 8.74)	0.6862	
>=10 mg/day	1/ 61 (1.6)	1.7	4/ 56 (7.1)	7.6	0.23 (0.03, 1.99)	0.1819	-5.92 (-17.82, 5.98)	0.3293	
Result of type I IFN gene signature test									NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
HIGH	2/ 96 (2.1)	2.2	7/ 97 (7.2)	7.2	0.29 (0.06, 1.35)	0.1152	-5.01 (-13.94, 3.91)	0.2709	
Age (years)									NE
<= 65	2/117 (1.7)	1.8	7/120 (5.8)	5.9	0.29 (0.06, 1.38)	0.1208	-4.07 (-11.89, 3.75)	0.3076	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-27.45, 27.45)	1.0000	
female	2/108 (1.9)	1.9	7/109 (6.4)	6.5	0.29 (0.06, 1.36)	0.1156	-4.60 (-13.04, 3.84)	0.2854	
Race									0.8343
White	2/ 75 (2.7)	2.8	4/ 78 (5.1)	5.4	0.52 (0.10, 2.76)	0.4421	-2.63 (-12.33, 7.06)	0.5944	
Black or African American	0/ 11 (0.0)	0.0	1/ 18 (5.6)	5.6	0.53 (0.02, 11.93)	0.6879	-5.56 (-31.15, 20.04)	0.6705	
Asian	0/ 17 (0.0)	0.0	2/ 16 (12.5)	12.5	0.19 (0.01, 3.66)	0.2703	-12.50 (-36.56, 11.56)	0.3085	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE		0.00 (-41.13, 41.13)	1.0000	
Ethnicity									0.7502
Hispanic/Latino	0/ 27 (0.0)	0.0	2/ 32 (6.3)	6.3	0.24 (0.01, 4.71)	0.3442	-6.25 (-20.55, 8.05)	0.3916	
Non-hispanic/Latino	2/ 84 (2.4)	2.5	5/ 86 (5.8)	5.6	0.41 (0.08, 2.05)	0.2777	-3.15 (-12.08, 5.78)	0.4892	
Geographic region									0.5015
EU	0/ 45 (0.0)	0.0	2/ 33 (6.1)	6.1	0.15 (0.01, 2.98)	0.2123	-6.06 (-18.13, 6.01)	0.3250	
non-EU	2/ 74 (2.7)	2.9	5/ 88 (5.7)	5.6	0.48 (0.10, 2.38)	0.3658	-2.74 (-12.17, 6.69)	0.5691	
Onset of disease									0.2257
Paediatric	1/ 11 (9.1)	9.1	0/ 5 (0.0)	0.0	1.50 (0.07, 31.57)	0.7942	9.09 (-34.34, 52.53)	0.6817	
Adult	1/108 (0.9)	0.9	7/116 (6.0)	6.0	0.15 (0.02, 1.23)	0.0772	-5.11 (-13.08, 2.87)	0.2096	
ADA result									0.9376
Negative	2/115 (1.7)	1.8	5/111 (4.5)	4.5	0.39 (0.08, 1.95)	0.2493	-2.71 (-10.68, 5.26)	0.5049	
Positive (At any time)	0/ 4 (0.0)	0.0	2/ 10 (20.0)	20.0	0.44 (0.03, 7.58)	0.5719	-20.00 (-70.84, 30.84)	0.4407	
BMI (kg/m2) at enrolment									0.6167
< 30	1/ 85 (1.2)	1.2	5/ 89 (5.6)	5.4	0.21 (0.02, 1.76)	0.1496	-4.22 (-12.66, 4.21)	0.3263	
>= 30	1/ 34 (2.9)	2.9	2/ 32 (6.3)	6.3	0.47 (0.04, 4.94)	0.5298	-3.31 (-17.48, 10.86)	0.6471	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.0886
All negative/normal	2/ 38 (5.3)	5.9	2/ 56 (3.6)	3.1	1.47 (0.22, 10.01)	0.6916	2.86 (-11.83, 17.54)	0.7032	
At least one positive/abnormal	0/ 81 (0.0)	0.0	5/ 65 (7.7)	7.7	0.07 (0.00, 1.30)	0.0748	-7.69 (-15.74, 0.36)	0.0610	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.50, 6.50)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.48, 15.48)	1.0000	
>= 10 points	0/ 78 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-7.36, 7.36)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 58 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-9.71, 9.71)	1.0000	
>=10 mg/day	0/ 61 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.81, 9.81)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	0/ 97 (0.0)	0.0	NE	0.00 (-7.23, 7.23)	1.0000	
Age (years)								NE
<= 65	0/117 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.57, 6.57)	1.0000	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-116.14, 116.14)	1.0000	
Sex								NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	0/109 (0.0)	0.0	NE	0.00 (-7.09, 7.09)	1.0000	
Race								NE
White	0/ 75 (0.0)	0.0	0/ 78 (0.0)	0.0	NE	0.00 (-7.93, 7.93)	1.0000	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE	0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE	0.00 (-41.13, 41.13)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	0/ 86 (0.0)	0.0	NE	0.00 (-7.13, 7.13)	1.0000	
Geographic region								NE
EU	0/ 45 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-9.64, 9.64)	1.0000	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-7.62, 7.62)	1.0000	
Onset of disease								NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
Adult	0/108 (0.0)	0.0	0/116 (0.0)	0.0	NE	0.00 (-6.89, 6.89)	1.0000	
ADA result								NE
Negative	0/115 (0.0)	0.0	0/111 (0.0)	0.0	NE	0.00 (-6.86, 6.86)	1.0000	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE	0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 85 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-6.95, 6.95)	1.0000	
>= 30	0/ 34 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-10.92, 10.92)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	0/ 81 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-5.25, 5.25)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.50, 6.50)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.48, 15.48)	1.0000	
>= 10 points	0/ 78 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-7.36, 7.36)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 58 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-9.71, 9.71)	1.0000	
>=10 mg/day	0/ 61 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.81, 9.81)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	0/ 97 (0.0)	0.0	NE	0.00 (-7.23, 7.23)	1.0000	
Age (years)								NE
<= 65	0/117 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.57, 6.57)	1.0000	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-116.14, 116.14)	1.0000	
Sex								NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	0/109 (0.0)	0.0	NE	0.00 (-7.09, 7.09)	1.0000	
Race								NE
White	0/ 75 (0.0)	0.0	0/ 78 (0.0)	0.0	NE	0.00 (-7.93, 7.93)	1.0000	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE	0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE	0.00 (-41.13, 41.13)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	0/ 86 (0.0)	0.0	NE	0.00 (-7.13, 7.13)	1.0000	
Geographic region								NE
EU	0/ 45 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-9.64, 9.64)	1.0000	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-7.62, 7.62)	1.0000	
Onset of disease								NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
Adult	0/108 (0.0)	0.0	0/116 (0.0)	0.0	NE	0.00 (-6.89, 6.89)	1.0000	
ADA result								NE
Negative	0/115 (0.0)	0.0	0/111 (0.0)	0.0	NE	0.00 (-6.86, 6.86)	1.0000	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE	0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 85 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-6.95, 6.95)	1.0000	
>= 30	0/ 34 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-10.92, 10.92)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	0/ 81 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-5.25, 5.25)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.50, 6.50)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.48, 15.48)	1.0000	
>= 10 points	0/ 78 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-7.36, 7.36)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 58 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-9.71, 9.71)	1.0000	
>=10 mg/day	0/ 61 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.81, 9.81)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	0/ 97 (0.0)	0.0	NE	0.00 (-7.23, 7.23)	1.0000	
Age (years)								NE
<= 65	0/117 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.57, 6.57)	1.0000	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-116.14, 116.14)	1.0000	
Sex								NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	0/109 (0.0)	0.0	NE	0.00 (-7.09, 7.09)	1.0000	
Race								NE
White	0/ 75 (0.0)	0.0	0/ 78 (0.0)	0.0	NE	0.00 (-7.93, 7.93)	1.0000	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE	0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE	0.00 (-41.13, 41.13)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	0/ 86 (0.0)	0.0	NE	0.00 (-7.13, 7.13)	1.0000	
Geographic region								NE
EU	0/ 45 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-9.64, 9.64)	1.0000	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-7.62, 7.62)	1.0000	
Onset of disease								NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
Adult	0/108 (0.0)	0.0	0/116 (0.0)	0.0	NE	0.00 (-6.89, 6.89)	1.0000	
ADA result								NE
Negative	0/115 (0.0)	0.0	0/111 (0.0)	0.0	NE	0.00 (-6.86, 6.86)	1.0000	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE	0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 85 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-6.95, 6.95)	1.0000	
>= 30	0/ 34 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-10.92, 10.92)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	0/ 81 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-5.25, 5.25)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.50, 6.50)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.48, 15.48)	1.0000	
>= 10 points	0/ 78 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-7.36, 7.36)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 58 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-9.71, 9.71)	1.0000	
>=10 mg/day	0/ 61 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.81, 9.81)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	0/ 97 (0.0)	0.0	NE	0.00 (-7.23, 7.23)	1.0000	
Age (years)								NE
<= 65	0/117 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.57, 6.57)	1.0000	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-116.14, 116.14)	1.0000	
Sex								NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	0/109 (0.0)	0.0	NE	0.00 (-7.09, 7.09)	1.0000	
Race								NE
White	0/ 75 (0.0)	0.0	0/ 78 (0.0)	0.0	NE	0.00 (-7.93, 7.93)	1.0000	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE	0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE	0.00 (-41.13, 41.13)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	0/ 86 (0.0)	0.0	NE	0.00 (-7.13, 7.13)	1.0000	
Geographic region								NE
EU	0/ 45 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-9.64, 9.64)	1.0000	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-7.62, 7.62)	1.0000	
Onset of disease								NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
Adult	0/108 (0.0)	0.0	0/116 (0.0)	0.0	NE	0.00 (-6.89, 6.89)	1.0000	
ADA result								NE
Negative	0/115 (0.0)	0.0	0/111 (0.0)	0.0	NE	0.00 (-6.86, 6.86)	1.0000	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE	0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 85 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-6.95, 6.95)	1.0000	
>= 30	0/ 34 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-10.92, 10.92)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	0/ 81 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-5.25, 5.25)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	2 (1.7)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	5.08 (0.25, 104.78)	
p-value	0.2923	
Odds Ratio (95% CI)	5.17 (0.25, 108.84)	
p-value	0.2906	
Risk Difference (95% CI)	1.68 (-0.63, 3.99)	
p-value	0.1538	
CMH approach		
Response rate	1.7	0.0
Difference in response rates (95% CI)	1.66 (-5.11, 8.42)	
p-value	0.6315	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8713
< 10 points	1/ 41 (2.4)	2.8	0/ 32 (0.0)	0.0	2.36 (0.10, 56.00)	0.5958	2.81 (-13.19, 18.81)	0.7307	
>= 10 points	1/ 78 (1.3)	1.2	0/ 89 (0.0)	0.0	3.42 (0.14, 82.71)	0.4497	1.17 (-6.47, 8.81)	0.7647	
OCS dose at baseline									0.9319
<10 mg/day	1/ 58 (1.7)	1.7	0/ 65 (0.0)	0.0	3.36 (0.14, 80.80)	0.4557	1.65 (-8.35, 11.65)	0.7463	
>=10 mg/day	1/ 61 (1.6)	1.7	0/ 56 (0.0)	0.0	2.76 (0.11, 66.34)	0.5318	1.68 (-8.56, 11.93)	0.7478	
Result of type I IFN gene signature test									NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
HIGH	2/ 96 (2.1)	2.1	0/ 97 (0.0)	0.0	5.05 (0.25, 103.86)	0.2937	2.06 (-5.53, 9.66)	0.5942	
Age (years)									NE
<= 65	2/117 (1.7)	1.7	0/120 (0.0)	0.0	5.13 (0.25, 105.67)	0.2897	1.69 (-5.15, 8.52)	0.6291	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-27.45, 27.45)	1.0000	
female	2/108 (1.9)	1.8	0/109 (0.0)	0.0	5.05 (0.25, 103.89)	0.2943	1.85 (-5.53, 9.23)	0.6238	
Race									NE
White	2/ 75 (2.7)	2.4	0/ 78 (0.0)	0.0	5.20 (0.25, 106.50)	0.2848	2.43 (-6.02, 10.88)	0.5734	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE		0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE		0.00 (-41.13, 41.13)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	2/ 84 (2.4)	2.3	0/ 86 (0.0)	0.0	5.12 (0.25, 105.04)	0.2896	2.26 (-5.38, 9.90)	0.5627	
Geographic region									NE
EU	2/ 45 (4.4)	4.4	0/ 33 (0.0)	0.0	3.70 (0.18, 74.51)	0.3937	4.44 (-6.67, 15.56)	0.4332	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE		0.00 (-7.62, 7.62)	1.0000	
Onset of disease									NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
Adult	2/108 (1.9)	1.8	0/116 (0.0)	0.0	5.37 (0.26, 110.54)	0.2763	1.82 (-5.37, 9.01)	0.6206	
ADA result									NE
Negative	2/115 (1.7)	1.7	0/111 (0.0)	0.0	4.83 (0.23, 99.44)	0.3077	1.71 (-5.42, 8.83)	0.6389	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE		0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment									0.9637
< 30	1/ 85 (1.2)	1.2	0/ 89 (0.0)	0.0	3.14 (0.13, 76.02)	0.4817	1.22 (-6.06, 8.50)	0.7429	
>= 30	1/ 34 (2.9)	2.9	0/ 32 (0.0)	0.0	2.83 (0.12, 67.01)	0.5197	2.94 (-9.11, 14.99)	0.6323	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.7948
All negative/normal	1/ 38 (2.6)	2.2	0/ 56 (0.0)	0.0	4.38 (0.18, 104.87)	0.3615	2.18 (-11.23, 15.58)	0.7503	
At least one positive/abnormal	1/ 81 (1.2)	1.2	0/ 65 (0.0)	0.0	2.41 (0.10, 58.31)	0.5874	1.23 (-4.49, 6.96)	0.6726	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.50, 6.50)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.48, 15.48)	1.0000	
>= 10 points	0/ 78 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-7.36, 7.36)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 58 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-9.71, 9.71)	1.0000	
>=10 mg/day	0/ 61 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.81, 9.81)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	0/ 97 (0.0)	0.0	NE	0.00 (-7.23, 7.23)	1.0000	
Age (years)								NE
<= 65	0/117 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.57, 6.57)	1.0000	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-116.14, 116.14)	1.0000	
Sex								NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	0/109 (0.0)	0.0	NE	0.00 (-7.09, 7.09)	1.0000	
Race								NE
White	0/ 75 (0.0)	0.0	0/ 78 (0.0)	0.0	NE	0.00 (-7.93, 7.93)	1.0000	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE	0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE	0.00 (-41.13, 41.13)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	0/ 86 (0.0)	0.0	NE	0.00 (-7.13, 7.13)	1.0000	
Geographic region								NE
EU	0/ 45 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-9.64, 9.64)	1.0000	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-7.62, 7.62)	1.0000	
Onset of disease								NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
Adult	0/108 (0.0)	0.0	0/116 (0.0)	0.0	NE	0.00 (-6.89, 6.89)	1.0000	
ADA result								NE
Negative	0/115 (0.0)	0.0	0/111 (0.0)	0.0	NE	0.00 (-6.86, 6.86)	1.0000	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE	0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 85 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-6.95, 6.95)	1.0000	
>= 30	0/ 34 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-10.92, 10.92)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	0/ 81 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-5.25, 5.25)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.50, 6.50)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.48, 15.48)	1.0000	
>= 10 points	0/ 78 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-7.36, 7.36)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 58 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-9.71, 9.71)	1.0000	
>=10 mg/day	0/ 61 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.81, 9.81)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	0/ 97 (0.0)	0.0	NE	0.00 (-7.23, 7.23)	1.0000	
Age (years)								NE
<= 65	0/117 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.57, 6.57)	1.0000	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-116.14, 116.14)	1.0000	
Sex								NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	0/109 (0.0)	0.0	NE	0.00 (-7.09, 7.09)	1.0000	
Race								NE
White	0/ 75 (0.0)	0.0	0/ 78 (0.0)	0.0	NE	0.00 (-7.93, 7.93)	1.0000	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE	0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE	0.00 (-41.13, 41.13)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	0/ 86 (0.0)	0.0	NE	0.00 (-7.13, 7.13)	1.0000	
Geographic region								NE
EU	0/ 45 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-9.64, 9.64)	1.0000	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-7.62, 7.62)	1.0000	
Onset of disease								NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
Adult	0/108 (0.0)	0.0	0/116 (0.0)	0.0	NE	0.00 (-6.89, 6.89)	1.0000	
ADA result								NE
Negative	0/115 (0.0)	0.0	0/111 (0.0)	0.0	NE	0.00 (-6.86, 6.86)	1.0000	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE	0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 85 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-6.95, 6.95)	1.0000	
>= 30	0/ 34 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-10.92, 10.92)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	0/ 81 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-5.25, 5.25)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	2 (1.7)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	5.08 (0.25, 104.78)	
p-value	0.2923	
Odds Ratio (95% CI)	5.17 (0.25, 108.84)	
p-value	0.2906	
Risk Difference (95% CI)	1.68 (-0.63, 3.99)	
p-value	0.1538	
CMH approach		
Response rate	1.7	0.0
Difference in response rates (95% CI)	1.66 (-5.11, 8.42)	
p-value	0.6315	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8713
< 10 points	1/ 41 (2.4)	2.8	0/ 32 (0.0)	0.0	2.36 (0.10, 56.00)	0.5958	2.81 (-13.19, 18.81)	0.7307	
>= 10 points	1/ 78 (1.3)	1.2	0/ 89 (0.0)	0.0	3.42 (0.14, 82.71)	0.4497	1.17 (-6.47, 8.81)	0.7647	
OCS dose at baseline									0.9319
<10 mg/day	1/ 58 (1.7)	1.7	0/ 65 (0.0)	0.0	3.36 (0.14, 80.80)	0.4557	1.65 (-8.35, 11.65)	0.7463	
>=10 mg/day	1/ 61 (1.6)	1.7	0/ 56 (0.0)	0.0	2.76 (0.11, 66.34)	0.5318	1.68 (-8.56, 11.93)	0.7478	
Result of type I IFN gene signature test									NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
HIGH	2/ 96 (2.1)	2.1	0/ 97 (0.0)	0.0	5.05 (0.25, 103.86)	0.2937	2.06 (-5.53, 9.66)	0.5942	
Age (years)									NE
<= 65	2/117 (1.7)	1.7	0/120 (0.0)	0.0	5.13 (0.25, 105.67)	0.2897	1.69 (-5.15, 8.52)	0.6291	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-27.45, 27.45)	1.0000	
female	2/108 (1.9)	1.8	0/109 (0.0)	0.0	5.05 (0.25, 103.89)	0.2943	1.85 (-5.53, 9.23)	0.6238	
Race									NE
White	2/ 75 (2.7)	2.4	0/ 78 (0.0)	0.0	5.20 (0.25, 106.50)	0.2848	2.43 (-6.02, 10.88)	0.5734	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE		0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE		0.00 (-41.13, 41.13)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	2/ 84 (2.4)	2.3	0/ 86 (0.0)	0.0	5.12 (0.25, 105.04)	0.2896	2.26 (-5.38, 9.90)	0.5627	
Geographic region									NE
EU	2/ 45 (4.4)	4.4	0/ 33 (0.0)	0.0	3.70 (0.18, 74.51)	0.3937	4.44 (-6.67, 15.56)	0.4332	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE		0.00 (-7.62, 7.62)	1.0000	
Onset of disease									NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
Adult	2/108 (1.9)	1.8	0/116 (0.0)	0.0	5.37 (0.26, 110.54)	0.2763	1.82 (-5.37, 9.01)	0.6206	
ADA result									NE
Negative	2/115 (1.7)	1.7	0/111 (0.0)	0.0	4.83 (0.23, 99.44)	0.3077	1.71 (-5.42, 8.83)	0.6389	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE		0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment									0.9637
< 30	1/ 85 (1.2)	1.2	0/ 89 (0.0)	0.0	3.14 (0.13, 76.02)	0.4817	1.22 (-6.06, 8.50)	0.7429	
>= 30	1/ 34 (2.9)	2.9	0/ 32 (0.0)	0.0	2.83 (0.12, 67.01)	0.5197	2.94 (-9.11, 14.99)	0.6323	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.7948
All negative/normal	1/ 38 (2.6)	2.2	0/ 56 (0.0)	0.0	4.38 (0.18, 104.87)	0.3615	2.18 (-11.23, 15.58)	0.7503	
At least one positive/abnormal	1/ 81 (1.2)	1.2	0/ 65 (0.0)	0.0	2.41 (0.10, 58.31)	0.5874	1.23 (-4.49, 6.96)	0.6726	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Vasculitis
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.50, 6.50)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.48, 15.48)	1.0000	
>= 10 points	0/ 78 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-7.36, 7.36)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 58 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-9.71, 9.71)	1.0000	
>=10 mg/day	0/ 61 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.81, 9.81)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	0/ 97 (0.0)	0.0	NE	0.00 (-7.23, 7.23)	1.0000	
Age (years)								NE
<= 65	0/117 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.57, 6.57)	1.0000	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-116.14, 116.14)	1.0000	
Sex								NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	0/109 (0.0)	0.0	NE	0.00 (-7.09, 7.09)	1.0000	
Race								NE
White	0/ 75 (0.0)	0.0	0/ 78 (0.0)	0.0	NE	0.00 (-7.93, 7.93)	1.0000	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE	0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE	0.00 (-41.13, 41.13)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	0/ 86 (0.0)	0.0	NE	0.00 (-7.13, 7.13)	1.0000	
Geographic region								NE
EU	0/ 45 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-9.64, 9.64)	1.0000	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-7.62, 7.62)	1.0000	
Onset of disease								NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
Adult	0/108 (0.0)	0.0	0/116 (0.0)	0.0	NE	0.00 (-6.89, 6.89)	1.0000	
ADA result								NE
Negative	0/115 (0.0)	0.0	0/111 (0.0)	0.0	NE	0.00 (-6.86, 6.86)	1.0000	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE	0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 85 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-6.95, 6.95)	1.0000	
>= 30	0/ 34 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-10.92, 10.92)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	0/ 81 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-5.25, 5.25)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Vasculitis
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.50, 6.50)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.48, 15.48)	1.0000	
>= 10 points	0/ 78 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-7.36, 7.36)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 58 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-9.71, 9.71)	1.0000	
>=10 mg/day	0/ 61 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.81, 9.81)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	0/ 97 (0.0)	0.0	NE	0.00 (-7.23, 7.23)	1.0000	
Age (years)								NE
<= 65	0/117 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.57, 6.57)	1.0000	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-116.14, 116.14)	1.0000	
Sex								NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	0/109 (0.0)	0.0	NE	0.00 (-7.09, 7.09)	1.0000	
Race								NE
White	0/ 75 (0.0)	0.0	0/ 78 (0.0)	0.0	NE	0.00 (-7.93, 7.93)	1.0000	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE	0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE	0.00 (-41.13, 41.13)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	0/ 86 (0.0)	0.0	NE	0.00 (-7.13, 7.13)	1.0000	
Geographic region								NE
EU	0/ 45 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-9.64, 9.64)	1.0000	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-7.62, 7.62)	1.0000	
Onset of disease								NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
Adult	0/108 (0.0)	0.0	0/116 (0.0)	0.0	NE	0.00 (-6.89, 6.89)	1.0000	
ADA result								NE
Negative	0/115 (0.0)	0.0	0/111 (0.0)	0.0	NE	0.00 (-6.86, 6.86)	1.0000	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE	0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 85 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-6.95, 6.95)	1.0000	
>= 30	0/ 34 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-10.92, 10.92)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	0/ 81 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-5.25, 5.25)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Vasculitis
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.50, 6.50)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.48, 15.48)	1.0000	
>= 10 points	0/ 78 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-7.36, 7.36)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 58 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-9.71, 9.71)	1.0000	
>=10 mg/day	0/ 61 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.81, 9.81)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	0/ 97 (0.0)	0.0	NE	0.00 (-7.23, 7.23)	1.0000	
Age (years)								NE
<= 65	0/117 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.57, 6.57)	1.0000	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-116.14, 116.14)	1.0000	
Sex								NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	0/109 (0.0)	0.0	NE	0.00 (-7.09, 7.09)	1.0000	
Race								NE
White	0/ 75 (0.0)	0.0	0/ 78 (0.0)	0.0	NE	0.00 (-7.93, 7.93)	1.0000	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE	0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE	0.00 (-41.13, 41.13)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	0/ 86 (0.0)	0.0	NE	0.00 (-7.13, 7.13)	1.0000	
Geographic region								NE
EU	0/ 45 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-9.64, 9.64)	1.0000	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-7.62, 7.62)	1.0000	
Onset of disease								NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
Adult	0/108 (0.0)	0.0	0/116 (0.0)	0.0	NE	0.00 (-6.89, 6.89)	1.0000	
ADA result								NE
Negative	0/115 (0.0)	0.0	0/111 (0.0)	0.0	NE	0.00 (-6.86, 6.86)	1.0000	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE	0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 85 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-6.95, 6.95)	1.0000	
>= 30	0/ 34 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-10.92, 10.92)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	0/ 81 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-5.25, 5.25)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Vasculitis
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.50, 6.50)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.48, 15.48)	1.0000	
>= 10 points	0/ 78 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-7.36, 7.36)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 58 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-9.71, 9.71)	1.0000	
>=10 mg/day	0/ 61 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.81, 9.81)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	0/ 97 (0.0)	0.0	NE	0.00 (-7.23, 7.23)	1.0000	
Age (years)								NE
<= 65	0/117 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.57, 6.57)	1.0000	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-116.14, 116.14)	1.0000	
Sex								NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	0/109 (0.0)	0.0	NE	0.00 (-7.09, 7.09)	1.0000	
Race								NE
White	0/ 75 (0.0)	0.0	0/ 78 (0.0)	0.0	NE	0.00 (-7.93, 7.93)	1.0000	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE	0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE	0.00 (-41.13, 41.13)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	0/ 86 (0.0)	0.0	NE	0.00 (-7.13, 7.13)	1.0000	
Geographic region								NE
EU	0/ 45 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-9.64, 9.64)	1.0000	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-7.62, 7.62)	1.0000	
Onset of disease								NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
Adult	0/108 (0.0)	0.0	0/116 (0.0)	0.0	NE	0.00 (-6.89, 6.89)	1.0000	
ADA result								NE
Negative	0/115 (0.0)	0.0	0/111 (0.0)	0.0	NE	0.00 (-6.86, 6.86)	1.0000	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE	0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 85 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-6.95, 6.95)	1.0000	
>= 30	0/ 34 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-10.92, 10.92)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	0/ 81 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-5.25, 5.25)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Malignancy
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	0 (0.0)	1 (0.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.34 (0.01, 8.24)	
p-value	0.5062	
Odds Ratio (95% CI)	0.34 (0.01, 8.33)	
p-value	0.5057	
Risk Difference (95% CI)	-0.83 (-2.44, 0.79)	
p-value	0.3153	
CMH approach		
Response rate	0.0	0.9
Difference in response rates (95% CI)	-0.88 (-7.55, 5.80)	
p-value	0.7968	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-15.48, 15.48)	1.0000	
>= 10 points	0/ 78 (0.0)	0.0	1/ 89 (1.1)	1.3	0.38 (0.02, 9.19)	0.5514	-1.26 (-8.94, 6.42)	0.7475	
OCS dose at baseline									NE
<10 mg/day	0/ 58 (0.0)	0.0	0/ 65 (0.0)	0.0	NE		0.00 (-9.71, 9.71)	1.0000	
>=10 mg/day	0/ 61 (0.0)	0.0	1/ 56 (1.8)	1.8	0.31 (0.01, 7.37)	0.4661	-1.82 (-12.13, 8.49)	0.7297	
Result of type I IFN gene signature test									NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	1/ 97 (1.0)	1.1	0.34 (0.01, 8.17)	0.5035	-1.09 (-8.57, 6.38)	0.7742	
Age (years)									NE
<= 65	0/117 (0.0)	0.0	1/120 (0.8)	0.9	0.34 (0.01, 8.31)	0.5096	-0.88 (-7.62, 5.87)	0.7989	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	1/109 (0.9)	1.0	0.34 (0.01, 8.17)	0.5032	-0.98 (-8.28, 6.31)	0.7912	
Race									NE
White	0/ 75 (0.0)	0.0	1/ 78 (1.3)	1.3	0.35 (0.01, 8.37)	0.5143	-1.27 (-9.51, 6.98)	0.7635	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE		0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE		0.00 (-41.13, 41.13)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	1/ 86 (1.2)	1.1	0.34 (0.01, 8.26)	0.5084	-1.13 (-8.54, 6.29)	0.7658	
Geographic region									NE
EU	0/ 45 (0.0)	0.0	1/ 33 (3.0)	3.0	0.25 (0.01, 5.86)	0.3864	-3.03 (-13.99, 7.93)	0.5879	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE		0.00 (-7.62, 7.62)	1.0000	
Onset of disease									NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
Adult	0/108 (0.0)	0.0	1/116 (0.9)	0.9	0.36 (0.01, 8.69)	0.5277	-0.89 (-7.95, 6.18)	0.8054	
ADA result									NE
Negative	0/115 (0.0)	0.0	1/111 (0.9)	1.0	0.32 (0.01, 7.82)	0.4861	-0.99 (-8.06, 6.08)	0.7837	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE		0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/ 85 (0.0)	0.0	1/ 89 (1.1)	1.1	0.35 (0.01, 8.45)	0.5172	-1.09 (-8.31, 6.13)	0.7677	
>= 30	0/ 34 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-10.92, 10.92)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	0/ 81 (0.0)	0.0	1/ 65 (1.5)	1.5	0.27 (0.01, 6.48)	0.4180	-1.54 (-7.49, 4.42)	0.6127	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Malignancy
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	0 (0.0)	1 (0.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.34 (0.01, 8.24)	
p-value	0.5062	
Odds Ratio (95% CI)	0.34 (0.01, 8.33)	
p-value	0.5057	
Risk Difference (95% CI)	-0.83 (-2.44, 0.79)	
p-value	0.3153	
CMH approach		
Response rate	0.0	0.9
Difference in response rates (95% CI)	-0.88 (-7.55, 5.80)	
p-value	0.7968	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-15.48, 15.48)	1.0000	
>= 10 points	0/ 78 (0.0)	0.0	1/ 89 (1.1)	1.3	0.38 (0.02, 9.19)	0.5514	-1.26 (-8.94, 6.42)	0.7475	
OCS dose at baseline									NE
<10 mg/day	0/ 58 (0.0)	0.0	0/ 65 (0.0)	0.0	NE		0.00 (-9.71, 9.71)	1.0000	
>=10 mg/day	0/ 61 (0.0)	0.0	1/ 56 (1.8)	1.8	0.31 (0.01, 7.37)	0.4661	-1.82 (-12.13, 8.49)	0.7297	
Result of type I IFN gene signature test									NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	1/ 97 (1.0)	1.1	0.34 (0.01, 8.17)	0.5035	-1.09 (-8.57, 6.38)	0.7742	
Age (years)									NE
<= 65	0/117 (0.0)	0.0	1/120 (0.8)	0.9	0.34 (0.01, 8.31)	0.5096	-0.88 (-7.62, 5.87)	0.7989	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	1/109 (0.9)	1.0	0.34 (0.01, 8.17)	0.5032	-0.98 (-8.28, 6.31)	0.7912	
Race									NE
White	0/ 75 (0.0)	0.0	1/ 78 (1.3)	1.3	0.35 (0.01, 8.37)	0.5143	-1.27 (-9.51, 6.98)	0.7635	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE		0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE		0.00 (-41.13, 41.13)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	1/ 86 (1.2)	1.1	0.34 (0.01, 8.26)	0.5084	-1.13 (-8.54, 6.29)	0.7658	
Geographic region									NE
EU	0/ 45 (0.0)	0.0	1/ 33 (3.0)	3.0	0.25 (0.01, 5.86)	0.3864	-3.03 (-13.99, 7.93)	0.5879	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE		0.00 (-7.62, 7.62)	1.0000	
Onset of disease									NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
Adult	0/108 (0.0)	0.0	1/116 (0.9)	0.9	0.36 (0.01, 8.69)	0.5277	-0.89 (-7.95, 6.18)	0.8054	
ADA result									NE
Negative	0/115 (0.0)	0.0	1/111 (0.9)	1.0	0.32 (0.01, 7.82)	0.4861	-0.99 (-8.06, 6.08)	0.7837	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE		0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/ 85 (0.0)	0.0	1/ 89 (1.1)	1.1	0.35 (0.01, 8.45)	0.5172	-1.09 (-8.31, 6.13)	0.7677	
>= 30	0/ 34 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-10.92, 10.92)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	0/ 81 (0.0)	0.0	1/ 65 (1.5)	1.5	0.27 (0.01, 6.48)	0.4180	-1.54 (-7.49, 4.42)	0.6127	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Malignancy
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.50, 6.50)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.48, 15.48)	1.0000	
>= 10 points	0/ 78 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-7.36, 7.36)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 58 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-9.71, 9.71)	1.0000	
>=10 mg/day	0/ 61 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.81, 9.81)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	0/ 97 (0.0)	0.0	NE	0.00 (-7.23, 7.23)	1.0000	
Age (years)								NE
<= 65	0/117 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.57, 6.57)	1.0000	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-116.14, 116.14)	1.0000	
Sex								NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	0/109 (0.0)	0.0	NE	0.00 (-7.09, 7.09)	1.0000	
Race								NE
White	0/ 75 (0.0)	0.0	0/ 78 (0.0)	0.0	NE	0.00 (-7.93, 7.93)	1.0000	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE	0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE	0.00 (-41.13, 41.13)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	0/ 86 (0.0)	0.0	NE	0.00 (-7.13, 7.13)	1.0000	
Geographic region								NE
EU	0/ 45 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-9.64, 9.64)	1.0000	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-7.62, 7.62)	1.0000	
Onset of disease								NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
Adult	0/108 (0.0)	0.0	0/116 (0.0)	0.0	NE	0.00 (-6.89, 6.89)	1.0000	
ADA result								NE
Negative	0/115 (0.0)	0.0	0/111 (0.0)	0.0	NE	0.00 (-6.86, 6.86)	1.0000	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE	0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 85 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-6.95, 6.95)	1.0000	
>= 30	0/ 34 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-10.92, 10.92)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	0/ 81 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-5.25, 5.25)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Malignancy
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	0 (0.0)	1 (0.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.34 (0.01, 8.24)	
p-value	0.5062	
Odds Ratio (95% CI)	0.34 (0.01, 8.33)	
p-value	0.5057	
Risk Difference (95% CI)	-0.83 (-2.44, 0.79)	
p-value	0.3153	
CMH approach		
Response rate	0.0	0.9
Difference in response rates (95% CI)	-0.88 (-7.55, 5.80)	
p-value	0.7968	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-15.48, 15.48)	1.0000	
>= 10 points	0/ 78 (0.0)	0.0	1/ 89 (1.1)	1.3	0.38 (0.02, 9.19)	0.5514	-1.26 (-8.94, 6.42)	0.7475	
OCS dose at baseline									NE
<10 mg/day	0/ 58 (0.0)	0.0	0/ 65 (0.0)	0.0	NE		0.00 (-9.71, 9.71)	1.0000	
>=10 mg/day	0/ 61 (0.0)	0.0	1/ 56 (1.8)	1.8	0.31 (0.01, 7.37)	0.4661	-1.82 (-12.13, 8.49)	0.7297	
Result of type I IFN gene signature test									NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	1/ 97 (1.0)	1.1	0.34 (0.01, 8.17)	0.5035	-1.09 (-8.57, 6.38)	0.7742	
Age (years)									NE
<= 65	0/117 (0.0)	0.0	1/120 (0.8)	0.9	0.34 (0.01, 8.31)	0.5096	-0.88 (-7.62, 5.87)	0.7989	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	1/109 (0.9)	1.0	0.34 (0.01, 8.17)	0.5032	-0.98 (-8.28, 6.31)	0.7912	
Race									NE
White	0/ 75 (0.0)	0.0	1/ 78 (1.3)	1.3	0.35 (0.01, 8.37)	0.5143	-1.27 (-9.51, 6.98)	0.7635	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE		0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE		0.00 (-41.13, 41.13)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	1/ 86 (1.2)	1.1	0.34 (0.01, 8.26)	0.5084	-1.13 (-8.54, 6.29)	0.7658	
Geographic region									NE
EU	0/ 45 (0.0)	0.0	1/ 33 (3.0)	3.0	0.25 (0.01, 5.86)	0.3864	-3.03 (-13.99, 7.93)	0.5879	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE		0.00 (-7.62, 7.62)	1.0000	
Onset of disease									NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
Adult	0/108 (0.0)	0.0	1/116 (0.9)	0.9	0.36 (0.01, 8.69)	0.5277	-0.89 (-7.95, 6.18)	0.8054	
ADA result									NE
Negative	0/115 (0.0)	0.0	1/111 (0.9)	1.0	0.32 (0.01, 7.82)	0.4861	-0.99 (-8.06, 6.08)	0.7837	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE		0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/ 85 (0.0)	0.0	1/ 89 (1.1)	1.1	0.35 (0.01, 8.45)	0.5172	-1.09 (-8.31, 6.13)	0.7677	
>= 30	0/ 34 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-10.92, 10.92)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	0/ 81 (0.0)	0.0	1/ 65 (1.5)	1.5	0.27 (0.01, 6.48)	0.4180	-1.54 (-7.49, 4.42)	0.6127	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of SOCs Cardiac disorders and/or Vascular disorders
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	5 (4.2)	7 (5.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.73 (0.24, 2.22)	
p-value	0.5755	
Odds Ratio (95% CI)	0.71 (0.22, 2.32)	
p-value	0.5752	
Risk Difference (95% CI)	-1.58 (-7.09, 3.92)	
p-value	0.5729	
CMH approach		
Response rate	4.3	5.7
Difference in response rates (95% CI)	-1.42 (-9.47, 6.63)	
p-value	0.7294	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of SOCs Cardiac disorders and/or Vascular disorders - Subgroup analysis
Full analysis set

	Anifrolumab 300mg (N=119)		Placebo (N=121)		Analysis Anifrolumab 300mg vs. Placebo				
Subgroup Level	n/ N (%)	Response rate	n/ N (%)	Response rate	Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.2643
< 10 points	1/ 41 (2.4)	2.4	3/ 32 (9.4)	8.8	0.26 (0.03, 2.38)	0.2336	-6.42 (-23.68, 10.84)	0.4659	
>= 10 points	4/ 78 (5.1)	4.9	4/ 89 (4.5)	4.6	1.14 (0.30, 4.41)	0.8483	0.33 (-9.01, 9.68)	0.9444	
OCS dose at baseline									0.3540
<10 mg/day	2/ 58 (3.4)	3.4	5/ 65 (7.7)	7.9	0.45 (0.09, 2.22)	0.3260	-4.48 (-16.27, 7.32)	0.4567	
>=10 mg/day	3/ 61 (4.9)	5.0	2/ 56 (3.6)	3.6	1.38 (0.24, 7.94)	0.7204	1.41 (-10.45, 13.27)	0.8160	
Result of type I IFN gene signature test									0.7734
LOW	1/ 23 (4.3)	4.3	1/ 24 (4.2)	4.2	1.04 (0.07, 15.72)	0.9755	0.18 (-17.65, 18.02)	0.9841	
HIGH	4/ 96 (4.2)	4.3	6/ 97 (6.2)	6.1	0.67 (0.20, 2.31)	0.5301	-1.82 (-10.84, 7.20)	0.6929	
Age (years)									NE
<= 65	5/117 (4.3)	4.4	7/120 (5.8)	5.7	0.73 (0.24, 2.24)	0.5858	-1.38 (-9.52, 6.76)	0.7396	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-27.45, 27.45)	1.0000	
female	5/108 (4.6)	4.7	7/109 (6.4)	6.3	0.72 (0.24, 2.20)	0.5656	-1.61 (-10.38, 7.15)	0.7181	
Race									0.5557
White	4/ 75 (5.3)	5.5	5/ 78 (6.4)	6.2	0.83 (0.23, 2.98)	0.7776	-0.66 (-11.03, 9.71)	0.9000	
Black or African American	0/ 11 (0.0)	0.0	2/ 18 (11.1)	11.1	0.32 (0.02, 6.04)	0.4447	-11.11 (-37.96, 15.74)	0.4174	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE		0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE		0.00 (-41.13, 41.13)	1.0000	
Ethnicity									0.6228
Hispanic/Latino	1/ 27 (3.7)	3.7	3/ 32 (9.4)	9.4	0.40 (0.04, 3.58)	0.4090	-5.67 (-22.04, 10.70)	0.4971	
Non-hispanic/Latino	3/ 84 (3.6)	3.7	4/ 86 (4.7)	4.9	0.77 (0.18, 3.33)	0.7241	-1.22 (-10.15, 7.71)	0.7891	
Geographic region									0.1069
EU	3/ 45 (6.7)	6.7	0/ 33 (0.0)	0.0	5.17 (0.28, 96.88)	0.2715	6.67 (-5.07, 18.40)	0.2656	
non-EU	2/ 74 (2.7)	2.9	7/ 88 (8.0)	8.2	0.34 (0.07, 1.59)	0.1697	-5.26 (-15.06, 4.54)	0.2931	
Onset of disease									0.5928
Paediatric	1/ 11 (9.1)	9.1	0/ 5 (0.0)	0.0	1.50 (0.07, 31.57)	0.7942	9.09 (-34.34, 52.53)	0.6817	
Adult	4/108 (3.7)	3.8	7/116 (6.0)	6.0	0.61 (0.18, 2.04)	0.4253	-2.17 (-10.58, 6.24)	0.6126	
ADA result									0.7018
Negative	4/115 (3.5)	3.5	5/111 (4.5)	4.2	0.77 (0.21, 2.80)	0.6941	-0.69 (-8.75, 7.36)	0.8657	
Positive (At any time)	1/ 4 (25.0)	25.0	2/ 10 (20.0)	20.0	1.25 (0.15, 10.23)	0.8352	5.00 (-50.09, 60.09)	0.8588	
BMI (kg/m2) at enrolment									0.4885
< 30	3/ 85 (3.5)	3.5	3/ 89 (3.4)	3.3	1.05 (0.22, 5.05)	0.9543	0.14 (-8.24, 8.51)	0.9746	
>= 30	2/ 34 (5.9)	5.9	4/ 32 (12.5)	12.5	0.47 (0.09, 2.40)	0.3639	-6.62 (-23.14, 9.91)	0.4326	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.7115
All negative/normal	1/ 38 (2.6)	3.0	3/ 56 (5.4)	6.4	0.49 (0.05, 4.55)	0.5313	-3.43 (-18.12, 11.26)	0.6474	
At least one positive/abnormal	4/ 81 (4.9)	4.9	4/ 65 (6.2)	6.2	0.80 (0.21, 3.09)	0.7488	-1.22 (-10.05, 7.62)	0.7874	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Time to first Onset of Herpes Zoster (on-treatment)
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	8 (6.7)	2 (1.7)
Number of censored subjects, n (%)	111 (93.3)	119 (98.3)
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Anifrolumab 300mg vs. Placebo (adjusted)		
Hazard Ratio (95% CI)	4.25 (0.90, 20.04)	
p-value	0.1097	
Analysis Anifrolumab 300mg vs. Placebo (unadjusted)		
Hazard Ratio (95% CI)	3.86 (0.82, 18.17)	
p-value	0.0659	

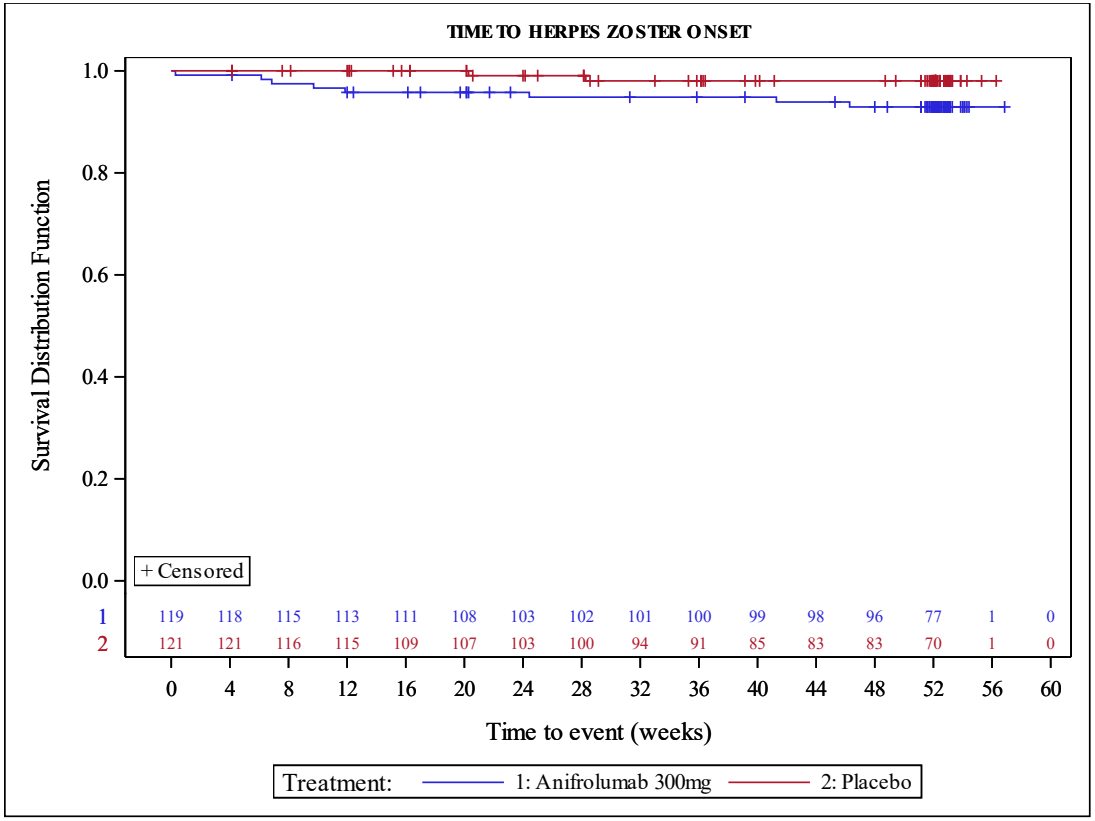
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model. Adjusted analysis also includes stratification factors in the model.
Two-sided log rank test used.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Time to first Onset of Herpes Zoster (on-treatment) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Anifrolumab 300mg (N=119) Median (95% CI)	Placebo (N=121) n/ N (%)	Placebo (N=121) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening							0.9943
< 10 points	1/ 41 (2.4)	NE (NE, NE)	0/ 32 (0.0)	NE (NE, NE)	NE		
>= 10 points	7/ 78 (9.0)	NE (NE, NE)	2/ 89 (2.2)	NE (NE, NE)	3.87 (0.80, 18.66)	0.1391	
OCS dose at baseline							0.9690
<10 mg/day	4/ 58 (6.9)	NE (NE, NE)	1/ 65 (1.5)	NE (NE, NE)	3.63 (0.39, 33.55)	0.3024	
>=10 mg/day	4/ 61 (6.6)	NE (NE, NE)	1/ 56 (1.8)	NE (NE, NE)	3.60 (0.40, 32.25)	0.2199	
Result of type I IFN gene signature test							0.5010
LOW	2/ 23 (8.7)	NE (NE, NE)	1/ 24 (4.2)	NE (NE, NE)	0.95 (0.08, 10.62)	0.9432	
HIGH	6/ 96 (6.3)	NE (NE, NE)	1/ 97 (1.0)	NE (NE, NE)	6.25 (0.75, 52.21)	0.0556	
Age (years)							0.9998
<= 65	8/117 (6.8)	NE (NE, NE)	2/120 (1.7)	NE (NE, NE)	4.25 (0.90, 20.04)	0.1056	
> 65	0/ 2 (0.0)	NE (NE, NE)	0/ 1 (0.0)	NE (NE, NE)	NE		
Sex							0.9935
male	1/ 11 (9.1)	NE (NE, NE)	0/ 12 (0.0)	NE (NE, NE)	NE		
female	7/108 (6.5)	NE (NE, NE)	2/109 (1.8)	NE (NE, NE)	3.61 (0.75, 17.44)	0.2075	
Race							1.0000
White	3/ 75 (4.0)	NE (NE, NE)	1/ 78 (1.3)	NE (NE, NE)	3.53 (0.36, 34.58)	0.4129	
Black or African American	0/ 11 (0.0)	NE (NE, NE)	1/ 18 (5.6)	NE (NE, NE)	NE		
Asian	1/ 17 (5.9)	NE (NE, NE)	0/ 16 (0.0)	NE (NE, NE)	NE		
Other	2/ 8 (25.0)	NE (6.14, NE)	0/ 6 (0.0)	NE (NE, NE)	NE		
Ethnicity							0.9966
Hispanic/Latino	3/ 27 (11.1)	NE (NE, NE)	0/ 32 (0.0)	NE (NE, NE)	NE		
Non-hispanic/Latino	3/ 84 (3.6)	NE (NE, NE)	2/ 86 (2.3)	NE (NE, NE)	1.38 (0.23, 8.47)	0.9976	
Geographic region							0.9938
EU	2/ 45 (4.4)	NE (NE, NE)	0/ 33 (0.0)	NE (NE, NE)	NE		
non-EU	6/ 74 (8.1)	NE (NE, NE)	2/ 88 (2.3)	NE (NE, NE)	4.40 (0.88, 21.97)	0.0890	
Onset of disease							0.9927
Paediatric	2/ 11 (18.2)	NE (24.43, NE)	0/ 5 (0.0)	NE (NE, NE)	NE		
Adult	6/108 (5.6)	NE (NE, NE)	2/116 (1.7)	NE (NE, NE)	3.24 (0.65, 16.13)	0.2397	
ADA result							0.9944
Negative	7/115 (6.1)	NE (NE, NE)	2/111 (1.8)	NE (NE, NE)	3.48 (0.72, 16.80)	0.2135	
Positive (At any time)	1/ 4 (25.0)	NE (0.29, NE)	0/ 10 (0.0)	NE (NE, NE)	NE		
BMI (kg/m2) at enrolment							0.9399
< 30	5/ 85 (5.9)	NE (NE, NE)	1/ 89 (1.1)	NE (NE, NE)	5.14 (0.60, 44.23)	0.1317	
>= 30	3/ 34 (8.8)	NE (NE, NE)	1/ 32 (3.1)	NE (NE, NE)	7.25 (0.55, 95.82)	0.6844	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group							0.5557
All negative/normal	1/ 38 (2.6)	NE (NE, NE)	1/ 56 (1.8)	NE (NE, NE)	0.71 (0.04, 11.79)	0.8084	
At least one positive/abnormal	7/ 81 (8.6)	NE (NE, NE)	1/ 65 (1.5)	NE (NE, NE)	5.58 (0.68, 45.65)	0.0917	

Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of Time to first Onset of Herpes Zoster (on-treatment)
Full analysis set



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Time to first Onset of non-opportunistic serious infection (on-treatment)
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	2 (1.7)	8 (6.6)
Number of censored subjects, n (%)	117 (98.3)	113 (93.4)
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Anifrolumab 300mg vs. Placebo (adjusted)		
Hazard Ratio (95% CI)	0.23 (0.05, 1.10)	
p-value	0.0387	
Analysis Anifrolumab 300mg vs. Placebo (unadjusted)		
Hazard Ratio (95% CI)	0.23 (0.05, 1.08)	
p-value	0.0424	

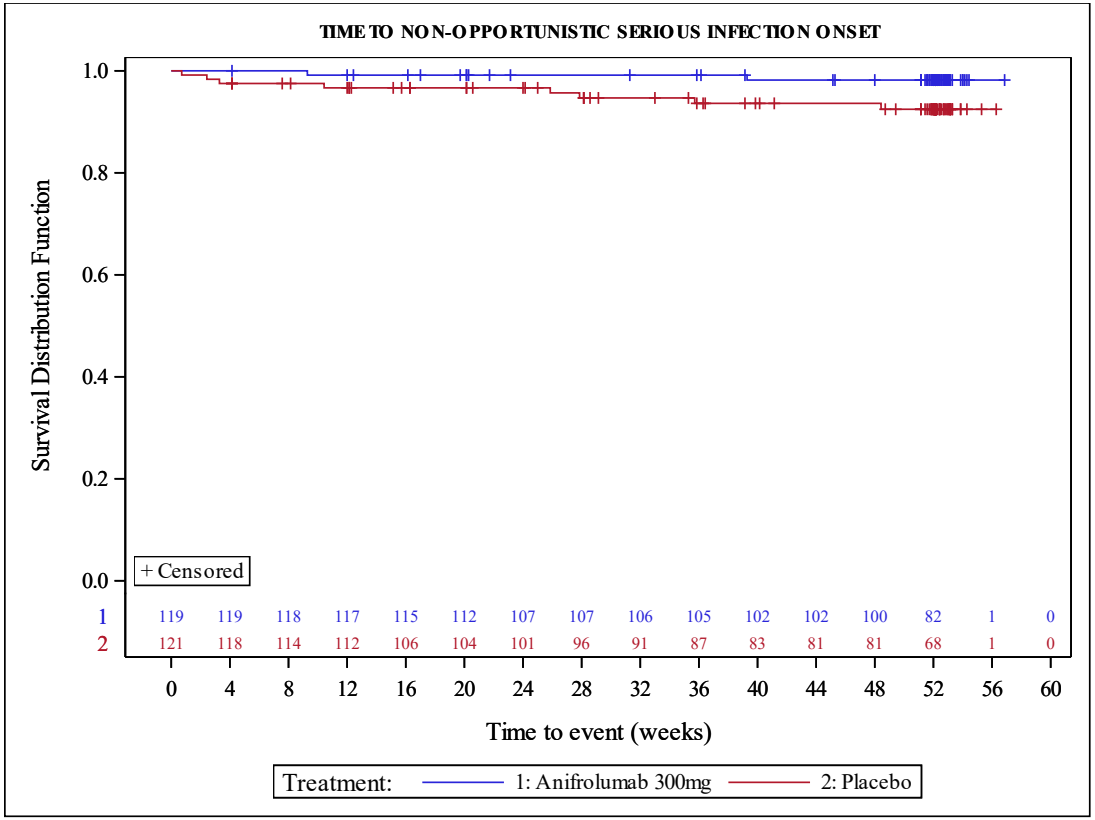
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model. Adjusted analysis also includes stratification factors in the model.
Two-sided log rank test used.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Time to first Onset of non-opportunistic serious infection (on-treatment) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Anifrolumab 300mg (N=119) Median (95% CI)	Placebo (N=121) n/ N (%)	Placebo (N=121) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening							0.9953
< 10 points	0/ 41 (0.0)	NE (NE, NE)	1/ 32 (3.1)	NE (NE, NE)	NE		
>= 10 points	2/ 78 (2.6)	NE (NE, NE)	7/ 89 (7.9)	NE (NE, NE)	0.29 (0.06, 1.39)	0.0929	
OCS dose at baseline							0.5202
<10 mg/day	1/ 58 (1.7)	NE (NE, NE)	3/ 65 (4.6)	NE (NE, NE)	0.44 (0.05, 4.27)	0.4695	
>=10 mg/day	1/ 61 (1.6)	NE (NE, NE)	5/ 56 (8.9)	NE (NE, NE)	0.14 (0.02, 1.21)	0.0372	
Result of type I IFN gene signature test							0.9996
LOW	0/ 23 (0.0)	NE (NE, NE)	0/ 24 (0.0)	NE (NE, NE)	NE		
HIGH	2/ 96 (2.1)	NE (NE, NE)	8/ 97 (8.2)	NE (NE, NE)	0.23 (0.05, 1.10)	0.0387	
Age (years)							0.9999
<= 65	2/117 (1.7)	NE (NE, NE)	8/120 (6.7)	NE (NE, NE)	0.23 (0.05, 1.10)	0.0379	
> 65	0/ 2 (0.0)	NE (NE, NE)	0/ 1 (0.0)	NE (NE, NE)	NE		
Sex							0.9998
male	0/ 11 (0.0)	NE (NE, NE)	0/ 12 (0.0)	NE (NE, NE)	NE		
female	2/108 (1.9)	NE (NE, NE)	8/109 (7.3)	NE (NE, NE)	0.22 (0.05, 1.04)	0.0291	
Race							1.0000
White	2/ 75 (2.7)	NE (NE, NE)	5/ 78 (6.4)	NE (NE, NE)	0.35 (0.07, 1.82)	0.2087	
Black or African American	0/ 11 (0.0)	NE (NE, NE)	1/ 18 (5.6)	NE (NE, NE)	NE		
Asian	0/ 17 (0.0)	NE (NE, NE)	2/ 16 (12.5)	NE (NE, NE)	NE		
Other	0/ 8 (0.0)	NE (NE, NE)	0/ 6 (0.0)	NE (NE, NE)	NE		
Ethnicity							0.9957
Hispanic/Latino	0/ 27 (0.0)	NE (NE, NE)	3/ 32 (9.4)	NE (NE, NE)	NE		
Non-hispanic/Latino	2/ 84 (2.4)	NE (NE, NE)	5/ 86 (5.8)	NE (NE, NE)	0.39 (0.08, 2.05)	0.2353	
Geographic region							0.9949
EU	0/ 45 (0.0)	NE (NE, NE)	2/ 33 (6.1)	NE (NE, NE)	NE		
non-EU	2/ 74 (2.7)	NE (NE, NE)	6/ 88 (6.8)	NE (NE, NE)	0.37 (0.07, 1.89)	0.1998	
Onset of disease							0.4887
Paediatric	1/ 11 (9.1)	NE (NE, NE)	1/ 5 (20.0)	NE (10.43, NE)	1.41 (0.05, 41.08)	0.9596	
Adult	1/108 (0.9)	NE (NE, NE)	7/116 (6.0)	NE (NE, NE)	0.14 (0.02, 1.12)	0.0261	
ADA result							0.9943
Negative	2/115 (1.7)	NE (NE, NE)	5/111 (4.5)	NE (NE, NE)	0.37 (0.07, 1.93)	0.2063	
Positive (At any time)	0/ 4 (0.0)	NE (NE, NE)	3/ 10 (30.0)	NE (10.43, NE)	NE		
BMI (kg/m2) at enrolment							0.8142
< 30	1/ 85 (1.2)	NE (NE, NE)	5/ 89 (5.6)	NE (NE, NE)	0.22 (0.03, 1.86)	0.1250	
>= 30	1/ 34 (2.9)	NE (NE, NE)	3/ 32 (9.4)	NE (NE, NE)	0.12 (0.01, 1.23)	0.0562	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group							0.9931
All negative/normal	2/ 38 (5.3)	NE (NE, NE)	2/ 56 (3.6)	NE (NE, NE)	1.99 (0.26, 15.02)	0.5455	
At least one positive/abnormal	0/ 81 (0.0)	NE (NE, NE)	6/ 65 (9.2)	NE (NE, NE)	NE		

Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of Time to first Onset of non-opportunistic serious infection (on-treatment)
Full analysis set



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=119)	Placebo (N=121)
SOC: Gastrointestinal disorders	Number of subjects with events, n (%)	21 (17.6)	33 (27.3)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.65 (0.40, 1.05)	
	p-value	0.0786	
	Odds Ratio (95% CI)	0.57 (0.31, 1.06)	
	p-value	0.0760	
	Risk Difference (95% CI)	-9.63 (-20.11, 0.86)	
	p-value	0.0719	
	CMH approach		
	Response rate	17.6	27.4
	Difference in response rates (95% CI)	-9.75 (-20.76, 1.26)	
	p-value	0.0827	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=119)	Placebo (N=121)
SOC: General disorders and administration site conditions	Number of subjects with events, n (%)	13 (10.9)	9 (7.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.47 (0.65, 3.31)	
	p-value	0.3531	
	Odds Ratio (95% CI)	1.53 (0.63, 3.72)	
	p-value	0.3521	
	Risk Difference (95% CI)	3.49 (-3.81, 10.78)	
	p-value	0.3492	
	CMH approach		
	Response rate	11.2	7.2
	Difference in response rates (95% CI)	4.01 (-5.01, 13.04)	
	p-value	0.3836	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=119)	Placebo (N=121)
SOC: Infections and infestations	Number of subjects with events, n (%)	81 (68.1)	73 (60.3)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.13 (0.93, 1.36)	
	p-value	0.2128	
	Odds Ratio (95% CI)	1.40 (0.82, 2.38)	
	p-value	0.2121	
	Risk Difference (95% CI)	7.74 (-4.35, 19.83)	
	p-value	0.2097	
	CMH approach		
	Response rate	68.2	59.6
	Difference in response rates (95% CI)	8.56 (-3.67, 20.79)	
	p-value	0.1700	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=119)	Placebo (N=121)
SOC: Infections and infestations, PT: Bronchitis	Number of subjects with events, n (%)	16 (13.4)	7 (5.8)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	2.32 (0.99, 5.45)	
	p-value	0.0522	
	Odds Ratio (95% CI)	2.53 (1.00, 6.39)	
	p-value	0.0498	
	Risk Difference (95% CI)	7.66 (0.25, 15.07)	
	p-value	0.0427	
	CMH approach		
	Response rate	13.7	6.0
	Difference in response rates (95% CI)	7.66 (-1.52, 16.85)	
	p-value	0.1021	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=119)	Placebo (N=121)
SOC: Infections and infestations, PT: Nasopharyngitis	Number of subjects with events, n (%)	17 (14.3)	11 (9.1)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.57 (0.77, 3.21)	
	p-value	0.2153	
	Odds Ratio (95% CI)	1.67 (0.75, 3.73)	
	p-value	0.2135	
	Risk Difference (95% CI)	5.19 (-2.91, 13.30)	
	p-value	0.2093	
	CMH approach		
	Response rate	14.0	8.4
	Difference in response rates (95% CI)	5.56 (-3.77, 14.89)	
	p-value	0.2430	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=119)	Placebo (N=121)
SOC: Infections and infestations, PT: Upper respiratory tract infection	Number of subjects with events, n (%)	27 (22.7)	12 (9.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	2.29 (1.22, 4.30)	
	p-value	0.0102	
	Odds Ratio (95% CI)	2.67 (1.28, 5.56)	
	p-value	0.0089	
	Risk Difference (95% CI)	12.77 (3.55, 21.99)	
	p-value	0.0066	
	CMH approach		
	Response rate	23.0	9.3
	Difference in response rates (95% CI)	13.72 (3.51, 23.93)	
	p-value	0.0084	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=119)	Placebo (N=121)
SOC: Infections and infestations, PT: Urinary tract infection	Number of subjects with events, n (%)	13 (10.9)	15 (12.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.88 (0.44, 1.77)	
	p-value	0.7227	
	Odds Ratio (95% CI)	0.87 (0.39, 1.91)	
	p-value	0.7226	
	Risk Difference (95% CI)	-1.47 (-9.59, 6.64)	
	p-value	0.7222	
	CMH approach		
	Response rate	10.8	12.3
	Difference in response rates (95% CI)	-1.52 (-11.05, 8.01)	
	p-value	0.7545	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=119)	Placebo (N=121)
SOC: Injury, poisoning and procedural complications	Number of subjects with events, n (%)	31 (26.1)	22 (18.2)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.43 (0.88, 2.33)	
	p-value	0.1455	
	Odds Ratio (95% CI)	1.59 (0.86, 2.94)	
	p-value	0.1435	
	Risk Difference (95% CI)	7.87 (-2.59, 18.33)	
	p-value	0.1404	
	CMH approach		
	Response rate	27.0	17.3
	Difference in response rates (95% CI)	9.73 (-1.28, 20.75)	
	p-value	0.0833	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=119)	Placebo (N=121)
SOC: Injury, poisoning and procedural complications, PT: Infusion related reaction	Number of subjects with events, n (%)	18 (15.1)	10 (8.3)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.83 (0.88, 3.80)	
	p-value	0.1048	
	Odds Ratio (95% CI)	1.98 (0.87, 4.49)	
	p-value	0.1024	
	Risk Difference (95% CI)	6.86 (-1.23, 14.96)	
	p-value	0.0966	
	CMH approach		
	Response rate	15.9	7.6
	Difference in response rates (95% CI)	8.38 (-1.10, 17.86)	
	p-value	0.0833	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=119)	Placebo (N=121)
SOC: Metabolism and nutrition disorders	Number of subjects with events, n (%)	5 (4.2)	10 (8.3)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.51 (0.18, 1.44)	
	p-value	0.2038	
	Odds Ratio (95% CI)	0.49 (0.16, 1.47)	
	p-value	0.2016	
	Risk Difference (95% CI)	-4.06 (-10.15, 2.03)	
	p-value	0.1909	
	CMH approach		
	Response rate	4.3	8.0
	Difference in response rates (95% CI)	-3.75 (-12.04, 4.54)	
	p-value	0.3753	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=119)	Placebo (N=121)
SOC: Musculoskeletal and connective tissue disorders	Number of subjects with events, n (%)	28 (23.5)	22 (18.2)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.29 (0.79, 2.13)	
	p-value	0.3100	
	Odds Ratio (95% CI)	1.38 (0.74, 2.59)	
	p-value	0.3088	
	Risk Difference (95% CI)	5.35 (-4.91, 15.61)	
	p-value	0.3071	
	CMH approach		
	Response rate	23.4	18.2
	Difference in response rates (95% CI)	5.25 (-5.65, 16.15)	
	p-value	0.3453	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=119)	Placebo (N=121)
SOC: Nervous system disorders	Number of subjects with events, n (%)	16 (13.4)	21 (17.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.77 (0.43, 1.41)	
	p-value	0.4037	
	Odds Ratio (95% CI)	0.74 (0.37, 1.50)	
	p-value	0.4027	
	Risk Difference (95% CI)	-3.91 (-13.03, 5.21)	
	p-value	0.4005	
	CMH approach		
	Response rate	13.3	16.3
	Difference in response rates (95% CI)	-2.98 (-12.81, 6.85)	
	p-value	0.5521	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=119)	Placebo (N=121)
SOC: Nervous system disorders, PT: Headache	Number of subjects with events, n (%)	6 (5.0)	14 (11.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.44 (0.17, 1.10)	
	p-value	0.0775	
	Odds Ratio (95% CI)	0.41 (0.15, 1.09)	
	p-value	0.0748	
	Risk Difference (95% CI)	-6.53 (-13.45, 0.40)	
	p-value	0.0646	
	CMH approach		
	Response rate	4.8	10.6
	Difference in response rates (95% CI)	-5.81 (-14.26, 2.65)	
	p-value	0.1785	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=119)	Placebo (N=121)
SOC: Psychiatric disorders	Number of subjects with events, n (%)	10 (8.4)	12 (9.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.85 (0.38, 1.89)	
	p-value	0.6849	
	Odds Ratio (95% CI)	0.83 (0.35, 2.01)	
	p-value	0.6848	
	Risk Difference (95% CI)	-1.51 (-8.81, 5.78)	
	p-value	0.6842	
	CMH approach		
	Response rate	8.4	9.8
	Difference in response rates (95% CI)	-1.31 (-10.28, 7.65)	
	p-value	0.7740	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=119)	Placebo (N=121)
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with events, n (%)	18 (15.1)	18 (14.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.02 (0.56, 1.86)	
	p-value	0.9567	
	Odds Ratio (95% CI)	1.02 (0.50, 2.07)	
	p-value	0.9567	
	Risk Difference (95% CI)	0.25 (-8.79, 9.29)	
	p-value	0.9568	
	CMH approach		
	Response rate	15.2	14.9
	Difference in response rates (95% CI)	0.30 (-9.83, 10.44)	
	p-value	0.9532	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=119)	Placebo (N=121)
SOC: Skin and subcutaneous tissue disorders	Number of subjects with events, n (%)	18 (15.1)	18 (14.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.02 (0.56, 1.86)	
	p-value	0.9567	
	Odds Ratio (95% CI)	1.02 (0.50, 2.07)	
	p-value	0.9567	
	Risk Difference (95% CI)	0.25 (-8.79, 9.29)	
	p-value	0.9568	
	CMH approach		
	Response rate	15.4	14.1
	Difference in response rates (95% CI)	1.34 (-8.46, 11.14)	
	p-value	0.7886	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Upper respiratory tract infection	SLEDAI-2K score at screening									0.2221
	< 10 points	9/ 41 (22.0)	22.8	1/ 32 (3.1)	2.8	7.02 (0.94, 52.61)	0.0578	19.98 (1.18, 38.77)	0.0373	
	>= 10 points	18/ 78 (23.1)	23.1	11/ 89 (12.4)	12.0	1.87 (0.94, 3.71)	0.0743	11.15 (-1.29, 23.58)	0.0790	
	OCS dose at baseline									0.3520
	<10 mg/day	15/ 58 (25.9)	25.6	9/ 65 (13.8)	13.2	1.87 (0.89, 3.94)	0.1010	12.36 (-2.78, 27.49)	0.1095	
	>=10 mg/day	12/ 61 (19.7)	20.1	3/ 56 (5.4)	5.5	3.67 (1.09, 12.34)	0.0354	14.62 (0.48, 28.75)	0.0427	
	Result of type I IFN gene signature test									0.2824
	LOW	6/ 23 (26.1)	26.1	1/ 24 (4.2)	4.2	6.26 (0.82, 48.07)	0.0778	21.92 (-0.47, 44.31)	0.0550	
	HIGH	21/ 96 (21.9)	22.2	11/ 97 (11.3)	10.6	1.93 (0.98, 3.78)	0.0556	11.69 (0.23, 23.15)	0.0456	
	Age (years)									NE
	<= 65	27/117 (23.1)	23.4	12/120 (10.0)	9.4	2.31 (1.23, 4.34)	0.0093	13.99 (3.67, 24.31)	0.0079	
	> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
	Sex									0.8062
	male	1/ 11 (9.1)	9.1	0/ 12 (0.0)	0.0	3.25 (0.15, 72.36)	0.4566	9.09 (-21.06, 39.24)	0.5545	
	female	26/108 (24.1)	24.5	12/109 (11.0)	10.4	2.19 (1.16, 4.11)	0.0149	14.08 (3.09, 25.06)	0.0120	
	Race									0.3645
	White	17/ 75 (22.7)	22.3	7/ 78 (9.0)	8.7	2.53 (1.11, 5.74)	0.0270	13.58 (0.94, 26.21)	0.0352	
	Black or African American	3/ 11 (27.3)	27.3	0/ 18 (0.0)	0.0	11.08 (0.63, 196.20)	0.1009	27.27 (-3.59, 58.13)	0.0833	
	Asian	4/ 17 (23.5)	23.5	4/ 16 (25.0)	25.0	0.94 (0.28, 3.14)	0.9215	-1.47 (-32.54, 29.60)	0.9261	
	Other	3/ 8 (37.5)	37.5	1/ 6 (16.7)	16.7	2.25 (0.30, 16.63)	0.4269	20.83 (-29.28, 70.95)	0.4152	
	Ethnicity									0.3179
	Hispanic/Latino	10/ 27 (37.0)	37.0	3/ 32 (9.4)	9.4	3.95 (1.21, 12.91)	0.0230	27.66 (5.73, 49.60)	0.0134	
	Non-hispanic/Latino	17/ 84 (20.2)	20.2	9/ 86 (10.5)	10.3	1.93 (0.91, 4.09)	0.0848	9.90 (-2.01, 21.80)	0.1031	
	Geographic region									0.7982
	EU	2/ 45 (4.4)	4.4	0/ 33 (0.0)	0.0	3.70 (0.18, 74.51)	0.3937	4.44 (-6.67, 15.56)	0.4332	
	non-EU	25/ 74 (33.8)	34.0	12/ 88 (13.6)	13.1	2.48 (1.34, 4.58)	0.0038	20.86 (7.26, 34.46)	0.0026	
	Onset of disease									0.3903
	Paediatric	2/ 11 (18.2)	18.2	1/ 5 (20.0)	20.0	0.91 (0.11, 7.84)	0.9309	-1.82 (-50.71, 47.07)	0.9419	
	Adult	25/108 (23.1)	23.4	11/116 (9.5)	8.9	2.44 (1.26, 4.72)	0.0079	14.44 (3.85, 25.04)	0.0076	
	ADA result									0.4570
	Negative	27/115 (23.5)	23.8	11/111 (9.9)	9.2	2.37 (1.24, 4.54)	0.0094	14.52 (3.93, 25.12)	0.0072	
	Positive (At any time)	0/ 4 (0.0)	0.0	1/ 10 (10.0)	10.0	0.73 (0.04, 15.04)	0.8405	-10.00 (-59.47, 39.47)	0.6920	
	BMI (kg/m2) at enrolment									0.2820
	< 30	15/ 85 (17.6)	17.6	9/ 89 (10.1)	10.0	1.75 (0.81, 3.77)	0.1570	7.57 (-3.83, 18.98)	0.1930	
	>= 30	12/ 34 (35.3)	35.3	3/ 32 (9.4)	9.4	3.76 (1.17, 12.12)	0.0263	25.92 (5.76, 46.08)	0.0117	
	Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.0679
	All negative/normal	13/ 38 (34.2)	33.4	4/ 56 (7.1)	6.2	4.79 (1.69, 13.58)	0.0032	27.19 (9.28, 45.10)	0.0029	
	At least one positive/abnormal	14/ 81 (17.3)	17.3	8/ 65 (12.3)	12.3	1.40 (0.63, 3.14)	0.4084	4.98 (-7.09, 17.05)	0.4191	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Serious Adverse Events by SOC, PT (incidence in either arm >= 5% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=119)	Placebo (N=121)
SOC: Infections and infestations	Number of subjects with events, n (%)	3 (2.5)	10 (8.3)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.31 (0.09, 1.08)	
	p-value	0.0659	
	Odds Ratio (95% CI)	0.29 (0.08, 1.07)	
	p-value	0.0631	
	Risk Difference (95% CI)	-5.74 (-11.40, -0.09)	
	p-value	0.0466	
	CMH approach		
	Response rate	2.8	8.1
	Difference in response rates (95% CI)	-5.35 (-13.52, 2.83)	
	p-value	0.1998	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Serious Adverse Events by SOC, PT (incidence in either arm >= 5% or >=10 patients) - Subgroup analysis
Full analysis set

- NO OBSERVATIONS FOR THIS ANALYSIS -

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Severe (Grade >=3) by SOC, PT (incidence in either arm >= 5% or >=10 patients)
Full analysis set

- NO OBSERVATIONS FOR THIS ANALYSIS -

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Severe (Grade >=3) by SOC, PT (incidence in either arm >= 5% or >=10 patients) - Subgroup analysis
Full analysis set

- NO OBSERVATIONS FOR THIS ANALYSIS -

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event (on-treatment)
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	103 (86.6)	104 (86.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.01 (0.91, 1.11)	
p-value	0.8919	
Odds Ratio (95% CI)	1.05 (0.50, 2.19)	
p-value	0.8919	
Risk Difference (95% CI)	0.60 (-8.11, 9.32)	
p-value	0.8919	
CMH approach		
Response rate	86.6	85.2
Difference in response rates (95% CI)	1.48 (-8.49, 11.44)	
p-value	0.7718	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event (on-treatment) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.2309
< 10 points	38/ 41 (92.7)	93.3	27/ 32 (84.4)	83.6	1.10 (0.92, 1.30)	0.2849	9.66 (-9.14, 28.47)	0.3138	
>= 10 points	65/ 78 (83.3)	83.4	77/ 89 (86.5)	86.0	0.96 (0.85, 1.10)	0.5682	-2.62 (-14.61, 9.37)	0.6683	
OCS dose at baseline									0.3941
<10 mg/day	53/ 58 (91.4)	91.3	61/ 65 (93.8)	93.8	0.97 (0.88, 1.08)	0.6038	-2.49 (-15.03, 10.05)	0.6972	
>=10 mg/day	50/ 61 (82.0)	81.0	43/ 56 (76.8)	77.1	1.07 (0.89, 1.29)	0.4914	3.97 (-11.73, 19.67)	0.6200	
Result of type I IFN gene signature test									0.8941
LOW	19/ 23 (82.6)	82.6	20/ 24 (83.3)	83.3	0.99 (0.76, 1.28)	0.9473	-0.72 (-24.35, 22.90)	0.9521	
HIGH	84/ 96 (87.5)	87.6	84/ 97 (86.6)	85.6	1.01 (0.91, 1.13)	0.8520	2.02 (-8.96, 13.00)	0.7184	
Age (years)									0.3175
<= 65	102/117 (87.2)	87.2	103/120 (85.8)	85.1	1.02 (0.92, 1.12)	0.7617	2.08 (-7.91, 12.07)	0.6834	
> 65	1/ 2 (50.0)	50.0	1/ 1 (100.0)	100.0	0.50 (0.13, 2.00)	0.3270	-50.00 (-168.41, 68.41)	0.4079	
Sex									0.5002
male	8/ 11 (72.7)	72.7	10/ 12 (83.3)	83.3	0.87 (0.56, 1.36)	0.5457	-10.61 (-47.70, 26.49)	0.5753	
female	95/108 (88.0)	88.1	94/109 (86.2)	85.7	1.02 (0.92, 1.13)	0.7048	2.36 (-8.05, 12.76)	0.6575	
Race									0.7721
White	62/ 75 (82.7)	82.2	65/ 78 (83.3)	83.3	0.99 (0.86, 1.15)	0.9126	-1.14 (-14.24, 11.95)	0.8644	
Black or African American	9/ 11 (81.8)	81.8	14/ 18 (77.8)	77.8	1.05 (0.72, 1.53)	0.7897	4.04 (-29.22, 37.30)	0.8118	
Asian	16/ 17 (94.1)	94.1	16/ 16 (100.0)	100.0	0.94 (0.84, 1.06)	0.3174	-5.88 (-28.08, 16.32)	0.6035	
Other	8/ 8 (100.0)	100.0	6/ 6 (100.0)	100.0	NE		0.00 (-41.13, 41.13)	1.0000	
Ethnicity									0.4913
Hispanic/Latino	25/ 27 (92.6)	92.6	28/ 32 (87.5)	87.5	1.06 (0.89, 1.25)	0.5116	5.09 (-12.98, 23.17)	0.5808	
Non-hispanic/Latino	70/ 84 (83.3)	82.8	73/ 86 (84.9)	85.0	0.98 (0.86, 1.12)	0.7823	-2.19 (-14.21, 9.83)	0.7213	
Geographic region									0.7316
EU	36/ 45 (80.0)	80.0	25/ 33 (75.8)	75.8	1.06 (0.83, 1.35)	0.6591	4.24 (-15.20, 23.69)	0.6690	
non-EU	67/ 74 (90.5)	90.2	79/ 88 (89.8)	89.3	1.01 (0.91, 1.12)	0.8700	0.89 (-10.34, 12.13)	0.8759	
Onset of disease									0.3426
Paediatric	10/ 11 (90.9)	90.9	5/ 5 (100.0)	100.0	0.91 (0.75, 1.10)	0.3175	-9.09 (-52.53, 34.34)	0.6817	
Adult	93/108 (86.1)	86.1	99/116 (85.3)	84.7	1.01 (0.91, 1.12)	0.8698	1.40 (-9.02, 11.82)	0.7923	
ADA result									NE
Negative	99/115 (86.1)	86.3	94/111 (84.7)	83.7	1.02 (0.91, 1.13)	0.7656	2.67 (-7.77, 13.11)	0.6165	
Positive (At any time)	4/ 4 (100.0)	100.0	10/ 10 (100.0)	100.0	NE		0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment									0.6526
< 30	73/ 85 (85.9)	85.9	77/ 89 (86.5)	86.5	0.99 (0.88, 1.12)	0.9035	-0.54 (-11.93, 10.86)	0.9264	
>= 30	30/ 34 (88.2)	88.2	27/ 32 (84.4)	84.4	1.05 (0.86, 1.27)	0.6498	3.86 (-14.53, 22.25)	0.6808	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.5999
All negative/normal	34/ 38 (89.5)	89.9	48/ 56 (85.7)	84.9	1.04 (0.90, 1.22)	0.5817	4.97 (-11.81, 21.74)	0.5616	
At least one positive/abnormal	69/ 81 (85.2)	85.2	56/ 65 (86.2)	86.2	0.99 (0.87, 1.13)	0.8679	-0.97 (-12.99, 11.05)	0.8745	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Serious Adverse Event (on-treatment)
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	10 (8.4)	26 (21.5)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.39 (0.20, 0.78)	
p-value	0.0071	
Odds Ratio (95% CI)	0.34 (0.15, 0.73)	
p-value	0.0060	
Risk Difference (95% CI)	-13.08 (-21.94, -4.23)	
p-value	0.0038	
CMH approach		
Response rate	8.6	21.1
Difference in response rates (95% CI)	-12.43 (-22.37, -2.49)	
p-value	0.0143	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Serious Adverse Event (on-treatment) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9415
< 10 points	1/ 41 (2.4)	2.8	2/ 32 (6.3)	6.3	0.39 (0.04, 4.11)	0.4336	-3.46 (-20.59, 13.67)	0.6923	
>= 10 points	9/ 78 (11.5)	11.2	24/ 89 (27.0)	27.4	0.43 (0.21, 0.86)	0.0180	-16.22 (-28.86, -3.59)	0.0119	
OCS dose at baseline									0.9418
<10 mg/day	4/ 58 (6.9)	7.4	12/ 65 (18.5)	17.0	0.37 (0.13, 1.09)	0.0726	-9.59 (-23.04, 3.85)	0.1620	
>=10 mg/day	6/ 61 (9.8)	10.1	14/ 56 (25.0)	25.2	0.39 (0.16, 0.95)	0.0388	-15.12 (-30.50, 0.25)	0.0539	
Result of type I IFN gene signature test									0.9264
LOW	0/ 23 (0.0)	0.0	1/ 24 (4.2)	4.2	0.35 (0.01, 8.11)	0.5106	-4.17 (-20.53, 12.19)	0.6177	
HIGH	10/ 96 (10.4)	10.8	25/ 97 (25.8)	25.3	0.40 (0.21, 0.80)	0.0087	-14.47 (-26.19, -2.75)	0.0155	
Age (years)									NE
<= 65	10/117 (8.5)	8.8	26/120 (21.7)	21.3	0.39 (0.20, 0.78)	0.0076	-12.52 (-22.55, -2.49)	0.0144	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									0.2333
male	2/ 11 (18.2)	18.2	2/ 12 (16.7)	16.7	1.09 (0.18, 6.48)	0.9237	1.52 (-34.31, 37.34)	0.9339	
female	8/108 (7.4)	7.5	24/109 (22.0)	21.9	0.34 (0.16, 0.72)	0.0047	-14.42 (-24.88, -3.96)	0.0069	
Race									0.6965
White	7/ 75 (9.3)	9.4	15/ 78 (19.2)	19.2	0.49 (0.21, 1.12)	0.0914	-9.85 (-22.26, 2.55)	0.1196	
Black or African American	0/ 11 (0.0)	0.0	4/ 18 (22.2)	22.2	0.18 (0.01, 2.98)	0.2290	-22.22 (-50.98, 6.53)	0.1299	
Asian	1/ 17 (5.9)	5.9	5/ 16 (31.3)	31.3	0.19 (0.02, 1.44)	0.1078	-25.37 (-54.05, 3.32)	0.0831	
Other	0/ 8 (0.0)	0.0	2/ 6 (33.3)	33.3	0.16 (0.01, 2.75)	0.2040	-33.33 (-80.27, 13.61)	0.1640	
Ethnicity									0.1669
Hispanic/Latino	0/ 27 (0.0)	0.0	9/ 32 (28.1)	28.1	0.06 (0.00, 1.02)	0.0516	-28.13 (-46.58, -9.67)	0.0028	
Non-hispanic/Latino	8/ 84 (9.5)	9.7	17/ 86 (19.8)	19.4	0.48 (0.22, 1.06)	0.0682	-9.67 (-21.31, 1.97)	0.1033	
Geographic region									0.0765
EU	6/ 45 (13.3)	13.3	5/ 33 (15.2)	15.2	0.88 (0.29, 2.64)	0.8196	-1.82 (-19.00, 15.36)	0.8357	
non-EU	4/ 74 (5.4)	5.5	21/ 88 (23.9)	23.0	0.23 (0.08, 0.63)	0.0045	-17.56 (-29.19, -5.93)	0.0031	
Onset of disease									0.3557
Paediatric	3/ 11 (27.3)	27.3	2/ 5 (40.0)	40.0	0.68 (0.16, 2.89)	0.6030	-12.73 (-64.43, 38.97)	0.6295	
Adult	7/108 (6.5)	6.6	24/116 (20.7)	20.3	0.31 (0.14, 0.70)	0.0045	-13.64 (-23.67, -3.60)	0.0077	
ADA result									0.5583
Negative	10/115 (8.7)	8.8	21/111 (18.9)	18.5	0.46 (0.23, 0.93)	0.0310	-9.72 (-19.89, 0.44)	0.0607	
Positive (At any time)	0/ 4 (0.0)	0.0	5/ 10 (50.0)	50.0	0.20 (0.01, 2.96)	0.2418	-50.00 (-102.55, 2.55)	0.0622	
BMI (kg/m2) at enrolment									0.6716
< 30	7/ 85 (8.2)	8.5	17/ 89 (19.1)	18.5	0.43 (0.19, 0.99)	0.0466	-10.04 (-21.27, 1.19)	0.0796	
>= 30	3/ 34 (8.8)	8.8	9/ 32 (28.1)	28.1	0.31 (0.09, 1.06)	0.0613	-19.30 (-38.89, 0.29)	0.0535	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.0467
All negative/normal	5/ 38 (13.2)	14.1	8/ 56 (14.3)	13.3	0.92 (0.33, 2.60)	0.8767	0.74 (-16.13, 17.60)	0.9319	
At least one positive/abnormal	5/ 81 (6.2)	6.2	18/ 65 (27.7)	27.7	0.22 (0.09, 0.57)	0.0017	-21.52 (-34.07, -8.97)	0.0008	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Severe Adverse Event (on-treatment)
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	4 (3.4)	8 (6.6)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.51 (0.16, 1.64)	
p-value	0.2584	
Odds Ratio (95% CI)	0.49 (0.14, 1.68)	
p-value	0.2567	
Risk Difference (95% CI)	-3.25 (-8.74, 2.24)	
p-value	0.2455	
CMH approach		
Response rate	3.3	6.7
Difference in response rates (95% CI)	-3.44 (-11.48, 4.61)	
p-value	0.4021	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Severe Adverse Event (on-treatment) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.7840
< 10 points	1/ 41 (2.4)	2.4	2/ 32 (6.3)	5.6	0.39 (0.04, 4.11)	0.4336	-3.21 (-19.98, 13.55)	0.7074	
>= 10 points	3/ 78 (3.8)	3.5	6/ 89 (6.7)	7.1	0.57 (0.15, 2.21)	0.4159	-3.60 (-13.06, 5.86)	0.4560	
OCS dose at baseline									0.7722
<10 mg/day	1/ 58 (1.7)	1.5	3/ 65 (4.6)	4.7	0.37 (0.04, 3.49)	0.3879	-3.19 (-13.97, 7.58)	0.5612	
>=10 mg/day	3/ 61 (4.9)	5.0	5/ 56 (8.9)	8.5	0.55 (0.14, 2.20)	0.3986	-3.48 (-16.14, 9.19)	0.5909	
Result of type I IFN gene signature test									0.5678
LOW	1/ 23 (4.3)	4.3	1/ 24 (4.2)	4.2	1.04 (0.07, 15.72)	0.9755	0.18 (-17.65, 18.02)	0.9841	
HIGH	3/ 96 (3.1)	3.0	7/ 97 (7.2)	7.4	0.43 (0.12, 1.63)	0.2149	-4.33 (-13.35, 4.68)	0.3459	
Age (years)									NE
<= 65	4/117 (3.4)	3.4	8/120 (6.7)	6.8	0.51 (0.16, 1.66)	0.2644	-3.38 (-11.50, 4.75)	0.4154	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									0.7827
male	0/ 11 (0.0)	0.0	1/ 12 (8.3)	8.3	0.36 (0.02, 8.04)	0.5200	-8.33 (-38.19, 21.52)	0.5843	
female	4/108 (3.7)	3.6	7/109 (6.4)	6.4	0.58 (0.17, 1.91)	0.3684	-2.84 (-11.47, 5.80)	0.5196	
Race									0.3334
White	1/ 75 (1.3)	1.4	7/ 78 (9.0)	9.1	0.15 (0.02, 1.18)	0.0712	-7.70 (-17.71, 2.32)	0.1320	
Black or African American	0/ 11 (0.0)	0.0	1/ 18 (5.6)	5.6	0.53 (0.02, 11.93)	0.6879	-5.56 (-31.15, 20.04)	0.6705	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE		0.00 (-20.27, 20.27)	1.0000	
Other	1/ 8 (12.5)	12.5	0/ 6 (0.0)	0.0	2.33 (0.11, 48.99)	0.5854	12.50 (-31.37, 56.37)	0.5765	
Ethnicity									0.8156
Hispanic/Latino	1/ 27 (3.7)	3.7	5/ 32 (15.6)	15.6	0.24 (0.03, 1.91)	0.1760	-11.92 (-29.60, 5.75)	0.1862	
Non-hispanic/Latino	1/ 84 (1.2)	1.2	3/ 86 (3.5)	3.8	0.34 (0.04, 3.22)	0.3475	-2.59 (-10.81, 5.62)	0.5365	
Geographic region									0.0982
EU	3/ 45 (6.7)	6.7	1/ 33 (3.0)	3.0	2.20 (0.24, 20.22)	0.4860	3.64 (-9.21, 16.48)	0.5789	
non-EU	1/ 74 (1.4)	1.5	7/ 88 (8.0)	7.8	0.17 (0.02, 1.35)	0.0936	-6.38 (-15.82, 3.07)	0.1856	
Onset of disease									0.9932
Paediatric	1/ 11 (9.1)	9.1	1/ 5 (20.0)	20.0	0.45 (0.04, 5.89)	0.5464	-10.91 (-58.51, 36.69)	0.6533	
Adult	3/108 (2.8)	2.8	7/116 (6.0)	6.1	0.46 (0.12, 1.74)	0.2518	-3.33 (-11.58, 4.93)	0.4297	
ADA result									0.8636
Negative	4/115 (3.5)	3.3	7/111 (6.3)	6.4	0.55 (0.17, 1.83)	0.3313	-3.09 (-11.45, 5.28)	0.4694	
Positive (At any time)	0/ 4 (0.0)	0.0	1/ 10 (10.0)	10.0	0.73 (0.04, 15.04)	0.8405	-10.00 (-59.47, 39.47)	0.6920	
BMI (kg/m2) at enrolment									0.9286
< 30	2/ 85 (2.4)	2.3	4/ 89 (4.5)	4.4	0.52 (0.10, 2.78)	0.4478	-2.17 (-10.49, 6.15)	0.6089	
>= 30	2/ 34 (5.9)	5.9	4/ 32 (12.5)	12.5	0.47 (0.09, 2.40)	0.3639	-6.62 (-23.14, 9.91)	0.4326	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.7115
All negative/normal	1/ 38 (2.6)	3.0	4/ 56 (7.1)	7.9	0.37 (0.04, 3.17)	0.3632	-4.98 (-19.89, 9.94)	0.5132	
At least one positive/abnormal	3/ 81 (3.7)	3.7	4/ 65 (6.2)	6.2	0.60 (0.14, 2.59)	0.4958	-2.45 (-11.00, 6.10)	0.5745	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Non-Severe Adverse Event (on-treatment)
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	103 (86.6)	103 (85.1)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.02 (0.92, 1.13)	
p-value	0.7506	
Odds Ratio (95% CI)	1.13 (0.54, 2.33)	
p-value	0.7507	
Risk Difference (95% CI)	1.43 (-7.39, 10.25)	
p-value	0.7505	
CMH approach		
Response rate	86.6	84.3
Difference in response rates (95% CI)	2.35 (-7.69, 12.39)	
p-value	0.6461	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Non-Severe Adverse Event (on-treatment) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.2840
< 10 points	38/ 41 (92.7)	93.3	27/ 32 (84.4)	83.6	1.10 (0.92, 1.30)	0.2849	9.66 (-9.14, 28.47)	0.3138	
>= 10 points	65/ 78 (83.3)	83.4	76/ 89 (85.4)	84.8	0.98 (0.86, 1.11)	0.7154	-1.36 (-13.48, 10.76)	0.8259	
OCS dose at baseline									0.2957
<10 mg/day	53/ 58 (91.4)	91.3	61/ 65 (93.8)	93.8	0.97 (0.88, 1.08)	0.6038	-2.49 (-15.03, 10.05)	0.6972	
>=10 mg/day	50/ 61 (82.0)	81.0	42/ 56 (75.0)	75.3	1.09 (0.90, 1.32)	0.3636	5.79 (-10.10, 21.68)	0.4753	
Result of type I IFN gene signature test									0.8291
LOW	19/ 23 (82.6)	82.6	20/ 24 (83.3)	83.3	0.99 (0.76, 1.28)	0.9473	-0.72 (-24.35, 22.90)	0.9521	
HIGH	84/ 96 (87.5)	87.6	83/ 97 (85.6)	84.5	1.02 (0.91, 1.14)	0.6941	3.11 (-7.96, 14.19)	0.5817	
Age (years)									0.3109
<= 65	102/117 (87.2)	87.2	102/120 (85.0)	84.2	1.03 (0.93, 1.14)	0.6278	2.95 (-7.10, 13.01)	0.5648	
> 65	1/ 2 (50.0)	50.0	1/ 1 (100.0)	100.0	0.50 (0.13, 2.00)	0.3270	-50.00 (-168.41, 68.41)	0.4079	
Sex									0.4717
male	8/ 11 (72.7)	72.7	10/ 12 (83.3)	83.3	0.87 (0.56, 1.36)	0.5457	-10.61 (-47.70, 26.49)	0.5753	
female	95/108 (88.0)	88.1	93/109 (85.3)	84.8	1.03 (0.93, 1.14)	0.5675	3.34 (-7.16, 13.84)	0.5328	
Race									0.7099
White	62/ 75 (82.7)	82.2	64/ 78 (82.1)	82.1	1.01 (0.87, 1.17)	0.9205	0.12 (-13.10, 13.35)	0.9852	
Black or African American	9/ 11 (81.8)	81.8	14/ 18 (77.8)	77.8	1.05 (0.72, 1.53)	0.7897	4.04 (-29.22, 37.30)	0.8118	
Asian	16/ 17 (94.1)	94.1	16/ 16 (100.0)	100.0	0.94 (0.84, 1.06)	0.3174	-5.88 (-28.08, 16.32)	0.6035	
Other	8/ 8 (100.0)	100.0	6/ 6 (100.0)	100.0	NE		0.00 (-41.13, 41.13)	1.0000	
Ethnicity									0.3324
Hispanic/Latino	25/ 27 (92.6)	92.6	27/ 32 (84.4)	84.4	1.10 (0.91, 1.32)	0.3204	8.22 (-10.44, 26.87)	0.3879	
Non-hispanic/Latino	70/ 84 (83.3)	82.8	73/ 86 (84.9)	85.0	0.98 (0.86, 1.12)	0.7823	-2.19 (-14.21, 9.83)	0.7213	
Geographic region									0.8050
EU	36/ 45 (80.0)	80.0	25/ 33 (75.8)	75.8	1.06 (0.83, 1.35)	0.6591	4.24 (-15.20, 23.69)	0.6690	
non-EU	67/ 74 (90.5)	90.2	78/ 88 (88.6)	88.3	1.02 (0.92, 1.13)	0.6915	1.96 (-9.41, 13.33)	0.7358	
Onset of disease									0.2997
Paediatric	10/ 11 (90.9)	90.9	5/ 5 (100.0)	100.0	0.91 (0.75, 1.10)	0.3175	-9.09 (-52.53, 34.34)	0.6817	
Adult	93/108 (86.1)	86.1	98/116 (84.5)	83.9	1.02 (0.91, 1.14)	0.7307	2.29 (-8.20, 12.78)	0.6689	
ADA result									NE
Negative	99/115 (86.1)	86.3	93/111 (83.8)	82.7	1.03 (0.92, 1.15)	0.6289	3.66 (-6.85, 14.17)	0.4953	
Positive (At any time)	4/ 4 (100.0)	100.0	10/ 10 (100.0)	100.0	NE		0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment									0.7376
< 30	73/ 85 (85.9)	85.9	76/ 89 (85.4)	85.4	1.01 (0.89, 1.14)	0.9267	0.55 (-10.97, 12.07)	0.9252	
>= 30	30/ 34 (88.2)	88.2	27/ 32 (84.4)	84.4	1.05 (0.86, 1.27)	0.6498	3.86 (-14.53, 22.25)	0.6808	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.7301
All negative/normal	34/ 38 (89.5)	89.9	48/ 56 (85.7)	84.9	1.04 (0.90, 1.22)	0.5817	4.97 (-11.81, 21.74)	0.5616	
At least one positive/abnormal	69/ 81 (85.2)	85.2	55/ 65 (84.6)	84.6	1.01 (0.88, 1.16)	0.9240	0.57 (-11.68, 12.82)	0.9274	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event leading to discontinuation of study drug (on-treatment)
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	3 (2.5)	10 (8.3)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.31 (0.09, 1.08)	
p-value	0.0659	
Odds Ratio (95% CI)	0.29 (0.08, 1.07)	
p-value	0.0631	
Risk Difference (95% CI)	-5.74 (-11.40, -0.09)	
p-value	0.0466	
CMH approach		
Response rate	2.6	8.3
Difference in response rates (95% CI)	-5.64 (-13.85, 2.57)	
p-value	0.1783	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event leading to discontinuation of study drug (on-treatment) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.5480
< 10 points	0/ 41 (0.0)	0.0	2/ 32 (6.3)	6.4	0.16 (0.01, 3.16)	0.2269	-6.42 (-22.83, 9.98)	0.4429	
>= 10 points	3/ 78 (3.8)	4.0	8/ 89 (9.0)	9.4	0.43 (0.12, 1.56)	0.1977	-5.41 (-15.30, 4.47)	0.2831	
OCS dose at baseline									0.7154
<10 mg/day	1/ 58 (1.7)	1.9	5/ 65 (7.7)	8.2	0.22 (0.03, 1.86)	0.1663	-6.28 (-17.88, 5.32)	0.2889	
>=10 mg/day	2/ 61 (3.3)	3.9	5/ 56 (8.9)	9.1	0.37 (0.07, 1.82)	0.2195	-5.16 (-17.58, 7.27)	0.4161	
Result of type I IFN gene signature test									0.8916
LOW	1/ 23 (4.3)	4.3	3/ 24 (12.5)	12.5	0.35 (0.04, 3.11)	0.3445	-8.15 (-28.15, 11.84)	0.4242	
HIGH	2/ 96 (2.1)	2.2	7/ 97 (7.2)	7.2	0.29 (0.06, 1.35)	0.1152	-5.02 (-13.99, 3.95)	0.2728	
Age (years)									NE
<= 65	3/117 (2.6)	2.7	10/120 (8.3)	8.3	0.31 (0.09, 1.09)	0.0678	-5.60 (-13.88, 2.68)	0.1849	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-27.45, 27.45)	1.0000	
female	3/108 (2.8)	2.9	10/109 (9.2)	9.2	0.30 (0.09, 1.07)	0.0636	-6.32 (-15.27, 2.63)	0.1667	
Race									0.6363
White	2/ 75 (2.7)	2.9	7/ 78 (9.0)	8.5	0.30 (0.06, 1.38)	0.1223	-5.61 (-15.72, 4.50)	0.2768	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	3/ 16 (18.8)	18.8	0.13 (0.01, 2.42)	0.1740	-18.75 (-44.14, 6.64)	0.1479	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE		0.00 (-41.13, 41.13)	1.0000	
Ethnicity									0.5199
Hispanic/Latino	1/ 27 (3.7)	3.7	3/ 32 (9.4)	9.4	0.40 (0.04, 3.58)	0.4090	-5.67 (-22.04, 10.70)	0.4971	
Non-hispanic/Latino	1/ 84 (1.2)	1.2	7/ 86 (8.1)	7.9	0.15 (0.02, 1.16)	0.0692	-6.61 (-15.58, 2.36)	0.1484	
Geographic region									0.8835
EU	1/ 45 (2.2)	2.2	2/ 33 (6.1)	6.1	0.37 (0.03, 3.88)	0.4043	-3.84 (-16.54, 8.86)	0.5536	
non-EU	2/ 74 (2.7)	2.9	8/ 88 (9.1)	8.7	0.30 (0.07, 1.36)	0.1174	-5.82 (-15.54, 3.90)	0.2408	
Onset of disease									0.2617
Paediatric	1/ 11 (9.1)	9.1	0/ 5 (0.0)	0.0	1.50 (0.07, 31.57)	0.7942	9.09 (-34.34, 52.53)	0.6817	
Adult	2/108 (1.9)	1.9	10/116 (8.6)	8.6	0.21 (0.05, 0.96)	0.0438	-6.71 (-15.17, 1.76)	0.1204	
ADA result									0.6226
Negative	3/115 (2.6)	2.7	9/111 (8.1)	8.2	0.32 (0.09, 1.16)	0.0826	-5.42 (-14.01, 3.17)	0.2161	
Positive (At any time)	0/ 4 (0.0)	0.0	1/ 10 (10.0)	10.0	0.73 (0.04, 15.04)	0.8405	-10.00 (-59.47, 39.47)	0.6920	
BMI (kg/m2) at enrolment									0.6598
< 30	3/ 85 (3.5)	3.5	8/ 89 (9.0)	9.1	0.39 (0.11, 1.43)	0.1565	-5.61 (-14.96, 3.75)	0.2403	
>= 30	0/ 34 (0.0)	0.0	2/ 32 (6.3)	6.3	0.19 (0.01, 3.78)	0.2756	-6.25 (-19.47, 6.97)	0.3543	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.1195
All negative/normal	2/ 38 (5.3)	5.9	3/ 56 (5.4)	5.0	0.98 (0.17, 5.60)	0.9841	0.97 (-13.96, 15.91)	0.8985	
At least one positive/abnormal	1/ 81 (1.2)	1.2	7/ 65 (10.8)	10.8	0.11 (0.01, 0.91)	0.0403	-9.53 (-18.65, -0.41)	0.0405	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Serious Adverse Event leading to discontinuation of study drug (on-treatment)
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	1 (0.8)	5 (4.1)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.20 (0.02, 1.71)	
p-value	0.1431	
Odds Ratio (95% CI)	0.20 (0.02, 1.71)	
p-value	0.1404	
Risk Difference (95% CI)	-3.29 (-7.20, 0.62)	
p-value	0.0987	
CMH approach		
Response rate	1.0	4.4
Difference in response rates (95% CI)	-3.41 (-10.85, 4.03)	
p-value	0.3690	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Serious Adverse Event leading to discontinuation of study drug (on-treatment) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-15.48, 15.48)	1.0000	
>= 10 points	1/ 78 (1.3)	1.4	5/ 89 (5.6)	6.3	0.23 (0.03, 1.91)	0.1730	-4.90 (-13.92, 4.11)	0.2862	
OCS dose at baseline									0.0913
<10 mg/day	1/ 58 (1.7)	1.9	0/ 65 (0.0)	0.0	3.36 (0.14, 80.80)	0.4557	1.91 (-8.32, 12.13)	0.7145	
>=10 mg/day	0/ 61 (0.0)	0.0	5/ 56 (8.9)	9.1	0.08 (0.00, 1.48)	0.0904	-9.09 (-20.96, 2.78)	0.1336	
Result of type I IFN gene signature test									NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
HIGH	1/ 96 (1.0)	1.2	5/ 97 (5.2)	5.5	0.20 (0.02, 1.70)	0.1409	-4.25 (-12.77, 4.27)	0.3279	
Age (years)									NE
<= 65	1/117 (0.9)	1.0	5/120 (4.2)	4.4	0.21 (0.02, 1.73)	0.1453	-3.41 (-10.90, 4.09)	0.3732	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-27.45, 27.45)	1.0000	
female	1/108 (0.9)	1.1	5/109 (4.6)	4.9	0.20 (0.02, 1.70)	0.1410	-3.87 (-11.99, 4.24)	0.3494	
Race									0.9216
White	1/ 75 (1.3)	1.4	4/ 78 (5.1)	5.1	0.26 (0.03, 2.27)	0.2234	-3.68 (-13.05, 5.70)	0.4421	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	1/ 16 (6.3)	6.3	0.31 (0.01, 7.21)	0.4694	-6.25 (-28.63, 16.13)	0.5841	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE		0.00 (-41.13, 41.13)	1.0000	
Ethnicity									0.8463
Hispanic/Latino	0/ 27 (0.0)	0.0	2/ 32 (6.3)	6.3	0.24 (0.01, 4.71)	0.3442	-6.25 (-20.55, 8.05)	0.3916	
Non-hispanic/Latino	1/ 84 (1.2)	1.2	3/ 86 (3.5)	3.4	0.34 (0.04, 3.22)	0.3475	-2.14 (-10.37, 6.09)	0.6106	
Geographic region									0.6060
EU	0/ 45 (0.0)	0.0	2/ 33 (6.1)	6.1	0.15 (0.01, 2.98)	0.2123	-6.06 (-18.13, 6.01)	0.3250	
non-EU	1/ 74 (1.4)	1.5	3/ 88 (3.4)	3.2	0.40 (0.04, 3.73)	0.4185	-1.73 (-10.40, 6.93)	0.6950	
Onset of disease									0.2017
Paediatric	1/ 11 (9.1)	9.1	0/ 5 (0.0)	0.0	1.50 (0.07, 31.57)	0.7942	9.09 (-34.34, 52.53)	0.6817	
Adult	0/108 (0.0)	0.0	5/116 (4.3)	4.4	0.10 (0.01, 1.74)	0.1137	-4.44 (-12.05, 3.17)	0.2528	
ADA result									0.5584
Negative	1/115 (0.9)	1.0	4/111 (3.6)	4.0	0.24 (0.03, 2.13)	0.2003	-2.94 (-10.71, 4.82)	0.4573	
Positive (At any time)	0/ 4 (0.0)	0.0	1/ 10 (10.0)	10.0	0.73 (0.04, 15.04)	0.8405	-10.00 (-59.47, 39.47)	0.6920	
BMI (kg/m2) at enrolment									0.9256
< 30	1/ 85 (1.2)	1.2	4/ 89 (4.5)	4.4	0.26 (0.03, 2.30)	0.2263	-3.14 (-11.37, 5.10)	0.4555	
>= 30	0/ 34 (0.0)	0.0	1/ 32 (3.1)	3.1	0.31 (0.01, 7.45)	0.4735	-3.13 (-15.29, 9.04)	0.6147	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.1690
All negative/normal	1/ 38 (2.6)	3.0	1/ 56 (1.8)	1.5	1.47 (0.10, 22.85)	0.7816	1.43 (-12.51, 15.37)	0.8409	
At least one positive/abnormal	0/ 81 (0.0)	0.0	4/ 65 (6.2)	6.2	0.09 (0.00, 1.63)	0.1032	-6.15 (-13.76, 1.45)	0.1127	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with Adverse Event leading to death (on-treatment)
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.50, 6.50)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with Adverse Event leading to death (on-treatment) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.48, 15.48)	1.0000	
>= 10 points	0/ 78 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-7.36, 7.36)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 58 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-9.71, 9.71)	1.0000	
>=10 mg/day	0/ 61 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.81, 9.81)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	0/ 97 (0.0)	0.0	NE	0.00 (-7.23, 7.23)	1.0000	
Age (years)								NE
<= 65	0/117 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.57, 6.57)	1.0000	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-116.14, 116.14)	1.0000	
Sex								NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	0/109 (0.0)	0.0	NE	0.00 (-7.09, 7.09)	1.0000	
Race								NE
White	0/ 75 (0.0)	0.0	0/ 78 (0.0)	0.0	NE	0.00 (-7.93, 7.93)	1.0000	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE	0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE	0.00 (-41.13, 41.13)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	0/ 86 (0.0)	0.0	NE	0.00 (-7.13, 7.13)	1.0000	
Geographic region								NE
EU	0/ 45 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-9.64, 9.64)	1.0000	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-7.62, 7.62)	1.0000	
Onset of disease								NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
Adult	0/108 (0.0)	0.0	0/116 (0.0)	0.0	NE	0.00 (-6.89, 6.89)	1.0000	
ADA result								NE
Negative	0/115 (0.0)	0.0	0/111 (0.0)	0.0	NE	0.00 (-6.86, 6.86)	1.0000	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE	0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 85 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-6.95, 6.95)	1.0000	
>= 30	0/ 34 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-10.92, 10.92)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	0/ 81 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-5.25, 5.25)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	8 (6.7)	2 (1.7)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	4.07 (0.88, 18.76)	
p-value	0.0721	
Odds Ratio (95% CI)	4.29 (0.89, 20.63)	
p-value	0.0693	
Risk Difference (95% CI)	5.07 (0.03, 10.11)	
p-value	0.0487	
CMH approach		
Response rate	6.9	1.7
Difference in response rates (95% CI)	5.22 (-2.71, 13.15)	
p-value	0.1971	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.7693
< 10 points	1/ 41 (2.4)	2.4	0/ 32 (0.0)	0.0	2.36 (0.10, 56.00)	0.5958	2.41 (-13.44, 18.25)	0.7658	
>= 10 points	7/ 78 (9.0)	8.9	2/ 89 (2.2)	2.3	3.99 (0.85, 18.66)	0.0784	6.59 (-2.96, 16.14)	0.1765	
OCS dose at baseline									0.8982
<10 mg/day	4/ 58 (6.9)	6.8	1/ 65 (1.5)	1.8	4.48 (0.52, 38.97)	0.1739	5.02 (-6.45, 16.49)	0.3911	
>=10 mg/day	4/ 61 (6.6)	6.7	1/ 56 (1.8)	1.8	3.67 (0.42, 31.88)	0.2381	4.91 (-6.87, 16.68)	0.4140	
Result of type I IFN gene signature test									0.5052
LOW	2/ 23 (8.7)	8.7	1/ 24 (4.2)	4.2	2.09 (0.20, 21.48)	0.5362	4.53 (-14.55, 23.61)	0.6417	
HIGH	6/ 96 (6.3)	6.5	1/ 97 (1.0)	1.1	6.06 (0.74, 49.41)	0.0923	5.39 (-3.30, 14.08)	0.2244	
Age (years)									NE
<= 65	8/117 (6.8)	7.1	2/120 (1.7)	1.7	4.10 (0.89, 18.92)	0.0703	5.37 (-2.65, 13.38)	0.1893	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									0.9624
male	1/ 11 (9.1)	9.1	0/ 12 (0.0)	0.0	3.25 (0.15, 72.36)	0.4566	9.09 (-21.06, 39.24)	0.5545	
female	7/108 (6.5)	6.7	2/109 (1.8)	1.9	3.53 (0.75, 16.62)	0.1103	4.81 (-3.69, 13.31)	0.2675	
Race									0.7837
White	3/ 75 (4.0)	4.3	1/ 78 (1.3)	1.1	3.12 (0.33, 29.33)	0.3196	3.13 (-5.99, 12.25)	0.5011	
Black or African American	0/ 11 (0.0)	0.0	1/ 18 (5.6)	5.6	0.53 (0.02, 11.93)	0.6879	-5.56 (-31.15, 20.04)	0.6705	
Asian	1/ 17 (5.9)	5.9	0/ 16 (0.0)	0.0	2.83 (0.12, 64.89)	0.5145	5.88 (-16.32, 28.08)	0.6035	
Other	2/ 8 (25.0)	25.0	0/ 6 (0.0)	0.0	3.89 (0.22, 68.67)	0.3539	25.00 (-20.73, 70.73)	0.2840	
Ethnicity									0.3341
Hispanic/Latino	3/ 27 (11.1)	11.1	0/ 32 (0.0)	0.0	8.25 (0.44, 152.98)	0.1567	11.11 (-4.87, 27.09)	0.1730	
Non-hispanic/Latino	3/ 84 (3.6)	3.7	2/ 86 (2.3)	2.2	1.54 (0.26, 8.96)	0.6336	1.50 (-6.93, 9.94)	0.7266	
Geographic region									0.9837
EU	2/ 45 (4.4)	4.4	0/ 33 (0.0)	0.0	3.70 (0.18, 74.51)	0.3937	4.44 (-6.67, 15.56)	0.4332	
non-EU	6/ 74 (8.1)	8.7	2/ 88 (2.3)	2.2	3.57 (0.74, 17.15)	0.1124	6.49 (-3.43, 16.40)	0.1997	
Onset of disease									0.8794
Paediatric	2/ 11 (18.2)	18.2	0/ 5 (0.0)	0.0	2.50 (0.14, 44.26)	0.5320	18.18 (-26.66, 63.02)	0.4268	
Adult	6/108 (5.6)	5.8	2/116 (1.7)	1.7	3.22 (0.66, 15.62)	0.1463	4.03 (-4.15, 12.20)	0.3340	
ADA result									0.6991
Negative	7/115 (6.1)	6.3	2/111 (1.8)	1.9	3.38 (0.72, 15.91)	0.1236	4.42 (-3.80, 12.64)	0.2922	
Positive (At any time)	1/ 4 (25.0)	25.0	0/ 10 (0.0)	0.0	6.60 (0.32, 135.38)	0.2208	25.00 (-27.17, 77.17)	0.3476	
BMI (kg/m2) at enrolment									0.6932
< 30	5/ 85 (5.9)	5.9	1/ 89 (1.1)	1.1	5.24 (0.62, 43.89)	0.1270	4.82 (-3.70, 13.35)	0.2674	
>= 30	3/ 34 (8.8)	8.8	1/ 32 (3.1)	3.1	2.82 (0.31, 25.77)	0.3575	5.70 (-9.16, 20.56)	0.4523	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.4451
All negative/normal	1/ 38 (2.6)	2.8	1/ 56 (1.8)	1.7	1.47 (0.10, 22.85)	0.7816	1.09 (-12.74, 14.93)	0.8772	
At least one positive/abnormal	7/ 81 (8.6)	8.6	1/ 65 (1.5)	1.5	5.62 (0.71, 44.50)	0.1022	7.10 (-1.23, 15.44)	0.0949	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Serious Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.50, 6.50)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Serious Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.48, 15.48)	1.0000	
>= 10 points	0/ 78 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-7.36, 7.36)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 58 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-9.71, 9.71)	1.0000	
>=10 mg/day	0/ 61 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.81, 9.81)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	0/ 97 (0.0)	0.0	NE	0.00 (-7.23, 7.23)	1.0000	
Age (years)								NE
<= 65	0/117 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.57, 6.57)	1.0000	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-116.14, 116.14)	1.0000	
Sex								NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	0/109 (0.0)	0.0	NE	0.00 (-7.09, 7.09)	1.0000	
Race								NE
White	0/ 75 (0.0)	0.0	0/ 78 (0.0)	0.0	NE	0.00 (-7.93, 7.93)	1.0000	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE	0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE	0.00 (-41.13, 41.13)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	0/ 86 (0.0)	0.0	NE	0.00 (-7.13, 7.13)	1.0000	
Geographic region								NE
EU	0/ 45 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-9.64, 9.64)	1.0000	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-7.62, 7.62)	1.0000	
Onset of disease								NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
Adult	0/108 (0.0)	0.0	0/116 (0.0)	0.0	NE	0.00 (-6.89, 6.89)	1.0000	
ADA result								NE
Negative	0/115 (0.0)	0.0	0/111 (0.0)	0.0	NE	0.00 (-6.86, 6.86)	1.0000	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE	0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 85 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-6.95, 6.95)	1.0000	
>= 30	0/ 34 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-10.92, 10.92)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	0/ 81 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-5.25, 5.25)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Severe Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.50, 6.50)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Severe Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.48, 15.48)	1.0000	
>= 10 points	0/ 78 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-7.36, 7.36)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 58 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-9.71, 9.71)	1.0000	
>=10 mg/day	0/ 61 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.81, 9.81)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	0/ 97 (0.0)	0.0	NE	0.00 (-7.23, 7.23)	1.0000	
Age (years)								NE
<= 65	0/117 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.57, 6.57)	1.0000	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-116.14, 116.14)	1.0000	
Sex								NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	0/109 (0.0)	0.0	NE	0.00 (-7.09, 7.09)	1.0000	
Race								NE
White	0/ 75 (0.0)	0.0	0/ 78 (0.0)	0.0	NE	0.00 (-7.93, 7.93)	1.0000	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE	0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE	0.00 (-41.13, 41.13)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	0/ 86 (0.0)	0.0	NE	0.00 (-7.13, 7.13)	1.0000	
Geographic region								NE
EU	0/ 45 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-9.64, 9.64)	1.0000	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-7.62, 7.62)	1.0000	
Onset of disease								NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
Adult	0/108 (0.0)	0.0	0/116 (0.0)	0.0	NE	0.00 (-6.89, 6.89)	1.0000	
ADA result								NE
Negative	0/115 (0.0)	0.0	0/111 (0.0)	0.0	NE	0.00 (-6.86, 6.86)	1.0000	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE	0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 85 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-6.95, 6.95)	1.0000	
>= 30	0/ 34 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-10.92, 10.92)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	0/ 81 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-5.25, 5.25)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Non-Severe Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	8 (6.7)	2 (1.7)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	4.07 (0.88, 18.76)	
p-value	0.0721	
Odds Ratio (95% CI)	4.29 (0.89, 20.63)	
p-value	0.0693	
Risk Difference (95% CI)	5.07 (0.03, 10.11)	
p-value	0.0487	
CMH approach		
Response rate	6.9	1.7
Difference in response rates (95% CI)	5.22 (-2.71, 13.15)	
p-value	0.1971	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Non-Severe Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.7693
< 10 points	1/ 41 (2.4)	2.4	0/ 32 (0.0)	0.0	2.36 (0.10, 56.00)	0.5958	2.41 (-13.44, 18.25)	0.7658	
>= 10 points	7/ 78 (9.0)	8.9	2/ 89 (2.2)	2.3	3.99 (0.85, 18.66)	0.0784	6.59 (-2.96, 16.14)	0.1765	
OCS dose at baseline									0.8982
<10 mg/day	4/ 58 (6.9)	6.8	1/ 65 (1.5)	1.8	4.48 (0.52, 38.97)	0.1739	5.02 (-6.45, 16.49)	0.3911	
>=10 mg/day	4/ 61 (6.6)	6.7	1/ 56 (1.8)	1.8	3.67 (0.42, 31.88)	0.2381	4.91 (-6.87, 16.68)	0.4140	
Result of type I IFN gene signature test									0.5052
LOW	2/ 23 (8.7)	8.7	1/ 24 (4.2)	4.2	2.09 (0.20, 21.48)	0.5362	4.53 (-14.55, 23.61)	0.6417	
HIGH	6/ 96 (6.3)	6.5	1/ 97 (1.0)	1.1	6.06 (0.74, 49.41)	0.0923	5.39 (-3.30, 14.08)	0.2244	
Age (years)									NE
<= 65	8/117 (6.8)	7.1	2/120 (1.7)	1.7	4.10 (0.89, 18.92)	0.0703	5.37 (-2.65, 13.38)	0.1893	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									0.9624
male	1/ 11 (9.1)	9.1	0/ 12 (0.0)	0.0	3.25 (0.15, 72.36)	0.4566	9.09 (-21.06, 39.24)	0.5545	
female	7/108 (6.5)	6.7	2/109 (1.8)	1.9	3.53 (0.75, 16.62)	0.1103	4.81 (-3.69, 13.31)	0.2675	
Race									0.7837
White	3/ 75 (4.0)	4.3	1/ 78 (1.3)	1.1	3.12 (0.33, 29.33)	0.3196	3.13 (-5.99, 12.25)	0.5011	
Black or African American	0/ 11 (0.0)	0.0	1/ 18 (5.6)	5.6	0.53 (0.02, 11.93)	0.6879	-5.56 (-31.15, 20.04)	0.6705	
Asian	1/ 17 (5.9)	5.9	0/ 16 (0.0)	0.0	2.83 (0.12, 64.89)	0.5145	5.88 (-16.32, 28.08)	0.6035	
Other	2/ 8 (25.0)	25.0	0/ 6 (0.0)	0.0	3.89 (0.22, 68.67)	0.3539	25.00 (-20.73, 70.73)	0.2840	
Ethnicity									0.3341
Hispanic/Latino	3/ 27 (11.1)	11.1	0/ 32 (0.0)	0.0	8.25 (0.44, 152.98)	0.1567	11.11 (-4.87, 27.09)	0.1730	
Non-hispanic/Latino	3/ 84 (3.6)	3.7	2/ 86 (2.3)	2.2	1.54 (0.26, 8.96)	0.6336	1.50 (-6.93, 9.94)	0.7266	
Geographic region									0.9837
EU	2/ 45 (4.4)	4.4	0/ 33 (0.0)	0.0	3.70 (0.18, 74.51)	0.3937	4.44 (-6.67, 15.56)	0.4332	
non-EU	6/ 74 (8.1)	8.7	2/ 88 (2.3)	2.2	3.57 (0.74, 17.15)	0.1124	6.49 (-3.43, 16.40)	0.1997	
Onset of disease									0.8794
Paediatric	2/ 11 (18.2)	18.2	0/ 5 (0.0)	0.0	2.50 (0.14, 44.26)	0.5320	18.18 (-26.66, 63.02)	0.4268	
Adult	6/108 (5.6)	5.8	2/116 (1.7)	1.7	3.22 (0.66, 15.62)	0.1463	4.03 (-4.15, 12.20)	0.3340	
ADA result									0.6991
Negative	7/115 (6.1)	6.3	2/111 (1.8)	1.9	3.38 (0.72, 15.91)	0.1236	4.42 (-3.80, 12.64)	0.2922	
Positive (At any time)	1/ 4 (25.0)	25.0	0/ 10 (0.0)	0.0	6.60 (0.32, 135.38)	0.2208	25.00 (-27.17, 77.17)	0.3476	
BMI (kg/m2) at enrolment									0.6932
< 30	5/ 85 (5.9)	5.9	1/ 89 (1.1)	1.1	5.24 (0.62, 43.89)	0.1270	4.82 (-3.70, 13.35)	0.2674	
>= 30	3/ 34 (8.8)	8.8	1/ 32 (3.1)	3.1	2.82 (0.31, 25.77)	0.3575	5.70 (-9.16, 20.56)	0.4523	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.4451
All negative/normal	1/ 38 (2.6)	2.8	1/ 56 (1.8)	1.7	1.47 (0.10, 22.85)	0.7816	1.09 (-12.74, 14.93)	0.8772	
At least one positive/abnormal	7/ 81 (8.6)	8.6	1/ 65 (1.5)	1.5	5.62 (0.71, 44.50)	0.1022	7.10 (-1.23, 15.44)	0.0949	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Herpes Zoster leading to discontinuation of study drug
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.50, 6.50)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Herpes Zoster leading to discontinuation of study drug - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.48, 15.48)	1.0000	
>= 10 points	0/ 78 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-7.36, 7.36)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 58 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-9.71, 9.71)	1.0000	
>=10 mg/day	0/ 61 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.81, 9.81)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	0/ 97 (0.0)	0.0	NE	0.00 (-7.23, 7.23)	1.0000	
Age (years)								NE
<= 65	0/117 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.57, 6.57)	1.0000	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-116.14, 116.14)	1.0000	
Sex								NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	0/109 (0.0)	0.0	NE	0.00 (-7.09, 7.09)	1.0000	
Race								NE
White	0/ 75 (0.0)	0.0	0/ 78 (0.0)	0.0	NE	0.00 (-7.93, 7.93)	1.0000	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE	0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE	0.00 (-41.13, 41.13)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	0/ 86 (0.0)	0.0	NE	0.00 (-7.13, 7.13)	1.0000	
Geographic region								NE
EU	0/ 45 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-9.64, 9.64)	1.0000	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-7.62, 7.62)	1.0000	
Onset of disease								NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
Adult	0/108 (0.0)	0.0	0/116 (0.0)	0.0	NE	0.00 (-6.89, 6.89)	1.0000	
ADA result								NE
Negative	0/115 (0.0)	0.0	0/111 (0.0)	0.0	NE	0.00 (-6.86, 6.86)	1.0000	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE	0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 85 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-6.95, 6.95)	1.0000	
>= 30	0/ 34 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-10.92, 10.92)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	0/ 81 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-5.25, 5.25)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Influenza
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	3 (2.5)	6 (5.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.51 (0.13, 1.99)	
p-value	0.3305	
Odds Ratio (95% CI)	0.50 (0.12, 2.03)	
p-value	0.3292	
Risk Difference (95% CI)	-2.44 (-7.22, 2.35)	
p-value	0.3180	
CMH approach		
Response rate	2.3	4.4
Difference in response rates (95% CI)	-2.08 (-9.53, 5.36)	
p-value	0.5835	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.2349
< 10 points	2/ 41 (4.9)	5.0	1/ 32 (3.1)	3.2	1.56 (0.15, 16.46)	0.7110	1.76 (-15.08, 18.60)	0.8377	
>= 10 points	1/ 78 (1.3)	1.2	5/ 89 (5.6)	5.1	0.23 (0.03, 1.91)	0.1730	-3.96 (-12.47, 4.56)	0.3628	
OCS dose at baseline									0.0869
<10 mg/day	1/ 58 (1.7)	1.7	6/ 65 (9.2)	8.8	0.19 (0.02, 1.51)	0.1151	-7.11 (-18.67, 4.44)	0.2274	
>=10 mg/day	2/ 61 (3.3)	3.0	0/ 56 (0.0)	0.0	4.60 (0.23, 93.72)	0.3214	3.03 (-7.42, 13.47)	0.5702	
Result of type I IFN gene signature test									0.7515
LOW	0/ 23 (0.0)	0.0	1/ 24 (4.2)	4.2	0.35 (0.01, 8.11)	0.5106	-4.17 (-20.53, 12.19)	0.6177	
HIGH	3/ 96 (3.1)	2.9	5/ 97 (5.2)	4.4	0.61 (0.15, 2.47)	0.4845	-1.57 (-9.93, 6.79)	0.7133	
Age (years)									NE
<= 65	3/117 (2.6)	2.3	6/120 (5.0)	4.5	0.51 (0.13, 2.00)	0.3366	-2.13 (-9.67, 5.40)	0.5787	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									0.7662
male	0/ 11 (0.0)	0.0	1/ 12 (8.3)	8.3	0.36 (0.02, 8.04)	0.5200	-8.33 (-38.19, 21.52)	0.5843	
female	3/108 (2.8)	2.6	5/109 (4.6)	4.1	0.61 (0.15, 2.47)	0.4845	-1.57 (-9.61, 6.48)	0.7029	
Race									0.9812
White	1/ 75 (1.3)	1.0	2/ 78 (2.6)	2.5	0.52 (0.05, 5.62)	0.5901	-1.49 (-10.17, 7.19)	0.7367	
Black or African American	0/ 11 (0.0)	0.0	1/ 18 (5.6)	5.6	0.53 (0.02, 11.93)	0.6879	-5.56 (-31.15, 20.04)	0.6705	
Asian	0/ 17 (0.0)	0.0	1/ 16 (6.3)	6.3	0.31 (0.01, 7.21)	0.4694	-6.25 (-28.63, 16.13)	0.5841	
Other	1/ 8 (12.5)	12.5	1/ 6 (16.7)	16.7	0.75 (0.06, 9.72)	0.8258	-4.17 (-51.55, 43.21)	0.8632	
Ethnicity									0.3884
Hispanic/Latino	1/ 27 (3.7)	3.7	1/ 32 (3.1)	3.1	1.19 (0.08, 18.06)	0.9027	0.58 (-14.12, 15.28)	0.9385	
Non-hispanic/Latino	1/ 84 (1.2)	1.0	4/ 86 (4.7)	4.5	0.26 (0.03, 2.24)	0.2185	-3.47 (-11.74, 4.79)	0.4099	
Geographic region									0.7429
EU	1/ 45 (2.2)	2.2	2/ 33 (6.1)	6.1	0.37 (0.03, 3.88)	0.4043	-3.84 (-16.54, 8.86)	0.5536	
non-EU	2/ 74 (2.7)	2.6	4/ 88 (4.5)	4.3	0.59 (0.11, 3.16)	0.5415	-1.73 (-10.76, 7.29)	0.7066	
Onset of disease									NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
Adult	3/108 (2.8)	2.6	6/116 (5.2)	4.7	0.54 (0.14, 2.09)	0.3706	-2.14 (-10.06, 5.79)	0.5971	
ADA result									0.8896
Negative	3/115 (2.6)	2.4	5/111 (4.5)	4.0	0.58 (0.14, 2.37)	0.4468	-1.65 (-9.43, 6.13)	0.6775	
Positive (At any time)	0/ 4 (0.0)	0.0	1/ 10 (10.0)	10.0	0.73 (0.04, 15.04)	0.8405	-10.00 (-59.47, 39.47)	0.6920	
BMI (kg/m2) at enrolment									0.4023
< 30	3/ 85 (3.5)	3.6	4/ 89 (4.5)	4.4	0.79 (0.18, 3.41)	0.7468	-0.77 (-9.39, 7.85)	0.8614	
>= 30	0/ 34 (0.0)	0.0	2/ 32 (6.3)	6.3	0.19 (0.01, 3.78)	0.2756	-6.25 (-19.47, 6.97)	0.3543	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.1766
All negative/normal	2/ 38 (5.3)	5.2	2/ 56 (3.6)	3.3	1.47 (0.22, 10.01)	0.6916	1.89 (-12.66, 16.44)	0.7991	
At least one positive/abnormal	1/ 81 (1.2)	1.2	4/ 65 (6.2)	6.2	0.20 (0.02, 1.75)	0.1462	-4.92 (-12.86, 3.02)	0.2247	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Serious Influenza
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	0 (0.0)	1 (0.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.34 (0.01, 8.24)	
p-value	0.5062	
Odds Ratio (95% CI)	0.34 (0.01, 8.33)	
p-value	0.5057	
Risk Difference (95% CI)	-0.83 (-2.44, 0.79)	
p-value	0.3153	
CMH approach		
Response rate	0.0	0.7
Difference in response rates (95% CI)	-0.71 (-7.33, 5.91)	
p-value	0.8329	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Serious Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-15.48, 15.48)	1.0000	
>= 10 points	0/ 78 (0.0)	0.0	1/ 89 (1.1)	1.0	0.38 (0.02, 9.19)	0.5514	-1.02 (-8.60, 6.55)	0.7909	
OCS dose at baseline									NE
<10 mg/day	0/ 58 (0.0)	0.0	1/ 65 (1.5)	1.4	0.37 (0.02, 8.98)	0.5433	-1.39 (-11.40, 8.62)	0.7851	
>=10 mg/day	0/ 61 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-9.81, 9.81)	1.0000	
Result of type I IFN gene signature test									NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	1/ 97 (1.0)	0.9	0.34 (0.01, 8.17)	0.5035	-0.89 (-8.28, 6.50)	0.8138	
Age (years)									NE
<= 65	0/117 (0.0)	0.0	1/120 (0.8)	0.7	0.34 (0.01, 8.31)	0.5096	-0.73 (-7.42, 5.96)	0.8302	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	1/109 (0.9)	0.8	0.34 (0.01, 8.17)	0.5032	-0.81 (-8.04, 6.41)	0.8254	
Race									NE
White	0/ 75 (0.0)	0.0	1/ 78 (1.3)	1.3	0.35 (0.01, 8.37)	0.5143	-1.27 (-9.51, 6.98)	0.7635	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE		0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE		0.00 (-41.13, 41.13)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	1/ 86 (1.2)	1.1	0.34 (0.01, 8.26)	0.5084	-1.13 (-8.54, 6.29)	0.7658	
Geographic region									NE
EU	0/ 45 (0.0)	0.0	0/ 33 (0.0)	0.0	NE		0.00 (-9.64, 9.64)	1.0000	
non-EU	0/ 74 (0.0)	0.0	1/ 88 (1.1)	1.1	0.40 (0.02, 9.57)	0.5683	-1.06 (-8.92, 6.80)	0.7910	
Onset of disease									NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
Adult	0/108 (0.0)	0.0	1/116 (0.9)	0.8	0.36 (0.01, 8.69)	0.5277	-0.77 (-7.79, 6.25)	0.8302	
ADA result									NE
Negative	0/115 (0.0)	0.0	1/111 (0.9)	0.8	0.32 (0.01, 7.82)	0.4861	-0.78 (-7.78, 6.21)	0.8265	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE		0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/ 85 (0.0)	0.0	0/ 89 (0.0)	0.0	NE		0.00 (-6.95, 6.95)	1.0000	
>= 30	0/ 34 (0.0)	0.0	1/ 32 (3.1)	3.1	0.31 (0.01, 7.45)	0.4735	-3.13 (-15.29, 9.04)	0.6147	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	0/ 81 (0.0)	0.0	1/ 65 (1.5)	1.5	0.27 (0.01, 6.48)	0.4180	-1.54 (-7.49, 4.42)	0.6127	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Severe Influenza
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	0 (0.0)	1 (0.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.34 (0.01, 8.24)	
p-value	0.5062	
Odds Ratio (95% CI)	0.34 (0.01, 8.33)	
p-value	0.5057	
Risk Difference (95% CI)	-0.83 (-2.44, 0.79)	
p-value	0.3153	
CMH approach		
Response rate	0.0	0.7
Difference in response rates (95% CI)	-0.71 (-7.33, 5.91)	
p-value	0.8329	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Severe Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-15.48, 15.48)	1.0000	
>= 10 points	0/ 78 (0.0)	0.0	1/ 89 (1.1)	1.0	0.38 (0.02, 9.19)	0.5514	-1.02 (-8.60, 6.55)	0.7909	
OCS dose at baseline									NE
<10 mg/day	0/ 58 (0.0)	0.0	1/ 65 (1.5)	1.4	0.37 (0.02, 8.98)	0.5433	-1.39 (-11.40, 8.62)	0.7851	
>=10 mg/day	0/ 61 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-9.81, 9.81)	1.0000	
Result of type I IFN gene signature test									NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	1/ 97 (1.0)	0.9	0.34 (0.01, 8.17)	0.5035	-0.89 (-8.28, 6.50)	0.8138	
Age (years)									NE
<= 65	0/117 (0.0)	0.0	1/120 (0.8)	0.7	0.34 (0.01, 8.31)	0.5096	-0.73 (-7.42, 5.96)	0.8302	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	1/109 (0.9)	0.8	0.34 (0.01, 8.17)	0.5032	-0.81 (-8.04, 6.41)	0.8254	
Race									NE
White	0/ 75 (0.0)	0.0	1/ 78 (1.3)	1.3	0.35 (0.01, 8.37)	0.5143	-1.27 (-9.51, 6.98)	0.7635	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE		0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE		0.00 (-41.13, 41.13)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	1/ 86 (1.2)	1.1	0.34 (0.01, 8.26)	0.5084	-1.13 (-8.54, 6.29)	0.7658	
Geographic region									NE
EU	0/ 45 (0.0)	0.0	0/ 33 (0.0)	0.0	NE		0.00 (-9.64, 9.64)	1.0000	
non-EU	0/ 74 (0.0)	0.0	1/ 88 (1.1)	1.1	0.40 (0.02, 9.57)	0.5683	-1.06 (-8.92, 6.80)	0.7910	
Onset of disease									NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
Adult	0/108 (0.0)	0.0	1/116 (0.9)	0.8	0.36 (0.01, 8.69)	0.5277	-0.77 (-7.79, 6.25)	0.8302	
ADA result									NE
Negative	0/115 (0.0)	0.0	1/111 (0.9)	0.8	0.32 (0.01, 7.82)	0.4861	-0.78 (-7.78, 6.21)	0.8265	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE		0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/ 85 (0.0)	0.0	0/ 89 (0.0)	0.0	NE		0.00 (-6.95, 6.95)	1.0000	
>= 30	0/ 34 (0.0)	0.0	1/ 32 (3.1)	3.1	0.31 (0.01, 7.45)	0.4735	-3.13 (-15.29, 9.04)	0.6147	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	0/ 81 (0.0)	0.0	1/ 65 (1.5)	1.5	0.27 (0.01, 6.48)	0.4180	-1.54 (-7.49, 4.42)	0.6127	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Non-Severe Influenza
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	3 (2.5)	5 (4.1)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.61 (0.15, 2.50)	
p-value	0.4918	
Odds Ratio (95% CI)	0.60 (0.14, 2.57)	
p-value	0.4912	
Risk Difference (95% CI)	-1.61 (-6.14, 2.92)	
p-value	0.4856	
CMH approach		
Response rate	2.3	3.7
Difference in response rates (95% CI)	-1.37 (-8.74, 5.99)	
p-value	0.7153	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Non-Severe Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.2983
< 10 points	2/ 41 (4.9)	5.0	1/ 32 (3.1)	3.2	1.56 (0.15, 16.46)	0.7110	1.76 (-15.08, 18.60)	0.8377	
>= 10 points	1/ 78 (1.3)	1.2	4/ 89 (4.5)	4.1	0.29 (0.03, 2.50)	0.2573	-2.93 (-11.30, 5.44)	0.4926	
OCS dose at baseline									0.1081
<10 mg/day	1/ 58 (1.7)	1.7	5/ 65 (7.7)	7.4	0.22 (0.03, 1.86)	0.1663	-5.72 (-17.07, 5.63)	0.3232	
>=10 mg/day	2/ 61 (3.3)	3.0	0/ 56 (0.0)	0.0	4.60 (0.23, 93.72)	0.3214	3.03 (-7.42, 13.47)	0.5702	
Result of type I IFN gene signature test									0.6600
LOW	0/ 23 (0.0)	0.0	1/ 24 (4.2)	4.2	0.35 (0.01, 8.11)	0.5106	-4.17 (-20.53, 12.19)	0.6177	
HIGH	3/ 96 (3.1)	2.9	4/ 97 (4.1)	3.6	0.76 (0.17, 3.30)	0.7116	-0.68 (-8.93, 7.57)	0.8718	
Age (years)									NE
<= 65	3/117 (2.6)	2.3	5/120 (4.2)	3.7	0.62 (0.15, 2.52)	0.4993	-1.40 (-8.85, 6.05)	0.7122	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									0.6728
male	0/ 11 (0.0)	0.0	1/ 12 (8.3)	8.3	0.36 (0.02, 8.04)	0.5200	-8.33 (-38.19, 21.52)	0.5843	
female	3/108 (2.8)	2.6	4/109 (3.7)	3.3	0.76 (0.17, 3.30)	0.7110	-0.75 (-8.70, 7.19)	0.8528	
Race									0.9512
White	1/ 75 (1.3)	1.0	1/ 78 (1.3)	1.3	1.04 (0.07, 16.33)	0.9777	-0.22 (-8.62, 8.17)	0.9583	
Black or African American	0/ 11 (0.0)	0.0	1/ 18 (5.6)	5.6	0.53 (0.02, 11.93)	0.6879	-5.56 (-31.15, 20.04)	0.6705	
Asian	0/ 17 (0.0)	0.0	1/ 16 (6.3)	6.3	0.31 (0.01, 7.21)	0.4694	-6.25 (-28.63, 16.13)	0.5841	
Other	1/ 8 (12.5)	12.5	1/ 6 (16.7)	16.7	0.75 (0.06, 9.72)	0.8258	-4.17 (-51.55, 43.21)	0.8632	
Ethnicity									0.4893
Hispanic/Latino	1/ 27 (3.7)	3.7	1/ 32 (3.1)	3.1	1.19 (0.08, 18.06)	0.9027	0.58 (-14.12, 15.28)	0.9385	
Non-hispanic/Latino	1/ 84 (1.2)	1.0	3/ 86 (3.5)	3.4	0.34 (0.04, 3.22)	0.3475	-2.35 (-10.38, 5.68)	0.5665	
Geographic region									0.6077
EU	1/ 45 (2.2)	2.2	2/ 33 (6.1)	6.1	0.37 (0.03, 3.88)	0.4043	-3.84 (-16.54, 8.86)	0.5536	
non-EU	2/ 74 (2.7)	2.6	3/ 88 (3.4)	3.2	0.79 (0.14, 4.62)	0.7962	-0.67 (-9.51, 8.17)	0.8817	
Onset of disease									NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
Adult	3/108 (2.8)	2.6	5/116 (4.3)	3.9	0.64 (0.16, 2.63)	0.5406	-1.37 (-9.20, 6.47)	0.7322	
ADA result									0.9940
Negative	3/115 (2.6)	2.4	4/111 (3.6)	3.2	0.72 (0.17, 3.16)	0.6675	-0.87 (-8.55, 6.81)	0.8247	
Positive (At any time)	0/ 4 (0.0)	0.0	1/ 10 (10.0)	10.0	0.73 (0.04, 15.04)	0.8405	-10.00 (-59.47, 39.47)	0.6920	
BMI (kg/m2) at enrolment									0.6069
< 30	3/ 85 (3.5)	3.6	4/ 89 (4.5)	4.4	0.79 (0.18, 3.41)	0.7468	-0.77 (-9.39, 7.85)	0.8614	
>= 30	0/ 34 (0.0)	0.0	1/ 32 (3.1)	3.1	0.31 (0.01, 7.45)	0.4735	-3.13 (-15.29, 9.04)	0.6147	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.2565
All negative/normal	2/ 38 (5.3)	5.2	2/ 56 (3.6)	3.3	1.47 (0.22, 10.01)	0.6916	1.89 (-12.66, 16.44)	0.7991	
At least one positive/abnormal	1/ 81 (1.2)	1.2	3/ 65 (4.6)	4.6	0.27 (0.03, 2.51)	0.2485	-3.38 (-10.86, 4.09)	0.3753	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	1 (0.8)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.05 (0.13, 74.13)	
p-value	0.4933	
Odds Ratio (95% CI)	3.08 (0.12, 76.26)	
p-value	0.4928	
Risk Difference (95% CI)	0.84 (-0.80, 2.48)	
p-value	0.3153	
CMH approach		
Response rate	0.8	0.0
Difference in response rates (95% CI)	0.84 (-5.77, 7.46)	
p-value	0.8024	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	1/ 41 (2.4)	2.8	0/ 32 (0.0)	0.0	2.36 (0.10, 56.00)	0.5958	2.81 (-13.19, 18.81)	0.7307	
>= 10 points	0/ 78 (0.0)	0.0	0/ 89 (0.0)	0.0	NE		0.00 (-7.36, 7.36)	1.0000	
OCS dose at baseline									NE
<10 mg/day	1/ 58 (1.7)	1.7	0/ 65 (0.0)	0.0	3.36 (0.14, 80.80)	0.4557	1.65 (-8.35, 11.65)	0.7463	
>=10 mg/day	0/ 61 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-9.81, 9.81)	1.0000	
Result of type I IFN gene signature test									NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
HIGH	1/ 96 (1.0)	1.1	0/ 97 (0.0)	0.0	3.03 (0.13, 73.49)	0.4954	1.05 (-6.33, 8.44)	0.7799	
Age (years)									NE
<= 65	1/117 (0.9)	0.9	0/120 (0.0)	0.0	3.08 (0.13, 74.76)	0.4900	0.85 (-5.83, 7.54)	0.8022	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-27.45, 27.45)	1.0000	
female	1/108 (0.9)	1.0	0/109 (0.0)	0.0	3.03 (0.12, 73.51)	0.4961	0.97 (-6.25, 8.19)	0.7926	
Race									NE
White	1/ 75 (1.3)	1.0	0/ 78 (0.0)	0.0	3.12 (0.13, 75.37)	0.4840	1.04 (-7.05, 9.13)	0.8007	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE		0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE		0.00 (-41.13, 41.13)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	1/ 84 (1.2)	1.0	0/ 86 (0.0)	0.0	3.07 (0.13, 74.33)	0.4902	1.01 (-6.29, 8.32)	0.7855	
Geographic region									NE
EU	1/ 45 (2.2)	2.2	0/ 33 (0.0)	0.0	2.22 (0.09, 52.78)	0.6224	2.22 (-8.20, 12.64)	0.6760	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE		0.00 (-7.62, 7.62)	1.0000	
Onset of disease									NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
Adult	1/108 (0.9)	0.9	0/116 (0.0)	0.0	3.22 (0.13, 78.21)	0.4724	0.90 (-6.11, 7.92)	0.8012	
ADA result									NE
Negative	1/115 (0.9)	0.9	0/111 (0.0)	0.0	2.90 (0.12, 70.36)	0.5135	0.90 (-6.09, 7.88)	0.8009	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE		0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/ 85 (0.0)	0.0	0/ 89 (0.0)	0.0	NE		0.00 (-6.95, 6.95)	1.0000	
>= 30	1/ 34 (2.9)	2.9	0/ 32 (0.0)	0.0	2.83 (0.12, 67.01)	0.5197	2.94 (-9.11, 14.99)	0.6323	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									NE
All negative/normal	1/ 38 (2.6)	2.2	0/ 56 (0.0)	0.0	4.38 (0.18, 104.87)	0.3615	2.18 (-11.23, 15.58)	0.7503	
At least one positive/abnormal	0/ 81 (0.0)	0.0	0/ 65 (0.0)	0.0	NE		0.00 (-5.25, 5.25)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Serious Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.50, 6.50)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Serious Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.48, 15.48)	1.0000	
>= 10 points	0/ 78 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-7.36, 7.36)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 58 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-9.71, 9.71)	1.0000	
>=10 mg/day	0/ 61 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.81, 9.81)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	0/ 97 (0.0)	0.0	NE	0.00 (-7.23, 7.23)	1.0000	
Age (years)								NE
<= 65	0/117 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.57, 6.57)	1.0000	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-116.14, 116.14)	1.0000	
Sex								NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	0/109 (0.0)	0.0	NE	0.00 (-7.09, 7.09)	1.0000	
Race								NE
White	0/ 75 (0.0)	0.0	0/ 78 (0.0)	0.0	NE	0.00 (-7.93, 7.93)	1.0000	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE	0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE	0.00 (-41.13, 41.13)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	0/ 86 (0.0)	0.0	NE	0.00 (-7.13, 7.13)	1.0000	
Geographic region								NE
EU	0/ 45 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-9.64, 9.64)	1.0000	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-7.62, 7.62)	1.0000	
Onset of disease								NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
Adult	0/108 (0.0)	0.0	0/116 (0.0)	0.0	NE	0.00 (-6.89, 6.89)	1.0000	
ADA result								NE
Negative	0/115 (0.0)	0.0	0/111 (0.0)	0.0	NE	0.00 (-6.86, 6.86)	1.0000	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE	0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 85 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-6.95, 6.95)	1.0000	
>= 30	0/ 34 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-10.92, 10.92)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	0/ 81 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-5.25, 5.25)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Severe Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.50, 6.50)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Severe Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.48, 15.48)	1.0000	
>= 10 points	0/ 78 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-7.36, 7.36)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 58 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-9.71, 9.71)	1.0000	
>=10 mg/day	0/ 61 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.81, 9.81)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	0/ 97 (0.0)	0.0	NE	0.00 (-7.23, 7.23)	1.0000	
Age (years)								NE
<= 65	0/117 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.57, 6.57)	1.0000	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-116.14, 116.14)	1.0000	
Sex								NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	0/109 (0.0)	0.0	NE	0.00 (-7.09, 7.09)	1.0000	
Race								NE
White	0/ 75 (0.0)	0.0	0/ 78 (0.0)	0.0	NE	0.00 (-7.93, 7.93)	1.0000	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE	0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE	0.00 (-41.13, 41.13)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	0/ 86 (0.0)	0.0	NE	0.00 (-7.13, 7.13)	1.0000	
Geographic region								NE
EU	0/ 45 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-9.64, 9.64)	1.0000	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-7.62, 7.62)	1.0000	
Onset of disease								NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
Adult	0/108 (0.0)	0.0	0/116 (0.0)	0.0	NE	0.00 (-6.89, 6.89)	1.0000	
ADA result								NE
Negative	0/115 (0.0)	0.0	0/111 (0.0)	0.0	NE	0.00 (-6.86, 6.86)	1.0000	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE	0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 85 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-6.95, 6.95)	1.0000	
>= 30	0/ 34 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-10.92, 10.92)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	0/ 81 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-5.25, 5.25)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Non-Severe Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	1 (0.8)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.05 (0.13, 74.13)	
p-value	0.4933	
Odds Ratio (95% CI)	3.08 (0.12, 76.26)	
p-value	0.4928	
Risk Difference (95% CI)	0.84 (-0.80, 2.48)	
p-value	0.3153	
CMH approach		
Response rate	0.8	0.0
Difference in response rates (95% CI)	0.84 (-5.77, 7.46)	
p-value	0.8024	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Non-Severe Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	1/ 41 (2.4)	2.8	0/ 32 (0.0)	0.0	2.36 (0.10, 56.00)	0.5958	2.81 (-13.19, 18.81)	0.7307	
>= 10 points	0/ 78 (0.0)	0.0	0/ 89 (0.0)	0.0	NE		0.00 (-7.36, 7.36)	1.0000	
OCS dose at baseline									NE
<10 mg/day	1/ 58 (1.7)	1.7	0/ 65 (0.0)	0.0	3.36 (0.14, 80.80)	0.4557	1.65 (-8.35, 11.65)	0.7463	
>=10 mg/day	0/ 61 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-9.81, 9.81)	1.0000	
Result of type I IFN gene signature test									NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
HIGH	1/ 96 (1.0)	1.1	0/ 97 (0.0)	0.0	3.03 (0.13, 73.49)	0.4954	1.05 (-6.33, 8.44)	0.7799	
Age (years)									NE
<= 65	1/117 (0.9)	0.9	0/120 (0.0)	0.0	3.08 (0.13, 74.76)	0.4900	0.85 (-5.83, 7.54)	0.8022	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-27.45, 27.45)	1.0000	
female	1/108 (0.9)	1.0	0/109 (0.0)	0.0	3.03 (0.12, 73.51)	0.4961	0.97 (-6.25, 8.19)	0.7926	
Race									NE
White	1/ 75 (1.3)	1.0	0/ 78 (0.0)	0.0	3.12 (0.13, 75.37)	0.4840	1.04 (-7.05, 9.13)	0.8007	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE		0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE		0.00 (-41.13, 41.13)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	1/ 84 (1.2)	1.0	0/ 86 (0.0)	0.0	3.07 (0.13, 74.33)	0.4902	1.01 (-6.29, 8.32)	0.7855	
Geographic region									NE
EU	1/ 45 (2.2)	2.2	0/ 33 (0.0)	0.0	2.22 (0.09, 52.78)	0.6224	2.22 (-8.20, 12.64)	0.6760	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE		0.00 (-7.62, 7.62)	1.0000	
Onset of disease									NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
Adult	1/108 (0.9)	0.9	0/116 (0.0)	0.0	3.22 (0.13, 78.21)	0.4724	0.90 (-6.11, 7.92)	0.8012	
ADA result									NE
Negative	1/115 (0.9)	0.9	0/111 (0.0)	0.0	2.90 (0.12, 70.36)	0.5135	0.90 (-6.09, 7.88)	0.8009	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE		0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/ 85 (0.0)	0.0	0/ 89 (0.0)	0.0	NE		0.00 (-6.95, 6.95)	1.0000	
>= 30	1/ 34 (2.9)	2.9	0/ 32 (0.0)	0.0	2.83 (0.12, 67.01)	0.5197	2.94 (-9.11, 14.99)	0.6323	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									NE
All negative/normal	1/ 38 (2.6)	2.2	0/ 56 (0.0)	0.0	4.38 (0.18, 104.87)	0.3615	2.18 (-11.23, 15.58)	0.7503	
At least one positive/abnormal	0/ 81 (0.0)	0.0	0/ 65 (0.0)	0.0	NE		0.00 (-5.25, 5.25)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Vasculitis
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.50, 6.50)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.48, 15.48)	1.0000	
>= 10 points	0/ 78 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-7.36, 7.36)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 58 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-9.71, 9.71)	1.0000	
>=10 mg/day	0/ 61 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.81, 9.81)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	0/ 97 (0.0)	0.0	NE	0.00 (-7.23, 7.23)	1.0000	
Age (years)								NE
<= 65	0/117 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.57, 6.57)	1.0000	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-116.14, 116.14)	1.0000	
Sex								NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	0/109 (0.0)	0.0	NE	0.00 (-7.09, 7.09)	1.0000	
Race								NE
White	0/ 75 (0.0)	0.0	0/ 78 (0.0)	0.0	NE	0.00 (-7.93, 7.93)	1.0000	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE	0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE	0.00 (-41.13, 41.13)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	0/ 86 (0.0)	0.0	NE	0.00 (-7.13, 7.13)	1.0000	
Geographic region								NE
EU	0/ 45 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-9.64, 9.64)	1.0000	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-7.62, 7.62)	1.0000	
Onset of disease								NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
Adult	0/108 (0.0)	0.0	0/116 (0.0)	0.0	NE	0.00 (-6.89, 6.89)	1.0000	
ADA result								NE
Negative	0/115 (0.0)	0.0	0/111 (0.0)	0.0	NE	0.00 (-6.86, 6.86)	1.0000	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE	0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 85 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-6.95, 6.95)	1.0000	
>= 30	0/ 34 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-10.92, 10.92)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	0/ 81 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-5.25, 5.25)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Serious Vasculitis
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.50, 6.50)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Serious Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Anifrolumab 300mg (N=119) Response rate	Placebo (N=121) n/ N (%)	Placebo (N=121) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Analysis Anifrolumab 300mg vs. Placebo Difference in response rates (95% CI)	Analysis Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.48, 15.48)	1.0000	
>= 10 points	0/ 78 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-7.36, 7.36)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 58 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-9.71, 9.71)	1.0000	
>=10 mg/day	0/ 61 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.81, 9.81)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	0/ 97 (0.0)	0.0	NE	0.00 (-7.23, 7.23)	1.0000	
Age (years)								NE
<= 65	0/117 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.57, 6.57)	1.0000	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-116.14, 116.14)	1.0000	
Sex								NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	0/109 (0.0)	0.0	NE	0.00 (-7.09, 7.09)	1.0000	
Race								NE
White	0/ 75 (0.0)	0.0	0/ 78 (0.0)	0.0	NE	0.00 (-7.93, 7.93)	1.0000	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE	0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE	0.00 (-41.13, 41.13)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	0/ 86 (0.0)	0.0	NE	0.00 (-7.13, 7.13)	1.0000	
Geographic region								NE
EU	0/ 45 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-9.64, 9.64)	1.0000	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-7.62, 7.62)	1.0000	
Onset of disease								NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
Adult	0/108 (0.0)	0.0	0/116 (0.0)	0.0	NE	0.00 (-6.89, 6.89)	1.0000	
ADA result								NE
Negative	0/115 (0.0)	0.0	0/111 (0.0)	0.0	NE	0.00 (-6.86, 6.86)	1.0000	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE	0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 85 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-6.95, 6.95)	1.0000	
>= 30	0/ 34 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-10.92, 10.92)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	0/ 81 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-5.25, 5.25)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Severe Vasculitis
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.50, 6.50)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Severe Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.48, 15.48)	1.0000	
>= 10 points	0/ 78 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-7.36, 7.36)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 58 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-9.71, 9.71)	1.0000	
>=10 mg/day	0/ 61 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.81, 9.81)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	0/ 97 (0.0)	0.0	NE	0.00 (-7.23, 7.23)	1.0000	
Age (years)								NE
<= 65	0/117 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.57, 6.57)	1.0000	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-116.14, 116.14)	1.0000	
Sex								NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	0/109 (0.0)	0.0	NE	0.00 (-7.09, 7.09)	1.0000	
Race								NE
White	0/ 75 (0.0)	0.0	0/ 78 (0.0)	0.0	NE	0.00 (-7.93, 7.93)	1.0000	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE	0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE	0.00 (-41.13, 41.13)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	0/ 86 (0.0)	0.0	NE	0.00 (-7.13, 7.13)	1.0000	
Geographic region								NE
EU	0/ 45 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-9.64, 9.64)	1.0000	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-7.62, 7.62)	1.0000	
Onset of disease								NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
Adult	0/108 (0.0)	0.0	0/116 (0.0)	0.0	NE	0.00 (-6.89, 6.89)	1.0000	
ADA result								NE
Negative	0/115 (0.0)	0.0	0/111 (0.0)	0.0	NE	0.00 (-6.86, 6.86)	1.0000	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE	0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 85 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-6.95, 6.95)	1.0000	
>= 30	0/ 34 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-10.92, 10.92)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	0/ 81 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-5.25, 5.25)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Non-Severe Vasculitis
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.50, 6.50)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Non-Severe Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.48, 15.48)	1.0000	
>= 10 points	0/ 78 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-7.36, 7.36)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 58 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-9.71, 9.71)	1.0000	
>=10 mg/day	0/ 61 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.81, 9.81)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	0/ 97 (0.0)	0.0	NE	0.00 (-7.23, 7.23)	1.0000	
Age (years)								NE
<= 65	0/117 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.57, 6.57)	1.0000	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-116.14, 116.14)	1.0000	
Sex								NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	0/109 (0.0)	0.0	NE	0.00 (-7.09, 7.09)	1.0000	
Race								NE
White	0/ 75 (0.0)	0.0	0/ 78 (0.0)	0.0	NE	0.00 (-7.93, 7.93)	1.0000	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE	0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE	0.00 (-41.13, 41.13)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	0/ 86 (0.0)	0.0	NE	0.00 (-7.13, 7.13)	1.0000	
Geographic region								NE
EU	0/ 45 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-9.64, 9.64)	1.0000	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-7.62, 7.62)	1.0000	
Onset of disease								NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
Adult	0/108 (0.0)	0.0	0/116 (0.0)	0.0	NE	0.00 (-6.89, 6.89)	1.0000	
ADA result								NE
Negative	0/115 (0.0)	0.0	0/111 (0.0)	0.0	NE	0.00 (-6.86, 6.86)	1.0000	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE	0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 85 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-6.95, 6.95)	1.0000	
>= 30	0/ 34 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-10.92, 10.92)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	0/ 81 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-5.25, 5.25)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Malignancy
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	0 (0.0)	1 (0.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.34 (0.01, 8.24)	
p-value	0.5062	
Odds Ratio (95% CI)	0.34 (0.01, 8.33)	
p-value	0.5057	
Risk Difference (95% CI)	-0.83 (-2.44, 0.79)	
p-value	0.3153	
CMH approach		
Response rate	0.0	0.9
Difference in response rates (95% CI)	-0.88 (-7.55, 5.80)	
p-value	0.7968	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-15.48, 15.48)	1.0000	
>= 10 points	0/ 78 (0.0)	0.0	1/ 89 (1.1)	1.3	0.38 (0.02, 9.19)	0.5514	-1.26 (-8.94, 6.42)	0.7475	
OCS dose at baseline									NE
<10 mg/day	0/ 58 (0.0)	0.0	0/ 65 (0.0)	0.0	NE		0.00 (-9.71, 9.71)	1.0000	
>=10 mg/day	0/ 61 (0.0)	0.0	1/ 56 (1.8)	1.8	0.31 (0.01, 7.37)	0.4661	-1.82 (-12.13, 8.49)	0.7297	
Result of type I IFN gene signature test									NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	1/ 97 (1.0)	1.1	0.34 (0.01, 8.17)	0.5035	-1.09 (-8.57, 6.38)	0.7742	
Age (years)									NE
<= 65	0/117 (0.0)	0.0	1/120 (0.8)	0.9	0.34 (0.01, 8.31)	0.5096	-0.88 (-7.62, 5.87)	0.7989	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	1/109 (0.9)	1.0	0.34 (0.01, 8.17)	0.5032	-0.98 (-8.28, 6.31)	0.7912	
Race									NE
White	0/ 75 (0.0)	0.0	1/ 78 (1.3)	1.3	0.35 (0.01, 8.37)	0.5143	-1.27 (-9.51, 6.98)	0.7635	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE		0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE		0.00 (-41.13, 41.13)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	1/ 86 (1.2)	1.1	0.34 (0.01, 8.26)	0.5084	-1.13 (-8.54, 6.29)	0.7658	
Geographic region									NE
EU	0/ 45 (0.0)	0.0	1/ 33 (3.0)	3.0	0.25 (0.01, 5.86)	0.3864	-3.03 (-13.99, 7.93)	0.5879	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE		0.00 (-7.62, 7.62)	1.0000	
Onset of disease									NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
Adult	0/108 (0.0)	0.0	1/116 (0.9)	0.9	0.36 (0.01, 8.69)	0.5277	-0.89 (-7.95, 6.18)	0.8054	
ADA result									NE
Negative	0/115 (0.0)	0.0	1/111 (0.9)	1.0	0.32 (0.01, 7.82)	0.4861	-0.99 (-8.06, 6.08)	0.7837	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE		0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/ 85 (0.0)	0.0	1/ 89 (1.1)	1.1	0.35 (0.01, 8.45)	0.5172	-1.09 (-8.31, 6.13)	0.7677	
>= 30	0/ 34 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-10.92, 10.92)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	0/ 81 (0.0)	0.0	1/ 65 (1.5)	1.5	0.27 (0.01, 6.48)	0.4180	-1.54 (-7.49, 4.42)	0.6127	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Serious Malignancy
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	0 (0.0)	1 (0.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.34 (0.01, 8.24)	
p-value	0.5062	
Odds Ratio (95% CI)	0.34 (0.01, 8.33)	
p-value	0.5057	
Risk Difference (95% CI)	-0.83 (-2.44, 0.79)	
p-value	0.3153	
CMH approach		
Response rate	0.0	0.9
Difference in response rates (95% CI)	-0.88 (-7.55, 5.80)	
p-value	0.7968	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Serious Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-15.48, 15.48)	1.0000	
>= 10 points	0/ 78 (0.0)	0.0	1/ 89 (1.1)	1.3	0.38 (0.02, 9.19)	0.5514	-1.26 (-8.94, 6.42)	0.7475	
OCS dose at baseline									NE
<10 mg/day	0/ 58 (0.0)	0.0	0/ 65 (0.0)	0.0	NE		0.00 (-9.71, 9.71)	1.0000	
>=10 mg/day	0/ 61 (0.0)	0.0	1/ 56 (1.8)	1.8	0.31 (0.01, 7.37)	0.4661	-1.82 (-12.13, 8.49)	0.7297	
Result of type I IFN gene signature test									NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	1/ 97 (1.0)	1.1	0.34 (0.01, 8.17)	0.5035	-1.09 (-8.57, 6.38)	0.7742	
Age (years)									NE
<= 65	0/117 (0.0)	0.0	1/120 (0.8)	0.9	0.34 (0.01, 8.31)	0.5096	-0.88 (-7.62, 5.87)	0.7989	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	1/109 (0.9)	1.0	0.34 (0.01, 8.17)	0.5032	-0.98 (-8.28, 6.31)	0.7912	
Race									NE
White	0/ 75 (0.0)	0.0	1/ 78 (1.3)	1.3	0.35 (0.01, 8.37)	0.5143	-1.27 (-9.51, 6.98)	0.7635	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE		0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE		0.00 (-41.13, 41.13)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	1/ 86 (1.2)	1.1	0.34 (0.01, 8.26)	0.5084	-1.13 (-8.54, 6.29)	0.7658	
Geographic region									NE
EU	0/ 45 (0.0)	0.0	1/ 33 (3.0)	3.0	0.25 (0.01, 5.86)	0.3864	-3.03 (-13.99, 7.93)	0.5879	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE		0.00 (-7.62, 7.62)	1.0000	
Onset of disease									NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
Adult	0/108 (0.0)	0.0	1/116 (0.9)	0.9	0.36 (0.01, 8.69)	0.5277	-0.89 (-7.95, 6.18)	0.8054	
ADA result									NE
Negative	0/115 (0.0)	0.0	1/111 (0.9)	1.0	0.32 (0.01, 7.82)	0.4861	-0.99 (-8.06, 6.08)	0.7837	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE		0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/ 85 (0.0)	0.0	1/ 89 (1.1)	1.1	0.35 (0.01, 8.45)	0.5172	-1.09 (-8.31, 6.13)	0.7677	
>= 30	0/ 34 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-10.92, 10.92)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	0/ 81 (0.0)	0.0	1/ 65 (1.5)	1.5	0.27 (0.01, 6.48)	0.4180	-1.54 (-7.49, 4.42)	0.6127	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Severe Malignancy
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-6.50, 6.50)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Severe Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.48, 15.48)	1.0000	
>= 10 points	0/ 78 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-7.36, 7.36)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 58 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-9.71, 9.71)	1.0000	
>=10 mg/day	0/ 61 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.81, 9.81)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	0/ 97 (0.0)	0.0	NE	0.00 (-7.23, 7.23)	1.0000	
Age (years)								NE
<= 65	0/117 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.57, 6.57)	1.0000	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-116.14, 116.14)	1.0000	
Sex								NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	0/109 (0.0)	0.0	NE	0.00 (-7.09, 7.09)	1.0000	
Race								NE
White	0/ 75 (0.0)	0.0	0/ 78 (0.0)	0.0	NE	0.00 (-7.93, 7.93)	1.0000	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE	0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE	0.00 (-41.13, 41.13)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	0/ 86 (0.0)	0.0	NE	0.00 (-7.13, 7.13)	1.0000	
Geographic region								NE
EU	0/ 45 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-9.64, 9.64)	1.0000	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE	0.00 (-7.62, 7.62)	1.0000	
Onset of disease								NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
Adult	0/108 (0.0)	0.0	0/116 (0.0)	0.0	NE	0.00 (-6.89, 6.89)	1.0000	
ADA result								NE
Negative	0/115 (0.0)	0.0	0/111 (0.0)	0.0	NE	0.00 (-6.86, 6.86)	1.0000	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE	0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/ 85 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-6.95, 6.95)	1.0000	
>= 30	0/ 34 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-10.92, 10.92)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	0/ 81 (0.0)	0.0	0/ 65 (0.0)	0.0	NE	0.00 (-5.25, 5.25)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Non-Severe Malignancy
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	0 (0.0)	1 (0.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.34 (0.01, 8.24)	
p-value	0.5062	
Odds Ratio (95% CI)	0.34 (0.01, 8.33)	
p-value	0.5057	
Risk Difference (95% CI)	-0.83 (-2.44, 0.79)	
p-value	0.3153	
CMH approach		
Response rate	0.0	0.9
Difference in response rates (95% CI)	-0.88 (-7.55, 5.80)	
p-value	0.7968	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Non-Severe Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 41 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-15.48, 15.48)	1.0000	
>= 10 points	0/ 78 (0.0)	0.0	1/ 89 (1.1)	1.3	0.38 (0.02, 9.19)	0.5514	-1.26 (-8.94, 6.42)	0.7475	
OCS dose at baseline									NE
<10 mg/day	0/ 58 (0.0)	0.0	0/ 65 (0.0)	0.0	NE		0.00 (-9.71, 9.71)	1.0000	
>=10 mg/day	0/ 61 (0.0)	0.0	1/ 56 (1.8)	1.8	0.31 (0.01, 7.37)	0.4661	-1.82 (-12.13, 8.49)	0.7297	
Result of type I IFN gene signature test									NE
LOW	0/ 23 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-14.86, 14.86)	1.0000	
HIGH	0/ 96 (0.0)	0.0	1/ 97 (1.0)	1.1	0.34 (0.01, 8.17)	0.5035	-1.09 (-8.57, 6.38)	0.7742	
Age (years)									NE
<= 65	0/117 (0.0)	0.0	1/120 (0.8)	0.9	0.34 (0.01, 8.31)	0.5096	-0.88 (-7.62, 5.87)	0.7989	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-27.45, 27.45)	1.0000	
female	0/108 (0.0)	0.0	1/109 (0.9)	1.0	0.34 (0.01, 8.17)	0.5032	-0.98 (-8.28, 6.31)	0.7912	
Race									NE
White	0/ 75 (0.0)	0.0	1/ 78 (1.3)	1.3	0.35 (0.01, 8.37)	0.5143	-1.27 (-9.51, 6.98)	0.7635	
Black or African American	0/ 11 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-24.08, 24.08)	1.0000	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE		0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE		0.00 (-41.13, 41.13)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 27 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-12.20, 12.20)	1.0000	
Non-hispanic/Latino	0/ 84 (0.0)	0.0	1/ 86 (1.2)	1.1	0.34 (0.01, 8.26)	0.5084	-1.13 (-8.54, 6.29)	0.7658	
Geographic region									NE
EU	0/ 45 (0.0)	0.0	1/ 33 (3.0)	3.0	0.25 (0.01, 5.86)	0.3864	-3.03 (-13.99, 7.93)	0.5879	
non-EU	0/ 74 (0.0)	0.0	0/ 88 (0.0)	0.0	NE		0.00 (-7.62, 7.62)	1.0000	
Onset of disease									NE
Paediatric	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
Adult	0/108 (0.0)	0.0	1/116 (0.9)	0.9	0.36 (0.01, 8.69)	0.5277	-0.89 (-7.95, 6.18)	0.8054	
ADA result									NE
Negative	0/115 (0.0)	0.0	1/111 (0.9)	1.0	0.32 (0.01, 7.82)	0.4861	-0.99 (-8.06, 6.08)	0.7837	
Positive (At any time)	0/ 4 (0.0)	0.0	0/ 10 (0.0)	0.0	NE		0.00 (-47.66, 47.66)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/ 85 (0.0)	0.0	1/ 89 (1.1)	1.1	0.35 (0.01, 8.45)	0.5172	-1.09 (-8.31, 6.13)	0.7677	
>= 30	0/ 34 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-10.92, 10.92)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									NE
All negative/normal	0/ 38 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-13.02, 13.02)	1.0000	
At least one positive/abnormal	0/ 81 (0.0)	0.0	1/ 65 (1.5)	1.5	0.27 (0.01, 6.48)	0.4180	-1.54 (-7.49, 4.42)	0.6127	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of SOCs Cardiac disorders and/or Vascular disorders (on-treatment)
Full analysis set

	Anifrolumab 300mg (N=119)	Placebo (N=121)
Number of subjects with events, n (%)	5 (4.2)	5 (4.1)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.02 (0.30, 3.42)	
p-value	0.9785	
Odds Ratio (95% CI)	1.02 (0.29, 3.61)	
p-value	0.9785	
Risk Difference (95% CI)	0.07 (-4.99, 5.13)	
p-value	0.9785	
CMH approach		
Response rate	4.3	4.1
Difference in response rates (95% CI)	0.17 (-7.65, 7.99)	
p-value	0.9664	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of SOCs Cardiac disorders and/or Vascular disorders (on-treatment) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.1250
< 10 points	1/ 41 (2.4)	2.4	3/ 32 (9.4)	8.8	0.26 (0.03, 2.38)	0.2336	-6.42 (-23.68, 10.84)	0.4659	
>= 10 points	4/ 78 (5.1)	4.9	2/ 89 (2.2)	2.3	2.28 (0.43, 12.12)	0.3329	2.62 (-6.31, 11.55)	0.5654	
OCS dose at baseline									0.2622
<10 mg/day	2/ 58 (3.4)	3.4	4/ 65 (6.2)	6.5	0.56 (0.11, 2.95)	0.4941	-3.09 (-14.64, 8.47)	0.6007	
>=10 mg/day	3/ 61 (4.9)	5.0	1/ 56 (1.8)	1.8	2.75 (0.29, 25.71)	0.3741	3.23 (-8.23, 14.68)	0.5810	
Result of type I IFN gene signature test									0.9834
LOW	1/ 23 (4.3)	4.3	1/ 24 (4.2)	4.2	1.04 (0.07, 15.72)	0.9755	0.18 (-17.65, 18.02)	0.9841	
HIGH	4/ 96 (4.2)	4.3	4/ 97 (4.1)	4.1	1.01 (0.26, 3.92)	0.9881	0.16 (-8.53, 8.86)	0.9704	
Age (years)									NE
<= 65	5/117 (4.3)	4.4	5/120 (4.2)	4.1	1.03 (0.30, 3.45)	0.9674	0.23 (-7.68, 8.13)	0.9548	
> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
Sex									NE
male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-27.45, 27.45)	1.0000	
female	5/108 (4.6)	4.7	5/109 (4.6)	4.5	1.01 (0.30, 3.39)	0.9881	0.18 (-8.32, 8.69)	0.9663	
Race									0.3793
White	4/ 75 (5.3)	5.5	3/ 78 (3.8)	3.7	1.39 (0.32, 5.99)	0.6614	1.87 (-8.06, 11.79)	0.7124	
Black or African American	0/ 11 (0.0)	0.0	2/ 18 (11.1)	11.1	0.32 (0.02, 6.04)	0.4447	-11.11 (-37.96, 15.74)	0.4174	
Asian	0/ 17 (0.0)	0.0	0/ 16 (0.0)	0.0	NE		0.00 (-20.27, 20.27)	1.0000	
Other	0/ 8 (0.0)	0.0	0/ 6 (0.0)	0.0	NE		0.00 (-41.13, 41.13)	1.0000	
Ethnicity									0.7833
Hispanic/Latino	1/ 27 (3.7)	3.7	1/ 32 (3.1)	3.1	1.19 (0.08, 18.06)	0.9027	0.58 (-14.12, 15.28)	0.9385	
Non-hispanic/Latino	3/ 84 (3.6)	3.7	4/ 86 (4.7)	4.9	0.77 (0.18, 3.33)	0.7241	-1.22 (-10.15, 7.71)	0.7891	
Geographic region									0.1618
EU	3/ 45 (6.7)	6.7	0/ 33 (0.0)	0.0	5.17 (0.28, 96.88)	0.2715	6.67 (-5.07, 18.40)	0.2656	
non-EU	2/ 74 (2.7)	2.9	5/ 88 (5.7)	6.0	0.48 (0.10, 2.38)	0.3658	-3.13 (-12.59, 6.33)	0.5163	
Onset of disease									0.7413
Paediatric	1/ 11 (9.1)	9.1	0/ 5 (0.0)	0.0	1.50 (0.07, 31.57)	0.7942	9.09 (-34.34, 52.53)	0.6817	
Adult	4/108 (3.7)	3.8	5/116 (4.3)	4.3	0.86 (0.24, 3.12)	0.8175	-0.52 (-8.69, 7.66)	0.9014	
ADA result									0.5146
Negative	4/115 (3.5)	3.5	4/111 (3.6)	3.5	0.97 (0.25, 3.76)	0.9593	0.09 (-7.86, 8.03)	0.9827	
Positive (At any time)	1/ 4 (25.0)	25.0	1/ 10 (10.0)	10.0	2.50 (0.20, 31.00)	0.4756	15.00 (-38.83, 68.83)	0.5850	
BMI (kg/m2) at enrolment									0.4658
< 30	3/ 85 (3.5)	3.5	2/ 89 (2.2)	2.2	1.57 (0.27, 9.17)	0.6160	1.22 (-6.91, 9.36)	0.7680	
>= 30	2/ 34 (5.9)	5.9	3/ 32 (9.4)	9.4	0.63 (0.11, 3.51)	0.5959	-3.49 (-19.30, 12.32)	0.6650	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.4038
All negative/normal	1/ 38 (2.6)	3.0	3/ 56 (5.4)	6.4	0.49 (0.05, 4.55)	0.5313	-3.43 (-18.12, 11.26)	0.6474	
At least one positive/abnormal	4/ 81 (4.9)	4.9	2/ 65 (3.1)	3.1	1.60 (0.30, 8.49)	0.5778	1.86 (-6.10, 9.82)	0.6468	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=119)	Placebo (N=121)
SOC: Gastrointestinal disorders	Number of subjects with events, n (%)	21 (17.6)	32 (26.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.67 (0.41, 1.09)	
	p-value	0.1048	
	Odds Ratio (95% CI)	0.60 (0.32, 1.11)	
	p-value	0.1022	
	Risk Difference (95% CI)	-8.80 (-19.22, 1.63)	
	p-value	0.0980	
	CMH approach		
	Response rate	17.6	26.5
	Difference in response rates (95% CI)	-8.87 (-19.82, 2.07)	
	p-value	0.1121	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=119)	Placebo (N=121)
SOC: General disorders and administration site conditions	Number of subjects with events, n (%)	12 (10.1)	8 (6.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.53 (0.65, 3.60)	
	p-value	0.3349	
	Odds Ratio (95% CI)	1.58 (0.62, 4.03)	
	p-value	0.3338	
	Risk Difference (95% CI)	3.47 (-3.52, 10.46)	
	p-value	0.3303	
	CMH approach		
	Response rate	10.4	6.4
	Difference in response rates (95% CI)	3.91 (-4.94, 12.77)	
	p-value	0.3862	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=119)	Placebo (N=121)
SOC: Infections and infestations	Number of subjects with events, n (%)	76 (63.9)	70 (57.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.10 (0.90, 1.35)	
	p-value	0.3407	
	Odds Ratio (95% CI)	1.29 (0.77, 2.17)	
	p-value	0.3403	
	Risk Difference (95% CI)	6.01 (-6.31, 18.34)	
	p-value	0.3389	
	CMH approach		
	Response rate	64.1	57.2
	Difference in response rates (95% CI)	6.92 (-5.46, 19.29)	
	p-value	0.2732	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=119)	Placebo (N=121)
SOC: Infections and infestations, PT: Bronchitis	Number of subjects with events, n (%)	15 (12.6)	6 (5.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	2.54 (1.02, 6.33)	
	p-value	0.0450	
	Odds Ratio (95% CI)	2.76 (1.03, 7.39)	
	p-value	0.0427	
	Risk Difference (95% CI)	7.65 (0.54, 14.75)	
	p-value	0.0350	
	CMH approach		
	Response rate	13.0	5.2
	Difference in response rates (95% CI)	7.84 (-1.21, 16.89)	
	p-value	0.0894	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=119)	Placebo (N=121)
SOC: Infections and infestations, PT: Nasopharyngitis	Number of subjects with events, n (%)	17 (14.3)	9 (7.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.92 (0.89, 4.14)	
	p-value	0.0955	
	Odds Ratio (95% CI)	2.07 (0.89, 4.86)	
	p-value	0.0931	
	Risk Difference (95% CI)	6.85 (-0.99, 14.68)	
	p-value	0.0867	
	CMH approach		
	Response rate	14.0	6.8
	Difference in response rates (95% CI)	7.15 (-2.01, 16.31)	
	p-value	0.1260	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=119)	Placebo (N=121)
SOC: Infections and infestations, PT: Upper respiratory tract infection	Number of subjects with events, n (%)	26 (21.8)	11 (9.1)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	2.40 (1.24, 4.64)	
	p-value	0.0090	
	Odds Ratio (95% CI)	2.80 (1.31, 5.96)	
	p-value	0.0078	
	Risk Difference (95% CI)	12.76 (3.74, 21.78)	
	p-value	0.0056	
	CMH approach		
	Response rate	22.4	8.5
	Difference in response rates (95% CI)	13.90 (3.82, 23.97)	
	p-value	0.0069	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=119)	Placebo (N=121)
SOC: Infections and infestations, PT: Urinary tract infection	Number of subjects with events, n (%)	12 (10.1)	15 (12.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.81 (0.40, 1.66)	
	p-value	0.5718	
	Odds Ratio (95% CI)	0.79 (0.35, 1.77)	
	p-value	0.5714	
	Risk Difference (95% CI)	-2.31 (-10.30, 5.67)	
	p-value	0.5702	
	CMH approach		
	Response rate	10.0	12.3
	Difference in response rates (95% CI)	-2.33 (-11.77, 7.10)	
	p-value	0.6283	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=119)	Placebo (N=121)
SOC: Injury, poisoning and procedural complications	Number of subjects with events, n (%)	31 (26.1)	22 (18.2)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.43 (0.88, 2.33)	
	p-value	0.1455	
	Odds Ratio (95% CI)	1.59 (0.86, 2.94)	
	p-value	0.1435	
	Risk Difference (95% CI)	7.87 (-2.59, 18.33)	
	p-value	0.1404	
	CMH approach		
	Response rate	27.0	17.3
	Difference in response rates (95% CI)	9.73 (-1.28, 20.75)	
	p-value	0.0833	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=119)	Placebo (N=121)
SOC: Injury, poisoning and procedural complications, PT: Infusion related reaction	Number of subjects with events, n (%)	18 (15.1)	10 (8.3)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.83 (0.88, 3.80)	
	p-value	0.1048	
	Odds Ratio (95% CI)	1.98 (0.87, 4.49)	
	p-value	0.1024	
	Risk Difference (95% CI)	6.86 (-1.23, 14.96)	
	p-value	0.0966	
	CMH approach		
	Response rate	15.9	7.6
	Difference in response rates (95% CI)	8.38 (-1.10, 17.86)	
	p-value	0.0833	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=119)	Placebo (N=121)
SOC: Metabolism and nutrition disorders	Number of subjects with events, n (%)	5 (4.2)	10 (8.3)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.51 (0.18, 1.44)	
	p-value	0.2038	
	Odds Ratio (95% CI)	0.49 (0.16, 1.47)	
	p-value	0.2016	
	Risk Difference (95% CI)	-4.06 (-10.15, 2.03)	
	p-value	0.1909	
	CMH approach		
	Response rate	4.3	8.0
	Difference in response rates (95% CI)	-3.75 (-12.04, 4.54)	
	p-value	0.3753	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=119)	Placebo (N=121)
SOC: Musculoskeletal and connective tissue disorders	Number of subjects with events, n (%)	28 (23.5)	22 (18.2)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.29 (0.79, 2.13)	
	p-value	0.3100	
	Odds Ratio (95% CI)	1.38 (0.74, 2.59)	
	p-value	0.3088	
	Risk Difference (95% CI)	5.35 (-4.91, 15.61)	
	p-value	0.3071	
	CMH approach		
	Response rate	23.4	18.2
	Difference in response rates (95% CI)	5.25 (-5.65, 16.15)	
	p-value	0.3453	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=119)	Placebo (N=121)
SOC: Nervous system disorders	Number of subjects with events, n (%)	16 (13.4)	19 (15.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.86 (0.46, 1.58)	
	p-value	0.6209	
	Odds Ratio (95% CI)	0.83 (0.41, 1.71)	
	p-value	0.6207	
	Risk Difference (95% CI)	-2.26 (-11.18, 6.66)	
	p-value	0.6200	
	CMH approach		
	Response rate	13.3	14.7
	Difference in response rates (95% CI)	-1.43 (-11.18, 8.33)	
	p-value	0.7745	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=119)	Placebo (N=121)
SOC: Nervous system disorders, PT: Headache	Number of subjects with events, n (%)	5 (4.2)	12 (9.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.42 (0.15, 1.17)	
	p-value	0.0963	
	Odds Ratio (95% CI)	0.40 (0.14, 1.17)	
	p-value	0.0936	
	Risk Difference (95% CI)	-5.72 (-12.15, 0.72)	
	p-value	0.0815	
	CMH approach		
	Response rate	3.9	9.0
	Difference in response rates (95% CI)	-5.06 (-13.28, 3.16)	
	p-value	0.2277	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=119)	Placebo (N=121)
SOC: Psychiatric disorders	Number of subjects with events, n (%)	10 (8.4)	11 (9.1)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.92 (0.41, 2.09)	
	p-value	0.8506	
	Odds Ratio (95% CI)	0.92 (0.37, 2.25)	
	p-value	0.8505	
	Risk Difference (95% CI)	-0.69 (-7.83, 6.46)	
	p-value	0.8505	
	CMH approach		
	Response rate	8.4	8.9
	Difference in response rates (95% CI)	-0.49 (-9.37, 8.40)	
	p-value	0.9145	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=119)	Placebo (N=121)
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with events, n (%)	17 (14.3)	16 (13.2)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.08 (0.57, 2.04)	
	p-value	0.8112	
	Odds Ratio (95% CI)	1.09 (0.52, 2.28)	
	p-value	0.8111	
	Risk Difference (95% CI)	1.06 (-7.65, 9.78)	
	p-value	0.8111	
	CMH approach		
	Response rate	14.3	13.1
	Difference in response rates (95% CI)	1.24 (-8.70, 11.18)	
	p-value	0.8063	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=119)	Placebo (N=121)
SOC: Skin and subcutaneous tissue disorders	Number of subjects with events, n (%)	17 (14.3)	16 (13.2)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.08 (0.57, 2.04)	
	p-value	0.8112	
	Odds Ratio (95% CI)	1.09 (0.52, 2.28)	
	p-value	0.8111	
	Risk Difference (95% CI)	1.06 (-7.65, 9.78)	
	p-value	0.8111	
	CMH approach		
	Response rate	14.4	12.5
	Difference in response rates (95% CI)	1.90 (-7.72, 11.52)	
	p-value	0.6982	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Bronchitis	SLEDAI-2K score									0.0779
	< 10 points	3/ 41 (7.3)	7.4	3/ 32 (9.4)	9.5	0.78 (0.17, 3.61)	0.7512	-2.10 (-20.33, 16.14)	0.8215	
	>= 10 points	12/ 78 (15.4)	15.7	3/ 89 (3.4)	3.5	4.56 (1.34, 15.58)	0.0154	12.11 (1.35, 22.87)	0.0274	
	OCS dose									0.7207
	<10 mg/day	8/ 58 (13.8)	14.2	3/ 65 (4.6)	4.8	2.99 (0.83, 10.74)	0.0934	9.35 (-3.78, 22.48)	0.1627	
	>=10 mg/day	7/ 61 (11.5)	12.0	3/ 56 (5.4)	5.8	2.14 (0.58, 7.88)	0.2518	6.21 (-6.91, 19.33)	0.3535	
	Result of type I IFN gene signature test									0.8354
	LOW	3/ 23 (13.0)	13.0	1/ 24 (4.2)	4.2	3.13 (0.35, 27.96)	0.3070	8.88 (-11.25, 29.00)	0.3874	
	HIGH	12/ 96 (12.5)	13.0	5/ 97 (5.2)	5.4	2.43 (0.89, 6.62)	0.0839	7.58 (-2.54, 17.71)	0.1422	
	Age (years)									NE
	<= 65	15/117 (12.8)	13.2	6/120 (5.0)	5.2	2.56 (1.03, 6.38)	0.0430	8.02 (-1.13, 17.16)	0.0857	
	> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
	Sex									NE
	male	0/ 11 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-27.45, 27.45)	1.0000	
	female	15/108 (13.9)	14.3	6/109 (5.5)	5.7	2.52 (1.02, 6.26)	0.0459	8.56 (-1.24, 18.36)	0.0868	
	Race									0.3891
	White	11/ 75 (14.7)	14.8	3/ 78 (3.8)	4.0	3.81 (1.11, 13.13)	0.0339	10.77 (-0.48, 22.03)	0.0606	
	Black or African American	2/ 11 (18.2)	18.2	1/ 18 (5.6)	5.6	3.27 (0.33, 32.00)	0.3082	12.63 (-17.94, 43.19)	0.4182	
	Asian	0/ 17 (0.0)	0.0	1/ 16 (6.3)	6.3	0.31 (0.01, 7.21)	0.4694	-6.25 (-28.63, 16.13)	0.5841	
	Other	1/ 8 (12.5)	12.5	1/ 6 (16.7)	16.7	0.75 (0.06, 9.72)	0.8258	-4.17 (-51.55, 43.21)	0.8632	
	Ethnicity									0.3928
	Hispanic/Latino	2/ 27 (7.4)	7.4	2/ 32 (6.3)	6.3	1.19 (0.18, 7.86)	0.8603	1.16 (-15.53, 17.84)	0.8919	
	Non-hispanic/Latino	12/ 84 (14.3)	14.7	4/ 86 (4.7)	5.0	3.07 (1.03, 9.14)	0.0438	9.76 (-0.83, 20.35)	0.0708	
	Geographic region									0.8409
	EU	6/ 45 (13.3)	13.3	2/ 33 (6.1)	6.1	2.20 (0.47, 10.22)	0.3144	7.27 (-7.86, 22.40)	0.3461	
	non-EU	9/ 74 (12.2)	12.2	4/ 88 (4.5)	4.6	2.68 (0.86, 8.34)	0.0896	7.61 (-3.09, 18.31)	0.1635	
	Onset of disease									0.7519
	Paediatric	1/ 11 (9.1)	9.1	0/ 5 (0.0)	0.0	1.50 (0.07, 31.57)	0.7942	9.09 (-34.34, 52.53)	0.6817	
	Adult	14/108 (13.0)	13.2	6/116 (5.2)	5.4	2.51 (1.00, 6.29)	0.0502	7.83 (-1.66, 17.31)	0.1060	
	ADA result									0.3966
	Negative	15/115 (13.0)	13.4	5/111 (4.5)	4.7	2.90 (1.09, 7.70)	0.0331	8.72 (-0.63, 18.07)	0.0674	
	Positive (At any time)	0/ 4 (0.0)	0.0	1/ 10 (10.0)	10.0	0.73 (0.04, 15.04)	0.8405	-10.00 (-59.47, 39.47)	0.6920	
	BMI (kg/m2)									0.9250
	< 30	12/ 85 (14.1)	14.0	5/ 89 (5.6)	5.5	2.51 (0.92, 6.83)	0.0709	8.53 (-1.88, 18.94)	0.1084	
	>= 30	3/ 34 (8.8)	8.8	1/ 32 (3.1)	3.1	2.82 (0.31, 25.77)	0.3575	5.70 (-9.16, 20.56)	0.4523	
	Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.5388
	All negative/normal	5/ 38 (13.2)	13.7	2/ 56 (3.6)	4.1	3.68 (0.75, 18.02)	0.1073	9.68 (-6.40, 25.76)	0.2381	
	At least one positive/abnormal	10/ 81 (12.3)	12.3	4/ 65 (6.2)	6.2	2.01 (0.66, 6.10)	0.2200	6.19 (-4.03, 16.41)	0.2350	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=119) n/ N (%)	Response rate	Placebo (N=121) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Upper respiratory tract infection	SLEDAI-2K score									0.3103
	< 10 points	8/ 41 (19.5)	20.6	1/ 32 (3.1)	2.8	6.24 (0.82, 47.39)	0.0765	17.81 (-0.73, 36.36)	0.0598	
	>= 10 points	18/ 78 (23.1)	23.1	10/ 89 (11.2)	11.0	2.05 (1.01, 4.18)	0.0472	12.17 (-0.17, 24.52)	0.0532	
	OCS dose									0.5248
	<10 mg/day	15/ 58 (25.9)	25.6	8/ 65 (12.3)	11.4	2.10 (0.96, 4.59)	0.0626	14.16 (-0.74, 29.05)	0.0624	
	>=10 mg/day	11/ 61 (18.0)	18.7	3/ 56 (5.4)	5.5	3.37 (0.99, 11.45)	0.0519	13.27 (-0.74, 27.28)	0.0634	
	Result of type I IFN gene signature test									0.1773
	LOW	6/ 23 (26.1)	26.1	0/ 24 (0.0)	0.0	13.54 (0.81, 227.50)	0.0703	26.09 (4.77, 47.40)	0.0165	
	HIGH	20/ 96 (20.8)	21.4	11/ 97 (11.3)	10.6	1.84 (0.93, 3.62)	0.0794	10.88 (-0.53, 22.29)	0.0615	
	Age (years)									NE
	<= 65	26/117 (22.2)	22.8	11/120 (9.2)	8.6	2.42 (1.26, 4.68)	0.0083	14.15 (3.96, 24.34)	0.0065	
	> 65	0/ 2 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-116.14, 116.14)	1.0000	
	Sex									0.8295
	male	1/ 11 (9.1)	9.1	0/ 12 (0.0)	0.0	3.25 (0.15, 72.36)	0.4566	9.09 (-21.06, 39.24)	0.5545	
	female	25/108 (23.1)	23.8	11/109 (10.1)	9.5	2.29 (1.19, 4.43)	0.0133	14.24 (3.40, 25.08)	0.0101	
	Race									0.3376
	White	16/ 75 (21.3)	21.3	6/ 78 (7.7)	7.6	2.77 (1.15, 6.71)	0.0236	13.68 (1.23, 26.13)	0.0312	
	Black or African American	3/ 11 (27.3)	27.3	0/ 18 (0.0)	0.0	11.08 (0.63, 196.20)	0.1009	27.27 (-3.59, 58.13)	0.0833	
	Asian	4/ 17 (23.5)	23.5	4/ 16 (25.0)	25.0	0.94 (0.28, 3.14)	0.9215	-1.47 (-32.54, 29.60)	0.9261	
	Other	3/ 8 (37.5)	37.5	1/ 6 (16.7)	16.7	2.25 (0.30, 16.63)	0.4269	20.83 (-29.28, 70.95)	0.4152	
	Ethnicity									0.5024
	Hispanic/Latino	9/ 27 (33.3)	33.3	3/ 32 (9.4)	9.4	3.56 (1.07, 11.83)	0.0386	23.96 (2.30, 45.62)	0.0302	
	Non-hispanic/Latino	17/ 84 (20.2)	20.2	8/ 86 (9.3)	9.2	2.18 (0.99, 4.77)	0.0522	11.01 (-0.77, 22.79)	0.0670	
	Geographic region									0.8214
	EU	2/ 45 (4.4)	4.4	0/ 33 (0.0)	0.0	3.70 (0.18, 74.51)	0.3937	4.44 (-6.67, 15.56)	0.4332	
	non-EU	24/ 74 (32.4)	32.9	11/ 88 (12.5)	12.0	2.59 (1.36, 4.94)	0.0037	20.86 (7.44, 34.29)	0.0023	
	Onset of disease									0.3667
	Paediatric	2/ 11 (18.2)	18.2	1/ 5 (20.0)	20.0	0.91 (0.11, 7.84)	0.9309	-1.82 (-50.71, 47.07)	0.9419	
	Adult	24/108 (22.2)	22.6	10/116 (8.6)	8.1	2.58 (1.29, 5.14)	0.0071	14.55 (4.10, 25.00)	0.0064	
	ADA result									0.4362
	Negative	26/115 (22.6)	23.1	10/111 (9.0)	8.4	2.51 (1.27, 4.96)	0.0081	14.75 (4.29, 25.21)	0.0057	
	Positive (At any time)	0/ 4 (0.0)	0.0	1/ 10 (10.0)	10.0	0.73 (0.04, 15.04)	0.8405	-10.00 (-59.47, 39.47)	0.6920	
	BMI (kg/m2)									0.3224
	< 30	14/ 85 (16.5)	16.4	8/ 89 (9.0)	8.7	1.83 (0.81, 4.14)	0.1459	7.66 (-3.49, 18.81)	0.1780	
	>= 30	12/ 34 (35.3)	35.3	3/ 32 (9.4)	9.4	3.76 (1.17, 12.12)	0.0263	25.92 (5.76, 46.08)	0.0117	
	Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.1418
	All negative/normal	12/ 38 (31.6)	31.2	4/ 56 (7.1)	6.2	4.42 (1.54, 12.68)	0.0057	25.01 (7.17, 42.85)	0.0060	
	At least one positive/abnormal	14/ 81 (17.3)	17.3	7/ 65 (10.8)	10.8	1.60 (0.69, 3.74)	0.2734	6.51 (-5.30, 18.33)	0.2797	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Serious Adverse Events by SOC, PT (incidence in either arm >= 5% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=119)	Placebo (N=121)
SOC: Infections and infestations	Number of subjects with events, n (%)	3 (2.5)	10 (8.3)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.31 (0.09, 1.08)	
	p-value	0.0659	
	Odds Ratio (95% CI)	0.29 (0.08, 1.07)	
	p-value	0.0631	
	Risk Difference (95% CI)	-5.74 (-11.40, -0.09)	
	p-value	0.0466	
	CMH approach		
	Response rate	2.8	8.1
	Difference in response rates (95% CI)	-5.35 (-13.52, 2.83)	
	p-value	0.1998	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Serious Adverse Events by SOC, PT (incidence in either arm >= 5% or >=10 patients) (on-treatment) - Subgroup analysis
Full analysis set

- NO OBSERVATIONS FOR THIS ANALYSIS -

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Severe (Grade >=3) by SOC, PT (incidence in either arm >= 5% or >=10 patients) (on-treatment)
Full analysis set

- NO OBSERVATIONS FOR THIS ANALYSIS -

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Severe (Grade >=3) by SOC, PT (incidence in either arm >= 5% or >=10 patients) (on-treatment) - Subgroup analysis
Full analysis set

- NO OBSERVATIONS FOR THIS ANALYSIS -

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Subject disposition and summary of treatment exposure
Full analysis set

		Anifrolumab 300mg (N=246)	Placebo (N=246)
Patients who completed the study		207 (84.1)	185 (75.2)
Patients withdrawn from the study		39 (15.9)	61 (24.8)
WITHDRAWAL BY SUBJECT		19 (7.7)	29 (11.8)
ADVERSE EVENT		9 (3.7)	9 (3.7)
LACK OF EFFICACY		4 (1.6)	10 (4.1)
OTHER		5 (2.0)	5 (2.0)
CONDITION UNDER INVESTIGATION WORSENED		2 (0.8)	2 (0.8)
LOST TO FOLLOW-UP		0	4 (1.6)
SEVERE NON-COMPLIANCE TO PROTOCOL		0	1 (0.4)
Duration of study (weeks)	n (missing)	246 (0)	246 (0)
	Mean (SD)	50.8 (10.95)	49.5 (11.95)
	Median	52.3	52.3
	Min, Max	0, 70	3, 70
Patients who completed investigational product		205 (83.3)	180 (73.2)
Patients discontinued investigational product		41 (16.7)	66 (26.8)
Withdrawal By Subject		15 (6.1)	24 (9.8)
Adverse Event		11 (4.5)	17 (6.9)
Lack Of Efficacy		4 (1.6)	13 (5.3)
Condition Under Investigation Worsened		3 (1.2)	5 (2.0)
Other		7 (2.8)	2 (0.8)
Lost To Follow-Up		1 (0.4)	3 (1.2)
Severe Non-Compliance To Protocol		0	2 (0.8)
Duration of exposure (weeks)	n (missing)	246 (0)	246 (0)
	Mean (SD)	47.5 (12.17)	45.1 (13.91)
	Median	52.1	52.1
	Min, Max	4, 57	4, 56
Number of Infusions	n (missing)	246 (0)	246 (0)
	Mean (SD)	11.5 (3.03)	11.0 (3.48)
	Median	13.0	13.0
	Min, Max	1, 13	1, 13
Subjects enrolled to the LTE study		173 (70.3)	148 (60.2)

Duration of study defined as time from randomization until end of participation date.
Duration of exposure defined as difference of date of first exposure to treatment and date of last exposure to treatment + 28 days.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Demographic and baseline characteristics
Full analysis set

		Anifrolumab 300mg (N=246)	Placebo (N=246)	Total (N=492)
Age	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	42.8 (11.73)	40.8 (11.53)	41.8 (11.66)
	Median	42.0	41.0	41.5
	Min, Max	18, 68	19, 69	18, 69
Age subgroups (%)	<= 65	239 (97.2)	243 (98.8)	482 (98.0)
	> 65	7 (2.8)	3 (1.2)	10 (2.0)
Sex (%)	female	223 (90.7)	226 (91.9)	449 (91.3)
	male	23 (9.3)	20 (8.1)	43 (8.7)
Race (%)	American Indian or Alaska Native	0	1 (0.4)	1 (0.2)
	Asian	24 (9.8)	19 (7.7)	43 (8.7)
	Black or African American	33 (13.4)	32 (13.0)	65 (13.2)
	Other	21 (8.5)	17 (6.9)	38 (7.7)
	White	160 (65.0)	174 (70.7)	334 (67.9)
	Missing	8 (3.3)	3 (1.2)	11 (2.2)
Ethnicity (%)	Hispanic/Latino	50 (20.3)	56 (22.8)	106 (21.5)
	Non-hispanic/Latino	188 (76.4)	187 (76.0)	375 (76.2)
	Missing	8 (3.3)	3 (1.2)	11 (2.2)
Geographic region (%)	Asia Pacific	21 (8.5)	16 (6.5)	37 (7.5)
	Europe	92 (37.4)	89 (36.2)	181 (36.8)
	Latin America	33 (13.4)	32 (13.0)	65 (13.2)
	North America	95 (38.6)	100 (40.7)	195 (39.6)
	Rest Of World	5 (2.0)	9 (3.7)	14 (2.8)
Geographic region subgroup (%)	EU	92 (37.4)	89 (36.2)	181 (36.8)
	non-EU	154 (62.6)	157 (63.8)	311 (63.2)
Height (cm)	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	163.20 (8.167)	163.38 (7.996)	163.29 (8.074)
	Median	162.60	163.00	163.00
	Min, Max	145.0, 198.0	140.0, 195.0	140.0, 198.0
Weight (cm)	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	74.56 (20.129)	73.16 (18.263)	73.86 (19.212)
	Median	70.60	68.90	69.90
	Min, Max	42.0, 132.7	42.2, 138.0	42.0, 138.0
BMI (kg/m^2)	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	27.92 (6.999)	27.46 (6.887)	27.69 (6.940)
	Median	25.91	25.67	25.79
	Min, Max	16.0, 49.8	17.2, 57.5	16.0, 57.5
BMI subgroup (%)	<=28 kg/m2	142 (57.7)	150 (61.0)	292 (59.3)
	>28 kg/m2	104 (42.3)	96 (39.0)	200 (40.7)

[a] Asia Pacific: Australia, New Zealand, South Korea, Taiwan. Europe: Germany, Hungary, Italy, Poland, Romania, Ukraine, United Kingdom. Latin America: Argentinia, Brazil, Chile, Colombia, Peru. Rest of World: Israel.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SLE disease characteristics
Full analysis set

		Anifrolumab 300mg (N=246)	Placebo (N=246)	Total (N=492)
SLEDAI-2K score at screening	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	11.4 (3.89)	11.1 (3.39)	11.3 (3.64)
	Median	10.0	10.0	10.0
	Min, Max	6, 25	6, 24	6, 25
SLEDAI-2K score at screening, categorisation (%)	< 10 points	80 (32.5)	69 (28.0)	149 (30.3)
	>= 10 points	166 (67.5)	177 (72.0)	343 (69.7)
Clinical SLEDAI-2K score at screening	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	8.7 (3.03)	8.6 (2.63)	8.6 (2.83)
	Median	8.0	8.0	8.0
	Min, Max	4, 20	4, 18	4, 20
SLEDAI-2K score at baseline	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	11.3 (3.77)	11.4 (3.65)	11.3 (3.71)
	Median	10.0	10.0	10.0
	Min, Max	4, 32	4, 26	4, 32
SLEDAI-2K score at baseline, categorisation (%)	< 10 points	78 (31.7)	69 (28.0)	147 (29.9)
	>= 10 points	168 (68.3)	177 (72.0)	345 (70.1)
Clinical SLEDAI-2K score at baseline	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	8.8 (2.95)	8.9 (2.68)	8.8 (2.82)
	Median	8.0	8.0	8.0
	Min, Max	4, 20	4, 18	4, 20
Total Organ Score CNS	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	0.0 (0.51)	0.1 (0.72)	0.0 (0.62)
	Median	0.0	0.0	0.0
	Min, Max	0, 8	0, 8	0, 8
Total Organ Score CVS and Respiratory	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	0.1 (0.49)	0.1 (0.55)	0.1 (0.52)
	Median	0.0	0.0	0.0
	Min, Max	0, 2	0, 4	0, 4
Total Organ Score Hematological	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	0.2 (0.37)	0.1 (0.36)	0.1 (0.36)
	Median	0.0	0.0	0.0
	Min, Max	0, 2	0, 2	0, 2
Total Organ Score Immunology	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	2.0 (1.61)	1.9 (1.64)	1.9 (1.62)
	Median	2.0	2.0	2.0
	Min, Max	0, 4	0, 4	0, 4
Total Organ Score Mucocutaneous	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	4.0 (1.59)	4.0 (1.61)	4.0 (1.60)
	Median	4.0	4.0	4.0
	Min, Max	0, 6	0, 6	0, 6
Total Organ Score Musculoskeletal	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	3.7 (1.16)	3.9 (1.05)	3.8 (1.11)
	Median	4.0	4.0	4.0
	Min, Max	0, 8	0, 8	0, 8
Total Organ Score Renal	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	0.4 (1.45)	0.5 (1.74)	0.4 (1.60)
	Median	0.0	0.0	0.0
	Min, Max	0, 12	0, 12	0, 12

Baseline is defined as the last measurement prior to randomisation and dose administration on Day 1.
Only subjects with baseline positive anti-dsDNA and abnormal complement level, respectively, are included in the summary statistics for the respective variables.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SLE disease characteristics
Full analysis set

		Anifrolumab 300mg (N=246)	Placebo (N=246)	Total (N=492)
Total Organ Score Vascular	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	0.9 (2.55)	0.8 (2.46)	0.9 (2.50)
	Median	0.0	0.0	0.0
	Min, Max	0, 8	0, 8	0, 8
Adjudication Scoring (BILAG) at baseline Overall (%)	At least one A	107 (43.5)	123 (50.0)	230 (46.7)
	No A and <2Bs	11 (4.5)	17 (6.9)	28 (5.7)
	No A and at least 2 Bs	128 (52.0)	106 (43.1)	234 (47.6)
Adjudication Scoring (BILAG) at baseline Constitutional (%)	A	1 (0.4)	0	1 (0.2)
	B	14 (5.7)	11 (4.5)	25 (5.1)
	C, D or E	231 (93.9)	235 (95.5)	466 (94.7)
Adjudication Scoring (BILAG) at baseline Mucocutaneous (%)	A	53 (21.5)	56 (22.8)	109 (22.2)
	B	163 (66.3)	151 (61.4)	314 (63.8)
	C, D or E	30 (12.2)	39 (15.9)	69 (14.0)
Adjudication Scoring (BILAG) at baseline Neuropsychiatric (%)	B	5 (2.0)	4 (1.6)	9 (1.8)
	C, D or E	241 (98.0)	242 (98.4)	483 (98.2)
Adjudication Scoring (BILAG) at baseline Musculoskeletal (%)	A	68 (27.6)	77 (31.3)	145 (29.5)
	B	146 (59.3)	146 (59.3)	292 (59.3)
	C, D or E	32 (13.0)	23 (9.3)	55 (11.2)
Adjudication Scoring (BILAG) at baseline Cardiorespiratory (%)	A	2 (0.8)	2 (0.8)	4 (0.8)
	B	13 (5.3)	13 (5.3)	26 (5.3)
	C, D or E	231 (93.9)	231 (93.9)	462 (93.9)
Adjudication Scoring (BILAG) at baseline Gastrointestinal (%)	B	0	2 (0.8)	2 (0.4)
	C, D or E	246 (100.0)	244 (99.2)	490 (99.6)
Adjudication Scoring (BILAG) at baseline Ophthalmic (%)	A	1 (0.4)	0	1 (0.2)
	B	0	1 (0.4)	1 (0.2)
	C, D or E	245 (99.6)	245 (99.6)	490 (99.6)
Adjudication Scoring (BILAG) at baseline Renal (%)	A	1 (0.4)	4 (1.6)	5 (1.0)
	B	16 (6.5)	16 (6.5)	32 (6.5)
	C, D or E	229 (93.1)	226 (91.9)	455 (92.5)
Adjudication Scoring (BILAG) at baseline Haematological (%)	B	1 (0.4)	1 (0.4)	2 (0.4)
	C, D or E	245 (99.6)	245 (99.6)	490 (99.6)
BILAG-2004 global score at baseline	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	18.6 (5.28)	18.8 (5.17)	18.7 (5.22)
	Median	17.0	18.0	17.0
	Min, Max	2, 40	4, 33	2, 40
Physician Global Assessment (PGA) score at baseline	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	1.8 (0.42)	1.8 (0.38)	1.8 (0.40)
	Median	1.7	1.8	1.8
	Min, Max	1, 3	1, 3	1, 3
CLASI activity score at baseline	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	8.0 (7.46)	8.0 (7.42)	8.0 (7.43)
	Median	6.0	6.0	6.0
	Min, Max	0, 51	0, 52	0, 52
CLASI activity score at baseline, categorisation 1 (%)	0	8 (3.3)	14 (5.7)	22 (4.5)
	> 0	238 (96.7)	232 (94.3)	470 (95.5)

Baseline is defined as the last measurement prior to randomisation and dose administration on Day 1.
Only subjects with baseline positive anti-dsDNA and abnormal complement level, respectively, are included in the summary statistics for the respective variables.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SLE disease characteristics
Full analysis set

		Anifrolumab 300mg (N=246)	Placebo (N=246)	Total (N=492)
CLASI activity score at baseline, categorisation 2 (%)	<10	181 (73.6)	176 (71.5)	357 (72.6)
	>=10	65 (26.4)	70 (28.5)	135 (27.4)
CLASI damage score at baseline	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	1.7 (3.61)	1.9 (4.55)	1.8 (4.10)
	Median	0.0	0.0	0.0
	Min, Max	0, 23	0, 35	0, 35
CLASI damage score at baseline, categorisation 1 (%)	0	164 (66.7)	163 (66.3)	327 (66.5)
	> 0	82 (33.3)	83 (33.7)	165 (33.5)
CLASI damage score at baseline, categorisation 2 (%)	<10	233 (94.7)	234 (95.1)	467 (94.9)
	>=10	13 (5.3)	12 (4.9)	25 (5.1)
Tender Joint Count at Baseline	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	10.0 (7.47)	10.9 (7.48)	10.4 (7.48)
	Median	8.0	10.0	9.0
	Min, Max	0, 28	0, 28	0, 28
Tender Joint Count at Baseline, categorisation (%)	0	20 (8.1)	10 (4.1)	30 (6.1)
	> 0	226 (91.9)	236 (95.9)	462 (93.9)
Swollen Joint Count at Baseline	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	6.7 (5.78)	7.1 (5.70)	6.9 (5.74)
	Median	5.0	6.0	6.0
	Min, Max	0, 28	0, 25	0, 28
Swollen Joint Count at Baseline, categorisation (%)	0	26 (10.6)	22 (8.9)	48 (9.8)
	> 0	220 (89.4)	224 (91.1)	444 (90.2)
Active Joint Count at Baseline	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	6.2 (5.77)	6.6 (5.50)	6.4 (5.63)
	Median	5.0	5.0	5.0
	Min, Max	0, 28	0, 25	0, 28
Active Joint Count at Baseline, categorisation (%)	0	29 (11.8)	23 (9.3)	52 (10.6)
	> 0	217 (88.2)	223 (90.7)	440 (89.4)
SDI global score at baseline	n (missing)	245 (1)	244 (2)	489 (3)
	Mean (SD)	0.5 (0.97)	0.6 (0.91)	0.6 (0.94)
	Median	0.0	0.0	0.0
	Min, Max	0, 5	0, 5	0, 5
SDI global score at baseline, categorisation (%)	0 (no damage)	170 (69.1)	152 (61.8)	322 (65.4)
	>=1 (damage)	75 (30.5)	92 (37.4)	167 (33.9)
	Missing	1 (0.4)	2 (0.8)	3 (0.6)
Time from initial SLE diagnosis to randomisation (months)	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	125.0 (105.56)	101.9 (91.51)	113.4 (99.36)
	Median	98.0	75.0	85.5
	Min, Max	0, 493	4, 503	0, 503
Cushingoid features (%)	Any Cushingoid Feature	74 (30.1)	82 (33.3)	156 (31.7)
	Moon Face	42 (17.1)	47 (19.1)	89 (18.1)
	Buffalo Hump	19 (7.7)	12 (4.9)	31 (6.3)
	Purple or Violaceous Striae	21 (8.5)	17 (6.9)	38 (7.7)
	Central Obesity	33 (13.4)	35 (14.2)	68 (13.8)
	Hirsutisim	14 (5.7)	7 (2.8)	21 (4.3)
	Acne	14 (5.7)	10 (4.1)	24 (4.9)
	Easy Bruising	36 (14.6)	28 (11.4)	64 (13.0)
	Fragile Skin	22 (8.9)	25 (10.2)	47 (9.6)

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Only subjects with baseline positive anti-dsDNA and abnormal complement level, respectively, are included in the summary statistics for the respective variables.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SLE disease characteristics
Full analysis set

		Anifrolumab 300mg (N=246)	Placebo (N=246)	Total (N=492)
Results of 4-gene Type 1 Interferon (IFN) test (%)	High	201 (81.7)	198 (80.5)	399 (81.1)
	Low	45 (18.3)	48 (19.5)	93 (18.9)
Anti-dsDNA levels at baseline	n (missing)	115 (0)	102 (0)	217 (0)
	Mean (SD)	126.0 (255.93)	228.3 (603.38)	174.1 (455.44)
	Median	45.5	53.1	49.9
	Min, Max	15, 1808	16, 3790	15, 3790
Anti-dsDNA levels at baseline, categorisation (%)	Negative	131 (53.3)	144 (58.5)	275 (55.9)
	Positive	115 (46.7)	102 (41.5)	217 (44.1)
ANA (%)	Abnormal (titre >= 1:80)	216 (87.8)	222 (90.2)	438 (89.0)
	Normal (titre < 1:80)	18 (7.3)	16 (6.5)	34 (6.9)
	Missing	12 (4.9)	8 (3.3)	20 (4.1)
Complement C3 level at baseline	n (missing)	92 (0)	91 (0)	183 (0)
	Mean (SD)	0.69 (0.152)	0.69 (0.142)	0.69 (0.147)
	Median	0.72	0.70	0.71
	Min, Max	0.2, 0.9	0.4, 0.9	0.2, 0.9
Complement C3 level at baseline, categorisation (%)	Abnormal	92 (37.4)	91 (37.0)	183 (37.2)
	Normal	154 (62.6)	155 (63.0)	309 (62.8)
Complement C4 level at baseline	n (missing)	54 (0)	56 (0)	110 (0)
	Mean (SD)	0.08 (0.016)	0.07 (0.014)	0.07 (0.015)
	Median	0.07	0.07	0.07
	Min, Max	0.1, 0.1	0.1, 0.1	0.1, 0.1
Complement C4 level at baseline, categorisation (%)	Abnormal	54 (22.0)	56 (22.8)	110 (22.4)
	Normal	192 (78.0)	190 (77.2)	382 (77.6)
Complement CH50 level at baseline	n (missing)	23 (0)	21 (0)	44 (0)
	Mean (SD)	39.48 (27.343)	49.43 (28.253)	44.23 (27.912)
	Median	40.00	55.00	41.50
	Min, Max	5.0, 89.0	5.0, 90.0	5.0, 90.0
Complement CH50 level at baseline, categorisation (%)	Abnormal	23 (9.3)	21 (8.5)	44 (8.9)
	Normal	223 (90.7)	225 (91.5)	448 (91.1)

Baseline is defined as the last measurement prior to randomisation and dose administration on Day 1.
Only subjects with baseline positive anti-dsDNA and abnormal complement level, respectively, are included in the summary statistics for the respective variables.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Observation times for Efficacy endpoints
Full analysis set

		Anifrolumab 300mg (N=246)	Placebo (N=246)
SRI4: Observation time (weeks)	n (missing)	246 (0)	246 (0)
	Mean (SD)	48.7 (10.21)	47.5 (11.59)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
CLASI activity score: Observation time (weeks)	n (missing)	246 (0)	246 (0)
	Mean (SD)	48.7 (10.18)	47.5 (11.60)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
CLASI damage score: Observation time (weeks)	n (missing)	246 (0)	246 (0)
	Mean (SD)	48.7 (10.18)	47.5 (11.60)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
BICLA: Observation time (weeks)	n (missing)	246 (0)	246 (0)
	Mean (SD)	48.7 (10.18)	47.5 (11.58)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
SLEDAI-2K Total Score: Observation time (weeks)	n (missing)	246 (0)	246 (0)
	Mean (SD)	48.4 (10.38)	46.9 (12.21)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
PGA: Observation time (weeks)	n (missing)	246 (0)	246 (0)
	Mean (SD)	48.6 (10.45)	47.5 (11.59)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
BILAG Global Score: Observation time (weeks)	n (missing)	246 (0)	246 (0)
	Mean (SD)	48.6 (10.40)	47.5 (11.58)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
Tender Joint Count: Observation time (weeks)	n (missing)	246 (0)	246 (0)
	Mean (SD)	48.7 (10.21)	47.5 (11.60)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
Swollen Joint Count: Observation time (weeks)	n (missing)	246 (0)	246 (0)
	Mean (SD)	48.7 (10.21)	47.5 (11.60)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
FACIT-F Total Score: Observation time (weeks)	n (missing)	246 (0)	246 (0)
	Mean (SD)	48.4 (10.57)	46.9 (12.25)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
SF-36 v2.0 Acute - Mental Component Score: Observation time (weeks)	n (missing)	246 (0)	246 (0)
	Mean (SD)	47.9 (11.99)	46.1 (13.37)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
SF-36 v2.0 Acute - Physical Component Score: Observation time (weeks)	n (missing)	246 (0)	246 (0)
	Mean (SD)	47.9 (11.99)	46.1 (13.37)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
EQ-5D VAS Score: Observation time (weeks)	n (missing)	246 (0)	246 (0)

Observation duration defined as time from randomization until last non-missing assessment after randomization. Subjects without assessment are censored at day 1.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Observation times for Efficacy endpoints
Full analysis set

		Anifrolumab 300mg (N=246)	Placebo (N=246)
EQ-5D VAS Score: Observation time (weeks)	Mean (SD)	46.0 (13.43)	44.6 (14.60)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
SDI Global Score: Observation time (weeks)	n (missing)	246 (0)	246 (0)
	Mean (SD)	44.0 (17.02)	43.7 (16.71)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
PtGA: Observation time (weeks)	n (missing)	246 (0)	246 (0)
	Mean (SD)	48.1 (11.17)	46.3 (12.94)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54

Observation duration defined as time from randomization until last non-missing assessment after randomization. Subjects without assessment are censored at day 1.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 4	Number of subjects with events, n (%)	23 (9.3)	21 (8.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.21 (0.68, 2.14)	
	p-value	0.5213	
	Odds Ratio (95% CI)	1.24 (0.65, 2.34)	
	p-value	0.5163	
	Risk Difference (95% CI)	1.65 (-3.32, 6.62)	
	p-value	0.5157	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.09 (0.62, 1.93)	
	p-value	0.7531	
	Odds Ratio (95% CI)	1.10 (0.59, 2.05)	
	p-value	0.7530	
	Risk Difference (95% CI)	0.81 (-4.23, 5.85)	
	p-value	0.7529	
	CMH approach		
	Response rate	9.6	8.1
	Difference in response rates (95% CI)	1.45 (-4.79, 7.69)	
	p-value	0.6491	
	p-Value for test for heterogenity between studies	0.9435	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 8	Number of subjects with events, n (%)	66 (26.8)	45 (18.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.51 (1.08, 2.10)	
	p-value	0.0147	
	Odds Ratio (95% CI)	1.76 (1.12, 2.74)	
	p-value	0.0137	
	Risk Difference (95% CI)	9.15 (1.97, 16.33)	
	p-value	0.0125	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.47 (1.06, 2.05)	
	p-value	0.0225	
	Odds Ratio (95% CI)	1.66 (1.08, 2.56)	
	p-value	0.0215	
	Risk Difference (95% CI)	8.63 (1.35, 15.91)	
	p-value	0.0202	
	CMH approach		
	Response rate	27.0	17.9
	Difference in response rates (95% CI)	9.09 (1.48, 16.70)	
	p-value	0.0193	
	p-Value for test for heterogenity between studies	0.9198	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 12	Number of subjects with events, n (%)	105 (42.7)	71 (28.9)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.51 (1.19, 1.93)	
	p-value	0.0008	
	Odds Ratio (95% CI)	1.95 (1.33, 2.87)	
	p-value	0.0007	
	Risk Difference (95% CI)	14.57 (6.31, 22.83)	
	p-value	0.0005	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.48 (1.16, 1.89)	
	p-value	0.0014	
	Odds Ratio (95% CI)	1.85 (1.27, 2.70)	
	p-value	0.0013	
	Risk Difference (95% CI)	13.90 (5.55, 22.24)	
	p-value	0.0011	
	CMH approach		
	Response rate	42.8	28.7
	Difference in response rates (95% CI)	14.09 (5.72, 22.46)	
	p-value	0.0010	
	p-Value for test for heterogenity between studies	0.8575	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 16	Number of subjects with events, n (%)	112 (45.5)	92 (37.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.24 (1.00, 1.53)	
	p-value	0.0455	
	Odds Ratio (95% CI)	1.45 (1.01, 2.09)	
	p-value	0.0456	
	Risk Difference (95% CI)	8.95 (0.24, 17.67)	
	p-value	0.0441	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.22 (0.99, 1.51)	
	p-value	0.0674	
	Odds Ratio (95% CI)	1.40 (0.98, 2.01)	
	p-value	0.0677	
	Risk Difference (95% CI)	8.15 (-0.54, 16.83)	
	p-value	0.0659	
	CMH approach		
	Response rate	45.8	37.3
	Difference in response rates (95% CI)	8.55 (-0.09, 17.19)	
	p-value	0.0523	
	p-Value for test for heterogenity between studies	0.3772	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 20	Number of subjects with events, n (%)	125 (50.8)	109 (44.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.14 (0.95, 1.38)	
	p-value	0.1573	
	Odds Ratio (95% CI)	1.30 (0.90, 1.86)	
	p-value	0.1571	
	Risk Difference (95% CI)	6.40 (-2.44, 15.25)	
	p-value	0.1558	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.15 (0.95, 1.38)	
	p-value	0.1475	
	Odds Ratio (95% CI)	1.30 (0.91, 1.85)	
	p-value	0.1485	
	Risk Difference (95% CI)	6.52 (-2.29, 15.33)	
	p-value	0.1471	
	CMH approach		
	Response rate	50.8	44.2
	Difference in response rates (95% CI)	6.58 (-2.19, 15.35)	
	p-value	0.1412	
	p-Value for test for heterogenity between studies	0.5860	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 24	Number of subjects with events, n (%)	130 (52.8)	109 (44.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.18 (0.99, 1.42)	
	p-value	0.0707	
	Odds Ratio (95% CI)	1.39 (0.97, 1.98)	
	p-value	0.0713	
	Risk Difference (95% CI)	8.26 (-0.66, 17.18)	
	p-value	0.0695	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.19 (0.99, 1.43)	
	p-value	0.0624	
	Odds Ratio (95% CI)	1.41 (0.99, 2.01)	
	p-value	0.0600	
	Risk Difference (95% CI)	8.54 (-0.28, 17.36)	
	p-value	0.0577	
	CMH approach		
	Response rate	52.7	44.1
	Difference in response rates (95% CI)	8.53 (-0.16, 17.21)	
	p-value	0.0543	
	p-Value for test for heterogenity between studies	0.1665	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 28	Number of subjects with events, n (%)	133 (54.1)	115 (46.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.15 (0.96, 1.38)	
	p-value	0.1185	
	Odds Ratio (95% CI)	1.33 (0.93, 1.89)	
	p-value	0.1174	
	Risk Difference (95% CI)	7.17 (-1.77, 16.11)	
	p-value	0.1161	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.15 (0.97, 1.38)	
	p-value	0.1112	
	Odds Ratio (95% CI)	1.34 (0.94, 1.91)	
	p-value	0.1066	
	Risk Difference (95% CI)	7.31 (-1.51, 16.13)	
	p-value	0.1044	
	CMH approach		
	Response rate	53.9	46.5
	Difference in response rates (95% CI)	7.40 (-1.39, 16.18)	
	p-value	0.0988	
	p-Value for test for heterogenity between studies	0.2571	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 32	Number of subjects with events, n (%)	134 (54.5)	113 (45.9)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.18 (0.99, 1.42)	
	p-value	0.0680	
	Odds Ratio (95% CI)	1.39 (0.98, 1.99)	
	p-value	0.0672	
	Risk Difference (95% CI)	8.40 (-0.55, 17.36)	
	p-value	0.0658	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.19 (0.99, 1.42)	
	p-value	0.0607	
	Odds Ratio (95% CI)	1.41 (0.99, 2.01)	
	p-value	0.0593	
	Risk Difference (95% CI)	8.54 (-0.27, 17.35)	
	p-value	0.0575	
	CMH approach		
	Response rate	54.2	45.7
	Difference in response rates (95% CI)	8.53 (-0.21, 17.26)	
	p-value	0.0557	
	p-Value for test for heterogenity between studies	0.3036	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 36	Number of subjects with events, n (%)	134 (54.5)	110 (44.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.22 (1.01, 1.47)	
	p-value	0.0352	
	Odds Ratio (95% CI)	1.47 (1.03, 2.10)	
	p-value	0.0337	
	Risk Difference (95% CI)	9.75 (0.81, 18.70)	
	p-value	0.0326	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.21 (1.01, 1.45)	
	p-value	0.0369	
	Odds Ratio (95% CI)	1.48 (1.03, 2.11)	
	p-value	0.0319	
	Risk Difference (95% CI)	9.74 (0.93, 18.54)	
	p-value	0.0303	
	CMH approach		
	Response rate	54.1	44.6
	Difference in response rates (95% CI)	9.52 (0.77, 18.27)	
	p-value	0.0330	
	p-Value for test for heterogenity between studies	0.1731	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 40	Number of subjects with events, n (%)	132 (53.7)	104 (42.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.27 (1.05, 1.53)	
	p-value	0.0142	
	Odds Ratio (95% CI)	1.57 (1.10, 2.25)	
	p-value	0.0133	
	Risk Difference (95% CI)	11.31 (2.43, 20.19)	
	p-value	0.0125	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.25 (1.04, 1.51)	
	p-value	0.0173	
	Odds Ratio (95% CI)	1.58 (1.10, 2.25)	
	p-value	0.0125	
	Risk Difference (95% CI)	11.34 (2.56, 20.12)	
	p-value	0.0114	
	CMH approach		
	Response rate	53.1	42.1
	Difference in response rates (95% CI)	11.01 (2.30, 19.71)	
	p-value	0.0132	
	p-Value for test for heterogenity between studies	0.1051	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 44	Number of subjects with events, n (%)	131 (53.3)	103 (41.9)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.27 (1.05, 1.54)	
	p-value	0.0135	
	Odds Ratio (95% CI)	1.57 (1.10, 2.24)	
	p-value	0.0129	
	Risk Difference (95% CI)	11.45 (2.51, 20.38)	
	p-value	0.0120	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.27 (1.05, 1.53)	
	p-value	0.0129	
	Odds Ratio (95% CI)	1.58 (1.11, 2.26)	
	p-value	0.0119	
	Risk Difference (95% CI)	11.38 (2.60, 20.15)	
	p-value	0.0111	
	CMH approach		
	Response rate	52.8	41.6
	Difference in response rates (95% CI)	11.20 (2.50, 19.89)	
	p-value	0.0116	
	p-Value for test for heterogenity between studies	0.4252	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 48	Number of subjects with events, n (%)	128 (52.0)	103 (41.9)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.25 (1.03, 1.52)	
	p-value	0.0230	
	Odds Ratio (95% CI)	1.53 (1.06, 2.19)	
	p-value	0.0218	
	Risk Difference (95% CI)	10.39 (1.59, 19.20)	
	p-value	0.0207	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.24 (1.03, 1.50)	
	p-value	0.0249	
	Odds Ratio (95% CI)	1.51 (1.06, 2.15)	
	p-value	0.0241	
	Risk Difference (95% CI)	10.17 (1.39, 18.94)	
	p-value	0.0232	
	CMH approach		
	Response rate	51.7	41.6
	Difference in response rates (95% CI)	10.14 (1.39, 18.89)	
	p-value	0.0231	
	p-Value for test for heterogenity between studies	0.9565	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 52	Number of subjects with events, n (%)	126 (51.2)	100 (40.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.25 (1.03, 1.52)	
	p-value	0.0270	
	Odds Ratio (95% CI)	1.50 (1.05, 2.15)	
	p-value	0.0265	
	Risk Difference (95% CI)	10.11 (1.24, 18.98)	
	p-value	0.0255	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.25 (1.03, 1.52)	
	p-value	0.0219	
	Odds Ratio (95% CI)	1.53 (1.07, 2.19)	
	p-value	0.0194	
	Risk Difference (95% CI)	10.54 (1.78, 19.30)	
	p-value	0.0183	
	CMH approach		
	Response rate	50.7	40.7
	Difference in response rates (95% CI)	9.99 (1.25, 18.72)	
	p-value	0.0250	
	p-Value for test for heterogenity between studies	0.3940	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.7866
< 10 points	41/ 80 (51.3)	51.2	27/ 69 (39.1)	39.0	1.31 (0.91, 1.89)	0.1422	12.19 (-3.77, 28.16)	0.1344	
>= 10 points	85/166 (51.2)	50.8	73/177 (41.2)	41.5	1.24 (0.98, 1.56)	0.0701	9.24 (-1.19, 19.67)	0.0824	
OCS dose at baseline									0.1117
<10 mg/day	54/115 (47.0)	46.6	51/117 (43.6)	44.0	1.05 (0.80, 1.39)	0.7160	2.56 (-10.14, 15.25)	0.6931	
>=10 mg/day	72/131 (55.0)	55.1	49/129 (38.0)	38.0	1.44 (1.10, 1.89)	0.0076	17.08 (5.11, 29.06)	0.0052	
Result of type I IFN gene signature test									0.3227
LOW	20/ 45 (44.4)	44.4	21/ 48 (43.8)	43.7	1.02 (0.64, 1.61)	0.9412	0.68 (-19.52, 20.89)	0.9473	
HIGH	106/201 (52.7)	52.2	79/198 (39.9)	40.0	1.31 (1.06, 1.63)	0.0126	12.17 (2.49, 21.86)	0.0138	
Age (years)									0.0720
<= 65	123/239 (51.5)	51.0	98/243 (40.3)	40.3	1.27 (1.05, 1.55)	0.0160	10.72 (1.89, 19.55)	0.0173	
> 65	3/ 7 (42.9)	43.2	2/ 3 (66.7)	68.2	0.50 (0.19, 1.36)	0.1742	-25.00 (-90.46, 40.46)	0.4542	
Sex									0.4768
male	13/ 23 (56.5)	58.6	10/ 20 (50.0)	46.5	1.04 (0.65, 1.67)	0.8627	12.05 (-15.96, 40.05)	0.3992	
female	113/223 (50.7)	50.1	90/226 (39.8)	39.9	1.26 (1.02, 1.54)	0.0288	10.18 (1.08, 19.28)	0.0284	
Race									0.1633
White	84/160 (52.5)	52.5	78/174 (44.8)	45.1	1.17 (0.94, 1.46)	0.1642	7.41 (-3.26, 18.09)	0.1736	
Black	15/ 33 (45.5)	45.5	12/ 32 (37.5)	38.6	1.17 (0.65, 2.11)	0.5907	6.82 (-17.92, 31.57)	0.5888	
Other	23/ 45 (51.1)	51.0	8/ 37 (21.6)	21.8	2.32 (1.18, 4.54)	0.0142	29.19 (8.81, 49.57)	0.0050	
Ethnicity									0.7646
Hispanic/Latino	25/ 50 (50.0)	50.1	21/ 56 (37.5)	37.4	1.33 (0.86, 2.07)	0.1955	12.68 (-6.15, 31.51)	0.1869	
Non-hispanic/Latino	97/188 (51.6)	51.4	77/187 (41.2)	41.3	1.24 (0.99, 1.54)	0.0566	10.06 (0.03, 20.09)	0.0493	
Geographic region									0.6121
EU	60/ 92 (65.2)	65.6	49/ 89 (55.1)	55.0	1.19 (0.94, 1.52)	0.1459	10.57 (-3.75, 24.89)	0.1479	
non-EU	66/154 (42.9)	43.0	51/157 (32.5)	32.5	1.32 (0.99, 1.76)	0.0626	10.43 (-0.45, 21.31)	0.0602	
Onset of disease									0.9364
Paediatric	6/ 19 (31.6)	28.3	2/ 12 (16.7)	14.9	1.17 (0.21, 6.42)	0.8544	13.42 (-19.64, 46.49)	0.4262	
Adult	120/227 (52.9)	52.6	98/234 (41.9)	41.9	1.26 (1.04, 1.53)	0.0210	10.65 (1.63, 19.67)	0.0206	
ADA result									0.5220
Negative	116/226 (51.3)	50.5	93/223 (41.7)	41.9	1.23 (1.01, 1.50)	0.0445	8.62 (-0.53, 17.77)	0.0649	
Positive (At any time)	10/ 19 (52.6)	52.4	7/ 23 (30.4)	33.1	1.58 (0.75, 3.30)	0.2265	19.27 (-11.56, 50.10)	0.2205	
BMI (kg/m2) at enrolment									0.4981
< 30	87/159 (54.7)	55.2	73/176 (41.5)	41.8	1.32 (1.05, 1.65)	0.0165	13.37 (2.83, 23.91)	0.0129	
>= 30	39/ 87 (44.8)	45.1	27/ 70 (38.6)	39.2	1.13 (0.78, 1.65)	0.5085	5.91 (-9.36, 21.19)	0.4478	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) - individual components at week 52 (Full analysis set)
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
>=4 point reduction in SLEDAI-2k [a]	127 (51.6)	101 (41.1)
No discontinuation of IP	205 (83.3)	180 (73.2)
No use of medication beyond protocol allowed threshold	195 (79.3)	174 (70.7)
No worsening of BILAG [a]	167 (67.9)	132 (53.7)
No worsening of PGA [a]	164 (66.7)	134 (54.5)

[a] Subjects who discontinued IP or used medications beyond protocol allowed threshold are considered non-responders and not included in this category.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate at week 52 sensitivity analysis, multiple imputation
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 52	Number of subjects with events, n (%)	126 (51.2)	99 (40.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.26 (1.03, 1.54)	
	p-value	0.0222	
	Odds Ratio (95% CI)	1.53 (1.06, 2.19)	
	p-value	0.0218	
	Risk Difference (95% CI)	10.57 (1.61, 19.52)	
	p-value	0.0207	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.27 (1.04, 1.54)	
	p-value	0.0188	
	Odds Ratio (95% CI)	1.55 (1.08, 2.23)	
	p-value	0.0166	
	Risk Difference (95% CI)	10.90 (2.07, 19.73)	
	p-value	0.0155	
	p-Value for test for heterogenity between studies	0.3771	

For each outcome and visit, 100 imputations were generated by randomised treatment group. Each imputed dataset was analysed separately, and the single estimates are combined using PROC MIANALYZE. The estimated number of responders and non-responders are rounded to an integer. Therefore, there might be slight mismatches between number of subjects and corresponding percentage.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (8) response rate at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=231)	Placebo (N=232)
Week 52	Number of subjects with events, n (%)	68 (29.4)	35 (15.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.96 (1.36, 2.83)	
	p-value	0.0003	
	Odds Ratio (95% CI)	2.34 (1.48, 3.70)	
	p-value	0.0003	
	Risk Difference (95% CI)	14.69 (7.06, 22.32)	
	p-value	0.0002	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.95 (1.35, 2.81)	
	p-value	0.0003	
	Odds Ratio (95% CI)	2.35 (1.48, 3.71)	
	p-value	0.0003	
	Risk Difference (95% CI)	14.34 (6.87, 21.81)	
	p-value	0.0002	
	CMH approach		
	Response rate	29.7	15.0
	Difference in response rates (95% CI)	14.63 (6.77, 22.48)	
	p-value	0.0003	
	p-Value for test for heterogenity between studies	0.8383	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (8) response rate at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=231) n/ N (%)	Response rate	Placebo (N=232) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.5691
< 10 points	13/ 65 (20.0)	20.4	7/ 55 (12.7)	12.7	1.60 (0.68, 3.74)	0.2821	7.69 (-6.72, 22.11)	0.2954	
>= 10 points	55/166 (33.1)	32.9	28/177 (15.8)	15.9	2.10 (1.40, 3.14)	0.0003	17.04 (7.72, 26.37)	0.0003	
OCS dose at baseline									0.0125
<10 mg/day	23/107 (21.5)	21.8	20/108 (18.5)	18.8	1.14 (0.67, 1.96)	0.6246	3.06 (-8.67, 14.80)	0.6091	
>=10 mg/day	45/124 (36.3)	36.4	15/124 (12.1)	12.3	2.98 (1.76, 5.06)	<.0001	24.08 (13.29, 34.87)	<.0001	
Result of type I IFN gene signature test									0.3053
LOW	7/ 42 (16.7)	16.7	6/ 43 (14.0)	14.0	1.19 (0.44, 3.27)	0.7299	2.72 (-14.54, 19.98)	0.7574	
HIGH	61/189 (32.3)	32.6	29/189 (15.3)	15.3	2.10 (1.42, 3.12)	0.0002	17.31 (8.51, 26.12)	0.0001	
Age (years)									0.0913
<= 65	68/224 (30.4)	30.5	34/229 (14.8)	14.8	2.04 (1.41, 2.95)	0.0001	15.74 (7.76, 23.71)	0.0001	
> 65	0/ 7 (0.0)	0.0	1/ 3 (33.3)	34.1	0.17 (0.01, 2.98)	0.2235	-34.09 (-99.01, 30.83)	0.3034	
Sex									0.8752
male	7/ 21 (33.3)	33.3	3/ 19 (15.8)	13.4	1.75 (0.52, 5.87)	0.3675	19.89 (-8.85, 48.63)	0.1749	
female	61/210 (29.0)	29.2	32/213 (15.0)	15.0	1.93 (1.32, 2.84)	0.0007	14.18 (5.99, 22.37)	0.0007	
Race									0.1348
White	40/151 (26.5)	26.8	26/164 (15.9)	15.5	1.67 (1.08, 2.60)	0.0225	11.28 (1.72, 20.83)	0.0208	
Black	8/ 30 (26.7)	26.0	6/ 29 (20.7)	20.9	1.25 (0.48, 3.26)	0.6530	5.17 (-18.63, 28.97)	0.6703	
Other	19/ 43 (44.2)	44.0	2/ 36 (5.6)	5.3	5.78 (1.65, 20.22)	0.0060	38.68 (20.09, 57.27)	<.0001	
Ethnicity									0.9859
Hispanic/Latino	15/ 46 (32.6)	32.5	6/ 52 (11.5)	11.1	1.84 (0.75, 4.48)	0.1819	21.43 (4.58, 38.27)	0.0127	
Non-hispanic/Latino	52/178 (29.2)	29.3	28/177 (15.8)	15.8	1.82 (1.21, 2.74)	0.0043	13.49 (4.45, 22.52)	0.0034	
Geographic region									0.7676
EU	33/ 86 (38.4)	38.8	18/ 87 (20.7)	21.0	1.84 (1.13, 3.01)	0.0143	17.78 (4.01, 31.54)	0.0114	
non-EU	35/145 (24.1)	24.6	17/145 (11.7)	11.7	2.06 (1.21, 3.50)	0.0080	12.93 (3.38, 22.49)	0.0080	
Onset of disease									0.6467
Paediatric	4/ 19 (21.1)	19.6	0/ 12 (0.0)	0.0	3.09 (0.39, 24.33)	0.2835	19.58 (-11.22, 50.38)	0.2128	
Adult	64/212 (30.2)	30.5	35/220 (15.9)	15.9	1.89 (1.31, 2.73)	0.0006	14.64 (6.41, 22.87)	0.0005	
ADA result									0.9025
Negative	61/212 (28.8)	29.0	31/209 (14.8)	14.8	1.94 (1.31, 2.85)	0.0008	14.14 (5.91, 22.37)	0.0008	
Positive (At any time)	7/ 18 (38.9)	40.0	4/ 23 (17.4)	19.2	2.08 (0.72, 5.95)	0.1736	20.78 (-9.12, 50.69)	0.1732	
BMI (kg/m2) at enrolment									0.9913
< 30	49/152 (32.2)	32.7	27/165 (16.4)	16.2	1.98 (1.30, 2.99)	0.0013	16.46 (6.68, 26.23)	0.0010	
>= 30	19/ 79 (24.1)	24.2	8/ 67 (11.9)	11.9	1.99 (0.92, 4.30)	0.0817	12.24 (-1.51, 25.99)	0.0810	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=4 reduction in SLEDAI-2K at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 52	Number of subjects with events, n (%)	127 (51.6)	101 (41.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.24 (1.02, 1.51)	
	p-value	0.0272	
	Odds Ratio (95% CI)	1.50 (1.05, 2.15)	
	p-value	0.0266	
	Risk Difference (95% CI)	10.12 (1.24, 19.00)	
	p-value	0.0255	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.25 (1.03, 1.52)	
	p-value	0.0213	
	Odds Ratio (95% CI)	1.53 (1.07, 2.19)	
	p-value	0.0194	
	Risk Difference (95% CI)	10.54 (1.78, 19.30)	
	p-value	0.0184	
	CMH approach		
	Response rate	51.1	41.1
	Difference in response rates (95% CI)	10.00 (1.26, 18.73)	
	p-value	0.0249	
	p-Value for test for heterogenity between studies	0.5020	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=4 reduction in SLEDAI-2K at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.6497
< 10 points	42/ 80 (52.5)	52.5	27/ 69 (39.1)	39.0	1.35 (0.94, 1.93)	0.1026	13.52 (-2.43, 29.47)	0.0967	
>= 10 points	85/166 (51.2)	50.8	74/177 (41.8)	42.0	1.22 (0.97, 1.54)	0.0857	8.75 (-1.69, 19.18)	0.1005	
OCS dose at baseline									0.0796
<10 mg/day	54/115 (47.0)	46.6	52/117 (44.4)	44.7	1.04 (0.79, 1.37)	0.7982	1.82 (-10.89, 14.53)	0.7786	
>=10 mg/day	73/131 (55.7)	55.8	49/129 (38.0)	38.0	1.47 (1.12, 1.92)	0.0053	17.75 (5.78, 29.72)	0.0037	
Result of type I IFN gene signature test									0.3251
LOW	20/ 45 (44.4)	44.4	21/ 48 (43.8)	43.7	1.02 (0.64, 1.61)	0.9412	0.68 (-19.52, 20.89)	0.9473	
HIGH	107/201 (53.2)	52.6	80/198 (40.4)	40.4	1.31 (1.06, 1.62)	0.0123	12.19 (2.50, 21.88)	0.0137	
Age (years)									0.0723
<= 65	124/239 (51.9)	51.4	99/243 (40.7)	40.6	1.27 (1.05, 1.54)	0.0157	10.71 (1.88, 19.54)	0.0175	
> 65	3/ 7 (42.9)	43.2	2/ 3 (66.7)	68.2	0.50 (0.19, 1.36)	0.1742	-25.00 (-90.46, 40.46)	0.4542	
Sex									0.4759
male	13/ 23 (56.5)	58.6	10/ 20 (50.0)	46.5	1.04 (0.65, 1.67)	0.8627	12.05 (-15.96, 40.05)	0.3992	
female	114/223 (51.1)	50.5	91/226 (40.3)	40.3	1.26 (1.03, 1.54)	0.0272	10.19 (1.08, 19.29)	0.0283	
Race									0.1558
White	84/160 (52.5)	52.5	79/174 (45.4)	45.7	1.16 (0.93, 1.44)	0.1967	6.83 (-3.85, 17.51)	0.2099	
Black	16/ 33 (48.5)	48.0	12/ 32 (37.5)	38.6	1.24 (0.70, 2.20)	0.4631	9.35 (-15.41, 34.11)	0.4591	
Other	23/ 45 (51.1)	51.0	8/ 37 (21.6)	21.8	2.32 (1.18, 4.54)	0.0142	29.19 (8.81, 49.57)	0.0050	
Ethnicity									0.7633
Hispanic/Latino	25/ 50 (50.0)	50.1	21/ 56 (37.5)	37.4	1.33 (0.86, 2.07)	0.1955	12.68 (-6.15, 31.51)	0.1869	
Non-hispanic/Latino	98/188 (52.1)	51.8	78/187 (41.7)	41.8	1.24 (1.00, 1.54)	0.0541	9.97 (-0.06, 20.00)	0.0515	
Geographic region									0.4802
EU	60/ 92 (65.2)	65.6	50/ 89 (56.2)	56.3	1.17 (0.92, 1.48)	0.1993	9.28 (-5.02, 23.58)	0.2034	
non-EU	67/154 (43.5)	43.6	51/157 (32.5)	32.5	1.33 (1.00, 1.78)	0.0496	11.08 (0.20, 21.97)	0.0460	
Onset of disease									0.9372
Paediatric	6/ 19 (31.6)	28.3	2/ 12 (16.7)	14.9	1.17 (0.21, 6.42)	0.8544	13.42 (-19.64, 46.49)	0.4262	
Adult	121/227 (53.3)	53.0	99/234 (42.3)	42.3	1.26 (1.04, 1.52)	0.0204	10.67 (1.65, 19.68)	0.0204	
ADA result									0.5197
Negative	117/226 (51.8)	50.9	94/223 (42.2)	42.3	1.23 (1.01, 1.50)	0.0437	8.59 (-0.56, 17.75)	0.0658	
Positive (At any time)	10/ 19 (52.6)	52.4	7/ 23 (30.4)	33.1	1.58 (0.75, 3.30)	0.2265	19.27 (-11.56, 50.10)	0.2205	
BMI (kg/m2) at enrolment									0.6106
< 30	87/159 (54.7)	55.2	74/176 (42.0)	42.4	1.30 (1.04, 1.63)	0.0215	12.80 (2.26, 23.35)	0.0173	
>= 30	40/ 87 (46.0)	46.3	27/ 70 (38.6)	39.2	1.16 (0.80, 1.68)	0.4227	7.08 (-8.13, 22.29)	0.3618	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=8 reduction in SLEDAI-2K at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 52	Number of subjects with events, n (%)	68 (27.6)	35 (14.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.98 (1.37, 2.86)	
	p-value	0.0003	
	Odds Ratio (95% CI)	2.36 (1.50, 3.72)	
	p-value	0.0002	
	Risk Difference (95% CI)	13.92 (6.75, 21.09)	
	p-value	0.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.94 (1.34, 2.80)	
	p-value	0.0004	
	Odds Ratio (95% CI)	2.30 (1.46, 3.62)	
	p-value	0.0003	
	Risk Difference (95% CI)	13.40 (6.31, 20.49)	
	p-value	0.0002	
	CMH approach		
	Response rate	27.7	14.0
	Difference in response rates (95% CI)	13.64 (6.09, 21.19)	
	p-value	0.0004	
	p-Value for test for heterogenity between studies	0.8164	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=8 reduction in SLEDAI-2K at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.6108
< 10 points	13/ 80 (16.3)	16.4	7/ 69 (10.1)	9.9	1.64 (0.69, 3.89)	0.2636	6.56 (-6.17, 19.28)	0.3127	
>= 10 points	55/166 (33.1)	32.9	28/177 (15.8)	15.9	2.10 (1.40, 3.14)	0.0003	17.04 (7.72, 26.37)	0.0003	
OCS dose at baseline									0.0156
<10 mg/day	23/115 (20.0)	20.4	20/117 (17.1)	17.2	1.16 (0.67, 1.99)	0.6002	3.19 (-7.84, 14.22)	0.5708	
>=10 mg/day	45/131 (34.4)	34.6	15/129 (11.6)	11.8	2.95 (1.73, 5.01)	<.0001	22.85 (12.44, 33.25)	<.0001	
Result of type I IFN gene signature test									0.3623
LOW	7/ 45 (15.6)	15.6	6/ 48 (12.5)	12.5	1.25 (0.45, 3.44)	0.6682	3.08 (-12.97, 19.13)	0.7065	
HIGH	61/201 (30.3)	30.5	29/198 (14.6)	14.4	2.07 (1.39, 3.08)	0.0003	16.12 (7.60, 24.64)	0.0002	
Age (years)									0.0920
<= 65	68/239 (28.5)	28.5	34/243 (14.0)	13.8	2.03 (1.40, 2.94)	0.0002	14.70 (7.04, 22.35)	0.0002	
> 65	0/ 7 (0.0)	0.0	1/ 3 (33.3)	34.1	0.17 (0.01, 2.98)	0.2235	-34.09 (-99.01, 30.83)	0.3034	
Sex									0.7260
male	7/ 23 (30.4)	30.0	3/ 20 (15.0)	13.6	1.53 (0.45, 5.26)	0.4981	16.42 (-10.56, 43.40)	0.2330	
female	61/223 (27.4)	27.2	32/226 (14.2)	14.0	1.93 (1.31, 2.84)	0.0008	13.21 (5.32, 21.09)	0.0010	
Race									0.1409
White	40/160 (25.0)	25.4	26/174 (14.9)	14.7	1.68 (1.07, 2.61)	0.0229	10.71 (1.44, 19.98)	0.0236	
Black	8/ 33 (24.2)	23.2	6/ 32 (18.8)	19.3	1.20 (0.46, 3.18)	0.7077	3.92 (-18.30, 26.14)	0.7293	
Other	19/ 45 (42.2)	42.1	2/ 37 (5.4)	5.2	5.62 (1.60, 19.67)	0.0070	36.87 (18.75, 54.98)	<.0001	
Ethnicity									0.9924
Hispanic/Latino	15/ 50 (30.0)	29.9	6/ 56 (10.7)	10.4	1.81 (0.73, 4.50)	0.2007	19.46 (3.58, 35.35)	0.0163	
Non-hispanic/Latino	52/188 (27.7)	28.0	28/187 (15.0)	15.1	1.82 (1.20, 2.75)	0.0045	12.89 (4.11, 21.68)	0.0040	
Geographic region									0.6427
EU	33/ 92 (35.9)	36.2	18/ 89 (20.2)	20.6	1.75 (1.07, 2.87)	0.0260	15.59 (2.29, 28.90)	0.0216	
non-EU	35/154 (22.7)	23.1	17/157 (10.8)	10.7	2.08 (1.22, 3.56)	0.0074	12.37 (3.37, 21.37)	0.0071	
Onset of disease									0.6420
Paediatric	4/ 19 (21.1)	19.6	0/ 12 (0.0)	0.0	3.09 (0.39, 24.33)	0.2835	19.58 (-11.22, 50.38)	0.2128	
Adult	64/227 (28.2)	28.4	35/234 (15.0)	14.8	1.88 (1.30, 2.72)	0.0008	13.65 (5.77, 21.52)	0.0007	
ADA result									0.9729
Negative	61/226 (27.0)	27.0	31/223 (13.9)	13.8	1.94 (1.31, 2.87)	0.0009	13.22 (5.30, 21.13)	0.0011	
Positive (At any time)	7/ 19 (36.8)	38.2	4/ 23 (17.4)	19.3	1.98 (0.69, 5.69)	0.2062	18.91 (-10.52, 48.34)	0.2079	
BMI (kg/m2) at enrolment									0.8663
< 30	49/159 (30.8)	31.2	27/176 (15.3)	15.2	2.01 (1.33, 3.06)	0.0010	16.01 (6.65, 25.36)	0.0008	
>= 30	19/ 87 (21.8)	21.7	8/ 70 (11.4)	11.4	1.87 (0.86, 4.06)	0.1153	10.26 (-2.68, 23.19)	0.1201	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
No worsening in BILAG-2004 (>=1A or >=2B compared to BL) at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 52	Number of subjects with events, n (%)	167 (67.9)	132 (53.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.25 (1.08, 1.45)	
	p-value	0.0024	
	Odds Ratio (95% CI)	1.78 (1.23, 2.58)	
	p-value	0.0022	
	Risk Difference (95% CI)	13.70 (5.06, 22.33)	
	p-value	0.0019	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.26 (1.09, 1.45)	
	p-value	0.0018	
	Odds Ratio (95% CI)	1.82 (1.26, 2.63)	
	p-value	0.0013	
	Risk Difference (95% CI)	14.19 (5.66, 22.72)	
	p-value	0.0011	
	CMH approach		
	Response rate	67.2	53.8
	Difference in response rates (95% CI)	13.45 (4.88, 22.02)	
	p-value	0.0021	
	p-Value for test for heterogenity between studies	0.3773	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
No worsening in BILAG-2004 (>=1A or >=2B compared to BL) at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9703
< 10 points	58/ 80 (72.5)	72.4	40/ 69 (58.0)	57.4	1.25 (0.98, 1.59)	0.0709	14.94 (-0.45, 30.34)	0.0571	
>= 10 points	109/166 (65.7)	65.3	92/177 (52.0)	52.4	1.26 (1.05, 1.50)	0.0125	12.86 (2.60, 23.12)	0.0141	
OCS dose at baseline									0.6712
<10 mg/day	79/115 (68.7)	67.7	65/117 (55.6)	55.9	1.21 (0.99, 1.48)	0.0570	11.81 (-0.60, 24.21)	0.0621	
>=10 mg/day	88/131 (67.2)	67.2	67/129 (51.9)	51.7	1.29 (1.05, 1.59)	0.0149	15.52 (3.69, 27.34)	0.0101	
Result of type I IFN gene signature test									0.9780
LOW	33/ 45 (73.3)	73.3	27/ 48 (56.3)	56.1	1.26 (0.93, 1.71)	0.1341	17.20 (-2.08, 36.47)	0.0804	
HIGH	134/201 (66.7)	65.8	105/198 (53.0)	53.2	1.25 (1.07, 1.48)	0.0065	12.57 (3.01, 22.13)	0.0100	
Age (years)									0.0638
<= 65	162/239 (67.8)	67.2	130/243 (53.5)	53.5	1.26 (1.09, 1.46)	0.0018	13.72 (5.05, 22.38)	0.0019	
> 65	5/ 7 (71.4)	70.5	2/ 3 (66.7)	68.2	0.82 (0.53, 1.26)	0.3675	2.27 (-62.51, 67.06)	0.9452	
Sex									0.8567
male	17/ 23 (73.9)	74.9	10/ 20 (50.0)	46.5	1.18 (0.78, 1.79)	0.4371	28.38 (1.02, 55.75)	0.0421	
female	150/223 (67.3)	66.7	122/226 (54.0)	54.1	1.23 (1.06, 1.43)	0.0068	12.61 (3.63, 21.59)	0.0059	
Race									0.2086
White	114/160 (71.3)	71.0	99/174 (56.9)	57.1	1.24 (1.06, 1.46)	0.0086	13.89 (3.55, 24.24)	0.0085	
Black	19/ 33 (57.6)	57.1	18/ 32 (56.3)	56.4	1.01 (0.65, 1.57)	0.9570	0.64 (-24.20, 25.47)	0.9600	
Other	29/ 45 (64.4)	64.2	13/ 37 (35.1)	35.1	1.82 (1.11, 2.98)	0.0170	29.15 (8.06, 50.23)	0.0068	
Ethnicity									0.4103
Hispanic/Latino	31/ 50 (62.0)	61.9	24/ 56 (42.9)	42.8	1.44 (0.99, 2.10)	0.0537	19.09 (0.31, 37.87)	0.0464	
Non-hispanic/Latino	131/188 (69.7)	69.2	106/187 (56.7)	56.9	1.22 (1.04, 1.42)	0.0132	12.31 (2.49, 22.13)	0.0140	
Geographic region									0.1739
EU	71/ 92 (77.2)	77.4	61/ 89 (68.5)	68.4	1.13 (0.95, 1.35)	0.1784	9.00 (-4.26, 22.26)	0.1834	
non-EU	96/154 (62.3)	62.1	71/157 (45.2)	45.5	1.37 (1.11, 1.69)	0.0034	16.67 (5.70, 27.64)	0.0029	
Onset of disease									0.9799
Paediatric	9/ 19 (47.4)	45.7	4/ 12 (33.3)	31.9	1.25 (0.45, 3.48)	0.6712	13.77 (-21.97, 49.51)	0.4501	
Adult	158/227 (69.6)	69.1	128/234 (54.7)	54.9	1.27 (1.10, 1.46)	0.0014	14.29 (5.50, 23.08)	0.0014	
ADA result									0.7651
Negative	155/226 (68.6)	67.7	123/223 (55.2)	55.5	1.24 (1.07, 1.44)	0.0041	12.19 (3.22, 21.16)	0.0077	
Positive (At any time)	12/ 19 (63.2)	61.8	9/ 23 (39.1)	44.0	1.36 (0.76, 2.42)	0.2960	17.82 (-12.83, 48.47)	0.2545	
BMI (kg/m2) at enrolment									0.2501
< 30	113/159 (71.1)	71.2	94/176 (53.4)	53.4	1.33 (1.12, 1.58)	0.0010	17.75 (7.49, 28.01)	0.0007	
>= 30	54/ 87 (62.1)	62.2	38/ 70 (54.3)	55.0	1.11 (0.85, 1.44)	0.4497	7.15 (-8.12, 22.42)	0.3586	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Maintained OCS Reduction at week 52 (for subjects with baseline OCS >=10 mg/day)
Full analysis set

Timepoint		Anifrolumab 300mg (N=131)	Placebo (N=129)
Week 52	Number of subjects with events, n (%)	70 (53.4)	38 (29.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.85 (1.35, 2.52)	
	p-value	0.0001	
	Odds Ratio (95% CI)	2.97 (1.74, 5.07)	
	p-value	<.0001	
	Risk Difference (95% CI)	24.50 (13.10, 35.90)	
	p-value	<.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.80 (1.32, 2.46)	
	p-value	0.0002	
	Odds Ratio (95% CI)	2.77 (1.66, 4.63)	
	p-value	0.0001	
	Risk Difference (95% CI)	24.13 (12.53, 35.73)	
	p-value	<.0001	
	CMH approach		
	Response rate	53.8	28.8
	Difference in response rates (95% CI)	25.08 (13.56, 36.60)	
	p-value	<.0001	
	p-Value for test for heterogenity between studies	0.4667	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Maintained OCS Reduction at week 52 (for subjects with baseline OCS >=10 mg/day) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=131) n/ N (%)	Response rate	Placebo (N=129) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9333
< 10 points	21/ 38 (55.3)	55.2	9/ 29 (31.0)	30.8	1.76 (0.95, 3.25)	0.0734	24.47 (0.97, 47.97)	0.0413	
>= 10 points	49/ 93 (52.7)	52.7	29/100 (29.0)	28.9	1.81 (1.26, 2.60)	0.0013	23.80 (10.24, 37.37)	0.0006	
OCS dose at baseline									NE
>=10 mg/day	70/131 (53.4)	53.8	38/129 (29.5)	28.8	1.80 (1.32, 2.46)	0.0002	25.08 (13.56, 36.60)	<.0001	
Result of type I IFN gene signature test									0.1367
LOW	8/ 13 (61.5)	60.4	10/ 21 (47.6)	48.8	1.29 (0.81, 2.06)	0.2862	11.59 (-20.24, 43.41)	0.4755	
HIGH	62/118 (52.5)	52.2	28/108 (25.9)	25.9	2.02 (1.40, 2.90)	0.0001	26.25 (13.79, 38.72)	<.0001	
Age (years)									0.1852
<= 65	70/129 (54.3)	54.3	37/128 (28.9)	28.8	1.87 (1.36, 2.56)	<.0001	25.48 (13.78, 37.17)	<.0001	
> 65	0/ 2 (0.0)	0.0	1/ 1 (100.0)	100.0	0.33 (0.03, 4.19)	0.3948	-100.00 (-235.79, 35.79)	0.1489	
Sex									0.4661
male	10/ 15 (66.7)	67.5	2/ 11 (18.2)	17.2	2.52 (0.89, 7.18)	0.0826	50.29 (14.55, 86.03)	0.0058	
female	60/116 (51.7)	51.8	36/118 (30.5)	30.3	1.68 (1.22, 2.32)	0.0017	21.58 (9.26, 33.90)	0.0006	
Race									0.9501
White	42/ 77 (54.5)	54.5	30/101 (29.7)	29.3	1.81 (1.25, 2.61)	0.0016	25.21 (10.93, 39.49)	0.0005	
Black	9/ 20 (45.0)	41.1	3/ 12 (25.0)	22.6	1.60 (0.41, 6.32)	0.5011	18.55 (-17.32, 54.41)	0.3108	
Other	16/ 30 (53.3)	54.9	5/ 15 (33.3)	33.8	1.59 (0.73, 3.48)	0.2455	21.03 (-9.72, 51.77)	0.1802	
Ethnicity									0.8692
Hispanic/Latino	13/ 31 (41.9)	42.3	7/ 31 (22.6)	22.3	1.88 (0.87, 4.05)	0.1066	20.03 (-3.52, 43.58)	0.0955	
Non-hispanic/Latino	54/ 96 (56.3)	56.4	31/ 97 (32.0)	31.7	1.75 (1.25, 2.46)	0.0011	24.69 (11.07, 38.30)	0.0004	
Geographic region									0.6341
EU	37/ 57 (64.9)	64.9	24/ 65 (36.9)	36.1	1.73 (1.19, 2.52)	0.0044	28.81 (11.57, 46.05)	0.0011	
non-EU	33/ 74 (44.6)	44.5	14/ 64 (21.9)	21.8	2.03 (1.19, 3.45)	0.0092	22.71 (7.18, 38.24)	0.0042	
Onset of disease									0.8668
Paediatric	8/ 15 (53.3)	52.5	2/ 8 (25.0)	26.0	1.99 (0.56, 7.14)	0.2903	26.48 (-16.54, 69.50)	0.2276	
Adult	62/116 (53.4)	53.5	36/121 (29.8)	29.7	1.78 (1.29, 2.45)	0.0004	23.76 (11.52, 35.99)	0.0001	
ADA result									0.6059
Negative	65/116 (56.0)	56.1	36/113 (31.9)	31.6	1.76 (1.28, 2.41)	0.0004	24.56 (12.05, 37.07)	0.0001	
Positive (At any time)	5/ 14 (35.7)	34.4	2/ 16 (12.5)	12.5	2.67 (0.56, 12.62)	0.2158	21.88 (-12.22, 55.97)	0.2085	
BMI (kg/m2) at enrolment									0.5713
< 30	53/ 90 (58.9)	58.8	30/ 99 (30.3)	30.0	1.92 (1.36, 2.73)	0.0002	28.80 (15.10, 42.50)	<.0001	
>= 30	17/ 41 (41.5)	41.1	8/ 30 (26.7)	26.8	1.54 (0.77, 3.08)	0.2248	14.27 (-8.16, 36.69)	0.2124	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=50% Reduction in CLASI activity score at week 52 (for subjects with baseline CLASI activity score >=10)
Full analysis set

Timepoint		Anifrolumab 300mg (N=65)	Placebo (N=70)
Week 52	Number of subjects with events, n (%)	39 (60.0)	35 (50.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.16 (0.86, 1.56)	
	p-value	0.3206	
	Odds Ratio (95% CI)	1.44 (0.70, 2.97)	
	p-value	0.3206	
	Risk Difference (95% CI)	8.29 (-8.04, 24.61)	
	p-value	0.3198	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.20 (0.88, 1.63)	
	p-value	0.2450	
	Odds Ratio (95% CI)	1.50 (0.76, 2.97)	
	p-value	0.2447	
	Risk Difference (95% CI)	10.00 (-6.72, 26.72)	
	p-value	0.2411	
	CMH approach		
	Response rate	60.0	50.0
	Difference in response rates (95% CI)	10.00 (-6.76, 26.76)	
	p-value	0.2422	
	p-Value for test for heterogenity between studies	1.0000	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=50% Reduction in CLASI activity score at week 52 (for subjects with baseline CLASI activity score >=10) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=65) n/ N (%)	Response rate	Placebo (N=70) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8742
< 10 points	8/ 12 (66.7)	67.0	7/ 13 (53.8)	53.8	1.27 (0.68, 2.38)	0.4595	13.21 (-25.21, 51.62)	0.5004	
>= 10 points	31/ 53 (58.5)	58.7	28/ 57 (49.1)	49.1	1.20 (0.85, 1.69)	0.3107	9.58 (-9.03, 28.19)	0.3131	
OCS dose at baseline									0.3961
<10 mg/day	14/ 22 (63.6)	63.6	10/ 23 (43.5)	43.5	1.46 (0.83, 2.57)	0.1859	20.16 (-8.70, 49.01)	0.1710	
>=10 mg/day	25/ 43 (58.1)	58.2	25/ 47 (53.2)	53.2	1.09 (0.76, 1.58)	0.6376	4.94 (-15.65, 25.52)	0.6385	
Result of type I IFN gene signature test									0.1603
LOW	6/ 9 (66.7)	65.2	9/ 12 (75.0)	78.3	0.83 (0.49, 1.41)	0.4962	-13.04 (-54.90, 28.82)	0.5414	
HIGH	33/ 56 (58.9)	59.0	26/ 58 (44.8)	44.8	1.31 (0.92, 1.88)	0.1356	14.19 (-4.00, 32.39)	0.1263	
Age (years)									NE
<= 65	38/ 64 (59.4)	59.4	34/ 69 (49.3)	49.2	1.21 (0.88, 1.65)	0.2422	10.15 (-6.75, 27.05)	0.2391	
> 65	1/ 1 (100.0)	100.0	1/ 1 (100.0)	100.0	NE		0.00 (-135.79, 135.79)	1.0000	
Sex									0.8000
male	3/ 7 (42.9)	41.3	3/ 8 (37.5)	31.3	0.99 (0.23, 4.32)	0.9857	9.95 (-40.22, 60.12)	0.6975	
female	36/ 58 (62.1)	62.1	32/ 62 (51.6)	51.7	1.20 (0.88, 1.64)	0.2566	10.41 (-7.27, 28.09)	0.2485	
Race									0.5088
White	29/ 48 (60.4)	60.3	30/ 56 (53.6)	53.8	1.12 (0.80, 1.56)	0.5137	6.56 (-12.52, 25.63)	0.5004	
Black	3/ 7 (42.9)	0.0	1/ 3 (33.3)	33.3	0.67 (0.04, 10.05)	0.7696	-33.33 (-144.49, 77.82)	0.5567	
Other	7/ 9 (77.8)	77.5	2/ 9 (22.2)	25.0	2.00 (0.74, 5.43)	0.1729	52.50 (8.66, 96.34)	0.0189	
Ethnicity									0.8283
Hispanic/Latino	2/ 7 (28.6)	29.0	3/ 9 (33.3)	33.1	1.11 (0.35, 3.55)	0.8623	-4.03 (-50.59, 42.53)	0.8652	
Non-hispanic/Latino	37/ 57 (64.9)	64.8	30/ 59 (50.8)	51.0	1.27 (0.93, 1.73)	0.1394	13.81 (-4.05, 31.67)	0.1297	
Geographic region									0.1557
EU	21/ 31 (67.7)	67.8	23/ 34 (67.6)	67.7	1.02 (0.73, 1.42)	0.9289	0.12 (-23.07, 23.32)	0.9917	
non-EU	18/ 34 (52.9)	53.5	12/ 36 (33.3)	33.2	1.63 (0.93, 2.83)	0.0869	20.37 (-2.61, 43.36)	0.0823	
Onset of disease									0.5818
Paediatric	2/ 5 (40.0)	33.3	2/ 4 (50.0)	50.0	0.82 (0.20, 3.42)	0.7827	-16.67 (-85.65, 52.32)	0.6358	
Adult	37/ 60 (61.7)	61.7	33/ 66 (50.0)	50.0	1.23 (0.90, 1.69)	0.1883	11.68 (-5.61, 28.97)	0.1854	
ADA result									0.3222
Negative	38/ 59 (64.4)	64.4	34/ 66 (51.5)	51.5	1.25 (0.92, 1.69)	0.1482	12.90 (-4.35, 30.15)	0.1427	
Positive (At any time)	1/ 6 (16.7)	13.6	1/ 4 (25.0)	34.1	0.40 (0.04, 3.74)	0.4216	-20.45 (-86.72, 45.81)	0.5452	
BMI (kg/m2) at enrolment									0.3729
< 30	29/ 45 (64.4)	64.3	24/ 49 (49.0)	49.1	1.31 (0.91, 1.87)	0.1408	15.15 (-4.76, 35.05)	0.1359	
>= 30	10/ 20 (50.0)	50.2	11/ 21 (52.4)	52.0	0.96 (0.53, 1.72)	0.8844	-1.78 (-32.29, 28.73)	0.9091	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 4	Number of subjects with events, n (%)	62 (25.2)	43 (17.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.41 (1.00, 2.00)	
	p-value	0.0528	
	Odds Ratio (95% CI)	1.55 (1.00, 2.40)	
	p-value	0.0523	
	Risk Difference (95% CI)	7.29 (-0.01, 14.58)	
	p-value	0.0502	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.44 (1.02, 2.04)	
	p-value	0.0397	
	Odds Ratio (95% CI)	1.59 (1.03, 2.47)	
	p-value	0.0373	
	Risk Difference (95% CI)	7.75 (0.55, 14.95)	
	p-value	0.0350	
	CMH approach		
	Response rate	25.0	17.6
	Difference in response rates (95% CI)	7.38 (-0.22, 14.98)	
	p-value	0.0568	
	p-Value for test for heterogenity between studies	0.5715	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 8	Number of subjects with events, n (%)	90 (36.6)	54 (22.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.65 (1.24, 2.19)	
	p-value	0.0005	
	Odds Ratio (95% CI)	2.04 (1.36, 3.05)	
	p-value	0.0005	
	Risk Difference (95% CI)	14.54 (6.54, 22.55)	
	p-value	0.0004	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.66 (1.25, 2.21)	
	p-value	0.0005	
	Odds Ratio (95% CI)	2.05 (1.38, 3.05)	
	p-value	0.0004	
	Risk Difference (95% CI)	14.61 (6.67, 22.54)	
	p-value	0.0003	
	CMH approach		
	Response rate	36.4	21.8
	Difference in response rates (95% CI)	14.58 (6.51, 22.65)	
	p-value	0.0004	
	p-Value for test for heterogenity between studies	0.6790	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 12	Number of subjects with events, n (%)	100 (40.7)	71 (28.9)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.39 (1.09, 1.79)	
	p-value	0.0089	
	Odds Ratio (95% CI)	1.66 (1.14, 2.41)	
	p-value	0.0087	
	Risk Difference (95% CI)	11.46 (2.99, 19.92)	
	p-value	0.0080	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.41 (1.10, 1.80)	
	p-value	0.0068	
	Odds Ratio (95% CI)	1.69 (1.16, 2.46)	
	p-value	0.0063	
	Risk Difference (95% CI)	11.78 (3.43, 20.13)	
	p-value	0.0057	
	CMH approach		
	Response rate	40.3	29.2
	Difference in response rates (95% CI)	11.02 (2.61, 19.44)	
	p-value	0.0102	
	p-Value for test for heterogenity between studies	0.8835	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 16	Number of subjects with events, n (%)	109 (44.3)	78 (31.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.38 (1.09, 1.75)	
	p-value	0.0081	
	Odds Ratio (95% CI)	1.66 (1.15, 2.39)	
	p-value	0.0070	
	Risk Difference (95% CI)	12.02 (3.35, 20.68)	
	p-value	0.0065	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.40 (1.11, 1.76)	
	p-value	0.0045	
	Odds Ratio (95% CI)	1.71 (1.19, 2.47)	
	p-value	0.0042	
	Risk Difference (95% CI)	12.59 (4.08, 21.09)	
	p-value	0.0037	
	CMH approach		
	Response rate	43.6	31.6
	Difference in response rates (95% CI)	12.02 (3.52, 20.51)	
	p-value	0.0056	
	p-Value for test for heterogenity between studies	0.8494	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 20	Number of subjects with events, n (%)	108 (43.9)	85 (34.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.26 (1.00, 1.58)	
	p-value	0.0508	
	Odds Ratio (95% CI)	1.44 (1.00, 2.07)	
	p-value	0.0484	
	Risk Difference (95% CI)	8.85 (0.11, 17.59)	
	p-value	0.0473	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.27 (1.02, 1.58)	
	p-value	0.0363	
	Odds Ratio (95% CI)	1.48 (1.03, 2.13)	
	p-value	0.0345	
	Risk Difference (95% CI)	9.32 (0.74, 17.91)	
	p-value	0.0333	
	CMH approach		
	Response rate	43.4	34.3
	Difference in response rates (95% CI)	9.11 (0.50, 17.71)	
	p-value	0.0381	
	p-Value for test for heterogenity between studies	0.7048	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 24	Number of subjects with events, n (%)	121 (49.2)	82 (33.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.47 (1.18, 1.84)	
	p-value	0.0007	
	Odds Ratio (95% CI)	1.90 (1.32, 2.73)	
	p-value	0.0006	
	Risk Difference (95% CI)	15.73 (6.97, 24.50)	
	p-value	0.0004	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.45 (1.17, 1.80)	
	p-value	0.0008	
	Odds Ratio (95% CI)	1.93 (1.34, 2.78)	
	p-value	0.0004	
	Risk Difference (95% CI)	15.81 (7.21, 24.42)	
	p-value	0.0003	
	CMH approach		
	Response rate	48.8	33.2
	Difference in response rates (95% CI)	15.62 (7.03, 24.22)	
	p-value	0.0004	
	p-Value for test for heterogenity between studies	0.0692	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 28	Number of subjects with events, n (%)	115 (46.7)	88 (35.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.29 (1.03, 1.60)	
	p-value	0.0234	
	Odds Ratio (95% CI)	1.52 (1.06, 2.19)	
	p-value	0.0223	
	Risk Difference (95% CI)	10.33 (1.53, 19.14)	
	p-value	0.0214	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.29 (1.04, 1.60)	
	p-value	0.0197	
	Odds Ratio (95% CI)	1.57 (1.09, 2.26)	
	p-value	0.0145	
	Risk Difference (95% CI)	10.92 (2.28, 19.57)	
	p-value	0.0132	
	CMH approach		
	Response rate	46.4	35.9
	Difference in response rates (95% CI)	10.51 (1.89, 19.14)	
	p-value	0.0169	
	p-Value for test for heterogenity between studies	0.1584	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 32	Number of subjects with events, n (%)	118 (48.0)	88 (35.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.31 (1.06, 1.63)	
	p-value	0.0129	
	Odds Ratio (95% CI)	1.60 (1.11, 2.30)	
	p-value	0.0119	
	Risk Difference (95% CI)	11.30 (2.56, 20.04)	
	p-value	0.0113	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.32 (1.07, 1.62)	
	p-value	0.0107	
	Odds Ratio (95% CI)	1.66 (1.15, 2.38)	
	p-value	0.0067	
	Risk Difference (95% CI)	12.11 (3.49, 20.73)	
	p-value	0.0059	
	CMH approach		
	Response rate	47.3	35.9
	Difference in response rates (95% CI)	11.39 (2.79, 20.00)	
	p-value	0.0095	
	p-Value for test for heterogenity between studies	0.1439	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 36	Number of subjects with events, n (%)	116 (47.2)	87 (35.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.32 (1.06, 1.63)	
	p-value	0.0126	
	Odds Ratio (95% CI)	1.59 (1.11, 2.30)	
	p-value	0.0121	
	Risk Difference (95% CI)	11.28 (2.55, 20.01)	
	p-value	0.0113	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.31 (1.06, 1.62)	
	p-value	0.0117	
	Odds Ratio (95% CI)	1.63 (1.13, 2.35)	
	p-value	0.0083	
	Risk Difference (95% CI)	11.70 (3.11, 20.28)	
	p-value	0.0076	
	CMH approach		
	Response rate	46.7	35.6
	Difference in response rates (95% CI)	11.11 (2.51, 19.72)	
	p-value	0.0114	
	p-Value for test for heterogenity between studies	0.2990	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 40	Number of subjects with events, n (%)	108 (43.9)	82 (33.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.29 (1.02, 1.62)	
	p-value	0.0300	
	Odds Ratio (95% CI)	1.51 (1.04, 2.19)	
	p-value	0.0289	
	Risk Difference (95% CI)	9.64 (1.05, 18.23)	
	p-value	0.0278	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.31 (1.05, 1.64)	
	p-value	0.0183	
	Odds Ratio (95% CI)	1.57 (1.09, 2.26)	
	p-value	0.0166	
	Risk Difference (95% CI)	10.49 (1.98, 18.99)	
	p-value	0.0157	
	CMH approach		
	Response rate	43.0	33.6
	Difference in response rates (95% CI)	9.48 (1.00, 17.96)	
	p-value	0.0285	
	p-Value for test for heterogenity between studies	0.7379	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 44	Number of subjects with events, n (%)	110 (44.7)	84 (34.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.29 (1.03, 1.62)	
	p-value	0.0298	
	Odds Ratio (95% CI)	1.50 (1.04, 2.15)	
	p-value	0.0283	
	Risk Difference (95% CI)	9.89 (1.11, 18.67)	
	p-value	0.0273	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.31 (1.05, 1.64)	
	p-value	0.0171	
	Odds Ratio (95% CI)	1.56 (1.08, 2.24)	
	p-value	0.0173	
	Risk Difference (95% CI)	10.53 (1.95, 19.12)	
	p-value	0.0162	
	CMH approach		
	Response rate	44.0	34.1
	Difference in response rates (95% CI)	9.89 (1.34, 18.43)	
	p-value	0.0234	
	p-Value for test for heterogenity between studies	0.4411	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 48	Number of subjects with events, n (%)	111 (45.1)	80 (32.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.36 (1.09, 1.71)	
	p-value	0.0075	
	Odds Ratio (95% CI)	1.66 (1.15, 2.41)	
	p-value	0.0070	
	Risk Difference (95% CI)	11.97 (3.35, 20.58)	
	p-value	0.0065	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.39 (1.10, 1.74)	
	p-value	0.0049	
	Odds Ratio (95% CI)	1.70 (1.18, 2.46)	
	p-value	0.0044	
	Risk Difference (95% CI)	12.59 (4.04, 21.14)	
	p-value	0.0039	
	CMH approach		
	Response rate	44.5	32.8
	Difference in response rates (95% CI)	11.77 (3.23, 20.30)	
	p-value	0.0069	
	p-Value for test for heterogenity between studies	0.3514	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 52	Number of subjects with events, n (%)	115 (46.7)	78 (31.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.43 (1.14, 1.79)	
	p-value	0.0019	
	Odds Ratio (95% CI)	1.81 (1.25, 2.62)	
	p-value	0.0017	
	Risk Difference (95% CI)	13.90 (5.31, 22.49)	
	p-value	0.0015	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.47 (1.18, 1.85)	
	p-value	0.0008	
	Odds Ratio (95% CI)	1.89 (1.31, 2.73)	
	p-value	0.0007	
	Risk Difference (95% CI)	15.00 (6.48, 23.52)	
	p-value	0.0006	
	CMH approach		
	Response rate	46.0	32.2
	Difference in response rates (95% CI)	13.80 (5.26, 22.33)	
	p-value	0.0015	
	p-Value for test for heterogenity between studies	0.6929	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9520
< 10 points	45/ 80 (56.3)	55.7	27/ 69 (39.1)	39.0	1.44 (1.01, 2.04)	0.0422	16.74 (0.87, 32.61)	0.0387	
>= 10 points	70/166 (42.2)	41.8	51/177 (28.8)	29.3	1.46 (1.09, 1.96)	0.0117	12.48 (2.36, 22.60)	0.0156	
OCS dose at baseline									0.6968
<10 mg/day	50/115 (43.5)	43.0	36/117 (30.8)	31.4	1.39 (0.99, 1.95)	0.0592	11.62 (-0.85, 24.08)	0.0677	
>=10 mg/day	65/131 (49.6)	49.6	42/129 (32.6)	32.9	1.52 (1.12, 2.06)	0.0069	16.68 (4.95, 28.42)	0.0053	
Result of type I IFN gene signature test									0.3718
LOW	19/ 45 (42.2)	42.3	17/ 48 (35.4)	35.4	1.19 (0.72, 1.99)	0.4953	6.86 (-13.05, 26.77)	0.4993	
HIGH	96/201 (47.8)	46.9	61/198 (30.8)	31.4	1.55 (1.20, 2.00)	0.0007	15.43 (5.98, 24.88)	0.0014	
Age (years)									0.9074
<= 65	111/239 (46.4)	45.6	77/243 (31.7)	32.1	1.47 (1.17, 1.84)	0.0011	13.54 (4.91, 22.18)	0.0021	
> 65	4/ 7 (57.1)	54.5	1/ 3 (33.3)	34.1	1.60 (0.37, 6.85)	0.5262	20.45 (-45.81, 86.72)	0.5452	
Sex									0.7694
male	12/ 23 (52.2)	52.5	7/ 20 (35.0)	32.9	1.31 (0.64, 2.71)	0.4615	19.55 (-9.56, 48.67)	0.1881	
female	103/223 (46.2)	45.6	71/226 (31.4)	31.8	1.47 (1.16, 1.87)	0.0015	13.75 (4.82, 22.68)	0.0026	
Race									0.2049
White	72/160 (45.0)	44.9	58/174 (33.3)	33.5	1.36 (1.04, 1.78)	0.0267	11.36 (0.91, 21.81)	0.0331	
Black	17/ 33 (51.5)	50.5	13/ 32 (40.6)	41.1	1.23 (0.71, 2.14)	0.4629	9.41 (-15.42, 34.25)	0.4574	
Other	21/ 45 (46.7)	46.5	6/ 37 (16.2)	16.1	2.82 (1.26, 6.27)	0.0113	30.40 (10.61, 50.20)	0.0026	
Ethnicity									0.6435
Hispanic/Latino	23/ 50 (46.0)	46.2	16/ 56 (28.6)	28.5	1.63 (0.98, 2.70)	0.0608	17.72 (-0.61, 36.06)	0.0582	
Non-hispanic/Latino	87/188 (46.3)	45.6	61/187 (32.6)	33.0	1.42 (1.10, 1.84)	0.0072	12.61 (2.81, 22.40)	0.0116	
Geographic region									0.4158
EU	50/ 92 (54.3)	55.6	37/ 89 (41.6)	41.9	1.34 (0.98, 1.82)	0.0627	13.63 (-0.79, 28.06)	0.0639	
non-EU	65/154 (42.2)	41.9	41/157 (26.1)	26.1	1.61 (1.17, 2.22)	0.0037	15.78 (5.22, 26.35)	0.0034	
Onset of disease									0.8710
Paediatric	8/ 19 (42.1)	41.3	3/ 12 (25.0)	24.5	1.62 (0.51, 5.15)	0.4138	16.85 (-18.54, 52.24)	0.3507	
Adult	107/227 (47.1)	46.6	75/234 (32.1)	32.5	1.47 (1.16, 1.85)	0.0012	14.16 (5.31, 23.01)	0.0017	
ADA result									0.5348
Negative	107/226 (47.3)	46.5	73/223 (32.7)	33.5	1.45 (1.15, 1.83)	0.0017	12.95 (3.98, 21.92)	0.0047	
Positive (At any time)	8/ 19 (42.1)	42.9	5/ 23 (21.7)	22.2	1.97 (0.77, 5.05)	0.1565	20.73 (-9.14, 50.59)	0.1737	
BMI (kg/m2) at enrolment									0.2624
< 30	78/159 (49.1)	49.3	54/176 (30.7)	31.2	1.60 (1.22, 2.10)	0.0007	18.10 (7.78, 28.41)	0.0006	
>= 30	37/ 87 (42.5)	42.5	24/ 70 (34.3)	34.7	1.21 (0.81, 1.81)	0.3457	7.79 (-7.35, 22.94)	0.3132	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA - individual components at week 52 (Full analysis set)
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
BILAG improvement [a]	116 (47.2)	80 (32.5)
No discontinuation of IP	205 (83.3)	180 (73.2)
No use of medication beyond protocol allowed threshold	195 (79.3)	174 (70.7)
No worsening of PGA [a]	164 (66.7)	134 (54.5)
No worsening of SLEDAI-2K [a]	167 (67.9)	131 (53.3)

[a] Subjects who discontinued IP or used medications beyond protocol allowed threshold are considered non-responders and not included in this category.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate at week 52 sensitivity analysis, multiple imputation
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 52	Number of subjects with events, n (%)	114 (46.5)	78 (31.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.41 (1.13, 1.78)	
	p-value	0.0028	
	Odds Ratio (95% CI)	1.78 (1.22, 2.58)	
	p-value	0.0026	
	Risk Difference (95% CI)	13.47 (4.80, 22.13)	
	p-value	0.0023	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.46 (1.16, 1.83)	
	p-value	0.0011	
	Odds Ratio (95% CI)	1.86 (1.28, 2.69)	
	p-value	0.0010	
	Risk Difference (95% CI)	14.62 (6.03, 23.21)	
	p-value	0.0008	
	p-Value for test for heterogenity between studies	0.7381	

For each outcome and visit, 100 imputations were generated by randomised treatment group. Each imputed dataset was analysed separately, and the single estimates are combined using PROC MIANALYZE. The estimated number of responders and non-responders are rounded to an integer. Therefore, there might be slight mismatches between number of subjects and corresponding percentage.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Change from baseline in PGA VAS < 0.3 at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 52	Number of subjects with events, n (%)	164 (66.7)	134 (54.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.21 (1.05, 1.40)	
	p-value	0.0102	
	Odds Ratio (95% CI)	1.62 (1.12, 2.34)	
	p-value	0.0098	
	Risk Difference (95% CI)	11.56 (2.88, 20.23)	
	p-value	0.0090	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.22 (1.05, 1.40)	
	p-value	0.0078	
	Odds Ratio (95% CI)	1.67 (1.16, 2.41)	
	p-value	0.0060	
	Risk Difference (95% CI)	12.15 (3.59, 20.71)	
	p-value	0.0054	
	CMH approach		
	Response rate	66.0	54.6
	Difference in response rates (95% CI)	11.40 (2.82, 19.99)	
	p-value	0.0092	
	p-Value for test for heterogenity between studies	0.3305	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Change from baseline in PGA VAS < 0.3 at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9667
< 10 points	56/ 80 (70.0)	69.5	40/ 69 (58.0)	57.4	1.21 (0.94, 1.54)	0.1355	12.07 (-3.45, 27.59)	0.1275	
>= 10 points	108/166 (65.1)	64.6	94/177 (53.1)	53.7	1.21 (1.02, 1.45)	0.0316	10.93 (0.63, 21.22)	0.0375	
OCS dose at baseline									0.8996
<10 mg/day	77/115 (67.0)	65.9	64/117 (54.7)	55.1	1.20 (0.98, 1.47)	0.0789	10.80 (-1.63, 23.23)	0.0886	
>=10 mg/day	87/131 (66.4)	66.5	70/129 (54.3)	54.0	1.22 (1.00, 1.49)	0.0509	12.54 (0.70, 24.39)	0.0380	
Result of type I IFN gene signature test									0.7851
LOW	33/ 45 (73.3)	73.3	27/ 48 (56.3)	56.1	1.26 (0.93, 1.71)	0.1341	17.20 (-2.08, 36.47)	0.0804	
HIGH	131/201 (65.2)	64.3	107/198 (54.0)	54.3	1.20 (1.02, 1.41)	0.0271	10.04 (0.45, 19.63)	0.0401	
Age (years)									0.0888
<= 65	159/239 (66.5)	66.0	132/243 (54.3)	54.4	1.22 (1.05, 1.41)	0.0080	11.65 (2.97, 20.34)	0.0086	
> 65	5/ 7 (71.4)	70.5	2/ 3 (66.7)	68.2	0.82 (0.53, 1.26)	0.3675	2.27 (-62.51, 67.06)	0.9452	
Sex									0.9952
male	17/ 23 (73.9)	74.9	11/ 20 (55.0)	52.2	1.20 (0.80, 1.80)	0.3873	22.69 (-5.30, 50.68)	0.1121	
female	147/223 (65.9)	65.4	123/226 (54.4)	54.6	1.19 (1.03, 1.39)	0.0205	10.77 (1.77, 19.77)	0.0190	
Race									0.1249
White	113/160 (70.6)	70.5	101/174 (58.0)	58.1	1.21 (1.03, 1.42)	0.0226	12.40 (2.06, 22.75)	0.0188	
Black	17/ 33 (51.5)	50.5	18/ 32 (56.3)	56.4	0.90 (0.56, 1.44)	0.6638	-5.93 (-30.81, 18.96)	0.6406	
Other	29/ 45 (64.4)	64.2	13/ 37 (35.1)	35.1	1.82 (1.11, 2.98)	0.0170	29.15 (8.06, 50.23)	0.0068	
Ethnicity									0.2118
Hispanic/Latino	32/ 50 (64.0)	64.0	24/ 56 (42.9)	42.8	1.49 (1.03, 2.16)	0.0329	21.14 (2.43, 39.85)	0.0268	
Non-hispanic/Latino	127/188 (67.6)	67.3	108/187 (57.8)	57.9	1.16 (0.99, 1.35)	0.0682	9.38 (-0.48, 19.24)	0.0621	
Geographic region									0.1849
EU	70/ 92 (76.1)	76.4	62/ 89 (69.7)	69.1	1.10 (0.92, 1.31)	0.2958	7.30 (-5.96, 20.55)	0.2806	
non-EU	94/154 (61.0)	61.0	72/157 (45.9)	46.0	1.33 (1.07, 1.64)	0.0089	15.03 (4.04, 26.02)	0.0073	
Onset of disease									0.9649
Paediatric	9/ 19 (47.4)	45.7	4/ 12 (33.3)	31.9	1.25 (0.45, 3.48)	0.6712	13.77 (-21.97, 49.51)	0.4501	
Adult	155/227 (68.3)	67.9	130/234 (55.6)	55.7	1.22 (1.06, 1.41)	0.0068	12.14 (3.34, 20.94)	0.0069	
ADA result									0.6743
Negative	152/226 (67.3)	66.4	125/223 (56.1)	56.4	1.20 (1.03, 1.39)	0.0169	9.99 (1.02, 18.97)	0.0291	
Positive (At any time)	12/ 19 (63.2)	61.8	9/ 23 (39.1)	44.0	1.36 (0.76, 2.42)	0.2960	17.82 (-12.83, 48.47)	0.2545	
BMI (kg/m2) at enrolment									0.1430
< 30	112/159 (70.4)	70.6	95/176 (54.0)	54.0	1.30 (1.10, 1.55)	0.0022	16.58 (6.29, 26.87)	0.0016	
>= 30	52/ 87 (59.8)	59.7	39/ 70 (55.7)	56.6	1.03 (0.80, 1.34)	0.8070	3.18 (-12.10, 18.45)	0.6834	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Change from baseline in PGA VAS < 0.45 at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 52	Number of subjects with events, n (%)	166 (67.5)	137 (55.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.20 (1.04, 1.38)	
	p-value	0.0127	
	Odds Ratio (95% CI)	1.60 (1.11, 2.32)	
	p-value	0.0122	
	Risk Difference (95% CI)	11.15 (2.52, 19.78)	
	p-value	0.0114	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.21 (1.05, 1.39)	
	p-value	0.0086	
	Odds Ratio (95% CI)	1.65 (1.14, 2.38)	
	p-value	0.0075	
	Risk Difference (95% CI)	11.74 (3.22, 20.27)	
	p-value	0.0069	
	CMH approach		
	Response rate	66.8	55.8
	Difference in response rates (95% CI)	11.01 (2.44, 19.58)	
	p-value	0.0118	
	p-Value for test for heterogenity between studies	0.6154	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Change from baseline in PGA VAS < 0.45 at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8369
< 10 points	57/ 80 (71.3)	70.8	40/ 69 (58.0)	57.4	1.23 (0.97, 1.57)	0.0937	13.39 (-2.05, 28.83)	0.0891	
>= 10 points	109/166 (65.7)	65.2	97/177 (54.8)	55.3	1.19 (1.00, 1.42)	0.0454	9.93 (-0.35, 20.22)	0.0584	
OCS dose at baseline									0.7214
<10 mg/day	77/115 (67.0)	65.9	66/117 (56.4)	56.8	1.17 (0.96, 1.43)	0.1205	9.12 (-3.33, 21.57)	0.1511	
>=10 mg/day	89/131 (67.9)	68.0	71/129 (55.0)	54.8	1.23 (1.01, 1.50)	0.0361	13.21 (1.40, 25.01)	0.0284	
Result of type I IFN gene signature test									0.8808
LOW	33/ 45 (73.3)	73.3	28/ 48 (58.3)	58.2	1.23 (0.92, 1.66)	0.1673	15.09 (-4.20, 34.38)	0.1252	
HIGH	133/201 (66.2)	65.3	109/198 (55.1)	55.2	1.20 (1.02, 1.41)	0.0249	10.05 (0.48, 19.62)	0.0395	
Age (years)									0.0938
<= 65	161/239 (67.4)	66.8	135/243 (55.6)	55.5	1.21 (1.05, 1.40)	0.0088	11.24 (2.57, 19.91)	0.0111	
> 65	5/ 7 (71.4)	70.5	2/ 3 (66.7)	68.2	0.82 (0.53, 1.26)	0.3675	2.27 (-62.51, 67.06)	0.9452	
Sex									0.9786
male	17/ 23 (73.9)	74.9	11/ 20 (55.0)	52.2	1.20 (0.80, 1.80)	0.3873	22.69 (-5.30, 50.68)	0.1121	
female	149/223 (66.8)	66.3	126/226 (55.8)	55.9	1.19 (1.03, 1.38)	0.0207	10.35 (1.37, 19.34)	0.0240	
Race									0.1191
White	113/160 (70.6)	70.5	104/174 (59.8)	59.8	1.18 (1.01, 1.38)	0.0425	10.72 (0.39, 21.05)	0.0420	
Black	18/ 33 (54.5)	53.0	18/ 32 (56.3)	56.4	0.95 (0.60, 1.50)	0.8309	-3.40 (-28.24, 21.44)	0.7885	
Other	30/ 45 (66.7)	66.3	13/ 37 (35.1)	35.1	1.88 (1.15, 3.06)	0.0116	31.26 (10.30, 52.22)	0.0035	
Ethnicity									0.2086
Hispanic/Latino	33/ 50 (66.0)	65.9	25/ 56 (44.6)	44.6	1.47 (1.03, 2.10)	0.0326	21.34 (2.71, 39.98)	0.0248	
Non-hispanic/Latino	128/188 (68.1)	67.7	110/187 (58.8)	58.9	1.15 (0.99, 1.34)	0.0765	8.79 (-1.06, 18.63)	0.0803	
Geographic region									0.1567
EU	70/ 92 (76.1)	76.4	63/ 89 (70.8)	70.4	1.08 (0.91, 1.29)	0.3696	6.00 (-7.19, 19.20)	0.3726	
non-EU	96/154 (62.3)	62.3	74/157 (47.1)	47.1	1.32 (1.07, 1.62)	0.0088	15.14 (4.16, 26.12)	0.0069	
Onset of disease									0.8152
Paediatric	9/ 19 (47.4)	45.7	5/ 12 (41.7)	41.5	1.10 (0.46, 2.60)	0.8292	4.18 (-32.16, 40.53)	0.8215	
Adult	157/227 (69.2)	68.7	132/234 (56.4)	56.5	1.22 (1.06, 1.41)	0.0058	12.20 (3.41, 20.98)	0.0065	
ADA result									0.7733
Negative	154/226 (68.1)	67.3	127/223 (57.0)	57.2	1.20 (1.04, 1.38)	0.0151	10.02 (1.06, 18.98)	0.0285	
Positive (At any time)	12/ 19 (63.2)	61.8	10/ 23 (43.5)	46.9	1.30 (0.74, 2.29)	0.3572	14.91 (-15.87, 45.69)	0.3425	
BMI (kg/m2) at enrolment									0.1592
< 30	112/159 (70.4)	70.6	96/176 (54.5)	54.6	1.29 (1.09, 1.53)	0.0030	16.01 (5.72, 26.30)	0.0023	
>= 30	54/ 87 (62.1)	61.9	41/ 70 (58.6)	59.2	1.04 (0.81, 1.33)	0.7590	2.71 (-12.52, 17.93)	0.7275	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Constitutional
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 52	Number of subjects with events, n (%)	2 (0.8)	2 (0.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.29 (0.18, 9.33)	
	p-value	0.8004	
	Odds Ratio (95% CI)	1.29 (0.18, 9.36)	
	p-value	0.8009	
	Risk Difference (95% CI)	0.20 (-1.39, 1.79)	
	p-value	0.8030	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.96 (0.14, 6.46)	
	p-value	0.9630	
	Odds Ratio (95% CI)	0.96 (0.14, 6.59)	
	p-value	0.9648	
	Risk Difference (95% CI)	0.01 (-1.58, 1.59)	
	p-value	0.9932	
	CMH approach		
	Response rate	0.8	0.7
	Difference in response rates (95% CI)	0.15 (-4.50, 4.81)	
	p-value	0.9481	
	p-Value for test for heterogenity between studies	0.3869	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Constitutional - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE		0.00 (-8.98, 8.98)	1.0000	
>= 10 points	2/166 (1.2)	1.2	2/177 (1.1)	1.0	1.03 (0.15, 6.97)	0.9726	0.25 (-5.08, 5.59)	0.9254	
OCS dose at baseline									0.5012
<10 mg/day	1/115 (0.9)	0.8	2/117 (1.7)	1.5	0.73 (0.08, 6.54)	0.7811	-0.66 (-8.17, 6.84)	0.8621	
>=10 mg/day	1/131 (0.8)	0.7	0/129 (0.0)	0.0	2.76 (0.11, 66.34)	0.5318	0.74 (-4.78, 6.26)	0.7925	
Result of type I IFN gene signature test									0.1498
LOW	2/ 45 (4.4)	4.4	0/ 48 (0.0)	0.0	3.19 (0.34, 29.62)	0.3072	4.45 (-7.34, 16.23)	0.4596	
HIGH	0/201 (0.0)	0.0	2/198 (1.0)	0.9	0.20 (0.01, 4.15)	0.2999	-0.85 (-5.89, 4.19)	0.7398	
Age (years)									NE
<= 65	2/239 (0.8)	0.9	2/243 (0.8)	0.7	0.97 (0.14, 6.55)	0.9745	0.18 (-4.57, 4.93)	0.9416	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-62.98, 62.98)	1.0000	
Sex									NE
male	0/ 23 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-20.84, 20.84)	1.0000	
female	2/223 (0.9)	0.9	2/226 (0.9)	0.8	0.96 (0.14, 6.50)	0.9685	0.17 (-4.89, 5.22)	0.9487	
Race									NE
White	2/160 (1.3)	1.3	2/174 (1.1)	1.2	1.02 (0.15, 6.84)	0.9866	0.14 (-6.01, 6.29)	0.9651	
Black	0/ 33 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-15.38, 15.38)	1.0000	
Other	0/ 45 (0.0)	0.0	0/ 37 (0.0)	0.0	NE		0.00 (-11.98, 11.98)	1.0000	
Ethnicity									0.3694
Hispanic/Latino	1/ 50 (2.0)	1.9	0/ 56 (0.0)	0.0	3.13 (0.13, 73.01)	0.4785	1.94 (-8.04, 11.91)	0.7038	
Non-hispanic/Latino	1/188 (0.5)	0.6	2/187 (1.1)	1.0	0.51 (0.05, 5.54)	0.5816	-0.45 (-5.89, 4.99)	0.8703	
Geographic region									0.1146
EU	0/ 92 (0.0)	0.0	2/ 89 (2.2)	2.6	0.15 (0.01, 2.98)	0.2123	-2.59 (-9.22, 4.04)	0.4441	
non-EU	2/154 (1.3)	1.3	0/157 (0.0)	0.0	3.04 (0.32, 28.89)	0.3336	1.31 (-4.43, 7.05)	0.6539	
Onset of disease									0.2224
Paediatric	0/ 19 (0.0)	0.0	1/ 12 (8.3)	9.6	0.17 (0.01, 3.51)	0.2491	-9.59 (-39.37, 20.20)	0.5281	
Adult	2/227 (0.9)	0.9	1/234 (0.4)	0.4	1.66 (0.21, 13.39)	0.6337	0.52 (-4.37, 5.41)	0.8349	
ADA result									NE
Negative	2/226 (0.9)	0.9	2/223 (0.9)	0.8	0.93 (0.14, 6.30)	0.9430	0.15 (-4.93, 5.22)	0.9549	
Positive (At any time)	0/ 19 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-21.63, 21.63)	1.0000	
BMI (kg/m2) at enrolment									0.4830
< 30	1/159 (0.6)	0.5	2/176 (1.1)	1.1	0.52 (0.05, 5.67)	0.5944	-0.60 (-5.95, 4.75)	0.8270	
>= 30	1/ 87 (1.1)	1.1	0/ 70 (0.0)	0.0	2.17 (0.09, 51.79)	0.6330	1.06 (-7.80, 9.92)	0.8146	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Mucocutaneous
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 52	Number of subjects with events, n (%)	64 (26.0)	83 (33.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.79 (0.60, 1.04)	
	p-value	0.0866	
	Odds Ratio (95% CI)	0.71 (0.48, 1.05)	
	p-value	0.0849	
	Risk Difference (95% CI)	-7.14 (-15.23, 0.95)	
	p-value	0.0835	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.77 (0.59, 1.02)	
	p-value	0.0674	
	Odds Ratio (95% CI)	0.69 (0.47, 1.02)	
	p-value	0.0641	
	Risk Difference (95% CI)	-7.73 (-15.81, 0.35)	
	p-value	0.0607	
	CMH approach		
	Response rate	26.0	33.4
	Difference in response rates (95% CI)	-7.43 (-15.66, 0.81)	
	p-value	0.0770	
	p-Value for test for heterogenity between studies	0.1816	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Mucocutaneous - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8556
< 10 points	18/ 80 (22.5)	22.4	19/ 69 (27.5)	27.0	0.82 (0.46, 1.45)	0.4911	-4.54 (-19.10, 10.02)	0.5411	
>= 10 points	46/166 (27.7)	27.8	64/177 (36.2)	36.2	0.77 (0.56, 1.05)	0.1036	-8.33 (-18.22, 1.56)	0.0989	
OCS dose at baseline									0.6491
<10 mg/day	31/115 (27.0)	26.7	38/117 (32.5)	32.2	0.83 (0.56, 1.24)	0.3617	-5.52 (-17.58, 6.55)	0.3702	
>=10 mg/day	33/131 (25.2)	25.6	45/129 (34.9)	34.4	0.73 (0.50, 1.08)	0.1115	-8.79 (-19.98, 2.41)	0.1240	
Result of type I IFN gene signature test									0.1470
LOW	16/ 45 (35.6)	35.6	15/ 48 (31.3)	31.2	1.14 (0.64, 2.02)	0.6602	4.34 (-15.15, 23.82)	0.6626	
HIGH	48/201 (23.9)	23.8	68/198 (34.3)	34.0	0.70 (0.51, 0.96)	0.0267	-10.20 (-19.28, -1.11)	0.0278	
Age (years)									0.7287
<= 65	62/239 (25.9)	26.1	82/243 (33.7)	33.5	0.77 (0.58, 1.02)	0.0672	-7.43 (-15.75, 0.90)	0.0804	
> 65	2/ 7 (28.6)	29.5	1/ 3 (33.3)	31.8	0.61 (0.18, 2.14)	0.4447	-2.27 (-67.06, 62.51)	0.9452	
Sex									0.5957
male	4/ 23 (17.4)	19.8	10/ 20 (50.0)	51.2	0.63 (0.24, 1.66)	0.3546	-31.35 (-59.58, -3.12)	0.0295	
female	60/223 (26.9)	27.0	73/226 (32.3)	32.0	0.83 (0.62, 1.11)	0.2125	-5.02 (-13.66, 3.62)	0.2546	
Race									0.5175
White	50/160 (31.3)	31.0	61/174 (35.1)	34.8	0.89 (0.66, 1.22)	0.4788	-3.81 (-14.01, 6.38)	0.4636	
Black	3/ 33 (9.1)	10.6	7/ 32 (21.9)	21.8	0.52 (0.15, 1.82)	0.3074	-11.18 (-32.24, 9.87)	0.2979	
Other	11/ 45 (24.4)	24.4	14/ 37 (37.8)	37.9	0.64 (0.33, 1.24)	0.1904	-13.48 (-34.03, 7.08)	0.1987	
Ethnicity									0.9274
Hispanic/Latino	12/ 50 (24.0)	23.8	16/ 56 (28.6)	28.8	0.82 (0.44, 1.55)	0.5512	-5.01 (-22.18, 12.17)	0.5678	
Non-hispanic/Latino	52/188 (27.7)	27.8	66/187 (35.3)	35.0	0.80 (0.59, 1.08)	0.1460	-7.23 (-16.77, 2.31)	0.1373	
Geographic region									0.9719
EU	24/ 92 (26.1)	26.0	30/ 89 (33.7)	32.9	0.79 (0.49, 1.26)	0.3170	-6.85 (-20.30, 6.61)	0.3187	
non-EU	40/154 (26.0)	25.9	53/157 (33.8)	33.6	0.78 (0.55, 1.10)	0.1561	-7.72 (-18.08, 2.64)	0.1440	
Onset of disease									0.4767
Paediatric	4/ 19 (21.1)	19.6	5/ 12 (41.7)	41.5	0.51 (0.16, 1.66)	0.2642	-21.91 (-56.94, 13.12)	0.2203	
Adult	60/227 (26.4)	26.3	78/234 (33.3)	33.0	0.79 (0.60, 1.05)	0.1112	-6.73 (-15.22, 1.76)	0.1201	
ADA result									0.5761
Negative	59/226 (26.1)	26.1	77/223 (34.5)	34.2	0.76 (0.57, 1.01)	0.0601	-8.15 (-16.83, 0.52)	0.0653	
Positive (At any time)	5/ 19 (26.3)	26.2	6/ 23 (26.1)	25.1	1.04 (0.35, 3.08)	0.9370	1.09 (-28.10, 30.28)	0.9416	
BMI (kg/m2) at enrolment									0.2223
< 30	36/159 (22.6)	22.6	60/176 (34.1)	33.9	0.68 (0.48, 0.98)	0.0396	-11.34 (-21.10, -1.58)	0.0228	
>= 30	28/ 87 (32.2)	32.1	23/ 70 (32.9)	32.8	0.98 (0.62, 1.55)	0.9372	-0.71 (-15.78, 14.36)	0.9263	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Neuropsychiatric
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 52	Number of subjects with events, n (%)	3 (1.2)	0 (0.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	NE	
	p-value		
	Odds Ratio (95% CI)	NE	
	p-value		
	Risk Difference (95% CI)	1.15 (-0.20, 2.49)	
	p-value	0.0940	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	6.89 (0.36, 132.04)	
	p-value	0.2002	
	Odds Ratio (95% CI)	7.06 (0.36, 138.03)	
	p-value	0.1978	
	Risk Difference (95% CI)	1.21 (-0.16, 2.58)	
	p-value	0.0826	
	CMH approach		
	Response rate	1.2	0.0
	Difference in response rates (95% CI)	1.24 (-3.39, 5.88)	
	p-value	0.5989	
	p-Value for test for heterogenity between studies	NE	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Neuropsychiatric - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE		0.00 (-8.98, 8.98)	1.0000	
>= 10 points	3/166 (1.8)	1.7	0/177 (0.0)	0.0	7.00 (0.37, 133.55)	0.1958	1.74 (-3.57, 7.05)	0.5212	
OCS dose at baseline									0.8653
<10 mg/day	2/115 (1.7)	1.6	0/117 (0.0)	0.0	4.57 (0.22, 93.01)	0.3231	1.64 (-5.78, 9.06)	0.6651	
>=10 mg/day	1/131 (0.8)	0.8	0/129 (0.0)	0.0	3.13 (0.13, 75.49)	0.4828	0.80 (-4.74, 6.34)	0.7773	
Result of type I IFN gene signature test									0.8614
LOW	1/ 45 (2.2)	2.2	0/ 48 (0.0)	0.0	3.26 (0.14, 76.10)	0.4621	2.25 (-8.98, 13.47)	0.6948	
HIGH	2/201 (1.0)	1.0	0/198 (0.0)	0.0	4.81 (0.23, 99.00)	0.3086	1.01 (-4.08, 6.09)	0.6973	
Age (years)									NE
<= 65	3/239 (1.3)	1.3	0/243 (0.0)	0.0	7.06 (0.37, 135.19)	0.1946	1.31 (-3.42, 6.04)	0.5877	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-62.98, 62.98)	1.0000	
Sex									NE
male	0/ 23 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-20.84, 20.84)	1.0000	
female	3/223 (1.3)	1.4	0/226 (0.0)	0.0	7.12 (0.37, 136.33)	0.1925	1.39 (-3.65, 6.42)	0.5893	
Race									0.6843
White	2/160 (1.3)	1.2	0/174 (0.0)	0.0	5.64 (0.27, 115.85)	0.2620	1.20 (-4.76, 7.16)	0.6932	
Black	0/ 33 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-15.38, 15.38)	1.0000	
Other	1/ 45 (2.2)	2.1	0/ 37 (0.0)	0.0	2.29 (0.10, 52.48)	0.6051	2.11 (-10.33, 14.56)	0.7392	
Ethnicity									0.8431
Hispanic/Latino	1/ 50 (2.0)	1.9	0/ 56 (0.0)	0.0	3.13 (0.13, 73.01)	0.4785	1.94 (-8.04, 11.91)	0.7038	
Non-hispanic/Latino	2/188 (1.1)	1.0	0/187 (0.0)	0.0	4.86 (0.24, 99.94)	0.3057	1.04 (-4.31, 6.39)	0.7029	
Geographic region									0.9312
EU	1/ 92 (1.1)	1.2	0/ 89 (0.0)	0.0	3.56 (0.15, 85.45)	0.4332	1.22 (-5.03, 7.47)	0.7022	
non-EU	2/154 (1.3)	1.2	0/157 (0.0)	0.0	4.32 (0.21, 88.50)	0.3421	1.17 (-4.55, 6.90)	0.6880	
Onset of disease									NE
Paediatric	0/ 19 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-28.28, 28.28)	1.0000	
Adult	3/227 (1.3)	1.3	0/234 (0.0)	0.0	6.94 (0.36, 132.94)	0.1983	1.33 (-3.58, 6.24)	0.5955	
ADA result									NE
Negative	3/226 (1.3)	1.4	0/223 (0.0)	0.0	7.06 (0.37, 135.16)	0.1943	1.39 (-3.66, 6.45)	0.5891	
Positive (At any time)	0/ 19 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-21.63, 21.63)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/159 (0.0)	0.0	0/176 (0.0)	0.0	NE		0.00 (-5.09, 5.09)	1.0000	
>= 30	3/ 87 (3.4)	3.1	0/ 70 (0.0)	0.0	5.06 (0.27, 95.10)	0.2791	3.13 (-6.04, 12.31)	0.5030	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Musculoskeletal
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 52	Number of subjects with events, n (%)	47 (19.1)	44 (17.9)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.08 (0.74, 1.57)	
	p-value	0.6923	
	Odds Ratio (95% CI)	1.10 (0.69, 1.74)	
	p-value	0.6913	
	Risk Difference (95% CI)	1.40 (-5.51, 8.31)	
	p-value	0.6912	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.07 (0.74, 1.55)	
	p-value	0.7287	
	Odds Ratio (95% CI)	1.08 (0.69, 1.71)	
	p-value	0.7283	
	Risk Difference (95% CI)	1.22 (-5.64, 8.08)	
	p-value	0.7281	
	CMH approach		
	Response rate	19.2	17.8
	Difference in response rates (95% CI)	1.34 (-5.97, 8.65)	
	p-value	0.7198	
	p-Value for test for heterogenity between studies	0.8309	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Musculoskeletal - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.4444
< 10 points	15/ 80 (18.8)	18.8	15/ 69 (21.7)	21.0	0.87 (0.46, 1.64)	0.6614	-2.22 (-16.03, 11.60)	0.7532	
>= 10 points	32/166 (19.3)	19.3	29/177 (16.4)	16.4	1.18 (0.75, 1.86)	0.4822	2.92 (-5.65, 11.50)	0.5039	
OCS dose at baseline									0.7098
<10 mg/day	27/115 (23.5)	23.1	24/117 (20.5)	20.4	1.14 (0.69, 1.87)	0.6085	2.75 (-8.44, 13.94)	0.6300	
>=10 mg/day	20/131 (15.3)	15.3	20/129 (15.5)	15.4	0.98 (0.54, 1.78)	0.9549	-0.10 (-9.50, 9.31)	0.9841	
Result of type I IFN gene signature test									0.0661
LOW	14/ 45 (31.1)	31.2	7/ 48 (14.6)	14.5	2.07 (0.92, 4.63)	0.0770	16.65 (-1.05, 34.36)	0.0652	
HIGH	33/201 (16.4)	16.4	37/198 (18.7)	18.6	0.88 (0.57, 1.35)	0.5573	-2.26 (-10.27, 5.75)	0.5799	
Age (years)									0.8164
<= 65	46/239 (19.2)	19.4	44/243 (18.1)	18.1	1.06 (0.73, 1.54)	0.7489	1.34 (-6.08, 8.76)	0.7233	
> 65	1/ 7 (14.3)	13.6	0/ 3 (0.0)	0.0	1.50 (0.08, 26.86)	0.7830	13.64 (-50.73, 78.01)	0.6780	
Sex									0.9109
male	2/ 23 (8.7)	7.6	1/ 20 (5.0)	4.5	1.20 (0.14, 10.04)	0.8666	3.05 (-19.91, 26.01)	0.7944	
female	45/223 (20.2)	20.2	43/226 (19.0)	19.0	1.06 (0.73, 1.54)	0.7585	1.27 (-6.52, 9.07)	0.7484	
Race									0.0927
White	36/160 (22.5)	22.5	28/174 (16.1)	16.1	1.40 (0.90, 2.18)	0.1407	6.39 (-2.80, 15.58)	0.1731	
Black	3/ 33 (9.1)	9.1	7/ 32 (21.9)	21.8	0.42 (0.11, 1.52)	0.1859	-12.69 (-33.52, 8.14)	0.2325	
Other	7/ 45 (15.6)	15.6	9/ 37 (24.3)	24.6	0.63 (0.26, 1.54)	0.3105	-9.01 (-27.73, 9.71)	0.3455	
Ethnicity									0.3093
Hispanic/Latino	7/ 50 (14.0)	14.0	11/ 56 (19.6)	19.7	0.71 (0.30, 1.70)	0.4461	-5.65 (-21.20, 9.89)	0.4762	
Non-hispanic/Latino	39/188 (20.7)	21.0	33/187 (17.6)	18.0	1.18 (0.77, 1.78)	0.4464	3.03 (-5.45, 11.51)	0.4842	
Geographic region									0.3447
EU	14/ 92 (15.2)	15.2	9/ 89 (10.1)	9.8	1.49 (0.66, 3.38)	0.3359	5.43 (-5.13, 15.99)	0.3140	
non-EU	33/154 (21.4)	21.5	35/157 (22.3)	22.6	0.96 (0.63, 1.46)	0.8451	-1.10 (-10.72, 8.52)	0.8233	
Onset of disease									0.7777
Paediatric	3/ 19 (15.8)	15.2	1/ 12 (8.3)	7.4	1.40 (0.20, 9.53)	0.7324	7.79 (-23.86, 39.43)	0.6296	
Adult	44/227 (19.4)	19.3	43/234 (18.4)	18.4	1.05 (0.72, 1.54)	0.7834	0.87 (-6.73, 8.48)	0.8218	
ADA result									0.3204
Negative	43/226 (19.0)	19.1	38/223 (17.0)	16.9	1.11 (0.75, 1.65)	0.5948	2.10 (-5.55, 9.76)	0.5899	
Positive (At any time)	4/ 19 (21.1)	21.5	6/ 23 (26.1)	32.7	0.62 (0.21, 1.84)	0.3876	-11.27 (-40.43, 17.88)	0.4486	
BMI (kg/m2) at enrolment									0.5248
< 30	28/159 (17.6)	17.2	27/176 (15.3)	15.1	1.15 (0.71, 1.86)	0.5794	2.06 (-6.43, 10.54)	0.6351	
>= 30	19/ 87 (21.8)	21.7	17/ 70 (24.3)	24.1	0.90 (0.50, 1.60)	0.7152	-2.48 (-16.32, 11.36)	0.7257	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Cardiorespiratory
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 52	Number of subjects with events, n (%)	4 (1.6)	0 (0.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	NE	
	p-value		
	Odds Ratio (95% CI)	NE	
	p-value		
	Risk Difference (95% CI)	1.71 (0.08, 3.34)	
	p-value	0.0403	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	4.73 (0.54, 41.32)	
	p-value	0.1599	
	Odds Ratio (95% CI)	4.81 (0.54, 42.61)	
	p-value	0.1583	
	Risk Difference (95% CI)	1.62 (0.04, 3.20)	
	p-value	0.0442	
	CMH approach		
	Response rate	1.7	0.0
	Difference in response rates (95% CI)	1.72 (-2.97, 6.41)	
	p-value	0.4717	
	p-Value for test for heterogenity between studies	0.7133	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Cardiorespiratory - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE		0.00 (-8.98, 8.98)	1.0000	
>= 10 points	4/166 (2.4)	2.4	0/177 (0.0)	0.0	5.03 (0.58, 43.79)	0.1435	2.38 (-3.01, 7.77)	0.3863	
OCS dose at baseline									0.9058
<10 mg/day	3/115 (2.6)	2.6	0/117 (0.0)	0.0	3.95 (0.44, 35.20)	0.2186	2.65 (-4.97, 10.26)	0.4958	
>=10 mg/day	1/131 (0.8)	0.9	0/129 (0.0)	0.0	3.13 (0.13, 75.49)	0.4828	0.93 (-4.54, 6.40)	0.7393	
Result of type I IFN gene signature test									0.7498
LOW	2/ 45 (4.4)	4.5	0/ 48 (0.0)	0.0	5.43 (0.28, 107.33)	0.2660	4.49 (-7.25, 16.24)	0.4533	
HIGH	2/201 (1.0)	1.1	0/198 (0.0)	0.0	2.96 (0.31, 28.20)	0.3458	1.07 (-4.02, 6.17)	0.6801	
Age (years)									NE
<= 65	4/239 (1.7)	1.8	0/243 (0.0)	0.0	4.81 (0.55, 42.02)	0.1554	1.81 (-2.97, 6.60)	0.4577	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-62.98, 62.98)	1.0000	
Sex									NE
male	0/ 23 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-20.84, 20.84)	1.0000	
female	4/223 (1.8)	1.9	0/226 (0.0)	0.0	4.80 (0.55, 41.89)	0.1559	1.90 (-3.19, 6.98)	0.4647	
Race									NE
White	4/160 (2.5)	2.4	0/174 (0.0)	0.0	5.14 (0.59, 44.76)	0.1380	2.44 (-3.69, 8.57)	0.4350	
Black	0/ 33 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-15.38, 15.38)	1.0000	
Other	0/ 45 (0.0)	0.0	0/ 37 (0.0)	0.0	NE		0.00 (-11.98, 11.98)	1.0000	
Ethnicity									0.9091
Hispanic/Latino	1/ 50 (2.0)	1.9	0/ 56 (0.0)	0.0	3.13 (0.13, 73.01)	0.4785	1.94 (-8.04, 11.91)	0.7038	
Non-hispanic/Latino	3/188 (1.6)	1.8	0/187 (0.0)	0.0	3.91 (0.44, 35.05)	0.2232	1.75 (-3.71, 7.21)	0.5295	
Geographic region									0.8225
EU	2/ 92 (2.2)	2.2	0/ 89 (0.0)	0.0	2.81 (0.30, 26.49)	0.3670	2.17 (-4.31, 8.64)	0.5116	
non-EU	2/154 (1.3)	1.2	0/157 (0.0)	0.0	4.32 (0.21, 88.50)	0.3421	1.17 (-4.55, 6.90)	0.6880	
Onset of disease									NE
Paediatric	0/ 19 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-28.28, 28.28)	1.0000	
Adult	4/227 (1.8)	1.8	0/234 (0.0)	0.0	4.87 (0.56, 42.52)	0.1521	1.81 (-3.15, 6.77)	0.4743	
ADA result									NE
Negative	4/226 (1.8)	1.9	0/223 (0.0)	0.0	4.68 (0.54, 40.86)	0.1626	1.88 (-3.22, 6.99)	0.4699	
Positive (At any time)	0/ 19 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-21.63, 21.63)	1.0000	
BMI (kg/m2) at enrolment									0.7220
< 30	3/159 (1.9)	2.0	0/176 (0.0)	0.0	4.36 (0.49, 39.09)	0.1878	2.04 (-3.38, 7.47)	0.4606	
>= 30	1/ 87 (1.1)	1.1	0/ 70 (0.0)	0.0	2.17 (0.09, 51.79)	0.6330	1.06 (-7.80, 9.92)	0.8146	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Gastrointestinal
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 52	Number of subjects with events, n (%)	0 (0.0)	2 (0.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.00 (NE, NE)	
	p-value	NE	
	Odds Ratio (95% CI)	0.00 (NE, NE)	
	p-value	NE	
	Risk Difference (95% CI)	-0.81 (-1.95, 0.32)	
	p-value	0.1592	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.33 (0.03, 3.18)	
	p-value	0.3401	
	Odds Ratio (95% CI)	0.33 (0.03, 3.20)	
	p-value	0.3395	
	Risk Difference (95% CI)	-0.81 (-1.94, 0.31)	
	p-value	0.1556	
	CMH approach		
	Response rate	0.0	0.8
	Difference in response rates (95% CI)	-0.81 (-5.38, 3.76)	
	p-value	0.7295	
	p-Value for test for heterogenity between studies	0.9888	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Gastrointestinal - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9162
< 10 points	0/ 80 (0.0)	0.0	1/ 69 (1.4)	1.4	0.26 (0.01, 6.22)	0.4072	-1.36 (-10.55, 7.83)	0.7718	
>= 10 points	0/166 (0.0)	0.0	1/177 (0.6)	0.6	0.33 (0.01, 8.07)	0.4993	-0.57 (-5.71, 4.58)	0.8286	
OCS dose at baseline									0.9754
<10 mg/day	0/115 (0.0)	0.0	1/117 (0.9)	0.9	0.37 (0.02, 8.98)	0.5433	-0.87 (-8.17, 6.43)	0.8154	
>=10 mg/day	0/131 (0.0)	0.0	1/129 (0.8)	0.7	0.35 (0.01, 8.39)	0.5152	-0.75 (-6.27, 4.77)	0.7901	
Result of type I IFN gene signature test									NE
LOW	0/ 45 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-10.61, 10.61)	1.0000	
HIGH	0/201 (0.0)	0.0	2/198 (1.0)	1.0	0.33 (0.03, 3.13)	0.3334	-1.00 (-6.06, 4.07)	0.6998	
Age (years)									NE
<= 65	0/239 (0.0)	0.0	2/243 (0.8)	0.8	0.34 (0.04, 3.24)	0.3472	-0.82 (-5.48, 3.83)	0.7289	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-62.98, 62.98)	1.0000	
Sex									NE
male	0/ 23 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-20.84, 20.84)	1.0000	
female	0/223 (0.0)	0.0	2/226 (0.9)	0.9	0.34 (0.04, 3.22)	0.3456	-0.85 (-5.80, 4.10)	0.7356	
Race									0.8815
White	0/160 (0.0)	0.0	1/174 (0.6)	0.5	0.38 (0.02, 9.11)	0.5475	-0.51 (-6.38, 5.36)	0.8657	
Black	0/ 33 (0.0)	0.0	1/ 32 (3.1)	2.5	0.53 (0.02, 11.93)	0.6879	-2.47 (-18.31, 13.38)	0.7604	
Other	0/ 45 (0.0)	0.0	0/ 37 (0.0)	0.0	NE		0.00 (-11.98, 11.98)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 50 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-9.46, 9.46)	1.0000	
Non-hispanic/Latino	0/188 (0.0)	0.0	2/187 (1.1)	1.1	0.33 (0.03, 3.17)	0.3382	-1.12 (-6.49, 4.25)	0.6827	
Geographic region									0.9998
EU	0/ 92 (0.0)	0.0	1/ 89 (1.1)	1.0	0.40 (0.02, 9.49)	0.5676	-1.02 (-7.17, 5.12)	0.7441	
non-EU	0/154 (0.0)	0.0	1/157 (0.6)	0.7	0.40 (0.02, 9.57)	0.5683	-0.72 (-6.39, 4.94)	0.8022	
Onset of disease									NE
Paediatric	0/ 19 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-28.28, 28.28)	1.0000	
Adult	0/227 (0.0)	0.0	2/234 (0.9)	0.9	0.34 (0.04, 3.28)	0.3537	-0.85 (-5.69, 3.98)	0.7296	
ADA result									NE
Negative	0/226 (0.0)	0.0	2/223 (0.9)	0.9	0.33 (0.03, 3.14)	0.3341	-0.86 (-5.83, 4.11)	0.7340	
Positive (At any time)	0/ 19 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-21.63, 21.63)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/159 (0.0)	0.0	2/176 (1.1)	1.1	0.37 (0.04, 3.52)	0.3863	-1.14 (-6.40, 4.13)	0.6719	
>= 30	0/ 87 (0.0)	0.0	0/ 70 (0.0)	0.0	NE		0.00 (-8.73, 8.73)	1.0000	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Ophthalmic
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 52	Number of subjects with events, n (%)	0 (0.0)	1 (0.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.00 (NE, NE)	
	p-value	NE	
	Odds Ratio (95% CI)	0.00 (NE, NE)	
	p-value	NE	
	Risk Difference (95% CI)	-0.35 (-1.09, 0.39)	
	p-value	0.3579	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.34 (0.01, 8.24)	
	p-value	0.5062	
	Odds Ratio (95% CI)	0.34 (0.01, 8.33)	
	p-value	0.5057	
	Risk Difference (95% CI)	-0.40 (-1.20, 0.39)	
	p-value	0.3184	
	CMH approach		
	Response rate	0.0	0.3
	Difference in response rates (95% CI)	-0.35 (-4.86, 4.17)	
	p-value	0.8807	
	p-Value for test for heterogenity between studies	NE	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Ophthalmic - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE		0.00 (-8.98, 8.98)	1.0000	
>= 10 points	0/166 (0.0)	0.0	1/177 (0.6)	0.5	0.38 (0.02, 9.19)	0.5514	-0.50 (-5.61, 4.62)	0.8494	
OCS dose at baseline									NE
<10 mg/day	0/115 (0.0)	0.0	1/117 (0.9)	0.7	0.37 (0.02, 8.98)	0.5433	-0.73 (-8.04, 6.57)	0.8439	
>=10 mg/day	0/131 (0.0)	0.0	0/129 (0.0)	0.0	NE		0.00 (-5.35, 5.35)	1.0000	
Result of type I IFN gene signature test									NE
LOW	0/ 45 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-10.61, 10.61)	1.0000	
HIGH	0/201 (0.0)	0.0	1/198 (0.5)	0.4	0.34 (0.01, 8.17)	0.5035	-0.43 (-5.42, 4.56)	0.8668	
Age (years)									NE
<= 65	0/239 (0.0)	0.0	1/243 (0.4)	0.4	0.34 (0.01, 8.31)	0.5096	-0.36 (-4.96, 4.24)	0.8786	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-62.98, 62.98)	1.0000	
Sex									NE
male	0/ 23 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-20.84, 20.84)	1.0000	
female	0/223 (0.0)	0.0	1/226 (0.4)	0.4	0.34 (0.01, 8.17)	0.5032	-0.39 (-5.29, 4.51)	0.8755	
Race									NE
White	0/160 (0.0)	0.0	1/174 (0.6)	0.6	0.35 (0.01, 8.37)	0.5143	-0.58 (-6.47, 5.31)	0.8471	
Black	0/ 33 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-15.38, 15.38)	1.0000	
Other	0/ 45 (0.0)	0.0	0/ 37 (0.0)	0.0	NE		0.00 (-11.98, 11.98)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 50 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-9.46, 9.46)	1.0000	
Non-hispanic/Latino	0/188 (0.0)	0.0	1/187 (0.5)	0.5	0.34 (0.01, 8.26)	0.5084	-0.51 (-5.81, 4.78)	0.8494	
Geographic region									NE
EU	0/ 92 (0.0)	0.0	1/ 89 (1.1)	1.3	0.25 (0.01, 5.86)	0.3864	-1.29 (-7.56, 4.97)	0.6857	
non-EU	0/154 (0.0)	0.0	0/157 (0.0)	0.0	NE		0.00 (-5.56, 5.56)	1.0000	
Onset of disease									NE
Paediatric	0/ 19 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-28.28, 28.28)	1.0000	
Adult	0/227 (0.0)	0.0	1/234 (0.4)	0.4	0.36 (0.01, 8.69)	0.5277	-0.37 (-5.15, 4.41)	0.8787	
ADA result									NE
Negative	0/226 (0.0)	0.0	1/223 (0.4)	0.4	0.32 (0.01, 7.82)	0.4861	-0.39 (-5.31, 4.53)	0.8757	
Positive (At any time)	0/ 19 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-21.63, 21.63)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/159 (0.0)	0.0	1/176 (0.6)	0.6	0.35 (0.01, 8.45)	0.5172	-0.57 (-5.76, 4.62)	0.8300	
>= 30	0/ 87 (0.0)	0.0	0/ 70 (0.0)	0.0	NE		0.00 (-8.73, 8.73)	1.0000	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Renal
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 52	Number of subjects with events, n (%)	9 (3.7)	14 (5.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.68 (0.30, 1.52)	
	p-value	0.3460	
	Odds Ratio (95% CI)	0.65 (0.27, 1.58)	
	p-value	0.3423	
	Risk Difference (95% CI)	-1.79 (-5.46, 1.88)	
	p-value	0.3389	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.64 (0.28, 1.46)	
	p-value	0.2917	
	Odds Ratio (95% CI)	0.63 (0.27, 1.49)	
	p-value	0.2907	
	Risk Difference (95% CI)	-2.03 (-5.76, 1.69)	
	p-value	0.2846	
	CMH approach		
	Response rate	3.7	5.5
	Difference in response rates (95% CI)	-1.77 (-7.32, 3.77)	
	p-value	0.5302	
	p-Value for test for heterogenity between studies	0.8202	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Renal - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE		0.00 (-8.98, 8.98)	1.0000	
>= 10 points	9/166 (5.4)	5.4	14/177 (7.9)	7.9	0.68 (0.30, 1.54)	0.3601	-2.54 (-9.43, 4.34)	0.4688	
OCS dose at baseline									0.8973
<10 mg/day	2/115 (1.7)	1.8	3/117 (2.6)	2.2	0.72 (0.12, 4.50)	0.7274	-0.36 (-8.18, 7.46)	0.9282	
>=10 mg/day	7/131 (5.3)	5.4	11/129 (8.5)	8.5	0.63 (0.25, 1.58)	0.3259	-3.05 (-10.84, 4.73)	0.4419	
Result of type I IFN gene signature test									NE
LOW	0/ 45 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-10.61, 10.61)	1.0000	
HIGH	9/201 (4.5)	4.6	14/198 (7.1)	6.8	0.63 (0.28, 1.43)	0.2728	-2.19 (-8.56, 4.18)	0.5002	
Age (years)									NE
<= 65	9/239 (3.8)	3.8	14/243 (5.8)	5.6	0.65 (0.29, 1.48)	0.3104	-1.78 (-7.44, 3.87)	0.5366	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-62.98, 62.98)	1.0000	
Sex									0.5840
male	1/ 23 (4.3)	3.8	3/ 20 (15.0)	14.8	0.40 (0.06, 2.86)	0.3644	-10.97 (-35.17, 13.23)	0.3741	
female	8/223 (3.6)	3.6	11/226 (4.9)	4.8	0.74 (0.30, 1.80)	0.5038	-1.19 (-7.03, 4.65)	0.6906	
Race									0.5478
White	4/160 (2.5)	2.8	8/174 (4.6)	4.3	0.58 (0.17, 1.97)	0.3864	-1.58 (-8.33, 5.16)	0.6456	
Black	2/ 33 (6.1)	5.1	0/ 32 (0.0)	0.0	3.26 (0.17, 63.30)	0.4347	5.06 (-11.33, 21.44)	0.5452	
Other	3/ 45 (6.7)	6.9	6/ 37 (16.2)	16.3	0.57 (0.15, 2.14)	0.4013	-9.40 (-26.09, 7.29)	0.2695	
Ethnicity									0.9438
Hispanic/Latino	3/ 50 (6.0)	6.2	6/ 56 (10.7)	10.8	0.76 (0.20, 2.92)	0.6905	-4.60 (-17.74, 8.54)	0.4927	
Non-hispanic/Latino	6/188 (3.2)	3.3	8/187 (4.3)	4.1	0.81 (0.27, 2.45)	0.7092	-0.75 (-6.96, 5.45)	0.8123	
Geographic region									0.9973
EU	3/ 92 (3.3)	3.7	5/ 89 (5.6)	5.4	0.72 (0.19, 2.67)	0.6183	-1.73 (-9.85, 6.39)	0.6763	
non-EU	6/154 (3.9)	4.2	9/157 (5.7)	5.5	0.71 (0.26, 1.95)	0.5114	-1.28 (-8.28, 5.73)	0.7212	
Onset of disease									0.4684
Paediatric	4/ 19 (21.1)	21.7	3/ 12 (25.0)	24.5	0.89 (0.24, 3.33)	0.8600	-2.73 (-37.12, 31.66)	0.8763	
Adult	5/227 (2.2)	2.3	11/234 (4.7)	4.5	0.48 (0.17, 1.36)	0.1651	-2.23 (-7.76, 3.30)	0.4295	
ADA result									0.6448
Negative	7/226 (3.1)	3.1	11/223 (4.9)	4.6	0.63 (0.25, 1.61)	0.3355	-1.50 (-7.27, 4.27)	0.6107	
Positive (At any time)	2/ 19 (10.5)	9.5	3/ 23 (13.0)	11.3	1.01 (0.17, 6.01)	0.9882	-1.82 (-27.29, 23.65)	0.8887	
BMI (kg/m2) at enrolment									0.8357
< 30	5/159 (3.1)	3.2	8/176 (4.5)	4.4	0.72 (0.22, 2.34)	0.5890	-1.22 (-7.54, 5.09)	0.7040	
>= 30	4/ 87 (4.6)	4.4	6/ 70 (8.6)	8.2	0.59 (0.13, 2.71)	0.4981	-3.86 (-14.70, 6.97)	0.4843	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Haematological
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 52	Number of subjects with events, n (%)	2 (0.8)	0 (0.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	NE	
	p-value		
	Odds Ratio (95% CI)	NE	
	p-value		
	Risk Difference (95% CI)	0.81 (-0.32, 1.94)	
	p-value	0.1588	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	3.00 (0.31, 28.65)	
	p-value	0.3397	
	Odds Ratio (95% CI)	3.03 (0.31, 29.29)	
	p-value	0.3391	
	Risk Difference (95% CI)	0.81 (-0.31, 1.94)	
	p-value	0.1556	
	CMH approach		
	Response rate	0.8	0.0
	Difference in response rates (95% CI)	0.81 (-3.75, 5.36)	
	p-value	0.7286	
	p-Value for test for heterogenity between studies	0.9888	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score A or B at week 52 - Haematological - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	2/ 80 (2.5)	2.7	0/ 69 (0.0)	0.0	2.59 (0.28, 24.36)	0.4048	2.68 (-6.79, 12.16)	0.5789	
>= 10 points	0/166 (0.0)	0.0	0/177 (0.0)	0.0	NE		0.00 (-5.04, 5.04)	1.0000	
OCS dose at baseline									NE
<10 mg/day	2/115 (1.7)	1.7	0/117 (0.0)	0.0	3.03 (0.32, 28.74)	0.3335	1.71 (-5.70, 9.13)	0.6509	
>=10 mg/day	0/131 (0.0)	0.0	0/129 (0.0)	0.0	NE		0.00 (-5.35, 5.35)	1.0000	
Result of type I IFN gene signature test									NE
LOW	0/ 45 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-10.61, 10.61)	1.0000	
HIGH	2/201 (1.0)	1.0	0/198 (0.0)	0.0	2.96 (0.31, 28.20)	0.3458	1.00 (-4.05, 6.04)	0.6986	
Age (years)									NE
<= 65	2/239 (0.8)	0.8	0/243 (0.0)	0.0	3.05 (0.32, 29.12)	0.3326	0.82 (-3.82, 5.47)	0.7280	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-62.98, 62.98)	1.0000	
Sex									NE
male	0/ 23 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-20.84, 20.84)	1.0000	
female	2/223 (0.9)	0.9	0/226 (0.0)	0.0	3.04 (0.32, 29.00)	0.3340	0.90 (-4.04, 5.84)	0.7210	
Race									0.8815
White	1/160 (0.6)	0.6	0/174 (0.0)	0.0	3.38 (0.14, 81.97)	0.4535	0.55 (-5.30, 6.41)	0.8533	
Black	1/ 33 (3.0)	4.0	0/ 32 (0.0)	0.0	4.75 (0.21, 107.35)	0.3274	4.03 (-12.30, 20.37)	0.6284	
Other	0/ 45 (0.0)	0.0	0/ 37 (0.0)	0.0	NE		0.00 (-11.98, 11.98)	1.0000	
Ethnicity									0.9939
Hispanic/Latino	1/ 50 (2.0)	1.9	0/ 56 (0.0)	0.0	3.13 (0.13, 73.01)	0.4785	1.94 (-8.04, 11.91)	0.7038	
Non-hispanic/Latino	1/188 (0.5)	0.5	0/187 (0.0)	0.0	3.07 (0.13, 74.33)	0.4902	0.46 (-4.80, 5.73)	0.8634	
Geographic region									NE
EU	0/ 92 (0.0)	0.0	0/ 89 (0.0)	0.0	NE		0.00 (-5.86, 5.86)	1.0000	
non-EU	2/154 (1.3)	1.2	0/157 (0.0)	0.0	3.04 (0.32, 28.89)	0.3336	1.23 (-4.50, 6.96)	0.6737	
Onset of disease									NE
Paediatric	0/ 19 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-28.28, 28.28)	1.0000	
Adult	2/227 (0.9)	0.8	0/234 (0.0)	0.0	3.10 (0.32, 29.54)	0.3263	0.84 (-3.97, 5.66)	0.7313	
ADA result									NE
Negative	2/226 (0.9)	0.9	0/223 (0.0)	0.0	2.96 (0.31, 28.25)	0.3456	0.88 (-4.07, 5.84)	0.7265	
Positive (At any time)	0/ 19 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-21.63, 21.63)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/159 (0.0)	0.0	0/176 (0.0)	0.0	NE		0.00 (-5.09, 5.09)	1.0000	
>= 30	2/ 87 (2.3)	2.4	0/ 70 (0.0)	0.0	2.48 (0.26, 23.29)	0.4277	2.42 (-6.75, 11.59)	0.6050	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Major clinical response at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 52	Number of subjects with events, n (%)	55 (22.4)	33 (13.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.62 (1.09, 2.39)	
	p-value	0.0164	
	Odds Ratio (95% CI)	1.82 (1.12, 2.95)	
	p-value	0.0152	
	Risk Difference (95% CI)	8.40 (1.71, 15.10)	
	p-value	0.0139	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.61 (1.08, 2.39)	
	p-value	0.0185	
	Odds Ratio (95% CI)	1.83 (1.13, 2.96)	
	p-value	0.0137	
	Risk Difference (95% CI)	8.89 (2.18, 15.61)	
	p-value	0.0095	
	CMH approach		
	Response rate	22.0	13.5
	Difference in response rates (95% CI)	8.49 (1.27, 15.71)	
	p-value	0.0211	
	p-Value for test for heterogenity between studies	0.1115	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Major clinical response at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.7201
< 10 points	24/ 80 (30.0)	29.6	12/ 69 (17.4)	17.1	1.71 (0.92, 3.18)	0.0882	12.50 (-1.81, 26.81)	0.0869	
>= 10 points	31/166 (18.7)	18.8	21/177 (11.9)	12.1	1.48 (0.89, 2.47)	0.1337	6.75 (-1.61, 15.12)	0.1136	
OCS dose at baseline									0.8834
<10 mg/day	27/115 (23.5)	23.6	16/117 (13.7)	13.9	1.68 (0.95, 2.95)	0.0737	9.68 (-1.29, 20.65)	0.0837	
>=10 mg/day	28/131 (21.4)	21.0	17/129 (13.2)	13.0	1.58 (0.91, 2.74)	0.1044	7.99 (-1.56, 17.54)	0.1010	
Result of type I IFN gene signature test									0.6971
LOW	7/ 45 (15.6)	15.5	5/ 48 (10.4)	10.3	1.27 (0.36, 4.48)	0.7145	5.14 (-10.43, 20.72)	0.5175	
HIGH	48/201 (23.9)	23.6	28/198 (14.1)	14.3	1.65 (1.08, 2.51)	0.0199	9.28 (1.15, 17.41)	0.0253	
Age (years)									0.1185
<= 65	55/239 (23.0)	22.6	32/243 (13.2)	13.2	1.70 (1.14, 2.53)	0.0095	9.37 (2.05, 16.69)	0.0121	
> 65	0/ 7 (0.0)	0.0	1/ 3 (33.3)	34.1	0.17 (0.01, 2.98)	0.2235	-34.09 (-99.01, 30.83)	0.3034	
Sex									0.3880
male	6/ 23 (26.1)	25.1	1/ 20 (5.0)	4.5	3.30 (0.57, 19.11)	0.1825	20.54 (-4.78, 45.86)	0.1118	
female	49/223 (22.0)	21.5	32/226 (14.2)	14.1	1.49 (0.99, 2.25)	0.0561	7.36 (-0.17, 14.89)	0.0554	
Race									0.8248
White	35/160 (21.9)	22.1	22/174 (12.6)	12.5	1.68 (1.03, 2.75)	0.0374	9.61 (0.84, 18.38)	0.0318	
Black	9/ 33 (27.3)	27.3	6/ 32 (18.8)	20.8	1.27 (0.52, 3.11)	0.5987	6.45 (-16.33, 29.23)	0.5789	
Other	8/ 45 (17.8)	17.9	5/ 37 (13.5)	13.5	1.32 (0.47, 3.71)	0.5925	4.38 (-13.42, 22.18)	0.6298	
Ethnicity									0.6084
Hispanic/Latino	10/ 50 (20.0)	20.3	9/ 56 (16.1)	16.3	1.30 (0.51, 3.36)	0.5837	3.98 (-11.71, 19.68)	0.6189	
Non-hispanic/Latino	42/188 (22.3)	21.5	24/187 (12.8)	13.1	1.72 (1.09, 2.70)	0.0201	8.31 (0.10, 16.53)	0.0474	
Geographic region									0.4805
EU	28/ 92 (30.4)	31.7	15/ 89 (16.9)	16.2	1.94 (1.13, 3.36)	0.0170	15.54 (3.01, 28.08)	0.0151	
non-EU	27/154 (17.5)	17.8	18/157 (11.5)	11.9	1.47 (0.83, 2.58)	0.1856	5.89 (-2.98, 14.75)	0.1933	
Onset of disease									0.5141
Paediatric	4/ 19 (21.1)	19.6	0/ 12 (0.0)	0.0	3.09 (0.39, 24.33)	0.2835	19.58 (-11.22, 50.38)	0.2128	
Adult	51/227 (22.5)	22.3	33/234 (14.1)	14.3	1.54 (1.03, 2.29)	0.0346	8.02 (0.48, 15.56)	0.0371	
ADA result									0.4534
Negative	49/226 (21.7)	21.4	31/223 (13.9)	13.9	1.53 (1.01, 2.31)	0.0434	7.50 (-0.11, 15.10)	0.0534	
Positive (At any time)	6/ 19 (31.6)	33.5	2/ 23 (8.7)	10.9	2.62 (0.68, 10.05)	0.1607	22.55 (-5.54, 50.63)	0.1156	
BMI (kg/m2) at enrolment									0.9764
< 30	38/159 (23.9)	23.8	25/176 (14.2)	13.9	1.64 (1.03, 2.61)	0.0372	9.89 (1.01, 18.77)	0.0290	
>= 30	17/ 87 (19.5)	19.5	8/ 70 (11.4)	11.8	1.62 (0.75, 3.50)	0.2224	7.75 (-4.88, 20.38)	0.2291	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Partial clinical response at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 52	Number of subjects with events, n (%)	119 (48.4)	100 (40.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.20 (0.98, 1.46)	
	p-value	0.0816	
	Odds Ratio (95% CI)	1.38 (0.96, 1.97)	
	p-value	0.0805	
	Risk Difference (95% CI)	7.94 (-0.92, 16.79)	
	p-value	0.0789	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.19 (0.97, 1.45)	
	p-value	0.0904	
	Odds Ratio (95% CI)	1.37 (0.96, 1.95)	
	p-value	0.0862	
	Risk Difference (95% CI)	7.71 (-1.05, 16.46)	
	p-value	0.0847	
	CMH approach		
	Response rate	48.0	40.6
	Difference in response rates (95% CI)	7.35 (-1.39, 16.09)	
	p-value	0.0993	
	p-Value for test for heterogenity between studies	0.4836	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Partial clinical response at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.6512
< 10 points	45/ 80 (56.3)	56.4	31/ 69 (44.9)	44.5	1.26 (0.91, 1.74)	0.1687	11.86 (-4.16, 27.88)	0.1469	
>= 10 points	74/166 (44.6)	44.8	69/177 (39.0)	38.9	1.14 (0.89, 1.47)	0.2973	5.83 (-4.58, 16.25)	0.2723	
OCS dose at baseline									0.2956
<10 mg/day	55/115 (47.8)	47.7	52/117 (44.4)	45.0	1.06 (0.81, 1.41)	0.6606	2.64 (-10.15, 15.43)	0.6855	
>=10 mg/day	64/131 (48.9)	48.5	48/129 (37.2)	37.3	1.32 (0.99, 1.75)	0.0580	11.20 (-0.80, 23.20)	0.0675	
Result of type I IFN gene signature test									0.1777
LOW	19/ 45 (42.2)	42.1	23/ 48 (47.9)	47.9	0.90 (0.58, 1.41)	0.6526	-5.83 (-25.90, 14.24)	0.5693	
HIGH	100/201 (49.8)	49.4	77/198 (38.9)	38.9	1.27 (1.02, 1.59)	0.0335	10.45 (0.74, 20.16)	0.0350	
Age (years)									0.8301
<= 65	115/239 (48.1)	47.6	99/243 (40.7)	40.6	1.18 (0.96, 1.44)	0.1082	7.00 (-1.82, 15.82)	0.1199	
> 65	4/ 7 (57.1)	56.8	1/ 3 (33.3)	34.1	1.37 (0.36, 5.25)	0.6477	22.73 (-44.61, 90.06)	0.5083	
Sex									0.4440
male	14/ 23 (60.9)	61.2	7/ 20 (35.0)	32.9	1.50 (0.76, 2.94)	0.2382	28.30 (-0.61, 57.21)	0.0551	
female	105/223 (47.1)	46.8	93/226 (41.2)	41.0	1.14 (0.92, 1.40)	0.2231	5.74 (-3.38, 14.86)	0.2177	
Race									0.0889
White	72/160 (45.0)	45.2	76/174 (43.7)	43.8	1.03 (0.81, 1.31)	0.8141	1.44 (-9.21, 12.08)	0.7914	
Black	15/ 33 (45.5)	45.5	11/ 32 (34.4)	39.2	1.04 (0.59, 1.84)	0.8898	6.28 (-17.99, 30.54)	0.6122	
Other	27/ 45 (60.0)	59.6	11/ 37 (29.7)	29.8	2.00 (1.16, 3.46)	0.0131	29.78 (8.93, 50.62)	0.0051	
Ethnicity									0.9360
Hispanic/Latino	26/ 50 (52.0)	52.2	25/ 56 (44.6)	44.8	1.17 (0.79, 1.75)	0.4302	7.44 (-11.47, 26.35)	0.4407	
Non-hispanic/Latino	88/188 (46.8)	46.2	73/187 (39.0)	39.2	1.20 (0.95, 1.51)	0.1345	7.03 (-2.96, 17.03)	0.1677	
Geographic region									0.9366
EU	53/ 92 (57.6)	58.1	43/ 89 (48.3)	48.9	1.19 (0.90, 1.56)	0.2241	9.26 (-5.27, 23.79)	0.2118	
non-EU	66/154 (42.9)	43.2	57/157 (36.3)	36.8	1.17 (0.89, 1.54)	0.2700	6.35 (-4.60, 17.30)	0.2555	
Onset of disease									0.6336
Paediatric	10/ 19 (52.6)	52.2	3/ 12 (25.0)	22.3	1.49 (0.54, 4.13)	0.4439	29.87 (-4.76, 64.49)	0.0909	
Adult	109/227 (48.0)	47.8	97/234 (41.5)	41.5	1.16 (0.94, 1.42)	0.1615	6.33 (-2.71, 15.38)	0.1700	
ADA result									0.1823
Negative	110/226 (48.7)	48.2	95/223 (42.6)	42.5	1.14 (0.93, 1.40)	0.2089	5.69 (-3.48, 14.86)	0.2237	
Positive (At any time)	9/ 19 (47.4)	47.6	5/ 23 (21.7)	19.6	2.24 (0.85, 5.91)	0.1041	28.00 (-1.43, 57.43)	0.0622	
BMI (kg/m2) at enrolment									0.0875
< 30	82/159 (51.6)	51.4	68/176 (38.6)	38.9	1.34 (1.05, 1.70)	0.0177	12.52 (1.96, 23.08)	0.0202	
>= 30	37/ 87 (42.5)	43.0	32/ 70 (45.7)	46.2	0.92 (0.65, 1.31)	0.6502	-3.18 (-18.69, 12.32)	0.6875	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=50% Joint reduction at week 52 (for subjects with at least 6 tender joints and swollen joints at baseline)
Full analysis set

Timepoint		Anifrolumab 300mg (N=110)	Placebo (N=126)
Week 52	Number of subjects with events, n (%)	53 (48.2)	51 (40.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.14 (0.87, 1.51)	
	p-value	0.3464	
	Odds Ratio (95% CI)	1.29 (0.75, 2.22)	
	p-value	0.3536	
	Risk Difference (95% CI)	5.97 (-6.66, 18.60)	
	p-value	0.3541	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.17 (0.88, 1.56)	
	p-value	0.2738	
	Odds Ratio (95% CI)	1.32 (0.78, 2.22)	
	p-value	0.3010	
	Risk Difference (95% CI)	6.68 (-5.94, 19.31)	
	p-value	0.2993	
	CMH approach		
	Response rate	47.1	41.5
	Difference in response rates (95% CI)	5.61 (-7.06, 18.28)	
	p-value	0.3854	
	p-Value for test for heterogenity between studies	0.6019	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=50% Joint reduction at week 52 (for subjects with at least 6 tender joints and swollen joints at baseline) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=110) n/ N (%)	Response rate	Placebo (N=126) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8498
< 10 points	21/ 39 (53.8)	53.2	15/ 33 (45.5)	45.4	1.20 (0.74, 1.94)	0.4690	7.78 (-15.09, 30.65)	0.5050	
>= 10 points	32/ 71 (45.1)	45.5	36/ 93 (38.7)	39.1	1.13 (0.79, 1.62)	0.5087	6.42 (-8.76, 21.59)	0.4072	
OCS dose at baseline									0.8493
<10 mg/day	22/ 50 (44.0)	42.9	22/ 58 (37.9)	38.6	1.14 (0.73, 1.77)	0.5622	4.32 (-13.96, 22.61)	0.6431	
>=10 mg/day	31/ 60 (51.7)	51.5	29/ 68 (42.6)	42.7	1.20 (0.83, 1.74)	0.3241	8.71 (-8.61, 26.04)	0.3244	
Result of type I IFN gene signature test									0.3530
LOW	11/ 23 (47.8)	47.7	8/ 27 (29.6)	29.9	1.59 (0.78, 3.26)	0.2051	17.82 (-9.38, 45.02)	0.1991	
HIGH	42/ 87 (48.3)	46.9	43/ 99 (43.4)	44.6	1.10 (0.80, 1.50)	0.5563	2.28 (-12.04, 16.59)	0.7553	
Age (years)									0.1688
<= 65	50/106 (47.2)	45.9	49/123 (39.8)	40.8	1.17 (0.87, 1.58)	0.2874	5.14 (-7.75, 18.02)	0.4347	
> 65	3/ 4 (75.0)	75.0	2/ 3 (66.7)	100.0	0.75 (0.43, 1.32)	0.3190	-25.00 (-105.74, 55.74)	0.5439	
Sex									0.9140
male	3/ 7 (42.9)	32.1	3/ 7 (42.9)	21.4	1.07 (0.18, 6.58)	0.9383	10.71 (-51.28, 72.71)	0.7348	
female	50/103 (48.5)	47.6	48/119 (40.3)	41.4	1.19 (0.89, 1.59)	0.2441	6.18 (-6.84, 19.20)	0.3522	
Race									0.6427
White	35/ 73 (47.9)	47.9	43/ 98 (43.9)	43.9	1.11 (0.80, 1.53)	0.5452	4.00 (-10.96, 18.96)	0.5999	
Black	7/ 17 (41.2)	39.2	5/ 14 (35.7)	37.5	1.05 (0.38, 2.92)	0.9273	1.77 (-38.08, 41.63)	0.9305	
Other	8/ 16 (50.0)	45.3	3/ 13 (23.1)	24.5	1.89 (0.64, 5.60)	0.2524	20.80 (-14.12, 55.71)	0.2430	
Ethnicity									0.3215
Hispanic/Latino	11/ 24 (45.8)	44.8	7/ 25 (28.0)	28.3	1.61 (0.76, 3.45)	0.2165	16.48 (-10.26, 43.22)	0.2272	
Non-hispanic/Latino	39/ 82 (47.6)	45.9	44/100 (44.0)	44.8	1.06 (0.77, 1.46)	0.7014	1.09 (-13.58, 15.76)	0.8841	
Geographic region									0.7542
EU	24/ 36 (66.7)	66.8	26/ 44 (59.1)	59.1	1.13 (0.81, 1.58)	0.4770	7.63 (-13.82, 29.07)	0.4858	
non-EU	29/ 74 (39.2)	37.0	25/ 82 (30.5)	31.2	1.24 (0.79, 1.93)	0.3512	5.80 (-9.17, 20.77)	0.4477	
Onset of disease									0.3071
Paediatric	3/ 6 (50.0)	50.0	1/ 7 (14.3)	13.8	2.66 (0.52, 13.54)	0.2380	36.21 (-16.97, 89.38)	0.1820	
Adult	50/104 (48.1)	47.0	50/119 (42.0)	42.8	1.13 (0.84, 1.50)	0.4223	4.13 (-8.95, 17.21)	0.5360	
ADA result									0.6936
Negative	49/ 99 (49.5)	48.5	49/117 (41.9)	42.5	1.18 (0.88, 1.57)	0.2695	5.99 (-7.21, 19.20)	0.3736	
Positive (At any time)	4/ 10 (40.0)	35.6	2/ 9 (22.2)	21.0	1.62 (0.34, 7.72)	0.5458	14.59 (-32.64, 61.82)	0.5448	
BMI (kg/m2) at enrolment									0.0319
< 30	35/ 65 (53.8)	53.6	33/ 90 (36.7)	36.8	1.49 (1.05, 2.12)	0.0243	16.81 (1.40, 32.22)	0.0326	
>= 30	18/ 45 (40.0)	39.4	18/ 36 (50.0)	50.7	0.78 (0.48, 1.26)	0.3077	-11.27 (-33.14, 10.61)	0.3127	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=50% Joint reduction at week 52 (for subjects with at least 8 tender joints and swollen joints at baseline)
Full analysis set

Timepoint		Anifrolumab 300mg (N=72)	Placebo (N=93)
Week 52	Number of subjects with events, n (%)	33 (45.8)	32 (34.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.23 (0.86, 1.75)	
	p-value	0.2507	
	Odds Ratio (95% CI)	1.51 (0.74, 3.09)	
	p-value	0.2568	
	Risk Difference (95% CI)	8.61 (-6.33, 23.55)	
	p-value	0.2585	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.27 (0.86, 1.86)	
	p-value	0.2258	
	Odds Ratio (95% CI)	1.46 (0.76, 2.80)	
	p-value	0.2604	
	Risk Difference (95% CI)	8.72 (-6.40, 23.84)	
	p-value	0.2582	
	CMH approach		
	Response rate	43.6	35.8
	Difference in response rates (95% CI)	7.84 (-7.12, 22.80)	
	p-value	0.3045	
	p-Value for test for heterogenity between studies	0.4420	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=50% Joint reduction at week 52 (for subjects with at least 8 tender joints and swollen joints at baseline) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=72) n/ N (%)	Response rate	Placebo (N=93) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.7649
< 10 points	15/ 27 (55.6)	55.2	12/ 28 (42.9)	42.9	1.33 (0.77, 2.30)	0.3064	12.34 (-13.55, 38.23)	0.3502	
>= 10 points	18/ 45 (40.0)	37.8	20/ 65 (30.8)	32.5	1.18 (0.70, 2.01)	0.5305	5.33 (-13.43, 24.09)	0.5776	
OCS dose at baseline									0.7659
<10 mg/day	13/ 30 (43.3)	39.6	11/ 39 (28.2)	30.2	1.36 (0.70, 2.64)	0.3566	9.34 (-13.57, 32.25)	0.4242	
>=10 mg/day	20/ 42 (47.6)	46.9	21/ 54 (38.9)	39.1	1.21 (0.75, 1.93)	0.4341	7.81 (-12.31, 27.93)	0.4468	
Result of type I IFN gene signature test									0.3504
LOW	8/ 19 (42.1)	41.3	4/ 20 (20.0)	20.7	1.97 (0.73, 5.32)	0.1833	20.58 (-9.25, 50.42)	0.1763	
HIGH	25/ 53 (47.2)	44.5	28/ 73 (38.4)	40.0	1.17 (0.77, 1.79)	0.4516	4.45 (-12.96, 21.86)	0.6164	
Age (years)									0.1969
<= 65	32/ 70 (45.7)	43.3	31/ 91 (34.1)	35.4	1.29 (0.87, 1.91)	0.2030	7.96 (-7.22, 23.13)	0.3041	
> 65	1/ 2 (50.0)	50.0	1/ 2 (50.0)	100.0	0.50 (0.13, 2.00)	0.3270	-50.00 (-168.41, 68.41)	0.4079	
Sex									0.5880
male	2/ 6 (33.3)	27.3	2/ 4 (50.0)	31.8	0.78 (0.13, 4.81)	0.7908	-4.55 (-69.60, 60.51)	0.8911	
female	31/ 66 (47.0)	44.9	30/ 89 (33.7)	35.4	1.31 (0.89, 1.92)	0.1747	9.46 (-5.96, 24.87)	0.2292	
Race									0.6097
White	24/ 49 (49.0)	48.1	28/ 73 (38.4)	38.6	1.26 (0.83, 1.90)	0.2738	9.46 (-8.25, 27.17)	0.2953	
Black	5/ 14 (35.7)	30.0	3/ 10 (30.0)	26.8	1.18 (0.27, 5.29)	0.8245	3.22 (-45.00, 51.44)	0.8959	
Other	3/ 8 (37.5)	38.0	1/ 10 (10.0)	9.6	2.88 (0.59, 14.14)	0.1932	28.36 (-14.44, 71.17)	0.1941	
Ethnicity									0.6868
Hispanic/Latino	7/ 17 (41.2)	41.4	5/ 18 (27.8)	27.6	1.50 (0.60, 3.77)	0.3889	13.80 (-18.27, 45.88)	0.3990	
Non-hispanic/Latino	25/ 54 (46.3)	42.0	27/ 75 (36.0)	38.1	1.22 (0.78, 1.89)	0.3854	3.95 (-13.51, 21.42)	0.6571	
Geographic region									0.8787
EU	14/ 18 (77.8)	77.6	17/ 29 (58.6)	58.7	1.32 (0.88, 1.98)	0.1777	18.88 (-9.59, 47.35)	0.1936	
non-EU	19/ 54 (35.2)	33.3	15/ 64 (23.4)	24.2	1.40 (0.77, 2.52)	0.2680	9.12 (-7.67, 25.90)	0.2870	
Onset of disease									0.8004
Paediatric	1/ 3 (33.3)	33.3	1/ 7 (14.3)	20.0	1.67 (0.16, 17.89)	0.6732	13.33 (-56.26, 82.93)	0.7073	
Adult	32/ 69 (46.4)	44.1	31/ 86 (36.0)	37.3	1.22 (0.83, 1.80)	0.3083	6.83 (-8.68, 22.35)	0.3882	
ADA result									0.7190
Negative	30/ 63 (47.6)	45.6	30/ 85 (35.3)	36.3	1.30 (0.88, 1.91)	0.1880	9.28 (-6.36, 24.93)	0.2449	
Positive (At any time)	3/ 8 (37.5)	37.5	2/ 8 (25.0)	20.0	1.88 (0.26, 13.42)	0.5313	17.50 (-36.11, 71.11)	0.5223	
BMI (kg/m2) at enrolment									0.0447
< 30	20/ 38 (52.6)	51.3	20/ 67 (29.9)	30.0	1.74 (1.06, 2.86)	0.0273	21.26 (2.12, 40.39)	0.0294	
>= 30	13/ 34 (38.2)	36.2	12/ 26 (46.2)	47.6	0.79 (0.44, 1.43)	0.4417	-11.39 (-36.69, 13.92)	0.3778	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Low Disease Activity State at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 52	Number of subjects with events, n (%)	61 (24.8)	39 (15.9)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.52 (1.06, 2.19)	
	p-value	0.0229	
	Odds Ratio (95% CI)	1.70 (1.08, 2.69)	
	p-value	0.0220	
	Risk Difference (95% CI)	8.39 (1.31, 15.47)	
	p-value	0.0202	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.56 (1.09, 2.23)	
	p-value	0.0158	
	Odds Ratio (95% CI)	1.75 (1.12, 2.74)	
	p-value	0.0147	
	Risk Difference (95% CI)	8.90 (1.85, 15.95)	
	p-value	0.0134	
	CMH approach		
	Response rate	24.6	16.0
	Difference in response rates (95% CI)	8.56 (1.10, 16.02)	
	p-value	0.0245	
	p-Value for test for heterogenity between studies	0.7933	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Low Disease Activity State at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.1417
< 10 points	23/ 80 (28.8)	28.8	18/ 69 (26.1)	25.9	1.11 (0.66, 1.88)	0.7006	2.89 (-11.97, 17.75)	0.7033	
>= 10 points	38/166 (22.9)	22.7	21/177 (11.9)	11.9	1.90 (1.17, 3.09)	0.0099	10.70 (2.18, 19.23)	0.0139	
OCS dose at baseline									0.2146
<10 mg/day	29/115 (25.2)	24.7	23/117 (19.7)	20.4	1.25 (0.77, 2.02)	0.3602	4.26 (-7.05, 15.58)	0.4603	
>=10 mg/day	32/131 (24.4)	24.4	16/129 (12.4)	12.3	1.98 (1.15, 3.43)	0.0142	12.11 (2.29, 21.92)	0.0156	
Result of type I IFN gene signature test									0.0791
LOW	11/ 45 (24.4)	24.4	13/ 48 (27.1)	27.1	0.90 (0.45, 1.80)	0.7674	-2.68 (-21.18, 15.81)	0.7763	
HIGH	50/201 (24.9)	24.6	26/198 (13.1)	13.4	1.87 (1.22, 2.87)	0.0043	11.20 (3.08, 19.32)	0.0069	
Age (years)									0.8560
<= 65	60/239 (25.1)	24.9	39/243 (16.0)	16.1	1.56 (1.09, 2.24)	0.0154	8.76 (1.21, 16.32)	0.0231	
> 65	1/ 7 (14.3)	15.9	0/ 3 (0.0)	0.0	2.00 (0.14, 28.42)	0.6087	15.91 (-47.50, 79.32)	0.6229	
Sex									0.3607
male	7/ 23 (30.4)	31.2	2/ 20 (10.0)	10.2	2.98 (0.70, 12.75)	0.1409	20.96 (-5.92, 47.84)	0.1265	
female	54/223 (24.2)	24.1	37/226 (16.4)	16.4	1.48 (1.02, 2.15)	0.0398	7.73 (-0.13, 15.59)	0.0540	
Race									0.4235
White	38/160 (23.8)	23.6	28/174 (16.1)	16.2	1.47 (0.95, 2.27)	0.0856	7.42 (-1.64, 16.49)	0.1083	
Black	10/ 33 (30.3)	29.8	8/ 32 (25.0)	24.2	1.22 (0.52, 2.84)	0.6495	5.55 (-17.61, 28.72)	0.6384	
Other	11/ 45 (24.4)	24.4	2/ 37 (5.4)	5.2	3.40 (0.91, 12.73)	0.0693	19.18 (2.09, 36.26)	0.0279	
Ethnicity									0.5280
Hispanic/Latino	13/ 50 (26.0)	25.9	7/ 56 (12.5)	12.4	1.98 (0.83, 4.69)	0.1225	13.50 (-2.44, 29.44)	0.0970	
Non-hispanic/Latino	46/188 (24.5)	24.1	31/187 (16.6)	16.8	1.45 (0.97, 2.18)	0.0718	7.28 (-1.27, 15.84)	0.0952	
Geographic region									0.4465
EU	27/ 92 (29.3)	30.2	20/ 89 (22.5)	21.8	1.38 (0.84, 2.27)	0.2035	8.40 (-4.63, 21.43)	0.2066	
non-EU	34/154 (22.1)	21.9	19/157 (12.1)	12.2	1.82 (1.09, 3.06)	0.0232	9.72 (0.75, 18.69)	0.0337	
Onset of disease									0.6126
Paediatric	2/ 19 (10.5)	8.7	1/ 12 (8.3)	7.4	0.92 (0.11, 7.45)	0.9368	1.28 (-29.35, 31.90)	0.9348	
Adult	59/227 (26.0)	25.7	38/234 (16.2)	16.5	1.59 (1.11, 2.29)	0.0123	9.25 (1.45, 17.05)	0.0201	
ADA result									0.5988
Negative	57/226 (25.2)	24.9	38/223 (17.0)	17.1	1.48 (1.02, 2.13)	0.0366	7.79 (-0.12, 15.71)	0.0535	
Positive (At any time)	4/ 19 (21.1)	18.9	1/ 23 (4.3)	2.9	2.59 (0.33, 20.48)	0.3659	16.00 (-9.29, 41.29)	0.2150	
BMI (kg/m2) at enrolment									0.6244
< 30	40/159 (25.2)	25.4	27/176 (15.3)	15.8	1.66 (1.07, 2.56)	0.0236	9.64 (0.63, 18.65)	0.0359	
>= 30	21/ 87 (24.1)	24.3	12/ 70 (17.1)	17.5	1.37 (0.73, 2.58)	0.3340	6.87 (-6.72, 20.45)	0.3216	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Mental Component Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 52	Number of subjects with events, n (%)	66 (26.8)	55 (22.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.20 (0.86, 1.65)	
	p-value	0.2824	
	Odds Ratio (95% CI)	1.26 (0.83, 1.91)	
	p-value	0.2753	
	Risk Difference (95% CI)	4.28 (-3.40, 11.96)	
	p-value	0.2745	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.20 (0.88, 1.64)	
	p-value	0.2516	
	Odds Ratio (95% CI)	1.27 (0.84, 1.92)	
	p-value	0.2518	
	Risk Difference (95% CI)	4.46 (-3.14, 12.06)	
	p-value	0.2502	
	CMH approach		
	Response rate	26.0	22.2
	Difference in response rates (95% CI)	3.76 (-3.99, 11.51)	
	p-value	0.3421	
	p-Value for test for heterogenity between studies	0.7216	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Mental Component Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.1820
< 10 points	30/ 80 (37.5)	37.2	16/ 69 (23.2)	23.0	1.55 (0.92, 2.62)	0.1000	14.22 (-0.85, 29.29)	0.0644	
>= 10 points	36/166 (21.7)	21.2	39/177 (22.0)	21.8	0.99 (0.66, 1.49)	0.9524	-0.63 (-9.67, 8.40)	0.8905	
OCS dose at baseline									0.0454
<10 mg/day	25/115 (21.7)	21.2	30/117 (25.6)	25.5	0.84 (0.53, 1.34)	0.4723	-4.36 (-15.67, 6.94)	0.4495	
>=10 mg/day	41/131 (31.3)	31.2	25/129 (19.4)	18.8	1.61 (1.05, 2.49)	0.0304	12.31 (1.68, 22.93)	0.0232	
Result of type I IFN gene signature test									0.2590
LOW	10/ 45 (22.2)	22.3	13/ 48 (27.1)	27.1	0.83 (0.41, 1.70)	0.6104	-4.78 (-23.05, 13.48)	0.6077	
HIGH	56/201 (27.9)	26.9	42/198 (21.2)	21.1	1.31 (0.93, 1.86)	0.1261	5.77 (-2.79, 14.32)	0.1867	
Age (years)									0.6236
<= 65	64/239 (26.8)	25.9	54/243 (22.2)	22.0	1.21 (0.88, 1.65)	0.2463	3.90 (-3.91, 11.71)	0.3279	
> 65	2/ 7 (28.6)	29.5	1/ 3 (33.3)	34.1	0.78 (0.14, 4.31)	0.7757	-4.55 (-71.22, 62.13)	0.8937	
Sex									0.7437
male	6/ 23 (26.1)	26.2	3/ 20 (15.0)	13.6	1.45 (0.42, 4.99)	0.5574	12.62 (-14.12, 39.36)	0.3548	
female	60/223 (26.9)	26.2	52/226 (23.0)	23.0	1.17 (0.85, 1.61)	0.3385	3.13 (-5.07, 11.32)	0.4550	
Race									0.3735
White	44/160 (27.5)	27.2	41/174 (23.6)	23.9	1.16 (0.80, 1.68)	0.4224	3.32 (-6.43, 13.08)	0.5043	
Black	11/ 33 (33.3)	32.3	11/ 32 (34.4)	37.7	0.83 (0.43, 1.60)	0.5826	-5.34 (-29.35, 18.66)	0.6627	
Other	8/ 45 (17.8)	17.9	3/ 37 (8.1)	8.1	2.22 (0.63, 7.76)	0.2129	9.82 (-7.12, 26.76)	0.2559	
Ethnicity									0.6535
Hispanic/Latino	13/ 50 (26.0)	26.2	11/ 56 (19.6)	19.6	1.36 (0.67, 2.73)	0.3958	6.68 (-10.06, 23.42)	0.4340	
Non-hispanic/Latino	50/188 (26.6)	26.0	44/187 (23.5)	23.2	1.13 (0.80, 1.61)	0.4897	2.71 (-6.27, 11.69)	0.5543	
Geographic region									0.9988
EU	28/ 92 (30.4)	31.2	23/ 89 (25.8)	25.7	1.22 (0.77, 1.94)	0.4016	5.46 (-7.98, 18.91)	0.4256	
non-EU	38/154 (24.7)	24.0	32/157 (20.4)	20.1	1.22 (0.80, 1.85)	0.3488	3.88 (-5.66, 13.43)	0.4256	
Onset of disease									0.4524
Paediatric	5/ 19 (26.3)	26.1	1/ 12 (8.3)	7.4	2.27 (0.41, 12.66)	0.3487	18.65 (-14.02, 51.33)	0.2632	
Adult	61/227 (26.9)	26.3	54/234 (23.1)	23.1	1.16 (0.85, 1.60)	0.3506	3.17 (-4.91, 11.25)	0.4415	
ADA result									0.4214
Negative	62/226 (27.4)	26.3	49/223 (22.0)	21.9	1.25 (0.90, 1.73)	0.1804	4.42 (-3.75, 12.59)	0.2892	
Positive (At any time)	4/ 19 (21.1)	21.5	6/ 23 (26.1)	27.6	0.78 (0.26, 2.35)	0.6577	-6.18 (-35.27, 22.90)	0.6770	
BMI (kg/m2) at enrolment									0.1590
< 30	44/159 (27.7)	28.2	35/176 (19.9)	19.7	1.39 (0.94, 2.05)	0.0972	8.42 (-0.95, 17.79)	0.0782	
>= 30	22/ 87 (25.3)	25.5	20/ 70 (28.6)	28.6	0.87 (0.52, 1.46)	0.6075	-3.05 (-17.45, 11.34)	0.6774	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Physical Component Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 52	Number of subjects with events, n (%)	75 (30.5)	66 (26.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.13 (0.86, 1.49)	
	p-value	0.3854	
	Odds Ratio (95% CI)	1.19 (0.80, 1.77)	
	p-value	0.3877	
	Risk Difference (95% CI)	3.55 (-4.50, 11.60)	
	p-value	0.3871	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.14 (0.86, 1.50)	
	p-value	0.3729	
	Odds Ratio (95% CI)	1.19 (0.81, 1.77)	
	p-value	0.3742	
	Risk Difference (95% CI)	3.62 (-4.35, 11.59)	
	p-value	0.3735	
	CMH approach		
	Response rate	30.4	27.1
	Difference in response rates (95% CI)	3.32 (-4.88, 11.53)	
	p-value	0.4273	
	p-Value for test for heterogenity between studies	0.9271	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Physical Component Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.0484
< 10 points	28/ 80 (35.0)	35.3	13/ 69 (18.8)	19.1	1.83 (1.03, 3.26)	0.0402	16.17 (1.53, 30.81)	0.0304	
>= 10 points	47/166 (28.3)	28.2	53/177 (29.9)	30.7	0.94 (0.67, 1.30)	0.6980	-2.54 (-12.37, 7.30)	0.6130	
OCS dose at baseline									0.3829
<10 mg/day	34/115 (29.6)	29.2	26/117 (22.2)	22.6	1.31 (0.84, 2.03)	0.2336	6.54 (-5.17, 18.24)	0.2738	
>=10 mg/day	41/131 (31.3)	31.5	40/129 (31.0)	30.7	1.01 (0.71, 1.46)	0.9411	0.78 (-10.62, 12.18)	0.8933	
Result of type I IFN gene signature test									0.7832
LOW	15/ 45 (33.3)	33.3	13/ 48 (27.1)	27.1	1.23 (0.66, 2.29)	0.5169	6.26 (-12.85, 25.36)	0.5209	
HIGH	60/201 (29.9)	29.7	53/198 (26.8)	27.1	1.11 (0.82, 1.52)	0.4970	2.63 (-6.45, 11.72)	0.5699	
Age (years)									0.6659
<= 65	73/239 (30.5)	30.4	65/243 (26.7)	26.8	1.14 (0.86, 1.51)	0.3550	3.62 (-4.67, 11.91)	0.3918	
> 65	2/ 7 (28.6)	29.5	1/ 3 (33.3)	34.1	0.78 (0.14, 4.31)	0.7757	-4.55 (-71.22, 62.13)	0.8937	
Sex									0.5812
male	7/ 23 (30.4)	28.9	7/ 20 (35.0)	34.1	0.87 (0.32, 2.34)	0.7861	-5.20 (-33.85, 23.45)	0.7222	
female	68/223 (30.5)	30.3	59/226 (26.1)	26.2	1.17 (0.87, 1.57)	0.3083	4.11 (-4.47, 12.69)	0.3475	
Race									0.7557
White	53/160 (33.1)	34.0	55/174 (31.6)	31.3	1.05 (0.77, 1.44)	0.7411	2.65 (-7.60, 12.89)	0.6129	
Black	7/ 33 (21.2)	22.2	7/ 32 (21.9)	21.8	1.03 (0.40, 2.60)	0.9559	0.44 (-21.98, 22.85)	0.9696	
Other	10/ 45 (22.2)	21.7	4/ 37 (10.8)	10.7	1.68 (0.51, 5.54)	0.3951	11.03 (-6.42, 28.49)	0.2154	
Ethnicity									0.9165
Hispanic/Latino	16/ 50 (32.0)	31.9	16/ 56 (28.6)	28.3	1.11 (0.61, 2.01)	0.7325	3.57 (-14.25, 21.40)	0.6942	
Non-hispanic/Latino	54/188 (28.7)	28.8	50/187 (26.7)	26.7	1.07 (0.77, 1.48)	0.6854	2.17 (-7.17, 11.51)	0.6485	
Geographic region									0.9948
EU	38/ 92 (41.3)	42.0	33/ 89 (37.1)	35.9	1.14 (0.79, 1.64)	0.4735	6.07 (-8.09, 20.24)	0.4009	
non-EU	37/154 (24.0)	24.1	33/157 (21.0)	20.4	1.14 (0.75, 1.75)	0.5327	3.68 (-6.00, 13.36)	0.4565	
Onset of disease									0.4828
Paediatric	3/ 19 (15.8)	13.1	2/ 12 (16.7)	19.2	0.68 (0.16, 2.89)	0.6030	-6.10 (-37.98, 25.78)	0.7076	
Adult	72/227 (31.7)	31.6	64/234 (27.4)	27.4	1.15 (0.87, 1.53)	0.3181	4.15 (-4.38, 12.68)	0.3401	
ADA result									0.8187
Negative	70/226 (31.0)	30.9	61/223 (27.4)	27.7	1.13 (0.85, 1.51)	0.3904	3.19 (-5.44, 11.82)	0.4693	
Positive (At any time)	5/ 19 (26.3)	26.2	5/ 23 (21.7)	19.6	1.31 (0.39, 4.35)	0.6585	6.55 (-21.93, 35.02)	0.6523	
BMI (kg/m2) at enrolment									0.5753
< 30	51/159 (32.1)	32.2	47/176 (26.7)	26.4	1.21 (0.87, 1.69)	0.2595	5.86 (-4.11, 15.84)	0.2493	
>= 30	24/ 87 (27.6)	28.0	19/ 70 (27.1)	27.3	1.02 (0.61, 1.70)	0.9530	0.69 (-13.75, 15.12)	0.9258	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - General Health Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 52	Number of subjects with events, n (%)	43 (17.5)	24 (9.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.88 (1.16, 3.07)	
	p-value	0.0111	
	Odds Ratio (95% CI)	2.07 (1.19, 3.58)	
	p-value	0.0097	
	Risk Difference (95% CI)	8.13 (2.13, 14.13)	
	p-value	0.0079	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.74 (1.09, 2.78)	
	p-value	0.0200	
	Odds Ratio (95% CI)	1.94 (1.13, 3.33)	
	p-value	0.0166	
	Risk Difference (95% CI)	7.67 (1.67, 13.68)	
	p-value	0.0122	
	CMH approach		
	Response rate	17.4	9.6
	Difference in response rates (95% CI)	7.71 (0.88, 14.54)	
	p-value	0.0270	
	p-Value for test for heterogenity between studies	0.2504	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - General Health Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.1217
< 10 points	16/ 80 (20.0)	19.9	3/ 69 (4.3)	4.2	3.57 (1.16, 10.99)	0.0268	15.72 (3.36, 28.07)	0.0126	
>= 10 points	27/166 (16.3)	16.2	21/177 (11.9)	12.0	1.34 (0.79, 2.27)	0.2827	4.14 (-3.99, 12.28)	0.3183	
OCS dose at baseline									0.7533
<10 mg/day	20/115 (17.4)	17.2	10/117 (8.5)	8.5	1.89 (0.92, 3.86)	0.0815	8.66 (-1.45, 18.77)	0.0933	
>=10 mg/day	23/131 (17.6)	17.6	14/129 (10.9)	10.3	1.62 (0.87, 3.01)	0.1251	7.27 (-1.80, 16.35)	0.1161	
Result of type I IFN gene signature test									0.3622
LOW	8/ 45 (17.8)	17.8	7/ 48 (14.6)	14.5	1.19 (0.46, 3.07)	0.7231	3.27 (-13.25, 19.79)	0.6981	
HIGH	35/201 (17.4)	17.3	17/198 (8.6)	8.5	1.98 (1.15, 3.40)	0.0143	8.75 (1.26, 16.25)	0.0220	
Age (years)									0.9742
<= 65	41/239 (17.2)	17.0	24/243 (9.9)	9.7	1.70 (1.06, 2.72)	0.0281	7.31 (0.42, 14.21)	0.0377	
> 65	2/ 7 (28.6)	29.5	0/ 3 (0.0)	0.0	1.75 (0.25, 12.36)	0.5733	29.55 (-35.24, 94.33)	0.3714	
Sex									0.9406
male	3/ 23 (13.0)	12.5	1/ 20 (5.0)	4.5	1.84 (0.26, 13.06)	0.5425	8.00 (-15.94, 31.94)	0.5123	
female	40/223 (17.9)	17.8	23/226 (10.2)	10.1	1.70 (1.05, 2.76)	0.0301	7.71 (0.46, 14.97)	0.0372	
Race									0.2367
White	29/160 (18.1)	18.2	19/174 (10.9)	10.8	1.66 (0.97, 2.84)	0.0657	7.36 (-1.24, 15.95)	0.0934	
Black	4/ 33 (12.1)	11.6	4/ 32 (12.5)	14.4	0.79 (0.22, 2.83)	0.7171	-2.76 (-23.11, 17.58)	0.7899	
Other	9/ 45 (20.0)	19.8	1/ 37 (2.7)	2.8	4.83 (0.92, 25.46)	0.0633	16.99 (0.95, 33.02)	0.0379	
Ethnicity									0.0584
Hispanic/Latino	14/ 50 (28.0)	28.1	3/ 56 (5.4)	5.4	4.64 (1.40, 15.41)	0.0122	22.61 (7.39, 37.83)	0.0036	
Non-hispanic/Latino	28/188 (14.9)	14.7	21/187 (11.2)	11.1	1.31 (0.77, 2.21)	0.3138	3.54 (-4.22, 11.30)	0.3708	
Geographic region									0.0891
EU	16/ 92 (17.4)	18.2	14/ 89 (15.7)	14.9	1.19 (0.62, 2.30)	0.5953	3.29 (-8.15, 14.72)	0.5730	
non-EU	27/154 (17.5)	17.6	10/157 (6.4)	6.3	2.73 (1.37, 5.44)	0.0044	11.28 (2.95, 19.61)	0.0079	
Onset of disease									0.7978
Paediatric	2/ 19 (10.5)	8.7	0/ 12 (0.0)	0.0	2.50 (0.14, 44.26)	0.5320	8.72 (-20.68, 38.11)	0.5612	
Adult	41/227 (18.1)	18.0	24/234 (10.3)	10.2	1.71 (1.07, 2.73)	0.0249	7.76 (0.58, 14.94)	0.0341	
ADA result									0.9173
Negative	39/226 (17.3)	17.1	22/223 (9.9)	9.7	1.73 (1.06, 2.82)	0.0282	7.40 (0.17, 14.62)	0.0447	
Positive (At any time)	4/ 19 (21.1)	21.5	2/ 23 (8.7)	10.9	1.87 (0.45, 7.85)	0.3904	10.55 (-16.79, 37.88)	0.4496	
BMI (kg/m2) at enrolment									0.5552
< 30	30/159 (18.9)	19.0	17/176 (9.7)	9.3	1.95 (1.12, 3.39)	0.0188	9.66 (1.40, 17.91)	0.0218	
>= 30	13/ 87 (14.9)	15.0	7/ 70 (10.0)	10.3	1.43 (0.60, 3.39)	0.4197	4.70 (-7.54, 16.95)	0.4516	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Mental Health Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 52	Number of subjects with events, n (%)	57 (23.2)	34 (13.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.70 (1.13, 2.53)	
	p-value	0.0101	
	Odds Ratio (95% CI)	1.89 (1.18, 3.04)	
	p-value	0.0085	
	Risk Difference (95% CI)	9.34 (2.50, 16.18)	
	p-value	0.0074	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.67 (1.13, 2.46)	
	p-value	0.0093	
	Odds Ratio (95% CI)	1.87 (1.17, 3.00)	
	p-value	0.0087	
	Risk Difference (95% CI)	9.33 (2.52, 16.14)	
	p-value	0.0073	
	CMH approach		
	Response rate	22.5	13.6
	Difference in response rates (95% CI)	8.84 (1.62, 16.07)	
	p-value	0.0164	
	p-Value for test for heterogenity between studies	0.4707	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Mental Health Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Anifrolumab 300mg (N=246) Response rate	Placebo (N=246) n/ N (%)	Placebo (N=246) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.0149
< 10 points	27/ 80 (33.8)	33.7	6/ 69 (8.7)	8.5	3.76 (1.64, 8.62)	0.0017	25.16 (11.51, 38.81)	0.0003	
>= 10 points	30/166 (18.1)	17.7	28/177 (15.8)	16.0	1.14 (0.71, 1.85)	0.5866	1.72 (-6.79, 10.23)	0.6918	
OCS dose at baseline									0.7776
<10 mg/day	25/115 (21.7)	21.3	16/117 (13.7)	13.5	1.57 (0.88, 2.80)	0.1301	7.76 (-2.85, 18.37)	0.1516	
>=10 mg/day	32/131 (24.4)	24.5	18/129 (14.0)	13.4	1.75 (1.04, 2.96)	0.0357	11.08 (1.22, 20.94)	0.0277	
Result of type I IFN gene signature test									0.0958
LOW	7/ 45 (15.6)	15.6	9/ 48 (18.8)	18.7	0.83 (0.34, 2.04)	0.6821	-3.10 (-19.83, 13.64)	0.7170	
HIGH	50/201 (24.9)	24.1	25/198 (12.6)	12.4	1.94 (1.25, 3.02)	0.0033	11.65 (3.65, 19.66)	0.0043	
Age (years)									0.9418
<= 65	56/239 (23.4)	22.7	34/243 (14.0)	13.7	1.67 (1.13, 2.46)	0.0094	8.97 (1.66, 16.29)	0.0162	
> 65	1/ 7 (14.3)	13.6	0/ 3 (0.0)	0.0	1.50 (0.08, 26.86)	0.7830	13.64 (-50.73, 78.01)	0.6780	
Sex									0.5874
male	6/ 23 (26.1)	27.4	4/ 20 (20.0)	18.2	1.27 (0.45, 3.60)	0.6589	9.24 (-17.85, 36.33)	0.5038	
female	51/223 (22.9)	22.4	30/226 (13.3)	13.2	1.73 (1.14, 2.60)	0.0092	9.19 (1.59, 16.80)	0.0179	
Race									0.6294
White	37/160 (23.1)	22.3	25/174 (14.4)	14.4	1.60 (1.00, 2.54)	0.0476	7.94 (-0.98, 16.86)	0.0809	
Black	10/ 33 (30.3)	28.3	7/ 32 (21.9)	23.3	1.22 (0.52, 2.85)	0.6458	5.01 (-17.90, 27.91)	0.6684	
Other	7/ 45 (15.6)	15.6	2/ 37 (5.4)	5.4	2.83 (0.62, 12.83)	0.1777	10.13 (-6.02, 26.29)	0.2188	
Ethnicity									0.5606
Hispanic/Latino	9/ 50 (18.0)	18.1	8/ 56 (14.3)	14.2	1.28 (0.54, 3.06)	0.5777	3.90 (-11.53, 19.34)	0.6202	
Non-hispanic/Latino	45/188 (23.9)	23.2	26/187 (13.9)	13.6	1.71 (1.10, 2.66)	0.0173	9.54 (1.22, 17.86)	0.0245	
Geographic region									0.7548
EU	25/ 92 (27.2)	27.8	16/ 89 (18.0)	17.7	1.57 (0.90, 2.74)	0.1101	10.05 (-2.57, 22.67)	0.1184	
non-EU	32/154 (20.8)	20.1	18/157 (11.5)	11.0	1.78 (1.03, 3.08)	0.0390	9.09 (0.37, 17.82)	0.0411	
Onset of disease									0.8342
Paediatric	4/ 19 (21.1)	21.7	1/ 12 (8.3)	7.4	1.99 (0.35, 11.29)	0.4359	14.29 (-18.05, 46.64)	0.3864	
Adult	53/227 (23.3)	22.8	33/234 (14.1)	13.9	1.65 (1.11, 2.45)	0.0136	8.86 (1.32, 16.40)	0.0212	
ADA result									0.8346
Negative	52/226 (23.0)	22.2	31/223 (13.9)	13.9	1.65 (1.10, 2.48)	0.0151	8.29 (0.68, 15.89)	0.0328	
Positive (At any time)	5/ 19 (26.3)	26.2	3/ 23 (13.0)	13.8	1.91 (0.52, 7.05)	0.3301	12.36 (-15.76, 40.48)	0.3888	
BMI (kg/m2) at enrolment									0.3188
< 30	38/159 (23.9)	24.2	22/176 (12.5)	12.0	1.91 (1.18, 3.09)	0.0087	12.21 (3.54, 20.87)	0.0058	
>= 30	19/ 87 (21.8)	22.1	12/ 70 (17.1)	17.1	1.26 (0.66, 2.42)	0.4820	5.00 (-8.39, 18.39)	0.4644	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Physical Functioning Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 52	Number of subjects with events, n (%)	59 (24.0)	54 (22.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.09 (0.79, 1.52)	
	p-value	0.6014	
	Odds Ratio (95% CI)	1.12 (0.73, 1.72)	
	p-value	0.5993	
	Risk Difference (95% CI)	2.00 (-5.45, 9.44)	
	p-value	0.5989	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.09 (0.79, 1.51)	
	p-value	0.5967	
	Odds Ratio (95% CI)	1.12 (0.74, 1.71)	
	p-value	0.5947	
	Risk Difference (95% CI)	2.02 (-5.41, 9.45)	
	p-value	0.5944	
	CMH approach		
	Response rate	23.7	21.8
	Difference in response rates (95% CI)	1.91 (-5.87, 9.68)	
	p-value	0.6309	
	p-Value for test for heterogenity between studies	0.8112	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Physical Functioning Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.0792
< 10 points	20/ 80 (25.0)	24.7	9/ 69 (13.0)	13.0	1.90 (0.93, 3.92)	0.0804	11.72 (-1.82, 25.26)	0.0899	
>= 10 points	39/166 (23.5)	23.3	45/177 (25.4)	25.9	0.92 (0.63, 1.34)	0.6599	-2.62 (-12.02, 6.79)	0.5859	
OCS dose at baseline									0.3441
<10 mg/day	26/115 (22.6)	22.2	20/117 (17.1)	17.3	1.32 (0.78, 2.23)	0.2971	4.95 (-6.13, 16.02)	0.3815	
>=10 mg/day	33/131 (25.2)	25.4	34/129 (26.4)	25.8	0.96 (0.63, 1.45)	0.8370	-0.39 (-11.24, 10.47)	0.9446	
Result of type I IFN gene signature test									0.3895
LOW	11/ 45 (24.4)	24.4	14/ 48 (29.2)	29.1	0.84 (0.42, 1.66)	0.6161	-4.69 (-23.30, 13.92)	0.6212	
HIGH	48/201 (23.9)	23.5	40/198 (20.2)	20.1	1.18 (0.82, 1.71)	0.3789	3.46 (-5.09, 12.01)	0.4281	
Age (years)									0.7040
<= 65	57/239 (23.8)	23.6	53/243 (21.8)	21.5	1.09 (0.79, 1.52)	0.5959	2.11 (-5.73, 9.95)	0.5982	
> 65	2/ 7 (28.6)	29.5	1/ 3 (33.3)	34.1	0.78 (0.14, 4.31)	0.7757	-4.55 (-71.22, 62.13)	0.8937	
Sex									0.8983
male	7/ 23 (30.4)	31.2	6/ 20 (30.0)	28.4	1.03 (0.41, 2.58)	0.9540	2.81 (-25.68, 31.29)	0.8470	
female	52/223 (23.3)	23.1	48/226 (21.2)	21.0	1.10 (0.78, 1.55)	0.6047	2.15 (-5.98, 10.28)	0.6036	
Race									0.6287
White	44/160 (27.5)	27.6	44/174 (25.3)	24.8	1.09 (0.76, 1.56)	0.6489	2.79 (-7.02, 12.60)	0.5776	
Black	6/ 33 (18.2)	16.7	7/ 32 (21.9)	23.3	0.73 (0.27, 1.99)	0.5413	-6.61 (-28.49, 15.27)	0.5536	
Other	6/ 45 (13.3)	13.3	3/ 37 (8.1)	8.1	1.62 (0.43, 6.14)	0.4800	5.20 (-11.12, 21.52)	0.5321	
Ethnicity									0.7901
Hispanic/Latino	11/ 50 (22.0)	22.2	13/ 56 (23.2)	23.0	0.98 (0.49, 1.96)	0.9487	-0.78 (-17.44, 15.88)	0.9271	
Non-hispanic/Latino	45/188 (23.9)	23.6	41/187 (21.9)	21.3	1.09 (0.75, 1.58)	0.6562	2.31 (-6.58, 11.20)	0.6110	
Geographic region									0.8970
EU	32/ 92 (34.8)	35.0	28/ 89 (31.5)	30.5	1.12 (0.73, 1.71)	0.6111	4.41 (-9.38, 18.21)	0.5307	
non-EU	27/154 (17.5)	17.3	26/157 (16.6)	15.6	1.07 (0.65, 1.77)	0.7944	1.69 (-7.23, 10.61)	0.7103	
Onset of disease									0.8608
Paediatric	2/ 19 (10.5)	8.7	1/ 12 (8.3)	9.6	0.91 (0.11, 7.84)	0.9309	-0.87 (-31.72, 29.97)	0.9558	
Adult	57/227 (25.1)	25.0	53/234 (22.6)	22.5	1.10 (0.80, 1.53)	0.5489	2.49 (-5.64, 10.61)	0.5485	
ADA result									0.7614
Negative	56/226 (24.8)	24.5	50/223 (22.4)	22.4	1.11 (0.79, 1.54)	0.5518	2.07 (-6.16, 10.30)	0.6218	
Positive (At any time)	3/ 19 (15.8)	16.7	4/ 23 (17.4)	19.3	0.89 (0.23, 3.49)	0.8671	-2.55 (-30.25, 25.16)	0.8571	
BMI (kg/m2) at enrolment									0.6395
< 30	42/159 (26.4)	26.9	40/176 (22.7)	22.2	1.16 (0.80, 1.70)	0.4358	4.64 (-4.87, 14.16)	0.3390	
>= 30	17/ 87 (19.5)	19.5	14/ 70 (20.0)	20.1	0.97 (0.51, 1.86)	0.9292	-0.54 (-14.04, 12.96)	0.9377	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Role Emotional Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 52	Number of subjects with events, n (%)	61 (24.8)	45 (18.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.37 (0.97, 1.93)	
	p-value	0.0749	
	Odds Ratio (95% CI)	1.50 (0.96, 2.35)	
	p-value	0.0722	
	Risk Difference (95% CI)	6.64 (-0.55, 13.82)	
	p-value	0.0703	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.35 (0.96, 1.91)	
	p-value	0.0843	
	Odds Ratio (95% CI)	1.47 (0.95, 2.28)	
	p-value	0.0803	
	Risk Difference (95% CI)	6.53 (-0.71, 13.77)	
	p-value	0.0773	
	CMH approach		
	Response rate	24.3	18.3
	Difference in response rates (95% CI)	6.06 (-1.47, 13.59)	
	p-value	0.1148	
	p-Value for test for heterogenity between studies	0.5242	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Role Emotional Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.3271
< 10 points	26/ 80 (32.5)	32.2	13/ 69 (18.8)	18.7	1.68 (0.93, 3.05)	0.0858	13.50 (-0.87, 27.86)	0.0655	
>= 10 points	35/166 (21.1)	20.7	32/177 (18.1)	18.0	1.16 (0.75, 1.81)	0.5067	2.71 (-6.08, 11.50)	0.5453	
OCS dose at baseline									0.3631
<10 mg/day	27/115 (23.5)	22.9	24/117 (20.5)	20.6	1.14 (0.70, 1.87)	0.5898	2.34 (-8.77, 13.45)	0.6798	
>=10 mg/day	34/131 (26.0)	26.4	21/129 (16.3)	15.8	1.57 (0.97, 2.56)	0.0666	10.60 (0.42, 20.77)	0.0413	
Result of type I IFN gene signature test									0.3154
LOW	11/ 45 (24.4)	24.5	12/ 48 (25.0)	25.0	0.98 (0.48, 2.00)	0.9587	-0.53 (-18.86, 17.81)	0.9552	
HIGH	50/201 (24.9)	24.3	33/198 (16.7)	16.7	1.49 (1.00, 2.21)	0.0480	7.61 (-0.63, 15.85)	0.0704	
Age (years)									0.5336
<= 65	59/239 (24.7)	24.3	44/243 (18.1)	17.9	1.36 (0.96, 1.92)	0.0853	6.34 (-1.24, 13.93)	0.1013	
> 65	2/ 7 (28.6)	29.5	1/ 3 (33.3)	34.1	0.78 (0.14, 4.31)	0.7757	-4.55 (-71.22, 62.13)	0.8937	
Sex									0.9975
male	5/ 23 (21.7)	22.4	3/ 20 (15.0)	13.6	1.35 (0.39, 4.67)	0.6395	8.83 (-17.57, 35.23)	0.5122	
female	56/223 (25.1)	24.7	42/226 (18.6)	18.7	1.35 (0.95, 1.92)	0.0984	6.06 (-1.92, 14.03)	0.1367	
Race									0.2201
White	45/160 (28.1)	27.4	33/174 (19.0)	19.2	1.47 (0.99, 2.17)	0.0574	8.18 (-1.36, 17.73)	0.0930	
Black	7/ 33 (21.2)	20.7	10/ 32 (31.3)	32.2	0.64 (0.28, 1.50)	0.3066	-11.48 (-34.58, 11.62)	0.3300	
Other	5/ 45 (11.1)	11.0	2/ 37 (5.4)	5.2	1.50 (0.31, 7.23)	0.6134	5.71 (-9.66, 21.09)	0.4665	
Ethnicity									0.9128
Hispanic/Latino	12/ 50 (24.0)	24.2	10/ 56 (17.9)	17.6	1.34 (0.64, 2.81)	0.4406	6.60 (-9.71, 22.91)	0.4276	
Non-hispanic/Latino	45/188 (23.9)	23.6	35/187 (18.7)	18.6	1.28 (0.86, 1.89)	0.2245	5.01 (-3.69, 13.70)	0.2590	
Geographic region									0.5549
EU	30/ 92 (32.6)	32.8	19/ 89 (21.3)	21.6	1.52 (0.93, 2.49)	0.0985	11.18 (-2.07, 24.44)	0.0981	
non-EU	31/154 (20.1)	19.5	26/157 (16.6)	16.5	1.23 (0.77, 1.99)	0.3859	3.00 (-6.00, 12.01)	0.5134	
Onset of disease									0.7096
Paediatric	5/ 19 (26.3)	23.9	1/ 12 (8.3)	7.4	1.88 (0.29, 12.36)	0.5103	16.50 (-15.70, 48.70)	0.3152	
Adult	56/227 (24.7)	24.3	44/234 (18.8)	18.8	1.31 (0.92, 1.86)	0.1352	5.51 (-2.33, 13.35)	0.1682	
ADA result									0.6796
Negative	56/226 (24.8)	24.4	39/223 (17.5)	17.6	1.40 (0.97, 2.02)	0.0701	6.77 (-1.14, 14.68)	0.0937	
Positive (At any time)	5/ 19 (26.3)	28.7	6/ 23 (26.1)	27.6	1.12 (0.41, 3.05)	0.8257	1.09 (-28.21, 30.39)	0.9418	
BMI (kg/m2) at enrolment									0.4927
< 30	37/159 (23.3)	23.8	33/176 (18.8)	18.5	1.24 (0.81, 1.88)	0.3181	5.23 (-3.82, 14.28)	0.2576	
>= 30	24/ 87 (27.6)	27.9	12/ 70 (17.1)	16.7	1.61 (0.86, 3.00)	0.1350	11.18 (-2.62, 24.98)	0.1123	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Role Physical Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 52	Number of subjects with events, n (%)	91 (37.0)	62 (25.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.48 (1.13, 1.94)	
	p-value	0.0045	
	Odds Ratio (95% CI)	1.78 (1.20, 2.65)	
	p-value	0.0042	
	Risk Difference (95% CI)	12.05 (3.95, 20.15)	
	p-value	0.0036	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.46 (1.12, 1.91)	
	p-value	0.0058	
	Odds Ratio (95% CI)	1.74 (1.18, 2.57)	
	p-value	0.0051	
	Risk Difference (95% CI)	11.75 (3.65, 19.86)	
	p-value	0.0045	
	CMH approach		
	Response rate	36.8	25.3
	Difference in response rates (95% CI)	11.48 (3.23, 19.73)	
	p-value	0.0064	
	p-Value for test for heterogenity between studies	0.6199	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Role Physical Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.2431
< 10 points	32/ 80 (40.0)	40.0	14/ 69 (20.3)	20.1	1.90 (1.10, 3.30)	0.0220	19.97 (5.06, 34.88)	0.0087	
>= 10 points	59/166 (35.5)	35.4	48/177 (27.1)	27.8	1.30 (0.95, 1.79)	0.1005	7.64 (-2.28, 17.56)	0.1313	
OCS dose at baseline									0.0930
<10 mg/day	44/115 (38.3)	37.8	23/117 (19.7)	20.3	1.92 (1.25, 2.96)	0.0032	17.45 (5.63, 29.27)	0.0038	
>=10 mg/day	47/131 (35.9)	36.3	39/129 (30.2)	29.4	1.19 (0.84, 1.69)	0.3199	6.91 (-4.51, 18.33)	0.2355	
Result of type I IFN gene signature test									0.2797
LOW	17/ 45 (37.8)	37.8	16/ 48 (33.3)	33.2	1.11 (0.64, 1.94)	0.7044	4.53 (-15.06, 24.11)	0.6506	
HIGH	74/201 (36.8)	36.6	46/198 (23.2)	23.5	1.58 (1.16, 2.16)	0.0038	13.11 (4.02, 22.20)	0.0047	
Age (years)									0.4683
<= 65	89/239 (37.2)	37.1	61/243 (25.1)	25.0	1.48 (1.13, 1.94)	0.0047	12.12 (3.79, 20.44)	0.0043	
> 65	2/ 7 (28.6)	29.5	1/ 3 (33.3)	34.1	0.78 (0.14, 4.31)	0.7757	-4.55 (-71.22, 62.13)	0.8937	
Sex									0.4747
male	9/ 23 (39.1)	37.6	7/ 20 (35.0)	34.1	1.07 (0.44, 2.58)	0.8815	3.55 (-25.63, 32.72)	0.8116	
female	82/223 (36.8)	36.6	55/226 (24.3)	24.3	1.50 (1.12, 2.00)	0.0058	12.34 (3.70, 20.98)	0.0051	
Race									0.2211
White	63/160 (39.4)	39.3	52/174 (29.9)	29.8	1.32 (0.98, 1.78)	0.0659	9.45 (-0.88, 19.79)	0.0731	
Black	11/ 33 (33.3)	32.3	8/ 32 (25.0)	24.2	1.31 (0.57, 3.03)	0.5226	8.08 (-15.20, 31.37)	0.4963	
Other	12/ 45 (26.7)	26.7	2/ 37 (5.4)	5.4	4.82 (1.15, 20.22)	0.0315	21.29 (3.95, 38.63)	0.0161	
Ethnicity									0.9504
Hispanic/Latino	12/ 50 (24.0)	23.9	9/ 56 (16.1)	15.8	1.41 (0.63, 3.17)	0.4024	8.09 (-8.06, 24.25)	0.3261	
Non-hispanic/Latino	74/188 (39.4)	39.3	53/187 (28.3)	28.0	1.38 (1.03, 1.83)	0.0300	11.25 (1.62, 20.89)	0.0220	
Geographic region									0.3202
EU	46/ 92 (50.0)	50.7	35/ 89 (39.3)	38.2	1.29 (0.93, 1.79)	0.1262	12.43 (-1.90, 26.76)	0.0892	
non-EU	45/154 (29.2)	28.6	27/157 (17.2)	16.7	1.70 (1.11, 2.61)	0.0153	11.92 (2.34, 21.50)	0.0147	
Onset of disease									0.9574
Paediatric	5/ 19 (26.3)	26.1	2/ 12 (16.7)	17.0	1.53 (0.35, 6.67)	0.5722	9.06 (-24.92, 43.05)	0.6011	
Adult	86/227 (37.9)	37.8	60/234 (25.6)	25.7	1.47 (1.12, 1.93)	0.0060	12.04 (3.48, 20.60)	0.0058	
ADA result									0.9556
Negative	85/226 (37.6)	37.5	57/223 (25.6)	25.8	1.47 (1.11, 1.94)	0.0072	11.69 (3.03, 20.36)	0.0082	
Positive (At any time)	6/ 19 (31.6)	28.4	5/ 23 (21.7)	22.2	1.42 (0.48, 4.20)	0.5240	6.18 (-22.82, 35.18)	0.6761	
BMI (kg/m2) at enrolment									0.7231
< 30	62/159 (39.0)	39.4	45/176 (25.6)	25.1	1.51 (1.10, 2.08)	0.0109	14.27 (4.32, 24.23)	0.0049	
>= 30	29/ 87 (33.3)	33.5	17/ 70 (24.3)	24.3	1.36 (0.81, 2.28)	0.2520	9.25 (-5.21, 23.71)	0.2100	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Social Functioning Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 52	Number of subjects with events, n (%)	55 (22.4)	42 (17.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.31 (0.90, 1.92)	
	p-value	0.1588	
	Odds Ratio (95% CI)	1.39 (0.89, 2.17)	
	p-value	0.1522	
	Risk Difference (95% CI)	5.21 (-1.90, 12.31)	
	p-value	0.1507	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.31 (0.91, 1.87)	
	p-value	0.1474	
	Odds Ratio (95% CI)	1.40 (0.89, 2.19)	
	p-value	0.1439	
	Risk Difference (95% CI)	5.26 (-1.75, 12.27)	
	p-value	0.1417	
	CMH approach		
	Response rate	21.6	16.9
	Difference in response rates (95% CI)	4.70 (-2.64, 12.04)	
	p-value	0.2098	
	p-Value for test for heterogenity between studies	0.7105	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Social Functioning Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.0285
< 10 points	28/ 80 (35.0)	34.5	10/ 69 (14.5)	14.2	2.23 (1.15, 4.34)	0.0177	20.38 (6.13, 34.64)	0.0051	
>= 10 points	27/166 (16.3)	15.9	32/177 (18.1)	18.0	0.90 (0.56, 1.44)	0.6591	-2.06 (-10.56, 6.44)	0.6347	
OCS dose at baseline									0.0929
<10 mg/day	21/115 (18.3)	17.7	23/117 (19.7)	19.5	0.92 (0.54, 1.57)	0.7625	-1.77 (-12.55, 9.00)	0.7472	
>=10 mg/day	34/131 (26.0)	25.9	19/129 (14.7)	14.2	1.74 (1.04, 2.89)	0.0344	11.67 (1.64, 21.70)	0.0226	
Result of type I IFN gene signature test									0.5837
LOW	9/ 45 (20.0)	20.0	9/ 48 (18.8)	18.7	1.06 (0.46, 2.43)	0.8916	1.35 (-15.90, 18.60)	0.8781	
HIGH	46/201 (22.9)	22.0	33/198 (16.7)	16.5	1.37 (0.92, 2.05)	0.1238	5.48 (-2.62, 13.59)	0.1850	
Age (years)									0.5597
<= 65	53/239 (22.2)	21.3	41/243 (16.9)	16.6	1.31 (0.91, 1.89)	0.1458	4.77 (-2.62, 12.16)	0.2062	
> 65	2/ 7 (28.6)	29.5	1/ 3 (33.3)	34.1	0.78 (0.14, 4.31)	0.7757	-4.55 (-71.22, 62.13)	0.8937	
Sex									0.8689
male	5/ 23 (21.7)	21.3	3/ 20 (15.0)	13.6	1.14 (0.29, 4.59)	0.8488	7.67 (-18.55, 33.89)	0.5662	
female	50/223 (22.4)	21.8	39/226 (17.3)	17.1	1.29 (0.89, 1.88)	0.1819	4.63 (-3.11, 12.38)	0.2409	
Race									0.5261
White	40/160 (25.0)	24.7	33/174 (19.0)	19.3	1.32 (0.88, 1.99)	0.1809	5.39 (-3.99, 14.77)	0.2598	
Black	8/ 33 (24.2)	23.2	8/ 32 (25.0)	27.3	0.84 (0.36, 1.94)	0.6834	-4.02 (-26.94, 18.89)	0.7308	
Other	5/ 45 (11.1)	11.3	1/ 37 (2.7)	2.8	2.27 (0.32, 16.12)	0.4138	8.53 (-6.43, 23.49)	0.2636	
Ethnicity									0.8571
Hispanic/Latino	10/ 50 (20.0)	20.4	9/ 56 (16.1)	16.0	1.41 (0.61, 3.23)	0.4209	4.46 (-11.14, 20.07)	0.5749	
Non-hispanic/Latino	43/188 (22.9)	22.5	33/187 (17.6)	17.6	1.29 (0.86, 1.93)	0.2135	4.93 (-3.63, 13.49)	0.2588	
Geographic region									0.7277
EU	23/ 92 (25.0)	26.1	19/ 89 (21.3)	20.8	1.27 (0.75, 2.15)	0.3709	5.35 (-7.34, 18.05)	0.4085	
non-EU	32/154 (20.8)	20.2	23/157 (14.6)	14.5	1.44 (0.89, 2.35)	0.1402	5.70 (-3.28, 14.67)	0.2133	
Onset of disease									0.9428
Paediatric	3/ 19 (15.8)	15.2	1/ 12 (8.3)	7.4	1.40 (0.20, 9.53)	0.7324	7.79 (-23.86, 39.43)	0.6296	
Adult	52/227 (22.9)	22.3	41/234 (17.5)	17.5	1.30 (0.90, 1.88)	0.1583	4.82 (-2.86, 12.50)	0.2189	
ADA result									0.3165
Negative	52/226 (23.0)	22.2	37/223 (16.6)	16.4	1.39 (0.95, 2.03)	0.0881	5.78 (-1.95, 13.50)	0.1428	
Positive (At any time)	3/ 19 (15.8)	16.7	5/ 23 (21.7)	24.7	0.69 (0.19, 2.56)	0.5833	-8.00 (-36.26, 20.26)	0.5790	
BMI (kg/m2) at enrolment									0.1319
< 30	36/159 (22.6)	22.8	25/176 (14.2)	14.0	1.59 (1.00, 2.53)	0.0521	8.75 (0.03, 17.47)	0.0491	
>= 30	19/ 87 (21.8)	21.7	17/ 70 (24.3)	24.4	0.89 (0.50, 1.60)	0.7076	-2.67 (-16.70, 11.37)	0.7095	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Bodily Pain Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 52	Number of subjects with events, n (%)	64 (26.0)	58 (23.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.10 (0.81, 1.50)	
	p-value	0.5302	
	Odds Ratio (95% CI)	1.14 (0.75, 1.73)	
	p-value	0.5322	
	Risk Difference (95% CI)	2.45 (-5.23, 10.12)	
	p-value	0.5320	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.10 (0.81, 1.50)	
	p-value	0.5344	
	Odds Ratio (95% CI)	1.14 (0.76, 1.72)	
	p-value	0.5349	
	Risk Difference (95% CI)	2.42 (-5.21, 10.04)	
	p-value	0.5346	
	CMH approach		
	Response rate	25.9	23.7
	Difference in response rates (95% CI)	2.20 (-5.71, 10.11)	
	p-value	0.5859	
	p-Value for test for heterogenity between studies	0.9562	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Bodily Pain Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.0789
< 10 points	29/ 80 (36.3)	37.1	16/ 69 (23.2)	23.1	1.59 (0.95, 2.67)	0.0782	14.01 (-1.08, 29.09)	0.0687	
>= 10 points	35/166 (21.1)	21.1	42/177 (23.7)	24.1	0.89 (0.60, 1.32)	0.5552	-2.98 (-12.25, 6.28)	0.5280	
OCS dose at baseline									0.8833
<10 mg/day	31/115 (27.0)	26.8	29/117 (24.8)	25.2	1.08 (0.70, 1.66)	0.7401	1.66 (-10.07, 13.38)	0.7820	
>=10 mg/day	33/131 (25.2)	25.1	29/129 (22.5)	22.3	1.13 (0.73, 1.74)	0.5900	2.76 (-7.85, 13.37)	0.6098	
Result of type I IFN gene signature test									0.9085
LOW	12/ 45 (26.7)	26.7	12/ 48 (25.0)	25.0	1.06 (0.53, 2.12)	0.8610	1.72 (-16.77, 20.21)	0.8553	
HIGH	52/201 (25.9)	25.7	46/198 (23.2)	23.4	1.11 (0.79, 1.57)	0.5432	2.31 (-6.44, 11.06)	0.6047	
Age (years)									0.6935
<= 65	62/239 (25.9)	25.7	57/243 (23.5)	23.5	1.11 (0.81, 1.51)	0.5266	2.28 (-5.70, 10.27)	0.5751	
> 65	2/ 7 (28.6)	29.5	1/ 3 (33.3)	34.1	0.78 (0.14, 4.31)	0.7757	-4.55 (-71.22, 62.13)	0.8937	
Sex									0.1156
male	3/ 23 (13.0)	12.5	7/ 20 (35.0)	34.1	0.41 (0.11, 1.52)	0.1821	-21.53 (-48.83, 5.76)	0.1221	
female	61/223 (27.4)	27.2	51/226 (22.6)	22.8	1.21 (0.88, 1.67)	0.2448	4.43 (-3.86, 12.73)	0.2947	
Race									0.9726
White	46/160 (28.8)	28.9	46/174 (26.4)	26.4	1.09 (0.77, 1.54)	0.6249	2.53 (-7.38, 12.44)	0.6163	
Black	8/ 33 (24.2)	23.2	7/ 32 (21.9)	21.8	1.07 (0.42, 2.77)	0.8857	1.46 (-20.98, 23.89)	0.8987	
Other	6/ 45 (13.3)	13.3	5/ 37 (13.5)	13.3	0.94 (0.29, 3.02)	0.9204	-0.04 (-17.19, 17.10)	0.9959	
Ethnicity									0.8359
Hispanic/Latino	15/ 50 (30.0)	30.0	15/ 56 (26.8)	26.7	1.12 (0.61, 2.06)	0.7130	3.25 (-14.42, 20.93)	0.7182	
Non-hispanic/Latino	45/188 (23.9)	23.8	43/187 (23.0)	22.9	1.04 (0.72, 1.50)	0.8339	0.91 (-8.08, 9.89)	0.8429	
Geographic region									0.5753
EU	30/ 92 (32.6)	33.1	24/ 89 (27.0)	25.9	1.23 (0.78, 1.94)	0.3791	7.15 (-6.25, 20.55)	0.2957	
non-EU	34/154 (22.1)	22.4	34/157 (21.7)	21.3	1.03 (0.67, 1.58)	0.9037	1.13 (-8.44, 10.69)	0.8176	
Onset of disease									0.3162
Paediatric	4/ 19 (21.1)	19.6	0/ 12 (0.0)	0.0	3.09 (0.39, 24.33)	0.2835	19.58 (-11.22, 50.38)	0.2128	
Adult	60/227 (26.4)	26.3	58/234 (24.8)	25.0	1.06 (0.78, 1.45)	0.6963	1.34 (-6.91, 9.58)	0.7504	
ADA result									0.8198
Negative	60/226 (26.5)	26.4	53/223 (23.8)	24.0	1.12 (0.81, 1.54)	0.4885	2.37 (-5.99, 10.73)	0.5785	
Positive (At any time)	4/ 19 (21.1)	21.5	5/ 23 (21.7)	22.2	0.97 (0.30, 3.15)	0.9620	-0.73 (-29.28, 27.82)	0.9602	
BMI (kg/m2) at enrolment									0.7202
< 30	41/159 (25.8)	25.9	43/176 (24.4)	24.3	1.06 (0.73, 1.53)	0.7698	1.60 (-8.04, 11.24)	0.7446	
>= 30	23/ 87 (26.4)	26.8	15/ 70 (21.4)	21.7	1.20 (0.68, 2.10)	0.5355	5.12 (-8.77, 19.01)	0.4698	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Vitality Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 52	Number of subjects with events, n (%)	62 (25.2)	46 (18.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.35 (0.96, 1.92)	
	p-value	0.0869	
	Odds Ratio (95% CI)	1.47 (0.95, 2.28)	
	p-value	0.0831	
	Risk Difference (95% CI)	6.52 (-0.80, 13.84)	
	p-value	0.0810	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.35 (0.96, 1.88)	
	p-value	0.0834	
	Odds Ratio (95% CI)	1.46 (0.95, 2.26)	
	p-value	0.0841	
	Risk Difference (95% CI)	6.44 (-0.82, 13.70)	
	p-value	0.0822	
	CMH approach		
	Response rate	24.9	18.6
	Difference in response rates (95% CI)	6.26 (-1.37, 13.89)	
	p-value	0.1078	
	p-Value for test for heterogenity between studies	0.8308	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SF-36 v2.0 Acute response rate at week 52 - Vitality Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.1776
< 10 points	27/ 80 (33.8)	34.2	13/ 69 (18.8)	18.7	1.83 (1.03, 3.25)	0.0391	15.51 (0.83, 30.19)	0.0383	
>= 10 points	35/166 (21.1)	21.0	33/177 (18.6)	18.8	1.12 (0.73, 1.71)	0.6016	2.21 (-6.73, 11.15)	0.6284	
OCS dose at baseline									0.8743
<10 mg/day	29/115 (25.2)	25.0	21/117 (17.9)	18.1	1.39 (0.84, 2.29)	0.1992	6.89 (-4.38, 18.16)	0.2311	
>=10 mg/day	33/131 (25.2)	25.0	25/129 (19.4)	18.8	1.32 (0.83, 2.07)	0.2387	6.24 (-4.02, 16.50)	0.2335	
Result of type I IFN gene signature test									0.1404
LOW	10/ 45 (22.2)	22.3	13/ 48 (27.1)	27.0	0.85 (0.42, 1.71)	0.6403	-4.69 (-22.79, 13.41)	0.6116	
HIGH	52/201 (25.9)	25.5	33/198 (16.7)	16.7	1.55 (1.05, 2.28)	0.0276	8.84 (0.42, 17.25)	0.0395	
Age (years)									0.5332
<= 65	60/239 (25.1)	24.7	45/243 (18.5)	18.3	1.36 (0.96, 1.91)	0.0793	6.42 (-1.26, 14.11)	0.1015	
> 65	2/ 7 (28.6)	29.5	1/ 3 (33.3)	34.1	0.78 (0.14, 4.31)	0.7757	-4.55 (-71.22, 62.13)	0.8937	
Sex									0.8609
male	6/ 23 (26.1)	25.1	4/ 20 (20.0)	19.3	1.20 (0.35, 4.18)	0.7709	5.78 (-21.59, 33.14)	0.6791	
female	56/223 (25.1)	24.8	42/226 (18.6)	18.5	1.35 (0.95, 1.92)	0.0945	6.32 (-1.67, 14.31)	0.1209	
Race									0.9883
White	46/160 (28.8)	28.8	36/174 (20.7)	20.7	1.40 (0.96, 2.05)	0.0784	8.15 (-1.50, 17.80)	0.0978	
Black	11/ 33 (33.3)	32.3	7/ 32 (21.9)	23.3	1.38 (0.61, 3.12)	0.4346	9.04 (-14.26, 32.35)	0.4471	
Other	4/ 45 (8.9)	9.0	2/ 37 (5.4)	5.4	1.60 (0.29, 8.73)	0.5881	3.60 (-11.60, 18.79)	0.6425	
Ethnicity									0.9508
Hispanic/Latino	10/ 50 (20.0)	20.2	8/ 56 (14.3)	14.4	1.41 (0.59, 3.37)	0.4364	5.84 (-9.81, 21.49)	0.4647	
Non-hispanic/Latino	51/188 (27.1)	26.6	37/187 (19.8)	19.6	1.37 (0.95, 1.98)	0.0947	7.08 (-1.75, 15.92)	0.1161	
Geographic region									0.4471
EU	25/ 92 (27.2)	28.6	22/ 89 (24.7)	23.9	1.21 (0.75, 1.95)	0.4371	4.72 (-8.26, 17.71)	0.4759	
non-EU	37/154 (24.0)	23.7	24/157 (15.3)	15.0	1.57 (0.98, 2.50)	0.0592	8.68 (-0.62, 17.99)	0.0675	
Onset of disease									0.9694
Paediatric	3/ 19 (15.8)	15.2	1/ 12 (8.3)	7.4	1.40 (0.20, 9.53)	0.7324	7.79 (-23.86, 39.43)	0.6296	
Adult	59/227 (26.0)	25.7	45/234 (19.2)	19.2	1.35 (0.96, 1.89)	0.0881	6.42 (-1.56, 14.39)	0.1150	
ADA result									0.6350
Negative	58/226 (25.7)	25.3	44/223 (19.7)	19.7	1.31 (0.93, 1.85)	0.1224	5.62 (-2.48, 13.73)	0.1740	
Positive (At any time)	4/ 19 (21.1)	21.5	2/ 23 (8.7)	10.9	1.87 (0.45, 7.85)	0.3904	10.55 (-16.79, 37.88)	0.4496	
BMI (kg/m2) at enrolment									0.8385
< 30	38/159 (23.9)	24.3	31/176 (17.6)	17.1	1.36 (0.89, 2.08)	0.1522	7.16 (-1.93, 16.25)	0.1228	
>= 30	24/ 87 (27.6)	27.4	15/ 70 (21.4)	21.5	1.26 (0.71, 2.26)	0.4292	5.93 (-8.00, 19.87)	0.4041	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
C-SSRS Suicidal ideation or behaviour
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
On-treatment/Follow-Up	Number of subjects with events, n (%)	5 (2.0)	5 (2.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.19 (0.31, 4.58)	
	p-value	0.8037	
	Odds Ratio (95% CI)	1.19 (0.31, 4.53)	
	p-value	0.7958	
	Risk Difference (95% CI)	0.32 (-2.07, 2.70)	
	p-value	0.7956	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.88 (0.25, 3.17)	
	p-value	0.8511	
	Odds Ratio (95% CI)	0.89 (0.24, 3.30)	
	p-value	0.8609	
	Risk Difference (95% CI)	0.02 (-2.46, 2.50)	
	p-value	0.9870	
	CMH approach		
	Response rate	2.0	2.0
	Difference in response rates (95% CI)	0.00 (-4.92, 4.93)	
	p-value	0.9993	
	p-Value for test for heterogenity between studies	0.2203	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
C-SSRS Suicidal ideation or behaviour - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9022
< 10 points	1/ 80 (1.3)	1.4	1/ 69 (1.4)	1.4	0.78 (0.05, 12.00)	0.8589	0.00 (-9.39, 9.39)	1.0000	
>= 10 points	4/166 (2.4)	2.3	4/177 (2.3)	2.1	0.95 (0.22, 4.09)	0.9428	0.16 (-5.50, 5.81)	0.9561	
OCS dose at baseline									0.5837
<10 mg/day	3/115 (2.6)	2.5	2/117 (1.7)	1.6	1.25 (0.19, 8.08)	0.8135	0.94 (-6.83, 8.70)	0.8127	
>=10 mg/day	2/131 (1.5)	1.5	3/129 (2.3)	2.4	0.61 (0.11, 3.53)	0.5828	-0.94 (-7.14, 5.26)	0.7664	
Result of type I IFN gene signature test									0.2554
LOW	0/ 45 (0.0)	0.0	2/ 48 (4.2)	4.2	0.21 (0.01, 4.12)	0.3029	-4.21 (-15.86, 7.43)	0.4782	
HIGH	5/201 (2.5)	2.5	3/198 (1.5)	1.5	1.41 (0.35, 5.70)	0.6300	0.99 (-4.44, 6.42)	0.7200	
Age (years)									NE
<= 65	5/239 (2.1)	2.1	5/243 (2.1)	2.0	0.89 (0.25, 3.21)	0.8647	0.06 (-4.96, 5.09)	0.9803	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-62.98, 62.98)	1.0000	
Sex									NE
male	0/ 23 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-20.84, 20.84)	1.0000	
female	5/223 (2.2)	2.2	5/226 (2.2)	2.2	0.88 (0.25, 3.16)	0.8495	0.02 (-5.31, 5.36)	0.9938	
Race									0.4470
White	4/160 (2.5)	2.3	3/174 (1.7)	1.6	1.31 (0.32, 5.35)	0.7077	0.71 (-5.62, 7.03)	0.8261	
Black	1/ 33 (3.0)	2.5	0/ 32 (0.0)	0.0	1.96 (0.09, 44.92)	0.6747	2.53 (-13.38, 18.44)	0.7555	
Other	0/ 45 (0.0)	0.0	2/ 37 (5.4)	5.2	0.18 (0.01, 3.50)	0.2553	-5.25 (-18.59, 8.09)	0.4407	
Ethnicity									0.2856
Hispanic/Latino	0/ 50 (0.0)	0.0	2/ 56 (3.6)	3.5	0.24 (0.01, 4.71)	0.3442	-3.47 (-13.80, 6.86)	0.5104	
Non-hispanic/Latino	5/188 (2.7)	2.5	3/187 (1.6)	1.6	1.43 (0.35, 5.75)	0.6182	0.85 (-4.90, 6.60)	0.7714	
Geographic region									0.5533
EU	1/ 92 (1.1)	0.9	0/ 89 (0.0)	0.0	2.22 (0.09, 52.78)	0.6224	0.95 (-5.15, 7.05)	0.7603	
non-EU	4/154 (2.6)	2.5	5/157 (3.2)	3.0	0.78 (0.19, 3.21)	0.7257	-0.48 (-6.83, 5.87)	0.8819	
Onset of disease									0.4888
Paediatric	1/ 19 (5.3)	6.5	0/ 12 (0.0)	0.0	2.67 (0.13, 56.63)	0.5293	6.51 (-22.87, 35.89)	0.6642	
Adult	4/227 (1.8)	1.8	5/234 (2.1)	2.1	0.83 (0.23, 3.00)	0.7721	-0.31 (-5.48, 4.86)	0.9051	
ADA result									NE
Negative	5/226 (2.2)	2.1	5/223 (2.2)	2.2	0.85 (0.24, 3.05)	0.8046	-0.10 (-5.46, 5.26)	0.9711	
Positive (At any time)	0/ 19 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-21.63, 21.63)	1.0000	
BMI (kg/m2) at enrolment									0.3724
< 30	2/159 (1.3)	1.3	4/176 (2.3)	2.4	0.52 (0.10, 2.78)	0.4478	-1.13 (-6.79, 4.52)	0.6943	
>= 30	3/ 87 (3.4)	3.3	1/ 70 (1.4)	1.3	1.73 (0.23, 13.04)	0.5962	2.00 (-7.58, 11.57)	0.6830	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Modified SELENA Flare Index based flares - mild/moderate flare
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
at least once during study	Number of subjects with events, n (%)	73 (29.7)	84 (34.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.88 (0.67, 1.14)	
	p-value	0.3327	
	Odds Ratio (95% CI)	0.83 (0.57, 1.21)	
	p-value	0.3297	
	Risk Difference (95% CI)	-4.15 (-12.50, 4.19)	
	p-value	0.3291	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.87 (0.67, 1.12)	
	p-value	0.2818	
	Odds Ratio (95% CI)	0.82 (0.56, 1.19)	
	p-value	0.2931	
	Risk Difference (95% CI)	-4.42 (-12.64, 3.79)	
	p-value	0.2914	
	CMH approach		
	Response rate	29.5	33.8
	Difference in response rates (95% CI)	-4.27 (-12.57, 4.04)	
	p-value	0.3142	
	p-Value for test for heterogenity between studies	0.4997	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Modified SELENA Flare Index based flares - mild/moderate flare - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.0472
< 10 points	29/ 80 (36.3)	35.9	19/ 69 (27.5)	27.9	1.30 (0.81, 2.10)	0.2824	8.03 (-7.13, 23.19)	0.2990	
>= 10 points	44/166 (26.5)	26.7	65/177 (36.7)	36.6	0.73 (0.53, 1.00)	0.0501	-9.91 (-19.84, 0.02)	0.0505	
OCS dose at baseline									0.5953
<10 mg/day	34/115 (29.6)	29.7	37/117 (31.6)	30.5	0.94 (0.63, 1.39)	0.7472	-0.84 (-12.82, 11.14)	0.8912	
>=10 mg/day	39/131 (29.8)	29.9	47/129 (36.4)	36.4	0.81 (0.57, 1.15)	0.2448	-6.41 (-18.00, 5.17)	0.2780	
Result of type I IFN gene signature test									0.4569
LOW	14/ 45 (31.1)	31.2	14/ 48 (29.2)	29.2	1.08 (0.58, 2.00)	0.8191	2.00 (-17.10, 21.09)	0.8374	
HIGH	59/201 (29.4)	29.1	70/198 (35.4)	34.9	0.83 (0.62, 1.10)	0.1984	-5.74 (-14.96, 3.49)	0.2228	
Age (years)									0.6179
<= 65	72/239 (30.1)	29.9	83/243 (34.2)	33.9	0.88 (0.68, 1.14)	0.3367	-3.95 (-12.37, 4.47)	0.3582	
> 65	1/ 7 (14.3)	13.6	1/ 3 (33.3)	31.8	0.53 (0.08, 3.76)	0.5280	-18.18 (-82.55, 46.19)	0.5798	
Sex									0.3326
male	4/ 23 (17.4)	17.5	7/ 20 (35.0)	34.1	0.52 (0.17, 1.56)	0.2402	-16.58 (-44.55, 11.38)	0.2451	
female	69/223 (30.9)	30.7	77/226 (34.1)	33.8	0.91 (0.69, 1.18)	0.4635	-3.08 (-11.81, 5.65)	0.4892	
Race									0.2561
White	42/160 (26.3)	25.6	58/174 (33.3)	33.2	0.78 (0.56, 1.09)	0.1509	-7.57 (-17.55, 2.40)	0.1365	
Black	15/ 33 (45.5)	45.5	10/ 32 (31.3)	32.2	1.41 (0.75, 2.68)	0.2879	13.26 (-11.20, 37.72)	0.2879	
Other	13/ 45 (28.9)	29.2	14/ 37 (37.8)	37.5	0.78 (0.43, 1.43)	0.4227	-8.28 (-28.97, 12.42)	0.4332	
Ethnicity									0.5316
Hispanic/Latino	13/ 50 (26.0)	26.2	20/ 56 (35.7)	35.4	0.74 (0.42, 1.32)	0.3111	-9.17 (-26.87, 8.54)	0.3102	
Non-hispanic/Latino	57/188 (30.3)	30.3	62/187 (33.2)	33.1	0.91 (0.68, 1.23)	0.5557	-2.76 (-12.33, 6.82)	0.5726	
Geographic region									0.0645
EU	15/ 92 (16.3)	16.1	25/ 89 (28.1)	28.8	0.55 (0.31, 0.98)	0.0414	-12.70 (-25.21, -0.20)	0.0465	
non-EU	58/154 (37.7)	37.0	59/157 (37.6)	36.8	1.01 (0.76, 1.35)	0.9470	0.26 (-10.40, 10.91)	0.9624	
Onset of disease									0.8891
Paediatric	8/ 19 (42.1)	43.5	5/ 12 (41.7)	43.6	0.90 (0.39, 2.09)	0.8139	-0.17 (-36.20, 35.86)	0.9924	
Adult	65/227 (28.6)	28.4	79/234 (33.8)	33.4	0.85 (0.65, 1.12)	0.2409	-5.01 (-13.53, 3.50)	0.2484	
ADA result									0.2642
Negative	69/226 (30.5)	30.5	72/223 (32.3)	31.9	0.94 (0.71, 1.24)	0.6574	-1.48 (-10.19, 7.22)	0.7386	
Positive (At any time)	4/ 19 (21.1)	24.0	12/ 23 (52.2)	50.2	0.56 (0.23, 1.33)	0.1902	-26.18 (-55.63, 3.26)	0.0814	
BMI (kg/m2) at enrolment									0.1946
< 30	38/159 (23.9)	23.7	57/176 (32.4)	32.0	0.73 (0.52, 1.04)	0.0821	-8.38 (-18.06, 1.31)	0.0899	
>= 30	35/ 87 (40.2)	40.4	27/ 70 (38.6)	38.4	1.04 (0.70, 1.54)	0.8446	1.99 (-13.34, 17.32)	0.7991	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Modified SELENA Flare Index based flares - severe flare
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
at least once during study	Number of subjects with events, n (%)	5 (2.0)	13 (5.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.40 (0.15, 1.09)	
	p-value	0.0745	
	Odds Ratio (95% CI)	0.39 (0.14, 1.10)	
	p-value	0.0762	
	Risk Difference (95% CI)	-3.15 (-6.50, 0.20)	
	p-value	0.0654	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.39 (0.14, 1.09)	
	p-value	0.0737	
	Odds Ratio (95% CI)	0.38 (0.13, 1.09)	
	p-value	0.0718	
	Risk Difference (95% CI)	-3.25 (-6.56, 0.06)	
	p-value	0.0541	
	CMH approach		
	Response rate	2.1	5.4
	Difference in response rates (95% CI)	-3.28 (-8.63, 2.08)	
	p-value	0.2301	
	p-Value for test for heterogenity between studies	0.5741	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
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Modified SELENA Flare Index based flares - severe flare - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.7947
< 10 points	1/ 80 (1.3)	1.4	2/ 69 (2.9)	3.1	0.53 (0.07, 4.21)	0.5492	-1.71 (-11.47, 8.05)	0.7315	
>= 10 points	4/166 (2.4)	2.5	11/177 (6.2)	6.3	0.39 (0.13, 1.20)	0.0997	-3.82 (-10.16, 2.53)	0.2381	
OCS dose at baseline									0.2374
<10 mg/day	2/115 (1.7)	1.9	2/117 (1.7)	1.6	1.10 (0.16, 7.35)	0.9241	0.24 (-7.51, 7.99)	0.9519	
>=10 mg/day	3/131 (2.3)	2.3	11/129 (8.5)	8.7	0.28 (0.08, 0.98)	0.0459	-6.32 (-13.68, 1.04)	0.0924	
Result of type I IFN gene signature test									0.9058
LOW	0/ 45 (0.0)	0.0	1/ 48 (2.1)	2.1	0.35 (0.01, 8.11)	0.5106	-2.11 (-13.27, 9.06)	0.7115	
HIGH	5/201 (2.5)	2.6	12/198 (6.1)	6.2	0.42 (0.15, 1.20)	0.1060	-3.55 (-9.62, 2.52)	0.2512	
Age (years)									NE
<= 65	5/239 (2.1)	2.2	13/243 (5.3)	5.5	0.40 (0.14, 1.11)	0.0785	-3.33 (-8.78, 2.12)	0.2314	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-62.98, 62.98)	1.0000	
Sex									0.6399
male	2/ 23 (8.7)	8.7	3/ 20 (15.0)	17.1	0.51 (0.09, 2.87)	0.4450	-8.33 (-33.09, 16.42)	0.5094	
female	3/223 (1.3)	1.4	10/226 (4.4)	4.5	0.31 (0.09, 1.10)	0.0689	-3.12 (-8.68, 2.45)	0.2724	
Race									0.7065
White	2/160 (1.3)	1.2	8/174 (4.6)	4.3	0.27 (0.06, 1.26)	0.0953	-3.08 (-9.57, 3.40)	0.3511	
Black	1/ 33 (3.0)	2.5	2/ 32 (6.3)	6.4	0.59 (0.08, 4.50)	0.6088	-3.91 (-21.29, 13.47)	0.6592	
Other	2/ 45 (4.4)	4.6	3/ 37 (8.1)	8.3	0.69 (0.11, 4.32)	0.6932	-3.64 (-18.56, 11.28)	0.6322	
Ethnicity									0.9287
Hispanic/Latino	2/ 50 (4.0)	4.0	5/ 56 (8.9)	8.9	0.45 (0.09, 2.24)	0.3292	-4.92 (-17.33, 7.49)	0.4370	
Non-hispanic/Latino	3/188 (1.6)	1.6	8/187 (4.3)	4.3	0.41 (0.11, 1.59)	0.1974	-2.71 (-8.70, 3.28)	0.3754	
Geographic region									0.5338
EU	0/ 92 (0.0)	0.0	3/ 89 (3.4)	3.3	0.24 (0.03, 2.15)	0.2024	-3.34 (-10.13, 3.44)	0.3346	
non-EU	5/154 (3.2)	3.3	10/157 (6.4)	6.5	0.52 (0.18, 1.50)	0.2269	-3.23 (-10.22, 3.77)	0.3659	
Onset of disease									0.8136
Paediatric	0/ 19 (0.0)	0.0	1/ 12 (8.3)	7.4	0.30 (0.01, 6.29)	0.4353	-7.44 (-37.00, 22.12)	0.6219	
Adult	5/227 (2.2)	2.3	12/234 (5.1)	5.2	0.44 (0.16, 1.22)	0.1153	-2.88 (-8.47, 2.71)	0.3128	
ADA result									0.5671
Negative	5/226 (2.2)	2.3	9/223 (4.0)	4.1	0.56 (0.19, 1.65)	0.2904	-1.79 (-7.42, 3.83)	0.5317	
Positive (At any time)	0/ 19 (0.0)	0.0	4/ 23 (17.4)	16.7	0.28 (0.04, 2.19)	0.2260	-16.73 (-41.37, 7.92)	0.1834	
BMI (kg/m2) at enrolment									0.2956
< 30	5/159 (3.1)	3.2	9/176 (5.1)	5.0	0.64 (0.21, 1.94)	0.4312	-1.83 (-8.19, 4.53)	0.5730	
>= 30	0/ 87 (0.0)	0.0	4/ 70 (5.7)	5.4	0.18 (0.02, 1.51)	0.1132	-5.44 (-15.19, 4.32)	0.2747	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Modified SELENA Flare Index based flares - mild/moderate or severe flare
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
at least once during study	Number of subjects with events, n (%)	75 (30.5)	92 (37.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.82 (0.64, 1.05)	
	p-value	0.1213	
	Odds Ratio (95% CI)	0.74 (0.51, 1.08)	
	p-value	0.1195	
	Risk Difference (95% CI)	-6.74 (-15.21, 1.72)	
	p-value	0.1182	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.82 (0.64, 1.04)	
	p-value	0.1065	
	Odds Ratio (95% CI)	0.73 (0.50, 1.07)	
	p-value	0.1079	
	Risk Difference (95% CI)	-6.86 (-15.19, 1.47)	
	p-value	0.1065	
	CMH approach		
	Response rate	30.4	37.2
	Difference in response rates (95% CI)	-6.83 (-15.23, 1.56)	
	p-value	0.1106	
	p-Value for test for heterogenity between studies	0.8081	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Modified SELENA Flare Index based flares - mild/moderate or severe flare - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.0594
< 10 points	29/ 80 (36.3)	35.9	21/ 69 (30.4)	30.9	1.18 (0.74, 1.86)	0.4851	4.96 (-10.34, 20.27)	0.5251	
>= 10 points	46/166 (27.7)	27.9	71/177 (40.1)	40.1	0.69 (0.51, 0.94)	0.0186	-12.20 (-22.26, -2.15)	0.0173	
OCS dose at baseline									0.3103
<10 mg/day	35/115 (30.4)	30.7	38/117 (32.5)	31.4	0.94 (0.64, 1.38)	0.7635	-0.73 (-12.79, 11.32)	0.9050	
>=10 mg/day	40/131 (30.5)	30.7	54/129 (41.9)	41.9	0.73 (0.52, 1.01)	0.0568	-11.22 (-22.96, 0.53)	0.0612	
Result of type I IFN gene signature test									0.3390
LOW	14/ 45 (31.1)	31.2	14/ 48 (29.2)	29.2	1.08 (0.58, 2.00)	0.8191	2.00 (-17.10, 21.09)	0.8374	
HIGH	61/201 (30.3)	30.2	78/198 (39.4)	39.1	0.77 (0.59, 1.01)	0.0614	-8.91 (-18.26, 0.44)	0.0617	
Age (years)									0.6623
<= 65	74/239 (31.0)	30.8	91/243 (37.4)	37.4	0.83 (0.64, 1.06)	0.1344	-6.56 (-15.07, 1.95)	0.1307	
> 65	1/ 7 (14.3)	13.6	1/ 3 (33.3)	31.8	0.53 (0.08, 3.76)	0.5280	-18.18 (-82.55, 46.19)	0.5798	
Sex									0.1254
male	4/ 23 (17.4)	17.5	9/ 20 (45.0)	45.5	0.38 (0.14, 1.05)	0.0626	-27.97 (-56.42, 0.48)	0.0540	
female	71/223 (31.8)	31.7	83/226 (36.7)	36.6	0.86 (0.67, 1.12)	0.2664	-4.96 (-13.77, 3.85)	0.2701	
Race									0.2564
White	42/160 (26.3)	25.6	62/174 (35.6)	35.3	0.73 (0.53, 1.02)	0.0638	-9.65 (-19.66, 0.36)	0.0588	
Black	15/ 33 (45.5)	45.5	11/ 32 (34.4)	34.7	1.31 (0.71, 2.44)	0.3888	10.80 (-13.79, 35.38)	0.3894	
Other	15/ 45 (33.3)	33.9	17/ 37 (45.9)	45.8	0.77 (0.45, 1.30)	0.3260	-11.92 (-33.09, 9.25)	0.2697	
Ethnicity									0.5348
Hispanic/Latino	14/ 50 (28.0)	28.3	23/ 56 (41.1)	40.8	0.71 (0.42, 1.21)	0.2087	-12.55 (-30.61, 5.50)	0.1730	
Non-hispanic/Latino	58/188 (30.9)	30.9	67/187 (35.8)	35.8	0.86 (0.65, 1.15)	0.3087	-4.98 (-14.64, 4.68)	0.3120	
Geographic region									0.0807
EU	15/ 92 (16.3)	16.1	26/ 89 (29.2)	29.9	0.54 (0.31, 0.94)	0.0302	-13.73 (-26.31, -1.15)	0.0325	
non-EU	60/154 (39.0)	38.5	66/157 (42.0)	41.4	0.94 (0.71, 1.23)	0.6290	-2.87 (-13.64, 7.90)	0.6013	
Onset of disease									0.9419
Paediatric	8/ 19 (42.1)	43.5	6/ 12 (50.0)	51.1	0.83 (0.39, 1.78)	0.6335	-7.61 (-43.98, 28.76)	0.6817	
Adult	67/227 (29.5)	29.3	86/234 (36.8)	36.5	0.81 (0.62, 1.05)	0.1056	-7.19 (-15.79, 1.40)	0.1011	
ADA result									0.1705
Negative	71/226 (31.4)	31.4	78/223 (35.0)	34.8	0.89 (0.69, 1.16)	0.4060	-3.46 (-12.26, 5.33)	0.4402	
Positive (At any time)	4/ 19 (21.1)	24.0	14/ 23 (60.9)	58.5	0.48 (0.21, 1.12)	0.0901	-34.55 (-63.91, -5.19)	0.0211	
BMI (kg/m2) at enrolment									0.2156
< 30	40/159 (25.2)	24.9	63/176 (35.8)	35.4	0.70 (0.50, 0.98)	0.0388	-10.46 (-20.32, -0.60)	0.0376	
>= 30	35/ 87 (40.2)	40.4	29/ 70 (41.4)	41.2	0.97 (0.66, 1.42)	0.8760	-0.78 (-16.20, 14.65)	0.9216	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score Improvement >=15% (of maxmimum value =40)
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
at least once during study	Number of subjects with events, n (%)	214 (87.0)	193 (78.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.11 (1.02, 1.20)	
	p-value	0.0112	
	Odds Ratio (95% CI)	1.88 (1.15, 3.07)	
	p-value	0.0117	
	Risk Difference (95% CI)	8.69 (2.06, 15.32)	
	p-value	0.0102	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.11 (1.03, 1.21)	
	p-value	0.0103	
	Odds Ratio (95% CI)	1.84 (1.13, 2.98)	
	p-value	0.0137	
	Risk Difference (95% CI)	8.57 (1.94, 15.20)	
	p-value	0.0113	
	p-Value for test for heterogenity between studies	0.6049	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BILAG-2004 Score Improvement >=15% (of maxmimum value =40) at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 52	Number of subjects with events, n (%)	138 (56.1)	109 (44.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.26 (1.05, 1.51)	
	p-value	0.0120	
	Odds Ratio (95% CI)	1.59 (1.11, 2.28)	
	p-value	0.0116	
	Risk Difference (95% CI)	11.48 (2.65, 20.31)	
	p-value	0.0108	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.27 (1.06, 1.51)	
	p-value	0.0096	
	Odds Ratio (95% CI)	1.61 (1.12, 2.29)	
	p-value	0.0093	
	Risk Difference (95% CI)	11.75 (2.98, 20.51)	
	p-value	0.0086	
	p-Value for test for heterogenity between studies	0.9425	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (5) response rate at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=245)
Week 52	Number of subjects with events, n (%)	104 (42.3)	72 (29.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.44 (1.13, 1.84)	
	p-value	0.0033	
	Odds Ratio (95% CI)	1.77 (1.21, 2.59)	
	p-value	0.0031	
	Risk Difference (95% CI)	12.96 (4.50, 21.42)	
	p-value	0.0027	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.43 (1.12, 1.83)	
	p-value	0.0036	
	Odds Ratio (95% CI)	1.76 (1.21, 2.56)	
	p-value	0.0031	
	Risk Difference (95% CI)	12.85 (4.46, 21.24)	
	p-value	0.0027	
	CMH approach		
	Response rate	42.1	29.4
	Difference in response rates (95% CI)	12.64 (4.17, 21.11)	
	p-value	0.0034	
	p-Value for test for heterogenity between studies	0.6582	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (6) response rate at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=245)
Week 52	Number of subjects with events, n (%)	102 (41.5)	69 (28.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.47 (1.15, 1.89)	
	p-value	0.0024	
	Odds Ratio (95% CI)	1.81 (1.24, 2.65)	
	p-value	0.0022	
	Risk Difference (95% CI)	13.33 (4.92, 21.75)	
	p-value	0.0019	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.46 (1.14, 1.87)	
	p-value	0.0029	
	Odds Ratio (95% CI)	1.81 (1.24, 2.64)	
	p-value	0.0022	
	Risk Difference (95% CI)	13.26 (4.93, 21.59)	
	p-value	0.0018	
	CMH approach		
	Response rate	41.3	28.3
	Difference in response rates (95% CI)	13.01 (4.58, 21.43)	
	p-value	0.0025	
	p-Value for test for heterogenity between studies	0.3370	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (7) response rate at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=231)	Placebo (N=234)
Week 52	Number of subjects with events, n (%)	71 (30.7)	36 (15.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	2.00 (1.40, 2.86)	
	p-value	0.0001	
	Odds Ratio (95% CI)	2.43 (1.55, 3.82)	
	p-value	0.0001	
	Risk Difference (95% CI)	15.63 (7.94, 23.32)	
	p-value	<.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	2.00 (1.40, 2.86)	
	p-value	0.0001	
	Odds Ratio (95% CI)	2.44 (1.55, 3.83)	
	p-value	0.0001	
	Risk Difference (95% CI)	15.34 (7.81, 22.88)	
	p-value	<.0001	
	CMH approach		
	Response rate	30.9	15.4
	Difference in response rates (95% CI)	15.55 (7.67, 23.43)	
	p-value	0.0001	
	p-Value for test for heterogenity between studies	0.9685	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate sensitivity analysis using modified BILAG at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 52	Number of subjects with events, n (%)	123 (50.0)	85 (34.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.41 (1.14, 1.75)	
	p-value	0.0015	
	Odds Ratio (95% CI)	1.83 (1.27, 2.64)	
	p-value	0.0013	
	Risk Difference (95% CI)	14.45 (5.77, 23.13)	
	p-value	0.0011	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.45 (1.17, 1.79)	
	p-value	0.0007	
	Odds Ratio (95% CI)	1.89 (1.32, 2.72)	
	p-value	0.0006	
	Risk Difference (95% CI)	15.41 (6.80, 24.03)	
	p-value	0.0005	
	CMH approach		
	Response rate	49.3	34.9
	Difference in response rates (95% CI)	14.42 (5.81, 23.02)	
	p-value	0.0010	
	p-Value for test for heterogenity between studies	0.8940	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate sensitivity analysis excluding subjects with no BILAG A or B or PGA VAS score >2.7 at baseline at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=243)	Placebo (N=245)
Week 52	Number of subjects with events, n (%)	114 (46.9)	78 (31.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.43 (1.14, 1.80)	
	p-value	0.0019	
	Odds Ratio (95% CI)	1.82 (1.25, 2.64)	
	p-value	0.0017	
	Risk Difference (95% CI)	14.02 (5.39, 22.66)	
	p-value	0.0015	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.47 (1.17, 1.85)	
	p-value	0.0008	
	Odds Ratio (95% CI)	1.89 (1.31, 2.73)	
	p-value	0.0007	
	Risk Difference (95% CI)	15.02 (6.46, 23.58)	
	p-value	0.0006	
	CMH approach		
	Response rate	46.2	32.3
	Difference in response rates (95% CI)	13.92 (5.33, 22.51)	
	p-value	0.0015	
	p-Value for test for heterogenity between studies	0.7996	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate sensitivity analysis excluding criterion of no restricted medications at week 52
Full analysis set

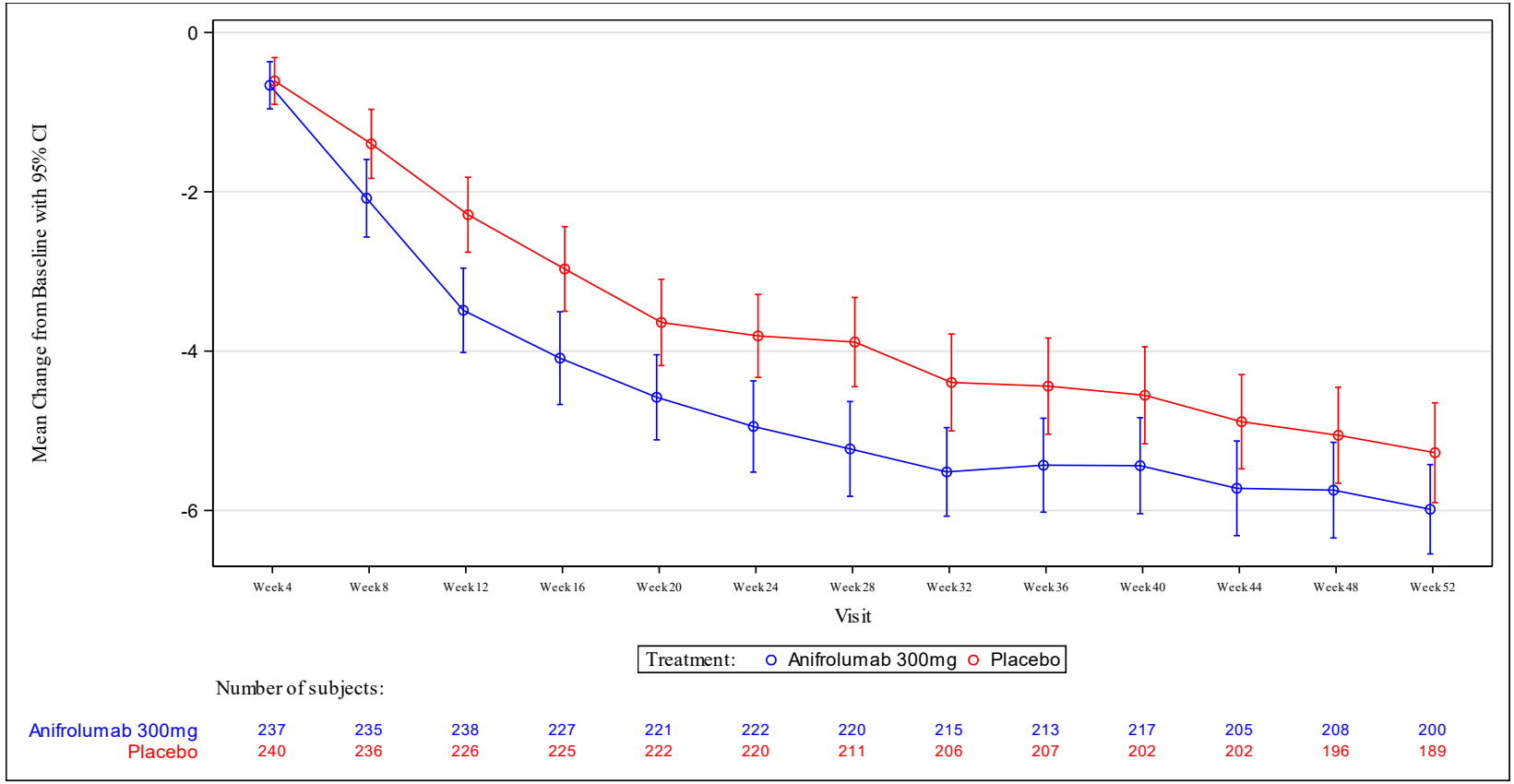
Timepoint		Anifrolumab 300mg (N=246)	Placebo (N=246)
Week 52	Number of subjects with events, n (%)	133 (54.1)	101 (41.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.29 (1.07, 1.56)	
	p-value	0.0083	
	Odds Ratio (95% CI)	1.62 (1.13, 2.32)	
	p-value	0.0081	
	Risk Difference (95% CI)	12.12 (3.23, 21.00)	
	p-value	0.0076	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.32 (1.09, 1.59)	
	p-value	0.0043	
	Odds Ratio (95% CI)	1.69 (1.18, 2.42)	
	p-value	0.0041	
	Risk Difference (95% CI)	12.96 (4.22, 21.70)	
	p-value	0.0036	
	CMH approach		
	Response rate	53.7	41.5
	Difference in response rates (95% CI)	12.22 (3.50, 20.95)	
	p-value	0.0060	
	p-Value for test for heterogenity between studies	0.8985	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - SLEDAI-2K Total Score
Full analysis set

	Anifrolumab 300mg (N=246)				Placebo (N=246)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	246	11.29 (3.76)	0	-	246	11.42 (3.71)	0	-
Week 4	237	10.68 (3.67)	237	-0.66 (2.31)	240	10.72 (3.72)	240	-0.61 (2.31)
Week 8	235	9.26 (4.25)	235	-2.08 (3.79)	236	9.98 (4.11)	236	-1.40 (3.38)
Week 12	238	7.84 (4.02)	238	-3.49 (4.15)	226	9.05 (4.02)	226	-2.29 (3.59)
Week 16	227	7.16 (4.18)	227	-4.09 (4.45)	225	8.36 (4.31)	225	-2.97 (4.04)
Week 20	221	6.53 (3.83)	221	-4.58 (4.03)	222	7.69 (4.08)	222	-3.64 (4.09)
Week 24	222	6.36 (3.99)	222	-4.95 (4.33)	220	7.50 (3.86)	220	-3.81 (3.92)
Week 28	220	6.10 (4.16)	220	-5.23 (4.48)	211	7.38 (3.98)	211	-3.89 (4.13)
Week 32	215	5.84 (3.92)	215	-5.52 (4.14)	206	6.99 (4.21)	206	-4.39 (4.43)
Week 36	213	5.84 (4.16)	213	-5.43 (4.37)	207	6.87 (4.17)	207	-4.44 (4.41)
Week 40	217	5.80 (4.06)	217	-5.44 (4.50)	202	6.63 (4.31)	202	-4.55 (4.39)
Week 44	205	5.45 (3.98)	205	-5.72 (4.31)	202	6.32 (4.03)	202	-4.89 (4.27)
Week 48	208	5.48 (3.99)	208	-5.75 (4.39)	196	6.17 (3.94)	196	-5.06 (4.28)
Week 52	200	5.20 (3.54)	200	-5.99 (4.02)	189	5.98 (3.91)	189	-5.28 (4.36)

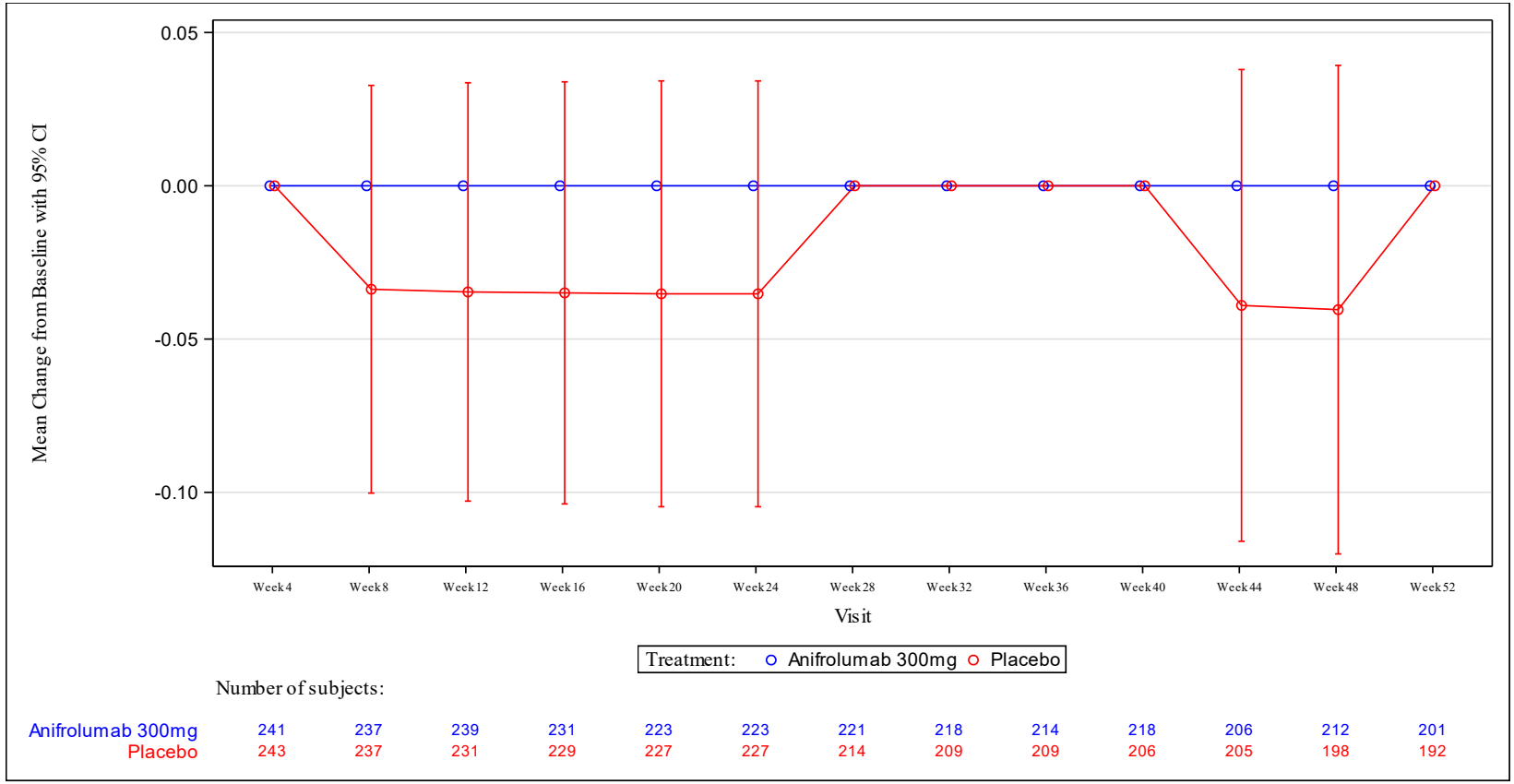
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - SLEDAI-2K Total Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score CNS
Full analysis set

	Anifrolumab 300mg (N=246)				Placebo (N=246)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	246	0.03 (0.51)	0	-	246	0.07 (0.72)	0	-
Week 4	241	0.03 (0.52)	241	0.00 (0.00)	243	0.07 (0.72)	243	0.00 (0.00)
Week 8	237	0.03 (0.52)	237	0.00 (0.00)	237	0.03 (0.52)	237	-0.03 (0.52)
Week 12	239	0.03 (0.52)	239	0.00 (0.00)	231	0.03 (0.53)	231	-0.03 (0.53)
Week 16	231	0.03 (0.53)	231	0.00 (0.00)	229	0.03 (0.53)	229	-0.03 (0.53)
Week 20	223	0.04 (0.54)	223	0.00 (0.00)	227	0.04 (0.53)	227	-0.04 (0.53)
Week 24	223	0.04 (0.54)	223	0.00 (0.00)	227	0.04 (0.53)	227	-0.04 (0.53)
Week 28	221	0.04 (0.54)	221	0.00 (0.00)	214	0.04 (0.55)	214	0.00 (0.00)
Week 32	218	0.04 (0.54)	218	0.00 (0.00)	209	0.00 (0.00)	209	0.00 (0.00)
Week 36	214	0.04 (0.55)	214	0.00 (0.00)	209	0.04 (0.55)	209	0.00 (0.00)
Week 40	218	0.00 (0.00)	218	0.00 (0.00)	206	0.04 (0.56)	206	0.00 (0.00)
Week 44	206	0.04 (0.56)	206	0.00 (0.00)	205	0.00 (0.00)	205	-0.04 (0.56)
Week 48	212	0.04 (0.55)	212	0.00 (0.00)	198	0.00 (0.00)	198	-0.04 (0.57)
Week 52	201	0.04 (0.56)	201	0.00 (0.00)	192	0.00 (0.00)	192	0.00 (0.00)

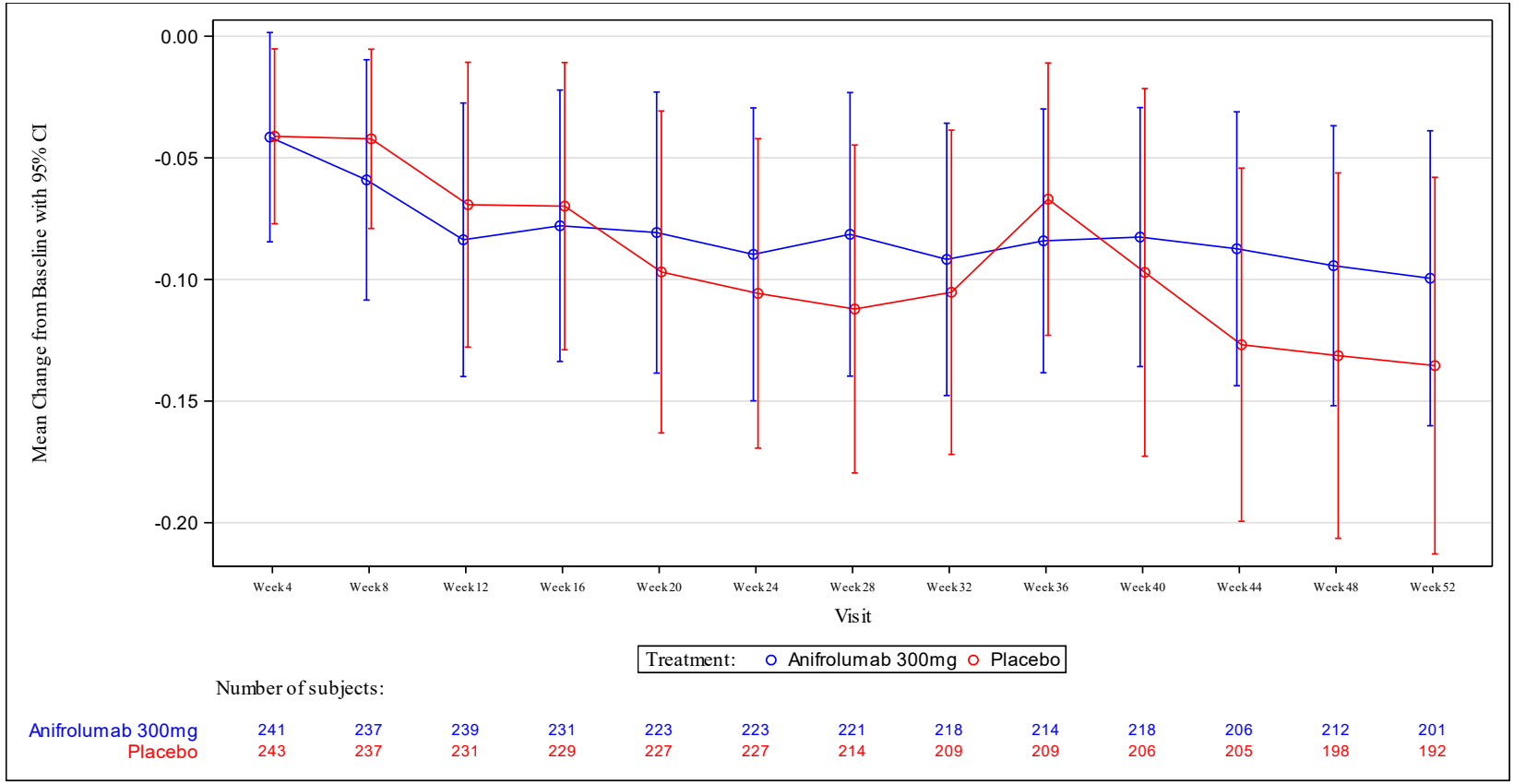
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Total Organ Score CNS
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score CVS and Respiratory
Full analysis set

	Anifrolumab 300mg (N=246)				Placebo (N=246)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	246	0.13 (0.49)	0	-	246	0.15 (0.55)	0	-
Week 4	241	0.09 (0.42)	241	-0.04 (0.34)	243	0.10 (0.43)	243	-0.04 (0.28)
Week 8	237	0.08 (0.38)	237	-0.06 (0.39)	237	0.08 (0.40)	237	-0.04 (0.29)
Week 12	239	0.04 (0.29)	239	-0.08 (0.44)	231	0.07 (0.37)	231	-0.07 (0.45)
Week 16	231	0.04 (0.29)	231	-0.08 (0.43)	229	0.04 (0.29)	229	-0.07 (0.45)
Week 20	223	0.04 (0.27)	223	-0.08 (0.44)	227	0.03 (0.23)	227	-0.10 (0.51)
Week 24	223	0.03 (0.23)	223	-0.09 (0.46)	227	0.02 (0.19)	227	-0.11 (0.49)
Week 28	221	0.04 (0.27)	221	-0.08 (0.44)	214	0.02 (0.19)	214	-0.11 (0.50)
Week 32	218	0.02 (0.19)	218	-0.09 (0.42)	209	0.02 (0.20)	209	-0.11 (0.49)
Week 36	214	0.04 (0.27)	214	-0.08 (0.40)	209	0.03 (0.24)	209	-0.07 (0.41)
Week 40	218	0.04 (0.27)	218	-0.08 (0.40)	206	0.03 (0.24)	206	-0.10 (0.55)
Week 44	206	0.03 (0.24)	206	-0.09 (0.41)	205	0.00 (0.00)	205	-0.13 (0.53)
Week 48	212	0.03 (0.24)	212	-0.09 (0.43)	198	0.00 (0.00)	198	-0.13 (0.54)
Week 52	201	0.02 (0.20)	201	-0.10 (0.44)	192	0.00 (0.00)	192	-0.14 (0.54)

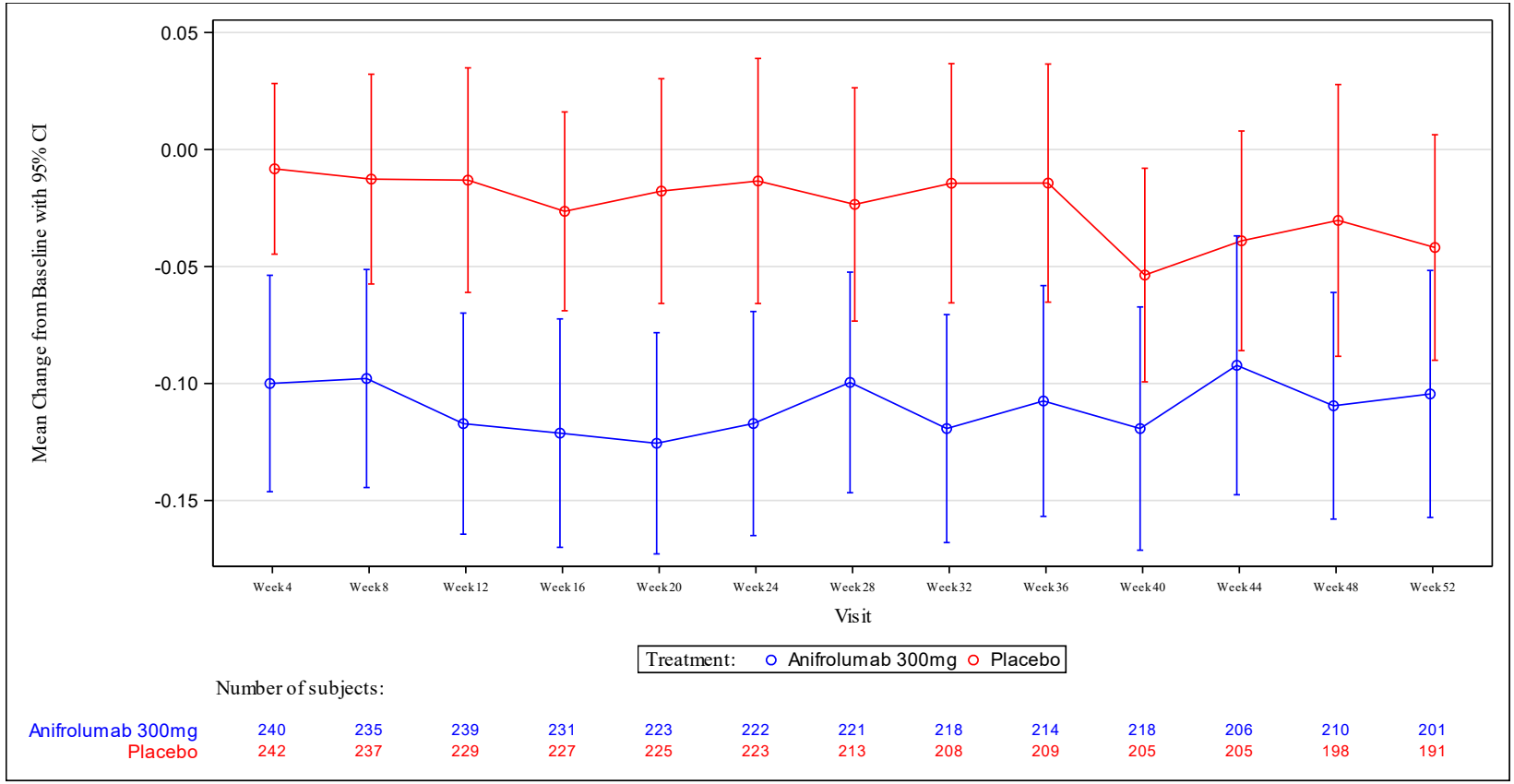
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Total Organ Score CVS and Respiratory
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score Hematological
Full analysis set

	Anifrolumab 300mg (N=246)				Placebo (N=246)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	246	0.15 (0.37)	0	-	246	0.13 (0.36)	0	-
Week 4	240	0.06 (0.23)	240	-0.10 (0.36)	242	0.12 (0.35)	242	-0.01 (0.29)
Week 8	235	0.06 (0.23)	235	-0.10 (0.36)	237	0.11 (0.31)	237	-0.01 (0.35)
Week 12	239	0.04 (0.19)	239	-0.12 (0.37)	229	0.10 (0.35)	229	-0.01 (0.37)
Week 16	231	0.03 (0.18)	231	-0.12 (0.38)	227	0.08 (0.28)	227	-0.03 (0.32)
Week 20	223	0.03 (0.17)	223	-0.13 (0.36)	225	0.10 (0.34)	225	-0.02 (0.37)
Week 24	222	0.04 (0.19)	222	-0.12 (0.36)	223	0.10 (0.33)	223	-0.01 (0.40)
Week 28	221	0.05 (0.22)	221	-0.10 (0.36)	213	0.11 (0.33)	213	-0.02 (0.37)
Week 32	218	0.04 (0.20)	218	-0.12 (0.36)	208	0.10 (0.33)	208	-0.01 (0.37)
Week 36	214	0.03 (0.18)	214	-0.11 (0.37)	209	0.11 (0.34)	209	-0.01 (0.37)
Week 40	218	0.03 (0.18)	218	-0.12 (0.39)	205	0.07 (0.27)	205	-0.05 (0.33)
Week 44	206	0.05 (0.23)	206	-0.09 (0.40)	205	0.08 (0.29)	205	-0.04 (0.34)
Week 48	210	0.04 (0.19)	210	-0.11 (0.36)	198	0.09 (0.35)	198	-0.03 (0.41)
Week 52	201	0.05 (0.22)	201	-0.10 (0.38)	191	0.08 (0.30)	191	-0.04 (0.34)

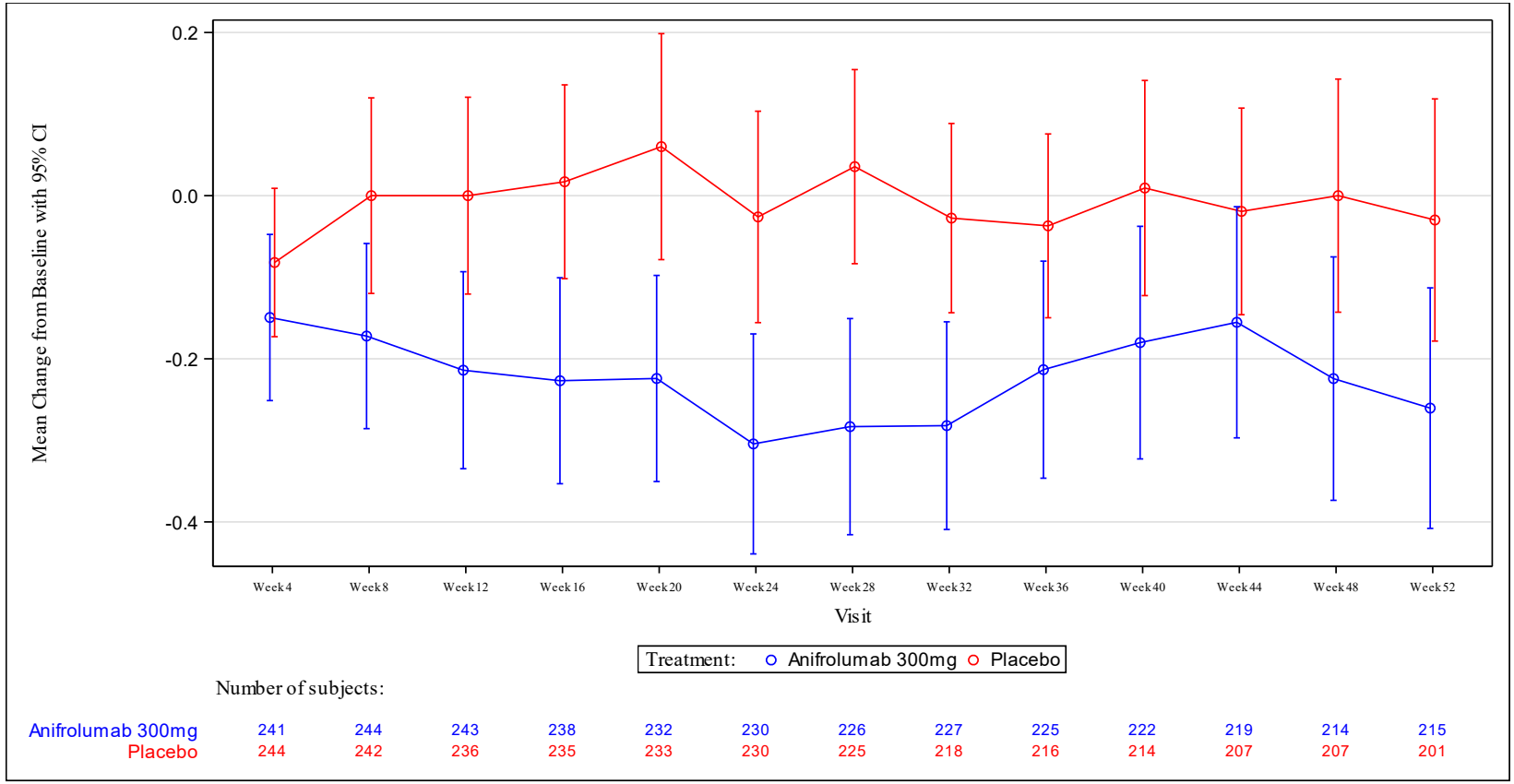
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Total Organ Score Hematological
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score Immunology
Full analysis set

	Anifrolumab 300mg (N=246)				Placebo (N=246)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	246	1.96 (1.61)	0	-	246	1.86 (1.64)	0	-
Week 4	241	1.81 (1.57)	241	-0.15 (0.80)	244	1.76 (1.58)	244	-0.08 (0.72)
Week 8	244	1.79 (1.56)	244	-0.17 (0.90)	242	1.85 (1.62)	242	0.00 (0.95)
Week 12	243	1.74 (1.54)	243	-0.21 (0.96)	236	1.82 (1.57)	236	0.00 (0.94)
Week 16	238	1.72 (1.60)	238	-0.23 (0.99)	235	1.86 (1.65)	235	0.02 (0.92)
Week 20	232	1.76 (1.57)	232	-0.22 (0.98)	233	1.90 (1.67)	233	0.06 (1.07)
Week 24	230	1.67 (1.56)	230	-0.30 (1.04)	230	1.81 (1.63)	230	-0.03 (1.00)
Week 28	226	1.68 (1.56)	226	-0.28 (1.01)	225	1.88 (1.67)	225	0.04 (0.91)
Week 32	227	1.66 (1.59)	227	-0.28 (0.97)	218	1.79 (1.59)	218	-0.03 (0.87)
Week 36	225	1.72 (1.54)	225	-0.21 (1.01)	216	1.78 (1.62)	216	-0.04 (0.84)
Week 40	222	1.79 (1.58)	222	-0.18 (1.08)	214	1.81 (1.60)	214	0.01 (0.98)
Week 44	219	1.84 (1.61)	219	-0.16 (1.06)	207	1.80 (1.63)	207	-0.02 (0.92)
Week 48	214	1.78 (1.56)	214	-0.22 (1.11)	207	1.82 (1.61)	207	0.00 (1.04)
Week 52	215	1.72 (1.59)	215	-0.26 (1.10)	201	1.81 (1.60)	201	-0.03 (1.07)

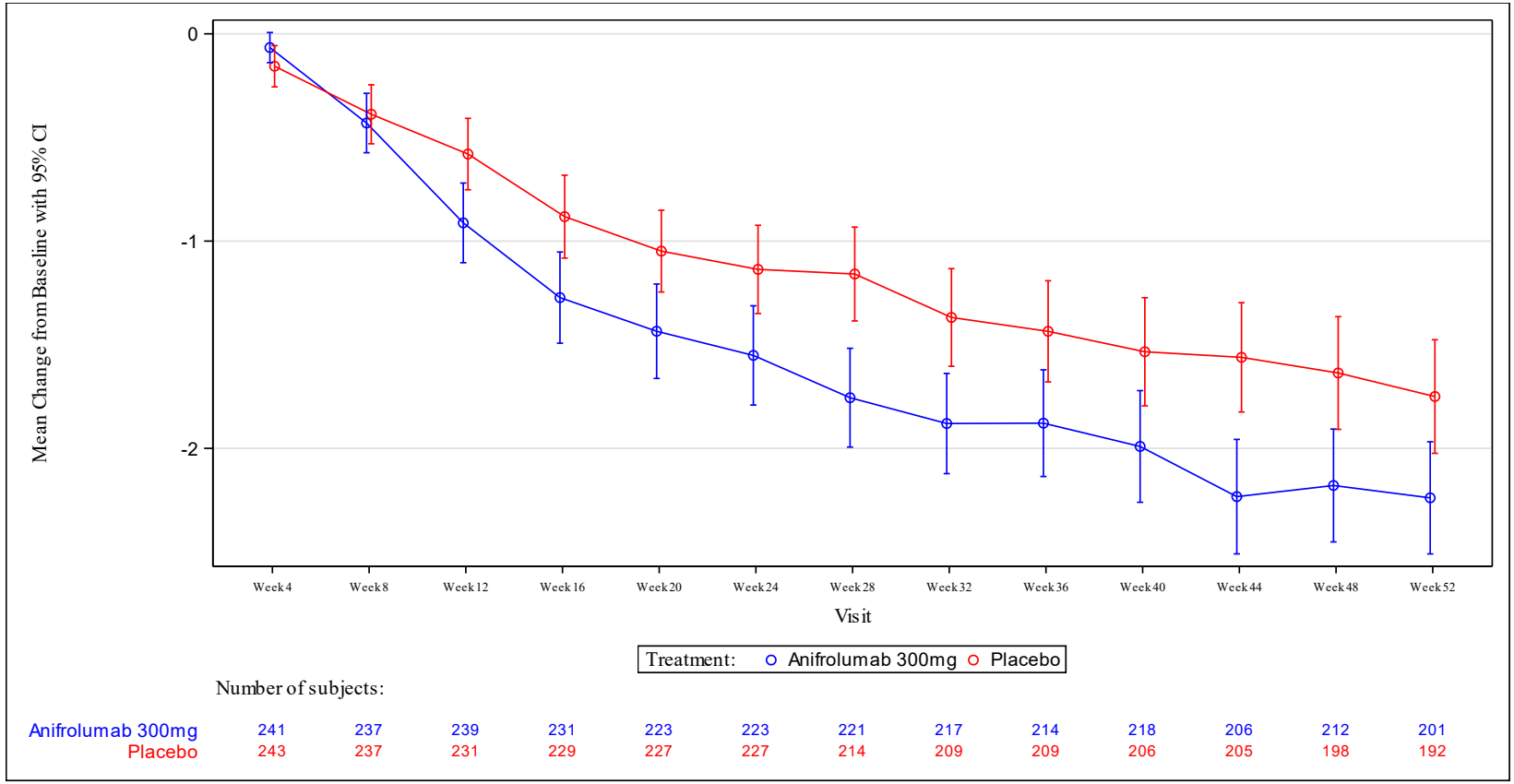
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Total Organ Score Immunology
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score Mucocutaneous
Full analysis set

	Anifrolumab 300mg (N=246)				Placebo (N=246)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	246	4.04 (1.59)	0	-	246	3.97 (1.61)	0	-
Week 4	241	4.00 (1.57)	241	-0.07 (0.57)	243	3.80 (1.62)	243	-0.16 (0.79)
Week 8	237	3.62 (1.61)	237	-0.43 (1.12)	237	3.59 (1.66)	237	-0.39 (1.11)
Week 12	239	3.15 (1.75)	239	-0.91 (1.51)	231	3.34 (1.76)	231	-0.58 (1.33)
Week 16	231	2.81 (1.78)	231	-1.27 (1.70)	229	3.08 (1.80)	229	-0.88 (1.54)
Week 20	223	2.65 (1.75)	223	-1.43 (1.73)	227	2.93 (1.69)	227	-1.05 (1.51)
Week 24	223	2.57 (1.78)	223	-1.55 (1.81)	227	2.87 (1.68)	227	-1.14 (1.63)
Week 28	221	2.33 (1.72)	221	-1.76 (1.80)	214	2.83 (1.71)	214	-1.16 (1.68)
Week 32	217	2.25 (1.70)	217	-1.88 (1.81)	209	2.62 (1.74)	209	-1.37 (1.73)
Week 36	214	2.19 (1.80)	214	-1.88 (1.91)	209	2.54 (1.76)	209	-1.44 (1.79)
Week 40	218	2.06 (1.78)	218	-1.99 (2.02)	206	2.39 (1.76)	206	-1.53 (1.90)
Week 44	206	1.83 (1.71)	206	-2.23 (2.01)	205	2.38 (1.78)	205	-1.56 (1.92)
Week 48	212	1.88 (1.72)	212	-2.18 (2.01)	198	2.31 (1.73)	198	-1.64 (1.94)
Week 52	201	1.81 (1.69)	201	-2.24 (1.94)	192	2.19 (1.71)	192	-1.75 (1.93)

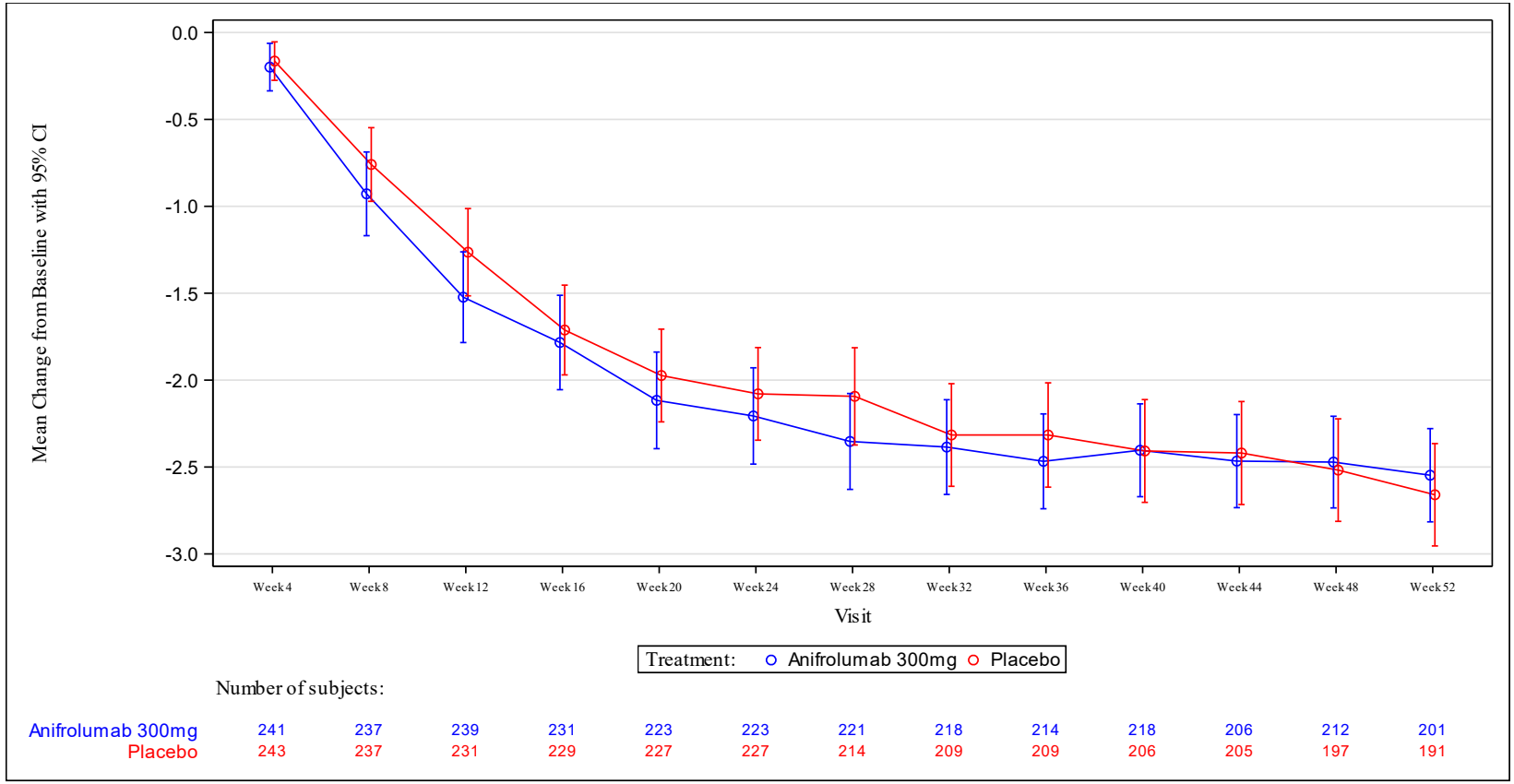
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Total Organ Score Mucocutaneous
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score Musculoskeletal
Full analysis set

	Anifrolumab 300mg (N=246)				Placebo (N=246)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	246	3.71 (1.16)	0	-	246	3.92 (1.05)	0	-
Week 4	241	3.50 (1.37)	241	-0.20 (1.08)	243	3.75 (1.26)	243	-0.16 (0.88)
Week 8	237	2.77 (1.85)	237	-0.93 (1.88)	237	3.16 (1.79)	237	-0.76 (1.66)
Week 12	239	2.19 (1.99)	239	-1.52 (2.05)	231	2.67 (2.03)	231	-1.26 (1.94)
Week 16	231	1.90 (2.04)	231	-1.78 (2.09)	229	2.22 (2.10)	229	-1.71 (1.98)
Week 20	223	1.56 (1.99)	223	-2.12 (2.11)	227	1.94 (2.11)	227	-1.97 (2.04)
Week 24	223	1.49 (1.97)	223	-2.21 (2.10)	227	1.85 (2.10)	227	-2.08 (2.04)
Week 28	221	1.36 (1.94)	221	-2.35 (2.08)	214	1.83 (2.07)	214	-2.09 (2.08)
Week 32	218	1.28 (1.87)	218	-2.39 (2.04)	209	1.61 (2.04)	209	-2.32 (2.17)
Week 36	214	1.21 (1.84)	214	-2.47 (2.02)	209	1.63 (2.12)	209	-2.32 (2.20)
Week 40	218	1.27 (1.86)	218	-2.40 (2.00)	206	1.53 (2.07)	206	-2.41 (2.15)
Week 44	206	1.18 (1.83)	206	-2.47 (1.95)	205	1.52 (2.06)	205	-2.42 (2.15)
Week 48	212	1.21 (1.84)	212	-2.47 (1.95)	197	1.42 (2.04)	197	-2.52 (2.10)
Week 52	201	1.13 (1.81)	201	-2.55 (1.93)	191	1.28 (2.00)	191	-2.66 (2.06)

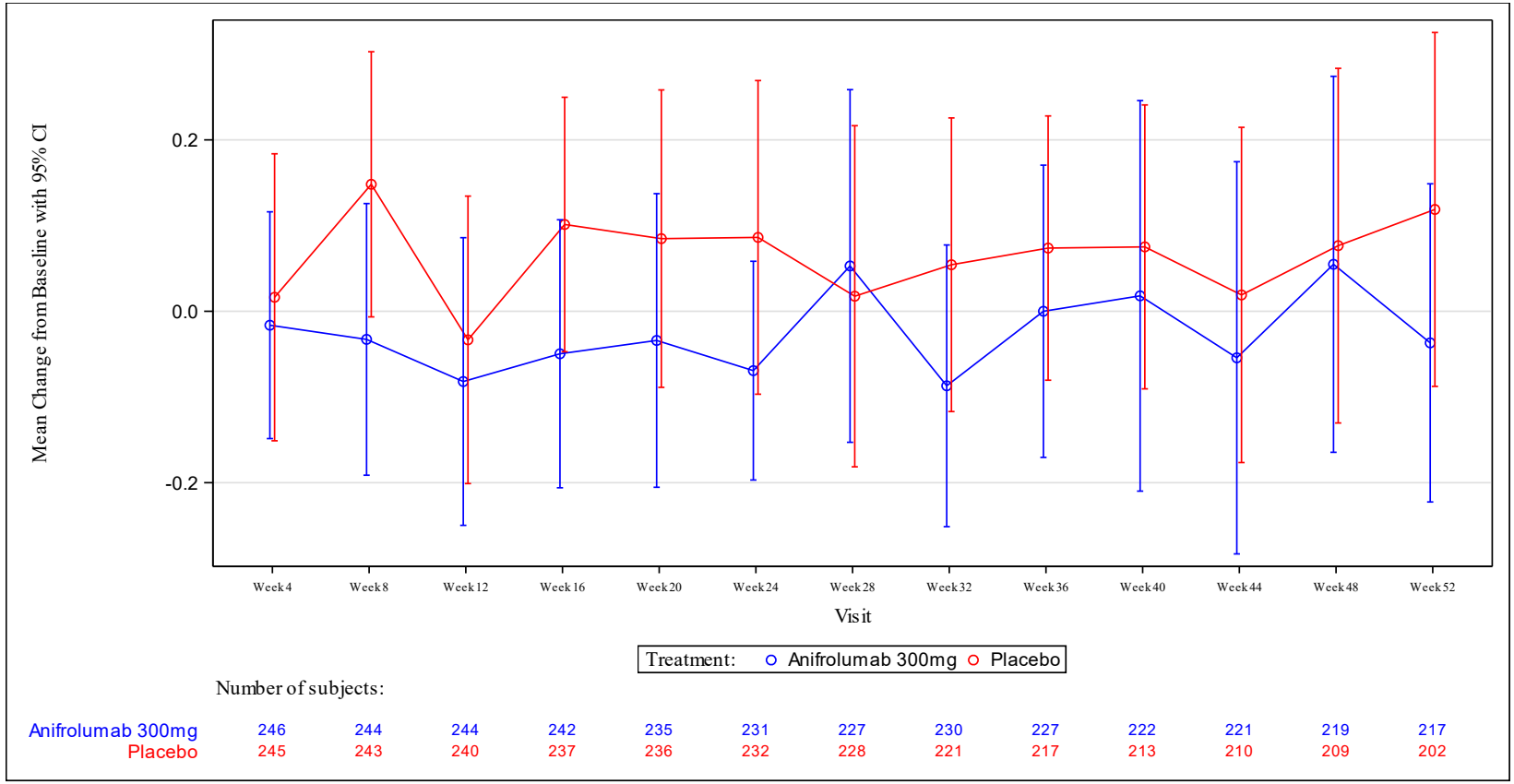
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Total Organ Score Musculoskeletal
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score Renal
Full analysis set

	Anifrolumab 300mg (N=246)				Placebo (N=246)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	246	0.36 (1.45)	0	-	246	0.49 (1.74)	0	-
Week 4	246	0.34 (1.38)	246	-0.02 (1.05)	245	0.51 (1.93)	245	0.02 (1.33)
Week 8	244	0.33 (1.46)	244	-0.03 (1.26)	243	0.64 (2.07)	243	0.15 (1.22)
Week 12	244	0.28 (1.35)	244	-0.08 (1.33)	240	0.42 (1.43)	240	-0.03 (1.32)
Week 16	242	0.31 (1.35)	242	-0.05 (1.23)	237	0.51 (1.77)	237	0.10 (1.16)
Week 20	235	0.29 (1.33)	235	-0.03 (1.33)	236	0.49 (1.72)	236	0.08 (1.35)
Week 24	231	0.24 (0.96)	231	-0.07 (0.98)	232	0.52 (1.83)	232	0.09 (1.41)
Week 28	227	0.35 (1.65)	227	0.05 (1.57)	228	0.46 (1.70)	228	0.02 (1.53)
Week 32	230	0.23 (1.07)	230	-0.09 (1.26)	221	0.43 (1.60)	221	0.05 (1.29)
Week 36	227	0.32 (1.32)	227	0.00 (1.30)	217	0.46 (1.54)	217	0.07 (1.15)
Week 40	222	0.31 (1.47)	222	0.02 (1.72)	213	0.47 (1.69)	213	0.08 (1.23)
Week 44	221	0.27 (1.43)	221	-0.05 (1.73)	210	0.38 (1.66)	210	0.02 (1.44)
Week 48	219	0.37 (1.63)	219	0.05 (1.65)	209	0.44 (1.81)	209	0.08 (1.52)
Week 52	217	0.28 (1.39)	217	-0.04 (1.39)	202	0.46 (1.70)	202	0.12 (1.49)

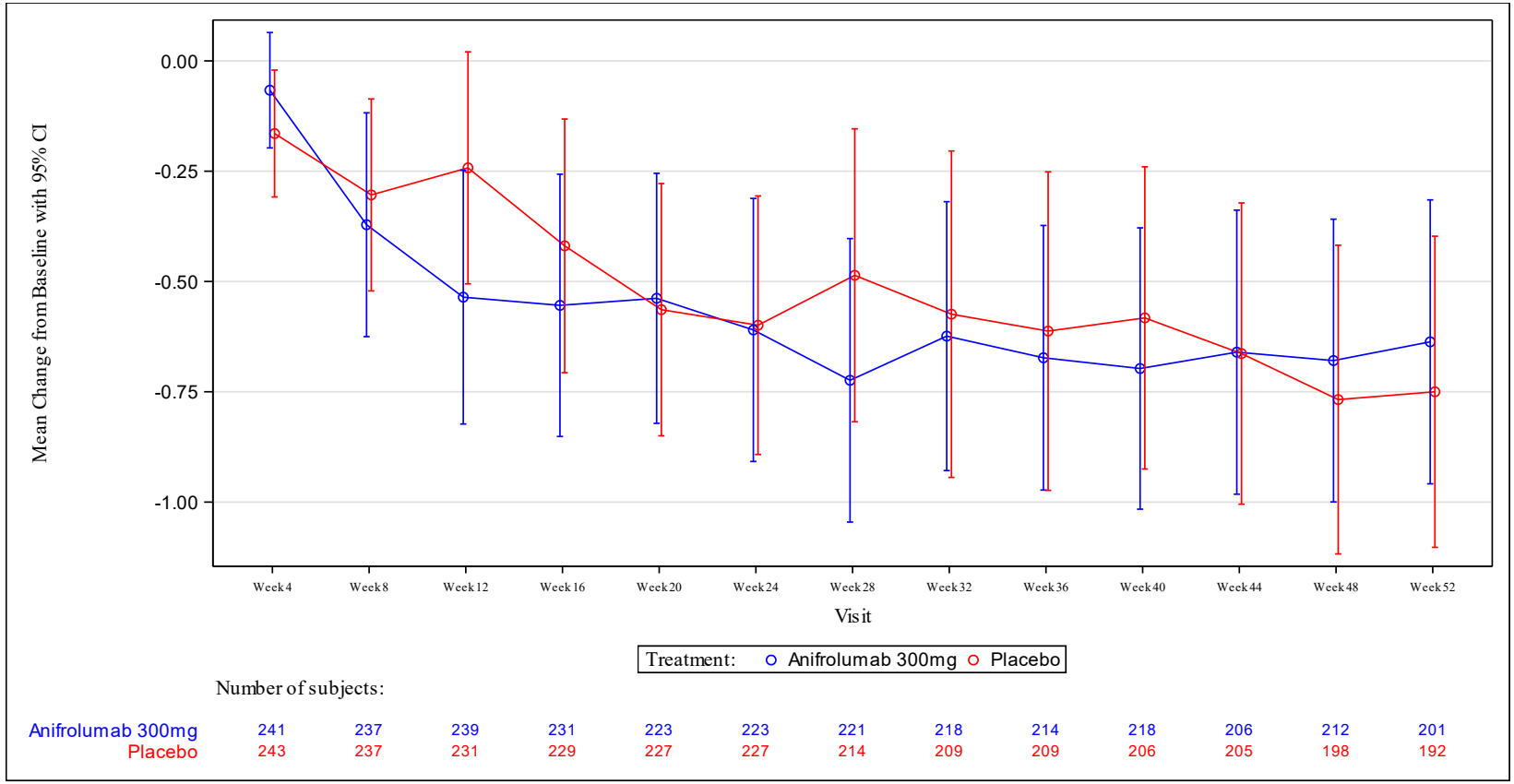
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Total Organ Score Renal
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score Vascular
Full analysis set

	Anifrolumab 300mg (N=246)				Placebo (N=246)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	246	0.91 (2.55)	0	-	246	0.85 (2.46)	0	-
Week 4	241	0.86 (2.49)	241	-0.07 (1.03)	243	0.69 (2.25)	243	-0.16 (1.14)
Week 8	237	0.57 (2.07)	237	-0.37 (1.98)	237	0.57 (2.07)	237	-0.30 (1.70)
Week 12	239	0.37 (1.68)	239	-0.54 (2.26)	231	0.59 (2.09)	231	-0.24 (2.03)
Week 16	231	0.35 (1.63)	231	-0.55 (2.29)	229	0.45 (1.86)	229	-0.42 (2.21)
Week 20	223	0.29 (1.49)	223	-0.54 (2.15)	227	0.32 (1.56)	227	-0.56 (2.19)
Week 24	223	0.32 (1.58)	223	-0.61 (2.26)	227	0.21 (1.29)	227	-0.60 (2.24)
Week 28	221	0.22 (1.30)	221	-0.72 (2.42)	214	0.37 (1.69)	214	-0.49 (2.46)
Week 32	218	0.33 (1.60)	218	-0.62 (2.28)	209	0.34 (1.63)	209	-0.57 (2.71)
Week 36	214	0.26 (1.43)	214	-0.67 (2.23)	209	0.31 (1.54)	209	-0.61 (2.65)
Week 40	218	0.26 (1.41)	218	-0.70 (2.39)	206	0.27 (1.45)	206	-0.58 (2.49)
Week 44	206	0.19 (1.23)	206	-0.66 (2.34)	205	0.16 (1.11)	205	-0.66 (2.48)
Week 48	212	0.23 (1.33)	212	-0.68 (2.37)	198	0.16 (1.13)	198	-0.77 (2.50)
Week 52	201	0.16 (1.12)	201	-0.64 (2.31)	192	0.17 (1.15)	192	-0.75 (2.48)

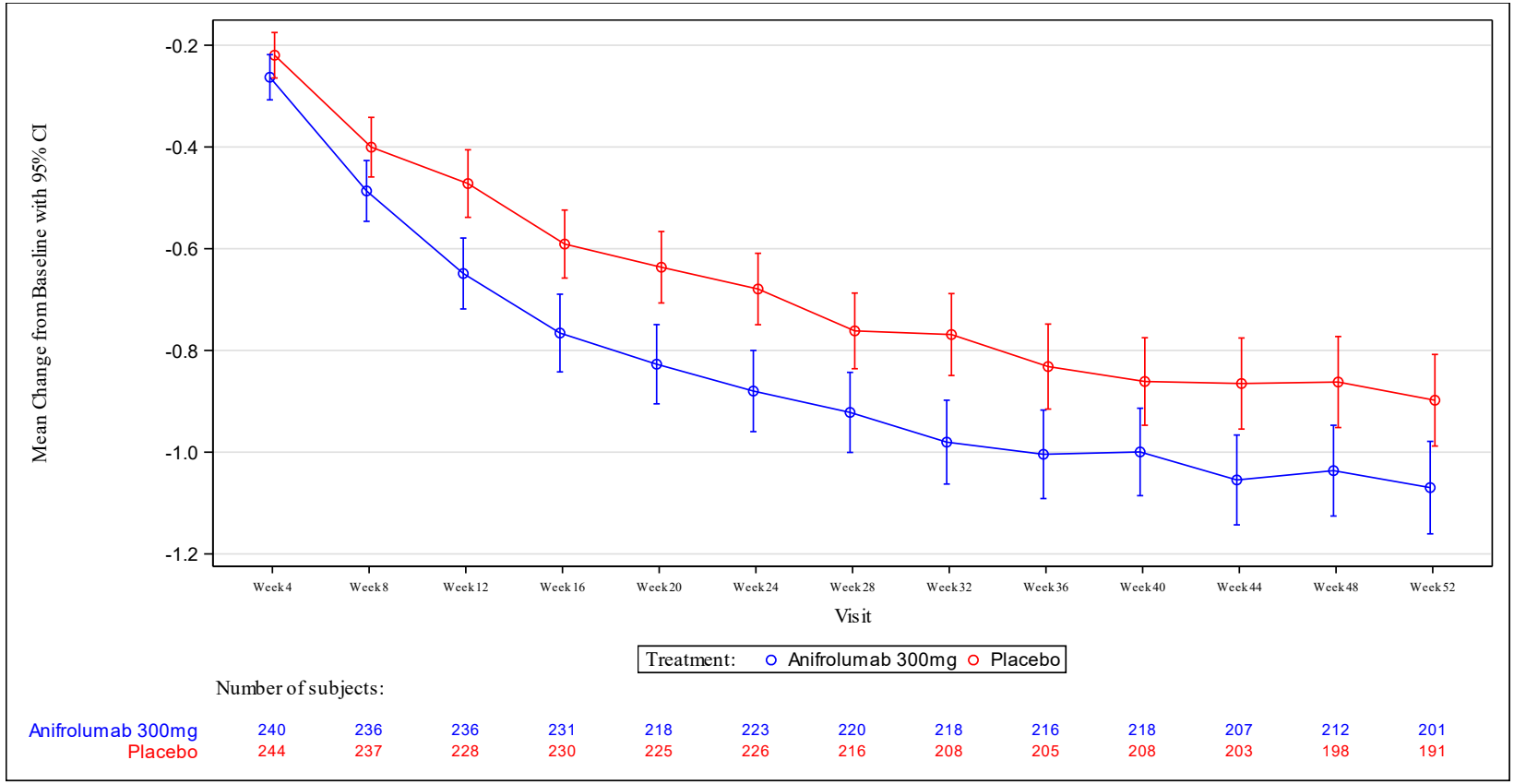
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Total Organ Score Vascular
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - PGA
Full analysis set

	Anifrolumab 300mg (N=246)				Placebo (N=246)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	246	1.77 (0.42)	0	-	246	1.80 (0.38)	0	-
Week 4	240	1.51 (0.52)	240	-0.26 (0.35)	244	1.58 (0.47)	244	-0.22 (0.35)
Week 8	236	1.27 (0.54)	236	-0.49 (0.47)	237	1.41 (0.53)	237	-0.40 (0.46)
Week 12	236	1.12 (0.56)	236	-0.65 (0.54)	228	1.34 (0.53)	228	-0.47 (0.51)
Week 16	231	1.00 (0.59)	231	-0.77 (0.59)	230	1.21 (0.51)	230	-0.59 (0.51)
Week 20	218	0.93 (0.58)	218	-0.83 (0.58)	225	1.17 (0.53)	225	-0.64 (0.53)
Week 24	223	0.88 (0.59)	223	-0.88 (0.60)	226	1.12 (0.52)	226	-0.68 (0.54)
Week 28	220	0.84 (0.59)	220	-0.92 (0.59)	216	1.05 (0.53)	216	-0.76 (0.55)
Week 32	218	0.79 (0.58)	218	-0.98 (0.62)	208	1.04 (0.57)	208	-0.77 (0.59)
Week 36	216	0.77 (0.60)	216	-1.00 (0.65)	205	0.97 (0.57)	205	-0.83 (0.61)
Week 40	218	0.77 (0.59)	218	-1.00 (0.64)	208	0.94 (0.55)	208	-0.86 (0.63)
Week 44	207	0.69 (0.56)	207	-1.05 (0.64)	203	0.95 (0.56)	203	-0.87 (0.65)
Week 48	212	0.73 (0.57)	212	-1.04 (0.66)	198	0.94 (0.57)	198	-0.86 (0.64)
Week 52	201	0.67 (0.55)	201	-1.07 (0.65)	191	0.90 (0.57)	191	-0.90 (0.63)

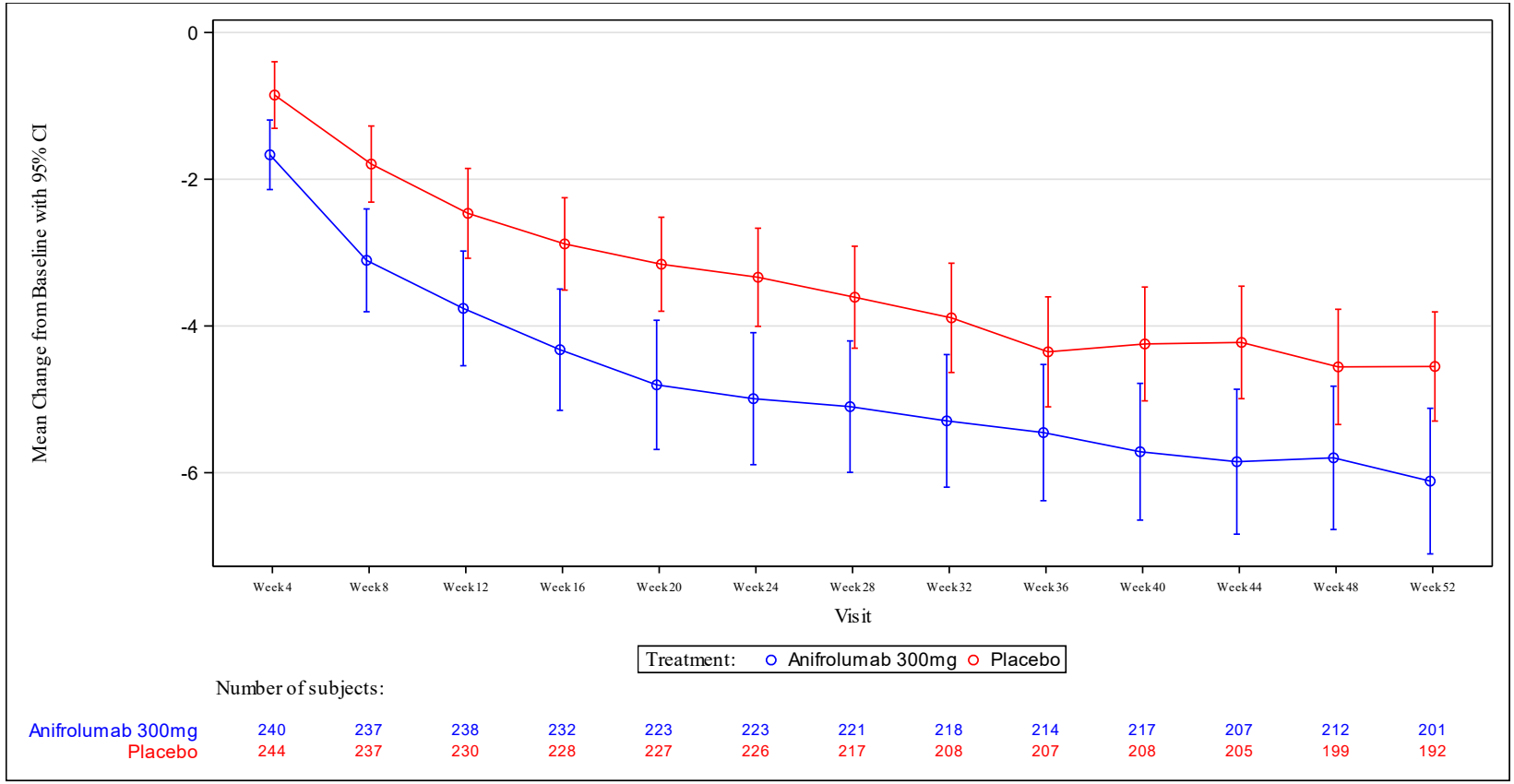
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - PGA
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - CLASI Total Activity Score
Full analysis set

	Anifrolumab 300mg (N=246)				Placebo (N=246)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	246	8.04 (7.46)	0	-	246	8.04 (7.42)	0	-
Week 4	240	6.45 (5.82)	240	-1.67 (3.73)	244	7.21 (7.20)	244	-0.85 (3.60)
Week 8	237	5.01 (4.43)	237	-3.11 (5.48)	237	6.36 (7.15)	237	-1.79 (4.05)
Week 12	238	4.34 (4.30)	238	-3.76 (6.12)	230	5.76 (6.75)	230	-2.47 (4.71)
Week 16	232	3.97 (4.00)	232	-4.32 (6.39)	228	5.22 (6.20)	228	-2.88 (4.82)
Week 20	223	3.47 (3.50)	223	-4.80 (6.67)	227	5.14 (6.49)	227	-3.16 (4.90)
Week 24	223	3.29 (3.66)	223	-4.99 (6.82)	226	4.99 (6.74)	226	-3.34 (5.10)
Week 28	221	3.04 (3.47)	221	-5.10 (6.76)	217	4.62 (6.34)	217	-3.61 (5.19)
Week 32	218	2.89 (3.34)	218	-5.29 (6.77)	208	4.56 (6.56)	208	-3.89 (5.45)
Week 36	214	2.69 (3.24)	214	-5.45 (6.89)	207	4.17 (6.09)	207	-4.35 (5.47)
Week 40	217	2.46 (3.08)	217	-5.71 (6.97)	208	4.22 (6.34)	208	-4.25 (5.67)
Week 44	207	2.51 (3.78)	207	-5.85 (7.21)	205	4.19 (6.33)	205	-4.22 (5.57)
Week 48	212	2.35 (3.02)	212	-5.80 (7.21)	199	3.89 (5.92)	199	-4.56 (5.62)
Week 52	201	2.34 (3.70)	201	-6.11 (7.14)	192	3.92 (6.02)	192	-4.55 (5.23)

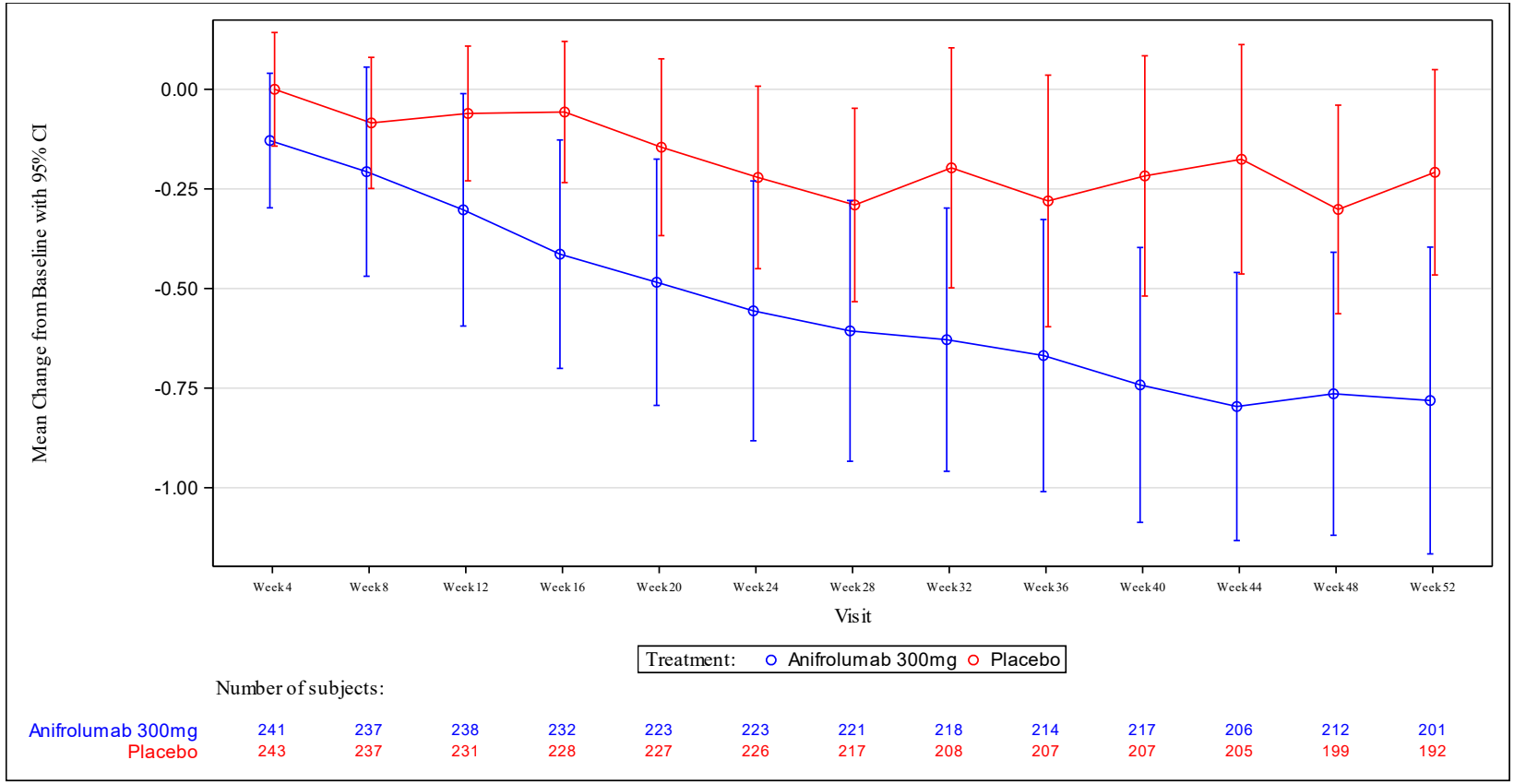
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - CLASI Total Activity Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - CLASI Total Damage Score
Full analysis set

	Anifrolumab 300mg (N=246)				Placebo (N=246)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	246	1.72 (3.61)	0	-	246	1.92 (4.55)	0	-
Week 4	241	1.58 (3.45)	241	-0.13 (1.33)	243	1.89 (4.58)	243	0.00 (1.13)
Week 8	237	1.52 (3.34)	237	-0.21 (2.05)	237	1.87 (4.57)	237	-0.08 (1.29)
Week 12	238	1.41 (3.22)	238	-0.30 (2.28)	231	1.89 (4.66)	231	-0.06 (1.30)
Week 16	232	1.35 (2.98)	232	-0.41 (2.22)	228	1.83 (4.58)	228	-0.06 (1.36)
Week 20	223	1.27 (2.63)	223	-0.48 (2.34)	227	1.78 (4.62)	227	-0.15 (1.70)
Week 24	223	1.17 (2.56)	223	-0.56 (2.47)	226	1.73 (4.31)	226	-0.22 (1.75)
Week 28	221	1.11 (2.45)	221	-0.61 (2.47)	217	1.60 (4.16)	217	-0.29 (1.81)
Week 32	218	1.10 (2.36)	218	-0.63 (2.47)	208	1.72 (4.30)	208	-0.20 (2.20)
Week 36	214	1.01 (2.19)	214	-0.67 (2.53)	207	1.69 (4.15)	207	-0.28 (2.30)
Week 40	217	0.98 (2.28)	217	-0.74 (2.58)	207	1.60 (4.15)	207	-0.22 (2.20)
Week 44	206	1.00 (2.30)	206	-0.80 (2.45)	205	1.61 (4.14)	205	-0.18 (2.09)
Week 48	212	0.96 (2.20)	212	-0.76 (2.62)	199	1.54 (4.06)	199	-0.30 (1.87)
Week 52	201	1.07 (2.77)	201	-0.78 (2.77)	192	1.56 (4.10)	192	-0.21 (1.81)

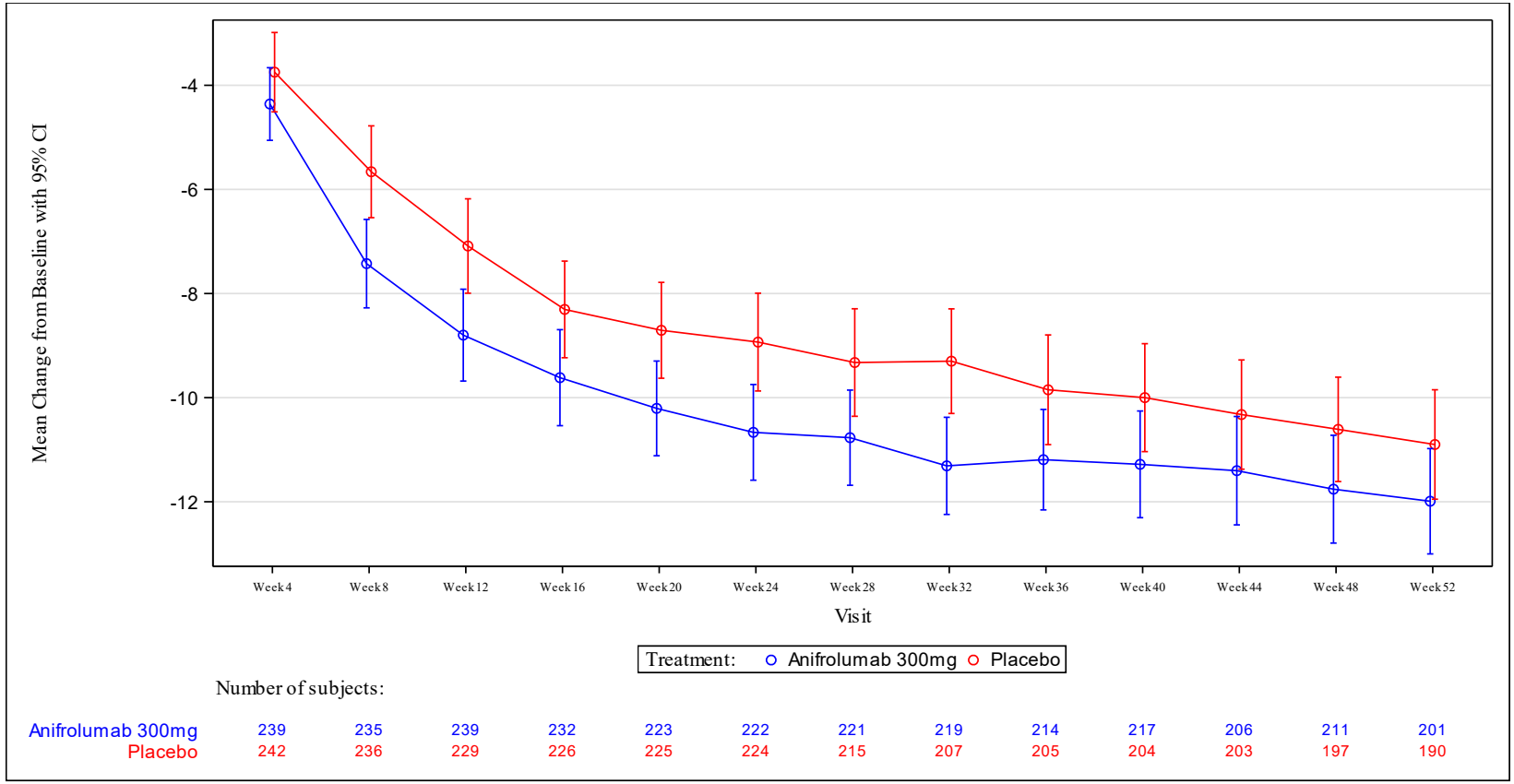
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - CLASI Total Damage Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - BILAG Global Score
Full analysis set

	Anifrolumab 300mg (N=246)				Placebo (N=246)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	246	18.62 (5.28)	0	-	246	18.81 (5.17)	0	-
Week 4	239	14.17 (7.14)	239	-4.36 (5.48)	242	15.03 (6.40)	242	-3.75 (6.02)
Week 8	235	11.04 (7.29)	235	-7.43 (6.61)	236	13.15 (7.12)	236	-5.66 (6.87)
Week 12	239	9.70 (7.39)	239	-8.80 (6.92)	229	11.77 (6.58)	229	-7.09 (6.96)
Week 16	232	8.94 (7.53)	232	-9.62 (7.13)	226	10.56 (6.95)	226	-8.31 (7.08)
Week 20	223	8.28 (7.05)	223	-10.21 (6.89)	225	10.02 (6.73)	225	-8.71 (7.01)
Week 24	222	7.92 (7.14)	222	-10.67 (6.95)	224	9.89 (6.78)	224	-8.93 (7.13)
Week 28	221	7.75 (7.08)	221	-10.77 (6.89)	215	9.42 (6.99)	215	-9.33 (7.68)
Week 32	219	7.13 (6.93)	219	-11.31 (7.01)	207	9.51 (7.09)	207	-9.30 (7.33)
Week 36	214	7.39 (7.07)	214	-11.19 (7.16)	205	8.84 (7.14)	205	-9.85 (7.65)
Week 40	217	7.25 (7.26)	217	-11.28 (7.66)	204	8.74 (7.04)	204	-10.00 (7.51)
Week 44	206	7.01 (7.19)	206	-11.40 (7.58)	203	8.43 (6.72)	203	-10.33 (7.58)
Week 48	211	6.75 (7.15)	211	-11.76 (7.63)	197	8.04 (6.56)	197	-10.61 (7.13)
Week 52	201	6.47 (6.97)	201	-11.99 (7.27)	190	7.80 (6.53)	190	-10.90 (7.34)

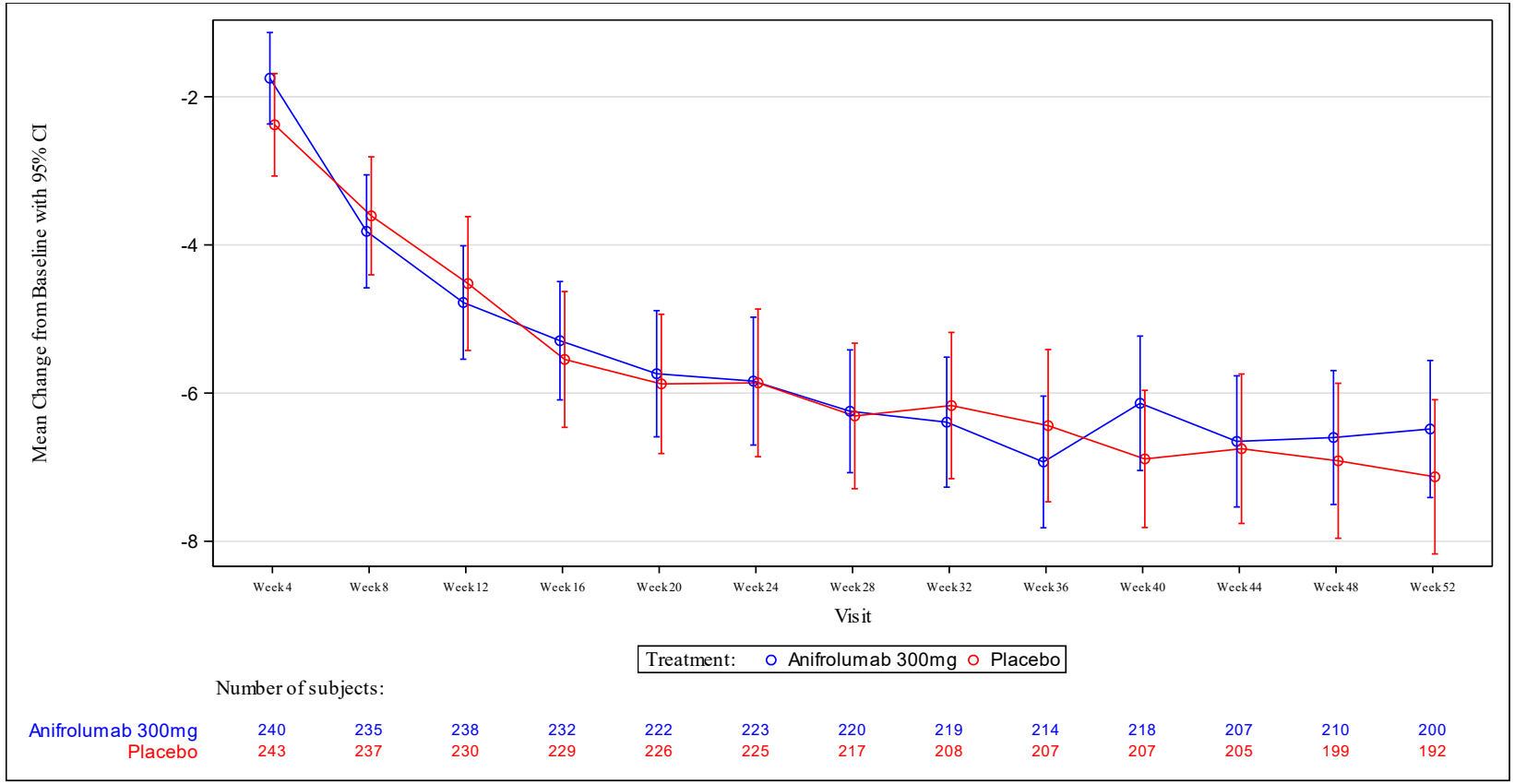
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - BILAG Global Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Tender Joint Count
Full analysis set

	Anifrolumab 300mg (N=246)				Placebo (N=246)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	246	9.96 (7.47)	0	-	246	10.88 (7.48)	0	-
Week 4	240	8.08 (7.75)	240	-1.75 (4.85)	243	8.52 (7.43)	243	-2.38 (5.48)
Week 8	235	6.03 (7.01)	235	-3.82 (5.93)	237	7.32 (7.15)	237	-3.61 (6.22)
Week 12	238	5.03 (6.81)	238	-4.78 (6.00)	230	6.41 (7.05)	230	-4.52 (6.95)
Week 16	232	4.56 (6.77)	232	-5.29 (6.18)	229	5.31 (6.38)	229	-5.55 (7.04)
Week 20	222	4.05 (6.61)	222	-5.74 (6.44)	226	4.93 (6.39)	226	-5.88 (7.17)
Week 24	223	4.14 (6.70)	223	-5.84 (6.54)	225	4.84 (6.59)	225	-5.86 (7.58)
Week 28	220	3.63 (6.17)	220	-6.25 (6.24)	217	4.34 (6.18)	217	-6.31 (7.34)
Week 32	219	3.38 (5.88)	219	-6.39 (6.59)	208	4.46 (6.49)	208	-6.17 (7.22)
Week 36	214	3.00 (5.75)	214	-6.93 (6.60)	207	4.20 (6.32)	207	-6.44 (7.50)
Week 40	218	3.59 (6.62)	218	-6.14 (6.79)	207	3.69 (5.36)	207	-6.89 (6.76)
Week 44	207	2.86 (5.33)	207	-6.65 (6.46)	205	3.73 (5.87)	205	-6.75 (7.32)
Week 48	210	3.41 (6.17)	210	-6.60 (6.64)	199	3.74 (5.84)	199	-6.91 (7.48)
Week 52	200	3.17 (5.97)	200	-6.49 (6.63)	192	3.28 (5.13)	192	-7.13 (7.31)

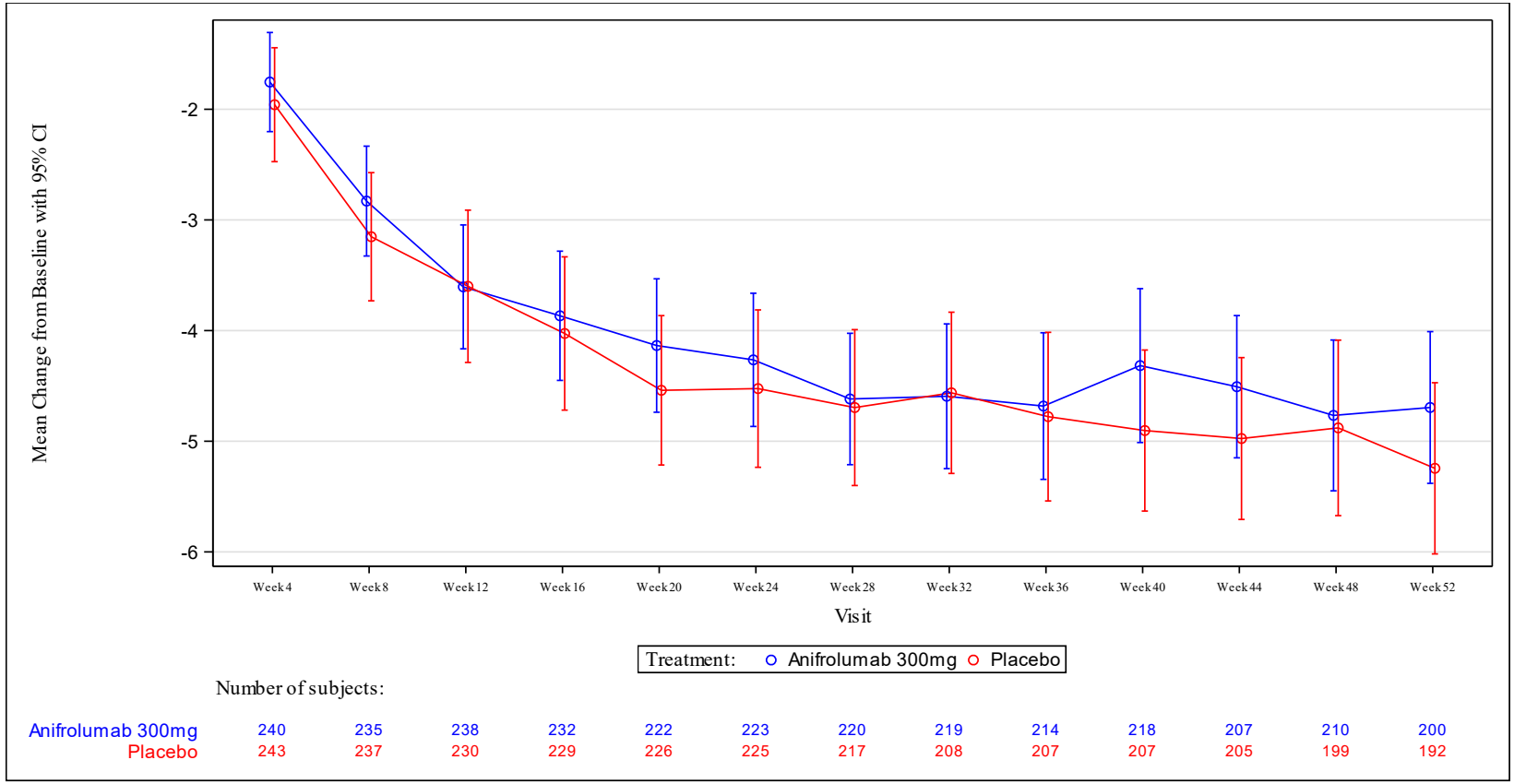
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Tender Joint Count
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Swollen Joint Count
Full analysis set

	Anifrolumab 300mg (N=246)				Placebo (N=246)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	246	6.71 (5.78)	0	-	246	7.15 (5.70)	0	-
Week 4	240	4.85 (5.74)	240	-1.75 (3.52)	243	5.16 (5.50)	243	-1.96 (4.07)
Week 8	235	3.69 (5.19)	235	-2.83 (3.86)	237	3.97 (4.90)	237	-3.15 (4.53)
Week 12	238	2.98 (4.97)	238	-3.61 (4.38)	230	3.51 (4.92)	230	-3.60 (5.30)
Week 16	232	2.72 (4.89)	232	-3.87 (4.51)	229	3.02 (4.39)	229	-4.03 (5.32)
Week 20	222	2.31 (4.65)	222	-4.14 (4.56)	226	2.61 (4.18)	226	-4.54 (5.15)
Week 24	223	2.40 (4.73)	223	-4.26 (4.56)	225	2.48 (4.27)	225	-4.52 (5.41)
Week 28	220	2.05 (4.24)	220	-4.62 (4.47)	217	2.36 (4.01)	217	-4.70 (5.26)
Week 32	219	1.79 (4.00)	219	-4.59 (4.91)	208	2.46 (4.28)	208	-4.56 (5.33)
Week 36	214	1.97 (4.38)	214	-4.68 (4.92)	207	2.25 (4.12)	207	-4.78 (5.56)
Week 40	218	2.28 (5.20)	218	-4.32 (5.21)	207	2.07 (3.64)	207	-4.90 (5.31)
Week 44	207	1.79 (4.05)	207	-4.51 (4.69)	205	2.02 (3.66)	205	-4.98 (5.31)
Week 48	210	1.93 (4.40)	210	-4.77 (5.01)	199	2.12 (4.22)	199	-4.88 (5.67)
Week 52	200	1.67 (3.83)	200	-4.70 (4.92)	192	1.79 (3.32)	192	-5.24 (5.43)

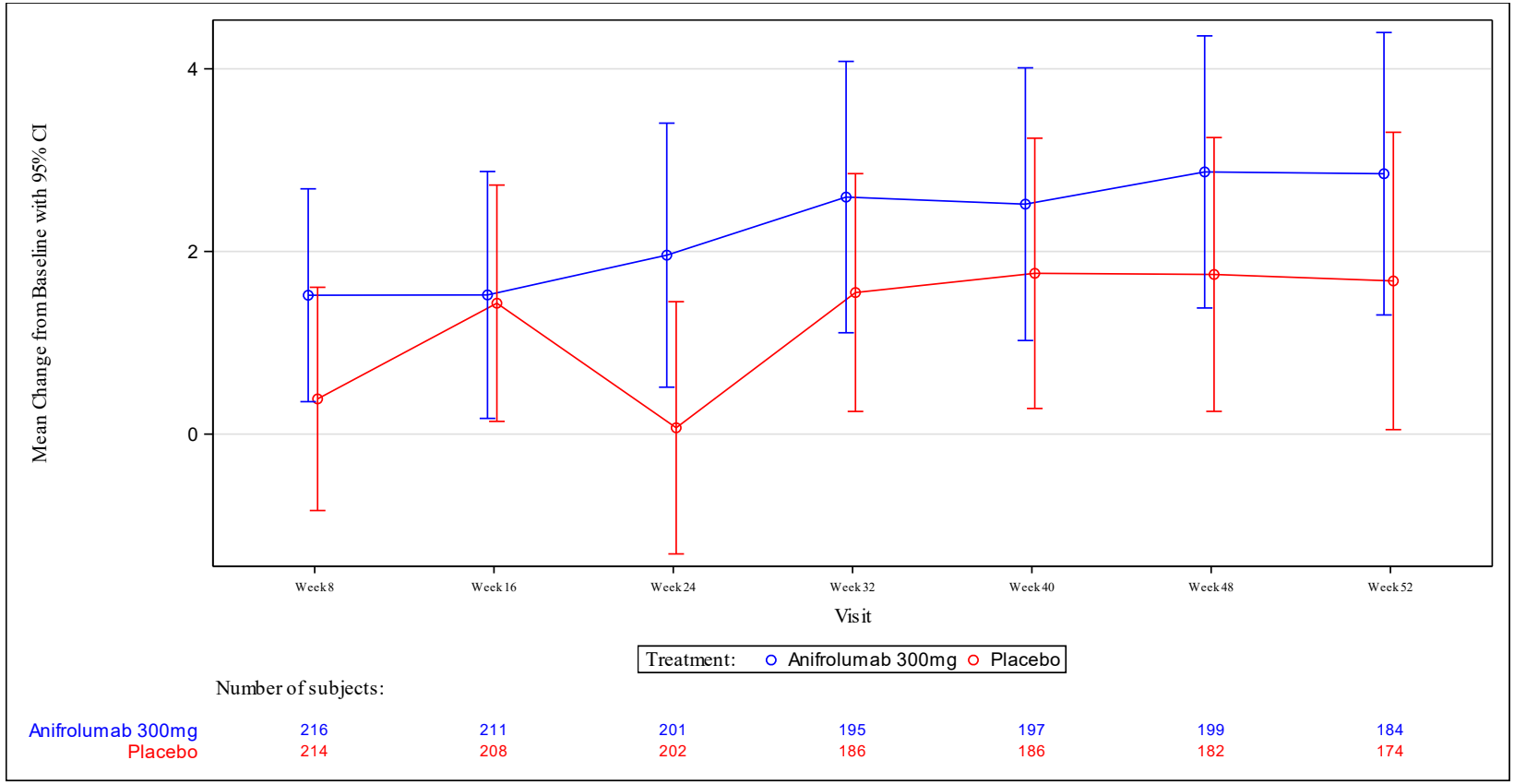
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Swollen Joint Count
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Mental Component Score
Full analysis set

	Anifrolumab 300mg (N=246)				Placebo (N=246)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	236	43.85 (11.75)	0	-	232	43.55 (11.29)	0	-
Week 8	222	45.40 (11.75)	216	1.52 (8.69)	224	43.80 (11.12)	214	0.39 (9.07)
Week 16	219	45.27 (11.48)	211	1.52 (9.96)	218	44.89 (10.96)	208	1.43 (9.46)
Week 24	211	45.56 (12.42)	201	1.96 (10.39)	214	43.60 (11.41)	202	0.07 (9.95)
Week 32	205	46.07 (11.31)	195	2.60 (10.52)	194	44.73 (10.44)	186	1.55 (9.00)
Week 40	207	46.01 (11.30)	197	2.52 (10.63)	195	44.98 (10.91)	186	1.76 (10.23)
Week 48	208	46.09 (11.16)	199	2.87 (10.66)	188	45.03 (10.31)	182	1.75 (10.25)
Week 52	194	46.17 (11.53)	184	2.85 (10.63)	181	44.98 (11.20)	174	1.68 (10.88)

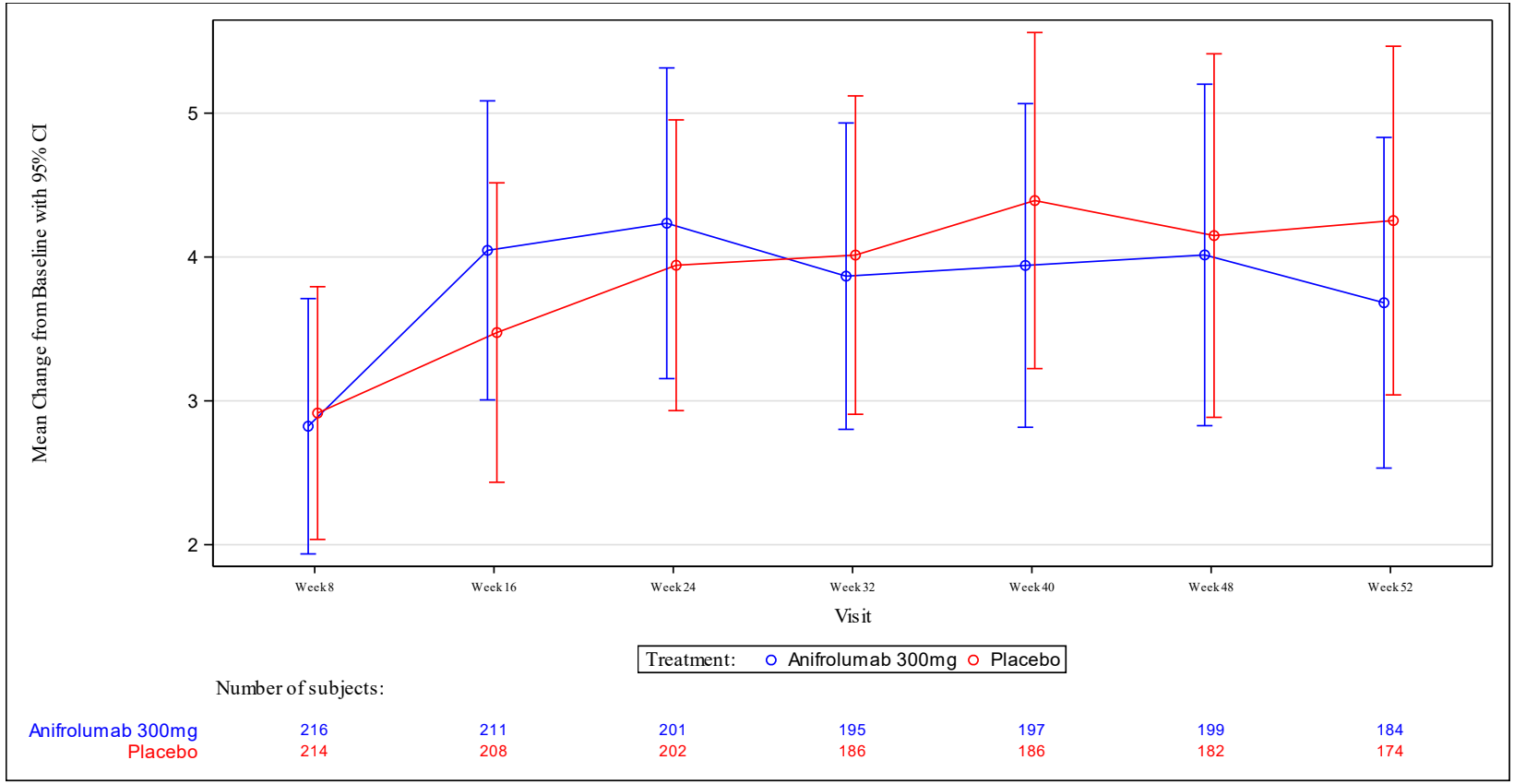
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Mental Component Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Physical Component Score
Full analysis set

	Anifrolumab 300mg (N=246)				Placebo (N=246)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	236	38.31 (8.72)	0	-	232	37.51 (9.25)	0	-
Week 8	222	41.48 (8.74)	216	2.82 (6.62)	224	40.45 (8.76)	214	2.92 (6.52)
Week 16	219	42.61 (9.40)	211	4.05 (7.66)	218	41.01 (9.10)	208	3.47 (7.61)
Week 24	211	43.02 (9.58)	201	4.23 (7.76)	214	41.78 (8.60)	202	3.94 (7.28)
Week 32	205	42.49 (9.19)	195	3.87 (7.54)	194	41.90 (8.64)	186	4.01 (7.65)
Week 40	207	42.89 (9.47)	197	3.94 (8.01)	195	41.97 (9.30)	186	4.39 (8.08)
Week 48	208	42.80 (9.93)	199	4.01 (8.49)	188	41.89 (9.56)	182	4.15 (8.64)
Week 52	194	42.70 (9.45)	184	3.68 (7.90)	181	42.46 (8.93)	174	4.25 (8.10)

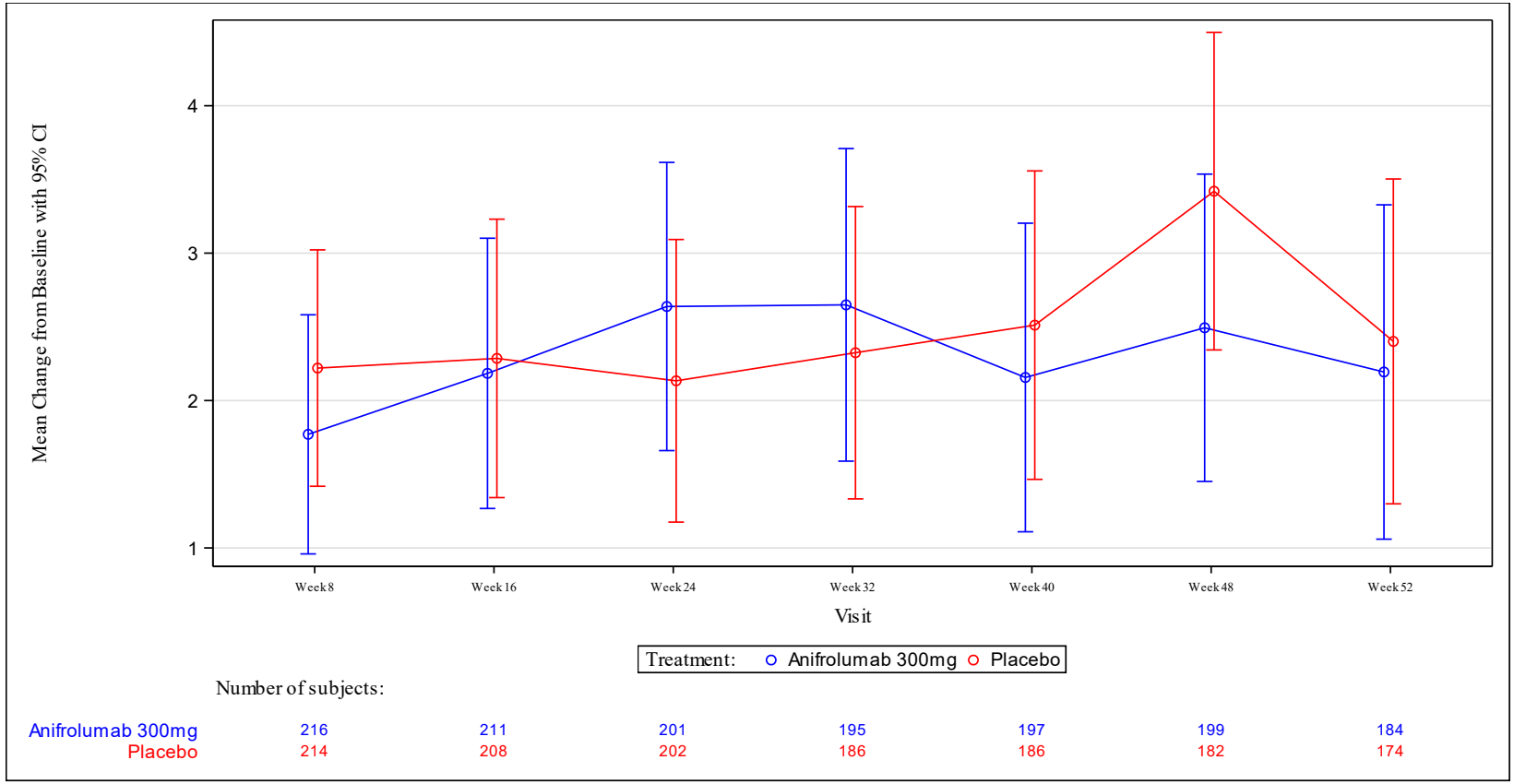
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Physical Component Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute General Health Score
Full analysis set

	Anifrolumab 300mg (N=246)				Placebo (N=246)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	236	38.54 (7.76)	0	-	232	38.80 (8.03)	0	-
Week 8	222	40.59 (8.25)	216	1.77 (6.05)	224	40.99 (8.04)	214	2.22 (5.95)
Week 16	219	40.97 (8.96)	211	2.18 (6.75)	218	40.99 (8.27)	208	2.29 (6.91)
Week 24	211	41.18 (9.59)	201	2.64 (7.03)	214	41.40 (8.31)	202	2.13 (6.91)
Week 32	205	41.13 (9.27)	195	2.65 (7.51)	194	41.44 (8.53)	186	2.32 (6.85)
Week 40	207	41.15 (8.89)	197	2.16 (7.45)	195	41.56 (8.69)	186	2.51 (7.23)
Week 48	208	41.05 (9.27)	199	2.49 (7.46)	188	42.57 (8.77)	182	3.42 (7.36)
Week 52	194	40.86 (9.49)	184	2.19 (7.80)	181	42.10 (8.91)	174	2.40 (7.36)

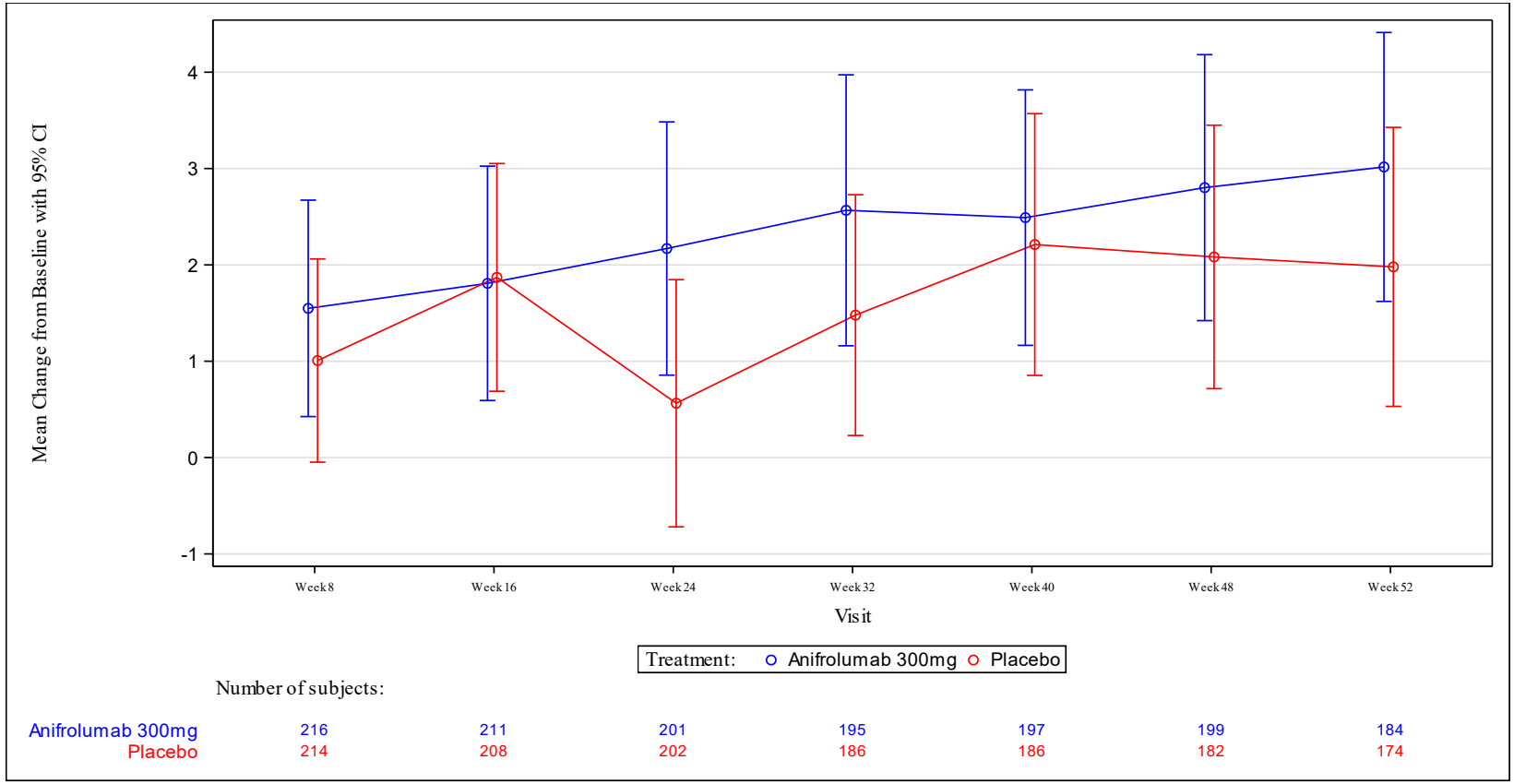
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute General Health Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Mental Health Score
Full analysis set

	Anifrolumab 300mg (N=246)				Placebo (N=246)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	236	44.03 (10.71)	0	-	232	43.67 (10.45)	0	-
Week 8	222	45.57 (10.77)	216	1.55 (8.37)	224	44.67 (9.88)	214	1.01 (7.83)
Week 16	219	45.76 (10.97)	211	1.81 (8.96)	218	45.38 (10.45)	208	1.87 (8.65)
Week 24	211	46.00 (11.65)	201	2.17 (9.45)	214	44.28 (10.19)	202	0.56 (9.25)
Week 32	205	46.25 (10.69)	195	2.57 (9.96)	194	44.96 (9.89)	186	1.48 (8.64)
Week 40	207	46.31 (10.19)	197	2.49 (9.44)	195	45.51 (10.10)	186	2.21 (9.39)
Week 48	208	46.32 (9.98)	199	2.80 (9.87)	188	45.40 (10.24)	182	2.08 (9.35)
Week 52	194	46.49 (10.53)	184	3.02 (9.60)	181	45.56 (10.29)	174	1.98 (9.67)

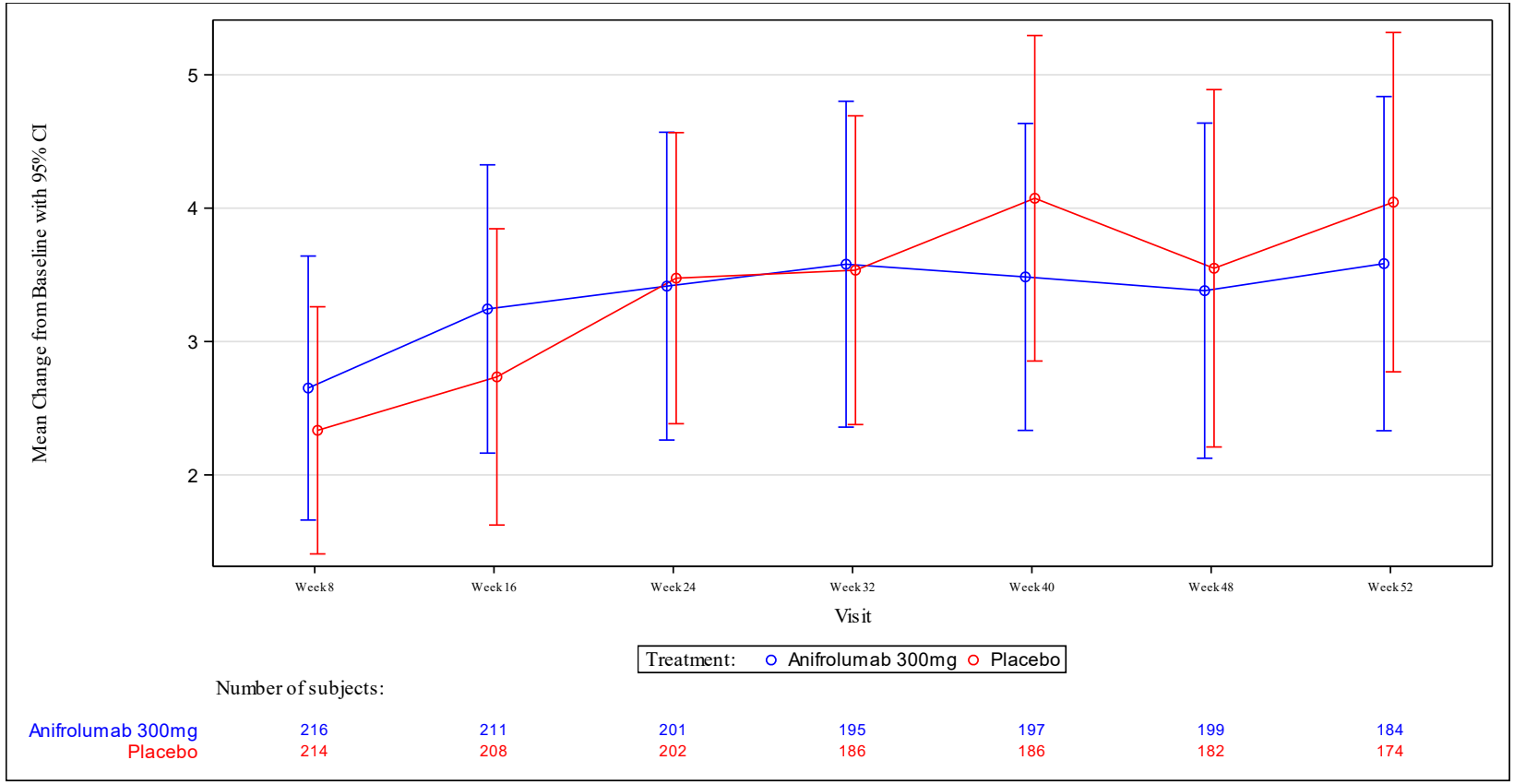
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Mental Health Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Physical Functioning Score
Full analysis set

	Anifrolumab 300mg (N=246)				Placebo (N=246)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	236	40.02 (9.90)	0	-	232	38.71 (10.01)	0	-
Week 8	222	42.99 (9.70)	216	2.65 (7.38)	224	41.19 (9.48)	214	2.33 (6.88)
Week 16	219	43.44 (10.03)	211	3.24 (7.96)	218	41.53 (9.81)	208	2.73 (8.12)
Week 24	211	43.91 (10.49)	201	3.42 (8.30)	214	42.43 (9.65)	202	3.48 (7.87)
Week 32	205	43.87 (10.15)	195	3.58 (8.65)	194	42.55 (9.52)	186	3.53 (8.00)
Week 40	207	43.89 (10.34)	197	3.48 (8.19)	195	42.51 (10.27)	186	4.07 (8.43)
Week 48	208	43.82 (10.16)	199	3.38 (8.99)	188	42.21 (10.63)	182	3.55 (9.16)
Week 52	194	44.26 (9.75)	184	3.58 (8.61)	181	43.23 (9.98)	174	4.05 (8.50)

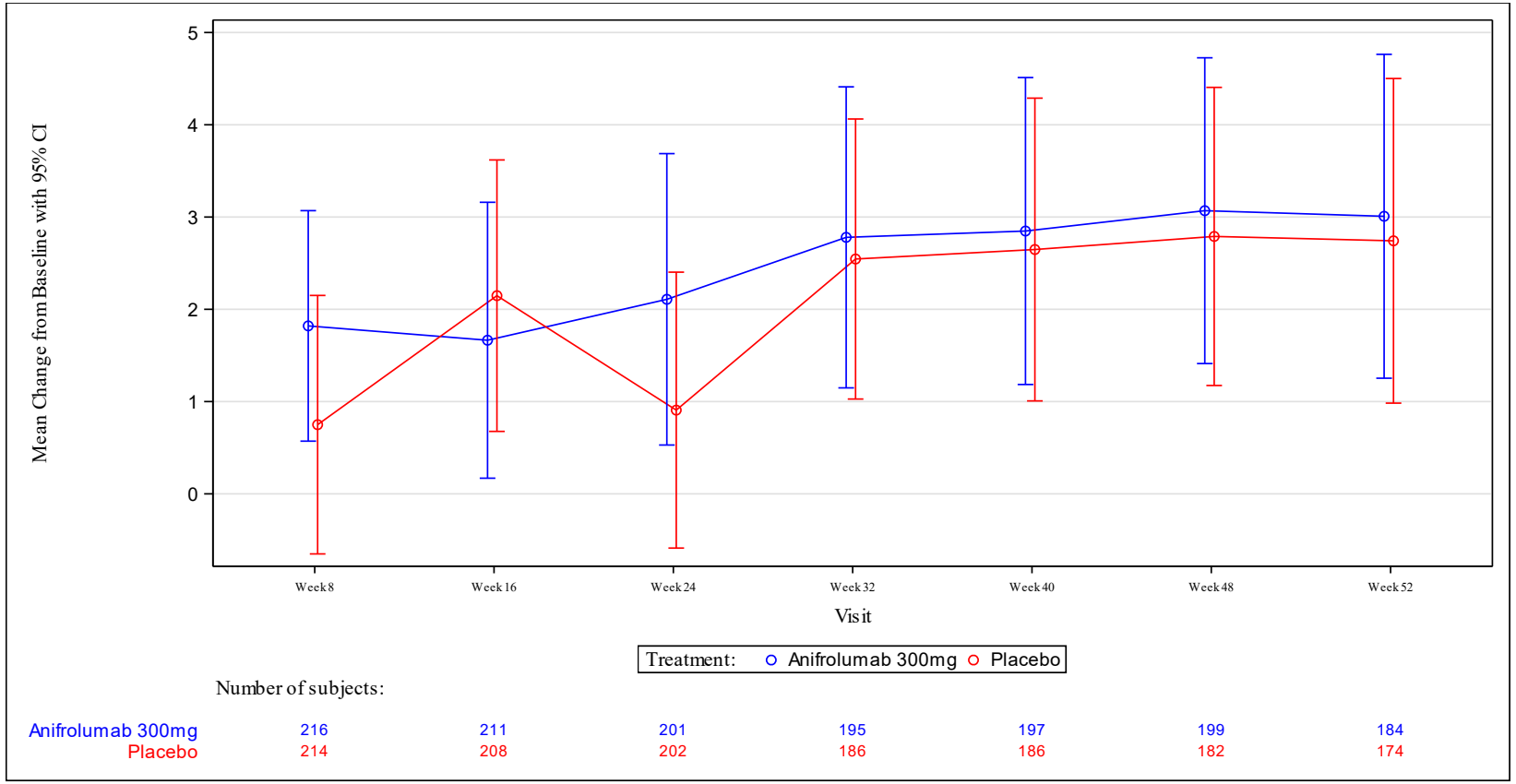
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Physical Functioning Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Role Emotional Score
Full analysis set

	Anifrolumab 300mg (N=246)				Placebo (N=246)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	236	40.89 (12.82)	0	-	232	39.71 (11.95)	0	-
Week 8	222	42.74 (12.65)	216	1.82 (9.31)	224	40.12 (12.02)	214	0.75 (10.39)
Week 16	219	42.67 (12.07)	211	1.66 (11.02)	218	41.75 (12.04)	208	2.15 (10.76)
Week 24	211	42.94 (12.96)	201	2.11 (11.35)	214	40.51 (12.36)	202	0.91 (10.78)
Week 32	205	43.44 (11.67)	195	2.78 (11.55)	194	41.81 (11.83)	186	2.55 (10.49)
Week 40	207	43.36 (11.93)	197	2.85 (11.84)	195	42.00 (11.95)	186	2.65 (11.34)
Week 48	208	43.20 (11.95)	199	3.07 (11.85)	188	42.10 (11.15)	182	2.79 (11.05)
Week 52	194	43.70 (11.78)	184	3.01 (12.07)	181	42.16 (11.87)	174	2.74 (11.76)

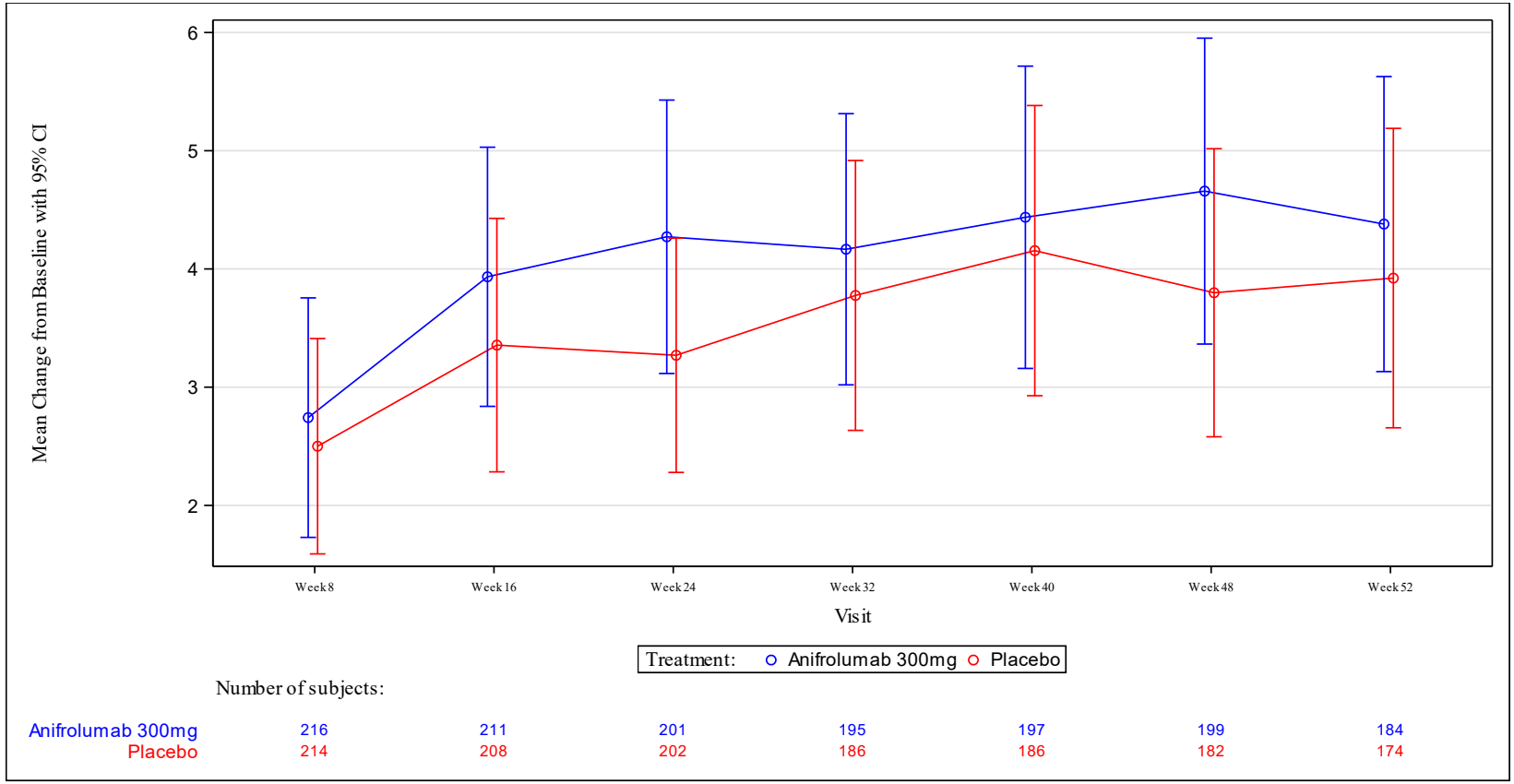
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Role Emotional Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Role Physical Score
Full analysis set

	Anifrolumab 300mg (N=246)				Placebo (N=246)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	236	38.16 (9.66)	0	-	232	37.24 (8.35)	0	-
Week 8	222	41.11 (9.40)	216	2.74 (7.55)	224	39.70 (8.42)	214	2.50 (6.76)
Week 16	219	42.33 (9.76)	211	3.93 (8.08)	218	40.61 (9.10)	208	3.36 (7.84)
Week 24	211	42.70 (9.86)	201	4.27 (8.31)	214	40.56 (8.69)	202	3.27 (7.14)
Week 32	205	42.34 (9.39)	195	4.17 (8.12)	194	41.23 (8.65)	186	3.78 (7.89)
Week 40	207	42.69 (9.35)	197	4.44 (9.10)	195	41.51 (8.97)	186	4.15 (8.48)
Week 48	208	42.72 (9.97)	199	4.66 (9.25)	188	41.12 (9.34)	182	3.80 (8.33)
Week 52	194	42.58 (9.36)	184	4.38 (8.58)	181	41.68 (8.87)	174	3.92 (8.46)

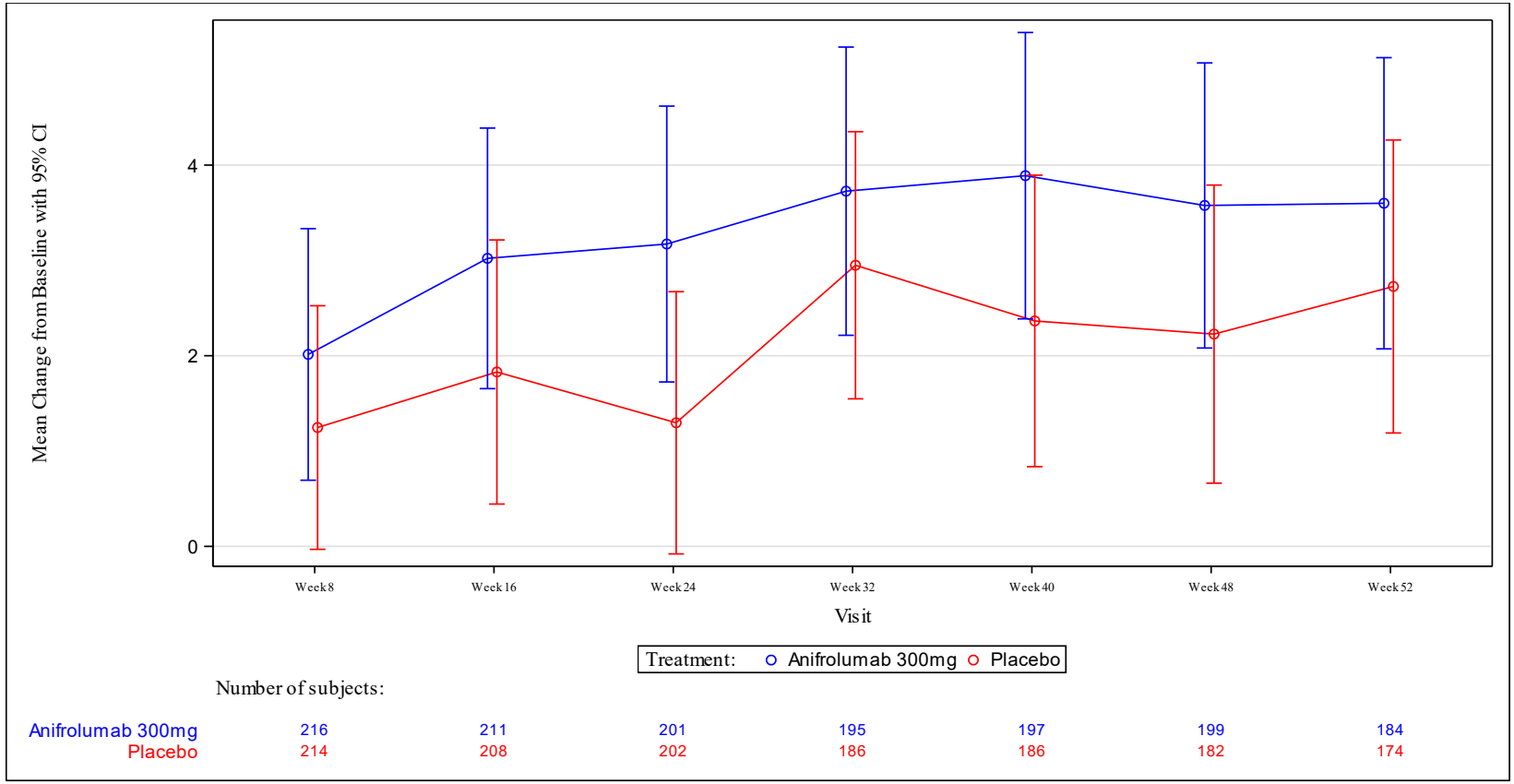
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Role Physical Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Social Functioning Score
Full analysis set

	Anifrolumab 300mg (N=246)				Placebo (N=246)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	236	40.99 (10.88)	0	-	232	40.42 (9.90)	0	-
Week 8	222	43.34 (10.46)	216	2.01 (9.84)	224	41.67 (10.38)	214	1.25 (9.48)
Week 16	219	43.85 (10.29)	211	3.02 (10.07)	218	42.20 (9.26)	208	1.83 (10.13)
Week 24	211	44.16 (10.65)	201	3.17 (10.40)	214	41.73 (10.25)	202	1.30 (9.92)
Week 32	205	44.54 (10.42)	195	3.73 (10.71)	194	42.85 (9.79)	186	2.95 (9.69)
Week 40	207	44.82 (10.09)	197	3.89 (10.69)	195	42.24 (9.81)	186	2.36 (10.57)
Week 48	208	44.48 (10.28)	199	3.58 (10.70)	188	42.38 (9.79)	182	2.23 (10.69)
Week 52	194	44.41 (10.60)	184	3.60 (10.50)	181	42.98 (9.55)	174	2.73 (10.27)

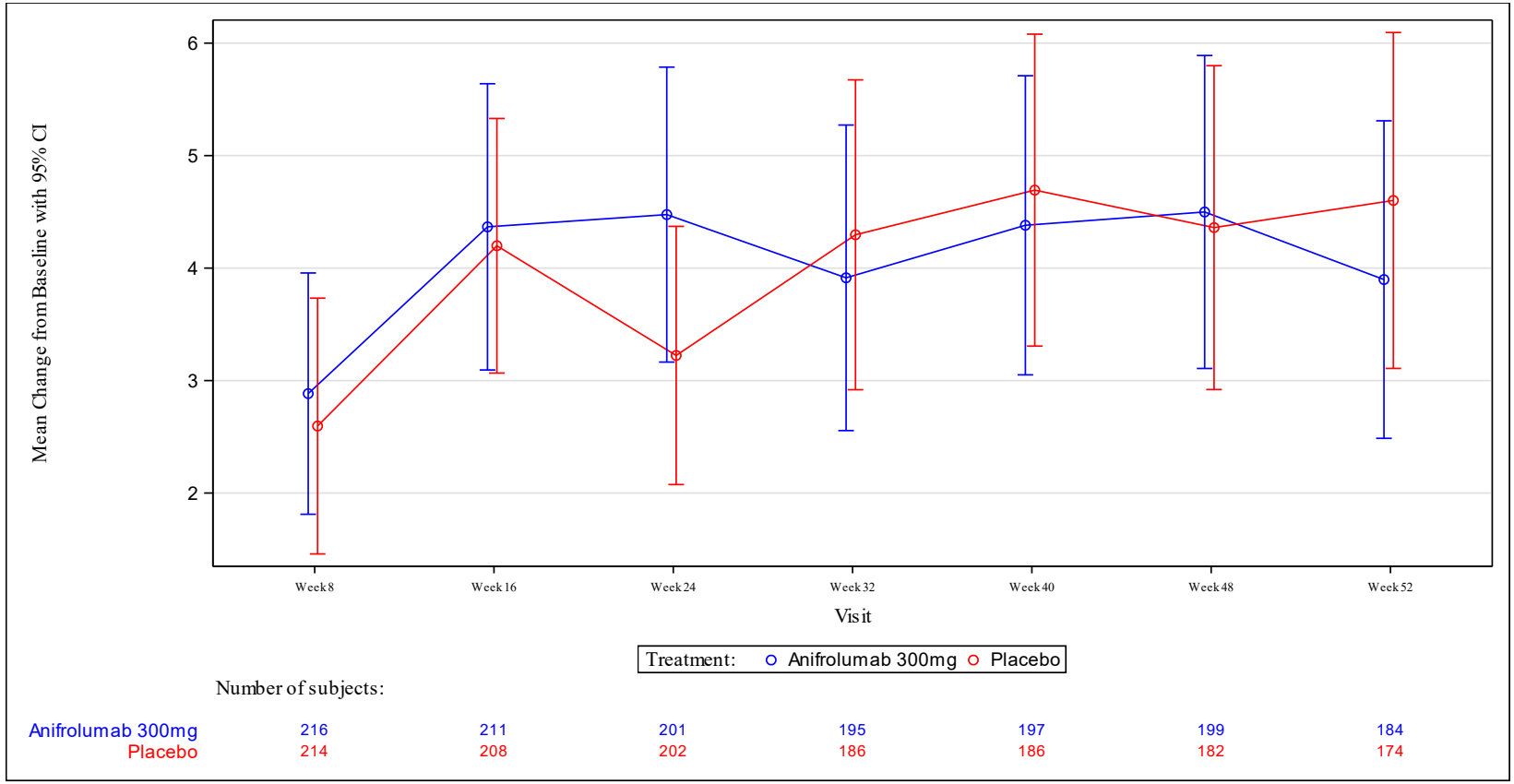
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Social Functioning Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Bodily Pain Score
Full analysis set

	Anifrolumab 300mg (N=246)				Placebo (N=246)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	236	39.44 (8.46)	0	-	232	38.51 (8.91)	0	-
Week 8	222	42.55 (9.27)	216	2.88 (8.00)	224	40.82 (9.05)	214	2.60 (8.44)
Week 16	219	43.92 (9.88)	211	4.37 (9.38)	218	42.52 (9.13)	208	4.20 (8.28)
Week 24	211	44.29 (10.22)	201	4.48 (9.43)	214	41.93 (9.25)	202	3.22 (8.27)
Week 32	205	43.63 (9.88)	195	3.91 (9.62)	194	42.61 (9.32)	186	4.30 (9.52)
Week 40	207	44.45 (9.38)	197	4.38 (9.46)	195	42.93 (8.92)	186	4.69 (9.59)
Week 48	208	44.14 (10.38)	199	4.50 (9.95)	188	42.73 (9.62)	182	4.36 (9.84)
Week 52	194	44.00 (9.83)	184	3.90 (9.70)	181	43.06 (9.10)	174	4.60 (9.98)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Bodily Pain Score
Full analysis set



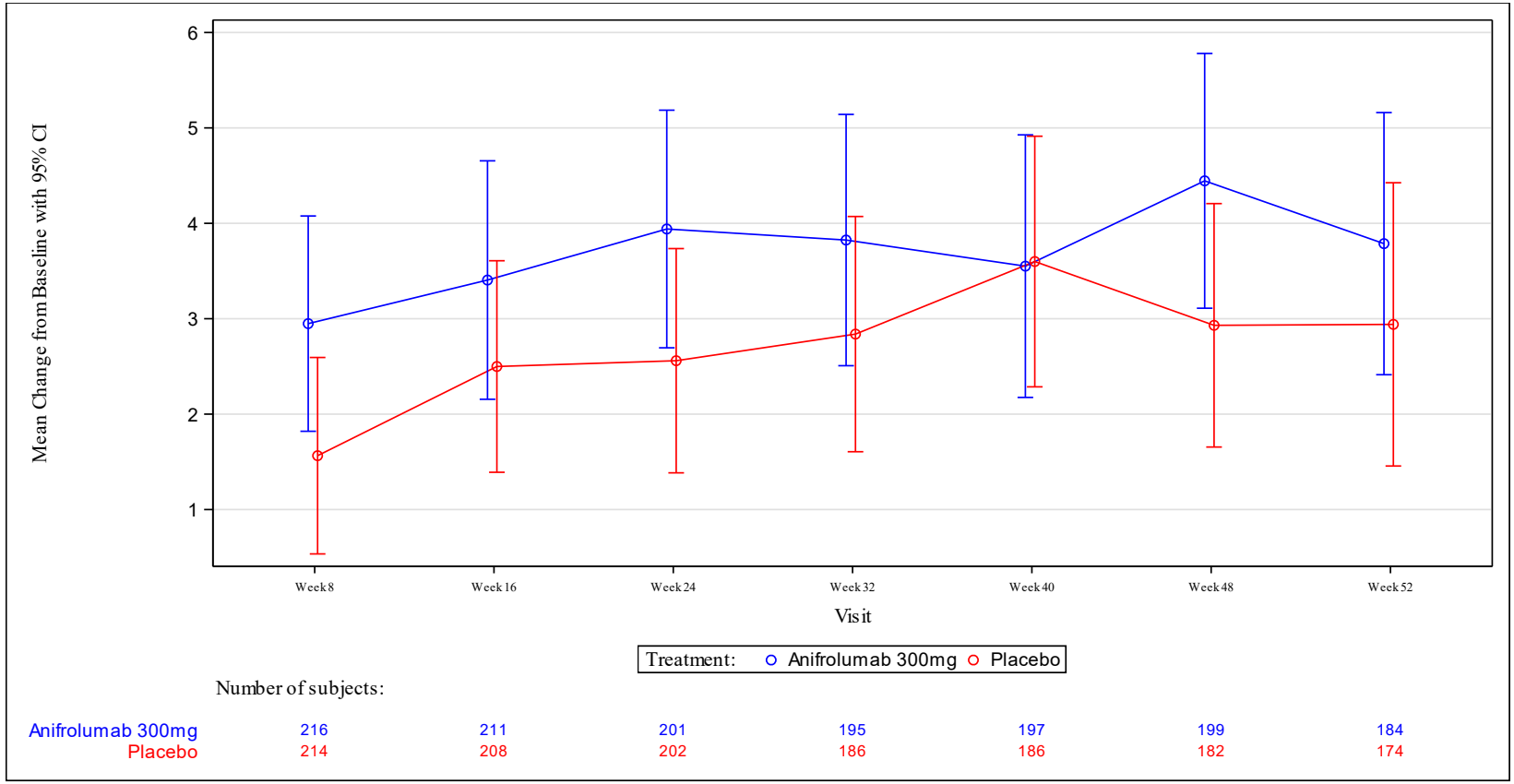
Number of subjects:

	Week 8	Week 16	Week 24	Week 32	Week 40	Week 48	Week 52
Anifrolumab 300mg	216	211	201	195	197	199	184
Placebo	214	208	202	186	186	182	174

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Vitality Score
Full analysis set

	Anifrolumab 300mg (N=246)				Placebo (N=246)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	236	42.21 (9.64)	0	-	232	42.37 (8.89)	0	-
Week 8	222	45.38 (9.79)	216	2.95 (8.41)	224	44.01 (9.22)	214	1.56 (7.64)
Week 16	219	45.65 (10.38)	211	3.41 (9.21)	218	45.05 (9.27)	208	2.50 (8.11)
Week 24	211	46.34 (10.40)	201	3.94 (8.95)	214	45.30 (9.75)	202	2.56 (8.47)
Week 32	205	46.14 (9.90)	195	3.82 (9.32)	194	45.78 (9.28)	186	2.84 (8.52)
Week 40	207	46.15 (10.27)	197	3.55 (9.79)	195	46.30 (9.83)	186	3.60 (9.08)
Week 48	208	46.97 (10.28)	199	4.45 (9.55)	188	45.88 (9.75)	182	2.93 (8.72)
Week 52	194	46.38 (10.09)	184	3.79 (9.45)	181	45.92 (10.09)	174	2.94 (9.92)

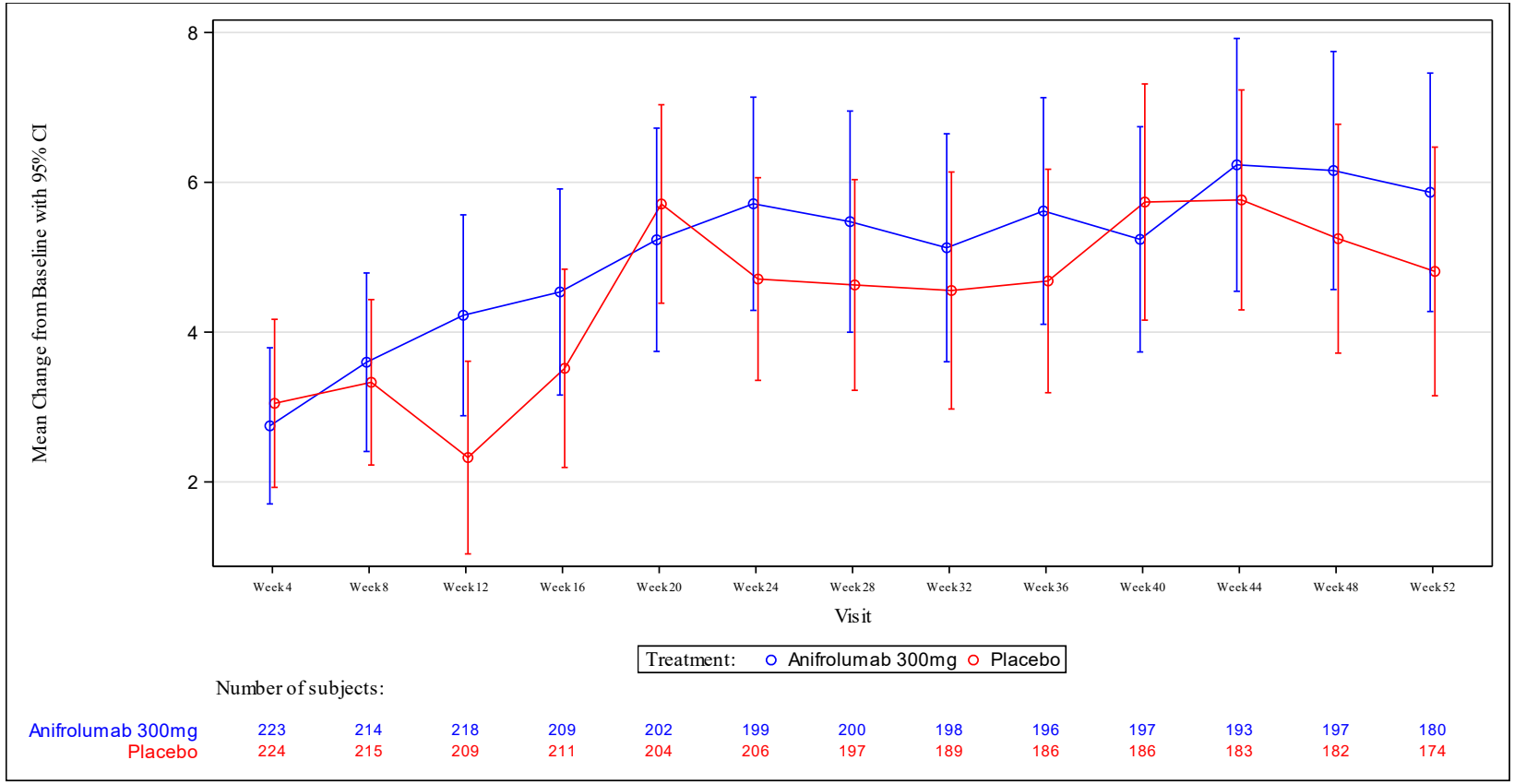
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Vitality Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - FACIT-F Total Score
Full analysis set

	Anifrolumab 300mg (N=246)				Placebo (N=246)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	232	26.33 (12.12)	0	-	233	25.32 (11.27)	0	-
Week 4	231	28.84 (11.58)	223	2.75 (7.90)	233	27.79 (11.57)	224	3.05 (8.52)
Week 8	223	30.39 (11.77)	214	3.60 (8.84)	226	28.52 (11.57)	215	3.33 (8.22)
Week 12	229	30.69 (12.93)	218	4.22 (10.04)	220	27.72 (12.45)	209	2.33 (9.43)
Week 16	221	31.14 (12.18)	209	4.54 (10.09)	220	28.76 (12.10)	211	3.52 (9.75)
Week 20	214	31.96 (12.32)	202	5.23 (10.74)	216	31.60 (11.39)	204	5.71 (9.60)
Week 24	213	32.27 (12.63)	199	5.71 (10.18)	217	29.89 (12.46)	206	4.71 (9.85)
Week 28	213	32.49 (11.98)	200	5.48 (10.59)	208	30.40 (11.72)	197	4.63 (10.01)
Week 32	211	31.57 (12.43)	198	5.13 (10.86)	198	30.62 (12.31)	189	4.56 (11.02)
Week 36	210	32.18 (12.51)	196	5.62 (10.74)	194	30.47 (12.42)	186	4.68 (10.31)
Week 40	211	32.11 (11.88)	197	5.24 (10.70)	196	31.22 (12.25)	186	5.74 (10.90)
Week 44	205	33.04 (12.92)	193	6.23 (11.89)	190	31.44 (11.65)	183	5.77 (10.06)
Week 48	210	32.90 (12.49)	197	6.16 (11.31)	191	31.22 (12.01)	182	5.25 (10.45)
Week 52	194	32.49 (12.33)	180	5.87 (10.82)	182	30.98 (12.36)	174	4.81 (11.09)

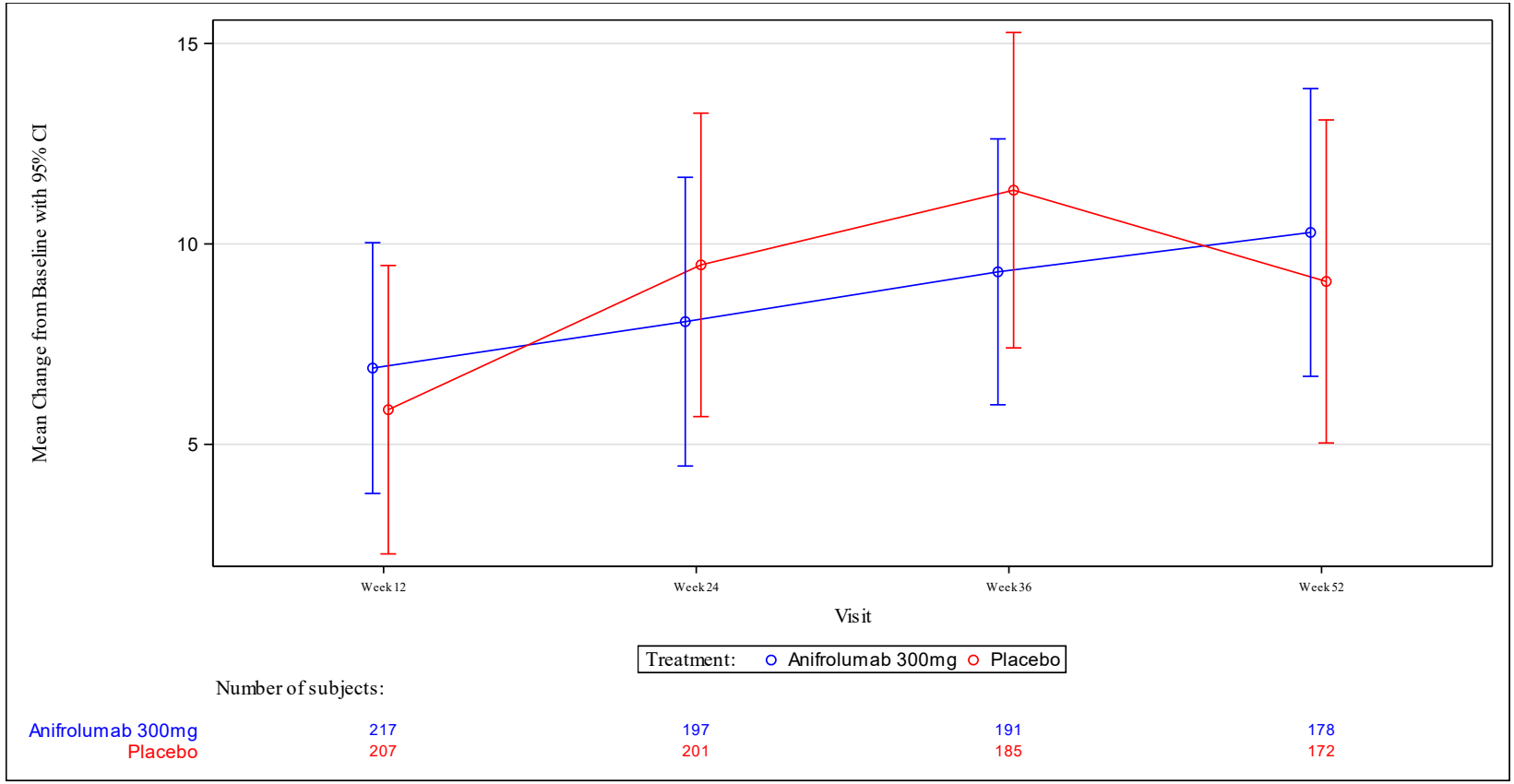
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - FACIT-F Total Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - EQ VAS Score
Full analysis set

	Anifrolumab 300mg (N=246)				Placebo (N=246)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	232	57.48 (19.92)	0	-	233	53.12 (21.90)	0	-
Week 12	228	63.75 (21.56)	217	6.90 (23.37)	218	59.01 (20.21)	207	5.86 (26.25)
Week 24	211	65.09 (21.13)	197	8.06 (25.63)	212	62.95 (20.48)	201	9.48 (27.21)
Week 36	205	66.45 (20.52)	191	9.30 (23.24)	192	65.12 (22.07)	185	11.34 (27.12)
Week 52	192	67.30 (19.90)	178	10.29 (24.27)	180	63.24 (21.74)	172	9.06 (26.77)

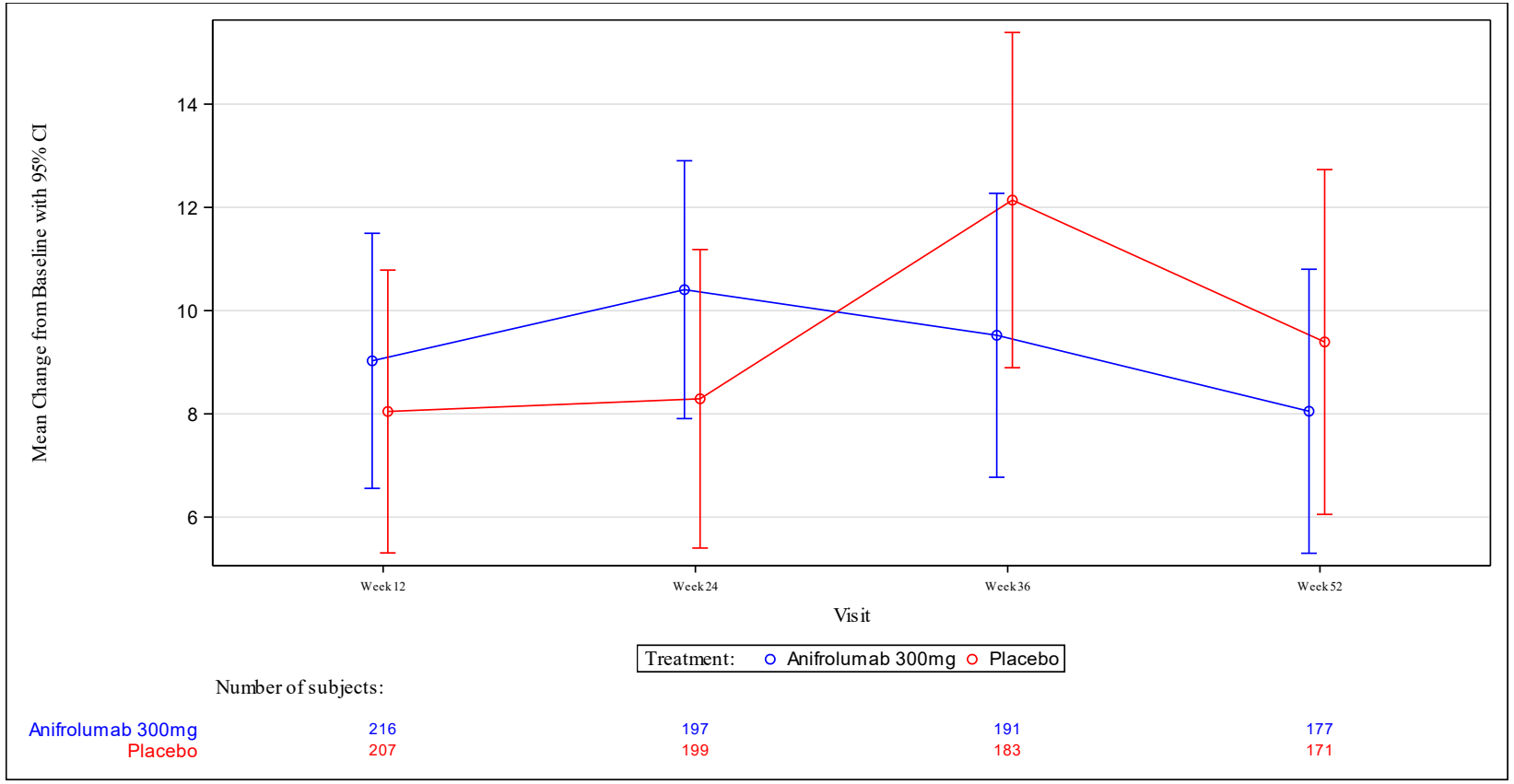
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - EQ VAS Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Physical Health domain score
Full analysis set

	Anifrolumab 300mg (N=246)				Placebo (N=246)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	232	56.21 (24.87)	0	-	233	52.75 (24.85)	0	-
Week 12	227	65.64 (25.65)	216	9.03 (18.42)	218	60.39 (25.07)	207	8.05 (19.99)
Week 24	211	66.71 (25.61)	197	10.41 (17.78)	210	61.42 (23.82)	199	8.29 (20.68)
Week 36	205	66.02 (24.72)	191	9.52 (19.27)	190	65.00 (23.40)	183	12.14 (22.26)
Week 52	191	65.74 (25.10)	177	8.05 (18.55)	179	63.41 (23.46)	171	9.39 (22.12)

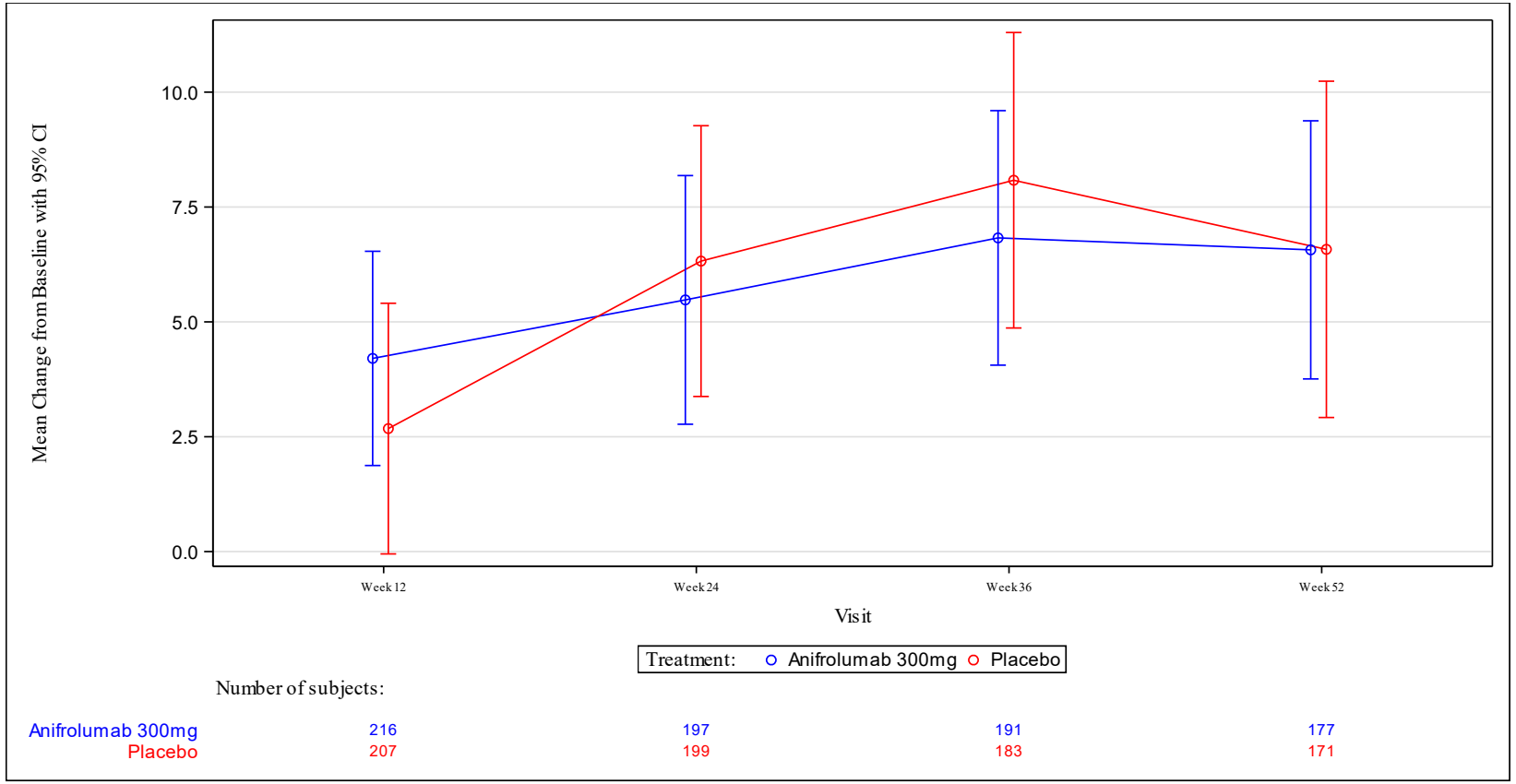
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Lupus QoL Physical Health domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Emotional Health domain score
Full analysis set

	Anifrolumab 300mg (N=246)				Placebo (N=246)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	232	68.09 (24.04)	0	-	233	64.20 (25.98)	0	-
Week 12	227	71.95 (23.59)	216	4.20 (17.38)	218	67.09 (24.40)	207	2.68 (19.91)
Week 24	211	73.95 (23.36)	197	5.48 (19.26)	210	70.28 (23.97)	199	6.32 (21.08)
Week 36	205	74.37 (21.89)	191	6.83 (19.41)	190	73.53 (22.04)	183	8.08 (22.05)
Week 52	191	74.76 (22.65)	177	6.57 (18.94)	179	72.93 (23.20)	171	6.58 (24.24)

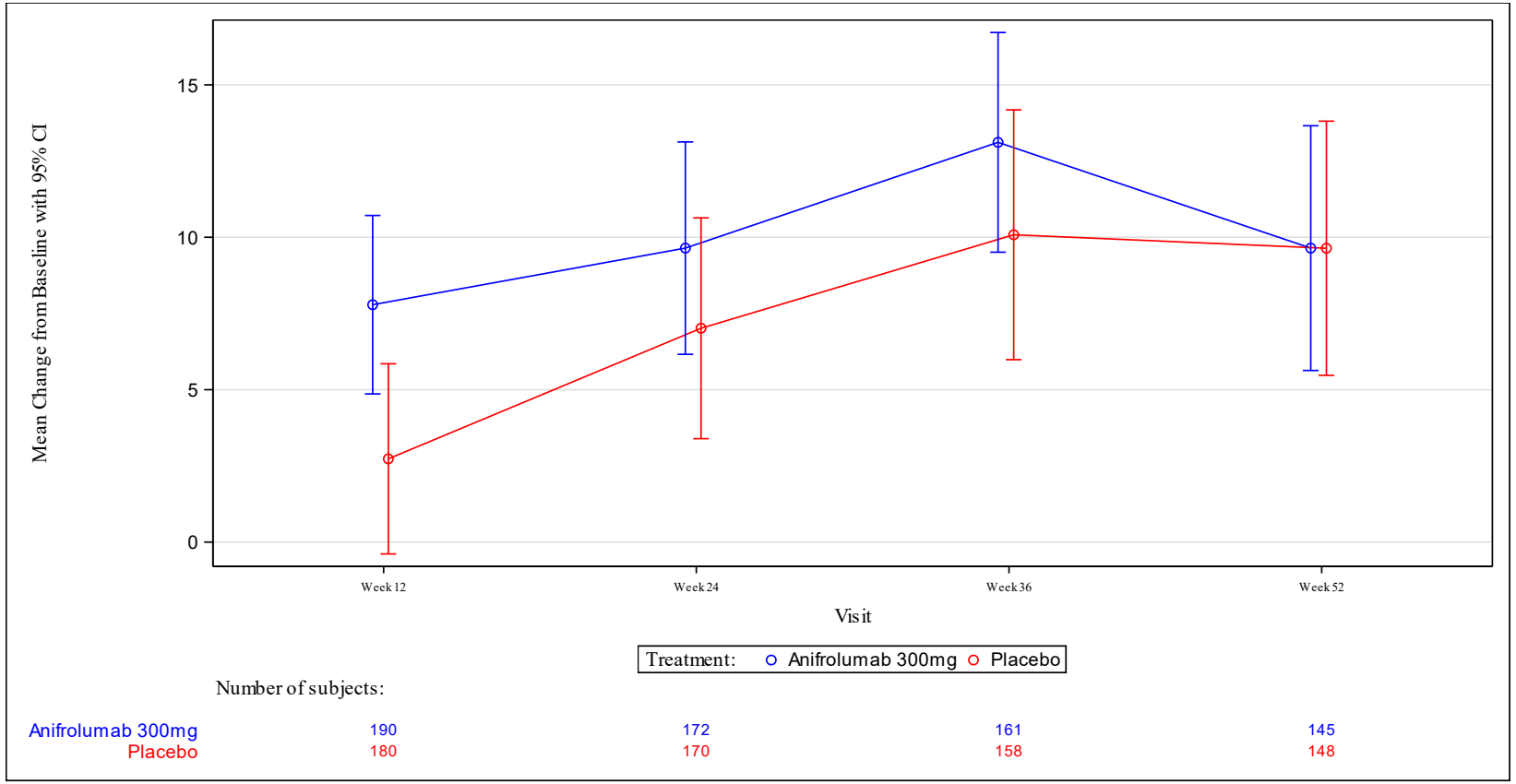
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Lupus QoL Emotional Health domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Body Image domain score
Full analysis set

	Anifrolumab 300mg (N=246)				Placebo (N=246)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	218	60.83 (29.65)	0	-	216	61.20 (28.25)	0	-
Week 12	206	67.86 (27.08)	190	7.79 (20.45)	196	63.37 (26.46)	180	2.73 (21.20)
Week 24	190	69.79 (27.42)	172	9.64 (23.14)	188	66.42 (26.58)	170	7.01 (23.92)
Week 36	179	72.15 (25.55)	161	13.11 (23.15)	172	70.37 (24.60)	158	10.08 (26.08)
Week 52	165	70.09 (27.01)	145	9.64 (24.45)	161	70.31 (26.13)	148	9.64 (25.66)

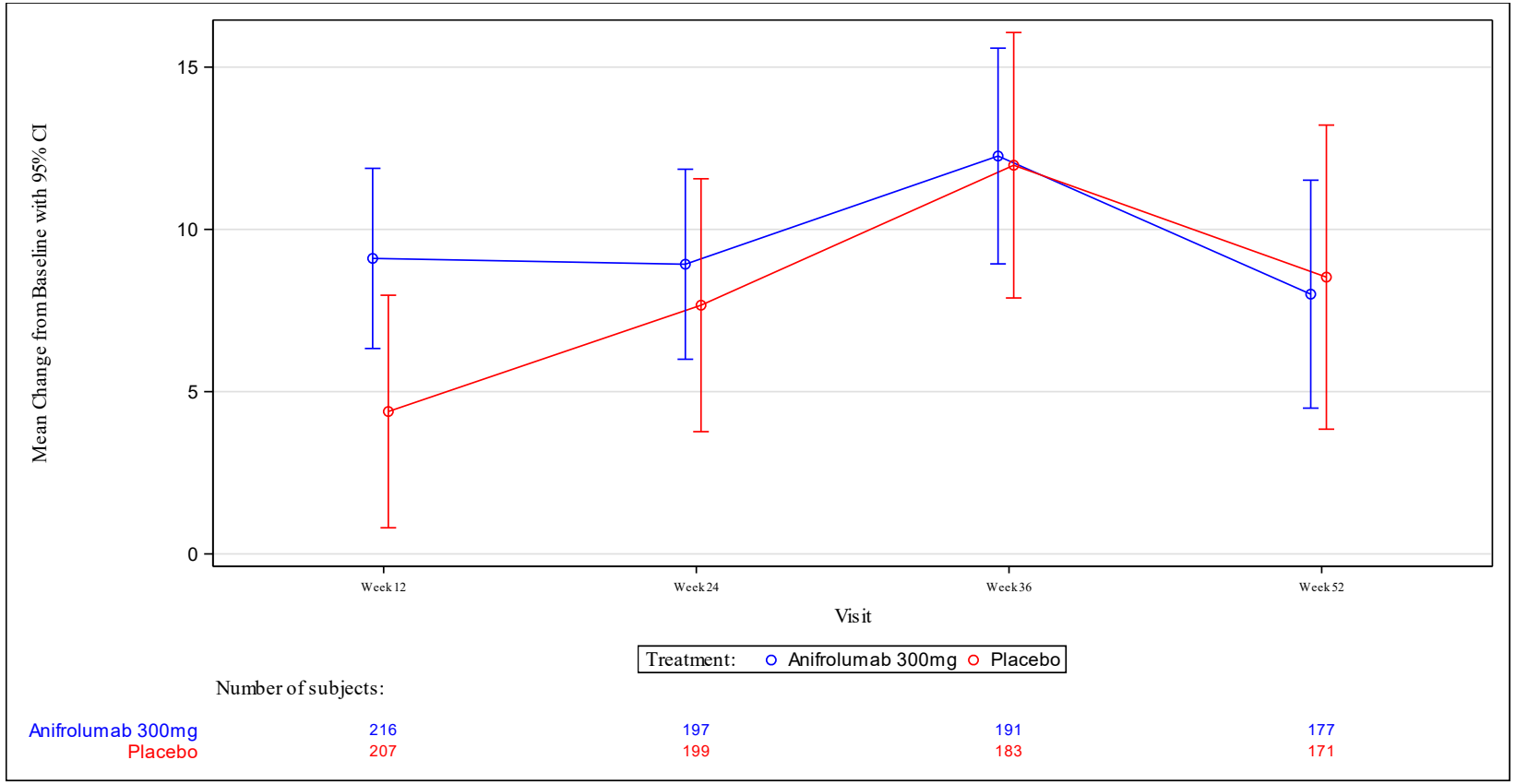
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Lupus QoL Body Image domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Burden to Others domain score
Full analysis set

	Anifrolumab 300mg (N=246)				Placebo (N=246)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	232	55.71 (30.63)	0	-	233	50.82 (30.94)	0	-
Week 12	227	63.99 (29.86)	216	9.11 (20.70)	218	55.89 (29.31)	207	4.39 (26.14)
Week 24	211	64.06 (31.12)	197	8.93 (20.83)	210	57.94 (30.15)	199	7.66 (27.87)
Week 36	205	66.50 (29.30)	191	12.26 (23.29)	190	64.03 (27.71)	183	11.98 (28.04)
Week 52	191	63.79 (30.28)	177	8.00 (23.68)	179	61.08 (29.85)	171	8.53 (31.04)

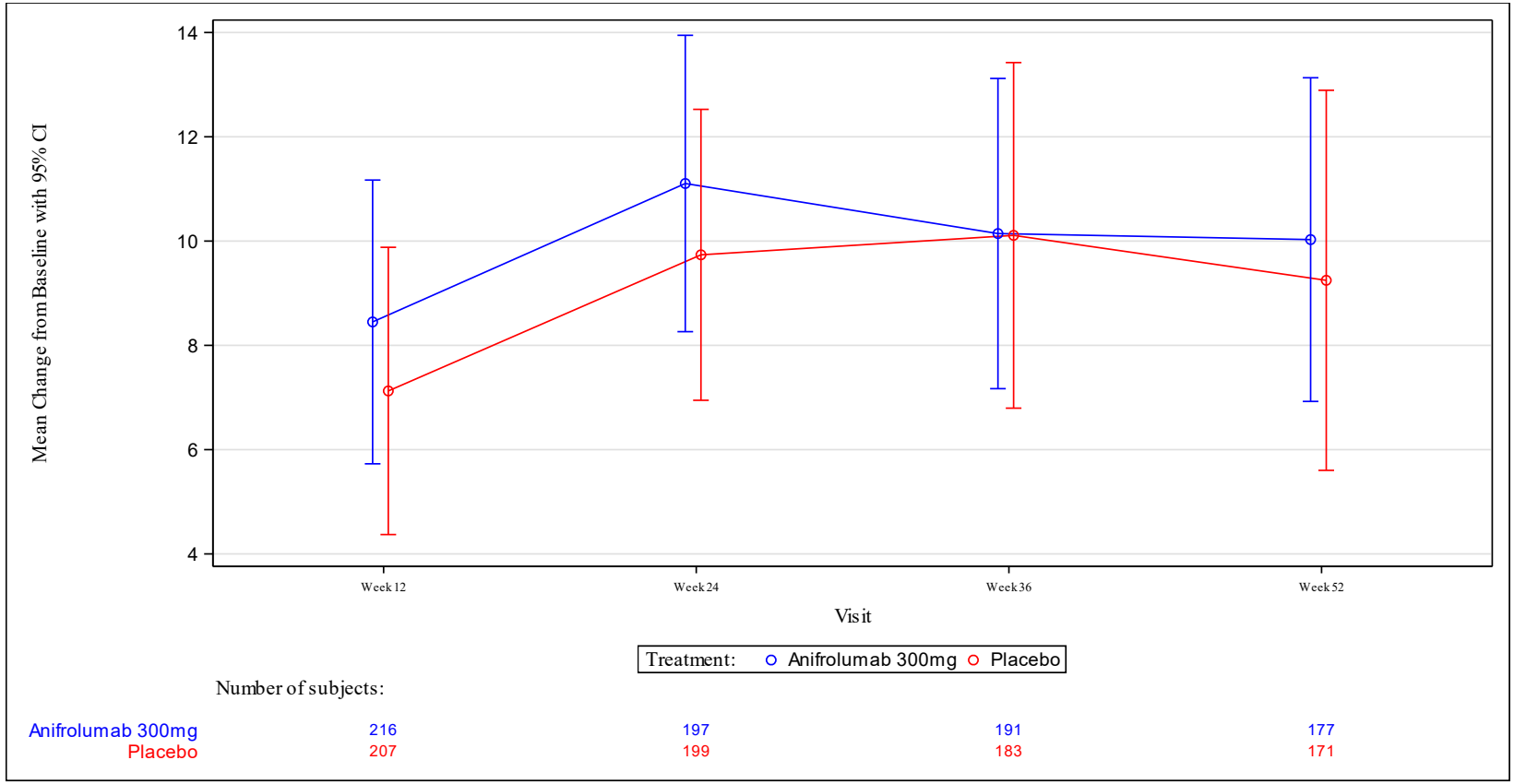
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Lupus QoL Burden to Others domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Fatigue domain score
Full analysis set

	Anifrolumab 300mg (N=246)				Placebo (N=246)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	232	49.54 (26.82)	0	-	233	46.75 (25.64)	0	-
Week 12	227	58.07 (27.04)	216	8.45 (20.29)	218	54.16 (26.30)	207	7.13 (20.10)
Week 24	211	60.99 (26.78)	197	11.10 (20.22)	210	57.02 (26.19)	199	9.74 (19.96)
Week 36	205	60.27 (26.40)	191	10.14 (20.84)	190	58.39 (25.54)	183	10.11 (22.72)
Week 52	191	60.34 (27.68)	177	10.03 (20.92)	179	58.00 (26.17)	171	9.25 (24.14)

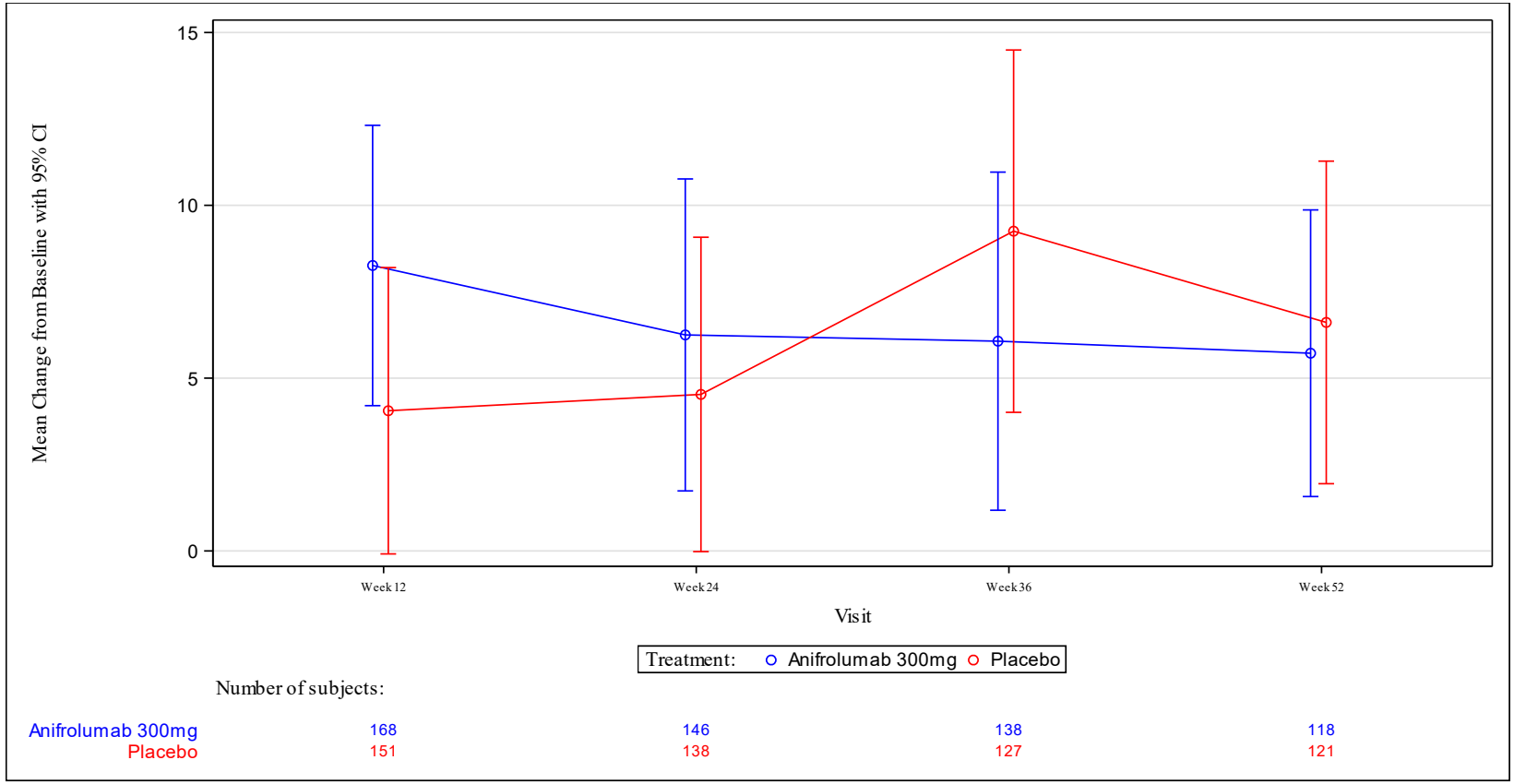
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Lupus QoL Fatigue domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Intimate Relationships domain score
Full analysis set

	Anifrolumab 300mg (N=246)				Placebo (N=246)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	195	55.32 (32.60)	0	-	192	58.66 (28.84)	0	-
Week 12	189	64.88 (31.65)	168	8.26 (26.62)	173	61.42 (31.11)	151	4.06 (25.76)
Week 24	165	64.02 (32.46)	146	6.25 (27.59)	153	62.66 (30.55)	138	4.53 (27.01)
Week 36	160	64.77 (32.42)	138	6.07 (29.06)	138	67.93 (28.45)	127	9.25 (29.85)
Week 52	140	66.25 (31.19)	118	5.72 (22.74)	132	66.19 (29.33)	121	6.61 (25.92)

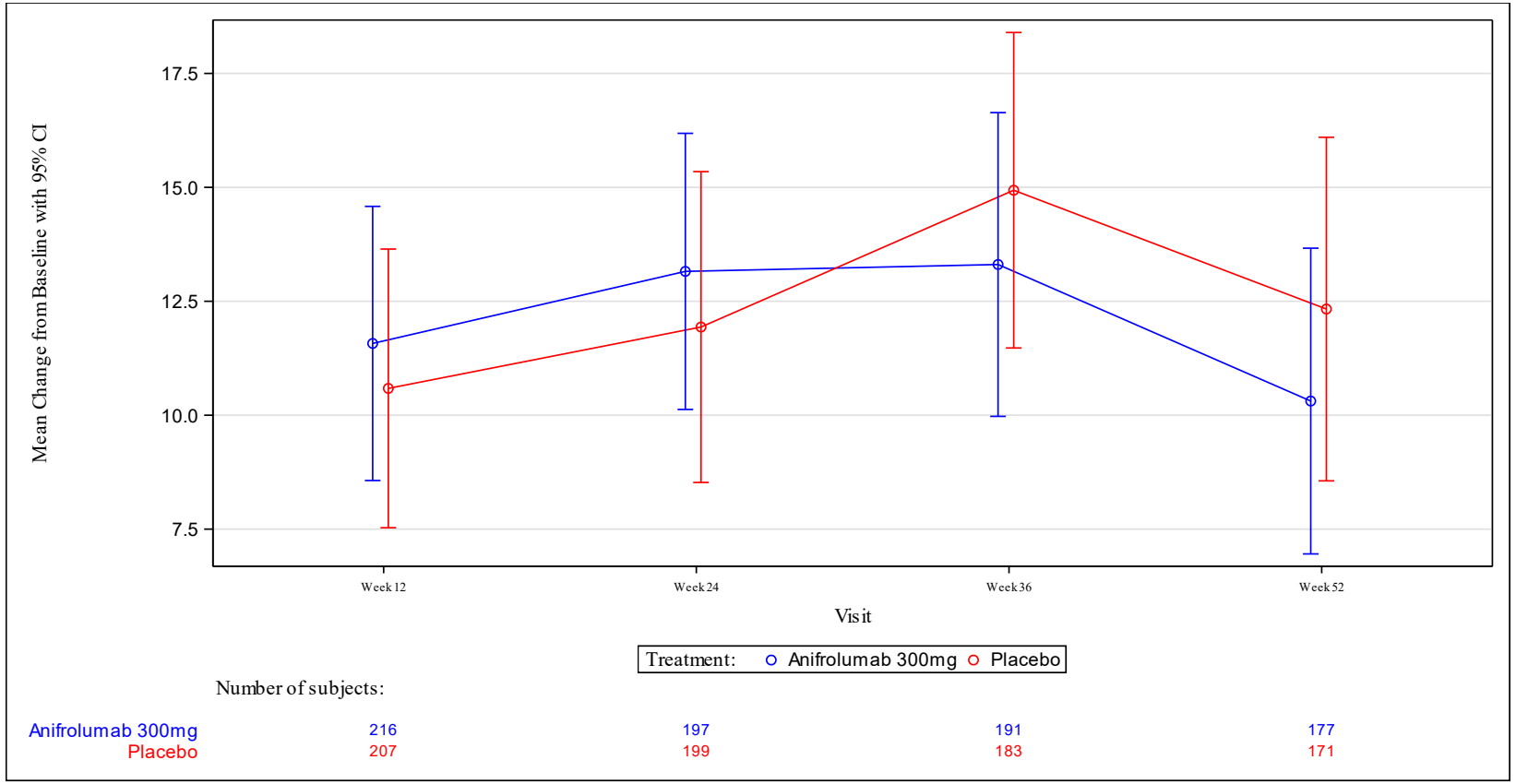
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Lupus QoL Intimate Relationships domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Pain domain score
Full analysis set

	Anifrolumab 300mg (N=246)				Placebo (N=246)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	232	55.60 (28.02)	0	-	233	50.68 (28.23)	0	-
Week 12	227	67.07 (27.49)	216	11.57 (22.43)	218	61.16 (27.36)	207	10.59 (22.31)
Week 24	211	68.88 (26.27)	197	13.16 (21.56)	210	62.38 (27.74)	199	11.93 (24.40)
Week 36	205	69.15 (25.74)	191	13.31 (23.35)	190	65.48 (26.61)	183	14.94 (23.73)
Week 52	191	68.59 (25.17)	177	10.31 (22.61)	179	64.90 (25.60)	171	12.33 (24.97)

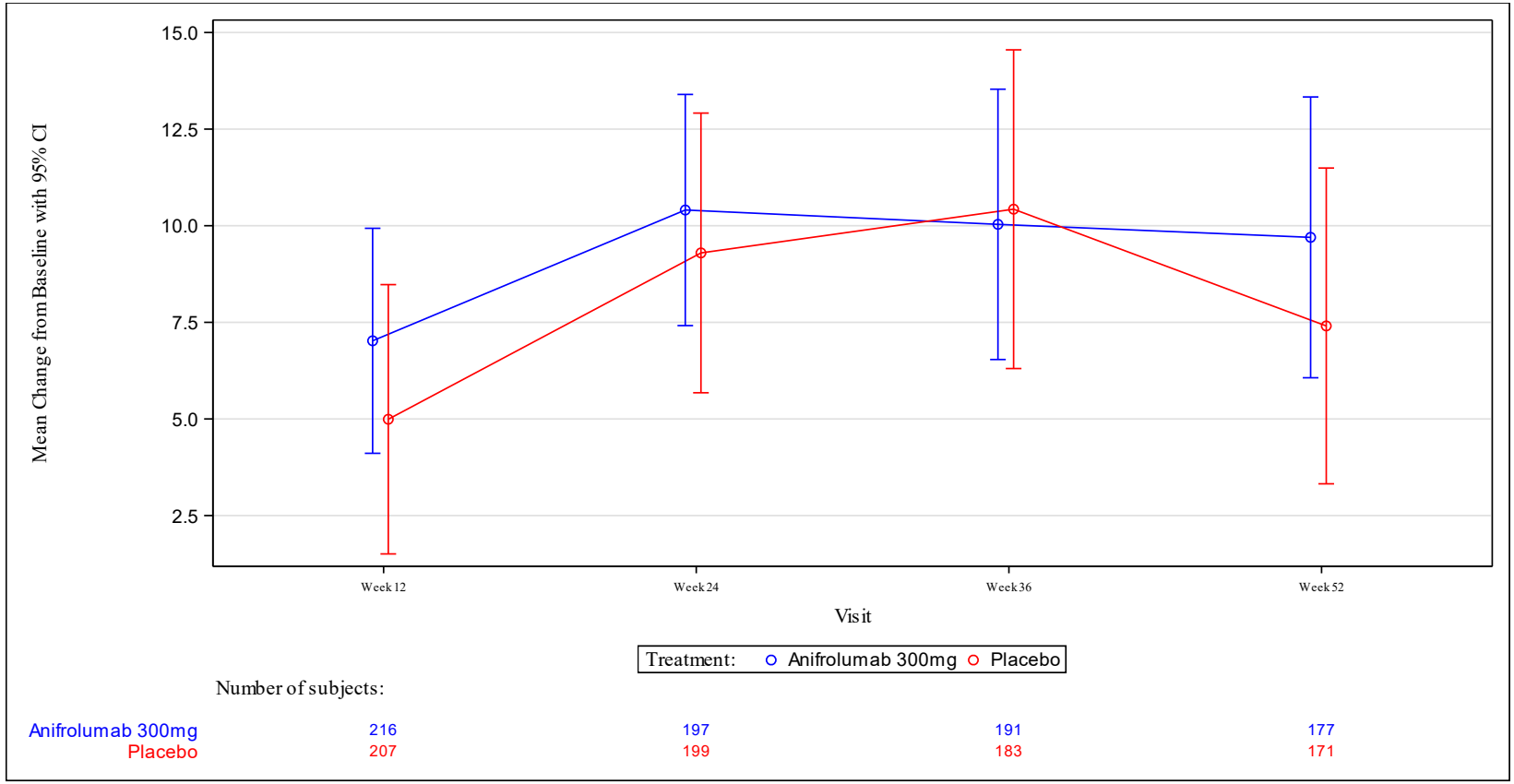
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Lupus QoL Pain domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Planning domain score
Full analysis set

	Anifrolumab 300mg (N=246)				Placebo (N=246)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	232	60.78 (29.39)	0	-	233	56.80 (30.05)	0	-
Week 12	227	67.36 (28.78)	216	7.02 (21.71)	218	62.00 (28.79)	207	4.99 (25.43)
Week 24	211	71.13 (28.00)	197	10.41 (21.29)	210	65.48 (28.46)	199	9.30 (25.89)
Week 36	205	70.33 (27.64)	191	10.04 (24.51)	190	68.25 (27.24)	183	10.43 (28.27)
Week 52	191	70.20 (28.14)	177	9.70 (24.49)	179	66.43 (27.17)	171	7.41 (27.06)

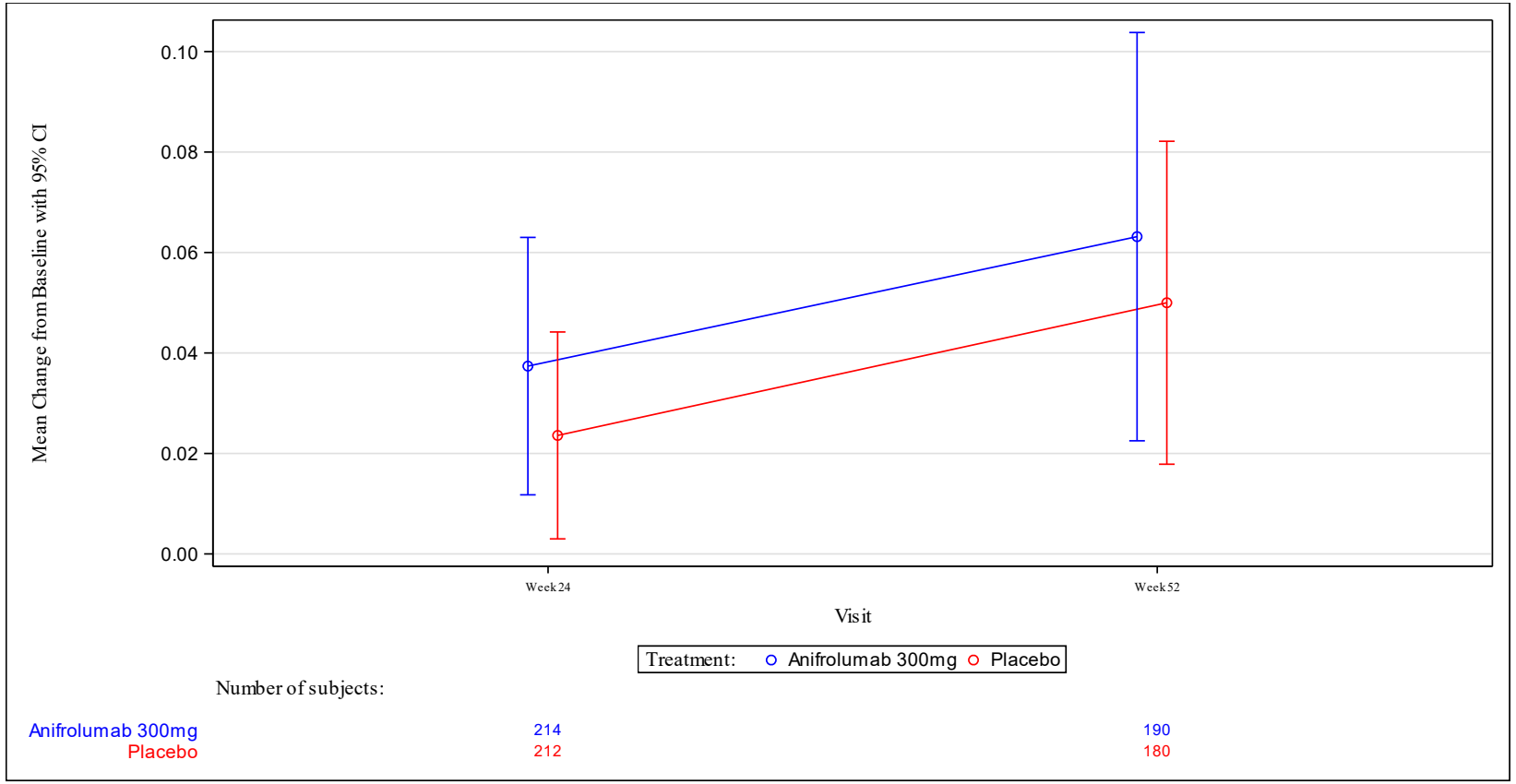
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - Lupus QoL Planning domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - SDI Global Score
Full analysis set

	Anifrolumab 300mg (N=246)				Placebo (N=246)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	240	0.53 (0.98)	0	-	238	0.58 (0.91)	0	-
Week 24	216	0.57 (0.99)	214	0.04 (0.19)	216	0.61 (0.98)	212	0.02 (0.15)
Week 52	193	0.62 (0.99)	190	0.06 (0.28)	188	0.58 (0.92)	180	0.05 (0.22)

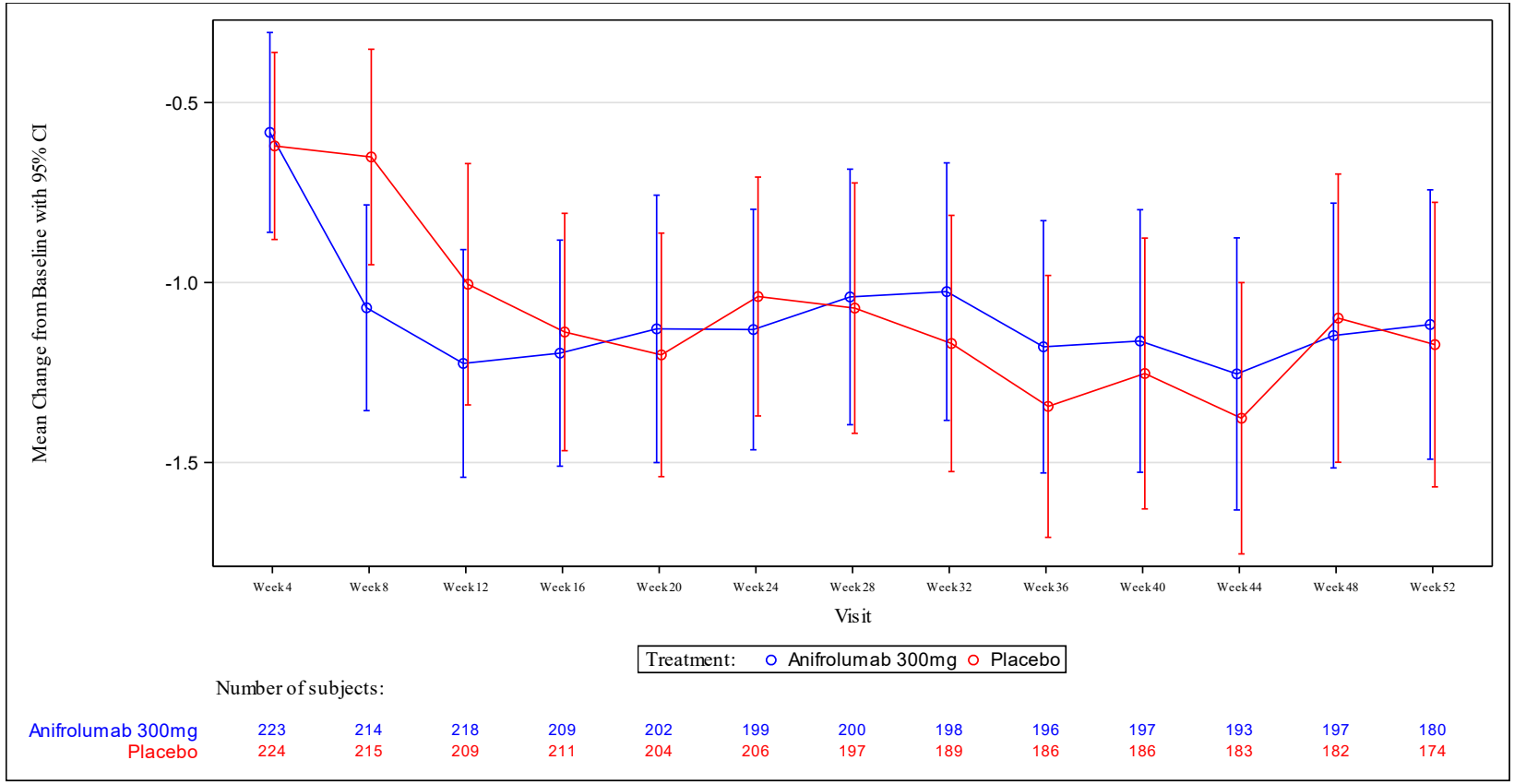
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - SDI Global Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - NRS Score
Full analysis set

	Anifrolumab 300mg (N=246)				Placebo (N=246)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	232	5.32 (2.43)	0	-	233	5.59 (2.44)	0	-
Week 4	231	4.77 (2.45)	223	-0.58 (2.10)	233	5.07 (2.59)	224	-0.62 (1.97)
Week 8	223	4.22 (2.55)	214	-1.07 (2.12)	226	5.05 (2.62)	215	-0.65 (2.23)
Week 12	229	4.08 (2.67)	218	-1.22 (2.37)	220	4.64 (2.65)	209	-1.00 (2.46)
Week 16	221	4.03 (2.55)	209	-1.20 (2.30)	220	4.55 (2.48)	211	-1.14 (2.43)
Week 20	214	4.05 (2.65)	202	-1.13 (2.68)	216	4.42 (2.54)	204	-1.20 (2.45)
Week 24	213	4.00 (2.59)	199	-1.13 (2.39)	217	4.61 (2.59)	206	-1.04 (2.42)
Week 28	213	4.08 (2.65)	200	-1.04 (2.55)	208	4.51 (2.60)	197	-1.07 (2.48)
Week 32	211	4.22 (2.53)	198	-1.03 (2.55)	198	4.41 (2.65)	189	-1.17 (2.48)
Week 36	210	4.02 (2.60)	196	-1.18 (2.49)	194	4.25 (2.50)	186	-1.34 (2.51)
Week 40	211	3.94 (2.54)	197	-1.16 (2.60)	196	4.41 (2.66)	186	-1.25 (2.60)
Week 44	205	3.86 (2.57)	193	-1.25 (2.66)	190	4.28 (2.58)	183	-1.38 (2.58)
Week 48	210	4.05 (2.63)	197	-1.15 (2.62)	191	4.42 (2.74)	182	-1.10 (2.74)
Week 52	194	3.96 (2.54)	180	-1.12 (2.54)	182	4.36 (2.71)	174	-1.17 (2.64)

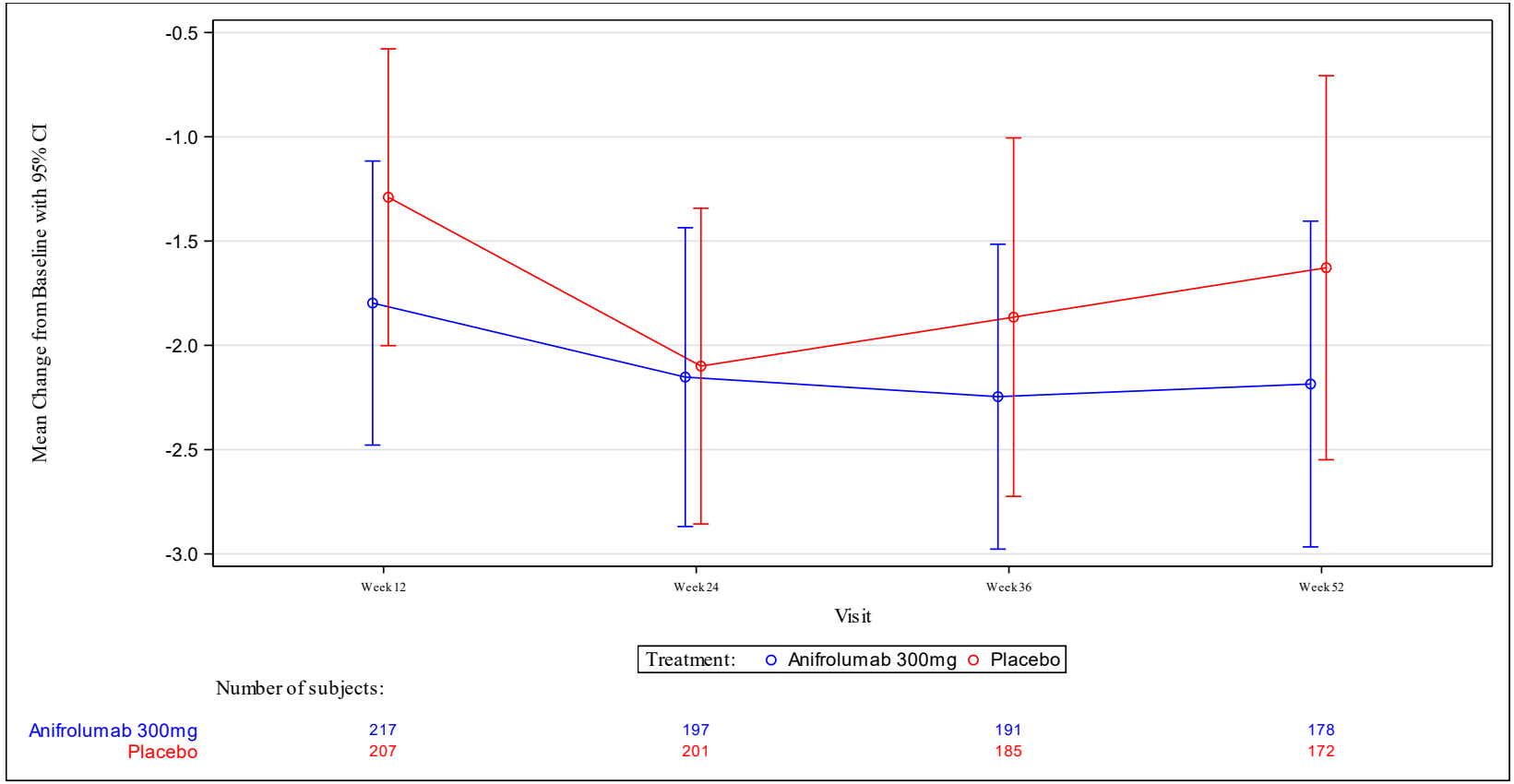
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - NRS Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - PHQ-8 Total Score
Full analysis set

	Anifrolumab 300mg (N=246)				Placebo (N=246)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	232	9.40 (6.19)	0	-	233	9.82 (6.03)	0	-
Week 12	228	7.70 (6.10)	217	-1.80 (5.09)	218	8.41 (5.80)	207	-1.29 (5.19)
Week 24	211	7.28 (5.77)	197	-2.15 (5.10)	212	7.92 (5.83)	201	-2.10 (5.44)
Week 36	205	7.33 (5.73)	191	-2.25 (5.12)	192	7.81 (5.79)	185	-1.86 (5.92)
Week 52	192	7.18 (5.70)	178	-2.19 (5.28)	180	7.82 (5.92)	172	-1.63 (6.12)

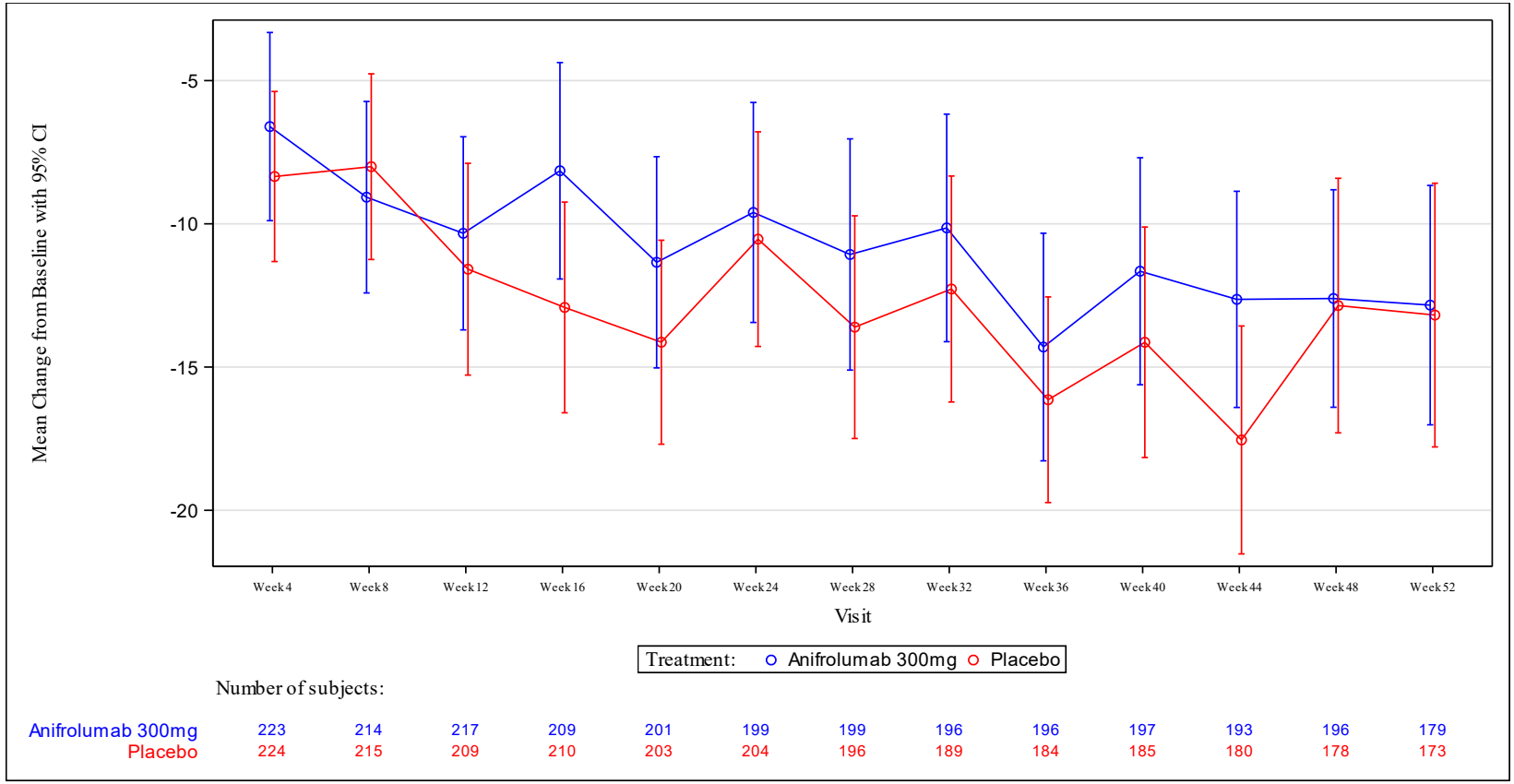
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - PHQ-8 Total Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - PtGA
Full analysis set

	Anifrolumab 300mg (N=246)				Placebo (N=246)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	232	53.10 (21.46)	0	-	233	56.88 (21.62)	0	-
Week 4	231	46.60 (22.07)	223	-6.61 (24.89)	233	49.04 (22.90)	224	-8.35 (22.54)
Week 8	223	43.80 (23.97)	214	-9.07 (24.81)	226	49.70 (22.85)	215	-8.00 (24.11)
Week 12	228	42.54 (23.96)	217	-10.33 (25.19)	220	46.50 (24.47)	209	-11.58 (27.11)
Week 16	221	44.61 (25.28)	209	-8.15 (27.70)	219	44.32 (24.23)	210	-12.92 (27.03)
Week 20	213	40.81 (24.56)	201	-11.34 (26.51)	214	42.39 (24.21)	203	-14.13 (25.73)
Week 24	213	42.44 (25.83)	199	-9.60 (27.47)	215	46.77 (25.03)	204	-10.53 (27.14)
Week 28	212	41.56 (24.93)	199	-11.07 (28.87)	207	42.41 (23.94)	196	-13.61 (27.59)
Week 32	209	42.70 (25.06)	196	-10.14 (28.19)	198	43.19 (25.10)	189	-12.28 (27.49)
Week 36	210	39.11 (23.98)	196	-14.30 (28.20)	192	39.35 (23.61)	184	-16.14 (24.68)
Week 40	211	41.01 (24.68)	197	-11.65 (28.20)	194	42.98 (25.22)	185	-14.14 (27.74)
Week 44	205	39.83 (23.72)	193	-12.64 (26.58)	187	39.74 (24.43)	180	-17.54 (27.05)
Week 48	209	40.47 (24.68)	196	-12.61 (26.95)	187	42.80 (26.27)	178	-12.85 (30.04)
Week 52	193	40.28 (25.42)	179	-12.84 (28.33)	181	43.23 (26.59)	173	-13.18 (30.67)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - PtGA
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SLEDAI-2K Total Score
Full analysis set

	Anifrolumab 300mg (N=246)		Placebo (N=246)		Difference of						
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		-0.70 (0.17)		-0.69 (0.17)	-0.01 (0.20)	(-0.41, 0.39)	0.9529				
Week 8		-2.14 (0.23)		-1.50 (0.24)	-0.64 (0.31)	(-1.25, -0.03)	0.0384				
Week 12		-3.54 (0.24)		-2.43 (0.25)	-1.11 (0.33)	(-1.75, -0.47)	0.0007				
Week 16		-4.17 (0.27)		-3.11 (0.27)	-1.06 (0.36)	(-1.76, -0.36)	0.0032				
Week 20		-4.66 (0.26)		-3.69 (0.26)	-0.96 (0.35)	(-1.64, -0.28)	0.0056				
Week 24		-5.01 (0.26)		-3.92 (0.26)	-1.09 (0.35)	(-1.77, -0.40)	0.0019				
Week 28		-5.27 (0.27)		-3.97 (0.28)	-1.30 (0.37)	(-2.03, -0.58)	0.0005				
Week 32		-5.53 (0.27)		-4.31 (0.27)	-1.22 (0.36)	(-1.94, -0.51)	0.0009				
Week 36		-5.51 (0.28)		-4.43 (0.28)	-1.08 (0.38)	(-1.82, -0.34)	0.0044				
Week 40		-5.44 (0.28)		-4.56 (0.29)	-0.89 (0.39)	(-1.65, -0.13)	0.0219				
Week 44		-5.67 (0.28)		-4.86 (0.28)	-0.81 (0.38)	(-1.55, -0.07)	0.0321				
Week 48		-5.67 (0.28)		-4.93 (0.28)	-0.75 (0.38)	(-1.49, -0.00)	0.0499				
Week 52		-5.96 (0.27)		-5.18 (0.27)	-0.78 (0.36)	(-1.49, -0.06)	0.0327				
OVERALL	245	-4.56 (0.21)	243	-3.66 (0.21)	-0.90 (0.27)	(-1.44, -0.36)	0.0011	-0.27 (0.09)	(-0.45, -0.09)	0.0029	0.4643

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SLEDAI-2K Total Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) N	LSMean (SE)	Placebo (N=246) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.5318
< 10 points	79	-3.44 (0.26)	69	-2.74 (0.28)	-0.70 (0.37)	(-1.44, 0.03)	0.0614	-0.30 (0.17)	(-0.63, 0.02)	0.0683	
>= 10 points	166	-4.85 (0.28)	174	-3.83 (0.27)	-1.02 (0.35)	(-1.72, -0.33)	0.0042	-0.28 (0.11)	(-0.50, -0.07)	0.0090	
OCS dose at baseline											0.0129
<10 mg/day	115	-3.96 (0.25)	116	-3.76 (0.26)	-0.20 (0.35)	(-0.89, 0.48)	0.5571	-0.07 (0.13)	(-0.33, 0.18)	0.5760	
>=10 mg/day	130	-5.12 (0.35)	127	-3.57 (0.34)	-1.55 (0.41)	(-2.36, -0.73)	0.0002	-0.39 (0.13)	(-0.64, -0.15)	0.0018	
Result of type I IFN gene signature test											0.0338
LOW	45	-3.16 (0.37)	48	-3.28 (0.36)	0.13 (0.51)	(-0.89, 1.15)	0.8029	0.05 (0.21)	(-0.36, 0.46)	0.8052	
HIGH	200	-4.96 (0.23)	195	-3.81 (0.23)	-1.15 (0.31)	(-1.77, -0.53)	0.0003	-0.35 (0.10)	(-0.55, -0.15)	0.0005	
Age (years)											NE
<= 65	238	-4.60 (0.22)	240	-3.64 (0.22)	-0.96 (0.28)	(-1.51, -0.42)	0.0006	-0.29 (0.09)	(-0.47, -0.11)	0.0018	
> 65	7	NE	3	NE	NE	NE		NE	NE		
Sex											0.0526
male	23	-5.45 (0.67)	19	-2.87 (0.76)	-2.59 (0.89)	(-4.39, -0.78)	0.0061	-0.77 (0.32)	(-1.41, -0.14)	0.0163	
female	222	-4.44 (0.22)	224	-3.67 (0.22)	-0.77 (0.29)	(-1.33, -0.21)	0.0073	-0.23 (0.10)	(-0.42, -0.05)	0.0143	
Race											0.0725
White	160	-4.17 (0.25)	172	-3.72 (0.24)	-0.45 (0.32)	(-1.09, 0.19)	0.1685	-0.14 (0.11)	(-0.36, 0.08)	0.2024	
Black	32	-4.92 (0.60)	32	-3.92 (0.57)	-1.01 (0.76)	(-2.53, 0.52)	0.1905	-0.30 (0.25)	(-0.79, 0.19)	0.2317	
Other	45	-5.19 (0.71)	36	-2.87 (0.79)	-2.32 (0.76)	(-3.84, -0.80)	0.0032	-0.48 (0.23)	(-0.93, -0.04)	0.0331	
Ethnicity											0.6790
Hispanic/Latino	50	-5.06 (0.49)	56	-3.92 (0.49)	-1.13 (0.62)	(-2.37, 0.11)	0.0727	-0.32 (0.20)	(-0.70, 0.07)	0.1073	
Non-hispanic/Latino	187	-4.47 (0.24)	184	-3.62 (0.24)	-0.85 (0.31)	(-1.45, -0.24)	0.0062	-0.26 (0.10)	(-0.46, -0.05)	0.0130	
Geographic region											0.7093
EU	92	-5.15 (0.37)	87	-4.43 (0.38)	-0.72 (0.46)	(-1.62, 0.18)	0.1178	-0.20 (0.15)	(-0.50, 0.09)	0.1778	
non-EU	153	-4.24 (0.26)	156	-3.31 (0.26)	-0.93 (0.34)	(-1.60, -0.26)	0.0068	-0.29 (0.11)	(-0.51, -0.06)	0.0126	
Onset of disease											NE
Paediatric	19	NE	12	NE	NE	NE		NE	NE		
Adult	226	-4.45 (0.21)	231	-3.62 (0.21)	-0.83 (0.28)	(-1.37, -0.28)	0.0032	-0.25 (0.09)	(-0.44, -0.07)	0.0067	
ADA result											0.0236
Negative	226	-4.50 (0.21)	220	-3.70 (0.22)	-0.80 (0.28)	(-1.35, -0.25)	0.0043	-0.25 (0.10)	(-0.44, -0.06)	0.0088	
Positive (At any time)	19	-5.72 (0.88)	23	-2.66 (0.77)	-3.06 (0.96)	(-5.01, -1.12)	0.0030	-0.80 (0.32)	(-1.44, -0.17)	0.0132	
BMI (kg/m2) at enrolment											0.1744
< 30	158	-4.89 (0.28)	173	-3.72 (0.28)	-1.16 (0.35)	(-1.84, -0.48)	0.0009	-0.32 (0.11)	(-0.54, -0.11)	0.0034	
>= 30	87	-3.82 (0.32)	70	-3.42 (0.34)	-0.40 (0.44)	(-1.28, 0.48)	0.3675	-0.14 (0.16)	(-0.45, 0.18)	0.3944	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score CNS
Full analysis set

Visit	Anifrolumab 300mg (N=246) N	Anifrolumab 300mg (N=246) LSMean (SE)	Placebo (N=246) N	Placebo (N=246) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		NE		NE	NE	NE					
Week 8		NE		NE	NE	NE					
Week 12		NE		NE	NE	NE					
Week 16		NE		NE	NE	NE					
Week 20		NE		NE	NE	NE					
Week 24		NE		NE	NE	NE					
Week 28		NE		NE	NE	NE					
Week 32		NE		NE	NE	NE					
Week 36		NE		NE	NE	NE					
Week 40		NE		NE	NE	NE					
Week 44		NE		NE	NE	NE					
Week 48		NE		NE	NE	NE					
Week 52		NE		NE	NE	NE					
OVERALL	245	NE	244	NE	NE	NE		NE	NE		NE

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score CNS - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=246)		Placebo (N=246)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											NE
< 10 points	79	NE	69	NE	NE	NE		NE	NE		
>= 10 points	166	NE	175	NE	NE	NE		NE	NE		
OCS dose at baseline											NE
<10 mg/day	115	NE	116	NE	NE	NE		NE	NE		
>=10 mg/day	130	NE	128	NE	NE	NE		NE	NE		
Result of type I IFN gene signature test											NE
LOW	45	NE	48	NE	NE	NE		NE	NE		
HIGH	200	NE	196	NE	NE	NE		NE	NE		
Age (years)											NE
<= 65	238	NE	241	NE	NE	NE		NE	NE		
> 65	7	NE	3	NE	NE	NE		NE	NE		
Sex											NE
male	23	NE	20	NE	NE	NE		NE	NE		
female	222	NE	224	NE	NE	NE		NE	NE		
Race											NE
White	160	NE	173	NE	NE	NE		NE	NE		
Black	32	NE	32	NE	NE	NE		NE	NE		
Other	45	NE	36	NE	NE	NE		NE	NE		
Ethnicity											NE
Hispanic/Latino	50	NE	56	NE	NE	NE		NE	NE		
Non-hispanic/Latino	187	NE	185	NE	NE	NE		NE	NE		
Geographic region											NE
EU	92	NE	88	NE	NE	NE		NE	NE		
non-EU	153	NE	156	NE	NE	NE		NE	NE		
Onset of disease											NE
Paediatric	19	NE	12	NE	NE	NE		NE	NE		
Adult	226	NE	232	NE	NE	NE		NE	NE		
ADA result											NE
Negative	226	NE	221	NE	NE	NE		NE	NE		
Positive (At any time)	19	NE	23	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											NE
< 30	158	NE	174	NE	NE	NE		NE	NE		
>= 30	87	NE	70	NE	NE	NE		NE	NE		

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score CVS and Respiratory
Full analysis set

Visit	Anifrolumab 300mg (N=246) N	Anifrolumab 300mg (N=246) LSMean (SE)	Placebo (N=246) N	Placebo (N=246) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		NE		NE	NE	NE					
Week 8		NE		NE	NE	NE					
Week 12		NE		NE	NE	NE					
Week 16		NE		NE	NE	NE					
Week 20		NE		NE	NE	NE					
Week 24		NE		NE	NE	NE					
Week 28		NE		NE	NE	NE					
Week 32		NE		NE	NE	NE					
Week 36		NE		NE	NE	NE					
Week 40		NE		NE	NE	NE					
Week 44		NE		NE	NE	NE					
Week 48		NE		NE	NE	NE					
Week 52		NE		NE	NE	NE					
OVERALL	245	NE	244	NE	NE	NE		NE	NE		NE

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score CVS and Respiratory - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) N	LSMean (SE)	Placebo (N=246) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											NE
< 10 points	79	NE	69	NE	NE	NE		NE	NE		
>= 10 points	166	NE	175	NE	NE	NE		NE	NE		
OCS dose at baseline											NE
<10 mg/day	115	NE	116	NE	NE	NE		NE	NE		
>=10 mg/day	130	NE	128	NE	NE	NE		NE	NE		
Result of type I IFN gene signature test											NE
LOW	45	NE	48	NE	NE	NE		NE	NE		
HIGH	200	NE	196	NE	NE	NE		NE	NE		
Age (years)											NE
<= 65	238	NE	241	NE	NE	NE		NE	NE		
> 65	7	NE	3	NE	NE	NE		NE	NE		
Sex											NE
male	23	NE	20	NE	NE	NE		NE	NE		
female	222	NE	224	NE	NE	NE		NE	NE		
Race											NE
White	160	NE	173	NE	NE	NE		NE	NE		
Black	32	NE	32	NE	NE	NE		NE	NE		
Other	45	NE	36	NE	NE	NE		NE	NE		
Ethnicity											NE
Hispanic/Latino	50	NE	56	NE	NE	NE		NE	NE		
Non-hispanic/Latino	187	NE	185	NE	NE	NE		NE	NE		
Geographic region											NE
EU	92	NE	88	NE	NE	NE		NE	NE		
non-EU	153	NE	156	NE	NE	NE		NE	NE		
Onset of disease											NE
Paediatric	19	NE	12	NE	NE	NE		NE	NE		
Adult	226	NE	232	NE	NE	NE		NE	NE		
ADA result											NE
Negative	226	NE	221	NE	NE	NE		NE	NE		
Positive (At any time)	19	NE	23	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											NE
< 30	158	NE	174	NE	NE	NE		NE	NE		
>= 30	87	NE	70	NE	NE	NE		NE	NE		

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score Hematological
Full analysis set

	Anifrolumab 300mg (N=246)		Placebo (N=246)		Difference of						
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		-0.09 (0.02)		-0.03 (0.02)	-0.06 (0.02)	(-0.11, -0.02)	0.0069				
Week 8		-0.10 (0.02)		-0.04 (0.02)	-0.06 (0.02)	(-0.11, -0.02)	0.0084				
Week 12		-0.12 (0.02)		-0.04 (0.02)	-0.08 (0.02)	(-0.12, -0.03)	0.0013				
Week 16		-0.12 (0.02)		-0.05 (0.02)	-0.07 (0.02)	(-0.11, -0.02)	0.0018				
Week 20		-0.12 (0.02)		-0.04 (0.02)	-0.08 (0.02)	(-0.13, -0.04)	0.0006				
Week 24		-0.11 (0.02)		-0.04 (0.02)	-0.08 (0.02)	(-0.12, -0.03)	0.0019				
Week 28		-0.10 (0.02)		-0.04 (0.02)	-0.06 (0.02)	(-0.11, -0.01)	0.0109				
Week 32		-0.11 (0.02)		-0.04 (0.02)	-0.07 (0.02)	(-0.12, -0.03)	0.0026				
Week 36		-0.11 (0.02)		-0.04 (0.02)	-0.07 (0.02)	(-0.11, -0.02)	0.0061				
Week 40		-0.12 (0.02)		-0.08 (0.02)	-0.04 (0.02)	(-0.08, 0.00)	0.0546				
Week 44		-0.09 (0.02)		-0.06 (0.02)	-0.03 (0.02)	(-0.08, 0.01)	0.1758				
Week 48		-0.11 (0.02)		-0.05 (0.02)	-0.06 (0.03)	(-0.11, -0.00)	0.0347				
Week 52		-0.10 (0.02)		-0.06 (0.02)	-0.04 (0.02)	(-0.08, 0.01)	0.1179				
OVERALL	245	-0.11 (0.01)	244	-0.05 (0.01)	-0.06 (0.02)	(-0.09, -0.03)	<.0001	-0.31 (0.09)	(-0.49, -0.13)	0.0006	0.3773

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score Hematological - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) N	LSMean (SE)	Placebo (N=246) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.5856
< 10 points	79	-0.09 (0.02)	69	-0.02 (0.02)	-0.07 (0.02)	(-0.12, -0.02)	0.0032	-0.46 (0.17)	(-0.79, -0.13)	0.0060	
>= 10 points	166	-0.12 (0.02)	175	-0.06 (0.02)	-0.06 (0.02)	(-0.09, -0.02)	0.0036	-0.28 (0.11)	(-0.49, -0.06)	0.0114	
OCS dose at baseline											0.8470
<10 mg/day	115	-0.09 (0.02)	116	-0.03 (0.02)	-0.06 (0.02)	(-0.10, -0.01)	0.0153	-0.30 (0.13)	(-0.56, -0.04)	0.0243	
>=10 mg/day	130	-0.13 (0.02)	128	-0.06 (0.02)	-0.06 (0.02)	(-0.10, -0.02)	0.0014	-0.31 (0.13)	(-0.56, -0.07)	0.0129	
Result of type I IFN gene signature test											NE
LOW	45	NE	48	NE	NE	NE		NE	NE		
HIGH	200	-0.11 (0.01)	196	-0.04 (0.01)	-0.07 (0.02)	(-0.11, -0.03)	0.0001	-0.37 (0.10)	(-0.57, -0.17)	0.0003	
Age (years)											NE
<= 65	238	-0.11 (0.01)	241	-0.05 (0.01)	-0.06 (0.02)	(-0.09, -0.03)	<.0001	-0.31 (0.09)	(-0.49, -0.13)	0.0007	
> 65	7	NE	3	NE	NE	NE		NE	NE		
Sex											NE
male	23	NE	20	NE	NE	NE		NE	NE		
female	222	-0.11 (0.01)	224	-0.05 (0.01)	-0.06 (0.02)	(-0.09, -0.03)	0.0003	-0.30 (0.10)	(-0.49, -0.11)	0.0017	
Race											NE
White	160	-0.06 (0.01)	173	-0.03 (0.01)	-0.03 (0.01)	(-0.06, -0.00)	0.0448	-0.19 (0.11)	(-0.41, 0.02)	0.0811	
Black	32	NE	32	NE	NE	NE		NE	NE		
Other	45	-0.25 (0.05)	36	-0.04 (0.06)	-0.21 (0.06)	(-0.32, -0.09)	0.0006	-0.59 (0.23)	(-1.04, -0.14)	0.0101	
Ethnicity											NE
Hispanic/Latino	50	NE	56	NE	NE	NE		NE	NE		
Non-hispanic/Latino	187	-0.11 (0.01)	185	-0.05 (0.01)	-0.06 (0.02)	(-0.09, -0.03)	0.0002	-0.33 (0.10)	(-0.54, -0.13)	0.0015	
Geographic region											0.6834
EU	92	-0.10 (0.02)	88	-0.05 (0.02)	-0.05 (0.02)	(-0.09, -0.01)	0.0104	-0.31 (0.15)	(-0.60, -0.02)	0.0387	
non-EU	153	-0.11 (0.02)	156	-0.05 (0.02)	-0.06 (0.02)	(-0.10, -0.02)	0.0042	-0.29 (0.11)	(-0.52, -0.07)	0.0103	
Onset of disease											NE
Paediatric	19	NE	12	NE	NE	NE		NE	NE		
Adult	226	-0.10 (0.01)	232	-0.04 (0.01)	-0.06 (0.02)	(-0.09, -0.03)	<.0001	-0.33 (0.09)	(-0.51, -0.14)	0.0005	
ADA result											NE
Negative	226	-0.11 (0.01)	221	-0.03 (0.01)	-0.07 (0.02)	(-0.10, -0.04)	<.0001	-0.37 (0.10)	(-0.56, -0.18)	0.0001	
Positive (At any time)	19	NE	23	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.0188
< 30	158	-0.14 (0.02)	174	-0.05 (0.02)	-0.08 (0.02)	(-0.12, -0.04)	<.0001	-0.36 (0.11)	(-0.57, -0.14)	0.0013	
>= 30	87	-0.04 (0.01)	70	-0.03 (0.02)	-0.01 (0.02)	(-0.05, 0.02)	0.4505	-0.11 (0.16)	(-0.43, 0.20)	0.4812	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score Immunology
Full analysis set

Visit	Anifrolumab 300mg (N=246) N	Anifrolumab 300mg (N=246) LSMean (SE)	Placebo (N=246) N	Placebo (N=246) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		-0.16 (0.05)		-0.13 (0.05)	-0.03 (0.07)	(-0.17, 0.10)	0.6095				
Week 8		-0.19 (0.06)		-0.04 (0.06)	-0.15 (0.08)	(-0.30, 0.01)	0.0617				
Week 12		-0.24 (0.06)		-0.05 (0.06)	-0.19 (0.08)	(-0.35, -0.04)	0.0168				
Week 16		-0.24 (0.06)		-0.03 (0.07)	-0.21 (0.08)	(-0.38, -0.05)	0.0120				
Week 20		-0.23 (0.07)		0.01 (0.07)	-0.24 (0.09)	(-0.41, -0.06)	0.0077				
Week 24		-0.33 (0.07)		-0.07 (0.07)	-0.26 (0.09)	(-0.43, -0.09)	0.0033				
Week 28		-0.32 (0.07)		-0.01 (0.07)	-0.31 (0.08)	(-0.48, -0.15)	0.0002				
Week 32		-0.32 (0.06)		-0.07 (0.06)	-0.25 (0.08)	(-0.41, -0.09)	0.0026				
Week 36		-0.25 (0.06)		-0.08 (0.07)	-0.17 (0.08)	(-0.34, -0.01)	0.0390				
Week 40		-0.20 (0.07)		-0.04 (0.07)	-0.16 (0.09)	(-0.34, 0.02)	0.0773				
Week 44		-0.17 (0.07)		-0.06 (0.07)	-0.11 (0.09)	(-0.29, 0.06)	0.2109				
Week 48		-0.23 (0.07)		-0.04 (0.07)	-0.19 (0.10)	(-0.38, 0.00)	0.0525				
Week 52		-0.27 (0.07)		-0.05 (0.08)	-0.22 (0.10)	(-0.41, -0.02)	0.0282				
OVERALL	245	-0.24 (0.05)	246	-0.05 (0.05)	-0.19 (0.06)	(-0.31, -0.07)	0.0016	-0.24 (0.09)	(-0.42, -0.07)	0.0073	0.4069

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score Immunology - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) N	LSMean (SE)	Placebo (N=246) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.7765
< 10 points	79	-0.14 (0.06)	69	0.08 (0.07)	-0.22 (0.09)	(-0.38, -0.05)	0.0122	-0.40 (0.17)	(-0.72, -0.07)	0.0173	
>= 10 points	166	-0.24 (0.07)	177	-0.06 (0.06)	-0.18 (0.08)	(-0.34, -0.03)	0.0202	-0.21 (0.11)	(-0.43, -0.00)	0.0494	
OCS dose at baseline											0.1504
<10 mg/day	115	-0.12 (0.05)	117	-0.00 (0.06)	-0.11 (0.07)	(-0.25, 0.03)	0.1155	-0.19 (0.13)	(-0.45, 0.07)	0.1463	
>=10 mg/day	130	-0.41 (0.09)	129	-0.12 (0.09)	-0.28 (0.10)	(-0.47, -0.10)	0.0033	-0.28 (0.12)	(-0.52, -0.03)	0.0272	
Result of type I IFN gene signature test											0.7532
LOW	45	-0.14 (0.08)	48	0.10 (0.07)	-0.23 (0.10)	(-0.44, -0.03)	0.0259	-0.46 (0.21)	(-0.87, -0.05)	0.0291	
HIGH	200	-0.26 (0.05)	198	-0.07 (0.05)	-0.19 (0.07)	(-0.33, -0.05)	0.0070	-0.26 (0.10)	(-0.45, -0.06)	0.0110	
Age (years)											NE
<= 65	238	-0.24 (0.05)	243	-0.05 (0.05)	-0.19 (0.06)	(-0.31, -0.07)	0.0023	-0.24 (0.09)	(-0.42, -0.06)	0.0099	
> 65	7	NE	3	NE	NE	NE		NE	NE		
Sex											0.1373
male	23	-0.43 (0.20)	20	-0.58 (0.23)	0.15 (0.24)	(-0.33, 0.64)	0.5270	0.15 (0.31)	(-0.45, 0.75)	0.6272	
female	222	-0.23 (0.05)	226	-0.02 (0.05)	-0.21 (0.06)	(-0.34, -0.09)	0.0008	-0.27 (0.09)	(-0.46, -0.09)	0.0039	
Race											0.2293
White	160	-0.19 (0.06)	174	-0.08 (0.06)	-0.12 (0.07)	(-0.26, 0.03)	0.1126	-0.15 (0.11)	(-0.37, 0.06)	0.1707	
Black	32	-0.27 (0.14)	32	0.00 (0.13)	-0.27 (0.16)	(-0.58, 0.05)	0.0970	-0.35 (0.25)	(-0.84, 0.14)	0.1655	
Other	45	-0.63 (0.20)	37	-0.19 (0.22)	-0.44 (0.19)	(-0.82, -0.06)	0.0229	-0.33 (0.22)	(-0.77, 0.11)	0.1406	
Ethnicity											0.6193
Hispanic/Latino	50	-0.27 (0.12)	56	-0.14 (0.13)	-0.13 (0.15)	(-0.43, 0.16)	0.3696	-0.15 (0.19)	(-0.53, 0.24)	0.4526	
Non-hispanic/Latino	187	-0.25 (0.06)	187	-0.04 (0.06)	-0.22 (0.07)	(-0.35, -0.08)	0.0017	-0.28 (0.10)	(-0.48, -0.07)	0.0079	
Geographic region											0.3916
EU	92	-0.23 (0.10)	89	-0.11 (0.10)	-0.12 (0.10)	(-0.33, 0.08)	0.2360	-0.13 (0.15)	(-0.42, 0.16)	0.3714	
non-EU	153	-0.25 (0.06)	157	-0.02 (0.06)	-0.23 (0.08)	(-0.38, -0.09)	0.0020	-0.31 (0.11)	(-0.54, -0.09)	0.0063	
Onset of disease											0.2646
Paediatric	19	-0.72 (0.24)	12	-0.17 (0.28)	-0.55 (0.33)	(-1.23, 0.13)	0.1078	-0.53 (0.38)	(-1.26, 0.21)	0.1616	
Adult	226	-0.23 (0.05)	234	-0.05 (0.05)	-0.18 (0.06)	(-0.30, -0.05)	0.0050	-0.22 (0.09)	(-0.41, -0.04)	0.0163	
ADA result											0.2877
Negative	226	-0.22 (0.05)	223	-0.05 (0.05)	-0.17 (0.06)	(-0.30, -0.05)	0.0073	-0.22 (0.09)	(-0.41, -0.03)	0.0202	
Positive (At any time)	19	-0.74 (0.27)	23	-0.35 (0.25)	-0.39 (0.19)	(-0.78, 0.00)	0.0505	-0.32 (0.31)	(-0.93, 0.29)	0.3064	
BMI (kg/m2) at enrolment											0.2908
< 30	158	-0.29 (0.07)	176	-0.06 (0.07)	-0.23 (0.08)	(-0.38, -0.07)	0.0043	-0.25 (0.11)	(-0.47, -0.04)	0.0225	
>= 30	87	-0.14 (0.06)	70	-0.03 (0.07)	-0.10 (0.09)	(-0.27, 0.07)	0.2299	-0.18 (0.16)	(-0.49, 0.14)	0.2724	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score Mucocutaneous
Full analysis set

	Anifrolumab 300mg (N=246)		Placebo (N=246)		Difference of						
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		-0.05 (0.05)		-0.16 (0.05)	0.11 (0.06)	(-0.01, 0.23)	0.0791				
Week 8		-0.42 (0.07)		-0.41 (0.07)	-0.01 (0.10)	(-0.20, 0.18)	0.9291				
Week 12		-0.88 (0.09)		-0.62 (0.09)	-0.26 (0.12)	(-0.50, -0.01)	0.0385				
Week 16		-1.25 (0.10)		-0.91 (0.10)	-0.34 (0.14)	(-0.62, -0.06)	0.0164				
Week 20		-1.42 (0.10)		-1.04 (0.10)	-0.38 (0.14)	(-0.66, -0.10)	0.0080				
Week 24		-1.55 (0.11)		-1.13 (0.11)	-0.42 (0.15)	(-0.72, -0.12)	0.0059				
Week 28		-1.74 (0.11)		-1.17 (0.11)	-0.57 (0.15)	(-0.88, -0.27)	0.0003				
Week 32		-1.86 (0.11)		-1.34 (0.11)	-0.52 (0.16)	(-0.83, -0.21)	0.0009				
Week 36		-1.91 (0.12)		-1.43 (0.12)	-0.48 (0.17)	(-0.80, -0.15)	0.0043				
Week 40		-1.98 (0.13)		-1.53 (0.13)	-0.45 (0.17)	(-0.79, -0.10)	0.0113				
Week 44		-2.14 (0.13)		-1.57 (0.13)	-0.57 (0.18)	(-0.92, -0.23)	0.0012				
Week 48		-2.15 (0.13)		-1.64 (0.13)	-0.51 (0.18)	(-0.86, -0.16)	0.0041				
Week 52		-2.23 (0.12)		-1.74 (0.13)	-0.49 (0.17)	(-0.83, -0.15)	0.0051				
OVERALL	245	-1.51 (0.09)	244	-1.13 (0.09)	-0.38 (0.12)	(-0.61, -0.14)	0.0016	-0.27 (0.09)	(-0.45, -0.10)	0.0026	0.7206

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score Mucocutaneous - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) N	LSMean (SE)	Placebo (N=246) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.8205
< 10 points	79	-1.23 (0.15)	69	-0.88 (0.16)	-0.35 (0.22)	(-0.78, 0.08)	0.1130	-0.26 (0.17)	(-0.58, 0.07)	0.1219	
>= 10 points	166	-1.62 (0.11)	175	-1.22 (0.10)	-0.41 (0.14)	(-0.69, -0.13)	0.0042	-0.30 (0.11)	(-0.51, -0.08)	0.0064	
OCS dose at baseline											0.0028
<10 mg/day	115	-1.23 (0.12)	116	-1.21 (0.12)	-0.03 (0.17)	(-0.36, 0.31)	0.8684	-0.02 (0.13)	(-0.28, 0.24)	0.8721	
>=10 mg/day	130	-1.79 (0.13)	128	-1.06 (0.13)	-0.74 (0.16)	(-1.06, -0.41)	<.0001	-0.52 (0.13)	(-0.76, -0.27)	<.0001	
Result of type I IFN gene signature test											0.6317
LOW	45	-1.29 (0.18)	48	-1.02 (0.17)	-0.27 (0.24)	(-0.75, 0.21)	0.2662	-0.23 (0.21)	(-0.64, 0.18)	0.2733	
HIGH	200	-1.59 (0.10)	196	-1.18 (0.10)	-0.40 (0.14)	(-0.67, -0.14)	0.0033	-0.29 (0.10)	(-0.49, -0.09)	0.0038	
Age (years)											NE
<= 65	238	-1.52 (0.09)	241	-1.12 (0.09)	-0.40 (0.12)	(-0.63, -0.16)	0.0010	-0.29 (0.09)	(-0.47, -0.11)	0.0016	
> 65	7	NE	3	NE	NE	NE		NE	NE		
Sex											0.0609
male	23	-1.62 (0.30)	20	-0.51 (0.33)	-1.11 (0.41)	(-1.94, -0.28)	0.0104	-0.75 (0.32)	(-1.38, -0.13)	0.0174	
female	222	-1.48 (0.09)	224	-1.17 (0.09)	-0.31 (0.12)	(-0.55, -0.07)	0.0128	-0.23 (0.10)	(-0.41, -0.04)	0.0170	
Race											0.0435
White	160	-1.50 (0.11)	173	-1.20 (0.11)	-0.30 (0.14)	(-0.58, -0.02)	0.0390	-0.22 (0.11)	(-0.43, -0.00)	0.0479	
Black	32	-1.45 (0.27)	32	-1.35 (0.26)	-0.10 (0.36)	(-0.82, 0.62)	0.7821	-0.07 (0.25)	(-0.56, 0.42)	0.7929	
Other	45	-1.54 (0.20)	36	-0.57 (0.23)	-0.98 (0.25)	(-1.49, -0.47)	0.0003	-0.71 (0.23)	(-1.16, -0.26)	0.0022	
Ethnicity											0.7121
Hispanic/Latino	50	-1.69 (0.20)	56	-1.22 (0.19)	-0.47 (0.26)	(-0.99, 0.06)	0.0796	-0.33 (0.20)	(-0.71, 0.06)	0.0952	
Non-hispanic/Latino	187	-1.49 (0.10)	185	-1.13 (0.10)	-0.36 (0.13)	(-0.62, -0.09)	0.0078	-0.26 (0.10)	(-0.47, -0.06)	0.0111	
Geographic region											0.9568
EU	92	-1.68 (0.14)	88	-1.32 (0.15)	-0.36 (0.19)	(-0.74, 0.02)	0.0661	-0.26 (0.15)	(-0.55, 0.03)	0.0809	
non-EU	153	-1.40 (0.11)	156	-1.03 (0.11)	-0.37 (0.15)	(-0.67, -0.08)	0.0135	-0.27 (0.11)	(-0.49, -0.05)	0.0182	
Onset of disease											NE
Paediatric	19	NE	12	NE	NE	NE		NE	NE		
Adult	226	-1.48 (0.09)	232	-1.12 (0.09)	-0.36 (0.12)	(-0.60, -0.12)	0.0035	-0.26 (0.09)	(-0.45, -0.08)	0.0053	
ADA result											NE
Negative	226	-1.50 (0.09)	221	-1.13 (0.09)	-0.36 (0.12)	(-0.61, -0.12)	0.0038	-0.26 (0.10)	(-0.45, -0.08)	0.0054	
Positive (At any time)	19	NE	23	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.1157
< 30	158	-1.65 (0.11)	174	-1.13 (0.10)	-0.52 (0.14)	(-0.79, -0.25)	0.0002	-0.39 (0.11)	(-0.60, -0.17)	0.0005	
>= 30	87	-1.26 (0.16)	70	-1.16 (0.17)	-0.10 (0.23)	(-0.55, 0.35)	0.6532	-0.07 (0.16)	(-0.38, 0.24)	0.6624	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score Musculoskeletal
Full analysis set

Visit	Anifrolumab 300mg (N=246) N	Anifrolumab 300mg (N=246) LSMean (SE)	Placebo (N=246) N	Placebo (N=246) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		-0.13 (0.07)		-0.03 (0.07)	-0.10 (0.09)	(-0.27, 0.08)	0.2748				
Week 8		-0.84 (0.12)		-0.63 (0.12)	-0.21 (0.16)	(-0.51, 0.10)	0.1894				
Week 12		-1.44 (0.13)		-1.15 (0.13)	-0.29 (0.18)	(-0.64, 0.06)	0.1026				
Week 16		-1.70 (0.13)		-1.59 (0.13)	-0.11 (0.18)	(-0.47, 0.24)	0.5318				
Week 20		-2.03 (0.14)		-1.85 (0.14)	-0.18 (0.19)	(-0.54, 0.19)	0.3361				
Week 24		-2.13 (0.14)		-1.92 (0.14)	-0.21 (0.18)	(-0.57, 0.15)	0.2524				
Week 28		-2.26 (0.14)		-1.99 (0.14)	-0.27 (0.19)	(-0.64, 0.09)	0.1425				
Week 32		-2.31 (0.14)		-2.13 (0.14)	-0.18 (0.19)	(-0.55, 0.19)	0.3396				
Week 36		-2.41 (0.14)		-2.17 (0.14)	-0.24 (0.19)	(-0.62, 0.13)	0.1964				
Week 40		-2.30 (0.14)		-2.19 (0.14)	-0.11 (0.19)	(-0.48, 0.25)	0.5421				
Week 44		-2.34 (0.14)		-2.22 (0.14)	-0.13 (0.19)	(-0.49, 0.24)	0.4933				
Week 48		-2.36 (0.13)		-2.32 (0.14)	-0.04 (0.18)	(-0.40, 0.32)	0.8176				
Week 52		-2.44 (0.13)		-2.48 (0.13)	0.04 (0.18)	(-0.32, 0.40)	0.8398				
OVERALL	245	-1.90 (0.10)	244	-1.74 (0.10)	-0.16 (0.13)	(-0.42, 0.11)	0.2405	-0.10 (0.09)	(-0.28, 0.08)	0.2720	0.4720

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score Musculoskeletal - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) N	LSMean (SE)	Placebo (N=246) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.9618
< 10 points	79	-1.86 (0.17)	69	-1.72 (0.18)	-0.14 (0.24)	(-0.62, 0.34)	0.5583	-0.09 (0.16)	(-0.42, 0.23)	0.5660	
>= 10 points	166	-1.91 (0.12)	175	-1.76 (0.12)	-0.16 (0.16)	(-0.47, 0.16)	0.3310	-0.10 (0.11)	(-0.31, 0.12)	0.3706	
OCS dose at baseline											0.7133
<10 mg/day	115	-1.93 (0.14)	116	-1.81 (0.14)	-0.11 (0.19)	(-0.49, 0.26)	0.5551	-0.08 (0.13)	(-0.33, 0.18)	0.5687	
>=10 mg/day	130	-1.87 (0.15)	128	-1.66 (0.15)	-0.21 (0.19)	(-0.58, 0.16)	0.2622	-0.12 (0.12)	(-0.37, 0.12)	0.3227	
Result of type I IFN gene signature test											0.2518
LOW	45	-1.54 (0.21)	48	-1.69 (0.20)	0.15 (0.29)	(-0.43, 0.73)	0.6045	0.11 (0.21)	(-0.30, 0.51)	0.6072	
HIGH	200	-2.07 (0.11)	196	-1.84 (0.11)	-0.22 (0.15)	(-0.52, 0.07)	0.1344	-0.15 (0.10)	(-0.34, 0.05)	0.1444	
Age (years)											NE
<= 65	238	-1.92 (0.10)	241	-1.73 (0.10)	-0.19 (0.14)	(-0.45, 0.08)	0.1689	-0.12 (0.09)	(-0.30, 0.06)	0.2005	
> 65	7	NE	3	NE	NE	NE		NE	NE		
Sex											NE
male	23	NE	20	NE	NE	NE		NE	NE		
female	222	-1.86 (0.11)	224	-1.69 (0.11)	-0.18 (0.14)	(-0.45, 0.10)	0.2093	-0.11 (0.09)	(-0.30, 0.07)	0.2392	
Race											0.6976
White	160	-1.89 (0.12)	173	-1.82 (0.12)	-0.07 (0.17)	(-0.39, 0.26)	0.6864	-0.04 (0.11)	(-0.26, 0.17)	0.6964	
Black	32	-2.09 (0.32)	32	-1.66 (0.31)	-0.43 (0.39)	(-1.21, 0.36)	0.2798	-0.24 (0.25)	(-0.73, 0.25)	0.3421	
Other	45	-1.33 (0.31)	36	-1.18 (0.36)	-0.15 (0.32)	(-0.79, 0.49)	0.6458	-0.07 (0.22)	(-0.51, 0.37)	0.7565	
Ethnicity											0.2302
Hispanic/Latino	50	-2.12 (0.22)	56	-1.67 (0.21)	-0.46 (0.28)	(-1.01, 0.10)	0.1060	-0.29 (0.20)	(-0.68, 0.09)	0.1356	
Non-hispanic/Latino	187	-1.84 (0.12)	185	-1.76 (0.12)	-0.07 (0.16)	(-0.38, 0.23)	0.6382	-0.05 (0.10)	(-0.25, 0.16)	0.6594	
Geographic region											0.5755
EU	92	-2.26 (0.15)	88	-2.21 (0.16)	-0.05 (0.20)	(-0.44, 0.35)	0.8197	-0.03 (0.15)	(-0.32, 0.26)	0.8371	
non-EU	153	-1.70 (0.13)	156	-1.50 (0.13)	-0.19 (0.17)	(-0.53, 0.15)	0.2616	-0.12 (0.11)	(-0.34, 0.10)	0.2907	
Onset of disease											NE
Paediatric	19	NE	12	NE	NE	NE		NE	NE		
Adult	226	-1.95 (0.10)	232	-1.75 (0.10)	-0.20 (0.14)	(-0.47, 0.07)	0.1477	-0.13 (0.09)	(-0.31, 0.06)	0.1745	
ADA result											NE
Negative	226	-1.91 (0.10)	221	-1.79 (0.11)	-0.11 (0.14)	(-0.39, 0.16)	0.4155	-0.07 (0.09)	(-0.26, 0.11)	0.4448	
Positive (At any time)	19	NE	23	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.8645
< 30	158	-2.00 (0.13)	174	-1.81 (0.12)	-0.19 (0.16)	(-0.50, 0.13)	0.2451	-0.11 (0.11)	(-0.33, 0.10)	0.2958	
>= 30	87	-1.72 (0.17)	70	-1.59 (0.18)	-0.14 (0.24)	(-0.61, 0.33)	0.5655	-0.09 (0.16)	(-0.40, 0.23)	0.5780	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score Renal
Full analysis set

	Anifrolumab 300mg (N=246)		Placebo (N=246)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 4		-0.08 (0.08)		-0.01 (0.08)	-0.07 (0.10)	(-0.28, 0.13)	0.4904				
Week 8		-0.10 (0.09)		0.12 (0.09)	-0.22 (0.11)	(-0.44, -0.00)	0.0475				
Week 12		-0.15 (0.08)		-0.07 (0.08)	-0.08 (0.10)	(-0.29, 0.12)	0.4244				
Week 16		-0.12 (0.08)		0.05 (0.08)	-0.17 (0.10)	(-0.37, 0.04)	0.1146				
Week 20		-0.12 (0.09)		0.01 (0.09)	-0.13 (0.11)	(-0.35, 0.10)	0.2620				
Week 24		-0.14 (0.08)		0.05 (0.08)	-0.19 (0.10)	(-0.39, 0.01)	0.0671				
Week 28		-0.03 (0.10)		-0.02 (0.10)	-0.01 (0.13)	(-0.28, 0.25)	0.9212				
Week 32		-0.16 (0.09)		0.03 (0.09)	-0.18 (0.12)	(-0.41, 0.04)	0.1091				
Week 36		-0.07 (0.09)		0.04 (0.09)	-0.11 (0.11)	(-0.33, 0.11)	0.3276				
Week 40		-0.07 (0.10)		0.04 (0.10)	-0.12 (0.14)	(-0.39, 0.15)	0.3975				
Week 44		-0.12 (0.11)		-0.01 (0.11)	-0.11 (0.14)	(-0.39, 0.17)	0.4441				
Week 48		-0.02 (0.11)		0.05 (0.11)	-0.08 (0.15)	(-0.37, 0.21)	0.5909				
Week 52		-0.10 (0.10)		0.09 (0.10)	-0.19 (0.13)	(-0.44, 0.07)	0.1528				
OVERALL	246	-0.10 (0.07)	246	0.03 (0.07)	-0.13 (0.09)	(-0.31, 0.05)	0.1660	-0.11 (0.09)	(-0.29, 0.07)	0.2264	0.6444

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score Renal - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) N	LSMean (SE)	Placebo (N=246) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											NE
< 10 points	80	NE	69	NE	NE	NE		NE	NE		
>= 10 points	166	-0.11 (0.11)	177	0.11 (0.10)	-0.21 (0.13)	(-0.47, 0.04)	0.0980	-0.16 (0.11)	(-0.37, 0.06)	0.1508	
OCS dose at baseline											0.1789
<10 mg/day	115	-0.03 (0.05)	117	-0.02 (0.05)	-0.02 (0.08)	(-0.17, 0.13)	0.8282	-0.03 (0.13)	(-0.29, 0.23)	0.8301	
>=10 mg/day	131	-0.21 (0.15)	129	0.05 (0.14)	-0.26 (0.17)	(-0.59, 0.06)	0.1153	-0.16 (0.12)	(-0.40, 0.09)	0.2100	
Result of type I IFN gene signature test											NE
LOW	45	NE	48	NE	NE	NE		NE	NE		
HIGH	201	-0.09 (0.08)	198	0.08 (0.08)	-0.16 (0.11)	(-0.39, 0.06)	0.1456	-0.14 (0.10)	(-0.34, 0.06)	0.1646	
Age (years)											NE
<= 65	239	-0.11 (0.08)	243	0.02 (0.08)	-0.13 (0.09)	(-0.31, 0.05)	0.1653	-0.11 (0.09)	(-0.29, 0.07)	0.2300	
> 65	7	NE	3	NE	NE	NE		NE	NE		
Sex											NE
male	23	NE	20	NE	NE	NE		NE	NE		
female	223	-0.08 (0.07)	226	0.06 (0.07)	-0.14 (0.10)	(-0.33, 0.05)	0.1413	-0.13 (0.09)	(-0.31, 0.06)	0.1834	
Race											NE
White	160	-0.08 (0.09)	174	0.07 (0.09)	-0.15 (0.12)	(-0.39, 0.09)	0.2274	-0.12 (0.11)	(-0.34, 0.09)	0.2622	
Black	33	NE	32	NE	NE	NE		NE	NE		
Other	45	0.01 (0.25)	37	0.22 (0.27)	-0.20 (0.25)	(-0.69, 0.28)	0.4069	-0.12 (0.22)	(-0.56, 0.31)	0.5817	
Ethnicity											NE
Hispanic/Latino	50	NE	56	NE	NE	NE		NE	NE		
Non-hispanic/Latino	188	-0.10 (0.09)	187	0.02 (0.09)	-0.12 (0.11)	(-0.33, 0.09)	0.2730	-0.10 (0.10)	(-0.30, 0.10)	0.3358	
Geographic region											NE
EU	92	NE	89	NE	NE	NE		NE	NE		
non-EU	154	-0.04 (0.07)	157	-0.05 (0.07)	0.01 (0.10)	(-0.18, 0.19)	0.9558	0.01 (0.11)	(-0.22, 0.23)	0.9594	
Onset of disease											NE
Paediatric	19	NE	12	NE	NE	NE		NE	NE		
Adult	227	-0.08 (0.07)	234	0.01 (0.07)	-0.09 (0.09)	(-0.27, 0.08)	0.2986	-0.09 (0.09)	(-0.27, 0.10)	0.3574	
ADA result											NE
Negative	226	-0.07 (0.06)	223	-0.01 (0.06)	-0.06 (0.08)	(-0.20, 0.09)	0.4626	-0.06 (0.09)	(-0.25, 0.12)	0.5179	
Positive (At any time)	19	NE	23	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.9753
< 30	159	-0.04 (0.10)	176	0.10 (0.09)	-0.14 (0.11)	(-0.36, 0.08)	0.2068	-0.11 (0.11)	(-0.33, 0.10)	0.2958	
>= 30	87	-0.23 (0.12)	70	-0.09 (0.14)	-0.14 (0.18)	(-0.50, 0.23)	0.4587	-0.12 (0.16)	(-0.43, 0.20)	0.4676	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score Vascular
Full analysis set

Visit	Anifrolumab 300mg (N=246) N	Anifrolumab 300mg (N=246) LSMean (SE)	Placebo (N=246) N	Placebo (N=246) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		NE		NE	NE	NE					
Week 8		NE		NE	NE	NE					
Week 12		NE		NE	NE	NE					
Week 16		NE		NE	NE	NE					
Week 20		NE		NE	NE	NE					
Week 24		NE		NE	NE	NE					
Week 28		NE		NE	NE	NE					
Week 32		NE		NE	NE	NE					
Week 36		NE		NE	NE	NE					
Week 40		NE		NE	NE	NE					
Week 44		NE		NE	NE	NE					
Week 48		NE		NE	NE	NE					
Week 52		NE		NE	NE	NE					
OVERALL	245	NE	244	NE	NE	NE		NE	NE		NE

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Total Organ Score Vascular - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=246)		Placebo (N=246)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											NE
< 10 points	79	NE	69	NE	NE	NE		NE	NE		
>= 10 points	166	NE	175	NE	NE	NE		NE	NE		
OCS dose at baseline											NE
<10 mg/day	115	NE	116	NE	NE	NE		NE	NE		
>=10 mg/day	130	NE	128	NE	NE	NE		NE	NE		
Result of type I IFN gene signature test											NE
LOW	45	NE	48	NE	NE	NE		NE	NE		
HIGH	200	NE	196	NE	NE	NE		NE	NE		
Age (years)											NE
<= 65	238	NE	241	NE	NE	NE		NE	NE		
> 65	7	NE	3	NE	NE	NE		NE	NE		
Sex											NE
male	23	NE	20	NE	NE	NE		NE	NE		
female	222	NE	224	NE	NE	NE		NE	NE		
Race											NE
White	160	NE	173	NE	NE	NE		NE	NE		
Black	32	NE	32	NE	NE	NE		NE	NE		
Other	45	NE	36	NE	NE	NE		NE	NE		
Ethnicity											NE
Hispanic/Latino	50	NE	56	NE	NE	NE		NE	NE		
Non-hispanic/Latino	187	NE	185	NE	NE	NE		NE	NE		
Geographic region											NE
EU	92	NE	88	NE	NE	NE		NE	NE		
non-EU	153	NE	156	NE	NE	NE		NE	NE		
Onset of disease											NE
Paediatric	19	NE	12	NE	NE	NE		NE	NE		
Adult	226	NE	232	NE	NE	NE		NE	NE		
ADA result											NE
Negative	226	NE	221	NE	NE	NE		NE	NE		
Positive (At any time)	19	NE	23	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											NE
< 30	158	NE	174	NE	NE	NE		NE	NE		
>= 30	87	NE	70	NE	NE	NE		NE	NE		

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - PGA
Full analysis set

Visit	Anifrolumab 300mg (N=246) N	Anifrolumab 300mg (N=246) LSMean (SE)	Placebo (N=246) N	Placebo (N=246) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		-0.24 (0.03)		-0.20 (0.03)	-0.05 (0.03)	(-0.11, 0.02)	0.1371				
Week 8		-0.46 (0.03)		-0.37 (0.03)	-0.09 (0.04)	(-0.17, -0.01)	0.0309				
Week 12		-0.63 (0.03)		-0.44 (0.03)	-0.19 (0.05)	(-0.28, -0.10)	<.0001				
Week 16		-0.75 (0.04)		-0.57 (0.04)	-0.18 (0.05)	(-0.27, -0.08)	0.0002				
Week 20		-0.80 (0.04)		-0.60 (0.04)	-0.20 (0.05)	(-0.30, -0.10)	<.0001				
Week 24		-0.86 (0.04)		-0.65 (0.04)	-0.21 (0.05)	(-0.31, -0.11)	<.0001				
Week 28		-0.90 (0.04)		-0.71 (0.04)	-0.19 (0.05)	(-0.29, -0.09)	0.0002				
Week 32		-0.94 (0.04)		-0.72 (0.04)	-0.22 (0.05)	(-0.32, -0.11)	<.0001				
Week 36		-0.97 (0.04)		-0.78 (0.04)	-0.19 (0.06)	(-0.30, -0.08)	0.0007				
Week 40		-0.95 (0.04)		-0.81 (0.04)	-0.14 (0.06)	(-0.26, -0.03)	0.0125				
Week 44		-0.99 (0.04)		-0.79 (0.04)	-0.20 (0.06)	(-0.31, -0.09)	0.0006				
Week 48		-0.98 (0.04)		-0.80 (0.04)	-0.18 (0.06)	(-0.30, -0.07)	0.0018				
Week 52		-1.02 (0.04)		-0.84 (0.04)	-0.18 (0.06)	(-0.30, -0.07)	0.0019				
OVERALL	245	-0.81 (0.03)	244	-0.64 (0.03)	-0.17 (0.04)	(-0.25, -0.09)	<.0001	-0.35 (0.09)	(-0.53, -0.17)	0.0001	0.5264

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - PGA - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) N	LSMean (SE)	Placebo (N=246) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.5900
< 10 points	79	-0.79 (0.06)	69	-0.65 (0.06)	-0.14 (0.08)	(-0.29, 0.01)	0.0756	-0.28 (0.17)	(-0.60, 0.05)	0.0945	
>= 10 points	166	-0.80 (0.04)	175	-0.62 (0.04)	-0.18 (0.05)	(-0.28, -0.09)	0.0002	-0.38 (0.11)	(-0.59, -0.16)	0.0005	
OCS dose at baseline											0.4522
<10 mg/day	115	-0.72 (0.04)	116	-0.58 (0.04)	-0.14 (0.06)	(-0.25, -0.03)	0.0161	-0.30 (0.13)	(-0.56, -0.04)	0.0228	
>=10 mg/day	130	-0.90 (0.05)	128	-0.70 (0.05)	-0.20 (0.06)	(-0.31, -0.08)	0.0007	-0.37 (0.13)	(-0.61, -0.12)	0.0036	
Result of type I IFN gene signature test											0.2221
LOW	45	-0.72 (0.06)	48	-0.64 (0.06)	-0.08 (0.08)	(-0.24, 0.08)	0.3032	-0.21 (0.21)	(-0.62, 0.20)	0.3138	
HIGH	200	-0.87 (0.03)	196	-0.67 (0.03)	-0.19 (0.05)	(-0.29, -0.10)	<.0001	-0.41 (0.10)	(-0.61, -0.21)	<.0001	
Age (years)											NE
<= 65	238	-0.81 (0.03)	241	-0.64 (0.03)	-0.17 (0.04)	(-0.25, -0.09)	<.0001	-0.35 (0.09)	(-0.53, -0.17)	0.0001	
> 65	7	NE	3	NE	NE	NE		NE	NE		
Sex											0.8546
male	23	-0.96 (0.11)	20	-0.81 (0.12)	-0.15 (0.13)	(-0.42, 0.12)	0.2755	-0.27 (0.31)	(-0.87, 0.33)	0.3781	
female	222	-0.80 (0.03)	224	-0.62 (0.03)	-0.17 (0.04)	(-0.26, -0.09)	<.0001	-0.35 (0.10)	(-0.54, -0.17)	0.0002	
Race											0.0141
White	160	-0.78 (0.04)	173	-0.68 (0.04)	-0.10 (0.05)	(-0.20, -0.01)	0.0346	-0.21 (0.11)	(-0.43, 0.00)	0.0508	
Black	32	-0.80 (0.09)	32	-0.64 (0.09)	-0.16 (0.12)	(-0.39, 0.08)	0.1836	-0.30 (0.25)	(-0.79, 0.20)	0.2385	
Other	45	-0.86 (0.10)	36	-0.42 (0.11)	-0.44 (0.10)	(-0.64, -0.23)	<.0001	-0.67 (0.23)	(-1.12, -0.22)	0.0038	
Ethnicity											0.5332
Hispanic/Latino	50	-0.83 (0.07)	56	-0.61 (0.07)	-0.22 (0.09)	(-0.40, -0.04)	0.0155	-0.43 (0.20)	(-0.82, -0.05)	0.0280	
Non-hispanic/Latino	187	-0.79 (0.04)	185	-0.63 (0.04)	-0.16 (0.05)	(-0.25, -0.07)	0.0007	-0.32 (0.10)	(-0.53, -0.12)	0.0020	
Geographic region											0.5371
EU	92	-0.88 (0.05)	88	-0.74 (0.05)	-0.14 (0.06)	(-0.26, -0.02)	0.0233	-0.29 (0.15)	(-0.58, 0.01)	0.0548	
non-EU	153	-0.77 (0.04)	156	-0.58 (0.04)	-0.19 (0.05)	(-0.29, -0.09)	0.0004	-0.38 (0.11)	(-0.60, -0.15)	0.0010	
Onset of disease											0.2257
Paediatric	19	-1.08 (0.26)	12	-0.63 (0.25)	-0.45 (0.24)	(-0.96, 0.06)	0.0789	-0.42 (0.37)	(-1.15, 0.31)	0.2587	
Adult	226	-0.81 (0.03)	232	-0.65 (0.03)	-0.16 (0.04)	(-0.24, -0.08)	0.0001	-0.33 (0.09)	(-0.51, -0.15)	0.0005	
ADA result											0.3814
Negative	226	-0.80 (0.03)	221	-0.64 (0.03)	-0.16 (0.04)	(-0.25, -0.08)	0.0001	-0.33 (0.10)	(-0.52, -0.15)	0.0004	
Positive (At any time)	19	-0.88 (0.23)	23	-0.57 (0.21)	-0.31 (0.16)	(-0.65, 0.03)	0.0705	-0.31 (0.31)	(-0.92, 0.30)	0.3226	
BMI (kg/m2) at enrolment											0.4144
< 30	158	-0.80 (0.04)	174	-0.61 (0.04)	-0.19 (0.05)	(-0.29, -0.10)	0.0001	-0.38 (0.11)	(-0.60, -0.16)	0.0006	
>= 30	87	-0.79 (0.05)	70	-0.67 (0.06)	-0.12 (0.07)	(-0.27, 0.03)	0.1103	-0.24 (0.16)	(-0.56, 0.07)	0.1325	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - CLASI Total Activity Score
Full analysis set

	Anifrolumab 300mg (N=246)		Placebo (N=246)		Difference of						
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		-1.56 (0.24)		-0.81 (0.24)	-0.75 (0.31)	(-1.35, -0.15)	0.0146				
Week 8		-2.98 (0.27)		-1.74 (0.27)	-1.23 (0.34)	(-1.90, -0.56)	0.0003				
Week 12		-3.67 (0.29)		-2.39 (0.29)	-1.28 (0.37)	(-2.01, -0.55)	0.0006				
Week 16		-4.12 (0.29)		-2.80 (0.29)	-1.32 (0.38)	(-2.06, -0.58)	0.0005				
Week 20		-4.50 (0.30)		-2.95 (0.30)	-1.55 (0.39)	(-2.31, -0.79)	<.0001				
Week 24		-4.78 (0.31)		-3.07 (0.31)	-1.71 (0.41)	(-2.53, -0.90)	<.0001				
Week 28		-4.98 (0.31)		-3.48 (0.31)	-1.49 (0.41)	(-2.30, -0.69)	0.0003				
Week 32		-5.13 (0.31)		-3.58 (0.31)	-1.55 (0.41)	(-2.36, -0.74)	0.0002				
Week 36		-5.28 (0.31)		-3.95 (0.31)	-1.34 (0.41)	(-2.14, -0.53)	0.0011				
Week 40		-5.43 (0.32)		-3.88 (0.32)	-1.55 (0.43)	(-2.39, -0.72)	0.0003				
Week 44		-5.44 (0.32)		-3.98 (0.32)	-1.46 (0.43)	(-2.30, -0.62)	0.0007				
Week 48		-5.49 (0.32)		-4.29 (0.32)	-1.20 (0.43)	(-2.04, -0.36)	0.0052				
Week 52		-5.65 (0.31)		-4.29 (0.32)	-1.37 (0.41)	(-2.18, -0.55)	0.0010				
OVERALL	245	-4.54 (0.26)	244	-3.17 (0.26)	-1.37 (0.33)	(-2.02, -0.72)	<.0001	-0.34 (0.09)	(-0.51, -0.16)	0.0002	0.3605

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - CLASI Total Activity Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) N	LSMean (SE)	Placebo (N=246) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.0578
< 10 points	79	-3.55 (0.30)	69	-2.97 (0.32)	-0.58 (0.42)	(-1.41, 0.25)	0.1697	-0.22 (0.17)	(-0.54, 0.11)	0.1911	
>= 10 points	166	-4.85 (0.35)	175	-3.11 (0.34)	-1.74 (0.44)	(-2.60, -0.87)	0.0001	-0.38 (0.11)	(-0.60, -0.17)	0.0005	
OCS dose at baseline											0.0103
<10 mg/day	115	-3.39 (0.34)	116	-3.04 (0.34)	-0.35 (0.46)	(-1.26, 0.56)	0.4506	-0.09 (0.13)	(-0.35, 0.16)	0.4708	
>=10 mg/day	130	-5.28 (0.40)	128	-3.25 (0.39)	-2.03 (0.46)	(-2.94, -1.11)	<.0001	-0.45 (0.13)	(-0.70, -0.21)	0.0003	
Result of type I IFN gene signature test											0.0055
LOW	45	-2.94 (0.39)	48	-3.16 (0.38)	0.22 (0.54)	(-0.86, 1.30)	0.6862	0.08 (0.21)	(-0.32, 0.49)	0.6889	
HIGH	200	-5.11 (0.29)	196	-3.47 (0.29)	-1.64 (0.40)	(-2.42, -0.86)	<.0001	-0.40 (0.10)	(-0.60, -0.20)	<.0001	
Age (years)											NE
<= 65	238	-4.51 (0.27)	241	-3.12 (0.27)	-1.39 (0.34)	(-2.05, -0.72)	<.0001	-0.33 (0.09)	(-0.51, -0.15)	0.0003	
> 65	7	NE	3	NE	NE	NE		NE	NE		
Sex											NE
male	23	NE	20	NE	NE	NE		NE	NE		
female	222	-4.31 (0.24)	224	-3.08 (0.24)	-1.23 (0.31)	(-1.84, -0.62)	<.0001	-0.34 (0.10)	(-0.52, -0.15)	0.0004	
Race											NE
White	160	-4.39 (0.27)	173	-3.53 (0.26)	-0.86 (0.34)	(-1.53, -0.19)	0.0123	-0.25 (0.11)	(-0.46, -0.03)	0.0237	
Black	32	NE	32	NE	NE	NE		NE	NE		
Other	45	NE	36	NE	NE	NE		NE	NE		
Ethnicity											0.4881
Hispanic/Latino	50	-3.10 (0.49)	56	-2.07 (0.49)	-1.03 (0.62)	(-2.28, 0.22)	0.1036	-0.29 (0.20)	(-0.67, 0.10)	0.1421	
Non-hispanic/Latino	187	-4.89 (0.32)	185	-3.34 (0.32)	-1.55 (0.41)	(-2.36, -0.74)	0.0002	-0.36 (0.10)	(-0.56, -0.15)	0.0006	
Geographic region											0.2197
EU	92	-5.26 (0.43)	88	-4.44 (0.45)	-0.81 (0.54)	(-1.88, 0.25)	0.1341	-0.19 (0.15)	(-0.49, 0.10)	0.1937	
non-EU	153	-4.19 (0.32)	156	-2.54 (0.33)	-1.65 (0.42)	(-2.48, -0.82)	0.0001	-0.41 (0.11)	(-0.63, -0.18)	0.0004	
Onset of disease											0.2997
Paediatric	19	-4.30 (1.12)	12	-4.47 (1.22)	0.16 (1.36)	(-2.63, 2.96)	0.9056	0.03 (0.37)	(-0.69, 0.76)	0.9260	
Adult	226	-4.41 (0.27)	232	-3.11 (0.27)	-1.29 (0.34)	(-1.96, -0.62)	0.0002	-0.32 (0.09)	(-0.50, -0.14)	0.0007	
ADA result											NE
Negative	226	-4.58 (0.26)	221	-3.34 (0.27)	-1.23 (0.34)	(-1.91, -0.56)	0.0004	-0.31 (0.10)	(-0.50, -0.12)	0.0012	
Positive (At any time)	19	NE	23	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.0066
< 30	158	-5.14 (0.36)	174	-3.15 (0.35)	-1.99 (0.43)	(-2.84, -1.15)	<.0001	-0.44 (0.11)	(-0.65, -0.22)	<.0001	
>= 30	87	-3.54 (0.35)	70	-3.31 (0.38)	-0.23 (0.49)	(-1.20, 0.75)	0.6450	-0.07 (0.16)	(-0.39, 0.24)	0.6618	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - CLASI Total Damage Score
Full analysis set

	Anifrolumab 300mg (N=246)		Placebo (N=246)		Difference of						
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		-0.16 (0.09)		-0.02 (0.09)	-0.14 (0.11)	(-0.36, 0.08)	0.2020				
Week 8		-0.23 (0.11)		-0.10 (0.12)	-0.12 (0.15)	(-0.42, 0.17)	0.4062				
Week 12		-0.34 (0.12)		-0.08 (0.12)	-0.26 (0.16)	(-0.58, 0.05)	0.1015				
Week 16		-0.44 (0.12)		-0.08 (0.12)	-0.36 (0.16)	(-0.68, -0.05)	0.0252				
Week 20		-0.42 (0.14)		-0.17 (0.14)	-0.24 (0.18)	(-0.60, 0.11)	0.1801				
Week 24		-0.56 (0.14)		-0.24 (0.14)	-0.32 (0.18)	(-0.68, 0.05)	0.0862				
Week 28		-0.58 (0.14)		-0.31 (0.14)	-0.27 (0.19)	(-0.64, 0.09)	0.1435				
Week 32		-0.58 (0.15)		-0.24 (0.15)	-0.34 (0.20)	(-0.73, 0.06)	0.0993				
Week 36		-0.62 (0.16)		-0.27 (0.16)	-0.35 (0.21)	(-0.76, 0.07)	0.1013				
Week 40		-0.66 (0.16)		-0.24 (0.16)	-0.42 (0.22)	(-0.84, 0.00)	0.0524				
Week 44		-0.70 (0.15)		-0.30 (0.16)	-0.40 (0.21)	(-0.81, 0.01)	0.0555				
Week 48		-0.67 (0.16)		-0.32 (0.16)	-0.35 (0.21)	(-0.77, 0.06)	0.0968				
Week 52		-0.69 (0.16)		-0.30 (0.16)	-0.39 (0.22)	(-0.82, 0.04)	0.0726				
OVERALL	245	-0.51 (0.12)	244	-0.21 (0.12)	-0.31 (0.16)	(-0.62, 0.01)	0.0597	-0.16 (0.09)	(-0.34, 0.02)	0.0810	0.9951

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - CLASI Total Damage Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) N	LSMean (SE)	Placebo (N=246) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											NE
< 10 points	79	NE	69	NE	NE	NE		NE	NE		
>= 10 points	166	-0.51 (0.15)	175	-0.24 (0.15)	-0.27 (0.20)	(-0.66, 0.13)	0.1822	-0.14 (0.11)	(-0.35, 0.08)	0.2095	
OCS dose at baseline											0.8209
<10 mg/day	115	-0.41 (0.14)	116	-0.20 (0.14)	-0.22 (0.19)	(-0.59, 0.16)	0.2513	-0.15 (0.13)	(-0.40, 0.11)	0.2685	
>=10 mg/day	130	-0.48 (0.20)	128	-0.19 (0.20)	-0.29 (0.25)	(-0.78, 0.21)	0.2527	-0.12 (0.12)	(-0.37, 0.12)	0.3164	
Result of type I IFN gene signature test											NE
LOW	45	NE	48	NE	NE	NE		NE	NE		
HIGH	200	-0.52 (0.14)	196	-0.22 (0.14)	-0.31 (0.19)	(-0.68, 0.07)	0.1092	-0.16 (0.10)	(-0.35, 0.04)	0.1189	
Age (years)											NE
<= 65	238	-0.50 (0.13)	241	-0.19 (0.13)	-0.31 (0.16)	(-0.63, 0.01)	0.0572	-0.16 (0.09)	(-0.34, 0.02)	0.0801	
> 65	7	NE	3	NE	NE	NE		NE	NE		
Sex											NE
male	23	NE	20	NE	NE	NE		NE	NE		
female	222	-0.47 (0.12)	224	-0.24 (0.12)	-0.23 (0.16)	(-0.55, 0.09)	0.1613	-0.12 (0.09)	(-0.31, 0.06)	0.1949	
Race											NE
White	160	-0.57 (0.13)	173	-0.31 (0.13)	-0.26 (0.17)	(-0.60, 0.08)	0.1337	-0.15 (0.11)	(-0.37, 0.06)	0.1627	
Black	32	-0.61 (0.40)	32	-0.57 (0.39)	-0.05 (0.51)	(-1.07, 0.98)	0.9261	-0.02 (0.25)	(-0.51, 0.47)	0.9328	
Other	45	NE	36	NE	NE	NE		NE	NE		
Ethnicity											NE
Hispanic/Latino	50	NE	56	NE	NE	NE		NE	NE		
Non-hispanic/Latino	187	-0.60 (0.14)	185	-0.28 (0.14)	-0.32 (0.19)	(-0.69, 0.05)	0.0877	-0.17 (0.10)	(-0.37, 0.04)	0.1114	
Geographic region											NE
EU	92	-0.82 (0.21)	88	-0.15 (0.22)	-0.66 (0.26)	(-1.17, -0.15)	0.0109	-0.32 (0.15)	(-0.62, -0.03)	0.0320	
non-EU	153	NE	156	NE	NE	NE		NE	NE		
Onset of disease											NE
Paediatric	19	NE	12	NE	NE	NE		NE	NE		
Adult	226	-0.45 (0.12)	232	-0.17 (0.12)	-0.28 (0.16)	(-0.61, 0.04)	0.0858	-0.15 (0.09)	(-0.33, 0.03)	0.1100	
ADA result											NE
Negative	226	-0.54 (0.12)	221	-0.25 (0.13)	-0.29 (0.16)	(-0.62, 0.03)	0.0748	-0.16 (0.09)	(-0.34, 0.03)	0.0970	
Positive (At any time)	19	NE	23	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											NE
< 30	158	-0.69 (0.15)	174	-0.12 (0.15)	-0.58 (0.19)	(-0.94, -0.21)	0.0021	-0.30 (0.11)	(-0.51, -0.08)	0.0074	
>= 30	87	NE	70	NE	NE	NE		NE	NE		

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - BILAG Global Score
Full analysis set

Visit	Anifrolumab 300mg (N=246) N	Anifrolumab 300mg (N=246) LSMean (SE)	Placebo (N=246) N	Placebo (N=246) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		-4.27 (0.41)		-3.63 (0.40)	-0.64 (0.51)	(-1.64, 0.37)	0.2142				
Week 8		-7.41 (0.46)		-5.56 (0.46)	-1.85 (0.59)	(-3.02, -0.69)	0.0019				
Week 12		-8.72 (0.46)		-6.99 (0.46)	-1.73 (0.59)	(-2.90, -0.56)	0.0037				
Week 16		-9.65 (0.47)		-8.19 (0.47)	-1.46 (0.61)	(-2.67, -0.26)	0.0177				
Week 20		-10.11 (0.46)		-8.51 (0.46)	-1.60 (0.60)	(-2.78, -0.42)	0.0082				
Week 24		-10.63 (0.47)		-8.65 (0.47)	-1.98 (0.61)	(-3.19, -0.78)	0.0013				
Week 28		-10.71 (0.48)		-9.11 (0.48)	-1.60 (0.63)	(-2.84, -0.36)	0.0114				
Week 32		-11.14 (0.48)		-9.02 (0.48)	-2.12 (0.63)	(-3.36, -0.89)	0.0008				
Week 36		-11.08 (0.49)		-9.63 (0.50)	-1.44 (0.65)	(-2.72, -0.17)	0.0262				
Week 40		-10.95 (0.50)		-9.65 (0.51)	-1.30 (0.66)	(-2.61, 0.00)	0.0506				
Week 44		-11.12 (0.50)		-9.82 (0.51)	-1.30 (0.66)	(-2.60, 0.01)	0.0510				
Week 48		-11.34 (0.50)		-10.04 (0.51)	-1.30 (0.67)	(-2.61, 0.01)	0.0524				
Week 52		-11.66 (0.49)		-10.49 (0.50)	-1.16 (0.65)	(-2.45, 0.12)	0.0761				
OVERALL	245	-9.91 (0.38)	244	-8.41 (0.39)	-1.50 (0.48)	(-2.44, -0.56)	0.0018	-0.25 (0.09)	(-0.43, -0.07)	0.0061	0.8274

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - BILAG Global Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) N	LSMean (SE)	Placebo (N=246) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.9363
< 10 points	79	-10.08 (0.56)	69	-8.47 (0.59)	-1.62 (0.75)	(-3.11, -0.13)	0.0336	-0.33 (0.17)	(-0.65, -0.00)	0.0497	
>= 10 points	166	-9.65 (0.50)	175	-8.11 (0.48)	-1.54 (0.61)	(-2.73, -0.34)	0.0117	-0.24 (0.11)	(-0.45, -0.03)	0.0271	
OCS dose at baseline											0.3421
<10 mg/day	115	-9.54 (0.50)	116	-8.53 (0.52)	-1.01 (0.67)	(-2.34, 0.31)	0.1340	-0.18 (0.13)	(-0.44, 0.07)	0.1624	
>=10 mg/day	130	-10.20 (0.61)	128	-8.28 (0.59)	-1.92 (0.68)	(-3.26, -0.58)	0.0051	-0.28 (0.13)	(-0.52, -0.03)	0.0255	
Result of type I IFN gene signature test											0.0416
LOW	45	-9.12 (0.75)	48	-9.49 (0.71)	0.37 (1.01)	(-1.64, 2.39)	0.7145	0.07 (0.21)	(-0.33, 0.48)	0.7217	
HIGH	200	-10.37 (0.39)	196	-8.41 (0.40)	-1.97 (0.54)	(-3.02, -0.91)	0.0003	-0.35 (0.10)	(-0.55, -0.15)	0.0005	
Age (years)											NE
<= 65	238	-9.96 (0.40)	241	-8.43 (0.39)	-1.53 (0.49)	(-2.48, -0.57)	0.0018	-0.25 (0.09)	(-0.43, -0.07)	0.0065	
> 65	7	NE	3	NE	NE	NE		NE	NE		
Sex											0.2888
male	23	-10.86 (1.11)	20	-7.90 (1.30)	-2.96 (1.42)	(-5.83, -0.08)	0.0444	-0.52 (0.31)	(-1.13, 0.09)	0.0932	
female	222	-9.84 (0.41)	224	-8.49 (0.40)	-1.36 (0.51)	(-2.35, -0.36)	0.0077	-0.22 (0.10)	(-0.41, -0.04)	0.0184	
Race											0.0703
White	160	-9.70 (0.47)	173	-8.95 (0.46)	-0.75 (0.59)	(-1.92, 0.42)	0.2094	-0.12 (0.11)	(-0.34, 0.09)	0.2623	
Black	32	-10.76 (1.02)	32	-7.33 (0.97)	-3.43 (1.26)	(-5.95, -0.90)	0.0087	-0.60 (0.26)	(-1.10, -0.10)	0.0190	
Other	45	-10.92 (1.26)	36	-7.93 (1.40)	-2.99 (1.27)	(-5.53, -0.45)	0.0216	-0.35 (0.23)	(-0.79, 0.09)	0.1189	
Ethnicity											0.5464
Hispanic/Latino	50	-9.92 (0.86)	56	-7.88 (0.88)	-2.04 (1.08)	(-4.18, 0.10)	0.0609	-0.32 (0.20)	(-0.70, 0.07)	0.1037	
Non-hispanic/Latino	187	-9.78 (0.44)	185	-8.47 (0.44)	-1.31 (0.55)	(-2.39, -0.24)	0.0166	-0.22 (0.10)	(-0.42, -0.01)	0.0354	
Geographic region											0.3320
EU	92	-11.12 (0.69)	88	-10.27 (0.71)	-0.85 (0.78)	(-2.39, 0.68)	0.2747	-0.13 (0.15)	(-0.42, 0.16)	0.3898	
non-EU	153	-9.31 (0.47)	156	-7.50 (0.47)	-1.80 (0.60)	(-2.99, -0.62)	0.0029	-0.31 (0.11)	(-0.53, -0.08)	0.0073	
Onset of disease											0.6552
Paediatric	19	-8.32 (2.18)	12	-7.85 (2.15)	-0.48 (2.20)	(-5.07, 4.11)	0.8297	-0.05 (0.37)	(-0.78, 0.67)	0.8855	
Adult	226	-9.92 (0.40)	232	-8.44 (0.40)	-1.48 (0.50)	(-2.46, -0.51)	0.0030	-0.25 (0.09)	(-0.43, -0.06)	0.0086	
ADA result											0.1967
Negative	226	-9.81 (0.40)	221	-8.53 (0.40)	-1.28 (0.50)	(-2.27, -0.30)	0.0107	-0.22 (0.09)	(-0.40, -0.03)	0.0231	
Positive (At any time)	19	-9.85 (2.21)	23	-6.32 (2.01)	-3.53 (1.67)	(-6.93, -0.13)	0.0426	-0.36 (0.31)	(-0.97, 0.25)	0.2503	
BMI (kg/m2) at enrolment											0.6133
< 30	158	-10.20 (0.49)	174	-8.50 (0.48)	-1.70 (0.57)	(-2.82, -0.58)	0.0031	-0.27 (0.11)	(-0.49, -0.05)	0.0144	
>= 30	87	-9.41 (0.65)	70	-8.25 (0.70)	-1.16 (0.90)	(-2.93, 0.61)	0.1964	-0.19 (0.16)	(-0.51, 0.12)	0.2264	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Tender Joint Count
Full analysis set

Visit	Anifrolumab 300mg (N=246) N	Anifrolumab 300mg (N=246) LSMean (SE)	Placebo (N=246) N	Placebo (N=246) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		-1.47 (0.36)		-1.67 (0.36)	0.20 (0.46)	(-0.71, 1.11)	0.6621				
Week 8		-3.40 (0.38)		-2.88 (0.38)	-0.52 (0.49)	(-1.48, 0.44)	0.2888				
Week 12		-4.35 (0.39)		-3.80 (0.39)	-0.54 (0.51)	(-1.54, 0.46)	0.2861				
Week 16		-4.99 (0.38)		-4.90 (0.39)	-0.08 (0.50)	(-1.06, 0.89)	0.8662				
Week 20		-5.43 (0.39)		-5.11 (0.39)	-0.32 (0.51)	(-1.33, 0.69)	0.5319				
Week 24		-5.45 (0.41)		-5.16 (0.41)	-0.29 (0.54)	(-1.35, 0.77)	0.5923				
Week 28		-5.87 (0.38)		-5.69 (0.39)	-0.18 (0.50)	(-1.16, 0.80)	0.7174				
Week 32		-5.96 (0.39)		-5.39 (0.40)	-0.57 (0.52)	(-1.58, 0.44)	0.2713				
Week 36		-6.45 (0.39)		-5.75 (0.40)	-0.70 (0.51)	(-1.71, 0.31)	0.1763				
Week 40		-5.81 (0.38)		-6.16 (0.39)	0.36 (0.50)	(-0.63, 1.35)	0.4765				
Week 44		-6.31 (0.39)		-5.99 (0.39)	-0.32 (0.51)	(-1.32, 0.68)	0.5276				
Week 48		-6.07 (0.40)		-6.02 (0.41)	-0.05 (0.53)	(-1.09, 0.98)	0.9174				
Week 52		-6.07 (0.39)		-6.46 (0.40)	0.40 (0.51)	(-0.61, 1.41)	0.4381				
OVERALL	245	-5.20 (0.31)	244	-5.00 (0.31)	-0.20 (0.38)	(-0.96, 0.55)	0.6000	-0.04 (0.09)	(-0.22, 0.14)	0.6479	0.1195

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Tender Joint Count - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) N	LSMean (SE)	Placebo (N=246) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.5202
< 10 points	79	-5.46 (0.57)	69	-5.67 (0.60)	0.21 (0.79)	(-1.35, 1.77)	0.7901	0.04 (0.16)	(-0.28, 0.36)	0.8024	
>= 10 points	166	-4.83 (0.36)	175	-4.46 (0.35)	-0.37 (0.44)	(-1.23, 0.49)	0.3990	-0.08 (0.11)	(-0.29, 0.13)	0.4667	
OCS dose at baseline											0.7148
<10 mg/day	115	-4.77 (0.42)	116	-4.69 (0.43)	-0.08 (0.55)	(-1.17, 1.01)	0.8815	-0.02 (0.13)	(-0.28, 0.24)	0.8907	
>=10 mg/day	130	-5.91 (0.47)	128	-5.55 (0.45)	-0.36 (0.52)	(-1.38, 0.66)	0.4893	-0.07 (0.12)	(-0.31, 0.18)	0.5813	
Result of type I IFN gene signature test											0.5267
LOW	45	-5.43 (0.77)	48	-4.58 (0.72)	-0.84 (1.03)	(-2.89, 1.20)	0.4137	-0.17 (0.21)	(-0.57, 0.24)	0.4273	
HIGH	200	-5.86 (0.30)	196	-5.72 (0.31)	-0.14 (0.41)	(-0.95, 0.66)	0.7261	-0.03 (0.10)	(-0.23, 0.16)	0.7374	
Age (years)											NE
<= 65	238	-5.11 (0.32)	241	-4.92 (0.32)	-0.19 (0.39)	(-0.96, 0.57)	0.6164	-0.04 (0.09)	(-0.22, 0.14)	0.6658	
> 65	7	NE	3	NE	NE	NE		NE	NE		
Sex											0.4106
male	23	-5.32 (0.82)	20	-4.30 (0.93)	-1.02 (1.07)	(-3.22, 1.17)	0.3484	-0.25 (0.31)	(-0.85, 0.35)	0.4177	
female	222	-5.23 (0.33)	224	-5.16 (0.33)	-0.08 (0.41)	(-0.88, 0.72)	0.8461	-0.02 (0.09)	(-0.20, 0.17)	0.8649	
Race											0.5278
White	160	-5.73 (0.37)	173	-5.81 (0.36)	0.08 (0.46)	(-0.83, 0.99)	0.8695	0.02 (0.11)	(-0.20, 0.23)	0.8839	
Black	32	-4.79 (1.22)	32	-3.88 (1.16)	-0.91 (1.45)	(-3.81, 1.98)	0.5302	-0.13 (0.25)	(-0.62, 0.36)	0.5919	
Other	45	-4.51 (0.71)	36	-3.71 (0.78)	-0.80 (0.72)	(-2.24, 0.65)	0.2738	-0.17 (0.22)	(-0.61, 0.27)	0.4547	
Ethnicity											0.6830
Hispanic/Latino	50	-5.19 (0.69)	56	-4.78 (0.71)	-0.40 (0.86)	(-2.12, 1.31)	0.6415	-0.08 (0.19)	(-0.46, 0.30)	0.6860	
Non-hispanic/Latino	187	-5.24 (0.36)	185	-5.23 (0.36)	-0.01 (0.44)	(-0.88, 0.87)	0.9874	-0.00 (0.10)	(-0.20, 0.20)	0.9890	
Geographic region											0.8684
EU	92	-5.98 (0.41)	88	-5.94 (0.42)	-0.05 (0.46)	(-0.95, 0.85)	0.9163	-0.01 (0.15)	(-0.30, 0.28)	0.9352	
non-EU	153	-4.89 (0.41)	156	-4.72 (0.42)	-0.16 (0.53)	(-1.20, 0.87)	0.7569	-0.03 (0.11)	(-0.25, 0.19)	0.7822	
Onset of disease											NE
Paediatric	19	NE	12	NE	NE	NE		NE	NE		
Adult	226	-5.45 (0.32)	232	-5.08 (0.32)	-0.37 (0.40)	(-1.15, 0.42)	0.3581	-0.08 (0.09)	(-0.26, 0.11)	0.4209	
ADA result											NE
Negative	226	-5.13 (0.32)	221	-5.14 (0.32)	0.01 (0.40)	(-0.77, 0.79)	0.9776	0.00 (0.09)	(-0.18, 0.19)	0.9802	
Positive (At any time)	19	NE	23	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.4827
< 30	158	-5.14 (0.37)	174	-4.71 (0.36)	-0.44 (0.43)	(-1.29, 0.42)	0.3159	-0.09 (0.11)	(-0.31, 0.12)	0.4027	
>= 30	87	-5.51 (0.57)	70	-5.69 (0.60)	0.18 (0.77)	(-1.34, 1.70)	0.8112	0.04 (0.16)	(-0.28, 0.35)	0.8262	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Swollen Joint Count
Full analysis set

	Anifrolumab 300mg (N=246)		Placebo (N=246)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 4		-1.77 (0.27)		-1.77 (0.27)	-0.01 (0.34)	(-0.68, 0.67)	0.9804				
Week 8		-2.79 (0.26)		-2.95 (0.26)	0.17 (0.34)	(-0.50, 0.83)	0.6228				
Week 12		-3.51 (0.28)		-3.41 (0.29)	-0.10 (0.37)	(-0.84, 0.63)	0.7849				
Week 16		-3.82 (0.28)		-3.79 (0.28)	-0.03 (0.36)	(-0.75, 0.68)	0.9328				
Week 20		-4.15 (0.27)		-4.19 (0.27)	0.04 (0.35)	(-0.64, 0.73)	0.9051				
Week 24		-4.17 (0.28)		-4.27 (0.28)	0.10 (0.36)	(-0.61, 0.82)	0.7790				
Week 28		-4.49 (0.26)		-4.36 (0.26)	-0.13 (0.34)	(-0.80, 0.53)	0.6953				
Week 32		-4.58 (0.27)		-4.28 (0.28)	-0.31 (0.36)	(-1.01, 0.40)	0.3926				
Week 36		-4.53 (0.28)		-4.44 (0.29)	-0.09 (0.37)	(-0.82, 0.64)	0.8120				
Week 40		-4.25 (0.29)		-4.60 (0.30)	0.35 (0.38)	(-0.41, 1.10)	0.3660				
Week 44		-4.54 (0.27)		-4.58 (0.27)	0.04 (0.35)	(-0.65, 0.72)	0.9165				
Week 48		-4.61 (0.29)		-4.48 (0.29)	-0.14 (0.38)	(-0.89, 0.62)	0.7234				
Week 52		-4.58 (0.27)		-4.81 (0.28)	0.23 (0.36)	(-0.47, 0.93)	0.5229				
OVERALL	245	-3.98 (0.22)	244	-3.99 (0.22)	0.01 (0.27)	(-0.53, 0.55)	0.9737	0.00 (0.09)	(-0.17, 0.18)	0.9771	0.0093

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Swollen Joint Count - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) N	LSMean (SE)	Placebo (N=246) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.8106
< 10 points	79	-4.05 (0.44)	69	-3.95 (0.46)	-0.10 (0.60)	(-1.28, 1.08)	0.8645	-0.03 (0.16)	(-0.35, 0.30)	0.8738	
>= 10 points	166	-3.85 (0.24)	175	-3.91 (0.24)	0.06 (0.30)	(-0.53, 0.64)	0.8465	0.02 (0.11)	(-0.19, 0.23)	0.8667	
OCS dose at baseline											0.3979
<10 mg/day	115	-3.85 (0.29)	116	-4.06 (0.30)	0.20 (0.39)	(-0.57, 0.97)	0.6067	0.06 (0.13)	(-0.20, 0.32)	0.6349	
>=10 mg/day	130	-4.24 (0.31)	128	-3.99 (0.31)	-0.25 (0.36)	(-0.95, 0.46)	0.4915	-0.07 (0.12)	(-0.31, 0.17)	0.5776	
Result of type I IFN gene signature test											0.9064
LOW	45	-4.27 (0.43)	48	-4.22 (0.41)	-0.05 (0.59)	(-1.21, 1.12)	0.9353	-0.02 (0.21)	(-0.42, 0.39)	0.9367	
HIGH	200	-4.03 (0.22)	196	-4.06 (0.23)	0.03 (0.31)	(-0.58, 0.64)	0.9222	0.01 (0.10)	(-0.19, 0.21)	0.9258	
Age (years)											NE
<= 65	238	-4.01 (0.23)	241	-3.98 (0.23)	-0.03 (0.28)	(-0.57, 0.51)	0.9181	-0.01 (0.09)	(-0.19, 0.17)	0.9294	
> 65	7	NE	3	NE	NE	NE		NE	NE		
Sex											0.5986
male	23	-4.28 (0.62)	20	-3.90 (0.74)	-0.38 (0.79)	(-2.01, 1.25)	0.6354	-0.12 (0.31)	(-0.72, 0.48)	0.6978	
female	222	-3.97 (0.23)	224	-4.03 (0.23)	0.06 (0.29)	(-0.50, 0.63)	0.8266	0.02 (0.09)	(-0.17, 0.20)	0.8482	
Race											0.2612
White	160	-4.09 (0.26)	173	-4.38 (0.26)	0.29 (0.33)	(-0.36, 0.94)	0.3783	0.09 (0.11)	(-0.13, 0.30)	0.4343	
Black	32	-5.06 (0.75)	32	-3.91 (0.71)	-1.15 (0.86)	(-2.87, 0.57)	0.1850	-0.28 (0.25)	(-0.77, 0.22)	0.2715	
Other	45	-3.25 (0.62)	36	-3.02 (0.69)	-0.23 (0.63)	(-1.48, 1.03)	0.7207	-0.05 (0.22)	(-0.49, 0.38)	0.8100	
Ethnicity											0.5099
Hispanic/Latino	50	-3.90 (0.55)	56	-4.34 (0.57)	0.44 (0.68)	(-0.91, 1.78)	0.5195	0.11 (0.19)	(-0.28, 0.49)	0.5852	
Non-hispanic/Latino	187	-4.04 (0.25)	185	-3.99 (0.25)	-0.05 (0.31)	(-0.66, 0.55)	0.8653	-0.02 (0.10)	(-0.22, 0.19)	0.8820	
Geographic region											0.8693
EU	92	-4.27 (0.23)	88	-4.19 (0.23)	-0.08 (0.26)	(-0.60, 0.44)	0.7623	-0.04 (0.15)	(-0.33, 0.26)	0.8070	
non-EU	153	-3.95 (0.30)	156	-3.95 (0.31)	-0.00 (0.38)	(-0.75, 0.74)	0.9923	-0.00 (0.11)	(-0.22, 0.22)	0.9932	
Onset of disease											NE
Paediatric	19	NE	12	NE	NE	NE		NE	NE		
Adult	226	-4.09 (0.23)	232	-3.97 (0.23)	-0.12 (0.28)	(-0.68, 0.44)	0.6753	-0.03 (0.09)	(-0.22, 0.15)	0.7143	
ADA result											0.0599
Negative	226	-3.94 (0.23)	221	-4.03 (0.23)	0.09 (0.29)	(-0.47, 0.66)	0.7476	0.03 (0.09)	(-0.16, 0.21)	0.7764	
Positive (At any time)	19	-5.34 (0.99)	23	-3.97 (0.89)	-1.36 (0.72)	(-2.83, 0.11)	0.0684	-0.31 (0.31)	(-0.92, 0.30)	0.3184	
BMI (kg/m2) at enrolment											0.8799
< 30	158	-3.88 (0.28)	174	-3.85 (0.27)	-0.02 (0.33)	(-0.66, 0.62)	0.9431	-0.01 (0.11)	(-0.22, 0.21)	0.9528	
>= 30	87	-4.21 (0.37)	70	-4.28 (0.39)	0.07 (0.50)	(-0.92, 1.06)	0.8938	0.02 (0.16)	(-0.29, 0.33)	0.9016	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Mental Component Score
Full analysis set

	Anifrolumab 300mg (N=246)		Placebo (N=246)		Difference of						
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 8		1.78 (0.62)		0.60 (0.62)	1.18 (0.78)	(-0.36, 2.72)	0.1314				
Week 16		1.44 (0.66)		1.51 (0.66)	-0.07 (0.85)	(-1.74, 1.61)	0.9375				
Week 24		1.93 (0.70)		0.31 (0.70)	1.62 (0.91)	(-0.17, 3.42)	0.0761				
Week 32		2.60 (0.66)		1.19 (0.68)	1.41 (0.86)	(-0.29, 3.11)	0.1029				
Week 40		2.39 (0.69)		1.73 (0.70)	0.66 (0.90)	(-1.12, 2.44)	0.4669				
Week 48		2.75 (0.68)		1.50 (0.71)	1.25 (0.90)	(-0.52, 3.02)	0.1649				
Week 52		2.74 (0.72)		1.64 (0.74)	1.10 (0.95)	(-0.76, 2.97)	0.2456				
OVERALL	231	2.23 (0.54)	226	1.21 (0.55)	1.02 (0.67)	(-0.29, 2.34)	0.1256	0.12 (0.09)	(-0.06, 0.31)	0.1866	0.7219

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Mental Component Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) N	LSMean (SE)	Placebo (N=246) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.0312
< 10 points	74	3.85 (0.87)	66	0.77 (0.92)	3.08 (1.17)	(0.76, 5.40)	0.0098	0.41 (0.17)	(0.07, 0.75)	0.0166	
>= 10 points	157	0.98 (0.68)	160	0.97 (0.67)	0.01 (0.81)	(-1.58, 1.60)	0.9899	0.00 (0.11)	(-0.22, 0.22)	0.9914	
OCS dose at baseline											0.9852
<10 mg/day	111	2.47 (0.72)	108	1.42 (0.76)	1.05 (0.96)	(-0.84, 2.95)	0.2749	0.14 (0.14)	(-0.13, 0.40)	0.3172	
>=10 mg/day	120	1.88 (0.86)	118	0.85 (0.82)	1.03 (0.94)	(-0.83, 2.88)	0.2751	0.11 (0.13)	(-0.14, 0.37)	0.3897	
Result of type I IFN gene signature test											0.9423
LOW	43	3.12 (1.12)	45	1.99 (1.06)	1.14 (1.52)	(-1.89, 4.17)	0.4555	0.16 (0.21)	(-0.26, 0.58)	0.4637	
HIGH	188	2.05 (0.55)	181	1.03 (0.57)	1.02 (0.75)	(-0.47, 2.50)	0.1787	0.13 (0.10)	(-0.07, 0.34)	0.2015	
Age (years)											NE
<= 65	224	2.16 (0.56)	225	1.20 (0.56)	0.95 (0.68)	(-0.37, 2.28)	0.1582	0.11 (0.09)	(-0.07, 0.30)	0.2283	
> 65	7	NE	1	NE	NE	NE		NE	NE		
Sex											0.9782
male	22	5.95 (2.01)	20	4.99 (2.31)	0.97 (2.16)	(-3.42, 5.35)	0.6572	0.10 (0.31)	(-0.51, 0.70)	0.7557	
female	209	1.92 (0.57)	206	0.90 (0.57)	1.03 (0.70)	(-0.34, 2.40)	0.1412	0.13 (0.10)	(-0.07, 0.32)	0.2008	
Race											0.7234
White	151	2.46 (0.67)	157	1.50 (0.66)	0.96 (0.84)	(-0.69, 2.60)	0.2539	0.11 (0.11)	(-0.11, 0.34)	0.3138	
Black	29	3.88 (1.74)	31	1.59 (1.66)	2.30 (2.05)	(-1.83, 6.42)	0.2689	0.24 (0.26)	(-0.27, 0.75)	0.3486	
Other	43	-0.55 (1.58)	36	-0.80 (1.84)	0.24 (1.52)	(-2.78, 3.26)	0.8739	0.02 (0.23)	(-0.42, 0.47)	0.9211	
Ethnicity											0.2444
Hispanic/Latino	49	2.65 (1.16)	54	3.37 (1.20)	-0.72 (1.46)	(-3.63, 2.19)	0.6254	-0.08 (0.20)	(-0.47, 0.30)	0.6706	
Non-hispanic/Latino	174	1.79 (0.64)	170	0.58 (0.63)	1.21 (0.77)	(-0.30, 2.72)	0.1168	0.14 (0.11)	(-0.07, 0.36)	0.1815	
Geographic region											0.8016
EU	86	2.54 (0.92)	80	1.56 (0.95)	0.98 (1.03)	(-1.06, 3.01)	0.3454	0.11 (0.16)	(-0.19, 0.42)	0.4633	
non-EU	145	1.84 (0.69)	146	0.52 (0.70)	1.32 (0.87)	(-0.41, 3.04)	0.1335	0.16 (0.12)	(-0.07, 0.39)	0.1829	
Onset of disease											0.9019
Paediatric	16	2.47 (2.40)	10	1.05 (2.48)	1.43 (2.98)	(-4.85, 7.71)	0.6379	0.15 (0.40)	(-0.64, 0.95)	0.7025	
Adult	215	2.21 (0.56)	216	1.16 (0.57)	1.05 (0.69)	(-0.31, 2.41)	0.1291	0.13 (0.10)	(-0.06, 0.32)	0.1902	
ADA result											0.8776
Negative	213	2.05 (0.57)	204	1.04 (0.58)	1.01 (0.70)	(-0.38, 2.39)	0.1537	0.12 (0.10)	(-0.07, 0.31)	0.2138	
Positive (At any time)	18	2.87 (2.83)	22	1.50 (2.64)	1.38 (2.29)	(-3.30, 6.05)	0.5529	0.11 (0.32)	(-0.51, 0.73)	0.7283	
BMI (kg/m2) at enrolment											0.4766
< 30	149	1.78 (0.69)	159	1.06 (0.68)	0.72 (0.78)	(-0.82, 2.26)	0.3592	0.08 (0.11)	(-0.14, 0.31)	0.4604	
>= 30	82	2.39 (0.92)	67	0.62 (0.97)	1.77 (1.25)	(-0.70, 4.24)	0.1587	0.22 (0.17)	(-0.11, 0.54)	0.1916	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Physical Component Score
Full analysis set

	Anifrolumab 300mg (N=246)		Placebo (N=246)		Difference of						
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 8		2.22 (0.46)		2.05 (0.46)	0.17 (0.57)	(-0.95, 1.29)	0.7659				
Week 16		3.48 (0.52)		2.52 (0.53)	0.95 (0.67)	(-0.36, 2.26)	0.1538				
Week 24		3.72 (0.53)		3.16 (0.53)	0.56 (0.67)	(-0.76, 1.88)	0.4051				
Week 32		3.22 (0.52)		3.20 (0.53)	0.02 (0.66)	(-1.28, 1.32)	0.9771				
Week 40		3.38 (0.55)		3.45 (0.56)	-0.06 (0.71)	(-1.46, 1.34)	0.9325				
Week 48		3.34 (0.58)		3.14 (0.59)	0.20 (0.76)	(-1.29, 1.70)	0.7901				
Week 52		3.10 (0.54)		3.30 (0.55)	-0.19 (0.71)	(-1.58, 1.19)	0.7837				
OVERALL	231	3.21 (0.45)	226	2.97 (0.45)	0.24 (0.55)	(-0.84, 1.32)	0.6680	0.03 (0.09)	(-0.15, 0.22)	0.7112	0.7707

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Physical Component Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) N	LSMean (SE)	Placebo (N=246) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.1569
< 10 points	74	3.25 (0.68)	66	1.93 (0.72)	1.32 (0.91)	(-0.48, 3.12)	0.1484	0.23 (0.17)	(-0.11, 0.56)	0.1846	
>= 10 points	157	3.25 (0.57)	160	3.54 (0.56)	-0.29 (0.68)	(-1.63, 1.05)	0.6744	-0.04 (0.11)	(-0.26, 0.18)	0.7199	
OCS dose at baseline											0.6795
<10 mg/day	111	2.92 (0.53)	108	2.52 (0.56)	0.40 (0.71)	(-1.00, 1.80)	0.5737	0.07 (0.14)	(-0.19, 0.34)	0.6045	
>=10 mg/day	120	3.13 (0.77)	118	3.19 (0.73)	-0.05 (0.83)	(-1.69, 1.59)	0.9510	-0.01 (0.13)	(-0.26, 0.25)	0.9617	
Result of type I IFN gene signature test											0.0475
LOW	43	2.23 (0.82)	45	4.09 (0.77)	-1.86 (1.11)	(-4.07, 0.35)	0.0987	-0.35 (0.21)	(-0.77, 0.07)	0.1058	
HIGH	188	3.86 (0.46)	181	3.19 (0.47)	0.67 (0.63)	(-0.56, 1.91)	0.2848	0.11 (0.10)	(-0.10, 0.31)	0.3089	
Age (years)											NE
<= 65	224	3.27 (0.46)	225	2.91 (0.46)	0.36 (0.55)	(-0.72, 1.45)	0.5118	0.05 (0.09)	(-0.13, 0.24)	0.5746	
> 65	7	NE	1	NE	NE	NE		NE	NE		
Sex											0.5336
male	22	1.98 (1.76)	20	2.88 (2.01)	-0.90 (1.95)	(-4.88, 3.08)	0.6468	-0.10 (0.31)	(-0.71, 0.50)	0.7398	
female	209	3.33 (0.47)	206	2.97 (0.47)	0.36 (0.58)	(-0.78, 1.50)	0.5303	0.05 (0.10)	(-0.14, 0.25)	0.5841	
Race											0.1219
White	151	2.98 (0.54)	157	3.62 (0.53)	-0.64 (0.68)	(-1.97, 0.69)	0.3462	-0.10 (0.11)	(-0.32, 0.13)	0.4014	
Black	29	4.39 (1.25)	31	2.56 (1.20)	1.83 (1.47)	(-1.11, 4.77)	0.2176	0.27 (0.26)	(-0.24, 0.78)	0.2993	
Other	43	1.74 (1.44)	36	-0.08 (1.63)	1.82 (1.34)	(-0.86, 4.50)	0.1804	0.19 (0.23)	(-0.26, 0.63)	0.4071	
Ethnicity											0.3956
Hispanic/Latino	49	3.23 (0.90)	54	2.36 (0.93)	0.87 (1.14)	(-1.40, 3.13)	0.4494	0.13 (0.20)	(-0.26, 0.52)	0.5085	
Non-hispanic/Latino	174	2.84 (0.53)	170	3.08 (0.52)	-0.24 (0.64)	(-1.50, 1.01)	0.7024	-0.04 (0.11)	(-0.25, 0.18)	0.7428	
Geographic region											0.0889
EU	86	3.74 (0.84)	80	4.86 (0.86)	-1.11 (0.95)	(-3.00, 0.77)	0.2442	-0.14 (0.16)	(-0.45, 0.16)	0.3591	
non-EU	145	3.04 (0.51)	146	2.19 (0.53)	0.85 (0.65)	(-0.43, 2.13)	0.1931	0.14 (0.12)	(-0.09, 0.37)	0.2494	
Onset of disease											0.9599
Paediatric	16	2.02 (3.57)	10	1.63 (3.45)	0.39 (3.92)	(-7.77, 8.55)	0.9217	0.03 (0.40)	(-0.76, 0.82)	0.9431	
Adult	215	3.22 (0.45)	216	3.03 (0.45)	0.19 (0.56)	(-0.90, 1.28)	0.7311	0.03 (0.10)	(-0.16, 0.22)	0.7653	
ADA result											0.0324
Negative	213	3.02 (0.47)	204	3.09 (0.48)	-0.06 (0.58)	(-1.21, 1.09)	0.9149	-0.01 (0.10)	(-0.20, 0.18)	0.9255	
Positive (At any time)	18	8.05 (2.31)	22	4.42 (2.13)	3.63 (1.62)	(0.34, 6.93)	0.0316	0.36 (0.32)	(-0.27, 0.99)	0.2630	
BMI (kg/m2) at enrolment											0.3186
< 30	149	3.16 (0.56)	159	3.16 (0.55)	-0.00 (0.64)	(-1.26, 1.25)	0.9943	-0.00 (0.11)	(-0.22, 0.22)	0.9954	
>= 30	82	3.81 (0.77)	67	2.60 (0.82)	1.22 (1.04)	(-0.85, 3.28)	0.2460	0.18 (0.17)	(-0.15, 0.50)	0.2844	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute General Health Score
Full analysis set

	Anifrolumab 300mg (N=246)		Placebo (N=246)		Difference of						
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 8		1.39 (0.44)		1.91 (0.44)	-0.52 (0.54)	(-1.58, 0.54)	0.3324				
Week 16		1.83 (0.49)		1.90 (0.49)	-0.06 (0.62)	(-1.28, 1.15)	0.9199				
Week 24		2.11 (0.50)		2.00 (0.51)	0.10 (0.65)	(-1.17, 1.37)	0.8750				
Week 32		2.04 (0.52)		2.09 (0.53)	-0.06 (0.68)	(-1.39, 1.27)	0.9335				
Week 40		2.00 (0.52)		2.17 (0.53)	-0.18 (0.68)	(-1.52, 1.17)	0.7964				
Week 48		2.04 (0.53)		2.97 (0.55)	-0.93 (0.70)	(-2.31, 0.45)	0.1849				
Week 52		2.00 (0.55)		2.19 (0.56)	-0.20 (0.73)	(-1.62, 1.23)	0.7862				
OVERALL	231	1.91 (0.43)	226	2.18 (0.44)	-0.26 (0.54)	(-1.32, 0.79)	0.6253	-0.04 (0.09)	(-0.22, 0.14)	0.6706	0.0991

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute General Health Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) N	LSMean (SE)	Placebo (N=246) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.1523
< 10 points	74	2.48 (0.65)	66	1.67 (0.69)	0.81 (0.88)	(-0.92, 2.55)	0.3558	0.14 (0.17)	(-0.19, 0.48)	0.3965	
>= 10 points	157	1.51 (0.56)	160	2.28 (0.54)	-0.77 (0.68)	(-2.10, 0.56)	0.2539	-0.11 (0.11)	(-0.33, 0.11)	0.3220	
OCS dose at baseline											0.3098
<10 mg/day	111	2.18 (0.59)	108	1.94 (0.62)	0.24 (0.80)	(-1.33, 1.81)	0.7638	0.04 (0.14)	(-0.23, 0.30)	0.7806	
>=10 mg/day	120	1.24 (0.67)	118	2.10 (0.64)	-0.86 (0.74)	(-2.31, 0.59)	0.2433	-0.12 (0.13)	(-0.37, 0.13)	0.3554	
Result of type I IFN gene signature test											0.0443
LOW	43	1.09 (0.95)	45	3.73 (0.90)	-2.64 (1.29)	(-5.19, -0.08)	0.0431	-0.43 (0.22)	(-0.85, -0.00)	0.0475	
HIGH	188	2.30 (0.43)	181	2.09 (0.44)	0.21 (0.59)	(-0.95, 1.37)	0.7274	0.03 (0.10)	(-0.17, 0.24)	0.7398	
Age (years)											NE
<= 65	224	1.97 (0.45)	225	2.21 (0.44)	-0.24 (0.54)	(-1.31, 0.83)	0.6585	-0.04 (0.09)	(-0.22, 0.15)	0.7031	
> 65	7	NE	1	NE	NE	NE		NE	NE		
Sex											0.2256
male	22	0.90 (1.31)	20	2.92 (1.49)	-2.02 (1.47)	(-5.00, 0.96)	0.1769	-0.31 (0.31)	(-0.92, 0.30)	0.3200	
female	209	2.01 (0.46)	206	2.12 (0.46)	-0.11 (0.58)	(-1.24, 1.02)	0.8476	-0.02 (0.10)	(-0.21, 0.18)	0.8660	
Race											0.4763
White	151	1.54 (0.54)	157	2.46 (0.53)	-0.92 (0.67)	(-2.25, 0.40)	0.1723	-0.14 (0.11)	(-0.36, 0.08)	0.2214	
Black	29	2.72 (1.24)	31	2.86 (1.18)	-0.14 (1.48)	(-3.11, 2.84)	0.9272	-0.02 (0.26)	(-0.53, 0.49)	0.9375	
Other	43	2.56 (1.35)	36	1.71 (1.54)	0.84 (1.32)	(-1.79, 3.48)	0.5262	0.09 (0.23)	(-0.35, 0.54)	0.6829	
Ethnicity											0.0369
Hispanic/Latino	49	4.14 (0.85)	54	2.46 (0.88)	1.69 (1.07)	(-0.43, 3.80)	0.1164	0.27 (0.20)	(-0.12, 0.66)	0.1767	
Non-hispanic/Latino	174	1.08 (0.51)	170	1.97 (0.51)	-0.89 (0.63)	(-2.12, 0.34)	0.1557	-0.13 (0.11)	(-0.34, 0.08)	0.2183	
Geographic region											0.1320
EU	86	1.76 (0.80)	80	3.15 (0.81)	-1.38 (0.92)	(-3.20, 0.44)	0.1352	-0.19 (0.16)	(-0.49, 0.12)	0.2276	
non-EU	145	2.07 (0.53)	146	1.74 (0.54)	0.33 (0.67)	(-0.99, 1.65)	0.6200	0.05 (0.12)	(-0.18, 0.28)	0.6594	
Onset of disease											0.1326
Paediatric	16	3.10 (2.11)	10	-0.06 (2.09)	3.16 (2.35)	(-1.75, 8.08)	0.1941	0.39 (0.41)	(-0.41, 1.19)	0.3358	
Adult	215	1.81 (0.45)	216	2.28 (0.45)	-0.47 (0.56)	(-1.57, 0.63)	0.3992	-0.07 (0.10)	(-0.26, 0.12)	0.4609	
ADA result											0.0808
Negative	213	1.60 (0.45)	204	2.20 (0.46)	-0.61 (0.57)	(-1.72, 0.51)	0.2843	-0.09 (0.10)	(-0.28, 0.10)	0.3445	
Positive (At any time)	18	7.39 (2.00)	22	5.04 (1.86)	2.35 (1.60)	(-0.89, 5.59)	0.1497	0.27 (0.32)	(-0.36, 0.89)	0.4025	
BMI (kg/m2) at enrolment											0.7811
< 30	149	2.12 (0.57)	159	2.38 (0.56)	-0.26 (0.66)	(-1.56, 1.04)	0.6920	-0.04 (0.11)	(-0.26, 0.19)	0.7424	
>= 30	82	2.00 (0.68)	67	1.95 (0.71)	0.05 (0.91)	(-1.75, 1.85)	0.9559	0.01 (0.16)	(-0.31, 0.33)	0.9594	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Mental Health Score
Full analysis set

	Anifrolumab 300mg (N=246)		Placebo (N=246)		Difference of						
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 8		1.78 (0.56)		1.23 (0.56)	0.55 (0.71)	(-0.84, 1.95)	0.4375				
Week 16		1.78 (0.61)		1.92 (0.61)	-0.13 (0.79)	(-1.68, 1.42)	0.8686				
Week 24		2.11 (0.64)		0.77 (0.64)	1.34 (0.83)	(-0.30, 2.98)	0.1096				
Week 32		2.60 (0.64)		1.26 (0.65)	1.34 (0.83)	(-0.30, 2.98)	0.1096				
Week 40		2.51 (0.62)		2.21 (0.63)	0.30 (0.81)	(-1.30, 1.90)	0.7120				
Week 48		2.73 (0.64)		1.92 (0.66)	0.81 (0.84)	(-0.85, 2.46)	0.3371				
Week 52		2.92 (0.65)		2.04 (0.67)	0.88 (0.86)	(-0.81, 2.57)	0.3057				
OVERALL	231	2.35 (0.49)	226	1.62 (0.50)	0.73 (0.60)	(-0.46, 1.92)	0.2299	0.10 (0.09)	(-0.09, 0.28)	0.3009	0.8699

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Mental Health Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) N	LSMean (SE)	Placebo (N=246) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.0637
< 10 points	74	3.85 (0.80)	66	1.51 (0.84)	2.34 (1.06)	(0.24, 4.45)	0.0295	0.34 (0.17)	(0.01, 0.68)	0.0455	
>= 10 points	157	1.17 (0.61)	160	1.23 (0.60)	-0.05 (0.73)	(-1.49, 1.39)	0.9434	-0.01 (0.11)	(-0.23, 0.21)	0.9518	
OCS dose at baseline											0.6129
<10 mg/day	111	2.59 (0.66)	108	1.54 (0.69)	1.04 (0.88)	(-0.69, 2.77)	0.2357	0.15 (0.14)	(-0.12, 0.41)	0.2773	
>=10 mg/day	120	1.86 (0.77)	118	1.43 (0.74)	0.43 (0.85)	(-1.24, 2.09)	0.6135	0.05 (0.13)	(-0.20, 0.31)	0.6898	
Result of type I IFN gene signature test											0.7975
LOW	43	2.53 (0.90)	45	2.12 (0.85)	0.41 (1.22)	(-2.03, 2.85)	0.7376	0.07 (0.21)	(-0.35, 0.49)	0.7418	
HIGH	188	2.30 (0.51)	181	1.53 (0.52)	0.77 (0.69)	(-0.59, 2.13)	0.2647	0.11 (0.10)	(-0.09, 0.31)	0.2896	
Age (years)											NE
<= 65	224	2.37 (0.51)	225	1.67 (0.50)	0.70 (0.61)	(-0.50, 1.90)	0.2507	0.09 (0.09)	(-0.09, 0.28)	0.3271	
> 65	7	NE	1	NE	NE	NE		NE	NE		
Sex											0.5905
male	22	4.31 (1.98)	20	4.64 (2.27)	-0.33 (2.07)	(-4.52, 3.86)	0.8748	-0.03 (0.31)	(-0.64, 0.57)	0.9147	
female	209	2.12 (0.51)	206	1.29 (0.51)	0.83 (0.62)	(-0.39, 2.06)	0.1825	0.11 (0.10)	(-0.08, 0.31)	0.2461	
Race											0.5418
White	151	2.43 (0.63)	157	1.91 (0.62)	0.52 (0.78)	(-1.01, 2.06)	0.5020	0.07 (0.11)	(-0.16, 0.29)	0.5532	
Black	29	3.90 (1.41)	31	1.41 (1.33)	2.49 (1.66)	(-0.84, 5.83)	0.1400	0.33 (0.26)	(-0.18, 0.84)	0.2075	
Other	43	0.41 (1.41)	36	-0.06 (1.62)	0.47 (1.30)	(-2.13, 3.06)	0.7204	0.05 (0.23)	(-0.39, 0.49)	0.8286	
Ethnicity											0.2165
Hispanic/Latino	49	2.54 (1.13)	54	3.61 (1.16)	-1.07 (1.43)	(-3.91, 1.76)	0.4539	-0.13 (0.20)	(-0.52, 0.26)	0.5115	
Non-hispanic/Latino	174	1.97 (0.56)	170	1.09 (0.56)	0.88 (0.68)	(-0.45, 2.21)	0.1956	0.12 (0.11)	(-0.09, 0.33)	0.2696	
Geographic region											0.6365
EU	86	2.96 (0.84)	80	2.42 (0.86)	0.54 (0.94)	(-1.31, 2.39)	0.5648	0.07 (0.16)	(-0.24, 0.37)	0.6554	
non-EU	145	1.85 (0.62)	146	0.73 (0.64)	1.12 (0.79)	(-0.44, 2.67)	0.1580	0.15 (0.12)	(-0.08, 0.38)	0.2109	
Onset of disease											0.5009
Paediatric	16	0.22 (2.04)	10	1.24 (2.20)	-1.02 (2.73)	(-6.69, 4.65)	0.7124	-0.13 (0.40)	(-0.92, 0.66)	0.7516	
Adult	215	2.47 (0.51)	216	1.61 (0.51)	0.87 (0.62)	(-0.36, 2.09)	0.1647	0.12 (0.10)	(-0.07, 0.30)	0.2310	
ADA result											0.7627
Negative	213	2.20 (0.51)	204	1.51 (0.52)	0.69 (0.63)	(-0.55, 1.93)	0.2727	0.09 (0.10)	(-0.10, 0.29)	0.3394	
Positive (At any time)	18	2.68 (2.97)	22	2.74 (2.79)	-0.05 (2.40)	(-4.94, 4.83)	0.9818	-0.00 (0.32)	(-0.63, 0.62)	0.9895	
BMI (kg/m2) at enrolment											0.3043
< 30	149	2.17 (0.64)	159	1.85 (0.63)	0.32 (0.72)	(-1.10, 1.74)	0.6598	0.04 (0.11)	(-0.18, 0.26)	0.7236	
>= 30	82	2.20 (0.82)	67	0.52 (0.86)	1.68 (1.11)	(-0.51, 3.86)	0.1324	0.23 (0.17)	(-0.09, 0.55)	0.1635	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Physical Functioning Score
Full analysis set

	Anifrolumab 300mg (N=246)		Placebo (N=246)		Difference of						
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 8		2.21 (0.50)		1.50 (0.50)	0.71 (0.62)	(-0.51, 1.93)	0.2556				
Week 16		2.72 (0.55)		1.87 (0.55)	0.85 (0.70)	(-0.53, 2.23)	0.2271				
Week 24		2.94 (0.57)		2.69 (0.57)	0.25 (0.73)	(-1.19, 1.69)	0.7340				
Week 32		3.03 (0.57)		2.53 (0.58)	0.50 (0.73)	(-0.94, 1.94)	0.4928				
Week 40		2.88 (0.58)		3.00 (0.59)	-0.12 (0.75)	(-1.59, 1.34)	0.8710				
Week 48		2.86 (0.61)		2.37 (0.63)	0.49 (0.81)	(-1.10, 2.08)	0.5456				
Week 52		3.10 (0.59)		2.98 (0.60)	0.11 (0.77)	(-1.39, 1.62)	0.8824				
OVERALL	231	2.82 (0.48)	226	2.42 (0.49)	0.40 (0.60)	(-0.78, 1.57)	0.5054	0.05 (0.09)	(-0.13, 0.24)	0.5639	0.9671

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Physical Functioning Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) N	LSMean (SE)	Placebo (N=246) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.0267
< 10 points	74	3.20 (0.72)	66	0.98 (0.77)	2.22 (0.97)	(0.30, 4.14)	0.0237	0.36 (0.17)	(0.02, 0.69)	0.0373	
>= 10 points	157	2.68 (0.62)	160	3.17 (0.61)	-0.49 (0.74)	(-1.95, 0.97)	0.5112	-0.06 (0.11)	(-0.28, 0.16)	0.5732	
OCS dose at baseline											0.8284
<10 mg/day	111	2.74 (0.56)	108	2.21 (0.59)	0.53 (0.75)	(-0.95, 2.01)	0.4782	0.09 (0.14)	(-0.18, 0.35)	0.5135	
>=10 mg/day	120	2.58 (0.84)	118	2.31 (0.80)	0.28 (0.92)	(-1.53, 2.09)	0.7643	0.03 (0.13)	(-0.22, 0.28)	0.8127	
Result of type I IFN gene signature test											0.2876
LOW	43	2.16 (0.96)	45	3.04 (0.90)	-0.88 (1.29)	(-3.44, 1.69)	0.4976	-0.14 (0.21)	(-0.56, 0.28)	0.5084	
HIGH	188	3.28 (0.49)	181	2.61 (0.51)	0.67 (0.68)	(-0.66, 2.00)	0.3228	0.10 (0.10)	(-0.11, 0.30)	0.3461	
Age (years)											NE
<= 65	224	2.80 (0.49)	225	2.30 (0.49)	0.50 (0.60)	(-0.68, 1.68)	0.4019	0.07 (0.09)	(-0.12, 0.25)	0.4716	
> 65	7	NE	1	NE	NE	NE		NE	NE		
Sex											0.7842
male	22	3.30 (1.85)	20	3.43 (2.11)	-0.12 (2.05)	(-4.29, 4.04)	0.9528	-0.01 (0.31)	(-0.62, 0.59)	0.9657	
female	209	2.84 (0.51)	206	2.37 (0.51)	0.47 (0.63)	(-0.77, 1.70)	0.4598	0.06 (0.10)	(-0.13, 0.26)	0.5182	
Race											0.3983
White	151	2.95 (0.59)	157	3.23 (0.58)	-0.27 (0.74)	(-1.73, 1.19)	0.7144	-0.04 (0.11)	(-0.26, 0.19)	0.7449	
Black	29	3.85 (1.55)	31	1.90 (1.51)	1.95 (1.84)	(-1.74, 5.65)	0.2934	0.23 (0.26)	(-0.28, 0.74)	0.3745	
Other	43	1.26 (1.42)	36	0.06 (1.60)	1.20 (1.35)	(-1.50, 3.89)	0.3785	0.13 (0.23)	(-0.32, 0.57)	0.5787	
Ethnicity											0.7509
Hispanic/Latino	49	2.27 (1.05)	54	2.48 (1.07)	-0.21 (1.35)	(-2.88, 2.46)	0.8782	-0.03 (0.20)	(-0.41, 0.36)	0.8915	
Non-hispanic/Latino	174	2.64 (0.57)	170	2.37 (0.56)	0.27 (0.68)	(-1.07, 1.62)	0.6901	0.04 (0.11)	(-0.17, 0.25)	0.7328	
Geographic region											0.2710
EU	86	4.16 (0.90)	80	4.61 (0.92)	-0.45 (1.01)	(-2.44, 1.54)	0.6551	-0.05 (0.16)	(-0.36, 0.25)	0.7270	
non-EU	145	2.17 (0.56)	146	1.27 (0.57)	0.91 (0.71)	(-0.49, 2.31)	0.2037	0.13 (0.12)	(-0.10, 0.36)	0.2576	
Onset of disease											0.9817
Paediatric	16	2.45 (3.64)	10	1.87 (3.69)	0.59 (4.11)	(-7.97, 9.14)	0.8881	0.04 (0.40)	(-0.75, 0.83)	0.9173	
Adult	215	2.96 (0.49)	216	2.47 (0.49)	0.49 (0.60)	(-0.69, 1.67)	0.4167	0.07 (0.10)	(-0.12, 0.26)	0.4797	
ADA result											0.1726
Negative	213	2.70 (0.50)	204	2.51 (0.51)	0.18 (0.63)	(-1.06, 1.42)	0.7744	0.02 (0.10)	(-0.17, 0.22)	0.8015	
Positive (At any time)	18	7.58 (2.81)	22	4.41 (2.58)	3.17 (2.10)	(-1.09, 7.44)	0.1400	0.26 (0.32)	(-0.37, 0.88)	0.4175	
BMI (kg/m2) at enrolment											0.2507
< 30	149	2.52 (0.60)	159	2.46 (0.59)	0.06 (0.68)	(-1.28, 1.39)	0.9341	0.01 (0.11)	(-0.22, 0.23)	0.9466	
>= 30	82	3.68 (0.87)	67	2.05 (0.92)	1.62 (1.19)	(-0.72, 3.97)	0.1724	0.21 (0.17)	(-0.11, 0.53)	0.2047	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Role Emotional Score
Full analysis set

	Anifrolumab 300mg (N=246)		Placebo (N=246)		Difference of							
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 8		2.10 (0.68)		0.54 (0.68)	1.56 (0.86)	(-0.13, 3.26)	0.0708				
Week 16		1.75 (0.72)		1.86 (0.73)	-0.11 (0.94)	(-1.95, 1.73)	0.9055				
Week 24		2.21 (0.76)		0.80 (0.76)	1.40 (0.98)	(-0.53, 3.33)	0.1547				
Week 32		2.83 (0.73)		1.87 (0.74)	0.96 (0.95)	(-0.90, 2.83)	0.3109				
Week 40		2.61 (0.76)		2.17 (0.78)	0.44 (1.00)	(-1.53, 2.41)	0.6585				
Week 48		2.98 (0.74)		2.01 (0.77)	0.97 (0.98)	(-0.95, 2.89)	0.3213				
Week 52		2.96 (0.77)		2.18 (0.79)	0.78 (1.02)	(-1.22, 2.79)	0.4433				
OVERALL	231	2.49 (0.59)	226	1.63 (0.60)	0.86 (0.72)	(-0.56, 2.28)	0.2351	0.10 (0.09)	(-0.09, 0.28)	0.3069	0.2885

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Role Emotional Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) N	LSMean (SE)	Placebo (N=246) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.0039
< 10 points	74	4.18 (0.93)	66	0.27 (0.99)	3.91 (1.26)	(1.42, 6.41)	0.0024	0.49 (0.17)	(0.15, 0.82)	0.0047	
>= 10 points	157	1.33 (0.73)	160	1.83 (0.72)	-0.50 (0.86)	(-2.20, 1.20)	0.5647	-0.05 (0.11)	(-0.27, 0.17)	0.6270	
OCS dose at baseline											0.8114
<10 mg/day	111	3.22 (0.78)	108	2.16 (0.82)	1.06 (1.04)	(-0.99, 3.11)	0.3082	0.13 (0.14)	(-0.14, 0.39)	0.3498	
>=10 mg/day	120	1.39 (0.94)	118	0.68 (0.90)	0.72 (1.02)	(-1.29, 2.72)	0.4815	0.07 (0.13)	(-0.18, 0.33)	0.5829	
Result of type I IFN gene signature test											0.8100
LOW	43	3.09 (1.27)	45	2.62 (1.20)	0.47 (1.72)	(-2.95, 3.89)	0.7836	0.06 (0.21)	(-0.36, 0.48)	0.7879	
HIGH	188	2.37 (0.59)	181	1.44 (0.61)	0.93 (0.80)	(-0.65, 2.51)	0.2477	0.11 (0.10)	(-0.09, 0.32)	0.2724	
Age (years)											NE
<= 65	224	2.41 (0.61)	225	1.56 (0.60)	0.85 (0.73)	(-0.59, 2.29)	0.2449	0.09 (0.09)	(-0.09, 0.28)	0.3220	
> 65	7	NE	1	NE	NE	NE		NE	NE		
Sex											0.8611
male	22	6.00 (1.86)	20	4.82 (2.17)	1.18 (2.03)	(-2.94, 5.31)	0.5643	0.13 (0.31)	(-0.48, 0.73)	0.6838	
female	209	2.27 (0.62)	206	1.47 (0.62)	0.80 (0.77)	(-0.70, 2.31)	0.2957	0.09 (0.10)	(-0.10, 0.28)	0.3640	
Race											0.5150
White	151	2.72 (0.70)	157	1.93 (0.70)	0.79 (0.87)	(-0.93, 2.51)	0.3673	0.09 (0.11)	(-0.13, 0.31)	0.4269	
Black	29	4.05 (2.15)	31	1.39 (2.13)	2.67 (2.55)	(-2.45, 7.79)	0.3005	0.22 (0.26)	(-0.28, 0.73)	0.3856	
Other	43	0.07 (1.75)	36	0.78 (2.10)	-0.72 (1.66)	(-4.03, 2.60)	0.6674	-0.06 (0.23)	(-0.50, 0.38)	0.7929	
Ethnicity											0.5394
Hispanic/Latino	49	3.16 (1.23)	54	3.46 (1.28)	-0.30 (1.55)	(-3.38, 2.78)	0.8451	-0.03 (0.20)	(-0.42, 0.35)	0.8655	
Non-hispanic/Latino	174	1.83 (0.69)	170	1.05 (0.68)	0.77 (0.83)	(-0.85, 2.40)	0.3492	0.09 (0.11)	(-0.13, 0.30)	0.4266	
Geographic region											0.9841
EU	86	2.69 (0.90)	80	1.66 (0.93)	1.03 (1.02)	(-0.98, 3.05)	0.3109	0.12 (0.16)	(-0.18, 0.43)	0.4265	
non-EU	145	2.03 (0.77)	146	0.97 (0.79)	1.06 (0.98)	(-0.86, 2.98)	0.2772	0.11 (0.12)	(-0.12, 0.34)	0.3373	
Onset of disease											0.2579
Paediatric	16	5.90 (2.62)	10	1.65 (2.59)	4.25 (3.05)	(-2.10, 10.61)	0.1783	0.43 (0.41)	(-0.37, 1.23)	0.2973	
Adult	215	2.31 (0.61)	216	1.61 (0.62)	0.70 (0.75)	(-0.77, 2.17)	0.3507	0.08 (0.10)	(-0.11, 0.27)	0.4212	
ADA result											0.4628
Negative	213	2.22 (0.62)	204	1.45 (0.63)	0.77 (0.77)	(-0.74, 2.28)	0.3162	0.09 (0.10)	(-0.11, 0.28)	0.3826	
Positive (At any time)	18	5.19 (3.13)	22	2.59 (2.94)	2.59 (2.36)	(-2.22, 7.41)	0.2808	0.19 (0.32)	(-0.44, 0.81)	0.5566	
BMI (kg/m2) at enrolment											0.1716
< 30	149	1.87 (0.72)	159	1.63 (0.71)	0.24 (0.82)	(-1.36, 1.85)	0.7681	0.03 (0.11)	(-0.20, 0.25)	0.8117	
>= 30	82	3.07 (1.06)	67	0.58 (1.12)	2.49 (1.43)	(-0.34, 5.32)	0.0837	0.26 (0.17)	(-0.06, 0.59)	0.1105	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Role Physical Score
Full analysis set

	Anifrolumab 300mg (N=246)		Placebo (N=246)		Difference of						
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 8		2.59 (0.49)		2.03 (0.50)	0.56 (0.62)	(-0.66, 1.77)	0.3675				
Week 16		3.68 (0.55)		2.65 (0.56)	1.03 (0.71)	(-0.36, 2.43)	0.1455				
Week 24		4.20 (0.55)		2.80 (0.55)	1.40 (0.70)	(0.03, 2.77)	0.0452				
Week 32		3.82 (0.55)		3.33 (0.56)	0.48 (0.71)	(-0.91, 1.87)	0.4949				
Week 40		3.86 (0.59)		3.48 (0.60)	0.38 (0.77)	(-1.13, 1.89)	0.6204				
Week 48		4.16 (0.60)		2.95 (0.61)	1.21 (0.79)	(-0.34, 2.75)	0.1256				
Week 52		3.84 (0.57)		3.27 (0.59)	0.57 (0.75)	(-0.91, 2.04)	0.4514				
OVERALL	231	3.73 (0.46)	226	2.93 (0.47)	0.80 (0.57)	(-0.31, 1.92)	0.1575	0.11 (0.09)	(-0.07, 0.30)	0.2231	0.7481

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Role Physical Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) N	LSMean (SE)	Placebo (N=246) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.1987
< 10 points	74	3.96 (0.73)	66	2.11 (0.78)	1.85 (0.99)	(-0.11, 3.80)	0.0637	0.29 (0.17)	(-0.04, 0.62)	0.0872	
>= 10 points	157	3.30 (0.58)	160	3.00 (0.57)	0.30 (0.69)	(-1.06, 1.65)	0.6656	0.04 (0.11)	(-0.18, 0.26)	0.7130	
OCS dose at baseline											0.6038
<10 mg/day	111	3.20 (0.60)	108	2.69 (0.64)	0.51 (0.81)	(-1.08, 2.10)	0.5275	0.08 (0.14)	(-0.19, 0.34)	0.5621	
>=10 mg/day	120	3.93 (0.74)	118	2.82 (0.71)	1.10 (0.81)	(-0.49, 2.69)	0.1732	0.14 (0.13)	(-0.12, 0.39)	0.2872	
Result of type I IFN gene signature test											0.0730
LOW	43	3.08 (0.81)	45	4.18 (0.76)	-1.09 (1.08)	(-3.24, 1.06)	0.3159	-0.21 (0.21)	(-0.63, 0.21)	0.3290	
HIGH	188	4.12 (0.48)	181	2.94 (0.49)	1.18 (0.65)	(-0.11, 2.46)	0.0735	0.18 (0.10)	(-0.03, 0.38)	0.0884	
Age (years)											NE
<= 65	224	3.78 (0.47)	225	2.89 (0.47)	0.88 (0.57)	(-0.24, 2.01)	0.1230	0.12 (0.09)	(-0.06, 0.31)	0.1878	
> 65	7	NE	1	NE	NE	NE		NE	NE		
Sex											0.7211
male	22	4.41 (1.64)	20	4.20 (1.98)	0.20 (1.83)	(-3.51, 3.92)	0.9114	0.02 (0.31)	(-0.58, 0.63)	0.9372	
female	209	3.72 (0.49)	206	2.82 (0.49)	0.89 (0.60)	(-0.29, 2.07)	0.1382	0.13 (0.10)	(-0.07, 0.32)	0.1966	
Race											0.1007
White	151	3.54 (0.55)	157	3.36 (0.54)	0.17 (0.68)	(-1.17, 1.52)	0.8020	0.03 (0.11)	(-0.20, 0.25)	0.8245	
Black	29	5.53 (1.38)	31	3.12 (1.35)	2.42 (1.64)	(-0.88, 5.71)	0.1472	0.32 (0.26)	(-0.19, 0.83)	0.2213	
Other	43	0.55 (1.50)	36	-2.58 (1.75)	3.14 (1.38)	(0.38, 5.89)	0.0263	0.31 (0.23)	(-0.14, 0.75)	0.1782	
Ethnicity											0.9434
Hispanic/Latino	49	3.36 (1.00)	54	2.76 (1.06)	0.60 (1.29)	(-1.96, 3.17)	0.6414	0.08 (0.20)	(-0.31, 0.47)	0.6830	
Non-hispanic/Latino	174	3.59 (0.54)	170	2.88 (0.53)	0.71 (0.65)	(-0.58, 1.99)	0.2796	0.10 (0.11)	(-0.11, 0.31)	0.3530	
Geographic region											0.3207
EU	86	3.96 (0.80)	80	3.86 (0.81)	0.10 (0.91)	(-1.69, 1.89)	0.9105	0.01 (0.16)	(-0.29, 0.32)	0.9289	
non-EU	145	3.46 (0.57)	146	2.21 (0.59)	1.25 (0.72)	(-0.17, 2.67)	0.0836	0.18 (0.12)	(-0.05, 0.41)	0.1263	
Onset of disease											0.9472
Paediatric	16	2.59 (2.78)	10	1.99 (2.75)	0.60 (3.13)	(-5.89, 7.10)	0.8493	0.06 (0.40)	(-0.73, 0.85)	0.8882	
Adult	215	3.77 (0.48)	216	2.96 (0.48)	0.81 (0.59)	(-0.34, 1.96)	0.1660	0.12 (0.10)	(-0.07, 0.30)	0.2311	
ADA result											0.2492
Negative	213	3.55 (0.49)	204	2.90 (0.49)	0.65 (0.61)	(-0.54, 1.84)	0.2809	0.09 (0.10)	(-0.10, 0.28)	0.3469	
Positive (At any time)	18	6.03 (2.15)	22	3.34 (2.04)	2.69 (1.66)	(-0.67, 6.05)	0.1134	0.28 (0.32)	(-0.35, 0.91)	0.3793	
BMI (kg/m2) at enrolment											0.3814
< 30	149	3.77 (0.57)	159	3.18 (0.56)	0.59 (0.64)	(-0.68, 1.86)	0.3595	0.08 (0.11)	(-0.14, 0.31)	0.4594	
>= 30	82	3.77 (0.82)	67	2.06 (0.87)	1.71 (1.10)	(-0.47, 3.89)	0.1236	0.23 (0.17)	(-0.09, 0.56)	0.1561	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Social Functioning Score
Full analysis set

	Anifrolumab 300mg (N=246)		Placebo (N=246)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 8		1.86 (0.64)		0.83 (0.64)	1.03 (0.82)	(-0.57, 2.63)	0.2066				
Week 16		2.47 (0.64)		1.20 (0.65)	1.27 (0.82)	(-0.34, 2.89)	0.1221				
Week 24		2.93 (0.68)		0.91 (0.68)	2.02 (0.87)	(0.30, 3.74)	0.0213				
Week 32		3.30 (0.67)		1.88 (0.68)	1.42 (0.87)	(-0.30, 3.14)	0.1046				
Week 40		3.36 (0.68)		1.54 (0.69)	1.82 (0.89)	(0.07, 3.56)	0.0412				
Week 48		3.15 (0.68)		1.27 (0.70)	1.89 (0.89)	(0.14, 3.64)	0.0344				
Week 52		2.97 (0.68)		1.93 (0.70)	1.04 (0.90)	(-0.72, 2.80)	0.2470				
OVERALL	231	2.86 (0.54)	226	1.36 (0.54)	1.50 (0.65)	(0.21, 2.78)	0.0223	0.18 (0.09)	(-0.00, 0.37)	0.0502	0.4202

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Social Functioning Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) N	LSMean (SE)	Placebo (N=246) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.0267
< 10 points	74	3.92 (0.88)	66	0.34 (0.93)	3.58 (1.17)	(1.26, 5.89)	0.0028	0.47 (0.17)	(0.13, 0.81)	0.0061	
>= 10 points	157	2.27 (0.66)	160	1.81 (0.65)	0.45 (0.78)	(-1.09, 2.00)	0.5634	0.05 (0.11)	(-0.17, 0.27)	0.6259	
OCS dose at baseline											0.5180
<10 mg/day	111	2.38 (0.69)	108	1.30 (0.73)	1.08 (0.92)	(-0.73, 2.90)	0.2415	0.15 (0.14)	(-0.12, 0.41)	0.2835	
>=10 mg/day	120	3.21 (0.88)	118	1.27 (0.84)	1.93 (0.94)	(0.08, 3.79)	0.0414	0.20 (0.13)	(-0.05, 0.46)	0.1156	
Result of type I IFN gene signature test											0.8873
LOW	43	3.25 (1.06)	45	1.93 (0.99)	1.32 (1.42)	(-1.52, 4.15)	0.3577	0.19 (0.21)	(-0.23, 0.61)	0.3697	
HIGH	188	3.13 (0.54)	181	1.58 (0.56)	1.54 (0.74)	(0.08, 3.00)	0.0384	0.20 (0.10)	(0.00, 0.41)	0.0496	
Age (years)											NE
<= 65	224	2.73 (0.55)	225	1.31 (0.55)	1.43 (0.66)	(0.13, 2.72)	0.0307	0.17 (0.09)	(-0.01, 0.36)	0.0668	
> 65	7	NE	1	NE	NE	NE		NE	NE		
Sex											0.7215
male	22	5.84 (1.62)	20	4.95 (1.90)	0.89 (1.78)	(-2.72, 4.49)	0.6202	0.11 (0.31)	(-0.50, 0.71)	0.7258	
female	209	2.66 (0.56)	206	1.09 (0.56)	1.57 (0.69)	(0.21, 2.93)	0.0237	0.19 (0.10)	(-0.00, 0.39)	0.0503	
Race											0.2887
White	151	2.81 (0.65)	157	1.84 (0.65)	0.96 (0.81)	(-0.63, 2.56)	0.2356	0.12 (0.11)	(-0.10, 0.34)	0.2964	
Black	29	5.34 (1.71)	31	2.19 (1.61)	3.15 (1.99)	(-0.85, 7.15)	0.1201	0.34 (0.26)	(-0.17, 0.85)	0.1891	
Other	43	-1.57 (1.61)	36	-4.87 (1.84)	3.30 (1.50)	(0.31, 6.29)	0.0311	0.30 (0.23)	(-0.14, 0.75)	0.1814	
Ethnicity											0.8167
Hispanic/Latino	49	3.46 (1.13)	54	2.37 (1.18)	1.10 (1.43)	(-1.74, 3.94)	0.4450	0.13 (0.20)	(-0.26, 0.52)	0.5069	
Non-hispanic/Latino	174	2.42 (0.63)	170	0.95 (0.63)	1.47 (0.76)	(-0.02, 2.96)	0.0526	0.18 (0.11)	(-0.03, 0.39)	0.0997	
Geographic region											0.4388
EU	86	3.55 (0.93)	80	2.56 (0.96)	0.99 (1.04)	(-1.05, 3.04)	0.3395	0.11 (0.16)	(-0.19, 0.42)	0.4608	
non-EU	145	2.56 (0.66)	146	0.54 (0.68)	2.02 (0.84)	(0.38, 3.67)	0.0161	0.25 (0.12)	(0.02, 0.48)	0.0335	
Onset of disease											0.4988
Paediatric	16	4.78 (3.12)	10	5.69 (3.13)	-0.91 (3.67)	(-8.51, 6.69)	0.8060	-0.08 (0.40)	(-0.87, 0.71)	0.8500	
Adult	215	2.83 (0.55)	216	1.22 (0.56)	1.61 (0.67)	(0.29, 2.94)	0.0173	0.20 (0.10)	(0.01, 0.39)	0.0409	
ADA result											0.5949
Negative	213	2.70 (0.57)	204	1.27 (0.58)	1.43 (0.70)	(0.05, 2.81)	0.0427	0.17 (0.10)	(-0.02, 0.37)	0.0784	
Positive (At any time)	18	4.17 (2.51)	22	1.76 (2.33)	2.41 (1.71)	(-1.06, 5.89)	0.1676	0.22 (0.32)	(-0.41, 0.84)	0.4929	
BMI (kg/m2) at enrolment											0.7335
< 30	149	2.51 (0.67)	159	1.06 (0.66)	1.45 (0.75)	(-0.02, 2.92)	0.0533	0.18 (0.11)	(-0.05, 0.40)	0.1232	
>= 30	82	3.52 (0.97)	67	1.56 (1.01)	1.96 (1.30)	(-0.61, 4.54)	0.1336	0.23 (0.17)	(-0.10, 0.55)	0.1663	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Bodily Pain Score
Full analysis set

	Anifrolumab 300mg (N=246)		Placebo (N=246)		Difference of						
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 8		2.41 (0.56)		1.65 (0.57)	0.76 (0.71)	(-0.64, 2.16)	0.2872				
Week 16		3.89 (0.60)		3.16 (0.60)	0.73 (0.77)	(-0.79, 2.25)	0.3467				
Week 24		4.06 (0.61)		2.47 (0.62)	1.59 (0.79)	(0.03, 3.15)	0.0459				
Week 32		3.40 (0.64)		3.14 (0.65)	0.26 (0.84)	(-1.40, 1.91)	0.7615				
Week 40		4.08 (0.62)		3.71 (0.63)	0.37 (0.81)	(-1.22, 1.96)	0.6491				
Week 48		3.94 (0.66)		3.30 (0.68)	0.63 (0.88)	(-1.09, 2.35)	0.4712				
Week 52		3.42 (0.65)		3.51 (0.67)	-0.09 (0.86)	(-1.78, 1.61)	0.9201				
OVERALL	231	3.60 (0.49)	226	2.99 (0.50)	0.61 (0.60)	(-0.57, 1.78)	0.3110	0.08 (0.09)	(-0.10, 0.26)	0.3844	0.9603

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Bodily Pain Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) N	LSMean (SE)	Placebo (N=246) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.0429
< 10 points	74	4.21 (0.77)	66	1.82 (0.81)	2.39 (1.02)	(0.37, 4.40)	0.0205	0.36 (0.17)	(0.03, 0.70)	0.0342	
>= 10 points	157	3.30 (0.62)	160	3.45 (0.61)	-0.15 (0.73)	(-1.60, 1.29)	0.8347	-0.02 (0.11)	(-0.24, 0.20)	0.8597	
OCS dose at baseline											0.2495
<10 mg/day	111	3.78 (0.58)	108	2.54 (0.61)	1.24 (0.77)	(-0.28, 2.75)	0.1101	0.20 (0.14)	(-0.07, 0.46)	0.1437	
>=10 mg/day	120	3.04 (0.84)	118	3.18 (0.81)	-0.14 (0.91)	(-1.94, 1.66)	0.8782	-0.02 (0.13)	(-0.27, 0.24)	0.9046	
Result of type I IFN gene signature test											0.1480
LOW	43	2.95 (0.82)	45	3.97 (0.77)	-1.02 (1.11)	(-3.22, 1.19)	0.3617	-0.19 (0.21)	(-0.61, 0.23)	0.3726	
HIGH	188	4.16 (0.51)	181	3.29 (0.52)	0.87 (0.69)	(-0.49, 2.23)	0.2076	0.12 (0.10)	(-0.08, 0.33)	0.2314	
Age (years)											NE
<= 65	224	3.71 (0.50)	225	2.97 (0.50)	0.73 (0.60)	(-0.45, 1.92)	0.2240	0.10 (0.09)	(-0.09, 0.28)	0.3013	
> 65	7	NE	1	NE	NE	NE		NE	NE		
Sex											0.5883
male	22	3.53 (1.94)	20	4.00 (2.28)	-0.48 (2.09)	(-4.72, 3.77)	0.8210	-0.05 (0.31)	(-0.65, 0.56)	0.8750	
female	209	3.66 (0.51)	206	2.95 (0.51)	0.71 (0.63)	(-0.53, 1.95)	0.2635	0.10 (0.10)	(-0.10, 0.29)	0.3316	
Race											0.2991
White	151	3.47 (0.58)	157	3.61 (0.57)	-0.14 (0.72)	(-1.56, 1.28)	0.8477	-0.02 (0.11)	(-0.24, 0.20)	0.8653	
Black	29	5.40 (1.45)	31	2.78 (1.40)	2.62 (1.73)	(-0.85, 6.09)	0.1358	0.33 (0.26)	(-0.18, 0.84)	0.2030	
Other	43	0.17 (1.53)	36	-0.88 (1.76)	1.05 (1.42)	(-1.78, 3.89)	0.4611	0.10 (0.23)	(-0.34, 0.54)	0.6532	
Ethnicity											0.1351
Hispanic/Latino	49	4.72 (0.97)	54	2.70 (1.02)	2.02 (1.22)	(-0.39, 4.44)	0.0998	0.28 (0.20)	(-0.11, 0.67)	0.1566	
Non-hispanic/Latino	174	2.92 (0.57)	170	2.99 (0.56)	-0.07 (0.69)	(-1.42, 1.29)	0.9231	-0.01 (0.11)	(-0.22, 0.20)	0.9342	
Geographic region											0.1131
EU	86	3.99 (0.95)	80	4.63 (0.98)	-0.64 (1.07)	(-2.74, 1.47)	0.5516	-0.07 (0.16)	(-0.38, 0.23)	0.6432	
non-EU	145	3.41 (0.56)	146	2.02 (0.58)	1.39 (0.71)	(0.00, 2.78)	0.0499	0.20 (0.12)	(-0.03, 0.43)	0.0844	
Onset of disease											0.4921
Paediatric	16	8.14 (4.24)	10	4.45 (4.02)	3.69 (4.72)	(-6.17, 13.55)	0.4431	0.23 (0.40)	(-0.56, 1.02)	0.5683	
Adult	215	3.43 (0.49)	216	3.00 (0.49)	0.43 (0.60)	(-0.75, 1.60)	0.4752	0.06 (0.10)	(-0.13, 0.25)	0.5381	
ADA result											0.1317
Negative	213	3.35 (0.51)	204	3.02 (0.52)	0.33 (0.63)	(-0.90, 1.57)	0.5970	0.05 (0.10)	(-0.15, 0.24)	0.6457	
Positive (At any time)	18	10.51 (2.82)	22	6.80 (2.62)	3.72 (2.15)	(-0.66, 8.09)	0.0934	0.30 (0.32)	(-0.33, 0.93)	0.3480	
BMI (kg/m2) at enrolment											0.0824
< 30	149	3.19 (0.64)	159	3.23 (0.63)	-0.04 (0.72)	(-1.46, 1.38)	0.9538	-0.01 (0.11)	(-0.23, 0.22)	0.9630	
>= 30	82	4.44 (0.80)	67	2.24 (0.84)	2.20 (1.07)	(0.08, 4.32)	0.0419	0.31 (0.17)	(-0.01, 0.64)	0.0608	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Vitality Score
Full analysis set

	Anifrolumab 300mg (N=246)		Placebo (N=246)		Difference of						
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 8		2.46 (0.55)		1.15 (0.55)	1.31 (0.69)	(-0.04, 2.67)	0.0576				
Week 16		2.72 (0.59)		2.06 (0.60)	0.65 (0.76)	(-0.84, 2.15)	0.3897				
Week 24		3.39 (0.61)		2.14 (0.61)	1.25 (0.78)	(-0.28, 2.78)	0.1098				
Week 32		3.21 (0.61)		2.36 (0.62)	0.86 (0.79)	(-0.70, 2.42)	0.2817				
Week 40		3.04 (0.64)		3.20 (0.65)	-0.17 (0.83)	(-1.81, 1.47)	0.8394				
Week 48		3.85 (0.64)		2.53 (0.65)	1.32 (0.84)	(-0.33, 2.96)	0.1163				
Week 52		3.40 (0.66)		2.58 (0.68)	0.81 (0.88)	(-0.91, 2.54)	0.3531				
OVERALL	231	3.15 (0.49)	226	2.29 (0.50)	0.86 (0.60)	(-0.33, 2.05)	0.1547	0.11 (0.09)	(-0.07, 0.30)	0.2211	0.8921

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SF-36 v2.0 Acute Vitality Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) N	LSMean (SE)	Placebo (N=246) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.1299
< 10 points	74	3.93 (0.81)	66	1.72 (0.85)	2.21 (1.08)	(0.08, 4.35)	0.0420	0.32 (0.17)	(-0.02, 0.65)	0.0623	
>= 10 points	157	2.64 (0.62)	160	2.40 (0.60)	0.24 (0.73)	(-1.20, 1.68)	0.7435	0.03 (0.11)	(-0.19, 0.25)	0.7816	
OCS dose at baseline											0.7625
<10 mg/day	111	2.62 (0.66)	108	1.97 (0.70)	0.65 (0.88)	(-1.09, 2.39)	0.4645	0.09 (0.14)	(-0.17, 0.36)	0.5024	
>=10 mg/day	120	3.46 (0.79)	118	2.45 (0.75)	1.02 (0.84)	(-0.65, 2.68)	0.2294	0.12 (0.13)	(-0.13, 0.38)	0.3513	
Result of type I IFN gene signature test											0.4244
LOW	43	3.99 (1.06)	45	4.14 (1.00)	-0.16 (1.44)	(-3.02, 2.70)	0.9129	-0.02 (0.21)	(-0.44, 0.40)	0.9144	
HIGH	188	3.32 (0.49)	181	2.21 (0.51)	1.11 (0.67)	(-0.21, 2.44)	0.1001	0.16 (0.10)	(-0.04, 0.37)	0.1179	
Age (years)											NE
<= 65	224	3.16 (0.51)	225	2.25 (0.50)	0.92 (0.61)	(-0.28, 2.11)	0.1342	0.12 (0.09)	(-0.06, 0.31)	0.2020	
> 65	7	NE	1	NE	NE	NE		NE	NE		
Sex											0.9026
male	22	5.82 (1.57)	20	5.19 (1.83)	0.63 (1.67)	(-2.77, 4.02)	0.7099	0.08 (0.31)	(-0.53, 0.68)	0.7978	
female	209	2.98 (0.52)	206	2.13 (0.52)	0.85 (0.65)	(-0.42, 2.12)	0.1907	0.11 (0.10)	(-0.08, 0.30)	0.2552	
Race											0.6020
White	151	3.55 (0.61)	157	3.17 (0.60)	0.38 (0.75)	(-1.10, 1.86)	0.6116	0.05 (0.11)	(-0.17, 0.27)	0.6546	
Black	29	3.88 (1.42)	31	2.02 (1.36)	1.86 (1.65)	(-1.45, 5.18)	0.2645	0.24 (0.26)	(-0.27, 0.75)	0.3502	
Other	43	-1.39 (1.62)	36	-3.03 (1.85)	1.64 (1.56)	(-1.46, 4.74)	0.2955	0.15 (0.23)	(-0.29, 0.59)	0.5082	
Ethnicity											0.8386
Hispanic/Latino	49	3.47 (1.01)	54	2.49 (1.05)	0.98 (1.29)	(-1.58, 3.54)	0.4498	0.13 (0.20)	(-0.26, 0.52)	0.5054	
Non-hispanic/Latino	174	2.76 (0.60)	170	2.08 (0.59)	0.68 (0.71)	(-0.73, 2.08)	0.3423	0.09 (0.11)	(-0.12, 0.30)	0.4180	
Geographic region											0.0725
EU	86	3.20 (0.92)	80	3.78 (0.93)	-0.58 (1.01)	(-2.57, 1.41)	0.5659	-0.07 (0.16)	(-0.37, 0.24)	0.6587	
non-EU	145	3.13 (0.59)	146	1.46 (0.60)	1.67 (0.75)	(0.20, 3.14)	0.0259	0.23 (0.12)	(0.00, 0.46)	0.0483	
Onset of disease											0.7197
Paediatric	16	3.38 (2.58)	10	1.42 (2.60)	1.96 (3.06)	(-4.46, 8.38)	0.5303	0.20 (0.40)	(-0.59, 0.99)	0.6245	
Adult	215	3.19 (0.51)	216	2.35 (0.51)	0.84 (0.63)	(-0.39, 2.07)	0.1816	0.11 (0.10)	(-0.08, 0.30)	0.2494	
ADA result											0.3115
Negative	213	3.00 (0.51)	204	2.37 (0.52)	0.63 (0.64)	(-0.62, 1.89)	0.3216	0.08 (0.10)	(-0.11, 0.28)	0.3885	
Positive (At any time)	18	4.51 (3.01)	22	1.54 (2.79)	2.96 (2.21)	(-1.54, 7.47)	0.1900	0.22 (0.32)	(-0.40, 0.85)	0.4823	
BMI (kg/m2) at enrolment											0.5550
< 30	149	2.64 (0.64)	159	1.97 (0.63)	0.67 (0.73)	(-0.76, 2.10)	0.3558	0.08 (0.11)	(-0.14, 0.31)	0.4583	
>= 30	82	4.07 (0.80)	67	2.63 (0.85)	1.44 (1.08)	(-0.70, 3.59)	0.1850	0.20 (0.17)	(-0.12, 0.53)	0.2211	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - FACIT-F Total Score
Full analysis set

	Anifrolumab 300mg (N=246)		Placebo (N=246)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 4		2.05 (0.57)		2.16 (0.57)	-0.11 (0.71)	(-1.51, 1.30)	0.8820				
Week 8		2.96 (0.59)		2.36 (0.59)	0.60 (0.74)	(-0.85, 2.06)	0.4163				
Week 12		3.65 (0.67)		1.41 (0.67)	2.24 (0.87)	(0.53, 3.94)	0.0105				
Week 16		3.92 (0.67)		2.36 (0.67)	1.56 (0.87)	(-0.15, 3.27)	0.0738				
Week 20		4.56 (0.68)		4.92 (0.68)	-0.36 (0.89)	(-2.10, 1.38)	0.6851				
Week 24		5.11 (0.69)		3.53 (0.69)	1.58 (0.90)	(-0.19, 3.36)	0.0801				
Week 28		5.13 (0.70)		3.98 (0.70)	1.15 (0.92)	(-0.66, 2.95)	0.2113				
Week 32		4.16 (0.75)		3.85 (0.75)	0.31 (0.99)	(-1.64, 2.26)	0.7548				
Week 36		4.75 (0.73)		3.47 (0.74)	1.28 (0.97)	(-0.63, 3.19)	0.1875				
Week 40		4.53 (0.74)		4.87 (0.74)	-0.34 (0.98)	(-2.26, 1.58)	0.7268				
Week 44		5.24 (0.76)		4.66 (0.77)	0.58 (1.01)	(-1.41, 2.56)	0.5677				
Week 48		5.15 (0.74)		4.12 (0.76)	1.03 (0.99)	(-0.92, 2.98)	0.3006				
Week 52		5.09 (0.76)		3.90 (0.77)	1.19 (1.01)	(-0.80, 3.18)	0.2414				
OVERALL	231	4.33 (0.56)	230	3.51 (0.57)	0.82 (0.70)	(-0.56, 2.21)	0.2435	0.10 (0.09)	(-0.09, 0.28)	0.3040	0.2360

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - FACIT-F Total Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) N	LSMean (SE)	Placebo (N=246) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.1103
< 10 points	73	5.14 (0.92)	67	2.68 (0.95)	2.46 (1.23)	(0.03, 4.88)	0.0470	0.31 (0.17)	(-0.02, 0.65)	0.0652	
>= 10 points	158	3.88 (0.69)	163	3.81 (0.68)	0.07 (0.85)	(-1.61, 1.75)	0.9319	0.01 (0.11)	(-0.21, 0.23)	0.9403	
OCS dose at baseline											0.6273
<10 mg/day	109	4.55 (0.74)	107	3.35 (0.76)	1.20 (0.99)	(-0.74, 3.15)	0.2245	0.15 (0.14)	(-0.11, 0.42)	0.2576	
>=10 mg/day	122	3.74 (0.89)	123	3.22 (0.86)	0.52 (1.00)	(-1.45, 2.49)	0.6040	0.05 (0.13)	(-0.20, 0.30)	0.6748	
Result of type I IFN gene signature test											0.4157
LOW	42	5.25 (1.23)	45	5.64 (1.16)	-0.39 (1.67)	(-3.72, 2.94)	0.8174	-0.05 (0.21)	(-0.47, 0.37)	0.8206	
HIGH	189	4.63 (0.57)	185	3.52 (0.58)	1.12 (0.78)	(-0.42, 2.66)	0.1550	0.14 (0.10)	(-0.06, 0.34)	0.1730	
Age (years)											NE
<= 65	225	4.42 (0.58)	229	3.53 (0.57)	0.89 (0.71)	(-0.51, 2.29)	0.2138	0.10 (0.09)	(-0.08, 0.29)	0.2761	
> 65	6	NE	1	NE	NE	NE		NE	NE		
Sex											0.6926
male	22	5.48 (1.41)	20	5.33 (1.66)	0.15 (1.71)	(-3.31, 3.61)	0.9302	0.02 (0.31)	(-0.58, 0.63)	0.9456	
female	209	4.31 (0.60)	210	3.42 (0.60)	0.89 (0.75)	(-0.59, 2.37)	0.2394	0.10 (0.10)	(-0.09, 0.29)	0.2951	
Race											0.2651
White	150	4.02 (0.71)	162	3.67 (0.69)	0.35 (0.89)	(-1.40, 2.10)	0.6922	0.04 (0.11)	(-0.18, 0.26)	0.7211	
Black	31	9.37 (1.77)	30	5.67 (1.73)	3.70 (2.13)	(-0.57, 7.97)	0.0879	0.38 (0.26)	(-0.13, 0.88)	0.1445	
Other	44	1.57 (1.56)	36	-0.58 (1.84)	2.15 (1.54)	(-0.92, 5.22)	0.1680	0.20 (0.23)	(-0.24, 0.64)	0.3762	
Ethnicity											0.3639
Hispanic/Latino	49	3.88 (1.27)	55	1.78 (1.30)	2.10 (1.60)	(-1.06, 5.27)	0.1907	0.22 (0.20)	(-0.16, 0.61)	0.2544	
Non-hispanic/Latino	176	4.46 (0.64)	173	3.97 (0.64)	0.48 (0.80)	(-1.08, 2.05)	0.5446	0.06 (0.11)	(-0.15, 0.27)	0.5936	
Geographic region											0.0470
EU	85	4.44 (0.88)	84	5.23 (0.89)	-0.79 (1.02)	(-2.82, 1.23)	0.4397	-0.10 (0.15)	(-0.40, 0.20)	0.5281	
non-EU	146	4.36 (0.71)	146	2.42 (0.73)	1.94 (0.92)	(0.13, 3.74)	0.0354	0.22 (0.12)	(-0.01, 0.45)	0.0588	
Onset of disease											NE
Paediatric	15	NE	10	NE	NE	NE		NE	NE		
Adult	216	4.53 (0.58)	220	3.56 (0.57)	0.97 (0.72)	(-0.45, 2.39)	0.1785	0.11 (0.10)	(-0.07, 0.30)	0.2342	
ADA result											0.1991
Negative	212	4.13 (0.58)	208	3.50 (0.59)	0.62 (0.74)	(-0.82, 2.07)	0.3977	0.07 (0.10)	(-0.12, 0.26)	0.4513	
Positive (At any time)	19	8.06 (3.80)	22	3.95 (3.58)	4.11 (2.62)	(-1.21, 9.44)	0.1255	0.24 (0.31)	(-0.37, 0.86)	0.4420	
BMI (kg/m2) at enrolment											0.3137
< 30	151	3.75 (0.70)	163	3.35 (0.69)	0.40 (0.82)	(-1.21, 2.00)	0.6283	0.05 (0.11)	(-0.18, 0.27)	0.6882	
>= 30	80	5.41 (1.00)	67	3.41 (1.05)	2.00 (1.37)	(-0.71, 4.72)	0.1466	0.23 (0.17)	(-0.10, 0.55)	0.1735	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - EQ VAS Score
Full analysis set

	Anifrolumab 300mg (N=246)		Placebo (N=246)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 12		6.34 (1.48)		2.47 (1.49)	3.86 (1.89)	(0.15, 7.57)	0.0414				
Week 24		6.72 (1.57)		6.39 (1.56)	0.32 (2.01)	(-3.63, 4.28)	0.8720				
Week 36		8.60 (1.58)		7.92 (1.59)	0.68 (2.04)	(-3.34, 4.69)	0.7405				
Week 52		9.45 (1.60)		5.86 (1.62)	3.59 (2.07)	(-0.48, 7.67)	0.0839				
OVERALL	226	7.77 (1.27)	224	5.66 (1.27)	2.11 (1.53)	(-0.90, 5.12)	0.1681	0.11 (0.09)	(-0.07, 0.30)	0.2391	0.6854

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - EQ VAS Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) N	LSMean (SE)	Placebo (N=246) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.5095
< 10 points	71	8.81 (2.13)	65	5.29 (2.19)	3.51 (2.82)	(-2.08, 9.10)	0.2159	0.20 (0.17)	(-0.14, 0.53)	0.2550	
>= 10 points	155	6.94 (1.55)	159	5.65 (1.52)	1.29 (1.83)	(-2.31, 4.89)	0.4802	0.07 (0.11)	(-0.15, 0.29)	0.5522	
OCS dose at baseline											0.5024
<10 mg/day	108	6.97 (1.73)	104	5.91 (1.81)	1.06 (2.29)	(-3.46, 5.58)	0.6439	0.06 (0.14)	(-0.21, 0.33)	0.6723	
>=10 mg/day	118	7.44 (1.93)	120	4.32 (1.84)	3.13 (2.06)	(-0.93, 7.19)	0.1303	0.15 (0.13)	(-0.10, 0.41)	0.2433	
Result of type I IFN gene signature test											0.0546
LOW	42	2.54 (2.44)	45	6.37 (2.28)	-3.83 (3.26)	(-10.33, 2.66)	0.2434	-0.24 (0.22)	(-0.67, 0.18)	0.2557	
HIGH	184	10.48 (1.28)	179	7.22 (1.30)	3.26 (1.73)	(-0.14, 6.66)	0.0601	0.19 (0.11)	(-0.02, 0.39)	0.0755	
Age (years)											NE
<= 65	220	8.15 (1.29)	223	5.72 (1.28)	2.43 (1.54)	(-0.60, 5.46)	0.1156	0.13 (0.10)	(-0.06, 0.31)	0.1820	
> 65	6	NE	1	NE	NE	NE		NE	NE		
Sex											0.6785
male	22	2.12 (4.60)	20	-1.83 (5.42)	3.96 (5.05)	(-6.30, 14.21)	0.4386	0.17 (0.31)	(-0.44, 0.78)	0.5838	
female	204	8.22 (1.33)	204	6.46 (1.31)	1.76 (1.62)	(-1.42, 4.93)	0.2769	0.09 (0.10)	(-0.10, 0.29)	0.3479	
Race											0.0031
White	147	7.25 (1.49)	158	8.40 (1.46)	-1.15 (1.82)	(-4.73, 2.43)	0.5265	-0.06 (0.11)	(-0.29, 0.16)	0.5815	
Black	30	12.14 (3.01)	30	4.92 (2.85)	7.23 (3.64)	(-0.07, 14.52)	0.0522	0.44 (0.26)	(-0.07, 0.96)	0.0895	
Other	43	2.89 (4.46)	34	-10.24 (5.05)	13.14 (4.38)	(4.40, 21.87)	0.0037	0.44 (0.23)	(-0.01, 0.90)	0.0565	
Ethnicity											0.4371
Hispanic/Latino	47	8.91 (2.78)	55	5.30 (2.81)	3.62 (3.35)	(-3.03, 10.27)	0.2829	0.18 (0.20)	(-0.21, 0.57)	0.3675	
Non-hispanic/Latino	173	6.44 (1.46)	167	5.76 (1.44)	0.68 (1.74)	(-2.75, 4.12)	0.6957	0.04 (0.11)	(-0.18, 0.25)	0.7393	
Geographic region											0.0209
EU	84	9.98 (2.19)	81	12.12 (2.23)	-2.14 (2.44)	(-6.95, 2.68)	0.3816	-0.11 (0.16)	(-0.41, 0.20)	0.4964	
non-EU	142	6.19 (1.53)	143	1.15 (1.56)	5.03 (1.92)	(1.25, 8.82)	0.0093	0.27 (0.12)	(0.04, 0.50)	0.0224	
Onset of disease											0.4573
Paediatric	14	13.85 (4.88)	10	7.14 (5.18)	6.71 (6.53)	(-7.01, 20.43)	0.3175	0.37 (0.42)	(-0.45, 1.19)	0.3764	
Adult	212	7.31 (1.31)	214	5.59 (1.31)	1.72 (1.59)	(-1.40, 4.84)	0.2791	0.09 (0.10)	(-0.10, 0.28)	0.3539	
ADA result											0.1191
Negative	207	7.02 (1.30)	202	5.68 (1.31)	1.34 (1.60)	(-1.82, 4.49)	0.4048	0.07 (0.10)	(-0.12, 0.27)	0.4707	
Positive (At any time)	19	30.39 (7.56)	22	20.14 (7.13)	10.25 (5.49)	(-0.90, 21.40)	0.0705	0.30 (0.32)	(-0.32, 0.92)	0.3371	
BMI (kg/m2) at enrolment											0.5936
< 30	148	8.28 (1.67)	159	5.32 (1.65)	2.97 (1.88)	(-0.73, 6.66)	0.1150	0.14 (0.11)	(-0.08, 0.37)	0.2080	
>= 30	78	6.91 (1.97)	65	5.66 (2.03)	1.25 (2.62)	(-3.94, 6.43)	0.6350	0.07 (0.17)	(-0.26, 0.40)	0.6631	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Lupus QoL Physical Health domain score
Full analysis set

	Anifrolumab 300mg (N=246)		Placebo (N=246)		Difference of						
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 12		9.06 (1.36)		6.69 (1.38)	2.37 (1.71)	(-0.99, 5.73)	0.1669				
Week 24		9.79 (1.40)		7.55 (1.40)	2.24 (1.75)	(-1.19, 5.68)	0.1999				
Week 36		8.75 (1.46)		10.29 (1.48)	-1.54 (1.86)	(-5.19, 2.11)	0.4066				
Week 52		7.32 (1.49)		8.23 (1.51)	-0.90 (1.91)	(-4.66, 2.86)	0.6377				
OVERALL	225	8.73 (1.25)	224	8.19 (1.26)	0.54 (1.52)	(-2.44, 3.52)	0.7209	0.03 (0.09)	(-0.16, 0.21)	0.7606	0.5763

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Lupus QoL Physical Health domain score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) N	LSMean (SE)	Placebo (N=246) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.9089
< 10 points	71	8.42 (1.99)	65	8.30 (2.06)	0.12 (2.65)	(-5.12, 5.37)	0.9627	0.01 (0.17)	(-0.33, 0.34)	0.9657	
>= 10 points	154	8.77 (1.56)	159	8.27 (1.53)	0.49 (1.84)	(-3.13, 4.12)	0.7889	0.03 (0.11)	(-0.20, 0.25)	0.8218	
OCS dose at baseline											0.7732
<10 mg/day	108	7.61 (1.51)	104	7.54 (1.58)	0.07 (2.00)	(-3.86, 4.01)	0.9709	0.00 (0.14)	(-0.26, 0.27)	0.9735	
>=10 mg/day	117	9.04 (2.12)	120	8.10 (2.03)	0.95 (2.28)	(-3.54, 5.43)	0.6783	0.04 (0.13)	(-0.21, 0.30)	0.7484	
Result of type I IFN gene signature test											0.2423
LOW	42	8.15 (2.34)	45	11.20 (2.17)	-3.05 (3.12)	(-9.28, 3.17)	0.3318	-0.20 (0.22)	(-0.63, 0.22)	0.3442	
HIGH	183	9.22 (1.27)	179	8.10 (1.30)	1.12 (1.72)	(-2.27, 4.51)	0.5163	0.06 (0.11)	(-0.14, 0.27)	0.5397	
Age (years)											NE
<= 65	219	9.30 (1.28)	223	8.44 (1.27)	0.86 (1.53)	(-2.15, 3.87)	0.5740	0.05 (0.10)	(-0.14, 0.23)	0.6340	
> 65	6	NE	1	NE	NE	NE		NE	NE		
Sex											0.8618
male	22	12.11 (4.32)	20	10.87 (5.06)	1.24 (4.72)	(-8.33, 10.82)	0.7935	0.06 (0.31)	(-0.55, 0.66)	0.8536	
female	203	8.53 (1.32)	204	8.15 (1.31)	0.38 (1.60)	(-2.78, 3.53)	0.8145	0.02 (0.10)	(-0.17, 0.21)	0.8397	
Race											0.4088
White	147	8.39 (1.56)	158	8.50 (1.53)	-0.11 (1.92)	(-3.88, 3.66)	0.9524	-0.01 (0.11)	(-0.23, 0.22)	0.9584	
Black	29	14.38 (3.99)	30	13.65 (3.91)	0.74 (4.87)	(-9.04, 10.51)	0.8805	0.03 (0.26)	(-0.48, 0.54)	0.8965	
Other	43	4.07 (3.37)	34	-0.82 (3.94)	4.88 (3.22)	(-1.54, 11.31)	0.1338	0.22 (0.23)	(-0.24, 0.67)	0.3501	
Ethnicity											0.8439
Hispanic/Latino	47	9.01 (2.79)	55	9.38 (2.86)	-0.36 (3.54)	(-7.40, 6.68)	0.9190	-0.02 (0.20)	(-0.41, 0.37)	0.9290	
Non-hispanic/Latino	172	8.08 (1.45)	167	7.67 (1.43)	0.42 (1.73)	(-2.99, 3.82)	0.8104	0.02 (0.11)	(-0.19, 0.24)	0.8387	
Geographic region											0.4195
EU	84	10.34 (2.14)	81	11.56 (2.16)	-1.22 (2.37)	(-5.90, 3.47)	0.6081	-0.06 (0.16)	(-0.37, 0.24)	0.6897	
non-EU	141	7.55 (1.48)	143	6.33 (1.53)	1.22 (1.88)	(-2.47, 4.92)	0.5151	0.07 (0.12)	(-0.16, 0.30)	0.5677	
Onset of disease											0.3702
Paediatric	14	0.60 (6.42)	10	6.63 (6.36)	-6.03 (7.57)	(-21.96, 9.90)	0.4364	-0.26 (0.42)	(-1.07, 0.56)	0.5342	
Adult	211	9.04 (1.30)	214	8.14 (1.30)	0.90 (1.57)	(-2.19, 3.99)	0.5678	0.05 (0.10)	(-0.14, 0.24)	0.6254	
ADA result											0.4470
Negative	206	8.51 (1.30)	202	8.43 (1.31)	0.08 (1.60)	(-3.07, 3.22)	0.9614	0.00 (0.10)	(-0.19, 0.20)	0.9667	
Positive (At any time)	19	17.39 (6.80)	22	13.21 (6.36)	4.18 (5.15)	(-6.27, 14.63)	0.4226	0.14 (0.31)	(-0.48, 0.75)	0.6603	
BMI (kg/m2) at enrolment											0.9759
< 30	147	9.67 (1.48)	159	8.71 (1.46)	0.95 (1.66)	(-2.31, 4.22)	0.5655	0.05 (0.11)	(-0.17, 0.28)	0.6474	
>= 30	78	8.19 (2.40)	65	7.34 (2.48)	0.84 (3.21)	(-5.51, 7.20)	0.7930	0.04 (0.17)	(-0.29, 0.37)	0.8085	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Lupus QoL Emotional Health domain score
Full analysis set

	Anifrolumab 300mg (N=246)		Placebo (N=246)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 12		3.78 (1.29)		1.19 (1.30)	2.59 (1.63)	(-0.60, 5.79)	0.1116				
Week 24		5.21 (1.37)		4.75 (1.36)	0.46 (1.73)	(-2.94, 3.87)	0.7903				
Week 36		6.22 (1.37)		6.52 (1.38)	-0.31 (1.75)	(-3.75, 3.14)	0.8615				
Week 52		6.41 (1.49)		5.85 (1.50)	0.56 (1.94)	(-3.25, 4.37)	0.7714				
OVERALL	225	5.41 (1.16)	224	4.58 (1.16)	0.83 (1.40)	(-1.93, 3.58)	0.5550	0.05 (0.09)	(-0.14, 0.23)	0.6135	0.6712

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

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Repeated measures model analysis - Lupus QoL Emotional Health domain score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) N	LSMean (SE)	Placebo (N=246) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.6332
< 10 points	71	6.62 (1.85)	65	4.99 (1.90)	1.63 (2.45)	(-3.22, 6.49)	0.5072	0.10 (0.17)	(-0.23, 0.44)	0.5413	
>= 10 points	154	4.42 (1.44)	159	4.22 (1.42)	0.20 (1.71)	(-3.16, 3.57)	0.9046	0.01 (0.11)	(-0.21, 0.23)	0.9194	
OCS dose at baseline											0.8383
<10 mg/day	108	4.66 (1.47)	104	3.59 (1.54)	1.07 (1.95)	(-2.77, 4.90)	0.5843	0.07 (0.14)	(-0.20, 0.34)	0.6170	
>=10 mg/day	117	5.74 (1.90)	120	5.26 (1.82)	0.49 (2.05)	(-3.55, 4.53)	0.8117	0.02 (0.13)	(-0.23, 0.28)	0.8529	
Result of type I IFN gene signature test											0.4394
LOW	42	3.50 (2.22)	45	4.92 (2.09)	-1.43 (3.00)	(-7.41, 4.55)	0.6354	-0.10 (0.21)	(-0.52, 0.32)	0.6423	
HIGH	183	6.77 (1.18)	179	5.57 (1.20)	1.20 (1.59)	(-1.93, 4.33)	0.4524	0.07 (0.11)	(-0.13, 0.28)	0.4778	
Age (years)											NE
<= 65	219	5.37 (1.19)	223	4.62 (1.17)	0.76 (1.42)	(-2.03, 3.55)	0.5938	0.04 (0.10)	(-0.14, 0.23)	0.6505	
> 65	6	NE	1	NE	NE	NE		NE	NE		
Sex											0.8336
male	22	8.98 (4.19)	20	7.14 (5.11)	1.84 (4.72)	(-7.73, 11.41)	0.6988	0.09 (0.31)	(-0.52, 0.69)	0.7832	
female	203	5.20 (1.20)	204	4.40 (1.19)	0.80 (1.46)	(-2.07, 3.68)	0.5833	0.05 (0.10)	(-0.15, 0.24)	0.6355	
Race											0.9115
White	147	5.79 (1.41)	158	4.20 (1.38)	1.59 (1.73)	(-1.81, 4.99)	0.3582	0.09 (0.11)	(-0.13, 0.32)	0.4212	
Black	29	9.06 (3.74)	30	9.41 (3.58)	-0.35 (4.50)	(-9.39, 8.69)	0.9384	-0.02 (0.26)	(-0.53, 0.49)	0.9468	
Other	43	0.41 (3.39)	34	-0.39 (3.93)	0.79 (3.15)	(-5.50, 7.08)	0.8019	0.03 (0.23)	(-0.41, 0.48)	0.8792	
Ethnicity											0.2232
Hispanic/Latino	47	6.47 (2.65)	55	9.45 (2.69)	-2.98 (3.27)	(-9.48, 3.52)	0.3646	-0.15 (0.20)	(-0.54, 0.24)	0.4372	
Non-hispanic/Latino	172	4.81 (1.31)	167	3.37 (1.30)	1.44 (1.57)	(-1.65, 4.53)	0.3602	0.08 (0.11)	(-0.13, 0.30)	0.4366	
Geographic region											0.9851
EU	84	8.14 (1.80)	81	6.95 (1.82)	1.19 (1.99)	(-2.74, 5.12)	0.5500	0.07 (0.16)	(-0.23, 0.38)	0.6436	
non-EU	141	3.43 (1.45)	143	2.29 (1.48)	1.14 (1.82)	(-2.45, 4.73)	0.5328	0.07 (0.12)	(-0.17, 0.30)	0.5828	
Onset of disease											0.7755
Paediatric	14	2.94 (5.79)	10	-0.11 (5.76)	3.06 (6.80)	(-11.18, 17.29)	0.6582	0.15 (0.41)	(-0.67, 0.96)	0.7262	
Adult	211	5.66 (1.18)	214	4.58 (1.18)	1.07 (1.43)	(-1.73, 3.88)	0.4518	0.06 (0.10)	(-0.13, 0.25)	0.5192	
ADA result											0.3711
Negative	206	5.53 (1.19)	202	4.36 (1.20)	1.17 (1.46)	(-1.71, 4.04)	0.4254	0.07 (0.10)	(-0.13, 0.26)	0.4901	
Positive (At any time)	19	-1.12 (8.23)	22	3.39 (8.33)	-4.50 (6.17)	(-17.24, 8.23)	0.4723	-0.12 (0.31)	(-0.73, 0.50)	0.7080	
BMI (kg/m2) at enrolment											0.6332
< 30	147	4.66 (1.45)	159	4.09 (1.44)	0.57 (1.63)	(-2.64, 3.79)	0.7270	0.03 (0.11)	(-0.19, 0.26)	0.7806	
>= 30	78	6.65 (2.02)	65	4.57 (2.07)	2.07 (2.69)	(-3.26, 7.40)	0.4427	0.12 (0.17)	(-0.21, 0.45)	0.4796	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

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Repeated measures model analysis - Lupus QoL Body Image domain score
Full analysis set

	Anifrolumab 300mg (N=246)		Placebo (N=246)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 12		7.28 (1.50)		2.72 (1.53)	4.57 (1.89)	(0.84, 8.29)	0.0164				
Week 24		9.77 (1.68)		6.10 (1.70)	3.67 (2.15)	(-0.56, 7.89)	0.0889				
Week 36		11.54 (1.70)		9.43 (1.72)	2.11 (2.18)	(-2.18, 6.40)	0.3344				
Week 52		9.50 (1.83)		8.62 (1.83)	0.88 (2.37)	(-3.79, 5.55)	0.7115				
OVERALL	209	9.52 (1.41)	207	6.72 (1.42)	2.81 (1.72)	(-0.57, 6.18)	0.1034	0.14 (0.10)	(-0.06, 0.33)	0.1620	0.6480

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p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
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Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) N	LSMean (SE)	Placebo (N=246) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.6451
< 10 points	67	7.08 (2.01)	60	5.67 (2.12)	1.40 (2.66)	(-3.86, 6.67)	0.5991	0.08 (0.18)	(-0.26, 0.43)	0.6331	
>= 10 points	142	10.83 (1.80)	147	7.85 (1.77)	2.99 (2.18)	(-1.30, 7.28)	0.1717	0.14 (0.12)	(-0.09, 0.37)	0.2393	
OCS dose at baseline											0.4033
<10 mg/day	101	7.77 (1.68)	95	6.39 (1.79)	1.38 (2.25)	(-3.06, 5.83)	0.5403	0.08 (0.14)	(-0.20, 0.36)	0.5745	
>=10 mg/day	108	10.59 (2.39)	112	6.35 (2.29)	4.24 (2.58)	(-0.84, 9.32)	0.1011	0.17 (0.14)	(-0.09, 0.44)	0.2020	
Result of type I IFN gene signature test											0.1176
LOW	40	5.05 (2.68)	41	7.94 (2.63)	-2.89 (3.67)	(-10.21, 4.43)	0.4336	-0.17 (0.22)	(-0.61, 0.27)	0.4467	
HIGH	169	10.88 (1.43)	166	7.27 (1.46)	3.61 (1.95)	(-0.22, 7.44)	0.0646	0.19 (0.11)	(-0.02, 0.41)	0.0790	
Age (years)											NE
<= 65	204	9.78 (1.44)	206	6.86 (1.44)	2.92 (1.74)	(-0.50, 6.33)	0.0943	0.14 (0.10)	(-0.05, 0.33)	0.1541	
> 65	5	NE	1	NE	NE	NE		NE	NE		
Sex											0.0705
male	20	15.93 (3.39)	19	5.35 (3.97)	10.58 (4.18)	(2.04, 19.13)	0.0169	0.64 (0.33)	(-0.01, 1.28)	0.0525	
female	189	9.15 (1.49)	188	6.82 (1.49)	2.34 (1.82)	(-1.25, 5.92)	0.2011	0.11 (0.10)	(-0.09, 0.32)	0.2680	
Race											0.6220
White	138	9.64 (1.65)	145	5.64 (1.65)	4.00 (2.06)	(-0.06, 8.06)	0.0532	0.20 (0.12)	(-0.03, 0.44)	0.0883	
Black	27	9.92 (4.50)	28	11.54 (4.36)	-1.63 (5.41)	(-12.50, 9.24)	0.7649	-0.07 (0.27)	(-0.60, 0.46)	0.7983	
Other	39	7.04 (4.50)	32	3.49 (5.09)	3.56 (4.32)	(-5.08, 12.19)	0.4138	0.12 (0.24)	(-0.34, 0.59)	0.6044	
Ethnicity											0.5862
Hispanic/Latino	44	8.22 (2.81)	51	7.48 (2.94)	0.74 (3.46)	(-6.15, 7.62)	0.8313	0.04 (0.21)	(-0.37, 0.44)	0.8580	
Non-hispanic/Latino	160	9.52 (1.67)	154	6.60 (1.67)	2.93 (2.03)	(-1.08, 6.93)	0.1512	0.14 (0.11)	(-0.08, 0.36)	0.2165	
Geographic region											0.2690
EU	78	14.04 (2.51)	73	8.64 (2.57)	5.40 (2.77)	(-0.08, 10.87)	0.0534	0.24 (0.16)	(-0.08, 0.56)	0.1367	
non-EU	131	7.01 (1.66)	134	5.47 (1.70)	1.55 (2.11)	(-2.61, 5.70)	0.4638	0.08 (0.12)	(-0.16, 0.32)	0.5167	
Onset of disease											0.9793
Paediatric	14	2.96 (8.25)	10	0.54 (8.92)	2.42 (11.10)	(-20.92, 25.76)	0.8299	0.08 (0.41)	(-0.73, 0.89)	0.8500	
Adult	195	9.81 (1.40)	197	7.10 (1.41)	2.71 (1.72)	(-0.66, 6.08)	0.1150	0.14 (0.10)	(-0.06, 0.34)	0.1753	
ADA result											0.3867
Negative	193	9.80 (1.46)	186	6.52 (1.49)	3.28 (1.81)	(-0.28, 6.84)	0.0706	0.16 (0.10)	(-0.04, 0.36)	0.1166	
Positive (At any time)	16	-1.25 (8.54)	21	1.05 (8.00)	-2.30 (6.18)	(-15.04, 10.45)	0.7137	-0.06 (0.33)	(-0.71, 0.59)	0.8494	
BMI (kg/m2) at enrolment											0.6601
< 30	135	9.93 (1.84)	147	6.40 (1.80)	3.53 (2.10)	(-0.61, 7.67)	0.0940	0.16 (0.12)	(-0.07, 0.40)	0.1731	
>= 30	74	9.23 (2.27)	60	7.33 (2.41)	1.90 (3.05)	(-4.14, 7.94)	0.5338	0.10 (0.17)	(-0.24, 0.44)	0.5699	

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p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

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Full analysis set

	Anifrolumab 300mg (N=246)		Placebo (N=246)		Difference of						
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 12		10.40 (1.62)		4.41 (1.63)	5.98 (2.05)	(1.95, 10.01)	0.0037				
Week 24		10.45 (1.72)		7.11 (1.72)	3.34 (2.18)	(-0.94, 7.62)	0.1256				
Week 36		12.85 (1.74)		11.90 (1.77)	0.95 (2.23)	(-3.44, 5.34)	0.6707				
Week 52		9.38 (1.91)		8.53 (1.93)	0.85 (2.49)	(-4.05, 5.74)	0.7345				
OVERALL	225	10.77 (1.47)	224	7.99 (1.47)	2.78 (1.79)	(-0.73, 6.29)	0.1204	0.13 (0.09)	(-0.06, 0.31)	0.1828	0.0451

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
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p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

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Subgroup Level	Anifrolumab 300mg (N=246) N	LSMean (SE)	Placebo (N=246) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.5396
< 10 points	71	9.81 (2.10)	65	5.57 (2.16)	4.24 (2.78)	(-1.26, 9.73)	0.1297	0.24 (0.17)	(-0.10, 0.58)	0.1638	
>= 10 points	154	11.24 (1.90)	159	9.20 (1.87)	2.04 (2.26)	(-2.42, 6.49)	0.3686	0.09 (0.11)	(-0.14, 0.31)	0.4467	
OCS dose at baseline											0.7158
<10 mg/day	108	9.31 (1.72)	104	7.23 (1.80)	2.08 (2.29)	(-2.43, 6.59)	0.3648	0.11 (0.14)	(-0.16, 0.38)	0.4054	
>=10 mg/day	117	12.21 (2.53)	120	8.84 (2.41)	3.37 (2.71)	(-1.98, 8.72)	0.2154	0.12 (0.13)	(-0.13, 0.38)	0.3366	
Result of type I IFN gene signature test											0.3703
LOW	42	12.01 (2.83)	45	12.39 (2.66)	-0.38 (3.80)	(-7.96, 7.20)	0.9206	-0.02 (0.21)	(-0.44, 0.40)	0.9227	
HIGH	183	9.13 (1.48)	179	5.66 (1.51)	3.47 (2.01)	(-0.47, 7.42)	0.0844	0.17 (0.11)	(-0.03, 0.38)	0.1026	
Age (years)											NE
<= 65	219	10.55 (1.50)	223	8.00 (1.49)	2.54 (1.81)	(-1.01, 6.09)	0.1601	0.11 (0.10)	(-0.07, 0.30)	0.2315	
> 65	6	NE	1	NE	NE	NE		NE	NE		
Sex											0.4807
male	22	18.89 (4.13)	20	19.52 (4.88)	-0.62 (4.87)	(-10.49, 9.24)	0.8986	-0.03 (0.31)	(-0.64, 0.58)	0.9231	
female	203	10.22 (1.55)	204	7.16 (1.53)	3.06 (1.89)	(-0.65, 6.77)	0.1061	0.14 (0.10)	(-0.06, 0.33)	0.1614	
Race											0.5322
White	147	10.87 (1.81)	158	8.82 (1.77)	2.06 (2.22)	(-2.32, 6.43)	0.3555	0.09 (0.11)	(-0.13, 0.32)	0.4177	
Black	29	15.38 (4.72)	30	11.34 (4.46)	4.04 (5.59)	(-7.17, 15.25)	0.4728	0.16 (0.26)	(-0.35, 0.67)	0.5396	
Other	43	4.76 (4.35)	34	-2.59 (5.03)	7.35 (4.20)	(-1.02, 15.72)	0.0844	0.25 (0.23)	(-0.20, 0.70)	0.2745	
Ethnicity											0.2490
Hispanic/Latino	47	11.91 (3.43)	55	13.46 (3.42)	-1.55 (4.20)	(-9.88, 6.78)	0.7129	-0.06 (0.20)	(-0.45, 0.33)	0.7523	
Non-hispanic/Latino	172	10.58 (1.69)	167	6.76 (1.67)	3.82 (2.02)	(-0.16, 7.81)	0.0598	0.17 (0.11)	(-0.04, 0.39)	0.1092	
Geographic region											0.3154
EU	84	10.91 (2.39)	81	10.18 (2.43)	0.73 (2.74)	(-4.67, 6.14)	0.7895	0.03 (0.16)	(-0.27, 0.34)	0.8309	
non-EU	141	10.47 (1.80)	143	6.18 (1.83)	4.29 (2.26)	(-0.16, 8.74)	0.0585	0.20 (0.12)	(-0.04, 0.43)	0.0959	
Onset of disease											0.7500
Paediatric	14	14.11 (7.69)	10	8.47 (7.43)	5.63 (8.46)	(-12.16, 23.43)	0.5140	0.20 (0.42)	(-0.61, 1.02)	0.6243	
Adult	211	10.90 (1.51)	214	8.02 (1.51)	2.88 (1.84)	(-0.73, 6.48)	0.1178	0.13 (0.10)	(-0.06, 0.32)	0.1785	
ADA result											0.9468
Negative	206	10.96 (1.54)	202	8.27 (1.55)	2.68 (1.90)	(-1.05, 6.42)	0.1588	0.12 (0.10)	(-0.07, 0.32)	0.2210	
Positive (At any time)	19	6.41 (7.13)	22	3.34 (6.76)	3.07 (5.49)	(-8.11, 14.25)	0.5798	0.10 (0.31)	(-0.52, 0.71)	0.7597	
BMI (kg/m2) at enrolment											0.8696
< 30	147	8.73 (1.93)	159	5.57 (1.91)	3.16 (2.18)	(-1.12, 7.45)	0.1474	0.13 (0.11)	(-0.09, 0.36)	0.2460	
>= 30	78	14.00 (2.35)	65	11.46 (2.39)	2.54 (3.12)	(-3.63, 8.71)	0.4171	0.13 (0.17)	(-0.20, 0.46)	0.4546	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Lupus QoL Fatigue domain score
Full analysis set

	Anifrolumab 300mg (N=246)		Placebo (N=246)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 12		7.25 (1.44)		5.19 (1.45)	2.06 (1.80)	(-1.48, 5.59)	0.2539				
Week 24		9.76 (1.44)		7.80 (1.44)	1.96 (1.80)	(-1.57, 5.49)	0.2766				
Week 36		8.60 (1.55)		8.31 (1.57)	0.29 (1.98)	(-3.60, 4.18)	0.8831				
Week 52		9.03 (1.67)		7.88 (1.68)	1.14 (2.16)	(-3.11, 5.39)	0.5973				
OVERALL	225	8.66 (1.32)	224	7.30 (1.32)	1.36 (1.60)	(-1.78, 4.50)	0.3942	0.07 (0.09)	(-0.12, 0.25)	0.4668	0.9843

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Lupus QoL Fatigue domain score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) N	LSMean (SE)	Placebo (N=246) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.7528
< 10 points	71	7.89 (2.12)	65	7.37 (2.19)	0.52 (2.80)	(-5.03, 6.07)	0.8529	0.03 (0.17)	(-0.31, 0.37)	0.8653	
>= 10 points	154	8.87 (1.64)	159	7.27 (1.61)	1.60 (1.95)	(-2.24, 5.43)	0.4134	0.08 (0.11)	(-0.14, 0.30)	0.4898	
OCS dose at baseline											0.5365
<10 mg/day	108	9.34 (1.57)	104	7.03 (1.64)	2.31 (2.08)	(-1.79, 6.42)	0.2681	0.14 (0.14)	(-0.13, 0.41)	0.3106	
>=10 mg/day	117	6.95 (2.25)	120	6.61 (2.14)	0.35 (2.40)	(-4.38, 5.08)	0.8846	0.01 (0.13)	(-0.24, 0.27)	0.9110	
Result of type I IFN gene signature test											0.2627
LOW	42	6.67 (2.91)	45	9.29 (2.72)	-2.62 (3.92)	(-10.42, 5.18)	0.5051	-0.14 (0.21)	(-0.56, 0.28)	0.5143	
HIGH	183	9.91 (1.30)	179	7.72 (1.33)	2.18 (1.75)	(-1.27, 5.63)	0.2138	0.12 (0.11)	(-0.08, 0.33)	0.2405	
Age (years)											NE
<= 65	219	8.87 (1.34)	223	7.47 (1.33)	1.40 (1.60)	(-1.76, 4.55)	0.3845	0.07 (0.10)	(-0.12, 0.26)	0.4605	
> 65	6	NE	1	NE	NE	NE		NE	NE		
Sex											0.8127
male	22	8.75 (4.11)	20	6.46 (4.90)	2.30 (4.67)	(-7.17, 11.77)	0.6252	0.11 (0.31)	(-0.50, 0.72)	0.7227	
female	203	8.65 (1.40)	204	7.53 (1.39)	1.12 (1.71)	(-2.23, 4.48)	0.5110	0.06 (0.10)	(-0.14, 0.25)	0.5705	
Race											0.4118
White	147	9.33 (1.62)	158	8.22 (1.58)	1.12 (1.99)	(-2.79, 5.02)	0.5745	0.06 (0.11)	(-0.17, 0.28)	0.6232	
Black	29	9.77 (4.49)	30	9.08 (4.27)	0.70 (5.25)	(-9.85, 11.25)	0.8946	0.03 (0.26)	(-0.48, 0.54)	0.9113	
Other	43	3.17 (3.59)	34	-3.03 (4.08)	6.20 (3.39)	(-0.56, 12.96)	0.0714	0.26 (0.23)	(-0.19, 0.71)	0.2600	
Ethnicity											0.6828
Hispanic/Latino	47	11.45 (2.85)	55	8.97 (2.93)	2.48 (3.51)	(-4.48, 9.45)	0.4805	0.12 (0.20)	(-0.27, 0.51)	0.5502	
Non-hispanic/Latino	172	7.47 (1.54)	167	6.60 (1.52)	0.86 (1.85)	(-2.77, 4.50)	0.6396	0.04 (0.11)	(-0.17, 0.26)	0.6903	
Geographic region											0.3779
EU	84	10.87 (2.11)	81	10.81 (2.13)	0.06 (2.34)	(-4.56, 4.68)	0.9795	0.00 (0.16)	(-0.30, 0.31)	0.9841	
non-EU	141	7.52 (1.62)	143	4.72 (1.66)	2.80 (2.04)	(-1.22, 6.81)	0.1719	0.14 (0.12)	(-0.09, 0.38)	0.2297	
Onset of disease											0.2284
Paediatric	14	12.25 (7.36)	10	0.79 (7.05)	11.46 (8.28)	(-5.92, 28.84)	0.1832	0.43 (0.42)	(-0.39, 1.26)	0.3014	
Adult	211	8.89 (1.35)	214	7.60 (1.35)	1.29 (1.63)	(-1.92, 4.50)	0.4302	0.07 (0.10)	(-0.12, 0.26)	0.4994	
ADA result											0.7104
Negative	206	8.34 (1.36)	202	7.26 (1.37)	1.08 (1.67)	(-2.21, 4.37)	0.5205	0.06 (0.10)	(-0.14, 0.25)	0.5778	
Positive (At any time)	19	10.36 (8.88)	22	6.96 (8.29)	3.39 (6.01)	(-8.84, 15.63)	0.5762	0.09 (0.31)	(-0.53, 0.70)	0.7843	
BMI (kg/m2) at enrolment											0.6606
< 30	147	8.37 (1.56)	159	6.22 (1.54)	2.15 (1.76)	(-1.32, 5.61)	0.2234	0.11 (0.11)	(-0.11, 0.34)	0.3303	
>= 30	78	9.38 (2.55)	65	8.92 (2.64)	0.47 (3.40)	(-6.26, 7.19)	0.8909	0.02 (0.17)	(-0.31, 0.35)	0.8996	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Lupus QoL Intimate Relationships domain score
Full analysis set

	Anifrolumab 300mg (N=246)		Placebo (N=246)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 12		6.07 (2.03)		3.71 (2.08)	2.36 (2.66)	(-2.88, 7.59)	0.3770				
Week 24		5.01 (2.18)		4.57 (2.22)	0.44 (2.87)	(-5.20, 6.09)	0.8777				
Week 36		4.90 (2.30)		7.64 (2.35)	-2.75 (3.06)	(-8.77, 3.27)	0.3698				
Week 52		4.54 (2.21)		5.45 (2.20)	-0.90 (2.85)	(-6.52, 4.71)	0.7515				
OVERALL	180	5.13 (1.77)	180	5.34 (1.78)	-0.21 (2.20)	(-4.53, 4.11)	0.9227	-0.01 (0.11)	(-0.22, 0.20)	0.9323	0.5243

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Lupus QoL Intimate Relationships domain score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) N	LSMean (SE)	Placebo (N=246) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.9899
< 10 points	56	3.02 (3.22)	53	3.11 (3.23)	-0.09 (4.27)	(-8.58, 8.39)	0.9830	-0.00 (0.19)	(-0.38, 0.37)	0.9841	
>= 10 points	124	6.78 (2.08)	127	6.80 (2.09)	-0.03 (2.58)	(-5.11, 5.05)	0.9913	-0.00 (0.13)	(-0.25, 0.25)	0.9924	
OCS dose at baseline											0.5697
<10 mg/day	87	4.66 (2.25)	79	6.21 (2.39)	-1.55 (3.09)	(-7.65, 4.55)	0.6167	-0.07 (0.16)	(-0.38, 0.23)	0.6386	
>=10 mg/day	93	4.23 (2.91)	101	3.27 (2.78)	0.96 (3.15)	(-5.26, 7.18)	0.7612	0.03 (0.14)	(-0.25, 0.32)	0.8122	
Result of type I IFN gene signature test											0.2965
LOW	38	0.21 (3.76)	39	5.21 (3.51)	-5.00 (4.98)	(-14.95, 4.95)	0.3193	-0.22 (0.23)	(-0.67, 0.23)	0.3368	
HIGH	142	6.86 (1.82)	141	6.06 (1.85)	0.80 (2.46)	(-4.04, 5.64)	0.7450	0.04 (0.12)	(-0.20, 0.27)	0.7584	
Age (years)											NE
<= 65	178	4.90 (1.79)	180	5.28 (1.78)	-0.38 (2.21)	(-4.72, 3.95)	0.8619	-0.02 (0.11)	(-0.22, 0.19)	0.8792	
> 65	2	NE	0	NE	NE	NE		NE	NE		
Sex											0.7087
male	17	10.07 (3.34)	17	8.81 (3.98)	1.26 (3.97)	(-6.88, 9.40)	0.7537	0.08 (0.34)	(-0.59, 0.75)	0.8130	
female	163	5.06 (1.91)	163	5.54 (1.90)	-0.47 (2.38)	(-5.16, 4.22)	0.8431	-0.02 (0.11)	(-0.24, 0.20)	0.8615	
Race											0.6739
White	125	7.02 (2.06)	131	6.39 (2.04)	0.64 (2.56)	(-4.40, 5.67)	0.8035	0.03 (0.13)	(-0.22, 0.27)	0.8265	
Black	24	4.87 (5.55)	25	7.83 (5.27)	-2.96 (6.89)	(-16.86, 10.94)	0.6699	-0.11 (0.29)	(-0.67, 0.45)	0.7035	
Other	26	-3.51 (6.00)	23	-8.76 (6.83)	5.25 (6.37)	(-7.68, 18.18)	0.4154	0.16 (0.29)	(-0.40, 0.73)	0.5689	
Ethnicity											0.2696
Hispanic/Latino	38	0.50 (3.73)	40	5.47 (3.90)	-4.97 (4.60)	(-14.15, 4.20)	0.2832	-0.21 (0.23)	(-0.65, 0.24)	0.3636	
Non-hispanic/Latino	137	6.38 (2.09)	139	5.54 (2.04)	0.84 (2.57)	(-4.22, 5.90)	0.7441	0.03 (0.12)	(-0.20, 0.27)	0.7740	
Geographic region											0.6375
EU	68	10.90 (2.93)	66	12.36 (3.10)	-1.46 (3.43)	(-8.25, 5.33)	0.6710	-0.06 (0.17)	(-0.40, 0.28)	0.7339	
non-EU	112	2.73 (2.16)	114	2.12 (2.18)	0.61 (2.76)	(-4.82, 6.05)	0.8243	0.03 (0.13)	(-0.23, 0.29)	0.8422	
Onset of disease											0.2217
Paediatric	10	-3.29 (9.33)	6	8.73 (10.11)	-12.02 (9.63)	(-34.80, 10.75)	0.2521	-0.41 (0.52)	(-1.43, 0.62)	0.4359	
Adult	170	5.04 (1.82)	174	4.96 (1.82)	0.07 (2.26)	(-4.38, 4.53)	0.9751	0.00 (0.11)	(-0.21, 0.21)	0.9782	
ADA result											0.8542
Negative	166	5.32 (1.85)	166	5.61 (1.86)	-0.29 (2.32)	(-4.85, 4.27)	0.9012	-0.01 (0.11)	(-0.23, 0.20)	0.9127	
Positive (At any time)	14	-8.69 (8.85)	14	-7.06 (8.40)	-1.63 (6.90)	(-16.04, 12.79)	0.8162	-0.05 (0.38)	(-0.79, 0.69)	0.8971	
BMI (kg/m2) at enrolment											0.1421
< 30	114	2.25 (2.22)	124	4.28 (2.16)	-2.04 (2.60)	(-7.17, 3.10)	0.4352	-0.09 (0.13)	(-0.34, 0.17)	0.5120	
>= 30	66	10.82 (3.03)	56	5.79 (3.20)	5.04 (4.05)	(-3.00, 13.07)	0.2167	0.21 (0.18)	(-0.15, 0.56)	0.2580	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Lupus QoL Pain domain score
Full analysis set

	Anifrolumab 300mg (N=246)		Placebo (N=246)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 12		12.07 (1.54)		9.15 (1.56)	2.92 (1.94)	(-0.90, 6.74)	0.1339				
Week 24		12.92 (1.59)		10.83 (1.59)	2.09 (2.00)	(-1.84, 6.02)	0.2969				
Week 36		13.31 (1.60)		13.69 (1.63)	-0.38 (2.04)	(-4.39, 3.62)	0.8505				
Week 52		11.18 (1.66)		11.98 (1.68)	-0.80 (2.13)	(-4.99, 3.39)	0.7063				
OVERALL	225	12.37 (1.37)	224	11.41 (1.38)	0.96 (1.66)	(-2.30, 4.21)	0.5642	0.05 (0.09)	(-0.14, 0.23)	0.6238	0.4722

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Lupus QoL Pain domain score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=246)		Placebo (N=246)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											0.5647
< 10 points	71	11.90 (2.23)	65	9.56 (2.30)	2.34 (2.95)	(-3.49, 8.18)	0.4281	0.12 (0.17)	(-0.21, 0.46)	0.4681	
>= 10 points	154	12.85 (1.69)	159	12.55 (1.68)	0.29 (2.00)	(-3.64, 4.23)	0.8839	0.01 (0.11)	(-0.21, 0.24)	0.9025	
OCS dose at baseline											0.9088
<10 mg/day	108	12.66 (1.70)	104	11.96 (1.79)	0.70 (2.25)	(-3.75, 5.14)	0.7573	0.04 (0.14)	(-0.23, 0.31)	0.7787	
>=10 mg/day	117	11.17 (2.26)	120	10.09 (2.17)	1.08 (2.43)	(-3.72, 5.87)	0.6585	0.04 (0.13)	(-0.21, 0.30)	0.7323	
Result of type I IFN gene signature test											0.4445
LOW	42	15.36 (2.63)	45	17.05 (2.43)	-1.69 (3.50)	(-8.67, 5.28)	0.6299	-0.10 (0.21)	(-0.52, 0.32)	0.6387	
HIGH	183	11.24 (1.38)	179	9.90 (1.41)	1.34 (1.87)	(-2.33, 5.01)	0.4736	0.07 (0.11)	(-0.13, 0.28)	0.4983	
Age (years)											NE
<= 65	219	12.78 (1.40)	223	11.61 (1.40)	1.17 (1.67)	(-2.11, 4.45)	0.4830	0.06 (0.10)	(-0.13, 0.24)	0.5535	
> 65	6	NE	1	NE	NE	NE		NE	NE		
Sex											0.9103
male	22	9.61 (4.19)	20	8.23 (5.08)	1.39 (4.72)	(-8.19, 10.96)	0.7709	0.06 (0.31)	(-0.54, 0.67)	0.8354	
female	203	12.67 (1.45)	204	11.85 (1.45)	0.82 (1.77)	(-2.66, 4.29)	0.6442	0.04 (0.10)	(-0.15, 0.23)	0.6913	
Race											0.1482
White	147	11.41 (1.67)	158	12.07 (1.64)	-0.66 (2.04)	(-4.67, 3.35)	0.7453	-0.03 (0.11)	(-0.26, 0.19)	0.7775	
Black	29	19.58 (4.28)	30	16.06 (4.19)	3.53 (5.18)	(-6.87, 13.92)	0.4992	0.15 (0.26)	(-0.36, 0.66)	0.5619	
Other	43	9.72 (3.86)	34	2.32 (4.63)	7.40 (3.71)	(0.01, 14.80)	0.0497	0.28 (0.23)	(-0.17, 0.73)	0.2228	
Ethnicity											0.5575
Hispanic/Latino	47	13.20 (2.93)	55	14.83 (3.03)	-1.62 (3.75)	(-9.06, 5.82)	0.6660	-0.08 (0.20)	(-0.46, 0.31)	0.7048	
Non-hispanic/Latino	172	11.24 (1.60)	167	10.39 (1.58)	0.84 (1.91)	(-2.91, 4.59)	0.6585	0.04 (0.11)	(-0.17, 0.25)	0.7086	
Geographic region											0.4613
EU	84	12.63 (2.14)	81	13.59 (2.16)	-0.97 (2.36)	(-5.64, 3.70)	0.6826	-0.05 (0.16)	(-0.35, 0.26)	0.7515	
non-EU	141	11.73 (1.65)	143	10.37 (1.72)	1.36 (2.09)	(-2.77, 5.48)	0.5173	0.07 (0.12)	(-0.17, 0.30)	0.5693	
Onset of disease											0.6223
Paediatric	14	3.07 (7.34)	10	6.14 (7.05)	-3.06 (8.43)	(-20.79, 14.66)	0.7206	-0.12 (0.41)	(-0.93, 0.70)	0.7793	
Adult	211	12.59 (1.41)	214	11.41 (1.42)	1.17 (1.70)	(-2.18, 4.53)	0.4911	0.06 (0.10)	(-0.13, 0.25)	0.5574	
ADA result											0.5084
Negative	206	12.12 (1.41)	202	11.65 (1.43)	0.48 (1.73)	(-2.93, 3.88)	0.7827	0.02 (0.10)	(-0.17, 0.22)	0.8119	
Positive (At any time)	19	17.80 (9.12)	22	13.02 (8.55)	4.79 (6.28)	(-8.03, 17.60)	0.4518	0.12 (0.31)	(-0.50, 0.73)	0.7077	
BMI (kg/m2) at enrolment											0.9024
< 30	147	11.51 (1.67)	159	10.21 (1.66)	1.30 (1.87)	(-2.37, 4.98)	0.4861	0.06 (0.11)	(-0.16, 0.29)	0.5817	
>= 30	78	14.34 (2.52)	65	13.51 (2.60)	0.83 (3.38)	(-5.86, 7.52)	0.8070	0.04 (0.17)	(-0.29, 0.37)	0.8212	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Lupus QoL Planning domain score
Full analysis set

	Anifrolumab 300mg (N=246)		Placebo (N=246)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 12		7.13 (1.61)		3.94 (1.63)	3.19 (2.03)	(-0.80, 7.18)	0.1171				
Week 24		10.29 (1.63)		8.16 (1.63)	2.13 (2.03)	(-1.87, 6.13)	0.2960				
Week 36		9.41 (1.76)		9.39 (1.78)	0.01 (2.26)	(-4.44, 4.47)	0.9948				
Week 52		8.72 (1.79)		7.12 (1.81)	1.59 (2.31)	(-2.95, 6.14)	0.4914				
OVERALL	225	8.89 (1.46)	224	7.15 (1.47)	1.73 (1.78)	(-1.76, 5.22)	0.3302	0.08 (0.09)	(-0.11, 0.26)	0.4046	0.8109

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - Lupus QoL Planning domain score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) N	LSMean (SE)	Placebo (N=246) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.7604
< 10 points	71	7.37 (2.38)	65	6.63 (2.47)	0.74 (3.16)	(-5.51, 6.99)	0.8159	0.04 (0.17)	(-0.30, 0.37)	0.8309	
>= 10 points	154	9.23 (1.80)	159	7.33 (1.77)	1.90 (2.14)	(-2.32, 6.12)	0.3761	0.08 (0.11)	(-0.14, 0.31)	0.4528	
OCS dose at baseline											0.6120
<10 mg/day	108	8.80 (1.84)	104	5.81 (1.93)	2.99 (2.44)	(-1.82, 7.80)	0.2223	0.15 (0.14)	(-0.12, 0.42)	0.2637	
>=10 mg/day	117	8.66 (2.40)	120	7.47 (2.30)	1.19 (2.58)	(-3.89, 6.27)	0.6453	0.05 (0.13)	(-0.21, 0.30)	0.7219	
Result of type I IFN gene signature test											0.1028
LOW	42	8.54 (3.10)	45	12.84 (2.89)	-4.31 (4.15)	(-12.58, 3.97)	0.3029	-0.22 (0.22)	(-0.64, 0.21)	0.3141	
HIGH	183	9.27 (1.45)	179	6.09 (1.48)	3.19 (1.96)	(-0.68, 7.05)	0.1058	0.16 (0.11)	(-0.05, 0.37)	0.1259	
Age (years)											NE
<= 65	219	8.81 (1.49)	223	7.18 (1.48)	1.63 (1.79)	(-1.89, 5.16)	0.3625	0.07 (0.10)	(-0.11, 0.26)	0.4387	
> 65	6	NE	1	NE	NE	NE		NE	NE		
Sex											0.4164
male	22	16.54 (5.01)	20	10.15 (5.87)	6.38 (5.74)	(-5.25, 18.02)	0.2734	0.25 (0.31)	(-0.36, 0.86)	0.4166	
female	203	8.43 (1.53)	204	6.95 (1.51)	1.48 (1.86)	(-2.18, 5.14)	0.4269	0.07 (0.10)	(-0.13, 0.26)	0.4922	
Race											0.3646
White	147	9.35 (1.81)	158	8.11 (1.77)	1.24 (2.23)	(-3.14, 5.63)	0.5774	0.06 (0.11)	(-0.17, 0.28)	0.6243	
Black	29	12.41 (4.60)	30	11.88 (4.48)	0.54 (5.47)	(-10.43, 11.50)	0.9220	0.02 (0.26)	(-0.49, 0.53)	0.9341	
Other	43	3.00 (4.22)	34	-4.46 (4.87)	7.46 (3.96)	(-0.43, 15.35)	0.0636	0.26 (0.23)	(-0.19, 0.72)	0.2525	
Ethnicity											0.8362
Hispanic/Latino	47	9.91 (3.34)	55	7.57 (3.39)	2.34 (4.17)	(-5.94, 10.62)	0.5754	0.10 (0.20)	(-0.29, 0.49)	0.6278	
Non-hispanic/Latino	172	8.17 (1.68)	167	6.79 (1.66)	1.39 (2.02)	(-2.59, 5.36)	0.4934	0.06 (0.11)	(-0.15, 0.28)	0.5588	
Geographic region											0.1614
EU	84	13.55 (2.30)	81	14.95 (2.33)	-1.40 (2.58)	(-6.49, 3.69)	0.5877	-0.07 (0.16)	(-0.37, 0.24)	0.6706	
non-EU	141	6.55 (1.79)	143	3.15 (1.84)	3.40 (2.26)	(-1.05, 7.85)	0.1337	0.16 (0.12)	(-0.08, 0.39)	0.1873	
Onset of disease											0.4394
Paediatric	14	0.47 (7.29)	10	4.95 (7.13)	-4.48 (8.39)	(-22.11, 13.14)	0.5995	-0.17 (0.41)	(-0.98, 0.64)	0.6817	
Adult	211	9.31 (1.50)	214	7.15 (1.50)	2.15 (1.82)	(-1.43, 5.74)	0.2386	0.10 (0.10)	(-0.09, 0.29)	0.3121	
ADA result											0.9871
Negative	206	9.06 (1.52)	202	7.29 (1.53)	1.77 (1.87)	(-1.91, 5.45)	0.3441	0.08 (0.10)	(-0.11, 0.28)	0.4121	
Positive (At any time)	19	5.07 (8.71)	22	3.40 (8.18)	1.66 (6.39)	(-11.34, 14.67)	0.7963	0.04 (0.31)	(-0.57, 0.66)	0.8915	
BMI (kg/m2) at enrolment											0.8354
< 30	147	8.76 (1.88)	159	6.43 (1.85)	2.33 (2.11)	(-1.82, 6.47)	0.2708	0.10 (0.11)	(-0.12, 0.32)	0.3798	
>= 30	78	9.63 (2.47)	65	8.12 (2.54)	1.51 (3.30)	(-5.02, 8.05)	0.6479	0.07 (0.17)	(-0.26, 0.40)	0.6729	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SDI Global Score
Full analysis set

	Anifrolumab 300mg (N=246)		Placebo (N=246)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 24		0.03 (0.01)		0.01 (0.01)	0.01 (0.02)	(-0.02, 0.05)	0.4082				
Week 52		0.06 (0.02)		0.04 (0.02)	0.02 (0.03)	(-0.03, 0.07)	0.5148				
OVERALL	219	0.04 (0.02)	217	0.03 (0.02)	0.02 (0.02)	(-0.02, 0.05)	0.4235	0.07 (0.10)	(-0.12, 0.25)	0.4841	0.2111

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SDI Global Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) N	LSMean (SE)	Placebo (N=246) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.0136
< 10 points	71	0.10 (0.03)	60	0.00 (0.03)	0.10 (0.04)	(0.02, 0.18)	0.0202	0.39 (0.18)	(0.04, 0.73)	0.0294	
>= 10 points	148	0.01 (0.02)	157	0.03 (0.02)	-0.02 (0.02)	(-0.06, 0.02)	0.4212	-0.08 (0.11)	(-0.30, 0.15)	0.4950	
OCS dose at baseline											0.1478
<10 mg/day	107	0.06 (0.02)	103	0.02 (0.02)	0.04 (0.03)	(-0.01, 0.10)	0.1047	0.21 (0.14)	(-0.06, 0.48)	0.1274	
>=10 mg/day	112	0.02 (0.03)	114	0.03 (0.02)	-0.01 (0.03)	(-0.07, 0.04)	0.6607	-0.05 (0.13)	(-0.31, 0.22)	0.7336	
Result of type I IFN gene signature test											NE
LOW	39	NE	39	NE	NE	NE		NE	NE		
HIGH	180	0.06 (0.02)	178	0.05 (0.02)	0.01 (0.02)	(-0.04, 0.05)	0.7111	0.04 (0.11)	(-0.17, 0.24)	0.7246	
Age (years)											NE
<= 65	215	0.05 (0.02)	214	0.03 (0.02)	0.02 (0.02)	(-0.02, 0.06)	0.2895	0.09 (0.10)	(-0.10, 0.28)	0.3555	
> 65	4	NE	3	NE	NE	NE		NE	NE		
Sex											NE
male	21	NE	20	NE	NE	NE		NE	NE		
female	198	0.05 (0.02)	197	0.03 (0.02)	0.02 (0.02)	(-0.02, 0.06)	0.2720	0.10 (0.10)	(-0.10, 0.29)	0.3334	
Race											0.7697
White	146	0.05 (0.02)	149	0.02 (0.02)	0.03 (0.02)	(-0.01, 0.07)	0.1874	0.14 (0.12)	(-0.09, 0.37)	0.2375	
Black	25	0.06 (0.06)	32	0.07 (0.05)	-0.01 (0.07)	(-0.15, 0.13)	0.8776	-0.03 (0.27)	(-0.56, 0.49)	0.8971	
Other	42	0.04 (0.06)	33	0.04 (0.06)	-0.00 (0.06)	(-0.12, 0.11)	0.9561	-0.01 (0.23)	(-0.46, 0.45)	0.9707	
Ethnicity											0.6767
Hispanic/Latino	44	0.08 (0.04)	50	0.04 (0.04)	0.04 (0.05)	(-0.06, 0.13)	0.4672	0.14 (0.21)	(-0.27, 0.54)	0.5125	
Non-hispanic/Latino	169	0.04 (0.02)	164	0.03 (0.02)	0.01 (0.02)	(-0.03, 0.06)	0.5343	0.06 (0.11)	(-0.16, 0.27)	0.5937	
Geographic region											0.3704
EU	86	0.06 (0.03)	79	0.02 (0.03)	0.04 (0.03)	(-0.02, 0.10)	0.1986	0.16 (0.16)	(-0.14, 0.47)	0.3018	
non-EU	133	0.04 (0.02)	138	0.03 (0.02)	0.00 (0.03)	(-0.05, 0.05)	0.8662	0.02 (0.12)	(-0.22, 0.26)	0.8801	
Onset of disease											NE
Paediatric	16	NE	9	NE	NE	NE		NE	NE		
Adult	203	0.04 (0.02)	208	0.03 (0.02)	0.01 (0.02)	(-0.03, 0.05)	0.5138	0.06 (0.10)	(-0.14, 0.25)	0.5678	
ADA result											NE
Negative	203	0.04 (0.02)	196	0.03 (0.02)	0.01 (0.02)	(-0.03, 0.05)	0.5871	0.05 (0.10)	(-0.15, 0.24)	0.6309	
Positive (At any time)	16	NE	21	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.2164
< 30	144	0.03 (0.02)	154	0.03 (0.02)	-0.01 (0.02)	(-0.05, 0.04)	0.7803	-0.03 (0.12)	(-0.25, 0.20)	0.8152	
>= 30	75	0.07 (0.03)	63	0.02 (0.03)	0.05 (0.04)	(-0.03, 0.13)	0.2133	0.20 (0.17)	(-0.14, 0.53)	0.2523	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - NRS Score
Full analysis set

	Anifrolumab 300mg (N=246)		Placebo (N=246)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 4		-0.42 (0.14)		-0.37 (0.14)	-0.05 (0.18)	(-0.40, 0.30)	0.7637				
Week 8		-0.88 (0.15)		-0.34 (0.15)	-0.54 (0.19)	(-0.91, -0.16)	0.0051				
Week 12		-1.08 (0.16)		-0.68 (0.16)	-0.40 (0.21)	(-0.81, 0.01)	0.0550				
Week 16		-1.05 (0.16)		-0.84 (0.16)	-0.21 (0.20)	(-0.62, 0.19)	0.2939				
Week 20		-0.95 (0.17)		-0.94 (0.17)	-0.01 (0.22)	(-0.45, 0.42)	0.9502				
Week 24		-1.03 (0.16)		-0.72 (0.16)	-0.30 (0.21)	(-0.71, 0.11)	0.1455				
Week 28		-0.99 (0.17)		-0.87 (0.17)	-0.12 (0.22)	(-0.56, 0.32)	0.5895				
Week 32		-0.84 (0.17)		-0.93 (0.17)	0.08 (0.22)	(-0.35, 0.52)	0.7060				
Week 36		-1.08 (0.17)		-1.04 (0.17)	-0.04 (0.22)	(-0.47, 0.39)	0.8508				
Week 40		-1.05 (0.17)		-1.00 (0.17)	-0.05 (0.23)	(-0.50, 0.40)	0.8306				
Week 44		-1.11 (0.17)		-1.10 (0.17)	-0.01 (0.23)	(-0.45, 0.44)	0.9688				
Week 48		-0.99 (0.18)		-0.88 (0.18)	-0.11 (0.23)	(-0.57, 0.35)	0.6441				
Week 52		-0.91 (0.17)		-0.90 (0.18)	-0.02 (0.23)	(-0.47, 0.44)	0.9468				
OVERALL	231	-0.95 (0.13)	230	-0.82 (0.13)	-0.14 (0.16)	(-0.45, 0.18)	0.3903	-0.07 (0.09)	(-0.25, 0.11)	0.4552	0.9758

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - NRS Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) N	LSMean (SE)	Placebo (N=246) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.1432
< 10 points	73	-1.14 (0.21)	67	-0.66 (0.22)	-0.48 (0.28)	(-1.04, 0.08)	0.0899	-0.27 (0.17)	(-0.60, 0.07)	0.1183	
>= 10 points	158	-0.92 (0.16)	163	-0.94 (0.16)	0.02 (0.19)	(-0.36, 0.40)	0.9224	0.01 (0.11)	(-0.21, 0.23)	0.9329	
OCS dose at baseline											0.1000
<10 mg/day	109	-1.10 (0.16)	107	-0.69 (0.17)	-0.41 (0.21)	(-0.83, 0.01)	0.0560	-0.24 (0.14)	(-0.51, 0.03)	0.0788	
>=10 mg/day	122	-0.79 (0.21)	123	-0.90 (0.20)	0.11 (0.24)	(-0.35, 0.58)	0.6347	0.05 (0.13)	(-0.20, 0.30)	0.7057	
Result of type I IFN gene signature test											0.0557
LOW	42	-0.69 (0.25)	45	-1.17 (0.23)	0.48 (0.34)	(-0.19, 1.14)	0.1590	0.30 (0.22)	(-0.13, 0.72)	0.1678	
HIGH	189	-1.16 (0.13)	185	-0.91 (0.14)	-0.25 (0.18)	(-0.61, 0.10)	0.1644	-0.14 (0.10)	(-0.34, 0.07)	0.1854	
Age (years)											NE
<= 65	225	-0.98 (0.13)	229	-0.81 (0.13)	-0.17 (0.16)	(-0.48, 0.15)	0.2990	-0.08 (0.09)	(-0.27, 0.10)	0.3696	
> 65	6	NE	1	NE	NE	NE		NE	NE		
Sex											0.5693
male	22	-0.95 (0.40)	20	-1.05 (0.47)	0.11 (0.43)	(-0.77, 0.99)	0.8057	0.05 (0.31)	(-0.55, 0.66)	0.8631	
female	209	-0.99 (0.14)	210	-0.83 (0.14)	-0.16 (0.17)	(-0.49, 0.18)	0.3564	-0.08 (0.10)	(-0.27, 0.11)	0.4182	
Race											0.7453
White	150	-1.00 (0.16)	162	-0.93 (0.15)	-0.06 (0.20)	(-0.45, 0.32)	0.7423	-0.03 (0.11)	(-0.26, 0.19)	0.7707	
Black	31	-1.37 (0.35)	30	-0.94 (0.34)	-0.44 (0.45)	(-1.33, 0.46)	0.3326	-0.23 (0.26)	(-0.73, 0.28)	0.3811	
Other	44	-0.14 (0.42)	36	0.02 (0.49)	-0.16 (0.40)	(-0.95, 0.63)	0.6867	-0.06 (0.22)	(-0.50, 0.39)	0.8052	
Ethnicity											0.0613
Hispanic/Latino	49	-1.48 (0.26)	55	-0.87 (0.27)	-0.62 (0.32)	(-1.26, 0.02)	0.0588	-0.32 (0.20)	(-0.70, 0.07)	0.1100	
Non-hispanic/Latino	176	-0.77 (0.15)	173	-0.85 (0.15)	0.08 (0.18)	(-0.28, 0.44)	0.6741	0.04 (0.11)	(-0.17, 0.25)	0.7134	
Geographic region											0.0177
EU	85	-0.96 (0.24)	84	-1.29 (0.24)	0.33 (0.27)	(-0.20, 0.86)	0.2186	0.15 (0.15)	(-0.15, 0.45)	0.3325	
non-EU	146	-0.98 (0.15)	146	-0.53 (0.15)	-0.45 (0.19)	(-0.82, -0.07)	0.0190	-0.25 (0.12)	(-0.48, -0.02)	0.0365	
Onset of disease											0.1232
Paediatric	15	-1.81 (0.84)	10	-0.35 (0.81)	-1.46 (0.88)	(-3.41, 0.49)	0.1270	-0.47 (0.41)	(-1.28, 0.34)	0.2556	
Adult	216	-0.97 (0.13)	220	-0.89 (0.13)	-0.08 (0.16)	(-0.40, 0.24)	0.6279	-0.04 (0.10)	(-0.23, 0.15)	0.6723	
ADA result											0.1889
Negative	212	-0.88 (0.13)	208	-0.81 (0.13)	-0.07 (0.17)	(-0.40, 0.25)	0.6656	-0.04 (0.10)	(-0.23, 0.15)	0.7037	
Positive (At any time)	19	-2.47 (0.75)	22	-1.57 (0.71)	-0.91 (0.61)	(-2.15, 0.34)	0.1495	-0.27 (0.31)	(-0.88, 0.35)	0.3953	
BMI (kg/m2) at enrolment											0.0743
< 30	151	-0.89 (0.17)	163	-0.93 (0.16)	0.04 (0.19)	(-0.34, 0.42)	0.8404	0.02 (0.11)	(-0.20, 0.24)	0.8697	
>= 30	80	-1.17 (0.21)	67	-0.59 (0.22)	-0.58 (0.29)	(-1.14, -0.01)	0.0461	-0.31 (0.17)	(-0.64, 0.02)	0.0622	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - PHQ-8 Total Score
Full analysis set

	Anifrolumab 300mg (N=246)		Placebo (N=246)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 12		-1.68 (0.35)		-1.13 (0.35)	-0.55 (0.44)	(-1.41, 0.32)	0.2151				
Week 24		-1.96 (0.36)		-1.76 (0.36)	-0.20 (0.45)	(-1.08, 0.68)	0.6488				
Week 36		-2.03 (0.37)		-1.73 (0.37)	-0.30 (0.47)	(-1.22, 0.62)	0.5242				
Week 52		-2.16 (0.39)		-1.60 (0.40)	-0.56 (0.51)	(-1.55, 0.43)	0.2696				
OVERALL	226	-1.96 (0.31)	224	-1.56 (0.31)	-0.40 (0.38)	(-1.14, 0.34)	0.2869	-0.09 (0.09)	(-0.27, 0.10)	0.3641	0.8162

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - PHQ-8 Total Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) N	LSMean (SE)	Placebo (N=246) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.2017
< 10 points	71	-2.26 (0.48)	65	-1.19 (0.50)	-1.08 (0.64)	(-2.34, 0.18)	0.0925	-0.27 (0.17)	(-0.60, 0.07)	0.1240	
>= 10 points	155	-1.77 (0.39)	159	-1.70 (0.39)	-0.07 (0.46)	(-0.99, 0.84)	0.8755	-0.01 (0.11)	(-0.24, 0.21)	0.8950	
OCS dose at baseline											0.8696
<10 mg/day	108	-1.98 (0.42)	104	-1.52 (0.44)	-0.46 (0.55)	(-1.55, 0.63)	0.4049	-0.10 (0.14)	(-0.37, 0.16)	0.4473	
>=10 mg/day	118	-1.75 (0.49)	120	-1.41 (0.47)	-0.34 (0.52)	(-1.37, 0.70)	0.5212	-0.06 (0.13)	(-0.32, 0.19)	0.6202	
Result of type I IFN gene signature test											0.6671
LOW	42	-2.21 (0.63)	45	-2.13 (0.59)	-0.08 (0.85)	(-1.77, 1.62)	0.9267	-0.02 (0.21)	(-0.44, 0.40)	0.9282	
HIGH	184	-1.96 (0.31)	179	-1.48 (0.32)	-0.49 (0.42)	(-1.32, 0.35)	0.2509	-0.11 (0.11)	(-0.32, 0.09)	0.2788	
Age (years)											NE
<= 65	220	-1.96 (0.32)	223	-1.54 (0.32)	-0.41 (0.38)	(-1.17, 0.34)	0.2777	-0.09 (0.10)	(-0.27, 0.10)	0.3582	
> 65	6	NE	1	NE	NE	NE		NE	NE		
Sex											0.9186
male	22	-2.36 (1.05)	20	-2.06 (1.28)	-0.30 (1.17)	(-2.67, 2.07)	0.7998	-0.06 (0.31)	(-0.66, 0.55)	0.8584	
female	204	-1.93 (0.33)	204	-1.51 (0.33)	-0.42 (0.40)	(-1.21, 0.36)	0.2885	-0.09 (0.10)	(-0.28, 0.10)	0.3606	
Race											0.1967
White	147	-1.58 (0.39)	158	-1.60 (0.38)	0.02 (0.47)	(-0.91, 0.95)	0.9611	0.00 (0.11)	(-0.22, 0.23)	0.9660	
Black	30	-4.62 (0.94)	30	-3.24 (0.91)	-1.38 (1.13)	(-3.64, 0.88)	0.2265	-0.27 (0.26)	(-0.78, 0.24)	0.2989	
Other	43	-1.06 (0.90)	34	0.42 (1.01)	-1.48 (0.82)	(-3.12, 0.16)	0.0757	-0.25 (0.23)	(-0.70, 0.20)	0.2790	
Ethnicity											0.5095
Hispanic/Latino	47	-1.43 (0.75)	55	-1.73 (0.76)	0.30 (0.93)	(-1.54, 2.14)	0.7475	0.05 (0.20)	(-0.33, 0.44)	0.7826	
Non-hispanic/Latino	173	-1.89 (0.35)	167	-1.52 (0.34)	-0.37 (0.41)	(-1.18, 0.44)	0.3714	-0.08 (0.11)	(-0.29, 0.13)	0.4490	
Geographic region											0.3360
EU	84	-2.27 (0.47)	81	-2.25 (0.48)	-0.02 (0.52)	(-1.04, 1.00)	0.9706	-0.00 (0.16)	(-0.31, 0.30)	0.9773	
non-EU	142	-1.71 (0.40)	143	-1.00 (0.41)	-0.72 (0.51)	(-1.71, 0.28)	0.1585	-0.15 (0.12)	(-0.38, 0.09)	0.2158	
Onset of disease											0.3736
Paediatric	14	-2.26 (1.77)	10	-0.12 (1.67)	-2.13 (1.96)	(-6.25, 1.98)	0.2899	-0.34 (0.42)	(-1.15, 0.48)	0.4201	
Adult	212	-1.95 (0.32)	214	-1.59 (0.32)	-0.36 (0.39)	(-1.12, 0.40)	0.3536	-0.08 (0.10)	(-0.27, 0.11)	0.4281	
ADA result											0.6065
Negative	207	-1.92 (0.33)	202	-1.49 (0.33)	-0.43 (0.40)	(-1.22, 0.36)	0.2814	-0.09 (0.10)	(-0.29, 0.10)	0.3520	
Positive (At any time)	19	-3.64 (1.64)	22	-3.82 (1.57)	0.18 (1.12)	(-2.10, 2.46)	0.8729	0.02 (0.31)	(-0.59, 0.64)	0.9379	
BMI (kg/m2) at enrolment											0.9007
< 30	148	-1.89 (0.37)	159	-1.37 (0.37)	-0.52 (0.42)	(-1.34, 0.30)	0.2123	-0.11 (0.11)	(-0.34, 0.11)	0.3211	
>= 30	78	-2.01 (0.59)	65	-1.60 (0.60)	-0.41 (0.78)	(-1.96, 1.14)	0.6003	-0.08 (0.17)	(-0.41, 0.25)	0.6288	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - PtGA
Full analysis set

Visit	Anifrolumab 300mg (N=246) N	LSMean (SE)	Placebo (N=246) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		-6.47 (1.51)		-6.12 (1.50)	-0.35 (1.92)	(-4.11, 3.42)	0.8565				
Week 8		-8.65 (1.57)		-5.42 (1.57)	-3.23 (2.02)	(-7.21, 0.75)	0.1111				
Week 12		-10.33 (1.65)		-8.21 (1.67)	-2.12 (2.17)	(-6.37, 2.14)	0.3287				
Week 16		-8.20 (1.72)		-9.87 (1.72)	1.67 (2.26)	(-2.77, 6.11)	0.4593				
Week 20		-10.68 (1.69)		-11.53 (1.68)	0.85 (2.20)	(-3.47, 5.18)	0.6980				
Week 24		-9.40 (1.78)		-7.60 (1.77)	-1.80 (2.34)	(-6.40, 2.80)	0.4427				
Week 28		-10.68 (1.78)		-11.35 (1.79)	0.67 (2.35)	(-3.95, 5.29)	0.7747				
Week 32		-8.88 (1.79)		-10.44 (1.81)	1.57 (2.37)	(-3.10, 6.23)	0.5093				
Week 36		-14.00 (1.68)		-13.45 (1.71)	-0.55 (2.22)	(-4.92, 3.81)	0.8034				
Week 40		-10.60 (1.79)		-11.03 (1.82)	0.42 (2.38)	(-4.25, 5.10)	0.8584				
Week 44		-11.62 (1.70)		-14.62 (1.73)	2.99 (2.25)	(-1.42, 7.41)	0.1835				
Week 48		-11.21 (1.82)		-9.96 (1.86)	-1.25 (2.44)	(-6.04, 3.55)	0.6097				
Week 52		-11.22 (1.91)		-9.98 (1.94)	-1.25 (2.56)	(-6.28, 3.78)	0.6265				
OVERALL	231	-10.15 (1.30)	230	-9.97 (1.30)	-0.18 (1.60)	(-3.32, 2.96)	0.9099	-0.01 (0.09)	(-0.19, 0.17)	0.9218	0.6269

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - PtGA - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) N	LSMean (SE)	Placebo (N=246) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.0877
< 10 points	73	-10.56 (2.08)	67	-6.15 (2.18)	-4.40 (2.77)	(-9.87, 1.07)	0.1139	-0.25 (0.17)	(-0.58, 0.09)	0.1473	
>= 10 points	158	-10.22 (1.61)	163	-11.59 (1.58)	1.37 (1.94)	(-2.45, 5.19)	0.4811	0.07 (0.11)	(-0.15, 0.29)	0.5445	
OCS dose at baseline											0.8578
<10 mg/day	109	-8.97 (1.65)	107	-9.27 (1.73)	0.30 (2.19)	(-4.02, 4.62)	0.8909	0.02 (0.14)	(-0.25, 0.28)	0.9000	
>=10 mg/day	122	-10.91 (2.12)	123	-10.64 (2.03)	-0.27 (2.34)	(-4.88, 4.34)	0.9070	-0.01 (0.13)	(-0.26, 0.24)	0.9260	
Result of type I IFN gene signature test											0.0131
LOW	42	-6.30 (2.51)	45	-14.12 (2.35)	7.82 (3.41)	(1.03, 14.60)	0.0245	0.48 (0.22)	(0.06, 0.91)	0.0261	
HIGH	189	-11.86 (1.33)	185	-10.10 (1.35)	-1.76 (1.80)	(-5.30, 1.79)	0.3305	-0.10 (0.10)	(-0.30, 0.11)	0.3546	
Age (years)											NE
<= 65	225	-10.32 (1.33)	229	-9.90 (1.31)	-0.42 (1.61)	(-3.59, 2.74)	0.7936	-0.02 (0.09)	(-0.21, 0.16)	0.8217	
> 65	6	NE	1	NE	NE	NE		NE	NE		
Sex											0.5001
male	22	-14.17 (3.98)	20	-17.15 (4.64)	2.98 (4.51)	(-6.17, 12.13)	0.5133	0.15 (0.31)	(-0.46, 0.75)	0.6313	
female	209	-10.06 (1.38)	210	-9.79 (1.37)	-0.27 (1.70)	(-3.61, 3.06)	0.8725	-0.01 (0.10)	(-0.21, 0.18)	0.8884	
Race											0.0774
White	150	-10.13 (1.64)	162	-12.17 (1.60)	2.05 (2.03)	(-1.95, 6.05)	0.3138	0.10 (0.11)	(-0.12, 0.32)	0.3729	
Black	31	-12.43 (3.19)	30	-4.58 (3.06)	-7.85 (3.89)	(-15.63, -0.06)	0.0484	-0.45 (0.26)	(-0.96, 0.06)	0.0843	
Other	44	-2.83 (4.13)	36	-2.10 (4.63)	-0.73 (3.93)	(-8.55, 7.10)	0.8532	-0.03 (0.22)	(-0.47, 0.41)	0.9072	
Ethnicity											0.2433
Hispanic/Latino	49	-14.46 (2.80)	55	-11.11 (2.91)	-3.35 (3.42)	(-10.14, 3.45)	0.3309	-0.16 (0.20)	(-0.55, 0.23)	0.4145	
Non-hispanic/Latino	176	-8.68 (1.51)	173	-9.87 (1.49)	1.19 (1.84)	(-2.43, 4.81)	0.5188	0.06 (0.11)	(-0.15, 0.27)	0.5765	
Geographic region											0.0072
EU	85	-11.95 (2.28)	84	-17.16 (2.31)	5.21 (2.56)	(0.14, 10.27)	0.0439	0.25 (0.15)	(-0.06, 0.55)	0.1109	
non-EU	146	-9.10 (1.54)	146	-5.67 (1.57)	-3.44 (1.94)	(-7.26, 0.39)	0.0780	-0.18 (0.12)	(-0.41, 0.05)	0.1194	
Onset of disease											NE
Paediatric	15	NE	10	NE	NE	NE		NE	NE		
Adult	216	-10.11 (1.34)	220	-10.12 (1.34)	0.01 (1.64)	(-3.22, 3.24)	0.9937	0.00 (0.10)	(-0.19, 0.19)	0.9945	
ADA result											0.3956
Negative	212	-9.85 (1.35)	208	-10.13 (1.36)	0.28 (1.68)	(-3.02, 3.59)	0.8660	0.01 (0.10)	(-0.18, 0.21)	0.8825	
Positive (At any time)	19	-23.22 (6.05)	22	-18.76 (5.63)	-4.46 (5.33)	(-15.27, 6.34)	0.4078	-0.17 (0.31)	(-0.78, 0.45)	0.5971	
BMI (kg/m2) at enrolment											0.0401
< 30	151	-9.87 (1.66)	163	-11.60 (1.64)	1.73 (1.91)	(-2.03, 5.50)	0.3654	0.08 (0.11)	(-0.14, 0.31)	0.4593	
>= 30	80	-11.30 (2.12)	67	-6.07 (2.19)	-5.23 (2.80)	(-10.77, 0.31)	0.0640	-0.28 (0.17)	(-0.61, 0.04)	0.0905	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SLEDAI-2K Total Score
Full analysis set

Visit	Anifrolumab 300mg (N=246) n/ N#	Anifrolumab 300mg (N=246) Compliance	Placebo (N=246) n/ N#	Placebo (N=246) Compliance
Baseline	246/ 246	100.0%	246/ 246	100.0%
Week 4	237/ 246	96.34%	240/ 246	97.56%
Week 8	235/ 246	95.53%	236/ 246	95.93%
Week 12	238/ 245	97.14%	226/ 246	91.87%
Week 16	227/ 245	92.65%	225/ 246	91.46%
Week 20	221/ 245	90.20%	222/ 246	90.24%
Week 24	222/ 245	90.61%	220/ 246	89.43%
Week 28	220/ 245	89.80%	211/ 246	85.77%
Week 32	215/ 245	87.76%	206/ 246	83.74%
Week 36	213/ 245	86.94%	207/ 246	84.15%
Week 40	217/ 245	88.57%	202/ 245	82.45%
Week 44	205/ 245	83.67%	202/ 245	82.45%
Week 48	208/ 245	84.90%	196/ 245	80.00%
Week 52	200/ 245	81.63%	189/ 245	77.14%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - PGA
Full analysis set

Visit	Anifrolumab 300mg (N=246) n/ N#	Anifrolumab 300mg (N=246) Compliance	Placebo (N=246) n/ N#	Placebo (N=246) Compliance
Baseline	246/ 246	100.0%	246/ 246	100.0%
Week 4	240/ 246	97.56%	244/ 246	99.19%
Week 8	236/ 246	95.93%	237/ 246	96.34%
Week 12	236/ 245	96.33%	228/ 246	92.68%
Week 16	231/ 245	94.29%	230/ 246	93.50%
Week 20	218/ 245	88.98%	225/ 246	91.46%
Week 24	223/ 245	91.02%	226/ 246	91.87%
Week 28	220/ 245	89.80%	216/ 246	87.80%
Week 32	218/ 245	88.98%	208/ 246	84.55%
Week 36	216/ 245	88.16%	205/ 246	83.33%
Week 40	218/ 245	88.98%	208/ 245	84.90%
Week 44	207/ 245	84.49%	203/ 245	82.86%
Week 48	212/ 245	86.53%	198/ 245	80.82%
Week 52	201/ 245	82.04%	191/ 245	77.96%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - CLASI Total Activity Score
Full analysis set

Visit	Anifrolumab 300mg (N=246) n/ N#	Anifrolumab 300mg (N=246) Compliance	Placebo (N=246) n/ N#	Placebo (N=246) Compliance
Baseline	246/ 246	100.0%	246/ 246	100.0%
Week 4	240/ 246	97.56%	244/ 246	99.19%
Week 8	237/ 246	96.34%	237/ 246	96.34%
Week 12	238/ 245	97.14%	230/ 246	93.50%
Week 16	232/ 245	94.69%	228/ 246	92.68%
Week 20	223/ 245	91.02%	227/ 246	92.28%
Week 24	223/ 245	91.02%	226/ 246	91.87%
Week 28	221/ 245	90.20%	217/ 246	88.21%
Week 32	218/ 245	88.98%	208/ 246	84.55%
Week 36	214/ 245	87.35%	207/ 246	84.15%
Week 40	217/ 245	88.57%	208/ 245	84.90%
Week 44	207/ 245	84.49%	205/ 245	83.67%
Week 48	212/ 245	86.53%	199/ 245	81.22%
Week 52	201/ 245	82.04%	192/ 245	78.37%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - CLASI Total Damage Score
Full analysis set

Visit	Anifrolumab 300mg (N=246) n/ N#	Anifrolumab 300mg (N=246) Compliance	Placebo (N=246) n/ N#	Placebo (N=246) Compliance
Baseline	246/ 246	100.0%	246/ 246	100.0%
Week 4	241/ 246	97.97%	243/ 246	98.78%
Week 8	237/ 246	96.34%	237/ 246	96.34%
Week 12	238/ 245	97.14%	231/ 246	93.90%
Week 16	232/ 245	94.69%	228/ 246	92.68%
Week 20	223/ 245	91.02%	227/ 246	92.28%
Week 24	223/ 245	91.02%	226/ 246	91.87%
Week 28	221/ 245	90.20%	217/ 246	88.21%
Week 32	218/ 245	88.98%	208/ 246	84.55%
Week 36	214/ 245	87.35%	207/ 246	84.15%
Week 40	217/ 245	88.57%	207/ 245	84.49%
Week 44	206/ 245	84.08%	205/ 245	83.67%
Week 48	212/ 245	86.53%	199/ 245	81.22%
Week 52	201/ 245	82.04%	192/ 245	78.37%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - BILAG Global Score
Full analysis set

Visit	Anifrolumab 300mg (N=246) n/ N#	Anifrolumab 300mg (N=246) Compliance	Placebo (N=246) n/ N#	Placebo (N=246) Compliance
Baseline	246/ 246	100.0%	246/ 246	100.0%
Week 4	239/ 246	97.15%	242/ 246	98.37%
Week 8	235/ 246	95.53%	236/ 246	95.93%
Week 12	239/ 245	97.55%	229/ 246	93.09%
Week 16	232/ 245	94.69%	226/ 246	91.87%
Week 20	223/ 245	91.02%	225/ 246	91.46%
Week 24	222/ 245	90.61%	224/ 246	91.06%
Week 28	221/ 245	90.20%	215/ 246	87.40%
Week 32	219/ 245	89.39%	207/ 246	84.15%
Week 36	214/ 245	87.35%	205/ 246	83.33%
Week 40	217/ 245	88.57%	204/ 245	83.27%
Week 44	206/ 245	84.08%	203/ 245	82.86%
Week 48	211/ 245	86.12%	197/ 245	80.41%
Week 52	201/ 245	82.04%	190/ 245	77.55%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Tender Joint Count
Full analysis set

Visit	Anifrolumab 300mg (N=246) n/ N#	Anifrolumab 300mg (N=246) Compliance	Placebo (N=246) n/ N#	Placebo (N=246) Compliance
Baseline	246/ 246	100.0%	246/ 246	100.0%
Week 4	240/ 246	97.56%	243/ 246	98.78%
Week 8	235/ 246	95.53%	237/ 246	96.34%
Week 12	238/ 245	97.14%	230/ 246	93.50%
Week 16	232/ 245	94.69%	229/ 246	93.09%
Week 20	222/ 245	90.61%	226/ 246	91.87%
Week 24	223/ 245	91.02%	225/ 246	91.46%
Week 28	220/ 245	89.80%	217/ 246	88.21%
Week 32	219/ 245	89.39%	208/ 246	84.55%
Week 36	214/ 245	87.35%	207/ 246	84.15%
Week 40	218/ 245	88.98%	207/ 245	84.49%
Week 44	207/ 245	84.49%	205/ 245	83.67%
Week 48	210/ 245	85.71%	199/ 245	81.22%
Week 52	200/ 245	81.63%	192/ 245	78.37%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Swollen Joint Count
Full analysis set

Visit	Anifrolumab 300mg (N=246) n/ N#	Anifrolumab 300mg (N=246) Compliance	Placebo (N=246) n/ N#	Placebo (N=246) Compliance
Baseline	246/ 246	100.0%	246/ 246	100.0%
Week 4	240/ 246	97.56%	243/ 246	98.78%
Week 8	235/ 246	95.53%	237/ 246	96.34%
Week 12	238/ 245	97.14%	230/ 246	93.50%
Week 16	232/ 245	94.69%	229/ 246	93.09%
Week 20	222/ 245	90.61%	226/ 246	91.87%
Week 24	223/ 245	91.02%	225/ 246	91.46%
Week 28	220/ 245	89.80%	217/ 246	88.21%
Week 32	219/ 245	89.39%	208/ 246	84.55%
Week 36	214/ 245	87.35%	207/ 246	84.15%
Week 40	218/ 245	88.98%	207/ 245	84.49%
Week 44	207/ 245	84.49%	205/ 245	83.67%
Week 48	210/ 245	85.71%	199/ 245	81.22%
Week 52	200/ 245	81.63%	192/ 245	78.37%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute Mental Component Score
Full analysis set

Visit	Anifrolumab 300mg (N=246) n/ N#	Anifrolumab 300mg (N=246) Compliance	Placebo (N=246) n/ N#	Placebo (N=246) Compliance
Baseline	236/ 246	95.93%	232/ 246	94.31%
Week 8	222/ 246	90.24%	224/ 246	91.06%
Week 16	219/ 245	89.39%	218/ 246	88.62%
Week 24	211/ 245	86.12%	214/ 246	86.99%
Week 32	205/ 245	83.67%	194/ 246	78.86%
Week 40	207/ 245	84.49%	195/ 245	79.59%
Week 48	208/ 245	84.90%	188/ 245	76.73%
Week 52	194/ 245	79.18%	181/ 245	73.88%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute Physical Component Score
Full analysis set

Visit	Anifrolumab 300mg (N=246) n/ N#	Anifrolumab 300mg (N=246) Compliance	Placebo (N=246) n/ N#	Placebo (N=246) Compliance
Baseline	236/ 246	95.93%	232/ 246	94.31%
Week 8	222/ 246	90.24%	224/ 246	91.06%
Week 16	219/ 245	89.39%	218/ 246	88.62%
Week 24	211/ 245	86.12%	214/ 246	86.99%
Week 32	205/ 245	83.67%	194/ 246	78.86%
Week 40	207/ 245	84.49%	195/ 245	79.59%
Week 48	208/ 245	84.90%	188/ 245	76.73%
Week 52	194/ 245	79.18%	181/ 245	73.88%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute General Health Score
Full analysis set

Visit	Anifrolumab 300mg (N=246) n/ N#	Anifrolumab 300mg (N=246) Compliance	Placebo (N=246) n/ N#	Placebo (N=246) Compliance
Baseline	236/ 246	95.93%	232/ 246	94.31%
Week 8	222/ 246	90.24%	224/ 246	91.06%
Week 16	219/ 245	89.39%	218/ 246	88.62%
Week 24	211/ 245	86.12%	214/ 246	86.99%
Week 32	205/ 245	83.67%	194/ 246	78.86%
Week 40	207/ 245	84.49%	195/ 245	79.59%
Week 48	208/ 245	84.90%	188/ 245	76.73%
Week 52	194/ 245	79.18%	181/ 245	73.88%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute Mental Health Score
Full analysis set

Visit	Anifrolumab 300mg (N=246) n/ N#	Anifrolumab 300mg (N=246) Compliance	Placebo (N=246) n/ N#	Placebo (N=246) Compliance
Baseline	236/ 246	95.93%	232/ 246	94.31%
Week 8	222/ 246	90.24%	224/ 246	91.06%
Week 16	219/ 245	89.39%	218/ 246	88.62%
Week 24	211/ 245	86.12%	214/ 246	86.99%
Week 32	205/ 245	83.67%	194/ 246	78.86%
Week 40	207/ 245	84.49%	195/ 245	79.59%
Week 48	208/ 245	84.90%	188/ 245	76.73%
Week 52	194/ 245	79.18%	181/ 245	73.88%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute Physical Functioning Score
Full analysis set

Visit	Anifrolumab 300mg (N=246) n/ N#	Anifrolumab 300mg (N=246) Compliance	Placebo (N=246) n/ N#	Placebo (N=246) Compliance
Baseline	236/ 246	95.93%	232/ 246	94.31%
Week 8	222/ 246	90.24%	224/ 246	91.06%
Week 16	219/ 245	89.39%	218/ 246	88.62%
Week 24	211/ 245	86.12%	214/ 246	86.99%
Week 32	205/ 245	83.67%	194/ 246	78.86%
Week 40	207/ 245	84.49%	195/ 245	79.59%
Week 48	208/ 245	84.90%	188/ 245	76.73%
Week 52	194/ 245	79.18%	181/ 245	73.88%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute Role Emotional Score
Full analysis set

Visit	Anifrolumab 300mg (N=246) n/ N#	Anifrolumab 300mg (N=246) Compliance	Placebo (N=246) n/ N#	Placebo (N=246) Compliance
Baseline	236/ 246	95.93%	232/ 246	94.31%
Week 8	222/ 246	90.24%	224/ 246	91.06%
Week 16	219/ 245	89.39%	218/ 246	88.62%
Week 24	211/ 245	86.12%	214/ 246	86.99%
Week 32	205/ 245	83.67%	194/ 246	78.86%
Week 40	207/ 245	84.49%	195/ 245	79.59%
Week 48	208/ 245	84.90%	188/ 245	76.73%
Week 52	194/ 245	79.18%	181/ 245	73.88%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute Role Physical Score
Full analysis set

Visit	Anifrolumab 300mg (N=246) n/ N#	Anifrolumab 300mg (N=246) Compliance	Placebo (N=246) n/ N#	Placebo (N=246) Compliance
Baseline	236/ 246	95.93%	232/ 246	94.31%
Week 8	222/ 246	90.24%	224/ 246	91.06%
Week 16	219/ 245	89.39%	218/ 246	88.62%
Week 24	211/ 245	86.12%	214/ 246	86.99%
Week 32	205/ 245	83.67%	194/ 246	78.86%
Week 40	207/ 245	84.49%	195/ 245	79.59%
Week 48	208/ 245	84.90%	188/ 245	76.73%
Week 52	194/ 245	79.18%	181/ 245	73.88%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute Social Functioning Score
Full analysis set

Visit	Anifrolumab 300mg (N=246) n/ N#	Anifrolumab 300mg (N=246) Compliance	Placebo (N=246) n/ N#	Placebo (N=246) Compliance
Baseline	236/ 246	95.93%	232/ 246	94.31%
Week 8	222/ 246	90.24%	224/ 246	91.06%
Week 16	219/ 245	89.39%	218/ 246	88.62%
Week 24	211/ 245	86.12%	214/ 246	86.99%
Week 32	205/ 245	83.67%	194/ 246	78.86%
Week 40	207/ 245	84.49%	195/ 245	79.59%
Week 48	208/ 245	84.90%	188/ 245	76.73%
Week 52	194/ 245	79.18%	181/ 245	73.88%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute Bodily Pain Score
Full analysis set

Visit	Anifrolumab 300mg (N=246) n/ N#	Anifrolumab 300mg (N=246) Compliance	Placebo (N=246) n/ N#	Placebo (N=246) Compliance
Baseline	236/ 246	95.93%	232/ 246	94.31%
Week 8	222/ 246	90.24%	224/ 246	91.06%
Week 16	219/ 245	89.39%	218/ 246	88.62%
Week 24	211/ 245	86.12%	214/ 246	86.99%
Week 32	205/ 245	83.67%	194/ 246	78.86%
Week 40	207/ 245	84.49%	195/ 245	79.59%
Week 48	208/ 245	84.90%	188/ 245	76.73%
Week 52	194/ 245	79.18%	181/ 245	73.88%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute Vitality Score
Full analysis set

Visit	Anifrolumab 300mg (N=246) n/ N#	Anifrolumab 300mg (N=246) Compliance	Placebo (N=246) n/ N#	Placebo (N=246) Compliance
Baseline	236/ 246	95.93%	232/ 246	94.31%
Week 8	222/ 246	90.24%	224/ 246	91.06%
Week 16	219/ 245	89.39%	218/ 246	88.62%
Week 24	211/ 245	86.12%	214/ 246	86.99%
Week 32	205/ 245	83.67%	194/ 246	78.86%
Week 40	207/ 245	84.49%	195/ 245	79.59%
Week 48	208/ 245	84.90%	188/ 245	76.73%
Week 52	194/ 245	79.18%	181/ 245	73.88%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - FACIT-F Total Score
Full analysis set

Visit	Anifrolumab 300mg (N=246) n/ N#	Anifrolumab 300mg (N=246) Compliance	Placebo (N=246) n/ N#	Placebo (N=246) Compliance
Baseline	232/ 246	94.31%	233/ 246	94.72%
Week 4	231/ 246	93.90%	233/ 246	94.72%
Week 8	223/ 246	90.65%	226/ 246	91.87%
Week 12	229/ 245	93.47%	220/ 246	89.43%
Week 16	221/ 245	90.20%	220/ 246	89.43%
Week 20	214/ 245	87.35%	216/ 246	87.80%
Week 24	213/ 245	86.94%	217/ 246	88.21%
Week 28	213/ 245	86.94%	208/ 246	84.55%
Week 32	211/ 245	86.12%	198/ 246	80.49%
Week 36	210/ 245	85.71%	194/ 246	78.86%
Week 40	211/ 245	86.12%	196/ 245	80.00%
Week 44	205/ 245	83.67%	190/ 245	77.55%
Week 48	210/ 245	85.71%	191/ 245	77.96%
Week 52	194/ 245	79.18%	182/ 245	74.29%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - EQ VAS Score
Full analysis set

Visit	Anifrolumab 300mg (N=246) n/ N#	Anifrolumab 300mg (N=246) Compliance	Placebo (N=246) n/ N#	Placebo (N=246) Compliance
Baseline	232/ 246	94.31%	233/ 246	94.72%
Week 12	228/ 245	93.06%	218/ 246	88.62%
Week 24	211/ 245	86.12%	212/ 246	86.18%
Week 36	205/ 245	83.67%	192/ 246	78.05%
Week 52	192/ 245	78.37%	180/ 245	73.47%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Lupus QoL Physical Health domain score
Full analysis set

Visit	Anifrolumab 300mg (N=246) n/ N#	Anifrolumab 300mg (N=246) Compliance	Placebo (N=246) n/ N#	Placebo (N=246) Compliance
Baseline	232/ 246	94.31%	233/ 246	94.72%
Week 12	227/ 245	92.65%	218/ 246	88.62%
Week 24	211/ 245	86.12%	210/ 246	85.37%
Week 36	205/ 245	83.67%	190/ 246	77.24%
Week 52	191/ 245	77.96%	179/ 245	73.06%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Lupus QoL Emotional Health domain score
Full analysis set

Visit	Anifrolumab 300mg (N=246) n/ N#	Anifrolumab 300mg (N=246) Compliance	Placebo (N=246) n/ N#	Placebo (N=246) Compliance
Baseline	232/ 246	94.31%	233/ 246	94.72%
Week 12	227/ 245	92.65%	218/ 246	88.62%
Week 24	211/ 245	86.12%	210/ 246	85.37%
Week 36	205/ 245	83.67%	190/ 246	77.24%
Week 52	191/ 245	77.96%	179/ 245	73.06%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Lupus QoL Body Image domain score
Full analysis set

Visit	Anifrolumab 300mg (N=246) n/ N#	Anifrolumab 300mg (N=246) Compliance	Placebo (N=246) n/ N#	Placebo (N=246) Compliance
Baseline	218/ 246	88.62%	216/ 246	87.80%
Week 12	206/ 245	84.08%	196/ 246	79.67%
Week 24	190/ 245	77.55%	188/ 246	76.42%
Week 36	179/ 245	73.06%	172/ 246	69.92%
Week 52	165/ 245	67.35%	161/ 245	65.71%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Lupus QoL Burden to Others domain score
Full analysis set

Visit	Anifrolumab 300mg (N=246) n/ N#	Anifrolumab 300mg (N=246) Compliance	Placebo (N=246) n/ N#	Placebo (N=246) Compliance
Baseline	232/ 246	94.31%	233/ 246	94.72%
Week 12	227/ 245	92.65%	218/ 246	88.62%
Week 24	211/ 245	86.12%	210/ 246	85.37%
Week 36	205/ 245	83.67%	190/ 246	77.24%
Week 52	191/ 245	77.96%	179/ 245	73.06%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Lupus QoL Fatigue domain score
Full analysis set

Visit	Anifrolumab 300mg (N=246) n/ N#	Anifrolumab 300mg (N=246) Compliance	Placebo (N=246) n/ N#	Placebo (N=246) Compliance
Baseline	232/ 246	94.31%	233/ 246	94.72%
Week 12	227/ 245	92.65%	218/ 246	88.62%
Week 24	211/ 245	86.12%	210/ 246	85.37%
Week 36	205/ 245	83.67%	190/ 246	77.24%
Week 52	191/ 245	77.96%	179/ 245	73.06%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Lupus QoL Intimate Relationships domain score
Full analysis set

Visit	Anifrolumab 300mg (N=246) n/ N#	Anifrolumab 300mg (N=246) Compliance	Placebo (N=246) n/ N#	Placebo (N=246) Compliance
Baseline	195/ 246	79.27%	192/ 246	78.05%
Week 12	189/ 245	77.14%	173/ 246	70.33%
Week 24	165/ 245	67.35%	153/ 246	62.20%
Week 36	160/ 245	65.31%	138/ 246	56.10%
Week 52	140/ 245	57.14%	132/ 245	53.88%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Lupus QoL Pain domain score
Full analysis set

Visit	Anifrolumab 300mg (N=246) n/ N#	Anifrolumab 300mg (N=246) Compliance	Placebo (N=246) n/ N#	Placebo (N=246) Compliance
Baseline	232/ 246	94.31%	233/ 246	94.72%
Week 12	227/ 245	92.65%	218/ 246	88.62%
Week 24	211/ 245	86.12%	210/ 246	85.37%
Week 36	205/ 245	83.67%	190/ 246	77.24%
Week 52	191/ 245	77.96%	179/ 245	73.06%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Lupus QoL Planning domain score
Full analysis set

Visit	Anifrolumab 300mg (N=246) n/ N#	Anifrolumab 300mg (N=246) Compliance	Placebo (N=246) n/ N#	Placebo (N=246) Compliance
Baseline	232/ 246	94.31%	233/ 246	94.72%
Week 12	227/ 245	92.65%	218/ 246	88.62%
Week 24	211/ 245	86.12%	210/ 246	85.37%
Week 36	205/ 245	83.67%	190/ 246	77.24%
Week 52	191/ 245	77.96%	179/ 245	73.06%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SDI Global Score
Full analysis set

Visit	Anifrolumab 300mg (N=246) n/ N#	Anifrolumab 300mg (N=246) Compliance	Placebo (N=246) n/ N#	Placebo (N=246) Compliance
Baseline	240/ 246	97.56%	238/ 246	96.75%
Week 24	216/ 245	88.16%	216/ 246	87.80%
Week 52	193/ 245	78.78%	188/ 245	76.73%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - NRS Score
Full analysis set

Visit	Anifrolumab 300mg (N=246) n/ N#	Anifrolumab 300mg (N=246) Compliance	Placebo (N=246) n/ N#	Placebo (N=246) Compliance
Baseline	232/ 246	94.31%	233/ 246	94.72%
Week 4	231/ 246	93.90%	233/ 246	94.72%
Week 8	223/ 246	90.65%	226/ 246	91.87%
Week 12	229/ 245	93.47%	220/ 246	89.43%
Week 16	221/ 245	90.20%	220/ 246	89.43%
Week 20	214/ 245	87.35%	216/ 246	87.80%
Week 24	213/ 245	86.94%	217/ 246	88.21%
Week 28	213/ 245	86.94%	208/ 246	84.55%
Week 32	211/ 245	86.12%	198/ 246	80.49%
Week 36	210/ 245	85.71%	194/ 246	78.86%
Week 40	211/ 245	86.12%	196/ 245	80.00%
Week 44	205/ 245	83.67%	190/ 245	77.55%
Week 48	210/ 245	85.71%	191/ 245	77.96%
Week 52	194/ 245	79.18%	182/ 245	74.29%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - PHQ-8 Total Score
Full analysis set

Visit	Anifrolumab 300mg (N=246) n/ N#	Anifrolumab 300mg (N=246) Compliance	Placebo (N=246) n/ N#	Placebo (N=246) Compliance
Baseline	232/ 246	94.31%	233/ 246	94.72%
Week 12	228/ 245	93.06%	218/ 246	88.62%
Week 24	211/ 245	86.12%	212/ 246	86.18%
Week 36	205/ 245	83.67%	192/ 246	78.05%
Week 52	192/ 245	78.37%	180/ 245	73.47%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - PtGA
Full analysis set

Visit	Anifrolumab 300mg (N=246) n/ N#	Anifrolumab 300mg (N=246) Compliance	Placebo (N=246) n/ N#	Placebo (N=246) Compliance
Baseline	232/ 246	94.31%	233/ 246	94.72%
Week 4	231/ 246	93.90%	233/ 246	94.72%
Week 8	223/ 246	90.65%	226/ 246	91.87%
Week 12	228/ 245	93.06%	220/ 246	89.43%
Week 16	221/ 245	90.20%	219/ 246	89.02%
Week 20	213/ 245	86.94%	214/ 246	86.99%
Week 24	213/ 245	86.94%	215/ 246	87.40%
Week 28	212/ 245	86.53%	207/ 246	84.15%
Week 32	209/ 245	85.31%	198/ 246	80.49%
Week 36	210/ 245	85.71%	192/ 246	78.05%
Week 40	211/ 245	86.12%	194/ 245	79.18%
Week 44	205/ 245	83.67%	187/ 245	76.33%
Week 48	209/ 245	85.31%	187/ 245	76.33%
Week 52	193/ 245	78.78%	181/ 245	73.88%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Flare rate through Week 52
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) Number of flares	Anifrolumab 300mg (N=246) Total Follow-up time (years)	Anifrolumab 300mg (N=246) Annual rate (SE)	Placebo (N=246) Number of flares	Placebo (N=246) Total Follow-up time (years)	Placebo (N=246) Annual rate (SE)	Rate ratio (95% CI)	p-Value	Heterogenity/ Interaction p-Value
									0.7150
Overall	109	229.70	0.42 (0.13)	159	224.03	0.62 (0.13)	0.67 (0.50, 0.90)	0.0086	
SLEDAI-2K score at screening									0.3377
< 10 points	28	74.34	0.34 (0.23)	27	62.86	0.42 (0.21)	0.80 (0.46, 1.38)	0.4215	
>= 10 points	81	155.36	0.50 (0.16)	132	161.17	0.82 (0.14)	0.60 (0.42, 0.85)	0.0045	
OCS dose at baseline									0.1781
<10 mg/day	50	108.51	0.42 (0.18)	61	108.67	0.49 (0.19)	0.85 (0.54, 1.34)	0.4877	
>=10 mg/day	59	121.19	0.42 (0.20)	98	115.36	0.75 (0.18)	0.55 (0.37, 0.81)	0.0028	
Result of type I IFN gene signature test									0.0164
LOW	27	42.82	0.58 (0.26)	20	43.68	0.40 (0.27)	1.43 (0.71, 2.90)	0.3139	
HIGH	82	186.88	0.39 (0.14)	139	180.35	0.68 (0.12)	0.57 (0.41, 0.79)	0.0007	
Age (years)									0.2355
<= 65	107	223.52	0.42 (0.14)	154	221.10	0.61 (0.13)	0.69 (0.51, 0.93)	0.0150	
> 65	2	6.18	0.00 (1795.07)	5	2.94	0.00 (1209.32)	0.00 (0.00, I)	0.9962	
Sex									0.1894
male	8	22.06	NE	20	19.39	NE	NE		
female	101	207.64	0.43 (0.14)	139	204.64	0.61 (0.13)	0.72 (0.53, 0.98)	0.0372	
Race									0.1085
White	70	151.63	0.39 (0.16)	110	156.52	0.57 (0.15)	0.69 (0.49, 0.97)	0.0337	
Black	22	28.95	0.90 (0.30)	18	31.06	0.67 (0.32)	1.34 (0.60, 2.96)	0.4713	
Other	15	42.44	0.22 (0.65)	30	33.41	0.55 (0.63)	0.41 (0.17, 0.96)	0.0392	
Ethnicity									0.3279
Hispanic/Latino	20	45.99	0.30 (0.34)	45	51.94	0.57 (0.31)	0.52 (0.27, 0.99)	0.0469	
Non-hispanic/Latino	87	177.02	0.45 (0.15)	113	169.05	0.62 (0.14)	0.73 (0.52, 1.02)	0.0670	
Geographic region									0.5149
EU	27	87.87	0.23 (0.29)	46	81.46	0.38 (0.28)	0.60 (0.34, 1.05)	0.0744	
non-EU	82	141.84	0.53 (0.15)	113	142.58	0.74 (0.14)	0.72 (0.51, 1.01)	0.0560	
Onset of disease									0.8911
Paediatric	14	17.97	0.87 (0.42)	14	11.48	1.24 (0.38)	0.70 (0.31, 1.62)	0.4098	
Adult	95	211.73	0.40 (0.14)	145	212.56	0.60 (0.13)	0.66 (0.48, 0.90)	0.0085	
ADA result									0.0396
Negative	102	212.08	0.44 (0.14)	130	203.16	0.58 (0.13)	0.76 (0.56, 1.04)	0.0834	
Positive (At any time)	7	17.62	0.13 (0.82)	29	20.87	0.58 (0.60)	0.22 (0.07, 0.70)	0.0098	
BMI (kg/m2) at enrolment									0.1232
< 30	58	149.72	0.38 (0.18)	112	157.69	0.71 (0.16)	0.55 (0.37, 0.80)	0.0019	
>= 30	51	79.98	0.49 (0.19)	47	66.34	0.53 (0.19)	0.92 (0.59, 1.43)	0.7205	

Rates and rate ratio from negative binomial regression model with factors for treatment group and the stratification factors. The logarithm (to base e) of the follow-up time is used as an offset variable in the model to adjust for subjects having different exposure times.
Study*treatment interaction also included to assess heterogenity between studies.
p-Value for interaction from same negative binomial regression model with additional factors for subgroup and subgroup*treatment interaction.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Flare rate through Week 52 using modified BILAG
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) Number of flares	Anifrolumab 300mg (N=246) Total Follow-up time (years)	Anifrolumab 300mg (N=246) Annual rate (SE)	Placebo (N=246) Number of flares	Placebo (N=246) Total Follow-up time (years)	Placebo (N=246) Annual rate (SE)	Rate ratio (95% CI)	p-Value	Heterogenity/ Interaction p-Value
Overall	72	229.70	0.24 (0.17)	127	224.03	0.43 (0.15)	0.57 (0.40, 0.80)	0.0011	0.7981

Rates and rate ratio from negative binomial regression model with factors for treatment group and the stratification factors. The logarithm (to base e) of the follow-up time is used as an offset variable in the model to adjust for subjects having different exposure times.
Study*treatment interaction also included to assess heterogenity between studies.
p-Value for interaction from same negative binomial regression model with additional factors for subgroup and subgroup*treatment interaction.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Flare rate through Week 52 while on treatment
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) Number of flares	Anifrolumab 300mg (N=246) Total Follow-up time (years)	Anifrolumab 300mg (N=246) Annual rate (SE)	Placebo (N=246) Number of flares	Placebo (N=246) Total Follow-up time (years)	Placebo (N=246) Annual rate (SE)	Rate ratio (95% CI)	p-Value	Heterogenity/ Interaction p-Value
Overall	99	224.09	0.40 (0.14)	141	212.69	0.59 (0.13)	0.67 (0.50, 0.92)	0.0125	0.8063

Rates and rate ratio from negative binomial regression model with factors for treatment group and the stratification factors. The logarithm (to base e) of the follow-up time is used as an offset variable in the model to adjust for subjects having different exposure times.
Study*treatment interaction also included to assess heterogenity between studies.
p-Value for interaction from same negative binomial regression model with additional factors for subgroup and subgroup*treatment interaction.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Flare rate through Week 52 sensitivity analysis, multiple imputation and negative binomial regression model
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) Number of flares	Anifrolumab 300mg (N=246) Total Follow-up time (years)	Anifrolumab 300mg (N=246) Annual rate (SE)	Placebo (N=246) Number of flares	Placebo (N=246) Total Follow-up time (years)	Placebo (N=246) Annual rate (SE)	Rate ratio (95% CI)	p-Value
Overall	118	246.54	0.42 (0.00)	177	246.76	0.62 (0.00)	0.68 (0.51, 0.91)	0.0101

The number of flares after withdrawal from study is imputed conditional upon the observed number of flares prior to the withdrawal, a post-withdrawal model assumption, the baseline covariates included in the main analysis model and the time the subject would have remained in the study if not withdrawn (ie, date of first administration of IP + 364 days â€“ date of withdrawal). This analysis is repeated multiple times and the results combined using Rubinâ€™s formula. Full details are given in SAP
Rates and rate ratio from negative binomial regression model with factors for treatment group and the stratification factors. The logarithm (to base e) of the follow-up time is used as an offset variable in the model to adjust for subjects having different exposure times.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Flare rate through Week 52 sensitivity analysis, tipping point analysis
Full analysis set

Shift (log(Delta A)) for Anifrolumab 300 mg	Shift (log(Delta P)) for Placebo						
	0	-0.25	-0.5	-0.75	-1	-1.25	-1.5
0	0.0102	0.0126	0.0149	0.0170	0.0187	0.0202	0.0215
0.25	0.0116	0.0144	0.0169	0.0192	0.0212	0.0228	0.0242
0.5	0.0138	0.0170	0.0199	0.0225	0.0248	0.0267	0.0282
0.75	0.0171	0.0210	0.0245	0.0276	0.0303	0.0325	0.0344
1	0.0226	0.0274	0.0318	0.0357	0.0390	0.0418	0.0441
1.25	0.0319	0.0384	0.0443	0.0493	0.0537	0.0573	0.0602
1.5	0.0490	0.0582	0.0664	0.0734	0.0794	0.0843	0.0883

The response variable in the model is the number of flares up to Week 52/EDV. The model includes covariates of treatment group, and the stratification factors (SLEDAI-2K Score at Screening (<10 points vs >= 10 points), Week 0 OCS dose (<10 mg/day vs >=10 mg/day prednisone or equivalent) and Type 1 IFN test result at screening (high vs low)).
The logarithm (to base e) of the follow-up time is used as an offset variable in the model to adjust for subjects having different exposure times.
P-values of this analysis are presented.
For the scenario in the upper left corner, missing at random analysis is performed, where for each subject the rate after withdrawal y1 is assumed to be the same as their rate before withdrawal y2, which itself is calculated based on their randomised treatment group and baseline covariates. For the other scenarios, the same analyses are performed with the rate after withdrawal modified to be Deltay2 (Delta P and Delta A for placebo and anifrolumab 300 mg, respectively).

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Overall Survival
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	1 (0.4)	1 (0.4)
Number of censored subjects, n (%)	245 (99.6)	245 (99.6)
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Anifrolumab 300mg vs. Placebo (adjusted)		
Hazard Ratio (95% CI)	0.92 (0.06, 14.74)	
p-value	0.9624	
Analysis Anifrolumab 300mg vs. Placebo (unadjusted)		
Hazard Ratio (95% CI)	0.98 (0.06, 15.73)	
p-value	0.9907	
p-Value for test for heterogenity between studies	1.0000	

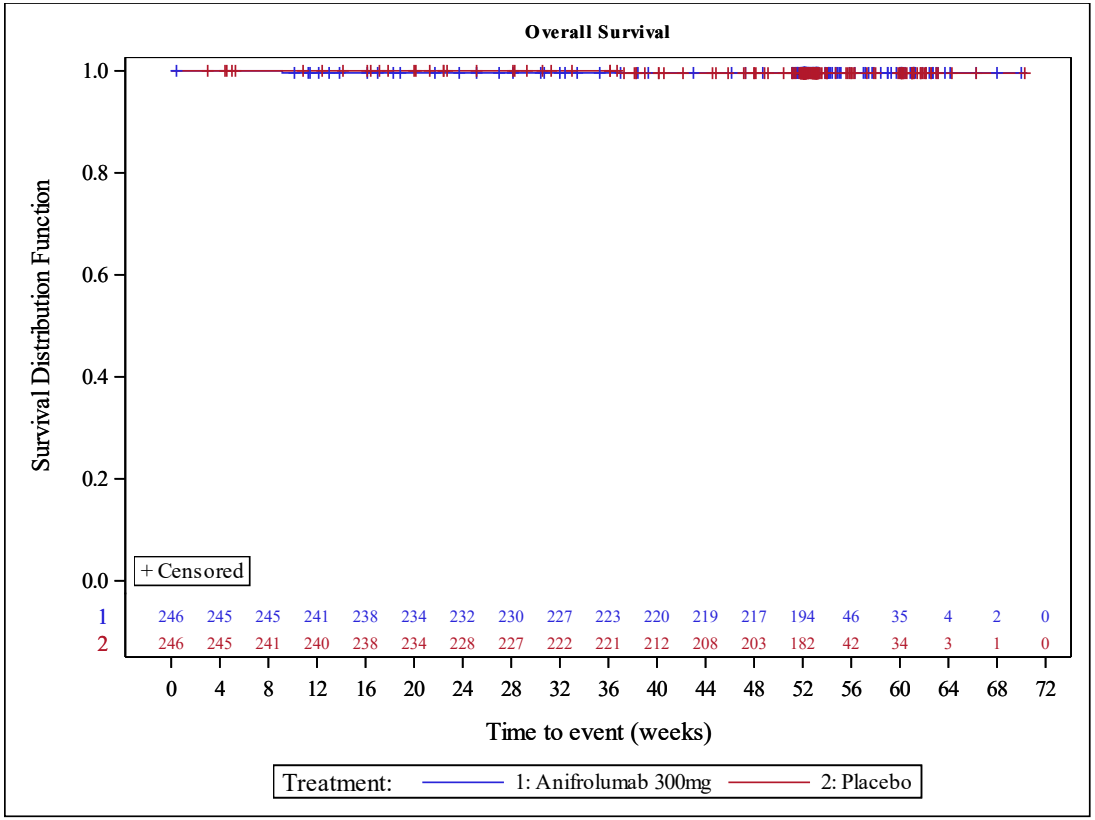
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model. Adjusted analysis also includes stratification factors in the model.
Two-sided log rank test used.
p-Value for heterogenity between studies from Cox proportional hazards model with factors for treatment, study, treatment*study interaction and stratfication factors.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unadjusted analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Overall Survival - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Anifrolumab 300mg (N=246) Median (95% CI)	Placebo (N=246) n/ N (%)	Placebo (N=246) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening							0.9989
< 10 points	1/ 80 (1.3)	NE (NE, NE)	0/ 69 (0.0)	NE (NE, NE)	NE		
>= 10 points	0/166 (0.0)	NE (NE, NE)	1/177 (0.6)	NE (NE, NE)	NE		
OCS dose at baseline							1.0000
<10 mg/day	0/115 (0.0)	NE (NE, NE)	0/117 (0.0)	NE (NE, NE)	NE		
>=10 mg/day	1/131 (0.8)	NE (NE, NE)	1/129 (0.8)	NE (NE, NE)	0.92 (0.06, 14.74)	0.9624	
Result of type I IFN gene signature test							1.0000
LOW	0/ 45 (0.0)	NE (NE, NE)	0/ 48 (0.0)	NE (NE, NE)	NE		
HIGH	1/201 (0.5)	NE (NE, NE)	1/198 (0.5)	NE (NE, NE)	0.92 (0.06, 14.74)	0.9624	
Age (years)							0.9997
<= 65	1/239 (0.4)	NE (NE, NE)	1/243 (0.4)	NE (NE, NE)	0.88 (0.05, 14.17)	0.9400	
> 65	0/ 7 (0.0)	NE (NE, NE)	0/ 3 (0.0)	NE (NE, NE)	NE		
Sex							1.0000
male	0/ 23 (0.0)	NE (NE, NE)	0/ 20 (0.0)	NE (NE, NE)	NE		
female	1/223 (0.4)	NE (NE, NE)	1/226 (0.4)	NE (NE, NE)	0.98 (0.06, 15.73)	0.9964	
Race							1.0000
White	0/160 (0.0)	NE (NE, NE)	0/174 (0.0)	NE (NE, NE)	NE		
Black	0/ 33 (0.0)	NE (NE, NE)	1/ 32 (3.1)	NE (NE, NE)	NE		
Other	1/ 45 (2.2)	NE (NE, NE)	0/ 37 (0.0)	NE (NE, NE)	NE		
Ethnicity							0.9999
Hispanic/Latino	1/ 50 (2.0)	NE (NE, NE)	0/ 56 (0.0)	NE (NE, NE)	NE		
Non-hispanic/Latino	0/188 (0.0)	NE (NE, NE)	1/187 (0.5)	NE (NE, NE)	NE		
Geographic region							1.0000
EU	0/ 92 (0.0)	NE (NE, NE)	0/ 89 (0.0)	NE (NE, NE)	NE		
non-EU	1/154 (0.6)	NE (NE, NE)	1/157 (0.6)	NE (NE, NE)	0.95 (0.06, 15.41)	0.9918	
Onset of disease							1.0000
Paediatric	0/ 19 (0.0)	NE (NE, NE)	0/ 12 (0.0)	NE (NE, NE)	NE		
Adult	1/227 (0.4)	NE (NE, NE)	1/234 (0.4)	NE (NE, NE)	0.95 (0.06, 15.25)	0.9791	
ADA result							1.0000
Negative	1/226 (0.4)	NE (NE, NE)	1/223 (0.4)	NE (NE, NE)	0.89 (0.05, 14.59)	0.9523	
Positive (At any time)	0/ 19 (0.0)	NE (NE, NE)	0/ 23 (0.0)	NE (NE, NE)	NE		
BMI (kg/m2) at enrolment							0.9990
< 30	1/159 (0.6)	NE (NE, NE)	0/176 (0.0)	NE (NE, NE)	NE		
>= 30	0/ 87 (0.0)	NE (NE, NE)	1/ 70 (1.4)	NE (NE, NE)	NE		

Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of Overall Survival
Full analysis set



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Time to first Flare
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	72 (29.3)	101 (41.1)
Number of censored subjects, n (%)	174 (70.7)	145 (58.9)
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	36.57 (28.14, 52.00)	20.14 (16.00, 27.86)
Median (95% CI)	NE (NE, NE)	NE (52.29, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Anifrolumab 300mg vs. Placebo (adjusted)		
Hazard Ratio (95% CI)	0.62 (0.46, 0.84)	
p-value	0.0021	
Analysis Anifrolumab 300mg vs. Placebo (unadjusted)		
Hazard Ratio (95% CI)	0.63 (0.46, 0.85)	
p-value	0.0023	
p-Value for test for heterogenity between studies	0.9071	

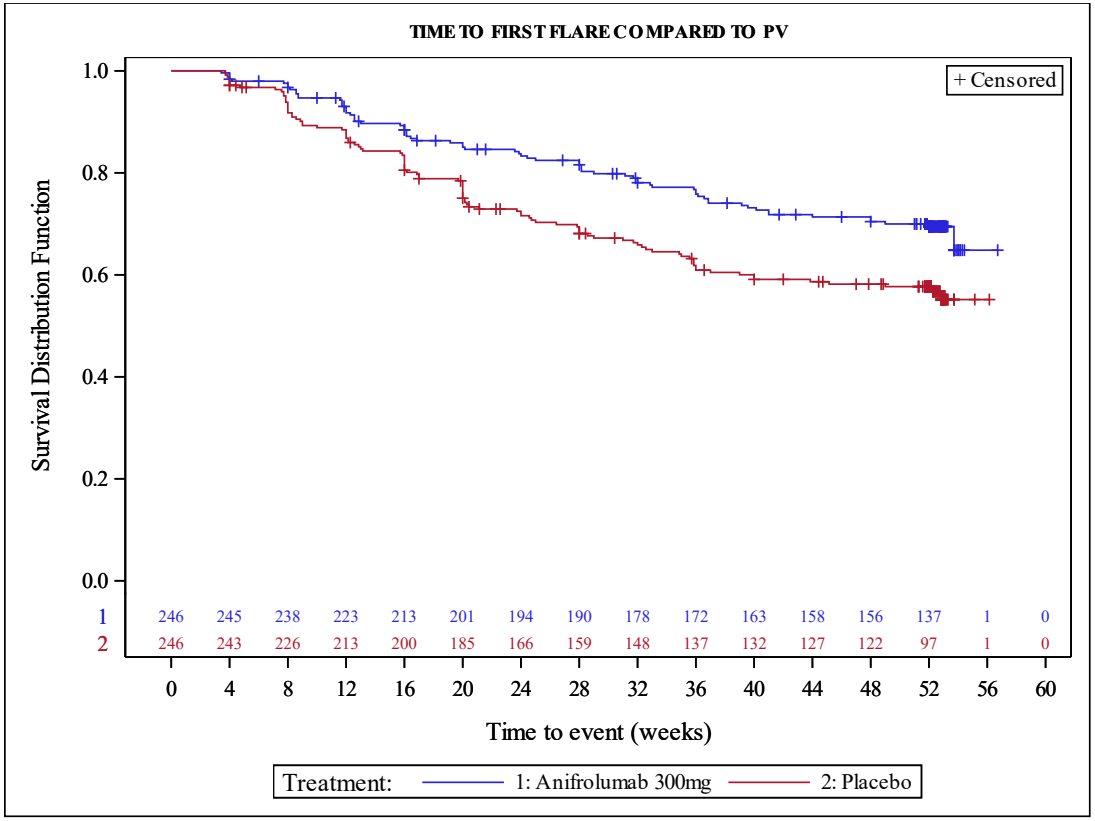
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model. Adjusted analysis also includes stratification factors in the model.
Two-sided log rank test used.
p-Value for heterogenity between studies from Cox proportional hazards model with factors for treatment, study, treatment*study interaction and stratfication factors.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unadjusted analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Time to first Flare - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Anifrolumab 300mg (N=246) Median (95% CI)	Placebo (N=246) n/ N (%)	Placebo (N=246) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening							0.4037
< 10 points	22/ 80 (27.5)	NE (53.71, NE)	23/ 69 (33.3)	NE (NE, NE)	0.71 (0.39, 1.28)	0.2493	
>= 10 points	50/166 (30.1)	NE (NE, NE)	78/177 (44.1)	NE (37.00, NE)	0.58 (0.41, 0.83)	0.0038	
OCS dose at baseline							0.0404
<10 mg/day	35/115 (30.4)	NE (NE, NE)	38/117 (32.5)	NE (NE, NE)	0.89 (0.56, 1.41)	0.6416	
>=10 mg/day	37/131 (28.2)	NE (NE, NE)	63/129 (48.8)	43.86 (28.57, NE)	0.47 (0.31, 0.71)	0.0002	
Result of type I IFN gene signature test							0.1226
LOW	15/ 45 (33.3)	NE (52.00, NE)	16/ 48 (33.3)	NE (52.29, NE)	1.06 (0.52, 2.18)	0.7826	
HIGH	57/201 (28.4)	NE (NE, NE)	85/198 (42.9)	NE (40.00, NE)	0.56 (0.40, 0.78)	0.0004	
Age (years)							0.5683
<= 65	70/239 (29.3)	NE (NE, NE)	99/243 (40.7)	NE (52.86, NE)	0.62 (0.46, 0.84)	0.0024	
> 65	2/ 7 (28.6)	NE (12.00, NE)	2/ 3 (66.7)	19.71 (8.00, NE)	0.00 (0.00,)	<.0001	
Sex							0.4741
male	7/ 23 (30.4)	NE (35.86, NE)	11/ 20 (55.0)	37.00 (15.71, NE)	0.52 (0.19, 1.39)	0.0141	
female	65/223 (29.1)	NE (NE, NE)	90/226 (39.8)	NE (NE, NE)	0.65 (0.47, 0.89)	0.0076	
Race							0.4192
White	48/160 (30.0)	NE (NE, NE)	74/174 (42.5)	NE (40.00, NE)	0.61 (0.42, 0.88)	0.0059	
Black	12/ 33 (36.4)	NE (32.86, NE)	12/ 32 (37.5)	NE (32.57, NE)	1.06 (0.46, 2.44)	0.8610	
Other	10/ 45 (22.2)	NE (NE, NE)	14/ 37 (37.8)	NE (27.86, NE)	0.50 (0.21, 1.18)	0.1450	
Ethnicity							0.6799
Hispanic/Latino	14/ 50 (28.0)	NE (NE, NE)	25/ 56 (44.6)	NE (28.00, NE)	0.57 (0.29, 1.10)	0.1102	
Non-hispanic/Latino	56/188 (29.8)	NE (53.71, NE)	75/187 (40.1)	NE (52.29, NE)	0.64 (0.45, 0.91)	0.0099	
Geographic region							0.4029
EU	19/ 92 (20.7)	NE (53.71, NE)	32/ 89 (36.0)	NE (52.86, NE)	0.49 (0.27, 0.86)	0.0153	
non-EU	53/154 (34.4)	NE (NE, NE)	69/157 (43.9)	NE (35.86, NE)	0.67 (0.47, 0.96)	0.0230	
Onset of disease							0.3736
Paediatric	8/ 19 (42.1)	NE (25.00, NE)	8/ 12 (66.7)	24.57 (4.00, NE)	0.28 (0.09, 0.87)	0.0230	
Adult	64/227 (28.2)	NE (NE, NE)	93/234 (39.7)	NE (52.86, NE)	0.63 (0.46, 0.86)	0.0041	
ADA result							0.1207
Negative	66/226 (29.2)	NE (NE, NE)	86/223 (38.6)	NE (52.86, NE)	0.67 (0.49, 0.93)	0.0148	
Positive (At any time)	6/ 19 (31.6)	NE (28.14, NE)	15/ 23 (65.2)	16.86 (8.29, NE)	0.30 (0.11, 0.81)	0.0192	
BMI (kg/m2) at enrolment							0.3776
< 30	41/159 (25.8)	NE (53.71, NE)	69/176 (39.2)	NE (52.86, NE)	0.56 (0.38, 0.82)	0.0058	
>= 30	31/ 87 (35.6)	NE (NE, NE)	32/ 70 (45.7)	NE (32.29, NE)	0.72 (0.44, 1.20)	0.0882	

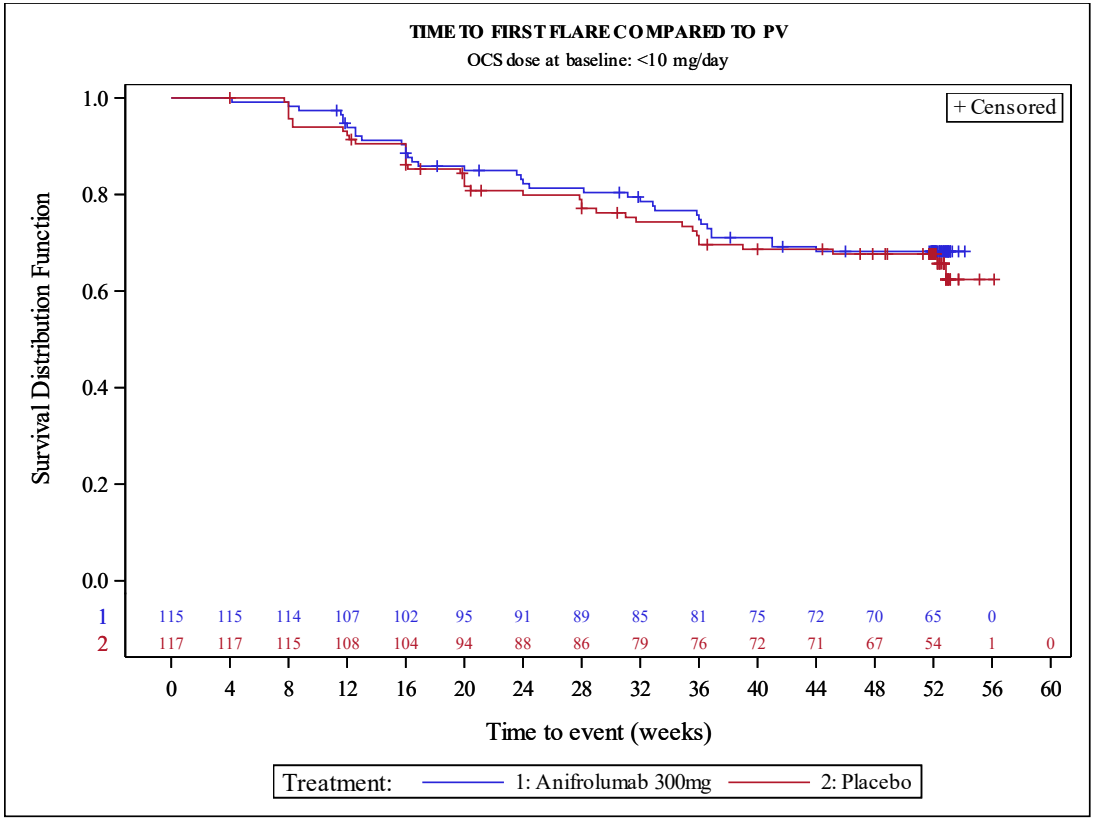
Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of Time to first Flare
Full analysis set



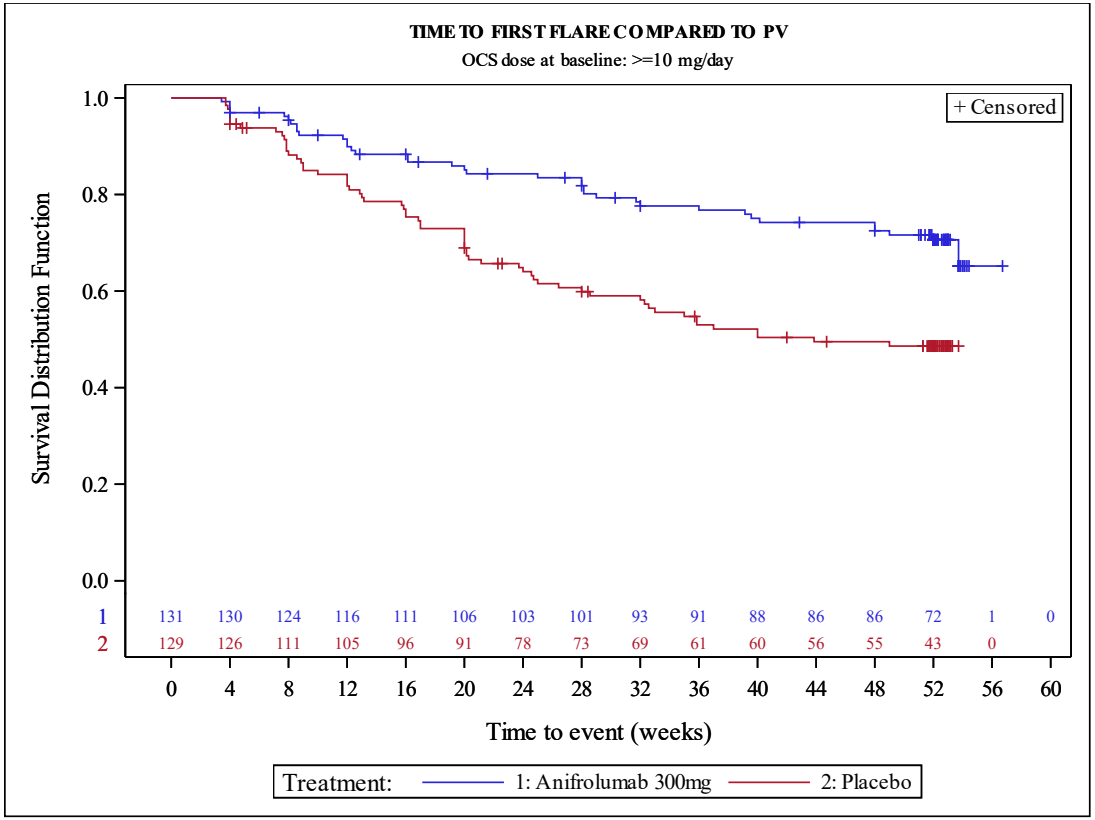
Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of Time to first Flare
Full analysis set



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of Time to first Flare
Full analysis set



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Time to sustained BICLA response up to week 52
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	115 (46.7)	78 (31.7)
Number of censored subjects, n (%)	131 (53.3)	168 (68.3)
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	20.14 (15.86, 27.86)	40.00 (32.00, 47.86)
Median (95% CI)	52.00 (48.00, 53.14)	NE (53.00, NE)
75%-ile (95% CI)	NE (53.14, NE)	NE (NE, NE)
Analysis Anifrolumab 300mg vs. Placebo (adjusted)		
Hazard Ratio (95% CI)	1.63 (1.22, 2.17)	
p-value	0.0015	
Analysis Anifrolumab 300mg vs. Placebo (unadjusted)		
Hazard Ratio (95% CI)	1.64 (1.23, 2.19)	
p-value	0.0009	
p-Value for test for heterogenity between studies	0.1511	

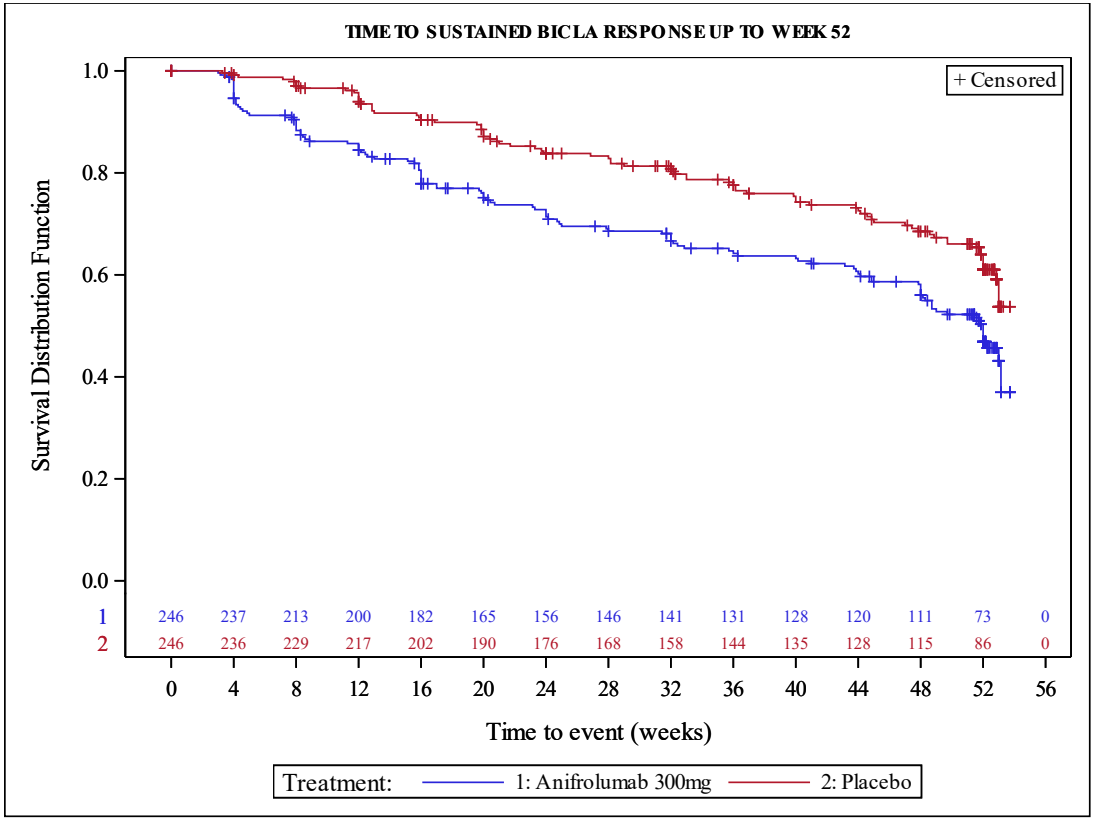
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model. Adjusted analysis also includes stratification factors in the model.
Two-sided log rank test used.
p-Value for heterogenity between studies from Cox proportional hazards model with factors for treatment, study, treatment*study interaction and stratfication factors.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unadjusted analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Time to sustained BICLA response up to week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Anifrolumab 300mg (N=246) Median (95% CI)	Placebo (N=246) n/ N (%)	Placebo (N=246) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening							0.7609
< 10 points	45/ 80 (56.3)	48.00 (24.14, 52.00)	27/ 69 (39.1)	53.00 (40.86, NE)	1.75 (1.08, 2.83)	0.0210	
>= 10 points	70/166 (42.2)	53.00 (48.71, NE)	51/177 (28.8)	NE (53.00, NE)	1.58 (1.10, 2.26)	0.0251	
OCS dose at baseline							0.6489
<10 mg/day	50/115 (43.5)	52.29 (47.86, NE)	36/117 (30.8)	53.00 (53.00, NE)	1.51 (0.98, 2.33)	0.0534	
>=10 mg/day	65/131 (49.6)	49.71 (43.14, 53.14)	42/129 (32.6)	NE (52.00, NE)	1.69 (1.14, 2.51)	0.0111	
Result of type I IFN gene signature test							0.3786
LOW	19/ 45 (42.2)	NE (32.86, NE)	17/ 48 (35.4)	NE (40.00, NE)	1.24 (0.63, 2.42)	0.5232	
HIGH	96/201 (47.8)	51.86 (48.00, 53.14)	61/198 (30.8)	NE (53.00, NE)	1.73 (1.25, 2.39)	0.0013	
Age (years)							0.9721
<= 65	111/239 (46.4)	52.00 (48.00, NE)	77/243 (31.7)	NE (53.00, NE)	1.62 (1.21, 2.17)	0.0020	
> 65	4/ 7 (57.1)	32.00 (15.86, NE)	1/ 3 (33.3)	NE (8.29, NE)	0.01 (0.00,)	<.0001	
Sex							0.9669
male	12/ 23 (52.2)	51.57 (19.86, NE)	7/ 20 (35.0)	NE (35.71, NE)	1.61 (0.61, 4.28)	0.3211	
female	103/223 (46.2)	52.00 (48.00, NE)	71/226 (31.4)	NE (53.00, NE)	1.64 (1.21, 2.22)	0.0021	
Race							0.3020
White	72/160 (45.0)	52.29 (49.71, NE)	58/174 (33.3)	NE (52.00, NE)	1.47 (1.03, 2.09)	0.0535	
Black	17/ 33 (51.5)	48.00 (24.00, NE)	13/ 32 (40.6)	52.86 (39.86, NE)	1.94 (0.89, 4.19)	0.1215	
Other	21/ 45 (46.7)	48.29 (36.29, NE)	6/ 37 (16.2)	NE (NE, NE)	2.91 (1.14, 7.44)	0.0346	
Ethnicity							0.7333
Hispanic/Latino	23/ 50 (46.0)	51.57 (28.00, NE)	16/ 56 (28.6)	NE (51.86, NE)	1.71 (0.89, 3.31)	0.1258	
Non-hispanic/Latino	87/188 (46.3)	52.00 (48.00, NE)	61/187 (32.6)	NE (52.86, NE)	1.56 (1.13, 2.18)	0.0136	
Geographic region							0.5303
EU	50/ 92 (54.3)	51.71 (32.43, 53.00)	37/ 89 (41.6)	53.00 (43.86, NE)	1.48 (0.96, 2.30)	0.1727	
non-EU	65/154 (42.2)	52.00 (48.00, NE)	41/157 (26.1)	NE (52.86, NE)	1.76 (1.19, 2.61)	0.0036	
Onset of disease							0.5874
Paediatric	8/ 19 (42.1)	49.00 (27.86, NE)	3/ 12 (25.0)	NE (23.86, NE)	2.30 (0.54, 9.83)	0.1924	
Adult	107/227 (47.1)	52.00 (48.00, NE)	75/234 (32.1)	NE (53.00, NE)	1.61 (1.19, 2.16)	0.0020	
ADA result							0.6383
Negative	107/226 (47.3)	52.00 (48.00, 53.14)	73/223 (32.7)	NE (52.86, NE)	1.59 (1.18, 2.15)	0.0058	
Positive (At any time)	8/ 19 (42.1)	NE (12.57, NE)	5/ 23 (21.7)	NE (53.00, NE)	2.28 (0.72, 7.23)	0.2526	
BMI (kg/m2) at enrolment							0.8005
< 30	78/159 (49.1)	51.86 (44.14, 53.14)	54/176 (30.7)	NE (53.00, NE)	1.66 (1.17, 2.36)	0.0069	
>= 30	37/ 87 (42.5)	52.00 (48.00, NE)	24/ 70 (34.3)	NE (52.00, NE)	1.56 (0.93, 2.62)	0.1080	

Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of Time to sustained BICLA response up to week 52
Full analysis set



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Time to OCS Reduction <=7.5 mg/day (for subjects with baseline OCS >=10 mg/day)
Full analysis set

	Anifrolumab 300mg (N=131)	Placebo (N=129)
Number of subjects with events, n (%)	88 (67.2)	65 (50.4)
Number of censored subjects, n (%)	43 (32.8)	64 (49.6)
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	13.00 (12.00, 16.29)	16.29 (13.14, 20.00)
Median (95% CI)	24.00 (19.43, 24.71)	28.29 (24.14, 48.29)
75%-ile (95% CI)	41.29 (29.00, NE)	NE (NE, NE)
Analysis Anifrolumab 300mg vs. Placebo (adjusted)		
Hazard Ratio (95% CI)	1.54 (1.12, 2.13)	
p-value	0.0100	
Analysis Anifrolumab 300mg vs. Placebo (unadjusted)		
Hazard Ratio (95% CI)	1.51 (1.10, 2.09)	
p-value	0.0121	
p-Value for test for heterogenity between studies	0.7480	

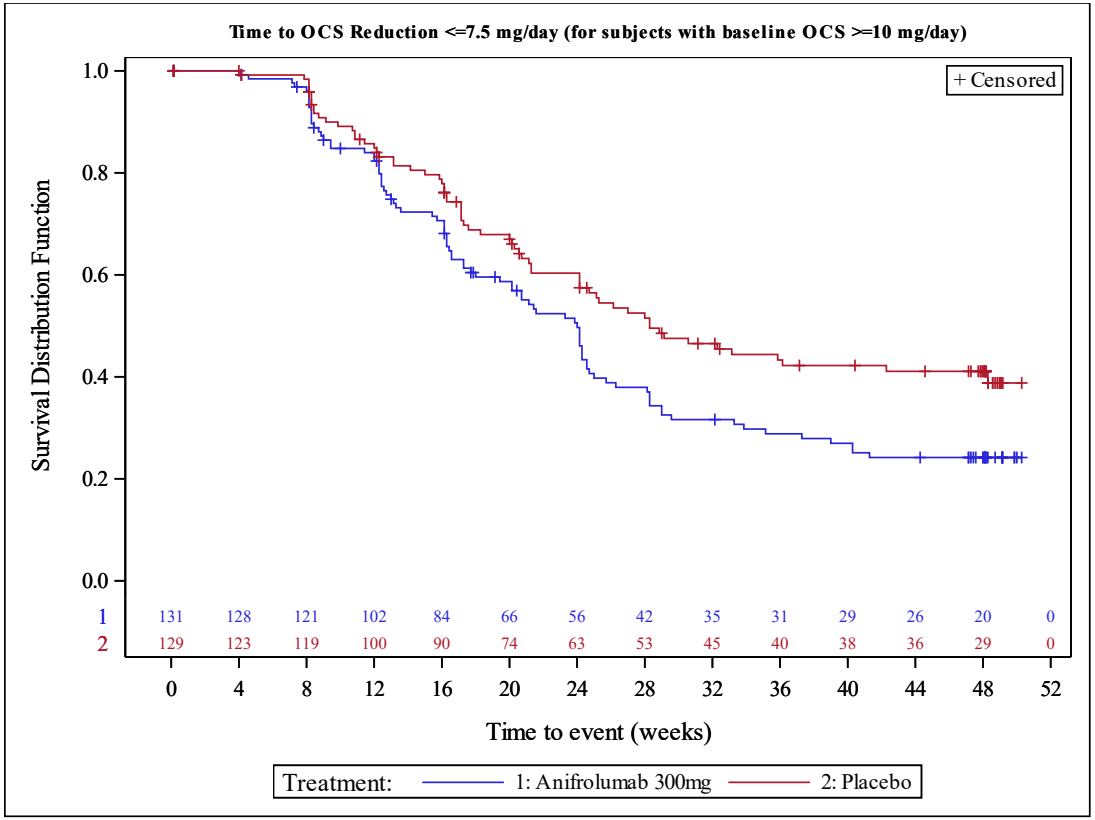
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model. Adjusted analysis also includes stratification factors in the model.
Two-sided log rank test used.
p-Value for heterogenity between studies from Cox proportional hazards model with factors for treatment, study, treatment*study interaction and stratfication factors.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unadjusted analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Time to OCS Reduction <=7.5 mg/day (for subjects with baseline OCS >=10 mg/day) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=131) n/ N (%)	Anifrolumab 300mg (N=131) Median (95% CI)	Placebo (N=129) n/ N (%)	Placebo (N=129) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening							0.2292
< 10 points	27/ 38 (71.1)	24.14 (16.29, 28.29)	13/ 29 (44.8)	29.14 (24.14, NE)	2.45 (1.22, 4.93)	0.0140	
>= 10 points	61/ 93 (65.6)	23.29 (17.29, 25.00)	52/100 (52.0)	26.14 (20.57, 48.29)	1.37 (0.94, 1.98)	0.1204	
OCS dose at baseline							NE
>=10 mg/day	88/131 (67.2)	24.00 (19.43, 24.71)	65/129 (50.4)	28.29 (24.14, 48.29)	1.54 (1.12, 2.13)	0.0100	
Result of type I IFN gene signature test							0.1567
LOW	9/ 13 (69.2)	25.00 (16.29, 40.29)	16/ 21 (76.2)	20.71 (17.14, 28.86)	0.94 (0.40, 2.20)	0.7778	
HIGH	79/118 (66.9)	23.29 (17.29, 24.57)	49/108 (45.4)	32.29 (24.71, NE)	1.70 (1.18, 2.43)	0.0040	
Age (years)							0.9755
<= 65	88/129 (68.2)	24.00 (18.00, 24.57)	64/128 (50.0)	28.86 (24.14, 48.29)	1.58 (1.14, 2.19)	0.0061	
> 65	0/ 2 (0.0)	NE (NE, NE)	1/ 1 (100.0)	20.29 (NE, NE)	NE		
Sex							0.0291
male	14/ 15 (93.3)	16.14 (8.29, 23.86)	4/ 11 (36.4)	NE (16.14, NE)	5.75 (1.79, 18.43)	0.0022	
female	74/116 (63.8)	24.14 (20.14, 26.29)	61/118 (51.7)	27.00 (21.14, 42.29)	1.35 (0.96, 1.90)	0.0976	
Race							0.9625
White	51/ 77 (66.2)	23.86 (16.43, 25.71)	49/101 (48.5)	29.14 (20.57, NE)	1.45 (0.98, 2.15)	0.1372	
Black	12/ 20 (60.0)	28.14 (8.14, 41.29)	7/ 12 (58.3)	32.07 (14.14, NE)	1.44 (0.50, 4.09)	0.2263	
Other	22/ 30 (73.3)	21.14 (13.57, 28.29)	8/ 15 (53.3)	26.14 (16.14, NE)	2.02 (0.87, 4.71)	0.2701	
Ethnicity							0.6618
Hispanic/Latino	20/ 31 (64.5)	16.57 (12.43, 24.14)	17/ 31 (54.8)	25.14 (20.00, NE)	1.90 (0.97, 3.74)	0.0980	
Non-hispanic/Latino	65/ 96 (67.7)	24.29 (20.71, 28.29)	47/ 97 (48.5)	32.29 (21.29, NE)	1.53 (1.05, 2.23)	0.0397	
Geographic region							0.6609
EU	42/ 57 (73.7)	23.29 (17.71, 25.00)	35/ 65 (53.8)	21.29 (17.14, 48.29)	1.39 (0.87, 2.22)	0.2701	
non-EU	46/ 74 (62.2)	24.14 (16.57, 29.57)	30/ 64 (46.9)	29.14 (24.71, NE)	1.66 (1.04, 2.63)	0.0353	
Onset of disease							0.5778
Paediatric	11/ 15 (73.3)	24.71 (9.43, 33.86)	4/ 8 (50.0)	36.14 (20.14, NE)	1.51 (0.44, 5.23)	0.3908	
Adult	77/116 (66.4)	23.29 (17.29, 24.57)	61/121 (50.4)	28.29 (21.29, 48.29)	1.50 (1.07, 2.10)	0.0208	
ADA result							0.3988
Negative	79/116 (68.1)	24.14 (20.14, 25.00)	59/113 (52.2)	28.29 (20.71, 42.29)	1.47 (1.05, 2.07)	0.0294	
Positive (At any time)	9/ 14 (64.3)	16.57 (8.14, NE)	6/ 16 (37.5)	NE (21.14, NE)	2.59 (0.85, 7.88)	0.4316	
BMI (kg/m2) at enrolment							0.0703
< 30	66/ 90 (73.3)	23.29 (17.29, 24.29)	45/ 99 (45.5)	29.14 (21.29, NE)	1.92 (1.31, 2.81)	0.0009	
>= 30	22/ 41 (53.7)	29.00 (16.14, NE)	20/ 30 (66.7)	25.29 (17.29, 42.29)	0.93 (0.49, 1.75)	0.3739	

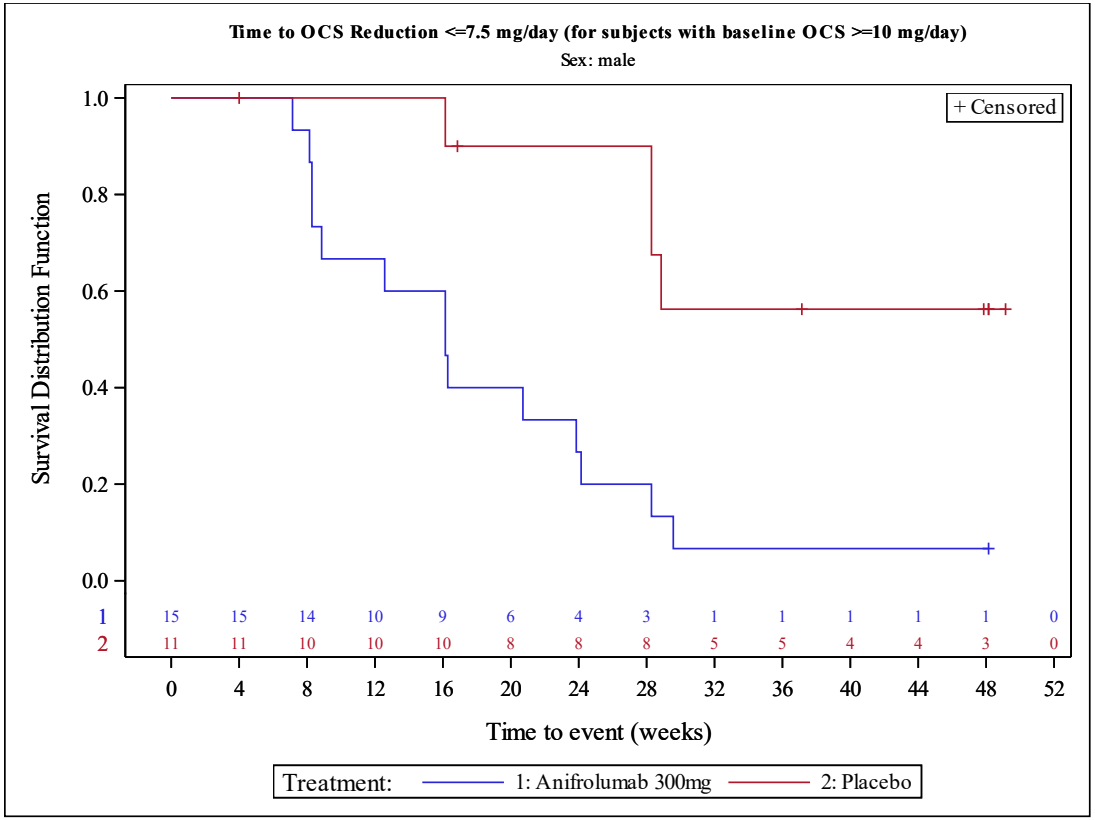
Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of Time to OCS Reduction <=7.5 mg/day (for subjects with baseline OCS >=10 mg/day)
Full analysis set



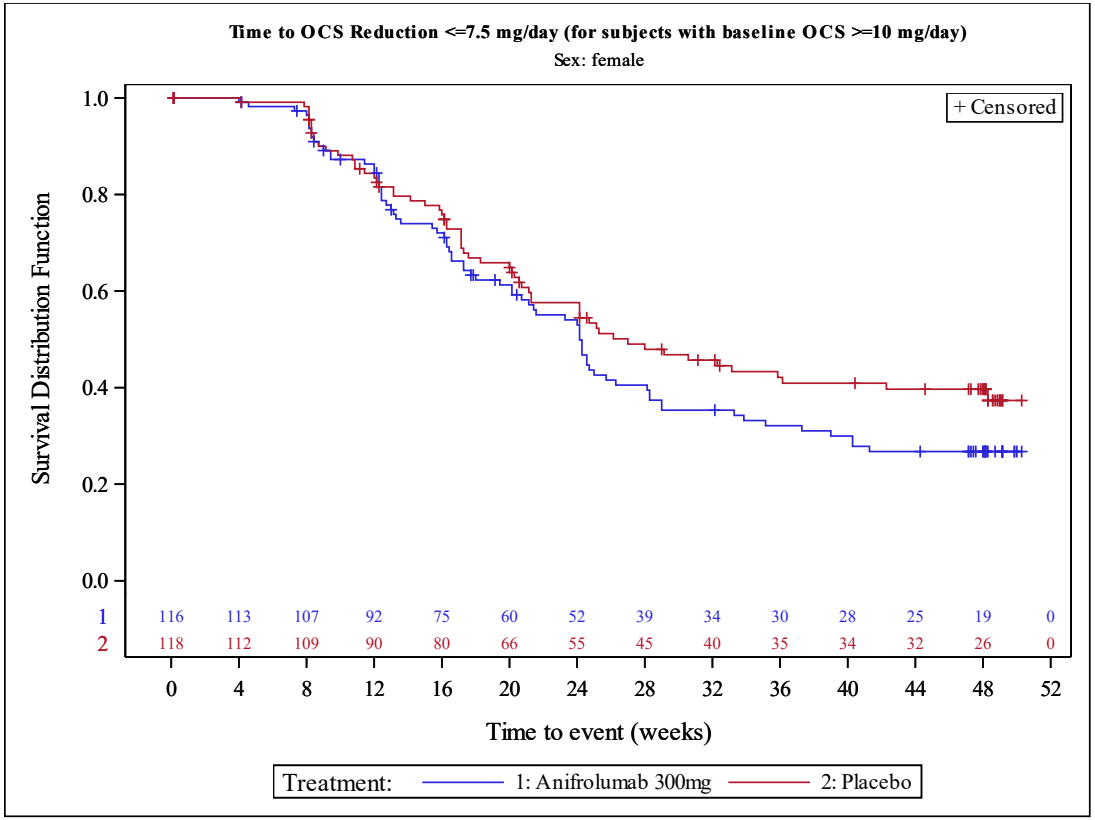
Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of Time to OCS Reduction <=7.5 mg/day (for subjects with baseline OCS >=10 mg/day)
Full analysis set



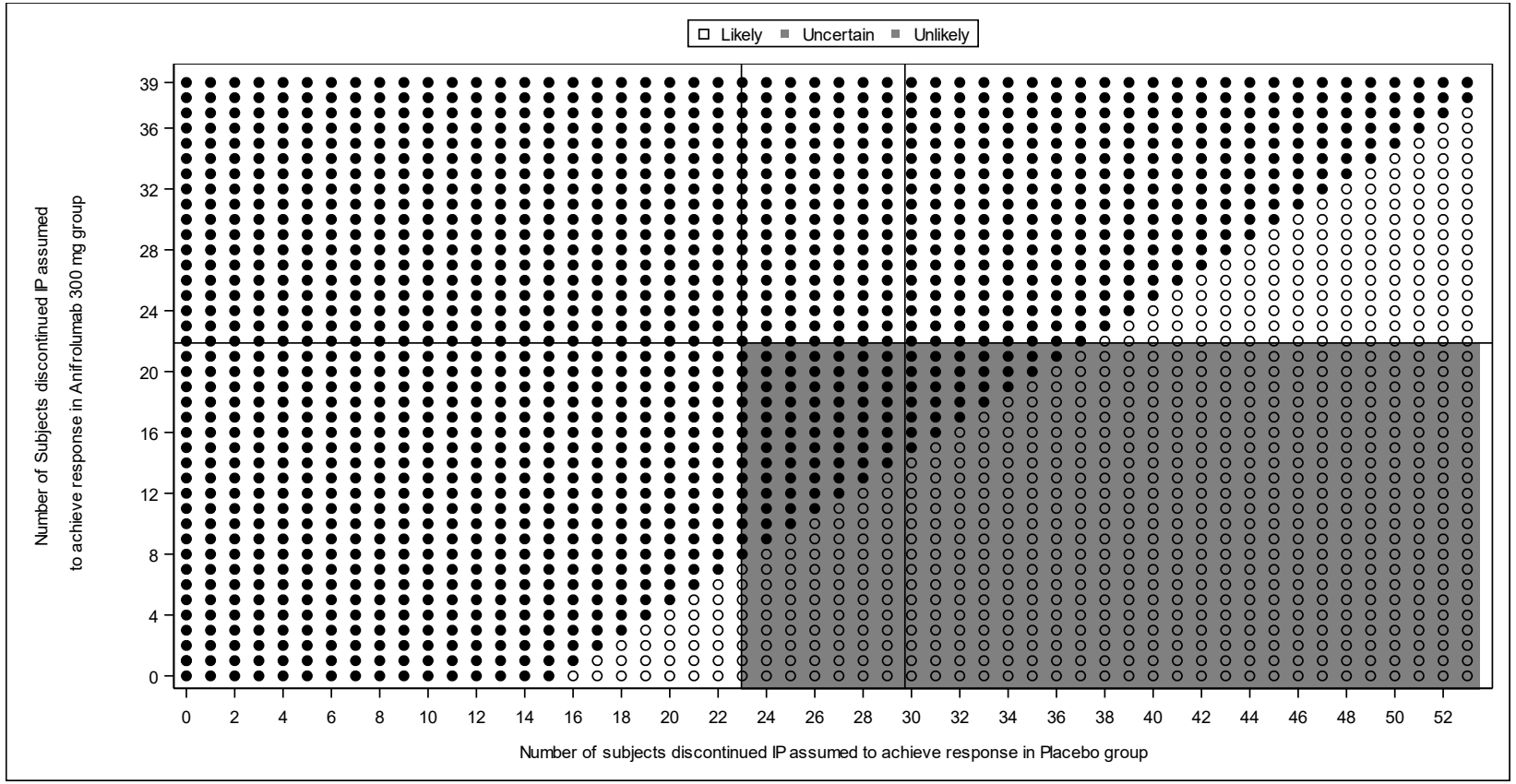
Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of Time to OCS Reduction <=7.5 mg/day (for subjects with baseline OCS >=10 mg/day)
Full analysis set



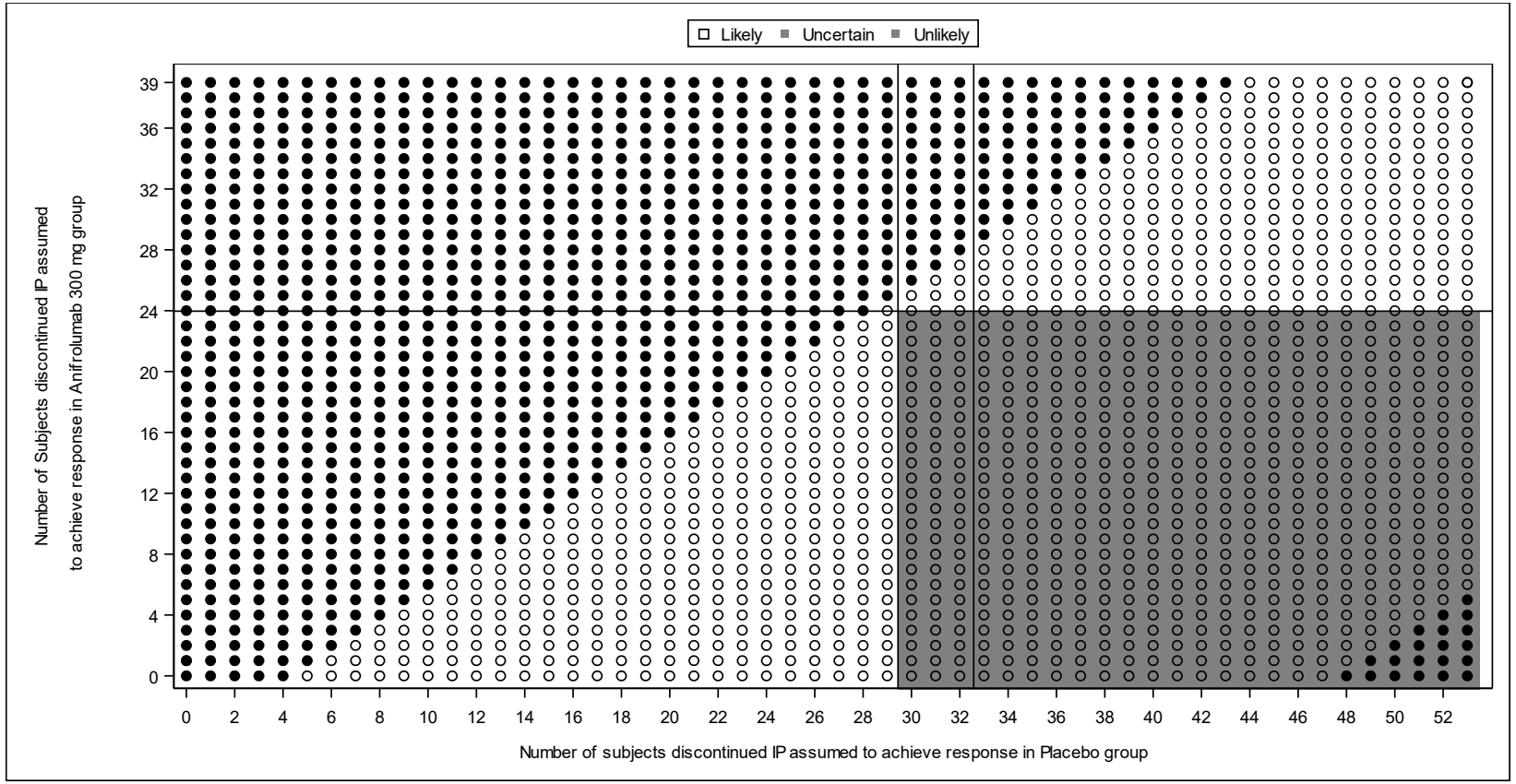
Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Plot of BICLA response rate sensitivity analysis at week 52, tipping point analysis
Full analysis set



Subjects with permanent discontinuation of IP are taken as non-responders at the bottom left grid. A certain number of such subjects from both groups are altered to be responders, while the numbers for both groups are as stated in both axes.
For each scenario, Pearson`s chi-squared test is used to compare the proportion of subjects achieving response at Week 52. The dots are presenting the results: filled = p-value <0.05, open = p-value >=0.05.
The three colors area indicate the tipping point area: white=likely, bright grey=uncertain, darker grey=Unlikely.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Plot of SRI (4) response rate sensitivity analysis at week 52, tipping point analysis
Full analysis set



Subjects with permanent discontinuation of IP are taken as non-responders at the bottom left grid. A certain number of such subjects from both groups are altered to be responders, while the numbers for both groups are as stated in both axes.
For each scenario, Pearson`s chi-squared test is used to compare the proportion of subjects achieving response at Week 52. The dots are presenting the results: filled = p-value <0.05, open = p-value >=0.05.
The three colors area indicate the tipping point area: white=likely, bright grey=uncertain, darker grey=Unlikely.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	219 (89.0)	198 (80.5)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.09 (1.01, 1.18)	
p-value	0.0207	
Odds Ratio (95% CI)	1.94 (1.16, 3.25)	
p-value	0.0114	
Risk Difference (95% CI)	8.57 (2.25, 14.90)	
p-value	0.0078	
CMH approach		
Response rate	89.1	80.2
Difference in response rates (95% CI)	8.88 (1.86, 15.90)	
p-value	0.0131	
p-Value for test for heterogenity between studies	0.0517	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8383
< 10 points	74/ 80 (92.5)	93.2	58/ 69 (84.1)	84.2	1.10 (0.98, 1.24)	0.1200	8.96 (-3.98, 21.89)	0.1746	
>= 10 points	145/166 (87.3)	87.2	140/177 (79.1)	78.6	1.08 (0.98, 1.19)	0.1005	8.61 (0.08, 17.14)	0.0478	
OCS dose at baseline									0.1410
<10 mg/day	107/115 (93.0)	92.9	103/117 (88.0)	87.6	1.03 (0.95, 1.12)	0.4313	5.31 (-4.25, 14.87)	0.2765	
>=10 mg/day	112/131 (85.5)	85.2	95/129 (73.6)	74.3	1.16 (1.02, 1.31)	0.0219	10.95 (0.63, 21.27)	0.0375	
Result of type I IFN gene signature test									0.4889
LOW	40/ 45 (88.9)	89.0	36/ 48 (75.0)	75.1	1.16 (0.96, 1.41)	0.1321	13.86 (-2.75, 30.48)	0.1020	
HIGH	179/201 (89.1)	89.1	162/198 (81.8)	81.4	1.08 (1.00, 1.17)	0.0649	7.71 (-0.03, 15.45)	0.0508	
Age (years)									0.0947
<= 65	214/239 (89.5)	89.6	195/243 (80.2)	80.1	1.10 (1.02, 1.19)	0.0120	9.53 (2.47, 16.60)	0.0082	
> 65	5/ 7 (71.4)	70.5	3/ 3 (100.0)	100.0	0.77 (0.50, 1.16)	0.2124	-29.55 (-94.33, 35.24)	0.3714	
Sex									0.6648
male	18/ 23 (78.3)	77.6	15/ 20 (75.0)	73.8	1.02 (0.71, 1.45)	0.9343	3.71 (-24.12, 31.55)	0.7937	
female	201/223 (90.1)	90.2	183/226 (81.0)	80.9	1.10 (1.02, 1.19)	0.0136	9.35 (2.06, 16.65)	0.0120	
Race									0.1090
White	140/160 (87.5)	87.0	135/174 (77.6)	78.0	1.12 (1.01, 1.23)	0.0283	9.00 (0.14, 17.87)	0.0466	
Black	28/ 33 (84.8)	84.3	26/ 32 (81.3)	82.2	1.02 (0.82, 1.27)	0.8407	2.15 (-19.02, 23.33)	0.8420	
Other	43/ 45 (95.6)	95.6	34/ 37 (91.9)	91.5	0.98 (0.90, 1.05)	0.5415	4.03 (-10.63, 18.70)	0.5899	
Ethnicity									0.9747
Hispanic/Latino	47/ 50 (94.0)	94.1	48/ 56 (85.7)	85.6	1.10 (0.97, 1.24)	0.1357	8.43 (-5.16, 22.02)	0.2242	
Non-hispanic/Latino	164/188 (87.2)	87.1	147/187 (78.6)	79.0	1.10 (1.00, 1.20)	0.0524	8.11 (-0.13, 16.35)	0.0536	
Geographic region									0.0887
EU	76/ 92 (82.6)	82.7	58/ 89 (65.2)	66.1	1.22 (1.03, 1.46)	0.0217	16.54 (3.73, 29.36)	0.0114	
non-EU	143/154 (92.9)	92.7	140/157 (89.2)	88.7	1.04 (0.97, 1.12)	0.2656	3.96 (-3.91, 11.83)	0.3241	
Onset of disease									0.1948
Paediatric	18/ 19 (94.7)	95.6	11/ 12 (91.7)	92.6	0.97 (0.83, 1.14)	0.7450	3.08 (-27.08, 33.24)	0.8414	
Adult	201/227 (88.5)	88.5	187/234 (79.9)	79.7	1.10 (1.01, 1.19)	0.0236	8.87 (1.54, 16.20)	0.0178	
ADA result									0.9297
Negative	202/226 (89.4)	89.5	178/223 (79.8)	79.6	1.11 (1.02, 1.20)	0.0111	9.92 (2.51, 17.34)	0.0087	
Positive (At any time)	17/ 19 (89.5)	90.5	20/ 23 (87.0)	83.6	1.13 (0.79, 1.61)	0.5136	6.91 (-19.82, 33.64)	0.6125	
BMI (kg/m2) at enrolment									0.9005
< 30	140/159 (88.1)	88.2	139/176 (79.0)	79.5	1.09 (0.99, 1.19)	0.0743	8.73 (0.28, 17.18)	0.0428	
>= 30	79/ 87 (90.8)	90.8	59/ 70 (84.3)	84.2	1.08 (0.95, 1.22)	0.2356	6.64 (-5.59, 18.87)	0.2874	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Serious Adverse Event
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	25 (10.2)	52 (21.1)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.49 (0.31, 0.76)	
p-value	0.0017	
Odds Ratio (95% CI)	0.43 (0.25, 0.72)	
p-value	0.0013	
Risk Difference (95% CI)	-10.97 (-17.33, -4.62)	
p-value	0.0007	
CMH approach		
Response rate	10.3	20.9
Difference in response rates (95% CI)	-10.53 (-17.55, -3.50)	
p-value	0.0033	
p-Value for test for heterogenity between studies	0.2518	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Serious Adverse Event - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9881
< 10 points	5/ 80 (6.3)	7.0	9/ 69 (13.0)	12.7	0.51 (0.18, 1.42)	0.1984	-5.70 (-18.41, 7.01)	0.3794	
>= 10 points	20/166 (12.0)	11.9	43/177 (24.3)	24.3	0.50 (0.31, 0.83)	0.0065	-12.46 (-21.10, -3.83)	0.0047	
OCS dose at baseline									0.9154
<10 mg/day	11/115 (9.6)	9.6	24/117 (20.5)	19.8	0.47 (0.24, 0.92)	0.0284	-10.16 (-20.30, -0.02)	0.0495	
>=10 mg/day	14/131 (10.7)	10.8	28/129 (21.7)	22.3	0.49 (0.27, 0.90)	0.0209	-11.46 (-21.47, -1.45)	0.0248	
Result of type I IFN gene signature test									0.1679
LOW	5/ 45 (11.1)	11.2	6/ 48 (12.5)	12.4	0.96 (0.34, 2.72)	0.9448	-1.17 (-16.19, 13.85)	0.8786	
HIGH	20/201 (10.0)	10.1	46/198 (23.2)	22.9	0.43 (0.26, 0.70)	0.0007	-12.72 (-20.65, -4.80)	0.0017	
Age (years)									0.2224
<= 65	23/239 (9.6)	9.8	52/243 (21.4)	21.2	0.45 (0.29, 0.72)	0.0008	-11.40 (-18.49, -4.30)	0.0016	
> 65	2/ 7 (28.6)	27.3	0/ 3 (0.0)	0.0	2.50 (0.17, 37.26)	0.5062	27.27 (-37.78, 92.32)	0.4112	
Sex									0.7963
male	2/ 23 (8.7)	9.9	4/ 20 (20.0)	20.5	0.62 (0.14, 2.85)	0.5409	-10.56 (-36.53, 15.41)	0.4254	
female	23/223 (10.3)	10.5	48/226 (21.2)	21.0	0.50 (0.32, 0.81)	0.0043	-10.57 (-17.98, -3.17)	0.0051	
Race									0.2523
White	18/160 (11.3)	11.4	32/174 (18.4)	18.5	0.62 (0.36, 1.06)	0.0818	-7.13 (-15.74, 1.49)	0.1051	
Black	2/ 33 (6.1)	5.1	9/ 32 (28.1)	29.7	0.23 (0.06, 0.88)	0.0318	-24.67 (-45.52, -3.82)	0.0204	
Other	3/ 45 (6.7)	6.5	11/ 37 (29.7)	29.4	0.27 (0.08, 0.97)	0.0441	-22.91 (-40.84, -4.97)	0.0123	
Ethnicity									0.6580
Hispanic/Latino	4/ 50 (8.0)	7.7	18/ 56 (32.1)	32.1	0.43 (0.16, 1.19)	0.1035	-24.32 (-39.75, -8.89)	0.0020	
Non-hispanic/Latino	19/188 (10.1)	10.4	34/187 (18.2)	18.2	0.56 (0.33, 0.94)	0.0294	-7.80 (-15.77, 0.18)	0.0553	
Geographic region									0.3703
EU	10/ 92 (10.9)	10.6	14/ 89 (15.7)	15.7	0.68 (0.31, 1.50)	0.3423	-5.11 (-15.85, 5.63)	0.3513	
non-EU	15/154 (9.7)	9.4	38/157 (24.2)	23.6	0.44 (0.25, 0.78)	0.0055	-14.25 (-23.08, -5.42)	0.0016	
Onset of disease									0.6031
Paediatric	4/ 19 (21.1)	19.6	7/ 12 (58.3)	58.5	0.37 (0.13, 1.03)	0.0574	-38.93 (-73.96, -3.90)	0.0294	
Adult	21/227 (9.3)	9.3	45/234 (19.2)	19.0	0.50 (0.31, 0.82)	0.0064	-9.68 (-16.78, -2.58)	0.0075	
ADA result									0.2211
Negative	24/226 (10.6)	10.8	42/223 (18.8)	18.6	0.57 (0.36, 0.91)	0.0190	-7.90 (-15.24, -0.56)	0.0349	
Positive (At any time)	1/ 19 (5.3)	4.7	10/ 23 (43.5)	39.3	0.20 (0.04, 1.01)	0.0516	-34.55 (-61.79, -7.30)	0.0130	
BMI (kg/m2) at enrolment									0.8877
< 30	16/159 (10.1)	10.2	36/176 (20.5)	20.2	0.50 (0.29, 0.87)	0.0136	-10.00 (-18.37, -1.63)	0.0192	
>= 30	9/ 87 (10.3)	10.1	16/ 70 (22.9)	22.7	0.47 (0.22, 1.01)	0.0544	-12.65 (-25.53, 0.23)	0.0543	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Severe Adverse Event
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	18 (7.3)	26 (10.6)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.71 (0.40, 1.26)	
p-value	0.2418	
Odds Ratio (95% CI)	0.67 (0.35, 1.28)	
p-value	0.2245	
Risk Difference (95% CI)	-3.30 (-8.31, 1.70)	
p-value	0.1961	
CMH approach		
Response rate	7.4	10.6
Difference in response rates (95% CI)	-3.21 (-9.45, 3.03)	
p-value	0.3135	
p-Value for test for heterogenity between studies	0.2641	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Severe Adverse Event - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.7583
< 10 points	4/ 80 (5.0)	5.0	6/ 69 (8.7)	8.4	0.61 (0.18, 2.05)	0.4206	-3.34 (-15.57, 8.89)	0.5924	
>= 10 points	14/166 (8.4)	8.2	20/177 (11.3)	11.5	0.75 (0.39, 1.45)	0.3967	-3.27 (-10.75, 4.21)	0.3909	
OCS dose at baseline									0.7229
<10 mg/day	6/115 (5.2)	4.9	10/117 (8.5)	8.7	0.61 (0.23, 1.67)	0.3392	-3.81 (-12.60, 4.98)	0.3961	
>=10 mg/day	12/131 (9.2)	9.4	16/129 (12.4)	12.4	0.77 (0.38, 1.56)	0.4644	-3.06 (-12.26, 6.15)	0.5152	
Result of type I IFN gene signature test									0.8580
LOW	3/ 45 (6.7)	6.7	4/ 48 (8.3)	8.3	0.80 (0.19, 3.38)	0.7669	-1.59 (-15.53, 12.34)	0.8227	
HIGH	15/201 (7.5)	7.5	22/198 (11.1)	11.1	0.70 (0.37, 1.32)	0.2672	-3.59 (-10.57, 3.39)	0.3133	
Age (years)									NE
<= 65	18/239 (7.5)	7.6	26/243 (10.7)	10.7	0.72 (0.41, 1.29)	0.2701	-3.12 (-9.48, 3.23)	0.3355	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-62.98, 62.98)	1.0000	
Sex									0.7405
male	1/ 23 (4.3)	3.8	2/ 20 (10.0)	10.2	0.52 (0.07, 3.83)	0.5178	-6.44 (-29.93, 17.06)	0.5914	
female	17/223 (7.6)	7.7	24/226 (10.6)	10.5	0.73 (0.41, 1.33)	0.3108	-2.77 (-9.41, 3.87)	0.4140	
Race									0.3234
White	11/160 (6.9)	7.2	16/174 (9.2)	9.1	0.97 (0.43, 2.19)	0.9484	-1.82 (-9.44, 5.79)	0.6385	
Black	3/ 33 (9.1)	7.6	7/ 32 (21.9)	26.3	0.34 (0.11, 1.05)	0.0615	-18.72 (-39.27, 1.84)	0.0743	
Other	2/ 45 (4.4)	4.4	3/ 37 (8.1)	8.3	0.54 (0.09, 3.11)	0.4869	-3.84 (-18.69, 11.01)	0.6124	
Ethnicity									0.4589
Hispanic/Latino	4/ 50 (8.0)	7.9	11/ 56 (19.6)	19.6	0.48 (0.15, 1.51)	0.2108	-11.70 (-26.22, 2.83)	0.1144	
Non-hispanic/Latino	12/188 (6.4)	6.7	15/187 (8.0)	8.4	0.80 (0.39, 1.67)	0.5586	-1.64 (-8.52, 5.24)	0.6409	
Geographic region									0.1038
EU	7/ 92 (7.6)	7.7	4/ 89 (4.5)	4.4	1.75 (0.52, 5.88)	0.3649	3.36 (-5.31, 12.03)	0.4475	
non-EU	11/154 (7.1)	6.8	22/157 (14.0)	14.3	0.55 (0.27, 1.11)	0.0950	-7.48 (-15.52, 0.57)	0.0685	
Onset of disease									0.1689
Paediatric	2/ 19 (10.5)	10.9	5/ 12 (41.7)	41.5	0.26 (0.06, 1.13)	0.0731	-30.62 (-64.93, 3.69)	0.0802	
Adult	16/227 (7.0)	7.1	21/234 (9.0)	9.1	0.80 (0.42, 1.51)	0.4919	-2.01 (-8.36, 4.34)	0.5349	
ADA result									0.2487
Negative	16/226 (7.1)	7.3	19/223 (8.5)	8.5	0.86 (0.45, 1.63)	0.6384	-1.22 (-7.68, 5.25)	0.7124	
Positive (At any time)	2/ 19 (10.5)	9.5	7/ 23 (30.4)	33.1	0.36 (0.10, 1.34)	0.1281	-23.64 (-51.79, 4.52)	0.0999	
BMI (kg/m2) at enrolment									0.3942
< 30	10/159 (6.3)	6.3	14/176 (8.0)	7.8	0.86 (0.39, 1.91)	0.7084	-1.52 (-8.56, 5.51)	0.6710	
>= 30	8/ 87 (9.2)	9.0	12/ 70 (17.1)	17.5	0.52 (0.23, 1.20)	0.1239	-8.45 (-20.80, 3.89)	0.1793	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Non-Severe Adverse Event
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	217 (88.2)	195 (79.3)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.10 (1.02, 1.19)	
p-value	0.0180	
Odds Ratio (95% CI)	1.95 (1.18, 3.21)	
p-value	0.0088	
Risk Difference (95% CI)	8.99 (2.51, 15.47)	
p-value	0.0065	
CMH approach		
Response rate	88.3	79.0
Difference in response rates (95% CI)	9.32 (2.21, 16.44)	
p-value	0.0102	
p-Value for test for heterogenity between studies	0.0720	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Non-Severe Adverse Event - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=246)		Placebo (N=246)		Analysis Anifrolumab 300mg vs. Placebo				Interaction
Level	n/ N (%)	Response rate	n/ N (%)	Response rate	Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	p-Value
SLEDAI-2K score at screening									0.9029
< 10 points	73/ 80 (91.3)	92.0	58/ 69 (84.1)	84.2	1.09 (0.96, 1.23)	0.1946	7.77 (-5.24, 20.78)	0.2419	
>= 10 points	144/166 (86.7)	86.6	137/177 (77.4)	76.8	1.10 (0.99, 1.21)	0.0677	9.75 (1.09, 18.41)	0.0274	
OCS dose at baseline									0.1148
<10 mg/day	107/115 (93.0)	92.9	103/117 (88.0)	87.6	1.03 (0.95, 1.12)	0.4313	5.31 (-4.25, 14.87)	0.2765	
>=10 mg/day	110/131 (84.0)	83.7	92/129 (71.3)	71.9	1.17 (1.03, 1.34)	0.0183	11.79 (1.24, 22.34)	0.0285	
Result of type I IFN gene signature test									0.5333
LOW	40/ 45 (88.9)	89.0	36/ 48 (75.0)	75.1	1.16 (0.96, 1.41)	0.1321	13.86 (-2.75, 30.48)	0.1020	
HIGH	177/201 (88.1)	88.2	159/198 (80.3)	79.9	1.09 (1.00, 1.18)	0.0527	8.26 (0.39, 16.13)	0.0397	
Age (years)									0.0907
<= 65	212/239 (88.7)	88.8	192/243 (79.0)	78.8	1.11 (1.02, 1.20)	0.0106	9.99 (2.83, 17.16)	0.0062	
> 65	5/ 7 (71.4)	70.5	3/ 3 (100.0)	100.0	0.77 (0.50, 1.16)	0.2124	-29.55 (-94.33, 35.24)	0.3714	
Sex									0.6439
male	18/ 23 (78.3)	77.6	15/ 20 (75.0)	73.8	1.02 (0.71, 1.45)	0.9343	3.71 (-24.12, 31.55)	0.7937	
female	199/223 (89.2)	89.4	180/226 (79.6)	79.6	1.11 (1.02, 1.20)	0.0119	9.80 (2.39, 17.20)	0.0096	
Race									0.0649
White	139/160 (86.9)	86.3	132/174 (75.9)	76.4	1.13 (1.02, 1.25)	0.0183	9.89 (0.91, 18.86)	0.0309	
Black	28/ 33 (84.8)	84.3	26/ 32 (81.3)	82.2	1.02 (0.82, 1.27)	0.8407	2.15 (-19.02, 23.33)	0.8420	
Other	42/ 45 (93.3)	93.5	34/ 37 (91.9)	91.5	0.97 (0.90, 1.05)	0.4498	1.92 (-13.09, 16.93)	0.8021	
Ethnicity									0.9195
Hispanic/Latino	46/ 50 (92.0)	92.1	47/ 56 (83.9)	83.9	1.11 (0.97, 1.27)	0.1398	8.23 (-5.90, 22.35)	0.2536	
Non-hispanic/Latino	163/188 (86.7)	86.5	145/187 (77.5)	78.0	1.10 (1.00, 1.21)	0.0516	8.54 (0.23, 16.85)	0.0439	
Geographic region									0.0874
EU	75/ 92 (81.5)	81.4	56/ 89 (62.9)	64.1	1.23 (1.03, 1.47)	0.0220	17.37 (4.40, 30.34)	0.0087	
non-EU	142/154 (92.2)	92.0	139/157 (88.5)	88.2	1.04 (0.97, 1.12)	0.2775	3.86 (-4.13, 11.84)	0.3436	
Onset of disease									0.1881
Paediatric	18/ 19 (94.7)	95.6	10/ 12 (83.3)	85.1	0.96 (0.81, 1.15)	0.6840	10.52 (-20.44, 41.48)	0.5055	
Adult	199/227 (87.7)	87.7	185/234 (79.1)	78.8	1.10 (1.01, 1.19)	0.0249	8.87 (1.46, 16.28)	0.0190	
ADA result									0.5746
Negative	200/226 (88.5)	88.6	176/223 (78.9)	78.7	1.11 (1.02, 1.20)	0.0125	9.97 (2.47, 17.48)	0.0092	
Positive (At any time)	17/ 19 (89.5)	90.5	19/ 23 (82.6)	78.2	1.25 (0.83, 1.89)	0.2867	12.36 (-14.94, 39.67)	0.3748	
BMI (kg/m2) at enrolment									0.8482
< 30	138/159 (86.8)	87.0	136/176 (77.3)	77.8	1.09 (0.99, 1.20)	0.0682	9.18 (0.56, 17.81)	0.0369	
>= 30	79/ 87 (90.8)	90.8	59/ 70 (84.3)	84.2	1.08 (0.95, 1.22)	0.2356	6.64 (-5.59, 18.87)	0.2874	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event leading to discontinuation of study drug
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	11 (4.5)	17 (6.9)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.70 (0.32, 1.55)	
p-value	0.3807	
Odds Ratio (95% CI)	0.68 (0.29, 1.57)	
p-value	0.3645	
Risk Difference (95% CI)	-2.44 (-6.54, 1.66)	
p-value	0.2439	
CMH approach		
Response rate	4.5	6.9
Difference in response rates (95% CI)	-2.40 (-8.10, 3.31)	
p-value	0.4103	
p-Value for test for heterogenity between studies	0.0601	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event leading to discontinuation of study drug - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.3933
< 10 points	4/ 80 (5.0)	5.3	3/ 69 (4.3)	4.5	1.29 (0.23, 7.41)	0.7723	0.80 (-10.96, 12.55)	0.8941	
>= 10 points	7/166 (4.2)	4.3	14/177 (7.9)	8.0	0.55 (0.22, 1.36)	0.1940	-3.77 (-10.49, 2.96)	0.2725	
OCS dose at baseline									0.9018
<10 mg/day	4/115 (3.5)	3.5	7/117 (6.0)	6.1	0.66 (0.17, 2.53)	0.5415	-2.63 (-11.11, 5.86)	0.5436	
>=10 mg/day	7/131 (5.3)	5.7	10/129 (7.8)	7.9	0.73 (0.27, 1.96)	0.5313	-2.24 (-10.43, 5.96)	0.5931	
Result of type I IFN gene signature test									0.6900
LOW	3/ 45 (6.7)	6.7	3/ 48 (6.3)	6.3	0.91 (0.16, 5.32)	0.9173	0.37 (-13.18, 13.92)	0.9573	
HIGH	8/201 (4.0)	4.0	14/198 (7.1)	7.0	0.61 (0.25, 1.48)	0.2752	-3.05 (-9.33, 3.24)	0.3419	
Age (years)									0.5808
<= 65	10/239 (4.2)	4.2	17/243 (7.0)	7.0	0.64 (0.29, 1.45)	0.2879	-2.81 (-8.57, 2.96)	0.3402	
> 65	1/ 7 (14.3)	13.6	0/ 3 (0.0)	0.0	1.50 (0.08, 26.86)	0.7830	13.64 (-50.73, 78.01)	0.6780	
Sex									NE
male	0/ 23 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-20.84, 20.84)	1.0000	
female	11/223 (4.9)	5.0	17/226 (7.5)	7.5	0.71 (0.32, 1.58)	0.4028	-2.56 (-8.73, 3.61)	0.4163	
Race									0.8623
White	7/160 (4.4)	4.6	11/174 (6.3)	6.3	0.76 (0.27, 2.12)	0.5951	-1.70 (-8.78, 5.39)	0.6384	
Black	1/ 33 (3.0)	2.5	1/ 32 (3.1)	4.0	0.64 (0.04, 9.37)	0.7419	-1.44 (-18.39, 15.50)	0.8673	
Other	2/ 45 (4.4)	4.2	5/ 37 (13.5)	13.5	0.45 (0.10, 2.14)	0.3154	-9.28 (-25.00, 6.44)	0.2471	
Ethnicity									0.1652
Hispanic/Latino	2/ 50 (4.0)	4.0	8/ 56 (14.3)	14.4	0.28 (0.06, 1.25)	0.0945	-10.36 (-23.62, 2.89)	0.1254	
Non-hispanic/Latino	8/188 (4.3)	4.3	9/187 (4.8)	4.6	1.10 (0.32, 3.81)	0.8766	-0.27 (-6.59, 6.05)	0.9326	
Geographic region									0.3980
EU	4/ 92 (4.3)	4.6	3/ 89 (3.4)	3.6	1.22 (0.24, 6.17)	0.8098	1.00 (-6.99, 8.99)	0.8070	
non-EU	7/154 (4.5)	4.5	14/157 (8.9)	8.6	0.54 (0.21, 1.39)	0.2029	-4.03 (-11.32, 3.26)	0.2790	
Onset of disease									0.6603
Paediatric	1/ 19 (5.3)	4.4	2/ 12 (16.7)	14.9	0.49 (0.06, 3.95)	0.5006	-10.52 (-41.48, 20.44)	0.5055	
Adult	10/227 (4.4)	4.3	15/234 (6.4)	6.3	0.81 (0.32, 2.04)	0.6596	-1.96 (-7.81, 3.90)	0.5126	
ADA result									0.9953
Negative	9/226 (4.0)	4.0	13/223 (5.8)	5.9	0.72 (0.29, 1.74)	0.4626	-1.88 (-7.83, 4.07)	0.5358	
Positive (At any time)	2/ 19 (10.5)	9.5	4/ 23 (17.4)	16.7	0.71 (0.15, 3.29)	0.6641	-7.27 (-33.73, 19.19)	0.5901	
BMI (kg/m2) at enrolment									0.8963
< 30	9/159 (5.7)	5.7	14/176 (8.0)	8.2	0.75 (0.32, 1.77)	0.5174	-2.49 (-9.45, 4.46)	0.4823	
>= 30	2/ 87 (2.3)	2.2	3/ 70 (4.3)	4.2	0.66 (0.10, 4.22)	0.6597	-2.00 (-11.87, 7.86)	0.6907	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Serious Adverse Event leading to discontinuation of study drug
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	5 (2.0)	10 (4.1)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.58 (0.19, 1.83)	
p-value	0.3575	
Odds Ratio (95% CI)	0.57 (0.18, 1.84)	
p-value	0.3474	
Risk Difference (95% CI)	-2.03 (-5.07, 1.00)	
p-value	0.1887	
CMH approach		
Response rate	2.0	4.1
Difference in response rates (95% CI)	-2.13 (-7.32, 3.05)	
p-value	0.4196	
p-Value for test for heterogenity between studies	0.1688	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Serious Adverse Event leading to discontinuation of study drug - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.0418
< 10 points	3/ 80 (3.8)	4.0	0/ 69 (0.0)	0.0	6.65 (0.36, 124.51)	0.2050	4.02 (-7.06, 15.09)	0.4771	
>= 10 points	2/166 (1.2)	1.2	10/177 (5.6)	5.9	0.22 (0.05, 0.98)	0.0470	-4.69 (-10.80, 1.42)	0.1325	
OCS dose at baseline									0.1618
<10 mg/day	2/115 (1.7)	1.8	0/117 (0.0)	0.0	3.03 (0.32, 28.74)	0.3335	1.84 (-5.68, 9.36)	0.6311	
>=10 mg/day	3/131 (2.3)	2.3	10/129 (7.8)	7.9	0.47 (0.13, 1.74)	0.2617	-5.60 (-13.38, 2.17)	0.1578	
Result of type I IFN gene signature test									0.2479
LOW	1/ 45 (2.2)	2.2	0/ 48 (0.0)	0.0	3.26 (0.14, 76.10)	0.4621	2.25 (-8.98, 13.47)	0.6948	
HIGH	4/201 (2.0)	1.9	10/198 (5.1)	5.1	0.45 (0.13, 1.49)	0.1896	-3.16 (-9.00, 2.67)	0.2877	
Age (years)									0.4611
<= 65	4/239 (1.7)	1.6	10/243 (4.1)	4.2	0.46 (0.14, 1.55)	0.2111	-2.61 (-7.84, 2.62)	0.3282	
> 65	1/ 7 (14.3)	13.6	0/ 3 (0.0)	0.0	1.50 (0.08, 26.86)	0.7830	13.64 (-50.73, 78.01)	0.6780	
Sex									NE
male	0/ 23 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-20.84, 20.84)	1.0000	
female	5/223 (2.2)	2.2	10/226 (4.4)	4.5	0.60 (0.19, 1.87)	0.3766	-2.32 (-7.93, 3.29)	0.4178	
Race									0.6913
White	4/160 (2.5)	2.6	6/174 (3.4)	3.4	0.78 (0.17, 3.63)	0.7488	-0.84 (-7.42, 5.73)	0.8017	
Black	0/ 33 (0.0)	0.0	1/ 32 (3.1)	4.0	0.22 (0.01, 4.99)	0.3399	-3.97 (-20.42, 12.47)	0.6359	
Other	1/ 45 (2.2)	2.1	3/ 37 (8.1)	8.3	0.34 (0.05, 2.22)	0.2621	-6.15 (-20.50, 8.20)	0.4011	
Ethnicity									0.4358
Hispanic/Latino	1/ 50 (2.0)	1.9	5/ 56 (8.9)	8.9	0.34 (0.05, 2.08)	0.2406	-6.98 (-18.90, 4.95)	0.2515	
Non-hispanic/Latino	4/188 (2.1)	2.0	5/187 (2.7)	2.5	0.84 (0.21, 3.35)	0.7995	-0.52 (-6.35, 5.31)	0.8618	
Geographic region									0.8306
EU	1/ 92 (1.1)	1.2	3/ 89 (3.4)	3.6	0.46 (0.06, 3.50)	0.4538	-2.39 (-9.61, 4.83)	0.5161	
non-EU	4/154 (2.6)	2.6	7/157 (4.5)	4.4	0.60 (0.17, 2.13)	0.4285	-1.78 (-8.39, 4.83)	0.5979	
Onset of disease									0.9375
Paediatric	1/ 19 (5.3)	4.4	1/ 12 (8.3)	7.4	0.67 (0.08, 5.78)	0.7142	-3.08 (-33.24, 27.08)	0.8414	
Adult	4/227 (1.8)	1.6	9/234 (3.8)	3.8	0.74 (0.20, 2.74)	0.6517	-2.18 (-7.51, 3.15)	0.4232	
ADA result									0.3451
Negative	5/226 (2.2)	2.1	6/223 (2.7)	2.8	0.91 (0.24, 3.45)	0.8951	-0.66 (-6.11, 4.79)	0.8121	
Positive (At any time)	0/ 19 (0.0)	0.0	4/ 23 (17.4)	16.7	0.28 (0.04, 2.19)	0.2260	-16.73 (-41.37, 7.92)	0.1834	
BMI (kg/m2) at enrolment									0.8468
< 30	4/159 (2.5)	2.4	8/176 (4.5)	4.5	0.64 (0.18, 2.26)	0.4880	-2.07 (-8.22, 4.07)	0.5083	
>= 30	1/ 87 (1.1)	1.1	2/ 70 (2.9)	2.9	0.50 (0.06, 4.00)	0.5163	-1.83 (-11.28, 7.62)	0.7043	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with Adverse Event leading to death
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	1 (0.4)	1 (0.4)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.98 (0.06, 15.56)	
p-value	0.9910	
Odds Ratio (95% CI)	0.98 (0.06, 15.91)	
p-value	0.9910	
Risk Difference (95% CI)	-0.01 (-1.13, 1.12)	
p-value	0.9910	
CMH approach		
Response rate	0.4	0.4
Difference in response rates (95% CI)	-0.04 (-4.61, 4.52)	
p-value	0.9858	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with Adverse Event leading to death - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.3494
< 10 points	1/ 80 (1.3)	1.2	0/ 69 (0.0)	0.0	2.85 (0.12, 67.83)	0.5172	1.19 (-9.61, 11.99)	0.8294	
>= 10 points	0/166 (0.0)	0.0	1/177 (0.6)	0.6	0.33 (0.01, 8.07)	0.4993	-0.57 (-5.71, 4.58)	0.8286	
OCS dose at baseline									NE
<10 mg/day	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE		0.00 (-7.19, 7.19)	1.0000	
>=10 mg/day	1/131 (0.8)	0.7	1/129 (0.8)	0.8	1.04 (0.07, 16.35)	0.9762	-0.08 (-6.62, 6.46)	0.9811	
Result of type I IFN gene signature test									NE
LOW	0/ 45 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-10.61, 10.61)	1.0000	
HIGH	1/201 (0.5)	0.4	1/198 (0.5)	0.5	0.96 (0.06, 15.17)	0.9780	-0.05 (-5.11, 5.00)	0.9842	
Age (years)									NE
<= 65	1/239 (0.4)	0.3	1/243 (0.4)	0.4	1.01 (0.06, 15.94)	0.9954	-0.06 (-4.71, 4.59)	0.9803	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-62.98, 62.98)	1.0000	
Sex									NE
male	0/ 23 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-20.84, 20.84)	1.0000	
female	1/223 (0.4)	0.4	1/226 (0.4)	0.4	1.02 (0.06, 16.07)	0.9902	-0.02 (-4.97, 4.92)	0.9928	
Race									0.2981
White	0/160 (0.0)	0.0	0/174 (0.0)	0.0	NE		0.00 (-5.80, 5.80)	1.0000	
Black	0/ 33 (0.0)	0.0	1/ 32 (3.1)	4.0	0.22 (0.01, 4.99)	0.3399	-3.97 (-20.42, 12.47)	0.6359	
Other	1/ 45 (2.2)	2.1	0/ 37 (0.0)	0.0	2.29 (0.10, 52.48)	0.6051	2.11 (-10.33, 14.56)	0.7392	
Ethnicity									0.3216
Hispanic/Latino	1/ 50 (2.0)	1.9	0/ 56 (0.0)	0.0	3.13 (0.13, 73.01)	0.4785	1.94 (-8.04, 11.91)	0.7038	
Non-hispanic/Latino	0/188 (0.0)	0.0	1/187 (0.5)	0.5	0.32 (0.01, 7.86)	0.4883	-0.50 (-5.79, 4.78)	0.8520	
Geographic region									NE
EU	0/ 92 (0.0)	0.0	0/ 89 (0.0)	0.0	NE		0.00 (-5.86, 5.86)	1.0000	
non-EU	1/154 (0.6)	0.7	1/157 (0.6)	0.7	0.86 (0.05, 13.53)	0.9161	-0.07 (-5.86, 5.73)	0.9820	
Onset of disease									NE
Paediatric	0/ 19 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-28.28, 28.28)	1.0000	
Adult	1/227 (0.4)	0.4	1/234 (0.4)	0.4	0.99 (0.06, 15.67)	0.9952	-0.03 (-4.86, 4.80)	0.9909	
ADA result									NE
Negative	1/226 (0.4)	0.4	1/223 (0.4)	0.4	1.01 (0.06, 15.93)	0.9949	-0.04 (-5.00, 4.91)	0.9863	
Positive (At any time)	0/ 19 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-21.63, 21.63)	1.0000	
BMI (kg/m2) at enrolment									0.2424
< 30	1/159 (0.6)	0.6	0/176 (0.0)	0.0	3.52 (0.15, 85.13)	0.4388	0.56 (-4.59, 5.72)	0.8301	
>= 30	0/ 87 (0.0)	0.0	1/ 70 (1.4)	1.6	0.24 (0.01, 5.75)	0.3792	-1.56 (-10.60, 7.49)	0.7361	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Anaphylaxis
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.48, 4.48)	
p-value	1.0000	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Anaphylaxis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-10.64, 10.64)	1.0000	
>= 10 points	0/166 (0.0)	0.0	0/177 (0.0)	0.0	NE	0.00 (-5.04, 5.04)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-7.19, 7.19)	1.0000	
>=10 mg/day	0/131 (0.0)	0.0	0/129 (0.0)	0.0	NE	0.00 (-6.32, 6.32)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 45 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-10.61, 10.61)	1.0000	
HIGH	0/201 (0.0)	0.0	0/198 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
Age (years)								NE
<= 65	0/239 (0.0)	0.0	0/243 (0.0)	0.0	NE	0.00 (-4.56, 4.56)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-62.98, 62.98)	1.0000	
Sex								NE
male	0/ 23 (0.0)	0.0	0/ 20 (0.0)	0.0	NE	0.00 (-20.84, 20.84)	1.0000	
female	0/223 (0.0)	0.0	0/226 (0.0)	0.0	NE	0.00 (-4.85, 4.85)	1.0000	
Race								NE
White	0/160 (0.0)	0.0	0/174 (0.0)	0.0	NE	0.00 (-5.80, 5.80)	1.0000	
Black	0/ 33 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.38, 15.38)	1.0000	
Other	0/ 45 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-11.98, 11.98)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 50 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.46, 9.46)	1.0000	
Non-hispanic/Latino	0/188 (0.0)	0.0	0/187 (0.0)	0.0	NE	0.00 (-5.21, 5.21)	1.0000	
Geographic region								NE
EU	0/ 92 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-5.86, 5.86)	1.0000	
non-EU	0/154 (0.0)	0.0	0/157 (0.0)	0.0	NE	0.00 (-5.56, 5.56)	1.0000	
Onset of disease								NE
Paediatric	0/ 19 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-28.28, 28.28)	1.0000	
Adult	0/227 (0.0)	0.0	0/234 (0.0)	0.0	NE	0.00 (-4.74, 4.74)	1.0000	
ADA result								NE
Negative	0/226 (0.0)	0.0	0/223 (0.0)	0.0	NE	0.00 (-4.87, 4.87)	1.0000	
Positive (At any time)	0/ 19 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-21.63, 21.63)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/159 (0.0)	0.0	0/176 (0.0)	0.0	NE	0.00 (-5.09, 5.09)	1.0000	
>= 30	0/ 87 (0.0)	0.0	0/ 70 (0.0)	0.0	NE	0.00 (-8.73, 8.73)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Anaphylaxis
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.48, 4.48)	
p-value	1.0000	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Anaphylaxis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-10.64, 10.64)	1.0000	
>= 10 points	0/166 (0.0)	0.0	0/177 (0.0)	0.0	NE	0.00 (-5.04, 5.04)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-7.19, 7.19)	1.0000	
>=10 mg/day	0/131 (0.0)	0.0	0/129 (0.0)	0.0	NE	0.00 (-6.32, 6.32)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 45 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-10.61, 10.61)	1.0000	
HIGH	0/201 (0.0)	0.0	0/198 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
Age (years)								NE
<= 65	0/239 (0.0)	0.0	0/243 (0.0)	0.0	NE	0.00 (-4.56, 4.56)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-62.98, 62.98)	1.0000	
Sex								NE
male	0/ 23 (0.0)	0.0	0/ 20 (0.0)	0.0	NE	0.00 (-20.84, 20.84)	1.0000	
female	0/223 (0.0)	0.0	0/226 (0.0)	0.0	NE	0.00 (-4.85, 4.85)	1.0000	
Race								NE
White	0/160 (0.0)	0.0	0/174 (0.0)	0.0	NE	0.00 (-5.80, 5.80)	1.0000	
Black	0/ 33 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.38, 15.38)	1.0000	
Other	0/ 45 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-11.98, 11.98)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 50 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.46, 9.46)	1.0000	
Non-hispanic/Latino	0/188 (0.0)	0.0	0/187 (0.0)	0.0	NE	0.00 (-5.21, 5.21)	1.0000	
Geographic region								NE
EU	0/ 92 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-5.86, 5.86)	1.0000	
non-EU	0/154 (0.0)	0.0	0/157 (0.0)	0.0	NE	0.00 (-5.56, 5.56)	1.0000	
Onset of disease								NE
Paediatric	0/ 19 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-28.28, 28.28)	1.0000	
Adult	0/227 (0.0)	0.0	0/234 (0.0)	0.0	NE	0.00 (-4.74, 4.74)	1.0000	
ADA result								NE
Negative	0/226 (0.0)	0.0	0/223 (0.0)	0.0	NE	0.00 (-4.87, 4.87)	1.0000	
Positive (At any time)	0/ 19 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-21.63, 21.63)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/159 (0.0)	0.0	0/176 (0.0)	0.0	NE	0.00 (-5.09, 5.09)	1.0000	
>= 30	0/ 87 (0.0)	0.0	0/ 70 (0.0)	0.0	NE	0.00 (-8.73, 8.73)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Anaphylaxis
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.48, 4.48)	
p-value	1.0000	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Anaphylaxis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-10.64, 10.64)	1.0000	
>= 10 points	0/166 (0.0)	0.0	0/177 (0.0)	0.0	NE	0.00 (-5.04, 5.04)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-7.19, 7.19)	1.0000	
>=10 mg/day	0/131 (0.0)	0.0	0/129 (0.0)	0.0	NE	0.00 (-6.32, 6.32)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 45 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-10.61, 10.61)	1.0000	
HIGH	0/201 (0.0)	0.0	0/198 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
Age (years)								NE
<= 65	0/239 (0.0)	0.0	0/243 (0.0)	0.0	NE	0.00 (-4.56, 4.56)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-62.98, 62.98)	1.0000	
Sex								NE
male	0/ 23 (0.0)	0.0	0/ 20 (0.0)	0.0	NE	0.00 (-20.84, 20.84)	1.0000	
female	0/223 (0.0)	0.0	0/226 (0.0)	0.0	NE	0.00 (-4.85, 4.85)	1.0000	
Race								NE
White	0/160 (0.0)	0.0	0/174 (0.0)	0.0	NE	0.00 (-5.80, 5.80)	1.0000	
Black	0/ 33 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.38, 15.38)	1.0000	
Other	0/ 45 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-11.98, 11.98)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 50 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.46, 9.46)	1.0000	
Non-hispanic/Latino	0/188 (0.0)	0.0	0/187 (0.0)	0.0	NE	0.00 (-5.21, 5.21)	1.0000	
Geographic region								NE
EU	0/ 92 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-5.86, 5.86)	1.0000	
non-EU	0/154 (0.0)	0.0	0/157 (0.0)	0.0	NE	0.00 (-5.56, 5.56)	1.0000	
Onset of disease								NE
Paediatric	0/ 19 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-28.28, 28.28)	1.0000	
Adult	0/227 (0.0)	0.0	0/234 (0.0)	0.0	NE	0.00 (-4.74, 4.74)	1.0000	
ADA result								NE
Negative	0/226 (0.0)	0.0	0/223 (0.0)	0.0	NE	0.00 (-4.87, 4.87)	1.0000	
Positive (At any time)	0/ 19 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-21.63, 21.63)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/159 (0.0)	0.0	0/176 (0.0)	0.0	NE	0.00 (-5.09, 5.09)	1.0000	
>= 30	0/ 87 (0.0)	0.0	0/ 70 (0.0)	0.0	NE	0.00 (-8.73, 8.73)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Anaphylaxis
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.48, 4.48)	
p-value	1.0000	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Anaphylaxis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-10.64, 10.64)	1.0000	
>= 10 points	0/166 (0.0)	0.0	0/177 (0.0)	0.0	NE	0.00 (-5.04, 5.04)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-7.19, 7.19)	1.0000	
>=10 mg/day	0/131 (0.0)	0.0	0/129 (0.0)	0.0	NE	0.00 (-6.32, 6.32)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 45 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-10.61, 10.61)	1.0000	
HIGH	0/201 (0.0)	0.0	0/198 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
Age (years)								NE
<= 65	0/239 (0.0)	0.0	0/243 (0.0)	0.0	NE	0.00 (-4.56, 4.56)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-62.98, 62.98)	1.0000	
Sex								NE
male	0/ 23 (0.0)	0.0	0/ 20 (0.0)	0.0	NE	0.00 (-20.84, 20.84)	1.0000	
female	0/223 (0.0)	0.0	0/226 (0.0)	0.0	NE	0.00 (-4.85, 4.85)	1.0000	
Race								NE
White	0/160 (0.0)	0.0	0/174 (0.0)	0.0	NE	0.00 (-5.80, 5.80)	1.0000	
Black	0/ 33 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.38, 15.38)	1.0000	
Other	0/ 45 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-11.98, 11.98)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 50 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.46, 9.46)	1.0000	
Non-hispanic/Latino	0/188 (0.0)	0.0	0/187 (0.0)	0.0	NE	0.00 (-5.21, 5.21)	1.0000	
Geographic region								NE
EU	0/ 92 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-5.86, 5.86)	1.0000	
non-EU	0/154 (0.0)	0.0	0/157 (0.0)	0.0	NE	0.00 (-5.56, 5.56)	1.0000	
Onset of disease								NE
Paediatric	0/ 19 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-28.28, 28.28)	1.0000	
Adult	0/227 (0.0)	0.0	0/234 (0.0)	0.0	NE	0.00 (-4.74, 4.74)	1.0000	
ADA result								NE
Negative	0/226 (0.0)	0.0	0/223 (0.0)	0.0	NE	0.00 (-4.87, 4.87)	1.0000	
Positive (At any time)	0/ 19 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-21.63, 21.63)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/159 (0.0)	0.0	0/176 (0.0)	0.0	NE	0.00 (-5.09, 5.09)	1.0000	
>= 30	0/ 87 (0.0)	0.0	0/ 70 (0.0)	0.0	NE	0.00 (-8.73, 8.73)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	13 (5.3)	5 (2.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	2.61 (0.95, 7.21)	
p-value	0.0640	
Odds Ratio (95% CI)	2.70 (0.95, 7.71)	
p-value	0.0627	
Risk Difference (95% CI)	3.27 (-0.04, 6.57)	
p-value	0.0526	
CMH approach		
Response rate	5.4	2.1
Difference in response rates (95% CI)	3.35 (-2.01, 8.71)	
p-value	0.2201	
p-Value for test for heterogenity between studies	0.9271	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.5313
< 10 points	2/ 80 (2.5)	2.5	1/ 69 (1.4)	1.4	1.40 (0.18, 11.09)	0.7504	1.09 (-10.07, 12.25)	0.8488	
>= 10 points	11/166 (6.6)	6.6	4/177 (2.3)	2.3	2.97 (0.96, 9.17)	0.0582	4.35 (-1.98, 10.69)	0.1780	
OCS dose at baseline									0.5612
<10 mg/day	7/115 (6.1)	6.1	2/117 (1.7)	1.8	3.53 (0.75, 16.68)	0.1114	4.23 (-4.07, 12.53)	0.3181	
>=10 mg/day	6/131 (4.6)	4.6	3/129 (2.3)	2.4	1.91 (0.49, 7.46)	0.3494	2.24 (-5.25, 9.73)	0.5582	
Result of type I IFN gene signature test									0.9986
LOW	3/ 45 (6.7)	6.6	1/ 48 (2.1)	2.1	2.44 (0.38, 15.92)	0.3500	4.54 (-8.21, 17.29)	0.4855	
HIGH	10/201 (5.0)	5.1	4/198 (2.0)	2.1	2.45 (0.78, 7.72)	0.1261	3.07 (-2.83, 8.97)	0.3072	
Age (years)									NE
<= 65	13/239 (5.4)	5.6	5/243 (2.1)	2.1	2.65 (0.96, 7.31)	0.0600	3.51 (-1.96, 8.98)	0.2082	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-62.98, 62.98)	1.0000	
Sex									0.6729
male	3/ 23 (13.0)	12.5	0/ 20 (0.0)	0.0	3.36 (0.40, 28.13)	0.2635	12.54 (-10.53, 35.61)	0.2867	
female	10/223 (4.5)	4.6	5/226 (2.2)	2.3	2.02 (0.70, 5.82)	0.1957	2.35 (-3.31, 8.00)	0.4164	
Race									0.5816
White	7/160 (4.4)	4.4	4/174 (2.3)	2.3	1.90 (0.56, 6.37)	0.3014	2.15 (-4.51, 8.81)	0.5277	
Black	0/ 33 (0.0)	0.0	1/ 32 (3.1)	2.5	0.53 (0.02, 11.93)	0.6879	-2.47 (-18.31, 13.38)	0.7604	
Other	4/ 45 (8.9)	9.0	0/ 37 (0.0)	0.0	3.90 (0.46, 32.92)	0.2106	9.04 (-4.92, 23.01)	0.2045	
Ethnicity									0.6441
Hispanic/Latino	3/ 50 (6.0)	6.2	1/ 56 (1.8)	1.7	3.56 (0.39, 32.23)	0.2594	4.43 (-7.02, 15.89)	0.4483	
Non-hispanic/Latino	8/188 (4.3)	4.4	4/187 (2.1)	2.1	1.97 (0.60, 6.49)	0.2649	2.37 (-3.69, 8.43)	0.4428	
Geographic region									0.8948
EU	4/ 92 (4.3)	4.3	1/ 89 (1.1)	1.0	2.82 (0.44, 18.11)	0.2747	3.31 (-3.94, 10.57)	0.3707	
non-EU	9/154 (5.8)	6.3	4/157 (2.5)	2.3	2.43 (0.76, 7.74)	0.1321	3.98 (-2.85, 10.82)	0.2532	
Onset of disease									0.8583
Paediatric	3/ 19 (15.8)	15.2	0/ 12 (0.0)	0.0	2.58 (0.32, 20.91)	0.3755	15.22 (-15.23, 45.68)	0.3272	
Adult	10/227 (4.4)	4.5	5/234 (2.1)	2.2	2.08 (0.72, 5.99)	0.1742	2.38 (-3.15, 7.90)	0.3993	
ADA result									0.9086
Negative	12/226 (5.3)	5.5	4/223 (1.8)	1.8	2.94 (0.96, 9.00)	0.0592	3.65 (-2.07, 9.38)	0.2108	
Positive (At any time)	1/ 19 (5.3)	7.3	1/ 23 (4.3)	2.9	2.50 (0.20, 31.00)	0.4756	4.36 (-18.46, 27.18)	0.7078	
BMI (kg/m2) at enrolment									0.1771
< 30	9/159 (5.7)	5.8	2/176 (1.1)	1.1	4.97 (1.09, 22.68)	0.0386	4.68 (-1.51, 10.88)	0.1384	
>= 30	4/ 87 (4.6)	4.9	3/ 70 (4.3)	4.1	1.17 (0.27, 5.01)	0.8372	0.83 (-9.51, 11.18)	0.8748	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.48, 4.48)	
p-value	1.0000	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-10.64, 10.64)	1.0000	
>= 10 points	0/166 (0.0)	0.0	0/177 (0.0)	0.0	NE	0.00 (-5.04, 5.04)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-7.19, 7.19)	1.0000	
>=10 mg/day	0/131 (0.0)	0.0	0/129 (0.0)	0.0	NE	0.00 (-6.32, 6.32)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 45 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-10.61, 10.61)	1.0000	
HIGH	0/201 (0.0)	0.0	0/198 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
Age (years)								NE
<= 65	0/239 (0.0)	0.0	0/243 (0.0)	0.0	NE	0.00 (-4.56, 4.56)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-62.98, 62.98)	1.0000	
Sex								NE
male	0/ 23 (0.0)	0.0	0/ 20 (0.0)	0.0	NE	0.00 (-20.84, 20.84)	1.0000	
female	0/223 (0.0)	0.0	0/226 (0.0)	0.0	NE	0.00 (-4.85, 4.85)	1.0000	
Race								NE
White	0/160 (0.0)	0.0	0/174 (0.0)	0.0	NE	0.00 (-5.80, 5.80)	1.0000	
Black	0/ 33 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.38, 15.38)	1.0000	
Other	0/ 45 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-11.98, 11.98)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 50 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.46, 9.46)	1.0000	
Non-hispanic/Latino	0/188 (0.0)	0.0	0/187 (0.0)	0.0	NE	0.00 (-5.21, 5.21)	1.0000	
Geographic region								NE
EU	0/ 92 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-5.86, 5.86)	1.0000	
non-EU	0/154 (0.0)	0.0	0/157 (0.0)	0.0	NE	0.00 (-5.56, 5.56)	1.0000	
Onset of disease								NE
Paediatric	0/ 19 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-28.28, 28.28)	1.0000	
Adult	0/227 (0.0)	0.0	0/234 (0.0)	0.0	NE	0.00 (-4.74, 4.74)	1.0000	
ADA result								NE
Negative	0/226 (0.0)	0.0	0/223 (0.0)	0.0	NE	0.00 (-4.87, 4.87)	1.0000	
Positive (At any time)	0/ 19 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-21.63, 21.63)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/159 (0.0)	0.0	0/176 (0.0)	0.0	NE	0.00 (-5.09, 5.09)	1.0000	
>= 30	0/ 87 (0.0)	0.0	0/ 70 (0.0)	0.0	NE	0.00 (-8.73, 8.73)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.48, 4.48)	
p-value	1.0000	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-10.64, 10.64)	1.0000	
>= 10 points	0/166 (0.0)	0.0	0/177 (0.0)	0.0	NE	0.00 (-5.04, 5.04)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-7.19, 7.19)	1.0000	
>=10 mg/day	0/131 (0.0)	0.0	0/129 (0.0)	0.0	NE	0.00 (-6.32, 6.32)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 45 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-10.61, 10.61)	1.0000	
HIGH	0/201 (0.0)	0.0	0/198 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
Age (years)								NE
<= 65	0/239 (0.0)	0.0	0/243 (0.0)	0.0	NE	0.00 (-4.56, 4.56)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-62.98, 62.98)	1.0000	
Sex								NE
male	0/ 23 (0.0)	0.0	0/ 20 (0.0)	0.0	NE	0.00 (-20.84, 20.84)	1.0000	
female	0/223 (0.0)	0.0	0/226 (0.0)	0.0	NE	0.00 (-4.85, 4.85)	1.0000	
Race								NE
White	0/160 (0.0)	0.0	0/174 (0.0)	0.0	NE	0.00 (-5.80, 5.80)	1.0000	
Black	0/ 33 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.38, 15.38)	1.0000	
Other	0/ 45 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-11.98, 11.98)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 50 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.46, 9.46)	1.0000	
Non-hispanic/Latino	0/188 (0.0)	0.0	0/187 (0.0)	0.0	NE	0.00 (-5.21, 5.21)	1.0000	
Geographic region								NE
EU	0/ 92 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-5.86, 5.86)	1.0000	
non-EU	0/154 (0.0)	0.0	0/157 (0.0)	0.0	NE	0.00 (-5.56, 5.56)	1.0000	
Onset of disease								NE
Paediatric	0/ 19 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-28.28, 28.28)	1.0000	
Adult	0/227 (0.0)	0.0	0/234 (0.0)	0.0	NE	0.00 (-4.74, 4.74)	1.0000	
ADA result								NE
Negative	0/226 (0.0)	0.0	0/223 (0.0)	0.0	NE	0.00 (-4.87, 4.87)	1.0000	
Positive (At any time)	0/ 19 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-21.63, 21.63)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/159 (0.0)	0.0	0/176 (0.0)	0.0	NE	0.00 (-5.09, 5.09)	1.0000	
>= 30	0/ 87 (0.0)	0.0	0/ 70 (0.0)	0.0	NE	0.00 (-8.73, 8.73)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	13 (5.3)	5 (2.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	2.61 (0.95, 7.21)	
p-value	0.0640	
Odds Ratio (95% CI)	2.70 (0.95, 7.71)	
p-value	0.0627	
Risk Difference (95% CI)	3.27 (-0.04, 6.57)	
p-value	0.0526	
CMH approach		
Response rate	5.4	2.1
Difference in response rates (95% CI)	3.35 (-2.01, 8.71)	
p-value	0.2201	
p-Value for test for heterogenity between studies	0.9271	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.5313
< 10 points	2/ 80 (2.5)	2.5	1/ 69 (1.4)	1.4	1.40 (0.18, 11.09)	0.7504	1.09 (-10.07, 12.25)	0.8488	
>= 10 points	11/166 (6.6)	6.6	4/177 (2.3)	2.3	2.97 (0.96, 9.17)	0.0582	4.35 (-1.98, 10.69)	0.1780	
OCS dose at baseline									0.5612
<10 mg/day	7/115 (6.1)	6.1	2/117 (1.7)	1.8	3.53 (0.75, 16.68)	0.1114	4.23 (-4.07, 12.53)	0.3181	
>=10 mg/day	6/131 (4.6)	4.6	3/129 (2.3)	2.4	1.91 (0.49, 7.46)	0.3494	2.24 (-5.25, 9.73)	0.5582	
Result of type I IFN gene signature test									0.9986
LOW	3/ 45 (6.7)	6.6	1/ 48 (2.1)	2.1	2.44 (0.38, 15.92)	0.3500	4.54 (-8.21, 17.29)	0.4855	
HIGH	10/201 (5.0)	5.1	4/198 (2.0)	2.1	2.45 (0.78, 7.72)	0.1261	3.07 (-2.83, 8.97)	0.3072	
Age (years)									NE
<= 65	13/239 (5.4)	5.6	5/243 (2.1)	2.1	2.65 (0.96, 7.31)	0.0600	3.51 (-1.96, 8.98)	0.2082	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-62.98, 62.98)	1.0000	
Sex									0.6729
male	3/ 23 (13.0)	12.5	0/ 20 (0.0)	0.0	3.36 (0.40, 28.13)	0.2635	12.54 (-10.53, 35.61)	0.2867	
female	10/223 (4.5)	4.6	5/226 (2.2)	2.3	2.02 (0.70, 5.82)	0.1957	2.35 (-3.31, 8.00)	0.4164	
Race									0.5816
White	7/160 (4.4)	4.4	4/174 (2.3)	2.3	1.90 (0.56, 6.37)	0.3014	2.15 (-4.51, 8.81)	0.5277	
Black	0/ 33 (0.0)	0.0	1/ 32 (3.1)	2.5	0.53 (0.02, 11.93)	0.6879	-2.47 (-18.31, 13.38)	0.7604	
Other	4/ 45 (8.9)	9.0	0/ 37 (0.0)	0.0	3.90 (0.46, 32.92)	0.2106	9.04 (-4.92, 23.01)	0.2045	
Ethnicity									0.6441
Hispanic/Latino	3/ 50 (6.0)	6.2	1/ 56 (1.8)	1.7	3.56 (0.39, 32.23)	0.2594	4.43 (-7.02, 15.89)	0.4483	
Non-hispanic/Latino	8/188 (4.3)	4.4	4/187 (2.1)	2.1	1.97 (0.60, 6.49)	0.2649	2.37 (-3.69, 8.43)	0.4428	
Geographic region									0.8948
EU	4/ 92 (4.3)	4.3	1/ 89 (1.1)	1.0	2.82 (0.44, 18.11)	0.2747	3.31 (-3.94, 10.57)	0.3707	
non-EU	9/154 (5.8)	6.3	4/157 (2.5)	2.3	2.43 (0.76, 7.74)	0.1321	3.98 (-2.85, 10.82)	0.2532	
Onset of disease									0.8583
Paediatric	3/ 19 (15.8)	15.2	0/ 12 (0.0)	0.0	2.58 (0.32, 20.91)	0.3755	15.22 (-15.23, 45.68)	0.3272	
Adult	10/227 (4.4)	4.5	5/234 (2.1)	2.2	2.08 (0.72, 5.99)	0.1742	2.38 (-3.15, 7.90)	0.3993	
ADA result									0.9086
Negative	12/226 (5.3)	5.5	4/223 (1.8)	1.8	2.94 (0.96, 9.00)	0.0592	3.65 (-2.07, 9.38)	0.2108	
Positive (At any time)	1/ 19 (5.3)	7.3	1/ 23 (4.3)	2.9	2.50 (0.20, 31.00)	0.4756	4.36 (-18.46, 27.18)	0.7078	
BMI (kg/m2) at enrolment									0.1771
< 30	9/159 (5.7)	5.8	2/176 (1.1)	1.1	4.97 (1.09, 22.68)	0.0386	4.68 (-1.51, 10.88)	0.1384	
>= 30	4/ 87 (4.6)	4.9	3/ 70 (4.3)	4.1	1.17 (0.27, 5.01)	0.8372	0.83 (-9.51, 11.18)	0.8748	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Herpes Zoster leading to discontinuation of study drug
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.48, 4.48)	
p-value	1.0000	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Herpes Zoster leading to discontinuation of study drug - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-10.64, 10.64)	1.0000	
>= 10 points	0/166 (0.0)	0.0	0/177 (0.0)	0.0	NE	0.00 (-5.04, 5.04)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-7.19, 7.19)	1.0000	
>=10 mg/day	0/131 (0.0)	0.0	0/129 (0.0)	0.0	NE	0.00 (-6.32, 6.32)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 45 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-10.61, 10.61)	1.0000	
HIGH	0/201 (0.0)	0.0	0/198 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
Age (years)								NE
<= 65	0/239 (0.0)	0.0	0/243 (0.0)	0.0	NE	0.00 (-4.56, 4.56)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-62.98, 62.98)	1.0000	
Sex								NE
male	0/ 23 (0.0)	0.0	0/ 20 (0.0)	0.0	NE	0.00 (-20.84, 20.84)	1.0000	
female	0/223 (0.0)	0.0	0/226 (0.0)	0.0	NE	0.00 (-4.85, 4.85)	1.0000	
Race								NE
White	0/160 (0.0)	0.0	0/174 (0.0)	0.0	NE	0.00 (-5.80, 5.80)	1.0000	
Black	0/ 33 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.38, 15.38)	1.0000	
Other	0/ 45 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-11.98, 11.98)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 50 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.46, 9.46)	1.0000	
Non-hispanic/Latino	0/188 (0.0)	0.0	0/187 (0.0)	0.0	NE	0.00 (-5.21, 5.21)	1.0000	
Geographic region								NE
EU	0/ 92 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-5.86, 5.86)	1.0000	
non-EU	0/154 (0.0)	0.0	0/157 (0.0)	0.0	NE	0.00 (-5.56, 5.56)	1.0000	
Onset of disease								NE
Paediatric	0/ 19 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-28.28, 28.28)	1.0000	
Adult	0/227 (0.0)	0.0	0/234 (0.0)	0.0	NE	0.00 (-4.74, 4.74)	1.0000	
ADA result								NE
Negative	0/226 (0.0)	0.0	0/223 (0.0)	0.0	NE	0.00 (-4.87, 4.87)	1.0000	
Positive (At any time)	0/ 19 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-21.63, 21.63)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/159 (0.0)	0.0	0/176 (0.0)	0.0	NE	0.00 (-5.09, 5.09)	1.0000	
>= 30	0/ 87 (0.0)	0.0	0/ 70 (0.0)	0.0	NE	0.00 (-8.73, 8.73)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Hypersensitivity
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	10 (4.1)	3 (1.2)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.25 (0.90, 11.78)	
p-value	0.0730	
Odds Ratio (95% CI)	3.36 (0.90, 12.52)	
p-value	0.0713	
Risk Difference (95% CI)	2.82 (0.01, 5.64)	
p-value	0.0493	
CMH approach		
Response rate	4.0	1.2
Difference in response rates (95% CI)	2.87 (-2.14, 7.87)	
p-value	0.2614	
p-Value for test for heterogenity between studies	0.6479	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Hypersensitivity - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8247
< 10 points	5/ 80 (6.3)	7.0	1/ 69 (1.4)	1.4	3.27 (0.55, 19.30)	0.1913	5.58 (-5.95, 17.10)	0.3429	
>= 10 points	5/166 (3.0)	2.8	2/177 (1.1)	1.1	2.47 (0.45, 13.61)	0.2979	1.77 (-3.80, 7.34)	0.5334	
OCS dose at baseline									0.9117
<10 mg/day	6/115 (5.2)	4.9	2/117 (1.7)	1.6	2.44 (0.43, 13.96)	0.3149	3.30 (-4.69, 11.28)	0.4183	
>=10 mg/day	4/131 (3.1)	3.2	1/129 (0.8)	0.8	2.82 (0.44, 18.27)	0.2758	2.47 (-4.35, 9.29)	0.4777	
Result of type I IFN gene signature test									0.2180
LOW	5/ 45 (11.1)	11.2	0/ 48 (0.0)	0.0	11.96 (0.70, 204.47)	0.0867	11.23 (-1.66, 24.13)	0.0878	
HIGH	5/201 (2.5)	2.3	3/198 (1.5)	1.4	1.63 (0.39, 6.73)	0.5022	0.90 (-4.49, 6.29)	0.7427	
Age (years)									0.9625
<= 65	8/239 (3.3)	3.3	3/243 (1.2)	1.2	2.69 (0.72, 10.04)	0.1416	2.14 (-2.91, 7.18)	0.4064	
> 65	2/ 7 (28.6)	27.3	0/ 3 (0.0)	0.0	2.50 (0.17, 37.26)	0.5062	27.27 (-37.78, 92.32)	0.4112	
Sex									0.2420
male	1/ 23 (4.3)	3.8	1/ 20 (5.0)	5.7	0.67 (0.05, 9.19)	0.7620	-1.90 (-24.51, 20.72)	0.8694	
female	9/223 (4.0)	4.0	2/226 (0.9)	0.8	4.13 (0.86, 19.81)	0.0761	3.18 (-2.17, 8.53)	0.2443	
Race									0.1293
White	9/160 (5.6)	5.2	2/174 (1.1)	1.2	4.22 (1.07, 16.65)	0.0400	4.04 (-2.39, 10.48)	0.2184	
Black	0/ 33 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-15.38, 15.38)	1.0000	
Other	0/ 45 (0.0)	0.0	1/ 37 (2.7)	2.6	0.29 (0.01, 6.89)	0.4475	-2.62 (-15.34, 10.09)	0.6858	
Ethnicity									0.7565
Hispanic/Latino	2/ 50 (4.0)	4.0	0/ 56 (0.0)	0.0	3.32 (0.36, 30.96)	0.2915	3.99 (-6.56, 14.54)	0.4587	
Non-hispanic/Latino	7/188 (3.7)	3.9	3/187 (1.6)	1.6	2.19 (0.54, 8.82)	0.2691	2.34 (-3.48, 8.16)	0.4303	
Geographic region									0.4962
EU	4/ 92 (4.3)	4.6	0/ 89 (0.0)	0.0	4.51 (0.52, 38.94)	0.1704	4.61 (-2.52, 11.73)	0.2052	
non-EU	6/154 (3.9)	3.6	3/157 (1.9)	1.9	1.85 (0.46, 7.43)	0.3837	1.67 (-4.59, 7.92)	0.6018	
Onset of disease									0.6950
Paediatric	1/ 19 (5.3)	4.4	0/ 12 (0.0)	0.0	1.50 (0.07, 31.57)	0.7942	4.36 (-24.55, 33.26)	0.7676	
Adult	9/227 (4.0)	3.8	3/234 (1.3)	1.3	2.92 (0.77, 11.11)	0.1164	2.54 (-2.69, 7.78)	0.3409	
ADA result									NE
Negative	10/226 (4.4)	4.4	3/223 (1.3)	1.3	3.26 (0.90, 11.79)	0.0719	3.12 (-2.31, 8.54)	0.2604	
Positive (At any time)	0/ 19 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-21.63, 21.63)	1.0000	
BMI (kg/m2) at enrolment									0.3132
< 30	2/159 (1.3)	1.5	2/176 (1.1)	1.2	1.19 (0.18, 7.99)	0.8599	0.30 (-5.13, 5.73)	0.9144	
>= 30	8/ 87 (9.2)	9.1	1/ 70 (1.4)	1.6	4.43 (0.80, 24.42)	0.0873	7.50 (-2.77, 17.77)	0.1523	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Hypersensitivity
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	1 (0.4)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.05 (0.13, 74.13)	
p-value	0.4933	
Odds Ratio (95% CI)	3.08 (0.12, 76.26)	
p-value	0.4928	
Risk Difference (95% CI)	0.41 (-0.39, 1.21)	
p-value	0.3143	
CMH approach		
Response rate	0.4	0.0
Difference in response rates (95% CI)	0.39 (-4.14, 4.92)	
p-value	0.8647	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Hypersensitivity - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE		0.00 (-10.64, 10.64)	1.0000	
>= 10 points	1/166 (0.6)	0.6	0/177 (0.0)	0.0	3.42 (0.14, 82.71)	0.4497	0.56 (-4.58, 5.70)	0.8296	
OCS dose at baseline									NE
<10 mg/day	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE		0.00 (-7.19, 7.19)	1.0000	
>=10 mg/day	1/131 (0.8)	0.8	0/129 (0.0)	0.0	2.76 (0.11, 66.34)	0.5318	0.75 (-5.70, 7.20)	0.8195	
Result of type I IFN gene signature test									NE
LOW	0/ 45 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-10.61, 10.61)	1.0000	
HIGH	1/201 (0.5)	0.5	0/198 (0.0)	0.0	3.03 (0.13, 73.49)	0.4954	0.49 (-4.52, 5.49)	0.8490	
Age (years)									NE
<= 65	1/239 (0.4)	0.4	0/243 (0.0)	0.0	3.08 (0.13, 74.76)	0.4900	0.41 (-4.21, 5.02)	0.8626	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-62.98, 62.98)	1.0000	
Sex									NE
male	0/ 23 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-20.84, 20.84)	1.0000	
female	1/223 (0.4)	0.4	0/226 (0.0)	0.0	3.03 (0.12, 73.51)	0.4961	0.42 (-4.48, 5.33)	0.8658	
Race									NE
White	0/160 (0.0)	0.0	0/174 (0.0)	0.0	NE		0.00 (-5.80, 5.80)	1.0000	
Black	0/ 33 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-15.38, 15.38)	1.0000	
Other	0/ 45 (0.0)	0.0	0/ 37 (0.0)	0.0	NE		0.00 (-11.98, 11.98)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 50 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-9.46, 9.46)	1.0000	
Non-hispanic/Latino	0/188 (0.0)	0.0	0/187 (0.0)	0.0	NE		0.00 (-5.21, 5.21)	1.0000	
Geographic region									NE
EU	1/ 92 (1.1)	0.9	0/ 89 (0.0)	0.0	2.22 (0.09, 52.78)	0.6224	0.95 (-5.15, 7.05)	0.7603	
non-EU	0/154 (0.0)	0.0	0/157 (0.0)	0.0	NE		0.00 (-5.56, 5.56)	1.0000	
Onset of disease									NE
Paediatric	1/ 19 (5.3)	4.4	0/ 12 (0.0)	0.0	1.50 (0.07, 31.57)	0.7942	4.36 (-24.55, 33.26)	0.7676	
Adult	0/227 (0.0)	0.0	0/234 (0.0)	0.0	NE		0.00 (-4.74, 4.74)	1.0000	
ADA result									NE
Negative	1/226 (0.4)	0.4	0/223 (0.0)	0.0	2.90 (0.12, 70.36)	0.5135	0.40 (-4.52, 5.33)	0.8719	
Positive (At any time)	0/ 19 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-21.63, 21.63)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/159 (0.0)	0.0	0/176 (0.0)	0.0	NE		0.00 (-5.09, 5.09)	1.0000	
>= 30	1/ 87 (1.1)	1.3	0/ 70 (0.0)	0.0	2.83 (0.12, 67.01)	0.5197	1.26 (-7.74, 10.25)	0.7842	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Hypersensitivity
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.48, 4.48)	
p-value	1.0000	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Hypersensitivity - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-10.64, 10.64)	1.0000	
>= 10 points	0/166 (0.0)	0.0	0/177 (0.0)	0.0	NE	0.00 (-5.04, 5.04)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-7.19, 7.19)	1.0000	
>=10 mg/day	0/131 (0.0)	0.0	0/129 (0.0)	0.0	NE	0.00 (-6.32, 6.32)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 45 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-10.61, 10.61)	1.0000	
HIGH	0/201 (0.0)	0.0	0/198 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
Age (years)								NE
<= 65	0/239 (0.0)	0.0	0/243 (0.0)	0.0	NE	0.00 (-4.56, 4.56)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-62.98, 62.98)	1.0000	
Sex								NE
male	0/ 23 (0.0)	0.0	0/ 20 (0.0)	0.0	NE	0.00 (-20.84, 20.84)	1.0000	
female	0/223 (0.0)	0.0	0/226 (0.0)	0.0	NE	0.00 (-4.85, 4.85)	1.0000	
Race								NE
White	0/160 (0.0)	0.0	0/174 (0.0)	0.0	NE	0.00 (-5.80, 5.80)	1.0000	
Black	0/ 33 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.38, 15.38)	1.0000	
Other	0/ 45 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-11.98, 11.98)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 50 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.46, 9.46)	1.0000	
Non-hispanic/Latino	0/188 (0.0)	0.0	0/187 (0.0)	0.0	NE	0.00 (-5.21, 5.21)	1.0000	
Geographic region								NE
EU	0/ 92 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-5.86, 5.86)	1.0000	
non-EU	0/154 (0.0)	0.0	0/157 (0.0)	0.0	NE	0.00 (-5.56, 5.56)	1.0000	
Onset of disease								NE
Paediatric	0/ 19 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-28.28, 28.28)	1.0000	
Adult	0/227 (0.0)	0.0	0/234 (0.0)	0.0	NE	0.00 (-4.74, 4.74)	1.0000	
ADA result								NE
Negative	0/226 (0.0)	0.0	0/223 (0.0)	0.0	NE	0.00 (-4.87, 4.87)	1.0000	
Positive (At any time)	0/ 19 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-21.63, 21.63)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/159 (0.0)	0.0	0/176 (0.0)	0.0	NE	0.00 (-5.09, 5.09)	1.0000	
>= 30	0/ 87 (0.0)	0.0	0/ 70 (0.0)	0.0	NE	0.00 (-8.73, 8.73)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Hypersensitivity
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	10 (4.1)	3 (1.2)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.25 (0.90, 11.78)	
p-value	0.0730	
Odds Ratio (95% CI)	3.36 (0.90, 12.52)	
p-value	0.0713	
Risk Difference (95% CI)	2.82 (0.01, 5.64)	
p-value	0.0493	
CMH approach		
Response rate	4.0	1.2
Difference in response rates (95% CI)	2.87 (-2.14, 7.87)	
p-value	0.2614	
p-Value for test for heterogenity between studies	0.6479	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Hypersensitivity - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8247
< 10 points	5/ 80 (6.3)	7.0	1/ 69 (1.4)	1.4	3.27 (0.55, 19.30)	0.1913	5.58 (-5.95, 17.10)	0.3429	
>= 10 points	5/166 (3.0)	2.8	2/177 (1.1)	1.1	2.47 (0.45, 13.61)	0.2979	1.77 (-3.80, 7.34)	0.5334	
OCS dose at baseline									0.9117
<10 mg/day	6/115 (5.2)	4.9	2/117 (1.7)	1.6	2.44 (0.43, 13.96)	0.3149	3.30 (-4.69, 11.28)	0.4183	
>=10 mg/day	4/131 (3.1)	3.2	1/129 (0.8)	0.8	2.82 (0.44, 18.27)	0.2758	2.47 (-4.35, 9.29)	0.4777	
Result of type I IFN gene signature test									0.2180
LOW	5/ 45 (11.1)	11.2	0/ 48 (0.0)	0.0	11.96 (0.70, 204.47)	0.0867	11.23 (-1.66, 24.13)	0.0878	
HIGH	5/201 (2.5)	2.3	3/198 (1.5)	1.4	1.63 (0.39, 6.73)	0.5022	0.90 (-4.49, 6.29)	0.7427	
Age (years)									0.9625
<= 65	8/239 (3.3)	3.3	3/243 (1.2)	1.2	2.69 (0.72, 10.04)	0.1416	2.14 (-2.91, 7.18)	0.4064	
> 65	2/ 7 (28.6)	27.3	0/ 3 (0.0)	0.0	2.50 (0.17, 37.26)	0.5062	27.27 (-37.78, 92.32)	0.4112	
Sex									0.2420
male	1/ 23 (4.3)	3.8	1/ 20 (5.0)	5.7	0.67 (0.05, 9.19)	0.7620	-1.90 (-24.51, 20.72)	0.8694	
female	9/223 (4.0)	4.0	2/226 (0.9)	0.8	4.13 (0.86, 19.81)	0.0761	3.18 (-2.17, 8.53)	0.2443	
Race									0.1293
White	9/160 (5.6)	5.2	2/174 (1.1)	1.2	4.22 (1.07, 16.65)	0.0400	4.04 (-2.39, 10.48)	0.2184	
Black	0/ 33 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-15.38, 15.38)	1.0000	
Other	0/ 45 (0.0)	0.0	1/ 37 (2.7)	2.6	0.29 (0.01, 6.89)	0.4475	-2.62 (-15.34, 10.09)	0.6858	
Ethnicity									0.7565
Hispanic/Latino	2/ 50 (4.0)	4.0	0/ 56 (0.0)	0.0	3.32 (0.36, 30.96)	0.2915	3.99 (-6.56, 14.54)	0.4587	
Non-hispanic/Latino	7/188 (3.7)	3.9	3/187 (1.6)	1.6	2.19 (0.54, 8.82)	0.2691	2.34 (-3.48, 8.16)	0.4303	
Geographic region									0.4962
EU	4/ 92 (4.3)	4.6	0/ 89 (0.0)	0.0	4.51 (0.52, 38.94)	0.1704	4.61 (-2.52, 11.73)	0.2052	
non-EU	6/154 (3.9)	3.6	3/157 (1.9)	1.9	1.85 (0.46, 7.43)	0.3837	1.67 (-4.59, 7.92)	0.6018	
Onset of disease									0.6950
Paediatric	1/ 19 (5.3)	4.4	0/ 12 (0.0)	0.0	1.50 (0.07, 31.57)	0.7942	4.36 (-24.55, 33.26)	0.7676	
Adult	9/227 (4.0)	3.8	3/234 (1.3)	1.3	2.92 (0.77, 11.11)	0.1164	2.54 (-2.69, 7.78)	0.3409	
ADA result									NE
Negative	10/226 (4.4)	4.4	3/223 (1.3)	1.3	3.26 (0.90, 11.79)	0.0719	3.12 (-2.31, 8.54)	0.2604	
Positive (At any time)	0/ 19 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-21.63, 21.63)	1.0000	
BMI (kg/m2) at enrolment									0.3132
< 30	2/159 (1.3)	1.5	2/176 (1.1)	1.2	1.19 (0.18, 7.99)	0.8599	0.30 (-5.13, 5.73)	0.9144	
>= 30	8/ 87 (9.2)	9.1	1/ 70 (1.4)	1.6	4.43 (0.80, 24.42)	0.0873	7.50 (-2.77, 17.77)	0.1523	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Influenza
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	4 (1.6)	7 (2.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.58 (0.17, 1.96)	
p-value	0.3802	
Odds Ratio (95% CI)	0.57 (0.16, 2.01)	
p-value	0.3813	
Risk Difference (95% CI)	-1.20 (-3.79, 1.40)	
p-value	0.3669	
CMH approach		
Response rate	1.5	2.5
Difference in response rates (95% CI)	-0.98 (-5.88, 3.93)	
p-value	0.6966	
p-Value for test for heterogenity between studies	0.6741	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Influenza - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=246)		Placebo (N=246)		Analysis Anifrolumab 300mg vs. Placebo				Interaction
Level	n/ N (%)	Response rate	n/ N (%)	Response rate	Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	p-Value
SLEDAI-2K score at screening									0.6703
< 10 points	2/ 80 (2.5)	2.4	2/ 69 (2.9)	2.7	0.88 (0.13, 5.86)	0.8992	-0.24 (-11.45, 10.97)	0.9668	
>= 10 points	2/166 (1.2)	1.1	5/177 (2.8)	2.5	0.50 (0.09, 2.96)	0.4480	-1.35 (-6.87, 4.18)	0.6331	
OCS dose at baseline									0.4115
<10 mg/day	2/115 (1.7)	1.7	6/117 (5.1)	4.6	0.42 (0.07, 2.40)	0.3292	-2.95 (-10.95, 5.05)	0.4705	
>=10 mg/day	2/131 (1.5)	1.4	1/129 (0.8)	0.6	1.36 (0.15, 12.11)	0.7852	0.73 (-5.85, 7.30)	0.8285	
Result of type I IFN gene signature test									0.9368
LOW	1/ 45 (2.2)	2.2	2/ 48 (4.2)	4.2	0.67 (0.09, 5.23)	0.7029	-1.92 (-14.14, 10.30)	0.7582	
HIGH	3/201 (1.5)	1.4	5/198 (2.5)	2.1	0.61 (0.15, 2.47)	0.4845	-0.75 (-6.08, 4.58)	0.7818	
Age (years)									NE
<= 65	4/239 (1.7)	1.6	7/243 (2.9)	2.6	0.59 (0.17, 1.99)	0.3903	-0.97 (-5.96, 4.03)	0.7047	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-62.98, 62.98)	1.0000	
Sex									0.7148
male	0/ 23 (0.0)	0.0	1/ 20 (5.0)	4.5	0.36 (0.02, 8.04)	0.5200	-4.54 (-26.34, 17.26)	0.6833	
female	4/223 (1.8)	1.7	6/226 (2.7)	2.4	0.67 (0.19, 2.36)	0.5371	-0.69 (-5.98, 4.59)	0.7977	
Race									0.7364
White	2/160 (1.3)	1.1	2/174 (1.1)	1.2	1.02 (0.15, 6.84)	0.9866	-0.07 (-6.18, 6.03)	0.9808	
Black	0/ 33 (0.0)	0.0	2/ 32 (6.3)	6.4	0.34 (0.04, 3.10)	0.3381	-6.44 (-23.33, 10.45)	0.4550	
Other	1/ 45 (2.2)	2.3	2/ 37 (5.4)	5.2	0.44 (0.04, 4.53)	0.4900	-2.94 (-16.81, 10.94)	0.6781	
Ethnicity									0.5329
Hispanic/Latino	1/ 50 (2.0)	2.1	1/ 56 (1.8)	1.7	1.19 (0.08, 18.06)	0.9027	0.32 (-10.18, 10.82)	0.9522	
Non-hispanic/Latino	2/188 (1.1)	1.1	5/187 (2.7)	2.5	0.43 (0.08, 2.35)	0.3271	-1.47 (-7.16, 4.21)	0.6110	
Geographic region									0.6952
EU	2/ 92 (2.2)	2.2	2/ 89 (2.2)	2.6	0.82 (0.12, 5.46)	0.8394	-0.42 (-7.60, 6.76)	0.9088	
non-EU	2/154 (1.3)	1.3	5/157 (3.2)	2.9	0.51 (0.12, 2.23)	0.3701	-1.61 (-7.80, 4.58)	0.6095	
Onset of disease									NE
Paediatric	0/ 19 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-28.28, 28.28)	1.0000	
Adult	4/227 (1.8)	1.7	7/234 (3.0)	2.7	0.61 (0.18, 2.05)	0.4204	-1.03 (-6.23, 4.16)	0.6963	
ADA result									0.9420
Negative	4/226 (1.8)	1.7	6/223 (2.7)	2.4	0.65 (0.19, 2.28)	0.4998	-0.79 (-6.09, 4.52)	0.7714	
Positive (At any time)	0/ 19 (0.0)	0.0	1/ 23 (4.3)	2.9	0.73 (0.04, 15.04)	0.8405	-2.91 (-24.88, 19.06)	0.7952	
BMI (kg/m2) at enrolment									0.2273
< 30	4/159 (2.5)	2.6	4/176 (2.3)	2.3	1.02 (0.27, 3.87)	0.9756	0.35 (-5.47, 6.18)	0.9057	
>= 30	0/ 87 (0.0)	0.0	3/ 70 (4.3)	4.2	0.21 (0.02, 1.87)	0.1626	-4.20 (-13.70, 5.29)	0.3858	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Influenza
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	0 (0.0)	1 (0.4)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.34 (0.01, 8.24)	
p-value	0.5062	
Odds Ratio (95% CI)	0.34 (0.01, 8.33)	
p-value	0.5057	
Risk Difference (95% CI)	-0.40 (-1.20, 0.39)	
p-value	0.3184	
CMH approach		
Response rate	0.0	0.3
Difference in response rates (95% CI)	-0.35 (-4.86, 4.17)	
p-value	0.8807	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE		0.00 (-10.64, 10.64)	1.0000	
>= 10 points	0/166 (0.0)	0.0	1/177 (0.6)	0.5	0.38 (0.02, 9.19)	0.5514	-0.50 (-5.61, 4.62)	0.8494	
OCS dose at baseline									NE
<10 mg/day	0/115 (0.0)	0.0	1/117 (0.9)	0.7	0.37 (0.02, 8.98)	0.5433	-0.73 (-8.04, 6.57)	0.8439	
>=10 mg/day	0/131 (0.0)	0.0	0/129 (0.0)	0.0	NE		0.00 (-6.32, 6.32)	1.0000	
Result of type I IFN gene signature test									NE
LOW	0/ 45 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-10.61, 10.61)	1.0000	
HIGH	0/201 (0.0)	0.0	1/198 (0.5)	0.4	0.34 (0.01, 8.17)	0.5035	-0.43 (-5.42, 4.56)	0.8668	
Age (years)									NE
<= 65	0/239 (0.0)	0.0	1/243 (0.4)	0.4	0.34 (0.01, 8.31)	0.5096	-0.36 (-4.96, 4.24)	0.8786	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-62.98, 62.98)	1.0000	
Sex									NE
male	0/ 23 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-20.84, 20.84)	1.0000	
female	0/223 (0.0)	0.0	1/226 (0.4)	0.4	0.34 (0.01, 8.17)	0.5032	-0.39 (-5.29, 4.51)	0.8755	
Race									NE
White	0/160 (0.0)	0.0	1/174 (0.6)	0.6	0.35 (0.01, 8.37)	0.5143	-0.58 (-6.47, 5.31)	0.8471	
Black	0/ 33 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-15.38, 15.38)	1.0000	
Other	0/ 45 (0.0)	0.0	0/ 37 (0.0)	0.0	NE		0.00 (-11.98, 11.98)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 50 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-9.46, 9.46)	1.0000	
Non-hispanic/Latino	0/188 (0.0)	0.0	1/187 (0.5)	0.5	0.34 (0.01, 8.26)	0.5084	-0.51 (-5.81, 4.78)	0.8494	
Geographic region									NE
EU	0/ 92 (0.0)	0.0	0/ 89 (0.0)	0.0	NE		0.00 (-5.86, 5.86)	1.0000	
non-EU	0/154 (0.0)	0.0	1/157 (0.6)	0.6	0.40 (0.02, 9.57)	0.5683	-0.55 (-6.20, 5.10)	0.8485	
Onset of disease									NE
Paediatric	0/ 19 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-28.28, 28.28)	1.0000	
Adult	0/227 (0.0)	0.0	1/234 (0.4)	0.4	0.36 (0.01, 8.69)	0.5277	-0.37 (-5.15, 4.41)	0.8787	
ADA result									NE
Negative	0/226 (0.0)	0.0	1/223 (0.4)	0.4	0.32 (0.01, 7.82)	0.4861	-0.39 (-5.31, 4.53)	0.8757	
Positive (At any time)	0/ 19 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-21.63, 21.63)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/159 (0.0)	0.0	0/176 (0.0)	0.0	NE		0.00 (-5.09, 5.09)	1.0000	
>= 30	0/ 87 (0.0)	0.0	1/ 70 (1.4)	1.3	0.31 (0.01, 7.45)	0.4735	-1.34 (-10.36, 7.69)	0.7718	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Influenza
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	0 (0.0)	1 (0.4)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.34 (0.01, 8.24)	
p-value	0.5062	
Odds Ratio (95% CI)	0.34 (0.01, 8.33)	
p-value	0.5057	
Risk Difference (95% CI)	-0.40 (-1.20, 0.39)	
p-value	0.3184	
CMH approach		
Response rate	0.0	0.3
Difference in response rates (95% CI)	-0.35 (-4.86, 4.17)	
p-value	0.8807	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE		0.00 (-10.64, 10.64)	1.0000	
>= 10 points	0/166 (0.0)	0.0	1/177 (0.6)	0.5	0.38 (0.02, 9.19)	0.5514	-0.50 (-5.61, 4.62)	0.8494	
OCS dose at baseline									NE
<10 mg/day	0/115 (0.0)	0.0	1/117 (0.9)	0.7	0.37 (0.02, 8.98)	0.5433	-0.73 (-8.04, 6.57)	0.8439	
>=10 mg/day	0/131 (0.0)	0.0	0/129 (0.0)	0.0	NE		0.00 (-6.32, 6.32)	1.0000	
Result of type I IFN gene signature test									NE
LOW	0/ 45 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-10.61, 10.61)	1.0000	
HIGH	0/201 (0.0)	0.0	1/198 (0.5)	0.4	0.34 (0.01, 8.17)	0.5035	-0.43 (-5.42, 4.56)	0.8668	
Age (years)									NE
<= 65	0/239 (0.0)	0.0	1/243 (0.4)	0.4	0.34 (0.01, 8.31)	0.5096	-0.36 (-4.96, 4.24)	0.8786	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-62.98, 62.98)	1.0000	
Sex									NE
male	0/ 23 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-20.84, 20.84)	1.0000	
female	0/223 (0.0)	0.0	1/226 (0.4)	0.4	0.34 (0.01, 8.17)	0.5032	-0.39 (-5.29, 4.51)	0.8755	
Race									NE
White	0/160 (0.0)	0.0	1/174 (0.6)	0.6	0.35 (0.01, 8.37)	0.5143	-0.58 (-6.47, 5.31)	0.8471	
Black	0/ 33 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-15.38, 15.38)	1.0000	
Other	0/ 45 (0.0)	0.0	0/ 37 (0.0)	0.0	NE		0.00 (-11.98, 11.98)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 50 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-9.46, 9.46)	1.0000	
Non-hispanic/Latino	0/188 (0.0)	0.0	1/187 (0.5)	0.5	0.34 (0.01, 8.26)	0.5084	-0.51 (-5.81, 4.78)	0.8494	
Geographic region									NE
EU	0/ 92 (0.0)	0.0	0/ 89 (0.0)	0.0	NE		0.00 (-5.86, 5.86)	1.0000	
non-EU	0/154 (0.0)	0.0	1/157 (0.6)	0.6	0.40 (0.02, 9.57)	0.5683	-0.55 (-6.20, 5.10)	0.8485	
Onset of disease									NE
Paediatric	0/ 19 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-28.28, 28.28)	1.0000	
Adult	0/227 (0.0)	0.0	1/234 (0.4)	0.4	0.36 (0.01, 8.69)	0.5277	-0.37 (-5.15, 4.41)	0.8787	
ADA result									NE
Negative	0/226 (0.0)	0.0	1/223 (0.4)	0.4	0.32 (0.01, 7.82)	0.4861	-0.39 (-5.31, 4.53)	0.8757	
Positive (At any time)	0/ 19 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-21.63, 21.63)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/159 (0.0)	0.0	0/176 (0.0)	0.0	NE		0.00 (-5.09, 5.09)	1.0000	
>= 30	0/ 87 (0.0)	0.0	1/ 70 (1.4)	1.3	0.31 (0.01, 7.45)	0.4735	-1.34 (-10.36, 7.69)	0.7718	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Influenza
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	4 (1.6)	6 (2.4)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.67 (0.19, 2.36)	
p-value	0.5369	
Odds Ratio (95% CI)	0.67 (0.18, 2.42)	
p-value	0.5383	
Risk Difference (95% CI)	-0.79 (-3.27, 1.69)	
p-value	0.5315	
CMH approach		
Response rate	1.5	2.2
Difference in response rates (95% CI)	-0.63 (-5.50, 4.24)	
p-value	0.8001	
p-Value for test for heterogenity between studies	0.7623	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.7711
< 10 points	2/ 80 (2.5)	2.4	2/ 69 (2.9)	2.7	0.88 (0.13, 5.86)	0.8992	-0.24 (-11.45, 10.97)	0.9668	
>= 10 points	2/166 (1.2)	1.1	4/177 (2.3)	2.0	0.60 (0.10, 3.61)	0.5781	-0.85 (-6.32, 4.62)	0.7608	
OCS dose at baseline									0.4725
<10 mg/day	2/115 (1.7)	1.7	5/117 (4.3)	3.9	0.48 (0.08, 2.82)	0.4195	-2.21 (-10.13, 5.71)	0.5841	
>=10 mg/day	2/131 (1.5)	1.4	1/129 (0.8)	0.6	1.36 (0.15, 12.11)	0.7852	0.73 (-5.85, 7.30)	0.8285	
Result of type I IFN gene signature test									0.9243
LOW	1/ 45 (2.2)	2.2	2/ 48 (4.2)	4.2	0.67 (0.09, 5.23)	0.7029	-1.92 (-14.14, 10.30)	0.7582	
HIGH	3/201 (1.5)	1.4	4/198 (2.0)	1.7	0.76 (0.17, 3.30)	0.7116	-0.33 (-5.62, 4.96)	0.9038	
Age (years)									NE
<= 65	4/239 (1.7)	1.6	6/243 (2.5)	2.2	0.68 (0.19, 2.39)	0.5491	-0.61 (-5.58, 4.36)	0.8105	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-62.98, 62.98)	1.0000	
Sex									0.6388
male	0/ 23 (0.0)	0.0	1/ 20 (5.0)	4.5	0.36 (0.02, 8.04)	0.5200	-4.54 (-26.34, 17.26)	0.6833	
female	4/223 (1.8)	1.7	5/226 (2.2)	2.0	0.81 (0.22, 2.96)	0.7481	-0.30 (-5.55, 4.95)	0.9110	
Race									0.5282
White	2/160 (1.3)	1.1	1/174 (0.6)	0.6	1.72 (0.21, 13.83)	0.6093	0.50 (-5.51, 6.52)	0.8694	
Black	0/ 33 (0.0)	0.0	2/ 32 (6.3)	6.4	0.34 (0.04, 3.10)	0.3381	-6.44 (-23.33, 10.45)	0.4550	
Other	1/ 45 (2.2)	2.3	2/ 37 (5.4)	5.2	0.44 (0.04, 4.53)	0.4900	-2.94 (-16.81, 10.94)	0.6781	
Ethnicity									0.6154
Hispanic/Latino	1/ 50 (2.0)	2.1	1/ 56 (1.8)	1.7	1.19 (0.08, 18.06)	0.9027	0.32 (-10.18, 10.82)	0.9522	
Non-hispanic/Latino	2/188 (1.1)	1.1	4/187 (2.1)	2.0	0.52 (0.09, 2.95)	0.4581	-0.96 (-6.57, 4.65)	0.7370	
Geographic region									0.8261
EU	2/ 92 (2.2)	2.2	2/ 89 (2.2)	2.6	0.82 (0.12, 5.46)	0.8394	-0.42 (-7.60, 6.76)	0.9088	
non-EU	2/154 (1.3)	1.3	4/157 (2.5)	2.4	0.63 (0.13, 2.92)	0.5506	-1.06 (-7.18, 5.05)	0.7334	
Onset of disease									NE
Paediatric	0/ 19 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-28.28, 28.28)	1.0000	
Adult	4/227 (1.8)	1.7	6/234 (2.6)	2.3	0.70 (0.20, 2.47)	0.5837	-0.66 (-5.83, 4.50)	0.8015	
ADA result									0.9711
Negative	4/226 (1.8)	1.7	5/223 (2.2)	2.0	0.78 (0.21, 2.86)	0.7070	-0.39 (-5.67, 4.88)	0.8835	
Positive (At any time)	0/ 19 (0.0)	0.0	1/ 23 (4.3)	2.9	0.73 (0.04, 15.04)	0.8405	-2.91 (-24.88, 19.06)	0.7952	
BMI (kg/m2) at enrolment									0.3243
< 30	4/159 (2.5)	2.6	4/176 (2.3)	2.3	1.02 (0.27, 3.87)	0.9756	0.35 (-5.47, 6.18)	0.9057	
>= 30	0/ 87 (0.0)	0.0	2/ 70 (2.9)	2.9	0.28 (0.03, 2.59)	0.2591	-2.87 (-12.10, 6.37)	0.5429	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - MACE
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	1 (0.4)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.05 (0.13, 74.13)	
p-value	0.4933	
Odds Ratio (95% CI)	3.08 (0.12, 76.26)	
p-value	0.4928	
Risk Difference (95% CI)	0.41 (-0.39, 1.21)	
p-value	0.3143	
CMH approach		
Response rate	0.4	0.0
Difference in response rates (95% CI)	0.39 (-4.14, 4.92)	
p-value	0.8647	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - MACE - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Anifrolumab 300mg (N=246) Response rate	Placebo (N=246) n/ N (%)	Placebo (N=246) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE		0.00 (-10.64, 10.64)	1.0000	
>= 10 points	1/166 (0.6)	0.6	0/177 (0.0)	0.0	3.42 (0.14, 82.71)	0.4497	0.56 (-4.58, 5.70)	0.8296	
OCS dose at baseline									NE
<10 mg/day	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE		0.00 (-7.19, 7.19)	1.0000	
>=10 mg/day	1/131 (0.8)	0.8	0/129 (0.0)	0.0	2.76 (0.11, 66.34)	0.5318	0.75 (-5.70, 7.20)	0.8195	
Result of type I IFN gene signature test									NE
LOW	0/ 45 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-10.61, 10.61)	1.0000	
HIGH	1/201 (0.5)	0.5	0/198 (0.0)	0.0	3.03 (0.13, 73.49)	0.4954	0.49 (-4.52, 5.49)	0.8490	
Age (years)									NE
<= 65	1/239 (0.4)	0.4	0/243 (0.0)	0.0	3.08 (0.13, 74.76)	0.4900	0.41 (-4.21, 5.02)	0.8626	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-62.98, 62.98)	1.0000	
Sex									NE
male	0/ 23 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-20.84, 20.84)	1.0000	
female	1/223 (0.4)	0.4	0/226 (0.0)	0.0	3.03 (0.12, 73.51)	0.4961	0.42 (-4.48, 5.33)	0.8658	
Race									NE
White	1/160 (0.6)	0.6	0/174 (0.0)	0.0	3.12 (0.13, 75.37)	0.4840	0.64 (-5.28, 6.55)	0.8332	
Black	0/ 33 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-15.38, 15.38)	1.0000	
Other	0/ 45 (0.0)	0.0	0/ 37 (0.0)	0.0	NE		0.00 (-11.98, 11.98)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 50 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-9.46, 9.46)	1.0000	
Non-hispanic/Latino	1/188 (0.5)	0.6	0/187 (0.0)	0.0	3.07 (0.13, 74.33)	0.4902	0.57 (-4.75, 5.88)	0.8347	
Geographic region									NE
EU	1/ 92 (1.1)	0.9	0/ 89 (0.0)	0.0	2.22 (0.09, 52.78)	0.6224	0.95 (-5.15, 7.05)	0.7603	
non-EU	0/154 (0.0)	0.0	0/157 (0.0)	0.0	NE		0.00 (-5.56, 5.56)	1.0000	
Onset of disease									NE
Paediatric	0/ 19 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-28.28, 28.28)	1.0000	
Adult	1/227 (0.4)	0.4	0/234 (0.0)	0.0	3.22 (0.13, 78.21)	0.4724	0.44 (-4.35, 5.24)	0.8564	
ADA result									NE
Negative	1/226 (0.4)	0.4	0/223 (0.0)	0.0	2.90 (0.12, 70.36)	0.5135	0.40 (-4.52, 5.33)	0.8719	
Positive (At any time)	0/ 19 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-21.63, 21.63)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/159 (0.0)	0.0	0/176 (0.0)	0.0	NE		0.00 (-5.09, 5.09)	1.0000	
>= 30	1/ 87 (1.1)	1.3	0/ 70 (0.0)	0.0	2.83 (0.12, 67.01)	0.5197	1.26 (-7.74, 10.25)	0.7842	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious MACE
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	1 (0.4)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.05 (0.13, 74.13)	
p-value	0.4933	
Odds Ratio (95% CI)	3.08 (0.12, 76.26)	
p-value	0.4928	
Risk Difference (95% CI)	0.41 (-0.39, 1.21)	
p-value	0.3143	
CMH approach		
Response rate	0.4	0.0
Difference in response rates (95% CI)	0.39 (-4.14, 4.92)	
p-value	0.8647	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious MACE - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE		0.00 (-10.64, 10.64)	1.0000	
>= 10 points	1/166 (0.6)	0.6	0/177 (0.0)	0.0	3.42 (0.14, 82.71)	0.4497	0.56 (-4.58, 5.70)	0.8296	
OCS dose at baseline									NE
<10 mg/day	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE		0.00 (-7.19, 7.19)	1.0000	
>=10 mg/day	1/131 (0.8)	0.8	0/129 (0.0)	0.0	2.76 (0.11, 66.34)	0.5318	0.75 (-5.70, 7.20)	0.8195	
Result of type I IFN gene signature test									NE
LOW	0/ 45 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-10.61, 10.61)	1.0000	
HIGH	1/201 (0.5)	0.5	0/198 (0.0)	0.0	3.03 (0.13, 73.49)	0.4954	0.49 (-4.52, 5.49)	0.8490	
Age (years)									NE
<= 65	1/239 (0.4)	0.4	0/243 (0.0)	0.0	3.08 (0.13, 74.76)	0.4900	0.41 (-4.21, 5.02)	0.8626	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-62.98, 62.98)	1.0000	
Sex									NE
male	0/ 23 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-20.84, 20.84)	1.0000	
female	1/223 (0.4)	0.4	0/226 (0.0)	0.0	3.03 (0.12, 73.51)	0.4961	0.42 (-4.48, 5.33)	0.8658	
Race									NE
White	1/160 (0.6)	0.6	0/174 (0.0)	0.0	3.12 (0.13, 75.37)	0.4840	0.64 (-5.28, 6.55)	0.8332	
Black	0/ 33 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-15.38, 15.38)	1.0000	
Other	0/ 45 (0.0)	0.0	0/ 37 (0.0)	0.0	NE		0.00 (-11.98, 11.98)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 50 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-9.46, 9.46)	1.0000	
Non-hispanic/Latino	1/188 (0.5)	0.6	0/187 (0.0)	0.0	3.07 (0.13, 74.33)	0.4902	0.57 (-4.75, 5.88)	0.8347	
Geographic region									NE
EU	1/ 92 (1.1)	0.9	0/ 89 (0.0)	0.0	2.22 (0.09, 52.78)	0.6224	0.95 (-5.15, 7.05)	0.7603	
non-EU	0/154 (0.0)	0.0	0/157 (0.0)	0.0	NE		0.00 (-5.56, 5.56)	1.0000	
Onset of disease									NE
Paediatric	0/ 19 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-28.28, 28.28)	1.0000	
Adult	1/227 (0.4)	0.4	0/234 (0.0)	0.0	3.22 (0.13, 78.21)	0.4724	0.44 (-4.35, 5.24)	0.8564	
ADA result									NE
Negative	1/226 (0.4)	0.4	0/223 (0.0)	0.0	2.90 (0.12, 70.36)	0.5135	0.40 (-4.52, 5.33)	0.8719	
Positive (At any time)	0/ 19 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-21.63, 21.63)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/159 (0.0)	0.0	0/176 (0.0)	0.0	NE		0.00 (-5.09, 5.09)	1.0000	
>= 30	1/ 87 (1.1)	1.3	0/ 70 (0.0)	0.0	2.83 (0.12, 67.01)	0.5197	1.26 (-7.74, 10.25)	0.7842	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe MACE
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	1 (0.4)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.05 (0.13, 74.13)	
p-value	0.4933	
Odds Ratio (95% CI)	3.08 (0.12, 76.26)	
p-value	0.4928	
Risk Difference (95% CI)	0.41 (-0.39, 1.21)	
p-value	0.3143	
CMH approach		
Response rate	0.4	0.0
Difference in response rates (95% CI)	0.39 (-4.14, 4.92)	
p-value	0.8647	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe MACE - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE		0.00 (-10.64, 10.64)	1.0000	
>= 10 points	1/166 (0.6)	0.6	0/177 (0.0)	0.0	3.42 (0.14, 82.71)	0.4497	0.56 (-4.58, 5.70)	0.8296	
OCS dose at baseline									NE
<10 mg/day	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE		0.00 (-7.19, 7.19)	1.0000	
>=10 mg/day	1/131 (0.8)	0.8	0/129 (0.0)	0.0	2.76 (0.11, 66.34)	0.5318	0.75 (-5.70, 7.20)	0.8195	
Result of type I IFN gene signature test									NE
LOW	0/ 45 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-10.61, 10.61)	1.0000	
HIGH	1/201 (0.5)	0.5	0/198 (0.0)	0.0	3.03 (0.13, 73.49)	0.4954	0.49 (-4.52, 5.49)	0.8490	
Age (years)									NE
<= 65	1/239 (0.4)	0.4	0/243 (0.0)	0.0	3.08 (0.13, 74.76)	0.4900	0.41 (-4.21, 5.02)	0.8626	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-62.98, 62.98)	1.0000	
Sex									NE
male	0/ 23 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-20.84, 20.84)	1.0000	
female	1/223 (0.4)	0.4	0/226 (0.0)	0.0	3.03 (0.12, 73.51)	0.4961	0.42 (-4.48, 5.33)	0.8658	
Race									NE
White	1/160 (0.6)	0.6	0/174 (0.0)	0.0	3.12 (0.13, 75.37)	0.4840	0.64 (-5.28, 6.55)	0.8332	
Black	0/ 33 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-15.38, 15.38)	1.0000	
Other	0/ 45 (0.0)	0.0	0/ 37 (0.0)	0.0	NE		0.00 (-11.98, 11.98)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 50 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-9.46, 9.46)	1.0000	
Non-hispanic/Latino	1/188 (0.5)	0.6	0/187 (0.0)	0.0	3.07 (0.13, 74.33)	0.4902	0.57 (-4.75, 5.88)	0.8347	
Geographic region									NE
EU	1/ 92 (1.1)	0.9	0/ 89 (0.0)	0.0	2.22 (0.09, 52.78)	0.6224	0.95 (-5.15, 7.05)	0.7603	
non-EU	0/154 (0.0)	0.0	0/157 (0.0)	0.0	NE		0.00 (-5.56, 5.56)	1.0000	
Onset of disease									NE
Paediatric	0/ 19 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-28.28, 28.28)	1.0000	
Adult	1/227 (0.4)	0.4	0/234 (0.0)	0.0	3.22 (0.13, 78.21)	0.4724	0.44 (-4.35, 5.24)	0.8564	
ADA result									NE
Negative	1/226 (0.4)	0.4	0/223 (0.0)	0.0	2.90 (0.12, 70.36)	0.5135	0.40 (-4.52, 5.33)	0.8719	
Positive (At any time)	0/ 19 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-21.63, 21.63)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/159 (0.0)	0.0	0/176 (0.0)	0.0	NE		0.00 (-5.09, 5.09)	1.0000	
>= 30	1/ 87 (1.1)	1.3	0/ 70 (0.0)	0.0	2.83 (0.12, 67.01)	0.5197	1.26 (-7.74, 10.25)	0.7842	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe MACE
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.48, 4.48)	
p-value	1.0000	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe MACE - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-10.64, 10.64)	1.0000	
>= 10 points	0/166 (0.0)	0.0	0/177 (0.0)	0.0	NE	0.00 (-5.04, 5.04)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-7.19, 7.19)	1.0000	
>=10 mg/day	0/131 (0.0)	0.0	0/129 (0.0)	0.0	NE	0.00 (-6.32, 6.32)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 45 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-10.61, 10.61)	1.0000	
HIGH	0/201 (0.0)	0.0	0/198 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
Age (years)								NE
<= 65	0/239 (0.0)	0.0	0/243 (0.0)	0.0	NE	0.00 (-4.56, 4.56)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-62.98, 62.98)	1.0000	
Sex								NE
male	0/ 23 (0.0)	0.0	0/ 20 (0.0)	0.0	NE	0.00 (-20.84, 20.84)	1.0000	
female	0/223 (0.0)	0.0	0/226 (0.0)	0.0	NE	0.00 (-4.85, 4.85)	1.0000	
Race								NE
White	0/160 (0.0)	0.0	0/174 (0.0)	0.0	NE	0.00 (-5.80, 5.80)	1.0000	
Black	0/ 33 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.38, 15.38)	1.0000	
Other	0/ 45 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-11.98, 11.98)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 50 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.46, 9.46)	1.0000	
Non-hispanic/Latino	0/188 (0.0)	0.0	0/187 (0.0)	0.0	NE	0.00 (-5.21, 5.21)	1.0000	
Geographic region								NE
EU	0/ 92 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-5.86, 5.86)	1.0000	
non-EU	0/154 (0.0)	0.0	0/157 (0.0)	0.0	NE	0.00 (-5.56, 5.56)	1.0000	
Onset of disease								NE
Paediatric	0/ 19 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-28.28, 28.28)	1.0000	
Adult	0/227 (0.0)	0.0	0/234 (0.0)	0.0	NE	0.00 (-4.74, 4.74)	1.0000	
ADA result								NE
Negative	0/226 (0.0)	0.0	0/223 (0.0)	0.0	NE	0.00 (-4.87, 4.87)	1.0000	
Positive (At any time)	0/ 19 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-21.63, 21.63)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/159 (0.0)	0.0	0/176 (0.0)	0.0	NE	0.00 (-5.09, 5.09)	1.0000	
>= 30	0/ 87 (0.0)	0.0	0/ 70 (0.0)	0.0	NE	0.00 (-8.73, 8.73)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	6 (2.4)	15 (6.1)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.42 (0.16, 1.07)	
p-value	0.0684	
Odds Ratio (95% CI)	0.40 (0.15, 1.06)	
p-value	0.0657	
Risk Difference (95% CI)	-3.66 (-7.22, -0.10)	
p-value	0.0437	
CMH approach		
Response rate	2.5	6.0
Difference in response rates (95% CI)	-3.54 (-8.98, 1.90)	
p-value	0.2023	
p-Value for test for heterogenity between studies	0.4237	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8139
< 10 points	1/ 80 (1.3)	1.2	2/ 69 (2.9)	2.8	0.55 (0.07, 4.34)	0.5685	-1.59 (-12.71, 9.52)	0.7786	
>= 10 points	5/166 (3.0)	3.0	13/177 (7.3)	7.4	0.42 (0.15, 1.15)	0.0902	-4.43 (-10.93, 2.07)	0.1816	
OCS dose at baseline									0.7042
<10 mg/day	3/115 (2.6)	2.6	6/117 (5.1)	5.0	0.51 (0.13, 2.00)	0.3316	-2.37 (-10.57, 5.83)	0.5714	
>=10 mg/day	3/131 (2.3)	2.2	9/129 (7.0)	7.2	0.35 (0.09, 1.29)	0.1157	-5.00 (-12.79, 2.79)	0.2083	
Result of type I IFN gene signature test									0.2546
LOW	2/ 45 (4.4)	4.5	2/ 48 (4.2)	4.1	1.09 (0.17, 7.10)	0.9274	0.37 (-12.27, 13.02)	0.9537	
HIGH	4/201 (2.0)	2.0	13/198 (6.6)	6.5	0.31 (0.10, 0.93)	0.0373	-4.46 (-10.49, 1.57)	0.1470	
Age (years)									NE
<= 65	6/239 (2.5)	2.6	15/243 (6.2)	6.1	0.42 (0.16, 1.09)	0.0742	-3.52 (-9.06, 2.01)	0.2119	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-62.98, 62.98)	1.0000	
Sex									0.6776
male	0/ 23 (0.0)	0.0	1/ 20 (5.0)	5.7	0.23 (0.01, 5.05)	0.3517	-5.69 (-27.67, 16.28)	0.6116	
female	6/223 (2.7)	2.8	14/226 (6.2)	6.1	0.46 (0.18, 1.20)	0.1116	-3.38 (-9.21, 2.46)	0.2569	
Race									0.8313
White	4/160 (2.5)	2.5	8/174 (4.6)	4.9	0.54 (0.17, 1.79)	0.3164	-2.41 (-9.17, 4.35)	0.4845	
Black	1/ 33 (3.0)	2.5	3/ 32 (9.4)	10.4	0.38 (0.06, 2.43)	0.3069	-7.88 (-26.07, 10.31)	0.3956	
Other	1/ 45 (2.2)	2.1	4/ 37 (10.8)	10.9	0.28 (0.05, 1.76)	0.1753	-8.77 (-23.68, 6.14)	0.2489	
Ethnicity									0.3188
Hispanic/Latino	1/ 50 (2.0)	1.9	7/ 56 (12.5)	12.6	0.22 (0.04, 1.24)	0.0873	-10.69 (-23.20, 1.83)	0.0943	
Non-hispanic/Latino	5/188 (2.7)	2.9	8/187 (4.3)	4.1	0.64 (0.21, 1.97)	0.4325	-1.16 (-7.32, 4.99)	0.7108	
Geographic region									0.5363
EU	0/ 92 (0.0)	0.0	3/ 89 (3.4)	3.6	0.24 (0.03, 2.09)	0.1939	-3.61 (-10.49, 3.27)	0.3038	
non-EU	6/154 (3.9)	3.9	12/157 (7.6)	7.8	0.50 (0.19, 1.31)	0.1588	-3.86 (-11.05, 3.33)	0.2921	
Onset of disease									0.8826
Paediatric	1/ 19 (5.3)	4.4	2/ 12 (16.7)	17.0	0.38 (0.05, 2.71)	0.3353	-12.67 (-44.24, 18.90)	0.4316	
Adult	5/227 (2.2)	2.2	13/234 (5.6)	5.5	0.45 (0.16, 1.31)	0.1423	-3.31 (-8.90, 2.27)	0.2449	
ADA result									0.7963
Negative	5/226 (2.2)	2.2	10/223 (4.5)	4.4	0.50 (0.17, 1.44)	0.1993	-2.20 (-7.84, 3.44)	0.4441	
Positive (At any time)	1/ 19 (5.3)	4.7	5/ 23 (21.7)	19.6	0.38 (0.07, 2.21)	0.2822	-14.91 (-40.71, 10.89)	0.2574	
BMI (kg/m2) at enrolment									0.4986
< 30	3/159 (1.9)	1.9	11/176 (6.3)	5.9	0.31 (0.09, 1.11)	0.0724	-4.09 (-10.33, 2.14)	0.1980	
>= 30	3/ 87 (3.4)	3.4	4/ 70 (5.7)	5.6	0.64 (0.13, 3.20)	0.5848	-2.18 (-12.46, 8.09)	0.6769	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Non-opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	6 (2.4)	15 (6.1)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.42 (0.16, 1.07)	
p-value	0.0684	
Odds Ratio (95% CI)	0.40 (0.15, 1.06)	
p-value	0.0657	
Risk Difference (95% CI)	-3.66 (-7.22, -0.10)	
p-value	0.0437	
CMH approach		
Response rate	2.5	6.0
Difference in response rates (95% CI)	-3.54 (-8.98, 1.90)	
p-value	0.2023	
p-Value for test for heterogenity between studies	0.4237	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Non-opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8139
< 10 points	1/ 80 (1.3)	1.2	2/ 69 (2.9)	2.8	0.55 (0.07, 4.34)	0.5685	-1.59 (-12.71, 9.52)	0.7786	
>= 10 points	5/166 (3.0)	3.0	13/177 (7.3)	7.4	0.42 (0.15, 1.15)	0.0902	-4.43 (-10.93, 2.07)	0.1816	
OCS dose at baseline									0.7042
<10 mg/day	3/115 (2.6)	2.6	6/117 (5.1)	5.0	0.51 (0.13, 2.00)	0.3316	-2.37 (-10.57, 5.83)	0.5714	
>=10 mg/day	3/131 (2.3)	2.2	9/129 (7.0)	7.2	0.35 (0.09, 1.29)	0.1157	-5.00 (-12.79, 2.79)	0.2083	
Result of type I IFN gene signature test									0.2546
LOW	2/ 45 (4.4)	4.5	2/ 48 (4.2)	4.1	1.09 (0.17, 7.10)	0.9274	0.37 (-12.27, 13.02)	0.9537	
HIGH	4/201 (2.0)	2.0	13/198 (6.6)	6.5	0.31 (0.10, 0.93)	0.0373	-4.46 (-10.49, 1.57)	0.1470	
Age (years)									NE
<= 65	6/239 (2.5)	2.6	15/243 (6.2)	6.1	0.42 (0.16, 1.09)	0.0742	-3.52 (-9.06, 2.01)	0.2119	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-62.98, 62.98)	1.0000	
Sex									0.6776
male	0/ 23 (0.0)	0.0	1/ 20 (5.0)	5.7	0.23 (0.01, 5.05)	0.3517	-5.69 (-27.67, 16.28)	0.6116	
female	6/223 (2.7)	2.8	14/226 (6.2)	6.1	0.46 (0.18, 1.20)	0.1116	-3.38 (-9.21, 2.46)	0.2569	
Race									0.8313
White	4/160 (2.5)	2.5	8/174 (4.6)	4.9	0.54 (0.17, 1.79)	0.3164	-2.41 (-9.17, 4.35)	0.4845	
Black	1/ 33 (3.0)	2.5	3/ 32 (9.4)	10.4	0.38 (0.06, 2.43)	0.3069	-7.88 (-26.07, 10.31)	0.3956	
Other	1/ 45 (2.2)	2.1	4/ 37 (10.8)	10.9	0.28 (0.05, 1.76)	0.1753	-8.77 (-23.68, 6.14)	0.2489	
Ethnicity									0.3188
Hispanic/Latino	1/ 50 (2.0)	1.9	7/ 56 (12.5)	12.6	0.22 (0.04, 1.24)	0.0873	-10.69 (-23.20, 1.83)	0.0943	
Non-hispanic/Latino	5/188 (2.7)	2.9	8/187 (4.3)	4.1	0.64 (0.21, 1.97)	0.4325	-1.16 (-7.32, 4.99)	0.7108	
Geographic region									0.5363
EU	0/ 92 (0.0)	0.0	3/ 89 (3.4)	3.6	0.24 (0.03, 2.09)	0.1939	-3.61 (-10.49, 3.27)	0.3038	
non-EU	6/154 (3.9)	3.9	12/157 (7.6)	7.8	0.50 (0.19, 1.31)	0.1588	-3.86 (-11.05, 3.33)	0.2921	
Onset of disease									0.8826
Paediatric	1/ 19 (5.3)	4.4	2/ 12 (16.7)	17.0	0.38 (0.05, 2.71)	0.3353	-12.67 (-44.24, 18.90)	0.4316	
Adult	5/227 (2.2)	2.2	13/234 (5.6)	5.5	0.45 (0.16, 1.31)	0.1423	-3.31 (-8.90, 2.27)	0.2449	
ADA result									0.7963
Negative	5/226 (2.2)	2.2	10/223 (4.5)	4.4	0.50 (0.17, 1.44)	0.1993	-2.20 (-7.84, 3.44)	0.4441	
Positive (At any time)	1/ 19 (5.3)	4.7	5/ 23 (21.7)	19.6	0.38 (0.07, 2.21)	0.2822	-14.91 (-40.71, 10.89)	0.2574	
BMI (kg/m2) at enrolment									0.4986
< 30	3/159 (1.9)	1.9	11/176 (6.3)	5.9	0.31 (0.09, 1.11)	0.0724	-4.09 (-10.33, 2.14)	0.1980	
>= 30	3/ 87 (3.4)	3.4	4/ 70 (5.7)	5.6	0.64 (0.13, 3.20)	0.5848	-2.18 (-12.46, 8.09)	0.6769	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Non-opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	4 (1.6)	5 (2.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.83 (0.24, 2.93)	
p-value	0.7778	
Odds Ratio (95% CI)	0.83 (0.23, 3.00)	
p-value	0.7731	
Risk Difference (95% CI)	-0.43 (-2.78, 1.93)	
p-value	0.7210	
CMH approach		
Response rate	1.6	2.0
Difference in response rates (95% CI)	-0.37 (-5.30, 4.55)	
p-value	0.8816	
p-Value for test for heterogenity between studies	0.5470	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Non-opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.4072
< 10 points	1/ 80 (1.3)	1.2	0/ 69 (0.0)	0.0	2.85 (0.12, 67.83)	0.5172	1.19 (-9.61, 11.99)	0.8294	
>= 10 points	3/166 (1.8)	1.7	5/177 (2.8)	2.9	0.67 (0.18, 2.52)	0.5497	-1.18 (-6.92, 4.56)	0.6872	
OCS dose at baseline									0.4225
<10 mg/day	2/115 (1.7)	1.6	1/117 (0.9)	0.9	1.82 (0.17, 19.53)	0.6191	0.67 (-6.82, 8.16)	0.8609	
>=10 mg/day	2/131 (1.5)	1.5	4/129 (3.1)	3.1	0.57 (0.12, 2.67)	0.4794	-1.60 (-8.69, 5.50)	0.6590	
Result of type I IFN gene signature test									0.3348
LOW	2/ 45 (4.4)	4.5	1/ 48 (2.1)	2.1	2.18 (0.21, 22.42)	0.5116	2.43 (-9.79, 14.66)	0.6963	
HIGH	2/201 (1.0)	1.0	4/198 (2.0)	2.0	0.55 (0.12, 2.59)	0.4501	-1.03 (-6.39, 4.32)	0.7052	
Age (years)									NE
<= 65	4/239 (1.7)	1.7	5/243 (2.1)	2.0	0.85 (0.24, 2.99)	0.8039	-0.33 (-5.34, 4.68)	0.8979	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-62.98, 62.98)	1.0000	
Sex									NE
male	0/ 23 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-20.84, 20.84)	1.0000	
female	4/223 (1.8)	1.8	5/226 (2.2)	2.2	0.86 (0.25, 3.00)	0.8103	-0.32 (-5.65, 5.01)	0.9057	
Race									0.6996
White	2/160 (1.3)	1.2	2/174 (1.1)	1.2	1.15 (0.17, 7.77)	0.8839	0.03 (-6.09, 6.15)	0.9929	
Black	1/ 33 (3.0)	2.5	2/ 32 (6.3)	7.9	0.32 (0.03, 3.19)	0.3302	-5.42 (-23.20, 12.36)	0.5504	
Other	1/ 45 (2.2)	2.1	1/ 37 (2.7)	2.8	0.75 (0.05, 11.05)	0.8340	-0.70 (-13.84, 12.43)	0.9163	
Ethnicity									0.3917
Hispanic/Latino	1/ 50 (2.0)	1.9	3/ 56 (5.4)	5.4	0.47 (0.07, 3.08)	0.4330	-3.51 (-14.74, 7.73)	0.5405	
Non-hispanic/Latino	3/188 (1.6)	1.8	2/187 (1.1)	1.0	1.46 (0.25, 8.54)	0.6767	0.75 (-4.84, 6.35)	0.7914	
Geographic region									NE
EU	0/ 92 (0.0)	0.0	0/ 89 (0.0)	0.0	NE		0.00 (-5.86, 5.86)	1.0000	
non-EU	4/154 (2.6)	2.4	5/157 (3.2)	3.4	0.77 (0.22, 2.65)	0.6742	-1.01 (-7.42, 5.40)	0.7581	
Onset of disease									0.2950
Paediatric	0/ 19 (0.0)	0.0	1/ 12 (8.3)	9.6	0.17 (0.01, 3.51)	0.2491	-9.59 (-39.37, 20.20)	0.5281	
Adult	4/227 (1.8)	1.7	4/234 (1.7)	1.7	0.99 (0.25, 3.87)	0.9903	0.03 (-5.11, 5.17)	0.9901	
ADA result									0.4135
Negative	3/226 (1.3)	1.3	2/223 (0.9)	0.8	1.51 (0.26, 8.88)	0.6463	0.47 (-4.65, 5.58)	0.8575	
Positive (At any time)	1/ 19 (5.3)	4.7	3/ 23 (13.0)	13.8	0.52 (0.08, 3.24)	0.4876	-9.09 (-34.50, 16.32)	0.4832	
BMI (kg/m2) at enrolment									0.9634
< 30	2/159 (1.3)	1.2	3/176 (1.7)	1.6	0.78 (0.13, 4.57)	0.7864	-0.33 (-5.85, 5.18)	0.9053	
>= 30	2/ 87 (2.3)	2.1	2/ 70 (2.9)	2.9	0.83 (0.13, 5.53)	0.8497	-0.77 (-10.33, 8.79)	0.8745	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Non-opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	2 (0.8)	11 (4.5)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.23 (0.06, 0.92)	
p-value	0.0376	
Odds Ratio (95% CI)	0.22 (0.06, 0.91)	
p-value	0.0358	
Risk Difference (95% CI)	-3.64 (-6.45, -0.83)	
p-value	0.0111	
CMH approach		
Response rate	0.9	4.4
Difference in response rates (95% CI)	-3.56 (-8.67, 1.55)	
p-value	0.1717	
p-Value for test for heterogenity between studies	0.5616	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Non-opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9634
< 10 points	0/ 80 (0.0)	0.0	2/ 69 (2.9)	2.8	0.29 (0.03, 2.71)	0.2762	-2.78 (-13.75, 8.19)	0.6191	
>= 10 points	2/166 (1.2)	1.2	9/177 (5.1)	5.1	0.31 (0.08, 1.23)	0.0944	-3.82 (-9.83, 2.19)	0.2126	
OCS dose at baseline									0.8356
<10 mg/day	1/115 (0.9)	1.0	5/117 (4.3)	4.0	0.29 (0.05, 1.75)	0.1764	-3.04 (-10.99, 4.91)	0.4542	
>=10 mg/day	1/131 (0.8)	0.8	6/129 (4.7)	4.9	0.22 (0.04, 1.29)	0.0933	-4.16 (-11.41, 3.09)	0.2608	
Result of type I IFN gene signature test									0.8252
LOW	0/ 45 (0.0)	0.0	1/ 48 (2.1)	2.1	0.36 (0.02, 8.46)	0.5276	-2.06 (-13.20, 9.08)	0.7172	
HIGH	2/201 (1.0)	1.1	10/198 (5.1)	5.0	0.25 (0.06, 0.97)	0.0448	-3.91 (-9.65, 1.82)	0.1812	
Age (years)									NE
<= 65	2/239 (0.8)	0.9	11/243 (4.5)	4.5	0.24 (0.06, 0.93)	0.0392	-3.60 (-8.80, 1.60)	0.1744	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-62.98, 62.98)	1.0000	
Sex									0.9653
male	0/ 23 (0.0)	0.0	1/ 20 (5.0)	5.7	0.23 (0.01, 5.05)	0.3517	-5.69 (-27.67, 16.28)	0.6116	
female	2/223 (0.9)	0.9	10/226 (4.4)	4.4	0.25 (0.06, 0.98)	0.0468	-3.48 (-8.95, 2.00)	0.2132	
Race									0.7292
White	2/160 (1.3)	1.3	6/174 (3.4)	3.7	0.43 (0.10, 1.84)	0.2545	-2.44 (-8.93, 4.05)	0.4616	
Black	0/ 33 (0.0)	0.0	1/ 32 (3.1)	2.5	0.53 (0.02, 11.93)	0.6879	-2.47 (-18.31, 13.38)	0.7604	
Other	0/ 45 (0.0)	0.0	4/ 37 (10.8)	10.9	0.16 (0.02, 1.35)	0.0922	-10.88 (-25.41, 3.64)	0.1418	
Ethnicity									0.5666
Hispanic/Latino	0/ 50 (0.0)	0.0	5/ 56 (8.9)	9.0	0.19 (0.02, 1.50)	0.1142	-9.03 (-20.53, 2.46)	0.1236	
Non-hispanic/Latino	2/188 (1.1)	1.1	6/187 (3.2)	3.1	0.39 (0.09, 1.65)	0.2001	-1.92 (-7.73, 3.89)	0.5174	
Geographic region									0.7668
EU	0/ 92 (0.0)	0.0	3/ 89 (3.4)	3.6	0.24 (0.03, 2.09)	0.1939	-3.61 (-10.49, 3.27)	0.3038	
non-EU	2/154 (1.3)	1.5	8/157 (5.1)	5.1	0.35 (0.08, 1.43)	0.1440	-3.58 (-10.18, 3.03)	0.2885	
Onset of disease									0.2852
Paediatric	1/ 19 (5.3)	4.4	1/ 12 (8.3)	7.4	0.67 (0.08, 5.78)	0.7142	-3.08 (-33.24, 27.08)	0.8414	
Adult	1/227 (0.4)	0.4	10/234 (4.3)	4.2	0.15 (0.03, 0.82)	0.0284	-3.76 (-9.03, 1.51)	0.1618	
ADA result									0.8944
Negative	2/226 (0.9)	0.9	8/223 (3.6)	3.6	0.31 (0.07, 1.27)	0.1034	-2.67 (-8.10, 2.76)	0.3349	
Positive (At any time)	0/ 19 (0.0)	0.0	3/ 23 (13.0)	11.3	0.37 (0.04, 2.99)	0.3475	-11.27 (-34.85, 12.31)	0.3487	
BMI (kg/m2) at enrolment									0.5115
< 30	1/159 (0.6)	0.6	9/176 (5.1)	4.9	0.18 (0.03, 0.99)	0.0483	-4.31 (-10.26, 1.64)	0.1559	
>= 30	1/ 87 (1.1)	1.3	2/ 70 (2.9)	2.7	0.47 (0.04, 4.94)	0.5298	-1.41 (-10.96, 8.13)	0.7715	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	1 (0.4)	1 (0.4)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.98 (0.06, 15.56)	
p-value	0.9910	
Odds Ratio (95% CI)	0.98 (0.06, 15.91)	
p-value	0.9910	
Risk Difference (95% CI)	-0.01 (-1.13, 1.12)	
p-value	0.9910	
CMH approach		
Response rate	0.4	0.4
Difference in response rates (95% CI)	-0.00 (-4.60, 4.59)	
p-value	0.9991	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE		0.00 (-10.64, 10.64)	1.0000	
>= 10 points	1/166 (0.6)	0.6	1/177 (0.6)	0.6	1.00 (0.06, 15.74)	1.0000	-0.00 (-5.26, 5.25)	0.9989	
OCS dose at baseline									0.3104
<10 mg/day	0/115 (0.0)	0.0	1/117 (0.9)	0.9	0.30 (0.01, 7.32)	0.4636	-0.90 (-8.25, 6.44)	0.8096	
>=10 mg/day	1/131 (0.8)	0.8	0/129 (0.0)	0.0	3.13 (0.13, 75.49)	0.4828	0.81 (-5.67, 7.28)	0.8071	
Result of type I IFN gene signature test									NE
LOW	0/ 45 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-10.61, 10.61)	1.0000	
HIGH	1/201 (0.5)	0.5	1/198 (0.5)	0.5	0.96 (0.06, 15.17)	0.9780	-0.00 (-5.10, 5.09)	0.9990	
Age (years)									NE
<= 65	1/239 (0.4)	0.4	1/243 (0.4)	0.4	1.01 (0.06, 15.94)	0.9954	0.01 (-4.66, 4.69)	0.9955	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-62.98, 62.98)	1.0000	
Sex									NE
male	0/ 23 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-20.84, 20.84)	1.0000	
female	1/223 (0.4)	0.5	1/226 (0.4)	0.5	1.02 (0.06, 16.07)	0.9902	0.01 (-4.97, 4.99)	0.9971	
Race									0.2981
White	0/160 (0.0)	0.0	0/174 (0.0)	0.0	NE		0.00 (-5.80, 5.80)	1.0000	
Black	0/ 33 (0.0)	0.0	1/ 32 (3.1)	4.0	0.22 (0.01, 4.99)	0.3399	-3.97 (-20.42, 12.47)	0.6359	
Other	1/ 45 (2.2)	2.1	0/ 37 (0.0)	0.0	2.29 (0.10, 52.48)	0.6051	2.11 (-10.33, 14.56)	0.7392	
Ethnicity									NE
Hispanic/Latino	0/ 50 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-9.46, 9.46)	1.0000	
Non-hispanic/Latino	1/188 (0.5)	0.6	1/187 (0.5)	0.6	0.97 (0.06, 15.32)	0.9834	-0.06 (-5.45, 5.34)	0.9837	
Geographic region									NE
EU	0/ 92 (0.0)	0.0	0/ 89 (0.0)	0.0	NE		0.00 (-5.86, 5.86)	1.0000	
non-EU	1/154 (0.6)	0.6	1/157 (0.6)	0.7	0.86 (0.05, 13.53)	0.9161	-0.13 (-5.93, 5.66)	0.9639	
Onset of disease									NE
Paediatric	0/ 19 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-28.28, 28.28)	1.0000	
Adult	1/227 (0.4)	0.5	1/234 (0.4)	0.4	0.99 (0.06, 15.67)	0.9952	0.02 (-4.84, 4.88)	0.9935	
ADA result									0.3040
Negative	1/226 (0.4)	0.5	0/223 (0.0)	0.0	3.03 (0.12, 73.51)	0.4962	0.49 (-4.46, 5.44)	0.8459	
Positive (At any time)	0/ 19 (0.0)	0.0	1/ 23 (4.3)	5.5	0.29 (0.01, 6.60)	0.4388	-5.45 (-28.46, 17.55)	0.6422	
BMI (kg/m2) at enrolment									0.2424
< 30	1/159 (0.6)	0.7	0/176 (0.0)	0.0	3.52 (0.15, 85.13)	0.4388	0.65 (-4.56, 5.87)	0.8059	
>= 30	0/ 87 (0.0)	0.0	1/ 70 (1.4)	1.6	0.24 (0.01, 5.75)	0.3792	-1.56 (-10.60, 7.49)	0.7361	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	0 (0.0)	1 (0.4)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.33 (0.01, 7.98)	
p-value	0.4937	
Odds Ratio (95% CI)	0.33 (0.01, 8.07)	
p-value	0.4932	
Risk Difference (95% CI)	-0.41 (-1.21, 0.39)	
p-value	0.3144	
CMH approach		
Response rate	0.0	0.4
Difference in response rates (95% CI)	-0.43 (-4.96, 4.11)	
p-value	0.8540	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE		0.00 (-10.64, 10.64)	1.0000	
>= 10 points	0/166 (0.0)	0.0	1/177 (0.6)	0.6	0.33 (0.01, 8.07)	0.4993	-0.61 (-5.75, 4.53)	0.8162	
OCS dose at baseline									NE
<10 mg/day	0/115 (0.0)	0.0	1/117 (0.9)	0.9	0.30 (0.01, 7.32)	0.4636	-0.90 (-8.25, 6.44)	0.8096	
>=10 mg/day	0/131 (0.0)	0.0	0/129 (0.0)	0.0	NE		0.00 (-6.32, 6.32)	1.0000	
Result of type I IFN gene signature test									NE
LOW	0/ 45 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-10.61, 10.61)	1.0000	
HIGH	0/201 (0.0)	0.0	1/198 (0.5)	0.5	0.32 (0.01, 7.78)	0.4847	-0.53 (-5.53, 4.48)	0.8371	
Age (years)									NE
<= 65	0/239 (0.0)	0.0	1/243 (0.4)	0.4	0.34 (0.01, 8.17)	0.5030	-0.42 (-5.03, 4.19)	0.8589	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-62.98, 62.98)	1.0000	
Sex									NE
male	0/ 23 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-20.84, 20.84)	1.0000	
female	0/223 (0.0)	0.0	1/226 (0.4)	0.5	0.34 (0.01, 8.24)	0.5064	-0.47 (-5.38, 4.45)	0.8523	
Race									NE
White	0/160 (0.0)	0.0	0/174 (0.0)	0.0	NE		0.00 (-5.80, 5.80)	1.0000	
Black	0/ 33 (0.0)	0.0	1/ 32 (3.1)	4.0	0.22 (0.01, 4.99)	0.3399	-3.97 (-20.42, 12.47)	0.6359	
Other	0/ 45 (0.0)	0.0	0/ 37 (0.0)	0.0	NE		0.00 (-11.98, 11.98)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 50 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-9.46, 9.46)	1.0000	
Non-hispanic/Latino	0/188 (0.0)	0.0	1/187 (0.5)	0.6	0.32 (0.01, 7.86)	0.4883	-0.63 (-5.93, 4.67)	0.8155	
Geographic region									NE
EU	0/ 92 (0.0)	0.0	0/ 89 (0.0)	0.0	NE		0.00 (-5.86, 5.86)	1.0000	
non-EU	0/154 (0.0)	0.0	1/157 (0.6)	0.7	0.29 (0.01, 6.96)	0.4437	-0.72 (-6.42, 4.98)	0.8048	
Onset of disease									NE
Paediatric	0/ 19 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-28.28, 28.28)	1.0000	
Adult	0/227 (0.0)	0.0	1/234 (0.4)	0.4	0.33 (0.01, 8.03)	0.4965	-0.44 (-5.23, 4.35)	0.8583	
ADA result									NE
Negative	0/226 (0.0)	0.0	0/223 (0.0)	0.0	NE		0.00 (-4.87, 4.87)	1.0000	
Positive (At any time)	0/ 19 (0.0)	0.0	1/ 23 (4.3)	5.5	0.29 (0.01, 6.60)	0.4388	-5.45 (-28.46, 17.55)	0.6422	
BMI (kg/m2) at enrolment									NE
< 30	0/159 (0.0)	0.0	0/176 (0.0)	0.0	NE		0.00 (-5.09, 5.09)	1.0000	
>= 30	0/ 87 (0.0)	0.0	1/ 70 (1.4)	1.6	0.24 (0.01, 5.75)	0.3792	-1.56 (-10.60, 7.49)	0.7361	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	0 (0.0)	1 (0.4)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.33 (0.01, 7.98)	
p-value	0.4937	
Odds Ratio (95% CI)	0.33 (0.01, 8.07)	
p-value	0.4932	
Risk Difference (95% CI)	-0.41 (-1.21, 0.39)	
p-value	0.3144	
CMH approach		
Response rate	0.0	0.4
Difference in response rates (95% CI)	-0.43 (-4.96, 4.11)	
p-value	0.8540	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE		0.00 (-10.64, 10.64)	1.0000	
>= 10 points	0/166 (0.0)	0.0	1/177 (0.6)	0.6	0.33 (0.01, 8.07)	0.4993	-0.61 (-5.75, 4.53)	0.8162	
OCS dose at baseline									NE
<10 mg/day	0/115 (0.0)	0.0	1/117 (0.9)	0.9	0.30 (0.01, 7.32)	0.4636	-0.90 (-8.25, 6.44)	0.8096	
>=10 mg/day	0/131 (0.0)	0.0	0/129 (0.0)	0.0	NE		0.00 (-6.32, 6.32)	1.0000	
Result of type I IFN gene signature test									NE
LOW	0/ 45 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-10.61, 10.61)	1.0000	
HIGH	0/201 (0.0)	0.0	1/198 (0.5)	0.5	0.32 (0.01, 7.78)	0.4847	-0.53 (-5.53, 4.48)	0.8371	
Age (years)									NE
<= 65	0/239 (0.0)	0.0	1/243 (0.4)	0.4	0.34 (0.01, 8.17)	0.5030	-0.42 (-5.03, 4.19)	0.8589	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-62.98, 62.98)	1.0000	
Sex									NE
male	0/ 23 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-20.84, 20.84)	1.0000	
female	0/223 (0.0)	0.0	1/226 (0.4)	0.5	0.34 (0.01, 8.24)	0.5064	-0.47 (-5.38, 4.45)	0.8523	
Race									NE
White	0/160 (0.0)	0.0	0/174 (0.0)	0.0	NE		0.00 (-5.80, 5.80)	1.0000	
Black	0/ 33 (0.0)	0.0	1/ 32 (3.1)	4.0	0.22 (0.01, 4.99)	0.3399	-3.97 (-20.42, 12.47)	0.6359	
Other	0/ 45 (0.0)	0.0	0/ 37 (0.0)	0.0	NE		0.00 (-11.98, 11.98)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 50 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-9.46, 9.46)	1.0000	
Non-hispanic/Latino	0/188 (0.0)	0.0	1/187 (0.5)	0.6	0.32 (0.01, 7.86)	0.4883	-0.63 (-5.93, 4.67)	0.8155	
Geographic region									NE
EU	0/ 92 (0.0)	0.0	0/ 89 (0.0)	0.0	NE		0.00 (-5.86, 5.86)	1.0000	
non-EU	0/154 (0.0)	0.0	1/157 (0.6)	0.7	0.29 (0.01, 6.96)	0.4437	-0.72 (-6.42, 4.98)	0.8048	
Onset of disease									NE
Paediatric	0/ 19 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-28.28, 28.28)	1.0000	
Adult	0/227 (0.0)	0.0	1/234 (0.4)	0.4	0.33 (0.01, 8.03)	0.4965	-0.44 (-5.23, 4.35)	0.8583	
ADA result									NE
Negative	0/226 (0.0)	0.0	0/223 (0.0)	0.0	NE		0.00 (-4.87, 4.87)	1.0000	
Positive (At any time)	0/ 19 (0.0)	0.0	1/ 23 (4.3)	5.5	0.29 (0.01, 6.60)	0.4388	-5.45 (-28.46, 17.55)	0.6422	
BMI (kg/m2) at enrolment									NE
< 30	0/159 (0.0)	0.0	0/176 (0.0)	0.0	NE		0.00 (-5.09, 5.09)	1.0000	
>= 30	0/ 87 (0.0)	0.0	1/ 70 (1.4)	1.6	0.24 (0.01, 5.75)	0.3792	-1.56 (-10.60, 7.49)	0.7361	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	1 (0.4)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	2.95 (0.12, 71.81)	
p-value	0.5060	
Odds Ratio (95% CI)	2.98 (0.12, 73.76)	
p-value	0.5055	
Risk Difference (95% CI)	0.40 (-0.39, 1.20)	
p-value	0.3183	
CMH approach		
Response rate	0.4	0.0
Difference in response rates (95% CI)	0.42 (-4.12, 4.96)	
p-value	0.8551	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE		0.00 (-10.64, 10.64)	1.0000	
>= 10 points	1/166 (0.6)	0.6	0/177 (0.0)	0.0	3.00 (0.12, 72.65)	0.4993	0.61 (-4.55, 5.76)	0.8178	
OCS dose at baseline									NE
<10 mg/day	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE		0.00 (-7.19, 7.19)	1.0000	
>=10 mg/day	1/131 (0.8)	0.8	0/129 (0.0)	0.0	3.13 (0.13, 75.49)	0.4828	0.81 (-5.67, 7.28)	0.8071	
Result of type I IFN gene signature test									NE
LOW	0/ 45 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-10.61, 10.61)	1.0000	
HIGH	1/201 (0.5)	0.5	0/198 (0.0)	0.0	2.89 (0.12, 70.05)	0.5147	0.52 (-4.50, 5.54)	0.8384	
Age (years)									NE
<= 65	1/239 (0.4)	0.4	0/243 (0.0)	0.0	3.02 (0.12, 73.52)	0.4966	0.43 (-4.19, 5.06)	0.8547	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-62.98, 62.98)	1.0000	
Sex									NE
male	0/ 23 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-20.84, 20.84)	1.0000	
female	1/223 (0.4)	0.5	0/226 (0.0)	0.0	3.05 (0.13, 74.15)	0.4931	0.48 (-4.45, 5.40)	0.8498	
Race									NE
White	0/160 (0.0)	0.0	0/174 (0.0)	0.0	NE		0.00 (-5.80, 5.80)	1.0000	
Black	0/ 33 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-15.38, 15.38)	1.0000	
Other	1/ 45 (2.2)	2.1	0/ 37 (0.0)	0.0	2.29 (0.10, 52.48)	0.6051	2.11 (-10.33, 14.56)	0.7392	
Ethnicity									NE
Hispanic/Latino	0/ 50 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-9.46, 9.46)	1.0000	
Non-hispanic/Latino	1/188 (0.5)	0.6	0/187 (0.0)	0.0	2.91 (0.12, 70.71)	0.5109	0.58 (-4.73, 5.88)	0.8318	
Geographic region									NE
EU	0/ 92 (0.0)	0.0	0/ 89 (0.0)	0.0	NE		0.00 (-5.86, 5.86)	1.0000	
non-EU	1/154 (0.6)	0.6	0/157 (0.0)	0.0	2.59 (0.11, 62.63)	0.5577	0.58 (-5.07, 6.24)	0.8394	
Onset of disease									NE
Paediatric	0/ 19 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-28.28, 28.28)	1.0000	
Adult	1/227 (0.4)	0.5	0/234 (0.0)	0.0	2.98 (0.12, 72.30)	0.5030	0.46 (-4.35, 5.26)	0.8521	
ADA result									NE
Negative	1/226 (0.4)	0.5	0/223 (0.0)	0.0	3.03 (0.12, 73.51)	0.4962	0.49 (-4.46, 5.44)	0.8459	
Positive (At any time)	0/ 19 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-21.63, 21.63)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	1/159 (0.6)	0.7	0/176 (0.0)	0.0	3.52 (0.15, 85.13)	0.4388	0.65 (-4.56, 5.87)	0.8059	
>= 30	0/ 87 (0.0)	0.0	0/ 70 (0.0)	0.0	NE		0.00 (-8.73, 8.73)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	2 (0.8)	2 (0.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.00 (0.12, 8.50)	
p-value	0.9995	
Odds Ratio (95% CI)	1.00 (0.12, 8.63)	
p-value	0.9996	
Risk Difference (95% CI)	0.00 (-1.60, 1.60)	
p-value	0.9997	
CMH approach		
Response rate	0.8	0.8
Difference in response rates (95% CI)	-0.02 (-4.68, 4.65)	
p-value	0.9946	
p-Value for test for heterogenity between studies	0.1365	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8964
< 10 points	1/ 80 (1.3)	1.4	1/ 69 (1.4)	1.4	0.86 (0.09, 8.13)	0.8986	-0.04 (-11.07, 10.99)	0.9937	
>= 10 points	1/166 (0.6)	0.6	1/177 (0.6)	0.6	1.07 (0.11, 10.16)	0.9546	-0.00 (-5.24, 5.24)	0.9988	
OCS dose at baseline									0.9851
<10 mg/day	1/115 (0.9)	0.9	1/117 (0.9)	0.9	1.01 (0.11, 9.57)	0.9930	-0.03 (-7.45, 7.40)	0.9941	
>=10 mg/day	1/131 (0.8)	0.8	1/129 (0.8)	0.8	0.98 (0.10, 9.30)	0.9860	-0.01 (-6.60, 6.59)	0.9988	
Result of type I IFN gene signature test									NE
LOW	0/ 45 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-10.61, 10.61)	1.0000	
HIGH	2/201 (1.0)	1.0	2/198 (1.0)	1.0	0.99 (0.12, 8.37)	0.9900	-0.02 (-5.21, 5.17)	0.9941	
Age (years)									NE
<= 65	2/239 (0.8)	0.8	2/243 (0.8)	0.8	1.02 (0.12, 8.64)	0.9877	-0.01 (-4.77, 4.75)	0.9964	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-62.98, 62.98)	1.0000	
Sex									NE
male	0/ 23 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-20.84, 20.84)	1.0000	
female	2/223 (0.9)	0.9	2/226 (0.9)	0.9	1.01 (0.12, 8.61)	0.9901	0.00 (-5.05, 5.06)	0.9988	
Race									NE
White	2/160 (1.3)	1.1	2/174 (1.1)	1.2	1.08 (0.13, 9.18)	0.9409	-0.06 (-6.14, 6.03)	0.9855	
Black	0/ 33 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-15.38, 15.38)	1.0000	
Other	0/ 45 (0.0)	0.0	0/ 37 (0.0)	0.0	NE		0.00 (-11.98, 11.98)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 50 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-9.46, 9.46)	1.0000	
Non-hispanic/Latino	2/188 (1.1)	1.0	2/187 (1.1)	1.0	1.00 (0.12, 8.47)	0.9989	-0.01 (-5.50, 5.47)	0.9958	
Geographic region									NE
EU	2/ 92 (2.2)	1.9	2/ 89 (2.2)	2.0	0.94 (0.11, 7.89)	0.9548	-0.15 (-6.98, 6.68)	0.9659	
non-EU	0/154 (0.0)	0.0	0/157 (0.0)	0.0	NE		0.00 (-5.56, 5.56)	1.0000	
Onset of disease									NE
Paediatric	0/ 19 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-28.28, 28.28)	1.0000	
Adult	2/227 (0.9)	0.9	2/234 (0.9)	0.9	1.03 (0.12, 8.77)	0.9769	-0.00 (-4.94, 4.94)	0.9993	
ADA result									NE
Negative	2/226 (0.9)	0.9	2/223 (0.9)	0.9	0.99 (0.12, 8.38)	0.9904	-0.02 (-5.09, 5.04)	0.9931	
Positive (At any time)	0/ 19 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-21.63, 21.63)	1.0000	
BMI (kg/m2) at enrolment									0.8576
< 30	1/159 (0.6)	0.6	1/176 (0.6)	0.6	1.11 (0.12, 10.54)	0.9291	-0.00 (-5.30, 5.30)	0.9990	
>= 30	1/ 87 (1.1)	1.3	1/ 70 (1.4)	1.6	0.83 (0.09, 7.79)	0.8690	-0.30 (-9.60, 9.00)	0.9498	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.48, 4.48)	
p-value	1.0000	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-10.64, 10.64)	1.0000	
>= 10 points	0/166 (0.0)	0.0	0/177 (0.0)	0.0	NE	0.00 (-5.04, 5.04)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-7.19, 7.19)	1.0000	
>=10 mg/day	0/131 (0.0)	0.0	0/129 (0.0)	0.0	NE	0.00 (-6.32, 6.32)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 45 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-10.61, 10.61)	1.0000	
HIGH	0/201 (0.0)	0.0	0/198 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
Age (years)								NE
<= 65	0/239 (0.0)	0.0	0/243 (0.0)	0.0	NE	0.00 (-4.56, 4.56)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-62.98, 62.98)	1.0000	
Sex								NE
male	0/ 23 (0.0)	0.0	0/ 20 (0.0)	0.0	NE	0.00 (-20.84, 20.84)	1.0000	
female	0/223 (0.0)	0.0	0/226 (0.0)	0.0	NE	0.00 (-4.85, 4.85)	1.0000	
Race								NE
White	0/160 (0.0)	0.0	0/174 (0.0)	0.0	NE	0.00 (-5.80, 5.80)	1.0000	
Black	0/ 33 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.38, 15.38)	1.0000	
Other	0/ 45 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-11.98, 11.98)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 50 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.46, 9.46)	1.0000	
Non-hispanic/Latino	0/188 (0.0)	0.0	0/187 (0.0)	0.0	NE	0.00 (-5.21, 5.21)	1.0000	
Geographic region								NE
EU	0/ 92 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-5.86, 5.86)	1.0000	
non-EU	0/154 (0.0)	0.0	0/157 (0.0)	0.0	NE	0.00 (-5.56, 5.56)	1.0000	
Onset of disease								NE
Paediatric	0/ 19 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-28.28, 28.28)	1.0000	
Adult	0/227 (0.0)	0.0	0/234 (0.0)	0.0	NE	0.00 (-4.74, 4.74)	1.0000	
ADA result								NE
Negative	0/226 (0.0)	0.0	0/223 (0.0)	0.0	NE	0.00 (-4.87, 4.87)	1.0000	
Positive (At any time)	0/ 19 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-21.63, 21.63)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/159 (0.0)	0.0	0/176 (0.0)	0.0	NE	0.00 (-5.09, 5.09)	1.0000	
>= 30	0/ 87 (0.0)	0.0	0/ 70 (0.0)	0.0	NE	0.00 (-8.73, 8.73)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.48, 4.48)	
p-value	1.0000	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-10.64, 10.64)	1.0000	
>= 10 points	0/166 (0.0)	0.0	0/177 (0.0)	0.0	NE	0.00 (-5.04, 5.04)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-7.19, 7.19)	1.0000	
>=10 mg/day	0/131 (0.0)	0.0	0/129 (0.0)	0.0	NE	0.00 (-6.32, 6.32)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 45 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-10.61, 10.61)	1.0000	
HIGH	0/201 (0.0)	0.0	0/198 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
Age (years)								NE
<= 65	0/239 (0.0)	0.0	0/243 (0.0)	0.0	NE	0.00 (-4.56, 4.56)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-62.98, 62.98)	1.0000	
Sex								NE
male	0/ 23 (0.0)	0.0	0/ 20 (0.0)	0.0	NE	0.00 (-20.84, 20.84)	1.0000	
female	0/223 (0.0)	0.0	0/226 (0.0)	0.0	NE	0.00 (-4.85, 4.85)	1.0000	
Race								NE
White	0/160 (0.0)	0.0	0/174 (0.0)	0.0	NE	0.00 (-5.80, 5.80)	1.0000	
Black	0/ 33 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.38, 15.38)	1.0000	
Other	0/ 45 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-11.98, 11.98)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 50 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.46, 9.46)	1.0000	
Non-hispanic/Latino	0/188 (0.0)	0.0	0/187 (0.0)	0.0	NE	0.00 (-5.21, 5.21)	1.0000	
Geographic region								NE
EU	0/ 92 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-5.86, 5.86)	1.0000	
non-EU	0/154 (0.0)	0.0	0/157 (0.0)	0.0	NE	0.00 (-5.56, 5.56)	1.0000	
Onset of disease								NE
Paediatric	0/ 19 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-28.28, 28.28)	1.0000	
Adult	0/227 (0.0)	0.0	0/234 (0.0)	0.0	NE	0.00 (-4.74, 4.74)	1.0000	
ADA result								NE
Negative	0/226 (0.0)	0.0	0/223 (0.0)	0.0	NE	0.00 (-4.87, 4.87)	1.0000	
Positive (At any time)	0/ 19 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-21.63, 21.63)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/159 (0.0)	0.0	0/176 (0.0)	0.0	NE	0.00 (-5.09, 5.09)	1.0000	
>= 30	0/ 87 (0.0)	0.0	0/ 70 (0.0)	0.0	NE	0.00 (-8.73, 8.73)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	2 (0.8)	2 (0.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.00 (0.12, 8.50)	
p-value	0.9995	
Odds Ratio (95% CI)	1.00 (0.12, 8.63)	
p-value	0.9996	
Risk Difference (95% CI)	0.00 (-1.60, 1.60)	
p-value	0.9997	
CMH approach		
Response rate	0.8	0.8
Difference in response rates (95% CI)	-0.02 (-4.68, 4.65)	
p-value	0.9946	
p-Value for test for heterogenity between studies	0.1365	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8964
< 10 points	1/ 80 (1.3)	1.4	1/ 69 (1.4)	1.4	0.86 (0.09, 8.13)	0.8986	-0.04 (-11.07, 10.99)	0.9937	
>= 10 points	1/166 (0.6)	0.6	1/177 (0.6)	0.6	1.07 (0.11, 10.16)	0.9546	-0.00 (-5.24, 5.24)	0.9988	
OCS dose at baseline									0.9851
<10 mg/day	1/115 (0.9)	0.9	1/117 (0.9)	0.9	1.01 (0.11, 9.57)	0.9930	-0.03 (-7.45, 7.40)	0.9941	
>=10 mg/day	1/131 (0.8)	0.8	1/129 (0.8)	0.8	0.98 (0.10, 9.30)	0.9860	-0.01 (-6.60, 6.59)	0.9988	
Result of type I IFN gene signature test									NE
LOW	0/ 45 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-10.61, 10.61)	1.0000	
HIGH	2/201 (1.0)	1.0	2/198 (1.0)	1.0	0.99 (0.12, 8.37)	0.9900	-0.02 (-5.21, 5.17)	0.9941	
Age (years)									NE
<= 65	2/239 (0.8)	0.8	2/243 (0.8)	0.8	1.02 (0.12, 8.64)	0.9877	-0.01 (-4.77, 4.75)	0.9964	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-62.98, 62.98)	1.0000	
Sex									NE
male	0/ 23 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-20.84, 20.84)	1.0000	
female	2/223 (0.9)	0.9	2/226 (0.9)	0.9	1.01 (0.12, 8.61)	0.9901	0.00 (-5.05, 5.06)	0.9988	
Race									NE
White	2/160 (1.3)	1.1	2/174 (1.1)	1.2	1.08 (0.13, 9.18)	0.9409	-0.06 (-6.14, 6.03)	0.9855	
Black	0/ 33 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-15.38, 15.38)	1.0000	
Other	0/ 45 (0.0)	0.0	0/ 37 (0.0)	0.0	NE		0.00 (-11.98, 11.98)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 50 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-9.46, 9.46)	1.0000	
Non-hispanic/Latino	2/188 (1.1)	1.0	2/187 (1.1)	1.0	1.00 (0.12, 8.47)	0.9989	-0.01 (-5.50, 5.47)	0.9958	
Geographic region									NE
EU	2/ 92 (2.2)	1.9	2/ 89 (2.2)	2.0	0.94 (0.11, 7.89)	0.9548	-0.15 (-6.98, 6.68)	0.9659	
non-EU	0/154 (0.0)	0.0	0/157 (0.0)	0.0	NE		0.00 (-5.56, 5.56)	1.0000	
Onset of disease									NE
Paediatric	0/ 19 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-28.28, 28.28)	1.0000	
Adult	2/227 (0.9)	0.9	2/234 (0.9)	0.9	1.03 (0.12, 8.77)	0.9769	-0.00 (-4.94, 4.94)	0.9993	
ADA result									NE
Negative	2/226 (0.9)	0.9	2/223 (0.9)	0.9	0.99 (0.12, 8.38)	0.9904	-0.02 (-5.09, 5.04)	0.9931	
Positive (At any time)	0/ 19 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-21.63, 21.63)	1.0000	
BMI (kg/m2) at enrolment									0.8576
< 30	1/159 (0.6)	0.6	1/176 (0.6)	0.6	1.11 (0.12, 10.54)	0.9291	-0.00 (-5.30, 5.30)	0.9990	
>= 30	1/ 87 (1.1)	1.3	1/ 70 (1.4)	1.6	0.83 (0.09, 7.79)	0.8690	-0.30 (-9.60, 9.00)	0.9498	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Vasculitis
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.48, 4.48)	
p-value	1.0000	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-10.64, 10.64)	1.0000	
>= 10 points	0/166 (0.0)	0.0	0/177 (0.0)	0.0	NE	0.00 (-5.04, 5.04)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-7.19, 7.19)	1.0000	
>=10 mg/day	0/131 (0.0)	0.0	0/129 (0.0)	0.0	NE	0.00 (-6.32, 6.32)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 45 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-10.61, 10.61)	1.0000	
HIGH	0/201 (0.0)	0.0	0/198 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
Age (years)								NE
<= 65	0/239 (0.0)	0.0	0/243 (0.0)	0.0	NE	0.00 (-4.56, 4.56)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-62.98, 62.98)	1.0000	
Sex								NE
male	0/ 23 (0.0)	0.0	0/ 20 (0.0)	0.0	NE	0.00 (-20.84, 20.84)	1.0000	
female	0/223 (0.0)	0.0	0/226 (0.0)	0.0	NE	0.00 (-4.85, 4.85)	1.0000	
Race								NE
White	0/160 (0.0)	0.0	0/174 (0.0)	0.0	NE	0.00 (-5.80, 5.80)	1.0000	
Black	0/ 33 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.38, 15.38)	1.0000	
Other	0/ 45 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-11.98, 11.98)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 50 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.46, 9.46)	1.0000	
Non-hispanic/Latino	0/188 (0.0)	0.0	0/187 (0.0)	0.0	NE	0.00 (-5.21, 5.21)	1.0000	
Geographic region								NE
EU	0/ 92 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-5.86, 5.86)	1.0000	
non-EU	0/154 (0.0)	0.0	0/157 (0.0)	0.0	NE	0.00 (-5.56, 5.56)	1.0000	
Onset of disease								NE
Paediatric	0/ 19 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-28.28, 28.28)	1.0000	
Adult	0/227 (0.0)	0.0	0/234 (0.0)	0.0	NE	0.00 (-4.74, 4.74)	1.0000	
ADA result								NE
Negative	0/226 (0.0)	0.0	0/223 (0.0)	0.0	NE	0.00 (-4.87, 4.87)	1.0000	
Positive (At any time)	0/ 19 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-21.63, 21.63)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/159 (0.0)	0.0	0/176 (0.0)	0.0	NE	0.00 (-5.09, 5.09)	1.0000	
>= 30	0/ 87 (0.0)	0.0	0/ 70 (0.0)	0.0	NE	0.00 (-8.73, 8.73)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Vasculitis
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.48, 4.48)	
p-value	1.0000	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-10.64, 10.64)	1.0000	
>= 10 points	0/166 (0.0)	0.0	0/177 (0.0)	0.0	NE	0.00 (-5.04, 5.04)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-7.19, 7.19)	1.0000	
>=10 mg/day	0/131 (0.0)	0.0	0/129 (0.0)	0.0	NE	0.00 (-6.32, 6.32)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 45 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-10.61, 10.61)	1.0000	
HIGH	0/201 (0.0)	0.0	0/198 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
Age (years)								NE
<= 65	0/239 (0.0)	0.0	0/243 (0.0)	0.0	NE	0.00 (-4.56, 4.56)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-62.98, 62.98)	1.0000	
Sex								NE
male	0/ 23 (0.0)	0.0	0/ 20 (0.0)	0.0	NE	0.00 (-20.84, 20.84)	1.0000	
female	0/223 (0.0)	0.0	0/226 (0.0)	0.0	NE	0.00 (-4.85, 4.85)	1.0000	
Race								NE
White	0/160 (0.0)	0.0	0/174 (0.0)	0.0	NE	0.00 (-5.80, 5.80)	1.0000	
Black	0/ 33 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.38, 15.38)	1.0000	
Other	0/ 45 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-11.98, 11.98)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 50 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.46, 9.46)	1.0000	
Non-hispanic/Latino	0/188 (0.0)	0.0	0/187 (0.0)	0.0	NE	0.00 (-5.21, 5.21)	1.0000	
Geographic region								NE
EU	0/ 92 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-5.86, 5.86)	1.0000	
non-EU	0/154 (0.0)	0.0	0/157 (0.0)	0.0	NE	0.00 (-5.56, 5.56)	1.0000	
Onset of disease								NE
Paediatric	0/ 19 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-28.28, 28.28)	1.0000	
Adult	0/227 (0.0)	0.0	0/234 (0.0)	0.0	NE	0.00 (-4.74, 4.74)	1.0000	
ADA result								NE
Negative	0/226 (0.0)	0.0	0/223 (0.0)	0.0	NE	0.00 (-4.87, 4.87)	1.0000	
Positive (At any time)	0/ 19 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-21.63, 21.63)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/159 (0.0)	0.0	0/176 (0.0)	0.0	NE	0.00 (-5.09, 5.09)	1.0000	
>= 30	0/ 87 (0.0)	0.0	0/ 70 (0.0)	0.0	NE	0.00 (-8.73, 8.73)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Vasculitis
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.48, 4.48)	
p-value	1.0000	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-10.64, 10.64)	1.0000	
>= 10 points	0/166 (0.0)	0.0	0/177 (0.0)	0.0	NE	0.00 (-5.04, 5.04)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-7.19, 7.19)	1.0000	
>=10 mg/day	0/131 (0.0)	0.0	0/129 (0.0)	0.0	NE	0.00 (-6.32, 6.32)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 45 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-10.61, 10.61)	1.0000	
HIGH	0/201 (0.0)	0.0	0/198 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
Age (years)								NE
<= 65	0/239 (0.0)	0.0	0/243 (0.0)	0.0	NE	0.00 (-4.56, 4.56)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-62.98, 62.98)	1.0000	
Sex								NE
male	0/ 23 (0.0)	0.0	0/ 20 (0.0)	0.0	NE	0.00 (-20.84, 20.84)	1.0000	
female	0/223 (0.0)	0.0	0/226 (0.0)	0.0	NE	0.00 (-4.85, 4.85)	1.0000	
Race								NE
White	0/160 (0.0)	0.0	0/174 (0.0)	0.0	NE	0.00 (-5.80, 5.80)	1.0000	
Black	0/ 33 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.38, 15.38)	1.0000	
Other	0/ 45 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-11.98, 11.98)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 50 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.46, 9.46)	1.0000	
Non-hispanic/Latino	0/188 (0.0)	0.0	0/187 (0.0)	0.0	NE	0.00 (-5.21, 5.21)	1.0000	
Geographic region								NE
EU	0/ 92 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-5.86, 5.86)	1.0000	
non-EU	0/154 (0.0)	0.0	0/157 (0.0)	0.0	NE	0.00 (-5.56, 5.56)	1.0000	
Onset of disease								NE
Paediatric	0/ 19 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-28.28, 28.28)	1.0000	
Adult	0/227 (0.0)	0.0	0/234 (0.0)	0.0	NE	0.00 (-4.74, 4.74)	1.0000	
ADA result								NE
Negative	0/226 (0.0)	0.0	0/223 (0.0)	0.0	NE	0.00 (-4.87, 4.87)	1.0000	
Positive (At any time)	0/ 19 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-21.63, 21.63)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/159 (0.0)	0.0	0/176 (0.0)	0.0	NE	0.00 (-5.09, 5.09)	1.0000	
>= 30	0/ 87 (0.0)	0.0	0/ 70 (0.0)	0.0	NE	0.00 (-8.73, 8.73)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Vasculitis
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.48, 4.48)	
p-value	1.0000	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-10.64, 10.64)	1.0000	
>= 10 points	0/166 (0.0)	0.0	0/177 (0.0)	0.0	NE	0.00 (-5.04, 5.04)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-7.19, 7.19)	1.0000	
>=10 mg/day	0/131 (0.0)	0.0	0/129 (0.0)	0.0	NE	0.00 (-6.32, 6.32)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 45 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-10.61, 10.61)	1.0000	
HIGH	0/201 (0.0)	0.0	0/198 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
Age (years)								NE
<= 65	0/239 (0.0)	0.0	0/243 (0.0)	0.0	NE	0.00 (-4.56, 4.56)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-62.98, 62.98)	1.0000	
Sex								NE
male	0/ 23 (0.0)	0.0	0/ 20 (0.0)	0.0	NE	0.00 (-20.84, 20.84)	1.0000	
female	0/223 (0.0)	0.0	0/226 (0.0)	0.0	NE	0.00 (-4.85, 4.85)	1.0000	
Race								NE
White	0/160 (0.0)	0.0	0/174 (0.0)	0.0	NE	0.00 (-5.80, 5.80)	1.0000	
Black	0/ 33 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.38, 15.38)	1.0000	
Other	0/ 45 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-11.98, 11.98)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 50 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.46, 9.46)	1.0000	
Non-hispanic/Latino	0/188 (0.0)	0.0	0/187 (0.0)	0.0	NE	0.00 (-5.21, 5.21)	1.0000	
Geographic region								NE
EU	0/ 92 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-5.86, 5.86)	1.0000	
non-EU	0/154 (0.0)	0.0	0/157 (0.0)	0.0	NE	0.00 (-5.56, 5.56)	1.0000	
Onset of disease								NE
Paediatric	0/ 19 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-28.28, 28.28)	1.0000	
Adult	0/227 (0.0)	0.0	0/234 (0.0)	0.0	NE	0.00 (-4.74, 4.74)	1.0000	
ADA result								NE
Negative	0/226 (0.0)	0.0	0/223 (0.0)	0.0	NE	0.00 (-4.87, 4.87)	1.0000	
Positive (At any time)	0/ 19 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-21.63, 21.63)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/159 (0.0)	0.0	0/176 (0.0)	0.0	NE	0.00 (-5.09, 5.09)	1.0000	
>= 30	0/ 87 (0.0)	0.0	0/ 70 (0.0)	0.0	NE	0.00 (-8.73, 8.73)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Malignancy
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	1 (0.4)	2 (0.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.62 (0.08, 5.03)	
p-value	0.6574	
Odds Ratio (95% CI)	0.62 (0.08, 5.08)	
p-value	0.6567	
Risk Difference (95% CI)	-0.41 (-1.78, 0.96)	
p-value	0.5589	
CMH approach		
Response rate	0.4	0.8
Difference in response rates (95% CI)	-0.47 (-5.09, 4.16)	
p-value	0.8431	
p-Value for test for heterogenity between studies	0.6204	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.2943
< 10 points	1/ 80 (1.3)	1.2	0/ 69 (0.0)	0.0	2.85 (0.12, 67.83)	0.5172	1.19 (-9.61, 11.99)	0.8294	
>= 10 points	0/166 (0.0)	0.0	2/177 (1.1)	1.2	0.36 (0.04, 3.39)	0.3687	-1.18 (-6.43, 4.08)	0.6602	
OCS dose at baseline									NE
<10 mg/day	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE		0.00 (-7.19, 7.19)	1.0000	
>=10 mg/day	1/131 (0.8)	0.7	2/129 (1.6)	1.6	0.62 (0.08, 4.95)	0.6496	-0.89 (-7.59, 5.80)	0.7942	
Result of type I IFN gene signature test									NE
LOW	0/ 45 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-10.61, 10.61)	1.0000	
HIGH	1/201 (0.5)	0.4	2/198 (1.0)	1.0	0.61 (0.08, 4.94)	0.6465	-0.58 (-5.71, 4.56)	0.8258	
Age (years)									NE
<= 65	1/239 (0.4)	0.3	2/243 (0.8)	0.8	0.63 (0.08, 5.12)	0.6693	-0.49 (-5.20, 4.22)	0.8390	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-62.98, 62.98)	1.0000	
Sex									NE
male	0/ 23 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-20.84, 20.84)	1.0000	
female	1/223 (0.4)	0.4	2/226 (0.9)	0.9	0.63 (0.08, 5.11)	0.6681	-0.50 (-5.51, 4.52)	0.8459	
Race									NE
White	1/160 (0.6)	0.7	2/174 (1.1)	1.1	0.68 (0.08, 5.47)	0.7178	-0.36 (-6.38, 5.67)	0.9075	
Black	0/ 33 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-15.38, 15.38)	1.0000	
Other	0/ 45 (0.0)	0.0	0/ 37 (0.0)	0.0	NE		0.00 (-11.98, 11.98)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 50 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-9.46, 9.46)	1.0000	
Non-hispanic/Latino	1/188 (0.5)	0.4	2/187 (1.1)	1.0	0.62 (0.08, 4.99)	0.6537	-0.59 (-6.00, 4.81)	0.8293	
Geographic region									NE
EU	1/ 92 (1.1)	1.2	2/ 89 (2.2)	2.3	0.61 (0.08, 4.83)	0.6366	-1.10 (-7.99, 5.79)	0.7548	
non-EU	0/154 (0.0)	0.0	0/157 (0.0)	0.0	NE		0.00 (-5.56, 5.56)	1.0000	
Onset of disease									NE
Paediatric	0/ 19 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-28.28, 28.28)	1.0000	
Adult	1/227 (0.4)	0.4	2/234 (0.9)	0.8	0.64 (0.08, 5.17)	0.6761	-0.46 (-5.34, 4.43)	0.8541	
ADA result									NE
Negative	1/226 (0.4)	0.4	2/223 (0.9)	0.9	0.62 (0.08, 4.99)	0.6521	-0.54 (-5.57, 4.49)	0.8334	
Positive (At any time)	0/ 19 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-21.63, 21.63)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	1/159 (0.6)	0.6	2/176 (1.1)	1.1	0.70 (0.09, 5.62)	0.7366	-0.55 (-5.91, 4.80)	0.8392	
>= 30	0/ 87 (0.0)	0.0	0/ 70 (0.0)	0.0	NE		0.00 (-8.73, 8.73)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Malignancy
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	1 (0.4)	1 (0.4)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.00 (0.10, 9.55)	
p-value	0.9998	
Odds Ratio (95% CI)	1.00 (0.10, 9.68)	
p-value	0.9998	
Risk Difference (95% CI)	0.00 (-1.12, 1.12)	
p-value	0.9998	
CMH approach		
Response rate	0.4	0.4
Difference in response rates (95% CI)	-0.07 (-4.64, 4.50)	
p-value	0.9758	
p-Value for test for heterogenity between studies	0.3471	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.3794
< 10 points	1/ 80 (1.3)	1.2	0/ 69 (0.0)	0.0	2.85 (0.12, 67.83)	0.5172	1.19 (-9.61, 11.99)	0.8294	
>= 10 points	0/166 (0.0)	0.0	1/177 (0.6)	0.6	0.38 (0.02, 9.19)	0.5514	-0.61 (-5.76, 4.54)	0.8165	
OCS dose at baseline									NE
<10 mg/day	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE		0.00 (-7.19, 7.19)	1.0000	
>=10 mg/day	1/131 (0.8)	0.7	1/129 (0.8)	0.8	0.98 (0.10, 9.28)	0.9842	-0.13 (-6.69, 6.42)	0.9679	
Result of type I IFN gene signature test									NE
LOW	0/ 45 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-10.61, 10.61)	1.0000	
HIGH	1/201 (0.5)	0.4	1/198 (0.5)	0.5	0.99 (0.10, 9.40)	0.9900	-0.09 (-5.15, 4.98)	0.9731	
Age (years)									NE
<= 65	1/239 (0.4)	0.3	1/243 (0.4)	0.4	1.02 (0.11, 9.71)	0.9886	-0.08 (-4.74, 4.57)	0.9720	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-62.98, 62.98)	1.0000	
Sex									NE
male	0/ 23 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-20.84, 20.84)	1.0000	
female	1/223 (0.4)	0.4	1/226 (0.4)	0.5	1.01 (0.11, 9.67)	0.9911	-0.08 (-5.03, 4.88)	0.9762	
Race									NE
White	1/160 (0.6)	0.7	1/174 (0.6)	0.6	1.08 (0.11, 10.30)	0.9454	0.15 (-5.81, 6.11)	0.9609	
Black	0/ 33 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-15.38, 15.38)	1.0000	
Other	0/ 45 (0.0)	0.0	0/ 37 (0.0)	0.0	NE		0.00 (-11.98, 11.98)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 50 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-9.46, 9.46)	1.0000	
Non-hispanic/Latino	1/188 (0.5)	0.4	1/187 (0.5)	0.5	1.00 (0.10, 9.49)	0.9975	-0.09 (-5.42, 5.24)	0.9733	
Geographic region									NE
EU	1/ 92 (1.1)	1.2	1/ 89 (1.1)	1.3	0.93 (0.10, 8.81)	0.9523	-0.07 (-6.71, 6.56)	0.9824	
non-EU	0/154 (0.0)	0.0	0/157 (0.0)	0.0	NE		0.00 (-5.56, 5.56)	1.0000	
Onset of disease									NE
Paediatric	0/ 19 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-28.28, 28.28)	1.0000	
Adult	1/227 (0.4)	0.4	1/234 (0.4)	0.4	1.03 (0.11, 9.84)	0.9785	-0.04 (-4.87, 4.79)	0.9864	
ADA result									NE
Negative	1/226 (0.4)	0.4	1/223 (0.4)	0.5	0.99 (0.10, 9.42)	0.9910	-0.13 (-5.11, 4.85)	0.9594	
Positive (At any time)	0/ 19 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-21.63, 21.63)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	1/159 (0.6)	0.6	1/176 (0.6)	0.6	1.11 (0.12, 10.55)	0.9285	-0.00 (-5.27, 5.26)	0.9989	
>= 30	0/ 87 (0.0)	0.0	0/ 70 (0.0)	0.0	NE		0.00 (-8.73, 8.73)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Malignancy
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.48, 4.48)	
p-value	1.0000	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 80 (0.0)	0.0	0/ 69 (0.0)	0.0	NE	0.00 (-10.64, 10.64)	1.0000	
>= 10 points	0/166 (0.0)	0.0	0/177 (0.0)	0.0	NE	0.00 (-5.04, 5.04)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE	0.00 (-7.19, 7.19)	1.0000	
>=10 mg/day	0/131 (0.0)	0.0	0/129 (0.0)	0.0	NE	0.00 (-6.32, 6.32)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 45 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-10.61, 10.61)	1.0000	
HIGH	0/201 (0.0)	0.0	0/198 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
Age (years)								NE
<= 65	0/239 (0.0)	0.0	0/243 (0.0)	0.0	NE	0.00 (-4.56, 4.56)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-62.98, 62.98)	1.0000	
Sex								NE
male	0/ 23 (0.0)	0.0	0/ 20 (0.0)	0.0	NE	0.00 (-20.84, 20.84)	1.0000	
female	0/223 (0.0)	0.0	0/226 (0.0)	0.0	NE	0.00 (-4.85, 4.85)	1.0000	
Race								NE
White	0/160 (0.0)	0.0	0/174 (0.0)	0.0	NE	0.00 (-5.80, 5.80)	1.0000	
Black	0/ 33 (0.0)	0.0	0/ 32 (0.0)	0.0	NE	0.00 (-15.38, 15.38)	1.0000	
Other	0/ 45 (0.0)	0.0	0/ 37 (0.0)	0.0	NE	0.00 (-11.98, 11.98)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 50 (0.0)	0.0	0/ 56 (0.0)	0.0	NE	0.00 (-9.46, 9.46)	1.0000	
Non-hispanic/Latino	0/188 (0.0)	0.0	0/187 (0.0)	0.0	NE	0.00 (-5.21, 5.21)	1.0000	
Geographic region								NE
EU	0/ 92 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-5.86, 5.86)	1.0000	
non-EU	0/154 (0.0)	0.0	0/157 (0.0)	0.0	NE	0.00 (-5.56, 5.56)	1.0000	
Onset of disease								NE
Paediatric	0/ 19 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-28.28, 28.28)	1.0000	
Adult	0/227 (0.0)	0.0	0/234 (0.0)	0.0	NE	0.00 (-4.74, 4.74)	1.0000	
ADA result								NE
Negative	0/226 (0.0)	0.0	0/223 (0.0)	0.0	NE	0.00 (-4.87, 4.87)	1.0000	
Positive (At any time)	0/ 19 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-21.63, 21.63)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/159 (0.0)	0.0	0/176 (0.0)	0.0	NE	0.00 (-5.09, 5.09)	1.0000	
>= 30	0/ 87 (0.0)	0.0	0/ 70 (0.0)	0.0	NE	0.00 (-8.73, 8.73)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Malignancy
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	1 (0.4)	2 (0.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.62 (0.08, 5.03)	
p-value	0.6574	
Odds Ratio (95% CI)	0.62 (0.08, 5.08)	
p-value	0.6567	
Risk Difference (95% CI)	-0.41 (-1.78, 0.96)	
p-value	0.5589	
CMH approach		
Response rate	0.4	0.8
Difference in response rates (95% CI)	-0.47 (-5.09, 4.16)	
p-value	0.8431	
p-Value for test for heterogenity between studies	0.6204	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.2943
< 10 points	1/ 80 (1.3)	1.2	0/ 69 (0.0)	0.0	2.85 (0.12, 67.83)	0.5172	1.19 (-9.61, 11.99)	0.8294	
>= 10 points	0/166 (0.0)	0.0	2/177 (1.1)	1.2	0.36 (0.04, 3.39)	0.3687	-1.18 (-6.43, 4.08)	0.6602	
OCS dose at baseline									NE
<10 mg/day	0/115 (0.0)	0.0	0/117 (0.0)	0.0	NE		0.00 (-7.19, 7.19)	1.0000	
>=10 mg/day	1/131 (0.8)	0.7	2/129 (1.6)	1.6	0.62 (0.08, 4.95)	0.6496	-0.89 (-7.59, 5.80)	0.7942	
Result of type I IFN gene signature test									NE
LOW	0/ 45 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-10.61, 10.61)	1.0000	
HIGH	1/201 (0.5)	0.4	2/198 (1.0)	1.0	0.61 (0.08, 4.94)	0.6465	-0.58 (-5.71, 4.56)	0.8258	
Age (years)									NE
<= 65	1/239 (0.4)	0.3	2/243 (0.8)	0.8	0.63 (0.08, 5.12)	0.6693	-0.49 (-5.20, 4.22)	0.8390	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-62.98, 62.98)	1.0000	
Sex									NE
male	0/ 23 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-20.84, 20.84)	1.0000	
female	1/223 (0.4)	0.4	2/226 (0.9)	0.9	0.63 (0.08, 5.11)	0.6681	-0.50 (-5.51, 4.52)	0.8459	
Race									NE
White	1/160 (0.6)	0.7	2/174 (1.1)	1.1	0.68 (0.08, 5.47)	0.7178	-0.36 (-6.38, 5.67)	0.9075	
Black	0/ 33 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-15.38, 15.38)	1.0000	
Other	0/ 45 (0.0)	0.0	0/ 37 (0.0)	0.0	NE		0.00 (-11.98, 11.98)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 50 (0.0)	0.0	0/ 56 (0.0)	0.0	NE		0.00 (-9.46, 9.46)	1.0000	
Non-hispanic/Latino	1/188 (0.5)	0.4	2/187 (1.1)	1.0	0.62 (0.08, 4.99)	0.6537	-0.59 (-6.00, 4.81)	0.8293	
Geographic region									NE
EU	1/ 92 (1.1)	1.2	2/ 89 (2.2)	2.3	0.61 (0.08, 4.83)	0.6366	-1.10 (-7.99, 5.79)	0.7548	
non-EU	0/154 (0.0)	0.0	0/157 (0.0)	0.0	NE		0.00 (-5.56, 5.56)	1.0000	
Onset of disease									NE
Paediatric	0/ 19 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-28.28, 28.28)	1.0000	
Adult	1/227 (0.4)	0.4	2/234 (0.9)	0.8	0.64 (0.08, 5.17)	0.6761	-0.46 (-5.34, 4.43)	0.8541	
ADA result									NE
Negative	1/226 (0.4)	0.4	2/223 (0.9)	0.9	0.62 (0.08, 4.99)	0.6521	-0.54 (-5.57, 4.49)	0.8334	
Positive (At any time)	0/ 19 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-21.63, 21.63)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	1/159 (0.6)	0.6	2/176 (1.1)	1.1	0.70 (0.09, 5.62)	0.7366	-0.55 (-5.91, 4.80)	0.8392	
>= 30	0/ 87 (0.0)	0.0	0/ 70 (0.0)	0.0	NE		0.00 (-8.73, 8.73)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of SOCs Cardiac disorders and/or Vascular disorders
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	10 (4.1)	24 (9.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.43 (0.21, 0.89)	
p-value	0.0232	
Odds Ratio (95% CI)	0.40 (0.19, 0.88)	
p-value	0.0217	
Risk Difference (95% CI)	-5.72 (-10.18, -1.26)	
p-value	0.0119	
CMH approach		
Response rate	4.1	9.7
Difference in response rates (95% CI)	-5.61 (-11.49, 0.28)	
p-value	0.0618	
p-Value for test for heterogenity between studies	0.2227	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of SOCs Cardiac disorders and/or Vascular disorders - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.7978
< 10 points	3/ 80 (3.8)	3.8	7/ 69 (10.1)	10.2	0.38 (0.10, 1.43)	0.1538	-6.41 (-18.75, 5.92)	0.3083	
>= 10 points	7/166 (4.2)	4.2	17/177 (9.6)	9.7	0.47 (0.19, 1.17)	0.1051	-5.57 (-12.45, 1.31)	0.1128	
OCS dose at baseline									0.8908
<10 mg/day	4/115 (3.5)	3.5	10/117 (8.5)	8.7	0.40 (0.13, 1.25)	0.1164	-5.22 (-13.97, 3.54)	0.2428	
>=10 mg/day	6/131 (4.6)	4.8	14/129 (10.9)	11.0	0.45 (0.16, 1.22)	0.1178	-6.15 (-14.63, 2.33)	0.1549	
Result of type I IFN gene signature test									0.3214
LOW	2/ 45 (4.4)	4.4	2/ 48 (4.2)	4.2	1.07 (0.16, 7.26)	0.9472	0.28 (-12.46, 13.02)	0.9658	
HIGH	8/201 (4.0)	4.1	22/198 (11.1)	11.1	0.37 (0.17, 0.83)	0.0162	-6.99 (-13.61, -0.37)	0.0385	
Age (years)									NE
<= 65	10/239 (4.2)	4.3	24/243 (9.9)	9.9	0.44 (0.21, 0.91)	0.0261	-5.66 (-11.65, 0.34)	0.0644	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-62.98, 62.98)	1.0000	
Sex									0.7377
male	1/ 23 (4.3)	3.8	1/ 20 (5.0)	5.7	0.67 (0.05, 9.19)	0.7620	-1.90 (-24.51, 20.72)	0.8694	
female	9/223 (4.0)	4.1	23/226 (10.2)	10.0	0.42 (0.19, 0.90)	0.0264	-5.95 (-12.22, 0.31)	0.0624	
Race									0.6093
White	8/160 (5.0)	5.1	18/174 (10.3)	9.9	0.50 (0.22, 1.14)	0.1004	-4.80 (-12.27, 2.67)	0.2080	
Black	1/ 33 (3.0)	2.5	3/ 32 (9.4)	8.9	0.46 (0.06, 3.38)	0.4483	-6.38 (-24.13, 11.37)	0.4814	
Other	0/ 45 (0.0)	0.0	3/ 37 (8.1)	8.5	0.11 (0.01, 1.96)	0.1327	-8.46 (-22.21, 5.30)	0.2282	
Ethnicity									0.4893
Hispanic/Latino	2/ 50 (4.0)	4.0	9/ 56 (16.1)	16.3	0.25 (0.06, 1.13)	0.0726	-12.34 (-25.75, 1.07)	0.0714	
Non-hispanic/Latino	7/188 (3.7)	4.0	15/187 (8.0)	8.1	0.47 (0.19, 1.14)	0.0936	-4.15 (-10.75, 2.45)	0.2177	
Geographic region									0.7916
EU	4/ 92 (4.3)	4.1	8/ 89 (9.0)	8.2	0.48 (0.09, 2.54)	0.3841	-4.12 (-12.56, 4.32)	0.3387	
non-EU	6/154 (3.9)	4.0	16/157 (10.2)	10.6	0.37 (0.15, 0.92)	0.0316	-6.58 (-14.07, 0.92)	0.0854	
Onset of disease									0.9020
Paediatric	1/ 19 (5.3)	4.4	2/ 12 (16.7)	14.9	0.49 (0.06, 3.95)	0.5006	-10.52 (-41.48, 20.44)	0.5055	
Adult	9/227 (4.0)	4.0	22/234 (9.4)	9.4	0.42 (0.20, 0.90)	0.0264	-5.38 (-11.48, 0.72)	0.0840	
ADA result									0.1487
Negative	8/226 (3.5)	3.7	22/223 (9.9)	9.6	0.38 (0.17, 0.86)	0.0208	-5.94 (-12.12, 0.23)	0.0593	
Positive (At any time)	2/ 19 (10.5)	12.0	2/ 23 (8.7)	5.8	1.58 (0.28, 9.01)	0.6090	6.18 (-17.95, 30.31)	0.6156	
BMI (kg/m2) at enrolment									0.6710
< 30	3/159 (1.9)	1.8	16/176 (9.1)	9.1	0.49 (0.12, 1.93)	0.3073	-7.26 (-13.77, -0.75)	0.0288	
>= 30	7/ 87 (8.0)	8.0	8/ 70 (11.4)	11.4	0.71 (0.26, 1.90)	0.4909	-3.47 (-15.16, 8.23)	0.5613	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Time to first Onset of Herpes Zoster (on-treatment)
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	13 (5.3)	4 (1.6)
Number of censored subjects, n (%)	233 (94.7)	242 (98.4)
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Anifrolumab 300mg vs. Placebo (adjusted)		
Hazard Ratio (95% CI)	3.29 (1.07, 10.11)	
p-value	0.0574	
Analysis Anifrolumab 300mg vs. Placebo (unadjusted)		
Hazard Ratio (95% CI)	3.16 (1.03, 9.69)	
p-value	0.0332	
p-Value for test for heterogenity between studies	0.6599	

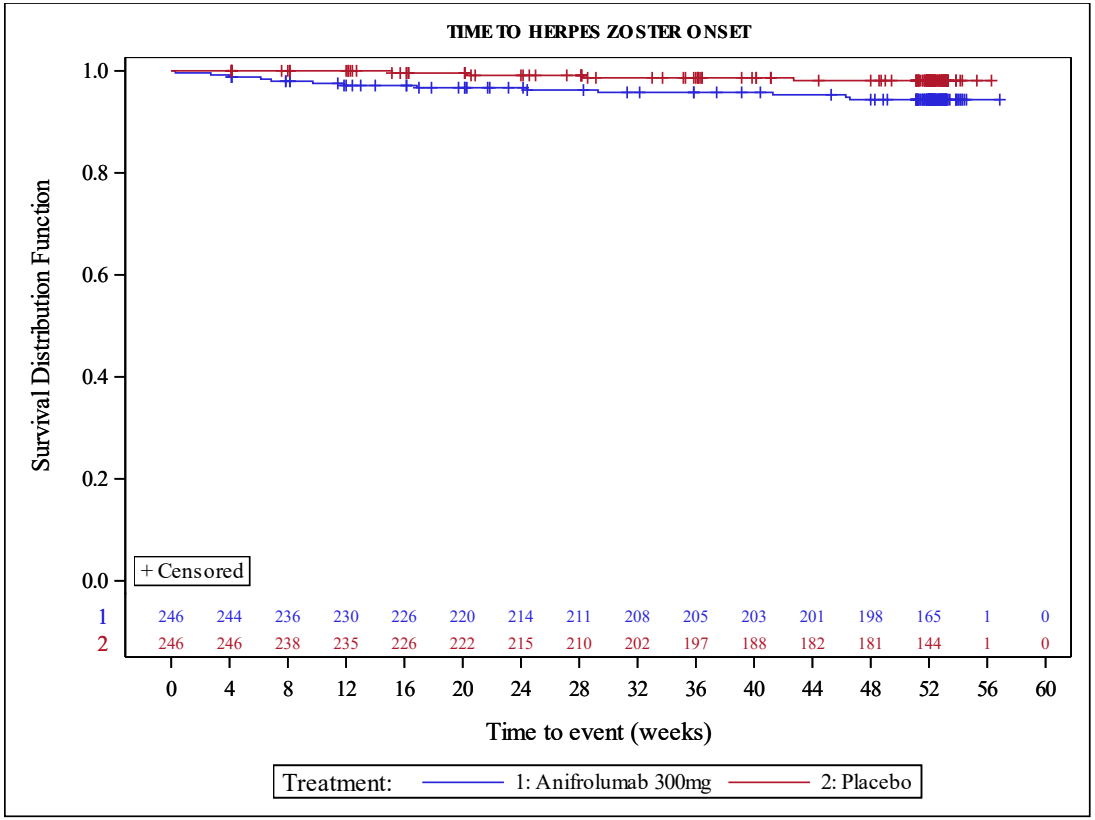
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model. Adjusted analysis also includes stratification factors in the model.
Two-sided log rank test used.
p-Value for heterogenity between studies from Cox proportional hazards model with factors for treatment, study, treatment*study interaction and stratfication factors.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unadjusted analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Time to first Onset of Herpes Zoster (on-treatment) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Anifrolumab 300mg (N=246) Median (95% CI)	Placebo (N=246) n/ N (%)	Placebo (N=246) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening							0.5393
< 10 points	2/ 80 (2.5)	NE (NE, NE)	1/ 69 (1.4)	NE (NE, NE)	1.81 (0.16, 20.15)	0.7480	
>= 10 points	11/166 (6.6)	NE (NE, NE)	3/177 (1.7)	NE (NE, NE)	3.91 (1.09, 14.02)	0.0523	
OCS dose at baseline							0.8675
<10 mg/day	7/115 (6.1)	NE (NE, NE)	2/117 (1.7)	NE (NE, NE)	3.27 (0.68, 15.86)	0.1781	
>=10 mg/day	6/131 (4.6)	NE (NE, NE)	2/129 (1.6)	NE (NE, NE)	2.86 (0.58, 14.21)	0.1801	
Result of type I IFN gene signature test							0.9124
LOW	3/ 45 (6.7)	NE (NE, NE)	1/ 48 (2.1)	NE (NE, NE)	1.86 (0.19, 18.25)	0.7055	
HIGH	10/201 (5.0)	NE (NE, NE)	3/198 (1.5)	NE (NE, NE)	3.35 (0.92, 12.20)	0.0516	
Age (years)							0.9997
<= 65	13/239 (5.4)	NE (NE, NE)	4/243 (1.6)	NE (NE, NE)	3.32 (1.08, 10.18)	0.0564	
> 65	0/ 7 (0.0)	NE (NE, NE)	0/ 3 (0.0)	NE (NE, NE)	NE		
Sex							0.9893
male	3/ 23 (13.0)	NE (NE, NE)	0/ 20 (0.0)	NE (NE, NE)	NE		
female	10/223 (4.5)	NE (NE, NE)	4/226 (1.8)	NE (NE, NE)	2.51 (0.79, 8.02)	0.2074	
Race							0.9999
White	7/160 (4.4)	NE (NE, NE)	3/174 (1.7)	NE (NE, NE)	2.42 (0.62, 9.44)	0.2530	
Black	0/ 33 (0.0)	NE (NE, NE)	1/ 32 (3.1)	NE (NE, NE)	NE		
Other	4/ 45 (8.9)	NE (NE, NE)	0/ 37 (0.0)	NE (NE, NE)	NE		
Ethnicity							0.9917
Hispanic/Latino	3/ 50 (6.0)	NE (NE, NE)	0/ 56 (0.0)	NE (NE, NE)	NE		
Non-hispanic/Latino	8/188 (4.3)	NE (NE, NE)	4/187 (2.1)	NE (NE, NE)	1.87 (0.56, 6.21)	0.4129	
Geographic region							0.9474
EU	4/ 92 (4.3)	NE (NE, NE)	1/ 89 (1.1)	NE (NE, NE)	4.51 (0.48, 42.53)	0.2421	
non-EU	9/154 (5.8)	NE (NE, NE)	3/157 (1.9)	NE (NE, NE)	3.58 (0.96, 13.41)	0.0565	
Onset of disease							0.9917
Paediatric	3/ 19 (15.8)	NE (NE, NE)	0/ 12 (0.0)	NE (NE, NE)	NE		
Adult	10/227 (4.4)	NE (NE, NE)	4/234 (1.7)	NE (NE, NE)	2.56 (0.80, 8.18)	0.1747	
ADA result							0.9919
Negative	12/226 (5.3)	NE (NE, NE)	4/223 (1.8)	NE (NE, NE)	2.96 (0.95, 9.19)	0.0960	
Positive (At any time)	1/ 19 (5.3)	NE (NE, NE)	0/ 23 (0.0)	NE (NE, NE)	NE		
BMI (kg/m2) at enrolment							0.4162
< 30	9/159 (5.7)	NE (NE, NE)	2/176 (1.1)	NE (NE, NE)	4.94 (1.07, 22.90)	0.0280	
>= 30	4/ 87 (4.6)	NE (NE, NE)	2/ 70 (2.9)	NE (NE, NE)	2.01 (0.36, 11.24)	0.7878	

Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of Time to first Onset of Herpes Zoster (on-treatment)
Full analysis set



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Time to first Onset of non-opportunistic serious infection (on-treatment)
Full analysis set

	Anifrolumab 300mg (N=246)	Placebo (N=246)
Number of subjects with events, n (%)	6 (2.4)	13 (5.3)
Number of censored subjects, n (%)	240 (97.6)	233 (94.7)
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Anifrolumab 300mg vs. Placebo (adjusted)		
Hazard Ratio (95% CI)	0.44 (0.17, 1.17)	
p-value	0.0573	
Analysis Anifrolumab 300mg vs. Placebo (unadjusted)		
Hazard Ratio (95% CI)	0.43 (0.16, 1.13)	
p-value	0.0803	
p-Value for test for heterogenity between studies	0.2460	

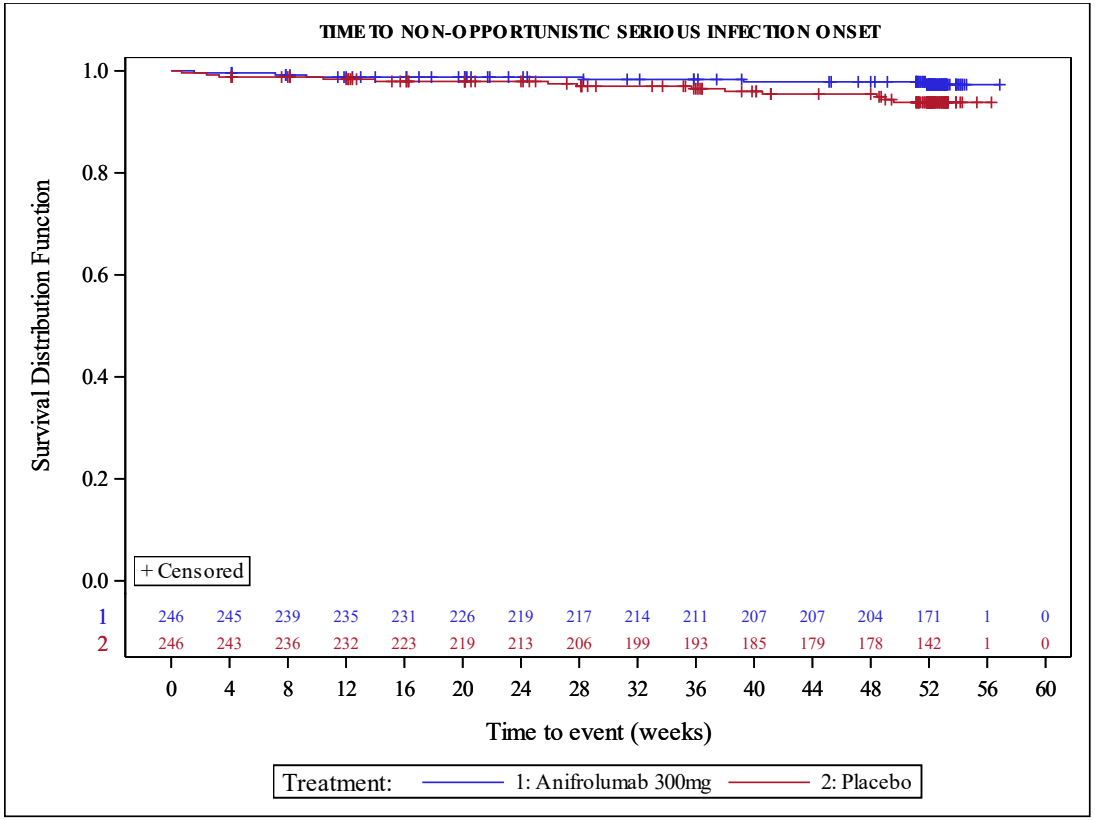
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model. Adjusted analysis also includes stratification factors in the model.
Two-sided log rank test used.
p-Value for heterogenity between studies from Cox proportional hazards model with factors for treatment, study, treatment*study interaction and stratfication factors.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unadjusted analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Time to first Onset of non-opportunistic serious infection (on-treatment) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Anifrolumab 300mg (N=246) Median (95% CI)	Placebo (N=246) n/ N (%)	Placebo (N=246) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening							0.9376
< 10 points	1/ 80 (1.3)	NE (NE, NE)	2/ 69 (2.9)	NE (NE, NE)	0.43 (0.04, 4.86)	0.2954	
>= 10 points	5/166 (3.0)	NE (NE, NE)	11/177 (6.2)	NE (NE, NE)	0.45 (0.16, 1.31)	0.1046	
OCS dose at baseline							0.8621
<10 mg/day	3/115 (2.6)	NE (NE, NE)	6/117 (5.1)	NE (NE, NE)	0.44 (0.11, 1.78)	0.2990	
>=10 mg/day	3/131 (2.3)	NE (NE, NE)	7/129 (5.4)	NE (NE, NE)	0.34 (0.09, 1.33)	0.1018	
Result of type I IFN gene signature test							0.3614
LOW	2/ 45 (4.4)	NE (NE, NE)	2/ 48 (4.2)	NE (NE, NE)	0.81 (0.11, 5.79)	0.7573	
HIGH	4/201 (2.0)	NE (NE, NE)	11/198 (5.6)	NE (NE, NE)	0.33 (0.11, 1.05)	0.0477	
Age (years)							0.9997
<= 65	6/239 (2.5)	NE (NE, NE)	13/243 (5.3)	NE (NE, NE)	0.45 (0.17, 1.18)	0.0674	
> 65	0/ 7 (0.0)	NE (NE, NE)	0/ 3 (0.0)	NE (NE, NE)	NE		
Sex							0.9908
male	0/ 23 (0.0)	NE (NE, NE)	1/ 20 (5.0)	NE (NE, NE)	NE		
female	6/223 (2.7)	NE (NE, NE)	12/226 (5.3)	NE (NE, NE)	0.48 (0.18, 1.28)	0.0898	
Race							0.8093
White	4/160 (2.5)	NE (NE, NE)	8/174 (4.6)	NE (NE, NE)	0.48 (0.14, 1.61)	0.1299	
Black	1/ 33 (3.0)	NE (NE, NE)	2/ 32 (6.3)	NE (NE, NE)	0.37 (0.02, 5.53)	0.4229	
Other	1/ 45 (2.2)	NE (NE, NE)	3/ 37 (8.1)	NE (NE, NE)	0.26 (0.02, 2.72)	0.2745	
Ethnicity							0.2900
Hispanic/Latino	1/ 50 (2.0)	NE (NE, NE)	6/ 56 (10.7)	NE (NE, NE)	0.18 (0.02, 1.50)	0.1123	
Non-hispanic/Latino	5/188 (2.7)	NE (NE, NE)	7/187 (3.7)	NE (NE, NE)	0.67 (0.21, 2.12)	0.5159	
Geographic region							0.9888
EU	0/ 92 (0.0)	NE (NE, NE)	3/ 89 (3.4)	NE (NE, NE)	NE		
non-EU	6/154 (3.9)	NE (NE, NE)	10/157 (6.4)	NE (NE, NE)	0.57 (0.21, 1.59)	0.2424	
Onset of disease							0.7668
Paediatric	1/ 19 (5.3)	NE (NE, NE)	2/ 12 (16.7)	NE (40.57, NE)	0.31 (0.03, 3.69)	0.3869	
Adult	5/227 (2.2)	NE (NE, NE)	11/234 (4.7)	NE (NE, NE)	0.45 (0.15, 1.29)	0.0697	
ADA result							0.6219
Negative	5/226 (2.2)	NE (NE, NE)	9/223 (4.0)	NE (NE, NE)	0.53 (0.18, 1.58)	0.1688	
Positive (At any time)	1/ 19 (5.3)	NE (NE, NE)	4/ 23 (17.4)	NE (49.57, NE)	0.27 (0.03, 2.57)	0.2164	
BMI (kg/m2) at enrolment							0.3216
< 30	3/159 (1.9)	NE (NE, NE)	10/176 (5.7)	NE (NE, NE)	0.31 (0.09, 1.13)	0.0919	
>= 30	3/ 87 (3.4)	NE (NE, NE)	3/ 70 (4.3)	NE (NE, NE)	0.95 (0.18, 4.98)	0.2973	

Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of Time to first Onset of non-opportunistic serious infection (on-treatment)
Full analysis set



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=246)	Placebo (N=246)
SOC: Blood and lymphatic system disorders	Number of subjects with events, n (%)	9 (3.7)	15 (6.1)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.60 (0.27, 1.34)	
	p-value	0.2142	
	Odds Ratio (95% CI)	0.58 (0.25, 1.36)	
	p-value	0.2132	
	Risk Difference (95% CI)	-2.44 (-6.24, 1.36)	
	p-value	0.2075	
	CMH approach		
	Response rate	3.7	6.0
	Difference in response rates (95% CI)	-2.34 (-7.82, 3.14)	
	p-value	0.4033	
	p-Value for test for heterogenity between studies	0.9450	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=246)	Placebo (N=246)
SOC: Cardiac disorders	Number of subjects with events, n (%)	4 (1.6)	14 (5.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.29 (0.10, 0.86)	
	p-value	0.0261	
	Odds Ratio (95% CI)	0.28 (0.09, 0.85)	
	p-value	0.0250	
	Risk Difference (95% CI)	-4.07 (-7.37, -0.77)	
	p-value	0.0156	
	CMH approach		
	Response rate	1.6	5.7
	Difference in response rates (95% CI)	-4.11 (-9.41, 1.19)	
	p-value	0.1283	
	p-Value for test for heterogenity between studies	0.7754	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=246)	Placebo (N=246)
SOC: Ear and labyrinth disorders	Number of subjects with events, n (%)	7 (2.8)	10 (4.1)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.70 (0.27, 1.82)	
	p-value	0.4680	
	Odds Ratio (95% CI)	0.69 (0.26, 1.86)	
	p-value	0.4668	
	Risk Difference (95% CI)	-1.21 (-4.44, 2.01)	
	p-value	0.4605	
	CMH approach		
	Response rate	2.7	4.0
	Difference in response rates (95% CI)	-1.35 (-6.54, 3.84)	
	p-value	0.6099	
	p-Value for test for heterogenity between studies	0.7426	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=246)	Placebo (N=246)
SOC: Eye disorders	Number of subjects with events, n (%)	17 (6.9)	10 (4.1)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.67 (0.77, 3.60)	
	p-value	0.1933	
	Odds Ratio (95% CI)	1.73 (0.77, 3.91)	
	p-value	0.1870	
	Risk Difference (95% CI)	2.86 (-1.15, 6.88)	
	p-value	0.1616	
	CMH approach		
	Response rate	6.5	3.9
	Difference in response rates (95% CI)	2.58 (-2.94, 8.10)	
	p-value	0.3601	
	p-Value for test for heterogenity between studies	0.3979	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=246)	Placebo (N=246)
SOC: Gastrointestinal disorders	Number of subjects with events, n (%)	50 (20.3)	62 (25.2)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.81 (0.58, 1.13)	
	p-value	0.2117	
	Odds Ratio (95% CI)	0.76 (0.50, 1.16)	
	p-value	0.2037	
	Risk Difference (95% CI)	-4.88 (-12.29, 2.52)	
	p-value	0.1964	
	CMH approach		
	Response rate	20.3	25.5
	Difference in response rates (95% CI)	-5.16 (-12.81, 2.48)	
	p-value	0.1852	
	p-Value for test for heterogenity between studies	0.2148	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=246)	Placebo (N=246)
SOC: Gastrointestinal disorders, PT: Diarrhoea	Number of subjects with events, n (%)	6 (2.4)	14 (5.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.43 (0.17, 1.10)	
	p-value	0.0792	
	Odds Ratio (95% CI)	0.42 (0.16, 1.10)	
	p-value	0.0778	
	Risk Difference (95% CI)	-3.26 (-6.74, 0.22)	
	p-value	0.0666	
	CMH approach		
	Response rate	2.5	5.7
	Difference in response rates (95% CI)	-3.24 (-8.59, 2.11)	
	p-value	0.2356	
	p-Value for test for heterogenity between studies	0.7393	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=246)	Placebo (N=246)
SOC: Gastrointestinal disorders, PT: Nausea	Number of subjects with events, n (%)	11 (4.5)	15 (6.1)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.73 (0.34, 1.56)	
	p-value	0.4211	
	Odds Ratio (95% CI)	0.72 (0.32, 1.60)	
	p-value	0.4207	
	Risk Difference (95% CI)	-1.63 (-5.58, 2.32)	
	p-value	0.4186	
	CMH approach		
	Response rate	4.4	6.1
	Difference in response rates (95% CI)	-1.71 (-7.28, 3.87)	
	p-value	0.5482	
	p-Value for test for heterogenity between studies	0.9833	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=246)	Placebo (N=246)
SOC: Gastrointestinal disorders, PT: Vomiting	Number of subjects with events, n (%)	11 (4.5)	4 (1.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	2.50 (0.77, 8.04)	
	p-value	0.1257	
	Odds Ratio (95% CI)	2.58 (0.78, 8.59)	
	p-value	0.1216	
	Risk Difference (95% CI)	2.85 (-0.18, 5.88)	
	p-value	0.0650	
	CMH approach		
	Response rate	4.3	1.6
	Difference in response rates (95% CI)	2.77 (-2.33, 7.87)	
	p-value	0.2872	
	p-Value for test for heterogenity between studies	0.3337	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=246)	Placebo (N=246)
SOC: General disorders and administration site conditions	Number of subjects with events, n (%)	30 (12.2)	21 (8.5)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.43 (0.84, 2.42)	
	p-value	0.1886	
	Odds Ratio (95% CI)	1.49 (0.82, 2.68)	
	p-value	0.1872	
	Risk Difference (95% CI)	3.64 (-1.73, 9.01)	
	p-value	0.1843	
	CMH approach		
	Response rate	12.3	8.5
	Difference in response rates (95% CI)	3.75 (-2.66, 10.16)	
	p-value	0.2516	
	p-Value for test for heterogenity between studies	0.9241	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=246)	Placebo (N=246)
SOC: Immune system disorders	Number of subjects with events, n (%)	17 (6.9)	8 (3.3)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	2.11 (0.93, 4.82)	
	p-value	0.0754	
	Odds Ratio (95% CI)	2.20 (0.93, 5.20)	
	p-value	0.0740	
	Risk Difference (95% CI)	3.65 (-0.22, 7.52)	
	p-value	0.0642	
	CMH approach		
	Response rate	6.8	3.3
	Difference in response rates (95% CI)	3.54 (-1.95, 9.03)	
	p-value	0.2064	
	p-Value for test for heterogenity between studies	0.7005	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=246)	Placebo (N=246)
SOC: Immune system disorders, PT: Hypersensitivity	Number of subjects with events, n (%)	10 (4.1)	3 (1.2)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	3.25 (0.90, 11.78)	
	p-value	0.0730	
	Odds Ratio (95% CI)	3.36 (0.90, 12.52)	
	p-value	0.0713	
	Risk Difference (95% CI)	2.82 (0.01, 5.64)	
	p-value	0.0493	
	CMH approach		
	Response rate	4.0	1.2
	Difference in response rates (95% CI)	2.87 (-2.14, 7.87)	
	p-value	0.2614	
	p-Value for test for heterogenity between studies	0.6479	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=246)	Placebo (N=246)
SOC: Infections and infestations	Number of subjects with events, n (%)	177 (72.0)	146 (59.3)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.21 (1.07, 1.38)	
	p-value	0.0034	
	Odds Ratio (95% CI)	1.75 (1.20, 2.56)	
	p-value	0.0036	
	Risk Difference (95% CI)	12.58 (4.25, 20.91)	
	p-value	0.0031	
	CMH approach		
	Response rate	71.9	59.2
	Difference in response rates (95% CI)	12.76 (4.33, 21.18)	
	p-value	0.0030	
	p-Value for test for heterogenity between studies	0.3007	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=246)	Placebo (N=246)
SOC: Infections and infestations, PT: Bronchitis	Number of subjects with events, n (%)	27 (11.0)	13 (5.3)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	2.08 (1.10, 3.94)	
	p-value	0.0245	
	Odds Ratio (95% CI)	2.21 (1.11, 4.41)	
	p-value	0.0236	
	Risk Difference (95% CI)	5.71 (0.91, 10.52)	
	p-value	0.0197	
	CMH approach		
	Response rate	11.2	5.5
	Difference in response rates (95% CI)	5.63 (-0.45, 11.72)	
	p-value	0.0696	
	p-Value for test for heterogenity between studies	0.6997	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=246)	Placebo (N=246)
SOC: Infections and infestations, PT: Herpes zoster	Number of subjects with events, n (%)	13 (5.3)	5 (2.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	2.61 (0.95, 7.21)	
	p-value	0.0640	
	Odds Ratio (95% CI)	2.70 (0.95, 7.71)	
	p-value	0.0627	
	Risk Difference (95% CI)	3.27 (-0.04, 6.57)	
	p-value	0.0526	
	CMH approach		
	Response rate	5.4	2.1
	Difference in response rates (95% CI)	3.35 (-2.01, 8.71)	
	p-value	0.2201	
	p-Value for test for heterogenity between studies	0.9271	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=246)	Placebo (N=246)
SOC: Infections and infestations, PT: Nasopharyngitis	Number of subjects with events, n (%)	45 (18.3)	30 (12.2)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.49 (0.98, 2.28)	
	p-value	0.0647	
	Odds Ratio (95% CI)	1.61 (0.98, 2.66)	
	p-value	0.0627	
	Risk Difference (95% CI)	6.04 (-0.26, 12.34)	
	p-value	0.0602	
	CMH approach		
	Response rate	18.3	11.9
	Difference in response rates (95% CI)	6.44 (-0.53, 13.41)	
	p-value	0.0700	
	p-Value for test for heterogenity between studies	0.8598	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=246)	Placebo (N=246)
SOC: Infections and infestations, PT: Pharyngitis	Number of subjects with events, n (%)	10 (4.1)	12 (4.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.82 (0.37, 1.84)	
	p-value	0.6338	
	Odds Ratio (95% CI)	0.81 (0.34, 1.94)	
	p-value	0.6360	
	Risk Difference (95% CI)	-0.87 (-4.47, 2.73)	
	p-value	0.6354	
	CMH approach		
	Response rate	4.1	5.0
	Difference in response rates (95% CI)	-0.92 (-6.34, 4.51)	
	p-value	0.7407	
	p-Value for test for heterogenity between studies	0.8742	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=246)	Placebo (N=246)
SOC: Infections and infestations, PT: Pneumonia	Number of subjects with events, n (%)	6 (2.4)	10 (4.1)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.61 (0.21, 1.75)	
	p-value	0.3608	
	Odds Ratio (95% CI)	0.60 (0.20, 1.79)	
	p-value	0.3625	
	Risk Difference (95% CI)	-1.60 (-4.73, 1.52)	
	p-value	0.3143	
	CMH approach		
	Response rate	2.5	4.2
	Difference in response rates (95% CI)	-1.66 (-6.90, 3.59)	
	p-value	0.5359	
	p-Value for test for heterogenity between studies	0.2276	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=246)	Placebo (N=246)
SOC: Infections and infestations, PT: Respiratory tract infection	Number of subjects with events, n (%)	11 (4.5)	1 (0.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	6.48 (1.15, 36.59)	
	p-value	0.0343	
	Odds Ratio (95% CI)	6.75 (1.17, 38.84)	
	p-value	0.0324	
	Risk Difference (95% CI)	4.07 (1.36, 6.78)	
	p-value	0.0032	
	CMH approach		
	Response rate	4.6	0.4
	Difference in response rates (95% CI)	4.14 (-0.89, 9.18)	
	p-value	0.1068	
	p-Value for test for heterogenity between studies	0.4594	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=246)	Placebo (N=246)
SOC: Infections and infestations, PT: Sinusitis	Number of subjects with events, n (%)	16 (6.5)	12 (4.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.33 (0.64, 2.76)	
	p-value	0.4375	
	Odds Ratio (95% CI)	1.36 (0.63, 2.93)	
	p-value	0.4372	
	Risk Difference (95% CI)	1.63 (-2.46, 5.72)	
	p-value	0.4354	
	CMH approach		
	Response rate	6.5	4.8
	Difference in response rates (95% CI)	1.70 (-3.93, 7.32)	
	p-value	0.5543	
	p-Value for test for heterogenity between studies	0.9650	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=246)	Placebo (N=246)
SOC: Infections and infestations, PT: Upper respiratory tract infection	Number of subjects with events, n (%)	41 (16.7)	23 (9.3)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.78 (1.10, 2.89)	
	p-value	0.0190	
	Odds Ratio (95% CI)	1.94 (1.12, 3.36)	
	p-value	0.0187	
	Risk Difference (95% CI)	7.37 (1.46, 13.27)	
	p-value	0.0144	
	CMH approach		
	Response rate	16.7	9.2
	Difference in response rates (95% CI)	7.53 (0.86, 14.19)	
	p-value	0.0269	
	p-Value for test for heterogenity between studies	0.2285	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=246)	Placebo (N=246)
SOC: Infections and infestations, PT: Urinary tract infection	Number of subjects with events, n (%)	26 (10.6)	35 (14.2)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.74 (0.46, 1.20)	
	p-value	0.2220	
	Odds Ratio (95% CI)	0.71 (0.41, 1.23)	
	p-value	0.2216	
	Risk Difference (95% CI)	-3.67 (-9.49, 2.15)	
	p-value	0.2163	
	CMH approach		
	Response rate	10.5	14.1
	Difference in response rates (95% CI)	-3.63 (-10.34, 3.08)	
	p-value	0.2889	
	p-Value for test for heterogenity between studies	0.5115	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=246)	Placebo (N=246)
SOC: Injury, poisoning and procedural complications	Number of subjects with events, n (%)	58 (23.6)	44 (17.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.32 (0.93, 1.87)	
	p-value	0.1193	
	Odds Ratio (95% CI)	1.42 (0.91, 2.20)	
	p-value	0.1195	
	Risk Difference (95% CI)	5.71 (-1.43, 12.86)	
	p-value	0.1171	
	CMH approach		
	Response rate	24.1	17.7
	Difference in response rates (95% CI)	6.38 (-1.12, 13.88)	
	p-value	0.0955	
	p-Value for test for heterogenity between studies	0.6328	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=246)	Placebo (N=246)
SOC: Injury, poisoning and procedural complications, PT: Infusion related reaction	Number of subjects with events, n (%)	26 (10.6)	18 (7.3)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.45 (0.81, 2.59)	
	p-value	0.2059	
	Odds Ratio (95% CI)	1.50 (0.79, 2.84)	
	p-value	0.2115	
	Risk Difference (95% CI)	3.30 (-1.73, 8.32)	
	p-value	0.1987	
	CMH approach		
	Response rate	11.0	7.1
	Difference in response rates (95% CI)	3.93 (-2.22, 10.08)	
	p-value	0.2099	
	p-Value for test for heterogenity between studies	0.3098	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=246)	Placebo (N=246)
SOC: Investigations	Number of subjects with events, n (%)	9 (3.7)	17 (6.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.55 (0.25, 1.22)	
	p-value	0.1422	
	Odds Ratio (95% CI)	0.53 (0.23, 1.23)	
	p-value	0.1369	
	Risk Difference (95% CI)	-3.24 (-7.19, 0.70)	
	p-value	0.1073	
	CMH approach		
	Response rate	3.8	6.7
	Difference in response rates (95% CI)	-2.99 (-8.60, 2.61)	
	p-value	0.2955	
	p-Value for test for heterogenity between studies	0.3146	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=246)	Placebo (N=246)
SOC: Metabolism and nutrition disorders	Number of subjects with events, n (%)	12 (4.9)	20 (8.1)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.60 (0.30, 1.21)	
	p-value	0.1526	
	Odds Ratio (95% CI)	0.58 (0.28, 1.22)	
	p-value	0.1506	
	Risk Difference (95% CI)	-3.26 (-7.60, 1.09)	
	p-value	0.1421	
	CMH approach		
	Response rate	4.9	8.0
	Difference in response rates (95% CI)	-3.13 (-8.94, 2.68)	
	p-value	0.2906	
	p-Value for test for heterogenity between studies	0.6705	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=246)	Placebo (N=246)
SOC: Musculoskeletal and connective tissue disorders	Number of subjects with events, n (%)	57 (23.2)	51 (20.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.11 (0.80, 1.56)	
	p-value	0.5280	
	Odds Ratio (95% CI)	1.15 (0.75, 1.77)	
	p-value	0.5189	
	Risk Difference (95% CI)	2.42 (-4.89, 9.74)	
	p-value	0.5165	
	CMH approach		
	Response rate	23.2	20.9
	Difference in response rates (95% CI)	2.27 (-5.42, 9.96)	
	p-value	0.5626	
	p-Value for test for heterogenity between studies	0.4248	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=246)	Placebo (N=246)
SOC: Musculoskeletal and connective tissue disorders, PT: Arthralgia	Number of subjects with events, n (%)	13 (5.3)	6 (2.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	2.09 (0.80, 5.52)	
	p-value	0.1346	
	Odds Ratio (95% CI)	2.17 (0.79, 5.90)	
	p-value	0.1310	
	Risk Difference (95% CI)	2.85 (-0.54, 6.25)	
	p-value	0.0998	
	CMH approach		
	Response rate	5.3	2.5
	Difference in response rates (95% CI)	2.76 (-2.58, 8.09)	
	p-value	0.3119	
	p-Value for test for heterogenity between studies	0.4214	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=246)	Placebo (N=246)
SOC: Musculoskeletal and connective tissue disorders, PT: Back pain	Number of subjects with events, n (%)	13 (5.3)	10 (4.1)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.09 (0.46, 2.61)	
	p-value	0.8415	
	Odds Ratio (95% CI)	1.12 (0.45, 2.81)	
	p-value	0.8102	
	Risk Difference (95% CI)	1.19 (-2.54, 4.92)	
	p-value	0.5313	
	CMH approach		
	Response rate	5.5	4.2
	Difference in response rates (95% CI)	1.28 (-4.21, 6.78)	
	p-value	0.6470	
	p-Value for test for heterogenity between studies	0.0781	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=246)	Placebo (N=246)
SOC: Nervous system disorders	Number of subjects with events, n (%)	43 (17.5)	41 (16.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.05 (0.71, 1.56)	
	p-value	0.7997	
	Odds Ratio (95% CI)	1.06 (0.66, 1.70)	
	p-value	0.8179	
	Risk Difference (95% CI)	0.79 (-5.87, 7.44)	
	p-value	0.8167	
	CMH approach		
	Response rate	17.2	16.2
	Difference in response rates (95% CI)	1.02 (-6.02, 8.05)	
	p-value	0.7767	
	p-Value for test for heterogenity between studies	0.1836	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=246)	Placebo (N=246)
SOC: Nervous system disorders, PT: Headache	Number of subjects with events, n (%)	17 (6.9)	26 (10.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.67 (0.37, 1.21)	
	p-value	0.1811	
	Odds Ratio (95% CI)	0.64 (0.33, 1.22)	
	p-value	0.1735	
	Risk Difference (95% CI)	-3.67 (-8.65, 1.32)	
	p-value	0.1494	
	CMH approach		
	Response rate	6.7	10.1
	Difference in response rates (95% CI)	-3.41 (-9.42, 2.59)	
	p-value	0.2654	
	p-Value for test for heterogenity between studies	0.2377	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=246)	Placebo (N=246)
SOC: Psychiatric disorders	Number of subjects with events, n (%)	21 (8.5)	25 (10.2)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.84 (0.48, 1.46)	
	p-value	0.5355	
	Odds Ratio (95% CI)	0.82 (0.45, 1.52)	
	p-value	0.5353	
	Risk Difference (95% CI)	-1.63 (-6.77, 3.51)	
	p-value	0.5347	
	CMH approach		
	Response rate	8.5	10.2
	Difference in response rates (95% CI)	-1.64 (-7.90, 4.61)	
	p-value	0.6066	
	p-Value for test for heterogenity between studies	0.9756	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=246)	Placebo (N=246)
SOC: Psychiatric disorders, PT: Insomnia	Number of subjects with events, n (%)	6 (2.4)	14 (5.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.44 (0.17, 1.14)	
	p-value	0.0895	
	Odds Ratio (95% CI)	0.42 (0.16, 1.13)	
	p-value	0.0869	
	Risk Difference (95% CI)	-3.26 (-6.73, 0.22)	
	p-value	0.0663	
	CMH approach		
	Response rate	2.5	5.8
	Difference in response rates (95% CI)	-3.24 (-8.61, 2.13)	
	p-value	0.2364	
	p-Value for test for heterogenity between studies	0.5095	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=246)	Placebo (N=246)
SOC: Renal and urinary disorders	Number of subjects with events, n (%)	10 (4.1)	10 (4.1)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.99 (0.42, 2.34)	
	p-value	0.9884	
	Odds Ratio (95% CI)	0.99 (0.40, 2.44)	
	p-value	0.9888	
	Risk Difference (95% CI)	-0.02 (-3.50, 3.45)	
	p-value	0.9888	
	CMH approach		
	Response rate	4.0	4.1
	Difference in response rates (95% CI)	-0.05 (-5.42, 5.32)	
	p-value	0.9849	
	p-Value for test for heterogenity between studies	0.9729	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=246)	Placebo (N=246)
SOC: Reproductive system and breast disorders	Number of subjects with events, n (%)	11 (4.5)	12 (4.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.95 (0.40, 2.27)	
	p-value	0.9038	
	Odds Ratio (95% CI)	0.94 (0.38, 2.33)	
	p-value	0.8939	
	Risk Difference (95% CI)	-0.40 (-4.15, 3.35)	
	p-value	0.8339	
	CMH approach		
	Response rate	4.6	4.9
	Difference in response rates (95% CI)	-0.28 (-5.81, 5.25)	
	p-value	0.9218	
	p-Value for test for heterogenity between studies	0.0565	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=246)	Placebo (N=246)
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with events, n (%)	43 (17.5)	32 (13.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.33 (0.87, 2.05)	
	p-value	0.1853	
	Odds Ratio (95% CI)	1.41 (0.85, 2.32)	
	p-value	0.1798	
	Risk Difference (95% CI)	4.47 (-1.88, 10.82)	
	p-value	0.1677	
	CMH approach		
	Response rate	17.4	13.0
	Difference in response rates (95% CI)	4.43 (-2.61, 11.46)	
	p-value	0.2175	
	p-Value for test for heterogenity between studies	0.2093	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=246)	Placebo (N=246)
SOC: Respiratory, thoracic and mediastinal disorders, PT: Cough	Number of subjects with events, n (%)	17 (6.9)	9 (3.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.88 (0.85, 4.14)	
	p-value	0.1187	
	Odds Ratio (95% CI)	1.94 (0.85, 4.46)	
	p-value	0.1178	
	Risk Difference (95% CI)	3.23 (-0.70, 7.17)	
	p-value	0.1075	
	CMH approach		
	Response rate	6.7	3.7
	Difference in response rates (95% CI)	2.98 (-2.57, 8.52)	
	p-value	0.2925	
	p-Value for test for heterogenity between studies	0.6697	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=246)	Placebo (N=246)
SOC: Skin and subcutaneous tissue disorders	Number of subjects with events, n (%)	37 (15.0)	31 (12.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.19 (0.76, 1.86)	
	p-value	0.4433	
	Odds Ratio (95% CI)	1.23 (0.73, 2.06)	
	p-value	0.4349	
	Risk Difference (95% CI)	2.46 (-3.64, 8.55)	
	p-value	0.4292	
	CMH approach		
	Response rate	15.2	12.2
	Difference in response rates (95% CI)	2.98 (-3.78, 9.73)	
	p-value	0.3877	
	p-Value for test for heterogenity between studies	0.4469	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=246)	Placebo (N=246)
SOC: Vascular disorders	Number of subjects with events, n (%)	6 (2.4)	13 (5.3)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.48 (0.18, 1.29)	
	p-value	0.1442	
	Odds Ratio (95% CI)	0.47 (0.17, 1.29)	
	p-value	0.1422	
	Risk Difference (95% CI)	-2.87 (-6.27, 0.53)	
	p-value	0.0985	
	CMH approach		
	Response rate	2.5	5.2
	Difference in response rates (95% CI)	-2.72 (-8.07, 2.63)	
	p-value	0.3190	
	p-Value for test for heterogenity between studies	0.2314	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SOC: Cardiac disorders	SLEDAI-2K score at screening									0.2281
	< 10 points	0/ 80 (0.0)	0.0	6/ 69 (8.7)	8.8	0.12 (0.02, 0.98)	0.0477	-8.82 (-20.57, 2.93)	0.1411	
	>= 10 points	4/166 (2.4)	2.3	8/177 (4.5)	4.6	0.54 (0.16, 1.76)	0.3045	-2.29 (-8.37, 3.78)	0.4596	
	OCS dose at baseline									0.3188
	<10 mg/day	0/115 (0.0)	0.0	6/117 (5.1)	5.3	0.15 (0.02, 1.21)	0.0748	-5.26 (-13.12, 2.61)	0.1900	
	>=10 mg/day	4/131 (3.1)	3.2	8/129 (6.2)	6.4	0.51 (0.15, 1.72)	0.2798	-3.17 (-10.95, 4.60)	0.4235	
	Result of type I IFN gene signature test									0.4596
	LOW	1/ 45 (2.2)	2.2	2/ 48 (4.2)	4.2	0.67 (0.09, 5.23)	0.7029	-1.92 (-14.14, 10.30)	0.7582	
	HIGH	3/201 (1.5)	1.5	12/198 (6.1)	6.1	0.27 (0.08, 0.96)	0.0437	-4.62 (-10.50, 1.25)	0.1230	
	Age (years)									NE
	<= 65	4/239 (1.7)	1.7	14/243 (5.8)	5.9	0.29 (0.10, 0.88)	0.0281	-4.16 (-9.56, 1.23)	0.1306	
	> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-62.98, 62.98)	1.0000	
	Sex									0.5045
	male	1/ 23 (4.3)	3.8	1/ 20 (5.0)	5.7	0.67 (0.05, 9.19)	0.7620	-1.90 (-24.51, 20.72)	0.8694	
	female	3/223 (1.3)	1.3	13/226 (5.8)	5.7	0.25 (0.07, 0.87)	0.0295	-4.38 (-10.01, 1.26)	0.1280	
	Race									0.8912
	White	4/160 (2.5)	2.6	10/174 (5.7)	5.5	0.44 (0.14, 1.38)	0.1578	-2.93 (-9.74, 3.87)	0.3980	
	Black	0/ 33 (0.0)	0.0	3/ 32 (9.4)	8.9	0.27 (0.03, 2.27)	0.2260	-8.90 (-26.17, 8.37)	0.3123	
	Other	0/ 45 (0.0)	0.0	1/ 37 (2.7)	2.8	0.25 (0.01, 5.83)	0.3914	-2.82 (-15.52, 9.88)	0.6636	
	Ethnicity									0.9811
	Hispanic/Latino	1/ 50 (2.0)	2.1	5/ 56 (8.9)	9.0	0.34 (0.06, 2.14)	0.2519	-6.98 (-18.98, 5.02)	0.2545	
	Non-hispanic/Latino	3/188 (1.6)	1.7	9/187 (4.8)	5.1	0.33 (0.09, 1.22)	0.0981	-3.34 (-9.39, 2.71)	0.2790	
	Geographic region									0.5926
	EU	1/ 92 (1.1)	0.9	3/ 89 (3.4)	3.1	0.56 (0.06, 4.80)	0.5939	-2.12 (-8.99, 4.74)	0.5447	
	non-EU	3/154 (1.9)	1.9	11/157 (7.0)	7.1	0.28 (0.08, 1.01)	0.0510	-5.21 (-12.04, 1.62)	0.1350	
	Onset of disease									0.6255
	Paediatric	1/ 19 (5.3)	4.4	2/ 12 (16.7)	14.9	0.49 (0.06, 3.95)	0.5006	-10.52 (-41.48, 20.44)	0.5055	
	Adult	3/227 (1.3)	1.3	12/234 (5.1)	5.2	0.26 (0.07, 0.94)	0.0392	-3.84 (-9.30, 1.61)	0.1675	
	ADA result									0.1955
	Negative	3/226 (1.3)	1.4	12/223 (5.4)	5.3	0.25 (0.07, 0.87)	0.0291	-3.98 (-9.56, 1.61)	0.1628	
	Positive (At any time)	1/ 19 (5.3)	7.3	2/ 23 (8.7)	5.8	1.25 (0.15, 10.23)	0.8352	1.45 (-21.62, 24.53)	0.9017	
	BMI (kg/m2) at enrolment									0.1554
	< 30	0/159 (0.0)	0.0	9/176 (5.1)	5.1	0.12 (0.01, 0.90)	0.0391	-5.13 (-10.93, 0.67)	0.0831	
	>= 30	4/ 87 (4.6)	4.6	5/ 70 (7.1)	7.0	0.67 (0.19, 2.40)	0.5340	-2.38 (-13.11, 8.35)	0.6637	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
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Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations	SLEDAI-2K score at screening									0.5547
	< 10 points	62/ 80 (77.5)	78.7	47/ 69 (68.1)	68.4	1.15 (0.94, 1.40)	0.1821	10.29 (-4.57, 25.15)	0.1747	
	>= 10 points	115/166 (69.3)	69.0	99/177 (55.9)	55.6	1.24 (1.05, 1.46)	0.0118	13.45 (3.22, 23.67)	0.0099	
	OCS dose at baseline									0.1853
	<10 mg/day	88/115 (76.5)	76.1	80/117 (68.4)	68.4	1.11 (0.95, 1.31)	0.1890	7.72 (-4.18, 19.61)	0.2036	
	>=10 mg/day	89/131 (67.9)	67.7	66/129 (51.2)	51.7	1.33 (1.08, 1.63)	0.0062	16.01 (4.13, 27.89)	0.0082	
	Result of type I IFN gene signature test									0.9706
	LOW	32/ 45 (71.1)	71.2	28/ 48 (58.3)	58.4	1.22 (0.90, 1.65)	0.2026	12.79 (-6.66, 32.25)	0.1974	
	HIGH	145/201 (72.1)	72.1	118/198 (59.6)	59.3	1.21 (1.05, 1.40)	0.0087	12.75 (3.40, 22.09)	0.0075	
	Age (years)									0.6105
	<= 65	172/239 (72.0)	71.9	145/243 (59.7)	59.5	1.21 (1.06, 1.38)	0.0046	12.44 (3.93, 20.94)	0.0042	
	> 65	5/ 7 (71.4)	70.5	1/ 3 (33.3)	34.1	1.68 (0.47, 6.03)	0.4227	36.36 (-30.31, 103.04)	0.2851	
	Sex									0.9037
	male	14/ 23 (60.9)	57.8	10/ 20 (50.0)	48.8	1.17 (0.61, 2.24)	0.6442	8.91 (-20.22, 38.04)	0.5488	
	female	163/223 (73.1)	73.1	136/226 (60.2)	60.1	1.22 (1.06, 1.39)	0.0040	12.93 (4.14, 21.72)	0.0040	
	Race									0.6176
	White	108/160 (67.5)	66.9	96/174 (55.2)	55.7	1.23 (1.04, 1.46)	0.0167	11.20 (0.76, 21.65)	0.0355	
	Black	24/ 33 (72.7)	72.7	21/ 32 (65.6)	68.4	1.03 (0.76, 1.41)	0.8357	4.37 (-18.92, 27.66)	0.7130	
	Other	38/ 45 (84.4)	84.2	26/ 37 (70.3)	70.0	1.17 (0.91, 1.49)	0.2260	14.26 (-4.91, 33.43)	0.1449	
	Ethnicity									0.2324
	Hispanic/Latino	36/ 50 (72.0)	71.8	38/ 56 (67.9)	67.9	1.06 (0.83, 1.36)	0.6262	3.88 (-13.96, 21.72)	0.6696	
	Non-hispanic/Latino	134/188 (71.3)	70.8	105/187 (56.1)	56.5	1.27 (1.09, 1.49)	0.0026	14.27 (4.49, 24.04)	0.0042	
	Geographic region									0.1307
	EU	57/ 92 (62.0)	63.0	39/ 89 (43.8)	44.0	1.45 (1.09, 1.92)	0.0101	19.04 (4.74, 33.34)	0.0091	
	non-EU	120/154 (77.9)	77.8	107/157 (68.2)	68.3	1.14 (0.99, 1.30)	0.0629	9.49 (-0.68, 19.66)	0.0674	
	Onset of disease									0.0754
	Paediatric	16/ 19 (84.2)	86.9	8/ 12 (66.7)	70.2	0.87 (0.62, 1.21)	0.4054	16.68 (-15.46, 48.82)	0.3092	
	Adult	161/227 (70.9)	70.8	138/234 (59.0)	59.0	1.20 (1.05, 1.38)	0.0075	11.75 (3.03, 20.48)	0.0083	
	ADA result									0.5700
	Negative	164/226 (72.6)	72.6	131/223 (58.7)	58.4	1.24 (1.08, 1.42)	0.0018	14.17 (5.35, 23.00)	0.0016	
	Positive (At any time)	13/ 19 (68.4)	69.1	15/ 23 (65.2)	61.5	1.08 (0.69, 1.69)	0.7233	7.64 (-22.80, 38.08)	0.6229	
	BMI (kg/m2) at enrolment									0.4144
	< 30	110/159 (69.2)	69.2	98/176 (55.7)	55.9	1.25 (1.06, 1.48)	0.0082	13.37 (3.05, 23.68)	0.0111	
	>= 30	67/ 87 (77.0)	77.3	48/ 70 (68.6)	68.3	1.13 (0.93, 1.37)	0.2340	9.04 (-5.36, 23.45)	0.2184	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
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Full analysis set

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Bronchitis	SLEDAI-2K score at screening									0.0424
	< 10 points	9/ 80 (11.3)	11.5	8/ 69 (11.6)	11.8	0.98 (0.40, 2.41)	0.9722	-0.33 (-13.50, 12.84)	0.9609	
	>= 10 points	18/166 (10.8)	11.1	5/177 (2.8)	2.8	3.86 (1.47, 10.15)	0.0062	8.35 (1.49, 15.22)	0.0171	
	OCS dose at baseline									0.3979
	<10 mg/day	14/115 (12.2)	12.4	5/117 (4.3)	4.4	2.76 (1.01, 7.53)	0.0478	8.02 (-1.19, 17.22)	0.0879	
	>=10 mg/day	13/131 (9.9)	9.9	8/129 (6.2)	6.6	1.55 (0.65, 3.72)	0.3222	3.24 (-5.20, 11.68)	0.4515	
	Result of type I IFN gene signature test									0.9972
	LOW	6/ 45 (13.3)	13.3	3/ 48 (6.3)	6.3	2.06 (0.54, 7.88)	0.2892	7.06 (-7.71, 21.84)	0.3488	
	HIGH	21/201 (10.4)	10.6	10/198 (5.1)	5.3	2.06 (0.99, 4.28)	0.0531	5.30 (-1.37, 11.97)	0.1193	
	Age (years)									0.8405
	<= 65	26/239 (10.9)	11.0	13/243 (5.3)	5.6	2.03 (1.07, 3.86)	0.0306	5.37 (-0.80, 11.54)	0.0881	
	> 65	1/ 7 (14.3)	13.6	0/ 3 (0.0)	0.0	1.50 (0.08, 26.86)	0.7830	13.64 (-50.73, 78.01)	0.6780	
	Sex									0.9867
	male	1/ 23 (4.3)	3.8	0/ 20 (0.0)	0.0	2.08 (0.09, 45.45)	0.6425	3.80 (-17.72, 25.31)	0.7296	
	female	26/223 (11.7)	11.8	13/226 (5.8)	6.0	2.02 (1.07, 3.84)	0.0313	5.81 (-0.71, 12.33)	0.0805	
	Race									0.4828
	White	19/160 (11.9)	11.8	8/174 (4.6)	4.5	2.56 (1.15, 5.69)	0.0212	7.34 (-0.21, 14.90)	0.0567	
	Black	5/ 33 (15.2)	17.2	3/ 32 (9.4)	10.4	1.52 (0.38, 6.14)	0.5554	6.75 (-13.73, 27.23)	0.5183	
	Other	2/ 45 (4.4)	4.4	2/ 37 (5.4)	5.2	0.79 (0.12, 5.14)	0.8062	-0.82 (-15.10, 13.45)	0.9099	
	Ethnicity									0.9229
	Hispanic/Latino	4/ 50 (8.0)	8.0	2/ 56 (3.6)	3.5	1.81 (0.37, 8.95)	0.4660	4.51 (-7.67, 16.70)	0.4680	
	Non-hispanic/Latino	22/188 (11.7)	12.2	11/187 (5.9)	6.3	1.97 (0.98, 3.98)	0.0571	5.91 (-1.24, 13.06)	0.1052	
	Geographic region									0.5039
	EU	10/ 92 (10.9)	10.6	3/ 89 (3.4)	3.6	2.85 (0.82, 9.97)	0.1004	6.96 (-2.00, 15.92)	0.1280	
	non-EU	17/154 (11.0)	11.2	10/157 (6.4)	6.4	1.73 (0.82, 3.68)	0.1509	4.85 (-2.86, 12.57)	0.2177	
	Onset of disease									0.9983
	Paediatric	2/ 19 (10.5)	10.9	0/ 12 (0.0)	0.0	2.00 (0.23, 17.29)	0.5294	10.87 (-19.12, 40.85)	0.4775	
	Adult	25/227 (11.0)	11.1	13/234 (5.6)	5.8	1.99 (1.05, 3.80)	0.0362	5.32 (-1.04, 11.68)	0.1011	
	ADA result									0.3268
	Negative	26/226 (11.5)	11.6	11/223 (4.9)	5.3	2.32 (1.17, 4.58)	0.0155	6.31 (-0.14, 12.77)	0.0553	
	Positive (At any time)	1/ 19 (5.3)	4.7	2/ 23 (8.7)	8.4	0.81 (0.11, 5.96)	0.8321	-3.64 (-28.01, 20.74)	0.7700	
	BMI (kg/m2) at enrolment									0.7082
	< 30	18/159 (11.3)	11.2	9/176 (5.1)	5.4	2.17 (1.01, 4.69)	0.0475	5.80 (-1.42, 13.02)	0.1154	
	>= 30	9/ 87 (10.3)	10.5	4/ 70 (5.7)	5.7	1.67 (0.53, 5.29)	0.3841	4.78 (-6.32, 15.88)	0.3985	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Respiratory tract infection	SLEDAI-2K score at screening									0.9865
	< 10 points	4/ 80 (5.0)	5.3	0/ 69 (0.0)	0.0	4.32 (0.52, 36.11)	0.1768	5.25 (-6.05, 16.56)	0.3626	
	>= 10 points	7/166 (4.2)	4.3	1/177 (0.6)	0.6	4.22 (0.67, 26.42)	0.1244	3.69 (-2.12, 9.49)	0.2132	
	OCS dose at baseline									0.8730
	<10 mg/day	8/115 (7.0)	7.3	1/117 (0.9)	0.9	4.82 (0.83, 28.08)	0.0804	6.37 (-2.01, 14.74)	0.1361	
	>=10 mg/day	3/131 (2.3)	2.2	0/129 (0.0)	0.0	3.83 (0.43, 34.21)	0.2292	2.18 (-4.48, 8.84)	0.5214	
	Result of type I IFN gene signature test									NE
	LOW	0/ 45 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-10.61, 10.61)	1.0000	
	HIGH	11/201 (5.5)	5.6	1/198 (0.5)	0.5	6.37 (1.13, 35.89)	0.0357	5.12 (-0.58, 10.81)	0.0783	
	Age (years)									NE
	<= 65	11/239 (4.6)	4.7	1/243 (0.4)	0.4	6.60 (1.17, 37.25)	0.0325	4.26 (-0.87, 9.39)	0.1038	
	> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-62.98, 62.98)	1.0000	
	Sex									0.1592
	male	2/ 23 (8.7)	9.9	1/ 20 (5.0)	5.7	1.21 (0.14, 10.15)	0.8599	4.21 (-19.58, 27.99)	0.7288	
	female	9/223 (4.0)	4.0	0/226 (0.0)	0.0	10.09 (1.30, 78.24)	0.0270	4.02 (-1.28, 9.32)	0.1375	
	Race									0.6110
	White	10/160 (6.3)	6.0	1/174 (0.6)	0.6	6.75 (1.20, 38.03)	0.0305	5.34 (-1.25, 11.93)	0.1123	
	Black	0/ 33 (0.0)	0.0	0/ 32 (0.0)	0.0	NE		0.00 (-15.38, 15.38)	1.0000	
	Other	1/ 45 (2.2)	2.3	0/ 37 (0.0)	0.0	2.65 (0.11, 62.00)	0.5438	2.31 (-10.27, 14.88)	0.7190	
	Ethnicity									0.0664
	Hispanic/Latino	0/ 50 (0.0)	0.0	1/ 56 (1.8)	1.9	0.35 (0.01, 8.11)	0.5106	-1.85 (-11.80, 8.09)	0.7147	
	Non-hispanic/Latino	11/188 (5.9)	5.6	0/187 (0.0)	0.0	11.66 (1.52, 89.17)	0.0180	5.61 (-0.30, 11.52)	0.0630	
	Geographic region									0.3028
	EU	8/ 92 (8.7)	8.7	0/ 89 (0.0)	0.0	8.43 (1.09, 65.13)	0.0411	8.67 (0.75, 16.59)	0.0318	
	non-EU	3/154 (1.9)	1.9	1/157 (0.6)	0.7	1.76 (0.20, 15.32)	0.6079	1.19 (-4.79, 7.18)	0.6959	
	Onset of disease									NE
	Paediatric	0/ 19 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-28.28, 28.28)	1.0000	
	Adult	11/227 (4.8)	4.9	1/234 (0.4)	0.4	6.64 (1.18, 37.48)	0.0319	4.49 (-0.84, 9.83)	0.0986	
	ADA result									NE
	Negative	11/226 (4.9)	4.9	1/223 (0.4)	0.5	6.46 (1.15, 36.41)	0.0345	4.43 (-1.02, 9.88)	0.1114	
	Positive (At any time)	0/ 19 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-21.63, 21.63)	1.0000	
	BMI (kg/m2) at enrolment									0.7804
	< 30	8/159 (5.0)	5.1	1/176 (0.6)	0.6	4.82 (0.77, 30.05)	0.0920	4.54 (-1.48, 10.56)	0.1394	
	>= 30	3/ 87 (3.4)	3.6	0/ 70 (0.0)	0.0	3.22 (0.36, 28.46)	0.2937	3.58 (-5.73, 12.89)	0.4511	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Upper respiratory tract infection	SLEDAI-2K score at screening									0.9355
	< 10 points	17/ 80 (21.3)	21.9	7/ 69 (10.1)	10.3	1.74 (0.73, 4.12)	0.2115	11.66 (-2.07, 25.40)	0.0959	
	>= 10 points	24/166 (14.5)	14.7	16/177 (9.0)	8.8	1.66 (0.92, 3.00)	0.0907	5.90 (-1.79, 13.60)	0.1328	
	OCS dose at baseline									0.9335
	<10 mg/day	24/115 (20.9)	20.9	14/117 (12.0)	11.5	1.79 (0.98, 3.27)	0.0597	9.46 (-1.10, 20.01)	0.0790	
	>=10 mg/day	17/131 (13.0)	12.6	9/129 (7.0)	7.2	1.71 (0.75, 3.92)	0.2055	5.38 (-3.33, 14.09)	0.2260	
	Result of type I IFN gene signature test									0.1642
	LOW	9/ 45 (20.0)	19.9	2/ 48 (4.2)	4.2	4.63 (1.04, 20.58)	0.0440	15.77 (0.54, 30.99)	0.0424	
	HIGH	32/201 (15.9)	16.0	21/198 (10.6)	10.4	1.51 (0.90, 2.54)	0.1186	5.59 (-1.83, 13.01)	0.1397	
	Age (years)									0.7898
	<= 65	39/239 (16.3)	16.3	23/243 (9.5)	9.4	1.72 (1.05, 2.81)	0.0299	6.90 (0.16, 13.63)	0.0447	
	> 65	2/ 7 (28.6)	27.3	0/ 3 (0.0)	0.0	2.50 (0.17, 37.26)	0.5062	27.27 (-37.78, 92.32)	0.4112	
	Sex									0.4392
	male	3/ 23 (13.0)	12.5	2/ 20 (10.0)	11.4	0.98 (0.21, 4.46)	0.9741	1.16 (-23.65, 25.96)	0.9273	
	female	38/223 (17.0)	17.2	21/226 (9.3)	9.2	1.83 (1.11, 3.03)	0.0176	7.97 (0.90, 15.03)	0.0270	
	Race									0.9343
	White	28/160 (17.5)	17.2	17/174 (9.8)	9.7	1.76 (0.99, 3.13)	0.0542	7.56 (-0.81, 15.93)	0.0768	
	Black	3/ 33 (9.1)	12.1	1/ 32 (3.1)	4.0	1.84 (0.22, 15.30)	0.5727	8.13 (-10.41, 26.68)	0.3900	
	Other	10/ 45 (22.2)	22.5	5/ 37 (13.5)	13.1	1.44 (0.56, 3.68)	0.4484	9.39 (-8.61, 27.38)	0.3066	
	Ethnicity									0.2718
	Hispanic/Latino	13/ 50 (26.0)	26.4	5/ 56 (8.9)	8.9	2.92 (1.10, 7.70)	0.0307	17.45 (2.06, 32.84)	0.0263	
	Non-hispanic/Latino	28/188 (14.9)	14.7	18/187 (9.6)	10.0	1.56 (0.89, 2.72)	0.1207	4.77 (-2.88, 12.41)	0.2217	
	Geographic region									0.6139
	EU	6/ 92 (6.5)	6.8	2/ 89 (2.2)	2.0	2.64 (0.62, 11.23)	0.1890	4.73 (-3.30, 12.75)	0.2482	
	non-EU	35/154 (22.7)	23.7	21/157 (13.4)	12.9	1.78 (1.08, 2.92)	0.0229	10.74 (1.59, 19.89)	0.0214	
	Onset of disease									0.6506
	Paediatric	4/ 19 (21.1)	21.7	2/ 12 (16.7)	17.0	1.26 (0.27, 5.81)	0.7694	4.71 (-28.96, 38.37)	0.7841	
	Adult	37/227 (16.3)	16.4	21/234 (9.0)	8.8	1.83 (1.10, 3.04)	0.0204	7.54 (0.67, 14.41)	0.0316	
	ADA result									0.2168
	Negative	41/226 (18.1)	18.0	21/223 (9.4)	9.3	1.91 (1.16, 3.14)	0.0107	8.71 (1.57, 15.86)	0.0168	
	Positive (At any time)	0/ 19 (0.0)	0.0	2/ 23 (8.7)	8.4	0.47 (0.05, 4.11)	0.4945	-8.36 (-31.69, 14.97)	0.4823	
	BMI (kg/m2) at enrolment									0.9001
	< 30	24/159 (15.1)	14.6	15/176 (8.5)	8.8	1.75 (0.95, 3.22)	0.0703	5.82 (-2.01, 13.66)	0.1452	
	>= 30	17/ 87 (19.5)	20.5	8/ 70 (11.4)	11.4	1.64 (0.72, 3.75)	0.2402	9.08 (-3.59, 21.75)	0.1602	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
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Summary of Incidence and Time to First Frequent Serious Adverse Events by SOC, PT (incidence in either arm >= 5% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=246)	Placebo (N=246)
SOC: Infections and infestations	Number of subjects with events, n (%)	7 (2.8)	19 (7.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.37 (0.16, 0.87)	
	p-value	0.0227	
	Odds Ratio (95% CI)	0.35 (0.15, 0.86)	
	p-value	0.0215	
	Risk Difference (95% CI)	-4.88 (-8.81, -0.95)	
	p-value	0.0150	
	CMH approach		
	Response rate	2.9	7.6
	Difference in response rates (95% CI)	-4.61 (-10.22, 1.01)	
	p-value	0.1076	
	p-Value for test for heterogenity between studies	0.6796	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
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Summary of Incidence and Time to First Frequent Serious Adverse Events by SOC, PT (incidence in either arm >= 5% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=246) n/ N (%)	Response rate	Placebo (N=246) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations	SLEDAI-2K score at screening									0.7474
	< 10 points	1/ 80 (1.3)	1.2	2/ 69 (2.9)	2.8	0.55 (0.07, 4.34)	0.5685	-1.59 (-12.71, 9.52)	0.7786	
	>= 10 points	6/166 (3.6)	3.6	17/177 (9.6)	9.6	0.38 (0.15, 0.94)	0.0353	-5.96 (-12.76, 0.83)	0.0855	
	OCS dose at baseline									0.2591
	<10 mg/day	5/115 (4.3)	4.5	9/117 (7.7)	7.4	0.57 (0.19, 1.66)	0.2985	-2.90 (-11.64, 5.85)	0.5163	
	>=10 mg/day	2/131 (1.5)	1.4	10/129 (7.8)	8.0	0.20 (0.04, 0.88)	0.0328	-6.56 (-14.31, 1.19)	0.0971	
	Result of type I IFN gene signature test									0.2207
	LOW	2/ 45 (4.4)	4.5	2/ 48 (4.2)	4.1	1.09 (0.17, 7.10)	0.9274	0.37 (-12.27, 13.02)	0.9537	
	HIGH	5/201 (2.5)	2.6	17/198 (8.6)	8.4	0.29 (0.11, 0.77)	0.0134	-5.78 (-12.04, 0.48)	0.0706	
	Age (years)									NE
	<= 65	7/239 (2.9)	3.0	19/243 (7.8)	7.6	0.38 (0.16, 0.89)	0.0251	-4.60 (-10.31, 1.11)	0.1143	
	> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-62.98, 62.98)	1.0000	
	Sex									0.7522
	male	0/ 23 (0.0)	0.0	2/ 20 (10.0)	10.2	0.29 (0.03, 2.57)	0.2652	-10.23 (-33.11, 12.65)	0.3809	
	female	7/223 (3.1)	3.2	17/226 (7.5)	7.4	0.42 (0.18, 1.00)	0.0499	-4.20 (-10.19, 1.80)	0.1700	
	Race									0.7806
	White	4/160 (2.5)	2.5	10/174 (5.7)	6.0	0.44 (0.14, 1.37)	0.1545	-3.50 (-10.38, 3.38)	0.3191	
	Black	0/ 33 (0.0)	0.0	4/ 32 (12.5)	14.4	0.21 (0.02, 1.73)	0.1462	-14.38 (-32.76, 3.99)	0.1250	
	Other	3/ 45 (6.7)	6.5	5/ 37 (13.5)	13.5	0.51 (0.12, 2.08)	0.3467	-6.97 (-23.15, 9.20)	0.3982	
	Ethnicity									0.9650
	Hispanic/Latino	2/ 50 (4.0)	3.9	7/ 56 (12.5)	12.6	0.40 (0.10, 1.63)	0.2027	-8.75 (-21.63, 4.13)	0.1829	
	Non-hispanic/Latino	5/188 (2.7)	2.9	12/187 (6.4)	6.2	0.42 (0.15, 1.16)	0.0943	-3.34 (-9.73, 3.06)	0.3066	
	Geographic region									0.4319
	EU	0/ 92 (0.0)	0.0	4/ 89 (4.5)	4.6	0.19 (0.02, 1.57)	0.1226	-4.63 (-11.75, 2.48)	0.2020	
	non-EU	7/154 (4.5)	4.7	15/157 (9.6)	9.6	0.47 (0.20, 1.13)	0.0908	-4.93 (-12.41, 2.54)	0.1961	
	Onset of disease									0.9916
	Paediatric	1/ 19 (5.3)	4.4	2/ 12 (16.7)	17.0	0.38 (0.05, 2.71)	0.3353	-12.67 (-44.24, 18.90)	0.4316	
	Adult	6/227 (2.6)	2.6	17/234 (7.3)	7.1	0.38 (0.15, 0.95)	0.0387	-4.43 (-10.20, 1.35)	0.1329	
	ADA result									0.3812
	Negative	7/226 (3.1)	3.2	13/223 (5.8)	5.6	0.54 (0.22, 1.33)	0.1776	-2.46 (-8.31, 3.40)	0.4104	
	Positive (At any time)	0/ 19 (0.0)	0.0	6/ 23 (26.1)	25.1	0.20 (0.03, 1.48)	0.1156	-25.09 (-50.72, 0.54)	0.0550	
	BMI (kg/m2) at enrolment									0.9625
	< 30	4/159 (2.5)	2.5	12/176 (6.8)	6.5	0.37 (0.12, 1.14)	0.0829	-4.01 (-10.41, 2.39)	0.2197	
	>= 30	3/ 87 (3.4)	3.4	7/ 70 (10.0)	9.8	0.39 (0.09, 1.60)	0.1910	-6.41 (-17.29, 4.47)	0.2483	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Severe (Grade >=3) by SOC, PT (incidence in either arm >= 5% or >=10 patients)
Full analysis set

- NO OBSERVATIONS FOR THIS ANALYSIS -

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and Time to First Frequent Severe (Grade >=3) by SOC, PT (incidence in either arm >= 5% or >=10 patients) - Subgroup analysis
Full analysis set

- NO OBSERVATIONS FOR THIS ANALYSIS -

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Subject disposition and summary of treatment exposure
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

		Anifrolumab 300mg (N=69)	Placebo (N=75)
Patients who completed the study		59 (85.5)	53 (70.7)
Patients withdrawn from the study		10 (14.5)	22 (29.3)
OTHER		8 (11.6)	17 (22.7)
LOST TO FOLLOW-UP		2 (2.9)	4 (5.3)
ADVERSE EVENT		0	1 (1.3)
Duration of study (weeks)	n (missing)	69 (0)	75 (0)
	Mean (SD)	57.7 (11.37)	51.5 (16.42)
	Median	60.3	60.1
	Min, Max	8, 71	4, 71
Patients who completed investigational product		61 (88.4)	51 (68.0)
Patients discontinued investigational product		8 (11.6)	24 (32.0)
Withdrawal Of Consent		1 (1.4)	9 (12.0)
Adverse Event		1 (1.4)	6 (8.0)
Sponsor Decision, Regional Political Circumstances Preclude Site Activities		0	3 (4.0)
Lost To Follow-Up		0	2 (2.7)
Inadequate Venous Access.		1 (1.4)	0
Investigator Decision Due To Exacerbation Of Her Disease.		0	1 (1.3)
Lack Of Efficacy		1 (1.4)	0
Medical Decision, The Patient Has Been Presenting Various Infections In A Relatively Short Amount Of Time.		1 (1.4)	0
Patient Is Moving Away		0	1 (1.3)
Patient Withdrawn Consent, She Has Decided To Finish Treatment And Participation In The Study Due To Sae.		1 (1.4)	0
Pregnancy		0	1 (1.3)
Prohibited Concomitant Medications (Steroid Pulses)		1 (1.4)	0
Subject Called Did Not Want To Come In And See The Pi Any Longer Has Found A New Doctor. She Never Said She Wanted To Withdraw Consent.		0	1 (1.3)
Subject Missed Visit Day 337, But Was Approved To Continue On Study By Sponsor And Completed Remaining Visits.		1 (1.4)	0
Duration of exposure (weeks)	n (missing)	69 (0)	75 (0)
	Mean (SD)	49.2 (10.54)	43.3 (15.31)
	Median	52.3	52.1
	Min, Max	4, 55	4, 54

Duration of study defined as time from randomization until end of participation date.
Duration of exposure defined as difference of date of first exposure to treatment and date of last exposure to treatment + 28 days.
'Full Analysis Set' Referred to as 'mITT population' in the study 1013 CSR

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Demographic and baseline characteristics
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

		Anifrolumab 300mg (N=69)	Placebo (N=75)	Total (N=144)
Age	n (missing)	69 (0)	75 (0)	144 (0)
	Mean (SD)	39.2 (11.95)	40.5 (13.14)	39.9 (12.56)
	Median	38.0	41.0	40.0
	Min, Max	20, 64	18, 65	18, 65
Age (years) (%)	<= 65	69 (100.0)	75 (100.0)	144 (100.0)
Sex (%) (%)	female	65 (94.2)	69 (92.0)	134 (93.1)
	male	4 (5.8)	6 (8.0)	10 (6.9)
Race (%) (%)	American Indian or Alaska Native	3 (4.3)	0	3 (2.1)
	Asian	2 (2.9)	10 (13.3)	12 (8.3)
	Black or African American	16 (23.2)	8 (10.7)	24 (16.7)
	Other	23 (33.3)	26 (34.7)	49 (34.0)
	White	25 (36.2)	31 (41.3)	56 (38.9)
Ethnicity (%) (%)	Hispanic/Latino	28 (40.6)	28 (37.3)	56 (38.9)
	Non-hispanic/Latino	41 (59.4)	47 (62.7)	88 (61.1)
Geographic region (%) (%)	Asia Pacific	1 (1.4)	9 (12.0)	10 (6.9)
	Europe	18 (26.1)	20 (26.7)	38 (26.4)
	Latin America	25 (36.2)	26 (34.7)	51 (35.4)
	North America	24 (34.8)	20 (26.7)	44 (30.6)
	Rest Of World	1 (1.4)	0	1 (0.7)
Geographic region subgroup (%)	EU	18 (26.1)	20 (26.7)	38 (26.4)
	non-EU	51 (73.9)	55 (73.3)	106 (73.6)
Height (cm)	n (missing)	69 (0)	75 (0)	144 (0)
	Mean (SD)	162.41 (8.249)	161.24 (7.724)	161.80 (7.973)
	Median	162.00	162.00	162.00
	Min, Max	146.0, 188.0	142.0, 179.0	142.0, 188.0
Weight (kg)	n (missing)	69 (0)	75 (0)	144 (0)
	Mean (SD)	69.98 (15.804)	67.41 (19.701)	68.65 (17.924)
	Median	68.20	62.50	64.65
	Min, Max	45.8, 113.4	40.0, 139.3	40.0, 139.3
BMI (kg/m2)	n (missing)	69 (0)	75 (0)	144 (0)
	Mean (SD)	26.53 (5.615)	25.79 (6.623)	26.15 (6.150)
	Median	25.91	24.75	25.25
	Min, Max	17.0, 41.6	16.1, 46.7	16.1, 46.7
BMI subgroup (%)	<=28 kg/m2	42 (60.9)	57 (76.0)	99 (68.8)
	>28 kg/m2	27 (39.1)	18 (24.0)	45 (31.3)

[a] Asia Pacific: Australia, New Zealand, South Korea, Taiwan. Europe: Germany, Hungary, Italy, Poland, Romania, Ukraine, United Kingdom. Latin America: Argentinia, Brazil, Chile, Colombia, Peru. Rest of World: India, Israel, South Africa.
Missing/multiple categories checked for Race grouped as 'Other'.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SLE disease characteristics
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

		Anifrolumab 300mg (N=69)	Placebo (N=75)	Total (N=144)
SLEDAI-2K score at screening	n (missing)	69 (0)	75 (0)	144 (0)
	Mean (SD)	10.6 (3.85)	10.9 (4.69)	10.7 (4.30)
	Median	10.0	10.0	10.0
	Min, Max	6, 24	6, 37	6, 37
SLEDAI-2K score at screening, categorisation (%)	<10	29 (42.0)	32 (42.7)	61 (42.4)
	>=10	40 (58.0)	43 (57.3)	83 (57.6)
Clinical SLEDAI-2K score at screening	n (missing)	69 (0)	75 (0)	144 (0)
	Mean (SD)	8.7 (2.73)	8.8 (2.96)	8.8 (2.84)
	Median	8.0	8.0	8.0
	Min, Max	4, 18	4, 21	4, 21
SLEDAI-2K score at baseline	n (missing)	69 (0)	75 (0)	144 (0)
	Mean (SD)	10.9 (4.04)	11.0 (4.55)	11.0 (4.30)
	Median	10.0	10.0	10.0
	Min, Max	6, 24	6, 29	6, 29
SLEDAI-2K score at baseline, categorisation (%)	<10	29 (42.0)	32 (42.7)	61 (42.4)
	>=10	40 (58.0)	43 (57.3)	83 (57.6)
Clinical SLEDAI-2K score at baseline	n (missing)	69 (0)	75 (0)	144 (0)
	Mean (SD)	8.8 (2.67)	8.9 (3.01)	8.9 (2.84)
	Median	8.0	8.0	8.0
	Min, Max	6, 18	4, 20	4, 20
Adjudication Scoring (BILAG) at baseline Overall (%)	At least one A	36 (52.2)	34 (45.3)	70 (48.6)
	No A and <2Bs	5 (7.2)	4 (5.3)	9 (6.3)
	No A and at least 2 Bs	28 (40.6)	37 (49.3)	65 (45.1)
Adjudication Scoring (BILAG) at baseline Constitutional (%)	A	1 (1.4)	0	1 (0.7)
	B	4 (5.8)	7 (9.3)	11 (7.6)
	C, D or E	64 (92.8)	68 (90.7)	132 (91.7)
Adjudication Scoring (BILAG) at baseline Mucocutaneous (%)	A	17 (24.6)	12 (16.0)	29 (20.1)
	B	43 (62.3)	52 (69.3)	95 (66.0)
	C, D or E	9 (13.0)	11 (14.7)	20 (13.9)
Adjudication Scoring (BILAG) at baseline Neuropsychiatric (%)	B	0	1 (1.3)	1 (0.7)
	C, D or E	69 (100.0)	74 (98.7)	143 (99.3)
Adjudication Scoring (BILAG) at baseline Musculoskeletal (%)	A	21 (30.4)	21 (28.0)	42 (29.2)
	B	44 (63.8)	48 (64.0)	92 (63.9)
	C, D or E	4 (5.8)	6 (8.0)	10 (6.9)
Adjudication Scoring (BILAG) at baseline Cardiorespiratory (%)	B	2 (2.9)	6 (8.0)	8 (5.6)
	C, D or E	67 (97.1)	69 (92.0)	136 (94.4)
Adjudication Scoring (BILAG) at baseline Gastrointestinal (%)	C, D or E	69 (100.0)	75 (100.0)	144 (100.0)
Adjudication Scoring (BILAG) at baseline Ophthalmic (%)	B	1 (1.4)	0	1 (0.7)
	C, D or E	68 (98.6)	75 (100.0)	143 (99.3)
Adjudication Scoring (BILAG) at baseline Renal (%)	A	1 (1.4)	1 (1.3)	2 (1.4)
	B	8 (11.6)	7 (9.3)	15 (10.4)
	C, D or E	60 (87.0)	67 (89.3)	127 (88.2)
Adjudication Scoring (BILAG) at baseline Haematological (%)	B	0	3 (4.0)	3 (2.1)
	C, D or E	69 (100.0)	72 (96.0)	141 (97.9)

Baseline is defined as the last measurement prior to randomisation and dose administration on Day 1.
Only subjects with baseline positive anti-dsDNA and abnormal complement level, respectively, are included in the summary statistics for the respective variables.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SLE disease characteristics
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

		Anifrolumab 300mg (N=69)	Placebo (N=75)	Total (N=144)
BILAG-2004 global score at baseline	n (missing)	69 (0)	75 (0)	144 (0)
	Mean (SD)	19.7 (6.09)	19.4 (5.60)	19.6 (5.82)
	Median	18.0	18.0	18.0
	Min, Max	9, 36	9, 36	9, 36
Physician Global Assessment (PGA) score at baseline	n (missing)	69 (0)	75 (0)	144 (0)
	Mean (SD)	1.8 (0.41)	1.7 (0.42)	1.8 (0.41)
	Median	1.9	1.6	1.8
	Min, Max	1, 3	1, 3	1, 3
CLASI activity score at baseline	n (missing)	69 (0)	75 (0)	144 (0)
	Mean (SD)	8.2 (6.88)	6.1 (4.43)	7.1 (5.82)
	Median	6.0	5.0	5.0
	Min, Max	1, 36	0, 20	0, 36
CLASI activity score at baseline, categorisation 1 (%)	0	0	1 (1.3)	1 (0.7)
	> 0	69 (100.0)	74 (98.7)	143 (99.3)
CLASI activity score at baseline, categorisation 2 (%)	<10	47 (68.1)	60 (80.0)	107 (74.3)
	>=10	22 (31.9)	15 (20.0)	37 (25.7)
CLASI damage score at baseline	n (missing)	69 (0)	75 (0)	144 (0)
	Mean (SD)	2.0 (4.47)	1.9 (4.72)	1.9 (4.58)
	Median	0.0	0.0	0.0
	Min, Max	0, 25	0, 31	0, 31
CLASI damage score at baseline, categorisation 1 (%)	0	49 (71.0)	54 (72.0)	103 (71.5)
	> 0	20 (29.0)	21 (28.0)	41 (28.5)
CLASI damage score at baseline, categorisation 2 (%)	<10	65 (94.2)	71 (94.7)	136 (94.4)
	>=10	4 (5.8)	4 (5.3)	8 (5.6)
Tender Joint Count at Baseline	n (missing)	69 (0)	75 (0)	144 (0)
	Mean (SD)	11.4 (6.45)	9.9 (7.04)	10.6 (6.78)
	Median	11.0	8.0	10.0
	Min, Max	2, 28	0, 28	0, 28
Tender Joint Count at Baseline, categorisation (%)	0	0	4 (5.3)	4 (2.8)
	> 0	69 (100.0)	71 (94.7)	140 (97.2)
Swollen Joint Count at Baseline	n (missing)	69 (0)	75 (0)	144 (0)
	Mean (SD)	7.6 (5.10)	7.9 (6.18)	7.7 (5.67)
	Median	6.0	6.0	6.0
	Min, Max	0, 19	0, 26	0, 26
Swollen Joint Count at Baseline, categorisation (%)	0	3 (4.3)	3 (4.0)	6 (4.2)
	> 0	66 (95.7)	72 (96.0)	138 (95.8)
Active Joint Count at Baseline	n (missing)	69 (0)	75 (0)	144 (0)
	Mean (SD)	10.5 (6.55)	9.3 (6.50)	9.9 (6.53)
	Median	10.0	7.0	8.0
	Min, Max	0, 28	0, 28	0, 28
Active Joint Count at Baseline, categorisation (%)	0	3 (4.3)	3 (4.0)	6 (4.2)
	> 0	66 (95.7)	72 (96.0)	138 (95.8)
SDI global score at baseline	n (missing)	69 (0)	75 (0)	144 (0)
	Mean (SD)	0.7 (0.98)	0.7 (1.23)	0.7 (1.12)
	Median	0.0	0.0	0.0
	Min, Max	0, 3	0, 7	0, 7

Baseline is defined as the last measurement prior to randomisation and dose administration on Day 1.
Only subjects with baseline positive anti-dsDNA and abnormal complement level, respectively, are included in the summary statistics for the respective variables.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SLE disease characteristics
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

		Anifrolumab 300mg (N=69)	Placebo (N=75)	Total (N=144)
SDI global score at baseline, categorisation (%)	0 (no damage)	40 (58.0)	48 (64.0)	88 (61.1)
	>=1 (damage)	29 (42.0)	27 (36.0)	56 (38.9)
Time from initial SLE diagnosis to randomisation (months)	n (missing)	69 (0)	75 (0)	144 (0)
	Mean (SD)	94.6 (71.93)	92.8 (86.65)	93.7 (79.67)
	Median	73.4	67.1	69.4
	Min, Max	7, 361	7, 404	7, 404
Cushingoid features (%)	Any Cushingoid Feature	32 (46.4)	28 (37.3)	60 (41.7)
	Moon Face	21 (30.4)	15 (20.0)	36 (25.0)
	Buffalo Hump	10 (14.5)	7 (9.3)	17 (11.8)
	Purple or Violaceous Striae	5 (7.2)	3 (4.0)	8 (5.6)
	Central Obesity	16 (23.2)	8 (10.7)	24 (16.7)
	Hirsutisim	6 (8.7)	4 (5.3)	10 (6.9)
	Acne	4 (5.8)	6 (8.0)	10 (6.9)
	Easy Bruising	20 (29.0)	14 (18.7)	34 (23.6)
	Fragile Skin	14 (20.3)	12 (16.0)	26 (18.1)
Results of 4-gene Type 1 Interferon (IFN) test (%)	High	55 (79.7)	56 (74.7)	111 (77.1)
	Low	14 (20.3)	19 (25.3)	33 (22.9)
Anti-dsDNA levels at baseline	n (missing)	40 (0)	50 (0)	90 (0)
	Mean (SD)	127.4 (200.53)	121.8 (174.17)	124.3 (185.29)
	Median	54.5	45.0	46.5
	Min, Max	14, 814	14, 778	14, 814
Anti-dsDNA levels at baseline, categorisation (%)	Negative	15 (21.7)	11 (14.7)	26 (18.1)
	Positive	40 (58.0)	50 (66.7)	90 (62.5)
	Missing	14 (20.3)	14 (18.7)	28 (19.4)
ANA (%)	Abnormal (titre >= 1:80)	68 (98.6)	73 (97.3)	141 (97.9)
	Normal (titre < 1:80)	1 (1.4)	2 (2.7)	3 (2.1)
Complement C3 level at baseline	n (missing)	20 (0)	30 (0)	50 (0)
	Mean (SD)	0.69 (0.188)	0.68 (0.162)	0.68 (0.171)
	Median	0.71	0.70	0.71
	Min, Max	0.2, 0.9	0.3, 0.9	0.2, 0.9
Complement C3 level at baseline, categorisation (%)	Abnormal	20 (29.0)	30 (40.0)	50 (34.7)
	Normal	49 (71.0)	45 (60.0)	94 (65.3)
Complement C4 level at baseline	n (missing)	17 (0)	19 (0)	36 (0)
	Mean (SD)	0.07 (0.024)	0.07 (0.020)	0.07 (0.022)
	Median	0.07	0.07	0.07
	Min, Max	0.0, 0.1	0.0, 0.1	0.0, 0.1
Complement C4 level at baseline, categorisation (%)	Abnormal	17 (24.6)	19 (25.3)	36 (25.0)
	Normal	52 (75.4)	56 (74.7)	108 (75.0)
Complement CH50 level at baseline	n (missing)	9 (0)	10 (0)	19 (0)
	Mean (SD)	37.83 (33.466)	50.55 (32.318)	44.53 (32.597)
	Median	33.00	51.00	38.00
	Min, Max	2.5, 94.0	2.5, 98.0	2.5, 98.0
Complement CH50 level at baseline, categorisation (%)	Abnormal	9 (13.0)	10 (13.3)	19 (13.2)
	Normal	60 (87.0)	65 (86.7)	125 (86.8)

Baseline is defined as the last measurement prior to randomisation and dose administration on Day 1.
Only subjects with baseline positive anti-dsDNA and abnormal complement level, respectively, are included in the summary statistics for the respective variables.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Observation times for Efficacy endpoints
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

		Anifrolumab 300mg (N=69)	Placebo (N=75)
SRI4: Observation time (weeks)	n (missing)	69 (0)	75 (0)
	Mean (SD)	49.5 (10.01)	43.2 (15.26)
	Median	52.3	52.1
	Min, Max	7, 57	4, 54
CLASI activity score: Observation time (weeks)	n (missing)	69 (0)	75 (0)
	Mean (SD)	49.5 (10.01)	43.2 (15.26)
	Median	52.3	52.1
	Min, Max	7, 57	4, 54
CLASI damage score: Observation time (weeks)	n (missing)	69 (0)	75 (0)
	Mean (SD)	49.5 (10.01)	43.2 (15.26)
	Median	52.3	52.1
	Min, Max	7, 57	4, 54
BICLA: Observation time (weeks)	n (missing)	69 (0)	75 (0)
	Mean (SD)	49.5 (10.01)	43.2 (15.26)
	Median	52.3	52.1
	Min, Max	7, 57	4, 54
SLEDAI-2K Total Score: Observation time (weeks)	n (missing)	69 (0)	75 (0)
	Mean (SD)	49.5 (10.01)	43.2 (15.26)
	Median	52.3	52.1
	Min, Max	7, 57	4, 54
PGA: Observation time (weeks)	n (missing)	69 (0)	75 (0)
	Mean (SD)	49.5 (10.01)	43.2 (15.26)
	Median	52.3	52.1
	Min, Max	7, 57	4, 54
BILAG Global Score: Observation time (weeks)	n (missing)	69 (0)	75 (0)
	Mean (SD)	49.5 (10.01)	43.2 (15.26)
	Median	52.3	52.1
	Min, Max	7, 57	4, 54
Tender Joint Count: Observation time (weeks)	n (missing)	69 (0)	75 (0)
	Mean (SD)	49.5 (10.01)	43.2 (15.26)
	Median	52.3	52.1
	Min, Max	7, 57	4, 54
Swollen Joint Count: Observation time (weeks)	n (missing)	69 (0)	75 (0)
	Mean (SD)	49.5 (10.01)	43.2 (15.26)
	Median	52.3	52.1
	Min, Max	7, 57	4, 54
FACIT-F Total Score: Observation time (weeks)	n (missing)	69 (0)	75 (0)
	Mean (SD)	49.3 (10.57)	42.0 (16.08)
	Median	52.3	52.1
	Min, Max	4, 57	4, 54
SF-36 v2.0 Acute - Mental Component Score: Observation time (weeks)	n (missing)	69 (0)	75 (0)
	Mean (SD)	49.3 (10.57)	42.0 (16.08)
	Median	52.3	52.1
	Min, Max	4, 57	4, 54
SF-36 v2.0 Acute - Physical Component Score: Observation time (weeks)	n (missing)	69 (0)	75 (0)
	Mean (SD)	49.3 (10.57)	42.0 (16.08)
	Median	52.3	52.1
	Min, Max	4, 57	4, 54
EQ-5D VAS Score: Observation time (weeks)	n (missing)	69 (0)	75 (0)

Observation duration defined as time from randomization until last non-missing assessment after randomization. Subjects without assessment are censored at day 1.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Observation times for Efficacy endpoints
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

		Anifrolumab 300mg (N=69)	Placebo (N=75)
EQ-5D VAS Score: Observation time (weeks)	Mean (SD)	49.3 (10.57)	42.0 (16.08)
	Median	52.3	52.1
	Min, Max	4, 57	4, 54
SDI Global Score: Observation time (weeks)	n (missing)	69 (0)	75 (0)
	Mean (SD)	48.2 (12.43)	39.7 (19.27)
	Median	52.3	52.1
	Min, Max	0, 54	0, 54
PtGA: Observation time (weeks)	n (missing)	69 (0)	75 (0)
	Mean (SD)	49.5 (10.01)	43.2 (15.26)
	Median	52.3	52.1
	Min, Max	7, 57	4, 54

Observation duration defined as time from randomization until last non-missing assessment after randomization. Subjects without assessment are censored at day 1.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=69)	Placebo (N=75)
Week 4	Number of subjects with events, n (%)	8 (11.6)	9 (12.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.96 (0.37, 2.51)	
	p-value	0.9295	
	Odds Ratio (95% CI)	0.95 (0.34, 2.68)	
	p-value	0.9277	
	Risk Difference (95% CI)	-0.49 (-11.08, 10.10)	
	p-value	0.9277	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.97 (0.39, 2.36)	
	p-value	0.9399	
	Odds Ratio (95% CI)	0.96 (0.35, 2.65)	
	p-value	0.9399	
	Risk Difference (95% CI)	-0.41 (-10.95, 10.14)	
	p-value	0.9399	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=69)	Placebo (N=75)
Week 8	Number of subjects with events, n (%)	18 (26.1)	23 (30.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.90 (0.52, 1.55)	
	p-value	0.6927	
	Odds Ratio (95% CI)	0.86 (0.42, 1.78)	
	p-value	0.6877	
	Risk Difference (95% CI)	-3.08 (-18.11, 11.95)	
	p-value	0.6876	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.85 (0.50, 1.44)	
	p-value	0.5444	
	Odds Ratio (95% CI)	0.80 (0.39, 1.65)	
	p-value	0.5433	
	Risk Difference (95% CI)	-4.58 (-19.29, 10.13)	
	p-value	0.5416	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=69)	Placebo (N=75)
Week 12	Number of subjects with events, n (%)	29 (42.0)	32 (42.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.04 (0.70, 1.55)	
	p-value	0.8366	
	Odds Ratio (95% CI)	1.08 (0.55, 2.12)	
	p-value	0.8330	
	Risk Difference (95% CI)	1.73 (-14.36, 17.83)	
	p-value	0.8328	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.99 (0.67, 1.44)	
	p-value	0.9384	
	Odds Ratio (95% CI)	0.97 (0.50, 1.89)	
	p-value	0.9383	
	Risk Difference (95% CI)	-0.64 (-16.79, 15.52)	
	p-value	0.9383	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=69)	Placebo (N=75)
Week 16	Number of subjects with events, n (%)	34 (49.3)	31 (41.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.28 (0.90, 1.83)	
	p-value	0.1750	
	Odds Ratio (95% CI)	1.64 (0.81, 3.33)	
	p-value	0.1712	
	Risk Difference (95% CI)	11.02 (-4.49, 26.53)	
	p-value	0.1639	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.19 (0.83, 1.71)	
	p-value	0.3394	
	Odds Ratio (95% CI)	1.38 (0.71, 2.66)	
	p-value	0.3392	
	Risk Difference (95% CI)	7.94 (-8.29, 24.17)	
	p-value	0.3375	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=69)	Placebo (N=75)
Week 20	Number of subjects with events, n (%)	37 (53.6)	31 (41.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.36 (0.96, 1.91)	
	p-value	0.0793	
	Odds Ratio (95% CI)	1.87 (0.93, 3.76)	
	p-value	0.0787	
	Risk Difference (95% CI)	14.42 (-1.31, 30.14)	
	p-value	0.0725	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.30 (0.92, 1.84)	
	p-value	0.1422	
	Odds Ratio (95% CI)	1.64 (0.85, 3.17)	
	p-value	0.1410	
	Risk Difference (95% CI)	12.29 (-3.92, 28.50)	
	p-value	0.1372	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=69)	Placebo (N=75)
Week 24	Number of subjects with events, n (%)	36 (52.2)	28 (37.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.43 (0.98, 2.09)	
	p-value	0.0643	
	Odds Ratio (95% CI)	1.91 (0.97, 3.78)	
	p-value	0.0615	
	Risk Difference (95% CI)	15.71 (-0.42, 31.84)	
	p-value	0.0563	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.40 (0.97, 2.02)	
	p-value	0.0764	
	Odds Ratio (95% CI)	1.83 (0.94, 3.56)	
	p-value	0.0745	
	Risk Difference (95% CI)	14.84 (-1.25, 30.93)	
	p-value	0.0706	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=69)	Placebo (N=75)
Week 28	Number of subjects with events, n (%)	38 (55.1)	29 (38.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.50 (1.05, 2.14)	
	p-value	0.0244	
	Odds Ratio (95% CI)	2.20 (1.11, 4.39)	
	p-value	0.0248	
	Risk Difference (95% CI)	18.92 (2.99, 34.86)	
	p-value	0.0199	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.42 (1.00, 2.03)	
	p-value	0.0514	
	Odds Ratio (95% CI)	1.94 (1.00, 3.78)	
	p-value	0.0497	
	Risk Difference (95% CI)	16.41 (0.31, 32.51)	
	p-value	0.0458	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=69)	Placebo (N=75)
Week 32	Number of subjects with events, n (%)	41 (59.4)	32 (42.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.48 (1.08, 2.04)	
	p-value	0.0157	
	Odds Ratio (95% CI)	2.35 (1.17, 4.72)	
	p-value	0.0166	
	Risk Difference (95% CI)	20.15 (4.41, 35.89)	
	p-value	0.0121	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.39 (1.00, 1.93)	
	p-value	0.0470	
	Odds Ratio (95% CI)	1.97 (1.01, 3.82)	
	p-value	0.0456	
	Risk Difference (95% CI)	16.75 (0.64, 32.86)	
	p-value	0.0415	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=69)	Placebo (N=75)
Week 36	Number of subjects with events, n (%)	39 (56.5)	29 (38.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.52 (1.08, 2.16)	
	p-value	0.0178	
	Odds Ratio (95% CI)	2.31 (1.16, 4.62)	
	p-value	0.0178	
	Risk Difference (95% CI)	19.92 (4.06, 35.78)	
	p-value	0.0138	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.46 (1.03, 2.08)	
	p-value	0.0346	
	Odds Ratio (95% CI)	2.06 (1.06, 4.01)	
	p-value	0.0330	
	Risk Difference (95% CI)	17.86 (1.78, 33.93)	
	p-value	0.0294	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=69)	Placebo (N=75)
Week 40	Number of subjects with events, n (%)	38 (55.1)	25 (33.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.78 (1.21, 2.63)	
	p-value	0.0038	
	Odds Ratio (95% CI)	2.96 (1.44, 6.09)	
	p-value	0.0031	
	Risk Difference (95% CI)	24.69 (9.33, 40.06)	
	p-value	0.0016	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.65 (1.12, 2.43)	
	p-value	0.0105	
	Odds Ratio (95% CI)	2.45 (1.25, 4.81)	
	p-value	0.0092	
	Risk Difference (95% CI)	21.74 (5.88, 37.60)	
	p-value	0.0072	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=69)	Placebo (N=75)
Week 44	Number of subjects with events, n (%)	39 (56.5)	29 (38.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.59 (1.11, 2.29)	
	p-value	0.0118	
	Odds Ratio (95% CI)	2.51 (1.23, 5.12)	
	p-value	0.0111	
	Risk Difference (95% CI)	21.53 (5.91, 37.15)	
	p-value	0.0069	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.46 (1.03, 2.08)	
	p-value	0.0346	
	Odds Ratio (95% CI)	2.06 (1.06, 4.01)	
	p-value	0.0330	
	Risk Difference (95% CI)	17.86 (1.78, 33.93)	
	p-value	0.0294	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=69)	Placebo (N=75)
Week 48	Number of subjects with events, n (%)	41 (59.4)	29 (38.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.66 (1.18, 2.35)	
	p-value	0.0038	
	Odds Ratio (95% CI)	2.93 (1.42, 6.06)	
	p-value	0.0037	
	Risk Difference (95% CI)	24.43 (9.11, 39.75)	
	p-value	0.0018	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.54 (1.09, 2.17)	
	p-value	0.0148	
	Odds Ratio (95% CI)	2.32 (1.19, 4.53)	
	p-value	0.0135	
	Risk Difference (95% CI)	20.75 (4.76, 36.74)	
	p-value	0.0110	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=69)	Placebo (N=75)
Week 52	Number of subjects with events, n (%)	42 (60.9)	30 (40.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.67 (1.19, 2.36)	
	p-value	0.0034	
	Odds Ratio (95% CI)	2.95 (1.44, 6.07)	
	p-value	0.0032	
	Risk Difference (95% CI)	25.24 (9.79, 40.70)	
	p-value	0.0014	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.52 (1.09, 2.13)	
	p-value	0.0142	
	Odds Ratio (95% CI)	2.33 (1.20, 4.55)	
	p-value	0.0130	
	Risk Difference (95% CI)	20.87 (4.88, 36.85)	
	p-value	0.0105	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate at week 52 - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	 p-Value	Interaction p-Value
SLEDAI-2K score					0.0191
< 10 points	15/ 29 (51.7)	17/ 32 (53.1)	0.97 (0.60, 1.57)	0.9130	
>= 10 points	27/ 40 (67.5)	13/ 43 (30.2)	2.23 (1.35, 3.69)	0.0017	
OCS dose					0.8098
<10 mg/day	16/ 33 (48.5)	8/ 28 (28.6)	1.70 (0.86, 3.36)	0.1292	
>=10 mg/day	26/ 36 (72.2)	22/ 47 (46.8)	1.54 (1.07, 2.22)	0.0202	
Result of type I IFN gene signature test					0.5998
LOW	10/ 14 (71.4)	10/ 19 (52.6)	1.36 (0.79, 2.33)	0.2678	
HIGH	32/ 55 (58.2)	20/ 56 (35.7)	1.63 (1.07, 2.47)	0.0217	
Age (years)					0.2943
<= 45	28/ 45 (62.2)	23/ 50 (46.0)	1.35 (0.93, 1.97)	0.1162	
> 45	14/ 24 (58.3)	7/ 25 (28.0)	2.08 (1.02, 4.25)	0.0439	
Sex					0.1989
male	2/ 4 (50.0)	4/ 6 (66.7)	0.75 (0.24, 2.33)	0.6183	
female	40/ 65 (61.5)	26/ 69 (37.7)	1.63 (1.14, 2.34)	0.0074	
Race					0.7964
White	17/ 25 (68.0)	12/ 31 (38.7)	1.76 (1.05, 2.95)	0.0331	
Black	9/ 16 (56.3)	3/ 8 (37.5)	1.50 (0.56, 4.05)	0.4238	
Other	16/ 28 (57.1)	15/ 36 (41.7)	1.37 (0.83, 2.27)	0.2178	
Ethnicity					0.0692
Hispanic/Latino	16/ 28 (57.1)	15/ 28 (53.6)	1.07 (0.67, 1.71)	0.7882	
Non-hispanic/Latino	26/ 41 (63.4)	15/ 47 (31.9)	1.99 (1.23, 3.20)	0.0049	
Geographic region					0.9917
Latin America, Eastern Europe and Asia	29/ 45 (64.4)	23/ 55 (41.8)	1.54 (1.05, 2.25)	0.0256	
North America	13/ 24 (54.2)	7/ 20 (35.0)	1.55 (0.77, 3.12)	0.2224	
Baseline weight					0.2177
<60 kg	13/ 18 (72.2)	11/ 31 (35.5)	2.04 (1.17, 3.54)	0.0120	
>=60 kg	29/ 51 (56.9)	19/ 44 (43.2)	1.32 (0.87, 1.99)	0.1934	
Low CH50					0.0237
Yes	2/ 9 (22.2)	6/ 10 (60.0)	0.37 (0.10, 1.39)	0.1411	
No	40/ 60 (66.7)	24/ 65 (36.9)	1.81 (1.25, 2.60)	0.0015	
Low C3 or C4					0.4334
Yes	15/ 25 (60.0)	11/ 33 (33.3)	1.80 (1.01, 3.21)	0.0466	
No	27/ 44 (61.4)	19/ 42 (45.2)	1.36 (0.90, 2.04)	0.1421	
Baseline FARR anti-dsDNA					0.1741
<5 IU/mL	9/ 15 (60.0)	7/ 11 (63.6)	0.94 (0.51, 1.73)	0.8497	
>=5 IU/mL	23/ 40 (57.5)	18/ 50 (36.0)	1.60 (1.01, 2.52)	0.0440	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.3719
Yes	30/ 50 (60.0)	22/ 60 (36.7)	1.64 (1.09, 2.45)	0.0164	
No	12/ 19 (63.2)	8/ 15 (53.3)	1.18 (0.66, 2.13)	0.5710	
OCS use					0.5864
Yes	36/ 54 (66.7)	26/ 63 (41.3)	1.62 (1.14, 2.29)	0.0072	
No	6/ 15 (40.0)	4/ 12 (33.3)	1.20 (0.44, 3.30)	0.7240	
SLICC score					0.4878
0	26/ 40 (65.0)	22/ 48 (45.8)	1.42 (0.97, 2.08)	0.0734	
>=1	16/ 29 (55.2)	8/ 27 (29.6)	1.86 (0.96, 3.63)	0.0679	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (8) response rate at week 52
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=69)	Placebo (N=75)
Week 52	Number of subjects with events, n (%)	21 (30.4)	11 (14.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	2.32 (1.20, 4.48)	
	p-value	0.0122	
	Odds Ratio (95% CI)	3.18 (1.31, 7.72)	
	p-value	0.0108	
	Risk Difference (95% CI)	17.93 (4.86, 31.00)	
	p-value	0.0072	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	2.08 (1.08, 3.98)	
	p-value	0.0282	
	Odds Ratio (95% CI)	2.55 (1.12, 5.78)	
	p-value	0.0255	
	Risk Difference (95% CI)	15.77 (2.28, 29.26)	
	p-value	0.0220	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (8) response rate at week 52 - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.4326
< 10 points	5/ 29 (17.2)	4/ 32 (12.5)	1.38 (0.41, 4.65)	0.6039	
>= 10 points	16/ 40 (40.0)	7/ 43 (16.3)	2.46 (1.13, 5.34)	0.0233	
OCS dose					0.6064
<10 mg/day	8/ 33 (24.2)	4/ 28 (14.3)	1.70 (0.57, 5.04)	0.3414	
>=10 mg/day	13/ 36 (36.1)	7/ 47 (14.9)	2.42 (1.08, 5.45)	0.0321	
Result of type I IFN gene signature test					0.1734
LOW	4/ 14 (28.6)	5/ 19 (26.3)	1.09 (0.35, 3.32)	0.8855	
HIGH	17/ 55 (30.9)	6/ 56 (10.7)	2.88 (1.23, 6.77)	0.0149	
Age (years)					0.7496
<= 45	16/ 45 (35.6)	9/ 50 (18.0)	1.98 (0.97, 4.02)	0.0604	
> 45	5/ 24 (20.8)	2/ 25 (8.0)	2.60 (0.56, 12.16)	0.2235	
Sex					NE
male	0/ 4 (0.0)	0/ 6 (0.0)	NE		
female	21/ 65 (32.3)	11/ 69 (15.9)	2.03 (1.06, 3.87)	0.0321	
Race					0.8638
White	7/ 25 (28.0)	4/ 31 (12.9)	2.17 (0.72, 6.58)	0.1712	
Black	6/ 16 (37.5)	1/ 8 (12.5)	3.00 (0.43, 20.86)	0.2669	
Other	8/ 28 (28.6)	6/ 36 (16.7)	1.71 (0.67, 4.37)	0.2592	
Ethnicity					0.1373
Hispanic/Latino	7/ 28 (25.0)	6/ 28 (21.4)	1.17 (0.45, 3.04)	0.7521	
Non-hispanic/Latino	14/ 41 (34.1)	5/ 47 (10.6)	3.21 (1.26, 8.15)	0.0141	
Geographic region					0.6703
Latin America, Eastern Europe and Asia	15/ 45 (33.3)	8/ 55 (14.5)	2.29 (1.07, 4.91)	0.0330	
North America	6/ 24 (25.0)	3/ 20 (15.0)	1.67 (0.48, 5.83)	0.4241	
Baseline weight					0.7361
<60 kg	9/ 18 (50.0)	6/ 31 (19.4)	2.58 (1.10, 6.07)	0.0294	
>=60 kg	12/ 51 (23.5)	5/ 44 (11.4)	2.07 (0.79, 5.42)	0.1382	
Low CH50					0.0769
Yes	1/ 9 (11.1)	3/ 10 (30.0)	0.37 (0.05, 2.95)	0.3484	
No	20/ 60 (33.3)	8/ 65 (12.3)	2.71 (1.29, 5.68)	0.0084	
Low C3 or C4					0.9751
Yes	8/ 25 (32.0)	5/ 33 (15.2)	2.11 (0.79, 5.68)	0.1385	
No	13/ 44 (29.5)	6/ 42 (14.3)	2.07 (0.87, 4.94)	0.1016	
Baseline FARR anti-dsDNA					0.8545
<5 IU/mL	5/ 15 (33.3)	2/ 11 (18.2)	1.83 (0.43, 7.77)	0.4105	
>=5 IU/mL	12/ 40 (30.0)	7/ 50 (14.0)	2.14 (0.93, 4.94)	0.0734	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.6285
Yes	15/ 50 (30.0)	8/ 60 (13.3)	2.25 (1.04, 4.87)	0.0394	
No	6/ 19 (31.6)	3/ 15 (20.0)	1.58 (0.47, 5.29)	0.4591	
OCS use					0.7879
Yes	19/ 54 (35.2)	10/ 63 (15.9)	2.22 (1.13, 4.35)	0.0206	
No	2/ 15 (13.3)	1/ 12 (8.3)	1.60 (0.16, 15.60)	0.6858	
SLICC score					0.3592
0	13/ 40 (32.5)	9/ 48 (18.8)	1.73 (0.83, 3.63)	0.1447	
>=1	8/ 29 (27.6)	2/ 27 (7.4)	3.72 (0.87, 16.01)	0.0772	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=4 reduction in SLEDAI-2K at week 52
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=69)	Placebo (N=75)
Week 52	Number of subjects with events, n (%)	42 (60.9)	30 (40.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.67 (1.19, 2.36)	
	p-value	0.0034	
	Odds Ratio (95% CI)	2.95 (1.44, 6.07)	
	p-value	0.0032	
	Risk Difference (95% CI)	25.24 (9.79, 40.70)	
	p-value	0.0014	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.52 (1.09, 2.13)	
	p-value	0.0142	
	Odds Ratio (95% CI)	2.33 (1.20, 4.55)	
	p-value	0.0130	
	Risk Difference (95% CI)	20.87 (4.88, 36.85)	
	p-value	0.0105	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=4 reduction in SLEDAI-2K at week 52 - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	 p-Value	Interaction p-Value
SLEDAI-2K score					0.0191
< 10 points	15/ 29 (51.7)	17/ 32 (53.1)	0.97 (0.60, 1.57)	0.9130	
>= 10 points	27/ 40 (67.5)	13/ 43 (30.2)	2.23 (1.35, 3.69)	0.0017	
OCS dose					0.8098
<10 mg/day	16/ 33 (48.5)	8/ 28 (28.6)	1.70 (0.86, 3.36)	0.1292	
>=10 mg/day	26/ 36 (72.2)	22/ 47 (46.8)	1.54 (1.07, 2.22)	0.0202	
Result of type I IFN gene signature test					0.5998
LOW	10/ 14 (71.4)	10/ 19 (52.6)	1.36 (0.79, 2.33)	0.2678	
HIGH	32/ 55 (58.2)	20/ 56 (35.7)	1.63 (1.07, 2.47)	0.0217	
Age (years)					0.2943
<= 45	28/ 45 (62.2)	23/ 50 (46.0)	1.35 (0.93, 1.97)	0.1162	
> 45	14/ 24 (58.3)	7/ 25 (28.0)	2.08 (1.02, 4.25)	0.0439	
Sex					0.1989
male	2/ 4 (50.0)	4/ 6 (66.7)	0.75 (0.24, 2.33)	0.6183	
female	40/ 65 (61.5)	26/ 69 (37.7)	1.63 (1.14, 2.34)	0.0074	
Race					0.7964
White	17/ 25 (68.0)	12/ 31 (38.7)	1.76 (1.05, 2.95)	0.0331	
Black	9/ 16 (56.3)	3/ 8 (37.5)	1.50 (0.56, 4.05)	0.4238	
Other	16/ 28 (57.1)	15/ 36 (41.7)	1.37 (0.83, 2.27)	0.2178	
Ethnicity					0.0692
Hispanic/Latino	16/ 28 (57.1)	15/ 28 (53.6)	1.07 (0.67, 1.71)	0.7882	
Non-hispanic/Latino	26/ 41 (63.4)	15/ 47 (31.9)	1.99 (1.23, 3.20)	0.0049	
Geographic region					0.9917
Latin America, Eastern Europe and Asia	29/ 45 (64.4)	23/ 55 (41.8)	1.54 (1.05, 2.25)	0.0256	
North America	13/ 24 (54.2)	7/ 20 (35.0)	1.55 (0.77, 3.12)	0.2224	
Baseline weight					0.2177
<60 kg	13/ 18 (72.2)	11/ 31 (35.5)	2.04 (1.17, 3.54)	0.0120	
>=60 kg	29/ 51 (56.9)	19/ 44 (43.2)	1.32 (0.87, 1.99)	0.1934	
Low CH50					0.0237
Yes	2/ 9 (22.2)	6/ 10 (60.0)	0.37 (0.10, 1.39)	0.1411	
No	40/ 60 (66.7)	24/ 65 (36.9)	1.81 (1.25, 2.60)	0.0015	
Low C3 or C4					0.4334
Yes	15/ 25 (60.0)	11/ 33 (33.3)	1.80 (1.01, 3.21)	0.0466	
No	27/ 44 (61.4)	19/ 42 (45.2)	1.36 (0.90, 2.04)	0.1421	
Baseline FARR anti-dsDNA					0.1741
<5 IU/mL	9/ 15 (60.0)	7/ 11 (63.6)	0.94 (0.51, 1.73)	0.8497	
>=5 IU/mL	23/ 40 (57.5)	18/ 50 (36.0)	1.60 (1.01, 2.52)	0.0440	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.3719
Yes	30/ 50 (60.0)	22/ 60 (36.7)	1.64 (1.09, 2.45)	0.0164	
No	12/ 19 (63.2)	8/ 15 (53.3)	1.18 (0.66, 2.13)	0.5710	
OCS use					0.5864
Yes	36/ 54 (66.7)	26/ 63 (41.3)	1.62 (1.14, 2.29)	0.0072	
No	6/ 15 (40.0)	4/ 12 (33.3)	1.20 (0.44, 3.30)	0.7240	
SLICC score					0.4878
0	26/ 40 (65.0)	22/ 48 (45.8)	1.42 (0.97, 2.08)	0.0734	
>=1	16/ 29 (55.2)	8/ 27 (29.6)	1.86 (0.96, 3.63)	0.0679	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=8 reduction in SLEDAI-2K at week 52
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=69)	Placebo (N=75)
Week 52	Number of subjects with events, n (%)	21 (30.4)	11 (14.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	2.32 (1.20, 4.48)	
	p-value	0.0122	
	Odds Ratio (95% CI)	3.18 (1.31, 7.72)	
	p-value	0.0108	
	Risk Difference (95% CI)	17.93 (4.86, 31.00)	
	p-value	0.0072	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	2.08 (1.08, 3.98)	
	p-value	0.0282	
	Odds Ratio (95% CI)	2.55 (1.12, 5.78)	
	p-value	0.0255	
	Risk Difference (95% CI)	15.77 (2.28, 29.26)	
	p-value	0.0220	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=8 reduction in SLEDAI-2K at week 52 - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	 p-Value	Interaction p-Value
SLEDAI-2K score					0.4326
< 10 points	5/ 29 (17.2)	4/ 32 (12.5)	1.38 (0.41, 4.65)	0.6039	
>= 10 points	16/ 40 (40.0)	7/ 43 (16.3)	2.46 (1.13, 5.34)	0.0233	
OCS dose					0.6064
<10 mg/day	8/ 33 (24.2)	4/ 28 (14.3)	1.70 (0.57, 5.04)	0.3414	
>=10 mg/day	13/ 36 (36.1)	7/ 47 (14.9)	2.42 (1.08, 5.45)	0.0321	
Result of type I IFN gene signature test					0.1734
LOW	4/ 14 (28.6)	5/ 19 (26.3)	1.09 (0.35, 3.32)	0.8855	
HIGH	17/ 55 (30.9)	6/ 56 (10.7)	2.88 (1.23, 6.77)	0.0149	
Age (years)					0.7496
<= 45	16/ 45 (35.6)	9/ 50 (18.0)	1.98 (0.97, 4.02)	0.0604	
> 45	5/ 24 (20.8)	2/ 25 (8.0)	2.60 (0.56, 12.16)	0.2235	
Sex					NE
male	0/ 4 (0.0)	0/ 6 (0.0)	NE		
female	21/ 65 (32.3)	11/ 69 (15.9)	2.03 (1.06, 3.87)	0.0321	
Race					0.8638
White	7/ 25 (28.0)	4/ 31 (12.9)	2.17 (0.72, 6.58)	0.1712	
Black	6/ 16 (37.5)	1/ 8 (12.5)	3.00 (0.43, 20.86)	0.2669	
Other	8/ 28 (28.6)	6/ 36 (16.7)	1.71 (0.67, 4.37)	0.2592	
Ethnicity					0.1373
Hispanic/Latino	7/ 28 (25.0)	6/ 28 (21.4)	1.17 (0.45, 3.04)	0.7521	
Non-hispanic/Latino	14/ 41 (34.1)	5/ 47 (10.6)	3.21 (1.26, 8.15)	0.0141	
Geographic region					0.6703
Latin America, Eastern Europe and Asia	15/ 45 (33.3)	8/ 55 (14.5)	2.29 (1.07, 4.91)	0.0330	
North America	6/ 24 (25.0)	3/ 20 (15.0)	1.67 (0.48, 5.83)	0.4241	
Baseline weight					0.7361
<60 kg	9/ 18 (50.0)	6/ 31 (19.4)	2.58 (1.10, 6.07)	0.0294	
>=60 kg	12/ 51 (23.5)	5/ 44 (11.4)	2.07 (0.79, 5.42)	0.1382	
Low CH50					0.0769
Yes	1/ 9 (11.1)	3/ 10 (30.0)	0.37 (0.05, 2.95)	0.3484	
No	20/ 60 (33.3)	8/ 65 (12.3)	2.71 (1.29, 5.68)	0.0084	
Low C3 or C4					0.9751
Yes	8/ 25 (32.0)	5/ 33 (15.2)	2.11 (0.79, 5.68)	0.1385	
No	13/ 44 (29.5)	6/ 42 (14.3)	2.07 (0.87, 4.94)	0.1016	
Baseline FARR anti-dsDNA					0.8545
<5 IU/mL	5/ 15 (33.3)	2/ 11 (18.2)	1.83 (0.43, 7.77)	0.4105	
>=5 IU/mL	12/ 40 (30.0)	7/ 50 (14.0)	2.14 (0.93, 4.94)	0.0734	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.6285
Yes	15/ 50 (30.0)	8/ 60 (13.3)	2.25 (1.04, 4.87)	0.0394	
No	6/ 19 (31.6)	3/ 15 (20.0)	1.58 (0.47, 5.29)	0.4591	
OCS use					0.7879
Yes	19/ 54 (35.2)	10/ 63 (15.9)	2.22 (1.13, 4.35)	0.0206	
No	2/ 15 (13.3)	1/ 12 (8.3)	1.60 (0.16, 15.60)	0.6858	
SLICC score					0.3592
0	13/ 40 (32.5)	9/ 48 (18.8)	1.73 (0.83, 3.63)	0.1447	
>=1	8/ 29 (27.6)	2/ 27 (7.4)	3.72 (0.87, 16.01)	0.0772	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
No worsening in BILAG-2004 (>=1A or >=2B compared to BL) at week 52
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=69)	Placebo (N=75)
Week 52	Number of subjects with events, n (%)	51 (73.9)	43 (57.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.34 (1.06, 1.70)	
	p-value	0.0137	
	Odds Ratio (95% CI)	2.49 (1.19, 5.22)	
	p-value	0.0158	
	Risk Difference (95% CI)	19.42 (4.45, 34.39)	
	p-value	0.0110	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.29 (1.01, 1.64)	
	p-value	0.0383	
	Odds Ratio (95% CI)	2.11 (1.04, 4.27)	
	p-value	0.0383	
	Risk Difference (95% CI)	16.58 (1.33, 31.83)	
	p-value	0.0331	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
No worsening in BILAG-2004 (>=1A or >=2B compared to BL) at week 52 - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	 p-Value	Interaction p-Value
SLEDAI-2K score					0.1097
< 10 points	22/ 29 (75.9)	23/ 32 (71.9)	1.06 (0.78, 1.42)	0.7230	
>= 10 points	29/ 40 (72.5)	20/ 43 (46.5)	1.56 (1.07, 2.26)	0.0197	
OCS dose					0.5316
<10 mg/day	21/ 33 (63.6)	15/ 28 (53.6)	1.19 (0.77, 1.83)	0.4332	
>=10 mg/day	30/ 36 (83.3)	28/ 47 (59.6)	1.40 (1.06, 1.85)	0.0176	
Result of type I IFN gene signature test					0.1316
LOW	13/ 14 (92.9)	10/ 19 (52.6)	1.76 (1.12, 2.77)	0.0135	
HIGH	38/ 55 (69.1)	33/ 56 (58.9)	1.17 (0.89, 1.55)	0.2674	
Age (years)					0.9115
<= 45	34/ 45 (75.6)	29/ 50 (58.0)	1.30 (0.98, 1.74)	0.0725	
> 45	17/ 24 (70.8)	14/ 25 (56.0)	1.26 (0.82, 1.95)	0.2864	
Sex					0.1322
male	2/ 4 (50.0)	5/ 6 (83.3)	0.60 (0.21, 1.70)	0.3372	
female	49/ 65 (75.4)	38/ 69 (55.1)	1.37 (1.06, 1.77)	0.0156	
Race					0.4023
White	19/ 25 (76.0)	18/ 31 (58.1)	1.31 (0.90, 1.90)	0.1556	
Black	13/ 16 (81.3)	3/ 8 (37.5)	2.17 (0.86, 5.46)	0.1014	
Other	19/ 28 (67.9)	22/ 36 (61.1)	1.11 (0.77, 1.60)	0.5734	
Ethnicity					0.3175
Hispanic/Latino	20/ 28 (71.4)	18/ 28 (64.3)	1.11 (0.77, 1.60)	0.5685	
Non-hispanic/Latino	31/ 41 (75.6)	25/ 47 (53.2)	1.42 (1.03, 1.96)	0.0310	
Geographic region					0.2275
Latin America, Eastern Europe and Asia	34/ 45 (75.6)	35/ 55 (63.6)	1.19 (0.92, 1.54)	0.1954	
North America	17/ 24 (70.8)	8/ 20 (40.0)	1.77 (0.98, 3.21)	0.0598	
Baseline weight					0.5553
<60 kg	15/ 18 (83.3)	18/ 31 (58.1)	1.44 (1.00, 2.06)	0.0514	
>=60 kg	36/ 51 (70.6)	25/ 44 (56.8)	1.24 (0.91, 1.70)	0.1737	
Low CH50					0.0217
Yes	2/ 9 (22.2)	7/ 10 (70.0)	0.32 (0.09, 1.15)	0.0808	
No	49/ 60 (81.7)	36/ 65 (55.4)	1.47 (1.15, 1.89)	0.0022	
Low C3 or C4					0.6441
Yes	15/ 25 (60.0)	17/ 33 (51.5)	1.16 (0.73, 1.85)	0.5163	
No	36/ 44 (81.8)	26/ 42 (61.9)	1.32 (1.00, 1.74)	0.0469	
Baseline FARR anti-dsDNA					0.7972
<5 IU/mL	11/ 15 (73.3)	7/ 11 (63.6)	1.15 (0.67, 1.98)	0.6074	
>=5 IU/mL	29/ 40 (72.5)	29/ 50 (58.0)	1.25 (0.92, 1.69)	0.1495	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.7023
Yes	36/ 50 (72.0)	33/ 60 (55.0)	1.31 (0.98, 1.74)	0.0657	
No	15/ 19 (78.9)	10/ 15 (66.7)	1.18 (0.77, 1.81)	0.4372	
OCS use					0.0888
Yes	43/ 54 (79.6)	35/ 63 (55.6)	1.43 (1.11, 1.86)	0.0064	
No	8/ 15 (53.3)	8/ 12 (66.7)	0.80 (0.43, 1.49)	0.4804	
SLICC score					0.8253
0	32/ 40 (80.0)	30/ 48 (62.5)	1.28 (0.98, 1.67)	0.0714	
>=1	19/ 29 (65.5)	13/ 27 (48.1)	1.36 (0.85, 2.18)	0.2010	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Maintained OCS Reduction at week 52 (for subjects with baseline OCS >=10 mg/day)
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=36)	Placebo (N=47)
Week 52	Number of subjects with events, n (%)	22 (61.1)	13 (27.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	2.23 (1.31, 3.81)	
	p-value	0.0031	
	Odds Ratio (95% CI)	4.24 (1.66, 10.81)	
	p-value	0.0025	
	Risk Difference (95% CI)	33.78 (13.49, 54.08)	
	p-value	0.0011	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	2.21 (1.30, 3.76)	
	p-value	0.0034	
	Odds Ratio (95% CI)	4.11 (1.63, 10.38)	
	p-value	0.0028	
	Risk Difference (95% CI)	33.45 (13.03, 53.88)	
	p-value	0.0013	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Maintained OCS Reduction at week 52 (for subjects with baseline OCS >=10 mg/day) - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=36) n/ N (%)	Placebo (N=47) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.4077
< 10 points	7/ 11 (63.6)	6/ 16 (37.5)	1.70 (0.78, 3.68)	0.1807	
>= 10 points	15/ 25 (60.0)	7/ 31 (22.6)	2.66 (1.29, 5.49)	0.0083	
OCS dose					NE
>=10 mg/day	22/ 36 (61.1)	13/ 47 (27.7)	2.21 (1.30, 3.76)	0.0034	
Result of type I IFN gene signature test					0.8837
LOW	3/ 6 (50.0)	2/ 8 (25.0)	2.00 (0.47, 8.46)	0.3463	
HIGH	19/ 30 (63.3)	11/ 39 (28.2)	2.25 (1.27, 3.97)	0.0054	
Age (years)					0.4475
<= 45	15/ 27 (55.6)	10/ 35 (28.6)	1.94 (1.04, 3.63)	0.0365	
> 45	7/ 9 (77.8)	3/ 12 (25.0)	3.11 (1.10, 8.81)	0.0325	
Sex					0.4867
male	0/ 1 (0.0)	1/ 4 (25.0)	0.83 (0.05, 13.02)	0.8966	
female	22/ 35 (62.9)	12/ 43 (27.9)	2.25 (1.31, 3.88)	0.0034	
Race					0.1478
White	8/ 14 (57.1)	3/ 18 (16.7)	3.43 (1.11, 10.59)	0.0323	
Black	6/ 6 (100.0)	0/ 4 (0.0)	9.29 (0.66, 129.81)	0.0977	
Other	8/ 16 (50.0)	10/ 25 (40.0)	1.25 (0.63, 2.48)	0.5238	
Ethnicity					0.3261
Hispanic/Latino	9/ 17 (52.9)	7/ 22 (31.8)	1.66 (0.78, 3.55)	0.1882	
Non-hispanic/Latino	13/ 19 (68.4)	6/ 25 (24.0)	2.85 (1.33, 6.11)	0.0070	
Geographic region					0.1252
Latin America, Eastern Europe and Asia	17/ 31 (54.8)	12/ 39 (30.8)	1.78 (1.01, 3.15)	0.0465	
North America	5/ 5 (100.0)	1/ 8 (12.5)	8.00 (1.28, 50.04)	0.0262	
Baseline weight					0.6991
<60 kg	6/ 11 (54.5)	6/ 21 (28.6)	1.91 (0.80, 4.53)	0.1429	
>=60 kg	16/ 25 (64.0)	7/ 26 (26.9)	2.38 (1.18, 4.78)	0.0151	
Low CH50					0.2437
Yes	1/ 4 (25.0)	3/ 9 (33.3)	0.75 (0.11, 5.18)	0.7705	
No	21/ 32 (65.6)	10/ 38 (26.3)	2.49 (1.38, 4.49)	0.0023	
Low C3 or C4					0.6570
Yes	10/ 16 (62.5)	7/ 22 (31.8)	1.96 (0.96, 4.03)	0.0660	
No	12/ 20 (60.0)	6/ 25 (24.0)	2.50 (1.14, 5.48)	0.0220	
Baseline FARR anti-dsDNA					0.9607
<5 IU/mL	3/ 4 (75.0)	2/ 6 (33.3)	2.25 (0.63, 7.97)	0.2090	
>=5 IU/mL	14/ 25 (56.0)	8/ 31 (25.8)	2.17 (1.09, 4.33)	0.0279	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.6167
Yes	17/ 30 (56.7)	11/ 40 (27.5)	2.06 (1.14, 3.73)	0.0168	
No	5/ 6 (83.3)	2/ 7 (28.6)	2.92 (0.86, 9.93)	0.0867	
OCS use					NE
Yes	22/ 36 (61.1)	13/ 47 (27.7)	2.21 (1.30, 3.76)	0.0034	
SLICC score					0.5604
0	15/ 24 (62.5)	10/ 32 (31.3)	2.00 (1.10, 3.64)	0.0236	
>=1	7/ 12 (58.3)	3/ 15 (20.0)	2.92 (0.95, 8.93)	0.0609	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=50% Reduction in CLASI activity score at week 52 (for subjects with baseline CLASI activity score >=10)
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=22)	Placebo (N=15)
Week 52	Number of subjects with events, n (%)	13 (59.1)	5 (33.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.45 (0.72, 2.92)	
	p-value	0.2940	
	Odds Ratio (95% CI)	2.41 (0.52, 11.17)	
	p-value	0.2623	
	Risk Difference (95% CI)	17.40 (-12.88, 47.68)	
	p-value	0.2600	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.77 (0.80, 3.93)	
	p-value	0.1585	
	Odds Ratio (95% CI)	2.89 (0.73, 11.36)	
	p-value	0.1289	
	Risk Difference (95% CI)	25.76 (-5.73, 57.24)	
	p-value	0.1088	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=50% Reduction in CLASI activity score at week 52 (for subjects with baseline CLASI activity score >=10) - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=22) n/ N (%)	Placebo (N=15) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.8514
< 10 points	2/ 5 (40.0)	1/ 5 (20.0)	2.00 (0.26, 15.62)	0.5087	
>= 10 points	11/ 17 (64.7)	4/ 10 (40.0)	1.62 (0.70, 3.73)	0.2597	
OCS dose					0.6023
<10 mg/day	5/ 9 (55.6)	2/ 8 (25.0)	2.22 (0.58, 8.44)	0.2410	
>=10 mg/day	8/ 13 (61.5)	3/ 7 (42.9)	1.44 (0.55, 3.74)	0.4589	
Result of type I IFN gene signature test					NE
LOW	0	0/ 1 (0.0)	NE		
HIGH	13/ 22 (59.1)	5/ 14 (35.7)	1.65 (0.76, 3.62)	0.2082	
Age (years)					0.6447
<= 45	11/ 16 (68.8)	2/ 5 (40.0)	1.72 (0.56, 5.28)	0.3446	
> 45	2/ 6 (33.3)	3/ 10 (30.0)	1.11 (0.25, 4.86)	0.8887	
Sex					0.0311
male	1/ 3 (33.3)	2/ 2 (100.0)	0.33 (0.07, 1.65)	0.1785	
female	12/ 19 (63.2)	3/ 13 (23.1)	2.74 (0.96, 7.82)	0.0602	
Race					0.6217
White	3/ 7 (42.9)	3/ 9 (33.3)	1.29 (0.37, 4.53)	0.6956	
Black	4/ 6 (66.7)	0	NE		
Other	6/ 9 (66.7)	2/ 6 (33.3)	2.00 (0.59, 6.79)	0.2663	
Ethnicity					0.7517
Hispanic/Latino	4/ 7 (57.1)	1/ 4 (25.0)	2.29 (0.37, 14.03)	0.3719	
Non-hispanic/Latino	9/ 15 (60.0)	4/ 11 (36.4)	1.65 (0.68, 3.99)	0.2670	
Geographic region					0.7115
Latin America, Eastern Europe and Asia	9/ 16 (56.3)	5/ 14 (35.7)	1.58 (0.69, 3.59)	0.2805	
North America	4/ 6 (66.7)	0/ 1 (0.0)	2.57 (0.22, 30.19)	0.4523	
Baseline weight					0.1131
<60 kg	6/ 8 (75.0)	1/ 7 (14.3)	5.25 (0.82, 33.66)	0.0803	
>=60 kg	7/ 14 (50.0)	4/ 8 (50.0)	1.00 (0.42, 2.38)	1.0000	
Low CH50					0.0760
Yes	0/ 3 (0.0)	2/ 3 (66.7)	0.20 (0.01, 2.98)	0.2430	
No	13/ 19 (68.4)	3/ 12 (25.0)	2.74 (0.98, 7.64)	0.0546	
Low C3 or C4					0.6439
Yes	6/ 11 (54.5)	2/ 8 (25.0)	2.18 (0.59, 8.13)	0.2452	
No	7/ 11 (63.6)	3/ 7 (42.9)	1.48 (0.57, 3.90)	0.4220	
Baseline FARR anti-dsDNA					0.5814
<5 IU/mL	3/ 4 (75.0)	0/ 1 (0.0)	2.80 (0.24, 33.04)	0.4136	
>=5 IU/mL	9/ 16 (56.3)	5/ 12 (41.7)	1.35 (0.61, 2.99)	0.4604	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.5163
Yes	11/ 19 (57.9)	5/ 13 (38.5)	1.51 (0.69, 3.31)	0.3086	
No	2/ 3 (66.7)	0/ 2 (0.0)	3.75 (0.27, 52.64)	0.3268	
OCS use					0.2813
Yes	13/ 21 (61.9)	3/ 11 (27.3)	2.27 (0.82, 6.31)	0.1158	
No	0/ 1 (0.0)	2/ 4 (50.0)	0.50 (0.04, 6.44)	0.5950	
SLICC score					0.3141
0	8/ 9 (88.9)	2/ 6 (33.3)	2.67 (0.84, 8.46)	0.0960	
>=1	5/ 13 (38.5)	3/ 9 (33.3)	1.15 (0.36, 3.65)	0.8076	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=69)	Placebo (N=75)
Week 4	Number of subjects with events, n (%)	14 (20.3)	15 (20.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.06 (0.53, 2.14)	
	p-value	0.8629	
	Odds Ratio (95% CI)	1.08 (0.48, 2.42)	
	p-value	0.8609	
	Risk Difference (95% CI)	1.21 (-12.29, 14.71)	
	p-value	0.8609	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.01 (0.53, 1.94)	
	p-value	0.9654	
	Odds Ratio (95% CI)	1.02 (0.45, 2.30)	
	p-value	0.9654	
	Risk Difference (95% CI)	0.29 (-12.82, 13.40)	
	p-value	0.9654	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=69)	Placebo (N=75)
Week 8	Number of subjects with events, n (%)	25 (36.2)	25 (33.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.20 (0.76, 1.90)	
	p-value	0.4282	
	Odds Ratio (95% CI)	1.34 (0.65, 2.73)	
	p-value	0.4260	
	Risk Difference (95% CI)	6.33 (-9.09, 21.75)	
	p-value	0.4212	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.09 (0.69, 1.70)	
	p-value	0.7151	
	Odds Ratio (95% CI)	1.14 (0.57, 2.26)	
	p-value	0.7152	
	Risk Difference (95% CI)	2.90 (-12.67, 18.47)	
	p-value	0.7152	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=69)	Placebo (N=75)
Week 12	Number of subjects with events, n (%)	23 (33.3)	22 (29.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.28 (0.78, 2.11)	
	p-value	0.3291	
	Odds Ratio (95% CI)	1.46 (0.69, 3.08)	
	p-value	0.3244	
	Risk Difference (95% CI)	7.57 (-7.23, 22.37)	
	p-value	0.3162	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.14 (0.70, 1.84)	
	p-value	0.6051	
	Odds Ratio (95% CI)	1.20 (0.59, 2.44)	
	p-value	0.6051	
	Risk Difference (95% CI)	4.00 (-11.16, 19.16)	
	p-value	0.6051	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=69)	Placebo (N=75)
Week 16	Number of subjects with events, n (%)	27 (39.1)	23 (30.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.39 (0.88, 2.19)	
	p-value	0.1595	
	Odds Ratio (95% CI)	1.70 (0.82, 3.52)	
	p-value	0.1538	
	Risk Difference (95% CI)	11.16 (-3.94, 26.27)	
	p-value	0.1474	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.28 (0.81, 2.00)	
	p-value	0.2883	
	Odds Ratio (95% CI)	1.45 (0.73, 2.89)	
	p-value	0.2874	
	Risk Difference (95% CI)	8.46 (-7.08, 24.00)	
	p-value	0.2858	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=69)	Placebo (N=75)
Week 20	Number of subjects with events, n (%)	27 (39.1)	23 (30.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.37 (0.86, 2.16)	
	p-value	0.1823	
	Odds Ratio (95% CI)	1.63 (0.80, 3.31)	
	p-value	0.1793	
	Risk Difference (95% CI)	10.72 (-4.73, 26.18)	
	p-value	0.1738	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.28 (0.81, 2.00)	
	p-value	0.2883	
	Odds Ratio (95% CI)	1.45 (0.73, 2.89)	
	p-value	0.2874	
	Risk Difference (95% CI)	8.46 (-7.08, 24.00)	
	p-value	0.2858	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=69)	Placebo (N=75)
Week 24	Number of subjects with events, n (%)	28 (40.6)	18 (24.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.81 (1.08, 3.02)	
	p-value	0.0242	
	Odds Ratio (95% CI)	2.38 (1.14, 5.00)	
	p-value	0.0216	
	Risk Difference (95% CI)	18.29 (3.25, 33.34)	
	p-value	0.0172	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.69 (1.03, 2.77)	
	p-value	0.0371	
	Odds Ratio (95% CI)	2.16 (1.06, 4.42)	
	p-value	0.0346	
	Risk Difference (95% CI)	16.58 (1.49, 31.67)	
	p-value	0.0313	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=69)	Placebo (N=75)
Week 28	Number of subjects with events, n (%)	27 (39.1)	22 (29.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.45 (0.91, 2.32)	
	p-value	0.1207	
	Odds Ratio (95% CI)	1.79 (0.87, 3.70)	
	p-value	0.1161	
	Risk Difference (95% CI)	12.39 (-2.78, 27.56)	
	p-value	0.1095	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.33 (0.84, 2.11)	
	p-value	0.2177	
	Odds Ratio (95% CI)	1.55 (0.77, 3.10)	
	p-value	0.2163	
	Risk Difference (95% CI)	9.80 (-5.66, 25.25)	
	p-value	0.2140	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=69)	Placebo (N=75)
Week 32	Number of subjects with events, n (%)	32 (46.4)	23 (30.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.59 (1.01, 2.48)	
	p-value	0.0430	
	Odds Ratio (95% CI)	2.07 (1.04, 4.14)	
	p-value	0.0396	
	Risk Difference (95% CI)	17.19 (1.27, 33.11)	
	p-value	0.0343	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.51 (0.99, 2.31)	
	p-value	0.0561	
	Odds Ratio (95% CI)	1.96 (0.99, 3.87)	
	p-value	0.0539	
	Risk Difference (95% CI)	15.71 (-0.02, 31.44)	
	p-value	0.0503	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=69)	Placebo (N=75)
Week 36	Number of subjects with events, n (%)	33 (47.8)	23 (30.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.66 (1.09, 2.53)	
	p-value	0.0178	
	Odds Ratio (95% CI)	2.44 (1.18, 5.07)	
	p-value	0.0164	
	Risk Difference (95% CI)	19.39 (4.18, 34.60)	
	p-value	0.0125	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.56 (1.02, 2.37)	
	p-value	0.0382	
	Odds Ratio (95% CI)	2.07 (1.05, 4.10)	
	p-value	0.0360	
	Risk Difference (95% CI)	17.16 (1.42, 32.90)	
	p-value	0.0326	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=69)	Placebo (N=75)
Week 40	Number of subjects with events, n (%)	32 (46.4)	21 (28.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.78 (1.11, 2.84)	
	p-value	0.0162	
	Odds Ratio (95% CI)	2.43 (1.20, 4.94)	
	p-value	0.0140	
	Risk Difference (95% CI)	20.48 (4.83, 36.12)	
	p-value	0.0103	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.66 (1.06, 2.58)	
	p-value	0.0255	
	Odds Ratio (95% CI)	2.22 (1.11, 4.44)	
	p-value	0.0235	
	Risk Difference (95% CI)	18.38 (2.83, 33.92)	
	p-value	0.0205	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=69)	Placebo (N=75)
Week 44	Number of subjects with events, n (%)	27 (39.1)	21 (28.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.50 (0.91, 2.45)	
	p-value	0.1091	
	Odds Ratio (95% CI)	1.82 (0.89, 3.73)	
	p-value	0.1029	
	Risk Difference (95% CI)	13.03 (-2.33, 28.39)	
	p-value	0.0963	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.40 (0.88, 2.23)	
	p-value	0.1603	
	Odds Ratio (95% CI)	1.65 (0.82, 3.32)	
	p-value	0.1584	
	Risk Difference (95% CI)	11.13 (-4.23, 26.49)	
	p-value	0.1555	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=69)	Placebo (N=75)
Week 48	Number of subjects with events, n (%)	32 (46.4)	24 (32.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.53 (1.01, 2.31)	
	p-value	0.0438	
	Odds Ratio (95% CI)	2.14 (1.03, 4.44)	
	p-value	0.0411	
	Risk Difference (95% CI)	16.24 (1.09, 31.39)	
	p-value	0.0357	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.45 (0.96, 2.20)	
	p-value	0.0806	
	Odds Ratio (95% CI)	1.84 (0.93, 3.62)	
	p-value	0.0784	
	Risk Difference (95% CI)	14.38 (-1.43, 30.19)	
	p-value	0.0747	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=69)	Placebo (N=75)
Week 52	Number of subjects with events, n (%)	32 (46.4)	22 (29.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.71 (1.10, 2.66)	
	p-value	0.0162	
	Odds Ratio (95% CI)	2.48 (1.19, 5.14)	
	p-value	0.0148	
	Risk Difference (95% CI)	19.80 (4.57, 35.02)	
	p-value	0.0108	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.58 (1.03, 2.44)	
	p-value	0.0383	
	Odds Ratio (95% CI)	2.08 (1.05, 4.14)	
	p-value	0.0360	
	Risk Difference (95% CI)	17.04 (1.40, 32.68)	
	p-value	0.0327	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate at week 52 - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	 p-Value	Interaction p-Value
SLEDAI-2K score					0.2961
< 10 points	15/ 29 (51.7)	13/ 32 (40.6)	1.27 (0.74, 2.20)	0.3867	
>= 10 points	17/ 40 (42.5)	9/ 43 (20.9)	2.03 (1.02, 4.02)	0.0423	
OCS dose					0.7299
<10 mg/day	13/ 33 (39.4)	6/ 28 (21.4)	1.84 (0.80, 4.20)	0.1485	
>=10 mg/day	19/ 36 (52.8)	16/ 47 (34.0)	1.55 (0.94, 2.57)	0.0880	
Result of type I IFN gene signature test					0.6535
LOW	7/ 14 (50.0)	5/ 19 (26.3)	1.90 (0.76, 4.75)	0.1700	
HIGH	25/ 55 (45.5)	17/ 56 (30.4)	1.50 (0.92, 2.45)	0.1072	
Age (years)					0.2172
<= 45	24/ 45 (53.3)	14/ 50 (28.0)	1.90 (1.13, 3.21)	0.0155	
> 45	8/ 24 (33.3)	8/ 25 (32.0)	1.04 (0.47, 2.33)	0.9207	
Sex					0.4610
male	1/ 4 (25.0)	2/ 6 (33.3)	0.75 (0.10, 5.77)	0.7822	
female	31/ 65 (47.7)	20/ 69 (29.0)	1.65 (1.05, 2.58)	0.0296	
Race					0.9241
White	10/ 25 (40.0)	8/ 31 (25.8)	1.55 (0.72, 3.33)	0.2621	
Black	8/ 16 (50.0)	2/ 8 (25.0)	2.00 (0.55, 7.31)	0.2947	
Other	14/ 28 (50.0)	12/ 36 (33.3)	1.50 (0.83, 2.71)	0.1796	
Ethnicity					0.2978
Hispanic/Latino	12/ 28 (42.9)	10/ 28 (35.7)	1.20 (0.62, 2.31)	0.5857	
Non-hispanic/Latino	20/ 41 (48.8)	12/ 47 (25.5)	1.91 (1.07, 3.41)	0.0288	
Geographic region					0.2859
Latin America, Eastern Europe and Asia	22/ 45 (48.9)	19/ 55 (34.5)	1.42 (0.88, 2.27)	0.1482	
North America	10/ 24 (41.7)	3/ 20 (15.0)	2.78 (0.88, 8.73)	0.0805	
Baseline weight					0.5305
<60 kg	10/ 18 (55.6)	12/ 31 (38.7)	1.44 (0.78, 2.63)	0.2424	
>=60 kg	22/ 51 (43.1)	10/ 44 (22.7)	1.90 (1.01, 3.56)	0.0460	
Low CH50					0.0489
Yes	2/ 9 (22.2)	5/ 10 (50.0)	0.44 (0.11, 1.75)	0.2461	
No	30/ 60 (50.0)	17/ 65 (26.2)	1.91 (1.18, 3.09)	0.0082	
Low C3 or C4					0.2649
Yes	11/ 25 (44.0)	12/ 33 (36.4)	1.21 (0.64, 2.28)	0.5543	
No	21/ 44 (47.7)	10/ 42 (23.8)	2.00 (1.07, 3.74)	0.0287	
Baseline FARR anti-dsDNA					0.8342
<5 IU/mL	7/ 15 (46.7)	3/ 11 (27.3)	1.71 (0.57, 5.17)	0.3413	
>=5 IU/mL	18/ 40 (45.0)	15/ 50 (30.0)	1.50 (0.87, 2.59)	0.1445	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.9812
Yes	24/ 50 (48.0)	18/ 60 (30.0)	1.60 (0.99, 2.59)	0.0561	
No	8/ 19 (42.1)	4/ 15 (26.7)	1.58 (0.59, 4.25)	0.3664	
OCS use					0.4941
Yes	28/ 54 (51.9)	19/ 63 (30.2)	1.72 (1.09, 2.71)	0.0196	
No	4/ 15 (26.7)	3/ 12 (25.0)	1.07 (0.29, 3.88)	0.9219	
SLICC score					0.7843
0	19/ 40 (47.5)	15/ 48 (31.3)	1.52 (0.89, 2.59)	0.1224	
>=1	13/ 29 (44.8)	7/ 27 (25.9)	1.73 (0.81, 3.68)	0.1550	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Change from baseline in PGA VAS < 0.3 at week 52
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=69)	Placebo (N=75)
Week 52	Number of subjects with events, n (%)	51 (73.9)	45 (60.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.28 (1.02, 1.60)	
	p-value	0.0341	
	Odds Ratio (95% CI)	2.17 (1.04, 4.53)	
	p-value	0.0392	
	Risk Difference (95% CI)	16.44 (1.42, 31.46)	
	p-value	0.0320	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.23 (0.98, 1.55)	
	p-value	0.0780	
	Odds Ratio (95% CI)	1.89 (0.93, 3.84)	
	p-value	0.0786	
	Risk Difference (95% CI)	13.91 (-1.26, 29.09)	
	p-value	0.0723	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Change from baseline in PGA VAS < 0.3 at week 52 - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.1026
< 10 points	22/ 29 (75.9)	24/ 32 (75.0)	1.01 (0.76, 1.35)	0.9377	
>= 10 points	29/ 40 (72.5)	21/ 43 (48.8)	1.48 (1.04, 2.13)	0.0317	
OCS dose					0.4417
<10 mg/day	21/ 33 (63.6)	16/ 28 (57.1)	1.11 (0.74, 1.68)	0.6083	
>=10 mg/day	30/ 36 (83.3)	29/ 47 (61.7)	1.35 (1.03, 1.77)	0.0282	
Result of type I IFN gene signature test					0.0809
LOW	13/ 14 (92.9)	10/ 19 (52.6)	1.76 (1.12, 2.77)	0.0135	
HIGH	38/ 55 (69.1)	35/ 56 (62.5)	1.11 (0.84, 1.45)	0.4652	
Age (years)					0.7992
<= 45	34/ 45 (75.6)	30/ 50 (60.0)	1.26 (0.95, 1.67)	0.1076	
> 45	17/ 24 (70.8)	15/ 25 (60.0)	1.18 (0.78, 1.78)	0.4278	
Sex					0.1571
male	2/ 4 (50.0)	5/ 6 (83.3)	0.60 (0.21, 1.70)	0.3372	
female	49/ 65 (75.4)	40/ 69 (58.0)	1.30 (1.02, 1.66)	0.0351	
Race					0.6528
White	19/ 25 (76.0)	19/ 31 (61.3)	1.24 (0.87, 1.77)	0.2364	
Black	13/ 16 (81.3)	4/ 8 (50.0)	1.63 (0.78, 3.38)	0.1935	
Other	19/ 28 (67.9)	22/ 36 (61.1)	1.11 (0.77, 1.60)	0.5734	
Ethnicity					0.4810
Hispanic/Latino	20/ 28 (71.4)	18/ 28 (64.3)	1.11 (0.77, 1.60)	0.5685	
Non-hispanic/Latino	31/ 41 (75.6)	27/ 47 (57.4)	1.32 (0.97, 1.78)	0.0739	
Geographic region					0.3144
Latin America, Eastern Europe and Asia	34/ 45 (75.6)	36/ 55 (65.5)	1.15 (0.90, 1.49)	0.2680	
North America	17/ 24 (70.8)	9/ 20 (45.0)	1.57 (0.91, 2.72)	0.1049	
Baseline weight					0.3536
<60 kg	15/ 18 (83.3)	18/ 31 (58.1)	1.44 (1.00, 2.06)	0.0514	
>=60 kg	36/ 51 (70.6)	27/ 44 (61.4)	1.15 (0.86, 1.54)	0.3503	
Low CH50					0.0266
Yes	2/ 9 (22.2)	7/ 10 (70.0)	0.32 (0.09, 1.15)	0.0808	
No	49/ 60 (81.7)	38/ 65 (58.5)	1.40 (1.10, 1.77)	0.0058	
Low C3 or C4					0.8455
Yes	15/ 25 (60.0)	17/ 33 (51.5)	1.16 (0.73, 1.85)	0.5163	
No	36/ 44 (81.8)	28/ 42 (66.7)	1.23 (0.95, 1.58)	0.1158	
Baseline FARR anti-dsDNA					0.9627
<5 IU/mL	11/ 15 (73.3)	7/ 11 (63.6)	1.15 (0.67, 1.98)	0.6074	
>=5 IU/mL	29/ 40 (72.5)	31/ 50 (62.0)	1.17 (0.88, 1.56)	0.2887	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.8729
Yes	36/ 50 (72.0)	35/ 60 (58.3)	1.23 (0.94, 1.62)	0.1335	
No	15/ 19 (78.9)	10/ 15 (66.7)	1.18 (0.77, 1.81)	0.4372	
OCS use					0.1212
Yes	43/ 54 (79.6)	37/ 63 (58.7)	1.36 (1.06, 1.74)	0.0157	
No	8/ 15 (53.3)	8/ 12 (66.7)	0.80 (0.43, 1.49)	0.4804	
SLICC score					0.7508
0	32/ 40 (80.0)	30/ 48 (62.5)	1.28 (0.98, 1.67)	0.0714	
>=1	19/ 29 (65.5)	15/ 27 (55.6)	1.18 (0.77, 1.81)	0.4505	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Change from baseline in PGA VAS < 0.45 at week 52
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=69)	Placebo (N=75)
Week 52	Number of subjects with events, n (%)	51 (73.9)	45 (60.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.28 (1.02, 1.60)	
	p-value	0.0341	
	Odds Ratio (95% CI)	2.17 (1.04, 4.53)	
	p-value	0.0392	
	Risk Difference (95% CI)	16.44 (1.42, 31.46)	
	p-value	0.0320	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.23 (0.98, 1.55)	
	p-value	0.0780	
	Odds Ratio (95% CI)	1.89 (0.93, 3.84)	
	p-value	0.0786	
	Risk Difference (95% CI)	13.91 (-1.26, 29.09)	
	p-value	0.0723	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Change from baseline in PGA VAS < 0.45 at week 52 - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	 p-Value	Interaction p-Value
SLEDAI-2K score					0.1026
< 10 points	22/ 29 (75.9)	24/ 32 (75.0)	1.01 (0.76, 1.35)	0.9377	
>= 10 points	29/ 40 (72.5)	21/ 43 (48.8)	1.48 (1.04, 2.13)	0.0317	
OCS dose					0.4417
<10 mg/day	21/ 33 (63.6)	16/ 28 (57.1)	1.11 (0.74, 1.68)	0.6083	
>=10 mg/day	30/ 36 (83.3)	29/ 47 (61.7)	1.35 (1.03, 1.77)	0.0282	
Result of type I IFN gene signature test					0.0809
LOW	13/ 14 (92.9)	10/ 19 (52.6)	1.76 (1.12, 2.77)	0.0135	
HIGH	38/ 55 (69.1)	35/ 56 (62.5)	1.11 (0.84, 1.45)	0.4652	
Age (years)					0.7992
<= 45	34/ 45 (75.6)	30/ 50 (60.0)	1.26 (0.95, 1.67)	0.1076	
> 45	17/ 24 (70.8)	15/ 25 (60.0)	1.18 (0.78, 1.78)	0.4278	
Sex					0.1571
male	2/ 4 (50.0)	5/ 6 (83.3)	0.60 (0.21, 1.70)	0.3372	
female	49/ 65 (75.4)	40/ 69 (58.0)	1.30 (1.02, 1.66)	0.0351	
Race					0.6528
White	19/ 25 (76.0)	19/ 31 (61.3)	1.24 (0.87, 1.77)	0.2364	
Black	13/ 16 (81.3)	4/ 8 (50.0)	1.63 (0.78, 3.38)	0.1935	
Other	19/ 28 (67.9)	22/ 36 (61.1)	1.11 (0.77, 1.60)	0.5734	
Ethnicity					0.4810
Hispanic/Latino	20/ 28 (71.4)	18/ 28 (64.3)	1.11 (0.77, 1.60)	0.5685	
Non-hispanic/Latino	31/ 41 (75.6)	27/ 47 (57.4)	1.32 (0.97, 1.78)	0.0739	
Geographic region					0.3144
Latin America, Eastern Europe and Asia	34/ 45 (75.6)	36/ 55 (65.5)	1.15 (0.90, 1.49)	0.2680	
North America	17/ 24 (70.8)	9/ 20 (45.0)	1.57 (0.91, 2.72)	0.1049	
Baseline weight					0.3536
<60 kg	15/ 18 (83.3)	18/ 31 (58.1)	1.44 (1.00, 2.06)	0.0514	
>=60 kg	36/ 51 (70.6)	27/ 44 (61.4)	1.15 (0.86, 1.54)	0.3503	
Low CH50					0.0266
Yes	2/ 9 (22.2)	7/ 10 (70.0)	0.32 (0.09, 1.15)	0.0808	
No	49/ 60 (81.7)	38/ 65 (58.5)	1.40 (1.10, 1.77)	0.0058	
Low C3 or C4					0.8455
Yes	15/ 25 (60.0)	17/ 33 (51.5)	1.16 (0.73, 1.85)	0.5163	
No	36/ 44 (81.8)	28/ 42 (66.7)	1.23 (0.95, 1.58)	0.1158	
Baseline FARR anti-dsDNA					0.9627
<5 IU/mL	11/ 15 (73.3)	7/ 11 (63.6)	1.15 (0.67, 1.98)	0.6074	
>=5 IU/mL	29/ 40 (72.5)	31/ 50 (62.0)	1.17 (0.88, 1.56)	0.2887	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.8729
Yes	36/ 50 (72.0)	35/ 60 (58.3)	1.23 (0.94, 1.62)	0.1335	
No	15/ 19 (78.9)	10/ 15 (66.7)	1.18 (0.77, 1.81)	0.4372	
OCS use					0.1212
Yes	43/ 54 (79.6)	37/ 63 (58.7)	1.36 (1.06, 1.74)	0.0157	
No	8/ 15 (53.3)	8/ 12 (66.7)	0.80 (0.43, 1.49)	0.4804	
SLICC score					0.7508
0	32/ 40 (80.0)	30/ 48 (62.5)	1.28 (0.98, 1.67)	0.0714	
>=1	19/ 29 (65.5)	15/ 27 (55.6)	1.18 (0.77, 1.81)	0.4505	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Major clinical response at week 52
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=69)	Placebo (N=75)
Week 52	Number of subjects with events, n (%)	12 (17.4)	5 (6.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	2.98 (1.02, 8.74)	
	p-value	0.0464	
	Odds Ratio (95% CI)	3.38 (1.05, 10.90)	
	p-value	0.0414	
	Risk Difference (95% CI)	11.61 (1.07, 22.15)	
	p-value	0.0308	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	2.61 (0.97, 7.03)	
	p-value	0.0578	
	Odds Ratio (95% CI)	2.95 (0.98, 8.86)	
	p-value	0.0542	
	Risk Difference (95% CI)	10.72 (0.15, 21.30)	
	p-value	0.0469	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Major clinical response at week 52 - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.1291
< 10 points	6/ 29 (20.7)	5/ 32 (15.6)	1.32 (0.45, 3.88)	0.6088	
>= 10 points	6/ 40 (15.0)	0/ 43 (0.0)	13.95 (0.81, 239.94)	0.0694	
OCS dose					0.6107
<10 mg/day	5/ 33 (15.2)	1/ 28 (3.6)	4.24 (0.53, 34.20)	0.1748	
>=10 mg/day	7/ 36 (19.4)	4/ 47 (8.5)	2.28 (0.72, 7.21)	0.1588	
Result of type I IFN gene signature test					0.4166
LOW	2/ 14 (14.3)	2/ 19 (10.5)	1.36 (0.22, 8.50)	0.7442	
HIGH	10/ 55 (18.2)	3/ 56 (5.4)	3.39 (0.99, 11.67)	0.0525	
Age (years)					0.7352
<= 45	8/ 45 (17.8)	3/ 50 (6.0)	2.96 (0.84, 10.49)	0.0922	
> 45	4/ 24 (16.7)	2/ 25 (8.0)	2.08 (0.42, 10.34)	0.3693	
Sex					0.6285
male	1/ 4 (25.0)	1/ 6 (16.7)	1.50 (0.13, 17.67)	0.7473	
female	11/ 65 (16.9)	4/ 69 (5.8)	2.92 (0.98, 8.71)	0.0547	
Race					0.8492
White	3/ 25 (12.0)	2/ 31 (6.5)	1.86 (0.34, 10.28)	0.4769	
Black	4/ 16 (25.0)	0/ 8 (0.0)	4.76 (0.29, 78.97)	0.2758	
Other	5/ 28 (17.9)	3/ 36 (8.3)	2.14 (0.56, 8.21)	0.2662	
Ethnicity					0.2370
Hispanic/Latino	4/ 28 (14.3)	3/ 28 (10.7)	1.33 (0.33, 5.42)	0.6876	
Non-hispanic/Latino	8/ 41 (19.5)	2/ 47 (4.3)	4.59 (1.03, 20.38)	0.0454	
Geographic region					0.2760
Latin America, Eastern Europe and Asia	7/ 45 (15.6)	5/ 55 (9.1)	1.71 (0.58, 5.03)	0.3287	
North America	5/ 24 (20.8)	0/ 20 (0.0)	9.24 (0.54, 157.57)	0.1244	
Baseline weight					0.1515
<60 kg	3/ 18 (16.7)	4/ 31 (12.9)	1.29 (0.33, 5.13)	0.7162	
>=60 kg	9/ 51 (17.6)	1/ 44 (2.3)	7.76 (1.02, 58.90)	0.0474	
Low CH50					0.8440
Yes	1/ 9 (11.1)	0/ 10 (0.0)	3.30 (0.15, 72.08)	0.4480	
No	11/ 60 (18.3)	5/ 65 (7.7)	2.38 (0.88, 6.46)	0.0878	
Low C3 or C4					0.4075
Yes	4/ 25 (16.0)	1/ 33 (3.0)	5.28 (0.63, 44.38)	0.1255	
No	8/ 44 (18.2)	4/ 42 (9.5)	1.91 (0.62, 5.87)	0.2592	
Baseline FARR anti-dsDNA					0.9051
<5 IU/mL	4/ 15 (26.7)	1/ 11 (9.1)	2.93 (0.38, 22.75)	0.3032	
>=5 IU/mL	4/ 40 (10.0)	2/ 50 (4.0)	2.50 (0.48, 12.96)	0.2751	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.7292
Yes	7/ 50 (14.0)	3/ 60 (5.0)	2.80 (0.76, 10.27)	0.1204	
No	5/ 19 (26.3)	2/ 15 (13.3)	1.97 (0.44, 8.79)	0.3723	
OCS use					0.7272
Yes	10/ 54 (18.5)	5/ 63 (7.9)	2.33 (0.85, 6.41)	0.1002	
No	2/ 15 (13.3)	0/ 12 (0.0)	4.06 (0.21, 77.37)	0.3512	
SLICC score					0.5199
0	6/ 40 (15.0)	2/ 48 (4.2)	3.60 (0.77, 16.87)	0.1040	
>=1	6/ 29 (20.7)	3/ 27 (11.1)	1.86 (0.52, 6.72)	0.3422	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Partial clinical response at week 52
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=69)	Placebo (N=75)
Week 52	Number of subjects with events, n (%)	29 (42.0)	23 (30.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.46 (0.92, 2.31)	
	p-value	0.1074	
	Odds Ratio (95% CI)	1.81 (0.89, 3.69)	
	p-value	0.1005	
	Risk Difference (95% CI)	13.27 (-2.25, 28.79)	
	p-value	0.0938	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.37 (0.88, 2.13)	
	p-value	0.1592	
	Odds Ratio (95% CI)	1.64 (0.83, 3.25)	
	p-value	0.1575	
	Risk Difference (95% CI)	11.36 (-4.28, 27.00)	
	p-value	0.1544	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Partial clinical response at week 52 - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	 p-Value	Interaction p-Value
SLEDAI-2K score					0.0960
< 10 points	12/ 29 (41.4)	14/ 32 (43.8)	0.95 (0.53, 1.70)	0.8519	
>= 10 points	17/ 40 (42.5)	9/ 43 (20.9)	2.03 (1.02, 4.02)	0.0423	
OCS dose					0.4202
<10 mg/day	13/ 33 (39.4)	6/ 28 (21.4)	1.84 (0.80, 4.20)	0.1485	
>=10 mg/day	16/ 36 (44.4)	17/ 47 (36.2)	1.23 (0.73, 2.08)	0.4435	
Result of type I IFN gene signature test					0.3961
LOW	5/ 14 (35.7)	7/ 19 (36.8)	0.97 (0.39, 2.42)	0.9470	
HIGH	24/ 55 (43.6)	16/ 56 (28.6)	1.53 (0.92, 2.55)	0.1047	
Age (years)					0.8037
<= 45	19/ 45 (42.2)	16/ 50 (32.0)	1.32 (0.78, 2.24)	0.3046	
> 45	10/ 24 (41.7)	7/ 25 (28.0)	1.49 (0.68, 3.27)	0.3221	
Sex					0.2651
male	2/ 4 (50.0)	4/ 6 (66.7)	0.75 (0.24, 2.33)	0.6183	
female	27/ 65 (41.5)	19/ 69 (27.5)	1.51 (0.93, 2.44)	0.0927	
Race					0.5769
White	9/ 25 (36.0)	8/ 31 (25.8)	1.40 (0.63, 3.08)	0.4109	
Black	5/ 16 (31.3)	0/ 8 (0.0)	5.82 (0.36, 93.87)	0.2142	
Other	15/ 28 (53.6)	15/ 36 (41.7)	1.29 (0.77, 2.16)	0.3416	
Ethnicity					0.0705
Hispanic/Latino	14/ 28 (50.0)	15/ 28 (53.6)	0.93 (0.56, 1.55)	0.7893	
Non-hispanic/Latino	15/ 41 (36.6)	8/ 47 (17.0)	2.15 (1.02, 4.55)	0.0452	
Geographic region					0.7199
Latin America, Eastern Europe and Asia	21/ 45 (46.7)	19/ 55 (34.5)	1.35 (0.84, 2.18)	0.2189	
North America	8/ 24 (33.3)	4/ 20 (20.0)	1.67 (0.59, 4.73)	0.3372	
Baseline weight					0.7337
<60 kg	9/ 18 (50.0)	10/ 31 (32.3)	1.55 (0.78, 3.08)	0.2120	
>=60 kg	20/ 51 (39.2)	13/ 44 (29.5)	1.33 (0.75, 2.35)	0.3303	
Low CH50					0.4084
Yes	2/ 9 (22.2)	3/ 10 (30.0)	0.74 (0.16, 3.48)	0.7036	
No	27/ 60 (45.0)	20/ 65 (30.8)	1.46 (0.92, 2.32)	0.1050	
Low C3 or C4					0.5527
Yes	11/ 25 (44.0)	9/ 33 (27.3)	1.61 (0.79, 3.29)	0.1875	
No	18/ 44 (40.9)	14/ 42 (33.3)	1.23 (0.70, 2.14)	0.4703	
Baseline FARR anti-dsDNA					0.5235
<5 IU/mL	7/ 15 (46.7)	5/ 11 (45.5)	1.03 (0.44, 2.39)	0.9512	
>=5 IU/mL	15/ 40 (37.5)	13/ 50 (26.0)	1.44 (0.78, 2.67)	0.2434	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.4866
Yes	21/ 50 (42.0)	17/ 60 (28.3)	1.48 (0.88, 2.49)	0.1362	
No	8/ 19 (42.1)	6/ 15 (40.0)	1.05 (0.47, 2.38)	0.9017	
OCS use					0.8610
Yes	25/ 54 (46.3)	21/ 63 (33.3)	1.39 (0.88, 2.18)	0.1545	
No	4/ 15 (26.7)	2/ 12 (16.7)	1.60 (0.35, 7.30)	0.5440	
SLICC score					0.9545
0	17/ 40 (42.5)	15/ 48 (31.3)	1.36 (0.78, 2.36)	0.2760	
>=1	12/ 29 (41.4)	8/ 27 (29.6)	1.40 (0.68, 2.88)	0.3665	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=50% Joint reduction at week 52 (for subjects with at least 6 tender joints and at least 6 swollen joints at baseline)
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=36)	Placebo (N=40)
Week 52	Number of subjects with events, n (%)	26 (72.2)	14 (35.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	2.13 (1.37, 3.30)	
	p-value	0.0007	
	Odds Ratio (95% CI)	9.45 (2.50, 35.64)	
	p-value	0.0009	
	Risk Difference (95% CI)	38.72 (20.32, 57.12)	
	p-value	<.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	2.06 (1.29, 3.30)	
	p-value	0.0024	
	Odds Ratio (95% CI)	4.83 (1.82, 12.82)	
	p-value	0.0016	
	Risk Difference (95% CI)	37.22 (16.42, 58.02)	
	p-value	0.0005	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=50% Joint reduction at week 52 (for subjects with at least 6 tender joints and at least 6 swollen joints at baseline) - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=36) n/ N (%)	Placebo (N=40) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.2536
< 10 points	11/ 13 (84.6)	8/ 15 (53.3)	1.59 (0.94, 2.69)	0.0861	
>= 10 points	15/ 23 (65.2)	6/ 25 (24.0)	2.72 (1.27, 5.80)	0.0098	
OCS dose					0.9276
<10 mg/day	6/ 12 (50.0)	3/ 13 (23.1)	2.17 (0.69, 6.79)	0.1847	
>=10 mg/day	20/ 24 (83.3)	11/ 27 (40.7)	2.05 (1.25, 3.33)	0.0041	
Result of type I IFN gene signature test					0.2258
LOW	7/ 8 (87.5)	3/ 12 (25.0)	3.50 (1.27, 9.65)	0.0155	
HIGH	19/ 28 (67.9)	11/ 28 (39.3)	1.73 (1.02, 2.92)	0.0418	
Age (years)					0.8999
<= 45	17/ 24 (70.8)	8/ 24 (33.3)	2.13 (1.14, 3.96)	0.0174	
> 45	9/ 12 (75.0)	6/ 16 (37.5)	2.00 (0.98, 4.08)	0.0564	
Sex					NE
male	0/ 2 (0.0)	0	NE		
female	26/ 34 (76.5)	14/ 40 (35.0)	2.18 (1.38, 3.47)	0.0009	
Race					0.3202
White	10/ 14 (71.4)	4/ 18 (22.2)	3.21 (1.27, 8.11)	0.0134	
Black	5/ 7 (71.4)	1/ 4 (25.0)	2.86 (0.49, 16.62)	0.2426	
Other	11/ 15 (73.3)	9/ 18 (50.0)	1.47 (0.84, 2.55)	0.1752	
Ethnicity					0.1300
Hispanic/Latino	11/ 15 (73.3)	9/ 18 (50.0)	1.47 (0.84, 2.55)	0.1752	
Non-hispanic/Latino	15/ 21 (71.4)	5/ 22 (22.7)	3.14 (1.39, 7.11)	0.0060	
Geographic region					0.2045
Latin America, Eastern Europe and Asia	22/ 29 (75.9)	13/ 29 (44.8)	1.69 (1.08, 2.66)	0.0228	
North America	4/ 7 (57.1)	1/ 11 (9.1)	6.29 (0.87, 45.34)	0.0682	
Baseline weight					0.1168
<60 kg	6/ 8 (75.0)	10/ 20 (50.0)	1.50 (0.83, 2.72)	0.1805	
>=60 kg	20/ 28 (71.4)	4/ 20 (20.0)	3.57 (1.44, 8.85)	0.0060	
Low CH50					0.1741
Yes	2/ 5 (40.0)	2/ 4 (50.0)	0.80 (0.19, 3.42)	0.7635	
No	24/ 31 (77.4)	12/ 36 (33.3)	2.32 (1.41, 3.83)	0.0009	
Low C3 or C4					0.3076
Yes	9/ 15 (60.0)	7/ 18 (38.9)	1.54 (0.76, 3.14)	0.2322	
No	17/ 21 (81.0)	7/ 22 (31.8)	2.54 (1.33, 4.85)	0.0046	
Baseline FARR anti-dsDNA					0.5977
<5 IU/mL	3/ 5 (60.0)	1/ 5 (20.0)	3.00 (0.45, 19.93)	0.2555	
>=5 IU/mL	15/ 23 (65.2)	10/ 27 (37.0)	1.76 (0.99, 3.13)	0.0539	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.6139
Yes	19/ 27 (70.4)	12/ 33 (36.4)	1.94 (1.16, 3.23)	0.0117	
No	7/ 9 (77.8)	2/ 7 (28.6)	2.72 (0.80, 9.24)	0.1083	
OCS use					0.8393
Yes	24/ 32 (75.0)	13/ 35 (37.1)	2.02 (1.26, 3.25)	0.0037	
No	2/ 4 (50.0)	1/ 5 (20.0)	2.50 (0.34, 18.63)	0.3712	
SLICC score					0.7443
0	18/ 24 (75.0)	9/ 23 (39.1)	1.92 (1.10, 3.35)	0.0227	
>=1	8/ 12 (66.7)	5/ 17 (29.4)	2.27 (0.98, 5.24)	0.0557	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=50% Joint reduction at week 52 (for subjects with at least 8 tender joints and at least 8 swollen joints at baseline)
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=28)	Placebo (N=26)
Week 52	Number of subjects with events, n (%)	20 (71.4)	11 (42.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.98 (1.22, 3.22)	
	p-value	0.0060	
	Odds Ratio (95% CI)	10.28 (2.03, 52.06)	
	p-value	0.0049	
	Risk Difference (95% CI)	39.22 (17.54, 60.90)	
	p-value	0.0004	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.69 (1.02, 2.80)	
	p-value	0.0426	
	Odds Ratio (95% CI)	3.41 (1.10, 10.56)	
	p-value	0.0334	
	Risk Difference (95% CI)	29.12 (3.81, 54.43)	
	p-value	0.0241	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=50% Joint reduction at week 52 (for subjects with at least 8 tender joints and at least 8 swollen joints at baseline) - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=28) n/ N (%)	Placebo (N=26) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	 p-Value	Interaction p-Value
SLEDAI-2K score					0.2002
< 10 points	8/ 10 (80.0)	7/ 11 (63.6)	1.26 (0.73, 2.17)	0.4094	
>= 10 points	12/ 18 (66.7)	4/ 15 (26.7)	2.50 (1.02, 6.15)	0.0461	
OCS dose					0.8589
<10 mg/day	4/ 9 (44.4)	2/ 7 (28.6)	1.56 (0.39, 6.19)	0.5304	
>=10 mg/day	16/ 19 (84.2)	9/ 19 (47.4)	1.78 (1.06, 2.97)	0.0278	
Result of type I IFN gene signature test					0.2661
LOW	6/ 7 (85.7)	2/ 7 (28.6)	3.00 (0.89, 10.06)	0.0751	
HIGH	14/ 21 (66.7)	9/ 19 (47.4)	1.41 (0.80, 2.47)	0.2335	
Age (years)					0.8241
<= 45	12/ 17 (70.6)	7/ 16 (43.8)	1.61 (0.86, 3.04)	0.1396	
> 45	8/ 11 (72.7)	4/ 10 (40.0)	1.82 (0.78, 4.22)	0.1635	
Sex					NE
male	0/ 2 (0.0)	0	NE		
female	20/ 26 (76.9)	11/ 26 (42.3)	1.82 (1.11, 2.99)	0.0181	
Race					0.7267
White	9/ 13 (69.2)	3/ 9 (33.3)	2.08 (0.77, 5.60)	0.1489	
Black	4/ 5 (80.0)	1/ 3 (33.3)	2.40 (0.46, 12.61)	0.3011	
Other	7/ 10 (70.0)	7/ 14 (50.0)	1.40 (0.72, 2.72)	0.3196	
Ethnicity					0.2833
Hispanic/Latino	7/ 10 (70.0)	7/ 13 (53.8)	1.30 (0.68, 2.48)	0.4264	
Non-hispanic/Latino	13/ 18 (72.2)	4/ 13 (30.8)	2.35 (0.99, 5.57)	0.0530	
Geographic region					0.3809
Latin America, Eastern Europe and Asia	17/ 23 (73.9)	10/ 20 (50.0)	1.48 (0.90, 2.44)	0.1263	
North America	3/ 5 (60.0)	1/ 6 (16.7)	3.60 (0.52, 24.73)	0.1926	
Baseline weight					0.1303
<60 kg	4/ 6 (66.7)	9/ 16 (56.3)	1.19 (0.58, 2.42)	0.6400	
>=60 kg	16/ 22 (72.7)	2/ 10 (20.0)	3.64 (1.03, 12.89)	0.0456	
Low CH50					0.1921
Yes	1/ 4 (25.0)	2/ 4 (50.0)	0.50 (0.07, 3.55)	0.4882	
No	19/ 24 (79.2)	9/ 22 (40.9)	1.94 (1.12, 3.33)	0.0171	
Low C3 or C4					0.1638
Yes	6/ 10 (60.0)	6/ 11 (54.5)	1.10 (0.52, 2.30)	0.8006	
No	14/ 18 (77.8)	5/ 15 (33.3)	2.33 (1.09, 4.97)	0.0283	
Baseline FARR anti-dsDNA					0.6322
<5 IU/mL	2/ 4 (50.0)	1/ 4 (25.0)	2.00 (0.28, 14.20)	0.4882	
>=5 IU/mL	11/ 17 (64.7)	8/ 15 (53.3)	1.21 (0.67, 2.19)	0.5203	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.3277
Yes	14/ 20 (70.0)	10/ 21 (47.6)	1.47 (0.86, 2.50)	0.1562	
No	6/ 8 (75.0)	1/ 5 (20.0)	3.75 (0.62, 22.64)	0.1497	
OCS use					0.7632
Yes	18/ 25 (72.0)	10/ 24 (41.7)	1.73 (1.01, 2.94)	0.0442	
No	2/ 3 (66.7)	1/ 2 (50.0)	1.33 (0.27, 6.61)	0.7246	
SLICC score					0.6845
0	14/ 19 (73.7)	8/ 17 (47.1)	1.57 (0.88, 2.77)	0.1240	
>=1	6/ 9 (66.7)	3/ 9 (33.3)	2.00 (0.71, 5.62)	0.1885	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=0.22 point Improvement in HAQ Score at week 52 (for subjects with baseline HAQ Score >= 0.25)
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=55)	Placebo (N=58)
Week 52	Number of subjects with events, n (%)	22 (40.0)	21 (36.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.22 (0.73, 2.04)	
	p-value	0.4455	
	Odds Ratio (95% CI)	1.39 (0.61, 3.17)	
	p-value	0.4318	
	Risk Difference (95% CI)	7.41 (-10.85, 25.67)	
	p-value	0.4265	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.10 (0.69, 1.77)	
	p-value	0.6782	
	Odds Ratio (95% CI)	1.17 (0.55, 2.51)	
	p-value	0.6782	
	Risk Difference (95% CI)	3.79 (-14.11, 21.70)	
	p-value	0.6780	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=0.22 point Improvement in HAQ Score at week 52 (for subjects with baseline HAQ Score >= 0.25) - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=55) n/ N (%)	Placebo (N=58) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.8495
< 10 points	10/ 22 (45.5)	9/ 23 (39.1)	1.16 (0.59, 2.30)	0.6682	
>= 10 points	12/ 33 (36.4)	12/ 35 (34.3)	1.06 (0.56, 2.02)	0.8578	
OCS dose					0.2286
<10 mg/day	10/ 29 (34.5)	3/ 19 (15.8)	2.18 (0.69, 6.92)	0.1843	
>=10 mg/day	12/ 26 (46.2)	18/ 39 (46.2)	1.00 (0.59, 1.71)	1.0000	
Result of type I IFN gene signature test					0.2158
LOW	4/ 11 (36.4)	3/ 18 (16.7)	2.18 (0.60, 7.97)	0.2379	
HIGH	18/ 44 (40.9)	18/ 40 (45.0)	0.91 (0.56, 1.49)	0.7050	
Age (years)					0.8194
<= 45	14/ 33 (42.4)	15/ 38 (39.5)	1.07 (0.61, 1.88)	0.8006	
> 45	8/ 22 (36.4)	6/ 20 (30.0)	1.21 (0.51, 2.89)	0.6641	
Sex					0.6435
male	2/ 3 (66.7)	3/ 4 (75.0)	0.89 (0.33, 2.37)	0.8138	
female	20/ 52 (38.5)	18/ 54 (33.3)	1.15 (0.69, 1.92)	0.5826	
Race					0.3563
White	8/ 21 (38.1)	11/ 27 (40.7)	0.94 (0.46, 1.90)	0.8530	
Black	6/ 12 (50.0)	1/ 8 (12.5)	4.00 (0.59, 27.25)	0.1567	
Other	8/ 22 (36.4)	9/ 23 (39.1)	0.93 (0.44, 1.97)	0.8484	
Ethnicity					0.3755
Hispanic/Latino	8/ 21 (38.1)	9/ 20 (45.0)	0.85 (0.41, 1.76)	0.6544	
Non-hispanic/Latino	14/ 34 (41.2)	12/ 38 (31.6)	1.30 (0.70, 2.42)	0.3991	
Geographic region					0.2341
Latin America, Eastern Europe and Asia	16/ 36 (44.4)	18/ 38 (47.4)	0.94 (0.57, 1.54)	0.8011	
North America	6/ 19 (31.6)	3/ 20 (15.0)	2.11 (0.61, 7.24)	0.2376	
Baseline weight					0.4676
<60 kg	7/ 13 (53.8)	9/ 24 (37.5)	1.44 (0.70, 2.95)	0.3255	
>=60 kg	15/ 42 (35.7)	12/ 34 (35.3)	1.01 (0.55, 1.86)	0.9697	
Low CH50					0.1403
Yes	2/ 7 (28.6)	5/ 8 (62.5)	0.46 (0.13, 1.66)	0.2338	
No	20/ 48 (41.7)	16/ 50 (32.0)	1.30 (0.77, 2.20)	0.3241	
Low C3 or C4					0.7134
Yes	6/ 19 (31.6)	9/ 27 (33.3)	0.95 (0.40, 2.22)	0.9008	
No	16/ 36 (44.4)	12/ 31 (38.7)	1.15 (0.65, 2.04)	0.6372	
Baseline FARR anti-dsDNA					0.1319
<5 IU/mL	6/ 11 (54.5)	1/ 7 (14.3)	3.82 (0.58, 25.35)	0.1654	
>=5 IU/mL	12/ 33 (36.4)	17/ 39 (43.6)	0.83 (0.47, 1.48)	0.5370	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.3861
Yes	15/ 41 (36.6)	18/ 48 (37.5)	0.98 (0.57, 1.68)	0.9291	
No	7/ 14 (50.0)	3/ 10 (30.0)	1.67 (0.56, 4.92)	0.3548	
OCS use					0.5101
Yes	20/ 43 (46.5)	19/ 50 (38.0)	1.22 (0.76, 1.97)	0.4068	
No	2/ 12 (16.7)	2/ 8 (25.0)	0.67 (0.12, 3.81)	0.6486	
SLICC score					0.6273
0	14/ 29 (48.3)	14/ 36 (38.9)	1.24 (0.71, 2.17)	0.4463	
>=1	8/ 26 (30.8)	7/ 22 (31.8)	0.97 (0.42, 2.24)	0.9377	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (5) response rate at week 52
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=69)	Placebo (N=75)
Week 52	Number of subjects with events, n (%)	31 (44.9)	21 (28.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.80 (1.14, 2.85)	
	p-value	0.0119	
	Odds Ratio (95% CI)	2.65 (1.26, 5.59)	
	p-value	0.0105	
	Risk Difference (95% CI)	20.63 (5.68, 35.57)	
	p-value	0.0068	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.60 (1.03, 2.51)	
	p-value	0.0382	
	Odds Ratio (95% CI)	2.10 (1.05, 4.19)	
	p-value	0.0359	
	Risk Difference (95% CI)	16.93 (1.40, 32.45)	
	p-value	0.0326	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (6) response rate at week 52
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=69)	Placebo (N=75)
Week 52	Number of subjects with events, n (%)	31 (44.9)	20 (26.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.89 (1.18, 3.03)	
	p-value	0.0078	
	Odds Ratio (95% CI)	2.82 (1.33, 5.98)	
	p-value	0.0067	
	Risk Difference (95% CI)	21.90 (7.00, 36.80)	
	p-value	0.0040	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.68 (1.07, 2.66)	
	p-value	0.0254	
	Odds Ratio (95% CI)	2.24 (1.12, 4.51)	
	p-value	0.0232	
	Risk Difference (95% CI)	18.26 (2.84, 33.69)	
	p-value	0.0203	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (7) response rate at week 52
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=69)	Placebo (N=75)
Week 52	Number of subjects with events, n (%)	21 (30.4)	11 (14.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	2.32 (1.20, 4.48)	
	p-value	0.0122	
	Odds Ratio (95% CI)	3.18 (1.31, 7.72)	
	p-value	0.0108	
	Risk Difference (95% CI)	17.93 (4.86, 31.00)	
	p-value	0.0072	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	2.08 (1.08, 3.98)	
	p-value	0.0282	
	Odds Ratio (95% CI)	2.55 (1.12, 5.78)	
	p-value	0.0255	
	Risk Difference (95% CI)	15.77 (2.28, 29.26)	
	p-value	0.0220	

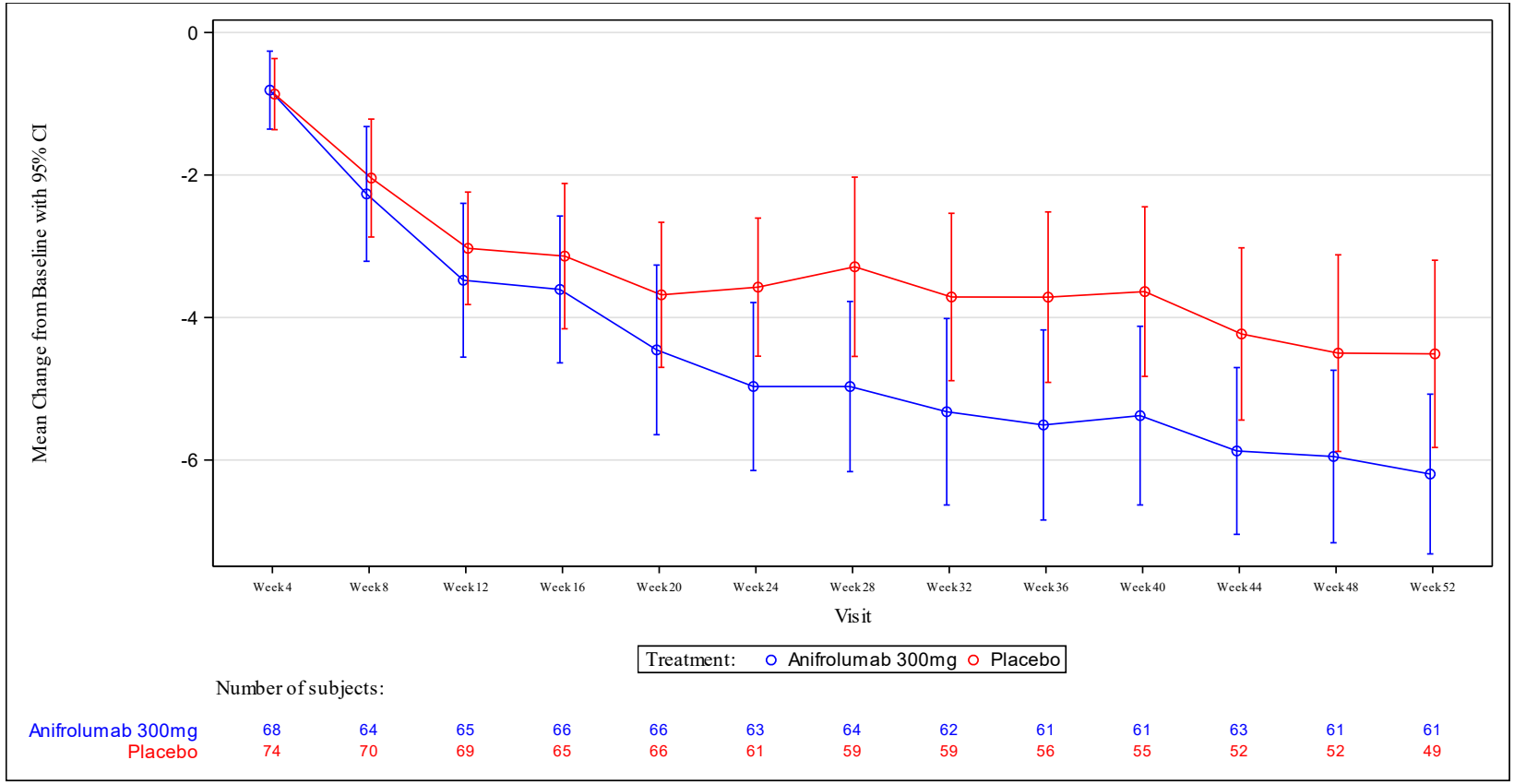
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - SLEDAI-2K Total Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)				Placebo (N=75)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	69	10.72 (4.25)	0	-	75	11.04 (4.55)	0	-
Week 4	68	10.03 (3.71)	68	-0.81 (2.26)	74	10.16 (3.95)	74	-0.86 (2.15)
Week 8	64	8.77 (4.32)	64	-2.27 (3.78)	70	9.17 (5.00)	70	-2.04 (3.47)
Week 12	65	7.32 (4.61)	65	-3.48 (4.36)	69	8.03 (4.51)	69	-3.03 (3.29)
Week 16	66	7.15 (4.63)	66	-3.61 (4.19)	65	7.69 (5.05)	65	-3.14 (4.12)
Week 20	66	6.30 (4.85)	66	-4.45 (4.84)	66	7.21 (4.74)	66	-3.68 (4.14)
Week 24	63	5.81 (4.59)	63	-4.97 (4.68)	61	7.23 (4.63)	61	-3.57 (3.78)
Week 28	64	5.77 (4.19)	64	-4.97 (4.78)	59	7.49 (5.94)	59	-3.29 (4.83)
Week 32	62	5.58 (4.51)	62	-5.32 (5.15)	59	7.05 (5.78)	59	-3.71 (4.51)
Week 36	61	5.31 (4.53)	61	-5.51 (5.21)	56	7.02 (5.68)	56	-3.71 (4.47)
Week 40	61	5.41 (4.01)	61	-5.38 (4.90)	55	7.11 (5.50)	55	-3.64 (4.40)
Week 44	63	4.98 (3.72)	63	-5.87 (4.65)	52	5.77 (4.58)	52	-4.23 (4.34)
Week 48	61	4.74 (3.71)	61	-5.95 (4.73)	52	5.83 (4.96)	52	-4.50 (4.96)
Week 52	61	4.49 (3.53)	61	-6.20 (4.38)	49	5.51 (4.97)	49	-4.51 (4.57)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - SLEDAI-2K Total Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)



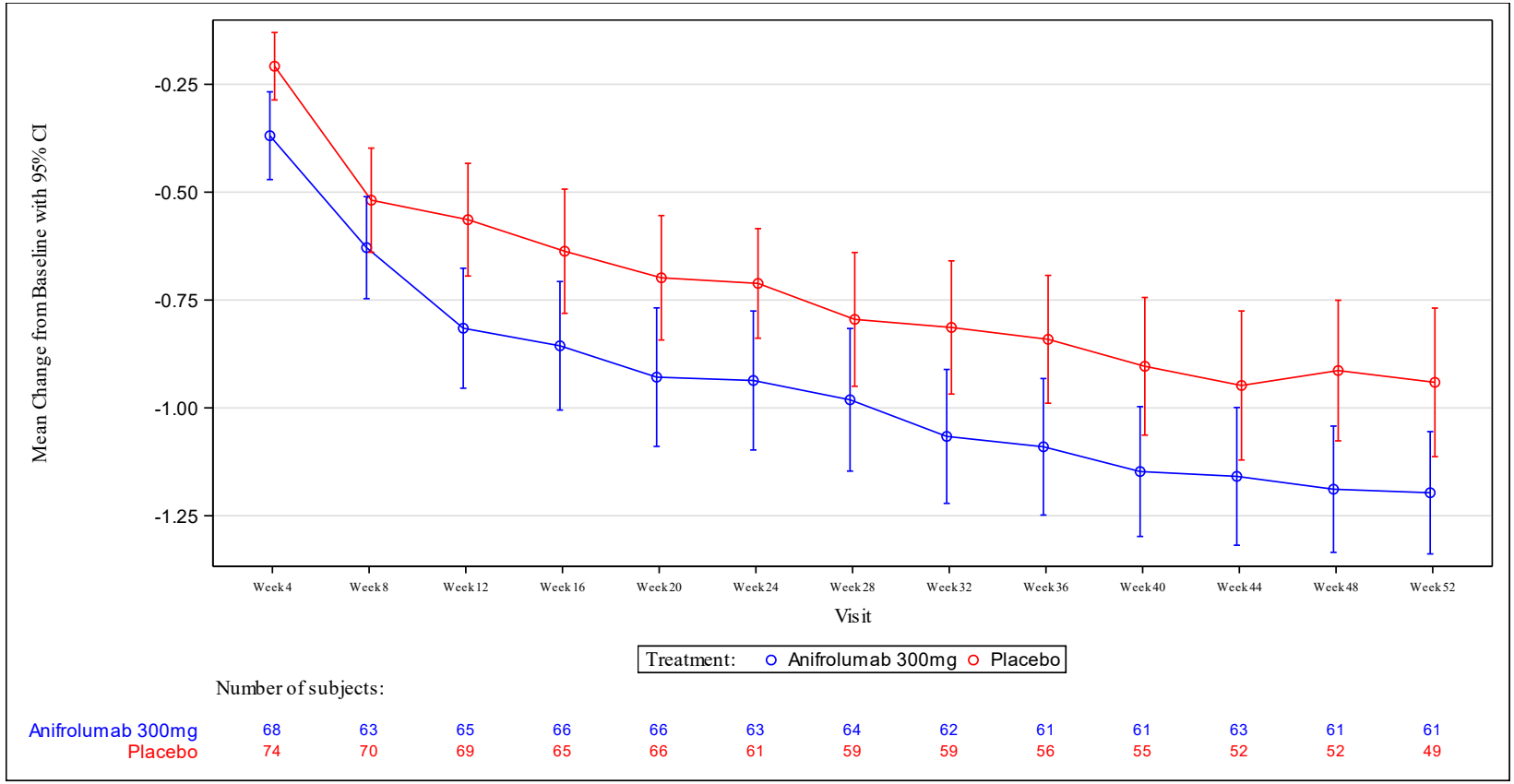
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - PGA
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)				Placebo (N=75)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	69	1.83 (0.41)	0	-	75	1.72 (0.42)	0	-
Week 4	68	1.46 (0.51)	68	-0.37 (0.42)	74	1.51 (0.44)	74	-0.21 (0.34)
Week 8	63	1.22 (0.50)	63	-0.63 (0.47)	70	1.22 (0.52)	70	-0.52 (0.51)
Week 12	65	1.00 (0.53)	65	-0.82 (0.56)	69	1.15 (0.54)	69	-0.56 (0.54)
Week 16	66	0.96 (0.57)	66	-0.86 (0.61)	65	1.07 (0.57)	65	-0.64 (0.58)
Week 20	66	0.88 (0.62)	66	-0.93 (0.65)	66	1.01 (0.55)	66	-0.70 (0.59)
Week 24	63	0.87 (0.61)	63	-0.94 (0.64)	61	0.97 (0.53)	61	-0.71 (0.50)
Week 28	64	0.83 (0.64)	64	-0.98 (0.66)	59	0.92 (0.60)	59	-0.79 (0.59)
Week 32	62	0.75 (0.54)	62	-1.07 (0.61)	59	0.88 (0.54)	59	-0.81 (0.59)
Week 36	61	0.73 (0.55)	61	-1.09 (0.62)	56	0.85 (0.51)	56	-0.84 (0.55)
Week 40	61	0.67 (0.53)	61	-1.15 (0.59)	55	0.80 (0.56)	55	-0.90 (0.59)
Week 44	63	0.64 (0.55)	63	-1.16 (0.63)	52	0.75 (0.57)	52	-0.95 (0.62)
Week 48	61	0.63 (0.53)	61	-1.19 (0.57)	52	0.78 (0.54)	52	-0.91 (0.59)
Week 52	61	0.62 (0.51)	61	-1.20 (0.55)	49	0.74 (0.57)	49	-0.94 (0.60)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - PGA
Full analysis set



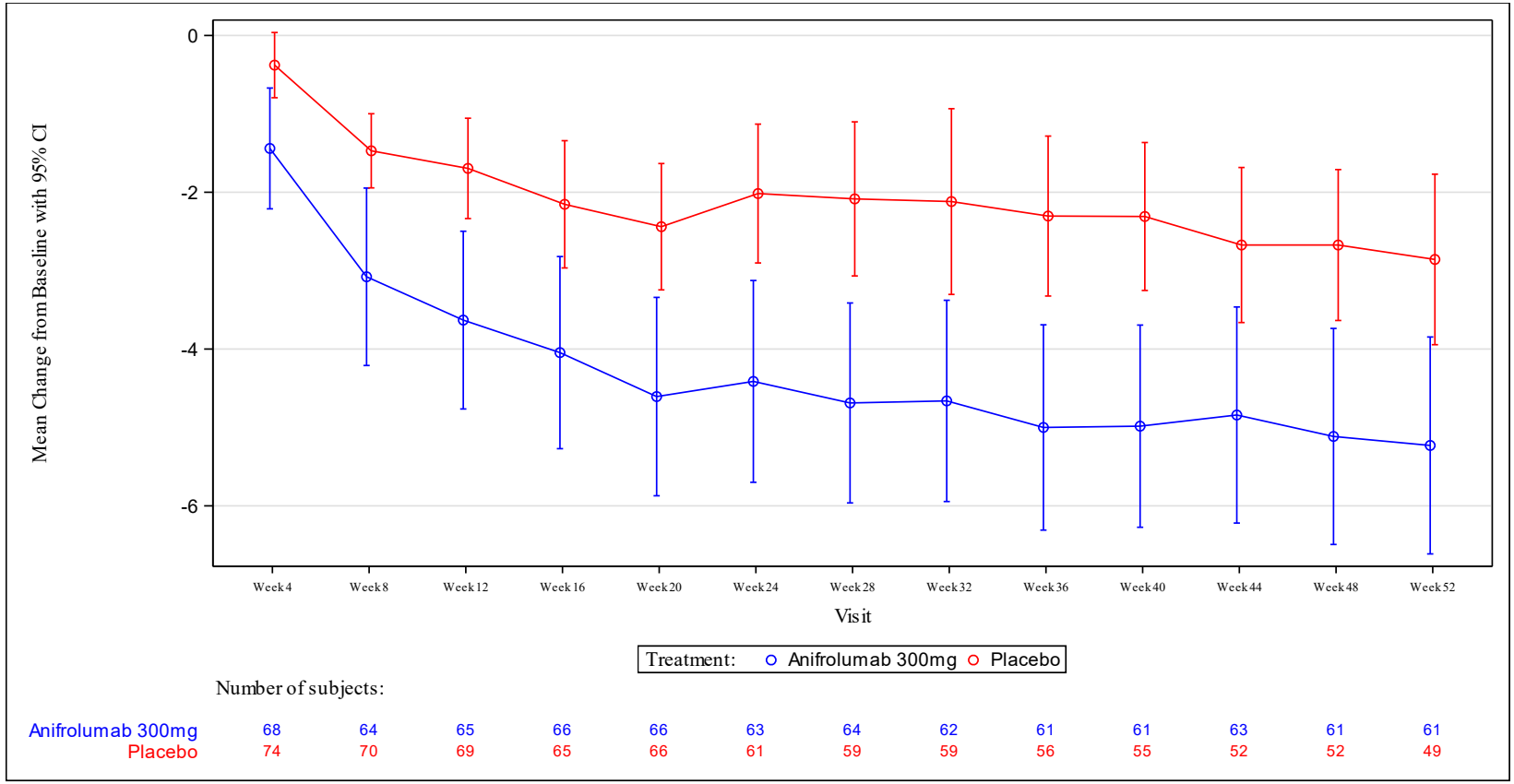
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - CLASI Total Activity Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)				Placebo (N=75)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	69	8.20 (6.88)	0	-	75	6.09 (4.43)	0	-
Week 4	68	6.81 (6.60)	68	-1.44 (3.18)	74	5.62 (4.20)	74	-0.38 (1.80)
Week 8	64	5.25 (5.69)	64	-3.08 (4.53)	70	4.73 (3.89)	70	-1.47 (1.98)
Week 12	65	4.28 (4.43)	65	-3.63 (4.57)	69	4.43 (3.79)	69	-1.70 (2.66)
Week 16	66	3.86 (4.45)	66	-4.05 (4.98)	65	4.09 (3.81)	65	-2.15 (3.28)
Week 20	66	3.30 (4.32)	66	-4.61 (5.15)	66	3.70 (3.69)	66	-2.44 (3.28)
Week 24	63	3.22 (4.27)	63	-4.41 (5.11)	61	4.13 (3.80)	61	-2.02 (3.46)
Week 28	64	3.33 (4.52)	64	-4.69 (5.10)	59	4.32 (4.19)	59	-2.08 (3.77)
Week 32	62	3.00 (4.41)	62	-4.66 (5.05)	59	4.03 (4.61)	59	-2.12 (4.55)
Week 36	61	2.77 (4.24)	61	-5.00 (5.11)	56	3.86 (3.95)	56	-2.30 (3.81)
Week 40	61	2.77 (4.32)	61	-4.98 (5.03)	55	3.87 (4.39)	55	-2.31 (3.49)
Week 44	63	2.83 (4.46)	63	-4.84 (5.47)	52	3.56 (4.05)	52	-2.67 (3.55)
Week 48	61	2.46 (3.97)	61	-5.11 (5.38)	52	3.54 (4.01)	52	-2.67 (3.46)
Week 52	61	2.34 (4.15)	61	-5.23 (5.40)	49	3.43 (3.75)	49	-2.86 (3.79)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - CLASI Total Activity Score
Full analysis set



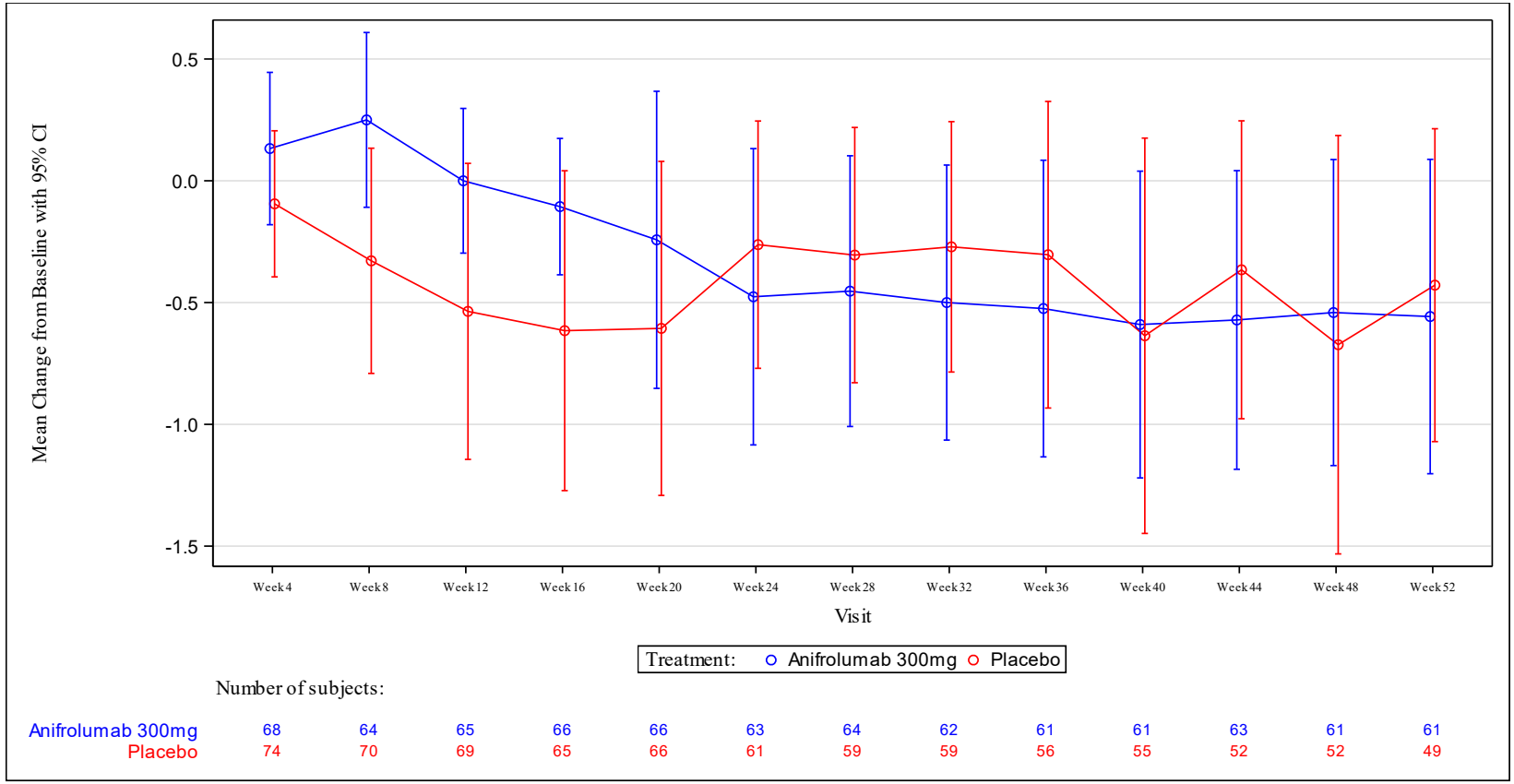
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - CLASI Total Damage Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)				Placebo (N=75)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	69	1.97 (4.47)	0	-	75	1.88 (4.72)	0	-
Week 4	68	2.13 (4.42)	68	0.13 (1.29)	74	1.80 (5.03)	74	-0.09 (1.29)
Week 8	64	2.20 (4.43)	64	0.25 (1.44)	70	1.69 (4.78)	70	-0.33 (1.94)
Week 12	65	1.89 (4.21)	65	0.00 (1.20)	69	1.49 (4.61)	69	-0.54 (2.53)
Week 16	66	1.82 (3.89)	66	-0.11 (1.14)	65	1.52 (4.73)	65	-0.62 (2.65)
Week 20	66	1.68 (3.35)	66	-0.24 (2.48)	66	1.50 (4.91)	66	-0.61 (2.79)
Week 24	63	1.44 (3.11)	63	-0.48 (2.42)	61	1.77 (5.53)	61	-0.26 (1.98)
Week 28	64	1.53 (3.17)	64	-0.45 (2.22)	59	1.92 (5.65)	59	-0.31 (2.01)
Week 32	62	1.39 (3.12)	62	-0.50 (2.22)	59	1.83 (5.51)	59	-0.27 (1.97)
Week 36	61	1.38 (3.15)	61	-0.52 (2.38)	56	1.88 (5.65)	56	-0.30 (2.35)
Week 40	61	1.39 (3.06)	61	-0.59 (2.46)	55	1.45 (5.08)	55	-0.64 (3.00)
Week 44	63	1.35 (3.01)	63	-0.57 (2.43)	52	1.54 (5.21)	52	-0.37 (2.20)
Week 48	61	1.34 (3.16)	61	-0.54 (2.45)	52	1.54 (5.21)	52	-0.67 (3.09)
Week 52	61	1.33 (3.29)	61	-0.56 (2.52)	49	1.51 (5.31)	49	-0.43 (2.24)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - CLASI Total Damage Score
Full analysis set



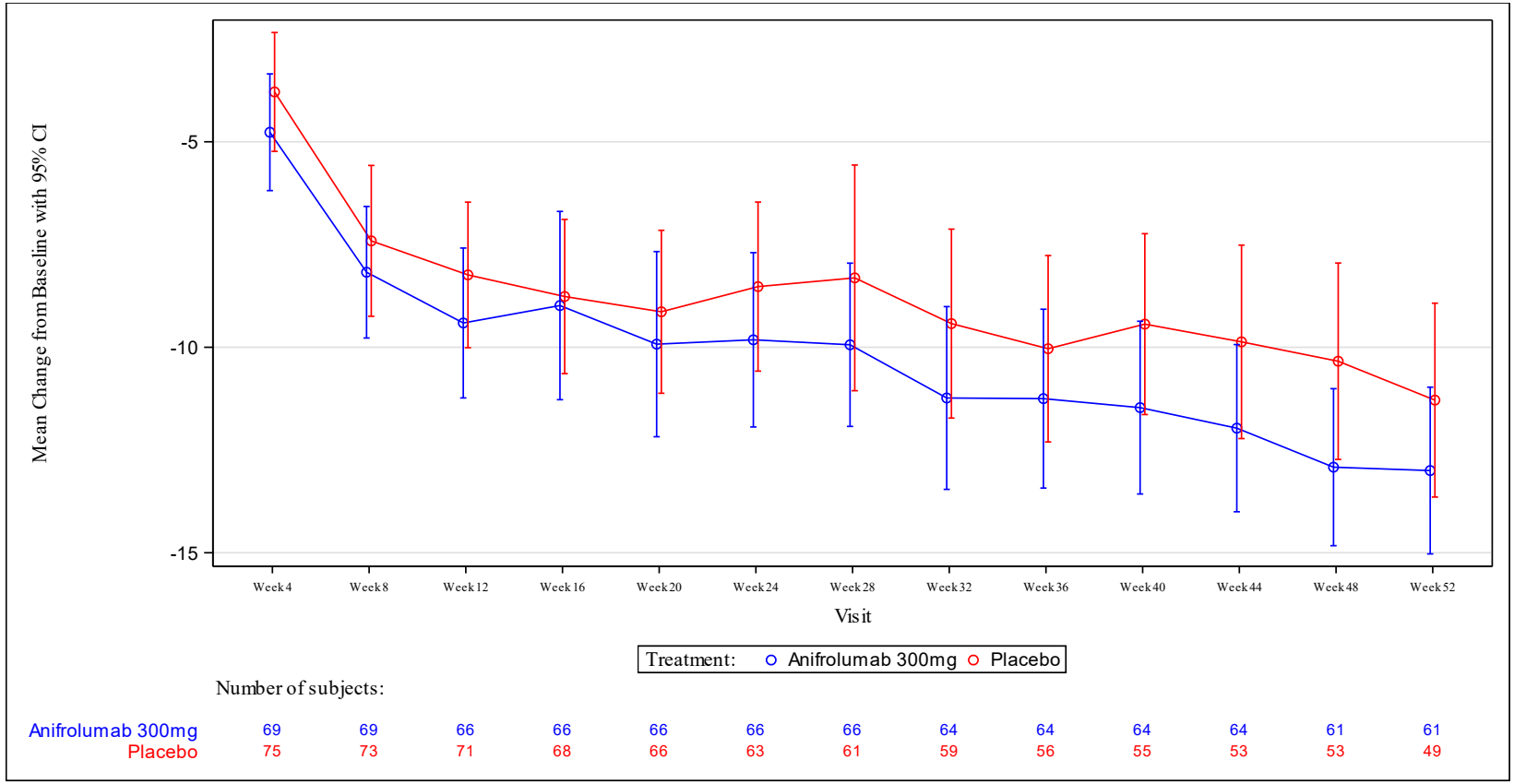
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - BILAG Global Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)				Placebo (N=75)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	69	19.72 (6.09)	0	-	75	19.43 (5.60)	0	-
Week 4	69	14.96 (7.29)	69	-4.77 (5.91)	75	15.64 (6.77)	75	-3.79 (6.29)
Week 8	69	11.55 (6.50)	69	-8.17 (6.66)	73	12.10 (8.10)	73	-7.41 (7.87)
Week 12	66	10.15 (7.22)	66	-9.41 (7.42)	71	11.27 (7.36)	71	-8.24 (7.48)
Week 16	66	10.58 (8.94)	66	-8.98 (9.32)	68	10.81 (7.94)	68	-8.76 (7.75)
Week 20	66	9.64 (8.05)	66	-9.92 (9.17)	66	10.32 (7.95)	66	-9.14 (8.06)
Week 24	66	9.74 (8.02)	66	-9.82 (8.63)	63	10.75 (7.33)	63	-8.52 (8.17)
Week 28	66	9.62 (7.44)	66	-9.94 (8.08)	61	11.05 (10.64)	61	-8.31 (10.72)
Week 32	64	8.28 (7.68)	64	-11.23 (8.90)	59	9.85 (8.64)	59	-9.42 (8.82)
Week 36	64	8.27 (7.47)	64	-11.25 (8.71)	56	8.95 (7.08)	56	-10.04 (8.47)
Week 40	64	8.05 (7.57)	64	-11.47 (8.41)	55	9.58 (7.63)	55	-9.44 (8.14)
Week 44	64	7.55 (6.46)	64	-11.97 (8.14)	53	8.91 (7.27)	53	-9.87 (8.54)
Week 48	61	6.77 (5.98)	61	-12.92 (7.46)	53	8.43 (6.88)	53	-10.34 (8.67)
Week 52	61	6.69 (6.23)	61	-13.00 (7.92)	49	7.43 (6.59)	49	-11.29 (8.21)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - BILAG Global Score
Full analysis set



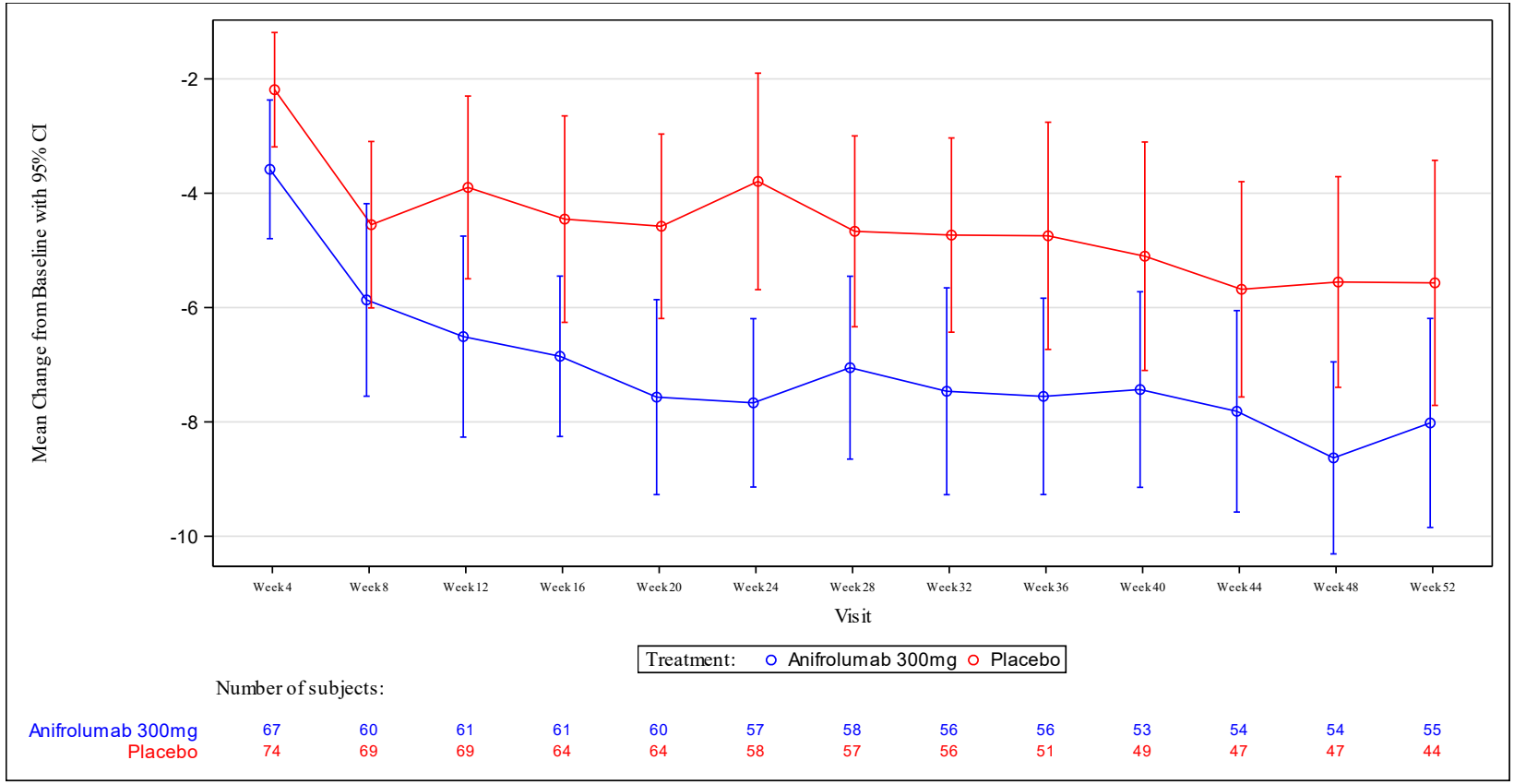
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - Tender Joint Count
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)				Placebo (N=75)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	69	11.43 (6.45)	0	-	75	9.85 (7.04)	0	-
Week 4	68	7.81 (6.75)	67	-3.58 (4.97)	74	7.61 (7.06)	74	-2.19 (4.32)
Week 8	64	5.52 (6.11)	60	-5.87 (6.52)	70	5.26 (6.05)	69	-4.55 (6.06)
Week 12	65	4.68 (6.25)	61	-6.51 (6.86)	69	5.55 (7.17)	69	-3.90 (6.65)
Week 16	66	4.27 (6.52)	61	-6.85 (5.48)	65	4.71 (7.42)	64	-4.45 (7.23)
Week 20	66	3.71 (6.05)	60	-7.57 (6.60)	66	4.58 (7.06)	64	-4.58 (6.46)
Week 24	63	3.57 (5.57)	57	-7.67 (5.55)	61	4.98 (7.28)	58	-3.79 (7.20)
Week 28	64	4.09 (6.79)	58	-7.05 (6.08)	59	4.41 (6.86)	57	-4.67 (6.29)
Week 32	62	3.69 (6.30)	56	-7.46 (6.76)	59	3.98 (6.52)	56	-4.73 (6.34)
Week 36	61	3.61 (6.27)	56	-7.55 (6.41)	56	3.45 (6.29)	51	-4.75 (7.06)
Week 40	61	3.66 (6.48)	53	-7.43 (6.21)	55	2.67 (4.90)	49	-5.10 (6.96)
Week 44	63	3.21 (6.06)	54	-7.81 (6.45)	52	2.33 (4.15)	47	-5.68 (6.41)
Week 48	61	2.72 (4.74)	54	-8.63 (6.15)	52	2.38 (4.09)	47	-5.55 (6.28)
Week 52	61	3.23 (5.50)	55	-8.02 (6.76)	49	2.55 (4.84)	44	-5.57 (7.05)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - Tender Joint Count
Full analysis set



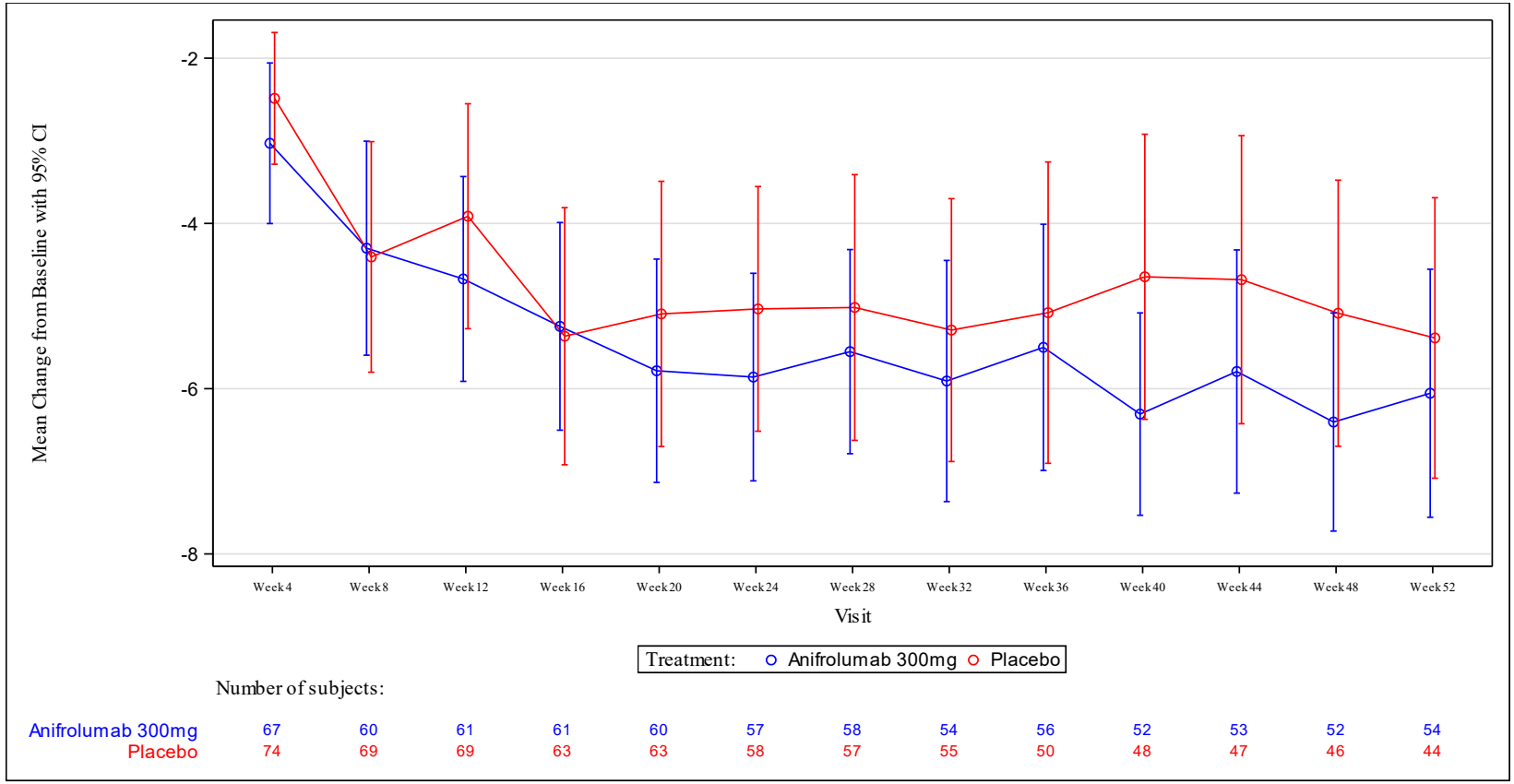
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - Swollen Joint Count
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)				Placebo (N=75)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	69	7.59 (5.10)	0	-	75	7.85 (6.18)	0	-
Week 4	68	4.38 (4.42)	67	-3.03 (3.98)	74	5.30 (5.64)	74	-2.49 (3.44)
Week 8	64	3.11 (4.02)	60	-4.30 (5.01)	70	3.20 (4.72)	69	-4.41 (5.81)
Week 12	65	2.72 (4.00)	61	-4.67 (4.84)	69	3.45 (5.21)	69	-3.91 (5.67)
Week 16	66	2.29 (3.59)	61	-5.25 (4.91)	65	2.08 (3.48)	63	-5.37 (6.18)
Week 20	66	1.80 (3.42)	60	-5.78 (5.23)	66	2.45 (4.74)	63	-5.10 (6.37)
Week 24	63	1.65 (3.30)	57	-5.86 (4.73)	61	2.44 (3.74)	58	-5.03 (5.63)
Week 28	64	2.00 (3.90)	58	-5.55 (4.70)	59	2.85 (5.63)	57	-5.02 (6.06)
Week 32	62	1.50 (2.81)	54	-5.91 (5.35)	59	2.15 (4.39)	55	-5.29 (5.88)
Week 36	61	2.10 (4.11)	56	-5.50 (5.56)	56	1.84 (4.22)	50	-5.08 (6.42)
Week 40	61	1.30 (2.49)	52	-6.31 (4.40)	55	1.89 (3.92)	48	-4.65 (5.94)
Week 44	63	1.60 (4.13)	53	-5.79 (5.34)	52	1.83 (4.09)	47	-4.68 (5.94)
Week 48	61	1.26 (2.89)	52	-6.40 (4.74)	52	1.81 (3.61)	46	-5.09 (5.42)
Week 52	61	1.52 (4.04)	54	-6.06 (5.50)	49	1.24 (2.83)	44	-5.39 (5.58)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - Swollen Joint Count
Full analysis set



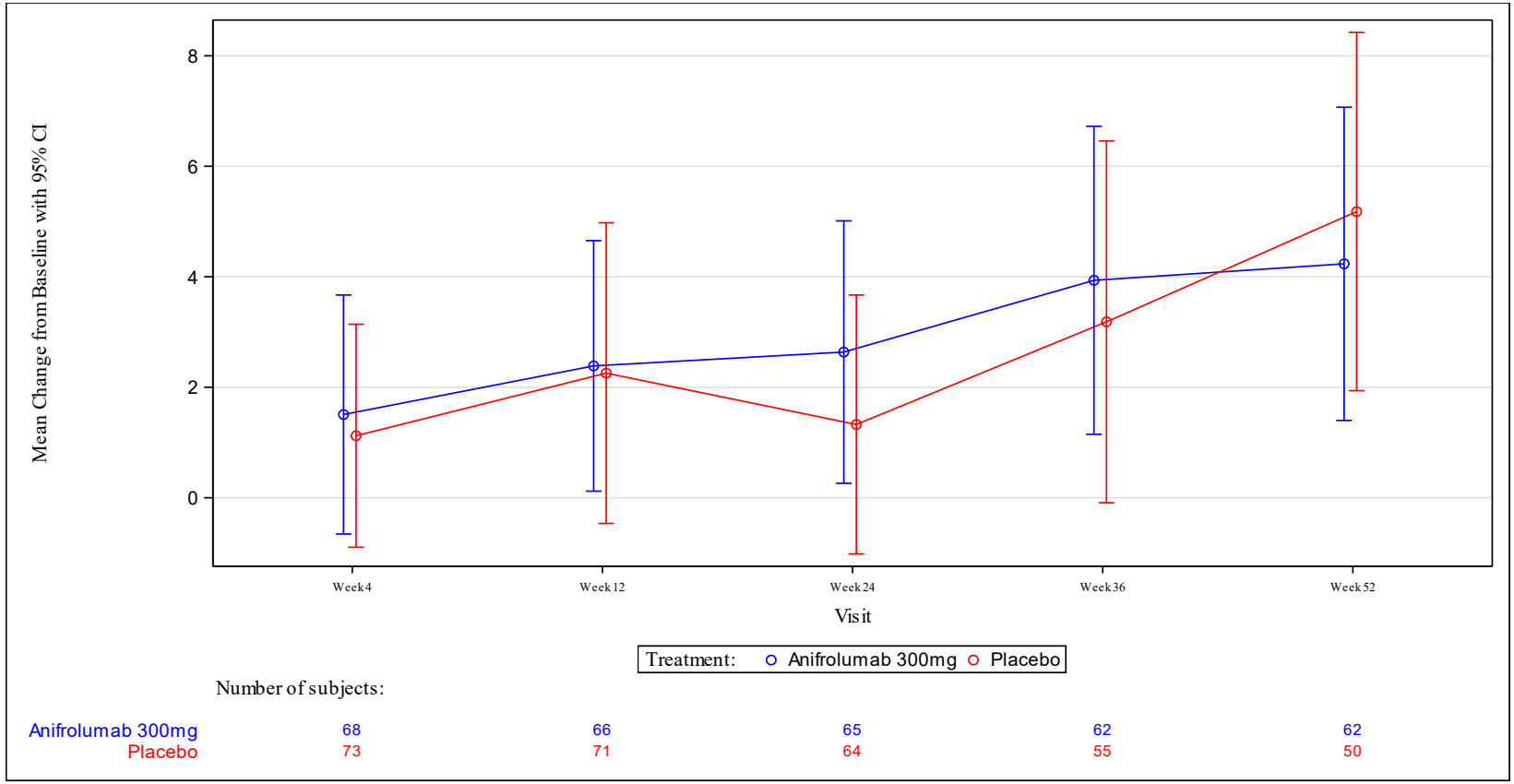
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Mental Component Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)				Placebo (N=75)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	69	37.99 (11.25)	0	-	75	37.66 (12.56)	0	-
Week 4	68	39.27 (11.58)	68	1.51 (8.94)	73	39.19 (11.66)	73	1.12 (8.65)
Week 12	66	40.15 (12.09)	66	2.39 (9.22)	71	40.04 (12.77)	71	2.26 (11.50)
Week 24	65	39.90 (11.39)	65	2.64 (9.58)	64	39.62 (11.37)	64	1.33 (9.38)
Week 36	62	42.12 (10.40)	62	3.94 (10.98)	55	42.78 (11.98)	55	3.18 (12.11)
Week 52	62	42.34 (10.41)	62	4.23 (11.16)	50	43.86 (11.72)	50	5.18 (11.41)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Mental Component Score
Full analysis set



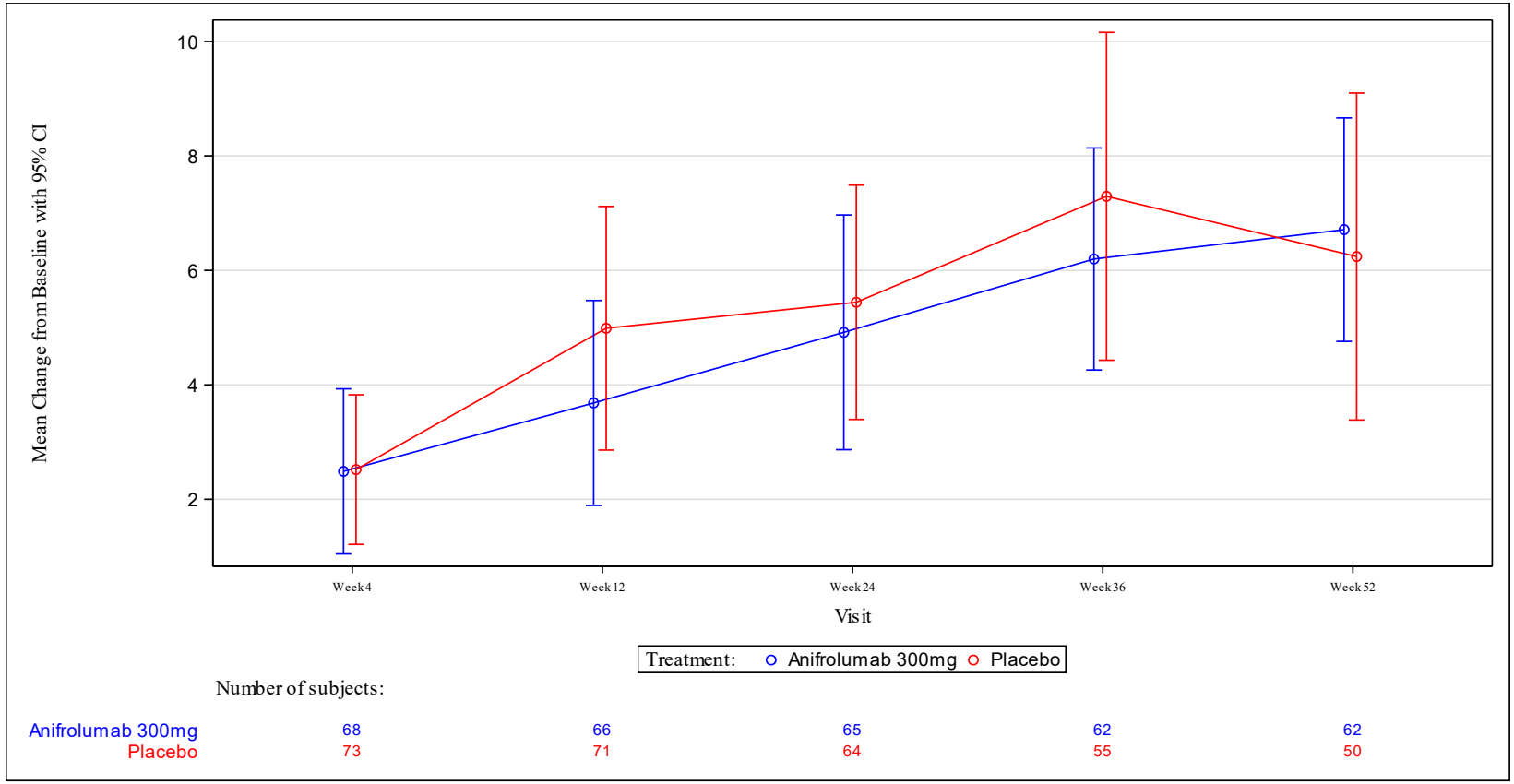
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Physical Component Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)				Placebo (N=75)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	69	35.21 (8.93)	0	-	75	35.29 (11.12)	0	-
Week 4	68	37.88 (8.13)	68	2.49 (5.96)	73	37.81 (10.21)	73	2.52 (5.60)
Week 12	66	39.38 (8.86)	66	3.68 (7.28)	71	40.25 (11.70)	71	4.99 (8.99)
Week 24	65	40.60 (8.97)	65	4.92 (8.27)	64	41.16 (12.22)	64	5.44 (8.19)
Week 36	62	41.67 (10.02)	62	6.20 (7.64)	55	43.60 (11.31)	55	7.29 (10.59)
Week 52	62	42.16 (9.28)	62	6.71 (7.69)	50	43.06 (11.73)	50	6.24 (10.05)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Physical Component Score
Full analysis set



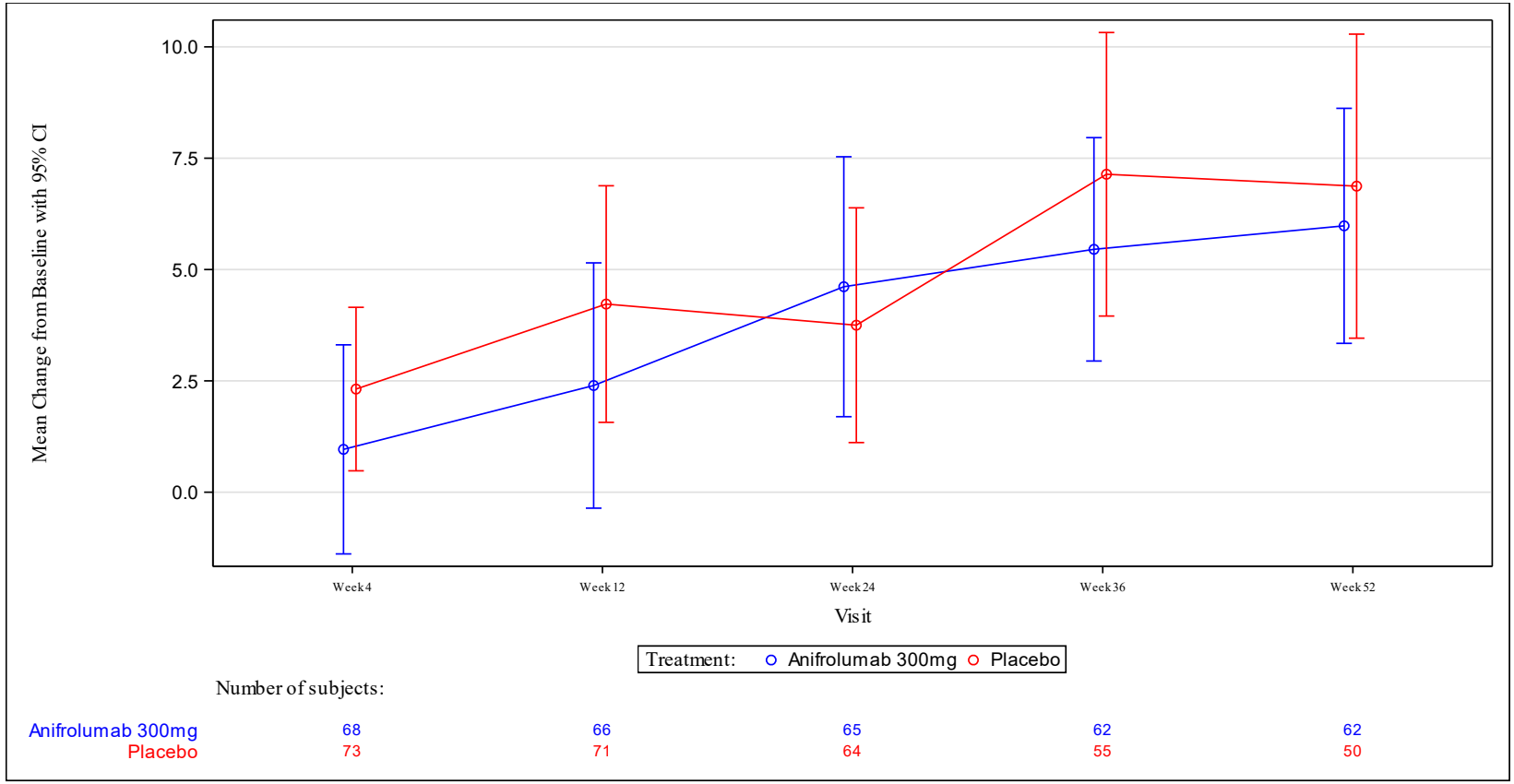
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - SF-36 v2.0 Acute General Health Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)				Placebo (N=75)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	69	35.51 (11.56)	0	-	75	34.45 (12.05)	0	-
Week 4	68	36.48 (11.05)	68	0.96 (9.70)	73	37.13 (11.56)	73	2.32 (7.87)
Week 12	66	38.01 (10.87)	66	2.40 (11.20)	71	38.49 (12.17)	71	4.22 (11.22)
Week 24	65	39.82 (11.10)	65	4.61 (11.78)	64	38.53 (12.15)	64	3.75 (10.55)
Week 36	62	41.46 (10.93)	62	5.45 (9.88)	55	42.97 (11.05)	55	7.14 (11.78)
Week 52	62	41.54 (10.44)	62	5.98 (10.39)	50	42.02 (11.61)	50	6.87 (12.01)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - SF-36 v2.0 Acute General Health Score
Full analysis set



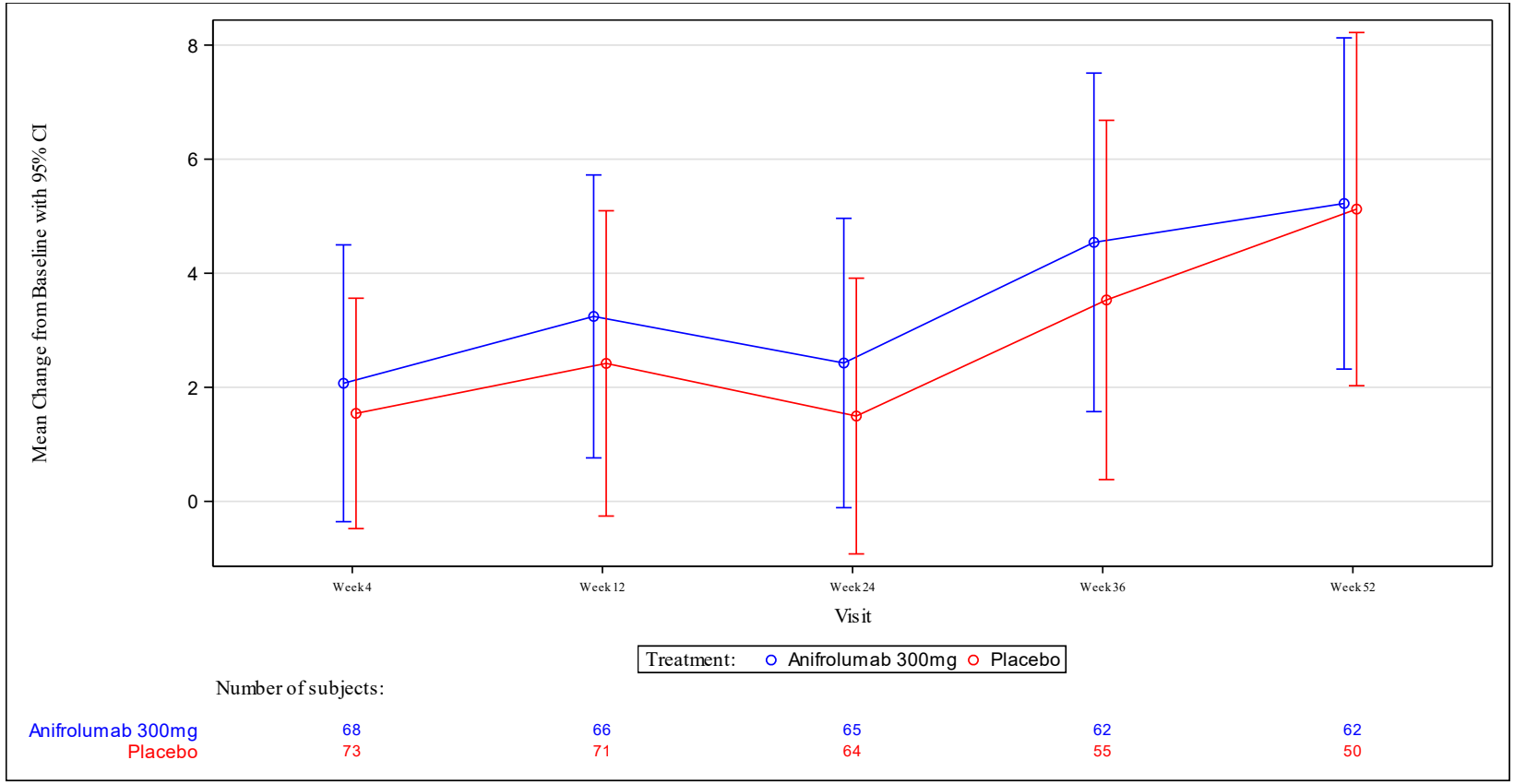
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Mental Health Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)				Placebo (N=75)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	69	38.01 (11.64)	0	-	75	38.14 (12.35)	0	-
Week 4	68	39.90 (11.76)	68	2.07 (10.03)	73	39.98 (11.28)	73	1.54 (8.65)
Week 12	66	41.01 (11.71)	66	3.24 (10.09)	71	40.77 (12.69)	71	2.42 (11.31)
Week 24	65	39.91 (11.81)	65	2.43 (10.24)	64	40.37 (11.48)	64	1.50 (9.68)
Week 36	62	42.47 (10.35)	62	4.54 (11.69)	55	43.61 (11.55)	55	3.53 (11.65)
Week 52	62	43.38 (10.31)	62	5.22 (11.43)	50	44.60 (10.99)	50	5.12 (10.90)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Mental Health Score
Full analysis set



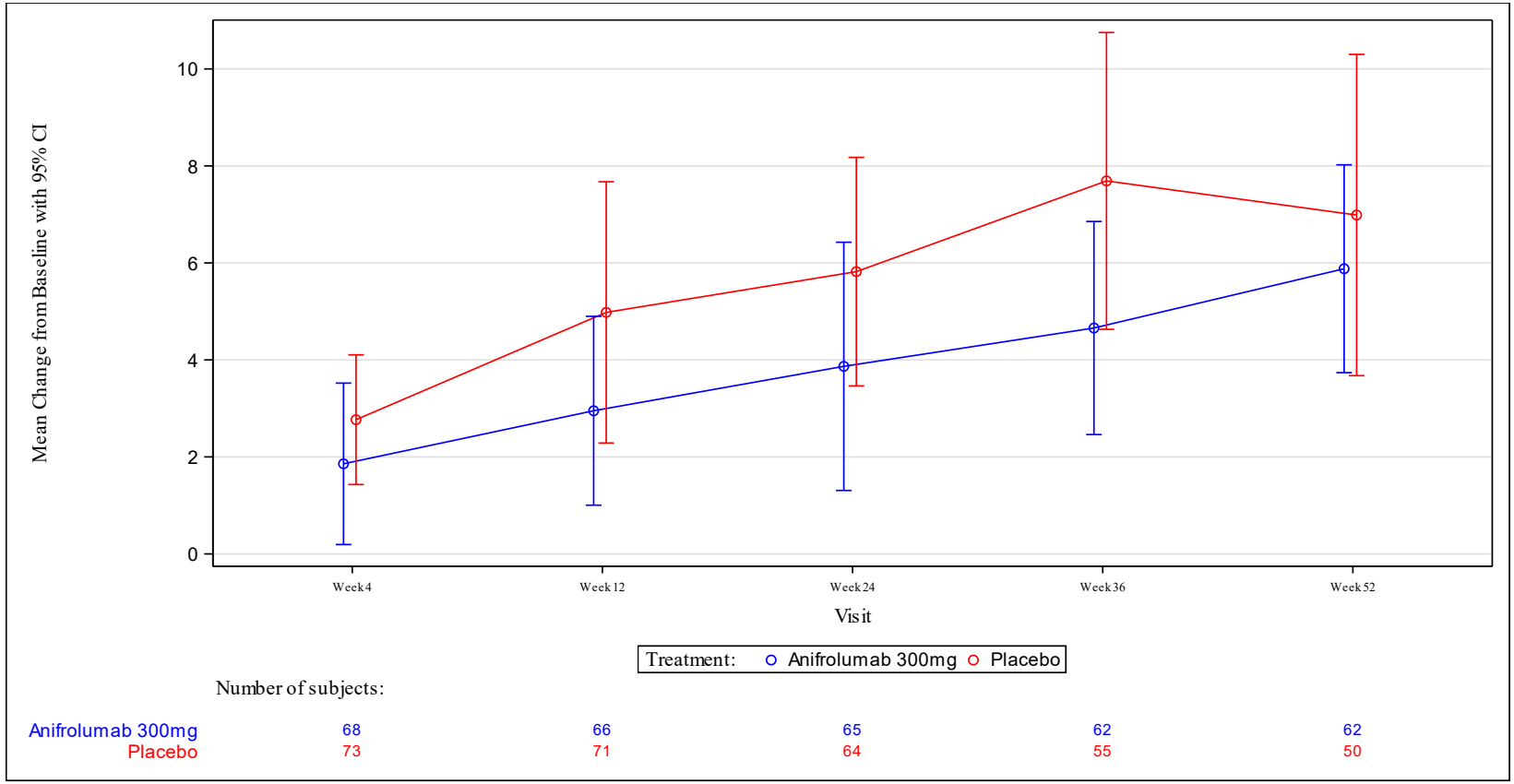
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Physical Functioning Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)				Placebo (N=75)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	69	35.86 (10.95)	0	-	75	34.00 (12.25)	0	-
Week 4	68	37.78 (10.20)	68	1.86 (6.87)	73	36.77 (12.23)	73	2.77 (5.73)
Week 12	66	39.09 (10.07)	66	2.95 (7.92)	71	39.10 (12.29)	71	4.98 (11.38)
Week 24	65	40.34 (10.65)	65	3.87 (10.33)	64	40.43 (12.65)	64	5.82 (9.43)
Week 36	62	40.94 (11.48)	62	4.66 (8.65)	55	42.87 (11.49)	55	7.69 (11.32)
Week 52	62	42.27 (9.92)	62	5.88 (8.44)	50	43.02 (11.61)	50	6.99 (11.65)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Physical Functioning Score
Full analysis set



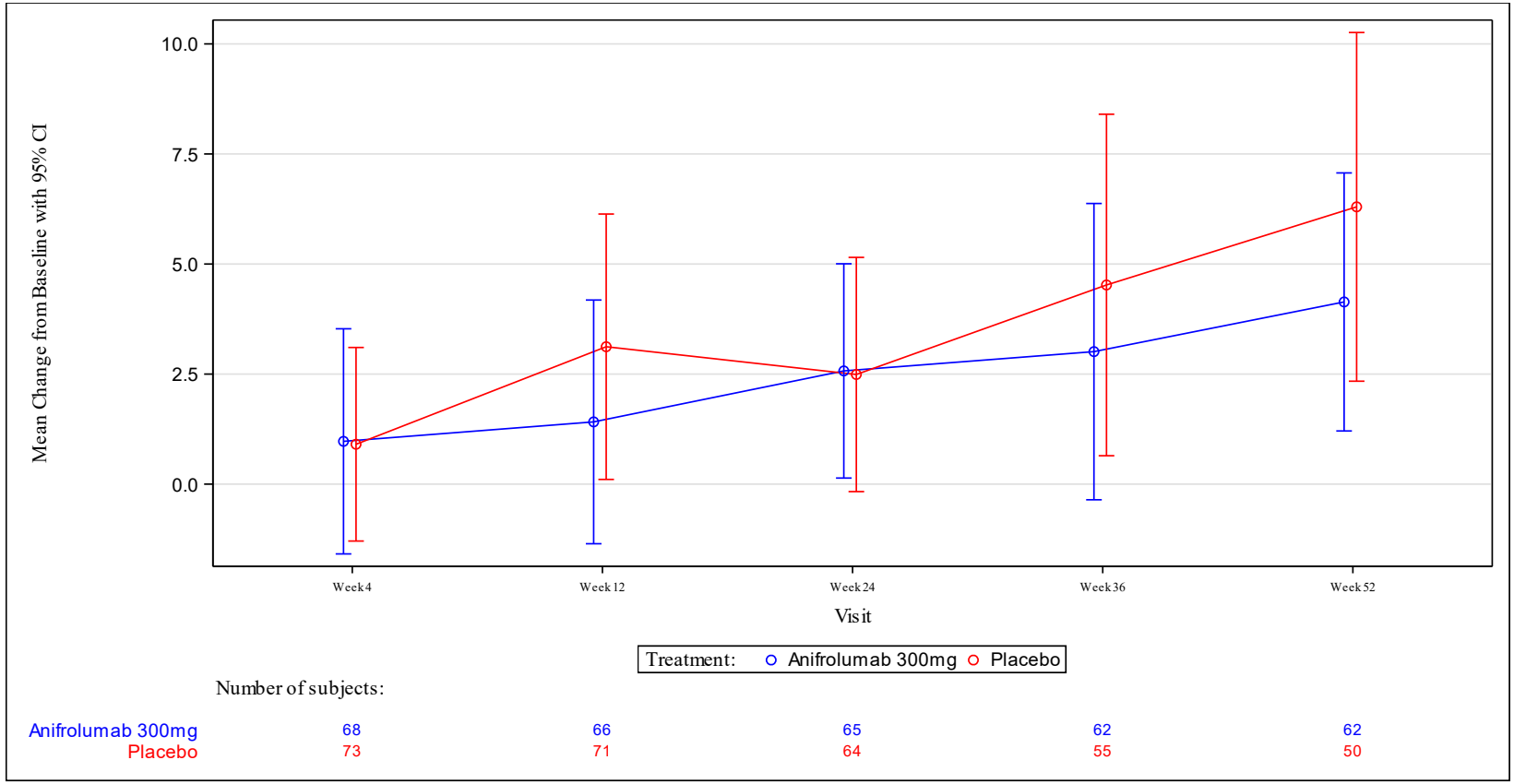
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Role Emotional Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)				Placebo (N=75)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	69	35.49 (12.12)	0	-	75	33.80 (12.91)	0	-
Week 4	68	36.16 (12.75)	68	0.97 (10.56)	73	35.01 (13.13)	73	0.91 (9.42)
Week 12	66	36.74 (12.98)	66	1.41 (11.26)	71	37.32 (13.31)	71	3.12 (12.73)
Week 24	65	37.58 (12.61)	65	2.57 (9.82)	64	37.17 (13.16)	64	2.49 (10.65)
Week 36	62	38.95 (12.63)	62	3.01 (13.25)	55	40.12 (13.20)	55	4.52 (14.35)
Week 52	62	39.83 (11.60)	62	4.14 (11.54)	50	41.89 (12.42)	50	6.30 (13.94)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Role Emotional Score
Full analysis set



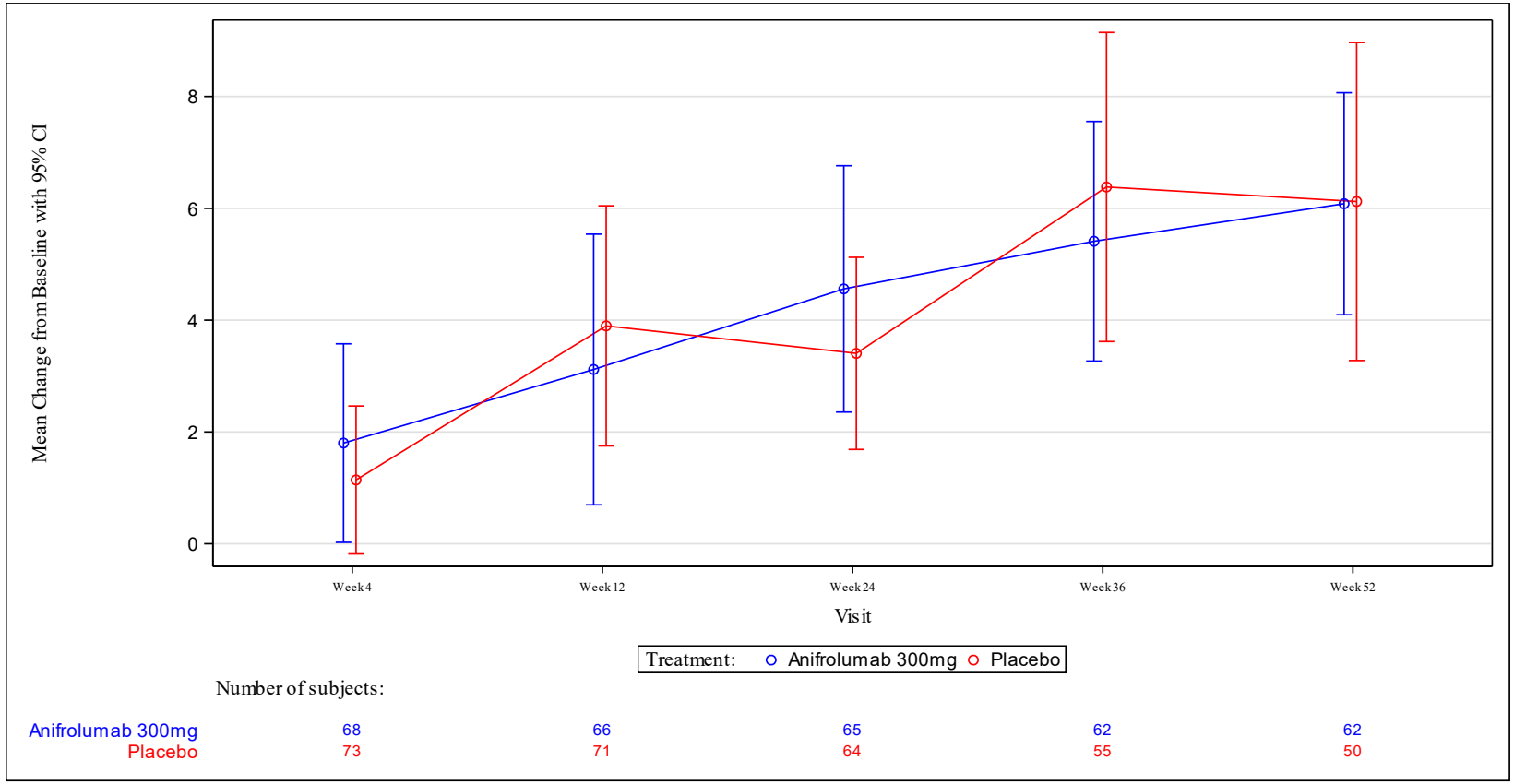
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Role Physical Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)				Placebo (N=75)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	69	34.78 (9.70)	0	-	75	34.32 (10.52)	0	-
Week 4	68	36.69 (9.67)	68	1.80 (7.34)	73	35.62 (9.81)	73	1.14 (5.67)
Week 12	66	38.41 (10.19)	66	3.12 (9.85)	71	38.40 (11.27)	71	3.90 (9.07)
Week 24	65	39.63 (10.29)	65	4.56 (8.89)	64	38.18 (11.26)	64	3.41 (6.88)
Week 36	62	40.82 (10.47)	62	5.41 (8.44)	55	42.31 (10.38)	55	6.38 (10.23)
Week 52	62	41.13 (9.97)	62	6.08 (7.82)	50	42.21 (11.21)	50	6.12 (10.01)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Role Physical Score
Full analysis set



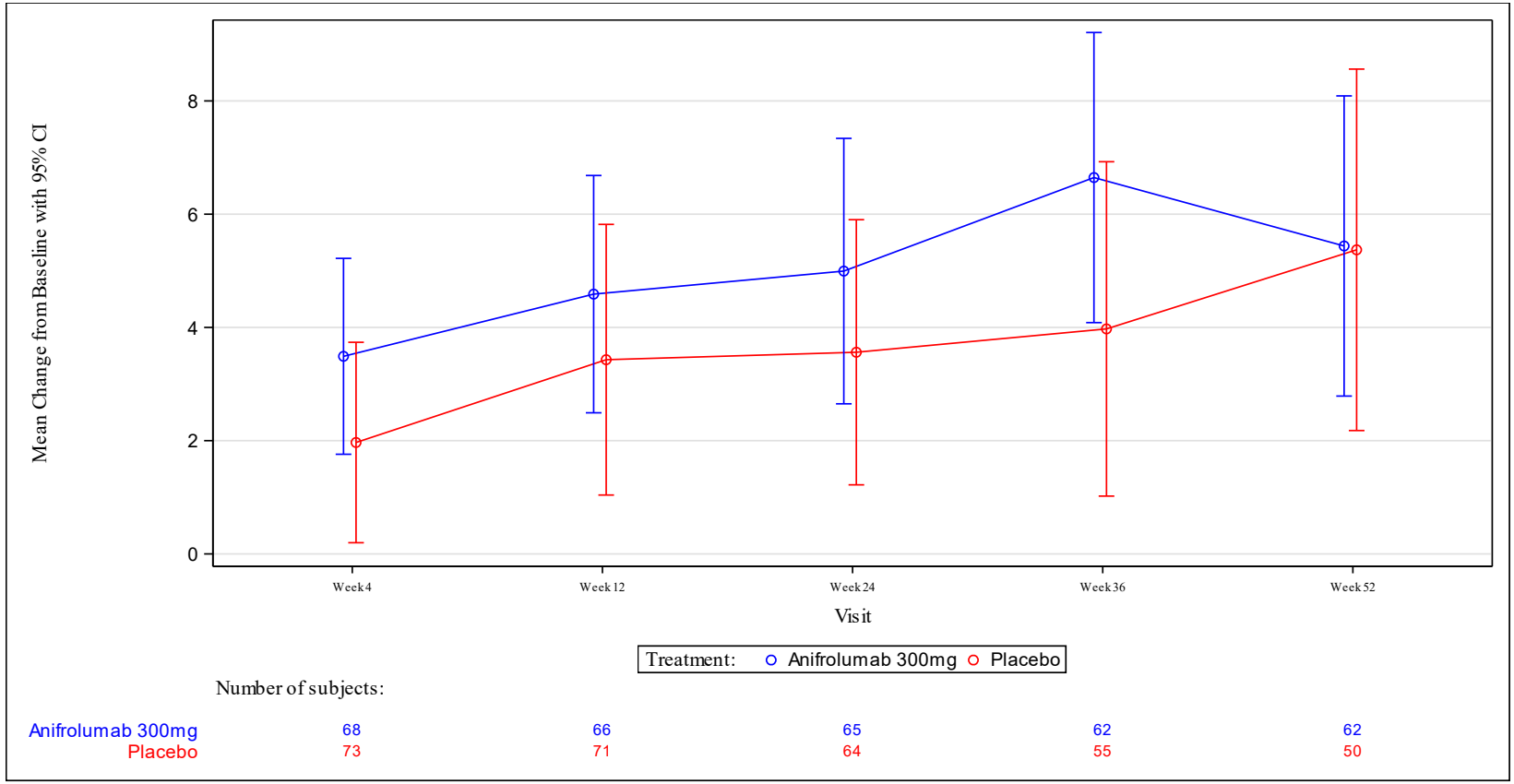
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Social Functioning Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)				Placebo (N=75)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	69	38.52 (10.44)	0	-	75	39.52 (11.96)	0	-
Week 4	68	42.08 (10.51)	68	3.49 (7.15)	73	41.78 (10.97)	73	1.97 (7.59)
Week 12	66	43.48 (10.84)	66	4.59 (8.52)	71	42.72 (13.17)	71	3.43 (10.10)
Week 24	65	43.40 (10.75)	65	4.99 (9.46)	64	43.36 (12.50)	64	3.56 (9.37)
Week 36	62	45.54 (11.73)	62	6.65 (10.09)	55	45.39 (12.35)	55	3.97 (10.92)
Week 52	62	44.44 (12.08)	62	5.44 (10.44)	50	45.85 (13.67)	50	5.37 (11.23)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Social Functioning Score
Full analysis set



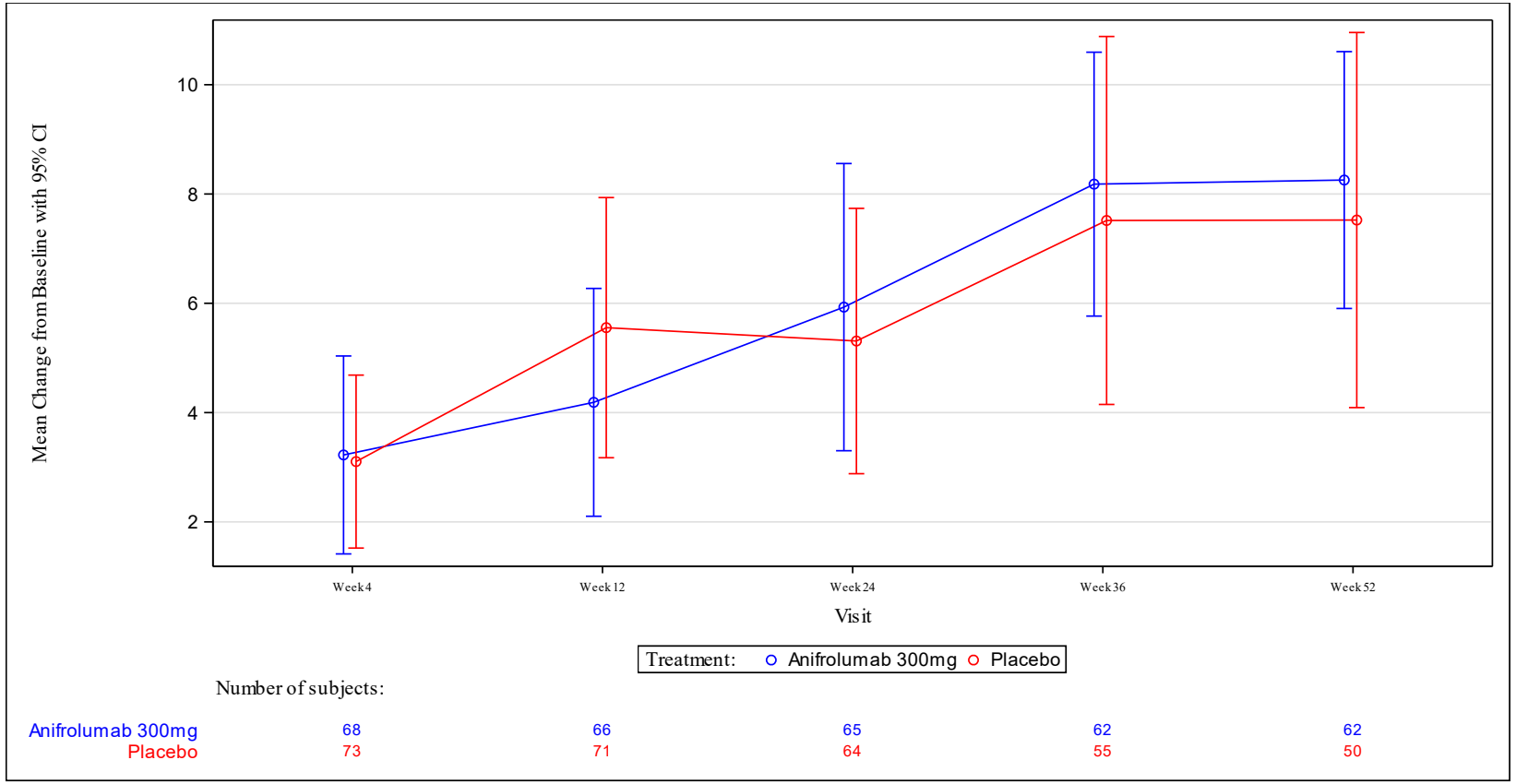
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Bodily Pain Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)				Placebo (N=75)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	69	36.62 (8.37)	0	-	75	37.24 (10.33)	0	-
Week 4	68	39.84 (8.69)	68	3.23 (7.48)	73	40.51 (10.16)	73	3.10 (6.78)
Week 12	66	40.97 (9.00)	66	4.19 (8.48)	71	42.78 (12.01)	71	5.55 (10.06)
Week 24	65	42.36 (11.14)	65	5.93 (10.60)	64	43.17 (12.29)	64	5.31 (9.72)
Week 36	62	44.90 (11.00)	62	8.18 (9.51)	55	45.84 (11.56)	55	7.52 (12.45)
Week 52	62	45.00 (10.77)	62	8.26 (9.25)	50	45.95 (11.57)	50	7.52 (12.08)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Bodily Pain Score
Full analysis set



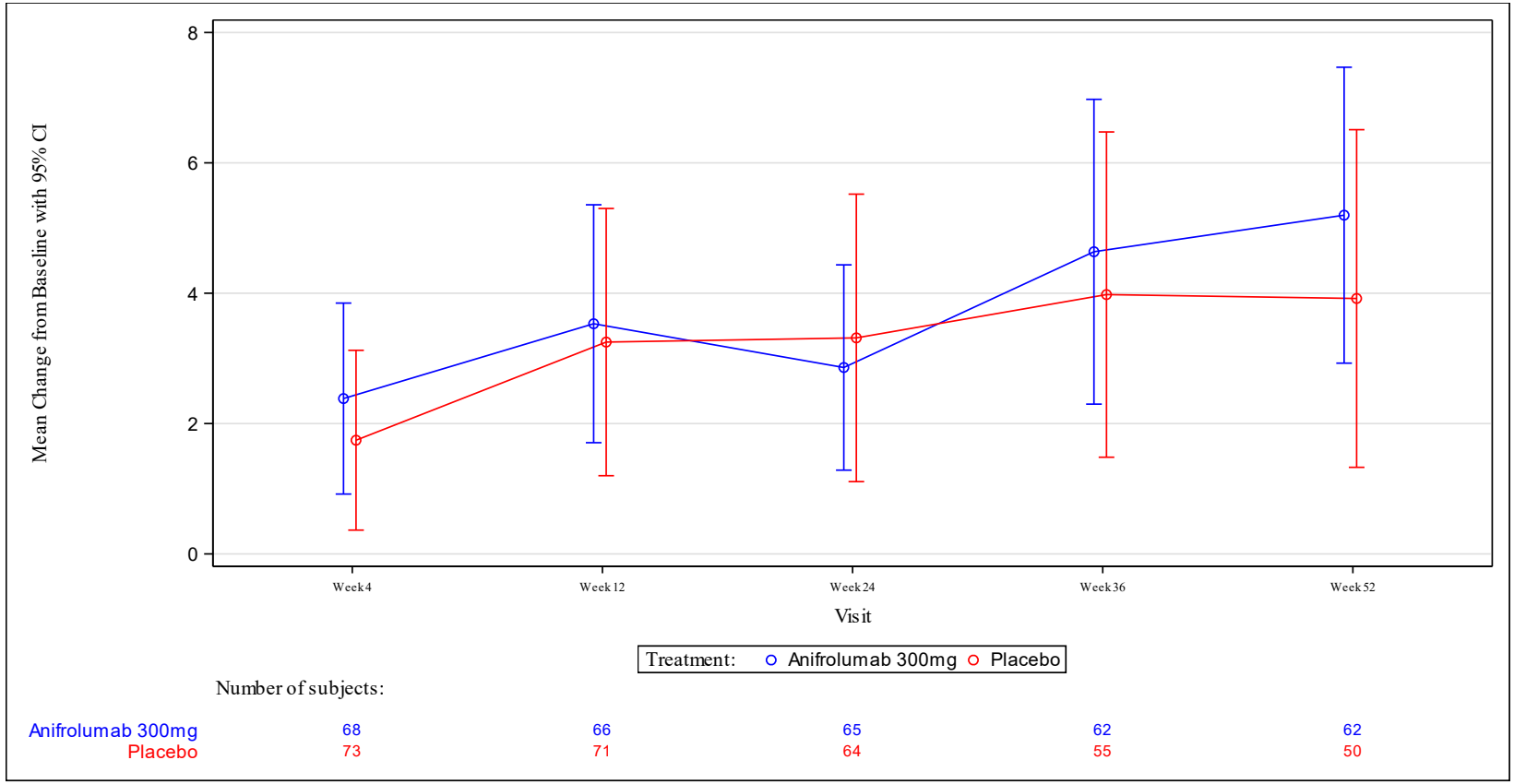
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Vitality Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)				Placebo (N=75)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	69	32.33 (8.18)	0	-	75	34.31 (9.57)	0	-
Week 4	68	34.77 (8.51)	68	2.38 (6.05)	73	36.13 (9.87)	73	1.74 (5.91)
Week 12	66	36.01 (9.38)	66	3.53 (7.42)	71	37.53 (10.68)	71	3.25 (8.66)
Week 24	65	35.03 (8.61)	65	2.86 (6.36)	64	38.21 (11.22)	64	3.31 (8.83)
Week 36	62	36.50 (9.58)	62	4.64 (9.21)	55	39.63 (10.40)	55	3.98 (9.23)
Week 52	62	37.27 (10.57)	62	5.20 (8.94)	50	39.40 (10.29)	50	3.92 (9.11)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Vitality Score
Full analysis set



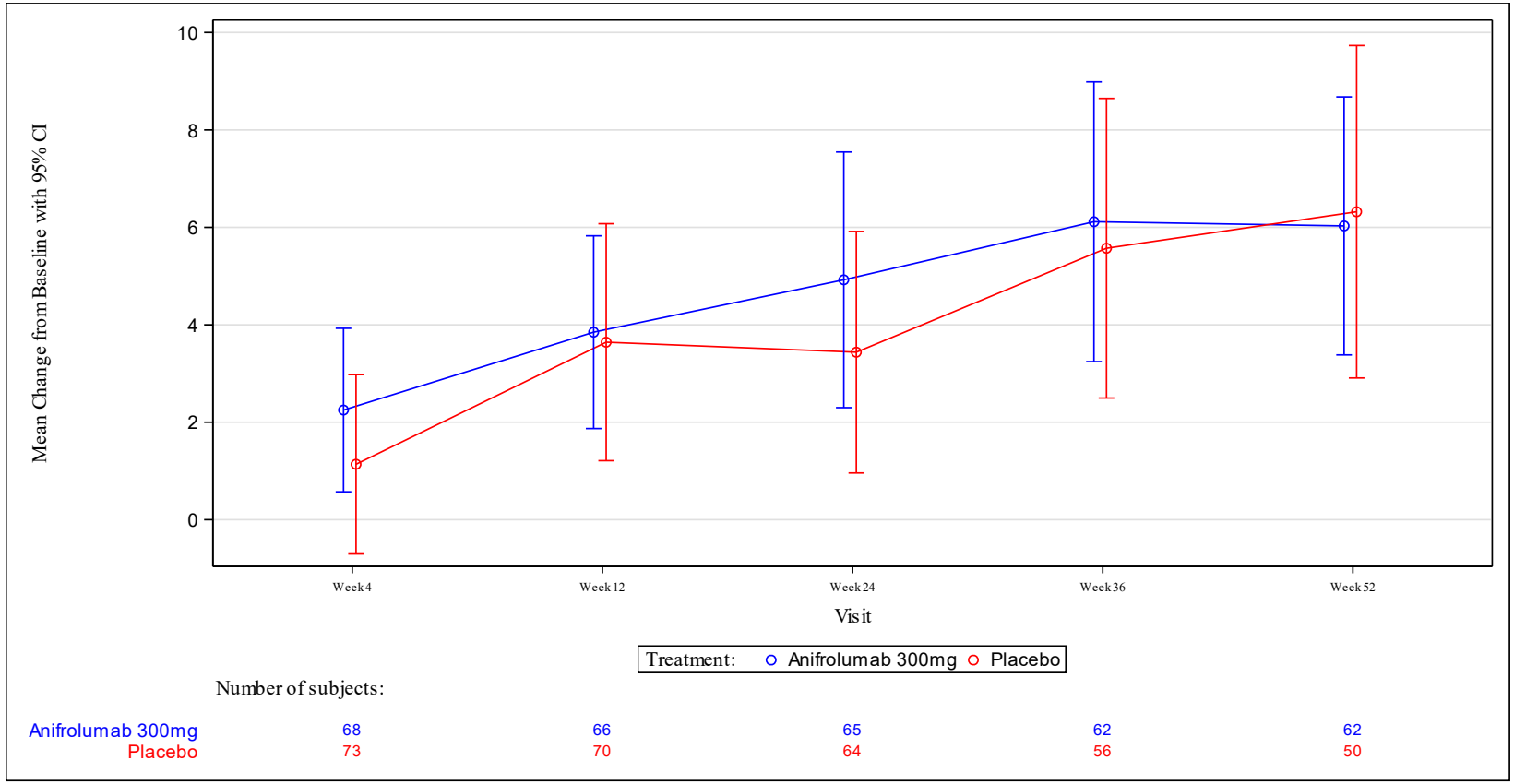
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - FACIT-F Total Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)				Placebo (N=75)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	69	26.09 (11.54)	0	-	75	26.24 (13.41)	0	-
Week 4	68	28.40 (11.91)	68	2.25 (6.93)	73	27.75 (13.35)	73	1.14 (7.89)
Week 12	66	30.42 (12.56)	66	3.85 (8.05)	70	29.89 (14.02)	70	3.64 (10.20)
Week 24	65	31.03 (13.14)	65	4.92 (10.59)	64	29.94 (14.66)	64	3.44 (9.92)
Week 36	62	32.45 (12.88)	62	6.12 (11.31)	56	33.50 (14.07)	56	5.57 (11.48)
Week 52	62	32.45 (12.83)	62	6.03 (10.43)	50	34.06 (13.86)	50	6.32 (12.01)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - FACIT-F Total Score
Full analysis set



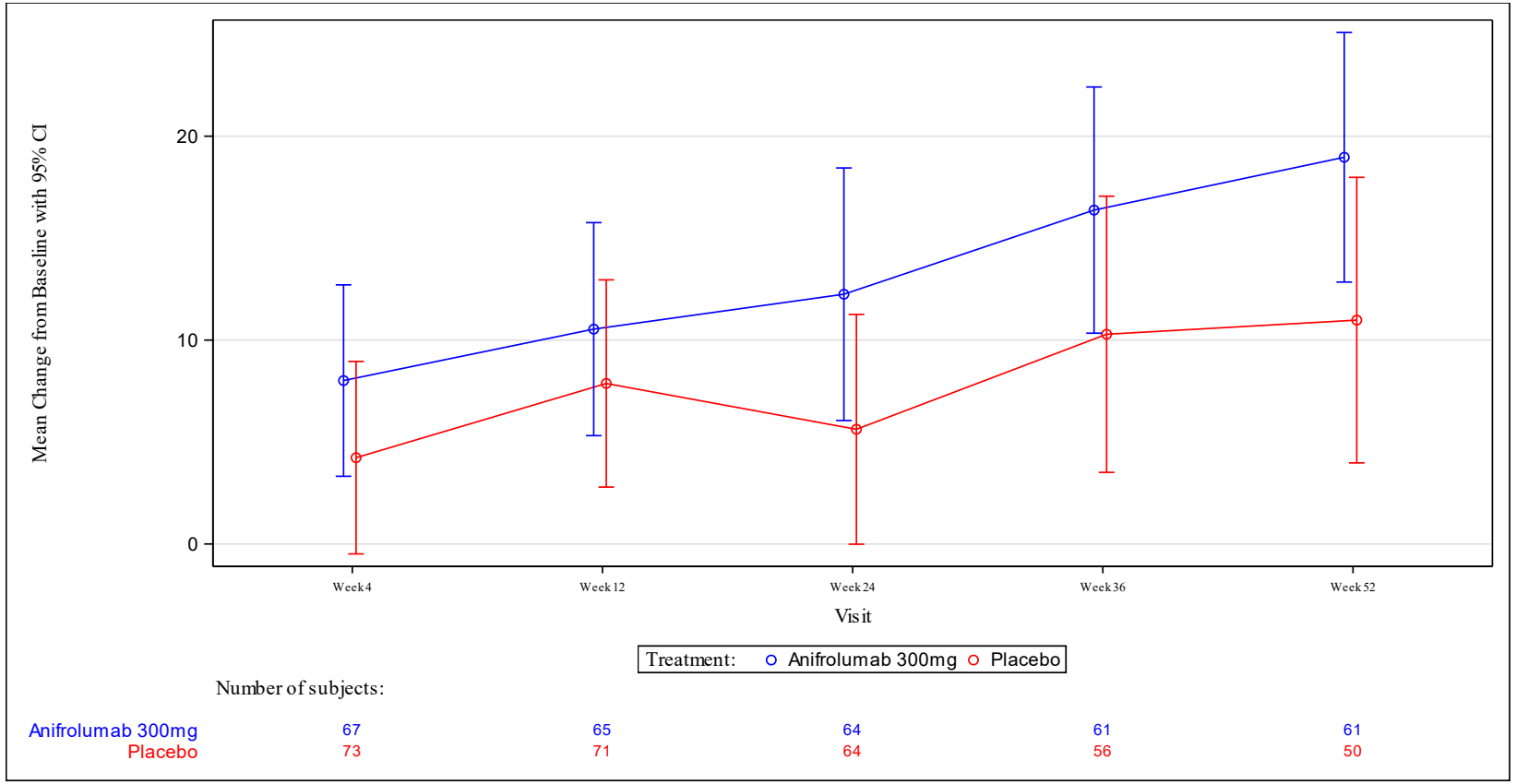
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - EQ VAS Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)				Placebo (N=75)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	68	51.00 (20.72)	0	-	75	56.63 (20.41)	0	-
Week 4	68	59.74 (19.44)	67	8.01 (19.24)	73	61.25 (19.67)	73	4.23 (20.23)
Week 12	66	61.67 (19.95)	65	10.54 (21.08)	71	63.89 (21.65)	71	7.87 (21.47)
Week 24	65	63.69 (22.04)	64	12.25 (24.79)	64	61.91 (23.89)	64	5.63 (22.56)
Week 36	62	67.56 (20.89)	61	16.38 (23.58)	56	68.23 (21.67)	56	10.29 (25.29)
Week 52	62	70.29 (20.67)	61	18.97 (23.89)	50	69.26 (21.47)	50	10.98 (24.64)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - EQ VAS Score
Full analysis set



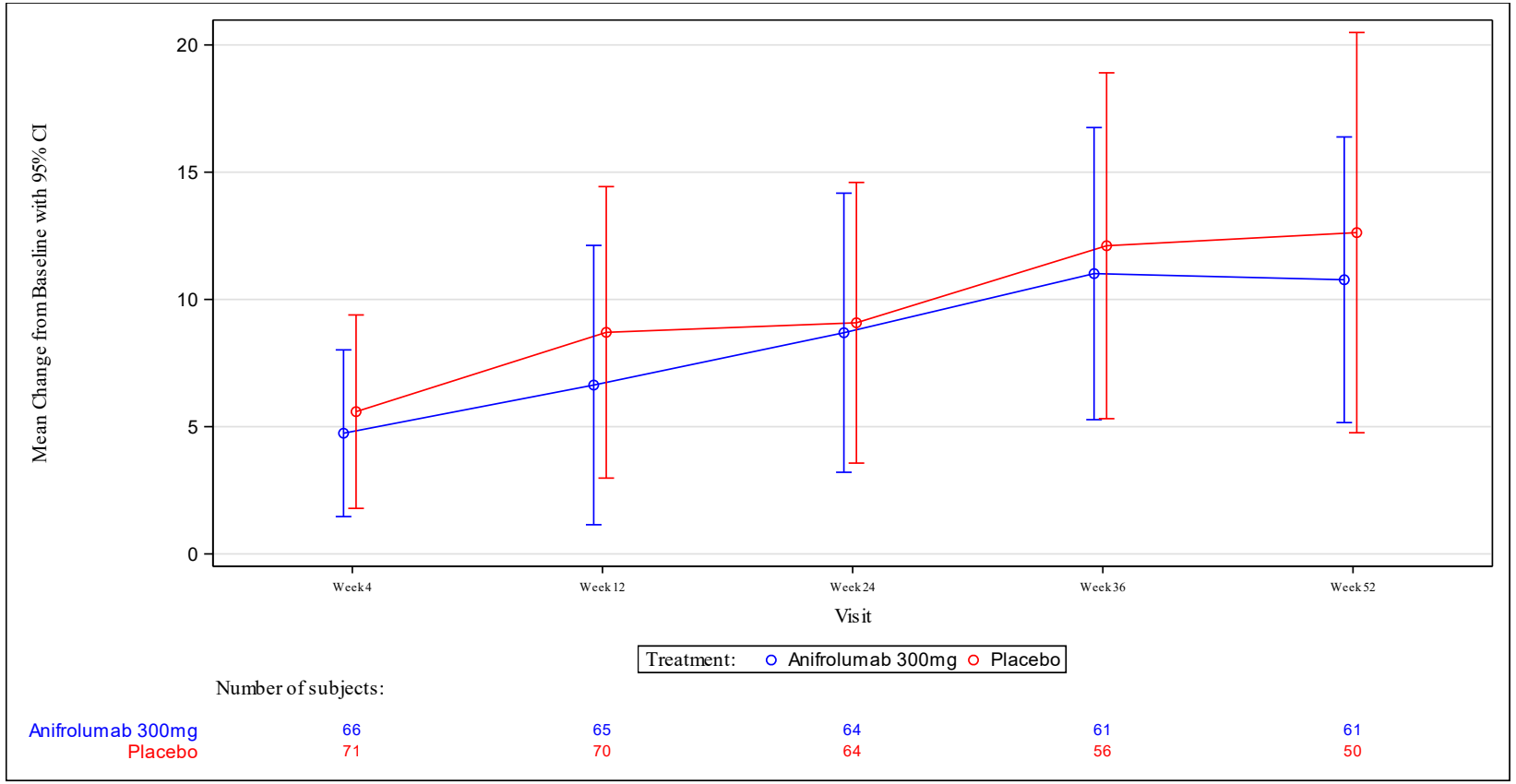
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - Lupus QoL Physical Health domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)				Placebo (N=75)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	68	57.22 (26.10)	0	-	74	53.42 (28.11)	0	-
Week 4	67	62.32 (25.99)	66	4.74 (13.32)	72	59.03 (24.83)	71	5.59 (16.06)
Week 12	66	64.44 (25.27)	65	6.63 (22.15)	71	61.93 (27.78)	70	8.71 (24.02)
Week 24	65	66.20 (25.01)	64	8.69 (21.95)	64	62.89 (28.57)	64	9.08 (22.07)
Week 36	62	68.75 (26.22)	61	11.01 (22.41)	56	68.81 (27.11)	56	12.11 (25.37)
Week 52	62	68.56 (25.66)	61	10.77 (21.91)	50	69.44 (26.48)	50	12.63 (27.67)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - Lupus QoL Physical Health domain score
Full analysis set



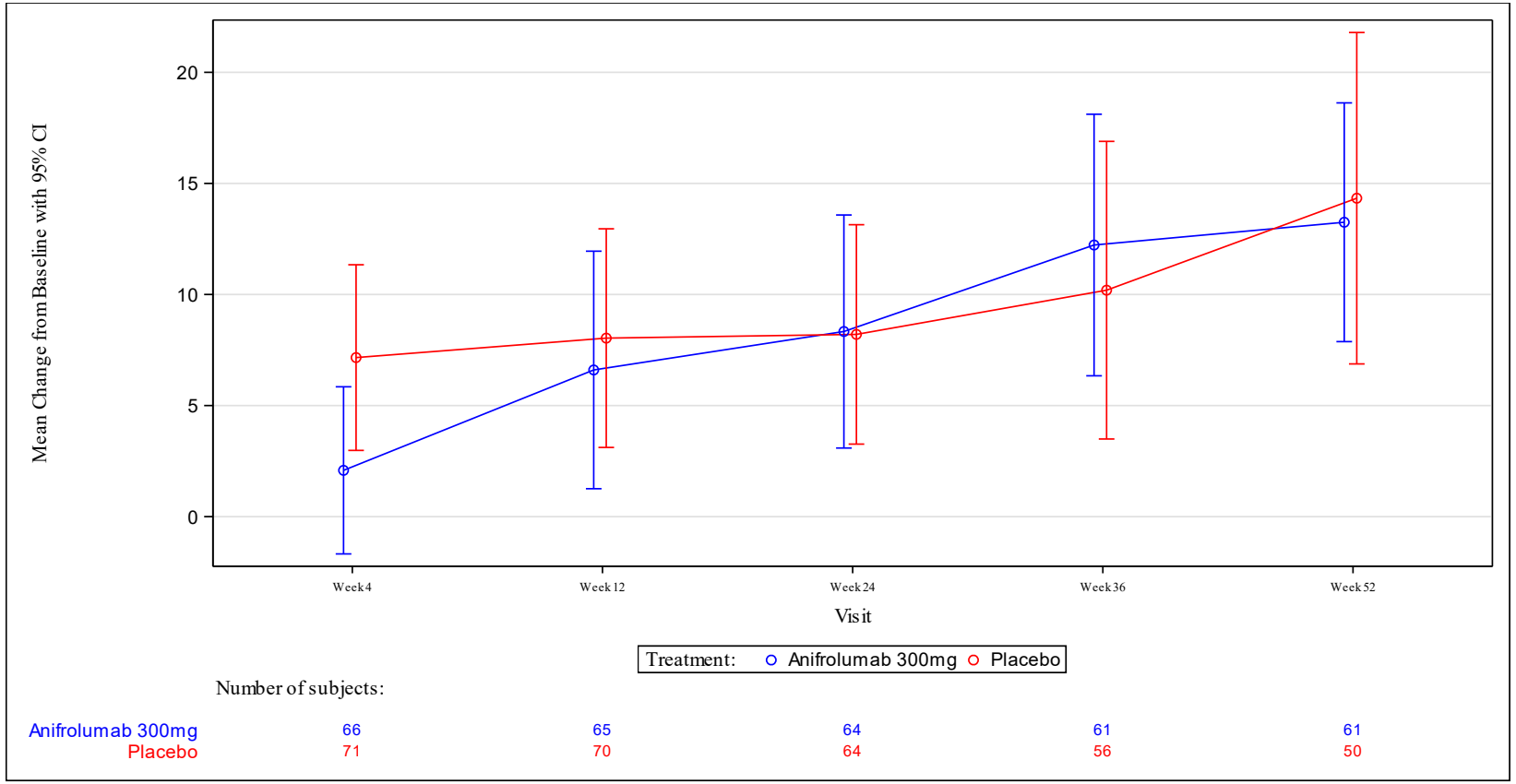
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - Lupus QoL Emotional Health domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)				Placebo (N=75)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	68	59.31 (23.81)	0	-	74	59.01 (28.25)	0	-
Week 4	67	61.38 (23.94)	66	2.08 (15.30)	72	66.09 (25.52)	71	7.16 (17.65)
Week 12	66	65.34 (21.99)	65	6.60 (21.57)	71	67.72 (25.93)	70	8.04 (20.64)
Week 24	65	66.35 (23.12)	64	8.33 (21.00)	64	69.47 (24.38)	64	8.20 (19.77)
Week 36	62	70.77 (22.64)	61	12.23 (22.98)	56	72.92 (22.36)	56	10.19 (25.01)
Week 52	62	72.31 (18.79)	61	13.25 (20.98)	50	76.17 (22.70)	50	14.33 (26.25)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - Lupus QoL Emotional Health domain score
Full analysis set



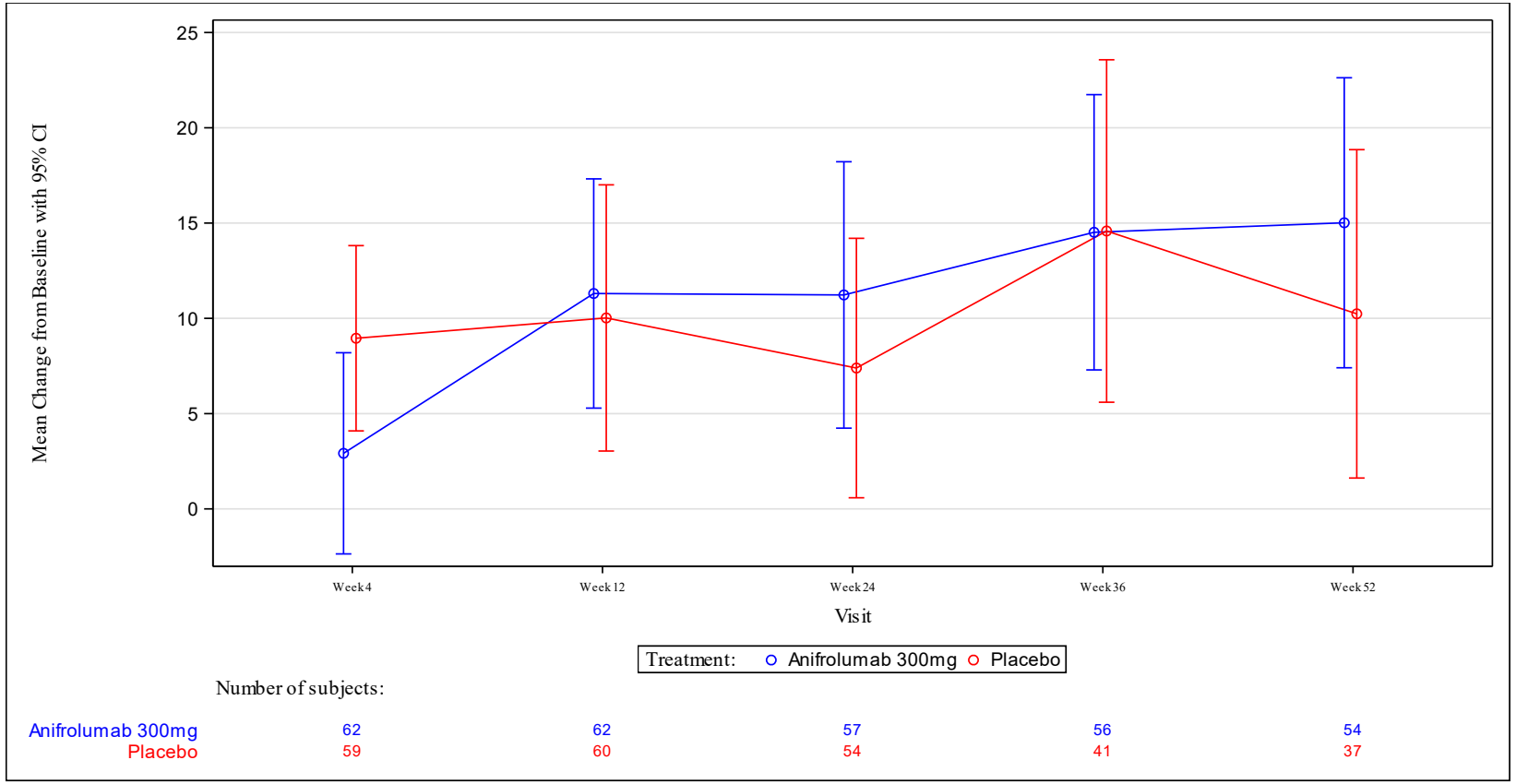
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - Lupus QoL Body Image domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)				Placebo (N=75)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	66	53.62 (31.01)	0	-	66	55.03 (29.02)	0	-
Week 4	65	56.76 (30.66)	62	2.92 (20.79)	63	63.94 (28.20)	59	8.95 (18.66)
Week 12	65	66.10 (26.43)	62	11.30 (23.68)	65	67.09 (26.93)	60	10.02 (27.04)
Week 24	59	63.14 (28.10)	57	11.23 (26.34)	58	63.64 (31.74)	54	7.39 (24.94)
Week 36	59	66.90 (29.00)	56	14.52 (26.97)	45	69.97 (27.35)	41	14.58 (28.47)
Week 52	57	68.03 (26.77)	54	15.02 (27.88)	39	65.25 (31.83)	37	10.24 (25.84)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - Lupus QoL Body Image domain score
Full analysis set



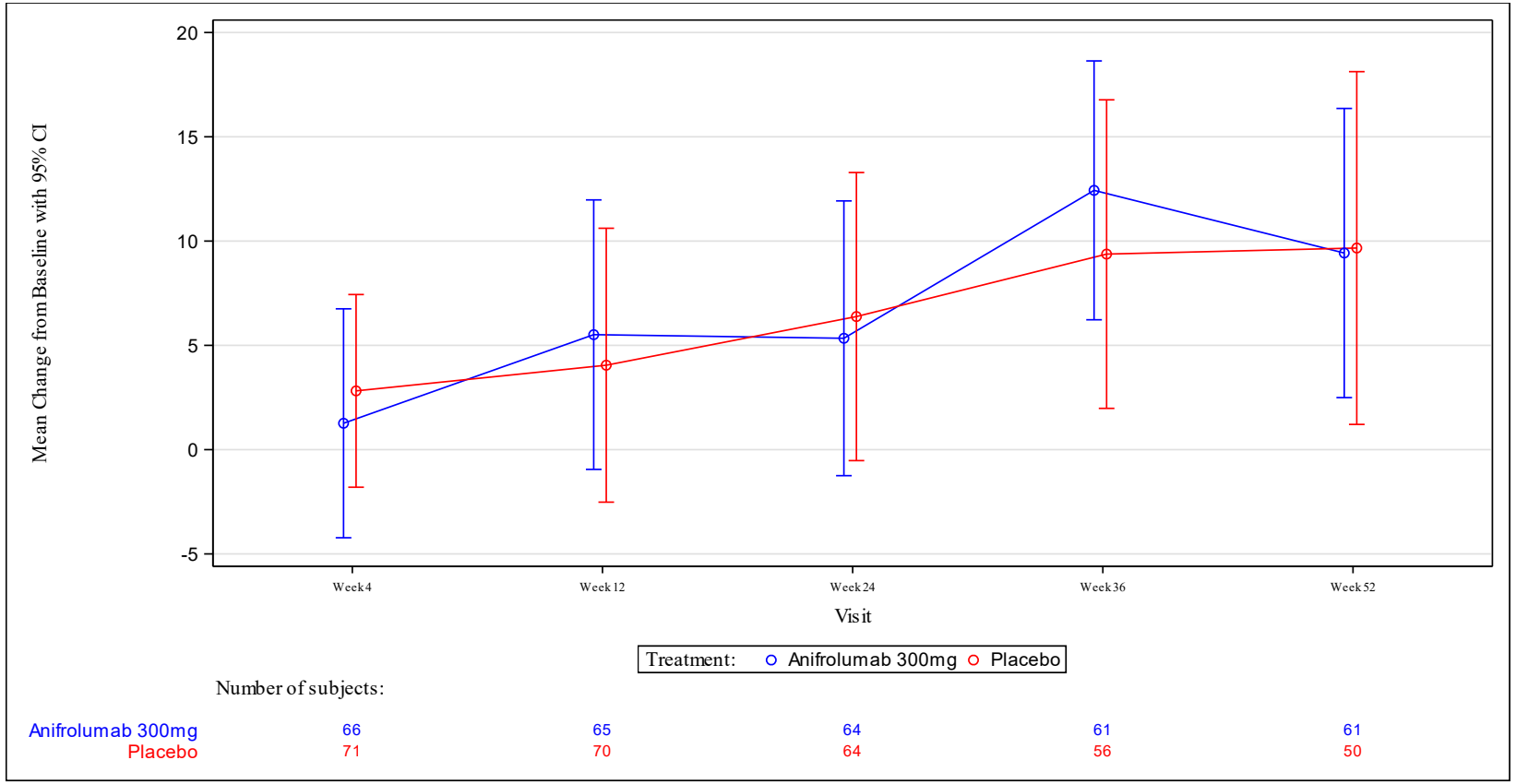
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - Lupus QoL Burden to Others domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)				Placebo (N=75)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	68	48.65 (29.10)	0	-	74	50.90 (31.68)	0	-
Week 4	67	50.25 (29.66)	66	1.26 (22.32)	72	52.55 (31.82)	71	2.82 (19.52)
Week 12	66	54.80 (31.15)	65	5.51 (26.07)	71	54.34 (32.39)	70	4.05 (27.54)
Week 24	65	54.62 (31.77)	64	5.34 (26.37)	64	58.20 (31.27)	64	6.38 (27.65)
Week 36	62	61.96 (30.24)	61	12.43 (24.23)	56	63.39 (30.30)	56	9.38 (27.62)
Week 52	62	60.35 (30.32)	61	9.43 (27.07)	50	61.50 (32.03)	50	9.67 (29.76)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - Lupus QoL Burden to Others domain score
Full analysis set



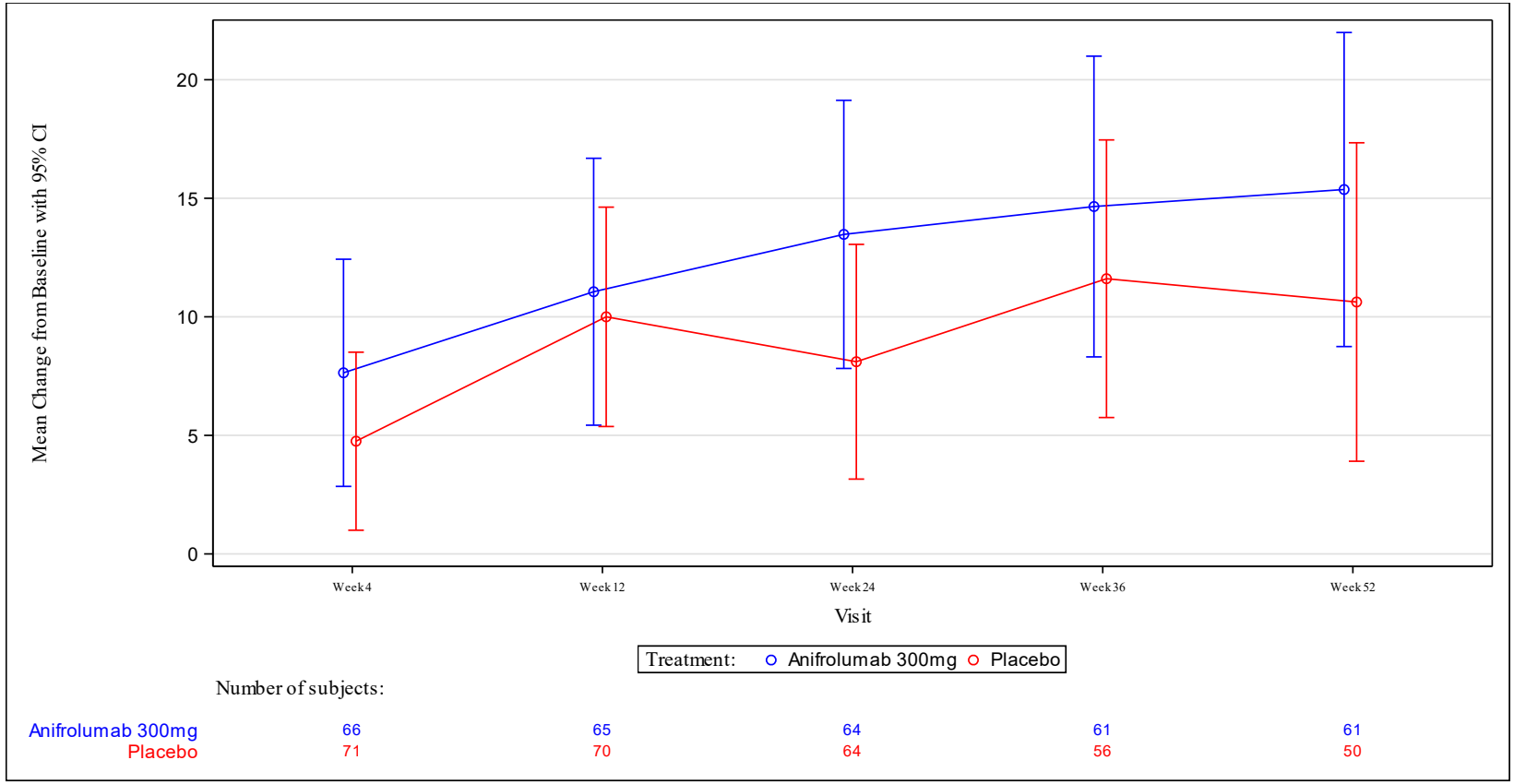
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - Lupus QoL Fatigue domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)				Placebo (N=75)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	68	46.23 (26.17)	0	-	74	49.66 (29.33)	0	-
Week 4	67	53.89 (25.05)	66	7.64 (19.49)	72	54.08 (29.36)	71	4.75 (15.86)
Week 12	66	58.14 (26.74)	65	11.06 (22.72)	71	59.24 (27.93)	70	10.00 (19.40)
Week 24	65	58.94 (27.38)	64	13.48 (22.64)	64	58.20 (30.17)	64	8.11 (19.82)
Week 36	62	61.49 (25.46)	61	14.65 (24.76)	56	65.29 (28.55)	56	11.61 (21.86)
Week 52	62	61.49 (26.71)	61	15.37 (25.86)	50	64.88 (30.22)	50	10.63 (23.63)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - Lupus QoL Fatigue domain score
Full analysis set



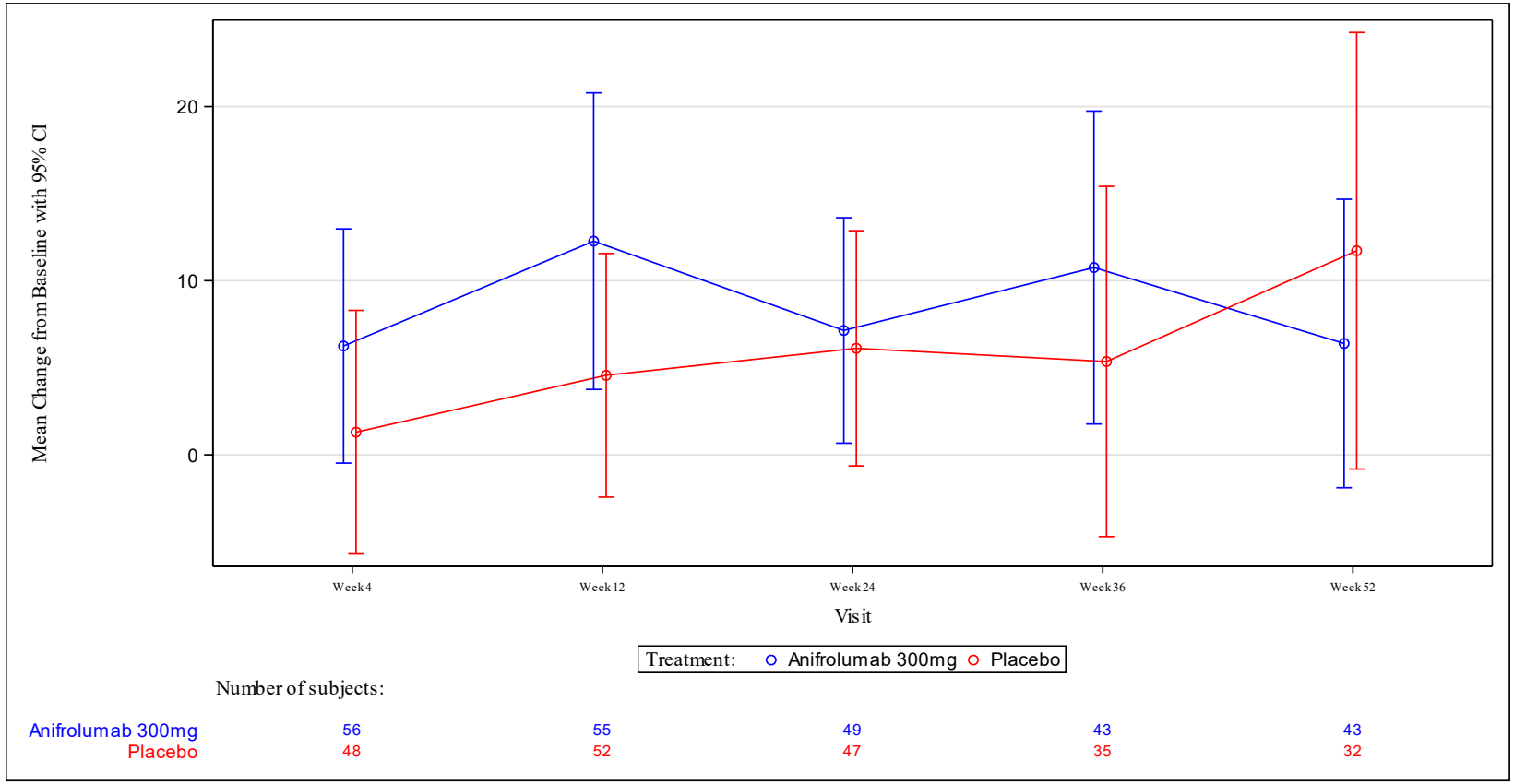
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - Lupus QoL Intimate Relationships domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)				Placebo (N=75)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	60	55.83 (31.93)	0	-	60	56.04 (35.17)	0	-
Week 4	59	61.23 (30.94)	56	6.25 (25.11)	54	60.88 (34.09)	48	1.30 (24.08)
Week 12	57	68.64 (29.89)	55	12.27 (31.50)	59	63.35 (33.95)	52	4.57 (25.13)
Week 24	54	62.27 (32.35)	49	7.14 (22.53)	51	64.46 (32.54)	47	6.12 (23.00)
Week 36	47	67.02 (31.21)	43	10.76 (29.20)	37	65.88 (31.82)	35	5.36 (29.28)
Week 52	47	63.83 (30.42)	43	6.40 (26.92)	33	68.18 (35.78)	32	11.72 (34.77)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - Lupus QoL Intimate Relationships domain score
Full analysis set



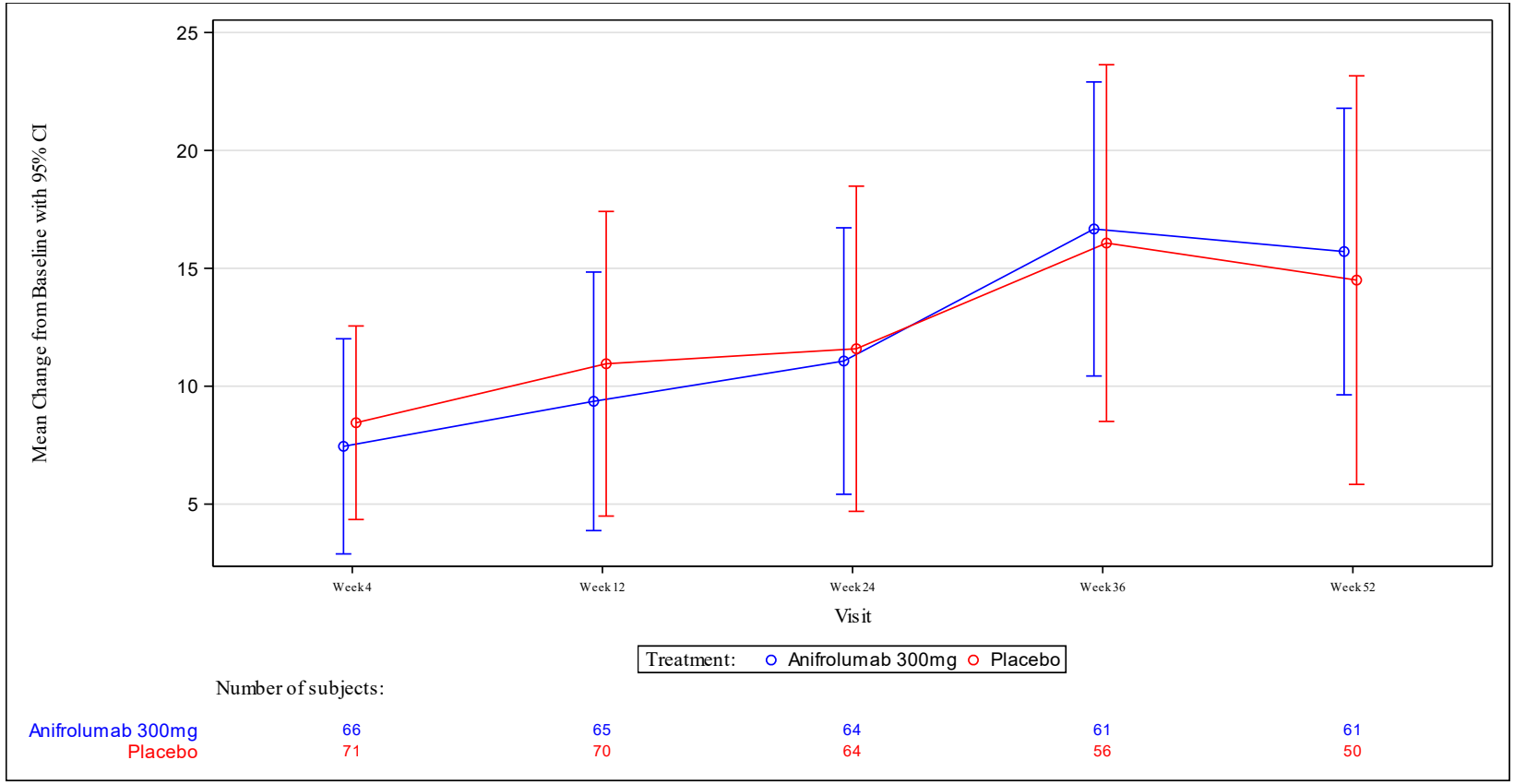
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - Lupus QoL Pain domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)				Placebo (N=75)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	68	51.47 (24.77)	0	-	74	49.66 (30.92)	0	-
Week 4	67	58.96 (25.10)	66	7.45 (18.56)	72	58.10 (27.44)	71	8.45 (17.34)
Week 12	66	60.86 (26.02)	65	9.36 (22.12)	71	60.92 (30.49)	70	10.95 (27.09)
Week 24	65	62.05 (28.03)	64	11.07 (22.62)	64	62.24 (32.46)	64	11.59 (27.60)
Week 36	62	67.34 (27.63)	61	16.67 (24.34)	56	69.64 (26.71)	56	16.07 (28.24)
Week 52	62	67.47 (26.30)	61	15.71 (23.72)	50	68.33 (28.82)	50	14.50 (30.48)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - Lupus QoL Pain domain score
Full analysis set



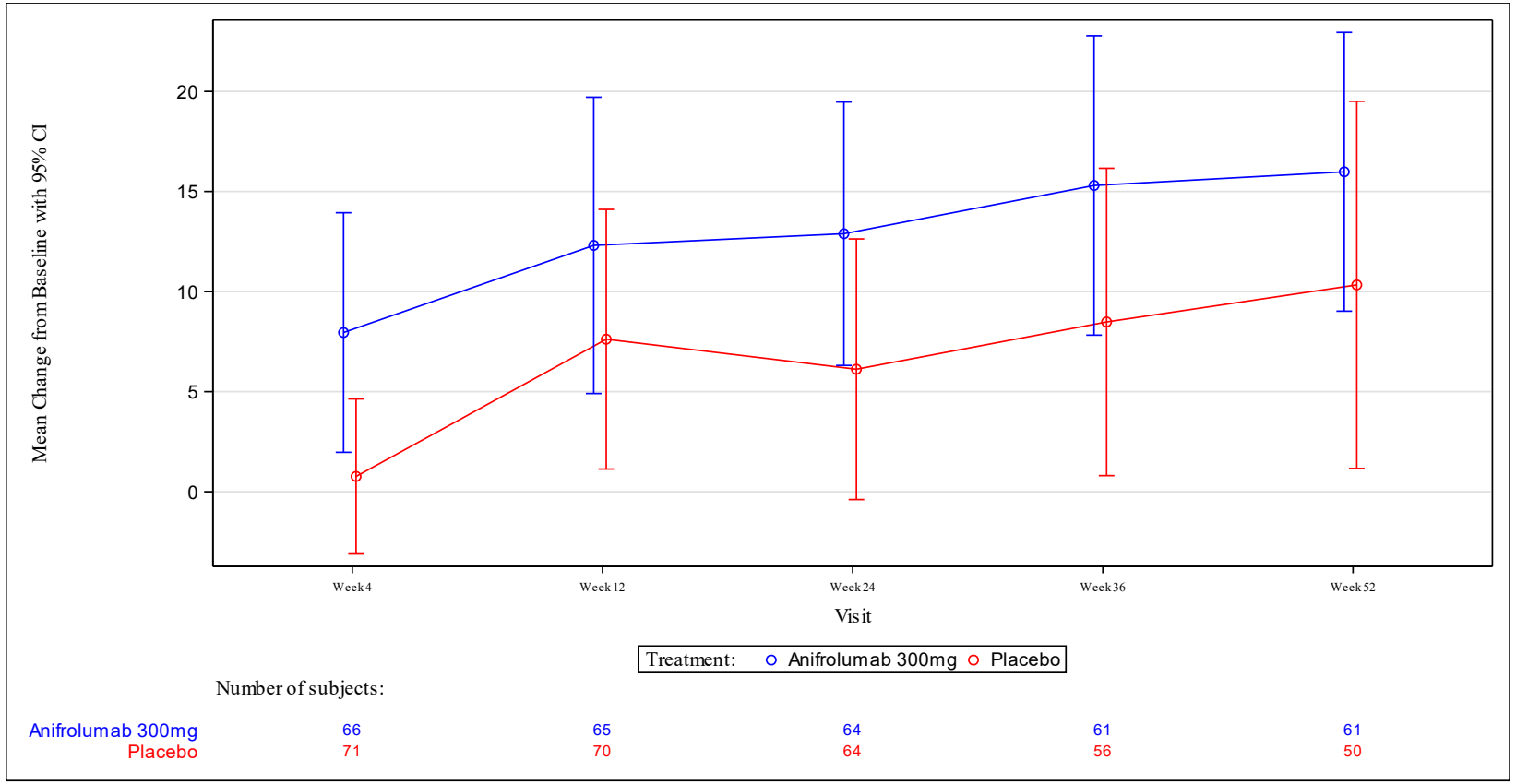
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - Lupus QoL Planning domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)				Placebo (N=75)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	68	53.19 (27.66)	0	-	74	55.97 (33.77)	0	-
Week 4	67	61.07 (28.63)	66	7.95 (24.35)	72	57.70 (32.86)	71	0.76 (16.36)
Week 12	66	66.29 (26.77)	65	12.31 (29.87)	71	63.85 (30.41)	70	7.62 (27.21)
Week 24	65	65.26 (28.78)	64	12.89 (26.35)	64	63.02 (31.56)	64	6.12 (26.07)
Week 36	62	69.09 (30.12)	61	15.30 (29.19)	56	69.20 (30.40)	56	8.48 (28.67)
Week 52	62	69.49 (27.03)	61	15.98 (27.19)	50	70.50 (30.17)	50	10.33 (32.28)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - Lupus QoL Planning domain score
Full analysis set



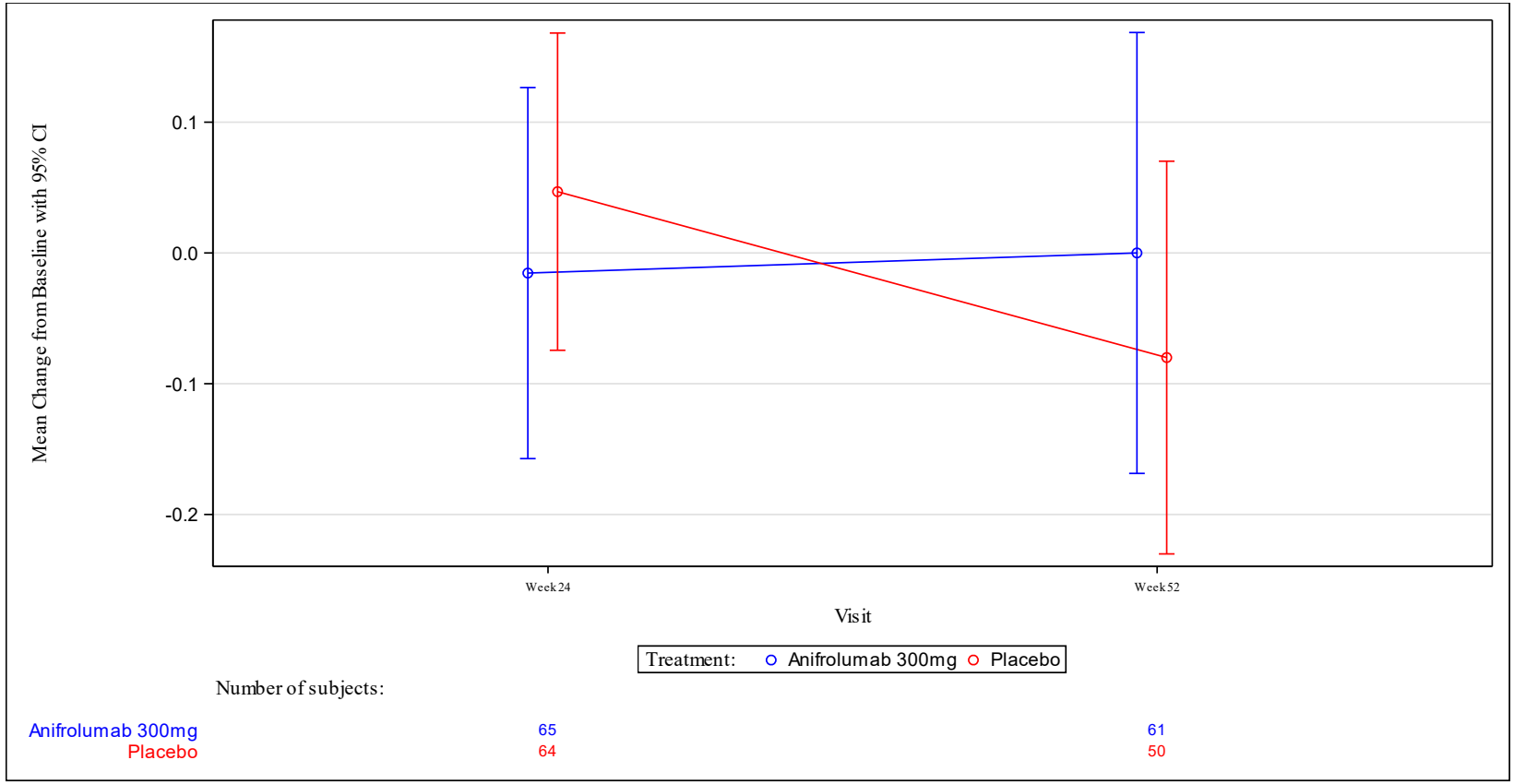
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - SDI Global Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)				Placebo (N=75)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	69	0.72 (0.98)	0	-	75	0.67 (1.23)	0	-
Week 24	65	0.69 (1.01)	65	-0.02 (0.57)	64	0.77 (1.35)	64	0.05 (0.49)
Week 52	61	0.70 (1.01)	61	0.00 (0.66)	50	0.54 (1.15)	50	-0.08 (0.53)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - SDI Global Score
Full analysis set



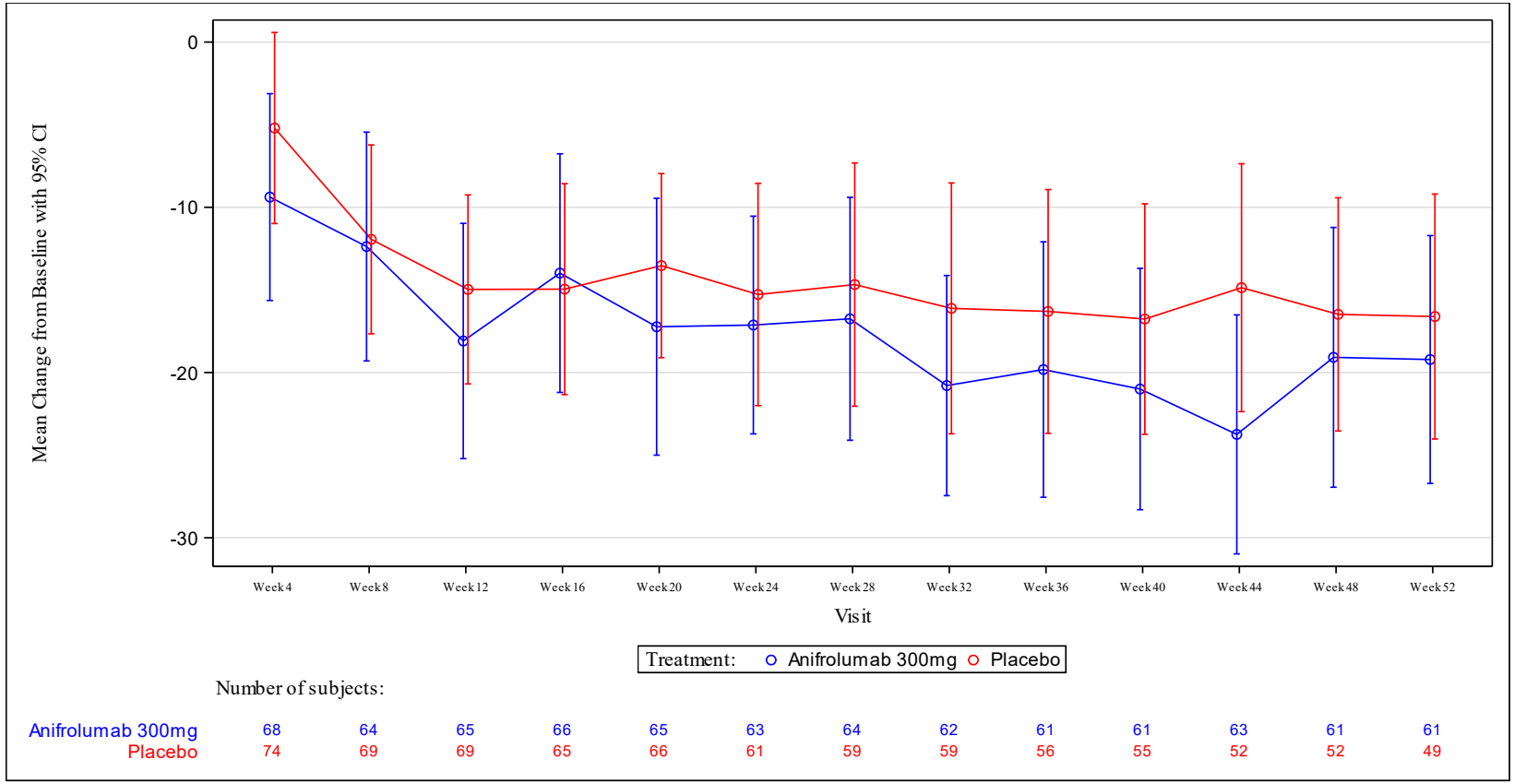
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - PtGA
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)				Placebo (N=75)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	69	54.84 (23.34)	0	-	75	56.65 (22.50)	0	-
Week 4	68	45.47 (23.90)	68	-9.38 (25.85)	74	51.14 (26.62)	74	-5.20 (24.95)
Week 8	64	43.19 (22.76)	64	-12.38 (27.72)	69	43.30 (24.33)	69	-11.94 (23.79)
Week 12	65	37.51 (23.65)	65	-18.09 (28.73)	69	40.65 (25.12)	69	-14.97 (23.81)
Week 16	66	41.45 (24.85)	66	-13.98 (29.38)	65	40.25 (25.17)	65	-14.95 (25.76)
Week 20	65	38.12 (22.36)	65	-17.23 (31.36)	66	42.85 (25.65)	66	-13.53 (22.67)
Week 24	63	38.70 (22.10)	63	-17.13 (26.16)	61	39.85 (24.67)	61	-15.28 (26.27)
Week 28	64	38.39 (23.42)	64	-16.75 (29.43)	59	39.83 (24.19)	59	-14.68 (28.24)
Week 32	62	34.66 (21.73)	62	-20.79 (26.23)	59	37.64 (24.50)	59	-16.12 (29.12)
Week 36	61	34.74 (25.72)	61	-19.82 (30.18)	56	37.05 (24.61)	56	-16.30 (27.54)
Week 40	61	34.03 (23.22)	61	-21.00 (28.52)	55	36.76 (23.32)	55	-16.76 (25.80)
Week 44	63	31.68 (22.35)	63	-23.75 (28.72)	52	39.29 (26.36)	52	-14.87 (26.95)
Week 48	61	36.26 (23.62)	61	-19.08 (30.69)	52	36.79 (23.91)	52	-16.48 (25.35)
Week 52	61	36.13 (24.10)	61	-19.21 (29.29)	49	37.98 (27.77)	49	-16.61 (25.81)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - PtGA
Full analysis set



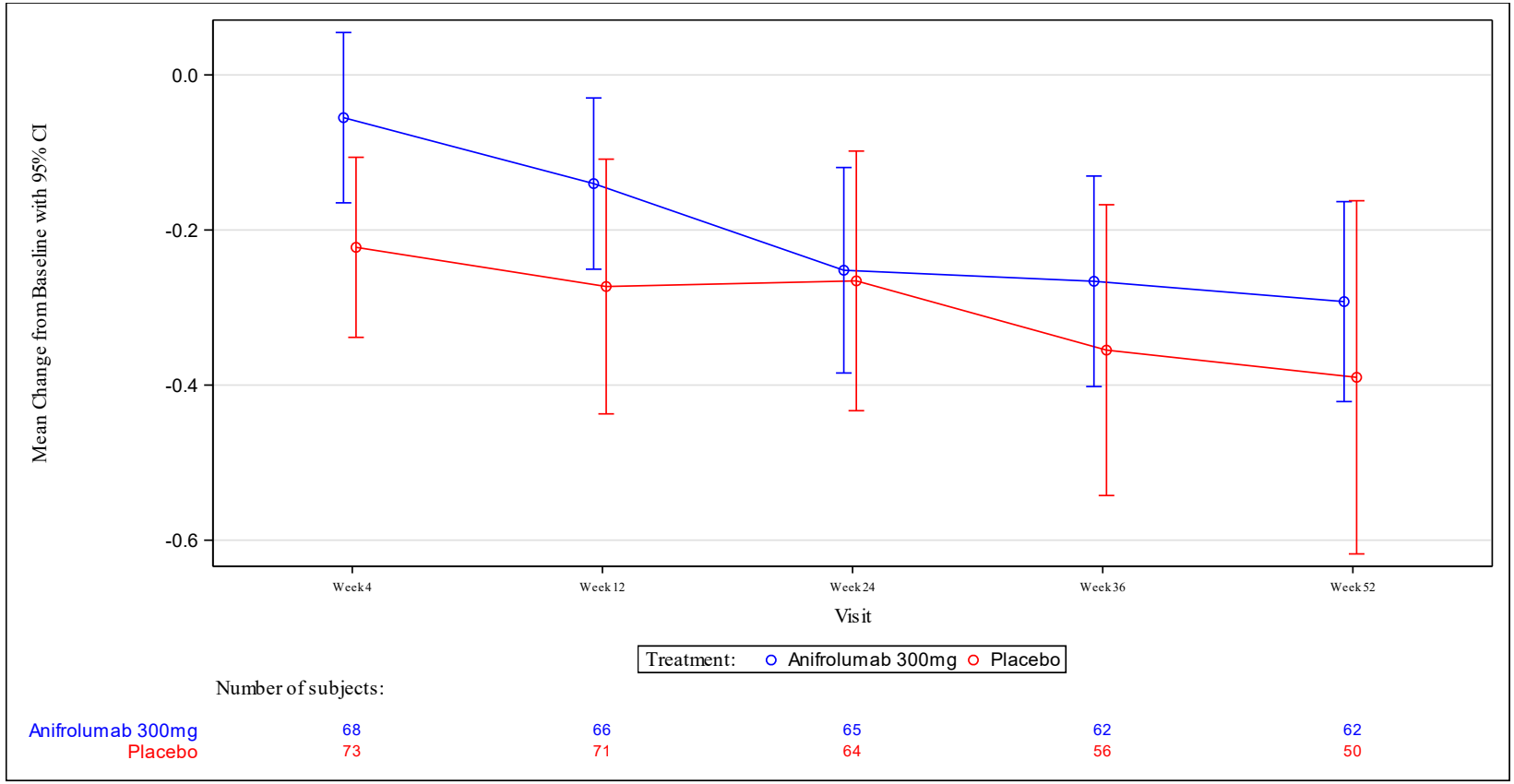
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - Total HAQ Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)				Placebo (N=75)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	69	0.95 (0.70)	0	-	75	1.02 (0.74)	0	-
Week 4	68	0.91 (0.70)	68	-0.06 (0.45)	73	0.78 (0.70)	73	-0.22 (0.50)
Week 12	66	0.81 (0.66)	66	-0.14 (0.45)	71	0.73 (0.73)	71	-0.27 (0.69)
Week 24	65	0.71 (0.67)	65	-0.25 (0.53)	64	0.71 (0.73)	64	-0.27 (0.67)
Week 36	62	0.70 (0.71)	62	-0.27 (0.53)	56	0.58 (0.62)	56	-0.35 (0.70)
Week 52	62	0.66 (0.62)	62	-0.29 (0.51)	50	0.54 (0.61)	50	-0.39 (0.80)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - Total HAQ Score
Full analysis set



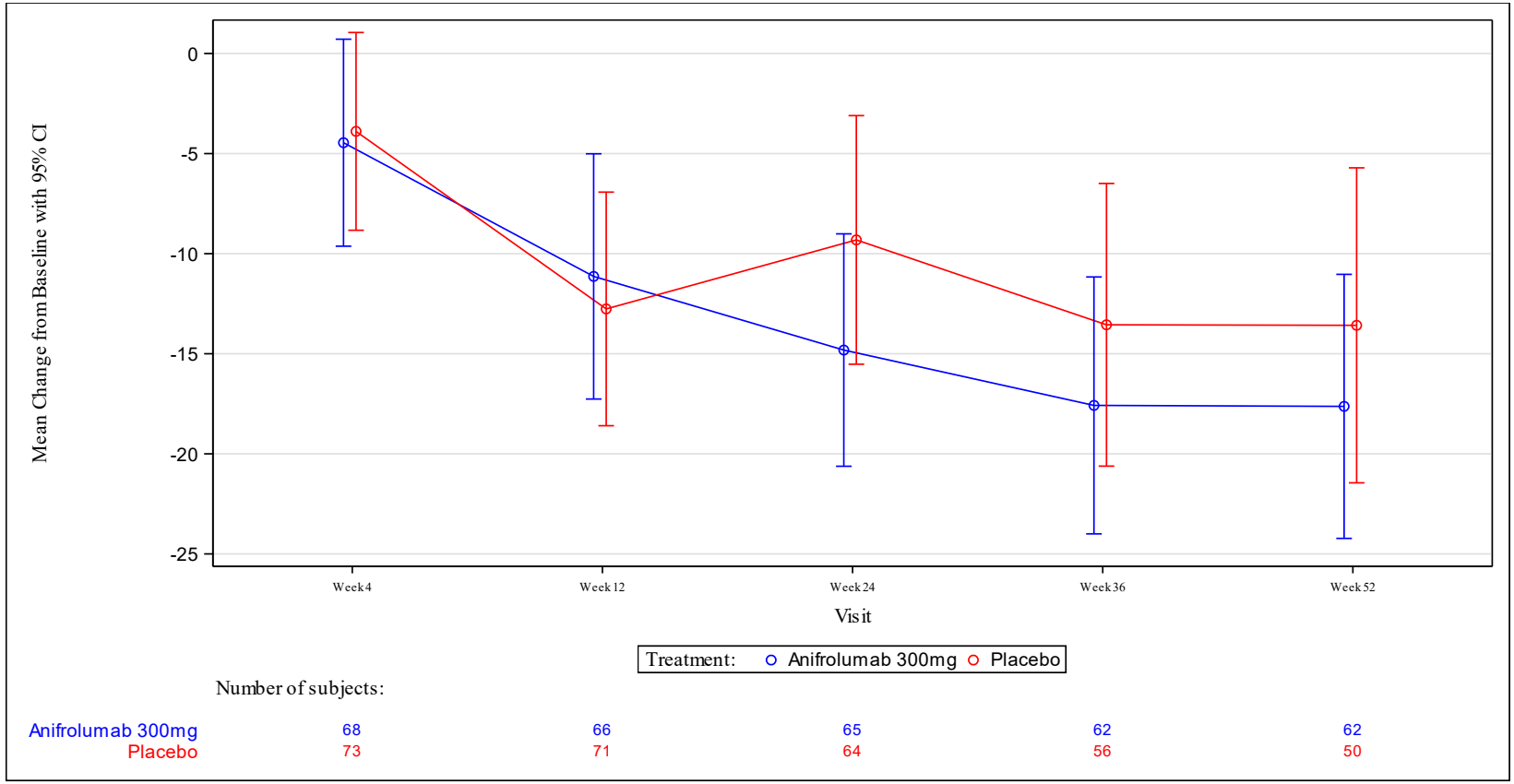
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - Pain Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)				Placebo (N=75)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	69	51.14 (24.37)	0	-	75	51.87 (24.66)	0	-
Week 4	68	46.68 (24.20)	68	-4.46 (21.36)	73	47.42 (25.52)	73	-3.89 (21.17)
Week 12	66	40.39 (24.53)	66	-11.14 (24.92)	71	39.18 (27.53)	71	-12.76 (24.65)
Week 24	65	36.72 (25.29)	65	-14.82 (23.43)	64	39.97 (28.24)	64	-9.31 (24.86)
Week 36	62	33.73 (26.25)	62	-17.58 (25.27)	56	32.91 (26.84)	56	-13.55 (26.37)
Week 52	62	33.47 (23.82)	62	-17.63 (25.97)	50	33.64 (28.57)	50	-13.58 (27.69)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - Pain Score
Full analysis set



N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SLEDAI-2K Total Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-0.88 (0.26)		-0.81 (0.25)	-0.07 (0.33)	(-0.73, 0.59)	0.8356			
Week 8		-2.22 (0.43)		-1.94 (0.41)	-0.28 (0.58)	(-1.42, 0.87)	0.6309			
Week 12		-3.64 (0.46)		-2.75 (0.45)	-0.89 (0.63)	(-2.13, 0.35)	0.1566			
Week 16		-3.80 (0.50)		-3.07 (0.49)	-0.74 (0.68)	(-2.08, 0.61)	0.2811			
Week 20		-4.65 (0.53)		-3.54 (0.52)	-1.11 (0.73)	(-2.55, 0.34)	0.1321			
Week 24		-5.14 (0.51)		-3.47 (0.50)	-1.67 (0.69)	(-3.04, -0.30)	0.0173			
Week 28		-5.21 (0.57)		-2.91 (0.58)	-2.29 (0.80)	(-3.88, -0.71)	0.0048			
Week 32		-5.34 (0.58)		-3.40 (0.59)	-1.94 (0.81)	(-3.55, -0.33)	0.0187			
Week 36		-5.52 (0.58)		-3.48 (0.59)	-2.04 (0.81)	(-3.64, -0.43)	0.0132			
Week 40		-5.53 (0.54)		-3.50 (0.55)	-2.04 (0.76)	(-3.54, -0.53)	0.0085			
Week 44		-5.85 (0.52)		-4.32 (0.54)	-1.53 (0.74)	(-2.99, -0.08)	0.0392			
Week 48		-6.02 (0.56)		-4.51 (0.57)	-1.51 (0.78)	(-3.06, 0.05)	0.0570			
Week 52		-6.30 (0.52)		-4.44 (0.54)	-1.86 (0.73)	(-3.31, -0.41)	0.0125			
OVERALL	69	-4.62 (0.41)	75	-3.24 (0.40)	-1.38 (0.56)	(-2.49, -0.28)	0.0148	-0.40 (0.17)	(-0.73, -0.07)	0.0186

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SLEDAI-2K Total Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.5426
< 10 points	29	-3.18 (0.51)	32	-2.19 (0.49)	-0.99 (0.69)	(-2.38, 0.40)	0.1603	-0.35 (0.26)	(-0.86, 0.15)	0.1700	
>= 10 points	40	-5.95 (0.63)	43	-4.30 (0.63)	-1.65 (0.83)	(-3.29, 0.00)	0.0505	-0.40 (0.22)	(-0.84, 0.03)	0.0715	
OCS dose											0.7027
<10 mg/day	33	-4.25 (0.65)	28	-3.06 (0.71)	-1.20 (0.95)	(-3.10, 0.70)	0.2115	-0.32 (0.26)	(-0.82, 0.19)	0.2227	
>=10 mg/day	36	-4.84 (0.56)	47	-3.19 (0.52)	-1.65 (0.71)	(-3.06, -0.24)	0.0224	-0.47 (0.22)	(-0.91, -0.03)	0.0349	
Result of type I IFN gene signature test											NE
LOW	14	NE	19	NE	NE	NE		NE	NE		
HIGH	55	-4.90 (0.46)	56	-2.88 (0.47)	-2.01 (0.66)	(-3.31, -0.71)	0.0028	-0.57 (0.19)	(-0.95, -0.19)	0.0031	
Age (years)											0.2256
<= 45	45	-5.14 (0.56)	50	-3.30 (0.54)	-1.84 (0.73)	(-3.29, -0.40)	0.0131	-0.49 (0.21)	(-0.89, -0.08)	0.0199	
> 45	24	-3.27 (0.60)	25	-2.78 (0.62)	-0.49 (0.85)	(-2.21, 1.23)	0.5656	-0.16 (0.29)	(-0.72, 0.40)	0.5770	
Sex											NE
male	4	NE	6	NE	NE	NE		NE	NE		
female	65	-4.77 (0.43)	69	-3.23 (0.43)	-1.55 (0.59)	(-2.72, -0.37)	0.0106	-0.43 (0.17)	(-0.78, -0.09)	0.0132	
Race											NE
White	25	-4.19 (0.61)	31	-3.57 (0.56)	-0.62 (0.81)	(-2.26, 1.02)	0.4529	-0.20 (0.27)	(-0.72, 0.33)	0.4670	
Black	16	NE	8	NE	NE	NE		NE	NE		
Other	28	-4.74 (0.64)	36	-3.30 (0.62)	-1.44 (0.85)	(-3.13, 0.26)	0.0949	-0.40 (0.25)	(-0.90, 0.10)	0.1179	
Ethnicity											0.1276
Hispanic/Latino	28	-4.10 (0.55)	28	-3.71 (0.59)	-0.38 (0.78)	(-1.96, 1.19)	0.6245	-0.13 (0.27)	(-0.65, 0.40)	0.6392	
Non-hispanic/Latino	41	-4.99 (0.59)	47	-2.92 (0.55)	-2.07 (0.78)	(-3.63, -0.51)	0.0101	-0.54 (0.22)	(-0.97, -0.12)	0.0126	
Geographic region											NE
Latin America, Eastern Europe and Asia	45	-4.87 (0.53)	55	-2.85 (0.52)	-2.03 (0.69)	(-3.40, -0.66)	0.0042	-0.54 (0.20)	(-0.94, -0.14)	0.0082	
North America	24	NE	20	NE	NE	NE		NE	NE		
Baseline weight											0.1757
<60 kg	18	-5.85 (0.89)	31	-3.24 (0.72)	-2.60 (1.13)	(-4.88, -0.33)	0.0258	-0.66 (0.30)	(-1.25, -0.06)	0.0309	
>=60 kg	51	-4.11 (0.46)	44	-3.26 (0.49)	-0.85 (0.64)	(-2.13, 0.43)	0.1908	-0.26 (0.21)	(-0.66, 0.15)	0.2132	
Low CH50											NE
Yes	9	NE	10	NE	NE	NE		NE	NE		
No	60	-4.40 (0.41)	65	-3.10 (0.41)	-1.30 (0.57)	(-2.44, -0.16)	0.0254	-0.40 (0.18)	(-0.75, -0.04)	0.0289	
Low C3 or C4											0.1205
Yes	25	-7.26 (0.98)	33	-4.49 (0.86)	-2.77 (1.03)	(-4.86, -0.69)	0.0103	-0.55 (0.27)	(-1.08, -0.02)	0.0403	
No	44	-3.55 (0.45)	42	-2.68 (0.47)	-0.88 (0.65)	(-2.16, 0.41)	0.1786	-0.29 (0.22)	(-0.71, 0.14)	0.1866	
Baseline FARR anti-dsDNA											NE
<5 IU/mL	15	NE	11	NE	NE	NE		NE	NE		
>=5 IU/mL	40	-5.14 (0.57)	50	-3.27 (0.52)	-1.87 (0.73)	(-3.33, -0.42)	0.0124	-0.51 (0.22)	(-0.93, -0.09)	0.0184	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.3943
Yes	50	-5.27 (0.52)	60	-3.50 (0.49)	-1.77 (0.67)	(-3.10, -0.44)	0.0097	-0.47 (0.19)	(-0.85, -0.09)	0.0159	
No	19	-3.27 (0.66)	15	-2.52 (0.75)	-0.75 (0.99)	(-2.78, 1.27)	0.4542	-0.25 (0.35)	(-0.93, 0.43)	0.4647	
OCS use											NE
Yes	54	-4.96 (0.49)	63	-3.41 (0.47)	-1.55 (0.64)	(-2.82, -0.28)	0.0173	-0.42 (0.19)	(-0.79, -0.05)	0.0252	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SLEDAI-2K Total Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=69) N	LSMean (SE)	Placebo (N=75) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
No	15	NE	12	NE	NE	NE		NE	NE		
SLICC score											0.7980
0	40	-4.19 (0.55)	48	-3.04 (0.53)	-1.16 (0.74)	(-2.63, 0.31)	0.1218	-0.32 (0.22)	(-0.74, 0.10)	0.1393	
>=1	29	-5.00 (0.59)	27	-3.56 (0.60)	-1.44 (0.82)	(-3.10, 0.23)	0.0883	-0.45 (0.27)	(-0.98, 0.08)	0.0960	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - PGA
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-0.34 (0.05)		-0.20 (0.05)	-0.14 (0.06)	(-0.27, -0.01)	0.0290			
Week 8		-0.60 (0.06)		-0.49 (0.06)	-0.11 (0.08)	(-0.27, 0.06)	0.1990			
Week 12		-0.77 (0.07)		-0.54 (0.06)	-0.23 (0.09)	(-0.41, -0.06)	0.0100			
Week 16		-0.82 (0.07)		-0.62 (0.07)	-0.20 (0.10)	(-0.39, -0.01)	0.0409			
Week 20		-0.89 (0.07)		-0.64 (0.07)	-0.25 (0.10)	(-0.45, -0.05)	0.0161			
Week 24		-0.89 (0.07)		-0.70 (0.07)	-0.19 (0.10)	(-0.39, 0.01)	0.0581			
Week 28		-0.95 (0.08)		-0.73 (0.08)	-0.21 (0.11)	(-0.43, -0.00)	0.0468			
Week 32		-1.02 (0.07)		-0.76 (0.07)	-0.25 (0.10)	(-0.45, -0.06)	0.0115			
Week 36		-1.02 (0.07)		-0.79 (0.07)	-0.23 (0.10)	(-0.42, -0.04)	0.0167			
Week 40		-1.08 (0.07)		-0.84 (0.07)	-0.24 (0.10)	(-0.43, -0.04)	0.0165			
Week 44		-1.10 (0.07)		-0.88 (0.07)	-0.21 (0.10)	(-0.41, -0.01)	0.0380			
Week 48		-1.10 (0.07)		-0.86 (0.07)	-0.24 (0.10)	(-0.43, -0.05)	0.0150			
Week 52		-1.11 (0.07)		-0.86 (0.07)	-0.25 (0.10)	(-0.44, -0.06)	0.0102			
OVERALL	69	-0.90 (0.06)	75	-0.69 (0.06)	-0.21 (0.08)	(-0.36, -0.06)	0.0070	-0.43 (0.17)	(-0.76, -0.10)	0.0104

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - PGA - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=69) N	LSMean (SE)	Placebo (N=75) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.9451
< 10 points	29	-0.90 (0.08)	32	-0.68 (0.08)	-0.22 (0.11)	(-0.44, 0.00)	0.0522	-0.49 (0.26)	(-1.00, 0.02)	0.0583	
>= 10 points	40	-0.92 (0.09)	43	-0.71 (0.08)	-0.21 (0.11)	(-0.42, 0.01)	0.0579	-0.38 (0.22)	(-0.81, 0.06)	0.0894	
OCS dose											0.6091
<10 mg/day	33	-0.84 (0.08)	28	-0.64 (0.08)	-0.19 (0.11)	(-0.42, 0.03)	0.0843	-0.43 (0.26)	(-0.94, 0.08)	0.0962	
>=10 mg/day	36	-1.02 (0.09)	47	-0.75 (0.08)	-0.27 (0.11)	(-0.49, -0.06)	0.0145	-0.50 (0.22)	(-0.94, -0.06)	0.0275	
Result of type I IFN gene signature test											NE
LOW	14	NE	19	NE	NE	NE		NE	NE		
HIGH	55	-0.95 (0.06)	56	-0.67 (0.06)	-0.29 (0.09)	(-0.46, -0.11)	0.0015	-0.61 (0.19)	(-0.99, -0.23)	0.0017	
Age (years)											0.8655
<= 45	45	-0.88 (0.08)	50	-0.66 (0.07)	-0.22 (0.10)	(-0.41, -0.02)	0.0277	-0.42 (0.21)	(-0.83, -0.01)	0.0430	
> 45	24	-0.88 (0.10)	25	-0.69 (0.10)	-0.19 (0.13)	(-0.46, 0.08)	0.1573	-0.40 (0.29)	(-0.96, 0.17)	0.1683	
Sex											NE
male	4	NE	6	NE	NE	NE		NE	NE		
female	65	-0.92 (0.06)	69	-0.69 (0.06)	-0.22 (0.08)	(-0.38, -0.07)	0.0060	-0.46 (0.18)	(-0.80, -0.11)	0.0090	
Race											NE
White	25	-0.82 (0.09)	31	-0.61 (0.08)	-0.21 (0.12)	(-0.46, 0.03)	0.0864	-0.46 (0.27)	(-0.99, 0.08)	0.0939	
Black	16	NE	8	NE	NE	NE		NE	NE		
Other	28	-0.89 (0.09)	36	-0.76 (0.09)	-0.13 (0.12)	(-0.37, 0.10)	0.2580	-0.26 (0.25)	(-0.75, 0.24)	0.3069	
Ethnicity											0.0072
Hispanic/Latino	28	-0.85 (0.09)	28	-0.90 (0.10)	0.06 (0.12)	(-0.19, 0.31)	0.6555	0.11 (0.27)	(-0.41, 0.64)	0.6753	
Non-hispanic/Latino	41	-0.94 (0.08)	47	-0.57 (0.07)	-0.37 (0.10)	(-0.57, -0.17)	0.0003	-0.76 (0.22)	(-1.20, -0.33)	0.0006	
Geographic region											0.8458
Latin America, Eastern Europe and Asia	45	-0.91 (0.08)	55	-0.66 (0.08)	-0.25 (0.10)	(-0.44, -0.05)	0.0160	-0.44 (0.20)	(-0.84, -0.04)	0.0303	
North America	24	-0.94 (0.11)	20	-0.73 (0.10)	-0.21 (0.15)	(-0.52, 0.10)	0.1738	-0.42 (0.31)	(-1.02, 0.18)	0.1737	
Baseline weight											NE
<60 kg	18	NE	31	NE	NE	NE		NE	NE		
>=60 kg	51	-0.88 (0.06)	44	-0.61 (0.06)	-0.27 (0.09)	(-0.44, -0.10)	0.0019	-0.61 (0.21)	(-1.02, -0.20)	0.0038	
Low CH50											NE
Yes	9	NE	10	NE	NE	NE		NE	NE		
No	60	-0.89 (0.06)	65	-0.65 (0.06)	-0.24 (0.08)	(-0.40, -0.08)	0.0044	-0.50 (0.18)	(-0.86, -0.14)	0.0060	
Low C3 or C4											0.6020
Yes	25	-1.00 (0.12)	33	-0.84 (0.11)	-0.17 (0.12)	(-0.42, 0.08)	0.1843	-0.26 (0.27)	(-0.78, 0.26)	0.3253	
No	44	-0.88 (0.07)	42	-0.63 (0.07)	-0.25 (0.10)	(-0.44, -0.06)	0.0122	-0.54 (0.22)	(-0.97, -0.11)	0.0144	
Baseline FARR anti-dsDNA											NE
<5 IU/mL	15	NE	11	NE	NE	NE		NE	NE		
>=5 IU/mL	40	-0.94 (0.08)	50	-0.63 (0.07)	-0.31 (0.10)	(-0.50, -0.12)	0.0020	-0.61 (0.22)	(-1.04, -0.19)	0.0047	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.5346
Yes	50	-0.91 (0.07)	60	-0.67 (0.07)	-0.24 (0.09)	(-0.42, -0.07)	0.0080	-0.46 (0.19)	(-0.84, -0.08)	0.0173	
No	19	-0.88 (0.11)	15	-0.76 (0.13)	-0.13 (0.17)	(-0.47, 0.22)	0.4647	-0.25 (0.35)	(-0.93, 0.43)	0.4725	
OCS use											NE
Yes	54	-0.91 (0.07)	63	-0.68 (0.07)	-0.23 (0.09)	(-0.41, -0.05)	0.0131	-0.43 (0.19)	(-0.80, -0.06)	0.0215	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - PGA - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=69) N	LSMean (SE)	Placebo (N=75) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
No	15	NE	12	NE	NE	NE		NE	NE		
SLICC score											0.7124
0	40	-0.89 (0.07)	48	-0.64 (0.07)	-0.25 (0.10)	(-0.44, -0.06)	0.0101	-0.53 (0.22)	(-0.96, -0.10)	0.0154	
>=1	29	-0.93 (0.10)	27	-0.74 (0.10)	-0.19 (0.14)	(-0.47, 0.09)	0.1812	-0.35 (0.27)	(-0.88, 0.18)	0.1968	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - CLASI Total Activity Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-1.17 (0.34)		-0.69 (0.32)	-0.49 (0.44)	(-1.36, 0.39)	0.2715			
Week 8		-2.65 (0.39)		-1.60 (0.37)	-1.05 (0.51)	(-2.06, -0.04)	0.0420			
Week 12		-3.38 (0.37)		-2.01 (0.36)	-1.37 (0.49)	(-2.33, -0.41)	0.0057			
Week 16		-3.84 (0.41)		-2.45 (0.40)	-1.39 (0.56)	(-2.49, -0.29)	0.0138			
Week 20		-4.40 (0.42)		-2.72 (0.41)	-1.69 (0.57)	(-2.81, -0.56)	0.0036			
Week 24		-4.39 (0.44)		-2.36 (0.44)	-2.03 (0.60)	(-3.22, -0.84)	0.0010			
Week 28		-4.45 (0.45)		-2.32 (0.45)	-2.12 (0.61)	(-3.33, -0.92)	0.0007			
Week 32		-4.61 (0.51)		-2.43 (0.50)	-2.18 (0.70)	(-3.56, -0.80)	0.0022			
Week 36		-4.81 (0.45)		-2.73 (0.45)	-2.09 (0.62)	(-3.32, -0.86)	0.0011			
Week 40		-4.87 (0.44)		-2.66 (0.45)	-2.22 (0.61)	(-3.42, -1.01)	0.0004			
Week 44		-4.74 (0.48)		-3.01 (0.48)	-1.73 (0.66)	(-3.04, -0.42)	0.0099			
Week 48		-4.95 (0.46)		-3.06 (0.46)	-1.89 (0.63)	(-3.14, -0.64)	0.0033			
Week 52		-5.11 (0.47)		-3.04 (0.48)	-2.07 (0.65)	(-3.37, -0.78)	0.0020			
OVERALL	69	-4.11 (0.37)	75	-2.39 (0.37)	-1.72 (0.50)	(-2.71, -0.72)	0.0009	-0.54 (0.17)	(-0.87, -0.21)	0.0015

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - CLASI Total Activity Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											NE
< 10 points	29	NE	32	NE	NE	NE		NE	NE		
>= 10 points	40	-4.80 (0.53)	43	-2.75 (0.54)	-2.05 (0.69)	(-3.42, -0.68)	0.0039	-0.59 (0.22)	(-1.03, -0.15)	0.0089	
OCS dose											NE
<10 mg/day	33	NE	28	NE	NE	NE		NE	NE		
>=10 mg/day	36	-4.28 (0.46)	47	-2.45 (0.43)	-1.83 (0.58)	(-2.99, -0.66)	0.0026	-0.63 (0.23)	(-1.07, -0.18)	0.0058	
Result of type I IFN gene signature test											NE
LOW	14	NE	19	NE	NE	NE		NE	NE		
HIGH	55	-4.61 (0.44)	56	-2.37 (0.45)	-2.24 (0.63)	(-3.49, -0.98)	0.0006	-0.66 (0.20)	(-1.05, -0.28)	0.0007	
Age (years)											NE
<= 45	45	-4.28 (0.45)	50	-2.12 (0.43)	-2.16 (0.57)	(-3.30, -1.02)	0.0003	-0.71 (0.21)	(-1.12, -0.29)	0.0009	
> 45	24	NE	25	NE	NE	NE		NE	NE		
Sex											NE
male	4	NE	6	NE	NE	NE		NE	NE		
female	65	-4.00 (0.37)	69	-2.09 (0.37)	-1.91 (0.51)	(-2.91, -0.91)	0.0003	-0.62 (0.18)	(-0.97, -0.28)	0.0004	
Race											NE
White	25	-3.71 (0.70)	31	-2.37 (0.63)	-1.34 (0.93)	(-3.24, 0.55)	0.1580	-0.38 (0.27)	(-0.91, 0.15)	0.1639	
Black	16	NE	8	NE	NE	NE		NE	NE		
Other	28	-4.42 (0.50)	36	-2.40 (0.51)	-2.02 (0.64)	(-3.32, -0.73)	0.0030	-0.69 (0.26)	(-1.20, -0.19)	0.0075	
Ethnicity											0.2667
Hispanic/Latino	28	-3.51 (0.40)	28	-2.28 (0.44)	-1.24 (0.56)	(-2.36, -0.11)	0.0325	-0.55 (0.27)	(-1.08, -0.01)	0.0446	
Non-hispanic/Latino	41	-4.55 (0.61)	47	-2.23 (0.57)	-2.32 (0.80)	(-3.93, -0.71)	0.0054	-0.59 (0.22)	(-1.02, -0.16)	0.0068	
Geographic region											NE
Latin America, Eastern Europe and Asia	45	-4.23 (0.51)	55	-2.29 (0.51)	-1.95 (0.65)	(-3.25, -0.65)	0.0037	-0.53 (0.20)	(-0.94, -0.13)	0.0090	
North America	24	NE	20	NE	NE	NE		NE	NE		
Baseline weight											NE
<60 kg	18	NE	31	NE	NE	NE		NE	NE		
>=60 kg	51	-3.83 (0.46)	44	-2.54 (0.48)	-1.29 (0.63)	(-2.53, -0.04)	0.0437	-0.39 (0.21)	(-0.80, 0.01)	0.0579	
Low CH50											NE
Yes	9	NE	10	NE	NE	NE		NE	NE		
No	60	-4.17 (0.41)	65	-2.16 (0.41)	-2.01 (0.56)	(-3.13, -0.89)	0.0006	-0.61 (0.18)	(-0.97, -0.26)	0.0008	
Low C3 or C4											NE
Yes	25	NE	33	NE	NE	NE		NE	NE		
No	44	-3.71 (0.43)	42	-2.06 (0.44)	-1.65 (0.61)	(-2.86, -0.43)	0.0087	-0.57 (0.22)	(-1.00, -0.14)	0.0094	
Baseline FARR anti-dsDNA											NE
<5 IU/mL	15	NE	11	NE	NE	NE		NE	NE		
>=5 IU/mL	40	-4.69 (0.55)	50	-2.49 (0.52)	-2.21 (0.71)	(-3.62, -0.79)	0.0028	-0.61 (0.22)	(-1.03, -0.18)	0.0051	
Low complement (C3 or C4) and positive FARR anti-dsDNA											NE
Yes	50	-4.53 (0.48)	60	-2.56 (0.46)	-1.97 (0.61)	(-3.17, -0.76)	0.0017	-0.56 (0.20)	(-0.94, -0.17)	0.0044	
No	19	NE	15	NE	NE	NE		NE	NE		
OCS use											NE
Yes	54	-4.43 (0.45)	63	-2.35 (0.44)	-2.09 (0.58)	(-3.24, -0.94)	0.0005	-0.61 (0.19)	(-0.99, -0.24)	0.0012	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - CLASI Total Activity Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
No	15	NE	12	NE	NE	NE		NE	NE		
SLICC score											NE
0	40	-3.74 (0.40)	48	-2.13 (0.40)	-1.61 (0.53)	(-2.67, -0.55)	0.0035	-0.60 (0.22)	(-1.03, -0.17)	0.0060	
>=1	29	NE	27	NE	NE	NE		NE	NE		

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - CLASI Total Damage Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		0.11 (0.21)		-0.10 (0.19)	0.22 (0.27)	(-0.31, 0.75)	0.4202			
Week 8		0.17 (0.30)		-0.32 (0.29)	0.48 (0.41)	(-0.33, 1.29)	0.2405			
Week 12		0.06 (0.31)		-0.52 (0.30)	0.58 (0.42)	(-0.25, 1.42)	0.1706			
Week 16		-0.09 (0.29)		-0.57 (0.28)	0.48 (0.39)	(-0.30, 1.26)	0.2247			
Week 20		-0.22 (0.36)		-0.57 (0.35)	0.35 (0.49)	(-0.62, 1.33)	0.4767			
Week 24		-0.41 (0.27)		-0.22 (0.26)	-0.19 (0.37)	(-0.92, 0.53)	0.6009			
Week 28		-0.41 (0.22)		-0.27 (0.22)	-0.14 (0.30)	(-0.73, 0.45)	0.6446			
Week 32		-0.49 (0.22)		-0.24 (0.22)	-0.25 (0.30)	(-0.84, 0.34)	0.4074			
Week 36		-0.49 (0.28)		-0.20 (0.27)	-0.28 (0.38)	(-1.03, 0.47)	0.4558			
Week 40		-0.56 (0.30)		-0.49 (0.30)	-0.06 (0.41)	(-0.87, 0.74)	0.8784			
Week 44		-0.56 (0.28)		-0.54 (0.28)	-0.03 (0.39)	(-0.80, 0.74)	0.9429			
Week 48		-0.50 (0.26)		-0.52 (0.26)	0.01 (0.36)	(-0.70, 0.73)	0.9688			
Week 52		-0.51 (0.23)		-0.45 (0.24)	-0.06 (0.32)	(-0.70, 0.58)	0.8613			
OVERALL	69	-0.30 (0.23)	75	-0.39 (0.22)	0.09 (0.30)	(-0.51, 0.69)	0.7759	0.05 (0.17)	(-0.28, 0.37)	0.7847

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - CLASI Total Damage Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.6538
< 10 points	29	-0.24 (0.19)	32	-0.41 (0.17)	0.17 (0.24)	(-0.32, 0.65)	0.4920	0.17 (0.26)	(-0.33, 0.67)	0.5114	
>= 10 points	40	-0.47 (0.38)	43	-0.39 (0.37)	-0.08 (0.50)	(-1.07, 0.91)	0.8724	-0.03 (0.22)	(-0.46, 0.40)	0.8815	
OCS dose											NE
<10 mg/day	33	-0.14 (0.32)	28	-0.38 (0.33)	0.24 (0.45)	(-0.66, 1.15)	0.5896	0.13 (0.26)	(-0.37, 0.64)	0.6051	
>=10 mg/day	36	NE	47	NE	NE	NE		NE	NE		
Result of type I IFN gene signature test											NE
LOW	14	NE	19	NE	NE	NE		NE	NE		
HIGH	55	-0.33 (0.28)	56	-0.48 (0.28)	0.15 (0.39)	(-0.63, 0.93)	0.7008	0.07 (0.19)	(-0.30, 0.44)	0.7043	
Age (years)											NE
<= 45	45	NE	50	NE	NE	NE		NE	NE		
> 45	24	NE	25	NE	NE	NE		NE	NE		
Sex											NE
male	4	NE	6	NE	NE	NE		NE	NE		
female	65	-0.34 (0.22)	69	-0.26 (0.22)	-0.08 (0.30)	(-0.68, 0.52)	0.7891	-0.04 (0.17)	(-0.38, 0.29)	0.7952	
Race											NE
White	25	NE	31	NE	NE	NE		NE	NE		
Black	16	-0.20 (0.58)	8	-1.20 (0.61)	1.00 (0.78)	(-0.63, 2.62)	0.2162	0.45 (0.44)	(-0.41, 1.31)	0.3044	
Other	28	-0.25 (0.23)	36	-0.35 (0.21)	0.10 (0.30)	(-0.51, 0.71)	0.7508	0.08 (0.25)	(-0.42, 0.57)	0.7633	
Ethnicity											0.8580
Hispanic/Latino	28	-0.26 (0.21)	28	-0.35 (0.21)	0.08 (0.29)	(-0.49, 0.66)	0.7696	0.07 (0.27)	(-0.45, 0.60)	0.7795	
Non-hispanic/Latino	41	-0.39 (0.35)	47	-0.38 (0.32)	-0.01 (0.46)	(-0.93, 0.91)	0.9774	-0.01 (0.21)	(-0.42, 0.41)	0.9783	
Geographic region											NE
Latin America, Eastern Europe and Asia	45	-0.33 (0.38)	55	-0.37 (0.35)	0.04 (0.50)	(-0.96, 1.03)	0.9385	0.01 (0.20)	(-0.38, 0.41)	0.9410	
North America	24	NE	20	NE	NE	NE		NE	NE		
Baseline weight											NE
<60 kg	18	-0.19 (0.30)	31	-0.69 (0.24)	0.50 (0.38)	(-0.27, 1.26)	0.1982	0.37 (0.30)	(-0.21, 0.96)	0.2100	
>=60 kg	51	NE	44	NE	NE	NE		NE	NE		
Low CH50											NE
Yes	9	NE	10	NE	NE	NE		NE	NE		
No	60	-0.38 (0.24)	65	-0.29 (0.24)	-0.09 (0.33)	(-0.75, 0.56)	0.7786	-0.05 (0.18)	(-0.40, 0.30)	0.7832	
Low C3 or C4											0.7649
Yes	25	-0.67 (0.35)	33	-0.73 (0.31)	0.06 (0.38)	(-0.70, 0.82)	0.8778	0.03 (0.27)	(-0.49, 0.55)	0.9025	
No	44	-0.15 (0.22)	42	-0.06 (0.23)	-0.09 (0.32)	(-0.72, 0.54)	0.7789	-0.06 (0.22)	(-0.48, 0.36)	0.7831	
Baseline FARR anti-dsDNA											0.8727
<5 IU/mL	15	-0.38 (0.13)	11	-0.58 (0.15)	0.20 (0.21)	(-0.24, 0.63)	0.3689	0.37 (0.40)	(-0.42, 1.15)	0.3603	
>=5 IU/mL	40	-0.28 (0.38)	50	-0.56 (0.34)	0.28 (0.49)	(-0.69, 1.25)	0.5654	0.12 (0.21)	(-0.30, 0.53)	0.5866	
Low complement (C3 or C4) and positive FARR anti-dsDNA											NE
Yes	50	-0.26 (0.31)	60	-0.46 (0.29)	0.20 (0.40)	(-0.59, 0.99)	0.6201	0.09 (0.19)	(-0.29, 0.46)	0.6448	
No	19	NE	15	NE	NE	NE		NE	NE		
OCS use											NE
Yes	54	-0.22 (0.20)	63	-0.41 (0.19)	0.20 (0.27)	(-0.33, 0.72)	0.4606	0.13 (0.19)	(-0.23, 0.49)	0.4853	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - CLASI Total Damage Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=69) N	LSMean (SE)	Placebo (N=75) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
No	15	NE	12	NE	NE	NE		NE	NE		
SLICC score											0.8390
0	40	-0.19 (0.13)	48	-0.23 (0.12)	0.04 (0.17)	(-0.29, 0.37)	0.8197	0.05 (0.21)	(-0.37, 0.47)	0.8310	
>=1	29	-0.42 (0.57)	27	-0.62 (0.57)	0.20 (0.78)	(-1.37, 1.78)	0.7985	0.07 (0.27)	(-0.46, 0.59)	0.8048	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - BILAG Global Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-5.06 (0.76)		-4.11 (0.72)	-0.96 (0.98)	(-2.90, 0.99)	0.3316			
Week 8		-8.47 (0.86)		-7.60 (0.83)	-0.87 (1.13)	(-3.11, 1.37)	0.4435			
Week 12		-9.91 (0.89)		-8.23 (0.85)	-1.67 (1.17)	(-3.99, 0.64)	0.1547			
Week 16		-9.46 (1.02)		-8.61 (0.98)	-0.85 (1.36)	(-3.54, 1.85)	0.5362			
Week 20		-10.42 (1.01)		-8.76 (0.98)	-1.66 (1.36)	(-4.35, 1.03)	0.2233			
Week 24		-10.28 (0.97)		-8.40 (0.95)	-1.88 (1.31)	(-4.47, 0.70)	0.1524			
Week 28		-10.41 (1.11)		-8.11 (1.13)	-2.30 (1.54)	(-5.34, 0.75)	0.1383			
Week 32		-11.51 (1.03)		-9.27 (1.04)	-2.24 (1.42)	(-5.04, 0.57)	0.1173			
Week 36		-11.54 (0.97)		-10.15 (0.98)	-1.39 (1.33)	(-4.02, 1.24)	0.2962			
Week 40		-11.67 (0.96)		-9.63 (0.97)	-2.04 (1.31)	(-4.64, 0.56)	0.1227			
Week 44		-12.23 (0.91)		-9.77 (0.94)	-2.46 (1.26)	(-4.95, 0.04)	0.0535			
Week 48		-12.67 (0.90)		-10.25 (0.92)	-2.42 (1.23)	(-4.86, 0.02)	0.0518			
Week 52		-12.84 (0.91)		-10.79 (0.94)	-2.04 (1.25)	(-4.51, 0.43)	0.1040			
OVERALL	69	-10.50 (0.75)	75	-8.74 (0.74)	-1.75 (0.99)	(-3.71, 0.20)	0.0780	-0.28 (0.17)	(-0.60, 0.05)	0.1004

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - BILAG Global Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.4636
< 10 points	29	-9.51 (1.05)	32	-8.65 (1.00)	-0.86 (1.41)	(-3.69, 1.97)	0.5427	-0.15 (0.26)	(-0.65, 0.35)	0.5570	
>= 10 points	40	-11.34 (1.15)	43	-9.02 (1.15)	-2.32 (1.40)	(-5.10, 0.47)	0.1016	-0.31 (0.22)	(-0.74, 0.12)	0.1614	
OCS dose											0.6033
<10 mg/day	33	-9.81 (1.00)	28	-7.35 (1.05)	-2.46 (1.40)	(-5.27, 0.34)	0.0839	-0.43 (0.26)	(-0.94, 0.08)	0.0992	
>=10 mg/day	36	-11.13 (1.14)	47	-9.67 (1.06)	-1.45 (1.35)	(-4.15, 1.24)	0.2861	-0.20 (0.22)	(-0.64, 0.23)	0.3593	
Result of type I IFN gene signature test											0.0531
LOW	14	-9.34 (1.39)	19	-10.81 (1.25)	1.47 (1.87)	(-2.39, 5.32)	0.4397	0.27 (0.35)	(-0.43, 0.96)	0.4497	
HIGH	55	-10.34 (0.80)	56	-7.58 (0.83)	-2.76 (1.14)	(-5.01, -0.50)	0.0170	-0.45 (0.19)	(-0.83, -0.07)	0.0190	
Age (years)											0.4126
<= 45	45	-10.66 (0.93)	50	-8.56 (0.90)	-2.10 (1.15)	(-4.39, 0.18)	0.0709	-0.33 (0.21)	(-0.74, 0.07)	0.1099	
> 45	24	-8.82 (1.39)	25	-8.56 (1.38)	-0.26 (1.93)	(-4.15, 3.62)	0.8915	-0.04 (0.29)	(-0.60, 0.52)	0.8944	
Sex											NE
male	4	NE	6	NE	NE	NE		NE	NE		
female	65	-10.59 (0.79)	69	-8.62 (0.79)	-1.97 (1.05)	(-4.05, 0.10)	0.0622	-0.30 (0.17)	(-0.64, 0.04)	0.0805	
Race											0.6430
White	25	-10.22 (1.22)	31	-9.66 (1.12)	-0.57 (1.62)	(-3.82, 2.69)	0.7273	-0.09 (0.27)	(-0.62, 0.44)	0.7362	
Black	16	-10.65 (2.75)	8	-6.98 (1.92)	-3.67 (2.91)	(-9.69, 2.36)	0.2203	-0.37 (0.44)	(-1.23, 0.49)	0.3976	
Other	28	-10.41 (1.18)	36	-8.86 (1.19)	-1.55 (1.49)	(-4.54, 1.43)	0.3010	-0.23 (0.25)	(-0.72, 0.27)	0.3697	
Ethnicity											0.0810
Hispanic/Latino	28	-9.73 (1.05)	28	-9.92 (1.15)	0.19 (1.42)	(-2.68, 3.07)	0.8919	0.03 (0.27)	(-0.49, 0.56)	0.9023	
Non-hispanic/Latino	41	-11.45 (1.03)	47	-8.27 (0.94)	-3.19 (1.32)	(-5.81, -0.56)	0.0179	-0.48 (0.22)	(-0.91, -0.06)	0.0258	
Geographic region											0.8226
Latin America, Eastern Europe and Asia	45	-10.73 (1.02)	55	-8.71 (1.07)	-2.02 (1.25)	(-4.49, 0.46)	0.1094	-0.27 (0.20)	(-0.67, 0.13)	0.1824	
North America	24	-9.76 (1.32)	20	-8.25 (1.29)	-1.51 (1.89)	(-5.32, 2.31)	0.4300	-0.24 (0.30)	(-0.84, 0.36)	0.4285	
Baseline weight											0.9106
<60 kg	18	-10.85 (1.69)	31	-9.09 (1.44)	-1.76 (2.11)	(-6.03, 2.51)	0.4097	-0.22 (0.30)	(-0.81, 0.36)	0.4508	
>=60 kg	51	-10.39 (0.87)	44	-8.36 (0.89)	-2.03 (1.16)	(-4.32, 0.27)	0.0831	-0.33 (0.21)	(-0.74, 0.08)	0.1103	
Low CH50											NE
Yes	9	NE	10	NE	NE	NE		NE	NE		
No	60	-10.51 (0.80)	65	-8.49 (0.79)	-2.02 (1.08)	(-4.15, 0.11)	0.0630	-0.32 (0.18)	(-0.67, 0.03)	0.0767	
Low C3 or C4											0.5782
Yes	25	-13.47 (1.89)	33	-11.07 (1.70)	-2.40 (1.67)	(-5.77, 0.96)	0.1569	-0.25 (0.27)	(-0.77, 0.28)	0.3543	
No	44	-9.74 (0.87)	42	-8.49 (0.92)	-1.25 (1.24)	(-3.71, 1.21)	0.3155	-0.21 (0.22)	(-0.64, 0.21)	0.3295	
Baseline FARR anti-dsDNA											0.4415
<5 IU/mL	15	-8.92 (1.85)	11	-9.52 (2.08)	0.60 (2.88)	(-5.92, 7.12)	0.8398	0.08 (0.40)	(-0.70, 0.86)	0.8360	
>=5 IU/mL	40	-10.73 (1.05)	50	-8.91 (0.97)	-1.82 (1.27)	(-4.35, 0.71)	0.1552	-0.27 (0.21)	(-0.68, 0.15)	0.2112	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.3616
Yes	50	-10.95 (0.98)	60	-8.84 (0.92)	-2.11 (1.17)	(-4.44, 0.22)	0.0751	-0.30 (0.19)	(-0.67, 0.08)	0.1226	
No	19	-8.99 (1.20)	15	-8.85 (1.38)	-0.14 (1.81)	(-3.94, 3.66)	0.9393	-0.03 (0.35)	(-0.70, 0.65)	0.9403	
OCS use											0.6602
Yes	54	-10.99 (0.90)	63	-9.43 (0.88)	-1.56 (1.13)	(-3.79, 0.68)	0.1703	-0.23 (0.19)	(-0.59, 0.14)	0.2234	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - BILAG Global Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
No	15	-8.79 (1.75)	12	-6.15 (1.68)	-2.65 (2.21)	(-7.29, 2.00)	0.2461	-0.40 (0.39)	(-1.17, 0.37)	0.3042	
SLICC score											0.5457
0	40	-9.87 (0.90)	48	-8.29 (0.92)	-1.58 (1.17)	(-3.92, 0.76)	0.1818	-0.26 (0.22)	(-0.68, 0.16)	0.2313	
>=1	29	-11.56 (1.38)	27	-8.66 (1.32)	-2.90 (1.85)	(-6.61, 0.81)	0.1223	-0.40 (0.27)	(-0.93, 0.13)	0.1392	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Tender Joint Count
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-2.98 (0.63)		-2.19 (0.59)	-0.79 (0.82)	(-2.41, 0.83)	0.3381			
Week 8		-4.89 (0.70)		-4.36 (0.65)	-0.53 (0.92)	(-2.35, 1.29)	0.5650			
Week 12		-5.80 (0.76)		-4.09 (0.71)	-1.70 (1.01)	(-3.69, 0.29)	0.0928			
Week 16		-6.06 (0.78)		-4.67 (0.74)	-1.39 (1.04)	(-3.44, 0.66)	0.1834			
Week 20		-6.65 (0.77)		-4.81 (0.73)	-1.84 (1.02)	(-3.87, 0.19)	0.0749			
Week 24		-6.65 (0.78)		-4.40 (0.75)	-2.25 (1.04)	(-4.31, -0.19)	0.0323			
Week 28		-6.10 (0.76)		-4.74 (0.74)	-1.36 (1.03)	(-3.39, 0.67)	0.1875			
Week 32		-6.50 (0.80)		-4.62 (0.79)	-1.88 (1.09)	(-4.03, 0.27)	0.0867			
Week 36		-6.53 (0.80)		-4.81 (0.79)	-1.73 (1.09)	(-3.89, 0.43)	0.1154			
Week 40		-6.33 (0.79)		-5.57 (0.80)	-0.76 (1.09)	(-2.92, 1.41)	0.4904			
Week 44		-6.79 (0.80)		-5.55 (0.82)	-1.24 (1.11)	(-3.44, 0.96)	0.2655			
Week 48		-7.63 (0.67)		-5.93 (0.69)	-1.70 (0.92)	(-3.54, 0.13)	0.0685			
Week 52		-7.03 (0.80)		-5.34 (0.84)	-1.69 (1.13)	(-3.94, 0.55)	0.1371			
OVERALL	68	-6.15 (0.59)	74	-4.70 (0.57)	-1.45 (0.77)	(-2.97, 0.07)	0.0611	-0.30 (0.17)	(-0.63, 0.03)	0.0785

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Tender Joint Count - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.9093
< 10 points	29	-6.15 (0.79)	32	-4.85 (0.73)	-1.30 (1.03)	(-3.38, 0.78)	0.2156	-0.30 (0.26)	(-0.81, 0.20)	0.2375	
>= 10 points	39	-6.10 (0.85)	42	-4.63 (0.84)	-1.47 (1.09)	(-3.64, 0.70)	0.1818	-0.27 (0.22)	(-0.71, 0.17)	0.2264	
OCS dose											0.9000
<10 mg/day	32	-5.20 (0.85)	28	-3.67 (0.87)	-1.54 (1.18)	(-3.91, 0.84)	0.1994	-0.32 (0.26)	(-0.83, 0.19)	0.2170	
>=10 mg/day	36	-7.34 (0.83)	46	-5.61 (0.77)	-1.73 (0.99)	(-3.70, 0.23)	0.0833	-0.34 (0.22)	(-0.78, 0.10)	0.1341	
Result of type I IFN gene signature test											NE
LOW	14	NE	19	NE	NE	NE		NE	NE		
HIGH	54	-6.26 (0.54)	55	-5.31 (0.56)	-0.95 (0.77)	(-2.48, 0.59)	0.2233	-0.23 (0.19)	(-0.61, 0.15)	0.2291	
Age (years)											0.4909
<= 45	44	-6.39 (0.75)	49	-4.56 (0.70)	-1.82 (0.94)	(-3.68, 0.04)	0.0545	-0.37 (0.21)	(-0.78, 0.04)	0.0797	
> 45	24	-5.08 (1.11)	25	-4.50 (1.13)	-0.58 (1.54)	(-3.71, 2.55)	0.7080	-0.10 (0.29)	(-0.66, 0.46)	0.7175	
Sex											NE
male	4	NE	6	NE	NE	NE		NE	NE		
female	64	-6.43 (0.60)	68	-4.78 (0.59)	-1.66 (0.79)	(-3.22, -0.09)	0.0389	-0.34 (0.18)	(-0.68, 0.00)	0.0520	
Race											NE
White	25	-5.98 (1.05)	30	-4.16 (0.94)	-1.83 (1.40)	(-4.64, 0.99)	0.1976	-0.35 (0.27)	(-0.88, 0.19)	0.2059	
Black	16	NE	8	NE	NE	NE		NE	NE		
Other	27	-6.56 (0.91)	36	-6.02 (0.86)	-0.54 (1.17)	(-2.90, 1.82)	0.6458	-0.11 (0.25)	(-0.61, 0.39)	0.6749	
Ethnicity											NE
Hispanic/Latino	27	NE	28	NE	NE	NE		NE	NE		
Non-hispanic/Latino	41	-6.29 (0.80)	46	-3.76 (0.70)	-2.53 (1.02)	(-4.56, -0.51)	0.0149	-0.51 (0.22)	(-0.94, -0.08)	0.0198	
Geographic region											0.1047
Latin America, Eastern Europe and Asia	44	-6.46 (0.64)	54	-6.27 (0.65)	-0.19 (0.79)	(-1.76, 1.39)	0.8134	-0.04 (0.20)	(-0.44, 0.36)	0.8408	
North America	24	-5.16 (1.28)	20	-1.69 (1.30)	-3.47 (1.86)	(-7.24, 0.30)	0.0699	-0.56 (0.31)	(-1.17, 0.04)	0.0692	
Baseline weight											NE
<60 kg	18	NE	30	NE	NE	NE		NE	NE		
>=60 kg	50	-6.06 (0.75)	44	-3.73 (0.73)	-2.33 (0.99)	(-4.30, -0.35)	0.0214	-0.45 (0.21)	(-0.87, -0.04)	0.0300	
Low CH50											NE
Yes	9	NE	10	NE	NE	NE		NE	NE		
No	59	-6.31 (0.62)	64	-4.66 (0.61)	-1.65 (0.84)	(-3.30, 0.01)	0.0512	-0.34 (0.18)	(-0.70, 0.02)	0.0622	
Low C3 or C4											NE
Yes	24	NE	32	NE	NE	NE		NE	NE		
No	44	-6.51 (0.76)	42	-4.33 (0.79)	-2.18 (1.07)	(-4.30, -0.05)	0.0450	-0.43 (0.22)	(-0.85, 0.00)	0.0511	
Baseline FARR anti-dsDNA											NE
<5 IU/mL	15	NE	11	NE	NE	NE		NE	NE		
>=5 IU/mL	39	-6.62 (0.78)	49	-4.89 (0.69)	-1.73 (0.96)	(-3.63, 0.17)	0.0738	-0.36 (0.22)	(-0.78, 0.07)	0.1005	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.6820
Yes	49	-6.72 (0.72)	59	-5.28 (0.67)	-1.44 (0.88)	(-3.18, 0.31)	0.1048	-0.28 (0.19)	(-0.66, 0.10)	0.1492	
No	19	-5.24 (1.28)	15	-2.94 (1.48)	-2.31 (1.94)	(-6.29, 1.67)	0.2442	-0.40 (0.35)	(-1.08, 0.29)	0.2538	
OCS use											NE
Yes	54	-5.97 (0.68)	62	-4.70 (0.65)	-1.27 (0.85)	(-2.96, 0.42)	0.1400	-0.25 (0.19)	(-0.61, 0.12)	0.1836	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Tender Joint Count - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=69) N	LSMean (SE)	Placebo (N=75) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
No	14	NE	12	NE	NE	NE		NE	NE		
SLICC score											NE
0	40	-6.44 (0.66)	48	-5.08 (0.66)	-1.35 (0.87)	(-3.10, 0.39)	0.1264	-0.30 (0.22)	(-0.73, 0.12)	0.1591	
>=1	28	NE	26	NE	NE	NE		NE	NE		

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Swollen Joint Count
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-3.19 (0.47)		-2.32 (0.44)	-0.87 (0.61)	(-2.09, 0.35)	0.1611			
Week 8		-4.23 (0.54)		-4.25 (0.50)	0.02 (0.71)	(-1.38, 1.42)	0.9787			
Week 12		-4.74 (0.55)		-4.02 (0.52)	-0.72 (0.73)	(-2.16, 0.73)	0.3287			
Week 16		-5.34 (0.50)		-5.33 (0.48)	-0.01 (0.66)	(-1.32, 1.29)	0.9837			
Week 20		-5.64 (0.58)		-4.78 (0.56)	-0.86 (0.78)	(-2.41, 0.68)	0.2713			
Week 24		-5.88 (0.48)		-4.98 (0.47)	-0.90 (0.64)	(-2.17, 0.37)	0.1618			
Week 28		-5.44 (0.61)		-4.24 (0.60)	-1.20 (0.83)	(-2.85, 0.45)	0.1523			
Week 32		-5.55 (0.57)		-4.66 (0.57)	-0.88 (0.78)	(-2.43, 0.66)	0.2593			
Week 36		-5.33 (0.59)		-4.85 (0.60)	-0.48 (0.82)	(-2.11, 1.15)	0.5624			
Week 40		-5.87 (0.54)		-4.63 (0.55)	-1.24 (0.74)	(-2.72, 0.24)	0.0982			
Week 44		-5.63 (0.63)		-4.48 (0.64)	-1.15 (0.87)	(-2.89, 0.59)	0.1918			
Week 48		-5.72 (0.59)		-4.83 (0.60)	-0.89 (0.82)	(-2.52, 0.74)	0.2818			
Week 52		-5.93 (0.56)		-4.96 (0.58)	-0.97 (0.78)	(-2.53, 0.59)	0.2181			
OVERALL	68	-5.27 (0.40)	74	-4.49 (0.40)	-0.78 (0.53)	(-1.83, 0.27)	0.1428	-0.23 (0.17)	(-0.56, 0.10)	0.1716

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Swollen Joint Count - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.1773
< 10 points	29	-4.85 (0.52)	32	-4.92 (0.49)	0.07 (0.69)	(-1.34, 1.47)	0.9238	0.02 (0.26)	(-0.48, 0.53)	0.9267	
>= 10 points	39	-5.68 (0.62)	42	-4.33 (0.62)	-1.35 (0.79)	(-2.93, 0.23)	0.0922	-0.34 (0.22)	(-0.78, 0.10)	0.1291	
OCS dose											0.0505
<10 mg/day	32	-3.62 (0.52)	28	-3.82 (0.53)	0.20 (0.70)	(-1.20, 1.60)	0.7746	0.07 (0.26)	(-0.44, 0.58)	0.7888	
>=10 mg/day	36	-6.85 (0.57)	46	-5.16 (0.53)	-1.69 (0.67)	(-3.03, -0.35)	0.0141	-0.48 (0.23)	(-0.92, -0.03)	0.0351	
Result of type I IFN gene signature test											NE
LOW	14	NE	19	NE	NE	NE		NE	NE		
HIGH	54	-5.07 (0.39)	55	-4.50 (0.39)	-0.57 (0.54)	(-1.65, 0.51)	0.2980	-0.20 (0.19)	(-0.57, 0.18)	0.3078	
Age (years)											0.2081
<= 45	44	-5.30 (0.59)	49	-3.91 (0.55)	-1.38 (0.72)	(-2.82, 0.05)	0.0578	-0.36 (0.21)	(-0.77, 0.05)	0.0889	
> 45	24	-4.88 (0.51)	25	-4.77 (0.55)	-0.11 (0.71)	(-1.59, 1.37)	0.8814	-0.04 (0.29)	(-0.60, 0.52)	0.8877	
Sex											NE
male	4	NE	6	NE	NE	NE		NE	NE		
female	64	-5.44 (0.39)	68	-4.63 (0.39)	-0.81 (0.52)	(-1.84, 0.22)	0.1213	-0.25 (0.17)	(-0.60, 0.09)	0.1473	
Race											NE
White	25	-5.22 (0.47)	30	-4.67 (0.43)	-0.56 (0.62)	(-1.81, 0.70)	0.3758	-0.23 (0.27)	(-0.76, 0.30)	0.3954	
Black	16	NE	8	NE	NE	NE		NE	NE		
Other	27	-5.55 (0.61)	36	-4.61 (0.57)	-0.93 (0.80)	(-2.55, 0.69)	0.2517	-0.28 (0.26)	(-0.78, 0.22)	0.2763	
Ethnicity											NE
Hispanic/Latino	27	NE	28	NE	NE	NE		NE	NE		
Non-hispanic/Latino	41	-4.87 (0.50)	46	-3.62 (0.46)	-1.25 (0.64)	(-2.52, 0.02)	0.0537	-0.39 (0.22)	(-0.82, 0.03)	0.0691	
Geographic region											0.5490
Latin America, Eastern Europe and Asia	44	-5.74 (0.44)	54	-5.20 (0.47)	-0.54 (0.54)	(-1.61, 0.52)	0.3130	-0.17 (0.20)	(-0.56, 0.23)	0.4139	
North America	24	-3.46 (0.92)	20	-2.08 (0.86)	-1.38 (1.29)	(-3.99, 1.23)	0.2910	-0.32 (0.30)	(-0.92, 0.28)	0.2918	
Baseline weight											NE
<60 kg	18	NE	30	NE	NE	NE		NE	NE		
>=60 kg	50	-5.25 (0.49)	44	-3.77 (0.49)	-1.48 (0.64)	(-2.76, -0.20)	0.0238	-0.43 (0.21)	(-0.84, -0.02)	0.0377	
Low CH50											NE
Yes	9	NE	10	NE	NE	NE		NE	NE		
No	59	-5.23 (0.42)	64	-4.34 (0.42)	-0.88 (0.57)	(-2.01, 0.24)	0.1228	-0.27 (0.18)	(-0.62, 0.09)	0.1415	
Low C3 or C4											NE
Yes	24	NE	32	NE	NE	NE		NE	NE		
No	44	-5.16 (0.49)	42	-3.95 (0.52)	-1.22 (0.70)	(-2.61, 0.18)	0.0870	-0.36 (0.22)	(-0.79, 0.06)	0.0961	
Baseline FARR anti-dsDNA											NE
<5 IU/mL	15	NE	11	NE	NE	NE		NE	NE		
>=5 IU/mL	39	-5.18 (0.48)	49	-4.46 (0.44)	-0.73 (0.56)	(-1.85, 0.39)	0.2002	-0.24 (0.22)	(-0.66, 0.18)	0.2686	
Low complement (C3 or C4) and positive FARR anti-dsDNA											NE
Yes	49	-5.54 (0.47)	59	-4.68 (0.45)	-0.86 (0.55)	(-1.95, 0.23)	0.1206	-0.25 (0.19)	(-0.63, 0.13)	0.1929	
No	19	NE	15	NE	NE	NE		NE	NE		
OCS use											NE
Yes	54	-5.53 (0.51)	62	-4.53 (0.50)	-1.00 (0.65)	(-2.28, 0.28)	0.1240	-0.26 (0.19)	(-0.63, 0.11)	0.1651	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Swollen Joint Count - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=69) N	Anifrolumab 300mg (N=69) LSMean (SE)	Placebo (N=75) N	Placebo (N=75) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
No	14	NE	12	NE	NE	NE		NE	NE		
SLICC score											0.5308
0	40	-5.77 (0.54)	48	-4.57 (0.55)	-1.20 (0.72)	(-2.64, 0.24)	0.1011	-0.33 (0.22)	(-0.75, 0.09)	0.1276	
>=1	28	-3.90 (0.81)	26	-3.51 (0.76)	-0.39 (1.07)	(-2.56, 1.78)	0.7152	-0.09 (0.27)	(-0.63, 0.44)	0.7297	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Mental Component Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		1.23 (1.08)		1.01 (1.02)	0.22 (1.38)	(-2.52, 2.96)	0.8741			
Week 12		2.17 (1.26)		1.74 (1.20)	0.44 (1.65)	(-2.83, 3.70)	0.7916			
Week 24		2.10 (1.16)		0.72 (1.14)	1.38 (1.53)	(-1.65, 4.41)	0.3692			
Week 36		3.76 (1.35)		2.21 (1.37)	1.55 (1.85)	(-2.11, 5.21)	0.4035			
Week 52		3.80 (1.31)		3.27 (1.36)	0.53 (1.81)	(-3.05, 4.10)	0.7711			
OVERALL	69	2.61 (1.01)	75	1.79 (0.97)	0.82 (1.29)	(-1.73, 3.37)	0.5246	0.10 (0.17)	(-0.23, 0.42)	0.5598

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Mental Component Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.9174
< 10 points	29	2.46 (1.57)	32	1.90 (1.44)	0.56 (2.03)	(-3.52, 4.64)	0.7851	0.07 (0.26)	(-0.44, 0.57)	0.7961	
>= 10 points	40	2.00 (1.39)	43	1.16 (1.38)	0.83 (1.70)	(-2.55, 4.21)	0.6255	0.09 (0.22)	(-0.34, 0.52)	0.6755	
OCS dose											0.9711
<10 mg/day	33	2.72 (1.40)	28	1.61 (1.46)	1.12 (1.93)	(-2.78, 5.01)	0.5667	0.14 (0.26)	(-0.36, 0.64)	0.5869	
>=10 mg/day	36	2.06 (1.54)	47	1.03 (1.41)	1.02 (1.77)	(-2.51, 4.55)	0.5657	0.11 (0.22)	(-0.33, 0.54)	0.6311	
Result of type I IFN gene signature test											0.8656
LOW	14	1.75 (2.04)	19	1.31 (1.83)	0.44 (2.72)	(-5.33, 6.22)	0.8728	0.06 (0.35)	(-0.64, 0.75)	0.8757	
HIGH	55	2.54 (1.05)	56	1.57 (1.10)	0.97 (1.49)	(-2.00, 3.93)	0.5184	0.12 (0.19)	(-0.25, 0.49)	0.5278	
Age (years)											0.4139
<= 45	45	2.78 (1.36)	50	1.31 (1.27)	1.47 (1.61)	(-1.73, 4.68)	0.3632	0.16 (0.21)	(-0.24, 0.56)	0.4335	
> 45	24	1.99 (1.66)	25	2.78 (1.67)	-0.79 (2.25)	(-5.36, 3.78)	0.7283	-0.09 (0.29)	(-0.65, 0.47)	0.7429	
Sex											NE
male	4	NE	6	NE	NE	NE		NE	NE		
female	65	2.62 (1.04)	69	1.82 (1.01)	0.80 (1.34)	(-1.85, 3.45)	0.5515	0.09 (0.17)	(-0.24, 0.43)	0.5833	
Race											0.2270
White	25	3.63 (1.58)	31	2.34 (1.45)	1.29 (2.08)	(-2.90, 5.48)	0.5378	0.16 (0.27)	(-0.37, 0.69)	0.5553	
Black	16	6.28 (3.72)	8	-0.96 (3.10)	7.25 (4.26)	(-1.62, 16.11)	0.1038	0.53 (0.44)	(-0.34, 1.39)	0.2312	
Other	28	1.81 (1.51)	36	2.47 (1.49)	-0.66 (1.86)	(-4.39, 3.06)	0.7223	-0.08 (0.25)	(-0.57, 0.42)	0.7613	
Ethnicity											0.2268
Hispanic/Latino	28	2.65 (1.52)	28	3.85 (1.66)	-1.20 (2.02)	(-5.27, 2.87)	0.5564	-0.14 (0.27)	(-0.67, 0.38)	0.5996	
Non-hispanic/Latino	41	2.39 (1.40)	47	0.36 (1.25)	2.03 (1.75)	(-1.45, 5.51)	0.2482	0.23 (0.21)	(-0.19, 0.65)	0.2832	
Geographic region											0.2705
Latin America, Eastern Europe and Asia	45	2.46 (1.25)	55	2.52 (1.31)	-0.06 (1.51)	(-3.06, 2.95)	0.9693	-0.01 (0.20)	(-0.40, 0.39)	0.9749	
North America	24	3.18 (2.17)	20	-0.54 (2.06)	3.72 (3.08)	(-2.51, 9.95)	0.2343	0.37 (0.31)	(-0.23, 0.96)	0.2318	
Baseline weight											0.5820
<60 kg	18	2.21 (2.19)	31	2.36 (1.87)	-0.16 (2.73)	(-5.67, 5.36)	0.9549	-0.02 (0.30)	(-0.60, 0.57)	0.9590	
>=60 kg	51	2.78 (1.18)	44	1.21 (1.17)	1.56 (1.50)	(-1.43, 4.55)	0.3021	0.19 (0.21)	(-0.21, 0.59)	0.3557	
Low CH50											0.9774
Yes	9	1.55 (3.06)	10	0.33 (5.40)	1.22 (6.26)	(-12.17, 14.62)	0.8479	0.08 (0.46)	(-0.82, 0.98)	0.8553	
No	60	2.81 (1.05)	65	1.77 (1.02)	1.04 (1.38)	(-1.68, 3.77)	0.4507	0.13 (0.18)	(-0.22, 0.48)	0.4790	
Low C3 or C4											0.8467
Yes	25	5.26 (2.40)	33	3.82 (2.08)	1.43 (2.26)	(-3.14, 6.01)	0.5305	0.12 (0.27)	(-0.40, 0.64)	0.6562	
No	44	1.79 (1.20)	42	0.90 (1.23)	0.89 (1.66)	(-2.42, 4.20)	0.5945	0.11 (0.22)	(-0.31, 0.53)	0.6082	
Baseline FARR anti-dsDNA											0.8189
<5 IU/mL	15	0.43 (2.25)	11	-1.27 (2.30)	1.71 (3.46)	(-5.53, 8.94)	0.6277	0.20 (0.40)	(-0.58, 0.98)	0.6157	
>=5 IU/mL	40	2.88 (1.42)	50	2.06 (1.29)	0.82 (1.70)	(-2.56, 4.20)	0.6289	0.09 (0.21)	(-0.33, 0.51)	0.6710	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.6908
Yes	50	2.98 (1.29)	60	1.75 (1.20)	1.23 (1.52)	(-1.78, 4.24)	0.4206	0.13 (0.19)	(-0.24, 0.51)	0.4894	
No	19	1.74 (1.57)	15	1.62 (1.79)	0.12 (2.34)	(-4.69, 4.92)	0.9607	0.02 (0.35)	(-0.66, 0.69)	0.9618	
OCS use											0.5147
Yes	54	2.15 (1.18)	63	1.03 (1.13)	1.12 (1.43)	(-1.72, 3.95)	0.4362	0.13 (0.19)	(-0.24, 0.49)	0.4986	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Mental Component Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
No	15	1.14 (2.50)	12	2.31 (2.48)	-1.17 (3.20)	(-7.99, 5.65)	0.7202	-0.12 (0.39)	(-0.88, 0.64)	0.7512	
SLICC score											0.1007
0	40	0.69 (1.23)	48	1.86 (1.25)	-1.17 (1.61)	(-4.38, 2.04)	0.4710	-0.14 (0.21)	(-0.56, 0.28)	0.5137	
>=1	29	5.79 (1.82)	27	2.24 (1.68)	3.55 (2.38)	(-1.23, 8.34)	0.1419	0.38 (0.27)	(-0.15, 0.91)	0.1634	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Physical Component Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		1.95 (0.70)		1.89 (0.66)	0.06 (0.88)	(-1.68, 1.80)	0.9450			
Week 12		3.25 (0.99)		4.33 (0.95)	-1.08 (1.31)	(-3.67, 1.52)	0.4136			
Week 24		4.31 (1.03)		4.97 (1.01)	-0.66 (1.39)	(-3.40, 2.08)	0.6352			
Week 36		5.26 (1.13)		5.71 (1.13)	-0.45 (1.54)	(-3.51, 2.61)	0.7724			
Week 52		5.73 (1.04)		5.25 (1.07)	0.47 (1.44)	(-2.37, 3.32)	0.7415			
OVERALL	69	4.10 (0.83)	75	4.43 (0.80)	-0.33 (1.08)	(-2.46, 1.81)	0.7607	-0.05 (0.17)	(-0.37, 0.28)	0.7756

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Physical Component Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.3230
< 10 points	29	3.84 (1.23)	32	5.30 (1.13)	-1.46 (1.61)	(-4.68, 1.77)	0.3685	-0.22 (0.26)	(-0.73, 0.28)	0.3894	
>= 10 points	40	4.24 (1.15)	43	3.55 (1.15)	0.68 (1.45)	(-2.21, 3.58)	0.6391	0.09 (0.22)	(-0.34, 0.52)	0.6760	
OCS dose											0.7836
<10 mg/day	33	4.33 (1.33)	28	4.05 (1.35)	0.28 (1.86)	(-3.45, 4.01)	0.8801	0.04 (0.26)	(-0.47, 0.54)	0.8837	
>=10 mg/day	36	4.62 (1.15)	47	4.98 (1.06)	-0.36 (1.40)	(-3.14, 2.43)	0.7990	-0.05 (0.22)	(-0.48, 0.38)	0.8221	
Result of type I IFN gene signature test											0.6402
LOW	14	4.86 (2.01)	19	4.28 (1.80)	0.58 (2.72)	(-4.99, 6.16)	0.8324	0.07 (0.35)	(-0.62, 0.76)	0.8347	
HIGH	55	4.53 (0.82)	56	5.33 (0.85)	-0.80 (1.17)	(-3.12, 1.51)	0.4935	-0.13 (0.19)	(-0.50, 0.24)	0.5007	
Age (years)											0.9358
<= 45	45	4.70 (1.02)	50	5.07 (0.96)	-0.37 (1.25)	(-2.85, 2.12)	0.7686	-0.05 (0.21)	(-0.46, 0.35)	0.7941	
> 45	24	3.28 (1.50)	25	3.45 (1.49)	-0.18 (2.06)	(-4.33, 3.97)	0.9324	-0.02 (0.29)	(-0.58, 0.54)	0.9350	
Sex											NE
male	4	NE	6	NE	NE	NE		NE	NE		
female	65	4.12 (0.85)	69	4.24 (0.84)	-0.13 (1.13)	(-2.36, 2.11)	0.9116	-0.02 (0.17)	(-0.36, 0.32)	0.9170	
Race											0.1590
White	25	4.81 (1.30)	31	4.43 (1.17)	0.38 (1.69)	(-3.01, 3.78)	0.8210	0.06 (0.27)	(-0.47, 0.59)	0.8284	
Black	16	5.88 (2.97)	8	0.95 (2.79)	4.93 (3.85)	(-3.03, 12.89)	0.2131	0.44 (0.44)	(-0.42, 1.30)	0.3136	
Other	28	2.95 (1.23)	36	5.30 (1.19)	-2.35 (1.55)	(-5.46, 0.75)	0.1349	-0.34 (0.25)	(-0.84, 0.16)	0.1824	
Ethnicity											0.0387
Hispanic/Latino	28	2.80 (1.24)	28	5.91 (1.33)	-3.10 (1.68)	(-6.48, 0.28)	0.0710	-0.45 (0.27)	(-0.98, 0.08)	0.0960	
Non-hispanic/Latino	41	5.23 (1.12)	47	3.78 (1.01)	1.45 (1.43)	(-1.39, 4.29)	0.3114	0.21 (0.21)	(-0.21, 0.63)	0.3385	
Geographic region											0.2223
Latin America, Eastern Europe and Asia	45	4.20 (1.02)	55	5.79 (1.05)	-1.59 (1.25)	(-4.08, 0.90)	0.2077	-0.21 (0.20)	(-0.61, 0.18)	0.2891	
North America	24	4.98 (1.57)	20	3.38 (1.58)	1.60 (2.29)	(-3.03, 6.22)	0.4899	0.21 (0.30)	(-0.38, 0.81)	0.4855	
Baseline weight											0.7269
<60 kg	18	5.90 (1.92)	31	6.77 (1.61)	-0.87 (2.43)	(-5.77, 4.03)	0.7223	-0.10 (0.30)	(-0.68, 0.48)	0.7392	
>=60 kg	51	3.26 (0.88)	44	3.19 (0.88)	0.07 (1.15)	(-2.22, 2.36)	0.9516	0.01 (0.21)	(-0.39, 0.41)	0.9557	
Low CH50											0.8917
Yes	9	5.00 (2.53)	10	4.23 (3.76)	0.78 (4.50)	(-8.93, 10.48)	0.8659	0.07 (0.46)	(-0.83, 0.97)	0.8732	
No	60	4.31 (0.84)	65	4.17 (0.82)	0.14 (1.12)	(-2.07, 2.36)	0.8981	0.02 (0.18)	(-0.33, 0.37)	0.9030	
Low C3 or C4											0.5333
Yes	25	3.80 (1.99)	33	4.88 (1.72)	-1.08 (2.04)	(-5.17, 3.02)	0.5985	-0.11 (0.27)	(-0.63, 0.41)	0.6857	
No	44	3.97 (0.89)	42	3.57 (0.93)	0.41 (1.25)	(-2.07, 2.89)	0.7443	0.07 (0.22)	(-0.36, 0.49)	0.7530	
Baseline FARR anti-dsDNA											0.0762
<5 IU/mL	15	5.87 (1.59)	11	1.47 (1.57)	4.40 (2.38)	(-0.56, 9.37)	0.0790	0.74 (0.41)	(-0.07, 1.55)	0.0731	
>=5 IU/mL	40	4.41 (1.14)	50	4.93 (1.04)	-0.52 (1.43)	(-3.37, 2.32)	0.7155	-0.07 (0.21)	(-0.49, 0.34)	0.7376	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.5806
Yes	50	4.32 (1.02)	60	4.95 (0.95)	-0.63 (1.26)	(-3.13, 1.87)	0.6184	-0.09 (0.19)	(-0.46, 0.29)	0.6536	
No	19	4.43 (1.56)	15	3.58 (1.79)	0.84 (2.35)	(-3.96, 5.64)	0.7222	0.12 (0.35)	(-0.56, 0.80)	0.7281	
OCS use											0.1507
Yes	54	4.45 (0.92)	63	4.98 (0.89)	-0.52 (1.15)	(-2.81, 1.76)	0.6502	-0.08 (0.19)	(-0.44, 0.29)	0.6839	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Physical Component Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=69) N	Anifrolumab 300mg (N=69) LSMean (SE)	Placebo (N=75) N	Placebo (N=75) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
No	15	4.64 (1.95)	12	1.06 (1.91)	3.58 (2.61)	(-1.89, 9.05)	0.1865	0.49 (0.39)	(-0.29, 1.26)	0.2173	
SLICC score											0.4174
0	40	4.76 (0.98)	48	4.34 (0.98)	0.42 (1.28)	(-2.13, 2.97)	0.7433	0.06 (0.21)	(-0.36, 0.48)	0.7661	
>=1	29	3.31 (1.44)	27	4.77 (1.41)	-1.47 (1.94)	(-5.37, 2.43)	0.4538	-0.19 (0.27)	(-0.72, 0.33)	0.4749	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute General Health Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		0.87 (1.06)		1.98 (1.00)	-1.11 (1.36)	(-3.80, 1.57)	0.4142			
Week 12		2.39 (1.29)		3.31 (1.24)	-0.91 (1.70)	(-4.29, 2.46)	0.5931			
Week 24		4.07 (1.30)		2.91 (1.27)	1.15 (1.73)	(-2.27, 4.58)	0.5061			
Week 36		5.38 (1.27)		5.97 (1.31)	-0.58 (1.74)	(-4.04, 2.87)	0.7384			
Week 52		5.33 (1.27)		5.22 (1.34)	0.11 (1.76)	(-3.39, 3.60)	0.9517			
OVERALL	69	3.61 (0.98)	75	3.88 (0.95)	-0.27 (1.26)	(-2.76, 2.22)	0.8309	-0.03 (0.17)	(-0.36, 0.29)	0.8448

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute General Health Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=69) N	LSMean (SE)	Placebo (N=75) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.0906
< 10 points	29	3.27 (1.39)	32	6.01 (1.28)	-2.74 (1.80)	(-6.35, 0.88)	0.1345	-0.37 (0.26)	(-0.87, 0.14)	0.1556	
>= 10 points	40	2.78 (1.42)	43	1.29 (1.42)	1.49 (1.73)	(-1.97, 4.94)	0.3933	0.16 (0.22)	(-0.27, 0.59)	0.4631	
OCS dose											0.9434
<10 mg/day	33	3.99 (1.43)	28	4.08 (1.49)	-0.09 (2.00)	(-4.11, 3.94)	0.9657	-0.01 (0.26)	(-0.51, 0.49)	0.9672	
>=10 mg/day	36	2.89 (1.47)	47	3.17 (1.35)	-0.27 (1.72)	(-3.71, 3.16)	0.8740	-0.03 (0.22)	(-0.46, 0.40)	0.8923	
Result of type I IFN gene signature test											0.6787
LOW	14	4.06 (2.19)	19	3.22 (1.98)	0.84 (2.95)	(-5.30, 6.98)	0.7789	0.10 (0.35)	(-0.59, 0.79)	0.7840	
HIGH	55	3.58 (0.96)	56	4.09 (1.00)	-0.51 (1.36)	(-3.21, 2.19)	0.7104	-0.07 (0.19)	(-0.44, 0.30)	0.7164	
Age (years)											0.1488
<= 45	45	4.96 (1.23)	50	3.83 (1.16)	1.12 (1.48)	(-1.81, 4.06)	0.4493	0.14 (0.21)	(-0.27, 0.54)	0.5116	
> 45	24	1.57 (1.70)	25	4.40 (1.72)	-2.83 (2.30)	(-7.50, 1.84)	0.2272	-0.33 (0.29)	(-0.89, 0.24)	0.2533	
Sex											NE
male	4	NE	6	NE	NE	NE		NE	NE		
female	65	3.54 (1.02)	69	3.56 (1.01)	-0.03 (1.33)	(-2.65, 2.60)	0.9837	-0.00 (0.17)	(-0.34, 0.34)	0.9850	
Race											0.1392
White	25	6.27 (1.61)	31	5.17 (1.47)	1.10 (2.08)	(-3.08, 5.28)	0.5981	0.13 (0.27)	(-0.39, 0.66)	0.6193	
Black	16	6.30 (3.32)	8	0.08 (2.92)	6.22 (4.13)	(-2.46, 14.90)	0.1495	0.50 (0.44)	(-0.36, 1.37)	0.2523	
Other	28	1.29 (1.56)	36	3.57 (1.53)	-2.29 (1.94)	(-6.17, 1.60)	0.2434	-0.26 (0.25)	(-0.75, 0.24)	0.3113	
Ethnicity											0.0363
Hispanic/Latino	28	1.79 (1.58)	28	5.32 (1.72)	-3.53 (2.13)	(-7.82, 0.77)	0.1050	-0.40 (0.27)	(-0.93, 0.13)	0.1409	
Non-hispanic/Latino	41	5.25 (1.31)	47	3.17 (1.17)	2.08 (1.62)	(-1.15, 5.31)	0.2033	0.25 (0.21)	(-0.17, 0.67)	0.2407	
Geographic region											0.1904
Latin America, Eastern Europe and Asia	45	3.04 (1.23)	55	4.55 (1.30)	-1.51 (1.47)	(-4.44, 1.42)	0.3098	-0.17 (0.20)	(-0.56, 0.23)	0.4125	
North America	24	4.77 (2.04)	20	1.99 (1.97)	2.78 (2.92)	(-3.15, 8.70)	0.3480	0.29 (0.30)	(-0.31, 0.88)	0.3451	
Baseline weight											0.8452
<60 kg	18	5.22 (2.15)	31	5.66 (1.86)	-0.44 (2.70)	(-5.89, 5.01)	0.8713	-0.04 (0.30)	(-0.62, 0.54)	0.8831	
>=60 kg	51	2.83 (1.11)	44	2.68 (1.10)	0.15 (1.41)	(-2.65, 2.96)	0.9131	0.02 (0.21)	(-0.38, 0.42)	0.9223	
Low CH50											0.1301
Yes	9	1.96 (2.63)	10	-4.52 (2.93)	6.48 (3.94)	(-2.05, 15.02)	0.1242	0.72 (0.48)	(-0.22, 1.65)	0.1334	
No	60	3.99 (1.02)	65	3.81 (0.99)	0.19 (1.35)	(-2.48, 2.85)	0.8905	0.02 (0.18)	(-0.33, 0.37)	0.8969	
Low C3 or C4											0.5850
Yes	25	4.76 (2.73)	33	3.99 (2.34)	0.77 (2.47)	(-4.21, 5.74)	0.7572	0.06 (0.27)	(-0.46, 0.58)	0.8326	
No	44	3.00 (1.05)	42	3.80 (1.10)	-0.80 (1.47)	(-3.74, 2.13)	0.5876	-0.11 (0.22)	(-0.54, 0.31)	0.6010	
Baseline FARR anti-dsDNA											0.7367
<5 IU/mL	15	1.22 (1.76)	11	2.02 (1.94)	-0.79 (2.80)	(-6.60, 5.02)	0.7797	-0.12 (0.40)	(-0.89, 0.66)	0.7715	
>=5 IU/mL	40	4.92 (1.43)	50	4.61 (1.31)	0.31 (1.69)	(-3.06, 3.67)	0.8564	0.03 (0.21)	(-0.38, 0.45)	0.8752	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.2936
Yes	50	4.45 (1.31)	60	3.95 (1.22)	0.50 (1.53)	(-2.54, 3.54)	0.7447	0.05 (0.19)	(-0.32, 0.43)	0.7820	
No	19	1.72 (1.45)	15	4.04 (1.69)	-2.33 (2.21)	(-6.86, 2.21)	0.3022	-0.35 (0.35)	(-1.04, 0.33)	0.3100	
OCS use											0.9445
Yes	54	3.02 (1.11)	63	3.33 (1.08)	-0.31 (1.36)	(-3.02, 2.39)	0.8192	-0.04 (0.19)	(-0.40, 0.33)	0.8421	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute General Health Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
No	15	3.48 (2.63)	12	4.05 (2.63)	-0.57 (3.46)	(-7.75, 6.60)	0.8703	-0.06 (0.39)	(-0.82, 0.70)	0.8831	
SLICC score											0.2585
0	40	2.66 (1.12)	48	4.28 (1.15)	-1.62 (1.48)	(-4.56, 1.32)	0.2761	-0.21 (0.21)	(-0.63, 0.21)	0.3250	
>=1	29	5.23 (1.91)	27	3.60 (1.75)	1.62 (2.46)	(-3.32, 6.57)	0.5127	0.16 (0.27)	(-0.36, 0.69)	0.5392	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Mental Health Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		1.72 (1.12)		1.28 (1.06)	0.44 (1.44)	(-2.40, 3.28)	0.7619			
Week 12		2.92 (1.28)		1.90 (1.22)	1.02 (1.67)	(-2.29, 4.32)	0.5444			
Week 24		1.93 (1.23)		0.70 (1.20)	1.23 (1.63)	(-1.99, 4.45)	0.4526			
Week 36		3.97 (1.33)		2.69 (1.36)	1.28 (1.81)	(-2.31, 4.87)	0.4806			
Week 52		4.80 (1.28)		3.41 (1.33)	1.39 (1.76)	(-2.09, 4.88)	0.4294			
OVERALL	69	3.07 (1.02)	75	2.00 (0.98)	1.07 (1.29)	(-1.49, 3.63)	0.4089	0.13 (0.17)	(-0.20, 0.45)	0.4502

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Mental Health Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.7666
< 10 points	29	3.20 (1.56)	32	1.74 (1.44)	1.46 (2.03)	(-2.62, 5.54)	0.4761	0.17 (0.26)	(-0.33, 0.68)	0.4986	
>= 10 points	40	2.02 (1.41)	43	1.35 (1.41)	0.67 (1.71)	(-2.75, 4.09)	0.6973	0.07 (0.22)	(-0.36, 0.50)	0.7401	
OCS dose											0.9203
<10 mg/day	33	3.14 (1.36)	28	2.16 (1.41)	0.98 (1.87)	(-2.77, 4.72)	0.6025	0.13 (0.26)	(-0.38, 0.63)	0.6243	
>=10 mg/day	36	2.52 (1.56)	47	1.28 (1.43)	1.24 (1.79)	(-2.33, 4.81)	0.4920	0.13 (0.22)	(-0.31, 0.56)	0.5649	
Result of type I IFN gene signature test											0.2996
LOW	14	1.52 (1.78)	19	2.80 (1.62)	-1.27 (2.40)	(-6.34, 3.79)	0.6024	-0.18 (0.35)	(-0.87, 0.51)	0.6104	
HIGH	55	3.34 (1.07)	56	1.67 (1.11)	1.67 (1.51)	(-1.33, 4.67)	0.2729	0.20 (0.19)	(-0.17, 0.58)	0.2841	
Age (years)											0.2488
<= 45	45	3.91 (1.30)	50	1.66 (1.22)	2.25 (1.54)	(-0.81, 5.31)	0.1473	0.26 (0.21)	(-0.15, 0.66)	0.2113	
> 45	24	1.99 (1.80)	25	3.05 (1.79)	-1.06 (2.42)	(-5.97, 3.85)	0.6644	-0.12 (0.29)	(-0.68, 0.44)	0.6821	
Sex											NE
male	4	NE	6	NE	NE	NE		NE	NE		
female	65	3.10 (1.04)	69	1.95 (1.02)	1.15 (1.35)	(-1.51, 3.82)	0.3942	0.14 (0.17)	(-0.20, 0.47)	0.4334	
Race											0.2602
White	25	3.09 (1.64)	31	2.15 (1.50)	0.93 (2.14)	(-3.38, 5.25)	0.6647	0.11 (0.27)	(-0.42, 0.64)	0.6793	
Black	16	10.03 (3.46)	8	2.79 (2.82)	7.23 (3.97)	(-1.01, 15.48)	0.0824	0.57 (0.44)	(-0.30, 1.43)	0.1991	
Other	28	2.20 (1.64)	36	2.23 (1.62)	-0.03 (2.02)	(-4.08, 4.03)	0.9892	-0.00 (0.25)	(-0.50, 0.49)	0.9907	
Ethnicity											0.3345
Hispanic/Latino	28	3.08 (1.63)	28	3.72 (1.77)	-0.64 (2.17)	(-5.01, 3.73)	0.7696	-0.07 (0.27)	(-0.59, 0.45)	0.7927	
Non-hispanic/Latino	41	2.95 (1.37)	47	0.93 (1.22)	2.02 (1.70)	(-1.37, 5.42)	0.2384	0.23 (0.21)	(-0.19, 0.65)	0.2755	
Geographic region											0.4555
Latin America, Eastern Europe and Asia	45	2.43 (1.34)	55	2.30 (1.40)	0.13 (1.62)	(-3.09, 3.35)	0.9344	0.01 (0.20)	(-0.38, 0.41)	0.9462	
North America	24	4.68 (1.93)	20	2.16 (1.84)	2.52 (2.75)	(-3.06, 8.09)	0.3664	0.28 (0.30)	(-0.32, 0.87)	0.3623	
Baseline weight											0.6208
<60 kg	18	2.73 (2.25)	31	2.75 (1.92)	-0.01 (2.81)	(-5.70, 5.67)	0.9960	-0.00 (0.30)	(-0.58, 0.58)	0.9963	
>=60 kg	51	3.13 (1.17)	44	1.56 (1.16)	1.56 (1.49)	(-1.40, 4.52)	0.2974	0.19 (0.21)	(-0.21, 0.60)	0.3510	
Low CH50											0.5754
Yes	9	3.34 (2.77)	10	-0.65 (4.39)	3.98 (5.16)	(-6.99, 14.96)	0.4516	0.33 (0.46)	(-0.58, 1.24)	0.4787	
No	60	3.10 (1.07)	65	2.11 (1.03)	0.99 (1.40)	(-1.78, 3.76)	0.4804	0.12 (0.18)	(-0.23, 0.47)	0.5086	
Low C3 or C4											0.5152
Yes	25	5.02 (2.46)	33	2.52 (2.13)	2.50 (2.41)	(-2.35, 7.36)	0.3048	0.20 (0.27)	(-0.32, 0.72)	0.4487	
No	44	2.11 (1.17)	42	1.50 (1.21)	0.61 (1.62)	(-2.62, 3.84)	0.7074	0.08 (0.22)	(-0.35, 0.50)	0.7183	
Baseline FARR anti-dsDNA											0.4318
<5 IU/mL	15	0.68 (2.38)	11	2.13 (2.44)	-1.45 (3.70)	(-9.19, 6.29)	0.6995	-0.16 (0.40)	(-0.94, 0.62)	0.6869	
>=5 IU/mL	40	3.33 (1.39)	50	1.60 (1.27)	1.73 (1.65)	(-1.55, 5.02)	0.2959	0.19 (0.21)	(-0.22, 0.61)	0.3620	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.2829
Yes	50	3.22 (1.27)	60	1.32 (1.18)	1.90 (1.50)	(-1.07, 4.87)	0.2068	0.21 (0.19)	(-0.17, 0.58)	0.2773	
No	19	2.40 (1.62)	15	3.57 (1.87)	-1.17 (2.44)	(-6.19, 3.85)	0.6352	-0.16 (0.35)	(-0.84, 0.52)	0.6436	
OCS use											0.5283
Yes	54	2.46 (1.23)	63	1.24 (1.18)	1.23 (1.49)	(-1.72, 4.17)	0.4113	0.13 (0.19)	(-0.23, 0.50)	0.4771	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Mental Health Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
No	15	1.70 (2.11)	12	2.37 (2.07)	-0.67 (2.61)	(-6.15, 4.81)	0.8005	-0.08 (0.39)	(-0.84, 0.68)	0.8285	
SLICC score											0.4298
0	40	1.33 (1.24)	48	1.20 (1.26)	0.13 (1.62)	(-3.09, 3.35)	0.9352	0.02 (0.21)	(-0.40, 0.44)	0.9418	
>=1	29	5.92 (1.87)	27	3.49 (1.73)	2.43 (2.42)	(-2.44, 7.30)	0.3205	0.25 (0.27)	(-0.28, 0.78)	0.3509	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Physical Functioning Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		1.57 (0.80)		1.93 (0.77)	-0.36 (1.02)	(-2.38, 1.66)	0.7261			
Week 12		2.74 (1.16)		4.09 (1.11)	-1.35 (1.55)	(-4.41, 1.71)	0.3839			
Week 24		3.70 (1.17)		5.07 (1.15)	-1.37 (1.59)	(-4.51, 1.76)	0.3877			
Week 36		4.16 (1.19)		5.96 (1.21)	-1.80 (1.64)	(-5.04, 1.44)	0.2745			
Week 52		5.58 (1.16)		5.72 (1.20)	-0.14 (1.62)	(-3.34, 3.06)	0.9329			
OVERALL	69	3.55 (0.90)	75	4.55 (0.88)	-1.00 (1.18)	(-3.34, 1.34)	0.3978	-0.13 (0.17)	(-0.46, 0.20)	0.4298

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Physical Functioning Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.1563
< 10 points	29	2.21 (1.30)	32	4.92 (1.20)	-2.71 (1.70)	(-6.11, 0.69)	0.1164	-0.39 (0.26)	(-0.90, 0.12)	0.1341	
>= 10 points	40	4.32 (1.25)	43	3.74 (1.27)	0.58 (1.58)	(-2.57, 3.74)	0.7141	0.07 (0.22)	(-0.36, 0.50)	0.7463	
OCS dose											0.6545
<10 mg/day	33	4.00 (1.28)	28	4.33 (1.34)	-0.33 (1.80)	(-3.94, 3.28)	0.8552	-0.05 (0.26)	(-0.55, 0.46)	0.8610	
>=10 mg/day	36	3.49 (1.36)	47	4.91 (1.25)	-1.42 (1.65)	(-4.70, 1.86)	0.3911	-0.17 (0.22)	(-0.60, 0.27)	0.4485	
Result of type I IFN gene signature test											0.6269
LOW	14	4.65 (1.99)	19	4.59 (1.78)	0.06 (2.70)	(-5.47, 5.59)	0.9826	0.01 (0.35)	(-0.68, 0.70)	0.9828	
HIGH	55	3.53 (0.90)	56	4.92 (0.93)	-1.39 (1.28)	(-3.93, 1.14)	0.2777	-0.20 (0.19)	(-0.58, 0.17)	0.2865	
Age (years)											0.2697
<= 45	45	4.23 (1.05)	50	4.11 (1.00)	0.12 (1.31)	(-2.48, 2.72)	0.9284	0.02 (0.21)	(-0.39, 0.42)	0.9357	
> 45	24	2.43 (1.73)	25	5.29 (1.74)	-2.87 (2.37)	(-7.66, 1.92)	0.2330	-0.33 (0.29)	(-0.89, 0.23)	0.2528	
Sex											NE
male	4	NE	6	NE	NE	NE		NE	NE		
female	65	3.41 (0.92)	69	4.33 (0.91)	-0.93 (1.22)	(-3.34, 1.48)	0.4481	-0.12 (0.17)	(-0.46, 0.22)	0.4770	
Race											0.0267
White	25	4.43 (1.31)	31	4.32 (1.19)	0.11 (1.70)	(-3.31, 3.53)	0.9474	0.02 (0.27)	(-0.51, 0.54)	0.9500	
Black	16	8.13 (3.28)	8	-0.05 (2.54)	8.18 (3.97)	(-0.06, 16.43)	0.0515	0.68 (0.45)	(-0.19, 1.56)	0.1258	
Other	28	2.54 (1.46)	36	5.89 (1.44)	-3.35 (1.87)	(-7.11, 0.41)	0.0794	-0.40 (0.25)	(-0.90, 0.10)	0.1153	
Ethnicity											0.0053
Hispanic/Latino	28	2.12 (1.42)	28	7.03 (1.56)	-4.91 (1.99)	(-8.92, -0.90)	0.0175	-0.61 (0.27)	(-1.15, -0.08)	0.0248	
Non-hispanic/Latino	41	5.00 (1.15)	47	3.08 (1.02)	1.92 (1.43)	(-0.93, 4.77)	0.1835	0.27 (0.21)	(-0.16, 0.69)	0.2161	
Geographic region											0.0077
Latin America, Eastern Europe and Asia	45	3.67 (1.16)	55	6.34 (1.20)	-2.67 (1.43)	(-5.52, 0.17)	0.0649	-0.32 (0.20)	(-0.71, 0.08)	0.1187	
North America	24	5.28 (1.35)	20	1.50 (1.33)	3.77 (1.95)	(-0.17, 7.72)	0.0604	0.59 (0.31)	(-0.02, 1.19)	0.0580	
Baseline weight											0.3157
<60 kg	18	4.51 (2.25)	31	7.52 (1.88)	-3.01 (2.87)	(-8.83, 2.80)	0.3010	-0.29 (0.30)	(-0.88, 0.29)	0.3262	
>=60 kg	51	2.74 (0.95)	44	2.62 (0.94)	0.12 (1.21)	(-2.29, 2.53)	0.9238	0.02 (0.21)	(-0.39, 0.42)	0.9317	
Low CH50											0.3726
Yes	9	2.68 (2.63)	10	-0.78 (3.59)	3.46 (4.41)	(-5.85, 12.77)	0.4435	0.34 (0.46)	(-0.57, 1.24)	0.4698	
No	60	3.79 (0.92)	65	4.41 (0.90)	-0.62 (1.23)	(-3.06, 1.82)	0.6155	-0.09 (0.18)	(-0.44, 0.27)	0.6319	
Low C3 or C4											0.7367
Yes	25	3.85 (2.32)	33	5.14 (2.02)	-1.30 (2.29)	(-5.90, 3.31)	0.5747	-0.11 (0.27)	(-0.63, 0.41)	0.6777	
No	44	3.04 (0.97)	42	3.44 (1.01)	-0.40 (1.36)	(-3.11, 2.31)	0.7702	-0.06 (0.22)	(-0.48, 0.36)	0.7777	
Baseline FARR anti-dsDNA											0.3414
<5 IU/mL	15	3.47 (1.51)	11	1.34 (1.60)	2.14 (2.31)	(-2.67, 6.94)	0.3657	0.37 (0.40)	(-0.42, 1.15)	0.3585	
>=5 IU/mL	40	4.21 (1.25)	50	4.71 (1.15)	-0.50 (1.53)	(-3.54, 2.54)	0.7443	-0.06 (0.21)	(-0.48, 0.35)	0.7710	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.9619
Yes	50	3.94 (1.14)	60	4.86 (1.06)	-0.92 (1.38)	(-3.66, 1.82)	0.5060	-0.11 (0.19)	(-0.49, 0.26)	0.5591	
No	19	3.05 (1.79)	15	4.12 (2.06)	-1.07 (2.75)	(-6.73, 4.59)	0.7008	-0.13 (0.35)	(-0.81, 0.55)	0.7024	
OCS use											0.0336
Yes	54	3.51 (1.07)	63	4.96 (1.05)	-1.45 (1.36)	(-4.15, 1.25)	0.2886	-0.18 (0.19)	(-0.54, 0.19)	0.3402	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Physical Functioning Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=69) N	LSMean (SE)	Placebo (N=75) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
No	15	5.46 (1.49)	12	1.85 (1.47)	3.60 (1.95)	(-0.43, 7.64)	0.0776	0.64 (0.40)	(-0.14, 1.42)	0.1093	
SLICC score											0.7940
0	40	3.16 (1.02)	48	3.71 (1.03)	-0.55 (1.34)	(-3.22, 2.11)	0.6801	-0.08 (0.21)	(-0.50, 0.34)	0.7072	
>=1	29	4.30 (1.78)	27	5.57 (1.71)	-1.26 (2.37)	(-6.03, 3.50)	0.5959	-0.13 (0.27)	(-0.66, 0.39)	0.6147	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Role Emotional Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		0.74 (1.25)		0.48 (1.18)	0.26 (1.61)	(-2.92, 3.44)	0.8711			
Week 12		1.34 (1.44)		2.48 (1.37)	-1.14 (1.89)	(-4.87, 2.60)	0.5476			
Week 24		2.16 (1.29)		1.71 (1.25)	0.45 (1.69)	(-2.89, 3.78)	0.7910			
Week 36		2.98 (1.63)		3.05 (1.66)	-0.07 (2.23)	(-4.49, 4.36)	0.9754			
Week 52		3.81 (1.47)		4.70 (1.53)	-0.89 (2.03)	(-4.90, 3.12)	0.6614			
OVERALL	69	2.21 (1.14)	75	2.48 (1.10)	-0.28 (1.45)	(-3.15, 2.60)	0.8488	-0.03 (0.17)	(-0.36, 0.30)	0.8615

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Role Emotional Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.7470
< 10 points	29	1.43 (1.81)	32	2.28 (1.66)	-0.85 (2.33)	(-5.53, 3.83)	0.7162	-0.09 (0.26)	(-0.59, 0.41)	0.7318	
>= 10 points	40	2.70 (1.53)	43	2.59 (1.52)	0.11 (1.85)	(-3.58, 3.80)	0.9534	0.01 (0.22)	(-0.42, 0.44)	0.9603	
OCS dose											0.8652
<10 mg/day	33	2.48 (1.63)	28	1.96 (1.72)	0.52 (2.28)	(-4.05, 5.10)	0.8188	0.06 (0.26)	(-0.45, 0.56)	0.8276	
>=10 mg/day	36	2.61 (1.73)	47	2.60 (1.58)	0.01 (1.96)	(-3.89, 3.92)	0.9943	0.00 (0.22)	(-0.43, 0.44)	0.9953	
Result of type I IFN gene signature test											0.6750
LOW	14	1.93 (2.64)	19	0.93 (2.38)	1.00 (3.53)	(-6.32, 8.32)	0.7796	0.10 (0.35)	(-0.59, 0.79)	0.7855	
HIGH	55	2.04 (1.13)	56	2.66 (1.17)	-0.62 (1.60)	(-3.79, 2.55)	0.6971	-0.07 (0.19)	(-0.44, 0.30)	0.7036	
Age (years)											0.9031
<= 45	45	1.64 (1.65)	50	2.36 (1.51)	-0.72 (1.93)	(-4.56, 3.12)	0.7098	-0.07 (0.21)	(-0.47, 0.34)	0.7486	
> 45	24	2.96 (1.59)	25	3.33 (1.64)	-0.37 (2.18)	(-4.80, 4.06)	0.8676	-0.05 (0.29)	(-0.61, 0.52)	0.8746	
Sex											NE
male	4	NE	6	NE	NE	NE		NE	NE		
female	65	2.09 (1.17)	69	2.61 (1.14)	-0.52 (1.51)	(-3.52, 2.47)	0.7308	-0.05 (0.17)	(-0.39, 0.28)	0.7516	
Race											0.1136
White	25	3.07 (1.67)	31	2.12 (1.53)	0.96 (2.18)	(-3.43, 5.34)	0.6627	0.11 (0.27)	(-0.42, 0.64)	0.6781	
Black	16	7.54 (6.23)	8	-1.84 (4.25)	9.38 (6.56)	(-4.41, 23.17)	0.1702	0.42 (0.44)	(-0.44, 1.28)	0.3399	
Other	28	2.07 (1.55)	36	5.05 (1.55)	-2.98 (1.91)	(-6.82, 0.86)	0.1257	-0.33 (0.25)	(-0.83, 0.16)	0.1897	
Ethnicity											0.2343
Hispanic/Latino	28	3.20 (1.55)	28	5.75 (1.71)	-2.55 (2.09)	(-6.75, 1.65)	0.2284	-0.29 (0.27)	(-0.82, 0.24)	0.2787	
Non-hispanic/Latino	41	1.44 (1.65)	47	0.51 (1.47)	0.93 (2.05)	(-3.14, 5.00)	0.6510	0.09 (0.21)	(-0.33, 0.51)	0.6758	
Geographic region											0.0856
Latin America, Eastern Europe and Asia	45	2.53 (1.27)	55	4.40 (1.35)	-1.87 (1.52)	(-4.88, 1.15)	0.2223	-0.20 (0.20)	(-0.59, 0.20)	0.3274	
North America	24	1.77 (2.75)	20	-3.59 (2.60)	5.35 (3.92)	(-2.57, 13.28)	0.1797	0.42 (0.31)	(-0.19, 1.02)	0.1754	
Baseline weight											0.3053
<60 kg	18	2.52 (2.32)	31	4.70 (1.97)	-2.18 (2.89)	(-8.02, 3.66)	0.4548	-0.20 (0.30)	(-0.79, 0.38)	0.4940	
>=60 kg	51	2.16 (1.38)	44	0.87 (1.36)	1.28 (1.75)	(-2.19, 4.75)	0.4654	0.13 (0.21)	(-0.27, 0.54)	0.5156	
Low CH50											0.7828
Yes	9	0.63 (3.80)	10	-1.80 (6.35)	2.43 (7.59)	(-13.60, 18.46)	0.7528	0.14 (0.46)	(-0.76, 1.04)	0.7608	
No	60	2.46 (1.14)	65	2.16 (1.10)	0.30 (1.49)	(-2.65, 3.25)	0.8417	0.03 (0.18)	(-0.32, 0.38)	0.8517	
Low C3 or C4											0.3088
Yes	25	4.69 (2.56)	33	6.62 (2.14)	-1.93 (2.22)	(-6.39, 2.54)	0.3896	-0.15 (0.27)	(-0.67, 0.37)	0.5678	
No	44	1.66 (1.43)	42	0.55 (1.47)	1.10 (1.99)	(-2.85, 5.06)	0.5800	0.12 (0.22)	(-0.31, 0.54)	0.5940	
Baseline FARR anti-dsDNA											0.0309
<5 IU/mL	15	4.44 (2.67)	11	-3.58 (2.81)	8.03 (4.09)	(-0.50, 16.55)	0.0637	0.78 (0.41)	(-0.03, 1.59)	0.0587	
>=5 IU/mL	40	1.87 (1.62)	50	3.60 (1.47)	-1.73 (1.93)	(-5.58, 2.11)	0.3727	-0.17 (0.21)	(-0.58, 0.25)	0.4335	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.2337
Yes	50	2.31 (1.47)	60	3.48 (1.36)	-1.17 (1.71)	(-4.56, 2.22)	0.4947	-0.11 (0.19)	(-0.49, 0.26)	0.5617	
No	19	2.45 (2.03)	15	-0.51 (2.30)	2.96 (3.02)	(-3.23, 9.14)	0.3354	0.33 (0.35)	(-0.36, 1.01)	0.3499	
OCS use											0.8442
Yes	54	2.34 (1.29)	63	2.22 (1.25)	0.12 (1.57)	(-2.99, 3.23)	0.9390	0.01 (0.19)	(-0.35, 0.38)	0.9472	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Role Emotional Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=69) N	Anifrolumab 300mg (N=69) LSMean (SE)	Placebo (N=75) N	Placebo (N=75) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
No	15	1.88 (3.29)	12	2.65 (3.29)	-0.77 (4.25)	(-9.66, 8.13)	0.8582	-0.06 (0.39)	(-0.82, 0.70)	0.8743	
SLICC score											0.1462
0	40	0.51 (1.52)	48	2.45 (1.53)	-1.94 (1.99)	(-5.90, 2.02)	0.3321	-0.19 (0.21)	(-0.61, 0.23)	0.3781	
>=1	29	5.17 (1.82)	27	2.58 (1.72)	2.59 (2.40)	(-2.23, 7.41)	0.2859	0.27 (0.27)	(-0.26, 0.80)	0.3127	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Role Physical Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		1.33 (0.81)		0.54 (0.76)	0.79 (1.03)	(-1.24, 2.82)	0.4422			
Week 12		2.78 (1.12)		3.16 (1.07)	-0.39 (1.48)	(-3.32, 2.55)	0.7948			
Week 24		3.86 (1.02)		2.55 (0.99)	1.32 (1.35)	(-1.36, 3.99)	0.3326			
Week 36		4.75 (1.17)		4.92 (1.19)	-0.18 (1.61)	(-3.37, 3.02)	0.9132			
Week 52		5.17 (1.09)		4.89 (1.16)	0.28 (1.53)	(-2.75, 3.31)	0.8547			
OVERALL	69	3.58 (0.83)	75	3.21 (0.80)	0.37 (1.07)	(-1.76, 2.49)	0.7342	0.05 (0.17)	(-0.27, 0.38)	0.7537

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Role Physical Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.9102
< 10 points	29	4.18 (1.31)	32	3.90 (1.18)	0.28 (1.69)	(-3.11, 3.66)	0.8712	0.04 (0.26)	(-0.46, 0.54)	0.8771	
>= 10 points	40	2.84 (1.11)	43	2.32 (1.12)	0.52 (1.39)	(-2.25, 3.30)	0.7085	0.07 (0.22)	(-0.36, 0.50)	0.7433	
OCS dose											0.3625
<10 mg/day	33	4.19 (1.29)	28	2.16 (1.31)	2.04 (1.80)	(-1.57, 5.65)	0.2632	0.28 (0.26)	(-0.23, 0.79)	0.2780	
>=10 mg/day	36	3.23 (1.18)	47	3.27 (1.08)	-0.04 (1.40)	(-2.83, 2.75)	0.9767	-0.01 (0.22)	(-0.44, 0.43)	0.9799	
Result of type I IFN gene signature test											0.2544
LOW	14	4.76 (1.89)	19	1.74 (1.70)	3.02 (2.53)	(-2.17, 8.21)	0.2433	0.41 (0.36)	(-0.29, 1.10)	0.2544	
HIGH	55	3.72 (0.83)	56	3.89 (0.86)	-0.16 (1.18)	(-2.50, 2.18)	0.8901	-0.03 (0.19)	(-0.40, 0.35)	0.8924	
Age (years)											0.3577
<= 45	45	3.05 (1.07)	50	3.56 (1.02)	-0.51 (1.30)	(-3.09, 2.07)	0.6939	-0.07 (0.21)	(-0.47, 0.33)	0.7304	
> 45	24	4.21 (1.57)	25	2.42 (1.54)	1.79 (2.14)	(-2.54, 6.12)	0.4083	0.23 (0.29)	(-0.33, 0.79)	0.4248	
Sex											NE
male	4	NE	6	NE	NE	NE		NE	NE		
female	65	3.52 (0.85)	69	3.27 (0.84)	0.25 (1.11)	(-1.95, 2.44)	0.8233	0.04 (0.17)	(-0.30, 0.37)	0.8359	
Race											0.0088
White	25	5.62 (1.22)	31	3.10 (1.09)	2.52 (1.57)	(-0.64, 5.69)	0.1154	0.41 (0.27)	(-0.12, 0.94)	0.1319	
Black	16	7.37 (3.59)	8	2.00 (2.96)	5.37 (4.34)	(-3.67, 14.41)	0.2300	0.41 (0.44)	(-0.45, 1.26)	0.3535	
Other	28	1.07 (1.17)	36	4.49 (1.17)	-3.42 (1.46)	(-6.36, -0.48)	0.0233	-0.51 (0.26)	(-1.01, -0.00)	0.0486	
Ethnicity											0.0193
Hispanic/Latino	28	1.78 (1.33)	28	4.55 (1.47)	-2.76 (1.79)	(-6.37, 0.84)	0.1294	-0.37 (0.27)	(-0.90, 0.16)	0.1728	
Non-hispanic/Latino	41	4.87 (1.10)	47	2.32 (0.99)	2.55 (1.40)	(-0.23, 5.33)	0.0718	0.37 (0.22)	(-0.06, 0.79)	0.0898	
Geographic region											0.0110
Latin America, Eastern Europe and Asia	45	2.35 (0.97)	55	4.24 (1.02)	-1.89 (1.17)	(-4.21, 0.44)	0.1109	-0.26 (0.20)	(-0.66, 0.13)	0.1908	
North America	24	7.80 (1.72)	20	2.70 (1.71)	5.10 (2.48)	(0.08, 10.11)	0.0467	0.62 (0.31)	(0.01, 1.23)	0.0465	
Baseline weight											0.6119
<60 kg	18	4.30 (1.70)	31	4.53 (1.48)	-0.23 (2.14)	(-4.57, 4.10)	0.9140	-0.03 (0.30)	(-0.61, 0.55)	0.9219	
>=60 kg	51	3.46 (1.00)	44	2.42 (1.00)	1.04 (1.30)	(-1.55, 3.62)	0.4264	0.15 (0.21)	(-0.25, 0.55)	0.4693	
Low CH50											0.5187
Yes	9	2.47 (3.05)	10	-1.73 (4.09)	4.20 (5.09)	(-6.55, 14.95)	0.4210	0.35 (0.46)	(-0.55, 1.26)	0.4448	
No	60	3.87 (0.82)	65	3.03 (0.80)	0.84 (1.08)	(-1.30, 2.98)	0.4393	0.13 (0.18)	(-0.22, 0.48)	0.4667	
Low C3 or C4											0.4803
Yes	25	3.04 (2.02)	33	3.61 (1.73)	-0.57 (1.92)	(-4.44, 3.30)	0.7665	-0.06 (0.27)	(-0.58, 0.46)	0.8316	
No	44	3.65 (0.94)	42	2.58 (0.97)	1.07 (1.31)	(-1.53, 3.67)	0.4172	0.17 (0.22)	(-0.25, 0.59)	0.4349	
Baseline FARR anti-dsDNA											0.0011
<5 IU/mL	15	9.04 (1.83)	11	-1.09 (1.83)	10.13 (2.75)	(4.45, 15.82)	0.0012	1.47 (0.45)	(0.58, 2.36)	0.0013	
>=5 IU/mL	40	3.71 (1.13)	50	3.61 (1.04)	0.10 (1.40)	(-2.68, 2.88)	0.9431	0.01 (0.21)	(-0.40, 0.43)	0.9487	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.3291
Yes	50	3.38 (1.04)	60	3.44 (0.97)	-0.06 (1.26)	(-2.56, 2.44)	0.9632	-0.01 (0.19)	(-0.38, 0.37)	0.9677	
No	19	4.19 (1.48)	15	1.77 (1.69)	2.42 (2.20)	(-2.09, 6.93)	0.2814	0.36 (0.35)	(-0.32, 1.05)	0.2963	
OCS use											0.3711
Yes	54	3.62 (0.91)	63	3.56 (0.89)	0.06 (1.13)	(-2.17, 2.29)	0.9569	0.01 (0.19)	(-0.35, 0.37)	0.9620	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Role Physical Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=69) N	Anifrolumab 300mg (N=69) LSMean (SE)	Placebo (N=75) N	Placebo (N=75) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
No	15	3.15 (2.33)	12	0.03 (2.38)	3.12 (3.23)	(-3.56, 9.81)	0.3440	0.35 (0.39)	(-0.42, 1.11)	0.3720	
SLICC score											0.3929
0	40	2.87 (0.99)	48	3.54 (1.02)	-0.67 (1.31)	(-3.27, 1.92)	0.6078	-0.10 (0.21)	(-0.52, 0.32)	0.6426	
>=1	29	4.72 (1.49)	27	3.40 (1.39)	1.33 (1.94)	(-2.58, 5.24)	0.4979	0.17 (0.27)	(-0.35, 0.70)	0.5230	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Social Functioning Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		3.14 (0.93)		1.81 (0.87)	1.33 (1.17)	(-0.98, 3.64)	0.2557			
Week 12		4.24 (1.16)		3.04 (1.10)	1.20 (1.51)	(-1.79, 4.19)	0.4301			
Week 24		4.53 (1.15)		3.21 (1.12)	1.32 (1.52)	(-1.70, 4.33)	0.3888			
Week 36		6.29 (1.27)		3.22 (1.28)	3.08 (1.73)	(-0.34, 6.50)	0.0774			
Week 52		5.08 (1.31)		4.12 (1.35)	0.95 (1.81)	(-2.62, 4.52)	0.5987			
OVERALL	69	4.65 (0.98)	75	3.08 (0.93)	1.58 (1.25)	(-0.90, 4.05)	0.2097	0.19 (0.17)	(-0.13, 0.52)	0.2476

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Social Functioning Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.7155
< 10 points	29	4.42 (1.38)	32	3.31 (1.27)	1.10 (1.80)	(-2.50, 4.71)	0.5427	0.15 (0.26)	(-0.35, 0.65)	0.5608	
>= 10 points	40	4.65 (1.44)	43	2.63 (1.42)	2.02 (1.76)	(-1.48, 5.52)	0.2537	0.22 (0.22)	(-0.21, 0.65)	0.3241	
OCS dose											0.9442
<10 mg/day	33	4.25 (1.37)	28	2.48 (1.41)	1.77 (1.91)	(-2.05, 5.59)	0.3580	0.23 (0.26)	(-0.28, 0.73)	0.3781	
>=10 mg/day	36	4.84 (1.45)	47	3.25 (1.33)	1.59 (1.70)	(-1.79, 4.97)	0.3516	0.18 (0.22)	(-0.26, 0.61)	0.4281	
Result of type I IFN gene signature test											0.3672
LOW	14	5.36 (1.95)	19	1.76 (1.76)	3.60 (2.62)	(-1.76, 8.97)	0.1800	0.47 (0.36)	(-0.23, 1.17)	0.1907	
HIGH	55	4.33 (1.01)	56	3.42 (1.05)	0.91 (1.43)	(-1.93, 3.75)	0.5276	0.12 (0.19)	(-0.25, 0.49)	0.5354	
Age (years)											0.4210
<= 45	45	4.84 (1.30)	50	2.58 (1.22)	2.26 (1.58)	(-0.88, 5.39)	0.1556	0.26 (0.21)	(-0.15, 0.66)	0.2115	
> 45	24	3.72 (1.56)	25	3.56 (1.53)	0.16 (2.08)	(-4.02, 4.34)	0.9384	0.02 (0.29)	(-0.54, 0.58)	0.9421	
Sex											NE
male	4	NE	6	NE	NE	NE		NE	NE		
female	65	4.63 (1.01)	69	2.90 (0.99)	1.73 (1.32)	(-0.87, 4.33)	0.1912	0.21 (0.17)	(-0.13, 0.55)	0.2264	
Race											0.2078
White	25	5.67 (1.45)	31	3.36 (1.31)	2.31 (1.89)	(-1.48, 6.09)	0.2272	0.31 (0.27)	(-0.22, 0.84)	0.2485	
Black	16	6.25 (3.75)	8	-1.67 (2.97)	7.92 (4.17)	(-0.79, 16.63)	0.0722	0.58 (0.44)	(-0.29, 1.44)	0.1924	
Other	28	4.70 (1.60)	36	4.80 (1.52)	-0.10 (1.99)	(-4.09, 3.89)	0.9588	-0.01 (0.25)	(-0.51, 0.48)	0.9634	
Ethnicity											0.0339
Hispanic/Latino	28	4.18 (1.55)	28	6.23 (1.65)	-2.05 (2.07)	(-6.21, 2.11)	0.3266	-0.24 (0.27)	(-0.76, 0.29)	0.3727	
Non-hispanic/Latino	41	5.23 (1.27)	47	1.75 (1.13)	3.49 (1.59)	(0.33, 6.65)	0.0310	0.44 (0.22)	(0.01, 0.86)	0.0441	
Geographic region											0.4203
Latin America, Eastern Europe and Asia	45	5.59 (1.20)	55	4.49 (1.24)	1.11 (1.46)	(-1.79, 4.00)	0.4499	0.13 (0.20)	(-0.27, 0.52)	0.5297	
North America	24	4.29 (1.93)	20	0.70 (1.82)	3.59 (2.72)	(-1.90, 9.07)	0.1937	0.40 (0.31)	(-0.20, 1.00)	0.1953	
Baseline weight											0.9895
<60 kg	18	4.34 (2.17)	31	2.69 (1.82)	1.65 (2.71)	(-3.82, 7.11)	0.5468	0.16 (0.30)	(-0.42, 0.75)	0.5783	
>=60 kg	51	4.80 (1.09)	44	3.12 (1.08)	1.69 (1.40)	(-1.10, 4.47)	0.2320	0.22 (0.21)	(-0.18, 0.63)	0.2814	
Low CH50											0.8835
Yes	9	4.24 (2.59)	10	1.78 (3.33)	2.46 (4.17)	(-6.39, 11.31)	0.5637	0.25 (0.46)	(-0.65, 1.16)	0.5851	
No	60	4.78 (1.03)	65	2.96 (0.99)	1.82 (1.35)	(-0.86, 4.49)	0.1812	0.23 (0.18)	(-0.13, 0.58)	0.2081	
Low C3 or C4											0.7714
Yes	25	8.28 (2.17)	33	5.78 (1.90)	2.50 (2.19)	(-1.90, 6.90)	0.2594	0.23 (0.27)	(-0.29, 0.75)	0.3944	
No	44	3.45 (1.11)	42	1.73 (1.14)	1.72 (1.53)	(-1.33, 4.77)	0.2647	0.23 (0.22)	(-0.19, 0.66)	0.2848	
Baseline FARR anti-dsDNA											0.6285
<5 IU/mL	15	1.77 (2.02)	11	-1.74 (2.04)	3.52 (3.01)	(-2.72, 9.75)	0.2549	0.46 (0.40)	(-0.33, 1.25)	0.2537	
>=5 IU/mL	40	5.70 (1.37)	50	3.85 (1.24)	1.85 (1.67)	(-1.48, 5.18)	0.2718	0.21 (0.21)	(-0.21, 0.63)	0.3229	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.9911
Yes	50	5.75 (1.21)	60	3.76 (1.11)	1.99 (1.45)	(-0.90, 4.87)	0.1745	0.23 (0.19)	(-0.15, 0.61)	0.2309	
No	19	2.65 (1.77)	15	0.70 (2.01)	1.96 (2.64)	(-3.43, 7.35)	0.4641	0.25 (0.35)	(-0.43, 0.93)	0.4774	
OCS use											0.8388
Yes	54	4.91 (1.14)	63	3.21 (1.10)	1.70 (1.41)	(-1.09, 4.49)	0.2308	0.20 (0.19)	(-0.17, 0.56)	0.2894	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Social Functioning Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
No	15	3.20 (2.29)	12	0.81 (2.28)	2.39 (3.08)	(-3.97, 8.74)	0.4461	0.27 (0.39)	(-0.49, 1.04)	0.4818	
SLICC score											0.4746
0	40	3.74 (1.18)	48	3.06 (1.18)	0.69 (1.53)	(-2.36, 3.73)	0.6551	0.09 (0.21)	(-0.33, 0.51)	0.6860	
>=1	29	6.28 (1.83)	27	3.61 (1.64)	2.67 (2.32)	(-1.98, 7.32)	0.2543	0.29 (0.27)	(-0.24, 0.81)	0.2884	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Bodily Pain Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		2.60 (0.89)		2.61 (0.84)	-0.01 (1.13)	(-2.24, 2.22)	0.9919			
Week 12		3.69 (1.14)		4.94 (1.09)	-1.25 (1.50)	(-4.22, 1.73)	0.4089			
Week 24		4.98 (1.27)		4.64 (1.25)	0.34 (1.72)	(-3.06, 3.73)	0.8457			
Week 36		7.12 (1.33)		5.78 (1.34)	1.34 (1.83)	(-2.28, 4.96)	0.4656			
Week 52		7.05 (1.28)		6.34 (1.33)	0.71 (1.78)	(-2.81, 4.24)	0.6886			
OVERALL	69	5.09 (0.98)	75	4.86 (0.95)	0.23 (1.28)	(-2.30, 2.75)	0.8598	0.03 (0.17)	(-0.30, 0.35)	0.8691

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Bodily Pain Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.9514
< 10 points	29	5.40 (1.51)	32	5.21 (1.38)	0.19 (1.97)	(-3.76, 4.14)	0.9234	0.02 (0.26)	(-0.48, 0.53)	0.9269	
>= 10 points	40	5.25 (1.38)	43	4.90 (1.37)	0.35 (1.75)	(-3.13, 3.83)	0.8416	0.04 (0.22)	(-0.39, 0.47)	0.8582	
OCS dose											0.8598
<10 mg/day	33	4.55 (1.63)	28	4.50 (1.69)	0.05 (2.31)	(-4.57, 4.68)	0.9814	0.01 (0.26)	(-0.50, 0.51)	0.9820	
>=10 mg/day	36	6.23 (1.31)	47	5.68 (1.19)	0.55 (1.60)	(-2.63, 3.73)	0.7317	0.07 (0.22)	(-0.37, 0.50)	0.7596	
Result of type I IFN gene signature test											0.7721
LOW	14	4.30 (2.56)	19	3.24 (2.29)	1.06 (3.43)	(-6.00, 8.11)	0.7605	0.11 (0.35)	(-0.59, 0.80)	0.7657	
HIGH	55	5.78 (0.95)	56	5.79 (0.98)	-0.01 (1.34)	(-2.68, 2.66)	0.9939	-0.00 (0.19)	(-0.37, 0.37)	0.9940	
Age (years)											0.7563
<= 45	45	5.47 (1.25)	50	5.58 (1.18)	-0.11 (1.52)	(-3.12, 2.91)	0.9442	-0.01 (0.21)	(-0.42, 0.39)	0.9509	
> 45	24	3.86 (1.75)	25	3.09 (1.73)	0.77 (2.40)	(-4.08, 5.63)	0.7486	0.09 (0.29)	(-0.47, 0.65)	0.7563	
Sex											NE
male	4	NE	6	NE	NE	NE		NE	NE		
female	65	5.15 (1.02)	69	4.66 (1.01)	0.49 (1.35)	(-2.18, 3.16)	0.7189	0.06 (0.17)	(-0.28, 0.40)	0.7362	
Race											0.4813
White	25	5.75 (1.59)	31	4.81 (1.44)	0.94 (2.08)	(-3.24, 5.11)	0.6535	0.12 (0.27)	(-0.41, 0.64)	0.6668	
Black	16	7.81 (3.75)	8	2.59 (3.15)	5.22 (4.75)	(-4.66, 15.10)	0.2846	0.38 (0.44)	(-0.48, 1.23)	0.3881	
Other	28	4.25 (1.57)	36	5.06 (1.53)	-0.81 (2.00)	(-4.82, 3.19)	0.6851	-0.09 (0.25)	(-0.59, 0.40)	0.7181	
Ethnicity											0.4488
Hispanic/Latino	28	5.15 (1.59)	28	6.69 (1.71)	-1.54 (2.19)	(-5.93, 2.85)	0.4845	-0.17 (0.27)	(-0.70, 0.35)	0.5158	
Non-hispanic/Latino	41	4.77 (1.29)	47	4.24 (1.16)	0.53 (1.63)	(-2.72, 3.77)	0.7478	0.06 (0.21)	(-0.35, 0.48)	0.7638	
Geographic region											0.4783
Latin America, Eastern Europe and Asia	45	5.84 (1.20)	55	5.99 (1.23)	-0.15 (1.48)	(-3.08, 2.78)	0.9198	-0.02 (0.20)	(-0.41, 0.38)	0.9324	
North America	24	5.23 (2.20)	20	2.85 (2.18)	2.38 (3.25)	(-4.19, 8.96)	0.4680	0.23 (0.30)	(-0.37, 0.82)	0.4555	
Baseline weight											0.7415
<60 kg	18	6.53 (2.24)	31	6.50 (1.86)	0.03 (2.82)	(-5.66, 5.71)	0.9923	0.00 (0.30)	(-0.58, 0.58)	0.9927	
>=60 kg	51	4.59 (1.07)	44	3.52 (1.08)	1.07 (1.41)	(-1.73, 3.86)	0.4502	0.14 (0.21)	(-0.26, 0.55)	0.4901	
Low CH50											0.4981
Yes	9	7.54 (3.43)	10	11.07 (4.78)	-3.53 (5.87)	(-16.07, 9.01)	0.5566	-0.26 (0.46)	(-1.16, 0.65)	0.5767	
No	60	4.96 (1.00)	65	4.41 (0.97)	0.54 (1.33)	(-2.09, 3.18)	0.6828	0.07 (0.18)	(-0.28, 0.42)	0.6980	
Low C3 or C4											0.7772
Yes	25	6.55 (2.40)	33	6.52 (2.07)	0.03 (2.45)	(-4.88, 4.95)	0.9889	0.00 (0.27)	(-0.52, 0.52)	0.9915	
No	44	4.67 (1.07)	42	3.82 (1.11)	0.85 (1.50)	(-2.14, 3.83)	0.5739	0.12 (0.22)	(-0.31, 0.54)	0.5861	
Baseline FARR anti-dsDNA											0.1842
<5 IU/mL	15	6.00 (2.37)	11	1.59 (2.32)	4.41 (3.55)	(-2.95, 11.76)	0.2276	0.50 (0.40)	(-0.29, 1.29)	0.2186	
>=5 IU/mL	40	5.23 (1.34)	50	6.02 (1.23)	-0.79 (1.63)	(-4.04, 2.46)	0.6315	-0.09 (0.21)	(-0.51, 0.33)	0.6689	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.6056
Yes	50	5.13 (1.20)	60	5.44 (1.12)	-0.31 (1.45)	(-3.19, 2.58)	0.8342	-0.04 (0.19)	(-0.41, 0.34)	0.8539	
No	19	5.39 (2.02)	15	3.96 (2.29)	1.43 (3.02)	(-4.75, 7.60)	0.6403	0.16 (0.35)	(-0.52, 0.84)	0.6489	
OCS use											0.9993
Yes	54	5.22 (1.08)	63	4.88 (1.04)	0.34 (1.35)	(-2.35, 3.02)	0.8041	0.04 (0.19)	(-0.32, 0.40)	0.8236	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Bodily Pain Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
No	15	3.45 (2.79)	12	3.11 (2.74)	0.34 (3.66)	(-7.22, 7.90)	0.9267	0.03 (0.39)	(-0.73, 0.79)	0.9339	
SLICC score											0.4317
0	40	5.01 (1.24)	48	3.80 (1.24)	1.20 (1.63)	(-2.03, 4.44)	0.4607	0.14 (0.21)	(-0.28, 0.56)	0.5003	
>=1	29	5.49 (1.64)	27	6.40 (1.54)	-0.91 (2.15)	(-5.23, 3.40)	0.6725	-0.11 (0.27)	(-0.63, 0.42)	0.6902	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Vitality Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		1.79 (0.77)		1.60 (0.72)	0.19 (0.97)	(-1.73, 2.11)	0.8468			
Week 12		2.98 (1.01)		2.96 (0.96)	0.02 (1.33)	(-2.60, 2.64)	0.9892			
Week 24		2.19 (0.97)		3.17 (0.94)	-0.98 (1.28)	(-3.52, 1.56)	0.4468			
Week 36		3.74 (1.12)		3.25 (1.12)	0.49 (1.53)	(-2.53, 3.51)	0.7483			
Week 52		4.33 (1.10)		3.04 (1.13)	1.29 (1.52)	(-1.73, 4.30)	0.3998			
OVERALL	69	3.01 (0.84)	75	2.81 (0.80)	0.20 (1.09)	(-1.95, 2.35)	0.8534	0.03 (0.17)	(-0.30, 0.36)	0.8634

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Vitality Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.6394
< 10 points	29	3.87 (1.33)	32	4.12 (1.22)	-0.25 (1.75)	(-3.75, 3.25)	0.8857	-0.04 (0.26)	(-0.54, 0.47)	0.8903	
>= 10 points	40	2.02 (1.13)	43	1.22 (1.12)	0.79 (1.39)	(-1.97, 3.55)	0.5693	0.11 (0.22)	(-0.32, 0.54)	0.6217	
OCS dose											0.8050
<10 mg/day	33	3.11 (1.28)	28	3.11 (1.33)	-0.00 (1.81)	(-3.62, 3.62)	0.9993	-0.00 (0.26)	(-0.50, 0.50)	0.9993	
>=10 mg/day	36	2.70 (1.16)	47	2.14 (1.07)	0.56 (1.36)	(-2.15, 3.27)	0.6834	0.08 (0.22)	(-0.36, 0.51)	0.7284	
Result of type I IFN gene signature test											0.2962
LOW	14	1.29 (1.73)	19	3.22 (1.53)	-1.93 (2.32)	(-6.68, 2.81)	0.4120	-0.29 (0.35)	(-0.98, 0.41)	0.4199	
HIGH	55	3.88 (0.87)	56	3.06 (0.90)	0.82 (1.25)	(-1.65, 3.29)	0.5121	0.12 (0.19)	(-0.25, 0.50)	0.5172	
Age (years)											0.7620
<= 45	45	4.22 (1.01)	50	3.79 (0.95)	0.43 (1.26)	(-2.07, 2.94)	0.7319	0.06 (0.21)	(-0.34, 0.47)	0.7572	
> 45	24	1.64 (1.49)	25	1.93 (1.47)	-0.29 (2.02)	(-4.35, 3.78)	0.8875	-0.04 (0.29)	(-0.60, 0.52)	0.8930	
Sex											NE
male	4	NE	6	NE	NE	NE		NE	NE		
female	65	3.12 (0.88)	69	2.71 (0.85)	0.42 (1.15)	(-1.85, 2.69)	0.7176	0.06 (0.17)	(-0.28, 0.40)	0.7356	
Race											0.1098
White	25	1.00 (1.14)	31	2.82 (1.03)	-1.82 (1.50)	(-4.82, 1.19)	0.2305	-0.31 (0.27)	(-0.84, 0.22)	0.2471	
Black	16	5.85 (2.66)	8	0.56 (2.23)	5.30 (3.04)	(-1.02, 11.62)	0.0960	0.54 (0.44)	(-0.32, 1.41)	0.2211	
Other	28	3.84 (1.44)	36	4.02 (1.38)	-0.18 (1.80)	(-3.77, 3.42)	0.9221	-0.02 (0.25)	(-0.52, 0.47)	0.9311	
Ethnicity											0.4233
Hispanic/Latino	28	3.24 (1.44)	28	4.55 (1.55)	-1.30 (1.92)	(-5.17, 2.56)	0.5002	-0.16 (0.27)	(-0.69, 0.36)	0.5434	
Non-hispanic/Latino	41	2.45 (1.03)	47	1.88 (0.94)	0.57 (1.33)	(-2.08, 3.21)	0.6715	0.09 (0.21)	(-0.33, 0.51)	0.6872	
Geographic region											0.8411
Latin America, Eastern Europe and Asia	45	3.12 (1.13)	55	3.72 (1.16)	-0.60 (1.38)	(-3.34, 2.13)	0.6627	-0.07 (0.20)	(-0.47, 0.32)	0.7146	
North America	24	2.65 (1.27)	20	2.79 (1.27)	-0.14 (1.83)	(-3.83, 3.55)	0.9377	-0.02 (0.30)	(-0.62, 0.57)	0.9378	
Baseline weight											0.9583
<60 kg	18	4.35 (1.74)	31	4.04 (1.51)	0.31 (2.18)	(-4.08, 4.71)	0.8859	0.04 (0.30)	(-0.54, 0.62)	0.8969	
>=60 kg	51	2.28 (0.97)	44	2.10 (0.98)	0.18 (1.29)	(-2.38, 2.75)	0.8882	0.03 (0.21)	(-0.38, 0.43)	0.8965	
Low CH50											0.9485
Yes	9	3.37 (1.87)	10	2.60 (3.68)	0.76 (4.18)	(-8.95, 10.48)	0.8597	0.08 (0.46)	(-0.82, 0.98)	0.8645	
No	60	3.16 (0.88)	65	2.67 (0.85)	0.48 (1.17)	(-1.83, 2.79)	0.6790	0.07 (0.18)	(-0.28, 0.42)	0.6941	
Low C3 or C4											0.5974
Yes	25	4.35 (1.89)	33	4.63 (1.65)	-0.28 (1.75)	(-3.81, 3.25)	0.8731	-0.03 (0.27)	(-0.55, 0.49)	0.9118	
No	44	2.53 (1.01)	42	1.62 (1.03)	0.91 (1.40)	(-1.89, 3.70)	0.5209	0.13 (0.22)	(-0.29, 0.56)	0.5341	
Baseline FARR anti-dsDNA											0.2736
<5 IU/mL	15	4.30 (1.59)	11	1.82 (1.73)	2.48 (2.44)	(-2.54, 7.51)	0.3184	0.40 (0.40)	(-0.38, 1.19)	0.3160	
>=5 IU/mL	40	2.05 (1.16)	50	2.65 (1.06)	-0.60 (1.41)	(-3.41, 2.20)	0.6713	-0.08 (0.21)	(-0.50, 0.34)	0.7047	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.7616
Yes	50	2.70 (1.05)	60	2.74 (0.97)	-0.05 (1.26)	(-2.55, 2.46)	0.9710	-0.01 (0.19)	(-0.38, 0.37)	0.9745	
No	19	3.60 (1.59)	15	2.83 (1.79)	0.77 (2.36)	(-4.08, 5.61)	0.7480	0.11 (0.35)	(-0.57, 0.79)	0.7545	
OCS use											0.7640
Yes	54	3.13 (1.00)	63	2.94 (0.96)	0.19 (1.24)	(-2.27, 2.64)	0.8812	0.02 (0.19)	(-0.34, 0.39)	0.8947	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Vitality Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
No	15	2.21 (1.57)	12	1.30 (1.60)	0.91 (2.08)	(-3.39, 5.21)	0.6651	0.15 (0.39)	(-0.61, 0.91)	0.6967	
SLICC score											0.8927
0	40	3.95 (0.99)	48	3.70 (0.99)	0.25 (1.31)	(-2.36, 2.85)	0.8506	0.04 (0.21)	(-0.38, 0.46)	0.8624	
>=1	29	1.61 (1.51)	27	1.68 (1.37)	-0.07 (1.93)	(-3.95, 3.81)	0.9722	-0.01 (0.27)	(-0.53, 0.52)	0.9740	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - FACIT-F Total Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		1.58 (0.97)		0.42 (0.91)	1.16 (1.22)	(-1.25, 3.56)	0.3432			
Week 12		3.38 (1.16)		2.83 (1.11)	0.55 (1.51)	(-2.44, 3.54)	0.7174			
Week 24		4.31 (1.29)		2.64 (1.26)	1.67 (1.72)	(-1.73, 5.07)	0.3323			
Week 36		5.08 (1.41)		3.95 (1.42)	1.14 (1.92)	(-2.67, 4.94)	0.5550			
Week 52		5.16 (1.35)		4.29 (1.38)	0.87 (1.85)	(-2.80, 4.53)	0.6402			
OVERALL	69	3.90 (1.05)	75	2.83 (1.01)	1.08 (1.36)	(-1.60, 3.76)	0.4284	0.12 (0.17)	(-0.20, 0.45)	0.4638

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - FACIT-F Total Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=69) N	LSMean (SE)	Placebo (N=75) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.5961
< 10 points	29	4.43 (1.50)	32	3.99 (1.38)	0.44 (1.95)	(-3.46, 4.35)	0.8209	0.06 (0.26)	(-0.45, 0.56)	0.8297	
>= 10 points	40	3.21 (1.49)	43	1.35 (1.48)	1.86 (1.83)	(-1.79, 5.51)	0.3132	0.19 (0.22)	(-0.24, 0.62)	0.3818	
OCS dose											0.3789
<10 mg/day	33	4.61 (1.48)	28	1.53 (1.53)	3.07 (2.07)	(-1.07, 7.22)	0.1425	0.37 (0.26)	(-0.14, 0.87)	0.1584	
>=10 mg/day	36	3.69 (1.51)	47	3.03 (1.40)	0.66 (1.80)	(-2.92, 4.25)	0.7140	0.07 (0.22)	(-0.36, 0.50)	0.7517	
Result of type I IFN gene signature test											0.7765
LOW	14	3.89 (2.18)	19	1.97 (2.00)	1.92 (2.99)	(-4.23, 8.06)	0.5264	0.22 (0.35)	(-0.47, 0.91)	0.5329	
HIGH	55	4.17 (1.06)	56	3.20 (1.09)	0.97 (1.50)	(-2.00, 3.94)	0.5186	0.12 (0.19)	(-0.25, 0.49)	0.5263	
Age (years)											0.7210
<= 45	45	4.35 (1.29)	50	2.96 (1.23)	1.39 (1.58)	(-1.75, 4.53)	0.3819	0.16 (0.21)	(-0.24, 0.56)	0.4410	
> 45	24	2.72 (2.02)	25	2.45 (1.96)	0.27 (2.70)	(-5.18, 5.72)	0.9200	0.03 (0.29)	(-0.53, 0.59)	0.9241	
Sex											NE
male	4	NE	6	NE	NE	NE		NE	NE		
female	65	4.06 (1.08)	69	2.61 (1.07)	1.46 (1.42)	(-1.34, 4.26)	0.3048	0.16 (0.17)	(-0.17, 0.50)	0.3408	
Race											0.2130
White	25	5.46 (1.49)	31	2.50 (1.34)	2.96 (1.93)	(-0.92, 6.84)	0.1313	0.39 (0.27)	(-0.14, 0.92)	0.1493	
Black	16	6.40 (3.48)	8	0.98 (3.30)	5.41 (4.30)	(-3.48, 14.30)	0.2206	0.41 (0.44)	(-0.44, 1.27)	0.3452	
Other	28	2.81 (1.73)	36	4.09 (1.69)	-1.28 (2.14)	(-5.57, 3.00)	0.5512	-0.13 (0.25)	(-0.62, 0.36)	0.6051	
Ethnicity											0.0287
Hispanic/Latino	28	3.70 (1.65)	28	6.22 (1.80)	-2.52 (2.22)	(-6.98, 1.94)	0.2619	-0.27 (0.27)	(-0.80, 0.25)	0.3117	
Non-hispanic/Latino	41	4.87 (1.35)	47	1.26 (1.21)	3.61 (1.71)	(0.21, 7.00)	0.0375	0.42 (0.22)	(-0.00, 0.85)	0.0508	
Geographic region											0.2142
Latin America, Eastern Europe and Asia	45	4.36 (1.34)	55	4.11 (1.39)	0.25 (1.64)	(-3.01, 3.51)	0.8789	0.03 (0.20)	(-0.37, 0.42)	0.8988	
North America	24	4.60 (1.87)	20	0.43 (1.84)	4.17 (2.70)	(-1.28, 9.62)	0.1297	0.47 (0.31)	(-0.14, 1.07)	0.1284	
Baseline weight											0.3659
<60 kg	18	4.60 (2.45)	31	5.18 (2.10)	-0.58 (3.07)	(-6.77, 5.61)	0.8513	-0.05 (0.30)	(-0.63, 0.53)	0.8643	
>=60 kg	51	3.72 (1.10)	44	1.24 (1.10)	2.48 (1.43)	(-0.36, 5.32)	0.0857	0.32 (0.21)	(-0.08, 0.73)	0.1183	
Low CH50											0.9437
Yes	9	1.82 (2.83)	10	-0.01 (4.28)	1.84 (5.04)	(-8.80, 12.47)	0.7202	0.15 (0.46)	(-0.75, 1.06)	0.7388	
No	60	4.29 (1.11)	65	2.82 (1.07)	1.47 (1.47)	(-1.44, 4.37)	0.3192	0.17 (0.18)	(-0.18, 0.52)	0.3460	
Low C3 or C4											0.8667
Yes	25	4.17 (2.60)	33	3.15 (2.25)	1.03 (2.48)	(-3.96, 6.02)	0.6812	0.08 (0.27)	(-0.44, 0.60)	0.7684	
No	44	3.60 (1.17)	42	2.07 (1.21)	1.53 (1.64)	(-1.74, 4.79)	0.3548	0.19 (0.22)	(-0.23, 0.62)	0.3715	
Baseline FARR anti-dsDNA											0.9283
<5 IU/mL	15	3.26 (1.96)	11	1.61 (2.11)	1.65 (2.99)	(-4.52, 7.82)	0.5862	0.22 (0.40)	(-0.56, 1.00)	0.5854	
>=5 IU/mL	40	3.97 (1.50)	50	2.64 (1.36)	1.33 (1.84)	(-2.32, 4.99)	0.4705	0.14 (0.21)	(-0.28, 0.55)	0.5159	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.8012
Yes	50	3.80 (1.33)	60	2.43 (1.23)	1.37 (1.59)	(-1.79, 4.53)	0.3918	0.14 (0.19)	(-0.23, 0.52)	0.4539	
No	19	4.45 (1.97)	15	3.93 (2.27)	0.52 (2.96)	(-5.55, 6.60)	0.8612	0.06 (0.35)	(-0.62, 0.74)	0.8648	
OCS use											0.6595
Yes	54	3.60 (1.22)	63	2.49 (1.17)	1.11 (1.52)	(-1.90, 4.11)	0.4676	0.12 (0.19)	(-0.24, 0.48)	0.5173	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - FACIT-F Total Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=69) N	LSMean (SE)	Placebo (N=75) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
No	15	4.67 (2.35)	12	2.07 (2.28)	2.60 (3.04)	(-3.69, 8.90)	0.4010	0.29 (0.39)	(-0.47, 1.06)	0.4508	
SLICC score											0.6600
0	40	3.08 (1.16)	48	2.30 (1.18)	0.77 (1.51)	(-2.24, 3.79)	0.6102	0.10 (0.21)	(-0.32, 0.52)	0.6457	
>=1	29	5.64 (2.10)	27	3.49 (1.96)	2.15 (2.74)	(-3.34, 7.63)	0.4355	0.20 (0.27)	(-0.33, 0.72)	0.4630	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - EQ VAS Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		6.45 (2.25)		5.34 (2.12)	1.11 (2.90)	(-4.63, 6.84)	0.7030			
Week 12		8.50 (2.45)		8.72 (2.33)	-0.22 (3.20)	(-6.56, 6.11)	0.9443			
Week 24		10.30 (2.75)		6.56 (2.67)	3.74 (3.68)	(-3.54, 11.01)	0.3114			
Week 36		13.83 (2.74)		9.65 (2.77)	4.19 (3.74)	(-3.22, 11.59)	0.2650			
Week 52		16.25 (2.65)		10.93 (2.73)	5.33 (3.65)	(-1.90, 12.55)	0.1471			
OVERALL	68	11.07 (2.09)	75	8.24 (2.02)	2.83 (2.70)	(-2.51, 8.16)	0.2965	0.16 (0.17)	(-0.17, 0.49)	0.3345

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - EQ VAS Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=69) N	LSMean (SE)	Placebo (N=75) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.3507
< 10 points	28	11.32 (2.65)	32	11.22 (2.44)	0.10 (3.45)	(-6.84, 7.03)	0.9776	0.01 (0.26)	(-0.50, 0.51)	0.9787	
>= 10 points	40	9.15 (3.14)	43	4.29 (3.11)	4.87 (3.77)	(-2.64, 12.38)	0.2005	0.24 (0.22)	(-0.19, 0.67)	0.2780	
OCS dose											0.7206
<10 mg/day	33	9.69 (3.00)	28	5.34 (3.16)	4.35 (4.22)	(-4.10, 12.80)	0.3072	0.25 (0.26)	(-0.25, 0.76)	0.3280	
>=10 mg/day	35	11.70 (3.09)	47	9.32 (2.82)	2.38 (3.55)	(-4.69, 9.45)	0.5050	0.12 (0.22)	(-0.31, 0.56)	0.5769	
Result of type I IFN gene signature test											0.7747
LOW	14	8.71 (4.29)	19	4.34 (3.91)	4.37 (5.79)	(-7.63, 16.36)	0.4588	0.26 (0.35)	(-0.44, 0.95)	0.4695	
HIGH	54	11.33 (2.14)	56	8.83 (2.20)	2.49 (3.04)	(-3.54, 8.52)	0.4142	0.15 (0.19)	(-0.22, 0.53)	0.4208	
Age (years)											0.4992
<= 45	44	11.84 (2.88)	50	7.74 (2.69)	4.10 (3.45)	(-2.76, 10.96)	0.2382	0.21 (0.21)	(-0.19, 0.62)	0.3029	
> 45	24	7.31 (3.21)	25	7.03 (3.28)	0.29 (4.46)	(-8.71, 9.29)	0.9492	0.02 (0.29)	(-0.54, 0.58)	0.9512	
Sex											NE
male	4	NE	6	NE	NE	NE		NE	NE		
female	64	10.96 (2.13)	69	7.78 (2.08)	3.18 (2.77)	(-2.31, 8.68)	0.2535	0.18 (0.17)	(-0.16, 0.53)	0.2892	
Race											0.2732
White	25	9.75 (3.26)	31	7.58 (2.93)	2.17 (4.22)	(-6.30, 10.64)	0.6091	0.13 (0.27)	(-0.40, 0.66)	0.6263	
Black	16	17.82 (7.17)	8	2.35 (5.80)	15.47 (8.22)	(-1.67, 32.62)	0.0744	0.59 (0.44)	(-0.28, 1.46)	0.1845	
Other	27	13.35 (3.22)	36	12.45 (3.23)	0.91 (4.13)	(-7.39, 9.20)	0.8267	0.05 (0.25)	(-0.45, 0.55)	0.8473	
Ethnicity											0.3037
Hispanic/Latino	27	10.23 (3.14)	28	10.75 (3.48)	-0.52 (4.31)	(-9.21, 8.17)	0.9052	-0.03 (0.27)	(-0.56, 0.50)	0.9137	
Non-hispanic/Latino	41	11.78 (2.73)	47	6.66 (2.42)	5.12 (3.38)	(-1.61, 11.85)	0.1339	0.30 (0.21)	(-0.12, 0.72)	0.1645	
Geographic region											0.4881
Latin America, Eastern Europe and Asia	44	13.11 (2.86)	55	11.94 (3.03)	1.17 (3.47)	(-5.72, 8.07)	0.7360	0.06 (0.20)	(-0.34, 0.45)	0.7840	
North America	24	6.06 (3.02)	20	1.02 (3.04)	5.04 (4.36)	(-3.77, 13.85)	0.2548	0.35 (0.31)	(-0.25, 0.95)	0.2555	
Baseline weight											0.3116
<60 kg	18	10.14 (4.80)	31	10.70 (4.09)	-0.56 (5.99)	(-12.65, 11.53)	0.9266	-0.02 (0.30)	(-0.61, 0.56)	0.9329	
>=60 kg	50	12.36 (2.28)	44	6.17 (2.25)	6.19 (2.93)	(0.38, 12.01)	0.0372	0.39 (0.21)	(-0.01, 0.80)	0.0589	
Low CH50											0.9704
Yes	9	11.34 (7.66)	10	8.07 (10.32)	3.26 (12.76)	(-23.97, 30.50)	0.8016	0.11 (0.46)	(-0.79, 1.01)	0.8120	
No	59	11.28 (2.12)	65	8.50 (2.05)	2.78 (2.81)	(-2.79, 8.35)	0.3247	0.17 (0.18)	(-0.18, 0.52)	0.3501	
Low C3 or C4											0.5680
Yes	25	14.97 (5.39)	33	9.78 (4.64)	5.19 (4.65)	(-4.14, 14.53)	0.2691	0.19 (0.27)	(-0.33, 0.71)	0.4719	
No	43	8.95 (2.25)	42	6.97 (2.32)	1.98 (3.17)	(-4.33, 8.29)	0.5333	0.13 (0.22)	(-0.29, 0.56)	0.5438	
Baseline FARR anti-dsDNA											0.4507
<5 IU/mL	15	5.27 (4.35)	11	6.60 (4.51)	-1.33 (6.78)	(-15.47, 12.81)	0.8466	-0.08 (0.40)	(-0.86, 0.70)	0.8404	
>=5 IU/mL	40	12.54 (2.93)	50	8.09 (2.72)	4.45 (3.56)	(-2.63, 11.53)	0.2152	0.23 (0.21)	(-0.18, 0.65)	0.2742	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.2814
Yes	50	12.62 (2.76)	60	8.54 (2.59)	4.08 (3.27)	(-2.40, 10.56)	0.2148	0.20 (0.19)	(-0.17, 0.58)	0.2873	
No	18	7.26 (2.90)	15	9.06 (3.28)	-1.80 (4.37)	(-10.78, 7.18)	0.6840	-0.14 (0.35)	(-0.83, 0.55)	0.6879	
OCS use											0.5747
Yes	53	12.49 (2.52)	63	10.35 (2.42)	2.14 (3.09)	(-3.98, 8.27)	0.4893	0.11 (0.19)	(-0.25, 0.48)	0.5443	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - EQ VAS Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=69) N	LSMean (SE)	Placebo (N=75) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
No	15	5.64 (4.45)	12	-0.10 (4.35)	5.74 (5.61)	(-5.92, 17.40)	0.3180	0.34 (0.39)	(-0.42, 1.11)	0.3819	
SLICC score											0.8533
0	40	12.52 (2.57)	48	9.65 (2.61)	2.87 (3.36)	(-3.83, 9.57)	0.3965	0.16 (0.21)	(-0.26, 0.58)	0.4430	
>=1	28	8.86 (3.67)	27	7.07 (3.35)	1.79 (4.74)	(-7.73, 11.32)	0.7070	0.10 (0.27)	(-0.43, 0.62)	0.7229	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Lupus QoL Physical Health domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		3.53 (1.83)		3.49 (1.75)	0.03 (2.31)	(-4.54, 4.61)	0.9882			
Week 12		5.64 (2.71)		6.07 (2.60)	-0.43 (3.61)	(-7.56, 6.70)	0.9059			
Week 24		6.42 (2.68)		6.22 (2.61)	0.20 (3.59)	(-6.90, 7.29)	0.9567			
Week 36		8.71 (2.85)		7.70 (2.84)	1.01 (3.88)	(-6.67, 8.69)	0.7953			
Week 52		8.19 (2.86)		6.74 (2.89)	1.46 (3.93)	(-6.32, 9.24)	0.7114			
OVERALL	68	6.50 (2.27)	74	6.04 (2.20)	0.45 (2.98)	(-5.45, 6.36)	0.8794	0.02 (0.17)	(-0.31, 0.35)	0.8867

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Lupus QoL Physical Health domain score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.4249
< 10 points	29	7.98 (2.86)	31	9.66 (2.69)	-1.68 (3.79)	(-9.28, 5.92)	0.6595	-0.11 (0.26)	(-0.62, 0.40)	0.6727	
>= 10 points	39	6.00 (3.43)	43	3.09 (3.37)	2.91 (4.32)	(-5.71, 11.52)	0.5031	0.13 (0.22)	(-0.30, 0.57)	0.5502	
OCS dose											0.9357
<10 mg/day	33	5.71 (3.38)	27	4.10 (3.64)	1.62 (4.86)	(-8.14, 11.37)	0.7412	0.08 (0.26)	(-0.43, 0.59)	0.7489	
>=10 mg/day	35	7.83 (3.29)	47	6.72 (2.98)	1.11 (3.98)	(-6.81, 9.03)	0.7812	0.05 (0.22)	(-0.38, 0.49)	0.8061	
Result of type I IFN gene signature test											0.9601
LOW	14	5.45 (5.18)	18	4.72 (4.72)	0.73 (7.07)	(-13.76, 15.21)	0.9191	0.04 (0.36)	(-0.66, 0.73)	0.9199	
HIGH	54	8.22 (2.32)	56	7.88 (2.37)	0.33 (3.27)	(-6.16, 6.83)	0.9188	0.02 (0.19)	(-0.35, 0.39)	0.9202	
Age (years)											0.5066
<= 45	44	8.17 (2.73)	49	6.05 (2.63)	2.12 (3.42)	(-4.66, 8.91)	0.5359	0.12 (0.21)	(-0.29, 0.52)	0.5789	
> 45	24	4.21 (4.51)	25	6.76 (4.42)	-2.54 (6.14)	(-14.99, 9.90)	0.6810	-0.11 (0.29)	(-0.67, 0.45)	0.6920	
Sex											NE
male	4	NE	6	NE	NE	NE		NE	NE		
female	64	6.40 (2.36)	68	5.35 (2.33)	1.05 (3.14)	(-5.17, 7.27)	0.7394	0.05 (0.17)	(-0.29, 0.40)	0.7533	
Race											0.4763
White	25	8.86 (2.61)	30	4.36 (2.40)	4.50 (3.44)	(-2.41, 11.41)	0.1970	0.34 (0.27)	(-0.20, 0.87)	0.2145	
Black	16	11.22 (9.93)	8	0.98 (8.58)	10.24 (13.03)	(-16.84, 37.32)	0.4406	0.28 (0.44)	(-0.57, 1.13)	0.5225	
Other	27	5.51 (3.99)	36	7.53 (3.74)	-2.02 (5.05)	(-12.14, 8.09)	0.6899	-0.09 (0.25)	(-0.59, 0.41)	0.7181	
Ethnicity											0.1282
Hispanic/Latino	27	4.54 (4.05)	28	8.92 (4.24)	-4.38 (5.55)	(-15.55, 6.78)	0.4341	-0.20 (0.27)	(-0.73, 0.33)	0.4635	
Non-hispanic/Latino	41	9.32 (2.62)	46	3.83 (2.40)	5.49 (3.35)	(-1.19, 12.17)	0.1059	0.33 (0.22)	(-0.09, 0.75)	0.1274	
Geographic region											0.9642
Latin America, Eastern Europe and Asia	44	8.85 (2.79)	55	8.66 (2.84)	0.19 (3.42)	(-6.61, 6.98)	0.9562	0.01 (0.20)	(-0.39, 0.41)	0.9630	
North America	24	0.75 (3.93)	19	0.87 (3.98)	-0.12 (5.87)	(-11.97, 11.73)	0.9842	-0.01 (0.31)	(-0.61, 0.60)	0.9838	
Baseline weight											0.2490
<60 kg	18	8.72 (5.18)	31	12.57 (4.35)	-3.85 (6.58)	(-17.12, 9.42)	0.5612	-0.16 (0.30)	(-0.74, 0.42)	0.5856	
>=60 kg	50	5.97 (2.37)	43	1.41 (2.41)	4.56 (3.15)	(-1.72, 10.83)	0.1522	0.28 (0.21)	(-0.13, 0.69)	0.1855	
Low CH50											0.3979
Yes	8	5.94 (9.60)	10	-8.67 (10.62)	14.62 (14.70)	(-16.44, 45.68)	0.3342	0.45 (0.48)	(-0.49, 1.39)	0.3505	
No	60	7.20 (2.24)	64	5.27 (2.19)	1.94 (2.98)	(-3.97, 7.84)	0.5174	0.11 (0.18)	(-0.24, 0.46)	0.5392	
Low C3 or C4											0.6708
Yes	24	4.51 (5.83)	33	5.53 (4.97)	-1.02 (5.99)	(-13.09, 11.05)	0.8657	-0.04 (0.27)	(-0.56, 0.49)	0.8956	
No	44	6.81 (2.44)	41	4.89 (2.57)	1.92 (3.45)	(-4.94, 8.78)	0.5795	0.12 (0.22)	(-0.31, 0.54)	0.5915	
Baseline FARR anti-dsDNA											0.3400
<5 IU/mL	15	11.30 (4.69)	10	3.16 (4.91)	8.14 (7.21)	(-6.82, 23.11)	0.2712	0.46 (0.41)	(-0.35, 1.27)	0.2687	
>=5 IU/mL	39	7.02 (3.13)	50	6.70 (2.83)	0.32 (3.90)	(-7.45, 8.09)	0.9354	0.02 (0.21)	(-0.40, 0.43)	0.9407	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.8556
Yes	49	6.43 (2.85)	60	5.66 (2.62)	0.78 (3.51)	(-6.18, 7.74)	0.8248	0.04 (0.19)	(-0.34, 0.42)	0.8420	
No	19	7.66 (4.21)	14	8.21 (4.90)	-0.55 (6.43)	(-13.67, 12.56)	0.9318	-0.03 (0.35)	(-0.72, 0.66)	0.9333	
OCS use											0.4655
Yes	53	8.03 (2.64)	63	5.46 (2.55)	2.57 (3.35)	(-4.06, 9.20)	0.4445	0.13 (0.19)	(-0.24, 0.49)	0.4898	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Lupus QoL Physical Health domain score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
No	15	1.29 (3.50)	11	3.03 (3.77)	-1.74 (4.86)	(-14.43, 10.96)	0.7360	-0.13 (0.40)	(-0.91, 0.65)	0.7471	
SLICC score											0.9176
0	39	5.58 (2.88)	47	5.64 (2.90)	-0.06 (3.80)	(-7.63, 7.50)	0.9871	-0.00 (0.22)	(-0.43, 0.42)	0.9882	
>=1	29	7.26 (3.98)	27	6.64 (3.83)	0.62 (5.34)	(-10.14, 11.37)	0.9086	0.03 (0.27)	(-0.49, 0.55)	0.9125	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Lupus QoL Emotional Health domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		0.05 (2.04)		5.90 (1.94)	-5.85 (2.62)	(-11.03, -0.67)	0.0271			
Week 12		5.02 (2.44)		7.09 (2.33)	-2.06 (3.20)	(-8.40, 4.27)	0.5201			
Week 24		6.12 (2.39)		6.58 (2.33)	-0.46 (3.17)	(-6.73, 5.81)	0.8848			
Week 36		9.99 (2.73)		7.85 (2.74)	2.14 (3.71)	(-5.21, 9.49)	0.5660			
Week 52		10.92 (2.57)		10.66 (2.67)	0.26 (3.56)	(-6.79, 7.31)	0.9414			
OVERALL	68	6.42 (1.99)	74	7.62 (1.93)	-1.20 (2.56)	(-6.25, 3.86)	0.6409	-0.07 (0.17)	(-0.40, 0.26)	0.6676

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Lupus QoL Emotional Health domain score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.6462
< 10 points	29	9.26 (2.56)	31	11.60 (2.43)	-2.34 (3.38)	(-9.14, 4.46)	0.4925	-0.17 (0.26)	(-0.68, 0.34)	0.5139	
>= 10 points	39	3.44 (3.08)	43	3.48 (3.02)	-0.04 (3.69)	(-7.41, 7.33)	0.9914	-0.00 (0.22)	(-0.44, 0.43)	0.9927	
OCS dose											0.6099
<10 mg/day	33	6.91 (2.60)	27	9.08 (2.80)	-2.17 (3.67)	(-9.54, 5.20)	0.5571	-0.15 (0.26)	(-0.65, 0.36)	0.5763	
>=10 mg/day	35	5.52 (3.07)	47	5.09 (2.79)	0.42 (3.52)	(-6.59, 7.44)	0.9043	0.02 (0.22)	(-0.42, 0.46)	0.9198	
Result of type I IFN gene signature test											0.6897
LOW	14	0.24 (3.89)	18	3.27 (3.55)	-3.04 (5.28)	(-13.90, 7.83)	0.5704	-0.20 (0.36)	(-0.90, 0.50)	0.5769	
HIGH	54	9.62 (2.05)	56	10.25 (2.12)	-0.63 (2.91)	(-6.41, 5.15)	0.8297	-0.04 (0.19)	(-0.41, 0.33)	0.8330	
Age (years)											0.1739
<= 45	44	9.29 (2.54)	49	7.63 (2.43)	1.65 (3.05)	(-4.41, 7.72)	0.5893	0.10 (0.21)	(-0.31, 0.50)	0.6413	
> 45	24	2.17 (3.50)	25	8.18 (3.45)	-6.00 (4.73)	(-15.57, 3.57)	0.2121	-0.34 (0.29)	(-0.91, 0.22)	0.2331	
Sex											NE
male	4	NE	6	NE	NE	NE		NE	NE		
female	64	6.54 (2.09)	68	8.05 (2.05)	-1.51 (2.72)	(-6.91, 3.88)	0.5799	-0.09 (0.17)	(-0.43, 0.25)	0.6081	
Race											0.5388
White	25	5.63 (2.34)	30	4.37 (2.19)	1.27 (3.08)	(-4.94, 7.47)	0.6831	0.11 (0.27)	(-0.43, 0.64)	0.6973	
Black	16	13.65 (8.13)	8	7.41 (5.98)	6.24 (8.99)	(-12.55, 25.03)	0.4961	0.21 (0.43)	(-0.64, 1.06)	0.6264	
Other	27	6.20 (3.88)	36	9.94 (3.75)	-3.74 (4.82)	(-13.42, 5.93)	0.4412	-0.17 (0.26)	(-0.67, 0.33)	0.5006	
Ethnicity											0.3027
Hispanic/Latino	27	6.81 (3.76)	28	10.98 (4.01)	-4.17 (5.04)	(-14.32, 5.97)	0.4121	-0.20 (0.27)	(-0.73, 0.33)	0.4561	
Non-hispanic/Latino	41	6.70 (2.28)	46	4.89 (2.08)	1.81 (2.88)	(-3.92, 7.54)	0.5311	0.13 (0.21)	(-0.30, 0.55)	0.5604	
Geographic region											0.5338
Latin America, Eastern Europe and Asia	44	6.35 (2.69)	55	7.98 (2.80)	-1.63 (3.22)	(-8.04, 4.78)	0.6141	-0.08 (0.20)	(-0.48, 0.31)	0.6815	
North America	24	6.88 (3.54)	19	4.73 (3.56)	2.15 (5.15)	(-8.26, 12.56)	0.6787	0.13 (0.31)	(-0.48, 0.73)	0.6787	
Baseline weight											0.7618
<60 kg	18	11.25 (5.02)	31	12.02 (4.23)	-0.77 (6.20)	(-13.31, 11.77)	0.9015	-0.03 (0.30)	(-0.61, 0.55)	0.9102	
>=60 kg	50	5.22 (1.95)	43	3.96 (1.99)	1.26 (2.56)	(-3.82, 6.34)	0.6233	0.09 (0.21)	(-0.32, 0.50)	0.6555	
Low CH50											0.7044
Yes	8	15.78 (7.15)	10	9.95 (14.48)	5.84 (17.40)	(-32.41, 44.09)	0.7436	0.15 (0.48)	(-0.78, 1.08)	0.7511	
No	60	5.99 (2.00)	64	6.83 (1.95)	-0.84 (2.64)	(-6.08, 4.40)	0.7510	-0.05 (0.18)	(-0.41, 0.30)	0.7649	
Low C3 or C4											0.4404
Yes	24	11.36 (5.37)	33	9.25 (4.59)	2.10 (4.85)	(-7.64, 11.85)	0.6662	0.08 (0.27)	(-0.45, 0.60)	0.7692	
No	44	4.79 (2.16)	41	7.10 (2.27)	-2.31 (3.04)	(-8.37, 3.75)	0.4498	-0.16 (0.22)	(-0.58, 0.27)	0.4656	
Baseline FARR anti-dsDNA											0.8033
<5 IU/mL	15	5.73 (2.90)	10	5.45 (3.27)	0.28 (4.61)	(-9.30, 9.86)	0.9523	0.02 (0.41)	(-0.78, 0.82)	0.9516	
>=5 IU/mL	39	7.08 (2.84)	50	8.23 (2.57)	-1.15 (3.40)	(-7.91, 5.62)	0.7364	-0.06 (0.21)	(-0.48, 0.36)	0.7670	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.4196
Yes	49	6.99 (2.58)	60	6.80 (2.38)	0.19 (3.06)	(-5.89, 6.27)	0.9504	0.01 (0.19)	(-0.37, 0.39)	0.9571	
No	19	5.54 (2.87)	14	9.66 (3.38)	-4.12 (4.38)	(-13.10, 4.86)	0.3548	-0.32 (0.35)	(-1.01, 0.38)	0.3676	
OCS use											0.8058
Yes	53	6.42 (2.35)	63	6.56 (2.26)	-0.13 (2.90)	(-5.88, 5.61)	0.9634	-0.01 (0.19)	(-0.37, 0.36)	0.9678	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Lupus QoL Emotional Health domain score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=69) N	LSMean (SE)	Placebo (N=75) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
No	15	4.34 (3.57)	11	5.90 (3.99)	-1.56 (5.03)	(-12.02, 8.90)	0.7595	-0.11 (0.40)	(-0.89, 0.67)	0.7794	
SLICC score											0.2989
0	39	4.09 (2.37)	47	7.33 (2.43)	-3.24 (3.09)	(-9.40, 2.92)	0.2982	-0.20 (0.22)	(-0.63, 0.22)	0.3503	
>=1	29	10.45 (3.58)	27	7.85 (3.37)	2.60 (4.70)	(-6.84, 12.05)	0.5820	0.14 (0.27)	(-0.39, 0.66)	0.6032	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Lupus QoL Body Image domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		1.58 (2.58)		8.36 (2.55)	-6.78 (3.40)	(-13.51, -0.05)	0.0484			
Week 12		11.07 (2.89)		10.47 (2.87)	0.59 (3.85)	(-7.03, 8.22)	0.8778			
Week 24		10.68 (3.13)		5.76 (3.13)	4.92 (4.23)	(-3.45, 13.28)	0.2468			
Week 36		12.52 (3.24)		13.91 (3.50)	-1.39 (4.57)	(-10.45, 7.66)	0.7611			
Week 52		14.13 (3.19)		9.36 (3.51)	4.77 (4.55)	(-4.25, 13.78)	0.2969			
OVERALL	66	9.99 (2.43)	66	9.57 (2.43)	0.42 (3.17)	(-5.85, 6.69)	0.8946	0.02 (0.17)	(-0.32, 0.36)	0.9031

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Lupus QoL Body Image domain score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.3477
< 10 points	29	11.67 (3.14)	25	14.23 (3.33)	-2.56 (4.47)	(-11.54, 6.41)	0.5688	-0.15 (0.27)	(-0.69, 0.39)	0.5822	
>= 10 points	37	7.84 (3.79)	41	4.55 (3.59)	3.29 (4.34)	(-5.37, 11.95)	0.4515	0.14 (0.23)	(-0.30, 0.59)	0.5332	
OCS dose											0.0776
<10 mg/day	31	3.46 (3.18)	24	8.83 (3.49)	-5.37 (4.56)	(-14.53, 3.79)	0.2450	-0.30 (0.27)	(-0.84, 0.23)	0.2679	
>=10 mg/day	35	15.29 (3.64)	42	9.70 (3.42)	5.59 (4.21)	(-2.81, 13.99)	0.1888	0.25 (0.23)	(-0.20, 0.70)	0.2711	
Result of type I IFN gene signature test											0.9948
LOW	13	3.02 (4.06)	18	2.64 (3.56)	0.38 (5.40)	(-10.73, 11.50)	0.9442	0.02 (0.36)	(-0.69, 0.74)	0.9454	
HIGH	53	12.34 (2.53)	48	11.91 (2.86)	0.42 (3.73)	(-6.97, 7.82)	0.9095	0.02 (0.20)	(-0.37, 0.41)	0.9116	
Age (years)											0.2880
<= 45	43	12.39 (3.43)	44	10.01 (3.33)	2.38 (4.14)	(-5.85, 10.61)	0.5664	0.11 (0.21)	(-0.31, 0.53)	0.6217	
> 45	23	5.90 (3.44)	22	10.26 (3.54)	-4.36 (4.81)	(-14.09, 5.37)	0.3705	-0.26 (0.30)	(-0.85, 0.33)	0.3882	
Sex											NE
male	4	NE	4	NE	NE	NE		NE	NE		
female	62	10.07 (2.53)	62	9.66 (2.52)	0.41 (3.30)	(-6.13, 6.95)	0.9010	0.02 (0.18)	(-0.33, 0.37)	0.9086	
Race											0.1392
White	25	11.14 (3.15)	26	6.72 (3.16)	4.42 (4.33)	(-4.29, 13.13)	0.3123	0.27 (0.28)	(-0.28, 0.82)	0.3327	
Black	15	16.75 (10.75)	8	3.19 (7.55)	13.56 (11.62)	(-10.75, 37.86)	0.2575	0.36 (0.44)	(-0.50, 1.23)	0.4132	
Other	26	7.89 (4.44)	32	14.84 (4.27)	-6.95 (5.42)	(-17.85, 3.95)	0.2061	-0.29 (0.27)	(-0.81, 0.23)	0.2714	
Ethnicity											0.2107
Hispanic/Latino	26	9.90 (4.46)	25	15.32 (4.76)	-5.41 (5.90)	(-17.30, 6.48)	0.3637	-0.23 (0.28)	(-0.78, 0.32)	0.4146	
Non-hispanic/Latino	40	9.57 (2.93)	41	6.21 (2.79)	3.36 (3.79)	(-4.19, 10.91)	0.3780	0.18 (0.22)	(-0.25, 0.62)	0.4114	
Geographic region											0.5041
Latin America, Eastern Europe and Asia	43	12.41 (3.23)	47	13.26 (3.48)	-0.85 (3.75)	(-8.32, 6.62)	0.8211	-0.04 (0.21)	(-0.45, 0.38)	0.8594	
North America	23	8.73 (4.61)	19	4.49 (4.50)	4.24 (6.63)	(-9.18, 17.65)	0.5265	0.20 (0.31)	(-0.41, 0.81)	0.5246	
Baseline weight											0.6790
<60 kg	17	25.06 (4.84)	29	21.29 (4.29)	3.77 (5.87)	(-8.18, 15.72)	0.5252	0.17 (0.31)	(-0.43, 0.77)	0.5819	
>=60 kg	49	3.93 (2.65)	37	3.01 (2.83)	0.91 (3.64)	(-6.34, 8.16)	0.8026	0.05 (0.22)	(-0.38, 0.48)	0.8176	
Low CH50											0.1359
Yes	8	16.12 (8.30)	9	36.45 (11.23)	-20.33 (14.47)	(-50.87, 10.20)	0.1780	-0.66 (0.50)	(-1.64, 0.33)	0.1912	
No	58	9.51 (2.45)	57	7.73 (2.46)	1.78 (3.27)	(-4.70, 8.26)	0.5873	0.09 (0.19)	(-0.27, 0.46)	0.6110	
Low C3 or C4											0.8047
Yes	24	14.20 (5.74)	30	12.58 (5.08)	1.62 (5.39)	(-9.25, 12.49)	0.7656	0.06 (0.27)	(-0.48, 0.59)	0.8351	
No	42	8.95 (2.87)	36	9.00 (3.07)	-0.05 (4.07)	(-8.16, 8.06)	0.9896	-0.00 (0.23)	(-0.45, 0.44)	0.9900	
Baseline FARR anti-dsDNA											0.3679
<5 IU/mL	14	12.78 (4.63)	8	3.75 (5.66)	9.03 (7.81)	(-7.31, 25.36)	0.2620	0.51 (0.45)	(-0.37, 1.40)	0.2543	
>=5 IU/mL	39	12.67 (3.35)	45	11.58 (3.20)	1.09 (4.09)	(-7.05, 9.23)	0.7904	0.05 (0.22)	(-0.38, 0.48)	0.8160	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.7928
Yes	49	10.37 (3.08)	54	9.47 (2.97)	0.90 (3.73)	(-6.50, 8.29)	0.8103	0.04 (0.20)	(-0.35, 0.43)	0.8353	
No	17	7.36 (3.68)	12	8.23 (4.39)	-0.87 (5.59)	(-12.54, 10.80)	0.8781	-0.06 (0.38)	(-0.79, 0.68)	0.8827	
OCS use											0.0953
Yes	51	12.61 (2.85)	57	9.24 (2.78)	3.37 (3.43)	(-3.44, 10.18)	0.3284	0.16 (0.19)	(-0.22, 0.54)	0.4022	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Lupus QoL Body Image domain score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
No	15	0.26 (4.65)	9	8.98 (5.12)	-8.72 (6.38)	(-22.07, 4.63)	0.1878	-0.49 (0.43)	(-1.33, 0.35)	0.2505	
SLICC score											0.4616
0	37	9.70 (3.15)	40	11.31 (3.26)	-1.61 (4.11)	(-9.81, 6.59)	0.6956	-0.08 (0.23)	(-0.53, 0.37)	0.7255	
>=1	29	11.15 (4.05)	26	7.80 (3.91)	3.35 (5.35)	(-7.39, 14.09)	0.5339	0.16 (0.27)	(-0.37, 0.69)	0.5604	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Lupus QoL Burden to Others domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-0.46 (2.63)		1.17 (2.49)	-1.63 (3.33)	(-8.21, 4.96)	0.6256			
Week 12		4.40 (3.21)		2.42 (3.06)	1.98 (4.19)	(-6.31, 10.28)	0.6371			
Week 24		3.89 (3.25)		3.49 (3.15)	0.40 (4.29)	(-8.08, 8.88)	0.9256			
Week 36		9.61 (3.31)		6.19 (3.30)	3.42 (4.45)	(-5.38, 12.23)	0.4429			
Week 52		7.60 (3.50)		3.96 (3.55)	3.64 (4.78)	(-5.82, 13.10)	0.4480			
OVERALL	68	5.01 (2.74)	74	3.45 (2.64)	1.56 (3.52)	(-5.40, 8.53)	0.6576	0.07 (0.17)	(-0.26, 0.40)	0.6827

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Lupus QoL Burden to Others domain score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.3515
< 10 points	29	4.08 (4.17)	31	6.32 (3.85)	-2.24 (5.40)	(-13.06, 8.58)	0.6796	-0.10 (0.26)	(-0.61, 0.41)	0.6967	
>= 10 points	39	7.28 (3.73)	43	2.92 (3.69)	4.36 (4.59)	(-4.79, 13.51)	0.3454	0.18 (0.22)	(-0.25, 0.62)	0.4119	
OCS dose											0.7114
<10 mg/day	33	1.81 (3.93)	27	1.56 (4.15)	0.25 (5.52)	(-10.82, 11.32)	0.9643	0.01 (0.26)	(-0.50, 0.52)	0.9660	
>=10 mg/day	35	8.68 (3.88)	47	5.80 (3.54)	2.88 (4.49)	(-6.08, 11.84)	0.5235	0.12 (0.22)	(-0.32, 0.56)	0.5905	
Result of type I IFN gene signature test											0.6563
LOW	14	5.69 (5.10)	18	1.13 (4.66)	4.57 (6.97)	(-9.84, 18.98)	0.5190	0.23 (0.36)	(-0.47, 0.93)	0.5229	
HIGH	54	5.00 (2.88)	56	4.03 (2.97)	0.97 (4.09)	(-7.14, 9.08)	0.8132	0.04 (0.19)	(-0.33, 0.42)	0.8161	
Age (years)											0.5324
<= 45	44	7.61 (3.52)	49	4.12 (3.34)	3.48 (4.21)	(-4.88, 11.85)	0.4100	0.15 (0.21)	(-0.26, 0.56)	0.4768	
> 45	24	2.20 (4.64)	25	3.41 (4.53)	-1.21 (6.23)	(-13.79, 11.37)	0.8470	-0.05 (0.29)	(-0.61, 0.51)	0.8545	
Sex											NE
male	4	NE	6	NE	NE	NE		NE	NE		
female	64	6.31 (2.81)	68	3.29 (2.76)	3.01 (3.67)	(-4.26, 10.28)	0.4138	0.13 (0.17)	(-0.21, 0.47)	0.4475	
Race											0.4259
White	25	0.70 (3.74)	30	-0.91 (3.45)	1.61 (4.90)	(-8.27, 11.49)	0.7445	0.08 (0.27)	(-0.45, 0.62)	0.7559	
Black	16	16.45 (14.40)	8	-2.93 (10.54)	19.38 (15.26)	(-12.49, 51.25)	0.2189	0.37 (0.44)	(-0.49, 1.23)	0.3959	
Other	27	6.74 (4.25)	36	8.36 (4.09)	-1.63 (5.33)	(-12.34, 9.09)	0.7617	-0.07 (0.25)	(-0.57, 0.43)	0.7887	
Ethnicity											0.2887
Hispanic/Latino	27	7.78 (4.29)	28	11.75 (4.60)	-3.97 (5.78)	(-15.61, 7.68)	0.4956	-0.17 (0.27)	(-0.70, 0.36)	0.5353	
Non-hispanic/Latino	41	2.85 (3.61)	46	-0.95 (3.23)	3.79 (4.49)	(-5.15, 12.73)	0.4008	0.17 (0.22)	(-0.25, 0.59)	0.4372	
Geographic region											0.2341
Latin America, Eastern Europe and Asia	44	6.42 (3.19)	55	7.11 (3.30)	-0.68 (3.85)	(-8.33, 6.97)	0.8596	-0.03 (0.20)	(-0.43, 0.37)	0.8845	
North America	24	7.95 (6.31)	19	-3.18 (6.21)	11.13 (9.16)	(-7.37, 29.64)	0.2311	0.37 (0.31)	(-0.23, 0.98)	0.2287	
Baseline weight											0.8224
<60 kg	18	9.51 (5.78)	31	5.54 (4.94)	3.97 (7.21)	(-10.68, 18.63)	0.5851	0.15 (0.30)	(-0.43, 0.73)	0.6185	
>=60 kg	50	3.65 (3.22)	43	1.54 (3.20)	2.11 (4.15)	(-6.14, 10.35)	0.6126	0.10 (0.21)	(-0.31, 0.50)	0.6471	
Low CH50											0.6824
Yes	8	3.23 (10.40)	10	-7.07 (14.71)	10.31 (18.62)	(-28.95, 49.57)	0.5870	0.25 (0.48)	(-0.69, 1.18)	0.6060	
No	60	5.48 (2.72)	64	2.93 (2.65)	2.55 (3.59)	(-4.56, 9.66)	0.4787	0.12 (0.18)	(-0.23, 0.47)	0.5045	
Low C3 or C4											0.8706
Yes	24	4.33 (6.51)	33	3.76 (5.62)	0.57 (6.11)	(-11.74, 12.88)	0.9256	0.02 (0.27)	(-0.51, 0.54)	0.9476	
No	44	4.82 (3.18)	41	3.01 (3.31)	1.80 (4.44)	(-7.04, 10.64)	0.6857	0.08 (0.22)	(-0.34, 0.51)	0.6973	
Baseline FARR anti-dsDNA											0.2184
<5 IU/mL	15	9.78 (6.95)	10	-3.33 (7.15)	13.11 (10.65)	(-9.12, 35.34)	0.2327	0.50 (0.42)	(-0.31, 1.31)	0.2284	
>=5 IU/mL	39	2.50 (3.84)	50	3.70 (3.47)	-1.20 (4.67)	(-10.49, 8.10)	0.7982	-0.05 (0.21)	(-0.47, 0.37)	0.8190	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.4329
Yes	49	3.06 (3.39)	60	2.15 (3.12)	0.92 (4.07)	(-7.16, 8.99)	0.8223	0.04 (0.19)	(-0.34, 0.42)	0.8437	
No	19	11.63 (4.90)	14	4.05 (5.73)	7.57 (7.45)	(-7.68, 22.83)	0.3181	0.35 (0.36)	(-0.35, 1.04)	0.3313	
OCS use											0.0654
Yes	53	6.78 (3.08)	63	1.97 (2.95)	4.81 (3.76)	(-2.66, 12.27)	0.2046	0.21 (0.19)	(-0.16, 0.57)	0.2666	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Lupus QoL Burden to Others domain score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=69) N	LSMean (SE)	Placebo (N=75) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
No	15	-3.93 (6.32)	11	8.11 (6.54)	-12.04 (8.33)	(-29.37, 5.29)	0.1633	-0.50 (0.40)	(-1.29, 0.29)	0.2165	
SLICC score											0.4271
0	39	4.01 (3.53)	47	5.25 (3.57)	-1.24 (4.61)	(-10.42, 7.95)	0.7895	-0.05 (0.22)	(-0.48, 0.37)	0.8093	
>=1	29	5.91 (4.69)	27	1.09 (4.31)	4.82 (6.07)	(-7.38, 17.02)	0.4311	0.20 (0.27)	(-0.33, 0.72)	0.4588	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Lupus QoL Fatigue domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		4.45 (2.23)		2.86 (2.11)	1.58 (2.83)	(-4.01, 7.18)	0.5770			
Week 12		9.03 (2.58)		8.23 (2.46)	0.80 (3.35)	(-5.83, 7.43)	0.8120			
Week 24		10.45 (2.64)		6.64 (2.57)	3.80 (3.49)	(-3.10, 10.71)	0.2776			
Week 36		11.82 (2.86)		9.87 (2.83)	1.96 (3.85)	(-5.65, 9.57)	0.6117			
Week 52		11.61 (2.99)		8.25 (3.05)	3.36 (4.09)	(-4.74, 11.46)	0.4134			
OVERALL	68	9.47 (2.25)	74	7.17 (2.16)	2.30 (2.89)	(-3.41, 8.01)	0.4267	0.12 (0.17)	(-0.21, 0.45)	0.4644

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Lupus QoL Fatigue domain score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.4475
< 10 points	29	12.93 (3.16)	31	7.98 (2.96)	4.95 (4.18)	(-3.42, 13.33)	0.2413	0.29 (0.26)	(-0.22, 0.80)	0.2609	
>= 10 points	39	6.26 (3.22)	43	5.64 (3.17)	0.61 (3.89)	(-7.14, 8.36)	0.8752	0.03 (0.22)	(-0.40, 0.46)	0.8932	
OCS dose											0.8745
<10 mg/day	33	11.78 (2.98)	27	8.96 (3.18)	2.82 (4.27)	(-5.73, 11.38)	0.5111	0.17 (0.26)	(-0.34, 0.67)	0.5250	
>=10 mg/day	35	8.11 (3.30)	47	4.38 (3.00)	3.73 (3.78)	(-3.80, 11.25)	0.3270	0.18 (0.22)	(-0.26, 0.62)	0.4126	
Result of type I IFN gene signature test											0.2738
LOW	14	10.58 (4.23)	18	2.54 (3.85)	8.04 (5.72)	(-3.73, 19.81)	0.1720	0.49 (0.36)	(-0.22, 1.20)	0.1797	
HIGH	54	10.63 (2.27)	56	9.78 (2.34)	0.85 (3.22)	(-5.54, 7.24)	0.7921	0.05 (0.19)	(-0.32, 0.42)	0.7955	
Age (years)											0.5362
<= 45	44	11.45 (2.92)	49	7.69 (2.76)	3.76 (3.49)	(-3.18, 10.70)	0.2846	0.19 (0.21)	(-0.22, 0.60)	0.3550	
> 45	24	6.70 (3.95)	25	6.88 (3.88)	-0.18 (5.33)	(-10.92, 10.56)	0.9729	-0.01 (0.29)	(-0.57, 0.55)	0.9742	
Sex											NE
male	4	NE	6	NE	NE	NE		NE	NE		
female	64	10.20 (2.33)	68	7.70 (2.28)	2.50 (3.02)	(-3.49, 8.48)	0.4105	0.13 (0.17)	(-0.21, 0.47)	0.4471	
Race											0.0384
White	25	12.84 (3.11)	30	3.31 (2.79)	9.53 (4.03)	(1.44, 17.62)	0.0219	0.61 (0.28)	(0.07, 1.15)	0.0280	
Black	16	4.40 (10.13)	8	5.66 (8.63)	-1.26 (12.03)	(-26.47, 23.95)	0.9177	-0.03 (0.43)	(-0.88, 0.82)	0.9381	
Other	27	6.02 (3.51)	36	11.66 (3.39)	-5.64 (4.42)	(-14.51, 3.23)	0.2081	-0.29 (0.26)	(-0.79, 0.22)	0.2638	
Ethnicity											0.0800
Hispanic/Latino	27	9.07 (3.82)	28	13.15 (4.12)	-4.09 (5.14)	(-14.42, 6.25)	0.4305	-0.19 (0.27)	(-0.72, 0.34)	0.4757	
Non-hispanic/Latino	41	10.55 (2.83)	46	3.75 (2.50)	6.80 (3.51)	(-0.17, 13.77)	0.0557	0.38 (0.22)	(-0.04, 0.81)	0.0762	
Geographic region											0.4841
Latin America, Eastern Europe and Asia	44	9.95 (2.57)	55	9.32 (2.66)	0.63 (3.13)	(-5.59, 6.84)	0.8417	0.03 (0.20)	(-0.36, 0.43)	0.8686	
North America	24	10.59 (4.98)	19	4.54 (4.86)	6.05 (7.10)	(-8.29, 20.39)	0.3988	0.26 (0.31)	(-0.35, 0.86)	0.4030	
Baseline weight											0.7677
<60 kg	18	13.97 (4.88)	31	9.49 (4.20)	4.49 (6.07)	(-7.77, 16.74)	0.4643	0.20 (0.30)	(-0.39, 0.78)	0.5077	
>=60 kg	50	8.09 (2.61)	43	5.65 (2.58)	2.44 (3.34)	(-4.20, 9.08)	0.4675	0.14 (0.21)	(-0.27, 0.54)	0.5129	
Low CH50											0.0617
Yes	8	5.27 (6.98)	10	26.11 (9.55)	-20.84 (12.49)	(-47.25, 5.56)	0.1139	-0.76 (0.50)	(-1.73, 0.21)	0.1255	
No	60	10.07 (2.35)	64	6.89 (2.26)	3.18 (3.08)	(-2.91, 9.28)	0.3028	0.17 (0.18)	(-0.18, 0.53)	0.3334	
Low C3 or C4											0.3588
Yes	24	5.35 (4.84)	33	6.70 (4.18)	-1.35 (4.79)	(-10.99, 8.28)	0.7789	-0.06 (0.27)	(-0.58, 0.47)	0.8351	
No	44	10.25 (2.75)	41	5.98 (2.84)	4.27 (3.82)	(-3.34, 11.88)	0.2672	0.23 (0.22)	(-0.19, 0.66)	0.2866	
Baseline FARR anti-dsDNA											0.1668
<5 IU/mL	15	12.16 (4.25)	10	-0.28 (4.65)	12.44 (6.60)	(-1.17, 26.06)	0.0715	0.76 (0.42)	(-0.07, 1.59)	0.0729	
>=5 IU/mL	39	10.31 (2.96)	50	8.26 (2.67)	2.05 (3.59)	(-5.09, 9.19)	0.5696	0.11 (0.21)	(-0.31, 0.53)	0.6112	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.6829
Yes	49	9.30 (2.71)	60	7.31 (2.48)	2.00 (3.22)	(-4.40, 8.39)	0.5372	0.10 (0.19)	(-0.27, 0.48)	0.5901	
No	19	10.20 (4.49)	14	5.15 (5.20)	5.06 (6.76)	(-8.82, 18.93)	0.4612	0.25 (0.35)	(-0.44, 0.95)	0.4749	
OCS use											0.8091
Yes	53	8.76 (2.58)	63	5.00 (2.47)	3.76 (3.15)	(-2.49, 10.01)	0.2360	0.19 (0.19)	(-0.17, 0.56)	0.2989	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Lupus QoL Fatigue domain score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=69) N	LSMean (SE)	Placebo (N=75) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
No	15	13.93 (4.39)	11	8.45 (4.75)	5.48 (6.38)	(-7.64, 18.60)	0.3984	0.32 (0.40)	(-0.46, 1.11)	0.4211	
SLICC score											0.5419
0	39	7.87 (2.73)	47	7.77 (2.77)	0.10 (3.55)	(-6.97, 7.17)	0.9782	0.01 (0.22)	(-0.42, 0.43)	0.9805	
>=1	29	11.14 (4.08)	27	7.15 (3.77)	3.99 (5.31)	(-6.65, 14.64)	0.4553	0.19 (0.27)	(-0.34, 0.71)	0.4817	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Lupus QoL Intimate Relationships domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		4.96 (3.52)		2.09 (3.60)	2.87 (4.59)	(-6.22, 11.96)	0.5331			
Week 12		12.68 (3.86)		3.46 (3.88)	9.22 (5.04)	(-0.77, 19.21)	0.0700			
Week 24		6.73 (3.48)		5.44 (3.44)	1.29 (4.41)	(-7.46, 10.05)	0.7699			
Week 36		10.82 (4.27)		5.04 (4.54)	5.78 (5.86)	(-5.88, 17.44)	0.3267			
Week 52		7.60 (4.34)		7.77 (4.74)	-0.17 (6.08)	(-12.24, 11.90)	0.9780			
OVERALL	59	8.56 (3.18)	56	4.76 (3.20)	3.80 (3.99)	(-4.13, 11.72)	0.3438	0.16 (0.19)	(-0.21, 0.52)	0.4044

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Lupus QoL Intimate Relationships domain score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.0272
< 10 points	25	3.41 (5.00)	22	10.23 (4.91)	-6.82 (6.45)	(-19.82, 6.19)	0.2965	-0.28 (0.29)	(-0.85, 0.30)	0.3437	
>= 10 points	34	14.88 (4.33)	34	3.27 (4.38)	11.61 (5.29)	(0.99, 22.23)	0.0327	0.45 (0.25)	(-0.03, 0.93)	0.0658	
OCS dose											0.7720
<10 mg/day	31	6.73 (4.53)	16	0.71 (5.72)	6.02 (6.61)	(-7.32, 19.36)	0.3675	0.24 (0.31)	(-0.36, 0.85)	0.4337	
>=10 mg/day	28	11.33 (4.52)	40	7.70 (3.80)	3.63 (4.96)	(-6.32, 13.57)	0.4682	0.15 (0.25)	(-0.33, 0.63)	0.5448	
Result of type I IFN gene signature test											0.8551
LOW	9	5.68 (9.14)	12	5.00 (7.83)	0.68 (12.64)	(-26.41, 27.77)	0.9579	0.02 (0.44)	(-0.84, 0.89)	0.9567	
HIGH	50	8.55 (2.77)	44	5.44 (3.18)	3.11 (4.18)	(-5.21, 11.43)	0.4592	0.15 (0.21)	(-0.25, 0.56)	0.4634	
Age (years)											0.5656
<= 45	39	9.89 (4.04)	40	7.74 (3.72)	2.15 (4.50)	(-6.83, 11.13)	0.6336	0.09 (0.23)	(-0.35, 0.53)	0.6975	
> 45	20	10.46 (6.10)	16	2.36 (7.06)	8.09 (9.31)	(-10.94, 27.12)	0.3917	0.29 (0.34)	(-0.38, 0.95)	0.3970	
Sex											NE
male	4	NE	4	NE	NE	NE		NE	NE		
female	55	6.78 (3.21)	52	3.81 (3.27)	2.97 (4.03)	(-5.04, 10.97)	0.4636	0.12 (0.19)	(-0.26, 0.50)	0.5210	
Race											0.2736
White	20	6.58 (4.03)	24	2.25 (3.95)	4.33 (5.32)	(-6.44, 15.10)	0.4211	0.23 (0.30)	(-0.37, 0.82)	0.4557	
Black	16	13.52 (8.84)	8	-7.70 (8.20)	21.22 (11.26)	(-2.17, 44.60)	0.0732	0.64 (0.44)	(-0.23, 1.51)	0.1499	
Other	23	12.10 (6.04)	24	11.96 (6.24)	0.14 (6.87)	(-13.89, 14.16)	0.9844	0.00 (0.29)	(-0.57, 0.58)	0.9878	
Ethnicity											0.6560
Hispanic/Latino	22	13.19 (6.78)	19	13.48 (7.57)	-0.29 (8.18)	(-17.19, 16.60)	0.9716	-0.01 (0.31)	(-0.62, 0.60)	0.9773	
Non-hispanic/Latino	37	4.78 (3.53)	37	0.93 (3.34)	3.84 (4.41)	(-4.96, 12.65)	0.3866	0.18 (0.23)	(-0.27, 0.64)	0.4349	
Geographic region											0.2263
Latin America, Eastern Europe and Asia	37	13.49 (3.85)	41	14.84 (4.33)	-1.35 (4.29)	(-9.95, 7.25)	0.7538	-0.05 (0.23)	(-0.50, 0.39)	0.8188	
North America	22	5.37 (6.46)	15	-5.65 (6.23)	11.02 (9.28)	(-7.81, 29.85)	0.2430	0.39 (0.34)	(-0.28, 1.05)	0.2546	
Baseline weight											0.6258
<60 kg	14	27.01 (7.00)	21	18.06 (7.15)	8.95 (8.38)	(-8.57, 26.47)	0.2987	0.29 (0.35)	(-0.39, 0.97)	0.4066	
>=60 kg	45	3.74 (3.50)	35	-0.59 (3.52)	4.33 (4.42)	(-4.48, 13.14)	0.3309	0.19 (0.23)	(-0.25, 0.63)	0.3966	
Low CH50											NE
Yes	8	NE	7	NE	NE	NE		NE	NE		
No	51	8.68 (3.22)	49	4.14 (3.20)	4.54 (4.13)	(-3.66, 12.74)	0.2741	0.20 (0.20)	(-0.19, 0.59)	0.3226	
Low C3 or C4											0.4731
Yes	19	8.81 (9.03)	24	2.62 (7.38)	6.19 (7.33)	(-8.84, 21.22)	0.4055	0.16 (0.31)	(-0.44, 0.76)	0.5993	
No	40	6.94 (3.69)	32	7.21 (4.10)	-0.27 (5.23)	(-10.72, 10.18)	0.9593	-0.01 (0.24)	(-0.48, 0.45)	0.9616	
Baseline FARR anti-dsDNA											0.3734
<5 IU/mL	13	7.77 (4.91)	8	17.75 (5.86)	-9.98 (8.75)	(-28.54, 8.58)	0.2710	-0.55 (0.46)	(-1.45, 0.35)	0.2279	
>=5 IU/mL	35	5.57 (3.77)	38	6.79 (3.69)	-1.22 (4.51)	(-10.22, 7.79)	0.7881	-0.05 (0.23)	(-0.51, 0.41)	0.8197	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.1966
Yes	43	6.80 (3.75)	46	4.25 (3.69)	2.55 (4.37)	(-6.14, 11.25)	0.5607	0.10 (0.21)	(-0.31, 0.52)	0.6312	
No	16	7.12 (6.18)	10	19.07 (7.27)	-11.95 (10.35)	(-34.08, 10.18)	0.2669	-0.48 (0.41)	(-1.28, 0.32)	0.2409	
OCS use											0.2161
Yes	45	12.03 (3.78)	48	5.41 (3.82)	6.63 (4.33)	(-2.01, 15.26)	0.1305	0.25 (0.21)	(-0.16, 0.66)	0.2242	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Lupus QoL Intimate Relationships domain score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=69) N	LSMean (SE)	Placebo (N=75) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
No	14	-3.73 (7.84)	8	3.54 (8.64)	-7.28 (10.37)	(-29.07, 14.52)	0.4920	-0.25 (0.45)	(-1.13, 0.62)	0.5706	
SLICC score											0.5153
0	32	6.04 (4.72)	35	3.35 (4.98)	2.69 (5.64)	(-8.64, 14.01)	0.6356	0.09 (0.24)	(-0.39, 0.57)	0.7000	
>=1	27	11.43 (4.69)	21	3.22 (4.64)	8.21 (6.35)	(-4.58, 21.00)	0.2025	0.35 (0.29)	(-0.22, 0.93)	0.2325	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Lupus QoL Pain domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		6.03 (2.15)		5.93 (2.05)	0.10 (2.72)	(-5.28, 5.48)	0.9712			
Week 12		8.01 (2.95)		8.68 (2.82)	-0.67 (3.89)	(-8.36, 7.03)	0.8643			
Week 24		9.14 (3.01)		9.30 (2.94)	-0.15 (4.02)	(-8.11, 7.80)	0.9694			
Week 36		14.10 (3.00)		11.78 (2.98)	2.32 (4.04)	(-5.68, 10.32)	0.5674			
Week 52		13.33 (3.08)		8.88 (3.12)	4.45 (4.21)	(-3.88, 12.78)	0.2926			
OVERALL	68	10.12 (2.46)	74	8.91 (2.38)	1.21 (3.19)	(-5.10, 7.52)	0.7055	0.06 (0.17)	(-0.27, 0.39)	0.7252

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Lupus QoL Pain domain score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.3100
< 10 points	29	11.59 (3.85)	31	13.92 (3.59)	-2.32 (5.03)	(-12.41, 7.76)	0.6462	-0.11 (0.26)	(-0.62, 0.39)	0.6633	
>= 10 points	39	9.36 (3.26)	43	5.11 (3.22)	4.25 (4.07)	(-3.87, 12.37)	0.3003	0.20 (0.22)	(-0.23, 0.64)	0.3602	
OCS dose											0.5286
<10 mg/day	33	9.66 (3.38)	27	5.08 (3.57)	4.58 (4.76)	(-4.96, 14.11)	0.3405	0.24 (0.26)	(-0.27, 0.75)	0.3624	
>=10 mg/day	35	12.46 (3.59)	47	11.92 (3.25)	0.54 (4.28)	(-7.98, 9.07)	0.8993	0.02 (0.22)	(-0.41, 0.46)	0.9122	
Result of type I IFN gene signature test											0.5916
LOW	14	10.03 (5.69)	18	5.07 (5.18)	4.96 (7.74)	(-10.96, 20.88)	0.5271	0.22 (0.36)	(-0.48, 0.92)	0.5331	
HIGH	54	11.33 (2.47)	56	10.92 (2.53)	0.41 (3.49)	(-6.52, 7.33)	0.9073	0.02 (0.19)	(-0.35, 0.40)	0.9090	
Age (years)											0.9218
<= 45	44	12.43 (3.00)	49	10.64 (2.87)	1.79 (3.68)	(-5.52, 9.11)	0.6275	0.09 (0.21)	(-0.32, 0.50)	0.6691	
> 45	24	7.06 (4.64)	25	5.98 (4.54)	1.08 (6.29)	(-11.62, 13.77)	0.8648	0.05 (0.29)	(-0.51, 0.61)	0.8704	
Sex											NE
male	4	NE	6	NE	NE	NE		NE	NE		
female	64	9.81 (2.49)	68	8.14 (2.45)	1.67 (3.28)	(-4.82, 8.17)	0.6115	0.08 (0.17)	(-0.26, 0.42)	0.6351	
Race											0.2227
White	25	9.97 (3.42)	30	5.11 (3.15)	4.86 (4.47)	(-4.14, 13.86)	0.2823	0.28 (0.27)	(-0.25, 0.81)	0.3053	
Black	16	23.26 (10.04)	8	6.81 (8.68)	16.44 (13.38)	(-11.63, 44.52)	0.2347	0.44 (0.44)	(-0.42, 1.30)	0.3140	
Other	27	8.27 (4.41)	36	12.93 (4.13)	-4.66 (5.57)	(-15.82, 6.49)	0.4062	-0.19 (0.26)	(-0.69, 0.31)	0.4520	
Ethnicity											0.0403
Hispanic/Latino	27	9.12 (4.24)	28	16.74 (4.48)	-7.63 (5.78)	(-19.23, 3.98)	0.1930	-0.33 (0.27)	(-0.86, 0.20)	0.2266	
Non-hispanic/Latino	41	11.49 (2.91)	46	5.10 (2.64)	6.40 (3.66)	(-0.88, 13.68)	0.0842	0.35 (0.22)	(-0.08, 0.77)	0.1086	
Geographic region											0.4648
Latin America, Eastern Europe and Asia	44	11.95 (2.99)	55	13.14 (3.05)	-1.19 (3.66)	(-8.47, 6.09)	0.7457	-0.06 (0.20)	(-0.45, 0.34)	0.7849	
North America	24	7.50 (4.68)	19	2.95 (4.64)	4.55 (6.96)	(-9.52, 18.62)	0.5165	0.21 (0.31)	(-0.40, 0.81)	0.5051	
Baseline weight											0.5577
<60 kg	18	15.25 (5.33)	31	15.54 (4.49)	-0.29 (6.73)	(-13.89, 13.31)	0.9660	-0.01 (0.30)	(-0.59, 0.57)	0.9683	
>=60 kg	50	7.43 (2.73)	43	3.27 (2.73)	4.16 (3.52)	(-2.83, 11.16)	0.2399	0.22 (0.21)	(-0.19, 0.63)	0.2892	
Low CH50											0.3201
Yes	8	25.31 (7.55)	10	10.23 (11.00)	15.08 (13.96)	(-14.21, 44.38)	0.2939	0.48 (0.48)	(-0.46, 1.43)	0.3160	
No	60	8.69 (2.54)	64	7.88 (2.48)	0.80 (3.38)	(-5.88, 7.49)	0.8120	0.04 (0.18)	(-0.31, 0.39)	0.8220	
Low C3 or C4											0.4053
Yes	24	15.51 (5.18)	33	10.18 (4.46)	5.33 (5.37)	(-5.47, 16.13)	0.3260	0.21 (0.27)	(-0.32, 0.73)	0.4436	
No	44	8.47 (2.97)	41	8.80 (3.11)	-0.33 (4.16)	(-8.62, 7.96)	0.9378	-0.02 (0.22)	(-0.44, 0.41)	0.9400	
Baseline FARR anti-dsDNA											0.4737
<5 IU/mL	15	13.92 (5.30)	10	6.08 (5.57)	7.84 (8.14)	(-9.15, 24.83)	0.3473	0.39 (0.41)	(-0.42, 1.20)	0.3448	
>=5 IU/mL	39	10.33 (3.41)	50	9.06 (3.08)	1.27 (4.22)	(-7.13, 9.66)	0.7649	0.06 (0.21)	(-0.36, 0.48)	0.7853	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.7092
Yes	49	10.58 (3.02)	60	8.58 (2.78)	2.01 (3.69)	(-5.31, 9.32)	0.5877	0.09 (0.19)	(-0.28, 0.47)	0.6284	
No	19	12.19 (4.79)	14	13.22 (5.57)	-1.03 (7.24)	(-15.87, 13.82)	0.8885	-0.05 (0.35)	(-0.74, 0.64)	0.8918	
OCS use											0.6565
Yes	53	11.05 (2.87)	63	8.26 (2.75)	2.79 (3.60)	(-4.35, 9.92)	0.4401	0.13 (0.19)	(-0.24, 0.50)	0.4875	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Lupus QoL Pain domain score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
No	15	5.55 (4.26)	11	5.76 (4.47)	-0.21 (5.69)	(-12.03, 11.62)	0.9714	-0.01 (0.40)	(-0.79, 0.77)	0.9747	
SLICC score											0.6986
0	39	7.53 (3.05)	47	7.56 (3.05)	-0.04 (3.99)	(-7.99, 7.91)	0.9926	-0.00 (0.22)	(-0.43, 0.42)	0.9932	
>=1	29	14.25 (4.39)	27	11.56 (4.15)	2.68 (5.78)	(-8.92, 14.28)	0.6444	0.12 (0.27)	(-0.41, 0.64)	0.6628	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Lupus QoL Planning domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		4.00 (2.64)		-1.25 (2.51)	5.25 (3.36)	(-1.40, 11.89)	0.1206			
Week 12		9.58 (3.28)		5.35 (3.14)	4.23 (4.30)	(-4.28, 12.75)	0.3272			
Week 24		8.78 (3.09)		3.73 (2.99)	5.05 (4.05)	(-2.96, 13.07)	0.2147			
Week 36		11.64 (3.37)		5.15 (3.34)	6.50 (4.51)	(-2.44, 15.43)	0.1526			
Week 52		11.59 (3.31)		5.75 (3.32)	5.84 (4.46)	(-2.99, 14.66)	0.1929			
OVERALL	68	9.12 (2.75)	74	3.75 (2.64)	5.37 (3.53)	(-1.60, 12.35)	0.1300	0.24 (0.17)	(-0.09, 0.57)	0.1621

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Lupus QoL Planning domain score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.6819
< 10 points	29	11.43 (3.99)	31	7.32 (3.68)	4.11 (5.21)	(-6.33, 14.56)	0.4333	0.19 (0.26)	(-0.31, 0.70)	0.4548	
>= 10 points	39	8.15 (3.87)	43	1.14 (3.79)	7.00 (4.76)	(-2.47, 16.48)	0.1450	0.28 (0.22)	(-0.15, 0.72)	0.2035	
OCS dose											0.5170
<10 mg/day	33	9.16 (3.82)	27	5.32 (4.05)	3.83 (5.38)	(-6.96, 14.63)	0.4797	0.18 (0.26)	(-0.33, 0.69)	0.4998	
>=10 mg/day	35	9.71 (4.02)	47	1.26 (3.65)	8.45 (4.68)	(-0.87, 17.77)	0.0748	0.34 (0.22)	(-0.10, 0.78)	0.1290	
Result of type I IFN gene signature test											0.3743
LOW	14	8.73 (6.93)	18	-3.98 (6.23)	12.71 (9.30)	(-6.56, 31.99)	0.1853	0.47 (0.36)	(-0.24, 1.18)	0.1917	
HIGH	54	11.44 (2.69)	56	7.65 (2.75)	3.79 (3.80)	(-3.75, 11.32)	0.3209	0.19 (0.19)	(-0.19, 0.56)	0.3296	
Age (years)											0.2195
<= 45	44	11.24 (3.52)	49	2.65 (3.31)	8.59 (4.17)	(0.30, 16.88)	0.0424	0.37 (0.21)	(-0.04, 0.78)	0.0806	
> 45	24	5.55 (5.00)	25	6.70 (4.91)	-1.15 (6.75)	(-14.80, 12.50)	0.8657	-0.05 (0.29)	(-0.61, 0.51)	0.8718	
Sex											NE
male	4	NE	6	NE	NE	NE		NE	NE		
female	64	9.14 (2.80)	68	3.67 (2.74)	5.46 (3.64)	(-1.74, 12.67)	0.1356	0.24 (0.17)	(-0.10, 0.58)	0.1673	
Race											0.4316
White	25	13.95 (4.08)	30	4.31 (3.75)	9.64 (5.29)	(-1.00, 20.29)	0.0748	0.46 (0.27)	(-0.07, 1.00)	0.0911	
Black	16	3.48 (9.84)	8	-10.95 (8.40)	14.43 (11.87)	(-10.16, 39.02)	0.2367	0.40 (0.44)	(-0.46, 1.25)	0.3649	
Other	27	7.60 (4.38)	36	6.22 (4.18)	1.37 (5.46)	(-9.57, 12.32)	0.8021	0.06 (0.25)	(-0.44, 0.56)	0.8250	
Ethnicity											0.3885
Hispanic/Latino	27	8.57 (4.53)	28	7.23 (4.78)	1.34 (6.07)	(-10.85, 13.54)	0.8258	0.05 (0.27)	(-0.47, 0.58)	0.8410	
Non-hispanic/Latino	41	8.68 (3.60)	46	0.83 (3.22)	7.85 (4.48)	(-1.07, 16.77)	0.0838	0.35 (0.22)	(-0.08, 0.77)	0.1088	
Geographic region											0.6369
Latin America, Eastern Europe and Asia	44	13.89 (3.19)	55	9.22 (3.30)	4.67 (3.83)	(-2.94, 12.27)	0.2257	0.20 (0.20)	(-0.20, 0.60)	0.3222	
North America	24	-0.39 (5.40)	19	-9.13 (5.21)	8.74 (7.74)	(-6.92, 24.40)	0.2656	0.34 (0.31)	(-0.26, 0.95)	0.2655	
Baseline weight											0.8741
<60 kg	18	16.30 (5.83)	31	9.08 (4.84)	7.21 (7.37)	(-7.63, 22.06)	0.3327	0.27 (0.30)	(-0.31, 0.85)	0.3625	
>=60 kg	50	5.83 (3.10)	43	-2.71 (3.11)	8.54 (4.00)	(0.59, 16.50)	0.0357	0.40 (0.21)	(-0.01, 0.81)	0.0576	
Low CH50											0.5246
Yes	8	18.58 (9.39)	10	0.64 (13.94)	17.93 (17.87)	(-20.21, 56.08)	0.3317	0.46 (0.48)	(-0.49, 1.40)	0.3439	
No	60	8.88 (2.72)	64	2.54 (2.64)	6.34 (3.58)	(-0.74, 13.42)	0.0788	0.30 (0.18)	(-0.06, 0.65)	0.0988	
Low C3 or C4											0.8954
Yes	24	9.88 (6.79)	33	4.91 (5.82)	4.97 (6.49)	(-8.12, 18.06)	0.4481	0.15 (0.27)	(-0.38, 0.67)	0.5845	
No	44	7.70 (3.07)	41	1.71 (3.18)	5.99 (4.26)	(-2.49, 14.47)	0.1637	0.29 (0.22)	(-0.14, 0.72)	0.1818	
Baseline FARR anti-dsDNA											0.6156
<5 IU/mL	15	6.25 (5.01)	10	-4.07 (5.34)	10.32 (7.68)	(-5.59, 26.23)	0.1927	0.54 (0.42)	(-0.28, 1.36)	0.1946	
>=5 IU/mL	39	12.09 (3.91)	50	6.32 (3.53)	5.77 (4.79)	(-3.76, 15.30)	0.2314	0.23 (0.21)	(-0.19, 0.65)	0.2801	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.5700
Yes	49	10.86 (3.52)	60	4.00 (3.22)	6.86 (4.22)	(-1.53, 15.24)	0.1078	0.27 (0.19)	(-0.10, 0.65)	0.1562	
No	19	5.02 (4.58)	14	2.76 (5.35)	2.25 (6.91)	(-11.92, 16.43)	0.7468	0.11 (0.35)	(-0.58, 0.80)	0.7548	
OCS use											0.3474
Yes	53	10.50 (3.12)	63	2.63 (2.99)	7.87 (3.86)	(0.22, 15.52)	0.0439	0.34 (0.19)	(-0.03, 0.70)	0.0737	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Lupus QoL Planning domain score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=69) N	LSMean (SE)	Placebo (N=75) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
No	15	3.31 (6.13)	11	4.47 (6.86)	-1.16 (8.80)	(-19.29, 16.97)	0.8963	-0.05 (0.40)	(-0.83, 0.73)	0.9036	
SLICC score											0.5175
0	39	7.13 (3.25)	47	3.21 (3.30)	3.92 (4.23)	(-4.49, 12.33)	0.3566	0.18 (0.22)	(-0.25, 0.61)	0.4075	
>=1	29	14.18 (5.20)	27	5.09 (4.84)	9.09 (6.78)	(-4.55, 22.72)	0.1865	0.34 (0.27)	(-0.19, 0.86)	0.2126	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SDI Global Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 24		0.00 (0.07)		0.06 (0.07)	-0.05 (0.09)	(-0.23, 0.13)	0.5736			
Week 52		0.02 (0.08)		-0.03 (0.09)	0.05 (0.11)	(-0.17, 0.27)	0.6520			
OVERALL	66	0.01 (0.07)	65	0.01 (0.07)	-0.00 (0.10)	(-0.19, 0.19)	0.9967	-0.00 (0.17)	(-0.34, 0.34)	0.9970

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SDI Global Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=69) N	LSMean (SE)	Placebo (N=75) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.1577
< 10 points	28	0.06 (0.11)	29	-0.14 (0.11)	0.20 (0.14)	(-0.09, 0.49)	0.1807	0.34 (0.27)	(-0.19, 0.86)	0.2057	
>= 10 points	38	0.02 (0.11)	36	0.10 (0.11)	-0.08 (0.13)	(-0.35, 0.19)	0.5415	-0.12 (0.23)	(-0.58, 0.33)	0.6020	
OCS dose											0.9144
<10 mg/day	30	-0.07 (0.10)	25	-0.07 (0.11)	-0.00 (0.14)	(-0.29, 0.28)	0.9926	-0.00 (0.27)	(-0.53, 0.53)	0.9930	
>=10 mg/day	36	0.13 (0.11)	40	0.12 (0.11)	0.02 (0.13)	(-0.24, 0.28)	0.8816	0.03 (0.23)	(-0.42, 0.48)	0.9026	
Result of type I IFN gene signature test											0.4386
LOW	14	0.07 (0.09)	16	-0.04 (0.08)	0.11 (0.12)	(-0.14, 0.36)	0.3748	0.33 (0.37)	(-0.40, 1.05)	0.3755	
HIGH	52	-0.03 (0.09)	49	-0.01 (0.09)	-0.02 (0.12)	(-0.26, 0.22)	0.8510	-0.04 (0.20)	(-0.43, 0.35)	0.8539	
Age (years)											0.0352
<= 45	44	-0.08 (0.07)	43	0.10 (0.07)	-0.18 (0.08)	(-0.34, -0.02)	0.0292	-0.41 (0.22)	(-0.83, 0.02)	0.0608	
> 45	22	0.20 (0.17)	22	-0.14 (0.18)	0.34 (0.23)	(-0.13, 0.82)	0.1534	0.41 (0.31)	(-0.18, 1.01)	0.1748	
Sex											NE
male	4	NE	6	NE	NE	NE		NE	NE		
female	62	0.00 (0.08)	59	0.03 (0.08)	-0.03 (0.10)	(-0.23, 0.18)	0.7977	-0.04 (0.18)	(-0.40, 0.31)	0.8139	
Race											0.7326
White	24	0.03 (0.08)	29	0.04 (0.07)	-0.01 (0.10)	(-0.22, 0.20)	0.9229	-0.03 (0.28)	(-0.57, 0.52)	0.9269	
Black	15	0.05 (0.16)	8	-0.10 (0.13)	0.15 (0.18)	(-0.23, 0.54)	0.4122	0.27 (0.44)	(-0.59, 1.14)	0.5326	
Other	27	-0.05 (0.14)	28	-0.10 (0.15)	0.05 (0.18)	(-0.31, 0.42)	0.7659	0.07 (0.27)	(-0.46, 0.60)	0.7989	
Ethnicity											0.6593
Hispanic/Latino	27	-0.11 (0.14)	23	-0.06 (0.16)	-0.05 (0.19)	(-0.42, 0.33)	0.8086	-0.06 (0.28)	(-0.62, 0.49)	0.8290	
Non-hispanic/Latino	39	0.04 (0.07)	42	0.00 (0.06)	0.04 (0.08)	(-0.12, 0.21)	0.5963	0.11 (0.22)	(-0.33, 0.55)	0.6239	
Geographic region											0.0133
Latin America, Eastern Europe and Asia	44	-0.08 (0.11)	47	0.02 (0.12)	-0.10 (0.13)	(-0.36, 0.16)	0.4411	-0.13 (0.21)	(-0.54, 0.28)	0.5297	
North America	22	0.21 (0.08)	18	-0.13 (0.09)	0.34 (0.12)	(0.09, 0.59)	0.0086	0.88 (0.33)	(0.23, 1.54)	0.0082	
Baseline weight											0.0353
<60 kg	18	-0.29 (0.16)	25	0.08 (0.15)	-0.36 (0.21)	(-0.79, 0.06)	0.0900	-0.50 (0.31)	(-1.12, 0.12)	0.1119	
>=60 kg	48	0.11 (0.07)	40	-0.01 (0.07)	0.12 (0.09)	(-0.07, 0.30)	0.2113	0.24 (0.21)	(-0.18, 0.66)	0.2643	
Low CH50											NE
Yes	7	NE	9	NE	NE	NE		NE	NE		
No	59	0.05 (0.06)	56	-0.05 (0.06)	0.09 (0.08)	(-0.07, 0.26)	0.2501	0.20 (0.19)	(-0.16, 0.57)	0.2761	
Low C3 or C4											0.7620
Yes	23	0.14 (0.25)	27	0.16 (0.21)	-0.03 (0.22)	(-0.47, 0.41)	0.9008	-0.02 (0.28)	(-0.58, 0.53)	0.9332	
No	43	0.03 (0.05)	38	-0.02 (0.06)	0.04 (0.08)	(-0.11, 0.19)	0.5802	0.12 (0.22)	(-0.32, 0.56)	0.5945	
Baseline FARR anti-dsDNA											0.4270
<5 IU/mL	14	-0.10 (0.20)	9	0.11 (0.22)	-0.21 (0.32)	(-0.88, 0.45)	0.5142	-0.29 (0.43)	(-1.13, 0.56)	0.5048	
>=5 IU/mL	39	0.03 (0.09)	45	-0.02 (0.09)	0.06 (0.11)	(-0.16, 0.27)	0.6135	0.10 (0.22)	(-0.33, 0.53)	0.6611	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.9490
Yes	48	0.02 (0.11)	52	0.03 (0.10)	-0.01 (0.12)	(-0.26, 0.24)	0.9356	-0.01 (0.20)	(-0.41, 0.38)	0.9462	
No	18	-0.01 (0.04)	13	-0.01 (0.05)	-0.00 (0.06)	(-0.13, 0.13)	0.9854	-0.01 (0.36)	(-0.72, 0.71)	0.9856	
OCS use											0.8604
Yes	53	-0.01 (0.09)	54	0.02 (0.09)	-0.02 (0.11)	(-0.25, 0.20)	0.8470	-0.03 (0.19)	(-0.41, 0.35)	0.8683	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SDI Global Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=69) N	LSMean (SE)	Placebo (N=75) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
No	13	-0.07 (0.11)	11	-0.08 (0.11)	0.01 (0.15)	(-0.31, 0.33)	0.9401	0.03 (0.41)	(-0.77, 0.83)	0.9448	
SLICC score											0.9187
0	39	0.09 (0.08)	41	0.04 (0.08)	0.04 (0.10)	(-0.16, 0.25)	0.6677	0.09 (0.22)	(-0.35, 0.52)	0.6998	
>=1	27	-0.08 (0.15)	24	-0.15 (0.15)	0.07 (0.20)	(-0.34, 0.47)	0.7421	0.09 (0.28)	(-0.46, 0.64)	0.7589	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - PtGA
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-9.81 (2.98)		-4.25 (2.82)	-5.56 (3.87)	(-13.21, 2.09)	0.1530			
Week 8		-12.13 (2.89)		-11.10 (2.75)	-1.03 (3.74)	(-8.42, 6.37)	0.7836			
Week 12		-18.15 (2.98)		-14.13 (2.85)	-4.02 (3.88)	(-11.69, 3.65)	0.3017			
Week 16		-14.09 (3.10)		-13.26 (3.04)	-0.82 (4.11)	(-8.96, 7.31)	0.8418			
Week 20		-17.14 (3.02)		-11.49 (2.94)	-5.65 (3.98)	(-13.52, 2.22)	0.1581			
Week 24		-15.60 (3.03)		-13.95 (2.98)	-1.65 (4.02)	(-9.61, 6.30)	0.6816			
Week 28		-16.71 (3.10)		-12.19 (3.09)	-4.52 (4.15)	(-12.74, 3.70)	0.2783			
Week 32		-20.73 (3.07)		-14.08 (3.05)	-6.66 (4.10)	(-14.77, 1.45)	0.1066			
Week 36		-20.05 (3.24)		-14.24 (3.24)	-5.81 (4.36)	(-14.44, 2.83)	0.1856			
Week 40		-20.99 (2.99)		-14.69 (3.00)	-6.30 (4.00)	(-14.23, 1.62)	0.1178			
Week 44		-22.44 (3.15)		-11.21 (3.19)	-11.23 (4.27)	(-19.67, -2.79)	0.0096			
Week 48		-18.33 (3.09)		-14.07 (3.18)	-4.26 (4.21)	(-12.59, 4.08)	0.3138			
Week 52		-18.59 (3.20)		-12.64 (3.31)	-5.95 (4.39)	(-14.64, 2.74)	0.1778			
OVERALL	69	-17.29 (2.43)	75	-12.41 (2.34)	-4.88 (3.08)	(-10.97, 1.21)	0.1152	-0.24 (0.17)	(-0.57, 0.09)	0.1518

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - PtGA - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=69) N	LSMean (SE)	Placebo (N=75) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.8335
< 10 points	29	-21.42 (3.86)	32	-17.40 (3.53)	-4.02 (4.93)	(-13.90, 5.86)	0.4180	-0.19 (0.26)	(-0.70, 0.31)	0.4483	
>= 10 points	40	-10.98 (3.25)	43	-5.65 (3.22)	-5.33 (3.81)	(-12.93, 2.27)	0.1663	-0.25 (0.22)	(-0.69, 0.18)	0.2513	
OCS dose											0.7964
<10 mg/day	33	-16.02 (3.35)	28	-10.02 (3.47)	-6.01 (4.58)	(-15.18, 3.17)	0.1949	-0.31 (0.26)	(-0.82, 0.19)	0.2233	
>=10 mg/day	36	-16.47 (3.68)	47	-12.06 (3.39)	-4.41 (4.17)	(-12.72, 3.90)	0.2934	-0.19 (0.22)	(-0.63, 0.24)	0.3865	
Result of type I IFN gene signature test											0.5644
LOW	14	-13.16 (4.88)	19	-12.52 (4.47)	-0.64 (6.71)	(-14.39, 13.11)	0.9245	-0.03 (0.35)	(-0.72, 0.66)	0.9254	
HIGH	55	-17.11 (2.45)	56	-12.11 (2.55)	-4.99 (3.47)	(-11.87, 1.89)	0.1529	-0.27 (0.19)	(-0.64, 0.11)	0.1626	
Age (years)											0.8693
<= 45	45	-15.98 (3.19)	50	-10.62 (2.99)	-5.36 (3.76)	(-12.85, 2.12)	0.1579	-0.25 (0.21)	(-0.65, 0.15)	0.2260	
> 45	24	-16.92 (4.18)	25	-12.67 (4.20)	-4.25 (5.63)	(-15.62, 7.12)	0.4545	-0.20 (0.29)	(-0.76, 0.36)	0.4821	
Sex											NE
male	4	NE	6	NE	NE	NE		NE	NE		
female	65	-16.82 (2.44)	69	-11.33 (2.40)	-5.49 (3.14)	(-11.71, 0.72)	0.0825	-0.28 (0.17)	(-0.62, 0.06)	0.1121	
Race											NE
White	25	-18.27 (3.53)	31	-17.53 (3.19)	-0.74 (4.58)	(-9.94, 8.46)	0.8720	-0.04 (0.27)	(-0.57, 0.49)	0.8781	
Black	16	NE	8	NE	NE	NE		NE	NE		
Other	28	-15.38 (3.99)	36	-11.99 (4.01)	-3.39 (4.91)	(-13.27, 6.48)	0.4929	-0.15 (0.25)	(-0.64, 0.35)	0.5606	
Ethnicity											0.1055
Hispanic/Latino	28	-15.74 (4.29)	28	-17.66 (4.74)	1.92 (5.71)	(-9.58, 13.43)	0.7381	0.08 (0.27)	(-0.44, 0.60)	0.7670	
Non-hispanic/Latino	41	-19.47 (2.97)	47	-10.42 (2.63)	-9.05 (3.65)	(-16.30, -1.79)	0.0152	-0.48 (0.22)	(-0.91, -0.06)	0.0254	
Geographic region											0.1769
Latin America, Eastern Europe and Asia	45	-17.17 (3.22)	55	-15.15 (3.42)	-2.02 (3.83)	(-9.62, 5.59)	0.5996	-0.08 (0.20)	(-0.48, 0.31)	0.6755	
North America	24	-19.08 (3.76)	20	-8.09 (3.72)	-10.99 (5.43)	(-22.00, 0.02)	0.0503	-0.61 (0.31)	(-1.22, -0.00)	0.0487	
Baseline weight											0.2971
<60 kg	18	-15.07 (5.08)	31	-14.83 (4.36)	-0.24 (6.46)	(-13.30, 12.82)	0.9708	-0.01 (0.30)	(-0.59, 0.57)	0.9730	
>=60 kg	51	-18.25 (2.87)	44	-10.30 (2.82)	-7.95 (3.60)	(-15.10, -0.80)	0.0298	-0.40 (0.21)	(-0.81, 0.01)	0.0541	
Low CH50											NE
Yes	9	NE	10	NE	NE	NE		NE	NE		
No	60	-17.44 (2.51)	65	-11.74 (2.43)	-5.70 (3.28)	(-12.19, 0.79)	0.0843	-0.29 (0.18)	(-0.64, 0.06)	0.1067	
Low C3 or C4											0.7669
Yes	25	-16.18 (6.28)	33	-10.37 (5.39)	-5.81 (5.28)	(-16.43, 4.82)	0.2771	-0.18 (0.27)	(-0.70, 0.34)	0.4893	
No	44	-17.34 (2.88)	42	-13.50 (2.98)	-3.84 (3.99)	(-11.78, 4.09)	0.3379	-0.20 (0.22)	(-0.62, 0.23)	0.3589	
Baseline FARR anti-dsDNA											0.8856
<5 IU/mL	15	-19.98 (5.14)	11	-14.24 (5.25)	-5.74 (8.02)	(-22.27, 10.79)	0.4807	-0.29 (0.40)	(-1.08, 0.49)	0.4614	
>=5 IU/mL	40	-18.09 (3.47)	50	-13.64 (3.18)	-4.44 (4.13)	(-12.66, 3.77)	0.2847	-0.20 (0.21)	(-0.61, 0.22)	0.3518	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.9398
Yes	50	-16.86 (3.11)	60	-11.57 (2.89)	-5.29 (3.60)	(-12.43, 1.85)	0.1449	-0.24 (0.19)	(-0.61, 0.14)	0.2182	
No	19	-19.47 (4.33)	15	-14.75 (4.95)	-4.73 (6.47)	(-17.94, 8.48)	0.4706	-0.24 (0.35)	(-0.92, 0.44)	0.4841	
OCS use											NE
Yes	54	-16.97 (2.94)	63	-12.43 (2.85)	-4.54 (3.55)	(-11.58, 2.50)	0.2039	-0.20 (0.19)	(-0.57, 0.16)	0.2736	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - PtGA - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=69) N	Anifrolumab 300mg (N=69) LSMean (SE)	Placebo (N=75) N	Placebo (N=75) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
No	15	NE	12	NE	NE	NE		NE	NE		
SLICC score											0.7690
0	40	-14.64 (2.90)	48	-9.79 (2.98)	-4.86 (3.77)	(-12.37, 2.65)	0.2017	-0.25 (0.21)	(-0.67, 0.18)	0.2540	
>=1	29	-19.36 (4.54)	27	-16.52 (4.12)	-2.84 (5.74)	(-14.39, 8.71)	0.6229	-0.12 (0.27)	(-0.65, 0.40)	0.6497	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Total HAQ Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		0.01 (0.06)		-0.14 (0.05)	0.15 (0.07)	(0.00, 0.29)	0.0482			
Week 12		-0.08 (0.07)		-0.18 (0.06)	0.10 (0.09)	(-0.07, 0.28)	0.2470			
Week 24		-0.18 (0.07)		-0.19 (0.07)	0.01 (0.10)	(-0.18, 0.20)	0.9109			
Week 36		-0.17 (0.07)		-0.21 (0.07)	0.04 (0.10)	(-0.15, 0.24)	0.6496			
Week 52		-0.21 (0.07)		-0.22 (0.07)	0.02 (0.10)	(-0.18, 0.22)	0.8540			
OVERALL	69	-0.12 (0.06)	75	-0.19 (0.06)	0.06 (0.08)	(-0.09, 0.22)	0.3964	0.13 (0.17)	(-0.20, 0.46)	0.4331

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Total HAQ Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.9761
< 10 points	29	-0.13 (0.09)	32	-0.19 (0.08)	0.06 (0.11)	(-0.16, 0.29)	0.5866	0.13 (0.26)	(-0.37, 0.64)	0.6037	
>= 10 points	40	-0.12 (0.09)	43	-0.18 (0.09)	0.06 (0.11)	(-0.15, 0.27)	0.5947	0.10 (0.22)	(-0.33, 0.53)	0.6504	
OCS dose											0.2014
<10 mg/day	33	-0.16 (0.08)	28	-0.04 (0.08)	-0.11 (0.12)	(-0.35, 0.12)	0.3260	-0.25 (0.26)	(-0.75, 0.26)	0.3401	
>=10 mg/day	36	-0.19 (0.09)	47	-0.28 (0.08)	0.09 (0.11)	(-0.13, 0.30)	0.4206	0.15 (0.22)	(-0.28, 0.59)	0.4908	
Result of type I IFN gene signature test											0.4485
LOW	14	-0.10 (0.14)	19	-0.07 (0.12)	-0.03 (0.18)	(-0.41, 0.34)	0.8625	-0.06 (0.35)	(-0.75, 0.63)	0.8651	
HIGH	55	-0.19 (0.06)	56	-0.31 (0.06)	0.12 (0.08)	(-0.05, 0.29)	0.1543	0.27 (0.19)	(-0.11, 0.64)	0.1637	
Age (years)											0.7936
<= 45	45	-0.15 (0.07)	50	-0.21 (0.07)	0.06 (0.09)	(-0.11, 0.24)	0.4734	0.13 (0.21)	(-0.27, 0.53)	0.5322	
> 45	24	-0.13 (0.11)	25	-0.15 (0.11)	0.02 (0.15)	(-0.29, 0.32)	0.9029	0.03 (0.29)	(-0.53, 0.59)	0.9062	
Sex											NE
male	4	NE	6	NE	NE	NE		NE	NE		
female	65	-0.12 (0.06)	69	-0.17 (0.06)	0.05 (0.08)	(-0.11, 0.21)	0.5373	0.10 (0.17)	(-0.24, 0.44)	0.5661	
Race											0.1833
White	25	-0.10 (0.08)	31	-0.19 (0.08)	0.09 (0.11)	(-0.13, 0.31)	0.3942	0.22 (0.27)	(-0.31, 0.75)	0.4152	
Black	16	-0.36 (0.25)	8	0.08 (0.18)	-0.44 (0.28)	(-1.02, 0.15)	0.1367	-0.48 (0.44)	(-1.34, 0.38)	0.2735	
Other	28	-0.09 (0.10)	36	-0.21 (0.10)	0.11 (0.13)	(-0.14, 0.37)	0.3730	0.20 (0.25)	(-0.29, 0.70)	0.4261	
Ethnicity											0.2049
Hispanic/Latino	28	-0.12 (0.10)	28	-0.30 (0.11)	0.17 (0.14)	(-0.11, 0.45)	0.2201	0.31 (0.27)	(-0.22, 0.83)	0.2548	
Non-hispanic/Latino	41	-0.17 (0.07)	47	-0.13 (0.06)	-0.04 (0.09)	(-0.22, 0.14)	0.6785	-0.08 (0.21)	(-0.50, 0.34)	0.7009	
Geographic region											0.0163
Latin America, Eastern Europe and Asia	45	-0.16 (0.07)	55	-0.34 (0.08)	0.18 (0.09)	(0.01, 0.36)	0.0433	0.34 (0.20)	(-0.06, 0.73)	0.0962	
North America	24	-0.11 (0.10)	20	0.12 (0.10)	-0.23 (0.15)	(-0.52, 0.07)	0.1259	-0.49 (0.31)	(-1.09, 0.12)	0.1141	
Baseline weight											0.3576
<60 kg	18	-0.37 (0.14)	31	-0.27 (0.12)	-0.10 (0.17)	(-0.45, 0.24)	0.5475	-0.16 (0.30)	(-0.75, 0.42)	0.5800	
>=60 kg	51	-0.03 (0.06)	44	-0.10 (0.06)	0.07 (0.08)	(-0.09, 0.23)	0.3794	0.16 (0.21)	(-0.24, 0.57)	0.4286	
Low CH50											0.6612
Yes	9	-0.25 (0.25)	10	-0.52 (0.42)	0.27 (0.48)	(-0.74, 1.28)	0.5828	0.24 (0.46)	(-0.67, 1.14)	0.6076	
No	60	-0.13 (0.06)	65	-0.18 (0.06)	0.06 (0.08)	(-0.10, 0.21)	0.4747	0.12 (0.18)	(-0.23, 0.47)	0.4989	
Low C3 or C4											0.6982
Yes	25	-0.24 (0.15)	33	-0.34 (0.13)	0.09 (0.14)	(-0.19, 0.38)	0.5043	0.12 (0.27)	(-0.40, 0.64)	0.6467	
No	44	-0.12 (0.07)	42	-0.15 (0.07)	0.03 (0.09)	(-0.16, 0.22)	0.7593	0.06 (0.22)	(-0.36, 0.49)	0.7668	
Baseline FARR anti-dsDNA											0.3718
<5 IU/mL	15	-0.14 (0.12)	11	-0.07 (0.12)	-0.07 (0.18)	(-0.45, 0.31)	0.7026	-0.16 (0.40)	(-0.94, 0.62)	0.6945	
>=5 IU/mL	40	-0.12 (0.08)	50	-0.23 (0.07)	0.11 (0.10)	(-0.08, 0.30)	0.2383	0.22 (0.21)	(-0.20, 0.64)	0.2973	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.3120
Yes	50	-0.10 (0.08)	60	-0.21 (0.07)	0.11 (0.09)	(-0.07, 0.29)	0.2169	0.21 (0.19)	(-0.17, 0.58)	0.2827	
No	19	-0.22 (0.11)	15	-0.14 (0.13)	-0.08 (0.16)	(-0.42, 0.26)	0.6372	-0.16 (0.35)	(-0.84, 0.52)	0.6464	
OCS use											0.6445
Yes	54	-0.16 (0.07)	63	-0.20 (0.07)	0.04 (0.09)	(-0.13, 0.22)	0.6400	0.08 (0.19)	(-0.29, 0.44)	0.6811	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Total HAQ Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
No	15	-0.04 (0.08)	12	-0.02 (0.08)	-0.02 (0.10)	(-0.23, 0.19)	0.8423	-0.07 (0.39)	(-0.83, 0.69)	0.8595	
SLICC score											0.5019
0	40	-0.14 (0.08)	48	-0.16 (0.08)	0.02 (0.10)	(-0.17, 0.22)	0.8235	0.04 (0.21)	(-0.38, 0.46)	0.8417	
>=1	29	-0.09 (0.10)	27	-0.23 (0.09)	0.13 (0.13)	(-0.13, 0.39)	0.3196	0.25 (0.27)	(-0.27, 0.78)	0.3428	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Pain Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-3.63 (2.57)		-2.51 (2.43)	-1.12 (3.30)	(-7.65, 5.41)	0.7350			
Week 12		-10.10 (2.94)		-10.94 (2.80)	0.84 (3.84)	(-6.76, 8.44)	0.8271			
Week 24		-13.70 (2.94)		-9.69 (2.89)	-4.01 (3.92)	(-11.76, 3.74)	0.3081			
Week 36		-16.41 (3.12)		-13.31 (3.15)	-3.10 (4.24)	(-11.50, 5.29)	0.4659			
Week 52		-16.09 (3.08)		-12.68 (3.17)	-3.41 (4.23)	(-11.79, 4.97)	0.4219			
OVERALL	69	-11.99 (2.37)	75	-9.83 (2.29)	-2.16 (3.04)	(-8.17, 3.85)	0.4783	-0.11 (0.17)	(-0.44, 0.22)	0.5151

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Pain Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=69)		Placebo (N=75)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.7325
< 10 points	29	-15.99 (3.11)	32	-12.48 (2.86)	-3.52 (4.01)	(-11.56, 4.53)	0.3846	-0.21 (0.26)	(-0.72, 0.29)	0.4118	
>= 10 points	40	-9.74 (3.58)	43	-8.25 (3.54)	-1.49 (4.37)	(-10.19, 7.21)	0.7340	-0.06 (0.22)	(-0.50, 0.37)	0.7696	
OCS dose											0.8942
<10 mg/day	33	-11.75 (3.53)	28	-8.54 (3.70)	-3.21 (4.92)	(-13.07, 6.66)	0.5171	-0.16 (0.26)	(-0.66, 0.35)	0.5378	
>=10 mg/day	36	-13.21 (3.39)	47	-10.84 (3.11)	-2.37 (3.91)	(-10.16, 5.42)	0.5462	-0.11 (0.22)	(-0.55, 0.32)	0.6121	
Result of type I IFN gene signature test											0.9047
LOW	14	-8.85 (5.79)	19	-5.41 (5.25)	-3.44 (8.09)	(-20.18, 13.29)	0.6746	-0.15 (0.35)	(-0.84, 0.54)	0.6707	
HIGH	55	-13.21 (2.27)	56	-10.81 (2.36)	-2.40 (3.23)	(-8.80, 4.00)	0.4591	-0.14 (0.19)	(-0.51, 0.23)	0.4683	
Age (years)											0.7716
<= 45	45	-11.69 (3.05)	50	-9.01 (2.86)	-2.68 (3.61)	(-9.86, 4.50)	0.4601	-0.13 (0.21)	(-0.53, 0.27)	0.5254	
> 45	24	-10.55 (4.26)	25	-9.85 (4.26)	-0.69 (5.81)	(-12.52, 11.13)	0.9056	-0.03 (0.29)	(-0.59, 0.53)	0.9097	
Sex											NE
male	4	NE	6	NE	NE	NE		NE	NE		
female	65	-12.59 (2.44)	69	-9.55 (2.40)	-3.04 (3.18)	(-9.33, 3.25)	0.3403	-0.15 (0.17)	(-0.49, 0.19)	0.3784	
Race											0.4789
White	25	-6.86 (3.81)	31	-7.35 (3.45)	0.50 (4.94)	(-9.45, 10.45)	0.9205	0.03 (0.27)	(-0.50, 0.55)	0.9243	
Black	16	-15.15 (9.16)	8	-1.78 (7.32)	-13.37 (10.40)	(-35.00, 8.26)	0.2125	-0.40 (0.44)	(-1.26, 0.46)	0.3629	
Other	28	-16.45 (3.38)	36	-15.30 (3.35)	-1.15 (4.21)	(-9.58, 7.27)	0.7846	-0.06 (0.25)	(-0.55, 0.43)	0.8134	
Ethnicity											0.2312
Hispanic/Latino	28	-12.18 (3.45)	28	-14.80 (3.81)	2.62 (4.69)	(-6.80, 12.03)	0.5787	0.13 (0.27)	(-0.39, 0.66)	0.6160	
Non-hispanic/Latino	41	-11.78 (3.27)	47	-6.97 (2.91)	-4.81 (4.06)	(-12.89, 3.28)	0.2403	-0.23 (0.21)	(-0.65, 0.19)	0.2772	
Geographic region											0.2748
Latin America, Eastern Europe and Asia	45	-14.07 (2.95)	55	-13.75 (3.09)	-0.32 (3.53)	(-7.34, 6.70)	0.9282	-0.01 (0.20)	(-0.41, 0.38)	0.9418	
North America	24	-11.19 (4.87)	20	-2.30 (4.67)	-8.89 (7.01)	(-23.17, 5.38)	0.2136	-0.39 (0.31)	(-0.99, 0.21)	0.2058	
Baseline weight											0.0351
<60 kg	18	-8.87 (5.23)	31	-16.31 (4.38)	7.45 (6.74)	(-6.13, 21.02)	0.2751	0.31 (0.30)	(-0.27, 0.89)	0.2985	
>=60 kg	51	-13.47 (2.65)	44	-5.01 (2.60)	-8.45 (3.40)	(-15.20, -1.70)	0.0147	-0.46 (0.21)	(-0.87, -0.05)	0.0269	
Low CH50											0.5722
Yes	9	-19.35 (6.34)	10	-23.45 (11.28)	4.09 (13.13)	(-24.20, 32.38)	0.7602	0.13 (0.46)	(-0.77, 1.04)	0.7700	
No	60	-11.69 (2.43)	65	-8.15 (2.36)	-3.54 (3.20)	(-9.88, 2.80)	0.2708	-0.19 (0.18)	(-0.54, 0.17)	0.2997	
Low C3 or C4											0.8565
Yes	25	-14.63 (5.64)	33	-12.17 (4.84)	-2.46 (4.94)	(-12.45, 7.53)	0.6216	-0.09 (0.27)	(-0.61, 0.43)	0.7439	
No	44	-9.65 (2.74)	42	-6.06 (2.84)	-3.59 (3.84)	(-11.22, 4.05)	0.3522	-0.19 (0.22)	(-0.62, 0.23)	0.3685	
Baseline FARR anti-dsDNA											0.8345
<5 IU/mL	15	-8.63 (5.49)	11	-5.79 (5.77)	-2.84 (8.44)	(-20.46, 14.78)	0.7402	-0.13 (0.40)	(-0.91, 0.64)	0.7346	
>=5 IU/mL	40	-12.16 (3.26)	50	-11.26 (3.00)	-0.90 (3.91)	(-8.67, 6.88)	0.8193	-0.04 (0.21)	(-0.46, 0.37)	0.8417	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.8146
Yes	50	-13.41 (2.95)	60	-11.37 (2.74)	-2.04 (3.45)	(-8.89, 4.81)	0.5564	-0.10 (0.19)	(-0.47, 0.28)	0.6157	
No	19	-11.69 (5.07)	15	-7.71 (5.72)	-3.98 (7.54)	(-19.46, 11.50)	0.6016	-0.18 (0.35)	(-0.85, 0.50)	0.6115	
OCS use											0.5170
Yes	54	-12.29 (2.72)	63	-8.82 (2.62)	-3.47 (3.33)	(-10.08, 3.14)	0.3001	-0.17 (0.19)	(-0.53, 0.20)	0.3635	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Pain Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=69) N	LSMean (SE)	Placebo (N=75) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
No	15	-10.36 (5.94)	12	-12.12 (5.80)	1.76 (7.35)	(-13.73, 17.25)	0.8137	0.08 (0.39)	(-0.68, 0.84)	0.8398	
SLICC score											0.4497
0	40	-12.77 (2.99)	48	-7.52 (3.03)	-5.26 (3.88)	(-12.97, 2.46)	0.1791	-0.26 (0.22)	(-0.68, 0.16)	0.2271	
>=1	29	-12.37 (4.10)	27	-12.07 (3.80)	-0.31 (5.28)	(-10.93, 10.32)	0.9541	-0.01 (0.27)	(-0.54, 0.51)	0.9572	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SLEDAI-2K Total Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Visit	Anifrolumab 300mg (N=69) n/	N#	Compliance	Placebo (N=75) n/	N#	Compliance
Baseline	69/	69	100.0%	75/	75	100.0%
Week 4	68/	69	98.55%	74/	75	98.67%
Week 8	64/	69	92.75%	70/	75	93.33%
Week 12	65/	69	94.20%	69/	75	92.00%
Week 16	66/	69	95.65%	65/	75	86.67%
Week 20	66/	69	95.65%	66/	75	88.00%
Week 24	63/	69	91.30%	61/	75	81.33%
Week 28	64/	69	92.75%	59/	75	78.67%
Week 32	62/	69	89.86%	59/	75	78.67%
Week 36	61/	69	88.41%	56/	75	74.67%
Week 40	61/	69	88.41%	55/	75	73.33%
Week 44	63/	69	91.30%	52/	75	69.33%
Week 48	61/	69	88.41%	52/	75	69.33%
Week 52	61/	69	88.41%	49/	75	65.33%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - PGA
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)			Placebo (N=75)		
Visit	n/	N#	Compliance	n/	N#	Compliance
Baseline	69/	69	100.0%	75/	75	100.0%
Week 4	68/	69	98.55%	74/	75	98.67%
Week 8	63/	69	91.30%	70/	75	93.33%
Week 12	65/	69	94.20%	69/	75	92.00%
Week 16	66/	69	95.65%	65/	75	86.67%
Week 20	66/	69	95.65%	66/	75	88.00%
Week 24	63/	69	91.30%	61/	75	81.33%
Week 28	64/	69	92.75%	59/	75	78.67%
Week 32	62/	69	89.86%	59/	75	78.67%
Week 36	61/	69	88.41%	56/	75	74.67%
Week 40	61/	69	88.41%	55/	75	73.33%
Week 44	63/	69	91.30%	52/	75	69.33%
Week 48	61/	69	88.41%	52/	75	69.33%
Week 52	61/	69	88.41%	49/	75	65.33%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - CLASI Total Activity Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)			Placebo (N=75)		
Visit	n/	N#	Compliance	n/	N#	Compliance
Baseline	69/	69	100.0%	75/	75	100.0%
Week 4	68/	69	98.55%	74/	75	98.67%
Week 8	64/	69	92.75%	70/	75	93.33%
Week 12	65/	69	94.20%	69/	75	92.00%
Week 16	66/	69	95.65%	65/	75	86.67%
Week 20	66/	69	95.65%	66/	75	88.00%
Week 24	63/	69	91.30%	61/	75	81.33%
Week 28	64/	69	92.75%	59/	75	78.67%
Week 32	62/	69	89.86%	59/	75	78.67%
Week 36	61/	69	88.41%	56/	75	74.67%
Week 40	61/	69	88.41%	55/	75	73.33%
Week 44	63/	69	91.30%	52/	75	69.33%
Week 48	61/	69	88.41%	52/	75	69.33%
Week 52	61/	69	88.41%	49/	75	65.33%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - CLASI Total Damage Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)			Placebo (N=75)		
Visit	n/	N#	Compliance	n/	N#	Compliance
Baseline	69/	69	100.0%	75/	75	100.0%
Week 4	68/	69	98.55%	74/	75	98.67%
Week 8	64/	69	92.75%	70/	75	93.33%
Week 12	65/	69	94.20%	69/	75	92.00%
Week 16	66/	69	95.65%	65/	75	86.67%
Week 20	66/	69	95.65%	66/	75	88.00%
Week 24	63/	69	91.30%	61/	75	81.33%
Week 28	64/	69	92.75%	59/	75	78.67%
Week 32	62/	69	89.86%	59/	75	78.67%
Week 36	61/	69	88.41%	56/	75	74.67%
Week 40	61/	69	88.41%	55/	75	73.33%
Week 44	63/	69	91.30%	52/	75	69.33%
Week 48	61/	69	88.41%	52/	75	69.33%
Week 52	61/	69	88.41%	49/	75	65.33%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - BILAG Global Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)			Placebo (N=75)		
Visit	n/	N#	Compliance	n/	N#	Compliance
Baseline	69/	69	100.0%	75/	75	100.0%
Week 4	69/	69	100.0%	75/	75	100.0%
Week 8	69/	69	100.0%	73/	75	97.33%
Week 12	66/	69	95.65%	71/	75	94.67%
Week 16	66/	69	95.65%	68/	75	90.67%
Week 20	66/	69	95.65%	66/	75	88.00%
Week 24	66/	69	95.65%	63/	75	84.00%
Week 28	66/	69	95.65%	61/	75	81.33%
Week 32	64/	69	92.75%	59/	75	78.67%
Week 36	64/	69	92.75%	56/	75	74.67%
Week 40	64/	69	92.75%	55/	75	73.33%
Week 44	64/	69	92.75%	53/	75	70.67%
Week 48	61/	69	88.41%	53/	75	70.67%
Week 52	61/	69	88.41%	49/	75	65.33%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Tender Joint Count
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Visit	Anifrolumab 300mg (N=69) n/ N#	Compliance	Placebo (N=75) n/ N#	Compliance
Baseline	69/ 69	100.0%	75/ 75	100.0%
Week 4	68/ 69	98.55%	74/ 75	98.67%
Week 8	64/ 69	92.75%	70/ 75	93.33%
Week 12	65/ 69	94.20%	69/ 75	92.00%
Week 16	66/ 69	95.65%	65/ 75	86.67%
Week 20	66/ 69	95.65%	66/ 75	88.00%
Week 24	63/ 69	91.30%	61/ 75	81.33%
Week 28	64/ 69	92.75%	59/ 75	78.67%
Week 32	62/ 69	89.86%	59/ 75	78.67%
Week 36	61/ 69	88.41%	56/ 75	74.67%
Week 40	61/ 69	88.41%	55/ 75	73.33%
Week 44	63/ 69	91.30%	52/ 75	69.33%
Week 48	61/ 69	88.41%	52/ 75	69.33%
Week 52	61/ 69	88.41%	49/ 75	65.33%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Swollen Joint Count
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)			Placebo (N=75)		
Visit	n/	N#	Compliance	n/	N#	Compliance
Baseline	69/	69	100.0%	75/	75	100.0%
Week 4	68/	69	98.55%	74/	75	98.67%
Week 8	64/	69	92.75%	70/	75	93.33%
Week 12	65/	69	94.20%	69/	75	92.00%
Week 16	66/	69	95.65%	65/	75	86.67%
Week 20	66/	69	95.65%	66/	75	88.00%
Week 24	63/	69	91.30%	61/	75	81.33%
Week 28	64/	69	92.75%	59/	75	78.67%
Week 32	62/	69	89.86%	59/	75	78.67%
Week 36	61/	69	88.41%	56/	75	74.67%
Week 40	61/	69	88.41%	55/	75	73.33%
Week 44	63/	69	91.30%	52/	75	69.33%
Week 48	61/	69	88.41%	52/	75	69.33%
Week 52	61/	69	88.41%	49/	75	65.33%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute Mental Component Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Visit	Anifrolumab 300mg (N=69) n/ N#	Compliance	Placebo (N=75) n/ N#	Compliance
Baseline	69/ 69	100.0%	75/ 75	100.0%
Week 4	68/ 69	98.55%	73/ 75	97.33%
Week 12	66/ 69	95.65%	71/ 75	94.67%
Week 24	65/ 69	94.20%	64/ 75	85.33%
Week 36	62/ 69	89.86%	55/ 75	73.33%
Week 52	62/ 69	89.86%	50/ 75	66.67%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute Physical Component Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)			Placebo (N=75)		
Visit	n/	N#	Compliance	n/	N#	Compliance
Baseline	69/	69	100.0%	75/	75	100.0%
Week 4	68/	69	98.55%	73/	75	97.33%
Week 12	66/	69	95.65%	71/	75	94.67%
Week 24	65/	69	94.20%	64/	75	85.33%
Week 36	62/	69	89.86%	55/	75	73.33%
Week 52	62/	69	89.86%	50/	75	66.67%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute General Health Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)			Placebo (N=75)		
Visit	n/	N#	Compliance	n/	N#	Compliance
Baseline	69/	69	100.0%	75/	75	100.0%
Week 4	68/	69	98.55%	73/	75	97.33%
Week 12	66/	69	95.65%	71/	75	94.67%
Week 24	65/	69	94.20%	64/	75	85.33%
Week 36	62/	69	89.86%	55/	75	73.33%
Week 52	62/	69	89.86%	50/	75	66.67%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute Mental Health Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Visit	Anifrolumab 300mg (N=69) n/ N#	Compliance	Placebo (N=75) n/ N#	Compliance
Baseline	69/ 69	100.0%	75/ 75	100.0%
Week 4	68/ 69	98.55%	73/ 75	97.33%
Week 12	66/ 69	95.65%	71/ 75	94.67%
Week 24	65/ 69	94.20%	64/ 75	85.33%
Week 36	62/ 69	89.86%	55/ 75	73.33%
Week 52	62/ 69	89.86%	50/ 75	66.67%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute Physical Functioning Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)			Placebo (N=75)		
Visit	n/	N#	Compliance	n/	N#	Compliance
Baseline	69/	69	100.0%	75/	75	100.0%
Week 4	68/	69	98.55%	73/	75	97.33%
Week 12	66/	69	95.65%	71/	75	94.67%
Week 24	65/	69	94.20%	64/	75	85.33%
Week 36	62/	69	89.86%	55/	75	73.33%
Week 52	62/	69	89.86%	50/	75	66.67%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute Role Emotional Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)			Placebo (N=75)		
Visit	n/	N#	Compliance	n/	N#	Compliance
Baseline	69/	69	100.0%	75/	75	100.0%
Week 4	68/	69	98.55%	73/	75	97.33%
Week 12	66/	69	95.65%	71/	75	94.67%
Week 24	65/	69	94.20%	64/	75	85.33%
Week 36	62/	69	89.86%	55/	75	73.33%
Week 52	62/	69	89.86%	50/	75	66.67%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute Role Physical Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Visit	Anifrolumab 300mg (N=69) n/ N#	Compliance	Placebo (N=75) n/ N#	Compliance
Baseline	69/ 69	100.0%	75/ 75	100.0%
Week 4	68/ 69	98.55%	73/ 75	97.33%
Week 12	66/ 69	95.65%	71/ 75	94.67%
Week 24	65/ 69	94.20%	64/ 75	85.33%
Week 36	62/ 69	89.86%	55/ 75	73.33%
Week 52	62/ 69	89.86%	50/ 75	66.67%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute Social Functioning Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)			Placebo (N=75)		
Visit	n/	N#	Compliance	n/	N#	Compliance
Baseline	69/	69	100.0%	75/	75	100.0%
Week 4	68/	69	98.55%	73/	75	97.33%
Week 12	66/	69	95.65%	71/	75	94.67%
Week 24	65/	69	94.20%	64/	75	85.33%
Week 36	62/	69	89.86%	55/	75	73.33%
Week 52	62/	69	89.86%	50/	75	66.67%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute Bodily Pain Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)			Placebo (N=75)		
Visit	n/	N#	Compliance	n/	N#	Compliance
Baseline	69/	69	100.0%	75/	75	100.0%
Week 4	68/	69	98.55%	73/	75	97.33%
Week 12	66/	69	95.65%	71/	75	94.67%
Week 24	65/	69	94.20%	64/	75	85.33%
Week 36	62/	69	89.86%	55/	75	73.33%
Week 52	62/	69	89.86%	50/	75	66.67%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute Vitality Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)			Placebo (N=75)		
Visit	n/	N#	Compliance	n/	N#	Compliance
Baseline	69/	69	100.0%	75/	75	100.0%
Week 4	68/	69	98.55%	73/	75	97.33%
Week 12	66/	69	95.65%	71/	75	94.67%
Week 24	65/	69	94.20%	64/	75	85.33%
Week 36	62/	69	89.86%	55/	75	73.33%
Week 52	62/	69	89.86%	50/	75	66.67%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - FACIT-F Total Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Visit	Anifrolumab 300mg (N=69) n/	N#	Compliance	Placebo (N=75) n/	N#	Compliance
Baseline	69/	69	100.0%	75/	75	100.0%
Week 4	68/	69	98.55%	73/	75	97.33%
Week 12	66/	69	95.65%	70/	75	93.33%
Week 24	65/	69	94.20%	64/	75	85.33%
Week 36	62/	69	89.86%	56/	75	74.67%
Week 52	62/	69	89.86%	50/	75	66.67%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - EQ VAS Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Visit	Anifrolumab 300mg (N=69) n/	N#	Compliance	Placebo (N=75) n/	N#	Compliance
Baseline	68/	69	98.55%	75/	75	100.0%
Week 4	68/	69	98.55%	73/	75	97.33%
Week 12	66/	69	95.65%	71/	75	94.67%
Week 24	65/	69	94.20%	64/	75	85.33%
Week 36	62/	69	89.86%	56/	75	74.67%
Week 52	62/	69	89.86%	50/	75	66.67%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Lupus QoL Physical Health domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)			Placebo (N=75)		
Visit	n/	N#	Compliance	n/	N#	Compliance
Baseline	68/	69	98.55%	74/	75	98.67%
Week 4	67/	69	97.10%	72/	75	96.00%
Week 12	66/	69	95.65%	71/	75	94.67%
Week 24	65/	69	94.20%	64/	75	85.33%
Week 36	62/	69	89.86%	56/	75	74.67%
Week 52	62/	69	89.86%	50/	75	66.67%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Lupus QoL Emotional Health domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)			Placebo (N=75)		
Visit	n/	N#	Compliance	n/	N#	Compliance
Baseline	68/	69	98.55%	74/	75	98.67%
Week 4	67/	69	97.10%	72/	75	96.00%
Week 12	66/	69	95.65%	71/	75	94.67%
Week 24	65/	69	94.20%	64/	75	85.33%
Week 36	62/	69	89.86%	56/	75	74.67%
Week 52	62/	69	89.86%	50/	75	66.67%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Lupus QoL Body Image domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Visit	Anifrolumab 300mg (N=69) n/	N#	Compliance	Placebo (N=75) n/	N#	Compliance
Baseline	66/	69	95.65%	66/	75	88.00%
Week 4	65/	69	94.20%	63/	75	84.00%
Week 12	65/	69	94.20%	65/	75	86.67%
Week 24	59/	69	85.51%	58/	75	77.33%
Week 36	59/	69	85.51%	45/	75	60.00%
Week 52	57/	69	82.61%	39/	75	52.00%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Lupus QoL Burden to Others domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Visit	Anifrolumab 300mg (N=69) n/	N#	Compliance	Placebo (N=75) n/	N#	Compliance
Baseline	68/	69	98.55%	74/	75	98.67%
Week 4	67/	69	97.10%	72/	75	96.00%
Week 12	66/	69	95.65%	71/	75	94.67%
Week 24	65/	69	94.20%	64/	75	85.33%
Week 36	62/	69	89.86%	56/	75	74.67%
Week 52	62/	69	89.86%	50/	75	66.67%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Lupus QoL Fatigue domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)			Placebo (N=75)		
Visit	n/	N#	Compliance	n/	N#	Compliance
Baseline	68/	69	98.55%	74/	75	98.67%
Week 4	67/	69	97.10%	72/	75	96.00%
Week 12	66/	69	95.65%	71/	75	94.67%
Week 24	65/	69	94.20%	64/	75	85.33%
Week 36	62/	69	89.86%	56/	75	74.67%
Week 52	62/	69	89.86%	50/	75	66.67%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Lupus QoL Intimate Relationships domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)			Placebo (N=75)		
Visit	n/	N#	Compliance	n/	N#	Compliance
Baseline	60/	69	86.96%	60/	75	80.00%
Week 4	59/	69	85.51%	54/	75	72.00%
Week 12	57/	69	82.61%	59/	75	78.67%
Week 24	54/	69	78.26%	51/	75	68.00%
Week 36	47/	69	68.12%	37/	75	49.33%
Week 52	47/	69	68.12%	33/	75	44.00%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Lupus QoL Pain domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)			Placebo (N=75)		
Visit	n/	N#	Compliance	n/	N#	Compliance
Baseline	68/	69	98.55%	74/	75	98.67%
Week 4	67/	69	97.10%	72/	75	96.00%
Week 12	66/	69	95.65%	71/	75	94.67%
Week 24	65/	69	94.20%	64/	75	85.33%
Week 36	62/	69	89.86%	56/	75	74.67%
Week 52	62/	69	89.86%	50/	75	66.67%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Lupus QoL Planning domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)			Placebo (N=75)		
Visit	n/	N#	Compliance	n/	N#	Compliance
Baseline	68/	69	98.55%	74/	75	98.67%
Week 4	67/	69	97.10%	72/	75	96.00%
Week 12	66/	69	95.65%	71/	75	94.67%
Week 24	65/	69	94.20%	64/	75	85.33%
Week 36	62/	69	89.86%	56/	75	74.67%
Week 52	62/	69	89.86%	50/	75	66.67%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SDI Global Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Visit	Anifrolumab 300mg (N=69) n/	N#	Compliance	Placebo (N=75) n/	N#	Compliance
Baseline	69/	69	100.0%	75/	75	100.0%
Week 24	65/	69	94.20%	64/	75	85.33%
Week 52	61/	69	88.41%	50/	75	66.67%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - PtGA
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)			Placebo (N=75)		
Visit	n/	N#	Compliance	n/	N#	Compliance
Baseline	69/	69	100.0%	75/	75	100.0%
Week 4	68/	69	98.55%	74/	75	98.67%
Week 8	64/	69	92.75%	69/	75	92.00%
Week 12	65/	69	94.20%	69/	75	92.00%
Week 16	66/	69	95.65%	65/	75	86.67%
Week 20	65/	69	94.20%	66/	75	88.00%
Week 24	63/	69	91.30%	61/	75	81.33%
Week 28	64/	69	92.75%	59/	75	78.67%
Week 32	62/	69	89.86%	59/	75	78.67%
Week 36	61/	69	88.41%	56/	75	74.67%
Week 40	61/	69	88.41%	55/	75	73.33%
Week 44	63/	69	91.30%	52/	75	69.33%
Week 48	61/	69	88.41%	52/	75	69.33%
Week 52	61/	69	88.41%	49/	75	65.33%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Total HAQ Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Visit	Anifrolumab 300mg (N=69) n/	N#	Compliance	Placebo (N=75) n/	N#	Compliance
Baseline	69/	69	100.0%	75/	75	100.0%
Week 4	68/	69	98.55%	73/	75	97.33%
Week 12	66/	69	95.65%	71/	75	94.67%
Week 24	65/	69	94.20%	64/	75	85.33%
Week 36	62/	69	89.86%	56/	75	74.67%
Week 52	62/	69	89.86%	50/	75	66.67%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Pain Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)			Placebo (N=75)		
Visit	n/	N#	Compliance	n/	N#	Compliance
Baseline	69/	69	100.0%	75/	75	100.0%
Week 4	68/	69	98.55%	73/	75	97.33%
Week 12	66/	69	95.65%	71/	75	94.67%
Week 24	65/	69	94.20%	64/	75	85.33%
Week 36	62/	69	89.86%	56/	75	74.67%
Week 52	62/	69	89.86%	50/	75	66.67%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Flare rate through Week 52
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=69) Number of flares	Anifrolumab 300mg (N=69) Total Follow-up time (years)	Anifrolumab 300mg (N=69) Annual rate (SE)	Placebo (N=75) Number of flares	Placebo (N=75) Total Follow-up time (years)	Placebo (N=75) Annual rate (SE)	Rate ratio (95% CI)	p-Value	Interaction p-Value
Overall	34	65.70	0.43 (0.26)	41	62.14	0.57 (0.27)	0.75 (0.40, 1.40)	0.3633	
SLEDAI-2K score									0.7222
< 10 points	14	27.95	0.48 (0.37)	17	28.44	0.64 (0.36)	0.76 (0.29, 2.00)	0.5794	
>= 10 points	20	37.75	0.20 (0.58)	24	33.70	0.30 (0.57)	0.68 (0.30, 1.54)	0.3547	
OCS dose									0.5645
<10 mg/day	18	30.90	0.54 (0.36)	15	22.60	0.61 (0.41)	0.90 (0.33, 2.42)	0.8315	
>=10 mg/day	16	34.80	0.25 (0.48)	26	39.54	0.40 (0.44)	0.64 (0.29, 1.44)	0.2791	
Result of type I IFN gene signature test									0.0322
LOW	8	14.05	NE	2	15.18	NE	NE		
HIGH	26	51.65	0.47 (0.26)	39	46.97	0.86 (0.24)	0.55 (0.28, 1.09)	0.0858	
Age (years)									0.5983
<= 45	24	43.70	0.45 (0.33)	26	42.01	0.56 (0.34)	0.79 (0.37, 1.68)	0.5421	
> 45	10	22.00	0.32 (0.48)	15	20.13	0.62 (0.45)	0.52 (0.17, 1.64)	0.2656	
Sex									0.8074
male	2	4.11	0.00 (151138.70)	4	5.82	0.00 (151138.70)	0.71 (0.10, 5.30)	0.7405	
female	32	61.59	0.43 (0.27)	37	56.32	0.57 (0.28)	0.76 (0.39, 1.46)	0.4050	
Race									0.3798
White	13	23.68	0.52 (0.36)	17	26.73	0.54 (0.36)	0.96 (0.38, 2.47)	0.9372	
Black	8	15.39	NE	10	7.03	NE	NE		
Other	13	26.63	0.40 (0.46)	14	28.38	0.42 (0.50)	0.97 (0.34, 2.78)	0.9513	
Ethnicity									0.2599
Hispanic/Latino	17	26.67	0.63 (0.40)	12	23.62	0.51 (0.49)	1.24 (0.41, 3.76)	0.7097	
Non-hispanic/Latino	17	39.03	0.26 (0.38)	29	38.52	0.51 (0.33)	0.52 (0.24, 1.12)	0.0945	
Geographic region									0.8637
Latin America, Eastern Europe and Asia	21	43.00	0.39 (0.36)	29	46.08	0.53 (0.39)	0.75 (0.35, 1.60)	0.4537	
North America	13	22.70	0.38 (0.49)	12	16.06	0.65 (0.44)	0.59 (0.17, 1.96)	0.3851	
Baseline weight									0.2637
<60 kg	8	17.52	0.41 (0.44)	22	24.17	0.93 (0.36)	0.45 (0.15, 1.30)	0.1383	
>=60 kg	26	48.18	0.37 (0.36)	19	37.97	0.34 (0.39)	1.06 (0.48, 2.38)	0.8793	
Low CH50									0.6942
Yes	6	7.32	0.80 (0.47)	9	8.55	1.18 (0.64)	0.67 (0.14, 3.31)	0.6273	
No	28	58.38	0.42 (0.29)	32	53.59	0.52 (0.30)	0.80 (0.39, 1.67)	0.5561	
Low C3 or C4									0.4533
Yes	15	22.67	0.00 (54696.67)	25	25.56	0.00 (54696.67)	0.58 (0.24, 1.38)	0.2182	
No	19	43.04	0.37 (0.32)	16	36.59	0.41 (0.35)	0.90 (0.38, 2.14)	0.8085	
Baseline FARR anti-dsDNA									0.1608
<5 IU/mL	10	14.31	0.64 (0.47)	2	9.03	0.15 (0.79)	4.34 (0.78, 24.27)	0.0949	
>=5 IU/mL	16	38.26	0.32 (0.39)	29	42.05	0.53 (0.36)	0.60 (0.27, 1.35)	0.2142	
Low complement (C3 or C4) and positive FARR anti-dsDNA									0.3830
Yes	26	47.26	0.36 (0.37)	37	49.20	0.53 (0.36)	0.68 (0.33, 1.38)	0.2853	
No	8	18.45	0.35 (0.44)	4	12.94	0.20 (0.61)	1.79 (0.53, 6.11)	0.3508	
OCS use									0.7298

Rates and rate ratio from negative binomial regression model with factors for treatment group and the stratification factors. The logarithm (to base e) of the follow-up time is used as an offset variable in the model to adjust for subjects having different exposure times.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Flare rate through Week 52
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)			Placebo (N=75)					
Subgroup Level	Number of flares	Total Follow-up time (years)	Annual rate (SE)	Number of flares	Total Follow-up time (years)	Annual rate (SE)	Rate ratio (95% CI)	p-Value	Interaction p-Value
Yes	28	52.19	0.37 (0.32)	31	51.43	0.46 (0.33)	0.80 (0.41, 1.59)	0.5285	
No	6	13.52	0.47 (0.70)	10	10.71	1.03 (0.68)	0.46 (0.07, 3.01)	0.4143	
SLICC score									0.2387
0	22	39.27	0.46 (0.33)	22	39.34	0.51 (0.36)	0.90 (0.40, 2.03)	0.8049	
>=1	12	26.43	0.33 (0.45)	19	22.80	0.76 (0.41)	0.43 (0.15, 1.24)	0.1197	

Rates and rate ratio from negative binomial regression model with factors for treatment group and the stratification factors. The logarithm (to base e) of the follow-up time is used as an offset variable in the model to adjust for subjects having different exposure times.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Overall Survival
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)	Placebo (N=75)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	69 (100.0)	75 (100.0)
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Anifrolumab 300mg vs. Placebo (adjusted)		
Hazard Ratio (95% CI)	NE	
p-value		
Analysis Anifrolumab 300mg vs. Placebo (unadjusted)		
Hazard Ratio (95% CI)	NE	
p-value		

Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model. Adjusted analysis also includes stratification factors in the model.
Two-sided log rank test used.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Overall Survival - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Anifrolumab 300mg (N=69) Median (95% CI)	Placebo (N=75) n/ N (%)	Placebo (N=75) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score							NE
< 10 points	0/ 29 (0.0)	NE (NE, NE)	0/ 32 (0.0)	NE (NE, NE)	NE		
>= 10 points	0/ 40 (0.0)	NE (NE, NE)	0/ 43 (0.0)	NE (NE, NE)	NE		
OCS dose							NE
<10 mg/day	0/ 33 (0.0)	NE (NE, NE)	0/ 28 (0.0)	NE (NE, NE)	NE		
>=10 mg/day	0/ 36 (0.0)	NE (NE, NE)	0/ 47 (0.0)	NE (NE, NE)	NE		
Result of type I IFN gene signature test							NE
LOW	0/ 14 (0.0)	NE (NE, NE)	0/ 19 (0.0)	NE (NE, NE)	NE		
HIGH	0/ 55 (0.0)	NE (NE, NE)	0/ 56 (0.0)	NE (NE, NE)	NE		
Age (years)							NE
<= 45	0/ 45 (0.0)	NE (NE, NE)	0/ 50 (0.0)	NE (NE, NE)	NE		
> 45	0/ 24 (0.0)	NE (NE, NE)	0/ 25 (0.0)	NE (NE, NE)	NE		
Sex							NE
male	0/ 4 (0.0)	NE (NE, NE)	0/ 6 (0.0)	NE (NE, NE)	NE		
female	0/ 65 (0.0)	NE (NE, NE)	0/ 69 (0.0)	NE (NE, NE)	NE		
Race							NE
White	0/ 25 (0.0)	NE (NE, NE)	0/ 31 (0.0)	NE (NE, NE)	NE		
Black	0/ 16 (0.0)	NE (NE, NE)	0/ 8 (0.0)	NE (NE, NE)	NE		
Other	0/ 28 (0.0)	NE (NE, NE)	0/ 36 (0.0)	NE (NE, NE)	NE		
Ethnicity							NE
Hispanic/Latino	0/ 28 (0.0)	NE (NE, NE)	0/ 28 (0.0)	NE (NE, NE)	NE		
Non-hispanic/Latino	0/ 41 (0.0)	NE (NE, NE)	0/ 47 (0.0)	NE (NE, NE)	NE		
Geographic region							NE
Latin America, Eastern Europe and Asia	0/ 45 (0.0)	NE (NE, NE)	0/ 55 (0.0)	NE (NE, NE)	NE		
North America	0/ 24 (0.0)	NE (NE, NE)	0/ 20 (0.0)	NE (NE, NE)	NE		
Baseline weight							NE
<60 kg	0/ 18 (0.0)	NE (NE, NE)	0/ 31 (0.0)	NE (NE, NE)	NE		
>=60 kg	0/ 51 (0.0)	NE (NE, NE)	0/ 44 (0.0)	NE (NE, NE)	NE		
Low CH50							NE
Yes	0/ 9 (0.0)	NE (NE, NE)	0/ 10 (0.0)	NE (NE, NE)	NE		
No	0/ 60 (0.0)	NE (NE, NE)	0/ 65 (0.0)	NE (NE, NE)	NE		
Low C3 or C4							NE
Yes	0/ 25 (0.0)	NE (NE, NE)	0/ 33 (0.0)	NE (NE, NE)	NE		
No	0/ 44 (0.0)	NE (NE, NE)	0/ 42 (0.0)	NE (NE, NE)	NE		
Baseline FARR anti-dsDNA							NE
<5 IU/mL	0/ 15 (0.0)	NE (NE, NE)	0/ 11 (0.0)	NE (NE, NE)	NE		
>=5 IU/mL	0/ 40 (0.0)	NE (NE, NE)	0/ 50 (0.0)	NE (NE, NE)	NE		
Low complement (C3 or C4) and positive FARR anti-dsDNA							NE
Yes	0/ 50 (0.0)	NE (NE, NE)	0/ 60 (0.0)	NE (NE, NE)	NE		
No	0/ 19 (0.0)	NE (NE, NE)	0/ 15 (0.0)	NE (NE, NE)	NE		
OCS use							NE
Yes	0/ 54 (0.0)	NE (NE, NE)	0/ 63 (0.0)	NE (NE, NE)	NE		
No	0/ 15 (0.0)	NE (NE, NE)	0/ 12 (0.0)	NE (NE, NE)	NE		

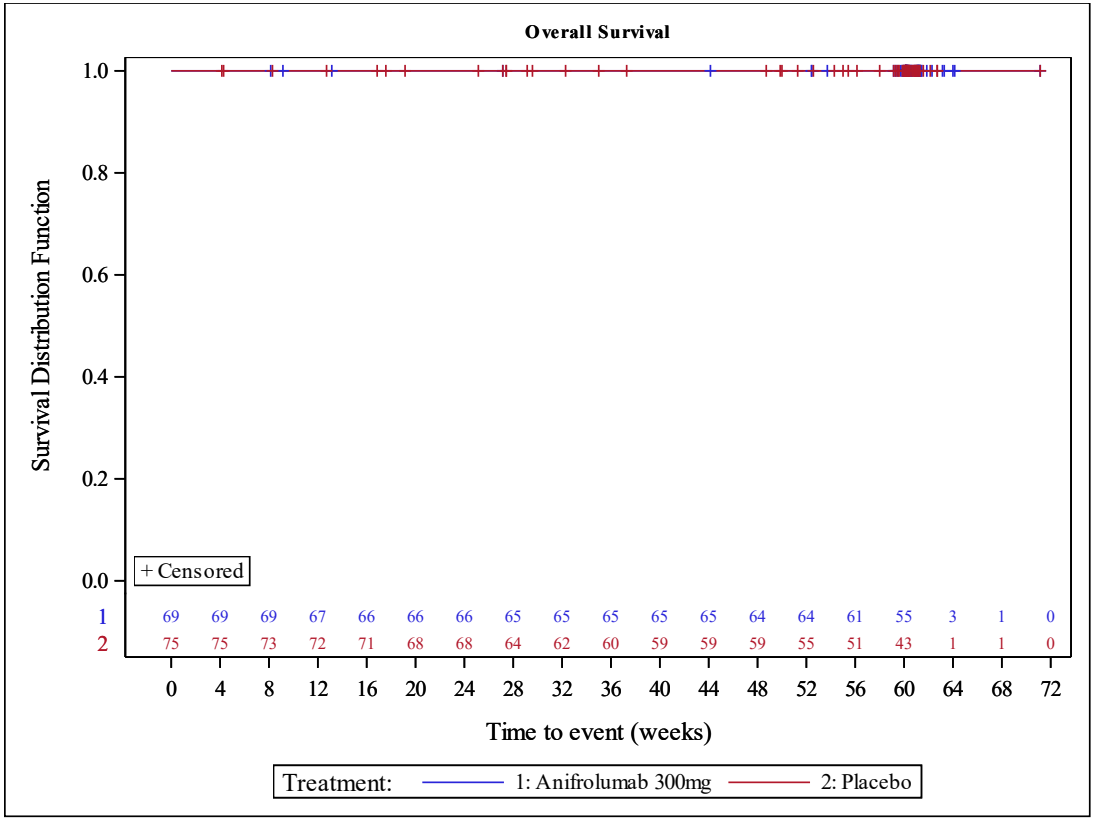
Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Overall Survival - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Anifrolumab 300mg (N=69) Median (95% CI)	Placebo (N=75) n/ N (%)	Placebo (N=75) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLICC score							NE
0	0/ 40 (0.0)	NE (NE, NE)	0/ 48 (0.0)	NE (NE, NE)	NE		
>=1	0/ 29 (0.0)	NE (NE, NE)	0/ 27 (0.0)	NE (NE, NE)	NE		

Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of Overall Survival
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Time to first Flare
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=69)	Placebo (N=75)
Number of subjects with events, n (%)	20 (29.0)	25 (33.3)
Number of censored subjects, n (%)	49 (71.0)	50 (66.7)
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	32.00 (16.00, NE)	24.14 (17.14, 40.14)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Anifrolumab 300mg vs. Placebo (adjusted)		
Hazard Ratio (95% CI)	0.79 (0.43, 1.43)	
p-value	0.5064	
Analysis Anifrolumab 300mg vs. Placebo (unadjusted)		
Hazard Ratio (95% CI)	0.82 (0.46, 1.48)	
p-value	0.5112	

Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model. Adjusted analysis also includes stratification factors in the model.
Two-sided log rank test used.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Time to first Flare - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	 Median (95% CI)	Placebo (N=75) n/ N (%)	 Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	 p-Value	Interaction p-Value
SLEDAI-2K score							0.8855
< 10 points	8/ 29 (27.6)	NE (NE, NE)	11/ 32 (34.4)	NE (33.14, NE)	0.81 (0.32, 2.05)	0.5995	
>= 10 points	12/ 40 (30.0)	NE (NE, NE)	14/ 43 (32.6)	NE (28.00, NE)	0.81 (0.37, 1.76)	0.6697	
OCS dose							0.5815
<10 mg/day	10/ 33 (30.3)	NE (39.57, NE)	8/ 28 (28.6)	NE (40.14, NE)	1.06 (0.41, 2.75)	0.9009	
>=10 mg/day	10/ 36 (27.8)	NE (NE, NE)	17/ 47 (36.2)	NE (33.14, NE)	0.68 (0.31, 1.49)	0.3406	
Result of type I IFN gene signature test							0.0527
LOW	5/ 14 (35.7)	NE (16.00, NE)	2/ 19 (10.5)	NE (NE, NE)	3.53 (0.68, 18.28)	0.1188	
HIGH	15/ 55 (27.3)	NE (NE, NE)	23/ 56 (41.1)	NE (30.00, NE)	0.61 (0.31, 1.17)	0.1641	
Age (years)							0.5532
<= 45	13/ 45 (28.9)	NE (NE, NE)	18/ 50 (36.0)	NE (33.14, NE)	0.65 (0.32, 1.35)	0.3077	
> 45	7/ 24 (29.2)	NE (35.29, NE)	7/ 25 (28.0)	NE (24.14, NE)	0.89 (0.31, 2.58)	0.8747	
Sex							0.3735
male	2/ 4 (50.0)	NE (4.14, NE)	2/ 6 (33.3)	NE (8.14, NE)	NE		
female	18/ 65 (27.7)	NE (NE, NE)	23/ 69 (33.3)	NE (40.14, NE)	0.73 (0.39, 1.36)	0.3126	
Race							0.5978
White	8/ 25 (32.0)	NE (35.29, NE)	10/ 31 (32.3)	NE (30.00, NE)	0.96 (0.37, 2.45)	0.7006	
Black	5/ 16 (31.3)	NE (24.14, NE)	4/ 8 (50.0)	33.14 (8.14, NE)	0.18 (0.04, 0.82)	0.1030	
Other	7/ 28 (25.0)	NE (NE, NE)	11/ 36 (30.6)	NE (31.43, NE)	0.84 (0.32, 2.20)	0.8938	
Ethnicity							0.3737
Hispanic/Latino	9/ 28 (32.1)	NE (16.29, NE)	9/ 28 (32.1)	NE (31.43, NE)	1.11 (0.43, 2.87)	0.7301	
Non-hispanic/Latino	11/ 41 (26.8)	NE (NE, NE)	16/ 47 (34.0)	NE (33.14, NE)	0.55 (0.25, 1.20)	0.2221	
Geographic region							0.7770
Latin America, Eastern Europe and Asia	13/ 45 (28.9)	NE (NE, NE)	19/ 55 (34.5)	NE (37.00, NE)	0.75 (0.37, 1.56)	0.5436	
North America	7/ 24 (29.2)	NE (24.14, NE)	6/ 20 (30.0)	NE (33.14, NE)	0.45 (0.13, 1.59)	0.3696	
Baseline weight							0.0444
<60 kg	4/ 18 (22.2)	NE (NE, NE)	15/ 31 (48.4)	37.00 (20.14, NE)	0.36 (0.12, 1.11)	0.0730	
>=60 kg	16/ 51 (31.4)	NE (NE, NE)	10/ 44 (22.7)	NE (NE, NE)	1.38 (0.62, 3.08)	0.3966	
Low CH50							0.6958
Yes	4/ 9 (44.4)	16.29 (4.14, NE)	6/ 10 (60.0)	26.07 (8.14, NE)	7.38 (0.90, 60.74)	0.0046	
No	16/ 60 (26.7)	NE (NE, NE)	19/ 65 (29.2)	NE (NE, NE)	0.81 (0.41, 1.59)	0.5345	
Low C3 or C4							0.6009
Yes	8/ 25 (32.0)	NE (16.29, NE)	14/ 33 (42.4)	NE (22.14, NE)	0.72 (0.30, 1.71)	0.4592	
No	12/ 44 (27.3)	NE (NE, NE)	11/ 42 (26.2)	NE (NE, NE)	0.95 (0.41, 2.21)	0.9474	
Baseline FARR anti-dsDNA							0.2657
<5 IU/mL	6/ 15 (40.0)	NE (16.00, NE)	2/ 11 (18.2)	NE (21.14, NE)	3.61 (0.56, 23.39)	0.1098	
>=5 IU/mL	10/ 40 (25.0)	NE (NE, NE)	16/ 50 (32.0)	NE (33.14, NE)	0.68 (0.31, 1.50)	0.4455	
Low complement (C3 or C4) and positive FARR anti-dsDNA							0.4874
Yes	14/ 50 (28.0)	NE (NE, NE)	21/ 60 (35.0)	NE (37.00, NE)	0.71 (0.36, 1.40)	0.3826	
No	6/ 19 (31.6)	NE (24.14, NE)	4/ 15 (26.7)	NE (31.43, NE)	1.73 (0.47, 6.37)	0.4906	
OCS use							0.5253
Yes	17/ 54 (31.5)	NE (NE, NE)	21/ 63 (33.3)	NE (37.00, NE)	0.86 (0.45, 1.64)	0.7640	
No	3/ 15 (20.0)	NE (39.57, NE)	4/ 12 (33.3)	NE (16.14, NE)	0.58 (0.12, 2.72)	0.4779	

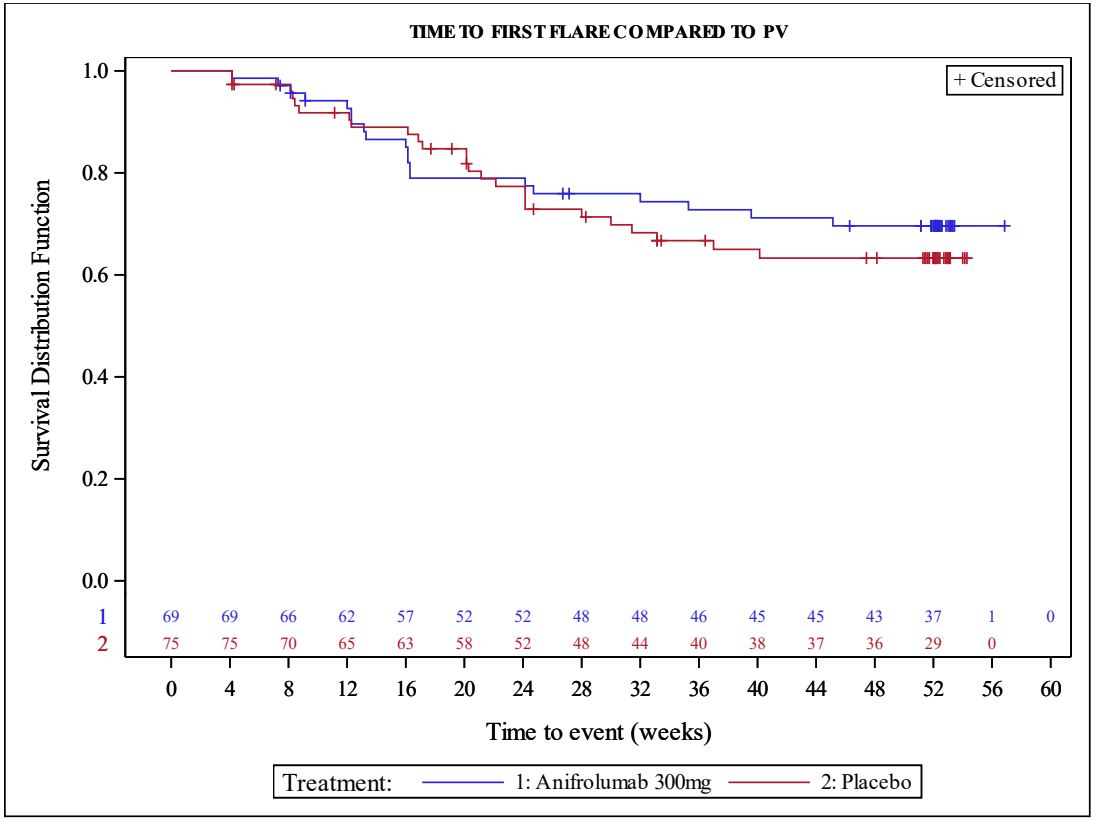
Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Time to first Flare - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Anifrolumab 300mg (N=69) Median (95% CI)	Placebo (N=75) n/ N (%)	Placebo (N=75) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLICC score							0.6092
0	12/ 40 (30.0)	NE (NE, NE)	16/ 48 (33.3)	NE (37.00, NE)	0.85 (0.40, 1.82)	0.8456	
>=1	8/ 29 (27.6)	NE (45.14, NE)	9/ 27 (33.3)	NE (20.14, NE)	0.65 (0.24, 1.74)	0.4640	

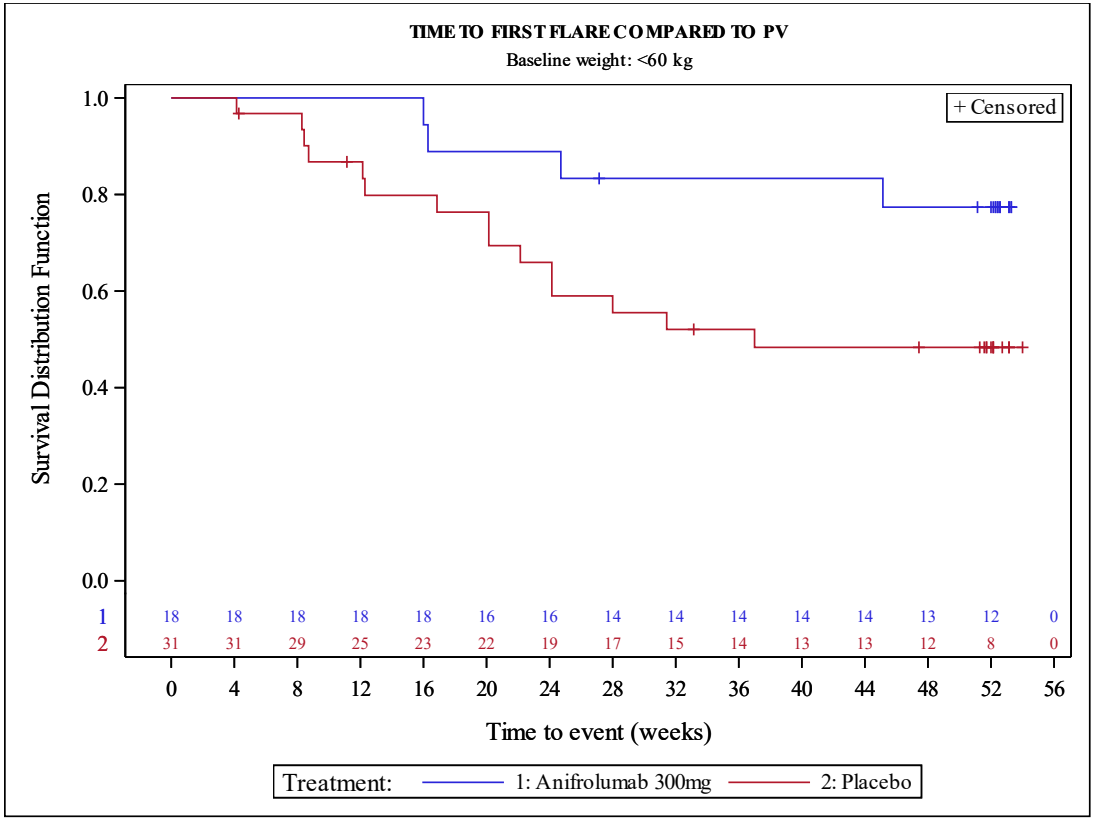
Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of Time to first Flare
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)



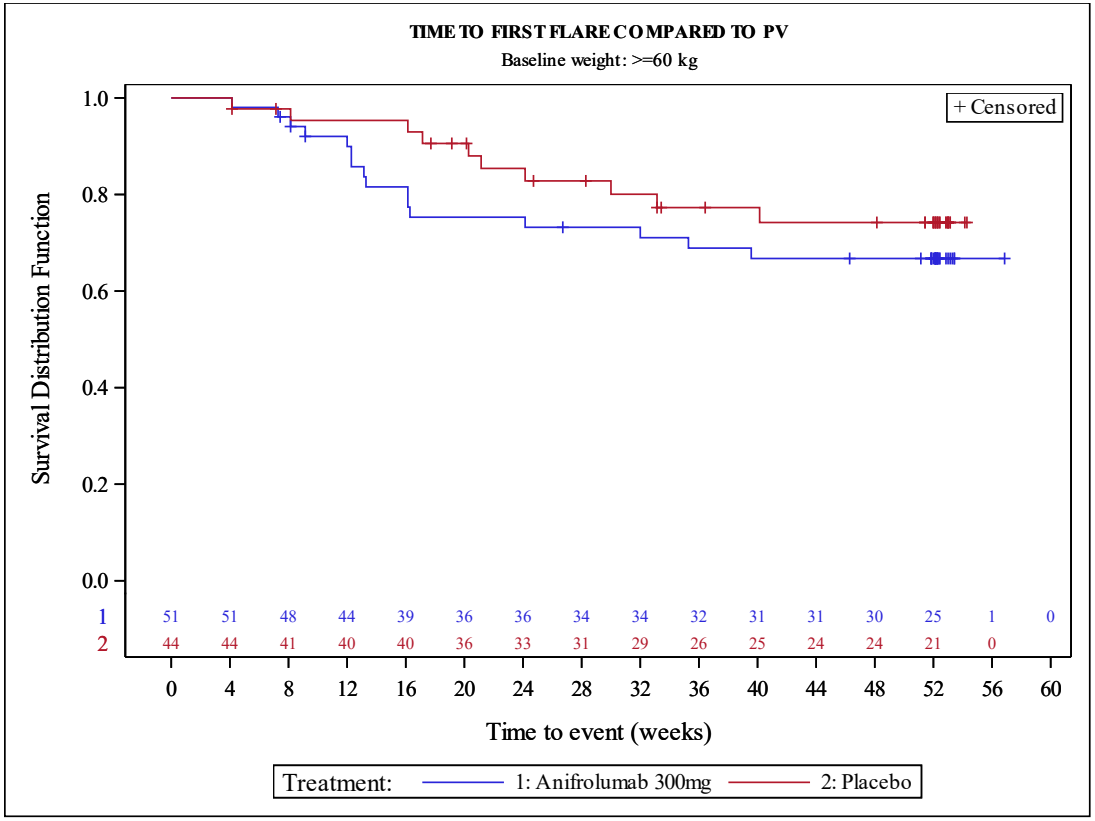
Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of Time to first Flare
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of Time to first Flare
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
OCS dose increases and cumulative OCS dose until week 52
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

		Anifrolumab 300mg (N=69)	Placebo (N=75)	Total (N=144)
Number of dose increases (%)	0	54 (78.3)	58 (77.3)	112 (77.8)
	1	10 (14.5)	12 (16.0)	22 (15.3)
	2	3 (4.3)	3 (4.0)	6 (4.2)
	>2	2 (2.9)	2 (2.7)	4 (2.8)
Cumulative OCS Dose (mg/day)	n (missing)	61 (8)	66 (9)	127 (17)
	Mean (SD)	2944.1 (1803.60)	3457.2 (2479.35)	3210.8 (2187.79)
	Median	2720.0	2990.0	2785.0
	Min, Max	84, 7480	100, 10581	84, 10581
AUC up to Week 52 (mg/day)	n (missing)	61 (8)	66 (9)	127 (17)
	Mean (SD)	3417.7 (2320.66)	4275.5 (3605.43)	3863.5 (3074.99)
	Median	2800.0	3449.6	3003.0
	Min, Max	130, 12858	141, 21809	130, 21809

Subjects without any documented dose value regarded as missing values for calculation of cumulative dose and AUC.
AUC defines the cumulative dose normalized for a period of 52 weeks.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event
Safety analysis set

	Anifrolumab 300mg (N=69)	Placebo (N=75)
Number of subjects with events, n (%)	59 (85.5)	59 (78.7)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.09 (0.93, 1.27)	
p-value	0.2846	
Odds Ratio (95% CI)	1.60 (0.67, 3.81)	
p-value	0.2889	
Risk Difference (95% CI)	6.84 (-5.61, 19.29)	
p-value	0.2814	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.3076
< 10 points	25/ 29 (86.2)	23/ 32 (71.9)	1.20 (0.92, 1.56)	0.1723	
>= 10 points	34/ 40 (85.0)	36/ 43 (83.7)	1.02 (0.84, 1.22)	0.8726	
OCS dose					0.0213
<10 mg/day	25/ 33 (75.8)	24/ 28 (85.7)	0.88 (0.69, 1.13)	0.3236	
>=10 mg/day	34/ 36 (94.4)	35/ 47 (74.5)	1.27 (1.05, 1.53)	0.0119	
Result of type I IFN gene signature test					0.1959
LOW	14/ 14 (100.0)	15/ 19 (78.9)	1.27 (1.00, 1.60)	0.0460	
HIGH	45/ 55 (81.8)	44/ 56 (78.6)	1.04 (0.87, 1.25)	0.6680	
Age (years)					0.5813
<= 45	36/ 45 (80.0)	38/ 50 (76.0)	1.05 (0.85, 1.30)	0.6378	
> 45	23/ 24 (95.8)	21/ 25 (84.0)	1.14 (0.94, 1.38)	0.1747	
Sex					0.1171
male	4/ 4 (100.0)	3/ 6 (50.0)	2.00 (0.90, 4.45)	0.0895	
female	55/ 65 (84.6)	56/ 69 (81.2)	1.04 (0.89, 1.22)	0.5952	
Race					0.5219
White	22/ 25 (88.0)	26/ 31 (83.9)	1.05 (0.85, 1.30)	0.6563	
Black	13/ 16 (81.3)	7/ 8 (87.5)	0.93 (0.65, 1.32)	0.6800	
Other	24/ 28 (85.7)	26/ 36 (72.2)	1.19 (0.92, 1.53)	0.1842	
Ethnicity					0.0890
Hispanic/Latino	24/ 28 (85.7)	18/ 28 (64.3)	1.33 (0.97, 1.83)	0.0733	
Non-hispanic/Latino	35/ 41 (85.4)	41/ 47 (87.2)	0.98 (0.83, 1.16)	0.7999	
Geographic region					0.0217
Latin America, Eastern Europe and Asia	41/ 45 (91.1)	41/ 55 (74.5)	1.22 (1.02, 1.46)	0.0283	
North America	18/ 24 (75.0)	18/ 20 (90.0)	0.83 (0.63, 1.10)	0.1910	
Baseline weight					0.3580
<60 kg	16/ 18 (88.9)	23/ 31 (74.2)	1.20 (0.92, 1.56)	0.1800	
>=60 kg	43/ 51 (84.3)	36/ 44 (81.8)	1.03 (0.86, 1.24)	0.7473	
Low CH50					0.9061
Yes	8/ 9 (88.9)	8/ 10 (80.0)	1.11 (0.75, 1.64)	0.5932	
No	51/ 60 (85.0)	51/ 65 (78.5)	1.08 (0.92, 1.28)	0.3443	
Low C3 or C4					0.4519
Yes	23/ 25 (92.0)	26/ 33 (78.8)	1.17 (0.95, 1.44)	0.1507	
No	36/ 44 (81.8)	33/ 42 (78.6)	1.04 (0.84, 1.29)	0.7063	
Baseline FARR anti-dsDNA					0.0798
<5 IU/mL	11/ 15 (73.3)	10/ 11 (90.9)	0.81 (0.56, 1.15)	0.2393	
>=5 IU/mL	36/ 40 (90.0)	39/ 50 (78.0)	1.15 (0.96, 1.38)	0.1189	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.0180
Yes	45/ 50 (90.0)	45/ 60 (75.0)	1.20 (1.01, 1.43)	0.0387	
No	14/ 19 (73.7)	14/ 15 (93.3)	0.79 (0.58, 1.07)	0.1235	
OCS use					0.1321
Yes	47/ 54 (87.0)	48/ 63 (76.2)	1.14 (0.96, 1.36)	0.1298	
No	12/ 15 (80.0)	11/ 12 (91.7)	0.87 (0.64, 1.18)	0.3819	
SLICC score					0.8579
0	33/ 40 (82.5)	37/ 48 (77.1)	1.07 (0.87, 1.32)	0.5265	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
>=1	26/ 29 (89.7)	22/ 27 (81.5)	1.10 (0.88, 1.37)	0.3906	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Serious Adverse Event
Safety analysis set

	Anifrolumab 300mg (N=69)	Placebo (N=75)
Number of subjects with events, n (%)	14 (20.3)	15 (20.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.01 (0.53, 1.94)	
p-value	0.9654	
Odds Ratio (95% CI)	1.02 (0.45, 2.30)	
p-value	0.9654	
Risk Difference (95% CI)	0.29 (-12.82, 13.40)	
p-value	0.9654	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Serious Adverse Event - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.2925
< 10 points	5/ 29 (17.2)	3/ 32 (9.4)	1.84 (0.48, 7.03)	0.3729	
>= 10 points	9/ 40 (22.5)	12/ 43 (27.9)	0.81 (0.38, 1.71)	0.5733	
OCS dose					0.7023
<10 mg/day	7/ 33 (21.2)	5/ 28 (17.9)	1.19 (0.42, 3.33)	0.7435	
>=10 mg/day	7/ 36 (19.4)	10/ 47 (21.3)	0.91 (0.39, 2.17)	0.8379	
Result of type I IFN gene signature test					0.1591
LOW	3/ 14 (21.4)	1/ 19 (5.3)	4.07 (0.47, 35.14)	0.2017	
HIGH	11/ 55 (20.0)	14/ 56 (25.0)	0.80 (0.40, 1.61)	0.5301	
Age (years)					0.3550
<= 45	7/ 45 (15.6)	10/ 50 (20.0)	0.78 (0.32, 1.87)	0.5748	
> 45	7/ 24 (29.2)	5/ 25 (20.0)	1.46 (0.54, 3.97)	0.4604	
Sex					0.5985
male	0/ 4 (0.0)	1/ 6 (16.7)	0.47 (0.02, 9.26)	0.6171	
female	14/ 65 (21.5)	14/ 69 (20.3)	1.06 (0.55, 2.05)	0.8590	
Race					0.3843
White	3/ 25 (12.0)	5/ 31 (16.1)	0.74 (0.20, 2.82)	0.6632	
Black	3/ 16 (18.8)	3/ 8 (37.5)	0.50 (0.13, 1.94)	0.3167	
Other	8/ 28 (28.6)	7/ 36 (19.4)	1.47 (0.61, 3.56)	0.3946	
Ethnicity					0.1035
Hispanic/Latino	9/ 28 (32.1)	5/ 28 (17.9)	1.80 (0.69, 4.70)	0.2299	
Non-hispanic/Latino	5/ 41 (12.2)	10/ 47 (21.3)	0.57 (0.21, 1.54)	0.2698	
Geographic region					0.9130
Latin America, Eastern Europe and Asia	10/ 45 (22.2)	12/ 55 (21.8)	1.02 (0.49, 2.14)	0.9613	
North America	4/ 24 (16.7)	3/ 20 (15.0)	1.11 (0.28, 4.39)	0.8806	
Baseline weight					0.9642
<60 kg	5/ 18 (27.8)	8/ 31 (25.8)	1.08 (0.41, 2.80)	0.8799	
>=60 kg	9/ 51 (17.6)	7/ 44 (15.9)	1.11 (0.45, 2.73)	0.8217	
Low CH50					0.7165
Yes	3/ 9 (33.3)	4/ 10 (40.0)	0.83 (0.25, 2.76)	0.7651	
No	11/ 60 (18.3)	11/ 65 (16.9)	1.08 (0.51, 2.31)	0.8361	
Low C3 or C4					0.7730
Yes	7/ 25 (28.0)	8/ 33 (24.2)	1.16 (0.48, 2.76)	0.7458	
No	7/ 44 (15.9)	7/ 42 (16.7)	0.95 (0.37, 2.49)	0.9242	
Baseline FARR anti-dsDNA					0.6210
<5 IU/mL	2/ 15 (13.3)	1/ 11 (9.1)	1.47 (0.15, 14.21)	0.7410	
>=5 IU/mL	7/ 40 (17.5)	11/ 50 (22.0)	0.80 (0.34, 1.86)	0.5984	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.8671
Yes	11/ 50 (22.0)	13/ 60 (21.7)	1.02 (0.50, 2.06)	0.9664	
No	3/ 19 (15.8)	2/ 15 (13.3)	1.18 (0.23, 6.20)	0.8414	
OCS use					0.8290
Yes	11/ 54 (20.4)	13/ 63 (20.6)	0.99 (0.48, 2.02)	0.9718	
No	3/ 15 (20.0)	2/ 12 (16.7)	1.20 (0.24, 6.06)	0.8254	
SLICC score					0.2815
0	5/ 40 (12.5)	9/ 48 (18.8)	0.67 (0.24, 1.83)	0.4311	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Serious Adverse Event - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
>=1	9/ 29 (31.0)	6/ 27 (22.2)	1.40 (0.57, 3.40)	0.4621	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Severe Adverse Event
Safety analysis set

	Anifrolumab 300mg (N=69)	Placebo (N=75)
Number of subjects with events, n (%)	17 (24.6)	10 (13.3)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.85 (0.91, 3.76)	
p-value	0.0898	
Odds Ratio (95% CI)	2.13 (0.90, 5.03)	
p-value	0.0866	
Risk Difference (95% CI)	11.30 (-1.45, 24.05)	
p-value	0.0823	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Severe Adverse Event - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.0580
< 10 points	8/ 29 (27.6)	1/ 32 (3.1)	8.83 (1.17, 66.36)	0.0343	
>= 10 points	9/ 40 (22.5)	9/ 43 (20.9)	1.08 (0.47, 2.43)	0.8623	
OCS dose					0.1375
<10 mg/day	8/ 33 (24.2)	1/ 28 (3.6)	6.79 (0.90, 51.01)	0.0627	
>=10 mg/day	9/ 36 (25.0)	9/ 47 (19.1)	1.31 (0.58, 2.95)	0.5217	
Result of type I IFN gene signature test					0.0948
LOW	5/ 14 (35.7)	0/ 19 (0.0)	14.67 (0.88, 245.22)	0.0617	
HIGH	12/ 55 (21.8)	10/ 56 (17.9)	1.22 (0.58, 2.59)	0.6017	
Age (years)					0.7989
<= 45	9/ 45 (20.0)	5/ 50 (10.0)	2.00 (0.72, 5.53)	0.1813	
> 45	8/ 24 (33.3)	5/ 25 (20.0)	1.67 (0.63, 4.38)	0.3004	
Sex					0.5635
male	1/ 4 (25.0)	0/ 6 (0.0)	4.20 (0.21, 83.33)	0.3465	
female	16/ 65 (24.6)	10/ 69 (14.5)	1.70 (0.83, 3.47)	0.1458	
Race					0.5868
White	5/ 25 (20.0)	5/ 31 (16.1)	1.24 (0.40, 3.81)	0.7071	
Black	5/ 16 (31.3)	0/ 8 (0.0)	5.82 (0.36, 93.87)	0.2142	
Other	7/ 28 (25.0)	5/ 36 (13.9)	1.80 (0.64, 5.07)	0.2661	
Ethnicity					0.9792
Hispanic/Latino	9/ 28 (32.1)	5/ 28 (17.9)	1.80 (0.69, 4.70)	0.2299	
Non-hispanic/Latino	8/ 41 (19.5)	5/ 47 (10.6)	1.83 (0.65, 5.17)	0.2511	
Geographic region					0.2185
Latin America, Eastern Europe and Asia	12/ 45 (26.7)	10/ 55 (18.2)	1.47 (0.70, 3.08)	0.3110	
North America	5/ 24 (20.8)	0/ 20 (0.0)	9.24 (0.54, 157.57)	0.1244	
Baseline weight					0.9067
<60 kg	6/ 18 (33.3)	5/ 31 (16.1)	2.07 (0.73, 5.82)	0.1692	
>=60 kg	11/ 51 (21.6)	5/ 44 (11.4)	1.90 (0.71, 5.04)	0.1987	
Low CH50					0.6826
Yes	4/ 9 (44.4)	3/ 10 (30.0)	1.48 (0.45, 4.90)	0.5194	
No	13/ 60 (21.7)	7/ 65 (10.8)	2.01 (0.86, 4.70)	0.1066	
Low C3 or C4					0.7857
Yes	8/ 25 (32.0)	6/ 33 (18.2)	1.76 (0.70, 4.43)	0.2295	
No	9/ 44 (20.5)	4/ 42 (9.5)	2.15 (0.72, 6.45)	0.1729	
Baseline FARR anti-dsDNA					0.5747
<5 IU/mL	2/ 15 (13.3)	0/ 11 (0.0)	3.75 (0.20, 71.12)	0.3787	
>=5 IU/mL	10/ 40 (25.0)	8/ 50 (16.0)	1.56 (0.68, 3.59)	0.2928	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.2240
Yes	12/ 50 (24.0)	10/ 60 (16.7)	1.44 (0.68, 3.05)	0.3410	
No	5/ 19 (26.3)	0/ 15 (0.0)	8.80 (0.52, 147.55)	0.1306	
OCS use					0.2916
Yes	13/ 54 (24.1)	10/ 63 (15.9)	1.52 (0.72, 3.18)	0.2699	
No	4/ 15 (26.7)	0/ 12 (0.0)	7.31 (0.43, 123.74)	0.1680	
SLICC score					0.8502
0	8/ 40 (20.0)	5/ 48 (10.4)	1.92 (0.68, 5.41)	0.2170	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Severe Adverse Event - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
>=1	9/ 29 (31.0)	5/ 27 (18.5)	1.68 (0.64, 4.37)	0.2915	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Non-Severe Adverse Event
Safety analysis set

	Anifrolumab 300mg (N=69)	Placebo (N=75)
Number of subjects with events, n (%)	58 (84.1)	59 (78.7)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.07 (0.91, 1.25)	
p-value	0.4060	
Odds Ratio (95% CI)	1.43 (0.61, 3.34)	
p-value	0.4090	
Risk Difference (95% CI)	5.39 (-7.28, 18.06)	
p-value	0.4043	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Non-Severe Adverse Event - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	 p-Value	Interaction p-Value
SLEDAI-2K score					0.2366
< 10 points	25/ 29 (86.2)	23/ 32 (71.9)	1.20 (0.92, 1.56)	0.1723	
>= 10 points	33/ 40 (82.5)	36/ 43 (83.7)	0.99 (0.81, 1.20)	0.8822	
OCS dose					0.0379
<10 mg/day	25/ 33 (75.8)	24/ 28 (85.7)	0.88 (0.69, 1.13)	0.3236	
>=10 mg/day	33/ 36 (91.7)	35/ 47 (74.5)	1.23 (1.01, 1.49)	0.0360	
Result of type I IFN gene signature test					0.1539
LOW	14/ 14 (100.0)	15/ 19 (78.9)	1.27 (1.00, 1.60)	0.0460	
HIGH	44/ 55 (80.0)	44/ 56 (78.6)	1.02 (0.84, 1.23)	0.8527	
Age (years)					0.4647
<= 45	35/ 45 (77.8)	38/ 50 (76.0)	1.02 (0.82, 1.28)	0.8372	
> 45	23/ 24 (95.8)	21/ 25 (84.0)	1.14 (0.94, 1.38)	0.1747	
Sex					0.1075
male	4/ 4 (100.0)	3/ 6 (50.0)	2.00 (0.90, 4.45)	0.0895	
female	54/ 65 (83.1)	56/ 69 (81.2)	1.02 (0.87, 1.20)	0.7721	
Race					0.3788
White	22/ 25 (88.0)	26/ 31 (83.9)	1.05 (0.85, 1.30)	0.6563	
Black	12/ 16 (75.0)	7/ 8 (87.5)	0.86 (0.58, 1.26)	0.4332	
Other	24/ 28 (85.7)	26/ 36 (72.2)	1.19 (0.92, 1.53)	0.1842	
Ethnicity					0.0663
Hispanic/Latino	24/ 28 (85.7)	18/ 28 (64.3)	1.33 (0.97, 1.83)	0.0733	
Non-hispanic/Latino	34/ 41 (82.9)	41/ 47 (87.2)	0.95 (0.80, 1.13)	0.5745	
Geographic region					0.0336
Latin America, Eastern Europe and Asia	40/ 45 (88.9)	41/ 55 (74.5)	1.19 (0.99, 1.44)	0.0634	
North America	18/ 24 (75.0)	18/ 20 (90.0)	0.83 (0.63, 1.10)	0.1910	
Baseline weight					0.6249
<60 kg	15/ 18 (83.3)	23/ 31 (74.2)	1.12 (0.84, 1.51)	0.4369	
>=60 kg	43/ 51 (84.3)	36/ 44 (81.8)	1.03 (0.86, 1.24)	0.7473	
Low CH50					0.8342
Yes	8/ 9 (88.9)	8/ 10 (80.0)	1.11 (0.75, 1.64)	0.5932	
No	50/ 60 (83.3)	51/ 65 (78.5)	1.06 (0.90, 1.26)	0.4883	
Low C3 or C4					0.6586
Yes	22/ 25 (88.0)	26/ 33 (78.8)	1.12 (0.89, 1.40)	0.3433	
No	36/ 44 (81.8)	33/ 42 (78.6)	1.04 (0.84, 1.29)	0.7063	
Baseline FARR anti-dsDNA					0.1099
<5 IU/mL	11/ 15 (73.3)	10/ 11 (90.9)	0.81 (0.56, 1.15)	0.2393	
>=5 IU/mL	35/ 40 (87.5)	39/ 50 (78.0)	1.12 (0.93, 1.35)	0.2311	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.0264
Yes	44/ 50 (88.0)	45/ 60 (75.0)	1.17 (0.98, 1.40)	0.0790	
No	14/ 19 (73.7)	14/ 15 (93.3)	0.79 (0.58, 1.07)	0.1235	
OCS use					0.1689
Yes	46/ 54 (85.2)	48/ 63 (76.2)	1.12 (0.94, 1.33)	0.2173	
No	12/ 15 (80.0)	11/ 12 (91.7)	0.87 (0.64, 1.18)	0.3819	
SLICC score					0.9423
0	33/ 40 (82.5)	37/ 48 (77.1)	1.07 (0.87, 1.32)	0.5265	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Non-Severe Adverse Event - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
>=1	25/ 29 (86.2)	22/ 27 (81.5)	1.06 (0.84, 1.33)	0.6330	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event leading to discontinuation of study drug
Safety analysis set

	Anifrolumab 300mg (N=69)	Placebo (N=75)
Number of subjects with events, n (%)	2 (2.9)	6 (8.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.36 (0.08, 1.74)	
p-value	0.2040	
Odds Ratio (95% CI)	0.34 (0.07, 1.76)	
p-value	0.2000	
Risk Difference (95% CI)	-5.10 (-12.41, 2.20)	
p-value	0.1711	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event leading to discontinuation of study drug - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					NE
< 10 points	0/ 29 (0.0)	0/ 32 (0.0)	NE		
>= 10 points	2/ 40 (5.0)	6/ 43 (14.0)	0.36 (0.08, 1.67)	0.1919	
OCS dose					0.5022
<10 mg/day	1/ 33 (3.0)	1/ 28 (3.6)	0.85 (0.06, 12.95)	0.9060	
>=10 mg/day	1/ 36 (2.8)	5/ 47 (10.6)	0.26 (0.03, 2.14)	0.2107	
Result of type I IFN gene signature test					0.9611
LOW	0/ 14 (0.0)	1/ 19 (5.3)	0.44 (0.02, 10.16)	0.6116	
HIGH	2/ 55 (3.6)	5/ 56 (8.9)	0.41 (0.08, 2.01)	0.2703	
Age (years)					0.6981
<= 45	1/ 45 (2.2)	4/ 50 (8.0)	0.28 (0.03, 2.39)	0.2438	
> 45	1/ 24 (4.2)	2/ 25 (8.0)	0.52 (0.05, 5.38)	0.5839	
Sex					NE
male	0/ 4 (0.0)	0/ 6 (0.0)	NE		
female	2/ 65 (3.1)	6/ 69 (8.7)	0.35 (0.07, 1.69)	0.1930	
Race					0.6037
White	1/ 25 (4.0)	3/ 31 (9.7)	0.41 (0.05, 3.73)	0.4314	
Black	1/ 16 (6.3)	0/ 8 (0.0)	1.59 (0.07, 35.15)	0.7697	
Other	0/ 28 (0.0)	3/ 36 (8.3)	0.18 (0.01, 3.39)	0.2537	
Ethnicity					0.3333
Hispanic/Latino	0/ 28 (0.0)	3/ 28 (10.7)	0.14 (0.01, 2.64)	0.1912	
Non-hispanic/Latino	2/ 41 (4.9)	3/ 47 (6.4)	0.76 (0.13, 4.35)	0.7619	
Geographic region					0.4838
Latin America, Eastern Europe and Asia	1/ 45 (2.2)	5/ 55 (9.1)	0.24 (0.03, 2.02)	0.1908	
North America	1/ 24 (4.2)	1/ 20 (5.0)	0.83 (0.06, 12.49)	0.8950	
Baseline weight					0.9991
<60 kg	1/ 18 (5.6)	4/ 31 (12.9)	0.43 (0.05, 3.56)	0.4344	
>=60 kg	1/ 51 (2.0)	2/ 44 (4.5)	0.43 (0.04, 4.60)	0.4862	
Low CH50					0.6500
Yes	1/ 9 (11.1)	2/ 10 (20.0)	0.56 (0.06, 5.14)	0.6046	
No	1/ 60 (1.7)	4/ 65 (6.2)	0.27 (0.03, 2.36)	0.2366	
Low C3 or C4					0.8201
Yes	1/ 25 (4.0)	4/ 33 (12.1)	0.33 (0.04, 2.77)	0.3074	
No	1/ 44 (2.3)	2/ 42 (4.8)	0.48 (0.04, 5.07)	0.5395	
Baseline FARR anti-dsDNA					0.5081
<5 IU/mL	0/ 15 (0.0)	1/ 11 (9.1)	0.25 (0.01, 5.62)	0.3826	
>=5 IU/mL	2/ 40 (5.0)	3/ 50 (6.0)	0.83 (0.15, 4.75)	0.8373	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.7431
Yes	2/ 50 (4.0)	5/ 60 (8.3)	0.48 (0.10, 2.37)	0.3675	
No	0/ 19 (0.0)	1/ 15 (6.7)	0.27 (0.01, 6.11)	0.4082	
OCS use					0.1862
Yes	1/ 54 (1.9)	6/ 63 (9.5)	0.19 (0.02, 1.57)	0.1238	
No	1/ 15 (6.7)	0/ 12 (0.0)	2.44 (0.11, 54.97)	0.5752	
SLICC score					0.7019
0	0/ 40 (0.0)	2/ 48 (4.2)	0.24 (0.01, 4.84)	0.3510	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event leading to discontinuation of study drug - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
>=1	2/ 29 (6.9)	4/ 27 (14.8)	0.47 (0.09, 2.34)	0.3533	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Serious Adverse Event leading to discontinuation of study drug
Safety analysis set

	Anifrolumab 300mg (N=69)	Placebo (N=75)
Number of subjects with events, n (%)	2 (2.9)	4 (5.3)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.54 (0.10, 2.87)	
p-value	0.4730	
Odds Ratio (95% CI)	0.53 (0.09, 2.99)	
p-value	0.4718	
Risk Difference (95% CI)	-2.43 (-8.88, 4.01)	
p-value	0.4590	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Serious Adverse Event leading to discontinuation of study drug - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					NE
< 10 points	0/ 29 (0.0)	0/ 32 (0.0)	NE		
>= 10 points	2/ 40 (5.0)	4/ 43 (9.3)	0.54 (0.10, 2.78)	0.4586	
OCS dose					0.7098
<10 mg/day	1/ 33 (3.0)	1/ 28 (3.6)	0.85 (0.06, 12.95)	0.9060	
>=10 mg/day	1/ 36 (2.8)	3/ 47 (6.4)	0.44 (0.05, 4.01)	0.4629	
Result of type I IFN gene signature test					NE
LOW	0/ 14 (0.0)	0/ 19 (0.0)	NE		
HIGH	2/ 55 (3.6)	4/ 56 (7.1)	0.51 (0.10, 2.67)	0.4243	
Age (years)					0.9696
<= 45	1/ 45 (2.2)	2/ 50 (4.0)	0.56 (0.05, 5.92)	0.6264	
> 45	1/ 24 (4.2)	2/ 25 (8.0)	0.52 (0.05, 5.38)	0.5839	
Sex					NE
male	0/ 4 (0.0)	0/ 6 (0.0)	NE		
female	2/ 65 (3.1)	4/ 69 (5.8)	0.53 (0.10, 2.80)	0.4554	
Race					0.7077
White	1/ 25 (4.0)	2/ 31 (6.5)	0.62 (0.06, 6.45)	0.6891	
Black	1/ 16 (6.3)	0/ 8 (0.0)	1.59 (0.07, 35.15)	0.7697	
Other	0/ 28 (0.0)	2/ 36 (5.6)	0.26 (0.01, 5.11)	0.3718	
Ethnicity					0.3354
Hispanic/Latino	0/ 28 (0.0)	2/ 28 (7.1)	0.20 (0.01, 3.99)	0.2918	
Non-hispanic/Latino	2/ 41 (4.9)	2/ 47 (4.3)	1.15 (0.17, 7.78)	0.8888	
Geographic region					0.2784
Latin America, Eastern Europe and Asia	1/ 45 (2.2)	4/ 55 (7.3)	0.31 (0.04, 2.64)	0.2810	
North America	1/ 24 (4.2)	0/ 20 (0.0)	2.52 (0.11, 58.67)	0.5649	
Baseline weight					0.8200
<60 kg	1/ 18 (5.6)	3/ 31 (9.7)	0.57 (0.06, 5.12)	0.6190	
>=60 kg	1/ 51 (2.0)	1/ 44 (2.3)	0.86 (0.06, 13.39)	0.9160	
Low CH50					0.9878
Yes	1/ 9 (11.1)	2/ 10 (20.0)	0.56 (0.06, 5.14)	0.6046	
No	1/ 60 (1.7)	2/ 65 (3.1)	0.54 (0.05, 5.82)	0.6128	
Low C3 or C4					0.6659
Yes	1/ 25 (4.0)	3/ 33 (9.1)	0.44 (0.05, 3.98)	0.4651	
No	1/ 44 (2.3)	1/ 42 (2.4)	0.95 (0.06, 14.77)	0.9734	
Baseline FARR anti-dsDNA					NE
<5 IU/mL	0/ 15 (0.0)	0/ 11 (0.0)	NE		
>=5 IU/mL	2/ 40 (5.0)	2/ 50 (4.0)	1.25 (0.18, 8.49)	0.8194	
Low complement (C3 or C4) and positive FARR anti-dsDNA					NE
Yes	2/ 50 (4.0)	4/ 60 (6.7)	0.60 (0.11, 3.14)	0.5453	
No	0/ 19 (0.0)	0/ 15 (0.0)	NE		
OCS use					0.2725
Yes	1/ 54 (1.9)	4/ 63 (6.3)	0.29 (0.03, 2.53)	0.2638	
No	1/ 15 (6.7)	0/ 12 (0.0)	2.44 (0.11, 54.97)	0.5752	
SLICC score					0.8095
0	0/ 40 (0.0)	1/ 48 (2.1)	0.40 (0.02, 9.52)	0.5698	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Serious Adverse Event leading to discontinuation of study drug - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
>=1	2/ 29 (6.9)	3/ 27 (11.1)	0.62 (0.11, 3.43)	0.5848	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with Adverse Event leading to death
Safety analysis set

	Anifrolumab 300mg (N=69)	Placebo (N=75)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with Adverse Event leading to death - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
SLEDAI-2K score				NE
< 10 points	0/ 29 (0.0)	0/ 32 (0.0)	NE	
>= 10 points	0/ 40 (0.0)	0/ 43 (0.0)	NE	
OCS dose				NE
<10 mg/day	0/ 33 (0.0)	0/ 28 (0.0)	NE	
>=10 mg/day	0/ 36 (0.0)	0/ 47 (0.0)	NE	
Result of type I IFN gene signature test				NE
LOW	0/ 14 (0.0)	0/ 19 (0.0)	NE	
HIGH	0/ 55 (0.0)	0/ 56 (0.0)	NE	
Age (years)				NE
<= 45	0/ 45 (0.0)	0/ 50 (0.0)	NE	
> 45	0/ 24 (0.0)	0/ 25 (0.0)	NE	
Sex				NE
male	0/ 4 (0.0)	0/ 6 (0.0)	NE	
female	0/ 65 (0.0)	0/ 69 (0.0)	NE	
Race				NE
White	0/ 25 (0.0)	0/ 31 (0.0)	NE	
Black	0/ 16 (0.0)	0/ 8 (0.0)	NE	
Other	0/ 28 (0.0)	0/ 36 (0.0)	NE	
Ethnicity				NE
Hispanic/Latino	0/ 28 (0.0)	0/ 28 (0.0)	NE	
Non-hispanic/Latino	0/ 41 (0.0)	0/ 47 (0.0)	NE	
Geographic region				NE
Latin America, Eastern Europe and Asia	0/ 45 (0.0)	0/ 55 (0.0)	NE	
North America	0/ 24 (0.0)	0/ 20 (0.0)	NE	
Baseline weight				NE
<60 kg	0/ 18 (0.0)	0/ 31 (0.0)	NE	
>=60 kg	0/ 51 (0.0)	0/ 44 (0.0)	NE	
Low CH50				NE
Yes	0/ 9 (0.0)	0/ 10 (0.0)	NE	
No	0/ 60 (0.0)	0/ 65 (0.0)	NE	
Low C3 or C4				NE
Yes	0/ 25 (0.0)	0/ 33 (0.0)	NE	
No	0/ 44 (0.0)	0/ 42 (0.0)	NE	
Baseline FARR anti-dsDNA				NE
<5 IU/mL	0/ 15 (0.0)	0/ 11 (0.0)	NE	
>=5 IU/mL	0/ 40 (0.0)	0/ 50 (0.0)	NE	
Low complement (C3 or C4) and positive FARR anti-dsDNA				NE
Yes	0/ 50 (0.0)	0/ 60 (0.0)	NE	
No	0/ 19 (0.0)	0/ 15 (0.0)	NE	
OCS use				NE
Yes	0/ 54 (0.0)	0/ 63 (0.0)	NE	
No	0/ 15 (0.0)	0/ 12 (0.0)	NE	
SLICC score				NE
0	0/ 40 (0.0)	0/ 48 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with Adverse Event leading to death - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
>=1	0/ 29 (0.0)	0/ 27 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Herpes Zoster
Safety analysis set

	Anifrolumab 300mg (N=69)	Placebo (N=75)
Number of subjects with events, n (%)	5 (7.2)	2 (2.7)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	2.72 (0.54, 13.55)	
p-value	0.2227	
Odds Ratio (95% CI)	2.85 (0.53, 15.21)	
p-value	0.2198	
Risk Difference (95% CI)	4.58 (-2.54, 11.70)	
p-value	0.2075	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Herpes Zoster - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.4424
< 10 points	1/ 29 (3.4)	1/ 32 (3.1)	1.10 (0.07, 16.85)	0.9436	
>= 10 points	4/ 40 (10.0)	1/ 43 (2.3)	4.30 (0.50, 36.86)	0.1833	
OCS dose					0.3047
<10 mg/day	1/ 33 (3.0)	1/ 28 (3.6)	0.85 (0.06, 12.95)	0.9060	
>=10 mg/day	4/ 36 (11.1)	1/ 47 (2.1)	5.22 (0.61, 44.74)	0.1315	
Result of type I IFN gene signature test					NE
LOW	0/ 14 (0.0)	0/ 19 (0.0)	NE		
HIGH	5/ 55 (9.1)	2/ 56 (3.6)	2.55 (0.52, 12.57)	0.2515	
Age (years)					0.8517
<= 45	4/ 45 (8.9)	2/ 50 (4.0)	2.22 (0.43, 11.56)	0.3425	
> 45	1/ 24 (4.2)	0/ 25 (0.0)	3.12 (0.13, 73.04)	0.4794	
Sex					0.6958
male	1/ 4 (25.0)	0/ 6 (0.0)	4.20 (0.21, 83.33)	0.3465	
female	4/ 65 (6.2)	2/ 69 (2.9)	2.12 (0.40, 11.20)	0.3750	
Race					0.9669
White	2/ 25 (8.0)	1/ 31 (3.2)	2.48 (0.24, 25.80)	0.4472	
Black	1/ 16 (6.3)	0/ 8 (0.0)	1.59 (0.07, 35.15)	0.7697	
Other	2/ 28 (7.1)	1/ 36 (2.8)	2.57 (0.25, 26.94)	0.4307	
Ethnicity					0.7422
Hispanic/Latino	2/ 28 (7.1)	1/ 28 (3.6)	2.00 (0.19, 20.82)	0.5620	
Non-hispanic/Latino	3/ 41 (7.3)	1/ 47 (2.1)	3.44 (0.37, 31.79)	0.2764	
Geographic region					0.9866
Latin America, Eastern Europe and Asia	4/ 45 (8.9)	2/ 55 (3.6)	2.44 (0.47, 12.74)	0.2887	
North America	1/ 24 (4.2)	0/ 20 (0.0)	2.52 (0.11, 58.67)	0.5649	
Baseline weight					0.5537
<60 kg	1/ 18 (5.6)	0/ 31 (0.0)	5.05 (0.22, 117.89)	0.3135	
>=60 kg	4/ 51 (7.8)	2/ 44 (4.5)	1.73 (0.33, 8.97)	0.5167	
Low CH50					0.4822
Yes	2/ 9 (22.2)	0/ 10 (0.0)	5.50 (0.30, 101.28)	0.2514	
No	3/ 60 (5.0)	2/ 65 (3.1)	1.63 (0.28, 9.39)	0.5876	
Low C3 or C4					0.9607
Yes	2/ 25 (8.0)	1/ 33 (3.0)	2.64 (0.25, 27.50)	0.4169	
No	3/ 44 (6.8)	1/ 42 (2.4)	2.86 (0.31, 26.45)	0.3537	
Baseline FARR anti-dsDNA					NE
<5 IU/mL	0/ 15 (0.0)	0/ 11 (0.0)	NE		
>=5 IU/mL	5/ 40 (12.5)	2/ 50 (4.0)	3.13 (0.64, 15.27)	0.1592	
Low complement (C3 or C4) and positive FARR anti-dsDNA					NE
Yes	5/ 50 (10.0)	2/ 60 (3.3)	3.00 (0.61, 14.80)	0.1774	
No	0/ 19 (0.0)	0/ 15 (0.0)	NE		
OCS use					0.3138
Yes	4/ 54 (7.4)	1/ 63 (1.6)	4.67 (0.54, 40.50)	0.1624	
No	1/ 15 (6.7)	1/ 12 (8.3)	0.80 (0.06, 11.50)	0.8697	
SLICC score					0.9267
0	2/ 40 (5.0)	1/ 48 (2.1)	2.40 (0.23, 25.51)	0.4678	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Herpes Zoster - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
>=1	3/ 29 (10.3)	1/ 27 (3.7)	2.79 (0.31, 25.25)	0.3605	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Herpes Zoster
Safety analysis set

	Anifrolumab 300mg (N=69)	Placebo (N=75)
Number of subjects with events, n (%)	1 (1.4)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.26 (0.13, 78.65)	
p-value	0.4673	
Odds Ratio (95% CI)	3.31 (0.13, 82.53)	
p-value	0.4663	
Risk Difference (95% CI)	1.45 (-1.37, 4.27)	
p-value	0.3138	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Herpes Zoster - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
SLEDAI-2K score				NE
< 10 points	0/ 29 (0.0)	0/ 32 (0.0)	NE	
>= 10 points	1/ 40 (2.5)	0/ 43 (0.0)	3.22 (0.13, 76.82) 0.4700	
OCS dose				NE
<10 mg/day	1/ 33 (3.0)	0/ 28 (0.0)	2.56 (0.11, 60.44) 0.5603	
>=10 mg/day	0/ 36 (0.0)	0/ 47 (0.0)	NE	
Result of type I IFN gene signature test				NE
LOW	0/ 14 (0.0)	0/ 19 (0.0)	NE	
HIGH	1/ 55 (1.8)	0/ 56 (0.0)	3.05 (0.13, 73.38) 0.4913	
Age (years)				NE
<= 45	0/ 45 (0.0)	0/ 50 (0.0)	NE	
> 45	1/ 24 (4.2)	0/ 25 (0.0)	3.12 (0.13, 73.04) 0.4794	
Sex				NE
male	0/ 4 (0.0)	0/ 6 (0.0)	NE	
female	1/ 65 (1.5)	0/ 69 (0.0)	3.18 (0.13, 76.73) 0.4760	
Race				NE
White	0/ 25 (0.0)	0/ 31 (0.0)	NE	
Black	1/ 16 (6.3)	0/ 8 (0.0)	1.59 (0.07, 35.15) 0.7697	
Other	0/ 28 (0.0)	0/ 36 (0.0)	NE	
Ethnicity				NE
Hispanic/Latino	0/ 28 (0.0)	0/ 28 (0.0)	NE	
Non-hispanic/Latino	1/ 41 (2.4)	0/ 47 (0.0)	3.43 (0.14, 81.93) 0.4467	
Geographic region				NE
Latin America, Eastern Europe and Asia	0/ 45 (0.0)	0/ 55 (0.0)	NE	
North America	1/ 24 (4.2)	0/ 20 (0.0)	2.52 (0.11, 58.67) 0.5649	
Baseline weight				NE
<60 kg	0/ 18 (0.0)	0/ 31 (0.0)	NE	
>=60 kg	1/ 51 (2.0)	0/ 44 (0.0)	2.60 (0.11, 62.16) 0.5560	
Low CH50				NE
Yes	1/ 9 (11.1)	0/ 10 (0.0)	3.30 (0.15, 72.08) 0.4480	
No	0/ 60 (0.0)	0/ 65 (0.0)	NE	
Low C3 or C4				NE
Yes	1/ 25 (4.0)	0/ 33 (0.0)	3.92 (0.17, 92.43) 0.3965	
No	0/ 44 (0.0)	0/ 42 (0.0)	NE	
Baseline FARR anti-dsDNA				NE
<5 IU/mL	0/ 15 (0.0)	0/ 11 (0.0)	NE	
>=5 IU/mL	1/ 40 (2.5)	0/ 50 (0.0)	3.73 (0.16, 89.21) 0.4161	
Low complement (C3 or C4) and positive FARR anti-dsDNA				NE
Yes	1/ 50 (2.0)	0/ 60 (0.0)	3.59 (0.15, 86.19) 0.4308	
No	0/ 19 (0.0)	0/ 15 (0.0)	NE	
OCS use				NE
Yes	0/ 54 (0.0)	0/ 63 (0.0)	NE	
No	1/ 15 (6.7)	0/ 12 (0.0)	2.44 (0.11, 54.97) 0.5752	
SLICC score				NE
0	0/ 40 (0.0)	0/ 48 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Herpes Zoster - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
>=1	1/ 29 (3.4)	0/ 27 (0.0)	2.80 (0.12, 65.93) 0.5229	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Herpes Zoster
Safety analysis set

	Anifrolumab 300mg (N=69)	Placebo (N=75)
Number of subjects with events, n (%)	1 (1.4)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.26 (0.13, 78.65)	
p-value	0.4673	
Odds Ratio (95% CI)	3.31 (0.13, 82.53)	
p-value	0.4663	
Risk Difference (95% CI)	1.45 (-1.37, 4.27)	
p-value	0.3138	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Herpes Zoster - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
SLEDAI-2K score				NE
< 10 points	0/ 29 (0.0)	0/ 32 (0.0)	NE	
>= 10 points	1/ 40 (2.5)	0/ 43 (0.0)	3.22 (0.13, 76.82) 0.4700	
OCS dose				NE
<10 mg/day	1/ 33 (3.0)	0/ 28 (0.0)	2.56 (0.11, 60.44) 0.5603	
>=10 mg/day	0/ 36 (0.0)	0/ 47 (0.0)	NE	
Result of type I IFN gene signature test				NE
LOW	0/ 14 (0.0)	0/ 19 (0.0)	NE	
HIGH	1/ 55 (1.8)	0/ 56 (0.0)	3.05 (0.13, 73.38) 0.4913	
Age (years)				NE
<= 45	0/ 45 (0.0)	0/ 50 (0.0)	NE	
> 45	1/ 24 (4.2)	0/ 25 (0.0)	3.12 (0.13, 73.04) 0.4794	
Sex				NE
male	0/ 4 (0.0)	0/ 6 (0.0)	NE	
female	1/ 65 (1.5)	0/ 69 (0.0)	3.18 (0.13, 76.73) 0.4760	
Race				NE
White	0/ 25 (0.0)	0/ 31 (0.0)	NE	
Black	1/ 16 (6.3)	0/ 8 (0.0)	1.59 (0.07, 35.15) 0.7697	
Other	0/ 28 (0.0)	0/ 36 (0.0)	NE	
Ethnicity				NE
Hispanic/Latino	0/ 28 (0.0)	0/ 28 (0.0)	NE	
Non-hispanic/Latino	1/ 41 (2.4)	0/ 47 (0.0)	3.43 (0.14, 81.93) 0.4467	
Geographic region				NE
Latin America, Eastern Europe and Asia	0/ 45 (0.0)	0/ 55 (0.0)	NE	
North America	1/ 24 (4.2)	0/ 20 (0.0)	2.52 (0.11, 58.67) 0.5649	
Baseline weight				NE
<60 kg	0/ 18 (0.0)	0/ 31 (0.0)	NE	
>=60 kg	1/ 51 (2.0)	0/ 44 (0.0)	2.60 (0.11, 62.16) 0.5560	
Low CH50				NE
Yes	1/ 9 (11.1)	0/ 10 (0.0)	3.30 (0.15, 72.08) 0.4480	
No	0/ 60 (0.0)	0/ 65 (0.0)	NE	
Low C3 or C4				NE
Yes	1/ 25 (4.0)	0/ 33 (0.0)	3.92 (0.17, 92.43) 0.3965	
No	0/ 44 (0.0)	0/ 42 (0.0)	NE	
Baseline FARR anti-dsDNA				NE
<5 IU/mL	0/ 15 (0.0)	0/ 11 (0.0)	NE	
>=5 IU/mL	1/ 40 (2.5)	0/ 50 (0.0)	3.73 (0.16, 89.21) 0.4161	
Low complement (C3 or C4) and positive FARR anti-dsDNA				NE
Yes	1/ 50 (2.0)	0/ 60 (0.0)	3.59 (0.15, 86.19) 0.4308	
No	0/ 19 (0.0)	0/ 15 (0.0)	NE	
OCS use				NE
Yes	0/ 54 (0.0)	0/ 63 (0.0)	NE	
No	1/ 15 (6.7)	0/ 12 (0.0)	2.44 (0.11, 54.97) 0.5752	
SLICC score				NE
0	0/ 40 (0.0)	0/ 48 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Herpes Zoster - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
>=1	1/ 29 (3.4)	0/ 27 (0.0)	2.80 (0.12, 65.93)	0.5229	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Herpes Zoster
Safety analysis set

	Anifrolumab 300mg (N=69)	Placebo (N=75)
Number of subjects with events, n (%)	4 (5.8)	2 (2.7)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	2.17 (0.41, 11.50)	
p-value	0.3608	
Odds Ratio (95% CI)	2.25 (0.40, 12.67)	
p-value	0.3592	
Risk Difference (95% CI)	3.13 (-3.48, 9.74)	
p-value	0.3533	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Herpes Zoster - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.5500
< 10 points	1/ 29 (3.4)	1/ 32 (3.1)	1.10 (0.07, 16.85)	0.9436	
>= 10 points	3/ 40 (7.5)	1/ 43 (2.3)	3.23 (0.35, 29.75)	0.3016	
OCS dose					0.1356
<10 mg/day	0/ 33 (0.0)	1/ 28 (3.6)	0.28 (0.01, 6.72)	0.4356	
>=10 mg/day	4/ 36 (11.1)	1/ 47 (2.1)	5.22 (0.61, 44.74)	0.1315	
Result of type I IFN gene signature test					NE
LOW	0/ 14 (0.0)	0/ 19 (0.0)	NE		
HIGH	4/ 55 (7.3)	2/ 56 (3.6)	2.04 (0.39, 10.67)	0.4000	
Age (years)					NE
<= 45	4/ 45 (8.9)	2/ 50 (4.0)	2.22 (0.43, 11.56)	0.3425	
> 45	0/ 24 (0.0)	0/ 25 (0.0)	NE		
Sex					0.5834
male	1/ 4 (25.0)	0/ 6 (0.0)	4.20 (0.21, 83.33)	0.3465	
female	3/ 65 (4.6)	2/ 69 (2.9)	1.59 (0.27, 9.23)	0.6038	
Race					0.9829
White	2/ 25 (8.0)	1/ 31 (3.2)	2.48 (0.24, 25.80)	0.4472	
Black	0/ 16 (0.0)	0/ 8 (0.0)	NE		
Other	2/ 28 (7.1)	1/ 36 (2.8)	2.57 (0.25, 26.94)	0.4307	
Ethnicity					0.9359
Hispanic/Latino	2/ 28 (7.1)	1/ 28 (3.6)	2.00 (0.19, 20.82)	0.5620	
Non-hispanic/Latino	2/ 41 (4.9)	1/ 47 (2.1)	2.29 (0.22, 24.37)	0.4914	
Geographic region					NE
Latin America, Eastern Europe and Asia	4/ 45 (8.9)	2/ 55 (3.6)	2.44 (0.47, 12.74)	0.2887	
North America	0/ 24 (0.0)	0/ 20 (0.0)	NE		
Baseline weight					0.4584
<60 kg	1/ 18 (5.6)	0/ 31 (0.0)	5.05 (0.22, 117.89)	0.3135	
>=60 kg	3/ 51 (5.9)	2/ 44 (4.5)	1.29 (0.23, 7.40)	0.7719	
Low CH50					0.6956
Yes	1/ 9 (11.1)	0/ 10 (0.0)	3.30 (0.15, 72.08)	0.4480	
No	3/ 60 (5.0)	2/ 65 (3.1)	1.63 (0.28, 9.39)	0.5876	
Low C3 or C4					0.6659
Yes	1/ 25 (4.0)	1/ 33 (3.0)	1.32 (0.09, 20.09)	0.8416	
No	3/ 44 (6.8)	1/ 42 (2.4)	2.86 (0.31, 26.45)	0.3537	
Baseline FARR anti-dsDNA					NE
<5 IU/mL	0/ 15 (0.0)	0/ 11 (0.0)	NE		
>=5 IU/mL	4/ 40 (10.0)	2/ 50 (4.0)	2.50 (0.48, 12.96)	0.2751	
Low complement (C3 or C4) and positive FARR anti-dsDNA					NE
Yes	4/ 50 (8.0)	2/ 60 (3.3)	2.40 (0.46, 12.56)	0.2999	
No	0/ 19 (0.0)	0/ 15 (0.0)	NE		
OCS use					0.1412
Yes	4/ 54 (7.4)	1/ 63 (1.6)	4.67 (0.54, 40.50)	0.1624	
No	0/ 15 (0.0)	1/ 12 (8.3)	0.27 (0.01, 6.11)	0.4113	
SLICC score					0.8812
0	2/ 40 (5.0)	1/ 48 (2.1)	2.40 (0.23, 25.51)	0.4678	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Herpes Zoster - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
>=1	2/ 29 (6.9)	1/ 27 (3.7)	1.86 (0.18, 19.38)	0.6030	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Herpes Zoster leading to discontinuation of study drug
Safety analysis set

	Anifrolumab 300mg (N=69)	Placebo (N=75)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Herpes Zoster leading to discontinuation of study drug - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
SLEDAI-2K score				NE
< 10 points	0/ 29 (0.0)	0/ 32 (0.0)	NE	
>= 10 points	0/ 40 (0.0)	0/ 43 (0.0)	NE	
OCS dose				NE
<10 mg/day	0/ 33 (0.0)	0/ 28 (0.0)	NE	
>=10 mg/day	0/ 36 (0.0)	0/ 47 (0.0)	NE	
Result of type I IFN gene signature test				NE
LOW	0/ 14 (0.0)	0/ 19 (0.0)	NE	
HIGH	0/ 55 (0.0)	0/ 56 (0.0)	NE	
Age (years)				NE
<= 45	0/ 45 (0.0)	0/ 50 (0.0)	NE	
> 45	0/ 24 (0.0)	0/ 25 (0.0)	NE	
Sex				NE
male	0/ 4 (0.0)	0/ 6 (0.0)	NE	
female	0/ 65 (0.0)	0/ 69 (0.0)	NE	
Race				NE
White	0/ 25 (0.0)	0/ 31 (0.0)	NE	
Black	0/ 16 (0.0)	0/ 8 (0.0)	NE	
Other	0/ 28 (0.0)	0/ 36 (0.0)	NE	
Ethnicity				NE
Hispanic/Latino	0/ 28 (0.0)	0/ 28 (0.0)	NE	
Non-hispanic/Latino	0/ 41 (0.0)	0/ 47 (0.0)	NE	
Geographic region				NE
Latin America, Eastern Europe and Asia	0/ 45 (0.0)	0/ 55 (0.0)	NE	
North America	0/ 24 (0.0)	0/ 20 (0.0)	NE	
Baseline weight				NE
<60 kg	0/ 18 (0.0)	0/ 31 (0.0)	NE	
>=60 kg	0/ 51 (0.0)	0/ 44 (0.0)	NE	
Low CH50				NE
Yes	0/ 9 (0.0)	0/ 10 (0.0)	NE	
No	0/ 60 (0.0)	0/ 65 (0.0)	NE	
Low C3 or C4				NE
Yes	0/ 25 (0.0)	0/ 33 (0.0)	NE	
No	0/ 44 (0.0)	0/ 42 (0.0)	NE	
Baseline FARR anti-dsDNA				NE
<5 IU/mL	0/ 15 (0.0)	0/ 11 (0.0)	NE	
>=5 IU/mL	0/ 40 (0.0)	0/ 50 (0.0)	NE	
Low complement (C3 or C4) and positive FARR anti-dsDNA				NE
Yes	0/ 50 (0.0)	0/ 60 (0.0)	NE	
No	0/ 19 (0.0)	0/ 15 (0.0)	NE	
OCS use				NE
Yes	0/ 54 (0.0)	0/ 63 (0.0)	NE	
No	0/ 15 (0.0)	0/ 12 (0.0)	NE	
SLICC score				NE
0	0/ 40 (0.0)	0/ 48 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Herpes Zoster leading to discontinuation of study drug - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
>=1	0/ 29 (0.0)	0/ 27 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Influenza
Safety analysis set

	Anifrolumab 300mg (N=69)	Placebo (N=75)
Number of subjects with events, n (%)	3 (4.3)	2 (2.7)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.63 (0.28, 9.47)	
p-value	0.5860	
Odds Ratio (95% CI)	1.66 (0.27, 10.24)	
p-value	0.5856	
Risk Difference (95% CI)	1.68 (-4.36, 7.72)	
p-value	0.5852	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Influenza - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.7170
< 10 points	1/ 29 (3.4)	1/ 32 (3.1)	1.10 (0.07, 16.85)	0.9436	
>= 10 points	2/ 40 (5.0)	1/ 43 (2.3)	2.15 (0.20, 22.81)	0.5252	
OCS dose					0.5412
<10 mg/day	1/ 33 (3.0)	1/ 28 (3.6)	0.85 (0.06, 12.95)	0.9060	
>=10 mg/day	2/ 36 (5.6)	1/ 47 (2.1)	2.61 (0.25, 27.68)	0.4256	
Result of type I IFN gene signature test					NE
LOW	0/ 14 (0.0)	0/ 19 (0.0)	NE		
HIGH	3/ 55 (5.5)	2/ 56 (3.6)	1.53 (0.27, 8.79)	0.6353	
Age (years)					0.0903
<= 45	3/ 45 (6.7)	0/ 50 (0.0)	7.76 (0.41, 146.26)	0.1714	
> 45	0/ 24 (0.0)	2/ 25 (8.0)	0.21 (0.01, 4.12)	0.3027	
Sex					NE
male	0/ 4 (0.0)	0/ 6 (0.0)	NE		
female	3/ 65 (4.6)	2/ 69 (2.9)	1.59 (0.27, 9.23)	0.6038	
Race					0.2545
White	0/ 25 (0.0)	1/ 31 (3.2)	0.41 (0.02, 9.66)	0.5803	
Black	0/ 16 (0.0)	0/ 8 (0.0)	NE		
Other	3/ 28 (10.7)	1/ 36 (2.8)	3.86 (0.42, 35.11)	0.2309	
Ethnicity					0.2950
Hispanic/Latino	3/ 28 (10.7)	1/ 28 (3.6)	3.00 (0.33, 27.12)	0.3281	
Non-hispanic/Latino	0/ 41 (0.0)	1/ 47 (2.1)	0.38 (0.02, 9.10)	0.5512	
Geographic region					NE
Latin America, Eastern Europe and Asia	3/ 45 (6.7)	2/ 55 (3.6)	1.83 (0.32, 10.50)	0.4961	
North America	0/ 24 (0.0)	0/ 20 (0.0)	NE		
Baseline weight					0.4375
<60 kg	0/ 18 (0.0)	1/ 31 (3.2)	0.56 (0.02, 13.10)	0.7194	
>=60 kg	3/ 51 (5.9)	1/ 44 (2.3)	2.59 (0.28, 24.00)	0.4026	
Low CH50					NE
Yes	0/ 9 (0.0)	0/ 10 (0.0)	NE		
No	3/ 60 (5.0)	2/ 65 (3.1)	1.63 (0.28, 9.39)	0.5876	
Low C3 or C4					0.1785
Yes	2/ 25 (8.0)	0/ 33 (0.0)	6.54 (0.33, 130.43)	0.2189	
No	1/ 44 (2.3)	2/ 42 (4.8)	0.48 (0.04, 5.07)	0.5395	
Baseline FARR anti-dsDNA					0.1456
<5 IU/mL	0/ 15 (0.0)	1/ 11 (9.1)	0.25 (0.01, 5.62)	0.3826	
>=5 IU/mL	2/ 40 (5.0)	0/ 50 (0.0)	6.22 (0.31, 125.98)	0.2338	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.0632
Yes	3/ 50 (6.0)	0/ 60 (0.0)	8.37 (0.44, 158.34)	0.1566	
No	0/ 19 (0.0)	2/ 15 (13.3)	0.16 (0.01, 3.10)	0.2256	
OCS use					0.6934
Yes	2/ 54 (3.7)	2/ 63 (3.2)	1.17 (0.17, 8.01)	0.8753	
No	1/ 15 (6.7)	0/ 12 (0.0)	2.44 (0.11, 54.97)	0.5752	
SLICC score					0.8112
0	1/ 40 (2.5)	1/ 48 (2.1)	1.20 (0.08, 18.58)	0.8962	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Influenza - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
>=1	2/ 29 (6.9)	1/ 27 (3.7)	1.86 (0.18, 19.38)	0.6030	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Influenza
Safety analysis set

	Anifrolumab 300mg (N=69)	Placebo (N=75)
Number of subjects with events, n (%)	2 (2.9)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	5.43 (0.27, 111.12)	
p-value	0.2721	
Odds Ratio (95% CI)	5.59 (0.26, 118.57)	
p-value	0.2693	
Risk Difference (95% CI)	2.90 (-1.06, 6.86)	
p-value	0.1512	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Influenza - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.9914
< 10 points	1/ 29 (3.4)	0/ 32 (0.0)	3.30 (0.14, 77.95)	0.4593	
>= 10 points	1/ 40 (2.5)	0/ 43 (0.0)	3.22 (0.13, 76.82)	0.4700	
OCS dose					0.8544
<10 mg/day	1/ 33 (3.0)	0/ 28 (0.0)	2.56 (0.11, 60.44)	0.5603	
>=10 mg/day	1/ 36 (2.8)	0/ 47 (0.0)	3.89 (0.16, 92.82)	0.4011	
Result of type I IFN gene signature test					NE
LOW	0/ 14 (0.0)	0/ 19 (0.0)	NE		
HIGH	2/ 55 (3.6)	0/ 56 (0.0)	5.09 (0.25, 103.65)	0.2900	
Age (years)					NE
<= 45	2/ 45 (4.4)	0/ 50 (0.0)	5.54 (0.27, 112.47)	0.2648	
> 45	0/ 24 (0.0)	0/ 25 (0.0)	NE		
Sex					NE
male	0/ 4 (0.0)	0/ 6 (0.0)	NE		
female	2/ 65 (3.1)	0/ 69 (0.0)	5.30 (0.26, 108.41)	0.2786	
Race					NE
White	0/ 25 (0.0)	0/ 31 (0.0)	NE		
Black	0/ 16 (0.0)	0/ 8 (0.0)	NE		
Other	2/ 28 (7.1)	0/ 36 (0.0)	6.38 (0.32, 127.77)	0.2256	
Ethnicity					NE
Hispanic/Latino	2/ 28 (7.1)	0/ 28 (0.0)	5.00 (0.25, 99.67)	0.2918	
Non-hispanic/Latino	0/ 41 (0.0)	0/ 47 (0.0)	NE		
Geographic region					NE
Latin America, Eastern Europe and Asia	2/ 45 (4.4)	0/ 55 (0.0)	6.09 (0.30, 123.64)	0.2398	
North America	0/ 24 (0.0)	0/ 20 (0.0)	NE		
Baseline weight					NE
<60 kg	0/ 18 (0.0)	0/ 31 (0.0)	NE		
>=60 kg	2/ 51 (3.9)	0/ 44 (0.0)	4.33 (0.21, 87.78)	0.3402	
Low CH50					NE
Yes	0/ 9 (0.0)	0/ 10 (0.0)	NE		
No	2/ 60 (3.3)	0/ 65 (0.0)	5.41 (0.26, 110.45)	0.2727	
Low C3 or C4					0.8908
Yes	1/ 25 (4.0)	0/ 33 (0.0)	3.92 (0.17, 92.43)	0.3965	
No	1/ 44 (2.3)	0/ 42 (0.0)	2.87 (0.12, 68.47)	0.5154	
Baseline FARR anti-dsDNA					NE
<5 IU/mL	0/ 15 (0.0)	0/ 11 (0.0)	NE		
>=5 IU/mL	2/ 40 (5.0)	0/ 50 (0.0)	6.22 (0.31, 125.98)	0.2338	
Low complement (C3 or C4) and positive FARR anti-dsDNA					NE
Yes	2/ 50 (4.0)	0/ 60 (0.0)	5.98 (0.29, 121.75)	0.2447	
No	0/ 19 (0.0)	0/ 15 (0.0)	NE		
OCS use					0.8744
Yes	1/ 54 (1.9)	0/ 63 (0.0)	3.49 (0.15, 83.97)	0.4410	
No	1/ 15 (6.7)	0/ 12 (0.0)	2.44 (0.11, 54.97)	0.5752	
SLICC score					NE
0	0/ 40 (0.0)	0/ 48 (0.0)	NE		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Influenza - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
>=1	2/ 29 (6.9)	0/ 27 (0.0)	4.67 (0.23, 93.02)	0.3130	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Influenza
Safety analysis set

	Anifrolumab 300mg (N=69)	Placebo (N=75)
Number of subjects with events, n (%)	1 (1.4)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.26 (0.13, 78.65)	
p-value	0.4673	
Odds Ratio (95% CI)	3.31 (0.13, 82.53)	
p-value	0.4663	
Risk Difference (95% CI)	1.45 (-1.37, 4.27)	
p-value	0.3138	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Influenza - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					NE
< 10 points	0/ 29 (0.0)	0/ 32 (0.0)	NE		
>= 10 points	1/ 40 (2.5)	0/ 43 (0.0)	3.22 (0.13, 76.82)	0.4700	
OCS dose					NE
<10 mg/day	1/ 33 (3.0)	0/ 28 (0.0)	2.56 (0.11, 60.44)	0.5603	
>=10 mg/day	0/ 36 (0.0)	0/ 47 (0.0)	NE		
Result of type I IFN gene signature test					NE
LOW	0/ 14 (0.0)	0/ 19 (0.0)	NE		
HIGH	1/ 55 (1.8)	0/ 56 (0.0)	3.05 (0.13, 73.38)	0.4913	
Age (years)					NE
<= 45	1/ 45 (2.2)	0/ 50 (0.0)	3.33 (0.14, 79.64)	0.4583	
> 45	0/ 24 (0.0)	0/ 25 (0.0)	NE		
Sex					NE
male	0/ 4 (0.0)	0/ 6 (0.0)	NE		
female	1/ 65 (1.5)	0/ 69 (0.0)	3.18 (0.13, 76.73)	0.4760	
Race					NE
White	0/ 25 (0.0)	0/ 31 (0.0)	NE		
Black	0/ 16 (0.0)	0/ 8 (0.0)	NE		
Other	1/ 28 (3.6)	0/ 36 (0.0)	3.83 (0.16, 90.53)	0.4056	
Ethnicity					NE
Hispanic/Latino	1/ 28 (3.6)	0/ 28 (0.0)	3.00 (0.13, 70.64)	0.4955	
Non-hispanic/Latino	0/ 41 (0.0)	0/ 47 (0.0)	NE		
Geographic region					NE
Latin America, Eastern Europe and Asia	1/ 45 (2.2)	0/ 55 (0.0)	3.65 (0.15, 87.54)	0.4242	
North America	0/ 24 (0.0)	0/ 20 (0.0)	NE		
Baseline weight					NE
<60 kg	0/ 18 (0.0)	0/ 31 (0.0)	NE		
>=60 kg	1/ 51 (2.0)	0/ 44 (0.0)	2.60 (0.11, 62.16)	0.5560	
Low CH50					NE
Yes	0/ 9 (0.0)	0/ 10 (0.0)	NE		
No	1/ 60 (1.7)	0/ 65 (0.0)	3.25 (0.13, 78.18)	0.4683	
Low C3 or C4					NE
Yes	1/ 25 (4.0)	0/ 33 (0.0)	3.92 (0.17, 92.43)	0.3965	
No	0/ 44 (0.0)	0/ 42 (0.0)	NE		
Baseline FARR anti-dsDNA					NE
<5 IU/mL	0/ 15 (0.0)	0/ 11 (0.0)	NE		
>=5 IU/mL	1/ 40 (2.5)	0/ 50 (0.0)	3.73 (0.16, 89.21)	0.4161	
Low complement (C3 or C4) and positive FARR anti-dsDNA					NE
Yes	1/ 50 (2.0)	0/ 60 (0.0)	3.59 (0.15, 86.19)	0.4308	
No	0/ 19 (0.0)	0/ 15 (0.0)	NE		
OCS use					NE
Yes	0/ 54 (0.0)	0/ 63 (0.0)	NE		
No	1/ 15 (6.7)	0/ 12 (0.0)	2.44 (0.11, 54.97)	0.5752	
SLICC score					NE
0	0/ 40 (0.0)	0/ 48 (0.0)	NE		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Influenza - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
>=1	1/ 29 (3.4)	0/ 27 (0.0)	2.80 (0.12, 65.93)	0.5229	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Influenza
Safety analysis set

	Anifrolumab 300mg (N=69)	Placebo (N=75)
Number of subjects with events, n (%)	3 (4.3)	2 (2.7)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.63 (0.28, 9.47)	
p-value	0.5860	
Odds Ratio (95% CI)	1.66 (0.27, 10.24)	
p-value	0.5856	
Risk Difference (95% CI)	1.68 (-4.36, 7.72)	
p-value	0.5852	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Influenza - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.7170
< 10 points	1/ 29 (3.4)	1/ 32 (3.1)	1.10 (0.07, 16.85)	0.9436	
>= 10 points	2/ 40 (5.0)	1/ 43 (2.3)	2.15 (0.20, 22.81)	0.5252	
OCS dose					0.5412
<10 mg/day	1/ 33 (3.0)	1/ 28 (3.6)	0.85 (0.06, 12.95)	0.9060	
>=10 mg/day	2/ 36 (5.6)	1/ 47 (2.1)	2.61 (0.25, 27.68)	0.4256	
Result of type I IFN gene signature test					NE
LOW	0/ 14 (0.0)	0/ 19 (0.0)	NE		
HIGH	3/ 55 (5.5)	2/ 56 (3.6)	1.53 (0.27, 8.79)	0.6353	
Age (years)					0.0903
<= 45	3/ 45 (6.7)	0/ 50 (0.0)	7.76 (0.41, 146.26)	0.1714	
> 45	0/ 24 (0.0)	2/ 25 (8.0)	0.21 (0.01, 4.12)	0.3027	
Sex					NE
male	0/ 4 (0.0)	0/ 6 (0.0)	NE		
female	3/ 65 (4.6)	2/ 69 (2.9)	1.59 (0.27, 9.23)	0.6038	
Race					0.2545
White	0/ 25 (0.0)	1/ 31 (3.2)	0.41 (0.02, 9.66)	0.5803	
Black	0/ 16 (0.0)	0/ 8 (0.0)	NE		
Other	3/ 28 (10.7)	1/ 36 (2.8)	3.86 (0.42, 35.11)	0.2309	
Ethnicity					0.2950
Hispanic/Latino	3/ 28 (10.7)	1/ 28 (3.6)	3.00 (0.33, 27.12)	0.3281	
Non-hispanic/Latino	0/ 41 (0.0)	1/ 47 (2.1)	0.38 (0.02, 9.10)	0.5512	
Geographic region					NE
Latin America, Eastern Europe and Asia	3/ 45 (6.7)	2/ 55 (3.6)	1.83 (0.32, 10.50)	0.4961	
North America	0/ 24 (0.0)	0/ 20 (0.0)	NE		
Baseline weight					0.4375
<60 kg	0/ 18 (0.0)	1/ 31 (3.2)	0.56 (0.02, 13.10)	0.7194	
>=60 kg	3/ 51 (5.9)	1/ 44 (2.3)	2.59 (0.28, 24.00)	0.4026	
Low CH50					NE
Yes	0/ 9 (0.0)	0/ 10 (0.0)	NE		
No	3/ 60 (5.0)	2/ 65 (3.1)	1.63 (0.28, 9.39)	0.5876	
Low C3 or C4					0.1785
Yes	2/ 25 (8.0)	0/ 33 (0.0)	6.54 (0.33, 130.43)	0.2189	
No	1/ 44 (2.3)	2/ 42 (4.8)	0.48 (0.04, 5.07)	0.5395	
Baseline FARR anti-dsDNA					0.1456
<5 IU/mL	0/ 15 (0.0)	1/ 11 (9.1)	0.25 (0.01, 5.62)	0.3826	
>=5 IU/mL	2/ 40 (5.0)	0/ 50 (0.0)	6.22 (0.31, 125.98)	0.2338	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.0632
Yes	3/ 50 (6.0)	0/ 60 (0.0)	8.37 (0.44, 158.34)	0.1566	
No	0/ 19 (0.0)	2/ 15 (13.3)	0.16 (0.01, 3.10)	0.2256	
OCS use					0.6934
Yes	2/ 54 (3.7)	2/ 63 (3.2)	1.17 (0.17, 8.01)	0.8753	
No	1/ 15 (6.7)	0/ 12 (0.0)	2.44 (0.11, 54.97)	0.5752	
SLICC score					0.8112
0	1/ 40 (2.5)	1/ 48 (2.1)	1.20 (0.08, 18.58)	0.8962	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Influenza - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
>=1	2/ 29 (6.9)	1/ 27 (3.7)	1.86 (0.18, 19.38)	0.6030	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Tuberculosis (including latent TB)
Safety analysis set

	Anifrolumab 300mg (N=69)	Placebo (N=75)
Number of subjects with events, n (%)	2 (2.9)	1 (1.3)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	2.17 (0.20, 23.44)	
p-value	0.5222	
Odds Ratio (95% CI)	2.21 (0.20, 24.92)	
p-value	0.5215	
Risk Difference (95% CI)	1.57 (-3.17, 6.30)	
p-value	0.5169	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Tuberculosis (including latent TB) - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.2281
< 10 points	0/ 29 (0.0)	1/ 32 (3.1)	0.37 (0.02, 8.66)	0.5340	
>= 10 points	2/ 40 (5.0)	0/ 43 (0.0)	5.37 (0.27, 108.47)	0.2734	
OCS dose					0.7525
<10 mg/day	1/ 33 (3.0)	0/ 28 (0.0)	2.56 (0.11, 60.44)	0.5603	
>=10 mg/day	1/ 36 (2.8)	1/ 47 (2.1)	1.31 (0.08, 20.17)	0.8486	
Result of type I IFN gene signature test					NE
LOW	0/ 14 (0.0)	0/ 19 (0.0)	NE		
HIGH	2/ 55 (3.6)	1/ 56 (1.8)	2.04 (0.19, 21.82)	0.5567	
Age (years)					NE
<= 45	2/ 45 (4.4)	1/ 50 (2.0)	2.22 (0.21, 23.69)	0.5084	
> 45	0/ 24 (0.0)	0/ 25 (0.0)	NE		
Sex					NE
male	0/ 4 (0.0)	0/ 6 (0.0)	NE		
female	2/ 65 (3.1)	1/ 69 (1.4)	2.12 (0.20, 22.86)	0.5346	
Race					NE
White	0/ 25 (0.0)	0/ 31 (0.0)	NE		
Black	0/ 16 (0.0)	0/ 8 (0.0)	NE		
Other	2/ 28 (7.1)	1/ 36 (2.8)	2.57 (0.25, 26.94)	0.4307	
Ethnicity					0.5635
Hispanic/Latino	1/ 28 (3.6)	1/ 28 (3.6)	1.00 (0.07, 15.21)	1.0000	
Non-hispanic/Latino	1/ 41 (2.4)	0/ 47 (0.0)	3.43 (0.14, 81.93)	0.4467	
Geographic region					NE
Latin America, Eastern Europe and Asia	2/ 45 (4.4)	1/ 55 (1.8)	2.44 (0.23, 26.09)	0.4594	
North America	0/ 24 (0.0)	0/ 20 (0.0)	NE		
Baseline weight					0.4068
<60 kg	1/ 18 (5.6)	0/ 31 (0.0)	5.05 (0.22, 117.89)	0.3135	
>=60 kg	1/ 51 (2.0)	1/ 44 (2.3)	0.86 (0.06, 13.39)	0.9160	
Low CH50					NE
Yes	0/ 9 (0.0)	0/ 10 (0.0)	NE		
No	2/ 60 (3.3)	1/ 65 (1.5)	2.17 (0.20, 23.29)	0.5234	
Low C3 or C4					0.5077
Yes	1/ 25 (4.0)	0/ 33 (0.0)	3.92 (0.17, 92.43)	0.3965	
No	1/ 44 (2.3)	1/ 42 (2.4)	0.95 (0.06, 14.77)	0.9734	
Baseline FARR anti-dsDNA					0.7811
<5 IU/mL	1/ 15 (6.7)	0/ 11 (0.0)	2.25 (0.10, 50.54)	0.6095	
>=5 IU/mL	1/ 40 (2.5)	1/ 50 (2.0)	1.25 (0.08, 19.37)	0.8732	
Low complement (C3 or C4) and positive FARR anti-dsDNA					NE
Yes	2/ 50 (4.0)	1/ 60 (1.7)	2.40 (0.22, 25.70)	0.4692	
No	0/ 19 (0.0)	0/ 15 (0.0)	NE		
OCS use					NE
Yes	2/ 54 (3.7)	1/ 63 (1.6)	2.33 (0.22, 25.03)	0.4840	
No	0/ 15 (0.0)	0/ 12 (0.0)	NE		
SLICC score					NE
0	2/ 40 (5.0)	1/ 48 (2.1)	2.40 (0.23, 25.51)	0.4678	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Tuberculosis (including latent TB) - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
>=1	0/ 29 (0.0)	0/ 27 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Tuberculosis (including latent TB)
Safety analysis set

	Anifrolumab 300mg (N=69)	Placebo (N=75)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Tuberculosis (including latent TB) - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
SLEDAI-2K score				NE
< 10 points	0/ 29 (0.0)	0/ 32 (0.0)	NE	
>= 10 points	0/ 40 (0.0)	0/ 43 (0.0)	NE	
OCS dose				NE
<10 mg/day	0/ 33 (0.0)	0/ 28 (0.0)	NE	
>=10 mg/day	0/ 36 (0.0)	0/ 47 (0.0)	NE	
Result of type I IFN gene signature test				NE
LOW	0/ 14 (0.0)	0/ 19 (0.0)	NE	
HIGH	0/ 55 (0.0)	0/ 56 (0.0)	NE	
Age (years)				NE
<= 45	0/ 45 (0.0)	0/ 50 (0.0)	NE	
> 45	0/ 24 (0.0)	0/ 25 (0.0)	NE	
Sex				NE
male	0/ 4 (0.0)	0/ 6 (0.0)	NE	
female	0/ 65 (0.0)	0/ 69 (0.0)	NE	
Race				NE
White	0/ 25 (0.0)	0/ 31 (0.0)	NE	
Black	0/ 16 (0.0)	0/ 8 (0.0)	NE	
Other	0/ 28 (0.0)	0/ 36 (0.0)	NE	
Ethnicity				NE
Hispanic/Latino	0/ 28 (0.0)	0/ 28 (0.0)	NE	
Non-hispanic/Latino	0/ 41 (0.0)	0/ 47 (0.0)	NE	
Geographic region				NE
Latin America, Eastern Europe and Asia	0/ 45 (0.0)	0/ 55 (0.0)	NE	
North America	0/ 24 (0.0)	0/ 20 (0.0)	NE	
Baseline weight				NE
<60 kg	0/ 18 (0.0)	0/ 31 (0.0)	NE	
>=60 kg	0/ 51 (0.0)	0/ 44 (0.0)	NE	
Low CH50				NE
Yes	0/ 9 (0.0)	0/ 10 (0.0)	NE	
No	0/ 60 (0.0)	0/ 65 (0.0)	NE	
Low C3 or C4				NE
Yes	0/ 25 (0.0)	0/ 33 (0.0)	NE	
No	0/ 44 (0.0)	0/ 42 (0.0)	NE	
Baseline FARR anti-dsDNA				NE
<5 IU/mL	0/ 15 (0.0)	0/ 11 (0.0)	NE	
>=5 IU/mL	0/ 40 (0.0)	0/ 50 (0.0)	NE	
Low complement (C3 or C4) and positive FARR anti-dsDNA				NE
Yes	0/ 50 (0.0)	0/ 60 (0.0)	NE	
No	0/ 19 (0.0)	0/ 15 (0.0)	NE	
OCS use				NE
Yes	0/ 54 (0.0)	0/ 63 (0.0)	NE	
No	0/ 15 (0.0)	0/ 12 (0.0)	NE	
SLICC score				NE
0	0/ 40 (0.0)	0/ 48 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Tuberculosis (including latent TB) - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
>=1	0/ 29 (0.0)	0/ 27 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Tuberculosis (including latent TB)
Safety analysis set

	Anifrolumab 300mg (N=69)	Placebo (N=75)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Tuberculosis (including latent TB) - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
SLEDAI-2K score				NE
< 10 points	0/ 29 (0.0)	0/ 32 (0.0)	NE	
>= 10 points	0/ 40 (0.0)	0/ 43 (0.0)	NE	
OCS dose				NE
<10 mg/day	0/ 33 (0.0)	0/ 28 (0.0)	NE	
>=10 mg/day	0/ 36 (0.0)	0/ 47 (0.0)	NE	
Result of type I IFN gene signature test				NE
LOW	0/ 14 (0.0)	0/ 19 (0.0)	NE	
HIGH	0/ 55 (0.0)	0/ 56 (0.0)	NE	
Age (years)				NE
<= 45	0/ 45 (0.0)	0/ 50 (0.0)	NE	
> 45	0/ 24 (0.0)	0/ 25 (0.0)	NE	
Sex				NE
male	0/ 4 (0.0)	0/ 6 (0.0)	NE	
female	0/ 65 (0.0)	0/ 69 (0.0)	NE	
Race				NE
White	0/ 25 (0.0)	0/ 31 (0.0)	NE	
Black	0/ 16 (0.0)	0/ 8 (0.0)	NE	
Other	0/ 28 (0.0)	0/ 36 (0.0)	NE	
Ethnicity				NE
Hispanic/Latino	0/ 28 (0.0)	0/ 28 (0.0)	NE	
Non-hispanic/Latino	0/ 41 (0.0)	0/ 47 (0.0)	NE	
Geographic region				NE
Latin America, Eastern Europe and Asia	0/ 45 (0.0)	0/ 55 (0.0)	NE	
North America	0/ 24 (0.0)	0/ 20 (0.0)	NE	
Baseline weight				NE
<60 kg	0/ 18 (0.0)	0/ 31 (0.0)	NE	
>=60 kg	0/ 51 (0.0)	0/ 44 (0.0)	NE	
Low CH50				NE
Yes	0/ 9 (0.0)	0/ 10 (0.0)	NE	
No	0/ 60 (0.0)	0/ 65 (0.0)	NE	
Low C3 or C4				NE
Yes	0/ 25 (0.0)	0/ 33 (0.0)	NE	
No	0/ 44 (0.0)	0/ 42 (0.0)	NE	
Baseline FARR anti-dsDNA				NE
<5 IU/mL	0/ 15 (0.0)	0/ 11 (0.0)	NE	
>=5 IU/mL	0/ 40 (0.0)	0/ 50 (0.0)	NE	
Low complement (C3 or C4) and positive FARR anti-dsDNA				NE
Yes	0/ 50 (0.0)	0/ 60 (0.0)	NE	
No	0/ 19 (0.0)	0/ 15 (0.0)	NE	
OCS use				NE
Yes	0/ 54 (0.0)	0/ 63 (0.0)	NE	
No	0/ 15 (0.0)	0/ 12 (0.0)	NE	
SLICC score				NE
0	0/ 40 (0.0)	0/ 48 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Tuberculosis (including latent TB) - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
>=1	0/ 29 (0.0)	0/ 27 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Tuberculosis (including latent TB)
Safety analysis set

	Anifrolumab 300mg (N=69)	Placebo (N=75)
Number of subjects with events, n (%)	2 (2.9)	1 (1.3)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	2.17 (0.20, 23.44)	
p-value	0.5222	
Odds Ratio (95% CI)	2.21 (0.20, 24.92)	
p-value	0.5215	
Risk Difference (95% CI)	1.57 (-3.17, 6.30)	
p-value	0.5169	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Tuberculosis (including latent TB) - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.2281
< 10 points	0/ 29 (0.0)	1/ 32 (3.1)	0.37 (0.02, 8.66)	0.5340	
>= 10 points	2/ 40 (5.0)	0/ 43 (0.0)	5.37 (0.27, 108.47)	0.2734	
OCS dose					0.7525
<10 mg/day	1/ 33 (3.0)	0/ 28 (0.0)	2.56 (0.11, 60.44)	0.5603	
>=10 mg/day	1/ 36 (2.8)	1/ 47 (2.1)	1.31 (0.08, 20.17)	0.8486	
Result of type I IFN gene signature test					NE
LOW	0/ 14 (0.0)	0/ 19 (0.0)	NE		
HIGH	2/ 55 (3.6)	1/ 56 (1.8)	2.04 (0.19, 21.82)	0.5567	
Age (years)					NE
<= 45	2/ 45 (4.4)	1/ 50 (2.0)	2.22 (0.21, 23.69)	0.5084	
> 45	0/ 24 (0.0)	0/ 25 (0.0)	NE		
Sex					NE
male	0/ 4 (0.0)	0/ 6 (0.0)	NE		
female	2/ 65 (3.1)	1/ 69 (1.4)	2.12 (0.20, 22.86)	0.5346	
Race					NE
White	0/ 25 (0.0)	0/ 31 (0.0)	NE		
Black	0/ 16 (0.0)	0/ 8 (0.0)	NE		
Other	2/ 28 (7.1)	1/ 36 (2.8)	2.57 (0.25, 26.94)	0.4307	
Ethnicity					0.5635
Hispanic/Latino	1/ 28 (3.6)	1/ 28 (3.6)	1.00 (0.07, 15.21)	1.0000	
Non-hispanic/Latino	1/ 41 (2.4)	0/ 47 (0.0)	3.43 (0.14, 81.93)	0.4467	
Geographic region					NE
Latin America, Eastern Europe and Asia	2/ 45 (4.4)	1/ 55 (1.8)	2.44 (0.23, 26.09)	0.4594	
North America	0/ 24 (0.0)	0/ 20 (0.0)	NE		
Baseline weight					0.4068
<60 kg	1/ 18 (5.6)	0/ 31 (0.0)	5.05 (0.22, 117.89)	0.3135	
>=60 kg	1/ 51 (2.0)	1/ 44 (2.3)	0.86 (0.06, 13.39)	0.9160	
Low CH50					NE
Yes	0/ 9 (0.0)	0/ 10 (0.0)	NE		
No	2/ 60 (3.3)	1/ 65 (1.5)	2.17 (0.20, 23.29)	0.5234	
Low C3 or C4					0.5077
Yes	1/ 25 (4.0)	0/ 33 (0.0)	3.92 (0.17, 92.43)	0.3965	
No	1/ 44 (2.3)	1/ 42 (2.4)	0.95 (0.06, 14.77)	0.9734	
Baseline FARR anti-dsDNA					0.7811
<5 IU/mL	1/ 15 (6.7)	0/ 11 (0.0)	2.25 (0.10, 50.54)	0.6095	
>=5 IU/mL	1/ 40 (2.5)	1/ 50 (2.0)	1.25 (0.08, 19.37)	0.8732	
Low complement (C3 or C4) and positive FARR anti-dsDNA					NE
Yes	2/ 50 (4.0)	1/ 60 (1.7)	2.40 (0.22, 25.70)	0.4692	
No	0/ 19 (0.0)	0/ 15 (0.0)	NE		
OCS use					NE
Yes	2/ 54 (3.7)	1/ 63 (1.6)	2.33 (0.22, 25.03)	0.4840	
No	0/ 15 (0.0)	0/ 12 (0.0)	NE		
SLICC score					NE
0	2/ 40 (5.0)	1/ 48 (2.1)	2.40 (0.23, 25.51)	0.4678	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Tuberculosis (including latent TB) - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
>=1	0/ 29 (0.0)	0/ 27 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Vasculitis
Safety analysis set

	Anifrolumab 300mg (N=69)	Placebo (N=75)
Number of subjects with events, n (%)	0 (0.0)	3 (4.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.16 (0.01, 2.95)	
p-value	0.2149	
Odds Ratio (95% CI)	0.15 (0.01, 2.94)	
p-value	0.2108	
Risk Difference (95% CI)	-4.00 (-8.43, 0.43)	
p-value	0.0771	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Vasculitis - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.8099
< 10 points	0/ 29 (0.0)	1/ 32 (3.1)	0.37 (0.02, 8.66)	0.5340	
>= 10 points	0/ 40 (0.0)	2/ 43 (4.7)	0.21 (0.01, 4.34)	0.3158	
OCS dose					0.9672
<10 mg/day	0/ 33 (0.0)	1/ 28 (3.6)	0.28 (0.01, 6.72)	0.4356	
>=10 mg/day	0/ 36 (0.0)	2/ 47 (4.3)	0.26 (0.01, 5.24)	0.3790	
Result of type I IFN gene signature test					NE
LOW	0/ 14 (0.0)	0/ 19 (0.0)	NE		
HIGH	0/ 55 (0.0)	3/ 56 (5.4)	0.15 (0.01, 2.75)	0.1987	
Age (years)					0.8408
<= 45	0/ 45 (0.0)	2/ 50 (4.0)	0.22 (0.01, 4.50)	0.3267	
> 45	0/ 24 (0.0)	1/ 25 (4.0)	0.35 (0.01, 8.12)	0.5102	
Sex					NE
male	0/ 4 (0.0)	0/ 6 (0.0)	NE		
female	0/ 65 (0.0)	3/ 69 (4.3)	0.15 (0.01, 2.88)	0.2090	
Race					0.8668
White	0/ 25 (0.0)	0/ 31 (0.0)	NE		
Black	0/ 16 (0.0)	1/ 8 (12.5)	0.18 (0.01, 3.91)	0.2723	
Other	0/ 28 (0.0)	2/ 36 (5.6)	0.26 (0.01, 5.11)	0.3718	
Ethnicity					0.8654
Hispanic/Latino	0/ 28 (0.0)	1/ 28 (3.6)	0.33 (0.01, 7.85)	0.4955	
Non-hispanic/Latino	0/ 41 (0.0)	2/ 47 (4.3)	0.23 (0.01, 4.63)	0.3362	
Geographic region					0.9499
Latin America, Eastern Europe and Asia	0/ 45 (0.0)	2/ 55 (3.6)	0.24 (0.01, 4.95)	0.3578	
North America	0/ 24 (0.0)	1/ 20 (5.0)	0.28 (0.01, 6.52)	0.4280	
Baseline weight					0.9444
<60 kg	0/ 18 (0.0)	2/ 31 (6.5)	0.34 (0.02, 6.65)	0.4746	
>=60 kg	0/ 51 (0.0)	1/ 44 (2.3)	0.29 (0.01, 6.91)	0.4429	
Low CH50					NE
Yes	0/ 9 (0.0)	0/ 10 (0.0)	NE		
No	0/ 60 (0.0)	3/ 65 (4.6)	0.15 (0.01, 2.93)	0.2136	
Low C3 or C4					0.9294
Yes	0/ 25 (0.0)	2/ 33 (6.1)	0.26 (0.01, 5.22)	0.3798	
No	0/ 44 (0.0)	1/ 42 (2.4)	0.32 (0.01, 7.61)	0.4798	
Baseline FARR anti-dsDNA					NE
<5 IU/mL	0/ 15 (0.0)	0/ 11 (0.0)	NE		
>=5 IU/mL	0/ 40 (0.0)	2/ 50 (4.0)	0.25 (0.01, 5.04)	0.3647	
Low complement (C3 or C4) and positive FARR anti-dsDNA					NE
Yes	0/ 50 (0.0)	3/ 60 (5.0)	0.17 (0.01, 3.23)	0.2388	
No	0/ 19 (0.0)	0/ 15 (0.0)	NE		
OCS use					NE
Yes	0/ 54 (0.0)	3/ 63 (4.8)	0.17 (0.01, 3.15)	0.2318	
No	0/ 15 (0.0)	0/ 12 (0.0)	NE		
SLICC score					NE
0	0/ 40 (0.0)	3/ 48 (6.3)	0.17 (0.01, 3.21)	0.2377	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Vasculitis - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
>=1	0/ 29 (0.0)	0/ 27 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Vasculitis
Safety analysis set

	Anifrolumab 300mg (N=69)	Placebo (N=75)
Number of subjects with events, n (%)	0 (0.0)	2 (2.7)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.22 (0.01, 4.44)	
p-value	0.3214	
Odds Ratio (95% CI)	0.21 (0.01, 4.48)	
p-value	0.3188	
Risk Difference (95% CI)	-2.67 (-6.31, 0.98)	
p-value	0.1517	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Vasculitis - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.9914
< 10 points	0/ 29 (0.0)	1/ 32 (3.1)	0.37 (0.02, 8.66)	0.5340	
>= 10 points	0/ 40 (0.0)	1/ 43 (2.3)	0.36 (0.01, 8.54)	0.5253	
OCS dose					0.8544
<10 mg/day	0/ 33 (0.0)	1/ 28 (3.6)	0.28 (0.01, 6.72)	0.4356	
>=10 mg/day	0/ 36 (0.0)	1/ 47 (2.1)	0.43 (0.02, 10.31)	0.6044	
Result of type I IFN gene signature test					NE
LOW	0/ 14 (0.0)	0/ 19 (0.0)	NE		
HIGH	0/ 55 (0.0)	2/ 56 (3.6)	0.20 (0.01, 4.15)	0.3006	
Age (years)					0.9777
<= 45	0/ 45 (0.0)	1/ 50 (2.0)	0.37 (0.02, 8.85)	0.5390	
> 45	0/ 24 (0.0)	1/ 25 (4.0)	0.35 (0.01, 8.12)	0.5102	
Sex					NE
male	0/ 4 (0.0)	0/ 6 (0.0)	NE		
female	0/ 65 (0.0)	2/ 69 (2.9)	0.21 (0.01, 4.34)	0.3139	
Race					0.6970
White	0/ 25 (0.0)	0/ 31 (0.0)	NE		
Black	0/ 16 (0.0)	1/ 8 (12.5)	0.18 (0.01, 3.91)	0.2723	
Other	0/ 28 (0.0)	1/ 36 (2.8)	0.43 (0.02, 10.06)	0.5963	
Ethnicity					NE
Hispanic/Latino	0/ 28 (0.0)	0/ 28 (0.0)	NE		
Non-hispanic/Latino	0/ 41 (0.0)	2/ 47 (4.3)	0.23 (0.01, 4.63)	0.3362	
Geographic region					0.8708
Latin America, Eastern Europe and Asia	0/ 45 (0.0)	1/ 55 (1.8)	0.41 (0.02, 9.73)	0.5779	
North America	0/ 24 (0.0)	1/ 20 (5.0)	0.28 (0.01, 6.52)	0.4280	
Baseline weight					0.7705
<60 kg	0/ 18 (0.0)	1/ 31 (3.2)	0.56 (0.02, 13.10)	0.7194	
>=60 kg	0/ 51 (0.0)	1/ 44 (2.3)	0.29 (0.01, 6.91)	0.4429	
Low CH50					NE
Yes	0/ 9 (0.0)	0/ 10 (0.0)	NE		
No	0/ 60 (0.0)	2/ 65 (3.1)	0.22 (0.01, 4.42)	0.3199	
Low C3 or C4					0.8908
Yes	0/ 25 (0.0)	1/ 33 (3.0)	0.44 (0.02, 10.27)	0.6065	
No	0/ 44 (0.0)	1/ 42 (2.4)	0.32 (0.01, 7.61)	0.4798	
Baseline FARR anti-dsDNA					NE
<5 IU/mL	0/ 15 (0.0)	0/ 11 (0.0)	NE		
>=5 IU/mL	0/ 40 (0.0)	2/ 50 (4.0)	0.25 (0.01, 5.04)	0.3647	
Low complement (C3 or C4) and positive FARR anti-dsDNA					NE
Yes	0/ 50 (0.0)	2/ 60 (3.3)	0.24 (0.01, 4.87)	0.3522	
No	0/ 19 (0.0)	0/ 15 (0.0)	NE		
OCS use					NE
Yes	0/ 54 (0.0)	2/ 63 (3.2)	0.23 (0.01, 4.74)	0.3433	
No	0/ 15 (0.0)	0/ 12 (0.0)	NE		
SLICC score					NE
0	0/ 40 (0.0)	2/ 48 (4.2)	0.24 (0.01, 4.84)	0.3510	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Vasculitis - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
>=1	0/ 29 (0.0)	0/ 27 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Vasculitis
Safety analysis set

	Anifrolumab 300mg (N=69)	Placebo (N=75)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Vasculitis - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
SLEDAI-2K score				NE
< 10 points	0/ 29 (0.0)	0/ 32 (0.0)	NE	
>= 10 points	0/ 40 (0.0)	0/ 43 (0.0)	NE	
OCS dose				NE
<10 mg/day	0/ 33 (0.0)	0/ 28 (0.0)	NE	
>=10 mg/day	0/ 36 (0.0)	0/ 47 (0.0)	NE	
Result of type I IFN gene signature test				NE
LOW	0/ 14 (0.0)	0/ 19 (0.0)	NE	
HIGH	0/ 55 (0.0)	0/ 56 (0.0)	NE	
Age (years)				NE
<= 45	0/ 45 (0.0)	0/ 50 (0.0)	NE	
> 45	0/ 24 (0.0)	0/ 25 (0.0)	NE	
Sex				NE
male	0/ 4 (0.0)	0/ 6 (0.0)	NE	
female	0/ 65 (0.0)	0/ 69 (0.0)	NE	
Race				NE
White	0/ 25 (0.0)	0/ 31 (0.0)	NE	
Black	0/ 16 (0.0)	0/ 8 (0.0)	NE	
Other	0/ 28 (0.0)	0/ 36 (0.0)	NE	
Ethnicity				NE
Hispanic/Latino	0/ 28 (0.0)	0/ 28 (0.0)	NE	
Non-hispanic/Latino	0/ 41 (0.0)	0/ 47 (0.0)	NE	
Geographic region				NE
Latin America, Eastern Europe and Asia	0/ 45 (0.0)	0/ 55 (0.0)	NE	
North America	0/ 24 (0.0)	0/ 20 (0.0)	NE	
Baseline weight				NE
<60 kg	0/ 18 (0.0)	0/ 31 (0.0)	NE	
>=60 kg	0/ 51 (0.0)	0/ 44 (0.0)	NE	
Low CH50				NE
Yes	0/ 9 (0.0)	0/ 10 (0.0)	NE	
No	0/ 60 (0.0)	0/ 65 (0.0)	NE	
Low C3 or C4				NE
Yes	0/ 25 (0.0)	0/ 33 (0.0)	NE	
No	0/ 44 (0.0)	0/ 42 (0.0)	NE	
Baseline FARR anti-dsDNA				NE
<5 IU/mL	0/ 15 (0.0)	0/ 11 (0.0)	NE	
>=5 IU/mL	0/ 40 (0.0)	0/ 50 (0.0)	NE	
Low complement (C3 or C4) and positive FARR anti-dsDNA				NE
Yes	0/ 50 (0.0)	0/ 60 (0.0)	NE	
No	0/ 19 (0.0)	0/ 15 (0.0)	NE	
OCS use				NE
Yes	0/ 54 (0.0)	0/ 63 (0.0)	NE	
No	0/ 15 (0.0)	0/ 12 (0.0)	NE	
SLICC score				NE
0	0/ 40 (0.0)	0/ 48 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Vasculitis - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
>=1	0/ 29 (0.0)	0/ 27 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Vasculitis
Safety analysis set

	Anifrolumab 300mg (N=69)	Placebo (N=75)
Number of subjects with events, n (%)	0 (0.0)	3 (4.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.16 (0.01, 2.95)	
p-value	0.2149	
Odds Ratio (95% CI)	0.15 (0.01, 2.94)	
p-value	0.2108	
Risk Difference (95% CI)	-4.00 (-8.43, 0.43)	
p-value	0.0771	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Vasculitis - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.8099
< 10 points	0/ 29 (0.0)	1/ 32 (3.1)	0.37 (0.02, 8.66)	0.5340	
>= 10 points	0/ 40 (0.0)	2/ 43 (4.7)	0.21 (0.01, 4.34)	0.3158	
OCS dose					0.9672
<10 mg/day	0/ 33 (0.0)	1/ 28 (3.6)	0.28 (0.01, 6.72)	0.4356	
>=10 mg/day	0/ 36 (0.0)	2/ 47 (4.3)	0.26 (0.01, 5.24)	0.3790	
Result of type I IFN gene signature test					NE
LOW	0/ 14 (0.0)	0/ 19 (0.0)	NE		
HIGH	0/ 55 (0.0)	3/ 56 (5.4)	0.15 (0.01, 2.75)	0.1987	
Age (years)					0.8408
<= 45	0/ 45 (0.0)	2/ 50 (4.0)	0.22 (0.01, 4.50)	0.3267	
> 45	0/ 24 (0.0)	1/ 25 (4.0)	0.35 (0.01, 8.12)	0.5102	
Sex					NE
male	0/ 4 (0.0)	0/ 6 (0.0)	NE		
female	0/ 65 (0.0)	3/ 69 (4.3)	0.15 (0.01, 2.88)	0.2090	
Race					0.8668
White	0/ 25 (0.0)	0/ 31 (0.0)	NE		
Black	0/ 16 (0.0)	1/ 8 (12.5)	0.18 (0.01, 3.91)	0.2723	
Other	0/ 28 (0.0)	2/ 36 (5.6)	0.26 (0.01, 5.11)	0.3718	
Ethnicity					0.8654
Hispanic/Latino	0/ 28 (0.0)	1/ 28 (3.6)	0.33 (0.01, 7.85)	0.4955	
Non-hispanic/Latino	0/ 41 (0.0)	2/ 47 (4.3)	0.23 (0.01, 4.63)	0.3362	
Geographic region					0.9499
Latin America, Eastern Europe and Asia	0/ 45 (0.0)	2/ 55 (3.6)	0.24 (0.01, 4.95)	0.3578	
North America	0/ 24 (0.0)	1/ 20 (5.0)	0.28 (0.01, 6.52)	0.4280	
Baseline weight					0.9444
<60 kg	0/ 18 (0.0)	2/ 31 (6.5)	0.34 (0.02, 6.65)	0.4746	
>=60 kg	0/ 51 (0.0)	1/ 44 (2.3)	0.29 (0.01, 6.91)	0.4429	
Low CH50					NE
Yes	0/ 9 (0.0)	0/ 10 (0.0)	NE		
No	0/ 60 (0.0)	3/ 65 (4.6)	0.15 (0.01, 2.93)	0.2136	
Low C3 or C4					0.9294
Yes	0/ 25 (0.0)	2/ 33 (6.1)	0.26 (0.01, 5.22)	0.3798	
No	0/ 44 (0.0)	1/ 42 (2.4)	0.32 (0.01, 7.61)	0.4798	
Baseline FARR anti-dsDNA					NE
<5 IU/mL	0/ 15 (0.0)	0/ 11 (0.0)	NE		
>=5 IU/mL	0/ 40 (0.0)	2/ 50 (4.0)	0.25 (0.01, 5.04)	0.3647	
Low complement (C3 or C4) and positive FARR anti-dsDNA					NE
Yes	0/ 50 (0.0)	3/ 60 (5.0)	0.17 (0.01, 3.23)	0.2388	
No	0/ 19 (0.0)	0/ 15 (0.0)	NE		
OCS use					NE
Yes	0/ 54 (0.0)	3/ 63 (4.8)	0.17 (0.01, 3.15)	0.2318	
No	0/ 15 (0.0)	0/ 12 (0.0)	NE		
SLICC score					NE
0	0/ 40 (0.0)	3/ 48 (6.3)	0.17 (0.01, 3.21)	0.2377	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Vasculitis - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
>=1	0/ 29 (0.0)	0/ 27 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Malignancy
Safety analysis set

	Anifrolumab 300mg (N=69)	Placebo (N=75)
Number of subjects with events, n (%)	1 (1.4)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.26 (0.13, 78.65)	
p-value	0.4673	
Odds Ratio (95% CI)	3.31 (0.13, 82.53)	
p-value	0.4663	
Risk Difference (95% CI)	1.45 (-1.37, 4.27)	
p-value	0.3138	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Malignancy - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					NE
< 10 points	1/ 29 (3.4)	0/ 32 (0.0)	3.30 (0.14, 77.95)	0.4593	
>= 10 points	0/ 40 (0.0)	0/ 43 (0.0)	NE		
OCS dose					NE
<10 mg/day	1/ 33 (3.0)	0/ 28 (0.0)	2.56 (0.11, 60.44)	0.5603	
>=10 mg/day	0/ 36 (0.0)	0/ 47 (0.0)	NE		
Result of type I IFN gene signature test					NE
LOW	1/ 14 (7.1)	0/ 19 (0.0)	4.00 (0.17, 91.48)	0.3853	
HIGH	0/ 55 (0.0)	0/ 56 (0.0)	NE		
Age (years)					NE
<= 45	0/ 45 (0.0)	0/ 50 (0.0)	NE		
> 45	1/ 24 (4.2)	0/ 25 (0.0)	3.12 (0.13, 73.04)	0.4794	
Sex					NE
male	0/ 4 (0.0)	0/ 6 (0.0)	NE		
female	1/ 65 (1.5)	0/ 69 (0.0)	3.18 (0.13, 76.73)	0.4760	
Race					NE
White	1/ 25 (4.0)	0/ 31 (0.0)	3.69 (0.16, 86.90)	0.4176	
Black	0/ 16 (0.0)	0/ 8 (0.0)	NE		
Other	0/ 28 (0.0)	0/ 36 (0.0)	NE		
Ethnicity					NE
Hispanic/Latino	0/ 28 (0.0)	0/ 28 (0.0)	NE		
Non-hispanic/Latino	1/ 41 (2.4)	0/ 47 (0.0)	3.43 (0.14, 81.93)	0.4467	
Geographic region					NE
Latin America, Eastern Europe and Asia	0/ 45 (0.0)	0/ 55 (0.0)	NE		
North America	1/ 24 (4.2)	0/ 20 (0.0)	2.52 (0.11, 58.67)	0.5649	
Baseline weight					NE
<60 kg	0/ 18 (0.0)	0/ 31 (0.0)	NE		
>=60 kg	1/ 51 (2.0)	0/ 44 (0.0)	2.60 (0.11, 62.16)	0.5560	
Low CH50					NE
Yes	0/ 9 (0.0)	0/ 10 (0.0)	NE		
No	1/ 60 (1.7)	0/ 65 (0.0)	3.25 (0.13, 78.18)	0.4683	
Low C3 or C4					NE
Yes	0/ 25 (0.0)	0/ 33 (0.0)	NE		
No	1/ 44 (2.3)	0/ 42 (0.0)	2.87 (0.12, 68.47)	0.5154	
Baseline FARR anti-dsDNA					NE
<5 IU/mL	0/ 15 (0.0)	0/ 11 (0.0)	NE		
>=5 IU/mL	1/ 40 (2.5)	0/ 50 (0.0)	3.73 (0.16, 89.21)	0.4161	
Low complement (C3 or C4) and positive FARR anti-dsDNA					NE
Yes	1/ 50 (2.0)	0/ 60 (0.0)	3.59 (0.15, 86.19)	0.4308	
No	0/ 19 (0.0)	0/ 15 (0.0)	NE		
OCS use					NE
Yes	0/ 54 (0.0)	0/ 63 (0.0)	NE		
No	1/ 15 (6.7)	0/ 12 (0.0)	2.44 (0.11, 54.97)	0.5752	
SLICC score					NE
0	0/ 40 (0.0)	0/ 48 (0.0)	NE		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Malignancy - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
>=1	1/ 29 (3.4)	0/ 27 (0.0)	2.80 (0.12, 65.93)	0.5229	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Malignancy
Safety analysis set

	Anifrolumab 300mg (N=69)	Placebo (N=75)
Number of subjects with events, n (%)	1 (1.4)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.26 (0.13, 78.65)	
p-value	0.4673	
Odds Ratio (95% CI)	3.31 (0.13, 82.53)	
p-value	0.4663	
Risk Difference (95% CI)	1.45 (-1.37, 4.27)	
p-value	0.3138	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Malignancy - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					NE
< 10 points	1/ 29 (3.4)	0/ 32 (0.0)	3.30 (0.14, 77.95)	0.4593	
>= 10 points	0/ 40 (0.0)	0/ 43 (0.0)	NE		
OCS dose					NE
<10 mg/day	1/ 33 (3.0)	0/ 28 (0.0)	2.56 (0.11, 60.44)	0.5603	
>=10 mg/day	0/ 36 (0.0)	0/ 47 (0.0)	NE		
Result of type I IFN gene signature test					NE
LOW	1/ 14 (7.1)	0/ 19 (0.0)	4.00 (0.17, 91.48)	0.3853	
HIGH	0/ 55 (0.0)	0/ 56 (0.0)	NE		
Age (years)					NE
<= 45	0/ 45 (0.0)	0/ 50 (0.0)	NE		
> 45	1/ 24 (4.2)	0/ 25 (0.0)	3.12 (0.13, 73.04)	0.4794	
Sex					NE
male	0/ 4 (0.0)	0/ 6 (0.0)	NE		
female	1/ 65 (1.5)	0/ 69 (0.0)	3.18 (0.13, 76.73)	0.4760	
Race					NE
White	1/ 25 (4.0)	0/ 31 (0.0)	3.69 (0.16, 86.90)	0.4176	
Black	0/ 16 (0.0)	0/ 8 (0.0)	NE		
Other	0/ 28 (0.0)	0/ 36 (0.0)	NE		
Ethnicity					NE
Hispanic/Latino	0/ 28 (0.0)	0/ 28 (0.0)	NE		
Non-hispanic/Latino	1/ 41 (2.4)	0/ 47 (0.0)	3.43 (0.14, 81.93)	0.4467	
Geographic region					NE
Latin America, Eastern Europe and Asia	0/ 45 (0.0)	0/ 55 (0.0)	NE		
North America	1/ 24 (4.2)	0/ 20 (0.0)	2.52 (0.11, 58.67)	0.5649	
Baseline weight					NE
<60 kg	0/ 18 (0.0)	0/ 31 (0.0)	NE		
>=60 kg	1/ 51 (2.0)	0/ 44 (0.0)	2.60 (0.11, 62.16)	0.5560	
Low CH50					NE
Yes	0/ 9 (0.0)	0/ 10 (0.0)	NE		
No	1/ 60 (1.7)	0/ 65 (0.0)	3.25 (0.13, 78.18)	0.4683	
Low C3 or C4					NE
Yes	0/ 25 (0.0)	0/ 33 (0.0)	NE		
No	1/ 44 (2.3)	0/ 42 (0.0)	2.87 (0.12, 68.47)	0.5154	
Baseline FARR anti-dsDNA					NE
<5 IU/mL	0/ 15 (0.0)	0/ 11 (0.0)	NE		
>=5 IU/mL	1/ 40 (2.5)	0/ 50 (0.0)	3.73 (0.16, 89.21)	0.4161	
Low complement (C3 or C4) and positive FARR anti-dsDNA					NE
Yes	1/ 50 (2.0)	0/ 60 (0.0)	3.59 (0.15, 86.19)	0.4308	
No	0/ 19 (0.0)	0/ 15 (0.0)	NE		
OCS use					NE
Yes	0/ 54 (0.0)	0/ 63 (0.0)	NE		
No	1/ 15 (6.7)	0/ 12 (0.0)	2.44 (0.11, 54.97)	0.5752	
SLICC score					NE
0	0/ 40 (0.0)	0/ 48 (0.0)	NE		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Malignancy - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
>=1	1/ 29 (3.4)	0/ 27 (0.0)	2.80 (0.12, 65.93)	0.5229	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Malignancy
Safety analysis set

	Anifrolumab 300mg (N=69)	Placebo (N=75)
Number of subjects with events, n (%)	1 (1.4)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.26 (0.13, 78.65)	
p-value	0.4673	
Odds Ratio (95% CI)	3.31 (0.13, 82.53)	
p-value	0.4663	
Risk Difference (95% CI)	1.45 (-1.37, 4.27)	
p-value	0.3138	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Malignancy - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					NE
< 10 points	1/ 29 (3.4)	0/ 32 (0.0)	3.30 (0.14, 77.95)	0.4593	
>= 10 points	0/ 40 (0.0)	0/ 43 (0.0)	NE		
OCS dose					NE
<10 mg/day	1/ 33 (3.0)	0/ 28 (0.0)	2.56 (0.11, 60.44)	0.5603	
>=10 mg/day	0/ 36 (0.0)	0/ 47 (0.0)	NE		
Result of type I IFN gene signature test					NE
LOW	1/ 14 (7.1)	0/ 19 (0.0)	4.00 (0.17, 91.48)	0.3853	
HIGH	0/ 55 (0.0)	0/ 56 (0.0)	NE		
Age (years)					NE
<= 45	0/ 45 (0.0)	0/ 50 (0.0)	NE		
> 45	1/ 24 (4.2)	0/ 25 (0.0)	3.12 (0.13, 73.04)	0.4794	
Sex					NE
male	0/ 4 (0.0)	0/ 6 (0.0)	NE		
female	1/ 65 (1.5)	0/ 69 (0.0)	3.18 (0.13, 76.73)	0.4760	
Race					NE
White	1/ 25 (4.0)	0/ 31 (0.0)	3.69 (0.16, 86.90)	0.4176	
Black	0/ 16 (0.0)	0/ 8 (0.0)	NE		
Other	0/ 28 (0.0)	0/ 36 (0.0)	NE		
Ethnicity					NE
Hispanic/Latino	0/ 28 (0.0)	0/ 28 (0.0)	NE		
Non-hispanic/Latino	1/ 41 (2.4)	0/ 47 (0.0)	3.43 (0.14, 81.93)	0.4467	
Geographic region					NE
Latin America, Eastern Europe and Asia	0/ 45 (0.0)	0/ 55 (0.0)	NE		
North America	1/ 24 (4.2)	0/ 20 (0.0)	2.52 (0.11, 58.67)	0.5649	
Baseline weight					NE
<60 kg	0/ 18 (0.0)	0/ 31 (0.0)	NE		
>=60 kg	1/ 51 (2.0)	0/ 44 (0.0)	2.60 (0.11, 62.16)	0.5560	
Low CH50					NE
Yes	0/ 9 (0.0)	0/ 10 (0.0)	NE		
No	1/ 60 (1.7)	0/ 65 (0.0)	3.25 (0.13, 78.18)	0.4683	
Low C3 or C4					NE
Yes	0/ 25 (0.0)	0/ 33 (0.0)	NE		
No	1/ 44 (2.3)	0/ 42 (0.0)	2.87 (0.12, 68.47)	0.5154	
Baseline FARR anti-dsDNA					NE
<5 IU/mL	0/ 15 (0.0)	0/ 11 (0.0)	NE		
>=5 IU/mL	1/ 40 (2.5)	0/ 50 (0.0)	3.73 (0.16, 89.21)	0.4161	
Low complement (C3 or C4) and positive FARR anti-dsDNA					NE
Yes	1/ 50 (2.0)	0/ 60 (0.0)	3.59 (0.15, 86.19)	0.4308	
No	0/ 19 (0.0)	0/ 15 (0.0)	NE		
OCS use					NE
Yes	0/ 54 (0.0)	0/ 63 (0.0)	NE		
No	1/ 15 (6.7)	0/ 12 (0.0)	2.44 (0.11, 54.97)	0.5752	
SLICC score					NE
0	0/ 40 (0.0)	0/ 48 (0.0)	NE		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Malignancy - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
>=1	1/ 29 (3.4)	0/ 27 (0.0)	2.80 (0.12, 65.93)	0.5229	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Malignancy
Safety analysis set

	Anifrolumab 300mg (N=69)	Placebo (N=75)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Malignancy - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
SLEDAI-2K score				NE
< 10 points	0/ 29 (0.0)	0/ 32 (0.0)	NE	
>= 10 points	0/ 40 (0.0)	0/ 43 (0.0)	NE	
OCS dose				NE
<10 mg/day	0/ 33 (0.0)	0/ 28 (0.0)	NE	
>=10 mg/day	0/ 36 (0.0)	0/ 47 (0.0)	NE	
Result of type I IFN gene signature test				NE
LOW	0/ 14 (0.0)	0/ 19 (0.0)	NE	
HIGH	0/ 55 (0.0)	0/ 56 (0.0)	NE	
Age (years)				NE
<= 45	0/ 45 (0.0)	0/ 50 (0.0)	NE	
> 45	0/ 24 (0.0)	0/ 25 (0.0)	NE	
Sex				NE
male	0/ 4 (0.0)	0/ 6 (0.0)	NE	
female	0/ 65 (0.0)	0/ 69 (0.0)	NE	
Race				NE
White	0/ 25 (0.0)	0/ 31 (0.0)	NE	
Black	0/ 16 (0.0)	0/ 8 (0.0)	NE	
Other	0/ 28 (0.0)	0/ 36 (0.0)	NE	
Ethnicity				NE
Hispanic/Latino	0/ 28 (0.0)	0/ 28 (0.0)	NE	
Non-hispanic/Latino	0/ 41 (0.0)	0/ 47 (0.0)	NE	
Geographic region				NE
Latin America, Eastern Europe and Asia	0/ 45 (0.0)	0/ 55 (0.0)	NE	
North America	0/ 24 (0.0)	0/ 20 (0.0)	NE	
Baseline weight				NE
<60 kg	0/ 18 (0.0)	0/ 31 (0.0)	NE	
>=60 kg	0/ 51 (0.0)	0/ 44 (0.0)	NE	
Low CH50				NE
Yes	0/ 9 (0.0)	0/ 10 (0.0)	NE	
No	0/ 60 (0.0)	0/ 65 (0.0)	NE	
Low C3 or C4				NE
Yes	0/ 25 (0.0)	0/ 33 (0.0)	NE	
No	0/ 44 (0.0)	0/ 42 (0.0)	NE	
Baseline FARR anti-dsDNA				NE
<5 IU/mL	0/ 15 (0.0)	0/ 11 (0.0)	NE	
>=5 IU/mL	0/ 40 (0.0)	0/ 50 (0.0)	NE	
Low complement (C3 or C4) and positive FARR anti-dsDNA				NE
Yes	0/ 50 (0.0)	0/ 60 (0.0)	NE	
No	0/ 19 (0.0)	0/ 15 (0.0)	NE	
OCS use				NE
Yes	0/ 54 (0.0)	0/ 63 (0.0)	NE	
No	0/ 15 (0.0)	0/ 12 (0.0)	NE	
SLICC score				NE
0	0/ 40 (0.0)	0/ 48 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Malignancy - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
>=1	0/ 29 (0.0)	0/ 27 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of SOCs Cardiac disorders and/or Vascular disorders
Safety analysis set

	Anifrolumab 300mg (N=69)	Placebo (N=75)
Number of subjects with events, n (%)	5 (7.2)	13 (17.3)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.42 (0.16, 1.11)	
p-value	0.0806	
Odds Ratio (95% CI)	0.37 (0.13, 1.11)	
p-value	0.0756	
Risk Difference (95% CI)	-10.09 (-20.61, 0.44)	
p-value	0.0604	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of SOCs Cardiac disorders and/or Vascular disorders - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	 p-Value	Interaction p-Value
SLEDAI-2K score					0.4424
< 10 points	2/ 29 (6.9)	3/ 32 (9.4)	0.74 (0.13, 4.10)	0.7260	
>= 10 points	3/ 40 (7.5)	10/ 43 (23.3)	0.32 (0.10, 1.09)	0.0682	
OCS dose					0.4496
<10 mg/day	3/ 33 (9.1)	4/ 28 (14.3)	0.64 (0.16, 2.61)	0.5297	
>=10 mg/day	2/ 36 (5.6)	9/ 47 (19.1)	0.29 (0.07, 1.26)	0.0988	
Result of type I IFN gene signature test					0.3852
LOW	0/ 14 (0.0)	4/ 19 (21.1)	0.15 (0.01, 2.55)	0.1882	
HIGH	5/ 55 (9.1)	9/ 56 (16.1)	0.57 (0.20, 1.58)	0.2773	
Age (years)					0.5364
<= 45	3/ 45 (6.7)	6/ 50 (12.0)	0.56 (0.15, 2.09)	0.3850	
> 45	2/ 24 (8.3)	7/ 25 (28.0)	0.30 (0.07, 1.29)	0.1057	
Sex					0.9734
male	0/ 4 (0.0)	1/ 6 (16.7)	0.47 (0.02, 9.26)	0.6171	
female	5/ 65 (7.7)	12/ 69 (17.4)	0.44 (0.16, 1.19)	0.1052	
Race					0.2031
White	0/ 25 (0.0)	8/ 31 (25.8)	0.07 (0.00, 1.20)	0.0665	
Black	2/ 16 (12.5)	2/ 8 (25.0)	0.50 (0.09, 2.93)	0.4419	
Other	3/ 28 (10.7)	3/ 36 (8.3)	1.29 (0.28, 5.89)	0.7462	
Ethnicity					0.0843
Hispanic/Latino	3/ 28 (10.7)	2/ 28 (7.1)	1.50 (0.27, 8.30)	0.6423	
Non-hispanic/Latino	2/ 41 (4.9)	11/ 47 (23.4)	0.21 (0.05, 0.89)	0.0337	
Geographic region					0.2794
Latin America, Eastern Europe and Asia	4/ 45 (8.9)	8/ 55 (14.5)	0.61 (0.20, 1.90)	0.3946	
North America	1/ 24 (4.2)	5/ 20 (25.0)	0.17 (0.02, 1.31)	0.0888	
Baseline weight					0.3111
<60 kg	0/ 18 (0.0)	6/ 31 (19.4)	0.13 (0.01, 2.17)	0.1555	
>=60 kg	5/ 51 (9.8)	7/ 44 (15.9)	0.62 (0.21, 1.80)	0.3772	
Low CH50					0.4155
Yes	2/ 9 (22.2)	3/ 10 (30.0)	0.74 (0.16, 3.48)	0.7036	
No	3/ 60 (5.0)	10/ 65 (15.4)	0.33 (0.09, 1.12)	0.0760	
Low C3 or C4					0.1378
Yes	3/ 25 (12.0)	4/ 33 (12.1)	0.99 (0.24, 4.03)	0.9888	
No	2/ 44 (4.5)	9/ 42 (21.4)	0.21 (0.05, 0.93)	0.0390	
Baseline FARR anti-dsDNA					0.3735
<5 IU/mL	0/ 15 (0.0)	4/ 11 (36.4)	0.08 (0.00, 1.40)	0.0846	
>=5 IU/mL	2/ 40 (5.0)	7/ 50 (14.0)	0.36 (0.08, 1.63)	0.1830	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.4099
Yes	4/ 50 (8.0)	9/ 60 (15.0)	0.53 (0.17, 1.63)	0.2698	
No	1/ 19 (5.3)	4/ 15 (26.7)	0.20 (0.02, 1.59)	0.1270	
OCS use					0.1959
Yes	3/ 54 (5.6)	12/ 63 (19.0)	0.29 (0.09, 0.98)	0.0463	
No	2/ 15 (13.3)	1/ 12 (8.3)	1.60 (0.16, 15.60)	0.6858	
SLICC score					0.9981
0	2/ 40 (5.0)	6/ 48 (12.5)	0.40 (0.09, 1.87)	0.2449	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of SOCs Cardiac disorders and/or Vascular disorders - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
>=1	3/ 29 (10.3)	7/ 27 (25.9)	0.40 (0.11, 1.39)	0.1487	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Safety analysis set

SOC / PT		Anifrolumab 300mg (N=69)	Placebo (N=75)
SOC: Eye disorders	Number of subjects with events, n (%)	9 (13.0)	2 (2.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	4.89 (1.09, 21.85)	
	p-value	0.0377	
	Odds Ratio (95% CI)	5.47 (1.14, 26.31)	
	p-value	0.0338	
	Risk Difference (95% CI)	10.38 (1.63, 19.12)	
	p-value	0.0200	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Safety analysis set

SOC / PT		Anifrolumab 300mg (N=69)	Placebo (N=75)
SOC: Gastrointestinal disorders	Number of subjects with events, n (%)	17 (24.6)	12 (16.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.54 (0.79, 2.99)	
	p-value	0.2017	
	Odds Ratio (95% CI)	1.72 (0.75, 3.92)	
	p-value	0.1995	
	Risk Difference (95% CI)	8.64 (-4.49, 21.76)	
	p-value	0.1970	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Safety analysis set

SOC / PT		Anifrolumab 300mg (N=69)	Placebo (N=75)
SOC: General disorders and administration site conditions	Number of subjects with events, n (%)	5 (7.2)	9 (12.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.60 (0.21, 1.71)	
	p-value	0.3433	
	Odds Ratio (95% CI)	0.57 (0.18, 1.80)	
	p-value	0.3408	
	Risk Difference (95% CI)	-4.75 (-14.32, 4.81)	
	p-value	0.3301	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Safety analysis set

SOC / PT		Anifrolumab 300mg (N=69)	Placebo (N=75)
SOC: Infections and infestations	Number of subjects with events, n (%)	44 (63.8)	39 (52.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.23 (0.93, 1.62)	
	p-value	0.1546	
	Odds Ratio (95% CI)	1.62 (0.83, 3.17)	
	p-value	0.1545	
	Risk Difference (95% CI)	11.77 (-4.25, 27.78)	
	p-value	0.1498	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Safety analysis set

SOC / PT		Anifrolumab 300mg (N=69)	Placebo (N=75)
SOC: Infections and infestations, PT: Nasopharyngitis	Number of subjects with events, n (%)	9 (13.0)	3 (4.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	3.26 (0.92, 11.55)	
	p-value	0.0671	
	Odds Ratio (95% CI)	3.60 (0.93, 13.90)	
	p-value	0.0631	
	Risk Difference (95% CI)	9.04 (-0.06, 18.14)	
	p-value	0.0514	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Safety analysis set

SOC / PT		Anifrolumab 300mg (N=69)	Placebo (N=75)
SOC: Infections and infestations, PT: Upper respiratory tract infection	Number of subjects with events, n (%)	9 (13.0)	8 (10.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.22 (0.50, 2.99)	
	p-value	0.6594	
	Odds Ratio (95% CI)	1.26 (0.46, 3.46)	
	p-value	0.6593	
	Risk Difference (95% CI)	2.38 (-8.20, 12.96)	
	p-value	0.6597	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Safety analysis set

SOC / PT		Anifrolumab 300mg (N=69)	Placebo (N=75)
SOC: Infections and infestations, PT: Urinary tract infection	Number of subjects with events, n (%)	7 (10.1)	8 (10.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.95 (0.36, 2.48)	
	p-value	0.9185	
	Odds Ratio (95% CI)	0.95 (0.32, 2.76)	
	p-value	0.9185	
	Risk Difference (95% CI)	-0.52 (-10.50, 9.46)	
	p-value	0.9184	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Safety analysis set

SOC / PT		Anifrolumab 300mg (N=69)	Placebo (N=75)
SOC: Injury, poisoning and procedural complications	Number of subjects with events, n (%)	10 (14.5)	8 (10.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.36 (0.57, 3.24)	
	p-value	0.4900	
	Odds Ratio (95% CI)	1.42 (0.53, 3.83)	
	p-value	0.4895	
	Risk Difference (95% CI)	3.83 (-7.03, 14.68)	
	p-value	0.4896	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Safety analysis set

SOC / PT		Anifrolumab 300mg (N=69)	Placebo (N=75)
SOC: Investigations	Number of subjects with events, n (%)	8 (11.6)	4 (5.3)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	2.17 (0.69, 6.90)	
	p-value	0.1875	
	Odds Ratio (95% CI)	2.33 (0.67, 8.11)	
	p-value	0.1845	
	Risk Difference (95% CI)	6.26 (-2.85, 15.37)	
	p-value	0.1778	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Safety analysis set

SOC / PT		Anifrolumab 300mg (N=69)	Placebo (N=75)
SOC: Metabolism and nutrition disorders	Number of subjects with events, n (%)	10 (14.5)	6 (8.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.81 (0.70, 4.72)	
	p-value	0.2240	
	Odds Ratio (95% CI)	1.95 (0.67, 5.68)	
	p-value	0.2216	
	Risk Difference (95% CI)	6.49 (-3.84, 16.82)	
	p-value	0.2179	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Safety analysis set

SOC / PT		Anifrolumab 300mg (N=69)	Placebo (N=75)
SOC: Musculoskeletal and connective tissue disorders	Number of subjects with events, n (%)	16 (23.2)	18 (24.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.97 (0.54, 1.74)	
	p-value	0.9088	
	Odds Ratio (95% CI)	0.96 (0.44, 2.07)	
	p-value	0.9088	
	Risk Difference (95% CI)	-0.81 (-14.69, 13.07)	
	p-value	0.9087	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Safety analysis set

SOC / PT		Anifrolumab 300mg (N=69)	Placebo (N=75)
SOC: Nervous system disorders	Number of subjects with events, n (%)	17 (24.6)	18 (24.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.03 (0.58, 1.83)	
	p-value	0.9290	
	Odds Ratio (95% CI)	1.04 (0.48, 2.22)	
	p-value	0.9290	
	Risk Difference (95% CI)	0.64 (-13.39, 14.67)	
	p-value	0.9290	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Safety analysis set

SOC / PT		Anifrolumab 300mg (N=69)	Placebo (N=75)
SOC: Nervous system disorders, PT: Headache	Number of subjects with events, n (%)	9 (13.0)	10 (13.3)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.98 (0.42, 2.26)	
	p-value	0.9591	
	Odds Ratio (95% CI)	0.98 (0.37, 2.56)	
	p-value	0.9591	
	Risk Difference (95% CI)	-0.29 (-11.35, 10.77)	
	p-value	0.9590	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Safety analysis set

SOC / PT		Anifrolumab 300mg (N=69)	Placebo (N=75)
SOC: Skin and subcutaneous tissue disorders	Number of subjects with events, n (%)	7 (10.1)	6 (8.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.27 (0.45, 3.59)	
	p-value	0.6545	
	Odds Ratio (95% CI)	1.30 (0.41, 4.07)	
	p-value	0.6544	
	Risk Difference (95% CI)	2.14 (-7.26, 11.55)	
	p-value	0.6549	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Safety analysis set

SOC / PT		Anifrolumab 300mg (N=69)	Placebo (N=75)
SOC: Vascular disorders	Number of subjects with events, n (%)	3 (4.3)	11 (14.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.30 (0.09, 1.02)	
	p-value	0.0535	
	Odds Ratio (95% CI)	0.26 (0.07, 0.99)	
	p-value	0.0486	
	Risk Difference (95% CI)	-10.32 (-19.66, -0.98)	
	p-value	0.0304	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Safety analysis set

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SOC: Eye disorders	SLEDAI-2K score					0.8820
	< 10 points	1/ 29 (3.4)	0/ 32 (0.0)	3.30 (0.14, 77.95)	0.4593	
	>= 10 points	8/ 40 (20.0)	2/ 43 (4.7)	4.30 (0.97, 19.05)	0.0548	
	OCS dose					0.6891
	<10 mg/day	1/ 33 (3.0)	0/ 28 (0.0)	2.56 (0.11, 60.44)	0.5603	
	>=10 mg/day	8/ 36 (22.2)	2/ 47 (4.3)	5.22 (1.18, 23.11)	0.0294	
	Result of type I IFN gene signature test					0.5401
	LOW	2/ 14 (14.3)	1/ 19 (5.3)	2.71 (0.27, 27.05)	0.3946	
	HIGH	7/ 55 (12.7)	1/ 56 (1.8)	7.13 (0.91, 56.03)	0.0619	
	Age (years)					0.6425
	<= 45	6/ 45 (13.3)	2/ 50 (4.0)	3.33 (0.71, 15.69)	0.1276	
	> 45	3/ 24 (12.5)	0/ 25 (0.0)	7.28 (0.40, 133.89)	0.1815	
	Sex					0.9949
	male	1/ 4 (25.0)	0/ 6 (0.0)	4.20 (0.21, 83.33)	0.3465	
	female	8/ 65 (12.3)	2/ 69 (2.9)	4.25 (0.94, 19.26)	0.0609	
	Race					0.4552
	White	3/ 25 (12.0)	2/ 31 (6.5)	1.86 (0.34, 10.28)	0.4769	
	Black	1/ 16 (6.3)	0/ 8 (0.0)	1.59 (0.07, 35.15)	0.7697	
	Other	5/ 28 (17.9)	0/ 36 (0.0)	14.03 (0.81, 243.59)	0.0697	
	Ethnicity					0.3501
	Hispanic/Latino	5/ 28 (17.9)	0/ 28 (0.0)	11.00 (0.64, 189.96)	0.0990	
	Non-hispanic/Latino	4/ 41 (9.8)	2/ 47 (4.3)	2.29 (0.44, 11.88)	0.3228	
	Geographic region					0.3019
	Latin America, Eastern Europe and Asia	7/ 45 (15.6)	1/ 55 (1.8)	8.56 (1.09, 66.99)	0.0409	
	North America	2/ 24 (8.3)	1/ 20 (5.0)	1.67 (0.16, 17.06)	0.6669	
	Baseline weight					0.9990
	<60 kg	3/ 18 (16.7)	1/ 31 (3.2)	5.17 (0.58, 46.04)	0.1412	
	>=60 kg	6/ 51 (11.8)	1/ 44 (2.3)	5.18 (0.65, 41.36)	0.1210	
	Low CH50					0.8247
	Yes	2/ 9 (22.2)	0/ 10 (0.0)	5.50 (0.30, 101.28)	0.2514	
	No	7/ 60 (11.7)	2/ 65 (3.1)	3.79 (0.82, 17.54)	0.0881	
	Low C3 or C4					0.2289
	Yes	5/ 25 (20.0)	0/ 33 (0.0)	14.38 (0.83, 248.60)	0.0667	
	No	4/ 44 (9.1)	2/ 42 (4.8)	1.91 (0.37, 9.88)	0.4407	
	Baseline FARR anti-dsDNA					0.2158
	<5 IU/mL	1/ 15 (6.7)	1/ 11 (9.1)	0.73 (0.05, 10.49)	0.8193	
	>=5 IU/mL	5/ 40 (12.5)	1/ 50 (2.0)	6.25 (0.76, 51.37)	0.0882	
	Low complement (C3 or C4) and positive FARR anti-dsDNA					0.4677
	Yes	6/ 50 (12.0)	1/ 60 (1.7)	7.20 (0.90, 57.83)	0.0633	
	No	3/ 19 (15.8)	1/ 15 (6.7)	2.37 (0.27, 20.53)	0.4339	
	OCS use					0.7130
	Yes	8/ 54 (14.8)	2/ 63 (3.2)	4.67 (1.03, 21.05)	0.0450	
	No	1/ 15 (6.7)	0/ 12 (0.0)	2.44 (0.11, 54.97)	0.5752	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Safety analysis set

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=69) n/ N (%)	Placebo (N=75) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SOC: Eye disorders	SLICC score					0.2441
	0	5/ 40 (12.5)	0/ 48 (0.0)	13.15 (0.75, 230.75)	0.0780	
	>=1	4/ 29 (13.8)	2/ 27 (7.4)	1.86 (0.37, 9.36)	0.4504	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Serious Adverse Events by SOC, PT (incidence in either arm >= 5% or >=10 patients)
Safety analysis set

SOC / PT		Anifrolumab 300mg (N=69)	Placebo (N=75)
SOC: Infections and infestations	Number of subjects with events, n (%)	6 (8.7)	6 (8.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.09 (0.37, 3.21)	
	p-value	0.8801	
	Odds Ratio (95% CI)	1.10 (0.34, 3.57)	
	p-value	0.8801	
	Risk Difference (95% CI)	0.70 (-8.35, 9.75)	
	p-value	0.8802	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Serious Adverse Events by SOC, PT (incidence in either arm >= 5% or >=10 patients)
Safety analysis set

SOC / PT		Anifrolumab 300mg (N=69)	Placebo (N=75)
SOC: Musculoskeletal and connective tissue disorders	Number of subjects with events, n (%)	2 (2.9)	4 (5.3)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.54 (0.10, 2.87)	
	p-value	0.4730	
	Odds Ratio (95% CI)	0.53 (0.09, 2.99)	
	p-value	0.4718	
	Risk Difference (95% CI)	-2.43 (-8.88, 4.01)	
	p-value	0.4590	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Serious Adverse Events by SOC, PT (incidence in either arm >= 5% or >=10 patients)
Safety analysis set

SOC / PT		Anifrolumab 300mg (N=69)	Placebo (N=75)
SOC: Musculoskeletal and connective tissue disorders, PT: Systemic lupus erythematosus	Number of subjects with events, n (%)	2 (2.9)	4 (5.3)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.54 (0.10, 2.87)	
	p-value	0.4730	
	Odds Ratio (95% CI)	0.53 (0.09, 2.99)	
	p-value	0.4718	
	Risk Difference (95% CI)	-2.43 (-8.88, 4.01)	
	p-value	0.4590	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Serious Adverse Events by SOC, PT (incidence in either arm >= 5% or >=10 patients)
Safety analysis set

SOC / PT		Anifrolumab 300mg (N=69)	Placebo (N=75)
SOC: Nervous system disorders	Number of subjects with events, n (%)	1 (1.4)	4 (5.3)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.27 (0.03, 2.37)	
	p-value	0.2386	
	Odds Ratio (95% CI)	0.26 (0.03, 2.39)	
	p-value	0.2349	
	Risk Difference (95% CI)	-3.88 (-9.70, 1.93)	
	p-value	0.1905	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Serious Adverse Events by SOC, PT (incidence in either arm >= 5% or >=10 patients) - Subgroup analysis
Safety analysis set

- NO OBSERVATIONS FOR THIS ANALYSIS -

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Severe (Grade >=3) by SOC, PT (incidence in either arm >= 5% or >=10 patients)
Safety analysis set

SOC / PT		Anifrolumab 300mg (N=69)	Placebo (N=75)
SOC: Infections and infestations	Number of subjects with events, n (%)	9 (13.0)	3 (4.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	3.26 (0.92, 11.55)	
	p-value	0.0671	
	Odds Ratio (95% CI)	3.60 (0.93, 13.90)	
	p-value	0.0631	
	Risk Difference (95% CI)	9.04 (-0.06, 18.14)	
	p-value	0.0514	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Severe (Grade >=3) by SOC, PT (incidence in either arm >= 5% or >=10 patients) - Subgroup analysis
Safety analysis set

- NO OBSERVATIONS FOR THIS ANALYSIS -

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Subject disposition and summary of treatment exposure
Full analysis set

		Anifrolumab 300mg (N=315)	Placebo (N=321)
Patients who completed the study		266 (84.4)	238 (74.1)
Patients withdrawn from the study		49 (15.6)	83 (25.9)
WITHDRAWAL BY SUBJECT		19 (6.0)	29 (9.0)
OTHER		13 (4.1)	22 (6.9)
ADVERSE EVENT		9 (2.9)	10 (3.1)
LACK OF EFFICACY		4 (1.3)	10 (3.1)
LOST TO FOLLOW-UP		2 (0.6)	8 (2.5)
CONDITION UNDER INVESTIGATION WORSENED		2 (0.6)	2 (0.6)
SEVERE NON-COMPLIANCE TO PROTOCOL		0	1 (0.3)
Duration of study (weeks)	n (missing)	315 (0)	321 (0)
	Mean (SD)	52.3 (11.38)	50.0 (13.13)
	Median	52.9	52.6
	Min, Max	0, 71	3, 71
Patients who completed investigational product		266 (84.4)	231 (72.0)
Patients discontinued investigational product		49 (15.6)	90 (28.0)
Withdrawal By Subject		15 (4.8)	24 (7.5)
Adverse Event		12 (3.8)	23 (7.2)
Lack Of Efficacy		5 (1.6)	13 (4.0)
Withdrawal Of Consent		1 (0.3)	9 (2.8)
Other		7 (2.2)	2 (0.6)
Condition Under Investigation Worsened		3 (1.0)	5 (1.6)
Lost To Follow-Up		1 (0.3)	5 (1.6)
Sponsor Decision, Regional Political Circumstances Preclude Site Activities		0	3 (0.9)
Severe Non-Compliance To Protocol		0	2 (0.6)
Inadequate Venous Access.		1 (0.3)	0
Investigator Decision Due To Exacerbation Of Her Disease.		0	1 (0.3)
Medical Decision, The Patient Has Been Presenting Various Infections In A Relatively Short Amount Of Time.		1 (0.3)	0
Patient Is Moving Away		0	1 (0.3)
Patient Withdrawn Consent, She Has Decided To Finish Treatment And Participation In The Study Due To Sae.		1 (0.3)	0
Pregnancy		0	1 (0.3)
Prohibited Concomitant Medications (Steroid Pulses)		1 (0.3)	0
Subject Called Did Not Want To Come In And See The Pi Any Longer Has Found A New Doctor. She Never Said She Wanted To Withdraw Consent.		0	1 (0.3)
Subject Missed Visit Day 337, But Was Approved To Continue On Study By Sponsor And Completed Remaining Visits.		1 (0.3)	0
Duration of exposure (weeks)	n (missing)	315 (0)	321 (0)
	Mean (SD)	47.9 (11.84)	44.7 (14.25)
	Median	52.1	52.1
	Min, Max	4, 57	4, 56

Duration of study defined as time from randomization until end of participation date.
Duration of exposure defined as difference of date of first exposure to treatment and date of last exposure to treatment + 28 days.
'Full Analysis Set' Referred to as 'mITT population' in the study 1013 CSR

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Demographic and baseline characteristics
Full analysis set

		Anifrolumab 300mg (N=315)	Placebo (N=321)	Total (N=636)
Age	n (missing)	315 (0)	321 (0)	636 (0)
	Mean (SD)	42.0 (11.85)	40.8 (11.91)	41.4 (11.89)
	Median	41.0	41.0	41.0
	Min, Max	18, 68	18, 69	18, 69
Age (years) (%)	<= 65	308 (97.8)	318 (99.1)	626 (98.4)
	> 65	7 (2.2)	3 (0.9)	10 (1.6)
Sex (%) (%)	female	288 (91.4)	295 (91.9)	583 (91.7)
	male	27 (8.6)	26 (8.1)	53 (8.3)
Race (%) (%)	American Indian or Alaska Native	3 (1.0)	1 (0.3)	4 (0.6)
	Asian	26 (8.3)	29 (9.0)	55 (8.6)
	Black or African American	49 (15.6)	40 (12.5)	89 (14.0)
	Other	44 (14.0)	43 (13.4)	87 (13.7)
	White	185 (58.7)	205 (63.9)	390 (61.3)
	Missing	8 (2.5)	3 (0.9)	11 (1.7)
Ethnicity (%) (%)	Hispanic/Latino	78 (24.8)	84 (26.2)	162 (25.5)
	Non-hispanic/Latino	229 (72.7)	234 (72.9)	463 (72.8)
	Missing	8 (2.5)	3 (0.9)	11 (1.7)
Geographic region (%) (%)	Asia Pacific	22 (7.0)	25 (7.8)	47 (7.4)
	Europe	110 (34.9)	109 (34.0)	219 (34.4)
	Latin America	58 (18.4)	58 (18.1)	116 (18.2)
	North America	119 (37.8)	120 (37.4)	239 (37.6)
	Rest Of World	6 (1.9)	9 (2.8)	15 (2.4)
Geographic region subgroup (%)	EU	110 (34.9)	109 (34.0)	219 (34.4)
	non-EU	205 (65.1)	212 (66.0)	417 (65.6)
Height (cm)	n (missing)	315 (0)	321 (0)	636 (0)
	Mean (SD)	163.03 (8.179)	162.88 (7.973)	162.95 (8.070)
	Median	162.60	163.00	162.60
	Min, Max	145.0, 198.0	140.0, 195.0	140.0, 198.0
Weight (kg)	n (missing)	315 (0)	321 (0)	636 (0)
	Mean (SD)	73.56 (19.334)	71.82 (18.737)	72.68 (19.040)
	Median	70.00	67.60	68.95
	Min, Max	42.0, 132.7	40.0, 139.3	40.0, 139.3
BMI (kg/m2)	n (missing)	315 (0)	321 (0)	636 (0)
	Mean (SD)	27.61 (6.736)	27.07 (6.852)	27.34 (6.795)
	Median	25.91	25.59	25.69
	Min, Max	16.0, 49.8	16.1, 57.5	16.0, 57.5
BMI subgroup (%)	<=28 kg/m2	184 (58.4)	207 (64.5)	391 (61.5)
	>28 kg/m2	131 (41.6)	114 (35.5)	245 (38.5)

[a] Asia Pacific: Australia, New Zealand, South Korea, Taiwan. Europe: Germany, Hungary, Italy, Poland, Romania, Ukraine, United Kingdom. Latin America: Argentinia, Brazil, Chile, Colombia, Peru. Rest of World: India, Israel, South Africa.
Missing/multiple categories checked for Race grouped as 'Other'.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SLE disease characteristics
Full analysis set

		Anifrolumab 300mg (N=315)	Placebo (N=321)	Total (N=636)
SLEDAI-2K score at screening	n (missing)	315 (0)	321 (0)	636 (0)
	Mean (SD)	11.2 (3.88)	11.1 (3.73)	11.1 (3.80)
	Median	10.0	10.0	10.0
	Min, Max	6, 25	6, 37	6, 37
SLEDAI-2K score at screening, categorisation (%)	<10	109 (34.6)	101 (31.5)	210 (33.0)
	>=10	206 (65.4)	220 (68.5)	426 (67.0)
Clinical SLEDAI-2K score at screening	n (missing)	315 (0)	321 (0)	636 (0)
	Mean (SD)	8.7 (2.96)	8.6 (2.70)	8.7 (2.83)
	Median	8.0	8.0	8.0
	Min, Max	4, 20	4, 21	4, 21
SLEDAI-2K score at baseline	n (missing)	315 (0)	321 (0)	636 (0)
	Mean (SD)	11.2 (3.83)	11.3 (3.87)	11.2 (3.85)
	Median	10.0	10.0	10.0
	Min, Max	4, 32	4, 29	4, 32
SLEDAI-2K score at baseline, categorisation (%)	<10	107 (34.0)	101 (31.5)	208 (32.7)
	>=10	208 (66.0)	220 (68.5)	428 (67.3)
Clinical SLEDAI-2K score at baseline	n (missing)	315 (0)	321 (0)	636 (0)
	Mean (SD)	8.8 (2.89)	8.9 (2.76)	8.8 (2.82)
	Median	8.0	8.0	8.0
	Min, Max	4, 20	4, 20	4, 20
Adjudication Scoring (BILAG) at baseline Overall (%)	At least one A	143 (45.4)	157 (48.9)	300 (47.2)
	No A and <2Bs	16 (5.1)	21 (6.5)	37 (5.8)
	No A and at least 2 Bs	156 (49.5)	143 (44.5)	299 (47.0)
Adjudication Scoring (BILAG) at baseline Constitutional (%)	A	2 (0.6)	0	2 (0.3)
	B	18 (5.7)	18 (5.6)	36 (5.7)
	C, D or E	295 (93.7)	303 (94.4)	598 (94.0)
Adjudication Scoring (BILAG) at baseline Mucocutaneous (%)	A	70 (22.2)	68 (21.2)	138 (21.7)
	B	206 (65.4)	203 (63.2)	409 (64.3)
	C, D or E	39 (12.4)	50 (15.6)	89 (14.0)
Adjudication Scoring (BILAG) at baseline Neuropsychiatric (%)	B	5 (1.6)	5 (1.6)	10 (1.6)
	C, D or E	310 (98.4)	316 (98.4)	626 (98.4)
Adjudication Scoring (BILAG) at baseline Musculoskeletal (%)	A	89 (28.3)	98 (30.5)	187 (29.4)
	B	190 (60.3)	194 (60.4)	384 (60.4)
	C, D or E	36 (11.4)	29 (9.0)	65 (10.2)
Adjudication Scoring (BILAG) at baseline Cardiorespiratory (%)	A	2 (0.6)	2 (0.6)	4 (0.6)
	B	15 (4.8)	19 (5.9)	34 (5.3)
	C, D or E	298 (94.6)	300 (93.5)	598 (94.0)
Adjudication Scoring (BILAG) at baseline Gastrointestinal (%)	B	0	2 (0.6)	2 (0.3)
	C, D or E	315 (100.0)	319 (99.4)	634 (99.7)
Adjudication Scoring (BILAG) at baseline Ophthalmic (%)	A	1 (0.3)	0	1 (0.2)
	B	1 (0.3)	1 (0.3)	2 (0.3)
	C, D or E	313 (99.4)	320 (99.7)	633 (99.5)
Adjudication Scoring (BILAG) at baseline Renal (%)	A	2 (0.6)	5 (1.6)	7 (1.1)
	B	24 (7.6)	23 (7.2)	47 (7.4)
	C, D or E	289 (91.7)	293 (91.3)	582 (91.5)

Baseline is defined as the last measurement prior to randomisation and dose administration on Day 1.
Only subjects with baseline positive anti-dsDNA and abnormal complement level, respectively, are included in the summary statistics for the respective variables.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SLE disease characteristics
Full analysis set

		Anifrolumab 300mg (N=315)	Placebo (N=321)	Total (N=636)
Adjudication Scoring (BILAG) at baseline Haematological (%)	B	1 (0.3)	4 (1.2)	5 (0.8)
	C, D or E	314 (99.7)	317 (98.8)	631 (99.2)
BILAG-2004 global score at baseline	n (missing)	315 (0)	321 (0)	636 (0)
	Mean (SD)	18.9 (5.48)	19.0 (5.27)	18.9 (5.37)
	Median	17.0	18.0	17.0
	Min, Max	2, 40	4, 36	2, 40
Physician Global Assessment (PGA) score at baseline	n (missing)	315 (0)	321 (0)	636 (0)
	Mean (SD)	1.8 (0.42)	1.8 (0.39)	1.8 (0.41)
	Median	1.8	1.8	1.8
	Min, Max	1, 3	1, 3	1, 3
CLASI activity score at baseline	n (missing)	315 (0)	321 (0)	636 (0)
	Mean (SD)	8.1 (7.32)	7.6 (6.88)	7.8 (7.10)
	Median	6.0	6.0	6.0
	Min, Max	0, 51	0, 52	0, 52
CLASI activity score at baseline, categorisation 1 (%)	0	8 (2.5)	15 (4.7)	23 (3.6)
	> 0	307 (97.5)	306 (95.3)	613 (96.4)
CLASI activity score at baseline, categorisation 2 (%)	<10	228 (72.4)	236 (73.5)	464 (73.0)
	>=10	87 (27.6)	85 (26.5)	172 (27.0)
CLASI damage score at baseline	n (missing)	315 (0)	321 (0)	636 (0)
	Mean (SD)	1.8 (3.81)	1.9 (4.58)	1.8 (4.21)
	Median	0.0	0.0	0.0
	Min, Max	0, 25	0, 35	0, 35
CLASI damage score at baseline, categorisation 1 (%)	0	213 (67.6)	217 (67.6)	430 (67.6)
	> 0	102 (32.4)	104 (32.4)	206 (32.4)
CLASI damage score at baseline, categorisation 2 (%)	<10	298 (94.6)	305 (95.0)	603 (94.8)
	>=10	17 (5.4)	16 (5.0)	33 (5.2)
Tender Joint Count at Baseline	n (missing)	315 (0)	321 (0)	636 (0)
	Mean (SD)	10.3 (7.28)	10.6 (7.38)	10.5 (7.33)
	Median	9.0	10.0	9.0
	Min, Max	0, 28	0, 28	0, 28
Tender Joint Count at Baseline, categorisation (%)	0	20 (6.3)	14 (4.4)	34 (5.3)
	> 0	295 (93.7)	307 (95.6)	602 (94.7)
Swollen Joint Count at Baseline	n (missing)	315 (0)	321 (0)	636 (0)
	Mean (SD)	6.9 (5.65)	7.3 (5.81)	7.1 (5.73)
	Median	5.0	6.0	6.0
	Min, Max	0, 28	0, 26	0, 28
Swollen Joint Count at Baseline, categorisation (%)	0	29 (9.2)	25 (7.8)	54 (8.5)
	> 0	286 (90.8)	296 (92.2)	582 (91.5)
Active Joint Count at Baseline	n (missing)	315 (0)	321 (0)	636 (0)
	Mean (SD)	7.2 (6.20)	7.2 (5.85)	7.2 (6.02)
	Median	6.0	6.0	6.0
	Min, Max	0, 28	0, 28	0, 28
Active Joint Count at Baseline, categorisation (%)	0	32 (10.2)	26 (8.1)	58 (9.1)
	> 0	283 (89.8)	295 (91.9)	578 (90.9)
SDI global score at baseline	n (missing)	314 (1)	319 (2)	633 (3)
	Mean (SD)	0.6 (0.97)	0.6 (1.00)	0.6 (0.99)

Baseline is defined as the last measurement prior to randomisation and dose administration on Day 1.
Only subjects with baseline positive anti-dsDNA and abnormal complement level, respectively, are included in the summary statistics for the respective variables.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SLE disease characteristics
Full analysis set

		Anifrolumab 300mg (N=315)	Placebo (N=321)	Total (N=636)
SDI global score at baseline	Median	0.0	0.0	0.0
	Min, Max	0, 5	0, 7	0, 7
SDI global score at baseline, categorisation (%)	0 (no damage)	210 (66.7)	200 (62.3)	410 (64.5)
	>=1 (damage)	104 (33.0)	119 (37.1)	223 (35.1)
	Missing	1 (0.3)	2 (0.6)	3 (0.5)
Time from initial SLE diagnosis to randomisation (months)	n (missing)	315 (0)	321 (0)	636 (0)
	Mean (SD)	118.3 (99.87)	99.8 (90.34)	109.0 (95.56)
	Median	90.0	73.0	84.0
	Min, Max	0, 493	4, 503	0, 503
Cushingoid features (%)	Any Cushingoid Feature	106 (33.7)	110 (34.3)	216 (34.0)
	Moon Face	63 (20.0)	62 (19.3)	125 (19.7)
	Buffalo Hump	29 (9.2)	19 (5.9)	48 (7.5)
	Purple or Violaceous Striae	26 (8.3)	20 (6.2)	46 (7.2)
	Central Obesity	49 (15.6)	43 (13.4)	92 (14.5)
	Hirsutisim	20 (6.3)	11 (3.4)	31 (4.9)
	Acne	18 (5.7)	16 (5.0)	34 (5.3)
	Easy Bruising	56 (17.8)	42 (13.1)	98 (15.4)
	Fragile Skin	36 (11.4)	37 (11.5)	73 (11.5)
Results of 4-gene Type 1 Interferon (IFN) test (%)	High	256 (81.3)	254 (79.1)	510 (80.2)
	Low	59 (18.7)	67 (20.9)	126 (19.8)
Anti-dsDNA levels at baseline	n (missing)	155 (0)	152 (0)	307 (0)
	Mean (SD)	126.4 (242.23)	193.3 (505.85)	159.5 (396.13)
	Median	46.0	49.4	48.0
	Min, Max	14, 1808	14, 3790	14, 3790
Anti-dsDNA levels at baseline, categorisation (%)	Negative	146 (46.3)	155 (48.3)	301 (47.3)
	Positive	155 (49.2)	152 (47.4)	307 (48.3)
	Missing	14 (4.4)	14 (4.4)	28 (4.4)
ANA (%)	Abnormal (titre >= 1:80)	284 (90.2)	295 (91.9)	579 (91.0)
	Normal (titre < 1:80)	19 (6.0)	18 (5.6)	37 (5.8)
	Missing	12 (3.8)	8 (2.5)	20 (3.1)
Complement C3 level at baseline	n (missing)	112 (0)	121 (0)	233 (0)
	Mean (SD)	0.69 (0.158)	0.69 (0.147)	0.69 (0.152)
	Median	0.72	0.70	0.71
	Min, Max	0.2, 0.9	0.3, 0.9	0.2, 0.9
Complement C3 level at baseline, categorisation (%)	Abnormal	112 (35.6)	121 (37.7)	233 (36.6)
	Normal	203 (64.4)	200 (62.3)	403 (63.4)
Complement C4 level at baseline	n (missing)	71 (0)	75 (0)	146 (0)
	Mean (SD)	0.07 (0.018)	0.07 (0.016)	0.07 (0.017)
	Median	0.07	0.07	0.07
	Min, Max	0.0, 0.1	0.0, 0.1	0.0, 0.1
Complement C4 level at baseline, categorisation (%)	Abnormal	71 (22.5)	75 (23.4)	146 (23.0)
	Normal	244 (77.5)	246 (76.6)	490 (77.0)
Complement CH50 level at baseline	n (missing)	32 (0)	31 (0)	63 (0)
	Mean (SD)	39.02 (28.639)	49.79 (29.083)	44.32 (29.135)
	Median	35.00	55.00	40.00
	Min, Max	2.5, 94.0	2.5, 98.0	2.5, 98.0
Complement CH50 level at baseline, categorisation (%)	Abnormal	32 (10.2)	31 (9.7)	63 (9.9)
	Normal	283 (89.8)	290 (90.3)	573 (90.1)

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Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Observation times for Efficacy endpoints
Full analysis set

		Anifrolumab 300mg (N=315)	Placebo (N=321)
SRI4: Observation time (weeks)	n (missing)	315 (0)	321 (0)
	Mean (SD)	48.9 (10.15)	46.5 (12.65)
	Median	52.1	52.1
	Min, Max	0, 57	0, 54
CLASI activity score: Observation time (weeks)	n (missing)	315 (0)	321 (0)
	Mean (SD)	48.9 (10.13)	46.5 (12.65)
	Median	52.1	52.1
	Min, Max	0, 57	0, 54
CLASI damage score: Observation time (weeks)	n (missing)	315 (0)	321 (0)
	Mean (SD)	48.9 (10.13)	46.5 (12.65)
	Median	52.1	52.1
	Min, Max	0, 57	0, 54
BICLA: Observation time (weeks)	n (missing)	315 (0)	321 (0)
	Mean (SD)	48.9 (10.13)	46.5 (12.64)
	Median	52.1	52.1
	Min, Max	0, 57	0, 54
SLEDAI-2K Total Score: Observation time (weeks)	n (missing)	315 (0)	321 (0)
	Mean (SD)	48.6 (10.30)	46.0 (13.06)
	Median	52.1	52.1
	Min, Max	0, 57	0, 54
PGA: Observation time (weeks)	n (missing)	315 (0)	321 (0)
	Mean (SD)	48.8 (10.35)	46.5 (12.65)
	Median	52.1	52.1
	Min, Max	0, 57	0, 54
BILAG Global Score: Observation time (weeks)	n (missing)	315 (0)	321 (0)
	Mean (SD)	48.8 (10.30)	46.5 (12.64)
	Median	52.1	52.1
	Min, Max	0, 57	0, 54
Tender Joint Count: Observation time (weeks)	n (missing)	315 (0)	321 (0)
	Mean (SD)	48.9 (10.16)	46.5 (12.66)
	Median	52.1	52.1
	Min, Max	0, 57	0, 54
Swollen Joint Count: Observation time (weeks)	n (missing)	315 (0)	321 (0)
	Mean (SD)	48.9 (10.16)	46.5 (12.66)
	Median	52.1	52.1
	Min, Max	0, 57	0, 54
FACIT-F Total Score: Observation time (weeks)	n (missing)	315 (0)	321 (0)
	Mean (SD)	48.6 (10.56)	45.8 (13.38)
	Median	52.1	52.1
	Min, Max	0, 57	0, 54
SF-36 v2.0 Acute - Mental Component Score: Observation time (weeks)	n (missing)	315 (0)	321 (0)
	Mean (SD)	48.2 (11.69)	45.2 (14.13)
	Median	52.1	52.1
	Min, Max	0, 57	0, 54
SF-36 v2.0 Acute - Physical Component Score: Observation time (weeks)	n (missing)	315 (0)	321 (0)
	Mean (SD)	48.2 (11.69)	45.2 (14.13)
	Median	52.1	52.1
	Min, Max	0, 57	0, 54
EQ-5D VAS Score: Observation time (weeks)	n (missing)	315 (0)	321 (0)

Observation duration defined as time from randomization until last non-missing assessment after randomization. Subjects without assessment are censored at day 1.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Observation times for Efficacy endpoints
Full analysis set

		Anifrolumab 300mg (N=315)	Placebo (N=321)
EQ-5D VAS Score: Observation time (weeks)	Mean (SD)	46.7 (12.91)	44.0 (14.98)
	Median	52.1	52.1
	Min, Max	0, 57	0, 54
SDI Global Score: Observation time (weeks)	n (missing)	315 (0)	321 (0)
	Mean (SD)	44.9 (16.21)	42.8 (17.39)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
PtGA: Observation time (weeks)	n (missing)	315 (0)	321 (0)
	Mean (SD)	48.4 (10.93)	45.5 (13.55)
	Median	52.1	52.1
	Min, Max	0, 57	0, 54

Observation duration defined as time from randomization until last non-missing assessment after randomization. Subjects without assessment are censored at day 1.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=315)	Placebo (N=321)
Week 4	Number of subjects with events, n (%)	31 (9.8)	30 (9.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.13 (0.69, 1.85)	
	p-value	0.6192	
	Odds Ratio (95% CI)	1.15 (0.67, 1.98)	
	p-value	0.6139	
	Risk Difference (95% CI)	1.17 (-3.37, 5.70)	
	p-value	0.6136	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.06 (0.66, 1.70)	
	p-value	0.8214	
	Odds Ratio (95% CI)	1.06 (0.63, 1.81)	
	p-value	0.8187	
	Risk Difference (95% CI)	0.54 (-4.04, 5.11)	
	p-value	0.8187	
	p-Value for test for heterogenity between studies	0.9711	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=315)	Placebo (N=321)
Week 8	Number of subjects with events, n (%)	84 (26.7)	68 (21.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.31 (0.99, 1.74)	
	p-value	0.0590	
	Odds Ratio (95% CI)	1.44 (0.99, 2.11)	
	p-value	0.0570	
	Risk Difference (95% CI)	6.40 (-0.14, 12.94)	
	p-value	0.0552	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.26 (0.95, 1.66)	
	p-value	0.1088	
	Odds Ratio (95% CI)	1.37 (0.95, 1.99)	
	p-value	0.0960	
	Risk Difference (95% CI)	5.64 (-0.93, 12.22)	
	p-value	0.0926	
	p-Value for test for heterogenity between studies	0.2214	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=315)	Placebo (N=321)
Week 12	Number of subjects with events, n (%)	134 (42.5)	103 (32.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.38 (1.12, 1.69)	
	p-value	0.0025	
	Odds Ratio (95% CI)	1.69 (1.21, 2.36)	
	p-value	0.0022	
	Risk Difference (95% CI)	11.68 (4.31, 19.06)	
	p-value	0.0019	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.32 (1.08, 1.62)	
	p-value	0.0079	
	Odds Ratio (95% CI)	1.58 (1.14, 2.20)	
	p-value	0.0059	
	Risk Difference (95% CI)	10.61 (3.16, 18.06)	
	p-value	0.0053	
	p-Value for test for heterogenity between studies	0.2029	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=315)	Placebo (N=321)
Week 16	Number of subjects with events, n (%)	146 (46.3)	123 (38.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.25 (1.04, 1.50)	
	p-value	0.0163	
	Odds Ratio (95% CI)	1.49 (1.08, 2.06)	
	p-value	0.0161	
	Risk Difference (95% CI)	9.42 (1.81, 17.02)	
	p-value	0.0152	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.21 (1.01, 1.45)	
	p-value	0.0393	
	Odds Ratio (95% CI)	1.39 (1.02, 1.91)	
	p-value	0.0393	
	Risk Difference (95% CI)	8.10 (0.44, 15.76)	
	p-value	0.0381	
	p-Value for test for heterogenity between studies	0.6735	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=315)	Placebo (N=321)
Week 20	Number of subjects with events, n (%)	162 (51.4)	140 (43.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.19 (1.01, 1.40)	
	p-value	0.0385	
	Odds Ratio (95% CI)	1.40 (1.02, 1.93)	
	p-value	0.0384	
	Risk Difference (95% CI)	8.21 (0.48, 15.93)	
	p-value	0.0373	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.18 (1.00, 1.39)	
	p-value	0.0488	
	Odds Ratio (95% CI)	1.37 (1.00, 1.87)	
	p-value	0.0489	
	Risk Difference (95% CI)	7.82 (0.08, 15.57)	
	p-value	0.0477	
	p-Value for test for heterogenity between studies	0.7163	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=315)	Placebo (N=321)
Week 24	Number of subjects with events, n (%)	166 (52.7)	137 (42.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.23 (1.04, 1.45)	
	p-value	0.0135	
	Odds Ratio (95% CI)	1.49 (1.09, 2.04)	
	p-value	0.0135	
	Risk Difference (95% CI)	9.94 (2.12, 17.75)	
	p-value	0.0127	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.23 (1.04, 1.45)	
	p-value	0.0140	
	Odds Ratio (95% CI)	1.49 (1.09, 2.04)	
	p-value	0.0124	
	Risk Difference (95% CI)	9.96 (2.23, 17.70)	
	p-value	0.0116	
	p-Value for test for heterogenity between studies	0.2879	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=315)	Placebo (N=321)
Week 28	Number of subjects with events, n (%)	171 (54.3)	144 (44.9)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.22 (1.04, 1.43)	
	p-value	0.0149	
	Odds Ratio (95% CI)	1.48 (1.08, 2.03)	
	p-value	0.0147	
	Risk Difference (95% CI)	9.81 (1.99, 17.64)	
	p-value	0.0140	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.20 (1.03, 1.41)	
	p-value	0.0219	
	Odds Ratio (95% CI)	1.46 (1.06, 1.99)	
	p-value	0.0189	
	Risk Difference (95% CI)	9.37 (1.62, 17.12)	
	p-value	0.0178	
	p-Value for test for heterogenity between studies	0.3073	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=315)	Placebo (N=321)
Week 32	Number of subjects with events, n (%)	175 (55.6)	145 (45.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.25 (1.06, 1.46)	
	p-value	0.0061	
	Odds Ratio (95% CI)	1.55 (1.13, 2.13)	
	p-value	0.0061	
	Risk Difference (95% CI)	11.05 (3.23, 18.86)	
	p-value	0.0056	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.23 (1.05, 1.44)	
	p-value	0.0094	
	Odds Ratio (95% CI)	1.52 (1.11, 2.07)	
	p-value	0.0092	
	Risk Difference (95% CI)	10.40 (2.66, 18.14)	
	p-value	0.0085	
	p-Value for test for heterogenity between studies	0.4106	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=315)	Placebo (N=321)
Week 36	Number of subjects with events, n (%)	173 (54.9)	139 (43.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.28 (1.09, 1.51)	
	p-value	0.0030	
	Odds Ratio (95% CI)	1.62 (1.18, 2.22)	
	p-value	0.0028	
	Risk Difference (95% CI)	12.04 (4.23, 19.85)	
	p-value	0.0025	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.26 (1.07, 1.48)	
	p-value	0.0048	
	Odds Ratio (95% CI)	1.59 (1.16, 2.18)	
	p-value	0.0038	
	Risk Difference (95% CI)	11.57 (3.84, 19.31)	
	p-value	0.0034	
	p-Value for test for heterogenity between studies	0.2565	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=315)	Placebo (N=321)
Week 40	Number of subjects with events, n (%)	170 (54.0)	129 (40.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.36 (1.15, 1.61)	
	p-value	0.0004	
	Odds Ratio (95% CI)	1.79 (1.30, 2.46)	
	p-value	0.0004	
	Risk Difference (95% CI)	14.32 (6.59, 22.05)	
	p-value	0.0003	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.32 (1.12, 1.56)	
	p-value	0.0011	
	Odds Ratio (95% CI)	1.74 (1.27, 2.38)	
	p-value	0.0006	
	Risk Difference (95% CI)	13.69 (5.99, 21.39)	
	p-value	0.0005	
	p-Value for test for heterogenity between studies	0.1211	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=315)	Placebo (N=321)
Week 44	Number of subjects with events, n (%)	170 (54.0)	132 (41.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.34 (1.13, 1.59)	
	p-value	0.0008	
	Odds Ratio (95% CI)	1.73 (1.26, 2.38)	
	p-value	0.0007	
	Risk Difference (95% CI)	13.72 (5.93, 21.50)	
	p-value	0.0006	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.31 (1.11, 1.55)	
	p-value	0.0014	
	Odds Ratio (95% CI)	1.68 (1.22, 2.30)	
	p-value	0.0013	
	Risk Difference (95% CI)	12.84 (5.13, 20.55)	
	p-value	0.0011	
	p-Value for test for heterogenity between studies	0.5731	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=315)	Placebo (N=321)
Week 48	Number of subjects with events, n (%)	169 (53.7)	132 (41.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.33 (1.13, 1.58)	
	p-value	0.0007	
	Odds Ratio (95% CI)	1.75 (1.27, 2.41)	
	p-value	0.0007	
	Risk Difference (95% CI)	13.55 (5.87, 21.23)	
	p-value	0.0005	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.31 (1.11, 1.54)	
	p-value	0.0017	
	Odds Ratio (95% CI)	1.66 (1.21, 2.27)	
	p-value	0.0016	
	Risk Difference (95% CI)	12.56 (4.85, 20.27)	
	p-value	0.0014	
	p-Value for test for heterogenity between studies	0.5719	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=315)	Placebo (N=321)
Week 52	Number of subjects with events, n (%)	168 (53.3)	130 (40.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.34 (1.13, 1.58)	
	p-value	0.0008	
	Odds Ratio (95% CI)	1.73 (1.26, 2.38)	
	p-value	0.0008	
	Risk Difference (95% CI)	13.52 (5.77, 21.26)	
	p-value	0.0006	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.32 (1.11, 1.56)	
	p-value	0.0013	
	Odds Ratio (95% CI)	1.68 (1.23, 2.30)	
	p-value	0.0012	
	Risk Difference (95% CI)	12.88 (5.18, 20.57)	
	p-value	0.0010	
	p-Value for test for heterogenity between studies	0.4321	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (4) response rate at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	 p-Value	Interaction p-Value
SLEDAI-2K score					0.4043
< 10 points	56/109 (51.4)	44/101 (43.6)	1.18 (0.88, 1.57)	0.2698	
>= 10 points	112/206 (54.4)	86/220 (39.1)	1.37 (1.11, 1.69)	0.0032	
OCS dose					0.1174
<10 mg/day	70/148 (47.3)	59/145 (40.7)	1.13 (0.87, 1.46)	0.3614	
>=10 mg/day	98/167 (58.7)	71/176 (40.3)	1.48 (1.19, 1.84)	0.0004	
Result of type I IFN gene signature test					0.3761
LOW	30/ 59 (50.8)	31/ 67 (46.3)	1.15 (0.81, 1.63)	0.4385	
HIGH	138/256 (53.9)	99/254 (39.0)	1.38 (1.14, 1.66)	0.0011	
Age (years)					0.0579
<= 65	165/308 (53.6)	128/318 (40.3)	1.33 (1.12, 1.58)	0.0009	
> 65	3/ 7 (42.9)	2/ 3 (66.7)	0.50 (0.19, 1.36)	0.1742	
Sex					0.2114
male	15/ 27 (55.6)	14/ 26 (53.8)	0.99 (0.64, 1.54)	0.9740	
female	153/288 (53.1)	116/295 (39.3)	1.34 (1.12, 1.60)	0.0013	
Race					0.4582
White	101/185 (54.6)	90/205 (43.9)	1.25 (1.02, 1.53)	0.0343	
Black	24/ 49 (49.0)	15/ 40 (37.5)	1.25 (0.76, 2.07)	0.3846	
Other	39/ 73 (53.4)	23/ 73 (31.5)	1.66 (1.11, 2.48)	0.0141	
Ethnicity					0.5631
Hispanic/Latino	41/ 78 (52.6)	36/ 84 (42.9)	1.20 (0.87, 1.66)	0.2578	
Non-hispanic/Latino	123/229 (53.7)	92/234 (39.3)	1.34 (1.10, 1.64)	0.0036	
Geographic region					0.6812
EU	73/110 (66.4)	57/109 (52.3)	1.26 (1.01, 1.58)	0.0403	
non-EU	95/205 (46.3)	73/212 (34.4)	1.35 (1.07, 1.71)	0.0120	
Onset of disease					0.7678
Paediatric	9/ 26 (34.6)	4/ 21 (19.0)	1.55 (0.51, 4.77)	0.4416	
Adult	159/289 (55.0)	126/300 (42.0)	1.31 (1.11, 1.55)	0.0017	
ADA result					0.5267
Negative	157/292 (53.8)	123/295 (41.7)	1.29 (1.09, 1.54)	0.0033	
Positive (At any time)	11/ 22 (50.0)	7/ 26 (26.9)	1.64 (0.80, 3.35)	0.1749	
BMI (kg/m2)					0.3355
< 30	121/213 (56.8)	96/235 (40.9)	1.39 (1.15, 1.69)	0.0009	
>= 30	47/102 (46.1)	34/ 86 (39.5)	1.15 (0.83, 1.60)	0.4062	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (8) response rate at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=300)	Placebo (N=307)
Week 52	Number of subjects with events, n (%)	89 (29.7)	46 (15.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	2.04 (1.48, 2.81)	
	p-value	<.0001	
	Odds Ratio (95% CI)	2.50 (1.67, 3.75)	
	p-value	<.0001	
	Risk Difference (95% CI)	15.46 (8.86, 22.05)	
	p-value	<.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.98 (1.44, 2.72)	
	p-value	<.0001	
	Odds Ratio (95% CI)	2.39 (1.60, 3.57)	
	p-value	<.0001	
	Risk Difference (95% CI)	14.68 (8.15, 21.21)	
	p-value	<.0001	
	p-Value for test for heterogenity between studies	0.9665	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (8) response rate at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=300) n/ N (%)	Placebo (N=307) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	 p-Value	Interaction p-Value
SLEDAI-2K score					0.3744
< 10 points	18/ 94 (19.1)	11/ 87 (12.6)	1.52 (0.76, 3.05)	0.2386	
>= 10 points	71/206 (34.5)	35/220 (15.9)	2.17 (1.52, 3.10)	<.0001	
OCS dose					0.0139
<10 mg/day	31/140 (22.1)	24/136 (17.6)	1.23 (0.76, 2.00)	0.3902	
>=10 mg/day	58/160 (36.3)	22/171 (12.9)	2.80 (1.80, 4.37)	<.0001	
Result of type I IFN gene signature test					0.1168
LOW	11/ 56 (19.6)	11/ 62 (17.7)	1.14 (0.54, 2.42)	0.7241	
HIGH	78/244 (32.0)	35/245 (14.3)	2.22 (1.55, 3.18)	<.0001	
Age (years)					0.0902
<= 65	89/293 (30.4)	45/304 (14.8)	2.05 (1.49, 2.83)	<.0001	
> 65	0/ 7 (0.0)	1/ 3 (33.3)	0.17 (0.01, 2.98)	0.2235	
Sex					0.8587
male	7/ 25 (28.0)	3/ 25 (12.0)	1.75 (0.52, 5.87)	0.3675	
female	82/275 (29.8)	43/282 (15.2)	1.96 (1.41, 2.72)	<.0001	
Race					0.5388
White	47/176 (26.7)	30/195 (15.4)	1.73 (1.15, 2.61)	0.0087	
Black	14/ 46 (30.4)	7/ 37 (18.9)	1.48 (0.63, 3.51)	0.3702	
Other	27/ 71 (38.0)	8/ 72 (11.1)	2.65 (1.25, 5.61)	0.0108	
Ethnicity					0.4437
Hispanic/Latino	22/ 74 (29.7)	12/ 80 (15.0)	1.49 (0.77, 2.85)	0.2333	
Non-hispanic/Latino	66/219 (30.1)	33/224 (14.7)	2.00 (1.37, 2.90)	0.0003	
Geographic region					0.9190
EU	40/104 (38.5)	21/107 (19.6)	1.94 (1.23, 3.05)	0.0042	
non-EU	49/196 (25.0)	25/200 (12.5)	2.00 (1.29, 3.11)	0.0020	
Onset of disease					0.8071
Paediatric	7/ 26 (26.9)	2/ 21 (9.5)	2.27 (0.68, 7.60)	0.1843	
Adult	82/274 (29.9)	44/286 (15.4)	1.94 (1.40, 2.69)	<.0001	
ADA result					0.8407
Negative	81/278 (29.1)	42/281 (14.9)	1.95 (1.40, 2.72)	<.0001	
Positive (At any time)	8/ 21 (38.1)	4/ 26 (15.4)	2.17 (0.81, 5.83)	0.1250	
BMI (kg/m2)					0.7718
< 30	67/206 (32.5)	38/224 (17.0)	1.92 (1.35, 2.72)	0.0003	
>= 30	22/ 94 (23.4)	8/ 83 (9.6)	2.17 (1.03, 4.57)	0.0419	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=4 reduction in SLEDAI-2K at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=315)	Placebo (N=321)
Week 52	Number of subjects with events, n (%)	169 (53.7)	131 (40.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.33 (1.13, 1.58)	
	p-value	0.0008	
	Odds Ratio (95% CI)	1.73 (1.26, 2.37)	
	p-value	0.0008	
	Risk Difference (95% CI)	13.52 (5.77, 21.28)	
	p-value	0.0006	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.31 (1.11, 1.55)	
	p-value	0.0013	
	Odds Ratio (95% CI)	1.68 (1.23, 2.30)	
	p-value	0.0012	
	Risk Difference (95% CI)	12.88 (5.18, 20.58)	
	p-value	0.0010	
	p-Value for test for heterogenity between studies	0.4924	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=4 reduction in SLEDAI-2K at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	 p-Value	Interaction p-Value
SLEDAI-2K score					0.5010
< 10 points	57/109 (52.3)	44/101 (43.6)	1.20 (0.90, 1.60)	0.2147	
>= 10 points	112/206 (54.4)	87/220 (39.5)	1.35 (1.10, 1.67)	0.0042	
OCS dose					0.0870
<10 mg/day	70/148 (47.3)	60/145 (41.4)	1.11 (0.86, 1.44)	0.4184	
>=10 mg/day	99/167 (59.3)	71/176 (40.3)	1.49 (1.20, 1.85)	0.0003	
Result of type I IFN gene signature test					0.3808
LOW	30/ 59 (50.8)	31/ 67 (46.3)	1.15 (0.81, 1.63)	0.4385	
HIGH	139/256 (54.3)	100/254 (39.4)	1.37 (1.14, 1.66)	0.0011	
Age (years)					0.0583
<= 65	166/308 (53.9)	129/318 (40.6)	1.33 (1.12, 1.57)	0.0009	
> 65	3/ 7 (42.9)	2/ 3 (66.7)	0.50 (0.19, 1.36)	0.1742	
Sex					0.2123
male	15/ 27 (55.6)	14/ 26 (53.8)	0.99 (0.64, 1.54)	0.9740	
female	154/288 (53.5)	117/295 (39.7)	1.34 (1.12, 1.60)	0.0012	
Race					0.4387
White	101/185 (54.6)	91/205 (44.4)	1.23 (1.01, 1.51)	0.0432	
Black	25/ 49 (51.0)	15/ 40 (37.5)	1.30 (0.79, 2.14)	0.3004	
Other	39/ 73 (53.4)	23/ 73 (31.5)	1.66 (1.11, 2.48)	0.0141	
Ethnicity					0.5682
Hispanic/Latino	41/ 78 (52.6)	36/ 84 (42.9)	1.20 (0.87, 1.66)	0.2578	
Non-hispanic/Latino	124/229 (54.1)	93/234 (39.7)	1.34 (1.10, 1.64)	0.0035	
Geographic region					0.5482
EU	73/110 (66.4)	58/109 (53.2)	1.24 (0.99, 1.54)	0.0594	
non-EU	96/205 (46.8)	73/212 (34.4)	1.36 (1.08, 1.72)	0.0095	
Onset of disease					0.7661
Paediatric	9/ 26 (34.6)	4/ 21 (19.0)	1.55 (0.51, 4.77)	0.4416	
Adult	160/289 (55.4)	127/300 (42.3)	1.31 (1.11, 1.55)	0.0017	
ADA result					0.5237
Negative	158/292 (54.1)	124/295 (42.0)	1.29 (1.09, 1.53)	0.0033	
Positive (At any time)	11/ 22 (50.0)	7/ 26 (26.9)	1.64 (0.80, 3.35)	0.1749	
BMI (kg/m2)					0.4153
< 30	121/213 (56.8)	97/235 (41.3)	1.38 (1.13, 1.67)	0.0012	
>= 30	48/102 (47.1)	34/ 86 (39.5)	1.17 (0.84, 1.63)	0.3393	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=8 reduction in SLEDAI-2K at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=315)	Placebo (N=321)
Week 52	Number of subjects with events, n (%)	89 (28.3)	46 (14.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	2.05 (1.49, 2.83)	
	p-value	<.0001	
	Odds Ratio (95% CI)	2.51 (1.68, 3.77)	
	p-value	<.0001	
	Risk Difference (95% CI)	14.82 (8.53, 21.11)	
	p-value	<.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.97 (1.43, 2.72)	
	p-value	<.0001	
	Odds Ratio (95% CI)	2.36 (1.58, 3.51)	
	p-value	<.0001	
	Risk Difference (95% CI)	13.94 (7.66, 20.21)	
	p-value	<.0001	
	p-Value for test for heterogenity between studies	0.9587	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=8 reduction in SLEDAI-2K at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	 p-Value	Interaction p-Value
SLEDAI-2K score					0.4005
< 10 points	18/109 (16.5)	11/101 (10.9)	1.55 (0.76, 3.13)	0.2256	
>= 10 points	71/206 (34.5)	35/220 (15.9)	2.17 (1.52, 3.10)	<.0001	
OCS dose					0.0169
<10 mg/day	31/148 (20.9)	24/145 (16.6)	1.25 (0.77, 2.03)	0.3720	
>=10 mg/day	58/167 (34.7)	22/176 (12.5)	2.78 (1.78, 4.33)	<.0001	
Result of type I IFN gene signature test					0.1396
LOW	11/ 59 (18.6)	11/ 67 (16.4)	1.17 (0.55, 2.49)	0.6787	
HIGH	78/256 (30.5)	35/254 (13.8)	2.20 (1.53, 3.15)	<.0001	
Age (years)					0.0907
<= 65	89/308 (28.9)	45/318 (14.2)	2.04 (1.48, 2.82)	<.0001	
> 65	0/ 7 (0.0)	1/ 3 (33.3)	0.17 (0.01, 2.98)	0.2235	
Sex					0.7082
male	7/ 27 (25.9)	3/ 26 (11.5)	1.53 (0.45, 5.26)	0.4981	
female	82/288 (28.5)	43/295 (14.6)	1.96 (1.40, 2.72)	<.0001	
Race					0.5418
White	47/185 (25.4)	30/205 (14.6)	1.74 (1.15, 2.62)	0.0088	
Black	14/ 49 (28.6)	7/ 40 (17.5)	1.45 (0.61, 3.45)	0.4050	
Other	27/ 73 (37.0)	8/ 73 (11.0)	2.62 (1.24, 5.55)	0.0118	
Ethnicity					0.4281
Hispanic/Latino	22/ 78 (28.2)	12/ 84 (14.3)	1.47 (0.76, 2.84)	0.2524	
Non-hispanic/Latino	66/229 (28.8)	33/234 (14.1)	2.00 (1.37, 2.91)	0.0003	
Geographic region					0.7958
EU	40/110 (36.4)	21/109 (19.3)	1.85 (1.18, 2.93)	0.0079	
non-EU	49/205 (23.9)	25/212 (11.8)	2.02 (1.30, 3.14)	0.0019	
Onset of disease					0.8007
Paediatric	7/ 26 (26.9)	2/ 21 (9.5)	2.27 (0.68, 7.60)	0.1843	
Adult	82/289 (28.4)	44/300 (14.7)	1.93 (1.39, 2.68)	<.0001	
ADA result					0.9062
Negative	81/292 (27.7)	42/295 (14.2)	1.95 (1.39, 2.73)	<.0001	
Positive (At any time)	8/ 22 (36.4)	4/ 26 (15.4)	2.08 (0.77, 5.61)	0.1488	
BMI (kg/m2)					0.9013
< 30	67/213 (31.5)	38/235 (16.2)	1.95 (1.37, 2.77)	0.0002	
>= 30	22/102 (21.6)	8/ 86 (9.3)	2.05 (0.97, 4.34)	0.0607	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
No worsening in BILAG-2004 (>=1A or >=2B compared to BL) at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=315)	Placebo (N=321)
Week 52	Number of subjects with events, n (%)	218 (69.2)	175 (54.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.27 (1.13, 1.44)	
	p-value	0.0001	
	Odds Ratio (95% CI)	1.91 (1.37, 2.65)	
	p-value	0.0001	
	Risk Difference (95% CI)	14.98 (7.48, 22.48)	
	p-value	<.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.27 (1.12, 1.43)	
	p-value	0.0002	
	Odds Ratio (95% CI)	1.88 (1.36, 2.61)	
	p-value	0.0001	
	Risk Difference (95% CI)	14.73 (7.28, 22.18)	
	p-value	0.0001	
	p-Value for test for heterogenity between studies	0.6677	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
No worsening in BILAG-2004 (>=1A or >=2B compared to BL) at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	 p-Value	Interaction p-Value
SLEDAI-2K score					0.3729
< 10 points	80/109 (73.4)	63/101 (62.4)	1.17 (0.97, 1.41)	0.1036	
>= 10 points	138/206 (67.0)	112/220 (50.9)	1.31 (1.11, 1.54)	0.0011	
OCS dose					0.4509
<10 mg/day	100/148 (67.6)	80/145 (55.2)	1.21 (1.01, 1.45)	0.0397	
>=10 mg/day	118/167 (70.7)	95/176 (54.0)	1.33 (1.13, 1.57)	0.0008	
Result of type I IFN gene signature test					0.3898
LOW	46/ 59 (78.0)	37/ 67 (55.2)	1.40 (1.09, 1.80)	0.0088	
HIGH	172/256 (67.2)	138/254 (54.3)	1.23 (1.07, 1.42)	0.0036	
Age (years)					0.0568
<= 65	213/308 (69.2)	173/318 (54.4)	1.27 (1.12, 1.44)	0.0002	
> 65	5/ 7 (71.4)	2/ 3 (66.7)	0.82 (0.53, 1.26)	0.3675	
Sex					0.4369
male	19/ 27 (70.4)	15/ 26 (57.7)	1.07 (0.73, 1.58)	0.7159	
female	199/288 (69.1)	160/295 (54.2)	1.26 (1.11, 1.44)	0.0004	
Race					0.8754
White	133/185 (71.9)	117/205 (57.1)	1.25 (1.08, 1.46)	0.0029	
Black	32/ 49 (65.3)	21/ 40 (52.5)	1.16 (0.78, 1.73)	0.4538	
Other	48/ 73 (65.8)	35/ 73 (47.9)	1.32 (0.99, 1.77)	0.0610	
Ethnicity					0.9735
Hispanic/Latino	51/ 78 (65.4)	42/ 84 (50.0)	1.26 (0.97, 1.64)	0.0797	
Non-hispanic/Latino	162/229 (70.7)	131/234 (56.0)	1.26 (1.09, 1.44)	0.0015	
Geographic region					0.1541
EU	85/110 (77.3)	74/109 (67.9)	1.14 (0.97, 1.35)	0.1137	
non-EU	133/205 (64.9)	101/212 (47.6)	1.36 (1.14, 1.61)	0.0005	
Onset of disease					0.7331
Paediatric	13/ 26 (50.0)	7/ 21 (33.3)	1.44 (0.68, 3.08)	0.3439	
Adult	205/289 (70.9)	168/300 (56.0)	1.26 (1.11, 1.43)	0.0002	
ADA result					0.8385
Negative	205/292 (70.2)	165/295 (55.9)	1.26 (1.11, 1.42)	0.0003	
Positive (At any time)	13/ 22 (59.1)	10/ 26 (38.5)	1.33 (0.76, 2.33)	0.3111	
BMI (kg/m2)					0.2339
< 30	154/213 (72.3)	128/235 (54.5)	1.33 (1.15, 1.53)	0.0001	
>= 30	64/102 (62.7)	47/ 86 (54.7)	1.12 (0.88, 1.42)	0.3492	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Maintained OCS Reduction at week 52 (for subjects with baseline OCS >=10 mg/day)
Full analysis set

Timepoint		Anifrolumab 300mg (N=167)	Placebo (N=176)
Week 52	Number of subjects with events, n (%)	92 (55.1)	51 (29.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.94 (1.48, 2.54)	
	p-value	<.0001	
	Odds Ratio (95% CI)	3.24 (2.03, 5.15)	
	p-value	<.0001	
	Risk Difference (95% CI)	26.75 (16.79, 36.70)	
	p-value	<.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.90 (1.45, 2.49)	
	p-value	<.0001	
	Odds Ratio (95% CI)	3.04 (1.94, 4.76)	
	p-value	<.0001	
	Risk Difference (95% CI)	26.36 (16.26, 36.46)	
	p-value	<.0001	
	p-Value for test for heterogenity between studies	0.6228	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Maintained OCS Reduction at week 52 (for subjects with baseline OCS >=10 mg/day) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=167) n/ N (%)	Placebo (N=176) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	 p-Value	Interaction p-Value
SLEDAI-2K score					0.6855
< 10 points	28/ 49 (57.1)	15/ 45 (33.3)	1.73 (1.07, 2.81)	0.0255	
>= 10 points	64/118 (54.2)	36/131 (27.5)	1.95 (1.41, 2.70)	<.0001	
OCS dose					NE
>=10 mg/day	92/167 (55.1)	51/176 (29.0)	1.90 (1.45, 2.49)	<.0001	
Result of type I IFN gene signature test					0.1115
LOW	11/ 19 (57.9)	12/ 29 (41.4)	1.34 (0.86, 2.09)	0.1920	
HIGH	81/148 (54.7)	39/147 (26.5)	2.08 (1.53, 2.83)	<.0001	
Age (years)					0.1734
<= 65	92/165 (55.8)	50/175 (28.6)	1.95 (1.49, 2.56)	<.0001	
> 65	0/ 2 (0.0)	1/ 1 (100.0)	0.33 (0.03, 4.19)	0.3948	
Sex					0.7136
male	10/ 16 (62.5)	3/ 15 (20.0)	2.19 (0.83, 5.83)	0.1150	
female	82/151 (54.3)	48/161 (29.8)	1.81 (1.37, 2.40)	<.0001	
Race					0.5322
White	50/ 91 (54.9)	33/119 (27.7)	1.92 (1.36, 2.72)	0.0002	
Black	15/ 26 (57.7)	3/ 16 (18.8)	2.33 (0.69, 7.87)	0.1734	
Other	24/ 46 (52.2)	15/ 40 (37.5)	1.39 (0.83, 2.33)	0.2133	
Ethnicity					0.8207
Hispanic/Latino	22/ 48 (45.8)	14/ 53 (26.4)	1.77 (1.03, 3.03)	0.0384	
Non-hispanic/Latino	67/115 (58.3)	37/122 (30.3)	1.90 (1.39, 2.59)	<.0001	
Geographic region					0.7465
EU	44/ 70 (62.9)	26/ 79 (32.9)	1.83 (1.27, 2.63)	0.0012	
non-EU	48/ 97 (49.5)	25/ 97 (25.8)	1.99 (1.35, 2.94)	0.0005	
Onset of disease					0.6174
Paediatric	10/ 18 (55.6)	3/ 14 (21.4)	2.45 (0.84, 7.14)	0.1004	
Adult	82/149 (55.0)	48/162 (29.6)	1.85 (1.40, 2.44)	<.0001	
ADA result					0.6639
Negative	87/149 (58.4)	49/157 (31.2)	1.88 (1.44, 2.46)	<.0001	
Positive (At any time)	5/ 17 (29.4)	2/ 19 (10.5)	2.67 (0.56, 12.62)	0.2158	
BMI (kg/m2)					0.7948
< 30	71/119 (59.7)	42/137 (30.7)	1.94 (1.44, 2.60)	<.0001	
>= 30	21/ 48 (43.8)	9/ 39 (23.1)	1.76 (0.91, 3.39)	0.0905	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=50% Reduction in CLASI activity score at week 52 (for subjects with baseline CLASI activity score >=10)
Full analysis set

Timepoint		Anifrolumab 300mg (N=87)	Placebo (N=85)
Week 52	Number of subjects with events, n (%)	52 (59.8)	40 (47.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.21 (0.92, 1.59)	
	p-value	0.1731	
	Odds Ratio (95% CI)	1.58 (0.82, 3.04)	
	p-value	0.1684	
	Risk Difference (95% CI)	10.15 (-4.25, 24.55)	
	p-value	0.1673	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.26 (0.95, 1.68)	
	p-value	0.1112	
	Odds Ratio (95% CI)	1.71 (0.93, 3.15)	
	p-value	0.0856	
	Risk Difference (95% CI)	13.30 (-1.54, 28.14)	
	p-value	0.0789	
	p-Value for test for heterogenity between studies	0.6690	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=50% Reduction in CLASI activity score at week 52 (for subjects with baseline CLASI activity score >=10) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=87) n/ N (%)	Placebo (N=85) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.8793
< 10 points	10/ 17 (58.8)	8/ 18 (44.4)	1.32 (0.72, 2.41)	0.3676	
>= 10 points	42/ 70 (60.0)	32/ 67 (47.8)	1.25 (0.91, 1.72)	0.1711	
OCS dose					0.3147
<10 mg/day	19/ 31 (61.3)	12/ 31 (38.7)	1.56 (0.93, 2.62)	0.0940	
>=10 mg/day	33/ 56 (58.9)	28/ 54 (51.9)	1.13 (0.80, 1.60)	0.4801	
Result of type I IFN gene signature test					0.1162
LOW	6/ 9 (66.7)	9/ 13 (69.2)	0.83 (0.49, 1.41)	0.4962	
HIGH	46/ 78 (59.0)	31/ 72 (43.1)	1.37 (0.99, 1.90)	0.0600	
Age (years)					NE
<= 65	51/ 86 (59.3)	39/ 84 (46.4)	1.27 (0.95, 1.70)	0.1084	
> 65	1/ 1 (100.0)	1/ 1 (100.0)	NE		
Sex					0.1849
male	4/ 10 (40.0)	5/ 10 (50.0)	0.60 (0.20, 1.77)	0.3547	
female	48/ 77 (62.3)	35/ 75 (46.7)	1.28 (0.95, 1.73)	0.1042	
Race					0.3685
White	32/ 55 (58.2)	33/ 65 (50.8)	1.13 (0.82, 1.55)	0.4646	
Black	7/ 13 (53.8)	1/ 3 (33.3)	0.67 (0.04, 10.05)	0.7696	
Other	13/ 18 (72.2)	4/ 15 (26.7)	2.00 (0.92, 4.34)	0.0786	
Ethnicity					0.9267
Hispanic/Latino	6/ 14 (42.9)	4/ 13 (30.8)	1.37 (0.51, 3.65)	0.5299	
Non-hispanic/Latino	46/ 72 (63.9)	34/ 70 (48.6)	1.30 (0.97, 1.75)	0.0777	
Geographic region					0.0874
EU	24/ 38 (63.2)	26/ 42 (61.9)	1.02 (0.74, 1.41)	0.8875	
non-EU	28/ 49 (57.1)	14/ 43 (32.6)	1.73 (1.04, 2.87)	0.0341	
Onset of disease					0.7971
Paediatric	3/ 7 (42.9)	2/ 6 (33.3)	1.07 (0.30, 3.83)	0.9116	
Adult	49/ 80 (61.3)	38/ 79 (48.1)	1.28 (0.95, 1.70)	0.1008	
ADA result					0.2978
Negative	51/ 79 (64.6)	39/ 81 (48.1)	1.32 (1.00, 1.75)	0.0513	
Positive (At any time)	1/ 8 (12.5)	1/ 4 (25.0)	0.40 (0.04, 3.74)	0.4216	
BMI (kg/m2)					0.2300
< 30	40/ 62 (64.5)	28/ 62 (45.2)	1.40 (1.00, 1.95)	0.0478	
>= 30	12/ 25 (48.0)	12/ 23 (52.2)	0.94 (0.54, 1.64)	0.8282	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=315)	Placebo (N=321)
Week 4	Number of subjects with events, n (%)	76 (24.1)	58 (18.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.33 (0.97, 1.81)	
	p-value	0.0739	
	Odds Ratio (95% CI)	1.42 (0.97, 2.09)	
	p-value	0.0725	
	Risk Difference (95% CI)	5.92 (-0.51, 12.34)	
	p-value	0.0709	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.33 (0.98, 1.81)	
	p-value	0.0665	
	Odds Ratio (95% CI)	1.44 (0.98, 2.12)	
	p-value	0.0636	
	Risk Difference (95% CI)	6.06 (-0.26, 12.39)	
	p-value	0.0604	
	p-Value for test for heterogenity between studies	0.5536	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=315)	Placebo (N=321)
Week 8	Number of subjects with events, n (%)	115 (36.5)	79 (24.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.52 (1.20, 1.94)	
	p-value	0.0006	
	Odds Ratio (95% CI)	1.84 (1.30, 2.62)	
	p-value	0.0006	
	Risk Difference (95% CI)	12.70 (5.58, 19.81)	
	p-value	0.0005	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.47 (1.15, 1.87)	
	p-value	0.0018	
	Odds Ratio (95% CI)	1.77 (1.25, 2.49)	
	p-value	0.0012	
	Risk Difference (95% CI)	11.96 (4.86, 19.06)	
	p-value	0.0010	
	p-Value for test for heterogenity between studies	0.2701	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=315)	Placebo (N=321)
Week 12	Number of subjects with events, n (%)	123 (39.0)	93 (29.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.37 (1.10, 1.71)	
	p-value	0.0056	
	Odds Ratio (95% CI)	1.61 (1.15, 2.26)	
	p-value	0.0054	
	Risk Difference (95% CI)	10.58 (3.23, 17.94)	
	p-value	0.0048	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.35 (1.08, 1.68)	
	p-value	0.0081	
	Odds Ratio (95% CI)	1.57 (1.12, 2.18)	
	p-value	0.0079	
	Risk Difference (95% CI)	10.02 (2.69, 17.35)	
	p-value	0.0073	
	p-Value for test for heterogenity between studies	0.7345	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=315)	Placebo (N=321)
Week 16	Number of subjects with events, n (%)	136 (43.2)	101 (31.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.38 (1.12, 1.71)	
	p-value	0.0027	
	Odds Ratio (95% CI)	1.67 (1.20, 2.31)	
	p-value	0.0023	
	Risk Difference (95% CI)	11.82 (4.30, 19.35)	
	p-value	0.0021	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.37 (1.12, 1.68)	
	p-value	0.0026	
	Odds Ratio (95% CI)	1.65 (1.19, 2.28)	
	p-value	0.0025	
	Risk Difference (95% CI)	11.66 (4.19, 19.12)	
	p-value	0.0022	
	p-Value for test for heterogenity between studies	0.9232	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=315)	Placebo (N=321)
Week 20	Number of subjects with events, n (%)	135 (42.9)	108 (33.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.28 (1.04, 1.57)	
	p-value	0.0189	
	Odds Ratio (95% CI)	1.48 (1.07, 2.04)	
	p-value	0.0178	
	Risk Difference (95% CI)	9.27 (1.65, 16.89)	
	p-value	0.0171	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.27 (1.04, 1.55)	
	p-value	0.0189	
	Odds Ratio (95% CI)	1.48 (1.07, 2.04)	
	p-value	0.0180	
	Risk Difference (95% CI)	9.13 (1.61, 16.65)	
	p-value	0.0173	
	p-Value for test for heterogenity between studies	0.9305	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=315)	Placebo (N=321)
Week 24	Number of subjects with events, n (%)	149 (47.3)	100 (31.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.53 (1.25, 1.88)	
	p-value	<.0001	
	Odds Ratio (95% CI)	1.98 (1.43, 2.75)	
	p-value	<.0001	
	Risk Difference (95% CI)	16.31 (8.72, 23.90)	
	p-value	<.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.49 (1.22, 1.81)	
	p-value	<.0001	
	Odds Ratio (95% CI)	1.97 (1.42, 2.73)	
	p-value	<.0001	
	Risk Difference (95% CI)	15.99 (8.51, 23.47)	
	p-value	<.0001	
	p-Value for test for heterogenity between studies	0.1640	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=315)	Placebo (N=321)
Week 28	Number of subjects with events, n (%)	142 (45.1)	110 (34.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.32 (1.08, 1.60)	
	p-value	0.0064	
	Odds Ratio (95% CI)	1.57 (1.14, 2.17)	
	p-value	0.0060	
	Risk Difference (95% CI)	10.80 (3.17, 18.42)	
	p-value	0.0055	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.30 (1.07, 1.57)	
	p-value	0.0084	
	Odds Ratio (95% CI)	1.57 (1.14, 2.16)	
	p-value	0.0062	
	Risk Difference (95% CI)	10.67 (3.12, 18.21)	
	p-value	0.0056	
	p-Value for test for heterogenity between studies	0.3666	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=315)	Placebo (N=321)
Week 32	Number of subjects with events, n (%)	150 (47.6)	111 (34.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.37 (1.13, 1.66)	
	p-value	0.0016	
	Odds Ratio (95% CI)	1.69 (1.22, 2.33)	
	p-value	0.0014	
	Risk Difference (95% CI)	12.63 (4.96, 20.29)	
	p-value	0.0012	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.35 (1.12, 1.63)	
	p-value	0.0017	
	Odds Ratio (95% CI)	1.72 (1.25, 2.37)	
	p-value	0.0010	
	Risk Difference (95% CI)	12.93 (5.37, 20.49)	
	p-value	0.0008	
	p-Value for test for heterogenity between studies	0.2909	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=315)	Placebo (N=321)
Week 36	Number of subjects with events, n (%)	149 (47.3)	110 (34.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.38 (1.14, 1.68)	
	p-value	0.0009	
	Odds Ratio (95% CI)	1.74 (1.26, 2.41)	
	p-value	0.0009	
	Risk Difference (95% CI)	13.10 (5.51, 20.70)	
	p-value	0.0007	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.36 (1.13, 1.64)	
	p-value	0.0014	
	Odds Ratio (95% CI)	1.72 (1.25, 2.38)	
	p-value	0.0009	
	Risk Difference (95% CI)	12.93 (5.39, 20.47)	
	p-value	0.0008	
	p-Value for test for heterogenity between studies	0.4520	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=315)	Placebo (N=321)
Week 40	Number of subjects with events, n (%)	140 (44.4)	103 (32.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.38 (1.12, 1.69)	
	p-value	0.0022	
	Odds Ratio (95% CI)	1.68 (1.21, 2.33)	
	p-value	0.0019	
	Risk Difference (95% CI)	12.08 (4.53, 19.63)	
	p-value	0.0017	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.37 (1.13, 1.68)	
	p-value	0.0018	
	Odds Ratio (95% CI)	1.69 (1.22, 2.34)	
	p-value	0.0015	
	Risk Difference (95% CI)	12.27 (4.80, 19.74)	
	p-value	0.0013	
	p-Value for test for heterogenity between studies	0.6156	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=315)	Placebo (N=321)
Week 44	Number of subjects with events, n (%)	137 (43.5)	105 (32.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.33 (1.08, 1.63)	
	p-value	0.0076	
	Odds Ratio (95% CI)	1.56 (1.13, 2.16)	
	p-value	0.0070	
	Risk Difference (95% CI)	10.59 (2.96, 18.23)	
	p-value	0.0065	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.33 (1.09, 1.62)	
	p-value	0.0059	
	Odds Ratio (95% CI)	1.58 (1.14, 2.18)	
	p-value	0.0057	
	Risk Difference (95% CI)	10.67 (3.17, 18.16)	
	p-value	0.0053	
	p-Value for test for heterogenity between studies	0.7218	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=315)	Placebo (N=321)
Week 48	Number of subjects with events, n (%)	143 (45.4)	104 (32.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.40 (1.15, 1.71)	
	p-value	0.0009	
	Odds Ratio (95% CI)	1.75 (1.26, 2.43)	
	p-value	0.0009	
	Risk Difference (95% CI)	12.93 (5.43, 20.43)	
	p-value	0.0007	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.40 (1.15, 1.71)	
	p-value	0.0009	
	Odds Ratio (95% CI)	1.73 (1.26, 2.39)	
	p-value	0.0008	
	Risk Difference (95% CI)	12.99 (5.47, 20.51)	
	p-value	0.0007	
	p-Value for test for heterogenity between studies	0.6368	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=315)	Placebo (N=321)
Week 52	Number of subjects with events, n (%)	147 (46.7)	100 (31.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.49 (1.22, 1.82)	
	p-value	0.0001	
	Odds Ratio (95% CI)	1.93 (1.39, 2.69)	
	p-value	<.0001	
	Risk Difference (95% CI)	15.23 (7.73, 22.72)	
	p-value	<.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.50 (1.22, 1.83)	
	p-value	<.0001	
	Odds Ratio (95% CI)	1.93 (1.40, 2.67)	
	p-value	<.0001	
	Risk Difference (95% CI)	15.46 (7.98, 22.94)	
	p-value	<.0001	
	p-Value for test for heterogenity between studies	0.8897	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
BICLA response rate at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	 p-Value	Interaction p-Value
SLEDAI-2K score					0.6198
< 10 points	60/109 (55.0)	40/101 (39.6)	1.39 (1.03, 1.87)	0.0295	
>= 10 points	87/206 (42.2)	60/220 (27.3)	1.54 (1.17, 2.01)	0.0018	
OCS dose					0.7906
<10 mg/day	63/148 (42.6)	42/145 (29.0)	1.44 (1.06, 1.98)	0.0217	
>=10 mg/day	84/167 (50.3)	58/176 (33.0)	1.53 (1.18, 1.98)	0.0014	
Result of type I IFN gene signature test					0.5759
LOW	26/ 59 (44.1)	22/ 67 (32.8)	1.33 (0.85, 2.08)	0.2062	
HIGH	121/256 (47.3)	78/254 (30.7)	1.54 (1.23, 1.93)	0.0002	
Age (years)					0.9246
<= 65	143/308 (46.4)	99/318 (31.1)	1.49 (1.22, 1.83)	0.0001	
> 65	4/ 7 (57.1)	1/ 3 (33.3)	1.60 (0.37, 6.85)	0.5262	
Sex					0.5807
male	13/ 27 (48.1)	9/ 26 (34.6)	1.23 (0.62, 2.44)	0.5475	
female	134/288 (46.5)	91/295 (30.8)	1.51 (1.22, 1.86)	0.0001	
Race					0.4995
White	82/185 (44.3)	66/205 (32.2)	1.38 (1.07, 1.78)	0.0138	
Black	25/ 49 (51.0)	15/ 40 (37.5)	1.33 (0.80, 2.20)	0.2775	
Other	35/ 73 (47.9)	18/ 73 (24.7)	1.87 (1.16, 3.02)	0.0098	
Ethnicity					0.9064
Hispanic/Latino	35/ 78 (44.9)	26/ 84 (31.0)	1.45 (0.97, 2.17)	0.0693	
Non-hispanic/Latino	107/229 (46.7)	73/234 (31.2)	1.49 (1.18, 1.89)	0.0008	
Geographic region					0.1752
EU	57/110 (51.8)	45/109 (41.3)	1.28 (0.96, 1.71)	0.0874	
non-EU	90/205 (43.9)	55/212 (25.9)	1.69 (1.28, 2.22)	0.0002	
Onset of disease					0.7887
Paediatric	12/ 26 (46.2)	6/ 21 (28.6)	1.67 (0.74, 3.74)	0.2139	
Adult	135/289 (46.7)	94/300 (31.3)	1.49 (1.21, 1.83)	0.0002	
ADA result					0.4751
Negative	138/292 (47.3)	95/295 (32.2)	1.47 (1.20, 1.81)	0.0002	
Positive (At any time)	9/ 22 (40.9)	5/ 26 (19.2)	2.05 (0.84, 5.02)	0.1145	
BMI (kg/m2)					0.4285
< 30	105/213 (49.3)	75/235 (31.9)	1.54 (1.23, 1.95)	0.0002	
>= 30	42/102 (41.2)	25/ 86 (29.1)	1.28 (0.87, 1.90)	0.2151	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Change from baseline in PGA VAS < 0.3 at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=315)	Placebo (N=321)
Week 52	Number of subjects with events, n (%)	215 (68.3)	179 (55.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.23 (1.08, 1.39)	
	p-value	0.0012	
	Odds Ratio (95% CI)	1.72 (1.24, 2.39)	
	p-value	0.0012	
	Risk Difference (95% CI)	12.65 (5.12, 20.19)	
	p-value	0.0010	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.22 (1.08, 1.38)	
	p-value	0.0014	
	Odds Ratio (95% CI)	1.71 (1.24, 2.37)	
	p-value	0.0012	
	Risk Difference (95% CI)	12.55 (5.09, 20.01)	
	p-value	0.0010	
	p-Value for test for heterogenity between studies	0.6199	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Change from baseline in PGA VAS < 0.3 at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	 p-Value	Interaction p-Value
SLEDAI-2K score					0.3366
< 10 points	78/109 (71.6)	64/101 (63.4)	1.12 (0.93, 1.35)	0.2366	
>= 10 points	137/206 (66.5)	115/220 (52.3)	1.26 (1.08, 1.48)	0.0040	
OCS dose					0.5781
<10 mg/day	98/148 (66.2)	80/145 (55.2)	1.18 (0.99, 1.42)	0.0715	
>=10 mg/day	117/167 (70.1)	99/176 (56.3)	1.27 (1.08, 1.49)	0.0040	
Result of type I IFN gene signature test					0.2332
LOW	46/ 59 (78.0)	37/ 67 (55.2)	1.40 (1.09, 1.80)	0.0088	
HIGH	169/256 (66.0)	142/254 (55.9)	1.18 (1.02, 1.35)	0.0233	
Age (years)					0.0818
<= 65	210/308 (68.2)	177/318 (55.7)	1.22 (1.08, 1.38)	0.0015	
> 65	5/ 7 (71.4)	2/ 3 (66.7)	0.82 (0.53, 1.26)	0.3675	
Sex					0.5798
male	19/ 27 (70.4)	16/ 26 (61.5)	1.09 (0.75, 1.60)	0.6477	
female	196/288 (68.1)	163/295 (55.3)	1.22 (1.08, 1.39)	0.0021	
Race					0.6964
White	132/185 (71.4)	120/205 (58.5)	1.21 (1.05, 1.40)	0.0103	
Black	30/ 49 (61.2)	22/ 40 (55.0)	1.07 (0.72, 1.59)	0.7370	
Other	48/ 73 (65.8)	35/ 73 (47.9)	1.32 (0.99, 1.77)	0.0610	
Ethnicity					0.6045
Hispanic/Latino	52/ 78 (66.7)	42/ 84 (50.0)	1.28 (0.99, 1.66)	0.0570	
Non-hispanic/Latino	158/229 (69.0)	135/234 (57.7)	1.19 (1.03, 1.37)	0.0146	
Geographic region					0.1442
EU	84/110 (76.4)	76/109 (69.7)	1.10 (0.94, 1.29)	0.2387	
non-EU	131/205 (63.9)	103/212 (48.6)	1.31 (1.11, 1.56)	0.0018	
Onset of disease					0.6572
Paediatric	13/ 26 (50.0)	7/ 21 (33.3)	1.44 (0.68, 3.08)	0.3439	
Adult	202/289 (69.9)	172/300 (57.3)	1.21 (1.07, 1.37)	0.0020	
ADA result					0.7357
Negative	202/292 (69.2)	169/295 (57.3)	1.21 (1.07, 1.37)	0.0027	
Positive (At any time)	13/ 22 (59.1)	10/ 26 (38.5)	1.33 (0.76, 2.33)	0.3111	
BMI (kg/m2)					0.1680
< 30	153/213 (71.8)	131/235 (55.7)	1.29 (1.12, 1.48)	0.0005	
>= 30	62/102 (60.8)	48/ 86 (55.8)	1.06 (0.84, 1.34)	0.6370	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Change from baseline in PGA VAS < 0.45 at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=315)	Placebo (N=321)
Week 52	Number of subjects with events, n (%)	217 (68.9)	182 (56.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.22 (1.08, 1.37)	
	p-value	0.0015	
	Odds Ratio (95% CI)	1.71 (1.23, 2.37)	
	p-value	0.0015	
	Risk Difference (95% CI)	12.34 (4.84, 19.84)	
	p-value	0.0013	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.21 (1.08, 1.37)	
	p-value	0.0016	
	Odds Ratio (95% CI)	1.70 (1.23, 2.35)	
	p-value	0.0015	
	Risk Difference (95% CI)	12.23 (4.80, 19.67)	
	p-value	0.0013	
	p-Value for test for heterogenity between studies	0.8724	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Change from baseline in PGA VAS < 0.45 at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	 p-Value	Interaction p-Value
SLEDAI-2K score					0.4591
< 10 points	79/109 (72.5)	64/101 (63.4)	1.13 (0.94, 1.36)	0.1835	
>= 10 points	138/206 (67.0)	118/220 (53.6)	1.24 (1.06, 1.45)	0.0063	
OCS dose					0.4502
<10 mg/day	98/148 (66.2)	82/145 (56.6)	1.16 (0.97, 1.39)	0.1051	
>=10 mg/day	119/167 (71.3)	100/176 (56.8)	1.27 (1.09, 1.49)	0.0028	
Result of type I IFN gene signature test					0.2817
LOW	46/ 59 (78.0)	38/ 67 (56.7)	1.37 (1.07, 1.76)	0.0121	
HIGH	171/256 (66.8)	144/254 (56.7)	1.17 (1.02, 1.35)	0.0213	
Age (years)					0.0854
<= 65	212/308 (68.8)	180/318 (56.6)	1.22 (1.08, 1.37)	0.0016	
> 65	5/ 7 (71.4)	2/ 3 (66.7)	0.82 (0.53, 1.26)	0.3675	
Sex					0.5932
male	19/ 27 (70.4)	16/ 26 (61.5)	1.09 (0.75, 1.60)	0.6477	
female	198/288 (68.8)	166/295 (56.3)	1.22 (1.07, 1.38)	0.0022	
Race					0.6943
White	132/185 (71.4)	123/205 (60.0)	1.19 (1.03, 1.37)	0.0196	
Black	31/ 49 (63.3)	22/ 40 (55.0)	1.11 (0.75, 1.63)	0.6105	
Other	49/ 73 (67.1)	35/ 73 (47.9)	1.34 (1.00, 1.79)	0.0500	
Ethnicity					0.5774
Hispanic/Latino	53/ 78 (67.9)	43/ 84 (51.2)	1.28 (1.00, 1.65)	0.0543	
Non-hispanic/Latino	159/229 (69.4)	137/234 (58.5)	1.18 (1.03, 1.36)	0.0168	
Geographic region					0.1203
EU	84/110 (76.4)	77/109 (70.6)	1.09 (0.93, 1.28)	0.2967	
non-EU	133/205 (64.9)	105/212 (49.5)	1.31 (1.11, 1.55)	0.0017	
Onset of disease					0.8507
Paediatric	13/ 26 (50.0)	8/ 21 (38.1)	1.30 (0.65, 2.57)	0.4577	
Adult	204/289 (70.6)	174/300 (58.0)	1.21 (1.07, 1.37)	0.0017	
ADA result					0.8341
Negative	204/292 (69.9)	171/295 (58.0)	1.21 (1.07, 1.37)	0.0024	
Positive (At any time)	13/ 22 (59.1)	11/ 26 (42.3)	1.28 (0.74, 2.21)	0.3716	
BMI (kg/m2)					0.1794
< 30	153/213 (71.8)	132/235 (56.2)	1.28 (1.11, 1.47)	0.0007	
>= 30	64/102 (62.7)	50/ 86 (58.1)	1.06 (0.85, 1.33)	0.6020	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Major clinical response at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=315)	Placebo (N=321)
Week 52	Number of subjects with events, n (%)	67 (21.3)	38 (11.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.77 (1.22, 2.55)	
	p-value	0.0024	
	Odds Ratio (95% CI)	2.01 (1.29, 3.13)	
	p-value	0.0021	
	Risk Difference (95% CI)	9.12 (3.42, 14.83)	
	p-value	0.0017	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.72 (1.19, 2.48)	
	p-value	0.0038	
	Odds Ratio (95% CI)	1.98 (1.27, 3.07)	
	p-value	0.0024	
	Risk Difference (95% CI)	9.31 (3.59, 15.03)	
	p-value	0.0014	
	p-Value for test for heterogenity between studies	0.1901	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Major clinical response at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.9736
< 10 points	30/109 (27.5)	17/101 (16.8)	1.61 (0.94, 2.75)	0.0831	
>= 10 points	37/206 (18.0)	21/220 (9.5)	1.59 (0.96, 2.63)	0.0723	
OCS dose					0.8870
<10 mg/day	32/148 (21.6)	17/145 (11.7)	1.79 (1.03, 3.08)	0.0374	
>=10 mg/day	35/167 (21.0)	21/176 (11.9)	1.69 (1.03, 2.78)	0.0381	
Result of type I IFN gene signature test					0.5768
LOW	9/ 59 (15.3)	7/ 67 (10.4)	1.29 (0.46, 3.67)	0.6267	
HIGH	58/256 (22.7)	31/254 (12.2)	1.78 (1.19, 2.65)	0.0047	
Age (years)					0.1088
<= 65	67/308 (21.8)	37/318 (11.6)	1.80 (1.24, 2.61)	0.0018	
> 65	0/ 7 (0.0)	1/ 3 (33.3)	0.17 (0.01, 2.98)	0.2235	
Sex					0.5551
male	7/ 27 (25.9)	2/ 26 (7.7)	2.53 (0.61, 10.58)	0.2031	
female	60/288 (20.8)	36/295 (12.2)	1.62 (1.10, 2.38)	0.0138	
Race					0.9435
White	38/185 (20.5)	24/205 (11.7)	1.70 (1.06, 2.72)	0.0281	
Black	13/ 49 (26.5)	6/ 40 (15.0)	1.44 (0.61, 3.37)	0.4051	
Other	13/ 73 (17.8)	8/ 73 (11.0)	1.58 (0.70, 3.58)	0.2709	
Ethnicity					0.4431
Hispanic/Latino	14/ 78 (17.9)	12/ 84 (14.3)	1.31 (0.60, 2.88)	0.4970	
Non-hispanic/Latino	50/229 (21.8)	26/234 (11.1)	1.86 (1.21, 2.88)	0.0050	
Geographic region					0.8263
EU	30/110 (27.3)	17/109 (15.6)	1.86 (1.10, 3.14)	0.0203	
non-EU	37/205 (18.0)	21/212 (9.9)	1.71 (1.02, 2.86)	0.0402	
Onset of disease					0.9873
Paediatric	4/ 26 (15.4)	1/ 21 (4.8)	1.65 (0.30, 9.15)	0.5643	
Adult	63/289 (21.8)	37/300 (12.3)	1.68 (1.15, 2.44)	0.0066	
ADA result					0.5203
Negative	61/292 (20.9)	36/295 (12.2)	1.66 (1.13, 2.42)	0.0094	
Positive (At any time)	6/ 22 (27.3)	2/ 26 (7.7)	2.62 (0.68, 10.05)	0.1607	
BMI (kg/m2)					0.9205
< 30	49/213 (23.0)	30/235 (12.8)	1.76 (1.15, 2.68)	0.0087	
>= 30	18/102 (17.6)	8/ 86 (9.3)	1.68 (0.79, 3.56)	0.1742	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Partial clinical response at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=315)	Placebo (N=321)
Week 52	Number of subjects with events, n (%)	148 (47.0)	123 (38.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.24 (1.03, 1.49)	
	p-value	0.0220	
	Odds Ratio (95% CI)	1.46 (1.06, 2.01)	
	p-value	0.0211	
	Risk Difference (95% CI)	9.14 (1.43, 16.84)	
	p-value	0.0201	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.22 (1.02, 1.46)	
	p-value	0.0338	
	Odds Ratio (95% CI)	1.42 (1.04, 1.95)	
	p-value	0.0296	
	Risk Difference (95% CI)	8.53 (0.89, 16.18)	
	p-value	0.0287	
	p-Value for test for heterogenity between studies	0.6597	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Partial clinical response at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	 p-Value	Interaction p-Value
SLEDAI-2K score					0.8309
< 10 points	57/109 (52.3)	45/101 (44.6)	1.17 (0.88, 1.56)	0.2656	
>= 10 points	91/206 (44.2)	78/220 (35.5)	1.22 (0.97, 1.55)	0.0935	
OCS dose					0.4474
<10 mg/day	68/148 (45.9)	58/145 (40.0)	1.13 (0.86, 1.47)	0.3798	
>=10 mg/day	80/167 (47.9)	65/176 (36.9)	1.30 (1.01, 1.66)	0.0421	
Result of type I IFN gene signature test					0.1188
LOW	24/ 59 (40.7)	30/ 67 (44.8)	0.91 (0.61, 1.37)	0.6646	
HIGH	124/256 (48.4)	93/254 (36.6)	1.31 (1.07, 1.61)	0.0094	
Age (years)					0.8593
<= 65	144/308 (46.8)	122/318 (38.4)	1.21 (1.01, 1.45)	0.0407	
> 65	4/ 7 (57.1)	1/ 3 (33.3)	1.37 (0.36, 5.25)	0.6477	
Sex					0.8746
male	16/ 27 (59.3)	11/ 26 (42.3)	1.25 (0.70, 2.23)	0.4481	
female	132/288 (45.8)	112/295 (38.0)	1.19 (0.98, 1.44)	0.0736	
Race					0.1937
White	81/185 (43.8)	84/205 (41.0)	1.06 (0.84, 1.33)	0.6430	
Black	20/ 49 (40.8)	11/ 40 (27.5)	1.12 (0.64, 1.95)	0.7001	
Other	42/ 73 (57.5)	26/ 73 (35.6)	1.58 (1.09, 2.31)	0.0166	
Ethnicity					0.4182
Hispanic/Latino	40/ 78 (51.3)	40/ 84 (47.6)	1.08 (0.79, 1.47)	0.6493	
Non-hispanic/Latino	103/229 (45.0)	81/234 (34.6)	1.26 (1.01, 1.58)	0.0427	
Geographic region					0.9656
EU	59/110 (53.6)	47/109 (43.1)	1.21 (0.93, 1.58)	0.1608	
non-EU	89/205 (43.4)	76/212 (35.8)	1.20 (0.95, 1.52)	0.1314	
Onset of disease					0.8879
Paediatric	11/ 26 (42.3)	5/ 21 (23.8)	1.28 (0.51, 3.23)	0.5983	
Adult	137/289 (47.4)	118/300 (39.3)	1.20 (1.00, 1.44)	0.0561	
ADA result					0.1569
Negative	138/292 (47.3)	118/295 (40.0)	1.17 (0.97, 1.41)	0.0945	
Positive (At any time)	10/ 22 (45.5)	5/ 26 (19.2)	2.31 (0.92, 5.79)	0.0753	
BMI (kg/m2)					0.1185
< 30	106/213 (49.8)	88/235 (37.4)	1.33 (1.08, 1.65)	0.0085	
>= 30	42/102 (41.2)	35/ 86 (40.7)	0.97 (0.69, 1.36)	0.8492	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=50% Joint reduction at week 52 (for subjects with at least 6 tender joints and at least 6 swollen joints at baseline)
Full analysis set

Timepoint		Anifrolumab 300mg (N=146)	Placebo (N=166)
Week 52	Number of subjects with events, n (%)	79 (54.1)	65 (39.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.35 (1.07, 1.70)	
	p-value	0.0118	
	Odds Ratio (95% CI)	1.84 (1.14, 2.97)	
	p-value	0.0127	
	Risk Difference (95% CI)	13.93 (3.10, 24.76)	
	p-value	0.0117	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.37 (1.07, 1.74)	
	p-value	0.0120	
	Odds Ratio (95% CI)	1.76 (1.11, 2.79)	
	p-value	0.0163	
	Risk Difference (95% CI)	14.17 (3.15, 25.18)	
	p-value	0.0117	
	p-Value for test for heterogenity between studies	0.1139	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=50% Joint reduction at week 52 (for subjects with at least 6 tender joints and at least 6 swollen joints at baseline) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=146) n/ N (%)	Placebo (N=166) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.9116
< 10 points	32/ 52 (61.5)	23/ 48 (47.9)	1.36 (0.95, 1.95)	0.0901	
>= 10 points	47/ 94 (50.0)	42/118 (35.6)	1.32 (0.96, 1.83)	0.0890	
OCS dose					0.5221
<10 mg/day	28/ 62 (45.2)	25/ 71 (35.2)	1.24 (0.82, 1.87)	0.3084	
>=10 mg/day	51/ 84 (60.7)	40/ 95 (42.1)	1.46 (1.09, 1.96)	0.0118	
Result of type I IFN gene signature test					0.1160
LOW	18/ 31 (58.1)	11/ 39 (28.2)	2.07 (1.15, 3.72)	0.0150	
HIGH	61/115 (53.0)	54/127 (42.5)	1.23 (0.94, 1.61)	0.1231	
Age (years)					0.0537
<= 65	76/142 (53.5)	63/163 (38.7)	1.38 (1.07, 1.77)	0.0118	
> 65	3/ 4 (75.0)	2/ 3 (66.7)	0.75 (0.43, 1.32)	0.3190	
Sex					0.7691
male	3/ 9 (33.3)	3/ 7 (42.9)	1.07 (0.18, 6.58)	0.9383	
female	76/137 (55.5)	62/159 (39.0)	1.41 (1.10, 1.81)	0.0059	
Race					0.7626
White	45/ 87 (51.7)	47/116 (40.5)	1.24 (0.91, 1.69)	0.1647	
Black	12/ 24 (50.0)	6/ 18 (33.3)	1.35 (0.56, 3.28)	0.5049	
Other	19/ 31 (61.3)	12/ 31 (38.7)	1.54 (0.94, 2.53)	0.0841	
Ethnicity					0.4415
Hispanic/Latino	22/ 39 (56.4)	16/ 43 (37.2)	1.52 (0.97, 2.37)	0.0682	
Non-hispanic/Latino	54/103 (52.4)	49/122 (40.2)	1.23 (0.91, 1.65)	0.1750	
Geographic region					0.4481
EU	33/ 48 (68.8)	30/ 56 (53.6)	1.24 (0.90, 1.69)	0.1833	
non-EU	46/ 98 (46.9)	35/110 (31.8)	1.48 (1.05, 2.10)	0.0263	
Onset of disease					0.8742
Paediatric	5/ 10 (50.0)	4/ 13 (30.8)	1.45 (0.53, 3.93)	0.4688	
Adult	74/136 (54.4)	61/153 (39.9)	1.33 (1.03, 1.71)	0.0269	
ADA result					0.5829
Negative	74/133 (55.6)	63/154 (40.9)	1.35 (1.06, 1.73)	0.0147	
Positive (At any time)	5/ 12 (41.7)	2/ 12 (16.7)	2.00 (0.51, 7.85)	0.3206	
BMI (kg/m2)					0.0422
< 30	55/ 93 (59.1)	46/121 (38.0)	1.56 (1.18, 2.07)	0.0019	
>= 30	24/ 53 (45.3)	19/ 45 (42.2)	0.89 (0.56, 1.42)	0.6181	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=50% Joint reduction at week 52 (for subjects with at least 8 tender joints and at least 8 swollen joints at baseline)
Full analysis set

Timepoint		Anifrolumab 300mg (N=100)	Placebo (N=119)
Week 52	Number of subjects with events, n (%)	53 (53.0)	43 (36.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.43 (1.08, 1.90)	
	p-value	0.0136	
	Odds Ratio (95% CI)	2.21 (1.18, 4.14)	
	p-value	0.0134	
	Risk Difference (95% CI)	16.42 (3.62, 29.22)	
	p-value	0.0119	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.41 (1.04, 1.91)	
	p-value	0.0285	
	Odds Ratio (95% CI)	1.80 (1.02, 3.17)	
	p-value	0.0415	
	Risk Difference (95% CI)	13.92 (0.81, 27.04)	
	p-value	0.0375	
	p-Value for test for heterogenity between studies	0.5038	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
>=50% Joint reduction at week 52 (for subjects with at least 8 tender joints and at least 8 swollen joints at baseline) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=100) n/ N (%)	Placebo (N=119) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.7324
< 10 points	23/ 37 (62.2)	19/ 39 (48.7)	1.29 (0.88, 1.90)	0.1915	
>= 10 points	30/ 63 (47.6)	24/ 80 (30.0)	1.44 (0.91, 2.27)	0.1208	
OCS dose					0.9329
<10 mg/day	17/ 39 (43.6)	13/ 46 (28.3)	1.40 (0.77, 2.54)	0.2703	
>=10 mg/day	36/ 61 (59.0)	30/ 73 (41.1)	1.44 (1.02, 2.04)	0.0390	
Result of type I IFN gene signature test					0.1470
LOW	14/ 26 (53.8)	6/ 27 (22.2)	2.33 (1.08, 5.03)	0.0309	
HIGH	39/ 74 (52.7)	37/ 92 (40.2)	1.25 (0.90, 1.75)	0.1882	
Age (years)					0.1476
<= 65	52/ 98 (53.1)	42/117 (35.9)	1.43 (1.05, 1.95)	0.0245	
> 65	1/ 2 (50.0)	1/ 2 (50.0)	0.50 (0.13, 2.00)	0.3270	
Sex					0.4971
male	2/ 8 (25.0)	2/ 4 (50.0)	0.78 (0.13, 4.81)	0.7908	
female	51/ 92 (55.4)	41/115 (35.7)	1.48 (1.09, 2.01)	0.0116	
Race					0.9052
White	33/ 62 (53.2)	31/ 82 (37.8)	1.36 (0.93, 1.99)	0.1175	
Black	9/ 19 (47.4)	4/ 13 (30.8)	1.63 (0.54, 4.94)	0.3912	
Other	10/ 18 (55.6)	8/ 24 (33.3)	1.56 (0.84, 2.87)	0.1560	
Ethnicity					0.9491
Hispanic/Latino	14/ 27 (51.9)	12/ 31 (38.7)	1.36 (0.80, 2.31)	0.2518	
Non-hispanic/Latino	38/ 72 (52.8)	31/ 88 (35.2)	1.39 (0.94, 2.06)	0.0985	
Geographic region					0.7169
EU	22/ 29 (75.9)	20/ 36 (55.6)	1.37 (0.95, 1.99)	0.0927	
non-EU	31/ 71 (43.7)	23/ 83 (27.7)	1.53 (1.00, 2.33)	0.0511	
Onset of disease					0.5838
Paediatric	2/ 6 (33.3)	4/ 13 (30.8)	0.93 (0.22, 3.88)	0.9197	
Adult	51/ 94 (54.3)	39/106 (36.8)	1.40 (1.01, 1.93)	0.0405	
ADA result					0.7803
Negative	50/ 90 (55.6)	41/109 (37.6)	1.41 (1.04, 1.91)	0.0259	
Positive (At any time)	3/ 9 (33.3)	2/ 10 (20.0)	1.88 (0.26, 13.42)	0.5313	
BMI (kg/m2)					0.1039
< 30	35/ 60 (58.3)	31/ 89 (34.8)	1.55 (1.09, 2.20)	0.0156	
>= 30	18/ 40 (45.0)	12/ 30 (40.0)	0.88 (0.50, 1.57)	0.6729	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (5) response rate at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=315)	Placebo (N=320)
Week 52	Number of subjects with events, n (%)	135 (42.9)	93 (29.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.51 (1.22, 1.88)	
	p-value	0.0002	
	Odds Ratio (95% CI)	1.93 (1.38, 2.70)	
	p-value	0.0001	
	Risk Difference (95% CI)	14.69 (7.31, 22.07)	
	p-value	<.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.47 (1.19, 1.82)	
	p-value	0.0004	
	Odds Ratio (95% CI)	1.83 (1.32, 2.55)	
	p-value	0.0003	
	Risk Difference (95% CI)	13.77 (6.39, 21.16)	
	p-value	0.0003	
	p-Value for test for heterogenity between studies	0.8244	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (6) response rate at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=315)	Placebo (N=320)
Week 52	Number of subjects with events, n (%)	133 (42.2)	89 (27.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.56 (1.25, 1.94)	
	p-value	<.0001	
	Odds Ratio (95% CI)	1.99 (1.42, 2.79)	
	p-value	<.0001	
	Risk Difference (95% CI)	15.26 (7.92, 22.61)	
	p-value	<.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.51 (1.21, 1.87)	
	p-value	0.0002	
	Odds Ratio (95% CI)	1.90 (1.36, 2.65)	
	p-value	0.0002	
	Risk Difference (95% CI)	14.39 (7.06, 21.72)	
	p-value	0.0001	
	p-Value for test for heterogenity between studies	0.5437	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SRI (7) response rate at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=300)	Placebo (N=309)
Week 52	Number of subjects with events, n (%)	92 (30.7)	47 (15.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	2.07 (1.51, 2.83)	
	p-value	<.0001	
	Odds Ratio (95% CI)	2.57 (1.72, 3.84)	
	p-value	<.0001	
	Risk Difference (95% CI)	16.17 (9.54, 22.81)	
	p-value	<.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	2.01 (1.47, 2.76)	
	p-value	<.0001	
	Odds Ratio (95% CI)	2.46 (1.66, 3.66)	
	p-value	<.0001	
	Risk Difference (95% CI)	15.44 (8.86, 22.02)	
	p-value	<.0001	
	p-Value for test for heterogenity between studies	0.9941	

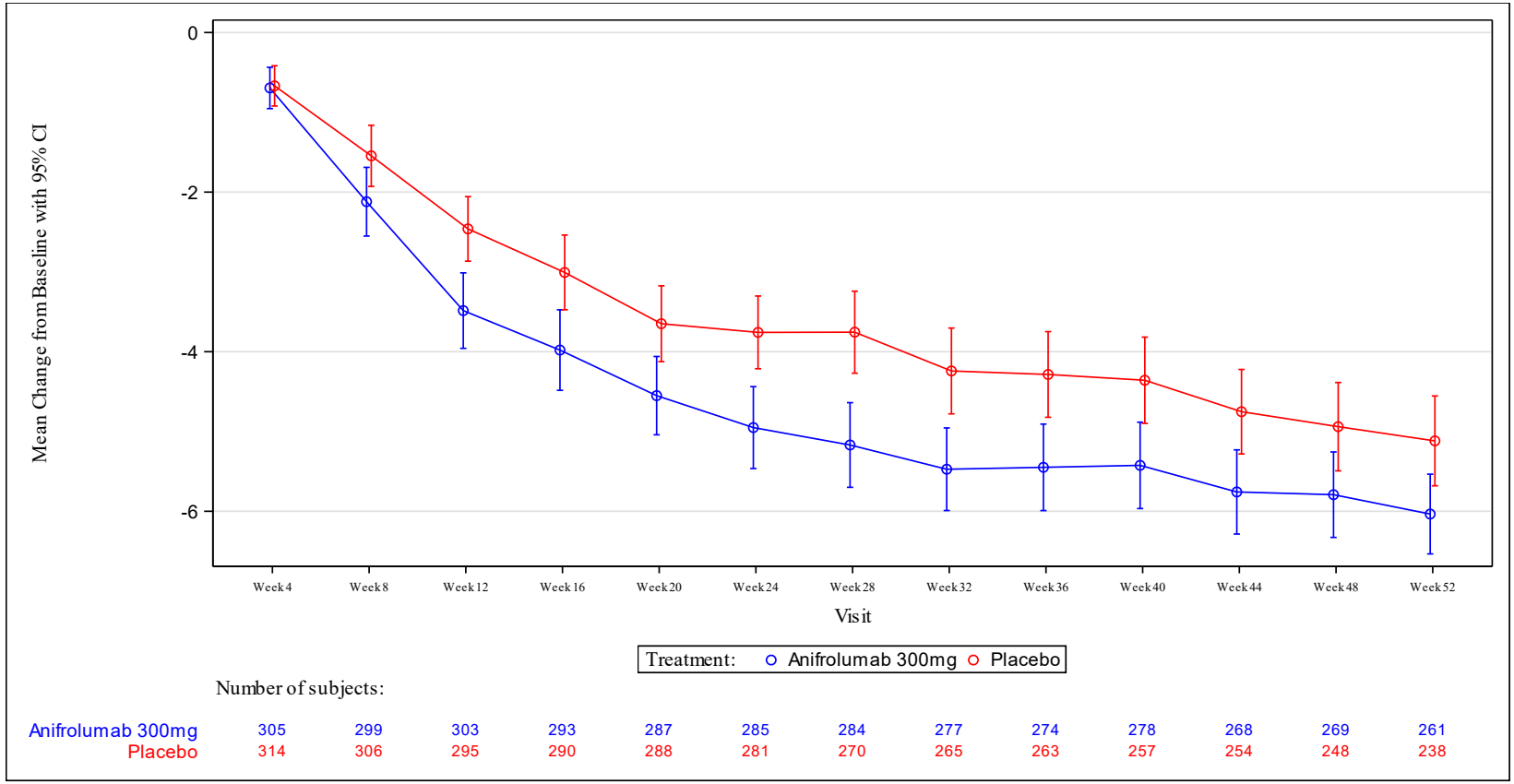
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - SLEDAI-2K Total Score
Full analysis set

	Anifrolumab 300mg (N=315)				Placebo (N=321)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	315	11.17 (3.87)	0	-	321	11.33 (3.91)	0	-
Week 4	305	10.54 (3.68)	305	-0.70 (2.30)	314	10.59 (3.78)	314	-0.67 (2.27)
Week 8	299	9.16 (4.26)	299	-2.12 (3.78)	306	9.80 (4.34)	306	-1.55 (3.41)
Week 12	303	7.73 (4.15)	303	-3.49 (4.18)	295	8.81 (4.15)	295	-2.46 (3.53)
Week 16	293	7.16 (4.28)	293	-3.98 (4.39)	290	8.21 (4.49)	290	-3.01 (4.05)
Week 20	287	6.48 (4.08)	287	-4.55 (4.22)	288	7.58 (4.24)	288	-3.65 (4.10)
Week 24	285	6.24 (4.13)	285	-4.95 (4.40)	281	7.44 (4.03)	281	-3.76 (3.88)
Week 28	284	6.02 (4.16)	284	-5.17 (4.54)	270	7.40 (4.47)	270	-3.76 (4.29)
Week 32	277	5.78 (4.05)	277	-5.47 (4.38)	265	7.00 (4.60)	265	-4.24 (4.45)
Week 36	274	5.72 (4.24)	274	-5.45 (4.56)	263	6.90 (4.52)	263	-4.29 (4.42)
Week 40	278	5.72 (4.05)	278	-5.42 (4.58)	257	6.74 (4.58)	257	-4.36 (4.40)
Week 44	268	5.34 (3.92)	268	-5.76 (4.39)	254	6.20 (4.14)	254	-4.75 (4.28)
Week 48	269	5.31 (3.93)	269	-5.79 (4.46)	248	6.10 (4.16)	248	-4.94 (4.42)
Week 52	261	5.03 (3.54)	261	-6.03 (4.10)	238	5.88 (4.15)	238	-5.12 (4.41)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - SLEDAI-2K Total Score
Full analysis set



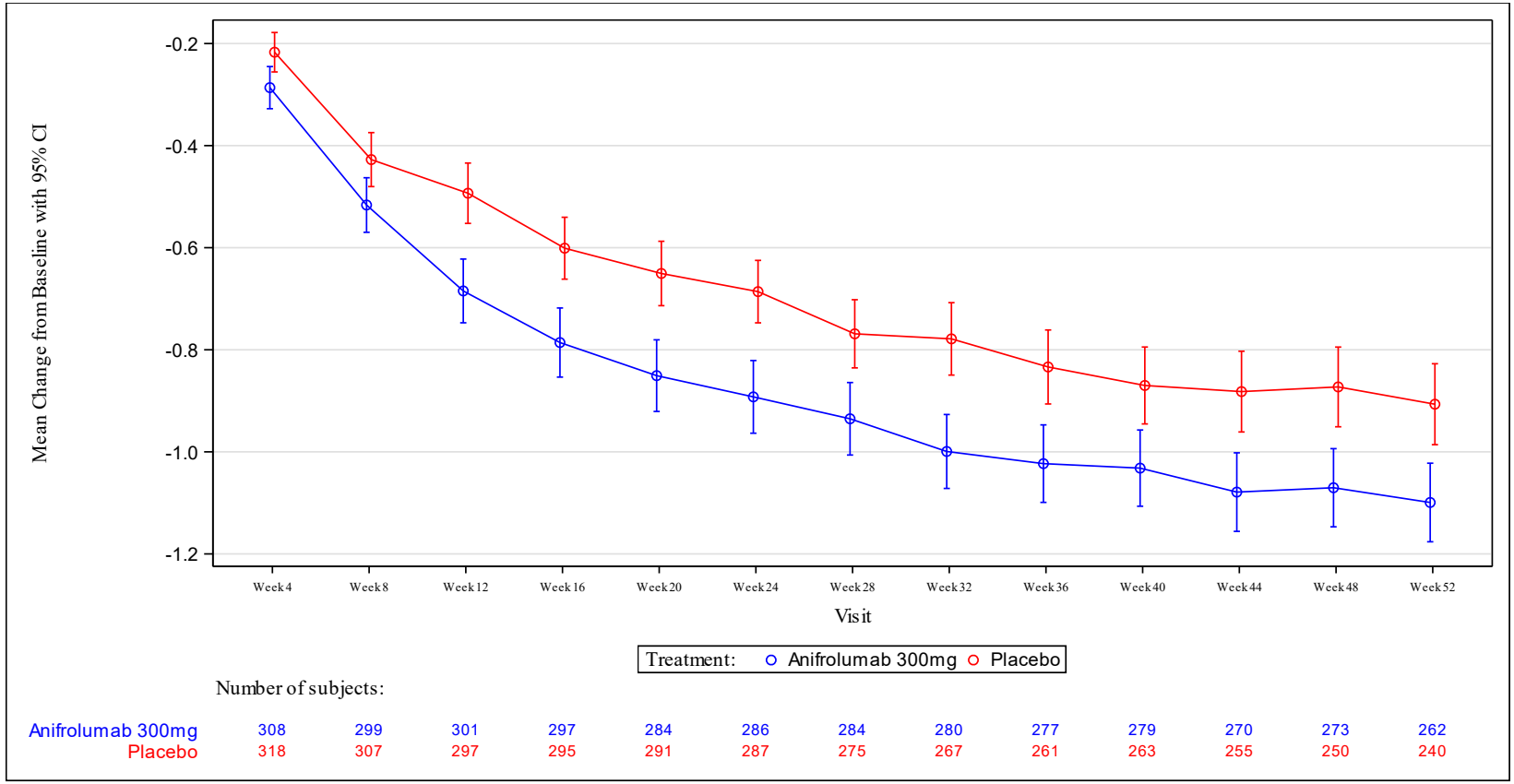
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - PGA
Full analysis set

	Anifrolumab 300mg (N=315)				Placebo (N=321)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	315	1.78 (0.42)	0	-	321	1.78 (0.39)	0	-
Week 4	308	1.50 (0.51)	308	-0.29 (0.37)	318	1.57 (0.46)	318	-0.22 (0.35)
Week 8	299	1.26 (0.53)	299	-0.52 (0.47)	307	1.36 (0.53)	307	-0.43 (0.47)
Week 12	301	1.09 (0.56)	301	-0.68 (0.55)	297	1.30 (0.54)	297	-0.49 (0.52)
Week 16	297	0.99 (0.59)	297	-0.79 (0.59)	295	1.18 (0.52)	295	-0.60 (0.53)
Week 20	284	0.92 (0.59)	284	-0.85 (0.60)	291	1.14 (0.54)	291	-0.65 (0.55)
Week 24	286	0.88 (0.60)	286	-0.89 (0.61)	287	1.09 (0.52)	287	-0.69 (0.53)
Week 28	284	0.84 (0.60)	284	-0.94 (0.61)	275	1.02 (0.54)	275	-0.77 (0.56)
Week 32	280	0.78 (0.57)	280	-1.00 (0.62)	267	1.00 (0.57)	267	-0.78 (0.59)
Week 36	277	0.76 (0.59)	277	-1.02 (0.64)	261	0.94 (0.56)	261	-0.83 (0.59)
Week 40	279	0.75 (0.58)	279	-1.03 (0.63)	263	0.91 (0.56)	263	-0.87 (0.62)
Week 44	270	0.68 (0.55)	270	-1.08 (0.64)	255	0.91 (0.57)	255	-0.88 (0.64)
Week 48	273	0.70 (0.56)	273	-1.07 (0.64)	250	0.90 (0.57)	250	-0.87 (0.63)
Week 52	262	0.66 (0.54)	262	-1.10 (0.63)	240	0.87 (0.57)	240	-0.91 (0.62)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - PGA
Full analysis set



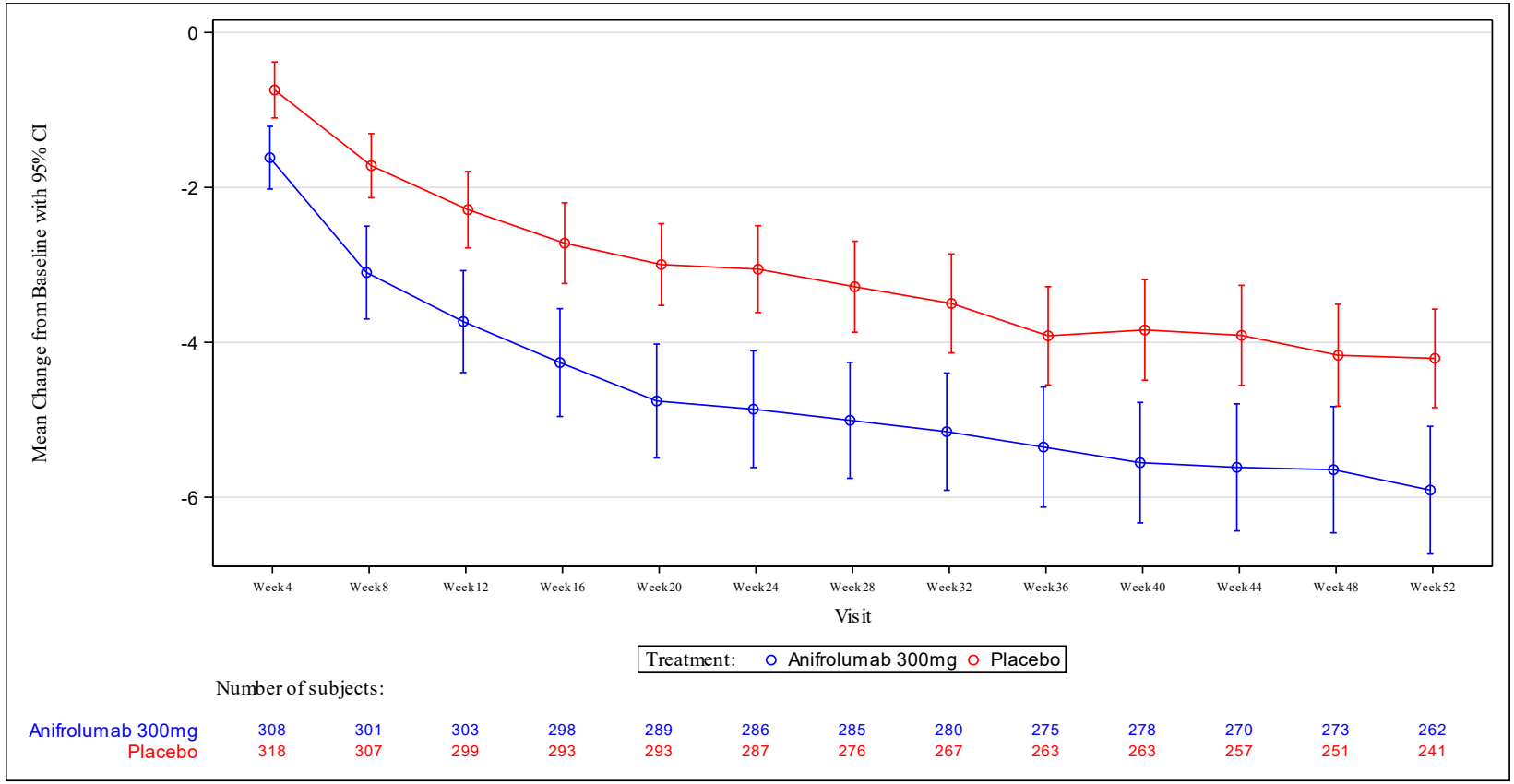
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - CLASI Total Activity Score
Full analysis set

	Anifrolumab 300mg (N=315)				Placebo (N=321)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	315	8.08 (7.32)	0	-	321	7.59 (6.88)	0	-
Week 4	308	6.53 (6.00)	308	-1.62 (3.61)	318	6.84 (6.65)	318	-0.74 (3.27)
Week 8	301	5.06 (4.72)	301	-3.10 (5.28)	307	5.99 (6.58)	307	-1.72 (3.68)
Week 12	303	4.33 (4.32)	303	-3.73 (5.82)	299	5.45 (6.22)	299	-2.29 (4.33)
Week 16	298	3.94 (4.10)	298	-4.26 (6.10)	293	4.97 (5.77)	293	-2.72 (4.53)
Week 20	289	3.43 (3.70)	289	-4.76 (6.35)	293	4.82 (6.00)	293	-3.00 (4.59)
Week 24	286	3.28 (3.79)	286	-4.86 (6.48)	287	4.81 (6.24)	287	-3.06 (4.82)
Week 28	285	3.11 (3.72)	285	-5.01 (6.42)	276	4.56 (5.94)	276	-3.28 (4.96)
Week 32	280	2.92 (3.60)	280	-5.15 (6.43)	267	4.44 (6.18)	267	-3.50 (5.31)
Week 36	275	2.71 (3.48)	275	-5.35 (6.53)	263	4.11 (5.69)	263	-3.92 (5.22)
Week 40	278	2.53 (3.39)	278	-5.55 (6.59)	263	4.14 (5.98)	263	-3.84 (5.35)
Week 44	270	2.58 (3.94)	270	-5.61 (6.85)	257	4.06 (5.93)	257	-3.91 (5.25)
Week 48	273	2.37 (3.25)	273	-5.64 (6.84)	251	3.82 (5.57)	251	-4.17 (5.29)
Week 52	262	2.34 (3.80)	262	-5.91 (6.77)	241	3.82 (5.63)	241	-4.21 (5.01)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - CLASI Total Activity Score
Full analysis set



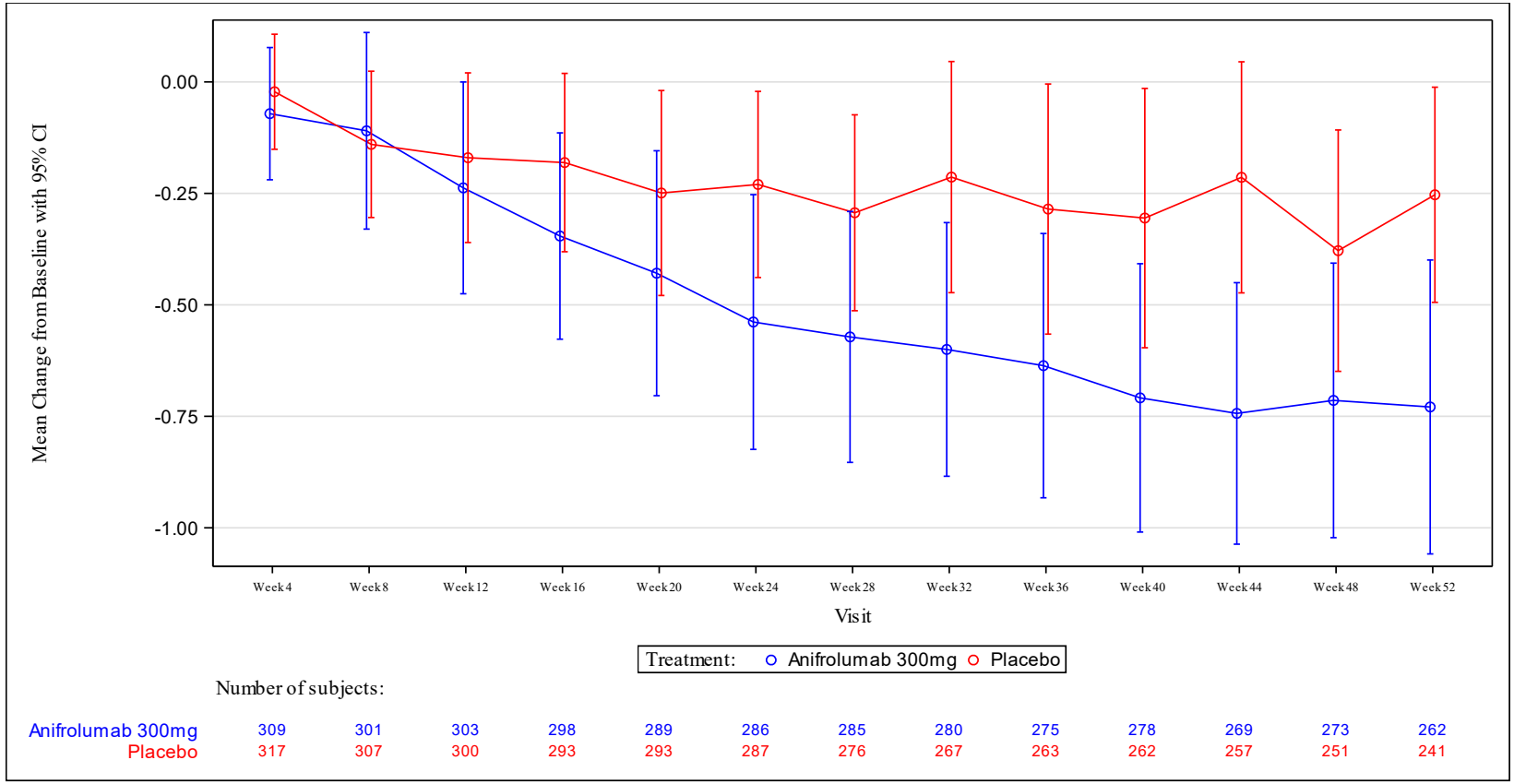
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - CLASI Total Damage Score
Full analysis set

	Anifrolumab 300mg (N=315)				Placebo (N=321)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	315	1.77 (3.81)	0	-	321	1.91 (4.58)	0	-
Week 4	309	1.70 (3.69)	309	-0.07 (1.32)	317	1.87 (4.69)	317	-0.02 (1.17)
Week 8	301	1.67 (3.60)	301	-0.11 (1.94)	307	1.83 (4.61)	307	-0.14 (1.46)
Week 12	303	1.51 (3.45)	303	-0.24 (2.10)	300	1.80 (4.64)	300	-0.17 (1.67)
Week 16	298	1.46 (3.20)	298	-0.35 (2.03)	293	1.76 (4.61)	293	-0.18 (1.74)
Week 20	289	1.36 (2.81)	289	-0.43 (2.37)	293	1.72 (4.68)	293	-0.25 (2.00)
Week 24	286	1.23 (2.68)	286	-0.54 (2.45)	287	1.74 (4.58)	287	-0.23 (1.80)
Week 28	285	1.20 (2.63)	285	-0.57 (2.41)	276	1.67 (4.51)	276	-0.29 (1.85)
Week 32	280	1.16 (2.55)	280	-0.60 (2.42)	267	1.74 (4.59)	267	-0.21 (2.15)
Week 36	275	1.09 (2.44)	275	-0.64 (2.50)	263	1.73 (4.50)	263	-0.29 (2.31)
Week 40	278	1.07 (2.47)	278	-0.71 (2.55)	262	1.57 (4.35)	262	-0.31 (2.39)
Week 44	269	1.08 (2.48)	269	-0.74 (2.44)	257	1.60 (4.37)	257	-0.21 (2.11)
Week 48	273	1.04 (2.45)	273	-0.71 (2.58)	251	1.54 (4.31)	251	-0.38 (2.18)
Week 52	262	1.13 (2.90)	262	-0.73 (2.71)	241	1.55 (4.36)	241	-0.25 (1.90)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - CLASI Total Damage Score
Full analysis set



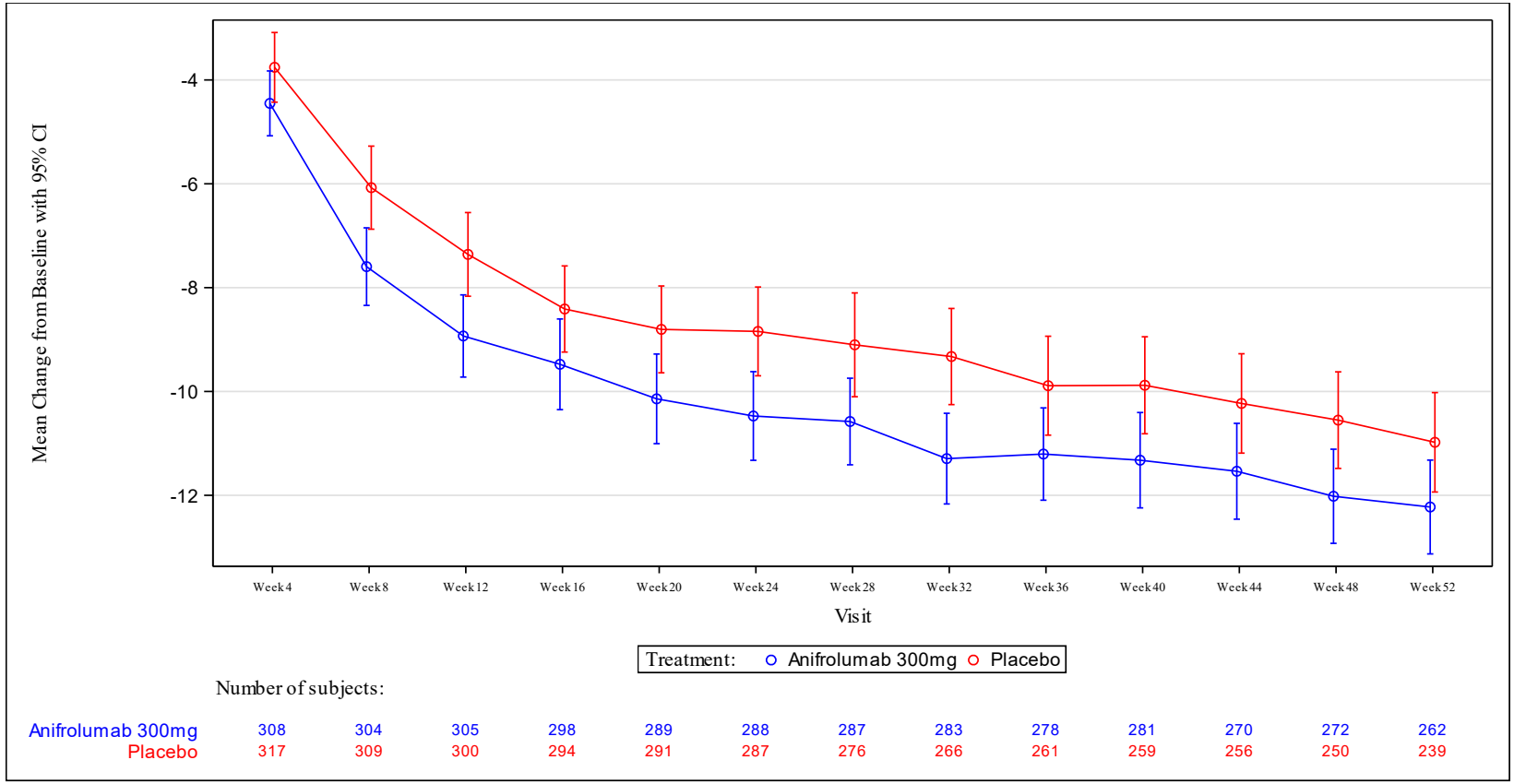
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - BILAG Global Score
Full analysis set

	Anifrolumab 300mg (N=315)				Placebo (N=321)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	315	18.86 (5.48)	0	-	321	18.96 (5.27)	0	-
Week 4	308	14.34 (7.17)	308	-4.45 (5.57)	317	15.18 (6.48)	317	-3.76 (6.07)
Week 8	304	11.16 (7.11)	304	-7.60 (6.62)	309	12.90 (7.37)	309	-6.07 (7.15)
Week 12	305	9.80 (7.34)	305	-8.93 (7.03)	300	11.65 (6.76)	300	-7.36 (7.09)
Week 16	298	9.30 (7.88)	298	-9.48 (7.66)	294	10.62 (7.18)	294	-8.41 (7.23)
Week 20	289	8.59 (7.30)	289	-10.14 (7.46)	291	10.09 (7.01)	291	-8.80 (7.25)
Week 24	288	8.34 (7.37)	288	-10.47 (7.36)	287	10.08 (6.90)	287	-8.84 (7.36)
Week 28	287	8.18 (7.19)	287	-10.58 (7.18)	276	9.78 (7.95)	276	-9.10 (8.44)
Week 32	283	7.39 (7.11)	283	-11.29 (7.46)	266	9.59 (7.44)	266	-9.33 (7.67)
Week 36	278	7.59 (7.16)	278	-11.21 (7.53)	261	8.86 (7.11)	261	-9.89 (7.82)
Week 40	281	7.43 (7.33)	281	-11.32 (7.82)	259	8.92 (7.16)	259	-9.88 (7.63)
Week 44	270	7.14 (7.02)	270	-11.54 (7.70)	256	8.53 (6.83)	256	-10.23 (7.77)
Week 48	272	6.75 (6.90)	272	-12.02 (7.59)	250	8.12 (6.61)	250	-10.55 (7.47)
Week 52	262	6.52 (6.80)	262	-12.23 (7.43)	239	7.72 (6.53)	239	-10.98 (7.51)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - BILAG Global Score
Full analysis set



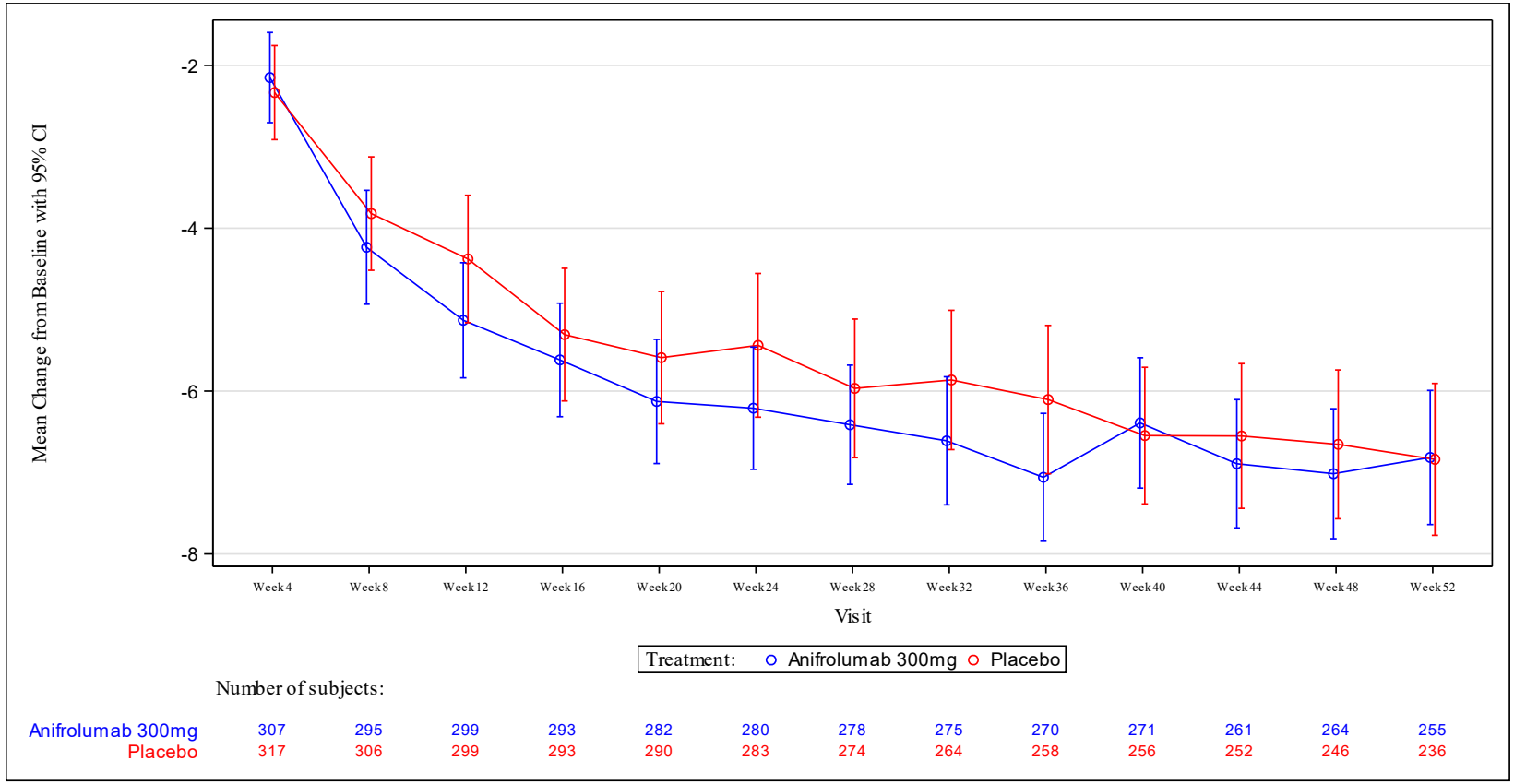
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - Tender Joint Count
Full analysis set

	Anifrolumab 300mg (N=315)				Placebo (N=321)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	315	10.28 (7.28)	0	-	321	10.64 (7.38)	0	-
Week 4	308	8.02 (7.53)	307	-2.15 (4.93)	317	8.31 (7.35)	317	-2.33 (5.22)
Week 8	299	5.92 (6.82)	295	-4.23 (6.10)	307	6.85 (6.96)	306	-3.82 (6.19)
Week 12	303	4.95 (6.68)	299	-5.13 (6.21)	299	6.21 (7.08)	299	-4.38 (6.88)
Week 16	298	4.50 (6.70)	293	-5.62 (6.06)	294	5.18 (6.61)	293	-5.31 (7.08)
Week 20	288	3.98 (6.48)	282	-6.13 (6.51)	292	4.85 (6.54)	290	-5.59 (7.03)
Week 24	286	4.01 (6.47)	280	-6.21 (6.38)	286	4.87 (6.73)	283	-5.44 (7.54)
Week 28	284	3.74 (6.31)	278	-6.41 (6.20)	276	4.36 (6.32)	274	-5.97 (7.16)
Week 32	281	3.45 (5.97)	275	-6.61 (6.62)	267	4.36 (6.49)	264	-5.86 (7.06)
Week 36	275	3.14 (5.86)	270	-7.06 (6.55)	263	4.04 (6.31)	258	-6.10 (7.43)
Week 40	279	3.61 (6.58)	271	-6.39 (6.69)	262	3.48 (5.27)	256	-6.55 (6.82)
Week 44	270	2.94 (5.50)	261	-6.89 (6.46)	257	3.45 (5.59)	252	-6.55 (7.16)
Week 48	271	3.25 (5.88)	264	-7.02 (6.59)	251	3.46 (5.54)	246	-6.65 (7.28)
Week 52	261	3.18 (5.85)	255	-6.82 (6.68)	241	3.13 (5.07)	236	-6.84 (7.27)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - Tender Joint Count
Full analysis set



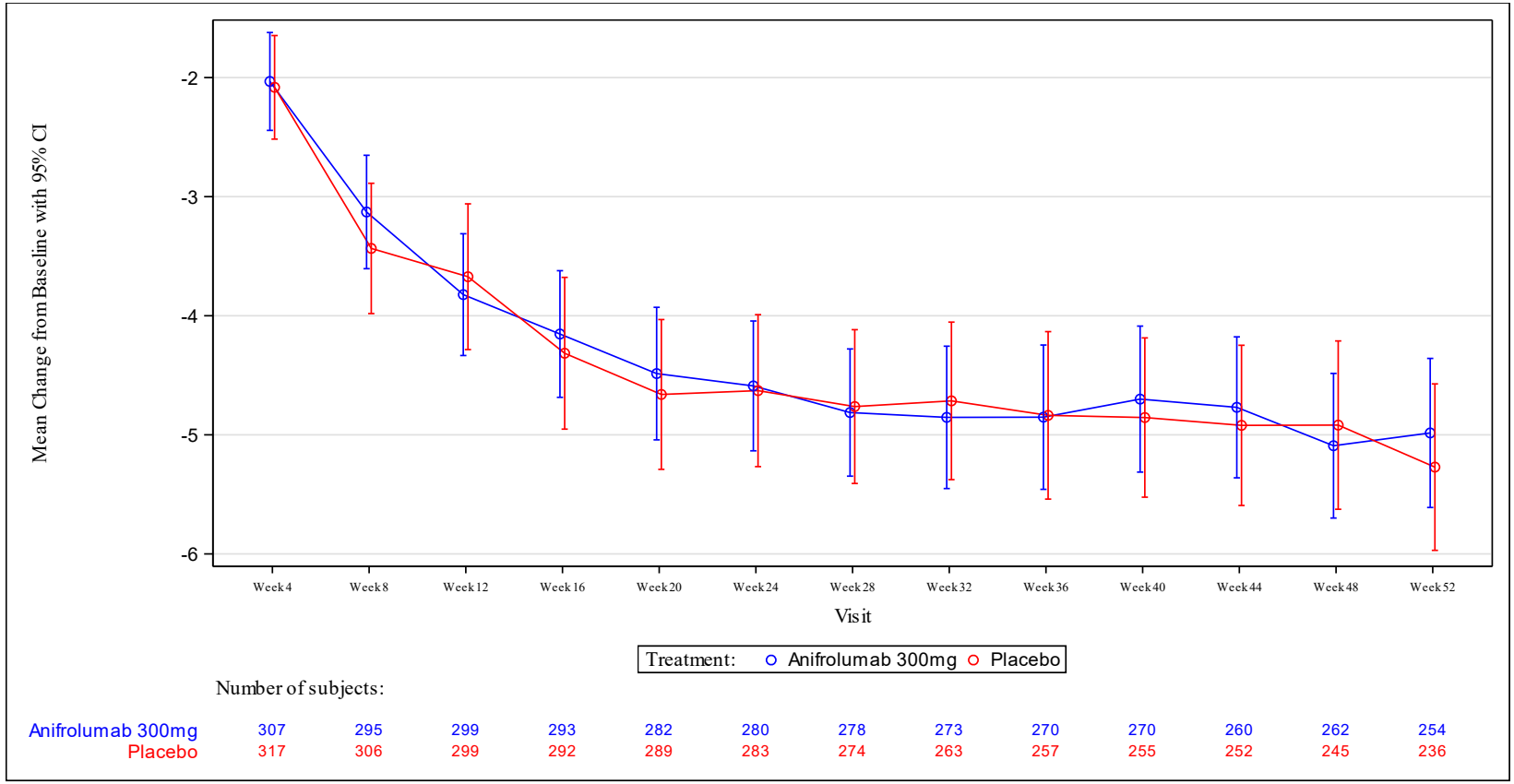
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - Swollen Joint Count
Full analysis set

	Anifrolumab 300mg (N=315)				Placebo (N=321)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	315	6.90 (5.65)	0	-	321	7.31 (5.81)	0	-
Week 4	308	4.74 (5.47)	307	-2.03 (3.66)	317	5.20 (5.53)	317	-2.08 (3.94)
Week 8	299	3.56 (4.96)	295	-3.13 (4.16)	307	3.80 (4.86)	306	-3.43 (4.86)
Week 12	303	2.93 (4.77)	299	-3.82 (4.49)	299	3.50 (4.98)	299	-3.67 (5.38)
Week 16	298	2.62 (4.64)	293	-4.15 (4.63)	294	2.81 (4.22)	292	-4.32 (5.53)
Week 20	288	2.19 (4.40)	282	-4.49 (4.75)	292	2.58 (4.30)	289	-4.66 (5.43)
Week 24	286	2.23 (4.46)	280	-4.59 (4.63)	286	2.48 (4.16)	283	-4.63 (5.45)
Week 28	284	2.04 (4.16)	278	-4.81 (4.52)	276	2.47 (4.40)	274	-4.76 (5.43)
Week 32	281	1.73 (3.76)	273	-4.85 (5.02)	267	2.39 (4.30)	263	-4.71 (5.45)
Week 36	275	2.00 (4.32)	270	-4.85 (5.06)	263	2.16 (4.13)	257	-4.84 (5.72)
Week 40	279	2.06 (4.76)	270	-4.70 (5.12)	262	2.03 (3.69)	255	-4.85 (5.42)
Week 44	270	1.74 (4.06)	260	-4.77 (4.85)	257	1.98 (3.74)	252	-4.92 (5.42)
Week 48	271	1.78 (4.11)	262	-5.09 (4.99)	251	2.06 (4.10)	245	-4.92 (5.62)
Week 52	261	1.63 (3.88)	254	-4.98 (5.07)	241	1.68 (3.23)	236	-5.27 (5.45)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - Swollen Joint Count
Full analysis set



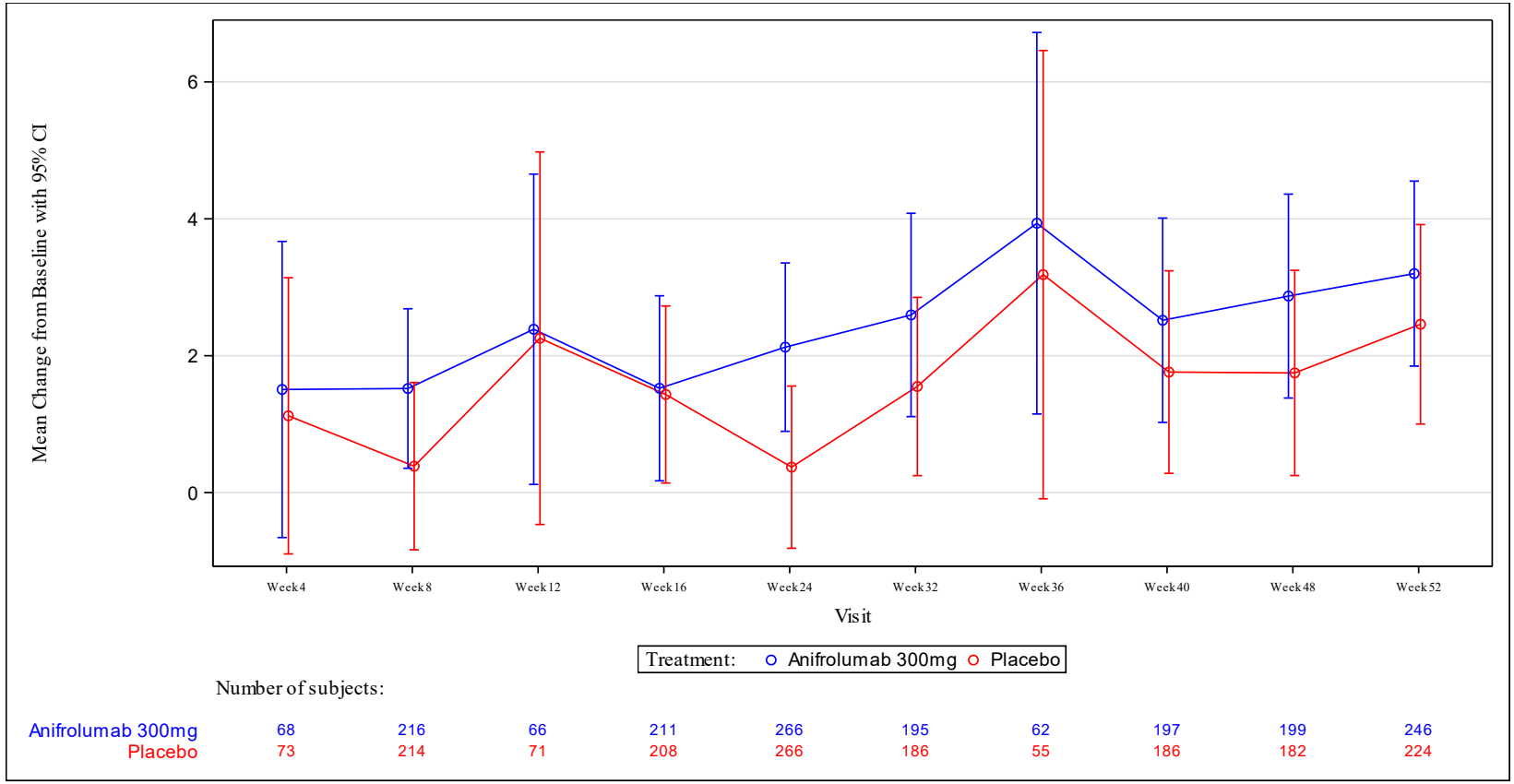
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Mental Component Score
Full analysis set

	Anifrolumab 300mg (N=315)				Placebo (N=321)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	305	42.52 (11.88)	0	-	307	42.11 (11.86)	0	-
Week 4	68	39.27 (11.58)	68	1.51 (8.94)	73	39.19 (11.66)	73	1.12 (8.65)
Week 8	222	45.40 (11.75)	216	1.52 (8.69)	224	43.80 (11.12)	214	0.39 (9.07)
Week 12	66	40.15 (12.09)	66	2.39 (9.22)	71	40.04 (12.77)	71	2.26 (11.50)
Week 16	219	45.27 (11.48)	211	1.52 (9.96)	218	44.89 (10.96)	208	1.43 (9.46)
Week 24	276	44.22 (12.40)	266	2.12 (10.19)	278	42.68 (11.50)	266	0.37 (9.82)
Week 32	205	46.07 (11.31)	195	2.60 (10.52)	194	44.73 (10.44)	186	1.55 (9.00)
Week 36	62	42.12 (10.40)	62	3.94 (10.98)	55	42.78 (11.98)	55	3.18 (12.11)
Week 40	207	46.01 (11.30)	197	2.52 (10.63)	195	44.98 (10.91)	186	1.76 (10.23)
Week 48	208	46.09 (11.16)	199	2.87 (10.66)	188	45.03 (10.31)	182	1.75 (10.25)
Week 52	256	45.24 (11.37)	246	3.20 (10.76)	231	44.73 (11.30)	224	2.46 (11.07)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Mental Component Score
Full analysis set



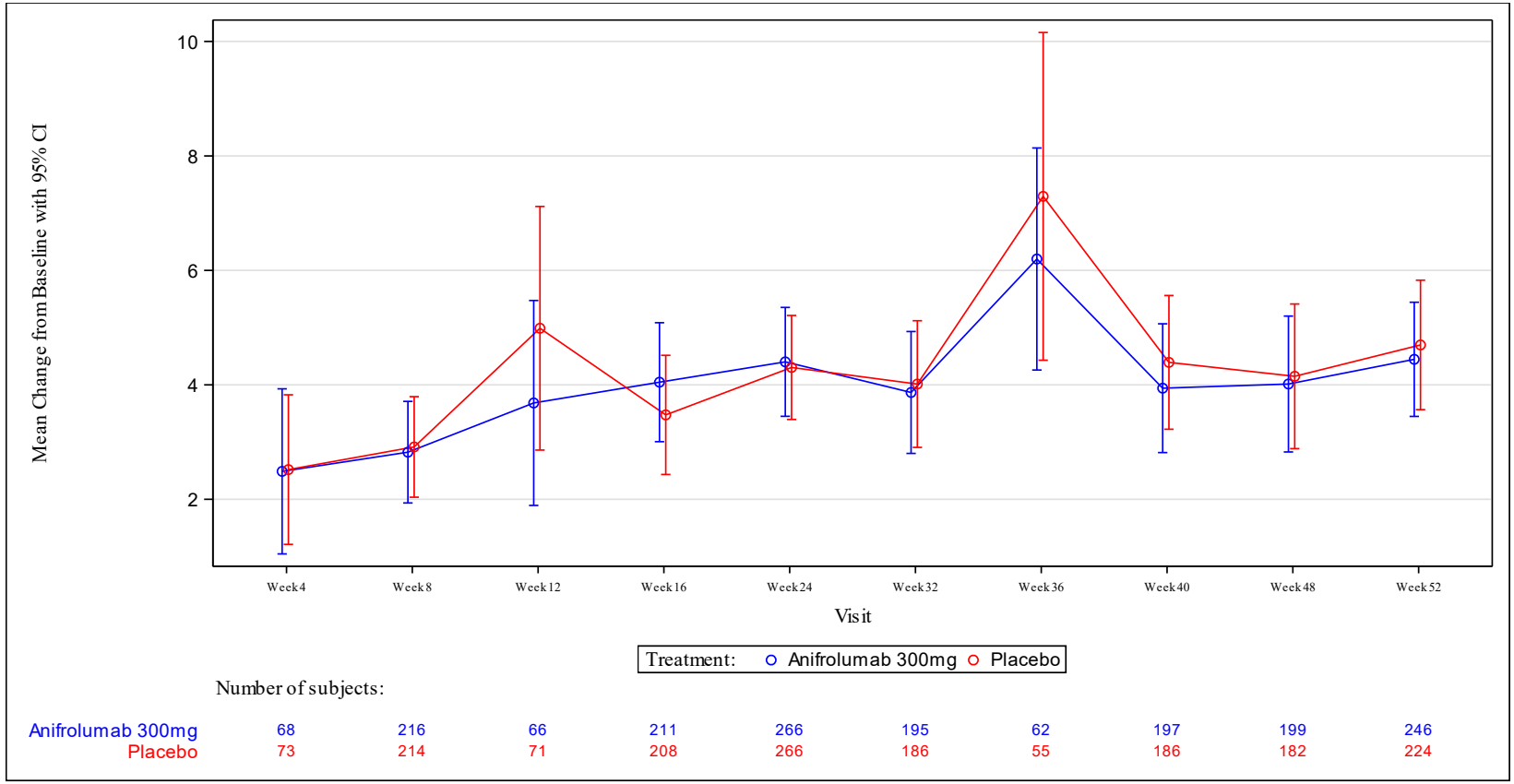
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Physical Component Score
Full analysis set

	Anifrolumab 300mg (N=315)				Placebo (N=321)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	305	37.61 (8.85)	0	-	307	36.97 (9.77)	0	-
Week 4	68	37.88 (8.13)	68	2.49 (5.96)	73	37.81 (10.21)	73	2.52 (5.60)
Week 8	222	41.48 (8.74)	216	2.82 (6.62)	224	40.45 (8.76)	214	2.92 (6.52)
Week 12	66	39.38 (8.86)	66	3.68 (7.28)	71	40.25 (11.70)	71	4.99 (8.99)
Week 16	219	42.61 (9.40)	211	4.05 (7.66)	218	41.01 (9.10)	208	3.47 (7.61)
Week 24	276	42.45 (9.48)	266	4.40 (7.88)	278	41.64 (9.53)	266	4.30 (7.52)
Week 32	205	42.49 (9.19)	195	3.87 (7.54)	194	41.90 (8.64)	186	4.01 (7.65)
Week 36	62	41.67 (10.02)	62	6.20 (7.64)	55	43.60 (11.31)	55	7.29 (10.59)
Week 40	207	42.89 (9.47)	197	3.94 (8.01)	195	41.97 (9.30)	186	4.39 (8.08)
Week 48	208	42.80 (9.93)	199	4.01 (8.49)	188	41.89 (9.56)	182	4.15 (8.64)
Week 52	256	42.57 (9.39)	246	4.45 (7.94)	231	42.59 (9.58)	224	4.70 (8.59)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Physical Component Score
Full analysis set



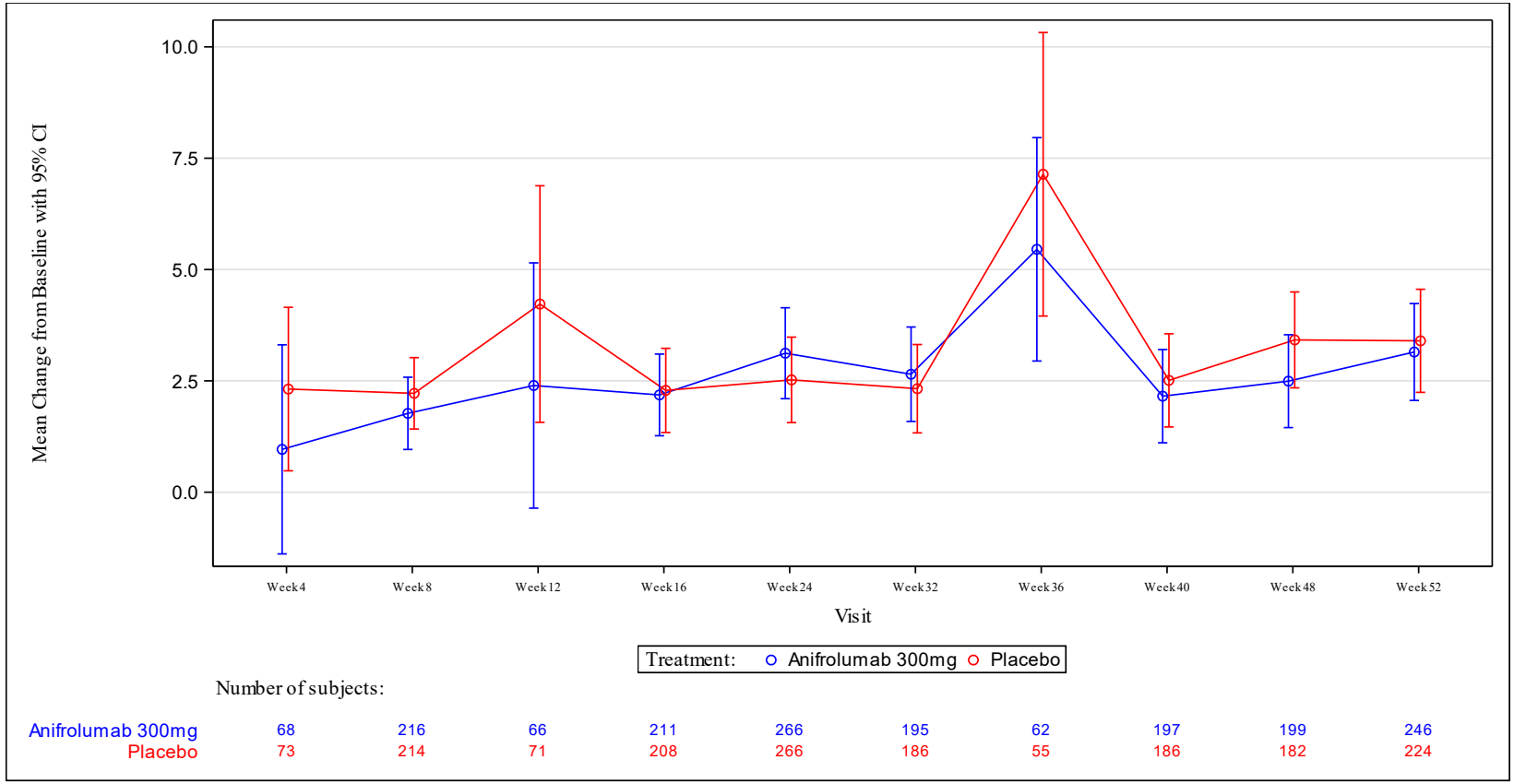
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - SF-36 v2.0 Acute General Health Score
Full analysis set

	Anifrolumab 300mg (N=315)				Placebo (N=321)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	305	37.86 (8.83)	0	-	307	37.74 (9.34)	0	-
Week 4	68	36.48 (11.05)	68	0.96 (9.70)	73	37.13 (11.56)	73	2.32 (7.87)
Week 8	222	40.59 (8.25)	216	1.77 (6.05)	224	40.99 (8.04)	214	2.22 (5.95)
Week 12	66	38.01 (10.87)	66	2.40 (11.20)	71	38.49 (12.17)	71	4.22 (11.22)
Week 16	219	40.97 (8.96)	211	2.18 (6.75)	218	40.99 (8.27)	208	2.29 (6.91)
Week 24	276	40.86 (9.96)	266	3.12 (8.46)	278	40.74 (9.39)	266	2.52 (7.95)
Week 32	205	41.13 (9.27)	195	2.65 (7.51)	194	41.44 (8.53)	186	2.32 (6.85)
Week 36	62	41.46 (10.93)	62	5.45 (9.88)	55	42.97 (11.05)	55	7.14 (11.78)
Week 40	207	41.15 (8.89)	197	2.16 (7.45)	195	41.56 (8.69)	186	2.51 (7.23)
Week 48	208	41.05 (9.27)	199	2.49 (7.46)	188	42.57 (8.77)	182	3.42 (7.36)
Week 52	256	41.03 (9.71)	246	3.15 (8.66)	231	42.08 (9.53)	224	3.40 (8.79)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - SF-36 v2.0 Acute General Health Score
Full analysis set



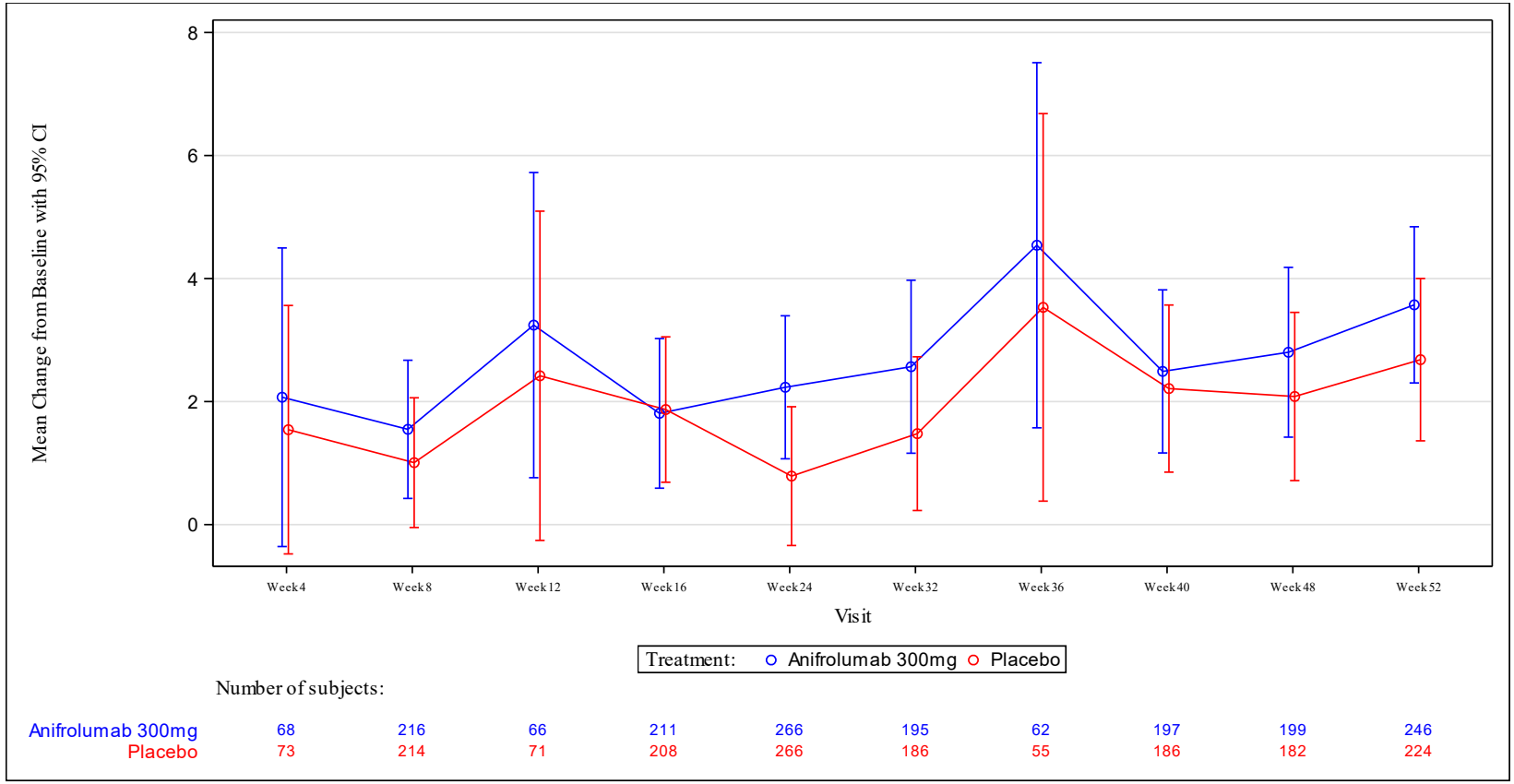
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Mental Health Score
Full analysis set

	Anifrolumab 300mg (N=315)				Placebo (N=321)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	305	42.67 (11.20)	0	-	307	42.32 (11.18)	0	-
Week 4	68	39.90 (11.76)	68	2.07 (10.03)	73	39.98 (11.28)	73	1.54 (8.65)
Week 8	222	45.57 (10.77)	216	1.55 (8.37)	224	44.67 (9.88)	214	1.01 (7.83)
Week 12	66	41.01 (11.71)	66	3.24 (10.09)	71	40.77 (12.69)	71	2.42 (11.31)
Week 16	219	45.76 (10.97)	211	1.81 (8.96)	218	45.38 (10.45)	208	1.87 (8.65)
Week 24	276	44.57 (11.95)	266	2.23 (9.63)	278	43.38 (10.61)	266	0.79 (9.34)
Week 32	205	46.25 (10.69)	195	2.57 (9.96)	194	44.96 (9.89)	186	1.48 (8.64)
Week 36	62	42.47 (10.35)	62	4.54 (11.69)	55	43.61 (11.55)	55	3.53 (11.65)
Week 40	207	46.31 (10.19)	197	2.49 (9.44)	195	45.51 (10.10)	186	2.21 (9.39)
Week 48	208	46.32 (9.98)	199	2.80 (9.87)	188	45.40 (10.24)	182	2.08 (9.35)
Week 52	256	45.74 (10.54)	246	3.57 (10.11)	231	45.36 (10.43)	224	2.68 (10.02)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Mental Health Score
Full analysis set



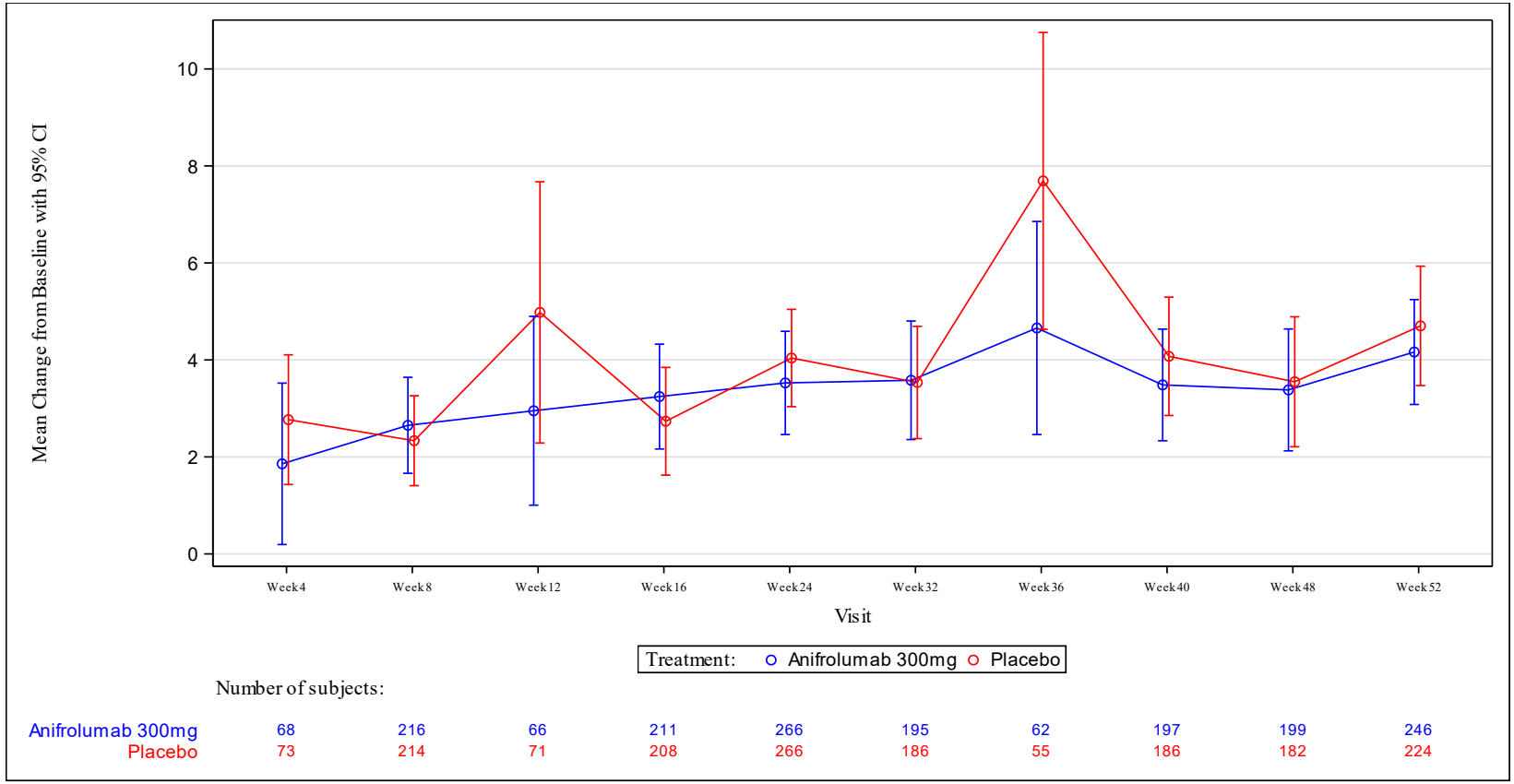
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Physical Functioning Score
Full analysis set

	Anifrolumab 300mg (N=315)				Placebo (N=321)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	305	39.08 (10.28)	0	-	307	37.56 (10.77)	0	-
Week 4	68	37.78 (10.20)	68	1.86 (6.87)	73	36.77 (12.23)	73	2.77 (5.73)
Week 8	222	42.99 (9.70)	216	2.65 (7.38)	224	41.19 (9.48)	214	2.33 (6.88)
Week 12	66	39.09 (10.07)	66	2.95 (7.92)	71	39.10 (12.29)	71	4.98 (11.38)
Week 16	219	43.44 (10.03)	211	3.24 (7.96)	218	41.53 (9.81)	208	2.73 (8.12)
Week 24	276	43.07 (10.61)	266	3.53 (8.82)	278	41.97 (10.42)	266	4.04 (8.31)
Week 32	205	43.87 (10.15)	195	3.58 (8.65)	194	42.55 (9.52)	186	3.53 (8.00)
Week 36	62	40.94 (11.48)	62	4.66 (8.65)	55	42.87 (11.49)	55	7.69 (11.32)
Week 40	207	43.89 (10.34)	197	3.48 (8.19)	195	42.51 (10.27)	186	4.07 (8.43)
Week 48	208	43.82 (10.16)	199	3.38 (8.99)	188	42.21 (10.63)	182	3.55 (9.16)
Week 52	256	43.78 (9.81)	246	4.16 (8.61)	231	43.19 (10.33)	224	4.70 (9.35)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Physical Functioning Score
Full analysis set



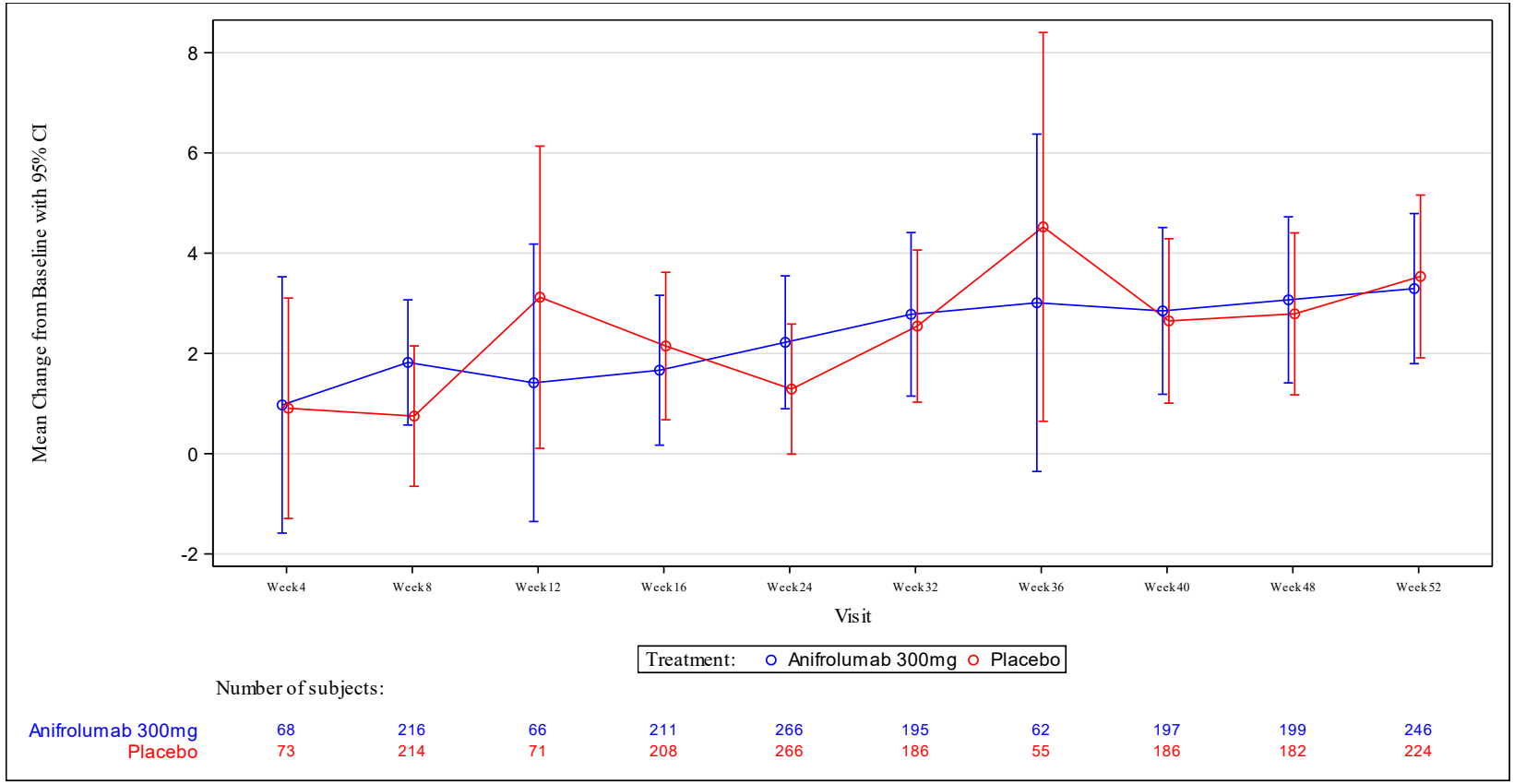
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Role Emotional Score
Full analysis set

	Anifrolumab 300mg (N=315)				Placebo (N=321)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	305	39.67 (12.85)	0	-	307	38.27 (12.43)	0	-
Week 4	68	36.16 (12.75)	68	0.97 (10.56)	73	35.01 (13.13)	73	0.91 (9.42)
Week 8	222	42.74 (12.65)	216	1.82 (9.31)	224	40.12 (12.02)	214	0.75 (10.39)
Week 12	66	36.74 (12.98)	66	1.41 (11.26)	71	37.32 (13.31)	71	3.12 (12.73)
Week 16	219	42.67 (12.07)	211	1.66 (11.02)	218	41.75 (12.04)	208	2.15 (10.76)
Week 24	276	41.68 (13.06)	266	2.22 (10.98)	278	39.74 (12.60)	266	1.29 (10.75)
Week 32	205	43.44 (11.67)	195	2.78 (11.55)	194	41.81 (11.83)	186	2.54 (10.49)
Week 36	62	38.95 (12.63)	62	3.01 (13.25)	55	40.12 (13.20)	55	4.52 (14.35)
Week 40	207	43.36 (11.93)	197	2.85 (11.84)	195	42.00 (11.95)	186	2.65 (11.34)
Week 48	208	43.20 (11.95)	199	3.07 (11.85)	188	42.10 (11.15)	182	2.79 (11.05)
Week 52	256	42.76 (11.83)	246	3.29 (11.92)	231	42.10 (11.96)	224	3.54 (12.33)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Role Emotional Score
Full analysis set



Number of subjects:

	Week 4	Week 8	Week 12	Week 16	Week 24	Week 32	Week 36	Week 40	Week 48	Week 52
Anifrolumab 300mg	68	216	66	211	266	195	62	197	199	246
Placebo	73	214	71	208	266	186	55	186	182	224

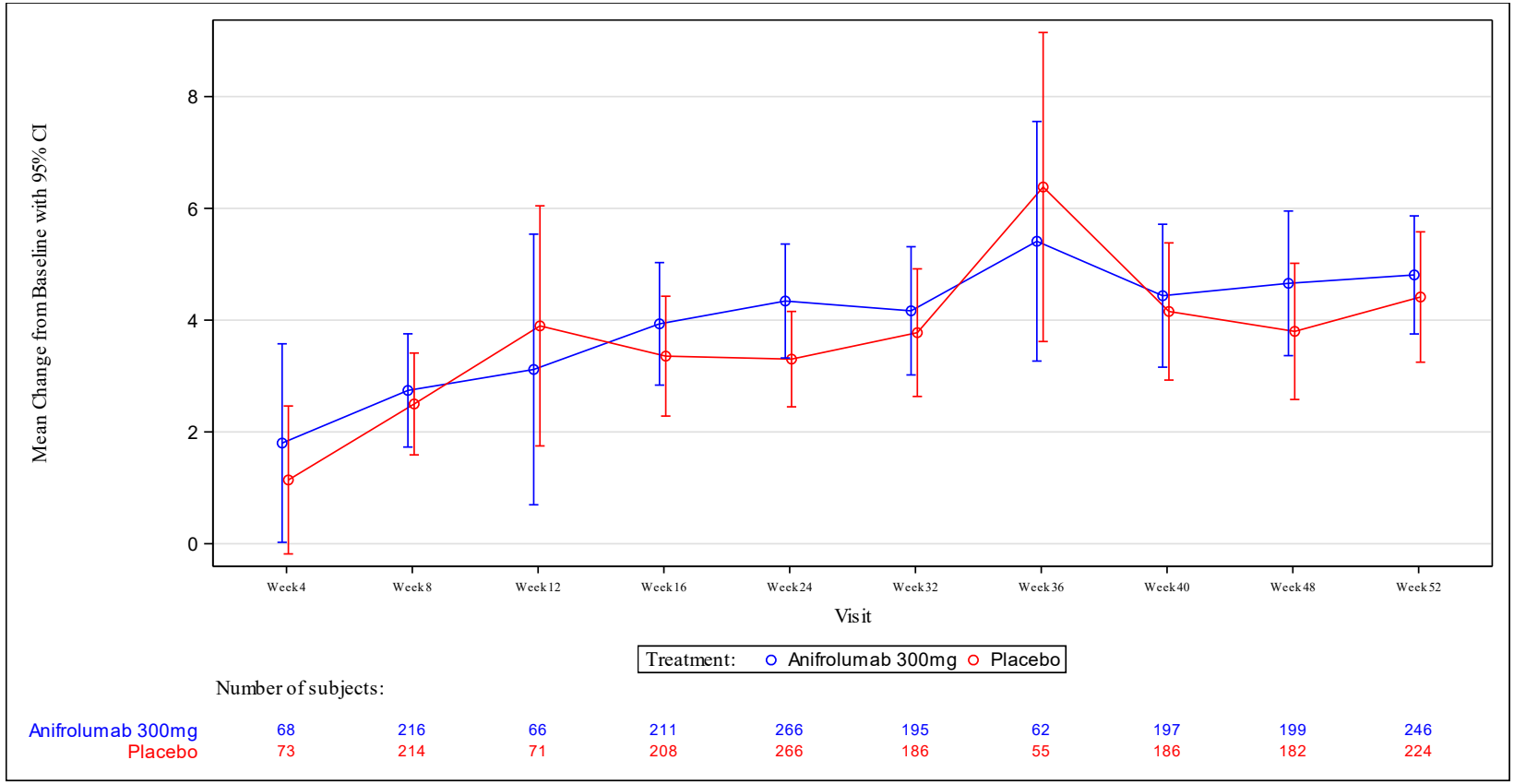
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Role Physical Score
Full analysis set

	Anifrolumab 300mg (N=315)				Placebo (N=321)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	305	37.40 (9.76)	0	-	307	36.53 (9.00)	0	-
Week 4	68	36.69 (9.67)	68	1.80 (7.34)	73	35.62 (9.81)	73	1.14 (5.67)
Week 8	222	41.11 (9.40)	216	2.74 (7.55)	224	39.70 (8.42)	214	2.50 (6.76)
Week 12	66	38.41 (10.19)	66	3.12 (9.85)	71	38.40 (11.27)	71	3.90 (9.07)
Week 16	219	42.33 (9.76)	211	3.93 (8.08)	218	40.61 (9.10)	208	3.36 (7.84)
Week 24	276	41.98 (10.03)	266	4.34 (8.44)	278	40.01 (9.38)	266	3.30 (7.07)
Week 32	205	42.34 (9.39)	195	4.17 (8.12)	194	41.23 (8.65)	186	3.78 (7.89)
Week 36	62	40.82 (10.47)	62	5.41 (8.44)	55	42.31 (10.38)	55	6.38 (10.23)
Week 40	207	42.69 (9.35)	197	4.44 (9.10)	195	41.51 (8.97)	186	4.16 (8.48)
Week 48	208	42.72 (9.97)	199	4.66 (9.25)	188	41.12 (9.34)	182	3.80 (8.33)
Week 52	256	42.23 (9.51)	246	4.81 (8.41)	231	41.80 (9.40)	224	4.41 (8.86)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Role Physical Score
Full analysis set



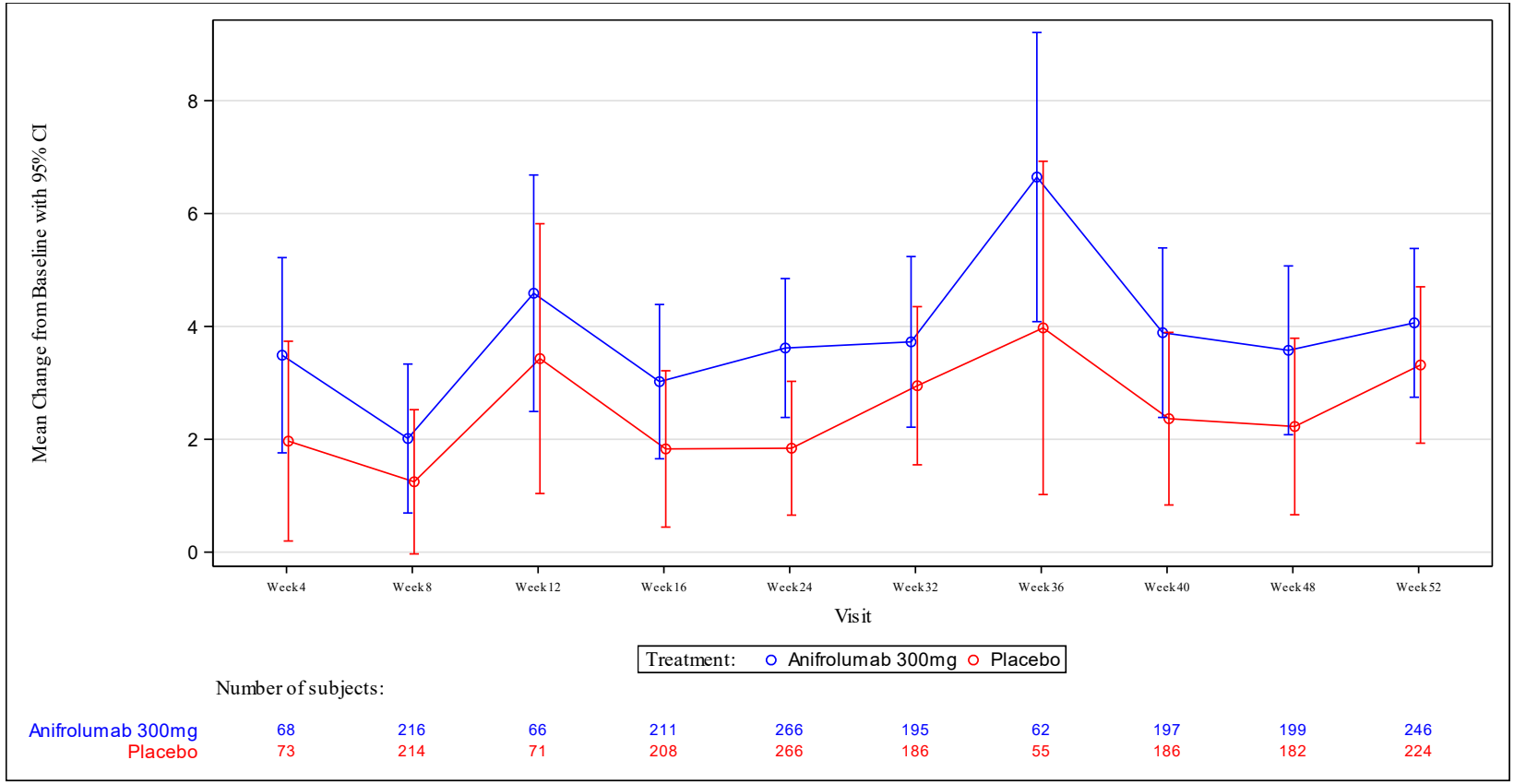
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Social Functioning Score
Full analysis set

	Anifrolumab 300mg (N=315)				Placebo (N=321)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	305	40.43 (10.81)	0	-	307	40.20 (10.43)	0	-
Week 4	68	42.08 (10.51)	68	3.49 (7.15)	73	41.78 (10.97)	73	1.97 (7.59)
Week 8	222	43.34 (10.46)	216	2.01 (9.84)	224	41.67 (10.38)	214	1.25 (9.48)
Week 12	66	43.48 (10.84)	66	4.59 (8.52)	71	42.72 (13.17)	71	3.43 (10.10)
Week 16	219	43.85 (10.29)	211	3.02 (10.07)	218	42.20 (9.26)	208	1.83 (10.13)
Week 24	276	43.98 (10.66)	266	3.62 (10.19)	278	42.10 (10.81)	266	1.84 (9.82)
Week 32	205	44.54 (10.42)	195	3.73 (10.71)	194	42.85 (9.79)	186	2.95 (9.69)
Week 36	62	45.54 (11.73)	62	6.65 (10.09)	55	45.39 (12.35)	55	3.97 (10.92)
Week 40	207	44.82 (10.09)	197	3.89 (10.69)	195	42.24 (9.81)	186	2.36 (10.57)
Week 48	208	44.48 (10.28)	199	3.58 (10.70)	188	42.38 (9.79)	182	2.23 (10.69)
Week 52	256	44.41 (10.96)	246	4.06 (10.50)	231	43.60 (10.61)	224	3.32 (10.52)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Social Functioning Score
Full analysis set



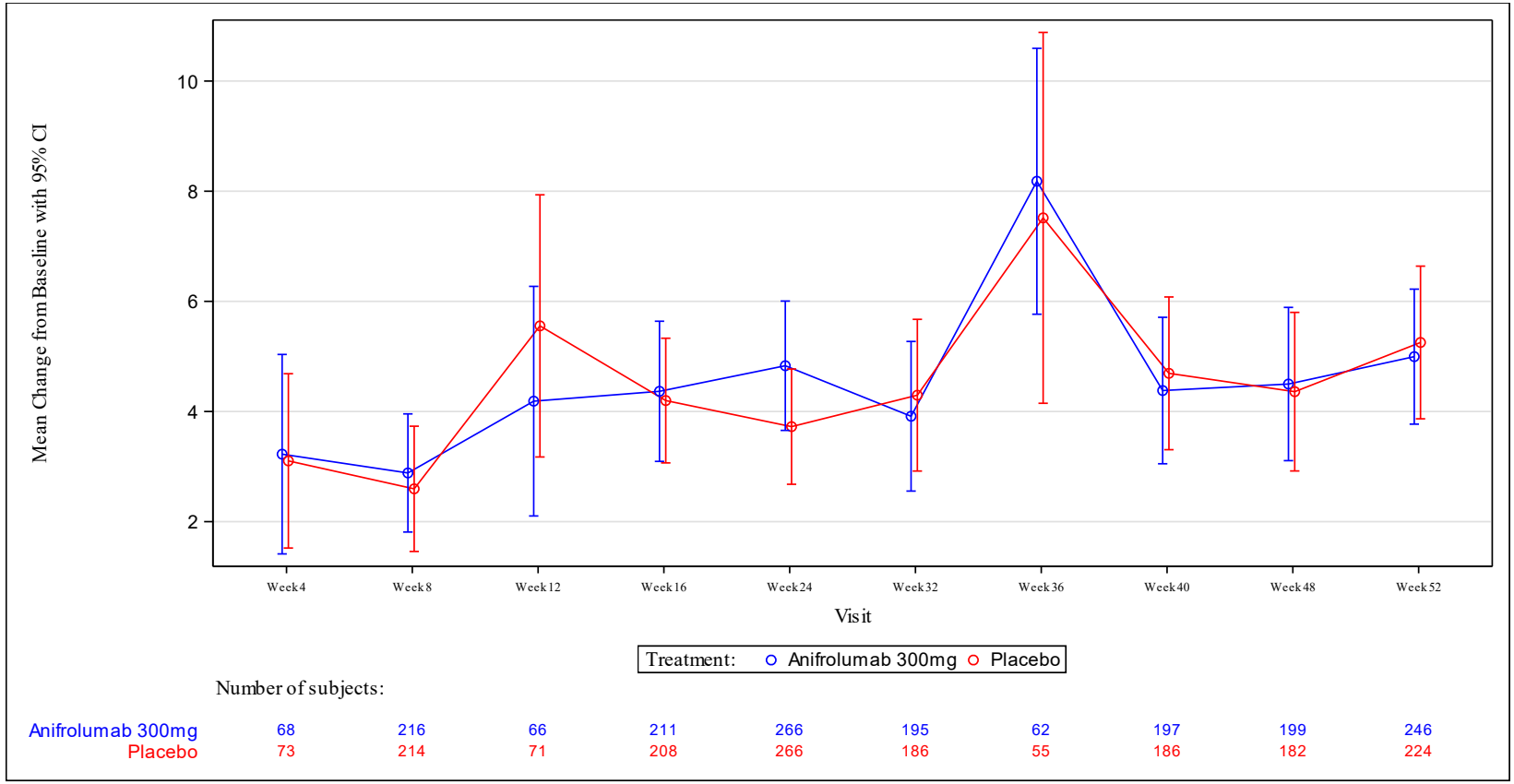
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Bodily Pain Score
Full analysis set

	Anifrolumab 300mg (N=315)				Placebo (N=321)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	305	38.81 (8.51)	0	-	307	38.20 (9.27)	0	-
Week 4	68	39.84 (8.69)	68	3.23 (7.48)	73	40.51 (10.16)	73	3.10 (6.78)
Week 8	222	42.55 (9.27)	216	2.88 (8.00)	224	40.82 (9.05)	214	2.60 (8.44)
Week 12	66	40.97 (9.00)	66	4.19 (8.48)	71	42.78 (12.01)	71	5.55 (10.06)
Week 16	219	43.92 (9.88)	211	4.37 (9.38)	218	42.52 (9.13)	208	4.20 (8.28)
Week 24	276	43.84 (10.46)	266	4.83 (9.73)	278	42.22 (10.02)	266	3.73 (8.67)
Week 32	205	43.63 (9.88)	195	3.91 (9.62)	194	42.61 (9.32)	186	4.30 (9.52)
Week 36	62	44.90 (11.00)	62	8.18 (9.51)	55	45.84 (11.56)	55	7.52 (12.45)
Week 40	207	44.45 (9.38)	197	4.38 (9.46)	195	42.93 (8.92)	186	4.69 (9.59)
Week 48	208	44.14 (10.38)	199	4.50 (9.95)	188	42.73 (9.62)	182	4.36 (9.84)
Week 52	256	44.24 (10.05)	246	5.00 (9.76)	231	43.69 (9.73)	224	5.25 (10.53)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Bodily Pain Score
Full analysis set



Number of subjects:

	Week 4	Week 8	Week 12	Week 16	Week 24	Week 32	Week 36	Week 40	Week 48	Week 52
Anifrolumab 300mg	68	216	66	211	266	195	62	197	199	246
Placebo	73	214	71	208	266	186	55	186	182	224

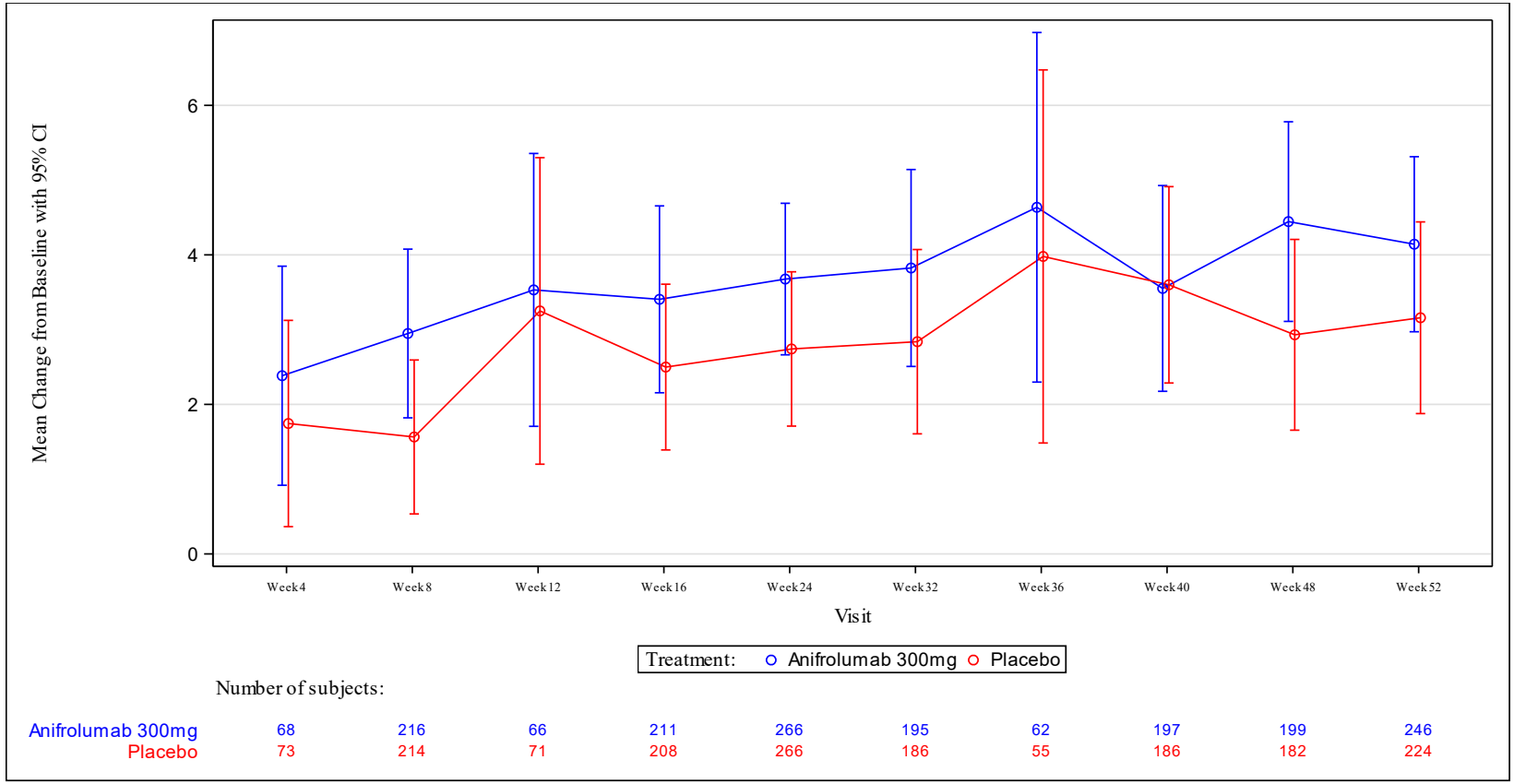
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Vitality Score
Full analysis set

	Anifrolumab 300mg (N=315)				Placebo (N=321)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	305	39.97 (10.19)	0	-	307	40.40 (9.69)	0	-
Week 4	68	34.77 (8.51)	68	2.38 (6.05)	73	36.13 (9.87)	73	1.74 (5.91)
Week 8	222	45.38 (9.79)	216	2.95 (8.41)	224	44.01 (9.22)	214	1.56 (7.64)
Week 12	66	36.01 (9.38)	66	3.53 (7.42)	71	37.53 (10.68)	71	3.25 (8.66)
Week 16	219	45.65 (10.38)	211	3.41 (9.21)	218	45.05 (9.27)	208	2.50 (8.11)
Week 24	276	43.68 (11.09)	266	3.68 (8.39)	278	43.67 (10.52)	266	2.74 (8.55)
Week 32	205	46.14 (9.90)	195	3.82 (9.32)	194	45.78 (9.28)	186	2.84 (8.52)
Week 36	62	36.50 (9.58)	62	4.64 (9.21)	55	39.63 (10.40)	55	3.98 (9.23)
Week 40	207	46.15 (10.27)	197	3.55 (9.79)	195	46.30 (9.83)	186	3.60 (9.08)
Week 48	208	46.97 (10.28)	199	4.45 (9.55)	188	45.88 (9.75)	182	2.93 (8.72)
Week 52	256	44.17 (10.91)	246	4.14 (9.32)	231	44.51 (10.47)	224	3.16 (9.74)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Vitality Score
Full analysis set



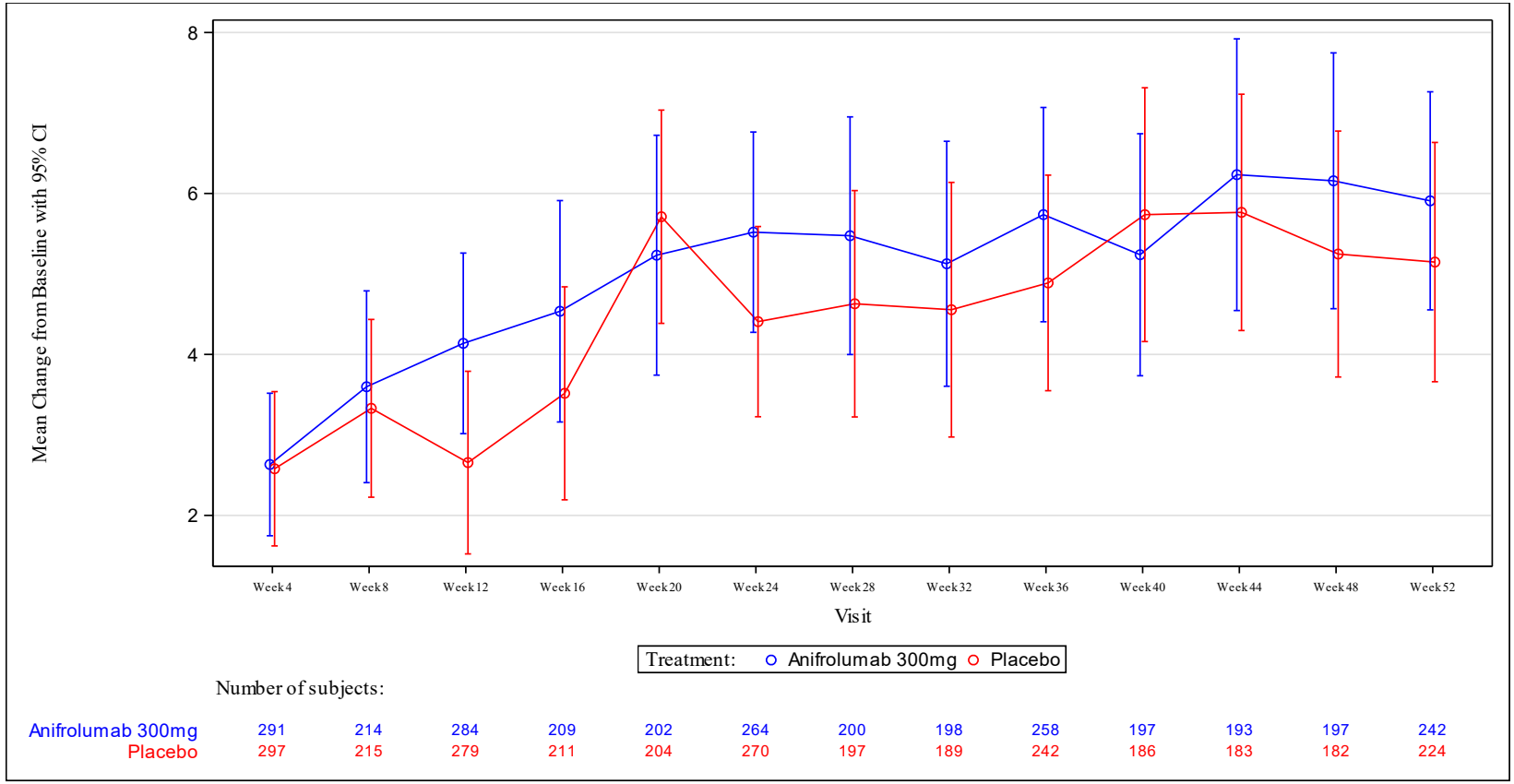
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - FACIT-F Total Score
Full analysis set

	Anifrolumab 300mg (N=315)				Placebo (N=321)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	301	26.28 (11.97)	0	-	308	25.55 (11.81)	0	-
Week 4	299	28.74 (11.63)	291	2.63 (7.68)	306	27.78 (11.99)	297	2.58 (8.40)
Week 8	223	30.39 (11.77)	214	3.60 (8.84)	226	28.52 (11.57)	215	3.33 (8.22)
Week 12	295	30.63 (12.83)	284	4.14 (9.61)	290	28.24 (12.86)	279	2.66 (9.63)
Week 16	221	31.14 (12.18)	209	4.54 (10.09)	220	28.76 (12.10)	211	3.52 (9.75)
Week 20	214	31.96 (12.32)	202	5.23 (10.74)	216	31.60 (11.39)	204	5.71 (9.60)
Week 24	278	31.98 (12.74)	264	5.52 (10.27)	281	29.90 (12.97)	270	4.41 (9.86)
Week 28	213	32.49 (11.98)	200	5.48 (10.59)	208	30.40 (11.72)	197	4.63 (10.01)
Week 32	211	31.57 (12.43)	198	5.13 (10.86)	198	30.62 (12.31)	189	4.56 (11.02)
Week 36	272	32.24 (12.57)	258	5.74 (10.86)	250	31.15 (12.84)	242	4.89 (10.58)
Week 40	211	32.11 (11.88)	197	5.24 (10.70)	196	31.22 (12.25)	186	5.74 (10.90)
Week 44	205	33.04 (12.92)	193	6.23 (11.89)	190	31.44 (11.65)	183	5.77 (10.06)
Week 48	210	32.90 (12.49)	197	6.16 (11.31)	191	31.22 (12.01)	182	5.25 (10.45)
Week 52	256	32.48 (12.43)	242	5.91 (10.70)	232	31.65 (12.73)	224	5.15 (11.29)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - FACIT-F Total Score
Full analysis set



Number of subjects:

	Week 4	Week 8	Week 12	Week 16	Week 20	Week 24	Week 28	Week 32	Week 36	Week 40	Week 44	Week 48	Week 52
Anifrolumab 300mg	291	214	284	209	202	264	200	198	258	197	193	197	242
Placebo	297	215	279	211	204	270	197	189	242	186	183	182	224

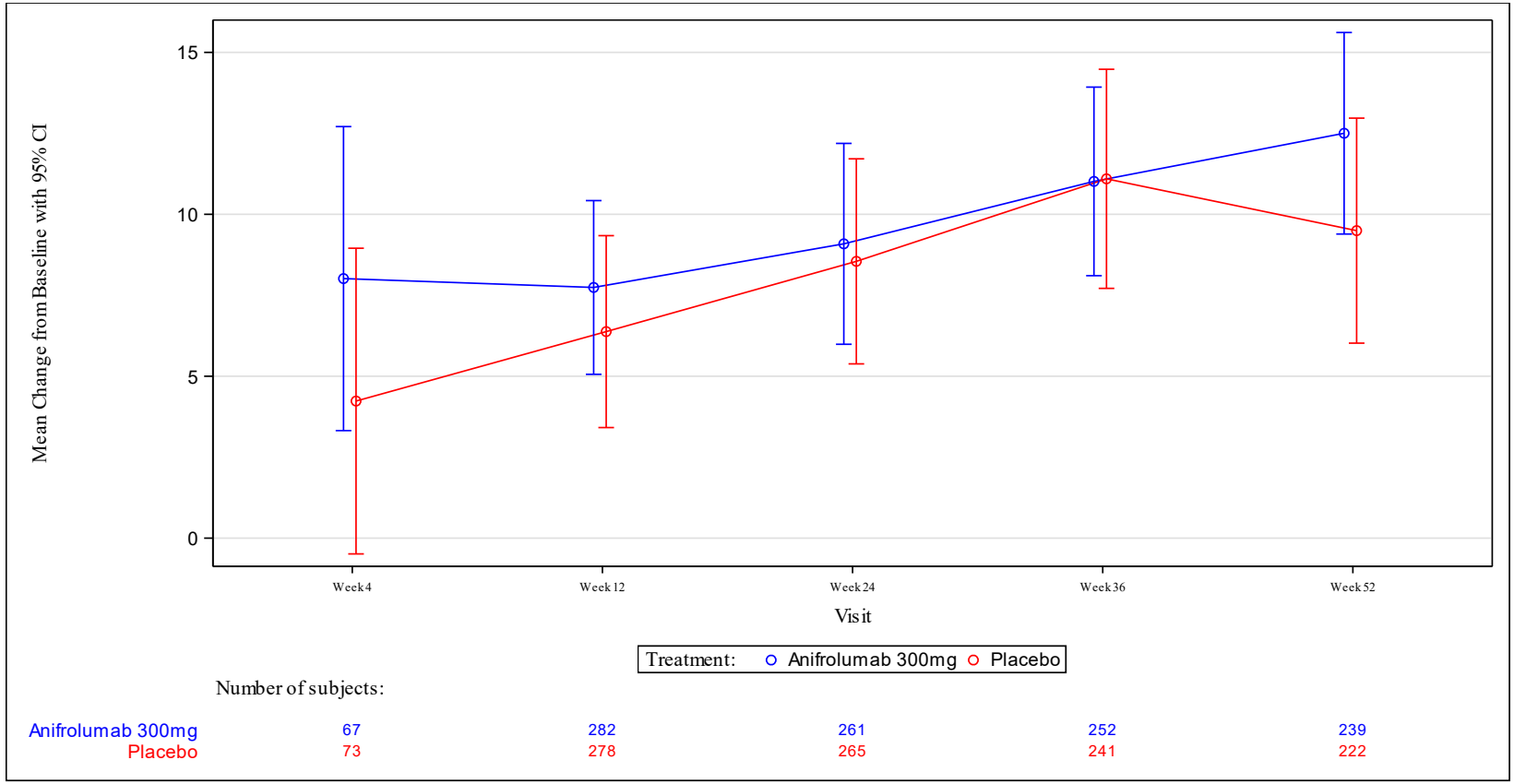
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - EQ VAS Score
Full analysis set

	Anifrolumab 300mg (N=315)				Placebo (N=321)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	300	56.01 (20.26)	0	-	308	53.97 (21.57)	0	-
Week 4	68	59.74 (19.44)	67	8.01 (19.24)	73	61.25 (19.67)	73	4.23 (20.23)
Week 12	294	63.28 (21.20)	282	7.74 (22.88)	289	60.21 (20.64)	278	6.38 (25.10)
Week 24	276	64.76 (21.32)	261	9.09 (25.44)	276	62.71 (21.28)	265	8.55 (26.18)
Week 36	267	66.71 (20.58)	252	11.02 (23.47)	248	65.82 (21.98)	241	11.10 (26.66)
Week 52	254	68.03 (20.09)	239	12.50 (24.42)	230	64.55 (21.78)	222	9.50 (26.26)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - EQ VAS Score
Full analysis set



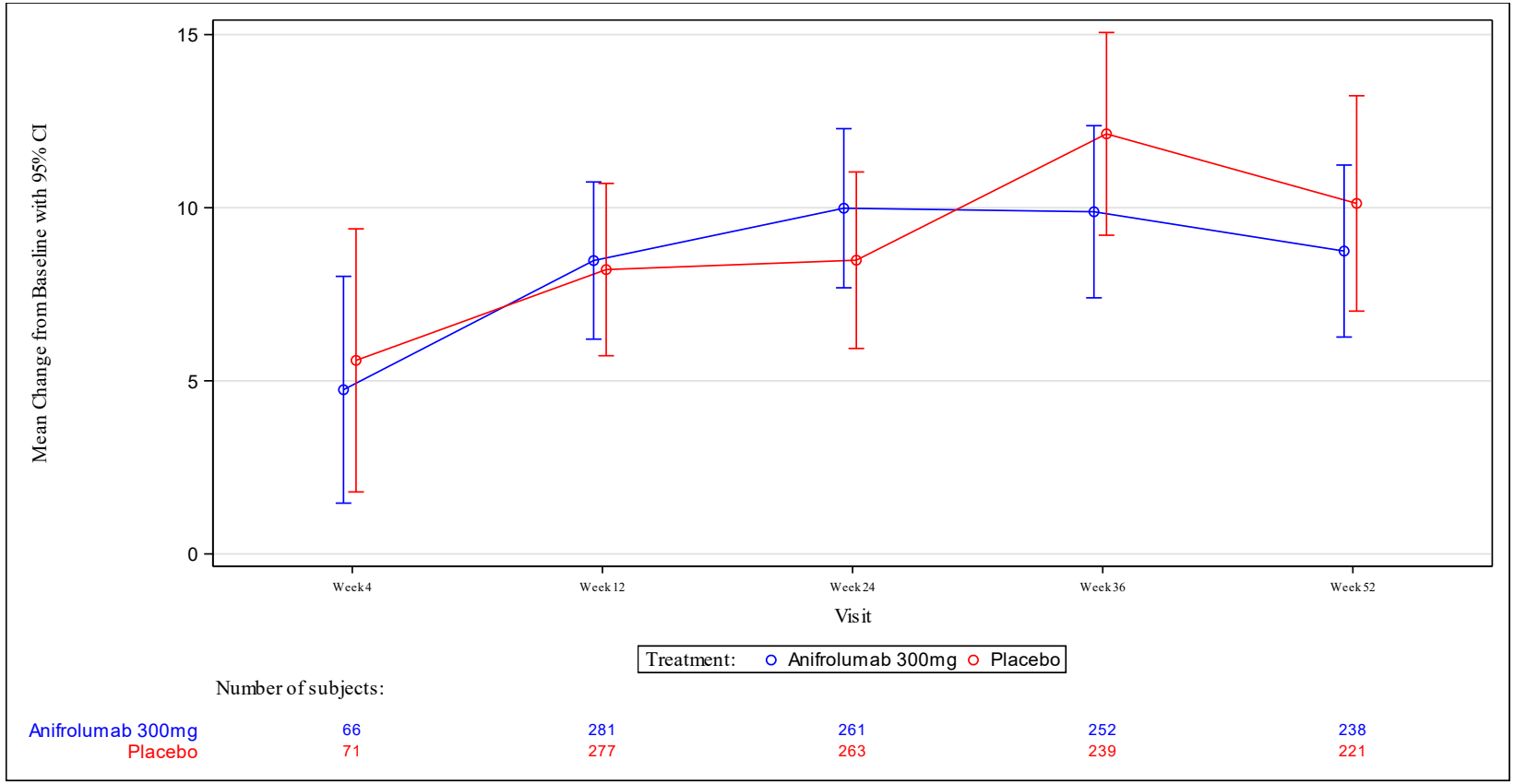
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - Lupus QoL Physical Health domain score
Full analysis set

	Anifrolumab 300mg (N=315)				Placebo (N=321)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	300	56.44 (25.11)	0	-	307	52.91 (25.62)	0	-
Week 4	67	62.32 (25.99)	66	4.74 (13.32)	72	59.03 (24.83)	71	5.59 (16.06)
Week 12	293	65.37 (25.53)	281	8.47 (19.33)	289	60.77 (25.72)	277	8.21 (21.04)
Week 24	276	66.59 (25.43)	261	9.99 (18.86)	274	61.76 (24.96)	263	8.48 (20.99)
Week 36	267	66.66 (25.05)	252	9.88 (20.04)	246	65.87 (24.29)	239	12.13 (22.98)
Week 52	253	66.43 (25.22)	238	8.75 (19.45)	229	64.73 (24.22)	221	10.12 (23.46)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - Lupus QoL Physical Health domain score
Full analysis set



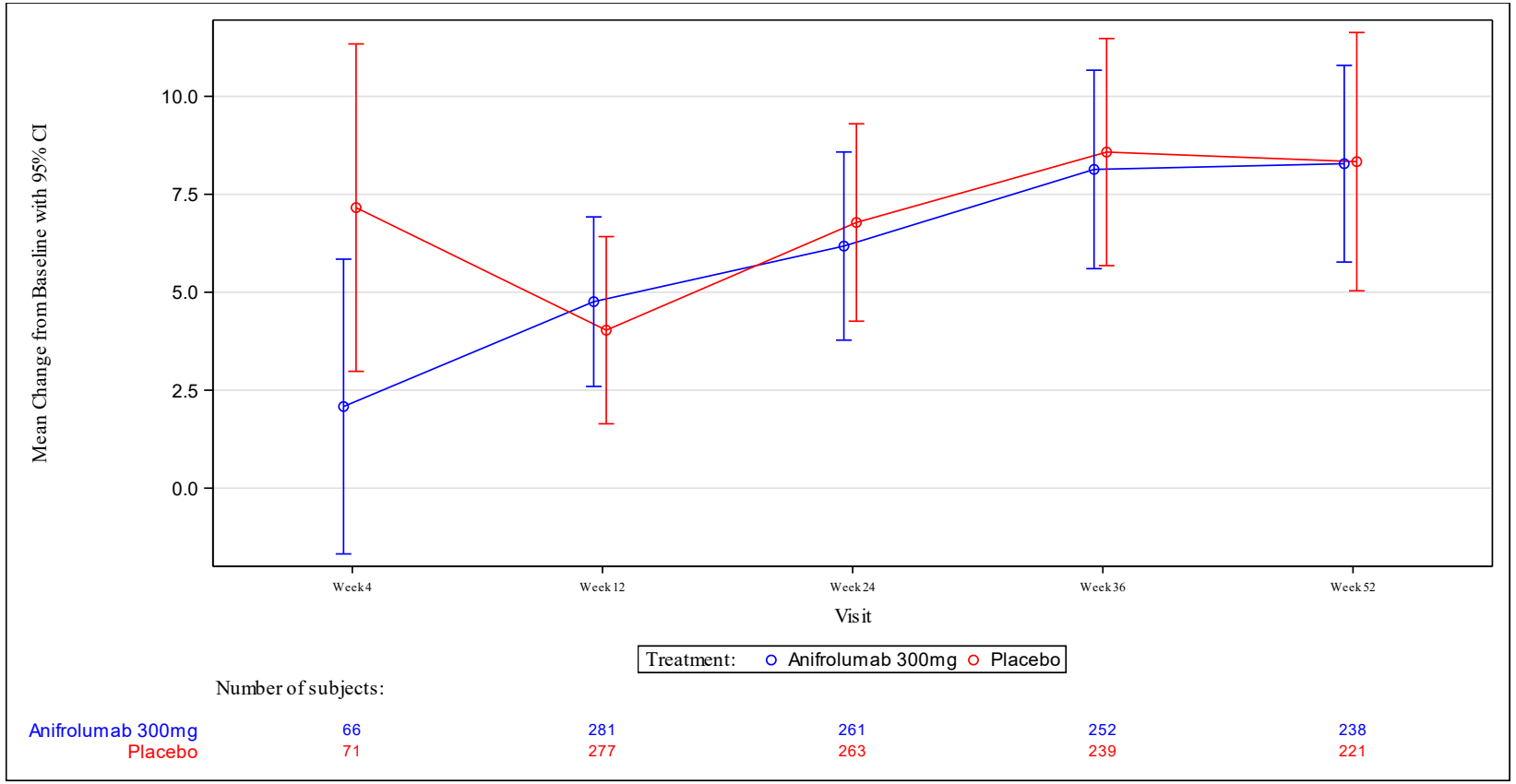
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - Lupus QoL Emotional Health domain score
Full analysis set

	Anifrolumab 300mg (N=315)				Placebo (N=321)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	300	66.10 (24.23)	0	-	307	62.95 (26.59)	0	-
Week 4	67	61.38 (23.94)	66	2.08 (15.30)	72	66.09 (25.52)	71	7.16 (17.65)
Week 12	293	70.46 (23.37)	281	4.76 (18.42)	289	67.24 (24.74)	277	4.03 (20.19)
Week 24	276	72.16 (23.48)	261	6.18 (19.70)	274	70.09 (24.02)	263	6.78 (20.75)
Week 36	267	73.53 (22.07)	252	8.13 (20.41)	246	73.39 (22.07)	239	8.58 (22.74)
Week 52	253	74.16 (21.76)	238	8.28 (19.65)	229	73.64 (23.08)	221	8.33 (24.86)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - Lupus QoL Emotional Health domain score
Full analysis set



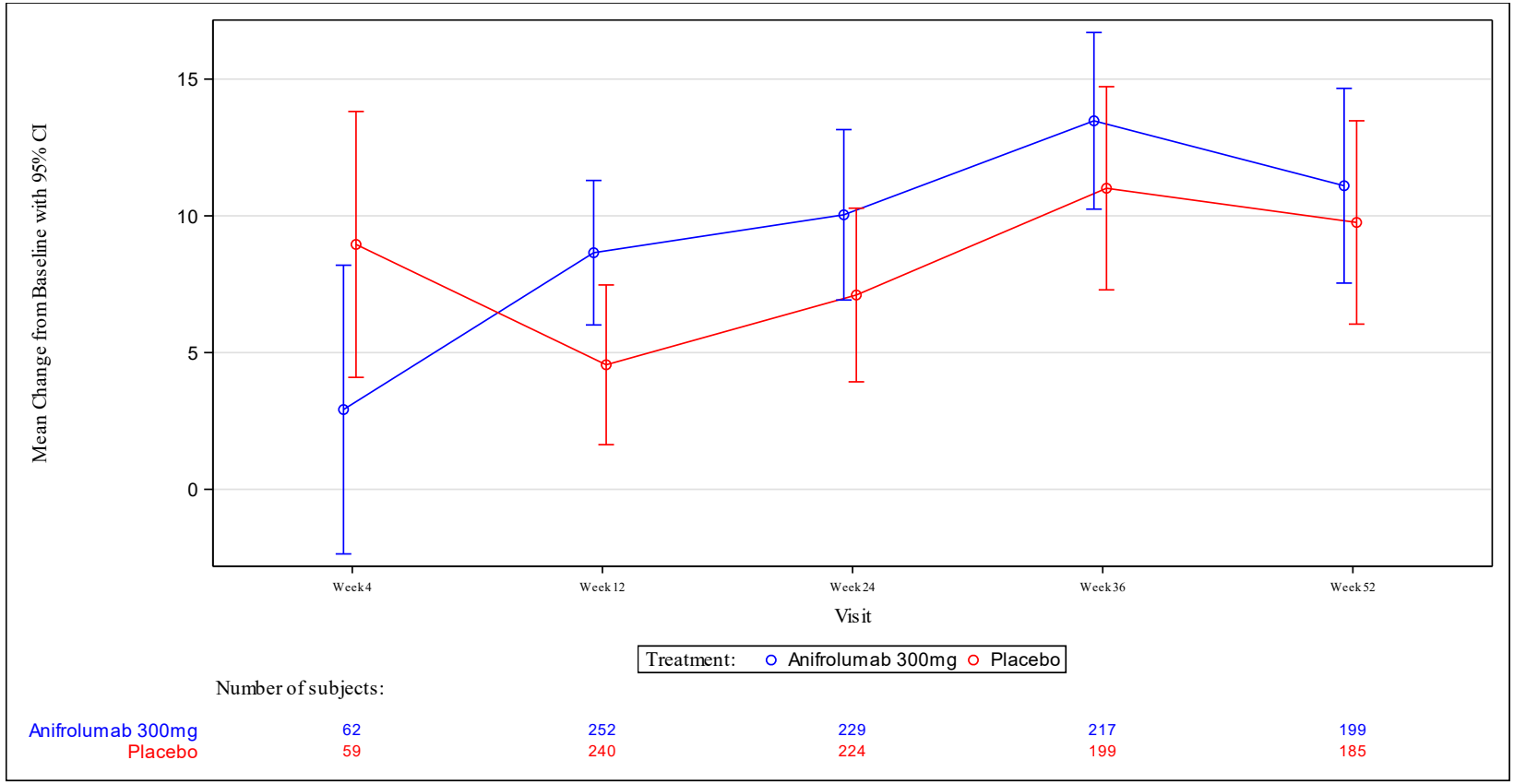
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - Lupus QoL Body Image domain score
Full analysis set

	Anifrolumab 300mg (N=315)				Placebo (N=321)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	284	59.16 (30.07)	0	-	282	59.76 (28.50)	0	-
Week 4	65	56.76 (30.66)	62	2.92 (20.79)	63	63.94 (28.20)	59	8.95 (18.66)
Week 12	271	67.44 (26.89)	252	8.65 (21.30)	261	64.29 (26.58)	240	4.55 (22.96)
Week 24	249	68.21 (27.67)	229	10.04 (23.93)	246	65.76 (27.84)	224	7.11 (24.11)
Week 36	238	70.85 (26.48)	217	13.48 (24.14)	217	70.28 (25.13)	199	11.01 (26.57)
Week 52	222	69.56 (26.90)	199	11.10 (25.47)	200	69.32 (27.32)	185	9.76 (25.63)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - Lupus QoL Body Image domain score
Full analysis set



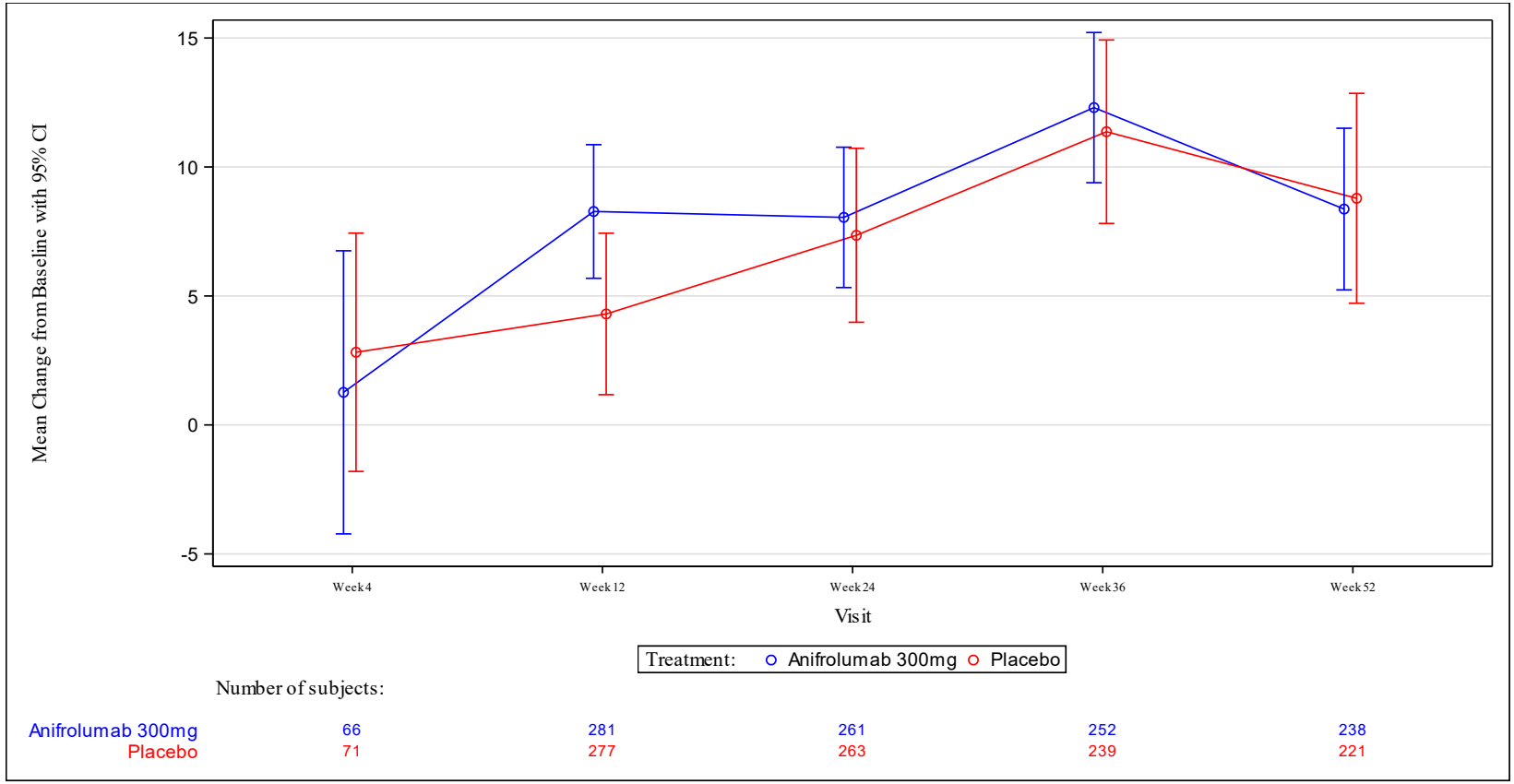
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - Lupus QoL Burden to Others domain score
Full analysis set

	Anifrolumab 300mg (N=315)				Placebo (N=321)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	300	54.11 (30.38)	0	-	307	50.84 (31.07)	0	-
Week 4	67	50.25 (29.66)	66	1.26 (22.32)	72	52.55 (31.82)	71	2.82 (19.52)
Week 12	293	61.92 (30.34)	281	8.27 (22.06)	289	55.51 (30.05)	277	4.30 (26.45)
Week 24	276	61.84 (31.48)	261	8.05 (22.32)	274	58.00 (30.36)	263	7.35 (27.77)
Week 36	267	65.45 (29.53)	252	12.30 (23.47)	246	63.89 (28.26)	239	11.37 (27.91)
Week 52	253	62.94 (30.27)	238	8.37 (24.54)	229	61.17 (30.27)	221	8.79 (30.69)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - Lupus QoL Burden to Others domain score
Full analysis set



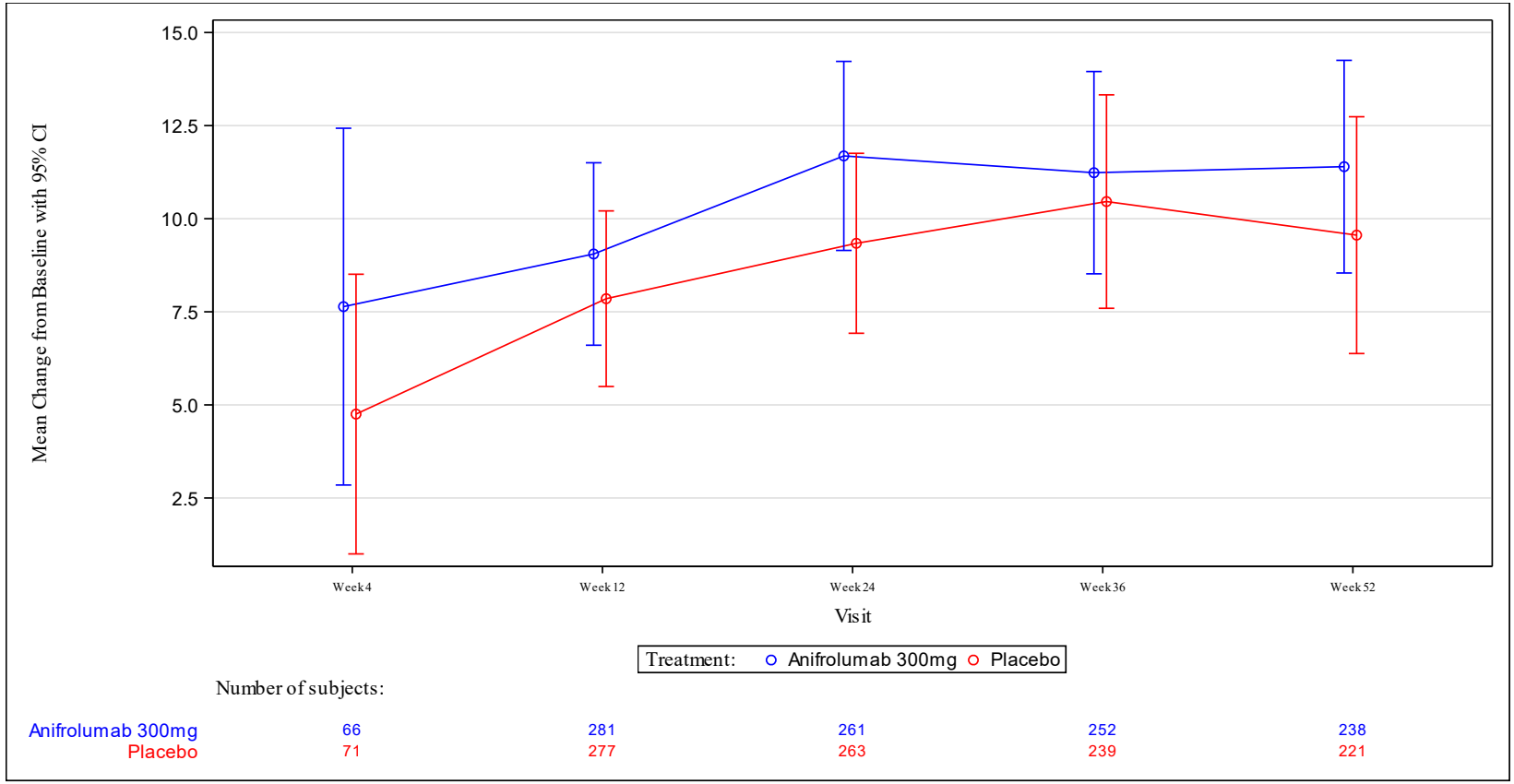
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - Lupus QoL Fatigue domain score
Full analysis set

	Anifrolumab 300mg (N=315)				Placebo (N=321)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	300	48.79 (26.67)	0	-	307	47.46 (26.56)	0	-
Week 4	67	53.89 (25.05)	66	7.64 (19.49)	72	54.08 (29.36)	71	4.75 (15.86)
Week 12	293	58.08 (26.92)	281	9.05 (20.86)	289	55.41 (26.75)	277	7.85 (19.93)
Week 24	276	60.51 (26.89)	261	11.69 (20.82)	274	57.30 (27.11)	263	9.34 (19.90)
Week 36	267	60.56 (26.14)	252	11.24 (21.89)	246	59.96 (26.36)	239	10.46 (22.49)
Week 52	253	60.62 (27.40)	238	11.40 (22.36)	229	59.50 (27.18)	221	9.56 (23.98)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - Lupus QoL Fatigue domain score
Full analysis set



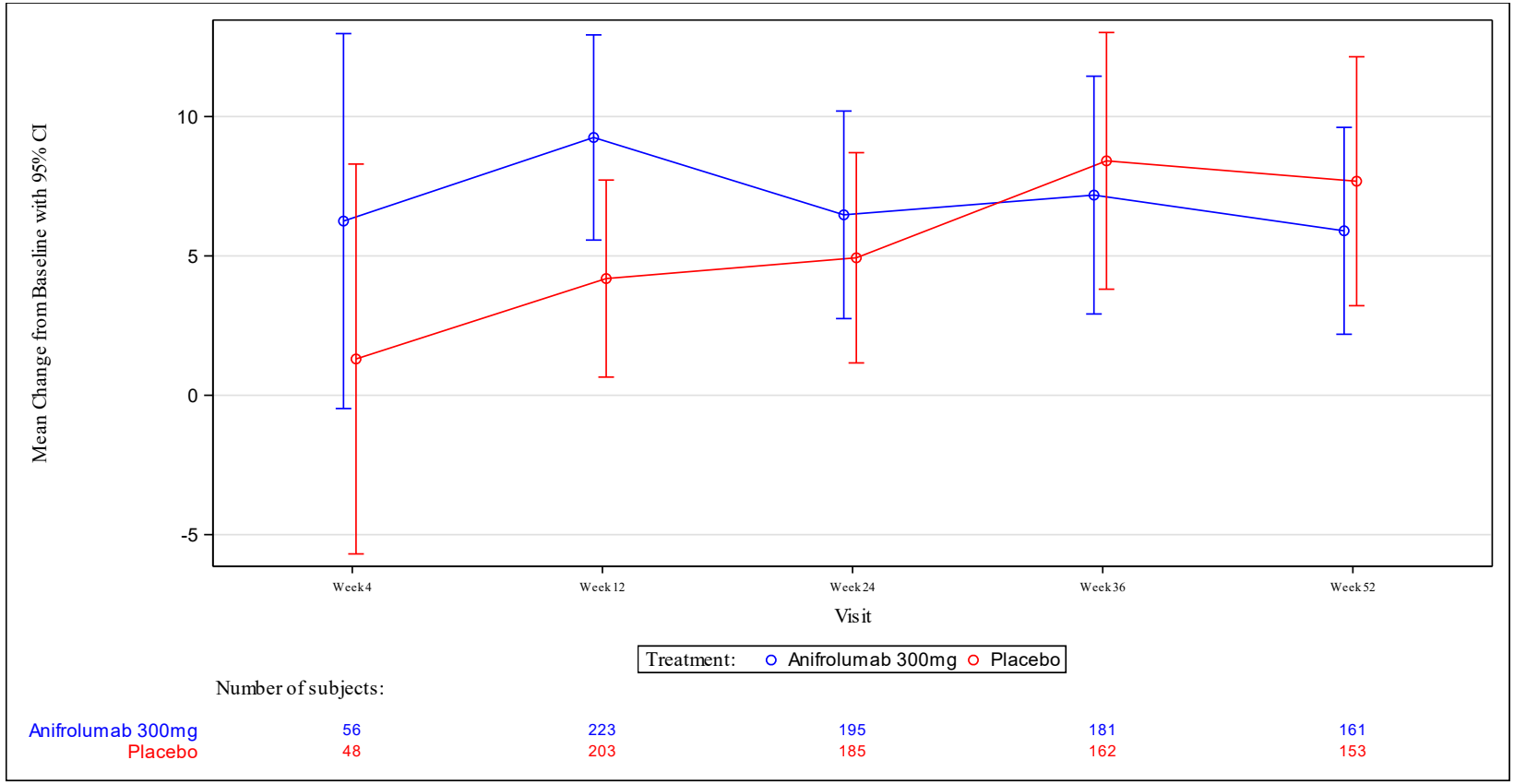
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - Lupus QoL Intimate Relationships domain score
Full analysis set

	Anifrolumab 300mg (N=315)				Placebo (N=321)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	255	55.44 (32.38)	0	-	252	58.04 (30.41)	0	-
Week 4	59	61.23 (30.94)	56	6.25 (25.11)	54	60.88 (34.09)	48	1.30 (24.08)
Week 12	246	65.75 (31.23)	223	9.25 (27.89)	232	61.91 (31.79)	203	4.19 (25.54)
Week 24	219	63.58 (32.36)	195	6.47 (26.36)	204	63.11 (30.99)	185	4.93 (26.00)
Week 36	207	65.28 (32.09)	181	7.18 (29.08)	175	67.50 (29.12)	162	8.41 (29.68)
Week 52	187	65.64 (30.94)	161	5.90 (23.84)	165	66.59 (30.62)	153	7.68 (27.96)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - Lupus QoL Intimate Relationships domain score
Full analysis set



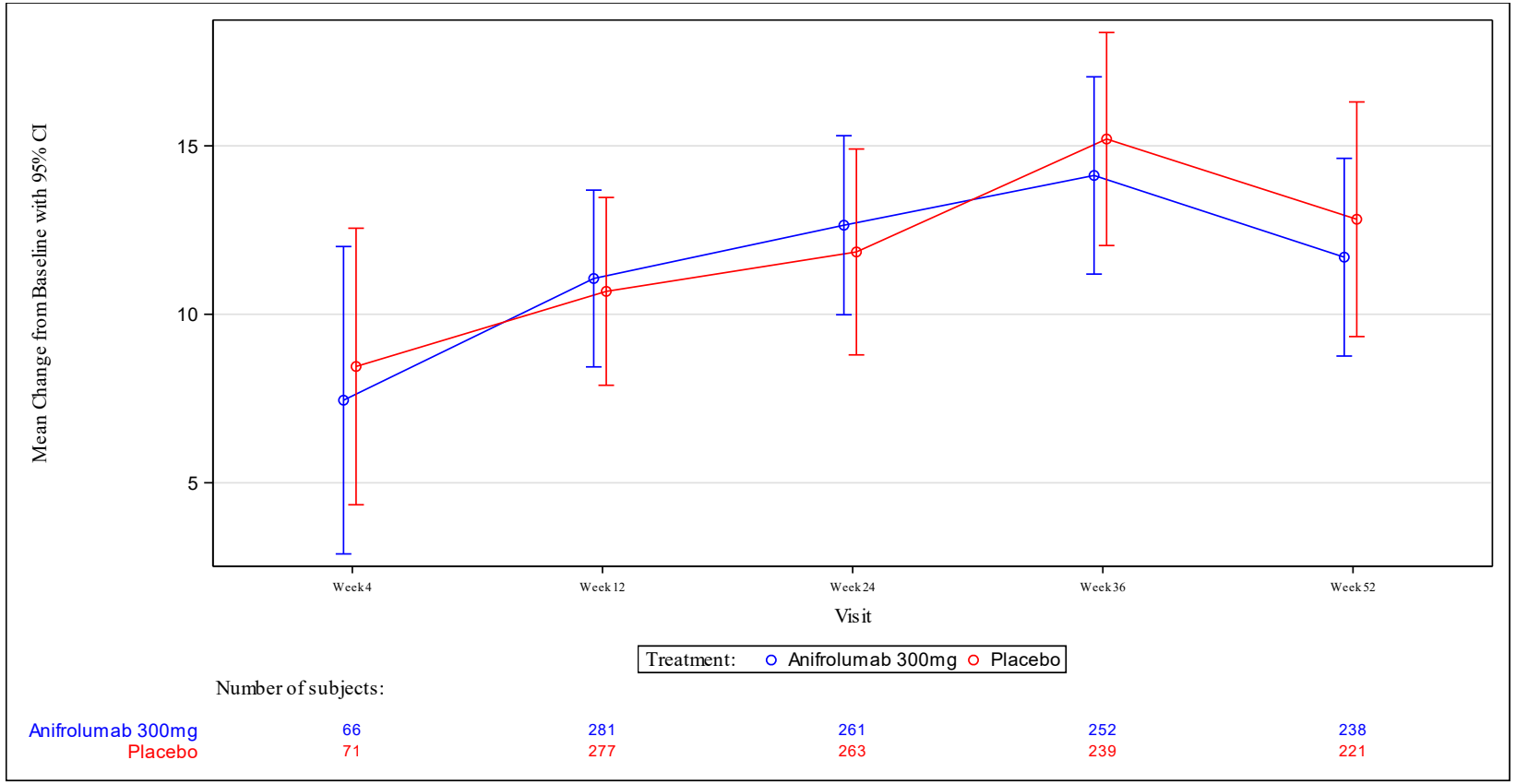
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - Lupus QoL Pain domain score
Full analysis set

	Anifrolumab 300mg (N=315)				Placebo (N=321)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	300	54.67 (27.33)	0	-	307	50.43 (28.85)	0	-
Week 4	67	58.96 (25.10)	66	7.45 (18.56)	72	58.10 (27.44)	71	8.45 (17.34)
Week 12	293	65.67 (27.24)	281	11.06 (22.34)	289	61.10 (28.11)	277	10.68 (23.56)
Week 24	276	67.27 (26.80)	261	12.64 (21.80)	274	62.35 (28.85)	263	11.85 (25.16)
Week 36	267	68.73 (26.15)	252	14.12 (23.59)	246	66.43 (26.64)	239	15.20 (24.80)
Week 52	253	68.31 (25.41)	238	11.69 (22.97)	229	65.65 (26.31)	221	12.82 (26.26)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - Lupus QoL Pain domain score
Full analysis set



Number of subjects:

	Week 4	Week 12	Week 24	Week 36	Week 52
Anifrolumab 300mg	66	281	261	252	238
Placebo	71	277	263	239	221

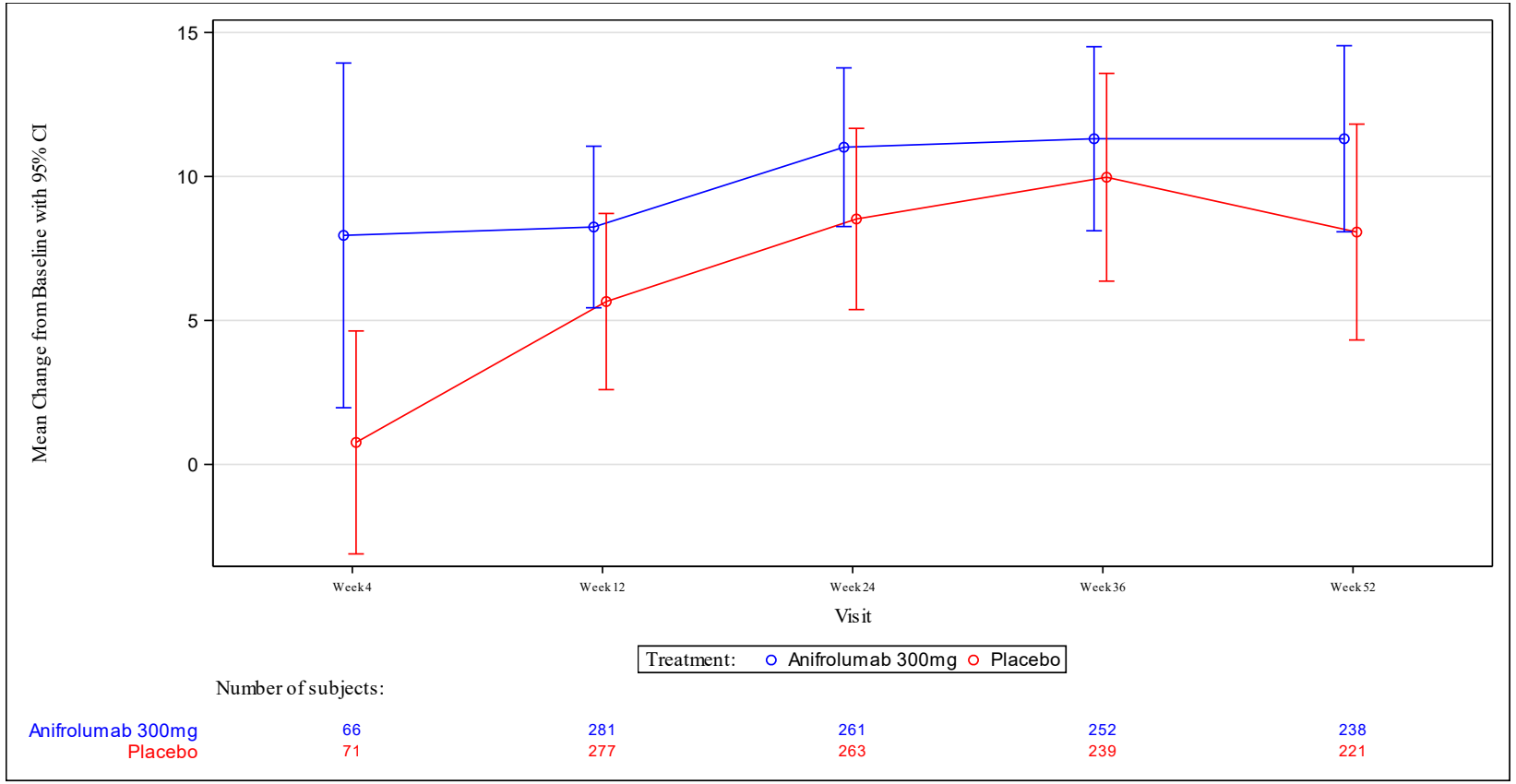
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - Lupus QoL Planning domain score
Full analysis set

	Anifrolumab 300mg (N=315)				Placebo (N=321)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	300	59.06 (29.14)	0	-	307	56.60 (30.93)	0	-
Week 4	67	61.07 (28.63)	66	7.95 (24.35)	72	57.70 (32.86)	71	0.76 (16.36)
Week 12	293	67.12 (28.30)	281	8.24 (23.89)	289	62.46 (29.15)	277	5.66 (25.86)
Week 24	276	69.75 (28.24)	261	11.02 (22.60)	274	64.90 (29.17)	263	8.52 (25.92)
Week 36	267	70.04 (28.18)	252	11.31 (25.76)	246	68.46 (27.93)	239	9.97 (28.32)
Week 52	253	70.03 (27.82)	238	11.31 (25.30)	229	67.32 (27.84)	221	8.07 (28.28)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - Lupus QoL Planning domain score
Full analysis set



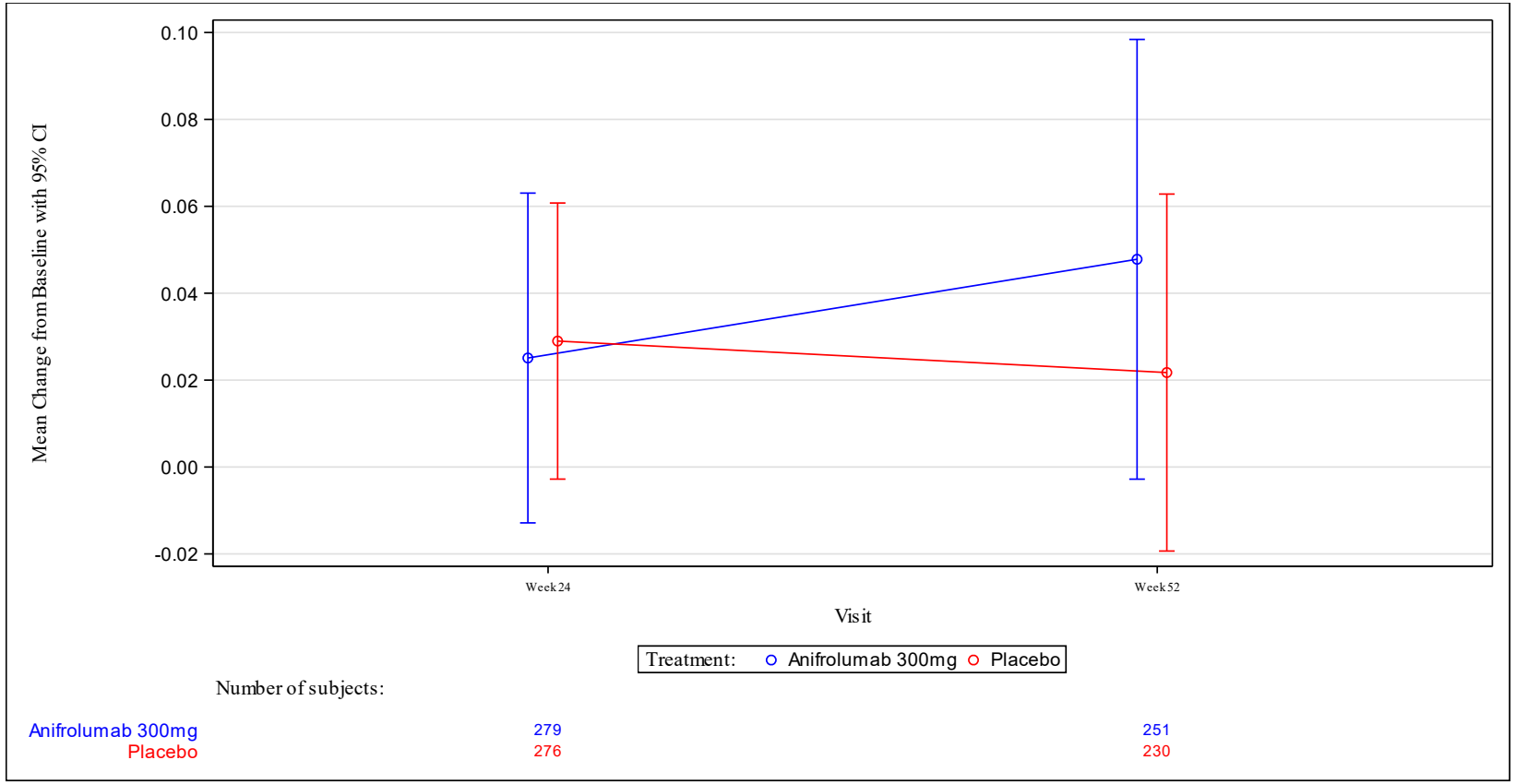
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - SDI Global Score
Full analysis set

	Anifrolumab 300mg (N=315)				Placebo (N=321)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	309	0.57 (0.98)	0	-	313	0.60 (0.99)	0	-
Week 24	281	0.60 (1.00)	279	0.03 (0.32)	280	0.64 (1.07)	276	0.03 (0.27)
Week 52	254	0.64 (1.00)	251	0.05 (0.41)	238	0.57 (0.97)	230	0.02 (0.32)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - SDI Global Score
Full analysis set



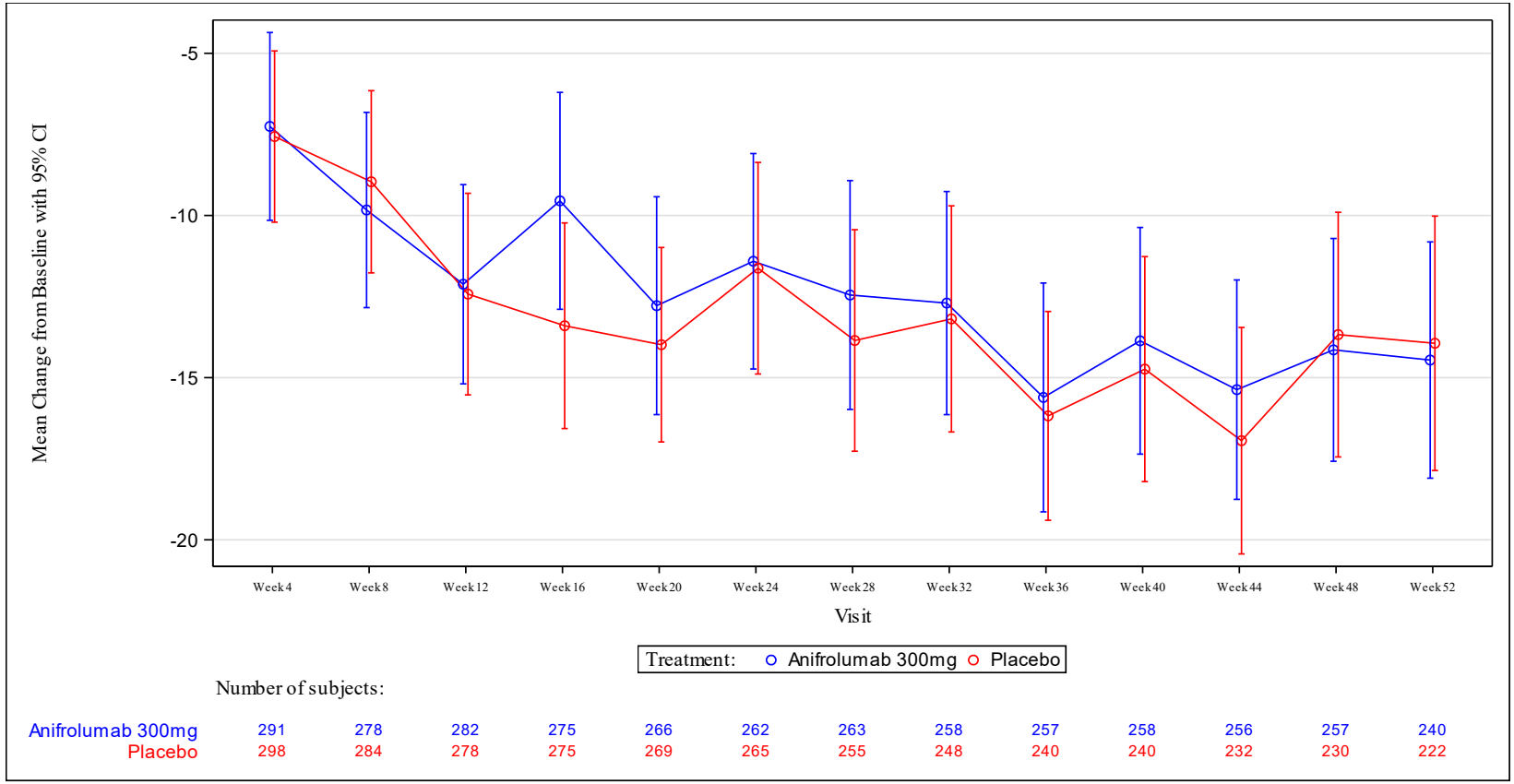
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint (observed values) - PtGA
Full analysis set

	Anifrolumab 300mg (N=315)				Placebo (N=321)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	301	53.50 (21.88)	0	-	308	56.82 (21.80)	0	-
Week 4	299	46.34 (22.46)	291	-7.25 (25.10)	307	49.54 (23.82)	298	-7.57 (23.16)
Week 8	287	43.66 (23.67)	278	-9.83 (25.49)	295	48.20 (23.32)	284	-8.96 (24.05)
Week 12	293	41.42 (23.95)	282	-12.12 (26.20)	289	45.10 (24.71)	278	-12.42 (26.33)
Week 16	287	43.88 (25.17)	275	-9.55 (28.17)	284	43.39 (24.46)	275	-13.40 (26.70)
Week 20	278	40.18 (24.05)	266	-12.78 (27.82)	280	42.50 (24.51)	269	-13.99 (24.97)
Week 24	276	41.59 (25.04)	262	-11.41 (27.30)	276	45.24 (25.07)	265	-11.63 (26.97)
Week 28	276	40.83 (24.58)	263	-12.45 (29.06)	266	41.84 (23.97)	255	-13.85 (27.69)
Week 32	271	40.86 (24.54)	258	-12.70 (28.06)	257	41.91 (25.03)	248	-13.19 (27.87)
Week 36	271	38.13 (24.40)	257	-15.61 (28.72)	248	38.83 (23.81)	240	-16.18 (25.32)
Week 40	272	39.44 (24.49)	258	-13.86 (28.50)	249	41.61 (24.90)	240	-14.74 (27.27)
Week 44	268	37.91 (23.62)	256	-15.37 (27.48)	239	39.64 (24.80)	232	-16.94 (26.99)
Week 48	270	39.52 (24.46)	257	-14.14 (27.96)	239	41.49 (25.84)	230	-13.67 (29.04)
Week 52	254	39.29 (25.12)	240	-14.46 (28.65)	230	42.11 (26.87)	222	-13.94 (29.65)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint (observed values) - PtGA
Full analysis set



N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SLEDAI-2K Total Score
Full analysis set

Visit	Anifrolumab 300mg (N=315) N	Anifrolumab 300mg (N=315) LSMean (SE)	Placebo (N=321) N	Placebo (N=321) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		-0.76 (0.14)		-0.73 (0.14)	-0.02 (0.17)	(-0.36, 0.32)	0.8986				
Week 8		-2.17 (0.21)		-1.62 (0.20)	-0.55 (0.27)	(-1.09, -0.02)	0.0425				
Week 12		-3.58 (0.22)		-2.53 (0.22)	-1.06 (0.29)	(-1.62, -0.49)	0.0003				
Week 16		-4.10 (0.23)		-3.13 (0.23)	-0.97 (0.32)	(-1.59, -0.35)	0.0022				
Week 20		-4.67 (0.23)		-3.69 (0.23)	-0.98 (0.31)	(-1.60, -0.36)	0.0019				
Week 24		-5.05 (0.23)		-3.87 (0.23)	-1.18 (0.31)	(-1.79, -0.57)	0.0002				
Week 28		-5.27 (0.25)		-3.78 (0.25)	-1.49 (0.34)	(-2.15, -0.83)	<.0001				
Week 32		-5.50 (0.25)		-4.14 (0.25)	-1.35 (0.34)	(-2.01, -0.69)	<.0001				
Week 36		-5.52 (0.25)		-4.28 (0.25)	-1.24 (0.34)	(-1.92, -0.57)	0.0003				
Week 40		-5.47 (0.25)		-4.36 (0.26)	-1.12 (0.34)	(-1.79, -0.44)	0.0013				
Week 44		-5.73 (0.24)		-4.76 (0.25)	-0.97 (0.33)	(-1.62, -0.31)	0.0040				
Week 48		-5.77 (0.25)		-4.86 (0.25)	-0.92 (0.34)	(-1.59, -0.25)	0.0073				
Week 52		-6.05 (0.24)		-5.06 (0.24)	-0.99 (0.33)	(-1.63, -0.35)	0.0025				
OVERALL	314	-4.59 (0.19)	318	-3.60 (0.19)	-0.99 (0.25)	(-1.47, -0.50)	<.0001	-0.30 (0.08)	(-0.45, -0.14)	0.0002	0.5767

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SLEDAI-2K Total Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=315) N	LSMean (SE)	Placebo (N=321) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.5373
< 10 points	108	-3.37 (0.24)	101	-2.56 (0.24)	-0.81 (0.33)	(-1.47, -0.16)	0.0157	-0.33 (0.14)	(-0.60, -0.06)	0.0183	
>= 10 points	206	-5.06 (0.26)	217	-3.96 (0.25)	-1.10 (0.33)	(-1.74, -0.46)	0.0008	-0.30 (0.10)	(-0.49, -0.10)	0.0024	
OCS dose											0.0125
<10 mg/day	148	-4.03 (0.24)	144	-3.68 (0.25)	-0.36 (0.33)	(-1.01, 0.29)	0.2797	-0.12 (0.12)	(-0.35, 0.11)	0.2990	
>=10 mg/day	166	-5.05 (0.29)	174	-3.48 (0.28)	-1.57 (0.35)	(-2.27, -0.87)	<.0001	-0.42 (0.11)	(-0.63, -0.20)	0.0001	
Result of type I IFN gene signature test											0.0025
LOW	59	-3.24 (0.34)	67	-3.58 (0.32)	0.35 (0.46)	(-0.57, 1.26)	0.4547	0.13 (0.18)	(-0.22, 0.48)	0.4599	
HIGH	255	-4.95 (0.21)	251	-3.66 (0.21)	-1.29 (0.28)	(-1.85, -0.74)	<.0001	-0.39 (0.09)	(-0.57, -0.21)	<.0001	
Age (years)											NE
<= 65	307	-4.62 (0.19)	315	-3.58 (0.19)	-1.04 (0.25)	(-1.53, -0.55)	<.0001	-0.31 (0.08)	(-0.47, -0.15)	0.0001	
> 65	7	NE	3	NE	NE	NE		NE	NE		
Sex											0.2549
male	27	-5.58 (0.62)	25	-3.71 (0.64)	-1.86 (0.79)	(-3.44, -0.29)	0.0216	-0.57 (0.28)	(-1.13, -0.02)	0.0440	
female	287	-4.53 (0.20)	293	-3.60 (0.20)	-0.92 (0.26)	(-1.43, -0.41)	0.0004	-0.28 (0.08)	(-0.44, -0.11)	0.0010	
Race											0.0712
White	185	-4.24 (0.24)	203	-3.73 (0.23)	-0.51 (0.30)	(-1.11, 0.08)	0.0914	-0.16 (0.10)	(-0.36, 0.04)	0.1205	
Black	48	-5.08 (0.52)	40	-3.76 (0.52)	-1.32 (0.68)	(-2.66, 0.03)	0.0545	-0.38 (0.22)	(-0.80, 0.05)	0.0817	
Other	73	-5.04 (0.45)	72	-3.13 (0.48)	-1.92 (0.56)	(-3.03, -0.80)	0.0009	-0.48 (0.17)	(-0.81, -0.15)	0.0043	
Ethnicity											0.6275
Hispanic/Latino	78	-4.64 (0.36)	84	-3.84 (0.36)	-0.80 (0.48)	(-1.74, 0.15)	0.0969	-0.24 (0.16)	(-0.55, 0.07)	0.1223	
Non-hispanic/Latino	228	-4.56 (0.22)	231	-3.49 (0.22)	-1.07 (0.29)	(-1.63, -0.50)	0.0003	-0.32 (0.09)	(-0.50, -0.13)	0.0008	
Geographic region											0.9826
EU	110	-5.15 (0.34)	107	-4.20 (0.35)	-0.95 (0.41)	(-1.77, -0.13)	0.0228	-0.26 (0.14)	(-0.53, 0.00)	0.0541	
non-EU	204	-4.31 (0.23)	211	-3.35 (0.23)	-0.96 (0.30)	(-1.56, -0.36)	0.0017	-0.29 (0.10)	(-0.49, -0.10)	0.0030	
Onset of disease											0.7599
Paediatric	26	-5.31 (0.80)	21	-4.10 (0.86)	-1.21 (1.03)	(-3.29, 0.87)	0.2466	-0.30 (0.30)	(-0.88, 0.28)	0.3146	
Adult	288	-4.45 (0.19)	297	-3.56 (0.19)	-0.89 (0.25)	(-1.38, -0.39)	0.0005	-0.27 (0.08)	(-0.43, -0.11)	0.0011	
ADA result											0.0531
Negative	292	-4.53 (0.19)	292	-3.64 (0.19)	-0.89 (0.25)	(-1.39, -0.40)	0.0004	-0.27 (0.08)	(-0.44, -0.11)	0.0010	
Positive (At any time)	22	-5.55 (1.13)	26	-2.69 (1.02)	-2.87 (0.99)	(-4.87, -0.86)	0.0064	-0.54 (0.30)	(-1.12, 0.04)	0.0683	
BMI (kg/m2)											0.1239
< 30	212	-4.87 (0.24)	232	-3.64 (0.24)	-1.22 (0.31)	(-1.83, -0.62)	<.0001	-0.34 (0.10)	(-0.53, -0.16)	0.0003	
>= 30	102	-3.91 (0.29)	86	-3.46 (0.30)	-0.45 (0.40)	(-1.24, 0.35)	0.2687	-0.15 (0.15)	(-0.44, 0.13)	0.2970	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - PGA
Full analysis set

Visit	Anifrolumab 300mg (N=315) N	Anifrolumab 300mg (N=315) LSMean (SE)	Placebo (N=321) N	Placebo (N=321) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		-0.28 (0.02)		-0.21 (0.02)	-0.07 (0.03)	(-0.13, -0.01)	0.0142				
Week 8		-0.50 (0.03)		-0.41 (0.03)	-0.09 (0.04)	(-0.16, -0.02)	0.0120				
Week 12		-0.67 (0.03)		-0.47 (0.03)	-0.20 (0.04)	(-0.28, -0.12)	<.0001				
Week 16		-0.77 (0.03)		-0.59 (0.03)	-0.18 (0.04)	(-0.27, -0.10)	<.0001				
Week 20		-0.83 (0.03)		-0.62 (0.03)	-0.21 (0.04)	(-0.30, -0.13)	<.0001				
Week 24		-0.88 (0.03)		-0.67 (0.03)	-0.21 (0.04)	(-0.29, -0.12)	<.0001				
Week 28		-0.92 (0.03)		-0.72 (0.03)	-0.20 (0.05)	(-0.29, -0.11)	<.0001				
Week 32		-0.97 (0.03)		-0.74 (0.03)	-0.23 (0.05)	(-0.32, -0.14)	<.0001				
Week 36		-0.99 (0.04)		-0.79 (0.04)	-0.20 (0.05)	(-0.29, -0.11)	<.0001				
Week 40		-0.99 (0.04)		-0.82 (0.04)	-0.16 (0.05)	(-0.26, -0.07)	0.0009				
Week 44		-1.03 (0.04)		-0.82 (0.04)	-0.20 (0.05)	(-0.30, -0.11)	<.0001				
Week 48		-1.02 (0.04)		-0.82 (0.04)	-0.20 (0.05)	(-0.29, -0.10)	<.0001				
Week 52		-1.05 (0.04)		-0.86 (0.04)	-0.20 (0.05)	(-0.30, -0.10)	0.0001				
OVERALL	314	-0.84 (0.03)	319	-0.66 (0.03)	-0.18 (0.04)	(-0.25, -0.11)	<.0001	-0.37 (0.08)	(-0.53, -0.21)	<.0001	0.7603

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - PGA - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=315)		Placebo (N=321)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.7803
< 10 points	108	-0.82 (0.05)	101	-0.65 (0.05)	-0.17 (0.06)	(-0.29, -0.05)	0.0070	-0.36 (0.14)	(-0.63, -0.08)	0.0105	
>= 10 points	206	-0.83 (0.03)	218	-0.65 (0.03)	-0.19 (0.04)	(-0.27, -0.10)	<.0001	-0.37 (0.10)	(-0.57, -0.18)	0.0001	
OCS dose											0.3048
<10 mg/day	148	-0.74 (0.04)	144	-0.60 (0.04)	-0.14 (0.05)	(-0.24, -0.04)	0.0047	-0.32 (0.12)	(-0.55, -0.08)	0.0075	
>=10 mg/day	166	-0.93 (0.04)	175	-0.72 (0.04)	-0.21 (0.05)	(-0.31, -0.12)	<.0001	-0.40 (0.11)	(-0.62, -0.19)	0.0002	
Result of type I IFN gene signature test											0.0385
LOW	59	-0.73 (0.05)	67	-0.68 (0.05)	-0.05 (0.07)	(-0.19, 0.09)	0.4744	-0.13 (0.18)	(-0.48, 0.22)	0.4819	
HIGH	255	-0.89 (0.03)	252	-0.68 (0.03)	-0.22 (0.04)	(-0.30, -0.14)	<.0001	-0.45 (0.09)	(-0.63, -0.28)	<.0001	
Age (years)											NE
<= 65	307	-0.84 (0.03)	316	-0.66 (0.03)	-0.18 (0.04)	(-0.25, -0.11)	<.0001	-0.37 (0.08)	(-0.53, -0.22)	<.0001	
> 65	7	NE	3	NE	NE	NE		NE	NE		
Sex											0.5620
male	27	-0.89 (0.10)	26	-0.77 (0.10)	-0.11 (0.12)	(-0.36, 0.13)	0.3520	-0.21 (0.28)	(-0.75, 0.33)	0.4397	
female	287	-0.83 (0.03)	293	-0.65 (0.03)	-0.19 (0.04)	(-0.26, -0.11)	<.0001	-0.38 (0.08)	(-0.55, -0.22)	<.0001	
Race											0.1347
White	185	-0.78 (0.03)	204	-0.67 (0.03)	-0.12 (0.04)	(-0.20, -0.03)	0.0079	-0.25 (0.10)	(-0.45, -0.05)	0.0152	
Black	48	-0.87 (0.08)	40	-0.70 (0.08)	-0.17 (0.10)	(-0.37, 0.03)	0.0902	-0.32 (0.22)	(-0.74, 0.11)	0.1412	
Other	73	-0.86 (0.06)	72	-0.56 (0.07)	-0.30 (0.08)	(-0.45, -0.14)	0.0002	-0.53 (0.17)	(-0.86, -0.20)	0.0017	
Ethnicity											0.3787
Hispanic/Latino	78	-0.84 (0.05)	84	-0.71 (0.05)	-0.13 (0.07)	(-0.27, 0.02)	0.0796	-0.26 (0.16)	(-0.57, 0.05)	0.1039	
Non-hispanic/Latino	228	-0.82 (0.03)	232	-0.63 (0.03)	-0.20 (0.04)	(-0.28, -0.12)	<.0001	-0.41 (0.09)	(-0.59, -0.23)	<.0001	
Geographic region											0.8042
EU	110	-0.84 (0.05)	108	-0.67 (0.05)	-0.17 (0.06)	(-0.28, -0.06)	0.0033	-0.34 (0.14)	(-0.60, -0.07)	0.0140	
non-EU	204	-0.82 (0.03)	211	-0.64 (0.03)	-0.19 (0.05)	(-0.27, -0.10)	<.0001	-0.38 (0.10)	(-0.57, -0.18)	0.0001	
Onset of disease											0.8151
Paediatric	26	-0.87 (0.16)	21	-0.65 (0.16)	-0.22 (0.18)	(-0.60, 0.15)	0.2368	-0.29 (0.30)	(-0.87, 0.29)	0.3286	
Adult	288	-0.84 (0.03)	298	-0.66 (0.03)	-0.18 (0.04)	(-0.25, -0.11)	<.0001	-0.38 (0.08)	(-0.54, -0.21)	<.0001	
ADA result											0.4730
Negative	292	-0.83 (0.03)	293	-0.66 (0.03)	-0.18 (0.04)	(-0.25, -0.10)	<.0001	-0.37 (0.08)	(-0.53, -0.20)	<.0001	
Positive (At any time)	22	-0.88 (0.21)	26	-0.59 (0.20)	-0.29 (0.15)	(-0.60, 0.02)	0.0691	-0.28 (0.29)	(-0.85, 0.29)	0.3375	
BMI (kg/m2)											0.3449
< 30	212	-0.84 (0.03)	233	-0.64 (0.03)	-0.20 (0.04)	(-0.29, -0.12)	<.0001	-0.40 (0.10)	(-0.59, -0.22)	<.0001	
>= 30	102	-0.81 (0.05)	86	-0.68 (0.05)	-0.13 (0.07)	(-0.26, 0.00)	0.0533	-0.26 (0.15)	(-0.55, 0.02)	0.0723	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - CLASI Total Activity Score
Full analysis set

Visit	Anifrolumab 300mg (N=315) N	Anifrolumab 300mg (N=315) LSMean (SE)	Placebo (N=321) N	Placebo (N=321) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		-1.47 (0.21)		-0.82 (0.20)	-0.64 (0.26)	(-1.15, -0.14)	0.0128				
Week 8		-2.90 (0.22)		-1.76 (0.22)	-1.14 (0.29)	(-1.70, -0.57)	<.0001				
Week 12		-3.60 (0.24)		-2.34 (0.24)	-1.26 (0.31)	(-1.87, -0.65)	<.0001				
Week 16		-4.05 (0.24)		-2.75 (0.24)	-1.30 (0.32)	(-1.92, -0.67)	<.0001				
Week 20		-4.48 (0.25)		-2.93 (0.25)	-1.55 (0.33)	(-2.19, -0.91)	<.0001				
Week 24		-4.70 (0.26)		-2.96 (0.26)	-1.74 (0.35)	(-2.42, -1.06)	<.0001				
Week 28		-4.85 (0.26)		-3.26 (0.26)	-1.59 (0.35)	(-2.27, -0.91)	<.0001				
Week 32		-5.00 (0.27)		-3.36 (0.27)	-1.64 (0.36)	(-2.34, -0.94)	<.0001				
Week 36		-5.17 (0.26)		-3.72 (0.26)	-1.45 (0.35)	(-2.13, -0.77)	<.0001				
Week 40		-5.31 (0.27)		-3.66 (0.27)	-1.65 (0.36)	(-2.35, -0.94)	<.0001				
Week 44		-5.27 (0.27)		-3.78 (0.27)	-1.49 (0.36)	(-2.20, -0.77)	<.0001				
Week 48		-5.37 (0.27)		-4.04 (0.27)	-1.33 (0.36)	(-2.04, -0.62)	0.0002				
Week 52		-5.52 (0.26)		-4.03 (0.27)	-1.49 (0.35)	(-2.18, -0.79)	<.0001				
OVERALL	314	-4.44 (0.22)	319	-3.03 (0.22)	-1.40 (0.28)	(-1.96, -0.85)	<.0001	-0.36 (0.08)	(-0.52, -0.20)	<.0001	0.5702

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - CLASI Total Activity Score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=315)		Placebo (N=321)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.0561
< 10 points	108	-3.47 (0.28)	101	-2.74 (0.28)	-0.73 (0.38)	(-1.48, 0.02)	0.0565	-0.25 (0.14)	(-0.53, 0.02)	0.0670	
>= 10 points	206	-4.88 (0.31)	218	-3.13 (0.30)	-1.75 (0.38)	(-2.50, -1.01)	<.0001	-0.40 (0.10)	(-0.59, -0.20)	<.0001	
OCS dose											0.0087
<10 mg/day	148	-3.46 (0.30)	144	-2.94 (0.30)	-0.52 (0.40)	(-1.32, 0.28)	0.1999	-0.14 (0.12)	(-0.37, 0.09)	0.2210	
>=10 mg/day	166	-5.12 (0.33)	175	-3.15 (0.32)	-1.98 (0.38)	(-2.73, -1.23)	<.0001	-0.47 (0.11)	(-0.69, -0.26)	<.0001	
Result of type I IFN gene signature test											0.0006
LOW	59	-2.76 (0.28)	67	-2.80 (0.27)	0.05 (0.38)	(-0.72, 0.81)	0.9064	0.02 (0.18)	(-0.33, 0.37)	0.9074	
HIGH	255	-4.92 (0.25)	252	-3.21 (0.25)	-1.71 (0.34)	(-2.37, -1.04)	<.0001	-0.43 (0.09)	(-0.61, -0.25)	<.0001	
Age (years)											NE
<= 65	307	-4.42 (0.22)	316	-3.00 (0.22)	-1.42 (0.29)	(-1.98, -0.86)	<.0001	-0.36 (0.08)	(-0.52, -0.20)	<.0001	
> 65	7	NE	3	NE	NE	NE		NE	NE		
Sex											NE
male	27	NE	26	NE	NE	NE		NE	NE		
female	287	-4.22 (0.21)	293	-2.90 (0.21)	-1.32 (0.27)	(-1.85, -0.79)	<.0001	-0.37 (0.08)	(-0.53, -0.21)	<.0001	
Race											NE
White	185	-4.18 (0.26)	204	-3.35 (0.25)	-0.84 (0.32)	(-1.46, -0.21)	0.0093	-0.24 (0.10)	(-0.44, -0.04)	0.0206	
Black	48	-4.15 (0.45)	40	-3.11 (0.44)	-1.04 (0.57)	(-2.17, 0.09)	0.0713	-0.35 (0.22)	(-0.77, 0.07)	0.1061	
Other	73	NE	72	NE	NE	NE		NE	NE		
Ethnicity											0.3366
Hispanic/Latino	78	-3.32 (0.33)	84	-2.21 (0.34)	-1.10 (0.43)	(-1.95, -0.26)	0.0111	-0.36 (0.16)	(-0.67, -0.05)	0.0221	
Non-hispanic/Latino	228	-4.80 (0.28)	232	-3.16 (0.28)	-1.64 (0.37)	(-2.36, -0.92)	<.0001	-0.39 (0.09)	(-0.57, -0.20)	<.0001	
Geographic region											0.2673
EU	110	-4.72 (0.43)	108	-3.80 (0.44)	-0.92 (0.51)	(-1.93, 0.10)	0.0760	-0.20 (0.14)	(-0.47, 0.06)	0.1350	
non-EU	204	-4.20 (0.26)	211	-2.60 (0.26)	-1.60 (0.34)	(-2.26, -0.93)	<.0001	-0.43 (0.10)	(-0.62, -0.23)	<.0001	
Onset of disease											0.9744
Paediatric	26	-5.19 (0.93)	21	-3.79 (1.04)	-1.40 (1.31)	(-4.07, 1.27)	0.2949	-0.29 (0.30)	(-0.87, 0.29)	0.3269	
Adult	288	-4.34 (0.23)	298	-2.99 (0.22)	-1.36 (0.29)	(-1.93, -0.79)	<.0001	-0.35 (0.08)	(-0.51, -0.19)	<.0001	
ADA result											NE
Negative	292	-4.40 (0.22)	293	-3.16 (0.22)	-1.25 (0.29)	(-1.81, -0.68)	<.0001	-0.33 (0.08)	(-0.49, -0.16)	<.0001	
Positive (At any time)	22	NE	26	NE	NE	NE		NE	NE		
BMI (kg/m2)											0.0019
< 30	212	-4.94 (0.29)	233	-2.98 (0.29)	-1.96 (0.36)	(-2.66, -1.25)	<.0001	-0.46 (0.10)	(-0.64, -0.27)	<.0001	
>= 30	102	-3.32 (0.31)	86	-3.06 (0.32)	-0.26 (0.42)	(-1.08, 0.56)	0.5366	-0.08 (0.15)	(-0.37, 0.20)	0.5646	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - CLASI Total Damage Score
Full analysis set

Visit	Anifrolumab 300mg (N=315) N	Anifrolumab 300mg (N=315) LSMean (SE)	Placebo (N=321) N	Placebo (N=321) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		-0.09 (0.08)		-0.03 (0.08)	-0.06 (0.10)	(-0.25, 0.13)	0.5453				
Week 8		-0.13 (0.10)		-0.15 (0.10)	0.02 (0.13)	(-0.24, 0.28)	0.8821				
Week 12		-0.25 (0.11)		-0.17 (0.11)	-0.08 (0.15)	(-0.36, 0.21)	0.6023				
Week 16		-0.35 (0.11)		-0.19 (0.11)	-0.16 (0.14)	(-0.45, 0.12)	0.2560				
Week 20		-0.37 (0.13)		-0.26 (0.13)	-0.11 (0.17)	(-0.45, 0.22)	0.5030				
Week 24		-0.52 (0.12)		-0.23 (0.12)	-0.29 (0.16)	(-0.61, 0.03)	0.0763				
Week 28		-0.54 (0.12)		-0.29 (0.12)	-0.25 (0.16)	(-0.57, 0.08)	0.1329				
Week 32		-0.56 (0.13)		-0.23 (0.13)	-0.33 (0.17)	(-0.68, 0.01)	0.0583				
Week 36		-0.58 (0.14)		-0.25 (0.14)	-0.33 (0.18)	(-0.69, 0.03)	0.0732				
Week 40		-0.63 (0.14)		-0.28 (0.14)	-0.35 (0.19)	(-0.73, 0.03)	0.0700				
Week 44		-0.66 (0.14)		-0.32 (0.14)	-0.34 (0.19)	(-0.71, 0.03)	0.0713				
Week 48		-0.62 (0.14)		-0.34 (0.14)	-0.28 (0.19)	(-0.66, 0.09)	0.1403				
Week 52		-0.64 (0.14)		-0.32 (0.14)	-0.31 (0.19)	(-0.69, 0.07)	0.1068				
OVERALL	314	-0.46 (0.11)	319	-0.24 (0.11)	-0.22 (0.14)	(-0.50, 0.06)	0.1214	-0.11 (0.08)	(-0.27, 0.04)	0.1491	0.4830

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - CLASI Total Damage Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=315) N	LSMean (SE)	Placebo (N=321) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.7114
< 10 points	108	-0.35 (0.14)	101	-0.22 (0.15)	-0.13 (0.19)	(-0.51, 0.25)	0.5073	-0.09 (0.14)	(-0.36, 0.18)	0.5302	
>= 10 points	206	-0.49 (0.14)	218	-0.26 (0.14)	-0.23 (0.19)	(-0.60, 0.14)	0.2250	-0.11 (0.10)	(-0.30, 0.08)	0.2615	
OCS dose											0.7914
<10 mg/day	148	-0.36 (0.13)	144	-0.23 (0.13)	-0.13 (0.18)	(-0.48, 0.22)	0.4712	-0.08 (0.12)	(-0.31, 0.15)	0.4892	
>=10 mg/day	166	-0.45 (0.16)	175	-0.25 (0.16)	-0.20 (0.20)	(-0.60, 0.20)	0.3219	-0.09 (0.11)	(-0.31, 0.12)	0.3820	
Result of type I IFN gene signature test											NE
LOW	59	NE	67	NE	NE	NE		NE	NE		
HIGH	255	-0.46 (0.12)	252	-0.24 (0.13)	-0.22 (0.17)	(-0.56, 0.12)	0.2028	-0.11 (0.09)	(-0.28, 0.06)	0.2161	
Age (years)											NE
<= 65	307	-0.45 (0.11)	316	-0.22 (0.11)	-0.22 (0.14)	(-0.51, 0.06)	0.1187	-0.12 (0.08)	(-0.27, 0.04)	0.1480	
> 65	7	NE	3	NE	NE	NE		NE	NE		
Sex											NE
male	27	NE	26	NE	NE	NE		NE	NE		
female	287	-0.44 (0.11)	293	-0.24 (0.11)	-0.19 (0.15)	(-0.48, 0.09)	0.1853	-0.10 (0.08)	(-0.27, 0.06)	0.2150	
Race											NE
White	185	-0.58 (0.14)	204	-0.28 (0.13)	-0.30 (0.18)	(-0.65, 0.04)	0.0873	-0.16 (0.10)	(-0.36, 0.04)	0.1133	
Black	48	NE	40	NE	NE	NE		NE	NE		
Other	73	NE	72	NE	NE	NE		NE	NE		
Ethnicity											NE
Hispanic/Latino	78	NE	84	NE	NE	NE		NE	NE		
Non-hispanic/Latino	228	-0.56 (0.14)	232	-0.29 (0.13)	-0.27 (0.18)	(-0.62, 0.08)	0.1238	-0.13 (0.09)	(-0.32, 0.05)	0.1512	
Geographic region											0.0226
EU	110	-0.76 (0.22)	108	-0.08 (0.23)	-0.68 (0.27)	(-1.21, -0.15)	0.0123	-0.29 (0.14)	(-0.56, -0.02)	0.0332	
non-EU	204	-0.28 (0.12)	211	-0.32 (0.12)	0.04 (0.17)	(-0.29, 0.37)	0.8064	0.02 (0.10)	(-0.17, 0.22)	0.8137	
Onset of disease											NE
Paediatric	26	NE	21	NE	NE	NE		NE	NE		
Adult	288	-0.37 (0.11)	298	-0.21 (0.11)	-0.16 (0.14)	(-0.44, 0.13)	0.2787	-0.08 (0.08)	(-0.25, 0.08)	0.3140	
ADA result											NE
Negative	292	-0.50 (0.11)	293	-0.28 (0.11)	-0.22 (0.15)	(-0.50, 0.07)	0.1370	-0.12 (0.08)	(-0.28, 0.05)	0.1629	
Positive (At any time)	22	NE	26	NE	NE	NE		NE	NE		
BMI (kg/m2)											NE
< 30	212	-0.60 (0.13)	233	-0.21 (0.12)	-0.39 (0.16)	(-0.70, -0.08)	0.0151	-0.21 (0.10)	(-0.39, -0.02)	0.0300	
>= 30	102	NE	86	NE	NE	NE		NE	NE		

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - BILAG Global Score
Full analysis set

Visit	Anifrolumab 300mg (N=315) N	Anifrolumab 300mg (N=315) LSMean (SE)	Placebo (N=321) N	Placebo (N=321) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		-4.48 (0.36)		-3.78 (0.35)	-0.70 (0.45)	(-1.59, 0.19)	0.1239				
Week 8		-7.67 (0.40)		-6.07 (0.40)	-1.60 (0.53)	(-2.63, -0.57)	0.0024				
Week 12		-9.00 (0.40)		-7.32 (0.40)	-1.68 (0.53)	(-2.72, -0.64)	0.0015				
Week 16		-9.63 (0.43)		-8.35 (0.43)	-1.28 (0.57)	(-2.39, -0.17)	0.0238				
Week 20		-10.19 (0.42)		-8.63 (0.42)	-1.56 (0.56)	(-2.66, -0.47)	0.0051				
Week 24		-10.57 (0.42)		-8.67 (0.42)	-1.90 (0.56)	(-3.00, -0.81)	0.0007				
Week 28		-10.66 (0.45)		-8.94 (0.45)	-1.72 (0.60)	(-2.90, -0.54)	0.0043				
Week 32		-11.22 (0.44)		-9.13 (0.44)	-2.09 (0.58)	(-3.23, -0.95)	0.0003				
Week 36		-11.19 (0.44)		-9.81 (0.44)	-1.38 (0.58)	(-2.53, -0.23)	0.0183				
Week 40		-11.14 (0.44)		-9.68 (0.45)	-1.46 (0.59)	(-2.62, -0.30)	0.0141				
Week 44		-11.39 (0.44)		-9.90 (0.44)	-1.49 (0.59)	(-2.64, -0.34)	0.0109				
Week 48		-11.68 (0.44)		-10.17 (0.44)	-1.51 (0.58)	(-2.66, -0.36)	0.0099				
Week 52		-11.95 (0.43)		-10.62 (0.44)	-1.32 (0.58)	(-2.46, -0.19)	0.0222				
OVERALL	314	-10.06 (0.34)	319	-8.54 (0.34)	-1.52 (0.43)	(-2.36, -0.67)	0.0005	-0.25 (0.08)	(-0.41, -0.09)	0.0018	0.9586

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - BILAG Global Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=315) N	LSMean (SE)	Placebo (N=321) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.7083
< 10 points	108	-9.83 (0.49)	101	-8.50 (0.50)	-1.33 (0.66)	(-2.62, -0.04)	0.0440	-0.26 (0.14)	(-0.54, 0.01)	0.0581	
>= 10 points	206	-10.01 (0.46)	218	-8.36 (0.45)	-1.65 (0.56)	(-2.75, -0.55)	0.0033	-0.25 (0.10)	(-0.44, -0.06)	0.0114	
OCS dose											0.4663
<10 mg/day	148	-9.48 (0.45)	144	-8.30 (0.47)	-1.17 (0.61)	(-2.38, 0.03)	0.0559	-0.21 (0.12)	(-0.44, 0.02)	0.0734	
>=10 mg/day	166	-10.48 (0.54)	175	-8.68 (0.51)	-1.80 (0.61)	(-2.99, -0.61)	0.0031	-0.26 (0.11)	(-0.48, -0.05)	0.0158	
Result of type I IFN gene signature test											0.0083
LOW	59	-9.10 (0.67)	67	-9.76 (0.63)	0.66 (0.91)	(-1.13, 2.45)	0.4676	0.13 (0.18)	(-0.22, 0.48)	0.4766	
HIGH	255	-10.29 (0.36)	252	-8.24 (0.36)	-2.05 (0.49)	(-3.01, -1.10)	<.0001	-0.36 (0.09)	(-0.53, -0.18)	<.0001	
Age (years)											NE
<= 65	307	-10.11 (0.35)	316	-8.57 (0.34)	-1.54 (0.44)	(-2.40, -0.68)	0.0004	-0.25 (0.08)	(-0.41, -0.09)	0.0018	
> 65	7	NE	3	NE	NE	NE		NE	NE		
Sex											0.5621
male	27	-11.22 (1.06)	26	-9.01 (1.09)	-2.21 (1.23)	(-4.68, 0.26)	0.0784	-0.39 (0.28)	(-0.94, 0.15)	0.1572	
female	287	-10.03 (0.36)	293	-8.58 (0.36)	-1.45 (0.46)	(-2.35, -0.55)	0.0016	-0.24 (0.08)	(-0.40, -0.07)	0.0046	
Race											0.0806
White	185	-9.73 (0.46)	204	-8.97 (0.44)	-0.76 (0.56)	(-1.87, 0.34)	0.1744	-0.12 (0.10)	(-0.32, 0.08)	0.2327	
Black	48	-10.95 (0.92)	40	-7.65 (0.89)	-3.31 (1.12)	(-5.54, -1.07)	0.0043	-0.54 (0.22)	(-0.97, -0.11)	0.0130	
Other	73	-10.19 (0.81)	72	-7.89 (0.88)	-2.30 (0.94)	(-4.16, -0.45)	0.0153	-0.32 (0.17)	(-0.65, 0.01)	0.0568	
Ethnicity											0.6441
Hispanic/Latino	78	-9.85 (0.67)	84	-8.68 (0.69)	-1.17 (0.86)	(-2.87, 0.53)	0.1760	-0.19 (0.16)	(-0.50, 0.12)	0.2282	
Non-hispanic/Latino	228	-10.04 (0.41)	232	-8.40 (0.40)	-1.63 (0.51)	(-2.63, -0.64)	0.0014	-0.27 (0.09)	(-0.45, -0.08)	0.0046	
Geographic region											0.5064
EU	110	-10.61 (0.66)	108	-9.54 (0.67)	-1.07 (0.73)	(-2.51, 0.37)	0.1438	-0.15 (0.14)	(-0.42, 0.11)	0.2593	
non-EU	204	-9.62 (0.41)	211	-7.95 (0.40)	-1.67 (0.53)	(-2.71, -0.63)	0.0017	-0.28 (0.10)	(-0.48, -0.09)	0.0039	
Onset of disease											0.8593
Paediatric	26	-11.30 (1.43)	21	-10.09 (1.42)	-1.21 (1.66)	(-4.57, 2.15)	0.4705	-0.17 (0.29)	(-0.75, 0.41)	0.5605	
Adult	288	-10.01 (0.36)	298	-8.50 (0.35)	-1.52 (0.45)	(-2.40, -0.63)	0.0008	-0.25 (0.08)	(-0.41, -0.09)	0.0028	
ADA result											0.0789
Negative	292	-9.96 (0.35)	293	-8.66 (0.35)	-1.30 (0.45)	(-2.18, -0.42)	0.0040	-0.22 (0.08)	(-0.38, -0.05)	0.0094	
Positive (At any time)	22	-9.82 (2.26)	26	-5.72 (2.11)	-4.11 (1.53)	(-7.22, -0.99)	0.0112	-0.38 (0.29)	(-0.95, 0.20)	0.1965	
BMI (kg/m2)											0.5248
< 30	212	-10.34 (0.42)	233	-8.64 (0.42)	-1.70 (0.51)	(-2.70, -0.70)	0.0009	-0.27 (0.10)	(-0.46, -0.08)	0.0044	
>= 30	102	-9.40 (0.62)	86	-8.32 (0.63)	-1.08 (0.83)	(-2.71, 0.55)	0.1927	-0.18 (0.15)	(-0.46, 0.11)	0.2291	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Tender Joint Count
Full analysis set

Visit	Anifrolumab 300mg (N=315) N	Anifrolumab 300mg (N=315) LSMean (SE)	Placebo (N=321) N	Placebo (N=321) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		-1.84 (0.31)		-1.83 (0.31)	-0.01 (0.40)	(-0.79, 0.77)	0.9816				
Week 8		-3.78 (0.33)		-3.26 (0.33)	-0.52 (0.43)	(-1.37, 0.32)	0.2228				
Week 12		-4.71 (0.35)		-3.92 (0.34)	-0.79 (0.45)	(-1.67, 0.10)	0.0818				
Week 16		-5.29 (0.34)		-4.87 (0.34)	-0.41 (0.45)	(-1.29, 0.47)	0.3577				
Week 20		-5.74 (0.35)		-5.10 (0.35)	-0.65 (0.46)	(-1.55, 0.26)	0.1598				
Week 24		-5.77 (0.36)		-5.02 (0.36)	-0.75 (0.48)	(-1.69, 0.19)	0.1184				
Week 28		-6.00 (0.34)		-5.48 (0.34)	-0.52 (0.45)	(-1.40, 0.36)	0.2483				
Week 32		-6.14 (0.35)		-5.29 (0.35)	-0.85 (0.47)	(-1.77, 0.06)	0.0677				
Week 36		-6.55 (0.35)		-5.61 (0.35)	-0.94 (0.47)	(-1.85, -0.02)	0.0442				
Week 40		-6.00 (0.34)		-6.09 (0.35)	0.09 (0.45)	(-0.80, 0.98)	0.8412				
Week 44		-6.47 (0.34)		-5.98 (0.35)	-0.48 (0.45)	(-1.38, 0.41)	0.2879				
Week 48		-6.46 (0.35)		-6.07 (0.35)	-0.38 (0.46)	(-1.29, 0.52)	0.4068				
Week 52		-6.33 (0.35)		-6.27 (0.36)	-0.06 (0.47)	(-0.98, 0.86)	0.8952				
OVERALL	313	-5.47 (0.27)	318	-4.98 (0.27)	-0.48 (0.34)	(-1.15, 0.19)	0.1584	-0.10 (0.08)	(-0.26, 0.06)	0.2125	0.1187

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Tender Joint Count - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=315) N	LSMean (SE)	Placebo (N=321) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.7279
< 10 points	108	-5.76 (0.47)	101	-5.45 (0.48)	-0.32 (0.64)	(-1.57, 0.94)	0.6199	-0.06 (0.14)	(-0.34, 0.21)	0.6395	
>= 10 points	205	-5.15 (0.34)	217	-4.57 (0.33)	-0.58 (0.41)	(-1.38, 0.22)	0.1543	-0.12 (0.10)	(-0.31, 0.07)	0.2262	
OCS dose											0.6059
<10 mg/day	147	-4.76 (0.37)	144	-4.45 (0.38)	-0.31 (0.50)	(-1.29, 0.67)	0.5324	-0.07 (0.12)	(-0.30, 0.16)	0.5635	
>=10 mg/day	166	-6.39 (0.41)	174	-5.73 (0.39)	-0.66 (0.46)	(-1.57, 0.25)	0.1542	-0.13 (0.11)	(-0.34, 0.09)	0.2427	
Result of type I IFN gene signature test											0.2674
LOW	59	-5.76 (0.69)	67	-4.35 (0.64)	-1.41 (0.93)	(-3.25, 0.43)	0.1307	-0.27 (0.18)	(-0.62, 0.09)	0.1381	
HIGH	254	-5.96 (0.27)	251	-5.65 (0.27)	-0.31 (0.36)	(-1.02, 0.40)	0.3952	-0.07 (0.09)	(-0.25, 0.10)	0.4191	
Age (years)											NE
<= 65	306	-5.41 (0.28)	315	-4.93 (0.27)	-0.48 (0.34)	(-1.16, 0.19)	0.1606	-0.10 (0.08)	(-0.26, 0.06)	0.2174	
> 65	7	NE	3	NE	NE	NE		NE	NE		
Sex											NE
male	27	NE	26	NE	NE	NE		NE	NE		
female	286	-5.56 (0.29)	292	-5.13 (0.29)	-0.43 (0.36)	(-1.14, 0.28)	0.2363	-0.09 (0.08)	(-0.25, 0.08)	0.2921	
Race											0.6452
White	185	-5.65 (0.36)	203	-5.43 (0.34)	-0.22 (0.44)	(-1.08, 0.64)	0.6145	-0.04 (0.10)	(-0.24, 0.15)	0.6589	
Black	48	-4.94 (0.98)	40	-3.64 (0.94)	-1.30 (1.17)	(-3.63, 1.03)	0.2700	-0.20 (0.21)	(-0.62, 0.22)	0.3499	
Other	72	-5.13 (0.52)	72	-4.52 (0.57)	-0.61 (0.61)	(-1.83, 0.60)	0.3184	-0.13 (0.17)	(-0.46, 0.20)	0.4290	
Ethnicity											0.8249
Hispanic/Latino	77	-5.67 (0.55)	84	-5.40 (0.57)	-0.28 (0.72)	(-1.70, 1.14)	0.6993	-0.05 (0.16)	(-0.36, 0.25)	0.7280	
Non-hispanic/Latino	228	-5.33 (0.33)	231	-4.87 (0.32)	-0.46 (0.40)	(-1.25, 0.33)	0.2507	-0.09 (0.09)	(-0.28, 0.09)	0.3145	
Geographic region											0.3641
EU	110	-5.65 (0.40)	107	-5.66 (0.41)	0.01 (0.43)	(-0.84, 0.86)	0.9796	0.00 (0.14)	(-0.26, 0.27)	0.9846	
non-EU	203	-5.29 (0.36)	211	-4.73 (0.35)	-0.56 (0.46)	(-1.47, 0.34)	0.2229	-0.11 (0.10)	(-0.30, 0.08)	0.2653	
Onset of disease											NE
Paediatric	26	NE	21	NE	NE	NE		NE	NE		
Adult	287	-5.65 (0.28)	297	-4.97 (0.28)	-0.68 (0.35)	(-1.38, 0.01)	0.0551	-0.14 (0.08)	(-0.30, 0.02)	0.0899	
ADA result											0.0868
Negative	291	-5.36 (0.28)	292	-5.05 (0.28)	-0.31 (0.35)	(-1.00, 0.38)	0.3771	-0.07 (0.08)	(-0.23, 0.10)	0.4302	
Positive (At any time)	22	-8.39 (1.60)	26	-5.69 (1.47)	-2.70 (1.35)	(-5.43, 0.03)	0.0526	-0.35 (0.29)	(-0.93, 0.22)	0.2263	
BMI (kg/m2)											0.9460
< 30	211	-5.44 (0.32)	232	-4.94 (0.31)	-0.50 (0.39)	(-1.25, 0.26)	0.1985	-0.11 (0.10)	(-0.29, 0.08)	0.2686	
>= 30	102	-5.79 (0.55)	86	-5.35 (0.56)	-0.44 (0.71)	(-1.85, 0.97)	0.5379	-0.08 (0.15)	(-0.37, 0.21)	0.5772	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Swollen Joint Count
Full analysis set

Visit	Anifrolumab 300mg (N=315) N	Anifrolumab 300mg (N=315) LSMean (SE)	Placebo (N=321) N	Placebo (N=321) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		-2.14 (0.23)		-1.95 (0.23)	-0.19 (0.30)	(-0.77, 0.40)	0.5314				
Week 8		-3.14 (0.24)		-3.28 (0.23)	0.13 (0.31)	(-0.47, 0.74)	0.6659				
Week 12		-3.83 (0.25)		-3.60 (0.25)	-0.23 (0.33)	(-0.88, 0.42)	0.4877				
Week 16		-4.21 (0.25)		-4.16 (0.24)	-0.04 (0.32)	(-0.67, 0.59)	0.8970				
Week 20		-4.55 (0.25)		-4.39 (0.24)	-0.16 (0.32)	(-0.79, 0.47)	0.6133				
Week 24		-4.59 (0.24)		-4.50 (0.24)	-0.09 (0.32)	(-0.72, 0.53)	0.7725				
Week 28		-4.78 (0.24)		-4.45 (0.24)	-0.34 (0.32)	(-0.96, 0.28)	0.2852				
Week 32		-4.85 (0.25)		-4.44 (0.25)	-0.42 (0.33)	(-1.07, 0.23)	0.2065				
Week 36		-4.78 (0.26)		-4.57 (0.26)	-0.20 (0.34)	(-0.87, 0.46)	0.5470				
Week 40		-4.64 (0.26)		-4.65 (0.26)	0.01 (0.35)	(-0.67, 0.69)	0.9820				
Week 44		-4.84 (0.25)		-4.66 (0.25)	-0.18 (0.33)	(-0.82, 0.47)	0.5884				
Week 48		-4.92 (0.26)		-4.66 (0.26)	-0.26 (0.34)	(-0.94, 0.42)	0.4517				
Week 52		-4.92 (0.25)		-4.98 (0.25)	0.05 (0.33)	(-0.59, 0.69)	0.8694				
OVERALL	313	-4.32 (0.20)	318	-4.18 (0.20)	-0.15 (0.24)	(-0.63, 0.33)	0.5456	-0.04 (0.08)	(-0.20, 0.11)	0.5942	0.0155

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Swollen Joint Count - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=315) N	LSMean (SE)	Placebo (N=321) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.6575
< 10 points	108	-4.41 (0.35)	101	-4.43 (0.35)	0.02 (0.46)	(-0.90, 0.93)	0.9700	0.00 (0.14)	(-0.27, 0.28)	0.9720	
>= 10 points	205	-4.23 (0.24)	217	-4.01 (0.24)	-0.22 (0.29)	(-0.79, 0.34)	0.4327	-0.07 (0.10)	(-0.26, 0.13)	0.5039	
OCS dose											0.0820
<10 mg/day	147	-3.76 (0.26)	144	-4.01 (0.27)	0.25 (0.35)	(-0.43, 0.93)	0.4726	0.08 (0.12)	(-0.15, 0.31)	0.5077	
>=10 mg/day	166	-4.94 (0.28)	174	-4.37 (0.27)	-0.57 (0.32)	(-1.19, 0.06)	0.0743	-0.16 (0.11)	(-0.37, 0.05)	0.1416	
Result of type I IFN gene signature test											0.4116
LOW	59	-4.84 (0.38)	67	-4.29 (0.36)	-0.55 (0.52)	(-1.58, 0.48)	0.2935	-0.18 (0.18)	(-0.54, 0.17)	0.3020	
HIGH	254	-4.25 (0.20)	251	-4.19 (0.20)	-0.07 (0.27)	(-0.60, 0.47)	0.8074	-0.02 (0.09)	(-0.20, 0.15)	0.8171	
Age (years)											NE
<= 65	306	-4.35 (0.20)	315	-4.17 (0.20)	-0.18 (0.25)	(-0.66, 0.31)	0.4687	-0.05 (0.08)	(-0.21, 0.11)	0.5246	
> 65	7	NE	3	NE	NE	NE		NE	NE		
Sex											0.6458
male	27	-3.94 (0.74)	26	-3.38 (0.77)	-0.56 (0.94)	(-2.47, 1.35)	0.5583	-0.14 (0.28)	(-0.68, 0.40)	0.6055	
female	286	-4.35 (0.20)	292	-4.24 (0.20)	-0.11 (0.25)	(-0.61, 0.39)	0.6700	-0.03 (0.08)	(-0.19, 0.13)	0.7060	
Race											0.2332
White	185	-4.29 (0.25)	203	-4.42 (0.24)	0.13 (0.30)	(-0.46, 0.72)	0.6619	0.04 (0.10)	(-0.16, 0.24)	0.7040	
Black	48	-4.84 (0.68)	40	-3.74 (0.65)	-1.09 (0.80)	(-2.69, 0.51)	0.1783	-0.24 (0.21)	(-0.66, 0.18)	0.2599	
Other	72	-4.30 (0.41)	72	-3.76 (0.45)	-0.53 (0.48)	(-1.48, 0.41)	0.2639	-0.15 (0.17)	(-0.47, 0.18)	0.3799	
Ethnicity											0.3279
Hispanic/Latino	77	-4.61 (0.41)	84	-4.92 (0.43)	0.31 (0.53)	(-0.73, 1.35)	0.5601	0.08 (0.16)	(-0.23, 0.39)	0.6073	
Non-hispanic/Latino	228	-4.24 (0.23)	231	-3.97 (0.22)	-0.27 (0.28)	(-0.82, 0.27)	0.3219	-0.08 (0.09)	(-0.26, 0.10)	0.3839	
Geographic region											0.7884
EU	110	-4.21 (0.22)	107	-4.14 (0.23)	-0.07 (0.25)	(-0.56, 0.42)	0.7869	-0.03 (0.14)	(-0.29, 0.24)	0.8345	
non-EU	203	-4.32 (0.26)	211	-4.14 (0.26)	-0.18 (0.34)	(-0.84, 0.48)	0.5954	-0.05 (0.10)	(-0.24, 0.15)	0.6300	
Onset of disease											NE
Paediatric	26	NE	21	NE	NE	NE		NE	NE		
Adult	287	-4.43 (0.20)	297	-4.13 (0.20)	-0.30 (0.25)	(-0.79, 0.19)	0.2268	-0.09 (0.08)	(-0.25, 0.07)	0.2877	
ADA result											NE
Negative	291	-4.24 (0.20)	292	-4.19 (0.20)	-0.05 (0.25)	(-0.55, 0.45)	0.8388	-0.02 (0.08)	(-0.18, 0.15)	0.8557	
Positive (At any time)	22	NE	26	NE	NE	NE		NE	NE		
BMI (kg/m2)											0.5436
< 30	211	-4.24 (0.23)	232	-4.18 (0.23)	-0.06 (0.28)	(-0.61, 0.50)	0.8428	-0.02 (0.10)	(-0.20, 0.17)	0.8654	
>= 30	102	-4.57 (0.37)	86	-4.18 (0.37)	-0.39 (0.48)	(-1.34, 0.55)	0.4127	-0.11 (0.15)	(-0.40, 0.18)	0.4561	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Mental Component Score
Full analysis set

	Anifrolumab 300mg (N=315)		Placebo (N=321)		Difference of						
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		0.38 (0.97)		0.01 (0.95)	0.37 (1.26)	(-2.12, 2.86)	0.7706				
Week 8		1.70 (0.61)		0.55 (0.61)	1.15 (0.76)	(-0.34, 2.65)	0.1294				
Week 12		1.58 (1.03)		0.96 (1.00)	0.62 (1.40)	(-2.14, 3.37)	0.6590				
Week 16		1.35 (0.64)		1.46 (0.64)	-0.11 (0.82)	(-1.71, 1.49)	0.8952				
Week 24		1.73 (0.60)		0.15 (0.60)	1.58 (0.78)	(0.05, 3.12)	0.0435				
Week 32		2.54 (0.63)		1.20 (0.63)	1.34 (0.81)	(-0.25, 2.94)	0.0992				
Week 36		2.96 (1.07)		1.15 (1.12)	1.81 (1.52)	(-1.19, 4.81)	0.2353				
Week 40		2.34 (0.66)		1.75 (0.67)	0.59 (0.87)	(-1.11, 2.29)	0.4943				
Week 48		2.74 (0.65)		1.57 (0.67)	1.17 (0.85)	(-0.51, 2.85)	0.1724				
Week 52		2.79 (0.63)		1.83 (0.65)	0.96 (0.84)	(-0.69, 2.61)	0.2523				
OVERALL	300	2.01 (0.49)	301	1.06 (0.48)	0.95 (0.61)	(-0.25, 2.15)	0.1201	0.11 (0.08)	(-0.05, 0.27)	0.1692	0.9343

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Mental Component Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=315) N	LSMean (SE)	Placebo (N=321) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											NE
< 10 points	103	3.18 (0.80)	98	0.97 (0.80)	2.21 (1.06)	(0.12, 4.30)	0.0387	0.27 (0.14)	(-0.00, 0.55)	0.0528	
>= 10 points	197	NE	203	NE	NE	NE		NE	NE		
OCS dose											0.7033
<10 mg/day	144	1.96 (0.66)	136	1.26 (0.69)	0.70 (0.89)	(-1.05, 2.45)	0.4306	0.09 (0.12)	(-0.15, 0.32)	0.4629	
>=10 mg/day	156	1.75 (0.76)	165	0.58 (0.72)	1.17 (0.85)	(-0.50, 2.84)	0.1694	0.12 (0.11)	(-0.09, 0.34)	0.2650	
Result of type I IFN gene signature test											NE
LOW	57	2.53 (1.00)	64	1.74 (0.93)	0.80 (1.34)	(-1.88, 3.47)	0.5553	0.11 (0.18)	(-0.25, 0.46)	0.5624	
HIGH	243	NE	237	NE	NE	NE		NE	NE		
Age (years)											NE
<= 65	293	NE	300	NE	NE	NE		NE	NE		
> 65	7	NE	1	NE	NE	NE		NE	NE		
Sex											NE
male	26	NE	26	NE	NE	NE		NE	NE		
female	274	1.84 (0.51)	275	0.86 (0.50)	0.97 (0.64)	(-0.28, 2.23)	0.1280	0.12 (0.09)	(-0.05, 0.28)	0.1747	
Race											NE
White	176	2.38 (0.67)	188	1.27 (0.64)	1.11 (0.84)	(-0.55, 2.77)	0.1895	0.13 (0.10)	(-0.08, 0.33)	0.2317	
Black	45	NE	39	NE	NE	NE		NE	NE		
Other	71	0.04 (1.02)	72	0.50 (1.12)	-0.46 (1.13)	(-2.70, 1.78)	0.6849	-0.05 (0.17)	(-0.38, 0.28)	0.7631	
Ethnicity											NE
Hispanic/Latino	77	NE	82	NE	NE	NE		NE	NE		
Non-hispanic/Latino	215	NE	217	NE	NE	NE		NE	NE		
Geographic region											NE
EU	104	2.02 (0.92)	100	0.88 (0.92)	1.13 (1.02)	(-0.88, 3.15)	0.2690	0.12 (0.14)	(-0.15, 0.40)	0.3867	
non-EU	196	NE	201	NE	NE	NE		NE	NE		
Onset of disease											NE
Paediatric	23	NE	19	NE	NE	NE		NE	NE		
Adult	277	NE	282	NE	NE	NE		NE	NE		
ADA result											NE
Negative	279	NE	276	NE	NE	NE		NE	NE		
Positive (At any time)	21	NE	25	NE	NE	NE		NE	NE		
BMI (kg/m2)											NE
< 30	203	1.66 (0.58)	218	0.94 (0.58)	0.72 (0.70)	(-0.65, 2.09)	0.2999	0.09 (0.10)	(-0.11, 0.28)	0.3810	
>= 30	97	NE	83	NE	NE	NE		NE	NE		

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Physical Component Score
Full analysis set

	Anifrolumab 300mg (N=315)		Placebo (N=321)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 4		0.79 (0.64)		0.37 (0.63)	0.43 (0.82)	(-1.19, 2.04)	0.6051				
Week 8		2.62 (0.45)		2.55 (0.45)	0.08 (0.55)	(-1.01, 1.17)	0.8888				
Week 12		2.22 (0.82)		2.88 (0.80)	-0.66 (1.11)	(-2.85, 1.53)	0.5524				
Week 16		3.86 (0.50)		3.02 (0.50)	0.84 (0.64)	(-0.42, 2.10)	0.1906				
Week 24		3.93 (0.47)		3.64 (0.47)	0.29 (0.61)	(-0.91, 1.49)	0.6351				
Week 32		3.62 (0.48)		3.72 (0.49)	-0.10 (0.62)	(-1.31, 1.12)	0.8766				
Week 36		4.11 (0.81)		4.44 (0.84)	-0.32 (1.14)	(-2.58, 1.93)	0.7762				
Week 40		3.84 (0.51)		3.95 (0.52)	-0.11 (0.67)	(-1.43, 1.20)	0.8652				
Week 48		3.88 (0.53)		3.68 (0.54)	0.19 (0.70)	(-1.18, 1.57)	0.7838				
Week 52		3.85 (0.47)		3.90 (0.48)	-0.05 (0.61)	(-1.26, 1.15)	0.9321				
OVERALL	300	3.27 (0.40)	301	3.21 (0.39)	0.06 (0.50)	(-0.92, 1.03)	0.9073	0.01 (0.08)	(-0.15, 0.17)	0.9181	0.8509

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Physical Component Score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=315)		Placebo (N=321)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.2293
< 10 points	103	3.49 (0.60)	98	2.77 (0.60)	0.72 (0.79)	(-0.84, 2.28)	0.3624	0.12 (0.14)	(-0.16, 0.40)	0.3978	
>= 10 points	197	2.91 (0.53)	203	3.41 (0.52)	-0.50 (0.64)	(-1.75, 0.75)	0.4339	-0.07 (0.10)	(-0.26, 0.13)	0.5039	
OCS dose											0.3629
<10 mg/day	144	3.24 (0.50)	136	2.65 (0.52)	0.59 (0.68)	(-0.75, 1.92)	0.3865	0.10 (0.12)	(-0.14, 0.33)	0.4197	
>=10 mg/day	156	3.19 (0.65)	165	3.51 (0.61)	-0.31 (0.72)	(-1.73, 1.11)	0.6649	-0.04 (0.11)	(-0.26, 0.18)	0.7254	
Result of type I IFN gene signature test											0.3022
LOW	57	2.98 (0.79)	64	3.93 (0.73)	-0.95 (1.06)	(-3.05, 1.15)	0.3727	-0.16 (0.18)	(-0.52, 0.20)	0.3793	
HIGH	243	3.86 (0.41)	237	3.57 (0.42)	0.29 (0.56)	(-0.81, 1.39)	0.6069	0.04 (0.09)	(-0.13, 0.22)	0.6226	
Age (years)											NE
<= 65	293	3.32 (0.40)	300	3.17 (0.40)	0.15 (0.50)	(-0.83, 1.13)	0.7659	0.02 (0.08)	(-0.14, 0.18)	0.7935	
> 65	7	NE	1	NE	NE	NE		NE	NE		
Sex											0.8004
male	26	3.63 (1.65)	26	3.91 (1.58)	-0.28 (1.69)	(-3.70, 3.15)	0.8708	-0.03 (0.28)	(-0.58, 0.51)	0.9047	
female	274	3.34 (0.42)	275	3.17 (0.41)	0.17 (0.52)	(-0.85, 1.20)	0.7434	0.02 (0.09)	(-0.14, 0.19)	0.7705	
Race											0.0591
White	176	2.77 (0.54)	188	3.64 (0.52)	-0.88 (0.67)	(-2.19, 0.44)	0.1914	-0.12 (0.10)	(-0.33, 0.08)	0.2425	
Black	45	4.62 (1.18)	39	1.75 (1.17)	2.87 (1.43)	(0.03, 5.72)	0.0476	0.37 (0.22)	(-0.06, 0.80)	0.0922	
Other	71	2.59 (0.88)	72	2.82 (0.96)	-0.24 (0.99)	(-2.19, 1.71)	0.8111	-0.03 (0.17)	(-0.36, 0.30)	0.8565	
Ethnicity											0.7302
Hispanic/Latino	77	3.18 (0.71)	82	3.69 (0.74)	-0.51 (0.92)	(-2.31, 1.30)	0.5815	-0.08 (0.16)	(-0.39, 0.23)	0.6245	
Non-hispanic/Latino	215	2.91 (0.50)	217	3.04 (0.48)	-0.13 (0.61)	(-1.32, 1.06)	0.8339	-0.02 (0.10)	(-0.21, 0.17)	0.8545	
Geographic region											0.0603
EU	104	3.03 (0.82)	100	4.42 (0.82)	-1.40 (0.91)	(-3.19, 0.40)	0.1262	-0.17 (0.14)	(-0.44, 0.11)	0.2328	
non-EU	196	3.35 (0.46)	201	2.72 (0.45)	0.63 (0.58)	(-0.52, 1.78)	0.2790	0.10 (0.10)	(-0.10, 0.30)	0.3252	
Onset of disease											0.7308
Paediatric	23	2.32 (2.04)	19	3.04 (1.97)	-0.72 (2.28)	(-5.35, 3.92)	0.7555	-0.08 (0.31)	(-0.68, 0.53)	0.8072	
Adult	277	3.27 (0.41)	282	3.18 (0.41)	0.09 (0.51)	(-0.92, 1.09)	0.8638	0.01 (0.08)	(-0.15, 0.18)	0.8792	
ADA result											0.0124
Negative	279	3.07 (0.41)	276	3.27 (0.41)	-0.21 (0.52)	(-1.23, 0.81)	0.6911	-0.03 (0.08)	(-0.20, 0.14)	0.7227	
Positive (At any time)	21	9.24 (2.41)	25	4.96 (2.30)	4.28 (1.72)	(0.78, 7.77)	0.0179	0.37 (0.30)	(-0.21, 0.96)	0.2128	
BMI (kg/m2)											0.3091
< 30	203	3.26 (0.48)	218	3.40 (0.47)	-0.14 (0.57)	(-1.26, 0.98)	0.8022	-0.02 (0.10)	(-0.21, 0.17)	0.8323	
>= 30	97	3.62 (0.74)	83	2.62 (0.73)	1.01 (0.97)	(-0.92, 2.93)	0.3036	0.14 (0.15)	(-0.15, 0.44)	0.3399	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute General Health Score
Full analysis set

	Anifrolumab 300mg (N=315)		Placebo (N=321)		Difference of						
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		-0.96 (0.90)		0.61 (0.88)	-1.57 (1.22)	(-3.98, 0.84)	0.1995				
Week 8		1.95 (0.45)		2.37 (0.45)	-0.42 (0.54)	(-1.48, 0.65)	0.4409				
Week 12		0.51 (1.04)		2.09 (1.01)	-1.58 (1.43)	(-4.40, 1.23)	0.2691				
Week 16		2.40 (0.48)		2.33 (0.48)	0.07 (0.61)	(-1.12, 1.26)	0.9123				
Week 24		2.60 (0.50)		2.27 (0.49)	0.33 (0.65)	(-0.93, 1.60)	0.6047				
Week 32		2.68 (0.49)		2.55 (0.49)	0.13 (0.63)	(-1.10, 1.36)	0.8367				
Week 36		3.21 (0.98)		3.98 (1.03)	-0.77 (1.39)	(-3.53, 1.98)	0.5803				
Week 40		2.62 (0.49)		2.73 (0.49)	-0.11 (0.62)	(-1.33, 1.12)	0.8654				
Week 48		2.70 (0.49)		3.59 (0.50)	-0.89 (0.63)	(-2.13, 0.36)	0.1631				
Week 52		2.82 (0.51)		2.98 (0.52)	-0.16 (0.67)	(-1.48, 1.16)	0.8075				
OVERALL	300	2.05 (0.44)	301	2.55 (0.43)	-0.50 (0.55)	(-1.58, 0.58)	0.3658	-0.07 (0.08)	(-0.23, 0.09)	0.4215	0.2565

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute General Health Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=315) N	LSMean (SE)	Placebo (N=321) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.3659
< 10 points	103	2.79 (0.66)	98	2.64 (0.66)	0.14 (0.88)	(-1.59, 1.88)	0.8715	0.02 (0.14)	(-0.26, 0.30)	0.8798	
>= 10 points	197	1.33 (0.58)	203	2.20 (0.57)	-0.87 (0.70)	(-2.25, 0.50)	0.2122	-0.11 (0.10)	(-0.30, 0.09)	0.2824	
OCS dose											0.4459
<10 mg/day	144	2.42 (0.63)	136	2.50 (0.66)	-0.08 (0.85)	(-1.74, 1.58)	0.9248	-0.01 (0.12)	(-0.24, 0.22)	0.9302	
>=10 mg/day	156	1.27 (0.65)	165	2.20 (0.61)	-0.93 (0.73)	(-2.37, 0.50)	0.2029	-0.12 (0.11)	(-0.34, 0.10)	0.2958	
Result of type I IFN gene signature test											0.1684
LOW	57	1.59 (1.00)	64	3.73 (0.92)	-2.14 (1.33)	(-4.77, 0.50)	0.1105	-0.28 (0.18)	(-0.64, 0.07)	0.1196	
HIGH	243	2.36 (0.44)	237	2.49 (0.44)	-0.13 (0.60)	(-1.30, 1.04)	0.8249	-0.02 (0.09)	(-0.20, 0.16)	0.8330	
Age (years)											NE
<= 65	293	2.10 (0.45)	300	2.57 (0.44)	-0.47 (0.55)	(-1.56, 0.61)	0.3896	-0.06 (0.08)	(-0.22, 0.10)	0.4464	
> 65	7	NE	1	NE	NE	NE		NE	NE		
Sex											0.1462
male	26	1.62 (1.65)	26	4.80 (1.52)	-3.17 (1.90)	(-7.04, 0.69)	0.1038	-0.39 (0.28)	(-0.94, 0.16)	0.1679	
female	274	2.12 (0.46)	275	2.40 (0.46)	-0.29 (0.58)	(-1.43, 0.85)	0.6187	-0.04 (0.09)	(-0.21, 0.13)	0.6563	
Race											0.2081
White	176	1.94 (0.63)	188	3.51 (0.60)	-1.57 (0.77)	(-3.08, -0.05)	0.0429	-0.19 (0.11)	(-0.39, 0.02)	0.0739	
Black	45	2.76 (1.12)	39	1.60 (1.14)	1.16 (1.40)	(-1.63, 3.96)	0.4094	0.16 (0.22)	(-0.27, 0.59)	0.4722	
Other	71	1.66 (0.98)	72	1.98 (1.06)	-0.32 (1.08)	(-2.46, 1.82)	0.7682	-0.04 (0.17)	(-0.36, 0.29)	0.8257	
Ethnicity											0.5951
Hispanic/Latino	77	3.11 (0.78)	82	3.34 (0.81)	-0.22 (1.02)	(-2.23, 1.78)	0.8253	-0.03 (0.16)	(-0.34, 0.28)	0.8436	
Non-hispanic/Latino	215	1.55 (0.55)	217	2.42 (0.53)	-0.87 (0.67)	(-2.18, 0.44)	0.1928	-0.11 (0.10)	(-0.30, 0.08)	0.2537	
Geographic region											0.1751
EU	104	2.03 (0.83)	100	3.52 (0.82)	-1.48 (0.92)	(-3.31, 0.34)	0.1102	-0.18 (0.14)	(-0.45, 0.10)	0.2066	
non-EU	196	2.17 (0.53)	201	2.09 (0.53)	0.08 (0.68)	(-1.27, 1.42)	0.9117	0.01 (0.10)	(-0.19, 0.21)	0.9193	
Onset of disease											0.2893
Paediatric	23	2.46 (1.73)	19	0.86 (1.70)	1.60 (2.00)	(-2.47, 5.67)	0.4287	0.20 (0.31)	(-0.41, 0.81)	0.5226	
Adult	277	2.00 (0.46)	282	2.60 (0.45)	-0.60 (0.57)	(-1.73, 0.52)	0.2939	-0.08 (0.08)	(-0.24, 0.09)	0.3508	
ADA result											0.5581
Negative	279	1.81 (0.45)	276	2.51 (0.44)	-0.71 (0.57)	(-1.82, 0.41)	0.2145	-0.09 (0.08)	(-0.26, 0.07)	0.2646	
Positive (At any time)	21	7.93 (2.78)	25	7.12 (2.68)	0.81 (2.53)	(-4.57, 6.19)	0.7522	0.06 (0.30)	(-0.52, 0.64)	0.8366	
BMI (kg/m2)											0.7011
< 30	203	2.05 (0.53)	218	2.60 (0.52)	-0.55 (0.64)	(-1.80, 0.70)	0.3875	-0.07 (0.10)	(-0.26, 0.12)	0.4576	
>= 30	97	2.30 (0.86)	83	2.36 (0.85)	-0.06 (1.11)	(-2.25, 2.12)	0.9561	-0.01 (0.15)	(-0.30, 0.29)	0.9601	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Mental Health Score
Full analysis set

Visit	Anifrolumab 300mg (N=315) N	Anifrolumab 300mg (N=315) LSMean (SE)	Placebo (N=321) N	Placebo (N=321) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		0.90 (0.97)		0.46 (0.95)	0.44 (1.29)	(-2.11, 3.00)	0.7334				
Week 8		1.77 (0.57)		1.24 (0.57)	0.54 (0.71)	(-0.87, 1.94)	0.4528				
Week 12		2.28 (1.06)		1.25 (1.03)	1.03 (1.44)	(-1.80, 3.86)	0.4736				
Week 16		1.76 (0.61)		1.88 (0.61)	-0.12 (0.79)	(-1.67, 1.42)	0.8762				
Week 24		1.90 (0.58)		0.61 (0.58)	1.28 (0.76)	(-0.20, 2.77)	0.0899				
Week 32		2.64 (0.61)		1.30 (0.61)	1.34 (0.79)	(-0.21, 2.89)	0.0910				
Week 36		3.13 (1.03)		1.74 (1.08)	1.38 (1.47)	(-1.51, 4.28)	0.3465				
Week 40		2.62 (0.59)		2.27 (0.60)	0.34 (0.76)	(-1.16, 1.85)	0.6523				
Week 48		2.89 (0.59)		2.07 (0.61)	0.83 (0.77)	(-0.69, 2.34)	0.2842				
Week 52		3.28 (0.56)		2.35 (0.58)	0.93 (0.75)	(-0.53, 2.40)	0.2118				
OVERALL	300	2.32 (0.46)	301	1.52 (0.45)	0.80 (0.57)	(-0.32, 1.92)	0.1609	0.10 (0.08)	(-0.06, 0.26)	0.2160	0.9515

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Mental Health Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=315) N	LSMean (SE)	Placebo (N=321) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.1735
< 10 points	103	3.45 (0.72)	98	1.59 (0.72)	1.86 (0.95)	(-0.01, 3.73)	0.0514	0.26 (0.14)	(-0.02, 0.53)	0.0704	
>= 10 points	197	1.37 (0.59)	203	1.12 (0.59)	0.24 (0.72)	(-1.16, 1.65)	0.7340	0.03 (0.10)	(-0.17, 0.23)	0.7712	
OCS dose											0.9957
<10 mg/day	144	2.30 (0.61)	136	1.48 (0.64)	0.82 (0.82)	(-0.80, 2.43)	0.3207	0.11 (0.12)	(-0.12, 0.35)	0.3545	
>=10 mg/day	156	2.06 (0.71)	165	1.25 (0.67)	0.81 (0.79)	(-0.75, 2.37)	0.3061	0.09 (0.11)	(-0.13, 0.31)	0.4068	
Result of type I IFN gene signature test											0.4256
LOW	57	2.21 (0.81)	64	2.27 (0.76)	-0.06 (1.10)	(-2.25, 2.13)	0.9569	-0.01 (0.18)	(-0.37, 0.35)	0.9573	
HIGH	243	2.29 (0.48)	237	1.33 (0.49)	0.96 (0.66)	(-0.33, 2.26)	0.1440	0.13 (0.09)	(-0.05, 0.31)	0.1628	
Age (years)											NE
<= 65	293	2.34 (0.47)	300	1.56 (0.46)	0.78 (0.57)	(-0.35, 1.91)	0.1751	0.10 (0.08)	(-0.06, 0.26)	0.2340	
> 65	7	NE	1	NE	NE	NE		NE	NE		
Sex											0.1302
male	26	3.13 (1.90)	26	5.09 (1.71)	-1.96 (1.83)	(-5.64, 1.72)	0.2892	-0.21 (0.28)	(-0.75, 0.34)	0.4508	
female	274	2.22 (0.47)	275	1.28 (0.47)	0.95 (0.59)	(-0.22, 2.11)	0.1102	0.12 (0.09)	(-0.05, 0.29)	0.1549	
Race											0.3507
White	176	2.26 (0.65)	188	1.59 (0.62)	0.67 (0.80)	(-0.91, 2.25)	0.4071	0.08 (0.10)	(-0.13, 0.28)	0.4572	
Black	45	4.68 (1.31)	39	1.97 (1.26)	2.70 (1.56)	(-0.40, 5.81)	0.0870	0.32 (0.22)	(-0.11, 0.75)	0.1462	
Other	71	0.60 (0.98)	72	0.62 (1.07)	-0.03 (1.08)	(-2.17, 2.11)	0.9794	-0.00 (0.17)	(-0.33, 0.32)	0.9846	
Ethnicity											0.1303
Hispanic/Latino	77	2.61 (0.90)	82	3.48 (0.94)	-0.87 (1.15)	(-3.15, 1.41)	0.4510	-0.11 (0.16)	(-0.42, 0.21)	0.5068	
Non-hispanic/Latino	215	1.92 (0.55)	217	0.77 (0.52)	1.14 (0.67)	(-0.17, 2.45)	0.0873	0.14 (0.10)	(-0.04, 0.33)	0.1339	
Geographic region											0.7369
EU	104	2.04 (0.87)	100	1.39 (0.87)	0.65 (0.96)	(-1.23, 2.54)	0.4954	0.07 (0.14)	(-0.20, 0.35)	0.5972	
non-EU	196	2.11 (0.56)	201	1.06 (0.55)	1.05 (0.71)	(-0.34, 2.45)	0.1380	0.14 (0.10)	(-0.06, 0.33)	0.1781	
Onset of disease											0.6226
Paediatric	23	2.37 (2.08)	19	2.66 (1.99)	-0.29 (2.36)	(-5.13, 4.56)	0.9040	-0.03 (0.31)	(-0.64, 0.58)	0.9229	
Adult	277	2.30 (0.48)	282	1.38 (0.47)	0.91 (0.59)	(-0.26, 2.08)	0.1255	0.11 (0.08)	(-0.05, 0.28)	0.1755	
ADA result											0.4746
Negative	279	2.23 (0.47)	276	1.39 (0.46)	0.84 (0.59)	(-0.32, 2.00)	0.1542	0.11 (0.08)	(-0.06, 0.27)	0.2041	
Positive (At any time)	21	1.71 (3.20)	25	2.90 (3.11)	-1.19 (2.78)	(-7.07, 4.69)	0.6736	-0.08 (0.30)	(-0.66, 0.50)	0.7938	
BMI (kg/m2)											0.6182
< 30	203	2.11 (0.56)	218	1.54 (0.56)	0.56 (0.67)	(-0.75, 1.88)	0.3980	0.07 (0.10)	(-0.12, 0.26)	0.4774	
>= 30	97	2.18 (0.88)	83	0.95 (0.87)	1.23 (1.15)	(-1.05, 3.51)	0.2886	0.15 (0.15)	(-0.15, 0.44)	0.3259	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Physical Functioning Score
Full analysis set

	Anifrolumab 300mg (N=315)		Placebo (N=321)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 4		0.30 (0.77)		-0.10 (0.75)	0.40 (1.01)	(-1.60, 2.40)	0.6916				
Week 8		2.56 (0.49)		2.03 (0.49)	0.53 (0.61)	(-0.67, 1.73)	0.3879				
Week 12		1.62 (0.95)		2.08 (0.93)	-0.47 (1.30)	(-3.03, 2.10)	0.7206				
Week 16		3.08 (0.52)		2.44 (0.53)	0.64 (0.67)	(-0.68, 1.96)	0.3407				
Week 24		3.12 (0.53)		3.22 (0.52)	-0.09 (0.68)	(-1.43, 1.25)	0.8897				
Week 32		3.45 (0.52)		3.14 (0.53)	0.31 (0.67)	(-1.01, 1.63)	0.6431				
Week 36		2.92 (0.89)		3.88 (0.93)	-0.96 (1.25)	(-3.43, 1.51)	0.4438				
Week 40		3.33 (0.53)		3.59 (0.54)	-0.26 (0.68)	(-1.60, 1.08)	0.7046				
Week 48		3.36 (0.56)		2.98 (0.57)	0.38 (0.73)	(-1.06, 1.82)	0.6022				
Week 52		3.76 (0.50)		3.72 (0.52)	0.04 (0.66)	(-1.25, 1.34)	0.9486				
OVERALL	300	2.75 (0.44)	301	2.70 (0.44)	0.05 (0.55)	(-1.03, 1.13)	0.9234	0.01 (0.08)	(-0.15, 0.17)	0.9323	0.5897

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Physical Functioning Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=315) N	LSMean (SE)	Placebo (N=321) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.1573
< 10 points	103	2.85 (0.65)	98	1.96 (0.65)	0.89 (0.86)	(-0.80, 2.59)	0.3006	0.14 (0.14)	(-0.14, 0.41)	0.3348	
>= 10 points	197	2.57 (0.60)	203	3.27 (0.59)	-0.69 (0.72)	(-2.10, 0.72)	0.3359	-0.08 (0.10)	(-0.28, 0.11)	0.4101	
OCS dose											0.6252
<10 mg/day	144	2.83 (0.53)	136	2.44 (0.56)	0.39 (0.72)	(-1.02, 1.80)	0.5842	0.06 (0.12)	(-0.17, 0.30)	0.6117	
>=10 mg/day	156	2.49 (0.73)	165	2.63 (0.69)	-0.14 (0.82)	(-1.74, 1.47)	0.8657	-0.02 (0.11)	(-0.23, 0.20)	0.8903	
Result of type I IFN gene signature test											0.6580
LOW	57	2.82 (0.90)	64	3.27 (0.83)	-0.45 (1.21)	(-2.85, 1.95)	0.7113	-0.07 (0.18)	(-0.42, 0.29)	0.7153	
HIGH	243	3.10 (0.45)	237	2.95 (0.46)	0.15 (0.62)	(-1.06, 1.37)	0.8053	0.02 (0.09)	(-0.16, 0.20)	0.8137	
Age (years)											NE
<= 65	293	2.74 (0.45)	300	2.62 (0.44)	0.12 (0.55)	(-0.96, 1.20)	0.8250	0.02 (0.08)	(-0.14, 0.18)	0.8456	
> 65	7	NE	1	NE	NE	NE		NE	NE		
Sex											0.9210
male	26	4.03 (1.92)	26	3.73 (1.85)	0.30 (2.03)	(-3.80, 4.40)	0.8845	0.03 (0.28)	(-0.51, 0.57)	0.9126	
female	274	2.71 (0.46)	275	2.62 (0.45)	0.09 (0.57)	(-1.04, 1.21)	0.8789	0.01 (0.09)	(-0.16, 0.18)	0.8920	
Race											0.1042
White	176	2.52 (0.60)	188	3.10 (0.57)	-0.57 (0.74)	(-2.02, 0.88)	0.4369	-0.07 (0.10)	(-0.28, 0.13)	0.4891	
Black	45	4.12 (1.33)	39	1.10 (1.31)	3.02 (1.61)	(-0.19, 6.22)	0.0647	0.35 (0.22)	(-0.08, 0.78)	0.1150	
Other	71	1.01 (0.92)	72	1.76 (1.01)	-0.75 (1.04)	(-2.81, 1.32)	0.4742	-0.09 (0.17)	(-0.42, 0.24)	0.5858	
Ethnicity											0.0532
Hispanic/Latino	77	2.03 (0.82)	82	4.08 (0.85)	-2.05 (1.08)	(-4.18, 0.07)	0.0584	-0.27 (0.16)	(-0.59, 0.04)	0.0861	
Non-hispanic/Latino	215	2.55 (0.54)	217	2.18 (0.51)	0.38 (0.65)	(-0.90, 1.65)	0.5616	0.05 (0.10)	(-0.14, 0.24)	0.6136	
Geographic region											0.2035
EU	104	2.95 (0.90)	100	3.97 (0.90)	-1.02 (1.00)	(-2.99, 0.95)	0.3090	-0.11 (0.14)	(-0.39, 0.16)	0.4245	
non-EU	196	2.54 (0.50)	201	2.04 (0.50)	0.49 (0.65)	(-0.78, 1.77)	0.4454	0.07 (0.10)	(-0.13, 0.27)	0.4863	
Onset of disease											0.4720
Paediatric	23	0.92 (2.17)	19	2.61 (2.13)	-1.68 (2.49)	(-6.76, 3.40)	0.5043	-0.17 (0.31)	(-0.78, 0.44)	0.5920	
Adult	277	2.80 (0.46)	282	2.65 (0.45)	0.16 (0.57)	(-0.96, 1.27)	0.7851	0.02 (0.08)	(-0.15, 0.19)	0.8092	
ADA result											0.1006
Negative	279	2.60 (0.45)	276	2.76 (0.45)	-0.15 (0.57)	(-1.27, 0.97)	0.7896	-0.02 (0.08)	(-0.19, 0.15)	0.8117	
Positive (At any time)	21	6.77 (3.02)	25	3.32 (2.90)	3.46 (2.12)	(-0.88, 7.79)	0.1137	0.24 (0.30)	(-0.34, 0.82)	0.4208	
BMI (kg/m2)											0.1194
< 30	203	2.59 (0.52)	218	2.94 (0.52)	-0.35 (0.62)	(-1.58, 0.87)	0.5708	-0.05 (0.10)	(-0.24, 0.14)	0.6314	
>= 30	97	3.26 (0.82)	83	1.67 (0.81)	1.59 (1.08)	(-0.54, 3.72)	0.1433	0.20 (0.15)	(-0.09, 0.50)	0.1743	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Role Emotional Score
Full analysis set

	Anifrolumab 300mg (N=315)		Placebo (N=321)		Difference of						
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		0.12 (1.08)		-0.72 (1.06)	0.83 (1.45)	(-2.03, 3.70)	0.5658				
Week 8		2.15 (0.68)		0.72 (0.68)	1.43 (0.87)	(-0.27, 3.13)	0.0990				
Week 12		0.89 (1.22)		1.31 (1.19)	-0.42 (1.66)	(-3.69, 2.85)	0.7986				
Week 16		1.74 (0.71)		2.05 (0.71)	-0.31 (0.92)	(-2.11, 1.49)	0.7358				
Week 24		2.10 (0.66)		0.92 (0.66)	1.18 (0.86)	(-0.51, 2.87)	0.1722				
Week 32		2.89 (0.69)		2.11 (0.70)	0.78 (0.90)	(-0.99, 2.54)	0.3869				
Week 36		2.59 (1.30)		1.73 (1.37)	0.86 (1.85)	(-2.80, 4.53)	0.6428				
Week 40		2.72 (0.71)		2.48 (0.73)	0.24 (0.93)	(-1.60, 2.07)	0.7995				
Week 48		3.10 (0.69)		2.32 (0.71)	0.78 (0.90)	(-1.00, 2.55)	0.3910				
Week 52		3.16 (0.67)		2.79 (0.69)	0.37 (0.88)	(-1.36, 2.11)	0.6710				
OVERALL	300	2.15 (0.54)	301	1.57 (0.54)	0.57 (0.68)	(-0.75, 1.90)	0.3966	0.06 (0.08)	(-0.10, 0.22)	0.4546	0.4580

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Role Emotional Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=315) N	LSMean (SE)	Placebo (N=321) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.0759
< 10 points	103	2.96 (0.87)	98	0.81 (0.87)	2.16 (1.15)	(-0.11, 4.42)	0.0620	0.25 (0.14)	(-0.03, 0.52)	0.0816	
>= 10 points	197	1.44 (0.70)	203	1.80 (0.69)	-0.36 (0.83)	(-1.99, 1.27)	0.6650	-0.04 (0.10)	(-0.23, 0.16)	0.7129	
OCS dose											0.9012
<10 mg/day	144	2.35 (0.73)	136	1.62 (0.77)	0.73 (0.99)	(-1.22, 2.69)	0.4590	0.08 (0.12)	(-0.15, 0.32)	0.4897	
>=10 mg/day	156	1.60 (0.84)	165	1.04 (0.79)	0.57 (0.93)	(-1.27, 2.40)	0.5437	0.05 (0.11)	(-0.16, 0.27)	0.6251	
Result of type I IFN gene signature test											0.9369
LOW	57	2.59 (1.15)	64	1.96 (1.06)	0.63 (1.55)	(-2.44, 3.69)	0.6852	0.07 (0.18)	(-0.28, 0.43)	0.6894	
HIGH	243	1.91 (0.56)	237	1.42 (0.57)	0.49 (0.76)	(-1.00, 1.98)	0.5174	0.06 (0.09)	(-0.12, 0.24)	0.5363	
Age (years)											NE
<= 65	293	2.09 (0.55)	300	1.53 (0.54)	0.56 (0.68)	(-0.78, 1.90)	0.4144	0.06 (0.08)	(-0.10, 0.22)	0.4740	
> 65	7	NE	1	NE	NE	NE		NE	NE		
Sex											0.8553
male	26	5.09 (1.87)	26	4.23 (1.73)	0.86 (1.93)	(-3.06, 4.78)	0.6589	0.09 (0.28)	(-0.45, 0.64)	0.7399	
female	274	1.97 (0.57)	275	1.49 (0.57)	0.48 (0.72)	(-0.92, 1.89)	0.4996	0.05 (0.09)	(-0.12, 0.22)	0.5481	
Race											0.0593
White	176	2.56 (0.71)	188	1.36 (0.67)	1.20 (0.88)	(-0.53, 2.93)	0.1724	0.13 (0.10)	(-0.08, 0.33)	0.2187	
Black	45	4.15 (1.99)	39	0.56 (1.93)	3.60 (2.36)	(-1.10, 8.29)	0.1310	0.28 (0.22)	(-0.15, 0.71)	0.2045	
Other	71	0.12 (1.10)	72	1.87 (1.23)	-1.75 (1.24)	(-4.20, 0.71)	0.1610	-0.18 (0.17)	(-0.50, 0.15)	0.2946	
Ethnicity											0.1616
Hispanic/Latino	77	3.05 (0.97)	82	4.20 (1.01)	-1.15 (1.24)	(-3.61, 1.31)	0.3577	-0.13 (0.16)	(-0.44, 0.18)	0.4162	
Non-hispanic/Latino	215	1.38 (0.68)	217	0.44 (0.65)	0.94 (0.82)	(-0.68, 2.56)	0.2542	0.10 (0.10)	(-0.09, 0.28)	0.3176	
Geographic region											0.7297
EU	104	2.51 (0.90)	100	1.43 (0.90)	1.08 (1.00)	(-0.90, 3.06)	0.2840	0.12 (0.14)	(-0.16, 0.39)	0.4009	
non-EU	196	1.72 (0.69)	201	1.11 (0.68)	0.62 (0.88)	(-1.12, 2.35)	0.4868	0.06 (0.10)	(-0.13, 0.26)	0.5279	
Onset of disease											0.8735
Paediatric	23	2.59 (2.10)	19	2.33 (2.06)	0.25 (2.50)	(-4.86, 5.37)	0.9199	0.03 (0.31)	(-0.58, 0.63)	0.9332	
Adult	277	2.13 (0.57)	282	1.46 (0.56)	0.67 (0.71)	(-0.72, 2.06)	0.3459	0.07 (0.08)	(-0.10, 0.24)	0.4049	
ADA result											0.8543
Negative	279	1.98 (0.57)	276	1.40 (0.56)	0.58 (0.71)	(-0.82, 1.97)	0.4156	0.06 (0.08)	(-0.10, 0.23)	0.4679	
Positive (At any time)	21	3.32 (3.37)	25	3.23 (3.28)	0.09 (2.56)	(-5.17, 5.36)	0.9718	0.01 (0.30)	(-0.57, 0.59)	0.9849	
BMI (kg/m2)											0.0968
< 30	203	1.81 (0.62)	218	1.96 (0.62)	-0.15 (0.74)	(-1.61, 1.31)	0.8408	-0.02 (0.10)	(-0.21, 0.17)	0.8654	
>= 30	97	2.22 (1.13)	83	-0.38 (1.12)	2.60 (1.48)	(-0.32, 5.51)	0.0806	0.24 (0.15)	(-0.05, 0.53)	0.1086	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Role Physical Score
Full analysis set

	Anifrolumab 300mg (N=315)		Placebo (N=321)		Difference of							
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		1.09 (0.73)		0.19 (0.71)	0.90 (0.92)	(-0.92, 2.72)	0.3306				
Week 8		2.58 (0.48)		2.05 (0.48)	0.54 (0.59)	(-0.63, 1.71)	0.3671				
Week 12		2.61 (0.86)		2.91 (0.84)	-0.30 (1.18)	(-2.63, 2.02)	0.7971				
Week 16		3.67 (0.52)		2.66 (0.53)	1.01 (0.68)	(-0.32, 2.34)	0.1360				
Week 24		4.03 (0.48)		2.65 (0.48)	1.38 (0.62)	(0.16, 2.60)	0.0264				
Week 32		3.84 (0.52)		3.37 (0.53)	0.46 (0.67)	(-0.86, 1.79)	0.4936				
Week 36		4.44 (0.94)		4.58 (0.99)	-0.15 (1.34)	(-2.80, 2.51)	0.9118				
Week 40		3.94 (0.56)		3.58 (0.57)	0.36 (0.74)	(-1.09, 1.81)	0.6246				
Week 48		4.27 (0.56)		3.09 (0.57)	1.18 (0.74)	(-0.28, 2.65)	0.1124				
Week 52		4.07 (0.51)		3.53 (0.53)	0.54 (0.68)	(-0.79, 1.87)	0.4284				
OVERALL	300	3.45 (0.41)	301	2.86 (0.40)	0.59 (0.51)	(-0.40, 1.59)	0.2425	0.08 (0.08)	(-0.08, 0.24)	0.3018	0.8972

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Role Physical Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=315) N	LSMean (SE)	Placebo (N=321) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											NE
< 10 points	103	NE	98	NE	NE	NE		NE	NE		
>= 10 points	197	2.59 (0.52)	203	2.57 (0.52)	0.03 (0.63)	(-1.22, 1.27)	0.9680	0.00 (0.10)	(-0.19, 0.20)	0.9726	
OCS dose											NE
<10 mg/day	144	NE	136	NE	NE	NE		NE	NE		
>=10 mg/day	156	3.53 (0.63)	165	3.01 (0.59)	0.52 (0.70)	(-0.85, 1.90)	0.4540	0.07 (0.11)	(-0.15, 0.29)	0.5441	
Result of type I IFN gene signature test											NE
LOW	57	NE	64	NE	NE	NE		NE	NE		
HIGH	243	3.74 (0.42)	237	3.03 (0.43)	0.71 (0.58)	(-0.43, 1.86)	0.2209	0.11 (0.09)	(-0.07, 0.29)	0.2398	
Age (years)											NE
<= 65	293	3.48 (0.41)	300	2.84 (0.41)	0.64 (0.51)	(-0.36, 1.64)	0.2076	0.09 (0.08)	(-0.07, 0.25)	0.2676	
> 65	7	NE	1	NE	NE	NE		NE	NE		
Sex											NE
male	26	NE	26	NE	NE	NE		NE	NE		
female	274	3.42 (0.42)	275	2.82 (0.42)	0.60 (0.53)	(-0.45, 1.64)	0.2639	0.09 (0.09)	(-0.08, 0.25)	0.3190	
Race											NE
White	176	NE	188	NE	NE	NE		NE	NE		
Black	45	NE	39	NE	NE	NE		NE	NE		
Other	71	NE	72	NE	NE	NE		NE	NE		
Ethnicity											NE
Hispanic/Latino	77	NE	82	NE	NE	NE		NE	NE		
Non-hispanic/Latino	215	3.57 (0.49)	217	2.55 (0.47)	1.02 (0.60)	(-0.16, 2.20)	0.0886	0.14 (0.10)	(-0.04, 0.33)	0.1342	
Geographic region											NE
EU	104	NE	100	NE	NE	NE		NE	NE		
non-EU	196	NE	201	NE	NE	NE		NE	NE		
Onset of disease											NE
Paediatric	23	3.97 (1.61)	19	4.08 (1.62)	-0.11 (1.84)	(-3.86, 3.64)	0.9543	-0.01 (0.31)	(-0.62, 0.59)	0.9640	
Adult	277	NE	282	NE	NE	NE		NE	NE		
ADA result											NE
Negative	279	3.31 (0.42)	276	2.77 (0.42)	0.53 (0.53)	(-0.51, 1.58)	0.3163	0.08 (0.08)	(-0.09, 0.24)	0.3708	
Positive (At any time)	21	NE	25	NE	NE	NE		NE	NE		
BMI (kg/m2)											NE
< 30	203	NE	218	NE	NE	NE		NE	NE		
>= 30	97	NE	83	NE	NE	NE		NE	NE		

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Social Functioning Score
Full analysis set

Visit	Anifrolumab 300mg (N=315) N	Anifrolumab 300mg (N=315) LSMean (SE)	Placebo (N=321) N	Placebo (N=321) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		1.64 (0.82)		0.27 (0.80)	1.37 (1.05)	(-0.69, 3.44)	0.1906				
Week 8		2.30 (0.63)		1.46 (0.63)	0.84 (0.81)	(-0.76, 2.45)	0.3009				
Week 12		2.83 (0.96)		1.49 (0.94)	1.34 (1.29)	(-1.20, 3.88)	0.2986				
Week 16		2.97 (0.63)		1.86 (0.63)	1.11 (0.80)	(-0.47, 2.69)	0.1696				
Week 24		3.34 (0.59)		1.58 (0.59)	1.76 (0.76)	(0.26, 3.26)	0.0218				
Week 32		3.85 (0.64)		2.54 (0.65)	1.31 (0.83)	(-0.33, 2.95)	0.1160				
Week 36		4.92 (0.98)		1.81 (1.03)	3.11 (1.38)	(0.38, 5.84)	0.0259				
Week 40		3.91 (0.65)		2.21 (0.66)	1.69 (0.84)	(0.03, 3.35)	0.0455				
Week 48		3.69 (0.64)		1.94 (0.66)	1.75 (0.85)	(0.09, 3.41)	0.0393				
Week 52		3.60 (0.60)		2.71 (0.61)	0.89 (0.79)	(-0.66, 2.44)	0.2622				
OVERALL	300	3.30 (0.47)	301	1.79 (0.47)	1.52 (0.58)	(0.37, 2.67)	0.0096	0.19 (0.08)	(0.03, 0.35)	0.0231	0.7213

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Social Functioning Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=315) N	LSMean (SE)	Placebo (N=321) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.1549
< 10 points	103	3.98 (0.75)	98	1.41 (0.75)	2.57 (0.98)	(0.64, 4.50)	0.0093	0.34 (0.14)	(0.06, 0.62)	0.0162	
>= 10 points	197	2.80 (0.62)	203	1.97 (0.61)	0.83 (0.74)	(-0.62, 2.27)	0.2610	0.10 (0.10)	(-0.10, 0.29)	0.3415	
OCS dose											0.4175
<10 mg/day	144	2.72 (0.61)	136	1.69 (0.63)	1.03 (0.82)	(-0.58, 2.64)	0.2102	0.14 (0.12)	(-0.09, 0.37)	0.2425	
>=10 mg/day	156	3.73 (0.77)	165	1.75 (0.72)	1.98 (0.84)	(0.33, 3.63)	0.0186	0.21 (0.11)	(-0.01, 0.43)	0.0609	
Result of type I IFN gene signature test											0.6559
LOW	57	3.82 (0.92)	64	1.83 (0.85)	1.99 (1.23)	(-0.45, 4.43)	0.1091	0.29 (0.18)	(-0.07, 0.65)	0.1151	
HIGH	243	3.47 (0.49)	237	2.11 (0.50)	1.37 (0.67)	(0.05, 2.68)	0.0417	0.18 (0.09)	(-0.00, 0.36)	0.0514	
Age (years)											NE
<= 65	293	3.21 (0.48)	300	1.75 (0.47)	1.46 (0.59)	(0.31, 2.61)	0.0131	0.18 (0.08)	(0.02, 0.34)	0.0304	
> 65	7	NE	1	NE	NE	NE		NE	NE		
Sex											0.3872
male	26	6.39 (1.67)	26	6.30 (1.59)	0.09 (1.71)	(-3.35, 3.53)	0.9585	0.01 (0.28)	(-0.53, 0.55)	0.9696	
female	274	3.19 (0.49)	275	1.53 (0.49)	1.66 (0.62)	(0.45, 2.87)	0.0072	0.20 (0.09)	(0.04, 0.37)	0.0174	
Race											0.3368
White	176	3.32 (0.65)	188	2.00 (0.62)	1.32 (0.81)	(-0.27, 2.91)	0.1039	0.15 (0.11)	(-0.05, 0.36)	0.1432	
Black	45	4.42 (1.51)	39	0.61 (1.40)	3.81 (1.73)	(0.36, 7.26)	0.0307	0.40 (0.22)	(-0.04, 0.83)	0.0728	
Other	71	2.16 (1.06)	72	1.37 (1.15)	0.79 (1.21)	(-1.59, 3.18)	0.5112	0.08 (0.17)	(-0.24, 0.41)	0.6142	
Ethnicity											0.0565
Hispanic/Latino	77	3.23 (0.89)	82	3.80 (0.93)	-0.57 (1.14)	(-2.83, 1.68)	0.6167	-0.07 (0.16)	(-0.38, 0.24)	0.6599	
Non-hispanic/Latino	215	2.86 (0.58)	217	0.88 (0.55)	1.98 (0.70)	(0.61, 3.35)	0.0047	0.24 (0.10)	(0.05, 0.43)	0.0136	
Geographic region											0.6535
EU	104	3.84 (0.92)	100	2.63 (0.92)	1.21 (1.02)	(-0.80, 3.22)	0.2353	0.13 (0.14)	(-0.14, 0.40)	0.3534	
non-EU	196	3.09 (0.57)	201	1.31 (0.56)	1.77 (0.72)	(0.35, 3.19)	0.0147	0.22 (0.10)	(0.02, 0.42)	0.0276	
Onset of disease											0.5526
Paediatric	23	2.58 (2.29)	19	2.56 (2.23)	0.02 (2.57)	(-5.19, 5.23)	0.9931	0.00 (0.31)	(-0.61, 0.61)	0.9946	
Adult	277	3.35 (0.49)	282	1.76 (0.48)	1.59 (0.61)	(0.40, 2.78)	0.0090	0.19 (0.08)	(0.03, 0.36)	0.0217	
ADA result											0.3647
Negative	279	3.14 (0.49)	276	1.73 (0.49)	1.41 (0.62)	(0.20, 2.62)	0.0225	0.17 (0.09)	(0.01, 0.34)	0.0428	
Positive (At any time)	21	7.23 (2.65)	25	3.99 (2.49)	3.24 (1.92)	(-0.72, 7.21)	0.1045	0.26 (0.30)	(-0.32, 0.84)	0.3834	
BMI (kg/m2)											0.9520
< 30	203	3.24 (0.56)	218	1.62 (0.56)	1.62 (0.66)	(0.31, 2.92)	0.0154	0.20 (0.10)	(0.01, 0.39)	0.0426	
>= 30	97	3.25 (0.91)	83	1.72 (0.90)	1.53 (1.20)	(-0.84, 3.90)	0.2039	0.18 (0.15)	(-0.12, 0.47)	0.2372	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Bodily Pain Score
Full analysis set

	Anifrolumab 300mg (N=315)		Placebo (N=321)		Difference of						
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		0.96 (0.82)		0.76 (0.80)	0.21 (1.05)	(-1.87, 2.28)	0.8453				
Week 8		3.03 (0.56)		2.41 (0.56)	0.62 (0.71)	(-0.77, 2.01)	0.3810				
Week 12		2.22 (0.95)		3.17 (0.93)	-0.95 (1.27)	(-3.46, 1.57)	0.4585				
Week 16		4.54 (0.59)		3.92 (0.59)	0.62 (0.76)	(-0.87, 2.11)	0.4143				
Week 24		4.38 (0.57)		3.16 (0.56)	1.22 (0.74)	(-0.23, 2.67)	0.0993				
Week 32		4.05 (0.62)		3.93 (0.63)	0.13 (0.81)	(-1.47, 1.73)	0.8748				
Week 36		5.54 (0.99)		4.29 (1.03)	1.25 (1.40)	(-1.52, 4.01)	0.3743				
Week 40		4.78 (0.60)		4.50 (0.61)	0.28 (0.78)	(-1.26, 1.82)	0.7209				
Week 48		4.70 (0.63)		4.13 (0.64)	0.57 (0.83)	(-1.06, 2.20)	0.4933				
Week 52		4.46 (0.57)		4.45 (0.59)	0.02 (0.76)	(-1.47, 1.51)	0.9820				
OVERALL	300	3.87 (0.44)	301	3.47 (0.44)	0.40 (0.55)	(-0.69, 1.48)	0.4733	0.05 (0.08)	(-0.11, 0.21)	0.5272	0.9675

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Bodily Pain Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=315) N	LSMean (SE)	Placebo (N=321) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.0941
< 10 points	103	4.54 (0.71)	98	2.91 (0.71)	1.64 (0.94)	(-0.21, 3.48)	0.0813	0.23 (0.14)	(-0.05, 0.51)	0.1052	
>= 10 points	197	3.37 (0.57)	203	3.67 (0.57)	-0.30 (0.69)	(-1.65, 1.05)	0.6584	-0.04 (0.10)	(-0.23, 0.16)	0.7071	
OCS dose											0.2786
<10 mg/day	144	3.92 (0.58)	136	2.89 (0.61)	1.03 (0.79)	(-0.52, 2.58)	0.1916	0.15 (0.12)	(-0.09, 0.38)	0.2225	
>=10 mg/day	156	3.67 (0.71)	165	3.85 (0.67)	-0.18 (0.79)	(-1.73, 1.37)	0.8226	-0.02 (0.11)	(-0.24, 0.20)	0.8563	
Result of type I IFN gene signature test											0.5555
LOW	57	3.40 (0.92)	64	3.71 (0.85)	-0.31 (1.24)	(-2.75, 2.14)	0.8036	-0.04 (0.18)	(-0.40, 0.31)	0.8062	
HIGH	243	4.44 (0.45)	237	3.93 (0.46)	0.51 (0.62)	(-0.71, 1.72)	0.4133	0.07 (0.09)	(-0.11, 0.25)	0.4330	
Age (years)											NE
<= 65	293	3.94 (0.45)	300	3.46 (0.44)	0.48 (0.56)	(-0.61, 1.57)	0.3875	0.06 (0.08)	(-0.10, 0.22)	0.4485	
> 65	7	NE	1	NE	NE	NE		NE	NE		
Sex											0.3063
male	26	4.97 (1.84)	26	6.45 (1.77)	-1.49 (1.92)	(-5.37, 2.40)	0.4446	-0.16 (0.28)	(-0.70, 0.39)	0.5664	
female	274	3.93 (0.46)	275	3.36 (0.46)	0.57 (0.58)	(-0.57, 1.71)	0.3274	0.07 (0.09)	(-0.09, 0.24)	0.3833	
Race											0.2699
White	176	3.66 (0.59)	188	3.75 (0.57)	-0.09 (0.74)	(-1.54, 1.36)	0.9051	-0.01 (0.10)	(-0.22, 0.19)	0.9146	
Black	45	5.63 (1.35)	39	2.91 (1.33)	2.72 (1.63)	(-0.52, 5.97)	0.0991	0.31 (0.22)	(-0.12, 0.74)	0.1587	
Other	71	2.50 (1.01)	72	2.63 (1.10)	-0.13 (1.13)	(-2.36, 2.10)	0.9090	-0.01 (0.17)	(-0.34, 0.31)	0.9313	
Ethnicity											0.7328
Hispanic/Latino	77	4.78 (0.81)	82	4.40 (0.85)	0.38 (1.04)	(-1.67, 2.44)	0.7127	0.05 (0.16)	(-0.26, 0.36)	0.7456	
Non-hispanic/Latino	215	3.14 (0.54)	217	3.18 (0.51)	-0.04 (0.65)	(-1.32, 1.25)	0.9568	-0.00 (0.10)	(-0.19, 0.18)	0.9621	
Geographic region											0.3084
EU	104	3.74 (0.91)	100	4.10 (0.92)	-0.36 (1.00)	(-2.33, 1.60)	0.7170	-0.04 (0.14)	(-0.31, 0.24)	0.7802	
non-EU	196	3.80 (0.52)	201	2.95 (0.51)	0.86 (0.66)	(-0.44, 2.15)	0.1951	0.12 (0.10)	(-0.08, 0.31)	0.2401	
Onset of disease											0.6887
Paediatric	23	4.72 (2.46)	19	5.37 (2.39)	-0.65 (2.75)	(-6.23, 4.93)	0.8144	-0.06 (0.31)	(-0.66, 0.55)	0.8542	
Adult	277	3.80 (0.45)	282	3.33 (0.45)	0.47 (0.56)	(-0.63, 1.58)	0.3997	0.06 (0.08)	(-0.10, 0.23)	0.4564	
ADA result											NE
Negative	279	3.64 (0.46)	276	3.45 (0.45)	0.18 (0.58)	(-0.95, 1.31)	0.7498	0.02 (0.08)	(-0.14, 0.19)	0.7761	
Positive (At any time)	21	NE	25	NE	NE	NE		NE	NE		
BMI (kg/m2)											0.2958
< 30	203	3.70 (0.54)	218	3.60 (0.54)	0.11 (0.64)	(-1.16, 1.37)	0.8693	0.01 (0.10)	(-0.18, 0.20)	0.8901	
>= 30	97	4.13 (0.83)	83	2.69 (0.82)	1.44 (1.10)	(-0.73, 3.61)	0.1924	0.18 (0.15)	(-0.11, 0.48)	0.2237	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Vitality Score
Full analysis set

	Anifrolumab 300mg (N=315)		Placebo (N=321)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 4		1.46 (0.70)		0.84 (0.68)	0.62 (0.87)	(-1.10, 2.35)	0.4764				
Week 8		2.07 (0.55)		1.00 (0.54)	1.08 (0.69)	(-0.28, 2.43)	0.1183				
Week 12		2.76 (0.83)		2.18 (0.81)	0.58 (1.10)	(-1.58, 2.75)	0.5971				
Week 16		2.29 (0.57)		1.91 (0.57)	0.38 (0.74)	(-1.07, 1.83)	0.6065				
Week 24		2.79 (0.53)		2.08 (0.52)	0.71 (0.67)	(-0.61, 2.03)	0.2913				
Week 32		2.83 (0.58)		2.23 (0.58)	0.61 (0.75)	(-0.87, 2.08)	0.4185				
Week 36		3.41 (0.86)		2.52 (0.90)	0.89 (1.21)	(-1.50, 3.28)	0.4635				
Week 40		2.68 (0.60)		3.07 (0.61)	-0.39 (0.79)	(-1.94, 1.17)	0.6255				
Week 48		3.57 (0.59)		2.41 (0.60)	1.16 (0.77)	(-0.35, 2.68)	0.1329				
Week 52		3.30 (0.56)		2.44 (0.57)	0.87 (0.74)	(-0.59, 2.32)	0.2442				
OVERALL	300	2.72 (0.43)	301	2.07 (0.42)	0.65 (0.52)	(-0.37, 1.67)	0.2114	0.09 (0.08)	(-0.07, 0.25)	0.2771	0.8349

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Vitality Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=315) N	LSMean (SE)	Placebo (N=321) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.2774
< 10 points	103	3.87 (0.68)	98	2.44 (0.68)	1.42 (0.89)	(-0.34, 3.19)	0.1127	0.21 (0.14)	(-0.07, 0.48)	0.1427	
>= 10 points	197	1.68 (0.56)	203	1.46 (0.54)	0.23 (0.65)	(-1.04, 1.50)	0.7250	0.03 (0.10)	(-0.17, 0.23)	0.7701	
OCS dose											0.6813
<10 mg/day	144	2.28 (0.58)	136	1.90 (0.60)	0.38 (0.77)	(-1.14, 1.90)	0.6227	0.05 (0.12)	(-0.18, 0.29)	0.6490	
>=10 mg/day	156	2.86 (0.66)	165	2.05 (0.62)	0.81 (0.71)	(-0.58, 2.21)	0.2531	0.10 (0.11)	(-0.12, 0.32)	0.3696	
Result of type I IFN gene signature test											0.1156
LOW	57	2.71 (0.88)	64	3.80 (0.84)	-1.09 (1.21)	(-3.49, 1.31)	0.3697	-0.16 (0.18)	(-0.52, 0.20)	0.3758	
HIGH	243	2.96 (0.43)	237	1.93 (0.43)	1.02 (0.58)	(-0.12, 2.17)	0.0801	0.15 (0.09)	(-0.03, 0.33)	0.0947	
Age (years)											NE
<= 65	293	2.75 (0.43)	300	2.06 (0.42)	0.69 (0.52)	(-0.34, 1.72)	0.1885	0.09 (0.08)	(-0.07, 0.25)	0.2548	
> 65	7	NE	1	NE	NE	NE		NE	NE		
Sex											0.4378
male	26	3.47 (1.46)	26	3.88 (1.32)	-0.41 (1.38)	(-3.20, 2.38)	0.7687	-0.06 (0.28)	(-0.60, 0.49)	0.8372	
female	274	2.63 (0.45)	275	1.89 (0.44)	0.75 (0.55)	(-0.34, 1.84)	0.1780	0.10 (0.09)	(-0.07, 0.27)	0.2371	
Race											0.0640
White	176	2.00 (0.54)	188	2.51 (0.51)	-0.51 (0.66)	(-1.81, 0.79)	0.4419	-0.07 (0.10)	(-0.28, 0.13)	0.4957	
Black	45	4.18 (1.25)	39	1.11 (1.18)	3.07 (1.43)	(0.24, 5.91)	0.0342	0.38 (0.22)	(-0.05, 0.82)	0.0827	
Other	71	1.97 (1.00)	72	1.14 (1.09)	0.83 (1.13)	(-1.41, 3.06)	0.4647	0.09 (0.17)	(-0.23, 0.42)	0.5775	
Ethnicity											0.6411
Hispanic/Latino	77	3.19 (0.79)	82	3.18 (0.83)	0.01 (1.01)	(-1.98, 2.00)	0.9943	0.00 (0.16)	(-0.31, 0.31)	0.9950	
Non-hispanic/Latino	215	2.10 (0.52)	217	1.54 (0.49)	0.56 (0.62)	(-0.65, 1.77)	0.3663	0.08 (0.10)	(-0.11, 0.26)	0.4358	
Geographic region											0.0100
EU	104	1.21 (0.83)	100	2.48 (0.82)	-1.27 (0.87)	(-2.98, 0.43)	0.1432	-0.15 (0.14)	(-0.43, 0.12)	0.2770	
non-EU	196	3.14 (0.50)	201	1.65 (0.49)	1.49 (0.63)	(0.24, 2.74)	0.0193	0.21 (0.10)	(0.01, 0.41)	0.0353	
Onset of disease											0.5123
Paediatric	23	2.69 (1.66)	19	3.21 (1.64)	-0.52 (1.89)	(-4.35, 3.32)	0.7864	-0.07 (0.31)	(-0.67, 0.54)	0.8298	
Adult	277	2.74 (0.45)	282	1.97 (0.44)	0.77 (0.55)	(-0.30, 1.85)	0.1581	0.10 (0.08)	(-0.06, 0.27)	0.2185	
ADA result											NE
Negative	279	2.62 (0.44)	276	2.17 (0.43)	0.44 (0.54)	(-0.62, 1.51)	0.4150	0.06 (0.08)	(-0.11, 0.23)	0.4729	
Positive (At any time)	21	NE	25	NE	NE	NE		NE	NE		
BMI (kg/m2)											0.3604
< 30	203	2.39 (0.53)	218	2.01 (0.52)	0.39 (0.61)	(-0.82, 1.59)	0.5297	0.05 (0.10)	(-0.14, 0.24)	0.6014	
>= 30	97	3.18 (0.77)	83	1.73 (0.75)	1.45 (0.99)	(-0.50, 3.41)	0.1445	0.20 (0.15)	(-0.09, 0.49)	0.1812	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - FACIT-F Total Score
Full analysis set

Visit	Anifrolumab 300mg (N=315) N	Anifrolumab 300mg (N=315) LSMean (SE)	Placebo (N=321) N	Placebo (N=321) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		1.89 (0.49)		1.71 (0.48)	0.17 (0.61)	(-1.03, 1.38)	0.7773				
Week 8		2.81 (0.56)		2.28 (0.55)	0.53 (0.71)	(-0.85, 1.92)	0.4514				
Week 12		3.53 (0.58)		1.73 (0.58)	1.80 (0.75)	(0.32, 3.28)	0.0173				
Week 16		3.78 (0.63)		2.34 (0.62)	1.44 (0.82)	(-0.17, 3.06)	0.0801				
Week 20		4.42 (0.64)		4.86 (0.63)	-0.45 (0.84)	(-2.10, 1.20)	0.5947				
Week 24		4.86 (0.61)		3.30 (0.60)	1.56 (0.80)	(-0.01, 3.13)	0.0508				
Week 28		5.02 (0.65)		3.87 (0.65)	1.15 (0.86)	(-0.54, 2.85)	0.1829				
Week 32		4.09 (0.69)		3.84 (0.70)	0.26 (0.93)	(-1.57, 2.08)	0.7821				
Week 36		4.78 (0.65)		3.57 (0.65)	1.21 (0.87)	(-0.49, 2.92)	0.1616				
Week 40		4.48 (0.68)		4.90 (0.69)	-0.42 (0.91)	(-2.22, 1.37)	0.6424				
Week 44		5.18 (0.71)		4.68 (0.71)	0.50 (0.95)	(-1.37, 2.37)	0.5992				
Week 48		5.08 (0.69)		4.16 (0.70)	0.92 (0.92)	(-0.89, 2.74)	0.3193				
Week 52		5.05 (0.66)		3.98 (0.67)	1.07 (0.89)	(-0.67, 2.81)	0.2269				
OVERALL	300	4.23 (0.50)	305	3.48 (0.50)	0.75 (0.63)	(-0.50, 2.00)	0.2375	0.09 (0.08)	(-0.07, 0.25)	0.2913	0.4867

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - FACIT-F Total Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=315) N	LSMean (SE)	Placebo (N=321) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.3935
< 10 points	102	5.12 (0.79)	99	3.64 (0.79)	1.49 (1.06)	(-0.60, 3.57)	0.1610	0.19 (0.14)	(-0.09, 0.46)	0.1882	
>= 10 points	198	3.55 (0.65)	206	3.19 (0.63)	0.36 (0.78)	(-1.18, 1.91)	0.6427	0.04 (0.10)	(-0.16, 0.24)	0.6882	
OCS dose											0.5326
<10 mg/day	142	4.31 (0.66)	135	3.08 (0.69)	1.22 (0.90)	(-0.54, 2.99)	0.1742	0.15 (0.12)	(-0.08, 0.39)	0.2034	
>=10 mg/day	158	3.81 (0.78)	170	3.37 (0.74)	0.44 (0.89)	(-1.31, 2.18)	0.6243	0.04 (0.11)	(-0.17, 0.26)	0.6852	
Result of type I IFN gene signature test											0.4314
LOW	56	4.69 (1.11)	64	5.02 (1.03)	-0.33 (1.50)	(-3.31, 2.65)	0.8265	-0.04 (0.18)	(-0.40, 0.32)	0.8285	
HIGH	244	4.54 (0.51)	241	3.57 (0.52)	0.97 (0.70)	(-0.40, 2.35)	0.1654	0.12 (0.09)	(-0.06, 0.30)	0.1851	
Age (years)											NE
<= 65	294	4.29 (0.51)	304	3.49 (0.50)	0.80 (0.64)	(-0.46, 2.06)	0.2145	0.09 (0.08)	(-0.07, 0.25)	0.2686	
> 65	6	NE	1	NE	NE	NE		NE	NE		
Sex											0.1929
male	26	4.58 (1.41)	26	5.88 (1.44)	-1.30 (1.56)	(-4.44, 1.85)	0.4096	-0.18 (0.28)	(-0.72, 0.37)	0.5260	
female	274	4.27 (0.53)	279	3.36 (0.53)	0.91 (0.68)	(-0.41, 2.24)	0.1765	0.10 (0.09)	(-0.06, 0.27)	0.2230	
Race											0.2433
White	175	4.05 (0.67)	193	3.46 (0.64)	0.59 (0.82)	(-1.02, 2.20)	0.4742	0.07 (0.10)	(-0.14, 0.27)	0.5265	
Black	47	8.10 (1.67)	38	4.27 (1.63)	3.83 (2.00)	(-0.16, 7.82)	0.0598	0.35 (0.22)	(-0.08, 0.78)	0.1109	
Other	72	2.24 (1.10)	72	2.32 (1.21)	-0.09 (1.29)	(-2.63, 2.46)	0.9448	-0.01 (0.17)	(-0.34, 0.32)	0.9567	
Ethnicity											0.7228
Hispanic/Latino	77	3.65 (1.00)	83	3.28 (1.04)	0.37 (1.29)	(-2.18, 2.91)	0.7772	0.04 (0.16)	(-0.27, 0.35)	0.8014	
Non-hispanic/Latino	217	4.23 (0.59)	220	3.34 (0.57)	0.89 (0.73)	(-0.55, 2.33)	0.2251	0.10 (0.10)	(-0.08, 0.29)	0.2820	
Geographic region											0.1497
EU	103	4.03 (0.84)	104	4.43 (0.84)	-0.40 (0.96)	(-2.29, 1.50)	0.6802	-0.05 (0.14)	(-0.32, 0.23)	0.7393	
non-EU	197	4.32 (0.63)	201	2.91 (0.63)	1.42 (0.81)	(-0.18, 3.02)	0.0824	0.16 (0.10)	(-0.04, 0.36)	0.1117	
Onset of disease											NE
Paediatric	22	NE	19	NE	NE	NE		NE	NE		
Adult	278	4.33 (0.52)	286	3.37 (0.52)	0.97 (0.66)	(-0.32, 2.25)	0.1410	0.11 (0.08)	(-0.05, 0.28)	0.1883	
ADA result											0.2386
Negative	278	4.09 (0.52)	280	3.48 (0.51)	0.62 (0.66)	(-0.68, 1.91)	0.3513	0.07 (0.08)	(-0.09, 0.24)	0.4000	
Positive (At any time)	22	6.79 (3.67)	25	3.19 (3.52)	3.60 (2.44)	(-1.34, 8.54)	0.1488	0.20 (0.29)	(-0.37, 0.78)	0.4886	
BMI (kg/m2)											0.3227
< 30	205	3.91 (0.60)	222	3.49 (0.60)	0.42 (0.73)	(-1.02, 1.86)	0.5642	0.05 (0.10)	(-0.14, 0.24)	0.6195	
>= 30	95	4.49 (0.94)	83	2.65 (0.94)	1.84 (1.23)	(-0.59, 4.26)	0.1364	0.21 (0.15)	(-0.09, 0.50)	0.1709	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - EQ VAS Score
Full analysis set

	Anifrolumab 300mg (N=315)		Placebo (N=321)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 4		3.48 (2.08)		2.32 (2.01)	1.16 (2.71)	(-4.20, 6.52)	0.6688				
Week 12		7.20 (1.27)		4.76 (1.26)	2.44 (1.63)	(-0.75, 5.63)	0.1339				
Week 24		7.88 (1.37)		7.15 (1.35)	0.73 (1.77)	(-2.74, 4.20)	0.6802				
Week 36		10.20 (1.36)		9.17 (1.37)	1.03 (1.78)	(-2.46, 4.53)	0.5622				
Week 52		11.47 (1.37)		7.91 (1.39)	3.56 (1.80)	(0.03, 7.09)	0.0479				
OVERALL	294	8.05 (1.07)	299	6.26 (1.05)	1.78 (1.32)	(-0.80, 4.37)	0.1755	0.10 (0.08)	(-0.06, 0.26)	0.2343	0.8997

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - EQ VAS Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=315) N	LSMean (SE)	Placebo (N=321) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.8715
< 10 points	99	9.12 (1.64)	97	7.15 (1.61)	1.98 (2.13)	(-2.23, 6.19)	0.3550	0.12 (0.14)	(-0.16, 0.40)	0.3928	
>= 10 points	195	6.21 (1.40)	202	4.67 (1.36)	1.54 (1.66)	(-1.72, 4.80)	0.3530	0.08 (0.10)	(-0.12, 0.28)	0.4308	
OCS dose											0.5316
<10 mg/day	141	7.11 (1.48)	132	6.22 (1.54)	0.88 (2.00)	(-3.06, 4.83)	0.6594	0.05 (0.12)	(-0.19, 0.29)	0.6796	
>=10 mg/day	153	7.97 (1.63)	167	5.41 (1.52)	2.56 (1.77)	(-0.93, 6.04)	0.1497	0.13 (0.11)	(-0.09, 0.35)	0.2525	
Result of type I IFN gene signature test											0.1902
LOW	56	4.37 (2.06)	64	5.82 (1.90)	-1.45 (2.74)	(-6.90, 3.99)	0.5982	-0.09 (0.18)	(-0.45, 0.26)	0.6061	
HIGH	238	9.81 (1.10)	235	7.16 (1.11)	2.65 (1.50)	(-0.30, 5.60)	0.0785	0.16 (0.09)	(-0.03, 0.34)	0.0922	
Age (years)											NE
<= 65	288	8.35 (1.09)	298	6.32 (1.05)	2.03 (1.32)	(-0.57, 4.63)	0.1251	0.11 (0.08)	(-0.05, 0.27)	0.1799	
> 65	6	NE	1	NE	NE	NE		NE	NE		
Sex											0.9446
male	26	5.47 (5.94)	26	4.02 (5.42)	1.45 (4.73)	(-8.10, 10.99)	0.7606	0.05 (0.28)	(-0.49, 0.59)	0.8591	
female	268	8.41 (1.12)	273	6.61 (1.09)	1.79 (1.38)	(-0.92, 4.50)	0.1950	0.10 (0.09)	(-0.07, 0.27)	0.2511	
Race											0.0230
White	172	6.61 (1.38)	189	8.01 (1.31)	-1.40 (1.72)	(-4.80, 1.99)	0.4174	-0.08 (0.11)	(-0.28, 0.13)	0.4617	
Black	46	11.04 (2.75)	38	3.09 (2.61)	7.95 (3.28)	(1.42, 14.48)	0.0177	0.45 (0.22)	(0.01, 0.88)	0.0433	
Other	70	8.55 (2.66)	70	4.33 (2.90)	4.22 (2.94)	(-1.60, 10.04)	0.1536	0.18 (0.17)	(-0.15, 0.51)	0.2870	
Ethnicity											0.6618
Hispanic/Latino	74	7.93 (2.04)	83	5.82 (2.09)	2.11 (2.53)	(-2.90, 7.11)	0.4064	0.11 (0.16)	(-0.20, 0.43)	0.4751	
Non-hispanic/Latino	214	6.86 (1.30)	214	6.05 (1.22)	0.81 (1.57)	(-2.27, 3.88)	0.6069	0.04 (0.10)	(-0.15, 0.23)	0.6513	
Geographic region											0.0080
EU	102	8.30 (2.04)	101	11.09 (2.05)	-2.80 (2.22)	(-7.19, 1.59)	0.2104	-0.14 (0.14)	(-0.41, 0.14)	0.3360	
non-EU	192	7.20 (1.26)	198	2.76 (1.22)	4.45 (1.58)	(1.33, 7.56)	0.0053	0.26 (0.10)	(0.06, 0.46)	0.0116	
Onset of disease											0.6329
Paediatric	21	12.46 (4.12)	19	8.54 (4.01)	3.92 (4.84)	(-5.97, 13.80)	0.4249	0.21 (0.32)	(-0.41, 0.83)	0.5072	
Adult	273	7.73 (1.12)	280	6.22 (1.10)	1.51 (1.38)	(-1.20, 4.23)	0.2748	0.08 (0.09)	(-0.08, 0.25)	0.3363	
ADA result											NE
Negative	272	7.50 (1.10)	274	6.32 (1.08)	1.17 (1.37)	(-1.52, 3.87)	0.3929	0.07 (0.09)	(-0.10, 0.23)	0.4476	
Positive (At any time)	22	NE	25	NE	NE	NE		NE	NE		
BMI (kg/m2)											0.7146
< 30	201	8.84 (1.35)	218	6.39 (1.33)	2.45 (1.58)	(-0.66, 5.56)	0.1217	0.13 (0.10)	(-0.07, 0.32)	0.1967	
>= 30	93	6.36 (1.84)	81	4.96 (1.74)	1.40 (2.42)	(-3.40, 6.19)	0.5653	0.08 (0.15)	(-0.22, 0.38)	0.5859	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Lupus QoL Physical Health domain score
Full analysis set

	Anifrolumab 300mg (N=315)		Placebo (N=321)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 4		4.94 (1.67)		4.34 (1.62)	0.59 (2.05)	(-3.45, 4.64)	0.7732				
Week 12		8.12 (1.21)		6.45 (1.21)	1.67 (1.55)	(-1.37, 4.71)	0.2802				
Week 24		8.86 (1.23)		7.13 (1.22)	1.72 (1.57)	(-1.36, 4.81)	0.2732				
Week 36		8.64 (1.30)		9.61 (1.30)	-0.97 (1.68)	(-4.27, 2.33)	0.5643				
Week 52		7.45 (1.32)		7.83 (1.34)	-0.38 (1.73)	(-3.78, 3.02)	0.8254				
OVERALL	293	7.60 (1.04)	298	7.07 (1.03)	0.53 (1.29)	(-2.00, 3.05)	0.6822	0.03 (0.08)	(-0.13, 0.19)	0.7192	0.8554

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Lupus QoL Physical Health domain score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=315) N	LSMean (SE)	Placebo (N=321) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.4608
< 10 points	100	7.69 (1.56)	96	8.52 (1.56)	-0.83 (2.06)	(-4.88, 3.23)	0.6883	-0.05 (0.14)	(-0.33, 0.23)	0.7095	
>= 10 points	193	7.46 (1.39)	202	6.34 (1.36)	1.12 (1.64)	(-2.12, 4.35)	0.4981	0.06 (0.10)	(-0.14, 0.25)	0.5668	
OCS dose											0.7171
<10 mg/day	141	6.84 (1.32)	131	6.50 (1.37)	0.34 (1.78)	(-3.17, 3.85)	0.8492	0.02 (0.12)	(-0.22, 0.26)	0.8589	
>=10 mg/day	152	8.40 (1.68)	167	7.13 (1.59)	1.27 (1.86)	(-2.39, 4.93)	0.4944	0.06 (0.11)	(-0.16, 0.28)	0.5838	
Result of type I IFN gene signature test											0.4627
LOW	56	6.95 (2.14)	63	8.52 (2.00)	-1.57 (2.91)	(-7.33, 4.19)	0.5894	-0.10 (0.18)	(-0.46, 0.26)	0.5931	
HIGH	237	8.39 (1.06)	235	7.58 (1.07)	0.81 (1.45)	(-2.03, 3.66)	0.5756	0.05 (0.09)	(-0.13, 0.23)	0.5910	
Age (years)											NE
<= 65	287	7.96 (1.06)	297	7.22 (1.03)	0.74 (1.29)	(-1.81, 3.28)	0.5690	0.04 (0.08)	(-0.12, 0.20)	0.6183	
> 65	6	NE	1	NE	NE	NE		NE	NE		
Sex											0.3574
male	26	11.06 (5.99)	26	16.30 (5.87)	-5.24 (6.16)	(-18.10, 7.62)	0.4050	-0.17 (0.28)	(-0.72, 0.37)	0.5391	
female	267	7.44 (1.09)	272	6.87 (1.08)	0.56 (1.36)	(-2.11, 3.24)	0.6798	0.03 (0.09)	(-0.14, 0.20)	0.7144	
Race											0.7825
White	172	7.60 (1.29)	188	6.65 (1.24)	0.95 (1.60)	(-2.20, 4.10)	0.5521	0.06 (0.11)	(-0.15, 0.26)	0.5963	
Black	45	12.85 (3.82)	38	8.88 (3.59)	3.97 (4.57)	(-5.13, 13.07)	0.3878	0.16 (0.22)	(-0.27, 0.60)	0.4594	
Other	70	3.81 (2.38)	70	3.53 (2.62)	0.29 (2.72)	(-5.09, 5.66)	0.9162	0.01 (0.17)	(-0.32, 0.34)	0.9359	
Ethnicity											0.1564
Hispanic/Latino	74	5.49 (2.20)	83	8.03 (2.25)	-2.53 (2.79)	(-8.05, 2.98)	0.3653	-0.13 (0.16)	(-0.44, 0.19)	0.4259	
Non-hispanic/Latino	213	8.04 (1.22)	213	6.11 (1.15)	1.93 (1.46)	(-0.94, 4.81)	0.1873	0.11 (0.10)	(-0.08, 0.30)	0.2505	
Geographic region											0.9708
EU	102	9.27 (1.88)	101	8.98 (1.89)	0.29 (2.02)	(-3.70, 4.28)	0.8866	0.02 (0.14)	(-0.26, 0.29)	0.9141	
non-EU	191	6.47 (1.28)	197	6.08 (1.27)	0.38 (1.64)	(-2.84, 3.61)	0.8150	0.02 (0.10)	(-0.18, 0.22)	0.8319	
Onset of disease											0.0806
Paediatric	21	2.10 (3.47)	19	9.02 (3.58)	-6.92 (4.29)	(-15.73, 1.89)	0.1186	-0.43 (0.32)	(-1.06, 0.20)	0.1797	
Adult	272	7.81 (1.09)	279	6.87 (1.08)	0.95 (1.36)	(-1.72, 3.61)	0.4858	0.05 (0.09)	(-0.11, 0.22)	0.5395	
ADA result											NE
Negative	271	7.48 (1.08)	273	7.31 (1.07)	0.17 (1.35)	(-2.48, 2.82)	0.9000	0.01 (0.09)	(-0.16, 0.18)	0.9111	
Positive (At any time)	22	NE	25	NE	NE	NE		NE	NE		
BMI (kg/m2)											0.7602
< 30	200	8.71 (1.24)	217	7.62 (1.24)	1.10 (1.46)	(-1.78, 3.97)	0.4530	0.06 (0.10)	(-0.13, 0.25)	0.5319	
>= 30	93	6.04 (1.97)	81	5.86 (1.91)	0.19 (2.61)	(-4.97, 5.34)	0.9432	0.01 (0.15)	(-0.29, 0.31)	0.9464	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Lupus QoL Emotional Health domain score
Full analysis set

	Anifrolumab 300mg (N=315)		Placebo (N=321)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 4		-1.55 (1.86)		3.62 (1.80)	-5.16 (2.42)	(-9.94, -0.38)	0.0345				
Week 12		4.35 (1.13)		2.89 (1.12)	1.46 (1.44)	(-1.37, 4.30)	0.3120				
Week 24		5.72 (1.18)		5.46 (1.17)	0.26 (1.51)	(-2.72, 3.23)	0.8659				
Week 36		7.37 (1.22)		7.14 (1.23)	0.23 (1.59)	(-2.89, 3.36)	0.8842				
Week 52		7.78 (1.28)		7.25 (1.30)	0.53 (1.69)	(-2.79, 3.86)	0.7526				
OVERALL	293	4.74 (0.98)	298	5.27 (0.96)	-0.54 (1.20)	(-2.90, 1.83)	0.6565	-0.03 (0.08)	(-0.19, 0.13)	0.6960	0.7164

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Lupus QoL Emotional Health domain score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=315) N	LSMean (SE)	Placebo (N=321) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.9587
< 10 points	100	6.49 (1.45)	96	7.05 (1.44)	-0.56 (1.89)	(-4.29, 3.17)	0.7678	-0.04 (0.14)	(-0.32, 0.24)	0.7854	
>= 10 points	193	3.10 (1.32)	202	3.79 (1.28)	-0.69 (1.57)	(-3.77, 2.40)	0.6616	-0.04 (0.10)	(-0.23, 0.16)	0.7096	
OCS dose											0.9742
<10 mg/day	141	4.69 (1.24)	131	5.22 (1.30)	-0.53 (1.68)	(-3.85, 2.79)	0.7533	-0.04 (0.12)	(-0.27, 0.20)	0.7683	
>=10 mg/day	152	4.30 (1.58)	167	4.91 (1.48)	-0.61 (1.73)	(-4.01, 2.79)	0.7252	-0.03 (0.11)	(-0.25, 0.19)	0.7794	
Result of type I IFN gene signature test											0.4418
LOW	56	1.73 (1.99)	63	4.31 (1.83)	-2.59 (2.69)	(-7.93, 2.75)	0.3390	-0.17 (0.18)	(-0.54, 0.19)	0.3424	
HIGH	237	6.43 (0.99)	235	6.70 (1.01)	-0.27 (1.36)	(-2.93, 2.40)	0.8437	-0.02 (0.09)	(-0.20, 0.16)	0.8499	
Age (years)											NE
<= 65	287	4.73 (0.99)	297	5.31 (0.97)	-0.58 (1.21)	(-2.96, 1.81)	0.6337	-0.03 (0.08)	(-0.20, 0.13)	0.6768	
> 65	6	NE	1	NE	NE	NE		NE	NE		
Sex											NE
male	26	NE	26	NE	NE	NE		NE	NE		
female	267	4.81 (1.02)	272	5.26 (1.00)	-0.45 (1.26)	(-2.93, 2.04)	0.7248	-0.03 (0.09)	(-0.20, 0.14)	0.7551	
Race											0.5339
White	172	4.64 (1.24)	188	3.84 (1.20)	0.80 (1.55)	(-2.25, 3.84)	0.6064	0.05 (0.11)	(-0.16, 0.26)	0.6448	
Black	45	8.02 (3.31)	38	9.97 (3.09)	-1.96 (3.87)	(-9.67, 5.76)	0.6151	-0.09 (0.22)	(-0.53, 0.34)	0.6731	
Other	70	3.14 (2.38)	70	5.43 (2.60)	-2.29 (2.63)	(-7.49, 2.91)	0.3848	-0.11 (0.17)	(-0.44, 0.22)	0.5179	
Ethnicity											0.0840
Hispanic/Latino	74	5.34 (2.11)	83	9.74 (2.15)	-4.39 (2.64)	(-9.61, 0.82)	0.0982	-0.23 (0.16)	(-0.55, 0.08)	0.1495	
Non-hispanic/Latino	213	4.37 (1.14)	213	3.63 (1.08)	0.75 (1.37)	(-1.95, 3.44)	0.5865	0.05 (0.10)	(-0.14, 0.24)	0.6353	
Geographic region											0.9147
EU	102	4.90 (1.60)	101	5.22 (1.62)	-0.32 (1.73)	(-3.72, 3.09)	0.8547	-0.02 (0.14)	(-0.29, 0.26)	0.8898	
non-EU	191	3.80 (1.23)	197	4.36 (1.20)	-0.57 (1.56)	(-3.63, 2.50)	0.7172	-0.03 (0.10)	(-0.23, 0.17)	0.7428	
Onset of disease											0.9118
Paediatric	21	6.53 (4.80)	19	6.45 (4.41)	0.08 (5.15)	(-10.58, 10.73)	0.9885	0.00 (0.32)	(-0.62, 0.62)	0.9910	
Adult	272	4.69 (1.01)	279	5.21 (0.99)	-0.51 (1.25)	(-2.96, 1.94)	0.6817	-0.03 (0.09)	(-0.20, 0.14)	0.7181	
ADA result											NE
Negative	271	4.77 (1.00)	273	5.09 (0.99)	-0.33 (1.25)	(-2.78, 2.13)	0.7946	-0.02 (0.09)	(-0.19, 0.15)	0.8171	
Positive (At any time)	22	NE	25	NE	NE	NE		NE	NE		
BMI (kg/m2)											0.7343
< 30	200	4.35 (1.20)	217	4.96 (1.20)	-0.61 (1.42)	(-3.40, 2.17)	0.6669	-0.04 (0.10)	(-0.23, 0.16)	0.7198	
>= 30	93	4.99 (1.74)	81	4.68 (1.65)	0.30 (2.29)	(-4.23, 4.84)	0.8944	0.02 (0.15)	(-0.28, 0.32)	0.9001	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Lupus QoL Body Image domain score
Full analysis set

	Anifrolumab 300mg (N=315)		Placebo (N=321)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 4		-0.52 (2.25)		5.55 (2.29)	-6.07 (3.05)	(-12.11, -0.03)	0.0488				
Week 12		8.65 (1.33)		5.12 (1.34)	3.53 (1.71)	(0.18, 6.88)	0.0392				
Week 24		10.40 (1.48)		6.49 (1.49)	3.91 (1.92)	(0.13, 7.69)	0.0428				
Week 36		12.22 (1.50)		10.96 (1.54)	1.26 (1.98)	(-2.63, 5.14)	0.5248				
Week 52		11.04 (1.58)		9.51 (1.62)	1.52 (2.10)	(-2.60, 5.65)	0.4684				
OVERALL	275	8.36 (1.20)	273	7.53 (1.20)	0.83 (1.50)	(-2.12, 3.78)	0.5812	0.04 (0.09)	(-0.13, 0.21)	0.6262	0.7516

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Lupus QoL Body Image domain score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=315) N	LSMean (SE)	Placebo (N=321) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.3582
< 10 points	96	7.20 (1.63)	85	8.35 (1.69)	-1.15 (2.17)	(-5.44, 3.14)	0.5975	-0.07 (0.15)	(-0.36, 0.22)	0.6263	
>= 10 points	179	8.65 (1.67)	188	7.09 (1.61)	1.57 (2.00)	(-2.38, 5.51)	0.4350	0.07 (0.10)	(-0.13, 0.28)	0.5012	
OCS dose											0.0834
<10 mg/day	132	5.47 (1.43)	119	7.25 (1.54)	-1.78 (1.98)	(-5.68, 2.12)	0.3688	-0.11 (0.13)	(-0.35, 0.14)	0.3981	
>=10 mg/day	143	10.42 (1.99)	154	7.06 (1.89)	3.36 (2.21)	(-1.00, 7.72)	0.1304	0.14 (0.12)	(-0.09, 0.37)	0.2230	
Result of type I IFN gene signature test											0.3766
LOW	53	4.24 (2.11)	59	5.81 (2.01)	-1.57 (2.87)	(-7.28, 4.14)	0.5857	-0.10 (0.19)	(-0.47, 0.27)	0.5927	
HIGH	222	9.68 (1.25)	214	8.28 (1.31)	1.40 (1.75)	(-2.03, 4.84)	0.4228	0.07 (0.10)	(-0.11, 0.26)	0.4410	
Age (years)											NE
<= 65	270	8.54 (1.22)	272	7.63 (1.21)	0.91 (1.51)	(-2.07, 3.88)	0.5500	0.05 (0.09)	(-0.12, 0.21)	0.5992	
> 65	5	NE	1	NE	NE	NE		NE	NE		
Sex											NE
male	24	NE	23	NE	NE	NE		NE	NE		
female	251	8.27 (1.26)	250	7.51 (1.26)	0.76 (1.59)	(-2.36, 3.88)	0.6325	0.04 (0.09)	(-0.14, 0.21)	0.6708	
Race											0.2165
White	163	8.54 (1.41)	171	5.51 (1.42)	3.03 (1.81)	(-0.53, 6.59)	0.0950	0.17 (0.11)	(-0.05, 0.38)	0.1320	
Black	42	8.52 (4.18)	36	9.53 (4.03)	-1.01 (4.99)	(-10.96, 8.95)	0.8406	-0.04 (0.23)	(-0.48, 0.41)	0.8648	
Other	65	7.01 (2.96)	64	10.20 (3.14)	-3.19 (3.23)	(-9.58, 3.21)	0.3254	-0.13 (0.18)	(-0.48, 0.22)	0.4624	
Ethnicity											0.1334
Hispanic/Latino	70	7.48 (2.36)	76	10.81 (2.48)	-3.33 (2.99)	(-9.24, 2.58)	0.2669	-0.16 (0.17)	(-0.48, 0.17)	0.3360	
Non-hispanic/Latino	200	8.15 (1.45)	195	6.26 (1.41)	1.89 (1.78)	(-1.62, 5.40)	0.2894	0.09 (0.10)	(-0.10, 0.29)	0.3498	
Geographic region											0.1395
EU	96	10.55 (2.25)	89	6.74 (2.36)	3.81 (2.50)	(-1.14, 8.75)	0.1302	0.17 (0.15)	(-0.12, 0.46)	0.2455	
non-EU	179	6.63 (1.45)	184	7.43 (1.43)	-0.80 (1.86)	(-4.46, 2.86)	0.6673	-0.04 (0.10)	(-0.25, 0.16)	0.6956	
Onset of disease											0.4889
Paediatric	21	8.13 (5.87)	19	2.88 (6.08)	5.24 (6.62)	(-8.30, 18.78)	0.4350	0.19 (0.32)	(-0.43, 0.81)	0.5444	
Adult	254	8.37 (1.23)	254	7.83 (1.24)	0.54 (1.54)	(-2.50, 3.57)	0.7286	0.03 (0.09)	(-0.15, 0.20)	0.7585	
ADA result											NE
Negative	256	8.55 (1.24)	249	7.33 (1.24)	1.22 (1.57)	(-1.86, 4.29)	0.4380	0.06 (0.09)	(-0.11, 0.24)	0.4891	
Positive (At any time)	19	NE	24	NE	NE	NE		NE	NE		
BMI (kg/m2)											0.4503
< 30	186	9.31 (1.50)	198	7.68 (1.51)	1.63 (1.80)	(-1.91, 5.16)	0.3658	0.08 (0.10)	(-0.12, 0.28)	0.4457	
>= 30	89	5.82 (2.10)	75	6.70 (2.06)	-0.88 (2.79)	(-6.40, 4.64)	0.7532	-0.05 (0.16)	(-0.35, 0.26)	0.7680	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Lupus QoL Burden to Others domain score
Full analysis set

	Anifrolumab 300mg (N=315)		Placebo (N=321)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 4		2.55 (2.24)		3.19 (2.17)	-0.64 (2.92)	(-6.40, 5.12)	0.8266				
Week 12		8.32 (1.46)		3.50 (1.44)	4.83 (1.85)	(1.19, 8.46)	0.0093				
Week 24		8.22 (1.52)		5.80 (1.50)	2.42 (1.94)	(-1.39, 6.22)	0.2133				
Week 36		11.46 (1.54)		10.17 (1.55)	1.30 (1.99)	(-2.61, 5.20)	0.5144				
Week 52		8.38 (1.67)		7.12 (1.69)	1.26 (2.20)	(-3.05, 5.57)	0.5663				
OVERALL	293	7.79 (1.27)	298	5.95 (1.25)	1.83 (1.56)	(-1.24, 4.91)	0.2420	0.08 (0.08)	(-0.08, 0.25)	0.3046	0.1304

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Lupus QoL Burden to Others domain score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=315)		Placebo (N=321)		Difference of			Hedges'g			Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	(SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.7344
< 10 points	100	6.58 (1.91)	96	5.45 (1.90)	1.13 (2.49)	(-3.79, 6.05)	0.6512	0.06 (0.14)	(-0.22, 0.34)	0.6761	
>= 10 points	193	9.44 (1.66)	202	7.24 (1.62)	2.21 (1.96)	(-1.65, 6.06)	0.2618	0.10 (0.10)	(-0.10, 0.29)	0.3420	
OCS dose											0.6516
<10 mg/day	141	6.27 (1.54)	131	5.18 (1.62)	1.09 (2.09)	(-3.02, 5.21)	0.6020	0.06 (0.12)	(-0.18, 0.30)	0.6259	
>=10 mg/day	152	9.51 (2.08)	167	7.02 (1.95)	2.49 (2.27)	(-1.98, 6.95)	0.2746	0.10 (0.11)	(-0.12, 0.32)	0.3840	
Result of type I IFN gene signature test											0.9616
LOW	56	10.09 (2.31)	63	8.19 (2.18)	1.91 (3.16)	(-4.36, 8.17)	0.5476	0.11 (0.18)	(-0.25, 0.47)	0.5519	
HIGH	237	6.61 (1.30)	235	4.88 (1.32)	1.73 (1.78)	(-1.77, 5.23)	0.3320	0.09 (0.09)	(-0.09, 0.27)	0.3523	
Age (years)											NE
<= 65	287	7.58 (1.29)	297	5.94 (1.26)	1.64 (1.58)	(-1.45, 4.74)	0.2979	0.08 (0.08)	(-0.09, 0.24)	0.3628	
> 65	6	NE	1	NE	NE	NE		NE	NE		
Sex											0.1528
male	26	11.46 (4.54)	26	16.12 (4.50)	-4.66 (4.77)	(-14.28, 4.95)	0.3333	-0.20 (0.28)	(-0.74, 0.35)	0.4734	
female	267	7.72 (1.32)	272	5.18 (1.30)	2.54 (1.64)	(-0.68, 5.77)	0.1219	0.12 (0.09)	(-0.05, 0.29)	0.1708	
Race											0.5690
White	172	7.39 (1.58)	188	5.17 (1.52)	2.22 (1.96)	(-1.63, 6.07)	0.2573	0.11 (0.11)	(-0.10, 0.31)	0.3132	
Black	45	14.76 (4.71)	38	7.31 (4.48)	7.45 (5.55)	(-3.60, 18.49)	0.1833	0.25 (0.22)	(-0.19, 0.68)	0.2638	
Other	70	5.98 (2.76)	70	5.28 (3.02)	0.71 (3.09)	(-5.40, 6.82)	0.8194	0.03 (0.17)	(-0.30, 0.36)	0.8635	
Ethnicity											0.0239
Hispanic/Latino	74	8.74 (2.55)	83	12.96 (2.60)	-4.22 (3.19)	(-10.52, 2.09)	0.1883	-0.18 (0.16)	(-0.50, 0.13)	0.2524	
Non-hispanic/Latino	213	7.31 (1.52)	213	3.23 (1.44)	4.08 (1.82)	(0.50, 7.66)	0.0254	0.19 (0.10)	(-0.00, 0.38)	0.0521	
Geographic region											0.4603
EU	102	7.19 (2.17)	101	6.86 (2.18)	0.33 (2.38)	(-4.37, 5.04)	0.8888	0.02 (0.14)	(-0.26, 0.29)	0.9138	
non-EU	191	8.10 (1.58)	197	5.46 (1.55)	2.63 (2.01)	(-1.31, 6.58)	0.1897	0.12 (0.10)	(-0.08, 0.32)	0.2353	
Onset of disease											0.8298
Paediatric	21	4.28 (6.75)	19	3.93 (6.29)	0.35 (6.85)	(-13.69, 14.39)	0.9593	0.01 (0.32)	(-0.61, 0.63)	0.9703	
Adult	272	7.81 (1.32)	279	5.94 (1.30)	1.87 (1.63)	(-1.33, 5.06)	0.2516	0.09 (0.09)	(-0.08, 0.25)	0.3134	
ADA result											NE
Negative	271	7.98 (1.32)	273	6.21 (1.30)	1.77 (1.64)	(-1.47, 5.00)	0.2835	0.08 (0.09)	(-0.09, 0.25)	0.3407	
Positive (At any time)	22	NE	25	NE	NE	NE		NE	NE		
BMI (kg/m2)											0.8145
< 30	200	6.17 (1.57)	217	3.88 (1.57)	2.29 (1.86)	(-1.36, 5.94)	0.2180	0.10 (0.10)	(-0.09, 0.29)	0.3051	
>= 30	93	10.92 (2.36)	81	9.48 (2.28)	1.44 (3.10)	(-4.69, 7.57)	0.6429	0.07 (0.15)	(-0.23, 0.36)	0.6645	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Lupus QoL Fatigue domain score
Full analysis set

	Anifrolumab 300mg (N=315)		Placebo (N=321)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 4		2.97 (1.80)		1.72 (1.75)	1.26 (2.34)	(-3.37, 5.88)	0.5922				
Week 12		7.80 (1.25)		6.14 (1.23)	1.65 (1.58)	(-1.44, 4.75)	0.2946				
Week 24		10.00 (1.27)		7.68 (1.25)	2.32 (1.60)	(-0.83, 5.46)	0.1479				
Week 36		9.50 (1.36)		8.85 (1.36)	0.64 (1.76)	(-2.81, 4.09)	0.7147				
Week 52		9.80 (1.45)		8.18 (1.47)	1.63 (1.91)	(-2.12, 5.37)	0.3945				
OVERALL	293	8.01 (1.11)	298	6.51 (1.09)	1.50 (1.37)	(-1.19, 4.19)	0.2734	0.08 (0.08)	(-0.08, 0.24)	0.3370	0.9721

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Lupus QoL Fatigue domain score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=315) N	LSMean (SE)	Placebo (N=321) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.9870
< 10 points	100	8.23 (1.71)	96	6.82 (1.70)	1.41 (2.24)	(-3.01, 5.83)	0.5309	0.08 (0.14)	(-0.20, 0.36)	0.5619	
>= 10 points	193	7.40 (1.45)	202	5.95 (1.41)	1.45 (1.71)	(-1.91, 4.82)	0.3960	0.07 (0.10)	(-0.13, 0.27)	0.4740	
OCS dose											0.7875
<10 mg/day	141	9.01 (1.32)	131	7.08 (1.38)	1.93 (1.79)	(-1.60, 5.45)	0.2826	0.12 (0.12)	(-0.12, 0.36)	0.3146	
>=10 mg/day	152	6.25 (1.84)	167	5.05 (1.72)	1.20 (2.00)	(-2.74, 5.14)	0.5481	0.05 (0.11)	(-0.17, 0.27)	0.6335	
Result of type I IFN gene signature test											0.8976
LOW	56	7.13 (2.41)	63	6.12 (2.23)	1.01 (3.26)	(-5.46, 7.48)	0.7574	0.06 (0.18)	(-0.30, 0.42)	0.7594	
HIGH	237	9.25 (1.10)	235	7.78 (1.12)	1.47 (1.50)	(-1.48, 4.43)	0.3274	0.09 (0.09)	(-0.09, 0.27)	0.3477	
Age (years)											NE
<= 65	287	8.14 (1.13)	297	6.62 (1.10)	1.52 (1.37)	(-1.17, 4.22)	0.2673	0.08 (0.08)	(-0.08, 0.24)	0.3326	
> 65	6	NE	1	NE	NE	NE		NE	NE		
Sex											NE
male	26	NE	26	NE	NE	NE		NE	NE		
female	267	8.15 (1.18)	272	6.67 (1.16)	1.49 (1.46)	(-1.38, 4.35)	0.3083	0.08 (0.09)	(-0.09, 0.25)	0.3676	
Race											0.7626
White	172	8.49 (1.44)	188	6.43 (1.39)	2.06 (1.78)	(-1.44, 5.55)	0.2482	0.11 (0.11)	(-0.10, 0.32)	0.3053	
Black	45	9.56 (3.98)	38	7.67 (3.74)	1.89 (4.65)	(-7.37, 11.15)	0.6860	0.07 (0.22)	(-0.36, 0.51)	0.7355	
Other	70	5.51 (2.32)	70	5.75 (2.54)	-0.24 (2.60)	(-5.39, 4.91)	0.9277	-0.01 (0.17)	(-0.34, 0.32)	0.9454	
Ethnicity											0.6042
Hispanic/Latino	74	8.92 (2.21)	83	8.96 (2.28)	-0.04 (2.78)	(-5.53, 5.46)	0.9896	-0.00 (0.16)	(-0.32, 0.31)	0.9909	
Non-hispanic/Latino	213	7.02 (1.34)	213	5.39 (1.27)	1.63 (1.60)	(-1.52, 4.78)	0.3106	0.09 (0.10)	(-0.10, 0.28)	0.3780	
Geographic region											0.4499
EU	102	8.58 (1.84)	101	8.34 (1.84)	0.23 (1.99)	(-3.69, 4.16)	0.9066	0.01 (0.14)	(-0.26, 0.29)	0.9287	
non-EU	191	7.58 (1.38)	197	5.34 (1.36)	2.24 (1.75)	(-1.21, 5.69)	0.2030	0.12 (0.10)	(-0.08, 0.32)	0.2491	
Onset of disease											0.9713
Paediatric	21	8.95 (4.98)	19	7.61 (5.01)	1.34 (5.77)	(-10.44, 13.12)	0.8183	0.06 (0.32)	(-0.56, 0.68)	0.8531	
Adult	272	8.16 (1.15)	279	6.60 (1.14)	1.55 (1.42)	(-1.24, 4.35)	0.2755	0.08 (0.09)	(-0.09, 0.25)	0.3378	
ADA result											NE
Negative	271	7.71 (1.15)	273	6.48 (1.13)	1.23 (1.43)	(-1.58, 4.05)	0.3887	0.07 (0.09)	(-0.10, 0.23)	0.4442	
Positive (At any time)	22	NE	25	NE	NE	NE		NE	NE		
BMI (kg/m2)											0.7964
< 30	200	7.82 (1.28)	217	5.81 (1.27)	2.01 (1.51)	(-0.95, 4.97)	0.1829	0.11 (0.10)	(-0.08, 0.30)	0.2671	
>= 30	93	8.71 (2.33)	81	7.57 (2.26)	1.14 (3.04)	(-4.87, 7.14)	0.7092	0.05 (0.15)	(-0.25, 0.35)	0.7293	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Lupus QoL Intimate Relationships domain score
Full analysis set

	Anifrolumab 300mg (N=315)		Placebo (N=321)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 4		1.71 (2.79)		1.93 (2.95)	-0.23 (3.90)	(-7.95, 7.49)	0.9538				
Week 12		7.88 (1.79)		3.88 (1.83)	4.00 (2.34)	(-0.60, 8.60)	0.0884				
Week 24		5.70 (1.84)		5.13 (1.87)	0.56 (2.40)	(-4.16, 5.29)	0.8145				
Week 36		6.53 (2.03)		7.45 (2.09)	-0.92 (2.70)	(-6.23, 4.39)	0.7337				
Week 52		5.38 (1.96)		6.34 (2.00)	-0.95 (2.58)	(-6.04, 4.13)	0.7125				
OVERALL	239	5.44 (1.54)	236	4.95 (1.55)	0.49 (1.93)	(-3.30, 4.28)	0.7985	0.02 (0.09)	(-0.16, 0.20)	0.8218	0.5597

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Lupus QoL Intimate Relationships domain score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=315) N	LSMean (SE)	Placebo (N=321) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.1576
< 10 points	81	1.95 (2.70)	75	5.38 (2.71)	-3.42 (3.54)	(-10.42, 3.57)	0.3347	-0.14 (0.16)	(-0.46, 0.17)	0.3743	
>= 10 points	158	7.82 (1.87)	161	5.27 (1.88)	2.54 (2.31)	(-2.00, 7.09)	0.2713	0.11 (0.11)	(-0.11, 0.33)	0.3390	
OCS dose											0.4464
<10 mg/day	118	4.40 (2.07)	95	6.06 (2.48)	-1.65 (3.04)	(-7.66, 4.35)	0.5877	-0.07 (0.14)	(-0.34, 0.20)	0.6074	
>=10 mg/day	121	5.54 (2.38)	141	4.16 (2.17)	1.38 (2.56)	(-3.67, 6.43)	0.5917	0.05 (0.12)	(-0.19, 0.30)	0.6698	
Result of type I IFN gene signature test											0.3968
LOW	47	0.19 (3.64)	51	3.38 (3.24)	-3.19 (4.84)	(-12.83, 6.45)	0.5116	-0.13 (0.20)	(-0.53, 0.26)	0.5146	
HIGH	192	6.71 (1.51)	185	5.43 (1.60)	1.29 (2.12)	(-2.88, 5.46)	0.5444	0.06 (0.10)	(-0.14, 0.26)	0.5595	
Age (years)											NE
<= 65	237	5.29 (1.55)	236	4.91 (1.55)	0.38 (1.93)	(-3.42, 4.18)	0.8447	0.02 (0.09)	(-0.16, 0.20)	0.8631	
> 65	2	NE	0	NE	NE	NE		NE	NE		
Sex											NE
male	21	NE	21	NE	NE	NE		NE	NE		
female	218	5.09 (1.64)	215	4.92 (1.65)	0.17 (2.07)	(-3.90, 4.23)	0.9363	0.01 (0.10)	(-0.18, 0.20)	0.9435	
Race											0.9152
White	145	6.46 (1.87)	155	5.01 (1.85)	1.45 (2.37)	(-3.22, 6.12)	0.5417	0.06 (0.12)	(-0.16, 0.29)	0.5823	
Black	40	5.36 (4.72)	33	1.29 (4.54)	4.06 (5.84)	(-7.61, 15.74)	0.4892	0.14 (0.24)	(-0.32, 0.60)	0.5453	
Other	49	4.73 (4.29)	47	3.28 (4.63)	1.45 (4.52)	(-7.54, 10.45)	0.7486	0.05 (0.20)	(-0.35, 0.45)	0.8193	
Ethnicity											0.3687
Hispanic/Latino	60	5.09 (3.26)	59	7.62 (3.47)	-2.53 (3.99)	(-10.44, 5.38)	0.5276	-0.10 (0.18)	(-0.46, 0.26)	0.5982	
Non-hispanic/Latino	174	5.45 (1.82)	176	3.86 (1.76)	1.59 (2.26)	(-2.86, 6.04)	0.4817	0.07 (0.11)	(-0.14, 0.28)	0.5302	
Geographic region											0.9769
EU	83	9.16 (2.51)	83	8.32 (2.64)	0.84 (2.92)	(-4.95, 6.64)	0.7732	0.04 (0.16)	(-0.27, 0.34)	0.8175	
non-EU	156	4.11 (1.93)	153	3.37 (1.92)	0.73 (2.47)	(-4.13, 5.59)	0.7669	0.03 (0.11)	(-0.19, 0.25)	0.7884	
Onset of disease											0.8077
Paediatric	17	9.82 (17.85)	12	13.44 (20.19)	-3.62 (16.72)	(-216.06, 208.83)	0.8644	-0.05 (0.38)	(-0.79, 0.69)	0.8972	
Adult	222	5.35 (1.62)	224	4.87 (1.63)	0.48 (2.03)	(-3.52, 4.48)	0.8122	0.02 (0.09)	(-0.17, 0.21)	0.8339	
ADA result											NE
Negative	222	5.46 (1.60)	219	4.82 (1.61)	0.64 (2.02)	(-3.33, 4.62)	0.7500	0.03 (0.10)	(-0.16, 0.21)	0.7766	
Positive (At any time)	17	NE	17	NE	NE	NE		NE	NE		
BMI (kg/m2)											0.2738
< 30	159	3.14 (1.89)	168	4.21 (1.89)	-1.07 (2.27)	(-5.53, 3.38)	0.6356	-0.04 (0.11)	(-0.26, 0.17)	0.6894	
>= 30	80	10.16 (2.82)	68	6.41 (2.87)	3.75 (3.78)	(-3.74, 11.24)	0.3235	0.15 (0.17)	(-0.17, 0.48)	0.3574	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Lupus QoL Pain domain score
Full analysis set

Visit	Anifrolumab 300mg (N=315) N	Anifrolumab 300mg (N=315) LSMean (SE)	Placebo (N=321) N	Placebo (N=321) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		7.30 (1.90)		7.03 (1.85)	0.27 (2.40)	(-4.48, 5.02)	0.9104				
Week 12		10.95 (1.36)		9.06 (1.35)	1.89 (1.73)	(-1.52, 5.30)	0.2761				
Week 24		11.78 (1.41)		10.45 (1.40)	1.33 (1.80)	(-2.21, 4.87)	0.4606				
Week 36		13.32 (1.41)		13.34 (1.42)	-0.02 (1.83)	(-3.61, 3.57)	0.9904				
Week 52		11.54 (1.47)		11.35 (1.48)	0.19 (1.92)	(-3.57, 3.95)	0.9205				
OVERALL	293	10.98 (1.16)	298	10.24 (1.14)	0.73 (1.42)	(-2.07, 3.53)	0.6075	0.04 (0.08)	(-0.12, 0.20)	0.6531	0.7714

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Lupus QoL Pain domain score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=315)		Placebo (N=321)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.9425
< 10 points	100	11.11 (1.95)	96	10.61 (1.93)	0.51 (2.54)	(-4.51, 5.52)	0.8418	0.03 (0.14)	(-0.25, 0.31)	0.8538	
>= 10 points	193	10.75 (1.46)	202	10.02 (1.44)	0.73 (1.73)	(-2.67, 4.13)	0.6734	0.04 (0.10)	(-0.16, 0.23)	0.7220	
OCS dose											0.9743
<10 mg/day	141	10.50 (1.48)	131	9.53 (1.55)	0.96 (1.99)	(-2.96, 4.89)	0.6289	0.05 (0.12)	(-0.18, 0.29)	0.6536	
>=10 mg/day	152	11.28 (1.84)	167	10.41 (1.74)	0.87 (2.03)	(-3.12, 4.87)	0.6678	0.04 (0.11)	(-0.18, 0.26)	0.7310	
Result of type I IFN gene signature test											0.8759
LOW	56	12.83 (2.38)	63	12.71 (2.21)	0.12 (3.22)	(-6.26, 6.51)	0.9694	0.01 (0.18)	(-0.35, 0.37)	0.9698	
HIGH	237	10.51 (1.16)	235	9.83 (1.18)	0.68 (1.59)	(-2.44, 3.81)	0.6666	0.04 (0.09)	(-0.14, 0.22)	0.6795	
Age (years)											NE
<= 65	287	11.22 (1.17)	297	10.36 (1.15)	0.86 (1.43)	(-1.96, 3.67)	0.5497	0.04 (0.08)	(-0.12, 0.21)	0.6021	
> 65	6	NE	1	NE	NE	NE		NE	NE		
Sex											0.4762
male	26	9.70 (4.61)	26	12.34 (4.22)	-2.63 (4.65)	(-12.02, 6.75)	0.5742	-0.12 (0.28)	(-0.66, 0.43)	0.6781	
female	267	11.15 (1.21)	272	10.30 (1.20)	0.85 (1.51)	(-2.11, 3.81)	0.5730	0.04 (0.09)	(-0.13, 0.21)	0.6185	
Race											0.6471
White	172	10.09 (1.46)	188	9.35 (1.41)	0.75 (1.81)	(-2.80, 4.30)	0.6785	0.04 (0.11)	(-0.17, 0.25)	0.7129	
Black	45	17.82 (3.91)	38	13.75 (3.85)	4.07 (4.74)	(-5.38, 13.52)	0.3937	0.16 (0.22)	(-0.27, 0.59)	0.4676	
Other	70	8.41 (2.70)	70	9.57 (2.95)	-1.16 (3.06)	(-7.21, 4.90)	0.7063	-0.05 (0.17)	(-0.38, 0.28)	0.7737	
Ethnicity											0.0220
Hispanic/Latino	74	9.85 (2.33)	83	15.19 (2.39)	-5.34 (2.93)	(-11.13, 0.45)	0.0703	-0.25 (0.16)	(-0.57, 0.06)	0.1145	
Non-hispanic/Latino	213	10.46 (1.37)	213	8.11 (1.31)	2.35 (1.64)	(-0.88, 5.59)	0.1529	0.12 (0.10)	(-0.07, 0.31)	0.2147	
Geographic region											0.8377
EU	102	11.63 (1.93)	101	10.87 (1.93)	0.76 (2.09)	(-3.36, 4.88)	0.7163	0.04 (0.14)	(-0.24, 0.31)	0.7820	
non-EU	191	10.18 (1.43)	197	9.99 (1.41)	0.19 (1.82)	(-3.39, 3.78)	0.9164	0.01 (0.10)	(-0.19, 0.21)	0.9243	
Onset of disease											0.1170
Paediatric	21	3.61 (5.58)	19	12.12 (5.27)	-8.51 (6.11)	(-20.99, 3.97)	0.1739	-0.34 (0.32)	(-0.97, 0.28)	0.2838	
Adult	272	11.12 (1.19)	279	9.78 (1.18)	1.34 (1.47)	(-1.56, 4.24)	0.3639	0.07 (0.09)	(-0.10, 0.23)	0.4259	
ADA result											NE
Negative	271	10.64 (1.19)	273	10.45 (1.17)	0.19 (1.48)	(-2.71, 3.10)	0.8956	0.01 (0.09)	(-0.16, 0.18)	0.9075	
Positive (At any time)	22	NE	25	NE	NE	NE		NE	NE		
BMI (kg/m2)											0.6691
< 30	200	11.18 (1.35)	217	9.73 (1.36)	1.45 (1.60)	(-1.70, 4.59)	0.3657	0.07 (0.10)	(-0.12, 0.27)	0.4522	
>= 30	93	10.88 (2.31)	81	10.90 (2.23)	-0.02 (3.03)	(-6.01, 5.98)	0.9955	-0.00 (0.15)	(-0.30, 0.30)	0.9958	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Lupus QoL Planning domain score
Full analysis set

	Anifrolumab 300mg (N=315)		Placebo (N=321)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 4		4.18 (2.27)		-0.81 (2.19)	4.99 (2.95)	(-0.84, 10.82)	0.0929				
Week 12		7.64 (1.45)		4.35 (1.43)	3.28 (1.83)	(-0.32, 6.89)	0.0739				
Week 24		9.80 (1.44)		7.13 (1.43)	2.68 (1.82)	(-0.89, 6.25)	0.1410				
Week 36		9.86 (1.56)		8.49 (1.57)	1.36 (2.03)	(-2.62, 5.35)	0.5012				
Week 52		9.33 (1.57)		6.89 (1.59)	2.44 (2.05)	(-1.58, 6.47)	0.2332				
OVERALL	293	8.16 (1.27)	298	5.21 (1.25)	2.95 (1.56)	(-0.11, 6.01)	0.0586	0.14 (0.08)	(-0.02, 0.30)	0.0974	0.6439

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - Lupus QoL Planning domain score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=315)		Placebo (N=321)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.5271
< 10 points	100	7.96 (2.01)	96	6.43 (2.00)	1.53 (2.63)	(-3.65, 6.72)	0.5606	0.08 (0.14)	(-0.20, 0.36)	0.5911	
>= 10 points	193	7.84 (1.64)	202	4.24 (1.60)	3.60 (1.95)	(-0.23, 7.44)	0.0656	0.16 (0.10)	(-0.04, 0.36)	0.1168	
OCS dose											0.9603
<10 mg/day	141	8.04 (1.62)	131	4.80 (1.70)	3.24 (2.19)	(-1.08, 7.56)	0.1406	0.17 (0.12)	(-0.07, 0.41)	0.1691	
>=10 mg/day	152	7.64 (2.04)	167	4.55 (1.91)	3.09 (2.22)	(-1.28, 7.45)	0.1650	0.12 (0.11)	(-0.10, 0.34)	0.2709	
Result of type I IFN gene signature test											0.5091
LOW	56	7.47 (2.85)	63	6.95 (2.64)	0.52 (3.85)	(-7.11, 8.14)	0.8933	0.02 (0.18)	(-0.34, 0.38)	0.8946	
HIGH	237	9.15 (1.24)	235	5.85 (1.26)	3.29 (1.70)	(-0.04, 6.62)	0.0529	0.17 (0.09)	(-0.01, 0.35)	0.0629	
Age (years)											NE
<= 65	287	8.10 (1.29)	297	5.22 (1.25)	2.87 (1.57)	(-0.20, 5.95)	0.0673	0.13 (0.08)	(-0.03, 0.29)	0.1101	
> 65	6	NE	1	NE	NE	NE		NE	NE		
Sex											0.3498
male	26	6.10 (5.41)	26	8.28 (4.88)	-2.18 (5.25)	(-12.83, 8.47)	0.6802	-0.08 (0.28)	(-0.63, 0.46)	0.7681	
female	267	8.07 (1.32)	272	5.11 (1.30)	2.96 (1.64)	(-0.25, 6.17)	0.0709	0.14 (0.09)	(-0.03, 0.31)	0.1103	
Race											0.6434
White	172	9.04 (1.69)	188	5.86 (1.63)	3.18 (2.09)	(-0.93, 7.29)	0.1284	0.14 (0.11)	(-0.06, 0.35)	0.1769	
Black	45	9.85 (4.18)	38	2.39 (3.88)	7.46 (4.83)	(-2.16, 17.08)	0.1266	0.28 (0.22)	(-0.15, 0.72)	0.2030	
Other	70	4.80 (2.80)	70	2.67 (3.07)	2.14 (3.11)	(-4.02, 8.30)	0.4939	0.09 (0.17)	(-0.24, 0.42)	0.6090	
Ethnicity											0.5103
Hispanic/Latino	74	7.71 (2.59)	83	6.60 (2.66)	1.11 (3.24)	(-5.29, 7.51)	0.7326	0.05 (0.16)	(-0.27, 0.36)	0.7672	
Non-hispanic/Latino	213	7.78 (1.52)	213	4.22 (1.44)	3.56 (1.82)	(-0.03, 7.14)	0.0519	0.16 (0.10)	(-0.03, 0.35)	0.0909	
Geographic region											0.5036
EU	102	13.02 (2.13)	101	11.47 (2.14)	1.55 (2.32)	(-3.03, 6.12)	0.5047	0.07 (0.14)	(-0.20, 0.35)	0.6090	
non-EU	191	5.86 (1.56)	197	2.27 (1.53)	3.59 (1.98)	(-0.30, 7.48)	0.0706	0.17 (0.10)	(-0.03, 0.37)	0.1024	
Onset of disease											0.3376
Paediatric	21	0.24 (6.38)	19	3.73 (5.92)	-3.49 (6.86)	(-17.51, 10.53)	0.6146	-0.12 (0.32)	(-0.74, 0.50)	0.6964	
Adult	272	8.51 (1.31)	279	5.24 (1.29)	3.27 (1.62)	(0.10, 6.44)	0.0434	0.15 (0.09)	(-0.02, 0.32)	0.0758	
ADA result											NE
Negative	271	8.20 (1.30)	273	5.28 (1.28)	2.92 (1.62)	(-0.26, 6.11)	0.0717	0.14 (0.09)	(-0.03, 0.31)	0.1101	
Positive (At any time)	22	NE	25	NE	NE	NE		NE	NE		
BMI (kg/m2)											0.9476
< 30	200	8.42 (1.52)	217	5.08 (1.52)	3.34 (1.79)	(-0.17, 6.85)	0.0625	0.15 (0.10)	(-0.04, 0.34)	0.1214	
>= 30	93	7.91 (2.45)	81	4.33 (2.37)	3.58 (3.22)	(-2.78, 9.93)	0.2676	0.16 (0.15)	(-0.14, 0.46)	0.3002	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SDI Global Score
Full analysis set

	Anifrolumab 300mg (N=315)		Placebo (N=321)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 24		0.02 (0.02)		0.02 (0.02)	-0.00 (0.02)	(-0.05, 0.05)	0.9026				
Week 52		0.05 (0.03)		0.03 (0.03)	0.02 (0.03)	(-0.04, 0.09)	0.5215				
OVERALL	285	0.03 (0.02)	282	0.02 (0.02)	0.01 (0.03)	(-0.04, 0.06)	0.7331	0.03 (0.08)	(-0.14, 0.19)	0.7657	0.4530

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - SDI Global Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=315) N	LSMean (SE)	Placebo (N=321) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.0319
< 10 points	99	0.08 (0.04)	89	-0.02 (0.04)	0.10 (0.05)	(-0.00, 0.20)	0.0555	0.26 (0.15)	(-0.03, 0.55)	0.0764	
>= 10 points	186	0.02 (0.03)	193	0.05 (0.03)	-0.03 (0.03)	(-0.09, 0.03)	0.3399	-0.08 (0.10)	(-0.28, 0.12)	0.4184	
OCS dose											0.6090
<10 mg/day	137	0.01 (0.03)	128	-0.01 (0.03)	0.02 (0.04)	(-0.05, 0.09)	0.5076	0.08 (0.12)	(-0.17, 0.32)	0.5383	
>=10 mg/day	148	0.05 (0.04)	154	0.05 (0.03)	-0.00 (0.04)	(-0.08, 0.07)	0.9293	-0.01 (0.12)	(-0.23, 0.22)	0.9444	
Result of type I IFN gene signature test											0.0984
LOW	53	0.06 (0.03)	55	-0.02 (0.03)	0.08 (0.04)	(-0.00, 0.17)	0.0577	0.36 (0.19)	(-0.02, 0.74)	0.0608	
HIGH	232	0.03 (0.02)	227	0.03 (0.02)	-0.01 (0.03)	(-0.07, 0.06)	0.8465	-0.02 (0.09)	(-0.20, 0.17)	0.8538	
Age (years)											NE
<= 65	281	0.04 (0.02)	279	0.02 (0.02)	0.01 (0.03)	(-0.04, 0.07)	0.6292	0.04 (0.08)	(-0.13, 0.20)	0.6738	
> 65	4	NE	3	NE	NE	NE		NE	NE		
Sex											NE
male	25	NE	26	NE	NE	NE		NE	NE		
female	260	0.04 (0.02)	256	0.03 (0.02)	0.01 (0.03)	(-0.05, 0.07)	0.7538	0.02 (0.09)	(-0.15, 0.20)	0.7825	
Race											0.8947
White	170	0.06 (0.02)	178	0.03 (0.02)	0.03 (0.02)	(-0.02, 0.07)	0.2961	0.10 (0.11)	(-0.11, 0.31)	0.3566	
Black	40	0.04 (0.06)	40	0.02 (0.05)	0.02 (0.06)	(-0.11, 0.15)	0.7840	0.05 (0.22)	(-0.39, 0.49)	0.8176	
Other	69	-0.01 (0.08)	61	0.01 (0.09)	-0.02 (0.09)	(-0.20, 0.16)	0.8354	-0.03 (0.18)	(-0.37, 0.32)	0.8747	
Ethnicity											0.4734
Hispanic/Latino	71	0.00 (0.06)	73	0.04 (0.07)	-0.04 (0.08)	(-0.21, 0.12)	0.6063	-0.08 (0.17)	(-0.40, 0.25)	0.6469	
Non-hispanic/Latino	208	0.04 (0.02)	206	0.02 (0.02)	0.02 (0.02)	(-0.03, 0.06)	0.4182	0.07 (0.10)	(-0.12, 0.26)	0.4847	
Geographic region											0.8680
EU	104	0.04 (0.03)	98	0.03 (0.03)	0.01 (0.03)	(-0.05, 0.08)	0.6992	0.04 (0.14)	(-0.23, 0.32)	0.7578	
non-EU	181	0.03 (0.03)	184	0.03 (0.03)	0.00 (0.04)	(-0.07, 0.08)	0.9146	0.01 (0.10)	(-0.20, 0.22)	0.9233	
Onset of disease											NE
Paediatric	23	NE	16	NE	NE	NE		NE	NE		
Adult	262	0.03 (0.02)	266	0.03 (0.02)	0.01 (0.03)	(-0.05, 0.06)	0.7688	0.02 (0.09)	(-0.15, 0.19)	0.7973	
ADA result											NE
Negative	266	0.03 (0.02)	258	0.03 (0.02)	0.01 (0.03)	(-0.05, 0.06)	0.8360	0.02 (0.09)	(-0.16, 0.19)	0.8547	
Positive (At any time)	19	NE	24	NE	NE	NE		NE	NE		
BMI (kg/m2)											0.1508
< 30	196	0.01 (0.03)	205	0.03 (0.03)	-0.02 (0.03)	(-0.08, 0.05)	0.5864	-0.05 (0.10)	(-0.24, 0.15)	0.6481	
>= 30	89	0.07 (0.03)	77	0.01 (0.03)	0.06 (0.04)	(-0.03, 0.15)	0.1644	0.20 (0.16)	(-0.11, 0.50)	0.2018	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - PtGA
Full analysis set

Visit	Anifrolumab 300mg (N=315) N	Anifrolumab 300mg (N=315) LSMean (SE)	Placebo (N=321) N	Placebo (N=321) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		-7.51 (1.35)		-5.99 (1.32)	-1.51 (1.72)	(-4.90, 1.87)	0.3799				
Week 8		-9.77 (1.38)		-7.08 (1.36)	-2.69 (1.78)	(-6.19, 0.81)	0.1321				
Week 12		-12.37 (1.44)		-9.99 (1.44)	-2.38 (1.89)	(-6.08, 1.33)	0.2082				
Week 16		-9.77 (1.51)		-11.06 (1.49)	1.29 (1.98)	(-2.59, 5.18)	0.5133				
Week 20		-12.50 (1.47)		-11.88 (1.46)	-0.62 (1.92)	(-4.39, 3.16)	0.7481				
Week 24		-11.14 (1.53)		-9.48 (1.52)	-1.66 (2.01)	(-5.61, 2.30)	0.4106				
Week 28		-12.32 (1.54)		-11.99 (1.54)	-0.33 (2.04)	(-4.33, 3.67)	0.8702				
Week 32		-11.89 (1.55)		-11.74 (1.56)	-0.15 (2.06)	(-4.20, 3.90)	0.9415				
Week 36		-15.61 (1.50)		-14.15 (1.51)	-1.46 (1.99)	(-5.36, 2.44)	0.4626				
Week 40		-13.28 (1.55)		-12.36 (1.57)	-0.92 (2.06)	(-4.97, 3.13)	0.6541				
Week 44		-14.52 (1.50)		-14.35 (1.53)	-0.17 (2.00)	(-4.09, 3.75)	0.9313				
Week 48		-13.14 (1.57)		-11.41 (1.61)	-1.73 (2.11)	(-5.88, 2.41)	0.4121				
Week 52		-13.16 (1.64)		-11.08 (1.67)	-2.09 (2.21)	(-6.43, 2.25)	0.3455				
OVERALL	300	-12.08 (1.15)	305	-10.97 (1.14)	-1.11 (1.42)	(-3.90, 1.68)	0.4350	-0.06 (0.08)	(-0.22, 0.10)	0.4927	0.3570

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis (observed values) - PtGA - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=315) N	LSMean (SE)	Placebo (N=321) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.1423
< 10 points	102	-14.16 (1.85)	99	-10.00 (1.85)	-4.17 (2.43)	(-8.95, 0.62)	0.0875	-0.22 (0.14)	(-0.50, 0.05)	0.1136	
>= 10 points	198	-10.30 (1.46)	206	-10.51 (1.44)	0.21 (1.74)	(-3.20, 3.63)	0.9028	0.01 (0.10)	(-0.18, 0.21)	0.9177	
OCS dose											0.9116
<10 mg/day	142	-11.11 (1.50)	135	-10.33 (1.57)	-0.78 (2.00)	(-4.73, 3.16)	0.6959	-0.04 (0.12)	(-0.28, 0.19)	0.7183	
>=10 mg/day	158	-12.22 (1.82)	170	-11.12 (1.72)	-1.10 (2.02)	(-5.08, 2.88)	0.5869	-0.05 (0.11)	(-0.27, 0.17)	0.6607	
Result of type I IFN gene signature test											0.0353
LOW	56	-9.07 (2.31)	64	-14.17 (2.15)	5.10 (3.16)	(-1.16, 11.35)	0.1095	0.29 (0.18)	(-0.07, 0.65)	0.1104	
HIGH	244	-13.20 (1.17)	241	-10.85 (1.19)	-2.35 (1.59)	(-5.48, 0.78)	0.1405	-0.13 (0.09)	(-0.31, 0.05)	0.1612	
Age (years)											NE
<= 65	294	-12.25 (1.16)	304	-10.94 (1.14)	-1.32 (1.43)	(-4.12, 1.49)	0.3576	-0.07 (0.08)	(-0.23, 0.09)	0.4204	
> 65	6	NE	1	NE	NE	NE		NE	NE		
Sex											0.3554
male	26	-15.70 (4.46)	26	-18.70 (4.46)	3.00 (4.52)	(-6.10, 12.09)	0.5101	0.13 (0.28)	(-0.41, 0.67)	0.6401	
female	274	-11.91 (1.20)	279	-10.51 (1.18)	-1.40 (1.49)	(-4.33, 1.54)	0.3496	-0.07 (0.09)	(-0.24, 0.10)	0.4069	
Race											0.0037
White	175	-11.90 (1.53)	193	-13.79 (1.47)	1.89 (1.85)	(-1.75, 5.54)	0.3073	0.09 (0.10)	(-0.11, 0.30)	0.3739	
Black	47	-14.74 (3.10)	38	-2.88 (2.96)	-11.86 (3.68)	(-19.19, -4.53)	0.0019	-0.59 (0.22)	(-1.03, -0.15)	0.0083	
Other	72	-10.20 (2.67)	72	-8.60 (2.93)	-1.61 (3.01)	(-7.56, 4.35)	0.5942	-0.07 (0.17)	(-0.39, 0.26)	0.6868	
Ethnicity											0.5754
Hispanic/Latino	77	-14.71 (2.28)	83	-12.46 (2.37)	-2.26 (2.87)	(-7.94, 3.42)	0.4337	-0.11 (0.16)	(-0.42, 0.20)	0.4965	
Non-hispanic/Latino	217	-10.74 (1.37)	220	-10.34 (1.32)	-0.40 (1.66)	(-3.65, 2.86)	0.8101	-0.02 (0.10)	(-0.21, 0.17)	0.8346	
Geographic region											0.0026
EU	103	-11.51 (2.13)	104	-15.98 (2.13)	4.47 (2.28)	(-0.02, 8.96)	0.0508	0.21 (0.14)	(-0.07, 0.48)	0.1394	
non-EU	197	-12.00 (1.36)	201	-7.82 (1.36)	-4.18 (1.74)	(-7.61, -0.74)	0.0172	-0.22 (0.10)	(-0.41, -0.02)	0.0309	
Onset of disease											0.4111
Paediatric	22	-11.81 (4.93)	19	-15.46 (4.84)	3.65 (5.87)	(-8.32, 15.62)	0.5386	0.16 (0.31)	(-0.45, 0.78)	0.6076	
Adult	278	-12.27 (1.19)	286	-10.94 (1.18)	-1.33 (1.48)	(-4.23, 1.58)	0.3698	-0.07 (0.08)	(-0.23, 0.10)	0.4308	
ADA result											0.6053
Negative	278	-11.99 (1.19)	280	-11.07 (1.18)	-0.92 (1.49)	(-3.84, 2.01)	0.5374	-0.05 (0.08)	(-0.21, 0.12)	0.5837	
Positive (At any time)	22	-27.08 (6.37)	25	-23.45 (6.00)	-3.63 (5.02)	(-13.77, 6.52)	0.4745	-0.12 (0.29)	(-0.69, 0.45)	0.6841	
BMI (kg/m2)											0.0500
< 30	205	-12.05 (1.40)	222	-12.45 (1.39)	0.40 (1.67)	(-2.88, 3.69)	0.8090	0.02 (0.10)	(-0.17, 0.21)	0.8383	
>= 30	95	-12.84 (2.06)	83	-7.12 (2.03)	-5.72 (2.64)	(-10.93, -0.51)	0.0316	-0.29 (0.15)	(-0.59, 0.00)	0.0514	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SLEDAI-2K Total Score
Full analysis set

Visit	Anifrolumab 300mg (N=315) n/ N#	Anifrolumab 300mg (N=315) Compliance	Placebo (N=321) n/ N#	Placebo (N=321) Compliance
Baseline	315/ 315	100.0%	321/ 321	100.0%
Week 4	305/ 315	96.83%	314/ 321	97.82%
Week 8	299/ 315	94.92%	306/ 321	95.33%
Week 12	303/ 314	96.50%	295/ 321	91.90%
Week 16	293/ 314	93.31%	290/ 321	90.34%
Week 20	287/ 314	91.40%	288/ 321	89.72%
Week 24	285/ 314	90.76%	281/ 321	87.54%
Week 28	284/ 314	90.45%	270/ 321	84.11%
Week 32	277/ 314	88.22%	265/ 321	82.55%
Week 36	274/ 314	87.26%	263/ 321	81.93%
Week 40	278/ 314	88.54%	257/ 320	80.31%
Week 44	268/ 314	85.35%	254/ 320	79.38%
Week 48	269/ 314	85.67%	248/ 320	77.50%
Week 52	261/ 314	83.12%	238/ 320	74.38%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - PGA
Full analysis set

Visit	Anifrolumab 300mg (N=315) n/ N#	Anifrolumab 300mg (N=315) Compliance	Placebo (N=321) n/ N#	Placebo (N=321) Compliance
Baseline	315/ 315	100.0%	321/ 321	100.0%
Week 4	308/ 315	97.78%	318/ 321	99.07%
Week 8	299/ 315	94.92%	307/ 321	95.64%
Week 12	301/ 314	95.86%	297/ 321	92.52%
Week 16	297/ 314	94.59%	295/ 321	91.90%
Week 20	284/ 314	90.45%	291/ 321	90.65%
Week 24	286/ 314	91.08%	287/ 321	89.41%
Week 28	284/ 314	90.45%	275/ 321	85.67%
Week 32	280/ 314	89.17%	267/ 321	83.18%
Week 36	277/ 314	88.22%	261/ 321	81.31%
Week 40	279/ 314	88.85%	263/ 320	82.19%
Week 44	270/ 314	85.99%	255/ 320	79.69%
Week 48	273/ 314	86.94%	250/ 320	78.13%
Week 52	262/ 314	83.44%	240/ 320	75.00%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - CLASI Total Activity Score
Full analysis set

Visit	Anifrolumab 300mg (N=315) n/ N#	Anifrolumab 300mg (N=315) Compliance	Placebo (N=321) n/ N#	Placebo (N=321) Compliance
Baseline	315/ 315	100.0%	321/ 321	100.0%
Week 4	308/ 315	97.78%	318/ 321	99.07%
Week 8	301/ 315	95.56%	307/ 321	95.64%
Week 12	303/ 314	96.50%	299/ 321	93.15%
Week 16	298/ 314	94.90%	293/ 321	91.28%
Week 20	289/ 314	92.04%	293/ 321	91.28%
Week 24	286/ 314	91.08%	287/ 321	89.41%
Week 28	285/ 314	90.76%	276/ 321	85.98%
Week 32	280/ 314	89.17%	267/ 321	83.18%
Week 36	275/ 314	87.58%	263/ 321	81.93%
Week 40	278/ 314	88.54%	263/ 320	82.19%
Week 44	270/ 314	85.99%	257/ 320	80.31%
Week 48	273/ 314	86.94%	251/ 320	78.44%
Week 52	262/ 314	83.44%	241/ 320	75.31%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - CLASI Total Damage Score
Full analysis set

Visit	Anifrolumab 300mg (N=315) n/ N#	Anifrolumab 300mg (N=315) Compliance	Placebo (N=321) n/ N#	Placebo (N=321) Compliance
Baseline	315/ 315	100.0%	321/ 321	100.0%
Week 4	309/ 315	98.10%	317/ 321	98.75%
Week 8	301/ 315	95.56%	307/ 321	95.64%
Week 12	303/ 314	96.50%	300/ 321	93.46%
Week 16	298/ 314	94.90%	293/ 321	91.28%
Week 20	289/ 314	92.04%	293/ 321	91.28%
Week 24	286/ 314	91.08%	287/ 321	89.41%
Week 28	285/ 314	90.76%	276/ 321	85.98%
Week 32	280/ 314	89.17%	267/ 321	83.18%
Week 36	275/ 314	87.58%	263/ 321	81.93%
Week 40	278/ 314	88.54%	262/ 320	81.88%
Week 44	269/ 314	85.67%	257/ 320	80.31%
Week 48	273/ 314	86.94%	251/ 320	78.44%
Week 52	262/ 314	83.44%	241/ 320	75.31%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - BILAG Global Score
Full analysis set

Visit	Anifrolumab 300mg (N=315) n/ N#	Anifrolumab 300mg (N=315) Compliance	Placebo (N=321) n/ N#	Placebo (N=321) Compliance
Baseline	315/ 315	100.0%	321/ 321	100.0%
Week 4	308/ 315	97.78%	317/ 321	98.75%
Week 8	304/ 315	96.51%	309/ 321	96.26%
Week 12	305/ 314	97.13%	300/ 321	93.46%
Week 16	298/ 314	94.90%	294/ 321	91.59%
Week 20	289/ 314	92.04%	291/ 321	90.65%
Week 24	288/ 314	91.72%	287/ 321	89.41%
Week 28	287/ 314	91.40%	276/ 321	85.98%
Week 32	283/ 314	90.13%	266/ 321	82.87%
Week 36	278/ 314	88.54%	261/ 321	81.31%
Week 40	281/ 314	89.49%	259/ 320	80.94%
Week 44	270/ 314	85.99%	256/ 320	80.00%
Week 48	272/ 314	86.62%	250/ 320	78.13%
Week 52	262/ 314	83.44%	239/ 320	74.69%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Tender Joint Count
Full analysis set

Visit	Anifrolumab 300mg (N=315) n/ N#	Anifrolumab 300mg (N=315) Compliance	Placebo (N=321) n/ N#	Placebo (N=321) Compliance
Baseline	315/ 315	100.0%	321/ 321	100.0%
Week 4	308/ 315	97.78%	317/ 321	98.75%
Week 8	299/ 315	94.92%	307/ 321	95.64%
Week 12	303/ 314	96.50%	299/ 321	93.15%
Week 16	298/ 314	94.90%	294/ 321	91.59%
Week 20	288/ 314	91.72%	292/ 321	90.97%
Week 24	286/ 314	91.08%	286/ 321	89.10%
Week 28	284/ 314	90.45%	276/ 321	85.98%
Week 32	281/ 314	89.49%	267/ 321	83.18%
Week 36	275/ 314	87.58%	263/ 321	81.93%
Week 40	279/ 314	88.85%	262/ 320	81.88%
Week 44	270/ 314	85.99%	257/ 320	80.31%
Week 48	271/ 314	86.31%	251/ 320	78.44%
Week 52	261/ 314	83.12%	241/ 320	75.31%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Swollen Joint Count
Full analysis set

Visit	Anifrolumab 300mg (N=315) n/ N#	Anifrolumab 300mg (N=315) Compliance	Placebo (N=321) n/ N#	Placebo (N=321) Compliance
Baseline	315/ 315	100.0%	321/ 321	100.0%
Week 4	308/ 315	97.78%	317/ 321	98.75%
Week 8	299/ 315	94.92%	307/ 321	95.64%
Week 12	303/ 314	96.50%	299/ 321	93.15%
Week 16	298/ 314	94.90%	294/ 321	91.59%
Week 20	288/ 314	91.72%	292/ 321	90.97%
Week 24	286/ 314	91.08%	286/ 321	89.10%
Week 28	284/ 314	90.45%	276/ 321	85.98%
Week 32	281/ 314	89.49%	267/ 321	83.18%
Week 36	275/ 314	87.58%	263/ 321	81.93%
Week 40	279/ 314	88.85%	262/ 320	81.88%
Week 44	270/ 314	85.99%	257/ 320	80.31%
Week 48	271/ 314	86.31%	251/ 320	78.44%
Week 52	261/ 314	83.12%	241/ 320	75.31%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute Mental Component Score
Full analysis set

Visit	Anifrolumab 300mg (N=315) n/ N#	Anifrolumab 300mg (N=315) Compliance	Placebo (N=321) n/ N#	Placebo (N=321) Compliance
Baseline	305/ 315	96.83%	307/ 321	95.64%
Week 4	68/ 315	21.59%	73/ 321	22.74%
Week 8	222/ 315	70.48%	224/ 321	69.78%
Week 12	66/ 314	21.02%	71/ 321	22.12%
Week 16	219/ 314	69.75%	218/ 321	67.91%
Week 24	276/ 314	87.90%	278/ 321	86.60%
Week 32	205/ 314	65.29%	194/ 321	60.44%
Week 36	62/ 314	19.75%	55/ 321	17.13%
Week 40	207/ 314	65.92%	195/ 320	60.94%
Week 48	208/ 314	66.24%	188/ 320	58.75%
Week 52	256/ 314	81.53%	231/ 320	72.19%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute Physical Component Score
Full analysis set

Visit	Anifrolumab 300mg (N=315) n/ N#	Anifrolumab 300mg (N=315) Compliance	Placebo (N=321) n/ N#	Placebo (N=321) Compliance
Baseline	305/ 315	96.83%	307/ 321	95.64%
Week 4	68/ 315	21.59%	73/ 321	22.74%
Week 8	222/ 315	70.48%	224/ 321	69.78%
Week 12	66/ 314	21.02%	71/ 321	22.12%
Week 16	219/ 314	69.75%	218/ 321	67.91%
Week 24	276/ 314	87.90%	278/ 321	86.60%
Week 32	205/ 314	65.29%	194/ 321	60.44%
Week 36	62/ 314	19.75%	55/ 321	17.13%
Week 40	207/ 314	65.92%	195/ 320	60.94%
Week 48	208/ 314	66.24%	188/ 320	58.75%
Week 52	256/ 314	81.53%	231/ 320	72.19%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute General Health Score
Full analysis set

Visit	Anifrolumab 300mg (N=315) n/ N#	Anifrolumab 300mg (N=315) Compliance	Placebo (N=321) n/ N#	Placebo (N=321) Compliance
Baseline	305/ 315	96.83%	307/ 321	95.64%
Week 4	68/ 315	21.59%	73/ 321	22.74%
Week 8	222/ 315	70.48%	224/ 321	69.78%
Week 12	66/ 314	21.02%	71/ 321	22.12%
Week 16	219/ 314	69.75%	218/ 321	67.91%
Week 24	276/ 314	87.90%	278/ 321	86.60%
Week 32	205/ 314	65.29%	194/ 321	60.44%
Week 36	62/ 314	19.75%	55/ 321	17.13%
Week 40	207/ 314	65.92%	195/ 320	60.94%
Week 48	208/ 314	66.24%	188/ 320	58.75%
Week 52	256/ 314	81.53%	231/ 320	72.19%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute Mental Health Score
Full analysis set

Visit	Anifrolumab 300mg (N=315) n/ N#	Anifrolumab 300mg (N=315) Compliance	Placebo (N=321) n/ N#	Placebo (N=321) Compliance
Baseline	305/ 315	96.83%	307/ 321	95.64%
Week 4	68/ 315	21.59%	73/ 321	22.74%
Week 8	222/ 315	70.48%	224/ 321	69.78%
Week 12	66/ 314	21.02%	71/ 321	22.12%
Week 16	219/ 314	69.75%	218/ 321	67.91%
Week 24	276/ 314	87.90%	278/ 321	86.60%
Week 32	205/ 314	65.29%	194/ 321	60.44%
Week 36	62/ 314	19.75%	55/ 321	17.13%
Week 40	207/ 314	65.92%	195/ 320	60.94%
Week 48	208/ 314	66.24%	188/ 320	58.75%
Week 52	256/ 314	81.53%	231/ 320	72.19%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute Physical Functioning Score
Full analysis set

Visit	Anifrolumab 300mg (N=315) n/ N#	Anifrolumab 300mg (N=315) Compliance	Placebo (N=321) n/ N#	Placebo (N=321) Compliance
Baseline	305/ 315	96.83%	307/ 321	95.64%
Week 4	68/ 315	21.59%	73/ 321	22.74%
Week 8	222/ 315	70.48%	224/ 321	69.78%
Week 12	66/ 314	21.02%	71/ 321	22.12%
Week 16	219/ 314	69.75%	218/ 321	67.91%
Week 24	276/ 314	87.90%	278/ 321	86.60%
Week 32	205/ 314	65.29%	194/ 321	60.44%
Week 36	62/ 314	19.75%	55/ 321	17.13%
Week 40	207/ 314	65.92%	195/ 320	60.94%
Week 48	208/ 314	66.24%	188/ 320	58.75%
Week 52	256/ 314	81.53%	231/ 320	72.19%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute Role Emotional Score
Full analysis set

Visit	Anifrolumab 300mg (N=315) n/ N#	Anifrolumab 300mg (N=315) Compliance	Placebo (N=321) n/ N#	Placebo (N=321) Compliance
Baseline	305/ 315	96.83%	307/ 321	95.64%
Week 4	68/ 315	21.59%	73/ 321	22.74%
Week 8	222/ 315	70.48%	224/ 321	69.78%
Week 12	66/ 314	21.02%	71/ 321	22.12%
Week 16	219/ 314	69.75%	218/ 321	67.91%
Week 24	276/ 314	87.90%	278/ 321	86.60%
Week 32	205/ 314	65.29%	194/ 321	60.44%
Week 36	62/ 314	19.75%	55/ 321	17.13%
Week 40	207/ 314	65.92%	195/ 320	60.94%
Week 48	208/ 314	66.24%	188/ 320	58.75%
Week 52	256/ 314	81.53%	231/ 320	72.19%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute Role Physical Score
Full analysis set

Visit	Anifrolumab 300mg (N=315) n/ N#	Anifrolumab 300mg (N=315) Compliance	Placebo (N=321) n/ N#	Placebo (N=321) Compliance
Baseline	305/ 315	96.83%	307/ 321	95.64%
Week 4	68/ 315	21.59%	73/ 321	22.74%
Week 8	222/ 315	70.48%	224/ 321	69.78%
Week 12	66/ 314	21.02%	71/ 321	22.12%
Week 16	219/ 314	69.75%	218/ 321	67.91%
Week 24	276/ 314	87.90%	278/ 321	86.60%
Week 32	205/ 314	65.29%	194/ 321	60.44%
Week 36	62/ 314	19.75%	55/ 321	17.13%
Week 40	207/ 314	65.92%	195/ 320	60.94%
Week 48	208/ 314	66.24%	188/ 320	58.75%
Week 52	256/ 314	81.53%	231/ 320	72.19%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute Social Functioning Score
Full analysis set

Visit	Anifrolumab 300mg (N=315) n/ N#	Anifrolumab 300mg (N=315) Compliance	Placebo (N=321) n/ N#	Placebo (N=321) Compliance
Baseline	305/ 315	96.83%	307/ 321	95.64%
Week 4	68/ 315	21.59%	73/ 321	22.74%
Week 8	222/ 315	70.48%	224/ 321	69.78%
Week 12	66/ 314	21.02%	71/ 321	22.12%
Week 16	219/ 314	69.75%	218/ 321	67.91%
Week 24	276/ 314	87.90%	278/ 321	86.60%
Week 32	205/ 314	65.29%	194/ 321	60.44%
Week 36	62/ 314	19.75%	55/ 321	17.13%
Week 40	207/ 314	65.92%	195/ 320	60.94%
Week 48	208/ 314	66.24%	188/ 320	58.75%
Week 52	256/ 314	81.53%	231/ 320	72.19%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute Bodily Pain Score
Full analysis set

Visit	Anifrolumab 300mg (N=315) n/ N#	Anifrolumab 300mg (N=315) Compliance	Placebo (N=321) n/ N#	Placebo (N=321) Compliance
Baseline	305/ 315	96.83%	307/ 321	95.64%
Week 4	68/ 315	21.59%	73/ 321	22.74%
Week 8	222/ 315	70.48%	224/ 321	69.78%
Week 12	66/ 314	21.02%	71/ 321	22.12%
Week 16	219/ 314	69.75%	218/ 321	67.91%
Week 24	276/ 314	87.90%	278/ 321	86.60%
Week 32	205/ 314	65.29%	194/ 321	60.44%
Week 36	62/ 314	19.75%	55/ 321	17.13%
Week 40	207/ 314	65.92%	195/ 320	60.94%
Week 48	208/ 314	66.24%	188/ 320	58.75%
Week 52	256/ 314	81.53%	231/ 320	72.19%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SF-36 v2.0 Acute Vitality Score
Full analysis set

Visit	Anifrolumab 300mg (N=315) n/ N#	Anifrolumab 300mg (N=315) Compliance	Placebo (N=321) n/ N#	Placebo (N=321) Compliance
Baseline	305/ 315	96.83%	307/ 321	95.64%
Week 4	68/ 315	21.59%	73/ 321	22.74%
Week 8	222/ 315	70.48%	224/ 321	69.78%
Week 12	66/ 314	21.02%	71/ 321	22.12%
Week 16	219/ 314	69.75%	218/ 321	67.91%
Week 24	276/ 314	87.90%	278/ 321	86.60%
Week 32	205/ 314	65.29%	194/ 321	60.44%
Week 36	62/ 314	19.75%	55/ 321	17.13%
Week 40	207/ 314	65.92%	195/ 320	60.94%
Week 48	208/ 314	66.24%	188/ 320	58.75%
Week 52	256/ 314	81.53%	231/ 320	72.19%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - FACIT-F Total Score
Full analysis set

Visit	Anifrolumab 300mg (N=315) n/ N#	Anifrolumab 300mg (N=315) Compliance	Placebo (N=321) n/ N#	Placebo (N=321) Compliance
Baseline	301/ 315	95.56%	308/ 321	95.95%
Week 4	299/ 315	94.92%	306/ 321	95.33%
Week 8	223/ 315	70.79%	226/ 321	70.40%
Week 12	295/ 314	93.95%	290/ 321	90.34%
Week 16	221/ 314	70.38%	220/ 321	68.54%
Week 20	214/ 314	68.15%	216/ 321	67.29%
Week 24	278/ 314	88.54%	281/ 321	87.54%
Week 28	213/ 314	67.83%	208/ 321	64.80%
Week 32	211/ 314	67.20%	198/ 321	61.68%
Week 36	272/ 314	86.62%	250/ 321	77.88%
Week 40	211/ 314	67.20%	196/ 320	61.25%
Week 44	205/ 314	65.29%	190/ 320	59.38%
Week 48	210/ 314	66.88%	191/ 320	59.69%
Week 52	256/ 314	81.53%	232/ 320	72.50%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - EQ VAS Score
Full analysis set

Visit	Anifrolumab 300mg (N=315) n/ N#	Anifrolumab 300mg (N=315) Compliance	Placebo (N=321) n/ N#	Placebo (N=321) Compliance
Baseline	300/ 315	95.24%	308/ 321	95.95%
Week 4	68/ 315	21.59%	73/ 321	22.74%
Week 12	294/ 314	93.63%	289/ 321	90.03%
Week 24	276/ 314	87.90%	276/ 321	85.98%
Week 36	267/ 314	85.03%	248/ 321	77.26%
Week 52	254/ 314	80.89%	230/ 320	71.88%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Lupus QoL Physical Health domain score
Full analysis set

Visit	Anifrolumab 300mg (N=315) n/ N#	Anifrolumab 300mg (N=315) Compliance	Placebo (N=321) n/ N#	Placebo (N=321) Compliance
Baseline	300/ 315	95.24%	307/ 321	95.64%
Week 4	67/ 315	21.27%	72/ 321	22.43%
Week 12	293/ 314	93.31%	289/ 321	90.03%
Week 24	276/ 314	87.90%	274/ 321	85.36%
Week 36	267/ 314	85.03%	246/ 321	76.64%
Week 52	253/ 314	80.57%	229/ 320	71.56%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Lupus QoL Emotional Health domain score
Full analysis set

Visit	Anifrolumab 300mg (N=315) n/ N#	Anifrolumab 300mg (N=315) Compliance	Placebo (N=321) n/ N#	Placebo (N=321) Compliance
Baseline	300/ 315	95.24%	307/ 321	95.64%
Week 4	67/ 315	21.27%	72/ 321	22.43%
Week 12	293/ 314	93.31%	289/ 321	90.03%
Week 24	276/ 314	87.90%	274/ 321	85.36%
Week 36	267/ 314	85.03%	246/ 321	76.64%
Week 52	253/ 314	80.57%	229/ 320	71.56%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Lupus QoL Body Image domain score
Full analysis set

Visit	Anifrolumab 300mg (N=315) n/ N#	Anifrolumab 300mg (N=315) Compliance	Placebo (N=321) n/ N#	Placebo (N=321) Compliance
Baseline	284/ 315	90.16%	282/ 321	87.85%
Week 4	65/ 315	20.63%	63/ 321	19.63%
Week 12	271/ 314	86.31%	261/ 321	81.31%
Week 24	249/ 314	79.30%	246/ 321	76.64%
Week 36	238/ 314	75.80%	217/ 321	67.60%
Week 52	222/ 314	70.70%	200/ 320	62.50%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Lupus QoL Burden to Others domain score
Full analysis set

Visit	Anifrolumab 300mg (N=315) n/ N#	Anifrolumab 300mg (N=315) Compliance	Placebo (N=321) n/ N#	Placebo (N=321) Compliance
Baseline	300/ 315	95.24%	307/ 321	95.64%
Week 4	67/ 315	21.27%	72/ 321	22.43%
Week 12	293/ 314	93.31%	289/ 321	90.03%
Week 24	276/ 314	87.90%	274/ 321	85.36%
Week 36	267/ 314	85.03%	246/ 321	76.64%
Week 52	253/ 314	80.57%	229/ 320	71.56%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Lupus QoL Fatigue domain score
Full analysis set

Visit	Anifrolumab 300mg (N=315) n/ N#	Anifrolumab 300mg (N=315) Compliance	Placebo (N=321) n/ N#	Placebo (N=321) Compliance
Baseline	300/ 315	95.24%	307/ 321	95.64%
Week 4	67/ 315	21.27%	72/ 321	22.43%
Week 12	293/ 314	93.31%	289/ 321	90.03%
Week 24	276/ 314	87.90%	274/ 321	85.36%
Week 36	267/ 314	85.03%	246/ 321	76.64%
Week 52	253/ 314	80.57%	229/ 320	71.56%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Lupus QoL Intimate Relationships domain score
Full analysis set

Visit	Anifrolumab 300mg (N=315) n/ N#	Anifrolumab 300mg (N=315) Compliance	Placebo (N=321) n/ N#	Placebo (N=321) Compliance
Baseline	255/ 315	80.95%	252/ 321	78.50%
Week 4	59/ 315	18.73%	54/ 321	16.82%
Week 12	246/ 314	78.34%	232/ 321	72.27%
Week 24	219/ 314	69.75%	204/ 321	63.55%
Week 36	207/ 314	65.92%	175/ 321	54.52%
Week 52	187/ 314	59.55%	165/ 320	51.56%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Lupus QoL Pain domain score
Full analysis set

Visit	Anifrolumab 300mg (N=315) n/ N#	Anifrolumab 300mg (N=315) Compliance	Placebo (N=321) n/ N#	Placebo (N=321) Compliance
Baseline	300/ 315	95.24%	307/ 321	95.64%
Week 4	67/ 315	21.27%	72/ 321	22.43%
Week 12	293/ 314	93.31%	289/ 321	90.03%
Week 24	276/ 314	87.90%	274/ 321	85.36%
Week 36	267/ 314	85.03%	246/ 321	76.64%
Week 52	253/ 314	80.57%	229/ 320	71.56%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Lupus QoL Planning domain score
Full analysis set

Visit	Anifrolumab 300mg (N=315) n/ N#	Anifrolumab 300mg (N=315) Compliance	Placebo (N=321) n/ N#	Placebo (N=321) Compliance
Baseline	300/ 315	95.24%	307/ 321	95.64%
Week 4	67/ 315	21.27%	72/ 321	22.43%
Week 12	293/ 314	93.31%	289/ 321	90.03%
Week 24	276/ 314	87.90%	274/ 321	85.36%
Week 36	267/ 314	85.03%	246/ 321	76.64%
Week 52	253/ 314	80.57%	229/ 320	71.56%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - SDI Global Score
Full analysis set

	Anifrolumab 300mg (N=315)		Placebo (N=321)	
Visit	n/ N#	Compliance	n/ N#	Compliance
Baseline	309/ 315	98.10%	313/ 321	97.51%
Week 24	281/ 314	89.49%	280/ 321	87.23%
Week 52	254/ 314	80.89%	238/ 320	74.38%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - PtGA
Full analysis set

Visit	Anifrolumab 300mg (N=315) n/ N#	Anifrolumab 300mg (N=315) Compliance	Placebo (N=321) n/ N#	Placebo (N=321) Compliance
Baseline	301/ 315	95.56%	308/ 321	95.95%
Week 4	299/ 315	94.92%	307/ 321	95.64%
Week 8	287/ 315	91.11%	295/ 321	91.90%
Week 12	293/ 314	93.31%	289/ 321	90.03%
Week 16	287/ 314	91.40%	284/ 321	88.47%
Week 20	278/ 314	88.54%	280/ 321	87.23%
Week 24	276/ 314	87.90%	276/ 321	85.98%
Week 28	276/ 314	87.90%	266/ 321	82.87%
Week 32	271/ 314	86.31%	257/ 321	80.06%
Week 36	271/ 314	86.31%	248/ 321	77.26%
Week 40	272/ 314	86.62%	249/ 320	77.81%
Week 44	268/ 314	85.35%	239/ 320	74.69%
Week 48	270/ 314	85.99%	239/ 320	74.69%
Week 52	254/ 314	80.89%	230/ 320	71.88%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Total HAQ Score
Full analysis set

Visit	Anifrolumab 300mg (N=315) n/ N#	Anifrolumab 300mg (N=315) Compliance	Placebo (N=321) n/ N#	Placebo (N=321) Compliance
Baseline	69/ 315	21.90%	75/ 321	23.36%
Week 4	68/ 315	21.59%	73/ 321	22.74%
Week 12	66/ 314	21.02%	71/ 321	22.12%
Week 24	65/ 314	20.70%	64/ 321	19.94%
Week 36	62/ 314	19.75%	56/ 321	17.45%
Week 52	62/ 314	19.75%	50/ 320	15.63%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Compliance rates by timepoint - Pain Score
Full analysis set

Visit	Anifrolumab 300mg (N=315) n/ N#	Anifrolumab 300mg (N=315) Compliance	Placebo (N=321) n/ N#	Placebo (N=321) Compliance
Baseline	69/ 315	21.90%	75/ 321	23.36%
Week 4	68/ 315	21.59%	73/ 321	22.74%
Week 12	66/ 314	21.02%	71/ 321	22.12%
Week 24	65/ 314	20.70%	64/ 321	19.94%
Week 36	62/ 314	19.75%	56/ 321	17.45%
Week 52	62/ 314	19.75%	50/ 320	15.63%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Flare rate through Week 52
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=315) Number of flares	Anifrolumab 300mg (N=315) Total Follow-up time (years)	Anifrolumab 300mg (N=315) Annual rate (SE)	Placebo (N=321) Number of flares	Placebo (N=321) Total Follow-up time (years)	Placebo (N=321) Annual rate (SE)	Rate ratio (95% CI)	p-Value	Heterogenity/ Interaction p-Value
									0.8818
Overall	143	295.41	0.44 (0.12)	200	286.17	0.62 (0.12)	0.70 (0.53, 0.92)	0.0114	
SLEDAI-2K score									0.3683
< 10 points	42	102.29	0.39 (0.19)	44	91.30	0.48 (0.18)	0.82 (0.51, 1.33)	0.4217	
>= 10 points	101	193.11	0.47 (0.15)	156	194.87	0.73 (0.14)	0.64 (0.45, 0.90)	0.0112	
OCS dose									0.1286
<10 mg/day	68	139.41	0.48 (0.16)	76	131.27	0.55 (0.17)	0.86 (0.56, 1.32)	0.4913	
>=10 mg/day	75	155.99	0.38 (0.19)	124	154.90	0.66 (0.16)	0.58 (0.40, 0.83)	0.0029	
Result of type I IFN gene signature test									0.0023
LOW	35	56.87	0.59 (0.23)	22	58.86	0.30 (0.31)	1.99 (0.96, 4.17)	0.0661	
HIGH	108	238.53	0.42 (0.12)	178	227.32	0.73 (0.11)	0.57 (0.42, 0.77)	0.0003	
Age (years)									0.2418
<= 65	141	289.23	0.44 (0.12)	195	283.24	0.61 (0.12)	0.71 (0.54, 0.94)	0.0174	
> 65	2	6.18	NE	5	2.94	NE	NE		
Sex									0.2436
male	10	26.17	NE	24	25.21	NE	NE		
female	133	269.23	0.45 (0.12)	176	260.96	0.62 (0.12)	0.73 (0.54, 0.98)	0.0347	
Race									0.5920
White	83	175.31	0.44 (0.15)	127	183.25	0.60 (0.14)	0.73 (0.51, 1.06)	0.0950	
Black	30	44.34	0.72 (0.30)	28	38.09	0.80 (0.30)	0.90 (0.45, 1.80)	0.7640	
Other	28	69.07	0.29 (0.37)	44	61.79	0.54 (0.37)	0.53 (0.27, 1.03)	0.0593	
Ethnicity									0.9671
Hispanic/Latino	37	72.67	0.41 (0.25)	57	75.56	0.58 (0.25)	0.70 (0.40, 1.22)	0.2124	
Non-hispanic/Latino	104	216.05	0.42 (0.15)	142	207.56	0.64 (0.13)	0.66 (0.47, 0.92)	0.0137	
Geographic region									0.2796
EU	35	105.35	0.27 (0.26)	61	99.19	0.48 (0.25)	0.57 (0.35, 0.95)	0.0300	
non-EU	108	190.05	0.52 (0.13)	139	186.98	0.66 (0.13)	0.79 (0.57, 1.09)	0.1523	
Onset of disease									0.8255
Paediatric	18	25.08	0.75 (0.34)	19	18.71	1.07 (0.31)	0.70 (0.34, 1.45)	0.3368	
Adult	125	270.33	0.41 (0.13)	181	267.47	0.60 (0.12)	0.69 (0.51, 0.92)	0.0127	
ADA result									0.0359
Negative	135	275.26	0.45 (0.12)	167	262.49	0.59 (0.12)	0.77 (0.58, 1.03)	0.0778	
Positive (At any time)	8	20.15	0.14 (0.79)	33	23.69	0.49 (0.64)	0.28 (0.10, 0.84)	0.0223	
BMI (kg/m2)									0.2421
< 30	86	201.17	0.42 (0.15)	143	206.27	0.68 (0.15)	0.61 (0.44, 0.86)	0.0051	
>= 30	57	94.24	0.43 (0.21)	57	79.91	0.56 (0.18)	0.76 (0.47, 1.24)	0.2712	

Rates and rate ratio from negative binomial regression model with factors for treatment group and the stratification factors. The logarithm (to base e) of the follow-up time is used as an offset variable in the model to adjust for subjects having different exposure times.
Study*treatment interaction also included to assess heterogenity between studies.
p-Value for interaction from same negative binomial regression model with additional factors for subgroup and subgroup*treatment interaction.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Overall Survival
Full analysis set

	Anifrolumab 300mg (N=315)	Placebo (N=321)
Number of subjects with events, n (%)	1 (0.3)	1 (0.3)
Number of censored subjects, n (%)	314 (99.7)	320 (99.7)
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Anifrolumab 300mg vs. Placebo (adjusted)		
Hazard Ratio (95% CI)	0.92 (0.06, 14.74)	
p-value	0.9624	
Analysis Anifrolumab 300mg vs. Placebo (unadjusted)		
Hazard Ratio (95% CI)	0.98 (0.06, 15.73)	
p-value	0.9907	
p-Value for test for heterogenity between studies	1.0000	

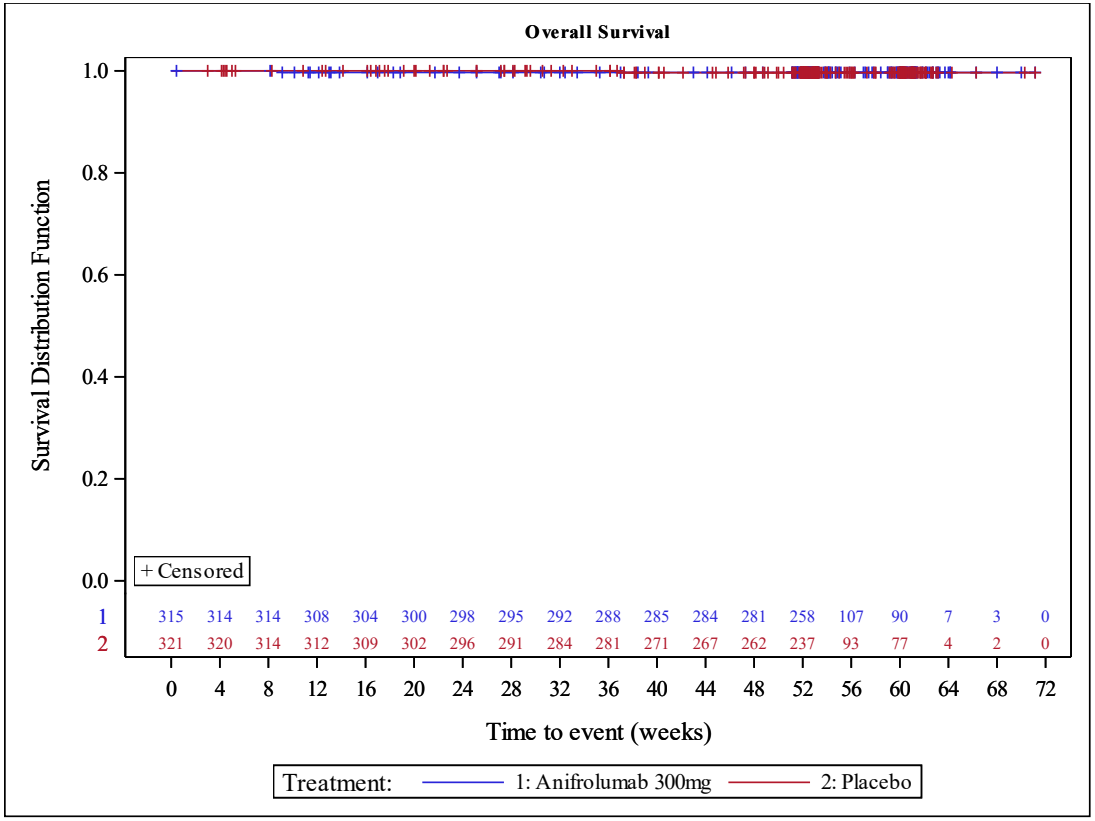
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model. Adjusted analysis also includes stratification factors in the model.
Two-sided log rank test used.
p-Value for heterogenity between studies from Cox proportional hazards model with factors for treatment, study, treatment*study interaction and stratfication factors.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unadjusted analysis also includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Overall Survival - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Anifrolumab 300mg (N=315) Median (95% CI)	Placebo (N=321) n/ N (%)	Placebo (N=321) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score							0.9988
< 10 points	1/109 (0.9)	NE (NE, NE)	0/101 (0.0)	NE (NE, NE)	NE		
>= 10 points	0/206 (0.0)	NE (NE, NE)	1/220 (0.5)	NE (NE, NE)	NE		
OCS dose							1.0000
<10 mg/day	0/148 (0.0)	NE (NE, NE)	0/145 (0.0)	NE (NE, NE)	NE		
>=10 mg/day	1/167 (0.6)	NE (NE, NE)	1/176 (0.6)	NE (NE, NE)	0.92 (0.06, 14.74)	0.9624	
Result of type I IFN gene signature test							1.0000
LOW	0/ 59 (0.0)	NE (NE, NE)	0/ 67 (0.0)	NE (NE, NE)	NE		
HIGH	1/256 (0.4)	NE (NE, NE)	1/254 (0.4)	NE (NE, NE)	0.92 (0.06, 14.74)	0.9624	
Age (years)							0.9998
<= 65	1/308 (0.3)	NE (NE, NE)	1/318 (0.3)	NE (NE, NE)	0.88 (0.05, 14.17)	0.9400	
> 65	0/ 7 (0.0)	NE (NE, NE)	0/ 3 (0.0)	NE (NE, NE)	NE		
Sex							1.0000
male	0/ 27 (0.0)	NE (NE, NE)	0/ 26 (0.0)	NE (NE, NE)	NE		
female	1/288 (0.3)	NE (NE, NE)	1/295 (0.3)	NE (NE, NE)	0.98 (0.06, 15.73)	0.9964	
Race							1.0000
White	0/185 (0.0)	NE (NE, NE)	0/205 (0.0)	NE (NE, NE)	NE		
Black	0/ 49 (0.0)	NE (NE, NE)	1/ 40 (2.5)	NE (NE, NE)	NE		
Other	1/ 73 (1.4)	NE (NE, NE)	0/ 73 (0.0)	NE (NE, NE)	NE		
Ethnicity							0.9992
Hispanic/Latino	1/ 78 (1.3)	NE (NE, NE)	0/ 84 (0.0)	NE (NE, NE)	NE		
Non-hispanic/Latino	0/229 (0.0)	NE (NE, NE)	1/234 (0.4)	NE (NE, NE)	NE		
Geographic region							1.0000
EU	0/110 (0.0)	NE (NE, NE)	0/109 (0.0)	NE (NE, NE)	NE		
non-EU	1/205 (0.5)	NE (NE, NE)	1/212 (0.5)	NE (NE, NE)	0.95 (0.06, 15.41)	0.9918	
Onset of disease							1.0000
Paediatric	0/ 26 (0.0)	NE (NE, NE)	0/ 21 (0.0)	NE (NE, NE)	NE		
Adult	1/289 (0.3)	NE (NE, NE)	1/300 (0.3)	NE (NE, NE)	0.95 (0.06, 15.25)	0.9791	
ADA result							1.0000
Negative	1/292 (0.3)	NE (NE, NE)	1/295 (0.3)	NE (NE, NE)	0.89 (0.05, 14.59)	0.9523	
Positive (At any time)	0/ 22 (0.0)	NE (NE, NE)	0/ 26 (0.0)	NE (NE, NE)	NE		
BMI (kg/m2)							0.9986
< 30	1/213 (0.5)	NE (NE, NE)	0/235 (0.0)	NE (NE, NE)	NE		
>= 30	0/102 (0.0)	NE (NE, NE)	1/ 86 (1.2)	NE (NE, NE)	NE		

Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of Overall Survival
Full analysis set



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Time to first Flare
Full analysis set

	Anifrolumab 300mg (N=315)	Placebo (N=321)
Number of subjects with events, n (%)	92 (29.2)	126 (39.3)
Number of censored subjects, n (%)	223 (70.8)	195 (60.7)
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	36.14 (28.14, 49.00)	20.43 (19.71, 27.86)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Anifrolumab 300mg vs. Placebo (adjusted)		
Hazard Ratio (95% CI)	0.66 (0.50, 0.86)	
p-value	0.0023	
Analysis Anifrolumab 300mg vs. Placebo (unadjusted)		
Hazard Ratio (95% CI)	0.66 (0.51, 0.87)	
p-value	0.0026	
p-Value for test for heterogenity between studies	0.7262	

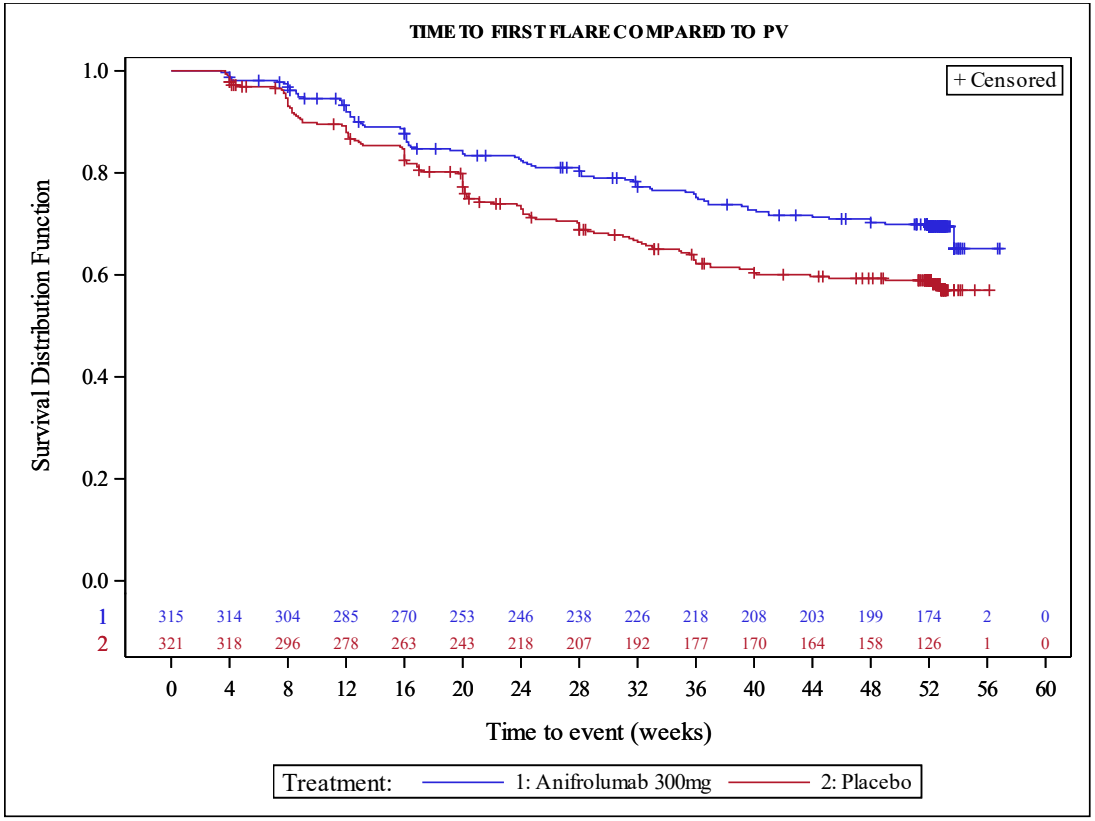
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model. Adjusted analysis also includes stratification factors in the model.
Two-sided log rank test used.
p-Value for heterogenity between studies from Cox proportional hazards model with factors for treatment, study, treatment*study interaction and stratfication factors.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unadjusted analysis also includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Time to first Flare - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Anifrolumab 300mg (N=315) Median (95% CI)	Placebo (N=321) n/ N (%)	Placebo (N=321) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score							0.4192
< 10 points	30/109 (27.5)	NE (53.71, NE)	34/101 (33.7)	NE (NE, NE)	0.76 (0.46, 1.25)	0.2112	
>= 10 points	62/206 (30.1)	NE (NE, NE)	92/220 (41.8)	NE (45.14, NE)	0.61 (0.44, 0.84)	0.0049	
OCS dose							0.0338
<10 mg/day	45/148 (30.4)	NE (NE, NE)	46/145 (31.7)	NE (NE, NE)	0.91 (0.60, 1.38)	0.7166	
>=10 mg/day	47/167 (28.1)	NE (NE, NE)	80/176 (45.5)	NE (33.14, NE)	0.50 (0.35, 0.73)	0.0002	
Result of type I IFN gene signature test							0.0247
LOW	20/ 59 (33.9)	NE (NE, NE)	18/ 67 (26.9)	NE (NE, NE)	1.26 (0.66, 2.39)	0.3529	
HIGH	72/256 (28.1)	NE (NE, NE)	108/254 (42.5)	NE (43.86, NE)	0.57 (0.43, 0.77)	0.0002	
Age (years)							0.5409
<= 65	90/308 (29.2)	NE (NE, NE)	124/318 (39.0)	NE (NE, NE)	0.66 (0.50, 0.86)	0.0027	
> 65	2/ 7 (28.6)	NE (12.00, NE)	2/ 3 (66.7)	19.71 (8.00, NE)	0.00 (0.00,)	<.0001	
Sex							0.7640
male	9/ 27 (33.3)	NE (35.86, NE)	13/ 26 (50.0)	52.86 (16.00, NE)	0.61 (0.25, 1.46)	0.0463	
female	83/288 (28.8)	NE (NE, NE)	113/295 (38.3)	NE (NE, NE)	0.67 (0.50, 0.89)	0.0046	
Race							0.7409
White	56/185 (30.3)	NE (NE, NE)	84/205 (41.0)	NE (49.00, NE)	0.64 (0.46, 0.90)	0.0067	
Black	17/ 49 (34.7)	NE (39.57, NE)	16/ 40 (40.0)	NE (33.14, NE)	0.90 (0.43, 1.89)	0.4812	
Other	17/ 73 (23.3)	NE (NE, NE)	25/ 73 (34.2)	NE (37.00, NE)	0.59 (0.31, 1.11)	0.2359	
Ethnicity							0.7922
Hispanic/Latino	23/ 78 (29.5)	NE (NE, NE)	34/ 84 (40.5)	NE (35.00, NE)	0.71 (0.42, 1.21)	0.2557	
Non-hispanic/Latino	67/229 (29.3)	NE (NE, NE)	91/234 (38.9)	NE (NE, NE)	0.64 (0.47, 0.88)	0.0043	
Geographic region							0.3116
EU	25/110 (22.7)	NE (53.71, NE)	40/109 (36.7)	NE (52.86, NE)	0.53 (0.32, 0.87)	0.0131	
non-EU	67/205 (32.7)	NE (NE, NE)	86/212 (40.6)	NE (52.29, NE)	0.72 (0.52, 0.99)	0.0218	
Onset of disease							0.7654
Paediatric	11/ 26 (42.3)	NE (25.00, NE)	11/ 21 (52.4)	37.00 (20.14, NE)	0.49 (0.19, 1.25)	0.0583	
Adult	81/289 (28.0)	NE (NE, NE)	115/300 (38.3)	NE (NE, NE)	0.65 (0.49, 0.87)	0.0040	
ADA result							0.1461
Negative	85/292 (29.1)	NE (NE, NE)	109/295 (36.9)	NE (NE, NE)	0.70 (0.53, 0.93)	0.0148	
Positive (At any time)	7/ 22 (31.8)	NE (28.14, NE)	17/ 26 (65.4)	27.93 (8.57, NE)	0.34 (0.13, 0.88)	0.0576	
BMI (kg/m2)							0.4894
< 30	57/213 (26.8)	NE (53.71, NE)	89/235 (37.9)	NE (NE, NE)	0.62 (0.44, 0.86)	0.0080	
>= 30	35/102 (34.3)	NE (NE, NE)	37/ 86 (43.0)	NE (35.86, NE)	0.70 (0.44, 1.13)	0.0534	

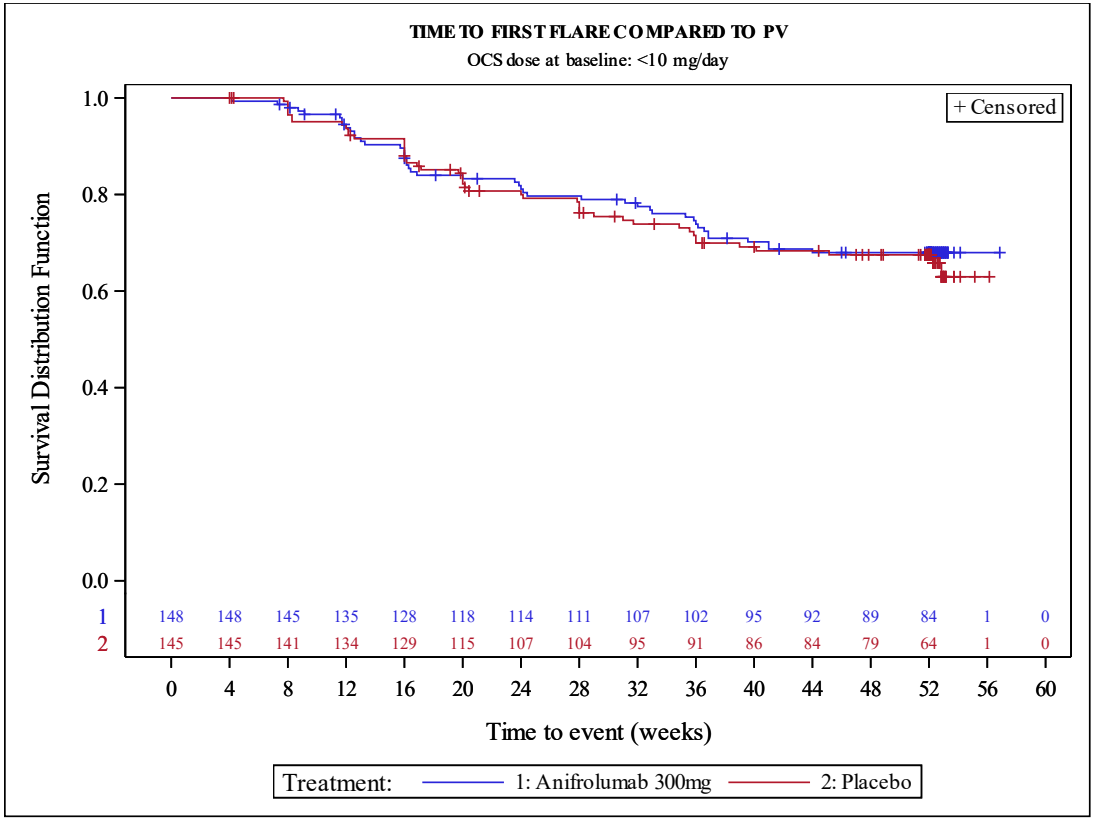
Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of Time to first Flare
Full analysis set



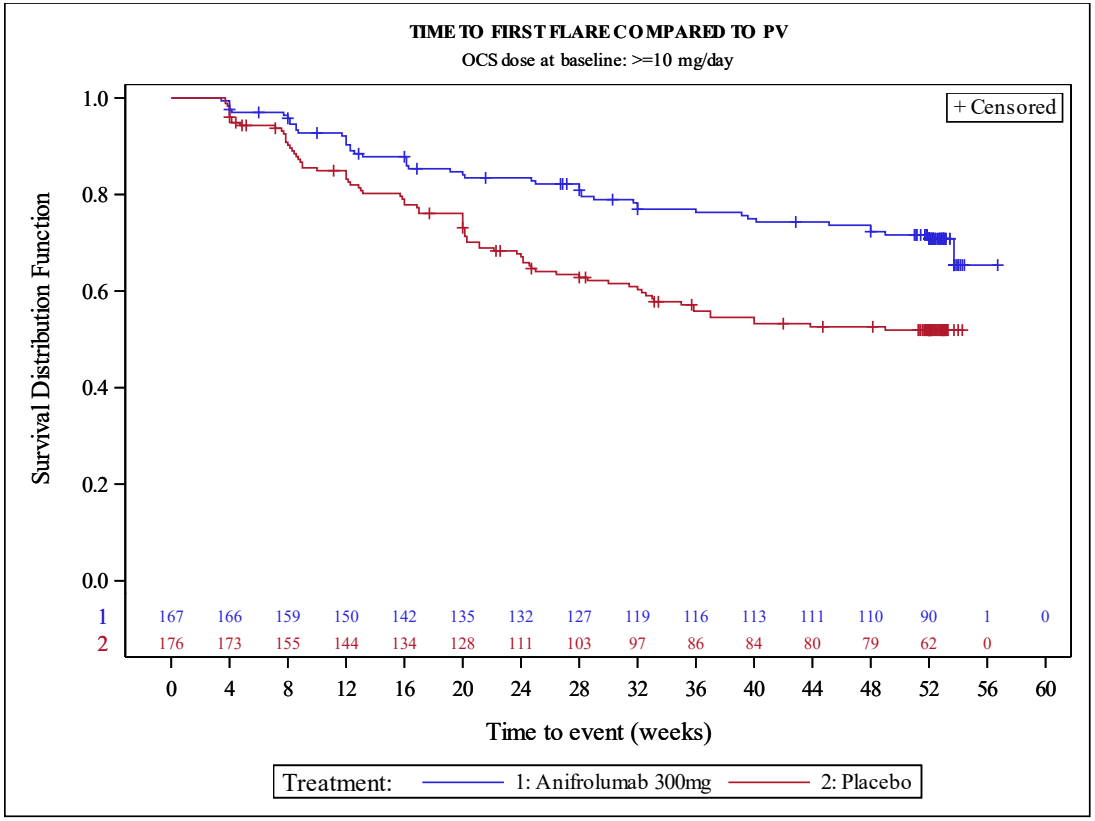
Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of Time to first Flare
Full analysis set



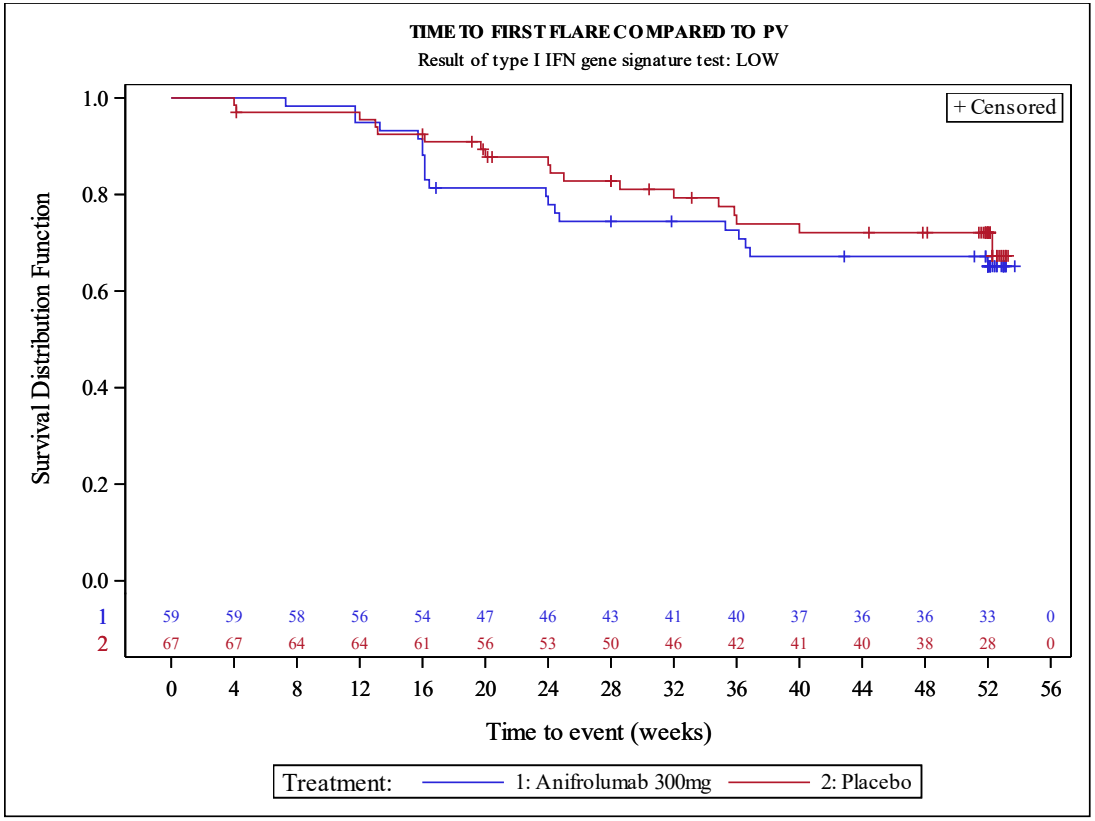
Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of Time to first Flare
Full analysis set



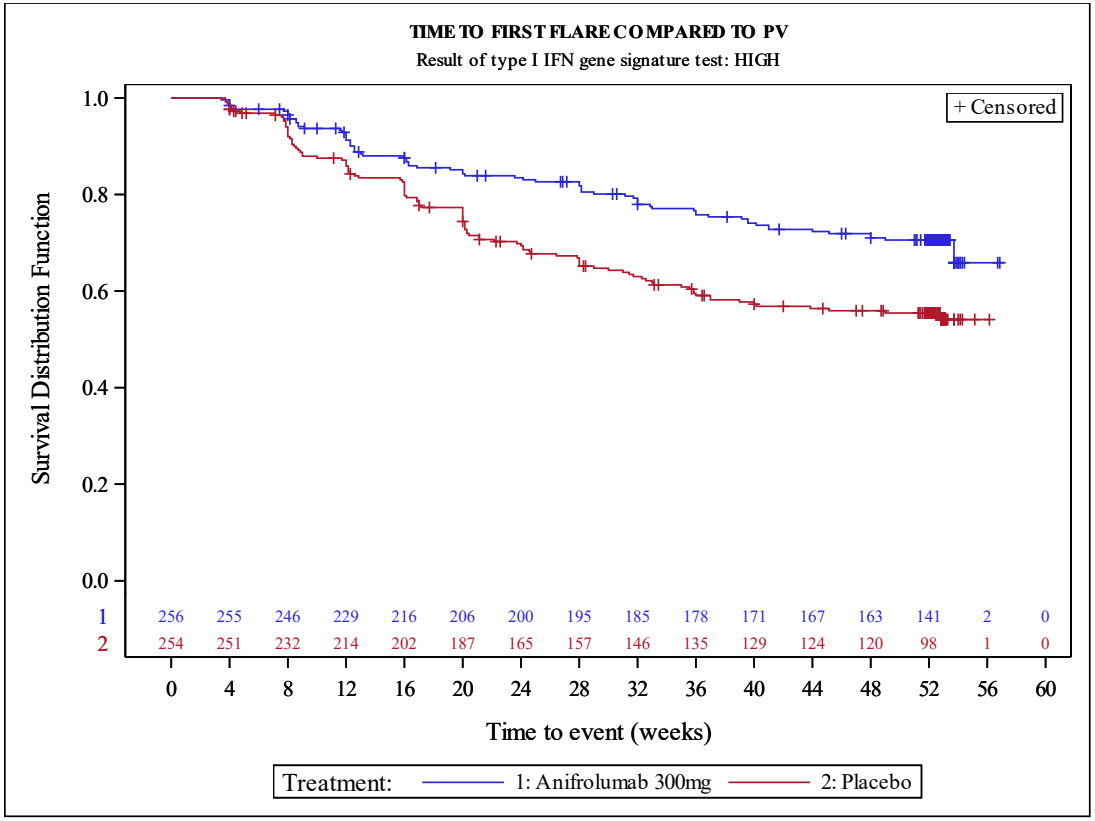
Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of Time to first Flare
Full analysis set



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of Time to first Flare
Full analysis set



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
OCS dose increases and cumulative OCS dose until week 52
Full analysis set

		Anifrolumab 300mg (N=315)	Placebo (N=321)	Total (N=636)
Number of dose increases (%)	0	231 (73.3)	211 (65.7)	442 (69.5)
	1	56 (17.8)	57 (17.8)	113 (17.8)
	2	17 (5.4)	26 (8.1)	43 (6.8)
	>2	11 (3.5)	27 (8.4)	38 (6.0)
Cumulative OCS Dose (mg/day)	n (missing)	307 (8)	312 (9)	619 (17)
	Mean (SD)	2542.7 (2656.02)	2818.2 (2143.98)	2681.6 (2413.54)
	Median	2261.0	2450.0	2292.5
	Min, Max	0, 35466	0, 10581	0, 35466
AUC up to Week 52 (mg/day)	n (missing)	307 (8)	312 (9)	619 (17)
	Mean (SD)	2788.2 (2818.78)	3239.9 (2596.58)	3015.9 (2716.29)
	Median	2441.1	2931.4	2677.8
	Min, Max	0, 35369	0, 21809	0, 35369

Subjects without any documented dose value regarded as missing values for calculation of cumulative dose and AUC.
AUC defines the cumulative dose normalized for a period of 52 weeks.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=315)	Placebo (N=321)
Number of subjects with events, n (%)	276 (87.6)	256 (79.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.09 (1.01, 1.16)	
p-value	0.0176	
Odds Ratio (95% CI)	1.77 (1.14, 2.74)	
p-value	0.0108	
Risk Difference (95% CI)	7.86 (2.14, 13.59)	
p-value	0.0071	
p-Value for test for heterogenity between studies	0.0751	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	 p-Value	Interaction p-Value
SLEDAI-2K score					0.3493
< 10 points	99/109 (90.8)	80/101 (79.2)	1.13 (1.01, 1.27)	0.0304	
>= 10 points	177/206 (85.9)	176/220 (80.0)	1.06 (0.97, 1.15)	0.2027	
OCS dose					0.0227
<10 mg/day	132/148 (89.2)	127/145 (87.6)	1.02 (0.94, 1.10)	0.6676	
>=10 mg/day	144/167 (86.2)	129/176 (73.3)	1.19 (1.07, 1.32)	0.0016	
Result of type I IFN gene signature test					0.1536
LOW	54/ 59 (91.5)	51/ 67 (76.1)	1.20 (1.04, 1.40)	0.0148	
HIGH	222/256 (86.7)	205/254 (80.7)	1.07 (0.99, 1.15)	0.0989	
Age (years)					0.1003
<= 65	271/308 (88.0)	253/318 (79.6)	1.09 (1.02, 1.17)	0.0111	
> 65	5/ 7 (71.4)	3/ 3 (100.0)	0.77 (0.50, 1.16)	0.2124	
Sex					0.7833
male	22/ 27 (81.5)	18/ 26 (69.2)	1.13 (0.82, 1.57)	0.4456	
female	254/288 (88.2)	238/295 (80.7)	1.08 (1.01, 1.16)	0.0248	
Race					0.2275
White	160/185 (86.5)	160/205 (78.0)	1.10 (1.00, 1.20)	0.0462	
Black	41/ 49 (83.7)	33/ 40 (82.5)	1.00 (0.83, 1.20)	0.9624	
Other	67/ 73 (91.8)	60/ 73 (82.2)	0.99 (0.92, 1.07)	0.8428	
Ethnicity					0.6054
Hispanic/Latino	70/ 78 (89.7)	66/ 84 (78.6)	1.11 (0.98, 1.25)	0.1013	
Non-hispanic/Latino	198/229 (86.5)	187/234 (79.9)	1.07 (0.98, 1.16)	0.1294	
Geographic region					0.1080
EU	91/110 (82.7)	73/109 (67.0)	1.19 (1.02, 1.38)	0.0227	
non-EU	185/205 (90.2)	183/212 (86.3)	1.04 (0.97, 1.11)	0.2538	
Onset of disease					0.1696
Paediatric	23/ 26 (88.5)	18/ 21 (85.7)	0.97 (0.83, 1.13)	0.6974	
Adult	253/289 (87.5)	238/300 (79.3)	1.09 (1.02, 1.17)	0.0164	
ADA result					0.8987
Negative	256/292 (87.7)	233/295 (79.0)	1.10 (1.02, 1.18)	0.0099	
Positive (At any time)	20/ 22 (90.9)	23/ 26 (88.5)	1.13 (0.79, 1.61)	0.5136	
BMI (kg/m2)					0.7508
< 30	184/213 (86.4)	183/235 (77.9)	1.09 (1.00, 1.18)	0.0559	
>= 30	92/102 (90.2)	73/ 86 (84.9)	1.06 (0.95, 1.19)	0.2922	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Serious Adverse Event
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=315)	Placebo (N=321)
Number of subjects with events, n (%)	38 (12.1)	61 (19.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.66 (0.45, 0.96)	
p-value	0.0318	
Odds Ratio (95% CI)	0.60 (0.38, 0.94)	
p-value	0.0243	
Risk Difference (95% CI)	-6.85 (-12.45, -1.24)	
p-value	0.0167	
p-Value for test for heterogenity between studies	0.1393	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Serious Adverse Event - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.3036
< 10 points	10/109 (9.2)	10/101 (9.9)	0.99 (0.43, 2.32)	0.9853	
>= 10 points	28/206 (13.6)	51/220 (23.2)	0.60 (0.40, 0.92)	0.0191	
OCS dose					0.7897
<10 mg/day	18/148 (12.2)	26/145 (17.9)	0.69 (0.39, 1.23)	0.2128	
>=10 mg/day	20/167 (12.0)	35/176 (19.9)	0.62 (0.38, 1.04)	0.0687	
Result of type I IFN gene signature test					0.1239
LOW	8/ 59 (13.6)	7/ 67 (10.4)	1.26 (0.50, 3.21)	0.6238	
HIGH	30/256 (11.7)	54/254 (21.3)	0.57 (0.38, 0.86)	0.0070	
Age (years)					0.3239
<= 65	36/308 (11.7)	61/318 (19.2)	0.63 (0.43, 0.93)	0.0201	
> 65	2/ 7 (28.6)	0/ 3 (0.0)	2.50 (0.17, 37.26)	0.5062	
Sex					0.8123
male	2/ 27 (7.4)	5/ 26 (19.2)	0.59 (0.15, 2.27)	0.4403	
female	36/288 (12.5)	56/295 (19.0)	0.70 (0.47, 1.03)	0.0717	
Race					0.3260
White	20/185 (10.8)	34/205 (16.6)	0.66 (0.39, 1.10)	0.1115	
Black	5/ 49 (10.2)	11/ 40 (27.5)	0.37 (0.14, 0.98)	0.0447	
Other	11/ 73 (15.1)	16/ 73 (21.9)	0.94 (0.45, 1.98)	0.8785	
Ethnicity					0.2346
Hispanic/Latino	12/ 78 (15.4)	19/ 84 (22.6)	1.01 (0.48, 2.12)	0.9866	
Non-hispanic/Latino	24/229 (10.5)	42/234 (17.9)	0.59 (0.37, 0.94)	0.0274	
Geographic region					0.8516
EU	12/110 (10.9)	18/109 (16.5)	0.66 (0.33, 1.32)	0.2368	
non-EU	26/205 (12.7)	43/212 (20.3)	0.71 (0.44, 1.14)	0.1598	
Onset of disease					0.7953
Paediatric	4/ 26 (15.4)	6/ 21 (28.6)	0.58 (0.18, 1.84)	0.3572	
Adult	34/289 (11.8)	55/300 (18.3)	0.68 (0.46, 1.03)	0.0671	
ADA result					0.3121
Negative	36/292 (12.3)	51/295 (17.3)	0.73 (0.49, 1.09)	0.1277	
Positive (At any time)	2/ 22 (9.1)	10/ 26 (38.5)	0.36 (0.10, 1.35)	0.1306	
BMI (kg/m2)					0.8776
< 30	26/213 (12.2)	44/235 (18.7)	0.67 (0.43, 1.05)	0.0802	
>= 30	12/102 (11.8)	17/ 86 (19.8)	0.63 (0.31, 1.28)	0.2001	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Severe Adverse Event
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=315)	Placebo (N=321)
Number of subjects with events, n (%)	33 (10.5)	32 (10.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.09 (0.69, 1.74)	
p-value	0.7075	
Odds Ratio (95% CI)	1.08 (0.63, 1.83)	
p-value	0.7883	
Risk Difference (95% CI)	0.64 (-4.03, 5.30)	
p-value	0.7898	
p-Value for test for heterogenity between studies	0.1211	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Severe Adverse Event - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.5969
< 10 points	12/109 (11.0)	7/101 (6.9)	1.24 (0.44, 3.53)	0.6842	
>= 10 points	21/206 (10.2)	25/220 (11.4)	0.90 (0.53, 1.55)	0.7154	
OCS dose					0.8540
<10 mg/day	13/148 (8.8)	10/145 (6.9)	0.94 (0.37, 2.41)	0.9017	
>=10 mg/day	20/167 (12.0)	22/176 (12.5)	1.04 (0.60, 1.83)	0.8789	
Result of type I IFN gene signature test					0.5064
LOW	8/ 59 (13.6)	4/ 67 (6.0)	1.46 (0.41, 5.27)	0.5587	
HIGH	25/256 (9.8)	28/254 (11.0)	0.92 (0.55, 1.53)	0.7435	
Age (years)					NE
<= 65	33/308 (10.7)	32/318 (10.1)	1.11 (0.69, 1.76)	0.6739	
> 65	0/ 7 (0.0)	0/ 3 (0.0)	NE		
Sex					0.9084
male	2/ 27 (7.4)	2/ 26 (7.7)	0.99 (0.19, 5.22)	0.9897	
female	31/288 (10.8)	30/295 (10.2)	1.10 (0.68, 1.77)	0.7095	
Race					0.3494
White	14/185 (7.6)	20/205 (9.8)	0.94 (0.48, 1.85)	0.8579	
Black	8/ 49 (16.3)	6/ 40 (15.0)	0.60 (0.20, 1.76)	0.3521	
Other	9/ 73 (12.3)	6/ 73 (8.2)	1.68 (0.67, 4.23)	0.2721	
Ethnicity					0.9250
Hispanic/Latino	12/ 78 (15.4)	13/ 84 (15.5)	1.11 (0.51, 2.42)	0.7833	
Non-hispanic/Latino	19/229 (8.3)	19/234 (8.1)	1.06 (0.58, 1.97)	0.8450	
Geographic region					0.8318
EU	9/110 (8.2)	9/109 (8.3)	0.99 (0.40, 2.44)	0.9805	
non-EU	24/205 (11.7)	23/212 (10.8)	1.11 (0.61, 2.01)	0.7268	
Onset of disease					0.6577
Paediatric	4/ 26 (15.4)	4/ 21 (19.0)	0.77 (0.16, 3.68)	0.7392	
Adult	29/289 (10.0)	28/300 (9.3)	1.11 (0.68, 1.82)	0.6762	
ADA result					0.4047
Negative	30/292 (10.3)	27/295 (9.2)	1.18 (0.72, 1.94)	0.5051	
Positive (At any time)	3/ 22 (13.6)	5/ 26 (19.2)	0.67 (0.20, 2.31)	0.5286	
BMI (kg/m2)					0.2418
< 30	22/213 (10.3)	21/235 (8.9)	1.20 (0.68, 2.09)	0.5280	
>= 30	11/102 (10.8)	11/ 86 (12.8)	0.65 (0.28, 1.53)	0.3242	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Non-Severe Adverse Event
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=315)	Placebo (N=321)
Number of subjects with events, n (%)	272 (86.3)	253 (78.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.08 (1.01, 1.16)	
p-value	0.0278	
Odds Ratio (95% CI)	1.69 (1.11, 2.57)	
p-value	0.0151	
Risk Difference (95% CI)	7.55 (1.68, 13.42)	
p-value	0.0117	
p-Value for test for heterogenity between studies	0.1320	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Non-Severe Adverse Event - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	 p-Value	Interaction p-Value
SLEDAI-2K score					0.5503
< 10 points	97/109 (89.0)	80/101 (79.2)	1.11 (0.99, 1.25)	0.0795	
>= 10 points	175/206 (85.0)	173/220 (78.6)	1.06 (0.97, 1.16)	0.1977	
OCS dose					0.0225
<10 mg/day	131/148 (88.5)	127/145 (87.6)	1.01 (0.93, 1.09)	0.8130	
>=10 mg/day	141/167 (84.4)	126/176 (71.6)	1.18 (1.06, 1.32)	0.0030	
Result of type I IFN gene signature test					0.1472
LOW	54/ 59 (91.5)	51/ 67 (76.1)	1.20 (1.04, 1.40)	0.0148	
HIGH	218/256 (85.2)	202/254 (79.5)	1.06 (0.98, 1.15)	0.1314	
Age (years)					0.1042
<= 65	267/308 (86.7)	250/318 (78.6)	1.09 (1.01, 1.17)	0.0185	
> 65	5/ 7 (71.4)	3/ 3 (100.0)	0.77 (0.50, 1.16)	0.2124	
Sex					0.7657
male	22/ 27 (81.5)	18/ 26 (69.2)	1.13 (0.82, 1.57)	0.4456	
female	250/288 (86.8)	235/295 (79.7)	1.08 (1.00, 1.16)	0.0399	
Race					0.1284
White	159/185 (85.9)	157/205 (76.6)	1.11 (1.01, 1.22)	0.0335	
Black	39/ 49 (79.6)	33/ 40 (82.5)	0.95 (0.78, 1.16)	0.6371	
Other	66/ 73 (90.4)	60/ 73 (82.2)	0.99 (0.92, 1.06)	0.7376	
Ethnicity					0.4790
Hispanic/Latino	69/ 78 (88.5)	65/ 84 (77.4)	1.12 (0.98, 1.28)	0.0970	
Non-hispanic/Latino	195/229 (85.2)	185/234 (79.1)	1.06 (0.97, 1.15)	0.2063	
Geographic region					0.0890
EU	90/110 (81.8)	71/109 (65.1)	1.19 (1.02, 1.39)	0.0240	
non-EU	182/205 (88.8)	182/212 (85.8)	1.03 (0.96, 1.11)	0.4053	
Onset of disease					0.1911
Paediatric	23/ 26 (88.5)	17/ 21 (81.0)	0.96 (0.81, 1.13)	0.6373	
Adult	249/289 (86.2)	236/300 (78.7)	1.08 (1.01, 1.17)	0.0315	
ADA result					0.8196
Negative	253/292 (86.6)	231/295 (78.3)	1.10 (1.02, 1.18)	0.0152	
Positive (At any time)	19/ 22 (86.4)	22/ 26 (84.6)	1.16 (0.74, 1.80)	0.5214	
BMI (kg/m2)					0.6587
< 30	181/213 (85.0)	180/235 (76.6)	1.08 (0.99, 1.18)	0.0701	
>= 30	91/102 (89.2)	73/ 86 (84.9)	1.05 (0.94, 1.18)	0.3976	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event leading to discontinuation of study drug
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=315)	Placebo (N=321)
Number of subjects with events, n (%)	13 (4.1)	20 (6.2)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.69 (0.32, 1.46)	
p-value	0.3258	
Odds Ratio (95% CI)	0.67 (0.30, 1.47)	
p-value	0.3174	
Risk Difference (95% CI)	-2.09 (-5.54, 1.35)	
p-value	0.2336	
p-Value for test for heterogenity between studies	0.0704	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event leading to discontinuation of study drug - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.4154
< 10 points	4/109 (3.7)	3/101 (3.0)	1.29 (0.23, 7.41)	0.7723	
>= 10 points	9/206 (4.4)	17/220 (7.7)	0.58 (0.26, 1.32)	0.1941	
OCS dose					0.9531
<10 mg/day	5/148 (3.4)	8/145 (5.5)	0.69 (0.21, 2.31)	0.5488	
>=10 mg/day	8/167 (4.8)	12/176 (6.8)	0.72 (0.27, 1.96)	0.5260	
Result of type I IFN gene signature test					0.8536
LOW	3/ 59 (5.1)	4/ 67 (6.0)	0.77 (0.16, 3.56)	0.7339	
HIGH	10/256 (3.9)	16/254 (6.3)	0.65 (0.28, 1.48)	0.3064	
Age (years)					0.5788
<= 65	12/308 (3.9)	20/318 (6.3)	0.64 (0.30, 1.38)	0.2579	
> 65	1/ 7 (14.3)	0/ 3 (0.0)	1.50 (0.08, 26.86)	0.7830	
Sex					NE
male	0/ 27 (0.0)	0/ 26 (0.0)	NE		
female	13/288 (4.5)	20/295 (6.8)	0.69 (0.32, 1.46)	0.3320	
Race					0.5765
White	8/185 (4.3)	13/205 (6.3)	0.72 (0.28, 1.84)	0.4937	
Black	2/ 49 (4.1)	0/ 40 (0.0)	1.76 (0.19, 15.93)	0.6147	
Other	2/ 73 (2.7)	7/ 73 (9.6)	0.42 (0.09, 1.95)	0.2686	
Ethnicity					0.2288
Hispanic/Latino	2/ 78 (2.6)	9/ 84 (10.7)	0.30 (0.08, 1.18)	0.0855	
Non-hispanic/Latino	10/229 (4.4)	11/234 (4.7)	0.89 (0.29, 2.74)	0.8401	
Geographic region					0.5658
EU	5/110 (4.5)	5/109 (4.6)	0.94 (0.25, 3.55)	0.9296	
non-EU	8/205 (3.9)	15/212 (7.1)	0.59 (0.23, 1.48)	0.2589	
Onset of disease					0.7871
Paediatric	1/ 26 (3.8)	2/ 21 (9.5)	0.49 (0.06, 3.95)	0.5006	
Adult	12/289 (4.2)	18/300 (6.0)	0.67 (0.28, 1.61)	0.3664	
ADA result					0.9862
Negative	11/292 (3.8)	16/295 (5.4)	0.67 (0.29, 1.55)	0.3457	
Positive (At any time)	2/ 22 (9.1)	4/ 26 (15.4)	0.68 (0.17, 2.65)	0.5741	
BMI (kg/m2)					0.8733
< 30	11/213 (5.2)	17/235 (7.2)	0.74 (0.34, 1.60)	0.4405	
>= 30	2/102 (2.0)	3/ 86 (3.5)	0.63 (0.11, 3.65)	0.6060	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Serious Adverse Event leading to discontinuation of study drug
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=315)	Placebo (N=321)
Number of subjects with events, n (%)	7 (2.2)	11 (3.4)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.70 (0.25, 1.98)	
p-value	0.5035	
Odds Ratio (95% CI)	0.69 (0.24, 2.00)	
p-value	0.4995	
Risk Difference (95% CI)	-1.18 (-3.75, 1.39)	
p-value	0.3684	
p-Value for test for heterogenity between studies	0.2422	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Serious Adverse Event leading to discontinuation of study drug - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.0832
< 10 points	3/109 (2.8)	0/101 (0.0)	6.65 (0.36, 124.51)	0.2050	
>= 10 points	4/206 (1.9)	11/220 (5.0)	0.41 (0.13, 1.29)	0.1287	
OCS dose					0.3143
<10 mg/day	3/148 (2.0)	1/145 (0.7)	1.81 (0.32, 10.26)	0.5024	
>=10 mg/day	4/167 (2.4)	10/176 (5.7)	0.61 (0.17, 2.10)	0.4288	
Result of type I IFN gene signature test					0.3116
LOW	1/ 59 (1.7)	0/ 67 (0.0)	3.26 (0.14, 76.10)	0.4621	
HIGH	6/256 (2.3)	11/254 (4.3)	0.59 (0.21, 1.68)	0.3209	
Age (years)					0.5697
<= 65	6/308 (1.9)	11/318 (3.5)	0.62 (0.21, 1.77)	0.3669	
> 65	1/ 7 (14.3)	0/ 3 (0.0)	1.50 (0.08, 26.86)	0.7830	
Sex					NE
male	0/ 27 (0.0)	0/ 26 (0.0)	NE		
female	7/288 (2.4)	11/295 (3.7)	0.70 (0.25, 1.98)	0.5051	
Race					0.7033
White	5/185 (2.7)	7/205 (3.4)	0.80 (0.22, 2.93)	0.7382	
Black	1/ 49 (2.0)	0/ 40 (0.0)	1.59 (0.07, 35.15)	0.7697	
Other	1/ 73 (1.4)	4/ 73 (5.5)	0.41 (0.08, 2.21)	0.2972	
Ethnicity					0.3501
Hispanic/Latino	1/ 78 (1.3)	5/ 84 (6.0)	0.39 (0.07, 2.09)	0.2731	
Non-hispanic/Latino	6/229 (2.6)	6/234 (2.6)	1.05 (0.31, 3.58)	0.9323	
Geographic region					0.6185
EU	2/110 (1.8)	5/109 (4.6)	0.50 (0.11, 2.30)	0.3727	
non-EU	5/205 (2.4)	6/212 (2.8)	0.83 (0.22, 3.11)	0.7871	
Onset of disease					0.9433
Paediatric	1/ 26 (3.8)	1/ 21 (4.8)	0.67 (0.08, 5.78)	0.7142	
Adult	6/289 (2.1)	10/300 (3.3)	0.73 (0.22, 2.43)	0.6088	
ADA result					0.5895
Negative	7/292 (2.4)	8/295 (2.7)	0.69 (0.21, 2.29)	0.5418	
Positive (At any time)	0/ 22 (0.0)	3/ 26 (11.5)	0.35 (0.04, 2.91)	0.3326	
BMI (kg/m2)					0.8971
< 30	6/213 (2.8)	10/235 (4.3)	0.70 (0.24, 2.01)	0.5056	
>= 30	1/102 (1.0)	1/ 86 (1.2)	0.82 (0.09, 7.74)	0.8647	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with Adverse Event leading to death
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=315)	Placebo (N=321)
Number of subjects with events, n (%)	1 (0.3)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	2.95 (0.12, 71.81)	
p-value	0.5060	
Odds Ratio (95% CI)	2.98 (0.12, 73.76)	
p-value	0.5055	
Risk Difference (95% CI)	0.31 (-0.30, 0.93)	
p-value	0.3208	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with Adverse Event leading to death - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					NE
< 10 points	1/109 (0.9)	0/101 (0.0)	2.85 (0.12, 67.83)	0.5172	
>= 10 points	0/206 (0.0)	0/220 (0.0)	NE		
OCS dose					NE
<10 mg/day	0/148 (0.0)	0/145 (0.0)	NE		
>=10 mg/day	1/167 (0.6)	0/176 (0.0)	3.13 (0.13, 75.49)	0.4828	
Result of type I IFN gene signature test					NE
LOW	0/ 59 (0.0)	0/ 67 (0.0)	NE		
HIGH	1/256 (0.4)	0/254 (0.0)	2.89 (0.12, 70.05)	0.5147	
Age (years)					NE
<= 65	1/308 (0.3)	0/318 (0.0)	3.02 (0.12, 73.52)	0.4966	
> 65	0/ 7 (0.0)	0/ 3 (0.0)	NE		
Sex					NE
male	0/ 27 (0.0)	0/ 26 (0.0)	NE		
female	1/288 (0.3)	0/295 (0.0)	3.05 (0.13, 74.15)	0.4931	
Race					NE
White	0/185 (0.0)	0/205 (0.0)	NE		
Black	0/ 49 (0.0)	0/ 40 (0.0)	NE		
Other	1/ 73 (1.4)	0/ 73 (0.0)	2.29 (0.10, 52.48)	0.6051	
Ethnicity					NE
Hispanic/Latino	1/ 78 (1.3)	0/ 84 (0.0)	3.13 (0.13, 73.01)	0.4785	
Non-hispanic/Latino	0/229 (0.0)	0/234 (0.0)	NE		
Geographic region					NE
EU	0/110 (0.0)	0/109 (0.0)	NE		
non-EU	1/205 (0.5)	0/212 (0.0)	2.59 (0.11, 62.63)	0.5577	
Onset of disease					NE
Paediatric	0/ 26 (0.0)	0/ 21 (0.0)	NE		
Adult	1/289 (0.3)	0/300 (0.0)	2.98 (0.12, 72.30)	0.5030	
ADA result					NE
Negative	1/292 (0.3)	0/295 (0.0)	3.03 (0.12, 73.51)	0.4962	
Positive (At any time)	0/ 22 (0.0)	0/ 26 (0.0)	NE		
BMI (kg/m2)					NE
< 30	1/213 (0.5)	0/235 (0.0)	3.52 (0.15, 85.13)	0.4388	
>= 30	0/102 (0.0)	0/ 86 (0.0)	NE		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Herpes Zoster
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=315)	Placebo (N=321)
Number of subjects with events, n (%)	18 (5.7)	6 (1.9)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.04 (1.22, 7.59)	
p-value	0.0171	
Odds Ratio (95% CI)	3.17 (1.24, 8.15)	
p-value	0.0163	
Risk Difference (95% CI)	3.88 (0.91, 6.84)	
p-value	0.0103	
p-Value for test for heterogenity between studies	0.8943	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Herpes Zoster - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.2515
< 10 points	3/109 (2.8)	2/101 (2.0)	1.28 (0.25, 6.67)	0.7671	
>= 10 points	15/206 (7.3)	4/220 (1.8)	4.07 (1.38, 12.05)	0.0112	
OCS dose					0.7126
<10 mg/day	8/148 (5.4)	3/145 (2.1)	2.49 (0.65, 9.60)	0.1853	
>=10 mg/day	10/167 (6.0)	3/176 (1.7)	3.53 (0.98, 12.74)	0.0539	
Result of type I IFN gene signature test					0.8972
LOW	3/ 59 (5.1)	1/ 67 (1.5)	2.44 (0.38, 15.92)	0.3500	
HIGH	15/256 (5.9)	5/254 (2.0)	2.81 (1.02, 7.74)	0.0453	
Age (years)					NE
<= 65	18/308 (5.8)	6/318 (1.9)	3.07 (1.23, 7.67)	0.0161	
> 65	0/ 7 (0.0)	0/ 3 (0.0)	NE		
Sex					0.6651
male	4/ 27 (14.8)	0/ 26 (0.0)	3.62 (0.64, 20.46)	0.1451	
female	14/288 (4.9)	6/295 (2.0)	2.34 (0.90, 6.08)	0.0808	
Race					0.6467
White	9/185 (4.9)	4/205 (2.0)	2.52 (0.79, 8.07)	0.1191	
Black	1/ 49 (2.0)	1/ 40 (2.5)	0.92 (0.10, 8.27)	0.9399	
Other	6/ 73 (8.2)	1/ 73 (1.4)	3.23 (0.67, 15.68)	0.1452	
Ethnicity					0.6785
Hispanic/Latino	5/ 78 (6.4)	1/ 84 (1.2)	3.48 (0.56, 21.66)	0.1807	
Non-hispanic/Latino	11/229 (4.8)	5/234 (2.1)	2.23 (0.78, 6.38)	0.1345	
Geographic region					0.8095
EU	6/110 (5.5)	2/109 (1.8)	2.57 (0.60, 10.95)	0.2023	
non-EU	12/205 (5.9)	4/212 (1.9)	3.22 (1.06, 9.80)	0.0399	
Onset of disease					0.4677
Paediatric	3/ 26 (11.5)	1/ 21 (4.8)	1.44 (0.26, 8.12)	0.6778	
Adult	15/289 (5.2)	5/300 (1.7)	3.03 (1.10, 8.32)	0.0316	
ADA result					0.4678
Negative	15/292 (5.1)	6/295 (2.0)	2.48 (0.97, 6.38)	0.0592	
Positive (At any time)	3/ 22 (13.6)	0/ 26 (0.0)	5.66 (0.76, 42.38)	0.0917	
BMI (kg/m2)					0.5472
< 30	13/213 (6.1)	4/235 (1.7)	3.41 (1.11, 10.46)	0.0316	
>= 30	5/102 (4.9)	2/ 86 (2.3)	1.92 (0.42, 8.66)	0.3971	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Herpes Zoster
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=315)	Placebo (N=321)
Number of subjects with events, n (%)	1 (0.3)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.26 (0.13, 78.65)	
p-value	0.4673	
Odds Ratio (95% CI)	3.31 (0.13, 82.53)	
p-value	0.4663	
Risk Difference (95% CI)	0.33 (-0.30, 0.96)	
p-value	0.3089	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Herpes Zoster - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
SLEDAI-2K score				NE
< 10 points	0/109 (0.0)	0/101 (0.0)	NE	
>= 10 points	1/206 (0.5)	0/220 (0.0)	3.22 (0.13, 76.82) 0.4700	
OCS dose				NE
<10 mg/day	1/148 (0.7)	0/145 (0.0)	2.56 (0.11, 60.44) 0.5603	
>=10 mg/day	0/167 (0.0)	0/176 (0.0)	NE	
Result of type I IFN gene signature test				NE
LOW	0/ 59 (0.0)	0/ 67 (0.0)	NE	
HIGH	1/256 (0.4)	0/254 (0.0)	3.05 (0.13, 73.38) 0.4913	
Age (years)				NE
<= 65	1/308 (0.3)	0/318 (0.0)	3.26 (0.13, 78.65) 0.4673	
> 65	0/ 7 (0.0)	0/ 3 (0.0)	NE	
Sex				NE
male	0/ 27 (0.0)	0/ 26 (0.0)	NE	
female	1/288 (0.3)	0/295 (0.0)	3.18 (0.13, 76.73) 0.4760	
Race				NE
White	0/185 (0.0)	0/205 (0.0)	NE	
Black	1/ 49 (2.0)	0/ 40 (0.0)	1.59 (0.07, 35.15) 0.7697	
Other	0/ 73 (0.0)	0/ 73 (0.0)	NE	
Ethnicity				NE
Hispanic/Latino	0/ 78 (0.0)	0/ 84 (0.0)	NE	
Non-hispanic/Latino	1/229 (0.4)	0/234 (0.0)	3.43 (0.14, 81.93) 0.4467	
Geographic region				NE
EU	0/110 (0.0)	0/109 (0.0)	NE	
non-EU	1/205 (0.5)	0/212 (0.0)	3.23 (0.13, 77.56) 0.4696	
Onset of disease				NE
Paediatric	0/ 26 (0.0)	0/ 21 (0.0)	NE	
Adult	1/289 (0.3)	0/300 (0.0)	3.19 (0.13, 76.88) 0.4749	
ADA result				NE
Negative	1/292 (0.3)	0/295 (0.0)	3.27 (0.14, 78.87) 0.4659	
Positive (At any time)	0/ 22 (0.0)	0/ 26 (0.0)	NE	
BMI (kg/m2)				NE
< 30	1/213 (0.5)	0/235 (0.0)	3.27 (0.14, 78.67) 0.4649	
>= 30	0/102 (0.0)	0/ 86 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Herpes Zoster
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=315)	Placebo (N=321)
Number of subjects with events, n (%)	1 (0.3)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.26 (0.13, 78.65)	
p-value	0.4673	
Odds Ratio (95% CI)	3.31 (0.13, 82.53)	
p-value	0.4663	
Risk Difference (95% CI)	0.33 (-0.30, 0.96)	
p-value	0.3089	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Herpes Zoster - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
SLEDAI-2K score				NE
< 10 points	0/109 (0.0)	0/101 (0.0)	NE	
>= 10 points	1/206 (0.5)	0/220 (0.0)	3.22 (0.13, 76.82) 0.4700	
OCS dose				NE
<10 mg/day	1/148 (0.7)	0/145 (0.0)	2.56 (0.11, 60.44) 0.5603	
>=10 mg/day	0/167 (0.0)	0/176 (0.0)	NE	
Result of type I IFN gene signature test				NE
LOW	0/ 59 (0.0)	0/ 67 (0.0)	NE	
HIGH	1/256 (0.4)	0/254 (0.0)	3.05 (0.13, 73.38) 0.4913	
Age (years)				NE
<= 65	1/308 (0.3)	0/318 (0.0)	3.26 (0.13, 78.65) 0.4673	
> 65	0/ 7 (0.0)	0/ 3 (0.0)	NE	
Sex				NE
male	0/ 27 (0.0)	0/ 26 (0.0)	NE	
female	1/288 (0.3)	0/295 (0.0)	3.18 (0.13, 76.73) 0.4760	
Race				NE
White	0/185 (0.0)	0/205 (0.0)	NE	
Black	1/ 49 (2.0)	0/ 40 (0.0)	1.59 (0.07, 35.15) 0.7697	
Other	0/ 73 (0.0)	0/ 73 (0.0)	NE	
Ethnicity				NE
Hispanic/Latino	0/ 78 (0.0)	0/ 84 (0.0)	NE	
Non-hispanic/Latino	1/229 (0.4)	0/234 (0.0)	3.43 (0.14, 81.93) 0.4467	
Geographic region				NE
EU	0/110 (0.0)	0/109 (0.0)	NE	
non-EU	1/205 (0.5)	0/212 (0.0)	3.23 (0.13, 77.56) 0.4696	
Onset of disease				NE
Paediatric	0/ 26 (0.0)	0/ 21 (0.0)	NE	
Adult	1/289 (0.3)	0/300 (0.0)	3.19 (0.13, 76.88) 0.4749	
ADA result				NE
Negative	1/292 (0.3)	0/295 (0.0)	3.27 (0.14, 78.87) 0.4659	
Positive (At any time)	0/ 22 (0.0)	0/ 26 (0.0)	NE	
BMI (kg/m2)				NE
< 30	1/213 (0.5)	0/235 (0.0)	3.27 (0.14, 78.67) 0.4649	
>= 30	0/102 (0.0)	0/ 86 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Herpes Zoster
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=315)	Placebo (N=321)
Number of subjects with events, n (%)	17 (5.4)	6 (1.9)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	2.85 (1.13, 7.18)	
p-value	0.0266	
Odds Ratio (95% CI)	2.96 (1.14, 7.67)	
p-value	0.0256	
Risk Difference (95% CI)	3.55 (0.65, 6.45)	
p-value	0.0166	
p-Value for test for heterogenity between studies	0.8432	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Herpes Zoster - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.2829
< 10 points	3/109 (2.8)	2/101 (2.0)	1.28 (0.25, 6.67)	0.7671	
>= 10 points	14/206 (6.8)	4/220 (1.8)	3.79 (1.27, 11.33)	0.0169	
OCS dose					0.6122
<10 mg/day	7/148 (4.7)	3/145 (2.1)	2.16 (0.54, 8.72)	0.2779	
>=10 mg/day	10/167 (6.0)	3/176 (1.7)	3.53 (0.98, 12.74)	0.0539	
Result of type I IFN gene signature test					0.9579
LOW	3/ 59 (5.1)	1/ 67 (1.5)	2.44 (0.38, 15.92)	0.3500	
HIGH	14/256 (5.5)	5/254 (2.0)	2.59 (0.93, 7.23)	0.0695	
Age (years)					NE
<= 65	17/308 (5.5)	6/318 (1.9)	2.88 (1.14, 7.26)	0.0251	
> 65	0/ 7 (0.0)	0/ 3 (0.0)	NE		
Sex					0.6069
male	4/ 27 (14.8)	0/ 26 (0.0)	3.62 (0.64, 20.46)	0.1451	
female	13/288 (4.5)	6/295 (2.0)	2.15 (0.81, 5.68)	0.1223	
Race					0.5915
White	9/185 (4.9)	4/205 (2.0)	2.52 (0.79, 8.07)	0.1191	
Black	0/ 49 (0.0)	1/ 40 (2.5)	0.53 (0.02, 11.93)	0.6879	
Other	6/ 73 (8.2)	1/ 73 (1.4)	3.23 (0.67, 15.68)	0.1452	
Ethnicity					0.6171
Hispanic/Latino	5/ 78 (6.4)	1/ 84 (1.2)	3.48 (0.56, 21.66)	0.1807	
Non-hispanic/Latino	10/229 (4.4)	5/234 (2.1)	2.03 (0.70, 5.89)	0.1918	
Geographic region					0.8876
EU	6/110 (5.5)	2/109 (1.8)	2.57 (0.60, 10.95)	0.2023	
non-EU	11/205 (5.4)	4/212 (1.9)	2.93 (0.95, 9.08)	0.0621	
Onset of disease					0.5015
Paediatric	3/ 26 (11.5)	1/ 21 (4.8)	1.44 (0.26, 8.12)	0.6778	
Adult	14/289 (4.8)	5/300 (1.7)	2.87 (1.04, 7.92)	0.0419	
ADA result					0.4277
Negative	14/292 (4.8)	6/295 (2.0)	2.29 (0.87, 6.03)	0.0936	
Positive (At any time)	3/ 22 (13.6)	0/ 26 (0.0)	5.66 (0.76, 42.38)	0.0917	
BMI (kg/m2)					0.6228
< 30	12/213 (5.6)	4/235 (1.7)	3.09 (0.98, 9.72)	0.0542	
>= 30	5/102 (4.9)	2/ 86 (2.3)	1.92 (0.42, 8.66)	0.3971	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Herpes Zoster leading to discontinuation of study drug
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=315)	Placebo (N=321)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Herpes Zoster leading to discontinuation of study drug - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
SLEDAI-2K score				NE
< 10 points	0/109 (0.0)	0/101 (0.0)	NE	
>= 10 points	0/206 (0.0)	0/220 (0.0)	NE	
OCS dose				NE
<10 mg/day	0/148 (0.0)	0/145 (0.0)	NE	
>=10 mg/day	0/167 (0.0)	0/176 (0.0)	NE	
Result of type I IFN gene signature test				NE
LOW	0/ 59 (0.0)	0/ 67 (0.0)	NE	
HIGH	0/256 (0.0)	0/254 (0.0)	NE	
Age (years)				NE
<= 65	0/308 (0.0)	0/318 (0.0)	NE	
> 65	0/ 7 (0.0)	0/ 3 (0.0)	NE	
Sex				NE
male	0/ 27 (0.0)	0/ 26 (0.0)	NE	
female	0/288 (0.0)	0/295 (0.0)	NE	
Race				NE
White	0/185 (0.0)	0/205 (0.0)	NE	
Black	0/ 49 (0.0)	0/ 40 (0.0)	NE	
Other	0/ 73 (0.0)	0/ 73 (0.0)	NE	
Ethnicity				NE
Hispanic/Latino	0/ 78 (0.0)	0/ 84 (0.0)	NE	
Non-hispanic/Latino	0/229 (0.0)	0/234 (0.0)	NE	
Geographic region				NE
EU	0/110 (0.0)	0/109 (0.0)	NE	
non-EU	0/205 (0.0)	0/212 (0.0)	NE	
Onset of disease				NE
Paediatric	0/ 26 (0.0)	0/ 21 (0.0)	NE	
Adult	0/289 (0.0)	0/300 (0.0)	NE	
ADA result				NE
Negative	0/292 (0.0)	0/295 (0.0)	NE	
Positive (At any time)	0/ 22 (0.0)	0/ 26 (0.0)	NE	
BMI (kg/m2)				NE
< 30	0/213 (0.0)	0/235 (0.0)	NE	
>= 30	0/102 (0.0)	0/ 86 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Influenza
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=315)	Placebo (N=321)
Number of subjects with events, n (%)	7 (2.2)	9 (2.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.81 (0.30, 2.21)	
p-value	0.6818	
Odds Ratio (95% CI)	0.81 (0.29, 2.27)	
p-value	0.6816	
Risk Difference (95% CI)	-0.55 (-2.97, 1.88)	
p-value	0.6600	
p-Value for test for heterogenity between studies	0.5841	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Influenza - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.9160
< 10 points	3/109 (2.8)	3/101 (3.0)	0.95 (0.20, 4.50)	0.9491	
>= 10 points	4/206 (1.9)	6/220 (2.7)	0.85 (0.21, 3.50)	0.8208	
OCS dose					0.2522
<10 mg/day	3/148 (2.0)	7/145 (4.8)	0.51 (0.12, 2.24)	0.3759	
>=10 mg/day	4/167 (2.4)	2/176 (1.1)	1.84 (0.37, 9.14)	0.4583	
Result of type I IFN gene signature test					0.8261
LOW	1/ 59 (1.7)	2/ 67 (3.0)	0.67 (0.09, 5.23)	0.7029	
HIGH	6/256 (2.3)	7/254 (2.8)	0.87 (0.29, 2.60)	0.8036	
Age (years)					NE
<= 65	7/308 (2.3)	9/318 (2.8)	0.82 (0.30, 2.23)	0.6929	
> 65	0/ 7 (0.0)	0/ 3 (0.0)	NE		
Sex					0.5834
male	0/ 27 (0.0)	1/ 26 (3.8)	0.36 (0.02, 8.04)	0.5200	
female	7/288 (2.4)	8/295 (2.7)	0.90 (0.32, 2.50)	0.8406	
Race					0.6010
White	2/185 (1.1)	3/205 (1.5)	0.80 (0.16, 4.08)	0.7861	
Black	0/ 49 (0.0)	2/ 40 (5.0)	0.34 (0.04, 3.10)	0.3381	
Other	4/ 73 (5.5)	3/ 73 (4.1)	1.38 (0.28, 6.86)	0.6930	
Ethnicity					0.1661
Hispanic/Latino	4/ 78 (5.1)	2/ 84 (2.4)	2.08 (0.38, 11.52)	0.4023	
Non-hispanic/Latino	2/229 (0.9)	6/234 (2.6)	0.42 (0.09, 1.87)	0.2521	
Geographic region					0.7740
EU	2/110 (1.8)	3/109 (2.8)	0.66 (0.13, 3.36)	0.6203	
non-EU	5/205 (2.4)	6/212 (2.8)	0.89 (0.26, 3.07)	0.8592	
Onset of disease					NE
Paediatric	0/ 26 (0.0)	0/ 21 (0.0)	NE		
Adult	7/289 (2.4)	9/300 (3.0)	0.83 (0.30, 2.26)	0.7165	
ADA result					0.5545
Negative	6/292 (2.1)	8/295 (2.7)	0.76 (0.26, 2.17)	0.6046	
Positive (At any time)	1/ 22 (4.5)	1/ 26 (3.8)	1.53 (0.19, 12.34)	0.6886	
BMI (kg/m2)					0.5077
< 30	6/213 (2.8)	6/235 (2.6)	1.04 (0.35, 3.12)	0.9390	
>= 30	1/102 (1.0)	3/ 86 (3.5)	0.51 (0.09, 3.07)	0.4654	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Influenza
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=315)	Placebo (N=321)
Number of subjects with events, n (%)	2 (0.6)	1 (0.3)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.46 (0.16, 13.12)	
p-value	0.7332	
Odds Ratio (95% CI)	1.47 (0.16, 13.45)	
p-value	0.7326	
Risk Difference (95% CI)	0.34 (-0.74, 1.43)	
p-value	0.5340	
p-Value for test for heterogenity between studies	0.2158	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Influenza - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.5823
< 10 points	1/109 (0.9)	0/101 (0.0)	3.30 (0.14, 77.95)	0.4593	
>= 10 points	1/206 (0.5)	1/220 (0.5)	1.11 (0.12, 10.52)	0.9269	
OCS dose					0.4873
<10 mg/day	1/148 (0.7)	1/145 (0.7)	0.98 (0.10, 9.25)	0.9877	
>=10 mg/day	1/167 (0.6)	0/176 (0.0)	3.89 (0.16, 92.82)	0.4011	
Result of type I IFN gene signature test					NE
LOW	0/ 59 (0.0)	0/ 67 (0.0)	NE		
HIGH	2/256 (0.8)	1/254 (0.4)	1.41 (0.16, 12.63)	0.7571	
Age (years)					NE
<= 65	2/308 (0.6)	1/318 (0.3)	1.47 (0.16, 13.17)	0.7305	
> 65	0/ 7 (0.0)	0/ 3 (0.0)	NE		
Sex					NE
male	0/ 27 (0.0)	0/ 26 (0.0)	NE		
female	2/288 (0.7)	1/295 (0.3)	1.44 (0.16, 12.91)	0.7437	
Race					0.1918
White	0/185 (0.0)	1/205 (0.5)	0.35 (0.01, 8.37)	0.5143	
Black	0/ 49 (0.0)	0/ 40 (0.0)	NE		
Other	2/ 73 (2.7)	0/ 73 (0.0)	6.38 (0.32, 127.77)	0.2256	
Ethnicity					0.2287
Hispanic/Latino	2/ 78 (2.6)	0/ 84 (0.0)	5.00 (0.25, 99.67)	0.2918	
Non-hispanic/Latino	0/229 (0.0)	1/234 (0.4)	0.34 (0.01, 8.26)	0.5084	
Geographic region					NE
EU	0/110 (0.0)	0/109 (0.0)	NE		
non-EU	2/205 (1.0)	1/212 (0.5)	1.57 (0.18, 14.01)	0.6864	
Onset of disease					NE
Paediatric	0/ 26 (0.0)	0/ 21 (0.0)	NE		
Adult	2/289 (0.7)	1/300 (0.3)	1.49 (0.17, 13.31)	0.7227	
ADA result					0.5664
Negative	1/292 (0.3)	1/295 (0.3)	1.03 (0.11, 9.79)	0.9807	
Positive (At any time)	1/ 22 (4.5)	0/ 26 (0.0)	3.00 (0.17, 53.71)	0.4554	
BMI (kg/m2)					0.2006
< 30	2/213 (0.9)	0/235 (0.0)	5.45 (0.27, 111.13)	0.2700	
>= 30	0/102 (0.0)	1/ 86 (1.2)	0.31 (0.01, 7.45)	0.4735	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Influenza
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=315)	Placebo (N=321)
Number of subjects with events, n (%)	1 (0.3)	1 (0.3)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.05 (0.11, 10.03)	
p-value	0.9641	
Odds Ratio (95% CI)	1.05 (0.11, 10.21)	
p-value	0.9653	
Risk Difference (95% CI)	0.02 (-0.86, 0.90)	
p-value	0.9720	
p-Value for test for heterogenity between studies	0.3251	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Influenza - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
SLEDAI-2K score				NE
< 10 points	0/109 (0.0)	0/101 (0.0)	NE	
>= 10 points	1/206 (0.5)	1/220 (0.5)	1.11 (0.12, 10.52) 0.9269	
OCS dose				NE
<10 mg/day	1/148 (0.7)	1/145 (0.7)	0.98 (0.10, 9.25) 0.9877	
>=10 mg/day	0/167 (0.0)	0/176 (0.0)	NE	
Result of type I IFN gene signature test				NE
LOW	0/ 59 (0.0)	0/ 67 (0.0)	NE	
HIGH	1/256 (0.4)	1/254 (0.4)	1.02 (0.11, 9.66) 0.9881	
Age (years)				NE
<= 65	1/308 (0.3)	1/318 (0.3)	1.06 (0.11, 10.07) 0.9612	
> 65	0/ 7 (0.0)	0/ 3 (0.0)	NE	
Sex				NE
male	0/ 27 (0.0)	0/ 26 (0.0)	NE	
female	1/288 (0.3)	1/295 (0.3)	1.04 (0.11, 9.87) 0.9748	
Race				0.2943
White	0/185 (0.0)	1/205 (0.5)	0.35 (0.01, 8.37) 0.5143	
Black	0/ 49 (0.0)	0/ 40 (0.0)	NE	
Other	1/ 73 (1.4)	0/ 73 (0.0)	3.83 (0.16, 90.53) 0.4056	
Ethnicity				0.3423
Hispanic/Latino	1/ 78 (1.3)	0/ 84 (0.0)	3.00 (0.13, 70.64) 0.4955	
Non-hispanic/Latino	0/229 (0.0)	1/234 (0.4)	0.34 (0.01, 8.26) 0.5084	
Geographic region				NE
EU	0/110 (0.0)	0/109 (0.0)	NE	
non-EU	1/205 (0.5)	1/212 (0.5)	1.13 (0.12, 10.75) 0.9132	
Onset of disease				NE
Paediatric	0/ 26 (0.0)	0/ 21 (0.0)	NE	
Adult	1/289 (0.3)	1/300 (0.3)	1.07 (0.11, 10.19) 0.9522	
ADA result				NE
Negative	1/292 (0.3)	1/295 (0.3)	1.03 (0.11, 9.79) 0.9807	
Positive (At any time)	0/ 22 (0.0)	0/ 26 (0.0)	NE	
BMI (kg/m2)				0.3060
< 30	1/213 (0.5)	0/235 (0.0)	3.27 (0.14, 78.67) 0.4649	
>= 30	0/102 (0.0)	1/ 86 (1.2)	0.31 (0.01, 7.45) 0.4735	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Influenza
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=315)	Placebo (N=321)
Number of subjects with events, n (%)	7 (2.2)	8 (2.5)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.91 (0.33, 2.52)	
p-value	0.8522	
Odds Ratio (95% CI)	0.90 (0.32, 2.59)	
p-value	0.8516	
Risk Difference (95% CI)	-0.23 (-2.59, 2.12)	
p-value	0.8462	
p-Value for test for heterogenity between studies	0.6926	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Influenza - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.9942
< 10 points	3/109 (2.8)	3/101 (3.0)	0.95 (0.20, 4.50)	0.9491	
>= 10 points	4/206 (1.9)	5/220 (2.3)	0.96 (0.23, 4.00)	0.9533	
OCS dose					0.2945
<10 mg/day	3/148 (2.0)	6/145 (4.1)	0.57 (0.13, 2.51)	0.4581	
>=10 mg/day	4/167 (2.4)	2/176 (1.1)	1.84 (0.37, 9.14)	0.4583	
Result of type I IFN gene signature test					0.7301
LOW	1/ 59 (1.7)	2/ 67 (3.0)	0.67 (0.09, 5.23)	0.7029	
HIGH	6/256 (2.3)	6/254 (2.4)	1.01 (0.33, 3.12)	0.9825	
Age (years)					NE
<= 65	7/308 (2.3)	8/318 (2.5)	0.91 (0.33, 2.54)	0.8638	
> 65	0/ 7 (0.0)	0/ 3 (0.0)	NE		
Sex					0.5314
male	0/ 27 (0.0)	1/ 26 (3.8)	0.36 (0.02, 8.04)	0.5200	
female	7/288 (2.4)	7/295 (2.4)	1.03 (0.36, 2.92)	0.9597	
Race					0.5846
White	2/185 (1.1)	2/205 (1.0)	1.11 (0.20, 6.35)	0.9027	
Black	0/ 49 (0.0)	2/ 40 (5.0)	0.34 (0.04, 3.10)	0.3381	
Other	4/ 73 (5.5)	3/ 73 (4.1)	1.38 (0.28, 6.86)	0.6930	
Ethnicity					0.2118
Hispanic/Latino	4/ 78 (5.1)	2/ 84 (2.4)	2.08 (0.38, 11.52)	0.4023	
Non-hispanic/Latino	2/229 (0.9)	5/234 (2.1)	0.48 (0.10, 2.22)	0.3487	
Geographic region					0.6534
EU	2/110 (1.8)	3/109 (2.8)	0.66 (0.13, 3.36)	0.6203	
non-EU	5/205 (2.4)	5/212 (2.4)	1.06 (0.30, 3.78)	0.9239	
Onset of disease					NE
Paediatric	0/ 26 (0.0)	0/ 21 (0.0)	NE		
Adult	7/289 (2.4)	8/300 (2.7)	0.93 (0.33, 2.58)	0.8869	
ADA result					0.6337
Negative	6/292 (2.1)	7/295 (2.4)	0.87 (0.29, 2.54)	0.7929	
Positive (At any time)	1/ 22 (4.5)	1/ 26 (3.8)	1.53 (0.19, 12.34)	0.6886	
BMI (kg/m2)					0.6436
< 30	6/213 (2.8)	6/235 (2.6)	1.04 (0.35, 3.12)	0.9390	
>= 30	1/102 (1.0)	2/ 86 (2.3)	0.63 (0.10, 3.91)	0.6214	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Tuberculosis (including latent TB)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=315)	Placebo (N=321)
Number of subjects with events, n (%)	3 (1.0)	2 (0.6)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.45 (0.28, 7.43)	
p-value	0.6593	
Odds Ratio (95% CI)	1.45 (0.28, 7.59)	
p-value	0.6610	
Risk Difference (95% CI)	0.35 (-1.03, 1.73)	
p-value	0.6151	
p-Value for test for heterogenity between studies	0.5619	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.7798
< 10 points	1/109 (0.9)	1/101 (1.0)	0.93 (0.10, 8.70)	0.9479	
>= 10 points	2/206 (1.0)	1/220 (0.5)	1.45 (0.16, 12.92)	0.7390	
OCS dose					0.3794
<10 mg/day	2/148 (1.4)	0/145 (0.0)	2.93 (0.31, 27.58)	0.3478	
>=10 mg/day	1/167 (0.6)	2/176 (1.1)	0.74 (0.09, 5.93)	0.7798	
Result of type I IFN gene signature test					NE
LOW	0/ 59 (0.0)	0/ 67 (0.0)	NE		
HIGH	3/256 (1.2)	2/254 (0.8)	1.39 (0.27, 7.13)	0.6919	
Age (years)					NE
<= 65	3/308 (1.0)	2/318 (0.6)	1.46 (0.28, 7.49)	0.6520	
> 65	0/ 7 (0.0)	0/ 3 (0.0)	NE		
Sex					NE
male	0/ 27 (0.0)	0/ 26 (0.0)	NE		
female	3/288 (1.0)	2/295 (0.7)	1.44 (0.28, 7.39)	0.6629	
Race					0.6028
White	1/185 (0.5)	1/205 (0.5)	1.08 (0.11, 10.31)	0.9443	
Black	0/ 49 (0.0)	0/ 40 (0.0)	NE		
Other	2/ 73 (2.7)	1/ 73 (1.4)	2.57 (0.25, 26.94)	0.4307	
Ethnicity					0.8059
Hispanic/Latino	1/ 78 (1.3)	1/ 84 (1.2)	1.00 (0.07, 15.21)	1.0000	
Non-hispanic/Latino	2/229 (0.9)	1/234 (0.4)	1.51 (0.24, 9.48)	0.6605	
Geographic region					0.6174
EU	1/110 (0.9)	1/109 (0.9)	0.94 (0.10, 8.85)	0.9560	
non-EU	2/205 (1.0)	1/212 (0.5)	2.16 (0.20, 23.07)	0.5250	
Onset of disease					NE
Paediatric	0/ 26 (0.0)	0/ 21 (0.0)	NE		
Adult	3/289 (1.0)	2/300 (0.7)	1.45 (0.28, 7.47)	0.6533	
ADA result					NE
Negative	3/292 (1.0)	2/295 (0.7)	1.44 (0.28, 7.38)	0.6639	
Positive (At any time)	0/ 22 (0.0)	0/ 26 (0.0)	NE		
BMI (kg/m2)					0.5600
< 30	2/213 (0.9)	1/235 (0.4)	2.19 (0.20, 23.42)	0.5183	
>= 30	1/102 (1.0)	1/ 86 (1.2)	0.83 (0.09, 7.79)	0.8690	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Tuberculosis (including latent TB)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=315)	Placebo (N=321)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
SLEDAI-2K score				NE
< 10 points	0/109 (0.0)	0/101 (0.0)	NE	
>= 10 points	0/206 (0.0)	0/220 (0.0)	NE	
OCS dose				NE
<10 mg/day	0/148 (0.0)	0/145 (0.0)	NE	
>=10 mg/day	0/167 (0.0)	0/176 (0.0)	NE	
Result of type I IFN gene signature test				NE
LOW	0/ 59 (0.0)	0/ 67 (0.0)	NE	
HIGH	0/256 (0.0)	0/254 (0.0)	NE	
Age (years)				NE
<= 65	0/308 (0.0)	0/318 (0.0)	NE	
> 65	0/ 7 (0.0)	0/ 3 (0.0)	NE	
Sex				NE
male	0/ 27 (0.0)	0/ 26 (0.0)	NE	
female	0/288 (0.0)	0/295 (0.0)	NE	
Race				NE
White	0/185 (0.0)	0/205 (0.0)	NE	
Black	0/ 49 (0.0)	0/ 40 (0.0)	NE	
Other	0/ 73 (0.0)	0/ 73 (0.0)	NE	
Ethnicity				NE
Hispanic/Latino	0/ 78 (0.0)	0/ 84 (0.0)	NE	
Non-hispanic/Latino	0/229 (0.0)	0/234 (0.0)	NE	
Geographic region				NE
EU	0/110 (0.0)	0/109 (0.0)	NE	
non-EU	0/205 (0.0)	0/212 (0.0)	NE	
Onset of disease				NE
Paediatric	0/ 26 (0.0)	0/ 21 (0.0)	NE	
Adult	0/289 (0.0)	0/300 (0.0)	NE	
ADA result				NE
Negative	0/292 (0.0)	0/295 (0.0)	NE	
Positive (At any time)	0/ 22 (0.0)	0/ 26 (0.0)	NE	
BMI (kg/m2)				NE
< 30	0/213 (0.0)	0/235 (0.0)	NE	
>= 30	0/102 (0.0)	0/ 86 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Tuberculosis (including latent TB)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=315)	Placebo (N=321)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
SLEDAI-2K score				NE
< 10 points	0/109 (0.0)	0/101 (0.0)	NE	
>= 10 points	0/206 (0.0)	0/220 (0.0)	NE	
OCS dose				NE
<10 mg/day	0/148 (0.0)	0/145 (0.0)	NE	
>=10 mg/day	0/167 (0.0)	0/176 (0.0)	NE	
Result of type I IFN gene signature test				NE
LOW	0/ 59 (0.0)	0/ 67 (0.0)	NE	
HIGH	0/256 (0.0)	0/254 (0.0)	NE	
Age (years)				NE
<= 65	0/308 (0.0)	0/318 (0.0)	NE	
> 65	0/ 7 (0.0)	0/ 3 (0.0)	NE	
Sex				NE
male	0/ 27 (0.0)	0/ 26 (0.0)	NE	
female	0/288 (0.0)	0/295 (0.0)	NE	
Race				NE
White	0/185 (0.0)	0/205 (0.0)	NE	
Black	0/ 49 (0.0)	0/ 40 (0.0)	NE	
Other	0/ 73 (0.0)	0/ 73 (0.0)	NE	
Ethnicity				NE
Hispanic/Latino	0/ 78 (0.0)	0/ 84 (0.0)	NE	
Non-hispanic/Latino	0/229 (0.0)	0/234 (0.0)	NE	
Geographic region				NE
EU	0/110 (0.0)	0/109 (0.0)	NE	
non-EU	0/205 (0.0)	0/212 (0.0)	NE	
Onset of disease				NE
Paediatric	0/ 26 (0.0)	0/ 21 (0.0)	NE	
Adult	0/289 (0.0)	0/300 (0.0)	NE	
ADA result				NE
Negative	0/292 (0.0)	0/295 (0.0)	NE	
Positive (At any time)	0/ 22 (0.0)	0/ 26 (0.0)	NE	
BMI (kg/m2)				NE
< 30	0/213 (0.0)	0/235 (0.0)	NE	
>= 30	0/102 (0.0)	0/ 86 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Tuberculosis (including latent TB)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=315)	Placebo (N=321)
Number of subjects with events, n (%)	3 (1.0)	2 (0.6)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.45 (0.28, 7.43)	
p-value	0.6593	
Odds Ratio (95% CI)	1.45 (0.28, 7.59)	
p-value	0.6610	
Risk Difference (95% CI)	0.35 (-1.03, 1.73)	
p-value	0.6151	
p-Value for test for heterogenity between studies	0.5619	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.7798
< 10 points	1/109 (0.9)	1/101 (1.0)	0.93 (0.10, 8.70)	0.9479	
>= 10 points	2/206 (1.0)	1/220 (0.5)	1.45 (0.16, 12.92)	0.7390	
OCS dose					0.3794
<10 mg/day	2/148 (1.4)	0/145 (0.0)	2.93 (0.31, 27.58)	0.3478	
>=10 mg/day	1/167 (0.6)	2/176 (1.1)	0.74 (0.09, 5.93)	0.7798	
Result of type I IFN gene signature test					NE
LOW	0/ 59 (0.0)	0/ 67 (0.0)	NE		
HIGH	3/256 (1.2)	2/254 (0.8)	1.39 (0.27, 7.13)	0.6919	
Age (years)					NE
<= 65	3/308 (1.0)	2/318 (0.6)	1.46 (0.28, 7.49)	0.6520	
> 65	0/ 7 (0.0)	0/ 3 (0.0)	NE		
Sex					NE
male	0/ 27 (0.0)	0/ 26 (0.0)	NE		
female	3/288 (1.0)	2/295 (0.7)	1.44 (0.28, 7.39)	0.6629	
Race					0.6028
White	1/185 (0.5)	1/205 (0.5)	1.08 (0.11, 10.31)	0.9443	
Black	0/ 49 (0.0)	0/ 40 (0.0)	NE		
Other	2/ 73 (2.7)	1/ 73 (1.4)	2.57 (0.25, 26.94)	0.4307	
Ethnicity					0.8059
Hispanic/Latino	1/ 78 (1.3)	1/ 84 (1.2)	1.00 (0.07, 15.21)	1.0000	
Non-hispanic/Latino	2/229 (0.9)	1/234 (0.4)	1.51 (0.24, 9.48)	0.6605	
Geographic region					0.6174
EU	1/110 (0.9)	1/109 (0.9)	0.94 (0.10, 8.85)	0.9560	
non-EU	2/205 (1.0)	1/212 (0.5)	2.16 (0.20, 23.07)	0.5250	
Onset of disease					NE
Paediatric	0/ 26 (0.0)	0/ 21 (0.0)	NE		
Adult	3/289 (1.0)	2/300 (0.7)	1.45 (0.28, 7.47)	0.6533	
ADA result					NE
Negative	3/292 (1.0)	2/295 (0.7)	1.44 (0.28, 7.38)	0.6639	
Positive (At any time)	0/ 22 (0.0)	0/ 26 (0.0)	NE		
BMI (kg/m2)					0.5600
< 30	2/213 (0.9)	1/235 (0.4)	2.19 (0.20, 23.42)	0.5183	
>= 30	1/102 (1.0)	1/ 86 (1.2)	0.83 (0.09, 7.79)	0.8690	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Vasculitis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=315)	Placebo (N=321)
Number of subjects with events, n (%)	0 (0.0)	3 (0.9)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.16 (0.01, 2.95)	
p-value	0.2149	
Odds Ratio (95% CI)	0.15 (0.01, 2.94)	
p-value	0.2108	
Risk Difference (95% CI)	-0.90 (-1.94, 0.13)	
p-value	0.0871	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Vasculitis - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.8099
< 10 points	0/109 (0.0)	1/101 (1.0)	0.37 (0.02, 8.66)	0.5340	
>= 10 points	0/206 (0.0)	2/220 (0.9)	0.21 (0.01, 4.34)	0.3158	
OCS dose					0.9672
<10 mg/day	0/148 (0.0)	1/145 (0.7)	0.28 (0.01, 6.72)	0.4356	
>=10 mg/day	0/167 (0.0)	2/176 (1.1)	0.26 (0.01, 5.24)	0.3790	
Result of type I IFN gene signature test					NE
LOW	0/ 59 (0.0)	0/ 67 (0.0)	NE		
HIGH	0/256 (0.0)	3/254 (1.2)	0.15 (0.01, 2.75)	0.1987	
Age (years)					NE
<= 65	0/308 (0.0)	3/318 (0.9)	0.16 (0.01, 2.95)	0.2149	
> 65	0/ 7 (0.0)	0/ 3 (0.0)	NE		
Sex					NE
male	0/ 27 (0.0)	0/ 26 (0.0)	NE		
female	0/288 (0.0)	3/295 (1.0)	0.15 (0.01, 2.88)	0.2090	
Race					0.8668
White	0/185 (0.0)	0/205 (0.0)	NE		
Black	0/ 49 (0.0)	1/ 40 (2.5)	0.18 (0.01, 3.91)	0.2723	
Other	0/ 73 (0.0)	2/ 73 (2.7)	0.26 (0.01, 5.11)	0.3718	
Ethnicity					0.8654
Hispanic/Latino	0/ 78 (0.0)	1/ 84 (1.2)	0.33 (0.01, 7.85)	0.4955	
Non-hispanic/Latino	0/229 (0.0)	2/234 (0.9)	0.23 (0.01, 4.63)	0.3362	
Geographic region					NE
EU	0/110 (0.0)	0/109 (0.0)	NE		
non-EU	0/205 (0.0)	3/212 (1.4)	0.15 (0.01, 2.91)	0.2119	
Onset of disease					0.7592
Paediatric	0/ 26 (0.0)	1/ 21 (4.8)	0.42 (0.02, 8.91)	0.5753	
Adult	0/289 (0.0)	2/300 (0.7)	0.21 (0.01, 4.34)	0.3146	
ADA result					0.8418
Negative	0/292 (0.0)	2/295 (0.7)	0.22 (0.01, 4.46)	0.3224	
Positive (At any time)	0/ 22 (0.0)	1/ 26 (3.8)	0.33 (0.02, 5.97)	0.4554	
BMI (kg/m2)					NE
< 30	0/213 (0.0)	3/235 (1.3)	0.16 (0.01, 2.95)	0.2153	
>= 30	0/102 (0.0)	0/ 86 (0.0)	NE		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Vasculitis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=315)	Placebo (N=321)
Number of subjects with events, n (%)	0 (0.0)	2 (0.6)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.22 (0.01, 4.44)	
p-value	0.3214	
Odds Ratio (95% CI)	0.21 (0.01, 4.48)	
p-value	0.3188	
Risk Difference (95% CI)	-0.60 (-1.45, 0.24)	
p-value	0.1630	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Vasculitis - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.9914
< 10 points	0/109 (0.0)	1/101 (1.0)	0.37 (0.02, 8.66)	0.5340	
>= 10 points	0/206 (0.0)	1/220 (0.5)	0.36 (0.01, 8.54)	0.5253	
OCS dose					0.8544
<10 mg/day	0/148 (0.0)	1/145 (0.7)	0.28 (0.01, 6.72)	0.4356	
>=10 mg/day	0/167 (0.0)	1/176 (0.6)	0.43 (0.02, 10.31)	0.6044	
Result of type I IFN gene signature test					NE
LOW	0/ 59 (0.0)	0/ 67 (0.0)	NE		
HIGH	0/256 (0.0)	2/254 (0.8)	0.20 (0.01, 4.15)	0.3006	
Age (years)					NE
<= 65	0/308 (0.0)	2/318 (0.6)	0.22 (0.01, 4.44)	0.3214	
> 65	0/ 7 (0.0)	0/ 3 (0.0)	NE		
Sex					NE
male	0/ 27 (0.0)	0/ 26 (0.0)	NE		
female	0/288 (0.0)	2/295 (0.7)	0.21 (0.01, 4.34)	0.3139	
Race					0.6970
White	0/185 (0.0)	0/205 (0.0)	NE		
Black	0/ 49 (0.0)	1/ 40 (2.5)	0.18 (0.01, 3.91)	0.2723	
Other	0/ 73 (0.0)	1/ 73 (1.4)	0.43 (0.02, 10.06)	0.5963	
Ethnicity					NE
Hispanic/Latino	0/ 78 (0.0)	0/ 84 (0.0)	NE		
Non-hispanic/Latino	0/229 (0.0)	2/234 (0.9)	0.23 (0.01, 4.63)	0.3362	
Geographic region					NE
EU	0/110 (0.0)	0/109 (0.0)	NE		
non-EU	0/205 (0.0)	2/212 (0.9)	0.22 (0.01, 4.38)	0.3179	
Onset of disease					NE
Paediatric	0/ 26 (0.0)	0/ 21 (0.0)	NE		
Adult	0/289 (0.0)	2/300 (0.7)	0.21 (0.01, 4.34)	0.3146	
ADA result					NE
Negative	0/292 (0.0)	2/295 (0.7)	0.22 (0.01, 4.46)	0.3224	
Positive (At any time)	0/ 22 (0.0)	0/ 26 (0.0)	NE		
BMI (kg/m2)					NE
< 30	0/213 (0.0)	2/235 (0.9)	0.22 (0.01, 4.45)	0.3222	
>= 30	0/102 (0.0)	0/ 86 (0.0)	NE		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Vasculitis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=315)	Placebo (N=321)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Vasculitis - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
SLEDAI-2K score				NE
< 10 points	0/109 (0.0)	0/101 (0.0)	NE	
>= 10 points	0/206 (0.0)	0/220 (0.0)	NE	
OCS dose				NE
<10 mg/day	0/148 (0.0)	0/145 (0.0)	NE	
>=10 mg/day	0/167 (0.0)	0/176 (0.0)	NE	
Result of type I IFN gene signature test				NE
LOW	0/ 59 (0.0)	0/ 67 (0.0)	NE	
HIGH	0/256 (0.0)	0/254 (0.0)	NE	
Age (years)				NE
<= 65	0/308 (0.0)	0/318 (0.0)	NE	
> 65	0/ 7 (0.0)	0/ 3 (0.0)	NE	
Sex				NE
male	0/ 27 (0.0)	0/ 26 (0.0)	NE	
female	0/288 (0.0)	0/295 (0.0)	NE	
Race				NE
White	0/185 (0.0)	0/205 (0.0)	NE	
Black	0/ 49 (0.0)	0/ 40 (0.0)	NE	
Other	0/ 73 (0.0)	0/ 73 (0.0)	NE	
Ethnicity				NE
Hispanic/Latino	0/ 78 (0.0)	0/ 84 (0.0)	NE	
Non-hispanic/Latino	0/229 (0.0)	0/234 (0.0)	NE	
Geographic region				NE
EU	0/110 (0.0)	0/109 (0.0)	NE	
non-EU	0/205 (0.0)	0/212 (0.0)	NE	
Onset of disease				NE
Paediatric	0/ 26 (0.0)	0/ 21 (0.0)	NE	
Adult	0/289 (0.0)	0/300 (0.0)	NE	
ADA result				NE
Negative	0/292 (0.0)	0/295 (0.0)	NE	
Positive (At any time)	0/ 22 (0.0)	0/ 26 (0.0)	NE	
BMI (kg/m2)				NE
< 30	0/213 (0.0)	0/235 (0.0)	NE	
>= 30	0/102 (0.0)	0/ 86 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Vasculitis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=315)	Placebo (N=321)
Number of subjects with events, n (%)	0 (0.0)	3 (0.9)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.16 (0.01, 2.95)	
p-value	0.2149	
Odds Ratio (95% CI)	0.15 (0.01, 2.94)	
p-value	0.2108	
Risk Difference (95% CI)	-0.90 (-1.94, 0.13)	
p-value	0.0871	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Vasculitis - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.8099
< 10 points	0/109 (0.0)	1/101 (1.0)	0.37 (0.02, 8.66)	0.5340	
>= 10 points	0/206 (0.0)	2/220 (0.9)	0.21 (0.01, 4.34)	0.3158	
OCS dose					0.9672
<10 mg/day	0/148 (0.0)	1/145 (0.7)	0.28 (0.01, 6.72)	0.4356	
>=10 mg/day	0/167 (0.0)	2/176 (1.1)	0.26 (0.01, 5.24)	0.3790	
Result of type I IFN gene signature test					NE
LOW	0/ 59 (0.0)	0/ 67 (0.0)	NE		
HIGH	0/256 (0.0)	3/254 (1.2)	0.15 (0.01, 2.75)	0.1987	
Age (years)					NE
<= 65	0/308 (0.0)	3/318 (0.9)	0.16 (0.01, 2.95)	0.2149	
> 65	0/ 7 (0.0)	0/ 3 (0.0)	NE		
Sex					NE
male	0/ 27 (0.0)	0/ 26 (0.0)	NE		
female	0/288 (0.0)	3/295 (1.0)	0.15 (0.01, 2.88)	0.2090	
Race					0.8668
White	0/185 (0.0)	0/205 (0.0)	NE		
Black	0/ 49 (0.0)	1/ 40 (2.5)	0.18 (0.01, 3.91)	0.2723	
Other	0/ 73 (0.0)	2/ 73 (2.7)	0.26 (0.01, 5.11)	0.3718	
Ethnicity					0.8654
Hispanic/Latino	0/ 78 (0.0)	1/ 84 (1.2)	0.33 (0.01, 7.85)	0.4955	
Non-hispanic/Latino	0/229 (0.0)	2/234 (0.9)	0.23 (0.01, 4.63)	0.3362	
Geographic region					NE
EU	0/110 (0.0)	0/109 (0.0)	NE		
non-EU	0/205 (0.0)	3/212 (1.4)	0.15 (0.01, 2.91)	0.2119	
Onset of disease					0.7592
Paediatric	0/ 26 (0.0)	1/ 21 (4.8)	0.42 (0.02, 8.91)	0.5753	
Adult	0/289 (0.0)	2/300 (0.7)	0.21 (0.01, 4.34)	0.3146	
ADA result					0.8418
Negative	0/292 (0.0)	2/295 (0.7)	0.22 (0.01, 4.46)	0.3224	
Positive (At any time)	0/ 22 (0.0)	1/ 26 (3.8)	0.33 (0.02, 5.97)	0.4554	
BMI (kg/m2)					NE
< 30	0/213 (0.0)	3/235 (1.3)	0.16 (0.01, 2.95)	0.2153	
>= 30	0/102 (0.0)	0/ 86 (0.0)	NE		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Malignancy
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=315)	Placebo (N=321)
Number of subjects with events, n (%)	2 (0.6)	2 (0.6)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.02 (0.18, 5.87)	
p-value	0.9779	
Odds Ratio (95% CI)	1.02 (0.18, 5.95)	
p-value	0.9788	
Risk Difference (95% CI)	0.01 (-1.23, 1.25)	
p-value	0.9864	
p-Value for test for heterogenity between studies	0.6158	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Malignancy - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.1838
< 10 points	2/109 (1.8)	0/101 (0.0)	3.07 (0.33, 28.77)	0.3265	
>= 10 points	0/206 (0.0)	2/220 (0.9)	0.36 (0.04, 3.39)	0.3687	
OCS dose					0.4616
<10 mg/day	1/148 (0.7)	0/145 (0.0)	2.56 (0.11, 60.44)	0.5603	
>=10 mg/day	1/167 (0.6)	2/176 (1.1)	0.62 (0.08, 4.95)	0.6496	
Result of type I IFN gene signature test					0.3287
LOW	1/ 59 (1.7)	0/ 67 (0.0)	4.00 (0.17, 91.48)	0.3853	
HIGH	1/256 (0.4)	2/254 (0.8)	0.61 (0.08, 4.94)	0.6465	
Age (years)					NE
<= 65	2/308 (0.6)	2/318 (0.6)	1.04 (0.18, 5.95)	0.9670	
> 65	0/ 7 (0.0)	0/ 3 (0.0)	NE		
Sex					NE
male	0/ 27 (0.0)	0/ 26 (0.0)	NE		
female	2/288 (0.7)	2/295 (0.7)	1.03 (0.18, 5.89)	0.9743	
Race					NE
White	2/185 (1.1)	2/205 (1.0)	1.14 (0.20, 6.48)	0.8848	
Black	0/ 49 (0.0)	0/ 40 (0.0)	NE		
Other	0/ 73 (0.0)	0/ 73 (0.0)	NE		
Ethnicity					NE
Hispanic/Latino	0/ 78 (0.0)	0/ 84 (0.0)	NE		
Non-hispanic/Latino	2/229 (0.9)	2/234 (0.9)	1.04 (0.18, 5.94)	0.9657	
Geographic region					0.3877
EU	1/110 (0.9)	2/109 (1.8)	0.61 (0.08, 4.83)	0.6366	
non-EU	1/205 (0.5)	0/212 (0.0)	3.23 (0.13, 77.56)	0.4696	
Onset of disease					NE
Paediatric	0/ 26 (0.0)	0/ 21 (0.0)	NE		
Adult	2/289 (0.7)	2/300 (0.7)	1.04 (0.18, 5.95)	0.9660	
ADA result					NE
Negative	2/292 (0.7)	2/295 (0.7)	1.02 (0.18, 5.84)	0.9819	
Positive (At any time)	0/ 22 (0.0)	0/ 26 (0.0)	NE		
BMI (kg/m2)					0.4288
< 30	1/213 (0.5)	2/235 (0.9)	0.70 (0.09, 5.62)	0.7366	
>= 30	1/102 (1.0)	0/ 86 (0.0)	3.19 (0.14, 72.69)	0.4675	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Malignancy
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=315)	Placebo (N=321)
Number of subjects with events, n (%)	2 (0.6)	1 (0.3)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.48 (0.24, 9.35)	
p-value	0.6742	
Odds Ratio (95% CI)	1.49 (0.23, 9.51)	
p-value	0.6743	
Risk Difference (95% CI)	0.33 (-0.75, 1.40)	
p-value	0.5495	
p-Value for test for heterogenity between studies	0.5391	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Malignancy - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.2931
< 10 points	2/109 (1.8)	0/101 (0.0)	3.07 (0.33, 28.77)	0.3265	
>= 10 points	0/206 (0.0)	1/220 (0.5)	0.38 (0.02, 9.19)	0.5514	
OCS dose					0.6270
<10 mg/day	1/148 (0.7)	0/145 (0.0)	2.56 (0.11, 60.44)	0.5603	
>=10 mg/day	1/167 (0.6)	1/176 (0.6)	0.98 (0.10, 9.28)	0.9842	
Result of type I IFN gene signature test					0.4767
LOW	1/ 59 (1.7)	0/ 67 (0.0)	4.00 (0.17, 91.48)	0.3853	
HIGH	1/256 (0.4)	1/254 (0.4)	0.99 (0.10, 9.40)	0.9900	
Age (years)					NE
<= 65	2/308 (0.6)	1/318 (0.3)	1.50 (0.24, 9.46)	0.6658	
> 65	0/ 7 (0.0)	0/ 3 (0.0)	NE		
Sex					NE
male	0/ 27 (0.0)	0/ 26 (0.0)	NE		
female	2/288 (0.7)	1/295 (0.3)	1.49 (0.24, 9.35)	0.6736	
Race					NE
White	2/185 (1.1)	1/205 (0.5)	1.64 (0.26, 10.25)	0.5986	
Black	0/ 49 (0.0)	0/ 40 (0.0)	NE		
Other	0/ 73 (0.0)	0/ 73 (0.0)	NE		
Ethnicity					NE
Hispanic/Latino	0/ 78 (0.0)	0/ 84 (0.0)	NE		
Non-hispanic/Latino	2/229 (0.9)	1/234 (0.4)	1.51 (0.24, 9.47)	0.6614	
Geographic region					0.5318
EU	1/110 (0.9)	1/109 (0.9)	0.93 (0.10, 8.81)	0.9523	
non-EU	1/205 (0.5)	0/212 (0.0)	3.23 (0.13, 77.56)	0.4696	
Onset of disease					NE
Paediatric	0/ 26 (0.0)	0/ 21 (0.0)	NE		
Adult	2/289 (0.7)	1/300 (0.3)	1.50 (0.24, 9.48)	0.6634	
ADA result					NE
Negative	2/292 (0.7)	1/295 (0.3)	1.47 (0.23, 9.28)	0.6801	
Positive (At any time)	0/ 22 (0.0)	0/ 26 (0.0)	NE		
BMI (kg/m2)					0.5912
< 30	1/213 (0.5)	1/235 (0.4)	1.11 (0.12, 10.55)	0.9285	
>= 30	1/102 (1.0)	0/ 86 (0.0)	3.19 (0.14, 72.69)	0.4675	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Malignancy
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=315)	Placebo (N=321)
Number of subjects with events, n (%)	1 (0.3)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.26 (0.13, 78.65)	
p-value	0.4673	
Odds Ratio (95% CI)	3.31 (0.13, 82.53)	
p-value	0.4663	
Risk Difference (95% CI)	0.33 (-0.30, 0.96)	
p-value	0.3089	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Malignancy - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					NE
< 10 points	1/109 (0.9)	0/101 (0.0)	3.30 (0.14, 77.95)	0.4593	
>= 10 points	0/206 (0.0)	0/220 (0.0)	NE		
OCS dose					NE
<10 mg/day	1/148 (0.7)	0/145 (0.0)	2.56 (0.11, 60.44)	0.5603	
>=10 mg/day	0/167 (0.0)	0/176 (0.0)	NE		
Result of type I IFN gene signature test					NE
LOW	1/ 59 (1.7)	0/ 67 (0.0)	4.00 (0.17, 91.48)	0.3853	
HIGH	0/256 (0.0)	0/254 (0.0)	NE		
Age (years)					NE
<= 65	1/308 (0.3)	0/318 (0.0)	3.26 (0.13, 78.65)	0.4673	
> 65	0/ 7 (0.0)	0/ 3 (0.0)	NE		
Sex					NE
male	0/ 27 (0.0)	0/ 26 (0.0)	NE		
female	1/288 (0.3)	0/295 (0.0)	3.18 (0.13, 76.73)	0.4760	
Race					NE
White	1/185 (0.5)	0/205 (0.0)	3.69 (0.16, 86.90)	0.4176	
Black	0/ 49 (0.0)	0/ 40 (0.0)	NE		
Other	0/ 73 (0.0)	0/ 73 (0.0)	NE		
Ethnicity					NE
Hispanic/Latino	0/ 78 (0.0)	0/ 84 (0.0)	NE		
Non-hispanic/Latino	1/229 (0.4)	0/234 (0.0)	3.43 (0.14, 81.93)	0.4467	
Geographic region					NE
EU	0/110 (0.0)	0/109 (0.0)	NE		
non-EU	1/205 (0.5)	0/212 (0.0)	3.23 (0.13, 77.56)	0.4696	
Onset of disease					NE
Paediatric	0/ 26 (0.0)	0/ 21 (0.0)	NE		
Adult	1/289 (0.3)	0/300 (0.0)	3.19 (0.13, 76.88)	0.4749	
ADA result					NE
Negative	1/292 (0.3)	0/295 (0.0)	3.27 (0.14, 78.87)	0.4659	
Positive (At any time)	0/ 22 (0.0)	0/ 26 (0.0)	NE		
BMI (kg/m2)					NE
< 30	0/213 (0.0)	0/235 (0.0)	NE		
>= 30	1/102 (1.0)	0/ 86 (0.0)	3.19 (0.14, 72.69)	0.4675	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Malignancy
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=315)	Placebo (N=321)
Number of subjects with events, n (%)	1 (0.3)	2 (0.6)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.62 (0.08, 5.03)	
p-value	0.6574	
Odds Ratio (95% CI)	0.62 (0.08, 5.08)	
p-value	0.6567	
Risk Difference (95% CI)	-0.32 (-1.38, 0.74)	
p-value	0.5583	
p-Value for test for heterogenity between studies	0.6204	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Malignancy - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.2943
< 10 points	1/109 (0.9)	0/101 (0.0)	2.85 (0.12, 67.83)	0.5172	
>= 10 points	0/206 (0.0)	2/220 (0.9)	0.36 (0.04, 3.39)	0.3687	
OCS dose					NE
<10 mg/day	0/148 (0.0)	0/145 (0.0)	NE		
>=10 mg/day	1/167 (0.6)	2/176 (1.1)	0.62 (0.08, 4.95)	0.6496	
Result of type I IFN gene signature test					NE
LOW	0/ 59 (0.0)	0/ 67 (0.0)	NE		
HIGH	1/256 (0.4)	2/254 (0.8)	0.61 (0.08, 4.94)	0.6465	
Age (years)					NE
<= 65	1/308 (0.3)	2/318 (0.6)	0.63 (0.08, 5.12)	0.6693	
> 65	0/ 7 (0.0)	0/ 3 (0.0)	NE		
Sex					NE
male	0/ 27 (0.0)	0/ 26 (0.0)	NE		
female	1/288 (0.3)	2/295 (0.7)	0.63 (0.08, 5.11)	0.6681	
Race					NE
White	1/185 (0.5)	2/205 (1.0)	0.68 (0.08, 5.47)	0.7178	
Black	0/ 49 (0.0)	0/ 40 (0.0)	NE		
Other	0/ 73 (0.0)	0/ 73 (0.0)	NE		
Ethnicity					NE
Hispanic/Latino	0/ 78 (0.0)	0/ 84 (0.0)	NE		
Non-hispanic/Latino	1/229 (0.4)	2/234 (0.9)	0.62 (0.08, 4.99)	0.6537	
Geographic region					NE
EU	1/110 (0.9)	2/109 (1.8)	0.61 (0.08, 4.83)	0.6366	
non-EU	0/205 (0.0)	0/212 (0.0)	NE		
Onset of disease					NE
Paediatric	0/ 26 (0.0)	0/ 21 (0.0)	NE		
Adult	1/289 (0.3)	2/300 (0.7)	0.64 (0.08, 5.17)	0.6761	
ADA result					NE
Negative	1/292 (0.3)	2/295 (0.7)	0.62 (0.08, 4.99)	0.6521	
Positive (At any time)	0/ 22 (0.0)	0/ 26 (0.0)	NE		
BMI (kg/m2)					NE
< 30	1/213 (0.5)	2/235 (0.9)	0.70 (0.09, 5.62)	0.7366	
>= 30	0/102 (0.0)	0/ 86 (0.0)	NE		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of SOCs Cardiac disorders and/or Vascular disorders
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=315)	Placebo (N=321)
Number of subjects with events, n (%)	12 (3.8)	34 (10.6)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.42 (0.22, 0.83)	
p-value	0.0122	
Odds Ratio (95% CI)	0.39 (0.19, 0.80)	
p-value	0.0101	
Risk Difference (95% CI)	-6.70 (-10.67, -2.73)	
p-value	0.0009	
p-Value for test for heterogenity between studies	0.0908	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one Adverse Event of SOCs Cardiac disorders and/or Vascular disorders - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	 p-Value	Interaction p-Value
SLEDAI-2K score					0.9677
< 10 points	3/109 (2.8)	9/101 (8.9)	0.40 (0.12, 1.36)	0.1402	
>= 10 points	9/206 (4.4)	25/220 (11.4)	0.41 (0.18, 0.92)	0.0312	
OCS dose					0.6382
<10 mg/day	5/148 (3.4)	12/145 (8.3)	0.49 (0.18, 1.33)	0.1609	
>=10 mg/day	7/167 (4.2)	22/176 (12.5)	0.35 (0.14, 0.89)	0.0283	
Result of type I IFN gene signature test					0.8674
LOW	1/ 59 (1.7)	6/ 67 (9.0)	0.40 (0.08, 2.10)	0.2775	
HIGH	11/256 (4.3)	28/254 (11.0)	0.46 (0.23, 0.95)	0.0347	
Age (years)					NE
<= 65	12/308 (3.9)	34/318 (10.7)	0.43 (0.22, 0.83)	0.0129	
> 65	0/ 7 (0.0)	0/ 3 (0.0)	NE		
Sex					0.8017
male	0/ 27 (0.0)	2/ 26 (7.7)	0.33 (0.04, 2.84)	0.3139	
female	12/288 (4.2)	32/295 (10.8)	0.44 (0.23, 0.87)	0.0183	
Race					0.7279
White	6/185 (3.2)	23/205 (11.2)	0.41 (0.15, 1.07)	0.0686	
Black	2/ 49 (4.1)	5/ 40 (12.5)	0.39 (0.10, 1.52)	0.1729	
Other	3/ 73 (4.1)	6/ 73 (8.2)	0.75 (0.20, 2.89)	0.6787	
Ethnicity					0.2176
Hispanic/Latino	4/ 78 (5.1)	8/ 84 (9.5)	0.80 (0.22, 2.92)	0.7409	
Non-hispanic/Latino	7/229 (3.1)	26/234 (11.1)	0.30 (0.13, 0.71)	0.0059	
Geographic region					0.6513
EU	4/110 (3.6)	13/109 (11.9)	0.32 (0.08, 1.34)	0.1186	
non-EU	8/205 (3.9)	21/212 (9.9)	0.46 (0.21, 1.04)	0.0632	
Onset of disease					0.7280
Paediatric	1/ 26 (3.8)	2/ 21 (9.5)	0.57 (0.10, 3.33)	0.5339	
Adult	11/289 (3.8)	32/300 (10.7)	0.41 (0.21, 0.81)	0.0108	
ADA result					0.1662
Negative	11/292 (3.8)	33/295 (11.2)	0.39 (0.20, 0.79)	0.0088	
Positive (At any time)	1/ 22 (4.5)	1/ 26 (3.8)	2.50 (0.20, 31.00)	0.4756	
BMI (kg/m2)					0.6996
< 30	6/213 (2.8)	24/235 (10.2)	0.41 (0.16, 1.07)	0.0695	
>= 30	6/102 (5.9)	10/ 86 (11.6)	0.54 (0.21, 1.42)	0.2110	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Blood and lymphatic system disorders	Number of subjects with events, n (%)	12 (3.8)	19 (5.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.64 (0.32, 1.31)	
	p-value	0.2226	
	Odds Ratio (95% CI)	0.63 (0.30, 1.32)	
	p-value	0.2215	
	Risk Difference (95% CI)	-2.11 (-5.45, 1.22)	
	p-value	0.2146	
	p-Value for test for heterogenity between studies	0.9347	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Cardiac disorders	Number of subjects with events, n (%)	5 (1.6)	14 (4.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.40 (0.14, 1.12)	
	p-value	0.0821	
	Odds Ratio (95% CI)	0.39 (0.13, 1.12)	
	p-value	0.0789	
	Risk Difference (95% CI)	-2.77 (-5.40, -0.13)	
	p-value	0.0395	
	p-Value for test for heterogenity between studies	0.5686	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Ear and labyrinth disorders	Number of subjects with events, n (%)	7 (2.2)	12 (3.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.63 (0.26, 1.57)	
	p-value	0.3221	
	Odds Ratio (95% CI)	0.62 (0.24, 1.58)	
	p-value	0.3180	
	Risk Difference (95% CI)	-1.54 (-4.18, 1.09)	
	p-value	0.2507	
	p-Value for test for heterogenity between studies	0.7273	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Eye disorders	Number of subjects with events, n (%)	26 (8.3)	11 (3.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	2.31 (1.14, 4.65)	
	p-value	0.0196	
	Odds Ratio (95% CI)	2.44 (1.17, 5.11)	
	p-value	0.0178	
	Risk Difference (95% CI)	4.88 (1.23, 8.52)	
	p-value	0.0087	
	p-Value for test for heterogenity between studies	0.4357	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Gastrointestinal disorders	Number of subjects with events, n (%)	66 (21.0)	72 (22.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.93 (0.69, 1.26)	
	p-value	0.6451	
	Odds Ratio (95% CI)	0.92 (0.63, 1.34)	
	p-value	0.6502	
	Risk Difference (95% CI)	-1.51 (-7.94, 4.92)	
	p-value	0.6456	
	p-Value for test for heterogenity between studies	0.1318	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Gastrointestinal disorders, PT: Diarrhoea	Number of subjects with events, n (%)	9 (2.9)	15 (4.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.58 (0.24, 1.39)	
	p-value	0.2236	
	Odds Ratio (95% CI)	0.57 (0.23, 1.41)	
	p-value	0.2245	
	Risk Difference (95% CI)	-1.84 (-4.81, 1.13)	
	p-value	0.2246	
	p-Value for test for heterogenity between studies	0.2489	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Gastrointestinal disorders, PT: Nausea	Number of subjects with events, n (%)	12 (3.8)	15 (4.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.81 (0.38, 1.70)	
	p-value	0.5778	
	Odds Ratio (95% CI)	0.80 (0.37, 1.74)	
	p-value	0.5754	
	Risk Difference (95% CI)	-0.91 (-4.03, 2.22)	
	p-value	0.5690	
	p-Value for test for heterogenity between studies	0.9420	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Gastrointestinal disorders, PT: Vomiting	Number of subjects with events, n (%)	11 (3.5)	6 (1.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.81 (0.61, 5.40)	
	p-value	0.2850	
	Odds Ratio (95% CI)	1.85 (0.60, 5.65)	
	p-value	0.2820	
	Risk Difference (95% CI)	1.60 (-0.90, 4.11)	
	p-value	0.2100	
	p-Value for test for heterogenity between studies	0.2103	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: General disorders and administration site conditions	Number of subjects with events, n (%)	34 (10.8)	29 (9.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.20 (0.74, 1.94)	
	p-value	0.4544	
	Odds Ratio (95% CI)	1.22 (0.72, 2.08)	
	p-value	0.4564	
	Risk Difference (95% CI)	1.74 (-2.91, 6.38)	
	p-value	0.4635	
	p-Value for test for heterogenity between studies	0.3425	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Immune system disorders	Number of subjects with events, n (%)	18 (5.7)	9 (2.8)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	2.00 (0.91, 4.41)	
	p-value	0.0854	
	Odds Ratio (95% CI)	2.07 (0.91, 4.71)	
	p-value	0.0846	
	Risk Difference (95% CI)	2.85 (-0.27, 5.98)	
	p-value	0.0736	
	p-Value for test for heterogenity between studies	0.8380	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Immune system disorders, PT: Hypersensitivity	Number of subjects with events, n (%)	10 (3.2)	3 (0.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	3.25 (0.90, 11.78)	
	p-value	0.0730	
	Odds Ratio (95% CI)	3.36 (0.90, 12.52)	
	p-value	0.0713	
	Risk Difference (95% CI)	2.19 (-0.00, 4.37)	
	p-value	0.0503	
	p-Value for test for heterogenity between studies	0.6479	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Infections and infestations	Number of subjects with events, n (%)	215 (68.3)	181 (56.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.21 (1.07, 1.37)	
	p-value	0.0020	
	Odds Ratio (95% CI)	1.66 (1.20, 2.29)	
	p-value	0.0024	
	Risk Difference (95% CI)	11.75 (4.28, 19.22)	
	p-value	0.0020	
	p-Value for test for heterogenity between studies	0.5030	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Infections and infestations, PT: Bronchitis	Number of subjects with events, n (%)	32 (10.2)	15 (4.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	2.16 (1.19, 3.92)	
	p-value	0.0109	
	Odds Ratio (95% CI)	2.30 (1.22, 4.34)	
	p-value	0.0104	
	Risk Difference (95% CI)	5.48 (1.42, 9.54)	
	p-value	0.0081	
	p-Value for test for heterogenity between studies	0.8797	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Infections and infestations, PT: Gastroenteritis	Number of subjects with events, n (%)	10 (3.2)	7 (2.2)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.46 (0.56, 3.83)	
	p-value	0.4385	
	Odds Ratio (95% CI)	1.48 (0.55, 3.97)	
	p-value	0.4394	
	Risk Difference (95% CI)	1.03 (-1.49, 3.54)	
	p-value	0.4236	
	p-Value for test for heterogenity between studies	0.8102	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Infections and infestations, PT: Herpes zoster	Number of subjects with events, n (%)	18 (5.7)	6 (1.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	3.04 (1.22, 7.59)	
	p-value	0.0171	
	Odds Ratio (95% CI)	3.17 (1.24, 8.15)	
	p-value	0.0163	
	Risk Difference (95% CI)	3.88 (0.91, 6.84)	
	p-value	0.0103	
	p-Value for test for heterogenity between studies	0.8943	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Infections and infestations, PT: Nasopharyngitis	Number of subjects with events, n (%)	54 (17.1)	29 (9.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.84 (1.21, 2.81)	
	p-value	0.0044	
	Odds Ratio (95% CI)	2.06 (1.27, 3.36)	
	p-value	0.0036	
	Risk Difference (95% CI)	7.98 (2.80, 13.16)	
	p-value	0.0025	
	p-Value for test for heterogenity between studies	0.6060	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Infections and infestations, PT: Oral herpes	Number of subjects with events, n (%)	10 (3.2)	7 (2.2)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.30 (0.47, 3.63)	
	p-value	0.6172	
	Odds Ratio (95% CI)	1.32 (0.46, 3.78)	
	p-value	0.6076	
	Risk Difference (95% CI)	1.00 (-1.51, 3.51)	
	p-value	0.4350	
	p-Value for test for heterogenity between studies	0.3621	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Infections and infestations, PT: Pharyngitis	Number of subjects with events, n (%)	15 (4.8)	13 (4.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.04 (0.49, 2.22)	
	p-value	0.9112	
	Odds Ratio (95% CI)	1.06 (0.47, 2.39)	
	p-value	0.8808	
	Risk Difference (95% CI)	0.66 (-2.51, 3.84)	
	p-value	0.6820	
	p-Value for test for heterogenity between studies	0.2613	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Infections and infestations, PT: Pneumonia	Number of subjects with events, n (%)	8 (2.5)	11 (3.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.75 (0.29, 1.97)	
	p-value	0.5636	
	Odds Ratio (95% CI)	0.75 (0.28, 2.02)	
	p-value	0.5687	
	Risk Difference (95% CI)	-0.89 (-3.53, 1.76)	
	p-value	0.5104	
	p-Value for test for heterogenity between studies	0.3063	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Infections and infestations, PT: Respiratory tract infection	Number of subjects with events, n (%)	12 (3.8)	1 (0.3)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	5.54 (1.21, 25.35)	
	p-value	0.0273	
	Odds Ratio (95% CI)	5.74 (1.23, 26.68)	
	p-value	0.0259	
	Risk Difference (95% CI)	3.48 (1.28, 5.68)	
	p-value	0.0019	
	p-Value for test for heterogenity between studies	0.7097	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Infections and infestations, PT: Sinusitis	Number of subjects with events, n (%)	20 (6.3)	15 (4.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.36 (0.71, 2.60)	
	p-value	0.3592	
	Odds Ratio (95% CI)	1.38 (0.69, 2.75)	
	p-value	0.3587	
	Risk Difference (95% CI)	1.67 (-1.88, 5.21)	
	p-value	0.3572	
	p-Value for test for heterogenity between studies	0.9941	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Infections and infestations, PT: Upper respiratory tract infection	Number of subjects with events, n (%)	49 (15.6)	29 (9.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.71 (1.11, 2.65)	
	p-value	0.0159	
	Odds Ratio (95% CI)	1.84 (1.12, 3.02)	
	p-value	0.0153	
	Risk Difference (95% CI)	6.55 (1.47, 11.63)	
	p-value	0.0115	
	p-Value for test for heterogenity between studies	0.3931	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Infections and infestations, PT: Urinary tract infection	Number of subjects with events, n (%)	31 (9.8)	42 (13.1)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.75 (0.48, 1.16)	
	p-value	0.2011	
	Odds Ratio (95% CI)	0.72 (0.44, 1.19)	
	p-value	0.2010	
	Risk Difference (95% CI)	-3.27 (-8.22, 1.68)	
	p-value	0.1951	
	p-Value for test for heterogenity between studies	0.7490	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Injury, poisoning and procedural complications	Number of subjects with events, n (%)	66 (21.0)	52 (16.2)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.29 (0.93, 1.79)	
	p-value	0.1303	
	Odds Ratio (95% CI)	1.37 (0.91, 2.05)	
	p-value	0.1311	
	Risk Difference (95% CI)	4.66 (-1.36, 10.68)	
	p-value	0.1289	
	p-Value for test for heterogenity between studies	0.7840	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Injury, poisoning and procedural complications, PT: Infusion related reaction	Number of subjects with events, n (%)	28 (8.9)	22 (6.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.31 (0.76, 2.26)	
	p-value	0.3374	
	Odds Ratio (95% CI)	1.33 (0.73, 2.41)	
	p-value	0.3555	
	Risk Difference (95% CI)	2.00 (-2.17, 6.17)	
	p-value	0.3469	
	p-Value for test for heterogenity between studies	0.3286	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Investigations	Number of subjects with events, n (%)	16 (5.1)	21 (6.5)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.81 (0.41, 1.58)	
	p-value	0.5283	
	Odds Ratio (95% CI)	0.78 (0.38, 1.60)	
	p-value	0.5030	
	Risk Difference (95% CI)	-1.41 (-5.07, 2.24)	
	p-value	0.4489	
	p-Value for test for heterogenity between studies	0.0861	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Metabolism and nutrition disorders	Number of subjects with events, n (%)	22 (7.0)	26 (8.1)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.88 (0.50, 1.55)	
	p-value	0.6580	
	Odds Ratio (95% CI)	0.86 (0.47, 1.58)	
	p-value	0.6272	
	Risk Difference (95% CI)	-1.05 (-5.16, 3.06)	
	p-value	0.6162	
	p-Value for test for heterogenity between studies	0.1730	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Musculoskeletal and connective tissue disorders	Number of subjects with events, n (%)	71 (22.5)	67 (20.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.08 (0.80, 1.45)	
	p-value	0.6133	
	Odds Ratio (95% CI)	1.10 (0.76, 1.61)	
	p-value	0.6055	
	Risk Difference (95% CI)	1.70 (-4.71, 8.11)	
	p-value	0.6031	
	p-Value for test for heterogenity between studies	0.6728	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Musculoskeletal and connective tissue disorders, PT: Arthralgia	Number of subjects with events, n (%)	14 (4.4)	7 (2.2)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.99 (0.81, 4.91)	
	p-value	0.1349	
	Odds Ratio (95% CI)	2.05 (0.81, 5.20)	
	p-value	0.1323	
	Risk Difference (95% CI)	2.25 (-0.53, 5.02)	
	p-value	0.1126	
	p-Value for test for heterogenity between studies	0.8100	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Musculoskeletal and connective tissue disorders, PT: Back pain	Number of subjects with events, n (%)	14 (4.4)	13 (4.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.95 (0.42, 2.13)	
	p-value	0.8922	
	Odds Ratio (95% CI)	0.95 (0.41, 2.24)	
	p-value	0.9122	
	Risk Difference (95% CI)	0.35 (-2.79, 3.48)	
	p-value	0.8288	
	p-Value for test for heterogenity between studies	0.1412	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Musculoskeletal and connective tissue disorders, PT: Systemic lupus erythematosus	Number of subjects with events, n (%)	7 (2.2)	11 (3.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.68 (0.26, 1.77)	
	p-value	0.4329	
	Odds Ratio (95% CI)	0.67 (0.25, 1.79)	
	p-value	0.4215	
	Risk Difference (95% CI)	-1.14 (-3.71, 1.42)	
	p-value	0.3821	
	p-Value for test for heterogenity between studies	0.6304	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Nervous system disorders	Number of subjects with events, n (%)	60 (19.0)	53 (16.5)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.15 (0.82, 1.62)	
	p-value	0.4089	
	Odds Ratio (95% CI)	1.20 (0.79, 1.81)	
	p-value	0.3971	
	Risk Difference (95% CI)	2.65 (-3.28, 8.57)	
	p-value	0.3813	
	p-Value for test for heterogenity between studies	0.2661	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Nervous system disorders, PT: Headache	Number of subjects with events, n (%)	25 (7.9)	32 (10.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.82 (0.50, 1.37)	
	p-value	0.4549	
	Odds Ratio (95% CI)	0.80 (0.46, 1.40)	
	p-value	0.4330	
	Risk Difference (95% CI)	-1.96 (-6.39, 2.46)	
	p-value	0.3850	
	p-Value for test for heterogenity between studies	0.3253	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Psychiatric disorders	Number of subjects with events, n (%)	26 (8.3)	28 (8.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.94 (0.56, 1.57)	
	p-value	0.8085	
	Odds Ratio (95% CI)	0.94 (0.53, 1.64)	
	p-value	0.8146	
	Risk Difference (95% CI)	-0.52 (-4.85, 3.82)	
	p-value	0.8154	
	p-Value for test for heterogenity between studies	0.8108	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Psychiatric disorders, PT: Anxiety	Number of subjects with events, n (%)	11 (3.5)	7 (2.2)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.59 (0.62, 4.06)	
	p-value	0.3325	
	Odds Ratio (95% CI)	1.61 (0.61, 4.22)	
	p-value	0.3316	
	Risk Difference (95% CI)	1.30 (-1.28, 3.88)	
	p-value	0.3233	
	p-Value for test for heterogenity between studies	0.9327	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Psychiatric disorders, PT: Depression	Number of subjects with events, n (%)	10 (3.2)	2 (0.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	3.09 (0.82, 11.57)	
	p-value	0.0941	
	Odds Ratio (95% CI)	3.18 (0.83, 12.18)	
	p-value	0.0912	
	Risk Difference (95% CI)	2.53 (0.41, 4.65)	
	p-value	0.0194	
	p-Value for test for heterogenity between studies	0.5939	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Psychiatric disorders, PT: Insomnia	Number of subjects with events, n (%)	7 (2.2)	16 (5.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.45 (0.19, 1.09)	
	p-value	0.0778	
	Odds Ratio (95% CI)	0.44 (0.18, 1.09)	
	p-value	0.0759	
	Risk Difference (95% CI)	-2.80 (-5.68, 0.09)	
	p-value	0.0574	
	p-Value for test for heterogenity between studies	0.7938	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Renal and urinary disorders	Number of subjects with events, n (%)	13 (4.1)	11 (3.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.16 (0.52, 2.57)	
	p-value	0.7220	
	Odds Ratio (95% CI)	1.17 (0.51, 2.70)	
	p-value	0.7139	
	Risk Difference (95% CI)	0.66 (-2.30, 3.62)	
	p-value	0.6612	
	p-Value for test for heterogenity between studies	0.6235	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Reproductive system and breast disorders	Number of subjects with events, n (%)	17 (5.4)	15 (4.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.21 (0.58, 2.52)	
	p-value	0.6081	
	Odds Ratio (95% CI)	1.21 (0.56, 2.61)	
	p-value	0.6187	
	Risk Difference (95% CI)	0.75 (-2.67, 4.17)	
	p-value	0.6670	
	p-Value for test for heterogenity between studies	0.0970	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with events, n (%)	48 (15.2)	36 (11.2)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.35 (0.90, 2.02)	
	p-value	0.1520	
	Odds Ratio (95% CI)	1.41 (0.88, 2.25)	
	p-value	0.1527	
	Risk Difference (95% CI)	3.92 (-1.33, 9.17)	
	p-value	0.1430	
	p-Value for test for heterogenity between studies	0.5075	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Respiratory, thoracic and mediastinal disorders, PT: Cough	Number of subjects with events, n (%)	17 (5.4)	10 (3.1)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.81 (0.82, 3.99)	
	p-value	0.1421	
	Odds Ratio (95% CI)	1.85 (0.81, 4.25)	
	p-value	0.1440	
	Risk Difference (95% CI)	2.21 (-0.91, 5.33)	
	p-value	0.1649	
	p-Value for test for heterogenity between studies	0.3606	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Skin and subcutaneous tissue disorders	Number of subjects with events, n (%)	43 (13.7)	35 (10.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.24 (0.82, 1.89)	
	p-value	0.3070	
	Odds Ratio (95% CI)	1.29 (0.80, 2.07)	
	p-value	0.3035	
	Risk Difference (95% CI)	2.69 (-2.40, 7.79)	
	p-value	0.2999	
	p-Value for test for heterogenity between studies	0.8282	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Vascular disorders	Number of subjects with events, n (%)	7 (2.2)	23 (7.2)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.37 (0.15, 0.91)	
	p-value	0.0300	
	Odds Ratio (95% CI)	0.34 (0.13, 0.89)	
	p-value	0.0273	
	Risk Difference (95% CI)	-4.86 (-8.11, -1.62)	
	p-value	0.0033	
	p-Value for test for heterogenity between studies	0.1226	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Vascular disorders, PT: Hypertension	Number of subjects with events, n (%)	4 (1.3)	16 (5.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.36 (0.12, 1.05)	
	p-value	0.0607	
	Odds Ratio (95% CI)	0.34 (0.11, 1.03)	
	p-value	0.0563	
	Risk Difference (95% CI)	-3.65 (-6.32, -0.98)	
	p-value	0.0073	
	p-Value for test for heterogenity between studies	0.4501	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SOC: Eye disorders	SLEDAI-2K score					0.9073
	< 10 points	9/109 (8.3)	3/101 (3.0)	2.00 (0.65, 6.14)	0.2246	
	>= 10 points	17/206 (8.3)	8/220 (3.6)	2.18 (0.94, 5.06)	0.0712	
	OCS dose					0.1263
	<10 mg/day	6/148 (4.1)	5/145 (3.4)	0.99 (0.27, 3.59)	0.9915	
	>=10 mg/day	20/167 (12.0)	6/176 (3.4)	3.39 (1.36, 8.45)	0.0086	
	Result of type I IFN gene signature test					0.8841
	LOW	4/ 59 (6.8)	2/ 67 (3.0)	1.97 (0.41, 9.53)	0.3995	
	HIGH	22/256 (8.6)	9/254 (3.5)	2.24 (1.04, 4.86)	0.0404	
	Age (years)					NE
	<= 65	26/308 (8.4)	11/318 (3.5)	2.33 (1.16, 4.70)	0.0180	
	> 65	0/ 7 (0.0)	0/ 3 (0.0)	NE		
	Sex					0.5857
	male	3/ 27 (11.1)	0/ 26 (0.0)	3.80 (0.47, 30.65)	0.2095	
	female	23/288 (8.0)	11/295 (3.7)	2.06 (1.01, 4.19)	0.0461	
	Race					0.5007
	White	11/185 (5.9)	6/205 (2.9)	1.96 (0.73, 5.26)	0.1842	
	Black	5/ 49 (10.2)	0/ 40 (0.0)	3.54 (0.62, 20.01)	0.1532	
	Other	9/ 73 (12.3)	5/ 73 (6.8)	1.07 (0.34, 3.36)	0.9039	
	Ethnicity					0.4655
	Hispanic/Latino	9/ 78 (11.5)	5/ 84 (6.0)	1.34 (0.42, 4.24)	0.6202	
	Non-hispanic/Latino	16/229 (7.0)	6/234 (2.6)	2.31 (0.93, 5.78)	0.0721	
	Geographic region					0.6756
	EU	7/110 (6.4)	2/109 (1.8)	2.75 (0.67, 11.26)	0.1597	
	non-EU	19/205 (9.3)	9/212 (4.2)	1.94 (0.86, 4.38)	0.1100	
	Onset of disease					0.8702
	Paediatric	3/ 26 (11.5)	0/ 21 (0.0)	2.46 (0.42, 14.37)	0.3167	
	Adult	23/289 (8.0)	11/300 (3.7)	2.10 (1.03, 4.29)	0.0418	
	ADA result					0.7077
	Negative	21/292 (7.2)	9/295 (3.1)	2.26 (1.03, 4.92)	0.0411	
	Positive (At any time)	5/ 22 (22.7)	2/ 26 (7.7)	3.07 (0.75, 12.56)	0.1188	
	BMI (kg/m2)					0.8856
	< 30	19/213 (8.9)	9/235 (3.8)	2.29 (1.06, 4.98)	0.0359	
	>= 30	7/102 (6.9)	2/ 86 (2.3)	2.02 (0.43, 9.49)	0.3737	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations	SLEDAI-2K score					0.8228
	< 10 points	79/109 (72.5)	61/101 (60.4)	1.18 (0.98, 1.42)	0.0880	
	>= 10 points	136/206 (66.0)	120/220 (54.5)	1.21 (1.04, 1.42)	0.0158	
	OCS dose					0.0311
	<10 mg/day	102/148 (68.9)	95/145 (65.5)	1.08 (0.92, 1.26)	0.3616	
	>=10 mg/day	113/167 (67.7)	86/176 (48.9)	1.40 (1.17, 1.68)	0.0003	
	Result of type I IFN gene signature test					0.2481
	LOW	44/ 59 (74.6)	36/ 67 (53.7)	1.41 (1.08, 1.84)	0.0126	
	HIGH	171/256 (66.8)	145/254 (57.1)	1.18 (1.03, 1.35)	0.0190	
	Age (years)					0.6092
	<= 65	210/308 (68.2)	180/318 (56.6)	1.21 (1.07, 1.36)	0.0027	
	> 65	5/ 7 (71.4)	1/ 3 (33.3)	1.68 (0.47, 6.03)	0.4227	
	Sex					0.7064
	male	17/ 27 (63.0)	11/ 26 (42.3)	1.35 (0.73, 2.50)	0.3409	
	female	198/288 (68.8)	170/295 (57.6)	1.20 (1.06, 1.35)	0.0050	
	Race					0.4849
	White	122/185 (65.9)	113/205 (55.1)	1.21 (1.03, 1.42)	0.0204	
	Black	32/ 49 (65.3)	24/ 40 (60.0)	1.02 (0.75, 1.38)	0.8927	
	Other	55/ 73 (75.3)	41/ 73 (56.2)	1.29 (1.02, 1.63)	0.0333	
	Ethnicity					0.4223
	Hispanic/Latino	53/ 78 (67.9)	50/ 84 (59.5)	1.12 (0.89, 1.40)	0.3456	
	Non-hispanic/Latino	156/229 (68.1)	128/234 (54.7)	1.25 (1.08, 1.45)	0.0032	
	Geographic region					0.1349
	EU	68/110 (61.8)	49/109 (45.0)	1.41 (1.10, 1.81)	0.0073	
	non-EU	147/205 (71.7)	132/212 (62.3)	1.13 (1.00, 1.29)	0.0593	
	Onset of disease					0.1255
	Paediatric	21/ 26 (80.8)	13/ 21 (61.9)	0.93 (0.68, 1.26)	0.6222	
	Adult	194/289 (67.1)	168/300 (56.0)	1.20 (1.05, 1.36)	0.0055	
	ADA result					0.8083
	Negative	199/292 (68.2)	164/295 (55.6)	1.23 (1.08, 1.40)	0.0014	
	Positive (At any time)	16/ 22 (72.7)	17/ 26 (65.4)	1.17 (0.79, 1.73)	0.4278	
	BMI (kg/m2)					0.1033
	< 30	143/213 (67.1)	123/235 (52.3)	1.30 (1.11, 1.51)	0.0009	
	>= 30	72/102 (70.6)	58/ 86 (67.4)	1.06 (0.87, 1.28)	0.5697	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Bronchitis	SLEDAI-2K score					0.0351
	< 10 points	12/109 (11.0)	10/101 (9.9)	1.11 (0.50, 2.46)	0.8062	
	>= 10 points	20/206 (9.7)	5/220 (2.3)	4.26 (1.62, 11.21)	0.0033	
	OCS dose					0.1609
	<10 mg/day	18/148 (12.2)	5/145 (3.4)	3.50 (1.33, 9.23)	0.0114	
	>=10 mg/day	14/167 (8.4)	10/176 (5.7)	1.42 (0.64, 3.17)	0.3876	
	Result of type I IFN gene signature test					0.2206
	LOW	10/ 59 (16.9)	2/ 67 (3.0)	4.33 (1.11, 16.86)	0.0346	
	HIGH	22/256 (8.6)	13/254 (5.1)	1.67 (0.85, 3.30)	0.1365	
	Age (years)					0.8178
	<= 65	31/308 (10.1)	15/318 (4.7)	2.12 (1.17, 3.86)	0.0138	
	> 65	1/ 7 (14.3)	0/ 3 (0.0)	1.50 (0.08, 26.86)	0.7830	
	Sex					0.9936
	male	1/ 27 (3.7)	0/ 26 (0.0)	2.08 (0.09, 45.45)	0.6425	
	female	31/288 (10.8)	15/295 (5.1)	2.10 (1.16, 3.82)	0.0146	
	Race					0.7128
	White	20/185 (10.8)	9/205 (4.4)	2.42 (1.09, 5.36)	0.0300	
	Black	4/ 49 (8.2)	3/ 40 (7.5)	1.21 (0.29, 5.09)	0.7901	
	Other	7/ 73 (9.6)	3/ 73 (4.1)	2.01 (0.50, 8.10)	0.3264	
	Ethnicity					0.6192
	Hispanic/Latino	9/ 78 (11.5)	3/ 84 (3.6)	2.64 (0.74, 9.38)	0.1335	
	Non-hispanic/Latino	22/229 (9.6)	12/234 (5.1)	1.83 (0.91, 3.69)	0.0924	
	Geographic region					0.9188
	EU	10/110 (9.1)	4/109 (3.7)	2.16 (0.67, 6.89)	0.1952	
	non-EU	22/205 (10.7)	11/212 (5.2)	2.01 (0.99, 4.06)	0.0525	
	Onset of disease					0.8287
	Paediatric	3/ 26 (11.5)	0/ 21 (0.0)	2.46 (0.42, 14.37)	0.3167	
	Adult	29/289 (10.0)	15/300 (5.0)	2.00 (1.10, 3.67)	0.0240	
	ADA result					0.3105
	Negative	31/292 (10.6)	13/295 (4.4)	2.38 (1.27, 4.48)	0.0068	
	Positive (At any time)	1/ 22 (4.5)	2/ 26 (7.7)	0.81 (0.11, 5.96)	0.8321	
	BMI (kg/m2)					0.5463
	< 30	22/213 (10.3)	10/235 (4.3)	2.40 (1.16, 4.95)	0.0176	
	>= 30	10/102 (9.8)	5/ 86 (5.8)	1.63 (0.58, 4.59)	0.3586	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Herpes zoster	SLEDAI-2K score					0.2515
	< 10 points	3/109 (2.8)	2/101 (2.0)	1.28 (0.25, 6.67)	0.7671	
	>= 10 points	15/206 (7.3)	4/220 (1.8)	4.07 (1.38, 12.05)	0.0112	
	OCS dose					0.7126
	<10 mg/day	8/148 (5.4)	3/145 (2.1)	2.49 (0.65, 9.60)	0.1853	
	>=10 mg/day	10/167 (6.0)	3/176 (1.7)	3.53 (0.98, 12.74)	0.0539	
	Result of type I IFN gene signature test					0.8972
	LOW	3/ 59 (5.1)	1/ 67 (1.5)	2.44 (0.38, 15.92)	0.3500	
	HIGH	15/256 (5.9)	5/254 (2.0)	2.81 (1.02, 7.74)	0.0453	
	Age (years)					NE
	<= 65	18/308 (5.8)	6/318 (1.9)	3.07 (1.23, 7.67)	0.0161	
	> 65	0/ 7 (0.0)	0/ 3 (0.0)	NE		
	Sex					0.6651
	male	4/ 27 (14.8)	0/ 26 (0.0)	3.62 (0.64, 20.46)	0.1451	
	female	14/288 (4.9)	6/295 (2.0)	2.34 (0.90, 6.08)	0.0808	
	Race					0.6467
	White	9/185 (4.9)	4/205 (2.0)	2.52 (0.79, 8.07)	0.1191	
	Black	1/ 49 (2.0)	1/ 40 (2.5)	0.92 (0.10, 8.27)	0.9399	
	Other	6/ 73 (8.2)	1/ 73 (1.4)	3.23 (0.67, 15.68)	0.1452	
	Ethnicity					0.6785
	Hispanic/Latino	5/ 78 (6.4)	1/ 84 (1.2)	3.48 (0.56, 21.66)	0.1807	
	Non-hispanic/Latino	11/229 (4.8)	5/234 (2.1)	2.23 (0.78, 6.38)	0.1345	
	Geographic region					0.8095
	EU	6/110 (5.5)	2/109 (1.8)	2.57 (0.60, 10.95)	0.2023	
	non-EU	12/205 (5.9)	4/212 (1.9)	3.22 (1.06, 9.80)	0.0399	
	Onset of disease					0.4677
	Paediatric	3/ 26 (11.5)	1/ 21 (4.8)	1.44 (0.26, 8.12)	0.6778	
	Adult	15/289 (5.2)	5/300 (1.7)	3.03 (1.10, 8.32)	0.0316	
	ADA result					0.4678
	Negative	15/292 (5.1)	6/295 (2.0)	2.48 (0.97, 6.38)	0.0592	
	Positive (At any time)	3/ 22 (13.6)	0/ 26 (0.0)	5.66 (0.76, 42.38)	0.0917	
	BMI (kg/m2)					0.5472
	< 30	13/213 (6.1)	4/235 (1.7)	3.41 (1.11, 10.46)	0.0316	
	>= 30	5/102 (4.9)	2/ 86 (2.3)	1.92 (0.42, 8.66)	0.3971	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Nasopharyngitis	SLEDAI-2K score					0.8277
	< 10 points	14/109 (12.8)	6/101 (5.9)	2.03 (0.79, 5.18)	0.1393	
	>= 10 points	40/206 (19.4)	23/220 (10.5)	1.81 (1.13, 2.89)	0.0138	
	OCS dose					0.5553
	<10 mg/day	20/148 (13.5)	13/145 (9.0)	1.47 (0.74, 2.92)	0.2683	
	>=10 mg/day	34/167 (20.4)	16/176 (9.1)	1.92 (1.10, 3.36)	0.0219	
	Result of type I IFN gene signature test					0.1250
	LOW	10/ 59 (16.9)	2/ 67 (3.0)	4.78 (1.25, 18.23)	0.0219	
	HIGH	44/256 (17.2)	27/254 (10.6)	1.59 (1.02, 2.47)	0.0403	
	Age (years)					0.8917
	<= 65	53/308 (17.2)	29/318 (9.1)	1.84 (1.20, 2.80)	0.0048	
	> 65	1/ 7 (14.3)	0/ 3 (0.0)	1.50 (0.08, 26.86)	0.7830	
	Sex					0.3346
	male	3/ 27 (11.1)	3/ 26 (11.5)	0.87 (0.19, 4.04)	0.8611	
	female	51/288 (17.7)	26/295 (8.8)	1.91 (1.23, 2.98)	0.0041	
	Race					0.4577
	White	24/185 (13.0)	18/205 (8.8)	1.48 (0.83, 2.64)	0.1842	
	Black	5/ 49 (10.2)	3/ 40 (7.5)	1.34 (0.30, 5.95)	0.7023	
	Other	25/ 73 (34.2)	8/ 73 (11.0)	2.54 (1.28, 5.07)	0.0079	
	Ethnicity					0.6672
	Hispanic/Latino	12/ 78 (15.4)	5/ 84 (6.0)	2.21 (0.87, 5.61)	0.0955	
	Non-hispanic/Latino	42/229 (18.3)	24/234 (10.3)	1.76 (1.10, 2.80)	0.0179	
	Geographic region					0.7644
	EU	21/110 (19.1)	13/109 (11.9)	1.73 (0.92, 3.26)	0.0895	
	non-EU	33/205 (16.1)	16/212 (7.5)	1.97 (1.12, 3.46)	0.0185	
	Onset of disease					0.8050
	Paediatric	3/ 26 (11.5)	1/ 21 (4.8)	1.44 (0.21, 9.80)	0.7092	
	Adult	51/289 (17.6)	28/300 (9.3)	1.84 (1.20, 2.83)	0.0050	
	ADA result					0.2849
	Negative	46/292 (15.8)	27/295 (9.2)	1.67 (1.07, 2.62)	0.0238	
	Positive (At any time)	8/ 22 (36.4)	2/ 26 (7.7)	3.47 (0.99, 12.23)	0.0526	
	BMI (kg/m2)					0.8799
	< 30	39/213 (18.3)	23/235 (9.8)	1.84 (1.14, 2.96)	0.0124	
	>= 30	15/102 (14.7)	6/ 86 (7.0)	2.00 (0.77, 5.17)	0.1543	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Respiratory tract infection	SLEDAI-2K score					0.9458
	< 10 points	4/109 (3.7)	0/101 (0.0)	4.32 (0.52, 36.11)	0.1768	
	>= 10 points	8/206 (3.9)	1/220 (0.5)	3.94 (0.80, 19.30)	0.0907	
	OCS dose					0.8617
	<10 mg/day	8/148 (5.4)	1/145 (0.7)	4.82 (0.83, 28.08)	0.0804	
	>=10 mg/day	4/167 (2.4)	0/176 (0.0)	3.85 (0.64, 23.34)	0.1425	
	Result of type I IFN gene signature test					NE
	LOW	0/ 59 (0.0)	0/ 67 (0.0)	NE		
	HIGH	12/256 (4.7)	1/254 (0.4)	5.39 (1.18, 24.60)	0.0297	
	Age (years)					NE
	<= 65	12/308 (3.9)	1/318 (0.3)	5.62 (1.23, 25.70)	0.0260	
	> 65	0/ 7 (0.0)	0/ 3 (0.0)	NE		
	Sex					0.2017
	male	2/ 27 (7.4)	1/ 26 (3.8)	1.21 (0.14, 10.15)	0.8599	
	female	10/288 (3.5)	0/295 (0.0)	7.20 (1.29, 40.29)	0.0247	
	Race					0.6564
	White	11/185 (5.9)	1/205 (0.5)	5.87 (1.29, 26.76)	0.0222	
	Black	0/ 49 (0.0)	0/ 40 (0.0)	NE		
	Other	1/ 73 (1.4)	0/ 73 (0.0)	2.65 (0.11, 62.00)	0.5438	
	Ethnicity					0.0845
	Hispanic/Latino	0/ 78 (0.0)	1/ 84 (1.2)	0.35 (0.01, 8.11)	0.5106	
	Non-hispanic/Latino	12/229 (5.2)	0/234 (0.0)	8.16 (1.47, 45.25)	0.0163	
	Geographic region					0.3605
	EU	9/110 (8.2)	0/109 (0.0)	6.38 (1.15, 35.42)	0.0340	
	non-EU	3/205 (1.5)	1/212 (0.5)	1.76 (0.20, 15.32)	0.6079	
	Onset of disease					NE
	Paediatric	0/ 26 (0.0)	0/ 21 (0.0)	NE		
	Adult	12/289 (4.2)	1/300 (0.3)	5.62 (1.23, 25.69)	0.0260	
	ADA result					NE
	Negative	12/292 (4.1)	1/295 (0.3)	5.53 (1.21, 25.28)	0.0274	
	Positive (At any time)	0/ 22 (0.0)	0/ 26 (0.0)	NE		
	BMI (kg/m2)					0.8225
	< 30	9/213 (4.2)	1/235 (0.4)	4.38 (0.90, 21.38)	0.0680	
	>= 30	3/102 (2.9)	0/ 86 (0.0)	3.22 (0.36, 28.46)	0.2937	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Upper respiratory tract infection	SLEDAI-2K score					0.5703
	< 10 points	18/109 (16.5)	7/101 (6.9)	2.05 (0.87, 4.79)	0.0992	
	>= 10 points	31/206 (15.0)	22/220 (10.0)	1.53 (0.92, 2.56)	0.1002	
	OCS dose					0.5462
	<10 mg/day	29/148 (19.6)	19/145 (13.1)	1.49 (0.87, 2.56)	0.1437	
	>=10 mg/day	20/167 (12.0)	10/176 (5.7)	1.99 (0.93, 4.25)	0.0754	
	Result of type I IFN gene signature test					0.5924
	LOW	11/ 59 (18.6)	4/ 67 (6.0)	2.15 (0.65, 7.11)	0.2078	
	HIGH	38/256 (14.8)	25/254 (9.8)	1.52 (0.94, 2.44)	0.0855	
	Age (years)					0.7695
	<= 65	47/308 (15.3)	29/318 (9.1)	1.66 (1.07, 2.58)	0.0245	
	> 65	2/ 7 (28.6)	0/ 3 (0.0)	2.50 (0.17, 37.26)	0.5062	
	Sex					0.7282
	male	4/ 27 (14.8)	2/ 26 (7.7)	1.32 (0.34, 5.10)	0.6907	
	female	45/288 (15.6)	27/295 (9.2)	1.70 (1.08, 2.67)	0.0224	
	Race					0.8659
	White	31/185 (16.8)	21/205 (10.2)	1.60 (0.93, 2.73)	0.0869	
	Black	6/ 49 (12.2)	1/ 40 (2.5)	2.36 (0.43, 12.92)	0.3222	
	Other	12/ 73 (16.4)	7/ 73 (9.6)	1.41 (0.61, 3.27)	0.4269	
	Ethnicity					0.3382
	Hispanic/Latino	14/ 78 (17.9)	6/ 84 (7.1)	2.58 (1.05, 6.38)	0.0397	
	Non-hispanic/Latino	35/229 (15.3)	23/234 (9.8)	1.56 (0.95, 2.57)	0.0800	
	Geographic region					0.8208
	EU	9/110 (8.2)	4/109 (3.7)	1.96 (0.63, 6.02)	0.2429	
	non-EU	40/205 (19.5)	25/212 (11.8)	1.70 (1.07, 2.70)	0.0256	
	Onset of disease					0.6479
	Paediatric	5/ 26 (19.2)	3/ 21 (14.3)	1.26 (0.34, 4.72)	0.7269	
	Adult	44/289 (15.2)	26/300 (8.7)	1.75 (1.10, 2.78)	0.0176	
	ADA result					0.2332
	Negative	49/292 (16.8)	27/295 (9.2)	1.81 (1.15, 2.83)	0.0096	
	Positive (At any time)	0/ 22 (0.0)	2/ 26 (7.7)	0.47 (0.05, 4.11)	0.4945	
	BMI (kg/m2)					0.3852
	< 30	32/213 (15.0)	17/235 (7.2)	2.05 (1.18, 3.59)	0.0115	
	>= 30	17/102 (16.7)	12/ 86 (14.0)	1.34 (0.60, 2.95)	0.4739	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=315) n/ N (%)	Placebo (N=321) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SOC: Vascular disorders	SLEDAI-2K score					0.3419
	< 10 points	3/109 (2.8)	5/101 (5.0)	0.64 (0.17, 2.42)	0.5143	
	>= 10 points	4/206 (1.9)	18/220 (8.2)	0.27 (0.08, 0.92)	0.0365	
	OCS dose					0.7759
	<10 mg/day	3/148 (2.0)	8/145 (5.5)	0.43 (0.11, 1.74)	0.2357	
	>=10 mg/day	4/167 (2.4)	15/176 (8.5)	0.33 (0.11, 1.01)	0.0522	
	Result of type I IFN gene signature test					0.8275
	LOW	1/ 59 (1.7)	4/ 67 (6.0)	0.47 (0.07, 3.39)	0.4541	
	HIGH	6/256 (2.3)	19/254 (7.5)	0.37 (0.14, 0.98)	0.0462	
	Age (years)					NE
	<= 65	7/308 (2.3)	23/318 (7.2)	0.37 (0.15, 0.91)	0.0312	
	> 65	0/ 7 (0.0)	0/ 3 (0.0)	NE		
	Sex					0.9019
	male	0/ 27 (0.0)	1/ 26 (3.8)	0.47 (0.02, 9.26)	0.6171	
	female	7/288 (2.4)	22/295 (7.5)	0.38 (0.15, 0.95)	0.0391	
	Race					0.6466
	White	3/185 (1.6)	17/205 (8.3)	0.30 (0.09, 1.07)	0.0644	
	Black	2/ 49 (4.1)	1/ 40 (2.5)	1.00 (0.11, 9.44)	1.0000	
	Other	1/ 73 (1.4)	5/ 73 (6.8)	0.32 (0.05, 1.96)	0.2171	
	Ethnicity					0.9029
	Hispanic/Latino	1/ 78 (1.3)	6/ 84 (7.1)	0.37 (0.07, 1.97)	0.2430	
	Non-hispanic/Latino	5/229 (2.2)	17/234 (7.3)	0.33 (0.11, 0.95)	0.0401	
	Geographic region					0.8800
	EU	3/110 (2.7)	10/109 (9.2)	0.36 (0.08, 1.59)	0.1799	
	non-EU	4/205 (2.0)	13/212 (6.1)	0.42 (0.14, 1.23)	0.1146	
	Onset of disease					0.8830
	Paediatric	0/ 26 (0.0)	1/ 21 (4.8)	0.30 (0.01, 6.29)	0.4353	
	Adult	7/289 (2.4)	22/300 (7.3)	0.38 (0.15, 0.93)	0.0344	
	ADA result					0.6521
	Negative	7/292 (2.4)	22/295 (7.5)	0.35 (0.14, 0.92)	0.0329	
	Positive (At any time)	0/ 22 (0.0)	1/ 26 (3.8)	0.73 (0.04, 15.04)	0.8405	
	BMI (kg/m2)					0.9521
	< 30	5/213 (2.3)	17/235 (7.2)	0.34 (0.10, 1.14)	0.0797	
	>= 30	2/102 (2.0)	6/ 86 (7.0)	0.36 (0.09, 1.53)	0.1671	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Serious Adverse Events by SOC, PT (incidence in either arm >= 5% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Infections and infestations	Number of subjects with events, n (%)	13 (4.1)	23 (7.2)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.61 (0.31, 1.20)	
	p-value	0.1550	
	Odds Ratio (95% CI)	0.58 (0.28, 1.20)	
	p-value	0.1432	
	Risk Difference (95% CI)	-2.98 (-6.56, 0.60)	
	p-value	0.1023	
	p-Value for test for heterogenity between studies	0.3226	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Serious Adverse Events by SOC, PT (incidence in either arm >= 5% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Musculoskeletal and connective tissue disorders	Number of subjects with events, n (%)	5 (1.6)	12 (3.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.44 (0.16, 1.23)	
	p-value	0.1153	
	Odds Ratio (95% CI)	0.42 (0.15, 1.23)	
	p-value	0.1136	
	Risk Difference (95% CI)	-2.11 (-4.59, 0.37)	
	p-value	0.0960	
	p-Value for test for heterogenity between studies	0.9164	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Serious Adverse Events by SOC, PT (incidence in either arm >= 5% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Musculoskeletal and connective tissue disorders, PT: Systemic lupus erythematosus	Number of subjects with events, n (%)	4 (1.3)	11 (3.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.40 (0.13, 1.26)	
	p-value	0.1174	
	Odds Ratio (95% CI)	0.39 (0.12, 1.26)	
	p-value	0.1144	
	Risk Difference (95% CI)	-2.12 (-4.45, 0.22)	
	p-value	0.0759	
	p-Value for test for heterogenity between studies	0.7612	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Serious Adverse Events by SOC, PT (incidence in either arm >= 5% or >=10 patients) - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

- NO OBSERVATIONS FOR THIS ANALYSIS -

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Severe (Grade >=3) by SOC, PT (incidence in either arm >= 5% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=315)	Placebo (N=321)
SOC: Infections and infestations	Number of subjects with events, n (%)	14 (4.4)	9 (2.8)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.58 (0.67, 3.75)	
	p-value	0.3003	
	Odds Ratio (95% CI)	1.60 (0.65, 3.95)	
	p-value	0.3073	
	Risk Difference (95% CI)	1.72 (-1.18, 4.62)	
	p-value	0.2459	
	p-Value for test for heterogenity between studies	0.2739	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
TULIP SLE Study 1 + TULIP SLE Study 2 + MUSE Meta-Analysis - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Proportion of patients with at least one frequent Severe (Grade >=3) by SOC, PT (incidence in either arm >= 5% or >=10 patients) - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

- NO OBSERVATIONS FOR THIS ANALYSIS -

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anhang 4-G2: Zusatzanalysen, TULIP-1, TULIP-2, TULIP-1+TULIP-2, MUSE, TULIP-1+TULIP-2+MUSE, ITT-Population

Contents

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Subject disposition and summary of treatment exposure
Full analysis set

		Anifrolumab 300mg (N=180)	Placebo (N=184)
Patients who completed the study		146 (81.1)	148 (80.4)
Patients withdrawn from the study		34 (18.9)	36 (19.6)
WITHDRAWAL BY SUBJECT		15 (8.3)	15 (8.2)
ADVERSE EVENT		12 (6.7)	5 (2.7)
LACK OF EFFICACY		4 (2.2)	7 (3.8)
OTHER		2 (1.1)	4 (2.2)
CONDITION UNDER INVESTIGATION WORSENED		1 (0.6)	1 (0.5)
LOST TO FOLLOW-UP		0	2 (1.1)
SEVERE NON-COMPLIANCE TO PROTOCOL		0	1 (0.5)
DEVELOPMENT OF STUDY-SPECIFIC WITHDRAWAL CRITERIA		0	0
Duration of study (weeks)	n (missing)	180 (0)	184 (0)
	Mean (SD)	50.3 (11.42)	50.2 (10.65)
	Median	52.5	52.3
	Min, Max	0, 78	5, 70
Patients who completed investigational product		145 (80.6)	146 (79.3)
Patients discontinued investigational product		35 (19.4)	38 (20.7)
Withdrawal By Subject		15 (8.3)	13 (7.1)
Adverse Event		13 (7.2)	8 (4.3)
Lack Of Efficacy		3 (1.7)	9 (4.9)
Condition Under Investigation Worsened		1 (0.6)	4 (2.2)
Other		3 (1.7)	0
Severe Non-Compliance To Protocol		0	2 (1.1)
Lost To Follow-Up		0	2 (1.1)
Duration of exposure (weeks)	n (missing)	180 (0)	184 (0)
	Mean (SD)	46.6 (13.37)	46.8 (12.57)
	Median	52.1	52.1
	Min, Max	4, 60	4, 54
Number of Infusions	n (missing)	180 (0)	184 (0)
	Mean (SD)	11.3 (3.31)	11.4 (3.19)
	Median	13.0	13.0
	Min, Max	1, 13	1, 13
Subjects enrolled to the LTE study		126 (70.0)	129 (70.1)

Duration of study defined as time from randomization until end of participation date.
Duration of exposure defined as difference of date of first exposure to treatment and date of last exposure to treatment + 28 days.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Demographic and baseline characteristics
Full analysis set

		Anifrolumab 300mg (N=180)	Placebo (N=184)	Total (N=364)
Age	n (missing)	180 (0)	184 (0)	364 (0)
	Mean (SD)	42.0 (11.99)	41.0 (12.30)	41.5 (12.14)
	Median	40.5	41.0	41.0
	Min, Max	18, 68	18, 69	18, 69
Age subgroups (%)	<= 65	173 (96.1)	181 (98.4)	354 (97.3)
	> 65	7 (3.9)	3 (1.6)	10 (2.7)
Sex (%)	female	165 (91.7)	171 (92.9)	336 (92.3)
	male	15 (8.3)	13 (7.1)	28 (7.7)
Race (%)	American Indian or Alaska Native	0	1 (0.5)	1 (0.3)
	Asian	11 (6.1)	5 (2.7)	16 (4.4)
	Black or African American	29 (16.1)	23 (12.5)	52 (14.3)
	Other	15 (8.3)	18 (9.8)	33 (9.1)
	White	125 (69.4)	137 (74.5)	262 (72.0)
Ethnicity (%)	Hispanic/Latino	32 (17.8)	35 (19.0)	67 (18.4)
	Non-hispanic/Latino	148 (82.2)	149 (81.0)	297 (81.6)
Geographic region (%)	Asia Pacific	11 (6.1)	6 (3.3)	17 (4.7)
	Europe	64 (35.6)	76 (41.3)	140 (38.5)
	Latin America	24 (13.3)	25 (13.6)	49 (13.5)
	North America	75 (41.7)	72 (39.1)	147 (40.4)
	Rest Of World	6 (3.3)	5 (2.7)	11 (3.0)
Geographic region subgroup (%)	EU	64 (35.6)	76 (41.3)	140 (38.5)
	non-EU	116 (64.4)	108 (58.7)	224 (61.5)
Height (cm)	n (missing)	180 (0)	184 (0)	364 (0)
	Mean (SD)	162.99 (7.829)	163.10 (8.030)	163.04 (7.920)
	Median	162.15	162.60	162.50
	Min, Max	142.0, 183.0	140.0, 195.0	140.0, 195.0
Weight (cm)	n (missing)	180 (0)	184 (0)	364 (0)
	Mean (SD)	75.36 (20.343)	74.69 (19.332)	75.02 (19.814)
	Median	71.25	69.70	70.60
	Min, Max	42.0, 132.7	42.2, 138.0	42.0, 138.0
BMI (kg/m^2)	n (missing)	180 (0)	184 (0)	364 (0)
	Mean (SD)	28.25 (6.899)	28.09 (7.145)	28.17 (7.015)
	Median	27.03	25.99	26.35
	Min, Max	16.0, 47.2	17.2, 57.5	16.0, 57.5
BMI subgroup (%)	<=28 kg/m2	98 (54.4)	109 (59.2)	207 (56.9)
	>28 kg/m2	82 (45.6)	75 (40.8)	157 (43.1)

[a] Asia Pacific: Australia, New Zealand, South Korea, Taiwan. Europe: Germany, Hungary, Italy, Poland, Romania, Ukraine, United Kingdom. Latin America: Argentinia, Brazil, Chile, Colombia, Peru. Rest of World: Israel.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
SLE disease characteristics
Full analysis set

		Anifrolumab 300mg (N=180)	Placebo (N=184)	Total (N=364)
SLEDAI-2K score at screening	n (missing)	180 (0)	184 (0)	364 (0)
	Mean (SD)	11.4 (3.90)	11.1 (3.39)	11.3 (3.65)
	Median	10.0	10.0	10.0
	Min, Max	6, 26	6, 24	6, 26
SLEDAI-2K score at screening, categorisation (%)	< 10 points	55 (30.6)	54 (29.3)	109 (29.9)
	>= 10 points	125 (69.4)	130 (70.7)	255 (70.1)
Clinical SLEDAI-2K score at screening	n (missing)	180 (0)	184 (0)	364 (0)
	Mean (SD)	8.9 (3.00)	8.7 (2.53)	8.8 (2.77)
	Median	8.0	8.0	8.0
	Min, Max	4, 20	4, 18	4, 20
SLEDAI-2K score at baseline	n (missing)	180 (0)	184 (0)	364 (0)
	Mean (SD)	11.3 (4.04)	11.5 (3.50)	11.4 (3.77)
	Median	10.0	10.5	10.0
	Min, Max	4, 32	6, 24	4, 32
SLEDAI-2K score at baseline, categorisation (%)	< 10 points	55 (30.6)	49 (26.6)	104 (28.6)
	>= 10 points	125 (69.4)	135 (73.4)	260 (71.4)
Clinical SLEDAI-2K score at baseline	n (missing)	180 (0)	184 (0)	364 (0)
	Mean (SD)	9.0 (2.93)	8.9 (2.63)	8.9 (2.77)
	Median	8.0	8.0	8.0
	Min, Max	4, 20	4, 18	4, 20
Total Organ Score CNS	n (missing)	180 (0)	184 (0)	364 (0)
	Mean (SD)	0.1 (0.84)	0.0 (0.59)	0.1 (0.72)
	Median	0.0	0.0	0.0
	Min, Max	0, 8	0, 8	0, 8
Total Organ Score CVS and Respiratory	n (missing)	180 (0)	184 (0)	364 (0)
	Mean (SD)	0.2 (0.57)	0.1 (0.52)	0.1 (0.55)
	Median	0.0	0.0	0.0
	Min, Max	0, 2	0, 4	0, 4
Total Organ Score Hematological	n (missing)	180 (0)	184 (0)	364 (0)
	Mean (SD)	0.1 (0.32)	0.1 (0.39)	0.1 (0.35)
	Median	0.0	0.0	0.0
	Min, Max	0, 1	0, 2	0, 2
Total Organ Score Immunology	n (missing)	180 (0)	184 (0)	364 (0)
	Mean (SD)	1.8 (1.66)	1.9 (1.65)	1.9 (1.66)
	Median	2.0	2.0	2.0
	Min, Max	0, 4	0, 4	0, 4
Total Organ Score Mucocutaneous	n (missing)	180 (0)	184 (0)	364 (0)
	Mean (SD)	4.2 (1.53)	4.0 (1.57)	4.1 (1.55)
	Median	4.0	4.0	4.0
	Min, Max	0, 6	0, 6	0, 6
Total Organ Score Musculoskeletal	n (missing)	180 (0)	184 (0)	364 (0)
	Mean (SD)	3.7 (1.09)	4.0 (0.98)	3.9 (1.04)
	Median	4.0	4.0	4.0
	Min, Max	0, 8	0, 8	0, 8
Total Organ Score Renal	n (missing)	180 (0)	184 (0)	364 (0)
	Mean (SD)	0.4 (1.55)	0.5 (1.71)	0.5 (1.63)
	Median	0.0	0.0	0.0
	Min, Max	0, 12	0, 12	0, 12

Baseline is defined as the last measurement prior to randomisation and dose administration on Day 1.
Only subjects with baseline positive anti-dsDNA and abnormal complement level, respectively, are included in the summary statistics for the respective variables.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
SLE disease characteristics
Full analysis set

		Anifrolumab 300mg (N=180)	Placebo (N=184)	Total (N=364)
Total Organ Score Vascular	n (missing)	180 (0)	184 (0)	364 (0)
	Mean (SD)	0.8 (2.41)	0.8 (2.38)	0.8 (2.39)
	Median	0.0	0.0	0.0
	Min, Max	0, 8	0, 8	0, 8
Adjudication Scoring (BILAG) at baseline Overall (%)	At least one A	93 (51.7)	84 (45.7)	177 (48.6)
	No A and <2Bs	8 (4.4)	16 (8.7)	24 (6.6)
	No A and at least 2 Bs	79 (43.9)	84 (45.7)	163 (44.8)
Adjudication Scoring (BILAG) at baseline Constitutional (%)	A	1 (0.6)	0	1 (0.3)
	B	9 (5.0)	11 (6.0)	20 (5.5)
	C, D or E	170 (94.4)	173 (94.0)	343 (94.2)
Adjudication Scoring (BILAG) at baseline Mucocutaneous (%)	A	53 (29.4)	39 (21.2)	92 (25.3)
	B	107 (59.4)	119 (64.7)	226 (62.1)
	C, D or E	20 (11.1)	26 (14.1)	46 (12.6)
Adjudication Scoring (BILAG) at baseline Neuropsychiatric (%)	A	0	1 (0.5)	1 (0.3)
	B	8 (4.4)	2 (1.1)	10 (2.7)
	C, D or E	172 (95.6)	181 (98.4)	353 (97.0)
Adjudication Scoring (BILAG) at baseline Musculoskeletal (%)	A	58 (32.2)	55 (29.9)	113 (31.0)
	B	101 (56.1)	112 (60.9)	213 (58.5)
	C, D or E	21 (11.7)	17 (9.2)	38 (10.4)
Adjudication Scoring (BILAG) at baseline Cardiorespiratory (%)	A	2 (1.1)	3 (1.6)	5 (1.4)
	B	14 (7.8)	6 (3.3)	20 (5.5)
	C, D or E	164 (91.1)	175 (95.1)	339 (93.1)
Adjudication Scoring (BILAG) at baseline Gastrointestinal (%)	B	0	1 (0.5)	1 (0.3)
	C, D or E	180 (100.0)	183 (99.5)	363 (99.7)
Adjudication Scoring (BILAG) at baseline Ophthalmic (%)	A	1 (0.6)	0	1 (0.3)
	C, D or E	179 (99.4)	184 (100.0)	363 (99.7)
Adjudication Scoring (BILAG) at baseline Renal (%)	A	1 (0.6)	3 (1.6)	4 (1.1)
	B	14 (7.8)	12 (6.5)	26 (7.1)
	C, D or E	165 (91.7)	169 (91.8)	334 (91.8)
Adjudication Scoring (BILAG) at baseline Haematological (%)	B	1 (0.6)	1 (0.5)	2 (0.5)
	C, D or E	179 (99.4)	183 (99.5)	362 (99.5)
BILAG-2004 global score at baseline	n (missing)	180 (0)	184 (0)	364 (0)
	Mean (SD)	19.8 (6.28)	18.9 (5.45)	19.4 (5.89)
	Median	18.0	17.5	18.0
	Min, Max	2, 40	4, 33	2, 40
Physician Global Assessment (PGA) score at baseline	n (missing)	180 (0)	184 (0)	364 (0)
	Mean (SD)	1.9 (0.40)	1.8 (0.38)	1.9 (0.39)
	Median	1.9	1.9	1.9
	Min, Max	1, 3	1, 3	1, 3
CLASI activity score at baseline	n (missing)	180 (0)	184 (0)	364 (0)
	Mean (SD)	8.5 (7.26)	8.1 (6.66)	8.3 (6.96)
	Median	6.0	6.0	6.0
	Min, Max	0, 41	0, 35	0, 41
CLASI activity score at baseline, categorisation 1 (%)	0	6 (3.3)	6 (3.3)	12 (3.3)
	> 0	174 (96.7)	178 (96.7)	352 (96.7)

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Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
SLE disease characteristics
Full analysis set

		Anifrolumab 300mg (N=180)	Placebo (N=184)	Total (N=364)
CLASI activity score at baseline, categorisation 2 (%)	<10	122 (67.8)	130 (70.7)	252 (69.2)
	>=10	58 (32.2)	54 (29.3)	112 (30.8)
CLASI damage score at baseline	n (missing)	180 (0)	184 (0)	364 (0)
	Mean (SD)	2.0 (4.38)	1.8 (4.08)	1.9 (4.23)
	Median	0.0	0.0	0.0
	Min, Max	0, 30	0, 35	0, 35
CLASI damage score at baseline, categorisation 1 (%)	0	117 (65.0)	120 (65.2)	237 (65.1)
	> 0	63 (35.0)	64 (34.8)	127 (34.9)
CLASI damage score at baseline, categorisation 2 (%)	<10	169 (93.9)	176 (95.7)	345 (94.8)
	>=10	11 (6.1)	8 (4.3)	19 (5.2)
Tender Joint Count at Baseline	n (missing)	180 (0)	184 (0)	364 (0)
	Mean (SD)	11.7 (7.50)	10.6 (7.17)	11.1 (7.35)
	Median	10.5	10.0	10.0
	Min, Max	0, 28	0, 28	0, 28
Tender Joint Count at Baseline, categorisation (%)	0	11 (6.1)	8 (4.3)	19 (5.2)
	> 0	169 (93.9)	176 (95.7)	345 (94.8)
Swollen Joint Count at Baseline	n (missing)	180 (0)	184 (0)	364 (0)
	Mean (SD)	7.4 (5.79)	7.0 (4.80)	7.2 (5.31)
	Median	6.0	6.0	6.0
	Min, Max	0, 25	0, 23	0, 25
Swollen Joint Count at Baseline, categorisation (%)	0	16 (8.9)	14 (7.6)	30 (8.2)
	> 0	164 (91.1)	170 (92.4)	334 (91.8)
Active Joint Count at Baseline	n (missing)	180 (0)	184 (0)	364 (0)
	Mean (SD)	7.1 (5.74)	6.3 (4.49)	6.7 (5.15)
	Median	6.0	6.0	6.0
	Min, Max	0, 25	0, 23	0, 25
Active Joint Count at Baseline, categorisation (%)	0	18 (10.0)	15 (8.2)	33 (9.1)
	> 0	162 (90.0)	169 (91.8)	331 (90.9)
SDI global score at baseline	n (missing)	179 (1)	181 (3)	360 (4)
	Mean (SD)	0.7 (1.16)	0.6 (0.98)	0.6 (1.07)
	Median	0.0	0.0	0.0
	Min, Max	0, 5	0, 5	0, 5
SDI global score at baseline, categorisation (%)	0 (no damage)	119 (66.1)	110 (59.8)	229 (62.9)
	>=1 (damage)	60 (33.3)	71 (38.6)	131 (36.0)
	Missing	1 (0.6)	3 (1.6)	4 (1.1)
Time from initial SLE diagnosis to randomisation (months)	n (missing)	180 (0)	184 (0)	364 (0)
	Mean (SD)	116.2 (97.00)	103.4 (90.29)	109.7 (93.76)
	Median	88.0	79.5	84.0
	Min, Max	0, 450	4, 503	0, 503
Cushingoid features (%)	Any Cushingoid Feature	68 (37.8)	74 (40.2)	142 (39.0)
	Moon Face	32 (17.8)	34 (18.5)	66 (18.1)
	Buffalo Hump	15 (8.3)	14 (7.6)	29 (8.0)
	Purple or Violaceous Striae	17 (9.4)	13 (7.1)	30 (8.2)
	Central Obesity	28 (15.6)	33 (17.9)	61 (16.8)
	Hirsutisim	10 (5.6)	8 (4.3)	18 (4.9)
	Acne	13 (7.2)	9 (4.9)	22 (6.0)
	Easy Bruising	38 (21.1)	35 (19.0)	73 (20.1)
	Fragile Skin	25 (13.9)	24 (13.0)	49 (13.5)

Baseline is defined as the last measurement prior to randomisation and dose administration on Day 1.
Only subjects with baseline positive anti-dsDNA and abnormal complement level, respectively, are included in the summary statistics for the respective variables.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
SLE disease characteristics
Full analysis set

		Anifrolumab 300mg (N=180)	Placebo (N=184)	Total (N=364)
Results of 4-gene Type 1 Interferon (IFN) test (%)	High	148 (82.2)	151 (82.1)	299 (82.1)
	Low	32 (17.8)	33 (17.9)	65 (17.9)
Anti-dsDNA levels at baseline	n (missing)	81 (0)	82 (0)	163 (0)
	Mean (SD)	148.2 (279.22)	193.8 (511.92)	171.2 (412.37)
	Median	58.8	52.6	53.5
	Min, Max	15, 1808	17, 3790	15, 3790
Anti-dsDNA levels at baseline, categorisation (%)	Negative	99 (55.0)	102 (55.4)	201 (55.2)
	Positive	81 (45.0)	82 (44.6)	163 (44.8)
ANA (%)	Abnormal (titre >= 1:80)	164 (91.1)	165 (89.7)	329 (90.4)
	Normal (titre < 1:80)	11 (6.1)	14 (7.6)	25 (6.9)
	Missing	5 (2.8)	5 (2.7)	10 (2.7)
Complement C3 level at baseline	n (missing)	58 (0)	65 (0)	123 (0)
	Mean (SD)	0.68 (0.160)	0.72 (0.133)	0.70 (0.147)
	Median	0.72	0.74	0.73
	Min, Max	0.2, 0.9	0.4, 0.9	0.2, 0.9
Complement C3 level at baseline, categorisation (%)	Abnormal	58 (32.2)	65 (35.3)	123 (33.8)
	Normal	122 (67.8)	119 (64.7)	241 (66.2)
Complement C4 level at baseline	n (missing)	35 (0)	39 (0)	74 (0)
	Mean (SD)	0.07 (0.017)	0.07 (0.013)	0.07 (0.015)
	Median	0.07	0.07	0.07
	Min, Max	0.1, 0.1	0.1, 0.1	0.1, 0.1
Complement C4 level at baseline, categorisation (%)	Abnormal	35 (19.4)	39 (21.2)	74 (20.3)
	Normal	145 (80.6)	145 (78.8)	290 (79.7)
Complement CH50 level at baseline	n (missing)	20 (0)	15 (0)	35 (0)
	Mean (SD)	38.75 (29.212)	49.87 (27.946)	43.51 (28.803)
	Median	36.00	55.00	40.00
	Min, Max	5.0, 89.0	5.0, 90.0	5.0, 90.0
Complement CH50 level at baseline, categorisation (%)	Abnormal	20 (11.1)	15 (8.2)	35 (9.6)
	Normal	160 (88.9)	169 (91.8)	329 (90.4)

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Only subjects with baseline positive anti-dsDNA and abnormal complement level, respectively, are included in the summary statistics for the respective variables.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Observation times for Efficacy endpoints
Full analysis set

		Anifrolumab 300mg (N=180)	Placebo (N=184)
SRI4: Observation time (weeks)	n (missing)	180 (0)	184 (0)
	Mean (SD)	48.3 (10.79)	48.4 (10.58)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
CLASI activity score: Observation time (weeks)	n (missing)	180 (0)	184 (0)
	Mean (SD)	48.3 (10.76)	48.4 (10.58)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
CLASI damage score: Observation time (weeks)	n (missing)	180 (0)	184 (0)
	Mean (SD)	48.3 (10.76)	48.4 (10.58)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
BICLA: Observation time (weeks)	n (missing)	180 (0)	184 (0)
	Mean (SD)	48.3 (10.76)	48.5 (10.58)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
SLEDAI-2K Total Score: Observation time (weeks)	n (missing)	180 (0)	184 (0)
	Mean (SD)	47.9 (11.09)	47.9 (11.29)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
PGA: Observation time (weeks)	n (missing)	180 (0)	184 (0)
	Mean (SD)	48.2 (11.10)	48.4 (10.59)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
BILAG Global Score: Observation time (weeks)	n (missing)	180 (0)	184 (0)
	Mean (SD)	48.1 (11.03)	48.4 (10.57)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
Tender Joint Count: Observation time (weeks)	n (missing)	180 (0)	184 (0)
	Mean (SD)	48.3 (10.79)	48.4 (10.59)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
Swollen Joint Count: Observation time (weeks)	n (missing)	180 (0)	184 (0)
	Mean (SD)	48.3 (10.79)	48.4 (10.59)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
FACIT-F Total Score: Observation time (weeks)	n (missing)	180 (0)	184 (0)
	Mean (SD)	47.5 (12.06)	47.8 (11.33)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
SF-36 v2.0 Acute - Mental Component Score: Observation time (weeks)	n (missing)	180 (0)	184 (0)
	Mean (SD)	46.7 (13.68)	47.2 (12.43)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
SF-36 v2.0 Acute - Physical Component Score: Observation time (weeks)	n (missing)	180 (0)	184 (0)
	Mean (SD)	46.7 (13.68)	47.2 (12.43)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
EQ-5D VAS Score: Observation time (weeks)	n (missing)	180 (0)	184 (0)

Observation duration defined as time from randomization until last non-missing assessment after randomization. Subjects without assessment are censored at day 1.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Observation times for Efficacy endpoints
Full analysis set

		Anifrolumab 300mg (N=180)	Placebo (N=184)
EQ-5D VAS Score: Observation time (weeks)	Mean (SD)	45.1 (14.86)	46.1 (13.80)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
SDI Global Score: Observation time (weeks)	n (missing)	180 (0)	184 (0)
	Mean (SD)	42.6 (17.98)	44.7 (16.48)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
PtGA: Observation time (weeks)	n (missing)	180 (0)	184 (0)
	Mean (SD)	47.3 (12.36)	47.3 (12.15)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54

Observation duration defined as time from randomization until last non-missing assessment after randomization. Subjects without assessment are censored at day 1.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 4	Number of subjects with events, n (%)	17 (9.4)	16 (8.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.09 (0.57, 2.08)	
	p-value	0.7886	
	Odds Ratio (95% CI)	1.10 (0.54, 2.26)	
	p-value	0.7891	
	Risk Difference (95% CI)	0.81 (-5.10, 6.72)	
	p-value	0.7891	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.09 (0.57, 2.08)	
	p-value	0.8036	
	Odds Ratio (95% CI)	1.10 (0.54, 2.24)	
	p-value	0.8036	
	Risk Difference (95% CI)	0.75 (-5.15, 6.65)	
	p-value	0.8036	
	CMH approach		
	Response rate	9.6	8.7
	Difference in response rates (95% CI)	0.82 (-6.14, 7.78)	
	p-value	0.8168	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 8	Number of subjects with events, n (%)	41 (22.8)	35 (19.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.20 (0.81, 1.79)	
	p-value	0.3583	
	Odds Ratio (95% CI)	1.27 (0.76, 2.13)	
	p-value	0.3577	
	Risk Difference (95% CI)	3.88 (-4.37, 12.14)	
	p-value	0.3567	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.20 (0.80, 1.79)	
	p-value	0.3791	
	Odds Ratio (95% CI)	1.26 (0.76, 2.08)	
	p-value	0.3786	
	Risk Difference (95% CI)	3.76 (-4.59, 12.10)	
	p-value	0.3779	
	CMH approach		
	Response rate	22.9	18.9
	Difference in response rates (95% CI)	3.99 (-4.71, 12.69)	
	p-value	0.3684	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 12	Number of subjects with events, n (%)	62 (34.4)	56 (30.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.14 (0.85, 1.52)	
	p-value	0.3932	
	Odds Ratio (95% CI)	1.21 (0.78, 1.89)	
	p-value	0.3939	
	Risk Difference (95% CI)	4.15 (-5.37, 13.67)	
	p-value	0.3931	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.13 (0.84, 1.52)	
	p-value	0.4144	
	Odds Ratio (95% CI)	1.20 (0.77, 1.86)	
	p-value	0.4141	
	Risk Difference (95% CI)	4.01 (-5.60, 13.62)	
	p-value	0.4136	
	CMH approach		
	Response rate	34.6	30.5
	Difference in response rates (95% CI)	4.17 (-5.49, 13.83)	
	p-value	0.3971	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 16	Number of subjects with events, n (%)	72 (40.0)	70 (38.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.05 (0.81, 1.35)	
	p-value	0.7103	
	Odds Ratio (95% CI)	1.08 (0.71, 1.65)	
	p-value	0.7119	
	Risk Difference (95% CI)	1.90 (-8.19, 11.99)	
	p-value	0.7119	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.05 (0.81, 1.36)	
	p-value	0.7020	
	Odds Ratio (95% CI)	1.09 (0.71, 1.65)	
	p-value	0.7020	
	Risk Difference (95% CI)	1.96 (-8.06, 11.98)	
	p-value	0.7020	
	CMH approach		
	Response rate	40.1	38.2
	Difference in response rates (95% CI)	1.91 (-8.14, 11.96)	
	p-value	0.7095	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 20	Number of subjects with events, n (%)	83 (46.1)	77 (41.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.11 (0.88, 1.39)	
	p-value	0.3937	
	Odds Ratio (95% CI)	1.20 (0.79, 1.81)	
	p-value	0.3961	
	Risk Difference (95% CI)	4.42 (-5.78, 14.62)	
	p-value	0.3954	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.10 (0.87, 1.39)	
	p-value	0.4130	
	Odds Ratio (95% CI)	1.19 (0.79, 1.80)	
	p-value	0.4127	
	Risk Difference (95% CI)	4.26 (-5.93, 14.45)	
	p-value	0.4122	
	CMH approach		
	Response rate	46.4	41.8
	Difference in response rates (95% CI)	4.56 (-5.55, 14.67)	
	p-value	0.3766	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 24	Number of subjects with events, n (%)	85 (47.2)	80 (43.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.08 (0.87, 1.36)	
	p-value	0.4750	
	Odds Ratio (95% CI)	1.16 (0.77, 1.75)	
	p-value	0.4781	
	Risk Difference (95% CI)	3.72 (-6.55, 14.00)	
	p-value	0.4776	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.09 (0.87, 1.36)	
	p-value	0.4734	
	Odds Ratio (95% CI)	1.16 (0.77, 1.76)	
	p-value	0.4732	
	Risk Difference (95% CI)	3.74 (-6.48, 13.97)	
	p-value	0.4729	
	CMH approach		
	Response rate	47.5	43.6
	Difference in response rates (95% CI)	3.85 (-6.22, 13.93)	
	p-value	0.4535	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 28	Number of subjects with events, n (%)	87 (48.3)	84 (45.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.06 (0.85, 1.31)	
	p-value	0.6254	
	Odds Ratio (95% CI)	1.11 (0.73, 1.67)	
	p-value	0.6270	
	Risk Difference (95% CI)	2.55 (-7.74, 12.85)	
	p-value	0.6269	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.06 (0.85, 1.32)	
	p-value	0.6084	
	Odds Ratio (95% CI)	1.11 (0.74, 1.68)	
	p-value	0.6084	
	Risk Difference (95% CI)	2.68 (-7.57, 12.93)	
	p-value	0.6082	
	CMH approach		
	Response rate	48.5	45.8
	Difference in response rates (95% CI)	2.62 (-7.59, 12.83)	
	p-value	0.6152	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 32	Number of subjects with events, n (%)	88 (48.9)	86 (46.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.05 (0.85, 1.29)	
	p-value	0.6788	
	Odds Ratio (95% CI)	1.09 (0.72, 1.64)	
	p-value	0.6804	
	Risk Difference (95% CI)	2.17 (-8.14, 12.47)	
	p-value	0.6803	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.05 (0.84, 1.30)	
	p-value	0.6815	
	Odds Ratio (95% CI)	1.09 (0.72, 1.64)	
	p-value	0.6814	
	Risk Difference (95% CI)	2.15 (-8.11, 12.41)	
	p-value	0.6814	
	CMH approach		
	Response rate	49.0	46.9
	Difference in response rates (95% CI)	2.13 (-8.08, 12.33)	
	p-value	0.6827	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 36	Number of subjects with events, n (%)	89 (49.4)	86 (46.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.06 (0.85, 1.31)	
	p-value	0.6135	
	Odds Ratio (95% CI)	1.11 (0.74, 1.67)	
	p-value	0.6151	
	Risk Difference (95% CI)	2.65 (-7.69, 13.00)	
	p-value	0.6150	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.06 (0.85, 1.31)	
	p-value	0.6056	
	Odds Ratio (95% CI)	1.11 (0.74, 1.68)	
	p-value	0.6056	
	Risk Difference (95% CI)	2.71 (-7.56, 12.97)	
	p-value	0.6054	
	CMH approach		
	Response rate	49.5	47.0
	Difference in response rates (95% CI)	2.56 (-7.63, 12.76)	
	p-value	0.6220	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 40	Number of subjects with events, n (%)	89 (49.4)	86 (46.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.06 (0.85, 1.31)	
	p-value	0.6202	
	Odds Ratio (95% CI)	1.11 (0.74, 1.67)	
	p-value	0.6216	
	Risk Difference (95% CI)	2.60 (-7.72, 12.92)	
	p-value	0.6215	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.06 (0.85, 1.31)	
	p-value	0.6056	
	Odds Ratio (95% CI)	1.11 (0.74, 1.68)	
	p-value	0.6056	
	Risk Difference (95% CI)	2.71 (-7.56, 12.97)	
	p-value	0.6054	
	CMH approach		
	Response rate	49.5	47.0
	Difference in response rates (95% CI)	2.52 (-7.69, 12.72)	
	p-value	0.6288	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 44	Number of subjects with events, n (%)	89 (49.4)	81 (44.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.12 (0.90, 1.40)	
	p-value	0.3023	
	Odds Ratio (95% CI)	1.24 (0.82, 1.86)	
	p-value	0.3063	
	Risk Difference (95% CI)	5.45 (-4.97, 15.88)	
	p-value	0.3051	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.12 (0.90, 1.40)	
	p-value	0.3006	
	Odds Ratio (95% CI)	1.24 (0.82, 1.88)	
	p-value	0.3001	
	Risk Difference (95% CI)	5.42 (-4.81, 15.66)	
	p-value	0.2992	
	CMH approach		
	Response rate	49.7	44.3
	Difference in response rates (95% CI)	5.42 (-4.73, 15.57)	
	p-value	0.2954	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 48	Number of subjects with events, n (%)	88 (48.9)	75 (40.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.20 (0.96, 1.51)	
	p-value	0.1135	
	Odds Ratio (95% CI)	1.39 (0.92, 2.10)	
	p-value	0.1147	
	Risk Difference (95% CI)	8.31 (-1.96, 18.59)	
	p-value	0.1128	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.20 (0.95, 1.51)	
	p-value	0.1204	
	Odds Ratio (95% CI)	1.39 (0.92, 2.10)	
	p-value	0.1194	
	Risk Difference (95% CI)	8.13 (-2.06, 18.31)	
	p-value	0.1178	
	CMH approach		
	Response rate	49.1	40.9
	Difference in response rates (95% CI)	8.21 (-1.93, 18.35)	
	p-value	0.1127	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 52	Number of subjects with events, n (%)	88 (48.9)	79 (42.9)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.14 (0.91, 1.43)	
	p-value	0.2453	
	Odds Ratio (95% CI)	1.27 (0.85, 1.92)	
	p-value	0.2475	
	Risk Difference (95% CI)	6.12 (-4.22, 16.46)	
	p-value	0.2460	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.14 (0.91, 1.42)	
	p-value	0.2553	
	Odds Ratio (95% CI)	1.27 (0.84, 1.92)	
	p-value	0.2547	
	Risk Difference (95% CI)	5.95 (-4.27, 16.18)	
	p-value	0.2536	
	CMH approach		
	Response rate	49.0	43.0
	Difference in response rates (95% CI)	6.01 (-4.18, 16.20)	
	p-value	0.2477	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.5981
< 10 points	28/ 55 (50.9)	51.2	22/ 54 (40.7)	41.2	1.25 (0.83, 1.89)	0.2907	10.00 (-8.62, 28.62)	0.2924	
>= 10 points	60/125 (48.0)	48.1	57/130 (43.8)	43.8	1.09 (0.84, 1.43)	0.5060	4.26 (-7.87, 16.40)	0.4913	
OCS dose at baseline									0.4528
<10 mg/day	37/ 77 (48.1)	48.4	38/ 82 (46.3)	46.5	1.04 (0.75, 1.44)	0.8290	1.95 (-13.39, 17.30)	0.8031	
>=10 mg/day	51/103 (49.5)	49.7	41/102 (40.2)	40.4	1.23 (0.91, 1.67)	0.1827	9.31 (-4.24, 22.86)	0.1780	
Result of type I IFN gene signature test									0.2251
LOW	13/ 32 (40.6)	40.6	16/ 33 (48.5)	48.5	0.84 (0.48, 1.45)	0.5262	-7.86 (-32.00, 16.28)	0.5233	
HIGH	75/148 (50.7)	50.8	63/151 (41.7)	41.8	1.21 (0.95, 1.55)	0.1222	9.03 (-2.21, 20.28)	0.1154	
Age (years)									0.5932
<= 65	84/173 (48.6)	48.7	77/181 (42.5)	42.6	1.14 (0.91, 1.43)	0.2567	6.11 (-4.25, 16.47)	0.2477	
> 65	4/ 7 (57.1)	57.1	2/ 3 (66.7)	66.7	0.86 (0.31, 2.39)	0.7683	-9.52 (-76.58, 57.53)	0.7807	
Sex									0.7975
male	6/ 15 (40.0)	40.0	4/ 13 (30.8)	30.8	1.30 (0.47, 3.62)	0.6156	9.23 (-26.81, 45.27)	0.6157	
female	82/165 (49.7)	49.7	75/171 (43.9)	43.9	1.13 (0.90, 1.42)	0.2843	5.81 (-4.80, 16.42)	0.2829	
Race									0.4906
White	63/125 (50.4)	50.9	63/137 (46.0)	45.9	1.10 (0.85, 1.41)	0.4747	4.98 (-7.04, 16.99)	0.4171	
Black or African American	12/ 29 (41.4)	41.4	9/ 23 (39.1)	39.1	1.06 (0.54, 2.06)	0.8699	2.25 (-24.71, 29.21)	0.8701	
Asian	4/ 11 (36.4)	36.4	2/ 5 (40.0)	40.0	0.91 (0.24, 3.43)	0.8881	-3.64 (-55.94, 48.66)	0.8916	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	9/ 15 (60.0)	60.0	5/ 18 (27.8)	27.8	2.16 (0.92, 5.06)	0.0764	32.22 (-0.75, 65.20)	0.0555	
Ethnicity									0.9070
Hispanic/Latino	15/ 32 (46.9)	46.9	14/ 35 (40.0)	40.0	1.17 (0.68, 2.03)	0.5708	6.88 (-16.89, 30.64)	0.5707	
Non-hispanic/Latino	73/148 (49.3)	49.3	65/149 (43.6)	44.2	1.13 (0.89, 1.44)	0.3257	5.16 (-6.17, 16.49)	0.3718	
Geographic region									0.8903
EU	41/ 64 (64.1)	64.1	41/ 76 (53.9)	53.9	1.19 (0.90, 1.57)	0.2243	10.12 (-6.17, 26.40)	0.2234	
non-EU	47/116 (40.5)	40.9	38/108 (35.2)	35.0	1.15 (0.82, 1.61)	0.4130	5.85 (-6.93, 18.63)	0.3699	
Onset of disease									0.8500
Paediatric	3/ 12 (25.0)	25.0	3/ 12 (25.0)	25.0	1.00 (0.25, 4.00)	1.0000	0.00 (-37.09, 37.09)	1.0000	
Adult	85/168 (50.6)	50.7	76/172 (44.2)	44.2	1.15 (0.91, 1.43)	0.2376	6.53 (-4.04, 17.10)	0.2259	
ADA result									0.6269
Negative	80/162 (49.4)	49.6	74/169 (43.8)	44.0	1.13 (0.89, 1.42)	0.3081	5.58 (-5.09, 16.26)	0.3054	
Positive (At any time)	8/ 17 (47.1)	47.1	5/ 15 (33.3)	33.3	1.41 (0.59, 3.39)	0.4401	13.73 (-20.33, 47.78)	0.4295	
BMI (kg/m2) at enrolment									0.8560
< 30	55/108 (50.9)	51.3	57/127 (44.9)	45.2	1.13 (0.87, 1.48)	0.3542	6.11 (-6.53, 18.76)	0.3433	
>= 30	33/ 72 (45.8)	46.6	22/ 57 (38.6)	39.3	1.19 (0.79, 1.79)	0.4144	7.32 (-9.45, 24.09)	0.3923	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
SRI (4) - individual components at week 52 (Full analysis set)
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
>=4 point reduction in SLEDAI-2k [a]	89 (49.4)	80 (43.5)
No discontinuation of IP	145 (80.6)	146 (79.3)
No use of medication beyond protocol allowed threshold	140 (77.8)	128 (69.6)
No worsening of BILAG [a]	119 (66.1)	105 (57.1)
No worsening of PGA [a]	117 (65.0)	105 (57.1)

[a] Subjects who discontinued IP or used medications beyond protocol allowed threshold are considered non-responders and not included in this category.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate at week 52 sensitivity analysis, multiple imputation
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 52	Number of subjects with events, n (%)	88 (48.7)	78 (42.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.15 (0.92, 1.45)	
	p-value	0.2240	
	Odds Ratio (95% CI)	1.29 (0.85, 1.95)	
	p-value	0.2261	
	Risk Difference (95% CI)	6.46 (-3.96, 16.88)	
	p-value	0.2244	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.15 (0.91, 1.44)	
	p-value	0.2360	
	Odds Ratio (95% CI)	1.29 (0.85, 1.95)	
	p-value	0.2352	
	Risk Difference (95% CI)	6.25 (-4.04, 16.54)	
	p-value	0.2341	

For each outcome and visit, 100 imputations were generated by randomised treatment group. Each imputed dataset was analysed separately, and the single estimates are combined using PROC MIANALYZE. The estimated number of responders and non-responders are rounded to an integer. Therefore, there might be slight mismatches between number of subjects and corresponding percentage.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
SRI (8) response rate at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=173)	Placebo (N=174)
Week 52	Number of subjects with events, n (%)	51 (29.5)	29 (16.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.78 (1.19, 2.67)	
	p-value	0.0054	
	Odds Ratio (95% CI)	2.08 (1.25, 3.48)	
	p-value	0.0050	
	Risk Difference (95% CI)	13.00 (4.14, 21.87)	
	p-value	0.0040	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.77 (1.18, 2.65)	
	p-value	0.0057	
	Odds Ratio (95% CI)	2.09 (1.25, 3.50)	
	p-value	0.0051	
	Risk Difference (95% CI)	12.81 (4.05, 21.58)	
	p-value	0.0042	
	CMH approach		
	Response rate	29.6	16.5
	Difference in response rates (95% CI)	13.04 (3.95, 22.13)	
	p-value	0.0049	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
SRI (8) response rate at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=173) n/ N (%)	Response rate	Placebo (N=174) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.7816
< 10 points	11/ 48 (22.9)	22.9	5/ 44 (11.4)	11.4	2.02 (0.76, 5.35)	0.1584	11.55 (-4.53, 27.64)	0.1593	
>= 10 points	40/125 (32.0)	32.0	24/130 (18.5)	18.4	1.73 (1.11, 2.70)	0.0148	13.60 (2.83, 24.37)	0.0133	
OCS dose at baseline									0.0310
<10 mg/day	18/ 74 (24.3)	24.7	17/ 76 (22.4)	22.4	1.09 (0.61, 1.94)	0.7771	2.26 (-11.92, 16.43)	0.7551	
>=10 mg/day	33/ 99 (33.3)	33.6	12/ 98 (12.2)	12.3	2.72 (1.50, 4.95)	0.0010	21.29 (9.32, 33.25)	0.0005	
Result of type I IFN gene signature test									0.2594
LOW	6/ 31 (19.4)	19.4	6/ 32 (18.8)	18.8	1.03 (0.37, 2.86)	0.9513	0.60 (-20.03, 21.24)	0.9542	
HIGH	45/142 (31.7)	31.8	23/142 (16.2)	16.0	1.96 (1.25, 3.05)	0.0031	15.81 (5.69, 25.93)	0.0022	
Age (years)									0.4719
<= 65	49/166 (29.5)	29.6	28/171 (16.4)	16.2	1.80 (1.19, 2.72)	0.0051	13.43 (4.19, 22.68)	0.0044	
> 65	2/ 7 (28.6)	28.6	1/ 3 (33.3)	33.3	0.86 (0.12, 6.23)	0.8789	-4.76 (-71.14, 61.61)	0.8882	
Sex									0.9562
male	5/ 15 (33.3)	33.3	2/ 11 (18.2)	18.2	1.83 (0.43, 7.77)	0.4105	15.15 (-20.61, 50.91)	0.4063	
female	46/158 (29.1)	29.1	27/163 (16.6)	16.4	1.76 (1.15, 2.68)	0.0088	12.71 (3.29, 22.14)	0.0082	
Race									0.6308
White	35/121 (28.9)	29.4	24/129 (18.6)	18.5	1.55 (0.99, 2.45)	0.0581	10.88 (-0.12, 21.89)	0.0525	
Black or African American	6/ 27 (22.2)	22.2	3/ 23 (13.0)	13.0	1.70 (0.48, 6.06)	0.4107	9.18 (-13.72, 32.08)	0.4321	
Asian	3/ 10 (30.0)	30.0	0/ 4 (0.0)	0.0	3.18 (0.20, 50.69)	0.4125	30.00 (-21.79, 81.79)	0.2563	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	7/ 15 (46.7)	46.7	2/ 17 (11.8)	11.8	3.97 (0.97, 16.24)	0.0554	34.90 (3.49, 66.32)	0.0294	
Ethnicity									0.1436
Hispanic/Latino	9/ 32 (28.1)	28.1	2/ 34 (5.9)	5.9	4.78 (1.12, 20.47)	0.0349	22.24 (3.24, 41.25)	0.0218	
Non-hispanic/Latino	42/141 (29.8)	30.2	27/140 (19.3)	19.6	1.54 (1.01, 2.36)	0.0441	10.68 (0.23, 21.12)	0.0451	
Geographic region									0.4925
EU	26/ 59 (44.1)	44.1	15/ 72 (20.8)	20.8	2.12 (1.24, 3.61)	0.0060	23.23 (7.32, 39.15)	0.0042	
non-EU	25/114 (21.9)	21.9	14/102 (13.7)	13.5	1.60 (0.88, 2.90)	0.1241	8.46 (-2.59, 19.51)	0.1333	
Onset of disease									0.3302
Paediatric	3/ 12 (25.0)	25.0	0/ 12 (0.0)	0.0	7.00 (0.40, 122.44)	0.1826	25.00 (-7.22, 57.22)	0.1283	
Adult	48/161 (29.8)	30.0	29/162 (17.9)	17.7	1.67 (1.11, 2.50)	0.0138	12.29 (2.74, 21.84)	0.0116	
ADA result									0.8311
Negative	46/156 (29.5)	29.7	26/159 (16.4)	16.2	1.80 (1.18, 2.76)	0.0068	13.50 (3.94, 23.06)	0.0056	
Positive (At any time)	5/ 16 (31.3)	31.3	3/ 15 (20.0)	20.0	1.56 (0.45, 5.43)	0.4827	11.25 (-21.04, 43.54)	0.4947	
BMI (kg/m2) at enrolment									0.2749
< 30	33/104 (31.7)	32.2	24/120 (20.0)	19.9	1.59 (1.01, 2.50)	0.0471	12.25 (0.49, 24.01)	0.0411	
>= 30	18/ 69 (26.1)	26.0	5/ 54 (9.3)	9.6	2.82 (1.12, 7.10)	0.0281	16.43 (1.74, 31.12)	0.0283	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
>=4 reduction in SLEDAI-2K at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 52	Number of subjects with events, n (%)	89 (49.4)	80 (43.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.14 (0.91, 1.42)	
	p-value	0.2471	
	Odds Ratio (95% CI)	1.27 (0.84, 1.92)	
	p-value	0.2490	
	Risk Difference (95% CI)	6.10 (-4.24, 16.43)	
	p-value	0.2475	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.14 (0.91, 1.42)	
	p-value	0.2547	
	Odds Ratio (95% CI)	1.27 (0.84, 1.92)	
	p-value	0.2541	
	Risk Difference (95% CI)	5.97 (-4.26, 16.20)	
	p-value	0.2530	
	CMH approach		
	Response rate	49.5	43.5
	Difference in response rates (95% CI)	5.99 (-4.21, 16.19)	
	p-value	0.2496	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
>=4 reduction in SLEDAI-2K at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.4560
< 10 points	29/ 55 (52.7)	52.9	22/ 54 (40.7)	41.2	1.29 (0.86, 1.95)	0.2149	11.68 (-6.95, 30.31)	0.2192	
>= 10 points	60/125 (48.0)	48.1	58/130 (44.6)	44.6	1.08 (0.83, 1.40)	0.5880	3.52 (-8.62, 15.66)	0.5702	
OCS dose at baseline									0.3380
<10 mg/day	37/ 77 (48.1)	48.4	39/ 82 (47.6)	47.7	1.01 (0.73, 1.40)	0.9506	0.76 (-14.60, 16.11)	0.9230	
>=10 mg/day	52/103 (50.5)	50.6	41/102 (40.2)	40.4	1.26 (0.93, 1.70)	0.1421	10.20 (-3.35, 23.75)	0.1401	
Result of type I IFN gene signature test									0.2272
LOW	13/ 32 (40.6)	40.6	16/ 33 (48.5)	48.5	0.84 (0.48, 1.45)	0.5262	-7.86 (-32.00, 16.28)	0.5233	
HIGH	76/148 (51.4)	51.4	64/151 (42.4)	42.4	1.21 (0.95, 1.55)	0.1220	9.01 (-2.24, 20.26)	0.1166	
Age (years)									0.5944
<= 65	85/173 (49.1)	49.2	78/181 (43.1)	43.1	1.14 (0.91, 1.43)	0.2551	6.09 (-4.27, 16.45)	0.2495	
> 65	4/ 7 (57.1)	57.1	2/ 3 (66.7)	66.7	0.86 (0.31, 2.39)	0.7683	-9.52 (-76.58, 57.53)	0.7807	
Sex									0.7957
male	6/ 15 (40.0)	40.0	4/ 13 (30.8)	30.8	1.30 (0.47, 3.62)	0.6156	9.23 (-26.81, 45.27)	0.6157	
female	83/165 (50.3)	50.2	76/171 (44.4)	44.4	1.13 (0.90, 1.42)	0.2829	5.80 (-4.80, 16.40)	0.2835	
Race									0.6714
White	63/125 (50.4)	50.9	63/137 (46.0)	45.9	1.10 (0.85, 1.41)	0.4747	4.98 (-7.04, 16.99)	0.4171	
Black or African American	13/ 29 (44.8)	44.8	9/ 23 (39.1)	39.1	1.15 (0.60, 2.20)	0.6820	5.70 (-21.35, 32.75)	0.6797	
Asian	4/ 11 (36.4)	36.4	2/ 5 (40.0)	40.0	0.91 (0.24, 3.43)	0.8881	-3.64 (-55.94, 48.66)	0.8916	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	9/ 15 (60.0)	60.0	6/ 18 (33.3)	33.3	1.80 (0.83, 3.90)	0.1361	26.67 (-6.77, 60.11)	0.1180	
Ethnicity									0.8753
Hispanic/Latino	15/ 32 (46.9)	46.9	15/ 35 (42.9)	42.9	1.09 (0.64, 1.86)	0.7410	4.02 (-19.84, 27.87)	0.7413	
Non-hispanic/Latino	74/148 (50.0)	49.8	65/149 (43.6)	44.2	1.15 (0.90, 1.46)	0.2721	5.68 (-5.65, 17.01)	0.3256	
Geographic region									0.8715
EU	41/ 64 (64.1)	64.1	41/ 76 (53.9)	53.9	1.19 (0.90, 1.57)	0.2243	10.12 (-6.17, 26.40)	0.2234	
non-EU	48/116 (41.4)	41.7	39/108 (36.1)	35.9	1.15 (0.82, 1.60)	0.4206	5.80 (-7.03, 18.62)	0.3758	
Onset of disease									0.8515
Paediatric	3/ 12 (25.0)	25.0	3/ 12 (25.0)	25.0	1.00 (0.25, 4.00)	1.0000	0.00 (-37.09, 37.09)	1.0000	
Adult	86/168 (51.2)	51.3	77/172 (44.8)	44.7	1.14 (0.92, 1.43)	0.2369	6.54 (-4.03, 17.11)	0.2252	
ADA result									0.6251
Negative	81/162 (50.0)	50.1	75/169 (44.4)	44.6	1.13 (0.90, 1.42)	0.3063	5.54 (-5.14, 16.21)	0.3095	
Positive (At any time)	8/ 17 (47.1)	47.1	5/ 15 (33.3)	33.3	1.41 (0.59, 3.39)	0.4401	13.73 (-20.33, 47.78)	0.4295	
BMI (kg/m2) at enrolment									0.7089
< 30	55/108 (50.9)	51.3	58/127 (45.7)	46.0	1.12 (0.86, 1.45)	0.4205	5.35 (-7.32, 18.01)	0.4080	
>= 30	34/ 72 (47.2)	48.1	22/ 57 (38.6)	39.3	1.22 (0.81, 1.84)	0.3331	8.86 (-7.83, 25.54)	0.2981	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
>=8 reduction in SLEDAI-2K at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 52	Number of subjects with events, n (%)	51 (28.3)	29 (15.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.81 (1.20, 2.72)	
	p-value	0.0044	
	Odds Ratio (95% CI)	2.12 (1.27, 3.53)	
	p-value	0.0041	
	Risk Difference (95% CI)	12.72 (4.24, 21.20)	
	p-value	0.0033	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.80 (1.20, 2.70)	
	p-value	0.0047	
	Odds Ratio (95% CI)	2.11 (1.27, 3.53)	
	p-value	0.0042	
	Risk Difference (95% CI)	12.57 (4.14, 21.00)	
	p-value	0.0035	
	CMH approach		
	Response rate	28.4	15.6
	Difference in response rates (95% CI)	12.77 (4.02, 21.52)	
	p-value	0.0042	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
>=8 reduction in SLEDAI-2K at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.6904
< 10 points	11/ 55 (20.0)	19.9	5/ 54 (9.3)	9.3	2.16 (0.80, 5.80)	0.1267	10.65 (-4.57, 25.87)	0.1702	
>= 10 points	40/125 (32.0)	32.0	24/130 (18.5)	18.4	1.73 (1.11, 2.70)	0.0148	13.60 (2.83, 24.37)	0.0133	
OCS dose at baseline									0.0395
<10 mg/day	18/ 77 (23.4)	23.6	17/ 82 (20.7)	20.8	1.13 (0.63, 2.02)	0.6877	2.78 (-10.76, 16.32)	0.6874	
>=10 mg/day	33/103 (32.0)	32.3	12/102 (11.8)	11.8	2.72 (1.49, 4.97)	0.0011	20.51 (8.94, 32.08)	0.0005	
Result of type I IFN gene signature test									0.2460
LOW	6/ 32 (18.8)	18.8	6/ 33 (18.2)	18.2	1.03 (0.37, 2.86)	0.9529	0.57 (-19.55, 20.69)	0.9559	
HIGH	45/148 (30.4)	30.5	23/151 (15.2)	15.1	2.00 (1.27, 3.13)	0.0025	15.42 (5.71, 25.14)	0.0019	
Age (years)									0.4628
<= 65	49/173 (28.3)	28.4	28/181 (15.5)	15.3	1.83 (1.21, 2.77)	0.0043	13.11 (4.22, 21.99)	0.0038	
> 65	2/ 7 (28.6)	28.6	1/ 3 (33.3)	33.3	0.86 (0.12, 6.23)	0.8789	-4.76 (-71.14, 61.61)	0.8882	
Sex									0.7922
male	5/ 15 (33.3)	33.3	2/ 13 (15.4)	15.4	2.17 (0.50, 9.35)	0.2999	17.95 (-15.63, 51.53)	0.2948	
female	46/165 (27.9)	27.9	27/171 (15.8)	15.6	1.77 (1.16, 2.70)	0.0086	12.30 (3.21, 21.39)	0.0080	
Race									0.5977
White	35/125 (28.0)	28.1	24/137 (17.5)	17.6	1.60 (1.01, 2.53)	0.0454	10.58 (-0.03, 21.20)	0.0507	
Black or African American	6/ 29 (20.7)	20.7	3/ 23 (13.0)	13.0	1.59 (0.44, 5.67)	0.4776	7.65 (-14.61, 29.90)	0.5007	
Asian	3/ 11 (27.3)	27.3	0/ 5 (0.0)	0.0	3.50 (0.21, 57.35)	0.3799	27.27 (-18.60, 73.14)	0.2439	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	7/ 15 (46.7)	46.7	2/ 18 (11.1)	11.1	4.20 (1.02, 17.28)	0.0467	35.56 (4.64, 66.47)	0.0242	
Ethnicity									0.1389
Hispanic/Latino	9/ 32 (28.1)	28.1	2/ 35 (5.7)	5.7	4.92 (1.15, 21.09)	0.0318	22.41 (3.55, 41.27)	0.0199	
Non-hispanic/Latino	42/148 (28.4)	28.8	27/149 (18.1)	18.4	1.57 (1.02, 2.40)	0.0393	10.47 (0.48, 20.47)	0.0400	
Geographic region									0.6044
EU	26/ 64 (40.6)	40.6	15/ 76 (19.7)	19.7	2.06 (1.20, 3.54)	0.0090	20.89 (5.72, 36.05)	0.0069	
non-EU	25/116 (21.6)	21.5	14/108 (13.0)	12.7	1.66 (0.91, 3.03)	0.0965	8.82 (-1.92, 19.57)	0.1076	
Onset of disease									0.3362
Paediatric	3/ 12 (25.0)	25.0	0/ 12 (0.0)	0.0	7.00 (0.40, 122.44)	0.1826	25.00 (-7.22, 57.22)	0.1283	
Adult	48/168 (28.6)	28.8	29/172 (16.9)	16.7	1.69 (1.13, 2.55)	0.0115	12.08 (2.92, 21.25)	0.0098	
ADA result									0.7365
Negative	46/162 (28.4)	28.6	26/169 (15.4)	15.3	1.85 (1.20, 2.84)	0.0052	13.36 (4.16, 22.56)	0.0044	
Positive (At any time)	5/ 17 (29.4)	29.4	3/ 15 (20.0)	20.0	1.47 (0.42, 5.14)	0.5459	9.41 (-22.19, 41.01)	0.5594	
BMI (kg/m2) at enrolment									0.2832
< 30	33/108 (30.6)	30.9	24/127 (18.9)	18.7	1.62 (1.02, 2.56)	0.0402	12.23 (0.93, 23.52)	0.0339	
>= 30	18/ 72 (25.0)	25.0	5/ 57 (8.8)	9.1	2.85 (1.13, 7.21)	0.0269	15.93 (1.75, 30.10)	0.0276	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
No worsening in BILAG-2004 (>=1A or >=2B compared to BL) at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 52	Number of subjects with events, n (%)	119 (66.1)	105 (57.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.16 (0.99, 1.36)	
	p-value	0.0666	
	Odds Ratio (95% CI)	1.49 (0.97, 2.30)	
	p-value	0.0674	
	Risk Difference (95% CI)	9.27 (-0.59, 19.13)	
	p-value	0.0653	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.16 (0.98, 1.36)	
	p-value	0.0773	
	Odds Ratio (95% CI)	1.47 (0.96, 2.24)	
	p-value	0.0767	
	Risk Difference (95% CI)	9.05 (-0.90, 18.99)	
	p-value	0.0747	
	CMH approach		
	Response rate	66.2	57.1
	Difference in response rates (95% CI)	9.10 (-0.79, 18.99)	
	p-value	0.0714	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
No worsening in BILAG-2004 (>=1A or >=2B compared to BL) at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9810
< 10 points	39/ 55 (70.9)	71.2	33/ 54 (61.1)	61.3	1.16 (0.88, 1.52)	0.2837	9.86 (-8.17, 27.89)	0.2839	
>= 10 points	80/125 (64.0)	64.1	72/130 (55.4)	55.4	1.16 (0.94, 1.42)	0.1621	8.73 (-3.09, 20.56)	0.1478	
OCS dose at baseline									0.8953
<10 mg/day	55/ 77 (71.4)	71.5	51/ 82 (62.2)	62.4	1.15 (0.92, 1.43)	0.2177	9.11 (-5.65, 23.88)	0.2263	
>=10 mg/day	64/103 (62.1)	62.2	54/102 (52.9)	53.0	1.17 (0.93, 1.49)	0.1855	9.17 (-4.22, 22.56)	0.1795	
Result of type I IFN gene signature test									0.2665
LOW	23/ 32 (71.9)	71.9	24/ 33 (72.7)	72.7	0.99 (0.73, 1.34)	0.9388	-0.85 (-23.17, 21.46)	0.9403	
HIGH	96/148 (64.9)	65.0	81/151 (53.6)	53.7	1.21 (1.00, 1.46)	0.0499	11.27 (0.24, 22.29)	0.0451	
Age (years)									0.0873
<= 65	113/173 (65.3)	65.4	102/181 (56.4)	56.3	1.16 (0.98, 1.37)	0.0851	9.08 (-1.00, 19.17)	0.0776	
> 65	6/ 7 (85.7)	85.7	3/ 3 (100.0)	100.0	0.86 (0.63, 1.16)	0.3178	-14.29 (-75.13, 46.56)	0.6454	
Sex									0.2486
male	9/ 15 (60.0)	60.0	4/ 13 (30.8)	30.8	1.95 (0.78, 4.86)	0.1522	29.23 (-6.81, 65.27)	0.1119	
female	110/165 (66.7)	66.6	101/171 (59.1)	59.1	1.13 (0.96, 1.33)	0.1503	7.52 (-2.75, 17.78)	0.1512	
Race									0.6690
White	85/125 (68.0)	68.0	82/137 (59.9)	60.0	1.14 (0.95, 1.36)	0.1703	8.10 (-3.53, 19.72)	0.1723	
Black or African American	17/ 29 (58.6)	58.6	13/ 23 (56.5)	56.5	1.04 (0.65, 1.66)	0.8794	2.10 (-25.03, 29.23)	0.8795	
Asian	7/ 11 (63.6)	63.6	3/ 5 (60.0)	60.0	1.06 (0.46, 2.47)	0.8913	3.64 (-48.66, 55.94)	0.8916	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	10/ 15 (66.7)	66.7	7/ 18 (38.9)	38.9	1.71 (0.87, 3.39)	0.1207	27.78 (-5.57, 61.12)	0.1025	
Ethnicity									0.6035
Hispanic/Latino	21/ 32 (65.6)	65.6	18/ 35 (51.4)	51.4	1.28 (0.85, 1.92)	0.2417	14.20 (-9.28, 37.67)	0.2359	
Non-hispanic/Latino	98/148 (66.2)	65.8	87/149 (58.4)	58.6	1.13 (0.95, 1.35)	0.1656	7.17 (-3.89, 18.24)	0.2039	
Geographic region									0.5905
EU	47/ 64 (73.4)	73.4	50/ 76 (65.8)	65.8	1.12 (0.90, 1.39)	0.3252	7.65 (-7.71, 23.01)	0.3290	
non-EU	72/116 (62.1)	63.1	55/108 (50.9)	50.5	1.22 (0.97, 1.54)	0.0967	12.60 (-0.04, 25.25)	0.0507	
Onset of disease									0.8841
Paediatric	5/ 12 (41.7)	41.7	4/ 12 (33.3)	33.3	1.25 (0.44, 3.55)	0.6751	8.33 (-30.89, 47.55)	0.6771	
Adult	114/168 (67.9)	67.9	101/172 (58.7)	58.9	1.16 (0.98, 1.36)	0.0819	9.07 (-1.12, 19.26)	0.0811	
ADA result									0.8521
Negative	109/162 (67.3)	67.2	97/169 (57.4)	57.7	1.17 (0.99, 1.39)	0.0645	9.51 (-0.86, 19.87)	0.0723	
Positive (At any time)	10/ 17 (58.8)	58.8	8/ 15 (53.3)	53.3	1.10 (0.59, 2.05)	0.7561	5.49 (-29.03, 40.01)	0.7553	
BMI (kg/m2) at enrolment									0.3125
< 30	72/108 (66.7)	67.0	69/127 (54.3)	54.6	1.23 (1.00, 1.51)	0.0537	12.32 (0.01, 24.64)	0.0498	
>= 30	47/ 72 (65.3)	66.3	36/ 57 (63.2)	63.3	1.03 (0.80, 1.34)	0.8036	3.00 (-13.61, 19.61)	0.7232	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Maintained OCS Reduction at week 52 (for subjects with baseline OCS >=10 mg/day)
Full analysis set

Timepoint		Anifrolumab 300mg (N=103)	Placebo (N=102)
Week 52	Number of subjects with events, n (%)	51 (49.5)	34 (33.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.51 (1.08, 2.11)	
	p-value	0.0167	
	Odds Ratio (95% CI)	2.04 (1.15, 3.61)	
	p-value	0.0151	
	Risk Difference (95% CI)	16.70 (3.55, 29.86)	
	p-value	0.0128	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.49 (1.06, 2.08)	
	p-value	0.0212	
	Odds Ratio (95% CI)	1.96 (1.12, 3.45)	
	p-value	0.0193	
	Risk Difference (95% CI)	16.18 (2.88, 29.48)	
	p-value	0.0171	
	CMH approach		
	Response rate	49.7	33.1
	Difference in response rates (95% CI)	16.58 (3.39, 29.78)	
	p-value	0.0138	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Maintained OCS Reduction at week 52 (for subjects with baseline OCS >=10 mg/day) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=103) n/ N (%)	Response rate	Placebo (N=102) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.7196
< 10 points	14/ 29 (48.3)	48.3	9/ 25 (36.0)	36.0	1.34 (0.70, 2.55)	0.3721	12.28 (-14.04, 38.59)	0.3606	
>= 10 points	37/ 74 (50.0)	50.0	25/ 77 (32.5)	32.5	1.54 (1.04, 2.28)	0.0320	17.53 (2.02, 33.05)	0.0267	
OCS dose at baseline									NE
>=10 mg/day	51/103 (49.5)	49.7	34/102 (33.3)	33.1	1.49 (1.06, 2.08)	0.0212	16.58 (3.39, 29.78)	0.0138	
Result of type I IFN gene signature test									0.1856
LOW	8/ 13 (61.5)	61.5	9/ 15 (60.0)	60.0	1.03 (0.57, 1.86)	0.9337	1.54 (-35.07, 38.14)	0.9344	
HIGH	43/ 90 (47.8)	47.8	25/ 87 (28.7)	28.9	1.66 (1.12, 2.47)	0.0117	18.95 (4.81, 33.10)	0.0086	
Age (years)									0.1280
<= 65	50/101 (49.5)	49.8	33/101 (32.7)	32.3	1.52 (1.08, 2.13)	0.0174	17.56 (4.30, 30.82)	0.0094	
> 65	1/ 2 (50.0)	50.0	1/ 1 (100.0)	100.0	0.50 (0.13, 2.00)	0.3270	-50.00 (-168.41, 68.41)	0.4079	
Sex									0.9728
male	5/ 11 (45.5)	45.5	3/ 10 (30.0)	30.0	1.52 (0.48, 4.77)	0.4777	15.45 (-26.39, 57.30)	0.4692	
female	46/ 92 (50.0)	50.0	31/ 92 (33.7)	33.5	1.48 (1.04, 2.11)	0.0280	16.53 (2.64, 30.41)	0.0197	
Race									0.7229
White	32/ 65 (49.2)	49.4	27/ 77 (35.1)	34.9	1.40 (0.95, 2.08)	0.0894	14.58 (-1.49, 30.65)	0.0754	
Black or African American	9/ 20 (45.0)	45.0	2/ 9 (22.2)	22.2	2.03 (0.54, 7.54)	0.2929	22.78 (-14.45, 60.01)	0.2305	
Asian	3/ 6 (50.0)	50.0	2/ 4 (50.0)	50.0	1.00 (0.28, 3.54)	1.0000	0.00 (-63.26, 63.26)	1.0000	
Other	7/ 12 (58.3)	58.3	3/ 12 (25.0)	25.0	2.33 (0.78, 6.94)	0.1278	33.33 (-5.08, 71.75)	0.0890	
Ethnicity									0.9366
Hispanic/Latino	9/ 21 (42.9)	42.9	5/ 18 (27.8)	27.8	1.54 (0.63, 3.77)	0.3416	15.08 (-15.15, 45.31)	0.3282	
Non-hispanic/Latino	42/ 82 (51.2)	51.1	29/ 84 (34.5)	34.7	1.48 (1.03, 2.13)	0.0329	16.42 (1.52, 31.31)	0.0308	
Geographic region									0.7231
EU	27/ 45 (60.0)	60.0	23/ 57 (40.4)	40.4	1.49 (1.00, 2.21)	0.0494	19.65 (0.43, 38.86)	0.0450	
non-EU	24/ 58 (41.4)	41.4	11/ 45 (24.4)	24.4	1.69 (0.93, 3.08)	0.0845	16.93 (-1.17, 35.04)	0.0667	
Onset of disease									0.3656
Paediatric	5/ 10 (50.0)	50.0	1/ 7 (14.3)	14.3	3.50 (0.51, 23.81)	0.2004	35.71 (-9.55, 80.98)	0.1220	
Adult	46/ 93 (49.5)	49.7	33/ 95 (34.7)	34.6	1.42 (1.01, 2.01)	0.0439	15.04 (1.24, 28.84)	0.0327	
ADA result									0.5087
Negative	47/ 91 (51.6)	51.8	33/ 94 (35.1)	35.1	1.47 (1.05, 2.07)	0.0257	16.69 (2.63, 30.75)	0.0200	
Positive (At any time)	4/ 11 (36.4)	36.4	1/ 8 (12.5)	12.5	2.91 (0.40, 21.35)	0.2937	23.86 (-17.83, 65.56)	0.2620	
BMI (kg/m2) at enrolment									0.8436
< 30	36/ 67 (53.7)	53.7	27/ 78 (34.6)	34.6	1.55 (1.06, 2.26)	0.0224	19.12 (3.14, 35.09)	0.0190	
>= 30	15/ 36 (41.7)	41.7	7/ 24 (29.2)	29.2	1.43 (0.69, 2.97)	0.3406	12.50 (-12.20, 37.20)	0.3212	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
>=50% Reduction in CLASI activity score at week 52 (for subjects with baseline CLASI activity score >=10)
Full analysis set

Timepoint		Anifrolumab 300mg (N=58)	Placebo (N=54)
Week 52	Number of subjects with events, n (%)	37 (63.8)	24 (44.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.43 (1.02, 2.01)	
	p-value	0.0402	
	Odds Ratio (95% CI)	2.29 (1.04, 5.01)	
	p-value	0.0388	
	Risk Difference (95% CI)	19.34 (1.49, 37.19)	
	p-value	0.0337	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.44 (1.01, 2.05)	
	p-value	0.0464	
	Odds Ratio (95% CI)	2.20 (1.03, 4.70)	
	p-value	0.0413	
	Risk Difference (95% CI)	19.35 (1.22, 37.48)	
	p-value	0.0364	
	CMH approach		
	Response rate	63.8	44.4
	Difference in response rates (95% CI)	19.35 (1.17, 37.53)	
	p-value	0.0370	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
>=50% Reduction in CLASI activity score at week 52 (for subjects with baseline CLASI activity score >=10) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=58) n/ N (%)	Response rate	Placebo (N=54) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.5116
< 10 points	9/ 11 (81.8)	81.8	7/ 15 (46.7)	46.7	1.75 (0.95, 3.22)	0.0705	35.15 (-1.20, 71.50)	0.0581	
>= 10 points	28/ 47 (59.6)	59.6	17/ 39 (43.6)	43.6	1.37 (0.89, 2.10)	0.1523	15.98 (-5.01, 36.98)	0.1357	
OCS dose at baseline									0.0768
<10 mg/day	15/ 21 (71.4)	71.4	6/ 20 (30.0)	30.0	2.38 (1.16, 4.90)	0.0185	41.43 (12.71, 70.15)	0.0047	
>=10 mg/day	22/ 37 (59.5)	59.5	18/ 34 (52.9)	52.9	1.12 (0.74, 1.70)	0.5823	6.52 (-16.58, 29.62)	0.5802	
Result of type I IFN gene signature test									0.0242
LOW	7/ 10 (70.0)	70.0	7/ 8 (87.5)	87.5	0.80 (0.49, 1.30)	0.3651	-17.50 (-59.72, 24.72)	0.4165	
HIGH	30/ 48 (62.5)	63.3	17/ 46 (37.0)	36.4	1.69 (1.09, 2.62)	0.0183	26.81 (7.22, 46.40)	0.0073	
Age (years)									NE
<= 65	34/ 55 (61.8)	61.8	23/ 53 (43.4)	43.4	1.42 (0.98, 2.06)	0.0616	18.42 (-0.14, 36.99)	0.0518	
> 65	3/ 3 (100.0)	100.0	1/ 1 (100.0)	100.0	NE		0.00 (-108.78, 108.78)	1.0000	
Sex									0.9434
male	3/ 5 (60.0)	60.0	2/ 5 (40.0)	40.0	1.50 (0.41, 5.45)	0.5379	20.00 (-41.60, 81.60)	0.5245	
female	34/ 53 (64.2)	64.2	22/ 49 (44.9)	44.9	1.43 (0.99, 2.07)	0.0586	19.25 (0.20, 38.30)	0.0476	
Race									0.1286
White	26/ 42 (61.9)	61.9	22/ 48 (45.8)	45.8	1.35 (0.92, 1.99)	0.1293	16.07 (-4.34, 36.49)	0.1228	
Black or African American	6/ 10 (60.0)	60.0	0/ 1 (0.0)	0.0	2.36 (0.20, 27.40)	0.4914	60.00 (-40.80, 160.80)	0.2433	
Asian	4/ 5 (80.0)	80.0	1/ 1 (100.0)	100.0	0.80 (0.52, 1.24)	0.3183	-20.00 (-124.53, 84.53)	0.7077	
Other	1/ 1 (100.0)	100.0	1/ 4 (25.0)	25.0	4.00 (0.73, 21.84)	0.1094	75.00 (-32.10, 182.10)	0.1699	
Ethnicity									0.8892
Hispanic/Latino	2/ 6 (33.3)	33.3	1/ 5 (20.0)	20.0	1.67 (0.21, 13.43)	0.6313	13.33 (-43.62, 70.29)	0.6464	
Non-hispanic/Latino	35/ 52 (67.3)	67.3	23/ 49 (46.9)	46.9	1.43 (1.01, 2.04)	0.0453	20.37 (1.37, 39.37)	0.0356	
Geographic region									0.1662
EU	18/ 26 (69.2)	69.2	16/ 27 (59.3)	59.3	1.17 (0.78, 1.75)	0.4509	9.97 (-16.00, 35.95)	0.4518	
non-EU	19/ 32 (59.4)	59.4	8/ 27 (29.6)	29.6	2.00 (1.05, 3.83)	0.0355	29.75 (5.20, 54.29)	0.0176	
Onset of disease									0.5709
Paediatric	3/ 5 (60.0)	60.0	1/ 4 (25.0)	25.0	2.40 (0.38, 15.14)	0.3516	35.00 (-29.40, 99.40)	0.2868	
Adult	34/ 53 (64.2)	64.2	23/ 50 (46.0)	46.0	1.39 (0.97, 2.00)	0.0714	18.15 (-0.81, 37.12)	0.0607	
ADA result									0.3648
Negative	36/ 52 (69.2)	69.2	23/ 51 (45.1)	45.1	1.54 (1.08, 2.18)	0.0173	24.13 (5.48, 42.78)	0.0112	
Positive (At any time)	1/ 6 (16.7)	16.7	1/ 3 (33.3)	33.3	0.50 (0.05, 5.51)	0.5714	-16.67 (-83.60, 50.27)	0.6255	
BMI (kg/m2) at enrolment									0.6806
< 30	21/ 31 (67.7)	67.7	15/ 34 (44.1)	44.1	1.54 (0.98, 2.41)	0.0615	23.62 (-0.01, 47.26)	0.0501	
>= 30	16/ 27 (59.3)	59.3	9/ 20 (45.0)	45.0	1.32 (0.74, 2.34)	0.3495	14.26 (-14.43, 42.95)	0.3300	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 4	Number of subjects with events, n (%)	43 (23.9)	33 (17.9)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.30 (0.87, 1.93)	
	p-value	0.1986	
	Odds Ratio (95% CI)	1.39 (0.84, 2.31)	
	p-value	0.2028	
	Risk Difference (95% CI)	5.50 (-2.91, 13.91)	
	p-value	0.2002	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.33 (0.89, 2.00)	
	p-value	0.1647	
	Odds Ratio (95% CI)	1.44 (0.86, 2.39)	
	p-value	0.1635	
	Risk Difference (95% CI)	5.95 (-2.38, 14.29)	
	p-value	0.1617	
	CMH approach		
	Response rate	23.8	18.3
	Difference in response rates (95% CI)	5.58 (-3.10, 14.27)	
	p-value	0.2074	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 8	Number of subjects with events, n (%)	63 (35.0)	43 (23.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.47 (1.07, 2.03)	
	p-value	0.0186	
	Odds Ratio (95% CI)	1.75 (1.10, 2.78)	
	p-value	0.0190	
	Risk Difference (95% CI)	11.21 (1.99, 20.42)	
	p-value	0.0172	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.50 (1.08, 2.08)	
	p-value	0.0160	
	Odds Ratio (95% CI)	1.77 (1.12, 2.79)	
	p-value	0.0151	
	Risk Difference (95% CI)	11.63 (2.36, 20.90)	
	p-value	0.0139	
	CMH approach		
	Response rate	34.7	23.7
	Difference in response rates (95% CI)	11.01 (1.74, 20.27)	
	p-value	0.0199	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 12	Number of subjects with events, n (%)	67 (37.2)	50 (27.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.35 (1.00, 1.82)	
	p-value	0.0494	
	Odds Ratio (95% CI)	1.57 (1.00, 2.45)	
	p-value	0.0495	
	Risk Difference (95% CI)	9.60 (0.09, 19.11)	
	p-value	0.0478	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.37 (1.01, 1.85)	
	p-value	0.0420	
	Odds Ratio (95% CI)	1.59 (1.02, 2.48)	
	p-value	0.0408	
	Risk Difference (95% CI)	10.05 (0.50, 19.60)	
	p-value	0.0392	
	CMH approach		
	Response rate	37.0	27.5
	Difference in response rates (95% CI)	9.43 (-0.14, 19.01)	
	p-value	0.0535	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 16	Number of subjects with events, n (%)	80 (44.4)	58 (31.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.40 (1.07, 1.83)	
	p-value	0.0142	
	Odds Ratio (95% CI)	1.71 (1.12, 2.61)	
	p-value	0.0137	
	Risk Difference (95% CI)	12.72 (2.72, 22.72)	
	p-value	0.0126	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.41 (1.08, 1.84)	
	p-value	0.0121	
	Odds Ratio (95% CI)	1.74 (1.13, 2.67)	
	p-value	0.0114	
	Risk Difference (95% CI)	12.92 (3.04, 22.81)	
	p-value	0.0104	
	CMH approach		
	Response rate	44.3	31.7
	Difference in response rates (95% CI)	12.68 (2.77, 22.58)	
	p-value	0.0121	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 20	Number of subjects with events, n (%)	76 (42.2)	68 (37.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.14 (0.89, 1.48)	
	p-value	0.3004	
	Odds Ratio (95% CI)	1.25 (0.82, 1.89)	
	p-value	0.3013	
	Risk Difference (95% CI)	5.35 (-4.78, 15.48)	
	p-value	0.3003	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.14 (0.89, 1.47)	
	p-value	0.3051	
	Odds Ratio (95% CI)	1.25 (0.82, 1.90)	
	p-value	0.3046	
	Risk Difference (95% CI)	5.27 (-4.77, 15.30)	
	p-value	0.3037	
	CMH approach		
	Response rate	42.3	37.0
	Difference in response rates (95% CI)	5.24 (-4.83, 15.31)	
	p-value	0.3080	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 24	Number of subjects with events, n (%)	84 (46.7)	67 (36.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.27 (1.00, 1.63)	
	p-value	0.0535	
	Odds Ratio (95% CI)	1.51 (0.99, 2.29)	
	p-value	0.0537	
	Risk Difference (95% CI)	10.07 (-0.08, 20.23)	
	p-value	0.0519	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.28 (1.00, 1.64)	
	p-value	0.0487	
	Odds Ratio (95% CI)	1.53 (1.00, 2.32)	
	p-value	0.0476	
	Risk Difference (95% CI)	10.25 (0.18, 20.33)	
	p-value	0.0460	
	CMH approach		
	Response rate	46.5	36.6
	Difference in response rates (95% CI)	9.90 (-0.10, 19.89)	
	p-value	0.0523	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 28	Number of subjects with events, n (%)	79 (43.9)	69 (37.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.16 (0.91, 1.49)	
	p-value	0.2361	
	Odds Ratio (95% CI)	1.29 (0.85, 1.95)	
	p-value	0.2381	
	Risk Difference (95% CI)	6.11 (-4.02, 16.23)	
	p-value	0.2370	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.17 (0.91, 1.50)	
	p-value	0.2159	
	Odds Ratio (95% CI)	1.30 (0.86, 1.98)	
	p-value	0.2151	
	Risk Difference (95% CI)	6.39 (-3.69, 16.46)	
	p-value	0.2139	
	CMH approach		
	Response rate	43.9	37.9
	Difference in response rates (95% CI)	5.97 (-4.01, 15.96)	
	p-value	0.2410	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 32	Number of subjects with events, n (%)	83 (46.1)	70 (38.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.21 (0.95, 1.54)	
	p-value	0.1213	
	Odds Ratio (95% CI)	1.39 (0.91, 2.11)	
	p-value	0.1228	
	Risk Difference (95% CI)	8.01 (-2.12, 18.14)	
	p-value	0.1211	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.21 (0.95, 1.55)	
	p-value	0.1205	
	Odds Ratio (95% CI)	1.39 (0.92, 2.12)	
	p-value	0.1194	
	Risk Difference (95% CI)	8.07 (-2.04, 18.18)	
	p-value	0.1179	
	CMH approach		
	Response rate	46.1	38.3
	Difference in response rates (95% CI)	7.83 (-2.17, 17.82)	
	p-value	0.1247	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 36	Number of subjects with events, n (%)	85 (47.2)	73 (39.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.19 (0.94, 1.50)	
	p-value	0.1498	
	Odds Ratio (95% CI)	1.35 (0.89, 2.04)	
	p-value	0.1519	
	Risk Difference (95% CI)	7.54 (-2.73, 17.81)	
	p-value	0.1502	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.19 (0.94, 1.51)	
	p-value	0.1477	
	Odds Ratio (95% CI)	1.36 (0.90, 2.06)	
	p-value	0.1467	
	Risk Difference (95% CI)	7.55 (-2.61, 17.70)	
	p-value	0.1452	
	CMH approach		
	Response rate	47.2	39.9
	Difference in response rates (95% CI)	7.31 (-2.75, 17.37)	
	p-value	0.1546	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 40	Number of subjects with events, n (%)	84 (46.7)	65 (35.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.31 (1.02, 1.67)	
	p-value	0.0324	
	Odds Ratio (95% CI)	1.58 (1.04, 2.42)	
	p-value	0.0329	
	Risk Difference (95% CI)	11.04 (0.98, 21.09)	
	p-value	0.0314	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.32 (1.03, 1.70)	
	p-value	0.0292	
	Odds Ratio (95% CI)	1.60 (1.05, 2.44)	
	p-value	0.0282	
	Risk Difference (95% CI)	11.34 (1.30, 21.38)	
	p-value	0.0268	
	CMH approach		
	Response rate	46.6	35.7
	Difference in response rates (95% CI)	10.85 (0.97, 20.73)	
	p-value	0.0314	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 44	Number of subjects with events, n (%)	81 (45.0)	61 (33.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.35 (1.04, 1.75)	
	p-value	0.0235	
	Odds Ratio (95% CI)	1.62 (1.07, 2.46)	
	p-value	0.0241	
	Risk Difference (95% CI)	11.82 (1.67, 21.97)	
	p-value	0.0225	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.36 (1.05, 1.76)	
	p-value	0.0218	
	Odds Ratio (95% CI)	1.65 (1.08, 2.52)	
	p-value	0.0209	
	Risk Difference (95% CI)	11.85 (1.89, 21.80)	
	p-value	0.0197	
	CMH approach		
	Response rate	45.2	33.4
	Difference in response rates (95% CI)	11.73 (1.90, 21.55)	
	p-value	0.0193	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 48	Number of subjects with events, n (%)	81 (45.0)	55 (29.9)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.49 (1.14, 1.96)	
	p-value	0.0038	
	Odds Ratio (95% CI)	1.89 (1.23, 2.91)	
	p-value	0.0036	
	Risk Difference (95% CI)	14.95 (5.05, 24.85)	
	p-value	0.0031	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.51 (1.14, 1.98)	
	p-value	0.0034	
	Odds Ratio (95% CI)	1.92 (1.25, 2.95)	
	p-value	0.0030	
	Risk Difference (95% CI)	15.11 (5.28, 24.94)	
	p-value	0.0026	
	CMH approach		
	Response rate	44.9	30.1
	Difference in response rates (95% CI)	14.79 (4.98, 24.60)	
	p-value	0.0031	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 52	Number of subjects with events, n (%)	85 (47.2)	55 (29.9)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.57 (1.20, 2.05)	
	p-value	0.0010	
	Odds Ratio (95% CI)	2.07 (1.35, 3.18)	
	p-value	0.0009	
	Risk Difference (95% CI)	17.22 (7.30, 27.15)	
	p-value	0.0007	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.58 (1.21, 2.07)	
	p-value	0.0009	
	Odds Ratio (95% CI)	2.10 (1.36, 3.23)	
	p-value	0.0007	
	Risk Difference (95% CI)	17.33 (7.49, 27.18)	
	p-value	0.0006	
	CMH approach		
	Response rate	47.1	30.2
	Difference in response rates (95% CI)	16.97 (7.17, 26.77)	
	p-value	0.0007	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
BICLA response rate at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8486
< 10 points	31/ 55 (56.4)	56.5	20/ 54 (37.0)	37.9	1.52 (1.00, 2.31)	0.0491	18.56 (0.25, 36.87)	0.0470	
>= 10 points	54/125 (43.2)	43.2	35/130 (26.9)	26.9	1.60 (1.13, 2.27)	0.0076	16.33 (4.79, 27.87)	0.0056	
OCS dose at baseline									0.8475
<10 mg/day	36/ 77 (46.8)	46.8	25/ 82 (30.5)	30.6	1.53 (1.02, 2.30)	0.0383	16.20 (1.14, 31.27)	0.0350	
>=10 mg/day	49/103 (47.6)	47.5	30/102 (29.4)	29.8	1.62 (1.13, 2.32)	0.0093	17.67 (4.77, 30.56)	0.0072	
Result of type I IFN gene signature test									0.2745
LOW	15/ 32 (46.9)	46.9	13/ 33 (39.4)	39.4	1.19 (0.68, 2.09)	0.5438	7.48 (-16.60, 31.56)	0.5426	
HIGH	70/148 (47.3)	47.2	42/151 (27.8)	28.2	1.70 (1.25, 2.31)	0.0007	19.04 (8.32, 29.75)	0.0005	
Age (years)									0.5382
<= 65	79/173 (45.7)	45.5	54/181 (29.8)	30.2	1.53 (1.16, 2.02)	0.0025	15.35 (5.41, 25.29)	0.0025	
> 65	6/ 7 (85.7)	85.7	1/ 3 (33.3)	33.3	2.57 (0.50, 13.11)	0.2557	52.38 (-12.61, 117.38)	0.1142	
Sex									0.6969
male	6/ 15 (40.0)	40.0	4/ 13 (30.8)	30.8	1.30 (0.47, 3.62)	0.6156	9.23 (-26.81, 45.27)	0.6157	
female	79/165 (47.9)	47.7	51/171 (29.8)	30.1	1.61 (1.21, 2.12)	0.0009	17.67 (7.47, 27.86)	0.0007	
Race									0.9697
White	61/125 (48.8)	49.1	43/137 (31.4)	31.0	1.55 (1.15, 2.11)	0.0047	18.16 (6.52, 29.80)	0.0022	
Black or African American	13/ 29 (44.8)	44.8	7/ 23 (30.4)	30.4	1.47 (0.70, 3.08)	0.3038	14.39 (-12.06, 40.84)	0.2862	
Asian	5/ 11 (45.5)	45.5	1/ 5 (20.0)	20.0	2.27 (0.35, 14.73)	0.3892	25.45 (-25.30, 76.21)	0.3257	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	6/ 15 (40.0)	40.0	4/ 18 (22.2)	22.2	1.80 (0.62, 5.21)	0.2787	17.78 (-14.59, 50.14)	0.2817	
Ethnicity									0.3641
Hispanic/Latino	12/ 32 (37.5)	37.5	11/ 35 (31.4)	31.4	1.19 (0.61, 2.32)	0.6016	6.07 (-16.93, 29.08)	0.6050	
Non-hispanic/Latino	73/148 (49.3)	49.1	44/149 (29.5)	30.4	1.67 (1.24, 2.25)	0.0007	18.70 (7.73, 29.67)	0.0008	
Geographic region									0.4898
EU	39/ 64 (60.9)	60.9	26/ 76 (34.2)	34.2	1.78 (1.23, 2.57)	0.0021	26.73 (10.64, 42.81)	0.0011	
non-EU	46/116 (39.7)	40.0	29/108 (26.9)	26.8	1.48 (1.01, 2.17)	0.0465	13.21 (0.91, 25.50)	0.0353	
Onset of disease									0.5177
Paediatric	5/ 12 (41.7)	41.7	2/ 12 (16.7)	16.7	2.50 (0.60, 10.46)	0.2096	25.00 (-12.26, 62.26)	0.1884	
Adult	80/168 (47.6)	47.6	53/172 (30.8)	31.1	1.55 (1.17, 2.03)	0.0019	16.55 (6.33, 26.76)	0.0015	
ADA result									0.8641
Negative	79/162 (48.8)	48.6	52/169 (30.8)	31.4	1.58 (1.20, 2.09)	0.0011	17.26 (6.93, 27.58)	0.0011	
Positive (At any time)	6/ 17 (35.3)	35.3	3/ 15 (20.0)	20.0	1.76 (0.53, 5.86)	0.3533	15.29 (-16.79, 47.38)	0.3502	
BMI (kg/m2) at enrolment									0.3362
< 30	55/108 (50.9)	51.1	37/127 (29.1)	29.7	1.75 (1.26, 2.43)	0.0009	21.45 (9.22, 33.67)	0.0006	
>= 30	30/ 72 (41.7)	42.7	18/ 57 (31.6)	31.7	1.32 (0.82, 2.11)	0.2475	11.01 (-5.59, 27.61)	0.1936	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
BICLA - individual components at week 52 (Full analysis set)
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
BILAG improvement [a]	85 (47.2)	58 (31.5)
No discontinuation of IP	145 (80.6)	146 (79.3)
No use of medication beyond protocol allowed threshold	140 (77.8)	128 (69.6)
No worsening of PGA [a]	117 (65.0)	105 (57.1)
No worsening of SLEDAI-2K [a]	121 (67.2)	104 (56.5)

[a] Subjects who discontinued IP or used medications beyond protocol allowed threshold are considered non-responders and not included in this category.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
BICLA response rate at week 52 sensitivity analysis, multiple imputation
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 52	Number of subjects with events, n (%)	84 (46.7)	55 (29.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.56 (1.19, 2.04)	
	p-value	0.0014	
	Odds Ratio (95% CI)	2.03 (1.32, 3.13)	
	p-value	0.0013	
	Risk Difference (95% CI)	16.79 (6.79, 26.79)	
	p-value	0.0010	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.57 (1.19, 2.06)	
	p-value	0.0013	
	Odds Ratio (95% CI)	2.06 (1.34, 3.18)	
	p-value	0.0011	
	Risk Difference (95% CI)	16.90 (6.99, 26.81)	
	p-value	0.0008	

For each outcome and visit, 100 imputations were generated by randomised treatment group. Each imputed dataset was analysed separately, and the single estimates are combined using PROC MIANALYZE. The estimated number of responders and non-responders are rounded to an integer. Therefore, there might be slight mismatches between number of subjects and corresponding percentage.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Change from baseline in PGA VAS < 0.3 at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 52	Number of subjects with events, n (%)	117 (65.0)	105 (57.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.14 (0.97, 1.34)	
	p-value	0.1098	
	Odds Ratio (95% CI)	1.41 (0.92, 2.16)	
	p-value	0.1120	
	Risk Difference (95% CI)	8.14 (-1.84, 18.11)	
	p-value	0.1098	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.14 (0.97, 1.34)	
	p-value	0.1218	
	Odds Ratio (95% CI)	1.40 (0.92, 2.13)	
	p-value	0.1212	
	Risk Difference (95% CI)	7.93 (-2.05, 17.92)	
	p-value	0.1194	
	CMH approach		
	Response rate	65.1	57.2
	Difference in response rates (95% CI)	7.92 (-2.01, 17.85)	
	p-value	0.1182	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Change from baseline in PGA VAS < 0.3 at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9578
< 10 points	38/ 55 (69.1)	69.5	33/ 54 (61.1)	61.6	1.13 (0.86, 1.49)	0.3845	7.93 (-10.10, 25.96)	0.3886	
>= 10 points	79/125 (63.2)	63.3	72/130 (55.4)	55.4	1.14 (0.93, 1.40)	0.2052	7.88 (-4.00, 19.76)	0.1936	
OCS dose at baseline									0.5896
<10 mg/day	54/ 77 (70.1)	70.3	48/ 82 (58.5)	58.8	1.20 (0.95, 1.51)	0.1290	11.48 (-3.39, 26.35)	0.1301	
>=10 mg/day	63/103 (61.2)	61.3	57/102 (55.9)	56.0	1.09 (0.87, 1.38)	0.4437	5.27 (-8.12, 18.66)	0.4403	
Result of type I IFN gene signature test									0.2080
LOW	22/ 32 (68.8)	68.8	24/ 33 (72.7)	72.7	0.95 (0.69, 1.29)	0.7251	-3.98 (-26.56, 18.60)	0.7299	
HIGH	95/148 (64.2)	64.3	81/151 (53.6)	53.8	1.20 (0.99, 1.45)	0.0654	10.51 (-0.54, 21.56)	0.0623	
Age (years)									0.1086
<= 65	111/173 (64.2)	64.3	102/181 (56.4)	56.5	1.14 (0.96, 1.35)	0.1342	7.82 (-2.31, 17.94)	0.1302	
> 65	6/ 7 (85.7)	85.7	3/ 3 (100.0)	100.0	0.86 (0.63, 1.16)	0.3178	-14.29 (-75.13, 46.56)	0.6454	
Sex									0.4272
male	9/ 15 (60.0)	60.0	5/ 13 (38.5)	38.5	1.56 (0.70, 3.48)	0.2773	21.54 (-15.07, 58.14)	0.2488	
female	108/165 (65.5)	65.5	100/171 (58.5)	58.6	1.12 (0.95, 1.32)	0.1888	6.83 (-3.48, 17.14)	0.1943	
Race									0.4469
White	84/125 (67.2)	67.3	83/137 (60.6)	60.6	1.11 (0.92, 1.33)	0.2652	6.75 (-4.89, 18.39)	0.2558	
Black or African American	16/ 29 (55.2)	55.2	13/ 23 (56.5)	56.5	0.98 (0.60, 1.59)	0.9224	-1.35 (-28.57, 25.87)	0.9226	
Asian	7/ 11 (63.6)	63.6	3/ 5 (60.0)	60.0	1.06 (0.46, 2.47)	0.8913	3.64 (-48.66, 55.94)	0.8916	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	10/ 15 (66.7)	66.7	6/ 18 (33.3)	33.3	2.00 (0.95, 4.21)	0.0682	33.33 (0.32, 66.34)	0.0478	
Ethnicity									0.3767
Hispanic/Latino	21/ 32 (65.6)	65.6	17/ 35 (48.6)	48.6	1.35 (0.88, 2.06)	0.1634	17.05 (-6.42, 40.53)	0.1545	
Non-hispanic/Latino	96/148 (64.9)	64.6	88/149 (59.1)	59.4	1.10 (0.92, 1.31)	0.3038	5.20 (-5.89, 16.30)	0.3578	
Geographic region									0.4079
EU	47/ 64 (73.4)	73.4	52/ 76 (68.4)	68.4	1.07 (0.87, 1.33)	0.5135	5.02 (-10.21, 20.24)	0.5184	
non-EU	70/116 (60.3)	61.4	53/108 (49.1)	48.8	1.23 (0.97, 1.57)	0.0944	12.61 (-0.06, 25.27)	0.0511	
Onset of disease									0.8583
Paediatric	5/ 12 (41.7)	41.7	4/ 12 (33.3)	33.3	1.25 (0.44, 3.55)	0.6751	8.33 (-30.89, 47.55)	0.6771	
Adult	112/168 (66.7)	66.8	101/172 (58.7)	58.9	1.14 (0.96, 1.34)	0.1310	7.86 (-2.36, 18.09)	0.1319	
ADA result									0.8968
Negative	107/162 (66.0)	66.1	97/169 (57.4)	57.8	1.15 (0.97, 1.36)	0.1064	8.26 (-2.15, 18.67)	0.1200	
Positive (At any time)	10/ 17 (58.8)	58.8	8/ 15 (53.3)	53.3	1.10 (0.59, 2.05)	0.7561	5.49 (-29.03, 40.01)	0.7553	
BMI (kg/m2) at enrolment									0.4313
< 30	71/108 (65.7)	66.0	70/127 (55.1)	55.5	1.19 (0.97, 1.47)	0.0964	10.49 (-1.83, 22.82)	0.0951	
>= 30	46/ 72 (63.9)	64.8	35/ 57 (61.4)	61.7	1.04 (0.79, 1.36)	0.7727	3.08 (-13.67, 19.84)	0.7184	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Change from baseline in PGA VAS < 0.45 at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 52	Number of subjects with events, n (%)	120 (66.7)	108 (58.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.14 (0.97, 1.33)	
	p-value	0.1061	
	Odds Ratio (95% CI)	1.42 (0.93, 2.19)	
	p-value	0.1076	
	Risk Difference (95% CI)	8.13 (-1.71, 17.97)	
	p-value	0.1055	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.14 (0.97, 1.33)	
	p-value	0.1171	
	Odds Ratio (95% CI)	1.41 (0.92, 2.16)	
	p-value	0.1165	
	Risk Difference (95% CI)	7.97 (-1.93, 17.87)	
	p-value	0.1146	
	CMH approach		
	Response rate	66.8	58.8
	Difference in response rates (95% CI)	7.96 (-1.91, 17.84)	
	p-value	0.1141	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Change from baseline in PGA VAS < 0.45 at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9492
< 10 points	39/ 55 (70.9)	71.2	34/ 54 (63.0)	63.3	1.13 (0.86, 1.47)	0.3803	7.85 (-10.08, 25.78)	0.3909	
>= 10 points	81/125 (64.8)	64.9	74/130 (56.9)	56.9	1.14 (0.93, 1.39)	0.1987	7.97 (-3.86, 19.79)	0.1867	
OCS dose at baseline									0.9169
<10 mg/day	55/ 77 (71.4)	71.5	51/ 82 (62.2)	62.4	1.15 (0.92, 1.43)	0.2177	9.11 (-5.65, 23.88)	0.2263	
>=10 mg/day	65/103 (63.1)	63.1	57/102 (55.9)	56.0	1.13 (0.90, 1.42)	0.2939	7.15 (-6.20, 20.49)	0.2939	
Result of type I IFN gene signature test									0.3291
LOW	23/ 32 (71.9)	71.9	24/ 33 (72.7)	72.7	0.99 (0.73, 1.34)	0.9388	-0.85 (-23.17, 21.46)	0.9403	
HIGH	97/148 (65.5)	65.6	84/151 (55.6)	55.8	1.18 (0.98, 1.42)	0.0811	9.88 (-1.12, 20.88)	0.0783	
Age (years)									0.1086
<= 65	114/173 (65.9)	66.0	105/181 (58.0)	58.1	1.14 (0.96, 1.34)	0.1274	7.91 (-2.16, 17.98)	0.1237	
> 65	6/ 7 (85.7)	85.7	3/ 3 (100.0)	100.0	0.86 (0.63, 1.16)	0.3178	-14.29 (-75.13, 46.56)	0.6454	
Sex									0.4235
male	9/ 15 (60.0)	60.0	5/ 13 (38.5)	38.5	1.56 (0.70, 3.48)	0.2773	21.54 (-15.07, 58.14)	0.2488	
female	111/165 (67.3)	67.2	103/171 (60.2)	60.3	1.12 (0.95, 1.31)	0.1805	6.89 (-3.35, 17.13)	0.1871	
Race									0.4562
White	85/125 (68.0)	68.0	85/137 (62.0)	62.0	1.10 (0.92, 1.31)	0.3123	6.02 (-5.58, 17.63)	0.3092	
Black or African American	17/ 29 (58.6)	58.6	13/ 23 (56.5)	56.5	1.04 (0.65, 1.66)	0.8794	2.10 (-25.03, 29.23)	0.8795	
Asian	7/ 11 (63.6)	63.6	3/ 5 (60.0)	60.0	1.06 (0.46, 2.47)	0.8913	3.64 (-48.66, 55.94)	0.8916	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	11/ 15 (73.3)	73.3	7/ 18 (38.9)	38.9	1.89 (0.98, 3.63)	0.0575	34.44 (1.75, 67.14)	0.0390	
Ethnicity									0.3703
Hispanic/Latino	22/ 32 (68.8)	68.8	18/ 35 (51.4)	51.4	1.34 (0.90, 1.99)	0.1526	17.32 (-5.94, 40.58)	0.1444	
Non-hispanic/Latino	98/148 (66.2)	65.8	90/149 (60.4)	60.7	1.10 (0.92, 1.30)	0.2996	5.08 (-5.97, 16.12)	0.3676	
Geographic region									0.3152
EU	47/ 64 (73.4)	73.4	53/ 76 (69.7)	69.7	1.05 (0.85, 1.30)	0.6276	3.70 (-11.45, 18.85)	0.6321	
non-EU	73/116 (62.9)	63.9	55/108 (50.9)	50.5	1.24 (0.98, 1.56)	0.0736	13.37 (0.72, 26.02)	0.0383	
Onset of disease									0.8540
Paediatric	5/ 12 (41.7)	41.7	4/ 12 (33.3)	33.3	1.25 (0.44, 3.55)	0.6751	8.33 (-30.89, 47.55)	0.6771	
Adult	115/168 (68.5)	68.5	104/172 (60.5)	60.6	1.13 (0.97, 1.33)	0.1251	7.90 (-2.26, 18.06)	0.1273	
ADA result									0.9033
Negative	110/162 (67.9)	67.9	100/169 (59.2)	59.5	1.15 (0.97, 1.35)	0.1000	8.31 (-2.03, 18.65)	0.1151	
Positive (At any time)	10/ 17 (58.8)	58.8	8/ 15 (53.3)	53.3	1.10 (0.59, 2.05)	0.7561	5.49 (-29.03, 40.01)	0.7553	
BMI (kg/m2) at enrolment									0.3657
< 30	72/108 (66.7)	67.0	71/127 (55.9)	56.3	1.19 (0.97, 1.46)	0.0909	10.68 (-1.61, 22.97)	0.0885	
>= 30	48/ 72 (66.7)	67.6	37/ 57 (64.9)	65.2	1.03 (0.80, 1.32)	0.8352	2.43 (-14.07, 18.93)	0.7726	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Constitutional
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 52	Number of subjects with events, n (%)	1 (0.6)	1 (0.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.86 (0.06, 12.28)	
	p-value	0.9097	
	Odds Ratio (95% CI)	0.85 (0.05, 15.16)	
	p-value	0.9097	
	Risk Difference (95% CI)	-0.08 (-1.55, 1.38)	
	p-value	0.9098	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.02 (0.06, 16.22)	
	p-value	0.9876	
	Odds Ratio (95% CI)	1.02 (0.06, 16.47)	
	p-value	0.9876	
	Risk Difference (95% CI)	0.01 (-1.51, 1.53)	
	p-value	0.9876	
	CMH approach		
	Response rate	0.6	0.5
	Difference in response rates (95% CI)	0.02 (-4.60, 4.63)	
	p-value	0.9943	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Constitutional - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 55 (0.0)	0.0	0/ 54 (0.0)	0.0	NE		0.00 (-10.69, 10.69)	1.0000	
>= 10 points	1/125 (0.8)	0.8	1/130 (0.8)	0.8	1.04 (0.07, 16.45)	0.9778	0.00 (-5.24, 5.24)	1.0000	
OCS dose at baseline									NE
<10 mg/day	1/ 77 (1.3)	1.2	1/ 82 (1.2)	1.3	1.06 (0.07, 16.73)	0.9643	-0.07 (-8.21, 8.08)	0.9869	
>=10 mg/day	0/103 (0.0)	0.0	0/102 (0.0)	0.0	NE		0.00 (-5.93, 5.93)	1.0000	
Result of type I IFN gene signature test									NE
LOW	1/ 32 (3.1)	3.1	1/ 33 (3.0)	3.0	1.03 (0.07, 15.79)	0.9824	0.09 (-13.26, 13.45)	0.9889	
HIGH	0/148 (0.0)	0.0	0/151 (0.0)	0.0	NE		0.00 (-4.81, 4.81)	1.0000	
Age (years)									0.1869
<= 65	1/173 (0.6)	0.6	0/181 (0.0)	0.0	3.14 (0.13, 76.51)	0.4828	0.59 (-4.06, 5.23)	0.8048	
> 65	0/ 7 (0.0)	0.0	1/ 3 (33.3)	33.3	0.17 (0.01, 3.24)	0.2366	-33.33 (-96.20, 29.53)	0.2987	
Sex									NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
female	1/165 (0.6)	0.6	1/171 (0.6)	0.6	1.04 (0.07, 16.43)	0.9798	0.02 (-4.94, 4.98)	0.9938	
Race									NE
White	1/125 (0.8)	0.7	1/137 (0.7)	0.8	1.10 (0.07, 17.34)	0.9481	-0.05 (-6.30, 6.19)	0.9863	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-20.43, 20.43)	1.0000	
Ethnicity									0.3208
Hispanic/Latino	1/ 32 (3.1)	3.1	0/ 35 (0.0)	0.0	3.27 (0.14, 77.57)	0.4629	3.13 (-8.92, 15.17)	0.6111	
Non-hispanic/Latino	0/148 (0.0)	0.0	1/149 (0.7)	0.7	0.34 (0.01, 8.17)	0.5026	-0.67 (-6.16, 4.82)	0.8114	
Geographic region									NE
EU	0/ 64 (0.0)	0.0	0/ 76 (0.0)	0.0	NE		0.00 (-5.43, 5.43)	1.0000	
non-EU	1/116 (0.9)	0.9	1/108 (0.9)	0.9	0.93 (0.06, 14.70)	0.9595	0.00 (-7.25, 7.25)	1.0000	
Onset of disease									NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
Adult	1/168 (0.6)	0.6	1/172 (0.6)	0.6	1.02 (0.06, 16.24)	0.9867	-0.02 (-4.93, 4.89)	0.9940	
ADA result									0.3015
Negative	1/162 (0.6)	0.6	0/169 (0.0)	0.0	3.13 (0.13, 76.25)	0.4839	0.61 (-4.34, 5.55)	0.8099	
Positive (At any time)	0/ 17 (0.0)	0.0	1/ 15 (6.7)	6.7	0.30 (0.01, 6.77)	0.4461	-6.67 (-29.80, 16.47)	0.5722	
BMI (kg/m2) at enrolment									NE
< 30	0/108 (0.0)	0.0	0/127 (0.0)	0.0	NE		0.00 (-5.30, 5.30)	1.0000	
>= 30	1/ 72 (1.4)	1.4	1/ 57 (1.8)	1.7	0.79 (0.05, 12.38)	0.8678	-0.33 (-10.29, 9.63)	0.9488	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Mucocutaneous
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 52	Number of subjects with events, n (%)	44 (24.4)	71 (38.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.64 (0.47, 0.87)	
	p-value	0.0050	
	Odds Ratio (95% CI)	0.52 (0.33, 0.81)	
	p-value	0.0043	
	Risk Difference (95% CI)	-13.92 (-23.30, -4.54)	
	p-value	0.0036	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.63 (0.46, 0.87)	
	p-value	0.0045	
	Odds Ratio (95% CI)	0.51 (0.33, 0.81)	
	p-value	0.0039	
	Risk Difference (95% CI)	-14.14 (-23.57, -4.71)	
	p-value	0.0033	
	CMH approach		
	Response rate	24.6	38.4
	Difference in response rates (95% CI)	-13.82 (-23.40, -4.24)	
	p-value	0.0047	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Mucocutaneous - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Anifrolumab 300mg (N=180) Response rate	Placebo (N=184) n/ N (%)	Placebo (N=184) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.1637
< 10 points	9/ 55 (16.4)	16.6	21/ 54 (38.9)	38.4	0.42 (0.21, 0.83)	0.0132	-21.84 (-38.89, -4.80)	0.0120	
>= 10 points	35/125 (28.0)	28.0	50/130 (38.5)	38.5	0.73 (0.51, 1.04)	0.0800	-10.44 (-22.04, 1.16)	0.0778	
OCS dose at baseline									0.7844
<10 mg/day	20/ 77 (26.0)	26.0	32/ 82 (39.0)	38.8	0.67 (0.42, 1.06)	0.0856	-12.86 (-27.49, 1.77)	0.0848	
>=10 mg/day	24/103 (23.3)	23.6	39/102 (38.2)	37.9	0.61 (0.40, 0.94)	0.0235	-14.32 (-26.99, -1.66)	0.0266	
Result of type I IFN gene signature test									0.7103
LOW	9/ 32 (28.1)	28.1	13/ 33 (39.4)	39.4	0.71 (0.36, 1.43)	0.3434	-11.27 (-34.41, 11.87)	0.3398	
HIGH	35/148 (23.6)	23.9	58/151 (38.4)	38.2	0.62 (0.43, 0.88)	0.0071	-14.37 (-24.89, -3.85)	0.0074	
Age (years)									0.7612
<= 65	42/173 (24.3)	24.5	70/181 (38.7)	38.5	0.63 (0.46, 0.87)	0.0044	-13.97 (-23.69, -4.25)	0.0049	
> 65	2/ 7 (28.6)	28.6	1/ 3 (33.3)	33.3	0.86 (0.12, 6.23)	0.8789	-4.76 (-71.14, 61.61)	0.8882	
Sex									0.1285
male	1/ 15 (6.7)	6.7	6/ 13 (46.2)	46.2	0.14 (0.02, 1.05)	0.0558	-39.49 (-72.30, -6.67)	0.0183	
female	43/165 (26.1)	26.2	65/171 (38.0)	37.9	0.69 (0.50, 0.94)	0.0210	-11.68 (-21.73, -1.64)	0.0226	
Race									0.4786
White	36/125 (28.8)	28.6	56/137 (40.9)	41.0	0.70 (0.50, 0.99)	0.0444	-12.46 (-24.02, -0.89)	0.0347	
Black or African American	2/ 29 (6.9)	6.9	7/ 23 (30.4)	30.4	0.23 (0.05, 0.99)	0.0482	-23.54 (-46.17, -0.91)	0.0415	
Asian	2/ 11 (18.2)	18.2	2/ 5 (40.0)	40.0	0.45 (0.09, 2.37)	0.3491	-21.82 (-72.61, 28.97)	0.3998	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	4/ 15 (26.7)	26.7	6/ 18 (33.3)	33.3	0.80 (0.28, 2.32)	0.6809	-6.67 (-39.03, 25.69)	0.6864	
Ethnicity									0.0843
Hispanic/Latino	11/ 32 (34.4)	34.4	11/ 35 (31.4)	31.4	1.09 (0.55, 2.17)	0.7975	2.95 (-19.88, 25.77)	0.8002	
Non-hispanic/Latino	33/148 (22.3)	22.4	60/149 (40.3)	40.1	0.55 (0.39, 0.79)	0.0012	-17.71 (-28.30, -7.12)	0.0010	
Geographic region									0.9132
EU	17/ 64 (26.6)	26.6	31/ 76 (40.8)	40.8	0.65 (0.40, 1.06)	0.0857	-14.23 (-29.83, 1.37)	0.0739	
non-EU	27/116 (23.3)	23.5	40/108 (37.0)	36.6	0.63 (0.42, 0.95)	0.0271	-13.15 (-25.38, -0.91)	0.0352	
Onset of disease									0.2420
Paediatric	1/ 12 (8.3)	8.3	5/ 12 (41.7)	41.7	0.20 (0.03, 1.47)	0.1134	-33.33 (-69.05, 2.38)	0.0674	
Adult	43/168 (25.6)	25.8	66/172 (38.4)	38.3	0.67 (0.48, 0.92)	0.0131	-12.53 (-22.50, -2.55)	0.0138	
ADA result									0.5149
Negative	39/162 (24.1)	24.3	66/169 (39.1)	38.9	0.62 (0.44, 0.86)	0.0043	-14.58 (-24.62, -4.53)	0.0045	
Positive (At any time)	5/ 17 (29.4)	29.4	5/ 15 (33.3)	33.3	0.88 (0.32, 2.46)	0.8112	-3.92 (-37.06, 29.22)	0.8166	
BMI (kg/m2) at enrolment									0.1873
< 30	21/108 (19.4)	19.8	48/127 (37.8)	38.0	0.51 (0.33, 0.80)	0.0033	-18.25 (-29.83, -6.68)	0.0020	
>= 30	23/ 72 (31.9)	31.6	23/ 57 (40.4)	40.5	0.79 (0.50, 1.26)	0.3215	-8.95 (-25.74, 7.84)	0.2960	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Neuropsychiatric
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 52	Number of subjects with events, n (%)	4 (2.2)	1 (0.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	4.23 (0.45, 39.32)	
	p-value	0.2054	
	Odds Ratio (95% CI)	4.23 (0.46, 38.53)	
	p-value	0.2013	
	Risk Difference (95% CI)	1.70 (-0.71, 4.10)	
	p-value	0.1672	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	4.09 (0.46, 36.23)	
	p-value	0.2058	
	Odds Ratio (95% CI)	4.16 (0.46, 37.58)	
	p-value	0.2044	
	Risk Difference (95% CI)	1.68 (-0.72, 4.08)	
	p-value	0.1706	
	CMH approach		
	Response rate	2.3	0.5
	Difference in response rates (95% CI)	1.75 (-3.17, 6.66)	
	p-value	0.4866	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Neuropsychiatric - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.1274
< 10 points	0/ 55 (0.0)	0.0	1/ 54 (1.9)	1.8	0.33 (0.01, 7.86)	0.4912	-1.76 (-12.83, 9.31)	0.7554	
>= 10 points	4/125 (3.2)	3.2	0/130 (0.0)	0.0	9.36 (0.51, 172.02)	0.1322	3.23 (-2.43, 8.89)	0.2638	
OCS dose at baseline									0.9709
<10 mg/day	3/ 77 (3.9)	3.9	1/ 82 (1.2)	1.2	3.19 (0.34, 30.06)	0.3098	2.67 (-6.07, 11.42)	0.5491	
>=10 mg/day	1/103 (1.0)	1.0	0/102 (0.0)	0.0	2.97 (0.12, 72.09)	0.5033	0.99 (-5.21, 7.18)	0.7554	
Result of type I IFN gene signature test									0.9961
LOW	1/ 32 (3.1)	3.1	0/ 33 (0.0)	0.0	3.09 (0.13, 73.19)	0.4846	3.13 (-9.17, 15.42)	0.6184	
HIGH	3/148 (2.0)	2.1	1/151 (0.7)	0.6	3.06 (0.32, 29.09)	0.3302	1.45 (-3.91, 6.80)	0.5969	
Age (years)									NE
<= 65	4/173 (2.3)	2.4	1/181 (0.6)	0.5	4.18 (0.47, 37.07)	0.1984	1.86 (-3.21, 6.92)	0.4720	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
Sex									0.9313
male	1/ 15 (6.7)	6.7	0/ 13 (0.0)	0.0	2.63 (0.12, 59.40)	0.5442	6.67 (-18.77, 32.11)	0.6075	
female	3/165 (1.8)	1.8	1/171 (0.6)	0.6	3.11 (0.33, 29.59)	0.3238	1.27 (-3.92, 6.45)	0.6323	
Race									0.9675
White	3/125 (2.4)	2.4	1/137 (0.7)	0.7	3.29 (0.35, 31.20)	0.2998	1.62 (-4.86, 8.10)	0.6247	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	1/ 15 (6.7)	6.7	0/ 18 (0.0)	0.0	3.56 (0.16, 81.55)	0.4264	6.67 (-16.07, 29.40)	0.5655	
Ethnicity									0.9677
Hispanic/Latino	1/ 32 (3.1)	3.1	0/ 35 (0.0)	0.0	3.27 (0.14, 77.57)	0.4629	3.13 (-8.92, 15.17)	0.6111	
Non-hispanic/Latino	3/148 (2.0)	2.0	1/149 (0.7)	0.6	3.02 (0.32, 28.70)	0.3360	1.36 (-4.44, 7.15)	0.6462	
Geographic region									0.9036
EU	1/ 64 (1.6)	1.6	0/ 76 (0.0)	0.0	3.55 (0.15, 85.76)	0.4350	1.56 (-4.57, 7.70)	0.6176	
non-EU	3/116 (2.6)	2.6	1/108 (0.9)	0.9	2.79 (0.29, 26.45)	0.3705	1.74 (-5.78, 9.26)	0.6496	
Onset of disease									NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
Adult	4/168 (2.4)	2.4	1/172 (0.6)	0.6	4.10 (0.46, 36.26)	0.2052	1.84 (-3.41, 7.08)	0.4925	
ADA result									NE
Negative	4/162 (2.5)	2.5	1/169 (0.6)	0.6	4.17 (0.47, 36.94)	0.1991	1.95 (-3.43, 7.32)	0.4773	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE		0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment									0.1867
< 30	0/108 (0.0)	0.0	1/127 (0.8)	0.9	0.39 (0.02, 9.51)	0.5645	-0.88 (-6.37, 4.62)	0.7545	
>= 30	4/ 72 (5.6)	5.3	0/ 57 (0.0)	0.0	7.15 (0.39, 130.13)	0.1839	5.30 (-5.06, 15.65)	0.3161	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Musculoskeletal
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 52	Number of subjects with events, n (%)	37 (20.6)	39 (21.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.97 (0.65, 1.45)	
	p-value	0.8888	
	Odds Ratio (95% CI)	0.96 (0.58, 1.61)	
	p-value	0.8886	
	Risk Difference (95% CI)	-0.59 (-8.84, 7.66)	
	p-value	0.8886	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.97 (0.65, 1.45)	
	p-value	0.8806	
	Odds Ratio (95% CI)	0.96 (0.58, 1.60)	
	p-value	0.8806	
	Risk Difference (95% CI)	-0.64 (-8.99, 7.71)	
	p-value	0.8806	
	CMH approach		
	Response rate	20.6	21.1
	Difference in response rates (95% CI)	-0.51 (-9.09, 8.06)	
	p-value	0.9065	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Musculoskeletal - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.4476
< 10 points	12/ 55 (21.8)	21.9	15/ 54 (27.8)	27.4	0.79 (0.41, 1.52)	0.4731	-5.51 (-22.48, 11.45)	0.5242	
>= 10 points	25/125 (20.0)	20.0	24/130 (18.5)	18.5	1.08 (0.65, 1.79)	0.7553	1.54 (-8.37, 11.44)	0.7613	
OCS dose at baseline									0.8429
<10 mg/day	20/ 77 (26.0)	25.8	21/ 82 (25.6)	25.6	1.01 (0.60, 1.72)	0.9581	0.20 (-13.70, 14.10)	0.9774	
>=10 mg/day	17/103 (16.5)	16.5	18/102 (17.6)	17.6	0.94 (0.51, 1.71)	0.8280	-1.09 (-11.91, 9.73)	0.8439	
Result of type I IFN gene signature test									0.2723
LOW	11/ 32 (34.4)	34.4	8/ 33 (24.2)	24.2	1.42 (0.66, 3.06)	0.3741	10.13 (-12.37, 32.64)	0.3776	
HIGH	26/148 (17.6)	17.6	31/151 (20.5)	20.4	0.86 (0.54, 1.37)	0.5152	-2.83 (-12.06, 6.39)	0.5471	
Age (years)									0.5029
<= 65	36/173 (20.8)	20.9	38/181 (21.0)	20.9	0.99 (0.66, 1.49)	0.9658	0.02 (-8.70, 8.74)	0.9967	
> 65	1/ 7 (14.3)	14.3	1/ 3 (33.3)	33.3	0.43 (0.04, 4.82)	0.4925	-19.05 (-84.04, 45.95)	0.5657	
Sex									0.3533
male	3/ 15 (20.0)	20.0	1/ 13 (7.7)	7.7	2.60 (0.31, 22.05)	0.3810	12.31 (-18.12, 42.74)	0.4279	
female	34/165 (20.6)	20.6	38/171 (22.2)	22.2	0.93 (0.62, 1.40)	0.7183	-1.61 (-10.63, 7.41)	0.7264	
Race									0.0948
White	28/125 (22.4)	22.2	24/137 (17.5)	17.7	1.28 (0.78, 2.08)	0.3238	4.51 (-5.72, 14.74)	0.3877	
Black or African American	5/ 29 (17.2)	17.2	10/ 23 (43.5)	43.5	0.40 (0.16, 1.00)	0.0497	-26.24 (-51.41, -1.06)	0.0411	
Asian	3/ 11 (27.3)	27.3	3/ 5 (60.0)	60.0	0.45 (0.14, 1.51)	0.1984	-32.73 (-84.43, 18.97)	0.2147	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	1/ 15 (6.7)	6.7	2/ 18 (11.1)	11.1	0.60 (0.06, 5.99)	0.6634	-4.44 (-30.10, 21.21)	0.7342	
Ethnicity									0.8673
Hispanic/Latino	4/ 32 (12.5)	12.5	5/ 35 (14.3)	14.3	0.88 (0.26, 2.98)	0.8307	-1.79 (-19.91, 16.34)	0.8468	
Non-hispanic/Latino	33/148 (22.3)	22.1	34/149 (22.8)	22.4	0.98 (0.64, 1.49)	0.9144	-0.35 (-10.12, 9.41)	0.9435	
Geographic region									0.3366
EU	11/ 64 (17.2)	17.2	10/ 76 (13.2)	13.2	1.31 (0.59, 2.88)	0.5070	4.03 (-8.51, 16.57)	0.5288	
non-EU	26/116 (22.4)	23.1	29/108 (26.9)	26.7	0.83 (0.53, 1.32)	0.4414	-3.57 (-15.21, 8.08)	0.5484	
Onset of disease									0.3078
Paediatric	1/ 12 (8.3)	8.3	3/ 12 (25.0)	25.0	0.33 (0.04, 2.77)	0.3091	-16.67 (-50.95, 17.62)	0.3407	
Adult	36/168 (21.4)	21.3	36/172 (20.9)	21.0	1.02 (0.68, 1.54)	0.9105	0.31 (-8.66, 9.29)	0.9452	
ADA result									0.0888
Negative	34/162 (21.0)	20.8	32/169 (18.9)	18.9	1.11 (0.72, 1.71)	0.6405	1.96 (-6.97, 10.89)	0.6670	
Positive (At any time)	3/ 17 (17.6)	17.6	7/ 15 (46.7)	46.7	0.38 (0.12, 1.21)	0.1006	-29.02 (-61.40, 3.36)	0.0790	
BMI (kg/m2) at enrolment									0.8361
< 30	18/108 (16.7)	16.5	22/127 (17.3)	17.5	0.96 (0.55, 1.70)	0.8939	-1.06 (-11.25, 9.13)	0.8382	
>= 30	19/ 72 (26.4)	26.7	17/ 57 (29.8)	29.4	0.88 (0.51, 1.54)	0.6653	-2.71 (-18.36, 12.95)	0.7347	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Cardiorespiratory
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 52	Number of subjects with events, n (%)	3 (1.7)	2 (1.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.55 (0.27, 9.04)	
	p-value	0.6270	
	Odds Ratio (95% CI)	1.55 (0.26, 9.19)	
	p-value	0.6303	
	Risk Difference (95% CI)	0.60 (-1.83, 3.04)	
	p-value	0.6278	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.53 (0.26, 9.07)	
	p-value	0.6374	
	Odds Ratio (95% CI)	1.54 (0.25, 9.34)	
	p-value	0.6373	
	Risk Difference (95% CI)	0.58 (-1.82, 2.98)	
	p-value	0.6354	
	CMH approach		
	Response rate	1.7	1.1
	Difference in response rates (95% CI)	0.61 (-4.31, 5.53)	
	p-value	0.8084	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Cardiorespiratory - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Anifrolumab 300mg (N=180) Response rate	Placebo (N=184) n/ N (%)	Placebo (N=184) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.2565
< 10 points	0/ 55 (0.0)	0.0	1/ 54 (1.9)	1.8	0.33 (0.01, 7.86)	0.4912	-1.76 (-12.71, 9.20)	0.7535	
>= 10 points	3/125 (2.4)	2.4	1/130 (0.8)	0.8	3.12 (0.33, 29.60)	0.3216	1.62 (-3.99, 7.23)	0.5723	
OCS dose at baseline									0.2266
<10 mg/day	2/ 77 (2.6)	2.6	0/ 82 (0.0)	0.0	5.32 (0.26, 109.09)	0.2781	2.55 (-5.67, 10.77)	0.5430	
>=10 mg/day	1/103 (1.0)	1.0	2/102 (2.0)	1.9	0.50 (0.05, 5.38)	0.5635	-0.83 (-7.35, 5.68)	0.8026	
Result of type I IFN gene signature test									0.7037
LOW	2/ 32 (6.3)	6.3	1/ 33 (3.0)	3.0	2.06 (0.20, 21.64)	0.5461	3.22 (-11.11, 17.55)	0.6596	
HIGH	1/148 (0.7)	0.7	1/151 (0.7)	0.7	1.02 (0.06, 16.16)	0.9886	0.04 (-5.07, 5.15)	0.9879	
Age (years)									NE
<= 65	3/173 (1.7)	1.8	2/181 (1.1)	1.1	1.57 (0.27, 9.28)	0.6191	0.68 (-4.38, 5.73)	0.7929	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
Sex									0.2280
male	0/ 15 (0.0)	0.0	1/ 13 (7.7)	7.7	0.29 (0.01, 6.60)	0.4388	-7.69 (-33.59, 18.20)	0.5604	
female	3/165 (1.8)	1.8	1/171 (0.6)	0.6	3.11 (0.33, 29.59)	0.3238	1.26 (-3.93, 6.45)	0.6338	
Race									NE
White	3/125 (2.4)	2.3	2/137 (1.5)	1.5	1.64 (0.28, 9.68)	0.5826	0.76 (-5.87, 7.40)	0.8221	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-20.43, 20.43)	1.0000	
Ethnicity									0.5341
Hispanic/Latino	1/ 32 (3.1)	3.1	0/ 35 (0.0)	0.0	3.27 (0.14, 77.57)	0.4629	3.13 (-8.92, 15.17)	0.6111	
Non-hispanic/Latino	2/148 (1.4)	1.4	2/149 (1.3)	1.3	1.01 (0.14, 7.05)	0.9946	0.09 (-5.75, 5.92)	0.9767	
Geographic region									0.8087
EU	1/ 64 (1.6)	1.6	1/ 76 (1.3)	1.3	1.19 (0.08, 18.61)	0.9026	0.25 (-6.35, 6.85)	0.9416	
non-EU	2/116 (1.7)	1.8	1/108 (0.9)	0.9	1.86 (0.17, 20.24)	0.6096	0.95 (-6.47, 8.37)	0.8020	
Onset of disease									NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
Adult	3/168 (1.8)	1.8	2/172 (1.2)	1.2	1.54 (0.26, 9.07)	0.6360	0.62 (-4.61, 5.84)	0.8177	
ADA result									NE
Negative	3/162 (1.9)	1.8	2/169 (1.2)	1.2	1.56 (0.26, 9.24)	0.6212	0.66 (-4.70, 6.03)	0.8087	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE		0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment									0.5578
< 30	2/108 (1.9)	1.9	1/127 (0.8)	0.8	2.35 (0.22, 25.58)	0.4825	1.14 (-4.80, 7.08)	0.7074	
>= 30	1/ 72 (1.4)	1.4	1/ 57 (1.8)	1.7	0.79 (0.05, 12.38)	0.8678	-0.33 (-10.29, 9.63)	0.9488	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Gastrointestinal
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 52	Number of subjects with events, n (%)	0 (0.0)	1 (0.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.00 (NE, NE)	
	p-value	NE	
	Odds Ratio (95% CI)	0.00 (NE, NE)	
	p-value	NE	
	Risk Difference (95% CI)	-0.55 (-1.61, 0.52)	
	p-value	0.3151	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.34 (0.01, 8.31)	
	p-value	0.5088	
	Odds Ratio (95% CI)	0.34 (0.01, 8.37)	
	p-value	0.5084	
	Risk Difference (95% CI)	-0.54 (-1.61, 0.52)	
	p-value	0.3160	
	CMH approach		
	Response rate	0.0	0.5
	Difference in response rates (95% CI)	-0.55 (-5.08, 3.98)	
	p-value	0.8131	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Gastrointestinal - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 55 (0.0)	0.0	0/ 54 (0.0)	0.0	NE		0.00 (-10.69, 10.69)	1.0000	
>= 10 points	0/125 (0.0)	0.0	1/130 (0.8)	0.8	0.35 (0.01, 8.43)	0.5152	-0.78 (-5.91, 4.35)	0.7660	
OCS dose at baseline									NE
<10 mg/day	0/ 77 (0.0)	0.0	0/ 82 (0.0)	0.0	NE		0.00 (-7.65, 7.65)	1.0000	
>=10 mg/day	0/103 (0.0)	0.0	1/102 (1.0)	1.0	0.33 (0.01, 8.01)	0.4958	-0.97 (-7.16, 5.22)	0.7586	
Result of type I IFN gene signature test									NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE		0.00 (-11.07, 11.07)	1.0000	
HIGH	0/148 (0.0)	0.0	1/151 (0.7)	0.7	0.34 (0.01, 8.28)	0.5078	-0.67 (-5.63, 4.30)	0.7927	
Age (years)									NE
<= 65	0/173 (0.0)	0.0	1/181 (0.6)	0.6	0.35 (0.01, 8.50)	0.5179	-0.56 (-5.21, 4.10)	0.8141	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
Sex									NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
female	0/165 (0.0)	0.0	1/171 (0.6)	0.6	0.35 (0.01, 8.42)	0.5141	-0.59 (-5.45, 4.28)	0.8133	
Race									NE
White	0/125 (0.0)	0.0	1/137 (0.7)	0.7	0.37 (0.02, 8.88)	0.5360	-0.74 (-6.85, 5.38)	0.8138	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-20.43, 20.43)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE		0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	0/148 (0.0)	0.0	1/149 (0.7)	0.6	0.34 (0.01, 8.17)	0.5026	-0.63 (-6.12, 4.86)	0.8224	
Geographic region									NE
EU	0/ 64 (0.0)	0.0	1/ 76 (1.3)	1.3	0.39 (0.02, 9.53)	0.5673	-1.32 (-7.26, 4.63)	0.6646	
non-EU	0/116 (0.0)	0.0	0/108 (0.0)	0.0	NE		0.00 (-6.94, 6.94)	1.0000	
Onset of disease									NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
Adult	0/168 (0.0)	0.0	1/172 (0.6)	0.6	0.34 (0.01, 8.32)	0.5093	-0.57 (-5.39, 4.24)	0.8151	
ADA result									NE
Negative	0/162 (0.0)	0.0	1/169 (0.6)	0.6	0.35 (0.01, 8.47)	0.5167	-0.58 (-5.52, 4.37)	0.8195	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE		0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/108 (0.0)	0.0	1/127 (0.8)	0.8	0.39 (0.02, 9.51)	0.5645	-0.77 (-6.26, 4.72)	0.7841	
>= 30	0/ 72 (0.0)	0.0	0/ 57 (0.0)	0.0	NE		0.00 (-9.40, 9.40)	1.0000	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Ophthalmic
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 52	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	NE	
	p-value		
	Odds Ratio (95% CI)	NE	
	p-value		
	Risk Difference (95% CI)	NE	
	p-value		
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	NE	
	p-value		
	Odds Ratio (95% CI)	NE	
	p-value		
	Risk Difference (95% CI)	NE	
	p-value		
	CMH approach		
	Response rate	0.0	0.0
	Difference in response rates (95% CI)	0.00 (-4.42, 4.42)	
	p-value	1.0000	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Ophthalmic - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 55 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>= 10 points	0/125 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 77 (0.0)	0.0	0/ 82 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
>=10 mg/day	0/103 (0.0)	0.0	0/102 (0.0)	0.0	NE	0.00 (-5.93, 5.93)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-11.07, 11.07)	1.0000	
HIGH	0/148 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.81, 4.81)	1.0000	
Age (years)								NE
<= 65	0/173 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.54, 4.54)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
Sex								NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
female	0/165 (0.0)	0.0	0/171 (0.0)	0.0	NE	0.00 (-4.75, 4.75)	1.0000	
Race								NE
White	0/125 (0.0)	0.0	0/137 (0.0)	0.0	NE	0.00 (-5.97, 5.97)	1.0000	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-20.43, 20.43)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE	0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	0/148 (0.0)	0.0	0/149 (0.0)	0.0	NE	0.00 (-5.37, 5.37)	1.0000	
Geographic region								NE
EU	0/ 64 (0.0)	0.0	0/ 76 (0.0)	0.0	NE	0.00 (-5.43, 5.43)	1.0000	
non-EU	0/116 (0.0)	0.0	0/108 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Onset of disease								NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
Adult	0/168 (0.0)	0.0	0/172 (0.0)	0.0	NE	0.00 (-4.70, 4.70)	1.0000	
ADA result								NE
Negative	0/162 (0.0)	0.0	0/169 (0.0)	0.0	NE	0.00 (-4.83, 4.83)	1.0000	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE	0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/108 (0.0)	0.0	0/127 (0.0)	0.0	NE	0.00 (-5.30, 5.30)	1.0000	
>= 30	0/ 72 (0.0)	0.0	0/ 57 (0.0)	0.0	NE	0.00 (-9.40, 9.40)	1.0000	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Renal
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 52	Number of subjects with events, n (%)	7 (3.9)	9 (4.9)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.80 (0.31, 2.07)	
	p-value	0.6477	
	Odds Ratio (95% CI)	0.79 (0.28, 2.21)	
	p-value	0.6473	
	Risk Difference (95% CI)	-0.97 (-5.09, 3.16)	
	p-value	0.6461	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.80 (0.30, 2.09)	
	p-value	0.6418	
	Odds Ratio (95% CI)	0.79 (0.29, 2.16)	
	p-value	0.6416	
	Risk Difference (95% CI)	-1.00 (-5.21, 3.20)	
	p-value	0.6404	
	CMH approach		
	Response rate	3.9	4.9
	Difference in response rates (95% CI)	-0.97 (-6.82, 4.89)	
	p-value	0.7464	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Renal - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.5471
< 10 points	0/ 55 (0.0)	0.0	1/ 54 (1.9)	1.8	0.33 (0.01, 7.86)	0.4912	-1.76 (-12.83, 9.31)	0.7554	
>= 10 points	7/125 (5.6)	5.6	8/130 (6.2)	6.2	0.91 (0.34, 2.43)	0.8510	-0.63 (-7.89, 6.63)	0.8655	
OCS dose at baseline									0.7256
<10 mg/day	1/ 77 (1.3)	1.3	2/ 82 (2.4)	2.4	0.53 (0.05, 5.75)	0.6038	-1.07 (-9.57, 7.42)	0.8043	
>=10 mg/day	6/103 (5.8)	5.9	7/102 (6.9)	6.8	0.85 (0.30, 2.44)	0.7609	-0.88 (-9.45, 7.69)	0.8401	
Result of type I IFN gene signature test									NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE		0.00 (-11.07, 11.07)	1.0000	
HIGH	7/148 (4.7)	4.8	9/151 (6.0)	5.9	0.79 (0.30, 2.08)	0.6373	-1.18 (-7.88, 5.53)	0.7311	
Age (years)									NE
<= 65	7/173 (4.0)	4.1	9/181 (5.0)	5.0	0.81 (0.31, 2.14)	0.6757	-0.89 (-6.91, 5.12)	0.7709	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
Sex									0.9406
male	1/ 15 (6.7)	6.7	1/ 13 (7.7)	7.7	0.87 (0.06, 12.52)	0.9164	-1.03 (-28.77, 26.72)	0.9422	
female	6/165 (3.6)	3.7	8/171 (4.7)	4.7	0.78 (0.28, 2.19)	0.6338	-0.99 (-7.12, 5.14)	0.7514	
Race									0.3131
White	5/125 (4.0)	4.0	4/137 (2.9)	2.9	1.37 (0.38, 4.99)	0.6330	1.07 (-6.10, 8.24)	0.7700	
Black or African American	2/ 29 (6.9)	6.9	1/ 23 (4.3)	4.3	1.59 (0.15, 16.42)	0.6988	2.55 (-14.95, 20.04)	0.7752	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 15 (0.0)	0.0	4/ 18 (22.2)	22.2	0.13 (0.01, 2.27)	0.1629	-22.22 (-48.00, 3.56)	0.0911	
Ethnicity									0.4210
Hispanic/Latino	1/ 32 (3.1)	3.1	3/ 35 (8.6)	8.6	0.36 (0.04, 3.33)	0.3713	-5.45 (-20.09, 9.20)	0.4660	
Non-hispanic/Latino	6/148 (4.1)	4.3	6/149 (4.0)	3.9	1.01 (0.33, 3.05)	0.9905	0.45 (-6.29, 7.18)	0.8964	
Geographic region									0.4477
EU	4/ 64 (6.3)	6.3	4/ 76 (5.3)	5.3	1.19 (0.31, 4.56)	0.8023	0.99 (-8.14, 10.12)	0.8322	
non-EU	3/116 (2.6)	2.5	5/108 (4.6)	4.8	0.56 (0.14, 2.28)	0.4173	-2.34 (-10.48, 5.80)	0.5730	
Onset of disease									0.7718
Paediatric	2/ 12 (16.7)	16.7	2/ 12 (16.7)	16.7	1.00 (0.17, 5.98)	1.0000	0.00 (-34.65, 34.65)	1.0000	
Adult	5/168 (3.0)	3.0	7/172 (4.1)	4.0	0.73 (0.24, 2.26)	0.5865	-1.01 (-6.90, 4.88)	0.7376	
ADA result									0.8777
Negative	5/162 (3.1)	3.2	7/169 (4.1)	4.0	0.75 (0.24, 2.30)	0.6090	-0.83 (-6.87, 5.21)	0.7871	
Positive (At any time)	2/ 17 (11.8)	11.8	2/ 15 (13.3)	13.3	0.88 (0.14, 5.52)	0.8935	-1.57 (-29.39, 26.25)	0.9120	
BMI (kg/m2) at enrolment									0.5998
< 30	4/108 (3.7)	3.8	7/127 (5.5)	5.4	0.67 (0.20, 2.23)	0.5166	-1.57 (-8.84, 5.71)	0.6725	
>= 30	3/ 72 (4.2)	3.9	2/ 57 (3.5)	3.5	1.19 (0.21, 6.87)	0.8478	0.40 (-10.49, 11.29)	0.9427	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Haematological
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 52	Number of subjects with events, n (%)	1 (0.6)	0 (0.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	NE	
	p-value		
	Odds Ratio (95% CI)	NE	
	p-value		
	Risk Difference (95% CI)	0.58 (-0.53, 1.68)	
	p-value	0.3078	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	3.07 (0.13, 74.78)	
	p-value	0.4917	
	Odds Ratio (95% CI)	3.08 (0.12, 76.19)	
	p-value	0.4913	
	Risk Difference (95% CI)	0.56 (-0.53, 1.64)	
	p-value	0.3160	
	CMH approach		
	Response rate	0.6	0.0
	Difference in response rates (95% CI)	0.58 (-3.94, 5.09)	
	p-value	0.8026	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Haematological - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	1/ 55 (1.8)	1.9	0/ 54 (0.0)	0.0	2.95 (0.12, 70.77)	0.5053	1.93 (-9.20, 13.06)	0.7344	
>= 10 points	0/125 (0.0)	0.0	0/130 (0.0)	0.0	NE		0.00 (-4.93, 4.93)	1.0000	
OCS dose at baseline									NE
<10 mg/day	1/ 77 (1.3)	1.3	0/ 82 (0.0)	0.0	3.19 (0.13, 77.20)	0.4751	1.32 (-6.62, 9.25)	0.7449	
>=10 mg/day	0/103 (0.0)	0.0	0/102 (0.0)	0.0	NE		0.00 (-5.93, 5.93)	1.0000	
Result of type I IFN gene signature test									NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE		0.00 (-11.07, 11.07)	1.0000	
HIGH	1/148 (0.7)	0.7	0/151 (0.0)	0.0	3.06 (0.13, 74.53)	0.4923	0.70 (-4.24, 5.64)	0.7809	
Age (years)									NE
<= 65	1/173 (0.6)	0.6	0/181 (0.0)	0.0	3.14 (0.13, 76.51)	0.4828	0.61 (-4.04, 5.25)	0.7978	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
Sex									NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
female	1/165 (0.6)	0.6	0/171 (0.0)	0.0	3.11 (0.13, 75.76)	0.4864	0.61 (-4.24, 5.46)	0.8048	
Race									NE
White	1/125 (0.8)	0.8	0/137 (0.0)	0.0	3.29 (0.14, 79.92)	0.4651	0.79 (-5.30, 6.88)	0.7985	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-20.43, 20.43)	1.0000	
Ethnicity									NE
Hispanic/Latino	1/ 32 (3.1)	3.1	0/ 35 (0.0)	0.0	3.27 (0.14, 77.57)	0.4629	3.13 (-8.92, 15.17)	0.6111	
Non-hispanic/Latino	0/148 (0.0)	0.0	0/149 (0.0)	0.0	NE		0.00 (-5.37, 5.37)	1.0000	
Geographic region									NE
EU	0/ 64 (0.0)	0.0	0/ 76 (0.0)	0.0	NE		0.00 (-5.43, 5.43)	1.0000	
non-EU	1/116 (0.9)	0.9	0/108 (0.0)	0.0	2.79 (0.12, 67.88)	0.5277	0.93 (-6.16, 8.02)	0.7979	
Onset of disease									NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
Adult	1/168 (0.6)	0.6	0/172 (0.0)	0.0	3.07 (0.13, 74.86)	0.4911	0.57 (-4.22, 5.37)	0.8141	
ADA result									NE
Negative	1/162 (0.6)	0.7	0/169 (0.0)	0.0	3.13 (0.13, 76.25)	0.4839	0.65 (-4.29, 5.59)	0.7954	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE		0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/108 (0.0)	0.0	0/127 (0.0)	0.0	NE		0.00 (-5.30, 5.30)	1.0000	
>= 30	1/ 72 (1.4)	1.5	0/ 57 (0.0)	0.0	2.38 (0.10, 57.43)	0.5926	1.54 (-8.17, 11.25)	0.7562	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Major clinical response at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 52	Number of subjects with events, n (%)	40 (22.2)	29 (15.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.41 (0.91, 2.17)	
	p-value	0.1200	
	Odds Ratio (95% CI)	1.52 (0.90, 2.58)	
	p-value	0.1192	
	Risk Difference (95% CI)	6.45 (-1.62, 14.52)	
	p-value	0.1173	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.41 (0.92, 2.17)	
	p-value	0.1187	
	Odds Ratio (95% CI)	1.53 (0.90, 2.59)	
	p-value	0.1173	
	Risk Difference (95% CI)	6.46 (-1.58, 14.50)	
	p-value	0.1151	
	CMH approach		
	Response rate	22.1	15.8
	Difference in response rates (95% CI)	6.27 (-2.18, 14.71)	
	p-value	0.1458	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Major clinical response at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.2892
< 10 points	16/ 55 (29.1)	28.8	8/ 54 (14.8)	15.1	1.96 (0.92, 4.20)	0.0823	13.76 (-2.74, 30.25)	0.1021	
>= 10 points	24/125 (19.2)	19.3	21/130 (16.2)	16.2	1.19 (0.70, 2.02)	0.5243	3.09 (-6.80, 12.99)	0.5398	
OCS dose at baseline									0.4183
<10 mg/day	18/ 77 (23.4)	23.5	11/ 82 (13.4)	13.5	1.74 (0.88, 3.45)	0.1108	10.05 (-2.90, 22.99)	0.1282	
>=10 mg/day	22/103 (21.4)	21.0	18/102 (17.6)	17.7	1.21 (0.69, 2.12)	0.5037	3.36 (-7.94, 14.67)	0.5599	
Result of type I IFN gene signature test									0.3268
LOW	5/ 32 (15.6)	15.6	6/ 33 (18.2)	18.2	0.86 (0.29, 2.54)	0.7838	-2.56 (-22.19, 17.07)	0.7985	
HIGH	35/148 (23.6)	23.5	23/151 (15.2)	15.3	1.55 (0.97, 2.50)	0.0693	8.19 (-1.16, 17.54)	0.0862	
Age (years)									0.3293
<= 65	39/173 (22.5)	22.4	28/181 (15.5)	15.5	1.46 (0.94, 2.26)	0.0923	6.87 (-1.72, 15.46)	0.1172	
> 65	1/ 7 (14.3)	14.3	1/ 3 (33.3)	33.3	0.43 (0.04, 4.82)	0.4925	-19.05 (-84.04, 45.95)	0.5657	
Sex									0.2154
male	4/ 15 (26.7)	26.7	0/ 13 (0.0)	0.0	7.88 (0.46, 133.76)	0.1533	26.67 (-2.66, 55.99)	0.0747	
female	36/165 (21.8)	21.7	29/171 (17.0)	17.1	1.29 (0.83, 2.00)	0.2615	4.60 (-4.21, 13.42)	0.3063	
Race									0.5348
White	29/125 (23.2)	23.8	20/137 (14.6)	14.3	1.59 (0.95, 2.66)	0.0782	9.43 (-0.58, 19.44)	0.0648	
Black or African American	8/ 29 (27.6)	27.6	5/ 23 (21.7)	21.7	1.27 (0.48, 3.36)	0.6318	5.85 (-18.66, 30.35)	0.6400	
Asian	0/ 11 (0.0)	0.0	1/ 5 (20.0)	20.0	0.17 (0.01, 3.51)	0.2491	-20.00 (-65.94, 25.94)	0.3936	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	3/ 15 (20.0)	20.0	3/ 18 (16.7)	16.7	1.20 (0.28, 5.10)	0.8048	3.33 (-26.19, 32.85)	0.8248	
Ethnicity									0.0165
Hispanic/Latino	2/ 32 (6.3)	6.3	8/ 35 (22.9)	22.9	0.27 (0.06, 1.19)	0.0846	-16.61 (-34.71, 1.50)	0.0722	
Non-hispanic/Latino	38/148 (25.7)	25.1	21/149 (14.1)	14.4	1.82 (1.13, 2.95)	0.0147	10.78 (1.27, 20.28)	0.0263	
Geographic region									0.2423
EU	22/ 64 (34.4)	34.4	14/ 76 (18.4)	18.4	1.87 (1.04, 3.34)	0.0356	15.95 (1.19, 30.72)	0.0342	
non-EU	18/116 (15.5)	16.0	15/108 (13.9)	14.2	1.12 (0.59, 2.10)	0.7314	1.81 (-8.75, 12.37)	0.7371	
Onset of disease									0.3852
Paediatric	2/ 12 (16.7)	16.7	0/ 12 (0.0)	0.0	5.00 (0.27, 94.34)	0.2829	16.67 (-14.16, 47.49)	0.2893	
Adult	38/168 (22.6)	22.6	29/172 (16.9)	16.9	1.34 (0.87, 2.07)	0.1845	5.67 (-3.19, 14.53)	0.2097	
ADA result									0.7724
Negative	36/162 (22.2)	22.0	27/169 (16.0)	16.0	1.39 (0.89, 2.18)	0.1507	5.97 (-2.93, 14.86)	0.1885	
Positive (At any time)	4/ 17 (23.5)	23.5	2/ 15 (13.3)	13.3	1.76 (0.37, 8.31)	0.4723	10.20 (-19.58, 39.98)	0.5022	
BMI (kg/m2) at enrolment									0.7941
< 30	26/108 (24.1)	24.1	22/127 (17.3)	17.2	1.39 (0.84, 2.31)	0.2028	6.89 (-3.90, 17.68)	0.2109	
>= 30	14/ 72 (19.4)	20.2	7/ 57 (12.3)	12.3	1.58 (0.68, 3.66)	0.2825	7.88 (-6.13, 21.89)	0.2703	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Partial clinical response at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 52	Number of subjects with events, n (%)	82 (45.6)	74 (40.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.14 (0.90, 1.44)	
	p-value	0.2898	
	Odds Ratio (95% CI)	1.25 (0.82, 1.91)	
	p-value	0.2904	
	Risk Difference (95% CI)	5.46 (-4.64, 15.57)	
	p-value	0.2892	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.13 (0.89, 1.44)	
	p-value	0.3043	
	Odds Ratio (95% CI)	1.24 (0.82, 1.89)	
	p-value	0.3038	
	Risk Difference (95% CI)	5.34 (-4.82, 15.49)	
	p-value	0.3029	
	CMH approach		
	Response rate	45.4	40.2
	Difference in response rates (95% CI)	5.20 (-4.90, 15.29)	
	p-value	0.3130	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Partial clinical response at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.6310
< 10 points	31/ 55 (56.4)	56.2	25/ 54 (46.3)	46.2	1.22 (0.84, 1.76)	0.2967	10.02 (-8.70, 28.74)	0.2941	
>= 10 points	51/125 (40.8)	40.9	49/130 (37.7)	37.6	1.08 (0.80, 1.47)	0.6115	3.28 (-8.64, 15.20)	0.5897	
OCS dose at baseline									0.1197
<10 mg/day	34/ 77 (44.2)	44.3	39/ 82 (47.6)	47.7	0.93 (0.66, 1.30)	0.6673	-3.42 (-18.87, 12.04)	0.6649	
>=10 mg/day	48/103 (46.6)	46.2	35/102 (34.3)	34.5	1.36 (0.97, 1.91)	0.0767	11.67 (-1.64, 24.99)	0.0858	
Result of type I IFN gene signature test									0.1506
LOW	11/ 32 (34.4)	34.4	15/ 33 (45.5)	45.5	0.76 (0.41, 1.39)	0.3673	-11.08 (-34.87, 12.71)	0.3614	
HIGH	71/148 (48.0)	47.8	59/151 (39.1)	39.0	1.23 (0.95, 1.59)	0.1225	8.74 (-2.41, 19.89)	0.1243	
Age (years)									0.6303
<= 65	78/173 (45.1)	44.8	73/181 (40.3)	40.2	1.12 (0.88, 1.42)	0.3662	4.59 (-5.64, 14.82)	0.3792	
> 65	4/ 7 (57.1)	57.1	1/ 3 (33.3)	33.3	1.71 (0.31, 9.61)	0.5401	23.81 (-43.25, 90.87)	0.4865	
Sex									0.3563
male	8/ 15 (53.3)	53.3	4/ 13 (30.8)	30.8	1.73 (0.68, 4.45)	0.2529	22.56 (-13.68, 58.80)	0.2223	
female	74/165 (44.8)	44.7	70/171 (40.9)	40.9	1.10 (0.86, 1.40)	0.4690	3.89 (-6.63, 14.40)	0.4687	
Race									0.8504
White	53/125 (42.4)	42.9	52/137 (38.0)	37.9	1.12 (0.83, 1.50)	0.4634	4.96 (-6.82, 16.73)	0.4094	
Black or African American	13/ 29 (44.8)	44.8	11/ 23 (47.8)	47.8	0.94 (0.52, 1.69)	0.8290	-3.00 (-30.30, 24.30)	0.8296	
Asian	6/ 11 (54.5)	54.5	2/ 5 (40.0)	40.0	1.36 (0.41, 4.53)	0.6129	14.55 (-38.05, 67.14)	0.5878	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	10/ 15 (66.7)	66.7	9/ 18 (50.0)	50.0	1.33 (0.74, 2.39)	0.3346	16.67 (-16.94, 50.27)	0.3311	
Ethnicity									0.1358
Hispanic/Latino	13/ 32 (40.6)	40.6	18/ 35 (51.4)	51.4	0.79 (0.47, 1.34)	0.3817	-10.80 (-34.59, 12.99)	0.3734	
Non-hispanic/Latino	69/148 (46.6)	46.4	56/149 (37.6)	38.0	1.24 (0.95, 1.62)	0.1168	8.31 (-2.88, 19.51)	0.1453	
Geographic region									0.0730
EU	36/ 64 (56.3)	56.3	29/ 76 (38.2)	38.2	1.47 (1.03, 2.11)	0.0339	18.09 (1.72, 34.46)	0.0303	
non-EU	46/116 (39.7)	39.7	45/108 (41.7)	41.5	0.95 (0.69, 1.31)	0.7593	-1.79 (-14.73, 11.15)	0.7861	
Onset of disease									0.3084
Paediatric	6/ 12 (50.0)	50.0	3/ 12 (25.0)	25.0	2.00 (0.65, 6.20)	0.2299	25.00 (-13.58, 63.58)	0.2040	
Adult	76/168 (45.2)	45.1	71/172 (41.3)	41.3	1.10 (0.86, 1.40)	0.4616	3.83 (-6.64, 14.30)	0.4735	
ADA result									0.1523
Negative	75/162 (46.3)	46.1	72/169 (42.6)	42.7	1.09 (0.85, 1.38)	0.4992	3.41 (-7.19, 14.01)	0.5282	
Positive (At any time)	7/ 17 (41.2)	41.2	2/ 15 (13.3)	13.3	3.09 (0.75, 12.65)	0.1170	27.84 (-3.45, 59.13)	0.0811	
BMI (kg/m2) at enrolment									0.2197
< 30	54/108 (50.0)	49.9	50/127 (39.4)	39.5	1.27 (0.95, 1.69)	0.1022	10.41 (-2.24, 23.07)	0.1067	
>= 30	28/ 72 (38.9)	39.7	24/ 57 (42.1)	42.3	0.92 (0.61, 1.41)	0.7109	-2.63 (-19.59, 14.33)	0.7608	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
>=50% Joint reduction at week 52 (for subjects with at least 6 tender joints and swollen joints at baseline)
Full analysis set

Timepoint		Anifrolumab 300mg (N=93)	Placebo (N=100)
Week 52	Number of subjects with events, n (%)	51 (54.8)	37 (37.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.56 (1.14, 2.13)	
	p-value	0.0060	
	Odds Ratio (95% CI)	2.31 (1.27, 4.20)	
	p-value	0.0060	
	Risk Difference (95% CI)	20.10 (6.33, 33.87)	
	p-value	0.0042	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.48 (1.08, 2.03)	
	p-value	0.0145	
	Odds Ratio (95% CI)	2.07 (1.16, 3.68)	
	p-value	0.0134	
	Risk Difference (95% CI)	17.84 (3.99, 31.69)	
	p-value	0.0116	
	CMH approach		
	Response rate	55.6	36.3
	Difference in response rates (95% CI)	19.32 (5.43, 33.20)	
	p-value	0.0064	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
>=50% Joint reduction at week 52 (for subjects with at least 6 tender joints and swollen joints at baseline) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=93) n/ N (%)	Response rate	Placebo (N=100) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8607
< 10 points	19/ 31 (61.3)	61.3	12/ 30 (40.0)	40.0	1.53 (0.91, 2.58)	0.1077	21.29 (-3.36, 45.94)	0.0905	
>= 10 points	32/ 62 (51.6)	53.3	25/ 70 (35.7)	35.0	1.45 (0.97, 2.15)	0.0684	18.28 (1.49, 35.06)	0.0329	
OCS dose at baseline									0.6843
<10 mg/day	23/ 39 (59.0)	60.9	17/ 46 (37.0)	35.8	1.60 (1.01, 2.53)	0.0461	25.09 (3.96, 46.22)	0.0200	
>=10 mg/day	28/ 54 (51.9)	51.9	20/ 54 (37.0)	37.0	1.40 (0.91, 2.16)	0.1272	14.81 (-3.76, 33.39)	0.1181	
Result of type I IFN gene signature test									0.9825
LOW	10/ 20 (50.0)	50.0	6/ 18 (33.3)	33.3	1.50 (0.68, 3.29)	0.3124	16.67 (-14.54, 47.88)	0.2953	
HIGH	41/ 73 (56.2)	57.0	31/ 82 (37.8)	37.0	1.49 (1.05, 2.10)	0.0240	19.98 (4.48, 35.49)	0.0115	
Age (years)									0.0359
<= 65	48/ 89 (53.9)	54.6	35/ 98 (35.7)	35.0	1.51 (1.09, 2.10)	0.0137	19.61 (5.48, 33.74)	0.0065	
> 65	3/ 4 (75.0)	75.0	2/ 2 (100.0)	100.0	0.75 (0.43, 1.32)	0.3190	-25.00 (-105.74, 55.74)	0.5439	
Sex									0.6472
male	4/ 9 (44.4)	44.4	2/ 5 (40.0)	40.0	1.11 (0.30, 4.07)	0.8736	4.44 (-49.94, 58.83)	0.8727	
female	47/ 84 (56.0)	55.8	35/ 95 (36.8)	36.9	1.52 (1.10, 2.10)	0.0116	18.82 (4.40, 33.25)	0.0106	
Race									0.5257
White	36/ 63 (57.1)	57.8	32/ 78 (41.0)	40.8	1.39 (0.99, 1.96)	0.0571	16.92 (0.42, 33.41)	0.0444	
Black or African American	7/ 19 (36.8)	36.8	2/ 11 (18.2)	18.2	2.03 (0.51, 8.09)	0.3176	18.66 (-15.46, 52.78)	0.2838	
Asian	1/ 2 (50.0)	50.0	1/ 2 (50.0)	50.0	1.00 (0.14, 7.10)	1.0000	0.00 (-98.00, 98.00)	1.0000	
Other	7/ 9 (77.8)	77.8	2/ 9 (22.2)	22.2	3.50 (0.98, 12.48)	0.0534	55.56 (12.91, 98.20)	0.0107	
Ethnicity									0.6589
Hispanic/Latino	11/ 20 (55.0)	55.0	5/ 16 (31.3)	31.3	1.76 (0.77, 4.03)	0.1808	23.75 (-8.24, 55.74)	0.1456	
Non-hispanic/Latino	40/ 73 (54.8)	55.0	32/ 84 (38.1)	38.2	1.44 (1.02, 2.03)	0.0379	16.75 (1.10, 32.40)	0.0359	
Geographic region									0.3660
EU	21/ 29 (72.4)	72.4	21/ 39 (53.8)	53.8	1.34 (0.93, 1.94)	0.1139	18.57 (-4.34, 41.48)	0.1122	
non-EU	30/ 64 (46.9)	47.0	16/ 61 (26.2)	26.3	1.79 (1.09, 2.93)	0.0215	20.71 (3.95, 37.46)	0.0154	
Onset of disease									0.4850
Paediatric	2/ 4 (50.0)	50.0	1/ 6 (16.7)	16.7	3.00 (0.39, 23.07)	0.2912	33.33 (-27.87, 94.53)	0.2857	
Adult	49/ 89 (55.1)	56.2	36/ 94 (38.3)	37.6	1.44 (1.05, 1.98)	0.0252	18.60 (4.26, 32.94)	0.0110	
ADA result									0.5551
Negative	47/ 83 (56.6)	56.8	36/ 94 (38.3)	38.2	1.48 (1.08, 2.03)	0.0160	18.55 (4.00, 33.09)	0.0124	
Positive (At any time)	4/ 9 (44.4)	44.4	1/ 6 (16.7)	16.7	2.67 (0.39, 18.42)	0.3199	27.78 (-21.27, 76.82)	0.2670	
BMI (kg/m2) at enrolment									0.2696
< 30	33/ 50 (66.0)	66.0	25/ 66 (37.9)	37.9	1.74 (1.21, 2.52)	0.0031	28.12 (10.43, 45.82)	0.0018	
>= 30	18/ 43 (41.9)	41.7	12/ 34 (35.3)	35.4	1.19 (0.67, 2.11)	0.5612	6.38 (-15.45, 28.22)	0.5668	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
>=50% Joint reduction at week 52 (for subjects with at least 8 tender joints and swollen joints at baseline)
Full analysis set

Timepoint		Anifrolumab 300mg (N=70)	Placebo (N=68)
Week 52	Number of subjects with events, n (%)	38 (54.3)	23 (33.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.80 (1.22, 2.65)	
	p-value	0.0032	
	Odds Ratio (95% CI)	3.23 (1.49, 6.99)	
	p-value	0.0030	
	Risk Difference (95% CI)	25.88 (10.08, 41.67)	
	p-value	0.0013	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.60 (1.08, 2.38)	
	p-value	0.0192	
	Odds Ratio (95% CI)	2.32 (1.17, 4.62)	
	p-value	0.0163	
	Risk Difference (95% CI)	20.46 (4.26, 36.67)	
	p-value	0.0133	
	CMH approach		
	Response rate	54.5	33.7
	Difference in response rates (95% CI)	20.79 (4.75, 36.83)	
	p-value	0.0111	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
>=50% Joint reduction at week 52 (for subjects with at least 8 tender joints and swollen joints at baseline) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=70) n/ N (%)	Response rate	Placebo (N=68) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.6712
< 10 points	15/ 22 (68.2)	68.2	11/ 24 (45.8)	45.8	1.49 (0.88, 2.50)	0.1346	22.35 (-5.82, 50.51)	0.1199	
>= 10 points	23/ 48 (47.9)	50.2	12/ 44 (27.3)	27.7	1.76 (1.00, 3.09)	0.0508	22.58 (2.86, 42.30)	0.0248	
OCS dose at baseline									0.3506
<10 mg/day	18/ 30 (60.0)	60.0	8/ 27 (29.6)	29.6	2.03 (1.06, 3.88)	0.0335	30.37 (5.45, 55.29)	0.0169	
>=10 mg/day	20/ 40 (50.0)	50.0	15/ 41 (36.6)	36.6	1.37 (0.82, 2.27)	0.2285	13.41 (-8.04, 34.87)	0.2204	
Result of type I IFN gene signature test									0.9901
LOW	9/ 18 (50.0)	50.0	4/ 13 (30.8)	30.8	1.63 (0.64, 4.15)	0.3099	19.23 (-15.53, 53.99)	0.2782	
HIGH	29/ 52 (55.8)	55.8	19/ 55 (34.5)	34.5	1.61 (1.04, 2.50)	0.0317	21.23 (3.16, 39.31)	0.0213	
Age (years)									0.1039
<= 65	37/ 68 (54.4)	54.4	22/ 67 (32.8)	32.9	1.66 (1.10, 2.49)	0.0147	21.51 (5.31, 37.71)	0.0092	
> 65	1/ 2 (50.0)	50.0	1/ 1 (100.0)	100.0	0.50 (0.13, 2.00)	0.3270	-50.00 (-168.41, 68.41)	0.4079	
Sex									0.3284
male	3/ 7 (42.9)	42.9	2/ 4 (50.0)	50.0	0.86 (0.23, 3.15)	0.8163	-7.14 (-68.47, 54.19)	0.8194	
female	35/ 63 (55.6)	55.8	21/ 64 (32.8)	32.9	1.69 (1.12, 2.56)	0.0127	22.98 (6.31, 39.65)	0.0069	
Race									0.3603
White	29/ 50 (58.0)	59.2	20/ 51 (39.2)	38.1	1.48 (0.98, 2.24)	0.0647	21.16 (2.04, 40.28)	0.0301	
Black or African American	6/ 16 (37.5)	37.5	1/ 8 (12.5)	12.5	3.00 (0.43, 20.86)	0.2669	25.00 (-13.43, 63.43)	0.2023	
Asian	0		1/ 2 (50.0)		NE		NE		
Other	3/ 4 (75.0)	75.0	1/ 7 (14.3)	14.3	5.25 (0.78, 35.13)	0.0873	60.71 (2.93, 118.50)	0.0395	
Ethnicity									0.8935
Hispanic/Latino	7/ 15 (46.7)	46.7	4/ 13 (30.8)	30.8	1.52 (0.57, 4.04)	0.4041	15.90 (-20.34, 52.14)	0.3899	
Non-hispanic/Latino	31/ 55 (56.4)	55.6	19/ 55 (34.5)	35.7	1.63 (1.06, 2.51)	0.0263	19.93 (1.53, 38.34)	0.0338	
Geographic region									0.4870
EU	15/ 19 (78.9)	78.9	12/ 22 (54.5)	54.5	1.45 (0.93, 2.26)	0.1046	24.40 (-4.30, 53.10)	0.0956	
non-EU	23/ 51 (45.1)	45.6	11/ 46 (23.9)	23.1	1.89 (1.04, 3.43)	0.0375	22.56 (3.90, 41.22)	0.0178	
Onset of disease									0.9659
Paediatric	1/ 3 (33.3)	33.3	1/ 5 (20.0)	20.0	1.67 (0.16, 17.89)	0.6732	13.33 (-56.26, 82.93)	0.7073	
Adult	37/ 67 (55.2)	55.6	22/ 63 (34.9)	34.8	1.58 (1.06, 2.36)	0.0248	20.81 (4.11, 37.50)	0.0146	
ADA result									0.7509
Negative	35/ 61 (57.4)	58.1	22/ 62 (35.5)	34.7	1.62 (1.08, 2.41)	0.0183	23.39 (6.40, 40.38)	0.0070	
Positive (At any time)	3/ 8 (37.5)	37.5	1/ 6 (16.7)	16.7	2.25 (0.30, 16.63)	0.4269	20.83 (-29.28, 70.95)	0.4152	
BMI (kg/m2) at enrolment									0.2483
< 30	22/ 34 (64.7)	64.7	14/ 43 (32.6)	32.6	1.99 (1.21, 3.27)	0.0067	32.15 (10.62, 53.68)	0.0034	
>= 30	16/ 36 (44.4)	44.4	9/ 25 (36.0)	36.0	1.23 (0.65, 2.34)	0.5172	8.44 (-16.57, 33.46)	0.5082	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Low Disease Activity State at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 52	Number of subjects with events, n (%)	36 (20.0)	23 (12.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.61 (0.99, 2.60)	
	p-value	0.0538	
	Odds Ratio (95% CI)	1.76 (0.99, 3.12)	
	p-value	0.0526	
	Risk Difference (95% CI)	7.57 (0.01, 15.12)	
	p-value	0.0496	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.60 (0.99, 2.59)	
	p-value	0.0556	
	Odds Ratio (95% CI)	1.75 (0.99, 3.09)	
	p-value	0.0541	
	Risk Difference (95% CI)	7.50 (-0.05, 15.05)	
	p-value	0.0515	
	CMH approach		
	Response rate	20.0	12.5
	Difference in response rates (95% CI)	7.54 (-0.51, 15.59)	
	p-value	0.0665	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Low Disease Activity State at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.3283
< 10 points	12/ 55 (21.8)	21.9	10/ 54 (18.5)	18.3	1.18 (0.56, 2.50)	0.6685	3.54 (-12.82, 19.89)	0.6718	
>= 10 points	24/125 (19.2)	19.2	13/130 (10.0)	10.0	1.92 (1.02, 3.60)	0.0420	9.26 (0.01, 18.50)	0.0496	
OCS dose at baseline									0.4040
<10 mg/day	16/ 77 (20.8)	20.9	13/ 82 (15.9)	15.9	1.31 (0.68, 2.54)	0.4234	4.99 (-7.95, 17.93)	0.4497	
>=10 mg/day	20/103 (19.4)	19.4	10/102 (9.8)	9.8	1.98 (0.98, 4.02)	0.0585	9.54 (-0.82, 19.91)	0.0711	
Result of type I IFN gene signature test									0.2119
LOW	5/ 32 (15.6)	15.6	6/ 33 (18.2)	18.2	0.86 (0.29, 2.54)	0.7838	-2.56 (-22.19, 17.07)	0.7985	
HIGH	31/148 (20.9)	21.0	17/151 (11.3)	11.2	1.86 (1.08, 3.21)	0.0259	9.74 (0.91, 18.56)	0.0305	
Age (years)									NE
<= 65	36/173 (20.8)	20.9	23/181 (12.7)	12.7	1.64 (1.01, 2.65)	0.0440	8.18 (-0.08, 16.43)	0.0522	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
Sex									0.6460
male	3/ 15 (20.0)	20.0	1/ 13 (7.7)	7.7	2.60 (0.31, 22.05)	0.3810	12.31 (-18.12, 42.74)	0.4279	
female	33/165 (20.0)	20.0	22/171 (12.9)	12.9	1.55 (0.95, 2.55)	0.0808	7.07 (-1.37, 15.50)	0.1006	
Race									0.5393
White	24/125 (19.2)	19.4	20/137 (14.6)	14.6	1.32 (0.77, 2.26)	0.3215	4.83 (-4.96, 14.61)	0.3340	
Black or African American	7/ 29 (24.1)	24.1	3/ 23 (13.0)	13.0	1.85 (0.54, 6.37)	0.3294	11.09 (-11.59, 33.78)	0.3379	
Asian	1/ 11 (9.1)	9.1	0/ 5 (0.0)	0.0	1.50 (0.07, 31.57)	0.7942	9.09 (-34.34, 52.53)	0.6817	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	4/ 15 (26.7)	26.7	0/ 18 (0.0)	0.0	10.69 (0.62, 183.85)	0.1027	26.67 (-0.35, 53.68)	0.0530	
Ethnicity									0.2096
Hispanic/Latino	7/ 32 (21.9)	21.9	2/ 35 (5.7)	5.7	3.83 (0.86, 17.10)	0.0787	16.16 (-1.90, 34.22)	0.0794	
Non-hispanic/Latino	29/148 (19.6)	19.4	21/149 (14.1)	14.4	1.39 (0.83, 2.32)	0.2085	4.95 (-4.21, 14.12)	0.2897	
Geographic region									0.4465
EU	18/ 64 (28.1)	28.1	15/ 76 (19.7)	19.7	1.43 (0.78, 2.59)	0.2466	8.39 (-6.08, 22.85)	0.2557	
non-EU	18/116 (15.5)	15.4	8/108 (7.4)	7.0	2.09 (0.95, 4.62)	0.0667	8.38 (-1.27, 18.02)	0.0887	
Onset of disease									0.7231
Paediatric	1/ 12 (8.3)	8.3	1/ 12 (8.3)	8.3	1.00 (0.07, 14.21)	1.0000	0.00 (-31.23, 31.23)	1.0000	
Adult	35/168 (20.8)	20.8	22/172 (12.8)	12.9	1.63 (1.00, 2.66)	0.0506	7.95 (-0.50, 16.40)	0.0651	
ADA result									0.2462
Negative	32/162 (19.8)	19.8	23/169 (13.6)	13.7	1.45 (0.89, 2.37)	0.1366	6.10 (-2.47, 14.68)	0.1628	
Positive (At any time)	4/ 17 (23.5)	23.5	0/ 15 (0.0)	0.0	8.00 (0.47, 137.35)	0.1517	23.53 (-2.97, 50.03)	0.0818	
BMI (kg/m2) at enrolment									0.6675
< 30	22/108 (20.4)	20.5	15/127 (11.8)	12.2	1.72 (0.94, 3.16)	0.0770	8.33 (-1.74, 18.41)	0.1050	
>= 30	14/ 72 (19.4)	19.8	8/ 57 (14.0)	14.1	1.39 (0.62, 3.07)	0.4222	5.77 (-8.50, 20.04)	0.4282	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Mental Component Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 52	Number of subjects with events, n (%)	46 (25.6)	36 (19.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.33 (0.91, 1.95)	
	p-value	0.1449	
	Odds Ratio (95% CI)	1.46 (0.88, 2.40)	
	p-value	0.1432	
	Risk Difference (95% CI)	6.37 (-2.11, 14.86)	
	p-value	0.1408	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.31 (0.89, 1.92)	
	p-value	0.1736	
	Odds Ratio (95% CI)	1.41 (0.86, 2.31)	
	p-value	0.1724	
	Risk Difference (95% CI)	5.99 (-2.58, 14.56)	
	p-value	0.1707	
	CMH approach		
	Response rate	25.5	19.5
	Difference in response rates (95% CI)	6.02 (-2.75, 14.78)	
	p-value	0.1785	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Mental Component Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9044
< 10 points	18/ 55 (32.7)	32.7	14/ 54 (25.9)	25.4	1.26 (0.70, 2.27)	0.4381	7.32 (-9.99, 24.63)	0.4071	
>= 10 points	28/125 (22.4)	22.5	22/130 (16.9)	16.9	1.32 (0.80, 2.19)	0.2732	5.52 (-4.56, 15.60)	0.2834	
OCS dose at baseline									0.6298
<10 mg/day	20/ 77 (26.0)	26.0	18/ 82 (22.0)	21.9	1.18 (0.68, 2.06)	0.5528	4.09 (-9.67, 17.85)	0.5600	
>=10 mg/day	26/103 (25.2)	25.2	18/102 (17.6)	17.3	1.43 (0.84, 2.44)	0.1897	7.84 (-3.43, 19.11)	0.1729	
Result of type I IFN gene signature test									0.4718
LOW	10/ 32 (31.3)	31.3	10/ 33 (30.3)	30.3	1.03 (0.50, 2.14)	0.9341	0.95 (-21.90, 23.79)	0.9352	
HIGH	36/148 (24.3)	24.2	26/151 (17.2)	17.1	1.41 (0.90, 2.22)	0.1329	7.12 (-2.32, 16.56)	0.1394	
Age (years)									0.6780
<= 65	44/173 (25.4)	25.3	35/181 (19.3)	19.1	1.32 (0.89, 1.95)	0.1706	6.22 (-2.64, 15.08)	0.1689	
> 65	2/ 7 (28.6)	28.6	1/ 3 (33.3)	33.3	0.86 (0.12, 6.23)	0.8789	-4.76 (-71.14, 61.61)	0.8882	
Sex									0.3384
male	4/ 15 (26.7)	26.7	1/ 13 (7.7)	7.7	3.47 (0.44, 27.24)	0.2372	18.97 (-12.37, 50.32)	0.2355	
female	42/165 (25.5)	25.3	35/171 (20.5)	20.4	1.24 (0.84, 1.84)	0.2784	4.95 (-4.24, 14.13)	0.2912	
Race									0.6811
White	33/125 (26.4)	26.3	25/137 (18.2)	18.5	1.45 (0.91, 2.29)	0.1153	7.80 (-2.74, 18.34)	0.1469	
Black or African American	9/ 29 (31.0)	31.0	8/ 23 (34.8)	34.8	0.89 (0.41, 1.95)	0.7743	-3.75 (-29.90, 22.40)	0.7788	
Asian	3/ 11 (27.3)	27.3	1/ 5 (20.0)	20.0	1.36 (0.18, 10.09)	0.7613	7.27 (-42.56, 57.11)	0.7748	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	1/ 15 (6.7)	6.7	2/ 18 (11.1)	11.1	0.60 (0.06, 5.99)	0.6634	-4.44 (-30.10, 21.21)	0.7342	
Ethnicity									0.2952
Hispanic/Latino	5/ 32 (15.6)	15.6	7/ 35 (20.0)	20.0	0.78 (0.28, 2.22)	0.6426	-4.38 (-23.94, 15.19)	0.6612	
Non-hispanic/Latino	41/148 (27.7)	27.3	29/149 (19.5)	19.1	1.42 (0.94, 2.16)	0.0976	8.22 (-1.66, 18.09)	0.1030	
Geographic region									0.8139
EU	20/ 64 (31.3)	31.3	17/ 76 (22.4)	22.4	1.40 (0.80, 2.43)	0.2373	8.88 (-6.05, 23.81)	0.2436	
non-EU	26/116 (22.4)	22.8	19/108 (17.6)	17.4	1.27 (0.75, 2.17)	0.3707	5.48 (-5.60, 16.55)	0.3323	
Onset of disease									0.7068
Paediatric	2/ 12 (16.7)	16.7	1/ 12 (8.3)	8.3	2.00 (0.21, 19.23)	0.5483	8.33 (-24.65, 41.32)	0.6205	
Adult	44/168 (26.2)	26.2	35/172 (20.3)	20.5	1.29 (0.87, 1.90)	0.2043	5.65 (-3.56, 14.85)	0.2293	
ADA result									0.2886
Negative	43/162 (26.5)	26.3	32/169 (18.9)	19.0	1.40 (0.94, 2.10)	0.1010	7.34 (-1.92, 16.59)	0.1202	
Positive (At any time)	3/ 17 (17.6)	17.6	4/ 15 (26.7)	26.7	0.66 (0.18, 2.49)	0.5418	-9.02 (-40.06, 22.02)	0.5690	
BMI (kg/m2) at enrolment									0.4578
< 30	27/108 (25.0)	25.3	22/127 (17.3)	17.3	1.44 (0.87, 2.38)	0.1513	7.97 (-2.64, 18.59)	0.1410	
>= 30	19/ 72 (26.4)	27.0	14/ 57 (24.6)	24.1	1.07 (0.59, 1.95)	0.8136	2.89 (-12.67, 18.45)	0.7157	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Physical Component Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 52	Number of subjects with events, n (%)	59 (32.8)	51 (27.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.20 (0.88, 1.64)	
	p-value	0.2512	
	Odds Ratio (95% CI)	1.30 (0.83, 2.03)	
	p-value	0.2523	
	Risk Difference (95% CI)	5.55 (-3.93, 15.04)	
	p-value	0.2511	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.18 (0.86, 1.62)	
	p-value	0.2943	
	Odds Ratio (95% CI)	1.27 (0.81, 1.99)	
	p-value	0.2936	
	Risk Difference (95% CI)	5.06 (-4.37, 14.49)	
	p-value	0.2927	
	CMH approach		
	Response rate	32.9	27.8
	Difference in response rates (95% CI)	5.11 (-4.46, 14.68)	
	p-value	0.2950	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Physical Component Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.0245
< 10 points	21/ 55 (38.2)	38.7	9/ 54 (16.7)	17.3	2.29 (1.16, 4.54)	0.0176	21.39 (4.31, 38.46)	0.0141	
>= 10 points	38/125 (30.4)	30.5	42/130 (32.3)	32.3	0.94 (0.65, 1.35)	0.7429	-1.86 (-13.36, 9.65)	0.7517	
OCS dose at baseline									0.2792
<10 mg/day	26/ 77 (33.8)	34.0	19/ 82 (23.2)	23.0	1.46 (0.88, 2.41)	0.1424	10.95 (-3.30, 25.21)	0.1322	
>=10 mg/day	33/103 (32.0)	32.2	32/102 (31.4)	31.3	1.02 (0.68, 1.53)	0.9184	0.95 (-11.91, 13.82)	0.8844	
Result of type I IFN gene signature test									0.9285
LOW	10/ 32 (31.3)	31.3	9/ 33 (27.3)	27.3	1.15 (0.54, 2.45)	0.7248	3.98 (-18.60, 26.56)	0.7299	
HIGH	49/148 (33.1)	33.2	42/151 (27.8)	27.9	1.19 (0.84, 1.68)	0.3212	5.36 (-5.21, 15.93)	0.3200	
Age (years)									0.3167
<= 65	56/173 (32.4)	32.5	49/181 (27.1)	27.1	1.20 (0.87, 1.65)	0.2763	5.43 (-4.25, 15.12)	0.2714	
> 65	3/ 7 (42.9)	42.9	2/ 3 (66.7)	66.7	0.64 (0.20, 2.07)	0.4597	-23.81 (-90.87, 43.25)	0.4865	
Sex									0.5029
male	6/ 15 (40.0)	40.0	3/ 13 (23.1)	23.1	1.73 (0.54, 5.59)	0.3569	16.92 (-18.26, 52.11)	0.3458	
female	53/165 (32.1)	32.1	48/171 (28.1)	28.0	1.14 (0.83, 1.59)	0.4187	4.04 (-5.89, 13.97)	0.4248	
Race									0.7735
White	46/125 (36.8)	37.2	41/137 (29.9)	30.0	1.23 (0.87, 1.73)	0.2390	7.20 (-4.34, 18.74)	0.2215	
Black or African American	5/ 29 (17.2)	17.2	5/ 23 (21.7)	21.7	0.79 (0.26, 2.41)	0.6829	-4.50 (-27.78, 18.79)	0.7050	
Asian	3/ 11 (27.3)	27.3	0/ 5 (0.0)	0.0	3.50 (0.21, 57.35)	0.3799	27.27 (-18.60, 73.14)	0.2439	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	5/ 15 (33.3)	33.3	5/ 18 (27.8)	27.8	1.20 (0.43, 3.37)	0.7294	5.56 (-26.99, 38.10)	0.7379	
Ethnicity									0.8179
Hispanic/Latino	10/ 32 (31.3)	31.3	10/ 35 (28.6)	28.6	1.09 (0.53, 2.28)	0.8108	2.68 (-19.69, 25.05)	0.8145	
Non-hispanic/Latino	49/148 (33.1)	33.3	41/149 (27.5)	27.4	1.20 (0.85, 1.70)	0.2960	5.97 (-4.70, 16.64)	0.2731	
Geographic region									0.4767
EU	29/ 64 (45.3)	45.3	31/ 76 (40.8)	40.8	1.11 (0.76, 1.63)	0.5894	4.52 (-11.95, 21.00)	0.5905	
non-EU	30/116 (25.9)	26.6	20/108 (18.5)	18.6	1.40 (0.85, 2.31)	0.1917	7.99 (-3.48, 19.47)	0.1721	
Onset of disease									0.3279
Paediatric	2/ 12 (16.7)	16.7	0/ 12 (0.0)	0.0	5.00 (0.27, 94.34)	0.2829	16.67 (-14.16, 47.49)	0.2893	
Adult	57/168 (33.9)	34.0	51/172 (29.7)	29.5	1.14 (0.84, 1.56)	0.3977	4.42 (-5.59, 14.43)	0.3866	
ADA result									0.9818
Negative	55/162 (34.0)	34.1	48/169 (28.4)	28.5	1.20 (0.87, 1.65)	0.2768	5.61 (-4.51, 15.73)	0.2773	
Positive (At any time)	4/ 17 (23.5)	23.5	3/ 15 (20.0)	20.0	1.18 (0.31, 4.43)	0.8102	3.53 (-27.42, 34.48)	0.8231	
BMI (kg/m2) at enrolment									0.9073
< 30	37/108 (34.3)	34.4	36/127 (28.3)	28.4	1.21 (0.83, 1.77)	0.3290	6.07 (-6.01, 18.14)	0.3249	
>= 30	22/ 72 (30.6)	31.2	15/ 57 (26.3)	27.1	1.16 (0.67, 2.03)	0.5990	4.05 (-11.98, 20.09)	0.6202	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - General Health Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 52	Number of subjects with events, n (%)	34 (18.9)	22 (12.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.62 (0.98, 2.66)	
	p-value	0.0586	
	Odds Ratio (95% CI)	1.77 (0.98, 3.18)	
	p-value	0.0573	
	Risk Difference (95% CI)	7.25 (-0.12, 14.62)	
	p-value	0.0539	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.58 (0.96, 2.59)	
	p-value	0.0704	
	Odds Ratio (95% CI)	1.71 (0.96, 3.07)	
	p-value	0.0689	
	Risk Difference (95% CI)	6.93 (-0.46, 14.33)	
	p-value	0.0661	
	CMH approach		
	Response rate	18.9	11.9
	Difference in response rates (95% CI)	7.00 (-0.95, 14.95)	
	p-value	0.0845	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - General Health Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.1156
< 10 points	13/ 55 (23.6)	23.8	4/ 54 (7.4)	7.5	3.19 (1.11, 9.17)	0.0313	16.27 (0.95, 31.58)	0.0374	
>= 10 points	21/125 (16.8)	16.9	18/130 (13.8)	13.9	1.21 (0.68, 2.17)	0.5133	3.01 (-6.35, 12.36)	0.5287	
OCS dose at baseline									0.2231
<10 mg/day	17/ 77 (22.1)	22.2	8/ 82 (9.8)	9.7	2.26 (1.04, 4.94)	0.0403	12.51 (0.05, 24.97)	0.0490	
>=10 mg/day	17/103 (16.5)	16.5	14/102 (13.7)	13.5	1.20 (0.63, 2.31)	0.5795	3.05 (-7.26, 13.37)	0.5621	
Result of type I IFN gene signature test									0.5352
LOW	7/ 32 (21.9)	21.9	6/ 33 (18.2)	18.2	1.20 (0.45, 3.19)	0.7104	3.69 (-16.86, 24.24)	0.7247	
HIGH	27/148 (18.2)	18.3	16/151 (10.6)	10.6	1.72 (0.97, 3.06)	0.0642	7.72 (-0.87, 16.30)	0.0780	
Age (years)									0.7314
<= 65	32/173 (18.5)	18.6	22/181 (12.2)	12.1	1.52 (0.92, 2.51)	0.1006	6.43 (-1.65, 14.51)	0.1188	
> 65	2/ 7 (28.6)	28.6	0/ 3 (0.0)	0.0	2.50 (0.15, 40.67)	0.5196	28.57 (-33.74, 90.89)	0.3688	
Sex									0.6363
male	3/ 15 (20.0)	20.0	1/ 13 (7.7)	7.7	2.60 (0.31, 22.05)	0.3810	12.31 (-18.12, 42.74)	0.4279	
female	31/165 (18.8)	18.8	21/171 (12.3)	12.2	1.53 (0.92, 2.55)	0.1029	6.55 (-1.75, 14.84)	0.1219	
Race									0.8560
White	24/125 (19.2)	19.3	16/137 (11.7)	11.8	1.64 (0.92, 2.95)	0.0954	7.45 (-2.15, 17.05)	0.1281	
Black or African American	4/ 29 (13.8)	13.8	3/ 23 (13.0)	13.0	1.06 (0.26, 4.26)	0.9373	0.75 (-20.44, 21.94)	0.9447	
Asian	3/ 11 (27.3)	27.3	0/ 5 (0.0)	0.0	3.50 (0.21, 57.35)	0.3799	27.27 (-18.60, 73.14)	0.2439	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	3/ 15 (20.0)	20.0	3/ 18 (16.7)	16.7	1.20 (0.28, 5.10)	0.8048	3.33 (-26.19, 32.85)	0.8248	
Ethnicity									0.7120
Hispanic/Latino	7/ 32 (21.9)	21.9	4/ 35 (11.4)	11.4	1.91 (0.62, 5.93)	0.2606	10.45 (-8.74, 29.63)	0.2858	
Non-hispanic/Latino	27/148 (18.2)	18.1	18/149 (12.1)	12.1	1.51 (0.87, 2.62)	0.1428	6.05 (-2.89, 14.99)	0.1846	
Geographic region									0.1286
EU	13/ 64 (20.3)	20.3	14/ 76 (18.4)	18.4	1.10 (0.56, 2.17)	0.7774	1.89 (-11.68, 15.46)	0.7847	
non-EU	21/116 (18.1)	18.5	8/108 (7.4)	7.4	2.44 (1.13, 5.28)	0.0231	11.05 (0.95, 21.16)	0.0321	
Onset of disease									0.6766
Paediatric	1/ 12 (8.3)	8.3	0/ 12 (0.0)	0.0	3.00 (0.13, 67.06)	0.4883	8.33 (-20.61, 37.28)	0.5726	
Adult	33/168 (19.6)	19.7	22/172 (12.8)	12.8	1.54 (0.94, 2.52)	0.0899	6.85 (-1.54, 15.24)	0.1096	
ADA result									0.8204
Negative	31/162 (19.1)	19.1	20/169 (11.8)	11.9	1.62 (0.96, 2.72)	0.0697	7.18 (-1.24, 15.59)	0.0945	
Positive (At any time)	3/ 17 (17.6)	17.6	2/ 15 (13.3)	13.3	1.32 (0.25, 6.88)	0.7390	4.31 (-24.59, 33.22)	0.7699	
BMI (kg/m2) at enrolment									0.6561
< 30	22/108 (20.4)	20.3	15/127 (11.8)	11.8	1.72 (0.94, 3.16)	0.0770	8.46 (-1.45, 18.37)	0.0943	
>= 30	12/ 72 (16.7)	16.7	7/ 57 (12.3)	12.7	1.36 (0.57, 3.22)	0.4889	4.07 (-9.92, 18.06)	0.5685	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Mental Health Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 52	Number of subjects with events, n (%)	43 (23.9)	23 (12.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.94 (1.22, 3.08)	
	p-value	0.0051	
	Odds Ratio (95% CI)	2.24 (1.28, 3.91)	
	p-value	0.0048	
	Risk Difference (95% CI)	11.62 (3.77, 19.47)	
	p-value	0.0037	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.91 (1.20, 3.04)	
	p-value	0.0061	
	Odds Ratio (95% CI)	2.20 (1.26, 3.83)	
	p-value	0.0055	
	Risk Difference (95% CI)	11.39 (3.54, 19.24)	
	p-value	0.0045	
	CMH approach		
	Response rate	23.9	12.6
	Difference in response rates (95% CI)	11.38 (3.13, 19.62)	
	p-value	0.0068	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Mental Health Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.2824
< 10 points	17/ 55 (30.9)	31.0	6/ 54 (11.1)	11.3	2.78 (1.19, 6.52)	0.0185	19.71 (3.43, 35.98)	0.0177	
>= 10 points	26/125 (20.8)	21.0	17/130 (13.1)	13.1	1.59 (0.91, 2.78)	0.1042	7.81 (-1.75, 17.37)	0.1093	
OCS dose at baseline									0.1814
<10 mg/day	21/ 77 (27.3)	27.6	8/ 82 (9.8)	9.8	2.80 (1.32, 5.93)	0.0074	17.80 (5.01, 30.59)	0.0064	
>=10 mg/day	22/103 (21.4)	21.3	15/102 (14.7)	14.5	1.45 (0.80, 2.64)	0.2200	6.78 (-3.99, 17.55)	0.2170	
Result of type I IFN gene signature test									0.0342
LOW	6/ 32 (18.8)	18.8	8/ 33 (24.2)	24.2	0.77 (0.30, 1.98)	0.5923	-5.49 (-26.40, 15.41)	0.6066	
HIGH	37/148 (25.0)	25.1	15/151 (9.9)	10.0	2.52 (1.44, 4.39)	0.0011	15.05 (6.10, 24.00)	0.0010	
Age (years)									0.8391
<= 65	41/173 (23.7)	23.8	23/181 (12.7)	12.8	1.87 (1.17, 2.97)	0.0088	10.97 (2.59, 19.36)	0.0103	
> 65	2/ 7 (28.6)	28.6	0/ 3 (0.0)	0.0	2.50 (0.15, 40.67)	0.5196	28.57 (-33.74, 90.89)	0.3688	
Sex									0.7732
male	3/ 15 (20.0)	20.0	1/ 13 (7.7)	7.7	2.60 (0.31, 22.05)	0.3810	12.31 (-18.12, 42.74)	0.4279	
female	40/165 (24.2)	24.3	22/171 (12.9)	12.9	1.88 (1.17, 3.03)	0.0088	11.37 (2.71, 20.03)	0.0101	
Race									0.4181
White	29/125 (23.2)	23.3	15/137 (10.9)	11.1	2.12 (1.19, 3.76)	0.0104	12.18 (2.42, 21.94)	0.0145	
Black or African American	9/ 29 (31.0)	31.0	5/ 23 (21.7)	21.7	1.43 (0.55, 3.68)	0.4610	9.30 (-15.51, 34.10)	0.4626	
Asian	4/ 11 (36.4)	36.4	0/ 5 (0.0)	0.0	4.50 (0.29, 70.57)	0.2842	36.36 (-10.18, 82.90)	0.1257	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	1/ 15 (6.7)	6.7	3/ 18 (16.7)	16.7	0.40 (0.05, 3.46)	0.4051	-10.00 (-36.75, 16.75)	0.4637	
Ethnicity									0.0780
Hispanic/Latino	4/ 32 (12.5)	12.5	6/ 35 (17.1)	17.1	0.73 (0.23, 2.35)	0.5970	-4.64 (-23.24, 13.95)	0.6245	
Non-hispanic/Latino	39/148 (26.4)	26.0	17/149 (11.4)	11.4	2.31 (1.37, 3.89)	0.0017	14.62 (5.34, 23.90)	0.0020	
Geographic region									0.4645
EU	18/ 64 (28.1)	28.1	13/ 76 (17.1)	17.1	1.64 (0.87, 3.09)	0.1225	11.02 (-3.18, 25.22)	0.1282	
non-EU	25/116 (21.6)	22.2	10/108 (9.3)	9.3	2.33 (1.17, 4.62)	0.0156	12.83 (2.43, 23.24)	0.0156	
Onset of disease									0.9682
Paediatric	2/ 12 (16.7)	16.7	1/ 12 (8.3)	8.3	2.00 (0.21, 19.23)	0.5483	8.33 (-24.65, 41.32)	0.6205	
Adult	41/168 (24.4)	24.5	22/172 (12.8)	12.9	1.91 (1.19, 3.06)	0.0073	11.58 (2.94, 20.23)	0.0086	
ADA result									0.9102
Negative	39/162 (24.1)	24.0	21/169 (12.4)	12.6	1.94 (1.19, 3.15)	0.0075	11.42 (2.73, 20.11)	0.0100	
Positive (At any time)	4/ 17 (23.5)	23.5	2/ 15 (13.3)	13.3	1.76 (0.37, 8.31)	0.4723	10.20 (-19.58, 39.98)	0.5022	
BMI (kg/m2) at enrolment									0.5556
< 30	25/108 (23.1)	23.2	14/127 (11.0)	10.8	2.10 (1.15, 3.83)	0.0157	12.41 (2.33, 22.49)	0.0159	
>= 30	18/ 72 (25.0)	25.6	9/ 57 (15.8)	15.6	1.58 (0.77, 3.26)	0.2114	10.06 (-4.64, 24.76)	0.1797	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Physical Functioning Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 52	Number of subjects with events, n (%)	45 (25.0)	44 (23.9)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.06 (0.74, 1.51)	
	p-value	0.7637	
	Odds Ratio (95% CI)	1.08 (0.67, 1.74)	
	p-value	0.7646	
	Risk Difference (95% CI)	1.35 (-7.48, 10.18)	
	p-value	0.7645	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.05 (0.73, 1.50)	
	p-value	0.8094	
	Odds Ratio (95% CI)	1.06 (0.66, 1.71)	
	p-value	0.8094	
	Risk Difference (95% CI)	1.09 (-7.74, 9.92)	
	p-value	0.8094	
	CMH approach		
	Response rate	25.1	24.0
	Difference in response rates (95% CI)	1.06 (-8.02, 10.14)	
	p-value	0.8189	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Physical Functioning Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.2609
< 10 points	15/ 55 (27.3)	27.4	10/ 54 (18.5)	19.1	1.47 (0.73, 2.99)	0.2829	8.31 (-8.48, 25.11)	0.3321	
>= 10 points	30/125 (24.0)	24.1	34/130 (26.2)	26.2	0.92 (0.60, 1.40)	0.6920	-2.08 (-12.89, 8.72)	0.7056	
OCS dose at baseline									0.1170
<10 mg/day	21/ 77 (27.3)	27.6	15/ 82 (18.3)	18.3	1.49 (0.83, 2.68)	0.1809	9.33 (-4.29, 22.95)	0.1793	
>=10 mg/day	24/103 (23.3)	23.4	29/102 (28.4)	28.3	0.82 (0.51, 1.31)	0.4031	-4.91 (-17.02, 7.21)	0.4274	
Result of type I IFN gene signature test									0.3337
LOW	7/ 32 (21.9)	21.9	10/ 33 (30.3)	30.3	0.72 (0.31, 1.66)	0.4440	-8.43 (-30.34, 13.48)	0.4510	
HIGH	38/148 (25.7)	25.8	34/151 (22.5)	22.7	1.14 (0.76, 1.71)	0.5235	3.13 (-6.84, 13.10)	0.5387	
Age (years)									0.8080
<= 65	42/173 (24.3)	24.4	43/181 (23.8)	23.9	1.02 (0.71, 1.48)	0.9087	0.55 (-8.61, 9.72)	0.9060	
> 65	3/ 7 (42.9)	42.9	1/ 3 (33.3)	33.3	1.29 (0.21, 7.89)	0.7860	9.52 (-57.53, 76.58)	0.7807	
Sex									0.5018
male	4/ 15 (26.7)	26.7	2/ 13 (15.4)	15.4	1.73 (0.38, 7.98)	0.4800	11.28 (-21.66, 44.22)	0.5020	
female	41/165 (24.8)	24.9	42/171 (24.6)	24.6	1.01 (0.70, 1.47)	0.9514	0.22 (-9.26, 9.69)	0.9640	
Race									0.5821
White	35/125 (28.0)	28.6	33/137 (24.1)	24.1	1.16 (0.77, 1.75)	0.4709	4.50 (-6.37, 15.37)	0.4170	
Black or African American	6/ 29 (20.7)	20.7	6/ 23 (26.1)	26.1	0.79 (0.29, 2.14)	0.6464	-5.40 (-29.72, 18.92)	0.6636	
Asian	2/ 11 (18.2)	18.2	0/ 5 (0.0)	0.0	2.50 (0.14, 44.26)	0.5320	18.18 (-26.66, 63.02)	0.4268	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	2/ 15 (13.3)	13.3	5/ 18 (27.8)	27.8	0.48 (0.11, 2.13)	0.3342	-14.44 (-44.25, 15.37)	0.3423	
Ethnicity									0.1290
Hispanic/Latino	4/ 32 (12.5)	12.5	9/ 35 (25.7)	25.7	0.49 (0.17, 1.43)	0.1888	-13.21 (-32.94, 6.51)	0.1891	
Non-hispanic/Latino	41/148 (27.7)	27.5	35/149 (23.5)	23.5	1.18 (0.80, 1.74)	0.4065	4.01 (-6.21, 14.23)	0.4420	
Geographic region									0.4853
EU	21/ 64 (32.8)	32.8	26/ 76 (34.2)	34.2	0.96 (0.60, 1.53)	0.8616	-1.40 (-17.19, 14.39)	0.8622	
non-EU	24/116 (20.7)	21.4	18/108 (16.7)	16.6	1.24 (0.71, 2.16)	0.4427	4.79 (-6.28, 15.86)	0.3962	
Onset of disease									0.5005
Paediatric	1/ 12 (8.3)	8.3	0/ 12 (0.0)	0.0	3.00 (0.13, 67.06)	0.4883	8.33 (-20.61, 37.28)	0.5726	
Adult	44/168 (26.2)	26.3	44/172 (25.6)	25.7	1.02 (0.71, 1.47)	0.8980	0.68 (-8.87, 10.22)	0.8897	
ADA result									0.4717
Negative	43/162 (26.5)	26.6	41/169 (24.3)	24.5	1.09 (0.76, 1.58)	0.6334	2.12 (-7.53, 11.77)	0.6666	
Positive (At any time)	2/ 17 (11.8)	11.8	3/ 15 (20.0)	20.0	0.59 (0.11, 3.06)	0.5282	-8.24 (-37.30, 20.83)	0.5787	
BMI (kg/m2) at enrolment									0.6518
< 30	27/108 (25.0)	25.2	32/127 (25.2)	25.2	0.99 (0.64, 1.55)	0.9723	0.07 (-11.31, 11.45)	0.9905	
>= 30	18/ 72 (25.0)	25.5	12/ 57 (21.1)	21.4	1.19 (0.62, 2.26)	0.6001	4.10 (-11.34, 19.55)	0.6025	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Role Emotional Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 52	Number of subjects with events, n (%)	39 (21.7)	26 (14.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.58 (1.01, 2.47)	
	p-value	0.0467	
	Odds Ratio (95% CI)	1.76 (1.01, 3.06)	
	p-value	0.0459	
	Risk Difference (95% CI)	8.02 (0.25, 15.79)	
	p-value	0.0432	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.53 (0.98, 2.41)	
	p-value	0.0636	
	Odds Ratio (95% CI)	1.68 (0.97, 2.90)	
	p-value	0.0622	
	Risk Difference (95% CI)	7.54 (-0.31, 15.38)	
	p-value	0.0597	
	CMH approach		
	Response rate	21.9	14.0
	Difference in response rates (95% CI)	7.85 (-0.41, 16.10)	
	p-value	0.0624	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Role Emotional Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.4714
< 10 points	11/ 55 (20.0)	20.5	9/ 54 (16.7)	16.3	1.20 (0.54, 2.66)	0.6539	4.13 (-11.70, 19.96)	0.6092	
>= 10 points	28/125 (22.4)	22.5	17/130 (13.1)	13.1	1.71 (0.99, 2.97)	0.0553	9.46 (-0.24, 19.16)	0.0560	
OCS dose at baseline									0.7876
<10 mg/day	20/ 77 (26.0)	26.2	13/ 82 (15.9)	15.9	1.64 (0.88, 3.06)	0.1217	10.30 (-3.06, 23.65)	0.1308	
>=10 mg/day	19/103 (18.4)	18.7	13/102 (12.7)	12.4	1.45 (0.76, 2.77)	0.2650	6.25 (-4.14, 16.63)	0.2385	
Result of type I IFN gene signature test									0.0924
LOW	7/ 32 (21.9)	21.9	9/ 33 (27.3)	27.3	0.80 (0.34, 1.89)	0.6151	-5.40 (-27.04, 16.24)	0.6249	
HIGH	32/148 (21.6)	21.9	17/151 (11.3)	11.2	1.92 (1.12, 3.30)	0.0185	10.73 (1.85, 19.61)	0.0178	
Age (years)									0.5692
<= 65	37/173 (21.4)	21.7	25/181 (13.8)	13.6	1.55 (0.97, 2.46)	0.0640	8.09 (-0.24, 16.42)	0.0569	
> 65	2/ 7 (28.6)	28.6	1/ 3 (33.3)	33.3	0.86 (0.12, 6.23)	0.8789	-4.76 (-71.14, 61.61)	0.8882	
Sex									0.8361
male	3/ 15 (20.0)	20.0	2/ 13 (15.4)	15.4	1.30 (0.26, 6.62)	0.7521	4.62 (-27.45, 36.68)	0.7779	
female	36/165 (21.8)	22.0	24/171 (14.0)	13.9	1.55 (0.97, 2.49)	0.0659	8.06 (-0.54, 16.66)	0.0661	
Race									0.7867
White	29/125 (23.2)	23.3	19/137 (13.9)	14.2	1.67 (0.99, 2.83)	0.0549	9.09 (-0.98, 19.15)	0.0767	
Black or African American	6/ 29 (20.7)	20.7	5/ 23 (21.7)	21.7	0.95 (0.33, 2.73)	0.9266	-1.05 (-24.80, 22.70)	0.9310	
Asian	2/ 11 (18.2)	18.2	0/ 5 (0.0)	0.0	2.50 (0.14, 44.26)	0.5320	18.18 (-26.66, 63.02)	0.4268	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	2/ 15 (13.3)	13.3	2/ 18 (11.1)	11.1	1.20 (0.19, 7.53)	0.8457	2.22 (-25.04, 29.48)	0.8731	
Ethnicity									0.8474
Hispanic/Latino	5/ 32 (15.6)	15.6	4/ 35 (11.4)	11.4	1.37 (0.40, 4.65)	0.6166	4.20 (-13.99, 22.39)	0.6512	
Non-hispanic/Latino	34/148 (23.0)	23.2	22/149 (14.8)	14.7	1.56 (0.96, 2.53)	0.0744	8.58 (-0.85, 18.00)	0.0744	
Geographic region									0.6751
EU	19/ 64 (29.7)	29.7	13/ 76 (17.1)	17.1	1.74 (0.93, 3.23)	0.0824	12.58 (-1.74, 26.90)	0.0851	
non-EU	20/116 (17.2)	18.0	13/108 (12.0)	11.7	1.43 (0.75, 2.74)	0.2765	6.27 (-4.01, 16.56)	0.2318	
Onset of disease									0.7476
Paediatric	1/ 12 (8.3)	8.3	1/ 12 (8.3)	8.3	1.00 (0.07, 14.21)	1.0000	0.00 (-31.23, 31.23)	1.0000	
Adult	38/168 (22.6)	22.8	25/172 (14.5)	14.6	1.56 (0.98, 2.46)	0.0583	8.18 (-0.49, 16.86)	0.0645	
ADA result									0.1884
Negative	36/162 (22.2)	22.5	22/169 (13.0)	13.1	1.71 (1.05, 2.77)	0.0306	9.36 (0.70, 18.03)	0.0342	
Positive (At any time)	3/ 17 (17.6)	17.6	4/ 15 (26.7)	26.7	0.66 (0.18, 2.49)	0.5418	-9.02 (-40.06, 22.02)	0.5690	
BMI (kg/m2) at enrolment									0.0720
< 30	20/108 (18.5)	19.0	21/127 (16.5)	16.4	1.12 (0.64, 1.95)	0.6897	2.62 (-7.57, 12.80)	0.6147	
>= 30	19/ 72 (26.4)	26.9	5/ 57 (8.8)	8.5	3.01 (1.20, 7.56)	0.0192	18.44 (4.43, 32.45)	0.0099	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Role Physical Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 52	Number of subjects with events, n (%)	63 (35.0)	51 (27.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.30 (0.96, 1.76)	
	p-value	0.0938	
	Odds Ratio (95% CI)	1.47 (0.94, 2.31)	
	p-value	0.0934	
	Risk Difference (95% CI)	8.12 (-1.30, 17.54)	
	p-value	0.0910	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.26 (0.93, 1.72)	
	p-value	0.1360	
	Odds Ratio (95% CI)	1.40 (0.90, 2.19)	
	p-value	0.1348	
	Risk Difference (95% CI)	7.28 (-2.22, 16.79)	
	p-value	0.1332	
	CMH approach		
	Response rate	35.2	27.6
	Difference in response rates (95% CI)	7.61 (-2.00, 17.22)	
	p-value	0.1206	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Role Physical Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.7830
< 10 points	18/ 55 (32.7)	33.2	13/ 54 (24.1)	23.6	1.36 (0.74, 2.49)	0.3211	9.59 (-7.62, 26.79)	0.2747	
>= 10 points	45/125 (36.0)	36.1	38/130 (29.2)	29.3	1.23 (0.86, 1.76)	0.2504	6.83 (-4.75, 18.41)	0.2478	
OCS dose at baseline									0.2693
<10 mg/day	29/ 77 (37.7)	37.9	20/ 82 (24.4)	24.3	1.54 (0.96, 2.49)	0.0744	13.53 (-1.04, 28.09)	0.0687	
>=10 mg/day	34/103 (33.0)	33.2	31/102 (30.4)	29.8	1.09 (0.73, 1.62)	0.6874	3.42 (-9.28, 16.12)	0.5975	
Result of type I IFN gene signature test									0.1277
LOW	10/ 32 (31.3)	31.3	13/ 33 (39.4)	39.4	0.79 (0.41, 1.54)	0.4953	-8.14 (-31.54, 15.25)	0.4951	
HIGH	53/148 (35.8)	36.1	38/151 (25.2)	25.0	1.42 (1.00, 2.02)	0.0479	11.04 (0.51, 21.58)	0.0399	
Age (years)									0.6974
<= 65	61/173 (35.3)	35.6	50/181 (27.6)	27.4	1.28 (0.94, 1.74)	0.1234	8.17 (-1.56, 17.91)	0.0999	
> 65	2/ 7 (28.6)	28.6	1/ 3 (33.3)	33.3	0.86 (0.12, 6.23)	0.8789	-4.76 (-71.14, 61.61)	0.8882	
Sex									0.3909
male	7/ 15 (46.7)	46.7	3/ 13 (23.1)	23.1	2.02 (0.65, 6.26)	0.2221	23.59 (-11.79, 58.97)	0.1913	
female	56/165 (33.9)	34.1	48/171 (28.1)	27.9	1.21 (0.88, 1.67)	0.2460	6.13 (-3.85, 16.11)	0.2286	
Race									0.9110
White	48/125 (38.4)	38.6	40/137 (29.2)	29.7	1.32 (0.93, 1.85)	0.1169	8.97 (-2.62, 20.55)	0.1292	
Black or African American	9/ 29 (31.0)	31.0	7/ 23 (30.4)	30.4	1.02 (0.45, 2.32)	0.9629	0.60 (-25.20, 26.40)	0.9637	
Asian	2/ 11 (18.2)	18.2	0/ 5 (0.0)	0.0	2.50 (0.14, 44.26)	0.5320	18.18 (-26.66, 63.02)	0.4268	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	4/ 15 (26.7)	26.7	4/ 18 (22.2)	22.2	1.20 (0.36, 4.00)	0.7667	4.44 (-26.81, 35.70)	0.7804	
Ethnicity									0.7384
Hispanic/Latino	8/ 32 (25.0)	25.0	6/ 35 (17.1)	17.1	1.46 (0.57, 3.75)	0.4333	7.86 (-12.63, 28.35)	0.4523	
Non-hispanic/Latino	55/148 (37.2)	37.5	45/149 (30.2)	29.8	1.23 (0.89, 1.70)	0.2063	7.69 (-3.16, 18.53)	0.1647	
Geographic region									0.3291
EU	31/ 64 (48.4)	48.4	32/ 76 (42.1)	42.1	1.15 (0.80, 1.66)	0.4522	6.33 (-10.20, 22.87)	0.4529	
non-EU	32/116 (27.6)	28.3	19/108 (17.6)	17.8	1.57 (0.95, 2.59)	0.0800	10.53 (-0.99, 22.05)	0.0732	
Onset of disease									0.5352
Paediatric	4/ 12 (33.3)	33.3	2/ 12 (16.7)	16.7	2.00 (0.45, 8.94)	0.3641	16.67 (-20.08, 53.42)	0.3741	
Adult	59/168 (35.1)	35.4	49/172 (28.5)	28.4	1.23 (0.90, 1.69)	0.1909	6.95 (-3.02, 16.93)	0.1719	
ADA result									0.5762
Negative	57/162 (35.2)	35.5	48/169 (28.4)	28.3	1.24 (0.90, 1.70)	0.1866	7.16 (-2.99, 17.31)	0.1667	
Positive (At any time)	6/ 17 (35.3)	35.3	3/ 15 (20.0)	20.0	1.76 (0.53, 5.86)	0.3533	15.29 (-16.79, 47.38)	0.3502	
BMI (kg/m2) at enrolment									0.3062
< 30	38/108 (35.2)	35.7	39/127 (30.7)	30.5	1.15 (0.79, 1.65)	0.4659	5.16 (-6.89, 17.21)	0.4011	
>= 30	25/ 72 (34.7)	35.4	12/ 57 (21.1)	21.5	1.65 (0.91, 2.99)	0.0988	13.89 (-2.00, 29.78)	0.0866	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Social Functioning Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 52	Number of subjects with events, n (%)	40 (22.2)	31 (16.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.34 (0.88, 2.04)	
	p-value	0.1768	
	Odds Ratio (95% CI)	1.43 (0.85, 2.42)	
	p-value	0.1765	
	Risk Difference (95% CI)	5.65 (-2.50, 13.80)	
	p-value	0.1741	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.32 (0.87, 2.01)	
	p-value	0.1980	
	Odds Ratio (95% CI)	1.41 (0.84, 2.38)	
	p-value	0.1969	
	Risk Difference (95% CI)	5.37 (-2.76, 13.51)	
	p-value	0.1952	
	CMH approach		
	Response rate	22.2	16.8
	Difference in response rates (95% CI)	5.42 (-3.07, 13.92)	
	p-value	0.2110	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Social Functioning Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.3453
< 10 points	16/ 55 (29.1)	29.3	9/ 54 (16.7)	16.6	1.75 (0.85, 3.60)	0.1322	12.76 (-3.91, 29.42)	0.1336	
>= 10 points	24/125 (19.2)	19.3	22/130 (16.9)	17.0	1.13 (0.67, 1.92)	0.6367	2.29 (-7.53, 12.11)	0.6474	
OCS dose at baseline									0.8783
<10 mg/day	18/ 77 (23.4)	23.5	14/ 82 (17.1)	17.1	1.37 (0.73, 2.56)	0.3247	6.44 (-6.83, 19.70)	0.3416	
>=10 mg/day	22/103 (21.4)	21.4	17/102 (16.7)	16.4	1.28 (0.72, 2.27)	0.3942	4.94 (-6.12, 15.99)	0.3814	
Result of type I IFN gene signature test									0.2006
LOW	7/ 32 (21.9)	21.9	9/ 33 (27.3)	27.3	0.80 (0.34, 1.89)	0.6151	-5.40 (-27.04, 16.24)	0.6249	
HIGH	33/148 (22.3)	22.3	22/151 (14.6)	14.5	1.53 (0.94, 2.50)	0.0884	7.78 (-1.43, 16.99)	0.0979	
Age (years)									0.1246
<= 65	38/173 (22.0)	22.0	29/181 (16.0)	15.9	1.37 (0.89, 2.12)	0.1561	6.08 (-2.49, 14.65)	0.1642	
> 65	2/ 7 (28.6)	28.6	2/ 3 (66.7)	66.7	0.43 (0.10, 1.77)	0.2417	-38.10 (-104.47, 28.28)	0.2606	
Sex									0.3403
male	4/ 15 (26.7)	26.7	1/ 13 (7.7)	7.7	3.47 (0.44, 27.24)	0.2372	18.97 (-12.37, 50.32)	0.2355	
female	36/165 (21.8)	21.7	30/171 (17.5)	17.5	1.24 (0.81, 1.92)	0.3256	4.23 (-4.63, 13.09)	0.3494	
Race									0.5045
White	31/125 (24.8)	25.0	22/137 (16.1)	16.3	1.54 (0.95, 2.52)	0.0819	8.72 (-1.62, 19.07)	0.0984	
Black or African American	7/ 29 (24.1)	24.1	6/ 23 (26.1)	26.1	0.93 (0.36, 2.38)	0.8718	-1.95 (-26.67, 22.77)	0.8772	
Asian	2/ 11 (18.2)	18.2	1/ 5 (20.0)	20.0	0.91 (0.11, 7.84)	0.9309	-1.82 (-50.71, 47.07)	0.9419	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 15 (0.0)	0.0	2/ 18 (11.1)	11.1	0.24 (0.01, 4.60)	0.3416	-11.11 (-34.75, 12.53)	0.3569	
Ethnicity									0.0774
Hispanic/Latino	2/ 32 (6.3)	6.3	6/ 35 (17.1)	17.1	0.36 (0.08, 1.68)	0.1952	-10.89 (-28.14, 6.36)	0.2158	
Non-hispanic/Latino	38/148 (25.7)	25.7	25/149 (16.8)	16.6	1.53 (0.98, 2.40)	0.0642	9.08 (-0.63, 18.79)	0.0668	
Geographic region									0.4314
EU	19/ 64 (29.7)	29.7	14/ 76 (18.4)	18.4	1.61 (0.88, 2.95)	0.1221	11.27 (-3.19, 25.72)	0.1266	
non-EU	21/116 (18.1)	18.8	17/108 (15.7)	15.8	1.15 (0.64, 2.06)	0.6384	3.00 (-7.84, 13.84)	0.5874	
Onset of disease									0.7124
Paediatric	2/ 12 (16.7)	16.7	1/ 12 (8.3)	8.3	2.00 (0.21, 19.23)	0.5483	8.33 (-24.65, 41.32)	0.6205	
Adult	38/168 (22.6)	22.6	30/172 (17.4)	17.6	1.30 (0.84, 1.99)	0.2349	5.09 (-3.82, 14.00)	0.2630	
ADA result									0.0647
Negative	38/162 (23.5)	23.4	26/169 (15.4)	15.5	1.52 (0.97, 2.39)	0.0661	7.96 (-0.97, 16.90)	0.0807	
Positive (At any time)	2/ 17 (11.8)	11.8	5/ 15 (33.3)	33.3	0.35 (0.08, 1.56)	0.1694	-21.57 (-52.30, 9.16)	0.1689	
BMI (kg/m2) at enrolment									0.5841
< 30	23/108 (21.3)	21.2	19/127 (15.0)	15.1	1.42 (0.82, 2.47)	0.2089	6.12 (-4.19, 16.44)	0.2448	
>= 30	17/ 72 (23.6)	23.8	12/ 57 (21.1)	21.3	1.12 (0.58, 2.15)	0.7303	2.56 (-12.85, 17.98)	0.7444	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Bodily Pain Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 52	Number of subjects with events, n (%)	49 (27.2)	42 (22.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.21 (0.85, 1.72)	
	p-value	0.2954	
	Odds Ratio (95% CI)	1.29 (0.80, 2.08)	
	p-value	0.2963	
	Risk Difference (95% CI)	4.75 (-4.15, 13.65)	
	p-value	0.2953	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.19 (0.83, 1.70)	
	p-value	0.3339	
	Odds Ratio (95% CI)	1.26 (0.79, 2.03)	
	p-value	0.3333	
	Risk Difference (95% CI)	4.40 (-4.50, 13.29)	
	p-value	0.3325	
	CMH approach		
	Response rate	27.3	22.9
	Difference in response rates (95% CI)	4.38 (-4.71, 13.46)	
	p-value	0.3450	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Bodily Pain Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.1372
< 10 points	21/ 55 (38.2)	38.7	12/ 54 (22.2)	22.6	1.72 (0.94, 3.14)	0.0779	16.11 (-1.45, 33.68)	0.0722	
>= 10 points	28/125 (22.4)	22.5	30/130 (23.1)	23.1	0.97 (0.62, 1.53)	0.8974	-0.61 (-11.17, 9.94)	0.9096	
OCS dose at baseline									0.6992
<10 mg/day	23/ 77 (29.9)	30.0	19/ 82 (23.2)	23.2	1.29 (0.76, 2.17)	0.3403	6.86 (-7.24, 20.97)	0.3402	
>=10 mg/day	26/103 (25.2)	25.3	23/102 (22.5)	22.6	1.12 (0.69, 1.83)	0.6515	2.67 (-9.23, 14.56)	0.6602	
Result of type I IFN gene signature test									0.6865
LOW	9/ 32 (28.1)	28.1	9/ 33 (27.3)	27.3	1.03 (0.47, 2.26)	0.9388	0.85 (-21.46, 23.17)	0.9403	
HIGH	40/148 (27.0)	27.1	33/151 (21.9)	21.9	1.24 (0.83, 1.85)	0.2995	5.15 (-4.80, 15.09)	0.3103	
Age (years)									0.1586
<= 65	47/173 (27.2)	27.2	40/181 (22.1)	22.1	1.23 (0.85, 1.77)	0.2696	5.11 (-4.09, 14.32)	0.2764	
> 65	2/ 7 (28.6)	28.6	2/ 3 (66.7)	66.7	0.43 (0.10, 1.77)	0.2417	-38.10 (-104.47, 28.28)	0.2606	
Sex									0.6454
male	3/ 15 (20.0)	20.0	3/ 13 (23.1)	23.1	0.87 (0.21, 3.58)	0.8432	-3.08 (-36.39, 30.24)	0.8564	
female	46/165 (27.9)	27.8	39/171 (22.8)	22.8	1.22 (0.85, 1.77)	0.2864	4.94 (-4.54, 14.42)	0.3069	
Race									0.6849
White	38/125 (30.4)	30.5	35/137 (25.5)	25.6	1.19 (0.81, 1.76)	0.3821	4.95 (-6.18, 16.08)	0.3835	
Black or African American	7/ 29 (24.1)	24.1	3/ 23 (13.0)	13.0	1.85 (0.54, 6.37)	0.3294	11.09 (-11.59, 33.78)	0.3379	
Asian	2/ 11 (18.2)	18.2	0/ 5 (0.0)	0.0	2.50 (0.14, 44.26)	0.5320	18.18 (-26.66, 63.02)	0.4268	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	2/ 15 (13.3)	13.3	4/ 18 (22.2)	22.2	0.60 (0.13, 2.84)	0.5191	-8.89 (-38.03, 20.25)	0.5499	
Ethnicity									0.8086
Hispanic/Latino	9/ 32 (28.1)	28.1	9/ 35 (25.7)	25.7	1.09 (0.50, 2.41)	0.8240	2.41 (-19.43, 24.25)	0.8287	
Non-hispanic/Latino	40/148 (27.0)	27.0	33/149 (22.1)	22.2	1.22 (0.82, 1.82)	0.3303	4.88 (-5.30, 15.06)	0.3475	
Geographic region									0.4945
EU	22/ 64 (34.4)	34.4	24/ 76 (31.6)	31.6	1.09 (0.68, 1.75)	0.7254	2.80 (-12.95, 18.54)	0.7278	
non-EU	27/116 (23.3)	24.0	18/108 (16.7)	16.6	1.40 (0.82, 2.39)	0.2217	7.43 (-3.66, 18.52)	0.1893	
Onset of disease									0.3291
Paediatric	2/ 12 (16.7)	16.7	0/ 12 (0.0)	0.0	5.00 (0.27, 94.34)	0.2829	16.67 (-14.16, 47.49)	0.2893	
Adult	47/168 (28.0)	27.9	42/172 (24.4)	24.5	1.15 (0.80, 1.64)	0.4562	3.37 (-6.16, 12.90)	0.4878	
ADA result									0.3578
Negative	46/162 (28.4)	28.4	38/169 (22.5)	22.7	1.26 (0.87, 1.83)	0.2185	5.71 (-3.91, 15.33)	0.2447	
Positive (At any time)	3/ 17 (17.6)	17.6	4/ 15 (26.7)	26.7	0.66 (0.18, 2.49)	0.5418	-9.02 (-40.06, 22.02)	0.5690	
BMI (kg/m2) at enrolment									0.8051
< 30	27/108 (25.0)	25.0	28/127 (22.0)	22.2	1.13 (0.71, 1.80)	0.5941	2.81 (-8.34, 13.96)	0.6217	
>= 30	22/ 72 (30.6)	31.3	14/ 57 (24.6)	24.7	1.24 (0.70, 2.21)	0.4550	6.53 (-9.42, 22.48)	0.4225	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Vitality Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 52	Number of subjects with events, n (%)	48 (26.7)	36 (19.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.38 (0.94, 2.02)	
	p-value	0.0993	
	Odds Ratio (95% CI)	1.52 (0.93, 2.48)	
	p-value	0.0981	
	Risk Difference (95% CI)	7.34 (-1.30, 15.98)	
	p-value	0.0960	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.36 (0.93, 1.99)	
	p-value	0.1104	
	Odds Ratio (95% CI)	1.49 (0.91, 2.44)	
	p-value	0.1090	
	Risk Difference (95% CI)	7.10 (-1.54, 15.74)	
	p-value	0.1071	
	CMH approach		
	Response rate	26.7	19.6
	Difference in response rates (95% CI)	7.04 (-1.86, 15.94)	
	p-value	0.1209	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Vitality Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.1755
< 10 points	20/ 55 (36.4)	36.8	10/ 54 (18.5)	18.6	1.96 (1.02, 3.80)	0.0450	18.22 (1.22, 35.22)	0.0357	
>= 10 points	28/125 (22.4)	22.4	26/130 (20.0)	20.1	1.12 (0.70, 1.80)	0.6393	2.37 (-8.01, 12.75)	0.6548	
OCS dose at baseline									0.1606
<10 mg/day	23/ 77 (29.9)	29.7	13/ 82 (15.9)	15.9	1.88 (1.03, 3.45)	0.0401	13.87 (0.34, 27.40)	0.0445	
>=10 mg/day	25/103 (24.3)	24.2	23/102 (22.5)	22.3	1.08 (0.66, 1.77)	0.7710	1.94 (-9.83, 13.71)	0.7469	
Result of type I IFN gene signature test									0.5623
LOW	11/ 32 (34.4)	34.4	10/ 33 (30.3)	30.3	1.13 (0.56, 2.30)	0.7259	4.07 (-18.99, 27.14)	0.7293	
HIGH	37/148 (25.0)	25.0	26/151 (17.2)	17.3	1.45 (0.93, 2.27)	0.1024	7.69 (-1.91, 17.29)	0.1166	
Age (years)									0.6466
<= 65	46/173 (26.6)	26.6	35/181 (19.3)	19.3	1.38 (0.93, 2.03)	0.1068	7.25 (-1.77, 16.28)	0.1153	
> 65	2/ 7 (28.6)	28.6	1/ 3 (33.3)	33.3	0.86 (0.12, 6.23)	0.8789	-4.76 (-71.14, 61.61)	0.8882	
Sex									0.5154
male	5/ 15 (33.3)	33.3	2/ 13 (15.4)	15.4	2.17 (0.50, 9.35)	0.2999	17.95 (-15.63, 51.53)	0.2948	
female	43/165 (26.1)	25.9	34/171 (19.9)	19.9	1.31 (0.88, 1.95)	0.1802	6.01 (-3.22, 15.24)	0.2021	
Race									0.5078
White	38/125 (30.4)	30.4	28/137 (20.4)	20.6	1.49 (0.97, 2.27)	0.0663	9.80 (-1.10, 20.70)	0.0781	
Black or African American	8/ 29 (27.6)	27.6	5/ 23 (21.7)	21.7	1.27 (0.48, 3.36)	0.6318	5.85 (-18.66, 30.35)	0.6400	
Asian	2/ 11 (18.2)	18.2	0/ 5 (0.0)	0.0	2.50 (0.14, 44.26)	0.5320	18.18 (-26.66, 63.02)	0.4268	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 15 (0.0)	0.0	3/ 18 (16.7)	16.7	0.17 (0.01, 3.05)	0.2285	-16.67 (-41.49, 8.15)	0.1881	
Ethnicity									0.1454
Hispanic/Latino	4/ 32 (12.5)	12.5	7/ 35 (20.0)	20.0	0.63 (0.20, 1.94)	0.4154	-7.50 (-26.51, 11.51)	0.4395	
Non-hispanic/Latino	44/148 (29.7)	29.7	29/149 (19.5)	19.3	1.53 (1.01, 2.30)	0.0428	10.37 (0.26, 20.47)	0.0443	
Geographic region									0.5513
EU	21/ 64 (32.8)	32.8	20/ 76 (26.3)	26.3	1.25 (0.75, 2.09)	0.4004	6.50 (-8.84, 21.83)	0.4063	
non-EU	27/116 (23.3)	24.1	16/108 (14.8)	14.9	1.57 (0.90, 2.75)	0.1139	9.20 (-1.82, 20.22)	0.1016	
Onset of disease									0.8160
Paediatric	1/ 12 (8.3)	8.3	1/ 12 (8.3)	8.3	1.00 (0.07, 14.21)	1.0000	0.00 (-31.23, 31.23)	1.0000	
Adult	47/168 (28.0)	27.9	35/172 (20.3)	20.4	1.37 (0.94, 2.02)	0.1028	7.45 (-1.90, 16.81)	0.1183	
ADA result									0.9610
Negative	45/162 (27.8)	27.7	34/169 (20.1)	20.3	1.38 (0.94, 2.04)	0.1047	7.40 (-2.06, 16.87)	0.1252	
Positive (At any time)	3/ 17 (17.6)	17.6	2/ 15 (13.3)	13.3	1.32 (0.25, 6.88)	0.7390	4.31 (-24.59, 33.22)	0.7699	
BMI (kg/m2) at enrolment									0.5265
< 30	26/108 (24.1)	24.3	25/127 (19.7)	19.6	1.22 (0.75, 1.99)	0.4164	4.72 (-6.10, 15.53)	0.3928	
>= 30	22/ 72 (30.6)	31.4	11/ 57 (19.3)	19.5	1.58 (0.84, 2.99)	0.1560	11.87 (-3.66, 27.40)	0.1340	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
C-SSRS Suicidal ideation or behaviour
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
On-treatment/Follow-Up	Number of subjects with events, n (%)	2 (1.1)	3 (1.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.70 (0.12, 4.04)	
	p-value	0.6938	
	Odds Ratio (95% CI)	0.70 (0.12, 4.12)	
	p-value	0.6970	
	Risk Difference (95% CI)	-0.49 (-2.92, 1.95)	
	p-value	0.6949	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.68 (0.12, 4.03)	
	p-value	0.6724	
	Odds Ratio (95% CI)	0.68 (0.11, 4.11)	
	p-value	0.6723	
	Risk Difference (95% CI)	-0.52 (-2.91, 1.87)	
	p-value	0.6697	
	CMH approach		
	Response rate	1.2	1.6
	Difference in response rates (95% CI)	-0.44 (-5.31, 4.44)	
	p-value	0.8610	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
C-SSRS Suicidal ideation or behaviour - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.2290
< 10 points	0/ 55 (0.0)	0.0	2/ 54 (3.7)	3.5	0.20 (0.01, 4.00)	0.2898	-3.52 (-14.92, 7.89)	0.5453	
>= 10 points	2/125 (1.6)	1.7	1/130 (0.8)	0.8	2.08 (0.19, 22.65)	0.5478	0.87 (-4.60, 6.34)	0.7565	
OCS dose at baseline									NE
<10 mg/day	2/ 77 (2.6)	2.7	3/ 82 (3.7)	3.7	0.71 (0.12, 4.13)	0.7032	-1.05 (-10.01, 7.91)	0.8183	
>=10 mg/day	0/103 (0.0)	0.0	0/102 (0.0)	0.0	NE		0.00 (-5.93, 5.93)	1.0000	
Result of type I IFN gene signature test									0.5657
LOW	0/ 32 (0.0)	0.0	1/ 33 (3.0)	3.0	0.34 (0.01, 8.13)	0.5080	-3.03 (-15.27, 9.21)	0.6274	
HIGH	2/148 (1.4)	1.4	2/151 (1.3)	1.3	1.02 (0.15, 7.15)	0.9839	0.13 (-5.18, 5.43)	0.9618	
Age (years)									NE
<= 65	2/173 (1.2)	1.2	3/181 (1.7)	1.6	0.70 (0.12, 4.12)	0.6911	-0.38 (-5.39, 4.63)	0.8819	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
Sex									0.4992
male	0/ 15 (0.0)	0.0	1/ 13 (7.7)	7.7	0.29 (0.01, 6.60)	0.4388	-7.69 (-33.59, 18.20)	0.5604	
female	2/165 (1.2)	1.3	2/171 (1.2)	1.2	1.04 (0.15, 7.27)	0.9713	0.10 (-5.07, 5.28)	0.9686	
Race									0.5818
White	1/125 (0.8)	0.8	1/137 (0.7)	0.7	1.10 (0.07, 17.34)	0.9481	0.07 (-6.16, 6.29)	0.9832	
Black or African American	1/ 29 (3.4)	3.4	2/ 23 (8.7)	8.7	0.40 (0.04, 4.11)	0.4380	-5.25 (-23.14, 12.65)	0.5655	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-20.43, 20.43)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE		0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	2/148 (1.4)	1.3	3/149 (2.0)	1.9	0.67 (0.11, 3.96)	0.6597	-0.63 (-6.50, 5.24)	0.8332	
Geographic region									NE
EU	0/ 64 (0.0)	0.0	0/ 76 (0.0)	0.0	NE		0.00 (-5.43, 5.43)	1.0000	
non-EU	2/116 (1.7)	1.9	3/108 (2.8)	2.6	0.62 (0.11, 3.64)	0.5974	-0.75 (-8.41, 6.91)	0.8477	
Onset of disease									0.2670
Paediatric	1/ 12 (8.3)	8.3	0/ 12 (0.0)	0.0	3.00 (0.13, 67.06)	0.4883	8.33 (-20.61, 37.28)	0.5726	
Adult	1/168 (0.6)	0.6	3/172 (1.7)	1.8	0.34 (0.04, 3.25)	0.3497	-1.18 (-6.28, 3.93)	0.6514	
ADA result									NE
Negative	2/162 (1.2)	1.3	3/169 (1.8)	1.7	0.70 (0.12, 4.11)	0.6886	-0.46 (-5.78, 4.86)	0.8648	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE		0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/108 (0.0)	0.0	0/127 (0.0)	0.0	NE		0.00 (-5.30, 5.30)	1.0000	
>= 30	2/ 72 (2.8)	2.6	3/ 57 (5.3)	5.0	0.53 (0.09, 3.05)	0.4754	-2.39 (-13.20, 8.41)	0.6643	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Modified SELENA Flare Index based flares - mild/moderate flare
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
at least once during study	Number of subjects with events, n (%)	56 (31.1)	60 (32.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.95 (0.70, 1.29)	
	p-value	0.7458	
	Odds Ratio (95% CI)	0.93 (0.60, 1.45)	
	p-value	0.7456	
	Risk Difference (95% CI)	-1.59 (-11.17, 8.00)	
	p-value	0.7455	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.95 (0.71, 1.29)	
	p-value	0.7592	
	Odds Ratio (95% CI)	0.93 (0.60, 1.45)	
	p-value	0.7592	
	Risk Difference (95% CI)	-1.50 (-11.07, 8.07)	
	p-value	0.7591	
	CMH approach		
	Response rate	31.0	32.6
	Difference in response rates (95% CI)	-1.63 (-11.30, 8.04)	
	p-value	0.7413	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Modified SELENA Flare Index based flares - mild/moderate flare - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.5374
< 10 points	19/ 55 (34.5)	34.6	17/ 54 (31.5)	31.7	1.10 (0.64, 1.88)	0.7341	2.96 (-15.05, 20.98)	0.7471	
>= 10 points	37/125 (29.6)	29.5	43/130 (33.1)	33.1	0.89 (0.62, 1.29)	0.5504	-3.58 (-15.05, 7.90)	0.5414	
OCS dose at baseline									0.7631
<10 mg/day	22/ 77 (28.6)	28.4	26/ 82 (31.7)	31.7	0.90 (0.56, 1.45)	0.6674	-3.32 (-17.79, 11.16)	0.6533	
>=10 mg/day	34/103 (33.0)	33.0	34/102 (33.3)	33.3	0.99 (0.67, 1.46)	0.9608	-0.26 (-13.28, 12.76)	0.9692	
Result of type I IFN gene signature test									0.7905
LOW	12/ 32 (37.5)	37.5	12/ 33 (36.4)	36.4	1.03 (0.55, 1.95)	0.9244	1.14 (-22.51, 24.78)	0.9250	
HIGH	44/148 (29.7)	29.6	48/151 (31.8)	31.8	0.94 (0.67, 1.31)	0.7000	-2.23 (-12.83, 8.36)	0.6797	
Age (years)									0.5086
<= 65	55/173 (31.8)	31.7	59/181 (32.6)	32.7	0.98 (0.72, 1.32)	0.8713	-0.98 (-10.83, 8.87)	0.8451	
> 65	1/ 7 (14.3)	14.3	1/ 3 (33.3)	33.3	0.43 (0.04, 4.82)	0.4925	-19.05 (-84.04, 45.95)	0.5657	
Sex									0.5461
male	3/ 15 (20.0)	20.0	4/ 13 (30.8)	30.8	0.65 (0.18, 2.38)	0.5159	-10.77 (-45.00, 23.46)	0.5374	
female	53/165 (32.1)	32.0	56/171 (32.7)	32.8	0.98 (0.72, 1.34)	0.9023	-0.79 (-10.90, 9.31)	0.8778	
Race									0.5805
White	39/125 (31.2)	31.3	44/137 (32.1)	32.1	0.97 (0.68, 1.39)	0.8735	-0.78 (-12.23, 10.67)	0.8933	
Black or African American	12/ 29 (41.4)	41.4	9/ 23 (39.1)	39.1	1.06 (0.54, 2.06)	0.8699	2.25 (-24.71, 29.21)	0.8701	
Asian	4/ 11 (36.4)	36.4	3/ 5 (60.0)	60.0	0.61 (0.21, 1.75)	0.3544	-23.64 (-75.94, 28.66)	0.3757	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	1/ 15 (6.7)	6.7	4/ 18 (22.2)	22.2	0.30 (0.04, 2.40)	0.2569	-15.56 (-43.19, 12.08)	0.2700	
Ethnicity									0.8207
Hispanic/Latino	8/ 32 (25.0)	25.0	10/ 35 (28.6)	28.6	0.88 (0.39, 1.94)	0.7425	-3.57 (-25.36, 18.21)	0.7480	
Non-hispanic/Latino	48/148 (32.4)	32.3	50/149 (33.6)	33.7	0.97 (0.70, 1.34)	0.8367	-1.37 (-12.20, 9.46)	0.8042	
Geographic region									0.6109
EU	13/ 64 (20.3)	20.3	19/ 76 (25.0)	25.0	0.81 (0.44, 1.51)	0.5131	-4.69 (-18.87, 9.49)	0.5170	
non-EU	43/116 (37.1)	36.7	41/108 (38.0)	38.2	0.98 (0.70, 1.37)	0.8901	-1.52 (-14.30, 11.26)	0.8157	
Onset of disease									0.3459
Paediatric	6/ 12 (50.0)	50.0	4/ 12 (33.3)	33.3	1.50 (0.56, 4.00)	0.4174	16.67 (-22.71, 56.04)	0.4068	
Adult	50/168 (29.8)	29.5	56/172 (32.6)	32.6	0.91 (0.67, 1.25)	0.5783	-3.06 (-13.00, 6.87)	0.5457	
ADA result									0.0981
Negative	53/162 (32.7)	32.6	53/169 (31.4)	31.5	1.04 (0.76, 1.43)	0.7917	1.18 (-9.00, 11.36)	0.8206	
Positive (At any time)	3/ 17 (17.6)	17.6	7/ 15 (46.7)	46.7	0.38 (0.12, 1.21)	0.1006	-29.02 (-61.40, 3.36)	0.0790	
BMI (kg/m2) at enrolment									0.4667
< 30	26/108 (24.1)	24.1	37/127 (29.1)	29.0	0.83 (0.54, 1.27)	0.3857	-4.94 (-16.51, 6.62)	0.4019	
>= 30	30/ 72 (41.7)	42.0	23/ 57 (40.4)	40.5	1.03 (0.68, 1.57)	0.8803	1.45 (-15.73, 18.62)	0.8688	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Modified SELENA Flare Index based flares - severe flare
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
at least once during study	Number of subjects with events, n (%)	5 (2.8)	10 (5.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.50 (0.17, 1.43)	
	p-value	0.1971	
	Odds Ratio (95% CI)	0.48 (0.16, 1.45)	
	p-value	0.1933	
	Risk Difference (95% CI)	-2.73 (-6.75, 1.29)	
	p-value	0.1829	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.51 (0.18, 1.47)	
	p-value	0.2119	
	Odds Ratio (95% CI)	0.50 (0.17, 1.48)	
	p-value	0.2105	
	Risk Difference (95% CI)	-2.66 (-6.72, 1.40)	
	p-value	0.1997	
	CMH approach		
	Response rate	2.7	5.4
	Difference in response rates (95% CI)	-2.73 (-8.47, 3.02)	
	p-value	0.3526	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Modified SELENA Flare Index based flares - severe flare - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.6200
< 10 points	1/ 55 (1.8)	1.7	1/ 54 (1.9)	2.0	0.98 (0.06, 15.30)	0.9896	-0.34 (-11.83, 11.16)	0.9544	
>= 10 points	4/125 (3.2)	3.2	9/130 (6.9)	6.9	0.46 (0.15, 1.46)	0.1892	-3.75 (-10.71, 3.22)	0.2922	
OCS dose at baseline									0.3388
<10 mg/day	0/ 77 (0.0)	0.0	3/ 82 (3.7)	3.6	0.15 (0.01, 2.90)	0.2103	-3.59 (-12.03, 4.85)	0.4047	
>=10 mg/day	5/103 (4.9)	4.8	7/102 (6.9)	6.9	0.71 (0.23, 2.16)	0.5426	-2.06 (-10.44, 6.32)	0.6299	
Result of type I IFN gene signature test									NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE		0.00 (-11.07, 11.07)	1.0000	
HIGH	5/148 (3.4)	3.3	10/151 (6.6)	6.6	0.51 (0.18, 1.46)	0.2087	-3.32 (-9.89, 3.25)	0.3221	
Age (years)									NE
<= 65	5/173 (2.9)	2.8	10/181 (5.5)	5.6	0.52 (0.18, 1.50)	0.2279	-2.75 (-8.65, 3.15)	0.3612	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
Sex									0.5668
male	1/ 15 (6.7)	6.7	3/ 13 (23.1)	23.1	0.29 (0.03, 2.45)	0.2550	-16.41 (-47.30, 14.48)	0.2977	
female	4/165 (2.4)	2.4	7/171 (4.1)	4.0	0.59 (0.18, 1.99)	0.3960	-1.65 (-7.47, 4.18)	0.5788	
Race									0.5520
White	2/125 (1.6)	1.6	6/137 (4.4)	4.3	0.37 (0.08, 1.78)	0.2122	-2.67 (-9.63, 4.30)	0.4529	
Black or African American	2/ 29 (6.9)	6.9	1/ 23 (4.3)	4.3	1.59 (0.15, 16.42)	0.6988	2.55 (-14.95, 20.04)	0.7752	
Asian	1/ 11 (9.1)	9.1	0/ 5 (0.0)	0.0	1.50 (0.07, 31.57)	0.7942	9.09 (-34.34, 52.53)	0.6817	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 15 (0.0)	0.0	3/ 18 (16.7)	16.7	0.17 (0.01, 3.05)	0.2285	-16.67 (-41.49, 8.15)	0.1881	
Ethnicity									0.9508
Hispanic/Latino	1/ 32 (3.1)	3.1	2/ 35 (5.7)	5.7	0.55 (0.05, 5.75)	0.6150	-2.59 (-16.47, 11.29)	0.7147	
Non-hispanic/Latino	4/148 (2.7)	2.7	8/149 (5.4)	5.4	0.50 (0.15, 1.64)	0.2536	-2.70 (-9.39, 4.00)	0.4298	
Geographic region									0.5623
EU	1/ 64 (1.6)	1.6	4/ 76 (5.3)	5.3	0.30 (0.03, 2.59)	0.2718	-3.70 (-11.47, 4.07)	0.3506	
non-EU	4/116 (3.4)	3.1	6/108 (5.6)	5.8	0.62 (0.18, 2.14)	0.4501	-2.70 (-10.99, 5.60)	0.5236	
Onset of disease									0.5941
Paediatric	1/ 12 (8.3)	8.3	1/ 12 (8.3)	8.3	1.00 (0.07, 14.21)	1.0000	0.00 (-31.23, 31.23)	1.0000	
Adult	4/168 (2.4)	2.4	9/172 (5.2)	5.1	0.46 (0.14, 1.45)	0.1828	-2.77 (-8.70, 3.16)	0.3599	
ADA result									0.2629
Negative	5/162 (3.1)	3.1	7/169 (4.1)	4.1	0.75 (0.24, 2.30)	0.6090	-1.06 (-7.10, 4.98)	0.7301	
Positive (At any time)	0/ 17 (0.0)	0.0	3/ 15 (20.0)	20.0	0.13 (0.01, 2.27)	0.1610	-20.00 (-46.29, 6.29)	0.1360	
BMI (kg/m2) at enrolment									0.7697
< 30	4/108 (3.7)	3.7	8/127 (6.3)	6.1	0.59 (0.18, 1.90)	0.3747	-2.45 (-9.78, 4.89)	0.5134	
>= 30	1/ 72 (1.4)	1.3	2/ 57 (3.5)	3.5	0.40 (0.04, 4.26)	0.4444	-2.19 (-12.65, 8.27)	0.6817	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Modified SELENA Flare Index based flares - mild/moderate or severe flare
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
at least once during study	Number of subjects with events, n (%)	58 (32.2)	67 (36.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.88 (0.66, 1.17)	
	p-value	0.3830	
	Odds Ratio (95% CI)	0.82 (0.53, 1.27)	
	p-value	0.3818	
	Risk Difference (95% CI)	-4.37 (-14.13, 5.40)	
	p-value	0.3808	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.88 (0.67, 1.18)	
	p-value	0.4008	
	Odds Ratio (95% CI)	0.83 (0.54, 1.28)	
	p-value	0.4001	
	Risk Difference (95% CI)	-4.19 (-13.93, 5.55)	
	p-value	0.3993	
	CMH approach		
	Response rate	32.1	36.5
	Difference in response rates (95% CI)	-4.40 (-14.21, 5.40)	
	p-value	0.3786	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Modified SELENA Flare Index based flares - mild/moderate or severe flare - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.3393
< 10 points	20/ 55 (36.4)	36.3	18/ 54 (33.3)	33.7	1.09 (0.65, 1.82)	0.7402	2.63 (-15.53, 20.79)	0.7765	
>= 10 points	38/125 (30.4)	30.3	49/130 (37.7)	37.7	0.81 (0.57, 1.14)	0.2222	-7.39 (-19.05, 4.27)	0.2142	
OCS dose at baseline									0.7680
<10 mg/day	22/ 77 (28.6)	28.4	28/ 82 (34.1)	34.1	0.84 (0.53, 1.33)	0.4513	-5.71 (-20.27, 8.85)	0.4421	
>=10 mg/day	36/103 (35.0)	34.9	39/102 (38.2)	38.3	0.91 (0.64, 1.31)	0.6258	-3.33 (-16.60, 9.94)	0.6227	
Result of type I IFN gene signature test									0.6017
LOW	12/ 32 (37.5)	37.5	12/ 33 (36.4)	36.4	1.03 (0.55, 1.95)	0.9244	1.14 (-22.51, 24.78)	0.9250	
HIGH	46/148 (31.1)	30.9	55/151 (36.4)	36.5	0.85 (0.62, 1.17)	0.3302	-5.61 (-16.38, 5.16)	0.3073	
Age (years)									0.5485
<= 65	57/173 (32.9)	32.8	66/181 (36.5)	36.6	0.90 (0.68, 1.20)	0.4881	-3.82 (-13.80, 6.16)	0.4535	
> 65	1/ 7 (14.3)	14.3	1/ 3 (33.3)	33.3	0.43 (0.04, 4.82)	0.4925	-19.05 (-84.04, 45.95)	0.5657	
Sex									0.2120
male	3/ 15 (20.0)	20.0	6/ 13 (46.2)	46.2	0.43 (0.13, 1.40)	0.1613	-26.15 (-61.26, 8.96)	0.1443	
female	55/165 (33.3)	33.1	61/171 (35.7)	35.7	0.93 (0.70, 1.26)	0.6524	-2.51 (-12.73, 7.71)	0.6300	
Race									0.3416
White	39/125 (31.2)	31.3	48/137 (35.0)	34.9	0.89 (0.63, 1.26)	0.5113	-3.59 (-15.14, 7.96)	0.5421	
Black or African American	13/ 29 (44.8)	44.8	9/ 23 (39.1)	39.1	1.15 (0.60, 2.20)	0.6820	5.70 (-21.35, 32.75)	0.6797	
Asian	5/ 11 (45.5)	45.5	3/ 5 (60.0)	60.0	0.76 (0.29, 1.99)	0.5728	-14.55 (-67.14, 38.05)	0.5878	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	1/ 15 (6.7)	6.7	7/ 18 (38.9)	38.9	0.17 (0.02, 1.24)	0.0809	-32.22 (-61.49, -2.96)	0.0309	
Ethnicity									0.5850
Hispanic/Latino	8/ 32 (25.0)	25.0	12/ 35 (34.3)	34.3	0.73 (0.34, 1.55)	0.4124	-9.29 (-31.50, 12.93)	0.4126	
Non-hispanic/Latino	50/148 (33.8)	33.6	55/149 (36.9)	37.1	0.92 (0.67, 1.25)	0.5731	-3.56 (-14.53, 7.41)	0.5251	
Geographic region									0.5393
EU	13/ 64 (20.3)	20.3	21/ 76 (27.6)	27.6	0.74 (0.40, 1.35)	0.3200	-7.32 (-21.70, 7.06)	0.3184	
non-EU	45/116 (38.8)	38.3	46/108 (42.6)	43.0	0.91 (0.66, 1.25)	0.5629	-4.72 (-17.57, 8.13)	0.4715	
Onset of disease									0.2559
Paediatric	7/ 12 (58.3)	58.3	5/ 12 (41.7)	41.7	1.40 (0.61, 3.19)	0.4228	16.67 (-23.03, 56.36)	0.4105	
Adult	51/168 (30.4)	30.1	62/172 (36.0)	36.0	0.84 (0.62, 1.14)	0.2672	-5.95 (-15.99, 4.10)	0.2459	
ADA result									0.0381
Negative	55/162 (34.0)	33.8	58/169 (34.3)	34.5	0.99 (0.73, 1.33)	0.9436	-0.64 (-10.94, 9.66)	0.9030	
Positive (At any time)	3/ 17 (17.6)	17.6	9/ 15 (60.0)	60.0	0.29 (0.10, 0.89)	0.0302	-42.35 (-74.51, -10.19)	0.0098	
BMI (kg/m2) at enrolment									0.3802
< 30	28/108 (25.9)	25.9	43/127 (33.9)	33.6	0.77 (0.51, 1.14)	0.1919	-7.76 (-19.61, 4.10)	0.1997	
>= 30	30/ 72 (41.7)	42.0	24/ 57 (42.1)	42.2	0.99 (0.66, 1.49)	0.9600	-0.17 (-17.39, 17.05)	0.9844	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score Improvement >=15% (of maxmimum value =40)
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
at least once during study	Number of subjects with events, n (%)	147 (81.7)	146 (79.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.03 (0.93, 1.14)	
	p-value	0.5426	
	Odds Ratio (95% CI)	1.18 (0.70, 1.99)	
	p-value	0.5445	
	Risk Difference (95% CI)	2.50 (-5.57, 10.57)	
	p-value	0.5439	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.03 (0.93, 1.14)	
	p-value	0.5766	
	Odds Ratio (95% CI)	1.16 (0.69, 1.95)	
	p-value	0.5769	
	Risk Difference (95% CI)	2.32 (-5.82, 10.45)	
	p-value	0.5763	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score Improvement >=15% (of maxmimum value =40) at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 52	Number of subjects with events, n (%)	102 (56.7)	81 (44.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.30 (1.06, 1.59)	
	p-value	0.0123	
	Odds Ratio (95% CI)	1.71 (1.12, 2.59)	
	p-value	0.0126	
	Risk Difference (95% CI)	13.11 (2.97, 23.25)	
	p-value	0.0112	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.29 (1.05, 1.58)	
	p-value	0.0168	
	Odds Ratio (95% CI)	1.66 (1.10, 2.52)	
	p-value	0.0161	
	Risk Difference (95% CI)	12.64 (2.45, 22.84)	
	p-value	0.0150	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
SRI (5) response rate at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 52	Number of subjects with events, n (%)	74 (41.1)	58 (31.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.30 (0.99, 1.71)	
	p-value	0.0595	
	Odds Ratio (95% CI)	1.51 (0.98, 2.31)	
	p-value	0.0604	
	Risk Difference (95% CI)	9.59 (-0.34, 19.52)	
	p-value	0.0583	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.30 (0.99, 1.72)	
	p-value	0.0589	
	Odds Ratio (95% CI)	1.52 (0.99, 2.33)	
	p-value	0.0576	
	Risk Difference (95% CI)	9.59 (-0.25, 19.42)	
	p-value	0.0560	
	CMH approach		
	Response rate	41.3	31.8
	Difference in response rates (95% CI)	9.50 (-0.34, 19.33)	
	p-value	0.0585	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
SRI (6) response rate at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 52	Number of subjects with events, n (%)	71 (39.4)	58 (31.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.25 (0.95, 1.65)	
	p-value	0.1160	
	Odds Ratio (95% CI)	1.41 (0.92, 2.16)	
	p-value	0.1179	
	Risk Difference (95% CI)	7.95 (-1.96, 17.87)	
	p-value	0.1157	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.25 (0.95, 1.65)	
	p-value	0.1159	
	Odds Ratio (95% CI)	1.42 (0.92, 2.18)	
	p-value	0.1147	
	Risk Difference (95% CI)	7.92 (-1.88, 17.72)	
	p-value	0.1131	
	CMH approach		
	Response rate	39.6	31.8
	Difference in response rates (95% CI)	7.86 (-1.95, 17.68)	
	p-value	0.1164	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
SRI (7) response rate at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=173)	Placebo (N=176)
Week 52	Number of subjects with events, n (%)	52 (30.1)	31 (17.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.70 (1.15, 2.52)	
	p-value	0.0077	
	Odds Ratio (95% CI)	1.99 (1.20, 3.29)	
	p-value	0.0074	
	Risk Difference (95% CI)	12.48 (3.53, 21.42)	
	p-value	0.0062	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.71 (1.15, 2.53)	
	p-value	0.0076	
	Odds Ratio (95% CI)	2.01 (1.21, 3.33)	
	p-value	0.0068	
	Risk Difference (95% CI)	12.44 (3.59, 21.30)	
	p-value	0.0059	
	CMH approach		
	Response rate	30.1	17.6
	Difference in response rates (95% CI)	12.57 (3.41, 21.73)	
	p-value	0.0072	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
BICLA response rate sensitivity analysis using modified BILAG at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 52	Number of subjects with events, n (%)	91 (50.6)	62 (33.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.50 (1.17, 1.92)	
	p-value	0.0013	
	Odds Ratio (95% CI)	2.01 (1.32, 3.08)	
	p-value	0.0012	
	Risk Difference (95% CI)	16.91 (6.88, 26.93)	
	p-value	0.0010	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.50 (1.17, 1.92)	
	p-value	0.0014	
	Odds Ratio (95% CI)	2.01 (1.32, 3.07)	
	p-value	0.0012	
	Risk Difference (95% CI)	16.86 (6.86, 26.86)	
	p-value	0.0010	
	CMH approach		
	Response rate	50.5	33.9
	Difference in response rates (95% CI)	16.61 (6.72, 26.50)	
	p-value	0.0010	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
BICLA response rate sensitivity analysis excluding subjects with no BILAG A or B or PGA VAS score >2.7 at baseline at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=178)	Placebo (N=181)
Week 52	Number of subjects with events, n (%)	84 (47.2)	55 (30.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.55 (1.18, 2.02)	
	p-value	0.0014	
	Odds Ratio (95% CI)	2.02 (1.31, 3.10)	
	p-value	0.0013	
	Risk Difference (95% CI)	16.84 (6.79, 26.89)	
	p-value	0.0010	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.55 (1.19, 2.03)	
	p-value	0.0014	
	Odds Ratio (95% CI)	2.05 (1.33, 3.15)	
	p-value	0.0012	
	Risk Difference (95% CI)	16.80 (6.87, 26.74)	
	p-value	0.0009	
	CMH approach		
	Response rate	47.2	30.6
	Difference in response rates (95% CI)	16.54 (6.66, 26.43)	
	p-value	0.0010	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
BICLA response rate sensitivity analysis excluding criterion of no restricted medications at week 52
Full analysis set

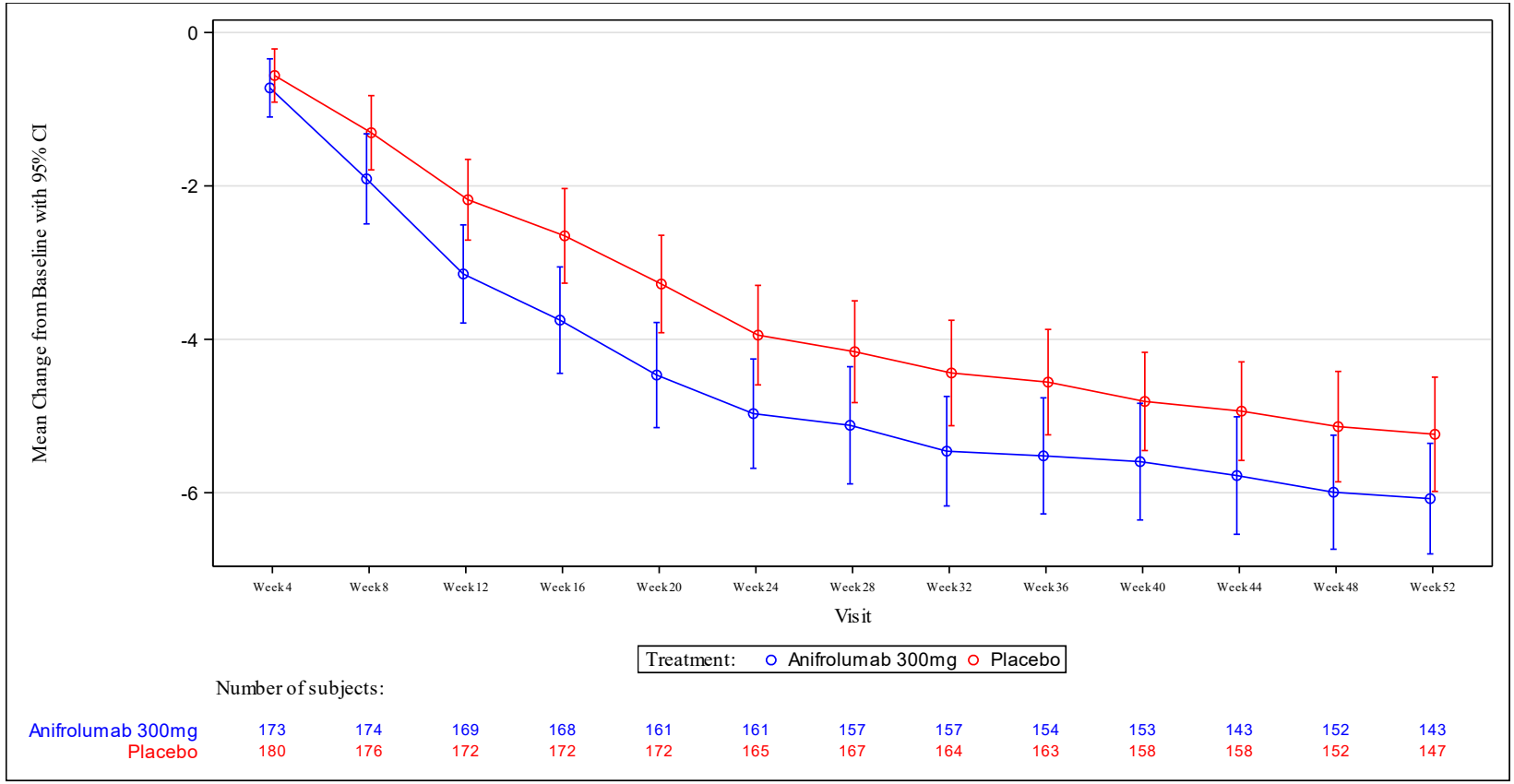
Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=184)
Week 52	Number of subjects with events, n (%)	98 (54.4)	72 (39.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.38 (1.11, 1.73)	
	p-value	0.0046	
	Odds Ratio (95% CI)	1.81 (1.20, 2.73)	
	p-value	0.0045	
	Risk Difference (95% CI)	15.18 (4.86, 25.50)	
	p-value	0.0039	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.39 (1.11, 1.74)	
	p-value	0.0039	
	Odds Ratio (95% CI)	1.86 (1.23, 2.82)	
	p-value	0.0035	
	Risk Difference (95% CI)	15.31 (5.18, 25.45)	
	p-value	0.0031	
	CMH approach		
	Response rate	54.4	39.4
	Difference in response rates (95% CI)	14.98 (4.91, 25.05)	
	p-value	0.0036	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - SLEDAI-2K Total Score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=184)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	180	11.41 (4.02)	0	-	184	11.49 (3.58)	0	-
Week 4	173	10.73 (3.52)	173	-0.72 (2.53)	180	10.87 (3.83)	180	-0.56 (2.36)
Week 8	174	9.55 (4.14)	174	-1.91 (3.92)	176	10.16 (3.91)	176	-1.31 (3.25)
Week 12	169	8.28 (4.20)	169	-3.15 (4.21)	172	9.28 (4.11)	172	-2.18 (3.50)
Week 16	168	7.68 (4.57)	168	-3.75 (4.55)	172	8.82 (4.68)	172	-2.65 (4.10)
Week 20	161	6.81 (4.43)	161	-4.47 (4.40)	172	8.16 (4.35)	172	-3.28 (4.22)
Week 24	161	6.61 (4.40)	161	-4.97 (4.58)	165	7.47 (4.08)	165	-3.95 (4.22)
Week 28	157	6.50 (4.80)	157	-5.12 (4.85)	167	7.35 (4.15)	167	-4.16 (4.34)
Week 32	157	6.03 (4.38)	157	-5.46 (4.53)	164	7.03 (4.38)	164	-4.44 (4.46)
Week 36	154	6.06 (4.69)	154	-5.52 (4.75)	163	6.80 (4.13)	163	-4.56 (4.44)
Week 40	153	5.76 (4.22)	153	-5.59 (4.76)	158	6.47 (4.15)	158	-4.81 (4.07)
Week 44	143	5.60 (4.52)	143	-5.78 (4.63)	158	6.41 (4.25)	158	-4.94 (4.09)
Week 48	152	5.47 (4.29)	152	-5.99 (4.64)	152	6.18 (4.14)	152	-5.14 (4.49)
Week 52	143	5.38 (3.86)	143	-6.08 (4.36)	147	6.03 (4.08)	147	-5.24 (4.57)

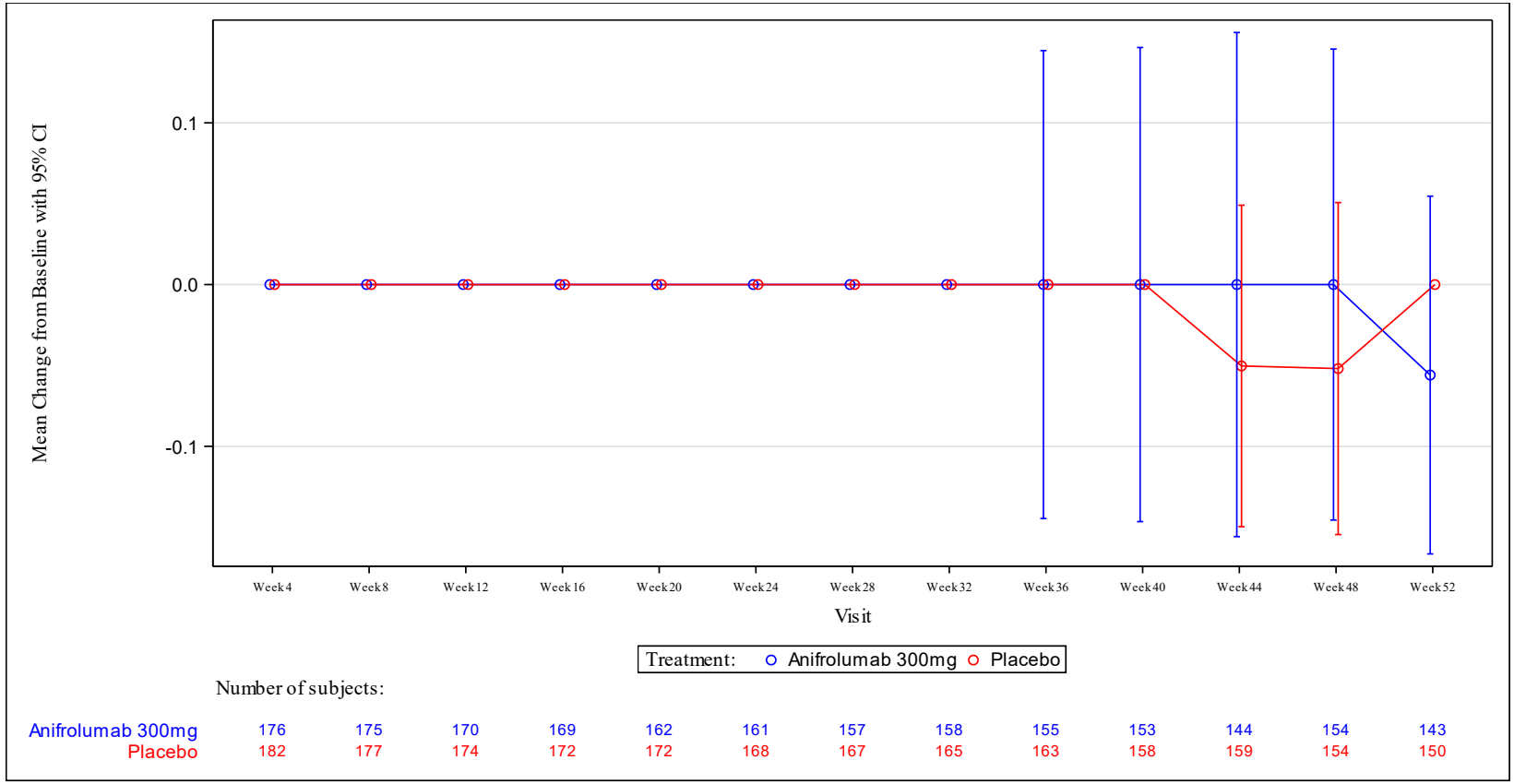
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - SLEDAI-2K Total Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score CNS
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=184)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	180	0.09 (0.84)	0	-	184	0.04 (0.59)	0	-
Week 4	176	0.09 (0.85)	176	0.00 (0.00)	182	0.04 (0.59)	182	0.00 (0.00)
Week 8	175	0.09 (0.85)	175	0.00 (0.00)	177	0.05 (0.60)	177	0.00 (0.00)
Week 12	170	0.09 (0.87)	170	0.00 (0.00)	174	0.05 (0.61)	174	0.00 (0.00)
Week 16	169	0.09 (0.87)	169	0.00 (0.00)	172	0.05 (0.61)	172	0.00 (0.00)
Week 20	162	0.10 (0.89)	162	0.00 (0.00)	172	0.05 (0.61)	172	0.00 (0.00)
Week 24	161	0.10 (0.89)	161	0.00 (0.00)	168	0.05 (0.62)	168	0.00 (0.00)
Week 28	157	0.10 (0.90)	157	0.00 (0.00)	167	0.05 (0.62)	167	0.00 (0.00)
Week 32	158	0.10 (0.90)	158	0.00 (0.00)	165	0.00 (0.00)	165	0.00 (0.00)
Week 36	155	0.10 (0.91)	155	0.00 (0.91)	163	0.05 (0.63)	163	0.00 (0.00)
Week 40	153	0.05 (0.65)	153	0.00 (0.92)	158	0.05 (0.64)	158	0.00 (0.00)
Week 44	144	0.11 (0.94)	144	0.00 (0.95)	159	0.00 (0.00)	159	-0.05 (0.63)
Week 48	154	0.10 (0.91)	154	0.00 (0.91)	154	0.00 (0.00)	154	-0.05 (0.64)
Week 52	143	0.06 (0.67)	143	-0.06 (0.67)	150	0.00 (0.00)	150	0.00 (0.00)

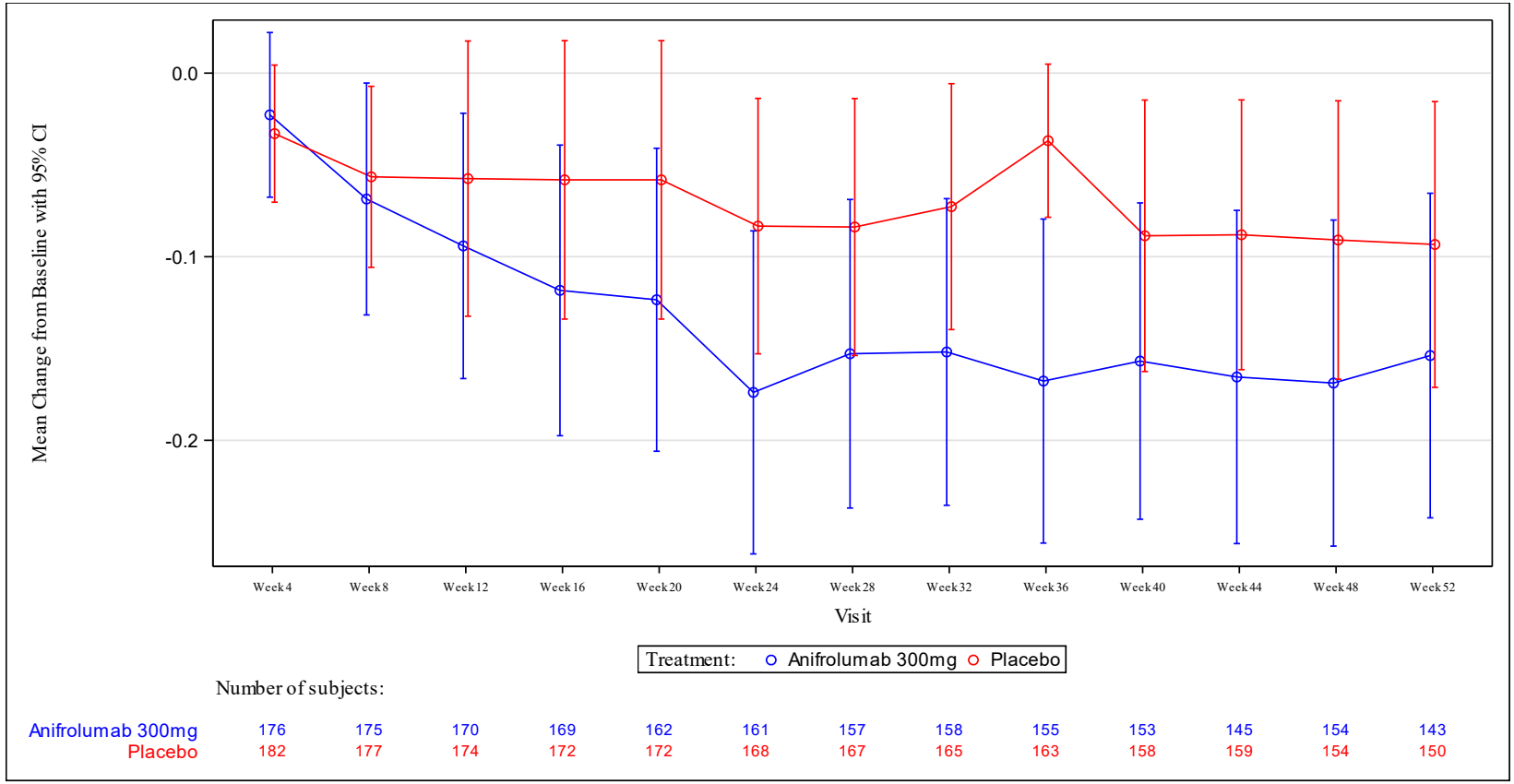
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Total Organ Score CNS
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score CVS and Respiratory
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=184)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	180	0.18 (0.57)	0	-	184	0.12 (0.52)	0	-
Week 4	176	0.16 (0.54)	176	-0.02 (0.30)	182	0.09 (0.41)	182	-0.03 (0.26)
Week 8	175	0.11 (0.47)	175	-0.07 (0.42)	177	0.05 (0.30)	177	-0.06 (0.33)
Week 12	170	0.08 (0.40)	170	-0.09 (0.48)	174	0.06 (0.34)	174	-0.06 (0.50)
Week 16	169	0.07 (0.37)	169	-0.12 (0.52)	172	0.03 (0.26)	172	-0.06 (0.50)
Week 20	162	0.06 (0.35)	162	-0.12 (0.53)	172	0.05 (0.30)	172	-0.06 (0.50)
Week 24	161	0.02 (0.22)	161	-0.17 (0.57)	168	0.02 (0.22)	168	-0.08 (0.46)
Week 28	157	0.04 (0.27)	157	-0.15 (0.53)	167	0.02 (0.22)	167	-0.08 (0.46)
Week 32	158	0.04 (0.27)	158	-0.15 (0.53)	165	0.04 (0.27)	165	-0.07 (0.44)
Week 36	155	0.04 (0.28)	155	-0.17 (0.56)	163	0.02 (0.22)	163	-0.04 (0.27)
Week 40	153	0.04 (0.28)	153	-0.16 (0.54)	158	0.01 (0.16)	158	-0.09 (0.47)
Week 44	145	0.03 (0.23)	145	-0.17 (0.55)	159	0.01 (0.16)	159	-0.09 (0.47)
Week 48	154	0.03 (0.23)	154	-0.17 (0.56)	154	0.01 (0.16)	154	-0.09 (0.48)
Week 52	143	0.03 (0.24)	143	-0.15 (0.53)	150	0.01 (0.16)	150	-0.09 (0.48)

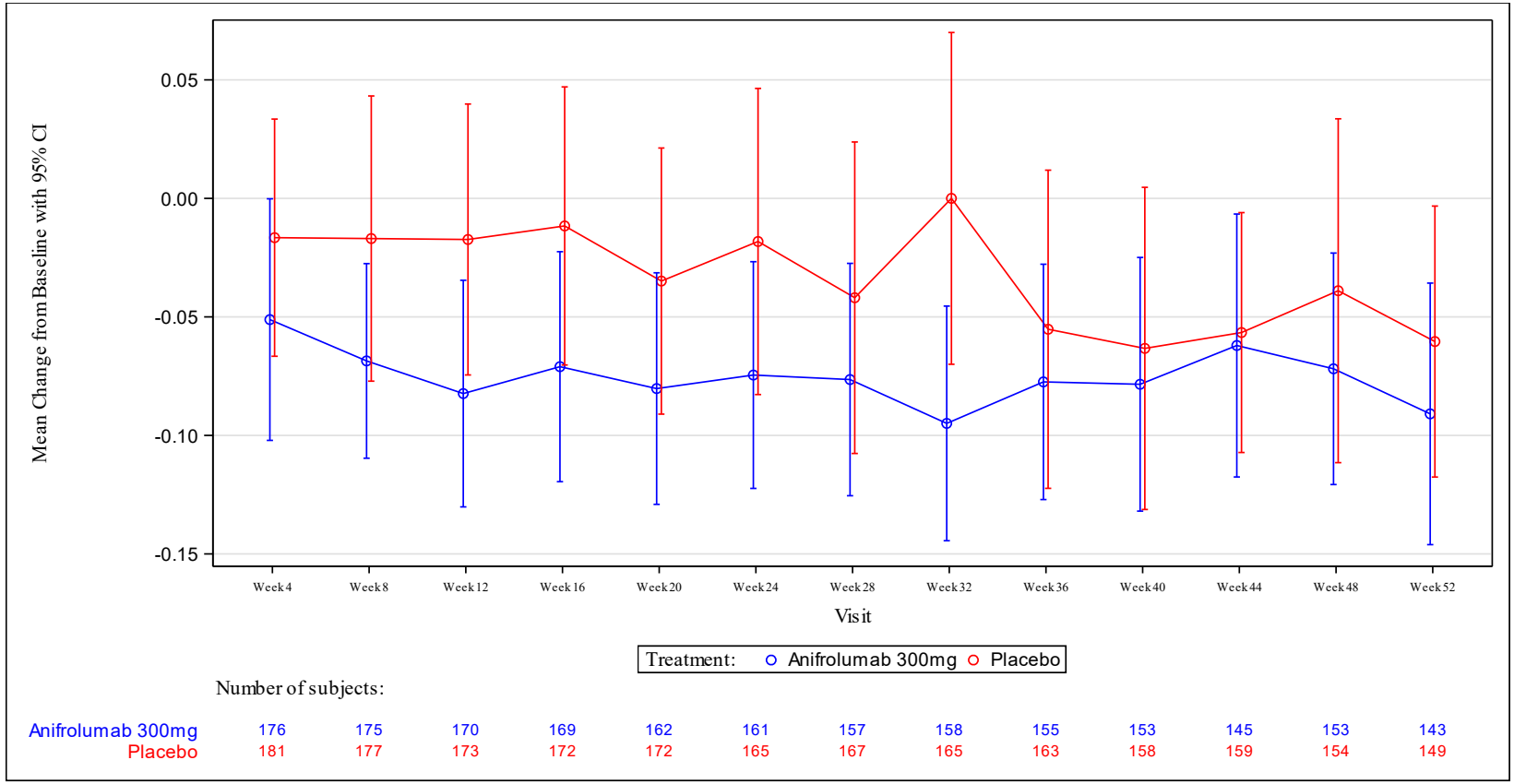
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Total Organ Score CVS and Respiratory
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score Hematological
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=184)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	180	0.11 (0.32)	0	-	184	0.14 (0.39)	0	-
Week 4	176	0.06 (0.24)	176	-0.05 (0.34)	181	0.12 (0.34)	181	-0.02 (0.34)
Week 8	175	0.04 (0.20)	175	-0.07 (0.28)	177	0.11 (0.32)	177	-0.02 (0.41)
Week 12	170	0.03 (0.17)	170	-0.08 (0.32)	173	0.12 (0.36)	173	-0.02 (0.38)
Week 16	169	0.04 (0.19)	169	-0.07 (0.32)	172	0.11 (0.31)	172	-0.01 (0.39)
Week 20	162	0.04 (0.19)	162	-0.08 (0.31)	172	0.10 (0.34)	172	-0.03 (0.37)
Week 24	161	0.04 (0.19)	161	-0.07 (0.31)	165	0.10 (0.34)	165	-0.02 (0.42)
Week 28	157	0.03 (0.16)	157	-0.08 (0.31)	167	0.09 (0.29)	167	-0.04 (0.43)
Week 32	158	0.02 (0.14)	158	-0.09 (0.31)	165	0.13 (0.35)	165	0.00 (0.46)
Week 36	155	0.03 (0.16)	155	-0.08 (0.31)	163	0.06 (0.27)	163	-0.06 (0.43)
Week 40	153	0.03 (0.16)	153	-0.08 (0.34)	158	0.06 (0.24)	158	-0.06 (0.43)
Week 44	145	0.05 (0.22)	145	-0.06 (0.34)	159	0.06 (0.27)	159	-0.06 (0.32)
Week 48	153	0.03 (0.18)	153	-0.07 (0.31)	154	0.06 (0.32)	154	-0.04 (0.46)
Week 52	143	0.02 (0.14)	143	-0.09 (0.33)	149	0.05 (0.21)	149	-0.06 (0.35)

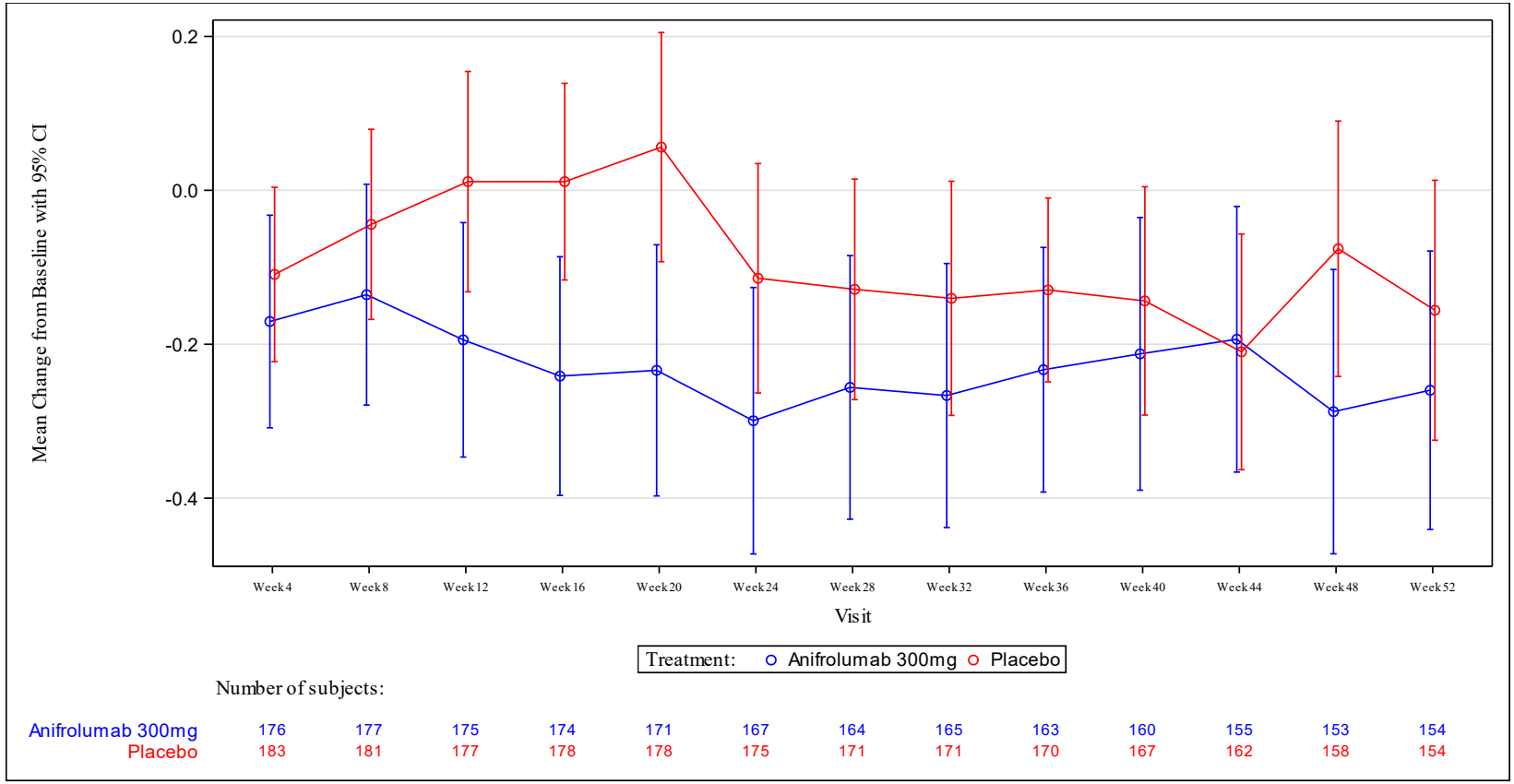
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Total Organ Score Hematological
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score Immunology
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=184)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	180	1.83 (1.66)	0	-	184	1.92 (1.65)	0	-
Week 4	176	1.68 (1.61)	176	-0.17 (0.93)	183	1.80 (1.60)	183	-0.11 (0.78)
Week 8	177	1.69 (1.57)	177	-0.14 (0.97)	181	1.89 (1.63)	181	-0.04 (0.84)
Week 12	175	1.63 (1.56)	175	-0.19 (1.02)	177	1.90 (1.60)	177	0.01 (0.97)
Week 16	174	1.59 (1.63)	174	-0.24 (1.04)	178	1.91 (1.63)	178	0.01 (0.86)
Week 20	171	1.61 (1.58)	171	-0.23 (1.08)	178	1.96 (1.67)	178	0.06 (1.01)
Week 24	167	1.56 (1.59)	167	-0.30 (1.13)	175	1.78 (1.64)	175	-0.11 (1.00)
Week 28	164	1.59 (1.60)	164	-0.26 (1.11)	171	1.79 (1.68)	171	-0.13 (0.95)
Week 32	165	1.56 (1.61)	165	-0.27 (1.12)	171	1.75 (1.60)	171	-0.14 (1.01)
Week 36	163	1.60 (1.57)	163	-0.23 (1.03)	170	1.76 (1.64)	170	-0.13 (0.79)
Week 40	160	1.64 (1.63)	160	-0.21 (1.13)	167	1.75 (1.63)	167	-0.14 (0.97)
Week 44	155	1.66 (1.59)	155	-0.19 (1.09)	162	1.65 (1.62)	162	-0.21 (0.99)
Week 48	153	1.59 (1.58)	153	-0.29 (1.16)	158	1.78 (1.59)	158	-0.08 (1.06)
Week 52	154	1.61 (1.62)	154	-0.26 (1.14)	154	1.73 (1.57)	154	-0.16 (1.06)

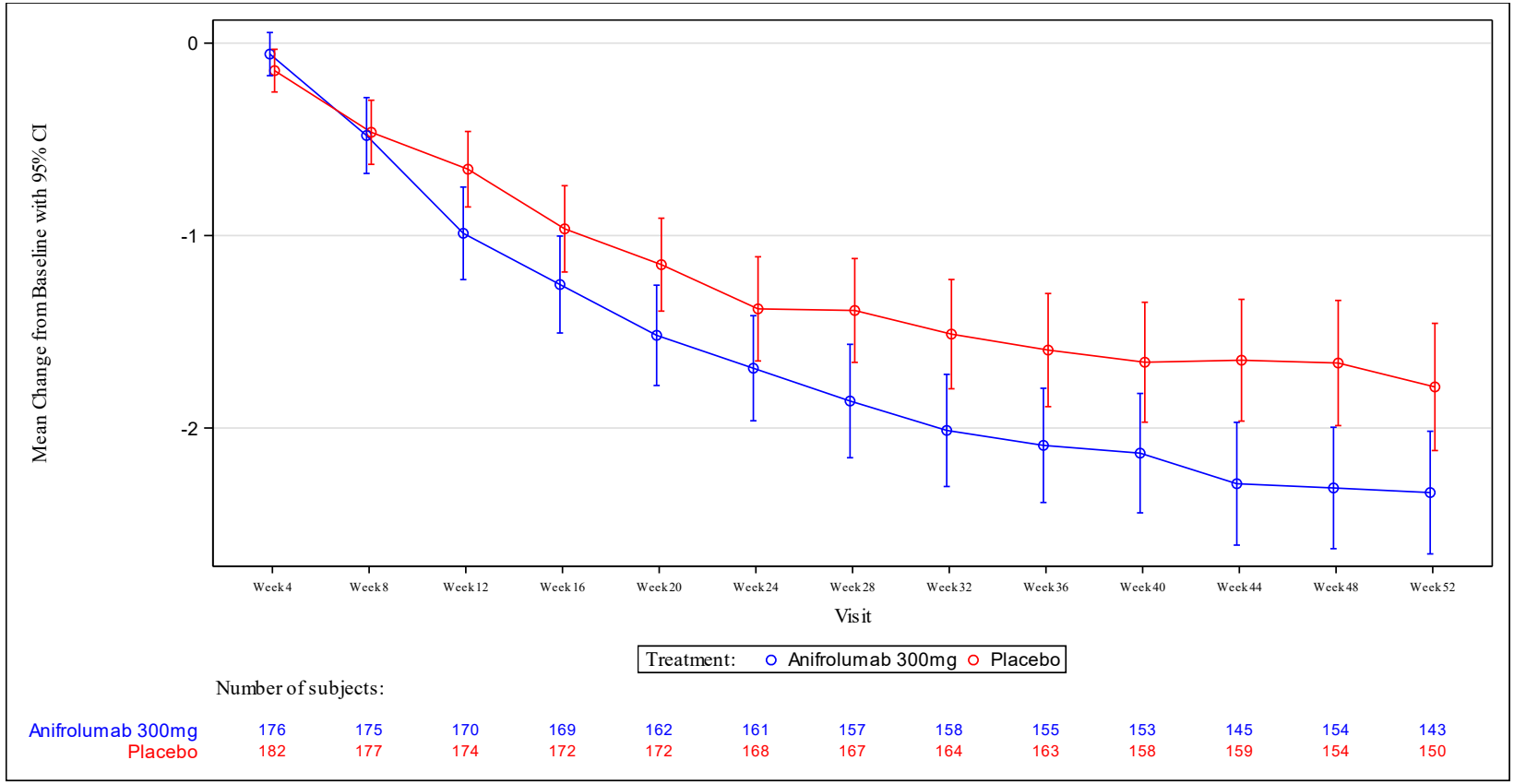
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Total Organ Score Immunology
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score Mucocutaneous
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=184)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	180	4.24 (1.53)	0	-	184	4.03 (1.57)	0	-
Week 4	176	4.23 (1.57)	176	-0.06 (0.75)	182	3.89 (1.54)	182	-0.14 (0.76)
Week 8	175	3.79 (1.69)	175	-0.48 (1.32)	177	3.60 (1.58)	177	-0.46 (1.12)
Week 12	170	3.29 (1.86)	170	-0.99 (1.59)	174	3.36 (1.69)	174	-0.66 (1.31)
Week 16	169	3.05 (1.90)	169	-1.25 (1.66)	172	3.08 (1.72)	172	-0.97 (1.49)
Week 20	162	2.77 (1.87)	162	-1.52 (1.68)	172	2.92 (1.69)	172	-1.15 (1.60)
Week 24	161	2.63 (1.90)	161	-1.69 (1.75)	168	2.74 (1.73)	168	-1.38 (1.78)
Week 28	157	2.48 (1.94)	157	-1.86 (1.87)	167	2.68 (1.75)	167	-1.39 (1.77)
Week 32	158	2.35 (1.85)	158	-2.01 (1.85)	164	2.61 (1.74)	164	-1.51 (1.84)
Week 36	155	2.23 (1.86)	155	-2.09 (1.87)	163	2.48 (1.72)	163	-1.60 (1.90)
Week 40	153	2.13 (1.91)	153	-2.13 (1.94)	158	2.37 (1.75)	158	-1.66 (1.98)
Week 44	145	1.99 (1.88)	145	-2.29 (1.94)	159	2.42 (1.79)	159	-1.65 (2.02)
Week 48	154	1.97 (1.90)	154	-2.31 (1.98)	154	2.38 (1.77)	154	-1.66 (2.04)
Week 52	143	1.96 (1.85)	143	-2.34 (1.93)	150	2.25 (1.72)	150	-1.79 (2.05)

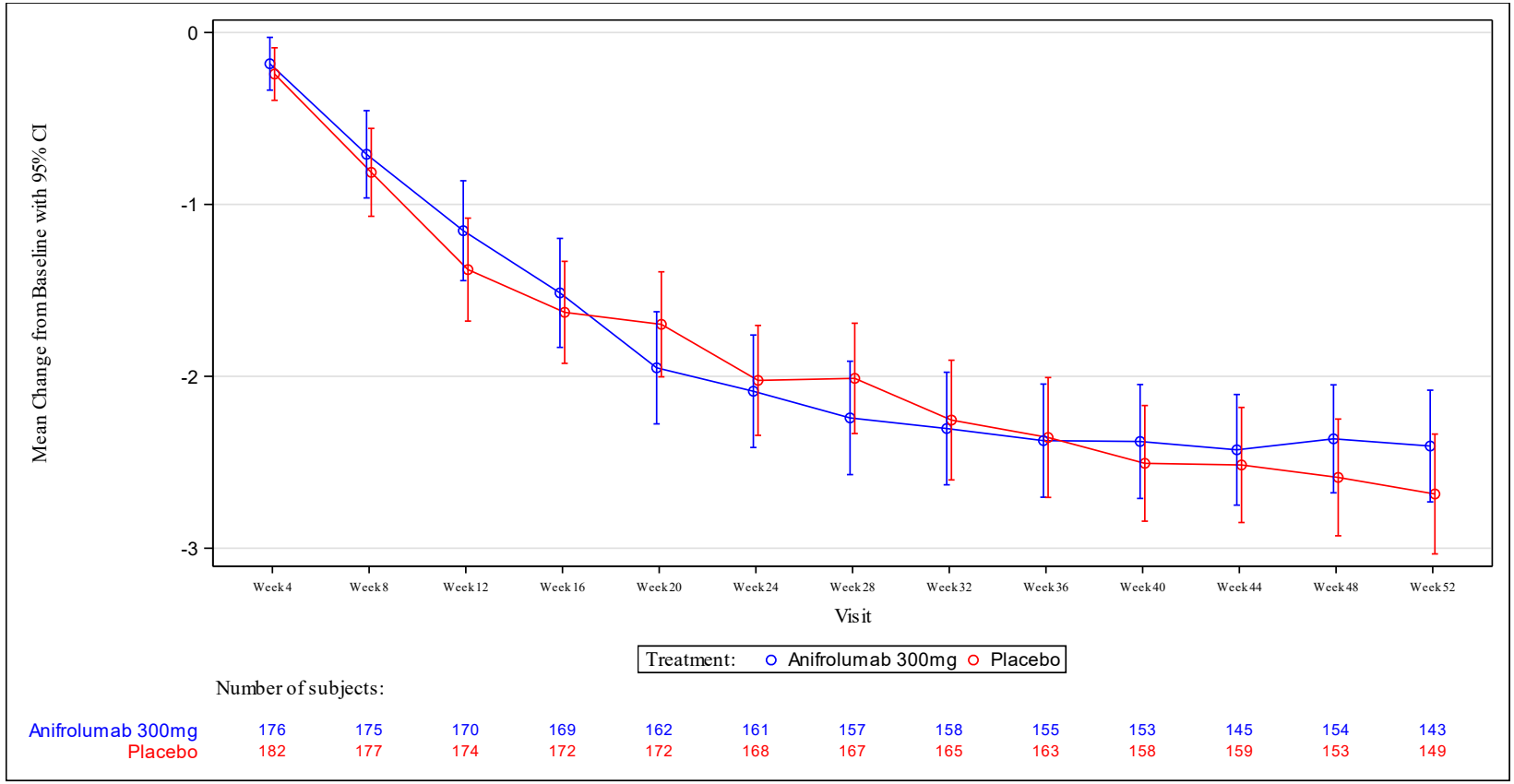
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Total Organ Score Mucocutaneous
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score Musculoskeletal
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=184)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	180	3.73 (1.09)	0	-	184	3.98 (0.98)	0	-
Week 4	176	3.55 (1.27)	176	-0.18 (1.03)	182	3.74 (1.30)	182	-0.24 (1.04)
Week 8	175	3.02 (1.73)	175	-0.71 (1.70)	177	3.16 (1.69)	177	-0.81 (1.72)
Week 12	170	2.59 (1.92)	170	-1.15 (1.92)	174	2.60 (1.96)	174	-1.38 (2.00)
Week 16	169	2.20 (2.09)	169	-1.51 (2.09)	172	2.40 (2.01)	172	-1.63 (1.97)
Week 20	162	1.75 (2.04)	162	-1.95 (2.10)	172	2.28 (2.03)	172	-1.70 (2.03)
Week 24	161	1.64 (2.02)	161	-2.09 (2.10)	168	1.95 (2.05)	168	-2.02 (2.10)
Week 28	157	1.50 (2.00)	157	-2.24 (2.09)	167	1.96 (2.05)	167	-2.01 (2.10)
Week 32	158	1.39 (1.91)	158	-2.30 (2.08)	165	1.72 (2.08)	165	-2.25 (2.26)
Week 36	155	1.32 (1.89)	155	-2.37 (2.07)	163	1.62 (2.11)	163	-2.36 (2.25)
Week 40	153	1.31 (1.88)	153	-2.38 (2.07)	158	1.49 (1.99)	158	-2.51 (2.14)
Week 44	145	1.21 (1.85)	145	-2.43 (1.96)	159	1.46 (1.98)	159	-2.52 (2.14)
Week 48	154	1.32 (1.89)	154	-2.36 (1.97)	153	1.39 (1.96)	153	-2.59 (2.13)
Week 52	143	1.34 (1.90)	143	-2.41 (1.97)	149	1.29 (1.93)	149	-2.68 (2.15)

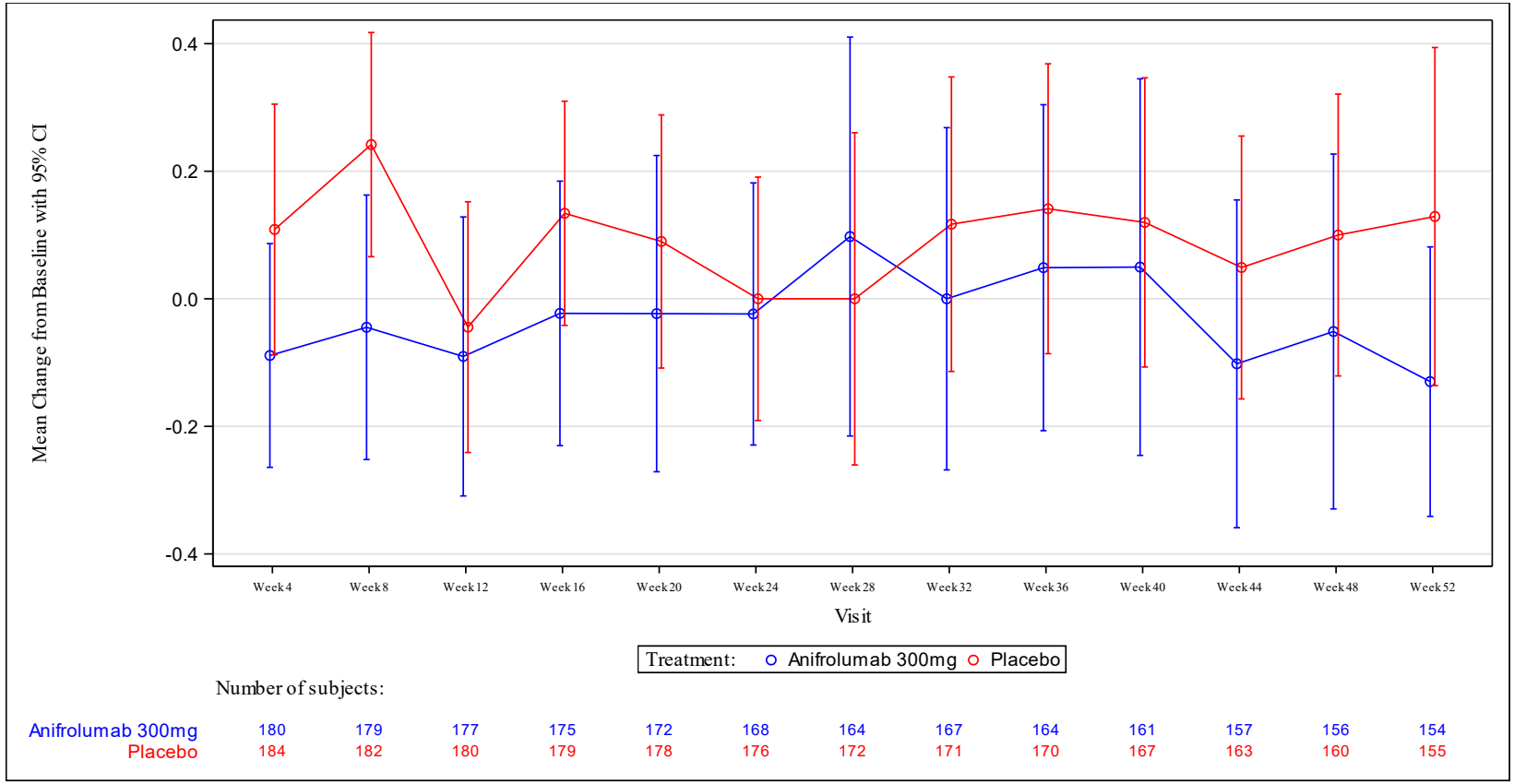
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Total Organ Score Musculoskeletal
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score Renal
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=184)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	180	0.42 (1.55)	0	-	184	0.48 (1.71)	0	-
Week 4	180	0.33 (1.26)	180	-0.09 (1.19)	184	0.59 (2.15)	184	0.11 (1.35)
Week 8	179	0.38 (1.45)	179	-0.04 (1.41)	182	0.73 (2.21)	182	0.24 (1.20)
Week 12	177	0.34 (1.34)	177	-0.09 (1.47)	180	0.38 (1.38)	180	-0.04 (1.34)
Week 16	175	0.41 (1.49)	175	-0.02 (1.39)	179	0.56 (1.93)	179	0.13 (1.19)
Week 20	172	0.40 (1.48)	172	-0.02 (1.65)	178	0.52 (1.90)	178	0.09 (1.34)
Week 24	168	0.36 (1.44)	168	-0.02 (1.35)	176	0.45 (1.59)	176	0.00 (1.28)
Week 28	164	0.46 (1.95)	164	0.10 (2.03)	172	0.47 (1.67)	172	0.00 (1.73)
Week 32	167	0.38 (1.47)	167	0.00 (1.76)	171	0.51 (1.77)	171	0.12 (1.53)
Week 36	164	0.44 (1.72)	164	0.05 (1.66)	170	0.54 (1.79)	170	0.14 (1.50)
Week 40	161	0.45 (1.79)	161	0.05 (1.90)	167	0.53 (1.89)	167	0.12 (1.48)
Week 44	157	0.31 (1.47)	157	-0.10 (1.63)	163	0.47 (1.91)	163	0.05 (1.33)
Week 48	156	0.36 (1.60)	156	-0.05 (1.76)	160	0.53 (1.91)	160	0.10 (1.42)
Week 52	154	0.29 (1.38)	154	-0.13 (1.33)	155	0.52 (1.86)	155	0.13 (1.67)

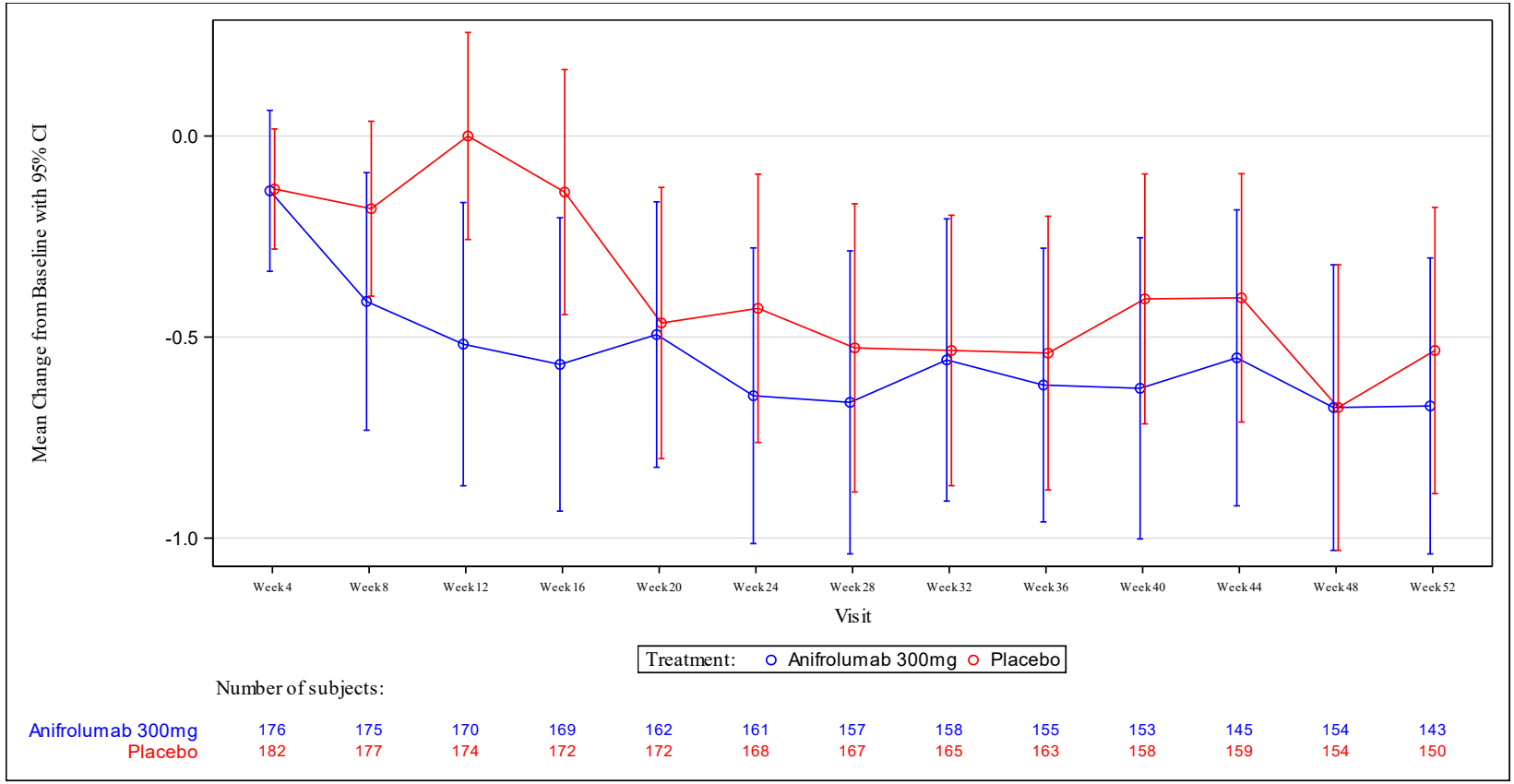
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Total Organ Score Renal
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score Vascular
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=184)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	180	0.80 (2.41)	0	-	184	0.78 (2.38)	0	-
Week 4	176	0.68 (2.24)	176	-0.14 (1.35)	182	0.66 (2.21)	182	-0.13 (1.02)
Week 8	175	0.41 (1.77)	175	-0.41 (2.15)	177	0.63 (2.17)	177	-0.18 (1.47)
Week 12	170	0.24 (1.36)	170	-0.52 (2.33)	174	0.78 (2.38)	174	0.00 (1.72)
Week 16	169	0.28 (1.48)	169	-0.57 (2.40)	172	0.65 (2.19)	172	-0.14 (2.02)
Week 20	162	0.25 (1.39)	162	-0.49 (2.13)	172	0.37 (1.69)	172	-0.47 (2.24)
Week 24	161	0.25 (1.39)	161	-0.65 (2.36)	168	0.29 (1.49)	168	-0.43 (2.19)
Week 28	157	0.25 (1.41)	157	-0.66 (2.39)	167	0.34 (1.61)	167	-0.53 (2.35)
Week 32	158	0.25 (1.40)	158	-0.56 (2.23)	165	0.29 (1.50)	165	-0.53 (2.19)
Week 36	155	0.26 (1.42)	155	-0.62 (2.14)	163	0.25 (1.38)	163	-0.54 (2.20)
Week 40	153	0.16 (1.11)	153	-0.63 (2.34)	158	0.30 (1.53)	158	-0.41 (1.98)
Week 44	145	0.22 (1.31)	145	-0.55 (2.24)	159	0.30 (1.53)	159	-0.40 (1.97)
Week 48	154	0.16 (1.11)	154	-0.68 (2.23)	154	0.10 (0.91)	154	-0.68 (2.23)
Week 52	143	0.11 (0.94)	143	-0.67 (2.23)	150	0.21 (1.29)	150	-0.53 (2.21)

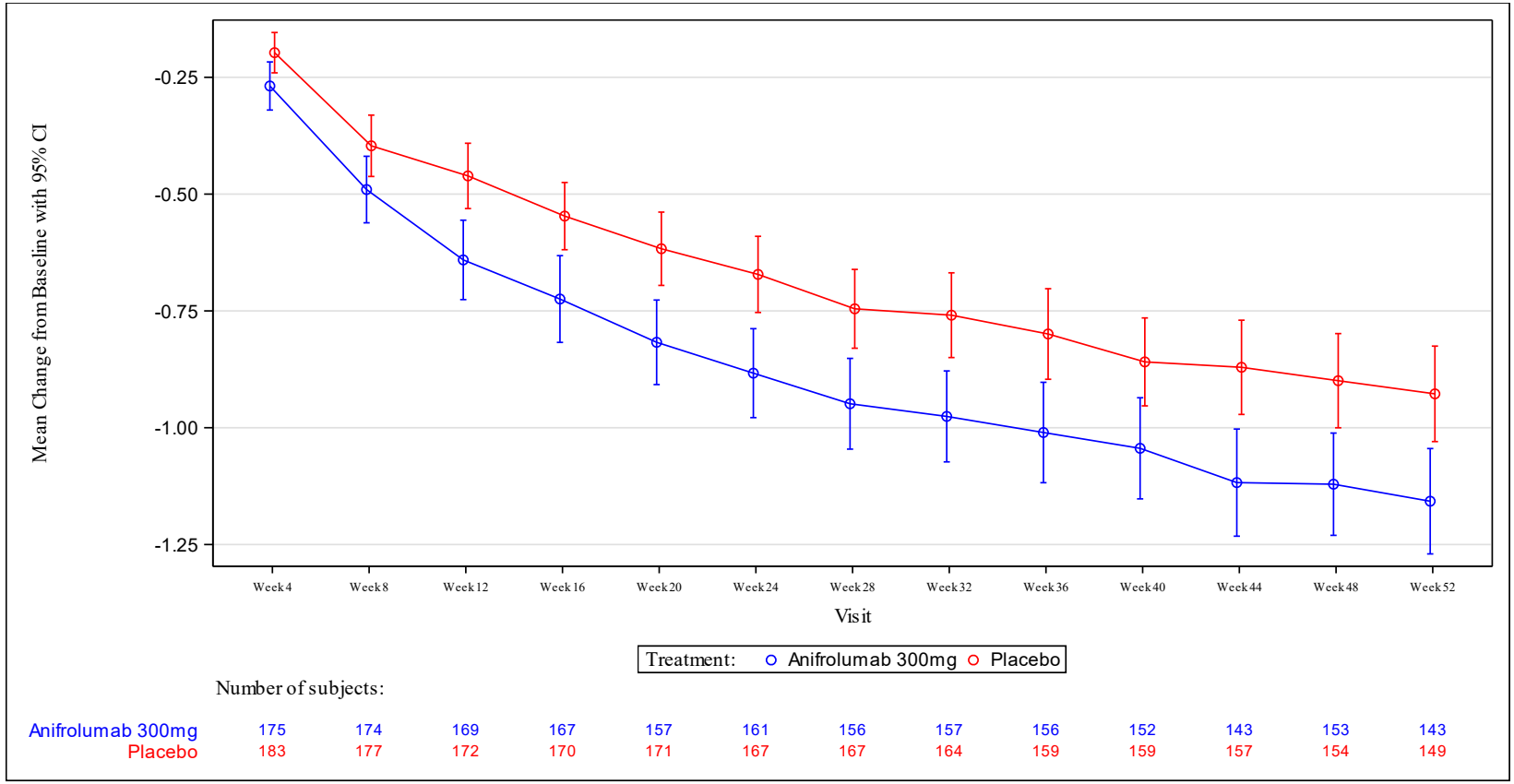
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Total Organ Score Vascular
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - PGA
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=184)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	180	1.87 (0.40)	0	-	184	1.84 (0.38)	0	-
Week 4	175	1.60 (0.52)	175	-0.27 (0.35)	183	1.64 (0.44)	183	-0.20 (0.30)
Week 8	174	1.38 (0.55)	174	-0.49 (0.48)	177	1.45 (0.52)	177	-0.40 (0.44)
Week 12	169	1.23 (0.58)	169	-0.64 (0.56)	172	1.38 (0.53)	172	-0.46 (0.46)
Week 16	167	1.14 (0.61)	167	-0.72 (0.61)	170	1.29 (0.53)	170	-0.55 (0.48)
Week 20	157	1.05 (0.60)	157	-0.82 (0.57)	171	1.23 (0.55)	171	-0.62 (0.52)
Week 24	161	0.98 (0.63)	161	-0.88 (0.61)	167	1.15 (0.54)	167	-0.67 (0.53)
Week 28	156	0.92 (0.63)	156	-0.95 (0.61)	167	1.09 (0.55)	167	-0.75 (0.55)
Week 32	157	0.89 (0.59)	157	-0.98 (0.62)	164	1.08 (0.58)	164	-0.76 (0.59)
Week 36	156	0.86 (0.62)	156	-1.01 (0.68)	159	1.02 (0.60)	159	-0.80 (0.62)
Week 40	152	0.82 (0.60)	152	-1.04 (0.68)	159	0.97 (0.55)	159	-0.86 (0.60)
Week 44	143	0.74 (0.60)	143	-1.12 (0.69)	157	0.96 (0.59)	157	-0.87 (0.64)
Week 48	153	0.73 (0.59)	153	-1.12 (0.69)	154	0.93 (0.58)	154	-0.90 (0.63)
Week 52	143	0.69 (0.59)	143	-1.16 (0.68)	149	0.90 (0.58)	149	-0.93 (0.63)

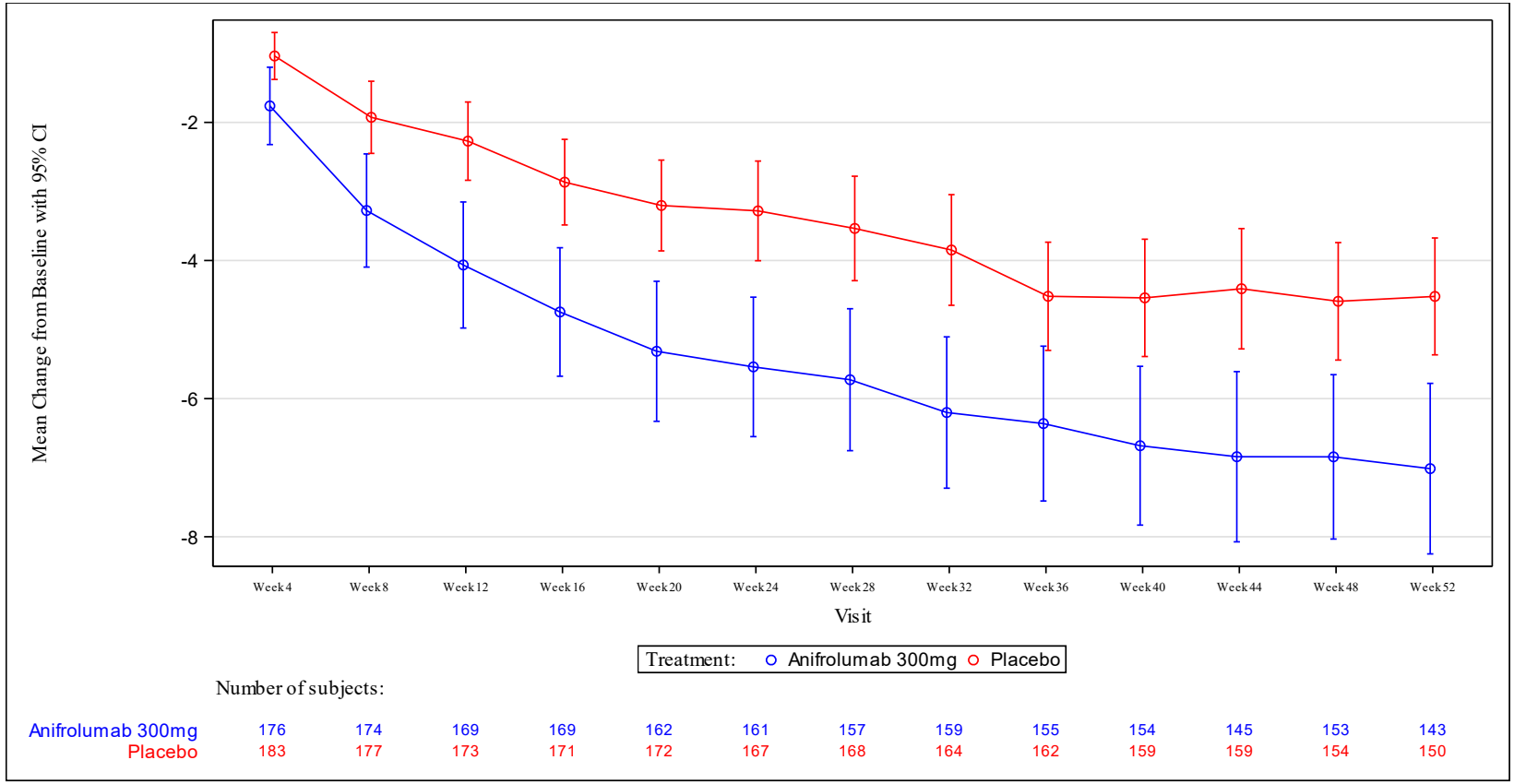
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - PGA
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - CLASI Total Activity Score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=184)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	180	8.54 (7.26)	0	-	184	8.07 (6.66)	0	-
Week 4	176	6.90 (6.07)	176	-1.76 (3.76)	183	7.05 (5.97)	183	-1.04 (2.33)
Week 8	174	5.37 (4.76)	174	-3.28 (5.48)	177	6.29 (6.07)	177	-1.93 (3.52)
Week 12	169	4.62 (4.66)	169	-4.07 (6.01)	173	5.82 (5.90)	173	-2.27 (3.78)
Week 16	169	4.02 (4.05)	169	-4.75 (6.13)	171	5.09 (5.08)	171	-2.87 (4.11)
Week 20	162	3.53 (3.65)	162	-5.31 (6.53)	172	5.10 (5.72)	172	-3.20 (4.37)
Week 24	161	3.29 (3.74)	161	-5.54 (6.49)	167	5.07 (6.23)	167	-3.28 (4.72)
Week 28	157	3.02 (3.31)	157	-5.73 (6.52)	168	4.82 (6.05)	168	-3.54 (4.96)
Week 32	159	2.85 (3.30)	159	-6.20 (7.00)	164	4.57 (5.56)	164	-3.85 (5.20)
Week 36	155	2.61 (3.06)	155	-6.36 (7.06)	162	3.96 (4.77)	162	-4.52 (5.05)
Week 40	154	2.36 (2.89)	154	-6.68 (7.22)	159	3.84 (4.71)	159	-4.54 (5.42)
Week 44	145	2.26 (2.83)	145	-6.84 (7.51)	159	3.92 (5.35)	159	-4.41 (5.56)
Week 48	153	2.18 (2.70)	153	-6.84 (7.45)	154	3.77 (4.91)	154	-4.59 (5.34)
Week 52	143	2.13 (2.82)	143	-7.01 (7.47)	150	3.60 (4.99)	150	-4.52 (5.24)

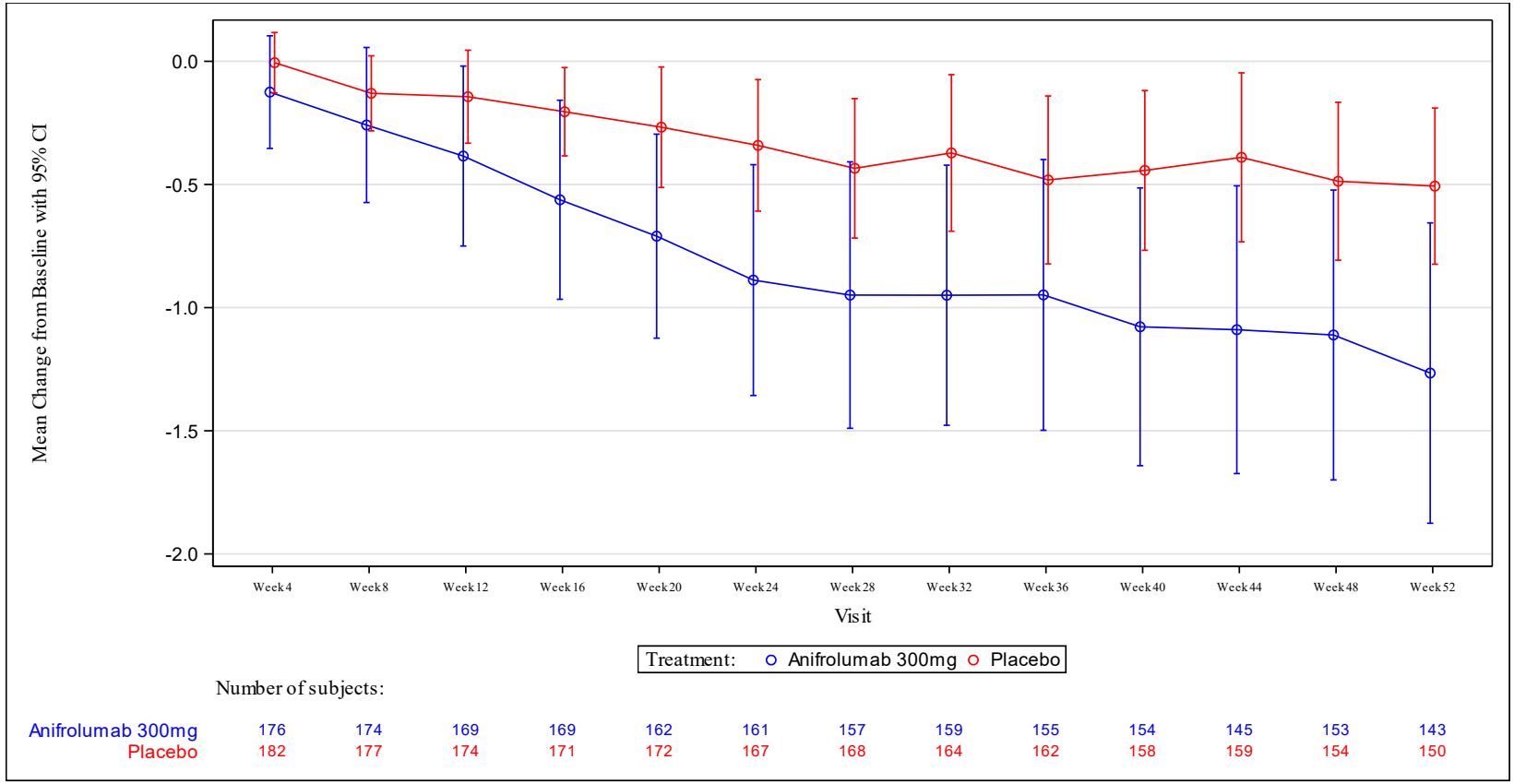
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - CLASI Total Activity Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - CLASI Total Damage Score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=184)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	180	1.97 (4.38)	0	-	184	1.80 (4.08)	0	-
Week 4	176	1.89 (4.27)	176	-0.13 (1.54)	182	1.77 (4.09)	182	-0.01 (0.84)
Week 8	174	1.75 (3.93)	174	-0.26 (2.10)	177	1.73 (4.08)	177	-0.13 (1.03)
Week 12	169	1.61 (3.93)	169	-0.38 (2.41)	174	1.67 (4.16)	174	-0.14 (1.26)
Week 16	169	1.51 (3.60)	169	-0.56 (2.66)	171	1.53 (3.86)	171	-0.20 (1.19)
Week 20	162	1.31 (2.92)	162	-0.71 (2.67)	172	1.60 (3.97)	172	-0.27 (1.63)
Week 24	161	1.09 (2.75)	161	-0.89 (3.01)	167	1.58 (3.72)	167	-0.34 (1.75)
Week 28	157	1.01 (2.38)	157	-0.95 (3.43)	168	1.46 (3.60)	168	-0.43 (1.86)
Week 32	159	1.06 (2.35)	159	-0.95 (3.37)	164	1.48 (3.58)	164	-0.37 (2.06)
Week 36	155	1.01 (2.27)	155	-0.95 (3.46)	162	1.44 (3.37)	162	-0.48 (2.20)
Week 40	154	0.94 (2.23)	154	-1.08 (3.54)	158	1.34 (3.36)	158	-0.44 (2.06)
Week 44	145	1.03 (2.29)	145	-1.09 (3.56)	159	1.40 (3.41)	159	-0.39 (2.19)
Week 48	153	0.93 (2.09)	153	-1.11 (3.68)	154	1.36 (3.31)	154	-0.49 (2.01)
Week 52	143	0.89 (2.09)	143	-1.27 (3.69)	150	1.25 (3.21)	150	-0.51 (1.97)

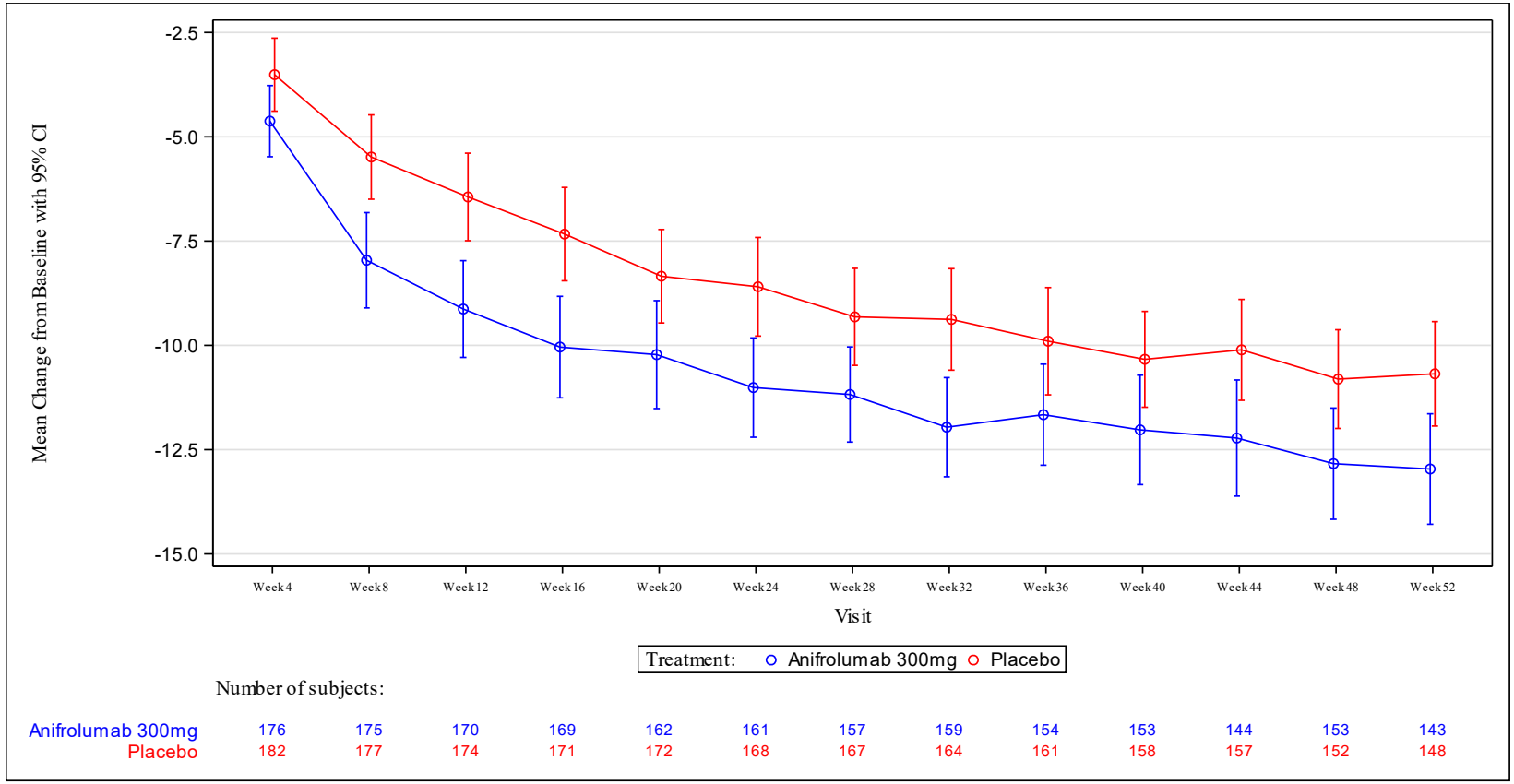
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - CLASI Total Damage Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - BILAG Global Score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=184)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	180	19.84 (6.28)	0	-	184	18.91 (5.45)	0	-
Week 4	176	15.24 (7.26)	176	-4.63 (5.74)	182	15.36 (6.79)	182	-3.51 (5.98)
Week 8	175	11.82 (7.69)	175	-7.96 (7.66)	177	13.44 (7.29)	177	-5.49 (6.82)
Week 12	170	10.59 (7.68)	170	-9.13 (7.66)	174	12.44 (7.21)	174	-6.44 (7.01)
Week 16	169	9.69 (8.22)	169	-10.04 (8.01)	171	11.70 (7.56)	171	-7.33 (7.42)
Week 20	162	9.44 (8.16)	162	-10.22 (8.34)	172	10.60 (7.54)	172	-8.34 (7.44)
Week 24	161	8.80 (8.00)	161	-11.01 (7.65)	168	10.33 (7.47)	168	-8.60 (7.76)
Week 28	157	8.60 (7.81)	157	-11.18 (7.23)	167	9.59 (7.61)	167	-9.32 (7.61)
Week 32	159	7.95 (7.38)	159	-11.96 (7.59)	164	9.59 (7.52)	164	-9.38 (7.89)
Week 36	154	8.29 (7.87)	154	-11.66 (7.61)	161	8.89 (7.63)	161	-9.90 (8.26)
Week 40	153	7.67 (7.84)	153	-12.03 (8.21)	158	8.78 (7.09)	158	-10.34 (7.31)
Week 44	144	7.49 (7.82)	144	-12.22 (8.45)	157	8.90 (7.14)	157	-10.11 (7.67)
Week 48	153	6.95 (7.51)	153	-12.84 (8.35)	152	8.22 (6.73)	152	-10.81 (7.38)
Week 52	143	6.84 (7.18)	143	-12.97 (8.01)	148	8.30 (6.87)	148	-10.68 (7.71)

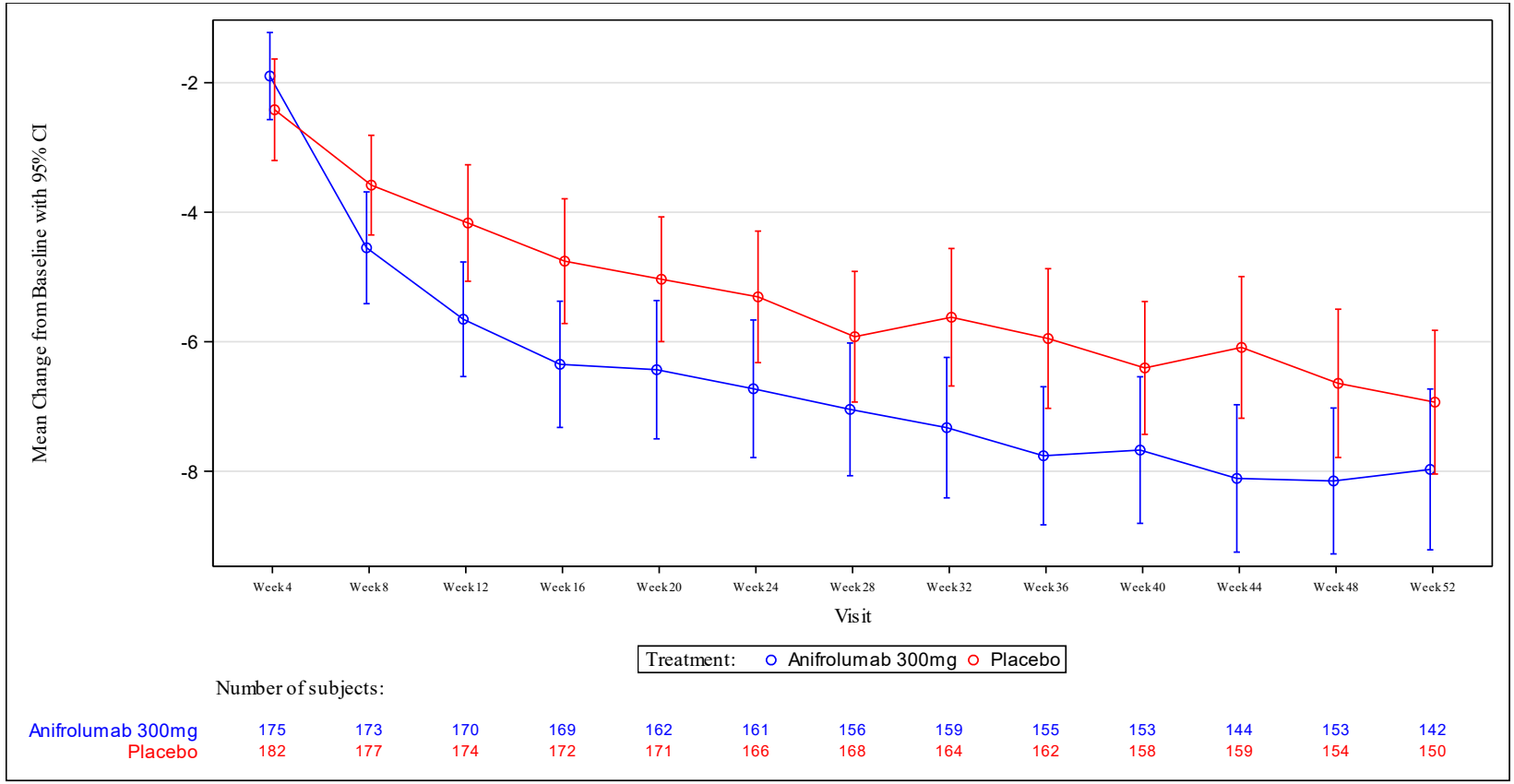
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - BILAG Global Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Tender Joint Count
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=184)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	180	11.66 (7.50)	0	-	184	10.56 (7.17)	0	-
Week 4	175	9.74 (7.85)	175	-1.90 (4.51)	182	8.12 (7.25)	182	-2.42 (5.36)
Week 8	173	7.21 (7.18)	173	-4.55 (5.75)	177	7.02 (6.82)	177	-3.58 (5.19)
Week 12	170	6.14 (6.95)	170	-5.65 (5.84)	174	6.30 (7.17)	174	-4.17 (6.01)
Week 16	169	5.33 (7.23)	169	-6.35 (6.42)	172	5.85 (6.74)	172	-4.76 (6.40)
Week 20	162	5.17 (7.49)	162	-6.43 (6.88)	171	5.47 (6.74)	171	-5.04 (6.38)
Week 24	161	5.06 (7.44)	161	-6.73 (6.83)	166	4.90 (6.71)	166	-5.31 (6.63)
Week 28	156	4.63 (6.89)	156	-7.04 (6.48)	168	4.48 (6.46)	168	-5.92 (6.62)
Week 32	159	4.48 (6.66)	159	-7.33 (6.92)	164	4.81 (7.05)	164	-5.62 (6.89)
Week 36	155	4.08 (6.34)	155	-7.76 (6.72)	162	4.48 (7.12)	162	-5.95 (6.95)
Week 40	153	3.92 (6.39)	153	-7.67 (7.09)	158	4.12 (6.26)	158	-6.41 (6.53)
Week 44	144	3.35 (5.45)	144	-8.11 (6.91)	159	4.07 (6.52)	159	-6.09 (6.98)
Week 48	153	3.65 (5.89)	153	-8.15 (7.05)	154	3.76 (5.82)	154	-6.64 (7.19)
Week 52	142	4.06 (6.75)	142	-7.97 (7.49)	150	3.35 (5.69)	150	-6.93 (6.88)

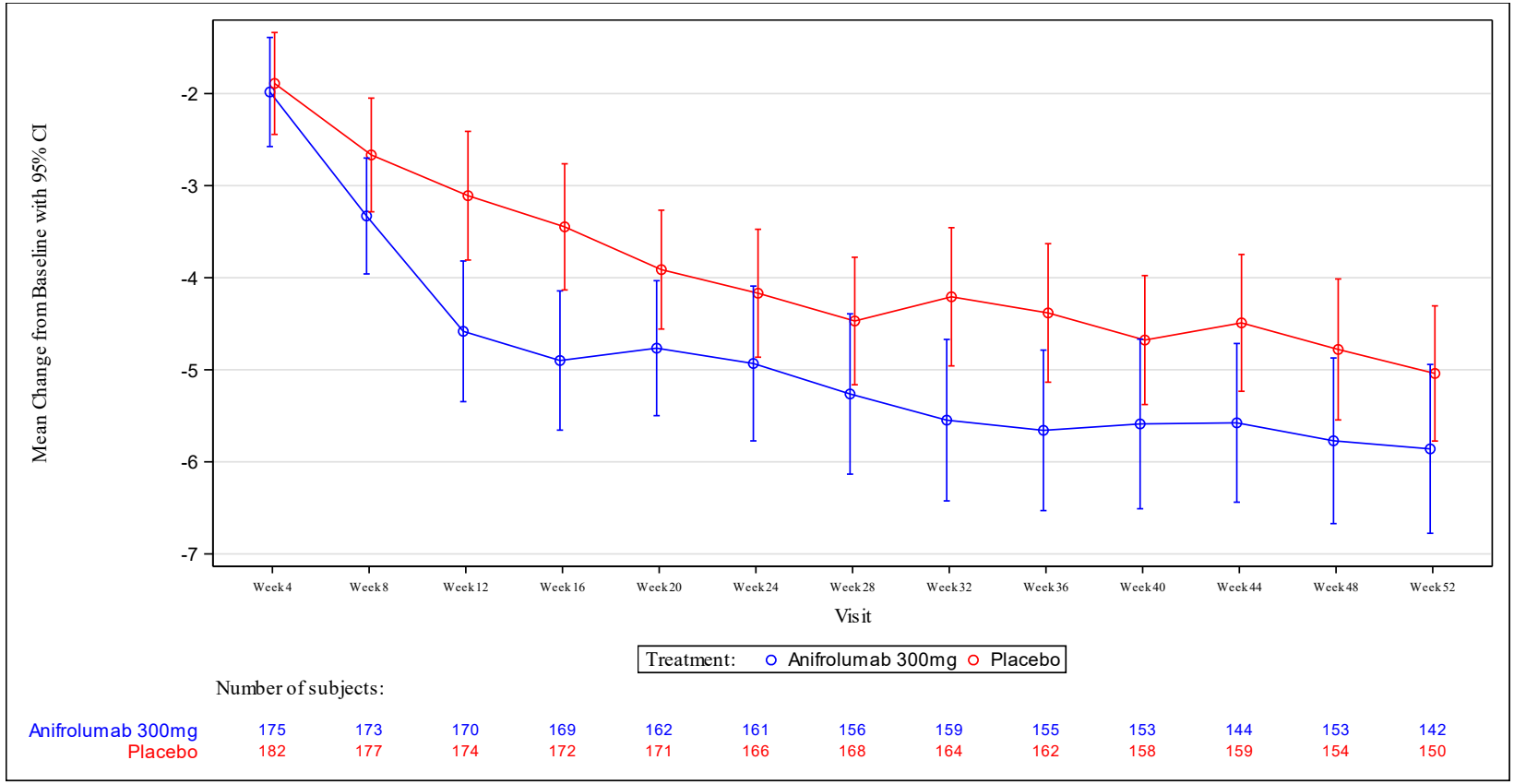
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Tender Joint Count
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Swollen Joint Count
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=184)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	180	7.37 (5.79)	0	-	184	7.01 (4.80)	0	-
Week 4	175	5.37 (5.35)	175	-1.98 (3.97)	182	5.09 (5.21)	182	-1.89 (3.78)
Week 8	173	4.04 (4.84)	173	-3.33 (4.19)	177	4.33 (4.98)	177	-2.67 (4.16)
Week 12	170	2.92 (3.88)	170	-4.58 (5.04)	174	3.76 (4.91)	174	-3.11 (4.67)
Week 16	169	2.54 (4.20)	169	-4.90 (4.98)	172	3.60 (4.65)	172	-3.45 (4.55)
Week 20	162	2.39 (4.39)	162	-4.77 (4.72)	171	3.08 (4.34)	171	-3.91 (4.28)
Week 24	161	2.48 (4.73)	161	-4.93 (5.40)	166	2.56 (3.91)	166	-4.17 (4.53)
Week 28	156	2.15 (4.23)	156	-5.26 (5.50)	168	2.55 (3.91)	168	-4.47 (4.55)
Week 32	159	1.87 (3.71)	159	-5.55 (5.60)	164	2.73 (4.28)	164	-4.21 (4.87)
Week 36	155	1.84 (3.49)	155	-5.66 (5.49)	162	2.51 (4.21)	162	-4.38 (4.85)
Week 40	153	1.76 (3.59)	153	-5.59 (5.77)	158	2.15 (3.19)	158	-4.68 (4.46)
Week 44	144	1.63 (3.42)	144	-5.58 (5.23)	159	2.34 (3.93)	159	-4.49 (4.74)
Week 48	153	1.69 (3.60)	153	-5.77 (5.63)	154	2.05 (3.56)	154	-4.78 (4.81)
Week 52	142	1.72 (3.40)	142	-5.86 (5.53)	150	1.82 (3.14)	150	-5.04 (4.55)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Swollen Joint Count
Full analysis set



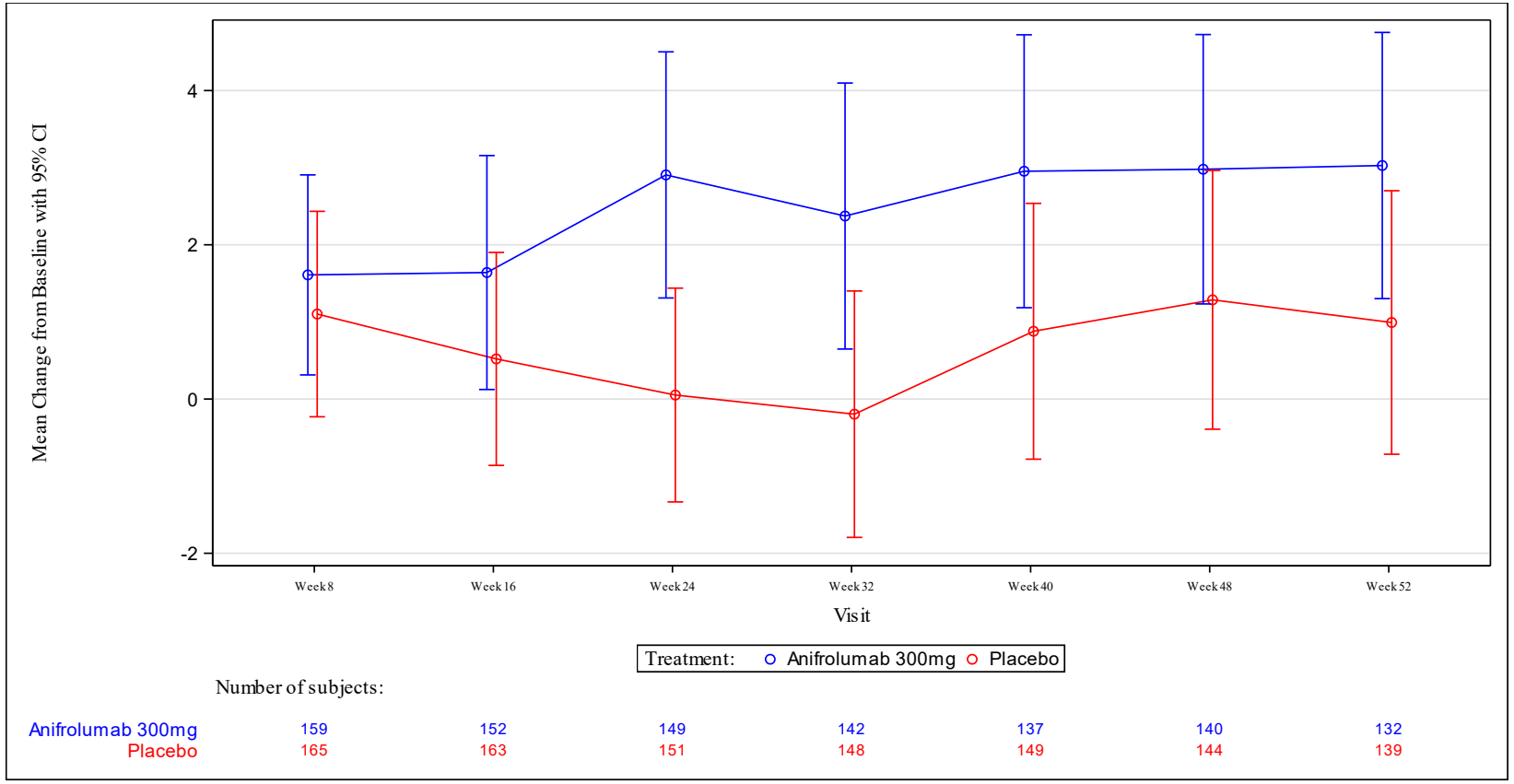
Number of subjects:

	Week 4	Week 8	Week 12	Week 16	Week 20	Week 24	Week 28	Week 32	Week 36	Week 40	Week 44	Week 48	Week 52
Anifrolumab 300mg	175	173	170	169	162	161	156	159	155	153	144	153	142
Placebo	182	177	174	172	171	166	168	164	162	158	159	154	150

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Mental Component Score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=184)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	172	43.34 (11.47)	0	-	175	44.99 (11.24)	0	-
Week 8	162	45.28 (11.00)	159	1.61 (8.28)	173	45.75 (10.67)	165	1.10 (8.67)
Week 16	156	45.13 (11.58)	152	1.64 (9.46)	170	45.25 (10.76)	163	0.52 (8.93)
Week 24	155	45.52 (11.89)	149	2.91 (9.86)	158	44.81 (10.64)	151	0.05 (8.62)
Week 32	148	44.99 (11.36)	142	2.37 (10.40)	154	44.69 (11.32)	148	-0.20 (9.84)
Week 40	143	46.00 (11.32)	137	2.95 (10.47)	155	45.99 (11.42)	149	0.88 (10.25)
Week 48	146	45.90 (11.07)	140	2.98 (10.45)	148	46.23 (10.92)	144	1.29 (10.18)
Week 52	138	46.10 (11.14)	132	3.03 (10.02)	144	45.85 (11.53)	139	0.99 (10.19)

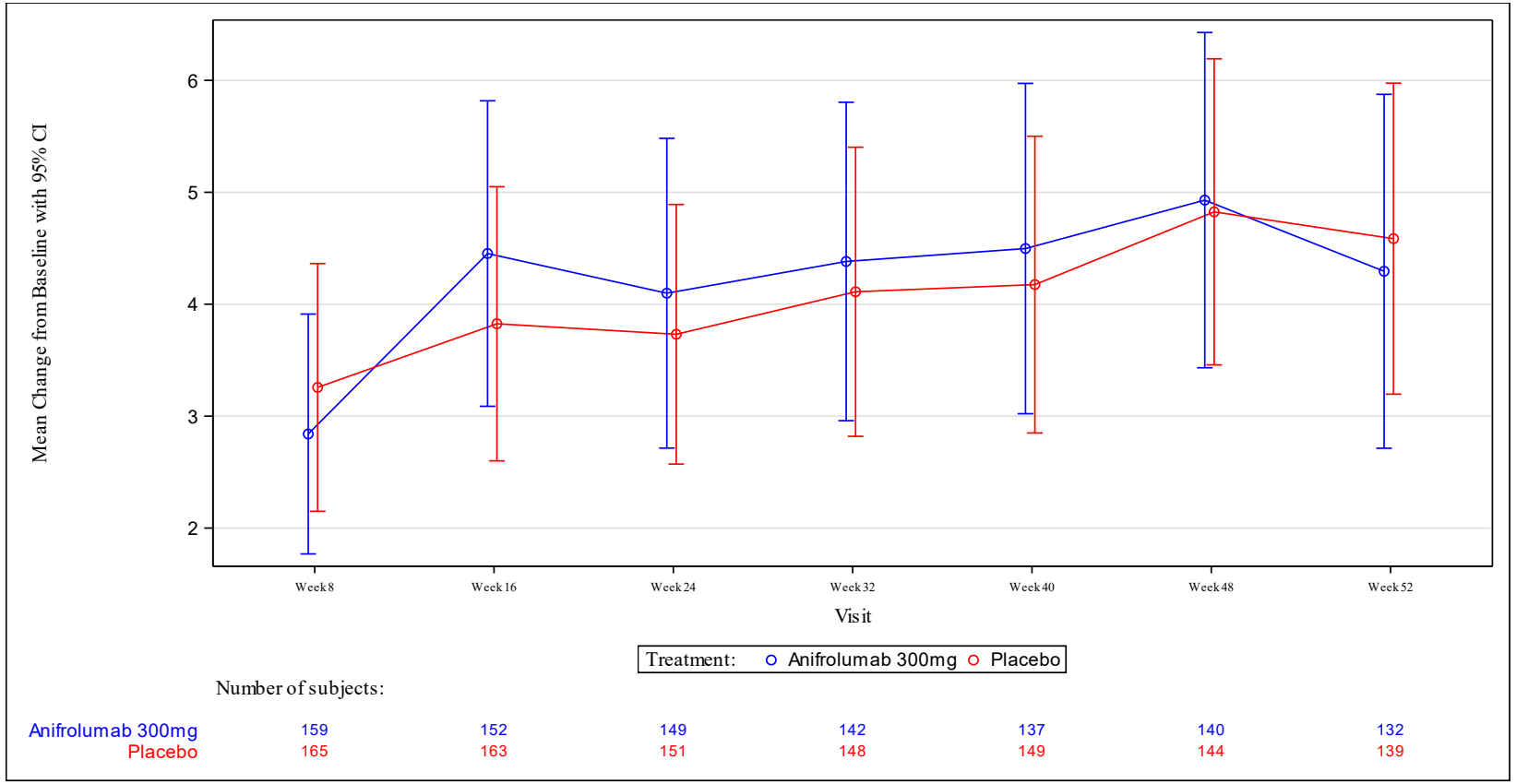
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Mental Component Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Physical Component Score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=184)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	172	36.93 (9.46)	0	-	175	37.13 (9.13)	0	-
Week 8	162	40.09 (8.94)	159	2.84 (6.84)	173	40.14 (8.70)	165	3.26 (7.20)
Week 16	156	41.77 (10.07)	152	4.45 (8.52)	170	40.67 (9.34)	163	3.82 (7.92)
Week 24	155	41.35 (9.91)	149	4.10 (8.55)	158	41.18 (8.92)	151	3.73 (7.21)
Week 32	148	41.77 (9.71)	142	4.38 (8.57)	154	41.53 (9.09)	148	4.11 (7.95)
Week 40	143	42.33 (10.36)	137	4.50 (8.73)	155	41.06 (9.63)	149	4.18 (8.19)
Week 48	146	42.71 (10.33)	140	4.93 (8.96)	148	41.92 (9.86)	144	4.82 (8.30)
Week 52	138	41.86 (9.88)	132	4.29 (9.18)	144	41.83 (9.19)	139	4.59 (8.28)

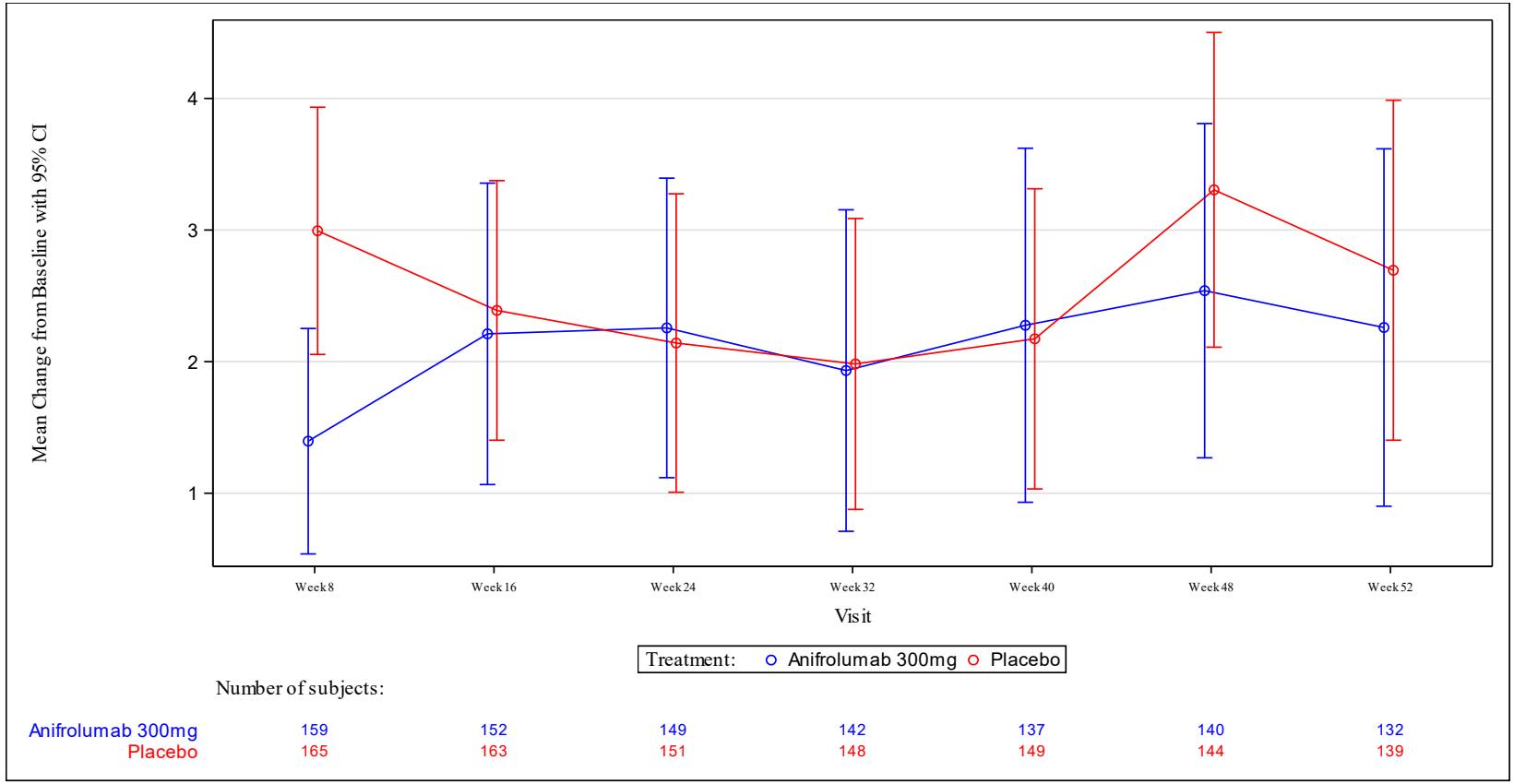
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Physical Component Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute General Health Score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=184)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	172	37.56 (8.13)	0	-	175	38.63 (8.21)	0	-
Week 8	162	39.32 (7.80)	159	1.40 (5.47)	173	41.32 (8.49)	165	2.99 (6.11)
Week 16	156	40.20 (9.06)	152	2.21 (7.15)	170	40.69 (8.28)	163	2.39 (6.38)
Week 24	155	39.79 (9.43)	149	2.26 (7.03)	158	40.98 (8.46)	151	2.14 (7.05)
Week 32	148	39.72 (9.72)	142	1.93 (7.36)	154	41.13 (8.50)	148	1.98 (6.80)
Week 40	143	40.57 (9.59)	137	2.28 (7.96)	155	41.11 (9.02)	149	2.17 (7.04)
Week 48	146	40.58 (9.34)	140	2.54 (7.60)	148	42.27 (9.30)	144	3.31 (7.26)
Week 52	138	40.09 (9.23)	132	2.26 (7.89)	144	41.97 (9.22)	139	2.69 (7.70)

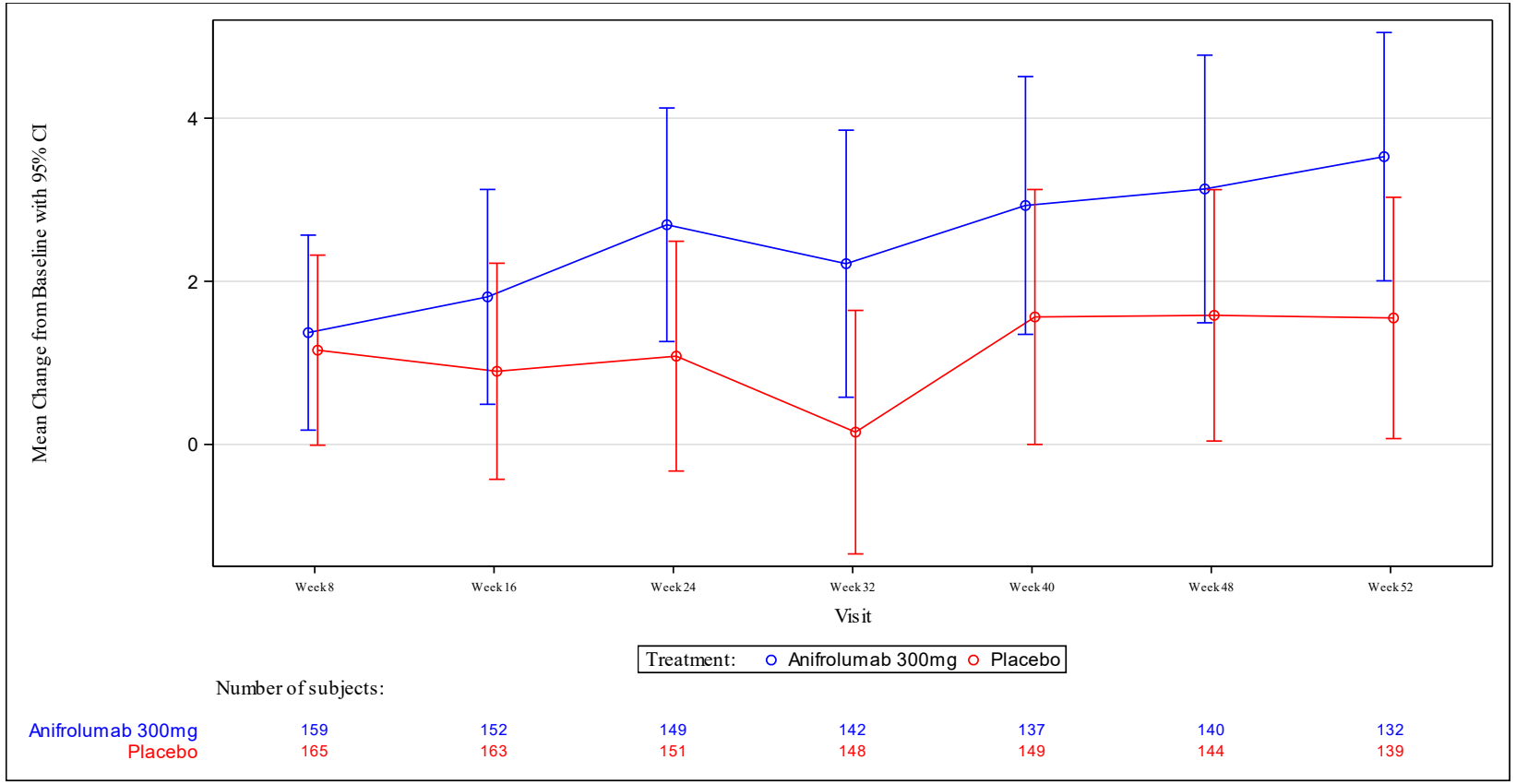
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute General Health Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Mental Health Score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=184)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	172	43.60 (10.65)	0	-	175	44.44 (10.46)	0	-
Week 8	162	45.25 (10.16)	159	1.37 (7.63)	173	45.50 (9.82)	165	1.16 (7.58)
Week 16	156	45.59 (11.06)	152	1.81 (8.22)	170	45.16 (10.54)	163	0.90 (8.56)
Week 24	155	45.67 (11.34)	149	2.69 (8.84)	158	45.33 (9.94)	151	1.08 (8.76)
Week 32	148	45.15 (10.77)	142	2.22 (9.87)	154	44.72 (10.19)	148	0.15 (9.19)
Week 40	143	46.28 (10.27)	137	2.93 (9.35)	155	46.23 (10.40)	149	1.56 (9.65)
Week 48	146	46.20 (10.09)	140	3.13 (9.82)	148	45.88 (10.64)	144	1.58 (9.36)
Week 52	138	46.55 (10.60)	132	3.53 (8.84)	144	45.80 (10.61)	139	1.55 (8.82)

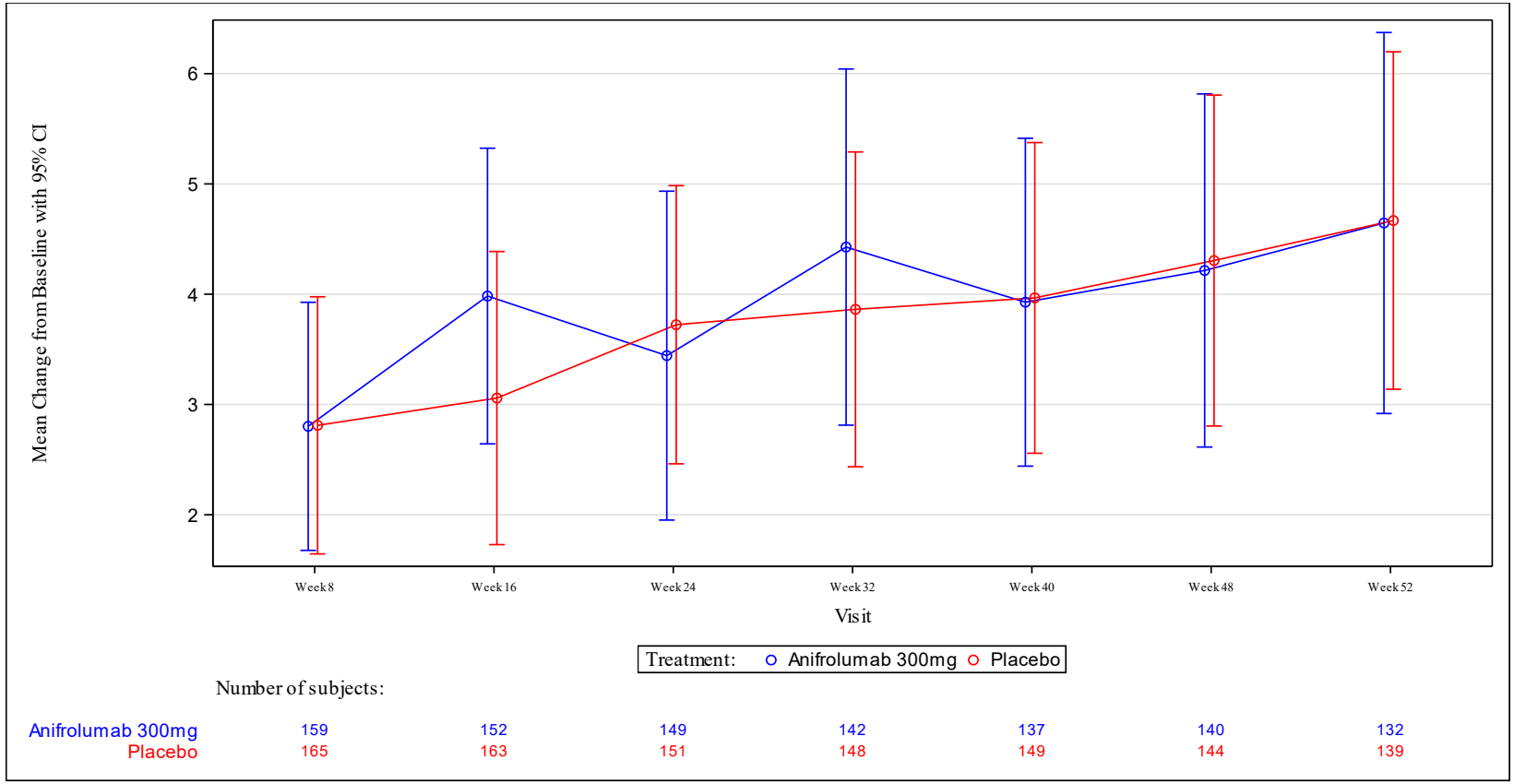
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Mental Health Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Physical Functioning Score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=184)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	172	38.57 (10.44)	0	-	175	38.65 (9.83)	0	-
Week 8	162	41.94 (9.74)	159	2.80 (7.18)	173	41.26 (9.11)	165	2.81 (7.58)
Week 16	156	42.85 (10.65)	152	3.98 (8.36)	170	41.53 (10.16)	163	3.06 (8.59)
Week 24	155	42.28 (10.97)	149	3.44 (9.21)	158	42.55 (9.62)	151	3.72 (7.85)
Week 32	148	43.31 (10.27)	142	4.43 (9.74)	154	42.67 (9.55)	148	3.86 (8.79)
Week 40	143	43.41 (10.86)	137	3.93 (8.80)	155	42.19 (10.37)	149	3.97 (8.70)
Week 48	146	43.65 (10.72)	140	4.21 (9.58)	148	42.61 (10.93)	144	4.31 (9.11)
Week 52	138	43.94 (10.31)	132	4.65 (10.03)	144	43.02 (9.98)	139	4.67 (9.12)

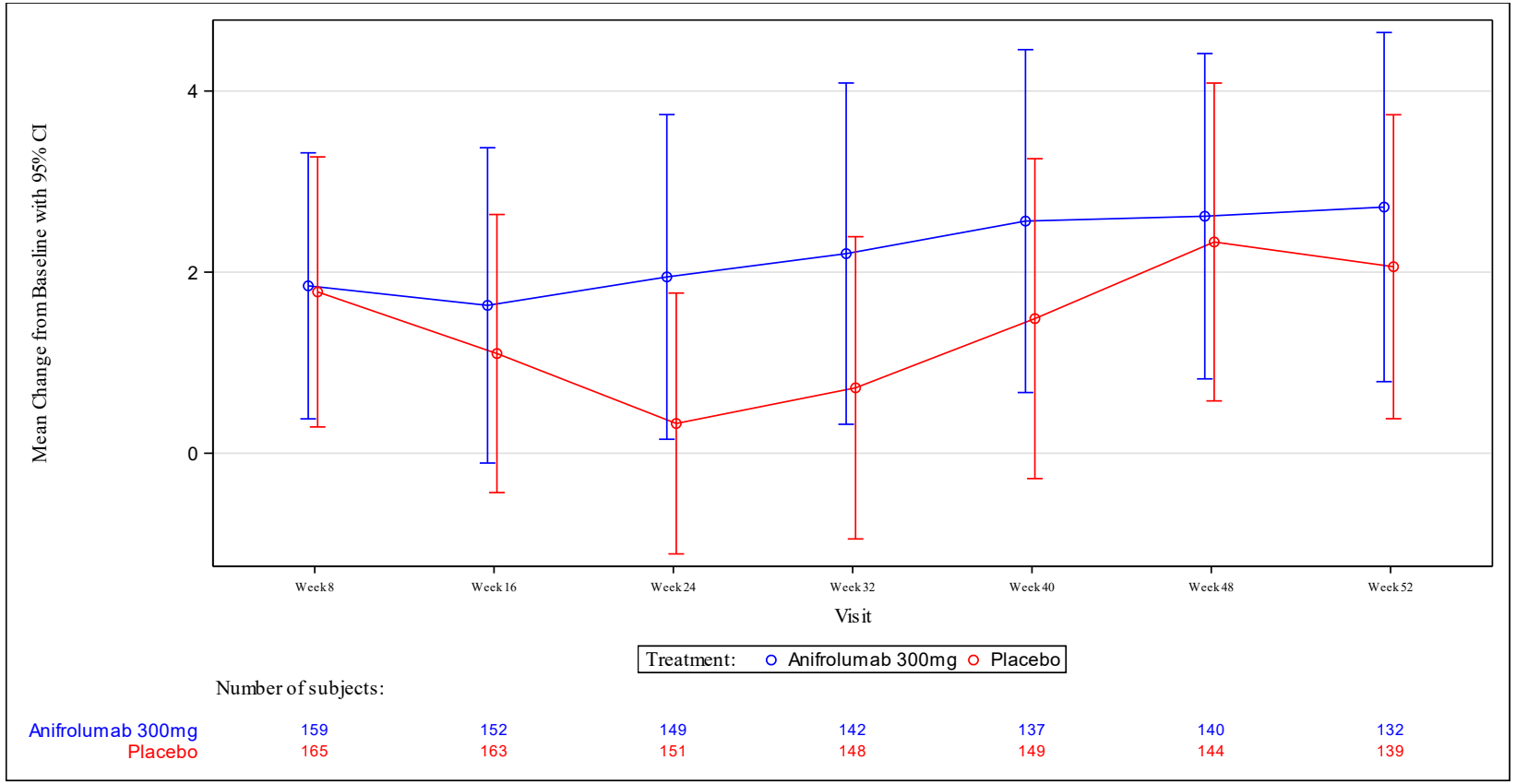
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Physical Functioning Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Role Emotional Score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=184)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	172	40.86 (12.39)	0	-	175	41.64 (11.56)	0	-
Week 8	162	43.25 (12.08)	159	1.85 (9.38)	173	42.75 (11.49)	165	1.78 (9.70)
Week 16	156	42.72 (12.01)	152	1.63 (10.86)	170	42.28 (11.89)	163	1.10 (9.93)
Week 24	155	42.51 (12.76)	149	1.95 (11.07)	158	41.65 (11.39)	151	0.33 (8.96)
Week 32	148	42.72 (11.90)	142	2.20 (11.36)	154	41.93 (12.50)	148	0.72 (10.27)
Week 40	143	43.55 (11.70)	137	2.56 (11.21)	155	42.88 (12.23)	149	1.49 (10.91)
Week 48	146	43.51 (11.73)	140	2.62 (10.75)	148	43.49 (11.71)	144	2.33 (10.65)
Week 52	138	43.77 (11.65)	132	2.72 (11.20)	144	43.34 (11.84)	139	2.06 (10.01)

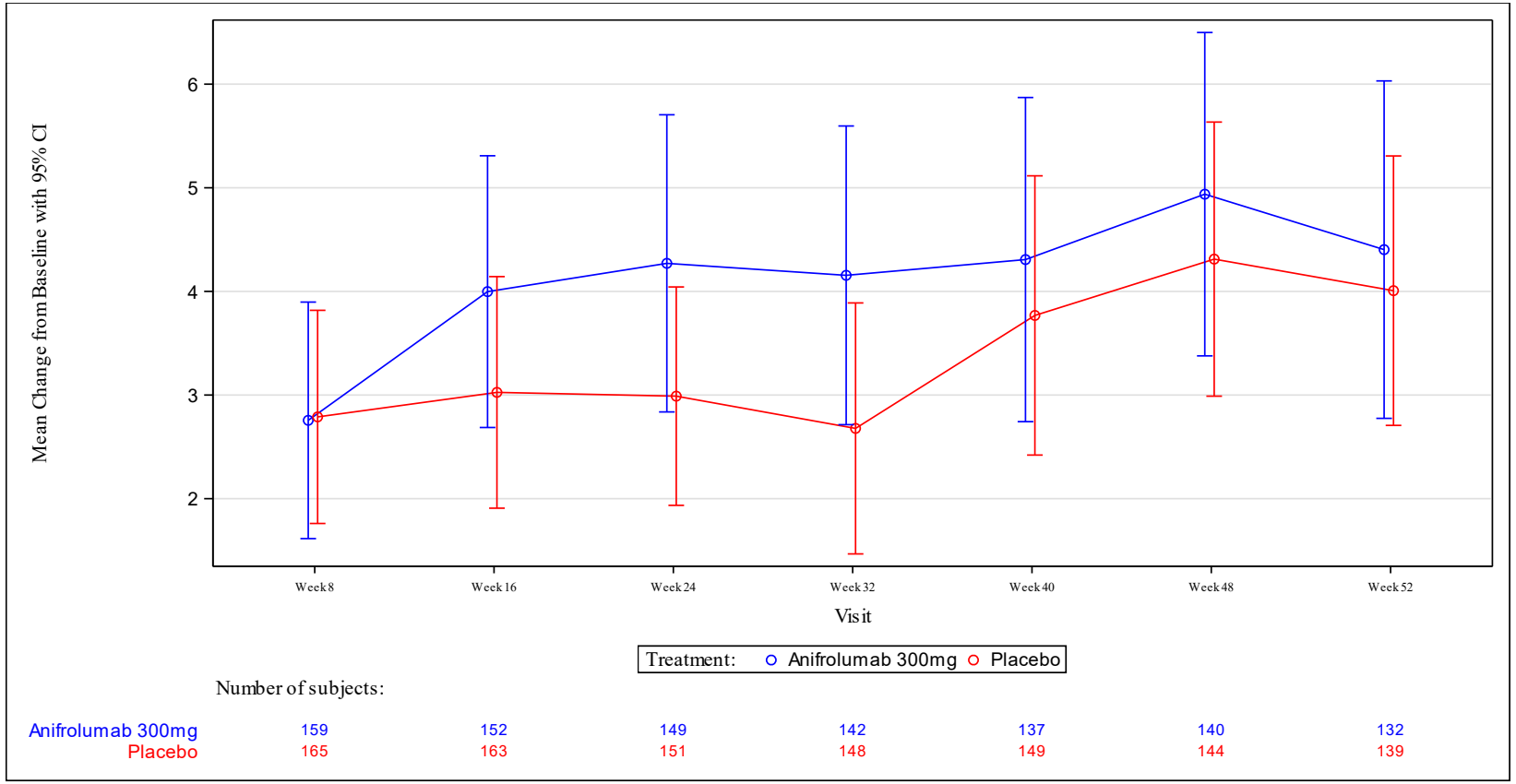
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Role Emotional Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Role Physical Score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=184)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	172	37.60 (9.39)	0	-	175	37.58 (8.14)	0	-
Week 8	162	40.59 (9.23)	159	2.76 (7.29)	173	40.16 (8.41)	165	2.79 (6.69)
Week 16	156	41.79 (9.61)	152	4.00 (8.18)	170	40.36 (9.00)	163	3.03 (7.22)
Week 24	155	41.78 (10.35)	149	4.27 (8.86)	158	40.77 (9.01)	151	2.99 (6.55)
Week 32	148	41.66 (9.51)	142	4.16 (8.69)	154	40.58 (8.91)	148	2.68 (7.45)
Week 40	143	42.19 (9.61)	137	4.31 (9.26)	155	41.45 (9.19)	149	3.77 (8.32)
Week 48	146	42.81 (9.69)	140	4.94 (9.34)	148	41.89 (9.41)	144	4.31 (8.03)
Week 52	138	42.11 (9.78)	132	4.40 (9.46)	144	41.83 (8.92)	139	4.01 (7.75)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Role Physical Score
Full analysis set



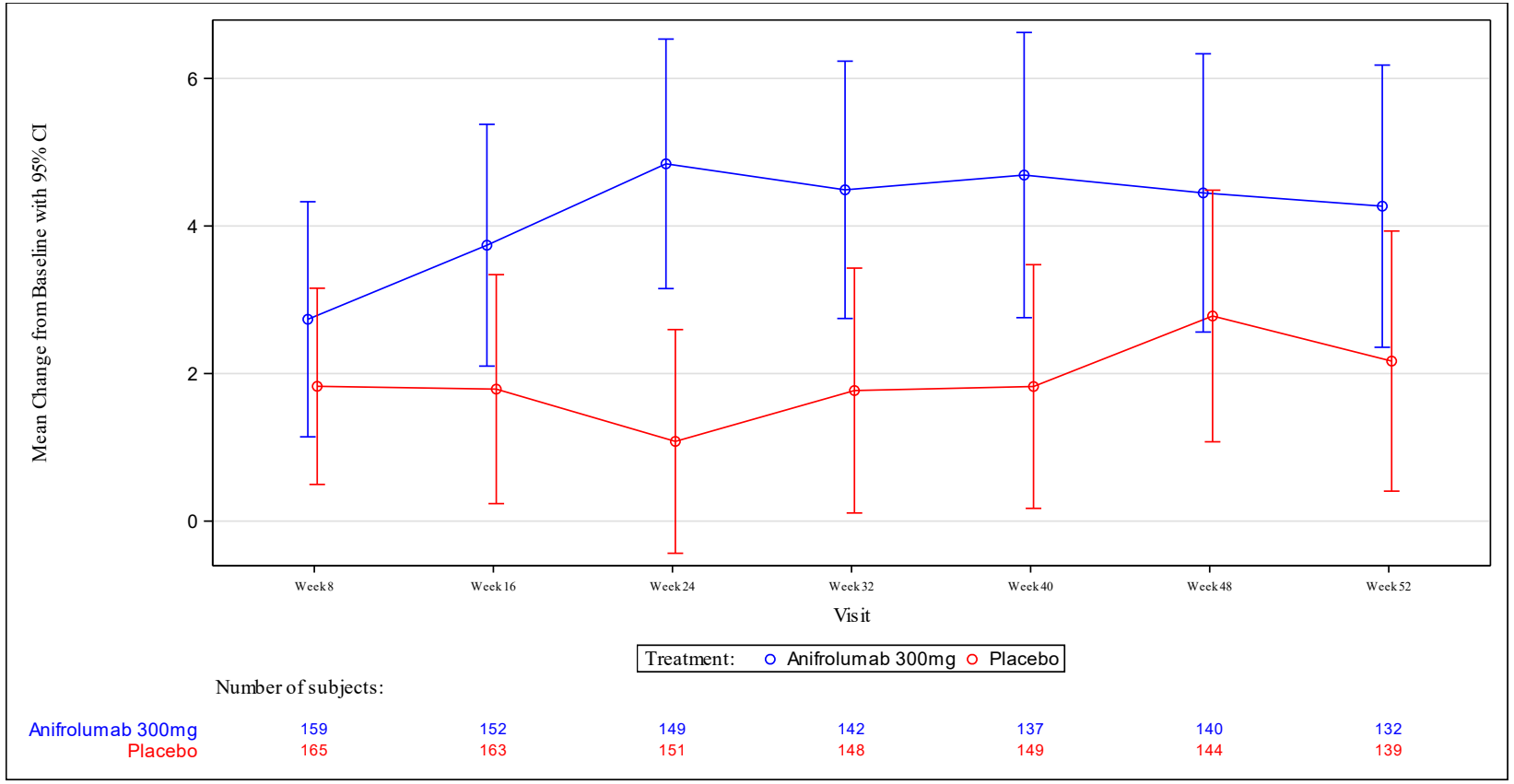
Number of subjects:

	Week 8	Week 16	Week 24	Week 32	Week 40	Week 48	Week 52
Anifrolumab 300mg	159	152	149	142	137	140	132
Placebo	165	163	151	148	149	144	139

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Social Functioning Score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=184)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	172	39.07 (10.73)	0	-	175	40.92 (10.40)	0	-
Week 8	162	42.19 (10.32)	159	2.74 (10.17)	173	42.45 (9.76)	165	1.83 (8.65)
Week 16	156	43.02 (10.41)	152	3.74 (10.22)	170	42.40 (9.37)	163	1.79 (10.03)
Week 24	155	43.41 (10.51)	149	4.84 (10.44)	158	42.16 (9.97)	151	1.08 (9.43)
Week 32	148	43.05 (10.38)	142	4.49 (10.51)	154	42.65 (10.35)	148	1.77 (10.22)
Week 40	143	43.92 (10.87)	137	4.69 (11.44)	155	42.58 (10.04)	149	1.82 (10.20)
Week 48	146	43.50 (10.76)	140	4.45 (11.28)	148	43.88 (9.88)	144	2.78 (10.35)
Week 52	138	43.56 (10.60)	132	4.27 (11.11)	144	43.11 (10.19)	139	2.17 (10.51)

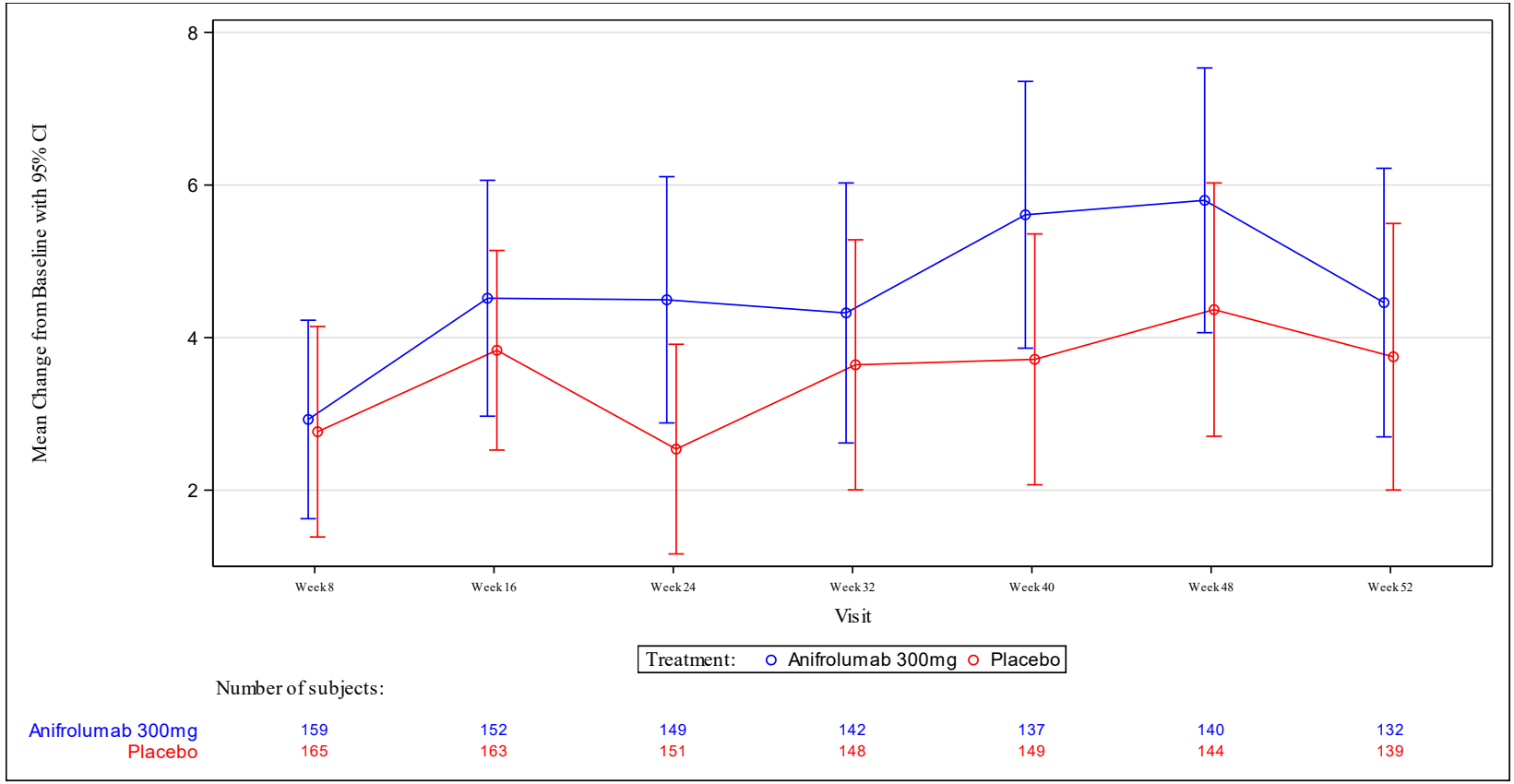
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Social Functioning Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Bodily Pain Score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=184)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	172	38.19 (8.73)	0	-	175	38.79 (9.11)	0	-
Week 8	162	41.33 (9.18)	159	2.93 (8.31)	173	41.07 (8.66)	165	2.77 (8.98)
Week 16	156	43.22 (10.04)	152	4.52 (9.65)	170	42.08 (9.18)	163	3.83 (8.46)
Week 24	155	42.88 (10.29)	149	4.50 (9.97)	158	41.39 (8.74)	151	2.54 (8.55)
Week 32	148	42.76 (10.20)	142	4.32 (10.27)	154	42.18 (9.61)	148	3.64 (10.09)
Week 40	143	44.43 (10.35)	137	5.61 (10.35)	155	41.94 (9.13)	149	3.71 (10.16)
Week 48	146	44.45 (10.51)	140	5.80 (10.38)	148	42.84 (9.40)	144	4.37 (10.08)
Week 52	138	43.03 (9.78)	132	4.46 (10.23)	144	42.15 (8.70)	139	3.75 (10.42)

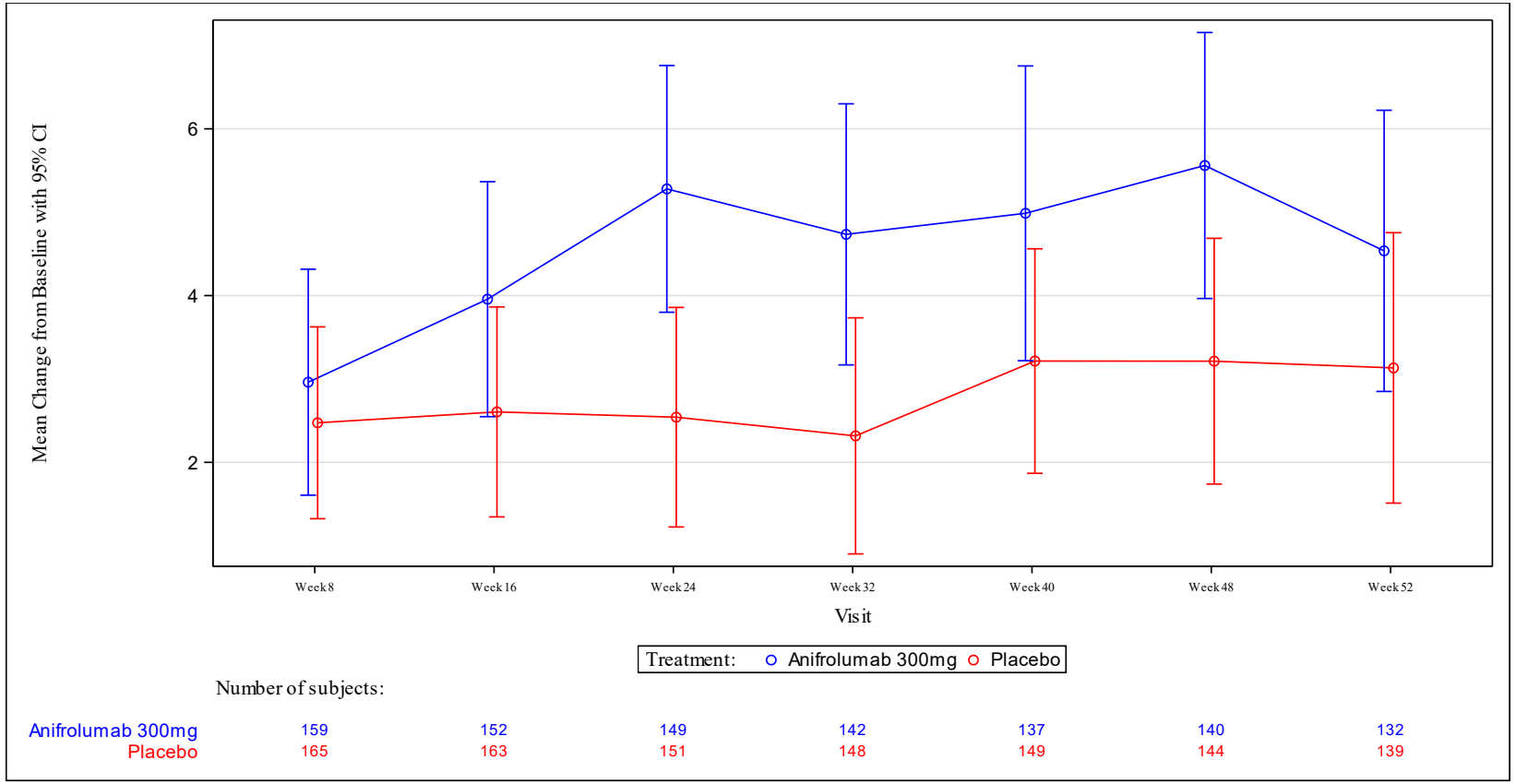
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Bodily Pain Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Vitality Score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=184)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	172	40.87 (9.17)	0	-	175	42.99 (9.15)	0	-
Week 8	162	44.02 (9.46)	159	2.96 (8.65)	173	45.24 (9.62)	165	2.47 (7.48)
Week 16	156	45.09 (10.66)	152	3.96 (8.79)	170	45.50 (9.95)	163	2.60 (8.14)
Week 24	155	45.76 (10.58)	149	5.28 (9.14)	158	45.67 (10.04)	151	2.54 (8.19)
Week 32	148	45.54 (10.31)	142	4.73 (9.44)	154	45.68 (9.80)	148	2.32 (8.71)
Week 40	143	46.06 (11.06)	137	4.99 (10.46)	155	46.30 (10.11)	149	3.21 (8.32)
Week 48	146	46.91 (11.09)	140	5.56 (9.55)	148	46.53 (10.02)	144	3.21 (8.95)
Week 52	138	45.80 (10.24)	132	4.54 (9.79)	144	46.32 (10.42)	139	3.13 (9.67)

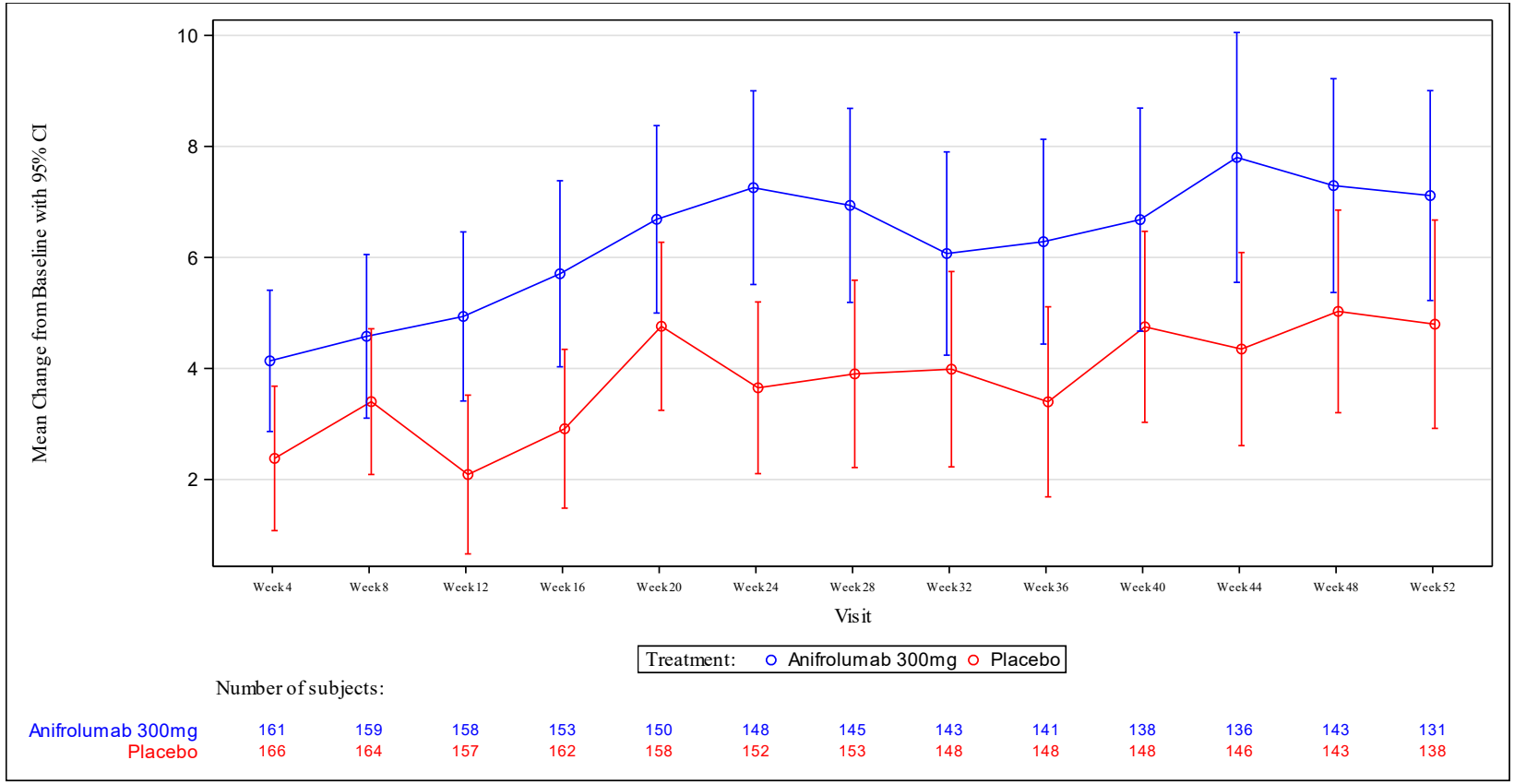
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Vitality Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - FACIT-F Total Score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=184)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	171	24.46 (11.87)	0	-	174	26.02 (12.56)	0	-
Week 4	166	28.40 (11.25)	161	4.14 (8.18)	174	27.58 (12.53)	166	2.38 (8.49)
Week 8	163	29.42 (11.36)	159	4.58 (9.41)	173	29.12 (12.80)	164	3.40 (8.51)
Week 12	162	29.28 (13.25)	158	4.94 (9.69)	166	28.19 (13.45)	157	2.09 (9.07)
Week 16	158	30.70 (12.55)	153	5.71 (10.49)	170	28.99 (12.86)	162	2.91 (9.22)
Week 20	154	31.49 (12.45)	150	6.69 (10.46)	167	30.87 (12.80)	158	4.76 (9.64)
Week 24	155	31.30 (13.20)	148	7.26 (10.74)	160	29.79 (13.48)	152	3.65 (9.65)
Week 28	151	31.89 (12.64)	145	6.94 (10.65)	161	30.37 (12.90)	153	3.90 (10.56)
Week 32	150	30.38 (13.03)	143	6.07 (11.08)	155	30.59 (13.66)	148	3.99 (10.83)
Week 36	148	31.03 (13.10)	141	6.28 (11.08)	154	30.09 (13.92)	148	3.40 (10.54)
Week 40	145	31.43 (12.83)	138	6.68 (11.94)	156	30.85 (13.70)	148	4.75 (10.59)
Week 44	141	32.72 (13.95)	136	7.80 (13.27)	152	30.82 (13.20)	146	4.35 (10.63)
Week 48	150	32.01 (13.44)	143	7.29 (11.65)	149	31.82 (13.29)	143	5.03 (11.04)
Week 52	138	31.72 (12.90)	131	7.11 (10.94)	144	31.35 (13.67)	138	4.80 (11.15)

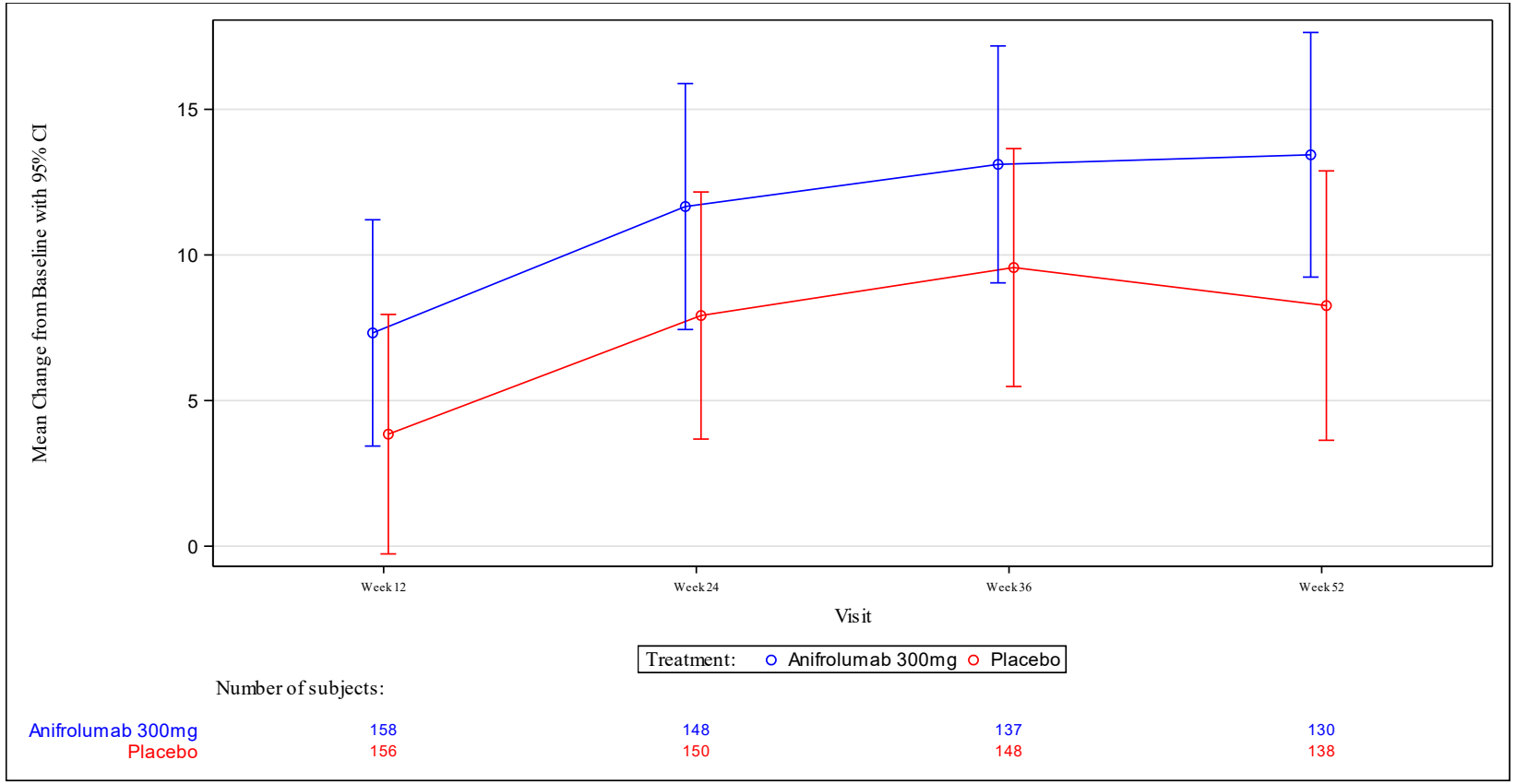
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - FACIT-F Total Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - EQ VAS Score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=184)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	171	53.33 (20.26)	0	-	174	54.57 (21.19)	0	-
Week 12	162	60.59 (21.64)	158	7.32 (24.73)	165	58.21 (20.30)	156	3.85 (26.00)
Week 24	155	64.32 (21.83)	148	11.66 (25.99)	158	62.29 (19.93)	150	7.92 (26.29)
Week 36	144	65.76 (21.05)	137	13.11 (24.08)	153	65.50 (21.00)	148	9.57 (25.14)
Week 52	137	65.73 (21.09)	130	13.44 (24.20)	144	63.47 (21.26)	138	8.26 (27.48)

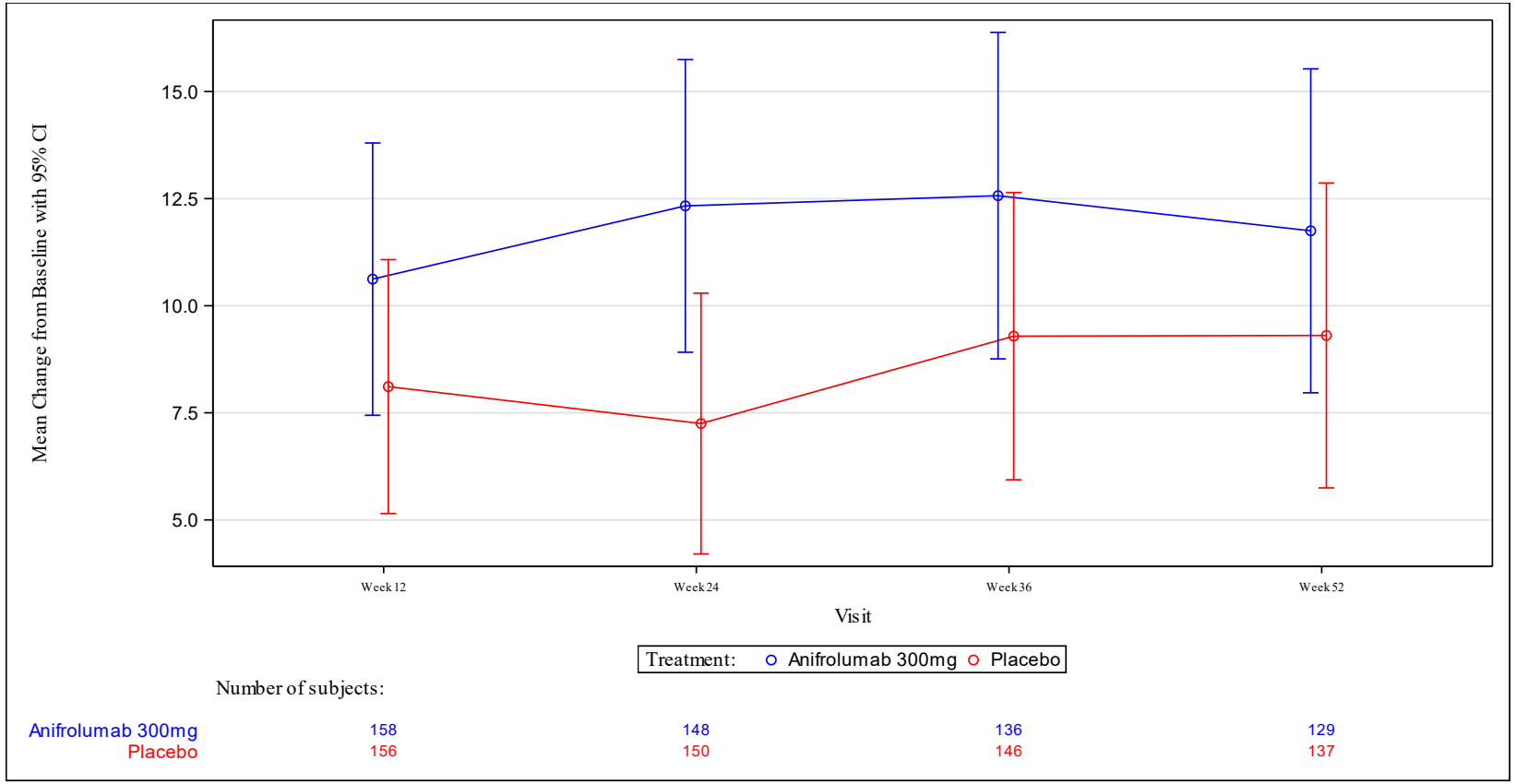
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - EQ VAS Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Physical Health domain score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=184)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	171	51.63 (25.01)	0	-	174	53.34 (25.30)	0	-
Week 12	162	62.06 (25.23)	158	10.62 (20.22)	165	60.53 (25.44)	156	8.11 (18.74)
Week 24	155	63.29 (25.96)	148	12.33 (21.03)	158	61.12 (24.54)	150	7.25 (18.87)
Week 36	143	64.32 (25.12)	136	12.57 (22.47)	151	63.06 (24.40)	146	9.29 (20.50)
Week 52	136	64.00 (26.24)	129	11.75 (21.71)	143	62.90 (24.71)	137	9.31 (21.06)

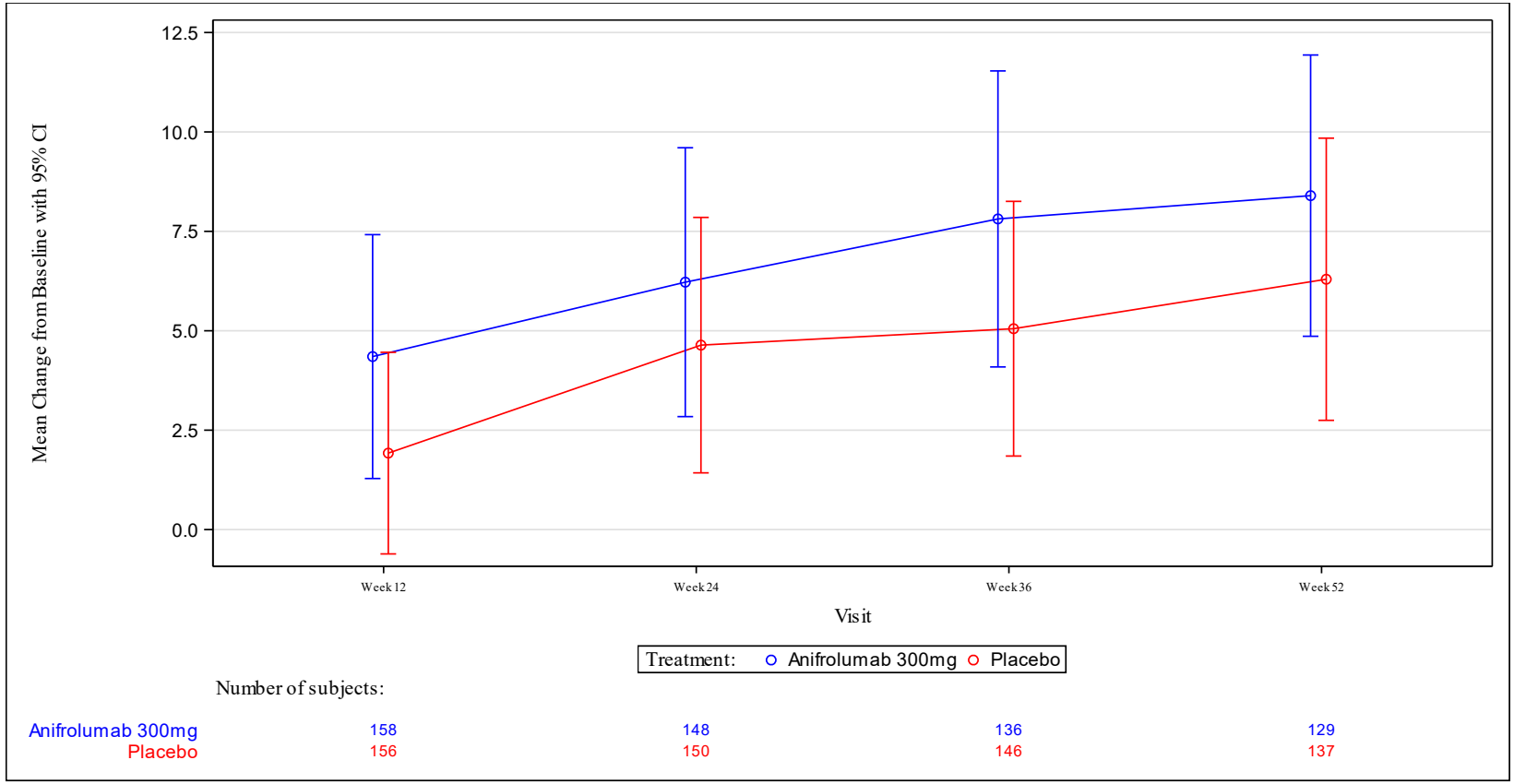
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Lupus QoL Physical Health domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Emotional Health domain score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=184)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	171	65.96 (24.25)	0	-	174	65.71 (24.82)	0	-
Week 12	162	69.88 (23.00)	158	4.35 (19.51)	165	67.78 (24.08)	156	1.92 (16.03)
Week 24	155	71.77 (24.03)	148	6.22 (20.81)	158	70.25 (23.95)	150	4.64 (19.91)
Week 36	143	72.93 (23.19)	136	7.81 (21.95)	151	72.19 (23.30)	146	5.05 (19.58)
Week 52	136	73.74 (23.47)	129	8.40 (20.30)	143	73.22 (23.15)	137	6.30 (21.00)

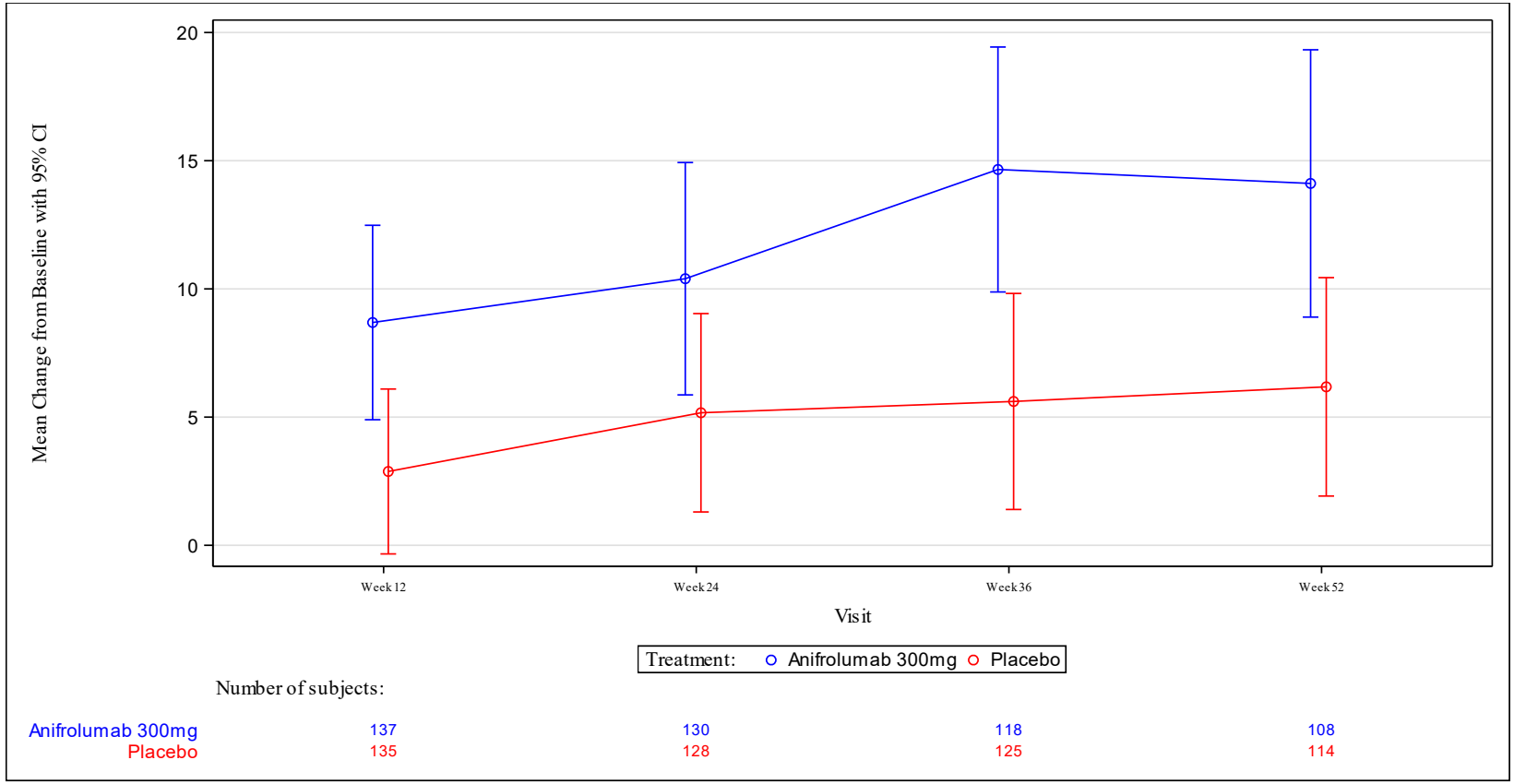
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Lupus QoL Emotional Health domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Body Image domain score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=184)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	162	57.35 (27.89)	0	-	160	61.80 (27.88)	0	-
Week 12	145	64.11 (26.70)	137	8.69 (22.44)	148	64.83 (25.96)	135	2.88 (18.89)
Week 24	141	66.20 (27.85)	130	10.40 (26.11)	142	65.82 (26.82)	128	5.17 (22.12)
Week 36	130	69.80 (26.61)	118	14.66 (26.20)	136	68.23 (25.01)	125	5.61 (23.80)
Week 52	118	67.77 (25.09)	108	14.11 (27.33)	124	68.67 (25.76)	114	6.18 (22.95)

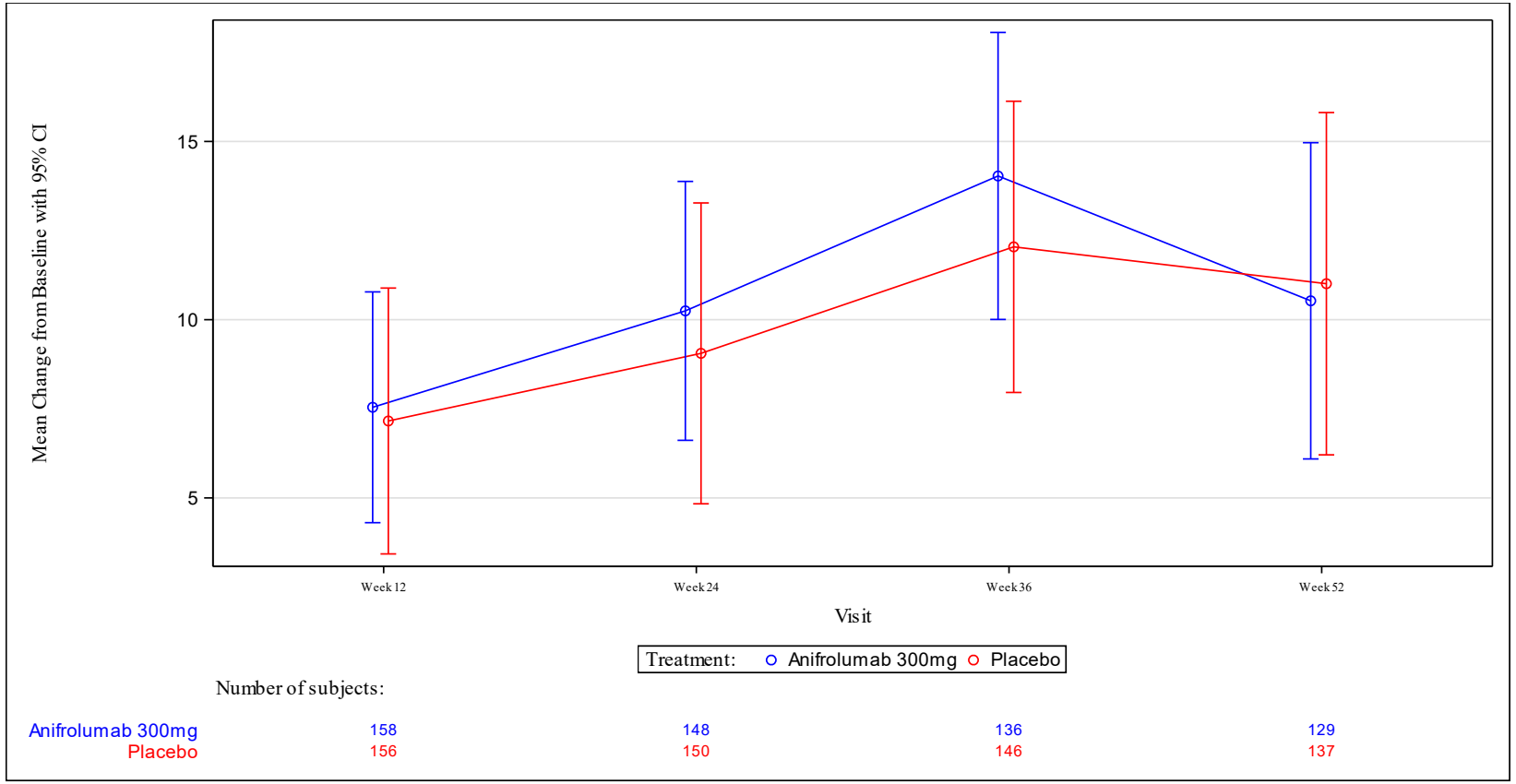
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Lupus QoL Body Image domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Burden to Others domain score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=184)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	171	50.68 (29.97)	0	-	174	49.09 (31.31)	0	-
Week 12	162	56.94 (29.96)	158	7.54 (20.60)	165	56.82 (30.16)	156	7.16 (23.58)
Week 24	155	59.84 (30.87)	148	10.25 (22.36)	158	58.49 (30.24)	150	9.06 (26.16)
Week 36	143	63.81 (29.54)	136	14.03 (23.74)	151	62.86 (28.83)	146	12.04 (24.97)
Week 52	136	61.09 (30.77)	129	10.53 (25.46)	143	62.82 (28.80)	137	11.01 (28.42)

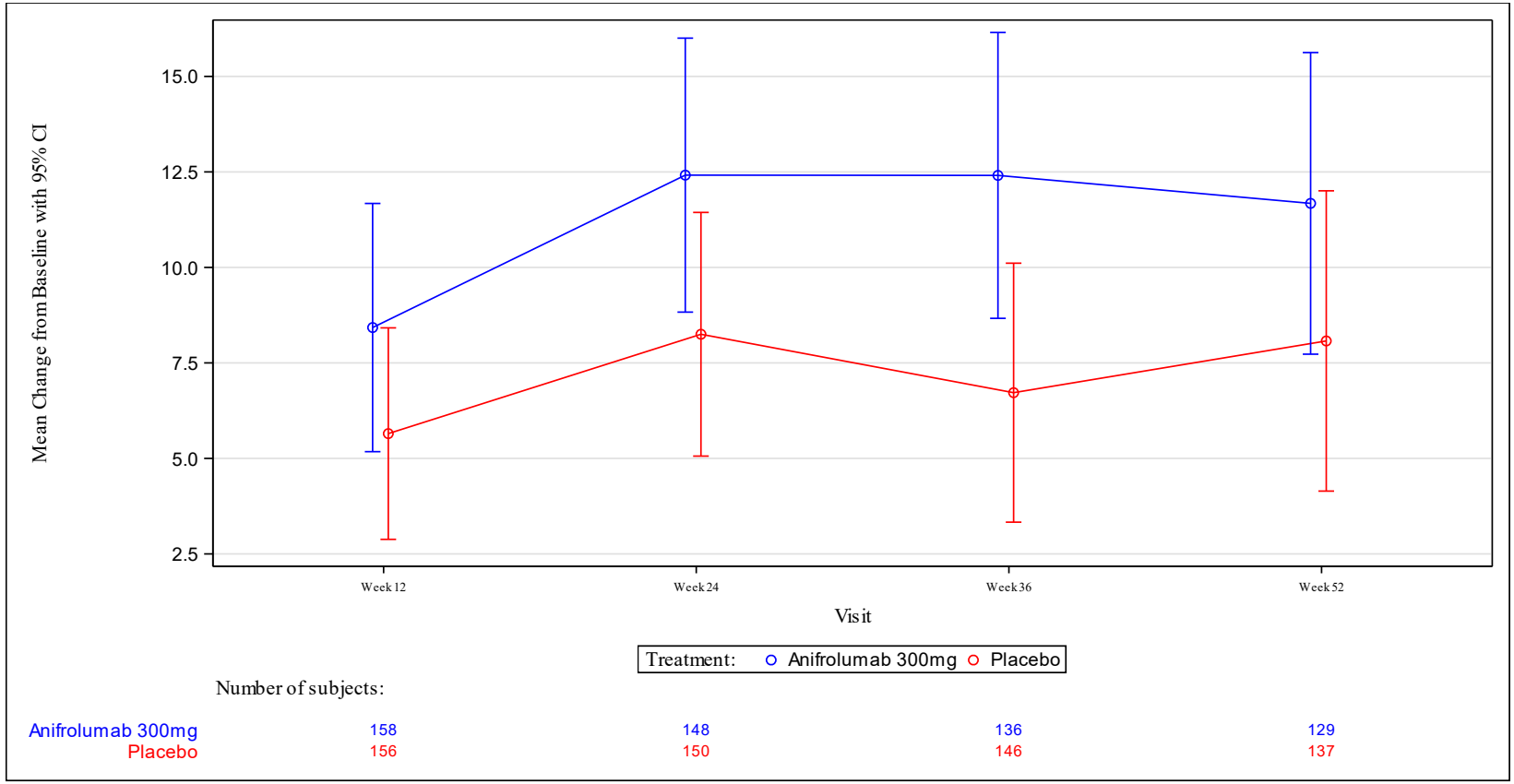
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Lupus QoL Burden to Others domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Fatigue domain score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=184)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	171	47.33 (25.92)	0	-	174	48.67 (26.61)	0	-
Week 12	162	54.82 (27.32)	158	8.43 (20.67)	165	54.39 (27.44)	156	5.65 (17.50)
Week 24	155	58.55 (27.64)	148	12.42 (22.08)	158	57.56 (27.79)	150	8.25 (19.77)
Week 36	143	59.88 (27.10)	136	12.41 (22.06)	151	57.24 (27.11)	146	6.72 (20.72)
Week 52	136	58.78 (28.57)	129	11.68 (22.66)	143	58.26 (26.71)	137	8.07 (23.26)

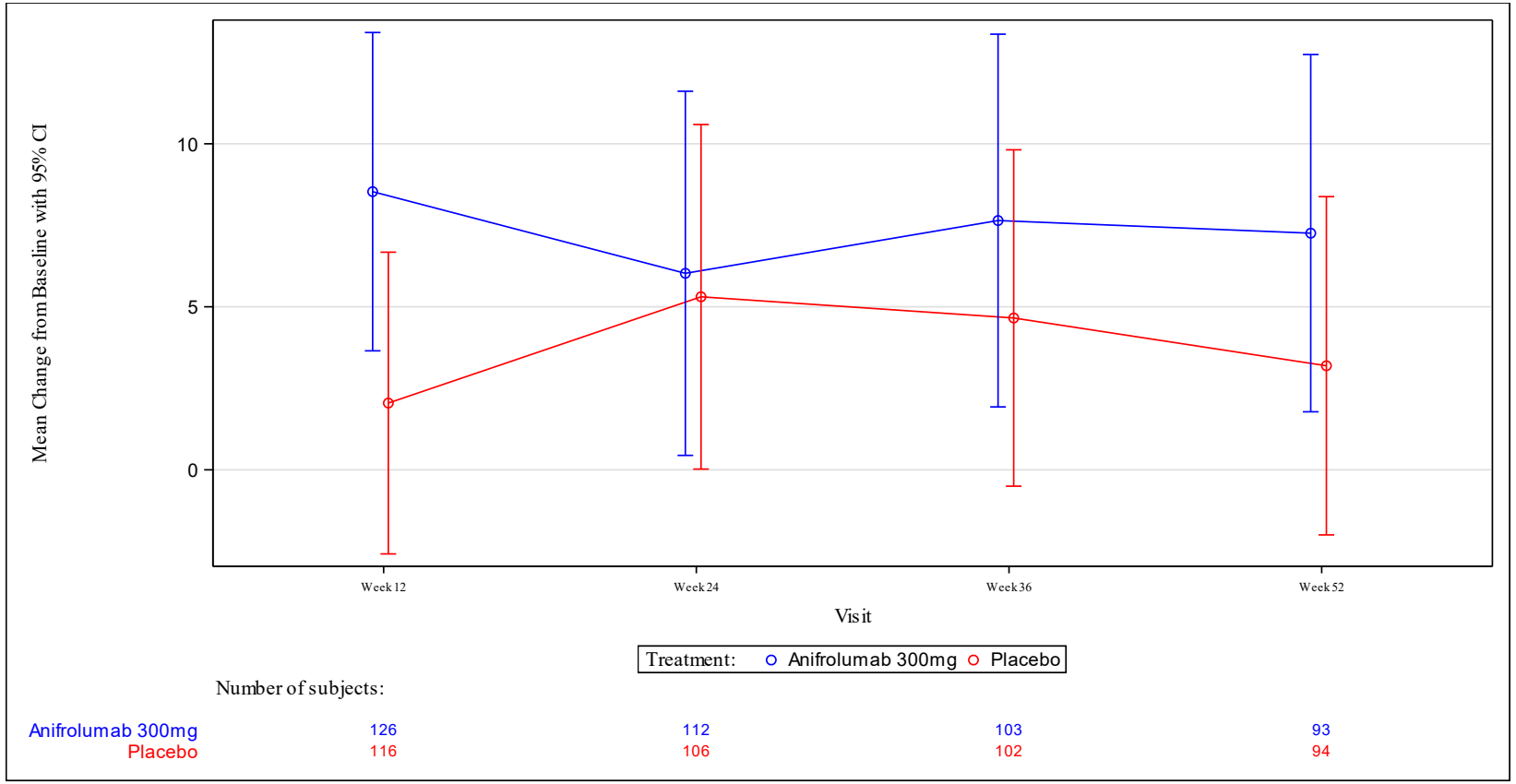
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Lupus QoL Fatigue domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Intimate Relationships domain score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=184)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	149	54.53 (32.92)	0	-	146	59.08 (29.23)	0	-
Week 12	138	63.59 (32.55)	126	8.53 (27.69)	130	60.48 (31.28)	116	2.05 (25.16)
Week 24	125	62.00 (32.00)	112	6.03 (29.83)	120	62.92 (31.42)	106	5.31 (27.44)
Week 36	116	64.22 (32.76)	103	7.65 (29.25)	112	63.84 (30.45)	102	4.66 (26.26)
Week 52	108	66.44 (30.41)	93	7.26 (26.60)	105	62.62 (32.45)	94	3.19 (25.33)

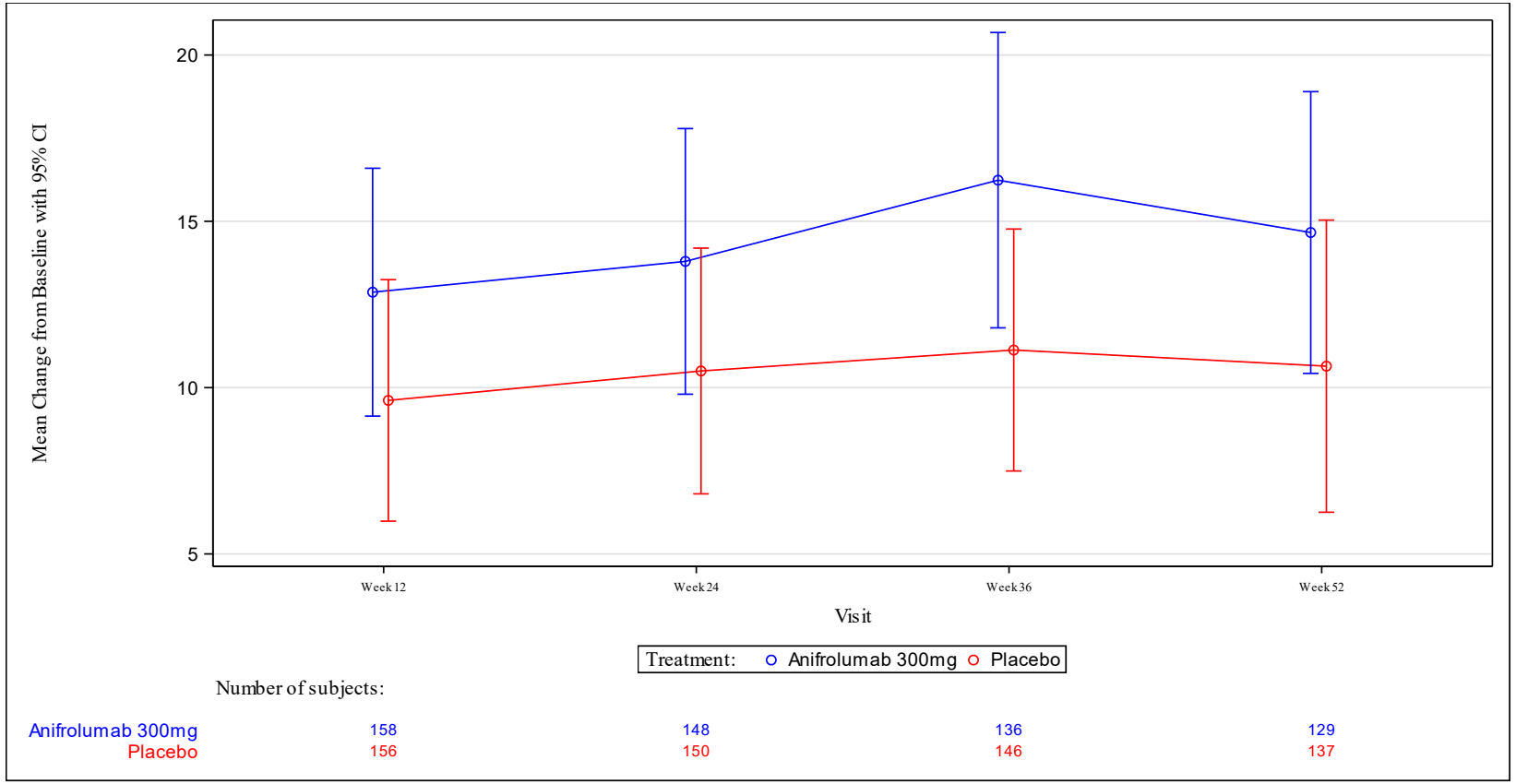
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Lupus QoL Intimate Relationships domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Pain domain score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=184)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	171	50.05 (28.22)	0	-	174	51.44 (28.21)	0	-
Week 12	162	62.14 (27.83)	158	12.87 (23.71)	165	60.51 (28.72)	156	9.62 (22.96)
Week 24	155	63.39 (27.94)	148	13.80 (24.59)	158	63.03 (27.53)	150	10.50 (22.90)
Week 36	143	66.90 (26.54)	136	16.24 (26.18)	151	63.19 (27.68)	146	11.13 (22.24)
Week 52	136	66.36 (27.03)	129	14.66 (24.31)	143	63.35 (27.30)	137	10.65 (26.00)

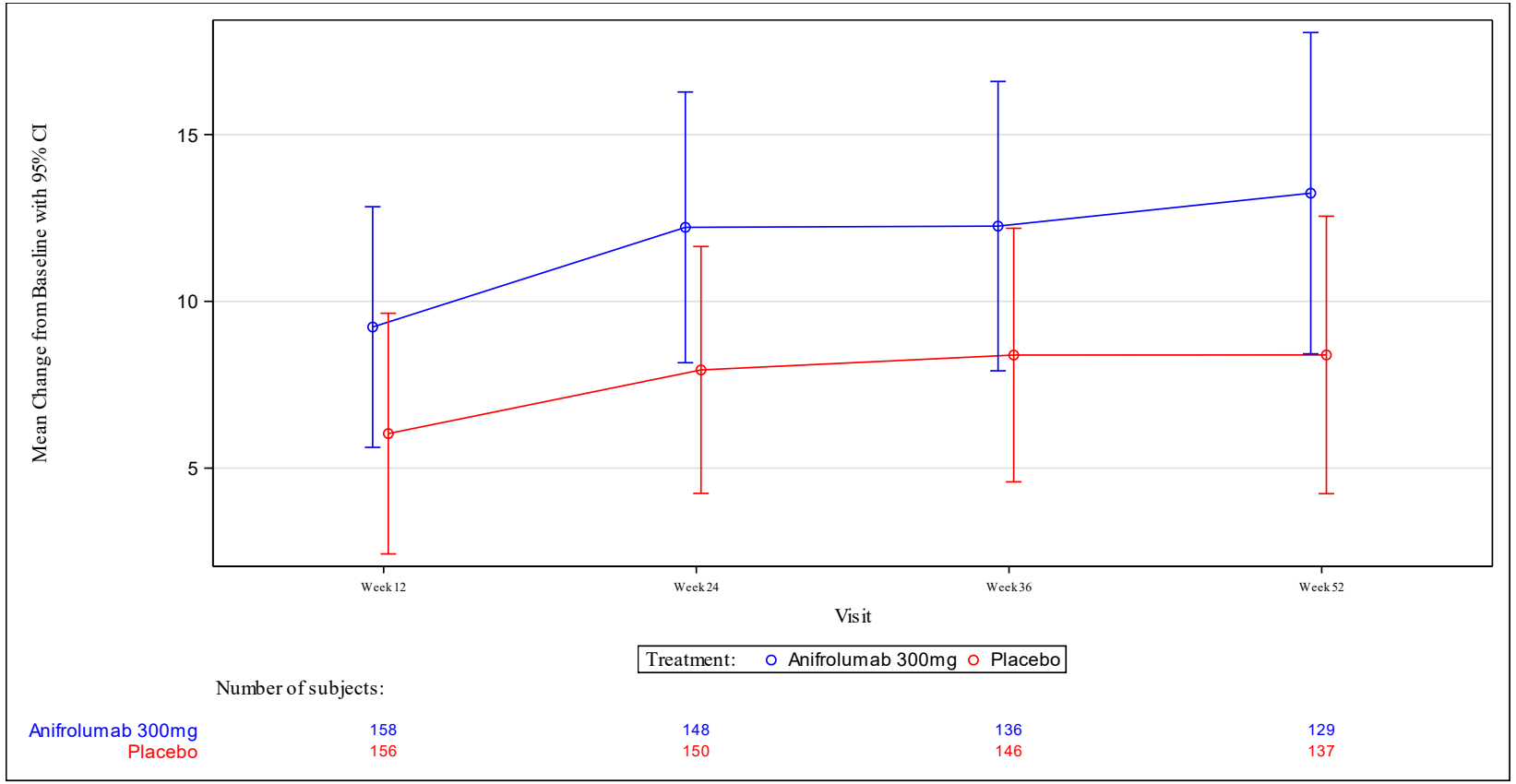
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Lupus QoL Pain domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Planning domain score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=184)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	171	55.90 (30.26)	0	-	174	57.33 (30.12)	0	-
Week 12	162	64.35 (28.33)	158	9.23 (22.95)	165	62.68 (29.10)	156	6.04 (22.81)
Week 24	155	66.99 (29.05)	148	12.22 (24.98)	158	65.03 (29.26)	150	7.94 (22.94)
Week 36	143	67.66 (28.64)	136	12.26 (25.58)	151	66.89 (27.59)	146	8.39 (23.23)
Week 52	136	68.20 (28.76)	129	13.24 (27.65)	143	66.03 (27.89)	137	8.39 (24.62)

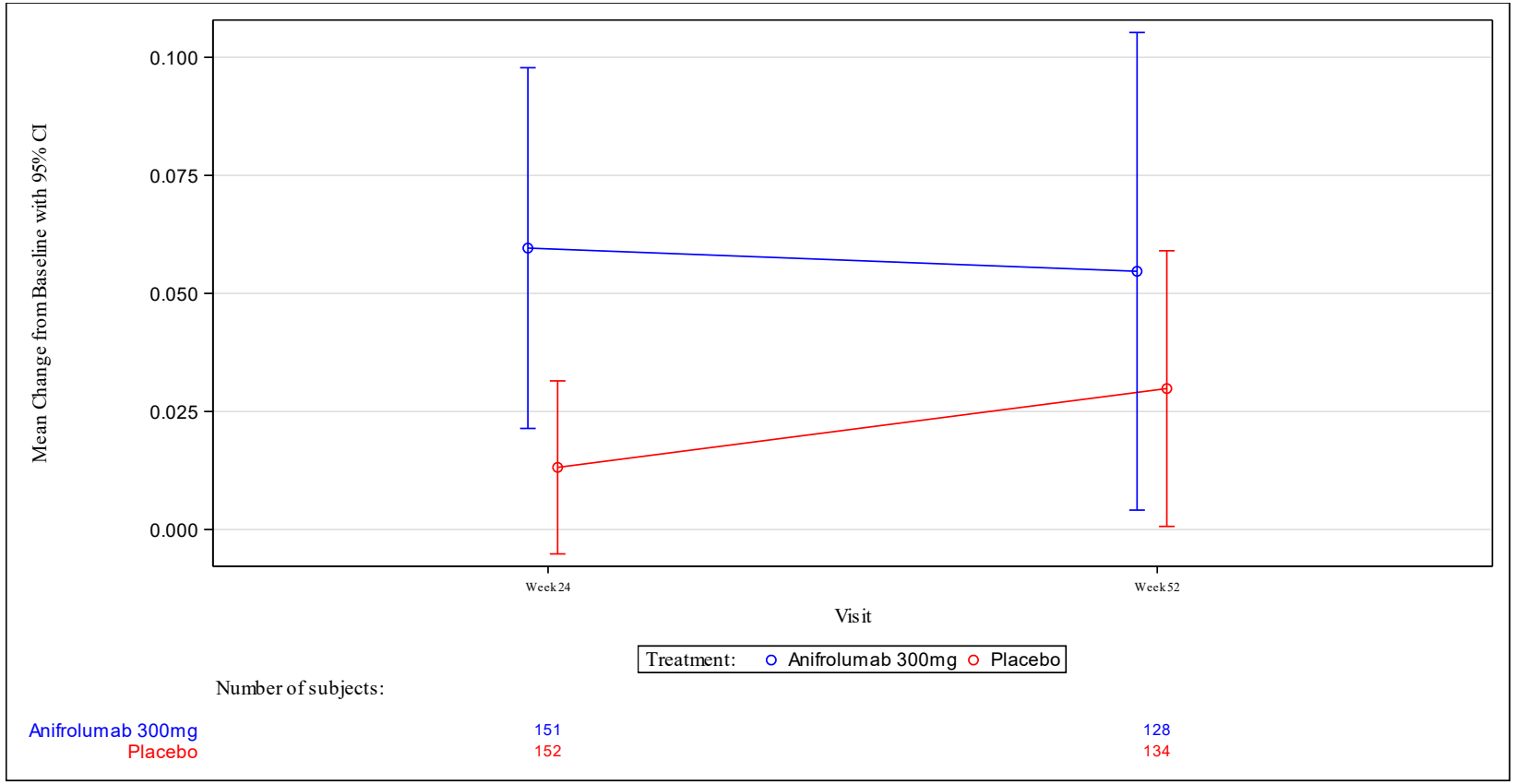
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Lupus QoL Planning domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - SDI Global Score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=184)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	170	0.66 (1.16)	0	-	169	0.66 (0.98)	0	-
Week 24	154	0.73 (1.20)	151	0.06 (0.24)	159	0.69 (1.01)	152	0.01 (0.11)
Week 52	134	0.71 (1.10)	128	0.05 (0.29)	147	0.65 (0.98)	134	0.03 (0.17)

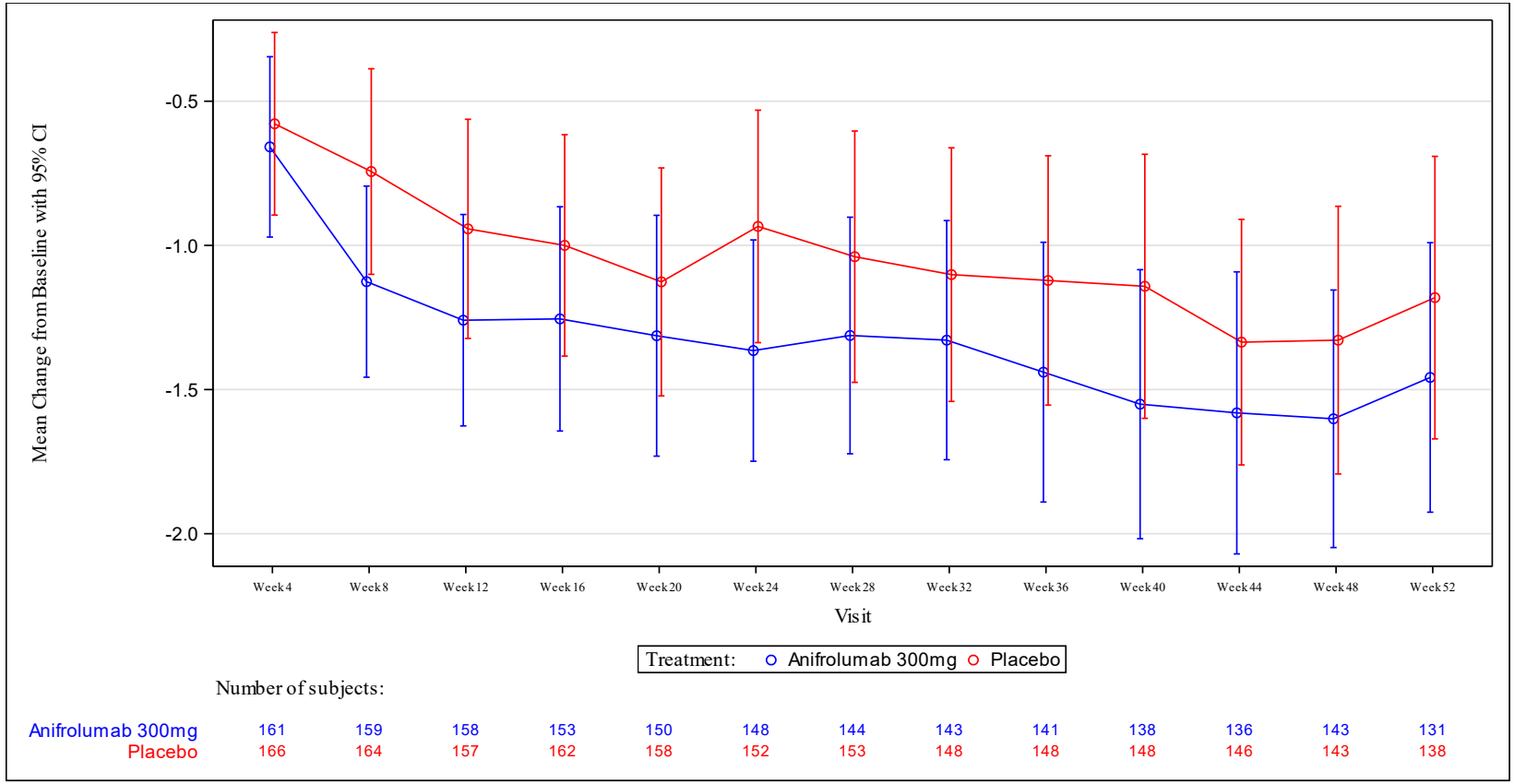
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - SDI Global Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - NRS Score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=184)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	171	5.68 (2.41)	0	-	174	5.45 (2.43)	0	-
Week 4	166	5.07 (2.35)	161	-0.66 (2.01)	174	5.01 (2.58)	166	-0.58 (2.07)
Week 8	163	4.53 (2.44)	159	-1.13 (2.12)	173	4.85 (2.52)	164	-0.74 (2.31)
Week 12	162	4.41 (2.62)	158	-1.26 (2.33)	166	4.58 (2.67)	157	-0.94 (2.41)
Week 16	158	4.27 (2.61)	153	-1.25 (2.43)	170	4.59 (2.44)	162	-1.00 (2.47)
Week 20	154	4.23 (2.64)	150	-1.31 (2.59)	167	4.40 (2.51)	158	-1.13 (2.52)
Week 24	155	4.22 (2.61)	148	-1.36 (2.36)	160	4.58 (2.50)	152	-0.93 (2.52)
Week 28	150	4.21 (2.65)	144	-1.31 (2.49)	161	4.49 (2.49)	153	-1.04 (2.73)
Week 32	150	4.35 (2.53)	143	-1.33 (2.51)	155	4.39 (2.60)	148	-1.10 (2.71)
Week 36	148	4.10 (2.56)	141	-1.44 (2.71)	154	4.31 (2.55)	148	-1.12 (2.66)
Week 40	145	3.96 (2.68)	138	-1.55 (2.77)	156	4.45 (2.61)	148	-1.14 (2.82)
Week 44	141	3.91 (2.70)	136	-1.58 (2.88)	152	4.22 (2.54)	146	-1.34 (2.60)
Week 48	150	3.95 (2.67)	143	-1.60 (2.70)	149	4.13 (2.65)	143	-1.33 (2.81)
Week 52	138	4.09 (2.62)	131	-1.46 (2.70)	144	4.31 (2.62)	138	-1.18 (2.91)

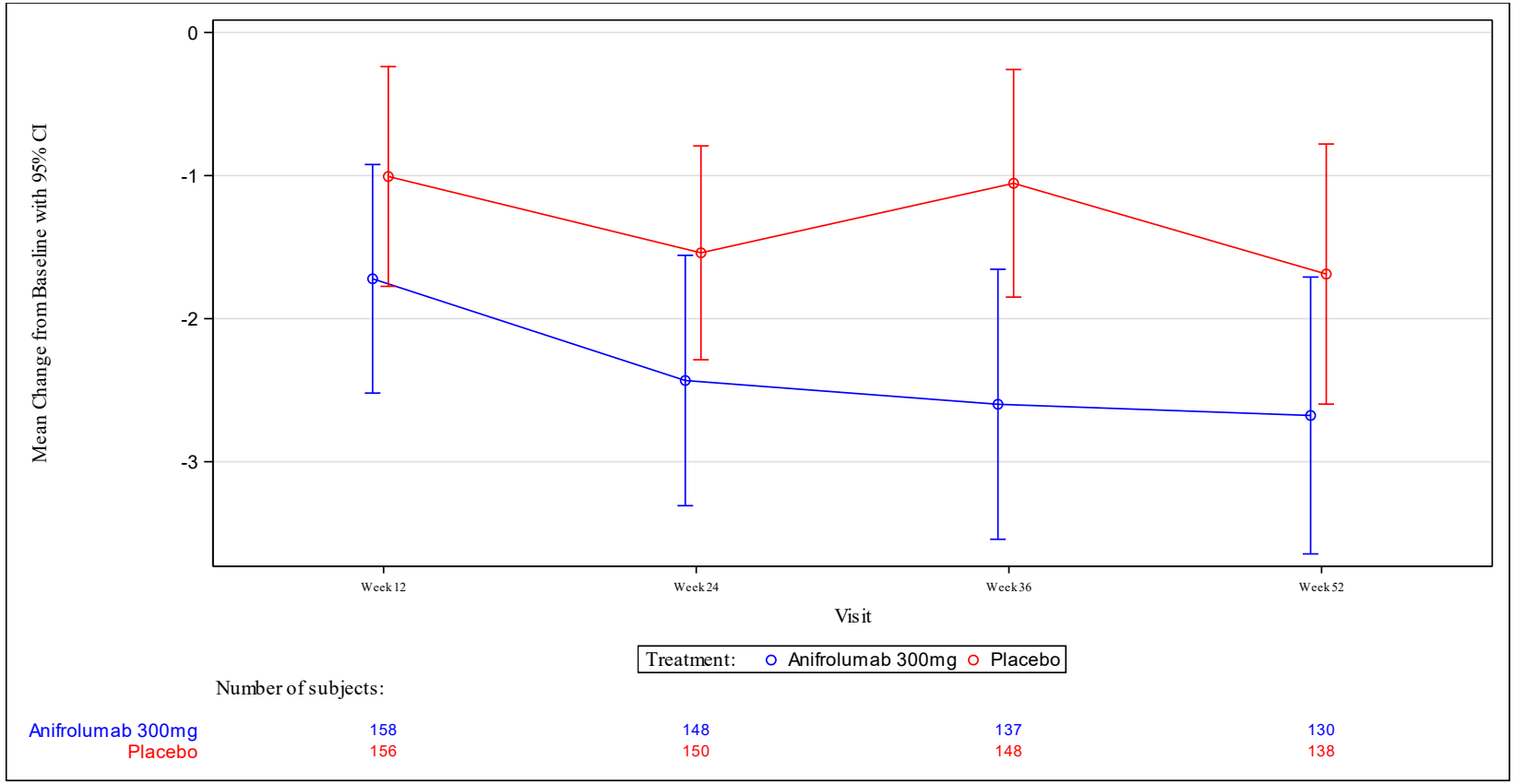
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - NRS Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - PHQ-8 Total Score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=184)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	171	10.11 (6.20)	0	-	174	9.44 (6.06)	0	-
Week 12	162	8.59 (6.24)	158	-1.72 (5.08)	165	8.42 (6.26)	156	-1.01 (4.86)
Week 24	155	7.91 (6.03)	148	-2.43 (5.39)	158	8.08 (6.23)	150	-1.54 (4.63)
Week 36	144	7.79 (5.81)	137	-2.60 (5.59)	153	8.13 (6.31)	148	-1.05 (4.90)
Week 52	137	7.66 (6.08)	130	-2.68 (5.58)	144	7.54 (6.31)	138	-1.69 (5.40)

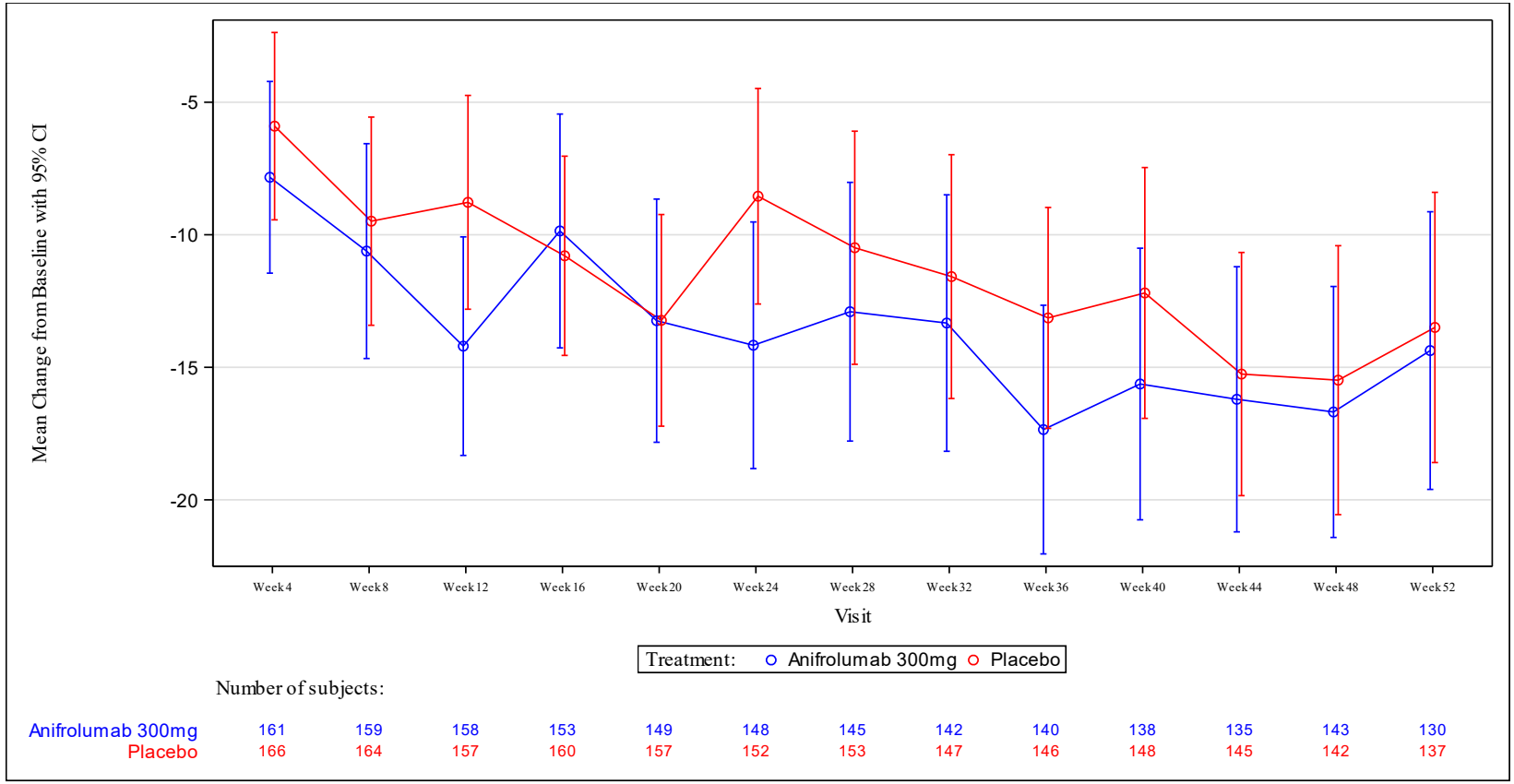
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - PHQ-8 Total Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - PtGA
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=184)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	171	57.19 (21.22)	0	-	174	54.08 (21.22)	0	-
Week 4	166	49.14 (21.10)	161	-7.83 (23.23)	174	49.52 (22.56)	166	-5.90 (23.06)
Week 8	163	46.12 (23.63)	159	-10.62 (25.87)	173	46.13 (23.06)	164	-9.49 (25.47)
Week 12	162	42.94 (23.38)	158	-14.20 (26.24)	166	45.95 (24.48)	157	-8.78 (25.58)
Week 16	158	46.51 (26.09)	153	-9.86 (27.61)	168	44.26 (24.09)	160	-10.79 (24.07)
Week 20	153	42.85 (24.80)	149	-13.24 (28.33)	165	41.07 (24.06)	157	-13.23 (25.33)
Week 24	155	43.45 (25.72)	148	-14.17 (28.63)	160	45.80 (24.56)	152	-8.55 (25.38)
Week 28	151	43.58 (25.73)	145	-12.90 (29.73)	161	43.11 (24.20)	153	-10.49 (27.53)
Week 32	149	43.56 (25.49)	142	-13.33 (29.16)	154	42.29 (24.85)	147	-11.58 (28.21)
Week 36	147	39.88 (24.14)	140	-17.35 (28.07)	152	39.80 (24.39)	146	-13.14 (25.48)
Week 40	145	41.20 (25.70)	138	-15.63 (30.43)	155	42.28 (26.53)	148	-12.20 (29.13)
Week 44	140	40.11 (25.78)	135	-16.21 (29.38)	151	39.58 (25.71)	145	-15.26 (27.94)
Week 48	150	39.52 (25.43)	143	-16.69 (28.64)	148	38.86 (25.47)	142	-15.49 (30.58)
Week 52	137	42.09 (26.50)	130	-14.37 (30.18)	143	41.64 (26.03)	137	-13.50 (30.17)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - PtGA
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SLEDAI-2K Total Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) N	Anifrolumab 300mg (N=180) LSMean (SE)	Placebo (N=184) N	Placebo (N=184) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-0.86 (0.21)		-0.72 (0.21)	-0.14 (0.24)	(-0.61, 0.34)	0.5738			
Week 8		-2.04 (0.27)		-1.53 (0.27)	-0.51 (0.35)	(-1.21, 0.18)	0.1441			
Week 12		-3.28 (0.29)		-2.38 (0.29)	-0.90 (0.38)	(-1.65, -0.16)	0.0180			
Week 16		-3.91 (0.33)		-2.83 (0.32)	-1.07 (0.43)	(-1.92, -0.23)	0.0130			
Week 20		-4.66 (0.33)		-3.45 (0.33)	-1.21 (0.44)	(-2.06, -0.35)	0.0060			
Week 24		-5.01 (0.33)		-4.18 (0.33)	-0.83 (0.43)	(-1.68, 0.02)	0.0566			
Week 28		-5.16 (0.34)		-4.30 (0.34)	-0.87 (0.45)	(-1.76, 0.03)	0.0575			
Week 32		-5.59 (0.34)		-4.58 (0.33)	-1.01 (0.45)	(-1.89, -0.13)	0.0243			
Week 36		-5.58 (0.34)		-4.74 (0.34)	-0.84 (0.46)	(-1.73, 0.06)	0.0660			
Week 40		-5.49 (0.35)		-4.91 (0.34)	-0.57 (0.46)	(-1.47, 0.33)	0.2120			
Week 44		-5.71 (0.35)		-5.07 (0.34)	-0.64 (0.46)	(-1.54, 0.27)	0.1653			
Week 48		-5.81 (0.36)		-5.17 (0.35)	-0.64 (0.47)	(-1.57, 0.29)	0.1776			
Week 52		-6.08 (0.34)		-5.29 (0.34)	-0.79 (0.45)	(-1.68, 0.10)	0.0806			
OVERALL	179	-4.55 (0.27)	182	-3.78 (0.27)	-0.77 (0.34)	(-1.44, -0.10)	0.0243	-0.21 (0.11)	(-0.42, -0.01)	0.0426

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SLEDAI-2K Total Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=184) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.7252
< 10 points	54	-3.57 (0.35)	53	-2.61 (0.34)	-0.96 (0.47)	(-1.89, -0.02)	0.0451	-0.38 (0.20)	(-0.76, 0.01)	0.0542	
>= 10 points	125	-4.69 (0.34)	129	-3.96 (0.34)	-0.73 (0.44)	(-1.60, 0.14)	0.0986	-0.19 (0.13)	(-0.44, 0.06)	0.1305	
OCS dose at baseline											0.9236
<10 mg/day	77	-4.51 (0.35)	82	-3.81 (0.34)	-0.70 (0.46)	(-1.61, 0.20)	0.1275	-0.23 (0.16)	(-0.54, 0.08)	0.1494	
>=10 mg/day	102	-4.48 (0.40)	100	-3.71 (0.40)	-0.77 (0.48)	(-1.72, 0.18)	0.1133	-0.19 (0.14)	(-0.47, 0.09)	0.1801	
Result of type I IFN gene signature test											0.6056
LOW	32	-3.52 (0.55)	33	-3.11 (0.54)	-0.41 (0.77)	(-1.94, 1.12)	0.5951	-0.13 (0.25)	(-0.62, 0.36)	0.6026	
HIGH	147	-4.82 (0.28)	149	-3.96 (0.28)	-0.85 (0.38)	(-1.60, -0.10)	0.0265	-0.25 (0.12)	(-0.48, -0.02)	0.0330	
Age (years)											NE
<= 65	172	-4.61 (0.28)	179	-3.81 (0.27)	-0.80 (0.35)	(-1.48, -0.11)	0.0227	-0.22 (0.11)	(-0.43, -0.01)	0.0425	
> 65	7	NE	3	NE	NE	NE		NE	NE		
Sex											NE
male	15	NE	12	NE	NE	NE		NE	NE		
female	164	-4.42 (0.28)	170	-3.86 (0.27)	-0.56 (0.35)	(-1.25, 0.13)	0.1117	-0.16 (0.11)	(-0.37, 0.06)	0.1538	
Race											NE
White	125	-4.25 (0.30)	135	-3.75 (0.29)	-0.51 (0.38)	(-1.26, 0.25)	0.1907	-0.15 (0.12)	(-0.39, 0.09)	0.2305	
Black or African American	28	-5.39 (0.73)	23	-3.72 (0.71)	-1.67 (0.90)	(-3.49, 0.15)	0.0707	-0.45 (0.29)	(-1.01, 0.11)	0.1160	
Asian	11	NE	5	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	NE	NE	NE		NE	NE		
Other	15	-5.15 (1.12)	18	-3.01 (1.02)	-2.14 (1.32)	(-4.85, 0.58)	0.1173	-0.48 (0.36)	(-1.18, 0.21)	0.1742	
Ethnicity											0.3890
Hispanic/Latino	32	-4.10 (0.75)	34	-4.04 (0.74)	-0.06 (0.85)	(-1.77, 1.65)	0.9424	-0.01 (0.25)	(-0.50, 0.47)	0.9535	
Non-hispanic/Latino	147	-4.64 (0.29)	148	-3.77 (0.29)	-0.86 (0.37)	(-1.59, -0.13)	0.0205	-0.25 (0.12)	(-0.48, -0.02)	0.0339	
Geographic region											0.3836
EU	64	-5.24 (0.46)	75	-4.09 (0.44)	-1.15 (0.54)	(-2.22, -0.09)	0.0342	-0.30 (0.17)	(-0.64, 0.03)	0.0757	
non-EU	115	-4.07 (0.34)	107	-3.53 (0.35)	-0.55 (0.44)	(-1.42, 0.33)	0.2191	-0.15 (0.13)	(-0.41, 0.11)	0.2615	
Onset of disease											NE
Paediatric	12	NE	12	NE	NE	NE		NE	NE		
Adult	167	-4.48 (0.27)	170	-3.85 (0.26)	-0.63 (0.34)	(-1.29, 0.03)	0.0628	-0.18 (0.11)	(-0.40, 0.03)	0.0934	
ADA result											0.0613
Negative	162	-4.55 (0.27)	167	-3.82 (0.28)	-0.73 (0.35)	(-1.43, -0.04)	0.0384	-0.21 (0.11)	(-0.42, 0.01)	0.0604	
Positive (At any time)	17	-6.13 (1.03)	15	-2.80 (0.99)	-3.33 (1.34)	(-6.12, -0.53)	0.0220	-0.80 (0.37)	(-1.52, -0.07)	0.0311	
BMI (kg/m2) at enrolment											0.9243
< 30	107	-4.94 (0.38)	125	-4.11 (0.36)	-0.83 (0.44)	(-1.71, 0.05)	0.0633	-0.21 (0.13)	(-0.47, 0.05)	0.1133	
>= 30	72	-4.04 (0.38)	57	-3.27 (0.42)	-0.76 (0.53)	(-1.82, 0.30)	0.1564	-0.24 (0.18)	(-0.59, 0.11)	0.1777	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score CNS
Full analysis set

Visit	Anifrolumab 300mg (N=180) N	Anifrolumab 300mg (N=180) LSMean (SE)	Placebo (N=184) N	Placebo (N=184) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		NE		NE	NE	NE				
Week 8		NE		NE	NE	NE				
Week 12		NE		NE	NE	NE				
Week 16		NE		NE	NE	NE				
Week 20		NE		NE	NE	NE				
Week 24		NE		NE	NE	NE				
Week 28		NE		NE	NE	NE				
Week 32		NE		NE	NE	NE				
Week 36		NE		NE	NE	NE				
Week 40		NE		NE	NE	NE				
Week 44		NE		NE	NE	NE				
Week 48		NE		NE	NE	NE				
Week 52		NE		NE	NE	NE				
OVERALL	179	NE	183	NE	NE	NE		NE	NE	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score CNS - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=184) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											NE
< 10 points	54	NE	53	NE	NE	NE		NE	NE		
>= 10 points	125	NE	130	NE	NE	NE		NE	NE		
OCS dose at baseline											NE
<10 mg/day	77	NE	82	NE	NE	NE		NE	NE		
>=10 mg/day	102	NE	101	NE	NE	NE		NE	NE		
Result of type I IFN gene signature test											NE
LOW	32	NE	33	NE	NE	NE		NE	NE		
HIGH	147	NE	150	NE	NE	NE		NE	NE		
Age (years)											NE
<= 65	172	NE	180	NE	NE	NE		NE	NE		
> 65	7	NE	3	NE	NE	NE		NE	NE		
Sex											NE
male	15	NE	13	NE	NE	NE		NE	NE		
female	164	NE	170	NE	NE	NE		NE	NE		
Race											NE
White	125	NE	136	NE	NE	NE		NE	NE		
Black or African American	28	NE	23	NE	NE	NE		NE	NE		
Asian	11	NE	5	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	NE	NE	NE		NE	NE		
Other	15	NE	18	NE	NE	NE		NE	NE		
Ethnicity											NE
Hispanic/Latino	32	NE	34	NE	NE	NE		NE	NE		
Non-hispanic/Latino	147	NE	149	NE	NE	NE		NE	NE		
Geographic region											NE
EU	64	NE	76	NE	NE	NE		NE	NE		
non-EU	115	NE	107	NE	NE	NE		NE	NE		
Onset of disease											NE
Paediatric	12	NE	12	NE	NE	NE		NE	NE		
Adult	167	NE	171	NE	NE	NE		NE	NE		
ADA result											NE
Negative	162	NE	168	NE	NE	NE		NE	NE		
Positive (At any time)	17	NE	15	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											NE
< 30	107	NE	126	NE	NE	NE		NE	NE		
>= 30	72	NE	57	NE	NE	NE		NE	NE		

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score CVS and Respiratory
Full analysis set

Visit	Anifrolumab 300mg (N=180) N	Anifrolumab 300mg (N=180) LSMean (SE)	Placebo (N=184) N	Placebo (N=184) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		NE		NE	NE	NE				
Week 8		NE		NE	NE	NE				
Week 12		NE		NE	NE	NE				
Week 16		NE		NE	NE	NE				
Week 20		NE		NE	NE	NE				
Week 24		NE		NE	NE	NE				
Week 28		NE		NE	NE	NE				
Week 32		NE		NE	NE	NE				
Week 36		NE		NE	NE	NE				
Week 40		NE		NE	NE	NE				
Week 44		NE		NE	NE	NE				
Week 48		NE		NE	NE	NE				
Week 52		NE		NE	NE	NE				
OVERALL	179	NE	183	NE	NE	NE		NE	NE	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score CVS and Respiratory - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=184) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											NE
< 10 points	54	NE	53	NE	NE	NE		NE	NE		
>= 10 points	125	NE	130	NE	NE	NE		NE	NE		
OCS dose at baseline											NE
<10 mg/day	77	NE	82	NE	NE	NE		NE	NE		
>=10 mg/day	102	NE	101	NE	NE	NE		NE	NE		
Result of type I IFN gene signature test											NE
LOW	32	NE	33	NE	NE	NE		NE	NE		
HIGH	147	NE	150	NE	NE	NE		NE	NE		
Age (years)											NE
<= 65	172	NE	180	NE	NE	NE		NE	NE		
> 65	7	NE	3	NE	NE	NE		NE	NE		
Sex											NE
male	15	NE	13	NE	NE	NE		NE	NE		
female	164	NE	170	NE	NE	NE		NE	NE		
Race											NE
White	125	NE	136	NE	NE	NE		NE	NE		
Black or African American	28	NE	23	NE	NE	NE		NE	NE		
Asian	11	NE	5	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	NE	NE	NE		NE	NE		
Other	15	NE	18	NE	NE	NE		NE	NE		
Ethnicity											NE
Hispanic/Latino	32	NE	34	NE	NE	NE		NE	NE		
Non-hispanic/Latino	147	NE	149	NE	NE	NE		NE	NE		
Geographic region											NE
EU	64	NE	76	NE	NE	NE		NE	NE		
non-EU	115	NE	107	NE	NE	NE		NE	NE		
Onset of disease											NE
Paediatric	12	NE	12	NE	NE	NE		NE	NE		
Adult	167	NE	171	NE	NE	NE		NE	NE		
ADA result											NE
Negative	162	NE	168	NE	NE	NE		NE	NE		
Positive (At any time)	17	NE	15	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											NE
< 30	107	NE	126	NE	NE	NE		NE	NE		
>= 30	72	NE	57	NE	NE	NE		NE	NE		

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score Hematological
Full analysis set

Visit	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=184) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-0.06 (0.02)		-0.01 (0.02)	-0.05 (0.03)	(-0.11, 0.00)	0.0707			
Week 8		-0.09 (0.02)		-0.02 (0.02)	-0.07 (0.03)	(-0.12, -0.01)	0.0134			
Week 12		-0.09 (0.02)		-0.01 (0.02)	-0.08 (0.03)	(-0.14, -0.02)	0.0045			
Week 16		-0.09 (0.02)		-0.01 (0.02)	-0.08 (0.03)	(-0.13, -0.02)	0.0059			
Week 20		-0.09 (0.02)		-0.03 (0.02)	-0.06 (0.03)	(-0.11, -0.00)	0.0350			
Week 24		-0.09 (0.02)		-0.02 (0.02)	-0.06 (0.03)	(-0.12, -0.00)	0.0338			
Week 28		-0.10 (0.02)		-0.04 (0.02)	-0.06 (0.03)	(-0.11, -0.01)	0.0300			
Week 32		-0.10 (0.02)		-0.01 (0.02)	-0.09 (0.03)	(-0.15, -0.04)	0.0013			
Week 36		-0.09 (0.02)		-0.07 (0.02)	-0.03 (0.03)	(-0.07, 0.02)	0.3177			
Week 40		-0.09 (0.02)		-0.07 (0.02)	-0.02 (0.02)	(-0.07, 0.03)	0.3648			
Week 44		-0.07 (0.02)		-0.06 (0.02)	-0.01 (0.03)	(-0.06, 0.04)	0.7411			
Week 48		-0.08 (0.02)		-0.06 (0.02)	-0.02 (0.03)	(-0.08, 0.04)	0.4373			
Week 52		-0.10 (0.02)		-0.08 (0.02)	-0.02 (0.02)	(-0.06, 0.02)	0.3395			
OVERALL	179	-0.09 (0.01)	183	-0.04 (0.01)	-0.05 (0.02)	(-0.08, -0.02)	0.0014	-0.29 (0.11)	(-0.50, -0.08)	0.0062

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score Hematological - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=184) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											NE
< 10 points	54	NE	53	NE	NE	NE		NE	NE		
>= 10 points	125	-0.10 (0.02)	130	-0.05 (0.02)	-0.05 (0.02)	(-0.08, -0.01)	0.0241	-0.25 (0.13)	(-0.50, -0.00)	0.0475	
OCS dose at baseline											0.2429
<10 mg/day	77	-0.08 (0.02)	82	-0.05 (0.02)	-0.03 (0.02)	(-0.07, 0.01)	0.1608	-0.21 (0.16)	(-0.52, 0.10)	0.1910	
>=10 mg/day	102	-0.09 (0.02)	101	-0.03 (0.02)	-0.07 (0.02)	(-0.11, -0.02)	0.0039	-0.34 (0.14)	(-0.61, -0.06)	0.0174	
Result of type I IFN gene signature test											NE
LOW	32	NE	33	NE	NE	NE		NE	NE		
HIGH	147	-0.08 (0.01)	150	-0.03 (0.01)	-0.05 (0.02)	(-0.09, -0.02)	0.0042	-0.32 (0.12)	(-0.55, -0.09)	0.0063	
Age (years)											NE
<= 65	172	-0.09 (0.01)	180	-0.04 (0.01)	-0.05 (0.02)	(-0.08, -0.02)	0.0023	-0.28 (0.11)	(-0.49, -0.07)	0.0099	
> 65	7	NE	3	NE	NE	NE		NE	NE		
Sex											NE
male	15	NE	13	NE	NE	NE		NE	NE		
female	164	-0.09 (0.01)	170	-0.04 (0.01)	-0.05 (0.02)	(-0.08, -0.02)	0.0030	-0.28 (0.11)	(-0.49, -0.06)	0.0115	
Race											NE
White	125	-0.08 (0.01)	136	-0.03 (0.01)	-0.05 (0.02)	(-0.08, -0.01)	0.0059	-0.31 (0.12)	(-0.55, -0.06)	0.0142	
Black or African American	28	NE	23	NE	NE	NE		NE	NE		
Asian	11	NE	5	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	NE	NE	NE		NE	NE		
Other	15	NE	18	NE	NE	NE		NE	NE		
Ethnicity											NE
Hispanic/Latino	32	NE	34	NE	NE	NE		NE	NE		
Non-hispanic/Latino	147	-0.09 (0.01)	149	-0.04 (0.01)	-0.05 (0.02)	(-0.08, -0.02)	0.0030	-0.31 (0.12)	(-0.54, -0.08)	0.0082	
Geographic region											0.1054
EU	64	-0.08 (0.02)	76	-0.00 (0.02)	-0.08 (0.02)	(-0.13, -0.03)	0.0013	-0.43 (0.17)	(-0.77, -0.09)	0.0125	
non-EU	115	-0.08 (0.02)	107	-0.05 (0.02)	-0.03 (0.02)	(-0.07, 0.01)	0.1281	-0.18 (0.13)	(-0.45, 0.08)	0.1781	
Onset of disease											NE
Paediatric	12	NE	12	NE	NE	NE		NE	NE		
Adult	167	-0.09 (0.01)	171	-0.03 (0.01)	-0.06 (0.02)	(-0.09, -0.03)	0.0002	-0.35 (0.11)	(-0.56, -0.13)	0.0015	
ADA result											NE
Negative	162	-0.09 (0.01)	168	-0.03 (0.01)	-0.06 (0.02)	(-0.09, -0.02)	0.0006	-0.33 (0.11)	(-0.55, -0.11)	0.0028	
Positive (At any time)	17	NE	15	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.3493
< 30	107	-0.10 (0.02)	126	-0.05 (0.02)	-0.06 (0.02)	(-0.10, -0.01)	0.0116	-0.27 (0.13)	(-0.53, -0.01)	0.0412	
>= 30	72	-0.05 (0.01)	57	-0.02 (0.01)	-0.03 (0.02)	(-0.06, 0.00)	0.0622	-0.31 (0.18)	(-0.66, 0.04)	0.0790	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score Immunology
Full analysis set

	Anifrolumab 300mg (N=180)		Placebo (N=184)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-0.20 (0.07)		-0.14 (0.07)	-0.07 (0.09)	(-0.24, 0.10)	0.4289			
Week 8		-0.18 (0.07)		-0.07 (0.07)	-0.11 (0.09)	(-0.28, 0.07)	0.2358			
Week 12		-0.24 (0.08)		-0.01 (0.08)	-0.23 (0.10)	(-0.42, -0.04)	0.0190			
Week 16		-0.29 (0.08)		-0.02 (0.08)	-0.28 (0.10)	(-0.47, -0.09)	0.0042			
Week 20		-0.28 (0.08)		0.03 (0.08)	-0.31 (0.10)	(-0.51, -0.10)	0.0035			
Week 24		-0.35 (0.08)		-0.14 (0.08)	-0.20 (0.11)	(-0.41, 0.01)	0.0581			
Week 28		-0.31 (0.08)		-0.16 (0.08)	-0.15 (0.10)	(-0.36, 0.05)	0.1435			
Week 32		-0.30 (0.08)		-0.17 (0.08)	-0.14 (0.11)	(-0.34, 0.07)	0.2033			
Week 36		-0.27 (0.08)		-0.15 (0.08)	-0.12 (0.09)	(-0.31, 0.07)	0.2068			
Week 40		-0.23 (0.09)		-0.16 (0.08)	-0.07 (0.11)	(-0.29, 0.14)	0.4968			
Week 44		-0.22 (0.08)		-0.23 (0.08)	0.01 (0.11)	(-0.20, 0.22)	0.9483			
Week 48		-0.31 (0.09)		-0.11 (0.09)	-0.20 (0.11)	(-0.43, 0.02)	0.0771			
Week 52		-0.29 (0.09)		-0.17 (0.09)	-0.12 (0.11)	(-0.34, 0.11)	0.3076			
OVERALL	179	-0.27 (0.06)	184	-0.11 (0.06)	-0.15 (0.07)	(-0.30, -0.01)	0.0370	-0.18 (0.11)	(-0.38, 0.03)	0.0897

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score Immunology - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=180)		Placebo (N=184)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											0.5498
< 10 points	54	-0.09 (0.08)	54	0.01 (0.08)	-0.10 (0.10)	(-0.30, 0.11)	0.3499	-0.16 (0.19)	(-0.54, 0.22)	0.4012	
>= 10 points	125	-0.29 (0.08)	130	-0.11 (0.08)	-0.18 (0.09)	(-0.36, 0.01)	0.0599	-0.20 (0.13)	(-0.45, 0.05)	0.1105	
OCS dose at baseline											0.2081
<10 mg/day	77	-0.11 (0.08)	82	-0.05 (0.08)	-0.05 (0.10)	(-0.24, 0.13)	0.5722	-0.08 (0.16)	(-0.39, 0.23)	0.6226	
>=10 mg/day	102	-0.42 (0.10)	102	-0.19 (0.10)	-0.23 (0.11)	(-0.44, -0.02)	0.0287	-0.23 (0.14)	(-0.51, 0.05)	0.1017	
Result of type I IFN gene signature test											0.1528
LOW	32	-0.15 (0.10)	33	0.18 (0.10)	-0.33 (0.13)	(-0.60, -0.06)	0.0175	-0.59 (0.25)	(-1.08, -0.09)	0.0206	
HIGH	147	-0.29 (0.06)	151	-0.18 (0.06)	-0.10 (0.08)	(-0.27, 0.06)	0.2275	-0.13 (0.12)	(-0.36, 0.10)	0.2581	
Age (years)											NE
<= 65	172	-0.26 (0.07)	181	-0.13 (0.06)	-0.14 (0.07)	(-0.28, 0.01)	0.0665	-0.16 (0.11)	(-0.37, 0.05)	0.1428	
> 65	7	NE	3	NE	NE	NE		NE	NE		
Sex											NE
male	15	NE	13	NE	NE	NE		NE	NE		
female	164	-0.26 (0.07)	171	-0.11 (0.06)	-0.16 (0.07)	(-0.30, -0.01)	0.0387	-0.18 (0.11)	(-0.40, 0.03)	0.0928	
Race											NE
White	125	-0.20 (0.07)	137	-0.13 (0.07)	-0.07 (0.08)	(-0.23, 0.09)	0.3920	-0.09 (0.12)	(-0.33, 0.15)	0.4713	
Black or African American	28	-0.28 (0.22)	23	-0.18 (0.17)	-0.10 (0.23)	(-0.56, 0.37)	0.6748	-0.09 (0.28)	(-0.65, 0.46)	0.7368	
Asian	11	NE	5	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	NE	NE	NE		NE	NE		
Other	15	-0.45 (0.53)	18	0.21 (0.53)	-0.66 (0.36)	(-1.40, 0.08)	0.0788	-0.30 (0.35)	(-0.99, 0.39)	0.3970	
Ethnicity											0.7127
Hispanic/Latino	32	-0.34 (0.21)	35	-0.11 (0.20)	-0.22 (0.21)	(-0.65, 0.20)	0.2933	-0.19 (0.25)	(-0.67, 0.29)	0.4460	
Non-hispanic/Latino	147	-0.24 (0.07)	149	-0.10 (0.07)	-0.14 (0.08)	(-0.29, 0.01)	0.0685	-0.18 (0.12)	(-0.40, 0.05)	0.1323	
Geographic region											0.3650
EU	64	-0.29 (0.12)	76	-0.22 (0.12)	-0.07 (0.12)	(-0.30, 0.16)	0.5719	-0.07 (0.17)	(-0.40, 0.27)	0.6918	
non-EU	115	-0.24 (0.08)	108	-0.04 (0.08)	-0.20 (0.09)	(-0.39, -0.02)	0.0340	-0.24 (0.13)	(-0.51, 0.02)	0.0708	
Onset of disease											NE
Paediatric	12	NE	12	NE	NE	NE		NE	NE		
Adult	167	-0.24 (0.07)	172	-0.09 (0.07)	-0.15 (0.08)	(-0.30, -0.00)	0.0469	-0.18 (0.11)	(-0.39, 0.04)	0.1039	
ADA result											0.5857
Negative	162	-0.27 (0.07)	169	-0.11 (0.07)	-0.15 (0.08)	(-0.30, 0.00)	0.0501	-0.18 (0.11)	(-0.39, 0.04)	0.1069	
Positive (At any time)	17	-0.11 (0.22)	15	-0.08 (0.19)	-0.03 (0.21)	(-0.45, 0.39)	0.8775	-0.04 (0.35)	(-0.73, 0.66)	0.9142	
BMI (kg/m2) at enrolment											0.4859
< 30	107	-0.30 (0.10)	127	-0.20 (0.09)	-0.10 (0.10)	(-0.30, 0.10)	0.3300	-0.10 (0.13)	(-0.35, 0.16)	0.4572	
>= 30	72	-0.19 (0.07)	57	0.00 (0.07)	-0.19 (0.09)	(-0.37, -0.02)	0.0320	-0.34 (0.18)	(-0.69, 0.01)	0.0593	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score Mucocutaneous
Full analysis set

Visit	Anifrolumab 300mg (N=180) N	Anifrolumab 300mg (N=180) LSMean (SE)	Placebo (N=184) N	Placebo (N=184) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-0.01 (0.07)		-0.14 (0.07)	0.13 (0.08)	(-0.03, 0.28)	0.1063			
Week 8		-0.42 (0.10)		-0.47 (0.09)	0.05 (0.13)	(-0.20, 0.30)	0.6938			
Week 12		-0.92 (0.11)		-0.67 (0.11)	-0.24 (0.15)	(-0.53, 0.05)	0.1051			
Week 16		-1.19 (0.12)		-0.97 (0.12)	-0.21 (0.16)	(-0.53, 0.10)	0.1844			
Week 20		-1.46 (0.12)		-1.15 (0.12)	-0.31 (0.17)	(-0.64, 0.02)	0.0656			
Week 24		-1.62 (0.13)		-1.33 (0.13)	-0.29 (0.18)	(-0.65, 0.06)	0.1051			
Week 28		-1.78 (0.14)		-1.40 (0.14)	-0.38 (0.19)	(-0.75, -0.01)	0.0443			
Week 32		-1.95 (0.14)		-1.51 (0.14)	-0.44 (0.19)	(-0.81, -0.07)	0.0192			
Week 36		-2.04 (0.14)		-1.59 (0.14)	-0.46 (0.19)	(-0.83, -0.08)	0.0176			
Week 40		-2.04 (0.15)		-1.65 (0.15)	-0.39 (0.20)	(-0.78, 0.01)	0.0563			
Week 44		-2.12 (0.15)		-1.63 (0.15)	-0.50 (0.20)	(-0.90, -0.10)	0.0152			
Week 48		-2.20 (0.15)		-1.66 (0.15)	-0.54 (0.21)	(-0.95, -0.12)	0.0116			
Week 52		-2.27 (0.15)		-1.74 (0.15)	-0.53 (0.21)	(-0.93, -0.13)	0.0103			
OVERALL	179	-1.54 (0.11)	183	-1.22 (0.10)	-0.32 (0.14)	(-0.59, -0.04)	0.0248	-0.22 (0.11)	(-0.43, -0.02)	0.0342

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score Mucocutaneous - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=184) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.4697
< 10 points	54	-1.34 (0.18)	53	-0.86 (0.18)	-0.48 (0.25)	(-0.97, 0.01)	0.0535	-0.36 (0.19)	(-0.74, 0.03)	0.0681	
>= 10 points	125	-1.62 (0.13)	130	-1.36 (0.13)	-0.26 (0.17)	(-0.60, 0.07)	0.1242	-0.18 (0.13)	(-0.43, 0.06)	0.1421	
OCS dose at baseline											0.5572
<10 mg/day	77	-1.54 (0.16)	82	-1.30 (0.16)	-0.24 (0.22)	(-0.67, 0.19)	0.2693	-0.17 (0.16)	(-0.48, 0.14)	0.2930	
>=10 mg/day	102	-1.59 (0.14)	101	-1.18 (0.14)	-0.41 (0.19)	(-0.78, -0.04)	0.0310	-0.29 (0.14)	(-0.56, -0.01)	0.0428	
Result of type I IFN gene signature test											0.6539
LOW	32	-1.40 (0.25)	33	-1.23 (0.25)	-0.17 (0.35)	(-0.88, 0.53)	0.6254	-0.12 (0.25)	(-0.61, 0.37)	0.6308	
HIGH	147	-1.63 (0.11)	150	-1.29 (0.11)	-0.35 (0.15)	(-0.65, -0.05)	0.0244	-0.26 (0.12)	(-0.49, -0.03)	0.0272	
Age (years)											NE
<= 65	172	-1.56 (0.11)	180	-1.24 (0.11)	-0.32 (0.14)	(-0.60, -0.04)	0.0264	-0.22 (0.11)	(-0.43, -0.01)	0.0371	
> 65	7	NE	3	NE	NE	NE		NE	NE		
Sex											NE
male	15	NE	13	NE	NE	NE		NE	NE		
female	164	-1.52 (0.11)	170	-1.26 (0.11)	-0.26 (0.15)	(-0.55, 0.03)	0.0780	-0.18 (0.11)	(-0.40, 0.03)	0.0969	
Race											NE
White	125	-1.46 (0.13)	136	-1.18 (0.12)	-0.28 (0.17)	(-0.61, 0.05)	0.1007	-0.19 (0.12)	(-0.44, 0.05)	0.1186	
Black or African American	28	-1.65 (0.27)	23	-1.42 (0.27)	-0.23 (0.36)	(-0.95, 0.49)	0.5238	-0.17 (0.28)	(-0.72, 0.39)	0.5544	
Asian	11	NE	5	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	NE	NE	NE		NE	NE		
Other	15	NE	18	NE	NE	NE		NE	NE		
Ethnicity											0.5028
Hispanic/Latino	32	-1.58 (0.29)	34	-1.50 (0.28)	-0.09 (0.35)	(-0.80, 0.62)	0.8033	-0.05 (0.25)	(-0.54, 0.43)	0.8262	
Non-hispanic/Latino	147	-1.55 (0.11)	149	-1.21 (0.11)	-0.35 (0.15)	(-0.65, -0.04)	0.0249	-0.25 (0.12)	(-0.48, -0.02)	0.0332	
Geographic region											0.7119
EU	64	-1.63 (0.17)	76	-1.24 (0.16)	-0.39 (0.22)	(-0.81, 0.04)	0.0747	-0.28 (0.17)	(-0.62, 0.05)	0.0991	
non-EU	115	-1.52 (0.14)	107	-1.23 (0.14)	-0.28 (0.19)	(-0.65, 0.08)	0.1294	-0.19 (0.13)	(-0.46, 0.07)	0.1508	
Onset of disease											NE
Paediatric	12	NE	12	NE	NE	NE		NE	NE		
Adult	167	-1.55 (0.11)	171	-1.24 (0.11)	-0.31 (0.14)	(-0.60, -0.03)	0.0329	-0.22 (0.11)	(-0.43, -0.01)	0.0443	
ADA result											NE
Negative	162	-1.56 (0.11)	168	-1.22 (0.11)	-0.34 (0.15)	(-0.63, -0.05)	0.0204	-0.24 (0.11)	(-0.46, -0.03)	0.0282	
Positive (At any time)	17	NE	15	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.8018
< 30	107	-1.70 (0.14)	126	-1.34 (0.13)	-0.36 (0.17)	(-0.70, -0.02)	0.0400	-0.25 (0.13)	(-0.51, 0.01)	0.0558	
>= 30	72	-1.35 (0.17)	57	-1.07 (0.19)	-0.29 (0.24)	(-0.76, 0.19)	0.2399	-0.20 (0.18)	(-0.55, 0.15)	0.2604	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score Musculoskeletal
Full analysis set

Visit	Anifrolumab 300mg (N=180) N	Anifrolumab 300mg (N=180) LSMean (SE)	Placebo (N=184) N	Placebo (N=184) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-0.13 (0.09)		-0.10 (0.09)	-0.03 (0.11)	(-0.24, 0.18)	0.7757			
Week 8		-0.64 (0.13)		-0.70 (0.13)	0.05 (0.18)	(-0.29, 0.40)	0.7622			
Week 12		-1.09 (0.15)		-1.23 (0.15)	0.14 (0.20)	(-0.26, 0.53)	0.4967			
Week 16		-1.47 (0.16)		-1.48 (0.16)	0.01 (0.21)	(-0.40, 0.43)	0.9469			
Week 20		-1.91 (0.16)		-1.57 (0.16)	-0.34 (0.22)	(-0.76, 0.08)	0.1153			
Week 24		-2.03 (0.16)		-1.87 (0.16)	-0.16 (0.22)	(-0.58, 0.27)	0.4723			
Week 28		-2.15 (0.16)		-1.88 (0.16)	-0.28 (0.22)	(-0.70, 0.15)	0.2048			
Week 32		-2.30 (0.17)		-2.11 (0.16)	-0.19 (0.22)	(-0.63, 0.25)	0.4024			
Week 36		-2.35 (0.17)		-2.20 (0.16)	-0.15 (0.22)	(-0.59, 0.29)	0.4963			
Week 40		-2.27 (0.16)		-2.30 (0.16)	0.03 (0.22)	(-0.40, 0.46)	0.9079			
Week 44		-2.32 (0.16)		-2.34 (0.16)	0.02 (0.21)	(-0.40, 0.44)	0.9269			
Week 48		-2.27 (0.16)		-2.42 (0.16)	0.15 (0.21)	(-0.27, 0.57)	0.4739			
Week 52		-2.35 (0.16)		-2.47 (0.16)	0.12 (0.22)	(-0.30, 0.55)	0.5639			
OVERALL	179	-1.79 (0.12)	183	-1.74 (0.12)	-0.05 (0.16)	(-0.35, 0.26)	0.7621	-0.03 (0.11)	(-0.24, 0.18)	0.7802

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score Musculoskeletal - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=184) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.4561
< 10 points	54	-1.79 (0.22)	53	-1.54 (0.22)	-0.25 (0.31)	(-0.86, 0.36)	0.4183	-0.15 (0.19)	(-0.53, 0.23)	0.4360	
>= 10 points	125	-1.83 (0.14)	130	-1.85 (0.14)	0.02 (0.18)	(-0.34, 0.38)	0.9270	0.01 (0.13)	(-0.23, 0.26)	0.9326	
OCS dose at baseline											0.6406
<10 mg/day	77	-1.90 (0.18)	82	-1.76 (0.17)	-0.14 (0.24)	(-0.61, 0.33)	0.5516	-0.09 (0.16)	(-0.40, 0.22)	0.5715	
>=10 mg/day	102	-1.71 (0.17)	101	-1.71 (0.16)	0.01 (0.21)	(-0.40, 0.41)	0.9801	0.00 (0.14)	(-0.27, 0.28)	0.9826	
Result of type I IFN gene signature test											0.3295
LOW	32	-1.15 (0.26)	33	-1.43 (0.26)	0.28 (0.37)	(-0.45, 1.02)	0.4466	0.19 (0.25)	(-0.30, 0.67)	0.4530	
HIGH	147	-2.00 (0.12)	150	-1.89 (0.12)	-0.11 (0.17)	(-0.45, 0.22)	0.5062	-0.08 (0.12)	(-0.30, 0.15)	0.5171	
Age (years)											NE
<= 65	172	-1.80 (0.12)	180	-1.74 (0.12)	-0.05 (0.16)	(-0.36, 0.26)	0.7402	-0.03 (0.11)	(-0.24, 0.18)	0.7622	
> 65	7	NE	3	NE	NE	NE		NE	NE		
Sex											NE
male	15	NE	13	NE	NE	NE		NE	NE		
female	164	-1.79 (0.13)	170	-1.74 (0.12)	-0.05 (0.16)	(-0.37, 0.26)	0.7405	-0.03 (0.11)	(-0.25, 0.18)	0.7613	
Race											NE
White	125	-1.81 (0.14)	136	-1.87 (0.14)	0.06 (0.19)	(-0.31, 0.43)	0.7477	0.04 (0.12)	(-0.21, 0.28)	0.7603	
Black or African American	28	NE	23	NE	NE	NE		NE	NE		
Asian	11	NE	5	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	NE	NE	NE		NE	NE		
Other	15	NE	18	NE	NE	NE		NE	NE		
Ethnicity											0.7044
Hispanic/Latino	32	-1.67 (0.32)	34	-1.75 (0.32)	0.08 (0.37)	(-0.67, 0.82)	0.8388	0.04 (0.25)	(-0.44, 0.52)	0.8684	
Non-hispanic/Latino	147	-1.80 (0.13)	149	-1.72 (0.13)	-0.08 (0.17)	(-0.42, 0.26)	0.6455	-0.05 (0.12)	(-0.28, 0.18)	0.6676	
Geographic region											0.7305
EU	64	-2.18 (0.19)	76	-2.05 (0.18)	-0.13 (0.24)	(-0.59, 0.34)	0.5962	-0.08 (0.17)	(-0.41, 0.25)	0.6333	
non-EU	115	-1.56 (0.15)	107	-1.55 (0.16)	-0.02 (0.20)	(-0.42, 0.39)	0.9302	-0.01 (0.13)	(-0.27, 0.25)	0.9355	
Onset of disease											NE
Paediatric	12	NE	12	NE	NE	NE		NE	NE		
Adult	167	-1.83 (0.12)	171	-1.76 (0.12)	-0.07 (0.16)	(-0.39, 0.25)	0.6689	-0.04 (0.11)	(-0.26, 0.17)	0.6925	
ADA result											NE
Negative	162	-1.78 (0.13)	168	-1.82 (0.12)	0.04 (0.16)	(-0.28, 0.36)	0.8202	0.02 (0.11)	(-0.19, 0.24)	0.8342	
Positive (At any time)	17	NE	15	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.7714
< 30	107	-1.96 (0.15)	126	-1.90 (0.14)	-0.06 (0.19)	(-0.42, 0.31)	0.7579	-0.04 (0.13)	(-0.29, 0.22)	0.7862	
>= 30	72	-1.58 (0.19)	57	-1.43 (0.21)	-0.15 (0.27)	(-0.69, 0.39)	0.5746	-0.10 (0.18)	(-0.44, 0.25)	0.5899	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score Renal
Full analysis set

	Anifrolumab 300mg (N=180)		Placebo (N=184)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-0.16 (0.10)		0.05 (0.10)	-0.22 (0.13)	(-0.47, 0.04)	0.0961			
Week 8		-0.12 (0.11)		0.18 (0.11)	-0.30 (0.14)	(-0.57, -0.03)	0.0270			
Week 12		-0.17 (0.10)		-0.13 (0.10)	-0.04 (0.13)	(-0.28, 0.21)	0.7681			
Week 16		-0.10 (0.11)		0.05 (0.10)	-0.15 (0.13)	(-0.40, 0.11)	0.2687			
Week 20		-0.10 (0.12)		-0.00 (0.11)	-0.09 (0.15)	(-0.38, 0.20)	0.5294			
Week 24		-0.08 (0.10)		-0.05 (0.10)	-0.03 (0.13)	(-0.28, 0.22)	0.8269			
Week 28		0.02 (0.14)		-0.05 (0.14)	0.07 (0.18)	(-0.29, 0.43)	0.7072			
Week 32		-0.05 (0.13)		0.03 (0.12)	-0.09 (0.16)	(-0.40, 0.23)	0.5990			
Week 36		-0.01 (0.13)		0.05 (0.12)	-0.06 (0.16)	(-0.38, 0.26)	0.7248			
Week 40		-0.00 (0.13)		0.02 (0.13)	-0.02 (0.17)	(-0.36, 0.32)	0.9077			
Week 44		-0.06 (0.14)		0.02 (0.13)	-0.08 (0.18)	(-0.43, 0.27)	0.6500			
Week 48		-0.00 (0.15)		0.08 (0.14)	-0.09 (0.19)	(-0.47, 0.29)	0.6533			
Week 52		-0.07 (0.13)		0.13 (0.13)	-0.20 (0.18)	(-0.54, 0.15)	0.2570			
OVERALL	180	-0.07 (0.10)	184	0.03 (0.10)	-0.10 (0.12)	(-0.34, 0.15)	0.4266	-0.07 (0.10)	(-0.28, 0.13)	0.4885

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score Renal - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=184) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											NE
< 10 points	55	NE	54	NE	NE	NE		NE	NE		
>= 10 points	125	-0.04 (0.14)	130	0.13 (0.13)	-0.17 (0.17)	(-0.50, 0.17)	0.3307	-0.11 (0.13)	(-0.35, 0.14)	0.3891	
OCS dose at baseline											NE
<10 mg/day	77	NE	82	NE	NE	NE		NE	NE		
>=10 mg/day	103	-0.04 (0.18)	102	-0.01 (0.18)	-0.03 (0.21)	(-0.44, 0.38)	0.8889	-0.02 (0.14)	(-0.29, 0.26)	0.9090	
Result of type I IFN gene signature test											NE
LOW	32	NE	33	NE	NE	NE		NE	NE		
HIGH	148	-0.05 (0.11)	151	0.08 (0.11)	-0.12 (0.15)	(-0.42, 0.17)	0.4186	-0.09 (0.12)	(-0.32, 0.14)	0.4371	
Age (years)											NE
<= 65	173	-0.07 (0.11)	181	0.03 (0.10)	-0.10 (0.13)	(-0.35, 0.15)	0.4323	-0.07 (0.11)	(-0.28, 0.14)	0.4995	
> 65	7	NE	3	NE	NE	NE		NE	NE		
Sex											NE
male	15	NE	13	NE	NE	NE		NE	NE		
female	165	-0.03 (0.10)	171	0.07 (0.10)	-0.10 (0.13)	(-0.36, 0.15)	0.4319	-0.08 (0.11)	(-0.29, 0.14)	0.4859	
Race											NE
White	125	-0.11 (0.11)	137	0.04 (0.11)	-0.16 (0.14)	(-0.44, 0.12)	0.2653	-0.13 (0.12)	(-0.37, 0.12)	0.3063	
Black or African American	29	NE	23	NE	NE	NE		NE	NE		
Asian	11	NE	5	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	NE	NE	NE		NE	NE		
Other	15	NE	18	NE	NE	NE		NE	NE		
Ethnicity											NE
Hispanic/Latino	32	NE	35	NE	NE	NE		NE	NE		
Non-hispanic/Latino	148	-0.06 (0.11)	149	-0.00 (0.11)	-0.06 (0.14)	(-0.33, 0.20)	0.6390	-0.05 (0.12)	(-0.28, 0.18)	0.6729	
Geographic region											NE
EU	64	NE	76	NE	NE	NE		NE	NE		
non-EU	116	0.07 (0.11)	108	0.04 (0.11)	0.03 (0.14)	(-0.24, 0.31)	0.8130	0.03 (0.13)	(-0.23, 0.29)	0.8272	
Onset of disease											NE
Paediatric	12	NE	12	NE	NE	NE		NE	NE		
Adult	168	-0.09 (0.09)	172	-0.05 (0.09)	-0.03 (0.11)	(-0.24, 0.17)	0.7421	-0.03 (0.11)	(-0.24, 0.18)	0.7783	
ADA result											NE
Negative	162	-0.05 (0.09)	169	-0.01 (0.09)	-0.04 (0.11)	(-0.26, 0.18)	0.7022	-0.04 (0.11)	(-0.25, 0.18)	0.7379	
Positive (At any time)	17	NE	15	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.8618
< 30	108	0.04 (0.14)	127	0.11 (0.13)	-0.07 (0.17)	(-0.39, 0.26)	0.6864	-0.04 (0.13)	(-0.30, 0.21)	0.7337	
>= 30	72	-0.20 (0.12)	57	-0.17 (0.13)	-0.03 (0.17)	(-0.37, 0.32)	0.8837	-0.02 (0.18)	(-0.37, 0.32)	0.8886	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score Vascular
Full analysis set

Visit	Anifrolumab 300mg (N=180) N	Anifrolumab 300mg (N=180) LSMean (SE)	Placebo (N=184) N	Placebo (N=184) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		NE		NE	NE	NE				
Week 8		NE		NE	NE	NE				
Week 12		NE		NE	NE	NE				
Week 16		NE		NE	NE	NE				
Week 20		NE		NE	NE	NE				
Week 24		NE		NE	NE	NE				
Week 28		NE		NE	NE	NE				
Week 32		NE		NE	NE	NE				
Week 36		NE		NE	NE	NE				
Week 40		NE		NE	NE	NE				
Week 44		NE		NE	NE	NE				
Week 48		NE		NE	NE	NE				
Week 52		NE		NE	NE	NE				
OVERALL	179	NE	183	NE	NE	NE		NE	NE	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score Vascular - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=184) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											NE
< 10 points	54	NE	53	NE	NE	NE		NE	NE		
>= 10 points	125	NE	130	NE	NE	NE		NE	NE		
OCS dose at baseline											NE
<10 mg/day	77	NE	82	NE	NE	NE		NE	NE		
>=10 mg/day	102	NE	101	NE	NE	NE		NE	NE		
Result of type I IFN gene signature test											NE
LOW	32	NE	33	NE	NE	NE		NE	NE		
HIGH	147	NE	150	NE	NE	NE		NE	NE		
Age (years)											NE
<= 65	172	NE	180	NE	NE	NE		NE	NE		
> 65	7	NE	3	NE	NE	NE		NE	NE		
Sex											NE
male	15	NE	13	NE	NE	NE		NE	NE		
female	164	NE	170	NE	NE	NE		NE	NE		
Race											NE
White	125	NE	136	NE	NE	NE		NE	NE		
Black or African American	28	NE	23	NE	NE	NE		NE	NE		
Asian	11	NE	5	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	NE	NE	NE		NE	NE		
Other	15	NE	18	NE	NE	NE		NE	NE		
Ethnicity											NE
Hispanic/Latino	32	NE	34	NE	NE	NE		NE	NE		
Non-hispanic/Latino	147	NE	149	NE	NE	NE		NE	NE		
Geographic region											NE
EU	64	NE	76	NE	NE	NE		NE	NE		
non-EU	115	NE	107	NE	NE	NE		NE	NE		
Onset of disease											NE
Paediatric	12	NE	12	NE	NE	NE		NE	NE		
Adult	167	NE	171	NE	NE	NE		NE	NE		
ADA result											NE
Negative	162	NE	168	NE	NE	NE		NE	NE		
Positive (At any time)	17	NE	15	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											NE
< 30	107	NE	126	NE	NE	NE		NE	NE		
>= 30	72	NE	57	NE	NE	NE		NE	NE		

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - PGA
Full analysis set

Visit	Anifrolumab 300mg (N=180) N	Anifrolumab 300mg (N=180) LSMean (SE)	Placebo (N=184) N	Placebo (N=184) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-0.25 (0.03)		-0.19 (0.03)	-0.06 (0.03)	(-0.13, 0.00)	0.0592			
Week 8		-0.47 (0.04)		-0.39 (0.04)	-0.08 (0.05)	(-0.17, 0.01)	0.0898			
Week 12		-0.61 (0.04)		-0.46 (0.04)	-0.16 (0.05)	(-0.26, -0.06)	0.0027			
Week 16		-0.70 (0.04)		-0.54 (0.04)	-0.16 (0.06)	(-0.28, -0.05)	0.0035			
Week 20		-0.80 (0.04)		-0.61 (0.04)	-0.18 (0.06)	(-0.30, -0.07)	0.0015			
Week 24		-0.86 (0.05)		-0.66 (0.05)	-0.20 (0.06)	(-0.32, -0.08)	0.0012			
Week 28		-0.92 (0.05)		-0.73 (0.05)	-0.19 (0.06)	(-0.31, -0.07)	0.0019			
Week 32		-0.94 (0.05)		-0.75 (0.05)	-0.19 (0.06)	(-0.31, -0.07)	0.0028			
Week 36		-0.97 (0.05)		-0.79 (0.05)	-0.18 (0.07)	(-0.32, -0.05)	0.0088			
Week 40		-0.98 (0.05)		-0.83 (0.05)	-0.15 (0.07)	(-0.29, -0.01)	0.0307			
Week 44		-1.02 (0.05)		-0.84 (0.05)	-0.19 (0.07)	(-0.33, -0.05)	0.0097			
Week 48		-1.06 (0.05)		-0.86 (0.05)	-0.20 (0.07)	(-0.34, -0.06)	0.0053			
Week 52		-1.11 (0.05)		-0.88 (0.05)	-0.22 (0.07)	(-0.36, -0.08)	0.0022			
OVERALL	179	-0.82 (0.04)	183	-0.66 (0.04)	-0.17 (0.05)	(-0.26, -0.07)	0.0007	-0.33 (0.11)	(-0.53, -0.12)	0.0020

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - PGA - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=180)		Placebo (N=184)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											0.2811
< 10 points	54	-0.88 (0.07)	53	-0.63 (0.07)	-0.25 (0.09)	(-0.42, -0.07)	0.0073	-0.49 (0.20)	(-0.87, -0.11)	0.0126	
>= 10 points	125	-0.78 (0.04)	130	-0.65 (0.04)	-0.13 (0.06)	(-0.25, -0.02)	0.0259	-0.26 (0.13)	(-0.51, -0.01)	0.0389	
OCS dose at baseline											0.7461
<10 mg/day	77	-0.76 (0.05)	82	-0.58 (0.05)	-0.19 (0.07)	(-0.32, -0.05)	0.0087	-0.39 (0.16)	(-0.71, -0.08)	0.0142	
>=10 mg/day	102	-0.89 (0.05)	101	-0.74 (0.05)	-0.15 (0.07)	(-0.29, -0.02)	0.0253	-0.28 (0.14)	(-0.56, -0.00)	0.0463	
Result of type I IFN gene signature test											0.0569
LOW	32	-0.68 (0.08)	33	-0.70 (0.08)	0.02 (0.11)	(-0.20, 0.23)	0.8727	0.04 (0.25)	(-0.45, 0.52)	0.8764	
HIGH	147	-0.89 (0.04)	150	-0.67 (0.04)	-0.21 (0.05)	(-0.32, -0.11)	0.0001	-0.44 (0.12)	(-0.67, -0.21)	0.0002	
Age (years)											NE
<= 65	172	-0.82 (0.04)	180	-0.66 (0.04)	-0.17 (0.05)	(-0.26, -0.07)	0.0010	-0.32 (0.11)	(-0.53, -0.11)	0.0028	
> 65	7	NE	3	NE	NE	NE		NE	NE		
Sex											NE
male	15	NE	13	NE	NE	NE		NE	NE		
female	164	-0.80 (0.04)	170	-0.65 (0.04)	-0.15 (0.05)	(-0.25, -0.05)	0.0037	-0.29 (0.11)	(-0.51, -0.08)	0.0080	
Race											NE
White	125	-0.78 (0.04)	136	-0.66 (0.04)	-0.12 (0.06)	(-0.23, -0.01)	0.0373	-0.24 (0.12)	(-0.48, 0.00)	0.0541	
Black or African American	28	-1.05 (0.10)	23	-0.71 (0.09)	-0.33 (0.12)	(-0.58, -0.09)	0.0086	-0.68 (0.29)	(-1.25, -0.12)	0.0183	
Asian	11	NE	5	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	NE	NE	NE		NE	NE		
Other	15	NE	18	NE	NE	NE		NE	NE		
Ethnicity											0.4157
Hispanic/Latino	32	-0.79 (0.11)	34	-0.72 (0.10)	-0.07 (0.13)	(-0.33, 0.19)	0.5802	-0.12 (0.25)	(-0.60, 0.36)	0.6313	
Non-hispanic/Latino	147	-0.83 (0.04)	149	-0.65 (0.04)	-0.19 (0.05)	(-0.29, -0.08)	0.0005	-0.37 (0.12)	(-0.60, -0.14)	0.0014	
Geographic region											0.6473
EU	64	-0.88 (0.06)	76	-0.68 (0.06)	-0.20 (0.07)	(-0.34, -0.05)	0.0094	-0.38 (0.17)	(-0.72, -0.05)	0.0251	
non-EU	115	-0.80 (0.05)	107	-0.65 (0.05)	-0.15 (0.07)	(-0.28, -0.02)	0.0213	-0.29 (0.14)	(-0.55, -0.02)	0.0327	
Onset of disease											NE
Paediatric	12	NE	12	NE	NE	NE		NE	NE		
Adult	167	-0.82 (0.04)	171	-0.67 (0.04)	-0.15 (0.05)	(-0.25, -0.05)	0.0035	-0.29 (0.11)	(-0.51, -0.08)	0.0074	
ADA result											NE
Negative	162	-0.82 (0.04)	168	-0.66 (0.04)	-0.16 (0.05)	(-0.26, -0.06)	0.0021	-0.31 (0.11)	(-0.53, -0.10)	0.0048	
Positive (At any time)	17	NE	15	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.6120
< 30	107	-0.87 (0.05)	126	-0.67 (0.05)	-0.20 (0.06)	(-0.32, -0.08)	0.0014	-0.38 (0.13)	(-0.64, -0.12)	0.0046	
>= 30	72	-0.77 (0.06)	57	-0.62 (0.07)	-0.14 (0.08)	(-0.31, 0.02)	0.0921	-0.28 (0.18)	(-0.63, 0.07)	0.1136	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - CLASI Total Activity Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) N	Anifrolumab 300mg (N=180) LSMean (SE)	Placebo (N=184) N	Placebo (N=184) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-1.63 (0.25)		-1.12 (0.24)	-0.51 (0.30)	(-1.10, 0.08)	0.0903			
Week 8		-3.15 (0.29)		-2.01 (0.29)	-1.14 (0.37)	(-1.87, -0.40)	0.0025			
Week 12		-3.91 (0.31)		-2.40 (0.31)	-1.51 (0.40)	(-2.29, -0.72)	0.0002			
Week 16		-4.47 (0.31)		-2.98 (0.31)	-1.50 (0.40)	(-2.28, -0.71)	0.0002			
Week 20		-4.96 (0.32)		-3.25 (0.32)	-1.71 (0.42)	(-2.53, -0.88)	<.0001			
Week 24		-5.22 (0.35)		-3.19 (0.34)	-2.03 (0.46)	(-2.92, -1.13)	<.0001			
Week 28		-5.54 (0.35)		-3.54 (0.35)	-2.00 (0.46)	(-2.91, -1.10)	<.0001			
Week 32		-5.72 (0.35)		-3.89 (0.35)	-1.82 (0.47)	(-2.74, -0.91)	0.0001			
Week 36		-5.97 (0.34)		-4.32 (0.34)	-1.65 (0.45)	(-2.54, -0.76)	0.0003			
Week 40		-6.10 (0.36)		-4.35 (0.35)	-1.74 (0.47)	(-2.67, -0.81)	0.0003			
Week 44		-6.11 (0.37)		-4.37 (0.37)	-1.74 (0.50)	(-2.72, -0.77)	0.0005			
Week 48		-6.24 (0.37)		-4.53 (0.36)	-1.71 (0.49)	(-2.67, -0.75)	0.0005			
Week 52		-6.31 (0.38)		-4.56 (0.37)	-1.75 (0.50)	(-2.74, -0.77)	0.0005			
OVERALL	179	-5.02 (0.29)	183	-3.42 (0.29)	-1.60 (0.37)	(-2.32, -0.88)	<.0001	-0.41 (0.11)	(-0.62, -0.21)	<.0001

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - CLASI Total Activity Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=184) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.0877
< 10 points	54	-4.08 (0.43)	53	-3.35 (0.42)	-0.73 (0.57)	(-1.86, 0.40)	0.2035	-0.23 (0.19)	(-0.61, 0.15)	0.2297	
>= 10 points	125	-5.35 (0.36)	130	-3.38 (0.35)	-1.97 (0.46)	(-2.88, -1.07)	<.0001	-0.49 (0.13)	(-0.74, -0.24)	0.0001	
OCS dose at baseline											0.2376
<10 mg/day	77	-3.99 (0.37)	82	-2.95 (0.36)	-1.04 (0.49)	(-2.02, -0.07)	0.0355	-0.32 (0.16)	(-0.63, -0.01)	0.0455	
>=10 mg/day	102	-5.63 (0.43)	101	-3.74 (0.43)	-1.89 (0.52)	(-2.92, -0.86)	0.0004	-0.44 (0.14)	(-0.71, -0.16)	0.0022	
Result of type I IFN gene signature test											0.0035
LOW	32	-3.57 (0.41)	33	-3.71 (0.41)	0.13 (0.57)	(-1.03, 1.29)	0.8172	0.06 (0.25)	(-0.43, 0.54)	0.8214	
HIGH	147	-5.51 (0.32)	150	-3.54 (0.32)	-1.96 (0.43)	(-2.82, -1.11)	<.0001	-0.51 (0.12)	(-0.74, -0.28)	<.0001	
Age (years)											NE
<= 65	172	-4.98 (0.30)	180	-3.39 (0.30)	-1.59 (0.38)	(-2.33, -0.85)	<.0001	-0.40 (0.11)	(-0.61, -0.19)	0.0002	
> 65	7	NE	3	NE	NE	NE		NE	NE		
Sex											NE
male	15	NE	13	NE	NE	NE		NE	NE		
female	164	-4.63 (0.29)	170	-3.20 (0.29)	-1.43 (0.37)	(-2.15, -0.71)	0.0001	-0.38 (0.11)	(-0.60, -0.17)	0.0005	
Race											NE
White	125	-4.72 (0.33)	136	-3.71 (0.32)	-1.02 (0.42)	(-1.84, -0.19)	0.0164	-0.28 (0.12)	(-0.52, -0.03)	0.0271	
Black or African American	28	NE	23	NE	NE	NE		NE	NE		
Asian	11	NE	5	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	1.50 (0.00)	NE	NE		NE	NE		
Other	15	NE	18	NE	NE	NE		NE	NE		
Ethnicity											0.0734
Hispanic/Latino	32	-3.21 (0.56)	34	-2.80 (0.55)	-0.41 (0.65)	(-1.72, 0.90)	0.5344	-0.13 (0.25)	(-0.61, 0.36)	0.6104	
Non-hispanic/Latino	147	-5.44 (0.33)	149	-3.64 (0.33)	-1.80 (0.43)	(-2.65, -0.96)	<.0001	-0.45 (0.12)	(-0.68, -0.22)	0.0001	
Geographic region											0.4560
EU	64	-5.55 (0.57)	76	-3.49 (0.54)	-2.06 (0.69)	(-3.44, -0.68)	0.0038	-0.44 (0.17)	(-0.78, -0.10)	0.0103	
non-EU	115	-4.69 (0.32)	107	-3.24 (0.33)	-1.46 (0.42)	(-2.28, -0.63)	0.0006	-0.42 (0.14)	(-0.69, -0.16)	0.0018	
Onset of disease											NE
Paediatric	12	NE	12	NE	NE	NE		NE	NE		
Adult	167	-4.81 (0.29)	171	-3.40 (0.29)	-1.42 (0.37)	(-2.14, -0.70)	0.0001	-0.38 (0.11)	(-0.60, -0.17)	0.0005	
ADA result											NE
Negative	162	-5.10 (0.29)	168	-3.54 (0.29)	-1.56 (0.38)	(-2.30, -0.81)	<.0001	-0.41 (0.11)	(-0.63, -0.19)	0.0002	
Positive (At any time)	17	NE	15	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.2522
< 30	107	-5.21 (0.39)	126	-3.25 (0.37)	-1.95 (0.47)	(-2.89, -1.02)	<.0001	-0.47 (0.13)	(-0.73, -0.21)	0.0004	
>= 30	72	-4.67 (0.40)	57	-3.54 (0.43)	-1.12 (0.55)	(-2.22, -0.02)	0.0452	-0.34 (0.18)	(-0.69, 0.01)	0.0600	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - CLASI Total Damage Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) N	Anifrolumab 300mg (N=180) LSMean (SE)	Placebo (N=184) N	Placebo (N=184) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-0.15 (0.11)		-0.06 (0.11)	-0.10 (0.13)	(-0.35, 0.16)	0.4632			
Week 8		-0.29 (0.13)		-0.18 (0.13)	-0.12 (0.16)	(-0.44, 0.20)	0.4655			
Week 12		-0.43 (0.15)		-0.19 (0.14)	-0.24 (0.19)	(-0.62, 0.13)	0.1957			
Week 16		-0.57 (0.15)		-0.24 (0.15)	-0.33 (0.20)	(-0.73, 0.07)	0.1027			
Week 20		-0.63 (0.16)		-0.30 (0.16)	-0.32 (0.21)	(-0.74, 0.09)	0.1260			
Week 24		-0.84 (0.17)		-0.37 (0.17)	-0.47 (0.23)	(-0.93, -0.01)	0.0437			
Week 28		-0.90 (0.19)		-0.47 (0.19)	-0.44 (0.26)	(-0.94, 0.07)	0.0930			
Week 32		-0.90 (0.20)		-0.40 (0.20)	-0.49 (0.27)	(-1.02, 0.03)	0.0670			
Week 36		-0.92 (0.20)		-0.44 (0.20)	-0.48 (0.28)	(-1.02, 0.07)	0.0854			
Week 40		-1.02 (0.21)		-0.48 (0.20)	-0.54 (0.28)	(-1.09, 0.02)	0.0568			
Week 44		-1.03 (0.21)		-0.51 (0.21)	-0.52 (0.28)	(-1.08, 0.03)	0.0653			
Week 48		-1.04 (0.21)		-0.50 (0.21)	-0.54 (0.29)	(-1.12, 0.03)	0.0645			
Week 52		-1.10 (0.21)		-0.53 (0.21)	-0.58 (0.29)	(-1.14, -0.01)	0.0458			
OVERALL	179	-0.76 (0.16)	183	-0.36 (0.15)	-0.40 (0.20)	(-0.80, 0.01)	0.0534	-0.19 (0.11)	(-0.40, 0.02)	0.0712

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - CLASI Total Damage Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=184) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.6865
< 10 points	54	-0.56 (0.23)	53	-0.09 (0.22)	-0.47 (0.29)	(-1.04, 0.11)	0.1104	-0.28 (0.19)	(-0.66, 0.10)	0.1469	
>= 10 points	125	-0.72 (0.21)	130	-0.41 (0.20)	-0.30 (0.28)	(-0.86, 0.25)	0.2776	-0.13 (0.13)	(-0.38, 0.11)	0.2928	
OCS dose at baseline											NE
<10 mg/day	77	NE	82	NE	NE	NE		NE	NE		
>=10 mg/day	102	NE	101	NE	NE	NE		NE	NE		
Result of type I IFN gene signature test											NE
LOW	32	NE	33	NE	NE	NE		NE	NE		
HIGH	147	-0.82 (0.18)	150	-0.36 (0.18)	-0.46 (0.24)	(-0.95, 0.02)	0.0590	-0.22 (0.12)	(-0.44, 0.01)	0.0637	
Age (years)											NE
<= 65	172	-0.75 (0.16)	180	-0.33 (0.16)	-0.41 (0.21)	(-0.82, -0.00)	0.0488	-0.19 (0.11)	(-0.40, 0.01)	0.0681	
> 65	7	NE	3	NE	NE	NE		NE	NE		
Sex											NE
male	15	NE	13	NE	NE	NE		NE	NE		
female	164	-0.65 (0.15)	170	-0.40 (0.15)	-0.25 (0.19)	(-0.63, 0.13)	0.1921	-0.13 (0.11)	(-0.35, 0.08)	0.2310	
Race											NE
White	125	NE	136	NE	NE	NE		NE	NE		
Black or African American	28	-1.31 (0.41)	23	-0.49 (0.42)	-0.82 (0.55)	(-1.95, 0.32)	0.1521	-0.38 (0.28)	(-0.94, 0.18)	0.1814	
Asian	11	NE	5	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	NE	NE	NE		NE	NE		
Other	15	NE	18	NE	NE	NE		NE	NE		
Ethnicity											NE
Hispanic/Latino	32	NE	34	NE	NE	NE		NE	NE		
Non-hispanic/Latino	147	-0.88 (0.16)	149	-0.38 (0.16)	-0.50 (0.22)	(-0.93, -0.07)	0.0230	-0.25 (0.12)	(-0.48, -0.02)	0.0323	
Geographic region											NE
EU	64	NE	76	NE	NE	NE		NE	NE		
non-EU	115	NE	107	NE	NE	NE		NE	NE		
Onset of disease											NE
Paediatric	12	NE	12	NE	NE	NE		NE	NE		
Adult	167	-0.66 (0.16)	171	-0.29 (0.16)	-0.38 (0.21)	(-0.79, 0.03)	0.0702	-0.18 (0.11)	(-0.40, 0.03)	0.0898	
ADA result											NE
Negative	162	-0.84 (0.16)	168	-0.34 (0.16)	-0.50 (0.21)	(-0.91, -0.09)	0.0183	-0.25 (0.11)	(-0.46, -0.03)	0.0266	
Positive (At any time)	17	NE	15	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.1553
< 30	107	-0.86 (0.19)	126	-0.20 (0.18)	-0.66 (0.24)	(-1.13, -0.20)	0.0054	-0.33 (0.13)	(-0.59, -0.07)	0.0136	
>= 30	72	-0.54 (0.29)	57	-0.58 (0.33)	0.04 (0.43)	(-0.82, 0.89)	0.9349	0.01 (0.18)	(-0.33, 0.36)	0.9359	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - BILAG Global Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) N	Anifrolumab 300mg (N=180) LSMean (SE)	Placebo (N=184) N	Placebo (N=184) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-4.39 (0.50)		-3.72 (0.49)	-0.66 (0.61)	(-1.85, 0.53)	0.2728			
Week 8		-7.82 (0.57)		-5.71 (0.56)	-2.12 (0.72)	(-3.54, -0.70)	0.0036			
Week 12		-8.93 (0.57)		-6.60 (0.57)	-2.33 (0.73)	(-3.77, -0.89)	0.0016			
Week 16		-9.90 (0.60)		-7.37 (0.60)	-2.53 (0.78)	(-4.06, -1.00)	0.0012			
Week 20		-10.06 (0.62)		-8.50 (0.61)	-1.56 (0.79)	(-3.12, -0.00)	0.0496			
Week 24		-10.78 (0.61)		-8.77 (0.60)	-2.01 (0.78)	(-3.54, -0.48)	0.0103			
Week 28		-11.03 (0.59)		-9.45 (0.58)	-1.58 (0.76)	(-3.07, -0.09)	0.0375			
Week 32		-11.53 (0.60)		-9.67 (0.59)	-1.86 (0.77)	(-3.37, -0.35)	0.0159			
Week 36		-11.22 (0.63)		-9.97 (0.62)	-1.25 (0.81)	(-2.84, 0.34)	0.1237			
Week 40		-11.54 (0.61)		-10.12 (0.61)	-1.42 (0.79)	(-2.98, 0.14)	0.0740			
Week 44		-11.59 (0.63)		-9.98 (0.62)	-1.61 (0.82)	(-3.22, -0.00)	0.0498			
Week 48		-12.08 (0.62)		-10.50 (0.62)	-1.59 (0.81)	(-3.17, 0.00)	0.0502			
Week 52		-12.34 (0.61)		-10.35 (0.61)	-1.99 (0.79)	(-3.55, -0.44)	0.0120			
OVERALL	179	-10.25 (0.49)	183	-8.52 (0.49)	-1.73 (0.60)	(-2.91, -0.55)	0.0042	-0.26 (0.11)	(-0.47, -0.06)	0.0130

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - BILAG Global Score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=180)		Placebo (N=184)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											0.2505
< 10 points	54	-10.62 (0.78)	53	-7.84 (0.78)	-2.78 (1.01)	(-4.78, -0.78)	0.0069	-0.48 (0.20)	(-0.87, -0.10)	0.0139	
>= 10 points	125	-9.93 (0.60)	130	-8.59 (0.59)	-1.34 (0.75)	(-2.81, 0.13)	0.0743	-0.20 (0.13)	(-0.44, 0.05)	0.1164	
OCS dose at baseline											0.8860
<10 mg/day	77	-10.28 (0.68)	82	-8.65 (0.67)	-1.63 (0.87)	(-3.35, 0.09)	0.0629	-0.27 (0.16)	(-0.58, 0.04)	0.0920	
>=10 mg/day	102	-10.14 (0.72)	101	-8.33 (0.71)	-1.81 (0.83)	(-3.44, -0.17)	0.0310	-0.25 (0.14)	(-0.53, 0.03)	0.0774	
Result of type I IFN gene signature test											0.0457
LOW	32	-9.25 (1.14)	33	-10.27 (1.11)	1.02 (1.54)	(-2.07, 4.10)	0.5111	0.16 (0.25)	(-0.33, 0.64)	0.5279	
HIGH	147	-10.55 (0.48)	150	-8.23 (0.48)	-2.32 (0.65)	(-3.60, -1.04)	0.0004	-0.40 (0.12)	(-0.63, -0.17)	0.0007	
Age (years)											NE
<= 65	172	-10.27 (0.51)	180	-8.55 (0.50)	-1.72 (0.61)	(-2.93, -0.51)	0.0053	-0.26 (0.11)	(-0.47, -0.05)	0.0172	
> 65	7	NE	3	NE	NE	NE		NE	NE		
Sex											NE
male	15	-16.13 (0.00)	13	-11.01 (0.00)	-5.13 (0.00)	(NE, NE)	<.0001	()	(NE, NE)	NE	
female	164	-10.01 (0.52)	170	-8.54 (0.51)	-1.47 (0.63)	(-2.71, -0.22)	0.0208	-0.22 (0.11)	(-0.43, -0.00)	0.0453	
Race											NE
White	125	-10.45 (0.58)	136	-8.92 (0.57)	-1.53 (0.72)	(-2.94, -0.11)	0.0343	-0.23 (0.12)	(-0.48, 0.01)	0.0623	
Black or African American	28	-10.81 (1.20)	23	-7.59 (1.11)	-3.23 (1.45)	(-6.14, -0.32)	0.0305	-0.54 (0.29)	(-1.10, 0.02)	0.0604	
Asian	11	NE	5	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	NE	NE	NE		NE	NE		
Other	15	-7.70 (2.42)	18	-6.28 (2.30)	-1.42 (2.11)	(-5.76, 2.93)	0.5086	-0.14 (0.35)	(-0.83, 0.54)	0.6810	
Ethnicity											0.0767
Hispanic/Latino	32	-8.29 (1.33)	34	-8.93 (1.31)	0.64 (1.44)	(-2.25, 3.54)	0.6582	0.08 (0.25)	(-0.40, 0.57)	0.7337	
Non-hispanic/Latino	147	-10.57 (0.53)	149	-8.40 (0.53)	-2.17 (0.66)	(-3.47, -0.87)	0.0012	-0.34 (0.12)	(-0.56, -0.11)	0.0042	
Geographic region											0.8624
EU	64	-11.15 (0.89)	76	-9.24 (0.87)	-1.91 (0.97)	(-3.83, 0.02)	0.0521	-0.26 (0.17)	(-0.59, 0.08)	0.1315	
non-EU	115	-9.88 (0.60)	107	-8.19 (0.61)	-1.69 (0.77)	(-3.20, -0.18)	0.0282	-0.26 (0.13)	(-0.53, 0.00)	0.0510	
Onset of disease											NE
Paediatric	12	NE	12	NE	NE	NE		NE	NE		
Adult	167	-10.27 (0.51)	171	-8.64 (0.51)	-1.64 (0.62)	(-2.86, -0.41)	0.0091	-0.25 (0.11)	(-0.46, -0.03)	0.0229	
ADA result											0.3369
Negative	162	-10.18 (0.51)	168	-8.66 (0.51)	-1.51 (0.63)	(-2.75, -0.27)	0.0168	-0.23 (0.11)	(-0.45, -0.01)	0.0368	
Positive (At any time)	17	-8.98 (1.52)	15	-5.65 (1.43)	-3.33 (1.78)	(-7.00, 0.35)	0.0739	-0.55 (0.36)	(-1.25, 0.16)	0.1317	
BMI (kg/m2) at enrolment											0.8662
< 30	107	-10.85 (0.65)	126	-9.08 (0.62)	-1.77 (0.74)	(-3.23, -0.32)	0.0173	-0.26 (0.13)	(-0.52, 0.00)	0.0508	
>= 30	72	-9.74 (0.74)	57	-7.76 (0.81)	-1.98 (1.01)	(-3.98, 0.02)	0.0523	-0.32 (0.18)	(-0.67, 0.03)	0.0753	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Tender Joint Count
Full analysis set

Visit	Anifrolumab 300mg (N=180) N	Anifrolumab 300mg (N=180) LSMean (SE)	Placebo (N=184) N	Placebo (N=184) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-1.37 (0.42)		-2.24 (0.41)	0.87 (0.52)	(-0.14, 1.89)	0.0925			
Week 8		-3.92 (0.42)		-3.36 (0.41)	-0.56 (0.52)	(-1.58, 0.45)	0.2760			
Week 12		-4.95 (0.44)		-4.02 (0.44)	-0.92 (0.56)	(-2.02, 0.17)	0.0988			
Week 16		-5.79 (0.46)		-4.62 (0.45)	-1.17 (0.59)	(-2.33, -0.02)	0.0462			
Week 20		-6.00 (0.48)		-4.82 (0.47)	-1.18 (0.62)	(-2.39, 0.04)	0.0570			
Week 24		-6.17 (0.49)		-5.15 (0.49)	-1.01 (0.64)	(-2.27, 0.24)	0.1133			
Week 28		-6.51 (0.47)		-5.64 (0.46)	-0.86 (0.60)	(-2.04, 0.32)	0.1515			
Week 32		-6.69 (0.49)		-5.37 (0.49)	-1.32 (0.64)	(-2.57, -0.07)	0.0382			
Week 36		-7.00 (0.49)		-5.67 (0.48)	-1.33 (0.63)	(-2.57, -0.09)	0.0355			
Week 40		-6.92 (0.48)		-6.05 (0.48)	-0.87 (0.62)	(-2.10, 0.35)	0.1629			
Week 44		-7.35 (0.50)		-5.79 (0.49)	-1.57 (0.64)	(-2.83, -0.30)	0.0157			
Week 48		-7.40 (0.50)		-6.16 (0.49)	-1.23 (0.64)	(-2.50, 0.03)	0.0557			
Week 52		-7.30 (0.50)		-6.44 (0.49)	-0.85 (0.64)	(-2.12, 0.41)	0.1859			
OVERALL	179	-5.95 (0.39)	183	-5.03 (0.38)	-0.92 (0.47)	(-1.85, -0.00)	0.0493	-0.18 (0.11)	(-0.39, 0.03)	0.0890

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Tender Joint Count - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=180)		Placebo (N=184)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											0.9021
< 10 points	54	-6.77 (0.73)	53	-5.89 (0.73)	-0.88 (0.91)	(-2.69, 0.93)	0.3358	-0.16 (0.19)	(-0.54, 0.22)	0.3960	
>= 10 points	125	-5.38 (0.44)	130	-4.37 (0.43)	-1.01 (0.55)	(-2.10, 0.07)	0.0668	-0.21 (0.13)	(-0.45, 0.04)	0.1020	
OCS dose at baseline											0.3382
<10 mg/day	77	-6.10 (0.58)	82	-4.73 (0.57)	-1.37 (0.73)	(-2.82, 0.07)	0.0621	-0.27 (0.16)	(-0.58, 0.05)	0.0935	
>=10 mg/day	102	-5.81 (0.52)	101	-5.35 (0.52)	-0.46 (0.62)	(-1.68, 0.76)	0.4604	-0.09 (0.14)	(-0.36, 0.19)	0.5377	
Result of type I IFN gene signature test											NE
LOW	32	NE	33	NE	NE	NE		NE	NE		
HIGH	147	-6.54 (0.36)	150	-5.96 (0.36)	-0.58 (0.48)	(-1.53, 0.38)	0.2341	-0.13 (0.12)	(-0.36, 0.10)	0.2561	
Age (years)											NE
<= 65	172	-5.85 (0.40)	180	-4.93 (0.39)	-0.92 (0.48)	(-1.86, 0.02)	0.0539	-0.18 (0.11)	(-0.38, 0.03)	0.1003	
> 65	7	NE	3	NE	NE	NE		NE	NE		
Sex											NE
male	15	NE	13	NE	NE	NE		NE	NE		
female	164	-5.87 (0.40)	170	-5.09 (0.40)	-0.78 (0.49)	(-1.74, 0.18)	0.1109	-0.15 (0.11)	(-0.36, 0.06)	0.1709	
Race											NE
White	125	-6.35 (0.46)	136	-5.35 (0.45)	-1.00 (0.57)	(-2.12, 0.12)	0.0803	-0.19 (0.12)	(-0.44, 0.05)	0.1198	
Black or African American	28	-5.71 (1.33)	23	-3.50 (1.18)	-2.21 (1.51)	(-5.24, 0.83)	0.1510	-0.34 (0.28)	(-0.89, 0.22)	0.2345	
Asian	11	NE	5	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	-17.00 (0.00)	NE	NE		NE	NE		
Other	15	NE	18	NE	NE	NE		NE	NE		
Ethnicity											0.5862
Hispanic/Latino	32	-5.49 (0.93)	34	-5.13 (0.91)	-0.37 (1.04)	(-2.44, 1.71)	0.7239	-0.07 (0.25)	(-0.55, 0.41)	0.7793	
Non-hispanic/Latino	147	-5.90 (0.42)	149	-4.89 (0.42)	-1.00 (0.53)	(-2.04, 0.03)	0.0580	-0.19 (0.12)	(-0.42, 0.03)	0.0955	
Geographic region											0.2818
EU	64	-6.24 (0.59)	76	-5.95 (0.58)	-0.29 (0.63)	(-1.54, 0.97)	0.6518	-0.06 (0.17)	(-0.39, 0.27)	0.7309	
non-EU	115	-5.86 (0.50)	107	-4.60 (0.51)	-1.25 (0.64)	(-2.51, 0.01)	0.0511	-0.23 (0.13)	(-0.50, 0.03)	0.0826	
Onset of disease											NE
Paediatric	12	NE	12	NE	NE	NE		NE	NE		
Adult	167	-6.12 (0.40)	171	-5.09 (0.40)	-1.03 (0.49)	(-1.99, -0.06)	0.0367	-0.20 (0.11)	(-0.41, 0.02)	0.0702	
ADA result											NE
Negative	162	-5.95 (0.40)	168	-5.30 (0.39)	-0.65 (0.49)	(-1.62, 0.31)	0.1837	-0.13 (0.11)	(-0.34, 0.09)	0.2454	
Positive (At any time)	17	NE	15	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.7806
< 30	107	-5.93 (0.46)	126	-4.88 (0.44)	-1.06 (0.53)	(-2.10, -0.01)	0.0472	-0.22 (0.13)	(-0.48, 0.04)	0.0988	
>= 30	72	-6.51 (0.67)	57	-5.75 (0.73)	-0.76 (0.90)	(-2.55, 1.02)	0.3976	-0.14 (0.18)	(-0.48, 0.21)	0.4463	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Swollen Joint Count
Full analysis set

Visit	Anifrolumab 300mg (N=180) N	Anifrolumab 300mg (N=180) LSMean (SE)	Placebo (N=184) N	Placebo (N=184) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-1.73 (0.32)		-1.81 (0.32)	0.08 (0.41)	(-0.72, 0.88)	0.8443			
Week 8		-3.06 (0.31)		-2.59 (0.31)	-0.47 (0.39)	(-1.24, 0.30)	0.2321			
Week 12		-4.19 (0.32)		-3.08 (0.32)	-1.11 (0.41)	(-1.91, -0.31)	0.0067			
Week 16		-4.50 (0.32)		-3.31 (0.31)	-1.19 (0.40)	(-1.98, -0.41)	0.0031			
Week 20		-4.59 (0.31)		-3.75 (0.31)	-0.84 (0.39)	(-1.61, -0.07)	0.0321			
Week 24		-4.54 (0.33)		-4.07 (0.33)	-0.47 (0.42)	(-1.30, 0.36)	0.2673			
Week 28		-4.89 (0.32)		-4.16 (0.31)	-0.73 (0.40)	(-1.52, 0.07)	0.0731			
Week 32		-5.20 (0.32)		-4.03 (0.32)	-1.17 (0.41)	(-1.98, -0.36)	0.0045			
Week 36		-5.21 (0.32)		-4.20 (0.31)	-1.01 (0.40)	(-1.80, -0.21)	0.0131			
Week 40		-5.09 (0.31)		-4.52 (0.31)	-0.57 (0.40)	(-1.35, 0.21)	0.1504			
Week 44		-5.22 (0.31)		-4.26 (0.31)	-0.96 (0.39)	(-1.73, -0.19)	0.0149			
Week 48		-5.32 (0.32)		-4.55 (0.31)	-0.77 (0.40)	(-1.56, 0.02)	0.0562			
Week 52		-5.36 (0.29)		-4.74 (0.29)	-0.62 (0.36)	(-1.34, 0.09)	0.0879			
OVERALL	179	-4.53 (0.26)	183	-3.78 (0.25)	-0.76 (0.31)	(-1.36, -0.16)	0.0137	-0.22 (0.11)	(-0.43, -0.01)	0.0374

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Swollen Joint Count - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=180)		Placebo (N=184)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											0.1083
< 10 points	54	-4.78 (0.47)	53	-3.22 (0.47)	-1.56 (0.60)	(-2.75, -0.36)	0.0111	-0.45 (0.20)	(-0.83, -0.06)	0.0223	
>= 10 points	125	-4.40 (0.29)	130	-3.96 (0.29)	-0.44 (0.35)	(-1.14, 0.26)	0.2188	-0.13 (0.13)	(-0.38, 0.11)	0.2879	
OCS dose at baseline											0.9576
<10 mg/day	77	-4.65 (0.35)	82	-3.94 (0.34)	-0.71 (0.43)	(-1.56, 0.14)	0.1003	-0.23 (0.16)	(-0.54, 0.08)	0.1465	
>=10 mg/day	102	-4.34 (0.38)	101	-3.59 (0.38)	-0.74 (0.44)	(-1.61, 0.12)	0.0923	-0.20 (0.14)	(-0.47, 0.08)	0.1641	
Result of type I IFN gene signature test											0.7408
LOW	32	-5.12 (0.50)	33	-4.20 (0.49)	-0.92 (0.68)	(-2.28, 0.44)	0.1809	-0.32 (0.25)	(-0.81, 0.17)	0.1993	
HIGH	147	-4.52 (0.25)	150	-3.86 (0.25)	-0.67 (0.34)	(-1.34, 0.00)	0.0508	-0.22 (0.12)	(-0.44, 0.01)	0.0636	
Age (years)											NE
<= 65	172	-4.57 (0.27)	180	-3.79 (0.26)	-0.79 (0.31)	(-1.40, -0.17)	0.0127	-0.22 (0.11)	(-0.43, -0.01)	0.0379	
> 65	7	NE	3	NE	NE	NE		NE	NE		
Sex											NE
male	15	NE	13	NE	NE	NE		NE	NE		
female	164	-4.43 (0.27)	170	-3.76 (0.27)	-0.67 (0.32)	(-1.30, -0.04)	0.0365	-0.19 (0.11)	(-0.41, 0.02)	0.0779	
Race											NE
White	125	-4.58 (0.30)	136	-3.76 (0.29)	-0.82 (0.37)	(-1.54, -0.10)	0.0260	-0.24 (0.12)	(-0.49, 0.00)	0.0522	
Black or African American	28	-5.20 (0.82)	23	-4.14 (0.72)	-1.06 (0.92)	(-2.92, 0.80)	0.2551	-0.26 (0.28)	(-0.82, 0.29)	0.3505	
Asian	11	NE	5	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	NE	NE	NE		NE	NE		
Other	15	NE	18	NE	NE	NE		NE	NE		
Ethnicity											0.5703
Hispanic/Latino	32	-5.07 (0.72)	34	-4.71 (0.70)	-0.35 (0.79)	(-1.94, 1.24)	0.6597	-0.08 (0.25)	(-0.57, 0.40)	0.7302	
Non-hispanic/Latino	147	-4.49 (0.27)	149	-3.65 (0.27)	-0.84 (0.33)	(-1.49, -0.19)	0.0120	-0.25 (0.12)	(-0.48, -0.02)	0.0305	
Geographic region											0.5046
EU	64	-4.51 (0.30)	76	-3.95 (0.29)	-0.56 (0.35)	(-1.25, 0.13)	0.1097	-0.22 (0.17)	(-0.56, 0.11)	0.1920	
non-EU	115	-4.62 (0.35)	107	-3.69 (0.35)	-0.93 (0.43)	(-1.78, -0.08)	0.0322	-0.25 (0.13)	(-0.51, 0.01)	0.0638	
Onset of disease											NE
Paediatric	12	NE	12	NE	NE	NE		NE	NE		
Adult	167	-4.64 (0.26)	171	-3.75 (0.26)	-0.88 (0.32)	(-1.51, -0.26)	0.0056	-0.26 (0.11)	(-0.47, -0.04)	0.0187	
ADA result											NE
Negative	162	-4.53 (0.27)	168	-3.86 (0.27)	-0.67 (0.32)	(-1.31, -0.03)	0.0402	-0.19 (0.11)	(-0.41, 0.02)	0.0803	
Positive (At any time)	17	NE	15	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.9511
< 30	107	-4.80 (0.29)	126	-3.95 (0.28)	-0.85 (0.34)	(-1.51, -0.19)	0.0119	-0.28 (0.13)	(-0.54, -0.02)	0.0365	
>= 30	72	-4.60 (0.44)	57	-3.71 (0.47)	-0.89 (0.59)	(-2.05, 0.27)	0.1301	-0.24 (0.18)	(-0.59, 0.11)	0.1744	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Mental Component Score
Full analysis set

	Anifrolumab 300mg (N=180)		Placebo (N=184)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 8		1.22 (0.70)		1.31 (0.69)	-0.09 (0.85)	(-1.77, 1.59)	0.9151			
Week 16		0.95 (0.75)		0.66 (0.74)	0.30 (0.94)	(-1.56, 2.15)	0.7532			
Week 24		2.05 (0.75)		0.27 (0.74)	1.78 (0.94)	(-0.08, 3.64)	0.0603			
Week 32		1.72 (0.81)		-0.14 (0.80)	1.86 (1.03)	(-0.16, 3.89)	0.0716			
Week 40		1.84 (0.84)		1.08 (0.81)	0.75 (1.07)	(-1.35, 2.85)	0.4803			
Week 48		2.15 (0.83)		1.21 (0.82)	0.94 (1.07)	(-1.16, 3.04)	0.3779			
Week 52		2.21 (0.84)		1.03 (0.82)	1.17 (1.07)	(-0.94, 3.28)	0.2760			
OVERALL	168	1.73 (0.64)	172	0.77 (0.63)	0.96 (0.77)	(-0.55, 2.47)	0.2127	0.11 (0.11)	(-0.10, 0.33)	0.2896

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Mental Component Score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=180)		Placebo (N=184)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											0.2782
< 10 points	50	2.65 (1.01)	51	0.48 (1.01)	2.17 (1.27)	(-0.34, 4.68)	0.0900	0.30 (0.20)	(-0.09, 0.69)	0.1335	
>= 10 points	118	1.23 (0.79)	121	0.78 (0.77)	0.45 (0.96)	(-1.45, 2.34)	0.6436	0.05 (0.13)	(-0.20, 0.31)	0.6884	
OCS dose at baseline											0.4050
<10 mg/day	72	2.33 (0.94)	76	0.67 (0.92)	1.66 (1.19)	(-0.70, 4.02)	0.1660	0.21 (0.16)	(-0.12, 0.53)	0.2108	
>=10 mg/day	96	1.22 (0.91)	96	0.86 (0.90)	0.36 (1.01)	(-1.62, 2.35)	0.7192	0.04 (0.14)	(-0.24, 0.32)	0.7785	
Result of type I IFN gene signature test											0.7155
LOW	30	2.61 (1.35)	31	1.04 (1.32)	1.57 (1.83)	(-2.11, 5.24)	0.3954	0.21 (0.26)	(-0.29, 0.71)	0.4134	
HIGH	138	1.87 (0.64)	141	1.03 (0.63)	0.83 (0.85)	(-0.84, 2.51)	0.3291	0.11 (0.12)	(-0.12, 0.35)	0.3526	
Age (years)											NE
<= 65	161	1.60 (0.67)	170	0.78 (0.65)	0.81 (0.78)	(-0.73, 2.35)	0.3001	0.10 (0.11)	(-0.12, 0.31)	0.3849	
> 65	7	NE	2	NE	NE	NE		NE	NE		
Sex											NE
male	15	NE	12	NE	NE	NE		NE	NE		
female	153	1.38 (0.68)	160	0.56 (0.66)	0.82 (0.81)	(-0.78, 2.42)	0.3135	0.10 (0.11)	(-0.12, 0.32)	0.3897	
Race											0.0170
White	117	1.74 (0.74)	126	0.39 (0.72)	1.35 (0.90)	(-0.43, 3.12)	0.1370	0.17 (0.13)	(-0.08, 0.42)	0.1930	
Black or African American	26	2.81 (2.32)	22	-0.55 (1.99)	3.35 (2.52)	(-1.74, 8.45)	0.1912	0.31 (0.29)	(-0.27, 0.88)	0.2935	
Asian	11	0.33 (2.28)	5	0.21 (3.52)	0.12 (4.13)	(-8.89, 9.12)	0.9777	0.01 (0.54)	(-1.04, 1.07)	0.9785	
American Indian or Alaska Native	0	NE	1	NE	NE	NE		NE	NE		
Other	14	-0.68 (2.41)	18	4.62 (2.27)	-5.30 (2.05)	(-9.49, -1.10)	0.0152	-0.55 (0.36)	(-1.26, 0.16)	0.1297	
Ethnicity											0.0037
Hispanic/Latino	30	-0.08 (1.60)	33	3.56 (1.58)	-3.64 (1.72)	(-7.08, -0.20)	0.0386	-0.40 (0.25)	(-0.90, 0.10)	0.1145	
Non-hispanic/Latino	138	2.26 (0.70)	139	0.33 (0.69)	1.93 (0.85)	(0.25, 3.61)	0.0243	0.23 (0.12)	(-0.00, 0.47)	0.0517	
Geographic region											0.6007
EU	61	2.67 (1.11)	72	1.27 (1.05)	1.40 (1.15)	(-0.87, 3.68)	0.2242	0.16 (0.17)	(-0.18, 0.50)	0.3635	
non-EU	107	1.21 (0.82)	100	0.62 (0.84)	0.59 (1.04)	(-1.46, 2.64)	0.5688	0.07 (0.14)	(-0.20, 0.34)	0.6158	
Onset of disease											NE
Paediatric	11	NE	11	NE	NE	NE		NE	NE		
Adult	157	1.83 (0.66)	161	0.50 (0.65)	1.33 (0.79)	(-0.22, 2.88)	0.0926	0.16 (0.11)	(-0.06, 0.38)	0.1526	
ADA result											0.7178
Negative	152	1.45 (0.68)	157	0.51 (0.67)	0.94 (0.82)	(-0.67, 2.55)	0.2508	0.11 (0.11)	(-0.11, 0.34)	0.3251	
Positive (At any time)	16	5.43 (2.18)	15	5.32 (1.98)	0.11 (2.13)	(-4.26, 4.49)	0.9580	0.01 (0.36)	(-0.69, 0.72)	0.9702	
BMI (kg/m2) at enrolment											0.2336
< 30	100	1.59 (0.82)	118	1.37 (0.77)	0.23 (0.91)	(-1.57, 2.03)	0.8025	0.03 (0.14)	(-0.24, 0.29)	0.8400	
>= 30	68	1.60 (1.08)	54	-0.65 (1.16)	2.26 (1.44)	(-0.59, 5.10)	0.1189	0.26 (0.18)	(-0.10, 0.62)	0.1599	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Physical Component Score
Full analysis set

	Anifrolumab 300mg (N=180)		Placebo (N=184)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 8		2.00 (0.58)		2.36 (0.57)	-0.36 (0.69)	(-1.72, 1.00)	0.6013			
Week 16		3.74 (0.67)		2.74 (0.66)	1.01 (0.83)	(-0.63, 2.64)	0.2268			
Week 24		3.46 (0.66)		2.95 (0.65)	0.50 (0.82)	(-1.10, 2.11)	0.5376			
Week 32		3.61 (0.67)		3.32 (0.67)	0.30 (0.84)	(-1.36, 1.95)	0.7235			
Week 40		3.86 (0.71)		3.10 (0.69)	0.76 (0.89)	(-0.99, 2.51)	0.3922			
Week 48		4.12 (0.71)		3.76 (0.70)	0.36 (0.90)	(-1.42, 2.13)	0.6927			
Week 52		3.68 (0.70)		3.40 (0.69)	0.28 (0.88)	(-1.46, 2.02)	0.7495			
OVERALL	168	3.50 (0.59)	172	3.09 (0.58)	0.41 (0.70)	(-0.97, 1.79)	0.5621	0.05 (0.11)	(-0.16, 0.27)	0.6229

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Physical Component Score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=180)		Placebo (N=184)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											0.0108
< 10 points	50	4.63 (0.96)	51	1.54 (0.95)	3.09 (1.19)	(0.72, 5.45)	0.0111	0.45 (0.20)	(0.06, 0.85)	0.0252	
>= 10 points	118	3.25 (0.70)	121	3.91 (0.69)	-0.65 (0.86)	(-2.34, 1.03)	0.4474	-0.09 (0.13)	(-0.34, 0.17)	0.5108	
OCS dose at baseline											0.6540
<10 mg/day	72	3.13 (0.77)	76	2.36 (0.75)	0.77 (0.97)	(-1.16, 2.70)	0.4313	0.12 (0.16)	(-0.21, 0.44)	0.4755	
>=10 mg/day	96	3.86 (0.90)	96	3.72 (0.89)	0.15 (0.99)	(-1.81, 2.10)	0.8834	0.02 (0.14)	(-0.27, 0.30)	0.9088	
Result of type I IFN gene signature test											0.0385
LOW	30	2.07 (1.13)	31	4.52 (1.10)	-2.44 (1.53)	(-5.50, 0.61)	0.1151	-0.39 (0.26)	(-0.90, 0.12)	0.1303	
HIGH	138	4.58 (0.58)	141	3.47 (0.58)	1.11 (0.78)	(-0.43, 2.65)	0.1578	0.16 (0.12)	(-0.07, 0.40)	0.1788	
Age (years)											NE
<= 65	161	3.58 (0.61)	170	3.09 (0.59)	0.49 (0.71)	(-0.91, 1.89)	0.4917	0.06 (0.11)	(-0.15, 0.28)	0.5650	
> 65	7	NE	2	NE	NE	NE		NE	NE		
Sex											0.0171
male	15	4.01 (2.39)	12	-1.63 (2.63)	5.64 (2.27)	(0.88, 10.40)	0.0229	0.59 (0.40)	(-0.18, 1.37)	0.1345	
female	153	3.26 (0.61)	160	3.31 (0.60)	-0.05 (0.73)	(-1.49, 1.39)	0.9493	-0.01 (0.11)	(-0.23, 0.22)	0.9568	
Race											NE
White	117	3.48 (0.66)	126	3.28 (0.65)	0.20 (0.82)	(-1.41, 1.81)	0.8114	0.03 (0.13)	(-0.22, 0.28)	0.8335	
Black or African American	26	4.87 (1.91)	22	2.07 (1.66)	2.80 (2.10)	(-1.44, 7.03)	0.1900	0.31 (0.29)	(-0.26, 0.88)	0.2894	
Asian	11	NE	5	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	NE	NE	NE		NE	NE		
Other	14	4.81 (3.00)	18	7.46 (3.05)	-2.65 (2.20)	(-7.17, 1.87)	0.2396	-0.21 (0.36)	(-0.91, 0.49)	0.5549	
Ethnicity											0.3957
Hispanic/Latino	30	3.15 (1.59)	33	4.04 (1.58)	-0.89 (1.68)	(-4.25, 2.47)	0.5967	-0.10 (0.25)	(-0.59, 0.40)	0.6947	
Non-hispanic/Latino	138	3.62 (0.64)	139	2.94 (0.63)	0.68 (0.78)	(-0.86, 2.21)	0.3846	0.09 (0.12)	(-0.15, 0.33)	0.4533	
Geographic region											0.1760
EU	61	3.87 (1.04)	72	4.44 (1.01)	-0.57 (1.11)	(-2.77, 1.62)	0.6064	-0.07 (0.17)	(-0.41, 0.27)	0.6956	
non-EU	107	3.67 (0.71)	100	2.33 (0.72)	1.34 (0.88)	(-0.39, 3.08)	0.1288	0.18 (0.14)	(-0.09, 0.46)	0.1848	
Onset of disease											0.3281
Paediatric	11	1.18 (3.64)	11	4.38 (2.68)	-3.20 (3.64)	(-11.27, 4.87)	0.3990	-0.29 (0.43)	(-1.13, 0.55)	0.4983	
Adult	157	3.50 (0.60)	161	3.08 (0.60)	0.43 (0.72)	(-1.00, 1.85)	0.5547	0.06 (0.11)	(-0.16, 0.28)	0.6146	
ADA result											0.0219
Negative	152	3.27 (0.62)	157	3.26 (0.61)	0.01 (0.75)	(-1.47, 1.49)	0.9891	0.00 (0.11)	(-0.22, 0.22)	0.9907	
Positive (At any time)	16	7.02 (1.98)	15	2.53 (1.79)	4.49 (1.80)	(0.80, 8.18)	0.0190	0.59 (0.37)	(-0.14, 1.31)	0.1119	
BMI (kg/m2) at enrolment											0.0600
< 30	100	3.71 (0.73)	118	4.01 (0.70)	-0.30 (0.82)	(-1.91, 1.31)	0.7101	-0.04 (0.14)	(-0.31, 0.23)	0.7661	
>= 30	68	4.01 (0.93)	54	1.51 (1.01)	2.50 (1.25)	(0.03, 4.98)	0.0474	0.33 (0.18)	(-0.03, 0.69)	0.0729	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute General Health Score
Full analysis set

	Anifrolumab 300mg (N=180)		Placebo (N=184)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 8		0.64 (0.50)		2.37 (0.49)	-1.74 (0.59)	(-2.90, -0.58)	0.0035			
Week 16		1.52 (0.57)		1.65 (0.55)	-0.13 (0.70)	(-1.51, 1.25)	0.8564			
Week 24		1.29 (0.58)		1.68 (0.57)	-0.38 (0.73)	(-1.81, 1.05)	0.6000			
Week 32		1.07 (0.60)		1.68 (0.59)	-0.61 (0.76)	(-2.10, 0.88)	0.4216			
Week 40		1.72 (0.64)		1.80 (0.62)	-0.08 (0.81)	(-1.67, 1.51)	0.9208			
Week 48		1.65 (0.63)		2.81 (0.62)	-1.16 (0.81)	(-2.75, 0.43)	0.1521			
Week 52		1.61 (0.66)		2.33 (0.65)	-0.72 (0.84)	(-2.38, 0.94)	0.3925			
OVERALL	168	1.36 (0.52)	172	2.05 (0.51)	-0.69 (0.62)	(-1.91, 0.53)	0.2687	-0.10 (0.11)	(-0.32, 0.11)	0.3422

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute General Health Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=184) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.2515
< 10 points	50	1.80 (0.90)	51	1.31 (0.90)	0.49 (1.14)	(-1.76, 2.75)	0.6646	0.08 (0.20)	(-0.31, 0.47)	0.7017	
>= 10 points	118	1.39 (0.61)	121	2.45 (0.60)	-1.07 (0.75)	(-2.55, 0.41)	0.1565	-0.16 (0.13)	(-0.42, 0.09)	0.2140	
OCS dose at baseline											0.5530
<10 mg/day	72	1.07 (0.76)	76	1.37 (0.74)	-0.30 (0.97)	(-2.22, 1.62)	0.7558	-0.05 (0.16)	(-0.37, 0.28)	0.7766	
>=10 mg/day	96	1.80 (0.73)	96	2.86 (0.72)	-1.05 (0.81)	(-2.66, 0.55)	0.1967	-0.15 (0.14)	(-0.43, 0.13)	0.3048	
Result of type I IFN gene signature test											0.3358
LOW	30	0.89 (1.13)	31	2.90 (1.11)	-2.01 (1.54)	(-5.09, 1.07)	0.1961	-0.32 (0.26)	(-0.83, 0.18)	0.2129	
HIGH	138	2.05 (0.51)	141	2.45 (0.50)	-0.39 (0.68)	(-1.73, 0.95)	0.5644	-0.07 (0.12)	(-0.30, 0.17)	0.5817	
Age (years)											NE
<= 65	161	1.39 (0.53)	170	2.17 (0.51)	-0.78 (0.63)	(-2.02, 0.46)	0.2163	-0.12 (0.11)	(-0.33, 0.10)	0.2946	
> 65	7	NE	2	NE	NE	NE		NE	NE		
Sex											NE
male	15	NE	12	NE	NE	NE		NE	NE		
female	153	1.22 (0.54)	160	2.11 (0.52)	-0.89 (0.65)	(-2.17, 0.38)	0.1697	-0.13 (0.11)	(-0.36, 0.09)	0.2366	
Race											0.4505
White	117	0.99 (0.60)	126	1.80 (0.59)	-0.81 (0.75)	(-2.28, 0.67)	0.2810	-0.12 (0.13)	(-0.38, 0.13)	0.3380	
Black or African American	26	3.01 (1.70)	22	2.36 (1.50)	0.65 (1.92)	(-3.22, 4.53)	0.7353	0.08 (0.29)	(-0.49, 0.65)	0.7810	
Asian	11	1.84 (1.83)	5	-0.46 (3.20)	2.30 (3.60)	(-5.91, 10.51)	0.5400	0.34 (0.54)	(-0.73, 1.41)	0.5320	
American Indian or Alaska Native	0	NE	1	NE	NE	NE		NE	NE		
Other	14	3.47 (2.32)	18	6.31 (2.22)	-2.84 (1.77)	(-6.47, 0.79)	0.1202	-0.30 (0.36)	(-1.01, 0.40)	0.3962	
Ethnicity											0.2659
Hispanic/Latino	30	1.85 (1.26)	33	3.93 (1.25)	-2.08 (1.33)	(-4.75, 0.58)	0.1225	-0.29 (0.25)	(-0.79, 0.21)	0.2495	
Non-hispanic/Latino	138	1.26 (0.57)	139	1.68 (0.56)	-0.41 (0.70)	(-1.79, 0.96)	0.5549	-0.06 (0.12)	(-0.30, 0.17)	0.6059	
Geographic region											0.9169
EU	61	2.00 (0.96)	72	2.84 (0.92)	-0.83 (1.05)	(-2.91, 1.24)	0.4269	-0.11 (0.17)	(-0.45, 0.23)	0.5342	
non-EU	107	1.28 (0.62)	100	1.97 (0.63)	-0.70 (0.78)	(-2.24, 0.84)	0.3731	-0.11 (0.14)	(-0.38, 0.16)	0.4313	
Onset of disease											0.8472
Paediatric	11	-1.13 (2.30)	11	0.08 (1.71)	-1.21 (2.37)	(-6.31, 3.88)	0.6170	-0.17 (0.43)	(-1.01, 0.66)	0.6847	
Adult	157	1.34 (0.53)	161	2.08 (0.53)	-0.74 (0.65)	(-2.01, 0.53)	0.2541	-0.11 (0.11)	(-0.33, 0.11)	0.3249	
ADA result											0.1257
Negative	152	1.02 (0.53)	157	2.10 (0.53)	-1.08 (0.65)	(-2.36, 0.21)	0.0996	-0.16 (0.11)	(-0.39, 0.06)	0.1520	
Positive (At any time)	16	5.96 (1.82)	15	4.05 (1.72)	1.91 (1.84)	(-1.86, 5.68)	0.3077	0.27 (0.36)	(-0.44, 0.97)	0.4607	
BMI (kg/m2) at enrolment											0.8771
< 30	100	1.94 (0.69)	118	2.66 (0.65)	-0.72 (0.78)	(-2.25, 0.80)	0.3513	-0.10 (0.14)	(-0.37, 0.16)	0.4444	
>= 30	68	0.75 (0.77)	54	1.28 (0.83)	-0.52 (1.04)	(-2.58, 1.53)	0.6136	-0.08 (0.18)	(-0.44, 0.27)	0.6476	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Mental Health Score
Full analysis set

	Anifrolumab 300mg (N=180)		Placebo (N=184)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 8		0.98 (0.62)		1.21 (0.62)	-0.23 (0.76)	(-1.73, 1.27)	0.7594			
Week 16		1.18 (0.70)		0.87 (0.68)	0.30 (0.88)	(-1.43, 2.03)	0.7308			
Week 24		1.85 (0.71)		1.01 (0.70)	0.84 (0.90)	(-0.93, 2.61)	0.3511			
Week 32		1.52 (0.76)		0.14 (0.74)	1.39 (0.97)	(-0.53, 3.30)	0.1547			
Week 40		1.88 (0.76)		1.56 (0.75)	0.32 (0.98)	(-1.61, 2.24)	0.7474			
Week 48		2.23 (0.78)		1.26 (0.77)	0.97 (1.00)	(-1.00, 2.95)	0.3328			
Week 52		2.50 (0.75)		1.30 (0.74)	1.21 (0.96)	(-0.69, 3.10)	0.2120			
OVERALL	168	1.74 (0.58)	172	1.05 (0.58)	0.68 (0.70)	(-0.69, 2.06)	0.3273	0.09 (0.11)	(-0.12, 0.30)	0.4048

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Mental Health Score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=180)		Placebo (N=184)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											0.0821
< 10 points	50	2.54 (0.88)	51	0.15 (0.87)	2.39 (1.10)	(0.22, 4.57)	0.0316	0.38 (0.20)	(-0.01, 0.78)	0.0576	
>= 10 points	118	1.11 (0.72)	121	1.16 (0.71)	-0.05 (0.88)	(-1.79, 1.68)	0.9534	-0.01 (0.13)	(-0.26, 0.25)	0.9595	
OCS dose at baseline											0.1811
<10 mg/day	72	2.14 (0.83)	76	0.40 (0.81)	1.75 (1.05)	(-0.32, 3.82)	0.0978	0.25 (0.17)	(-0.08, 0.57)	0.1357	
>=10 mg/day	96	1.40 (0.84)	96	1.54 (0.83)	-0.13 (0.94)	(-1.98, 1.71)	0.8875	-0.02 (0.14)	(-0.30, 0.27)	0.9111	
Result of type I IFN gene signature test											0.5905
LOW	30	1.55 (1.19)	31	0.07 (1.16)	1.47 (1.62)	(-1.78, 4.72)	0.3664	0.22 (0.26)	(-0.28, 0.73)	0.3827	
HIGH	138	2.32 (0.58)	141	1.81 (0.57)	0.51 (0.78)	(-1.03, 2.04)	0.5150	0.07 (0.12)	(-0.16, 0.31)	0.5358	
Age (years)											NE
<= 65	161	1.72 (0.60)	170	1.12 (0.59)	0.60 (0.71)	(-0.79, 2.00)	0.3961	0.08 (0.11)	(-0.14, 0.29)	0.4767	
> 65	7	NE	2	NE	NE	NE		NE	NE		
Sex											NE
male	15	NE	12	NE	NE	NE		NE	NE		
female	153	1.54 (0.62)	160	0.96 (0.60)	0.58 (0.74)	(-0.87, 2.03)	0.4303	0.08 (0.11)	(-0.15, 0.30)	0.5010	
Race											0.0276
White	117	1.64 (0.67)	126	0.70 (0.66)	0.94 (0.83)	(-0.69, 2.57)	0.2553	0.13 (0.13)	(-0.12, 0.38)	0.3174	
Black or African American	26	1.24 (1.98)	22	-1.53 (1.71)	2.77 (2.18)	(-1.64, 7.19)	0.2118	0.30 (0.29)	(-0.28, 0.87)	0.3098	
Asian	11	2.64 (1.98)	5	1.33 (3.09)	1.31 (3.64)	(-6.63, 9.25)	0.7260	0.19 (0.54)	(-0.87, 1.25)	0.7316	
American Indian or Alaska Native	0	NE	1	2.48 (0.00)	NE	NE		NE	NE		
Other	14	1.48 (2.21)	18	6.54 (2.07)	-5.07 (2.00)	(-9.20, -0.93)	0.0186	-0.58 (0.36)	(-1.29, 0.14)	0.1142	
Ethnicity											0.0071
Hispanic/Latino	30	0.61 (1.65)	33	4.13 (1.63)	-3.52 (1.75)	(-7.02, -0.02)	0.0487	-0.38 (0.25)	(-0.88, 0.12)	0.1373	
Non-hispanic/Latino	138	2.16 (0.62)	139	0.57 (0.61)	1.59 (0.75)	(0.11, 3.08)	0.0354	0.22 (0.12)	(-0.02, 0.46)	0.0685	
Geographic region											0.9110
EU	61	2.81 (1.02)	72	1.99 (0.97)	0.82 (1.06)	(-1.28, 2.91)	0.4431	0.10 (0.17)	(-0.24, 0.44)	0.5662	
non-EU	107	1.08 (0.74)	100	0.42 (0.75)	0.66 (0.93)	(-1.18, 2.49)	0.4805	0.09 (0.14)	(-0.19, 0.36)	0.5361	
Onset of disease											0.0412
Paediatric	11	-2.25 (3.24)	11	3.53 (2.29)	-5.78 (3.31)	(-12.80, 1.24)	0.1002	-0.60 (0.44)	(-1.46, 0.26)	0.1726	
Adult	157	1.91 (0.59)	161	0.76 (0.59)	1.14 (0.71)	(-0.26, 2.54)	0.1099	0.15 (0.11)	(-0.07, 0.37)	0.1738	
ADA result											0.7711
Negative	152	1.44 (0.61)	157	0.83 (0.61)	0.61 (0.74)	(-0.84, 2.06)	0.4089	0.08 (0.11)	(-0.14, 0.30)	0.4791	
Positive (At any time)	16	4.20 (1.98)	15	4.23 (1.82)	-0.03 (2.07)	(-4.29, 4.23)	0.9890	-0.00 (0.36)	(-0.71, 0.70)	0.9917	
BMI (kg/m2) at enrolment											0.0806
< 30	100	1.52 (0.76)	118	1.76 (0.73)	-0.24 (0.86)	(-1.93, 1.45)	0.7763	-0.03 (0.14)	(-0.30, 0.24)	0.8183	
>= 30	68	1.94 (0.93)	54	-0.45 (1.00)	2.38 (1.24)	(-0.06, 4.83)	0.0563	0.31 (0.18)	(-0.04, 0.67)	0.0863	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Physical Functioning Score
Full analysis set

	Anifrolumab 300mg (N=180)		Placebo (N=184)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 8		2.11 (0.61)		1.98 (0.61)	0.13 (0.73)	(-1.30, 1.56)	0.8600			
Week 16		3.22 (0.70)		2.19 (0.69)	1.03 (0.86)	(-0.67, 2.73)	0.2342			
Week 24		2.73 (0.71)		2.85 (0.71)	-0.12 (0.89)	(-1.87, 1.63)	0.8939			
Week 32		3.70 (0.73)		2.90 (0.72)	0.80 (0.91)	(-0.99, 2.59)	0.3816			
Week 40		3.21 (0.73)		2.86 (0.72)	0.35 (0.92)	(-1.46, 2.15)	0.7060			
Week 48		3.53 (0.76)		3.05 (0.75)	0.47 (0.97)	(-1.43, 2.38)	0.6245			
Week 52		3.98 (0.76)		3.36 (0.75)	0.61 (0.97)	(-1.29, 2.52)	0.5272			
OVERALL	168	3.21 (0.63)	172	2.74 (0.62)	0.47 (0.76)	(-1.02, 1.95)	0.5368	0.06 (0.11)	(-0.16, 0.27)	0.5982

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Physical Functioning Score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=180)		Placebo (N=184)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											0.0051
< 10 points	50	4.16 (1.01)	51	0.59 (1.00)	3.57 (1.26)	(1.07, 6.07)	0.0057	0.50 (0.20)	(0.10, 0.89)	0.0142	
>= 10 points	118	3.10 (0.76)	121	3.91 (0.75)	-0.81 (0.93)	(-2.63, 1.02)	0.3837	-0.10 (0.13)	(-0.35, 0.16)	0.4487	
OCS dose at baseline											0.5198
<10 mg/day	72	3.23 (0.81)	76	2.21 (0.79)	1.02 (1.03)	(-1.02, 3.07)	0.3240	0.15 (0.16)	(-0.18, 0.47)	0.3708	
>=10 mg/day	96	3.13 (0.97)	96	3.07 (0.96)	0.06 (1.08)	(-2.07, 2.19)	0.9549	0.01 (0.14)	(-0.28, 0.29)	0.9645	
Result of type I IFN gene signature test											0.0678
LOW	30	1.32 (1.26)	31	3.64 (1.22)	-2.33 (1.69)	(-5.71, 1.06)	0.1743	-0.34 (0.26)	(-0.84, 0.17)	0.1940	
HIGH	138	4.32 (0.63)	141	3.20 (0.62)	1.12 (0.84)	(-0.54, 2.78)	0.1839	0.15 (0.12)	(-0.08, 0.39)	0.2047	
Age (years)											NE
<= 65	161	3.20 (0.65)	170	2.65 (0.63)	0.55 (0.77)	(-0.96, 2.06)	0.4749	0.07 (0.11)	(-0.15, 0.28)	0.5471	
> 65	7	NE	2	NE	NE	NE		NE	NE		
Sex											0.0583
male	15	4.26 (2.38)	12	-0.74 (2.68)	4.99 (2.47)	(-0.15, 10.14)	0.0565	0.52 (0.39)	(-0.25, 1.30)	0.1851	
female	153	2.98 (0.66)	160	2.89 (0.65)	0.09 (0.79)	(-1.47, 1.65)	0.9096	0.01 (0.11)	(-0.21, 0.23)	0.9225	
Race											NE
White	117	3.30 (0.70)	126	2.93 (0.69)	0.37 (0.86)	(-1.33, 2.07)	0.6707	0.05 (0.13)	(-0.20, 0.30)	0.7092	
Black or African American	26	5.23 (2.10)	22	1.45 (1.84)	3.77 (2.31)	(-0.89, 8.44)	0.1101	0.38 (0.29)	(-0.20, 0.95)	0.1963	
Asian	11	NE	5	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	NE	NE	NE		NE	NE		
Other	14	2.70 (3.51)	18	7.07 (3.49)	-4.36 (2.65)	(-9.80, 1.08)	0.1114	-0.30 (0.36)	(-1.00, 0.40)	0.4011	
Ethnicity											0.2170
Hispanic/Latino	30	2.35 (1.76)	33	3.97 (1.74)	-1.62 (1.95)	(-5.52, 2.28)	0.4086	-0.16 (0.25)	(-0.66, 0.33)	0.5192	
Non-hispanic/Latino	138	3.56 (0.68)	139	2.57 (0.67)	0.99 (0.82)	(-0.63, 2.61)	0.2304	0.12 (0.12)	(-0.11, 0.36)	0.2995	
Geographic region											0.2111
EU	61	3.61 (1.05)	72	4.03 (1.02)	-0.42 (1.11)	(-2.62, 1.77)	0.7042	-0.05 (0.17)	(-0.39, 0.29)	0.7758	
non-EU	107	3.25 (0.77)	100	1.82 (0.79)	1.43 (0.98)	(-0.50, 3.36)	0.1463	0.18 (0.14)	(-0.09, 0.45)	0.1993	
Onset of disease											NE
Paediatric	11	NE	11	NE	NE	NE		NE	NE		
Adult	157	3.28 (0.64)	161	2.72 (0.64)	0.56 (0.78)	(-0.97, 2.09)	0.4720	0.07 (0.11)	(-0.15, 0.29)	0.5358	
ADA result											0.0592
Negative	152	2.97 (0.66)	157	2.86 (0.65)	0.10 (0.80)	(-1.48, 1.68)	0.8985	0.01 (0.11)	(-0.21, 0.24)	0.9122	
Positive (At any time)	16	7.27 (2.33)	15	2.63 (2.12)	4.64 (2.26)	(-0.01, 9.28)	0.0505	0.51 (0.37)	(-0.21, 1.23)	0.1617	
BMI (kg/m2) at enrolment											0.0890
< 30	100	3.27 (0.80)	118	3.47 (0.76)	-0.19 (0.89)	(-1.95, 1.56)	0.8268	-0.02 (0.14)	(-0.29, 0.24)	0.8604	
>= 30	68	4.05 (1.01)	54	1.50 (1.09)	2.55 (1.35)	(-0.12, 5.21)	0.0608	0.31 (0.18)	(-0.05, 0.67)	0.0909	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Role Emotional Score
Full analysis set

	Anifrolumab 300mg (N=180)		Placebo (N=184)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 8		1.39 (0.78)		1.38 (0.77)	0.01 (0.96)	(-1.88, 1.89)	0.9943			
Week 16		0.95 (0.83)		0.69 (0.81)	0.25 (1.05)	(-1.80, 2.31)	0.8079			
Week 24		1.18 (0.81)		0.11 (0.81)	1.07 (1.02)	(-0.94, 3.08)	0.2957			
Week 32		1.67 (0.87)		0.03 (0.86)	1.64 (1.11)	(-0.54, 3.81)	0.1399			
Week 40		1.53 (0.89)		1.03 (0.87)	0.50 (1.13)	(-1.73, 2.74)	0.6572			
Week 48		1.94 (0.87)		1.61 (0.86)	0.33 (1.11)	(-1.86, 2.52)	0.7670			
Week 52		2.02 (0.87)		1.45 (0.86)	0.57 (1.11)	(-1.62, 2.76)	0.6103			
OVERALL	168	1.53 (0.68)	172	0.90 (0.68)	0.62 (0.81)	(-0.97, 2.22)	0.4426	0.07 (0.11)	(-0.14, 0.28)	0.5175

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Role Emotional Score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=180)		Placebo (N=184)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											0.1754
< 10 points	50	2.21 (1.13)	51	-0.08 (1.14)	2.29 (1.41)	(-0.52, 5.10)	0.1084	0.28 (0.20)	(-0.11, 0.67)	0.1581	
>= 10 points	118	1.32 (0.82)	121	1.37 (0.81)	-0.05 (0.99)	(-2.01, 1.91)	0.9594	-0.01 (0.13)	(-0.26, 0.25)	0.9650	
OCS dose at baseline											0.1571
<10 mg/day	72	2.44 (1.01)	76	0.50 (0.99)	1.94 (1.27)	(-0.57, 4.46)	0.1282	0.22 (0.16)	(-0.10, 0.55)	0.1736	
>=10 mg/day	96	0.81 (0.96)	96	1.20 (0.95)	-0.39 (1.05)	(-2.46, 1.68)	0.7123	-0.04 (0.14)	(-0.32, 0.24)	0.7748	
Result of type I IFN gene signature test											0.6400
LOW	30	1.60 (1.54)	31	1.83 (1.52)	-0.23 (2.10)	(-4.43, 3.98)	0.9141	-0.03 (0.26)	(-0.53, 0.48)	0.9175	
HIGH	138	2.09 (0.66)	141	1.25 (0.65)	0.84 (0.88)	(-0.90, 2.58)	0.3451	0.11 (0.12)	(-0.13, 0.34)	0.3705	
Age (years)											NE
<= 65	161	1.35 (0.71)	170	0.81 (0.69)	0.54 (0.83)	(-1.09, 2.16)	0.5178	0.06 (0.11)	(-0.16, 0.27)	0.5909	
> 65	7	NE	2	NE	NE	NE		NE	NE		
Sex											0.6416
male	15	5.88 (2.17)	12	4.34 (2.42)	1.54 (2.26)	(-3.19, 6.27)	0.5036	0.18 (0.39)	(-0.58, 0.94)	0.6471	
female	153	1.15 (0.72)	160	0.73 (0.70)	0.42 (0.85)	(-1.26, 2.09)	0.6253	0.05 (0.11)	(-0.17, 0.27)	0.6794	
Race											NE
White	117	1.62 (0.74)	126	0.53 (0.72)	1.09 (0.90)	(-0.69, 2.86)	0.2300	0.13 (0.13)	(-0.12, 0.39)	0.2957	
Black or African American	26	2.96 (2.84)	22	0.11 (2.52)	2.84 (3.15)	(-3.51, 9.19)	0.3717	0.21 (0.29)	(-0.36, 0.78)	0.4701	
Asian	11	NE	5	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	NE	NE	NE		NE	NE		
Other	14	-3.01 (3.21)	18	3.44 (3.06)	-6.45 (2.51)	(-11.63, -1.27)	0.0166	-0.50 (0.36)	(-1.21, 0.21)	0.1679	
Ethnicity											0.0540
Hispanic/Latino	30	-0.14 (1.69)	33	2.43 (1.67)	-2.57 (1.81)	(-6.20, 1.06)	0.1613	-0.27 (0.25)	(-0.77, 0.23)	0.2882	
Non-hispanic/Latino	138	1.91 (0.75)	139	0.58 (0.74)	1.33 (0.90)	(-0.44, 3.10)	0.1416	0.15 (0.12)	(-0.08, 0.39)	0.2077	
Geographic region											0.8456
EU	61	2.47 (1.01)	72	1.64 (0.97)	0.83 (1.06)	(-1.26, 2.92)	0.4345	0.10 (0.17)	(-0.24, 0.44)	0.5590	
non-EU	107	0.98 (0.92)	100	0.46 (0.94)	0.52 (1.15)	(-1.74, 2.79)	0.6490	0.06 (0.14)	(-0.22, 0.33)	0.6920	
Onset of disease											NE
Paediatric	11	NE	11	NE	NE	NE		NE	NE		
Adult	157	1.62 (0.70)	161	0.77 (0.70)	0.85 (0.84)	(-0.80, 2.50)	0.3131	0.10 (0.11)	(-0.12, 0.32)	0.3943	
ADA result											0.5875
Negative	152	1.13 (0.72)	157	0.66 (0.71)	0.47 (0.86)	(-1.23, 2.17)	0.5860	0.05 (0.11)	(-0.17, 0.28)	0.6430	
Positive (At any time)	16	5.82 (2.55)	15	3.95 (2.35)	1.88 (2.44)	(-3.14, 6.89)	0.4492	0.19 (0.36)	(-0.52, 0.89)	0.6008	
BMI (kg/m2) at enrolment											0.2314
< 30	100	1.44 (0.84)	118	1.49 (0.80)	-0.05 (0.93)	(-1.89, 1.78)	0.9564	-0.01 (0.14)	(-0.27, 0.26)	0.9651	
>= 30	68	1.47 (1.18)	54	-0.67 (1.27)	2.13 (1.57)	(-0.98, 5.24)	0.1768	0.22 (0.18)	(-0.14, 0.58)	0.2265	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Role Physical Score
Full analysis set

	Anifrolumab 300mg (N=180)		Placebo (N=184)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 8		2.06 (0.59)		2.11 (0.58)	-0.04 (0.71)	(-1.44, 1.35)	0.9499			
Week 16		3.37 (0.65)		2.11 (0.64)	1.26 (0.80)	(-0.32, 2.83)	0.1172			
Week 24		3.75 (0.67)		2.40 (0.66)	1.35 (0.83)	(-0.28, 2.99)	0.1048			
Week 32		3.47 (0.67)		2.06 (0.66)	1.41 (0.84)	(-0.24, 3.06)	0.0938			
Week 40		3.31 (0.73)		2.92 (0.71)	0.39 (0.92)	(-1.43, 2.20)	0.6759			
Week 48		4.13 (0.72)		3.25 (0.71)	0.88 (0.91)	(-0.90, 2.67)	0.3319			
Week 52		3.66 (0.71)		2.94 (0.70)	0.72 (0.90)	(-1.05, 2.50)	0.4235			
OVERALL	168	3.40 (0.58)	172	2.54 (0.58)	0.85 (0.70)	(-0.52, 2.22)	0.2214	0.11 (0.11)	(-0.10, 0.33)	0.3000

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Role Physical Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=184) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.0815
< 10 points	50	4.12 (0.98)	51	1.39 (0.98)	2.72 (1.23)	(0.28, 5.16)	0.0290	0.39 (0.20)	(-0.01, 0.78)	0.0536	
>= 10 points	118	3.09 (0.69)	121	2.96 (0.68)	0.13 (0.84)	(-1.53, 1.79)	0.8783	0.02 (0.13)	(-0.24, 0.27)	0.8949	
OCS dose at baseline											0.9061
<10 mg/day	72	2.85 (0.82)	76	2.09 (0.80)	0.76 (1.04)	(-1.30, 2.83)	0.4668	0.11 (0.16)	(-0.21, 0.43)	0.5103	
>=10 mg/day	96	3.72 (0.85)	96	2.79 (0.84)	0.93 (0.93)	(-0.91, 2.77)	0.3206	0.11 (0.14)	(-0.17, 0.39)	0.4409	
Result of type I IFN gene signature test											0.0512
LOW	30	2.12 (1.02)	31	3.78 (1.00)	-1.66 (1.38)	(-4.42, 1.10)	0.2329	-0.29 (0.26)	(-0.80, 0.21)	0.2556	
HIGH	138	4.47 (0.59)	141	3.04 (0.58)	1.44 (0.79)	(-0.12, 2.99)	0.0708	0.21 (0.12)	(-0.03, 0.44)	0.0852	
Age (years)											NE
<= 65	161	3.44 (0.60)	170	2.55 (0.59)	0.89 (0.70)	(-0.49, 2.27)	0.2066	0.12 (0.11)	(-0.10, 0.33)	0.2911	
> 65	7	NE	2	NE	NE	NE		NE	NE		
Sex											0.0134
male	15	5.92 (1.78)	12	-0.02 (1.97)	5.94 (2.13)	(1.53, 10.36)	0.0107	0.84 (0.41)	(0.04, 1.64)	0.0390	
female	153	3.01 (0.61)	160	2.63 (0.59)	0.39 (0.72)	(-1.04, 1.81)	0.5940	0.05 (0.11)	(-0.17, 0.27)	0.6499	
Race											0.1647
White	117	3.35 (0.65)	126	2.47 (0.63)	0.88 (0.79)	(-0.68, 2.44)	0.2666	0.13 (0.13)	(-0.13, 0.38)	0.3299	
Black or African American	26	4.66 (2.17)	22	2.22 (1.89)	2.44 (2.35)	(-2.32, 7.19)	0.3065	0.24 (0.29)	(-0.33, 0.81)	0.4149	
Asian	11	4.42 (3.59)	5	-1.54 (5.61)	5.96 (6.64)	(-9.24, 21.16)	0.3946	0.47 (0.55)	(-0.61, 1.54)	0.3952	
American Indian or Alaska Native	0	NE	1	NE	NE	NE		NE	NE		
Other	14	3.16 (2.40)	18	6.13 (2.43)	-2.97 (1.85)	(-6.76, 0.83)	0.1201	-0.30 (0.36)	(-1.00, 0.41)	0.4075	
Ethnicity											0.2452
Hispanic/Latino	30	1.88 (1.58)	33	2.70 (1.57)	-0.82 (1.65)	(-4.11, 2.47)	0.6210	-0.09 (0.25)	(-0.59, 0.40)	0.7168	
Non-hispanic/Latino	138	3.89 (0.64)	139	2.60 (0.63)	1.29 (0.77)	(-0.23, 2.82)	0.0954	0.17 (0.12)	(-0.06, 0.41)	0.1495	
Geographic region											0.3917
EU	61	3.80 (0.95)	72	3.54 (0.93)	0.26 (1.02)	(-1.75, 2.27)	0.7984	0.03 (0.17)	(-0.31, 0.37)	0.8463	
non-EU	107	3.39 (0.74)	100	1.95 (0.76)	1.44 (0.93)	(-0.39, 3.27)	0.1225	0.19 (0.14)	(-0.09, 0.46)	0.1771	
Onset of disease											NE
Paediatric	11	NE	11	NE	NE	NE		NE	NE		
Adult	157	3.48 (0.60)	161	2.47 (0.60)	1.01 (0.72)	(-0.42, 2.43)	0.1647	0.13 (0.11)	(-0.09, 0.35)	0.2367	
ADA result											0.0882
Negative	152	3.07 (0.62)	157	2.54 (0.61)	0.53 (0.75)	(-0.93, 2.00)	0.4739	0.07 (0.11)	(-0.15, 0.29)	0.5392	
Positive (At any time)	16	7.48 (1.81)	15	3.67 (1.70)	3.80 (1.77)	(0.18, 7.42)	0.0403	0.53 (0.37)	(-0.18, 1.25)	0.1453	
BMI (kg/m2) at enrolment											0.0773
< 30	100	3.63 (0.70)	118	3.54 (0.67)	0.10 (0.78)	(-1.44, 1.64)	0.8997	0.01 (0.14)	(-0.25, 0.28)	0.9198	
>= 30	68	3.59 (0.98)	54	0.78 (1.06)	2.80 (1.32)	(0.20, 5.41)	0.0354	0.35 (0.18)	(-0.01, 0.71)	0.0567	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Social Functioning Score
Full analysis set

	Anifrolumab 300mg (N=180)		Placebo (N=184)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 8		1.97 (0.74)		1.87 (0.73)	0.10 (0.91)	(-1.68, 1.89)	0.9103			
Week 16		2.76 (0.77)		1.64 (0.75)	1.12 (0.96)	(-0.76, 3.00)	0.2422			
Week 24		3.84 (0.78)		1.28 (0.77)	2.56 (0.97)	(0.64, 4.48)	0.0091			
Week 32		3.50 (0.81)		1.73 (0.80)	1.78 (1.02)	(-0.24, 3.79)	0.0836			
Week 40		3.48 (0.86)		1.69 (0.83)	1.79 (1.08)	(-0.35, 3.92)	0.1001			
Week 48		3.36 (0.84)		2.51 (0.82)	0.85 (1.06)	(-1.24, 2.94)	0.4242			
Week 52		3.20 (0.86)		2.04 (0.84)	1.16 (1.09)	(-0.99, 3.30)	0.2902			
OVERALL	168	3.16 (0.67)	172	1.82 (0.66)	1.34 (0.79)	(-0.22, 2.89)	0.0915	0.15 (0.11)	(-0.06, 0.37)	0.1545

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Social Functioning Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=184) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.2162
< 10 points	50	3.38 (1.18)	51	0.51 (1.16)	2.87 (1.46)	(-0.03, 5.76)	0.0520	0.34 (0.20)	(-0.05, 0.73)	0.0886	
>= 10 points	118	3.28 (0.78)	121	2.56 (0.77)	0.72 (0.95)	(-1.14, 2.58)	0.4473	0.08 (0.13)	(-0.17, 0.34)	0.5135	
OCS dose at baseline											0.8008
<10 mg/day	72	3.16 (0.90)	76	2.04 (0.88)	1.12 (1.13)	(-1.12, 3.36)	0.3250	0.15 (0.16)	(-0.18, 0.47)	0.3759	
>=10 mg/day	96	3.17 (1.01)	96	1.65 (1.00)	1.52 (1.10)	(-0.65, 3.69)	0.1696	0.15 (0.14)	(-0.13, 0.44)	0.2885	
Result of type I IFN gene signature test											0.2186
LOW	30	3.16 (1.22)	31	3.63 (1.19)	-0.47 (1.64)	(-3.77, 2.83)	0.7759	-0.07 (0.26)	(-0.57, 0.43)	0.7854	
HIGH	138	3.53 (0.67)	141	1.70 (0.66)	1.83 (0.89)	(0.08, 3.58)	0.0406	0.23 (0.12)	(-0.00, 0.47)	0.0515	
Age (years)											NE
<= 65	161	3.02 (0.69)	170	1.80 (0.67)	1.23 (0.80)	(-0.35, 2.80)	0.1260	0.14 (0.11)	(-0.08, 0.36)	0.2029	
> 65	7	NE	2	NE	NE	NE		NE	NE		
Sex											0.1434
male	15	7.25 (2.19)	12	2.72 (2.45)	4.53 (2.31)	(-0.32, 9.37)	0.0652	0.52 (0.39)	(-0.26, 1.29)	0.1903	
female	153	2.69 (0.70)	160	1.75 (0.68)	0.94 (0.82)	(-0.69, 2.56)	0.2569	0.11 (0.11)	(-0.11, 0.33)	0.3363	
Race											NE
White	117	3.08 (0.75)	126	1.68 (0.73)	1.41 (0.91)	(-0.39, 3.21)	0.1253	0.17 (0.13)	(-0.08, 0.42)	0.1820	
Black or African American	26	6.33 (2.53)	22	1.53 (2.12)	4.80 (2.71)	(-0.69, 10.29)	0.0846	0.41 (0.29)	(-0.17, 0.98)	0.1661	
Asian	11	1.00 (3.69)	5	-0.73 (5.89)	1.73 (6.89)	(-14.33, 17.79)	0.8081	0.13 (0.54)	(-0.93, 1.19)	0.8084	
American Indian or Alaska Native	0	NE	1	NE	NE	NE		NE	NE		
Other	14	1.19 (3.53)	18	4.76 (3.38)	-3.56 (2.35)	(-8.39, 1.27)	0.1419	-0.25 (0.36)	(-0.95, 0.45)	0.4839	
Ethnicity											0.0163
Hispanic/Latino	30	1.14 (1.67)	33	3.56 (1.66)	-2.42 (1.75)	(-5.93, 1.08)	0.1716	-0.26 (0.25)	(-0.75, 0.24)	0.3135	
Non-hispanic/Latino	138	3.81 (0.73)	139	1.52 (0.72)	2.29 (0.88)	(0.55, 4.03)	0.0102	0.27 (0.12)	(0.03, 0.50)	0.0271	
Geographic region											0.8865
EU	61	3.85 (1.10)	72	2.32 (1.06)	1.53 (1.15)	(-0.74, 3.80)	0.1849	0.17 (0.17)	(-0.17, 0.51)	0.3217	
non-EU	107	2.96 (0.86)	100	1.65 (0.87)	1.31 (1.07)	(-0.80, 3.41)	0.2232	0.15 (0.14)	(-0.13, 0.42)	0.2890	
Onset of disease											0.3822
Paediatric	11	6.41 (4.75)	11	8.60 (3.29)	-2.19 (4.21)	(-11.28, 6.90)	0.6117	-0.16 (0.43)	(-0.99, 0.68)	0.7156	
Adult	157	3.05 (0.68)	161	1.50 (0.68)	1.56 (0.81)	(-0.04, 3.16)	0.0564	0.18 (0.11)	(-0.04, 0.40)	0.1062	
ADA result											0.3703
Negative	152	2.87 (0.71)	157	1.71 (0.70)	1.16 (0.86)	(-0.52, 2.85)	0.1750	0.13 (0.11)	(-0.09, 0.35)	0.2475	
Positive (At any time)	16	6.44 (1.74)	15	3.65 (1.54)	2.79 (1.60)	(-0.50, 6.08)	0.0934	0.42 (0.36)	(-0.29, 1.13)	0.2502	
BMI (kg/m2) at enrolment											0.3410
< 30	100	3.41 (0.80)	118	2.68 (0.76)	0.73 (0.88)	(-0.99, 2.46)	0.4028	0.09 (0.14)	(-0.18, 0.36)	0.5083	
>= 30	68	3.33 (1.18)	54	0.88 (1.27)	2.45 (1.58)	(-0.68, 5.58)	0.1231	0.26 (0.18)	(-0.10, 0.61)	0.1632	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Bodily Pain Score
Full analysis set

	Anifrolumab 300mg (N=180)		Placebo (N=184)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 8		1.93 (0.68)		1.96 (0.67)	-0.02 (0.84)	(-1.67, 1.62)	0.9763			
Week 16		3.68 (0.73)		2.81 (0.71)	0.87 (0.91)	(-0.92, 2.66)	0.3390			
Week 24		3.59 (0.74)		1.95 (0.73)	1.64 (0.93)	(-0.18, 3.47)	0.0779			
Week 32		3.39 (0.79)		2.71 (0.78)	0.67 (1.01)	(-1.32, 2.66)	0.5059			
Week 40		4.74 (0.80)		2.70 (0.78)	2.04 (1.02)	(0.04, 4.05)	0.0460			
Week 48		4.66 (0.80)		3.42 (0.79)	1.24 (1.03)	(-0.78, 3.25)	0.2281			
Week 52		3.53 (0.80)		2.66 (0.78)	0.87 (1.01)	(-1.12, 2.87)	0.3902			
OVERALL	168	3.65 (0.62)	172	2.60 (0.61)	1.04 (0.73)	(-0.40, 2.48)	0.1545	0.13 (0.11)	(-0.08, 0.34)	0.2305

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Bodily Pain Score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=180)		Placebo (N=184)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											0.0073
< 10 points	50	5.00 (1.04)	51	0.94 (1.02)	4.06 (1.28)	(1.53, 6.59)	0.0020	0.55 (0.20)	(0.15, 0.95)	0.0066	
>= 10 points	118	3.29 (0.74)	121	3.40 (0.72)	-0.11 (0.89)	(-1.86, 1.64)	0.9019	-0.01 (0.13)	(-0.27, 0.24)	0.9156	
OCS dose at baseline											0.0829
<10 mg/day	72	4.02 (0.80)	76	1.64 (0.78)	2.38 (1.00)	(0.40, 4.36)	0.0190	0.35 (0.17)	(0.03, 0.68)	0.0346	
>=10 mg/day	96	3.48 (0.94)	96	3.61 (0.94)	-0.13 (1.04)	(-2.18, 1.92)	0.9037	-0.01 (0.14)	(-0.30, 0.27)	0.9246	
Result of type I IFN gene signature test											0.1340
LOW	30	2.37 (1.13)	31	3.42 (1.10)	-1.05 (1.53)	(-4.11, 2.00)	0.4924	-0.17 (0.26)	(-0.67, 0.33)	0.5101	
HIGH	138	4.69 (0.62)	141	3.14 (0.61)	1.55 (0.83)	(-0.08, 3.18)	0.0628	0.21 (0.12)	(-0.02, 0.45)	0.0773	
Age (years)											NE
<= 65	161	3.71 (0.64)	170	2.61 (0.62)	1.10 (0.74)	(-0.35, 2.55)	0.1369	0.14 (0.11)	(-0.08, 0.35)	0.2167	
> 65	7	NE	2	NE	NE	NE		NE	NE		
Sex											0.0953
male	15	6.71 (2.61)	12	1.37 (2.94)	5.34 (2.71)	(-0.28, 10.96)	0.0614	0.51 (0.39)	(-0.26, 1.28)	0.1958	
female	153	3.38 (0.64)	160	2.74 (0.62)	0.64 (0.76)	(-0.85, 2.13)	0.3980	0.08 (0.11)	(-0.14, 0.30)	0.4742	
Race											NE
White	117	3.63 (0.69)	126	2.64 (0.68)	0.98 (0.85)	(-0.70, 2.66)	0.2499	0.13 (0.13)	(-0.12, 0.38)	0.3141	
Black or African American	26	4.65 (2.20)	22	1.29 (1.85)	3.37 (2.34)	(-1.36, 8.09)	0.1581	0.33 (0.29)	(-0.25, 0.90)	0.2626	
Asian	11	NE	5	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	-7.51 (0.00)	NE	NE		NE	NE		
Other	14	2.67 (3.15)	18	6.22 (3.13)	-3.55 (2.32)	(-8.32, 1.22)	0.1381	-0.27 (0.36)	(-0.98, 0.43)	0.4450	
Ethnicity											0.1833
Hispanic/Latino	30	3.55 (1.65)	33	4.56 (1.65)	-1.01 (1.72)	(-4.45, 2.43)	0.5586	-0.11 (0.25)	(-0.60, 0.39)	0.6701	
Non-hispanic/Latino	138	3.76 (0.67)	139	2.24 (0.66)	1.52 (0.81)	(-0.08, 3.12)	0.0630	0.19 (0.12)	(-0.04, 0.43)	0.1097	
Geographic region											0.2904
EU	61	4.37 (1.11)	72	4.08 (1.08)	0.29 (1.17)	(-2.03, 2.60)	0.8059	0.03 (0.17)	(-0.31, 0.37)	0.8537	
non-EU	107	3.38 (0.75)	100	1.51 (0.76)	1.87 (0.93)	(0.04, 3.70)	0.0456	0.24 (0.14)	(-0.03, 0.52)	0.0837	
Onset of disease											0.4033
Paediatric	11	3.32 (4.45)	11	5.35 (2.44)	-2.03 (3.85)	(-10.36, 6.30)	0.6074	-0.16 (0.43)	(-1.00, 0.67)	0.7011	
Adult	157	3.74 (0.64)	161	2.49 (0.63)	1.25 (0.76)	(-0.24, 2.75)	0.1004	0.16 (0.11)	(-0.06, 0.38)	0.1644	
ADA result											0.3334
Negative	152	3.37 (0.65)	157	2.54 (0.64)	0.84 (0.78)	(-0.69, 2.37)	0.2814	0.10 (0.11)	(-0.12, 0.33)	0.3601	
Positive (At any time)	16	7.18 (2.49)	15	3.87 (2.26)	3.31 (2.43)	(-1.72, 8.34)	0.1867	0.34 (0.36)	(-0.37, 1.05)	0.3438	
BMI (kg/m2) at enrolment											0.0118
< 30	100	3.52 (0.79)	118	3.64 (0.76)	-0.12 (0.87)	(-1.84, 1.60)	0.8897	-0.01 (0.14)	(-0.28, 0.25)	0.9126	
>= 30	68	4.63 (0.96)	54	0.84 (1.03)	3.78 (1.28)	(1.25, 6.32)	0.0038	0.48 (0.18)	(0.12, 0.85)	0.0089	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Vitality Score
Full analysis set

	Anifrolumab 300mg (N=180)		Placebo (N=184)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 8		1.97 (0.68)		2.27 (0.66)	-0.29 (0.82)	(-1.91, 1.32)	0.7199			
Week 16		2.90 (0.74)		2.30 (0.71)	0.60 (0.91)	(-1.19, 2.38)	0.5102			
Week 24		4.05 (0.74)		2.33 (0.73)	1.71 (0.92)	(-0.11, 3.53)	0.0647			
Week 32		3.63 (0.76)		2.08 (0.75)	1.55 (0.96)	(-0.33, 3.43)	0.1054			
Week 40		3.71 (0.80)		3.03 (0.78)	0.69 (1.01)	(-1.30, 2.67)	0.4982			
Week 48		4.45 (0.80)		3.01 (0.78)	1.44 (1.01)	(-0.54, 3.42)	0.1521			
Week 52		3.80 (0.82)		2.91 (0.80)	0.89 (1.05)	(-1.17, 2.95)	0.3968			
OVERALL	168	3.50 (0.64)	172	2.56 (0.63)	0.94 (0.76)	(-0.56, 2.44)	0.2172	0.11 (0.11)	(-0.10, 0.33)	0.2966

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Vitality Score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=180)		Placebo (N=184)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											0.0923
< 10 points	50	5.12 (1.16)	51	2.15 (1.13)	2.97 (1.43)	(0.13, 5.81)	0.0406	0.36 (0.20)	(-0.03, 0.75)	0.0720	
>= 10 points	118	2.81 (0.75)	121	2.69 (0.73)	0.12 (0.91)	(-1.66, 1.90)	0.8947	0.01 (0.13)	(-0.24, 0.27)	0.9088	
OCS dose at baseline											0.9905
<10 mg/day	72	3.70 (0.94)	76	2.83 (0.91)	0.87 (1.18)	(-1.47, 3.21)	0.4649	0.11 (0.16)	(-0.21, 0.43)	0.5110	
>=10 mg/day	96	3.20 (0.92)	96	2.31 (0.89)	0.89 (1.01)	(-1.10, 2.87)	0.3794	0.10 (0.14)	(-0.18, 0.38)	0.4912	
Result of type I IFN gene signature test											0.7727
LOW	30	4.52 (1.31)	31	4.05 (1.28)	0.47 (1.78)	(-3.09, 4.03)	0.7930	0.06 (0.26)	(-0.44, 0.57)	0.8006	
HIGH	138	3.80 (0.63)	141	2.76 (0.62)	1.04 (0.85)	(-0.63, 2.71)	0.2215	0.14 (0.12)	(-0.10, 0.37)	0.2431	
Age (years)											NE
<= 65	161	3.54 (0.67)	170	2.63 (0.64)	0.91 (0.77)	(-0.60, 2.42)	0.2381	0.11 (0.11)	(-0.11, 0.32)	0.3246	
> 65	7	NE	2	NE	NE	NE		NE	NE		
Sex											0.1531
male	15	6.07 (2.30)	12	1.80 (2.51)	4.27 (2.43)	(-0.78, 9.31)	0.0933	0.47 (0.39)	(-0.30, 1.24)	0.2336	
female	153	3.12 (0.68)	160	2.51 (0.65)	0.62 (0.80)	(-0.95, 2.18)	0.4397	0.07 (0.11)	(-0.15, 0.30)	0.5117	
Race											NE
White	117	3.73 (0.75)	126	2.65 (0.72)	1.09 (0.91)	(-0.71, 2.89)	0.2358	0.13 (0.13)	(-0.12, 0.39)	0.2990	
Black or African American	26	5.08 (1.83)	22	1.07 (1.56)	4.01 (1.97)	(0.02, 8.01)	0.0492	0.47 (0.29)	(-0.11, 1.04)	0.1130	
Asian	11	NE	5	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	NE	NE	NE		NE	NE		
Other	14	3.29 (2.60)	18	7.59 (2.62)	-4.30 (2.15)	(-8.72, 0.13)	0.0564	-0.40 (0.36)	(-1.10, 0.31)	0.2702	
Ethnicity											0.0214
Hispanic/Latino	30	2.41 (1.57)	33	5.01 (1.56)	-2.60 (1.69)	(-5.98, 0.78)	0.1292	-0.29 (0.25)	(-0.79, 0.21)	0.2507	
Non-hispanic/Latino	138	3.91 (0.71)	139	2.16 (0.69)	1.75 (0.85)	(0.07, 3.42)	0.0411	0.21 (0.12)	(-0.02, 0.45)	0.0783	
Geographic region											0.5230
EU	61	3.48 (1.14)	72	3.14 (1.09)	0.34 (1.20)	(-2.05, 2.72)	0.7797	0.04 (0.17)	(-0.30, 0.38)	0.8319	
non-EU	107	3.75 (0.80)	100	2.41 (0.81)	1.33 (0.99)	(-0.63, 3.29)	0.1809	0.16 (0.14)	(-0.11, 0.44)	0.2433	
Onset of disease											NE
Paediatric	11	NE	11	NE	NE	NE		NE	NE		
Adult	157	3.58 (0.66)	161	2.50 (0.65)	1.09 (0.79)	(-0.46, 2.64)	0.1672	0.13 (0.11)	(-0.09, 0.35)	0.2414	
ADA result											0.8345
Negative	152	3.41 (0.68)	157	2.63 (0.66)	0.78 (0.81)	(-0.82, 2.37)	0.3388	0.09 (0.11)	(-0.13, 0.32)	0.4134	
Positive (At any time)	16	3.91 (2.59)	15	2.59 (2.36)	1.32 (2.49)	(-3.84, 6.49)	0.6008	0.13 (0.36)	(-0.57, 0.84)	0.7142	
BMI (kg/m2) at enrolment											0.0585
< 30	100	3.64 (0.84)	118	3.64 (0.79)	-0.00 (0.92)	(-1.81, 1.81)	0.9997	-0.00 (0.14)	(-0.27, 0.27)	0.9998	
>= 30	68	3.87 (0.99)	54	0.81 (1.05)	3.05 (1.33)	(0.42, 5.68)	0.0234	0.38 (0.18)	(0.02, 0.74)	0.0390	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - FACIT-F Total Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) N	Anifrolumab 300mg (N=180) LSMean (SE)	Placebo (N=184) N	Placebo (N=184) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		2.85 (0.69)		1.66 (0.68)	1.19 (0.83)	(-0.45, 2.83)	0.1545			
Week 8		3.46 (0.74)		2.72 (0.73)	0.74 (0.91)	(-1.05, 2.53)	0.4154			
Week 12		3.79 (0.79)		1.50 (0.79)	2.29 (1.00)	(0.32, 4.26)	0.0229			
Week 16		4.73 (0.81)		2.15 (0.79)	2.59 (1.01)	(0.59, 4.58)	0.0112			
Week 20		5.56 (0.82)		4.16 (0.81)	1.40 (1.04)	(-0.64, 3.44)	0.1789			
Week 24		6.05 (0.85)		2.86 (0.83)	3.20 (1.08)	(1.07, 5.32)	0.0033			
Week 28		6.04 (0.87)		3.32 (0.85)	2.72 (1.11)	(0.54, 4.90)	0.0145			
Week 32		5.00 (0.90)		3.65 (0.88)	1.35 (1.16)	(-0.92, 3.62)	0.2432			
Week 36		5.14 (0.91)		2.64 (0.90)	2.51 (1.18)	(0.18, 4.83)	0.0345			
Week 40		5.21 (0.94)		3.96 (0.92)	1.24 (1.21)	(-1.14, 3.63)	0.3050			
Week 44		6.33 (1.00)		3.61 (0.97)	2.72 (1.30)	(0.16, 5.29)	0.0374			
Week 48		5.90 (0.93)		4.11 (0.92)	1.79 (1.21)	(-0.60, 4.18)	0.1414			
Week 52		5.98 (0.93)		3.97 (0.92)	2.01 (1.21)	(-0.38, 4.39)	0.0987			
OVERALL	170	5.08 (0.72)	172	3.10 (0.71)	1.98 (0.88)	(0.25, 3.71)	0.0251	0.21 (0.11)	(-0.00, 0.42)	0.0512

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - FACIT-F Total Score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=180)		Placebo (N=184)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											0.1041
< 10 points	52	6.56 (1.25)	51	2.33 (1.24)	4.23 (1.58)	(1.09, 7.37)	0.0088	0.47 (0.20)	(0.08, 0.86)	0.0186	
>= 10 points	118	4.77 (0.86)	121	3.64 (0.84)	1.13 (1.06)	(-0.97, 3.23)	0.2888	0.12 (0.13)	(-0.13, 0.38)	0.3483	
OCS dose at baseline											0.6226
<10 mg/day	72	5.14 (1.03)	75	2.63 (1.00)	2.52 (1.33)	(-0.12, 5.15)	0.0611	0.29 (0.17)	(-0.04, 0.61)	0.0837	
>=10 mg/day	98	5.13 (1.04)	97	3.49 (1.03)	1.64 (1.18)	(-0.69, 3.97)	0.1664	0.16 (0.14)	(-0.12, 0.44)	0.2671	
Result of type I IFN gene signature test											0.4066
LOW	30	5.89 (1.73)	31	5.59 (1.70)	0.30 (2.34)	(-4.37, 4.98)	0.8970	0.03 (0.26)	(-0.47, 0.53)	0.9015	
HIGH	140	5.50 (0.70)	141	3.11 (0.69)	2.39 (0.95)	(0.53, 4.26)	0.0119	0.29 (0.12)	(0.06, 0.53)	0.0153	
Age (years)											NE
<= 65	163	5.12 (0.75)	170	3.19 (0.72)	1.93 (0.89)	(0.18, 3.69)	0.0308	0.20 (0.11)	(-0.01, 0.42)	0.0634	
> 65	7	NE	2	NE	NE	NE		NE	NE		
Sex											NE
male	15	NE	12	NE	NE	NE		NE	NE		
female	155	4.97 (0.76)	160	3.36 (0.74)	1.61 (0.93)	(-0.23, 3.44)	0.0856	0.17 (0.11)	(-0.05, 0.39)	0.1329	
Race											NE
White	117	4.81 (0.83)	127	2.57 (0.79)	2.24 (1.03)	(0.20, 4.28)	0.0312	0.25 (0.13)	(-0.00, 0.50)	0.0522	
Black or African American	27	9.22 (2.28)	21	6.01 (2.09)	3.21 (2.60)	(-2.08, 8.49)	0.2263	0.29 (0.29)	(-0.28, 0.86)	0.3242	
Asian	11	NE	5	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	-0.50 (0.00)	NE	NE		NE	NE		
Other	15	2.58 (2.70)	18	6.83 (2.87)	-4.25 (2.35)	(-9.09, 0.59)	0.0824	-0.36 (0.35)	(-1.05, 0.33)	0.3037	
Ethnicity											0.2410
Hispanic/Latino	31	3.09 (2.01)	33	3.44 (1.99)	-0.35 (2.14)	(-4.64, 3.94)	0.8708	-0.03 (0.25)	(-0.52, 0.46)	0.9027	
Non-hispanic/Latino	139	5.68 (0.77)	139	3.28 (0.76)	2.40 (0.95)	(0.52, 4.27)	0.0124	0.27 (0.12)	(0.03, 0.50)	0.0268	
Geographic region											0.1992
EU	62	5.68 (1.11)	73	4.91 (1.07)	0.78 (1.22)	(-1.64, 3.19)	0.5267	0.09 (0.17)	(-0.25, 0.42)	0.6186	
non-EU	108	5.14 (0.95)	99	2.17 (0.97)	2.98 (1.21)	(0.60, 5.36)	0.0144	0.30 (0.14)	(0.03, 0.58)	0.0295	
Onset of disease											NE
Paediatric	11	NE	11	NE	NE	NE		NE	NE		
Adult	159	5.20 (0.74)	161	2.99 (0.73)	2.22 (0.91)	(0.43, 4.00)	0.0151	0.24 (0.11)	(0.02, 0.46)	0.0337	
ADA result											0.8264
Negative	153	4.83 (0.77)	157	2.87 (0.75)	1.96 (0.94)	(0.10, 3.81)	0.0385	0.21 (0.11)	(-0.02, 0.43)	0.0693	
Positive (At any time)	17	8.45 (2.39)	15	5.88 (2.33)	2.57 (2.65)	(-2.90, 8.04)	0.3408	0.26 (0.36)	(-0.43, 0.96)	0.4570	
BMI (kg/m2) at enrolment											0.2716
< 30	102	5.32 (0.91)	118	4.02 (0.86)	1.30 (1.03)	(-0.73, 3.32)	0.2079	0.14 (0.14)	(-0.13, 0.40)	0.3051	
>= 30	68	5.26 (1.15)	54	1.88 (1.25)	3.38 (1.59)	(0.23, 6.52)	0.0355	0.36 (0.18)	(-0.00, 0.72)	0.0508	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - EQ VAS Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=184) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 12		4.93 (1.79)		2.49 (1.79)	2.44 (2.24)	(-1.97, 6.85)	0.2780			
Week 24		8.34 (1.83)		6.50 (1.83)	1.84 (2.30)	(-2.68, 6.36)	0.4246			
Week 36		9.55 (1.85)		8.46 (1.81)	1.09 (2.31)	(-3.45, 5.63)	0.6380			
Week 52		9.77 (1.94)		6.41 (1.90)	3.37 (2.44)	(-1.44, 8.18)	0.1692			
OVERALL	164	8.15 (1.54)	168	5.96 (1.53)	2.18 (1.82)	(-1.41, 5.77)	0.2324	0.11 (0.11)	(-0.11, 0.33)	0.3172

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - EQ VAS Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=184) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.4173
< 10 points	49	6.94 (2.68)	49	2.42 (2.66)	4.51 (3.32)	(-2.09, 11.12)	0.1781	0.24 (0.20)	(-0.16, 0.64)	0.2374	
>= 10 points	115	9.05 (1.82)	119	7.77 (1.80)	1.28 (2.19)	(-3.04, 5.60)	0.5590	0.07 (0.13)	(-0.19, 0.32)	0.6176	
OCS dose at baseline											0.6538
<10 mg/day	70	6.89 (2.32)	74	3.87 (2.27)	3.02 (2.90)	(-2.71, 8.75)	0.2986	0.15 (0.17)	(-0.17, 0.48)	0.3551	
>=10 mg/day	94	8.93 (2.11)	94	7.57 (2.10)	1.36 (2.32)	(-3.22, 5.94)	0.5591	0.07 (0.15)	(-0.22, 0.35)	0.6497	
Result of type I IFN gene signature test											0.2802
LOW	30	3.80 (3.03)	31	5.60 (3.01)	-1.80 (4.10)	(-10.01, 6.41)	0.6628	-0.11 (0.26)	(-0.61, 0.40)	0.6783	
HIGH	134	11.01 (1.53)	137	7.87 (1.51)	3.15 (2.04)	(-0.87, 7.16)	0.1244	0.18 (0.12)	(-0.06, 0.42)	0.1464	
Age (years)											NE
<= 65	157	8.37 (1.60)	166	6.17 (1.56)	2.20 (1.85)	(-1.44, 5.84)	0.2344	0.11 (0.11)	(-0.11, 0.33)	0.3257	
> 65	7	NE	2	NE	NE	NE		NE	NE		
Sex											0.0553
male	15	12.83 (6.77)	12	-3.05 (7.57)	15.88 (7.29)	(0.56, 31.20)	0.0430	0.59 (0.40)	(-0.19, 1.36)	0.1391	
female	149	7.96 (1.60)	156	6.51 (1.57)	1.44 (1.89)	(-2.28, 5.16)	0.4458	0.07 (0.11)	(-0.15, 0.30)	0.5216	
Race											0.6833
White	114	8.99 (1.78)	125	7.41 (1.75)	1.58 (2.16)	(-2.67, 5.83)	0.4637	0.08 (0.13)	(-0.17, 0.34)	0.5280	
Black or African American	26	8.23 (4.33)	21	1.61 (3.80)	6.62 (4.99)	(-3.45, 16.69)	0.1915	0.32 (0.30)	(-0.26, 0.90)	0.2738	
Asian	10	5.41 (7.13)	5	-7.03 (11.52)	12.44 (12.99)	(-14.82, 39.71)	0.3508	0.50 (0.56)	(-0.60, 1.59)	0.3733	
American Indian or Alaska Native	0	NE	0	NE	NE	NE		NE	NE		
Other	14	11.81 (8.51)	17	7.59 (8.24)	4.21 (6.94)	(-10.04, 18.47)	0.5488	0.12 (0.36)	(-0.58, 0.83)	0.7311	
Ethnicity											0.6260
Hispanic/Latino	29	9.36 (4.56)	32	9.26 (4.49)	0.11 (4.73)	(-9.36, 9.58)	0.9821	0.00 (0.26)	(-0.50, 0.51)	0.9869	
Non-hispanic/Latino	135	8.36 (1.64)	136	5.75 (1.64)	2.60 (1.98)	(-1.30, 6.51)	0.1897	0.14 (0.12)	(-0.10, 0.37)	0.2632	
Geographic region											0.3455
EU	61	12.35 (2.62)	72	12.08 (2.57)	0.27 (2.76)	(-5.20, 5.73)	0.9225	0.01 (0.17)	(-0.33, 0.35)	0.9421	
non-EU	103	5.39 (1.91)	96	1.68 (1.95)	3.70 (2.37)	(-0.97, 8.38)	0.1199	0.19 (0.14)	(-0.09, 0.47)	0.1773	
Onset of disease											0.2545
Paediatric	10	19.56 (10.14)	10	5.64 (7.37)	13.92 (10.19)	(-7.81, 35.65)	0.1921	0.48 (0.46)	(-0.42, 1.37)	0.2958	
Adult	154	8.20 (1.58)	158	6.09 (1.58)	2.11 (1.88)	(-1.59, 5.81)	0.2624	0.11 (0.11)	(-0.12, 0.33)	0.3464	
ADA result											0.3263
Negative	148	7.91 (1.61)	153	6.27 (1.61)	1.64 (1.93)	(-2.16, 5.44)	0.3968	0.08 (0.12)	(-0.14, 0.31)	0.4729	
Positive (At any time)	16	14.29 (6.93)	15	6.29 (6.17)	8.00 (6.19)	(-4.74, 20.75)	0.2077	0.30 (0.36)	(-0.41, 1.01)	0.4060	
BMI (kg/m2) at enrolment											0.5557
< 30	98	9.73 (2.07)	115	7.98 (1.99)	1.75 (2.28)	(-2.75, 6.26)	0.4434	0.08 (0.14)	(-0.19, 0.35)	0.5441	
>= 30	66	6.07 (2.31)	53	2.08 (2.46)	3.99 (3.03)	(-2.02, 10.00)	0.1907	0.22 (0.18)	(-0.15, 0.58)	0.2436	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Physical Health domain score
Full analysis set

	Anifrolumab 300mg (N=180)		Placebo (N=184)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 12		8.95 (1.66)		6.98 (1.65)	1.97 (2.01)	(-1.98, 5.92)	0.3267			
Week 24		9.80 (1.72)		6.45 (1.70)	3.35 (2.10)	(-0.77, 7.48)	0.1106			
Week 36		9.88 (1.81)		7.83 (1.77)	2.05 (2.23)	(-2.34, 6.44)	0.3585			
Week 52		9.36 (1.86)		7.92 (1.82)	1.44 (2.31)	(-3.10, 5.98)	0.5334			
OVERALL	164	9.50 (1.58)	168	7.29 (1.56)	2.20 (1.87)	(-1.47, 5.88)	0.2390	0.11 (0.11)	(-0.11, 0.32)	0.3226

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Physical Health domain score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=184) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.0297
< 10 points	49	11.38 (2.42)	49	3.27 (2.39)	8.11 (3.00)	(2.15, 14.07)	0.0082	0.48 (0.21)	(0.08, 0.88)	0.0199	
>= 10 points	115	9.47 (1.93)	119	9.61 (1.90)	-0.14 (2.33)	(-4.73, 4.44)	0.9511	-0.01 (0.13)	(-0.26, 0.25)	0.9581	
OCS dose at baseline											0.4676
<10 mg/day	70	10.03 (2.20)	74	6.19 (2.13)	3.84 (2.76)	(-1.62, 9.30)	0.1670	0.21 (0.17)	(-0.12, 0.54)	0.2140	
>=10 mg/day	94	9.32 (2.33)	94	8.22 (2.32)	1.10 (2.55)	(-3.94, 6.14)	0.6662	0.05 (0.15)	(-0.24, 0.33)	0.7383	
Result of type I IFN gene signature test											0.2027
LOW	30	7.77 (3.33)	31	10.70 (3.26)	-2.93 (4.50)	(-11.96, 6.10)	0.5178	-0.16 (0.26)	(-0.66, 0.34)	0.5350	
HIGH	134	10.89 (1.55)	137	7.51 (1.53)	3.38 (2.06)	(-0.69, 7.44)	0.1028	0.19 (0.12)	(-0.05, 0.43)	0.1225	
Age (years)											NE
<= 65	157	9.98 (1.64)	166	7.70 (1.59)	2.29 (1.89)	(-1.43, 6.01)	0.2271	0.11 (0.11)	(-0.11, 0.33)	0.3169	
> 65	7	NE	2	NE	NE	NE		NE	NE		
Sex											0.0088
male	15	12.01 (5.12)	12	-4.64 (5.74)	16.65 (5.68)	(4.84, 28.46)	0.0080	0.81 (0.41)	(0.02, 1.61)	0.0448	
female	149	8.80 (1.66)	156	7.89 (1.62)	0.91 (1.96)	(-2.96, 4.78)	0.6434	0.04 (0.11)	(-0.18, 0.27)	0.6960	
Race											0.1016
White	114	8.87 (1.82)	125	6.54 (1.77)	2.33 (2.22)	(-2.04, 6.70)	0.2939	0.12 (0.13)	(-0.14, 0.37)	0.3617	
Black or African American	26	15.82 (4.51)	21	9.94 (4.15)	5.88 (5.15)	(-4.51, 16.28)	0.2599	0.27 (0.29)	(-0.31, 0.85)	0.3576	
Asian	10	14.50 (5.74)	5	-6.10 (9.14)	20.59 (10.74)	(-2.78, 43.96)	0.0790	1.03 (0.59)	(-0.13, 2.18)	0.0817	
American Indian or Alaska Native	0	NE	0	NE	NE	NE		NE	NE		
Other	14	10.82 (7.39)	17	17.99 (7.14)	-7.17 (5.63)	(-18.77, 4.42)	0.2145	-0.24 (0.36)	(-0.95, 0.47)	0.5009	
Ethnicity											0.2800
Hispanic/Latino	29	6.72 (4.40)	32	8.82 (4.33)	-2.09 (4.66)	(-11.45, 7.26)	0.6552	-0.09 (0.26)	(-0.59, 0.42)	0.7385	
Non-hispanic/Latino	135	10.49 (1.71)	136	7.08 (1.69)	3.41 (2.05)	(-0.64, 7.45)	0.0983	0.17 (0.12)	(-0.07, 0.41)	0.1575	
Geographic region											0.7340
EU	61	12.14 (2.50)	72	10.41 (2.43)	1.73 (2.63)	(-3.47, 6.93)	0.5112	0.09 (0.17)	(-0.26, 0.43)	0.6231	
non-EU	103	8.26 (1.98)	96	5.30 (2.01)	2.95 (2.46)	(-1.90, 7.81)	0.2318	0.15 (0.14)	(-0.13, 0.43)	0.2977	
Onset of disease											0.6085
Paediatric	10	11.96 (9.60)	10	14.22 (6.60)	-2.26 (9.68)	(-22.88, 18.36)	0.8187	-0.08 (0.45)	(-0.96, 0.79)	0.8528	
Adult	154	9.62 (1.63)	158	6.82 (1.63)	2.80 (1.95)	(-1.03, 6.63)	0.1511	0.14 (0.11)	(-0.08, 0.36)	0.2259	
ADA result											0.7535
Negative	148	9.29 (1.67)	153	7.26 (1.65)	2.02 (2.00)	(-1.92, 5.97)	0.3139	0.10 (0.12)	(-0.13, 0.33)	0.3908	
Positive (At any time)	16	14.93 (5.78)	15	10.97 (5.69)	3.97 (5.85)	(-8.09, 16.02)	0.5044	0.17 (0.36)	(-0.53, 0.88)	0.6350	
BMI (kg/m2) at enrolment											0.7845
< 30	98	11.66 (1.88)	115	8.85 (1.78)	2.81 (2.07)	(-1.26, 6.89)	0.1747	0.15 (0.14)	(-0.12, 0.42)	0.2802	
>= 30	66	7.54 (2.79)	53	5.89 (3.01)	1.65 (3.71)	(-5.71, 9.01)	0.6575	0.07 (0.18)	(-0.29, 0.44)	0.6908	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Emotional Health domain score
Full analysis set

	Anifrolumab 300mg (N=180)		Placebo (N=184)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 12		2.82 (1.48)		0.92 (1.48)	1.90 (1.81)	(-1.67, 5.47)	0.2966			
Week 24		4.32 (1.62)		3.46 (1.61)	0.86 (2.03)	(-3.14, 4.86)	0.6733			
Week 36		6.05 (1.69)		4.07 (1.66)	1.98 (2.13)	(-2.21, 6.17)	0.3535			
Week 52		6.67 (1.70)		5.30 (1.67)	1.38 (2.15)	(-2.85, 5.60)	0.5218			
OVERALL	164	4.97 (1.38)	168	3.44 (1.37)	1.53 (1.64)	(-1.70, 4.75)	0.3518	0.09 (0.11)	(-0.13, 0.30)	0.4331

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Emotional Health domain score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=180)		Placebo (N=184)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											0.1201
< 10 points	49	6.77 (1.93)	49	1.88 (1.93)	4.89 (2.42)	(0.07, 9.70)	0.0467	0.36 (0.20)	(-0.04, 0.76)	0.0785	
>= 10 points	115	3.98 (1.72)	119	4.06 (1.69)	-0.07 (2.08)	(-4.17, 4.02)	0.9715	-0.00 (0.13)	(-0.26, 0.25)	0.9755	
OCS dose at baseline											0.4920
<10 mg/day	70	4.83 (1.93)	74	2.10 (1.88)	2.73 (2.41)	(-2.04, 7.50)	0.2599	0.17 (0.17)	(-0.16, 0.50)	0.3149	
>=10 mg/day	94	4.92 (2.01)	94	4.44 (2.01)	0.47 (2.22)	(-3.91, 4.86)	0.8313	0.02 (0.15)	(-0.26, 0.31)	0.8682	
Result of type I IFN gene signature test											0.4518
LOW	30	2.47 (2.73)	31	3.54 (2.70)	-1.07 (3.69)	(-8.48, 6.33)	0.7721	-0.07 (0.26)	(-0.57, 0.43)	0.7823	
HIGH	134	7.05 (1.37)	137	5.02 (1.36)	2.03 (1.83)	(-1.58, 5.63)	0.2697	0.13 (0.12)	(-0.11, 0.37)	0.2960	
Age (years)											NE
<= 65	157	4.74 (1.44)	166	3.60 (1.40)	1.13 (1.67)	(-2.15, 4.41)	0.4975	0.06 (0.11)	(-0.16, 0.28)	0.5734	
> 65	7	NE	2	NE	NE	NE		NE	NE		
Sex											0.0818
male	15	6.49 (6.07)	12	-6.39 (7.00)	12.88 (6.97)	(-1.60, 27.37)	0.0785	0.52 (0.39)	(-0.25, 1.30)	0.1845	
female	149	4.39 (1.42)	156	3.98 (1.39)	0.41 (1.68)	(-2.90, 3.71)	0.8077	0.02 (0.11)	(-0.20, 0.25)	0.8371	
Race											0.0765
White	114	5.34 (1.54)	125	2.35 (1.51)	2.99 (1.87)	(-0.70, 6.68)	0.1117	0.18 (0.13)	(-0.08, 0.43)	0.1676	
Black or African American	26	7.37 (4.94)	21	6.30 (4.48)	1.07 (5.65)	(-10.37, 12.52)	0.8501	0.05 (0.29)	(-0.53, 0.62)	0.8768	
Asian	10	3.01 (4.22)	5	-4.92 (6.58)	7.94 (7.45)	(-8.66, 24.53)	0.3117	0.54 (0.56)	(-0.56, 1.64)	0.3330	
American Indian or Alaska Native	0	NE	0	NE	NE	NE		NE	NE		
Other	14	1.35 (8.36)	17	14.22 (7.92)	-12.87 (6.11)	(-25.43, -0.31)	0.0450	-0.39 (0.36)	(-1.11, 0.32)	0.2837	
Ethnicity											0.0134
Hispanic/Latino	29	2.80 (4.00)	32	10.89 (3.98)	-8.09 (4.37)	(-16.85, 0.67)	0.0696	-0.36 (0.26)	(-0.87, 0.14)	0.1614	
Non-hispanic/Latino	135	5.54 (1.44)	136	2.00 (1.43)	3.54 (1.73)	(0.13, 6.95)	0.0420	0.21 (0.12)	(-0.03, 0.45)	0.0821	
Geographic region											0.7179
EU	61	7.89 (2.11)	72	5.67 (2.06)	2.22 (2.23)	(-2.20, 6.64)	0.3224	0.13 (0.17)	(-0.21, 0.47)	0.4577	
non-EU	103	3.67 (1.80)	96	2.60 (1.84)	1.07 (2.26)	(-3.39, 5.53)	0.6360	0.06 (0.14)	(-0.22, 0.34)	0.6787	
Onset of disease											0.6488
Paediatric	10	11.58 (11.59)	10	13.91 (6.83)	-2.34 (9.99)	(-23.58, 18.91)	0.8183	-0.07 (0.45)	(-0.95, 0.80)	0.8680	
Adult	154	5.20 (1.40)	158	2.92 (1.41)	2.28 (1.68)	(-1.03, 5.58)	0.1757	0.13 (0.11)	(-0.09, 0.35)	0.2529	
ADA result											0.1340
Negative	148	5.15 (1.44)	153	2.99 (1.43)	2.16 (1.73)	(-1.25, 5.56)	0.2138	0.12 (0.12)	(-0.10, 0.35)	0.2902	
Positive (At any time)	16	1.62 (6.21)	15	9.23 (6.23)	-7.61 (6.28)	(-20.73, 5.50)	0.2401	-0.30 (0.36)	(-1.01, 0.41)	0.4028	
BMI (kg/m2) at enrolment											0.3790
< 30	98	6.03 (1.72)	115	5.58 (1.65)	0.45 (1.89)	(-3.28, 4.19)	0.8115	0.03 (0.14)	(-0.24, 0.30)	0.8503	
>= 30	66	3.81 (2.40)	53	0.09 (2.57)	3.71 (3.19)	(-2.61, 10.03)	0.2466	0.19 (0.18)	(-0.17, 0.56)	0.2968	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Body Image domain score
Full analysis set

	Anifrolumab 300mg (N=180)		Placebo (N=184)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 12		6.50 (1.78)		3.23 (1.80)	3.27 (2.19)	(-1.04, 7.58)	0.1367			
Week 24		8.21 (2.02)		4.46 (2.04)	3.75 (2.56)	(-1.30, 8.80)	0.1447			
Week 36		10.26 (2.08)		6.25 (2.08)	4.00 (2.66)	(-1.23, 9.23)	0.1329			
Week 52		9.91 (2.11)		6.51 (2.09)	3.40 (2.68)	(-1.87, 8.67)	0.2053			
OVERALL	152	8.72 (1.72)	153	5.11 (1.74)	3.61 (2.09)	(-0.51, 7.72)	0.0854	0.17 (0.11)	(-0.06, 0.39)	0.1424

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Body Image domain score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=184) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.3479
< 10 points	46	6.65 (2.43)	45	6.72 (2.55)	-0.06 (3.11)	(-6.24, 6.12)	0.9843	-0.00 (0.21)	(-0.41, 0.41)	0.9862	
>= 10 points	106	8.92 (2.12)	108	5.14 (2.11)	3.78 (2.66)	(-1.47, 9.03)	0.1570	0.17 (0.14)	(-0.10, 0.44)	0.2082	
OCS dose at baseline											0.9219
<10 mg/day	65	6.64 (2.43)	64	3.20 (2.44)	3.44 (3.13)	(-2.75, 9.63)	0.2736	0.17 (0.18)	(-0.17, 0.52)	0.3222	
>=10 mg/day	87	10.64 (2.54)	89	6.78 (2.53)	3.85 (2.86)	(-1.79, 9.50)	0.1797	0.16 (0.15)	(-0.13, 0.46)	0.2856	
Result of type I IFN gene signature test											0.2474
LOW	30	4.99 (3.32)	28	6.53 (3.53)	-1.54 (4.65)	(-10.88, 7.80)	0.7421	-0.08 (0.26)	(-0.60, 0.43)	0.7539	
HIGH	122	11.09 (1.73)	125	6.62 (1.71)	4.48 (2.33)	(-0.11, 9.06)	0.0556	0.23 (0.13)	(-0.02, 0.48)	0.0676	
Age (years)											NE
<= 65	146	8.93 (1.80)	151	5.46 (1.79)	3.47 (2.14)	(-0.74, 7.67)	0.1056	0.16 (0.12)	(-0.07, 0.39)	0.1739	
> 65	6	NE	2	NE	NE	NE		NE	NE		
Sex											0.2654
male	12	13.91 (4.75)	10	3.98 (5.92)	9.93 (6.08)	(-3.00, 22.86)	0.1227	0.55 (0.44)	(-0.31, 1.40)	0.2127	
female	140	7.94 (1.80)	143	5.21 (1.80)	2.74 (2.18)	(-1.55, 7.02)	0.2101	0.13 (0.12)	(-0.11, 0.36)	0.2847	
Race											NE
White	106	9.42 (1.87)	115	3.91 (1.85)	5.51 (2.31)	(0.95, 10.07)	0.0180	0.28 (0.14)	(0.02, 0.55)	0.0380	
Black or African American	23	12.01 (6.19)	18	5.58 (5.43)	6.43 (7.03)	(-7.83, 20.69)	0.3664	0.23 (0.32)	(-0.39, 0.85)	0.4597	
Asian	9	NE	5	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	0	NE	NE	NE		NE	NE		
Other	14	-2.19 (10.48)	15	10.35 (9.94)	-12.54 (7.48)	(-28.00, 2.92)	0.1069	-0.31 (0.37)	(-1.05, 0.42)	0.4019	
Ethnicity											0.0199
Hispanic/Latino	26	6.27 (4.66)	29	13.65 (4.62)	-7.38 (5.27)	(-17.98, 3.21)	0.1675	-0.30 (0.27)	(-0.83, 0.23)	0.2712	
Non-hispanic/Latino	126	9.58 (1.84)	124	3.62 (1.87)	5.96 (2.27)	(1.50, 10.43)	0.0091	0.29 (0.13)	(0.04, 0.54)	0.0243	
Geographic region											0.1746
EU	57	15.53 (2.83)	65	8.68 (2.83)	6.85 (3.07)	(0.77, 12.93)	0.0275	0.31 (0.18)	(-0.05, 0.67)	0.0918	
non-EU	95	5.27 (2.12)	88	3.97 (2.18)	1.30 (2.70)	(-4.03, 6.63)	0.6312	0.06 (0.15)	(-0.23, 0.35)	0.6710	
Onset of disease											0.9411
Paediatric	10	13.27 (14.00)	10	8.18 (9.57)	5.09 (12.71)	(-21.60, 31.79)	0.6932	0.13 (0.45)	(-0.75, 1.01)	0.7738	
Adult	142	8.96 (1.69)	143	4.82 (1.72)	4.14 (2.07)	(0.06, 8.22)	0.0466	0.20 (0.12)	(-0.03, 0.44)	0.0880	
ADA result											0.6061
Negative	139	8.72 (1.82)	139	4.89 (1.86)	3.84 (2.24)	(-0.57, 8.24)	0.0874	0.18 (0.12)	(-0.06, 0.41)	0.1417	
Positive (At any time)	13	9.77 (5.89)	14	9.15 (5.35)	0.62 (5.83)	(-11.61, 12.84)	0.9170	0.03 (0.39)	(-0.73, 0.78)	0.9400	
BMI (kg/m2) at enrolment											0.8529
< 30	90	9.32 (2.31)	104	6.73 (2.25)	2.59 (2.66)	(-2.66, 7.85)	0.3320	0.11 (0.14)	(-0.17, 0.40)	0.4254	
>= 30	62	8.63 (2.63)	49	5.22 (2.89)	3.41 (3.54)	(-3.61, 10.44)	0.3373	0.17 (0.19)	(-0.21, 0.54)	0.3880	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Burden to Others domain score
Full analysis set

Visit	Anifrolumab 300mg (N=180) N	Anifrolumab 300mg (N=180) LSMean (SE)	Placebo (N=184) N	Placebo (N=184) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 12		7.28 (1.85)		7.35 (1.85)	-0.07 (2.29)	(-4.58, 4.43)	0.9746			
Week 24		9.91 (2.00)		8.25 (1.99)	1.65 (2.52)	(-3.31, 6.61)	0.5127			
Week 36		13.12 (2.01)		11.44 (1.96)	1.67 (2.51)	(-3.27, 6.62)	0.5056			
Week 52		10.10 (2.21)		10.67 (2.16)	-0.56 (2.83)	(-6.13, 5.00)	0.8419			
OVERALL	164	10.10 (1.68)	168	9.43 (1.66)	0.67 (1.99)	(-3.25, 4.59)	0.7360	0.03 (0.11)	(-0.18, 0.25)	0.7762

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Burden to Others domain score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=180)		Placebo (N=184)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											0.1503
< 10 points	49	12.07 (2.39)	49	7.63 (2.39)	4.44 (2.98)	(-1.48, 10.35)	0.1398	0.26 (0.20)	(-0.13, 0.66)	0.1952	
>= 10 points	115	9.17 (2.08)	119	10.34 (2.04)	-1.17 (2.51)	(-6.13, 3.78)	0.6418	-0.05 (0.13)	(-0.31, 0.20)	0.6887	
OCS dose at baseline											0.7296
<10 mg/day	70	9.36 (2.32)	74	9.43 (2.26)	-0.07 (2.91)	(-5.82, 5.68)	0.9809	-0.00 (0.17)	(-0.33, 0.32)	0.9829	
>=10 mg/day	94	10.93 (2.48)	94	9.62 (2.47)	1.31 (2.74)	(-4.10, 6.73)	0.6330	0.05 (0.15)	(-0.23, 0.34)	0.7090	
Result of type I IFN gene signature test											0.7162
LOW	30	13.43 (3.67)	31	11.28 (3.62)	2.15 (4.96)	(-7.79, 12.10)	0.6664	0.11 (0.26)	(-0.40, 0.61)	0.6807	
HIGH	134	9.07 (1.62)	137	8.88 (1.60)	0.18 (2.16)	(-4.07, 4.44)	0.9325	0.01 (0.12)	(-0.23, 0.25)	0.9360	
Age (years)											NE
<= 65	157	9.42 (1.73)	166	9.47 (1.69)	-0.06 (2.02)	(-4.03, 3.91)	0.9776	-0.00 (0.11)	(-0.22, 0.22)	0.9814	
> 65	7	NE	2	NE	NE	NE		NE	NE		
Sex											0.3531
male	15	12.52 (4.92)	12	6.65 (5.77)	5.88 (5.74)	(-5.98, 17.73)	0.3162	0.29 (0.39)	(-0.47, 1.06)	0.4522	
female	149	9.74 (1.78)	156	9.54 (1.74)	0.20 (2.11)	(-3.95, 4.35)	0.9243	0.01 (0.11)	(-0.22, 0.23)	0.9358	
Race											0.3152
White	114	10.36 (1.92)	125	8.86 (1.88)	1.50 (2.33)	(-3.09, 6.09)	0.5199	0.07 (0.13)	(-0.18, 0.33)	0.5774	
Black or African American	26	9.78 (5.32)	21	12.84 (4.93)	-3.06 (6.30)	(-15.80, 9.68)	0.6299	-0.12 (0.29)	(-0.69, 0.46)	0.6844	
Asian	10	1.78 (6.32)	5	-10.06 (11.17)	11.84 (13.00)	(-16.75, 40.42)	0.3820	0.51 (0.56)	(-0.58, 1.61)	0.3565	
American Indian or Alaska Native	0	NE	0	NE	NE	NE		NE	NE		
Other	14	11.81 (8.17)	17	20.87 (7.75)	-9.06 (6.30)	(-22.01, 3.89)	0.1623	-0.28 (0.36)	(-0.99, 0.43)	0.4376	
Ethnicity											0.0082
Hispanic/Latino	29	7.78 (4.21)	32	18.16 (4.13)	-10.37 (4.57)	(-19.53, -1.21)	0.0272	-0.44 (0.26)	(-0.95, 0.06)	0.0870	
Non-hispanic/Latino	135	10.69 (1.84)	136	7.64 (1.83)	3.06 (2.22)	(-1.31, 7.43)	0.1696	0.14 (0.12)	(-0.10, 0.38)	0.2403	
Geographic region											0.5779
EU	61	12.02 (2.73)	72	12.36 (2.68)	-0.34 (2.93)	(-6.14, 5.47)	0.9083	-0.02 (0.17)	(-0.36, 0.33)	0.9303	
non-EU	103	10.23 (2.09)	96	8.38 (2.12)	1.85 (2.61)	(-3.30, 6.99)	0.4802	0.09 (0.14)	(-0.19, 0.37)	0.5375	
Onset of disease											0.9321
Paediatric	10	13.87 (13.99)	10	11.93 (8.38)	1.93 (11.53)	(-23.17, 27.03)	0.8697	0.05 (0.45)	(-0.83, 0.93)	0.9097	
Adult	154	10.28 (1.72)	158	9.35 (1.72)	0.93 (2.06)	(-3.12, 4.99)	0.6508	0.04 (0.11)	(-0.18, 0.27)	0.7016	
ADA result											0.6462
Negative	148	10.56 (1.79)	153	9.59 (1.78)	0.97 (2.15)	(-3.27, 5.21)	0.6517	0.04 (0.12)	(-0.18, 0.27)	0.7006	
Positive (At any time)	16	6.01 (4.52)	15	7.58 (4.30)	-1.57 (5.09)	(-12.05, 8.92)	0.7611	-0.09 (0.36)	(-0.79, 0.62)	0.8075	
BMI (kg/m2) at enrolment											0.6066
< 30	98	9.83 (2.19)	115	9.91 (2.09)	-0.08 (2.42)	(-4.85, 4.70)	0.9752	-0.00 (0.14)	(-0.27, 0.27)	0.9803	
>= 30	66	11.03 (2.65)	53	8.90 (2.81)	2.13 (3.52)	(-4.86, 9.11)	0.5475	0.10 (0.18)	(-0.26, 0.46)	0.5868	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Fatigue domain score
Full analysis set

	Anifrolumab 300mg (N=180)		Placebo (N=184)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 12		6.43 (1.68)		4.57 (1.67)	1.86 (2.02)	(-2.11, 5.82)	0.3582			
Week 24		9.96 (1.81)		6.66 (1.79)	3.31 (2.22)	(-1.07, 7.68)	0.1376			
Week 36		9.65 (1.87)		5.61 (1.83)	4.05 (2.30)	(-0.48, 8.58)	0.0797			
Week 52		9.65 (2.00)		6.58 (1.96)	3.07 (2.51)	(-1.87, 8.01)	0.2218			
OVERALL	164	8.92 (1.64)	168	5.85 (1.61)	3.07 (1.93)	(-0.73, 6.87)	0.1131	0.15 (0.11)	(-0.07, 0.36)	0.1832

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Fatigue domain score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=184) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.3484
< 10 points	49	10.95 (2.77)	49	5.20 (2.75)	5.75 (3.41)	(-1.02, 12.52)	0.0950	0.30 (0.20)	(-0.10, 0.69)	0.1460	
>= 10 points	115	8.40 (1.95)	119	6.53 (1.91)	1.87 (2.34)	(-2.74, 6.49)	0.4247	0.09 (0.13)	(-0.17, 0.35)	0.4939	
OCS dose at baseline											0.2942
<10 mg/day	70	11.73 (2.12)	74	6.40 (2.05)	5.33 (2.67)	(0.05, 10.60)	0.0477	0.30 (0.17)	(-0.03, 0.63)	0.0738	
>=10 mg/day	94	6.61 (2.50)	94	5.28 (2.49)	1.32 (2.74)	(-4.08, 6.72)	0.6293	0.05 (0.15)	(-0.23, 0.34)	0.7092	
Result of type I IFN gene signature test											0.5119
LOW	30	10.61 (3.81)	31	10.48 (3.75)	0.13 (5.15)	(-10.20, 10.46)	0.9800	0.01 (0.26)	(-0.50, 0.51)	0.9809	
HIGH	134	9.95 (1.56)	137	6.18 (1.53)	3.77 (2.07)	(-0.31, 7.86)	0.0700	0.21 (0.12)	(-0.03, 0.45)	0.0859	
Age (years)											NE
<= 65	157	9.21 (1.70)	166	6.18 (1.64)	3.03 (1.96)	(-0.82, 6.89)	0.1226	0.14 (0.11)	(-0.08, 0.36)	0.2007	
> 65	7	NE	2	NE	NE	NE		NE	NE		
Sex											0.0024
male	15	12.68 (5.58)	12	-8.57 (6.41)	21.25 (6.20)	(8.42, 34.07)	0.0023	0.94 (0.41)	(0.14, 1.75)	0.0220	
female	149	8.04 (1.70)	156	6.59 (1.66)	1.45 (2.00)	(-2.50, 5.39)	0.4708	0.07 (0.11)	(-0.15, 0.29)	0.5432	
Race											0.0524
White	114	9.76 (1.87)	125	5.76 (1.82)	4.00 (2.27)	(-0.46, 8.47)	0.0788	0.20 (0.13)	(-0.06, 0.45)	0.1274	
Black or African American	26	0.92 (5.07)	21	4.51 (4.59)	-3.59 (5.76)	(-15.24, 8.07)	0.5372	-0.15 (0.29)	(-0.72, 0.43)	0.6142	
Asian	10	10.31 (6.33)	5	-17.30 (9.97)	27.62 (11.82)	(1.75, 53.49)	0.0384	1.25 (0.61)	(0.06, 2.45)	0.0396	
American Indian or Alaska Native	0	NE	0	NE	NE	NE		NE	NE		
Other	14	8.58 (6.94)	17	13.47 (6.47)	-4.89 (5.75)	(-16.69, 6.91)	0.4024	-0.18 (0.36)	(-0.89, 0.53)	0.6172	
Ethnicity											0.2648
Hispanic/Latino	29	8.42 (4.72)	32	10.17 (4.68)	-1.75 (4.98)	(-11.73, 8.23)	0.7267	-0.07 (0.26)	(-0.57, 0.44)	0.7954	
Non-hispanic/Latino	135	9.44 (1.73)	136	5.17 (1.70)	4.26 (2.07)	(0.19, 8.34)	0.0405	0.21 (0.12)	(-0.03, 0.45)	0.0802	
Geographic region											0.8022
EU	61	13.06 (2.44)	72	10.11 (2.36)	2.95 (2.56)	(-2.13, 8.03)	0.2522	0.15 (0.17)	(-0.19, 0.49)	0.3908	
non-EU	103	7.27 (2.12)	96	3.40 (2.16)	3.87 (2.65)	(-1.35, 9.10)	0.1454	0.18 (0.14)	(-0.10, 0.46)	0.2035	
Onset of disease											0.9664
Paediatric	10	14.03 (13.86)	10	11.00 (8.27)	3.03 (11.76)	(-22.07, 28.13)	0.8003	0.08 (0.45)	(-0.80, 0.96)	0.8574	
Adult	154	9.16 (1.67)	158	5.62 (1.66)	3.53 (1.98)	(-0.37, 7.43)	0.0757	0.17 (0.11)	(-0.05, 0.39)	0.1345	
ADA result											0.9981
Negative	148	8.58 (1.74)	153	5.65 (1.72)	2.93 (2.08)	(-1.17, 7.02)	0.1606	0.14 (0.12)	(-0.09, 0.36)	0.2331	
Positive (At any time)	16	10.33 (5.64)	15	7.42 (5.29)	2.91 (5.24)	(-7.96, 13.78)	0.5840	0.13 (0.36)	(-0.57, 0.84)	0.7152	
BMI (kg/m2) at enrolment											0.8254
< 30	98	11.15 (2.02)	115	7.77 (1.91)	3.38 (2.19)	(-0.94, 7.71)	0.1244	0.17 (0.14)	(-0.10, 0.44)	0.2259	
>= 30	66	7.18 (2.75)	53	4.74 (2.97)	2.44 (3.69)	(-4.88, 9.75)	0.5105	0.11 (0.18)	(-0.25, 0.47)	0.5519	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Intimate Relationships domain score
Full analysis set

	Anifrolumab 300mg (N=180)		Placebo (N=184)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 12		6.18 (2.43)		1.38 (2.46)	4.79 (3.04)	(-1.19, 10.78)	0.1158			
Week 24		3.89 (2.68)		5.29 (2.71)	-1.39 (3.44)	(-8.18, 5.39)	0.6858			
Week 36		5.90 (2.61)		3.81 (2.61)	2.09 (3.30)	(-4.42, 8.59)	0.5284			
Week 52		7.11 (2.65)		2.33 (2.64)	4.77 (3.35)	(-1.83, 11.38)	0.1559			
OVERALL	136	5.77 (2.21)	135	3.20 (2.21)	2.56 (2.66)	(-2.67, 7.80)	0.3351	0.10 (0.12)	(-0.14, 0.34)	0.4136

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Intimate Relationships domain score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=180)		Placebo (N=184)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											0.4977
< 10 points	38	7.78 (3.89)	39	2.73 (3.94)	5.06 (4.81)	(-4.55, 14.66)	0.2972	0.21 (0.23)	(-0.24, 0.65)	0.3674	
>= 10 points	98	4.95 (2.50)	96	3.80 (2.52)	1.14 (3.19)	(-5.14, 7.43)	0.7201	0.05 (0.14)	(-0.24, 0.33)	0.7484	
OCS dose at baseline											0.5437
<10 mg/day	58	5.21 (3.06)	56	0.76 (3.07)	4.46 (3.95)	(-3.38, 12.29)	0.2618	0.19 (0.19)	(-0.18, 0.56)	0.3086	
>=10 mg/day	78	6.04 (3.27)	79	4.84 (3.22)	1.20 (3.63)	(-5.98, 8.37)	0.7421	0.04 (0.16)	(-0.27, 0.35)	0.7952	
Result of type I IFN gene signature test											0.3864
LOW	27	2.69 (5.12)	27	5.35 (5.11)	-2.66 (6.72)	(-16.17, 10.85)	0.6939	-0.10 (0.27)	(-0.63, 0.44)	0.7170	
HIGH	109	8.15 (2.15)	108	4.48 (2.15)	3.67 (2.88)	(-2.01, 9.35)	0.2037	0.16 (0.14)	(-0.10, 0.43)	0.2291	
Age (years)											NE
<= 65	133	4.76 (2.23)	134	2.84 (2.22)	1.92 (2.65)	(-3.30, 7.14)	0.4691	0.07 (0.12)	(-0.17, 0.31)	0.5424	
> 65	3	NE	1	NE	NE	NE		NE	NE		
Sex											0.2221
male	11	11.35 (5.59)	10	0.11 (6.74)	11.24 (7.26)	(-4.52, 27.00)	0.1466	0.54 (0.45)	(-0.33, 1.42)	0.2246	
female	125	5.41 (2.37)	125	3.68 (2.35)	1.73 (2.82)	(-3.84, 7.29)	0.5410	0.07 (0.13)	(-0.18, 0.31)	0.6055	
Race											NE
White	97	6.39 (2.51)	101	2.81 (2.50)	3.58 (3.06)	(-2.46, 9.61)	0.2438	0.14 (0.14)	(-0.14, 0.42)	0.3148	
Black or African American	22	0.45 (7.68)	17	-0.55 (7.16)	0.99 (9.71)	(-18.83, 20.82)	0.9191	0.03 (0.32)	(-0.60, 0.66)	0.9279	
Asian	7	NE	5	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	0	NE	NE	NE		NE	NE		
Other	10	-8.62 (11.32)	12	2.77 (11.29)	-11.39 (9.13)	(-30.75, 7.97)	0.2305	-0.29 (0.43)	(-1.14, 0.55)	0.4996	
Ethnicity											0.0046
Hispanic/Latino	23	-1.42 (5.14)	22	11.58 (5.03)	-13.00 (5.71)	(-24.57, -1.44)	0.0285	-0.53 (0.30)	(-1.12, 0.07)	0.0816	
Non-hispanic/Latino	113	7.01 (2.44)	113	1.77 (2.45)	5.25 (2.99)	(-0.65, 11.14)	0.0809	0.20 (0.13)	(-0.06, 0.46)	0.1315	
Geographic region											0.5246
EU	49	12.39 (3.72)	57	11.47 (3.69)	0.91 (3.96)	(-6.94, 8.77)	0.8179	0.03 (0.19)	(-0.35, 0.42)	0.8633	
non-EU	87	3.22 (2.74)	78	-1.04 (2.81)	4.25 (3.45)	(-2.56, 11.07)	0.2195	0.17 (0.16)	(-0.14, 0.47)	0.2822	
Onset of disease											NE
Paediatric	8	NE	7	NE	NE	NE		NE	NE		
Adult	128	6.10 (2.28)	128	2.37 (2.29)	3.73 (2.75)	(-1.69, 9.15)	0.1764	0.14 (0.13)	(-0.10, 0.39)	0.2506	
ADA result											0.6902
Negative	124	6.08 (2.31)	124	3.48 (2.32)	2.60 (2.80)	(-2.92, 8.12)	0.3542	0.10 (0.13)	(-0.15, 0.35)	0.4291	
Positive (At any time)	12	-3.50 (9.16)	11	-2.23 (7.97)	-1.27 (9.29)	(-20.80, 18.27)	0.8929	-0.04 (0.42)	(-0.86, 0.78)	0.9204	
BMI (kg/m2) at enrolment											0.0722
< 30	78	5.74 (2.59)	91	6.58 (2.51)	-0.84 (3.00)	(-6.77, 5.08)	0.7790	-0.04 (0.15)	(-0.34, 0.27)	0.8164	
>= 30	58	6.54 (3.96)	44	-3.21 (4.21)	9.75 (5.07)	(-0.32, 19.81)	0.0575	0.33 (0.20)	(-0.06, 0.73)	0.1002	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Pain domain score
Full analysis set

	Anifrolumab 300mg (N=180)		Placebo (N=184)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 12		11.11 (1.94)		8.63 (1.93)	2.47 (2.37)	(-2.19, 7.13)	0.2972			
Week 24		11.13 (1.98)		10.01 (1.97)	1.12 (2.43)	(-3.65, 5.89)	0.6449			
Week 36		13.68 (2.02)		10.43 (1.98)	3.25 (2.47)	(-1.60, 8.11)	0.1882			
Week 52		12.76 (2.12)		9.64 (2.08)	3.13 (2.63)	(-2.05, 8.30)	0.2353			
OVERALL	164	12.17 (1.79)	168	9.68 (1.76)	2.49 (2.10)	(-1.64, 6.63)	0.2363	0.11 (0.11)	(-0.11, 0.32)	0.3226

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Pain domain score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=184) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.0156
< 10 points	49	15.26 (3.07)	49	4.96 (3.01)	10.30 (3.79)	(2.76, 17.84)	0.0080	0.48 (0.21)	(0.08, 0.88)	0.0192	
>= 10 points	115	10.82 (2.09)	119	11.52 (2.06)	-0.70 (2.51)	(-5.65, 4.25)	0.7798	-0.03 (0.13)	(-0.29, 0.23)	0.8114	
OCS dose at baseline											0.5420
<10 mg/day	70	12.81 (2.65)	74	8.84 (2.58)	3.97 (3.29)	(-2.54, 10.49)	0.2299	0.18 (0.17)	(-0.15, 0.51)	0.2858	
>=10 mg/day	94	12.06 (2.50)	94	10.70 (2.48)	1.36 (2.74)	(-4.04, 6.76)	0.6194	0.06 (0.15)	(-0.23, 0.34)	0.7003	
Result of type I IFN gene signature test											0.4405
LOW	30	13.14 (3.74)	31	14.19 (3.67)	-1.05 (5.04)	(-11.15, 9.05)	0.8360	-0.05 (0.26)	(-0.55, 0.45)	0.8434	
HIGH	134	12.78 (1.75)	137	9.55 (1.72)	3.23 (2.32)	(-1.34, 7.81)	0.1654	0.16 (0.12)	(-0.08, 0.40)	0.1900	
Age (years)											NE
<= 65	157	12.24 (1.85)	166	9.86 (1.79)	2.38 (2.12)	(-1.79, 6.55)	0.2625	0.10 (0.11)	(-0.12, 0.32)	0.3560	
> 65	7	NE	2	NE	NE	NE		NE	NE		
Sex											0.0021
male	15	13.91 (5.63)	12	-6.62 (6.46)	20.52 (5.99)	(8.07, 32.98)	0.0025	0.90 (0.41)	(0.10, 1.70)	0.0276	
female	149	11.51 (1.88)	156	10.59 (1.84)	0.92 (2.21)	(-3.44, 5.27)	0.6789	0.04 (0.11)	(-0.18, 0.26)	0.7285	
Race											0.2122
White	114	11.40 (1.99)	125	9.60 (1.94)	1.80 (2.40)	(-2.92, 6.52)	0.4536	0.08 (0.13)	(-0.17, 0.34)	0.5188	
Black or African American	26	14.74 (6.24)	21	9.54 (5.55)	5.20 (6.98)	(-8.91, 19.30)	0.4608	0.18 (0.29)	(-0.40, 0.75)	0.5509	
Asian	10	16.55 (5.55)	5	-5.44 (9.14)	21.99 (10.17)	(-0.70, 44.68)	0.0561	1.12 (0.60)	(-0.05, 2.29)	0.0609	
American Indian or Alaska Native	0	NE	0	NE	NE	NE		NE	NE		
Other	14	20.29 (9.43)	17	23.47 (9.52)	-3.18 (7.38)	(-18.36, 12.01)	0.6707	-0.08 (0.36)	(-0.79, 0.63)	0.8195	
Ethnicity											0.4974
Hispanic/Latino	29	14.93 (5.05)	32	15.51 (5.05)	-0.58 (5.38)	(-11.38, 10.22)	0.9150	-0.02 (0.26)	(-0.52, 0.48)	0.9365	
Non-hispanic/Latino	135	11.94 (1.92)	136	8.54 (1.89)	3.39 (2.29)	(-1.12, 7.91)	0.1403	0.15 (0.12)	(-0.09, 0.39)	0.2096	
Geographic region											0.1404
EU	61	13.10 (2.58)	72	13.70 (2.52)	-0.60 (2.73)	(-6.00, 4.80)	0.8259	-0.03 (0.17)	(-0.37, 0.31)	0.8692	
non-EU	103	12.79 (2.27)	96	7.61 (2.31)	5.17 (2.81)	(-0.38, 10.72)	0.0674	0.23 (0.14)	(-0.05, 0.50)	0.1135	
Onset of disease											0.0438
Paediatric	10	-2.70 (10.59)	10	13.20 (6.43)	-15.91 (9.33)	(-36.15, 4.34)	0.1130	-0.55 (0.46)	(-1.45, 0.35)	0.2295	
Adult	154	12.61 (1.84)	158	9.21 (1.83)	3.40 (2.18)	(-0.88, 7.69)	0.1193	0.15 (0.11)	(-0.07, 0.37)	0.1922	
ADA result											0.3953
Negative	148	11.80 (1.86)	153	9.69 (1.84)	2.11 (2.22)	(-2.27, 6.48)	0.3442	0.09 (0.12)	(-0.13, 0.32)	0.4232	
Positive (At any time)	16	28.25 (8.16)	15	19.10 (7.78)	9.14 (7.97)	(-7.58, 25.86)	0.2662	0.28 (0.36)	(-0.43, 0.99)	0.4338	
BMI (kg/m2) at enrolment											0.7286
< 30	98	13.20 (2.21)	115	10.96 (2.10)	2.24 (2.41)	(-2.51, 6.99)	0.3536	0.10 (0.14)	(-0.17, 0.37)	0.4652	
>= 30	66	11.52 (2.97)	53	7.68 (3.20)	3.84 (3.94)	(-3.97, 11.65)	0.3317	0.16 (0.18)	(-0.20, 0.52)	0.3852	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Planning domain score
Full analysis set

	Anifrolumab 300mg (N=180)		Placebo (N=184)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 12		7.49 (1.85)		4.79 (1.85)	2.70 (2.27)	(-1.77, 7.17)	0.2357			
Week 24		9.74 (1.93)		6.84 (1.91)	2.91 (2.38)	(-1.78, 7.59)	0.2233			
Week 36		9.74 (1.97)		7.11 (1.93)	2.63 (2.44)	(-2.16, 7.42)	0.2811			
Week 52		9.88 (2.12)		6.46 (2.08)	3.42 (2.67)	(-1.83, 8.67)	0.2008			
OVERALL	164	9.22 (1.72)	168	6.30 (1.70)	2.91 (2.04)	(-1.10, 6.93)	0.1539	0.13 (0.11)	(-0.08, 0.35)	0.2298

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Planning domain score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=184) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.0510
< 10 points	49	9.70 (2.80)	49	1.01 (2.80)	8.69 (3.46)	(1.82, 15.55)	0.0138	0.44 (0.20)	(0.04, 0.84)	0.0316	
>= 10 points	115	9.52 (2.07)	119	9.16 (2.03)	0.36 (2.50)	(-4.57, 5.29)	0.8862	0.02 (0.13)	(-0.24, 0.27)	0.9018	
OCS dose at baseline											0.4849
<10 mg/day	70	8.64 (2.38)	74	4.23 (2.33)	4.41 (2.98)	(-1.49, 10.31)	0.1415	0.22 (0.17)	(-0.11, 0.55)	0.1890	
>=10 mg/day	94	9.96 (2.53)	94	8.39 (2.51)	1.57 (2.77)	(-3.91, 7.04)	0.5731	0.06 (0.15)	(-0.22, 0.35)	0.6620	
Result of type I IFN gene signature test											0.0293
LOW	30	5.88 (3.58)	31	12.38 (3.52)	-6.50 (4.84)	(-16.21, 3.20)	0.1846	-0.33 (0.26)	(-0.83, 0.18)	0.2046	
HIGH	134	11.30 (1.68)	137	6.19 (1.66)	5.11 (2.24)	(0.71, 9.52)	0.0230	0.26 (0.12)	(0.02, 0.50)	0.0312	
Age (years)											NE
<= 65	157	8.64 (1.78)	166	6.11 (1.73)	2.53 (2.06)	(-1.53, 6.59)	0.2207	0.11 (0.11)	(-0.10, 0.33)	0.3086	
> 65	7	NE	2	NE	NE	NE		NE	NE		
Sex											0.0361
male	15	11.05 (5.81)	12	-5.16 (6.60)	16.21 (6.64)	(2.45, 29.98)	0.0231	0.69 (0.40)	(-0.09, 1.48)	0.0834	
female	149	8.45 (1.79)	156	6.84 (1.75)	1.61 (2.12)	(-2.56, 5.79)	0.4474	0.07 (0.11)	(-0.15, 0.30)	0.5209	
Race											0.2958
White	114	9.21 (1.99)	125	5.40 (1.94)	3.80 (2.42)	(-0.96, 8.57)	0.1172	0.18 (0.13)	(-0.08, 0.43)	0.1731	
Black or African American	26	16.20 (4.58)	21	11.38 (4.25)	4.81 (5.34)	(-5.96, 15.59)	0.3723	0.22 (0.29)	(-0.36, 0.79)	0.4591	
Asian	10	9.93 (6.54)	5	0.91 (11.23)	9.01 (12.64)	(-18.90, 36.93)	0.4910	0.38 (0.55)	(-0.70, 1.47)	0.4887	
American Indian or Alaska Native	0	NE	0	NE	NE	NE		NE	NE		
Other	14	6.37 (8.96)	17	15.30 (8.39)	-8.93 (6.62)	(-22.53, 4.67)	0.1887	-0.26 (0.36)	(-0.97, 0.46)	0.4818	
Ethnicity											0.2076
Hispanic/Latino	29	6.54 (5.20)	32	9.67 (5.19)	-3.13 (5.52)	(-14.18, 7.93)	0.5732	-0.11 (0.26)	(-0.61, 0.40)	0.6757	
Non-hispanic/Latino	135	10.11 (1.80)	136	5.76 (1.78)	4.35 (2.18)	(0.06, 8.63)	0.0468	0.21 (0.12)	(-0.03, 0.45)	0.0880	
Geographic region											0.9558
EU	61	13.69 (2.55)	72	10.83 (2.48)	2.86 (2.71)	(-2.50, 8.21)	0.2932	0.14 (0.17)	(-0.20, 0.48)	0.4265	
non-EU	103	7.39 (2.23)	96	4.32 (2.27)	3.07 (2.77)	(-2.40, 8.54)	0.2696	0.14 (0.14)	(-0.14, 0.41)	0.3365	
Onset of disease											0.8329
Paediatric	10	23.26 (10.14)	10	21.79 (6.34)	1.47 (9.09)	(-18.00, 20.93)	0.8740	0.05 (0.45)	(-0.82, 0.93)	0.9065	
Adult	154	9.06 (1.77)	158	5.62 (1.77)	3.44 (2.12)	(-0.73, 7.61)	0.1060	0.16 (0.11)	(-0.07, 0.38)	0.1712	
ADA result											0.4174
Negative	148	9.26 (1.82)	153	5.91 (1.81)	3.35 (2.19)	(-0.97, 7.66)	0.1280	0.15 (0.12)	(-0.08, 0.38)	0.1943	
Positive (At any time)	16	9.60 (6.39)	15	11.77 (6.24)	-2.17 (6.44)	(-15.48, 11.13)	0.7390	-0.08 (0.36)	(-0.79, 0.62)	0.8133	
BMI (kg/m2) at enrolment											0.6356
< 30	98	9.88 (2.15)	115	7.37 (2.05)	2.52 (2.37)	(-2.16, 7.19)	0.2901	0.12 (0.14)	(-0.15, 0.39)	0.4011	
>= 30	66	9.84 (2.90)	53	5.17 (3.12)	4.67 (3.87)	(-3.01, 12.34)	0.2306	0.20 (0.18)	(-0.16, 0.56)	0.2798	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SDI Global Score
Full analysis set

	Anifrolumab 300mg (N=180)		Placebo (N=184)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 24		0.06 (0.02)		0.01 (0.02)	0.05 (0.02)	(0.01, 0.09)	0.0196			
Week 52		0.06 (0.02)		0.03 (0.02)	0.03 (0.03)	(-0.03, 0.08)	0.2974			
OVERALL	154	0.06 (0.02)	155	0.02 (0.02)	0.04 (0.02)	(-0.00, 0.08)	0.0812	0.16 (0.11)	(-0.06, 0.39)	0.1496

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SDI Global Score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=180)		Placebo (N=184)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											NE
< 10 points	44	NE	43	NE	NE	NE		NE	NE		
>= 10 points	110	0.03 (0.02)	112	0.03 (0.02)	-0.00 (0.02)	(-0.05, 0.05)	0.9657	-0.00 (0.13)	(-0.27, 0.26)	0.9706	
OCS dose at baseline											0.5190
<10 mg/day	69	0.08 (0.03)	70	0.03 (0.03)	0.06 (0.04)	(-0.02, 0.13)	0.1279	0.23 (0.17)	(-0.11, 0.56)	0.1854	
>=10 mg/day	85	0.04 (0.03)	85	0.01 (0.03)	0.03 (0.03)	(-0.03, 0.08)	0.3626	0.11 (0.15)	(-0.19, 0.41)	0.4773	
Result of type I IFN gene signature test											0.0605
LOW	26	-0.02 (0.04)	24	0.04 (0.04)	-0.06 (0.05)	(-0.16, 0.05)	0.3038	-0.28 (0.28)	(-0.84, 0.27)	0.3174	
HIGH	128	0.09 (0.02)	131	0.03 (0.02)	0.06 (0.03)	(0.01, 0.10)	0.0290	0.26 (0.12)	(0.01, 0.50)	0.0396	
Age (years)											NE
<= 65	150	0.06 (0.02)	153	0.02 (0.02)	0.04 (0.02)	(-0.00, 0.09)	0.0759	0.17 (0.12)	(-0.06, 0.39)	0.1445	
> 65	4	NE	2	NE	NE	NE		NE	NE		
Sex											NE
male	14	NE	12	NE	NE	NE		NE	NE		
female	140	0.07 (0.02)	143	0.03 (0.02)	0.04 (0.02)	(-0.01, 0.09)	0.0969	0.16 (0.12)	(-0.07, 0.40)	0.1681	
Race											NE
White	109	0.05 (0.02)	112	0.00 (0.02)	0.04 (0.02)	(-0.00, 0.09)	0.0778	0.20 (0.13)	(-0.06, 0.47)	0.1316	
Black or African American	21	NE	23	NE	NE	NE		NE	NE		
Asian	10	0.15 (0.14)	3	0.07 (0.31)	0.08 (0.32)	(-0.68, 0.83)	0.8183	0.15 (0.66)	(-1.14, 1.45)	0.8151	
American Indian or Alaska Native	0	NE	0	NE	NE	NE		NE	NE		
Other	14	NE	17	NE	NE	NE		NE	NE		
Ethnicity											0.2703
Hispanic/Latino	26	0.12 (0.05)	29	0.02 (0.05)	0.10 (0.06)	(-0.01, 0.21)	0.0843	0.37 (0.27)	(-0.17, 0.90)	0.1760	
Non-hispanic/Latino	128	0.05 (0.02)	126	0.02 (0.02)	0.03 (0.02)	(-0.02, 0.08)	0.2102	0.13 (0.13)	(-0.12, 0.38)	0.2962	
Geographic region											0.5472
EU	61	0.07 (0.03)	67	0.01 (0.03)	0.06 (0.03)	(-0.00, 0.12)	0.0680	0.25 (0.18)	(-0.10, 0.60)	0.1648	
non-EU	93	0.06 (0.03)	88	0.03 (0.03)	0.03 (0.03)	(-0.04, 0.09)	0.3714	0.11 (0.15)	(-0.18, 0.41)	0.4458	
Onset of disease											NE
Paediatric	9	NE	7	NE	NE	NE		NE	NE		
Adult	145	0.06 (0.02)	148	0.02 (0.02)	0.04 (0.02)	(-0.01, 0.09)	0.0820	0.17 (0.12)	(-0.06, 0.40)	0.1495	
ADA result											NE
Negative	141	0.06 (0.02)	143	0.02 (0.02)	0.04 (0.02)	(-0.01, 0.08)	0.1351	0.15 (0.12)	(-0.08, 0.38)	0.2120	
Positive (At any time)	13	NE	12	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.4214
< 30	96	0.03 (0.02)	107	0.01 (0.02)	0.02 (0.02)	(-0.02, 0.07)	0.3669	0.11 (0.14)	(-0.17, 0.38)	0.4434	
>= 30	58	0.10 (0.04)	48	0.04 (0.04)	0.07 (0.05)	(-0.04, 0.17)	0.2035	0.21 (0.20)	(-0.17, 0.60)	0.2795	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - NRS Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) N	Anifrolumab 300mg (N=180) LSMean (SE)	Placebo (N=184) N	Placebo (N=184) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-0.25 (0.17)		-0.28 (0.16)	0.03 (0.20)	(-0.37, 0.43)	0.8793			
Week 8		-0.72 (0.18)		-0.42 (0.17)	-0.30 (0.22)	(-0.73, 0.13)	0.1706			
Week 12		-0.89 (0.19)		-0.62 (0.19)	-0.27 (0.24)	(-0.74, 0.20)	0.2591			
Week 16		-0.94 (0.19)		-0.66 (0.19)	-0.28 (0.24)	(-0.75, 0.19)	0.2431			
Week 20		-0.93 (0.20)		-0.80 (0.19)	-0.13 (0.25)	(-0.62, 0.37)	0.6169			
Week 24		-1.04 (0.19)		-0.59 (0.19)	-0.45 (0.24)	(-0.93, 0.02)	0.0629			
Week 28		-1.03 (0.20)		-0.71 (0.20)	-0.31 (0.26)	(-0.82, 0.19)	0.2223			
Week 32		-0.95 (0.20)		-0.81 (0.20)	-0.14 (0.26)	(-0.64, 0.36)	0.5862			
Week 36		-1.10 (0.21)		-0.81 (0.20)	-0.29 (0.26)	(-0.81, 0.23)	0.2761			
Week 40		-1.14 (0.22)		-0.79 (0.21)	-0.35 (0.28)	(-0.90, 0.20)	0.2064			
Week 44		-1.16 (0.21)		-0.98 (0.21)	-0.18 (0.27)	(-0.72, 0.35)	0.5024			
Week 48		-1.19 (0.21)		-0.96 (0.21)	-0.23 (0.27)	(-0.77, 0.31)	0.4065			
Week 52		-1.03 (0.22)		-0.76 (0.21)	-0.27 (0.28)	(-0.82, 0.28)	0.3388			
OVERALL	170	-0.95 (0.16)	172	-0.71 (0.16)	-0.24 (0.19)	(-0.62, 0.13)	0.2037	-0.12 (0.11)	(-0.33, 0.09)	0.2766

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - NRS Score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=180)		Placebo (N=184)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											0.1001
< 10 points	52	-1.15 (0.28)	51	-0.43 (0.28)	-0.72 (0.35)	(-1.42, -0.03)	0.0411	-0.36 (0.20)	(-0.75, 0.03)	0.0716	
>= 10 points	118	-0.90 (0.19)	121	-0.87 (0.18)	-0.03 (0.23)	(-0.49, 0.42)	0.8810	-0.02 (0.13)	(-0.27, 0.24)	0.8959	
OCS dose at baseline											0.2300
<10 mg/day	72	-1.09 (0.22)	75	-0.58 (0.21)	-0.51 (0.28)	(-1.06, 0.04)	0.0681	-0.27 (0.17)	(-0.60, 0.05)	0.0982	
>=10 mg/day	98	-0.91 (0.24)	97	-0.86 (0.23)	-0.05 (0.26)	(-0.57, 0.47)	0.8508	-0.02 (0.14)	(-0.30, 0.26)	0.8812	
Result of type I IFN gene signature test											0.1355
LOW	30	-0.53 (0.32)	31	-0.88 (0.32)	0.35 (0.44)	(-0.53, 1.22)	0.4315	0.19 (0.26)	(-0.31, 0.70)	0.4496	
HIGH	140	-1.38 (0.16)	141	-1.00 (0.16)	-0.38 (0.21)	(-0.80, 0.04)	0.0772	-0.20 (0.12)	(-0.44, 0.03)	0.0916	
Age (years)											NE
<= 65	163	-0.94 (0.16)	170	-0.68 (0.16)	-0.26 (0.19)	(-0.64, 0.12)	0.1806	-0.12 (0.11)	(-0.34, 0.09)	0.2578	
> 65	7	NE	2	NE	NE	NE		NE	NE		
Sex											NE
male	15	NE	12	NE	NE	NE		NE	NE		
female	155	-0.94 (0.17)	160	-0.75 (0.16)	-0.19 (0.20)	(-0.59, 0.20)	0.3405	-0.09 (0.11)	(-0.31, 0.13)	0.4124	
Race											NE
White	117	-0.93 (0.18)	127	-0.71 (0.18)	-0.22 (0.23)	(-0.67, 0.22)	0.3245	-0.11 (0.13)	(-0.36, 0.14)	0.3845	
Black or African American	27	-1.08 (0.53)	21	-0.36 (0.46)	-0.72 (0.60)	(-1.92, 0.48)	0.2337	-0.28 (0.29)	(-0.86, 0.29)	0.3311	
Asian	11	NE	5	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	NE	NE	NE		NE	NE		
Other	15	-2.19 (0.72)	18	-2.74 (0.76)	0.55 (0.52)	(-0.53, 1.63)	0.3056	0.18 (0.35)	(-0.51, 0.86)	0.6134	
Ethnicity											0.2793
Hispanic/Latino	31	-1.32 (0.40)	33	-1.50 (0.40)	0.18 (0.42)	(-0.65, 1.01)	0.6640	0.08 (0.25)	(-0.41, 0.57)	0.7508	
Non-hispanic/Latino	139	-0.93 (0.17)	139	-0.61 (0.17)	-0.32 (0.22)	(-0.75, 0.10)	0.1326	-0.16 (0.12)	(-0.39, 0.08)	0.1887	
Geographic region											0.2226
EU	62	-1.24 (0.29)	73	-1.25 (0.28)	0.01 (0.31)	(-0.59, 0.62)	0.9665	0.01 (0.17)	(-0.33, 0.34)	0.9745	
non-EU	108	-0.89 (0.19)	99	-0.43 (0.19)	-0.46 (0.24)	(-0.93, 0.01)	0.0548	-0.23 (0.14)	(-0.51, 0.04)	0.0924	
Onset of disease											NE
Paediatric	11	NE	11	NE	NE	NE		NE	NE		
Adult	159	-0.98 (0.16)	161	-0.73 (0.16)	-0.25 (0.20)	(-0.64, 0.15)	0.2200	-0.12 (0.11)	(-0.34, 0.10)	0.2907	
ADA result											0.4572
Negative	153	-0.83 (0.16)	157	-0.63 (0.16)	-0.20 (0.20)	(-0.59, 0.20)	0.3227	-0.10 (0.11)	(-0.32, 0.13)	0.3908	
Positive (At any time)	17	-2.62 (0.71)	15	-1.89 (0.68)	-0.73 (0.69)	(-2.14, 0.68)	0.2966	-0.25 (0.36)	(-0.95, 0.44)	0.4763	
BMI (kg/m2) at enrolment											0.0365
< 30	102	-0.99 (0.21)	118	-1.01 (0.20)	0.01 (0.23)	(-0.44, 0.47)	0.9567	0.01 (0.14)	(-0.26, 0.27)	0.9654	
>= 30	68	-1.00 (0.24)	54	-0.18 (0.26)	-0.82 (0.33)	(-1.47, -0.18)	0.0130	-0.42 (0.18)	(-0.78, -0.06)	0.0238	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - PHQ-8 Total Score
Full analysis set

	Anifrolumab 300mg (N=180)		Placebo (N=184)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 12		-1.35 (0.42)		-1.00 (0.42)	-0.35 (0.52)	(-1.37, 0.66)	0.4927			
Week 24		-1.94 (0.42)		-1.39 (0.41)	-0.55 (0.51)	(-1.56, 0.46)	0.2863			
Week 36		-2.09 (0.44)		-1.24 (0.43)	-0.84 (0.54)	(-1.91, 0.23)	0.1234			
Week 52		-2.26 (0.47)		-1.70 (0.46)	-0.56 (0.59)	(-1.73, 0.61)	0.3482			
OVERALL	164	-1.91 (0.37)	168	-1.33 (0.37)	-0.58 (0.44)	(-1.44, 0.29)	0.1909	-0.12 (0.11)	(-0.34, 0.09)	0.2729

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - PHQ-8 Total Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=184) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.0282
< 10 points	49	-2.38 (0.61)	49	-0.40 (0.60)	-1.99 (0.75)	(-3.48, -0.49)	0.0097	-0.46 (0.20)	(-0.87, -0.06)	0.0232	
>= 10 points	115	-1.84 (0.45)	119	-1.88 (0.44)	0.04 (0.53)	(-1.02, 1.09)	0.9445	0.01 (0.13)	(-0.25, 0.26)	0.9525	
OCS dose at baseline											0.5040
<10 mg/day	70	-1.90 (0.53)	74	-0.98 (0.52)	-0.91 (0.67)	(-2.23, 0.40)	0.1726	-0.20 (0.17)	(-0.53, 0.12)	0.2228	
>=10 mg/day	94	-2.08 (0.54)	94	-1.76 (0.54)	-0.32 (0.59)	(-1.48, 0.84)	0.5894	-0.06 (0.15)	(-0.35, 0.23)	0.6768	
Result of type I IFN gene signature test											0.9501
LOW	30	-2.57 (0.86)	31	-2.05 (0.85)	-0.52 (1.16)	(-2.85, 1.81)	0.6548	-0.11 (0.26)	(-0.61, 0.39)	0.6696	
HIGH	134	-1.81 (0.36)	137	-1.21 (0.35)	-0.60 (0.47)	(-1.54, 0.33)	0.2066	-0.15 (0.12)	(-0.38, 0.09)	0.2317	
Age (years)											NE
<= 65	157	-1.85 (0.39)	166	-1.34 (0.38)	-0.51 (0.45)	(-1.39, 0.37)	0.2580	-0.10 (0.11)	(-0.32, 0.11)	0.3492	
> 65	7	NE	2	NE	NE	NE		NE	NE		
Sex											0.0588
male	15	-2.39 (1.36)	12	0.88 (1.57)	-3.27 (1.49)	(-6.36, -0.17)	0.0395	-0.59 (0.40)	(-1.37, 0.19)	0.1355	
female	149	-1.75 (0.39)	156	-1.43 (0.38)	-0.32 (0.46)	(-1.22, 0.58)	0.4902	-0.07 (0.11)	(-0.29, 0.16)	0.5609	
Race											0.1147
White	114	-1.76 (0.41)	125	-1.07 (0.40)	-0.69 (0.50)	(-1.68, 0.29)	0.1682	-0.15 (0.13)	(-0.41, 0.10)	0.2344	
Black or African American	26	-3.19 (1.26)	21	-2.04 (1.11)	-1.16 (1.41)	(-4.00, 1.68)	0.4158	-0.19 (0.29)	(-0.77, 0.38)	0.5099	
Asian	10	-1.78 (0.99)	5	0.14 (1.64)	-1.93 (1.90)	(-6.13, 2.27)	0.3329	-0.55 (0.56)	(-1.64, 0.55)	0.3284	
American Indian or Alaska Native	0	NE	0	NE	NE	NE		NE	NE		
Other	14	-3.66 (1.66)	17	-5.86 (1.62)	2.20 (1.20)	(-0.28, 4.67)	0.0793	0.33 (0.36)	(-0.38, 1.04)	0.3639	
Ethnicity											0.0734
Hispanic/Latino	29	-1.38 (1.14)	32	-2.70 (1.13)	1.32 (1.21)	(-1.11, 3.75)	0.2814	0.21 (0.26)	(-0.30, 0.71)	0.4188	
Non-hispanic/Latino	135	-2.10 (0.39)	136	-1.09 (0.38)	-1.00 (0.46)	(-1.91, -0.09)	0.0305	-0.22 (0.12)	(-0.46, 0.01)	0.0653	
Geographic region											0.6830
EU	61	-2.49 (0.59)	72	-2.11 (0.57)	-0.38 (0.61)	(-1.59, 0.83)	0.5344	-0.08 (0.17)	(-0.42, 0.26)	0.6432	
non-EU	103	-1.87 (0.49)	96	-1.14 (0.50)	-0.73 (0.61)	(-1.94, 0.47)	0.2316	-0.15 (0.14)	(-0.43, 0.13)	0.2967	
Onset of disease											0.7607
Paediatric	10	-4.18 (2.89)	10	-2.71 (1.67)	-1.46 (2.50)	(-6.78, 3.85)	0.5664	-0.19 (0.45)	(-1.07, 0.69)	0.6755	
Adult	154	-1.98 (0.38)	158	-1.29 (0.38)	-0.69 (0.45)	(-1.58, 0.20)	0.1290	-0.14 (0.11)	(-0.37, 0.08)	0.2011	
ADA result											0.3115
Negative	148	-1.85 (0.40)	153	-1.19 (0.39)	-0.66 (0.47)	(-1.59, 0.27)	0.1633	-0.14 (0.12)	(-0.36, 0.09)	0.2365	
Positive (At any time)	16	-2.71 (1.25)	15	-3.35 (1.21)	0.65 (1.20)	(-1.82, 3.12)	0.5949	0.13 (0.36)	(-0.58, 0.84)	0.7182	
BMI (kg/m2) at enrolment											0.5226
< 30	98	-2.22 (0.46)	115	-1.84 (0.43)	-0.38 (0.50)	(-1.37, 0.61)	0.4512	-0.08 (0.14)	(-0.35, 0.19)	0.5512	
>= 30	66	-1.66 (0.62)	53	-0.66 (0.67)	-1.00 (0.83)	(-2.63, 0.64)	0.2303	-0.20 (0.18)	(-0.56, 0.16)	0.2803	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - PtGA
Full analysis set

Visit	Anifrolumab 300mg (N=180) N	Anifrolumab 300mg (N=180) LSMean (SE)	Placebo (N=184) N	Placebo (N=184) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-4.56 (1.75)		-4.75 (1.73)	0.19 (2.16)	(-4.06, 4.43)	0.9315			
Week 8		-7.71 (1.90)		-8.04 (1.88)	0.33 (2.40)	(-4.39, 5.05)	0.8906			
Week 12		-11.41 (1.94)		-7.49 (1.94)	-3.92 (2.48)	(-8.80, 0.96)	0.1152			
Week 16		-7.32 (2.01)		-9.14 (1.98)	1.82 (2.56)	(-3.21, 6.86)	0.4767			
Week 20		-9.91 (2.03)		-11.45 (1.99)	1.54 (2.59)	(-3.55, 6.64)	0.5517			
Week 24		-10.58 (2.08)		-7.21 (2.06)	-3.37 (2.69)	(-8.66, 1.92)	0.2109			
Week 28		-9.75 (2.13)		-8.85 (2.09)	-0.90 (2.74)	(-6.29, 4.50)	0.7441			
Week 32		-9.86 (2.13)		-10.20 (2.10)	0.34 (2.75)	(-5.07, 5.76)	0.9007			
Week 36		-13.90 (2.04)		-11.54 (2.01)	-2.36 (2.62)	(-7.53, 2.80)	0.3687			
Week 40		-11.50 (2.25)		-10.33 (2.21)	-1.17 (2.93)	(-6.94, 4.60)	0.6899			
Week 44		-12.32 (2.19)		-13.04 (2.14)	0.72 (2.83)	(-4.85, 6.29)	0.7993			
Week 48		-13.05 (2.19)		-12.73 (2.18)	-0.32 (2.87)	(-5.95, 5.32)	0.9125			
Week 52		-11.03 (2.30)		-10.44 (2.26)	-0.58 (3.01)	(-6.50, 5.33)	0.8460			
OVERALL	170	-10.22 (1.61)	172	-9.63 (1.60)	-0.59 (1.94)	(-4.41, 3.23)	0.7616	-0.03 (0.11)	(-0.24, 0.18)	0.7951

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - PtGA - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=180)		Placebo (N=184)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											0.1742
< 10 points	52	-9.63 (2.92)	51	-4.90 (2.89)	-4.73 (3.61)	(-11.90, 2.44)	0.1936	-0.23 (0.20)	(-0.61, 0.16)	0.2549	
>= 10 points	118	-10.80 (1.88)	121	-11.90 (1.86)	1.10 (2.32)	(-3.46, 5.67)	0.6346	0.05 (0.13)	(-0.20, 0.31)	0.6780	
OCS dose at baseline											0.9445
<10 mg/day	72	-9.76 (2.28)	75	-9.27 (2.23)	-0.48 (2.89)	(-6.19, 5.22)	0.8673	-0.02 (0.16)	(-0.35, 0.30)	0.8800	
>=10 mg/day	98	-10.48 (2.35)	97	-9.72 (2.35)	-0.76 (2.65)	(-5.98, 4.47)	0.7757	-0.03 (0.14)	(-0.31, 0.25)	0.8211	
Result of type I IFN gene signature test											0.0155
LOW	30	-2.82 (3.10)	31	-11.68 (3.07)	8.86 (4.23)	(0.39, 17.34)	0.0408	0.51 (0.26)	(0.00, 1.02)	0.0488	
HIGH	140	-13.99 (1.61)	141	-11.35 (1.60)	-2.65 (2.17)	(-6.92, 1.63)	0.2241	-0.14 (0.12)	(-0.37, 0.10)	0.2455	
Age (years)											NE
<= 65	163	-10.11 (1.66)	170	-9.52 (1.62)	-0.59 (1.97)	(-4.46, 3.27)	0.7631	-0.03 (0.11)	(-0.24, 0.19)	0.7990	
> 65	7	NE	2	NE	NE	NE		NE	NE		
Sex											NE
male	15	NE	12	NE	NE	NE		NE	NE		
female	155	-9.76 (1.67)	160	-9.78 (1.64)	0.02 (2.02)	(-3.95, 3.99)	0.9907	0.00 (0.11)	(-0.22, 0.22)	0.9920	
Race											NE
White	117	-9.78 (1.89)	127	-10.33 (1.85)	0.55 (2.33)	(-4.05, 5.15)	0.8150	0.03 (0.13)	(-0.22, 0.28)	0.8371	
Black or African American	27	-9.33 (4.57)	21	-1.63 (4.02)	-7.70 (5.23)	(-18.27, 2.87)	0.1488	-0.35 (0.29)	(-0.93, 0.22)	0.2318	
Asian	11	NE	5	NE	NE	NE		NE	NE		
American Indian or Alaska Native	0	NE	1	18.00 (0.00)	NE	NE		NE	NE		
Other	15	NE	18	NE	NE	NE		NE	NE		
Ethnicity											0.3296
Hispanic/Latino	31	-13.19 (4.16)	33	-16.61 (4.17)	3.41 (4.41)	(-5.43, 12.25)	0.4426	0.14 (0.25)	(-0.35, 0.63)	0.5679	
Non-hispanic/Latino	139	-10.06 (1.76)	139	-8.68 (1.75)	-1.38 (2.17)	(-5.65, 2.89)	0.5247	-0.07 (0.12)	(-0.30, 0.17)	0.5798	
Geographic region											0.2883
EU	62	-15.82 (2.82)	73	-17.62 (2.75)	1.81 (3.02)	(-4.18, 7.79)	0.5510	0.08 (0.17)	(-0.26, 0.42)	0.6497	
non-EU	108	-8.56 (1.97)	99	-6.21 (2.02)	-2.35 (2.49)	(-7.27, 2.57)	0.3465	-0.12 (0.14)	(-0.39, 0.16)	0.4065	
Onset of disease											NE
Paediatric	11	NE	11	NE	NE	NE		NE	NE		
Adult	159	-10.31 (1.65)	161	-9.63 (1.65)	-0.68 (2.01)	(-4.63, 3.27)	0.7352	-0.03 (0.11)	(-0.25, 0.19)	0.7711	
ADA result											0.2768
Negative	153	-9.74 (1.70)	157	-9.98 (1.69)	0.24 (2.08)	(-3.84, 4.33)	0.9072	0.01 (0.11)	(-0.21, 0.23)	0.9197	
Positive (At any time)	17	-20.75 (4.68)	15	-14.86 (4.42)	-5.89 (5.25)	(-16.66, 4.87)	0.2711	-0.31 (0.36)	(-1.01, 0.39)	0.3790	
BMI (kg/m2) at enrolment											0.0194
< 30	102	-11.30 (2.06)	118	-13.53 (1.97)	2.23 (2.30)	(-2.31, 6.76)	0.3341	0.10 (0.14)	(-0.16, 0.37)	0.4381	
>= 30	68	-10.46 (2.52)	54	-3.13 (2.72)	-7.33 (3.38)	(-14.03, -0.64)	0.0321	-0.36 (0.18)	(-0.72, 0.00)	0.0525	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SLEDAI-2K Total Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=184) n/ N#	Placebo (N=184) Compliance
Baseline	180/ 180	100.0%	184/ 184	100.0%
Week 4	173/ 180	96.11%	180/ 184	97.83%
Week 8	174/ 180	96.67%	176/ 184	95.65%
Week 12	169/ 179	94.41%	172/ 184	93.48%
Week 16	168/ 179	93.85%	172/ 184	93.48%
Week 20	161/ 179	89.94%	172/ 184	93.48%
Week 24	161/ 179	89.94%	165/ 184	89.67%
Week 28	157/ 179	87.71%	167/ 184	90.76%
Week 32	157/ 179	87.71%	164/ 184	89.13%
Week 36	154/ 179	86.03%	163/ 184	88.59%
Week 40	153/ 179	85.47%	158/ 183	86.34%
Week 44	143/ 179	79.89%	158/ 183	86.34%
Week 48	152/ 179	84.92%	152/ 183	83.06%
Week 52	143/ 179	79.89%	147/ 183	80.33%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - PGA
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=184) n/ N#	Placebo (N=184) Compliance
Baseline	180/ 180	100.0%	184/ 184	100.0%
Week 4	175/ 180	97.22%	183/ 184	99.46%
Week 8	174/ 180	96.67%	177/ 184	96.20%
Week 12	169/ 179	94.41%	172/ 184	93.48%
Week 16	167/ 179	93.30%	170/ 184	92.39%
Week 20	157/ 179	87.71%	171/ 184	92.93%
Week 24	161/ 179	89.94%	167/ 184	90.76%
Week 28	156/ 179	87.15%	167/ 184	90.76%
Week 32	157/ 179	87.71%	164/ 184	89.13%
Week 36	156/ 179	87.15%	159/ 184	86.41%
Week 40	152/ 179	84.92%	159/ 183	86.89%
Week 44	143/ 179	79.89%	157/ 183	85.79%
Week 48	153/ 179	85.47%	154/ 183	84.15%
Week 52	143/ 179	79.89%	149/ 183	81.42%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - CLASI Total Activity Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=184) n/ N#	Placebo (N=184) Compliance
Baseline	180/ 180	100.0%	184/ 184	100.0%
Week 4	176/ 180	97.78%	183/ 184	99.46%
Week 8	174/ 180	96.67%	177/ 184	96.20%
Week 12	169/ 179	94.41%	173/ 184	94.02%
Week 16	169/ 179	94.41%	171/ 184	92.93%
Week 20	162/ 179	90.50%	172/ 184	93.48%
Week 24	161/ 179	89.94%	167/ 184	90.76%
Week 28	157/ 179	87.71%	168/ 184	91.30%
Week 32	159/ 179	88.83%	164/ 184	89.13%
Week 36	155/ 179	86.59%	162/ 184	88.04%
Week 40	154/ 179	86.03%	159/ 183	86.89%
Week 44	145/ 179	81.01%	159/ 183	86.89%
Week 48	153/ 179	85.47%	154/ 183	84.15%
Week 52	143/ 179	79.89%	150/ 183	81.97%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - CLASI Total Damage Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=184) n/ N#	Placebo (N=184) Compliance
Baseline	180/ 180	100.0%	184/ 184	100.0%
Week 4	176/ 180	97.78%	182/ 184	98.91%
Week 8	174/ 180	96.67%	177/ 184	96.20%
Week 12	169/ 179	94.41%	174/ 184	94.57%
Week 16	169/ 179	94.41%	171/ 184	92.93%
Week 20	162/ 179	90.50%	172/ 184	93.48%
Week 24	161/ 179	89.94%	167/ 184	90.76%
Week 28	157/ 179	87.71%	168/ 184	91.30%
Week 32	159/ 179	88.83%	164/ 184	89.13%
Week 36	155/ 179	86.59%	162/ 184	88.04%
Week 40	154/ 179	86.03%	158/ 183	86.34%
Week 44	145/ 179	81.01%	159/ 183	86.89%
Week 48	153/ 179	85.47%	154/ 183	84.15%
Week 52	143/ 179	79.89%	150/ 183	81.97%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - BILAG Global Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=184) n/ N#	Placebo (N=184) Compliance
Baseline	180/ 180	100.0%	184/ 184	100.0%
Week 4	176/ 180	97.78%	182/ 184	98.91%
Week 8	175/ 180	97.22%	177/ 184	96.20%
Week 12	170/ 179	94.97%	174/ 184	94.57%
Week 16	169/ 179	94.41%	171/ 184	92.93%
Week 20	162/ 179	90.50%	172/ 184	93.48%
Week 24	161/ 179	89.94%	168/ 184	91.30%
Week 28	157/ 179	87.71%	167/ 184	90.76%
Week 32	159/ 179	88.83%	164/ 184	89.13%
Week 36	154/ 179	86.03%	161/ 184	87.50%
Week 40	153/ 179	85.47%	158/ 183	86.34%
Week 44	144/ 179	80.45%	157/ 183	85.79%
Week 48	153/ 179	85.47%	152/ 183	83.06%
Week 52	143/ 179	79.89%	148/ 183	80.87%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Tender Joint Count
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=184) n/ N#	Placebo (N=184) Compliance
Baseline	180/ 180	100.0%	184/ 184	100.0%
Week 4	175/ 180	97.22%	182/ 184	98.91%
Week 8	173/ 180	96.11%	177/ 184	96.20%
Week 12	170/ 179	94.97%	174/ 184	94.57%
Week 16	169/ 179	94.41%	172/ 184	93.48%
Week 20	162/ 179	90.50%	171/ 184	92.93%
Week 24	161/ 179	89.94%	166/ 184	90.22%
Week 28	156/ 179	87.15%	168/ 184	91.30%
Week 32	159/ 179	88.83%	164/ 184	89.13%
Week 36	155/ 179	86.59%	162/ 184	88.04%
Week 40	153/ 179	85.47%	158/ 183	86.34%
Week 44	144/ 179	80.45%	159/ 183	86.89%
Week 48	153/ 179	85.47%	154/ 183	84.15%
Week 52	142/ 179	79.33%	150/ 183	81.97%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Swollen Joint Count
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=184) n/ N#	Placebo (N=184) Compliance
Baseline	180/ 180	100.0%	184/ 184	100.0%
Week 4	175/ 180	97.22%	182/ 184	98.91%
Week 8	173/ 180	96.11%	177/ 184	96.20%
Week 12	170/ 179	94.97%	174/ 184	94.57%
Week 16	169/ 179	94.41%	172/ 184	93.48%
Week 20	162/ 179	90.50%	171/ 184	92.93%
Week 24	161/ 179	89.94%	166/ 184	90.22%
Week 28	156/ 179	87.15%	168/ 184	91.30%
Week 32	159/ 179	88.83%	164/ 184	89.13%
Week 36	155/ 179	86.59%	162/ 184	88.04%
Week 40	153/ 179	85.47%	158/ 183	86.34%
Week 44	144/ 179	80.45%	159/ 183	86.89%
Week 48	153/ 179	85.47%	154/ 183	84.15%
Week 52	142/ 179	79.33%	150/ 183	81.97%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute Mental Component Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=184) n/ N#	Placebo (N=184) Compliance
Baseline	172/ 180	95.56%	175/ 184	95.11%
Week 8	162/ 180	90.00%	173/ 184	94.02%
Week 16	156/ 179	87.15%	170/ 184	92.39%
Week 24	155/ 179	86.59%	158/ 184	85.87%
Week 32	148/ 179	82.68%	154/ 184	83.70%
Week 40	143/ 179	79.89%	155/ 183	84.70%
Week 48	146/ 179	81.56%	148/ 183	80.87%
Week 52	138/ 179	77.09%	144/ 183	78.69%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute Physical Component Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=184) n/ N#	Placebo (N=184) Compliance
Baseline	172/ 180	95.56%	175/ 184	95.11%
Week 8	162/ 180	90.00%	173/ 184	94.02%
Week 16	156/ 179	87.15%	170/ 184	92.39%
Week 24	155/ 179	86.59%	158/ 184	85.87%
Week 32	148/ 179	82.68%	154/ 184	83.70%
Week 40	143/ 179	79.89%	155/ 183	84.70%
Week 48	146/ 179	81.56%	148/ 183	80.87%
Week 52	138/ 179	77.09%	144/ 183	78.69%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute General Health Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=184) n/ N#	Placebo (N=184) Compliance
Baseline	172/ 180	95.56%	175/ 184	95.11%
Week 8	162/ 180	90.00%	173/ 184	94.02%
Week 16	156/ 179	87.15%	170/ 184	92.39%
Week 24	155/ 179	86.59%	158/ 184	85.87%
Week 32	148/ 179	82.68%	154/ 184	83.70%
Week 40	143/ 179	79.89%	155/ 183	84.70%
Week 48	146/ 179	81.56%	148/ 183	80.87%
Week 52	138/ 179	77.09%	144/ 183	78.69%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute Mental Health Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=184) n/ N#	Placebo (N=184) Compliance
Baseline	172/ 180	95.56%	175/ 184	95.11%
Week 8	162/ 180	90.00%	173/ 184	94.02%
Week 16	156/ 179	87.15%	170/ 184	92.39%
Week 24	155/ 179	86.59%	158/ 184	85.87%
Week 32	148/ 179	82.68%	154/ 184	83.70%
Week 40	143/ 179	79.89%	155/ 183	84.70%
Week 48	146/ 179	81.56%	148/ 183	80.87%
Week 52	138/ 179	77.09%	144/ 183	78.69%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute Physical Functioning Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=184) n/ N#	Placebo (N=184) Compliance
Baseline	172/ 180	95.56%	175/ 184	95.11%
Week 8	162/ 180	90.00%	173/ 184	94.02%
Week 16	156/ 179	87.15%	170/ 184	92.39%
Week 24	155/ 179	86.59%	158/ 184	85.87%
Week 32	148/ 179	82.68%	154/ 184	83.70%
Week 40	143/ 179	79.89%	155/ 183	84.70%
Week 48	146/ 179	81.56%	148/ 183	80.87%
Week 52	138/ 179	77.09%	144/ 183	78.69%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute Role Emotional Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=184) n/ N#	Placebo (N=184) Compliance
Baseline	172/ 180	95.56%	175/ 184	95.11%
Week 8	162/ 180	90.00%	173/ 184	94.02%
Week 16	156/ 179	87.15%	170/ 184	92.39%
Week 24	155/ 179	86.59%	158/ 184	85.87%
Week 32	148/ 179	82.68%	154/ 184	83.70%
Week 40	143/ 179	79.89%	155/ 183	84.70%
Week 48	146/ 179	81.56%	148/ 183	80.87%
Week 52	138/ 179	77.09%	144/ 183	78.69%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute Role Physical Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=184) n/ N#	Placebo (N=184) Compliance
Baseline	172/ 180	95.56%	175/ 184	95.11%
Week 8	162/ 180	90.00%	173/ 184	94.02%
Week 16	156/ 179	87.15%	170/ 184	92.39%
Week 24	155/ 179	86.59%	158/ 184	85.87%
Week 32	148/ 179	82.68%	154/ 184	83.70%
Week 40	143/ 179	79.89%	155/ 183	84.70%
Week 48	146/ 179	81.56%	148/ 183	80.87%
Week 52	138/ 179	77.09%	144/ 183	78.69%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute Social Functioning Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=184) n/ N#	Placebo (N=184) Compliance
Baseline	172/ 180	95.56%	175/ 184	95.11%
Week 8	162/ 180	90.00%	173/ 184	94.02%
Week 16	156/ 179	87.15%	170/ 184	92.39%
Week 24	155/ 179	86.59%	158/ 184	85.87%
Week 32	148/ 179	82.68%	154/ 184	83.70%
Week 40	143/ 179	79.89%	155/ 183	84.70%
Week 48	146/ 179	81.56%	148/ 183	80.87%
Week 52	138/ 179	77.09%	144/ 183	78.69%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute Bodily Pain Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=184) n/ N#	Placebo (N=184) Compliance
Baseline	172/ 180	95.56%	175/ 184	95.11%
Week 8	162/ 180	90.00%	173/ 184	94.02%
Week 16	156/ 179	87.15%	170/ 184	92.39%
Week 24	155/ 179	86.59%	158/ 184	85.87%
Week 32	148/ 179	82.68%	154/ 184	83.70%
Week 40	143/ 179	79.89%	155/ 183	84.70%
Week 48	146/ 179	81.56%	148/ 183	80.87%
Week 52	138/ 179	77.09%	144/ 183	78.69%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute Vitality Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=184) n/ N#	Placebo (N=184) Compliance
Baseline	172/ 180	95.56%	175/ 184	95.11%
Week 8	162/ 180	90.00%	173/ 184	94.02%
Week 16	156/ 179	87.15%	170/ 184	92.39%
Week 24	155/ 179	86.59%	158/ 184	85.87%
Week 32	148/ 179	82.68%	154/ 184	83.70%
Week 40	143/ 179	79.89%	155/ 183	84.70%
Week 48	146/ 179	81.56%	148/ 183	80.87%
Week 52	138/ 179	77.09%	144/ 183	78.69%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - FACIT-F Total Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=184) n/ N#	Placebo (N=184) Compliance
Baseline	171/ 180	95.00%	174/ 184	94.57%
Week 4	166/ 180	92.22%	174/ 184	94.57%
Week 8	163/ 180	90.56%	173/ 184	94.02%
Week 12	162/ 179	90.50%	166/ 184	90.22%
Week 16	158/ 179	88.27%	170/ 184	92.39%
Week 20	154/ 179	86.03%	167/ 184	90.76%
Week 24	155/ 179	86.59%	160/ 184	86.96%
Week 28	151/ 179	84.36%	161/ 184	87.50%
Week 32	150/ 179	83.80%	155/ 184	84.24%
Week 36	148/ 179	82.68%	154/ 184	83.70%
Week 40	145/ 179	81.01%	156/ 183	85.25%
Week 44	141/ 179	78.77%	152/ 183	83.06%
Week 48	150/ 179	83.80%	149/ 183	81.42%
Week 52	138/ 179	77.09%	144/ 183	78.69%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - EQ VAS Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=184) n/ N#	Placebo (N=184) Compliance
Baseline	171/ 180	95.00%	174/ 184	94.57%
Week 12	162/ 179	90.50%	165/ 184	89.67%
Week 24	155/ 179	86.59%	158/ 184	85.87%
Week 36	144/ 179	80.45%	153/ 184	83.15%
Week 52	137/ 179	76.54%	144/ 183	78.69%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Lupus QoL Physical Health domain score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=184) n/ N#	Placebo (N=184) Compliance
Baseline	171/ 180	95.00%	174/ 184	94.57%
Week 12	162/ 179	90.50%	165/ 184	89.67%
Week 24	155/ 179	86.59%	158/ 184	85.87%
Week 36	143/ 179	79.89%	151/ 184	82.07%
Week 52	136/ 179	75.98%	143/ 183	78.14%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Lupus QoL Emotional Health domain score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=184) n/ N#	Placebo (N=184) Compliance
Baseline	171/ 180	95.00%	174/ 184	94.57%
Week 12	162/ 179	90.50%	165/ 184	89.67%
Week 24	155/ 179	86.59%	158/ 184	85.87%
Week 36	143/ 179	79.89%	151/ 184	82.07%
Week 52	136/ 179	75.98%	143/ 183	78.14%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Lupus QoL Body Image domain score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=184) n/ N#	Placebo (N=184) Compliance
Baseline	162/ 180	90.00%	160/ 184	86.96%
Week 12	145/ 179	81.01%	148/ 184	80.43%
Week 24	141/ 179	78.77%	142/ 184	77.17%
Week 36	130/ 179	72.63%	136/ 184	73.91%
Week 52	118/ 179	65.92%	124/ 183	67.76%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Lupus QoL Burden to Others domain score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=184) n/ N#	Placebo (N=184) Compliance
Baseline	171/ 180	95.00%	174/ 184	94.57%
Week 12	162/ 179	90.50%	165/ 184	89.67%
Week 24	155/ 179	86.59%	158/ 184	85.87%
Week 36	143/ 179	79.89%	151/ 184	82.07%
Week 52	136/ 179	75.98%	143/ 183	78.14%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Lupus QoL Fatigue domain score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=184) n/ N#	Placebo (N=184) Compliance
Baseline	171/ 180	95.00%	174/ 184	94.57%
Week 12	162/ 179	90.50%	165/ 184	89.67%
Week 24	155/ 179	86.59%	158/ 184	85.87%
Week 36	143/ 179	79.89%	151/ 184	82.07%
Week 52	136/ 179	75.98%	143/ 183	78.14%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Lupus QoL Intimate Relationships domain score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=184) n/ N#	Placebo (N=184) Compliance
Baseline	149/ 180	82.78%	146/ 184	79.35%
Week 12	138/ 179	77.09%	130/ 184	70.65%
Week 24	125/ 179	69.83%	120/ 184	65.22%
Week 36	116/ 179	64.80%	112/ 184	60.87%
Week 52	108/ 179	60.34%	105/ 183	57.38%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Lupus QoL Pain domain score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=184) n/ N#	Placebo (N=184) Compliance
Baseline	171/ 180	95.00%	174/ 184	94.57%
Week 12	162/ 179	90.50%	165/ 184	89.67%
Week 24	155/ 179	86.59%	158/ 184	85.87%
Week 36	143/ 179	79.89%	151/ 184	82.07%
Week 52	136/ 179	75.98%	143/ 183	78.14%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Lupus QoL Planning domain score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=184) n/ N#	Placebo (N=184) Compliance
Baseline	171/ 180	95.00%	174/ 184	94.57%
Week 12	162/ 179	90.50%	165/ 184	89.67%
Week 24	155/ 179	86.59%	158/ 184	85.87%
Week 36	143/ 179	79.89%	151/ 184	82.07%
Week 52	136/ 179	75.98%	143/ 183	78.14%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SDI Global Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=184) n/ N#	Placebo (N=184) Compliance
Baseline	170/ 180	94.44%	169/ 184	91.85%
Week 24	154/ 179	86.03%	159/ 184	86.41%
Week 52	134/ 179	74.86%	147/ 183	80.33%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - NRS Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=184) n/ N#	Placebo (N=184) Compliance
Baseline	171/ 180	95.00%	174/ 184	94.57%
Week 4	166/ 180	92.22%	174/ 184	94.57%
Week 8	163/ 180	90.56%	173/ 184	94.02%
Week 12	162/ 179	90.50%	166/ 184	90.22%
Week 16	158/ 179	88.27%	170/ 184	92.39%
Week 20	154/ 179	86.03%	167/ 184	90.76%
Week 24	155/ 179	86.59%	160/ 184	86.96%
Week 28	150/ 179	83.80%	161/ 184	87.50%
Week 32	150/ 179	83.80%	155/ 184	84.24%
Week 36	148/ 179	82.68%	154/ 184	83.70%
Week 40	145/ 179	81.01%	156/ 183	85.25%
Week 44	141/ 179	78.77%	152/ 183	83.06%
Week 48	150/ 179	83.80%	149/ 183	81.42%
Week 52	138/ 179	77.09%	144/ 183	78.69%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - PHQ-8 Total Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=184) n/ N#	Placebo (N=184) Compliance
Baseline	171/ 180	95.00%	174/ 184	94.57%
Week 12	162/ 179	90.50%	165/ 184	89.67%
Week 24	155/ 179	86.59%	158/ 184	85.87%
Week 36	144/ 179	80.45%	153/ 184	83.15%
Week 52	137/ 179	76.54%	144/ 183	78.69%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - PtGA
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=184) n/ N#	Placebo (N=184) Compliance
Baseline	171/ 180	95.00%	174/ 184	94.57%
Week 4	166/ 180	92.22%	174/ 184	94.57%
Week 8	163/ 180	90.56%	173/ 184	94.02%
Week 12	162/ 179	90.50%	166/ 184	90.22%
Week 16	158/ 179	88.27%	168/ 184	91.30%
Week 20	153/ 179	85.47%	165/ 184	89.67%
Week 24	155/ 179	86.59%	160/ 184	86.96%
Week 28	151/ 179	84.36%	161/ 184	87.50%
Week 32	149/ 179	83.24%	154/ 184	83.70%
Week 36	147/ 179	82.12%	152/ 184	82.61%
Week 40	145/ 179	81.01%	155/ 183	84.70%
Week 44	140/ 179	78.21%	151/ 183	82.51%
Week 48	150/ 179	83.80%	148/ 183	80.87%
Week 52	137/ 179	76.54%	143/ 183	78.14%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Flare rate through Week 52
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) Number of flares	Anifrolumab 300mg (N=180) Total Follow-up time (years)	Anifrolumab 300mg (N=180) Annual rate (SE)	Placebo (N=184) Number of flares	Placebo (N=184) Total Follow-up time (years)	Placebo (N=184) Annual rate (SE)	Rate ratio (95% CI)	p-Value	Interaction p-Value
Overall	109	166.65	0.57 (0.14)	133	170.84	0.68 (0.14)	0.83 (0.61, 1.15)	0.2696	
SLEDAI-2K score at screening									0.8771
< 10 points	23	49.40	0.44 (0.27)	28	49.24	0.56 (0.26)	0.79 (0.42, 1.50)	0.4751	
>= 10 points	86	117.26	0.71 (0.16)	105	121.60	0.84 (0.16)	0.85 (0.58, 1.23)	0.3787	
OCS dose at baseline									0.7210
<10 mg/day	42	72.55	0.47 (0.23)	50	78.26	0.52 (0.23)	0.91 (0.53, 1.55)	0.7177	
>=10 mg/day	67	94.11	0.69 (0.18)	83	92.59	0.87 (0.18)	0.79 (0.53, 1.18)	0.2526	
Result of type I IFN gene signature test									0.1409
LOW	24	31.09	0.70 (0.25)	18	32.09	0.49 (0.28)	1.43 (0.73, 2.78)	0.2956	
HIGH	85	135.57	0.55 (0.15)	115	138.75	0.74 (0.14)	0.75 (0.52, 1.07)	0.1139	
Age (years)									0.5295
<= 65	106	159.79	0.57 (0.15)	130	167.93	0.67 (0.15)	0.85 (0.61, 1.18)	0.3258	
> 65	3	6.87	0.49 (0.66)	3	2.92	0.00 (15754.31)	37156156.77 (0.00, I)	0.9991	
Sex									0.5664
male	9	14.32	NE	13	12.39	NE	NE		
female	100	152.33	0.58 (0.15)	120	158.45	0.68 (0.15)	0.86 (0.61, 1.20)	0.3676	
Race									0.2634
White	76	117.56	0.56 (0.16)	102	126.90	0.70 (0.16)	0.80 (0.56, 1.16)	0.2366	
Black or African American	18	25.68	0.53 (0.42)	15	22.18	0.66 (0.40)	0.80 (0.31, 2.05)	0.6445	
Asian	11	9.83	NE	2	4.51	NE	NE		
American Indian or Alaska Native	0		NE	0	0.16	NE	NE		
Other	4	13.59	0.00 (0.87)	14	17.10	0.00 (0.65)	0.33 (0.08, 1.36)	0.1245	
Ethnicity									0.2420
Hispanic/Latino	12	27.87	0.22 (0.56)	25	32.20	0.39 (0.53)	0.56 (0.22, 1.41)	0.2191	
Non-hispanic/Latino	97	138.78	0.63 (0.15)	108	138.64	0.70 (0.15)	0.90 (0.64, 1.27)	0.5408	
Geographic region									0.9947
EU	35	62.72	0.43 (0.28)	50	71.18	0.52 (0.28)	0.83 (0.48, 1.43)	0.4966	
non-EU	74	103.93	0.62 (0.17)	83	99.66	0.75 (0.17)	0.83 (0.56, 1.23)	0.3425	
Onset of disease									0.9666
Paediatric	9	10.43	NE	9	9.81	NE	NE		
Adult	100	156.22	0.58 (0.15)	124	161.03	0.70 (0.15)	0.83 (0.59, 1.16)	0.2735	
ADA result									0.2806
Negative	100	151.93	0.60 (0.15)	117	156.87	0.68 (0.15)	0.88 (0.63, 1.24)	0.4701	
Positive (At any time)	9	14.72	0.16 (0.78)	16	13.97	0.43 (0.64)	0.36 (0.14, 0.95)	0.0379	
BMI (kg/m2) at enrolment									0.0168
< 30	56	99.90	0.52 (0.20)	105	116.78	0.82 (0.18)	0.63 (0.42, 0.95)	0.0259	
>= 30	53	66.76	0.65 (0.20)	28	54.06	0.46 (0.24)	1.42 (0.83, 2.42)	0.2031	

Rates and rate ratio from negative binomial regression model with factors for treatment group and the stratification factors. The logarithm (to base e) of the follow-up time is used as an offset variable in the model to adjust for subjects having different exposure times.
p-Value for interaction from same negative binomial regression model with additional factors for subgroup and subgroup*treatment interaction.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Flare rate through Week 52 using modified BILAG
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) Number of flares	Anifrolumab 300mg (N=180) Total Follow-up time (years)	Anifrolumab 300mg (N=180) Annual rate (SE)	Placebo (N=184) Number of flares	Placebo (N=184) Total Follow-up time (years)	Placebo (N=184) Annual rate (SE)	Rate ratio (95% CI)	p-Value	Interaction p-Value
Overall	66	166.65	0.29 (0.20)	96	170.84	0.41 (0.19)	0.71 (0.48, 1.06)	0.0944	

Rates and rate ratio from negative binomial regression model with factors for treatment group and the stratification factors. The logarithm (to base e) of the follow-up time is used as an offset variable in the model to adjust for subjects having different exposure times.
p-Value for interaction from same negative binomial regression model with additional factors for subgroup and subgroup*treatment interaction.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Flare rate through Week 52 while on treatment
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) Number of flares	Anifrolumab 300mg (N=180) Total Follow-up time (years)	Anifrolumab 300mg (N=180) Annual rate (SE)	Placebo (N=184) Number of flares	Placebo (N=184) Total Follow-up time (years)	Placebo (N=184) Annual rate (SE)	Rate ratio (95% CI)	p-Value	Interaction p-Value
Overall	97	160.89	0.53 (0.15)	118	165.07	0.63 (0.14)	0.84 (0.60, 1.17)	0.2948	

Rates and rate ratio from negative binomial regression model with factors for treatment group and the stratification factors. The logarithm (to base e) of the follow-up time is used as an offset variable in the model to adjust for subjects having different exposure times.
p-Value for interaction from same negative binomial regression model with additional factors for subgroup and subgroup*treatment interaction.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Flare rate through Week 52 sensitivity analysis, multiple imputation and negative binomial regression model
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) Number of flares	Anifrolumab 300mg (N=180) Total Follow-up time (years)	Anifrolumab 300mg (N=180) Annual rate (SE)	Placebo (N=184) Number of flares	Placebo (N=184) Total Follow-up time (years)	Placebo (N=184) Annual rate (SE)	Rate ratio (95% CI)	p-Value
Overall	119	180.64	0.57 (0.00)	145	184.78	0.68 (0.00)	0.84 (0.61, 1.16)	0.2809

The number of flares after withdrawal from study is imputed conditional upon the observed number of flares prior to the withdrawal, a post-withdrawal model assumption, the baseline covariates included in the main analysis model and the time the subject would have remained in the study if not withdrawn (ie, date of first administration of IP + 364 days â€“ date of withdrawal). This analysis is repeated multiple times and the results combined using Rubinâ€™s formula. Full details are given in SAP
Rates and rate ratio from negative binomial regression model with factors for treatment group and the stratification factors. The logarithm (to base e) of the follow-up time is used as an offset variable in the model to adjust for subjects having different exposure times.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Flare rate through Week 52 sensitivity analysis, tipping point analysis
Full analysis set

Shift (log(Delta A)) for Anifrolumab 300 mg	Shift (log(Delta P)) for Placebo						
	0	-0.25	-0.5	-0.75	-1	-1.25	-1.5
0	0.2606	0.2834	0.3022	0.3175	0.3297	0.3395	0.3472
0.25	0.2846	0.3088	0.3287	0.3448	0.3577	0.3679	0.3761
0.5	0.3180	0.3440	0.3652	0.3824	0.3961	0.4070	0.4156
0.75	0.3649	0.3931	0.4161	0.4346	0.4493	0.4610	0.4702
1	0.4315	0.4626	0.4877	0.5078	0.5238	0.5364	0.5463
1.25	0.5271	0.5615	0.5891	0.6110	0.6283	0.6419	0.6526
1.5	0.6639	0.7017	0.7316	0.7553	0.7738	0.7883	0.7997

The response variable in the model is the number of flares up to Week 52/EDV. The model includes covariates of treatment group, and the stratification factors (SLEDAI-2K Score at Screening (<10 points vs >= 10 points), Week 0 OCS dose (<10 mg/day vs >=10 mg/day prednisone or equivalent) and Type 1 IFN test result at screening (high vs low)).
The logarithm (to base e) of the follow-up time is used as an offset variable in the model to adjust for subjects having different exposure times.
P-values of this analysis are presented.
For the scenario in the upper left corner, missing at random analysis is performed, where for each subject the rate after withdrawal y1 is assumed to be the same as their rate before withdrawal y2, which itself is calculated based on their randomised treatment group and baseline covariates. For the other scenarios, the same analyses are performed with the rate after withdrawal modified to be Deltay2 (Delta P and Delta A for placebo and anifrolumab 300 mg, respectively).

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Overall Survival
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	1 (0.6)	1 (0.5)
Number of censored subjects, n (%)	179 (99.4)	183 (99.5)
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Anifrolumab 300mg vs. Placebo (adjusted)		
Hazard Ratio (95% CI)	0.92 (0.06, 14.73)	
p-value	0.9557	
Analysis Anifrolumab 300mg vs. Placebo (unadjusted)		
Hazard Ratio (95% CI)	1.03 (0.06, 16.42)	
p-value	0.9850	

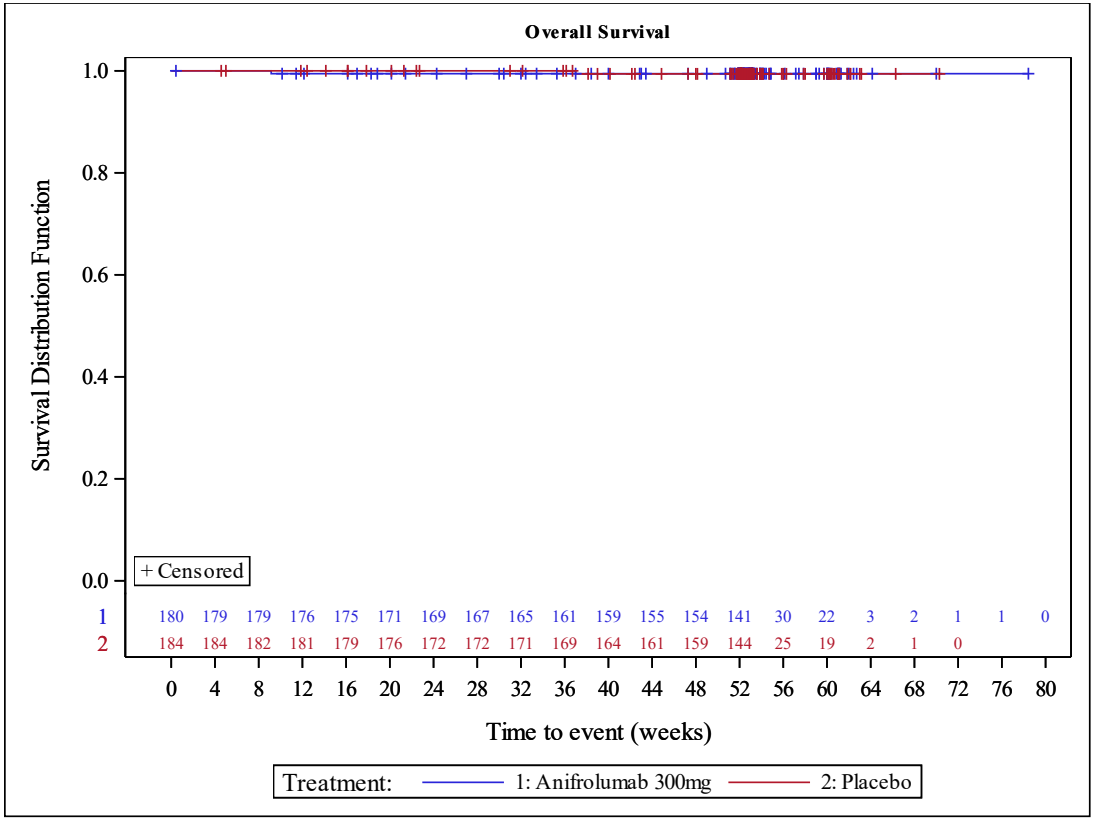
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model. Adjusted analysis also includes stratification factors in the model.
Two-sided log rank test used.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Overall Survival - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Anifrolumab 300mg (N=180) Median (95% CI)	Placebo (N=184) n/ N (%)	Placebo (N=184) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening							0.9984
< 10 points	1/ 55 (1.8)	NE (NE, NE)	0/ 54 (0.0)	NE (NE, NE)	NE		
>= 10 points	0/125 (0.0)	NE (NE, NE)	1/130 (0.8)	NE (NE, NE)	NE		
OCS dose at baseline							1.0000
<10 mg/day	0/ 77 (0.0)	NE (NE, NE)	0/ 82 (0.0)	NE (NE, NE)	NE		
>=10 mg/day	1/103 (1.0)	NE (NE, NE)	1/102 (1.0)	NE (NE, NE)	0.92 (0.06, 14.73)	0.9557	
Result of type I IFN gene signature test							1.0000
LOW	0/ 32 (0.0)	NE (NE, NE)	0/ 33 (0.0)	NE (NE, NE)	NE		
HIGH	1/148 (0.7)	NE (NE, NE)	1/151 (0.7)	NE (NE, NE)	0.92 (0.06, 14.73)	0.9557	
Age (years)							1.0000
<= 65	1/173 (0.6)	NE (NE, NE)	1/181 (0.6)	NE (NE, NE)	0.90 (0.06, 14.47)	0.9462	
> 65	0/ 7 (0.0)	NE (NE, NE)	0/ 3 (0.0)	NE (NE, NE)	NE		
Sex							1.0000
male	0/ 15 (0.0)	NE (NE, NE)	0/ 13 (0.0)	NE (NE, NE)	NE		
female	1/165 (0.6)	NE (NE, NE)	1/171 (0.6)	NE (NE, NE)	0.93 (0.06, 14.92)	0.9740	
Race							1.0000
White	0/125 (0.0)	NE (NE, NE)	0/137 (0.0)	NE (NE, NE)	NE		
Black or African American	0/ 29 (0.0)	NE (NE, NE)	1/ 23 (4.3)	NE (NE, NE)	NE		
Asian	0/ 11 (0.0)	NE (NE, NE)	0/ 5 (0.0)	NE (NE, NE)	NE		
American Indian or Alaska Native	0	NE (NE, NE)	0/ 1 (0.0)	NE (NE, NE)	NE		
Other	1/ 15 (6.7)	NE (NE, NE)	0/ 18 (0.0)	NE (NE, NE)	NE		
Ethnicity							0.9982
Hispanic/Latino	1/ 32 (3.1)	NE (NE, NE)	0/ 35 (0.0)	NE (NE, NE)	NE		
Non-hispanic/Latino	0/148 (0.0)	NE (NE, NE)	1/149 (0.7)	NE (NE, NE)	NE		
Geographic region							1.0000
EU	0/ 64 (0.0)	NE (NE, NE)	0/ 76 (0.0)	NE (NE, NE)	NE		
non-EU	1/116 (0.9)	NE (NE, NE)	1/108 (0.9)	NE (NE, NE)	0.81 (0.05, 13.00)	0.9012	
Onset of disease							1.0000
Paediatric	0/ 12 (0.0)	NE (NE, NE)	0/ 12 (0.0)	NE (NE, NE)	NE		
Adult	1/168 (0.6)	NE (NE, NE)	1/172 (0.6)	NE (NE, NE)	0.98 (0.06, 15.69)	0.9909	
ADA result							1.0000
Negative	1/162 (0.6)	NE (NE, NE)	1/169 (0.6)	NE (NE, NE)	0.91 (0.06, 14.67)	0.9532	
Positive (At any time)	0/ 17 (0.0)	NE (NE, NE)	0/ 15 (0.0)	NE (NE, NE)	NE		
BMI (kg/m2) at enrolment							0.9981
< 30	1/108 (0.9)	NE (NE, NE)	0/127 (0.0)	NE (NE, NE)	NE		
>= 30	0/ 72 (0.0)	NE (NE, NE)	1/ 57 (1.8)	NE (NE, NE)	NE		

Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Overall Survival
Full analysis set



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Time to first Flare
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	65 (36.1)	80 (43.5)
Number of censored subjects, n (%)	115 (63.9)	104 (56.5)
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	25.00 (19.14, 36.14)	19.71 (16.00, 28.00)
Median (95% CI)	NE (53.71, NE)	NE (40.00, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Anifrolumab 300mg vs. Placebo (adjusted)		
Hazard Ratio (95% CI)	0.76 (0.55, 1.06)	
p-value	0.1169	
Analysis Anifrolumab 300mg vs. Placebo (unadjusted)		
Hazard Ratio (95% CI)	0.77 (0.56, 1.07)	
p-value	0.1258	

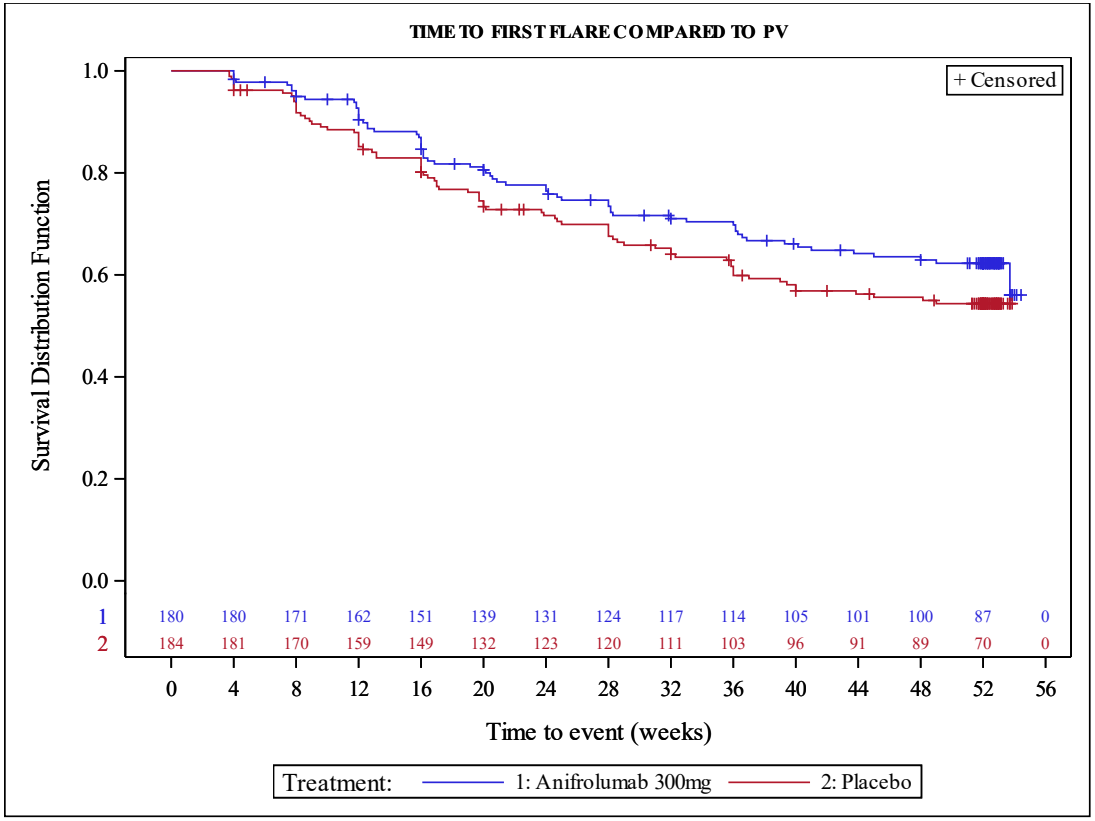
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model. Adjusted analysis also includes stratification factors in the model.
Two-sided log rank test used.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Time to first Flare - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Anifrolumab 300mg (N=180) Median (95% CI)	Placebo (N=184) n/ N (%)	Placebo (N=184) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening							0.9428
< 10 points	16/ 55 (29.1)	NE (53.71, NE)	20/ 54 (37.0)	NE (43.86, NE)	0.75 (0.38, 1.46)	0.3975	
>= 10 points	49/125 (39.2)	NE (49.00, NE)	60/130 (46.2)	NE (32.00, NE)	0.76 (0.52, 1.11)	0.1859	
OCS dose at baseline							0.2031
<10 mg/day	27/ 77 (35.1)	NE (NE, NE)	29/ 82 (35.4)	NE (NE, NE)	0.99 (0.59, 1.67)	0.9715	
>=10 mg/day	38/103 (36.9)	NE (53.71, NE)	51/102 (50.0)	43.86 (28.00, NE)	0.65 (0.43, 1.00)	0.0473	
Result of type I IFN gene signature test							0.0733
LOW	15/ 32 (46.9)	NE (16.14, NE)	13/ 33 (39.4)	NE (32.00, NE)	1.48 (0.70, 3.12)	0.2759	
HIGH	50/148 (33.8)	NE (53.71, NE)	67/151 (44.4)	NE (37.00, NE)	0.66 (0.46, 0.96)	0.0235	
Age (years)							0.5647
<= 65	62/173 (35.8)	NE (53.71, NE)	79/181 (43.6)	NE (40.00, NE)	0.75 (0.54, 1.04)	0.1047	
> 65	3/ 7 (42.9)	NE (12.00, NE)	1/ 3 (33.3)	NE (19.71, NE)	NE		
Sex							0.4649
male	6/ 15 (40.0)	NE (16.00, NE)	8/ 13 (61.5)	37.00 (16.00, NE)	0.47 (0.15, 1.45)	0.0423	
female	59/165 (35.8)	NE (53.71, NE)	72/171 (42.1)	NE (40.00, NE)	0.79 (0.56, 1.11)	0.2079	
Race							0.5576
White	46/125 (36.8)	NE (53.71, NE)	62/137 (45.3)	NE (36.00, NE)	0.71 (0.49, 1.05)	0.0963	
Black or African American	10/ 29 (34.5)	NE (28.14, NE)	9/ 23 (39.1)	NE (35.86, NE)	0.92 (0.32, 2.59)	0.5742	
Asian	6/ 11 (54.5)	40.14 (8.00, NE)	2/ 5 (40.0)	NE (16.00, NE)	1.44 (0.28, 7.38)	0.8866	
American Indian or Alaska Native	0	NE (NE, NE)	0/ 1 (0.0)	NE (NE, NE)	NE		
Other	3/ 15 (20.0)	NE (20.86, NE)	7/ 18 (38.9)	NE (20.00, NE)	0.48 (0.12, 1.91)	0.3533	
Ethnicity							0.4526
Hispanic/Latino	11/ 32 (34.4)	NE (36.14, NE)	11/ 35 (31.4)	NE (32.29, NE)	1.01 (0.43, 2.37)	0.9338	
Non-hispanic/Latino	54/148 (36.5)	NE (53.71, NE)	69/149 (46.3)	NE (36.00, NE)	0.72 (0.50, 1.03)	0.0779	
Geographic region							0.4280
EU	19/ 64 (29.7)	NE (53.71, NE)	31/ 76 (40.8)	NE (40.00, NE)	0.61 (0.34, 1.10)	0.1232	
non-EU	46/116 (39.7)	NE (43.71, NE)	49/108 (45.4)	NE (35.86, NE)	0.83 (0.55, 1.24)	0.3618	
Onset of disease							0.7602
Paediatric	6/ 12 (50.0)	39.29 (16.00, NE)	6/ 12 (50.0)	43.86 (4.00, NE)	0.19 (0.04, 0.82)	0.0190	
Adult	59/168 (35.1)	NE (53.71, NE)	74/172 (43.0)	NE (40.00, NE)	0.77 (0.54, 1.08)	0.1438	
ADA result							0.4122
Negative	59/162 (36.4)	NE (53.71, NE)	71/169 (42.0)	NE (43.86, NE)	0.79 (0.56, 1.12)	0.2058	
Positive (At any time)	6/ 17 (35.3)	NE (13.00, NE)	9/ 15 (60.0)	36.00 (8.00, NE)	0.33 (0.11, 1.02)	0.0527	
BMI (kg/m2) at enrolment							0.1191
< 30	36/108 (33.3)	53.71 (53.71, NE)	58/127 (45.7)	NE (36.00, NE)	0.63 (0.41, 0.95)	0.0200	
>= 30	29/ 72 (40.3)	NE (36.00, NE)	22/ 57 (38.6)	NE (39.43, NE)	1.07 (0.61, 1.87)	0.7162	

Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Time to first Flare
Full analysis set



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Time to sustained BICLA response up to week 52
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	85 (47.2)	55 (29.9)
Number of censored subjects, n (%)	95 (52.8)	129 (70.1)
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	20.00 (13.29, 25.00)	39.86 (24.71, 51.86)
Median (95% CI)	48.71 (44.14, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Anifrolumab 300mg vs. Placebo (adjusted)		
Hazard Ratio (95% CI)	1.94 (1.38, 2.72)	
p-value	0.0001	
Analysis Anifrolumab 300mg vs. Placebo (unadjusted)		
Hazard Ratio (95% CI)	1.92 (1.37, 2.70)	
p-value	0.0001	

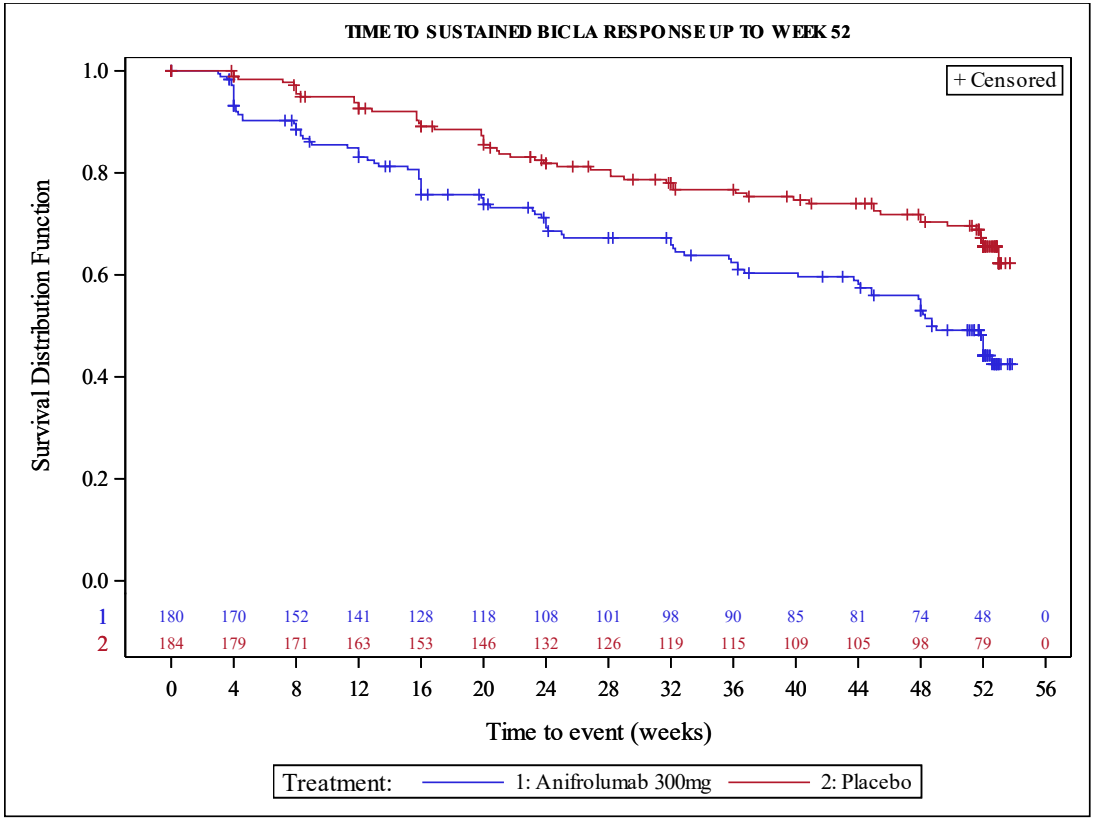
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model. Adjusted analysis also includes stratification factors in the model.
Two-sided log rank test used.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Time to sustained BICLA response up to week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Anifrolumab 300mg (N=180) Median (95% CI)	Placebo (N=184) n/ N (%)	Placebo (N=184) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening							0.7145
< 10 points	31/ 55 (56.4)	35.71 (16.00, 52.00)	20/ 54 (37.0)	NE (45.00, NE)	2.02 (1.14, 3.56)	0.0106	
>= 10 points	54/125 (43.2)	52.00 (44.86, NE)	35/130 (26.9)	NE (NE, NE)	1.84 (1.20, 2.82)	0.0037	
OCS dose at baseline							0.9704
<10 mg/day	36/ 77 (46.8)	52.00 (35.71, NE)	25/ 82 (30.5)	NE (53.00, NE)	1.93 (1.15, 3.23)	0.0092	
>=10 mg/day	49/103 (47.6)	48.29 (40.14, NE)	30/102 (29.4)	NE (NE, NE)	1.91 (1.21, 3.02)	0.0045	
Result of type I IFN gene signature test							0.2957
LOW	15/ 32 (46.9)	52.00 (32.14, NE)	13/ 33 (39.4)	NE (29.00, NE)	1.32 (0.63, 2.79)	0.4445	
HIGH	70/148 (47.3)	48.71 (43.71, NE)	42/151 (27.8)	NE (NE, NE)	2.12 (1.45, 3.12)	<.0001	
Age (years)							0.8101
<= 65	79/173 (45.7)	49.00 (44.14, NE)	54/181 (29.8)	NE (NE, NE)	1.87 (1.32, 2.65)	0.0004	
> 65	6/ 7 (85.7)	32.00 (7.86, 52.57)	1/ 3 (33.3)	NE (8.29, NE)	0.00 (0.00,)	<.0001	
Sex							0.8002
male	6/ 15 (40.0)	NE (12.00, NE)	4/ 13 (30.8)	NE (24.71, NE)	1.59 (0.44, 5.80)	0.8984	
female	79/165 (47.9)	48.71 (44.00, NE)	51/171 (29.8)	NE (NE, NE)	1.97 (1.38, 2.81)	0.0001	
Race							0.9748
White	61/125 (48.8)	49.00 (35.86, NE)	43/137 (31.4)	NE (53.00, NE)	1.99 (1.34, 2.94)	0.0003	
Black or African American	13/ 29 (44.8)	48.71 (24.14, NE)	7/ 23 (30.4)	NE (39.86, NE)	2.40 (0.84, 6.90)	0.1186	
Asian	5/ 11 (45.5)	44.86 (4.57, NE)	1/ 5 (20.0)	NE (51.57, NE)	4.03 (0.42, 38.48)	0.0513	
American Indian or Alaska Native	0	NE (NE, NE)	0/ 1 (0.0)	NE (NE, NE)	NE		
Other	6/ 15 (40.0)	NE (12.57, NE)	4/ 18 (22.2)	NE (24.71, NE)	1.54 (0.42, 5.71)	0.1806	
Ethnicity							0.1917
Hispanic/Latino	12/ 32 (37.5)	52.00 (36.29, NE)	11/ 35 (31.4)	NE (32.14, NE)	1.07 (0.46, 2.51)	0.3894	
Non-hispanic/Latino	73/148 (49.3)	48.14 (36.71, NE)	44/149 (29.5)	NE (NE, NE)	2.13 (1.47, 3.10)	0.0001	
Geographic region							0.4407
EU	39/ 64 (60.9)	35.71 (16.00, 52.00)	26/ 76 (34.2)	NE (51.86, NE)	2.36 (1.44, 3.89)	0.0004	
non-EU	46/116 (39.7)	52.00 (48.00, NE)	29/108 (26.9)	NE (NE, NE)	1.77 (1.11, 2.83)	0.0185	
Onset of disease							0.3934
Paediatric	5/ 12 (41.7)	48.00 (4.00, NE)	2/ 12 (16.7)	NE (23.86, NE)	7.72 (0.58, 102.99)	0.0991	
Adult	80/168 (47.6)	49.00 (44.00, NE)	53/172 (30.8)	NE (NE, NE)	1.87 (1.32, 2.65)	0.0003	
ADA result							0.7786
Negative	79/162 (48.8)	48.71 (44.00, 52.57)	52/169 (30.8)	NE (53.00, NE)	1.92 (1.35, 2.73)	0.0003	
Positive (At any time)	6/ 17 (35.3)	NE (12.00, NE)	3/ 15 (20.0)	NE (39.86, NE)	2.19 (0.51, 9.38)	0.2677	
BMI (kg/m2) at enrolment							0.6977
< 30	55/108 (50.9)	48.00 (35.86, 52.00)	37/127 (29.1)	NE (53.00, NE)	2.05 (1.35, 3.13)	0.0005	
>= 30	30/ 72 (41.7)	NE (36.71, NE)	18/ 57 (31.6)	NE (52.00, NE)	1.85 (1.02, 3.35)	0.0724	

Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Time to sustained BICLA response up to week 52
Full analysis set



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Time to OCS Reduction <=7.5 mg/day (for subjects with baseline OCS >=10 mg/day)
Full analysis set

	Anifrolumab 300mg (N=103)	Placebo (N=102)
Number of subjects with events, n (%)	70 (68.0)	55 (53.9)
Number of censored subjects, n (%)	33 (32.0)	47 (46.1)
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	12.57 (11.57, 15.43)	13.43 (9.43, 17.57)
Median (95% CI)	20.14 (16.29, 24.14)	28.29 (20.57, 42.29)
75%-ile (95% CI)	41.29 (24.71, NE)	NE (NE, NE)
Analysis Anifrolumab 300mg vs. Placebo (adjusted)		
Hazard Ratio (95% CI)	1.48 (1.04, 2.12)	
p-value	0.0249	
Analysis Anifrolumab 300mg vs. Placebo (unadjusted)		
Hazard Ratio (95% CI)	1.49 (1.04, 2.12)	
p-value	0.0277	

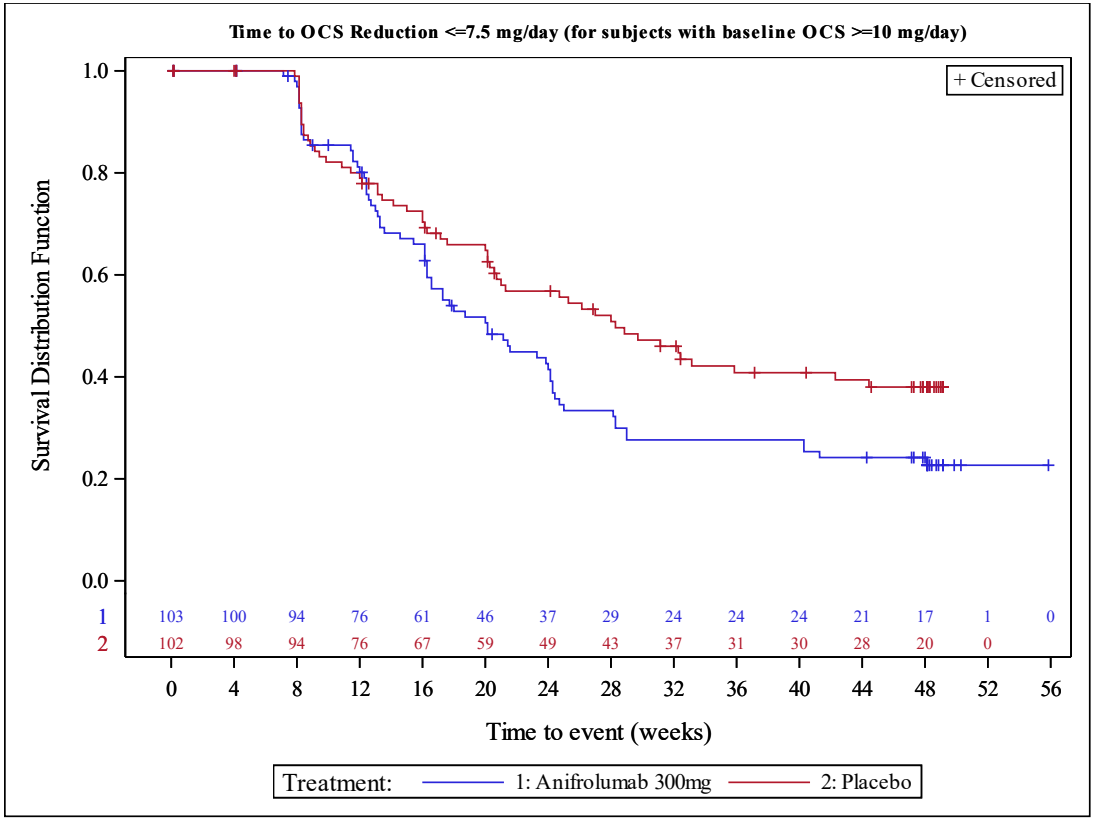
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model. Adjusted analysis also includes stratification factors in the model.
Two-sided log rank test used.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Time to OCS Reduction <=7.5 mg/day (for subjects with baseline OCS >=10 mg/day) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=103) n/ N (%)	Anifrolumab 300mg (N=103) Median (95% CI)	Placebo (N=102) n/ N (%)	Placebo (N=102) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening							0.3676
< 10 points	22/ 29 (75.9)	18.71 (12.43, 29.00)	14/ 25 (56.0)	31.07 (20.29, NE)	2.07 (1.05, 4.06)	0.0216	
>= 10 points	48/ 74 (64.9)	20.14 (16.29, 24.14)	41/ 77 (53.2)	26.14 (17.57, NE)	1.32 (0.87, 2.00)	0.2259	
OCS dose at baseline							NE
>=10 mg/day	70/103 (68.0)	20.14 (16.29, 24.14)	55/102 (53.9)	28.29 (20.57, 42.29)	1.48 (1.04, 2.12)	0.0249	
Result of type I IFN gene signature test							0.1474
LOW	9/ 13 (69.2)	25.00 (12.43, NE)	12/ 15 (80.0)	20.71 (9.86, 28.86)	0.81 (0.34, 1.94)	0.6195	
HIGH	61/ 90 (67.8)	20.14 (16.14, 24.14)	43/ 87 (49.4)	32.29 (20.57, NE)	1.66 (1.12, 2.46)	0.0073	
Age (years)							0.6267
<= 65	69/101 (68.3)	20.14 (16.29, 24.14)	54/101 (53.5)	28.86 (20.71, 44.43)	1.50 (1.05, 2.14)	0.0209	
> 65	1/ 2 (50.0)	NE (11.57, NE)	1/ 1 (100.0)	20.29 (NE, NE)	1.00 (0.00,)	<.0001	
Sex							0.2229
male	11/ 11 (100.0)	14.57 (8.29, 23.86)	6/ 10 (60.0)	28.86 (8.14, NE)	5.64 (1.48, 21.56)	0.0318	
female	59/ 92 (64.1)	21.14 (16.57, 24.43)	49/ 92 (53.3)	28.00 (20.29, 44.43)	1.37 (0.94, 2.01)	0.0913	
Race							0.2168
White	41/ 65 (63.1)	21.57 (16.29, 24.43)	41/ 77 (53.2)	28.86 (20.29, 44.43)	1.28 (0.83, 1.98)	0.2969	
Black or African American	14/ 20 (70.0)	18.00 (8.14, 40.29)	5/ 9 (55.6)	28.00 (8.29, NE)	1.60 (0.55, 4.64)	0.1714	
Asian	5/ 6 (83.3)	22.71 (7.86, NE)	3/ 4 (75.0)	14.07 (8.86, NE)	0.49 (0.09, 2.58)	0.4000	
Other	10/ 12 (83.3)	13.57 (8.43, 17.29)	6/ 12 (50.0)	29.71 (15.00, NE)	3.75 (1.31, 10.75)	0.0105	
Ethnicity							0.1909
Hispanic/Latino	14/ 21 (66.7)	16.57 (11.57, 24.14)	9/ 18 (50.0)	27.93 (15.00, NE)	2.25 (0.92, 5.46)	0.0791	
Non-hispanic/Latino	56/ 82 (68.3)	21.43 (16.29, 24.43)	46/ 84 (54.8)	28.29 (20.14, 42.29)	1.33 (0.90, 1.96)	0.1696	
Geographic region							0.1942
EU	31/ 45 (68.9)	21.57 (16.14, 25.00)	33/ 57 (57.9)	21.29 (17.14, 35.86)	1.18 (0.72, 1.93)	0.5356	
non-EU	39/ 58 (67.2)	18.00 (16.14, 24.14)	22/ 45 (48.9)	29.71 (20.29, NE)	1.94 (1.14, 3.28)	0.0059	
Onset of disease							0.3374
Paediatric	8/ 10 (80.0)	21.43 (11.57, 28.29)	2/ 7 (28.6)	26.14 (20.14, NE)	2.10 (0.38, 11.50)	0.1663	
Adult	62/ 93 (66.7)	20.00 (16.29, 24.29)	53/ 95 (55.8)	28.29 (20.29, 42.29)	1.40 (0.97, 2.02)	0.0718	
ADA result							0.0664
Negative	63/ 91 (69.2)	20.14 (16.29, 24.29)	54/ 94 (57.4)	26.14 (20.14, 32.43)	1.34 (0.93, 1.93)	0.1063	
Positive (At any time)	7/ 11 (63.6)	16.57 (8.00, NE)	1/ 8 (12.5)	NE (35.86, NE)	NE		
BMI (kg/m2) at enrolment							0.3454
< 30	51/ 67 (76.1)	17.29 (16.14, 23.29)	42/ 78 (53.8)	27.00 (20.14, 35.86)	1.78 (1.18, 2.69)	0.0034	
>= 30	19/ 36 (52.8)	29.00 (16.29, NE)	13/ 24 (54.2)	33.14 (14.14, NE)	1.16 (0.57, 2.36)	0.6328	

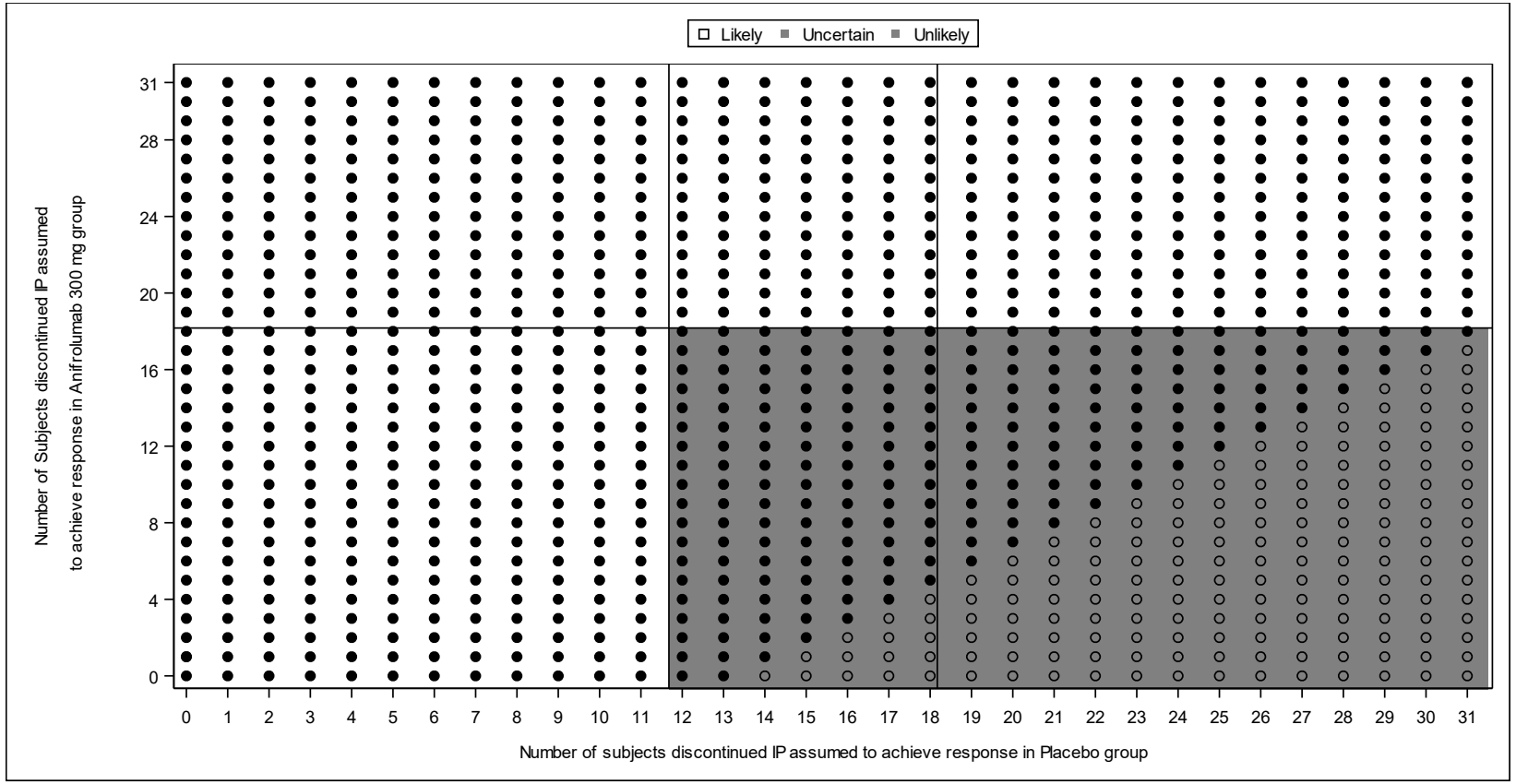
Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Time to OCS Reduction <=7.5 mg/day (for subjects with baseline OCS >=10 mg/day)
Full analysis set



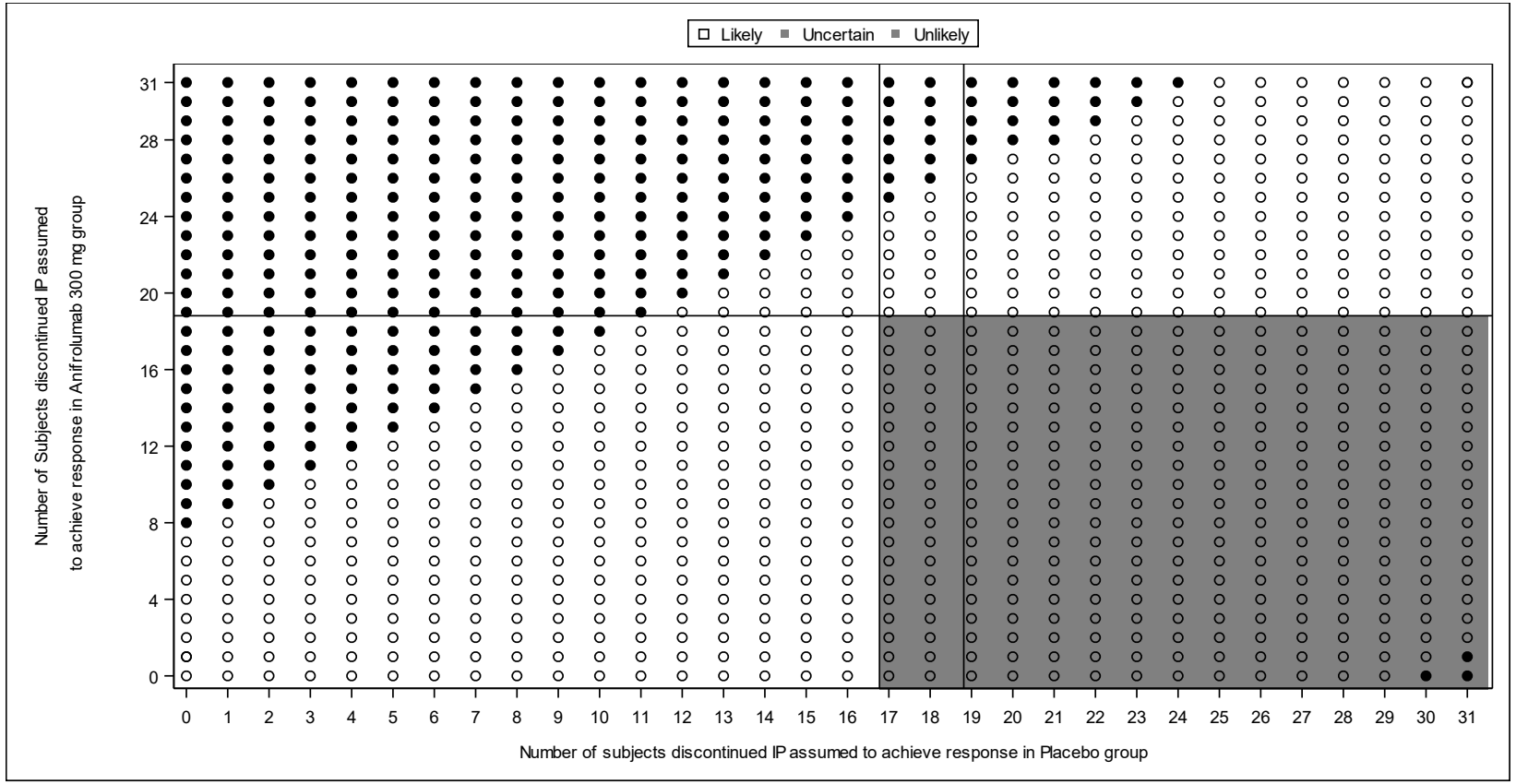
Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Plot of BICLA response rate sensitivity analysis at week 52, tipping point analysis
Full analysis set



Subjects with permanent discontinuation of IP are taken as non-responders at the bottom left grid. A certain number of such subjects from both groups are altered to be responders, while the numbers for both groups are as stated in both axes.
For each scenario, Pearson`s chi-squared test is used to compare the proportion of subjects achieving response at Week 52. The dots are presenting the results: filled = p-value <0.05, open = p-value >=0.05.
The three colors area indicate the tipping point area: white=likely, bright grey=uncertain, darker grey=Unlikely.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Plot of SRI (4) response rate sensitivity analysis at week 52, tipping point analysis
Full analysis set



Subjects with permanent discontinuation of IP are taken as non-responders at the bottom left grid. A certain number of such subjects from both groups are altered to be responders, while the numbers for both groups are as stated in both axes.
For each scenario, Pearson`s chi-squared test is used to compare the proportion of subjects achieving response at Week 52. The dots are presenting the results: filled = p-value <0.05, open = p-value >=0.05.
The three colors area indicate the tipping point area: white=likely, bright grey=uncertain, darker grey=Unlikely.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
OCS dose increases and cumulative OCS dose until week 52
Full analysis set

		Anifrolumab 300mg (N=180)	Placebo (N=184)	Total (N=364)
Number of dose increases (%)	0	121 (67.2)	118 (64.1)	239 (65.7)
	1	42 (23.3)	28 (15.2)	70 (19.2)
	2	8 (4.4)	17 (9.2)	25 (6.9)
	>2	9 (5.0)	21 (11.4)	30 (8.2)
Cumulative OCS Dose (mg/day)	n (missing)	180 (0)	184 (0)	364 (0)
	Mean (SD)	2688.9 (3881.61)	2643.5 (1979.52)	2666.0 (3066.86)
	Median	2022.3	2296.0	2137.5
	Min, Max	0, 35466	0, 9000	0, 35466
AUC up to Week 52 (mg/day)	n (missing)	180 (0)	184 (0)	364 (0)
	Mean (SD)	2906.9 (3866.81)	2913.7 (2132.99)	2910.3 (3109.14)
	Median	2308.4	2668.8	2517.1
	Min, Max	0, 35369	0, 11988	0, 35369

Subjects without any documented dose value regarded as missing values for calculation of cumulative dose and AUC.
AUC defines the cumulative dose normalized for a period of 52 weeks.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	161 (89.4)	145 (78.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.14 (1.04, 1.24)	
p-value	0.0059	
Odds Ratio (95% CI)	2.28 (1.26, 4.12)	
p-value	0.0064	
Risk Difference (95% CI)	10.64 (3.22, 18.06)	
p-value	0.0049	
CMH approach		
Response rate	89.6	78.7
Difference in response rates (95% CI)	10.91 (2.94, 18.88)	
p-value	0.0073	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.4056
< 10 points	48/ 55 (87.3)	87.8	44/ 54 (81.5)	81.2	1.07 (0.91, 1.26)	0.4071	6.60 (-8.63, 21.83)	0.3954	
>= 10 points	113/125 (90.4)	90.4	101/130 (77.7)	77.7	1.16 (1.04, 1.30)	0.0062	12.73 (3.27, 22.20)	0.0084	
OCS dose at baseline									0.6747
<10 mg/day	73/ 77 (94.8)	94.7	67/ 82 (81.7)	81.7	1.16 (1.03, 1.30)	0.0113	13.05 (1.61, 24.50)	0.0254	
>=10 mg/day	88/103 (85.4)	85.6	78/102 (76.5)	76.5	1.12 (0.98, 1.28)	0.1048	9.04 (-2.15, 20.23)	0.1132	
Result of type I IFN gene signature test									0.2216
LOW	30/ 32 (93.8)	93.8	24/ 33 (72.7)	72.7	1.29 (1.03, 1.62)	0.0285	21.02 (2.00, 40.04)	0.0303	
HIGH	131/148 (88.5)	88.7	121/151 (80.1)	80.0	1.10 (1.00, 1.22)	0.0475	8.71 (-0.07, 17.49)	0.0518	
Age (years)									0.0751
<= 65	155/173 (89.6)	89.9	142/181 (78.5)	78.3	1.14 (1.04, 1.25)	0.0045	11.56 (3.48, 19.65)	0.0051	
> 65	6/ 7 (85.7)	85.7	3/ 3 (100.0)	100.0	0.86 (0.63, 1.16)	0.3178	-14.29 (-75.13, 46.56)	0.6454	
Sex									0.6290
male	13/ 15 (86.7)	86.7	9/ 13 (69.2)	69.2	1.25 (0.83, 1.89)	0.2867	17.44 (-15.74, 50.61)	0.3029	
female	148/165 (89.7)	89.9	136/171 (79.5)	79.5	1.13 (1.03, 1.24)	0.0104	10.38 (2.14, 18.61)	0.0135	
Race									0.0994
White	112/125 (89.6)	89.3	105/137 (76.6)	76.7	1.17 (1.05, 1.31)	0.0054	12.60 (2.86, 22.35)	0.0113	
Black or African American	26/ 29 (89.7)	89.7	20/ 23 (87.0)	87.0	1.03 (0.84, 1.26)	0.7655	2.70 (-17.85, 23.25)	0.7969	
Asian	9/ 11 (81.8)	81.8	5/ 5 (100.0)	100.0	0.82 (0.62, 1.08)	0.1580	-18.18 (-63.02, 26.66)	0.4268	
American Indian or Alaska Native	0		1/ 1 (100.0)		NE		NE		
Other	14/ 15 (93.3)	93.3	14/ 18 (77.8)	77.8	1.20 (0.91, 1.59)	0.2044	15.56 (-12.08, 43.19)	0.2700	
Ethnicity									0.7222
Hispanic/Latino	30/ 32 (93.8)	93.8	28/ 35 (80.0)	80.0	1.17 (0.97, 1.41)	0.0987	13.75 (-3.95, 31.45)	0.1279	
Non-hispanic/Latino	131/148 (88.5)	88.9	117/149 (78.5)	78.3	1.13 (1.02, 1.25)	0.0215	10.57 (1.52, 19.63)	0.0221	
Geographic region									0.1865
EU	53/ 64 (82.8)	82.8	51/ 76 (67.1)	67.1	1.23 (1.02, 1.50)	0.0327	15.71 (1.36, 30.05)	0.0319	
non-EU	108/116 (93.1)	93.4	94/108 (87.0)	87.3	1.07 (0.98, 1.17)	0.1336	6.09 (-3.27, 15.45)	0.2024	
Onset of disease									0.6629
Paediatric	12/ 12 (100.0)	100.0	10/ 12 (83.3)	83.3	1.20 (0.93, 1.55)	0.1579	16.67 (-14.16, 47.49)	0.2893	
Adult	149/168 (88.7)	88.8	135/172 (78.5)	78.5	1.13 (1.03, 1.24)	0.0118	10.25 (1.91, 18.60)	0.0160	
ADA result									0.5229
Negative	147/162 (90.7)	90.9	133/169 (78.7)	78.5	1.15 (1.05, 1.26)	0.0026	12.44 (4.12, 20.76)	0.0034	
Positive (At any time)	14/ 17 (82.4)	82.4	12/ 15 (80.0)	80.0	1.03 (0.74, 1.44)	0.8655	2.35 (-27.76, 32.46)	0.8783	
BMI (kg/m2) at enrolment									0.4373
< 30	93/108 (86.1)	86.4	95/127 (74.8)	74.8	1.15 (1.01, 1.31)	0.0288	11.58 (1.18, 21.98)	0.0291	
>= 30	68/ 72 (94.4)	94.8	50/ 57 (87.7)	87.6	1.08 (0.96, 1.20)	0.1966	7.26 (-5.20, 19.72)	0.2535	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Serious Adverse Event
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	27 (15.0)	35 (19.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.79 (0.50, 1.25)	
p-value	0.3095	
Odds Ratio (95% CI)	0.75 (0.43, 1.30)	
p-value	0.3084	
Risk Difference (95% CI)	-4.02 (-11.73, 3.68)	
p-value	0.3063	
CMH approach		
Response rate	14.9	19.0
Difference in response rates (95% CI)	-4.09 (-12.33, 4.16)	
p-value	0.3312	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Serious Adverse Event - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9312
< 10 points	7/ 55 (12.7)	12.5	9/ 54 (16.7)	16.6	0.76 (0.31, 1.90)	0.5629	-4.09 (-19.20, 11.03)	0.5959	
>= 10 points	20/125 (16.0)	16.0	26/130 (20.0)	20.1	0.80 (0.47, 1.36)	0.4081	-4.07 (-14.01, 5.87)	0.4226	
OCS dose at baseline									0.7832
<10 mg/day	11/ 77 (14.3)	14.2	16/ 82 (19.5)	19.8	0.73 (0.36, 1.48)	0.3839	-5.58 (-18.11, 6.95)	0.3827	
>=10 mg/day	16/103 (15.5)	15.4	19/102 (18.6)	18.7	0.83 (0.45, 1.53)	0.5570	-3.29 (-14.35, 7.77)	0.5600	
Result of type I IFN gene signature test									0.8637
LOW	5/ 32 (15.6)	15.6	6/ 33 (18.2)	18.2	0.86 (0.29, 2.54)	0.7838	-2.56 (-22.19, 17.07)	0.7985	
HIGH	22/148 (14.9)	14.8	29/151 (19.2)	19.2	0.77 (0.47, 1.28)	0.3207	-4.42 (-13.50, 4.66)	0.3402	
Age (years)									0.9172
<= 65	25/173 (14.5)	14.4	34/181 (18.8)	18.8	0.77 (0.48, 1.23)	0.2766	-4.45 (-12.77, 3.87)	0.2947	
> 65	2/ 7 (28.6)	28.6	1/ 3 (33.3)	33.3	0.86 (0.12, 6.23)	0.8789	-4.76 (-71.14, 61.61)	0.8882	
Sex									0.9177
male	2/ 15 (13.3)	13.3	2/ 13 (15.4)	15.4	0.87 (0.14, 5.32)	0.8771	-2.05 (-32.99, 28.89)	0.8966	
female	25/165 (15.2)	15.1	33/171 (19.3)	19.3	0.79 (0.49, 1.26)	0.3168	-4.17 (-12.81, 4.47)	0.3439	
Race									0.3182
White	19/125 (15.2)	15.1	21/137 (15.3)	15.3	0.99 (0.56, 1.76)	0.9770	-0.26 (-9.92, 9.40)	0.9581	
Black or African American	4/ 29 (13.8)	13.8	8/ 23 (34.8)	34.8	0.40 (0.14, 1.15)	0.0897	-20.99 (-45.21, 3.23)	0.0894	
Asian	1/ 11 (9.1)	9.1	2/ 5 (40.0)	40.0	0.23 (0.03, 1.96)	0.1778	-30.91 (-80.46, 18.65)	0.2215	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	3/ 15 (20.0)	20.0	4/ 18 (22.2)	22.2	0.90 (0.24, 3.41)	0.8767	-2.22 (-32.55, 28.11)	0.8858	
Ethnicity									0.4425
Hispanic/Latino	7/ 32 (21.9)	21.9	7/ 35 (20.0)	20.0	1.09 (0.43, 2.78)	0.8504	1.88 (-18.62, 22.37)	0.8577	
Non-hispanic/Latino	20/148 (13.5)	13.4	28/149 (18.8)	18.8	0.72 (0.42, 1.22)	0.2199	-5.40 (-14.53, 3.72)	0.2458	
Geographic region									0.3694
EU	6/ 64 (9.4)	9.4	13/ 76 (17.1)	17.1	0.55 (0.22, 1.36)	0.1945	-7.73 (-19.53, 4.07)	0.1993	
non-EU	21/116 (18.1)	17.6	22/108 (20.4)	20.9	0.89 (0.52, 1.52)	0.6670	-3.27 (-14.41, 7.86)	0.5646	
Onset of disease									0.6350
Paediatric	3/ 12 (25.0)	25.0	5/ 12 (41.7)	41.7	0.60 (0.18, 1.97)	0.3989	-16.67 (-55.08, 21.75)	0.3951	
Adult	24/168 (14.3)	14.3	30/172 (17.4)	17.4	0.82 (0.50, 1.34)	0.4273	-3.09 (-11.48, 5.31)	0.4711	
ADA result									0.0780
Negative	26/162 (16.0)	16.0	29/169 (17.2)	17.1	0.94 (0.58, 1.52)	0.7863	-1.14 (-9.77, 7.50)	0.7961	
Positive (At any time)	1/ 17 (5.9)	5.9	6/ 15 (40.0)	40.0	0.15 (0.02, 1.09)	0.0603	-34.12 (-64.13, -4.10)	0.0259	
BMI (kg/m2) at enrolment									0.3776
< 30	15/108 (13.9)	13.7	26/127 (20.5)	20.5	0.68 (0.38, 1.21)	0.1909	-6.77 (-16.96, 3.43)	0.1932	
>= 30	12/ 72 (16.7)	16.0	9/ 57 (15.8)	15.9	1.06 (0.48, 2.33)	0.8935	0.10 (-13.93, 14.13)	0.9893	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Severe Adverse Event
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	24 (13.3)	20 (10.9)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.23 (0.70, 2.14)	
p-value	0.4720	
Odds Ratio (95% CI)	1.26 (0.67, 2.37)	
p-value	0.4716	
Risk Difference (95% CI)	2.46 (-4.24, 9.16)	
p-value	0.4711	
CMH approach		
Response rate	13.3	10.9
Difference in response rates (95% CI)	2.36 (-5.12, 9.85)	
p-value	0.5361	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Severe Adverse Event - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9306
< 10 points	6/ 55 (10.9)	10.8	5/ 54 (9.3)	9.3	1.18 (0.38, 3.63)	0.7753	1.51 (-12.70, 15.72)	0.8348	
>= 10 points	18/125 (14.4)	14.3	15/130 (11.5)	11.6	1.25 (0.66, 2.37)	0.4973	2.69 (-6.31, 11.69)	0.5578	
OCS dose at baseline									0.7607
<10 mg/day	9/ 77 (11.7)	11.6	7/ 82 (8.5)	8.7	1.37 (0.54, 3.50)	0.5112	2.93 (-8.14, 14.00)	0.6044	
>=10 mg/day	15/103 (14.6)	14.5	13/102 (12.7)	12.8	1.14 (0.57, 2.28)	0.7050	1.68 (-8.74, 12.11)	0.7520	
Result of type I IFN gene signature test									0.8103
LOW	3/ 32 (9.4)	9.4	3/ 33 (9.1)	9.1	1.03 (0.22, 4.74)	0.9684	0.28 (-16.44, 17.01)	0.9734	
HIGH	21/148 (14.2)	14.2	17/151 (11.3)	11.3	1.26 (0.69, 2.29)	0.4482	2.82 (-5.54, 11.18)	0.5090	
Age (years)									NE
<= 65	24/173 (13.9)	13.8	20/181 (11.0)	11.2	1.26 (0.72, 2.19)	0.4222	2.67 (-5.02, 10.36)	0.4961	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
Sex									0.7595
male	2/ 15 (13.3)	13.3	1/ 13 (7.7)	7.7	1.73 (0.18, 16.99)	0.6367	5.64 (-23.60, 34.88)	0.7054	
female	22/165 (13.3)	13.3	19/171 (11.1)	11.1	1.20 (0.67, 2.13)	0.5346	2.19 (-5.68, 10.06)	0.5856	
Race									0.2933
White	17/125 (13.6)	13.4	11/137 (8.0)	7.9	1.69 (0.83, 3.48)	0.1506	5.50 (-3.32, 14.33)	0.2218	
Black or African American	5/ 29 (17.2)	17.2	6/ 23 (26.1)	26.1	0.66 (0.23, 1.89)	0.4409	-8.85 (-32.71, 15.02)	0.4676	
Asian	0/ 11 (0.0)	0.0	1/ 5 (20.0)	20.0	0.17 (0.01, 3.51)	0.2491	-20.00 (-65.94, 25.94)	0.3936	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	2/ 15 (13.3)	13.3	2/ 18 (11.1)	11.1	1.20 (0.19, 7.53)	0.8457	2.22 (-25.04, 29.48)	0.8731	
Ethnicity									0.5854
Hispanic/Latino	6/ 32 (18.8)	18.8	4/ 35 (11.4)	11.4	1.64 (0.51, 5.29)	0.4072	7.32 (-11.40, 26.04)	0.4433	
Non-hispanic/Latino	18/148 (12.2)	12.5	16/149 (10.7)	10.7	1.13 (0.60, 2.13)	0.7002	1.77 (-6.61, 10.15)	0.6793	
Geographic region									0.9901
EU	6/ 64 (9.4)	9.4	6/ 76 (7.9)	7.9	1.19 (0.40, 3.50)	0.7555	1.48 (-8.90, 11.86)	0.7799	
non-EU	18/116 (15.5)	15.0	14/108 (13.0)	13.5	1.20 (0.63, 2.29)	0.5861	1.54 (-8.80, 11.88)	0.7703	
Onset of disease									0.2092
Paediatric	2/ 12 (16.7)	16.7	4/ 12 (33.3)	33.3	0.50 (0.11, 2.23)	0.3641	-16.67 (-53.42, 20.08)	0.3741	
Adult	22/168 (13.1)	13.1	16/172 (9.3)	9.3	1.41 (0.77, 2.59)	0.2702	3.76 (-3.86, 11.38)	0.3339	
ADA result									0.1553
Negative	21/162 (13.0)	13.0	15/169 (8.9)	8.9	1.46 (0.78, 2.73)	0.2361	4.07 (-3.66, 11.79)	0.3022	
Positive (At any time)	3/ 17 (17.6)	17.6	5/ 15 (33.3)	33.3	0.53 (0.15, 1.85)	0.3193	-15.69 (-47.40, 16.03)	0.3323	
BMI (kg/m2) at enrolment									0.5703
< 30	14/108 (13.0)	12.9	12/127 (9.4)	9.4	1.37 (0.66, 2.84)	0.3940	3.45 (-5.66, 12.57)	0.4577	
>= 30	10/ 72 (13.9)	13.7	8/ 57 (14.0)	14.2	0.99 (0.42, 2.34)	0.9810	-0.50 (-14.34, 13.33)	0.9430	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Non-Severe Adverse Event
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	159 (88.3)	143 (77.7)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.14 (1.03, 1.25)	
p-value	0.0075	
Odds Ratio (95% CI)	2.17 (1.22, 3.85)	
p-value	0.0080	
Risk Difference (95% CI)	10.62 (2.99, 18.24)	
p-value	0.0064	
CMH approach		
Response rate	88.6	77.6
Difference in response rates (95% CI)	10.95 (2.84, 19.06)	
p-value	0.0082	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Non-Severe Adverse Event - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.2650
< 10 points	47/ 55 (85.5)	86.1	44/ 54 (81.5)	81.2	1.05 (0.89, 1.24)	0.5775	4.93 (-10.44, 20.30)	0.5298	
>= 10 points	112/125 (89.6)	89.6	99/130 (76.2)	76.1	1.18 (1.05, 1.32)	0.0049	13.50 (3.83, 23.17)	0.0062	
OCS dose at baseline									0.7091
<10 mg/day	73/ 77 (94.8)	94.7	67/ 82 (81.7)	81.7	1.16 (1.03, 1.30)	0.0113	13.05 (1.61, 24.50)	0.0254	
>=10 mg/day	86/103 (83.5)	83.7	76/102 (74.5)	74.6	1.12 (0.97, 1.29)	0.1169	9.11 (-2.40, 20.61)	0.1208	
Result of type I IFN gene signature test									0.2292
LOW	30/ 32 (93.8)	93.8	24/ 33 (72.7)	72.7	1.29 (1.03, 1.62)	0.0285	21.02 (2.00, 40.04)	0.0303	
HIGH	129/148 (87.2)	87.4	119/151 (78.8)	78.7	1.11 (1.00, 1.23)	0.0558	8.76 (-0.21, 17.72)	0.0557	
Age (years)									0.0749
<= 65	153/173 (88.4)	88.8	140/181 (77.3)	77.2	1.14 (1.04, 1.26)	0.0060	11.60 (3.37, 19.83)	0.0057	
> 65	6/ 7 (85.7)	85.7	3/ 3 (100.0)	100.0	0.86 (0.63, 1.16)	0.3178	-14.29 (-75.13, 46.56)	0.6454	
Sex									0.6337
male	13/ 15 (86.7)	86.7	9/ 13 (69.2)	69.2	1.25 (0.83, 1.89)	0.2867	17.44 (-15.74, 50.61)	0.3029	
female	146/165 (88.5)	88.7	134/171 (78.4)	78.3	1.13 (1.03, 1.24)	0.0132	10.39 (2.00, 18.79)	0.0153	
Race									0.1013
White	111/125 (88.8)	88.5	103/137 (75.2)	75.2	1.18 (1.05, 1.32)	0.0044	13.27 (3.37, 23.17)	0.0086	
Black or African American	26/ 29 (89.7)	89.7	20/ 23 (87.0)	87.0	1.03 (0.84, 1.26)	0.7655	2.70 (-17.85, 23.25)	0.7969	
Asian	9/ 11 (81.8)	81.8	5/ 5 (100.0)	100.0	0.82 (0.62, 1.08)	0.1580	-18.18 (-63.02, 26.66)	0.4268	
American Indian or Alaska Native	0		1/ 1 (100.0)		NE		NE		
Other	13/ 15 (86.7)	86.7	14/ 18 (77.8)	77.8	1.11 (0.81, 1.53)	0.5032	8.89 (-20.25, 38.03)	0.5499	
Ethnicity									0.9680
Hispanic/Latino	29/ 32 (90.6)	90.6	28/ 35 (80.0)	80.0	1.13 (0.93, 1.38)	0.2209	10.63 (-7.77, 29.02)	0.2576	
Non-hispanic/Latino	130/148 (87.8)	88.1	115/149 (77.2)	77.0	1.14 (1.02, 1.27)	0.0167	11.10 (1.90, 20.29)	0.0180	
Geographic region									0.1282
EU	52/ 64 (81.3)	81.3	49/ 76 (64.5)	64.5	1.26 (1.03, 1.55)	0.0264	16.78 (2.12, 31.44)	0.0249	
non-EU	107/116 (92.2)	92.6	94/108 (87.0)	87.3	1.06 (0.97, 1.16)	0.2055	5.29 (-4.12, 14.69)	0.2704	
Onset of disease									0.3242
Paediatric	12/ 12 (100.0)	100.0	9/ 12 (75.0)	75.0	1.33 (0.96, 1.85)	0.0843	25.00 (-7.22, 57.22)	0.1283	
Adult	147/168 (87.5)	87.6	134/172 (77.9)	77.9	1.12 (1.02, 1.24)	0.0202	9.66 (1.21, 18.12)	0.0251	
ADA result									0.9186
Negative	145/162 (89.5)	89.8	132/169 (78.1)	77.9	1.15 (1.04, 1.26)	0.0053	11.85 (3.40, 20.30)	0.0060	
Positive (At any time)	14/ 17 (82.4)	82.4	11/ 15 (73.3)	73.3	1.12 (0.77, 1.64)	0.5456	9.02 (-22.02, 40.06)	0.5690	
BMI (kg/m2) at enrolment									0.4542
< 30	91/108 (84.3)	84.6	93/127 (73.2)	73.3	1.15 (1.01, 1.31)	0.0387	11.32 (0.66, 21.98)	0.0374	
>= 30	68/ 72 (94.4)	94.8	50/ 57 (87.7)	87.6	1.08 (0.96, 1.20)	0.1966	7.26 (-5.20, 19.72)	0.2535	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event leading to discontinuation of study drug
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	13 (7.2)	8 (4.3)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.66 (0.71, 3.91)	
p-value	0.2455	
Odds Ratio (95% CI)	1.71 (0.69, 4.24)	
p-value	0.2444	
Risk Difference (95% CI)	2.87 (-1.92, 7.67)	
p-value	0.2399	
CMH approach		
Response rate	7.2	4.3
Difference in response rates (95% CI)	2.87 (-3.31, 9.06)	
p-value	0.3620	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event leading to discontinuation of study drug - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.2332
< 10 points	5/ 55 (9.1)	9.1	1/ 54 (1.9)	1.8	4.91 (0.59, 40.65)	0.1402	7.38 (-5.35, 20.10)	0.2558	
>= 10 points	8/125 (6.4)	6.4	7/130 (5.4)	5.4	1.19 (0.44, 3.18)	0.7308	0.97 (-6.30, 8.24)	0.7936	
OCS dose at baseline									0.4711
<10 mg/day	5/ 77 (6.5)	6.5	2/ 82 (2.4)	2.4	2.66 (0.53, 13.32)	0.2333	4.11 (-5.35, 13.57)	0.3941	
>=10 mg/day	8/103 (7.8)	7.8	6/102 (5.9)	5.8	1.32 (0.47, 3.67)	0.5942	1.93 (-6.70, 10.56)	0.6613	
Result of type I IFN gene signature test									0.4147
LOW	2/ 32 (6.3)	6.3	0/ 33 (0.0)	0.0	5.15 (0.26, 103.30)	0.2839	6.25 (-7.09, 19.59)	0.3587	
HIGH	11/148 (7.4)	7.4	8/151 (5.3)	5.3	1.40 (0.58, 3.39)	0.4519	2.14 (-4.80, 9.08)	0.5459	
Age (years)									0.9771
<= 65	12/173 (6.9)	6.9	8/181 (4.4)	4.4	1.57 (0.66, 3.75)	0.3100	2.50 (-3.78, 8.79)	0.4350	
> 65	1/ 7 (14.3)	14.3	0/ 3 (0.0)	0.0	1.50 (0.08, 29.15)	0.7888	14.29 (-46.56, 75.13)	0.6454	
Sex									NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
female	13/165 (7.9)	7.8	8/171 (4.7)	4.7	1.68 (0.72, 3.96)	0.2318	3.18 (-3.46, 9.81)	0.3483	
Race									0.9188
White	9/125 (7.2)	7.2	5/137 (3.6)	3.7	1.97 (0.68, 5.73)	0.2116	3.55 (-4.12, 11.22)	0.3644	
Black or African American	1/ 29 (3.4)	3.4	1/ 23 (4.3)	4.3	0.79 (0.05, 12.01)	0.8672	-0.90 (-17.47, 15.67)	0.9152	
Asian	1/ 11 (9.1)	9.1	0/ 5 (0.0)	0.0	1.50 (0.07, 31.57)	0.7942	9.09 (-34.34, 52.53)	0.6817	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	2/ 15 (13.3)	13.3	2/ 18 (11.1)	11.1	1.20 (0.19, 7.53)	0.8457	2.22 (-25.04, 29.48)	0.8731	
Ethnicity									0.2267
Hispanic/Latino	3/ 32 (9.4)	9.4	4/ 35 (11.4)	11.4	0.82 (0.20, 3.39)	0.7843	-2.05 (-18.98, 14.87)	0.8120	
Non-hispanic/Latino	10/148 (6.8)	6.9	4/149 (2.7)	2.5	2.52 (0.81, 7.85)	0.1116	4.34 (-2.50, 11.19)	0.2139	
Geographic region									0.9508
EU	4/ 64 (6.3)	6.3	3/ 76 (3.9)	3.9	1.58 (0.37, 6.81)	0.5372	2.30 (-6.52, 11.13)	0.6091	
non-EU	9/116 (7.8)	7.8	5/108 (4.6)	4.8	1.68 (0.58, 4.84)	0.3403	2.93 (-5.88, 11.73)	0.5145	
Onset of disease									0.2608
Paediatric	1/ 12 (8.3)	8.3	2/ 12 (16.7)	16.7	0.50 (0.05, 4.81)	0.5483	-8.33 (-41.32, 24.65)	0.6205	
Adult	12/168 (7.1)	7.1	6/172 (3.5)	3.4	2.05 (0.79, 5.33)	0.1420	3.68 (-2.66, 10.01)	0.2551	
ADA result									0.4648
Negative	11/162 (6.8)	6.7	6/169 (3.6)	3.4	1.91 (0.72, 5.05)	0.1906	3.30 (-3.13, 9.73)	0.3140	
Positive (At any time)	2/ 17 (11.8)	11.8	2/ 15 (13.3)	13.3	0.88 (0.14, 5.52)	0.8935	-1.57 (-29.39, 26.25)	0.9120	
BMI (kg/m2) at enrolment									0.7794
< 30	10/108 (9.3)	9.2	7/127 (5.5)	5.5	1.68 (0.66, 4.26)	0.2749	3.70 (-4.42, 11.82)	0.3717	
>= 30	3/ 72 (4.2)	4.2	1/ 57 (1.8)	1.9	2.38 (0.25, 22.23)	0.4484	2.38 (-8.27, 13.04)	0.6609	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Serious Adverse Event leading to discontinuation of study drug
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	6 (3.3)	5 (2.7)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.23 (0.38, 3.95)	
p-value	0.7319	
Odds Ratio (95% CI)	1.23 (0.37, 4.12)	
p-value	0.7319	
Risk Difference (95% CI)	0.62 (-2.90, 4.14)	
p-value	0.7317	
CMH approach		
Response rate	3.3	2.7
Difference in response rates (95% CI)	0.56 (-4.85, 5.97)	
p-value	0.8390	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Serious Adverse Event leading to discontinuation of study drug - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.0712
< 10 points	4/ 55 (7.3)	7.2	0/ 54 (0.0)	0.0	8.84 (0.49, 160.32)	0.1405	7.21 (-4.83, 19.25)	0.2406	
>= 10 points	2/125 (1.6)	1.7	5/130 (3.8)	3.9	0.42 (0.08, 2.10)	0.2890	-2.24 (-8.40, 3.91)	0.4749	
OCS dose at baseline									0.1290
<10 mg/day	3/ 77 (3.9)	4.0	0/ 82 (0.0)	0.0	7.45 (0.39, 141.89)	0.1817	3.97 (-4.60, 12.53)	0.3640	
>=10 mg/day	3/103 (2.9)	2.8	5/102 (4.9)	4.9	0.59 (0.15, 2.42)	0.4677	-2.03 (-9.54, 5.49)	0.5969	
Result of type I IFN gene signature test									0.5218
LOW	1/ 32 (3.1)	3.1	0/ 33 (0.0)	0.0	3.09 (0.13, 73.19)	0.4846	3.13 (-9.17, 15.42)	0.6184	
HIGH	5/148 (3.4)	3.3	5/151 (3.3)	3.3	1.02 (0.30, 3.45)	0.9743	0.00 (-6.02, 6.02)	0.9993	
Age (years)									0.8258
<= 65	5/173 (2.9)	2.8	5/181 (2.8)	2.8	1.05 (0.31, 3.55)	0.9422	0.04 (-5.43, 5.51)	0.9885	
> 65	1/ 7 (14.3)	14.3	0/ 3 (0.0)	0.0	1.50 (0.08, 29.15)	0.7888	14.29 (-46.56, 75.13)	0.6454	
Sex									NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
female	6/165 (3.6)	3.6	5/171 (2.9)	2.9	1.24 (0.39, 4.00)	0.7143	0.65 (-5.15, 6.46)	0.8257	
Race									0.5099
White	4/125 (3.2)	3.3	2/137 (1.5)	1.5	2.19 (0.41, 11.76)	0.3599	1.81 (-4.94, 8.55)	0.5994	
Black or African American	0/ 29 (0.0)	0.0	1/ 23 (4.3)	4.3	0.27 (0.01, 6.26)	0.4116	-4.35 (-19.85, 11.16)	0.5826	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	2/ 15 (13.3)	13.3	2/ 18 (11.1)	11.1	1.20 (0.19, 7.53)	0.8457	2.22 (-25.04, 29.48)	0.8731	
Ethnicity									0.4233
Hispanic/Latino	1/ 32 (3.1)	3.1	2/ 35 (5.7)	5.7	0.55 (0.05, 5.75)	0.6150	-2.59 (-16.47, 11.29)	0.7147	
Non-hispanic/Latino	5/148 (3.4)	3.2	3/149 (2.0)	1.9	1.68 (0.41, 6.89)	0.4729	1.35 (-4.84, 7.54)	0.6689	
Geographic region									0.4955
EU	1/ 64 (1.6)	1.6	2/ 76 (2.6)	2.6	0.59 (0.06, 6.40)	0.6674	-1.07 (-8.09, 5.95)	0.7654	
non-EU	5/116 (4.3)	4.5	3/108 (2.8)	3.1	1.55 (0.38, 6.34)	0.5406	1.43 (-6.75, 9.60)	0.7324	
Onset of disease									0.3712
Paediatric	0/ 12 (0.0)	0.0	1/ 12 (8.3)	8.3	0.33 (0.01, 7.45)	0.4883	-8.33 (-37.28, 20.61)	0.5726	
Adult	6/168 (3.6)	3.5	4/172 (2.3)	2.3	1.54 (0.44, 5.34)	0.5002	1.23 (-4.42, 6.89)	0.6691	
ADA result									0.1389
Negative	6/162 (3.7)	3.6	3/169 (1.8)	1.7	2.09 (0.53, 8.20)	0.2924	1.86 (-3.83, 7.56)	0.5215	
Positive (At any time)	0/ 17 (0.0)	0.0	2/ 15 (13.3)	13.3	0.18 (0.01, 3.43)	0.2529	-13.33 (-38.24, 11.57)	0.2941	
BMI (kg/m2) at enrolment									0.8314
< 30	4/108 (3.7)	3.5	4/127 (3.1)	3.1	1.18 (0.30, 4.59)	0.8156	0.41 (-6.25, 7.06)	0.9050	
>= 30	2/ 72 (2.8)	2.7	1/ 57 (1.8)	1.9	1.58 (0.15, 17.03)	0.7045	0.85 (-9.52, 11.21)	0.8729	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with Adverse Event leading to death
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	1 (0.6)	1 (0.5)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.02 (0.06, 16.22)	
p-value	0.9876	
Odds Ratio (95% CI)	1.02 (0.06, 16.47)	
p-value	0.9876	
Risk Difference (95% CI)	0.01 (-1.51, 1.53)	
p-value	0.9876	
CMH approach		
Response rate	0.5	0.5
Difference in response rates (95% CI)	-0.05 (-4.65, 4.56)	
p-value	0.9844	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with Adverse Event leading to death - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.3517
< 10 points	1/ 55 (1.8)	1.7	0/ 54 (0.0)	0.0	2.95 (0.12, 70.77)	0.5053	1.68 (-9.37, 12.72)	0.7661	
>= 10 points	0/125 (0.0)	0.0	1/130 (0.8)	0.8	0.35 (0.01, 8.43)	0.5152	-0.78 (-5.91, 4.35)	0.7660	
OCS dose at baseline									NE
<10 mg/day	0/ 77 (0.0)	0.0	0/ 82 (0.0)	0.0	NE		0.00 (-7.65, 7.65)	1.0000	
>=10 mg/day	1/103 (1.0)	0.9	1/102 (1.0)	1.0	0.99 (0.06, 15.62)	0.9945	-0.08 (-6.44, 6.28)	0.9800	
Result of type I IFN gene signature test									NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE		0.00 (-11.07, 11.07)	1.0000	
HIGH	1/148 (0.7)	0.6	1/151 (0.7)	0.7	1.02 (0.06, 16.16)	0.9886	-0.06 (-5.12, 5.01)	0.9827	
Age (years)									NE
<= 65	1/173 (0.6)	0.5	1/181 (0.6)	0.6	1.05 (0.07, 16.60)	0.9744	-0.06 (-4.78, 4.67)	0.9810	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
Sex									NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
female	1/165 (0.6)	0.5	1/171 (0.6)	0.6	1.04 (0.07, 16.43)	0.9798	-0.04 (-4.98, 4.91)	0.9878	
Race									0.2530
White	0/125 (0.0)	0.0	0/137 (0.0)	0.0	NE		0.00 (-5.97, 5.97)	1.0000	
Black or African American	0/ 29 (0.0)	0.0	1/ 23 (4.3)	4.3	0.27 (0.01, 6.26)	0.4116	-4.35 (-19.85, 11.16)	0.5826	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	1/ 15 (6.7)	6.7	0/ 18 (0.0)	0.0	3.56 (0.16, 81.55)	0.4264	6.67 (-16.07, 29.40)	0.5655	
Ethnicity									0.3208
Hispanic/Latino	1/ 32 (3.1)	3.1	0/ 35 (0.0)	0.0	3.27 (0.14, 77.57)	0.4629	3.13 (-8.92, 15.17)	0.6111	
Non-hispanic/Latino	0/148 (0.0)	0.0	1/149 (0.7)	0.6	0.34 (0.01, 8.17)	0.5026	-0.63 (-6.12, 4.86)	0.8224	
Geographic region									NE
EU	0/ 64 (0.0)	0.0	0/ 76 (0.0)	0.0	NE		0.00 (-5.43, 5.43)	1.0000	
non-EU	1/116 (0.9)	0.8	1/108 (0.9)	1.0	0.93 (0.06, 14.70)	0.9595	-0.23 (-7.49, 7.02)	0.9498	
Onset of disease									NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
Adult	1/168 (0.6)	0.6	1/172 (0.6)	0.6	1.02 (0.06, 16.24)	0.9867	-0.01 (-4.91, 4.88)	0.9953	
ADA result									NE
Negative	1/162 (0.6)	0.5	1/169 (0.6)	0.6	1.04 (0.07, 16.54)	0.9761	-0.04 (-5.06, 4.98)	0.9866	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE		0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment									0.2603
< 30	1/108 (0.9)	0.8	0/127 (0.0)	0.0	3.52 (0.14, 85.60)	0.4392	0.84 (-4.64, 6.32)	0.7635	
>= 30	0/ 72 (0.0)	0.0	1/ 57 (1.8)	1.9	0.26 (0.01, 6.38)	0.4131	-1.86 (-11.75, 8.03)	0.7119	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Anaphylaxis
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.42, 4.42)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Anaphylaxis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 55 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>= 10 points	0/125 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 77 (0.0)	0.0	0/ 82 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
>=10 mg/day	0/103 (0.0)	0.0	0/102 (0.0)	0.0	NE	0.00 (-5.93, 5.93)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-11.07, 11.07)	1.0000	
HIGH	0/148 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.81, 4.81)	1.0000	
Age (years)								NE
<= 65	0/173 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.54, 4.54)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
Sex								NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
female	0/165 (0.0)	0.0	0/171 (0.0)	0.0	NE	0.00 (-4.75, 4.75)	1.0000	
Race								NE
White	0/125 (0.0)	0.0	0/137 (0.0)	0.0	NE	0.00 (-5.97, 5.97)	1.0000	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-20.43, 20.43)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE	0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	0/148 (0.0)	0.0	0/149 (0.0)	0.0	NE	0.00 (-5.37, 5.37)	1.0000	
Geographic region								NE
EU	0/ 64 (0.0)	0.0	0/ 76 (0.0)	0.0	NE	0.00 (-5.43, 5.43)	1.0000	
non-EU	0/116 (0.0)	0.0	0/108 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Onset of disease								NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
Adult	0/168 (0.0)	0.0	0/172 (0.0)	0.0	NE	0.00 (-4.70, 4.70)	1.0000	
ADA result								NE
Negative	0/162 (0.0)	0.0	0/169 (0.0)	0.0	NE	0.00 (-4.83, 4.83)	1.0000	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE	0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/108 (0.0)	0.0	0/127 (0.0)	0.0	NE	0.00 (-5.30, 5.30)	1.0000	
>= 30	0/ 72 (0.0)	0.0	0/ 57 (0.0)	0.0	NE	0.00 (-9.40, 9.40)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Anaphylaxis
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.42, 4.42)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Anaphylaxis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 55 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>= 10 points	0/125 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 77 (0.0)	0.0	0/ 82 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
>=10 mg/day	0/103 (0.0)	0.0	0/102 (0.0)	0.0	NE	0.00 (-5.93, 5.93)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-11.07, 11.07)	1.0000	
HIGH	0/148 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.81, 4.81)	1.0000	
Age (years)								NE
<= 65	0/173 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.54, 4.54)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
Sex								NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
female	0/165 (0.0)	0.0	0/171 (0.0)	0.0	NE	0.00 (-4.75, 4.75)	1.0000	
Race								NE
White	0/125 (0.0)	0.0	0/137 (0.0)	0.0	NE	0.00 (-5.97, 5.97)	1.0000	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-20.43, 20.43)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE	0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	0/148 (0.0)	0.0	0/149 (0.0)	0.0	NE	0.00 (-5.37, 5.37)	1.0000	
Geographic region								NE
EU	0/ 64 (0.0)	0.0	0/ 76 (0.0)	0.0	NE	0.00 (-5.43, 5.43)	1.0000	
non-EU	0/116 (0.0)	0.0	0/108 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Onset of disease								NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
Adult	0/168 (0.0)	0.0	0/172 (0.0)	0.0	NE	0.00 (-4.70, 4.70)	1.0000	
ADA result								NE
Negative	0/162 (0.0)	0.0	0/169 (0.0)	0.0	NE	0.00 (-4.83, 4.83)	1.0000	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE	0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/108 (0.0)	0.0	0/127 (0.0)	0.0	NE	0.00 (-5.30, 5.30)	1.0000	
>= 30	0/ 72 (0.0)	0.0	0/ 57 (0.0)	0.0	NE	0.00 (-9.40, 9.40)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Anaphylaxis
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.42, 4.42)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Anaphylaxis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 55 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>= 10 points	0/125 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 77 (0.0)	0.0	0/ 82 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
>=10 mg/day	0/103 (0.0)	0.0	0/102 (0.0)	0.0	NE	0.00 (-5.93, 5.93)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-11.07, 11.07)	1.0000	
HIGH	0/148 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.81, 4.81)	1.0000	
Age (years)								NE
<= 65	0/173 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.54, 4.54)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
Sex								NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
female	0/165 (0.0)	0.0	0/171 (0.0)	0.0	NE	0.00 (-4.75, 4.75)	1.0000	
Race								NE
White	0/125 (0.0)	0.0	0/137 (0.0)	0.0	NE	0.00 (-5.97, 5.97)	1.0000	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-20.43, 20.43)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE	0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	0/148 (0.0)	0.0	0/149 (0.0)	0.0	NE	0.00 (-5.37, 5.37)	1.0000	
Geographic region								NE
EU	0/ 64 (0.0)	0.0	0/ 76 (0.0)	0.0	NE	0.00 (-5.43, 5.43)	1.0000	
non-EU	0/116 (0.0)	0.0	0/108 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Onset of disease								NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
Adult	0/168 (0.0)	0.0	0/172 (0.0)	0.0	NE	0.00 (-4.70, 4.70)	1.0000	
ADA result								NE
Negative	0/162 (0.0)	0.0	0/169 (0.0)	0.0	NE	0.00 (-4.83, 4.83)	1.0000	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE	0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/108 (0.0)	0.0	0/127 (0.0)	0.0	NE	0.00 (-5.30, 5.30)	1.0000	
>= 30	0/ 72 (0.0)	0.0	0/ 57 (0.0)	0.0	NE	0.00 (-9.40, 9.40)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Anaphylaxis
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.42, 4.42)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Anaphylaxis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 55 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>= 10 points	0/125 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 77 (0.0)	0.0	0/ 82 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
>=10 mg/day	0/103 (0.0)	0.0	0/102 (0.0)	0.0	NE	0.00 (-5.93, 5.93)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-11.07, 11.07)	1.0000	
HIGH	0/148 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.81, 4.81)	1.0000	
Age (years)								NE
<= 65	0/173 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.54, 4.54)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
Sex								NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
female	0/165 (0.0)	0.0	0/171 (0.0)	0.0	NE	0.00 (-4.75, 4.75)	1.0000	
Race								NE
White	0/125 (0.0)	0.0	0/137 (0.0)	0.0	NE	0.00 (-5.97, 5.97)	1.0000	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-20.43, 20.43)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE	0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	0/148 (0.0)	0.0	0/149 (0.0)	0.0	NE	0.00 (-5.37, 5.37)	1.0000	
Geographic region								NE
EU	0/ 64 (0.0)	0.0	0/ 76 (0.0)	0.0	NE	0.00 (-5.43, 5.43)	1.0000	
non-EU	0/116 (0.0)	0.0	0/108 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Onset of disease								NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
Adult	0/168 (0.0)	0.0	0/172 (0.0)	0.0	NE	0.00 (-4.70, 4.70)	1.0000	
ADA result								NE
Negative	0/162 (0.0)	0.0	0/169 (0.0)	0.0	NE	0.00 (-4.83, 4.83)	1.0000	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE	0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/108 (0.0)	0.0	0/127 (0.0)	0.0	NE	0.00 (-5.30, 5.30)	1.0000	
>= 30	0/ 72 (0.0)	0.0	0/ 57 (0.0)	0.0	NE	0.00 (-9.40, 9.40)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	10 (5.6)	3 (1.6)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.41 (0.95, 12.18)	
p-value	0.0592	
Odds Ratio (95% CI)	3.55 (0.96, 13.11)	
p-value	0.0575	
Risk Difference (95% CI)	3.93 (0.11, 7.74)	
p-value	0.0437	
CMH approach		
Response rate	5.6	1.7
Difference in response rates (95% CI)	3.95 (-1.67, 9.58)	
p-value	0.1685	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.1377
< 10 points	2/ 55 (3.6)	3.9	2/ 54 (3.7)	3.8	0.98 (0.14, 6.72)	0.9851	0.09 (-12.12, 12.29)	0.9888	
>= 10 points	8/125 (6.4)	6.4	1/130 (0.8)	0.8	8.32 (1.06, 65.56)	0.0443	5.61 (-0.86, 12.08)	0.0891	
OCS dose at baseline									0.5740
<10 mg/day	5/ 77 (6.5)	6.4	1/ 82 (1.2)	1.2	5.32 (0.64, 44.56)	0.1229	5.22 (-3.96, 14.40)	0.2654	
>=10 mg/day	5/103 (4.9)	4.9	2/102 (2.0)	2.0	2.48 (0.49, 12.47)	0.2718	2.89 (-4.63, 10.41)	0.4514	
Result of type I IFN gene signature test									0.7021
LOW	2/ 32 (6.3)	6.3	0/ 33 (0.0)	0.0	5.15 (0.26, 103.30)	0.2839	6.25 (-7.09, 19.59)	0.3587	
HIGH	8/148 (5.4)	5.5	3/151 (2.0)	2.0	2.72 (0.74, 10.06)	0.1335	3.45 (-2.75, 9.65)	0.2755	
Age (years)									NE
<= 65	10/173 (5.8)	5.9	3/181 (1.7)	1.7	3.49 (0.98, 12.46)	0.0545	4.16 (-1.64, 9.96)	0.1595	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
Sex									0.7803
male	2/ 15 (13.3)	13.3	0/ 13 (0.0)	0.0	4.37 (0.23, 83.62)	0.3269	13.33 (-13.73, 40.40)	0.3342	
female	8/165 (4.8)	4.9	3/171 (1.8)	1.8	2.76 (0.75, 10.24)	0.1282	3.07 (-2.79, 8.94)	0.3047	
Race									0.9109
White	8/125 (6.4)	6.3	3/137 (2.2)	2.1	2.92 (0.79, 10.77)	0.1071	4.22 (-3.08, 11.52)	0.2573	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-13.78, 13.78)	1.0000	
Asian	1/ 11 (9.1)	9.1	0/ 5 (0.0)	0.0	1.50 (0.07, 31.57)	0.7942	9.09 (-34.34, 52.53)	0.6817	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	1/ 15 (6.7)	6.7	0/ 18 (0.0)	0.0	3.56 (0.16, 81.55)	0.4264	6.67 (-16.07, 29.40)	0.5655	
Ethnicity									0.6711
Hispanic/Latino	2/ 32 (6.3)	6.3	0/ 35 (0.0)	0.0	5.45 (0.27, 109.49)	0.2676	6.25 (-6.86, 19.36)	0.3502	
Non-hispanic/Latino	8/148 (5.4)	5.7	3/149 (2.0)	2.1	2.68 (0.73, 9.92)	0.1387	3.59 (-3.06, 10.24)	0.2898	
Geographic region									0.3504
EU	3/ 64 (4.7)	4.7	2/ 76 (2.6)	2.6	1.78 (0.31, 10.33)	0.5198	2.06 (-6.00, 10.11)	0.6169	
non-EU	7/116 (6.0)	6.2	1/108 (0.9)	0.9	6.52 (0.82, 52.11)	0.0772	5.29 (-2.74, 13.32)	0.1970	
Onset of disease									0.5046
Paediatric	3/ 12 (25.0)	25.0	0/ 12 (0.0)	0.0	7.00 (0.40, 122.44)	0.1826	25.00 (-7.22, 57.22)	0.1283	
Adult	7/168 (4.2)	4.2	3/172 (1.7)	1.8	2.39 (0.63, 9.08)	0.2013	2.40 (-3.30, 8.10)	0.4090	
ADA result									NE
Negative	10/162 (6.2)	6.3	3/169 (1.8)	1.8	3.48 (0.97, 12.41)	0.0548	4.50 (-1.66, 10.67)	0.1524	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE		0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment									0.4499
< 30	8/108 (7.4)	7.6	2/127 (1.6)	1.6	4.70 (1.02, 21.68)	0.0470	5.97 (-1.31, 13.25)	0.1082	
>= 30	2/ 72 (2.8)	2.8	1/ 57 (1.8)	1.6	1.58 (0.15, 17.03)	0.7045	1.21 (-9.08, 11.50)	0.8173	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.42, 4.42)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Anifrolumab 300mg (N=180) Response rate	Placebo (N=184) n/ N (%)	Placebo (N=184) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Analysis Anifrolumab 300mg vs. Placebo Difference in response rates (95% CI)	Analysis Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 55 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>= 10 points	0/125 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 77 (0.0)	0.0	0/ 82 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
>=10 mg/day	0/103 (0.0)	0.0	0/102 (0.0)	0.0	NE	0.00 (-5.93, 5.93)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-11.07, 11.07)	1.0000	
HIGH	0/148 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.81, 4.81)	1.0000	
Age (years)								NE
<= 65	0/173 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.54, 4.54)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
Sex								NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
female	0/165 (0.0)	0.0	0/171 (0.0)	0.0	NE	0.00 (-4.75, 4.75)	1.0000	
Race								NE
White	0/125 (0.0)	0.0	0/137 (0.0)	0.0	NE	0.00 (-5.97, 5.97)	1.0000	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0	NE	0/ 1 (0.0)		NE	NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-20.43, 20.43)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE	0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	0/148 (0.0)	0.0	0/149 (0.0)	0.0	NE	0.00 (-5.37, 5.37)	1.0000	
Geographic region								NE
EU	0/ 64 (0.0)	0.0	0/ 76 (0.0)	0.0	NE	0.00 (-5.43, 5.43)	1.0000	
non-EU	0/116 (0.0)	0.0	0/108 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Onset of disease								NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
Adult	0/168 (0.0)	0.0	0/172 (0.0)	0.0	NE	0.00 (-4.70, 4.70)	1.0000	
ADA result								NE
Negative	0/162 (0.0)	0.0	0/169 (0.0)	0.0	NE	0.00 (-4.83, 4.83)	1.0000	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE	0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/108 (0.0)	0.0	0/127 (0.0)	0.0	NE	0.00 (-5.30, 5.30)	1.0000	
>= 30	0/ 72 (0.0)	0.0	0/ 57 (0.0)	0.0	NE	0.00 (-9.40, 9.40)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	1 (0.6)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.07 (0.13, 74.78)	
p-value	0.4917	
Odds Ratio (95% CI)	3.08 (0.12, 76.19)	
p-value	0.4913	
Risk Difference (95% CI)	0.56 (-0.53, 1.64)	
p-value	0.3160	
CMH approach		
Response rate	0.6	0.0
Difference in response rates (95% CI)	0.58 (-3.95, 5.11)	
p-value	0.8023	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 55 (0.0)	0.0	0/ 54 (0.0)	0.0	NE		0.00 (-10.69, 10.69)	1.0000	
>= 10 points	1/125 (0.8)	0.8	0/130 (0.0)	0.0	3.12 (0.13, 75.85)	0.4848	0.83 (-4.31, 5.96)	0.7527	
OCS dose at baseline									NE
<10 mg/day	1/ 77 (1.3)	1.3	0/ 82 (0.0)	0.0	3.19 (0.13, 77.20)	0.4751	1.33 (-6.67, 9.32)	0.7452	
>=10 mg/day	0/103 (0.0)	0.0	0/102 (0.0)	0.0	NE		0.00 (-5.93, 5.93)	1.0000	
Result of type I IFN gene signature test									NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE		0.00 (-11.07, 11.07)	1.0000	
HIGH	1/148 (0.7)	0.7	0/151 (0.0)	0.0	3.06 (0.13, 74.53)	0.4923	0.70 (-4.26, 5.67)	0.7808	
Age (years)									NE
<= 65	1/173 (0.6)	0.6	0/181 (0.0)	0.0	3.14 (0.13, 76.51)	0.4828	0.61 (-4.05, 5.27)	0.7970	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
Sex									NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
female	1/165 (0.6)	0.6	0/171 (0.0)	0.0	3.11 (0.13, 75.76)	0.4864	0.64 (-4.24, 5.51)	0.7981	
Race									NE
White	1/125 (0.8)	0.8	0/137 (0.0)	0.0	3.29 (0.14, 79.92)	0.4651	0.81 (-5.31, 6.93)	0.7954	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-20.43, 20.43)	1.0000	
Ethnicity									NE
Hispanic/Latino	1/ 32 (3.1)	3.1	0/ 35 (0.0)	0.0	3.27 (0.14, 77.57)	0.4629	3.13 (-8.92, 15.17)	0.6111	
Non-hispanic/Latino	0/148 (0.0)	0.0	0/149 (0.0)	0.0	NE		0.00 (-5.37, 5.37)	1.0000	
Geographic region									NE
EU	0/ 64 (0.0)	0.0	0/ 76 (0.0)	0.0	NE		0.00 (-5.43, 5.43)	1.0000	
non-EU	1/116 (0.9)	0.9	0/108 (0.0)	0.0	2.79 (0.12, 67.88)	0.5277	0.95 (-6.17, 8.07)	0.7939	
Onset of disease									NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
Adult	1/168 (0.6)	0.6	0/172 (0.0)	0.0	3.07 (0.13, 74.86)	0.4911	0.63 (-4.20, 5.45)	0.7985	
ADA result									NE
Negative	1/162 (0.6)	0.6	0/169 (0.0)	0.0	3.13 (0.13, 76.25)	0.4839	0.63 (-4.32, 5.59)	0.8025	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE		0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/108 (0.0)	0.0	0/127 (0.0)	0.0	NE		0.00 (-5.30, 5.30)	1.0000	
>= 30	1/ 72 (1.4)	1.3	0/ 57 (0.0)	0.0	2.38 (0.10, 57.43)	0.5926	1.29 (-8.37, 10.96)	0.7930	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	9 (5.0)	3 (1.6)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.07 (0.84, 11.14)	
p-value	0.0887	
Odds Ratio (95% CI)	3.18 (0.85, 11.93)	
p-value	0.0870	
Risk Difference (95% CI)	3.37 (-0.30, 7.04)	
p-value	0.0721	
CMH approach		
Response rate	5.0	1.7
Difference in response rates (95% CI)	3.37 (-2.17, 8.91)	
p-value	0.2326	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.1658
< 10 points	2/ 55 (3.6)	3.9	2/ 54 (3.7)	3.8	0.98 (0.14, 6.72)	0.9851	0.09 (-12.12, 12.29)	0.9888	
>= 10 points	7/125 (5.6)	5.6	1/130 (0.8)	0.8	7.28 (0.91, 58.32)	0.0615	4.79 (-1.53, 11.10)	0.1375	
OCS dose at baseline									0.6942
<10 mg/day	4/ 77 (5.2)	5.1	1/ 82 (1.2)	1.2	4.26 (0.49, 37.28)	0.1904	3.89 (-5.01, 12.80)	0.3915	
>=10 mg/day	5/103 (4.9)	4.9	2/102 (2.0)	2.0	2.48 (0.49, 12.47)	0.2718	2.89 (-4.63, 10.41)	0.4514	
Result of type I IFN gene signature test									0.6448
LOW	2/ 32 (6.3)	6.3	0/ 33 (0.0)	0.0	5.15 (0.26, 103.30)	0.2839	6.25 (-7.09, 19.59)	0.3587	
HIGH	7/148 (4.7)	4.8	3/151 (2.0)	2.0	2.38 (0.63, 9.03)	0.2023	2.75 (-3.34, 8.83)	0.3765	
Age (years)									NE
<= 65	9/173 (5.2)	5.3	3/181 (1.7)	1.7	3.14 (0.86, 11.40)	0.0822	3.55 (-2.16, 9.26)	0.2228	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
Sex									0.7197
male	2/ 15 (13.3)	13.3	0/ 13 (0.0)	0.0	4.37 (0.23, 83.62)	0.3269	13.33 (-13.73, 40.40)	0.3342	
female	7/165 (4.2)	4.2	3/171 (1.8)	1.8	2.42 (0.64, 9.19)	0.1950	2.43 (-3.33, 8.19)	0.4074	
Race									0.9240
White	7/125 (5.6)	5.5	3/137 (2.2)	2.1	2.56 (0.68, 9.68)	0.1666	3.41 (-3.78, 10.59)	0.3524	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-13.78, 13.78)	1.0000	
Asian	1/ 11 (9.1)	9.1	0/ 5 (0.0)	0.0	1.50 (0.07, 31.57)	0.7942	9.09 (-34.34, 52.53)	0.6817	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	1/ 15 (6.7)	6.7	0/ 18 (0.0)	0.0	3.56 (0.16, 81.55)	0.4264	6.67 (-16.07, 29.40)	0.5655	
Ethnicity									0.9098
Hispanic/Latino	1/ 32 (3.1)	3.1	0/ 35 (0.0)	0.0	3.27 (0.14, 77.57)	0.4629	3.13 (-8.92, 15.17)	0.6111	
Non-hispanic/Latino	8/148 (5.4)	5.7	3/149 (2.0)	2.1	2.68 (0.73, 9.92)	0.1387	3.59 (-3.06, 10.24)	0.2898	
Geographic region									0.4135
EU	3/ 64 (4.7)	4.7	2/ 76 (2.6)	2.6	1.78 (0.31, 10.33)	0.5198	2.06 (-6.00, 10.11)	0.6169	
non-EU	6/116 (5.2)	5.2	1/108 (0.9)	0.9	5.59 (0.68, 45.65)	0.1085	4.34 (-3.55, 12.22)	0.2811	
Onset of disease									0.4476
Paediatric	3/ 12 (25.0)	25.0	0/ 12 (0.0)	0.0	7.00 (0.40, 122.44)	0.1826	25.00 (-7.22, 57.22)	0.1283	
Adult	6/168 (3.6)	3.6	3/172 (1.7)	1.8	2.05 (0.52, 8.05)	0.3050	1.77 (-3.83, 7.38)	0.5350	
ADA result									NE
Negative	9/162 (5.6)	5.7	3/169 (1.8)	1.8	3.13 (0.86, 11.36)	0.0827	3.87 (-2.20, 9.94)	0.2118	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE		0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment									0.2669
< 30	8/108 (7.4)	7.6	2/127 (1.6)	1.6	4.70 (1.02, 21.68)	0.0470	5.97 (-1.31, 13.25)	0.1082	
>= 30	1/ 72 (1.4)	1.5	1/ 57 (1.8)	1.6	0.79 (0.05, 12.38)	0.8678	-0.08 (-10.12, 9.96)	0.9874	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Herpes Zoster leading to discontinuation of study drug
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	2 (1.1)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	5.11 (0.25, 105.71)	
p-value	0.2912	
Odds Ratio (95% CI)	5.17 (0.25, 108.40)	
p-value	0.2901	
Risk Difference (95% CI)	1.11 (-0.42, 2.64)	
p-value	0.1550	
CMH approach		
Response rate	1.1	0.0
Difference in response rates (95% CI)	1.11 (-3.53, 5.75)	
p-value	0.6395	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Herpes Zoster leading to discontinuation of study drug - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 55 (0.0)	0.0	0/ 54 (0.0)	0.0	NE		0.00 (-10.69, 10.69)	1.0000	
>= 10 points	2/125 (1.6)	1.6	0/130 (0.0)	0.0	5.20 (0.25, 107.22)	0.2858	1.58 (-3.75, 6.91)	0.5609	
OCS dose at baseline									NE
<10 mg/day	0/ 77 (0.0)	0.0	0/ 82 (0.0)	0.0	NE		0.00 (-7.65, 7.65)	1.0000	
>=10 mg/day	2/103 (1.9)	2.0	0/102 (0.0)	0.0	4.95 (0.24, 101.89)	0.2998	1.97 (-4.48, 8.42)	0.5492	
Result of type I IFN gene signature test									NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE		0.00 (-11.07, 11.07)	1.0000	
HIGH	2/148 (1.4)	1.4	0/151 (0.0)	0.0	5.10 (0.25, 105.35)	0.2916	1.35 (-3.76, 6.46)	0.6046	
Age (years)									NE
<= 65	2/173 (1.2)	1.2	0/181 (0.0)	0.0	5.23 (0.25, 108.16)	0.2844	1.15 (-3.62, 5.93)	0.6365	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
Sex									NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
female	2/165 (1.2)	1.2	0/171 (0.0)	0.0	5.18 (0.25, 107.11)	0.2871	1.21 (-3.78, 6.21)	0.6342	
Race									NE
White	2/125 (1.6)	1.6	0/137 (0.0)	0.0	5.48 (0.27, 112.97)	0.2709	1.60 (-4.69, 7.90)	0.6176	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-20.43, 20.43)	1.0000	
Ethnicity									0.9721
Hispanic/Latino	1/ 32 (3.1)	3.1	0/ 35 (0.0)	0.0	3.27 (0.14, 77.57)	0.4629	3.13 (-8.92, 15.17)	0.6111	
Non-hispanic/Latino	1/148 (0.7)	0.7	0/149 (0.0)	0.0	3.02 (0.12, 73.54)	0.4974	0.73 (-4.80, 6.26)	0.7954	
Geographic region									0.9168
EU	1/ 64 (1.6)	1.6	0/ 76 (0.0)	0.0	3.55 (0.15, 85.76)	0.4350	1.56 (-4.57, 7.70)	0.6176	
non-EU	1/116 (0.9)	0.8	0/108 (0.0)	0.0	2.79 (0.12, 67.88)	0.5277	0.77 (-6.30, 7.84)	0.8315	
Onset of disease									0.9918
Paediatric	1/ 12 (8.3)	8.3	0/ 12 (0.0)	0.0	3.00 (0.13, 67.06)	0.4883	8.33 (-20.61, 37.28)	0.5726	
Adult	1/168 (0.6)	0.6	0/172 (0.0)	0.0	3.07 (0.13, 74.86)	0.4911	0.60 (-4.22, 5.43)	0.8063	
ADA result									NE
Negative	2/162 (1.2)	1.3	0/169 (0.0)	0.0	5.21 (0.25, 107.80)	0.2852	1.27 (-3.82, 6.37)	0.6239	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE		0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	2/108 (1.9)	1.9	0/127 (0.0)	0.0	5.87 (0.28, 120.99)	0.2515	1.90 (-3.94, 7.74)	0.5234	
>= 30	0/ 72 (0.0)	0.0	0/ 57 (0.0)	0.0	NE		0.00 (-9.40, 9.40)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Hypersensitivity
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	11 (6.1)	2 (1.1)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	5.62 (1.26, 25.01)	
p-value	0.0234	
Odds Ratio (95% CI)	5.92 (1.29, 27.11)	
p-value	0.0219	
Risk Difference (95% CI)	5.02 (1.22, 8.83)	
p-value	0.0097	
CMH approach		
Response rate	6.2	1.1
Difference in response rates (95% CI)	5.14 (-0.36, 10.64)	
p-value	0.0668	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Hypersensitivity - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Anifrolumab 300mg (N=180) Response rate	Placebo (N=184) n/ N (%)	Placebo (N=184) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8747
< 10 points	5/ 55 (9.1)	9.6	1/ 54 (1.9)	1.8	4.91 (0.59, 40.65)	0.1402	7.88 (-4.77, 20.54)	0.2221	
>= 10 points	6/125 (4.8)	4.8	1/130 (0.8)	0.8	6.24 (0.76, 51.10)	0.0879	3.98 (-2.03, 9.98)	0.1942	
OCS dose at baseline									0.4977
<10 mg/day	8/ 77 (10.4)	10.2	1/ 82 (1.2)	1.2	8.52 (1.09, 66.54)	0.0411	8.98 (-0.63, 18.59)	0.0669	
>=10 mg/day	3/103 (2.9)	3.1	1/102 (1.0)	1.0	2.97 (0.31, 28.09)	0.3421	2.11 (-4.66, 8.88)	0.5409	
Result of type I IFN gene signature test									0.3200
LOW	6/ 32 (18.8)	18.8	0/ 33 (0.0)	0.0	13.39 (0.79, 228.40)	0.0730	18.75 (2.41, 35.09)	0.0245	
HIGH	5/148 (3.4)	3.5	2/151 (1.3)	1.3	2.55 (0.50, 12.94)	0.2585	2.18 (-3.49, 7.85)	0.4518	
Age (years)									0.9104
<= 65	8/173 (4.6)	4.7	2/181 (1.1)	1.1	4.18 (0.90, 19.43)	0.0677	3.66 (-1.81, 9.13)	0.1899	
> 65	3/ 7 (42.9)	42.9	0/ 3 (0.0)	0.0	3.50 (0.23, 52.56)	0.3648	42.86 (-20.18, 105.90)	0.1827	
Sex									0.1482
male	1/ 15 (6.7)	6.7	1/ 13 (7.7)	7.7	0.87 (0.06, 12.52)	0.9164	-1.03 (-28.77, 26.72)	0.9422	
female	10/165 (6.1)	6.1	1/171 (0.6)	0.6	10.36 (1.34, 80.06)	0.0250	5.52 (-0.25, 11.28)	0.0606	
Race									0.4545
White	10/125 (8.0)	7.6	2/137 (1.5)	1.5	5.48 (1.22, 24.53)	0.0261	6.16 (-1.04, 13.36)	0.0938	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-13.78, 13.78)	1.0000	
Asian	1/ 11 (9.1)	9.1	0/ 5 (0.0)	0.0	1.50 (0.07, 31.57)	0.7942	9.09 (-34.34, 52.53)	0.6817	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-20.43, 20.43)	1.0000	
Ethnicity									0.8097
Hispanic/Latino	1/ 32 (3.1)	3.1	0/ 35 (0.0)	0.0	3.27 (0.14, 77.57)	0.4629	3.13 (-8.92, 15.17)	0.6111	
Non-hispanic/Latino	10/148 (6.8)	7.0	2/149 (1.3)	1.3	5.03 (1.12, 22.58)	0.0348	5.78 (-0.81, 12.36)	0.0854	
Geographic region									0.6362
EU	3/ 64 (4.7)	4.7	0/ 76 (0.0)	0.0	8.29 (0.44, 157.60)	0.1592	4.69 (-2.61, 11.98)	0.2079	
non-EU	8/116 (6.9)	7.1	2/108 (1.9)	1.9	3.72 (0.81, 17.15)	0.0915	5.21 (-3.00, 13.43)	0.2135	
Onset of disease									0.7616
Paediatric	1/ 12 (8.3)	8.3	0/ 12 (0.0)	0.0	3.00 (0.13, 67.06)	0.4883	8.33 (-20.61, 37.28)	0.5726	
Adult	10/168 (6.0)	5.8	2/172 (1.2)	1.2	5.12 (1.14, 23.02)	0.0332	4.65 (-1.05, 10.36)	0.1101	
ADA result									NE
Negative	11/162 (6.8)	6.9	2/169 (1.2)	1.1	5.74 (1.29, 25.49)	0.0217	5.73 (-0.26, 11.72)	0.0608	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE		0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment									0.9147
< 30	4/108 (3.7)	3.8	1/127 (0.8)	0.9	4.70 (0.53, 41.45)	0.1632	2.94 (-3.28, 9.16)	0.3547	
>= 30	7/ 72 (9.7)	10.2	1/ 57 (1.8)	1.9	5.54 (0.70, 43.75)	0.1043	8.29 (-3.15, 19.74)	0.1556	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Hypersensitivity
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.42, 4.42)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Hypersensitivity - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 55 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>= 10 points	0/125 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 77 (0.0)	0.0	0/ 82 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
>=10 mg/day	0/103 (0.0)	0.0	0/102 (0.0)	0.0	NE	0.00 (-5.93, 5.93)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-11.07, 11.07)	1.0000	
HIGH	0/148 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.81, 4.81)	1.0000	
Age (years)								NE
<= 65	0/173 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.54, 4.54)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
Sex								NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
female	0/165 (0.0)	0.0	0/171 (0.0)	0.0	NE	0.00 (-4.75, 4.75)	1.0000	
Race								NE
White	0/125 (0.0)	0.0	0/137 (0.0)	0.0	NE	0.00 (-5.97, 5.97)	1.0000	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-20.43, 20.43)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE	0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	0/148 (0.0)	0.0	0/149 (0.0)	0.0	NE	0.00 (-5.37, 5.37)	1.0000	
Geographic region								NE
EU	0/ 64 (0.0)	0.0	0/ 76 (0.0)	0.0	NE	0.00 (-5.43, 5.43)	1.0000	
non-EU	0/116 (0.0)	0.0	0/108 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Onset of disease								NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
Adult	0/168 (0.0)	0.0	0/172 (0.0)	0.0	NE	0.00 (-4.70, 4.70)	1.0000	
ADA result								NE
Negative	0/162 (0.0)	0.0	0/169 (0.0)	0.0	NE	0.00 (-4.83, 4.83)	1.0000	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE	0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/108 (0.0)	0.0	0/127 (0.0)	0.0	NE	0.00 (-5.30, 5.30)	1.0000	
>= 30	0/ 72 (0.0)	0.0	0/ 57 (0.0)	0.0	NE	0.00 (-9.40, 9.40)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Hypersensitivity
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.42, 4.42)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Hypersensitivity - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 55 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>= 10 points	0/125 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 77 (0.0)	0.0	0/ 82 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
>=10 mg/day	0/103 (0.0)	0.0	0/102 (0.0)	0.0	NE	0.00 (-5.93, 5.93)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-11.07, 11.07)	1.0000	
HIGH	0/148 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.81, 4.81)	1.0000	
Age (years)								NE
<= 65	0/173 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.54, 4.54)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
Sex								NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
female	0/165 (0.0)	0.0	0/171 (0.0)	0.0	NE	0.00 (-4.75, 4.75)	1.0000	
Race								NE
White	0/125 (0.0)	0.0	0/137 (0.0)	0.0	NE	0.00 (-5.97, 5.97)	1.0000	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-20.43, 20.43)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE	0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	0/148 (0.0)	0.0	0/149 (0.0)	0.0	NE	0.00 (-5.37, 5.37)	1.0000	
Geographic region								NE
EU	0/ 64 (0.0)	0.0	0/ 76 (0.0)	0.0	NE	0.00 (-5.43, 5.43)	1.0000	
non-EU	0/116 (0.0)	0.0	0/108 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Onset of disease								NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
Adult	0/168 (0.0)	0.0	0/172 (0.0)	0.0	NE	0.00 (-4.70, 4.70)	1.0000	
ADA result								NE
Negative	0/162 (0.0)	0.0	0/169 (0.0)	0.0	NE	0.00 (-4.83, 4.83)	1.0000	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE	0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/108 (0.0)	0.0	0/127 (0.0)	0.0	NE	0.00 (-5.30, 5.30)	1.0000	
>= 30	0/ 72 (0.0)	0.0	0/ 57 (0.0)	0.0	NE	0.00 (-9.40, 9.40)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Hypersensitivity
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	11 (6.1)	2 (1.1)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	5.62 (1.26, 25.01)	
p-value	0.0234	
Odds Ratio (95% CI)	5.92 (1.29, 27.11)	
p-value	0.0219	
Risk Difference (95% CI)	5.02 (1.22, 8.83)	
p-value	0.0097	
CMH approach		
Response rate	6.2	1.1
Difference in response rates (95% CI)	5.14 (-0.36, 10.64)	
p-value	0.0668	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Hypersensitivity - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8747
< 10 points	5/ 55 (9.1)	9.6	1/ 54 (1.9)	1.8	4.91 (0.59, 40.65)	0.1402	7.88 (-4.77, 20.54)	0.2221	
>= 10 points	6/125 (4.8)	4.8	1/130 (0.8)	0.8	6.24 (0.76, 51.10)	0.0879	3.98 (-2.03, 9.98)	0.1942	
OCS dose at baseline									0.4977
<10 mg/day	8/ 77 (10.4)	10.2	1/ 82 (1.2)	1.2	8.52 (1.09, 66.54)	0.0411	8.98 (-0.63, 18.59)	0.0669	
>=10 mg/day	3/103 (2.9)	3.1	1/102 (1.0)	1.0	2.97 (0.31, 28.09)	0.3421	2.11 (-4.66, 8.88)	0.5409	
Result of type I IFN gene signature test									0.3200
LOW	6/ 32 (18.8)	18.8	0/ 33 (0.0)	0.0	13.39 (0.79, 228.40)	0.0730	18.75 (2.41, 35.09)	0.0245	
HIGH	5/148 (3.4)	3.5	2/151 (1.3)	1.3	2.55 (0.50, 12.94)	0.2585	2.18 (-3.49, 7.85)	0.4518	
Age (years)									0.9104
<= 65	8/173 (4.6)	4.7	2/181 (1.1)	1.1	4.18 (0.90, 19.43)	0.0677	3.66 (-1.81, 9.13)	0.1899	
> 65	3/ 7 (42.9)	42.9	0/ 3 (0.0)	0.0	3.50 (0.23, 52.56)	0.3648	42.86 (-20.18, 105.90)	0.1827	
Sex									0.1482
male	1/ 15 (6.7)	6.7	1/ 13 (7.7)	7.7	0.87 (0.06, 12.52)	0.9164	-1.03 (-28.77, 26.72)	0.9422	
female	10/165 (6.1)	6.1	1/171 (0.6)	0.6	10.36 (1.34, 80.06)	0.0250	5.52 (-0.25, 11.28)	0.0606	
Race									0.4545
White	10/125 (8.0)	7.6	2/137 (1.5)	1.5	5.48 (1.22, 24.53)	0.0261	6.16 (-1.04, 13.36)	0.0938	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-13.78, 13.78)	1.0000	
Asian	1/ 11 (9.1)	9.1	0/ 5 (0.0)	0.0	1.50 (0.07, 31.57)	0.7942	9.09 (-34.34, 52.53)	0.6817	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-20.43, 20.43)	1.0000	
Ethnicity									0.8097
Hispanic/Latino	1/ 32 (3.1)	3.1	0/ 35 (0.0)	0.0	3.27 (0.14, 77.57)	0.4629	3.13 (-8.92, 15.17)	0.6111	
Non-hispanic/Latino	10/148 (6.8)	7.0	2/149 (1.3)	1.3	5.03 (1.12, 22.58)	0.0348	5.78 (-0.81, 12.36)	0.0854	
Geographic region									0.6362
EU	3/ 64 (4.7)	4.7	0/ 76 (0.0)	0.0	8.29 (0.44, 157.60)	0.1592	4.69 (-2.61, 11.98)	0.2079	
non-EU	8/116 (6.9)	7.1	2/108 (1.9)	1.9	3.72 (0.81, 17.15)	0.0915	5.21 (-3.00, 13.43)	0.2135	
Onset of disease									0.7616
Paediatric	1/ 12 (8.3)	8.3	0/ 12 (0.0)	0.0	3.00 (0.13, 67.06)	0.4883	8.33 (-20.61, 37.28)	0.5726	
Adult	10/168 (6.0)	5.8	2/172 (1.2)	1.2	5.12 (1.14, 23.02)	0.0332	4.65 (-1.05, 10.36)	0.1101	
ADA result									NE
Negative	11/162 (6.8)	6.9	2/169 (1.2)	1.1	5.74 (1.29, 25.49)	0.0217	5.73 (-0.26, 11.72)	0.0608	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE		0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment									0.9147
< 30	4/108 (3.7)	3.8	1/127 (0.8)	0.9	4.70 (0.53, 41.45)	0.1632	2.94 (-3.28, 9.16)	0.3547	
>= 30	7/ 72 (9.7)	10.2	1/ 57 (1.8)	1.9	5.54 (0.70, 43.75)	0.1043	8.29 (-3.15, 19.74)	0.1556	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Influenza
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	2 (1.1)	2 (1.1)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.02 (0.15, 7.18)	
p-value	0.9824	
Odds Ratio (95% CI)	1.02 (0.14, 7.34)	
p-value	0.9824	
Risk Difference (95% CI)	0.02 (-2.12, 2.17)	
p-value	0.9824	
CMH approach		
Response rate	1.1	1.1
Difference in response rates (95% CI)	0.03 (-4.78, 4.84)	
p-value	0.9904	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9769
< 10 points	1/ 55 (1.8)	1.9	1/ 54 (1.9)	1.8	0.98 (0.06, 15.30)	0.9896	0.18 (-11.08, 11.43)	0.9756	
>= 10 points	1/125 (0.8)	0.8	1/130 (0.8)	0.8	1.04 (0.07, 16.45)	0.9778	0.01 (-5.28, 5.29)	0.9983	
OCS dose at baseline									0.1313
<10 mg/day	2/ 77 (2.6)	2.5	0/ 82 (0.0)	0.0	5.32 (0.26, 109.09)	0.2781	2.45 (-5.64, 10.55)	0.5527	
>=10 mg/day	0/103 (0.0)	0.0	2/102 (2.0)	1.9	0.20 (0.01, 4.08)	0.2940	-1.88 (-8.22, 4.46)	0.5612	
Result of type I IFN gene signature test									0.3729
LOW	2/ 32 (6.3)	6.3	1/ 33 (3.0)	3.0	2.06 (0.20, 21.64)	0.5461	3.22 (-11.11, 17.55)	0.6596	
HIGH	0/148 (0.0)	0.0	1/151 (0.7)	0.7	0.34 (0.01, 8.28)	0.5078	-0.67 (-5.63, 4.30)	0.7927	
Age (years)									NE
<= 65	2/173 (1.2)	1.2	2/181 (1.1)	1.1	1.05 (0.15, 7.35)	0.9637	0.07 (-4.88, 5.01)	0.9793	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
Sex									NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
female	2/165 (1.2)	1.2	2/171 (1.2)	1.2	1.04 (0.15, 7.27)	0.9713	0.04 (-5.13, 5.21)	0.9882	
Race									0.2257
White	2/125 (1.6)	1.5	0/137 (0.0)	0.0	5.48 (0.27, 112.97)	0.2709	1.48 (-4.74, 7.70)	0.6406	
Black or African American	0/ 29 (0.0)	0.0	1/ 23 (4.3)	4.3	0.27 (0.01, 6.26)	0.4116	-4.35 (-19.85, 11.16)	0.5826	
Asian	0/ 11 (0.0)	0.0	1/ 5 (20.0)	20.0	0.17 (0.01, 3.51)	0.2491	-20.00 (-65.94, 25.94)	0.3936	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-20.43, 20.43)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE		0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	2/148 (1.4)	1.4	2/149 (1.3)	1.3	1.01 (0.14, 7.05)	0.9946	0.09 (-5.75, 5.92)	0.9767	
Geographic region									0.3167
EU	1/ 64 (1.6)	1.6	0/ 76 (0.0)	0.0	3.55 (0.15, 85.76)	0.4350	1.56 (-4.57, 7.70)	0.6176	
non-EU	1/116 (0.9)	0.9	2/108 (1.9)	1.9	0.47 (0.04, 5.06)	0.5300	-1.03 (-8.48, 6.42)	0.7858	
Onset of disease									NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
Adult	2/168 (1.2)	1.2	2/172 (1.2)	1.2	1.02 (0.15, 7.18)	0.9811	-0.01 (-5.13, 5.10)	0.9959	
ADA result									NE
Negative	2/162 (1.2)	1.2	2/169 (1.2)	1.2	1.04 (0.15, 7.32)	0.9661	0.03 (-5.22, 5.28)	0.9908	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE		0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment									0.2819
< 30	2/108 (1.9)	1.9	1/127 (0.8)	0.8	2.35 (0.22, 25.58)	0.4825	1.14 (-4.69, 6.98)	0.7015	
>= 30	0/ 72 (0.0)	0.0	1/ 57 (1.8)	1.7	0.26 (0.01, 6.38)	0.4131	-1.74 (-11.47, 7.98)	0.7256	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Influenza
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.42, 4.42)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 55 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>= 10 points	0/125 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 77 (0.0)	0.0	0/ 82 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
>=10 mg/day	0/103 (0.0)	0.0	0/102 (0.0)	0.0	NE	0.00 (-5.93, 5.93)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-11.07, 11.07)	1.0000	
HIGH	0/148 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.81, 4.81)	1.0000	
Age (years)								NE
<= 65	0/173 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.54, 4.54)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
Sex								NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
female	0/165 (0.0)	0.0	0/171 (0.0)	0.0	NE	0.00 (-4.75, 4.75)	1.0000	
Race								NE
White	0/125 (0.0)	0.0	0/137 (0.0)	0.0	NE	0.00 (-5.97, 5.97)	1.0000	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-20.43, 20.43)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE	0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	0/148 (0.0)	0.0	0/149 (0.0)	0.0	NE	0.00 (-5.37, 5.37)	1.0000	
Geographic region								NE
EU	0/ 64 (0.0)	0.0	0/ 76 (0.0)	0.0	NE	0.00 (-5.43, 5.43)	1.0000	
non-EU	0/116 (0.0)	0.0	0/108 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Onset of disease								NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
Adult	0/168 (0.0)	0.0	0/172 (0.0)	0.0	NE	0.00 (-4.70, 4.70)	1.0000	
ADA result								NE
Negative	0/162 (0.0)	0.0	0/169 (0.0)	0.0	NE	0.00 (-4.83, 4.83)	1.0000	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE	0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/108 (0.0)	0.0	0/127 (0.0)	0.0	NE	0.00 (-5.30, 5.30)	1.0000	
>= 30	0/ 72 (0.0)	0.0	0/ 57 (0.0)	0.0	NE	0.00 (-9.40, 9.40)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Influenza
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.42, 4.42)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 55 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>= 10 points	0/125 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 77 (0.0)	0.0	0/ 82 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
>=10 mg/day	0/103 (0.0)	0.0	0/102 (0.0)	0.0	NE	0.00 (-5.93, 5.93)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-11.07, 11.07)	1.0000	
HIGH	0/148 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.81, 4.81)	1.0000	
Age (years)								NE
<= 65	0/173 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.54, 4.54)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
Sex								NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
female	0/165 (0.0)	0.0	0/171 (0.0)	0.0	NE	0.00 (-4.75, 4.75)	1.0000	
Race								NE
White	0/125 (0.0)	0.0	0/137 (0.0)	0.0	NE	0.00 (-5.97, 5.97)	1.0000	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-20.43, 20.43)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE	0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	0/148 (0.0)	0.0	0/149 (0.0)	0.0	NE	0.00 (-5.37, 5.37)	1.0000	
Geographic region								NE
EU	0/ 64 (0.0)	0.0	0/ 76 (0.0)	0.0	NE	0.00 (-5.43, 5.43)	1.0000	
non-EU	0/116 (0.0)	0.0	0/108 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Onset of disease								NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
Adult	0/168 (0.0)	0.0	0/172 (0.0)	0.0	NE	0.00 (-4.70, 4.70)	1.0000	
ADA result								NE
Negative	0/162 (0.0)	0.0	0/169 (0.0)	0.0	NE	0.00 (-4.83, 4.83)	1.0000	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE	0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/108 (0.0)	0.0	0/127 (0.0)	0.0	NE	0.00 (-5.30, 5.30)	1.0000	
>= 30	0/ 72 (0.0)	0.0	0/ 57 (0.0)	0.0	NE	0.00 (-9.40, 9.40)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Influenza
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	2 (1.1)	2 (1.1)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.02 (0.15, 7.18)	
p-value	0.9824	
Odds Ratio (95% CI)	1.02 (0.14, 7.34)	
p-value	0.9824	
Risk Difference (95% CI)	0.02 (-2.12, 2.17)	
p-value	0.9824	
CMH approach		
Response rate	1.1	1.1
Difference in response rates (95% CI)	0.03 (-4.78, 4.84)	
p-value	0.9904	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9769
< 10 points	1/ 55 (1.8)	1.9	1/ 54 (1.9)	1.8	0.98 (0.06, 15.30)	0.9896	0.18 (-11.08, 11.43)	0.9756	
>= 10 points	1/125 (0.8)	0.8	1/130 (0.8)	0.8	1.04 (0.07, 16.45)	0.9778	0.01 (-5.28, 5.29)	0.9983	
OCS dose at baseline									0.1313
<10 mg/day	2/ 77 (2.6)	2.5	0/ 82 (0.0)	0.0	5.32 (0.26, 109.09)	0.2781	2.45 (-5.64, 10.55)	0.5527	
>=10 mg/day	0/103 (0.0)	0.0	2/102 (2.0)	1.9	0.20 (0.01, 4.08)	0.2940	-1.88 (-8.22, 4.46)	0.5612	
Result of type I IFN gene signature test									0.3729
LOW	2/ 32 (6.3)	6.3	1/ 33 (3.0)	3.0	2.06 (0.20, 21.64)	0.5461	3.22 (-11.11, 17.55)	0.6596	
HIGH	0/148 (0.0)	0.0	1/151 (0.7)	0.7	0.34 (0.01, 8.28)	0.5078	-0.67 (-5.63, 4.30)	0.7927	
Age (years)									NE
<= 65	2/173 (1.2)	1.2	2/181 (1.1)	1.1	1.05 (0.15, 7.35)	0.9637	0.07 (-4.88, 5.01)	0.9793	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
Sex									NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
female	2/165 (1.2)	1.2	2/171 (1.2)	1.2	1.04 (0.15, 7.27)	0.9713	0.04 (-5.13, 5.21)	0.9882	
Race									0.2257
White	2/125 (1.6)	1.5	0/137 (0.0)	0.0	5.48 (0.27, 112.97)	0.2709	1.48 (-4.74, 7.70)	0.6406	
Black or African American	0/ 29 (0.0)	0.0	1/ 23 (4.3)	4.3	0.27 (0.01, 6.26)	0.4116	-4.35 (-19.85, 11.16)	0.5826	
Asian	0/ 11 (0.0)	0.0	1/ 5 (20.0)	20.0	0.17 (0.01, 3.51)	0.2491	-20.00 (-65.94, 25.94)	0.3936	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-20.43, 20.43)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE		0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	2/148 (1.4)	1.4	2/149 (1.3)	1.3	1.01 (0.14, 7.05)	0.9946	0.09 (-5.75, 5.92)	0.9767	
Geographic region									0.3167
EU	1/ 64 (1.6)	1.6	0/ 76 (0.0)	0.0	3.55 (0.15, 85.76)	0.4350	1.56 (-4.57, 7.70)	0.6176	
non-EU	1/116 (0.9)	0.9	2/108 (1.9)	1.9	0.47 (0.04, 5.06)	0.5300	-1.03 (-8.48, 6.42)	0.7858	
Onset of disease									NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
Adult	2/168 (1.2)	1.2	2/172 (1.2)	1.2	1.02 (0.15, 7.18)	0.9811	-0.01 (-5.13, 5.10)	0.9959	
ADA result									NE
Negative	2/162 (1.2)	1.2	2/169 (1.2)	1.2	1.04 (0.15, 7.32)	0.9661	0.03 (-5.22, 5.28)	0.9908	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE		0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment									0.2819
< 30	2/108 (1.9)	1.9	1/127 (0.8)	0.8	2.35 (0.22, 25.58)	0.4825	1.14 (-4.69, 6.98)	0.7015	
>= 30	0/ 72 (0.0)	0.0	1/ 57 (1.8)	1.7	0.26 (0.01, 6.38)	0.4131	-1.74 (-11.47, 7.98)	0.7256	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - MACE
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.42, 4.42)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - MACE - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 55 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>= 10 points	0/125 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 77 (0.0)	0.0	0/ 82 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
>=10 mg/day	0/103 (0.0)	0.0	0/102 (0.0)	0.0	NE	0.00 (-5.93, 5.93)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-11.07, 11.07)	1.0000	
HIGH	0/148 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.81, 4.81)	1.0000	
Age (years)								NE
<= 65	0/173 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.54, 4.54)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
Sex								NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
female	0/165 (0.0)	0.0	0/171 (0.0)	0.0	NE	0.00 (-4.75, 4.75)	1.0000	
Race								NE
White	0/125 (0.0)	0.0	0/137 (0.0)	0.0	NE	0.00 (-5.97, 5.97)	1.0000	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-20.43, 20.43)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE	0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	0/148 (0.0)	0.0	0/149 (0.0)	0.0	NE	0.00 (-5.37, 5.37)	1.0000	
Geographic region								NE
EU	0/ 64 (0.0)	0.0	0/ 76 (0.0)	0.0	NE	0.00 (-5.43, 5.43)	1.0000	
non-EU	0/116 (0.0)	0.0	0/108 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Onset of disease								NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
Adult	0/168 (0.0)	0.0	0/172 (0.0)	0.0	NE	0.00 (-4.70, 4.70)	1.0000	
ADA result								NE
Negative	0/162 (0.0)	0.0	0/169 (0.0)	0.0	NE	0.00 (-4.83, 4.83)	1.0000	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE	0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/108 (0.0)	0.0	0/127 (0.0)	0.0	NE	0.00 (-5.30, 5.30)	1.0000	
>= 30	0/ 72 (0.0)	0.0	0/ 57 (0.0)	0.0	NE	0.00 (-9.40, 9.40)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious MACE
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.42, 4.42)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious MACE - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 55 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>= 10 points	0/125 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 77 (0.0)	0.0	0/ 82 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
>=10 mg/day	0/103 (0.0)	0.0	0/102 (0.0)	0.0	NE	0.00 (-5.93, 5.93)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-11.07, 11.07)	1.0000	
HIGH	0/148 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.81, 4.81)	1.0000	
Age (years)								NE
<= 65	0/173 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.54, 4.54)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
Sex								NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
female	0/165 (0.0)	0.0	0/171 (0.0)	0.0	NE	0.00 (-4.75, 4.75)	1.0000	
Race								NE
White	0/125 (0.0)	0.0	0/137 (0.0)	0.0	NE	0.00 (-5.97, 5.97)	1.0000	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-20.43, 20.43)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE	0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	0/148 (0.0)	0.0	0/149 (0.0)	0.0	NE	0.00 (-5.37, 5.37)	1.0000	
Geographic region								NE
EU	0/ 64 (0.0)	0.0	0/ 76 (0.0)	0.0	NE	0.00 (-5.43, 5.43)	1.0000	
non-EU	0/116 (0.0)	0.0	0/108 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Onset of disease								NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
Adult	0/168 (0.0)	0.0	0/172 (0.0)	0.0	NE	0.00 (-4.70, 4.70)	1.0000	
ADA result								NE
Negative	0/162 (0.0)	0.0	0/169 (0.0)	0.0	NE	0.00 (-4.83, 4.83)	1.0000	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE	0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/108 (0.0)	0.0	0/127 (0.0)	0.0	NE	0.00 (-5.30, 5.30)	1.0000	
>= 30	0/ 72 (0.0)	0.0	0/ 57 (0.0)	0.0	NE	0.00 (-9.40, 9.40)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe MACE
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.42, 4.42)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe MACE - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 55 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>= 10 points	0/125 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 77 (0.0)	0.0	0/ 82 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
>=10 mg/day	0/103 (0.0)	0.0	0/102 (0.0)	0.0	NE	0.00 (-5.93, 5.93)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-11.07, 11.07)	1.0000	
HIGH	0/148 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.81, 4.81)	1.0000	
Age (years)								NE
<= 65	0/173 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.54, 4.54)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
Sex								NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
female	0/165 (0.0)	0.0	0/171 (0.0)	0.0	NE	0.00 (-4.75, 4.75)	1.0000	
Race								NE
White	0/125 (0.0)	0.0	0/137 (0.0)	0.0	NE	0.00 (-5.97, 5.97)	1.0000	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-20.43, 20.43)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE	0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	0/148 (0.0)	0.0	0/149 (0.0)	0.0	NE	0.00 (-5.37, 5.37)	1.0000	
Geographic region								NE
EU	0/ 64 (0.0)	0.0	0/ 76 (0.0)	0.0	NE	0.00 (-5.43, 5.43)	1.0000	
non-EU	0/116 (0.0)	0.0	0/108 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Onset of disease								NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
Adult	0/168 (0.0)	0.0	0/172 (0.0)	0.0	NE	0.00 (-4.70, 4.70)	1.0000	
ADA result								NE
Negative	0/162 (0.0)	0.0	0/169 (0.0)	0.0	NE	0.00 (-4.83, 4.83)	1.0000	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE	0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/108 (0.0)	0.0	0/127 (0.0)	0.0	NE	0.00 (-5.30, 5.30)	1.0000	
>= 30	0/ 72 (0.0)	0.0	0/ 57 (0.0)	0.0	NE	0.00 (-9.40, 9.40)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe MACE
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.42, 4.42)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe MACE - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 55 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>= 10 points	0/125 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 77 (0.0)	0.0	0/ 82 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
>=10 mg/day	0/103 (0.0)	0.0	0/102 (0.0)	0.0	NE	0.00 (-5.93, 5.93)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-11.07, 11.07)	1.0000	
HIGH	0/148 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.81, 4.81)	1.0000	
Age (years)								NE
<= 65	0/173 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.54, 4.54)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
Sex								NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
female	0/165 (0.0)	0.0	0/171 (0.0)	0.0	NE	0.00 (-4.75, 4.75)	1.0000	
Race								NE
White	0/125 (0.0)	0.0	0/137 (0.0)	0.0	NE	0.00 (-5.97, 5.97)	1.0000	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-20.43, 20.43)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE	0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	0/148 (0.0)	0.0	0/149 (0.0)	0.0	NE	0.00 (-5.37, 5.37)	1.0000	
Geographic region								NE
EU	0/ 64 (0.0)	0.0	0/ 76 (0.0)	0.0	NE	0.00 (-5.43, 5.43)	1.0000	
non-EU	0/116 (0.0)	0.0	0/108 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Onset of disease								NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
Adult	0/168 (0.0)	0.0	0/172 (0.0)	0.0	NE	0.00 (-4.70, 4.70)	1.0000	
ADA result								NE
Negative	0/162 (0.0)	0.0	0/169 (0.0)	0.0	NE	0.00 (-4.83, 4.83)	1.0000	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE	0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/108 (0.0)	0.0	0/127 (0.0)	0.0	NE	0.00 (-5.30, 5.30)	1.0000	
>= 30	0/ 72 (0.0)	0.0	0/ 57 (0.0)	0.0	NE	0.00 (-9.40, 9.40)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	9 (5.0)	10 (5.4)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.92 (0.38, 2.21)	
p-value	0.8521	
Odds Ratio (95% CI)	0.92 (0.36, 2.31)	
p-value	0.8521	
Risk Difference (95% CI)	-0.43 (-5.00, 4.13)	
p-value	0.8520	
CMH approach		
Response rate	4.9	5.4
Difference in response rates (95% CI)	-0.49 (-6.51, 5.53)	
p-value	0.8723	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9451
< 10 points	2/ 55 (3.6)	3.4	2/ 54 (3.7)	3.5	0.98 (0.14, 6.72)	0.9851	-0.16 (-12.12, 11.79)	0.9786	
>= 10 points	7/125 (5.6)	5.5	8/130 (6.2)	6.2	0.91 (0.34, 2.43)	0.8510	-0.65 (-7.84, 6.55)	0.8605	
OCS dose at baseline									0.2375
<10 mg/day	2/ 77 (2.6)	2.5	5/ 82 (6.1)	6.2	0.43 (0.09, 2.13)	0.2989	-3.73 (-12.99, 5.53)	0.4298	
>=10 mg/day	7/103 (6.8)	6.7	5/102 (4.9)	4.9	1.39 (0.45, 4.23)	0.5656	1.85 (-6.48, 10.19)	0.6633	
Result of type I IFN gene signature test									0.8949
LOW	2/ 32 (6.3)	6.3	2/ 33 (6.1)	6.1	1.03 (0.15, 6.89)	0.9747	0.19 (-15.00, 15.38)	0.9805	
HIGH	7/148 (4.7)	4.6	8/151 (5.3)	5.2	0.89 (0.33, 2.40)	0.8220	-0.64 (-7.18, 5.90)	0.8473	
Age (years)									NE
<= 65	9/173 (5.2)	5.1	10/181 (5.5)	5.5	0.94 (0.39, 2.26)	0.8929	-0.41 (-6.58, 5.76)	0.8968	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
Sex									0.9662
male	1/ 15 (6.7)	6.7	1/ 13 (7.7)	7.7	0.87 (0.06, 12.52)	0.9164	-1.03 (-28.77, 26.72)	0.9422	
female	8/165 (4.8)	4.8	9/171 (5.3)	5.2	0.92 (0.36, 2.33)	0.8624	-0.45 (-6.79, 5.88)	0.8885	
Race									0.7686
White	5/125 (4.0)	3.9	4/137 (2.9)	3.1	1.37 (0.38, 4.99)	0.6330	0.83 (-6.30, 7.95)	0.8203	
Black or African American	2/ 29 (6.9)	6.9	3/ 23 (13.0)	13.0	0.53 (0.10, 2.90)	0.4634	-6.15 (-25.97, 13.68)	0.5434	
Asian	1/ 11 (9.1)	9.1	1/ 5 (20.0)	20.0	0.45 (0.04, 5.89)	0.5464	-10.91 (-58.51, 36.69)	0.6533	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	1/ 15 (6.7)	6.7	2/ 18 (11.1)	11.1	0.60 (0.06, 5.99)	0.6634	-4.44 (-30.10, 21.21)	0.7342	
Ethnicity									0.4415
Hispanic/Latino	2/ 32 (6.3)	6.3	4/ 35 (11.4)	11.4	0.55 (0.11, 2.79)	0.4675	-5.18 (-21.35, 10.99)	0.5302	
Non-hispanic/Latino	7/148 (4.7)	4.8	6/149 (4.0)	3.9	1.17 (0.40, 3.41)	0.7675	0.93 (-5.86, 7.73)	0.7875	
Geographic region									0.7303
EU	1/ 64 (1.6)	1.6	2/ 76 (2.6)	2.6	0.59 (0.06, 6.40)	0.6674	-1.07 (-8.09, 5.95)	0.7654	
non-EU	8/116 (6.9)	6.5	8/108 (7.4)	7.8	0.93 (0.36, 2.39)	0.8821	-1.30 (-10.25, 7.65)	0.7763	
Onset of disease									0.9161
Paediatric	2/ 12 (16.7)	16.7	2/ 12 (16.7)	16.7	1.00 (0.17, 5.98)	1.0000	0.00 (-34.65, 34.65)	1.0000	
Adult	7/168 (4.2)	4.1	8/172 (4.7)	4.6	0.90 (0.33, 2.42)	0.8279	-0.50 (-6.59, 5.58)	0.8709	
ADA result									0.4979
Negative	8/162 (4.9)	4.8	8/169 (4.7)	4.7	1.04 (0.40, 2.71)	0.9309	0.17 (-6.16, 6.49)	0.9590	
Positive (At any time)	1/ 17 (5.9)	5.9	2/ 15 (13.3)	13.3	0.44 (0.04, 4.39)	0.4852	-7.45 (-33.95, 19.05)	0.5816	
BMI (kg/m2) at enrolment									0.1993
< 30	5/108 (4.6)	4.5	9/127 (7.1)	7.0	0.65 (0.23, 1.89)	0.4323	-2.47 (-10.02, 5.08)	0.5210	
>= 30	4/ 72 (5.6)	5.4	1/ 57 (1.8)	1.9	3.17 (0.36, 27.56)	0.2964	3.56 (-7.23, 14.34)	0.5181	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Non-opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	9 (5.0)	10 (5.4)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.92 (0.38, 2.21)	
p-value	0.8521	
Odds Ratio (95% CI)	0.92 (0.36, 2.31)	
p-value	0.8521	
Risk Difference (95% CI)	-0.43 (-5.00, 4.13)	
p-value	0.8520	
CMH approach		
Response rate	4.9	5.4
Difference in response rates (95% CI)	-0.49 (-6.51, 5.53)	
p-value	0.8723	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Non-opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9451
< 10 points	2/ 55 (3.6)	3.4	2/ 54 (3.7)	3.5	0.98 (0.14, 6.72)	0.9851	-0.16 (-12.12, 11.79)	0.9786	
>= 10 points	7/125 (5.6)	5.5	8/130 (6.2)	6.2	0.91 (0.34, 2.43)	0.8510	-0.65 (-7.84, 6.55)	0.8605	
OCS dose at baseline									0.2375
<10 mg/day	2/ 77 (2.6)	2.5	5/ 82 (6.1)	6.2	0.43 (0.09, 2.13)	0.2989	-3.73 (-12.99, 5.53)	0.4298	
>=10 mg/day	7/103 (6.8)	6.7	5/102 (4.9)	4.9	1.39 (0.45, 4.23)	0.5656	1.85 (-6.48, 10.19)	0.6633	
Result of type I IFN gene signature test									0.8949
LOW	2/ 32 (6.3)	6.3	2/ 33 (6.1)	6.1	1.03 (0.15, 6.89)	0.9747	0.19 (-15.00, 15.38)	0.9805	
HIGH	7/148 (4.7)	4.6	8/151 (5.3)	5.2	0.89 (0.33, 2.40)	0.8220	-0.64 (-7.18, 5.90)	0.8473	
Age (years)									NE
<= 65	9/173 (5.2)	5.1	10/181 (5.5)	5.5	0.94 (0.39, 2.26)	0.8929	-0.41 (-6.58, 5.76)	0.8968	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
Sex									0.9662
male	1/ 15 (6.7)	6.7	1/ 13 (7.7)	7.7	0.87 (0.06, 12.52)	0.9164	-1.03 (-28.77, 26.72)	0.9422	
female	8/165 (4.8)	4.8	9/171 (5.3)	5.2	0.92 (0.36, 2.33)	0.8624	-0.45 (-6.79, 5.88)	0.8885	
Race									0.7686
White	5/125 (4.0)	3.9	4/137 (2.9)	3.1	1.37 (0.38, 4.99)	0.6330	0.83 (-6.30, 7.95)	0.8203	
Black or African American	2/ 29 (6.9)	6.9	3/ 23 (13.0)	13.0	0.53 (0.10, 2.90)	0.4634	-6.15 (-25.97, 13.68)	0.5434	
Asian	1/ 11 (9.1)	9.1	1/ 5 (20.0)	20.0	0.45 (0.04, 5.89)	0.5464	-10.91 (-58.51, 36.69)	0.6533	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	1/ 15 (6.7)	6.7	2/ 18 (11.1)	11.1	0.60 (0.06, 5.99)	0.6634	-4.44 (-30.10, 21.21)	0.7342	
Ethnicity									0.4415
Hispanic/Latino	2/ 32 (6.3)	6.3	4/ 35 (11.4)	11.4	0.55 (0.11, 2.79)	0.4675	-5.18 (-21.35, 10.99)	0.5302	
Non-hispanic/Latino	7/148 (4.7)	4.8	6/149 (4.0)	3.9	1.17 (0.40, 3.41)	0.7675	0.93 (-5.86, 7.73)	0.7875	
Geographic region									0.7303
EU	1/ 64 (1.6)	1.6	2/ 76 (2.6)	2.6	0.59 (0.06, 6.40)	0.6674	-1.07 (-8.09, 5.95)	0.7654	
non-EU	8/116 (6.9)	6.5	8/108 (7.4)	7.8	0.93 (0.36, 2.39)	0.8821	-1.30 (-10.25, 7.65)	0.7763	
Onset of disease									0.9161
Paediatric	2/ 12 (16.7)	16.7	2/ 12 (16.7)	16.7	1.00 (0.17, 5.98)	1.0000	0.00 (-34.65, 34.65)	1.0000	
Adult	7/168 (4.2)	4.1	8/172 (4.7)	4.6	0.90 (0.33, 2.42)	0.8279	-0.50 (-6.59, 5.58)	0.8709	
ADA result									0.4979
Negative	8/162 (4.9)	4.8	8/169 (4.7)	4.7	1.04 (0.40, 2.71)	0.9309	0.17 (-6.16, 6.49)	0.9590	
Positive (At any time)	1/ 17 (5.9)	5.9	2/ 15 (13.3)	13.3	0.44 (0.04, 4.39)	0.4852	-7.45 (-33.95, 19.05)	0.5816	
BMI (kg/m2) at enrolment									0.1993
< 30	5/108 (4.6)	4.5	9/127 (7.1)	7.0	0.65 (0.23, 1.89)	0.4323	-2.47 (-10.02, 5.08)	0.5210	
>= 30	4/ 72 (5.6)	5.4	1/ 57 (1.8)	1.9	3.17 (0.36, 27.56)	0.2964	3.56 (-7.23, 14.34)	0.5181	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Non-opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	6 (3.3)	5 (2.7)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.23 (0.38, 3.95)	
p-value	0.7319	
Odds Ratio (95% CI)	1.23 (0.37, 4.12)	
p-value	0.7319	
Risk Difference (95% CI)	0.62 (-2.90, 4.14)	
p-value	0.7317	
CMH approach		
Response rate	3.3	2.7
Difference in response rates (95% CI)	0.58 (-4.86, 6.01)	
p-value	0.8354	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Non-opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8561
< 10 points	1/ 55 (1.8)	1.7	1/ 54 (1.9)	1.8	0.98 (0.06, 15.30)	0.9896	-0.08 (-11.49, 11.32)	0.9885	
>= 10 points	5/125 (4.0)	3.9	4/130 (3.1)	3.1	1.30 (0.36, 4.73)	0.6905	0.82 (-5.59, 7.23)	0.8018	
OCS dose at baseline									0.8624
<10 mg/day	2/ 77 (2.6)	2.5	2/ 82 (2.4)	2.5	1.06 (0.15, 7.37)	0.9492	-0.04 (-8.62, 8.53)	0.9918	
>=10 mg/day	4/103 (3.9)	3.8	3/102 (2.9)	2.9	1.32 (0.30, 5.75)	0.7113	0.93 (-6.55, 8.42)	0.8069	
Result of type I IFN gene signature test									0.6120
LOW	2/ 32 (6.3)	6.3	1/ 33 (3.0)	3.0	2.06 (0.20, 21.64)	0.5461	3.22 (-11.11, 17.55)	0.6596	
HIGH	4/148 (2.7)	2.6	4/151 (2.6)	2.6	1.02 (0.26, 4.00)	0.9771	-0.00 (-5.83, 5.83)	0.9999	
Age (years)									NE
<= 65	6/173 (3.5)	3.4	5/181 (2.8)	2.8	1.26 (0.39, 4.04)	0.7027	0.65 (-4.93, 6.23)	0.8196	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
Sex									NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
female	6/165 (3.6)	3.6	5/171 (2.9)	2.9	1.24 (0.39, 4.00)	0.7143	0.65 (-5.19, 6.49)	0.8271	
Race									0.5077
White	4/125 (3.2)	3.1	2/137 (1.5)	1.5	2.19 (0.41, 11.76)	0.3599	1.55 (-5.22, 8.31)	0.6540	
Black or African American	1/ 29 (3.4)	3.4	2/ 23 (8.7)	8.7	0.40 (0.04, 4.11)	0.4380	-5.25 (-23.14, 12.65)	0.5655	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	1/ 15 (6.7)	6.7	1/ 18 (5.6)	5.6	1.20 (0.08, 17.60)	0.8942	1.11 (-23.22, 25.44)	0.9287	
Ethnicity									0.8676
Hispanic/Latino	2/ 32 (6.3)	6.3	2/ 35 (5.7)	5.7	1.09 (0.16, 7.32)	0.9264	0.54 (-14.28, 15.35)	0.9435	
Non-hispanic/Latino	4/148 (2.7)	2.8	3/149 (2.0)	1.9	1.34 (0.31, 5.89)	0.6965	0.96 (-5.24, 7.16)	0.7611	
Geographic region									0.4685
EU	0/ 64 (0.0)	0.0	1/ 76 (1.3)	1.3	0.39 (0.02, 9.53)	0.5673	-1.32 (-7.26, 4.63)	0.6646	
non-EU	6/116 (5.2)	4.9	4/108 (3.7)	4.0	1.40 (0.41, 4.81)	0.5969	0.90 (-7.41, 9.22)	0.8313	
Onset of disease									0.8700
Paediatric	1/ 12 (8.3)	8.3	1/ 12 (8.3)	8.3	1.00 (0.07, 14.21)	1.0000	0.00 (-31.23, 31.23)	1.0000	
Adult	5/168 (3.0)	2.9	4/172 (2.3)	2.3	1.28 (0.35, 4.68)	0.7094	0.60 (-5.00, 6.21)	0.8326	
ADA result									0.3192
Negative	5/162 (3.1)	3.0	3/169 (1.8)	1.7	1.74 (0.42, 7.16)	0.4436	1.28 (-4.36, 6.92)	0.6568	
Positive (At any time)	1/ 17 (5.9)	5.9	2/ 15 (13.3)	13.3	0.44 (0.04, 4.39)	0.4852	-7.45 (-33.95, 19.05)	0.5816	
BMI (kg/m2) at enrolment									0.4686
< 30	3/108 (2.8)	2.7	4/127 (3.1)	3.2	0.88 (0.20, 3.85)	0.8674	-0.43 (-7.04, 6.17)	0.8980	
>= 30	3/ 72 (4.2)	4.1	1/ 57 (1.8)	1.9	2.38 (0.25, 22.23)	0.4484	2.26 (-8.30, 12.82)	0.6747	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Non-opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	3 (1.7)	6 (3.3)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.51 (0.13, 2.01)	
p-value	0.3372	
Odds Ratio (95% CI)	0.50 (0.12, 2.04)	
p-value	0.3363	
Risk Difference (95% CI)	-1.59 (-4.77, 1.58)	
p-value	0.3251	
CMH approach		
Response rate	1.6	3.2
Difference in response rates (95% CI)	-1.62 (-6.88, 3.64)	
p-value	0.5472	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Non-opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Anifrolumab 300mg (N=180) Response rate	Placebo (N=184) n/ N (%)	Placebo (N=184) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.5977
< 10 points	1/ 55 (1.8)	1.7	1/ 54 (1.9)	1.8	0.98 (0.06, 15.30)	0.9896	-0.08 (-11.38, 11.22)	0.9890	
>= 10 points	2/125 (1.6)	1.6	5/130 (3.8)	3.8	0.42 (0.08, 2.10)	0.2890	-2.24 (-8.39, 3.90)	0.4738	
OCS dose at baseline									0.2718
<10 mg/day	0/ 77 (0.0)	0.0	3/ 82 (3.7)	3.7	0.15 (0.01, 2.90)	0.2103	-3.69 (-12.13, 4.76)	0.3921	
>=10 mg/day	3/103 (2.9)	2.9	3/102 (2.9)	2.9	0.99 (0.20, 4.79)	0.9903	-0.05 (-7.33, 7.23)	0.9888	
Result of type I IFN gene signature test									0.7438
LOW	0/ 32 (0.0)	0.0	1/ 33 (3.0)	3.0	0.34 (0.01, 8.13)	0.5080	-3.03 (-15.27, 9.21)	0.6274	
HIGH	3/148 (2.0)	2.0	5/151 (3.3)	3.3	0.61 (0.15, 2.52)	0.4961	-1.31 (-7.13, 4.52)	0.6600	
Age (years)									NE
<= 65	3/173 (1.7)	1.7	6/181 (3.3)	3.3	0.52 (0.13, 2.06)	0.3540	-1.62 (-7.01, 3.78)	0.5569	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
Sex									0.6439
male	1/ 15 (6.7)	6.7	1/ 13 (7.7)	7.7	0.87 (0.06, 12.52)	0.9164	-1.03 (-28.77, 26.72)	0.9422	
female	2/165 (1.2)	1.2	5/171 (2.9)	2.9	0.41 (0.08, 2.11)	0.2884	-1.69 (-7.19, 3.81)	0.5467	
Race									0.9481
White	1/125 (0.8)	0.8	2/137 (1.5)	1.5	0.55 (0.05, 5.97)	0.6216	-0.72 (-7.12, 5.68)	0.8254	
Black or African American	1/ 29 (3.4)	3.4	1/ 23 (4.3)	4.3	0.79 (0.05, 12.01)	0.8672	-0.90 (-17.47, 15.67)	0.9152	
Asian	1/ 11 (9.1)	9.1	1/ 5 (20.0)	20.0	0.45 (0.04, 5.89)	0.5464	-10.91 (-58.51, 36.69)	0.6533	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 15 (0.0)	0.0	2/ 18 (11.1)	11.1	0.24 (0.01, 4.60)	0.3416	-11.11 (-34.75, 12.53)	0.3569	
Ethnicity									0.2717
Hispanic/Latino	0/ 32 (0.0)	0.0	3/ 35 (8.6)	8.6	0.16 (0.01, 2.90)	0.2130	-8.57 (-22.20, 5.05)	0.2176	
Non-hispanic/Latino	3/148 (2.0)	2.0	3/149 (2.0)	2.0	1.01 (0.21, 4.91)	0.9934	-0.03 (-6.11, 6.05)	0.9929	
Geographic region									0.4765
EU	1/ 64 (1.6)	1.6	1/ 76 (1.3)	1.3	1.19 (0.08, 18.61)	0.9026	0.25 (-6.35, 6.85)	0.9416	
non-EU	2/116 (1.7)	1.6	5/108 (4.6)	4.8	0.37 (0.07, 1.88)	0.2317	-3.23 (-11.21, 4.74)	0.4267	
Onset of disease									0.5740
Paediatric	1/ 12 (8.3)	8.3	1/ 12 (8.3)	8.3	1.00 (0.07, 14.21)	1.0000	0.00 (-31.23, 31.23)	1.0000	
Adult	2/168 (1.2)	1.2	5/172 (2.9)	2.8	0.41 (0.08, 2.08)	0.2819	-1.68 (-7.08, 3.71)	0.5410	
ADA result									0.6695
Negative	3/162 (1.9)	1.8	5/169 (3.0)	2.9	0.63 (0.15, 2.58)	0.5164	-1.11 (-6.77, 4.54)	0.6998	
Positive (At any time)	0/ 17 (0.0)	0.0	1/ 15 (6.7)	6.7	0.30 (0.01, 6.77)	0.4461	-6.67 (-29.80, 16.47)	0.5722	
BMI (kg/m2) at enrolment									0.3193
< 30	2/108 (1.9)	1.8	6/127 (4.7)	4.6	0.39 (0.08, 1.90)	0.2452	-2.81 (-9.46, 3.84)	0.4080	
>= 30	1/ 72 (1.4)	1.3	0/ 57 (0.0)	0.0	2.38 (0.10, 57.43)	0.5926	1.29 (-8.37, 10.96)	0.7930	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	1 (0.6)	1 (0.5)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.02 (0.06, 16.22)	
p-value	0.9876	
Odds Ratio (95% CI)	1.02 (0.06, 16.47)	
p-value	0.9876	
Risk Difference (95% CI)	0.01 (-1.51, 1.53)	
p-value	0.9876	
CMH approach		
Response rate	0.6	0.5
Difference in response rates (95% CI)	0.03 (-4.59, 4.66)	
p-value	0.9891	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 55 (0.0)	0.0	0/ 54 (0.0)	0.0	NE		0.00 (-10.69, 10.69)	1.0000	
>= 10 points	1/125 (0.8)	0.8	1/130 (0.8)	0.7	1.04 (0.07, 16.45)	0.9778	0.05 (-5.26, 5.35)	0.9864	
OCS dose at baseline									0.3554
<10 mg/day	0/ 77 (0.0)	0.0	1/ 82 (1.2)	1.2	0.35 (0.01, 8.58)	0.5237	-1.20 (-9.13, 6.74)	0.7677	
>=10 mg/day	1/103 (1.0)	1.0	0/102 (0.0)	0.0	2.97 (0.12, 72.09)	0.5033	0.99 (-5.21, 7.18)	0.7554	
Result of type I IFN gene signature test									NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE		0.00 (-11.07, 11.07)	1.0000	
HIGH	1/148 (0.7)	0.7	1/151 (0.7)	0.6	1.02 (0.06, 16.16)	0.9886	0.04 (-5.05, 5.13)	0.9879	
Age (years)									NE
<= 65	1/173 (0.6)	0.6	1/181 (0.6)	0.5	1.05 (0.07, 16.60)	0.9744	0.05 (-4.70, 4.80)	0.9824	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
Sex									NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
female	1/165 (0.6)	0.6	1/171 (0.6)	0.6	1.04 (0.07, 16.43)	0.9798	0.05 (-4.92, 5.02)	0.9844	
Race									0.4402
White	0/125 (0.0)	0.0	0/137 (0.0)	0.0	NE		0.00 (-5.97, 5.97)	1.0000	
Black or African American	0/ 29 (0.0)	0.0	1/ 23 (4.3)	4.3	0.27 (0.01, 6.26)	0.4116	-4.35 (-19.85, 11.16)	0.5826	
Asian	1/ 11 (9.1)	9.1	0/ 5 (0.0)	0.0	1.50 (0.07, 31.57)	0.7942	9.09 (-34.34, 52.53)	0.6817	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-20.43, 20.43)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE		0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	1/148 (0.7)	0.7	1/149 (0.7)	0.7	1.01 (0.06, 15.95)	0.9962	0.02 (-5.64, 5.68)	0.9951	
Geographic region									NE
EU	0/ 64 (0.0)	0.0	0/ 76 (0.0)	0.0	NE		0.00 (-5.43, 5.43)	1.0000	
non-EU	1/116 (0.9)	0.8	1/108 (0.9)	0.9	0.93 (0.06, 14.70)	0.9595	-0.08 (-7.30, 7.13)	0.9819	
Onset of disease									NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
Adult	1/168 (0.6)	0.6	1/172 (0.6)	0.5	1.02 (0.06, 16.24)	0.9867	0.05 (-4.87, 4.98)	0.9829	
ADA result									0.3015
Negative	1/162 (0.6)	0.6	0/169 (0.0)	0.0	3.13 (0.13, 76.25)	0.4839	0.64 (-4.33, 5.61)	0.8015	
Positive (At any time)	0/ 17 (0.0)	0.0	1/ 15 (6.7)	6.7	0.30 (0.01, 6.77)	0.4461	-6.67 (-29.80, 16.47)	0.5722	
BMI (kg/m2) at enrolment									0.2603
< 30	1/108 (0.9)	1.0	0/127 (0.0)	0.0	3.52 (0.14, 85.60)	0.4392	0.95 (-4.63, 6.53)	0.7385	
>= 30	0/ 72 (0.0)	0.0	1/ 57 (1.8)	1.9	0.26 (0.01, 6.38)	0.4131	-1.86 (-11.75, 8.03)	0.7119	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	0 (0.0)	1 (0.5)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.34 (0.01, 8.31)	
p-value	0.5088	
Odds Ratio (95% CI)	0.34 (0.01, 8.37)	
p-value	0.5084	
Risk Difference (95% CI)	-0.54 (-1.61, 0.52)	
p-value	0.3160	
CMH approach		
Response rate	0.0	0.5
Difference in response rates (95% CI)	-0.52 (-5.03, 3.99)	
p-value	0.8205	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 55 (0.0)	0.0	0/ 54 (0.0)	0.0	NE		0.00 (-10.69, 10.69)	1.0000	
>= 10 points	0/125 (0.0)	0.0	1/130 (0.8)	0.7	0.35 (0.01, 8.43)	0.5152	-0.74 (-5.84, 4.35)	0.7747	
OCS dose at baseline									NE
<10 mg/day	0/ 77 (0.0)	0.0	1/ 82 (1.2)	1.2	0.35 (0.01, 8.58)	0.5237	-1.20 (-9.13, 6.74)	0.7677	
>=10 mg/day	0/103 (0.0)	0.0	0/102 (0.0)	0.0	NE		0.00 (-5.93, 5.93)	1.0000	
Result of type I IFN gene signature test									NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE		0.00 (-11.07, 11.07)	1.0000	
HIGH	0/148 (0.0)	0.0	1/151 (0.7)	0.6	0.34 (0.01, 8.28)	0.5078	-0.64 (-5.57, 4.30)	0.8007	
Age (years)									NE
<= 65	0/173 (0.0)	0.0	1/181 (0.6)	0.5	0.35 (0.01, 8.50)	0.5179	-0.52 (-5.16, 4.11)	0.8251	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
Sex									NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
female	0/165 (0.0)	0.0	1/171 (0.6)	0.6	0.35 (0.01, 8.42)	0.5141	-0.56 (-5.40, 4.29)	0.8219	
Race									NE
White	0/125 (0.0)	0.0	0/137 (0.0)	0.0	NE		0.00 (-5.97, 5.97)	1.0000	
Black or African American	0/ 29 (0.0)	0.0	1/ 23 (4.3)	4.3	0.27 (0.01, 6.26)	0.4116	-4.35 (-19.85, 11.16)	0.5826	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-20.43, 20.43)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE		0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	0/148 (0.0)	0.0	1/149 (0.7)	0.7	0.34 (0.01, 8.17)	0.5026	-0.71 (-6.22, 4.79)	0.7995	
Geographic region									NE
EU	0/ 64 (0.0)	0.0	0/ 76 (0.0)	0.0	NE		0.00 (-5.43, 5.43)	1.0000	
non-EU	0/116 (0.0)	0.0	1/108 (0.9)	0.9	0.31 (0.01, 7.54)	0.4724	-0.85 (-7.94, 6.24)	0.8140	
Onset of disease									NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
Adult	0/168 (0.0)	0.0	1/172 (0.6)	0.5	0.34 (0.01, 8.32)	0.5093	-0.55 (-5.35, 4.25)	0.8223	
ADA result									NE
Negative	0/162 (0.0)	0.0	0/169 (0.0)	0.0	NE		0.00 (-4.83, 4.83)	1.0000	
Positive (At any time)	0/ 17 (0.0)	0.0	1/ 15 (6.7)	6.7	0.30 (0.01, 6.77)	0.4461	-6.67 (-29.80, 16.47)	0.5722	
BMI (kg/m2) at enrolment									NE
< 30	0/108 (0.0)	0.0	0/127 (0.0)	0.0	NE		0.00 (-5.30, 5.30)	1.0000	
>= 30	0/ 72 (0.0)	0.0	1/ 57 (1.8)	1.9	0.26 (0.01, 6.38)	0.4131	-1.86 (-11.75, 8.03)	0.7119	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	0 (0.0)	1 (0.5)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.34 (0.01, 8.31)	
p-value	0.5088	
Odds Ratio (95% CI)	0.34 (0.01, 8.37)	
p-value	0.5084	
Risk Difference (95% CI)	-0.54 (-1.61, 0.52)	
p-value	0.3160	
CMH approach		
Response rate	0.0	0.5
Difference in response rates (95% CI)	-0.52 (-5.03, 3.99)	
p-value	0.8205	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 55 (0.0)	0.0	0/ 54 (0.0)	0.0	NE		0.00 (-10.69, 10.69)	1.0000	
>= 10 points	0/125 (0.0)	0.0	1/130 (0.8)	0.7	0.35 (0.01, 8.43)	0.5152	-0.74 (-5.84, 4.35)	0.7747	
OCS dose at baseline									NE
<10 mg/day	0/ 77 (0.0)	0.0	1/ 82 (1.2)	1.2	0.35 (0.01, 8.58)	0.5237	-1.20 (-9.13, 6.74)	0.7677	
>=10 mg/day	0/103 (0.0)	0.0	0/102 (0.0)	0.0	NE		0.00 (-5.93, 5.93)	1.0000	
Result of type I IFN gene signature test									NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE		0.00 (-11.07, 11.07)	1.0000	
HIGH	0/148 (0.0)	0.0	1/151 (0.7)	0.6	0.34 (0.01, 8.28)	0.5078	-0.64 (-5.57, 4.30)	0.8007	
Age (years)									NE
<= 65	0/173 (0.0)	0.0	1/181 (0.6)	0.5	0.35 (0.01, 8.50)	0.5179	-0.52 (-5.16, 4.11)	0.8251	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
Sex									NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
female	0/165 (0.0)	0.0	1/171 (0.6)	0.6	0.35 (0.01, 8.42)	0.5141	-0.56 (-5.40, 4.29)	0.8219	
Race									NE
White	0/125 (0.0)	0.0	0/137 (0.0)	0.0	NE		0.00 (-5.97, 5.97)	1.0000	
Black or African American	0/ 29 (0.0)	0.0	1/ 23 (4.3)	4.3	0.27 (0.01, 6.26)	0.4116	-4.35 (-19.85, 11.16)	0.5826	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-20.43, 20.43)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE		0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	0/148 (0.0)	0.0	1/149 (0.7)	0.7	0.34 (0.01, 8.17)	0.5026	-0.71 (-6.22, 4.79)	0.7995	
Geographic region									NE
EU	0/ 64 (0.0)	0.0	0/ 76 (0.0)	0.0	NE		0.00 (-5.43, 5.43)	1.0000	
non-EU	0/116 (0.0)	0.0	1/108 (0.9)	0.9	0.31 (0.01, 7.54)	0.4724	-0.85 (-7.94, 6.24)	0.8140	
Onset of disease									NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
Adult	0/168 (0.0)	0.0	1/172 (0.6)	0.5	0.34 (0.01, 8.32)	0.5093	-0.55 (-5.35, 4.25)	0.8223	
ADA result									NE
Negative	0/162 (0.0)	0.0	0/169 (0.0)	0.0	NE		0.00 (-4.83, 4.83)	1.0000	
Positive (At any time)	0/ 17 (0.0)	0.0	1/ 15 (6.7)	6.7	0.30 (0.01, 6.77)	0.4461	-6.67 (-29.80, 16.47)	0.5722	
BMI (kg/m2) at enrolment									NE
< 30	0/108 (0.0)	0.0	0/127 (0.0)	0.0	NE		0.00 (-5.30, 5.30)	1.0000	
>= 30	0/ 72 (0.0)	0.0	1/ 57 (1.8)	1.9	0.26 (0.01, 6.38)	0.4131	-1.86 (-11.75, 8.03)	0.7119	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	1 (0.6)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.07 (0.13, 74.78)	
p-value	0.4917	
Odds Ratio (95% CI)	3.08 (0.12, 76.19)	
p-value	0.4913	
Risk Difference (95% CI)	0.56 (-0.53, 1.64)	
p-value	0.3160	
CMH approach		
Response rate	0.6	0.0
Difference in response rates (95% CI)	0.55 (-3.98, 5.09)	
p-value	0.8105	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 55 (0.0)	0.0	0/ 54 (0.0)	0.0	NE		0.00 (-10.69, 10.69)	1.0000	
>= 10 points	1/125 (0.8)	0.8	0/130 (0.0)	0.0	3.12 (0.13, 75.85)	0.4848	0.79 (-4.35, 5.93)	0.7628	
OCS dose at baseline									NE
<10 mg/day	0/ 77 (0.0)	0.0	0/ 82 (0.0)	0.0	NE		0.00 (-7.65, 7.65)	1.0000	
>=10 mg/day	1/103 (1.0)	1.0	0/102 (0.0)	0.0	2.97 (0.12, 72.09)	0.5033	0.99 (-5.21, 7.18)	0.7554	
Result of type I IFN gene signature test									NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE		0.00 (-11.07, 11.07)	1.0000	
HIGH	1/148 (0.7)	0.7	0/151 (0.0)	0.0	3.06 (0.13, 74.53)	0.4923	0.68 (-4.29, 5.64)	0.7898	
Age (years)									NE
<= 65	1/173 (0.6)	0.6	0/181 (0.0)	0.0	3.14 (0.13, 76.51)	0.4828	0.58 (-4.09, 5.24)	0.8087	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
Sex									NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
female	1/165 (0.6)	0.6	0/171 (0.0)	0.0	3.11 (0.13, 75.76)	0.4864	0.61 (-4.27, 5.48)	0.8074	
Race									NE
White	0/125 (0.0)	0.0	0/137 (0.0)	0.0	NE		0.00 (-5.97, 5.97)	1.0000	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-13.78, 13.78)	1.0000	
Asian	1/ 11 (9.1)	9.1	0/ 5 (0.0)	0.0	1.50 (0.07, 31.57)	0.7942	9.09 (-34.34, 52.53)	0.6817	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-20.43, 20.43)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE		0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	1/148 (0.7)	0.7	0/149 (0.0)	0.0	3.02 (0.12, 73.54)	0.4974	0.73 (-4.80, 6.26)	0.7954	
Geographic region									NE
EU	0/ 64 (0.0)	0.0	0/ 76 (0.0)	0.0	NE		0.00 (-5.43, 5.43)	1.0000	
non-EU	1/116 (0.9)	0.8	0/108 (0.0)	0.0	2.79 (0.12, 67.88)	0.5277	0.77 (-6.30, 7.84)	0.8315	
Onset of disease									NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
Adult	1/168 (0.6)	0.6	0/172 (0.0)	0.0	3.07 (0.13, 74.86)	0.4911	0.60 (-4.22, 5.43)	0.8063	
ADA result									NE
Negative	1/162 (0.6)	0.6	0/169 (0.0)	0.0	3.13 (0.13, 76.25)	0.4839	0.64 (-4.33, 5.61)	0.8015	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE		0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	1/108 (0.9)	1.0	0/127 (0.0)	0.0	3.52 (0.14, 85.60)	0.4392	0.95 (-4.63, 6.53)	0.7385	
>= 30	0/ 72 (0.0)	0.0	0/ 57 (0.0)	0.0	NE		0.00 (-9.40, 9.40)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	1 (0.6)	2 (1.1)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.51 (0.05, 5.59)	
p-value	0.5823	
Odds Ratio (95% CI)	0.51 (0.05, 5.66)	
p-value	0.5821	
Risk Difference (95% CI)	-0.53 (-2.38, 1.32)	
p-value	0.5735	
CMH approach		
Response rate	0.6	1.1
Difference in response rates (95% CI)	-0.49 (-5.21, 4.23)	
p-value	0.8377	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.5905
< 10 points	0/ 55 (0.0)	0.0	1/ 54 (1.9)	1.8	0.33 (0.01, 7.86)	0.4912	-1.76 (-12.83, 9.31)	0.7554	
>= 10 points	1/125 (0.8)	0.8	1/130 (0.8)	0.8	1.04 (0.07, 16.45)	0.9778	0.05 (-5.28, 5.37)	0.9865	
OCS dose at baseline									0.5859
<10 mg/day	1/ 77 (1.3)	1.3	1/ 82 (1.2)	1.2	1.06 (0.07, 16.73)	0.9643	0.12 (-8.11, 8.35)	0.9768	
>=10 mg/day	0/103 (0.0)	0.0	1/102 (1.0)	1.0	0.33 (0.01, 8.01)	0.4958	-0.97 (-7.16, 5.22)	0.7586	
Result of type I IFN gene signature test									NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE		0.00 (-11.07, 11.07)	1.0000	
HIGH	1/148 (0.7)	0.7	2/151 (1.3)	1.3	0.51 (0.05, 5.57)	0.5809	-0.60 (-5.82, 4.62)	0.8215	
Age (years)									NE
<= 65	1/173 (0.6)	0.6	2/181 (1.1)	1.1	0.52 (0.05, 5.72)	0.5954	-0.47 (-5.33, 4.38)	0.8481	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
Sex									NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
female	1/165 (0.6)	0.6	2/171 (1.2)	1.2	0.52 (0.05, 5.66)	0.5899	-0.53 (-5.61, 4.54)	0.8372	
Race									NE
White	1/125 (0.8)	0.8	2/137 (1.5)	1.5	0.55 (0.05, 5.97)	0.6216	-0.67 (-7.03, 5.70)	0.8369	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-20.43, 20.43)	1.0000	
Ethnicity									0.2122
Hispanic/Latino	1/ 32 (3.1)	3.1	0/ 35 (0.0)	0.0	3.27 (0.14, 77.57)	0.4629	3.13 (-8.92, 15.17)	0.6111	
Non-hispanic/Latino	0/148 (0.0)	0.0	2/149 (1.3)	1.3	0.20 (0.01, 4.16)	0.2995	-1.26 (-6.84, 4.33)	0.6591	
Geographic region									0.2707
EU	0/ 64 (0.0)	0.0	2/ 76 (2.6)	2.6	0.24 (0.01, 4.85)	0.3498	-2.63 (-9.05, 3.78)	0.4213	
non-EU	1/116 (0.9)	0.9	0/108 (0.0)	0.0	2.79 (0.12, 67.88)	0.5277	0.95 (-6.17, 8.07)	0.7939	
Onset of disease									NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
Adult	1/168 (0.6)	0.6	2/172 (1.2)	1.2	0.51 (0.05, 5.59)	0.5831	-0.55 (-5.58, 4.48)	0.8304	
ADA result									NE
Negative	1/162 (0.6)	0.6	2/169 (1.2)	1.1	0.52 (0.05, 5.70)	0.5936	-0.50 (-5.65, 4.64)	0.8479	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE		0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment									0.7431
< 30	0/108 (0.0)	0.0	1/127 (0.8)	0.9	0.39 (0.02, 9.51)	0.5645	-0.88 (-6.37, 4.62)	0.7545	
>= 30	1/ 72 (1.4)	1.3	1/ 57 (1.8)	1.9	0.79 (0.05, 12.38)	0.8678	-0.57 (-10.71, 9.57)	0.9124	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.42, 4.42)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 55 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>= 10 points	0/125 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 77 (0.0)	0.0	0/ 82 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
>=10 mg/day	0/103 (0.0)	0.0	0/102 (0.0)	0.0	NE	0.00 (-5.93, 5.93)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-11.07, 11.07)	1.0000	
HIGH	0/148 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.81, 4.81)	1.0000	
Age (years)								NE
<= 65	0/173 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.54, 4.54)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
Sex								NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
female	0/165 (0.0)	0.0	0/171 (0.0)	0.0	NE	0.00 (-4.75, 4.75)	1.0000	
Race								NE
White	0/125 (0.0)	0.0	0/137 (0.0)	0.0	NE	0.00 (-5.97, 5.97)	1.0000	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-20.43, 20.43)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE	0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	0/148 (0.0)	0.0	0/149 (0.0)	0.0	NE	0.00 (-5.37, 5.37)	1.0000	
Geographic region								NE
EU	0/ 64 (0.0)	0.0	0/ 76 (0.0)	0.0	NE	0.00 (-5.43, 5.43)	1.0000	
non-EU	0/116 (0.0)	0.0	0/108 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Onset of disease								NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
Adult	0/168 (0.0)	0.0	0/172 (0.0)	0.0	NE	0.00 (-4.70, 4.70)	1.0000	
ADA result								NE
Negative	0/162 (0.0)	0.0	0/169 (0.0)	0.0	NE	0.00 (-4.83, 4.83)	1.0000	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE	0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/108 (0.0)	0.0	0/127 (0.0)	0.0	NE	0.00 (-5.30, 5.30)	1.0000	
>= 30	0/ 72 (0.0)	0.0	0/ 57 (0.0)	0.0	NE	0.00 (-9.40, 9.40)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.42, 4.42)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 55 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>= 10 points	0/125 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 77 (0.0)	0.0	0/ 82 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
>=10 mg/day	0/103 (0.0)	0.0	0/102 (0.0)	0.0	NE	0.00 (-5.93, 5.93)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-11.07, 11.07)	1.0000	
HIGH	0/148 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.81, 4.81)	1.0000	
Age (years)								NE
<= 65	0/173 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.54, 4.54)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
Sex								NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
female	0/165 (0.0)	0.0	0/171 (0.0)	0.0	NE	0.00 (-4.75, 4.75)	1.0000	
Race								NE
White	0/125 (0.0)	0.0	0/137 (0.0)	0.0	NE	0.00 (-5.97, 5.97)	1.0000	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-20.43, 20.43)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE	0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	0/148 (0.0)	0.0	0/149 (0.0)	0.0	NE	0.00 (-5.37, 5.37)	1.0000	
Geographic region								NE
EU	0/ 64 (0.0)	0.0	0/ 76 (0.0)	0.0	NE	0.00 (-5.43, 5.43)	1.0000	
non-EU	0/116 (0.0)	0.0	0/108 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Onset of disease								NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
Adult	0/168 (0.0)	0.0	0/172 (0.0)	0.0	NE	0.00 (-4.70, 4.70)	1.0000	
ADA result								NE
Negative	0/162 (0.0)	0.0	0/169 (0.0)	0.0	NE	0.00 (-4.83, 4.83)	1.0000	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE	0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/108 (0.0)	0.0	0/127 (0.0)	0.0	NE	0.00 (-5.30, 5.30)	1.0000	
>= 30	0/ 72 (0.0)	0.0	0/ 57 (0.0)	0.0	NE	0.00 (-9.40, 9.40)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	1 (0.6)	2 (1.1)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.51 (0.05, 5.59)	
p-value	0.5823	
Odds Ratio (95% CI)	0.51 (0.05, 5.66)	
p-value	0.5821	
Risk Difference (95% CI)	-0.53 (-2.38, 1.32)	
p-value	0.5735	
CMH approach		
Response rate	0.6	1.1
Difference in response rates (95% CI)	-0.49 (-5.21, 4.23)	
p-value	0.8377	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.5905
< 10 points	0/ 55 (0.0)	0.0	1/ 54 (1.9)	1.8	0.33 (0.01, 7.86)	0.4912	-1.76 (-12.83, 9.31)	0.7554	
>= 10 points	1/125 (0.8)	0.8	1/130 (0.8)	0.8	1.04 (0.07, 16.45)	0.9778	0.05 (-5.28, 5.37)	0.9865	
OCS dose at baseline									0.5859
<10 mg/day	1/ 77 (1.3)	1.3	1/ 82 (1.2)	1.2	1.06 (0.07, 16.73)	0.9643	0.12 (-8.11, 8.35)	0.9768	
>=10 mg/day	0/103 (0.0)	0.0	1/102 (1.0)	1.0	0.33 (0.01, 8.01)	0.4958	-0.97 (-7.16, 5.22)	0.7586	
Result of type I IFN gene signature test									NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE		0.00 (-11.07, 11.07)	1.0000	
HIGH	1/148 (0.7)	0.7	2/151 (1.3)	1.3	0.51 (0.05, 5.57)	0.5809	-0.60 (-5.82, 4.62)	0.8215	
Age (years)									NE
<= 65	1/173 (0.6)	0.6	2/181 (1.1)	1.1	0.52 (0.05, 5.72)	0.5954	-0.47 (-5.33, 4.38)	0.8481	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
Sex									NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
female	1/165 (0.6)	0.6	2/171 (1.2)	1.2	0.52 (0.05, 5.66)	0.5899	-0.53 (-5.61, 4.54)	0.8372	
Race									NE
White	1/125 (0.8)	0.8	2/137 (1.5)	1.5	0.55 (0.05, 5.97)	0.6216	-0.67 (-7.03, 5.70)	0.8369	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-20.43, 20.43)	1.0000	
Ethnicity									0.2122
Hispanic/Latino	1/ 32 (3.1)	3.1	0/ 35 (0.0)	0.0	3.27 (0.14, 77.57)	0.4629	3.13 (-8.92, 15.17)	0.6111	
Non-hispanic/Latino	0/148 (0.0)	0.0	2/149 (1.3)	1.3	0.20 (0.01, 4.16)	0.2995	-1.26 (-6.84, 4.33)	0.6591	
Geographic region									0.2707
EU	0/ 64 (0.0)	0.0	2/ 76 (2.6)	2.6	0.24 (0.01, 4.85)	0.3498	-2.63 (-9.05, 3.78)	0.4213	
non-EU	1/116 (0.9)	0.9	0/108 (0.0)	0.0	2.79 (0.12, 67.88)	0.5277	0.95 (-6.17, 8.07)	0.7939	
Onset of disease									NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
Adult	1/168 (0.6)	0.6	2/172 (1.2)	1.2	0.51 (0.05, 5.59)	0.5831	-0.55 (-5.58, 4.48)	0.8304	
ADA result									NE
Negative	1/162 (0.6)	0.6	2/169 (1.2)	1.1	0.52 (0.05, 5.70)	0.5936	-0.50 (-5.65, 4.64)	0.8479	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE		0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment									0.7431
< 30	0/108 (0.0)	0.0	1/127 (0.8)	0.9	0.39 (0.02, 9.51)	0.5645	-0.88 (-6.37, 4.62)	0.7545	
>= 30	1/ 72 (1.4)	1.3	1/ 57 (1.8)	1.9	0.79 (0.05, 12.38)	0.8678	-0.57 (-10.71, 9.57)	0.9124	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Vasculitis
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.42, 4.42)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 55 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>= 10 points	0/125 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 77 (0.0)	0.0	0/ 82 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
>=10 mg/day	0/103 (0.0)	0.0	0/102 (0.0)	0.0	NE	0.00 (-5.93, 5.93)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-11.07, 11.07)	1.0000	
HIGH	0/148 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.81, 4.81)	1.0000	
Age (years)								NE
<= 65	0/173 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.54, 4.54)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
Sex								NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
female	0/165 (0.0)	0.0	0/171 (0.0)	0.0	NE	0.00 (-4.75, 4.75)	1.0000	
Race								NE
White	0/125 (0.0)	0.0	0/137 (0.0)	0.0	NE	0.00 (-5.97, 5.97)	1.0000	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-20.43, 20.43)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE	0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	0/148 (0.0)	0.0	0/149 (0.0)	0.0	NE	0.00 (-5.37, 5.37)	1.0000	
Geographic region								NE
EU	0/ 64 (0.0)	0.0	0/ 76 (0.0)	0.0	NE	0.00 (-5.43, 5.43)	1.0000	
non-EU	0/116 (0.0)	0.0	0/108 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Onset of disease								NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
Adult	0/168 (0.0)	0.0	0/172 (0.0)	0.0	NE	0.00 (-4.70, 4.70)	1.0000	
ADA result								NE
Negative	0/162 (0.0)	0.0	0/169 (0.0)	0.0	NE	0.00 (-4.83, 4.83)	1.0000	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE	0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/108 (0.0)	0.0	0/127 (0.0)	0.0	NE	0.00 (-5.30, 5.30)	1.0000	
>= 30	0/ 72 (0.0)	0.0	0/ 57 (0.0)	0.0	NE	0.00 (-9.40, 9.40)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Vasculitis
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.42, 4.42)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Anifrolumab 300mg (N=180) Response rate	Placebo (N=184) n/ N (%)	Placebo (N=184) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Analysis Anifrolumab 300mg vs. Placebo Difference in response rates (95% CI)	Analysis Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 55 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>= 10 points	0/125 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 77 (0.0)	0.0	0/ 82 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
>=10 mg/day	0/103 (0.0)	0.0	0/102 (0.0)	0.0	NE	0.00 (-5.93, 5.93)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-11.07, 11.07)	1.0000	
HIGH	0/148 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.81, 4.81)	1.0000	
Age (years)								NE
<= 65	0/173 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.54, 4.54)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
Sex								NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
female	0/165 (0.0)	0.0	0/171 (0.0)	0.0	NE	0.00 (-4.75, 4.75)	1.0000	
Race								NE
White	0/125 (0.0)	0.0	0/137 (0.0)	0.0	NE	0.00 (-5.97, 5.97)	1.0000	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-20.43, 20.43)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE	0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	0/148 (0.0)	0.0	0/149 (0.0)	0.0	NE	0.00 (-5.37, 5.37)	1.0000	
Geographic region								NE
EU	0/ 64 (0.0)	0.0	0/ 76 (0.0)	0.0	NE	0.00 (-5.43, 5.43)	1.0000	
non-EU	0/116 (0.0)	0.0	0/108 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Onset of disease								NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
Adult	0/168 (0.0)	0.0	0/172 (0.0)	0.0	NE	0.00 (-4.70, 4.70)	1.0000	
ADA result								NE
Negative	0/162 (0.0)	0.0	0/169 (0.0)	0.0	NE	0.00 (-4.83, 4.83)	1.0000	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE	0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/108 (0.0)	0.0	0/127 (0.0)	0.0	NE	0.00 (-5.30, 5.30)	1.0000	
>= 30	0/ 72 (0.0)	0.0	0/ 57 (0.0)	0.0	NE	0.00 (-9.40, 9.40)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Vasculitis
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.42, 4.42)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Anifrolumab 300mg (N=180) Response rate	Placebo (N=184) n/ N (%)	Placebo (N=184) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Analysis Anifrolumab 300mg vs. Placebo Difference in response rates (95% CI)	Analysis Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 55 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>= 10 points	0/125 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 77 (0.0)	0.0	0/ 82 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
>=10 mg/day	0/103 (0.0)	0.0	0/102 (0.0)	0.0	NE	0.00 (-5.93, 5.93)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-11.07, 11.07)	1.0000	
HIGH	0/148 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.81, 4.81)	1.0000	
Age (years)								NE
<= 65	0/173 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.54, 4.54)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
Sex								NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
female	0/165 (0.0)	0.0	0/171 (0.0)	0.0	NE	0.00 (-4.75, 4.75)	1.0000	
Race								NE
White	0/125 (0.0)	0.0	0/137 (0.0)	0.0	NE	0.00 (-5.97, 5.97)	1.0000	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0	NE	0/ 1 (0.0)		NE	NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-20.43, 20.43)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE	0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	0/148 (0.0)	0.0	0/149 (0.0)	0.0	NE	0.00 (-5.37, 5.37)	1.0000	
Geographic region								NE
EU	0/ 64 (0.0)	0.0	0/ 76 (0.0)	0.0	NE	0.00 (-5.43, 5.43)	1.0000	
non-EU	0/116 (0.0)	0.0	0/108 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Onset of disease								NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
Adult	0/168 (0.0)	0.0	0/172 (0.0)	0.0	NE	0.00 (-4.70, 4.70)	1.0000	
ADA result								NE
Negative	0/162 (0.0)	0.0	0/169 (0.0)	0.0	NE	0.00 (-4.83, 4.83)	1.0000	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE	0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/108 (0.0)	0.0	0/127 (0.0)	0.0	NE	0.00 (-5.30, 5.30)	1.0000	
>= 30	0/ 72 (0.0)	0.0	0/ 57 (0.0)	0.0	NE	0.00 (-9.40, 9.40)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Vasculitis
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.42, 4.42)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 55 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>= 10 points	0/125 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 77 (0.0)	0.0	0/ 82 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
>=10 mg/day	0/103 (0.0)	0.0	0/102 (0.0)	0.0	NE	0.00 (-5.93, 5.93)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-11.07, 11.07)	1.0000	
HIGH	0/148 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.81, 4.81)	1.0000	
Age (years)								NE
<= 65	0/173 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.54, 4.54)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
Sex								NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
female	0/165 (0.0)	0.0	0/171 (0.0)	0.0	NE	0.00 (-4.75, 4.75)	1.0000	
Race								NE
White	0/125 (0.0)	0.0	0/137 (0.0)	0.0	NE	0.00 (-5.97, 5.97)	1.0000	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-20.43, 20.43)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE	0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	0/148 (0.0)	0.0	0/149 (0.0)	0.0	NE	0.00 (-5.37, 5.37)	1.0000	
Geographic region								NE
EU	0/ 64 (0.0)	0.0	0/ 76 (0.0)	0.0	NE	0.00 (-5.43, 5.43)	1.0000	
non-EU	0/116 (0.0)	0.0	0/108 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Onset of disease								NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
Adult	0/168 (0.0)	0.0	0/172 (0.0)	0.0	NE	0.00 (-4.70, 4.70)	1.0000	
ADA result								NE
Negative	0/162 (0.0)	0.0	0/169 (0.0)	0.0	NE	0.00 (-4.83, 4.83)	1.0000	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE	0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/108 (0.0)	0.0	0/127 (0.0)	0.0	NE	0.00 (-5.30, 5.30)	1.0000	
>= 30	0/ 72 (0.0)	0.0	0/ 57 (0.0)	0.0	NE	0.00 (-9.40, 9.40)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Malignancy
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	4 (2.2)	1 (0.5)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	4.09 (0.46, 36.23)	
p-value	0.2058	
Odds Ratio (95% CI)	4.16 (0.46, 37.58)	
p-value	0.2044	
Risk Difference (95% CI)	1.68 (-0.72, 4.08)	
p-value	0.1706	
CMH approach		
Response rate	2.2	0.5
Difference in response rates (95% CI)	1.67 (-3.23, 6.56)	
p-value	0.5046	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.6615
< 10 points	2/ 55 (3.6)	3.6	0/ 54 (0.0)	0.0	4.91 (0.24, 99.97)	0.3006	3.60 (-7.86, 15.07)	0.5380	
>= 10 points	2/125 (1.6)	1.6	1/130 (0.8)	0.8	2.08 (0.19, 22.65)	0.5478	0.83 (-4.65, 6.31)	0.7662	
OCS dose at baseline									0.3272
<10 mg/day	3/ 77 (3.9)	3.9	0/ 82 (0.0)	0.0	7.45 (0.39, 141.89)	0.1817	3.87 (-4.62, 12.36)	0.3717	
>=10 mg/day	1/103 (1.0)	0.9	1/102 (1.0)	1.0	0.99 (0.06, 15.62)	0.9945	-0.08 (-6.44, 6.28)	0.9800	
Result of type I IFN gene signature test									0.9961
LOW	1/ 32 (3.1)	3.1	0/ 33 (0.0)	0.0	3.09 (0.13, 73.19)	0.4846	3.13 (-9.17, 15.42)	0.6184	
HIGH	3/148 (2.0)	2.0	1/151 (0.7)	0.7	3.06 (0.32, 29.09)	0.3302	1.35 (-3.98, 6.68)	0.6196	
Age (years)									NE
<= 65	4/173 (2.3)	2.3	1/181 (0.6)	0.6	4.18 (0.47, 37.07)	0.1984	1.75 (-3.29, 6.79)	0.4967	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
Sex									NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
female	4/165 (2.4)	2.4	1/171 (0.6)	0.6	4.15 (0.47, 36.70)	0.2013	1.81 (-3.45, 7.08)	0.4990	
Race									NE
White	4/125 (3.2)	3.3	1/137 (0.7)	0.7	4.38 (0.50, 38.70)	0.1835	2.54 (-4.08, 9.16)	0.4517	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-20.43, 20.43)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE		0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	4/148 (2.7)	2.6	1/149 (0.7)	0.6	4.03 (0.46, 35.61)	0.2103	1.96 (-3.93, 7.86)	0.5140	
Geographic region									0.7315
EU	2/ 64 (3.1)	3.1	1/ 76 (1.3)	1.3	2.38 (0.22, 25.59)	0.4758	1.81 (-5.37, 8.98)	0.6211	
non-EU	2/116 (1.7)	1.8	0/108 (0.0)	0.0	4.66 (0.23, 95.94)	0.3188	1.83 (-5.41, 9.07)	0.6210	
Onset of disease									NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
Adult	4/168 (2.4)	2.3	1/172 (0.6)	0.6	4.10 (0.46, 36.26)	0.2052	1.77 (-3.43, 6.97)	0.5050	
ADA result									NE
Negative	4/162 (2.5)	2.4	1/169 (0.6)	0.6	4.17 (0.47, 36.94)	0.1991	1.85 (-3.49, 7.19)	0.4974	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE		0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	4/108 (3.7)	3.6	1/127 (0.8)	0.8	4.70 (0.53, 41.45)	0.1632	2.82 (-3.42, 9.07)	0.3761	
>= 30	0/ 72 (0.0)	0.0	0/ 57 (0.0)	0.0	NE		0.00 (-9.40, 9.40)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Malignancy
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	2 (1.1)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	5.11 (0.25, 105.71)	
p-value	0.2912	
Odds Ratio (95% CI)	5.17 (0.25, 108.40)	
p-value	0.2901	
Risk Difference (95% CI)	1.11 (-0.42, 2.64)	
p-value	0.1550	
CMH approach		
Response rate	1.1	0.0
Difference in response rates (95% CI)	1.08 (-3.51, 5.66)	
p-value	0.6457	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	2/ 55 (3.6)	3.6	0/ 54 (0.0)	0.0	4.91 (0.24, 99.97)	0.3006	3.60 (-7.86, 15.07)	0.5380	
>= 10 points	0/125 (0.0)	0.0	0/130 (0.0)	0.0	NE		0.00 (-4.93, 4.93)	1.0000	
OCS dose at baseline									0.9751
<10 mg/day	1/ 77 (1.3)	1.3	0/ 82 (0.0)	0.0	3.19 (0.13, 77.20)	0.4751	1.32 (-6.62, 9.25)	0.7449	
>=10 mg/day	1/103 (1.0)	0.9	0/102 (0.0)	0.0	2.97 (0.12, 72.09)	0.5033	0.89 (-5.22, 7.00)	0.7754	
Result of type I IFN gene signature test									NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE		0.00 (-11.07, 11.07)	1.0000	
HIGH	2/148 (1.4)	1.3	0/151 (0.0)	0.0	5.10 (0.25, 105.35)	0.2916	1.31 (-3.73, 6.35)	0.6103	
Age (years)									NE
<= 65	2/173 (1.2)	1.1	0/181 (0.0)	0.0	5.23 (0.25, 108.16)	0.2844	1.11 (-3.61, 5.82)	0.6451	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
Sex									NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
female	2/165 (1.2)	1.2	0/171 (0.0)	0.0	5.18 (0.25, 107.11)	0.2871	1.16 (-3.77, 6.08)	0.6446	
Race									NE
White	2/125 (1.6)	1.7	0/137 (0.0)	0.0	5.48 (0.27, 112.97)	0.2709	1.73 (-4.50, 7.95)	0.5866	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-20.43, 20.43)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE		0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	2/148 (1.4)	1.3	0/149 (0.0)	0.0	5.03 (0.24, 103.96)	0.2955	1.25 (-4.30, 6.81)	0.6585	
Geographic region									0.9168
EU	1/ 64 (1.6)	1.6	0/ 76 (0.0)	0.0	3.55 (0.15, 85.76)	0.4350	1.56 (-4.57, 7.70)	0.6176	
non-EU	1/116 (0.9)	0.9	0/108 (0.0)	0.0	2.79 (0.12, 67.88)	0.5277	0.93 (-6.16, 8.02)	0.7979	
Onset of disease									NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
Adult	2/168 (1.2)	1.1	0/172 (0.0)	0.0	5.12 (0.25, 105.82)	0.2907	1.13 (-3.74, 6.01)	0.6482	
ADA result									NE
Negative	2/162 (1.2)	1.2	0/169 (0.0)	0.0	5.21 (0.25, 107.80)	0.2852	1.19 (-3.83, 6.20)	0.6430	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE		0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	2/108 (1.9)	1.7	0/127 (0.0)	0.0	5.87 (0.28, 120.99)	0.2515	1.68 (-3.96, 7.32)	0.5588	
>= 30	0/ 72 (0.0)	0.0	0/ 57 (0.0)	0.0	NE		0.00 (-9.40, 9.40)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Malignancy
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	1 (0.6)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.07 (0.13, 74.78)	
p-value	0.4917	
Odds Ratio (95% CI)	3.08 (0.12, 76.19)	
p-value	0.4913	
Risk Difference (95% CI)	0.56 (-0.53, 1.64)	
p-value	0.3160	
CMH approach		
Response rate	0.6	0.0
Difference in response rates (95% CI)	0.58 (-3.94, 5.09)	
p-value	0.8026	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	1/ 55 (1.8)	1.9	0/ 54 (0.0)	0.0	2.95 (0.12, 70.77)	0.5053	1.93 (-9.20, 13.06)	0.7344	
>= 10 points	0/125 (0.0)	0.0	0/130 (0.0)	0.0	NE		0.00 (-4.93, 4.93)	1.0000	
OCS dose at baseline									NE
<10 mg/day	1/ 77 (1.3)	1.3	0/ 82 (0.0)	0.0	3.19 (0.13, 77.20)	0.4751	1.32 (-6.62, 9.25)	0.7449	
>=10 mg/day	0/103 (0.0)	0.0	0/102 (0.0)	0.0	NE		0.00 (-5.93, 5.93)	1.0000	
Result of type I IFN gene signature test									NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE		0.00 (-11.07, 11.07)	1.0000	
HIGH	1/148 (0.7)	0.7	0/151 (0.0)	0.0	3.06 (0.13, 74.53)	0.4923	0.70 (-4.24, 5.64)	0.7809	
Age (years)									NE
<= 65	1/173 (0.6)	0.6	0/181 (0.0)	0.0	3.14 (0.13, 76.51)	0.4828	0.61 (-4.04, 5.25)	0.7978	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
Sex									NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
female	1/165 (0.6)	0.6	0/171 (0.0)	0.0	3.11 (0.13, 75.76)	0.4864	0.61 (-4.24, 5.46)	0.8048	
Race									NE
White	1/125 (0.8)	0.8	0/137 (0.0)	0.0	3.29 (0.14, 79.92)	0.4651	0.79 (-5.30, 6.88)	0.7985	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-20.43, 20.43)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE		0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	1/148 (0.7)	0.7	0/149 (0.0)	0.0	3.02 (0.12, 73.54)	0.4974	0.73 (-4.76, 6.22)	0.7938	
Geographic region									NE
EU	0/ 64 (0.0)	0.0	0/ 76 (0.0)	0.0	NE		0.00 (-5.43, 5.43)	1.0000	
non-EU	1/116 (0.9)	0.9	0/108 (0.0)	0.0	2.79 (0.12, 67.88)	0.5277	0.93 (-6.16, 8.02)	0.7979	
Onset of disease									NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
Adult	1/168 (0.6)	0.6	0/172 (0.0)	0.0	3.07 (0.13, 74.86)	0.4911	0.57 (-4.22, 5.37)	0.8141	
ADA result									NE
Negative	1/162 (0.6)	0.7	0/169 (0.0)	0.0	3.13 (0.13, 76.25)	0.4839	0.65 (-4.29, 5.59)	0.7954	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE		0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	1/108 (0.9)	0.8	0/127 (0.0)	0.0	3.52 (0.14, 85.60)	0.4392	0.84 (-4.64, 6.32)	0.7635	
>= 30	0/ 72 (0.0)	0.0	0/ 57 (0.0)	0.0	NE		0.00 (-9.40, 9.40)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Malignancy
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	3 (1.7)	1 (0.5)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.07 (0.32, 29.21)	
p-value	0.3298	
Odds Ratio (95% CI)	3.10 (0.32, 30.10)	
p-value	0.3289	
Risk Difference (95% CI)	1.12 (-1.03, 3.27)	
p-value	0.3061	
CMH approach		
Response rate	1.6	0.5
Difference in response rates (95% CI)	1.09 (-3.72, 5.90)	
p-value	0.6564	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8637
< 10 points	1/ 55 (1.8)	1.7	0/ 54 (0.0)	0.0	2.95 (0.12, 70.77)	0.5053	1.68 (-9.37, 12.72)	0.7661	
>= 10 points	2/125 (1.6)	1.6	1/130 (0.8)	0.8	2.08 (0.19, 22.65)	0.5478	0.83 (-4.65, 6.31)	0.7662	
OCS dose at baseline									0.4205
<10 mg/day	2/ 77 (2.6)	2.6	0/ 82 (0.0)	0.0	5.32 (0.26, 109.09)	0.2781	2.55 (-5.67, 10.77)	0.5430	
>=10 mg/day	1/103 (1.0)	0.9	1/102 (1.0)	1.0	0.99 (0.06, 15.62)	0.9945	-0.08 (-6.44, 6.28)	0.9800	
Result of type I IFN gene signature test									0.8374
LOW	1/ 32 (3.1)	3.1	0/ 33 (0.0)	0.0	3.09 (0.13, 73.19)	0.4846	3.13 (-9.17, 15.42)	0.6184	
HIGH	2/148 (1.4)	1.3	1/151 (0.7)	0.7	2.04 (0.19, 22.26)	0.5586	0.65 (-4.56, 5.86)	0.8071	
Age (years)									NE
<= 65	3/173 (1.7)	1.7	1/181 (0.6)	0.6	3.14 (0.33, 29.89)	0.3198	1.14 (-3.80, 6.09)	0.6512	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
Sex									NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
female	3/165 (1.8)	1.8	1/171 (0.6)	0.6	3.11 (0.33, 29.59)	0.3238	1.20 (-3.97, 6.37)	0.6481	
Race									NE
White	3/125 (2.4)	2.5	1/137 (0.7)	0.7	3.29 (0.35, 31.20)	0.2998	1.75 (-4.76, 8.26)	0.5987	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-20.43, 20.43)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE		0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	3/148 (2.0)	1.9	1/149 (0.7)	0.6	3.02 (0.32, 28.70)	0.3360	1.23 (-4.55, 7.01)	0.6767	
Geographic region									0.9361
EU	2/ 64 (3.1)	3.1	1/ 76 (1.3)	1.3	2.38 (0.22, 25.59)	0.4758	1.81 (-5.37, 8.98)	0.6211	
non-EU	1/116 (0.9)	0.9	0/108 (0.0)	0.0	2.79 (0.12, 67.88)	0.5277	0.90 (-6.20, 8.00)	0.8037	
Onset of disease									NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
Adult	3/168 (1.8)	1.8	1/172 (0.6)	0.6	3.07 (0.32, 29.23)	0.3290	1.19 (-3.92, 6.31)	0.6476	
ADA result									NE
Negative	3/162 (1.9)	1.8	1/169 (0.6)	0.6	3.13 (0.33, 29.78)	0.3209	1.20 (-4.05, 6.44)	0.6548	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE		0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	3/108 (2.8)	2.7	1/127 (0.8)	0.8	3.53 (0.37, 33.42)	0.2718	1.98 (-4.12, 8.08)	0.5249	
>= 30	0/ 72 (0.0)	0.0	0/ 57 (0.0)	0.0	NE		0.00 (-9.40, 9.40)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of SOCs Cardiac disorders and/or Vascular disorders
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	9 (5.0)	22 (12.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.42 (0.20, 0.88)	
p-value	0.0223	
Odds Ratio (95% CI)	0.39 (0.17, 0.87)	
p-value	0.0210	
Risk Difference (95% CI)	-6.96 (-12.62, -1.29)	
p-value	0.0161	
CMH approach		
Response rate	5.0	12.0
Difference in response rates (95% CI)	-7.00 (-13.75, -0.24)	
p-value	0.0423	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of SOCs Cardiac disorders and/or Vascular disorders - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.3854
< 10 points	3/ 55 (5.5)	5.5	4/ 54 (7.4)	7.5	0.74 (0.17, 3.14)	0.6789	-2.01 (-15.25, 11.23)	0.7659	
>= 10 points	6/125 (4.8)	4.8	18/130 (13.8)	13.9	0.35 (0.14, 0.84)	0.0197	-9.16 (-17.27, -1.05)	0.0268	
OCS dose at baseline									0.8621
<10 mg/day	3/ 77 (3.9)	4.0	7/ 82 (8.5)	8.6	0.46 (0.12, 1.70)	0.2428	-4.62 (-14.63, 5.38)	0.3652	
>=10 mg/day	6/103 (5.8)	5.9	15/102 (14.7)	14.8	0.40 (0.16, 0.98)	0.0452	-8.87 (-18.43, 0.68)	0.0687	
Result of type I IFN gene signature test									0.8533
LOW	1/ 32 (3.1)	3.1	2/ 33 (6.1)	6.1	0.52 (0.05, 5.41)	0.5808	-2.94 (-17.22, 11.35)	0.6870	
HIGH	8/148 (5.4)	5.4	20/151 (13.2)	13.3	0.41 (0.19, 0.90)	0.0258	-7.88 (-15.50, -0.27)	0.0425	
Age (years)									0.5263
<= 65	9/173 (5.2)	5.2	21/181 (11.6)	11.7	0.45 (0.21, 0.95)	0.0367	-6.48 (-13.35, 0.39)	0.0644	
> 65	0/ 7 (0.0)	0.0	1/ 3 (33.3)	33.3	0.17 (0.01, 3.24)	0.2366	-33.33 (-96.20, 29.53)	0.2987	
Sex									0.0656
male	3/ 15 (20.0)	20.0	1/ 13 (7.7)	7.7	2.60 (0.31, 22.05)	0.3810	12.31 (-18.12, 42.74)	0.4279	
female	6/165 (3.6)	3.6	21/171 (12.3)	12.3	0.30 (0.12, 0.72)	0.0068	-8.63 (-15.58, -1.68)	0.0149	
Race									0.7597
White	8/125 (6.4)	6.5	17/137 (12.4)	12.4	0.52 (0.23, 1.15)	0.1068	-5.88 (-14.40, 2.64)	0.1763	
Black or African American	1/ 29 (3.4)	3.4	2/ 23 (8.7)	8.7	0.40 (0.04, 4.11)	0.4380	-5.25 (-23.14, 12.65)	0.5655	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 15 (0.0)	0.0	3/ 18 (16.7)	16.7	0.17 (0.01, 3.05)	0.2285	-16.67 (-41.49, 8.15)	0.1881	
Ethnicity									0.3695
Hispanic/Latino	1/ 32 (3.1)	3.1	6/ 35 (17.1)	17.1	0.18 (0.02, 1.43)	0.1057	-14.02 (-30.47, 2.43)	0.0949	
Non-hispanic/Latino	8/148 (5.4)	5.5	16/149 (10.7)	10.6	0.50 (0.22, 1.14)	0.0999	-5.09 (-12.71, 2.53)	0.1907	
Geographic region									0.5725
EU	3/ 64 (4.7)	4.7	11/ 76 (14.5)	14.5	0.32 (0.09, 1.11)	0.0730	-9.79 (-20.26, 0.69)	0.0670	
non-EU	6/116 (5.2)	5.3	11/108 (10.2)	10.4	0.51 (0.19, 1.33)	0.1664	-5.09 (-14.26, 4.08)	0.2764	
Onset of disease									0.5898
Paediatric	0/ 12 (0.0)	0.0	2/ 12 (16.7)	16.7	0.20 (0.01, 3.77)	0.2829	-16.67 (-47.49, 14.16)	0.2893	
Adult	9/168 (5.4)	5.3	20/172 (11.6)	11.6	0.46 (0.22, 0.98)	0.0449	-6.25 (-13.29, 0.79)	0.0817	
ADA result									0.5761
Negative	8/162 (4.9)	5.0	21/169 (12.4)	12.3	0.40 (0.18, 0.87)	0.0213	-7.34 (-14.53, -0.15)	0.0453	
Positive (At any time)	1/ 17 (5.9)	5.9	1/ 15 (6.7)	6.7	0.88 (0.06, 12.91)	0.9272	-0.78 (-25.63, 24.06)	0.9507	
BMI (kg/m2) at enrolment									0.0243
< 30	2/108 (1.9)	1.9	17/127 (13.4)	13.4	0.14 (0.03, 0.59)	0.0072	-11.47 (-19.46, -3.48)	0.0049	
>= 30	7/ 72 (9.7)	9.9	5/ 57 (8.8)	9.0	1.11 (0.37, 3.31)	0.8538	0.96 (-11.78, 13.70)	0.8825	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Time to first Onset of Herpes Zoster (on-treatment)
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	10 (5.6)	3 (1.6)
Number of censored subjects, n (%)	170 (94.4)	181 (98.4)
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Anifrolumab 300mg vs. Placebo (adjusted)		
Hazard Ratio (95% CI)	3.46 (0.95, 12.58)	
p-value	0.0490	
Analysis Anifrolumab 300mg vs. Placebo (unadjusted)		
Hazard Ratio (95% CI)	3.46 (0.95, 12.56)	
p-value	0.0447	

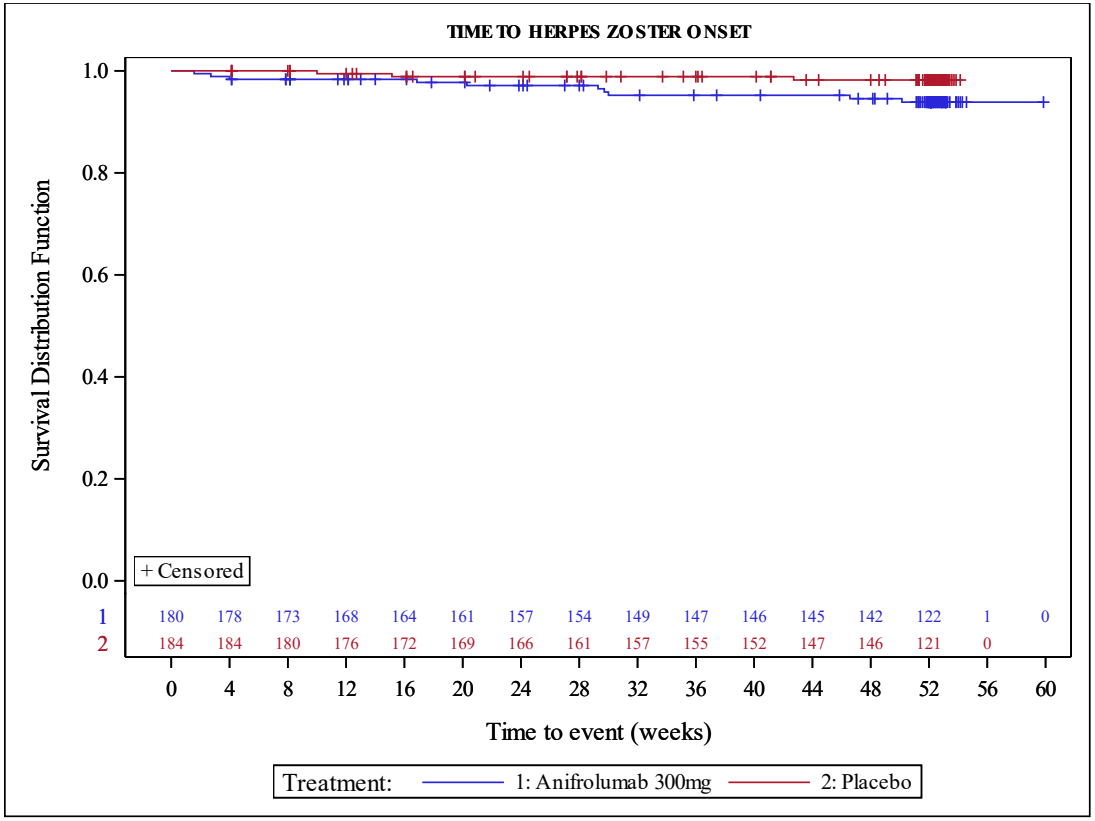
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model. Adjusted analysis also includes stratification factors in the model.
Two-sided log rank test used.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Time to first Onset of Herpes Zoster (on-treatment) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Anifrolumab 300mg (N=180) Median (95% CI)	Placebo (N=184) n/ N (%)	Placebo (N=184) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening							0.1488
< 10 points	2/ 55 (3.6)	NE (NE, NE)	2/ 54 (3.7)	NE (NE, NE)	1.08 (0.15, 7.69)	0.9818	
>= 10 points	8/125 (6.4)	NE (NE, NE)	1/130 (0.8)	NE (NE, NE)	8.28 (1.04, 66.21)	0.0188	
OCS dose at baseline							0.5473
<10 mg/day	5/ 77 (6.5)	NE (NE, NE)	1/ 82 (1.2)	NE (NE, NE)	5.54 (0.65, 47.48)	0.0847	
>=10 mg/day	5/103 (4.9)	NE (NE, NE)	2/102 (2.0)	NE (NE, NE)	2.43 (0.47, 12.53)	0.2772	
Result of type I IFN gene signature test							0.9933
LOW	2/ 32 (6.3)	NE (NE, NE)	0/ 33 (0.0)	NE (NE, NE)	NE		
HIGH	8/148 (5.4)	NE (NE, NE)	3/151 (2.0)	NE (NE, NE)	2.70 (0.72, 10.19)	0.1215	
Age (years)							0.9996
<= 65	10/173 (5.8)	NE (NE, NE)	3/181 (1.7)	NE (NE, NE)	3.56 (0.98, 12.94)	0.0394	
> 65	0/ 7 (0.0)	NE (NE, NE)	0/ 3 (0.0)	NE (NE, NE)	NE		
Sex							0.9914
male	2/ 15 (13.3)	NE (NE, NE)	0/ 13 (0.0)	NE (NE, NE)	NE		
female	8/165 (4.8)	NE (NE, NE)	3/171 (1.8)	NE (NE, NE)	2.80 (0.74, 10.55)	0.1111	
Race							1.0000
White	8/125 (6.4)	NE (NE, NE)	3/137 (2.2)	NE (NE, NE)	2.96 (0.78, 11.17)	0.1049	
Black or African American	0/ 29 (0.0)	NE (NE, NE)	0/ 23 (0.0)	NE (NE, NE)	NE		
Asian	1/ 11 (9.1)	NE (30.00, NE)	0/ 5 (0.0)	NE (NE, NE)	NE		
American Indian or Alaska Native	0	NE (NE, NE)	0/ 1 (0.0)	NE (NE, NE)	NE		
Other	1/ 15 (6.7)	NE (NE, NE)	0/ 18 (0.0)	NE (NE, NE)	NE		
Ethnicity							0.9933
Hispanic/Latino	2/ 32 (6.3)	NE (NE, NE)	0/ 35 (0.0)	NE (NE, NE)	NE		
Non-hispanic/Latino	8/148 (5.4)	NE (NE, NE)	3/149 (2.0)	NE (NE, NE)	2.69 (0.71, 10.15)	0.1150	
Geographic region							0.3208
EU	3/ 64 (4.7)	NE (NE, NE)	2/ 76 (2.6)	NE (NE, NE)	1.77 (0.29, 10.66)	0.5243	
non-EU	7/116 (6.0)	NE (NE, NE)	1/108 (0.9)	NE (NE, NE)	7.45 (0.92, 60.72)	0.0335	
Onset of disease							0.9908
Paediatric	3/ 12 (25.0)	NE (29.71, NE)	0/ 12 (0.0)	NE (NE, NE)	NE		
Adult	7/168 (4.2)	NE (NE, NE)	3/172 (1.7)	NE (NE, NE)	2.43 (0.63, 9.42)	0.1901	
ADA result							0.9997
Negative	10/162 (6.2)	NE (NE, NE)	3/169 (1.8)	NE (NE, NE)	3.50 (0.96, 12.73)	0.0428	
Positive (At any time)	0/ 17 (0.0)	NE (NE, NE)	0/ 15 (0.0)	NE (NE, NE)	NE		
BMI (kg/m2) at enrolment							0.4784
< 30	8/108 (7.4)	NE (NE, NE)	2/127 (1.6)	NE (NE, NE)	4.83 (1.02, 22.83)	0.0297	
>= 30	2/ 72 (2.8)	NE (NE, NE)	1/ 57 (1.8)	NE (NE, NE)	2.10 (0.19, 23.29)	0.5150	

Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Time to first Onset of Herpes Zoster (on-treatment)
Full analysis set



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Time to first Onset of non-opportunistic serious infection (on-treatment)
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	9 (5.0)	8 (4.3)
Number of censored subjects, n (%)	171 (95.0)	176 (95.7)
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Anifrolumab 300mg vs. Placebo (adjusted)		
Hazard Ratio (95% CI)	1.16 (0.45, 3.01)	
p-value	0.8537	
Analysis Anifrolumab 300mg vs. Placebo (unadjusted)		
Hazard Ratio (95% CI)	1.16 (0.45, 3.00)	
p-value	0.7635	

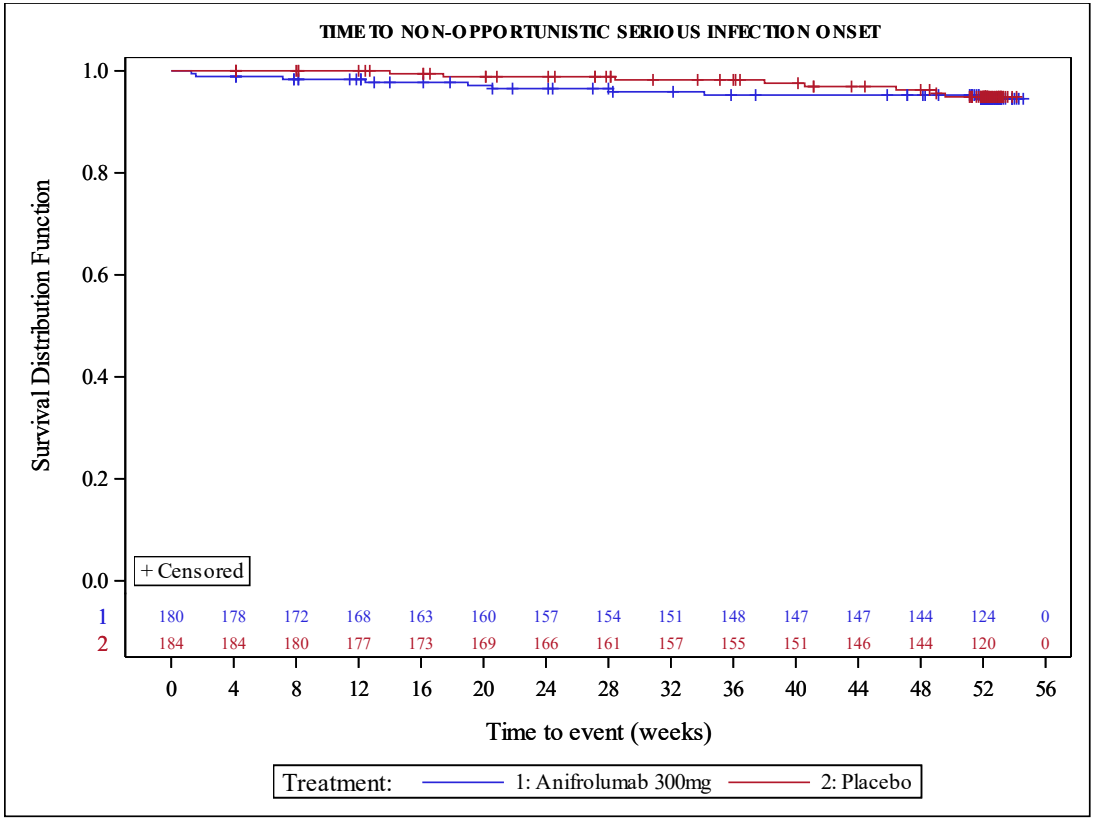
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model. Adjusted analysis also includes stratification factors in the model.
Two-sided log rank test used.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Time to first Onset of non-opportunistic serious infection (on-treatment) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Anifrolumab 300mg (N=180) Median (95% CI)	Placebo (N=184) n/ N (%)	Placebo (N=184) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening							0.8539
< 10 points	2/ 55 (3.6)	NE (NE, NE)	2/ 54 (3.7)	NE (NE, NE)	0.98 (0.14, 6.93)	0.8377	
>= 10 points	7/125 (5.6)	NE (NE, NE)	6/130 (4.6)	NE (NE, NE)	1.22 (0.41, 3.62)	0.7468	
OCS dose at baseline							0.1105
<10 mg/day	2/ 77 (2.6)	NE (NE, NE)	5/ 82 (6.1)	NE (NE, NE)	0.41 (0.08, 2.11)	0.2473	
>=10 mg/day	7/103 (6.8)	NE (NE, NE)	3/102 (2.9)	NE (NE, NE)	2.29 (0.59, 8.87)	0.2288	
Result of type I IFN gene signature test							0.9225
LOW	2/ 32 (6.3)	NE (NE, NE)	2/ 33 (6.1)	NE (NE, NE)	0.98 (0.14, 6.98)	0.9280	
HIGH	7/148 (4.7)	NE (NE, NE)	6/151 (4.0)	NE (NE, NE)	1.18 (0.40, 3.50)	0.7948	
Age (years)							1.0000
<= 65	9/173 (5.2)	NE (NE, NE)	8/181 (4.4)	NE (NE, NE)	1.18 (0.46, 3.07)	0.8329	
> 65	0/ 7 (0.0)	NE (NE, NE)	0/ 3 (0.0)	NE (NE, NE)	NE		
Sex							0.7688
male	1/ 15 (6.7)	NE (NE, NE)	1/ 13 (7.7)	NE (NE, NE)	0.89 (0.05, 15.65)	0.7276	
female	8/165 (4.8)	NE (NE, NE)	7/171 (4.1)	NE (NE, NE)	1.21 (0.44, 3.33)	0.7708	
Race							0.9374
White	5/125 (4.0)	NE (NE, NE)	4/137 (2.9)	NE (NE, NE)	1.27 (0.34, 4.75)	0.8064	
Black or African American	2/ 29 (6.9)	NE (NE, NE)	2/ 23 (8.7)	NE (NE, NE)	0.61 (0.08, 4.85)	0.4024	
Asian	1/ 11 (9.1)	NE (NE, NE)	1/ 5 (20.0)	NE (46.43, NE)	1.00 (0.06, 15.99)	1.0000	
American Indian or Alaska Native	0	NE (NE, NE)	0/ 1 (0.0)	NE (NE, NE)	NE		
Other	1/ 15 (6.7)	NE (NE, NE)	1/ 18 (5.6)	NE (NE, NE)	1.18 (0.07, 19.72)	0.9191	
Ethnicity							0.5381
Hispanic/Latino	2/ 32 (6.3)	NE (NE, NE)	3/ 35 (8.6)	NE (NE, NE)	0.73 (0.12, 4.45)	0.8325	
Non-hispanic/Latino	7/148 (4.7)	NE (NE, NE)	5/149 (3.4)	NE (NE, NE)	1.42 (0.45, 4.48)	0.5511	
Geographic region							0.5835
EU	1/ 64 (1.6)	NE (NE, NE)	2/ 76 (2.6)	NE (NE, NE)	0.52 (0.05, 5.70)	0.6340	
non-EU	8/116 (6.9)	NE (NE, NE)	6/108 (5.6)	NE (NE, NE)	1.18 (0.41, 3.42)	0.7926	
Onset of disease							0.7668
Paediatric	2/ 12 (16.7)	NE (12.43, NE)	2/ 12 (16.7)	NE (17.43, NE)	0.60 (0.08, 4.57)	0.9351	
Adult	7/168 (4.2)	NE (NE, NE)	6/172 (3.5)	NE (NE, NE)	1.21 (0.41, 3.60)	0.8333	
ADA result							0.8916
Negative	8/162 (4.9)	NE (NE, NE)	7/169 (4.1)	NE (NE, NE)	1.18 (0.43, 3.27)	0.8436	
Positive (At any time)	1/ 17 (5.9)	NE (NE, NE)	1/ 15 (6.7)	NE (NE, NE)	0.38 (0.02, 6.21)	0.4795	
BMI (kg/m2) at enrolment							0.9891
< 30	5/108 (4.6)	NE (NE, NE)	8/127 (6.3)	NE (NE, NE)	0.72 (0.24, 2.21)	0.5278	
>= 30	4/ 72 (5.6)	NE (NE, NE)	0/ 57 (0.0)	NE (NE, NE)	NE		

Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Time to first Onset of non-opportunistic serious infection (on-treatment)
Full analysis set



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Blood and lymphatic system disorders	Number of subjects with events, n (%)	9 (5.0)	15 (8.2)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.61 (0.28, 1.37)	
	p-value	0.2313	
	Odds Ratio (95% CI)	0.59 (0.25, 1.39)	
	p-value	0.2300	
	Risk Difference (95% CI)	-3.15 (-8.23, 1.92)	
	p-value	0.2236	
	CMH approach		
	Response rate	5.0	8.2
	Difference in response rates (95% CI)	-3.19 (-9.55, 3.16)	
	p-value	0.3248	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Eye disorders	Number of subjects with events, n (%)	10 (5.6)	5 (2.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	2.04 (0.71, 5.86)	
	p-value	0.1834	
	Odds Ratio (95% CI)	2.11 (0.71, 6.29)	
	p-value	0.1821	
	Risk Difference (95% CI)	2.84 (-1.25, 6.93)	
	p-value	0.1737	
	CMH approach		
	Response rate	5.6	2.8
	Difference in response rates (95% CI)	2.78 (-3.00, 8.57)	
	p-value	0.3459	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Gastrointestinal disorders	Number of subjects with events, n (%)	46 (25.6)	43 (23.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.09 (0.76, 1.57)	
	p-value	0.6277	
	Odds Ratio (95% CI)	1.13 (0.70, 1.82)	
	p-value	0.6277	
	Risk Difference (95% CI)	2.19 (-6.65, 11.02)	
	p-value	0.6276	
	CMH approach		
	Response rate	25.9	23.6
	Difference in response rates (95% CI)	2.24 (-6.68, 11.16)	
	p-value	0.6224	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Gastrointestinal disorders, PT: Diarrhoea	Number of subjects with events, n (%)	6 (3.3)	14 (7.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.44 (0.17, 1.11)	
	p-value	0.0833	
	Odds Ratio (95% CI)	0.42 (0.16, 1.12)	
	p-value	0.0815	
	Risk Difference (95% CI)	-4.28 (-8.92, 0.37)	
	p-value	0.0711	
	CMH approach		
	Response rate	3.4	7.6
	Difference in response rates (95% CI)	-4.19 (-10.24, 1.86)	
	p-value	0.1750	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Gastrointestinal disorders, PT: Nausea	Number of subjects with events, n (%)	9 (5.0)	14 (7.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.66 (0.29, 1.48)	
	p-value	0.3107	
	Odds Ratio (95% CI)	0.64 (0.27, 1.52)	
	p-value	0.3098	
	Risk Difference (95% CI)	-2.61 (-7.59, 2.37)	
	p-value	0.3047	
	CMH approach		
	Response rate	5.0	7.7
	Difference in response rates (95% CI)	-2.73 (-9.00, 3.54)	
	p-value	0.3930	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: General disorders and administration site conditions	Number of subjects with events, n (%)	28 (15.6)	20 (10.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.43 (0.84, 2.45)	
	p-value	0.1898	
	Odds Ratio (95% CI)	1.51 (0.82, 2.79)	
	p-value	0.1885	
	Risk Difference (95% CI)	4.69 (-2.26, 11.63)	
	p-value	0.1861	
	CMH approach		
	Response rate	15.6	11.0
	Difference in response rates (95% CI)	4.67 (-3.00, 12.33)	
	p-value	0.2330	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Immune system disorders	Number of subjects with events, n (%)	14 (7.8)	5 (2.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	2.86 (1.05, 7.78)	
	p-value	0.0393	
	Odds Ratio (95% CI)	3.02 (1.06, 8.57)	
	p-value	0.0378	
	Risk Difference (95% CI)	5.06 (0.50, 9.62)	
	p-value	0.0298	
	CMH approach		
	Response rate	7.9	2.6
	Difference in response rates (95% CI)	5.26 (-0.70, 11.23)	
	p-value	0.0838	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Immune system disorders, PT: Hypersensitivity	Number of subjects with events, n (%)	11 (6.1)	2 (1.1)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	5.62 (1.26, 25.01)	
	p-value	0.0234	
	Odds Ratio (95% CI)	5.92 (1.29, 27.11)	
	p-value	0.0219	
	Risk Difference (95% CI)	5.02 (1.22, 8.83)	
	p-value	0.0097	
	CMH approach		
	Response rate	6.2	1.1
	Difference in response rates (95% CI)	5.14 (-0.36, 10.64)	
	p-value	0.0668	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Infections and infestations	Number of subjects with events, n (%)	137 (76.1)	106 (57.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.32 (1.14, 1.53)	
	p-value	0.0002	
	Odds Ratio (95% CI)	2.34 (1.49, 3.68)	
	p-value	0.0002	
	Risk Difference (95% CI)	18.50 (9.03, 27.98)	
	p-value	0.0001	
	CMH approach		
	Response rate	76.3	57.7
	Difference in response rates (95% CI)	18.57 (9.04, 28.11)	
	p-value	0.0001	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Infections and infestations, PT: Bronchitis	Number of subjects with events, n (%)	16 (8.9)	10 (5.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.64 (0.76, 3.51)	
	p-value	0.2062	
	Odds Ratio (95% CI)	1.70 (0.75, 3.85)	
	p-value	0.2050	
	Risk Difference (95% CI)	3.45 (-1.84, 8.75)	
	p-value	0.2009	
	CMH approach		
	Response rate	8.9	5.6
	Difference in response rates (95% CI)	3.38 (-3.08, 9.83)	
	p-value	0.3051	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Infections and infestations, PT: Herpes zoster	Number of subjects with events, n (%)	10 (5.6)	3 (1.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	3.41 (0.95, 12.18)	
	p-value	0.0592	
	Odds Ratio (95% CI)	3.55 (0.96, 13.11)	
	p-value	0.0575	
	Risk Difference (95% CI)	3.93 (0.11, 7.74)	
	p-value	0.0437	
	CMH approach		
	Response rate	5.6	1.7
	Difference in response rates (95% CI)	3.95 (-1.67, 9.58)	
	p-value	0.1685	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Infections and infestations, PT: Nasopharyngitis	Number of subjects with events, n (%)	36 (20.0)	24 (13.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.53 (0.95, 2.46)	
	p-value	0.0771	
	Odds Ratio (95% CI)	1.67 (0.95, 2.93)	
	p-value	0.0756	
	Risk Difference (95% CI)	6.96 (-0.65, 14.56)	
	p-value	0.0730	
	CMH approach		
	Response rate	20.0	13.2
	Difference in response rates (95% CI)	6.80 (-1.33, 14.94)	
	p-value	0.1010	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Infections and infestations, PT: Pharyngitis	Number of subjects with events, n (%)	12 (6.7)	13 (7.1)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.94 (0.44, 2.01)	
	p-value	0.8805	
	Odds Ratio (95% CI)	0.94 (0.42, 2.12)	
	p-value	0.8805	
	Risk Difference (95% CI)	-0.40 (-5.59, 4.80)	
	p-value	0.8805	
	CMH approach		
	Response rate	6.8	7.2
	Difference in response rates (95% CI)	-0.36 (-6.78, 6.05)	
	p-value	0.9117	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Infections and infestations, PT: Sinusitis	Number of subjects with events, n (%)	8 (4.4)	13 (7.1)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.63 (0.27, 1.48)	
	p-value	0.2888	
	Odds Ratio (95% CI)	0.61 (0.25, 1.51)	
	p-value	0.2877	
	Risk Difference (95% CI)	-2.62 (-7.39, 2.15)	
	p-value	0.2817	
	CMH approach		
	Response rate	4.5	6.9
	Difference in response rates (95% CI)	-2.46 (-8.46, 3.54)	
	p-value	0.4217	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Infections and infestations, PT: Upper respiratory tract infection	Number of subjects with events, n (%)	22 (12.2)	19 (10.3)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.18 (0.66, 2.11)	
	p-value	0.5678	
	Odds Ratio (95% CI)	1.21 (0.63, 2.32)	
	p-value	0.5677	
	Risk Difference (95% CI)	1.90 (-4.60, 8.39)	
	p-value	0.5674	
	CMH approach		
	Response rate	12.2	10.4
	Difference in response rates (95% CI)	1.81 (-5.43, 9.05)	
	p-value	0.6243	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Infections and infestations, PT: Urinary tract infection	Number of subjects with events, n (%)	23 (12.8)	28 (15.2)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.84 (0.50, 1.40)	
	p-value	0.5035	
	Odds Ratio (95% CI)	0.82 (0.45, 1.48)	
	p-value	0.5030	
	Risk Difference (95% CI)	-2.44 (-9.56, 4.68)	
	p-value	0.5020	
	CMH approach		
	Response rate	12.7	15.3
	Difference in response rates (95% CI)	-2.53 (-10.33, 5.27)	
	p-value	0.5256	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Injury, poisoning and procedural complications	Number of subjects with events, n (%)	42 (23.3)	34 (18.5)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.26 (0.84, 1.89)	
	p-value	0.2563	
	Odds Ratio (95% CI)	1.34 (0.81, 2.23)	
	p-value	0.2554	
	Risk Difference (95% CI)	4.86 (-3.49, 13.20)	
	p-value	0.2541	
	CMH approach		
	Response rate	23.6	18.5
	Difference in response rates (95% CI)	5.04 (-3.52, 13.61)	
	p-value	0.2484	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Injury, poisoning and procedural complications, PT: Infusion related reaction	Number of subjects with events, n (%)	16 (8.9)	13 (7.1)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.26 (0.62, 2.54)	
	p-value	0.5217	
	Odds Ratio (95% CI)	1.28 (0.60, 2.75)	
	p-value	0.5214	
	Risk Difference (95% CI)	1.82 (-3.74, 7.39)	
	p-value	0.5208	
	CMH approach		
	Response rate	9.0	7.2
	Difference in response rates (95% CI)	1.81 (-4.74, 8.36)	
	p-value	0.5881	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Investigations	Number of subjects with events, n (%)	11 (6.1)	12 (6.5)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.94 (0.42, 2.07)	
	p-value	0.8721	
	Odds Ratio (95% CI)	0.93 (0.40, 2.17)	
	p-value	0.8721	
	Risk Difference (95% CI)	-0.41 (-5.41, 4.59)	
	p-value	0.8721	
	CMH approach		
	Response rate	6.1	6.5
	Difference in response rates (95% CI)	-0.45 (-6.76, 5.87)	
	p-value	0.8899	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Metabolism and nutrition disorders	Number of subjects with events, n (%)	9 (5.0)	16 (8.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.58 (0.26, 1.27)	
	p-value	0.1700	
	Odds Ratio (95% CI)	0.55 (0.24, 1.29)	
	p-value	0.1684	
	Risk Difference (95% CI)	-3.70 (-8.86, 1.47)	
	p-value	0.1611	
	CMH approach		
	Response rate	4.8	8.7
	Difference in response rates (95% CI)	-3.91 (-10.26, 2.45)	
	p-value	0.2282	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Musculoskeletal and connective tissue disorders	Number of subjects with events, n (%)	43 (23.9)	48 (26.1)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.92 (0.64, 1.31)	
	p-value	0.6285	
	Odds Ratio (95% CI)	0.89 (0.55, 1.43)	
	p-value	0.6283	
	Risk Difference (95% CI)	-2.20 (-11.09, 6.69)	
	p-value	0.6280	
	CMH approach		
	Response rate	24.1	26.1
	Difference in response rates (95% CI)	-2.04 (-11.17, 7.09)	
	p-value	0.6618	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Musculoskeletal and connective tissue disorders, PT: Arthralgia	Number of subjects with events, n (%)	11 (6.1)	3 (1.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	3.75 (1.06, 13.21)	
	p-value	0.0398	
	Odds Ratio (95% CI)	3.93 (1.08, 14.32)	
	p-value	0.0382	
	Risk Difference (95% CI)	4.48 (0.53, 8.43)	
	p-value	0.0262	
	CMH approach		
	Response rate	6.2	1.7
	Difference in response rates (95% CI)	4.56 (-1.13, 10.25)	
	p-value	0.1162	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Musculoskeletal and connective tissue disorders, PT: Back pain	Number of subjects with events, n (%)	10 (5.6)	13 (7.1)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.79 (0.35, 1.75)	
	p-value	0.5551	
	Odds Ratio (95% CI)	0.77 (0.33, 1.81)	
	p-value	0.5548	
	Risk Difference (95% CI)	-1.51 (-6.50, 3.48)	
	p-value	0.5533	
	CMH approach		
	Response rate	5.7	7.1
	Difference in response rates (95% CI)	-1.39 (-7.68, 4.90)	
	p-value	0.6646	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Number of subjects with events, n (%)	10 (5.6)	2 (1.1)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	5.11 (1.14, 23.00)	
	p-value	0.0335	
	Odds Ratio (95% CI)	5.35 (1.16, 24.78)	
	p-value	0.0319	
	Risk Difference (95% CI)	4.47 (0.80, 8.13)	
	p-value	0.0169	
	CMH approach		
	Response rate	5.5	1.1
	Difference in response rates (95% CI)	4.39 (-1.08, 9.85)	
	p-value	0.1160	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Nervous system disorders	Number of subjects with events, n (%)	43 (23.9)	35 (19.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.26 (0.85, 1.87)	
	p-value	0.2596	
	Odds Ratio (95% CI)	1.34 (0.81, 2.21)	
	p-value	0.2587	
	Risk Difference (95% CI)	4.87 (-3.56, 13.29)	
	p-value	0.2575	
	CMH approach		
	Response rate	23.9	19.0
	Difference in response rates (95% CI)	4.87 (-3.78, 13.53)	
	p-value	0.2697	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Nervous system disorders, PT: Headache	Number of subjects with events, n (%)	17 (9.4)	18 (9.8)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.97 (0.51, 1.81)	
	p-value	0.9129	
	Odds Ratio (95% CI)	0.96 (0.48, 1.93)	
	p-value	0.9129	
	Risk Difference (95% CI)	-0.34 (-6.39, 5.72)	
	p-value	0.9129	
	CMH approach		
	Response rate	9.5	9.8
	Difference in response rates (95% CI)	-0.24 (-7.18, 6.70)	
	p-value	0.9460	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Psychiatric disorders	Number of subjects with events, n (%)	14 (7.8)	20 (10.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.72 (0.37, 1.37)	
	p-value	0.3139	
	Odds Ratio (95% CI)	0.69 (0.34, 1.42)	
	p-value	0.3129	
	Risk Difference (95% CI)	-3.09 (-9.05, 2.87)	
	p-value	0.3094	
	CMH approach		
	Response rate	7.8	11.0
	Difference in response rates (95% CI)	-3.20 (-10.09, 3.69)	
	p-value	0.3625	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Renal and urinary disorders	Number of subjects with events, n (%)	11 (6.1)	10 (5.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.12 (0.49, 2.58)	
	p-value	0.7822	
	Odds Ratio (95% CI)	1.13 (0.47, 2.74)	
	p-value	0.7821	
	Risk Difference (95% CI)	0.68 (-4.12, 5.47)	
	p-value	0.7821	
	CMH approach		
	Response rate	6.1	5.4
	Difference in response rates (95% CI)	0.69 (-5.44, 6.82)	
	p-value	0.8252	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Reproductive system and breast disorders	Number of subjects with events, n (%)	8 (4.4)	10 (5.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.82 (0.33, 2.02)	
	p-value	0.6637	
	Odds Ratio (95% CI)	0.81 (0.31, 2.10)	
	p-value	0.6635	
	Risk Difference (95% CI)	-0.99 (-5.44, 3.46)	
	p-value	0.6626	
	CMH approach		
	Response rate	4.6	5.4
	Difference in response rates (95% CI)	-0.85 (-6.82, 5.13)	
	p-value	0.7805	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with events, n (%)	32 (17.8)	26 (14.1)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.26 (0.78, 2.02)	
	p-value	0.3434	
	Odds Ratio (95% CI)	1.31 (0.75, 2.31)	
	p-value	0.3427	
	Risk Difference (95% CI)	3.65 (-3.87, 11.17)	
	p-value	0.3417	
	CMH approach		
	Response rate	17.8	14.2
	Difference in response rates (95% CI)	3.57 (-4.50, 11.64)	
	p-value	0.3859	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Respiratory, thoracic and mediastinal disorders, PT: Cough	Number of subjects with events, n (%)	11 (6.1)	7 (3.8)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.61 (0.64, 4.05)	
	p-value	0.3153	
	Odds Ratio (95% CI)	1.65 (0.62, 4.35)	
	p-value	0.3145	
	Risk Difference (95% CI)	2.31 (-2.15, 6.77)	
	p-value	0.3106	
	CMH approach		
	Response rate	6.1	3.8
	Difference in response rates (95% CI)	2.31 (-3.62, 8.24)	
	p-value	0.4457	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Skin and subcutaneous tissue disorders	Number of subjects with events, n (%)	27 (15.0)	15 (8.2)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.84 (1.01, 3.34)	
	p-value	0.0452	
	Odds Ratio (95% CI)	1.99 (1.02, 3.88)	
	p-value	0.0438	
	Risk Difference (95% CI)	6.85 (0.30, 13.39)	
	p-value	0.0403	
	CMH approach		
	Response rate	15.2	8.3
	Difference in response rates (95% CI)	6.87 (-0.50, 14.24)	
	p-value	0.0677	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Vascular disorders	Number of subjects with events, n (%)	6 (3.3)	14 (7.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.44 (0.17, 1.11)	
	p-value	0.0833	
	Odds Ratio (95% CI)	0.42 (0.16, 1.12)	
	p-value	0.0815	
	Risk Difference (95% CI)	-4.28 (-8.92, 0.37)	
	p-value	0.0711	
	CMH approach		
	Response rate	3.3	7.6
	Difference in response rates (95% CI)	-4.24 (-10.30, 1.81)	
	p-value	0.1699	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SOC: Immune system disorders	SLEDAI-2K score at screening									0.5464
	< 10 points	5/ 55 (9.1)	9.6	1/ 54 (1.9)	1.8	4.91 (0.59, 40.65)	0.1402	7.88 (-4.77, 20.54)	0.2221	
	>= 10 points	9/125 (7.2)	7.2	4/130 (3.1)	3.0	2.34 (0.74, 7.40)	0.1480	4.15 (-2.70, 11.00)	0.2351	
	OCS dose at baseline									0.5556
	<10 mg/day	9/ 77 (11.7)	11.5	4/ 82 (4.9)	4.8	2.40 (0.77, 7.46)	0.1316	6.72 (-3.77, 17.21)	0.2093	
	>=10 mg/day	5/103 (4.9)	5.1	1/102 (1.0)	1.0	4.95 (0.59, 41.65)	0.1409	4.08 (-3.13, 11.29)	0.2673	
	Result of type I IFN gene signature test									0.1748
	LOW	6/ 32 (18.8)	18.8	0/ 33 (0.0)	0.0	13.39 (0.79, 228.40)	0.0730	18.75 (2.41, 35.09)	0.0245	
	HIGH	8/148 (5.4)	5.5	5/151 (3.3)	3.2	1.63 (0.55, 4.88)	0.3800	2.33 (-4.01, 8.66)	0.4718	
	Age (years)									0.7770
	<= 65	11/173 (6.4)	6.5	5/181 (2.8)	2.7	2.30 (0.82, 6.49)	0.1149	3.86 (-2.11, 9.82)	0.2049	
	> 65	3/ 7 (42.9)	42.9	0/ 3 (0.0)	0.0	3.50 (0.23, 52.56)	0.3648	42.86 (-20.18, 105.90)	0.1827	
	Sex									0.3569
	male	1/ 15 (6.7)	6.7	1/ 13 (7.7)	7.7	0.87 (0.06, 12.52)	0.9164	-1.03 (-28.77, 26.72)	0.9422	
	female	13/165 (7.9)	8.0	4/171 (2.3)	2.3	3.37 (1.12, 10.12)	0.0305	5.70 (-0.58, 11.98)	0.0753	
	Race									0.2208
	White	13/125 (10.4)	10.0	3/137 (2.2)	2.2	4.75 (1.39, 16.28)	0.0132	7.84 (0.16, 15.53)	0.0454	
	Black or African American	0/ 29 (0.0)	0.0	1/ 23 (4.3)	4.3	0.27 (0.01, 6.26)	0.4116	-4.35 (-19.85, 11.16)	0.5826	
	Asian	1/ 11 (9.1)	9.1	0/ 5 (0.0)	0.0	1.50 (0.07, 31.57)	0.7942	9.09 (-34.34, 52.53)	0.6817	
	American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
	Other	0/ 15 (0.0)	0.0	1/ 18 (5.6)	5.6	0.40 (0.02, 9.06)	0.5618	-5.56 (-27.75, 16.64)	0.6237	
	Ethnicity									0.4654
	Hispanic/Latino	1/ 32 (3.1)	3.1	1/ 35 (2.9)	2.9	1.09 (0.07, 16.77)	0.9487	0.27 (-12.76, 13.29)	0.9678	
	Non-hispanic/Latino	13/148 (8.8)	9.1	4/149 (2.7)	2.7	3.27 (1.09, 9.80)	0.0342	6.46 (-0.65, 13.57)	0.0749	
	Geographic region									0.2675
	EU	4/ 64 (6.3)	6.3	0/ 76 (0.0)	0.0	10.66 (0.58, 194.35)	0.1101	6.25 (-1.54, 14.04)	0.1156	
	non-EU	10/116 (8.6)	8.8	5/108 (4.6)	4.5	1.86 (0.66, 5.27)	0.2418	4.38 (-4.42, 13.18)	0.3296	
	Onset of disease									0.9428
	Paediatric	1/ 12 (8.3)	8.3	0/ 12 (0.0)	0.0	3.00 (0.13, 67.06)	0.4883	8.33 (-20.61, 37.28)	0.5726	
	Adult	13/168 (7.7)	7.7	5/172 (2.9)	2.8	2.66 (0.97, 7.30)	0.0573	4.84 (-1.38, 11.06)	0.1275	
	ADA result									0.1374
	Negative	14/162 (8.6)	8.8	4/169 (2.4)	2.3	3.65 (1.23, 10.86)	0.0199	6.48 (0.03, 12.92)	0.0489	
	Positive (At any time)	0/ 17 (0.0)	0.0	1/ 15 (6.7)	6.7	0.30 (0.01, 6.77)	0.4461	-6.67 (-29.80, 16.47)	0.5722	
	BMI (kg/m2) at enrolment									0.4387
	< 30	7/108 (6.5)	6.7	2/127 (1.6)	1.6	4.12 (0.87, 19.40)	0.0737	5.02 (-2.00, 12.04)	0.1610	
	>= 30	7/ 72 (9.7)	10.2	3/ 57 (5.3)	5.6	1.85 (0.50, 6.83)	0.3575	4.56 (-7.59, 16.72)	0.4615	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

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Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SOC: Immune system disorders, PT: Hypersensitivity	SLEDAI-2K score at screening									0.8747
	< 10 points	5/ 55 (9.1)	9.6	1/ 54 (1.9)	1.8	4.91 (0.59, 40.65)	0.1402	7.88 (-4.77, 20.54)	0.2221	
	>= 10 points	6/125 (4.8)	4.8	1/130 (0.8)	0.8	6.24 (0.76, 51.10)	0.0879	3.98 (-2.03, 9.98)	0.1942	
	OCS dose at baseline									0.4977
	<10 mg/day	8/ 77 (10.4)	10.2	1/ 82 (1.2)	1.2	8.52 (1.09, 66.54)	0.0411	8.98 (-0.63, 18.59)	0.0669	
	>=10 mg/day	3/103 (2.9)	3.1	1/102 (1.0)	1.0	2.97 (0.31, 28.09)	0.3421	2.11 (-4.66, 8.88)	0.5409	
	Result of type I IFN gene signature test									0.3200
	LOW	6/ 32 (18.8)	18.8	0/ 33 (0.0)	0.0	13.39 (0.79, 228.40)	0.0730	18.75 (2.41, 35.09)	0.0245	
	HIGH	5/148 (3.4)	3.5	2/151 (1.3)	1.3	2.55 (0.50, 12.94)	0.2585	2.18 (-3.49, 7.85)	0.4518	
	Age (years)									0.9104
	<= 65	8/173 (4.6)	4.7	2/181 (1.1)	1.1	4.18 (0.90, 19.43)	0.0677	3.66 (-1.81, 9.13)	0.1899	
	> 65	3/ 7 (42.9)	42.9	0/ 3 (0.0)	0.0	3.50 (0.23, 52.56)	0.3648	42.86 (-20.18, 105.90)	0.1827	
	Sex									0.1482
	male	1/ 15 (6.7)	6.7	1/ 13 (7.7)	7.7	0.87 (0.06, 12.52)	0.9164	-1.03 (-28.77, 26.72)	0.9422	
	female	10/165 (6.1)	6.1	1/171 (0.6)	0.6	10.36 (1.34, 80.06)	0.0250	5.52 (-0.25, 11.28)	0.0606	
	Race									0.4545
	White	10/125 (8.0)	7.6	2/137 (1.5)	1.5	5.48 (1.22, 24.53)	0.0261	6.16 (-1.04, 13.36)	0.0938	
	Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-13.78, 13.78)	1.0000	
	Asian	1/ 11 (9.1)	9.1	0/ 5 (0.0)	0.0	1.50 (0.07, 31.57)	0.7942	9.09 (-34.34, 52.53)	0.6817	
	American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
	Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-20.43, 20.43)	1.0000	
	Ethnicity									0.8097
	Hispanic/Latino	1/ 32 (3.1)	3.1	0/ 35 (0.0)	0.0	3.27 (0.14, 77.57)	0.4629	3.13 (-8.92, 15.17)	0.6111	
	Non-hispanic/Latino	10/148 (6.8)	7.0	2/149 (1.3)	1.3	5.03 (1.12, 22.58)	0.0348	5.78 (-0.81, 12.36)	0.0854	
	Geographic region									0.6362
	EU	3/ 64 (4.7)	4.7	0/ 76 (0.0)	0.0	8.29 (0.44, 157.60)	0.1592	4.69 (-2.61, 11.98)	0.2079	
	non-EU	8/116 (6.9)	7.1	2/108 (1.9)	1.9	3.72 (0.81, 17.15)	0.0915	5.21 (-3.00, 13.43)	0.2135	
	Onset of disease									0.7616
	Paediatric	1/ 12 (8.3)	8.3	0/ 12 (0.0)	0.0	3.00 (0.13, 67.06)	0.4883	8.33 (-20.61, 37.28)	0.5726	
	Adult	10/168 (6.0)	5.8	2/172 (1.2)	1.2	5.12 (1.14, 23.02)	0.0332	4.65 (-1.05, 10.36)	0.1101	
	ADA result									NE
	Negative	11/162 (6.8)	6.9	2/169 (1.2)	1.1	5.74 (1.29, 25.49)	0.0217	5.73 (-0.26, 11.72)	0.0608	
	Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE		0.00 (-20.88, 20.88)	1.0000	
	BMI (kg/m2) at enrolment									0.9147
	< 30	4/108 (3.7)	3.8	1/127 (0.8)	0.9	4.70 (0.53, 41.45)	0.1632	2.94 (-3.28, 9.16)	0.3547	
	>= 30	7/ 72 (9.7)	10.2	1/ 57 (1.8)	1.9	5.54 (0.70, 43.75)	0.1043	8.29 (-3.15, 19.74)	0.1556	

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Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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SOC / PT	Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations	SLEDAI-2K score at screening									0.2042
	< 10 points	41/ 55 (74.5)	74.8	35/ 54 (64.8)	64.8	1.15 (0.90, 1.48)	0.2727	9.94 (-7.45, 27.33)	0.2626	
	>= 10 points	96/125 (76.8)	76.9	71/130 (54.6)	54.7	1.41 (1.17, 1.69)	0.0003	22.22 (10.85, 33.59)	0.0001	
	OCS dose at baseline									0.8239
	<10 mg/day	62/ 77 (80.5)	80.6	49/ 82 (59.8)	59.8	1.35 (1.09, 1.66)	0.0051	20.75 (6.76, 34.75)	0.0037	
	>=10 mg/day	75/103 (72.8)	72.8	57/102 (55.9)	56.1	1.30 (1.06, 1.61)	0.0130	16.75 (3.72, 29.78)	0.0118	
	Result of type I IFN gene signature test									0.9314
	LOW	24/ 32 (75.0)	75.0	19/ 33 (57.6)	57.6	1.30 (0.91, 1.86)	0.1440	17.42 (-5.52, 40.37)	0.1367	
	HIGH	113/148 (76.4)	76.5	87/151 (57.6)	57.7	1.33 (1.13, 1.56)	0.0007	18.82 (8.34, 29.30)	0.0004	
	Age (years)									0.9556
	<= 65	131/173 (75.7)	75.9	104/181 (57.5)	57.5	1.32 (1.13, 1.53)	0.0003	18.41 (8.73, 28.09)	0.0002	
	> 65	6/ 7 (85.7)	85.7	2/ 3 (66.7)	66.7	1.29 (0.55, 3.02)	0.5647	19.05 (-45.95, 84.04)	0.5657	
	Sex									0.2444
	male	13/ 15 (86.7)	86.7	6/ 13 (46.2)	46.2	1.88 (1.01, 3.49)	0.0463	40.51 (6.43, 74.60)	0.0198	
	female	124/165 (75.2)	75.4	100/171 (58.5)	58.7	1.29 (1.10, 1.50)	0.0014	16.73 (6.80, 26.65)	0.0010	
	Race									0.5307
	White	94/125 (75.2)	75.2	77/137 (56.2)	56.1	1.34 (1.12, 1.60)	0.0014	19.11 (7.75, 30.47)	0.0010	
	Black or African American	21/ 29 (72.4)	72.4	15/ 23 (65.2)	65.2	1.11 (0.76, 1.61)	0.5829	7.20 (-18.67, 33.07)	0.5856	
	Asian	9/ 11 (81.8)	81.8	4/ 5 (80.0)	80.0	1.02 (0.61, 1.72)	0.9324	1.82 (-47.07, 50.71)	0.9419	
	American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
	Other	13/ 15 (86.7)	86.7	10/ 18 (55.6)	55.6	1.56 (0.99, 2.47)	0.0573	31.11 (0.21, 62.01)	0.0485	
	Ethnicity									0.6210
	Hispanic/Latino	26/ 32 (81.3)	81.3	23/ 35 (65.7)	65.7	1.24 (0.92, 1.65)	0.1536	15.54 (-5.91, 36.98)	0.1557	
	Non-hispanic/Latino	111/148 (75.0)	74.8	83/149 (55.7)	55.6	1.35 (1.14, 1.60)	0.0006	19.23 (8.51, 29.95)	0.0004	
	Geographic region									0.0435
	EU	47/ 64 (73.4)	73.4	34/ 76 (44.7)	44.7	1.64 (1.23, 2.19)	0.0008	28.70 (13.02, 44.38)	0.0003	
	non-EU	90/116 (77.6)	77.9	72/108 (66.7)	67.1	1.16 (0.99, 1.37)	0.0722	10.78 (-1.16, 22.72)	0.0768	
	Onset of disease									0.1357
	Paediatric	12/ 12 (100.0)	100.0	6/ 12 (50.0)	50.0	2.00 (1.14, 3.52)	0.0163	50.00 (16.08, 83.92)	0.0039	
	Adult	125/168 (74.4)	74.6	100/172 (58.1)	58.5	1.28 (1.10, 1.49)	0.0018	16.13 (6.22, 26.04)	0.0014	
	ADA result									0.7467
	Negative	126/162 (77.8)	77.9	98/169 (58.0)	58.0	1.34 (1.15, 1.56)	0.0002	19.92 (9.95, 29.89)	<.0001	
	Positive (At any time)	11/ 17 (64.7)	64.7	8/ 15 (53.3)	53.3	1.21 (0.67, 2.19)	0.5203	11.37 (-22.85, 45.60)	0.5149	
	BMI (kg/m2) at enrolment									0.3086
	< 30	80/108 (74.1)	74.2	68/127 (53.5)	53.9	1.38 (1.14, 1.68)	0.0012	20.35 (8.37, 32.33)	0.0009	
	>= 30	57/ 72 (79.2)	79.1	38/ 57 (66.7)	66.3	1.19 (0.95, 1.48)	0.1232	12.83 (-3.11, 28.76)	0.1146	

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SOC / PT	Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SOC: Musculoskeletal and connective tissue disorders, PT: Arthralgia	SLEDAI-2K score at screening									0.0558
	< 10 points	1/ 55 (1.8)	1.9	2/ 54 (3.7)	3.8	0.49 (0.05, 5.26)	0.5564	-1.84 (-13.78, 10.09)	0.7621	
	>= 10 points	10/125 (8.0)	8.0	1/130 (0.8)	0.8	10.40 (1.35, 80.06)	0.0245	7.25 (0.57, 13.93)	0.0334	
	OCS dose at baseline									0.7455
	<10 mg/day	6/ 77 (7.8)	7.8	2/ 82 (2.4)	2.5	3.19 (0.66, 15.35)	0.1470	5.35 (-4.36, 15.06)	0.2804	
	>=10 mg/day	5/103 (4.9)	5.0	1/102 (1.0)	1.1	4.95 (0.59, 41.65)	0.1409	3.92 (-3.34, 11.19)	0.2899	
	Result of type I IFN gene signature test									0.5749
	LOW	2/ 32 (6.3)	6.3	1/ 33 (3.0)	3.0	2.06 (0.20, 21.64)	0.5461	3.22 (-11.11, 17.55)	0.6596	
	HIGH	9/148 (6.1)	6.2	2/151 (1.3)	1.4	4.59 (1.01, 20.89)	0.0487	4.85 (-1.33, 11.03)	0.1242	
	Age (years)									0.0366
	<= 65	11/173 (6.4)	6.5	2/181 (1.1)	1.2	5.75 (1.29, 25.59)	0.0215	5.37 (-0.42, 11.16)	0.0692	
	> 65	0/ 7 (0.0)	0.0	1/ 3 (33.3)	33.3	0.17 (0.01, 3.24)	0.2366	-33.33 (-96.20, 29.53)	0.2987	
	Sex									0.8731
	male	1/ 15 (6.7)	6.7	0/ 13 (0.0)	0.0	2.63 (0.12, 59.40)	0.5442	6.67 (-18.77, 32.11)	0.6075	
	female	10/165 (6.1)	6.2	3/171 (1.8)	1.8	3.45 (0.97, 12.33)	0.0562	4.37 (-1.66, 10.40)	0.1552	
	Race									0.4662
	White	9/125 (7.2)	7.1	2/137 (1.5)	1.4	4.93 (1.09, 22.39)	0.0387	5.73 (-1.59, 13.05)	0.1250	
	Black or African American	1/ 29 (3.4)	3.4	1/ 23 (4.3)	4.3	0.79 (0.05, 12.01)	0.8672	-0.90 (-17.47, 15.67)	0.9152	
	Asian	1/ 11 (9.1)	9.1	0/ 5 (0.0)	0.0	1.50 (0.07, 31.57)	0.7942	9.09 (-34.34, 52.53)	0.6817	
	American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
	Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-20.43, 20.43)	1.0000	
	Ethnicity									NE
	Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE		0.00 (-10.79, 10.79)	1.0000	
	Non-hispanic/Latino	11/148 (7.4)	7.6	3/149 (2.0)	2.1	3.69 (1.05, 12.96)	0.0416	5.49 (-1.39, 12.38)	0.1180	
	Geographic region									0.4628
	EU	3/ 64 (4.7)	4.7	0/ 76 (0.0)	0.0	8.29 (0.44, 157.60)	0.1592	4.69 (-2.61, 11.98)	0.2079	
	non-EU	8/116 (6.9)	7.1	3/108 (2.8)	2.8	2.48 (0.68, 9.12)	0.1706	4.33 (-4.08, 12.74)	0.3124	
	Onset of disease									0.9400
	Paediatric	1/ 12 (8.3)	8.3	0/ 12 (0.0)	0.0	3.00 (0.13, 67.06)	0.4883	8.33 (-20.61, 37.28)	0.5726	
	Adult	10/168 (6.0)	6.1	3/172 (1.7)	1.8	3.41 (0.96, 12.18)	0.0587	4.24 (-1.73, 10.21)	0.1638	
	ADA result									0.0230
	Negative	11/162 (6.8)	6.9	1/169 (0.6)	0.7	11.48 (1.50, 87.88)	0.0188	6.26 (0.18, 12.34)	0.0435	
	Positive (At any time)	0/ 17 (0.0)	0.0	2/ 15 (13.3)	13.3	0.18 (0.01, 3.43)	0.2529	-13.33 (-38.24, 11.57)	0.2941	
	BMI (kg/m2) at enrolment									0.1958
	< 30	5/108 (4.6)	4.8	0/127 (0.0)	0.0	12.92 (0.72, 230.98)	0.0820	4.76 (-1.71, 11.23)	0.1495	
	>= 30	6/ 72 (8.3)	8.1	3/ 57 (5.3)	5.0	1.58 (0.41, 6.06)	0.5020	3.15 (-8.51, 14.81)	0.5967	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)	SLEDAI-2K score at screening									0.3972
	< 10 points	5/ 55 (9.1)	8.9	0/ 54 (0.0)	0.0	10.80 (0.61, 190.74)	0.1042	8.88 (-3.50, 21.26)	0.1598	
	>= 10 points	5/125 (4.0)	4.0	2/130 (1.5)	1.6	2.60 (0.51, 13.16)	0.2481	2.46 (-3.71, 8.63)	0.4349	
	OCS dose at baseline									0.3564
	<10 mg/day	5/ 77 (6.5)	6.5	0/ 82 (0.0)	0.0	11.71 (0.66, 208.21)	0.0939	6.51 (-2.50, 15.52)	0.1566	
	>=10 mg/day	5/103 (4.9)	4.6	2/102 (2.0)	1.9	2.48 (0.49, 12.47)	0.2718	2.70 (-4.63, 10.02)	0.4707	
	Result of type I IFN gene signature test									0.8251
	LOW	1/ 32 (3.1)	3.1	0/ 33 (0.0)	0.0	3.09 (0.13, 73.19)	0.4846	3.13 (-9.17, 15.42)	0.6184	
	HIGH	9/148 (6.1)	6.0	2/151 (1.3)	1.3	4.59 (1.01, 20.89)	0.0487	4.66 (-1.44, 10.76)	0.1342	
	Age (years)									0.5012
	<= 65	9/173 (5.2)	5.1	2/181 (1.1)	1.1	4.71 (1.03, 21.48)	0.0455	3.95 (-1.60, 9.51)	0.1628	
	> 65	1/ 7 (14.3)	14.3	0/ 3 (0.0)	0.0	1.50 (0.08, 29.15)	0.7888	14.29 (-46.56, 75.13)	0.6454	
	Sex									0.7454
	male	1/ 15 (6.7)	6.7	0/ 13 (0.0)	0.0	2.63 (0.12, 59.40)	0.5442	6.67 (-18.77, 32.11)	0.6075	
	female	9/165 (5.5)	5.3	2/171 (1.2)	1.2	4.66 (1.02, 21.26)	0.0467	4.15 (-1.62, 9.92)	0.1590	
	Race									0.4482
	White	7/125 (5.6)	5.8	1/137 (0.7)	0.7	7.67 (0.96, 61.49)	0.0550	5.08 (-1.85, 12.01)	0.1509	
	Black or African American	3/ 29 (10.3)	10.3	1/ 23 (4.3)	4.3	2.38 (0.26, 21.39)	0.4391	6.00 (-12.31, 24.31)	0.5209	
	Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
	American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
	Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-20.43, 20.43)	1.0000	
	Ethnicity									NE
	Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE		0.00 (-10.79, 10.79)	1.0000	
	Non-hispanic/Latino	10/148 (6.8)	6.5	2/149 (1.3)	1.3	5.03 (1.12, 22.58)	0.0348	5.21 (-1.33, 11.76)	0.1184	
	Geographic region									0.9161
	EU	4/ 64 (6.3)	6.3	1/ 76 (1.3)	1.3	4.75 (0.54, 41.43)	0.1585	4.93 (-3.22, 13.09)	0.2358	
	non-EU	6/116 (5.2)	5.2	1/108 (0.9)	1.0	5.59 (0.68, 45.65)	0.1085	4.20 (-3.74, 12.15)	0.2996	
	Onset of disease									NE
	Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
	Adult	10/168 (6.0)	5.9	2/172 (1.2)	1.1	5.12 (1.14, 23.02)	0.0332	4.72 (-1.08, 10.53)	0.1109	
	ADA result									0.7499
	Negative	9/162 (5.6)	5.4	2/169 (1.2)	1.2	4.69 (1.03, 21.40)	0.0457	4.26 (-1.59, 10.11)	0.1536	
	Positive (At any time)	1/ 17 (5.9)	5.9	0/ 15 (0.0)	0.0	2.67 (0.12, 60.93)	0.5390	5.88 (-16.87, 28.64)	0.6124	
	BMI (kg/m2) at enrolment									0.6026
	< 30	6/108 (5.6)	5.5	1/127 (0.8)	0.8	7.06 (0.86, 57.70)	0.0684	4.72 (-1.97, 11.42)	0.1669	
	>= 30	4/ 72 (5.6)	5.9	1/ 57 (1.8)	1.9	3.17 (0.36, 27.56)	0.2964	4.05 (-6.86, 14.95)	0.4673	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SOC: Skin and subcutaneous tissue disorders	SLEDAI-2K score at screening									0.9287
	< 10 points	9/ 55 (16.4)	16.9	5/ 54 (9.3)	9.5	1.77 (0.63, 4.93)	0.2770	7.31 (-7.31, 21.93)	0.3272	
	>= 10 points	18/125 (14.4)	14.5	10/130 (7.7)	7.8	1.87 (0.90, 3.90)	0.0936	6.76 (-1.78, 15.31)	0.1208	
	OCS dose at baseline									0.0503
	<10 mg/day	15/ 77 (19.5)	19.6	4/ 82 (4.9)	5.0	3.99 (1.39, 11.51)	0.0103	14.57 (3.00, 26.14)	0.0136	
	>=10 mg/day	12/103 (11.7)	11.8	11/102 (10.8)	10.9	1.08 (0.50, 2.34)	0.8443	0.92 (-8.86, 10.69)	0.8542	
	Result of type I IFN gene signature test									0.8466
	LOW	6/ 32 (18.8)	18.8	3/ 33 (9.1)	9.1	2.06 (0.56, 7.55)	0.2743	9.66 (-8.88, 28.19)	0.3071	
	HIGH	21/148 (14.2)	14.4	12/151 (7.9)	8.1	1.79 (0.91, 3.50)	0.0909	6.27 (-1.75, 14.28)	0.1256	
	Age (years)									0.8046
	<= 65	25/173 (14.5)	14.7	15/181 (8.3)	8.5	1.74 (0.95, 3.19)	0.0718	6.17 (-1.32, 13.67)	0.1066	
	> 65	2/ 7 (28.6)	28.6	0/ 3 (0.0)	0.0	2.50 (0.15, 40.67)	0.5196	28.57 (-33.74, 90.89)	0.3688	
	Sex									0.2352
	male	0/ 15 (0.0)	0.0	1/ 13 (7.7)	7.7	0.29 (0.01, 6.60)	0.4388	-7.69 (-33.59, 18.20)	0.5604	
	female	27/165 (16.4)	16.5	14/171 (8.2)	8.3	2.00 (1.09, 3.67)	0.0258	8.24 (0.39, 16.09)	0.0396	
	Race									0.4678
	White	14/125 (11.2)	10.9	12/137 (8.8)	8.5	1.28 (0.62, 2.66)	0.5104	2.39 (-6.19, 10.97)	0.5851	
	Black or African American	6/ 29 (20.7)	20.7	1/ 23 (4.3)	4.3	4.76 (0.62, 36.78)	0.1349	16.34 (-3.86, 36.55)	0.1129	
	Asian	3/ 11 (27.3)	27.3	1/ 5 (20.0)	20.0	1.36 (0.18, 10.09)	0.7613	7.27 (-42.56, 57.11)	0.7748	
	American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
	Other	4/ 15 (26.7)	26.7	1/ 18 (5.6)	5.6	4.80 (0.60, 38.48)	0.1397	21.11 (-7.26, 49.48)	0.1447	
	Ethnicity									0.7257
	Hispanic/Latino	4/ 32 (12.5)	12.5	3/ 35 (8.6)	8.6	1.46 (0.35, 6.02)	0.6020	3.93 (-13.08, 20.94)	0.6508	
	Non-hispanic/Latino	23/148 (15.5)	15.7	12/149 (8.1)	8.3	1.93 (1.00, 3.73)	0.0509	7.40 (-0.99, 15.78)	0.0838	
	Geographic region									0.4396
	EU	7/ 64 (10.9)	10.9	3/ 76 (3.9)	3.9	2.77 (0.75, 10.28)	0.1276	6.99 (-2.94, 16.92)	0.1675	
	non-EU	20/116 (17.2)	17.4	12/108 (11.1)	11.7	1.55 (0.80, 3.02)	0.1960	5.69 (-4.71, 16.08)	0.2838	
	Onset of disease									0.6340
	Paediatric	3/ 12 (25.0)	25.0	1/ 12 (8.3)	8.3	3.00 (0.36, 24.92)	0.3091	16.67 (-17.62, 50.95)	0.3407	
	Adult	24/168 (14.3)	14.3	14/172 (8.1)	8.3	1.76 (0.94, 3.28)	0.0772	6.09 (-1.51, 13.69)	0.1161	
	ADA result									0.7318
	Negative	24/162 (14.8)	14.9	14/169 (8.3)	8.5	1.79 (0.96, 3.33)	0.0674	6.49 (-1.31, 14.28)	0.1028	
	Positive (At any time)	3/ 17 (17.6)	17.6	1/ 15 (6.7)	6.7	2.65 (0.31, 22.82)	0.3758	10.98 (-16.41, 38.37)	0.4321	
	BMI (kg/m2) at enrolment									0.7159
	< 30	17/108 (15.7)	15.8	10/127 (7.9)	7.9	2.00 (0.96, 4.18)	0.0657	7.96 (-1.24, 17.17)	0.0899	
	>= 30	10/ 72 (13.9)	13.7	5/ 57 (8.8)	8.7	1.58 (0.57, 4.37)	0.3752	4.96 (-8.12, 18.05)	0.4571	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Serious Adverse Events by SOC, PT (incidence in either arm >= 5% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Infections and infestations	Number of subjects with events, n (%)	9 (5.0)	12 (6.5)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.77 (0.33, 1.77)	
	p-value	0.5350	
	Odds Ratio (95% CI)	0.75 (0.31, 1.84)	
	p-value	0.5347	
	Risk Difference (95% CI)	-1.52 (-6.30, 3.26)	
	p-value	0.5328	
	CMH approach		
	Response rate	4.9	6.5
	Difference in response rates (95% CI)	-1.54 (-7.70, 4.62)	
	p-value	0.6246	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Serious Adverse Events by SOC, PT (incidence in either arm >= 5% or >=10 patients) - Subgroup analysis
Full analysis set

- NO OBSERVATIONS FOR THIS ANALYSIS -

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Severe (Grade >=3) by SOC, PT (incidence in either arm >= 5% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Infections and infestations	Number of subjects with events, n (%)	9 (5.0)	7 (3.8)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.31 (0.50, 3.45)	
	p-value	0.5793	
	Odds Ratio (95% CI)	1.33 (0.48, 3.65)	
	p-value	0.5791	
	Risk Difference (95% CI)	1.20 (-3.02, 5.41)	
	p-value	0.5783	
	CMH approach		
	Response rate	5.0	3.8
	Difference in response rates (95% CI)	1.15 (-4.69, 6.98)	
	p-value	0.7004	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Severe (Grade >=3) by SOC, PT (incidence in either arm >= 5% or >=10 patients) - Subgroup analysis
Full analysis set

- NO OBSERVATIONS FOR THIS ANALYSIS -

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event (on-treatment)
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	161 (89.4)	144 (78.3)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.14 (1.04, 1.25)	
p-value	0.0041	
Odds Ratio (95% CI)	2.35 (1.30, 4.25)	
p-value	0.0045	
Risk Difference (95% CI)	11.18 (3.72, 18.64)	
p-value	0.0033	
CMH approach		
Response rate	89.6	78.1
Difference in response rates (95% CI)	11.51 (3.52, 19.51)	
p-value	0.0048	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event (on-treatment) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.5583
< 10 points	48/ 55 (87.3)	87.8	43/ 54 (79.6)	79.1	1.10 (0.93, 1.30)	0.2863	8.61 (-6.77, 24.00)	0.2726	
>= 10 points	113/125 (90.4)	90.4	101/130 (77.7)	77.7	1.16 (1.04, 1.30)	0.0062	12.73 (3.27, 22.20)	0.0084	
OCS dose at baseline									0.7843
<10 mg/day	73/ 77 (94.8)	94.7	67/ 82 (81.7)	81.7	1.16 (1.03, 1.30)	0.0113	13.05 (1.61, 24.50)	0.0254	
>=10 mg/day	88/103 (85.4)	85.6	77/102 (75.5)	75.5	1.13 (0.99, 1.30)	0.0752	10.11 (-1.14, 21.36)	0.0782	
Result of type I IFN gene signature test									0.2485
LOW	30/ 32 (93.8)	93.8	24/ 33 (72.7)	72.7	1.29 (1.03, 1.62)	0.0285	21.02 (2.00, 40.04)	0.0303	
HIGH	131/148 (88.5)	88.7	120/151 (79.5)	79.3	1.11 (1.01, 1.23)	0.0341	9.44 (0.63, 18.25)	0.0358	
Age (years)									0.0685
<= 65	155/173 (89.6)	89.9	141/181 (77.9)	77.7	1.15 (1.05, 1.26)	0.0031	12.19 (4.08, 20.31)	0.0032	
> 65	6/ 7 (85.7)	85.7	3/ 3 (100.0)	100.0	0.86 (0.63, 1.16)	0.3178	-14.29 (-75.13, 46.56)	0.6454	
Sex									0.6536
male	13/ 15 (86.7)	86.7	9/ 13 (69.2)	69.2	1.25 (0.83, 1.89)	0.2867	17.44 (-15.74, 50.61)	0.3029	
female	148/165 (89.7)	89.9	135/171 (78.9)	78.9	1.14 (1.04, 1.25)	0.0072	11.02 (2.75, 19.29)	0.0090	
Race									0.0865
White	112/125 (89.6)	89.3	104/137 (75.9)	76.1	1.18 (1.06, 1.32)	0.0036	13.21 (3.44, 22.97)	0.0080	
Black or African American	26/ 29 (89.7)	89.7	20/ 23 (87.0)	87.0	1.03 (0.84, 1.26)	0.7655	2.70 (-17.85, 23.25)	0.7969	
Asian	9/ 11 (81.8)	81.8	5/ 5 (100.0)	100.0	0.82 (0.62, 1.08)	0.1580	-18.18 (-63.02, 26.66)	0.4268	
American Indian or Alaska Native	0		1/ 1 (100.0)		NE		NE		
Other	14/ 15 (93.3)	93.3	14/ 18 (77.8)	77.8	1.20 (0.91, 1.59)	0.2044	15.56 (-12.08, 43.19)	0.2700	
Ethnicity									0.7824
Hispanic/Latino	30/ 32 (93.8)	93.8	28/ 35 (80.0)	80.0	1.17 (0.97, 1.41)	0.0987	13.75 (-3.95, 31.45)	0.1279	
Non-hispanic/Latino	131/148 (88.5)	88.9	116/149 (77.9)	77.5	1.14 (1.03, 1.26)	0.0150	11.41 (2.33, 20.49)	0.0138	
Geographic region									0.1391
EU	53/ 64 (82.8)	82.8	50/ 76 (65.8)	65.8	1.26 (1.03, 1.53)	0.0219	17.02 (2.61, 31.44)	0.0206	
non-EU	108/116 (93.1)	93.4	94/108 (87.0)	87.3	1.07 (0.98, 1.17)	0.1336	6.09 (-3.27, 15.45)	0.2024	
Onset of disease									0.7029
Paediatric	12/ 12 (100.0)	100.0	10/ 12 (83.3)	83.3	1.20 (0.93, 1.55)	0.1579	16.67 (-14.16, 47.49)	0.2893	
Adult	149/168 (88.7)	88.8	134/172 (77.9)	77.9	1.14 (1.03, 1.25)	0.0082	10.87 (2.50, 19.24)	0.0109	
ADA result									0.4960
Negative	147/162 (90.7)	90.9	132/169 (78.1)	77.8	1.16 (1.06, 1.28)	0.0017	13.12 (4.77, 21.47)	0.0021	
Positive (At any time)	14/ 17 (82.4)	82.4	12/ 15 (80.0)	80.0	1.03 (0.74, 1.44)	0.8655	2.35 (-27.76, 32.46)	0.8783	
BMI (kg/m2) at enrolment									0.3719
< 30	93/108 (86.1)	86.4	94/127 (74.0)	73.9	1.16 (1.02, 1.32)	0.0204	12.45 (2.00, 22.90)	0.0195	
>= 30	68/ 72 (94.4)	94.8	50/ 57 (87.7)	87.6	1.08 (0.96, 1.20)	0.1966	7.26 (-5.20, 19.72)	0.2535	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Serious Adverse Event (on-treatment)
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	25 (13.9)	30 (16.3)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.85 (0.52, 1.39)	
p-value	0.5208	
Odds Ratio (95% CI)	0.83 (0.47, 1.47)	
p-value	0.5204	
Risk Difference (95% CI)	-2.42 (-9.76, 4.93)	
p-value	0.5195	
CMH approach		
Response rate	13.8	16.3
Difference in response rates (95% CI)	-2.53 (-10.49, 5.44)	
p-value	0.5344	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Serious Adverse Event (on-treatment) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9723
< 10 points	6/ 55 (10.9)	10.6	7/ 54 (13.0)	13.1	0.84 (0.30, 2.34)	0.7412	-2.50 (-16.85, 11.86)	0.7331	
>= 10 points	19/125 (15.2)	15.2	23/130 (17.7)	17.7	0.86 (0.49, 1.50)	0.5924	-2.52 (-12.21, 7.17)	0.6100	
OCS dose at baseline									0.6937
<10 mg/day	10/ 77 (13.0)	12.9	14/ 82 (17.1)	17.3	0.76 (0.36, 1.61)	0.4744	-4.49 (-16.60, 7.61)	0.4670	
>=10 mg/day	15/103 (14.6)	14.5	16/102 (15.7)	15.8	0.93 (0.49, 1.78)	0.8225	-1.36 (-12.06, 9.34)	0.8031	
Result of type I IFN gene signature test									0.9862
LOW	5/ 32 (15.6)	15.6	6/ 33 (18.2)	18.2	0.86 (0.29, 2.54)	0.7838	-2.56 (-22.19, 17.07)	0.7985	
HIGH	20/148 (13.5)	13.4	24/151 (15.9)	15.9	0.85 (0.49, 1.47)	0.5620	-2.52 (-11.23, 6.19)	0.5708	
Age (years)									0.9752
<= 65	23/173 (13.3)	13.2	29/181 (16.0)	16.1	0.83 (0.50, 1.38)	0.4698	-2.90 (-10.93, 5.14)	0.4794	
> 65	2/ 7 (28.6)	28.6	1/ 3 (33.3)	33.3	0.86 (0.12, 6.23)	0.8789	-4.76 (-71.14, 61.61)	0.8882	
Sex									0.9851
male	2/ 15 (13.3)	13.3	2/ 13 (15.4)	15.4	0.87 (0.14, 5.32)	0.8771	-2.05 (-32.99, 28.89)	0.8966	
female	23/165 (13.9)	13.9	28/171 (16.4)	16.4	0.85 (0.51, 1.42)	0.5348	-2.46 (-10.81, 5.88)	0.5628	
Race									0.3488
White	17/125 (13.6)	13.5	18/137 (13.1)	13.1	1.04 (0.56, 1.92)	0.9127	0.37 (-8.97, 9.71)	0.9384	
Black or African American	4/ 29 (13.8)	13.8	7/ 23 (30.4)	30.4	0.45 (0.15, 1.36)	0.1584	-16.64 (-40.48, 7.20)	0.1712	
Asian	1/ 11 (9.1)	9.1	2/ 5 (40.0)	40.0	0.23 (0.03, 1.96)	0.1778	-30.91 (-80.46, 18.65)	0.2215	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	3/ 15 (20.0)	20.0	3/ 18 (16.7)	16.7	1.20 (0.28, 5.10)	0.8048	3.33 (-26.19, 32.85)	0.8248	
Ethnicity									0.3851
Hispanic/Latino	6/ 32 (18.8)	18.8	5/ 35 (14.3)	14.3	1.31 (0.44, 3.89)	0.6235	4.46 (-14.75, 23.68)	0.6488	
Non-hispanic/Latino	19/148 (12.8)	12.7	25/149 (16.8)	16.9	0.77 (0.44, 1.33)	0.3414	-4.25 (-13.17, 4.67)	0.3505	
Geographic region									0.5188
EU	6/ 64 (9.4)	9.4	11/ 76 (14.5)	14.5	0.65 (0.25, 1.65)	0.3639	-5.10 (-16.55, 6.35)	0.3828	
non-EU	19/116 (16.4)	15.9	19/108 (17.6)	18.0	0.93 (0.52, 1.66)	0.8090	-2.02 (-12.84, 8.79)	0.7137	
Onset of disease									0.4624
Paediatric	2/ 12 (16.7)	16.7	4/ 12 (33.3)	33.3	0.50 (0.11, 2.23)	0.3641	-16.67 (-53.42, 20.08)	0.3741	
Adult	23/168 (13.7)	13.7	26/172 (15.1)	15.1	0.91 (0.54, 1.52)	0.7084	-1.33 (-9.50, 6.84)	0.7491	
ADA result									0.0632
Negative	24/162 (14.8)	14.7	24/169 (14.2)	14.3	1.04 (0.62, 1.76)	0.8741	0.42 (-7.91, 8.74)	0.9216	
Positive (At any time)	1/ 17 (5.9)	5.9	6/ 15 (40.0)	40.0	0.15 (0.02, 1.09)	0.0603	-34.12 (-64.13, -4.10)	0.0259	
BMI (kg/m2) at enrolment									0.3130
< 30	13/108 (12.0)	11.9	22/127 (17.3)	17.2	0.69 (0.37, 1.31)	0.2618	-5.27 (-15.02, 4.48)	0.2891	
>= 30	12/ 72 (16.7)	16.0	8/ 57 (14.0)	14.1	1.19 (0.52, 2.71)	0.6828	1.96 (-11.81, 15.73)	0.7804	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Severe Adverse Event (on-treatment)
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	21 (11.7)	16 (8.7)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.34 (0.72, 2.49)	
p-value	0.3506	
Odds Ratio (95% CI)	1.39 (0.70, 2.75)	
p-value	0.3499	
Risk Difference (95% CI)	2.97 (-3.24, 9.18)	
p-value	0.3484	
CMH approach		
Response rate	11.6	8.7
Difference in response rates (95% CI)	2.84 (-4.29, 9.97)	
p-value	0.4348	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Severe Adverse Event (on-treatment) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.5414
< 10 points	5/ 55 (9.1)	8.9	5/ 54 (9.3)	9.3	0.98 (0.30, 3.20)	0.9757	-0.41 (-14.35, 13.52)	0.9535	
>= 10 points	16/125 (12.8)	12.7	11/130 (8.5)	8.5	1.51 (0.73, 3.13)	0.2647	4.19 (-4.28, 12.66)	0.3320	
OCS dose at baseline									0.5706
<10 mg/day	7/ 77 (9.1)	9.0	7/ 82 (8.5)	8.7	1.06 (0.39, 2.90)	0.9019	0.28 (-10.40, 10.97)	0.9586	
>=10 mg/day	14/103 (13.6)	13.5	9/102 (8.8)	8.9	1.54 (0.70, 3.40)	0.2846	4.58 (-5.28, 14.43)	0.3625	
Result of type I IFN gene signature test									0.7115
LOW	3/ 32 (9.4)	9.4	3/ 33 (9.1)	9.1	1.03 (0.22, 4.74)	0.9684	0.28 (-16.44, 17.01)	0.9734	
HIGH	18/148 (12.2)	12.1	13/151 (8.6)	8.7	1.41 (0.72, 2.78)	0.3168	3.40 (-4.48, 11.28)	0.3981	
Age (years)									NE
<= 65	21/173 (12.1)	12.0	16/181 (8.8)	8.9	1.37 (0.74, 2.54)	0.3130	3.11 (-4.21, 10.43)	0.4048	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
Sex									0.8183
male	2/ 15 (13.3)	13.3	1/ 13 (7.7)	7.7	1.73 (0.18, 16.99)	0.6367	5.64 (-23.60, 34.88)	0.7054	
female	19/165 (11.5)	11.5	15/171 (8.8)	8.8	1.31 (0.69, 2.50)	0.4063	2.68 (-4.80, 10.17)	0.4823	
Race									0.3608
White	14/125 (11.2)	11.0	9/137 (6.6)	6.5	1.70 (0.76, 3.80)	0.1920	4.57 (-3.85, 12.99)	0.2877	
Black or African American	5/ 29 (17.2)	17.2	5/ 23 (21.7)	21.7	0.79 (0.26, 2.41)	0.6829	-4.50 (-27.78, 18.79)	0.7050	
Asian	0/ 11 (0.0)	0.0	1/ 5 (20.0)	20.0	0.17 (0.01, 3.51)	0.2491	-20.00 (-65.94, 25.94)	0.3936	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	2/ 15 (13.3)	13.3	1/ 18 (5.6)	5.6	2.40 (0.24, 23.95)	0.4558	7.78 (-18.24, 33.80)	0.5580	
Ethnicity									0.6180
Hispanic/Latino	5/ 32 (15.6)	15.6	3/ 35 (8.6)	8.6	1.82 (0.47, 7.02)	0.3829	7.05 (-10.57, 24.68)	0.4329	
Non-hispanic/Latino	16/148 (10.8)	11.1	13/149 (8.7)	8.8	1.24 (0.62, 2.48)	0.5458	2.28 (-5.80, 10.35)	0.5808	
Geographic region									0.8094
EU	5/ 64 (7.8)	7.8	4/ 76 (5.3)	5.3	1.48 (0.42, 5.30)	0.5428	2.55 (-6.96, 12.06)	0.5994	
non-EU	16/116 (13.8)	13.3	12/108 (11.1)	11.4	1.24 (0.62, 2.50)	0.5455	1.91 (-8.12, 11.94)	0.7085	
Onset of disease									0.0802
Paediatric	1/ 12 (8.3)	8.3	4/ 12 (33.3)	33.3	0.25 (0.03, 1.92)	0.1829	-25.00 (-60.18, 10.18)	0.1637	
Adult	20/168 (11.9)	11.9	12/172 (7.0)	7.0	1.71 (0.86, 3.38)	0.1254	4.85 (-2.42, 12.12)	0.1909	
ADA result									0.2604
Negative	18/162 (11.1)	11.1	12/169 (7.1)	7.2	1.56 (0.78, 3.14)	0.2086	3.87 (-3.49, 11.23)	0.3025	
Positive (At any time)	3/ 17 (17.6)	17.6	4/ 15 (26.7)	26.7	0.66 (0.18, 2.49)	0.5418	-9.02 (-40.06, 22.02)	0.5690	
BMI (kg/m2) at enrolment									0.4945
< 30	12/108 (11.1)	11.1	9/127 (7.1)	7.1	1.57 (0.69, 3.58)	0.2855	3.96 (-4.65, 12.58)	0.3673	
>= 30	9/ 72 (12.5)	12.4	7/ 57 (12.3)	12.3	1.02 (0.40, 2.57)	0.9701	0.06 (-13.38, 13.51)	0.9925	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Non-Severe Adverse Event (on-treatment)
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	158 (87.8)	142 (77.2)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.14 (1.03, 1.25)	
p-value	0.0083	
Odds Ratio (95% CI)	2.12 (1.21, 3.73)	
p-value	0.0088	
Risk Difference (95% CI)	10.60 (2.88, 18.33)	
p-value	0.0071	
CMH approach		
Response rate	88.0	77.0
Difference in response rates (95% CI)	10.97 (2.79, 19.16)	
p-value	0.0086	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Non-Severe Adverse Event (on-treatment) - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=180)		Placebo (N=184)		Analysis Anifrolumab 300mg vs. Placebo				Interaction
Level	n/ N (%)	Response rate	n/ N (%)	Response rate	Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	p-Value
SLEDAI-2K score at screening									0.2926
< 10 points	46/ 55 (83.6)	84.2	43/ 54 (79.6)	79.1	1.05 (0.88, 1.26)	0.5899	5.01 (-10.79, 20.81)	0.5342	
>= 10 points	112/125 (89.6)	89.6	99/130 (76.2)	76.1	1.18 (1.05, 1.32)	0.0049	13.50 (3.83, 23.17)	0.0062	
OCS dose at baseline									0.9349
<10 mg/day	72/ 77 (93.5)	93.4	67/ 82 (81.7)	81.7	1.14 (1.02, 1.29)	0.0252	11.74 (0.12, 23.35)	0.0477	
>=10 mg/day	86/103 (83.5)	83.7	75/102 (73.5)	73.5	1.14 (0.98, 1.31)	0.0851	10.17 (-1.39, 21.74)	0.0846	
Result of type I IFN gene signature test									0.2331
LOW	30/ 32 (93.8)	93.8	24/ 33 (72.7)	72.7	1.29 (1.03, 1.62)	0.0285	21.02 (2.00, 40.04)	0.0303	
HIGH	128/148 (86.5)	86.7	118/151 (78.1)	78.0	1.11 (1.00, 1.23)	0.0600	8.79 (-0.28, 17.85)	0.0576	
Age (years)									0.0749
<= 65	152/173 (87.9)	88.2	139/181 (76.8)	76.6	1.14 (1.04, 1.26)	0.0067	11.63 (3.32, 19.94)	0.0061	
> 65	6/ 7 (85.7)	85.7	3/ 3 (100.0)	100.0	0.86 (0.63, 1.16)	0.3178	-14.29 (-75.13, 46.56)	0.6454	
Sex									0.6361
male	13/ 15 (86.7)	86.7	9/ 13 (69.2)	69.2	1.25 (0.83, 1.89)	0.2867	17.44 (-15.74, 50.61)	0.3029	
female	145/165 (87.9)	88.1	133/171 (77.8)	77.7	1.13 (1.02, 1.25)	0.0147	10.43 (1.95, 18.91)	0.0159	
Race									0.0687
White	111/125 (88.8)	88.5	102/137 (74.5)	74.6	1.19 (1.06, 1.34)	0.0029	13.88 (3.96, 23.79)	0.0061	
Black or African American	25/ 29 (86.2)	86.2	20/ 23 (87.0)	87.0	0.99 (0.80, 1.23)	0.9371	-0.75 (-21.94, 20.44)	0.9447	
Asian	9/ 11 (81.8)	81.8	5/ 5 (100.0)	100.0	0.82 (0.62, 1.08)	0.1580	-18.18 (-63.02, 26.66)	0.4268	
American Indian or Alaska Native	0		1/ 1 (100.0)		NE		NE		
Other	13/ 15 (86.7)	86.7	14/ 18 (77.8)	77.8	1.11 (0.81, 1.53)	0.5032	8.89 (-20.25, 38.03)	0.5499	
Ethnicity									0.9612
Hispanic/Latino	29/ 32 (90.6)	90.6	28/ 35 (80.0)	80.0	1.13 (0.93, 1.38)	0.2209	10.63 (-7.77, 29.02)	0.2576	
Non-hispanic/Latino	129/148 (87.2)	87.4	114/149 (76.5)	76.2	1.14 (1.02, 1.27)	0.0184	11.21 (1.92, 20.49)	0.0180	
Geographic region									0.0800
EU	52/ 64 (81.3)	81.3	48/ 76 (63.2)	63.2	1.29 (1.04, 1.58)	0.0177	18.09 (3.37, 32.81)	0.0160	
non-EU	106/116 (91.4)	91.7	94/108 (87.0)	87.3	1.05 (0.96, 1.15)	0.2984	4.36 (-5.14, 13.86)	0.3681	
Onset of disease									0.3269
Paediatric	12/ 12 (100.0)	100.0	9/ 12 (75.0)	75.0	1.33 (0.96, 1.85)	0.0843	25.00 (-7.22, 57.22)	0.1283	
Adult	146/168 (86.9)	87.0	133/172 (77.3)	77.3	1.12 (1.02, 1.24)	0.0220	9.71 (1.18, 18.24)	0.0257	
ADA result									0.6300
Negative	145/162 (89.5)	89.8	131/169 (77.5)	77.2	1.15 (1.05, 1.27)	0.0036	12.53 (4.05, 21.01)	0.0038	
Positive (At any time)	13/ 17 (76.5)	76.5	11/ 15 (73.3)	73.3	1.04 (0.70, 1.56)	0.8387	3.14 (-28.71, 34.99)	0.8469	
BMI (kg/m2) at enrolment									0.3098
< 30	91/108 (84.3)	84.6	92/127 (72.4)	72.4	1.16 (1.02, 1.33)	0.0279	12.20 (1.49, 22.90)	0.0255	
>= 30	67/ 72 (93.1)	93.3	50/ 57 (87.7)	87.6	1.06 (0.94, 1.19)	0.3177	5.72 (-6.98, 18.42)	0.3772	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event leading to discontinuation of study drug (on-treatment)
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	12 (6.7)	5 (2.7)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	2.45 (0.88, 6.82)	
p-value	0.0855	
Odds Ratio (95% CI)	2.56 (0.88, 7.41)	
p-value	0.0838	
Risk Difference (95% CI)	3.95 (-0.39, 8.28)	
p-value	0.0742	
CMH approach		
Response rate	6.6	2.7
Difference in response rates (95% CI)	3.94 (-1.96, 9.84)	
p-value	0.1906	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event leading to discontinuation of study drug (on-treatment) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.6123
< 10 points	4/ 55 (7.3)	7.2	1/ 54 (1.9)	1.8	3.93 (0.45, 34.02)	0.2143	5.45 (-6.93, 17.83)	0.3882	
>= 10 points	8/125 (6.4)	6.4	4/130 (3.1)	3.1	2.08 (0.64, 6.73)	0.2218	3.31 (-3.58, 10.20)	0.3467	
OCS dose at baseline									0.8420
<10 mg/day	4/ 77 (5.2)	5.2	2/ 82 (2.4)	2.4	2.13 (0.40, 11.30)	0.3745	2.80 (-6.45, 12.04)	0.5534	
>=10 mg/day	8/103 (7.8)	7.8	3/102 (2.9)	2.9	2.64 (0.72, 9.67)	0.1427	4.84 (-3.29, 12.97)	0.2431	
Result of type I IFN gene signature test									0.5677
LOW	2/ 32 (6.3)	6.3	0/ 33 (0.0)	0.0	5.15 (0.26, 103.30)	0.2839	6.25 (-7.09, 19.59)	0.3587	
HIGH	10/148 (6.8)	6.7	5/151 (3.3)	3.3	2.04 (0.71, 5.83)	0.1828	3.43 (-3.13, 10.00)	0.3054	
Age (years)									0.7894
<= 65	11/173 (6.4)	6.3	5/181 (2.8)	2.7	2.30 (0.82, 6.49)	0.1149	3.57 (-2.42, 9.56)	0.2425	
> 65	1/ 7 (14.3)	14.3	0/ 3 (0.0)	0.0	1.50 (0.08, 29.15)	0.7888	14.29 (-46.56, 75.13)	0.6454	
Sex									NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
female	12/165 (7.3)	7.2	5/171 (2.9)	2.9	2.49 (0.90, 6.91)	0.0803	4.32 (-2.02, 10.66)	0.1813	
Race									0.9954
White	8/125 (6.4)	6.4	4/137 (2.9)	2.9	2.19 (0.68, 7.10)	0.1907	3.49 (-3.98, 10.97)	0.3598	
Black or African American	1/ 29 (3.4)	3.4	0/ 23 (0.0)	0.0	2.40 (0.10, 56.30)	0.5866	3.45 (-11.52, 18.42)	0.6516	
Asian	1/ 11 (9.1)	9.1	0/ 5 (0.0)	0.0	1.50 (0.07, 31.57)	0.7942	9.09 (-34.34, 52.53)	0.6817	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	2/ 15 (13.3)	13.3	1/ 18 (5.6)	5.6	2.40 (0.24, 23.95)	0.4558	7.78 (-18.24, 33.80)	0.5580	
Ethnicity									0.1953
Hispanic/Latino	3/ 32 (9.4)	9.4	3/ 35 (8.6)	8.6	1.09 (0.24, 5.04)	0.9084	0.80 (-15.51, 17.12)	0.9231	
Non-hispanic/Latino	9/148 (6.1)	6.1	2/149 (1.3)	1.3	4.53 (1.00, 20.61)	0.0507	4.87 (-1.72, 11.45)	0.1474	
Geographic region									0.9672
EU	4/ 64 (6.3)	6.3	2/ 76 (2.6)	2.6	2.38 (0.45, 12.55)	0.3084	3.62 (-4.88, 12.12)	0.4042	
non-EU	8/116 (6.9)	6.8	3/108 (2.8)	2.8	2.48 (0.68, 9.12)	0.1706	4.07 (-4.33, 12.47)	0.3424	
Onset of disease									0.1271
Paediatric	1/ 12 (8.3)	8.3	2/ 12 (16.7)	16.7	0.50 (0.05, 4.81)	0.5483	-8.33 (-41.32, 24.65)	0.6205	
Adult	11/168 (6.5)	6.5	3/172 (1.7)	1.7	3.75 (1.07, 13.22)	0.0394	4.83 (-1.20, 10.86)	0.1168	
ADA result									0.2283
Negative	10/162 (6.2)	6.1	3/169 (1.8)	1.7	3.48 (0.97, 12.41)	0.0548	4.38 (-1.72, 10.47)	0.1595	
Positive (At any time)	2/ 17 (11.8)	11.8	2/ 15 (13.3)	13.3	0.88 (0.14, 5.52)	0.8935	-1.57 (-29.39, 26.25)	0.9120	
BMI (kg/m2) at enrolment									0.5451
< 30	9/108 (8.3)	8.3	5/127 (3.9)	3.9	2.12 (0.73, 6.13)	0.1667	4.40 (-3.40, 12.19)	0.2690	
>= 30	3/ 72 (4.2)	4.2	0/ 57 (0.0)	0.0	5.56 (0.29, 105.53)	0.2532	4.25 (-5.95, 14.45)	0.4143	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Serious Adverse Event leading to discontinuation of study drug (on-treatment)
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	5 (2.8)	2 (1.1)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	2.56 (0.50, 13.00)	
p-value	0.2583	
Odds Ratio (95% CI)	2.60 (0.50, 13.58)	
p-value	0.2572	
Risk Difference (95% CI)	1.69 (-1.14, 4.52)	
p-value	0.2416	
CMH approach		
Response rate	2.7	1.1
Difference in response rates (95% CI)	1.62 (-3.44, 6.69)	
p-value	0.5298	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Serious Adverse Event leading to discontinuation of study drug (on-treatment) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.2936
< 10 points	3/ 55 (5.5)	5.3	0/ 54 (0.0)	0.0	6.88 (0.36, 130.01)	0.1987	5.28 (-6.35, 16.92)	0.3736	
>= 10 points	2/125 (1.6)	1.7	2/130 (1.5)	1.6	1.04 (0.15, 7.27)	0.9685	0.09 (-5.59, 5.78)	0.9746	
OCS dose at baseline									0.4749
<10 mg/day	2/ 77 (2.6)	2.7	0/ 82 (0.0)	0.0	5.32 (0.26, 109.09)	0.2781	2.65 (-5.65, 10.95)	0.5315	
>=10 mg/day	3/103 (2.9)	2.8	2/102 (2.0)	1.9	1.49 (0.25, 8.70)	0.6609	0.88 (-6.03, 7.80)	0.8019	
Result of type I IFN gene signature test									0.8204
LOW	1/ 32 (3.1)	3.1	0/ 33 (0.0)	0.0	3.09 (0.13, 73.19)	0.4846	3.13 (-9.17, 15.42)	0.6184	
HIGH	4/148 (2.7)	2.6	2/151 (1.3)	1.3	2.04 (0.38, 10.97)	0.4060	1.30 (-4.26, 6.86)	0.6474	
Age (years)									0.8483
<= 65	4/173 (2.3)	2.2	2/181 (1.1)	1.1	2.09 (0.39, 11.28)	0.3903	1.11 (-4.01, 6.22)	0.6709	
> 65	1/ 7 (14.3)	14.3	0/ 3 (0.0)	0.0	1.50 (0.08, 29.15)	0.7888	14.29 (-46.56, 75.13)	0.6454	
Sex									NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
female	5/165 (3.0)	3.0	2/171 (1.2)	1.2	2.59 (0.51, 13.17)	0.2511	1.80 (-3.65, 7.25)	0.5168	
Race									0.8479
White	3/125 (2.4)	2.5	1/137 (0.7)	0.7	3.29 (0.35, 31.20)	0.2998	1.75 (-4.76, 8.26)	0.5987	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	2/ 15 (13.3)	13.3	1/ 18 (5.6)	5.6	2.40 (0.24, 23.95)	0.4558	7.78 (-18.24, 33.80)	0.5580	
Ethnicity									0.4646
Hispanic/Latino	1/ 32 (3.1)	3.1	1/ 35 (2.9)	2.9	1.09 (0.07, 16.77)	0.9487	0.27 (-12.76, 13.29)	0.9678	
Non-hispanic/Latino	4/148 (2.7)	2.5	1/149 (0.7)	0.6	4.03 (0.46, 35.61)	0.2103	1.88 (-4.00, 7.76)	0.5317	
Geographic region									0.5231
EU	1/ 64 (1.6)	1.6	1/ 76 (1.3)	1.3	1.19 (0.08, 18.61)	0.9026	0.25 (-6.35, 6.85)	0.9416	
non-EU	4/116 (3.4)	3.6	1/108 (0.9)	1.0	3.72 (0.42, 32.80)	0.2362	2.57 (-5.15, 10.29)	0.5146	
Onset of disease									0.1556
Paediatric	0/ 12 (0.0)	0.0	1/ 12 (8.3)	8.3	0.33 (0.01, 7.45)	0.4883	-8.33 (-37.28, 20.61)	0.5726	
Adult	5/168 (3.0)	3.0	1/172 (0.6)	0.6	5.12 (0.60, 43.36)	0.1341	2.38 (-2.91, 7.68)	0.3779	
ADA result									0.0483
Negative	5/162 (3.1)	2.9	0/169 (0.0)	0.0	11.47 (0.64, 205.82)	0.0976	2.94 (-2.37, 8.24)	0.2783	
Positive (At any time)	0/ 17 (0.0)	0.0	2/ 15 (13.3)	13.3	0.18 (0.01, 3.43)	0.2529	-13.33 (-38.24, 11.57)	0.2941	
BMI (kg/m2) at enrolment									0.6492
< 30	3/108 (2.8)	2.6	2/127 (1.6)	1.5	1.76 (0.30, 10.36)	0.5299	1.10 (-5.14, 7.34)	0.7298	
>= 30	2/ 72 (2.8)	2.7	0/ 57 (0.0)	0.0	3.97 (0.19, 81.14)	0.3701	2.71 (-7.19, 12.61)	0.5916	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with Adverse Event leading to death (on-treatment)
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	1 (0.6)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.07 (0.13, 74.78)	
p-value	0.4917	
Odds Ratio (95% CI)	3.08 (0.12, 76.19)	
p-value	0.4913	
Risk Difference (95% CI)	0.56 (-0.53, 1.64)	
p-value	0.3160	
CMH approach		
Response rate	0.5	0.0
Difference in response rates (95% CI)	0.50 (-3.99, 4.99)	
p-value	0.8272	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with Adverse Event leading to death (on-treatment) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	1/ 55 (1.8)	1.7	0/ 54 (0.0)	0.0	2.95 (0.12, 70.77)	0.5053	1.68 (-9.37, 12.72)	0.7661	
>= 10 points	0/125 (0.0)	0.0	0/130 (0.0)	0.0	NE		0.00 (-4.93, 4.93)	1.0000	
OCS dose at baseline									NE
<10 mg/day	0/ 77 (0.0)	0.0	0/ 82 (0.0)	0.0	NE		0.00 (-7.65, 7.65)	1.0000	
>=10 mg/day	1/103 (1.0)	0.9	0/102 (0.0)	0.0	2.97 (0.12, 72.09)	0.5033	0.89 (-5.22, 7.00)	0.7754	
Result of type I IFN gene signature test									NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE		0.00 (-11.07, 11.07)	1.0000	
HIGH	1/148 (0.7)	0.6	0/151 (0.0)	0.0	3.06 (0.13, 74.53)	0.4923	0.61 (-4.30, 5.52)	0.8079	
Age (years)									NE
<= 65	1/173 (0.6)	0.5	0/181 (0.0)	0.0	3.14 (0.13, 76.51)	0.4828	0.50 (-4.11, 5.12)	0.8314	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
Sex									NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
female	1/165 (0.6)	0.5	0/171 (0.0)	0.0	3.11 (0.13, 75.76)	0.4864	0.55 (-4.28, 5.38)	0.8239	
Race									NE
White	0/125 (0.0)	0.0	0/137 (0.0)	0.0	NE		0.00 (-5.97, 5.97)	1.0000	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	1/ 15 (6.7)	6.7	0/ 18 (0.0)	0.0	3.56 (0.16, 81.55)	0.4264	6.67 (-16.07, 29.40)	0.5655	
Ethnicity									NE
Hispanic/Latino	1/ 32 (3.1)	3.1	0/ 35 (0.0)	0.0	3.27 (0.14, 77.57)	0.4629	3.13 (-8.92, 15.17)	0.6111	
Non-hispanic/Latino	0/148 (0.0)	0.0	0/149 (0.0)	0.0	NE		0.00 (-5.37, 5.37)	1.0000	
Geographic region									NE
EU	0/ 64 (0.0)	0.0	0/ 76 (0.0)	0.0	NE		0.00 (-5.43, 5.43)	1.0000	
non-EU	1/116 (0.9)	0.8	0/108 (0.0)	0.0	2.79 (0.12, 67.88)	0.5277	0.80 (-6.25, 7.85)	0.8239	
Onset of disease									NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
Adult	1/168 (0.6)	0.6	0/172 (0.0)	0.0	3.07 (0.13, 74.86)	0.4911	0.56 (-4.23, 5.35)	0.8187	
ADA result									NE
Negative	1/162 (0.6)	0.5	0/169 (0.0)	0.0	3.13 (0.13, 76.25)	0.4839	0.53 (-4.38, 5.44)	0.8316	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE		0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	1/108 (0.9)	0.8	0/127 (0.0)	0.0	3.52 (0.14, 85.60)	0.4392	0.84 (-4.64, 6.32)	0.7635	
>= 30	0/ 72 (0.0)	0.0	0/ 57 (0.0)	0.0	NE		0.00 (-9.40, 9.40)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	10 (5.6)	3 (1.6)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.41 (0.95, 12.18)	
p-value	0.0592	
Odds Ratio (95% CI)	3.55 (0.96, 13.11)	
p-value	0.0575	
Risk Difference (95% CI)	3.93 (0.11, 7.74)	
p-value	0.0437	
CMH approach		
Response rate	5.6	1.7
Difference in response rates (95% CI)	3.95 (-1.67, 9.58)	
p-value	0.1685	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.1377
< 10 points	2/ 55 (3.6)	3.9	2/ 54 (3.7)	3.8	0.98 (0.14, 6.72)	0.9851	0.09 (-12.12, 12.29)	0.9888	
>= 10 points	8/125 (6.4)	6.4	1/130 (0.8)	0.8	8.32 (1.06, 65.56)	0.0443	5.61 (-0.86, 12.08)	0.0891	
OCS dose at baseline									0.5740
<10 mg/day	5/ 77 (6.5)	6.4	1/ 82 (1.2)	1.2	5.32 (0.64, 44.56)	0.1229	5.22 (-3.96, 14.40)	0.2654	
>=10 mg/day	5/103 (4.9)	4.9	2/102 (2.0)	2.0	2.48 (0.49, 12.47)	0.2718	2.89 (-4.63, 10.41)	0.4514	
Result of type I IFN gene signature test									0.7021
LOW	2/ 32 (6.3)	6.3	0/ 33 (0.0)	0.0	5.15 (0.26, 103.30)	0.2839	6.25 (-7.09, 19.59)	0.3587	
HIGH	8/148 (5.4)	5.5	3/151 (2.0)	2.0	2.72 (0.74, 10.06)	0.1335	3.45 (-2.75, 9.65)	0.2755	
Age (years)									NE
<= 65	10/173 (5.8)	5.9	3/181 (1.7)	1.7	3.49 (0.98, 12.46)	0.0545	4.16 (-1.64, 9.96)	0.1595	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
Sex									0.7803
male	2/ 15 (13.3)	13.3	0/ 13 (0.0)	0.0	4.37 (0.23, 83.62)	0.3269	13.33 (-13.73, 40.40)	0.3342	
female	8/165 (4.8)	4.9	3/171 (1.8)	1.8	2.76 (0.75, 10.24)	0.1282	3.07 (-2.79, 8.94)	0.3047	
Race									0.9109
White	8/125 (6.4)	6.3	3/137 (2.2)	2.1	2.92 (0.79, 10.77)	0.1071	4.22 (-3.08, 11.52)	0.2573	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-13.78, 13.78)	1.0000	
Asian	1/ 11 (9.1)	9.1	0/ 5 (0.0)	0.0	1.50 (0.07, 31.57)	0.7942	9.09 (-34.34, 52.53)	0.6817	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	1/ 15 (6.7)	6.7	0/ 18 (0.0)	0.0	3.56 (0.16, 81.55)	0.4264	6.67 (-16.07, 29.40)	0.5655	
Ethnicity									0.6711
Hispanic/Latino	2/ 32 (6.3)	6.3	0/ 35 (0.0)	0.0	5.45 (0.27, 109.49)	0.2676	6.25 (-6.86, 19.36)	0.3502	
Non-hispanic/Latino	8/148 (5.4)	5.7	3/149 (2.0)	2.1	2.68 (0.73, 9.92)	0.1387	3.59 (-3.06, 10.24)	0.2898	
Geographic region									0.3504
EU	3/ 64 (4.7)	4.7	2/ 76 (2.6)	2.6	1.78 (0.31, 10.33)	0.5198	2.06 (-6.00, 10.11)	0.6169	
non-EU	7/116 (6.0)	6.2	1/108 (0.9)	0.9	6.52 (0.82, 52.11)	0.0772	5.29 (-2.74, 13.32)	0.1970	
Onset of disease									0.5046
Paediatric	3/ 12 (25.0)	25.0	0/ 12 (0.0)	0.0	7.00 (0.40, 122.44)	0.1826	25.00 (-7.22, 57.22)	0.1283	
Adult	7/168 (4.2)	4.2	3/172 (1.7)	1.8	2.39 (0.63, 9.08)	0.2013	2.40 (-3.30, 8.10)	0.4090	
ADA result									NE
Negative	10/162 (6.2)	6.3	3/169 (1.8)	1.8	3.48 (0.97, 12.41)	0.0548	4.50 (-1.66, 10.67)	0.1524	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE		0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment									0.4499
< 30	8/108 (7.4)	7.6	2/127 (1.6)	1.6	4.70 (1.02, 21.68)	0.0470	5.97 (-1.31, 13.25)	0.1082	
>= 30	2/ 72 (2.8)	2.8	1/ 57 (1.8)	1.6	1.58 (0.15, 17.03)	0.7045	1.21 (-9.08, 11.50)	0.8173	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Serious Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.42, 4.42)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Serious Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 55 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>= 10 points	0/125 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 77 (0.0)	0.0	0/ 82 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
>=10 mg/day	0/103 (0.0)	0.0	0/102 (0.0)	0.0	NE	0.00 (-5.93, 5.93)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-11.07, 11.07)	1.0000	
HIGH	0/148 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.81, 4.81)	1.0000	
Age (years)								NE
<= 65	0/173 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.54, 4.54)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
Sex								NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
female	0/165 (0.0)	0.0	0/171 (0.0)	0.0	NE	0.00 (-4.75, 4.75)	1.0000	
Race								NE
White	0/125 (0.0)	0.0	0/137 (0.0)	0.0	NE	0.00 (-5.97, 5.97)	1.0000	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-20.43, 20.43)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE	0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	0/148 (0.0)	0.0	0/149 (0.0)	0.0	NE	0.00 (-5.37, 5.37)	1.0000	
Geographic region								NE
EU	0/ 64 (0.0)	0.0	0/ 76 (0.0)	0.0	NE	0.00 (-5.43, 5.43)	1.0000	
non-EU	0/116 (0.0)	0.0	0/108 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Onset of disease								NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
Adult	0/168 (0.0)	0.0	0/172 (0.0)	0.0	NE	0.00 (-4.70, 4.70)	1.0000	
ADA result								NE
Negative	0/162 (0.0)	0.0	0/169 (0.0)	0.0	NE	0.00 (-4.83, 4.83)	1.0000	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE	0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/108 (0.0)	0.0	0/127 (0.0)	0.0	NE	0.00 (-5.30, 5.30)	1.0000	
>= 30	0/ 72 (0.0)	0.0	0/ 57 (0.0)	0.0	NE	0.00 (-9.40, 9.40)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Severe Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	1 (0.6)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.07 (0.13, 74.78)	
p-value	0.4917	
Odds Ratio (95% CI)	3.08 (0.12, 76.19)	
p-value	0.4913	
Risk Difference (95% CI)	0.56 (-0.53, 1.64)	
p-value	0.3160	
CMH approach		
Response rate	0.6	0.0
Difference in response rates (95% CI)	0.58 (-3.95, 5.11)	
p-value	0.8023	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Severe Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 55 (0.0)	0.0	0/ 54 (0.0)	0.0	NE		0.00 (-10.69, 10.69)	1.0000	
>= 10 points	1/125 (0.8)	0.8	0/130 (0.0)	0.0	3.12 (0.13, 75.85)	0.4848	0.83 (-4.31, 5.96)	0.7527	
OCS dose at baseline									NE
<10 mg/day	1/ 77 (1.3)	1.3	0/ 82 (0.0)	0.0	3.19 (0.13, 77.20)	0.4751	1.33 (-6.67, 9.32)	0.7452	
>=10 mg/day	0/103 (0.0)	0.0	0/102 (0.0)	0.0	NE		0.00 (-5.93, 5.93)	1.0000	
Result of type I IFN gene signature test									NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE		0.00 (-11.07, 11.07)	1.0000	
HIGH	1/148 (0.7)	0.7	0/151 (0.0)	0.0	3.06 (0.13, 74.53)	0.4923	0.70 (-4.26, 5.67)	0.7808	
Age (years)									NE
<= 65	1/173 (0.6)	0.6	0/181 (0.0)	0.0	3.14 (0.13, 76.51)	0.4828	0.61 (-4.05, 5.27)	0.7970	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
Sex									NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
female	1/165 (0.6)	0.6	0/171 (0.0)	0.0	3.11 (0.13, 75.76)	0.4864	0.64 (-4.24, 5.51)	0.7981	
Race									NE
White	1/125 (0.8)	0.8	0/137 (0.0)	0.0	3.29 (0.14, 79.92)	0.4651	0.81 (-5.31, 6.93)	0.7954	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-20.43, 20.43)	1.0000	
Ethnicity									NE
Hispanic/Latino	1/ 32 (3.1)	3.1	0/ 35 (0.0)	0.0	3.27 (0.14, 77.57)	0.4629	3.13 (-8.92, 15.17)	0.6111	
Non-hispanic/Latino	0/148 (0.0)	0.0	0/149 (0.0)	0.0	NE		0.00 (-5.37, 5.37)	1.0000	
Geographic region									NE
EU	0/ 64 (0.0)	0.0	0/ 76 (0.0)	0.0	NE		0.00 (-5.43, 5.43)	1.0000	
non-EU	1/116 (0.9)	0.9	0/108 (0.0)	0.0	2.79 (0.12, 67.88)	0.5277	0.95 (-6.17, 8.07)	0.7939	
Onset of disease									NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
Adult	1/168 (0.6)	0.6	0/172 (0.0)	0.0	3.07 (0.13, 74.86)	0.4911	0.63 (-4.20, 5.45)	0.7985	
ADA result									NE
Negative	1/162 (0.6)	0.6	0/169 (0.0)	0.0	3.13 (0.13, 76.25)	0.4839	0.63 (-4.32, 5.59)	0.8025	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE		0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/108 (0.0)	0.0	0/127 (0.0)	0.0	NE		0.00 (-5.30, 5.30)	1.0000	
>= 30	1/ 72 (1.4)	1.3	0/ 57 (0.0)	0.0	2.38 (0.10, 57.43)	0.5926	1.29 (-8.37, 10.96)	0.7930	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Non-Severe Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	9 (5.0)	3 (1.6)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.07 (0.84, 11.14)	
p-value	0.0887	
Odds Ratio (95% CI)	3.18 (0.85, 11.93)	
p-value	0.0870	
Risk Difference (95% CI)	3.37 (-0.30, 7.04)	
p-value	0.0721	
CMH approach		
Response rate	5.0	1.7
Difference in response rates (95% CI)	3.37 (-2.17, 8.91)	
p-value	0.2326	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Non-Severe Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.1658
< 10 points	2/ 55 (3.6)	3.9	2/ 54 (3.7)	3.8	0.98 (0.14, 6.72)	0.9851	0.09 (-12.12, 12.29)	0.9888	
>= 10 points	7/125 (5.6)	5.6	1/130 (0.8)	0.8	7.28 (0.91, 58.32)	0.0615	4.79 (-1.53, 11.10)	0.1375	
OCS dose at baseline									0.6942
<10 mg/day	4/ 77 (5.2)	5.1	1/ 82 (1.2)	1.2	4.26 (0.49, 37.28)	0.1904	3.89 (-5.01, 12.80)	0.3915	
>=10 mg/day	5/103 (4.9)	4.9	2/102 (2.0)	2.0	2.48 (0.49, 12.47)	0.2718	2.89 (-4.63, 10.41)	0.4514	
Result of type I IFN gene signature test									0.6448
LOW	2/ 32 (6.3)	6.3	0/ 33 (0.0)	0.0	5.15 (0.26, 103.30)	0.2839	6.25 (-7.09, 19.59)	0.3587	
HIGH	7/148 (4.7)	4.8	3/151 (2.0)	2.0	2.38 (0.63, 9.03)	0.2023	2.75 (-3.34, 8.83)	0.3765	
Age (years)									NE
<= 65	9/173 (5.2)	5.3	3/181 (1.7)	1.7	3.14 (0.86, 11.40)	0.0822	3.55 (-2.16, 9.26)	0.2228	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
Sex									0.7197
male	2/ 15 (13.3)	13.3	0/ 13 (0.0)	0.0	4.37 (0.23, 83.62)	0.3269	13.33 (-13.73, 40.40)	0.3342	
female	7/165 (4.2)	4.2	3/171 (1.8)	1.8	2.42 (0.64, 9.19)	0.1950	2.43 (-3.33, 8.19)	0.4074	
Race									0.9240
White	7/125 (5.6)	5.5	3/137 (2.2)	2.1	2.56 (0.68, 9.68)	0.1666	3.41 (-3.78, 10.59)	0.3524	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-13.78, 13.78)	1.0000	
Asian	1/ 11 (9.1)	9.1	0/ 5 (0.0)	0.0	1.50 (0.07, 31.57)	0.7942	9.09 (-34.34, 52.53)	0.6817	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	1/ 15 (6.7)	6.7	0/ 18 (0.0)	0.0	3.56 (0.16, 81.55)	0.4264	6.67 (-16.07, 29.40)	0.5655	
Ethnicity									0.9098
Hispanic/Latino	1/ 32 (3.1)	3.1	0/ 35 (0.0)	0.0	3.27 (0.14, 77.57)	0.4629	3.13 (-8.92, 15.17)	0.6111	
Non-hispanic/Latino	8/148 (5.4)	5.7	3/149 (2.0)	2.1	2.68 (0.73, 9.92)	0.1387	3.59 (-3.06, 10.24)	0.2898	
Geographic region									0.4135
EU	3/ 64 (4.7)	4.7	2/ 76 (2.6)	2.6	1.78 (0.31, 10.33)	0.5198	2.06 (-6.00, 10.11)	0.6169	
non-EU	6/116 (5.2)	5.2	1/108 (0.9)	0.9	5.59 (0.68, 45.65)	0.1085	4.34 (-3.55, 12.22)	0.2811	
Onset of disease									0.4476
Paediatric	3/ 12 (25.0)	25.0	0/ 12 (0.0)	0.0	7.00 (0.40, 122.44)	0.1826	25.00 (-7.22, 57.22)	0.1283	
Adult	6/168 (3.6)	3.6	3/172 (1.7)	1.8	2.05 (0.52, 8.05)	0.3050	1.77 (-3.83, 7.38)	0.5350	
ADA result									NE
Negative	9/162 (5.6)	5.7	3/169 (1.8)	1.8	3.13 (0.86, 11.36)	0.0827	3.87 (-2.20, 9.94)	0.2118	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE		0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment									0.2669
< 30	8/108 (7.4)	7.6	2/127 (1.6)	1.6	4.70 (1.02, 21.68)	0.0470	5.97 (-1.31, 13.25)	0.1082	
>= 30	1/ 72 (1.4)	1.5	1/ 57 (1.8)	1.6	0.79 (0.05, 12.38)	0.8678	-0.08 (-10.12, 9.96)	0.9874	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Herpes Zoster leading to discontinuation of study drug
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	2 (1.1)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	5.11 (0.25, 105.71)	
p-value	0.2912	
Odds Ratio (95% CI)	5.17 (0.25, 108.40)	
p-value	0.2901	
Risk Difference (95% CI)	1.11 (-0.42, 2.64)	
p-value	0.1550	
CMH approach		
Response rate	1.1	0.0
Difference in response rates (95% CI)	1.11 (-3.53, 5.75)	
p-value	0.6395	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Herpes Zoster leading to discontinuation of study drug - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 55 (0.0)	0.0	0/ 54 (0.0)	0.0	NE		0.00 (-10.69, 10.69)	1.0000	
>= 10 points	2/125 (1.6)	1.6	0/130 (0.0)	0.0	5.20 (0.25, 107.22)	0.2858	1.58 (-3.75, 6.91)	0.5609	
OCS dose at baseline									NE
<10 mg/day	0/ 77 (0.0)	0.0	0/ 82 (0.0)	0.0	NE		0.00 (-7.65, 7.65)	1.0000	
>=10 mg/day	2/103 (1.9)	2.0	0/102 (0.0)	0.0	4.95 (0.24, 101.89)	0.2998	1.97 (-4.48, 8.42)	0.5492	
Result of type I IFN gene signature test									NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE		0.00 (-11.07, 11.07)	1.0000	
HIGH	2/148 (1.4)	1.4	0/151 (0.0)	0.0	5.10 (0.25, 105.35)	0.2916	1.35 (-3.76, 6.46)	0.6046	
Age (years)									NE
<= 65	2/173 (1.2)	1.2	0/181 (0.0)	0.0	5.23 (0.25, 108.16)	0.2844	1.15 (-3.62, 5.93)	0.6365	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
Sex									NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
female	2/165 (1.2)	1.2	0/171 (0.0)	0.0	5.18 (0.25, 107.11)	0.2871	1.21 (-3.78, 6.21)	0.6342	
Race									NE
White	2/125 (1.6)	1.6	0/137 (0.0)	0.0	5.48 (0.27, 112.97)	0.2709	1.60 (-4.69, 7.90)	0.6176	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-20.43, 20.43)	1.0000	
Ethnicity									0.9721
Hispanic/Latino	1/ 32 (3.1)	3.1	0/ 35 (0.0)	0.0	3.27 (0.14, 77.57)	0.4629	3.13 (-8.92, 15.17)	0.6111	
Non-hispanic/Latino	1/148 (0.7)	0.7	0/149 (0.0)	0.0	3.02 (0.12, 73.54)	0.4974	0.73 (-4.80, 6.26)	0.7954	
Geographic region									0.9168
EU	1/ 64 (1.6)	1.6	0/ 76 (0.0)	0.0	3.55 (0.15, 85.76)	0.4350	1.56 (-4.57, 7.70)	0.6176	
non-EU	1/116 (0.9)	0.8	0/108 (0.0)	0.0	2.79 (0.12, 67.88)	0.5277	0.77 (-6.30, 7.84)	0.8315	
Onset of disease									0.9918
Paediatric	1/ 12 (8.3)	8.3	0/ 12 (0.0)	0.0	3.00 (0.13, 67.06)	0.4883	8.33 (-20.61, 37.28)	0.5726	
Adult	1/168 (0.6)	0.6	0/172 (0.0)	0.0	3.07 (0.13, 74.86)	0.4911	0.60 (-4.22, 5.43)	0.8063	
ADA result									NE
Negative	2/162 (1.2)	1.3	0/169 (0.0)	0.0	5.21 (0.25, 107.80)	0.2852	1.27 (-3.82, 6.37)	0.6239	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE		0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	2/108 (1.9)	1.9	0/127 (0.0)	0.0	5.87 (0.28, 120.99)	0.2515	1.90 (-3.94, 7.74)	0.5234	
>= 30	0/ 72 (0.0)	0.0	0/ 57 (0.0)	0.0	NE		0.00 (-9.40, 9.40)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Influenza
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	2 (1.1)	2 (1.1)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.02 (0.15, 7.18)	
p-value	0.9824	
Odds Ratio (95% CI)	1.02 (0.14, 7.34)	
p-value	0.9824	
Risk Difference (95% CI)	0.02 (-2.12, 2.17)	
p-value	0.9824	
CMH approach		
Response rate	1.1	1.1
Difference in response rates (95% CI)	0.03 (-4.78, 4.84)	
p-value	0.9904	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Anifrolumab 300mg (N=180) Response rate	Placebo (N=184) n/ N (%)	Placebo (N=184) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9769
< 10 points	1/ 55 (1.8)	1.9	1/ 54 (1.9)	1.8	0.98 (0.06, 15.30)	0.9896	0.18 (-11.08, 11.43)	0.9756	
>= 10 points	1/125 (0.8)	0.8	1/130 (0.8)	0.8	1.04 (0.07, 16.45)	0.9778	0.01 (-5.28, 5.29)	0.9983	
OCS dose at baseline									0.1313
<10 mg/day	2/ 77 (2.6)	2.5	0/ 82 (0.0)	0.0	5.32 (0.26, 109.09)	0.2781	2.45 (-5.64, 10.55)	0.5527	
>=10 mg/day	0/103 (0.0)	0.0	2/102 (2.0)	1.9	0.20 (0.01, 4.08)	0.2940	-1.88 (-8.22, 4.46)	0.5612	
Result of type I IFN gene signature test									0.3729
LOW	2/ 32 (6.3)	6.3	1/ 33 (3.0)	3.0	2.06 (0.20, 21.64)	0.5461	3.22 (-11.11, 17.55)	0.6596	
HIGH	0/148 (0.0)	0.0	1/151 (0.7)	0.7	0.34 (0.01, 8.28)	0.5078	-0.67 (-5.63, 4.30)	0.7927	
Age (years)									NE
<= 65	2/173 (1.2)	1.2	2/181 (1.1)	1.1	1.05 (0.15, 7.35)	0.9637	0.07 (-4.88, 5.01)	0.9793	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
Sex									NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
female	2/165 (1.2)	1.2	2/171 (1.2)	1.2	1.04 (0.15, 7.27)	0.9713	0.04 (-5.13, 5.21)	0.9882	
Race									0.2257
White	2/125 (1.6)	1.5	0/137 (0.0)	0.0	5.48 (0.27, 112.97)	0.2709	1.48 (-4.74, 7.70)	0.6406	
Black or African American	0/ 29 (0.0)	0.0	1/ 23 (4.3)	4.3	0.27 (0.01, 6.26)	0.4116	-4.35 (-19.85, 11.16)	0.5826	
Asian	0/ 11 (0.0)	0.0	1/ 5 (20.0)	20.0	0.17 (0.01, 3.51)	0.2491	-20.00 (-65.94, 25.94)	0.3936	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-20.43, 20.43)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE		0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	2/148 (1.4)	1.4	2/149 (1.3)	1.3	1.01 (0.14, 7.05)	0.9946	0.09 (-5.75, 5.92)	0.9767	
Geographic region									0.3167
EU	1/ 64 (1.6)	1.6	0/ 76 (0.0)	0.0	3.55 (0.15, 85.76)	0.4350	1.56 (-4.57, 7.70)	0.6176	
non-EU	1/116 (0.9)	0.9	2/108 (1.9)	1.9	0.47 (0.04, 5.06)	0.5300	-1.03 (-8.48, 6.42)	0.7858	
Onset of disease									NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
Adult	2/168 (1.2)	1.2	2/172 (1.2)	1.2	1.02 (0.15, 7.18)	0.9811	-0.01 (-5.13, 5.10)	0.9959	
ADA result									NE
Negative	2/162 (1.2)	1.2	2/169 (1.2)	1.2	1.04 (0.15, 7.32)	0.9661	0.03 (-5.22, 5.28)	0.9908	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE		0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment									0.2819
< 30	2/108 (1.9)	1.9	1/127 (0.8)	0.8	2.35 (0.22, 25.58)	0.4825	1.14 (-4.69, 6.98)	0.7015	
>= 30	0/ 72 (0.0)	0.0	1/ 57 (1.8)	1.7	0.26 (0.01, 6.38)	0.4131	-1.74 (-11.47, 7.98)	0.7256	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Serious Influenza
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.42, 4.42)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Serious Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 55 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>= 10 points	0/125 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 77 (0.0)	0.0	0/ 82 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
>=10 mg/day	0/103 (0.0)	0.0	0/102 (0.0)	0.0	NE	0.00 (-5.93, 5.93)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-11.07, 11.07)	1.0000	
HIGH	0/148 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.81, 4.81)	1.0000	
Age (years)								NE
<= 65	0/173 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.54, 4.54)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
Sex								NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
female	0/165 (0.0)	0.0	0/171 (0.0)	0.0	NE	0.00 (-4.75, 4.75)	1.0000	
Race								NE
White	0/125 (0.0)	0.0	0/137 (0.0)	0.0	NE	0.00 (-5.97, 5.97)	1.0000	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-20.43, 20.43)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE	0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	0/148 (0.0)	0.0	0/149 (0.0)	0.0	NE	0.00 (-5.37, 5.37)	1.0000	
Geographic region								NE
EU	0/ 64 (0.0)	0.0	0/ 76 (0.0)	0.0	NE	0.00 (-5.43, 5.43)	1.0000	
non-EU	0/116 (0.0)	0.0	0/108 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Onset of disease								NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
Adult	0/168 (0.0)	0.0	0/172 (0.0)	0.0	NE	0.00 (-4.70, 4.70)	1.0000	
ADA result								NE
Negative	0/162 (0.0)	0.0	0/169 (0.0)	0.0	NE	0.00 (-4.83, 4.83)	1.0000	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE	0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/108 (0.0)	0.0	0/127 (0.0)	0.0	NE	0.00 (-5.30, 5.30)	1.0000	
>= 30	0/ 72 (0.0)	0.0	0/ 57 (0.0)	0.0	NE	0.00 (-9.40, 9.40)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Severe Influenza
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.42, 4.42)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Severe Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 55 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>= 10 points	0/125 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 77 (0.0)	0.0	0/ 82 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
>=10 mg/day	0/103 (0.0)	0.0	0/102 (0.0)	0.0	NE	0.00 (-5.93, 5.93)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-11.07, 11.07)	1.0000	
HIGH	0/148 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.81, 4.81)	1.0000	
Age (years)								NE
<= 65	0/173 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.54, 4.54)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
Sex								NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
female	0/165 (0.0)	0.0	0/171 (0.0)	0.0	NE	0.00 (-4.75, 4.75)	1.0000	
Race								NE
White	0/125 (0.0)	0.0	0/137 (0.0)	0.0	NE	0.00 (-5.97, 5.97)	1.0000	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-20.43, 20.43)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE	0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	0/148 (0.0)	0.0	0/149 (0.0)	0.0	NE	0.00 (-5.37, 5.37)	1.0000	
Geographic region								NE
EU	0/ 64 (0.0)	0.0	0/ 76 (0.0)	0.0	NE	0.00 (-5.43, 5.43)	1.0000	
non-EU	0/116 (0.0)	0.0	0/108 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Onset of disease								NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
Adult	0/168 (0.0)	0.0	0/172 (0.0)	0.0	NE	0.00 (-4.70, 4.70)	1.0000	
ADA result								NE
Negative	0/162 (0.0)	0.0	0/169 (0.0)	0.0	NE	0.00 (-4.83, 4.83)	1.0000	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE	0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/108 (0.0)	0.0	0/127 (0.0)	0.0	NE	0.00 (-5.30, 5.30)	1.0000	
>= 30	0/ 72 (0.0)	0.0	0/ 57 (0.0)	0.0	NE	0.00 (-9.40, 9.40)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Non-Severe Influenza
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	2 (1.1)	2 (1.1)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.02 (0.15, 7.18)	
p-value	0.9824	
Odds Ratio (95% CI)	1.02 (0.14, 7.34)	
p-value	0.9824	
Risk Difference (95% CI)	0.02 (-2.12, 2.17)	
p-value	0.9824	
CMH approach		
Response rate	1.1	1.1
Difference in response rates (95% CI)	0.03 (-4.78, 4.84)	
p-value	0.9904	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Non-Severe Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Anifrolumab 300mg (N=180) Response rate	Placebo (N=184) n/ N (%)	Placebo (N=184) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9769
< 10 points	1/ 55 (1.8)	1.9	1/ 54 (1.9)	1.8	0.98 (0.06, 15.30)	0.9896	0.18 (-11.08, 11.43)	0.9756	
>= 10 points	1/125 (0.8)	0.8	1/130 (0.8)	0.8	1.04 (0.07, 16.45)	0.9778	0.01 (-5.28, 5.29)	0.9983	
OCS dose at baseline									0.1313
<10 mg/day	2/ 77 (2.6)	2.5	0/ 82 (0.0)	0.0	5.32 (0.26, 109.09)	0.2781	2.45 (-5.64, 10.55)	0.5527	
>=10 mg/day	0/103 (0.0)	0.0	2/102 (2.0)	1.9	0.20 (0.01, 4.08)	0.2940	-1.88 (-8.22, 4.46)	0.5612	
Result of type I IFN gene signature test									0.3729
LOW	2/ 32 (6.3)	6.3	1/ 33 (3.0)	3.0	2.06 (0.20, 21.64)	0.5461	3.22 (-11.11, 17.55)	0.6596	
HIGH	0/148 (0.0)	0.0	1/151 (0.7)	0.7	0.34 (0.01, 8.28)	0.5078	-0.67 (-5.63, 4.30)	0.7927	
Age (years)									NE
<= 65	2/173 (1.2)	1.2	2/181 (1.1)	1.1	1.05 (0.15, 7.35)	0.9637	0.07 (-4.88, 5.01)	0.9793	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
Sex									NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
female	2/165 (1.2)	1.2	2/171 (1.2)	1.2	1.04 (0.15, 7.27)	0.9713	0.04 (-5.13, 5.21)	0.9882	
Race									0.2257
White	2/125 (1.6)	1.5	0/137 (0.0)	0.0	5.48 (0.27, 112.97)	0.2709	1.48 (-4.74, 7.70)	0.6406	
Black or African American	0/ 29 (0.0)	0.0	1/ 23 (4.3)	4.3	0.27 (0.01, 6.26)	0.4116	-4.35 (-19.85, 11.16)	0.5826	
Asian	0/ 11 (0.0)	0.0	1/ 5 (20.0)	20.0	0.17 (0.01, 3.51)	0.2491	-20.00 (-65.94, 25.94)	0.3936	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-20.43, 20.43)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE		0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	2/148 (1.4)	1.4	2/149 (1.3)	1.3	1.01 (0.14, 7.05)	0.9946	0.09 (-5.75, 5.92)	0.9767	
Geographic region									0.3167
EU	1/ 64 (1.6)	1.6	0/ 76 (0.0)	0.0	3.55 (0.15, 85.76)	0.4350	1.56 (-4.57, 7.70)	0.6176	
non-EU	1/116 (0.9)	0.9	2/108 (1.9)	1.9	0.47 (0.04, 5.06)	0.5300	-1.03 (-8.48, 6.42)	0.7858	
Onset of disease									NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
Adult	2/168 (1.2)	1.2	2/172 (1.2)	1.2	1.02 (0.15, 7.18)	0.9811	-0.01 (-5.13, 5.10)	0.9959	
ADA result									NE
Negative	2/162 (1.2)	1.2	2/169 (1.2)	1.2	1.04 (0.15, 7.32)	0.9661	0.03 (-5.22, 5.28)	0.9908	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE		0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment									0.2819
< 30	2/108 (1.9)	1.9	1/127 (0.8)	0.8	2.35 (0.22, 25.58)	0.4825	1.14 (-4.69, 6.98)	0.7015	
>= 30	0/ 72 (0.0)	0.0	1/ 57 (1.8)	1.7	0.26 (0.01, 6.38)	0.4131	-1.74 (-11.47, 7.98)	0.7256	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	1 (0.6)	1 (0.5)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.02 (0.06, 16.22)	
p-value	0.9876	
Odds Ratio (95% CI)	1.02 (0.06, 16.47)	
p-value	0.9876	
Risk Difference (95% CI)	0.01 (-1.51, 1.53)	
p-value	0.9876	
CMH approach		
Response rate	0.6	0.5
Difference in response rates (95% CI)	0.03 (-4.61, 4.67)	
p-value	0.9891	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 55 (0.0)	0.0	0/ 54 (0.0)	0.0	NE		0.00 (-10.69, 10.69)	1.0000	
>= 10 points	1/125 (0.8)	0.8	1/130 (0.8)	0.8	1.04 (0.07, 16.45)	0.9778	0.05 (-5.28, 5.37)	0.9865	
OCS dose at baseline									0.3238
<10 mg/day	1/ 77 (1.3)	1.3	0/ 82 (0.0)	0.0	3.19 (0.13, 77.20)	0.4751	1.33 (-6.67, 9.32)	0.7452	
>=10 mg/day	0/103 (0.0)	0.0	1/102 (1.0)	1.0	0.33 (0.01, 8.01)	0.4958	-0.97 (-7.16, 5.22)	0.7586	
Result of type I IFN gene signature test									NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE		0.00 (-11.07, 11.07)	1.0000	
HIGH	1/148 (0.7)	0.7	1/151 (0.7)	0.7	1.02 (0.06, 16.16)	0.9886	0.04 (-5.07, 5.15)	0.9879	
Age (years)									NE
<= 65	1/173 (0.6)	0.6	1/181 (0.6)	0.6	1.05 (0.07, 16.60)	0.9744	0.05 (-4.72, 4.83)	0.9825	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
Sex									NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
female	1/165 (0.6)	0.6	1/171 (0.6)	0.6	1.04 (0.07, 16.43)	0.9798	0.05 (-4.94, 5.04)	0.9845	
Race									NE
White	1/125 (0.8)	0.8	1/137 (0.7)	0.7	1.10 (0.07, 17.34)	0.9481	0.08 (-6.19, 6.34)	0.9812	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-20.43, 20.43)	1.0000	
Ethnicity									0.3208
Hispanic/Latino	1/ 32 (3.1)	3.1	0/ 35 (0.0)	0.0	3.27 (0.14, 77.57)	0.4629	3.13 (-8.92, 15.17)	0.6111	
Non-hispanic/Latino	0/148 (0.0)	0.0	1/149 (0.7)	0.6	0.34 (0.01, 8.17)	0.5026	-0.63 (-6.12, 4.86)	0.8224	
Geographic region									0.3947
EU	0/ 64 (0.0)	0.0	1/ 76 (1.3)	1.3	0.39 (0.02, 9.53)	0.5673	-1.32 (-7.26, 4.63)	0.6646	
non-EU	1/116 (0.9)	0.9	0/108 (0.0)	0.0	2.79 (0.12, 67.88)	0.5277	0.95 (-6.17, 8.07)	0.7939	
Onset of disease									NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
Adult	1/168 (0.6)	0.6	1/172 (0.6)	0.6	1.02 (0.06, 16.24)	0.9867	0.05 (-4.88, 4.99)	0.9829	
ADA result									NE
Negative	1/162 (0.6)	0.6	1/169 (0.6)	0.6	1.04 (0.07, 16.54)	0.9761	0.06 (-5.01, 5.12)	0.9826	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE		0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/108 (0.0)	0.0	0/127 (0.0)	0.0	NE		0.00 (-5.30, 5.30)	1.0000	
>= 30	1/ 72 (1.4)	1.3	1/ 57 (1.8)	1.9	0.79 (0.05, 12.38)	0.8678	-0.57 (-10.71, 9.57)	0.9124	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Serious Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.42, 4.42)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Serious Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 55 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>= 10 points	0/125 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 77 (0.0)	0.0	0/ 82 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
>=10 mg/day	0/103 (0.0)	0.0	0/102 (0.0)	0.0	NE	0.00 (-5.93, 5.93)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-11.07, 11.07)	1.0000	
HIGH	0/148 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.81, 4.81)	1.0000	
Age (years)								NE
<= 65	0/173 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.54, 4.54)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
Sex								NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
female	0/165 (0.0)	0.0	0/171 (0.0)	0.0	NE	0.00 (-4.75, 4.75)	1.0000	
Race								NE
White	0/125 (0.0)	0.0	0/137 (0.0)	0.0	NE	0.00 (-5.97, 5.97)	1.0000	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-20.43, 20.43)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE	0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	0/148 (0.0)	0.0	0/149 (0.0)	0.0	NE	0.00 (-5.37, 5.37)	1.0000	
Geographic region								NE
EU	0/ 64 (0.0)	0.0	0/ 76 (0.0)	0.0	NE	0.00 (-5.43, 5.43)	1.0000	
non-EU	0/116 (0.0)	0.0	0/108 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Onset of disease								NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
Adult	0/168 (0.0)	0.0	0/172 (0.0)	0.0	NE	0.00 (-4.70, 4.70)	1.0000	
ADA result								NE
Negative	0/162 (0.0)	0.0	0/169 (0.0)	0.0	NE	0.00 (-4.83, 4.83)	1.0000	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE	0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/108 (0.0)	0.0	0/127 (0.0)	0.0	NE	0.00 (-5.30, 5.30)	1.0000	
>= 30	0/ 72 (0.0)	0.0	0/ 57 (0.0)	0.0	NE	0.00 (-9.40, 9.40)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Severe Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.42, 4.42)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Severe Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Anifrolumab 300mg (N=180) Response rate	Placebo (N=184) n/ N (%)	Placebo (N=184) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Analysis Anifrolumab 300mg vs. Placebo Difference in response rates (95% CI)	Analysis Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 55 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>= 10 points	0/125 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 77 (0.0)	0.0	0/ 82 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
>=10 mg/day	0/103 (0.0)	0.0	0/102 (0.0)	0.0	NE	0.00 (-5.93, 5.93)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-11.07, 11.07)	1.0000	
HIGH	0/148 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.81, 4.81)	1.0000	
Age (years)								NE
<= 65	0/173 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.54, 4.54)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
Sex								NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
female	0/165 (0.0)	0.0	0/171 (0.0)	0.0	NE	0.00 (-4.75, 4.75)	1.0000	
Race								NE
White	0/125 (0.0)	0.0	0/137 (0.0)	0.0	NE	0.00 (-5.97, 5.97)	1.0000	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-20.43, 20.43)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE	0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	0/148 (0.0)	0.0	0/149 (0.0)	0.0	NE	0.00 (-5.37, 5.37)	1.0000	
Geographic region								NE
EU	0/ 64 (0.0)	0.0	0/ 76 (0.0)	0.0	NE	0.00 (-5.43, 5.43)	1.0000	
non-EU	0/116 (0.0)	0.0	0/108 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Onset of disease								NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
Adult	0/168 (0.0)	0.0	0/172 (0.0)	0.0	NE	0.00 (-4.70, 4.70)	1.0000	
ADA result								NE
Negative	0/162 (0.0)	0.0	0/169 (0.0)	0.0	NE	0.00 (-4.83, 4.83)	1.0000	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE	0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/108 (0.0)	0.0	0/127 (0.0)	0.0	NE	0.00 (-5.30, 5.30)	1.0000	
>= 30	0/ 72 (0.0)	0.0	0/ 57 (0.0)	0.0	NE	0.00 (-9.40, 9.40)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Non-Severe Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	1 (0.6)	1 (0.5)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.02 (0.06, 16.22)	
p-value	0.9876	
Odds Ratio (95% CI)	1.02 (0.06, 16.47)	
p-value	0.9876	
Risk Difference (95% CI)	0.01 (-1.51, 1.53)	
p-value	0.9876	
CMH approach		
Response rate	0.6	0.5
Difference in response rates (95% CI)	0.03 (-4.61, 4.67)	
p-value	0.9891	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Non-Severe Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 55 (0.0)	0.0	0/ 54 (0.0)	0.0	NE		0.00 (-10.69, 10.69)	1.0000	
>= 10 points	1/125 (0.8)	0.8	1/130 (0.8)	0.8	1.04 (0.07, 16.45)	0.9778	0.05 (-5.28, 5.37)	0.9865	
OCS dose at baseline									0.3238
<10 mg/day	1/ 77 (1.3)	1.3	0/ 82 (0.0)	0.0	3.19 (0.13, 77.20)	0.4751	1.33 (-6.67, 9.32)	0.7452	
>=10 mg/day	0/103 (0.0)	0.0	1/102 (1.0)	1.0	0.33 (0.01, 8.01)	0.4958	-0.97 (-7.16, 5.22)	0.7586	
Result of type I IFN gene signature test									NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE		0.00 (-11.07, 11.07)	1.0000	
HIGH	1/148 (0.7)	0.7	1/151 (0.7)	0.7	1.02 (0.06, 16.16)	0.9886	0.04 (-5.07, 5.15)	0.9879	
Age (years)									NE
<= 65	1/173 (0.6)	0.6	1/181 (0.6)	0.6	1.05 (0.07, 16.60)	0.9744	0.05 (-4.72, 4.83)	0.9825	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
Sex									NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
female	1/165 (0.6)	0.6	1/171 (0.6)	0.6	1.04 (0.07, 16.43)	0.9798	0.05 (-4.94, 5.04)	0.9845	
Race									NE
White	1/125 (0.8)	0.8	1/137 (0.7)	0.7	1.10 (0.07, 17.34)	0.9481	0.08 (-6.19, 6.34)	0.9812	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-20.43, 20.43)	1.0000	
Ethnicity									0.3208
Hispanic/Latino	1/ 32 (3.1)	3.1	0/ 35 (0.0)	0.0	3.27 (0.14, 77.57)	0.4629	3.13 (-8.92, 15.17)	0.6111	
Non-hispanic/Latino	0/148 (0.0)	0.0	1/149 (0.7)	0.6	0.34 (0.01, 8.17)	0.5026	-0.63 (-6.12, 4.86)	0.8224	
Geographic region									0.3947
EU	0/ 64 (0.0)	0.0	1/ 76 (1.3)	1.3	0.39 (0.02, 9.53)	0.5673	-1.32 (-7.26, 4.63)	0.6646	
non-EU	1/116 (0.9)	0.9	0/108 (0.0)	0.0	2.79 (0.12, 67.88)	0.5277	0.95 (-6.17, 8.07)	0.7939	
Onset of disease									NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
Adult	1/168 (0.6)	0.6	1/172 (0.6)	0.6	1.02 (0.06, 16.24)	0.9867	0.05 (-4.88, 4.99)	0.9829	
ADA result									NE
Negative	1/162 (0.6)	0.6	1/169 (0.6)	0.6	1.04 (0.07, 16.54)	0.9761	0.06 (-5.01, 5.12)	0.9826	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE		0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/108 (0.0)	0.0	0/127 (0.0)	0.0	NE		0.00 (-5.30, 5.30)	1.0000	
>= 30	1/ 72 (1.4)	1.3	1/ 57 (1.8)	1.9	0.79 (0.05, 12.38)	0.8678	-0.57 (-10.71, 9.57)	0.9124	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Vasculitis
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.42, 4.42)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 55 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>= 10 points	0/125 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 77 (0.0)	0.0	0/ 82 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
>=10 mg/day	0/103 (0.0)	0.0	0/102 (0.0)	0.0	NE	0.00 (-5.93, 5.93)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-11.07, 11.07)	1.0000	
HIGH	0/148 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.81, 4.81)	1.0000	
Age (years)								NE
<= 65	0/173 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.54, 4.54)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
Sex								NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
female	0/165 (0.0)	0.0	0/171 (0.0)	0.0	NE	0.00 (-4.75, 4.75)	1.0000	
Race								NE
White	0/125 (0.0)	0.0	0/137 (0.0)	0.0	NE	0.00 (-5.97, 5.97)	1.0000	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-20.43, 20.43)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE	0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	0/148 (0.0)	0.0	0/149 (0.0)	0.0	NE	0.00 (-5.37, 5.37)	1.0000	
Geographic region								NE
EU	0/ 64 (0.0)	0.0	0/ 76 (0.0)	0.0	NE	0.00 (-5.43, 5.43)	1.0000	
non-EU	0/116 (0.0)	0.0	0/108 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Onset of disease								NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
Adult	0/168 (0.0)	0.0	0/172 (0.0)	0.0	NE	0.00 (-4.70, 4.70)	1.0000	
ADA result								NE
Negative	0/162 (0.0)	0.0	0/169 (0.0)	0.0	NE	0.00 (-4.83, 4.83)	1.0000	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE	0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/108 (0.0)	0.0	0/127 (0.0)	0.0	NE	0.00 (-5.30, 5.30)	1.0000	
>= 30	0/ 72 (0.0)	0.0	0/ 57 (0.0)	0.0	NE	0.00 (-9.40, 9.40)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Serious Vasculitis
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.42, 4.42)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Serious Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 55 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>= 10 points	0/125 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 77 (0.0)	0.0	0/ 82 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
>=10 mg/day	0/103 (0.0)	0.0	0/102 (0.0)	0.0	NE	0.00 (-5.93, 5.93)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-11.07, 11.07)	1.0000	
HIGH	0/148 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.81, 4.81)	1.0000	
Age (years)								NE
<= 65	0/173 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.54, 4.54)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
Sex								NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
female	0/165 (0.0)	0.0	0/171 (0.0)	0.0	NE	0.00 (-4.75, 4.75)	1.0000	
Race								NE
White	0/125 (0.0)	0.0	0/137 (0.0)	0.0	NE	0.00 (-5.97, 5.97)	1.0000	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-20.43, 20.43)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE	0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	0/148 (0.0)	0.0	0/149 (0.0)	0.0	NE	0.00 (-5.37, 5.37)	1.0000	
Geographic region								NE
EU	0/ 64 (0.0)	0.0	0/ 76 (0.0)	0.0	NE	0.00 (-5.43, 5.43)	1.0000	
non-EU	0/116 (0.0)	0.0	0/108 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Onset of disease								NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
Adult	0/168 (0.0)	0.0	0/172 (0.0)	0.0	NE	0.00 (-4.70, 4.70)	1.0000	
ADA result								NE
Negative	0/162 (0.0)	0.0	0/169 (0.0)	0.0	NE	0.00 (-4.83, 4.83)	1.0000	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE	0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/108 (0.0)	0.0	0/127 (0.0)	0.0	NE	0.00 (-5.30, 5.30)	1.0000	
>= 30	0/ 72 (0.0)	0.0	0/ 57 (0.0)	0.0	NE	0.00 (-9.40, 9.40)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Severe Vasculitis
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.42, 4.42)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Severe Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 55 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>= 10 points	0/125 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 77 (0.0)	0.0	0/ 82 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
>=10 mg/day	0/103 (0.0)	0.0	0/102 (0.0)	0.0	NE	0.00 (-5.93, 5.93)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-11.07, 11.07)	1.0000	
HIGH	0/148 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.81, 4.81)	1.0000	
Age (years)								NE
<= 65	0/173 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.54, 4.54)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
Sex								NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
female	0/165 (0.0)	0.0	0/171 (0.0)	0.0	NE	0.00 (-4.75, 4.75)	1.0000	
Race								NE
White	0/125 (0.0)	0.0	0/137 (0.0)	0.0	NE	0.00 (-5.97, 5.97)	1.0000	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-20.43, 20.43)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE	0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	0/148 (0.0)	0.0	0/149 (0.0)	0.0	NE	0.00 (-5.37, 5.37)	1.0000	
Geographic region								NE
EU	0/ 64 (0.0)	0.0	0/ 76 (0.0)	0.0	NE	0.00 (-5.43, 5.43)	1.0000	
non-EU	0/116 (0.0)	0.0	0/108 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Onset of disease								NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
Adult	0/168 (0.0)	0.0	0/172 (0.0)	0.0	NE	0.00 (-4.70, 4.70)	1.0000	
ADA result								NE
Negative	0/162 (0.0)	0.0	0/169 (0.0)	0.0	NE	0.00 (-4.83, 4.83)	1.0000	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE	0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/108 (0.0)	0.0	0/127 (0.0)	0.0	NE	0.00 (-5.30, 5.30)	1.0000	
>= 30	0/ 72 (0.0)	0.0	0/ 57 (0.0)	0.0	NE	0.00 (-9.40, 9.40)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Non-Severe Vasculitis
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.42, 4.42)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Non-Severe Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 55 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>= 10 points	0/125 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 77 (0.0)	0.0	0/ 82 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
>=10 mg/day	0/103 (0.0)	0.0	0/102 (0.0)	0.0	NE	0.00 (-5.93, 5.93)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-11.07, 11.07)	1.0000	
HIGH	0/148 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.81, 4.81)	1.0000	
Age (years)								NE
<= 65	0/173 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.54, 4.54)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
Sex								NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
female	0/165 (0.0)	0.0	0/171 (0.0)	0.0	NE	0.00 (-4.75, 4.75)	1.0000	
Race								NE
White	0/125 (0.0)	0.0	0/137 (0.0)	0.0	NE	0.00 (-5.97, 5.97)	1.0000	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-20.43, 20.43)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE	0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	0/148 (0.0)	0.0	0/149 (0.0)	0.0	NE	0.00 (-5.37, 5.37)	1.0000	
Geographic region								NE
EU	0/ 64 (0.0)	0.0	0/ 76 (0.0)	0.0	NE	0.00 (-5.43, 5.43)	1.0000	
non-EU	0/116 (0.0)	0.0	0/108 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Onset of disease								NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
Adult	0/168 (0.0)	0.0	0/172 (0.0)	0.0	NE	0.00 (-4.70, 4.70)	1.0000	
ADA result								NE
Negative	0/162 (0.0)	0.0	0/169 (0.0)	0.0	NE	0.00 (-4.83, 4.83)	1.0000	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE	0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/108 (0.0)	0.0	0/127 (0.0)	0.0	NE	0.00 (-5.30, 5.30)	1.0000	
>= 30	0/ 72 (0.0)	0.0	0/ 57 (0.0)	0.0	NE	0.00 (-9.40, 9.40)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Malignancy
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	3 (1.7)	1 (0.5)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.07 (0.32, 29.21)	
p-value	0.3298	
Odds Ratio (95% CI)	3.10 (0.32, 30.10)	
p-value	0.3289	
Risk Difference (95% CI)	1.12 (-1.03, 3.27)	
p-value	0.3061	
CMH approach		
Response rate	1.6	0.5
Difference in response rates (95% CI)	1.09 (-3.72, 5.90)	
p-value	0.6564	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8637
< 10 points	1/ 55 (1.8)	1.7	0/ 54 (0.0)	0.0	2.95 (0.12, 70.77)	0.5053	1.68 (-9.37, 12.72)	0.7661	
>= 10 points	2/125 (1.6)	1.6	1/130 (0.8)	0.8	2.08 (0.19, 22.65)	0.5478	0.83 (-4.65, 6.31)	0.7662	
OCS dose at baseline									0.4205
<10 mg/day	2/ 77 (2.6)	2.6	0/ 82 (0.0)	0.0	5.32 (0.26, 109.09)	0.2781	2.55 (-5.67, 10.77)	0.5430	
>=10 mg/day	1/103 (1.0)	0.9	1/102 (1.0)	1.0	0.99 (0.06, 15.62)	0.9945	-0.08 (-6.44, 6.28)	0.9800	
Result of type I IFN gene signature test									0.8374
LOW	1/ 32 (3.1)	3.1	0/ 33 (0.0)	0.0	3.09 (0.13, 73.19)	0.4846	3.13 (-9.17, 15.42)	0.6184	
HIGH	2/148 (1.4)	1.3	1/151 (0.7)	0.7	2.04 (0.19, 22.26)	0.5586	0.65 (-4.56, 5.86)	0.8071	
Age (years)									NE
<= 65	3/173 (1.7)	1.7	1/181 (0.6)	0.6	3.14 (0.33, 29.89)	0.3198	1.14 (-3.80, 6.09)	0.6512	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
Sex									NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
female	3/165 (1.8)	1.8	1/171 (0.6)	0.6	3.11 (0.33, 29.59)	0.3238	1.20 (-3.97, 6.37)	0.6481	
Race									NE
White	3/125 (2.4)	2.5	1/137 (0.7)	0.7	3.29 (0.35, 31.20)	0.2998	1.75 (-4.76, 8.26)	0.5987	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-20.43, 20.43)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE		0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	3/148 (2.0)	1.9	1/149 (0.7)	0.6	3.02 (0.32, 28.70)	0.3360	1.23 (-4.55, 7.01)	0.6767	
Geographic region									0.9361
EU	2/ 64 (3.1)	3.1	1/ 76 (1.3)	1.3	2.38 (0.22, 25.59)	0.4758	1.81 (-5.37, 8.98)	0.6211	
non-EU	1/116 (0.9)	0.9	0/108 (0.0)	0.0	2.79 (0.12, 67.88)	0.5277	0.90 (-6.20, 8.00)	0.8037	
Onset of disease									NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
Adult	3/168 (1.8)	1.8	1/172 (0.6)	0.6	3.07 (0.32, 29.23)	0.3290	1.19 (-3.92, 6.31)	0.6476	
ADA result									NE
Negative	3/162 (1.9)	1.8	1/169 (0.6)	0.6	3.13 (0.33, 29.78)	0.3209	1.20 (-4.05, 6.44)	0.6548	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE		0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	3/108 (2.8)	2.7	1/127 (0.8)	0.8	3.53 (0.37, 33.42)	0.2718	1.98 (-4.12, 8.08)	0.5249	
>= 30	0/ 72 (0.0)	0.0	0/ 57 (0.0)	0.0	NE		0.00 (-9.40, 9.40)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Serious Malignancy
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	1 (0.6)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.07 (0.13, 74.78)	
p-value	0.4917	
Odds Ratio (95% CI)	3.08 (0.12, 76.19)	
p-value	0.4913	
Risk Difference (95% CI)	0.56 (-0.53, 1.64)	
p-value	0.3160	
CMH approach		
Response rate	0.5	0.0
Difference in response rates (95% CI)	0.50 (-3.99, 4.99)	
p-value	0.8272	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Serious Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	1/ 55 (1.8)	1.7	0/ 54 (0.0)	0.0	2.95 (0.12, 70.77)	0.5053	1.68 (-9.37, 12.72)	0.7661	
>= 10 points	0/125 (0.0)	0.0	0/130 (0.0)	0.0	NE		0.00 (-4.93, 4.93)	1.0000	
OCS dose at baseline									NE
<10 mg/day	0/ 77 (0.0)	0.0	0/ 82 (0.0)	0.0	NE		0.00 (-7.65, 7.65)	1.0000	
>=10 mg/day	1/103 (1.0)	0.9	0/102 (0.0)	0.0	2.97 (0.12, 72.09)	0.5033	0.89 (-5.22, 7.00)	0.7754	
Result of type I IFN gene signature test									NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE		0.00 (-11.07, 11.07)	1.0000	
HIGH	1/148 (0.7)	0.6	0/151 (0.0)	0.0	3.06 (0.13, 74.53)	0.4923	0.61 (-4.30, 5.52)	0.8079	
Age (years)									NE
<= 65	1/173 (0.6)	0.5	0/181 (0.0)	0.0	3.14 (0.13, 76.51)	0.4828	0.50 (-4.11, 5.12)	0.8314	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
Sex									NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
female	1/165 (0.6)	0.5	0/171 (0.0)	0.0	3.11 (0.13, 75.76)	0.4864	0.55 (-4.28, 5.38)	0.8239	
Race									NE
White	1/125 (0.8)	0.9	0/137 (0.0)	0.0	3.29 (0.14, 79.92)	0.4651	0.93 (-5.18, 7.04)	0.7646	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-20.43, 20.43)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE		0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	1/148 (0.7)	0.5	0/149 (0.0)	0.0	3.02 (0.12, 73.54)	0.4974	0.52 (-4.91, 5.95)	0.8512	
Geographic region									NE
EU	1/ 64 (1.6)	1.6	0/ 76 (0.0)	0.0	3.55 (0.15, 85.76)	0.4350	1.56 (-4.57, 7.70)	0.6176	
non-EU	0/116 (0.0)	0.0	0/108 (0.0)	0.0	NE		0.00 (-6.94, 6.94)	1.0000	
Onset of disease									NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
Adult	1/168 (0.6)	0.6	0/172 (0.0)	0.0	3.07 (0.13, 74.86)	0.4911	0.56 (-4.23, 5.35)	0.8187	
ADA result									NE
Negative	1/162 (0.6)	0.5	0/169 (0.0)	0.0	3.13 (0.13, 76.25)	0.4839	0.53 (-4.38, 5.44)	0.8316	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE		0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	1/108 (0.9)	0.8	0/127 (0.0)	0.0	3.52 (0.14, 85.60)	0.4392	0.84 (-4.64, 6.32)	0.7635	
>= 30	0/ 72 (0.0)	0.0	0/ 57 (0.0)	0.0	NE		0.00 (-9.40, 9.40)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Severe Malignancy
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.42, 4.42)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Severe Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 55 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.69, 10.69)	1.0000	
>= 10 points	0/125 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.93, 4.93)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 77 (0.0)	0.0	0/ 82 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
>=10 mg/day	0/103 (0.0)	0.0	0/102 (0.0)	0.0	NE	0.00 (-5.93, 5.93)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE	0.00 (-11.07, 11.07)	1.0000	
HIGH	0/148 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.81, 4.81)	1.0000	
Age (years)								NE
<= 65	0/173 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.54, 4.54)	1.0000	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE	0.00 (-58.56, 58.56)	1.0000	
Sex								NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE	0.00 (-23.41, 23.41)	1.0000	
female	0/165 (0.0)	0.0	0/171 (0.0)	0.0	NE	0.00 (-4.75, 4.75)	1.0000	
Race								NE
White	0/125 (0.0)	0.0	0/137 (0.0)	0.0	NE	0.00 (-5.97, 5.97)	1.0000	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE	0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE	0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE	NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE	0.00 (-20.43, 20.43)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE	0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	0/148 (0.0)	0.0	0/149 (0.0)	0.0	NE	0.00 (-5.37, 5.37)	1.0000	
Geographic region								NE
EU	0/ 64 (0.0)	0.0	0/ 76 (0.0)	0.0	NE	0.00 (-5.43, 5.43)	1.0000	
non-EU	0/116 (0.0)	0.0	0/108 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Onset of disease								NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
Adult	0/168 (0.0)	0.0	0/172 (0.0)	0.0	NE	0.00 (-4.70, 4.70)	1.0000	
ADA result								NE
Negative	0/162 (0.0)	0.0	0/169 (0.0)	0.0	NE	0.00 (-4.83, 4.83)	1.0000	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE	0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/108 (0.0)	0.0	0/127 (0.0)	0.0	NE	0.00 (-5.30, 5.30)	1.0000	
>= 30	0/ 72 (0.0)	0.0	0/ 57 (0.0)	0.0	NE	0.00 (-9.40, 9.40)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Non-Severe Malignancy
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	3 (1.7)	1 (0.5)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.07 (0.32, 29.21)	
p-value	0.3298	
Odds Ratio (95% CI)	3.10 (0.32, 30.10)	
p-value	0.3289	
Risk Difference (95% CI)	1.12 (-1.03, 3.27)	
p-value	0.3061	
CMH approach		
Response rate	1.6	0.5
Difference in response rates (95% CI)	1.09 (-3.72, 5.90)	
p-value	0.6564	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Non-Severe Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Anifrolumab 300mg (N=180) Response rate	Placebo (N=184) n/ N (%)	Placebo (N=184) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8637
< 10 points	1/ 55 (1.8)	1.7	0/ 54 (0.0)	0.0	2.95 (0.12, 70.77)	0.5053	1.68 (-9.37, 12.72)	0.7661	
>= 10 points	2/125 (1.6)	1.6	1/130 (0.8)	0.8	2.08 (0.19, 22.65)	0.5478	0.83 (-4.65, 6.31)	0.7662	
OCS dose at baseline									0.4205
<10 mg/day	2/ 77 (2.6)	2.6	0/ 82 (0.0)	0.0	5.32 (0.26, 109.09)	0.2781	2.55 (-5.67, 10.77)	0.5430	
>=10 mg/day	1/103 (1.0)	0.9	1/102 (1.0)	1.0	0.99 (0.06, 15.62)	0.9945	-0.08 (-6.44, 6.28)	0.9800	
Result of type I IFN gene signature test									0.8374
LOW	1/ 32 (3.1)	3.1	0/ 33 (0.0)	0.0	3.09 (0.13, 73.19)	0.4846	3.13 (-9.17, 15.42)	0.6184	
HIGH	2/148 (1.4)	1.3	1/151 (0.7)	0.7	2.04 (0.19, 22.26)	0.5586	0.65 (-4.56, 5.86)	0.8071	
Age (years)									NE
<= 65	3/173 (1.7)	1.7	1/181 (0.6)	0.6	3.14 (0.33, 29.89)	0.3198	1.14 (-3.80, 6.09)	0.6512	
> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
Sex									NE
male	0/ 15 (0.0)	0.0	0/ 13 (0.0)	0.0	NE		0.00 (-23.41, 23.41)	1.0000	
female	3/165 (1.8)	1.8	1/171 (0.6)	0.6	3.11 (0.33, 29.59)	0.3238	1.20 (-3.97, 6.37)	0.6481	
Race									NE
White	3/125 (2.4)	2.5	1/137 (0.7)	0.7	3.29 (0.35, 31.20)	0.2998	1.75 (-4.76, 8.26)	0.5987	
Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-13.78, 13.78)	1.0000	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-20.43, 20.43)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE		0.00 (-10.79, 10.79)	1.0000	
Non-hispanic/Latino	3/148 (2.0)	1.9	1/149 (0.7)	0.6	3.02 (0.32, 28.70)	0.3360	1.23 (-4.55, 7.01)	0.6767	
Geographic region									0.9361
EU	2/ 64 (3.1)	3.1	1/ 76 (1.3)	1.3	2.38 (0.22, 25.59)	0.4758	1.81 (-5.37, 8.98)	0.6211	
non-EU	1/116 (0.9)	0.9	0/108 (0.0)	0.0	2.79 (0.12, 67.88)	0.5277	0.90 (-6.20, 8.00)	0.8037	
Onset of disease									NE
Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
Adult	3/168 (1.8)	1.8	1/172 (0.6)	0.6	3.07 (0.32, 29.23)	0.3290	1.19 (-3.92, 6.31)	0.6476	
ADA result									NE
Negative	3/162 (1.9)	1.8	1/169 (0.6)	0.6	3.13 (0.33, 29.78)	0.3209	1.20 (-4.05, 6.44)	0.6548	
Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE		0.00 (-20.88, 20.88)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	3/108 (2.8)	2.7	1/127 (0.8)	0.8	3.53 (0.37, 33.42)	0.2718	1.98 (-4.12, 8.08)	0.5249	
>= 30	0/ 72 (0.0)	0.0	0/ 57 (0.0)	0.0	NE		0.00 (-9.40, 9.40)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of SOCs Cardiac disorders and/or Vascular disorders (on-treatment)
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=184)
Number of subjects with events, n (%)	6 (3.3)	21 (11.4)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.29 (0.12, 0.71)	
p-value	0.0063	
Odds Ratio (95% CI)	0.27 (0.11, 0.68)	
p-value	0.0056	
Risk Difference (95% CI)	-8.08 (-13.37, -2.79)	
p-value	0.0028	
CMH approach		
Response rate	3.3	11.5
Difference in response rates (95% CI)	-8.18 (-14.70, -1.67)	
p-value	0.0138	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of SOCs Cardiac disorders and/or Vascular disorders (on-treatment) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9198
< 10 points	1/ 55 (1.8)	1.7	3/ 54 (5.6)	5.8	0.33 (0.04, 3.05)	0.3266	-4.11 (-16.34, 8.12)	0.5106	
>= 10 points	5/125 (4.0)	4.0	18/130 (13.8)	13.9	0.29 (0.11, 0.75)	0.0112	-9.94 (-17.95, -1.94)	0.0149	
OCS dose at baseline									0.5985
<10 mg/day	1/ 77 (1.3)	1.3	6/ 82 (7.3)	7.4	0.18 (0.02, 1.44)	0.1056	-6.05 (-15.44, 3.33)	0.2060	
>=10 mg/day	5/103 (4.9)	4.8	15/102 (14.7)	14.8	0.33 (0.12, 0.87)	0.0258	-9.92 (-19.36, -0.49)	0.0393	
Result of type I IFN gene signature test									0.7794
LOW	0/ 32 (0.0)	0.0	2/ 33 (6.1)	6.1	0.21 (0.01, 4.13)	0.3018	-6.06 (-19.30, 7.18)	0.3695	
HIGH	6/148 (4.1)	4.0	19/151 (12.6)	12.7	0.32 (0.13, 0.78)	0.0126	-8.64 (-16.03, -1.25)	0.0219	
Age (years)									0.6887
<= 65	6/173 (3.5)	3.4	20/181 (11.0)	11.2	0.31 (0.13, 0.76)	0.0106	-7.75 (-14.37, -1.14)	0.0216	
> 65	0/ 7 (0.0)	0.0	1/ 3 (33.3)	33.3	0.17 (0.01, 3.24)	0.2366	-33.33 (-96.20, 29.53)	0.2987	
Sex									0.0977
male	2/ 15 (13.3)	13.3	1/ 13 (7.7)	7.7	1.73 (0.18, 16.99)	0.6367	5.64 (-23.60, 34.88)	0.7054	
female	4/165 (2.4)	2.4	20/171 (11.7)	11.7	0.21 (0.07, 0.59)	0.0034	-9.27 (-16.03, -2.51)	0.0072	
Race									0.7317
White	6/125 (4.8)	5.0	16/137 (11.7)	11.6	0.41 (0.17, 1.02)	0.0545	-6.67 (-14.95, 1.61)	0.1143	
Black or African American	0/ 29 (0.0)	0.0	2/ 23 (8.7)	8.7	0.16 (0.01, 3.18)	0.2294	-8.70 (-25.61, 8.22)	0.3137	
Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
Other	0/ 15 (0.0)	0.0	3/ 18 (16.7)	16.7	0.17 (0.01, 3.05)	0.2285	-16.67 (-41.49, 8.15)	0.1881	
Ethnicity									0.3821
Hispanic/Latino	0/ 32 (0.0)	0.0	5/ 35 (14.3)	14.3	0.10 (0.01, 1.73)	0.1128	-14.29 (-29.27, 0.70)	0.0617	
Non-hispanic/Latino	6/148 (4.1)	4.1	16/149 (10.7)	10.6	0.38 (0.15, 0.94)	0.0360	-6.51 (-13.96, 0.93)	0.0864	
Geographic region									0.8695
EU	3/ 64 (4.7)	4.7	11/ 76 (14.5)	14.5	0.32 (0.09, 1.11)	0.0730	-9.79 (-20.26, 0.69)	0.0670	
non-EU	3/116 (2.6)	2.5	10/108 (9.3)	9.5	0.28 (0.08, 0.99)	0.0478	-6.97 (-15.70, 1.76)	0.1177	
Onset of disease									0.9604
Paediatric	0/ 12 (0.0)	0.0	1/ 12 (8.3)	8.3	0.33 (0.01, 7.45)	0.4883	-8.33 (-37.28, 20.61)	0.5726	
Adult	6/168 (3.6)	3.6	20/172 (11.6)	11.6	0.31 (0.13, 0.75)	0.0091	-7.98 (-14.83, -1.13)	0.0224	
ADA result									0.9737
Negative	6/162 (3.7)	3.7	20/169 (11.8)	11.8	0.31 (0.13, 0.76)	0.0102	-8.04 (-15.03, -1.05)	0.0241	
Positive (At any time)	0/ 17 (0.0)	0.0	1/ 15 (6.7)	6.7	0.30 (0.01, 6.77)	0.4461	-6.67 (-29.80, 16.47)	0.5722	
BMI (kg/m2) at enrolment									0.1368
< 30	2/108 (1.9)	1.9	16/127 (12.6)	12.5	0.15 (0.03, 0.63)	0.0094	-10.59 (-18.47, -2.71)	0.0085	
>= 30	4/ 72 (5.6)	5.4	5/ 57 (8.8)	9.0	0.63 (0.18, 2.25)	0.4802	-3.53 (-15.68, 8.62)	0.5689	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Blood and lymphatic system disorders	Number of subjects with events, n (%)	9 (5.0)	14 (7.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.66 (0.29, 1.48)	
	p-value	0.3107	
	Odds Ratio (95% CI)	0.64 (0.27, 1.52)	
	p-value	0.3098	
	Risk Difference (95% CI)	-2.61 (-7.59, 2.37)	
	p-value	0.3047	
	CMH approach		
	Response rate	5.0	7.6
	Difference in response rates (95% CI)	-2.65 (-8.94, 3.65)	
	p-value	0.4097	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Gastrointestinal disorders	Number of subjects with events, n (%)	44 (24.4)	41 (22.3)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.10 (0.76, 1.59)	
	p-value	0.6261	
	Odds Ratio (95% CI)	1.13 (0.69, 1.83)	
	p-value	0.6261	
	Risk Difference (95% CI)	2.16 (-6.53, 10.85)	
	p-value	0.6260	
	CMH approach		
	Response rate	24.7	22.6
	Difference in response rates (95% CI)	2.14 (-6.72, 11.00)	
	p-value	0.6364	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Gastrointestinal disorders, PT: Diarrhoea	Number of subjects with events, n (%)	5 (2.8)	13 (7.1)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.39 (0.14, 1.08)	
	p-value	0.0703	
	Odds Ratio (95% CI)	0.38 (0.13, 1.08)	
	p-value	0.0684	
	Risk Difference (95% CI)	-4.29 (-8.70, 0.13)	
	p-value	0.0569	
	CMH approach		
	Response rate	2.9	7.1
	Difference in response rates (95% CI)	-4.22 (-10.13, 1.70)	
	p-value	0.1624	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Gastrointestinal disorders, PT: Nausea	Number of subjects with events, n (%)	9 (5.0)	13 (7.1)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.71 (0.31, 1.61)	
	p-value	0.4112	
	Odds Ratio (95% CI)	0.69 (0.29, 1.66)	
	p-value	0.4106	
	Risk Difference (95% CI)	-2.07 (-6.95, 2.82)	
	p-value	0.4072	
	CMH approach		
	Response rate	5.0	7.2
	Difference in response rates (95% CI)	-2.21 (-8.43, 4.01)	
	p-value	0.4869	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: General disorders and administration site conditions	Number of subjects with events, n (%)	28 (15.6)	20 (10.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.43 (0.84, 2.45)	
	p-value	0.1898	
	Odds Ratio (95% CI)	1.51 (0.82, 2.79)	
	p-value	0.1885	
	Risk Difference (95% CI)	4.69 (-2.26, 11.63)	
	p-value	0.1861	
	CMH approach		
	Response rate	15.6	11.0
	Difference in response rates (95% CI)	4.67 (-3.00, 12.33)	
	p-value	0.2330	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Immune system disorders	Number of subjects with events, n (%)	14 (7.8)	5 (2.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	2.86 (1.05, 7.78)	
	p-value	0.0393	
	Odds Ratio (95% CI)	3.02 (1.06, 8.57)	
	p-value	0.0378	
	Risk Difference (95% CI)	5.06 (0.50, 9.62)	
	p-value	0.0298	
	CMH approach		
	Response rate	7.9	2.6
	Difference in response rates (95% CI)	5.26 (-0.70, 11.23)	
	p-value	0.0838	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Immune system disorders, PT: Hypersensitivity	Number of subjects with events, n (%)	11 (6.1)	2 (1.1)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	5.62 (1.26, 25.01)	
	p-value	0.0234	
	Odds Ratio (95% CI)	5.92 (1.29, 27.11)	
	p-value	0.0219	
	Risk Difference (95% CI)	5.02 (1.22, 8.83)	
	p-value	0.0097	
	CMH approach		
	Response rate	6.2	1.1
	Difference in response rates (95% CI)	5.14 (-0.36, 10.64)	
	p-value	0.0668	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Infections and infestations	Number of subjects with events, n (%)	135 (75.0)	104 (56.5)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.33 (1.14, 1.55)	
	p-value	0.0003	
	Odds Ratio (95% CI)	2.31 (1.48, 3.60)	
	p-value	0.0002	
	Risk Difference (95% CI)	18.48 (8.92, 28.03)	
	p-value	0.0002	
	CMH approach		
	Response rate	75.1	56.5
	Difference in response rates (95% CI)	18.58 (8.97, 28.19)	
	p-value	0.0002	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Infections and infestations, PT: Bronchitis	Number of subjects with events, n (%)	16 (8.9)	10 (5.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.64 (0.76, 3.51)	
	p-value	0.2062	
	Odds Ratio (95% CI)	1.70 (0.75, 3.85)	
	p-value	0.2050	
	Risk Difference (95% CI)	3.45 (-1.84, 8.75)	
	p-value	0.2009	
	CMH approach		
	Response rate	8.9	5.6
	Difference in response rates (95% CI)	3.38 (-3.08, 9.83)	
	p-value	0.3051	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Infections and infestations, PT: Herpes zoster	Number of subjects with events, n (%)	10 (5.6)	3 (1.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	3.41 (0.95, 12.18)	
	p-value	0.0592	
	Odds Ratio (95% CI)	3.55 (0.96, 13.11)	
	p-value	0.0575	
	Risk Difference (95% CI)	3.93 (0.11, 7.74)	
	p-value	0.0437	
	CMH approach		
	Response rate	5.6	1.7
	Difference in response rates (95% CI)	3.95 (-1.67, 9.58)	
	p-value	0.1685	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Infections and infestations, PT: Nasopharyngitis	Number of subjects with events, n (%)	36 (20.0)	22 (12.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.67 (1.03, 2.73)	
	p-value	0.0392	
	Odds Ratio (95% CI)	1.84 (1.03, 3.27)	
	p-value	0.0378	
	Risk Difference (95% CI)	8.04 (0.55, 15.54)	
	p-value	0.0353	
	CMH approach		
	Response rate	20.0	12.1
	Difference in response rates (95% CI)	7.90 (-0.16, 15.95)	
	p-value	0.0546	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Infections and infestations, PT: Pharyngitis	Number of subjects with events, n (%)	12 (6.7)	13 (7.1)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.94 (0.44, 2.01)	
	p-value	0.8805	
	Odds Ratio (95% CI)	0.94 (0.42, 2.12)	
	p-value	0.8805	
	Risk Difference (95% CI)	-0.40 (-5.59, 4.80)	
	p-value	0.8805	
	CMH approach		
	Response rate	6.8	7.2
	Difference in response rates (95% CI)	-0.36 (-6.78, 6.05)	
	p-value	0.9117	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Infections and infestations, PT: Sinusitis	Number of subjects with events, n (%)	8 (4.4)	13 (7.1)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.63 (0.27, 1.48)	
	p-value	0.2888	
	Odds Ratio (95% CI)	0.61 (0.25, 1.51)	
	p-value	0.2877	
	Risk Difference (95% CI)	-2.62 (-7.39, 2.15)	
	p-value	0.2817	
	CMH approach		
	Response rate	4.5	6.9
	Difference in response rates (95% CI)	-2.46 (-8.46, 3.54)	
	p-value	0.4217	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Infections and infestations, PT: Upper respiratory tract infection	Number of subjects with events, n (%)	22 (12.2)	18 (9.8)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.25 (0.69, 2.25)	
	p-value	0.4580	
	Odds Ratio (95% CI)	1.28 (0.66, 2.48)	
	p-value	0.4577	
	Risk Difference (95% CI)	2.44 (-3.99, 8.87)	
	p-value	0.4570	
	CMH approach		
	Response rate	12.2	9.8
	Difference in response rates (95% CI)	2.41 (-4.79, 9.61)	
	p-value	0.5117	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Infections and infestations, PT: Urinary tract infection	Number of subjects with events, n (%)	22 (12.2)	27 (14.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.83 (0.49, 1.41)	
	p-value	0.4942	
	Odds Ratio (95% CI)	0.81 (0.44, 1.48)	
	p-value	0.4938	
	Risk Difference (95% CI)	-2.45 (-9.45, 4.55)	
	p-value	0.4926	
	CMH approach		
	Response rate	12.2	14.7
	Difference in response rates (95% CI)	-2.53 (-10.24, 5.17)	
	p-value	0.5193	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Injury, poisoning and procedural complications	Number of subjects with events, n (%)	38 (21.1)	34 (18.5)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.14 (0.75, 1.73)	
	p-value	0.5288	
	Odds Ratio (95% CI)	1.18 (0.70, 1.98)	
	p-value	0.5286	
	Risk Difference (95% CI)	2.63 (-5.55, 10.82)	
	p-value	0.5284	
	CMH approach		
	Response rate	21.3	18.5
	Difference in response rates (95% CI)	2.84 (-5.61, 11.28)	
	p-value	0.5105	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Injury, poisoning and procedural complications, PT: Infusion related reaction	Number of subjects with events, n (%)	16 (8.9)	13 (7.1)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.26 (0.62, 2.54)	
	p-value	0.5217	
	Odds Ratio (95% CI)	1.28 (0.60, 2.75)	
	p-value	0.5214	
	Risk Difference (95% CI)	1.82 (-3.74, 7.39)	
	p-value	0.5208	
	CMH approach		
	Response rate	9.0	7.2
	Difference in response rates (95% CI)	1.81 (-4.74, 8.36)	
	p-value	0.5881	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Investigations	Number of subjects with events, n (%)	10 (5.6)	12 (6.5)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.85 (0.38, 1.92)	
	p-value	0.6993	
	Odds Ratio (95% CI)	0.84 (0.35, 2.00)	
	p-value	0.6992	
	Risk Difference (95% CI)	-0.97 (-5.86, 3.93)	
	p-value	0.6986	
	CMH approach		
	Response rate	5.5	6.5
	Difference in response rates (95% CI)	-1.00 (-7.24, 5.24)	
	p-value	0.7532	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Metabolism and nutrition disorders	Number of subjects with events, n (%)	9 (5.0)	15 (8.2)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.61 (0.28, 1.37)	
	p-value	0.2313	
	Odds Ratio (95% CI)	0.59 (0.25, 1.39)	
	p-value	0.2300	
	Risk Difference (95% CI)	-3.15 (-8.23, 1.92)	
	p-value	0.2236	
	CMH approach		
	Response rate	4.8	8.2
	Difference in response rates (95% CI)	-3.36 (-9.65, 2.93)	
	p-value	0.2948	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Musculoskeletal and connective tissue disorders	Number of subjects with events, n (%)	41 (22.8)	44 (23.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.95 (0.66, 1.38)	
	p-value	0.7980	
	Odds Ratio (95% CI)	0.94 (0.58, 1.53)	
	p-value	0.7980	
	Risk Difference (95% CI)	-1.14 (-9.83, 7.56)	
	p-value	0.7979	
	CMH approach		
	Response rate	23.0	23.9
	Difference in response rates (95% CI)	-0.91 (-9.85, 8.03)	
	p-value	0.8423	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Musculoskeletal and connective tissue disorders, PT: Arthralgia	Number of subjects with events, n (%)	10 (5.6)	3 (1.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	3.41 (0.95, 12.18)	
	p-value	0.0592	
	Odds Ratio (95% CI)	3.55 (0.96, 13.11)	
	p-value	0.0575	
	Risk Difference (95% CI)	3.93 (0.11, 7.74)	
	p-value	0.0437	
	CMH approach		
	Response rate	5.7	1.7
	Difference in response rates (95% CI)	3.98 (-1.63, 9.59)	
	p-value	0.1642	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Musculoskeletal and connective tissue disorders, PT: Back pain	Number of subjects with events, n (%)	10 (5.6)	13 (7.1)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.79 (0.35, 1.75)	
	p-value	0.5551	
	Odds Ratio (95% CI)	0.77 (0.33, 1.81)	
	p-value	0.5548	
	Risk Difference (95% CI)	-1.51 (-6.50, 3.48)	
	p-value	0.5533	
	CMH approach		
	Response rate	5.7	7.1
	Difference in response rates (95% CI)	-1.39 (-7.68, 4.90)	
	p-value	0.6646	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Number of subjects with events, n (%)	10 (5.6)	2 (1.1)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	5.11 (1.14, 23.00)	
	p-value	0.0335	
	Odds Ratio (95% CI)	5.35 (1.16, 24.78)	
	p-value	0.0319	
	Risk Difference (95% CI)	4.47 (0.80, 8.13)	
	p-value	0.0169	
	CMH approach		
	Response rate	5.5	1.1
	Difference in response rates (95% CI)	4.39 (-1.08, 9.85)	
	p-value	0.1160	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Nervous system disorders	Number of subjects with events, n (%)	42 (23.3)	29 (15.8)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.48 (0.97, 2.27)	
	p-value	0.0712	
	Odds Ratio (95% CI)	1.63 (0.96, 2.75)	
	p-value	0.0698	
	Risk Difference (95% CI)	7.57 (-0.55, 15.69)	
	p-value	0.0675	
	CMH approach		
	Response rate	23.4	15.7
	Difference in response rates (95% CI)	7.69 (-0.73, 16.10)	
	p-value	0.0735	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Nervous system disorders, PT: Headache	Number of subjects with events, n (%)	17 (9.4)	16 (8.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.09 (0.57, 2.08)	
	p-value	0.8036	
	Odds Ratio (95% CI)	1.10 (0.54, 2.24)	
	p-value	0.8036	
	Risk Difference (95% CI)	0.75 (-5.15, 6.65)	
	p-value	0.8036	
	CMH approach		
	Response rate	9.5	8.7
	Difference in response rates (95% CI)	0.83 (-6.01, 7.68)	
	p-value	0.8117	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Psychiatric disorders	Number of subjects with events, n (%)	14 (7.8)	20 (10.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.72 (0.37, 1.37)	
	p-value	0.3139	
	Odds Ratio (95% CI)	0.69 (0.34, 1.42)	
	p-value	0.3129	
	Risk Difference (95% CI)	-3.09 (-9.05, 2.87)	
	p-value	0.3094	
	CMH approach		
	Response rate	7.8	11.0
	Difference in response rates (95% CI)	-3.20 (-10.09, 3.69)	
	p-value	0.3625	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Renal and urinary disorders	Number of subjects with events, n (%)	11 (6.1)	9 (4.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.25 (0.53, 2.94)	
	p-value	0.6105	
	Odds Ratio (95% CI)	1.27 (0.51, 3.13)	
	p-value	0.6103	
	Risk Difference (95% CI)	1.22 (-3.47, 5.91)	
	p-value	0.6099	
	CMH approach		
	Response rate	6.1	4.8
	Difference in response rates (95% CI)	1.24 (-4.82, 7.29)	
	p-value	0.6889	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Reproductive system and breast disorders	Number of subjects with events, n (%)	7 (3.9)	10 (5.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.72 (0.28, 1.84)	
	p-value	0.4870	
	Odds Ratio (95% CI)	0.70 (0.26, 1.89)	
	p-value	0.4866	
	Risk Difference (95% CI)	-1.55 (-5.87, 2.78)	
	p-value	0.4836	
	CMH approach		
	Response rate	4.0	5.4
	Difference in response rates (95% CI)	-1.43 (-7.33, 4.48)	
	p-value	0.6354	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with events, n (%)	32 (17.8)	25 (13.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.31 (0.81, 2.12)	
	p-value	0.2734	
	Odds Ratio (95% CI)	1.38 (0.78, 2.43)	
	p-value	0.2726	
	Risk Difference (95% CI)	4.19 (-3.27, 11.65)	
	p-value	0.2711	
	CMH approach		
	Response rate	17.8	13.7
	Difference in response rates (95% CI)	4.09 (-3.94, 12.12)	
	p-value	0.3180	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Respiratory, thoracic and mediastinal disorders, PT: Cough	Number of subjects with events, n (%)	11 (6.1)	7 (3.8)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.61 (0.64, 4.05)	
	p-value	0.3153	
	Odds Ratio (95% CI)	1.65 (0.62, 4.35)	
	p-value	0.3145	
	Risk Difference (95% CI)	2.31 (-2.15, 6.77)	
	p-value	0.3106	
	CMH approach		
	Response rate	6.1	3.8
	Difference in response rates (95% CI)	2.31 (-3.62, 8.24)	
	p-value	0.4457	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Skin and subcutaneous tissue disorders	Number of subjects with events, n (%)	27 (15.0)	15 (8.2)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.84 (1.01, 3.34)	
	p-value	0.0452	
	Odds Ratio (95% CI)	1.99 (1.02, 3.88)	
	p-value	0.0438	
	Risk Difference (95% CI)	6.85 (0.30, 13.39)	
	p-value	0.0403	
	CMH approach		
	Response rate	15.2	8.3
	Difference in response rates (95% CI)	6.87 (-0.50, 14.24)	
	p-value	0.0677	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Vascular disorders	Number of subjects with events, n (%)	4 (2.2)	14 (7.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.29 (0.10, 0.87)	
	p-value	0.0272	
	Odds Ratio (95% CI)	0.28 (0.09, 0.86)	
	p-value	0.0257	
	Risk Difference (95% CI)	-5.39 (-9.78, -0.99)	
	p-value	0.0163	
	CMH approach		
	Response rate	2.2	7.6
	Difference in response rates (95% CI)	-5.39 (-11.31, 0.53)	
	p-value	0.0742	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SOC: Immune system disorders	SLEDAI-2K score									0.5464
	< 10 points	5/ 55 (9.1)	9.6	1/ 54 (1.9)	1.8	4.91 (0.59, 40.65)	0.1402	7.88 (-4.77, 20.54)	0.2221	
	>= 10 points	9/125 (7.2)	7.2	4/130 (3.1)	3.0	2.34 (0.74, 7.40)	0.1480	4.15 (-2.70, 11.00)	0.2351	
	OCS dose									0.5556
	<10 mg/day	9/ 77 (11.7)	11.5	4/ 82 (4.9)	4.8	2.40 (0.77, 7.46)	0.1316	6.72 (-3.77, 17.21)	0.2093	
	>=10 mg/day	5/103 (4.9)	5.1	1/102 (1.0)	1.0	4.95 (0.59, 41.65)	0.1409	4.08 (-3.13, 11.29)	0.2673	
	Result of type I IFN gene signature test									0.1748
	LOW	6/ 32 (18.8)	18.8	0/ 33 (0.0)	0.0	13.39 (0.79, 228.40)	0.0730	18.75 (2.41, 35.09)	0.0245	
	HIGH	8/148 (5.4)	5.5	5/151 (3.3)	3.2	1.63 (0.55, 4.88)	0.3800	2.33 (-4.01, 8.66)	0.4718	
	Age (years)									0.7770
	<= 65	11/173 (6.4)	6.5	5/181 (2.8)	2.7	2.30 (0.82, 6.49)	0.1149	3.86 (-2.11, 9.82)	0.2049	
	> 65	3/ 7 (42.9)	42.9	0/ 3 (0.0)	0.0	3.50 (0.23, 52.56)	0.3648	42.86 (-20.18, 105.90)	0.1827	
	Sex									0.3569
	male	1/ 15 (6.7)	6.7	1/ 13 (7.7)	7.7	0.87 (0.06, 12.52)	0.9164	-1.03 (-28.77, 26.72)	0.9422	
	female	13/165 (7.9)	8.0	4/171 (2.3)	2.3	3.37 (1.12, 10.12)	0.0305	5.70 (-0.58, 11.98)	0.0753	
	Race									0.2208
	White	13/125 (10.4)	10.0	3/137 (2.2)	2.2	4.75 (1.39, 16.28)	0.0132	7.84 (0.16, 15.53)	0.0454	
	Black or African American	0/ 29 (0.0)	0.0	1/ 23 (4.3)	4.3	0.27 (0.01, 6.26)	0.4116	-4.35 (-19.85, 11.16)	0.5826	
	Asian	1/ 11 (9.1)	9.1	0/ 5 (0.0)	0.0	1.50 (0.07, 31.57)	0.7942	9.09 (-34.34, 52.53)	0.6817	
	American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
	Other	0/ 15 (0.0)	0.0	1/ 18 (5.6)	5.6	0.40 (0.02, 9.06)	0.5618	-5.56 (-27.75, 16.64)	0.6237	
	Ethnicity									0.4654
	Hispanic/Latino	1/ 32 (3.1)	3.1	1/ 35 (2.9)	2.9	1.09 (0.07, 16.77)	0.9487	0.27 (-12.76, 13.29)	0.9678	
	Non-hispanic/Latino	13/148 (8.8)	9.1	4/149 (2.7)	2.7	3.27 (1.09, 9.80)	0.0342	6.46 (-0.65, 13.57)	0.0749	
	Geographic region									0.2675
	EU	4/ 64 (6.3)	6.3	0/ 76 (0.0)	0.0	10.66 (0.58, 194.35)	0.1101	6.25 (-1.54, 14.04)	0.1156	
	non-EU	10/116 (8.6)	8.8	5/108 (4.6)	4.5	1.86 (0.66, 5.27)	0.2418	4.38 (-4.42, 13.18)	0.3296	
	Onset of disease									0.9428
	Paediatric	1/ 12 (8.3)	8.3	0/ 12 (0.0)	0.0	3.00 (0.13, 67.06)	0.4883	8.33 (-20.61, 37.28)	0.5726	
	Adult	13/168 (7.7)	7.7	5/172 (2.9)	2.8	2.66 (0.97, 7.30)	0.0573	4.84 (-1.38, 11.06)	0.1275	
	ADA result									0.1374
	Negative	14/162 (8.6)	8.8	4/169 (2.4)	2.3	3.65 (1.23, 10.86)	0.0199	6.48 (0.03, 12.92)	0.0489	
	Positive (At any time)	0/ 17 (0.0)	0.0	1/ 15 (6.7)	6.7	0.30 (0.01, 6.77)	0.4461	-6.67 (-29.80, 16.47)	0.5722	
	BMI (kg/m2)									0.4387
	< 30	7/108 (6.5)	6.7	2/127 (1.6)	1.6	4.12 (0.87, 19.40)	0.0737	5.02 (-2.00, 12.04)	0.1610	
	>= 30	7/ 72 (9.7)	10.2	3/ 57 (5.3)	5.6	1.85 (0.50, 6.83)	0.3575	4.56 (-7.59, 16.72)	0.4615	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SOC: Immune system disorders, PT: Hypersensitivity	SLEDAI-2K score									0.8747
	< 10 points	5/ 55 (9.1)	9.6	1/ 54 (1.9)	1.8	4.91 (0.59, 40.65)	0.1402	7.88 (-4.77, 20.54)	0.2221	
	>= 10 points	6/125 (4.8)	4.8	1/130 (0.8)	0.8	6.24 (0.76, 51.10)	0.0879	3.98 (-2.03, 9.98)	0.1942	
	OCS dose									0.4977
	<10 mg/day	8/ 77 (10.4)	10.2	1/ 82 (1.2)	1.2	8.52 (1.09, 66.54)	0.0411	8.98 (-0.63, 18.59)	0.0669	
	>=10 mg/day	3/103 (2.9)	3.1	1/102 (1.0)	1.0	2.97 (0.31, 28.09)	0.3421	2.11 (-4.66, 8.88)	0.5409	
	Result of type I IFN gene signature test									0.3200
	LOW	6/ 32 (18.8)	18.8	0/ 33 (0.0)	0.0	13.39 (0.79, 228.40)	0.0730	18.75 (2.41, 35.09)	0.0245	
	HIGH	5/148 (3.4)	3.5	2/151 (1.3)	1.3	2.55 (0.50, 12.94)	0.2585	2.18 (-3.49, 7.85)	0.4518	
	Age (years)									0.9104
	<= 65	8/173 (4.6)	4.7	2/181 (1.1)	1.1	4.18 (0.90, 19.43)	0.0677	3.66 (-1.81, 9.13)	0.1899	
	> 65	3/ 7 (42.9)	42.9	0/ 3 (0.0)	0.0	3.50 (0.23, 52.56)	0.3648	42.86 (-20.18, 105.90)	0.1827	
	Sex									0.1482
	male	1/ 15 (6.7)	6.7	1/ 13 (7.7)	7.7	0.87 (0.06, 12.52)	0.9164	-1.03 (-28.77, 26.72)	0.9422	
	female	10/165 (6.1)	6.1	1/171 (0.6)	0.6	10.36 (1.34, 80.06)	0.0250	5.52 (-0.25, 11.28)	0.0606	
	Race									0.4545
	White	10/125 (8.0)	7.6	2/137 (1.5)	1.5	5.48 (1.22, 24.53)	0.0261	6.16 (-1.04, 13.36)	0.0938	
	Black or African American	0/ 29 (0.0)	0.0	0/ 23 (0.0)	0.0	NE		0.00 (-13.78, 13.78)	1.0000	
	Asian	1/ 11 (9.1)	9.1	0/ 5 (0.0)	0.0	1.50 (0.07, 31.57)	0.7942	9.09 (-34.34, 52.53)	0.6817	
	American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
	Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-20.43, 20.43)	1.0000	
	Ethnicity									0.8097
	Hispanic/Latino	1/ 32 (3.1)	3.1	0/ 35 (0.0)	0.0	3.27 (0.14, 77.57)	0.4629	3.13 (-8.92, 15.17)	0.6111	
	Non-hispanic/Latino	10/148 (6.8)	7.0	2/149 (1.3)	1.3	5.03 (1.12, 22.58)	0.0348	5.78 (-0.81, 12.36)	0.0854	
	Geographic region									0.6362
	EU	3/ 64 (4.7)	4.7	0/ 76 (0.0)	0.0	8.29 (0.44, 157.60)	0.1592	4.69 (-2.61, 11.98)	0.2079	
	non-EU	8/116 (6.9)	7.1	2/108 (1.9)	1.9	3.72 (0.81, 17.15)	0.0915	5.21 (-3.00, 13.43)	0.2135	
	Onset of disease									0.7616
	Paediatric	1/ 12 (8.3)	8.3	0/ 12 (0.0)	0.0	3.00 (0.13, 67.06)	0.4883	8.33 (-20.61, 37.28)	0.5726	
	Adult	10/168 (6.0)	5.8	2/172 (1.2)	1.2	5.12 (1.14, 23.02)	0.0332	4.65 (-1.05, 10.36)	0.1101	
	ADA result									NE
	Negative	11/162 (6.8)	6.9	2/169 (1.2)	1.1	5.74 (1.29, 25.49)	0.0217	5.73 (-0.26, 11.72)	0.0608	
	Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE		0.00 (-20.88, 20.88)	1.0000	
	BMI (kg/m2)									0.9147
	< 30	4/108 (3.7)	3.8	1/127 (0.8)	0.9	4.70 (0.53, 41.45)	0.1632	2.94 (-3.28, 9.16)	0.3547	
	>= 30	7/ 72 (9.7)	10.2	1/ 57 (1.8)	1.9	5.54 (0.70, 43.75)	0.1043	8.29 (-3.15, 19.74)	0.1556	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations	SLEDAI-2K score									0.3088
	< 10 points	41/ 55 (74.5)	74.8	34/ 54 (63.0)	62.8	1.18 (0.92, 1.53)	0.1966	11.95 (-5.52, 29.42)	0.1799	
	>= 10 points	94/125 (75.2)	75.3	70/130 (53.8)	53.9	1.40 (1.16, 1.69)	0.0005	21.39 (9.92, 32.85)	0.0003	
	OCS dose									0.8211
	<10 mg/day	60/ 77 (77.9)	78.0	49/ 82 (59.8)	59.8	1.30 (1.05, 1.61)	0.0149	18.20 (4.00, 32.40)	0.0120	
	>=10 mg/day	75/103 (72.8)	72.8	55/102 (53.9)	54.0	1.35 (1.09, 1.67)	0.0061	18.79 (5.72, 31.85)	0.0048	
	Result of type I IFN gene signature test									0.7173
	LOW	23/ 32 (71.9)	71.9	19/ 33 (57.6)	57.6	1.25 (0.87, 1.80)	0.2328	14.30 (-8.95, 37.55)	0.2280	
	HIGH	112/148 (75.7)	75.8	85/151 (56.3)	56.3	1.34 (1.14, 1.59)	0.0005	19.52 (8.96, 30.07)	0.0003	
	Age (years)									0.9484
	<= 65	129/173 (74.6)	74.7	102/181 (56.4)	56.3	1.32 (1.13, 1.54)	0.0004	18.40 (8.64, 28.16)	0.0002	
	> 65	6/ 7 (85.7)	85.7	2/ 3 (66.7)	66.7	1.29 (0.55, 3.02)	0.5647	19.05 (-45.95, 84.04)	0.5657	
	Sex									0.2501
	male	13/ 15 (86.7)	86.7	6/ 13 (46.2)	46.2	1.88 (1.01, 3.49)	0.0463	40.51 (6.43, 74.60)	0.0198	
	female	122/165 (73.9)	74.1	98/171 (57.3)	57.4	1.29 (1.10, 1.51)	0.0016	16.71 (6.70, 26.72)	0.0011	
	Race									0.5248
	White	92/125 (73.6)	73.7	75/137 (54.7)	54.8	1.34 (1.12, 1.62)	0.0017	18.90 (7.45, 30.34)	0.0012	
	Black or African American	21/ 29 (72.4)	72.4	15/ 23 (65.2)	65.2	1.11 (0.76, 1.61)	0.5829	7.20 (-18.67, 33.07)	0.5856	
	Asian	9/ 11 (81.8)	81.8	4/ 5 (80.0)	80.0	1.02 (0.61, 1.72)	0.9324	1.82 (-47.07, 50.71)	0.9419	
	American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
	Other	13/ 15 (86.7)	86.7	10/ 18 (55.6)	55.6	1.56 (0.99, 2.47)	0.0573	31.11 (0.21, 62.01)	0.0485	
	Ethnicity									0.4319
	Hispanic/Latino	25/ 32 (78.1)	78.1	23/ 35 (65.7)	65.7	1.19 (0.88, 1.61)	0.2607	12.41 (-9.44, 34.27)	0.2657	
	Non-hispanic/Latino	110/148 (74.3)	74.1	81/149 (54.4)	54.1	1.37 (1.15, 1.63)	0.0005	20.01 (9.24, 30.78)	0.0003	
	Geographic region									0.0155
	EU	47/ 64 (73.4)	73.4	32/ 76 (42.1)	42.1	1.74 (1.29, 2.36)	0.0003	31.33 (15.70, 46.96)	<.0001	
	non-EU	88/116 (75.9)	76.0	72/108 (66.7)	67.1	1.14 (0.96, 1.35)	0.1324	8.93 (-3.14, 20.99)	0.1469	
	Onset of disease									0.1401
	Paediatric	12/ 12 (100.0)	100.0	6/ 12 (50.0)	50.0	2.00 (1.14, 3.52)	0.0163	50.00 (16.08, 83.92)	0.0039	
	Adult	123/168 (73.2)	73.4	98/172 (57.0)	57.3	1.28 (1.10, 1.51)	0.0020	16.12 (6.12, 26.11)	0.0016	
	ADA result									0.7359
	Negative	124/162 (76.5)	76.7	96/169 (56.8)	56.7	1.35 (1.15, 1.58)	0.0002	19.93 (9.89, 29.98)	0.0001	
	Positive (At any time)	11/ 17 (64.7)	64.7	8/ 15 (53.3)	53.3	1.21 (0.67, 2.19)	0.5203	11.37 (-22.85, 45.60)	0.5149	
	BMI (kg/m2)									0.2200
	< 30	79/108 (73.1)	73.3	66/127 (52.0)	52.2	1.41 (1.15, 1.72)	0.0009	21.04 (8.97, 33.12)	0.0006	
	>= 30	56/ 72 (77.8)	77.7	38/ 57 (66.7)	66.3	1.17 (0.94, 1.46)	0.1720	11.41 (-4.63, 27.45)	0.1632	

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Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Nasopharyngitis	SLEDAI-2K score									0.4869
	< 10 points	6/ 55 (10.9)	10.8	5/ 54 (9.3)	9.8	1.18 (0.38, 3.63)	0.7753	1.01 (-13.23, 15.25)	0.8895	
	>= 10 points	30/125 (24.0)	23.9	17/130 (13.1)	13.2	1.84 (1.07, 3.16)	0.0281	10.80 (0.85, 20.74)	0.0334	
	OCS dose									0.4183
	<10 mg/day	11/ 77 (14.3)	14.4	5/ 82 (6.1)	6.1	2.34 (0.85, 6.43)	0.0986	8.28 (-2.94, 19.50)	0.1481	
	>=10 mg/day	25/103 (24.3)	24.5	17/102 (16.7)	16.8	1.46 (0.84, 2.53)	0.1819	7.65 (-3.96, 19.25)	0.1966	
	Result of type I IFN gene signature test									0.7880
	LOW	4/ 32 (12.5)	12.5	2/ 33 (6.1)	6.1	2.06 (0.41, 10.49)	0.3829	6.44 (-10.26, 23.14)	0.4499	
	HIGH	32/148 (21.6)	21.7	20/151 (13.2)	13.5	1.63 (0.98, 2.72)	0.0600	8.21 (-0.89, 17.32)	0.0772	
	Age (years)									0.9459
	<= 65	35/173 (20.2)	20.2	22/181 (12.2)	12.4	1.66 (1.02, 2.72)	0.0419	7.82 (-0.42, 16.06)	0.0627	
	> 65	1/ 7 (14.3)	14.3	0/ 3 (0.0)	0.0	1.50 (0.08, 29.15)	0.7888	14.29 (-46.56, 75.13)	0.6454	
	Sex									0.4605
	male	2/ 15 (13.3)	13.3	2/ 13 (15.4)	15.4	0.87 (0.14, 5.32)	0.8771	-2.05 (-32.99, 28.89)	0.8966	
	female	34/165 (20.6)	20.7	20/171 (11.7)	11.8	1.76 (1.06, 2.93)	0.0293	8.90 (0.45, 17.35)	0.0389	
	Race									0.8669
	White	20/125 (16.0)	16.0	14/137 (10.2)	10.2	1.57 (0.83, 2.96)	0.1687	5.79 (-3.51, 15.09)	0.2224	
	Black or African American	5/ 29 (17.2)	17.2	2/ 23 (8.7)	8.7	1.98 (0.42, 9.30)	0.3855	8.55 (-12.24, 29.33)	0.4204	
	Asian	2/ 11 (18.2)	18.2	1/ 5 (20.0)	20.0	0.91 (0.11, 7.84)	0.9309	-1.82 (-50.71, 47.07)	0.9419	
	American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
	Other	9/ 15 (60.0)	60.0	5/ 18 (27.8)	27.8	2.16 (0.92, 5.06)	0.0764	32.22 (-0.75, 65.20)	0.0555	
	Ethnicity									0.6504
	Hispanic/Latino	11/ 32 (34.4)	34.4	6/ 35 (17.1)	17.1	2.01 (0.84, 4.79)	0.1177	17.23 (-4.12, 38.58)	0.1137	
	Non-hispanic/Latino	25/148 (16.9)	17.2	16/149 (10.7)	10.6	1.57 (0.88, 2.82)	0.1289	6.63 (-2.17, 15.44)	0.1398	
	Geographic region									0.6850
	EU	16/ 64 (25.0)	25.0	10/ 76 (13.2)	13.2	1.90 (0.93, 3.89)	0.0792	11.84 (-1.62, 25.31)	0.0847	
	non-EU	20/116 (17.2)	16.6	12/108 (11.1)	11.6	1.55 (0.80, 3.02)	0.1960	4.93 (-5.26, 15.12)	0.3432	
	Onset of disease									0.7035
	Paediatric	1/ 12 (8.3)	8.3	0/ 12 (0.0)	0.0	3.00 (0.13, 67.06)	0.4883	8.33 (-20.61, 37.28)	0.5726	
	Adult	35/168 (20.8)	21.0	22/172 (12.8)	12.8	1.63 (1.00, 2.66)	0.0506	8.20 (-0.27, 16.67)	0.0578	
	ADA result									0.3527
	Negative	29/162 (17.9)	18.1	20/169 (11.8)	11.9	1.51 (0.89, 2.56)	0.1240	6.19 (-2.18, 14.56)	0.1471	
	Positive (At any time)	7/ 17 (41.2)	41.2	2/ 15 (13.3)	13.3	3.09 (0.75, 12.65)	0.1170	27.84 (-3.45, 59.13)	0.0811	
	BMI (kg/m2)									0.2656
	< 30	24/108 (22.2)	22.4	19/127 (15.0)	15.0	1.49 (0.86, 2.56)	0.1543	7.37 (-3.22, 17.96)	0.1724	
	>= 30	12/ 72 (16.7)	16.0	3/ 57 (5.3)	5.2	3.17 (0.94, 10.69)	0.0633	10.79 (-1.87, 23.46)	0.0949	

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Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

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Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)	SLEDAI-2K score									0.3972
	< 10 points	5/ 55 (9.1)	8.9	0/ 54 (0.0)	0.0	10.80 (0.61, 190.74)	0.1042	8.88 (-3.50, 21.26)	0.1598	
	>= 10 points	5/125 (4.0)	4.0	2/130 (1.5)	1.6	2.60 (0.51, 13.16)	0.2481	2.46 (-3.71, 8.63)	0.4349	
	OCS dose									0.3564
	<10 mg/day	5/ 77 (6.5)	6.5	0/ 82 (0.0)	0.0	11.71 (0.66, 208.21)	0.0939	6.51 (-2.50, 15.52)	0.1566	
	>=10 mg/day	5/103 (4.9)	4.6	2/102 (2.0)	1.9	2.48 (0.49, 12.47)	0.2718	2.70 (-4.63, 10.02)	0.4707	
	Result of type I IFN gene signature test									0.8251
	LOW	1/ 32 (3.1)	3.1	0/ 33 (0.0)	0.0	3.09 (0.13, 73.19)	0.4846	3.13 (-9.17, 15.42)	0.6184	
	HIGH	9/148 (6.1)	6.0	2/151 (1.3)	1.3	4.59 (1.01, 20.89)	0.0487	4.66 (-1.44, 10.76)	0.1342	
	Age (years)									0.5012
	<= 65	9/173 (5.2)	5.1	2/181 (1.1)	1.1	4.71 (1.03, 21.48)	0.0455	3.95 (-1.60, 9.51)	0.1628	
	> 65	1/ 7 (14.3)	14.3	0/ 3 (0.0)	0.0	1.50 (0.08, 29.15)	0.7888	14.29 (-46.56, 75.13)	0.6454	
	Sex									0.7454
	male	1/ 15 (6.7)	6.7	0/ 13 (0.0)	0.0	2.63 (0.12, 59.40)	0.5442	6.67 (-18.77, 32.11)	0.6075	
	female	9/165 (5.5)	5.3	2/171 (1.2)	1.2	4.66 (1.02, 21.26)	0.0467	4.15 (-1.62, 9.92)	0.1590	
	Race									0.4482
	White	7/125 (5.6)	5.8	1/137 (0.7)	0.7	7.67 (0.96, 61.49)	0.0550	5.08 (-1.85, 12.01)	0.1509	
	Black or African American	3/ 29 (10.3)	10.3	1/ 23 (4.3)	4.3	2.38 (0.26, 21.39)	0.4391	6.00 (-12.31, 24.31)	0.5209	
	Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
	American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
	Other	0/ 15 (0.0)	0.0	0/ 18 (0.0)	0.0	NE		0.00 (-20.43, 20.43)	1.0000	
	Ethnicity									NE
	Hispanic/Latino	0/ 32 (0.0)	0.0	0/ 35 (0.0)	0.0	NE		0.00 (-10.79, 10.79)	1.0000	
	Non-hispanic/Latino	10/148 (6.8)	6.5	2/149 (1.3)	1.3	5.03 (1.12, 22.58)	0.0348	5.21 (-1.33, 11.76)	0.1184	
	Geographic region									0.9161
	EU	4/ 64 (6.3)	6.3	1/ 76 (1.3)	1.3	4.75 (0.54, 41.43)	0.1585	4.93 (-3.22, 13.09)	0.2358	
	non-EU	6/116 (5.2)	5.2	1/108 (0.9)	1.0	5.59 (0.68, 45.65)	0.1085	4.20 (-3.74, 12.15)	0.2996	
	Onset of disease									NE
	Paediatric	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
	Adult	10/168 (6.0)	5.9	2/172 (1.2)	1.1	5.12 (1.14, 23.02)	0.0332	4.72 (-1.08, 10.53)	0.1109	
	ADA result									0.7499
	Negative	9/162 (5.6)	5.4	2/169 (1.2)	1.2	4.69 (1.03, 21.40)	0.0457	4.26 (-1.59, 10.11)	0.1536	
	Positive (At any time)	1/ 17 (5.9)	5.9	0/ 15 (0.0)	0.0	2.67 (0.12, 60.93)	0.5390	5.88 (-16.87, 28.64)	0.6124	
	BMI (kg/m2)									0.6026
	< 30	6/108 (5.6)	5.5	1/127 (0.8)	0.8	7.06 (0.86, 57.70)	0.0684	4.72 (-1.97, 11.42)	0.1669	
	>= 30	4/ 72 (5.6)	5.9	1/ 57 (1.8)	1.9	3.17 (0.36, 27.56)	0.2964	4.05 (-6.86, 14.95)	0.4673	

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SOC / PT	Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SOC: Skin and subcutaneous tissue disorders	SLEDAI-2K score									0.9287
	< 10 points	9/ 55 (16.4)	16.9	5/ 54 (9.3)	9.5	1.77 (0.63, 4.93)	0.2770	7.31 (-7.31, 21.93)	0.3272	
	>= 10 points	18/125 (14.4)	14.5	10/130 (7.7)	7.8	1.87 (0.90, 3.90)	0.0936	6.76 (-1.78, 15.31)	0.1208	
	OCS dose									0.0503
	<10 mg/day	15/ 77 (19.5)	19.6	4/ 82 (4.9)	5.0	3.99 (1.39, 11.51)	0.0103	14.57 (3.00, 26.14)	0.0136	
	>=10 mg/day	12/103 (11.7)	11.8	11/102 (10.8)	10.9	1.08 (0.50, 2.34)	0.8443	0.92 (-8.86, 10.69)	0.8542	
	Result of type I IFN gene signature test									0.8466
	LOW	6/ 32 (18.8)	18.8	3/ 33 (9.1)	9.1	2.06 (0.56, 7.55)	0.2743	9.66 (-8.88, 28.19)	0.3071	
	HIGH	21/148 (14.2)	14.4	12/151 (7.9)	8.1	1.79 (0.91, 3.50)	0.0909	6.27 (-1.75, 14.28)	0.1256	
	Age (years)									0.8046
	<= 65	25/173 (14.5)	14.7	15/181 (8.3)	8.5	1.74 (0.95, 3.19)	0.0718	6.17 (-1.32, 13.67)	0.1066	
	> 65	2/ 7 (28.6)	28.6	0/ 3 (0.0)	0.0	2.50 (0.15, 40.67)	0.5196	28.57 (-33.74, 90.89)	0.3688	
	Sex									0.2352
	male	0/ 15 (0.0)	0.0	1/ 13 (7.7)	7.7	0.29 (0.01, 6.60)	0.4388	-7.69 (-33.59, 18.20)	0.5604	
	female	27/165 (16.4)	16.5	14/171 (8.2)	8.3	2.00 (1.09, 3.67)	0.0258	8.24 (0.39, 16.09)	0.0396	
	Race									0.4678
	White	14/125 (11.2)	10.9	12/137 (8.8)	8.5	1.28 (0.62, 2.66)	0.5104	2.39 (-6.19, 10.97)	0.5851	
	Black or African American	6/ 29 (20.7)	20.7	1/ 23 (4.3)	4.3	4.76 (0.62, 36.78)	0.1349	16.34 (-3.86, 36.55)	0.1129	
	Asian	3/ 11 (27.3)	27.3	1/ 5 (20.0)	20.0	1.36 (0.18, 10.09)	0.7613	7.27 (-42.56, 57.11)	0.7748	
	American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
	Other	4/ 15 (26.7)	26.7	1/ 18 (5.6)	5.6	4.80 (0.60, 38.48)	0.1397	21.11 (-7.26, 49.48)	0.1447	
	Ethnicity									0.7257
	Hispanic/Latino	4/ 32 (12.5)	12.5	3/ 35 (8.6)	8.6	1.46 (0.35, 6.02)	0.6020	3.93 (-13.08, 20.94)	0.6508	
	Non-hispanic/Latino	23/148 (15.5)	15.7	12/149 (8.1)	8.3	1.93 (1.00, 3.73)	0.0509	7.40 (-0.99, 15.78)	0.0838	
	Geographic region									0.4396
	EU	7/ 64 (10.9)	10.9	3/ 76 (3.9)	3.9	2.77 (0.75, 10.28)	0.1276	6.99 (-2.94, 16.92)	0.1675	
	non-EU	20/116 (17.2)	17.4	12/108 (11.1)	11.7	1.55 (0.80, 3.02)	0.1960	5.69 (-4.71, 16.08)	0.2838	
	Onset of disease									0.6340
	Paediatric	3/ 12 (25.0)	25.0	1/ 12 (8.3)	8.3	3.00 (0.36, 24.92)	0.3091	16.67 (-17.62, 50.95)	0.3407	
	Adult	24/168 (14.3)	14.3	14/172 (8.1)	8.3	1.76 (0.94, 3.28)	0.0772	6.09 (-1.51, 13.69)	0.1161	
	ADA result									0.7318
	Negative	24/162 (14.8)	14.9	14/169 (8.3)	8.5	1.79 (0.96, 3.33)	0.0674	6.49 (-1.31, 14.28)	0.1028	
	Positive (At any time)	3/ 17 (17.6)	17.6	1/ 15 (6.7)	6.7	2.65 (0.31, 22.82)	0.3758	10.98 (-16.41, 38.37)	0.4321	
	BMI (kg/m2)									0.7159
	< 30	17/108 (15.7)	15.8	10/127 (7.9)	7.9	2.00 (0.96, 4.18)	0.0657	7.96 (-1.24, 17.17)	0.0899	
	>= 30	10/ 72 (13.9)	13.7	5/ 57 (8.8)	8.7	1.58 (0.57, 4.37)	0.3752	4.96 (-8.12, 18.05)	0.4571	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=184) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SOC: Vascular disorders	SLEDAI-2K score									0.3589
	< 10 points	1/ 55 (1.8)	1.7	1/ 54 (1.9)	1.8	0.98 (0.06, 15.30)	0.9896	-0.08 (-11.49, 11.32)	0.9885	
	>= 10 points	3/125 (2.4)	2.4	13/130 (10.0)	10.0	0.24 (0.07, 0.82)	0.0231	-7.65 (-14.93, -0.37)	0.0393	
	OCS dose									0.4470
	<10 mg/day	0/ 77 (0.0)	0.0	4/ 82 (4.9)	4.8	0.12 (0.01, 2.16)	0.1498	-4.79 (-13.45, 3.87)	0.2785	
	>=10 mg/day	4/103 (3.9)	3.8	10/102 (9.8)	9.7	0.40 (0.13, 1.22)	0.1072	-5.86 (-14.48, 2.75)	0.1823	
	Result of type I IFN gene signature test									NE
	LOW	0/ 32 (0.0)	0.0	0/ 33 (0.0)	0.0	NE		0.00 (-11.07, 11.07)	1.0000	
	HIGH	4/148 (2.7)	2.6	14/151 (9.3)	9.2	0.29 (0.10, 0.87)	0.0264	-6.57 (-13.36, 0.23)	0.0582	
	Age (years)									NE
	<= 65	4/173 (2.3)	2.2	14/181 (7.7)	7.7	0.30 (0.10, 0.89)	0.0301	-5.45 (-11.52, 0.61)	0.0780	
	> 65	0/ 7 (0.0)	0.0	0/ 3 (0.0)	0.0	NE		0.00 (-58.56, 58.56)	1.0000	
	Sex									0.1487
	male	1/ 15 (6.7)	6.7	0/ 13 (0.0)	0.0	2.63 (0.12, 59.40)	0.5442	6.67 (-18.77, 32.11)	0.6075	
	female	3/165 (1.8)	1.8	14/171 (8.2)	8.1	0.22 (0.07, 0.76)	0.0164	-6.30 (-12.58, -0.02)	0.0494	
	Race									0.8157
	White	4/125 (3.2)	3.3	10/137 (7.3)	7.4	0.44 (0.14, 1.36)	0.1541	-4.01 (-11.61, 3.58)	0.3006	
	Black or African American	0/ 29 (0.0)	0.0	1/ 23 (4.3)	4.3	0.27 (0.01, 6.26)	0.4116	-4.35 (-19.85, 11.16)	0.5826	
	Asian	0/ 11 (0.0)	0.0	0/ 5 (0.0)	0.0	NE		0.00 (-41.61, 41.61)	1.0000	
	American Indian or Alaska Native	0		0/ 1 (0.0)		NE		NE		
	Other	0/ 15 (0.0)	0.0	3/ 18 (16.7)	16.7	0.17 (0.01, 3.05)	0.2285	-16.67 (-41.49, 8.15)	0.1881	
	Ethnicity									0.4477
	Hispanic/Latino	0/ 32 (0.0)	0.0	4/ 35 (11.4)	11.4	0.12 (0.01, 2.17)	0.1514	-11.43 (-25.78, 2.92)	0.1185	
	Non-hispanic/Latino	4/148 (2.7)	2.7	10/149 (6.7)	6.4	0.40 (0.13, 1.26)	0.1169	-3.66 (-10.44, 3.13)	0.2911	
	Geographic region									0.4014
	EU	3/ 64 (4.7)	4.7	8/ 76 (10.5)	10.5	0.45 (0.12, 1.61)	0.2171	-5.84 (-15.65, 3.97)	0.2432	
	non-EU	1/116 (0.9)	0.8	6/108 (5.6)	5.7	0.16 (0.02, 1.27)	0.0821	-4.85 (-12.83, 3.12)	0.2331	
	Onset of disease									0.9732
	Paediatric	0/ 12 (0.0)	0.0	1/ 12 (8.3)	8.3	0.33 (0.01, 7.45)	0.4883	-8.33 (-37.28, 20.61)	0.5726	
	Adult	4/168 (2.4)	2.4	13/172 (7.6)	7.4	0.32 (0.10, 0.95)	0.0396	-5.05 (-11.27, 1.16)	0.1109	
	ADA result									NE
	Negative	4/162 (2.5)	2.4	14/169 (8.3)	8.1	0.30 (0.10, 0.89)	0.0295	-5.62 (-12.03, 0.80)	0.0861	
	Positive (At any time)	0/ 17 (0.0)	0.0	0/ 15 (0.0)	0.0	NE		0.00 (-20.88, 20.88)	1.0000	
	BMI (kg/m2)									0.2598
	< 30	2/108 (1.9)	1.9	12/127 (9.4)	9.3	0.20 (0.04, 0.86)	0.0303	-7.42 (-14.89, 0.06)	0.0517	
	>= 30	2/ 72 (2.8)	2.8	2/ 57 (3.5)	3.7	0.79 (0.12, 5.45)	0.8124	-0.89 (-11.74, 9.95)	0.8716	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Serious Adverse Events by SOC, PT (incidence in either arm >= 5% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Infections and infestations	Number of subjects with events, n (%)	9 (5.0)	10 (5.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.92 (0.38, 2.21)	
	p-value	0.8521	
	Odds Ratio (95% CI)	0.92 (0.36, 2.31)	
	p-value	0.8521	
	Risk Difference (95% CI)	-0.43 (-5.00, 4.13)	
	p-value	0.8520	
	CMH approach		
	Response rate	4.9	5.4
	Difference in response rates (95% CI)	-0.45 (-6.46, 5.57)	
	p-value	0.8846	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Serious Adverse Events by SOC, PT (incidence in either arm >= 5% or >=10 patients) (on-treatment) - Subgroup analysis
Full analysis set

- NO OBSERVATIONS FOR THIS ANALYSIS -

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Severe (Grade >=3) by SOC, PT (incidence in either arm >= 5% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=184)
SOC: Infections and infestations	Number of subjects with events, n (%)	9 (5.0)	5 (2.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.84 (0.63, 5.38)	
	p-value	0.2657	
	Odds Ratio (95% CI)	1.88 (0.62, 5.74)	
	p-value	0.2646	
	Risk Difference (95% CI)	2.28 (-1.67, 6.24)	
	p-value	0.2582	
	CMH approach		
	Response rate	5.0	2.7
	Difference in response rates (95% CI)	2.24 (-3.43, 7.90)	
	p-value	0.4389	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Severe (Grade >=3) by SOC, PT (incidence in either arm >= 5% or >=10 patients) (on-treatment) - Subgroup analysis
Full analysis set

- NO OBSERVATIONS FOR THIS ANALYSIS -

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Subject disposition and summary of treatment exposure
Full analysis set

		Anifrolumab 300mg (N=180)	Placebo (N=182)
Patients who completed the study		156 (86.7)	136 (74.7)
Patients withdrawn from the study		24 (13.3)	46 (25.3)
WITHDRAWAL BY SUBJECT		11 (6.1)	19 (10.4)
ADVERSE EVENT		3 (1.7)	7 (3.8)
LACK OF EFFICACY		2 (1.1)	8 (4.4)
OTHER		5 (2.8)	4 (2.2)
CONDITION UNDER INVESTIGATION WORSENED		1 (0.6)	4 (2.2)
LOST TO FOLLOW-UP		1 (0.6)	3 (1.6)
DEVELOPMENT OF STUDY-SPECIFIC WITHDRAWAL CRITERIA		1 (0.6)	0
SEVERE NON-COMPLIANCE TO PROTOCOL		0	1 (0.5)
Duration of study (weeks)	n (missing)	180 (0)	182 (0)
	Mean (SD)	51.2 (10.08)	49.5 (11.72)
	Median	52.3	52.3
	Min, Max	2, 68	3, 71
Patients who completed investigational product		153 (85.0)	130 (71.4)
Patients discontinued investigational product		27 (15.0)	52 (28.6)
Withdrawal By Subject		7 (3.9)	16 (8.8)
Adverse Event		5 (2.8)	14 (7.7)
Lack Of Efficacy		2 (1.1)	12 (6.6)
Other		9 (5.0)	2 (1.1)
Condition Under Investigation Worsened		2 (1.1)	4 (2.2)
Lost To Follow-Up		2 (1.1)	3 (1.6)
Severe Non-Compliance To Protocol		0	1 (0.5)
Duration of exposure (weeks)	n (missing)	180 (0)	182 (0)
	Mean (SD)	48.2 (10.98)	44.6 (14.08)
	Median	52.1	52.1
	Min, Max	4, 57	4, 56
Number of Infusions	n (missing)	180 (0)	182 (0)
	Mean (SD)	11.7 (2.73)	10.8 (3.47)
	Median	13.0	13.0
	Min, Max	1, 13	1, 13
Subjects enrolled to the LTE study		133 (73.9)	104 (57.1)

Duration of study defined as time from randomization until end of participation date.
Duration of exposure defined as difference of date of first exposure to treatment and date of last exposure to treatment + 28 days.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Demographic and baseline characteristics
Full analysis set

		Anifrolumab 300mg (N=180)	Placebo (N=182)	Total (N=362)
Age	n (missing)	180 (0)	182 (0)	362 (0)
	Mean (SD)	43.1 (11.95)	41.1 (11.47)	42.1 (11.74)
	Median	44.0	42.0	43.0
	Min, Max	18, 69	19, 66	18, 69
Age subgroups (%)	<= 65	175 (97.2)	181 (99.5)	356 (98.3)
	> 65	5 (2.8)	1 (0.5)	6 (1.7)
Sex (%)	female	168 (93.3)	170 (93.4)	338 (93.4)
	male	12 (6.7)	12 (6.6)	24 (6.6)
Race (%)	American Indian or Alaska Native	4 (2.2)	1 (0.5)	5 (1.4)
	Asian	30 (16.7)	30 (16.5)	60 (16.6)
	Black or African American	17 (9.4)	25 (13.7)	42 (11.6)
	Other	11 (6.1)	11 (6.0)	22 (6.1)
	White	110 (61.1)	107 (58.8)	217 (59.9)
	Missing	8 (4.4)	8 (4.4)	16 (4.4)
Ethnicity (%)	Hispanic/Latino	54 (30.0)	54 (29.7)	108 (29.8)
	Non-hispanic/Latino	118 (65.6)	120 (65.9)	238 (65.7)
	Missing	8 (4.4)	8 (4.4)	16 (4.4)
Geographic region (%)	Asia Pacific	27 (15.0)	26 (14.3)	53 (14.6)
	Europe	51 (28.3)	46 (25.3)	97 (26.8)
	Latin America	35 (19.4)	32 (17.6)	67 (18.5)
	North America	64 (35.6)	68 (37.4)	132 (36.5)
	Rest Of World	3 (1.7)	10 (5.5)	13 (3.6)
Geographic region subgroup (%)	EU	51 (28.3)	46 (25.3)	97 (26.8)
	non-EU	129 (71.7)	136 (74.7)	265 (73.2)
Height (cm)	n (missing)	180 (0)	182 (0)	362 (0)
	Mean (SD)	161.65 (8.917)	162.62 (8.048)	162.14 (8.494)
	Median	161.00	162.60	162.00
	Min, Max	138.0, 198.0	130.0, 188.0	130.0, 198.0
Weight (cm)	n (missing)	180 (0)	182 (0)	362 (0)
	Mean (SD)	71.58 (18.725)	70.95 (17.214)	71.26 (17.959)
	Median	67.85	67.15	67.30
	Min, Max	43.9, 130.8	45.0, 134.5	43.9, 134.5
BMI (kg/m^2)	n (missing)	180 (0)	182 (0)	362 (0)
	Mean (SD)	27.38 (6.832)	26.85 (6.306)	27.11 (6.569)
	Median	25.78	25.42	25.60
	Min, Max	16.7, 49.8	17.5, 51.8	16.7, 51.8
BMI subgroup (%)	<=28 kg/m2	107 (59.4)	114 (62.6)	221 (61.0)
	>28 kg/m2	73 (40.6)	68 (37.4)	141 (39.0)

[a] Asia Pacific: Australia, New Zealand, South Korea, Taiwan. Europe: Germany, Hungary, Italy, Poland, Romania, Ukraine, United Kingdom. Latin America: Argentinia, Brazil, Chile, Colombia, Peru. Rest of World: Israel.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
SLE disease characteristics
Full analysis set

		Anifrolumab 300mg (N=180)	Placebo (N=182)	Total (N=362)
SLEDAI-2K score at screening	n (missing)	180 (0)	182 (0)	362 (0)
	Mean (SD)	11.4 (3.85)	11.4 (3.82)	11.4 (3.83)
	Median	10.0	10.0	10.0
	Min, Max	6, 24	6, 26	6, 26
SLEDAI-2K score at screening, categorisation (%)	< 10 points	54 (30.0)	52 (28.6)	106 (29.3)
	>= 10 points	126 (70.0)	130 (71.4)	256 (70.7)
Clinical SLEDAI-2K score at screening	n (missing)	180 (0)	182 (0)	362 (0)
	Mean (SD)	8.8 (2.93)	8.7 (2.93)	8.8 (2.92)
	Median	8.0	8.0	8.0
	Min, Max	4, 18	4, 18	4, 18
SLEDAI-2K score at baseline	n (missing)	180 (0)	182 (0)	362 (0)
	Mean (SD)	11.4 (3.64)	11.5 (3.88)	11.5 (3.76)
	Median	11.0	10.0	10.0
	Min, Max	6, 25	4, 26	4, 26
SLEDAI-2K score at baseline, categorisation (%)	< 10 points	51 (28.3)	51 (28.0)	102 (28.2)
	>= 10 points	129 (71.7)	131 (72.0)	260 (71.8)
Clinical SLEDAI-2K score at baseline	n (missing)	180 (0)	182 (0)	362 (0)
	Mean (SD)	8.9 (2.94)	8.9 (2.83)	8.9 (2.88)
	Median	8.0	8.0	8.0
	Min, Max	4, 18	4, 18	4, 18
Total Organ Score CNS	n (missing)	180 (0)	182 (0)	362 (0)
	Mean (SD)	0.0 (0.00)	0.0 (0.59)	0.0 (0.42)
	Median	0.0	0.0	0.0
	Min, Max	0, 0	0, 8	0, 8
Total Organ Score CVS and Respiratory	n (missing)	180 (0)	182 (0)	362 (0)
	Mean (SD)	0.2 (0.54)	0.2 (0.61)	0.2 (0.58)
	Median	0.0	0.0	0.0
	Min, Max	0, 2	0, 2	0, 2
Total Organ Score Hematological	n (missing)	180 (0)	182 (0)	362 (0)
	Mean (SD)	0.2 (0.41)	0.1 (0.38)	0.2 (0.40)
	Median	0.0	0.0	0.0
	Min, Max	0, 2	0, 2	0, 2
Total Organ Score Immunology	n (missing)	180 (0)	182 (0)	362 (0)
	Mean (SD)	2.0 (1.55)	1.9 (1.68)	1.9 (1.62)
	Median	2.0	2.0	2.0
	Min, Max	0, 4	0, 4	0, 4
Total Organ Score Mucocutaneous	n (missing)	180 (0)	182 (0)	362 (0)
	Mean (SD)	4.1 (1.60)	3.9 (1.62)	4.0 (1.61)
	Median	4.0	4.0	4.0
	Min, Max	0, 6	0, 6	0, 6
Total Organ Score Musculoskeletal	n (missing)	180 (0)	182 (0)	362 (0)
	Mean (SD)	3.8 (1.10)	3.8 (1.10)	3.8 (1.10)
	Median	4.0	4.0	4.0
	Min, Max	0, 8	0, 8	0, 8
Total Organ Score Renal	n (missing)	180 (0)	182 (0)	362 (0)
	Mean (SD)	0.3 (1.27)	0.5 (1.70)	0.4 (1.51)
	Median	0.0	0.0	0.0
	Min, Max	0, 8	0, 12	0, 12

Baseline is defined as the last measurement prior to randomisation and dose administration on Day 1.
Only subjects with baseline positive anti-dsDNA and abnormal complement level, respectively, are included in the summary statistics for the respective variables.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
SLE disease characteristics
Full analysis set

		Anifrolumab 300mg (N=180)	Placebo (N=182)	Total (N=362)
Total Organ Score Vascular	n (missing)	180 (0)	182 (0)	362 (0)
	Mean (SD)	0.9 (2.58)	1.0 (2.62)	1.0 (2.59)
	Median	0.0	0.0	0.0
	Min, Max	0, 8	0, 8	0, 8
Adjudication Scoring (BILAG) at baseline Overall (%)	At least one A	81 (45.0)	95 (52.2)	176 (48.6)
	No A and <2Bs	8 (4.4)	9 (4.9)	17 (4.7)
	No A and at least 2 Bs	91 (50.6)	78 (42.9)	169 (46.7)
Adjudication Scoring (BILAG) at baseline Constitutional (%)	B	15 (8.3)	6 (3.3)	21 (5.8)
	C, D or E	165 (91.7)	176 (96.7)	341 (94.2)
Adjudication Scoring (BILAG) at baseline Mucocutaneous (%)	A	31 (17.2)	36 (19.8)	67 (18.5)
	B	124 (68.9)	118 (64.8)	242 (66.9)
	C, D or E	25 (13.9)	28 (15.4)	53 (14.6)
Adjudication Scoring (BILAG) at baseline Neuropsychiatric (%)	A	1 (0.6)	0	1 (0.3)
	B	0	2 (1.1)	2 (0.6)
	C, D or E	179 (99.4)	180 (98.9)	359 (99.2)
Adjudication Scoring (BILAG) at baseline Musculoskeletal (%)	A	56 (31.1)	60 (33.0)	116 (32.0)
	B	102 (56.7)	101 (55.5)	203 (56.1)
	C, D or E	22 (12.2)	21 (11.5)	43 (11.9)
Adjudication Scoring (BILAG) at baseline Cardiorespiratory (%)	A	1 (0.6)	1 (0.5)	2 (0.6)
	B	13 (7.2)	17 (9.3)	30 (8.3)
	C, D or E	166 (92.2)	164 (90.1)	330 (91.2)
Adjudication Scoring (BILAG) at baseline Gastrointestinal (%)	A	0	1 (0.5)	1 (0.3)
	B	1 (0.6)	2 (1.1)	3 (0.8)
	C, D or E	179 (99.4)	179 (98.4)	358 (98.9)
Adjudication Scoring (BILAG) at baseline Ophthalmic (%)	B	0	1 (0.5)	1 (0.3)
	C, D or E	180 (100.0)	181 (99.5)	361 (99.7)
Adjudication Scoring (BILAG) at baseline Renal (%)	A	1 (0.6)	4 (2.2)	5 (1.4)
	B	9 (5.0)	13 (7.1)	22 (6.1)
	C, D or E	170 (94.4)	165 (90.7)	335 (92.5)
Adjudication Scoring (BILAG) at baseline Haematological (%)	B	1 (0.6)	0	1 (0.3)
	C, D or E	179 (99.4)	182 (100.0)	361 (99.7)
BILAG-2004 global score at baseline	n (missing)	180 (0)	182 (0)	362 (0)
	Mean (SD)	18.6 (4.72)	19.0 (5.00)	18.8 (4.86)
	Median	17.0	18.0	17.0
	Min, Max	3, 33	9, 33	3, 33
Physician Global Assessment (PGA) score at baseline	n (missing)	180 (0)	182 (0)	362 (0)
	Mean (SD)	1.7 (0.41)	1.8 (0.40)	1.7 (0.41)
	Median	1.6	1.7	1.7
	Min, Max	1, 3	1, 3	1, 3
CLASI activity score at baseline	n (missing)	180 (0)	182 (0)	362 (0)
	Mean (SD)	8.3 (7.94)	7.6 (7.75)	7.9 (7.84)
	Median	6.0	5.5	6.0
	Min, Max	0, 51	0, 52	0, 52
CLASI activity score at baseline, categorisation 1 (%)	0	6 (3.3)	12 (6.6)	18 (5.0)
	> 0	174 (96.7)	170 (93.4)	344 (95.0)

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Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
SLE disease characteristics
Full analysis set

		Anifrolumab 300mg (N=180)	Placebo (N=182)	Total (N=362)
CLASI activity score at baseline, categorisation 2 (%)	<10	131 (72.8)	142 (78.0)	273 (75.4)
	>=10	49 (27.2)	40 (22.0)	89 (24.6)
CLASI damage score at baseline	n (missing)	180 (0)	182 (0)	362 (0)
	Mean (SD)	2.3 (5.34)	2.0 (4.63)	2.1 (4.99)
	Median	0.0	0.0	0.0
	Min, Max	0, 29	0, 33	0, 33
CLASI damage score at baseline, categorisation 1 (%)	0	123 (68.3)	119 (65.4)	242 (66.9)
	> 0	57 (31.7)	63 (34.6)	120 (33.1)
CLASI damage score at baseline, categorisation 2 (%)	<10	164 (91.1)	174 (95.6)	338 (93.4)
	>=10	16 (8.9)	8 (4.4)	24 (6.6)
Tender Joint Count at Baseline	n (missing)	180 (0)	182 (0)	362 (0)
	Mean (SD)	9.0 (7.07)	11.0 (7.89)	10.0 (7.55)
	Median	7.0	10.0	8.0
	Min, Max	0, 28	0, 28	0, 28
Tender Joint Count at Baseline, categorisation (%)	0	12 (6.7)	10 (5.5)	22 (6.1)
	> 0	168 (93.3)	172 (94.5)	340 (93.9)
Swollen Joint Count at Baseline	n (missing)	180 (0)	182 (0)	362 (0)
	Mean (SD)	6.2 (5.65)	7.4 (6.55)	6.8 (6.15)
	Median	5.0	6.0	5.0
	Min, Max	0, 28	0, 28	0, 28
Swollen Joint Count at Baseline, categorisation (%)	0	20 (11.1)	18 (9.9)	38 (10.5)
	> 0	160 (88.9)	164 (90.1)	324 (89.5)
Active Joint Count at Baseline	n (missing)	180 (0)	182 (0)	362 (0)
	Mean (SD)	5.7 (5.58)	7.1 (6.49)	6.4 (6.08)
	Median	4.0	5.0	4.0
	Min, Max	0, 28	0, 28	0, 28
Active Joint Count at Baseline, categorisation (%)	0	22 (12.2)	19 (10.4)	41 (11.3)
	> 0	158 (87.8)	163 (89.6)	321 (88.7)
SDI global score at baseline	n (missing)	180 (0)	182 (0)	362 (0)
	Mean (SD)	0.5 (0.91)	0.5 (0.79)	0.5 (0.85)
	Median	0.0	0.0	0.0
	Min, Max	0, 5	0, 3	0, 5
SDI global score at baseline, categorisation (%)	0 (no damage)	126 (70.0)	122 (67.0)	248 (68.5)
	>=1 (damage)	54 (30.0)	60 (33.0)	114 (31.5)
Time from initial SLE diagnosis to randomisation (months)	n (missing)	180 (0)	182 (0)	362 (0)
	Mean (SD)	130.2 (109.28)	107.7 (99.16)	118.9 (104.78)
	Median	94.5	78.0	85.0
	Min, Max	6, 555	6, 494	6, 555
Cushingoid features (%)	Any Cushingoid Feature	40 (22.2)	53 (29.1)	93 (25.7)
	Moon Face	25 (13.9)	32 (17.6)	57 (15.7)
	Buffalo Hump	13 (7.2)	10 (5.5)	23 (6.4)
	Purple or Violaceous Striae	10 (5.6)	15 (8.2)	25 (6.9)
	Central Obesity	22 (12.2)	21 (11.5)	43 (11.9)
	Hirsutisim	10 (5.6)	4 (2.2)	14 (3.9)
	Acne	11 (6.1)	7 (3.8)	18 (5.0)
	Easy Bruising	15 (8.3)	17 (9.3)	32 (8.8)
	Fragile Skin	10 (5.6)	19 (10.4)	29 (8.0)

Baseline is defined as the last measurement prior to randomisation and dose administration on Day 1.
Only subjects with baseline positive anti-dsDNA and abnormal complement level, respectively, are included in the summary statistics for the respective variables.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
SLE disease characteristics
Full analysis set

		Anifrolumab 300mg (N=180)	Placebo (N=182)	Total (N=362)
Results of 4-gene Type 1 Interferon (IFN) test (%)	High	150 (83.3)	151 (83.0)	301 (83.1)
	Low	30 (16.7)	31 (17.0)	61 (16.9)
Anti-dsDNA levels at baseline	n (missing)	86 (0)	73 (0)	159 (0)
	Mean (SD)	111.6 (243.74)	232.3 (592.09)	167.0 (442.00)
	Median	44.5	53.7	45.5
	Min, Max	15, 1897	15, 3790	15, 3790
Anti-dsDNA levels at baseline, categorisation (%)	Negative	94 (52.2)	109 (59.9)	203 (56.1)
	Positive	86 (47.8)	73 (40.1)	159 (43.9)
ANA (%)	Abnormal (titre >= 1:80)	160 (88.9)	165 (90.7)	325 (89.8)
	Normal (titre < 1:80)	12 (6.7)	12 (6.6)	24 (6.6)
	Missing	8 (4.4)	5 (2.7)	13 (3.6)
Complement C3 level at baseline	n (missing)	72 (0)	72 (0)	144 (0)
	Mean (SD)	0.70 (0.143)	0.69 (0.146)	0.69 (0.144)
	Median	0.72	0.70	0.71
	Min, Max	0.3, 0.9	0.4, 0.9	0.3, 0.9
Complement C3 level at baseline, categorisation (%)	Abnormal	72 (40.0)	72 (39.6)	144 (39.8)
	Normal	108 (60.0)	110 (60.4)	218 (60.2)
Complement C4 level at baseline	n (missing)	49 (0)	46 (0)	95 (0)
	Mean (SD)	0.07 (0.015)	0.07 (0.016)	0.07 (0.015)
	Median	0.07	0.07	0.07
	Min, Max	0.1, 0.1	0.1, 0.1	0.1, 0.1
Complement C4 level at baseline, categorisation (%)	Abnormal	49 (27.2)	46 (25.3)	95 (26.2)
	Normal	131 (72.8)	136 (74.7)	267 (73.8)
Complement CH50 level at baseline	n (missing)	15 (0)	16 (0)	31 (0)
	Mean (SD)	54.53 (27.126)	48.44 (30.529)	51.39 (28.618)
	Median	55.00	53.50	55.00
	Min, Max	8.0, 90.0	5.0, 85.0	5.0, 90.0
Complement CH50 level at baseline, categorisation (%)	Abnormal	15 (8.3)	16 (8.8)	31 (8.6)
	Normal	165 (91.7)	166 (91.2)	331 (91.4)

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Only subjects with baseline positive anti-dsDNA and abnormal complement level, respectively, are included in the summary statistics for the respective variables.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Observation times for Efficacy endpoints
Full analysis set

		Anifrolumab 300mg (N=180)	Placebo (N=182)
SRI4: Observation time (weeks)	n (missing)	180 (0)	182 (0)
	Mean (SD)	49.4 (9.25)	47.2 (11.47)
	Median	52.1	52.1
	Min, Max	2, 54	0, 54
CLASI activity score: Observation time (weeks)	n (missing)	180 (0)	182 (0)
	Mean (SD)	49.4 (9.26)	47.2 (11.47)
	Median	52.1	52.1
	Min, Max	2, 54	0, 54
CLASI damage score: Observation time (weeks)	n (missing)	180 (0)	182 (0)
	Mean (SD)	49.4 (9.26)	47.2 (11.47)
	Median	52.1	52.1
	Min, Max	2, 54	0, 54
BICLA: Observation time (weeks)	n (missing)	180 (0)	182 (0)
	Mean (SD)	49.4 (9.25)	47.2 (11.45)
	Median	52.1	52.1
	Min, Max	2, 54	0, 54
SLEDAI-2K Total Score: Observation time (weeks)	n (missing)	180 (0)	182 (0)
	Mean (SD)	49.1 (9.34)	46.7 (11.89)
	Median	52.1	52.1
	Min, Max	2, 54	0, 54
PGA: Observation time (weeks)	n (missing)	180 (0)	182 (0)
	Mean (SD)	49.4 (9.26)	47.2 (11.45)
	Median	52.1	52.1
	Min, Max	2, 54	0, 54
BILAG Global Score: Observation time (weeks)	n (missing)	180 (0)	182 (0)
	Mean (SD)	49.4 (9.26)	47.2 (11.46)
	Median	52.1	52.1
	Min, Max	2, 54	0, 54
Tender Joint Count: Observation time (weeks)	n (missing)	180 (0)	182 (0)
	Mean (SD)	49.4 (9.26)	47.2 (11.47)
	Median	52.1	52.1
	Min, Max	2, 54	0, 54
Swollen Joint Count: Observation time (weeks)	n (missing)	180 (0)	182 (0)
	Mean (SD)	49.4 (9.26)	47.2 (11.47)
	Median	52.1	52.1
	Min, Max	2, 54	0, 54
FACIT-F Total Score: Observation time (weeks)	n (missing)	180 (0)	182 (0)
	Mean (SD)	49.2 (9.23)	46.5 (12.25)
	Median	52.1	52.1
	Min, Max	2, 54	0, 54
SF-36 v2.0 Acute - Mental Component Score: Observation time (weeks)	n (missing)	180 (0)	182 (0)
	Mean (SD)	48.7 (10.91)	45.6 (13.70)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
SF-36 v2.0 Acute - Physical Component Score: Observation time (weeks)	n (missing)	180 (0)	182 (0)
	Mean (SD)	48.7 (10.91)	45.6 (13.70)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
EQ-5D VAS Score: Observation time (weeks)	n (missing)	180 (0)	182 (0)

Observation duration defined as time from randomization until last non-missing assessment after randomization. Subjects without assessment are censored at day 1.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Observation times for Efficacy endpoints
Full analysis set

		Anifrolumab 300mg (N=180)	Placebo (N=182)
EQ-5D VAS Score: Observation time (weeks)	Mean (SD)	47.3 (11.78)	43.8 (14.85)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
SDI Global Score: Observation time (weeks)	n (missing)	180 (0)	182 (0)
	Mean (SD)	46.4 (14.76)	42.6 (17.86)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
PtGA: Observation time (weeks)	n (missing)	180 (0)	182 (0)
	Mean (SD)	48.9 (10.16)	45.7 (13.08)
	Median	52.1	52.1
	Min, Max	2, 54	0, 54

Observation duration defined as time from randomization until last non-missing assessment after randomization. Subjects without assessment are censored at day 1.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 4	Number of subjects with events, n (%)	17 (9.4)	13 (7.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.37 (0.68, 2.77)	
	p-value	0.3770	
	Odds Ratio (95% CI)	1.42 (0.66, 3.08)	
	p-value	0.3714	
	Risk Difference (95% CI)	2.55 (-3.02, 8.13)	
	p-value	0.3694	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.32 (0.66, 2.64)	
	p-value	0.4290	
	Odds Ratio (95% CI)	1.36 (0.64, 2.88)	
	p-value	0.4285	
	Risk Difference (95% CI)	2.30 (-3.38, 7.98)	
	p-value	0.4270	
	CMH approach		
	Response rate	9.4	6.9
	Difference in response rates (95% CI)	2.51 (-4.23, 9.26)	
	p-value	0.4648	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 8	Number of subjects with events, n (%)	57 (31.7)	43 (23.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.36 (0.97, 1.89)	
	p-value	0.0723	
	Odds Ratio (95% CI)	1.55 (0.96, 2.49)	
	p-value	0.0700	
	Risk Difference (95% CI)	8.37 (-0.63, 17.37)	
	p-value	0.0682	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.34 (0.96, 1.88)	
	p-value	0.0895	
	Odds Ratio (95% CI)	1.50 (0.94, 2.38)	
	p-value	0.0880	
	Risk Difference (95% CI)	8.04 (-1.14, 17.22)	
	p-value	0.0860	
	CMH approach		
	Response rate	31.8	23.4
	Difference in response rates (95% CI)	8.40 (-0.84, 17.64)	
	p-value	0.0748	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 12	Number of subjects with events, n (%)	87 (48.3)	60 (33.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.48 (1.15, 1.92)	
	p-value	0.0028	
	Odds Ratio (95% CI)	1.94 (1.26, 2.98)	
	p-value	0.0024	
	Risk Difference (95% CI)	15.73 (5.77, 25.70)	
	p-value	0.0020	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.47 (1.13, 1.89)	
	p-value	0.0034	
	Odds Ratio (95% CI)	1.90 (1.24, 2.91)	
	p-value	0.0031	
	Risk Difference (95% CI)	15.37 (5.37, 25.36)	
	p-value	0.0026	
	CMH approach		
	Response rate	48.6	32.8
	Difference in response rates (95% CI)	15.74 (5.86, 25.62)	
	p-value	0.0018	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 16	Number of subjects with events, n (%)	92 (51.1)	70 (38.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.33 (1.06, 1.68)	
	p-value	0.0147	
	Odds Ratio (95% CI)	1.70 (1.11, 2.60)	
	p-value	0.0139	
	Risk Difference (95% CI)	12.81 (2.73, 22.89)	
	p-value	0.0128	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.33 (1.05, 1.68)	
	p-value	0.0167	
	Odds Ratio (95% CI)	1.67 (1.10, 2.54)	
	p-value	0.0158	
	Risk Difference (95% CI)	12.65 (2.49, 22.81)	
	p-value	0.0147	
	CMH approach		
	Response rate	51.4	38.4
	Difference in response rates (95% CI)	13.03 (2.99, 23.07)	
	p-value	0.0110	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 20	Number of subjects with events, n (%)	99 (55.0)	79 (43.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.28 (1.03, 1.58)	
	p-value	0.0255	
	Odds Ratio (95% CI)	1.61 (1.06, 2.45)	
	p-value	0.0244	
	Risk Difference (95% CI)	11.88 (1.65, 22.11)	
	p-value	0.0229	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.27 (1.02, 1.57)	
	p-value	0.0287	
	Odds Ratio (95% CI)	1.59 (1.05, 2.41)	
	p-value	0.0277	
	Risk Difference (95% CI)	11.59 (1.36, 21.82)	
	p-value	0.0264	
	CMH approach		
	Response rate	55.2	43.3
	Difference in response rates (95% CI)	11.90 (1.73, 22.06)	
	p-value	0.0218	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 24	Number of subjects with events, n (%)	105 (58.3)	78 (42.9)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.37 (1.11, 1.69)	
	p-value	0.0032	
	Odds Ratio (95% CI)	1.89 (1.25, 2.88)	
	p-value	0.0028	
	Risk Difference (95% CI)	15.78 (5.61, 25.94)	
	p-value	0.0024	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.36 (1.11, 1.68)	
	p-value	0.0037	
	Odds Ratio (95% CI)	1.87 (1.23, 2.83)	
	p-value	0.0034	
	Risk Difference (95% CI)	15.48 (5.30, 25.65)	
	p-value	0.0029	
	CMH approach		
	Response rate	58.5	42.7
	Difference in response rates (95% CI)	15.84 (5.81, 25.87)	
	p-value	0.0020	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 28	Number of subjects with events, n (%)	104 (57.8)	81 (44.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.31 (1.06, 1.60)	
	p-value	0.0110	
	Odds Ratio (95% CI)	1.73 (1.14, 2.62)	
	p-value	0.0102	
	Risk Difference (95% CI)	13.55 (3.35, 23.76)	
	p-value	0.0092	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.30 (1.06, 1.59)	
	p-value	0.0125	
	Odds Ratio (95% CI)	1.71 (1.13, 2.59)	
	p-value	0.0118	
	Risk Difference (95% CI)	13.27 (3.06, 23.48)	
	p-value	0.0108	
	CMH approach		
	Response rate	57.9	44.3
	Difference in response rates (95% CI)	13.58 (3.42, 23.74)	
	p-value	0.0088	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 32	Number of subjects with events, n (%)	107 (59.4)	80 (44.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.36 (1.11, 1.67)	
	p-value	0.0031	
	Odds Ratio (95% CI)	1.90 (1.25, 2.89)	
	p-value	0.0027	
	Risk Difference (95% CI)	15.82 (5.67, 25.96)	
	p-value	0.0023	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.35 (1.10, 1.66)	
	p-value	0.0037	
	Odds Ratio (95% CI)	1.87 (1.23, 2.84)	
	p-value	0.0033	
	Risk Difference (95% CI)	15.49 (5.32, 25.66)	
	p-value	0.0028	
	CMH approach		
	Response rate	59.6	43.7
	Difference in response rates (95% CI)	15.84 (5.70, 25.98)	
	p-value	0.0022	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 36	Number of subjects with events, n (%)	103 (57.2)	80 (44.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.31 (1.06, 1.61)	
	p-value	0.0108	
	Odds Ratio (95% CI)	1.73 (1.14, 2.63)	
	p-value	0.0102	
	Risk Difference (95% CI)	13.55 (3.35, 23.74)	
	p-value	0.0092	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.30 (1.06, 1.60)	
	p-value	0.0125	
	Odds Ratio (95% CI)	1.71 (1.13, 2.58)	
	p-value	0.0118	
	Risk Difference (95% CI)	13.27 (3.06, 23.48)	
	p-value	0.0109	
	CMH approach		
	Response rate	57.3	43.8
	Difference in response rates (95% CI)	13.53 (3.34, 23.72)	
	p-value	0.0093	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 40	Number of subjects with events, n (%)	104 (57.8)	72 (39.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.46 (1.17, 1.82)	
	p-value	0.0008	
	Odds Ratio (95% CI)	2.09 (1.37, 3.18)	
	p-value	0.0006	
	Risk Difference (95% CI)	18.06 (7.94, 28.17)	
	p-value	0.0005	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.46 (1.17, 1.82)	
	p-value	0.0007	
	Odds Ratio (95% CI)	2.09 (1.37, 3.18)	
	p-value	0.0006	
	Risk Difference (95% CI)	18.22 (8.09, 28.34)	
	p-value	0.0004	
	CMH approach		
	Response rate	57.6	39.4
	Difference in response rates (95% CI)	18.17 (8.07, 28.27)	
	p-value	0.0004	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 44	Number of subjects with events, n (%)	104 (57.8)	72 (39.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.47 (1.18, 1.84)	
	p-value	0.0006	
	Odds Ratio (95% CI)	2.14 (1.40, 3.26)	
	p-value	0.0004	
	Risk Difference (95% CI)	18.55 (8.47, 28.63)	
	p-value	0.0003	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.46 (1.17, 1.82)	
	p-value	0.0007	
	Odds Ratio (95% CI)	2.09 (1.37, 3.18)	
	p-value	0.0006	
	Risk Difference (95% CI)	18.22 (8.09, 28.34)	
	p-value	0.0004	
	CMH approach		
	Response rate	57.6	39.3
	Difference in response rates (95% CI)	18.28 (8.20, 28.37)	
	p-value	0.0004	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 48	Number of subjects with events, n (%)	100 (55.6)	78 (42.9)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.31 (1.06, 1.62)	
	p-value	0.0127	
	Odds Ratio (95% CI)	1.72 (1.13, 2.62)	
	p-value	0.0119	
	Risk Difference (95% CI)	13.16 (3.04, 23.28)	
	p-value	0.0108	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.30 (1.05, 1.60)	
	p-value	0.0168	
	Odds Ratio (95% CI)	1.67 (1.10, 2.53)	
	p-value	0.0160	
	Risk Difference (95% CI)	12.70 (2.48, 22.92)	
	p-value	0.0149	
	CMH approach		
	Response rate	55.6	42.7
	Difference in response rates (95% CI)	12.90 (2.70, 23.09)	
	p-value	0.0131	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 52	Number of subjects with events, n (%)	100 (55.6)	68 (37.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.49 (1.18, 1.87)	
	p-value	0.0006	
	Odds Ratio (95% CI)	2.11 (1.38, 3.22)	
	p-value	0.0005	
	Risk Difference (95% CI)	18.27 (8.17, 28.36)	
	p-value	0.0004	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.49 (1.18, 1.87)	
	p-value	0.0007	
	Odds Ratio (95% CI)	2.10 (1.38, 3.19)	
	p-value	0.0006	
	Risk Difference (95% CI)	18.19 (8.09, 28.30)	
	p-value	0.0004	
	CMH approach		
	Response rate	55.5	37.3
	Difference in response rates (95% CI)	18.21 (8.10, 28.32)	
	p-value	0.0004	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8222
< 10 points	26/ 54 (48.1)	48.1	16/ 52 (30.8)	30.7	1.56 (0.96, 2.56)	0.0749	17.36 (-1.09, 35.81)	0.0651	
>= 10 points	74/126 (58.7)	58.6	52/130 (40.0)	40.0	1.47 (1.14, 1.90)	0.0033	18.60 (6.53, 30.67)	0.0025	
OCS dose at baseline									0.7738
<10 mg/day	50/ 93 (53.8)	53.8	37/ 99 (37.4)	37.3	1.44 (1.05, 1.98)	0.0246	16.47 (2.56, 30.38)	0.0203	
>=10 mg/day	50/ 87 (57.5)	57.5	31/ 83 (37.3)	37.3	1.54 (1.10, 2.14)	0.0110	20.12 (5.39, 34.86)	0.0074	
Result of type I IFN gene signature test									0.3871
LOW	15/ 30 (50.0)	50.0	13/ 31 (41.9)	41.9	1.19 (0.69, 2.06)	0.5288	8.06 (-16.91, 33.04)	0.5268	
HIGH	85/150 (56.7)	56.6	55/151 (36.4)	36.3	1.56 (1.21, 2.00)	0.0006	20.27 (9.21, 31.32)	0.0003	
Age (years)									0.7198
<= 65	97/175 (55.4)	55.3	68/181 (37.6)	37.4	1.48 (1.17, 1.86)	0.0009	17.88 (7.69, 28.08)	0.0006	
> 65	3/ 5 (60.0)	60.0	0/ 1 (0.0)	0.0	2.33 (0.19, 28.25)	0.5055	60.00 (-45.43, 165.43)	0.2647	
Sex									0.0496
male	8/ 12 (66.7)	66.7	9/ 12 (75.0)	75.0	0.89 (0.53, 1.49)	0.6549	-8.33 (-46.25, 29.59)	0.6667	
female	92/168 (54.8)	54.6	59/170 (34.7)	34.6	1.58 (1.23, 2.02)	0.0003	19.99 (9.60, 30.38)	0.0002	
Race									0.0785
White	59/110 (53.6)	54.2	45/107 (42.1)	41.7	1.28 (0.96, 1.69)	0.0912	12.52 (-0.67, 25.70)	0.0628	
Black or African American	9/ 17 (52.9)	52.9	7/ 25 (28.0)	28.0	1.89 (0.87, 4.09)	0.1058	24.94 (-4.93, 54.82)	0.1018	
Asian	19/ 30 (63.3)	63.3	9/ 30 (30.0)	30.0	2.11 (1.15, 3.89)	0.0165	33.33 (9.20, 57.47)	0.0068	
American Indian or Alaska Native	3/ 4 (75.0)	75.0	1/ 1 (100.0)	100.0	0.75 (0.43, 1.32)	0.3190	-25.00 (-132.10, 82.10)	0.6473	
Other	6/ 11 (54.5)	54.5	2/ 11 (18.2)	18.2	3.00 (0.77, 11.74)	0.1146	36.36 (-3.03, 75.76)	0.0704	
Ethnicity									0.2735
Hispanic/Latino	32/ 54 (59.3)	58.9	25/ 54 (46.3)	46.6	1.28 (0.89, 1.84)	0.1820	12.30 (-6.42, 31.03)	0.1978	
Non-hispanic/Latino	64/118 (54.2)	54.3	39/120 (32.5)	32.3	1.67 (1.23, 2.27)	0.0011	21.99 (9.67, 34.31)	0.0005	
Geographic region									0.3621
EU	31/ 51 (60.8)	60.8	22/ 46 (47.8)	47.8	1.27 (0.87, 1.85)	0.2087	12.96 (-6.77, 32.69)	0.1980	
non-EU	69/129 (53.5)	53.5	46/136 (33.8)	33.6	1.58 (1.19, 2.10)	0.0016	19.90 (8.14, 31.66)	0.0009	
Onset of disease									0.7653
Paediatric	6/ 14 (42.9)	42.9	4/ 12 (33.3)	33.3	1.29 (0.47, 3.51)	0.6234	9.52 (-28.26, 47.31)	0.6213	
Adult	94/166 (56.6)	56.6	64/170 (37.6)	37.6	1.50 (1.19, 1.90)	0.0007	18.98 (8.52, 29.45)	0.0004	
ADA result									0.3270
Negative	96/172 (55.8)	55.7	64/162 (39.5)	39.5	1.41 (1.12, 1.78)	0.0036	16.11 (5.55, 26.67)	0.0028	
Positive (At any time)	4/ 8 (50.0)	50.0	4/ 20 (20.0)	20.0	2.50 (0.82, 7.64)	0.1080	30.00 (-9.50, 69.50)	0.1366	
BMI (kg/m2) at enrolment									0.4231
< 30	73/125 (58.4)	58.4	55/134 (41.0)	41.4	1.42 (1.11, 1.83)	0.0059	16.98 (5.05, 28.91)	0.0053	
>= 30	27/ 55 (49.1)	49.1	13/ 48 (27.1)	27.4	1.81 (1.06, 3.10)	0.0298	21.65 (2.89, 40.40)	0.0237	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.6150
All negative/normal	28/ 58 (48.3)	48.6	29/ 81 (35.8)	35.2	1.35 (0.91, 2.00)	0.1380	13.39 (-3.21, 29.99)	0.1139	
At least one positive/abnormal	72/122 (59.0)	59.2	39/101 (38.6)	38.7	1.53 (1.15, 2.04)	0.0038	20.51 (7.57, 33.44)	0.0019	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
SRI (4) - individual components at week 52 (Full analysis set)
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
>=4 point reduction in SLEDAI-2k [a]	101 (56.1)	71 (39.0)
No discontinuation of IP	153 (85.0)	130 (71.4)
No use of medication beyond protocol allowed threshold	144 (80.0)	123 (67.6)
No worsening of BILAG [a]	125 (69.4)	94 (51.6)
No worsening of PGA [a]	122 (67.8)	95 (52.2)

[a] Subjects who discontinued IP or used medications beyond protocol allowed threshold are considered non-responders and not included in this category.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate at week 52 sensitivity analysis, multiple imputation
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 52	Number of subjects with events, n (%)	100 (55.6)	68 (37.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.50 (1.19, 1.89)	
	p-value	0.0006	
	Odds Ratio (95% CI)	2.14 (1.40, 3.28)	
	p-value	0.0005	
	Risk Difference (95% CI)	18.59 (8.41, 28.78)	
	p-value	0.0003	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.50 (1.19, 1.89)	
	p-value	0.0006	
	Odds Ratio (95% CI)	2.12 (1.39, 3.24)	
	p-value	0.0005	
	Risk Difference (95% CI)	18.49 (8.30, 28.68)	
	p-value	0.0004	

For each outcome and visit, 100 imputations were generated by randomised treatment group. Each imputed dataset was analysed separately, and the single estimates are combined using PROC MIANALYZE. The estimated number of responders and non-responders are rounded to an integer. Therefore, there might be slight mismatches between number of subjects and corresponding percentage.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
SRI (8) response rate at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=166)	Placebo (N=167)
Week 52	Number of subjects with events, n (%)	50 (30.1)	33 (19.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.54 (1.05, 2.26)	
	p-value	0.0281	
	Odds Ratio (95% CI)	1.78 (1.07, 2.95)	
	p-value	0.0265	
	Risk Difference (95% CI)	10.56 (1.35, 19.77)	
	p-value	0.0246	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.52 (1.04, 2.24)	
	p-value	0.0312	
	Odds Ratio (95% CI)	1.75 (1.06, 2.90)	
	p-value	0.0298	
	Risk Difference (95% CI)	10.36 (1.13, 19.59)	
	p-value	0.0278	
	CMH approach		
	Response rate	30.2	19.6
	Difference in response rates (95% CI)	10.66 (1.17, 20.16)	
	p-value	0.0277	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
SRI (8) response rate at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=166) n/ N (%)	Response rate	Placebo (N=167) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.1801
< 10 points	5/ 40 (12.5)	12.5	6/ 37 (16.2)	16.2	0.77 (0.26, 2.31)	0.6426	-3.72 (-20.79, 13.36)	0.6697	
>= 10 points	45/126 (35.7)	35.7	27/130 (20.8)	20.7	1.72 (1.14, 2.59)	0.0095	14.99 (3.89, 26.09)	0.0081	
OCS dose at baseline									0.2307
<10 mg/day	24/ 84 (28.6)	28.9	21/ 91 (23.1)	23.2	1.24 (0.75, 2.05)	0.4072	5.72 (-7.65, 19.08)	0.4018	
>=10 mg/day	26/ 82 (31.7)	31.7	12/ 76 (15.8)	15.8	2.01 (1.09, 3.69)	0.0248	15.92 (2.66, 29.18)	0.0186	
Result of type I IFN gene signature test									0.1470
LOW	4/ 26 (15.4)	15.4	6/ 27 (22.2)	22.2	0.69 (0.22, 2.18)	0.5290	-6.84 (-29.39, 15.72)	0.5524	
HIGH	46/140 (32.9)	33.0	27/140 (19.3)	19.1	1.70 (1.13, 2.58)	0.0115	13.99 (3.53, 24.45)	0.0087	
Age (years)									NE
<= 65	50/161 (31.1)	31.2	33/166 (19.9)	19.6	1.56 (1.07, 2.29)	0.0222	11.51 (1.87, 21.14)	0.0192	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									0.7195
male	3/ 10 (30.0)	30.0	3/ 12 (25.0)	25.0	1.20 (0.31, 4.69)	0.7931	5.00 (-34.62, 44.62)	0.8046	
female	47/156 (30.1)	30.1	30/155 (19.4)	19.2	1.56 (1.04, 2.32)	0.0303	10.96 (1.19, 20.72)	0.0279	
Race									0.0884
White	26/102 (25.5)	26.4	22/ 99 (22.2)	21.4	1.15 (0.70, 1.88)	0.5876	4.94 (-7.31, 17.18)	0.4296	
Black or African American	4/ 14 (28.6)	28.6	4/ 21 (19.0)	19.0	1.50 (0.45, 5.03)	0.5112	9.52 (-21.19, 40.24)	0.5434	
Asian	12/ 28 (42.9)	42.9	3/ 27 (11.1)	11.1	3.86 (1.22, 12.17)	0.0213	31.75 (8.72, 54.77)	0.0069	
American Indian or Alaska Native	3/ 4 (75.0)	75.0	1/ 1 (100.0)	100.0	0.75 (0.43, 1.32)	0.3190	-25.00 (-132.10, 82.10)	0.6473	
Other	4/ 11 (36.4)	36.4	1/ 11 (9.1)	9.1	4.00 (0.53, 30.33)	0.1798	27.27 (-10.10, 64.65)	0.1527	
Ethnicity									0.0508
Hispanic/Latino	16/ 49 (32.7)	32.7	16/ 49 (32.7)	32.7	1.00 (0.57, 1.77)	1.0000	0.00 (-18.75, 18.75)	1.0000	
Non-hispanic/Latino	33/110 (30.0)	30.6	15/110 (13.6)	13.5	2.20 (1.27, 3.81)	0.0050	17.11 (5.87, 28.35)	0.0028	
Geographic region									0.8697
EU	17/ 49 (34.7)	34.7	11/ 46 (23.9)	23.9	1.45 (0.76, 2.76)	0.2566	10.78 (-7.68, 29.25)	0.2525	
non-EU	33/117 (28.2)	28.3	22/121 (18.2)	18.0	1.55 (0.96, 2.50)	0.0705	10.32 (-0.56, 21.20)	0.0631	
Onset of disease									0.8757
Paediatric	4/ 14 (28.6)	28.6	2/ 12 (16.7)	16.7	1.71 (0.38, 7.78)	0.4848	11.90 (-22.88, 46.69)	0.5024	
Adult	46/152 (30.3)	30.3	31/155 (20.0)	19.9	1.51 (1.02, 2.25)	0.0407	10.45 (0.52, 20.38)	0.0391	
ADA result									0.2703
Negative	47/158 (29.7)	29.9	31/148 (20.9)	20.8	1.42 (0.96, 2.11)	0.0811	9.12 (-0.89, 19.13)	0.0742	
Positive (At any time)	3/ 8 (37.5)	37.5	2/ 19 (10.5)	10.5	3.56 (0.73, 17.42)	0.1167	26.97 (-11.20, 65.15)	0.1661	
BMI (kg/m2) at enrolment									0.9260
< 30	39/118 (33.1)	33.0	27/125 (21.6)	21.7	1.53 (1.00, 2.33)	0.0478	11.35 (-0.11, 22.82)	0.0523	
>= 30	11/ 48 (22.9)	21.6	6/ 42 (14.3)	14.1	1.60 (0.65, 3.96)	0.3058	7.53 (-9.63, 24.69)	0.3896	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.0897
All negative/normal	10/ 46 (21.7)	22.1	16/ 68 (23.5)	23.3	0.92 (0.46, 1.85)	0.8236	-1.22 (-17.93, 15.50)	0.8867	
At least one positive/abnormal	40/120 (33.3)	33.8	17/ 99 (17.2)	17.4	1.94 (1.18, 3.20)	0.0095	16.41 (4.79, 28.02)	0.0056	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
>=4 reduction in SLEDAI-2K at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 52	Number of subjects with events, n (%)	101 (56.1)	71 (39.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.44 (1.16, 1.81)	
	p-value	0.0012	
	Odds Ratio (95% CI)	2.02 (1.33, 3.08)	
	p-value	0.0011	
	Risk Difference (95% CI)	17.29 (7.16, 27.42)	
	p-value	0.0008	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.44 (1.15, 1.80)	
	p-value	0.0014	
	Odds Ratio (95% CI)	2.00 (1.31, 3.04)	
	p-value	0.0012	
	Risk Difference (95% CI)	17.10 (6.96, 27.24)	
	p-value	0.0009	
	CMH approach		
	Response rate	56.1	38.9
	Difference in response rates (95% CI)	17.22 (7.09, 27.34)	
	p-value	0.0009	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
>=4 reduction in SLEDAI-2K at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9207
< 10 points	26/ 54 (48.1)	48.1	17/ 52 (32.7)	32.6	1.47 (0.91, 2.38)	0.1126	15.48 (-3.01, 33.96)	0.1008	
>= 10 points	75/126 (59.5)	59.4	54/130 (41.5)	41.4	1.43 (1.12, 1.84)	0.0047	17.97 (5.89, 30.05)	0.0036	
OCS dose at baseline									0.5838
<10 mg/day	51/ 93 (54.8)	54.9	40/ 99 (40.4)	40.2	1.36 (1.00, 1.84)	0.0475	14.63 (0.69, 28.58)	0.0397	
>=10 mg/day	50/ 87 (57.5)	57.5	31/ 83 (37.3)	37.3	1.54 (1.10, 2.14)	0.0110	20.12 (5.39, 34.86)	0.0074	
Result of type I IFN gene signature test									0.2876
LOW	15/ 30 (50.0)	50.0	14/ 31 (45.2)	45.2	1.11 (0.65, 1.88)	0.7054	4.84 (-20.21, 29.89)	0.7050	
HIGH	86/150 (57.3)	57.3	57/151 (37.7)	37.6	1.52 (1.19, 1.94)	0.0009	19.73 (8.66, 30.80)	0.0005	
Age (years)									0.7006
<= 65	98/175 (56.0)	55.9	71/181 (39.2)	39.0	1.43 (1.14, 1.79)	0.0018	16.91 (6.71, 27.12)	0.0012	
> 65	3/ 5 (60.0)	60.0	0/ 1 (0.0)	0.0	2.33 (0.19, 28.25)	0.5055	60.00 (-45.43, 165.43)	0.2647	
Sex									0.0656
male	8/ 12 (66.7)	66.7	9/ 12 (75.0)	75.0	0.89 (0.53, 1.49)	0.6549	-8.33 (-46.25, 29.59)	0.6667	
female	93/168 (55.4)	55.2	62/170 (36.5)	36.4	1.52 (1.19, 1.93)	0.0007	18.89 (8.48, 29.31)	0.0004	
Race									0.1256
White	60/110 (54.5)	55.2	46/107 (43.0)	42.6	1.27 (0.96, 1.67)	0.0921	12.56 (-0.61, 25.73)	0.0616	
Black or African American	9/ 17 (52.9)	52.9	8/ 25 (32.0)	32.0	1.65 (0.80, 3.42)	0.1742	20.94 (-9.24, 51.12)	0.1738	
Asian	19/ 30 (63.3)	63.3	10/ 30 (33.3)	33.3	1.90 (1.07, 3.38)	0.0286	30.00 (5.61, 54.39)	0.0159	
American Indian or Alaska Native	3/ 4 (75.0)	75.0	1/ 1 (100.0)	100.0	0.75 (0.43, 1.32)	0.3190	-25.00 (-132.10, 82.10)	0.6473	
Other	6/ 11 (54.5)	54.5	2/ 11 (18.2)	18.2	3.00 (0.77, 11.74)	0.1146	36.36 (-3.03, 75.76)	0.0704	
Ethnicity									0.3850
Hispanic/Latino	32/ 54 (59.3)	58.9	25/ 54 (46.3)	46.6	1.28 (0.89, 1.84)	0.1820	12.30 (-6.42, 31.03)	0.1978	
Non-hispanic/Latino	65/118 (55.1)	55.2	42/120 (35.0)	34.7	1.57 (1.17, 2.11)	0.0024	20.52 (8.15, 32.90)	0.0012	
Geographic region									0.3140
EU	31/ 51 (60.8)	60.8	23/ 46 (50.0)	50.0	1.22 (0.85, 1.75)	0.2923	10.78 (-8.95, 30.52)	0.2842	
non-EU	70/129 (54.3)	54.3	48/136 (35.3)	35.0	1.54 (1.17, 2.03)	0.0024	19.31 (7.55, 31.08)	0.0013	
Onset of disease									0.8167
Paediatric	6/ 14 (42.9)	42.9	4/ 12 (33.3)	33.3	1.29 (0.47, 3.51)	0.6234	9.52 (-28.26, 47.31)	0.6213	
Adult	95/166 (57.2)	57.2	67/170 (39.4)	39.3	1.45 (1.16, 1.82)	0.0014	17.89 (7.41, 28.38)	0.0008	
ADA result									0.2973
Negative	97/172 (56.4)	56.3	67/162 (41.4)	41.3	1.36 (1.09, 1.71)	0.0071	14.95 (4.37, 25.53)	0.0056	
Positive (At any time)	4/ 8 (50.0)	50.0	4/ 20 (20.0)	20.0	2.50 (0.82, 7.64)	0.1080	30.00 (-9.50, 69.50)	0.1366	
BMI (kg/m2) at enrolment									0.5145
< 30	74/125 (59.2)	59.2	57/134 (42.5)	42.9	1.39 (1.09, 1.78)	0.0081	16.35 (4.43, 28.27)	0.0072	
>= 30	27/ 55 (49.1)	49.1	14/ 48 (29.2)	29.2	1.68 (1.00, 2.82)	0.0482	19.88 (1.04, 38.72)	0.0386	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.6140
All negative/normal	28/ 58 (48.3)	48.6	30/ 81 (37.0)	36.4	1.30 (0.88, 1.92)	0.1822	12.17 (-4.45, 28.79)	0.1514	
At least one positive/abnormal	73/122 (59.8)	60.1	41/101 (40.6)	40.7	1.47 (1.12, 1.94)	0.0061	19.42 (6.45, 32.38)	0.0033	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
>=8 reduction in SLEDAI-2K at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 52	Number of subjects with events, n (%)	50 (27.8)	33 (18.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.55 (1.05, 2.27)	
	p-value	0.0262	
	Odds Ratio (95% CI)	1.79 (1.08, 2.96)	
	p-value	0.0246	
	Risk Difference (95% CI)	9.86 (1.35, 18.36)	
	p-value	0.0231	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.53 (1.04, 2.26)	
	p-value	0.0313	
	Odds Ratio (95% CI)	1.74 (1.05, 2.86)	
	p-value	0.0300	
	Risk Difference (95% CI)	9.65 (1.04, 18.26)	
	p-value	0.0281	
	CMH approach		
	Response rate	27.9	18.0
	Difference in response rates (95% CI)	9.88 (1.03, 18.73)	
	p-value	0.0287	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
>=8 reduction in SLEDAI-2K at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.2118
< 10 points	5/ 54 (9.3)	9.2	6/ 52 (11.5)	11.5	0.80 (0.26, 2.47)	0.7012	-2.31 (-16.75, 12.13)	0.7537	
>= 10 points	45/126 (35.7)	35.7	27/130 (20.8)	20.7	1.72 (1.14, 2.59)	0.0095	14.99 (3.89, 26.09)	0.0081	
OCS dose at baseline									0.1942
<10 mg/day	24/ 93 (25.8)	26.1	21/ 99 (21.2)	21.2	1.22 (0.73, 2.03)	0.4536	4.95 (-7.52, 17.43)	0.4364	
>=10 mg/day	26/ 87 (29.9)	29.9	12/ 83 (14.5)	14.5	2.07 (1.12, 3.82)	0.0205	15.43 (2.92, 27.94)	0.0157	
Result of type I IFN gene signature test									0.1475
LOW	4/ 30 (13.3)	13.3	6/ 31 (19.4)	19.4	0.69 (0.22, 2.20)	0.5294	-6.02 (-26.14, 14.09)	0.5574	
HIGH	46/150 (30.7)	30.8	27/151 (17.9)	17.7	1.72 (1.13, 2.61)	0.0114	13.11 (3.27, 22.94)	0.0090	
Age (years)									NE
<= 65	50/175 (28.6)	28.7	33/181 (18.2)	18.1	1.57 (1.06, 2.31)	0.0230	10.61 (1.64, 19.58)	0.0204	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									0.5317
male	3/ 12 (25.0)	25.0	3/ 12 (25.0)	25.0	1.00 (0.25, 4.00)	1.0000	0.00 (-37.09, 37.09)	1.0000	
female	47/168 (28.0)	27.9	30/170 (17.6)	17.6	1.59 (1.06, 2.38)	0.0259	10.26 (1.17, 19.36)	0.0270	
Race									0.0833
White	26/110 (23.6)	24.4	22/107 (20.6)	19.8	1.15 (0.70, 1.90)	0.5859	4.62 (-6.81, 16.06)	0.4283	
Black or African American	4/ 17 (23.5)	23.5	4/ 25 (16.0)	16.0	1.47 (0.42, 5.09)	0.5426	7.53 (-19.18, 34.24)	0.5806	
Asian	12/ 30 (40.0)	40.0	3/ 30 (10.0)	10.0	4.00 (1.25, 12.75)	0.0191	30.00 (8.30, 51.70)	0.0067	
American Indian or Alaska Native	3/ 4 (75.0)	75.0	1/ 1 (100.0)	100.0	0.75 (0.43, 1.32)	0.3190	-25.00 (-132.10, 82.10)	0.6473	
Other	4/ 11 (36.4)	36.4	1/ 11 (9.1)	9.1	4.00 (0.53, 30.33)	0.1798	27.27 (-10.10, 64.65)	0.1527	
Ethnicity									0.0495
Hispanic/Latino	16/ 54 (29.6)	28.4	16/ 54 (29.6)	30.5	1.00 (0.56, 1.79)	1.0000	-2.10 (-19.65, 15.46)	0.8147	
Non-hispanic/Latino	33/118 (28.0)	28.4	15/120 (12.5)	12.4	2.24 (1.28, 3.90)	0.0045	16.04 (5.28, 26.80)	0.0035	
Geographic region									0.7589
EU	17/ 51 (33.3)	33.3	11/ 46 (23.9)	23.9	1.39 (0.73, 2.66)	0.3130	9.42 (-8.77, 27.61)	0.3102	
non-EU	33/129 (25.6)	25.5	22/136 (16.2)	16.0	1.58 (0.98, 2.56)	0.0628	9.53 (-0.58, 19.65)	0.0648	
Onset of disease									0.8800
Paediatric	4/ 14 (28.6)	28.6	2/ 12 (16.7)	16.7	1.71 (0.38, 7.78)	0.4848	11.90 (-22.88, 46.69)	0.5024	
Adult	46/166 (27.7)	27.7	31/170 (18.2)	18.2	1.52 (1.02, 2.27)	0.0414	9.53 (0.33, 18.73)	0.0423	
ADA result									0.2485
Negative	47/172 (27.3)	27.4	31/162 (19.1)	19.0	1.43 (0.96, 2.13)	0.0805	8.43 (-0.85, 17.71)	0.0750	
Positive (At any time)	3/ 8 (37.5)	37.5	2/ 20 (10.0)	10.0	3.75 (0.76, 18.39)	0.1033	27.50 (-10.37, 65.37)	0.1546	
BMI (kg/m2) at enrolment									0.9493
< 30	39/125 (31.2)	31.2	27/134 (20.1)	20.3	1.55 (1.01, 2.37)	0.0442	10.90 (0.01, 21.79)	0.0498	
>= 30	11/ 55 (20.0)	19.4	6/ 48 (12.5)	12.8	1.60 (0.64, 4.00)	0.3147	6.58 (-9.32, 22.49)	0.4171	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.0717
All negative/normal	10/ 58 (17.2)	17.9	16/ 81 (19.8)	19.1	0.87 (0.43, 1.78)	0.7091	-1.20 (-15.27, 12.87)	0.8672	
At least one positive/abnormal	40/122 (32.8)	33.2	17/101 (16.8)	17.1	1.95 (1.18, 3.22)	0.0093	16.16 (4.72, 27.59)	0.0056	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
No worsening in BILAG-2004 (>=1A or >=2B compared to BL) at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 52	Number of subjects with events, n (%)	125 (69.4)	94 (51.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.34 (1.13, 1.59)	
	p-value	0.0008	
	Odds Ratio (95% CI)	2.08 (1.36, 3.19)	
	p-value	0.0008	
	Risk Difference (95% CI)	17.64 (7.62, 27.67)	
	p-value	0.0006	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.34 (1.13, 1.59)	
	p-value	0.0007	
	Odds Ratio (95% CI)	2.13 (1.38, 3.27)	
	p-value	0.0006	
	Risk Difference (95% CI)	17.80 (7.90, 27.70)	
	p-value	0.0004	
	CMH approach		
	Response rate	69.4	51.6
	Difference in response rates (95% CI)	17.71 (7.73, 27.68)	
	p-value	0.0005	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
No worsening in BILAG-2004 (>=1A or >=2B compared to BL) at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.6806
< 10 points	37/ 54 (68.5)	68.4	28/ 52 (53.8)	53.8	1.27 (0.93, 1.73)	0.1274	14.63 (-3.74, 33.01)	0.1186	
>= 10 points	88/126 (69.8)	69.8	66/130 (50.8)	50.8	1.38 (1.12, 1.69)	0.0022	19.01 (7.19, 30.83)	0.0016	
OCS dose at baseline									0.8423
<10 mg/day	66/ 93 (71.0)	70.6	53/ 99 (53.5)	53.6	1.33 (1.06, 1.66)	0.0140	16.97 (3.33, 30.62)	0.0148	
>=10 mg/day	59/ 87 (67.8)	67.8	41/ 83 (49.4)	49.4	1.37 (1.06, 1.78)	0.0175	18.42 (3.81, 33.02)	0.0134	
Result of type I IFN gene signature test									0.7695
LOW	22/ 30 (73.3)	73.3	16/ 31 (51.6)	51.6	1.42 (0.95, 2.13)	0.0879	21.72 (-2.27, 45.71)	0.0759	
HIGH	103/150 (68.7)	68.5	78/151 (51.7)	51.7	1.33 (1.10, 1.60)	0.0031	16.89 (5.93, 27.86)	0.0025	
Age (years)									0.5158
<= 65	121/175 (69.1)	69.0	94/181 (51.9)	51.9	1.33 (1.12, 1.58)	0.0011	17.09 (7.03, 27.16)	0.0009	
> 65	4/ 5 (80.0)	80.0	0/ 1 (0.0)	0.0	3.00 (0.26, 34.57)	0.3784	80.00 (-24.53, 184.53)	0.1336	
Sex									0.2024
male	9/ 12 (75.0)	75.0	9/ 12 (75.0)	75.0	1.00 (0.63, 1.59)	1.0000	0.00 (-37.09, 37.09)	1.0000	
female	116/168 (69.0)	69.0	85/170 (50.0)	50.0	1.38 (1.15, 1.66)	0.0005	19.06 (8.72, 29.40)	0.0003	
Race									0.2331
White	79/110 (71.8)	72.1	58/107 (54.2)	54.2	1.32 (1.07, 1.63)	0.0086	17.92 (5.14, 30.71)	0.0060	
Black or African American	10/ 17 (58.8)	58.8	14/ 25 (56.0)	56.0	1.05 (0.62, 1.78)	0.8551	2.82 (-27.73, 33.38)	0.8563	
Asian	22/ 30 (73.3)	73.3	13/ 30 (43.3)	43.3	1.69 (1.07, 2.69)	0.0258	30.00 (5.88, 54.12)	0.0148	
American Indian or Alaska Native	3/ 4 (75.0)	75.0	1/ 1 (100.0)	100.0	0.75 (0.43, 1.32)	0.3190	-25.00 (-132.10, 82.10)	0.6473	
Other	6/ 11 (54.5)	54.5	4/ 11 (36.4)	36.4	1.50 (0.58, 3.88)	0.4028	18.18 (-23.14, 59.50)	0.3884	
Ethnicity									0.3289
Hispanic/Latino	37/ 54 (68.5)	68.7	31/ 54 (57.4)	57.5	1.19 (0.89, 1.60)	0.2355	11.18 (-7.22, 29.58)	0.2338	
Non-hispanic/Latino	83/118 (70.3)	70.2	59/120 (49.2)	49.2	1.43 (1.15, 1.78)	0.0012	21.04 (8.74, 33.34)	0.0008	
Geographic region									0.7446
EU	37/ 51 (72.5)	72.5	26/ 46 (56.5)	56.5	1.28 (0.95, 1.74)	0.1081	16.03 (-2.98, 35.03)	0.0983	
non-EU	88/129 (68.2)	68.3	68/136 (50.0)	50.1	1.36 (1.11, 1.68)	0.0030	18.19 (6.46, 29.92)	0.0024	
Onset of disease									0.7802
Paediatric	7/ 14 (50.0)	50.0	5/ 12 (41.7)	41.7	1.20 (0.51, 2.81)	0.6742	8.33 (-30.06, 46.72)	0.6705	
Adult	118/166 (71.1)	71.1	89/170 (52.4)	52.4	1.36 (1.14, 1.61)	0.0005	18.68 (8.41, 28.95)	0.0004	
ADA result									0.2381
Negative	121/172 (70.3)	70.2	90/162 (55.6)	55.6	1.27 (1.07, 1.50)	0.0060	14.52 (4.18, 24.87)	0.0059	
Positive (At any time)	4/ 8 (50.0)	50.0	4/ 20 (20.0)	20.0	2.50 (0.82, 7.64)	0.1080	30.00 (-9.50, 69.50)	0.1366	
BMI (kg/m2) at enrolment									0.8664
< 30	90/125 (72.0)	72.0	72/134 (53.7)	53.8	1.34 (1.11, 1.62)	0.0027	18.21 (6.50, 29.93)	0.0023	
>= 30	35/ 55 (63.6)	64.1	22/ 48 (45.8)	45.9	1.39 (0.96, 2.00)	0.0794	18.18 (-1.02, 37.38)	0.0634	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.4132
All negative/normal	40/ 58 (69.0)	68.9	45/ 81 (55.6)	55.2	1.24 (0.96, 1.61)	0.1035	13.68 (-2.68, 30.04)	0.1012	
At least one positive/abnormal	85/122 (69.7)	69.2	49/101 (48.5)	48.5	1.44 (1.14, 1.81)	0.0023	20.66 (7.83, 33.50)	0.0016	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Maintained OCS Reduction at week 52 (for subjects with baseline OCS >=10 mg/day)
Full analysis set

Timepoint		Anifrolumab 300mg (N=87)	Placebo (N=83)
Week 52	Number of subjects with events, n (%)	45 (51.7)	25 (30.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.70 (1.16, 2.49)	
	p-value	0.0066	
	Odds Ratio (95% CI)	2.44 (1.30, 4.59)	
	p-value	0.0055	
	Risk Difference (95% CI)	21.31 (6.82, 35.80)	
	p-value	0.0040	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.72 (1.17, 2.52)	
	p-value	0.0060	
	Odds Ratio (95% CI)	2.49 (1.32, 4.67)	
	p-value	0.0046	
	Risk Difference (95% CI)	21.60 (7.19, 36.01)	
	p-value	0.0033	
	CMH approach		
	Response rate	51.7	30.1
	Difference in response rates (95% CI)	21.60 (7.14, 36.07)	
	p-value	0.0034	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Maintained OCS Reduction at week 52 (for subjects with baseline OCS >=10 mg/day) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=87) n/ N (%)	Response rate	Placebo (N=83) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8583
< 10 points	12/ 23 (52.2)	52.2	6/ 21 (28.6)	28.6	1.83 (0.84, 3.99)	0.1309	23.60 (-4.95, 52.15)	0.1051	
>= 10 points	33/ 64 (51.6)	51.6	19/ 62 (30.6)	30.6	1.68 (1.08, 2.62)	0.0215	20.92 (4.05, 37.78)	0.0150	
OCS dose at baseline									NE
>=10 mg/day	45/ 87 (51.7)	51.7	25/ 83 (30.1)	30.1	1.72 (1.17, 2.52)	0.0060	21.60 (7.14, 36.07)	0.0034	
Result of type I IFN gene signature test									0.6180
LOW	2/ 9 (22.2)	22.2	2/ 10 (20.0)	20.0	1.11 (0.19, 6.34)	0.9056	2.22 (-38.93, 43.37)	0.9157	
HIGH	43/ 78 (55.1)	55.1	23/ 73 (31.5)	31.5	1.75 (1.18, 2.59)	0.0053	23.62 (8.17, 39.08)	0.0027	
Age (years)									NE
<= 65	45/ 86 (52.3)	52.3	25/ 83 (30.1)	30.1	1.74 (1.18, 2.55)	0.0049	22.21 (7.70, 36.71)	0.0027	
> 65	0/ 1 (0.0)		0		NE		NE		
Sex									0.9348
male	5/ 7 (71.4)	71.4	2/ 5 (40.0)	40.0	1.79 (0.55, 5.76)	0.3319	31.43 (-24.85, 87.70)	0.2737	
female	40/ 80 (50.0)	50.0	23/ 78 (29.5)	29.5	1.70 (1.13, 2.55)	0.0110	20.51 (5.53, 35.49)	0.0073	
Race									0.1981
White	28/ 51 (54.9)	54.9	14/ 54 (25.9)	25.9	2.12 (1.27, 3.54)	0.0043	28.98 (10.84, 47.11)	0.0017	
Black or African American	1/ 7 (14.3)	14.3	3/ 10 (30.0)	30.0	0.48 (0.06, 3.69)	0.4774	-15.71 (-60.10, 28.68)	0.4878	
Asian	9/ 17 (52.9)	52.9	5/ 11 (45.5)	45.5	1.16 (0.53, 2.56)	0.7043	7.49 (-30.37, 45.34)	0.6983	
Other	4/ 8 (50.0)	50.0	3/ 5 (60.0)	60.0	0.83 (0.31, 2.26)	0.7198	-10.00 (-65.65, 45.65)	0.7247	
Ethnicity									0.8416
Hispanic/Latino	16/ 28 (57.1)	57.1	10/ 27 (37.0)	37.0	1.54 (0.86, 2.78)	0.1478	20.11 (-5.88, 46.09)	0.1294	
Non-hispanic/Latino	26/ 55 (47.3)	47.3	15/ 53 (28.3)	28.3	1.67 (1.00, 2.79)	0.0493	18.97 (0.92, 37.02)	0.0394	
Geographic region									0.1958
EU	18/ 29 (62.1)	62.1	7/ 28 (25.0)	25.0	2.48 (1.23, 5.01)	0.0111	37.07 (12.71, 61.43)	0.0029	
non-EU	27/ 58 (46.6)	46.6	18/ 55 (32.7)	32.7	1.42 (0.89, 2.27)	0.1406	13.82 (-4.10, 31.75)	0.1307	
Onset of disease									0.6232
Paediatric	6/ 12 (50.0)	50.0	3/ 8 (37.5)	37.5	1.33 (0.46, 3.84)	0.5943	12.50 (-31.86, 56.86)	0.5807	
Adult	39/ 75 (52.0)	52.0	22/ 75 (29.3)	29.3	1.77 (1.17, 2.68)	0.0066	22.67 (7.30, 38.04)	0.0038	
ADA result									0.4084
Negative	43/ 80 (53.8)	53.8	24/ 69 (34.8)	34.8	1.55 (1.05, 2.26)	0.0254	18.97 (3.25, 34.69)	0.0180	
Positive (At any time)	2/ 7 (28.6)	28.6	1/ 14 (7.1)	7.1	4.00 (0.43, 36.92)	0.2215	21.43 (-19.20, 62.06)	0.3013	
BMI (kg/m2) at enrolment									0.7752
< 30	34/ 62 (54.8)	54.8	21/ 65 (32.3)	32.3	1.70 (1.12, 2.58)	0.0131	22.53 (5.65, 39.41)	0.0089	
>= 30	11/ 25 (44.0)	44.0	4/ 18 (22.2)	22.2	1.98 (0.75, 5.23)	0.1679	21.78 (-6.57, 50.12)	0.1321	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.4000
All negative/normal	14/ 24 (58.3)	58.3	8/ 30 (26.7)	26.7	2.19 (1.10, 4.33)	0.0247	31.67 (6.02, 57.31)	0.0155	
At least one positive/abnormal	31/ 63 (49.2)	49.2	17/ 53 (32.1)	32.1	1.53 (0.96, 2.44)	0.0714	17.13 (-0.57, 34.84)	0.0579	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
>=50% Reduction in CLASI activity score at week 52 (for subjects with baseline CLASI activity score >=10)
Full analysis set

Timepoint		Anifrolumab 300mg (N=49)	Placebo (N=40)
Week 52	Number of subjects with events, n (%)	31 (63.3)	18 (45.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.38 (0.92, 2.07)	
	p-value	0.1216	
	Odds Ratio (95% CI)	2.03 (0.86, 4.83)	
	p-value	0.1074	
	Risk Difference (95% CI)	17.12 (-3.35, 37.59)	
	p-value	0.1012	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.41 (0.94, 2.10)	
	p-value	0.0981	
	Odds Ratio (95% CI)	2.10 (0.90, 4.93)	
	p-value	0.0867	
	Risk Difference (95% CI)	18.27 (-2.23, 38.76)	
	p-value	0.0806	
	CMH approach		
	Response rate	63.3	45.0
	Difference in response rates (95% CI)	18.27 (-2.28, 38.82)	
	p-value	0.0815	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
>=50% Reduction in CLASI activity score at week 52 (for subjects with baseline CLASI activity score >=10) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=49) n/ N (%)	Response rate	Placebo (N=40) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.7255
< 10 points	7/ 10 (70.0)	70.0	3/ 7 (42.9)	42.9	1.63 (0.63, 4.21)	0.3098	27.14 (-20.21, 74.50)	0.2613	
>= 10 points	24/ 39 (61.5)	61.5	15/ 33 (45.5)	45.5	1.35 (0.86, 2.12)	0.1856	16.08 (-6.82, 38.99)	0.1687	
OCS dose at baseline									0.1840
<10 mg/day	12/ 17 (70.6)	70.6	5/ 15 (33.3)	33.3	2.12 (0.97, 4.61)	0.0590	37.25 (4.12, 70.39)	0.0276	
>=10 mg/day	19/ 32 (59.4)	59.4	13/ 25 (52.0)	52.0	1.14 (0.71, 1.83)	0.5828	7.38 (-18.61, 33.36)	0.5781	
Result of type I IFN gene signature test									0.1725
LOW	1/ 4 (25.0)	25.0	3/ 5 (60.0)	60.0	0.42 (0.07, 2.63)	0.3516	-35.00 (-99.40, 29.40)	0.2868	
HIGH	30/ 45 (66.7)	66.7	15/ 35 (42.9)	42.9	1.56 (1.01, 2.40)	0.0464	23.81 (2.29, 45.33)	0.0302	
Age (years)									NE
<= 65	31/ 49 (63.3)	63.3	18/ 40 (45.0)	45.0	1.41 (0.94, 2.10)	0.0981	18.27 (-2.28, 38.82)	0.0815	
Sex									0.1725
male	1/ 4 (25.0)	25.0	3/ 5 (60.0)	60.0	0.42 (0.07, 2.63)	0.3516	-35.00 (-99.40, 29.40)	0.2868	
female	30/ 45 (66.7)	66.7	15/ 35 (42.9)	42.9	1.56 (1.01, 2.40)	0.0464	23.81 (2.29, 45.33)	0.0302	
Race									0.2535
White	20/ 32 (62.5)	62.5	13/ 23 (56.5)	56.5	1.11 (0.71, 1.73)	0.6599	5.98 (-20.44, 32.39)	0.6573	
Black or African American	3/ 6 (50.0)	50.0	1/ 4 (25.0)	25.0	2.00 (0.31, 13.06)	0.4691	25.00 (-37.06, 87.06)	0.4298	
Asian	7/ 7 (100.0)	100.0	2/ 8 (25.0)	25.0	4.00 (1.20, 13.28)	0.0236	75.00 (31.60, 118.40)	0.0007	
Other	1/ 3 (33.3)	33.3	0/ 1 (0.0)	0.0	1.50 (0.10, 22.62)	0.7696	33.33 (-77.82, 144.49)	0.5567	
Ethnicity									0.7578
Hispanic/Latino	7/ 11 (63.6)	63.6	3/ 6 (50.0)	50.0	1.27 (0.51, 3.18)	0.6060	13.64 (-35.75, 63.02)	0.5884	
Non-hispanic/Latino	24/ 37 (64.9)	64.9	13/ 30 (43.3)	43.3	1.50 (0.93, 2.40)	0.0946	21.53 (-2.06, 45.12)	0.0736	
Geographic region									0.4279
EU	8/ 13 (61.5)	61.5	9/ 17 (52.9)	52.9	1.16 (0.62, 2.16)	0.6348	8.60 (-27.17, 44.37)	0.6376	
non-EU	23/ 36 (63.9)	63.9	9/ 23 (39.1)	39.1	1.63 (0.93, 2.87)	0.0895	24.76 (-0.80, 50.32)	0.0576	
Onset of disease									0.2983
Paediatric	0/ 2 (0.0)	0.0	1/ 2 (50.0)	50.0	0.33 (0.02, 5.33)	0.4373	-50.00 (-145.24, 45.24)	0.3035	
Adult	31/ 47 (66.0)	66.0	17/ 38 (44.7)	44.7	1.47 (0.98, 2.22)	0.0627	21.22 (0.31, 42.13)	0.0467	
ADA result									0.5877
Negative	30/ 46 (65.2)	65.2	18/ 37 (48.6)	48.6	1.34 (0.91, 1.99)	0.1434	16.57 (-4.69, 37.82)	0.1266	
Positive (At any time)	1/ 3 (33.3)	33.3	0/ 3 (0.0)	0.0	3.00 (0.17, 53.71)	0.4554	33.33 (-42.49, 109.16)	0.3889	
BMI (kg/m2) at enrolment									0.5718
< 30	23/ 35 (65.7)	65.7	14/ 32 (43.8)	43.8	1.50 (0.95, 2.38)	0.0830	21.96 (-1.47, 45.39)	0.0662	
>= 30	8/ 14 (57.1)	57.1	4/ 8 (50.0)	50.0	1.14 (0.50, 2.62)	0.7520	7.14 (-36.19, 50.48)	0.7467	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.6870
All negative/normal	7/ 11 (63.6)	63.6	8/ 16 (50.0)	50.0	1.27 (0.66, 2.47)	0.4759	13.64 (-24.29, 51.56)	0.4810	
At least one positive/abnormal	24/ 38 (63.2)	63.2	10/ 24 (41.7)	41.7	1.52 (0.89, 2.58)	0.1255	21.49 (-3.62, 46.60)	0.0934	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 4	Number of subjects with events, n (%)	48 (26.7)	39 (21.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.25 (0.86, 1.81)	
	p-value	0.2401	
	Odds Ratio (95% CI)	1.34 (0.82, 2.18)	
	p-value	0.2375	
	Risk Difference (95% CI)	5.31 (-3.47, 14.08)	
	p-value	0.2359	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.24 (0.86, 1.80)	
	p-value	0.2453	
	Odds Ratio (95% CI)	1.33 (0.82, 2.16)	
	p-value	0.2443	
	Risk Difference (95% CI)	5.24 (-3.55, 14.03)	
	p-value	0.2428	
	CMH approach		
	Response rate	26.8	21.3
	Difference in response rates (95% CI)	5.46 (-3.61, 14.52)	
	p-value	0.2384	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 8	Number of subjects with events, n (%)	63 (35.0)	40 (22.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.61 (1.15, 2.25)	
	p-value	0.0058	
	Odds Ratio (95% CI)	1.98 (1.23, 3.18)	
	p-value	0.0051	
	Risk Difference (95% CI)	13.20 (4.15, 22.25)	
	p-value	0.0043	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.59 (1.14, 2.23)	
	p-value	0.0071	
	Odds Ratio (95% CI)	1.91 (1.20, 3.05)	
	p-value	0.0064	
	Risk Difference (95% CI)	13.02 (3.82, 22.23)	
	p-value	0.0056	
	CMH approach		
	Response rate	35.3	21.6
	Difference in response rates (95% CI)	13.63 (4.34, 22.92)	
	p-value	0.0040	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 12	Number of subjects with events, n (%)	77 (42.8)	58 (31.9)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.35 (1.02, 1.77)	
	p-value	0.0332	
	Odds Ratio (95% CI)	1.60 (1.04, 2.46)	
	p-value	0.0316	
	Risk Difference (95% CI)	10.99 (1.06, 20.92)	
	p-value	0.0301	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.34 (1.02, 1.76)	
	p-value	0.0335	
	Odds Ratio (95% CI)	1.60 (1.04, 2.46)	
	p-value	0.0323	
	Risk Difference (95% CI)	10.91 (1.01, 20.81)	
	p-value	0.0308	
	CMH approach		
	Response rate	42.9	31.8
	Difference in response rates (95% CI)	11.12 (1.16, 21.07)	
	p-value	0.0287	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 16	Number of subjects with events, n (%)	75 (41.7)	59 (32.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.29 (0.98, 1.69)	
	p-value	0.0721	
	Odds Ratio (95% CI)	1.49 (0.97, 2.29)	
	p-value	0.0701	
	Risk Difference (95% CI)	9.22 (-0.70, 19.14)	
	p-value	0.0684	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.29 (0.98, 1.69)	
	p-value	0.0703	
	Odds Ratio (95% CI)	1.49 (0.97, 2.29)	
	p-value	0.0690	
	Risk Difference (95% CI)	9.25 (-0.66, 19.15)	
	p-value	0.0672	
	CMH approach		
	Response rate	41.8	32.3
	Difference in response rates (95% CI)	9.47 (-0.44, 19.37)	
	p-value	0.0610	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 20	Number of subjects with events, n (%)	82 (45.6)	62 (34.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.34 (1.04, 1.74)	
	p-value	0.0259	
	Odds Ratio (95% CI)	1.63 (1.07, 2.50)	
	p-value	0.0241	
	Risk Difference (95% CI)	11.61 (1.62, 21.59)	
	p-value	0.0228	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.34 (1.03, 1.73)	
	p-value	0.0270	
	Odds Ratio (95% CI)	1.62 (1.06, 2.48)	
	p-value	0.0259	
	Risk Difference (95% CI)	11.49 (1.47, 21.51)	
	p-value	0.0246	
	CMH approach		
	Response rate	45.7	33.9
	Difference in response rates (95% CI)	11.82 (1.79, 21.84)	
	p-value	0.0209	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 24	Number of subjects with events, n (%)	91 (50.6)	56 (30.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.66 (1.28, 2.17)	
	p-value	0.0002	
	Odds Ratio (95% CI)	2.36 (1.53, 3.65)	
	p-value	0.0001	
	Risk Difference (95% CI)	20.18 (10.32, 30.04)	
	p-value	<.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.64 (1.27, 2.13)	
	p-value	0.0002	
	Odds Ratio (95% CI)	2.30 (1.50, 3.53)	
	p-value	0.0001	
	Risk Difference (95% CI)	19.79 (9.87, 29.70)	
	p-value	<.0001	
	CMH approach		
	Response rate	50.7	30.5
	Difference in response rates (95% CI)	20.18 (10.26, 30.11)	
	p-value	<.0001	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 28	Number of subjects with events, n (%)	89 (49.4)	59 (32.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.54 (1.19, 1.99)	
	p-value	0.0011	
	Odds Ratio (95% CI)	2.07 (1.35, 3.18)	
	p-value	0.0009	
	Risk Difference (95% CI)	17.32 (7.36, 27.28)	
	p-value	0.0007	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.53 (1.18, 1.97)	
	p-value	0.0013	
	Odds Ratio (95% CI)	2.04 (1.33, 3.12)	
	p-value	0.0011	
	Risk Difference (95% CI)	17.03 (7.05, 27.01)	
	p-value	0.0008	
	CMH approach		
	Response rate	49.6	32.2
	Difference in response rates (95% CI)	17.40 (7.40, 27.40)	
	p-value	0.0006	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 32	Number of subjects with events, n (%)	87 (48.3)	57 (31.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.56 (1.20, 2.04)	
	p-value	0.0010	
	Odds Ratio (95% CI)	2.09 (1.36, 3.21)	
	p-value	0.0008	
	Risk Difference (95% CI)	17.37 (7.44, 27.30)	
	p-value	0.0006	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.54 (1.19, 2.01)	
	p-value	0.0012	
	Odds Ratio (95% CI)	2.05 (1.34, 3.15)	
	p-value	0.0010	
	Risk Difference (95% CI)	17.01 (7.08, 26.95)	
	p-value	0.0008	
	CMH approach		
	Response rate	48.3	31.0
	Difference in response rates (95% CI)	17.31 (7.37, 27.25)	
	p-value	0.0006	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 36	Number of subjects with events, n (%)	84 (46.7)	58 (31.9)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.47 (1.13, 1.91)	
	p-value	0.0045	
	Odds Ratio (95% CI)	1.88 (1.22, 2.89)	
	p-value	0.0040	
	Risk Difference (95% CI)	14.86 (4.91, 24.81)	
	p-value	0.0034	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.46 (1.12, 1.91)	
	p-value	0.0046	
	Odds Ratio (95% CI)	1.87 (1.22, 2.87)	
	p-value	0.0041	
	Risk Difference (95% CI)	14.80 (4.85, 24.75)	
	p-value	0.0035	
	CMH approach		
	Response rate	46.8	31.7
	Difference in response rates (95% CI)	15.06 (5.09, 25.03)	
	p-value	0.0031	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 40	Number of subjects with events, n (%)	77 (42.8)	53 (29.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.47 (1.10, 1.95)	
	p-value	0.0082	
	Odds Ratio (95% CI)	1.81 (1.17, 2.80)	
	p-value	0.0074	
	Risk Difference (95% CI)	13.63 (3.80, 23.46)	
	p-value	0.0066	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.47 (1.11, 1.95)	
	p-value	0.0077	
	Odds Ratio (95% CI)	1.82 (1.18, 2.81)	
	p-value	0.0070	
	Risk Difference (95% CI)	13.66 (3.87, 23.44)	
	p-value	0.0062	
	CMH approach		
	Response rate	42.8	29.0
	Difference in response rates (95% CI)	13.73 (3.88, 23.58)	
	p-value	0.0063	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 44	Number of subjects with events, n (%)	79 (43.9)	55 (30.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.46 (1.11, 1.93)	
	p-value	0.0073	
	Odds Ratio (95% CI)	1.82 (1.18, 2.80)	
	p-value	0.0067	
	Risk Difference (95% CI)	13.91 (4.01, 23.81)	
	p-value	0.0059	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.45 (1.10, 1.91)	
	p-value	0.0080	
	Odds Ratio (95% CI)	1.81 (1.17, 2.78)	
	p-value	0.0073	
	Risk Difference (95% CI)	13.67 (3.82, 23.52)	
	p-value	0.0065	
	CMH approach		
	Response rate	43.9	30.1
	Difference in response rates (95% CI)	13.80 (3.91, 23.69)	
	p-value	0.0062	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 48	Number of subjects with events, n (%)	81 (45.0)	61 (33.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.35 (1.04, 1.75)	
	p-value	0.0246	
	Odds Ratio (95% CI)	1.64 (1.07, 2.51)	
	p-value	0.0238	
	Risk Difference (95% CI)	11.63 (1.65, 21.62)	
	p-value	0.0224	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.34 (1.03, 1.74)	
	p-value	0.0267	
	Odds Ratio (95% CI)	1.62 (1.06, 2.48)	
	p-value	0.0257	
	Risk Difference (95% CI)	11.48 (1.49, 21.48)	
	p-value	0.0243	
	CMH approach		
	Response rate	45.1	33.5
	Difference in response rates (95% CI)	11.62 (1.61, 21.63)	
	p-value	0.0229	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 52	Number of subjects with events, n (%)	86 (47.8)	57 (31.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.52 (1.17, 1.97)	
	p-value	0.0018	
	Odds Ratio (95% CI)	1.99 (1.30, 3.06)	
	p-value	0.0016	
	Risk Difference (95% CI)	16.37 (6.39, 26.35)	
	p-value	0.0013	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.53 (1.17, 1.99)	
	p-value	0.0017	
	Odds Ratio (95% CI)	2.01 (1.31, 3.08)	
	p-value	0.0014	
	Risk Difference (95% CI)	16.46 (6.53, 26.39)	
	p-value	0.0012	
	CMH approach		
	Response rate	47.8	31.5
	Difference in response rates (95% CI)	16.31 (6.35, 26.27)	
	p-value	0.0013	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
BICLA response rate at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.7103
< 10 points	28/ 54 (51.9)	51.8	19/ 52 (36.5)	36.5	1.42 (0.91, 2.21)	0.1197	15.33 (-3.28, 33.94)	0.1064	
>= 10 points	58/126 (46.0)	46.2	38/130 (29.2)	29.5	1.57 (1.13, 2.19)	0.0066	16.68 (4.90, 28.47)	0.0055	
OCS dose at baseline									0.4263
<10 mg/day	46/ 93 (49.5)	49.5	29/ 99 (29.3)	29.4	1.69 (1.17, 2.44)	0.0053	20.07 (6.46, 33.68)	0.0039	
>=10 mg/day	40/ 87 (46.0)	46.0	28/ 83 (33.7)	33.7	1.36 (0.93, 1.99)	0.1083	12.24 (-2.40, 26.88)	0.1012	
Result of type I IFN gene signature test									0.6005
LOW	14/ 30 (46.7)	46.7	11/ 31 (35.5)	35.5	1.32 (0.71, 2.42)	0.3784	11.18 (-13.48, 35.85)	0.3742	
HIGH	72/150 (48.0)	48.0	46/151 (30.5)	30.7	1.58 (1.18, 2.11)	0.0023	17.35 (6.46, 28.24)	0.0018	
Age (years)									0.9462
<= 65	84/175 (48.0)	48.0	57/181 (31.5)	31.7	1.52 (1.17, 1.99)	0.0018	16.35 (6.28, 26.41)	0.0015	
> 65	2/ 5 (40.0)	40.0	0/ 1 (0.0)	0.0	1.67 (0.13, 22.00)	0.6980	40.00 (-65.43, 145.43)	0.4571	
Sex									0.2852
male	6/ 12 (50.0)	50.0	6/ 12 (50.0)	50.0	1.00 (0.45, 2.23)	1.0000	0.00 (-40.01, 40.01)	1.0000	
female	80/168 (47.6)	47.7	51/170 (30.0)	30.0	1.59 (1.20, 2.10)	0.0012	17.68 (7.41, 27.95)	0.0007	
Race									0.1279
White	49/110 (44.5)	44.6	36/107 (33.6)	33.8	1.32 (0.94, 1.86)	0.1037	10.79 (-2.22, 23.81)	0.1041	
Black or African American	9/ 17 (52.9)	52.9	9/ 25 (36.0)	36.0	1.47 (0.74, 2.93)	0.2723	16.94 (-13.48, 47.36)	0.2751	
Asian	15/ 30 (50.0)	50.0	6/ 30 (20.0)	20.0	2.50 (1.12, 5.56)	0.0248	30.00 (6.54, 53.46)	0.0122	
American Indian or Alaska Native	3/ 4 (75.0)	75.0	1/ 1 (100.0)	100.0	0.75 (0.43, 1.32)	0.3190	-25.00 (-132.10, 82.10)	0.6473	
Other	5/ 11 (45.5)	45.5	2/ 11 (18.2)	18.2	2.50 (0.61, 10.25)	0.2031	27.27 (-12.12, 66.67)	0.1748	
Ethnicity									0.5304
Hispanic/Latino	30/ 54 (55.6)	55.9	22/ 54 (40.7)	40.1	1.36 (0.91, 2.04)	0.1290	15.76 (-2.91, 34.43)	0.0980	
Non-hispanic/Latino	51/118 (43.2)	43.2	32/120 (26.7)	26.8	1.62 (1.13, 2.33)	0.0089	16.43 (4.33, 28.52)	0.0078	
Geographic region									0.1000
EU	23/ 51 (45.1)	45.1	19/ 46 (41.3)	41.3	1.09 (0.69, 1.73)	0.7073	3.79 (-15.96, 23.55)	0.7066	
non-EU	63/129 (48.8)	49.1	38/136 (27.9)	28.0	1.75 (1.27, 2.41)	0.0007	21.06 (9.52, 32.60)	0.0003	
Onset of disease									0.6400
Paediatric	5/ 14 (35.7)	35.7	2/ 12 (16.7)	16.7	2.14 (0.50, 9.11)	0.3020	19.05 (-16.34, 54.44)	0.2915	
Adult	81/166 (48.8)	48.9	55/170 (32.4)	32.5	1.51 (1.15, 1.97)	0.0026	16.39 (6.01, 26.77)	0.0020	
ADA result									0.4444
Negative	83/172 (48.3)	48.1	54/162 (33.3)	33.6	1.45 (1.11, 1.89)	0.0066	14.49 (4.05, 24.92)	0.0065	
Positive (At any time)	3/ 8 (37.5)	37.5	3/ 20 (15.0)	15.0	2.50 (0.63, 9.88)	0.1913	22.50 (-16.02, 61.02)	0.2523	
BMI (kg/m2) at enrolment									0.5755
< 30	60/125 (48.0)	48.1	44/134 (32.8)	33.1	1.46 (1.08, 1.98)	0.0141	14.96 (3.14, 26.78)	0.0131	
>= 30	26/ 55 (47.3)	47.6	13/ 48 (27.1)	27.8	1.75 (1.02, 3.00)	0.0438	19.78 (1.26, 38.30)	0.0363	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.2111
All negative/normal	26/ 58 (44.8)	44.9	29/ 81 (35.8)	35.7	1.25 (0.83, 1.88)	0.2803	9.16 (-7.49, 25.81)	0.2808	
At least one positive/abnormal	60/122 (49.2)	49.2	28/101 (27.7)	27.9	1.77 (1.23, 2.55)	0.0020	21.33 (8.79, 33.86)	0.0009	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
BICLA - individual components at week 52 (Full analysis set)
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
BILAG improvement [a]	88 (48.9)	59 (32.4)
No discontinuation of IP	153 (85.0)	130 (71.4)
No use of medication beyond protocol allowed threshold	144 (80.0)	123 (67.6)
No worsening of PGA [a]	122 (67.8)	95 (52.2)
No worsening of SLEDAI-2K [a]	122 (67.8)	94 (51.6)

[a] Subjects who discontinued IP or used medications beyond protocol allowed threshold are considered non-responders and not included in this category.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
BICLA response rate at week 52 sensitivity analysis, multiple imputation
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 52	Number of subjects with events, n (%)	86 (47.8)	57 (31.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.52 (1.17, 1.97)	
	p-value	0.0020	
	Odds Ratio (95% CI)	1.99 (1.29, 3.06)	
	p-value	0.0018	
	Risk Difference (95% CI)	16.34 (6.29, 26.38)	
	p-value	0.0014	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.52 (1.17, 1.99)	
	p-value	0.0018	
	Odds Ratio (95% CI)	2.00 (1.30, 3.08)	
	p-value	0.0016	
	Risk Difference (95% CI)	16.44 (6.44, 26.44)	
	p-value	0.0013	

For each outcome and visit, 100 imputations were generated by randomised treatment group. Each imputed dataset was analysed separately, and the single estimates are combined using PROC MIANALYZE. The estimated number of responders and non-responders are rounded to an integer. Therefore, there might be slight mismatches between number of subjects and corresponding percentage.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Change from baseline in PGA VAS < 0.3 at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 52	Number of subjects with events, n (%)	122 (67.8)	95 (52.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.30 (1.09, 1.54)	
	p-value	0.0034	
	Odds Ratio (95% CI)	1.89 (1.24, 2.88)	
	p-value	0.0033	
	Risk Difference (95% CI)	15.50 (5.39, 25.61)	
	p-value	0.0027	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.30 (1.09, 1.54)	
	p-value	0.0029	
	Odds Ratio (95% CI)	1.93 (1.26, 2.95)	
	p-value	0.0026	
	Risk Difference (95% CI)	15.58 (5.62, 25.54)	
	p-value	0.0022	
	CMH approach		
	Response rate	67.7	52.2
	Difference in response rates (95% CI)	15.47 (5.45, 25.48)	
	p-value	0.0025	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Change from baseline in PGA VAS < 0.3 at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9338
< 10 points	36/ 54 (66.7)	66.6	27/ 52 (51.9)	51.9	1.28 (0.93, 1.77)	0.1287	14.72 (-3.82, 33.27)	0.1196	
>= 10 points	86/126 (68.3)	68.2	68/130 (52.3)	52.4	1.30 (1.07, 1.60)	0.0101	15.80 (3.91, 27.69)	0.0092	
OCS dose at baseline									0.9327
<10 mg/day	63/ 93 (67.7)	67.5	52/ 99 (52.5)	52.6	1.29 (1.02, 1.63)	0.0331	14.92 (1.14, 28.69)	0.0339	
>=10 mg/day	59/ 87 (67.8)	67.8	43/ 83 (51.8)	51.8	1.31 (1.02, 1.69)	0.0370	16.01 (1.41, 30.61)	0.0316	
Result of type I IFN gene signature test									0.6322
LOW	22/ 30 (73.3)	73.3	16/ 31 (51.6)	51.6	1.42 (0.95, 2.13)	0.0879	21.72 (-2.27, 45.71)	0.0759	
HIGH	100/150 (66.7)	66.5	79/151 (52.3)	52.3	1.27 (1.05, 1.54)	0.0123	14.19 (3.18, 25.21)	0.0116	
Age (years)									0.4976
<= 65	118/175 (67.4)	67.3	95/181 (52.5)	52.5	1.28 (1.08, 1.53)	0.0045	14.81 (4.70, 24.91)	0.0041	
> 65	4/ 5 (80.0)	80.0	0/ 1 (0.0)	0.0	3.00 (0.26, 34.57)	0.3784	80.00 (-24.53, 184.53)	0.1336	
Sex									0.2609
male	9/ 12 (75.0)	75.0	9/ 12 (75.0)	75.0	1.00 (0.63, 1.59)	1.0000	0.00 (-37.09, 37.09)	1.0000	
female	113/168 (67.3)	67.2	86/170 (50.6)	50.6	1.33 (1.11, 1.60)	0.0022	16.65 (6.26, 27.03)	0.0017	
Race									0.3159
White	77/110 (70.0)	70.4	58/107 (54.2)	54.2	1.29 (1.04, 1.60)	0.0185	16.25 (3.40, 29.11)	0.0132	
Black or African American	9/ 17 (52.9)	52.9	13/ 25 (52.0)	52.0	1.02 (0.57, 1.83)	0.9521	0.94 (-29.84, 31.72)	0.9522	
Asian	22/ 30 (73.3)	73.3	14/ 30 (46.7)	46.7	1.57 (1.01, 2.44)	0.0437	26.67 (2.48, 50.85)	0.0307	
American Indian or Alaska Native	3/ 4 (75.0)	75.0	1/ 1 (100.0)	100.0	0.75 (0.43, 1.32)	0.3190	-25.00 (-132.10, 82.10)	0.6473	
Other	6/ 11 (54.5)	54.5	5/ 11 (45.5)	45.5	1.20 (0.52, 2.79)	0.6715	9.09 (-32.60, 50.78)	0.6691	
Ethnicity									0.6323
Hispanic/Latino	38/ 54 (70.4)	70.8	31/ 54 (57.4)	57.5	1.23 (0.92, 1.63)	0.1653	13.23 (-5.02, 31.49)	0.1554	
Non-hispanic/Latino	79/118 (66.9)	66.8	60/120 (50.0)	50.0	1.34 (1.08, 1.67)	0.0091	16.85 (4.46, 29.24)	0.0077	
Geographic region									0.9886
EU	36/ 51 (70.6)	70.6	25/ 46 (54.3)	54.3	1.30 (0.94, 1.79)	0.1078	16.24 (-2.95, 35.43)	0.0972	
non-EU	86/129 (66.7)	66.8	70/136 (51.5)	51.5	1.30 (1.06, 1.59)	0.0128	15.24 (3.50, 26.99)	0.0110	
Onset of disease									0.8449
Paediatric	7/ 14 (50.0)	50.0	5/ 12 (41.7)	41.7	1.20 (0.51, 2.81)	0.6742	8.33 (-30.06, 46.72)	0.6705	
Adult	115/166 (69.3)	69.3	90/170 (52.9)	53.0	1.31 (1.10, 1.56)	0.0025	16.29 (5.98, 26.60)	0.0019	
ADA result									0.3644
Negative	118/172 (68.6)	68.4	90/162 (55.6)	55.7	1.23 (1.04, 1.46)	0.0155	12.70 (2.32, 23.07)	0.0164	
Positive (At any time)	4/ 8 (50.0)	50.0	5/ 20 (25.0)	25.0	2.00 (0.72, 5.59)	0.1862	25.00 (-14.97, 64.97)	0.2202	
BMI (kg/m2) at enrolment									0.6366
< 30	88/125 (70.4)	70.3	74/134 (55.2)	55.4	1.27 (1.05, 1.54)	0.0123	14.96 (3.20, 26.72)	0.0127	
>= 30	34/ 55 (61.8)	62.7	21/ 48 (43.8)	44.2	1.41 (0.96, 2.07)	0.0762	18.50 (-0.70, 37.70)	0.0589	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.3454
All negative/normal	39/ 58 (67.2)	67.6	46/ 81 (56.8)	56.4	1.18 (0.91, 1.54)	0.2054	11.20 (-5.19, 27.59)	0.1804	
At least one positive/abnormal	83/122 (68.0)	67.7	49/101 (48.5)	48.5	1.40 (1.11, 1.77)	0.0048	19.15 (6.26, 32.04)	0.0036	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Change from baseline in PGA VAS < 0.45 at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 52	Number of subjects with events, n (%)	122 (67.8)	99 (54.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.24 (1.05, 1.47)	
	p-value	0.0109	
	Odds Ratio (95% CI)	1.74 (1.14, 2.66)	
	p-value	0.0108	
	Risk Difference (95% CI)	13.30 (3.24, 23.36)	
	p-value	0.0095	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.25 (1.05, 1.47)	
	p-value	0.0098	
	Odds Ratio (95% CI)	1.76 (1.15, 2.70)	
	p-value	0.0093	
	Risk Difference (95% CI)	13.38 (3.43, 23.33)	
	p-value	0.0084	
	CMH approach		
	Response rate	67.7	54.4
	Difference in response rates (95% CI)	13.29 (3.29, 23.28)	
	p-value	0.0092	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Change from baseline in PGA VAS < 0.45 at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9606
< 10 points	36/ 54 (66.7)	66.6	28/ 52 (53.8)	53.8	1.24 (0.90, 1.70)	0.1831	12.84 (-5.67, 31.35)	0.1741	
>= 10 points	86/126 (68.3)	68.2	71/130 (54.6)	54.7	1.25 (1.03, 1.52)	0.0264	13.49 (1.62, 25.37)	0.0259	
OCS dose at baseline									0.7795
<10 mg/day	63/ 93 (67.7)	67.5	55/ 99 (55.6)	55.7	1.22 (0.97, 1.53)	0.0843	11.85 (-1.92, 25.61)	0.0916	
>=10 mg/day	59/ 87 (67.8)	67.8	44/ 83 (53.0)	53.0	1.28 (1.00, 1.64)	0.0525	14.80 (0.21, 29.40)	0.0467	
Result of type I IFN gene signature test									0.9392
LOW	22/ 30 (73.3)	73.3	18/ 31 (58.1)	58.1	1.26 (0.87, 1.83)	0.2148	15.27 (-8.59, 39.13)	0.2098	
HIGH	100/150 (66.7)	66.5	81/151 (53.6)	53.7	1.24 (1.03, 1.50)	0.0224	12.88 (1.88, 23.89)	0.0218	
Age (years)									0.4768
<= 65	118/175 (67.4)	67.3	99/181 (54.7)	54.7	1.23 (1.04, 1.46)	0.0146	12.64 (2.55, 22.73)	0.0141	
> 65	4/ 5 (80.0)	80.0	0/ 1 (0.0)	0.0	3.00 (0.26, 34.57)	0.3784	80.00 (-24.53, 184.53)	0.1336	
Sex									0.3428
male	9/ 12 (75.0)	75.0	9/ 12 (75.0)	75.0	1.00 (0.63, 1.59)	1.0000	0.00 (-37.09, 37.09)	1.0000	
female	113/168 (67.3)	67.2	90/170 (52.9)	52.9	1.27 (1.06, 1.52)	0.0079	14.32 (3.94, 24.70)	0.0068	
Race									0.3064
White	77/110 (70.0)	70.4	61/107 (57.0)	56.9	1.23 (1.00, 1.51)	0.0497	13.56 (0.74, 26.38)	0.0382	
Black or African American	9/ 17 (52.9)	52.9	14/ 25 (56.0)	56.0	0.95 (0.54, 1.67)	0.8461	-3.06 (-33.78, 27.66)	0.8453	
Asian	22/ 30 (73.3)	73.3	14/ 30 (46.7)	46.7	1.57 (1.01, 2.44)	0.0437	26.67 (2.48, 50.85)	0.0307	
American Indian or Alaska Native	3/ 4 (75.0)	75.0	1/ 1 (100.0)	100.0	0.75 (0.43, 1.32)	0.3190	-25.00 (-132.10, 82.10)	0.6473	
Other	6/ 11 (54.5)	54.5	5/ 11 (45.5)	45.5	1.20 (0.52, 2.79)	0.6715	9.09 (-32.60, 50.78)	0.6691	
Ethnicity									0.6915
Hispanic/Latino	38/ 54 (70.4)	70.8	32/ 54 (59.3)	59.6	1.19 (0.90, 1.57)	0.2304	11.23 (-6.97, 29.42)	0.2266	
Non-hispanic/Latino	79/118 (66.9)	66.8	63/120 (52.5)	52.5	1.28 (1.03, 1.58)	0.0247	14.39 (2.00, 26.78)	0.0228	
Geographic region									0.9766
EU	36/ 51 (70.6)	70.6	26/ 46 (56.5)	56.5	1.25 (0.92, 1.70)	0.1590	14.07 (-5.08, 33.21)	0.1499	
non-EU	86/129 (66.7)	66.8	73/136 (53.7)	53.7	1.24 (1.02, 1.51)	0.0321	13.07 (1.33, 24.82)	0.0291	
Onset of disease									0.5578
Paediatric	7/ 14 (50.0)	50.0	6/ 12 (50.0)	50.0	1.00 (0.46, 2.16)	1.0000	0.00 (-38.55, 38.55)	1.0000	
Adult	115/166 (69.3)	69.3	93/170 (54.7)	54.7	1.27 (1.07, 1.50)	0.0065	14.59 (4.29, 24.88)	0.0055	
ADA result									0.5049
Negative	118/172 (68.6)	68.4	93/162 (57.4)	57.5	1.20 (1.01, 1.41)	0.0363	10.89 (0.53, 21.26)	0.0394	
Positive (At any time)	4/ 8 (50.0)	50.0	6/ 20 (30.0)	30.0	1.67 (0.64, 4.37)	0.2988	20.00 (-20.34, 60.34)	0.3312	
BMI (kg/m2) at enrolment									0.9325
< 30	88/125 (70.4)	70.3	75/134 (56.0)	56.1	1.26 (1.04, 1.52)	0.0170	14.23 (2.48, 25.98)	0.0176	
>= 30	34/ 55 (61.8)	62.7	24/ 48 (50.0)	49.8	1.24 (0.87, 1.76)	0.2360	12.84 (-6.41, 32.10)	0.1911	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.3250
All negative/normal	39/ 58 (67.2)	67.6	48/ 81 (59.3)	58.8	1.13 (0.88, 1.46)	0.3308	8.76 (-7.60, 25.12)	0.2941	
At least one positive/abnormal	83/122 (68.0)	67.7	51/101 (50.5)	50.5	1.35 (1.07, 1.69)	0.0105	17.22 (4.32, 30.11)	0.0089	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Constitutional
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 52	Number of subjects with events, n (%)	2 (1.1)	3 (1.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.73 (0.13, 4.24)	
	p-value	0.7246	
	Odds Ratio (95% CI)	0.73 (0.12, 4.33)	
	p-value	0.7277	
	Risk Difference (95% CI)	-0.44 (-2.87, 2.00)	
	p-value	0.7248	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.67 (0.11, 3.99)	
	p-value	0.6636	
	Odds Ratio (95% CI)	0.67 (0.11, 4.06)	
	p-value	0.6635	
	Risk Difference (95% CI)	-0.54 (-2.94, 1.86)	
	p-value	0.6610	
	CMH approach		
	Response rate	1.1	1.6
	Difference in response rates (95% CI)	-0.51 (-5.42, 4.40)	
	p-value	0.8397	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Constitutional - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.2839
< 10 points	1/ 54 (1.9)	1.8	0/ 52 (0.0)	0.0	2.89 (0.12, 69.40)	0.5127	1.84 (-9.53, 13.22)	0.7510	
>= 10 points	1/126 (0.8)	0.8	3/130 (2.3)	2.3	0.34 (0.04, 3.26)	0.3525	-1.47 (-7.05, 4.11)	0.6054	
OCS dose at baseline									0.7536
<10 mg/day	1/ 93 (1.1)	1.0	2/ 99 (2.0)	2.0	0.53 (0.05, 5.77)	0.6041	-0.94 (-8.54, 6.67)	0.8094	
>=10 mg/day	1/ 87 (1.1)	1.1	1/ 83 (1.2)	1.2	0.95 (0.06, 15.00)	0.9733	-0.06 (-5.49, 5.37)	0.9840	
Result of type I IFN gene signature test									0.2619
LOW	1/ 30 (3.3)	3.3	0/ 31 (0.0)	0.0	3.10 (0.13, 73.16)	0.4836	3.33 (-9.70, 16.36)	0.6161	
HIGH	1/150 (0.7)	0.6	3/151 (2.0)	1.9	0.34 (0.04, 3.19)	0.3419	-1.29 (-6.57, 3.99)	0.6330	
Age (years)									NE
<= 65	2/175 (1.1)	1.1	3/181 (1.7)	1.6	0.69 (0.12, 4.08)	0.6818	-0.48 (-5.47, 4.51)	0.8509	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
female	2/168 (1.2)	1.2	3/170 (1.8)	1.8	0.67 (0.11, 3.99)	0.6641	-0.55 (-5.79, 4.69)	0.8378	
Race									0.2609
White	1/110 (0.9)	1.0	3/107 (2.8)	2.7	0.32 (0.03, 3.07)	0.3260	-1.74 (-8.36, 4.88)	0.6063	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.13, 17.13)	1.0000	
Asian	1/ 30 (3.3)	3.3	0/ 30 (0.0)	0.0	3.00 (0.13, 70.83)	0.4958	3.33 (-9.85, 16.52)	0.6203	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-28.41, 28.41)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE		0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	2/118 (1.7)	1.6	3/120 (2.5)	2.4	0.68 (0.12, 3.98)	0.6671	-0.75 (-7.88, 6.38)	0.8370	
Geographic region									0.0848
EU	0/ 51 (0.0)	0.0	3/ 46 (6.5)	6.5	0.13 (0.01, 2.43)	0.1719	-6.52 (-16.60, 3.56)	0.2046	
non-EU	2/129 (1.6)	1.6	0/136 (0.0)	0.0	5.27 (0.26, 108.72)	0.2819	1.55 (-4.60, 7.71)	0.6211	
Onset of disease									0.2019
Paediatric	0/ 14 (0.0)	0.0	2/ 12 (16.7)	16.7	0.17 (0.01, 3.29)	0.2433	-16.67 (-46.18, 12.85)	0.2684	
Adult	2/166 (1.2)	1.2	1/170 (0.6)	0.6	2.05 (0.19, 22.37)	0.5567	0.63 (-4.42, 5.69)	0.8057	
ADA result									NE
Negative	2/172 (1.2)	1.2	3/162 (1.9)	1.8	0.63 (0.11, 3.71)	0.6076	-0.63 (-5.94, 4.67)	0.8151	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	2/125 (1.6)	1.6	3/134 (2.2)	2.2	0.71 (0.12, 4.21)	0.7103	-0.62 (-7.23, 5.98)	0.8530	
>= 30	0/ 55 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-11.37, 11.37)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.5128
All negative/normal	1/ 58 (1.7)	1.6	1/ 81 (1.2)	1.1	1.40 (0.09, 21.87)	0.8119	0.44 (-9.14, 10.02)	0.9282	
At least one positive/abnormal	1/122 (0.8)	0.7	2/101 (2.0)	1.9	0.41 (0.04, 4.50)	0.4687	-1.28 (-7.33, 4.77)	0.6792	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Mucocutaneous
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 52	Number of subjects with events, n (%)	53 (29.4)	55 (30.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.97 (0.71, 1.33)	
	p-value	0.8381	
	Odds Ratio (95% CI)	0.95 (0.61, 1.50)	
	p-value	0.8382	
	Risk Difference (95% CI)	-0.98 (-10.38, 8.42)	
	p-value	0.8382	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.97 (0.71, 1.34)	
	p-value	0.8719	
	Odds Ratio (95% CI)	0.96 (0.61, 1.51)	
	p-value	0.8719	
	Risk Difference (95% CI)	-0.78 (-10.20, 8.65)	
	p-value	0.8719	
	CMH approach		
	Response rate	29.2	30.2
	Difference in response rates (95% CI)	-1.05 (-10.51, 8.42)	
	p-value	0.8284	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Mucocutaneous - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.7510
< 10 points	12/ 54 (22.2)	22.1	13/ 52 (25.0)	25.0	0.89 (0.45, 1.77)	0.7365	-2.87 (-19.55, 13.82)	0.7361	
>= 10 points	41/126 (32.5)	32.2	42/130 (32.3)	32.4	1.01 (0.71, 1.43)	0.9684	-0.21 (-11.62, 11.21)	0.9715	
OCS dose at baseline									0.0864
<10 mg/day	22/ 93 (23.7)	23.3	32/ 99 (32.3)	32.5	0.73 (0.46, 1.16)	0.1865	-9.20 (-22.04, 3.64)	0.1602	
>=10 mg/day	31/ 87 (35.6)	35.6	23/ 83 (27.7)	27.7	1.29 (0.82, 2.01)	0.2711	7.92 (-6.11, 21.95)	0.2685	
Result of type I IFN gene signature test									0.4386
LOW	10/ 30 (33.3)	33.3	8/ 31 (25.8)	25.8	1.29 (0.59, 2.82)	0.5215	7.53 (-15.83, 30.88)	0.5276	
HIGH	43/150 (28.7)	28.4	47/151 (31.1)	31.1	0.92 (0.65, 1.30)	0.6415	-2.79 (-13.14, 7.56)	0.5976	
Age (years)									0.1184
<= 65	51/175 (29.1)	28.9	54/181 (29.8)	29.9	0.98 (0.71, 1.35)	0.8863	-1.01 (-10.52, 8.50)	0.8344	
> 65	2/ 5 (40.0)	40.0	1/ 1 (100.0)	100.0	0.40 (0.14, 1.17)	0.0943	-60.00 (-165.43, 45.43)	0.2647	
Sex									0.9549
male	5/ 12 (41.7)	41.7	5/ 12 (41.7)	41.7	1.00 (0.39, 2.58)	1.0000	0.00 (-39.69, 39.69)	1.0000	
female	48/168 (28.6)	28.4	50/170 (29.4)	29.6	0.97 (0.70, 1.36)	0.8648	-1.18 (-10.91, 8.56)	0.8125	
Race									0.2826
White	38/110 (34.5)	34.7	31/107 (29.0)	28.4	1.19 (0.81, 1.77)	0.3798	6.32 (-6.18, 18.81)	0.3218	
Black or African American	4/ 17 (23.5)	23.5	4/ 25 (16.0)	16.0	1.47 (0.42, 5.09)	0.5426	7.53 (-19.18, 34.24)	0.5806	
Asian	10/ 30 (33.3)	33.3	16/ 30 (53.3)	53.3	0.63 (0.34, 1.15)	0.1290	-20.00 (-44.73, 4.73)	0.1129	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	1/ 11 (9.1)	9.1	2/ 11 (18.2)	18.2	0.50 (0.05, 4.75)	0.5460	-9.09 (-44.33, 26.15)	0.6131	
Ethnicity									0.6296
Hispanic/Latino	14/ 54 (25.9)	25.7	12/ 54 (22.2)	22.6	1.17 (0.60, 2.29)	0.6532	3.04 (-14.14, 20.23)	0.7285	
Non-hispanic/Latino	39/118 (33.1)	32.9	41/120 (34.2)	33.9	0.97 (0.68, 1.38)	0.8555	-0.97 (-13.03, 11.09)	0.8745	
Geographic region									0.5653
EU	12/ 51 (23.5)	23.5	9/ 46 (19.6)	19.6	1.20 (0.56, 2.59)	0.6373	3.96 (-12.95, 20.88)	0.6461	
non-EU	41/129 (31.8)	31.5	46/136 (33.8)	34.2	0.94 (0.67, 1.33)	0.7239	-2.71 (-13.99, 8.57)	0.6383	
Onset of disease									0.7934
Paediatric	5/ 14 (35.7)	35.7	5/ 12 (41.7)	41.7	0.86 (0.32, 2.26)	0.7556	-5.95 (-43.90, 31.99)	0.7585	
Adult	48/166 (28.9)	28.8	50/170 (29.4)	29.5	0.98 (0.70, 1.37)	0.9203	-0.72 (-10.50, 9.06)	0.8851	
ADA result									0.4540
Negative	50/172 (29.1)	28.9	50/162 (30.9)	30.7	0.94 (0.68, 1.31)	0.7204	-1.85 (-11.75, 8.05)	0.7137	
Positive (At any time)	3/ 8 (37.5)	37.5	5/ 20 (25.0)	25.0	1.50 (0.46, 4.85)	0.4982	12.50 (-27.05, 52.05)	0.5356	
BMI (kg/m2) at enrolment									0.2913
< 30	33/125 (26.4)	26.3	41/134 (30.6)	30.2	0.86 (0.59, 1.27)	0.4563	-3.99 (-15.09, 7.10)	0.4804	
>= 30	20/ 55 (36.4)	36.3	14/ 48 (29.2)	28.0	1.25 (0.71, 2.19)	0.4423	8.25 (-10.22, 26.71)	0.3812	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.5149
All negative/normal	15/ 58 (25.9)	25.7	25/ 81 (30.9)	30.7	0.84 (0.49, 1.44)	0.5242	-5.02 (-20.67, 10.64)	0.5300	
At least one positive/abnormal	38/122 (31.1)	30.9	30/101 (29.7)	29.6	1.05 (0.70, 1.56)	0.8158	1.33 (-10.97, 13.62)	0.8323	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Neuropsychiatric
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 52	Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	NE	
	p-value		
	Odds Ratio (95% CI)	NE	
	p-value		
	Risk Difference (95% CI)	NE	
	p-value		
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	NE	
	p-value		
	Odds Ratio (95% CI)	NE	
	p-value		
	Risk Difference (95% CI)	NE	
	p-value		
	CMH approach		
	Response rate	0.0	0.0
	Difference in response rates (95% CI)	0.00 (-4.43, 4.43)	
	p-value	1.0000	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Neuropsychiatric - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Anifrolumab 300mg (N=180) Response rate	Placebo (N=182) n/ N (%)	Placebo (N=182) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Analysis Anifrolumab 300mg vs. Placebo Difference in response rates (95% CI)	Analysis Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.98, 10.98)	1.0000	
>= 10 points	0/126 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.90, 4.90)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 93 (0.0)	0.0	0/ 99 (0.0)	0.0	NE	0.00 (-7.00, 7.00)	1.0000	
>=10 mg/day	0/ 87 (0.0)	0.0	0/ 83 (0.0)	0.0	NE	0.00 (-4.46, 4.46)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE	0.00 (-11.73, 11.73)	1.0000	
HIGH	0/150 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Age (years)								NE
<= 65	0/175 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.50, 4.50)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-102.70, 102.70)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
female	0/168 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.71, 4.71)	1.0000	
Race								NE
White	0/110 (0.0)	0.0	0/107 (0.0)	0.0	NE	0.00 (-5.75, 5.75)	1.0000	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE	0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE	0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-28.41, 28.41)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	0/118 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.46, 6.46)	1.0000	
Geographic region								NE
EU	0/ 51 (0.0)	0.0	0/ 46 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
non-EU	0/129 (0.0)	0.0	0/136 (0.0)	0.0	NE	0.00 (-5.90, 5.90)	1.0000	
Onset of disease								NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-24.92, 24.92)	1.0000	
Adult	0/166 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.74, 4.74)	1.0000	
ADA result								NE
Negative	0/172 (0.0)	0.0	0/162 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE	0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/125 (0.0)	0.0	0/134 (0.0)	0.0	NE	0.00 (-5.98, 5.98)	1.0000	
>= 30	0/ 55 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-11.37, 11.37)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE	0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	0/122 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-5.42, 5.42)	1.0000	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Musculoskeletal
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 52	Number of subjects with events, n (%)	31 (17.2)	36 (19.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.88 (0.57, 1.36)	
	p-value	0.5545	
	Odds Ratio (95% CI)	0.85 (0.50, 1.45)	
	p-value	0.5523	
	Risk Difference (95% CI)	-2.41 (-10.35, 5.53)	
	p-value	0.5519	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.87 (0.56, 1.34)	
	p-value	0.5315	
	Odds Ratio (95% CI)	0.84 (0.50, 1.44)	
	p-value	0.5312	
	Risk Difference (95% CI)	-2.56 (-10.55, 5.44)	
	p-value	0.5306	
	CMH approach		
	Response rate	17.3	19.6
	Difference in response rates (95% CI)	-2.37 (-10.75, 6.01)	
	p-value	0.5793	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Musculoskeletal - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9831
< 10 points	10/ 54 (18.5)	18.5	11/ 52 (21.2)	21.2	0.88 (0.41, 1.89)	0.7339	-2.68 (-19.07, 13.71)	0.7484	
>= 10 points	21/126 (16.7)	16.8	25/130 (19.2)	19.0	0.87 (0.51, 1.47)	0.5938	-2.22 (-12.03, 7.60)	0.6581	
OCS dose at baseline									0.4095
<10 mg/day	18/ 93 (19.4)	19.2	25/ 99 (25.3)	25.4	0.77 (0.45, 1.31)	0.3305	-6.18 (-18.49, 6.14)	0.3257	
>=10 mg/day	13/ 87 (14.9)	14.9	11/ 83 (13.3)	13.3	1.13 (0.54, 2.37)	0.7521	1.69 (-9.25, 12.63)	0.7621	
Result of type I IFN gene signature test									0.7158
LOW	6/ 30 (20.0)	20.0	6/ 31 (19.4)	19.4	1.03 (0.37, 2.85)	0.9495	0.65 (-20.54, 21.83)	0.9524	
HIGH	25/150 (16.7)	16.7	30/151 (19.9)	19.7	0.84 (0.52, 1.36)	0.4734	-2.98 (-12.10, 6.13)	0.5214	
Age (years)									0.9173
<= 65	30/175 (17.1)	17.2	36/181 (19.9)	19.7	0.86 (0.56, 1.34)	0.5058	-2.57 (-11.02, 5.89)	0.5519	
> 65	1/ 5 (20.0)	20.0	0/ 1 (0.0)	0.0	1.00 (0.06, 15.99)	1.0000	20.00 (-84.53, 124.53)	0.7077	
Sex									0.5366
male	0/ 12 (0.0)	0.0	1/ 12 (8.3)	8.3	0.33 (0.01, 7.45)	0.4883	-8.33 (-37.28, 20.61)	0.5726	
female	31/168 (18.5)	18.5	35/170 (20.6)	20.5	0.90 (0.58, 1.38)	0.6207	-1.94 (-10.79, 6.90)	0.6663	
Race									0.3749
White	23/110 (20.9)	21.1	20/107 (18.7)	18.5	1.12 (0.65, 1.91)	0.6824	2.60 (-8.64, 13.84)	0.6504	
Black or African American	1/ 17 (5.9)	5.9	7/ 25 (28.0)	28.0	0.21 (0.03, 1.56)	0.1268	-22.12 (-46.73, 2.49)	0.0781	
Asian	5/ 30 (16.7)	16.7	7/ 30 (23.3)	23.3	0.71 (0.25, 2.00)	0.5220	-6.67 (-28.08, 14.75)	0.5418	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	1/ 11 (9.1)	9.1	2/ 11 (18.2)	18.2	0.50 (0.05, 4.75)	0.5460	-9.09 (-44.33, 26.15)	0.6131	
Ethnicity									0.4952
Hispanic/Latino	8/ 54 (14.8)	14.7	12/ 54 (22.2)	22.3	0.67 (0.30, 1.50)	0.3272	-7.66 (-23.77, 8.44)	0.3512	
Non-hispanic/Latino	22/118 (18.6)	18.7	24/120 (20.0)	19.9	0.93 (0.55, 1.57)	0.7912	-1.21 (-11.84, 9.42)	0.8239	
Geographic region									0.0747
EU	7/ 51 (13.7)	13.7	2/ 46 (4.3)	4.3	3.16 (0.69, 14.44)	0.1383	9.38 (-3.45, 22.21)	0.1519	
non-EU	24/129 (18.6)	18.6	34/136 (25.0)	24.9	0.74 (0.47, 1.18)	0.2117	-6.36 (-16.76, 4.04)	0.2307	
Onset of disease									0.5518
Paediatric	2/ 14 (14.3)	14.3	1/ 12 (8.3)	8.3	1.71 (0.18, 16.65)	0.6421	5.95 (-25.06, 36.97)	0.7068	
Adult	29/166 (17.5)	17.5	35/170 (20.6)	20.6	0.85 (0.54, 1.32)	0.4677	-3.08 (-11.89, 5.74)	0.4936	
ADA result									0.4065
Negative	29/172 (16.9)	17.0	33/162 (20.4)	20.2	0.83 (0.53, 1.30)	0.4105	-3.19 (-11.97, 5.59)	0.4760	
Positive (At any time)	2/ 8 (25.0)	25.0	3/ 20 (15.0)	15.0	1.67 (0.34, 8.18)	0.5290	10.00 (-27.20, 47.20)	0.5983	
BMI (kg/m2) at enrolment									0.1009
< 30	22/125 (17.6)	17.6	21/134 (15.7)	15.4	1.12 (0.65, 1.94)	0.6770	2.19 (-7.54, 11.92)	0.6588	
>= 30	9/ 55 (16.4)	16.1	15/ 48 (31.3)	30.9	0.52 (0.25, 1.09)	0.0824	-14.81 (-32.33, 2.70)	0.0974	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.3909
All negative/normal	12/ 58 (20.7)	20.6	22/ 81 (27.2)	27.1	0.76 (0.41, 1.41)	0.3876	-6.43 (-21.50, 8.64)	0.4029	
At least one positive/abnormal	19/122 (15.6)	15.2	14/101 (13.9)	13.7	1.12 (0.59, 2.13)	0.7205	1.55 (-8.43, 11.54)	0.7605	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Cardiorespiratory
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 52	Number of subjects with events, n (%)	1 (0.6)	1 (0.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.24 (0.07, 22.21)	
	p-value	0.8831	
	Odds Ratio (95% CI)	1.24 (0.07, 21.21)	
	p-value	0.8812	
	Risk Difference (95% CI)	0.11 (-1.39, 1.62)	
	p-value	0.8813	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.01 (0.06, 16.04)	
	p-value	0.9937	
	Odds Ratio (95% CI)	1.01 (0.06, 16.29)	
	p-value	0.9937	
	Risk Difference (95% CI)	0.01 (-1.52, 1.53)	
	p-value	0.9937	
	CMH approach		
	Response rate	0.6	0.5
	Difference in response rates (95% CI)	0.04 (-4.60, 4.69)	
	p-value	0.9850	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Cardiorespiratory - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Anifrolumab 300mg (N=180) Response rate	Placebo (N=182) n/ N (%)	Placebo (N=182) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE		0.00 (-10.98, 10.98)	1.0000	
>= 10 points	1/126 (0.8)	0.8	1/130 (0.8)	0.8	1.03 (0.07, 16.32)	0.9823	0.07 (-5.18, 5.33)	0.9784	
OCS dose at baseline									0.3161
<10 mg/day	1/ 93 (1.1)	1.1	0/ 99 (0.0)	0.0	3.19 (0.13, 77.38)	0.4756	1.11 (-6.17, 8.39)	0.7646	
>=10 mg/day	0/ 87 (0.0)	0.0	1/ 83 (1.2)	1.2	0.32 (0.01, 7.70)	0.4812	-1.20 (-6.19, 3.79)	0.6361	
Result of type I IFN gene signature test									0.3434
LOW	0/ 30 (0.0)	0.0	1/ 31 (3.2)	3.2	0.34 (0.01, 8.13)	0.5085	-3.23 (-16.19, 9.74)	0.6257	
HIGH	1/150 (0.7)	0.7	0/151 (0.0)	0.0	3.02 (0.12, 73.54)	0.4975	0.71 (-4.22, 5.64)	0.7783	
Age (years)									NE
<= 65	1/175 (0.6)	0.6	1/181 (0.6)	0.5	1.03 (0.07, 16.41)	0.9809	0.07 (-4.65, 4.79)	0.9764	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
female	1/168 (0.6)	0.6	1/170 (0.6)	0.6	1.01 (0.06, 16.05)	0.9933	0.04 (-4.89, 4.98)	0.9860	
Race									0.3389
White	1/110 (0.9)	1.0	0/107 (0.0)	0.0	2.92 (0.12, 70.87)	0.5104	0.95 (-5.06, 6.96)	0.7560	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE		0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	1/ 11 (9.1)	9.1	0.33 (0.02, 7.39)	0.4872	-9.09 (-40.11, 21.93)	0.5657	
Ethnicity									NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE		0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	1/118 (0.8)	0.9	1/120 (0.8)	0.8	1.02 (0.06, 16.07)	0.9905	0.07 (-6.71, 6.86)	0.9833	
Geographic region									0.3737
EU	1/ 51 (2.0)	2.0	0/ 46 (0.0)	0.0	2.71 (0.11, 64.96)	0.5382	1.96 (-6.46, 10.38)	0.6481	
non-EU	0/129 (0.0)	0.0	1/136 (0.7)	0.7	0.35 (0.01, 8.55)	0.5206	-0.70 (-6.71, 5.32)	0.8204	
Onset of disease									NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-24.92, 24.92)	1.0000	
Adult	1/166 (0.6)	0.6	1/170 (0.6)	0.6	1.02 (0.06, 16.24)	0.9865	0.05 (-4.91, 5.02)	0.9832	
ADA result									0.5701
Negative	1/172 (0.6)	0.6	0/162 (0.0)	0.0	2.83 (0.12, 68.89)	0.5237	0.62 (-4.28, 5.52)	0.8047	
Positive (At any time)	0/ 8 (0.0)	0.0	1/ 20 (5.0)	5.0	0.78 (0.03, 17.33)	0.8739	-5.00 (-34.61, 24.61)	0.7407	
BMI (kg/m2) at enrolment									NE
< 30	1/125 (0.8)	0.8	1/134 (0.7)	0.8	1.07 (0.07, 16.96)	0.9606	0.00 (-6.27, 6.28)	0.9991	
>= 30	0/ 55 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-11.37, 11.37)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.4647
All negative/normal	0/ 58 (0.0)	0.0	1/ 81 (1.2)	1.2	0.46 (0.02, 11.17)	0.6357	-1.22 (-10.48, 8.03)	0.7956	
At least one positive/abnormal	1/122 (0.8)	0.8	0/101 (0.0)	0.0	2.49 (0.10, 60.41)	0.5755	0.85 (-4.79, 6.49)	0.7684	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Gastrointestinal
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 52	Number of subjects with events, n (%)	0 (0.0)	2 (1.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.00 (NE, NE)	
	p-value	NE	
	Odds Ratio (95% CI)	0.00 (NE, NE)	
	p-value	NE	
	Risk Difference (95% CI)	-1.14 (-2.68, 0.41)	
	p-value	0.1487	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.20 (0.01, 4.18)	
	p-value	0.3011	
	Odds Ratio (95% CI)	0.20 (0.01, 4.20)	
	p-value	0.3000	
	Risk Difference (95% CI)	-1.10 (-2.61, 0.42)	
	p-value	0.1550	
	CMH approach		
	Response rate	0.0	1.1
	Difference in response rates (95% CI)	-1.13 (-5.74, 3.47)	
	p-value	0.6293	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Gastrointestinal - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 54 (0.0)	0.0	2/ 52 (3.8)	3.9	0.19 (0.01, 3.92)	0.2841	-3.87 (-15.68, 7.94)	0.5206	
>= 10 points	0/126 (0.0)	0.0	0/130 (0.0)	0.0	NE		0.00 (-4.90, 4.90)	1.0000	
OCS dose at baseline									0.9624
<10 mg/day	0/ 93 (0.0)	0.0	1/ 99 (1.0)	1.1	0.35 (0.01, 8.60)	0.5239	-1.07 (-8.27, 6.13)	0.7709	
>=10 mg/day	0/ 87 (0.0)	0.0	1/ 83 (1.2)	1.2	0.32 (0.01, 7.70)	0.4812	-1.20 (-6.19, 3.79)	0.6361	
Result of type I IFN gene signature test									NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE		0.00 (-11.73, 11.73)	1.0000	
HIGH	0/150 (0.0)	0.0	2/151 (1.3)	1.4	0.20 (0.01, 4.16)	0.2995	-1.37 (-6.37, 3.64)	0.5929	
Age (years)									NE
<= 65	0/175 (0.0)	0.0	2/181 (1.1)	1.2	0.21 (0.01, 4.28)	0.3079	-1.15 (-5.84, 3.53)	0.6291	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
female	0/168 (0.0)	0.0	2/170 (1.2)	1.2	0.20 (0.01, 4.18)	0.3012	-1.18 (-6.08, 3.71)	0.6353	
Race									0.8716
White	0/110 (0.0)	0.0	0/107 (0.0)	0.0	NE		0.00 (-5.75, 5.75)	1.0000	
Black or African American	0/ 17 (0.0)	0.0	1/ 25 (4.0)	4.0	0.48 (0.02, 11.17)	0.6486	-4.00 (-22.36, 14.36)	0.6694	
Asian	0/ 30 (0.0)	0.0	1/ 30 (3.3)	3.3	0.33 (0.01, 7.87)	0.4958	-3.33 (-16.52, 9.85)	0.6203	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-28.41, 28.41)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE		0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	0/118 (0.0)	0.0	2/120 (1.7)	1.8	0.20 (0.01, 4.19)	0.3022	-1.82 (-8.53, 4.89)	0.5948	
Geographic region									NE
EU	0/ 51 (0.0)	0.0	0/ 46 (0.0)	0.0	NE		0.00 (-7.65, 7.65)	1.0000	
non-EU	0/129 (0.0)	0.0	2/136 (1.5)	1.5	0.21 (0.01, 4.35)	0.3134	-1.54 (-7.66, 4.58)	0.6225	
Onset of disease									0.9416
Paediatric	0/ 14 (0.0)	0.0	1/ 12 (8.3)	8.3	0.29 (0.01, 6.50)	0.4344	-8.33 (-35.88, 19.21)	0.5532	
Adult	0/166 (0.0)	0.0	1/170 (0.6)	0.6	0.34 (0.01, 8.32)	0.5094	-0.61 (-5.45, 4.23)	0.8049	
ADA result									NE
Negative	0/172 (0.0)	0.0	2/162 (1.2)	1.3	0.19 (0.01, 3.90)	0.2801	-1.29 (-6.26, 3.68)	0.6108	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/125 (0.0)	0.0	2/134 (1.5)	1.4	0.21 (0.01, 4.42)	0.3185	-1.44 (-7.62, 4.73)	0.6471	
>= 30	0/ 55 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-11.37, 11.37)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.8223
All negative/normal	0/ 58 (0.0)	0.0	1/ 81 (1.2)	1.4	0.46 (0.02, 11.17)	0.6357	-1.42 (-10.75, 7.91)	0.7650	
At least one positive/abnormal	0/122 (0.0)	0.0	1/101 (1.0)	1.0	0.28 (0.01, 6.71)	0.4295	-1.01 (-6.64, 4.62)	0.7253	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Ophthalmic
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 52	Number of subjects with events, n (%)	0 (0.0)	1 (0.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.00 (NE, NE)	
	p-value	NE	
	Odds Ratio (95% CI)	0.00 (NE, NE)	
	p-value	NE	
	Risk Difference (95% CI)	-0.52 (-1.56, 0.53)	
	p-value	0.3309	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.34 (0.01, 8.22)	
	p-value	0.5045	
	Odds Ratio (95% CI)	0.34 (0.01, 8.28)	
	p-value	0.5041	
	Risk Difference (95% CI)	-0.55 (-1.62, 0.52)	
	p-value	0.3160	
	CMH approach		
	Response rate	0.0	0.5
	Difference in response rates (95% CI)	-0.52 (-5.05, 4.01)	
	p-value	0.8226	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Ophthalmic - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE		0.00 (-10.98, 10.98)	1.0000	
>= 10 points	0/126 (0.0)	0.0	1/130 (0.8)	0.7	0.34 (0.01, 8.36)	0.5120	-0.73 (-5.81, 4.34)	0.7771	
OCS dose at baseline									NE
<10 mg/day	0/ 93 (0.0)	0.0	1/ 99 (1.0)	1.0	0.35 (0.01, 8.60)	0.5239	-0.98 (-8.20, 6.24)	0.7907	
>=10 mg/day	0/ 87 (0.0)	0.0	0/ 83 (0.0)	0.0	NE		0.00 (-4.46, 4.46)	1.0000	
Result of type I IFN gene signature test									NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE		0.00 (-11.73, 11.73)	1.0000	
HIGH	0/150 (0.0)	0.0	1/151 (0.7)	0.6	0.34 (0.01, 8.17)	0.5026	-0.62 (-5.52, 4.28)	0.8031	
Age (years)									NE
<= 65	0/175 (0.0)	0.0	1/181 (0.6)	0.5	0.34 (0.01, 8.40)	0.5134	-0.52 (-5.12, 4.08)	0.8245	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
female	0/168 (0.0)	0.0	1/170 (0.6)	0.6	0.34 (0.01, 8.22)	0.5048	-0.57 (-5.39, 4.26)	0.8173	
Race									NE
White	0/110 (0.0)	0.0	1/107 (0.9)	0.9	0.32 (0.01, 7.87)	0.4890	-0.91 (-6.90, 5.08)	0.7658	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE		0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-28.41, 28.41)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE		0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	0/118 (0.0)	0.0	1/120 (0.8)	0.8	0.34 (0.01, 8.24)	0.5063	-0.77 (-7.37, 5.83)	0.8189	
Geographic region									NE
EU	0/ 51 (0.0)	0.0	1/ 46 (2.2)	2.2	0.30 (0.01, 7.22)	0.4591	-2.17 (-10.75, 6.40)	0.6192	
non-EU	0/129 (0.0)	0.0	0/136 (0.0)	0.0	NE		0.00 (-5.90, 5.90)	1.0000	
Onset of disease									NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-24.92, 24.92)	1.0000	
Adult	0/166 (0.0)	0.0	1/170 (0.6)	0.6	0.34 (0.01, 8.32)	0.5094	-0.57 (-5.43, 4.28)	0.8171	
ADA result									NE
Negative	0/172 (0.0)	0.0	1/162 (0.6)	0.6	0.31 (0.01, 7.65)	0.4772	-0.58 (-5.47, 4.30)	0.8151	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/125 (0.0)	0.0	1/134 (0.7)	0.7	0.36 (0.01, 8.69)	0.5272	-0.73 (-6.84, 5.39)	0.8162	
>= 30	0/ 55 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-11.37, 11.37)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE		0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	0/122 (0.0)	0.0	1/101 (1.0)	1.0	0.28 (0.01, 6.71)	0.4295	-0.97 (-6.67, 4.74)	0.7393	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Renal
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 52	Number of subjects with events, n (%)	5 (2.8)	9 (4.9)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.55 (0.19, 1.58)	
	p-value	0.2628	
	Odds Ratio (95% CI)	0.52 (0.17, 1.62)	
	p-value	0.2601	
	Risk Difference (95% CI)	-2.27 (-6.17, 1.62)	
	p-value	0.2528	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.56 (0.19, 1.64)	
	p-value	0.2924	
	Odds Ratio (95% CI)	0.55 (0.18, 1.67)	
	p-value	0.2914	
	Risk Difference (95% CI)	-2.17 (-6.13, 1.79)	
	p-value	0.2835	
	CMH approach		
	Response rate	2.7	5.0
	Difference in response rates (95% CI)	-2.27 (-7.99, 3.45)	
	p-value	0.4367	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Renal - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE		0.00 (-10.98, 10.98)	1.0000	
>= 10 points	5/126 (4.0)	3.9	9/130 (6.9)	7.1	0.57 (0.20, 1.66)	0.3059	-3.21 (-10.30, 3.87)	0.3743	
OCS dose at baseline									0.6550
<10 mg/day	1/ 93 (1.1)	1.1	3/ 99 (3.0)	2.9	0.35 (0.04, 3.35)	0.3658	-1.82 (-9.70, 6.06)	0.6506	
>=10 mg/day	4/ 87 (4.6)	4.6	6/ 83 (7.2)	7.2	0.64 (0.19, 2.17)	0.4705	-2.63 (-10.75, 5.48)	0.5251	
Result of type I IFN gene signature test									NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE		0.00 (-11.73, 11.73)	1.0000	
HIGH	5/150 (3.3)	3.3	9/151 (6.0)	6.0	0.56 (0.19, 1.63)	0.2869	-2.73 (-9.18, 3.72)	0.4071	
Age (years)									NE
<= 65	5/175 (2.9)	2.8	9/181 (5.0)	5.0	0.57 (0.20, 1.68)	0.3116	-2.24 (-8.04, 3.57)	0.4507	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									0.4235
male	0/ 12 (0.0)	0.0	2/ 12 (16.7)	16.7	0.20 (0.01, 3.77)	0.2829	-16.67 (-47.49, 14.16)	0.2893	
female	5/168 (3.0)	2.9	7/170 (4.1)	4.3	0.72 (0.23, 2.23)	0.5726	-1.37 (-7.29, 4.56)	0.6514	
Race									0.1657
White	1/110 (0.9)	1.0	5/107 (4.7)	4.6	0.19 (0.02, 1.64)	0.1321	-3.60 (-10.62, 3.42)	0.3148	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.13, 17.13)	1.0000	
Asian	1/ 30 (3.3)	3.3	3/ 30 (10.0)	10.0	0.33 (0.04, 3.03)	0.3290	-6.67 (-22.90, 9.57)	0.4210	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	3/ 11 (27.3)	27.3	1/ 11 (9.1)	9.1	3.00 (0.37, 24.58)	0.3059	18.18 (-18.35, 54.72)	0.3294	
Ethnicity									0.3389
Hispanic/Latino	3/ 54 (5.6)	5.2	3/ 54 (5.6)	6.0	1.00 (0.21, 4.74)	1.0000	-0.84 (-13.89, 12.22)	0.9000	
Non-hispanic/Latino	2/118 (1.7)	1.8	6/120 (5.0)	4.9	0.34 (0.07, 1.65)	0.1796	-3.16 (-10.76, 4.45)	0.4161	
Geographic region									0.3841
EU	0/ 51 (0.0)	0.0	2/ 46 (4.3)	4.3	0.18 (0.01, 3.67)	0.2655	-4.35 (-13.72, 5.03)	0.3633	
non-EU	5/129 (3.9)	3.8	7/136 (5.1)	5.2	0.75 (0.25, 2.31)	0.6203	-1.46 (-8.81, 5.88)	0.6967	
Onset of disease									0.5586
Paediatric	2/ 14 (14.3)	14.3	2/ 12 (16.7)	16.7	0.86 (0.14, 5.20)	0.8668	-2.38 (-35.16, 30.40)	0.8868	
Adult	3/166 (1.8)	1.8	7/170 (4.1)	4.2	0.44 (0.12, 1.67)	0.2268	-2.40 (-8.16, 3.36)	0.4138	
ADA result									0.8196
Negative	5/172 (2.9)	2.9	7/162 (4.3)	4.3	0.67 (0.22, 2.08)	0.4908	-1.47 (-7.47, 4.53)	0.6306	
Positive (At any time)	0/ 8 (0.0)	0.0	2/ 20 (10.0)	10.0	0.47 (0.02, 8.78)	0.6107	-10.00 (-40.56, 20.56)	0.5212	
BMI (kg/m2) at enrolment									0.1571
< 30	4/125 (3.2)	3.2	4/134 (3.0)	3.0	1.07 (0.27, 4.19)	0.9204	0.20 (-6.89, 7.30)	0.9551	
>= 30	1/ 55 (1.8)	1.8	5/ 48 (10.4)	10.7	0.17 (0.02, 1.44)	0.1052	-8.82 (-22.64, 4.99)	0.2106	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.7744
All negative/normal	1/ 58 (1.7)	1.9	2/ 81 (2.5)	2.2	0.70 (0.06, 7.52)	0.7671	-0.37 (-10.27, 9.52)	0.9412	
At least one positive/abnormal	4/122 (3.3)	3.4	7/101 (6.9)	6.8	0.47 (0.14, 1.57)	0.2214	-3.39 (-11.12, 4.34)	0.3898	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Haematological
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 52	Number of subjects with events, n (%)	1 (0.6)	0 (0.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	NE	
	p-value		
	Odds Ratio (95% CI)	NE	
	p-value		
	Risk Difference (95% CI)	0.54 (-0.53, 1.61)	
	p-value	0.3233	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	3.03 (0.12, 73.97)	
	p-value	0.4959	
	Odds Ratio (95% CI)	3.05 (0.12, 75.37)	
	p-value	0.4956	
	Risk Difference (95% CI)	0.56 (-0.53, 1.64)	
	p-value	0.3160	
	CMH approach		
	Response rate	0.5	0.0
	Difference in response rates (95% CI)	0.54 (-3.97, 5.05)	
	p-value	0.8146	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Haematological - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	1/ 54 (1.9)	1.8	0/ 52 (0.0)	0.0	2.89 (0.12, 69.40)	0.5127	1.84 (-9.53, 13.22)	0.7510	
>= 10 points	0/126 (0.0)	0.0	0/130 (0.0)	0.0	NE		0.00 (-4.90, 4.90)	1.0000	
OCS dose at baseline									NE
<10 mg/day	1/ 93 (1.1)	1.0	0/ 99 (0.0)	0.0	3.19 (0.13, 77.38)	0.4756	1.02 (-6.17, 8.21)	0.7810	
>=10 mg/day	0/ 87 (0.0)	0.0	0/ 83 (0.0)	0.0	NE		0.00 (-4.46, 4.46)	1.0000	
Result of type I IFN gene signature test									NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE		0.00 (-11.73, 11.73)	1.0000	
HIGH	1/150 (0.7)	0.6	0/151 (0.0)	0.0	3.02 (0.12, 73.54)	0.4975	0.65 (-4.23, 5.53)	0.7941	
Age (years)									NE
<= 65	1/175 (0.6)	0.5	0/181 (0.0)	0.0	3.10 (0.13, 75.64)	0.4872	0.55 (-4.04, 5.14)	0.8144	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
female	1/168 (0.6)	0.6	0/170 (0.0)	0.0	3.04 (0.12, 73.99)	0.4956	0.59 (-4.22, 5.40)	0.8092	
Race									NE
White	0/110 (0.0)	0.0	0/107 (0.0)	0.0	NE		0.00 (-5.75, 5.75)	1.0000	
Black or African American	1/ 17 (5.9)	5.9	0/ 25 (0.0)	0.0	4.33 (0.19, 100.49)	0.3606	5.88 (-13.49, 25.26)	0.5518	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE		0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-28.41, 28.41)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE		0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	1/118 (0.8)	0.8	0/120 (0.0)	0.0	3.05 (0.13, 74.13)	0.4933	0.79 (-5.79, 7.37)	0.8131	
Geographic region									NE
EU	0/ 51 (0.0)	0.0	0/ 46 (0.0)	0.0	NE		0.00 (-7.65, 7.65)	1.0000	
non-EU	1/129 (0.8)	0.7	0/136 (0.0)	0.0	3.16 (0.13, 76.91)	0.4796	0.73 (-5.27, 6.74)	0.8107	
Onset of disease									NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-24.92, 24.92)	1.0000	
Adult	1/166 (0.6)	0.6	0/170 (0.0)	0.0	3.07 (0.13, 74.87)	0.4910	0.58 (-4.25, 5.42)	0.8137	
ADA result									NE
Negative	1/172 (0.6)	0.6	0/162 (0.0)	0.0	2.83 (0.12, 68.89)	0.5237	0.59 (-4.28, 5.45)	0.8133	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/125 (0.0)	0.0	0/134 (0.0)	0.0	NE		0.00 (-5.98, 5.98)	1.0000	
>= 30	1/ 55 (1.8)	1.4	0/ 48 (0.0)	0.0	2.63 (0.11, 62.97)	0.5517	1.44 (-10.12, 13.01)	0.8067	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									NE
All negative/normal	1/ 58 (1.7)	1.6	0/ 81 (0.0)	0.0	4.17 (0.17, 100.57)	0.3793	1.56 (-7.82, 10.94)	0.7446	
At least one positive/abnormal	0/122 (0.0)	0.0	0/101 (0.0)	0.0	NE		0.00 (-5.42, 5.42)	1.0000	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Major clinical response at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 52	Number of subjects with events, n (%)	37 (20.6)	20 (11.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.89 (1.15, 3.11)	
	p-value	0.0114	
	Odds Ratio (95% CI)	2.19 (1.20, 4.01)	
	p-value	0.0105	
	Risk Difference (95% CI)	9.77 (2.44, 17.09)	
	p-value	0.0090	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.87 (1.13, 3.09)	
	p-value	0.0148	
	Odds Ratio (95% CI)	2.10 (1.16, 3.78)	
	p-value	0.0137	
	Risk Difference (95% CI)	9.57 (2.12, 17.02)	
	p-value	0.0118	
	CMH approach		
	Response rate	20.8	10.9
	Difference in response rates (95% CI)	9.86 (1.89, 17.82)	
	p-value	0.0153	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Major clinical response at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.6226
< 10 points	15/ 54 (27.8)	27.8	9/ 52 (17.3)	17.3	1.60 (0.77, 3.34)	0.2061	10.57 (-6.21, 27.35)	0.2171	
>= 10 points	22/126 (17.5)	17.8	11/130 (8.5)	8.3	2.06 (1.04, 4.08)	0.0371	9.49 (0.59, 18.39)	0.0367	
OCS dose at baseline									0.8236
<10 mg/day	24/ 93 (25.8)	26.0	14/ 99 (14.1)	14.1	1.82 (1.01, 3.31)	0.0476	11.88 (-0.07, 23.82)	0.0513	
>=10 mg/day	13/ 87 (14.9)	14.9	6/ 83 (7.2)	7.2	2.07 (0.82, 5.18)	0.1216	7.71 (-2.26, 17.69)	0.1295	
Result of type I IFN gene signature test									0.9466
LOW	7/ 30 (23.3)	23.3	4/ 31 (12.9)	12.9	1.81 (0.59, 5.55)	0.3004	10.43 (-10.19, 31.05)	0.3215	
HIGH	30/150 (20.0)	20.3	16/151 (10.6)	10.5	1.89 (1.07, 3.31)	0.0270	9.74 (1.12, 18.35)	0.0267	
Age (years)									NE
<= 65	37/175 (21.1)	21.4	20/181 (11.0)	11.0	1.91 (1.16, 3.16)	0.0114	10.42 (2.33, 18.50)	0.0115	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									0.9526
male	2/ 12 (16.7)	16.7	1/ 12 (8.3)	8.3	2.00 (0.21, 19.23)	0.5483	8.33 (-24.65, 41.32)	0.6205	
female	35/168 (20.8)	21.1	19/170 (11.2)	11.1	1.86 (1.11, 3.12)	0.0181	10.02 (1.76, 18.28)	0.0175	
Race									0.2102
White	19/110 (17.3)	17.3	12/107 (11.2)	11.5	1.54 (0.79, 3.02)	0.2078	5.80 (-4.39, 15.98)	0.2646	
Black or African American	4/ 17 (23.5)	23.5	2/ 25 (8.0)	8.0	2.94 (0.60, 14.30)	0.1813	15.53 (-9.85, 40.90)	0.2303	
Asian	7/ 30 (23.3)	23.3	3/ 30 (10.0)	10.0	2.33 (0.67, 8.18)	0.1855	13.33 (-6.91, 33.58)	0.1968	
American Indian or Alaska Native	1/ 4 (25.0)	25.0	1/ 1 (100.0)	100.0	0.25 (0.05, 1.36)	0.1094	-75.00 (-182.10, 32.10)	0.1699	
Other	3/ 11 (27.3)	27.3	1/ 11 (9.1)	9.1	3.00 (0.37, 24.58)	0.3059	18.18 (-18.35, 54.72)	0.3294	
Ethnicity									0.9177
Hispanic/Latino	14/ 54 (25.9)	26.0	8/ 54 (14.8)	14.7	1.75 (0.80, 3.83)	0.1610	11.32 (-4.91, 27.56)	0.1716	
Non-hispanic/Latino	20/118 (16.9)	17.2	11/120 (9.2)	9.3	1.85 (0.93, 3.69)	0.0810	7.94 (-1.70, 17.59)	0.1066	
Geographic region									0.5927
EU	10/ 51 (19.6)	19.6	6/ 46 (13.0)	13.0	1.50 (0.59, 3.81)	0.3905	6.56 (-8.95, 22.08)	0.4070	
non-EU	27/129 (20.9)	21.3	14/136 (10.3)	10.1	2.03 (1.12, 3.70)	0.0202	11.17 (1.64, 20.71)	0.0216	
Onset of disease									0.7618
Paediatric	3/ 14 (21.4)	21.4	1/ 12 (8.3)	8.3	2.57 (0.31, 21.59)	0.3843	13.10 (-19.13, 45.32)	0.4257	
Adult	34/166 (20.5)	20.7	19/170 (11.2)	11.1	1.83 (1.09, 3.08)	0.0222	9.53 (1.19, 17.87)	0.0251	
ADA result									0.3700
Negative	35/172 (20.3)	20.6	19/162 (11.7)	11.7	1.74 (1.04, 2.91)	0.0362	8.84 (0.47, 17.20)	0.0385	
Positive (At any time)	2/ 8 (25.0)	25.0	1/ 20 (5.0)	5.0	5.00 (0.52, 47.73)	0.1621	20.00 (-15.74, 55.74)	0.2727	
BMI (kg/m2) at enrolment									0.9428
< 30	28/125 (22.4)	22.5	16/134 (11.9)	12.0	1.88 (1.07, 3.30)	0.0287	10.49 (0.71, 20.26)	0.0355	
>= 30	9/ 55 (16.4)	16.9	4/ 48 (8.3)	9.0	1.96 (0.65, 5.97)	0.2344	7.91 (-7.31, 23.13)	0.3084	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.4106
All negative/normal	14/ 58 (24.1)	24.3	8/ 81 (9.9)	10.1	2.44 (1.10, 5.44)	0.0287	14.27 (0.21, 28.34)	0.0467	
At least one positive/abnormal	23/122 (18.9)	18.9	12/101 (11.9)	12.1	1.59 (0.83, 3.03)	0.1614	6.76 (-3.24, 16.76)	0.1853	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Partial clinical response at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 52	Number of subjects with events, n (%)	84 (46.7)	70 (38.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.22 (0.96, 1.56)	
	p-value	0.1070	
	Odds Ratio (95% CI)	1.41 (0.93, 2.15)	
	p-value	0.1056	
	Risk Difference (95% CI)	8.46 (-1.73, 18.64)	
	p-value	0.1036	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.21 (0.95, 1.54)	
	p-value	0.1161	
	Odds Ratio (95% CI)	1.40 (0.92, 2.13)	
	p-value	0.1148	
	Risk Difference (95% CI)	8.21 (-1.95, 18.36)	
	p-value	0.1132	
	CMH approach		
	Response rate	46.8	38.4
	Difference in response rates (95% CI)	8.39 (-1.74, 18.53)	
	p-value	0.1046	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Partial clinical response at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.7639
< 10 points	25/ 54 (46.3)	46.3	21/ 52 (40.4)	40.3	1.15 (0.74, 1.78)	0.5407	5.99 (-12.79, 24.77)	0.5316	
>= 10 points	59/126 (46.8)	47.0	49/130 (37.7)	37.6	1.24 (0.93, 1.66)	0.1410	9.40 (-2.65, 21.44)	0.1263	
OCS dose at baseline									0.9585
<10 mg/day	46/ 93 (49.5)	49.5	40/ 99 (40.4)	40.5	1.22 (0.89, 1.68)	0.2087	8.99 (-5.01, 22.99)	0.2083	
>=10 mg/day	38/ 87 (43.7)	43.7	30/ 83 (36.1)	36.1	1.21 (0.83, 1.75)	0.3191	7.53 (-7.18, 22.24)	0.3155	
Result of type I IFN gene signature test									0.6736
LOW	16/ 30 (53.3)	53.3	15/ 31 (48.4)	48.4	1.10 (0.67, 1.81)	0.6995	4.95 (-20.12, 30.02)	0.6990	
HIGH	68/150 (45.3)	45.5	55/151 (36.4)	36.4	1.24 (0.95, 1.64)	0.1180	9.09 (-1.99, 20.18)	0.1078	
Age (years)									0.6015
<= 65	81/175 (46.3)	46.4	70/181 (38.7)	38.5	1.20 (0.94, 1.53)	0.1476	7.86 (-2.37, 18.10)	0.1322	
> 65	3/ 5 (60.0)	60.0	0/ 1 (0.0)	0.0	2.33 (0.19, 28.25)	0.5055	60.00 (-45.43, 165.43)	0.2647	
Sex									0.9151
male	7/ 12 (58.3)	58.3	6/ 12 (50.0)	50.0	1.17 (0.56, 2.45)	0.6834	8.33 (-31.52, 48.18)	0.6819	
female	77/168 (45.8)	46.0	64/170 (37.6)	37.5	1.22 (0.94, 1.57)	0.1288	8.47 (-1.98, 18.93)	0.1122	
Race									0.0995
White	48/110 (43.6)	44.0	47/107 (43.9)	43.7	0.99 (0.73, 1.34)	0.9658	0.37 (-12.87, 13.60)	0.9567	
Black or African American	7/ 17 (41.2)	41.2	5/ 25 (20.0)	20.0	2.06 (0.78, 5.42)	0.1438	21.18 (-7.72, 50.07)	0.1508	
Asian	15/ 30 (50.0)	50.0	8/ 30 (26.7)	26.7	1.88 (0.94, 3.75)	0.0754	23.33 (-0.87, 47.54)	0.0589	
American Indian or Alaska Native	2/ 4 (50.0)	50.0	1/ 1 (100.0)	100.0	0.50 (0.19, 1.33)	0.1657	-50.00 (-157.80, 57.80)	0.3633	
Other	7/ 11 (63.6)	63.6	4/ 11 (36.4)	36.4	1.75 (0.71, 4.31)	0.2232	27.27 (-13.67, 68.22)	0.1917	
Ethnicity									0.8761
Hispanic/Latino	29/ 54 (53.7)	53.4	23/ 54 (42.6)	42.3	1.26 (0.85, 1.87)	0.2519	11.13 (-7.57, 29.83)	0.2434	
Non-hispanic/Latino	50/118 (42.4)	42.5	42/120 (35.0)	35.1	1.21 (0.88, 1.67)	0.2447	7.36 (-5.05, 19.77)	0.2454	
Geographic region									0.3084
EU	27/ 51 (52.9)	52.9	24/ 46 (52.2)	52.2	1.01 (0.69, 1.48)	0.9398	0.77 (-19.14, 20.67)	0.9398	
non-EU	57/129 (44.2)	44.4	46/136 (33.8)	33.6	1.31 (0.96, 1.77)	0.0857	10.80 (-0.90, 22.50)	0.0703	
Onset of disease									0.2807
Paediatric	6/ 14 (42.9)	42.9	2/ 12 (16.7)	16.7	2.57 (0.63, 10.45)	0.1868	26.19 (-9.55, 61.94)	0.1510	
Adult	78/166 (47.0)	47.2	68/170 (40.0)	39.9	1.17 (0.92, 1.50)	0.1976	7.23 (-3.32, 17.79)	0.1791	
ADA result									0.8146
Negative	82/172 (47.7)	47.7	65/162 (40.1)	40.1	1.19 (0.93, 1.52)	0.1673	7.65 (-2.96, 18.27)	0.1576	
Positive (At any time)	2/ 8 (25.0)	25.0	5/ 20 (25.0)	25.0	1.00 (0.24, 4.14)	1.0000	0.00 (-38.26, 38.26)	1.0000	
BMI (kg/m2) at enrolment									0.4870
< 30	61/125 (48.8)	48.6	51/134 (38.1)	38.3	1.28 (0.97, 1.70)	0.0828	10.31 (-1.65, 22.26)	0.0910	
>= 30	23/ 55 (41.8)	42.5	19/ 48 (39.6)	39.5	1.06 (0.66, 1.69)	0.8182	3.02 (-16.27, 22.31)	0.7588	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.4977
All negative/normal	28/ 58 (48.3)	48.8	35/ 81 (43.2)	42.9	1.12 (0.78, 1.61)	0.5517	5.86 (-10.92, 22.64)	0.4935	
At least one positive/abnormal	56/122 (45.9)	45.8	35/101 (34.7)	35.1	1.32 (0.95, 1.84)	0.0949	10.67 (-2.13, 23.48)	0.1023	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
>=50% Joint reduction at week 52 (for subjects with at least 6 tender joints and swollen joints at baseline)
Full analysis set

Timepoint		Anifrolumab 300mg (N=71)	Placebo (N=90)
Week 52	Number of subjects with events, n (%)	30 (42.3)	34 (37.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.13 (0.77, 1.67)	
	p-value	0.5267	
	Odds Ratio (95% CI)	1.23 (0.65, 2.32)	
	p-value	0.5266	
	Risk Difference (95% CI)	4.99 (-10.48, 20.46)	
	p-value	0.5271	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.12 (0.77, 1.64)	
	p-value	0.5634	
	Odds Ratio (95% CI)	1.21 (0.64, 2.27)	
	p-value	0.5647	
	Risk Difference (95% CI)	4.48 (-10.77, 19.72)	
	p-value	0.5650	
	CMH approach		
	Response rate	42.2	37.5
	Difference in response rates (95% CI)	4.69 (-10.58, 19.97)	
	p-value	0.5469	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
>=50% Joint reduction at week 52 (for subjects with at least 6 tender joints and swollen joints at baseline) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=71) n/ N (%)	Response rate	Placebo (N=90) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.4990
< 10 points	7/ 21 (33.3)	33.3	9/ 24 (37.5)	37.5	0.89 (0.40, 1.97)	0.7716	-4.17 (-32.51, 24.17)	0.7732	
>= 10 points	23/ 50 (46.0)	45.9	25/ 66 (37.9)	37.6	1.21 (0.79, 1.87)	0.3769	8.29 (-9.92, 26.49)	0.3722	
OCS dose at baseline									0.7116
<10 mg/day	19/ 42 (45.2)	44.8	18/ 47 (38.3)	38.1	1.18 (0.72, 1.93)	0.5073	6.72 (-13.61, 27.05)	0.5172	
>=10 mg/day	11/ 29 (37.9)	37.9	16/ 43 (37.2)	37.2	1.02 (0.56, 1.87)	0.9505	0.72 (-22.24, 23.69)	0.9509	
Result of type I IFN gene signature test									0.3344
LOW	7/ 15 (46.7)	46.7	4/ 15 (26.7)	26.7	1.75 (0.64, 4.75)	0.2720	20.00 (-14.52, 54.52)	0.2562	
HIGH	23/ 56 (41.1)	41.1	30/ 75 (40.0)	40.0	1.03 (0.68, 1.56)	0.9015	1.11 (-15.92, 18.14)	0.8980	
Age (years)									0.6622
<= 65	29/ 69 (42.0)	42.0	34/ 89 (38.2)	37.9	1.10 (0.75, 1.61)	0.6251	4.11 (-11.33, 19.55)	0.6018	
> 65	1/ 2 (50.0)	50.0	0/ 1 (0.0)	0.0	2.00 (0.14, 28.42)	0.6087	50.00 (-68.41, 168.41)	0.4079	
Sex									0.2903
male	0/ 2 (0.0)	0.0	3/ 5 (60.0)	60.0	0.29 (0.02, 3.92)	0.3485	-60.00 (-138.52, 18.52)	0.1342	
female	30/ 69 (43.5)	43.5	31/ 85 (36.5)	36.2	1.19 (0.81, 1.76)	0.3755	7.23 (-8.34, 22.80)	0.3630	
Race									0.7056
White	21/ 52 (40.4)	41.3	25/ 60 (41.7)	40.7	0.97 (0.62, 1.51)	0.8907	0.54 (-17.79, 18.87)	0.9539	
Black or African American	2/ 5 (40.0)	40.0	4/ 13 (30.8)	30.8	1.30 (0.34, 5.01)	0.7029	9.23 (-41.48, 59.94)	0.7213	
Asian	1/ 3 (33.3)	33.3	1/ 8 (12.5)	12.5	2.67 (0.23, 30.40)	0.4296	20.83 (-42.70, 84.36)	0.5204	
American Indian or Alaska Native	3/ 4 (75.0)	75.0	1/ 1 (100.0)	100.0	0.75 (0.43, 1.32)	0.3190	-25.00 (-132.10, 82.10)	0.6473	
Other	0/ 3 (0.0)	0.0	2/ 5 (40.0)	40.0	0.30 (0.02, 4.74)	0.3926	-40.00 (-107.16, 27.16)	0.2431	
Ethnicity									0.7100
Hispanic/Latino	11/ 25 (44.0)	44.0	9/ 24 (37.5)	37.5	1.17 (0.59, 2.32)	0.6450	6.50 (-21.10, 34.10)	0.6444	
Non-hispanic/Latino	16/ 42 (38.1)	38.8	24/ 63 (38.1)	37.9	1.00 (0.61, 1.64)	1.0000	0.91 (-18.28, 20.10)	0.9261	
Geographic region									0.9176
EU	11/ 17 (64.7)	64.7	12/ 20 (60.0)	60.0	1.08 (0.65, 1.78)	0.7678	4.71 (-26.91, 36.32)	0.7705	
non-EU	19/ 54 (35.2)	34.9	22/ 70 (31.4)	31.0	1.12 (0.68, 1.85)	0.6586	3.95 (-13.05, 20.96)	0.6488	
Onset of disease									0.9203
Paediatric	1/ 3 (33.3)	33.3	1/ 3 (33.3)	33.3	1.00 (0.10, 9.61)	1.0000	0.00 (-79.19, 79.19)	1.0000	
Adult	29/ 68 (42.6)	42.5	33/ 87 (37.9)	37.7	1.12 (0.77, 1.65)	0.5508	4.84 (-10.73, 20.41)	0.5425	
ADA result									0.3786
Negative	29/ 69 (42.0)	41.8	33/ 84 (39.3)	39.0	1.07 (0.73, 1.57)	0.7305	2.86 (-12.83, 18.54)	0.7211	
Positive (At any time)	1/ 2 (50.0)	50.0	1/ 6 (16.7)	16.7	3.00 (0.31, 28.84)	0.3414	33.33 (-45.07, 111.73)	0.4047	
BMI (kg/m2) at enrolment									0.9170
< 30	21/ 48 (43.8)	43.8	25/ 65 (38.5)	38.5	1.14 (0.73, 1.77)	0.5699	5.29 (-13.10, 23.68)	0.5730	
>= 30	9/ 23 (39.1)	39.1	9/ 25 (36.0)	36.0	1.09 (0.52, 2.26)	0.8229	3.13 (-24.53, 30.79)	0.8244	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.6069
All negative/normal	11/ 29 (37.9)	37.9	18/ 47 (38.3)	36.6	0.99 (0.55, 1.79)	0.9745	1.31 (-21.75, 24.37)	0.9113	
At least one positive/abnormal	19/ 42 (45.2)	45.2	16/ 43 (37.2)	37.2	1.22 (0.73, 2.03)	0.4539	8.03 (-12.90, 28.96)	0.4521	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
>=50% Joint reduction at week 52 (for subjects with at least 8 tender joints and swollen joints at baseline)
Full analysis set

Timepoint		Anifrolumab 300mg (N=45)	Placebo (N=72)
Week 52	Number of subjects with events, n (%)	17 (37.8)	25 (34.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.16 (0.70, 1.93)	
	p-value	0.5716	
	Odds Ratio (95% CI)	1.26 (0.57, 2.79)	
	p-value	0.5687	
	Risk Difference (95% CI)	5.27 (-12.95, 23.49)	
	p-value	0.5708	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.09 (0.67, 1.78)	
	p-value	0.7363	
	Odds Ratio (95% CI)	1.14 (0.53, 2.47)	
	p-value	0.7375	
	Risk Difference (95% CI)	3.06 (-14.88, 20.99)	
	p-value	0.7384	
	CMH approach		
	Response rate	37.8	33.1
	Difference in response rates (95% CI)	4.66 (-13.63, 22.96)	
	p-value	0.6173	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
>=50% Joint reduction at week 52 (for subjects with at least 8 tender joints and swollen joints at baseline) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=45) n/ N (%)	Response rate	Placebo (N=72) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.7210
< 10 points	5/ 15 (33.3)	33.3	6/ 17 (35.3)	35.3	0.94 (0.36, 2.47)	0.9073	-1.96 (-35.56, 31.64)	0.9089	
>= 10 points	12/ 30 (40.0)	40.0	19/ 55 (34.5)	34.5	1.16 (0.66, 2.05)	0.6139	5.45 (-16.23, 27.14)	0.6220	
OCS dose at baseline									0.4677
<10 mg/day	12/ 27 (44.4)	44.4	14/ 39 (35.9)	35.9	1.24 (0.68, 2.24)	0.4815	8.55 (-15.59, 32.68)	0.4876	
>=10 mg/day	5/ 18 (27.8)	27.8	11/ 33 (33.3)	33.3	0.83 (0.34, 2.02)	0.6872	-5.56 (-32.54, 21.43)	0.6866	
Result of type I IFN gene signature test									0.2752
LOW	5/ 13 (38.5)	38.5	2/ 12 (16.7)	16.7	2.31 (0.55, 9.74)	0.2550	21.79 (-14.48, 58.07)	0.2390	
HIGH	12/ 32 (37.5)	37.6	23/ 60 (38.3)	38.1	0.98 (0.56, 1.70)	0.9376	-0.53 (-21.68, 20.62)	0.9608	
Age (years)									0.6434
<= 65	16/ 43 (37.2)	37.6	25/ 71 (35.2)	33.6	1.06 (0.64, 1.74)	0.8288	4.00 (-14.61, 22.61)	0.6736	
> 65	1/ 2 (50.0)	50.0	0/ 1 (0.0)	0.0	2.00 (0.14, 28.42)	0.6087	50.00 (-68.41, 168.41)	0.4079	
Sex									0.1808
male	0/ 2 (0.0)	0.0	2/ 2 (100.0)	100.0	0.20 (0.02, 2.64)	0.2215	-100.00 (-192.39, -7.61)	0.0339	
female	17/ 43 (39.5)	39.8	23/ 70 (32.9)	31.4	1.20 (0.73, 1.98)	0.4672	8.42 (-10.31, 27.16)	0.3783	
Race									0.8629
White	12/ 33 (36.4)	36.0	19/ 49 (38.8)	36.5	0.94 (0.53, 1.66)	0.8259	-0.49 (-22.27, 21.30)	0.9650	
Black or African American	1/ 3 (33.3)	33.3	3/ 10 (30.0)	30.0	1.11 (0.17, 7.13)	0.9116	3.33 (-60.05, 66.72)	0.9179	
Asian	1/ 3 (33.3)	33.3	1/ 7 (14.3)	14.3	2.33 (0.21, 26.23)	0.4925	19.05 (-45.95, 84.04)	0.5657	
American Indian or Alaska Native	2/ 3 (66.7)	66.7	1/ 1 (100.0)	100.0	0.67 (0.30, 1.48)	0.3206	-33.33 (-144.49, 77.82)	0.5567	
Other	0/ 2 (0.0)	0.0	1/ 4 (25.0)	25.0	0.56 (0.03, 9.73)	0.6874	-25.00 (-105.74, 55.74)	0.5439	
Ethnicity									0.6327
Hispanic/Latino	9/ 20 (45.0)	45.0	8/ 20 (40.0)	40.0	1.13 (0.55, 2.32)	0.7495	5.00 (-25.72, 35.72)	0.7497	
Non-hispanic/Latino	7/ 24 (29.2)	29.2	17/ 51 (33.3)	33.3	0.88 (0.42, 1.82)	0.7216	-4.17 (-26.96, 18.62)	0.7201	
Geographic region									0.6681
EU	3/ 4 (75.0)	75.0	8/ 15 (53.3)	53.3	1.41 (0.67, 2.94)	0.3650	21.67 (-32.09, 75.42)	0.4295	
non-EU	14/ 41 (34.1)	34.0	17/ 57 (29.8)	28.6	1.14 (0.64, 2.05)	0.6489	5.39 (-13.99, 24.77)	0.5855	
Onset of disease									0.7167
Paediatric	0/ 1 (0.0)	0.0	1/ 3 (33.3)	33.3	0.67 (0.04, 10.05)	0.7696	-33.33 (-144.49, 77.82)	0.5567	
Adult	17/ 44 (38.6)	38.5	24/ 69 (34.8)	33.4	1.11 (0.68, 1.82)	0.6761	5.09 (-13.43, 23.61)	0.5902	
ADA result									0.0867
Negative	16/ 44 (36.4)	36.1	24/ 67 (35.8)	33.8	1.02 (0.61, 1.68)	0.9535	2.37 (-16.31, 21.04)	0.8038	
Positive (At any time)	1/ 1 (100.0)	100.0	1/ 5 (20.0)	20.0	5.00 (0.87, 28.86)	0.0720	80.00 (-24.53, 184.53)	0.1336	
BMI (kg/m2) at enrolment									0.9238
< 30	11/ 28 (39.3)	39.3	19/ 54 (35.2)	35.2	1.12 (0.62, 2.01)	0.7122	4.10 (-18.15, 26.35)	0.7180	
>= 30	6/ 17 (35.3)	35.3	6/ 18 (33.3)	33.3	1.06 (0.42, 2.65)	0.9028	1.96 (-30.08, 34.00)	0.9045	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.5326
All negative/normal	8/ 22 (36.4)	36.4	14/ 36 (38.9)	38.9	0.94 (0.47, 1.86)	0.8483	-2.53 (-28.40, 23.35)	0.8483	
At least one positive/abnormal	9/ 23 (39.1)	39.1	11/ 36 (30.6)	30.6	1.28 (0.63, 2.60)	0.4940	8.57 (-16.67, 33.82)	0.5056	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Low Disease Activity State at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 52	Number of subjects with events, n (%)	27 (15.0)	16 (8.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.70 (0.95, 3.05)	
	p-value	0.0734	
	Odds Ratio (95% CI)	1.84 (0.95, 3.58)	
	p-value	0.0724	
	Risk Difference (95% CI)	6.17 (-0.44, 12.77)	
	p-value	0.0672	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.71 (0.95, 3.06)	
	p-value	0.0725	
	Odds Ratio (95% CI)	1.83 (0.95, 3.53)	
	p-value	0.0709	
	Risk Difference (95% CI)	6.21 (-0.43, 12.85)	
	p-value	0.0670	
	CMH approach		
	Response rate	14.9	8.8
	Difference in response rates (95% CI)	6.12 (-1.20, 13.44)	
	p-value	0.1013	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Low Disease Activity State at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.4533
< 10 points	11/ 54 (20.4)	20.4	8/ 52 (15.4)	15.3	1.32 (0.58, 3.03)	0.5060	5.14 (-10.74, 21.03)	0.5255	
>= 10 points	16/126 (12.7)	12.6	8/130 (6.2)	6.1	2.06 (0.92, 4.65)	0.0806	6.47 (-1.58, 14.53)	0.1152	
OCS dose at baseline									0.5910
<10 mg/day	14/ 93 (15.1)	15.0	10/ 99 (10.1)	10.2	1.49 (0.70, 3.19)	0.3038	4.76 (-5.59, 15.11)	0.3672	
>=10 mg/day	13/ 87 (14.9)	14.9	6/ 83 (7.2)	7.2	2.07 (0.82, 5.18)	0.1216	7.71 (-2.26, 17.69)	0.1295	
Result of type I IFN gene signature test									0.1181
LOW	6/ 30 (20.0)	20.0	7/ 31 (22.6)	22.6	0.89 (0.34, 2.33)	0.8059	-2.58 (-24.19, 19.03)	0.8150	
HIGH	21/150 (14.0)	13.9	9/151 (6.0)	6.0	2.35 (1.11, 4.96)	0.0251	7.89 (0.25, 15.53)	0.0430	
Age (years)									0.7195
<= 65	26/175 (14.9)	14.8	16/181 (8.8)	8.8	1.68 (0.93, 3.02)	0.0830	5.99 (-1.40, 13.39)	0.1122	
> 65	1/ 5 (20.0)	20.0	0/ 1 (0.0)	0.0	1.00 (0.06, 15.99)	1.0000	20.00 (-84.53, 124.53)	0.7077	
Sex									0.3836
male	4/ 12 (33.3)	33.3	1/ 12 (8.3)	8.3	4.00 (0.52, 30.76)	0.1829	25.00 (-10.18, 60.18)	0.1637	
female	23/168 (13.7)	13.7	15/170 (8.8)	8.7	1.55 (0.84, 2.87)	0.1612	4.95 (-2.60, 12.50)	0.1992	
Race									0.8555
White	15/110 (13.6)	13.5	8/107 (7.5)	7.3	1.82 (0.81, 4.12)	0.1488	6.14 (-3.01, 15.28)	0.1886	
Black or African American	4/ 17 (23.5)	23.5	5/ 25 (20.0)	20.0	1.18 (0.37, 3.76)	0.7839	3.53 (-23.72, 30.78)	0.7996	
Asian	5/ 30 (16.7)	16.7	2/ 30 (6.7)	6.7	2.50 (0.53, 11.89)	0.2496	10.00 (-8.50, 28.50)	0.2894	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	1/ 11 (9.1)	9.1	0/ 11 (0.0)	0.0	3.00 (0.14, 66.53)	0.4872	9.09 (-21.93, 40.11)	0.5657	
Ethnicity									0.4851
Hispanic/Latino	6/ 54 (11.1)	11.8	5/ 54 (9.3)	8.6	1.20 (0.39, 3.70)	0.7508	3.27 (-10.34, 16.88)	0.6380	
Non-hispanic/Latino	19/118 (16.1)	16.1	10/120 (8.3)	8.3	1.93 (0.94, 3.98)	0.0739	7.78 (-1.78, 17.33)	0.1106	
Geographic region									0.8710
EU	10/ 51 (19.6)	19.6	5/ 46 (10.9)	10.9	1.80 (0.67, 4.89)	0.2460	8.74 (-6.40, 23.87)	0.2578	
non-EU	17/129 (13.2)	13.2	11/136 (8.1)	7.9	1.63 (0.79, 3.34)	0.1834	5.30 (-3.27, 13.88)	0.2251	
Onset of disease									0.5155
Paediatric	2/ 14 (14.3)	14.3	0/ 12 (0.0)	0.0	4.33 (0.23, 82.31)	0.3290	14.29 (-14.43, 43.00)	0.3295	
Adult	25/166 (15.1)	15.1	16/170 (9.4)	9.3	1.60 (0.89, 2.89)	0.1183	5.74 (-1.98, 13.46)	0.1448	
ADA result									0.6289
Negative	27/172 (15.7)	15.5	15/162 (9.3)	9.2	1.70 (0.94, 3.07)	0.0813	6.36 (-1.39, 14.11)	0.1075	
Positive (At any time)	0/ 8 (0.0)	0.0	1/ 20 (5.0)	5.0	0.78 (0.03, 17.33)	0.8739	-5.00 (-34.61, 24.61)	0.7407	
BMI (kg/m2) at enrolment									0.9670
< 30	19/125 (15.2)	15.2	12/134 (9.0)	9.1	1.70 (0.86, 3.35)	0.1275	6.06 (-2.97, 15.10)	0.1883	
>= 30	8/ 55 (14.5)	15.0	4/ 48 (8.3)	7.8	1.75 (0.56, 5.44)	0.3366	7.20 (-7.48, 21.88)	0.3366	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.0343
All negative/normal	8/ 58 (13.8)	13.8	12/ 81 (14.8)	14.7	0.93 (0.41, 2.13)	0.8658	-0.89 (-13.97, 12.20)	0.8945	
At least one positive/abnormal	19/122 (15.6)	15.7	4/101 (4.0)	4.1	3.93 (1.38, 11.19)	0.0103	11.58 (2.95, 20.20)	0.0085	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Mental Component Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 52	Number of subjects with events, n (%)	50 (27.8)	39 (21.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.30 (0.89, 1.90)	
	p-value	0.1784	
	Odds Ratio (95% CI)	1.39 (0.87, 2.23)	
	p-value	0.1735	
	Risk Difference (95% CI)	6.30 (-2.74, 15.34)	
	p-value	0.1719	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.30 (0.90, 1.87)	
	p-value	0.1629	
	Odds Ratio (95% CI)	1.41 (0.87, 2.28)	
	p-value	0.1616	
	Risk Difference (95% CI)	6.35 (-2.50, 15.20)	
	p-value	0.1598	
	CMH approach		
	Response rate	27.4	21.2
	Difference in response rates (95% CI)	6.22 (-2.72, 15.16)	
	p-value	0.1724	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Mental Component Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.0015
< 10 points	22/ 54 (40.7)	40.6	5/ 52 (9.6)	9.6	4.24 (1.73, 10.35)	0.0015	31.00 (14.44, 47.57)	0.0002	
>= 10 points	28/126 (22.2)	22.0	34/130 (26.2)	26.0	0.85 (0.55, 1.31)	0.4640	-4.02 (-14.67, 6.62)	0.4589	
OCS dose at baseline									0.2725
<10 mg/day	23/ 93 (24.7)	24.5	23/ 99 (23.2)	23.2	1.06 (0.64, 1.76)	0.8079	1.30 (-11.04, 13.64)	0.8367	
>=10 mg/day	27/ 87 (31.0)	31.0	16/ 83 (19.3)	19.3	1.61 (0.94, 2.76)	0.0841	11.76 (-1.35, 24.87)	0.0787	
Result of type I IFN gene signature test									0.1364
LOW	5/ 30 (16.7)	16.7	8/ 31 (25.8)	25.8	0.65 (0.24, 1.75)	0.3907	-9.14 (-30.64, 12.36)	0.4047	
HIGH	45/150 (30.0)	29.6	31/151 (20.5)	20.3	1.46 (0.98, 2.18)	0.0616	9.34 (-0.49, 19.17)	0.0624	
Age (years)									0.8394
<= 65	48/175 (27.4)	27.0	39/181 (21.5)	21.3	1.27 (0.88, 1.84)	0.1985	5.70 (-3.28, 14.67)	0.2138	
> 65	2/ 5 (40.0)	40.0	0/ 1 (0.0)	0.0	1.67 (0.13, 22.00)	0.6980	40.00 (-65.43, 145.43)	0.4571	
Sex									0.7040
male	3/ 12 (25.0)	25.0	3/ 12 (25.0)	25.0	1.00 (0.25, 4.00)	1.0000	0.00 (-37.09, 37.09)	1.0000	
female	47/168 (28.0)	27.7	36/170 (21.2)	21.1	1.32 (0.91, 1.93)	0.1489	6.65 (-2.65, 15.94)	0.1611	
Race									0.1634
White	27/110 (24.5)	23.8	27/107 (25.2)	24.8	0.97 (0.61, 1.54)	0.9067	-1.07 (-12.81, 10.67)	0.8587	
Black or African American	7/ 17 (41.2)	41.2	4/ 25 (16.0)	16.0	2.57 (0.89, 7.45)	0.0813	25.18 (-3.21, 53.56)	0.0821	
Asian	8/ 30 (26.7)	26.7	4/ 30 (13.3)	13.3	2.00 (0.67, 5.94)	0.2119	13.33 (-7.93, 34.59)	0.2190	
American Indian or Alaska Native	2/ 4 (50.0)	50.0	1/ 1 (100.0)	100.0	0.50 (0.19, 1.33)	0.1657	-50.00 (-157.80, 57.80)	0.3633	
Other	3/ 11 (27.3)	27.3	2/ 11 (18.2)	18.2	1.50 (0.31, 7.30)	0.6154	9.09 (-29.11, 47.29)	0.6409	
Ethnicity									0.8138
Hispanic/Latino	16/ 54 (29.6)	30.7	12/ 54 (22.2)	22.3	1.33 (0.70, 2.55)	0.3831	8.38 (-8.71, 25.46)	0.3367	
Non-hispanic/Latino	31/118 (26.3)	25.9	26/120 (21.7)	21.3	1.21 (0.77, 1.91)	0.4066	4.57 (-6.57, 15.72)	0.4210	
Geographic region									0.3773
EU	12/ 51 (23.5)	23.5	11/ 46 (23.9)	23.9	0.98 (0.48, 2.01)	0.9646	-0.38 (-17.81, 17.04)	0.9656	
non-EU	38/129 (29.5)	29.0	28/136 (20.6)	20.4	1.43 (0.94, 2.19)	0.0982	8.57 (-1.99, 19.12)	0.1116	
Onset of disease									0.5205
Paediatric	3/ 14 (21.4)	21.4	1/ 12 (8.3)	8.3	2.57 (0.31, 21.59)	0.3843	13.10 (-19.13, 45.32)	0.4257	
Adult	47/166 (28.3)	28.0	38/170 (22.4)	22.2	1.27 (0.87, 1.83)	0.2108	5.82 (-3.56, 15.21)	0.2241	
ADA result									0.6935
Negative	49/172 (28.5)	28.0	36/162 (22.2)	22.0	1.28 (0.88, 1.86)	0.1917	5.97 (-3.41, 15.36)	0.2121	
Positive (At any time)	1/ 8 (12.5)	12.5	3/ 20 (15.0)	15.0	0.83 (0.10, 6.87)	0.8655	-2.50 (-37.39, 32.39)	0.8883	
BMI (kg/m2) at enrolment									0.5664
< 30	34/125 (27.2)	27.4	30/134 (22.4)	22.5	1.21 (0.79, 1.86)	0.3706	4.97 (-5.75, 15.69)	0.3633	
>= 30	16/ 55 (29.1)	28.5	9/ 48 (18.8)	18.1	1.55 (0.76, 3.18)	0.2312	10.40 (-6.82, 27.63)	0.2365	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.0131
All negative/normal	23/ 58 (39.7)	38.9	14/ 81 (17.3)	16.6	2.29 (1.29, 4.07)	0.0045	22.30 (7.26, 37.34)	0.0037	
At least one positive/abnormal	27/122 (22.1)	22.2	25/101 (24.8)	24.7	0.89 (0.56, 1.44)	0.6447	-2.48 (-14.01, 9.04)	0.6728	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Physical Component Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 52	Number of subjects with events, n (%)	59 (32.8)	44 (24.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.35 (0.97, 1.87)	
	p-value	0.0741	
	Odds Ratio (95% CI)	1.52 (0.96, 2.40)	
	p-value	0.0754	
	Risk Difference (95% CI)	8.52 (-0.80, 17.83)	
	p-value	0.0730	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.36 (0.97, 1.89)	
	p-value	0.0720	
	Odds Ratio (95% CI)	1.53 (0.97, 2.42)	
	p-value	0.0706	
	Risk Difference (95% CI)	8.60 (-0.66, 17.86)	
	p-value	0.0686	
	CMH approach		
	Response rate	32.8	24.4
	Difference in response rates (95% CI)	8.36 (-1.06, 17.79)	
	p-value	0.0819	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Physical Component Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9845
< 10 points	17/ 54 (31.5)	31.5	12/ 52 (23.1)	23.0	1.36 (0.72, 2.57)	0.3365	8.54 (-8.82, 25.90)	0.3351	
>= 10 points	42/126 (33.3)	33.3	32/130 (24.6)	25.1	1.35 (0.92, 2.00)	0.1268	8.25 (-2.98, 19.48)	0.1501	
OCS dose at baseline									0.1358
<10 mg/day	30/ 93 (32.3)	32.5	18/ 99 (18.2)	18.2	1.77 (1.06, 2.96)	0.0279	14.28 (1.76, 26.79)	0.0253	
>=10 mg/day	29/ 87 (33.3)	33.3	26/ 83 (31.3)	31.3	1.06 (0.69, 1.65)	0.7798	2.01 (-12.14, 16.16)	0.7809	
Result of type I IFN gene signature test									0.6302
LOW	10/ 30 (33.3)	33.3	9/ 31 (29.0)	29.0	1.15 (0.54, 2.42)	0.7172	4.30 (-19.35, 27.95)	0.7215	
HIGH	49/150 (32.7)	32.7	35/151 (23.2)	23.5	1.41 (0.97, 2.04)	0.0693	9.19 (-1.08, 19.46)	0.0795	
Age (years)									0.6557
<= 65	56/175 (32.0)	32.0	44/181 (24.3)	24.5	1.32 (0.94, 1.84)	0.1086	7.43 (-2.05, 16.92)	0.1247	
> 65	3/ 5 (60.0)	60.0	0/ 1 (0.0)	0.0	2.33 (0.19, 28.25)	0.5055	60.00 (-45.43, 165.43)	0.2647	
Sex									0.0818
male	2/ 12 (16.7)	16.7	5/ 12 (41.7)	41.7	0.40 (0.10, 1.67)	0.2096	-25.00 (-62.26, 12.26)	0.1884	
female	57/168 (33.9)	33.9	39/170 (22.9)	23.1	1.48 (1.05, 2.09)	0.0271	10.85 (1.09, 20.61)	0.0293	
Race									0.8617
White	35/110 (31.8)	32.4	30/107 (28.0)	27.7	1.13 (0.75, 1.71)	0.5440	4.76 (-7.67, 17.20)	0.4527	
Black or African American	7/ 17 (41.2)	41.2	6/ 25 (24.0)	24.0	1.72 (0.70, 4.22)	0.2396	17.18 (-12.16, 46.51)	0.2511	
Asian	6/ 30 (20.0)	20.0	4/ 30 (13.3)	13.3	1.50 (0.47, 4.78)	0.4931	6.67 (-13.74, 27.07)	0.5220	
American Indian or Alaska Native	3/ 4 (75.0)	75.0	0/ 1 (0.0)	0.0	2.80 (0.24, 33.04)	0.4136	75.00 (-32.10, 182.10)	0.1699	
Other	3/ 11 (27.3)	27.3	3/ 11 (27.3)	27.3	1.00 (0.26, 3.91)	1.0000	0.00 (-39.40, 39.40)	1.0000	
Ethnicity									0.8547
Hispanic/Latino	22/ 54 (40.7)	40.6	18/ 54 (33.3)	33.3	1.22 (0.74, 2.01)	0.4276	7.27 (-11.12, 25.66)	0.4382	
Non-hispanic/Latino	32/118 (27.1)	27.3	25/120 (20.8)	20.9	1.30 (0.82, 2.06)	0.2585	6.44 (-4.89, 17.77)	0.2655	
Geographic region									0.5317
EU	18/ 51 (35.3)	35.3	10/ 46 (21.7)	21.7	1.62 (0.84, 3.15)	0.1516	13.55 (-4.52, 31.63)	0.1416	
non-EU	41/129 (31.8)	31.8	34/136 (25.0)	25.2	1.27 (0.86, 1.87)	0.2223	6.63 (-4.44, 17.70)	0.2404	
Onset of disease									0.9430
Paediatric	3/ 14 (21.4)	21.4	2/ 12 (16.7)	16.7	1.29 (0.26, 6.46)	0.7603	4.76 (-29.16, 38.68)	0.7832	
Adult	56/166 (33.7)	33.8	42/170 (24.7)	24.8	1.37 (0.97, 1.91)	0.0710	8.96 (-0.86, 18.79)	0.0738	
ADA result									0.4572
Negative	58/172 (33.7)	33.7	40/162 (24.7)	25.1	1.37 (0.97, 1.92)	0.0732	8.63 (-1.22, 18.48)	0.0860	
Positive (At any time)	1/ 8 (12.5)	12.5	4/ 20 (20.0)	20.0	0.63 (0.08, 4.77)	0.6503	-7.50 (-43.00, 28.00)	0.6788	
BMI (kg/m2) at enrolment									0.6959
< 30	40/125 (32.0)	31.9	33/134 (24.6)	24.9	1.30 (0.88, 1.92)	0.1895	7.01 (-4.18, 18.19)	0.2196	
>= 30	19/ 55 (34.5)	34.4	11/ 48 (22.9)	22.0	1.51 (0.80, 2.84)	0.2043	12.41 (-5.61, 30.44)	0.1770	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.1704
All negative/normal	18/ 58 (31.0)	31.4	24/ 81 (29.6)	28.8	1.05 (0.63, 1.74)	0.8586	2.60 (-13.21, 18.40)	0.7473	
At least one positive/abnormal	41/122 (33.6)	33.7	20/101 (19.8)	19.9	1.70 (1.07, 2.70)	0.0258	13.85 (2.07, 25.64)	0.0213	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - General Health Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 52	Number of subjects with events, n (%)	30 (16.7)	17 (9.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.81 (1.04, 3.17)	
	p-value	0.0370	
	Odds Ratio (95% CI)	1.99 (1.05, 3.78)	
	p-value	0.0354	
	Risk Difference (95% CI)	7.50 (0.64, 14.37)	
	p-value	0.0321	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.78 (1.02, 3.12)	
	p-value	0.0420	
	Odds Ratio (95% CI)	1.94 (1.03, 3.66)	
	p-value	0.0406	
	Risk Difference (95% CI)	7.33 (0.43, 14.22)	
	p-value	0.0372	
	CMH approach		
	Response rate	16.7	9.3
	Difference in response rates (95% CI)	7.32 (-0.32, 14.96)	
	p-value	0.0603	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - General Health Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.3822
< 10 points	9/ 54 (16.7)	16.7	3/ 52 (5.8)	5.8	2.89 (0.83, 10.08)	0.0962	10.94 (-3.53, 25.42)	0.1384	
>= 10 points	21/126 (16.7)	16.6	14/130 (10.8)	10.8	1.55 (0.82, 2.91)	0.1745	5.82 (-3.29, 14.93)	0.2104	
OCS dose at baseline									0.4182
<10 mg/day	15/ 93 (16.1)	16.2	7/ 99 (7.1)	7.0	2.28 (0.97, 5.34)	0.0576	9.23 (-1.19, 19.65)	0.0825	
>=10 mg/day	15/ 87 (17.2)	17.2	10/ 83 (12.0)	12.0	1.43 (0.68, 3.00)	0.3435	5.19 (-5.86, 16.24)	0.3570	
Result of type I IFN gene signature test									0.7882
LOW	6/ 30 (20.0)	20.0	4/ 31 (12.9)	12.9	1.55 (0.49, 4.95)	0.4595	7.10 (-13.06, 27.26)	0.4902	
HIGH	24/150 (16.0)	16.0	13/151 (8.6)	8.6	1.86 (0.98, 3.51)	0.0562	7.37 (-0.86, 15.59)	0.0792	
Age (years)									0.7880
<= 65	27/175 (15.4)	15.4	17/181 (9.4)	9.4	1.64 (0.93, 2.91)	0.0880	6.01 (-1.61, 13.63)	0.1219	
> 65	3/ 5 (60.0)	60.0	0/ 1 (0.0)	0.0	2.33 (0.19, 28.25)	0.5055	60.00 (-45.43, 165.43)	0.2647	
Sex									0.6615
male	1/ 12 (8.3)	8.3	1/ 12 (8.3)	8.3	1.00 (0.07, 14.21)	1.0000	0.00 (-31.23, 31.23)	1.0000	
female	29/168 (17.3)	17.3	16/170 (9.4)	9.4	1.83 (1.04, 3.25)	0.0377	7.85 (-0.14, 15.84)	0.0542	
Race									0.9420
White	19/110 (17.3)	17.6	10/107 (9.3)	9.0	1.85 (0.90, 3.79)	0.0936	8.60 (-1.35, 18.55)	0.0902	
Black or African American	2/ 17 (11.8)	11.8	3/ 25 (12.0)	12.0	0.98 (0.18, 5.26)	0.9816	-0.24 (-24.06, 23.59)	0.9846	
Asian	3/ 30 (10.0)	10.0	2/ 30 (6.7)	6.7	1.50 (0.27, 8.34)	0.6433	3.33 (-13.80, 20.47)	0.7030	
American Indian or Alaska Native	2/ 4 (50.0)	50.0	0/ 1 (0.0)	0.0	2.00 (0.16, 25.75)	0.5950	50.00 (-57.80, 157.80)	0.3633	
Other	3/ 11 (27.3)	27.3	1/ 11 (9.1)	9.1	3.00 (0.37, 24.58)	0.3059	18.18 (-18.35, 54.72)	0.3294	
Ethnicity									0.0690
Hispanic/Latino	17/ 54 (31.5)	31.8	5/ 54 (9.3)	9.3	3.40 (1.35, 8.56)	0.0094	22.54 (6.64, 38.44)	0.0055	
Non-hispanic/Latino	12/118 (10.2)	10.2	11/120 (9.2)	9.1	1.11 (0.51, 2.41)	0.7936	1.17 (-8.00, 10.33)	0.8031	
Geographic region									0.4115
EU	5/ 51 (9.8)	9.8	4/ 46 (8.7)	8.7	1.13 (0.32, 3.95)	0.8511	1.11 (-12.00, 14.22)	0.8684	
non-EU	25/129 (19.4)	19.5	13/136 (9.6)	9.5	2.03 (1.08, 3.79)	0.0268	9.94 (0.50, 19.37)	0.0390	
Onset of disease									0.5373
Paediatric	2/ 14 (14.3)	14.3	0/ 12 (0.0)	0.0	4.33 (0.23, 82.31)	0.3290	14.29 (-14.43, 43.00)	0.3295	
Adult	28/166 (16.9)	16.9	17/170 (10.0)	10.0	1.69 (0.96, 2.96)	0.0690	6.94 (-1.11, 14.99)	0.0911	
ADA result									0.3604
Negative	29/172 (16.9)	16.8	17/162 (10.5)	10.6	1.61 (0.92, 2.81)	0.0963	6.22 (-1.88, 14.32)	0.1326	
Positive (At any time)	1/ 8 (12.5)	12.5	0/ 20 (0.0)	0.0	7.00 (0.31, 155.99)	0.2192	12.50 (-19.86, 44.86)	0.4490	
BMI (kg/m2) at enrolment									0.5085
< 30	19/125 (15.2)	15.2	13/134 (9.7)	9.8	1.57 (0.81, 3.04)	0.1837	5.48 (-3.75, 14.70)	0.2448	
>= 30	11/ 55 (20.0)	21.3	4/ 48 (8.3)	7.4	2.40 (0.82, 7.05)	0.1111	13.87 (-1.62, 29.36)	0.0792	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.0895
All negative/normal	14/ 58 (24.1)	25.1	6/ 81 (7.4)	7.0	3.26 (1.33, 7.97)	0.0097	18.04 (4.45, 31.62)	0.0093	
At least one positive/abnormal	16/122 (13.1)	13.0	11/101 (10.9)	10.9	1.20 (0.59, 2.48)	0.6135	2.10 (-7.32, 11.52)	0.6618	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Mental Health Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 52	Number of subjects with events, n (%)	43 (23.9)	23 (12.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.90 (1.18, 3.05)	
	p-value	0.0085	
	Odds Ratio (95% CI)	2.11 (1.22, 3.64)	
	p-value	0.0073	
	Risk Difference (95% CI)	11.21 (3.19, 19.22)	
	p-value	0.0061	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.89 (1.19, 3.00)	
	p-value	0.0070	
	Odds Ratio (95% CI)	2.17 (1.25, 3.78)	
	p-value	0.0063	
	Risk Difference (95% CI)	11.25 (3.37, 19.13)	
	p-value	0.0051	
	CMH approach		
	Response rate	23.6	12.5
	Difference in response rates (95% CI)	11.10 (2.91, 19.30)	
	p-value	0.0079	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Mental Health Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.0052
< 10 points	20/ 54 (37.0)	36.9	2/ 52 (3.8)	3.8	9.63 (2.37, 39.16)	0.0016	33.08 (17.49, 48.67)	<.0001	
>= 10 points	23/126 (18.3)	18.1	21/130 (16.2)	16.2	1.13 (0.66, 1.94)	0.6564	2.00 (-7.79, 11.78)	0.6893	
OCS dose at baseline									0.6748
<10 mg/day	21/ 93 (22.6)	22.2	13/ 99 (13.1)	12.9	1.72 (0.91, 3.23)	0.0923	9.31 (-2.16, 20.78)	0.1116	
>=10 mg/day	22/ 87 (25.3)	25.3	10/ 83 (12.0)	12.0	2.10 (1.06, 4.16)	0.0337	13.24 (1.37, 25.10)	0.0287	
Result of type I IFN gene signature test									0.8855
LOW	5/ 30 (16.7)	16.7	3/ 31 (9.7)	9.7	1.72 (0.45, 6.58)	0.4267	6.99 (-12.01, 25.99)	0.4710	
HIGH	38/150 (25.3)	25.1	20/151 (13.2)	13.1	1.91 (1.17, 3.13)	0.0098	11.94 (2.86, 21.02)	0.0099	
Age (years)									0.6574
<= 65	42/175 (24.0)	23.7	23/181 (12.7)	12.6	1.89 (1.19, 3.00)	0.0072	11.08 (2.80, 19.36)	0.0088	
> 65	1/ 5 (20.0)	20.0	0/ 1 (0.0)	0.0	1.00 (0.06, 15.99)	1.0000	20.00 (-84.53, 124.53)	0.7077	
Sex									0.2477
male	4/ 12 (33.3)	33.3	4/ 12 (33.3)	33.3	1.00 (0.32, 3.10)	1.0000	0.00 (-38.74, 38.74)	1.0000	
female	39/168 (23.2)	23.1	19/170 (11.2)	11.2	2.08 (1.25, 3.44)	0.0046	11.89 (3.46, 20.32)	0.0057	
Race									0.5993
White	24/110 (21.8)	20.4	17/107 (15.9)	15.4	1.37 (0.78, 2.41)	0.2682	4.99 (-5.59, 15.56)	0.3552	
Black or African American	5/ 17 (29.4)	29.4	3/ 25 (12.0)	12.0	2.45 (0.67, 8.92)	0.1738	17.41 (-9.45, 44.27)	0.2039	
Asian	7/ 30 (23.3)	23.3	1/ 30 (3.3)	3.3	7.00 (0.92, 53.47)	0.0607	20.00 (1.23, 38.77)	0.0367	
American Indian or Alaska Native	2/ 4 (50.0)	50.0	0/ 1 (0.0)	0.0	2.00 (0.16, 25.75)	0.5950	50.00 (-57.80, 157.80)	0.3633	
Other	2/ 11 (18.2)	18.2	1/ 11 (9.1)	9.1	2.00 (0.21, 18.98)	0.5460	9.09 (-26.15, 44.33)	0.6131	
Ethnicity									0.9778
Hispanic/Latino	13/ 54 (24.1)	24.8	7/ 54 (13.0)	13.7	1.86 (0.80, 4.29)	0.1476	11.03 (-5.07, 27.13)	0.1794	
Non-hispanic/Latino	27/118 (22.9)	22.4	15/120 (12.5)	12.3	1.83 (1.03, 3.26)	0.0403	10.17 (-0.12, 20.45)	0.0527	
Geographic region									0.1615
EU	10/ 51 (19.6)	19.6	8/ 46 (17.4)	17.4	1.13 (0.49, 2.61)	0.7795	2.22 (-13.97, 18.41)	0.7884	
non-EU	33/129 (25.6)	25.3	15/136 (11.0)	11.1	2.32 (1.32, 4.06)	0.0033	14.21 (4.44, 23.99)	0.0044	
Onset of disease									0.5697
Paediatric	2/ 14 (14.3)	14.3	0/ 12 (0.0)	0.0	4.33 (0.23, 82.31)	0.3290	14.29 (-14.43, 43.00)	0.3295	
Adult	41/166 (24.7)	24.5	23/170 (13.5)	13.5	1.83 (1.15, 2.90)	0.0109	10.99 (2.31, 19.66)	0.0131	
ADA result									0.8102
Negative	42/172 (24.4)	24.0	22/162 (13.6)	13.5	1.80 (1.12, 2.87)	0.0142	10.56 (1.92, 19.21)	0.0167	
Positive (At any time)	1/ 8 (12.5)	12.5	1/ 20 (5.0)	5.0	2.50 (0.18, 35.31)	0.4976	7.50 (-25.82, 40.82)	0.6591	
BMI (kg/m2) at enrolment									0.5311
< 30	29/125 (23.2)	23.4	18/134 (13.4)	13.4	1.73 (1.01, 2.95)	0.0454	9.98 (0.03, 19.92)	0.0492	
>= 30	14/ 55 (25.5)	24.5	5/ 48 (10.4)	10.3	2.44 (0.95, 6.29)	0.0638	14.15 (-1.89, 30.19)	0.0838	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.2625
All negative/normal	17/ 58 (29.3)	28.1	9/ 81 (11.1)	10.6	2.64 (1.27, 5.50)	0.0096	17.54 (3.67, 31.40)	0.0132	
At least one positive/abnormal	26/122 (21.3)	21.2	14/101 (13.9)	13.8	1.54 (0.85, 2.78)	0.1557	7.45 (-3.04, 17.93)	0.1639	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Physical Functioning Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 52	Number of subjects with events, n (%)	46 (25.6)	34 (18.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.35 (0.92, 2.00)	
	p-value	0.1285	
	Odds Ratio (95% CI)	1.48 (0.89, 2.44)	
	p-value	0.1284	
	Risk Difference (95% CI)	6.66 (-1.87, 15.18)	
	p-value	0.1258	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.37 (0.92, 2.03)	
	p-value	0.1177	
	Odds Ratio (95% CI)	1.49 (0.91, 2.47)	
	p-value	0.1162	
	Risk Difference (95% CI)	6.87 (-1.65, 15.40)	
	p-value	0.1140	
	CMH approach		
	Response rate	25.5	18.7
	Difference in response rates (95% CI)	6.74 (-2.12, 15.59)	
	p-value	0.1360	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Physical Functioning Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.7024
< 10 points	13/ 54 (24.1)	24.1	8/ 52 (15.4)	15.3	1.56 (0.71, 3.46)	0.2691	8.77 (-7.45, 25.00)	0.2892	
>= 10 points	33/126 (26.2)	26.1	26/130 (20.0)	20.2	1.31 (0.83, 2.06)	0.2421	5.88 (-4.75, 16.51)	0.2786	
OCS dose at baseline									0.7263
<10 mg/day	22/ 93 (23.7)	23.7	16/ 99 (16.2)	16.1	1.46 (0.82, 2.61)	0.1967	7.55 (-4.35, 19.45)	0.2138	
>=10 mg/day	24/ 87 (27.6)	27.6	18/ 83 (21.7)	21.7	1.27 (0.75, 2.17)	0.3754	5.90 (-7.22, 19.02)	0.3780	
Result of type I IFN gene signature test									0.3080
LOW	7/ 30 (23.3)	23.3	8/ 31 (25.8)	25.8	0.90 (0.37, 2.18)	0.8228	-2.47 (-24.88, 19.93)	0.8287	
HIGH	39/150 (26.0)	25.9	26/151 (17.2)	17.3	1.51 (0.97, 2.35)	0.0675	8.61 (-1.03, 18.24)	0.0800	
Age (years)									0.6533
<= 65	43/175 (24.6)	24.4	34/181 (18.8)	18.8	1.31 (0.88, 1.95)	0.1870	5.62 (-3.26, 14.50)	0.2145	
> 65	3/ 5 (60.0)	60.0	0/ 1 (0.0)	0.0	2.33 (0.19, 28.25)	0.5055	60.00 (-45.43, 165.43)	0.2647	
Sex									0.2918
male	4/ 12 (33.3)	33.3	5/ 12 (41.7)	41.7	0.80 (0.28, 2.27)	0.6751	-8.33 (-47.55, 30.89)	0.6771	
female	42/168 (25.0)	24.9	29/170 (17.1)	17.0	1.47 (0.96, 2.24)	0.0762	7.89 (-1.16, 16.95)	0.0875	
Race									0.5246
White	31/110 (28.2)	28.1	27/107 (25.2)	24.7	1.12 (0.72, 1.74)	0.6241	3.33 (-8.72, 15.38)	0.5878	
Black or African American	2/ 17 (11.8)	11.8	4/ 25 (16.0)	16.0	0.74 (0.15, 3.58)	0.7032	-4.24 (-28.74, 20.27)	0.7348	
Asian	4/ 30 (13.3)	13.3	1/ 30 (3.3)	3.3	4.00 (0.47, 33.73)	0.2025	10.00 (-7.00, 27.00)	0.2490	
American Indian or Alaska Native	2/ 4 (50.0)	50.0	0/ 1 (0.0)	0.0	2.00 (0.16, 25.75)	0.5950	50.00 (-57.80, 157.80)	0.3633	
Other	4/ 11 (36.4)	36.4	1/ 11 (9.1)	9.1	4.00 (0.53, 30.33)	0.1798	27.27 (-10.10, 64.65)	0.1527	
Ethnicity									0.4808
Hispanic/Latino	18/ 54 (33.3)	33.3	16/ 54 (29.6)	30.0	1.13 (0.64, 1.97)	0.6790	3.23 (-14.74, 21.21)	0.7245	
Non-hispanic/Latino	25/118 (21.2)	21.2	17/120 (14.2)	14.1	1.50 (0.85, 2.62)	0.1599	7.12 (-3.42, 17.67)	0.1854	
Geographic region									0.4444
EU	17/ 51 (33.3)	33.3	9/ 46 (19.6)	19.6	1.70 (0.84, 3.44)	0.1373	13.77 (-3.94, 31.48)	0.1276	
non-EU	29/129 (22.5)	22.4	25/136 (18.4)	18.3	1.22 (0.76, 1.97)	0.4088	4.11 (-6.18, 14.40)	0.4334	
Onset of disease									0.8468
Paediatric	2/ 14 (14.3)	14.3	1/ 12 (8.3)	8.3	1.71 (0.18, 16.65)	0.6421	5.95 (-25.06, 36.97)	0.7068	
Adult	44/166 (26.5)	26.4	33/170 (19.4)	19.4	1.37 (0.92, 2.03)	0.1245	7.07 (-2.22, 16.36)	0.1358	
ADA result									0.6258
Negative	45/172 (26.2)	26.0	33/162 (20.4)	20.6	1.28 (0.87, 1.91)	0.2139	5.43 (-3.92, 14.77)	0.2553	
Positive (At any time)	1/ 8 (12.5)	12.5	1/ 20 (5.0)	5.0	2.50 (0.18, 35.31)	0.4976	7.50 (-25.82, 40.82)	0.6591	
BMI (kg/m2) at enrolment									0.5879
< 30	31/125 (24.8)	24.8	26/134 (19.4)	19.6	1.28 (0.81, 2.03)	0.2965	5.20 (-5.43, 15.82)	0.3376	
>= 30	15/ 55 (27.3)	27.9	8/ 48 (16.7)	15.6	1.64 (0.76, 3.52)	0.2075	12.25 (-4.64, 29.13)	0.1551	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.7952
All negative/normal	16/ 58 (27.6)	27.9	17/ 81 (21.0)	20.2	1.31 (0.73, 2.38)	0.3667	7.62 (-7.48, 22.73)	0.3226	
At least one positive/abnormal	30/122 (24.6)	24.7	17/101 (16.8)	16.9	1.46 (0.86, 2.49)	0.1636	7.74 (-3.34, 18.83)	0.1711	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Role Emotional Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 52	Number of subjects with events, n (%)	50 (27.8)	36 (19.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.40 (0.96, 2.05)	
	p-value	0.0832	
	Odds Ratio (95% CI)	1.55 (0.95, 2.53)	
	p-value	0.0800	
	Risk Difference (95% CI)	7.86 (-0.89, 16.61)	
	p-value	0.0782	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.40 (0.96, 2.04)	
	p-value	0.0764	
	Odds Ratio (95% CI)	1.56 (0.96, 2.54)	
	p-value	0.0749	
	Risk Difference (95% CI)	8.00 (-0.74, 16.73)	
	p-value	0.0727	
	CMH approach		
	Response rate	27.5	19.8
	Difference in response rates (95% CI)	7.66 (-1.23, 16.54)	
	p-value	0.0912	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Role Emotional Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.0601
< 10 points	22/ 54 (40.7)	40.6	9/ 52 (17.3)	17.3	2.35 (1.20, 4.63)	0.0130	23.31 (5.93, 40.70)	0.0086	
>= 10 points	28/126 (22.2)	22.0	27/130 (20.8)	20.8	1.07 (0.67, 1.71)	0.7772	1.18 (-9.17, 11.54)	0.8226	
OCS dose at baseline									0.8314
<10 mg/day	24/ 93 (25.8)	25.5	19/ 99 (19.2)	19.3	1.34 (0.79, 2.29)	0.2745	6.14 (-5.98, 18.26)	0.3206	
>=10 mg/day	26/ 87 (29.9)	29.9	17/ 83 (20.5)	20.5	1.46 (0.86, 2.48)	0.1641	9.40 (-3.75, 22.56)	0.1612	
Result of type I IFN gene signature test									0.1707
LOW	6/ 30 (20.0)	20.0	8/ 31 (25.8)	25.8	0.78 (0.31, 1.97)	0.5919	-5.81 (-27.79, 16.18)	0.6047	
HIGH	44/150 (29.3)	29.0	28/151 (18.5)	18.6	1.58 (1.04, 2.40)	0.0309	10.39 (0.68, 20.11)	0.0360	
Age (years)									0.6709
<= 65	47/175 (26.9)	26.4	36/181 (19.9)	19.9	1.35 (0.92, 1.98)	0.1225	6.53 (-2.37, 15.42)	0.1504	
> 65	3/ 5 (60.0)	60.0	0/ 1 (0.0)	0.0	2.33 (0.19, 28.25)	0.5055	60.00 (-45.43, 165.43)	0.2647	
Sex									0.6189
male	3/ 12 (25.0)	25.0	3/ 12 (25.0)	25.0	1.00 (0.25, 4.00)	1.0000	0.00 (-37.09, 37.09)	1.0000	
female	47/168 (28.0)	27.8	33/170 (19.4)	19.5	1.44 (0.98, 2.13)	0.0668	8.33 (-0.90, 17.55)	0.0769	
Race									0.4049
White	31/110 (28.2)	27.1	24/107 (22.4)	22.4	1.26 (0.79, 1.99)	0.3325	4.77 (-7.00, 16.53)	0.4270	
Black or African American	6/ 17 (35.3)	35.3	6/ 25 (24.0)	24.0	1.47 (0.57, 3.80)	0.4258	11.29 (-17.69, 40.27)	0.4450	
Asian	4/ 30 (13.3)	13.3	3/ 30 (10.0)	10.0	1.33 (0.33, 5.45)	0.6890	3.33 (-15.29, 21.95)	0.7257	
American Indian or Alaska Native	2/ 4 (50.0)	50.0	1/ 1 (100.0)	100.0	0.50 (0.19, 1.33)	0.1657	-50.00 (-157.80, 57.80)	0.3633	
Other	3/ 11 (27.3)	27.3	1/ 11 (9.1)	9.1	3.00 (0.37, 24.58)	0.3059	18.18 (-18.35, 54.72)	0.3294	
Ethnicity									0.5499
Hispanic/Latino	16/ 54 (29.6)	30.7	14/ 54 (25.9)	25.8	1.14 (0.62, 2.10)	0.6679	4.84 (-12.49, 22.18)	0.5839	
Non-hispanic/Latino	30/118 (25.4)	25.1	21/120 (17.5)	17.4	1.45 (0.88, 2.39)	0.1403	7.71 (-3.18, 18.59)	0.1652	
Geographic region									0.9127
EU	16/ 51 (31.4)	31.4	10/ 46 (21.7)	21.7	1.44 (0.73, 2.85)	0.2919	9.63 (-8.20, 27.47)	0.2898	
non-EU	34/129 (26.4)	26.1	26/136 (19.1)	19.2	1.38 (0.88, 2.16)	0.1622	6.91 (-3.52, 17.34)	0.1943	
Onset of disease									0.7892
Paediatric	4/ 14 (28.6)	28.6	2/ 12 (16.7)	16.7	1.71 (0.38, 7.78)	0.4848	11.90 (-22.88, 46.69)	0.5024	
Adult	46/166 (27.7)	27.5	34/170 (20.0)	20.0	1.39 (0.94, 2.04)	0.0997	7.49 (-1.79, 16.76)	0.1137	
ADA result									0.8144
Negative	48/172 (27.9)	27.6	33/162 (20.4)	20.4	1.37 (0.93, 2.02)	0.1116	7.13 (-2.19, 16.46)	0.1336	
Positive (At any time)	2/ 8 (25.0)	25.0	3/ 20 (15.0)	15.0	1.67 (0.34, 8.18)	0.5290	10.00 (-27.20, 47.20)	0.5983	
BMI (kg/m2) at enrolment									0.5912
< 30	33/125 (26.4)	26.6	27/134 (20.1)	20.3	1.31 (0.84, 2.05)	0.2355	6.36 (-4.25, 16.96)	0.2401	
>= 30	17/ 55 (30.9)	30.4	9/ 48 (18.8)	18.5	1.65 (0.81, 3.35)	0.1671	11.85 (-5.46, 29.16)	0.1798	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.2163
All negative/normal	19/ 58 (32.8)	32.0	14/ 81 (17.3)	16.9	1.90 (1.04, 3.46)	0.0375	15.15 (0.21, 30.08)	0.0468	
At least one positive/abnormal	31/122 (25.4)	25.4	22/101 (21.8)	21.9	1.17 (0.72, 1.88)	0.5281	3.46 (-7.91, 14.84)	0.5505	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Role Physical Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 52	Number of subjects with events, n (%)	63 (35.0)	42 (23.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.51 (1.08, 2.10)	
	p-value	0.0147	
	Odds Ratio (95% CI)	1.79 (1.13, 2.83)	
	p-value	0.0139	
	Risk Difference (95% CI)	11.84 (2.54, 21.14)	
	p-value	0.0126	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.52 (1.09, 2.11)	
	p-value	0.0138	
	Odds Ratio (95% CI)	1.79 (1.13, 2.85)	
	p-value	0.0129	
	Risk Difference (95% CI)	11.92 (2.65, 21.20)	
	p-value	0.0117	
	CMH approach		
	Response rate	34.9	23.2
	Difference in response rates (95% CI)	11.70 (2.31, 21.09)	
	p-value	0.0146	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Role Physical Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.2198
< 10 points	22/ 54 (40.7)	40.7	10/ 52 (19.2)	19.1	2.12 (1.11, 4.03)	0.0222	21.56 (4.18, 38.95)	0.0150	
>= 10 points	41/126 (32.5)	32.5	32/130 (24.6)	24.9	1.32 (0.89, 1.96)	0.1629	7.62 (-3.53, 18.76)	0.1804	
OCS dose at baseline									0.5448
<10 mg/day	33/ 93 (35.5)	35.1	21/ 99 (21.2)	21.2	1.67 (1.05, 2.67)	0.0313	13.93 (1.25, 26.61)	0.0313	
>=10 mg/day	30/ 87 (34.5)	34.5	21/ 83 (25.3)	25.3	1.36 (0.85, 2.18)	0.1963	9.18 (-4.63, 22.99)	0.1925	
Result of type I IFN gene signature test									0.9568
LOW	13/ 30 (43.3)	43.3	9/ 31 (29.0)	29.0	1.49 (0.75, 2.96)	0.2524	14.30 (-9.84, 38.44)	0.2456	
HIGH	50/150 (33.3)	33.2	33/151 (21.9)	22.0	1.53 (1.05, 2.22)	0.0282	11.17 (0.99, 21.35)	0.0314	
Age (years)									0.5647
<= 65	59/175 (33.7)	33.5	42/181 (23.2)	23.3	1.45 (1.04, 2.03)	0.0297	10.27 (0.83, 19.70)	0.0329	
> 65	4/ 5 (80.0)	80.0	0/ 1 (0.0)	0.0	3.00 (0.26, 34.57)	0.3784	80.00 (-24.53, 184.53)	0.1336	
Sex									0.1110
male	3/ 12 (25.0)	25.0	5/ 12 (41.7)	41.7	0.60 (0.18, 1.97)	0.3989	-16.67 (-55.08, 21.75)	0.3951	
female	60/168 (35.7)	35.7	37/170 (21.8)	21.8	1.64 (1.16, 2.33)	0.0055	13.92 (4.20, 23.64)	0.0050	
Race									0.5895
White	38/110 (34.5)	34.2	29/107 (27.1)	26.6	1.27 (0.85, 1.91)	0.2384	7.59 (-4.80, 19.97)	0.2297	
Black or African American	7/ 17 (41.2)	41.2	8/ 25 (32.0)	32.0	1.29 (0.57, 2.88)	0.5397	9.18 (-20.83, 39.19)	0.5489	
Asian	7/ 30 (23.3)	23.3	2/ 30 (6.7)	6.7	3.50 (0.79, 15.49)	0.0989	16.67 (-2.88, 36.22)	0.0947	
American Indian or Alaska Native	2/ 4 (50.0)	50.0	0/ 1 (0.0)	0.0	2.00 (0.16, 25.75)	0.5950	50.00 (-57.80, 157.80)	0.3633	
Other	4/ 11 (36.4)	36.4	1/ 11 (9.1)	9.1	4.00 (0.53, 30.33)	0.1798	27.27 (-10.10, 64.65)	0.1527	
Ethnicity									0.3362
Hispanic/Latino	16/ 54 (29.6)	29.9	14/ 54 (25.9)	26.0	1.14 (0.62, 2.10)	0.6679	3.87 (-13.67, 21.41)	0.6654	
Non-hispanic/Latino	42/118 (35.6)	35.3	26/120 (21.7)	21.6	1.64 (1.08, 2.49)	0.0199	13.74 (2.14, 25.35)	0.0203	
Geographic region									0.8952
EU	21/ 51 (41.2)	41.2	13/ 46 (28.3)	28.3	1.46 (0.83, 2.56)	0.1919	12.92 (-6.02, 31.85)	0.1813	
non-EU	42/129 (32.6)	32.5	29/136 (21.3)	21.3	1.53 (1.02, 2.29)	0.0417	11.27 (0.43, 22.11)	0.0416	
Onset of disease									0.6232
Paediatric	3/ 14 (21.4)	21.4	1/ 12 (8.3)	8.3	2.57 (0.31, 21.59)	0.3843	13.10 (-19.13, 45.32)	0.4257	
Adult	60/166 (36.1)	36.1	41/170 (24.1)	24.1	1.50 (1.07, 2.09)	0.0178	12.00 (2.18, 21.83)	0.0167	
ADA result									0.3012
Negative	63/172 (36.6)	36.4	39/162 (24.1)	24.2	1.52 (1.09, 2.13)	0.0146	12.15 (2.30, 22.01)	0.0157	
Positive (At any time)	0/ 8 (0.0)	0.0	3/ 20 (15.0)	15.0	0.33 (0.02, 5.81)	0.4513	-15.00 (-46.36, 16.36)	0.3486	
BMI (kg/m2) at enrolment									0.9618
< 30	42/125 (33.6)	33.5	30/134 (22.4)	22.7	1.50 (1.01, 2.24)	0.0467	10.84 (-0.27, 21.94)	0.0558	
>= 30	21/ 55 (38.2)	38.4	12/ 48 (25.0)	24.5	1.53 (0.84, 2.77)	0.1625	13.90 (-4.34, 32.15)	0.1352	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.6956
All negative/normal	24/ 58 (41.4)	41.3	20/ 81 (24.7)	23.8	1.68 (1.03, 2.73)	0.0382	17.54 (1.66, 33.42)	0.0304	
At least one positive/abnormal	39/122 (32.0)	31.4	22/101 (21.8)	21.6	1.47 (0.93, 2.30)	0.0956	9.77 (-1.96, 21.49)	0.1026	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Social Functioning Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 52	Number of subjects with events, n (%)	41 (22.8)	24 (13.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.74 (1.09, 2.77)	
	p-value	0.0209	
	Odds Ratio (95% CI)	1.92 (1.11, 3.31)	
	p-value	0.0193	
	Risk Difference (95% CI)	9.66 (1.69, 17.63)	
	p-value	0.0175	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.73 (1.09, 2.74)	
	p-value	0.0198	
	Odds Ratio (95% CI)	1.94 (1.12, 3.38)	
	p-value	0.0186	
	Risk Difference (95% CI)	9.59 (1.74, 17.45)	
	p-value	0.0167	
	CMH approach		
	Response rate	22.6	13.1
	Difference in response rates (95% CI)	9.46 (1.22, 17.69)	
	p-value	0.0244	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Social Functioning Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.0125
< 10 points	18/ 54 (33.3)	33.3	3/ 52 (5.8)	5.8	5.78 (1.81, 18.46)	0.0031	27.46 (11.64, 43.29)	0.0007	
>= 10 points	23/126 (18.3)	18.1	21/130 (16.2)	16.1	1.13 (0.66, 1.94)	0.6564	2.00 (-7.76, 11.76)	0.6885	
OCS dose at baseline									0.2307
<10 mg/day	17/ 93 (18.3)	18.3	14/ 99 (14.1)	14.1	1.29 (0.68, 2.47)	0.4377	4.19 (-7.19, 15.56)	0.4705	
>=10 mg/day	24/ 87 (27.6)	27.6	10/ 83 (12.0)	12.0	2.29 (1.17, 4.49)	0.0159	15.54 (3.49, 27.59)	0.0115	
Result of type I IFN gene signature test									0.9978
LOW	5/ 30 (16.7)	16.7	3/ 31 (9.7)	9.7	1.72 (0.45, 6.58)	0.4267	6.99 (-12.01, 25.99)	0.4710	
HIGH	36/150 (24.0)	23.8	21/151 (13.9)	13.8	1.73 (1.06, 2.81)	0.0286	9.96 (0.83, 19.09)	0.0325	
Age (years)									0.7041
<= 65	40/175 (22.9)	22.6	24/181 (13.3)	13.2	1.72 (1.09, 2.73)	0.0207	9.40 (1.08, 17.73)	0.0269	
> 65	1/ 5 (20.0)	20.0	0/ 1 (0.0)	0.0	1.00 (0.06, 15.99)	1.0000	20.00 (-84.53, 124.53)	0.7077	
Sex									0.2245
male	2/ 12 (16.7)	16.7	3/ 12 (25.0)	25.0	0.67 (0.13, 3.30)	0.6195	-8.33 (-44.22, 27.56)	0.6490	
female	39/168 (23.2)	23.1	21/170 (12.4)	12.3	1.88 (1.16, 3.05)	0.0109	10.75 (2.20, 19.30)	0.0137	
Race									0.5066
White	23/110 (20.9)	20.2	19/107 (17.8)	17.7	1.18 (0.68, 2.03)	0.5577	2.53 (-8.45, 13.50)	0.6518	
Black or African American	4/ 17 (23.5)	23.5	3/ 25 (12.0)	12.0	1.96 (0.50, 7.67)	0.3334	11.53 (-14.56, 37.61)	0.3863	
Asian	7/ 30 (23.3)	23.3	2/ 30 (6.7)	6.7	3.50 (0.79, 15.49)	0.0989	16.67 (-2.88, 36.22)	0.0947	
American Indian or Alaska Native	2/ 4 (50.0)	50.0	0/ 1 (0.0)	0.0	2.00 (0.16, 25.75)	0.5950	50.00 (-57.80, 157.80)	0.3633	
Other	3/ 11 (27.3)	27.3	0/ 11 (0.0)	0.0	7.00 (0.40, 121.39)	0.1813	27.27 (-7.07, 61.62)	0.1196	
Ethnicity									0.3909
Hispanic/Latino	17/ 54 (31.5)	32.3	8/ 54 (14.8)	15.3	2.13 (1.00, 4.50)	0.0491	17.00 (0.27, 33.73)	0.0464	
Non-hispanic/Latino	22/118 (18.6)	18.4	16/120 (13.3)	13.2	1.40 (0.77, 2.53)	0.2668	5.20 (-4.97, 15.38)	0.3159	
Geographic region									0.4024
EU	8/ 51 (15.7)	15.7	6/ 46 (13.0)	13.0	1.20 (0.45, 3.21)	0.7123	2.64 (-12.33, 17.62)	0.7294	
non-EU	33/129 (25.6)	25.4	18/136 (13.2)	13.2	1.93 (1.15, 3.26)	0.0132	12.16 (2.16, 22.16)	0.0171	
Onset of disease									0.5291
Paediatric	2/ 14 (14.3)	14.3	0/ 12 (0.0)	0.0	4.33 (0.23, 82.31)	0.3290	14.29 (-14.43, 43.00)	0.3295	
Adult	39/166 (23.5)	23.3	24/170 (14.1)	14.1	1.66 (1.05, 2.64)	0.0305	9.23 (0.51, 17.95)	0.0380	
ADA result									0.7579
Negative	40/172 (23.3)	22.8	23/162 (14.2)	14.0	1.64 (1.03, 2.61)	0.0379	8.80 (0.13, 17.48)	0.0467	
Positive (At any time)	1/ 8 (12.5)	12.5	1/ 20 (5.0)	5.0	2.50 (0.18, 35.31)	0.4976	7.50 (-25.82, 40.82)	0.6591	
BMI (kg/m2) at enrolment									0.2398
< 30	29/125 (23.2)	23.5	15/134 (11.2)	11.3	2.07 (1.17, 3.68)	0.0128	12.22 (2.37, 22.06)	0.0150	
>= 30	12/ 55 (21.8)	22.0	9/ 48 (18.8)	19.2	1.16 (0.54, 2.52)	0.7007	2.71 (-14.23, 19.65)	0.7541	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.3851
All negative/normal	16/ 58 (27.6)	27.4	10/ 81 (12.3)	12.0	2.23 (1.09, 4.57)	0.0274	15.37 (0.93, 29.80)	0.0370	
At least one positive/abnormal	25/122 (20.5)	20.5	14/101 (13.9)	13.8	1.48 (0.81, 2.69)	0.2007	6.71 (-3.70, 17.11)	0.2065	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Bodily Pain Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 52	Number of subjects with events, n (%)	50 (27.8)	39 (21.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.30 (0.90, 1.86)	
	p-value	0.1622	
	Odds Ratio (95% CI)	1.41 (0.87, 2.27)	
	p-value	0.1624	
	Risk Difference (95% CI)	6.38 (-2.53, 15.30)	
	p-value	0.1606	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.30 (0.90, 1.87)	
	p-value	0.1629	
	Odds Ratio (95% CI)	1.41 (0.87, 2.28)	
	p-value	0.1616	
	Risk Difference (95% CI)	6.35 (-2.50, 15.20)	
	p-value	0.1598	
	CMH approach		
	Response rate	27.8	21.5
	Difference in response rates (95% CI)	6.23 (-2.89, 15.36)	
	p-value	0.1807	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Bodily Pain Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.2665
< 10 points	17/ 54 (31.5)	31.5	9/ 52 (17.3)	17.3	1.82 (0.89, 3.71)	0.0999	14.16 (-2.93, 31.25)	0.1045	
>= 10 points	33/126 (26.2)	26.2	30/130 (23.1)	23.3	1.13 (0.74, 1.74)	0.5635	2.95 (-7.92, 13.81)	0.5950	
OCS dose at baseline									0.2816
<10 mg/day	28/ 93 (30.1)	30.1	19/ 99 (19.2)	19.2	1.57 (0.94, 2.61)	0.0831	10.85 (-1.72, 23.42)	0.0908	
>=10 mg/day	22/ 87 (25.3)	25.3	20/ 83 (24.1)	24.1	1.05 (0.62, 1.78)	0.8572	1.19 (-11.97, 14.35)	0.8592	
Result of type I IFN gene signature test									0.8881
LOW	8/ 30 (26.7)	26.7	6/ 31 (19.4)	19.4	1.38 (0.54, 3.50)	0.5003	7.31 (-14.70, 29.32)	0.5149	
HIGH	42/150 (28.0)	28.0	33/151 (21.9)	22.0	1.28 (0.86, 1.90)	0.2200	6.02 (-4.02, 16.05)	0.2399	
Age (years)									0.6260
<= 65	47/175 (26.9)	26.8	39/181 (21.5)	21.7	1.25 (0.86, 1.80)	0.2435	5.13 (-4.04, 14.31)	0.2729	
> 65	3/ 5 (60.0)	60.0	0/ 1 (0.0)	0.0	2.33 (0.19, 28.25)	0.5055	60.00 (-45.43, 165.43)	0.2647	
Sex									0.0549
male	1/ 12 (8.3)	8.3	5/ 12 (41.7)	41.7	0.20 (0.03, 1.47)	0.1134	-33.33 (-69.05, 2.38)	0.0674	
female	49/168 (29.2)	29.2	34/170 (20.0)	20.1	1.46 (1.00, 2.14)	0.0529	9.03 (-0.40, 18.47)	0.0605	
Race									0.8719
White	30/110 (27.3)	27.2	25/107 (23.4)	22.8	1.17 (0.74, 1.85)	0.5092	4.44 (-7.41, 16.29)	0.4630	
Black or African American	6/ 17 (35.3)	35.3	5/ 25 (20.0)	20.0	1.76 (0.64, 4.87)	0.2724	15.29 (-13.24, 43.83)	0.2935	
Asian	5/ 30 (16.7)	16.7	6/ 30 (20.0)	20.0	0.83 (0.28, 2.44)	0.7392	-3.33 (-24.30, 17.64)	0.7554	
American Indian or Alaska Native	2/ 4 (50.0)	50.0	0/ 1 (0.0)	0.0	2.00 (0.16, 25.75)	0.5950	50.00 (-57.80, 157.80)	0.3633	
Other	3/ 11 (27.3)	27.3	2/ 11 (18.2)	18.2	1.50 (0.31, 7.30)	0.6154	9.09 (-29.11, 47.29)	0.6409	
Ethnicity									0.8768
Hispanic/Latino	19/ 54 (35.2)	35.4	15/ 54 (27.8)	27.9	1.27 (0.72, 2.22)	0.4098	7.46 (-10.52, 25.44)	0.4163	
Non-hispanic/Latino	27/118 (22.9)	23.0	23/120 (19.2)	19.1	1.19 (0.73, 1.96)	0.4828	3.82 (-7.18, 14.82)	0.4960	
Geographic region									0.4996
EU	13/ 51 (25.5)	25.5	7/ 46 (15.2)	15.2	1.68 (0.73, 3.83)	0.2220	10.27 (-6.24, 26.79)	0.2227	
non-EU	37/129 (28.7)	28.9	32/136 (23.5)	23.7	1.22 (0.81, 1.83)	0.3406	5.19 (-5.77, 16.14)	0.3533	
Onset of disease									0.2805
Paediatric	3/ 14 (21.4)	21.4	0/ 12 (0.0)	0.0	6.07 (0.34, 106.85)	0.2180	21.43 (-8.58, 51.44)	0.1617	
Adult	47/166 (28.3)	28.3	39/170 (22.9)	23.0	1.23 (0.86, 1.78)	0.2608	5.26 (-4.33, 14.84)	0.2822	
ADA result									0.9985
Negative	49/172 (28.5)	28.5	37/162 (22.8)	23.0	1.25 (0.86, 1.80)	0.2405	5.49 (-4.13, 15.11)	0.2631	
Positive (At any time)	1/ 8 (12.5)	12.5	2/ 20 (10.0)	10.0	1.25 (0.13, 11.93)	0.8463	2.50 (-31.66, 36.66)	0.8860	
BMI (kg/m2) at enrolment									0.0824
< 30	33/125 (26.4)	26.6	33/134 (24.6)	24.7	1.07 (0.71, 1.63)	0.7435	1.92 (-9.11, 12.95)	0.7327	
>= 30	17/ 55 (30.9)	31.1	6/ 48 (12.5)	11.7	2.47 (1.06, 5.76)	0.0360	19.43 (2.67, 36.19)	0.0231	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.2188
All negative/normal	21/ 58 (36.2)	36.3	17/ 81 (21.0)	20.0	1.73 (1.00, 2.97)	0.0492	16.23 (0.75, 31.70)	0.0399	
At least one positive/abnormal	29/122 (23.8)	24.2	22/101 (21.8)	21.9	1.09 (0.67, 1.78)	0.7254	2.26 (-9.17, 13.69)	0.6978	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Vitality Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 52	Number of subjects with events, n (%)	42 (23.3)	25 (13.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.68 (1.07, 2.65)	
	p-value	0.0241	
	Odds Ratio (95% CI)	1.87 (1.09, 3.21)	
	p-value	0.0234	
	Risk Difference (95% CI)	9.47 (1.42, 17.52)	
	p-value	0.0211	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.70 (1.08, 2.66)	
	p-value	0.0211	
	Odds Ratio (95% CI)	1.91 (1.11, 3.30)	
	p-value	0.0199	
	Risk Difference (95% CI)	9.60 (1.65, 17.55)	
	p-value	0.0180	
	CMH approach		
	Response rate	23.2	13.7
	Difference in response rates (95% CI)	9.49 (1.10, 17.88)	
	p-value	0.0266	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Vitality Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.1831
< 10 points	15/ 54 (27.8)	27.7	5/ 52 (9.6)	9.6	2.89 (1.13, 7.38)	0.0266	18.12 (2.14, 34.10)	0.0263	
>= 10 points	27/126 (21.4)	21.4	20/130 (15.4)	15.4	1.39 (0.82, 2.35)	0.2150	5.91 (-4.07, 15.89)	0.2461	
OCS dose at baseline									0.8862
<10 mg/day	20/ 93 (21.5)	21.5	13/ 99 (13.1)	13.1	1.64 (0.87, 3.10)	0.1299	8.38 (-3.24, 20.01)	0.1575	
>=10 mg/day	22/ 87 (25.3)	25.3	12/ 83 (14.5)	14.5	1.75 (0.93, 3.30)	0.0848	10.83 (-1.35, 23.00)	0.0813	
Result of type I IFN gene signature test									0.2098
LOW	4/ 30 (13.3)	13.3	5/ 31 (16.1)	16.1	0.83 (0.25, 2.79)	0.7588	-2.80 (-22.40, 16.81)	0.7799	
HIGH	38/150 (25.3)	25.2	20/151 (13.2)	13.2	1.91 (1.17, 3.13)	0.0098	11.98 (2.71, 21.26)	0.0113	
Age (years)									0.7123
<= 65	41/175 (23.4)	23.2	25/181 (13.8)	13.8	1.70 (1.08, 2.67)	0.0219	9.47 (1.00, 17.94)	0.0284	
> 65	1/ 5 (20.0)	20.0	0/ 1 (0.0)	0.0	1.00 (0.06, 15.99)	1.0000	20.00 (-84.53, 124.53)	0.7077	
Sex									0.2333
male	2/ 12 (16.7)	16.7	3/ 12 (25.0)	25.0	0.67 (0.13, 3.30)	0.6195	-8.33 (-44.22, 27.56)	0.6490	
female	40/168 (23.8)	23.7	22/170 (12.9)	13.0	1.84 (1.14, 2.96)	0.0118	10.77 (2.09, 19.46)	0.0150	
Race									0.7985
White	24/110 (21.8)	21.4	17/107 (15.9)	15.8	1.37 (0.78, 2.41)	0.2682	5.57 (-5.38, 16.53)	0.3185	
Black or African American	6/ 17 (35.3)	35.3	3/ 25 (12.0)	12.0	2.94 (0.85, 10.18)	0.0885	23.29 (-4.13, 50.72)	0.0960	
Asian	6/ 30 (20.0)	20.0	3/ 30 (10.0)	10.0	2.00 (0.55, 7.27)	0.2924	10.00 (-9.77, 29.77)	0.3216	
American Indian or Alaska Native	2/ 4 (50.0)	50.0	0/ 1 (0.0)	0.0	2.00 (0.16, 25.75)	0.5950	50.00 (-57.80, 157.80)	0.3633	
Other	3/ 11 (27.3)	27.3	1/ 11 (9.1)	9.1	3.00 (0.37, 24.58)	0.3059	18.18 (-18.35, 54.72)	0.3294	
Ethnicity									0.1122
Hispanic/Latino	16/ 54 (29.6)	29.9	5/ 54 (9.3)	9.3	3.20 (1.26, 8.12)	0.0143	20.56 (4.60, 36.53)	0.0116	
Non-hispanic/Latino	25/118 (21.2)	21.1	19/120 (15.8)	15.6	1.34 (0.78, 2.30)	0.2902	5.54 (-5.03, 16.11)	0.3040	
Geographic region									0.1425
EU	7/ 51 (13.7)	13.7	7/ 46 (15.2)	15.2	0.90 (0.34, 2.38)	0.8347	-1.49 (-16.54, 13.55)	0.8459	
non-EU	35/129 (27.1)	27.0	18/136 (13.2)	13.2	2.05 (1.22, 3.43)	0.0063	13.76 (3.62, 23.91)	0.0078	
Onset of disease									0.5222
Paediatric	2/ 14 (14.3)	14.3	0/ 12 (0.0)	0.0	4.33 (0.23, 82.31)	0.3290	14.29 (-14.43, 43.00)	0.3295	
Adult	40/166 (24.1)	24.0	25/170 (14.7)	14.7	1.64 (1.04, 2.57)	0.0321	9.26 (0.40, 18.12)	0.0405	
ADA result									0.3450
Negative	41/172 (23.8)	23.6	25/162 (15.4)	15.4	1.54 (0.99, 2.42)	0.0575	8.20 (-0.70, 17.10)	0.0709	
Positive (At any time)	1/ 8 (12.5)	12.5	0/ 20 (0.0)	0.0	7.00 (0.31, 155.99)	0.2192	12.50 (-19.86, 44.86)	0.4490	
BMI (kg/m2) at enrolment									0.8999
< 30	29/125 (23.2)	23.4	18/134 (13.4)	13.4	1.73 (1.01, 2.95)	0.0454	10.03 (-0.06, 20.12)	0.0515	
>= 30	13/ 55 (23.6)	23.4	7/ 48 (14.6)	13.9	1.62 (0.70, 3.73)	0.2560	9.57 (-6.85, 26.00)	0.2533	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.4128
All negative/normal	17/ 58 (29.3)	29.8	11/ 81 (13.6)	13.3	2.16 (1.09, 4.26)	0.0265	16.51 (1.87, 31.15)	0.0271	
At least one positive/abnormal	25/122 (20.5)	20.7	14/101 (13.9)	13.8	1.48 (0.81, 2.69)	0.2007	6.89 (-3.55, 17.33)	0.1958	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
C-SSRS Suicidal ideation or behaviour
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
On-treatment/Follow-Up	Number of subjects with events, n (%)	3 (1.7)	8 (4.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.38 (0.10, 1.49)	
	p-value	0.1665	
	Odds Ratio (95% CI)	0.37 (0.10, 1.45)	
	p-value	0.1556	
	Risk Difference (95% CI)	-2.62 (-6.09, 0.86)	
	p-value	0.1398	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.38 (0.10, 1.41)	
	p-value	0.1470	
	Odds Ratio (95% CI)	0.37 (0.10, 1.41)	
	p-value	0.1454	
	Risk Difference (95% CI)	-2.73 (-6.25, 0.79)	
	p-value	0.1283	
	CMH approach		
	Response rate	1.6	4.4
	Difference in response rates (95% CI)	-2.77 (-8.16, 2.62)	
	p-value	0.3140	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
C-SSRS Suicidal ideation or behaviour - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8582
< 10 points	1/ 54 (1.9)	1.8	3/ 52 (5.8)	5.8	0.32 (0.03, 2.99)	0.3181	-3.92 (-16.39, 8.56)	0.5383	
>= 10 points	2/126 (1.6)	1.5	5/130 (3.8)	3.8	0.41 (0.08, 2.09)	0.2847	-2.29 (-8.28, 3.71)	0.4546	
OCS dose at baseline									0.6765
<10 mg/day	1/ 93 (1.1)	1.0	4/ 99 (4.0)	4.0	0.27 (0.03, 2.34)	0.2325	-3.00 (-10.91, 4.91)	0.4572	
>=10 mg/day	2/ 87 (2.3)	2.3	4/ 83 (4.8)	4.8	0.48 (0.09, 2.54)	0.3851	-2.52 (-9.47, 4.43)	0.4771	
Result of type I IFN gene signature test									0.3945
LOW	0/ 30 (0.0)	0.0	3/ 31 (9.7)	9.7	0.15 (0.01, 2.74)	0.1991	-9.68 (-24.60, 5.24)	0.2037	
HIGH	3/150 (2.0)	1.9	5/151 (3.3)	3.3	0.60 (0.15, 2.48)	0.4845	-1.37 (-7.10, 4.37)	0.6403	
Age (years)									NE
<= 65	3/175 (1.7)	1.6	8/181 (4.4)	4.4	0.39 (0.10, 1.44)	0.1566	-2.73 (-8.20, 2.73)	0.3269	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
female	3/168 (1.8)	1.7	8/170 (4.7)	4.7	0.38 (0.10, 1.41)	0.1470	-2.92 (-8.65, 2.81)	0.3179	
Race									0.6900
White	3/110 (2.7)	2.6	4/107 (3.7)	3.8	0.73 (0.17, 3.18)	0.6748	-1.18 (-8.26, 5.91)	0.7443	
Black or African American	0/ 17 (0.0)	0.0	2/ 25 (8.0)	8.0	0.29 (0.01, 5.67)	0.4135	-8.00 (-27.43, 11.43)	0.4196	
Asian	0/ 30 (0.0)	0.0	2/ 30 (6.7)	6.7	0.20 (0.01, 4.00)	0.2923	-6.67 (-20.94, 7.61)	0.3601	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-28.41, 28.41)	1.0000	
Ethnicity									0.5802
Hispanic/Latino	0/ 54 (0.0)	0.0	2/ 54 (3.7)	3.7	0.20 (0.01, 4.07)	0.2952	-3.69 (-15.05, 7.66)	0.5241	
Non-hispanic/Latino	3/118 (2.5)	2.5	6/120 (5.0)	5.0	0.51 (0.13, 1.99)	0.3306	-2.57 (-10.17, 5.03)	0.5075	
Geographic region									0.1951
EU	1/ 51 (2.0)	2.0	0/ 46 (0.0)	0.0	2.71 (0.11, 64.96)	0.5382	1.96 (-6.46, 10.38)	0.6481	
non-EU	2/129 (1.6)	1.5	8/136 (5.9)	5.8	0.26 (0.06, 1.22)	0.0877	-4.34 (-11.34, 2.66)	0.2245	
Onset of disease									NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-24.92, 24.92)	1.0000	
Adult	3/166 (1.8)	1.7	8/170 (4.7)	4.7	0.38 (0.10, 1.42)	0.1520	-2.91 (-8.67, 2.86)	0.3226	
ADA result									NE
Negative	3/172 (1.7)	1.7	8/162 (4.9)	4.9	0.35 (0.10, 1.31)	0.1193	-3.23 (-9.07, 2.61)	0.2779	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment									0.5193
< 30	2/125 (1.6)	1.6	4/134 (3.0)	3.0	0.54 (0.10, 2.88)	0.4668	-1.35 (-8.09, 5.39)	0.6944	
>= 30	1/ 55 (1.8)	1.8	4/ 48 (8.3)	8.2	0.22 (0.03, 1.89)	0.1665	-6.35 (-19.54, 6.83)	0.3452	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.1433
All negative/normal	3/ 58 (5.2)	5.3	4/ 81 (4.9)	5.0	1.05 (0.24, 4.50)	0.9504	0.30 (-10.74, 11.33)	0.9578	
At least one positive/abnormal	0/122 (0.0)	0.0	4/101 (4.0)	4.1	0.09 (0.01, 1.69)	0.1083	-4.10 (-10.43, 2.22)	0.2037	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Modified SELENA Flare Index based flares - mild/moderate flare
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
at least once during study	Number of subjects with events, n (%)	58 (32.2)	67 (36.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.88 (0.66, 1.17)	
	p-value	0.3687	
	Odds Ratio (95% CI)	0.82 (0.53, 1.26)	
	p-value	0.3672	
	Risk Difference (95% CI)	-4.56 (-14.44, 5.33)	
	p-value	0.3661	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.88 (0.66, 1.16)	
	p-value	0.3593	
	Odds Ratio (95% CI)	0.82 (0.53, 1.26)	
	p-value	0.3586	
	Risk Difference (95% CI)	-4.59 (-14.37, 5.19)	
	p-value	0.3577	
	CMH approach		
	Response rate	32.1	36.7
	Difference in response rates (95% CI)	-4.59 (-14.34, 5.17)	
	p-value	0.3567	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Modified SELENA Flare Index based flares - mild/moderate flare - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.0189
< 10 points	24/ 54 (44.4)	44.3	16/ 52 (30.8)	30.7	1.44 (0.87, 2.39)	0.1536	13.59 (-4.70, 31.87)	0.1452	
>= 10 points	34/126 (27.0)	27.1	51/130 (39.2)	39.2	0.69 (0.48, 0.98)	0.0406	-12.14 (-23.70, -0.57)	0.0397	
OCS dose at baseline									0.7595
<10 mg/day	30/ 93 (32.3)	32.0	35/ 99 (35.4)	35.0	0.91 (0.61, 1.36)	0.6511	-2.94 (-16.39, 10.51)	0.6683	
>=10 mg/day	28/ 87 (32.2)	32.2	32/ 83 (38.6)	38.6	0.83 (0.55, 1.26)	0.3861	-6.37 (-20.78, 8.04)	0.3864	
Result of type I IFN gene signature test									0.8777
LOW	8/ 30 (26.7)	26.7	10/ 31 (32.3)	32.3	0.83 (0.38, 1.81)	0.6335	-5.59 (-28.94, 17.75)	0.6388	
HIGH	50/150 (33.3)	33.3	57/151 (37.7)	37.6	0.88 (0.65, 1.20)	0.4245	-4.38 (-15.12, 6.35)	0.4235	
Age (years)									0.0987
<= 65	57/175 (32.6)	32.4	66/181 (36.5)	36.4	0.89 (0.67, 1.19)	0.4409	-3.98 (-13.82, 5.86)	0.4280	
> 65	1/ 5 (20.0)	20.0	1/ 1 (100.0)	100.0	0.20 (0.03, 1.15)	0.0720	-80.00 (-184.53, 24.53)	0.1336	
Sex									0.2675
male	2/ 12 (16.7)	16.7	5/ 12 (41.7)	41.7	0.40 (0.10, 1.67)	0.2096	-25.00 (-62.26, 12.26)	0.1884	
female	56/168 (33.3)	33.3	62/170 (36.5)	36.5	0.91 (0.68, 1.22)	0.5456	-3.15 (-13.28, 6.97)	0.5413	
Race									0.9189
White	35/110 (31.8)	30.5	39/107 (36.4)	36.2	0.87 (0.60, 1.26)	0.4726	-5.67 (-18.20, 6.86)	0.3751	
Black or African American	7/ 17 (41.2)	41.2	9/ 25 (36.0)	36.0	1.14 (0.53, 2.48)	0.7330	5.18 (-25.08, 35.43)	0.7373	
Asian	9/ 30 (30.0)	30.0	9/ 30 (30.0)	30.0	1.00 (0.46, 2.17)	1.0000	0.00 (-23.67, 23.67)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	4/ 11 (36.4)	36.4	5/ 11 (45.5)	45.5	0.80 (0.29, 2.21)	0.6665	-9.09 (-50.41, 32.23)	0.6663	
Ethnicity									0.5917
Hispanic/Latino	15/ 54 (27.8)	28.6	19/ 54 (35.2)	36.0	0.79 (0.45, 1.39)	0.4098	-7.34 (-25.16, 10.49)	0.4198	
Non-hispanic/Latino	40/118 (33.9)	33.5	43/120 (35.8)	35.4	0.95 (0.67, 1.34)	0.7542	-1.85 (-13.92, 10.23)	0.7645	
Geographic region									0.0344
EU	11/ 51 (21.6)	21.6	20/ 46 (43.5)	43.5	0.50 (0.27, 0.92)	0.0263	-21.91 (-40.40, -3.42)	0.0202	
non-EU	47/129 (36.4)	36.3	47/136 (34.6)	34.4	1.05 (0.76, 1.46)	0.7498	1.83 (-9.60, 13.26)	0.7537	
Onset of disease									0.9675
Paediatric	5/ 14 (35.7)	35.7	5/ 12 (41.7)	41.7	0.86 (0.32, 2.26)	0.7556	-5.95 (-43.90, 31.99)	0.7585	
Adult	53/166 (31.9)	31.8	62/170 (36.5)	36.4	0.88 (0.65, 1.18)	0.3813	-4.63 (-14.73, 5.47)	0.3686	
ADA result									0.7176
Negative	55/172 (32.0)	31.8	57/162 (35.2)	35.0	0.91 (0.67, 1.23)	0.5349	-3.23 (-13.35, 6.89)	0.5316	
Positive (At any time)	3/ 8 (37.5)	37.5	10/ 20 (50.0)	50.0	0.75 (0.28, 2.03)	0.5714	-12.50 (-53.09, 28.09)	0.5461	
BMI (kg/m2) at enrolment									0.8490
< 30	37/125 (29.6)	29.7	45/134 (33.6)	33.4	0.88 (0.61, 1.26)	0.4923	-3.67 (-14.99, 7.65)	0.5254	
>= 30	21/ 55 (38.2)	36.2	22/ 48 (45.8)	44.0	0.83 (0.53, 1.31)	0.4321	-7.79 (-26.22, 10.64)	0.4075	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.7030
All negative/normal	18/ 58 (31.0)	30.8	27/ 81 (33.3)	33.1	0.93 (0.57, 1.52)	0.7759	-2.28 (-18.24, 13.67)	0.7793	
At least one positive/abnormal	40/122 (32.8)	32.5	40/101 (39.6)	39.0	0.83 (0.58, 1.17)	0.2902	-6.51 (-18.88, 5.86)	0.3025	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Modified SELENA Flare Index based flares - severe flare
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
at least once during study	Number of subjects with events, n (%)	3 (1.7)	7 (3.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.43 (0.11, 1.65)	
	p-value	0.2192	
	Odds Ratio (95% CI)	0.42 (0.11, 1.66)	
	p-value	0.2174	
	Risk Difference (95% CI)	-2.19 (-5.57, 1.19)	
	p-value	0.2034	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.43 (0.11, 1.65)	
	p-value	0.2201	
	Odds Ratio (95% CI)	0.42 (0.11, 1.67)	
	p-value	0.2188	
	Risk Difference (95% CI)	-2.18 (-5.54, 1.18)	
	p-value	0.2039	
	CMH approach		
	Response rate	1.7	3.9
	Difference in response rates (95% CI)	-2.26 (-7.65, 3.13)	
	p-value	0.4110	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Modified SELENA Flare Index based flares - severe flare - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.5242
< 10 points	1/ 54 (1.9)	1.8	1/ 52 (1.9)	1.9	0.96 (0.06, 15.00)	0.9785	-0.09 (-11.87, 11.68)	0.9875	
>= 10 points	2/126 (1.6)	1.6	6/130 (4.6)	4.7	0.34 (0.07, 1.67)	0.1859	-3.15 (-9.43, 3.13)	0.3254	
OCS dose at baseline									0.1091
<10 mg/day	2/ 93 (2.2)	2.1	1/ 99 (1.0)	1.0	2.13 (0.20, 23.09)	0.5344	1.15 (-6.52, 8.82)	0.7681	
>=10 mg/day	1/ 87 (1.1)	1.1	6/ 83 (7.2)	7.2	0.16 (0.02, 1.29)	0.0855	-6.08 (-13.34, 1.18)	0.1008	
Result of type I IFN gene signature test									0.8287
LOW	0/ 30 (0.0)	0.0	1/ 31 (3.2)	3.2	0.34 (0.01, 8.13)	0.5085	-3.23 (-16.19, 9.74)	0.6257	
HIGH	3/150 (2.0)	2.0	6/151 (4.0)	4.1	0.50 (0.13, 1.98)	0.3251	-2.06 (-7.99, 3.86)	0.4946	
Age (years)									NE
<= 65	3/175 (1.7)	1.7	7/181 (3.9)	3.9	0.44 (0.12, 1.69)	0.2328	-2.24 (-7.71, 3.23)	0.4214	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									0.1870
male	1/ 12 (8.3)	8.3	0/ 12 (0.0)	0.0	3.00 (0.13, 67.06)	0.4883	8.33 (-20.61, 37.28)	0.5726	
female	2/168 (1.2)	1.2	7/170 (4.1)	4.2	0.29 (0.06, 1.37)	0.1183	-3.01 (-8.66, 2.64)	0.2969	
Race									0.5211
White	1/110 (0.9)	0.7	5/107 (4.7)	4.5	0.19 (0.02, 1.64)	0.1321	-3.80 (-10.67, 3.07)	0.2788	
Black or African American	0/ 17 (0.0)	0.0	1/ 25 (4.0)	4.0	0.48 (0.02, 11.17)	0.6486	-4.00 (-22.36, 14.36)	0.6694	
Asian	1/ 30 (3.3)	3.3	1/ 30 (3.3)	3.3	1.00 (0.07, 15.26)	1.0000	0.00 (-14.35, 14.35)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	1/ 11 (9.1)	9.1	0/ 11 (0.0)	0.0	3.00 (0.14, 66.53)	0.4872	9.09 (-21.93, 40.11)	0.5657	
Ethnicity									0.7669
Hispanic/Latino	1/ 54 (1.9)	1.7	3/ 54 (5.6)	5.7	0.33 (0.04, 3.10)	0.3346	-3.97 (-16.18, 8.24)	0.5238	
Non-hispanic/Latino	2/118 (1.7)	1.7	4/120 (3.3)	3.4	0.51 (0.09, 2.72)	0.4296	-1.68 (-8.97, 5.62)	0.6524	
Geographic region									0.7511
EU	0/ 51 (0.0)	0.0	1/ 46 (2.2)	2.2	0.30 (0.01, 7.22)	0.4591	-2.17 (-10.75, 6.40)	0.6192	
non-EU	3/129 (2.3)	2.3	6/136 (4.4)	4.6	0.53 (0.13, 2.06)	0.3578	-2.28 (-9.28, 4.72)	0.5225	
Onset of disease									NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-24.92, 24.92)	1.0000	
Adult	3/166 (1.8)	1.8	7/170 (4.1)	4.2	0.44 (0.12, 1.67)	0.2268	-2.38 (-8.13, 3.36)	0.4160	
ADA result									0.9083
Negative	3/172 (1.7)	1.8	5/162 (3.1)	3.2	0.57 (0.14, 2.33)	0.4293	-1.39 (-7.02, 4.23)	0.6273	
Positive (At any time)	0/ 8 (0.0)	0.0	2/ 20 (10.0)	10.0	0.47 (0.02, 8.78)	0.6107	-10.00 (-40.56, 20.56)	0.5212	
BMI (kg/m2) at enrolment									0.2673
< 30	3/125 (2.4)	2.5	4/134 (3.0)	3.0	0.80 (0.18, 3.52)	0.7722	-0.55 (-7.46, 6.36)	0.8764	
>= 30	0/ 55 (0.0)	0.0	3/ 48 (6.3)	6.0	0.13 (0.01, 2.36)	0.1654	-6.03 (-18.68, 6.62)	0.3503	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.3192
All negative/normal	0/ 58 (0.0)	0.0	4/ 81 (4.9)	4.9	0.15 (0.01, 2.81)	0.2072	-4.88 (-14.80, 5.03)	0.3346	
At least one positive/abnormal	3/122 (2.5)	2.5	3/101 (3.0)	2.9	0.83 (0.17, 4.01)	0.8145	-0.40 (-7.14, 6.33)	0.9064	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Modified SELENA Flare Index based flares - mild/moderate or severe flare
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
at least once during study	Number of subjects with events, n (%)	60 (33.3)	70 (38.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.87 (0.65, 1.15)	
	p-value	0.3131	
	Odds Ratio (95% CI)	0.80 (0.52, 1.23)	
	p-value	0.3118	
	Risk Difference (95% CI)	-5.15 (-15.10, 4.80)	
	p-value	0.3105	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.87 (0.66, 1.14)	
	p-value	0.3104	
	Odds Ratio (95% CI)	0.80 (0.52, 1.23)	
	p-value	0.3095	
	Risk Difference (95% CI)	-5.13 (-15.00, 4.74)	
	p-value	0.3084	
	CMH approach		
	Response rate	33.3	38.4
	Difference in response rates (95% CI)	-5.18 (-15.01, 4.65)	
	p-value	0.3019	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Modified SELENA Flare Index based flares - mild/moderate or severe flare - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.0305
< 10 points	24/ 54 (44.4)	44.3	17/ 52 (32.7)	32.7	1.36 (0.83, 2.22)	0.2202	11.65 (-6.72, 30.02)	0.2137	
>= 10 points	36/126 (28.6)	28.7	53/130 (40.8)	40.9	0.70 (0.50, 0.99)	0.0435	-12.17 (-23.84, -0.50)	0.0410	
OCS dose at baseline									0.5318
<10 mg/day	31/ 93 (33.3)	33.2	35/ 99 (35.4)	35.0	0.94 (0.64, 1.40)	0.7685	-1.83 (-15.33, 11.68)	0.7908	
>=10 mg/day	29/ 87 (33.3)	33.3	35/ 83 (42.2)	42.2	0.79 (0.54, 1.17)	0.2369	-8.84 (-23.41, 5.74)	0.2346	
Result of type I IFN gene signature test									0.8995
LOW	8/ 30 (26.7)	26.7	10/ 31 (32.3)	32.3	0.83 (0.38, 1.81)	0.6335	-5.59 (-28.94, 17.75)	0.6388	
HIGH	52/150 (34.7)	34.6	60/151 (39.7)	39.7	0.87 (0.65, 1.17)	0.3641	-5.09 (-15.93, 5.74)	0.3568	
Age (years)									0.1007
<= 65	59/175 (33.7)	33.6	69/181 (38.1)	38.1	0.88 (0.67, 1.17)	0.3874	-4.56 (-14.48, 5.36)	0.3676	
> 65	1/ 5 (20.0)	20.0	1/ 1 (100.0)	100.0	0.20 (0.03, 1.15)	0.0720	-80.00 (-184.53, 24.53)	0.1336	
Sex									0.2741
male	2/ 12 (16.7)	16.7	5/ 12 (41.7)	41.7	0.40 (0.10, 1.67)	0.2096	-25.00 (-62.26, 12.26)	0.1884	
female	58/168 (34.5)	34.5	65/170 (38.2)	38.3	0.90 (0.68, 1.20)	0.4789	-3.79 (-13.99, 6.41)	0.4663	
Race									0.9523
White	35/110 (31.8)	30.5	40/107 (37.4)	37.1	0.85 (0.59, 1.23)	0.3898	-6.58 (-19.13, 5.97)	0.3040	
Black or African American	7/ 17 (41.2)	41.2	10/ 25 (40.0)	40.0	1.03 (0.49, 2.17)	0.9391	1.18 (-29.26, 31.61)	0.9396	
Asian	10/ 30 (33.3)	33.3	10/ 30 (33.3)	33.3	1.00 (0.49, 2.05)	1.0000	0.00 (-24.18, 24.18)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	5/ 11 (45.5)	45.5	5/ 11 (45.5)	45.5	1.00 (0.40, 2.50)	1.0000	0.00 (-41.69, 41.69)	1.0000	
Ethnicity									0.6508
Hispanic/Latino	16/ 54 (29.6)	30.4	20/ 54 (37.0)	38.0	0.80 (0.47, 1.37)	0.4166	-7.61 (-25.62, 10.39)	0.4071	
Non-hispanic/Latino	41/118 (34.7)	34.4	45/120 (37.5)	37.1	0.93 (0.66, 1.30)	0.6586	-2.70 (-14.85, 9.45)	0.6632	
Geographic region									0.0379
EU	11/ 51 (21.6)	21.6	20/ 46 (43.5)	43.5	0.50 (0.27, 0.92)	0.0263	-21.91 (-40.40, -3.42)	0.0202	
non-EU	49/129 (38.0)	37.8	50/136 (36.8)	36.7	1.03 (0.76, 1.41)	0.8374	1.07 (-10.48, 12.61)	0.8565	
Onset of disease									0.9832
Paediatric	5/ 14 (35.7)	35.7	5/ 12 (41.7)	41.7	0.86 (0.32, 2.26)	0.7556	-5.95 (-43.90, 31.99)	0.7585	
Adult	55/166 (33.1)	33.0	65/170 (38.2)	38.3	0.87 (0.65, 1.16)	0.3304	-5.24 (-15.42, 4.94)	0.3128	
ADA result									0.5798
Negative	57/172 (33.1)	33.0	59/162 (36.4)	36.4	0.91 (0.68, 1.22)	0.5293	-3.37 (-13.58, 6.83)	0.5171	
Positive (At any time)	3/ 8 (37.5)	37.5	11/ 20 (55.0)	55.0	0.68 (0.26, 1.81)	0.4430	-17.50 (-58.05, 23.05)	0.3976	
BMI (kg/m2) at enrolment									0.7034
< 30	39/125 (31.2)	31.3	47/134 (35.1)	34.9	0.89 (0.63, 1.26)	0.5092	-3.56 (-14.99, 7.88)	0.5423	
>= 30	21/ 55 (38.2)	36.2	23/ 48 (47.9)	46.1	0.80 (0.51, 1.25)	0.3197	-9.92 (-28.29, 8.45)	0.2899	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.9420
All negative/normal	18/ 58 (31.0)	30.8	29/ 81 (35.8)	35.6	0.87 (0.54, 1.40)	0.5611	-4.82 (-20.89, 11.25)	0.5564	
At least one positive/abnormal	42/122 (34.4)	34.1	41/101 (40.6)	39.9	0.85 (0.60, 1.19)	0.3422	-5.78 (-18.26, 6.70)	0.3639	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score Improvement >=15% (of maxmimum value =33)
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
at least once during study	Number of subjects with events, n (%)	165 (91.7)	149 (81.9)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.12 (1.03, 1.22)	
	p-value	0.0058	
	Odds Ratio (95% CI)	2.48 (1.29, 4.76)	
	p-value	0.0066	
	Risk Difference (95% CI)	9.91 (3.02, 16.80)	
	p-value	0.0048	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.12 (1.03, 1.21)	
	p-value	0.0064	
	Odds Ratio (95% CI)	2.44 (1.27, 4.66)	
	p-value	0.0072	
	Risk Difference (95% CI)	9.80 (2.90, 16.70)	
	p-value	0.0054	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score Improvement >=15% (of maxmimum value =33) at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 52	Number of subjects with events, n (%)	107 (59.4)	79 (43.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.37 (1.12, 1.68)	
	p-value	0.0027	
	Odds Ratio (95% CI)	1.91 (1.26, 2.90)	
	p-value	0.0024	
	Risk Difference (95% CI)	16.05 (5.86, 26.24)	
	p-value	0.0020	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.37 (1.12, 1.68)	
	p-value	0.0027	
	Odds Ratio (95% CI)	1.91 (1.26, 2.90)	
	p-value	0.0024	
	Risk Difference (95% CI)	16.04 (5.87, 26.20)	
	p-value	0.0020	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
SRI (5) response rate at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=181)
Week 52	Number of subjects with events, n (%)	79 (43.9)	51 (28.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.58 (1.19, 2.09)	
	p-value	0.0016	
	Odds Ratio (95% CI)	2.08 (1.33, 3.25)	
	p-value	0.0013	
	Risk Difference (95% CI)	16.12 (6.50, 25.73)	
	p-value	0.0010	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.56 (1.17, 2.07)	
	p-value	0.0023	
	Odds Ratio (95% CI)	1.99 (1.29, 3.09)	
	p-value	0.0020	
	Risk Difference (95% CI)	15.71 (5.94, 25.48)	
	p-value	0.0016	
	CMH approach		
	Response rate	44.0	28.1
	Difference in response rates (95% CI)	15.94 (6.11, 25.76)	
	p-value	0.0015	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
SRI (6) response rate at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=181)
Week 52	Number of subjects with events, n (%)	79 (43.9)	48 (26.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.67 (1.25, 2.24)	
	p-value	0.0005	
	Odds Ratio (95% CI)	2.26 (1.44, 3.55)	
	p-value	0.0004	
	Risk Difference (95% CI)	17.73 (8.18, 27.28)	
	p-value	0.0003	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.65 (1.23, 2.22)	
	p-value	0.0008	
	Odds Ratio (95% CI)	2.17 (1.39, 3.37)	
	p-value	0.0006	
	Risk Difference (95% CI)	17.37 (7.68, 27.06)	
	p-value	0.0004	
	CMH approach		
	Response rate	44.0	26.4
	Difference in response rates (95% CI)	17.55 (7.79, 27.31)	
	p-value	0.0004	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
SRI (7) response rate at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=167)	Placebo (N=169)
Week 52	Number of subjects with events, n (%)	56 (33.5)	34 (20.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.67 (1.16, 2.42)	
	p-value	0.0063	
	Odds Ratio (95% CI)	2.02 (1.23, 3.33)	
	p-value	0.0056	
	Risk Difference (95% CI)	13.48 (4.13, 22.83)	
	p-value	0.0047	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.67 (1.15, 2.41)	
	p-value	0.0066	
	Odds Ratio (95% CI)	2.00 (1.22, 3.28)	
	p-value	0.0059	
	Risk Difference (95% CI)	13.41 (4.04, 22.78)	
	p-value	0.0050	
	CMH approach		
	Response rate	33.6	20.0
	Difference in response rates (95% CI)	13.58 (3.99, 23.17)	
	p-value	0.0055	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
BICLA response rate sensitivity analysis using modified BILAG at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 52	Number of subjects with events, n (%)	93 (51.7)	62 (34.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.51 (1.18, 1.93)	
	p-value	0.0010	
	Odds Ratio (95% CI)	2.06 (1.35, 3.15)	
	p-value	0.0008	
	Risk Difference (95% CI)	17.52 (7.45, 27.59)	
	p-value	0.0006	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.52 (1.19, 1.94)	
	p-value	0.0009	
	Odds Ratio (95% CI)	2.07 (1.35, 3.16)	
	p-value	0.0008	
	Risk Difference (95% CI)	17.60 (7.57, 27.64)	
	p-value	0.0006	
	CMH approach		
	Response rate	51.7	34.2
	Difference in response rates (95% CI)	17.50 (7.43, 27.57)	
	p-value	0.0007	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
BICLA response rate sensitivity analysis excluding subjects with no BILAG A or B or PGA VAS score >2.7 at baseline at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=178)	Placebo (N=182)
Week 52	Number of subjects with events, n (%)	86 (48.3)	57 (31.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.53 (1.18, 2.00)	
	p-value	0.0014	
	Odds Ratio (95% CI)	2.03 (1.32, 3.12)	
	p-value	0.0012	
	Risk Difference (95% CI)	16.89 (6.87, 26.91)	
	p-value	0.0010	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.54 (1.19, 2.01)	
	p-value	0.0013	
	Odds Ratio (95% CI)	2.05 (1.33, 3.15)	
	p-value	0.0011	
	Risk Difference (95% CI)	17.00 (7.03, 26.96)	
	p-value	0.0008	
	CMH approach		
	Response rate	48.4	31.5
	Difference in response rates (95% CI)	16.83 (6.83, 26.83)	
	p-value	0.0010	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
BICLA response rate sensitivity analysis excluding criterion of no restricted medications at week 52
Full analysis set

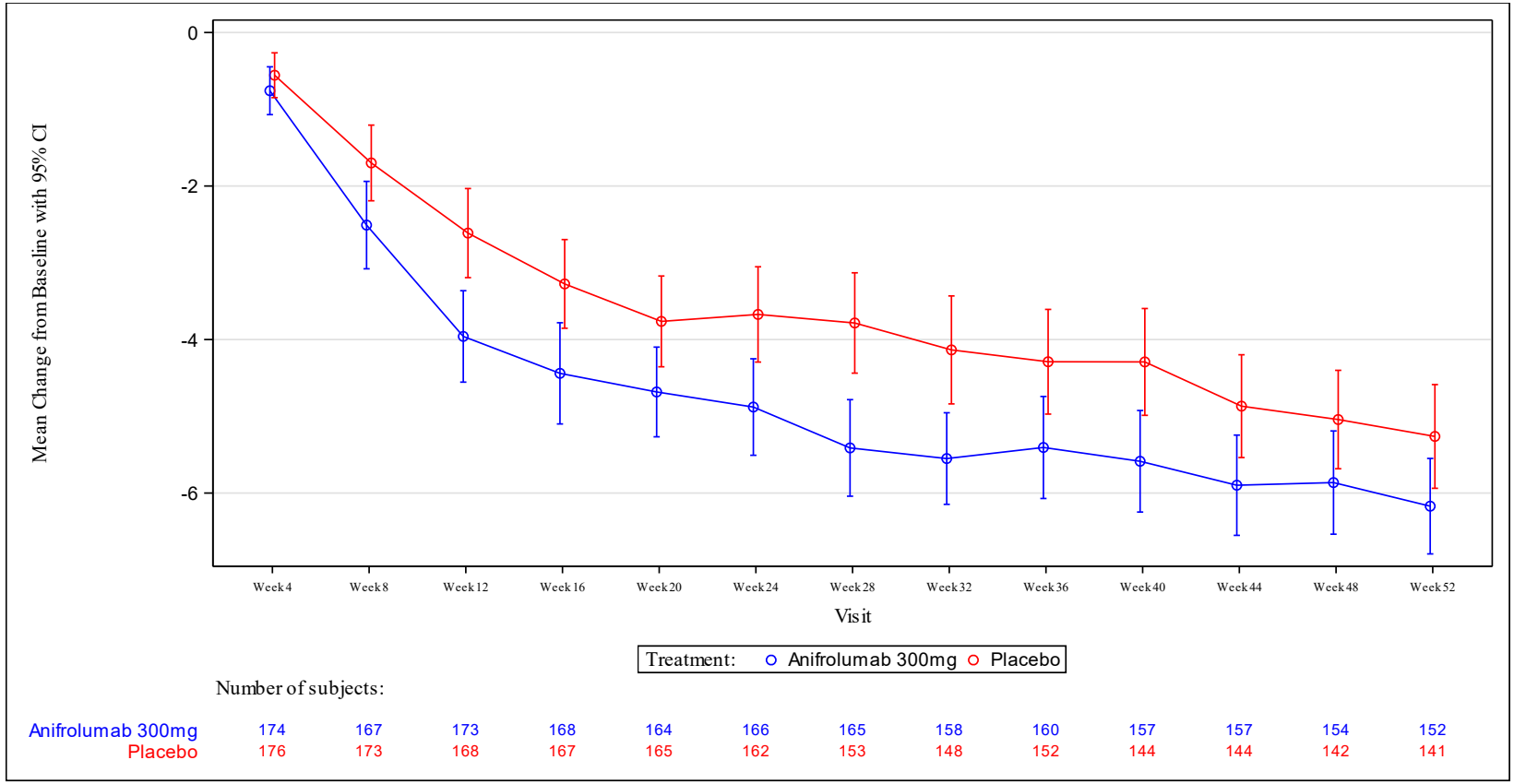
Timepoint		Anifrolumab 300mg (N=180)	Placebo (N=182)
Week 52	Number of subjects with events, n (%)	99 (55.0)	70 (38.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.43 (1.14, 1.79)	
	p-value	0.0018	
	Odds Ratio (95% CI)	1.97 (1.29, 3.00)	
	p-value	0.0016	
	Risk Difference (95% CI)	16.63 (6.50, 26.77)	
	p-value	0.0013	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.43 (1.14, 1.79)	
	p-value	0.0020	
	Odds Ratio (95% CI)	1.96 (1.29, 2.97)	
	p-value	0.0017	
	Risk Difference (95% CI)	16.54 (6.40, 26.68)	
	p-value	0.0014	
	CMH approach		
	Response rate	55.1	38.6
	Difference in response rates (95% CI)	16.57 (6.43, 26.72)	
	p-value	0.0014	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - SLEDAI-2K Total Score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=182)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	180	11.43 (3.64)	0	-	182	11.52 (3.88)	0	-
Week 4	174	10.68 (3.73)	174	-0.76 (2.08)	176	10.90 (3.87)	176	-0.56 (1.96)
Week 8	167	8.98 (4.16)	167	-2.51 (3.73)	173	9.88 (4.31)	173	-1.70 (3.29)
Week 12	173	7.45 (3.79)	173	-3.96 (3.97)	168	8.86 (4.43)	168	-2.61 (3.81)
Week 16	168	6.87 (4.38)	168	-4.44 (4.33)	167	8.21 (4.33)	167	-3.28 (3.78)
Week 20	164	6.65 (3.66)	164	-4.68 (3.79)	165	7.65 (4.30)	165	-3.76 (3.85)
Week 24	166	6.43 (3.78)	166	-4.88 (4.10)	162	7.65 (4.53)	162	-3.67 (4.00)
Week 28	165	5.92 (3.50)	165	-5.41 (4.09)	153	7.40 (4.36)	153	-3.78 (4.09)
Week 32	158	5.79 (3.54)	158	-5.55 (3.80)	148	7.16 (4.54)	148	-4.14 (4.33)
Week 36	160	5.89 (3.78)	160	-5.41 (4.26)	152	6.97 (4.62)	152	-4.29 (4.26)
Week 40	157	5.62 (3.74)	157	-5.59 (4.20)	144	6.76 (4.18)	144	-4.29 (4.22)
Week 44	157	5.33 (3.44)	157	-5.90 (4.14)	144	6.17 (3.64)	144	-4.87 (4.06)
Week 48	154	5.34 (3.68)	154	-5.86 (4.22)	142	6.11 (3.63)	142	-5.04 (3.86)
Week 52	152	5.00 (3.24)	152	-6.17 (3.88)	141	5.93 (3.75)	141	-5.26 (4.06)

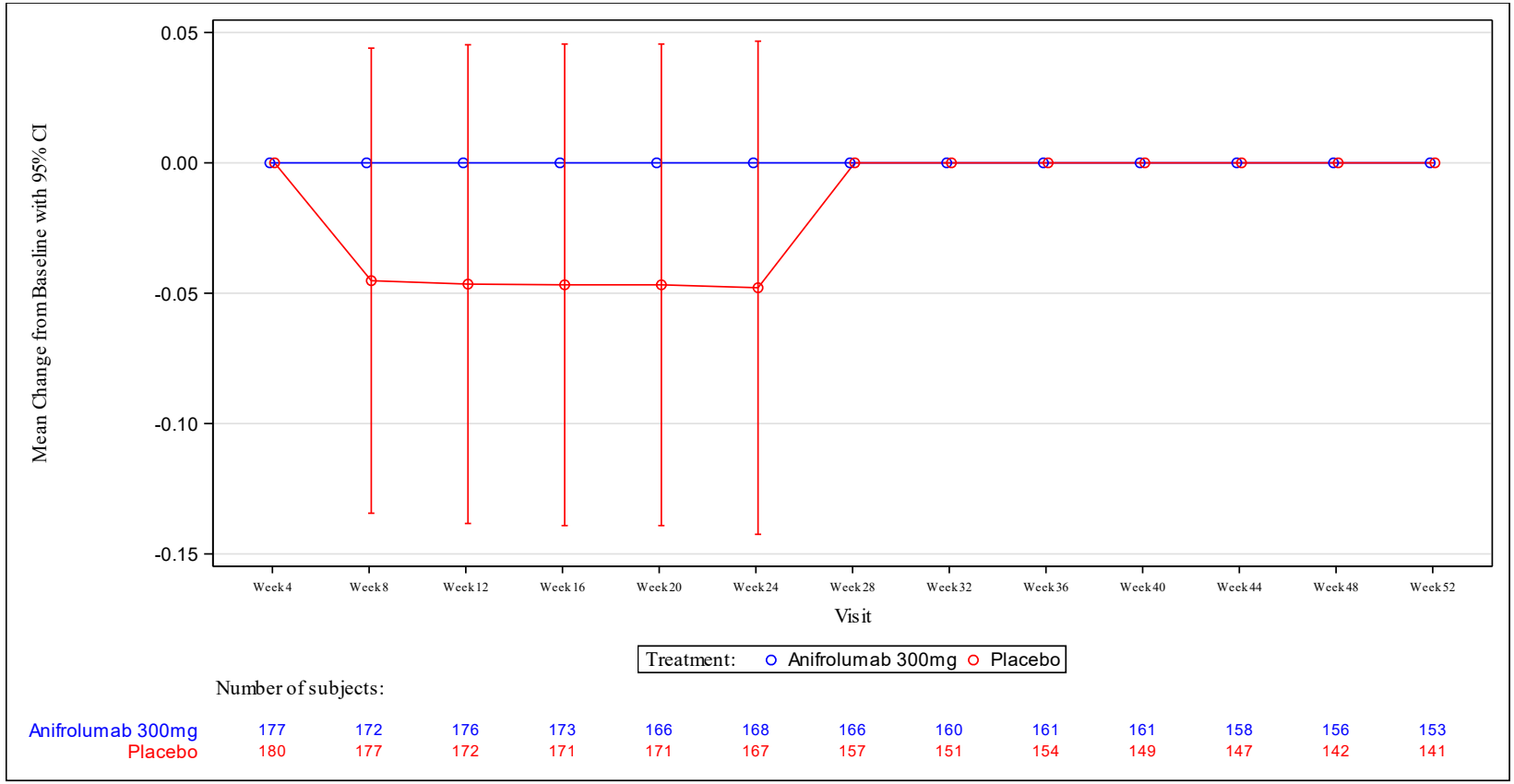
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - SLEDAI-2K Total Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score CNS
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=182)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	180	0.00 (0.00)	0	-	182	0.04 (0.59)	0	-
Week 4	177	0.00 (0.00)	177	0.00 (0.00)	180	0.04 (0.60)	180	0.00 (0.00)
Week 8	172	0.00 (0.00)	172	0.00 (0.00)	177	0.00 (0.00)	177	-0.05 (0.60)
Week 12	176	0.00 (0.00)	176	0.00 (0.00)	172	0.00 (0.00)	172	-0.05 (0.61)
Week 16	173	0.00 (0.00)	173	0.00 (0.00)	171	0.00 (0.00)	171	-0.05 (0.61)
Week 20	166	0.00 (0.00)	166	0.00 (0.00)	171	0.00 (0.00)	171	-0.05 (0.61)
Week 24	168	0.00 (0.00)	168	0.00 (0.00)	167	0.00 (0.00)	167	-0.05 (0.62)
Week 28	166	0.00 (0.00)	166	0.00 (0.00)	157	0.00 (0.00)	157	0.00 (0.00)
Week 32	160	0.00 (0.00)	160	0.00 (0.00)	151	0.00 (0.00)	151	0.00 (0.00)
Week 36	161	0.00 (0.00)	161	0.00 (0.00)	154	0.00 (0.00)	154	0.00 (0.00)
Week 40	161	0.00 (0.00)	161	0.00 (0.00)	149	0.00 (0.00)	149	0.00 (0.00)
Week 44	158	0.00 (0.00)	158	0.00 (0.00)	147	0.00 (0.00)	147	0.00 (0.00)
Week 48	156	0.00 (0.00)	156	0.00 (0.00)	142	0.00 (0.00)	142	0.00 (0.00)
Week 52	153	0.00 (0.00)	153	0.00 (0.00)	141	0.00 (0.00)	141	0.00 (0.00)

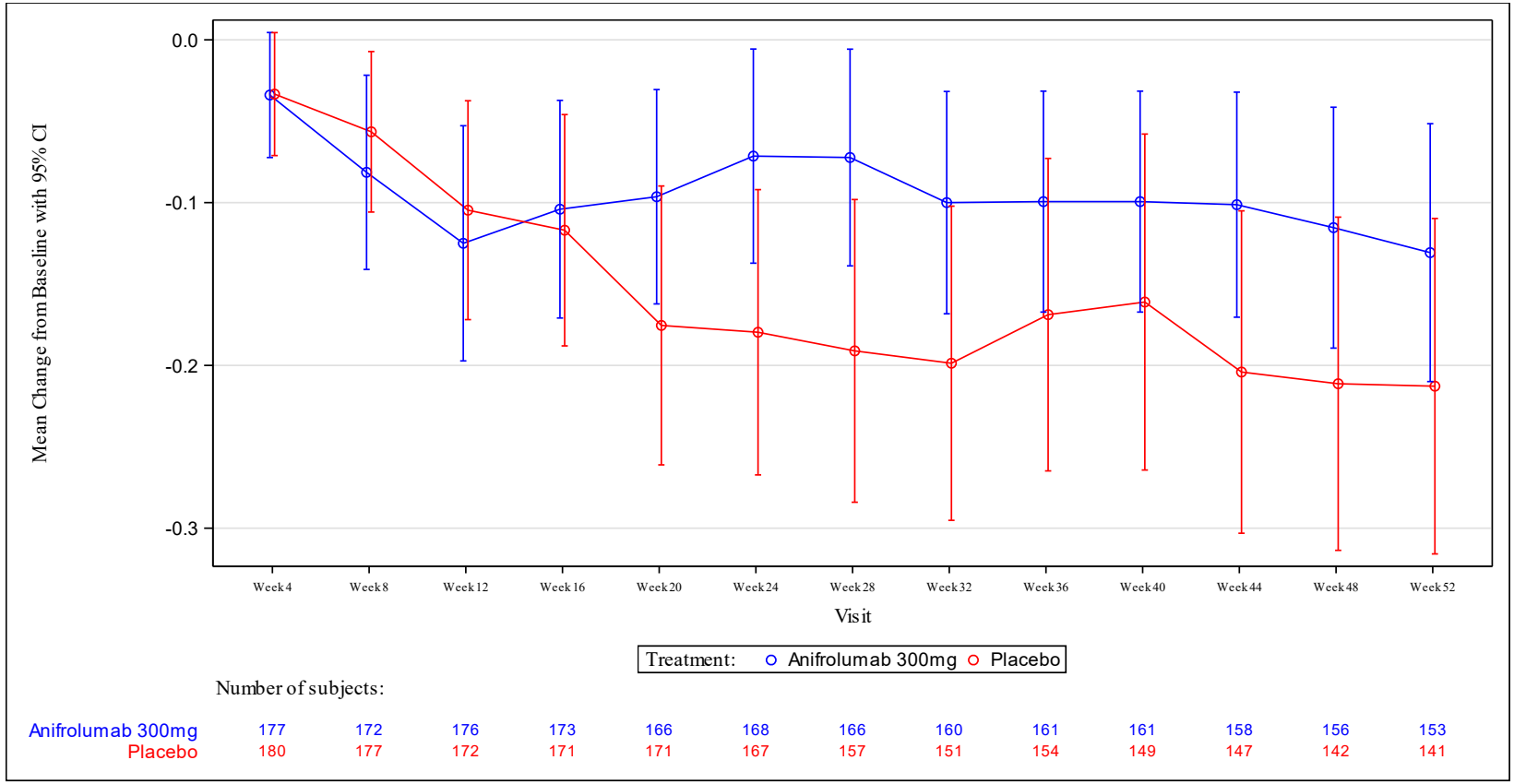
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Total Organ Score CNS
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score CVS and Respiratory
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=182)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	180	0.16 (0.54)	0	-	182	0.21 (0.61)	0	-
Week 4	177	0.12 (0.48)	177	-0.03 (0.26)	180	0.17 (0.55)	180	-0.03 (0.26)
Week 8	172	0.07 (0.37)	172	-0.08 (0.40)	177	0.15 (0.52)	177	-0.06 (0.33)
Week 12	176	0.02 (0.21)	176	-0.13 (0.49)	172	0.09 (0.42)	172	-0.10 (0.45)
Week 16	173	0.03 (0.26)	173	-0.10 (0.45)	171	0.07 (0.37)	171	-0.12 (0.47)
Week 20	166	0.05 (0.31)	166	-0.10 (0.43)	171	0.02 (0.22)	171	-0.18 (0.57)
Week 24	168	0.05 (0.31)	168	-0.07 (0.43)	167	0.02 (0.22)	167	-0.18 (0.57)
Week 28	166	0.05 (0.31)	166	-0.07 (0.43)	157	0.03 (0.23)	157	-0.19 (0.59)
Week 32	160	0.03 (0.22)	160	-0.10 (0.44)	151	0.01 (0.16)	151	-0.20 (0.60)
Week 36	161	0.04 (0.27)	161	-0.10 (0.44)	154	0.04 (0.28)	154	-0.17 (0.60)
Week 40	161	0.01 (0.16)	161	-0.10 (0.44)	149	0.05 (0.32)	149	-0.16 (0.64)
Week 44	158	0.03 (0.22)	158	-0.10 (0.44)	147	0.01 (0.16)	147	-0.20 (0.61)
Week 48	156	0.01 (0.16)	156	-0.12 (0.47)	142	0.01 (0.17)	142	-0.21 (0.62)
Week 52	153	0.00 (0.00)	153	-0.13 (0.50)	141	0.01 (0.17)	141	-0.21 (0.62)

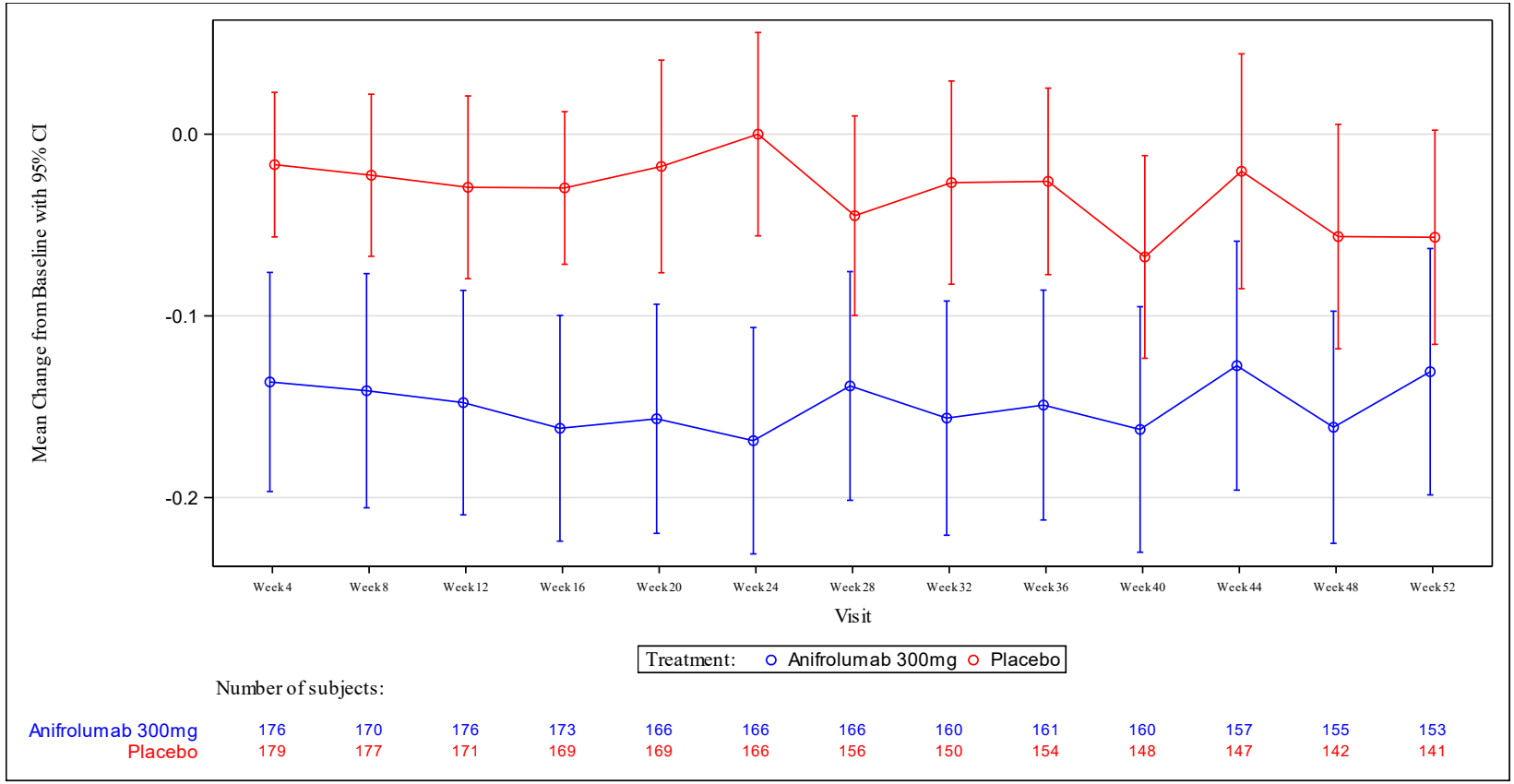
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Total Organ Score CVS and Respiratory
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score Hematological
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=182)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	180	0.20 (0.41)	0	-	182	0.14 (0.38)	0	-
Week 4	176	0.07 (0.27)	176	-0.14 (0.41)	179	0.12 (0.36)	179	-0.02 (0.27)
Week 8	170	0.06 (0.25)	170	-0.14 (0.43)	177	0.11 (0.32)	177	-0.02 (0.30)
Week 12	176	0.05 (0.22)	176	-0.15 (0.42)	171	0.10 (0.34)	171	-0.03 (0.33)
Week 16	173	0.05 (0.21)	173	-0.16 (0.41)	169	0.09 (0.29)	169	-0.03 (0.28)
Week 20	166	0.04 (0.19)	166	-0.16 (0.41)	169	0.12 (0.36)	169	-0.02 (0.39)
Week 24	166	0.02 (0.15)	166	-0.17 (0.41)	166	0.14 (0.36)	166	0.00 (0.37)
Week 28	166	0.05 (0.23)	166	-0.14 (0.41)	156	0.10 (0.32)	156	-0.04 (0.35)
Week 32	160	0.04 (0.21)	160	-0.16 (0.41)	150	0.11 (0.33)	150	-0.03 (0.35)
Week 36	161	0.03 (0.17)	161	-0.15 (0.41)	154	0.11 (0.33)	154	-0.03 (0.32)
Week 40	160	0.03 (0.17)	160	-0.16 (0.43)	148	0.07 (0.29)	148	-0.07 (0.34)
Week 44	157	0.06 (0.26)	157	-0.13 (0.43)	147	0.12 (0.34)	147	-0.02 (0.40)
Week 48	155	0.03 (0.18)	155	-0.16 (0.40)	142	0.10 (0.32)	142	-0.06 (0.37)
Week 52	153	0.07 (0.27)	153	-0.13 (0.42)	141	0.10 (0.32)	141	-0.06 (0.35)

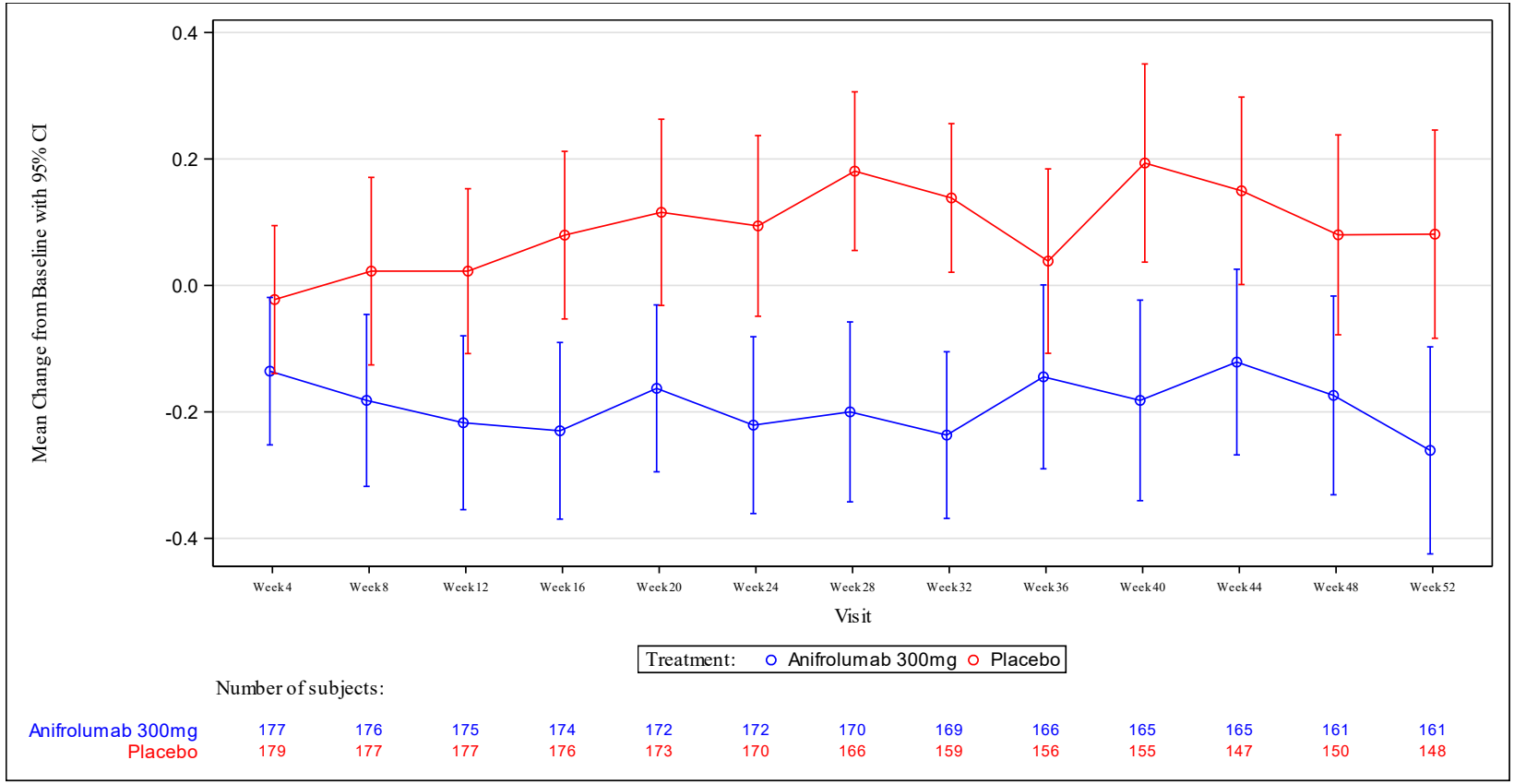
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Total Organ Score Hematological
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score Immunology
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=182)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	180	2.02 (1.55)	0	-	182	1.87 (1.68)	0	-
Week 4	177	1.86 (1.52)	177	-0.14 (0.79)	179	1.81 (1.62)	179	-0.02 (0.79)
Week 8	176	1.83 (1.54)	176	-0.18 (0.91)	177	1.89 (1.66)	177	0.02 (1.00)
Week 12	175	1.78 (1.52)	175	-0.22 (0.92)	177	1.90 (1.66)	177	0.02 (0.88)
Week 16	174	1.78 (1.53)	174	-0.23 (0.93)	176	1.95 (1.70)	176	0.08 (0.89)
Week 20	172	1.88 (1.49)	172	-0.16 (0.88)	173	1.98 (1.70)	173	0.12 (0.98)
Week 24	172	1.81 (1.53)	172	-0.22 (0.93)	170	1.92 (1.69)	170	0.09 (0.94)
Week 28	170	1.84 (1.51)	170	-0.20 (0.94)	166	2.01 (1.66)	166	0.18 (0.82)
Week 32	169	1.76 (1.54)	169	-0.24 (0.87)	159	1.92 (1.64)	159	0.14 (0.75)
Week 36	166	1.84 (1.53)	166	-0.14 (0.95)	156	1.81 (1.68)	156	0.04 (0.92)
Week 40	165	1.84 (1.51)	165	-0.18 (1.03)	155	1.95 (1.61)	155	0.19 (0.99)
Week 44	165	1.90 (1.57)	165	-0.12 (0.96)	147	1.90 (1.66)	147	0.15 (0.91)
Week 48	161	1.85 (1.56)	161	-0.17 (1.01)	150	1.83 (1.69)	150	0.08 (0.98)
Week 52	161	1.75 (1.53)	161	-0.26 (1.05)	148	1.84 (1.67)	148	0.08 (1.01)

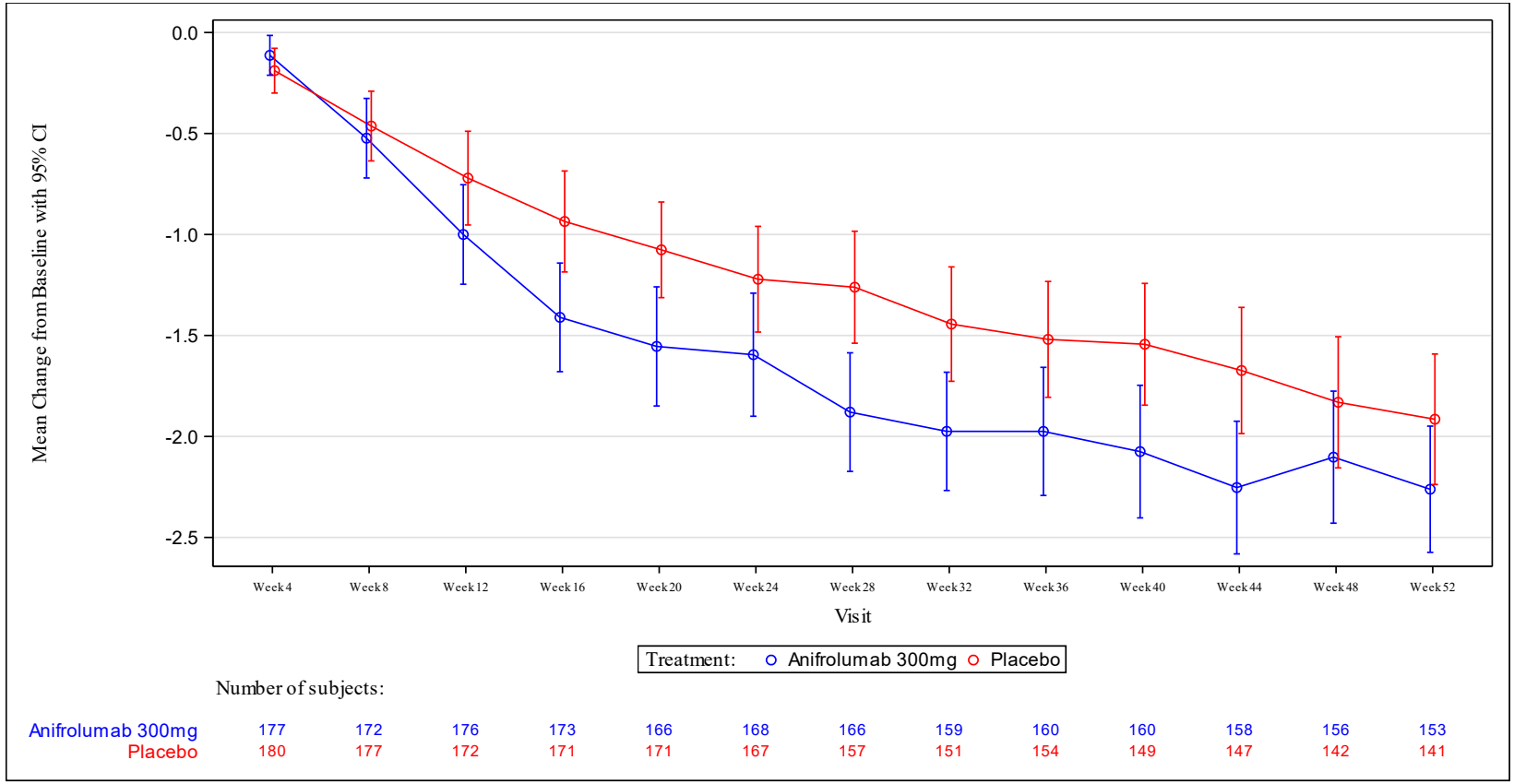
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Total Organ Score Immunology
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score Mucocutaneous
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=182)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	180	4.06 (1.60)	0	-	182	3.95 (1.62)	0	-
Week 4	177	3.93 (1.64)	177	-0.11 (0.66)	180	3.74 (1.65)	180	-0.19 (0.75)
Week 8	172	3.49 (1.67)	172	-0.52 (1.31)	177	3.46 (1.76)	177	-0.46 (1.16)
Week 12	176	3.03 (1.80)	176	-1.00 (1.66)	172	3.17 (1.88)	172	-0.72 (1.54)
Week 16	173	2.65 (1.72)	173	-1.41 (1.79)	171	2.99 (1.91)	171	-0.94 (1.66)
Week 20	166	2.49 (1.71)	166	-1.55 (1.92)	171	2.85 (1.75)	171	-1.08 (1.57)
Week 24	168	2.49 (1.77)	168	-1.60 (2.00)	167	2.69 (1.76)	167	-1.22 (1.71)
Week 28	166	2.17 (1.61)	166	-1.88 (1.92)	157	2.65 (1.77)	157	-1.26 (1.76)
Week 32	159	2.04 (1.60)	159	-1.97 (1.87)	151	2.46 (1.80)	151	-1.44 (1.76)
Week 36	160	2.05 (1.75)	160	-1.98 (2.03)	154	2.38 (1.78)	154	-1.52 (1.80)
Week 40	160	1.94 (1.67)	160	-2.08 (2.10)	149	2.31 (1.74)	149	-1.54 (1.86)
Week 44	158	1.82 (1.68)	158	-2.25 (2.09)	147	2.19 (1.76)	147	-1.67 (1.92)
Week 48	156	1.91 (1.66)	156	-2.10 (2.07)	142	2.10 (1.72)	142	-1.83 (1.96)
Week 52	153	1.82 (1.64)	153	-2.26 (1.96)	141	1.99 (1.72)	141	-1.91 (1.94)

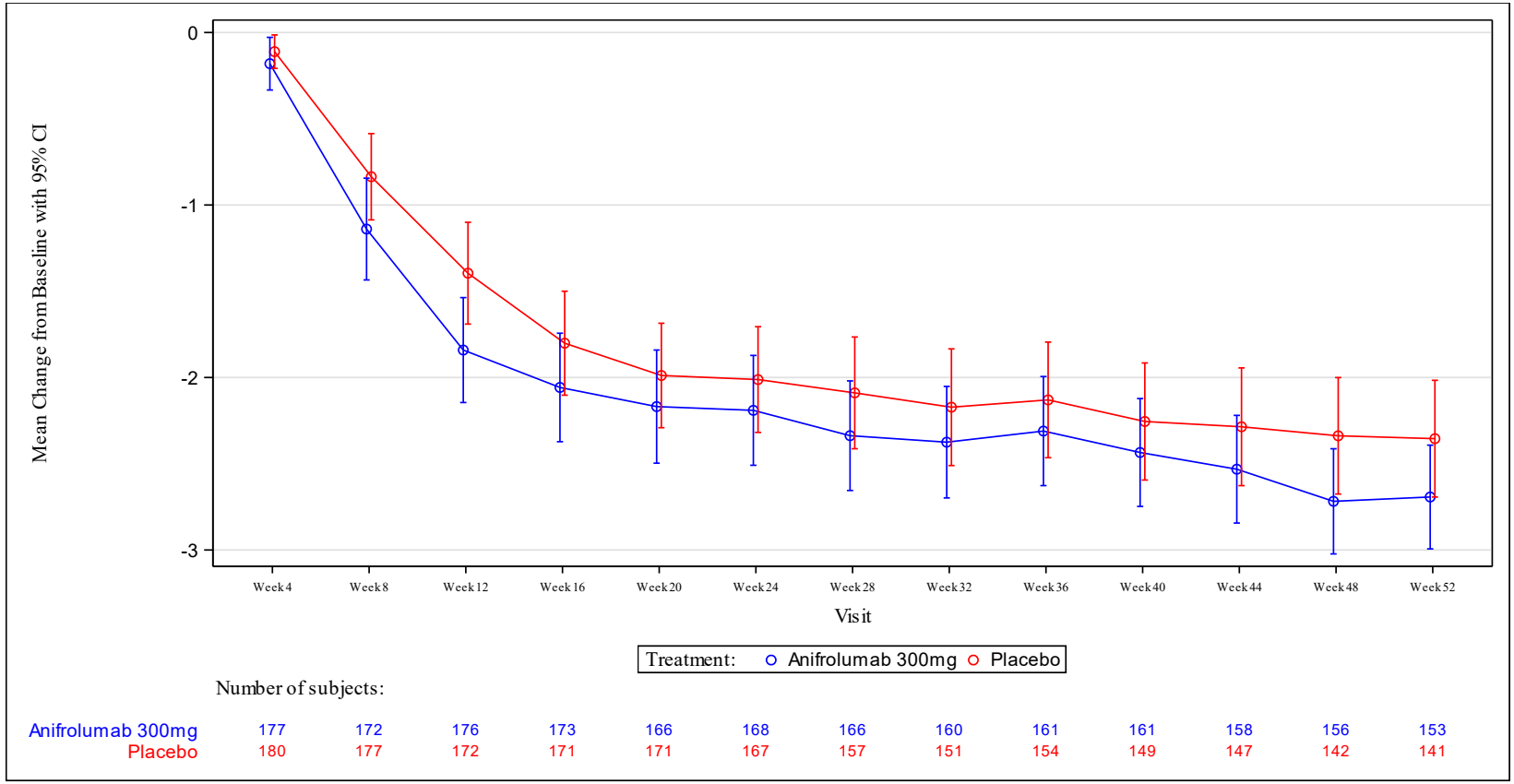
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Total Organ Score Mucocutaneous
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score Musculoskeletal
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=182)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	180	3.78 (1.10)	0	-	182	3.82 (1.10)	0	-
Week 4	177	3.59 (1.35)	177	-0.18 (1.03)	180	3.71 (1.27)	180	-0.11 (0.66)
Week 8	172	2.63 (1.90)	172	-1.14 (1.96)	177	2.98 (1.90)	177	-0.84 (1.69)
Week 12	176	1.93 (2.00)	176	-1.84 (2.04)	172	2.44 (2.09)	172	-1.40 (1.96)
Week 16	173	1.71 (1.98)	173	-2.06 (2.10)	171	2.01 (2.10)	171	-1.80 (2.00)
Week 20	166	1.61 (1.97)	166	-2.17 (2.14)	171	1.82 (2.09)	171	-1.99 (2.01)
Week 24	168	1.60 (1.96)	168	-2.19 (2.09)	167	1.82 (2.09)	167	-2.01 (2.01)
Week 28	166	1.45 (1.93)	166	-2.34 (2.07)	157	1.76 (2.04)	157	-2.09 (2.05)
Week 32	160	1.38 (1.91)	160	-2.38 (2.07)	151	1.67 (2.03)	151	-2.17 (2.10)
Week 36	161	1.47 (1.93)	161	-2.31 (2.03)	154	1.71 (2.09)	154	-2.13 (2.10)
Week 40	161	1.32 (1.94)	161	-2.43 (2.01)	149	1.61 (2.08)	149	-2.26 (2.10)
Week 44	158	1.24 (1.86)	158	-2.53 (1.99)	147	1.58 (2.07)	147	-2.29 (2.09)
Week 48	156	1.05 (1.77)	156	-2.72 (1.93)	142	1.52 (2.06)	142	-2.34 (2.03)
Week 52	153	1.02 (1.75)	153	-2.69 (1.88)	141	1.50 (2.06)	141	-2.35 (2.03)

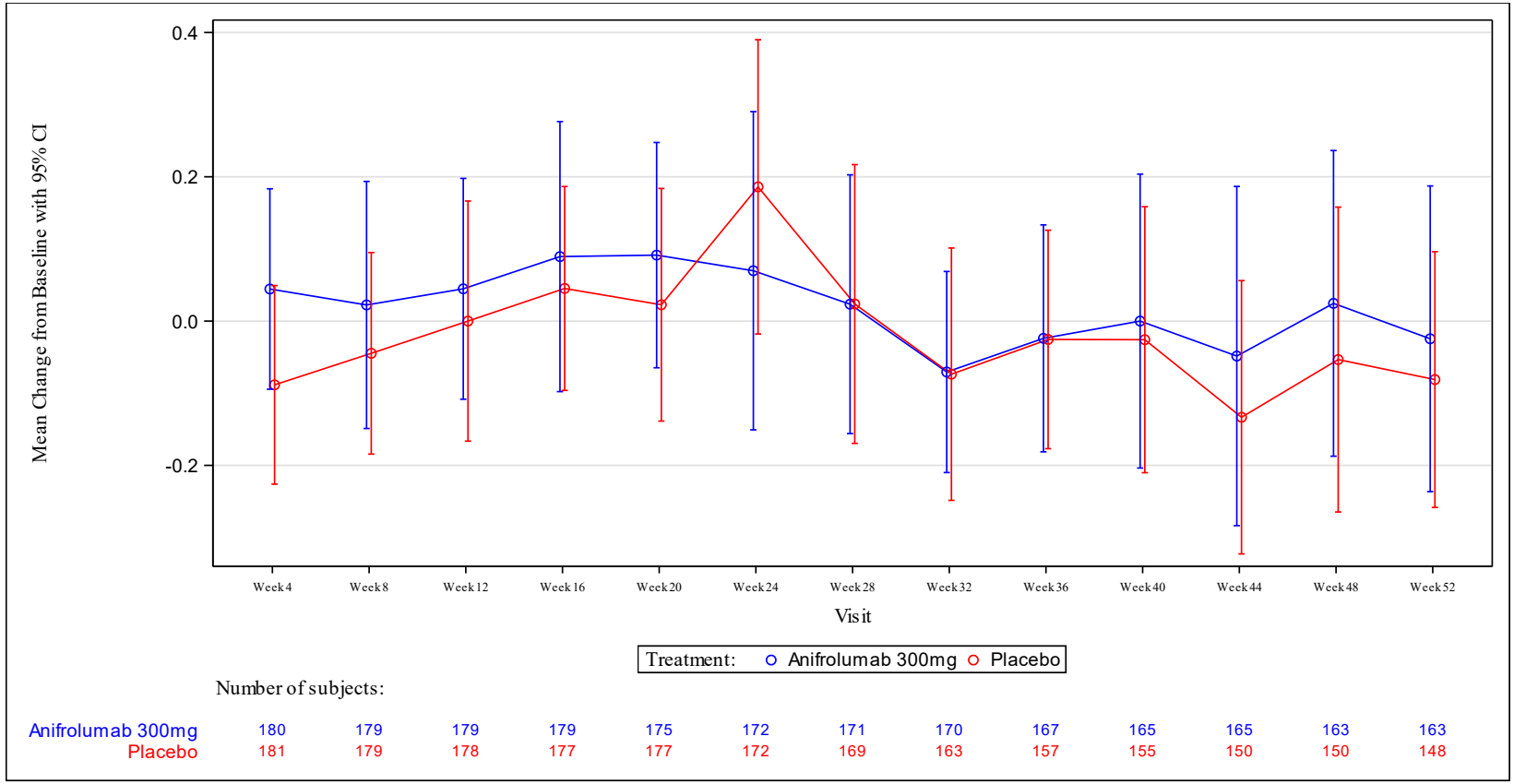
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Total Organ Score Musculoskeletal
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score Renal
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=182)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	180	0.29 (1.27)	0	-	182	0.53 (1.70)	0	-
Week 4	180	0.33 (1.57)	180	0.04 (0.94)	181	0.44 (1.63)	181	-0.09 (0.94)
Week 8	179	0.31 (1.50)	179	0.02 (1.16)	179	0.49 (1.62)	179	-0.04 (0.95)
Week 12	179	0.34 (1.58)	179	0.04 (1.04)	178	0.54 (1.67)	178	0.00 (1.12)
Week 16	179	0.38 (1.78)	179	0.09 (1.27)	177	0.52 (1.54)	177	0.05 (0.95)
Week 20	175	0.34 (1.54)	175	0.09 (1.05)	177	0.50 (1.52)	177	0.02 (1.09)
Week 24	172	0.33 (1.53)	172	0.07 (1.47)	172	0.65 (2.06)	172	0.19 (1.36)
Week 28	171	0.28 (1.48)	171	0.02 (1.19)	169	0.50 (1.70)	169	0.02 (1.27)
Week 32	170	0.16 (0.80)	170	-0.07 (0.92)	163	0.39 (1.49)	163	-0.07 (1.13)
Week 36	167	0.22 (1.01)	167	-0.02 (1.03)	157	0.46 (1.50)	157	-0.03 (0.96)
Week 40	165	0.19 (1.15)	165	0.00 (1.33)	155	0.46 (1.58)	155	-0.03 (1.16)
Week 44	165	0.19 (1.15)	165	-0.05 (1.53)	150	0.24 (1.06)	150	-0.13 (1.17)
Week 48	163	0.25 (1.38)	163	0.02 (1.37)	150	0.32 (1.35)	150	-0.05 (1.31)
Week 52	163	0.20 (1.16)	163	-0.02 (1.37)	148	0.30 (1.15)	148	-0.08 (1.09)

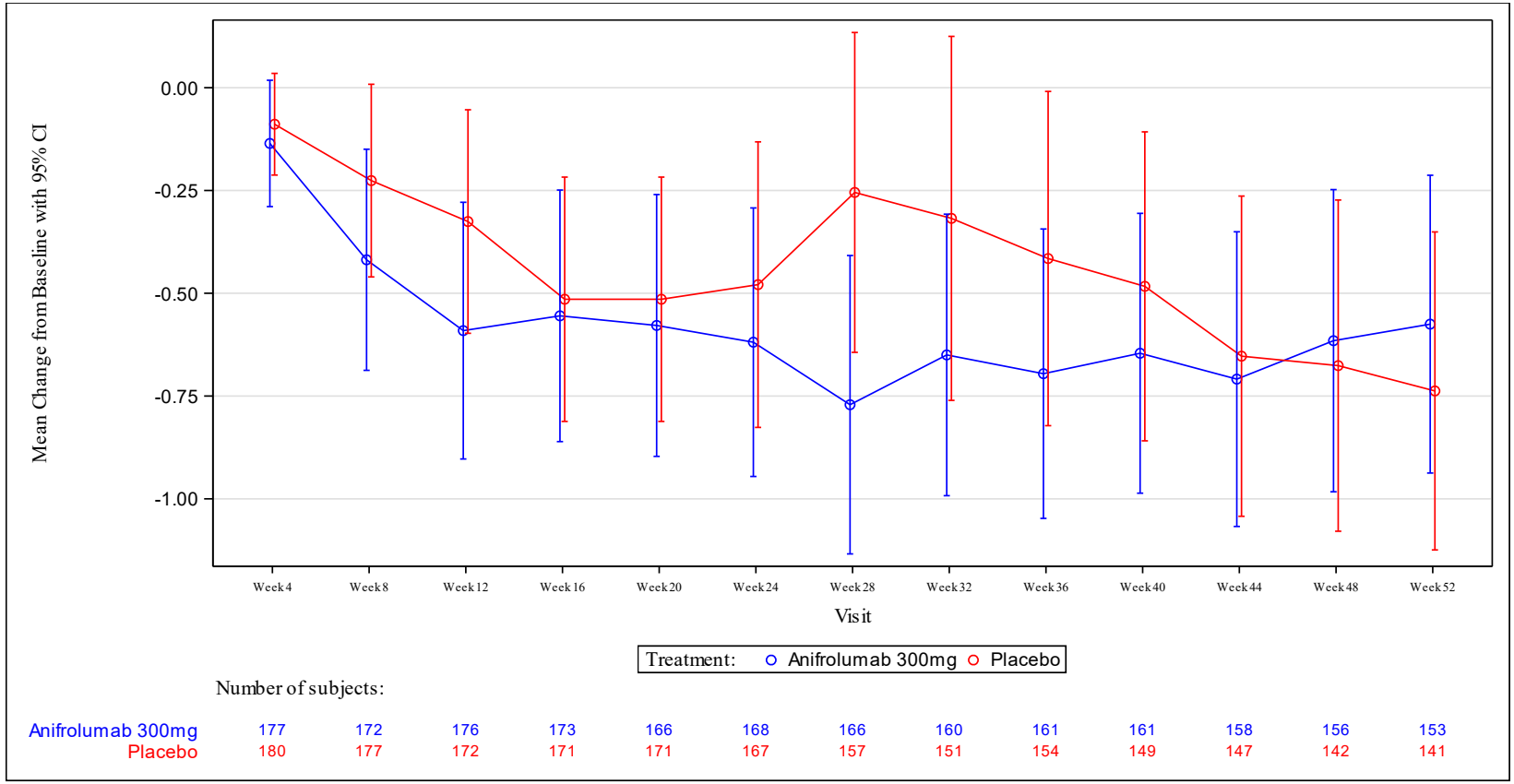
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Total Organ Score Renal
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score Vascular
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=182)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	180	0.93 (2.58)	0	-	182	0.97 (2.62)	0	-
Week 4	177	0.81 (2.42)	177	-0.14 (1.04)	180	0.89 (2.52)	180	-0.09 (0.84)
Week 8	172	0.56 (2.04)	172	-0.42 (1.79)	177	0.77 (2.36)	177	-0.23 (1.58)
Week 12	176	0.36 (1.67)	176	-0.59 (2.10)	172	0.60 (2.12)	172	-0.33 (1.81)
Week 16	173	0.32 (1.58)	173	-0.55 (2.04)	171	0.51 (1.97)	171	-0.51 (1.97)
Week 20	166	0.29 (1.50)	166	-0.58 (2.08)	171	0.47 (1.88)	171	-0.51 (1.97)
Week 24	168	0.29 (1.49)	168	-0.62 (2.14)	167	0.43 (1.81)	167	-0.48 (2.27)
Week 28	166	0.14 (1.07)	166	-0.77 (2.37)	157	0.61 (2.13)	157	-0.25 (2.47)
Week 32	160	0.30 (1.52)	160	-0.65 (2.19)	151	0.53 (2.00)	151	-0.32 (2.75)
Week 36	161	0.25 (1.39)	161	-0.70 (2.26)	154	0.47 (1.88)	154	-0.42 (2.55)
Week 40	161	0.25 (1.39)	161	-0.65 (2.19)	149	0.38 (1.70)	149	-0.48 (2.32)
Week 44	158	0.15 (1.10)	158	-0.71 (2.28)	147	0.16 (1.14)	147	-0.65 (2.39)
Week 48	156	0.26 (1.41)	156	-0.62 (2.32)	142	0.23 (1.33)	142	-0.68 (2.43)
Week 52	153	0.21 (1.28)	153	-0.58 (2.27)	141	0.17 (1.16)	141	-0.74 (2.32)

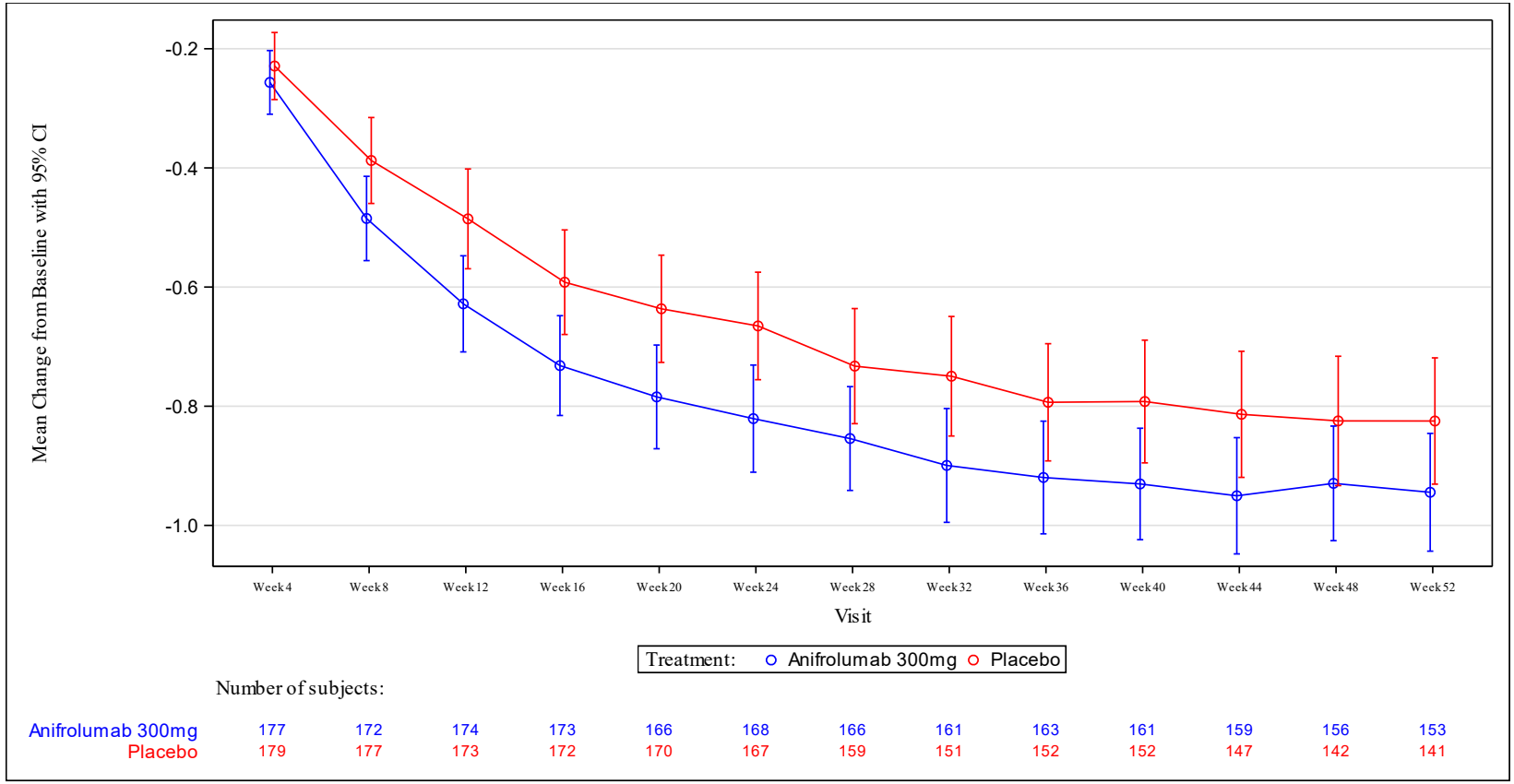
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Total Organ Score Vascular
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - PGA
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=182)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	180	1.68 (0.41)	0	-	182	1.76 (0.40)	0	-
Week 4	177	1.43 (0.48)	177	-0.26 (0.36)	179	1.53 (0.49)	179	-0.23 (0.38)
Week 8	172	1.18 (0.51)	172	-0.48 (0.47)	177	1.37 (0.55)	177	-0.39 (0.49)
Week 12	174	1.05 (0.56)	174	-0.63 (0.54)	173	1.28 (0.57)	173	-0.49 (0.56)
Week 16	173	0.95 (0.57)	173	-0.73 (0.56)	172	1.17 (0.57)	172	-0.59 (0.58)
Week 20	166	0.88 (0.54)	166	-0.78 (0.57)	170	1.13 (0.60)	170	-0.64 (0.59)
Week 24	168	0.86 (0.57)	168	-0.82 (0.59)	167	1.09 (0.59)	167	-0.67 (0.59)
Week 28	166	0.83 (0.55)	166	-0.85 (0.57)	159	1.03 (0.61)	159	-0.73 (0.62)
Week 32	161	0.78 (0.56)	161	-0.90 (0.61)	151	1.01 (0.63)	151	-0.75 (0.62)
Week 36	163	0.76 (0.59)	163	-0.92 (0.61)	152	0.96 (0.61)	152	-0.79 (0.61)
Week 40	161	0.75 (0.58)	161	-0.93 (0.60)	152	0.95 (0.60)	152	-0.79 (0.64)
Week 44	159	0.71 (0.57)	159	-0.95 (0.62)	147	0.93 (0.60)	147	-0.81 (0.65)
Week 48	156	0.75 (0.58)	156	-0.93 (0.61)	142	0.92 (0.60)	142	-0.82 (0.65)
Week 52	153	0.71 (0.59)	153	-0.94 (0.62)	141	0.90 (0.61)	141	-0.82 (0.64)

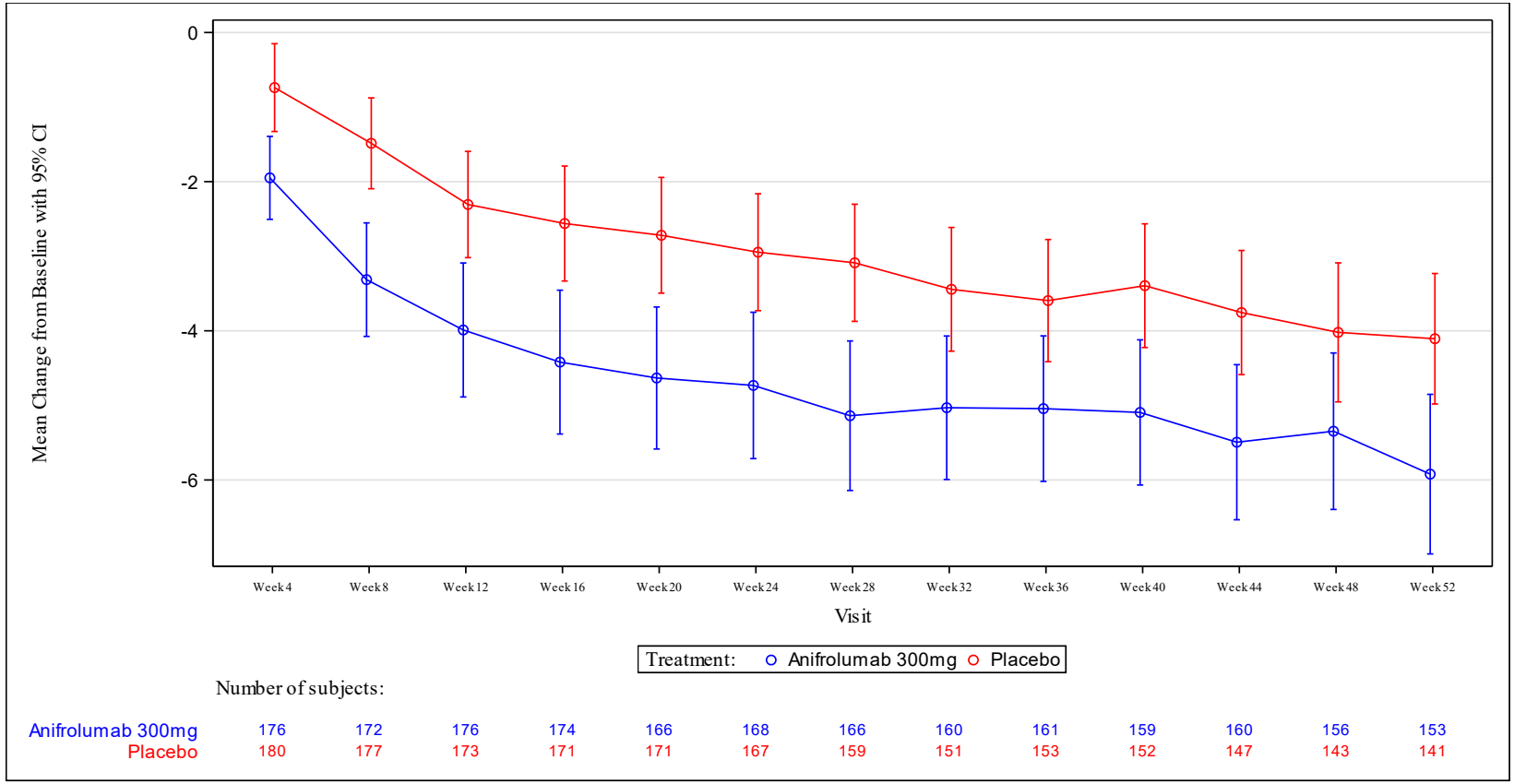
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - PGA
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - CLASI Total Activity Score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=182)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	180	8.29 (7.94)	0	-	182	7.57 (7.75)	0	-
Week 4	176	6.39 (5.94)	176	-1.95 (3.74)	180	6.86 (7.89)	180	-0.74 (4.00)
Week 8	172	5.03 (5.03)	172	-3.31 (5.06)	177	6.11 (7.76)	177	-1.49 (4.11)
Week 12	176	4.39 (4.43)	176	-3.99 (6.04)	173	5.28 (7.16)	173	-2.31 (4.75)
Week 16	174	4.01 (4.57)	174	-4.42 (6.45)	171	5.11 (7.19)	171	-2.56 (5.11)
Week 20	166	3.75 (4.57)	166	-4.63 (6.21)	171	5.02 (7.13)	171	-2.72 (5.14)
Week 24	168	3.71 (4.80)	168	-4.73 (6.44)	167	4.72 (7.00)	167	-2.95 (5.13)
Week 28	166	3.31 (4.14)	166	-5.14 (6.54)	159	4.34 (6.67)	159	-3.09 (5.01)
Week 32	160	3.03 (3.94)	160	-5.03 (6.16)	151	4.13 (6.65)	151	-3.44 (5.16)
Week 36	161	3.04 (4.03)	161	-5.04 (6.27)	153	4.03 (6.50)	153	-3.59 (5.13)
Week 40	159	2.72 (3.71)	159	-5.09 (6.21)	152	4.05 (6.74)	152	-3.39 (5.17)
Week 44	160	2.96 (4.53)	160	-5.49 (6.66)	147	3.81 (6.27)	147	-3.76 (5.11)
Week 48	156	2.73 (3.72)	156	-5.35 (6.63)	143	3.64 (6.01)	143	-4.02 (5.64)
Week 52	153	2.73 (4.28)	153	-5.92 (6.70)	141	3.60 (5.95)	141	-4.11 (5.26)

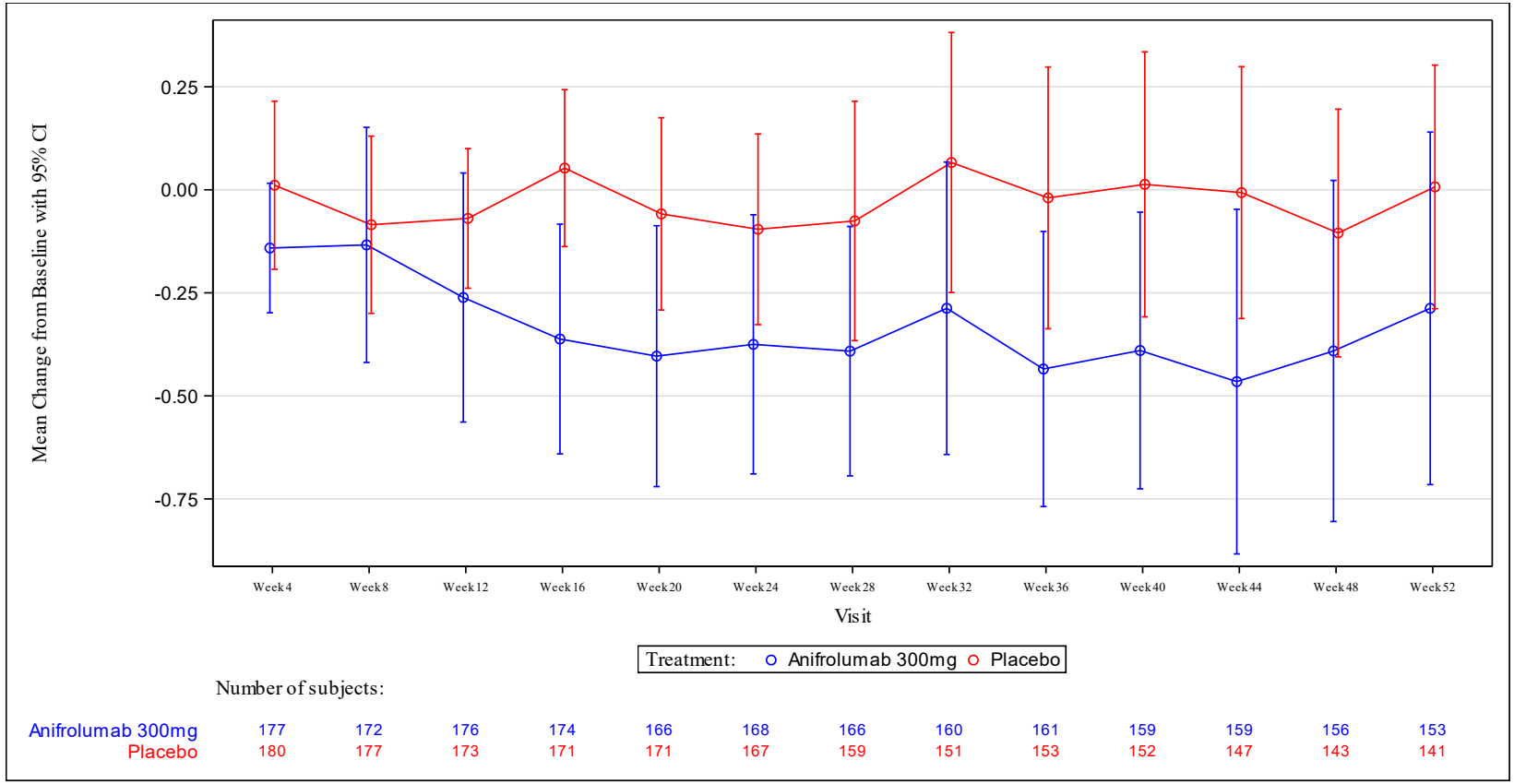
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - CLASI Total Activity Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - CLASI Total Damage Score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=182)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	180	2.32 (5.34)	0	-	182	1.96 (4.63)	0	-
Week 4	177	2.16 (5.15)	177	-0.14 (1.06)	180	1.97 (4.75)	180	0.01 (1.39)
Week 8	172	2.19 (5.34)	172	-0.13 (1.89)	177	1.88 (4.53)	177	-0.08 (1.45)
Week 12	176	2.10 (5.18)	176	-0.26 (2.03)	173	1.88 (4.58)	173	-0.07 (1.13)
Week 16	174	1.98 (5.01)	174	-0.36 (1.86)	171	1.92 (4.54)	171	0.05 (1.26)
Week 20	166	1.99 (4.95)	166	-0.40 (2.07)	171	1.84 (4.61)	171	-0.06 (1.54)
Week 24	168	1.98 (4.78)	168	-0.38 (2.06)	167	1.84 (4.47)	167	-0.10 (1.51)
Week 28	166	2.01 (5.08)	166	-0.39 (1.97)	159	1.77 (4.47)	159	-0.08 (1.85)
Week 32	160	2.02 (5.16)	160	-0.29 (2.27)	151	1.76 (4.39)	151	0.07 (1.96)
Week 36	161	1.95 (5.08)	161	-0.43 (2.14)	153	1.65 (4.22)	153	-0.02 (1.99)
Week 40	159	1.75 (4.76)	159	-0.39 (2.14)	152	1.59 (4.18)	152	0.01 (2.01)
Week 44	159	2.02 (5.47)	159	-0.47 (2.67)	147	1.60 (4.28)	147	-0.01 (1.87)
Week 48	156	1.96 (5.18)	156	-0.39 (2.62)	143	1.54 (4.25)	143	-0.10 (1.82)
Week 52	153	2.32 (5.79)	153	-0.29 (2.68)	141	1.64 (4.32)	141	0.01 (1.77)

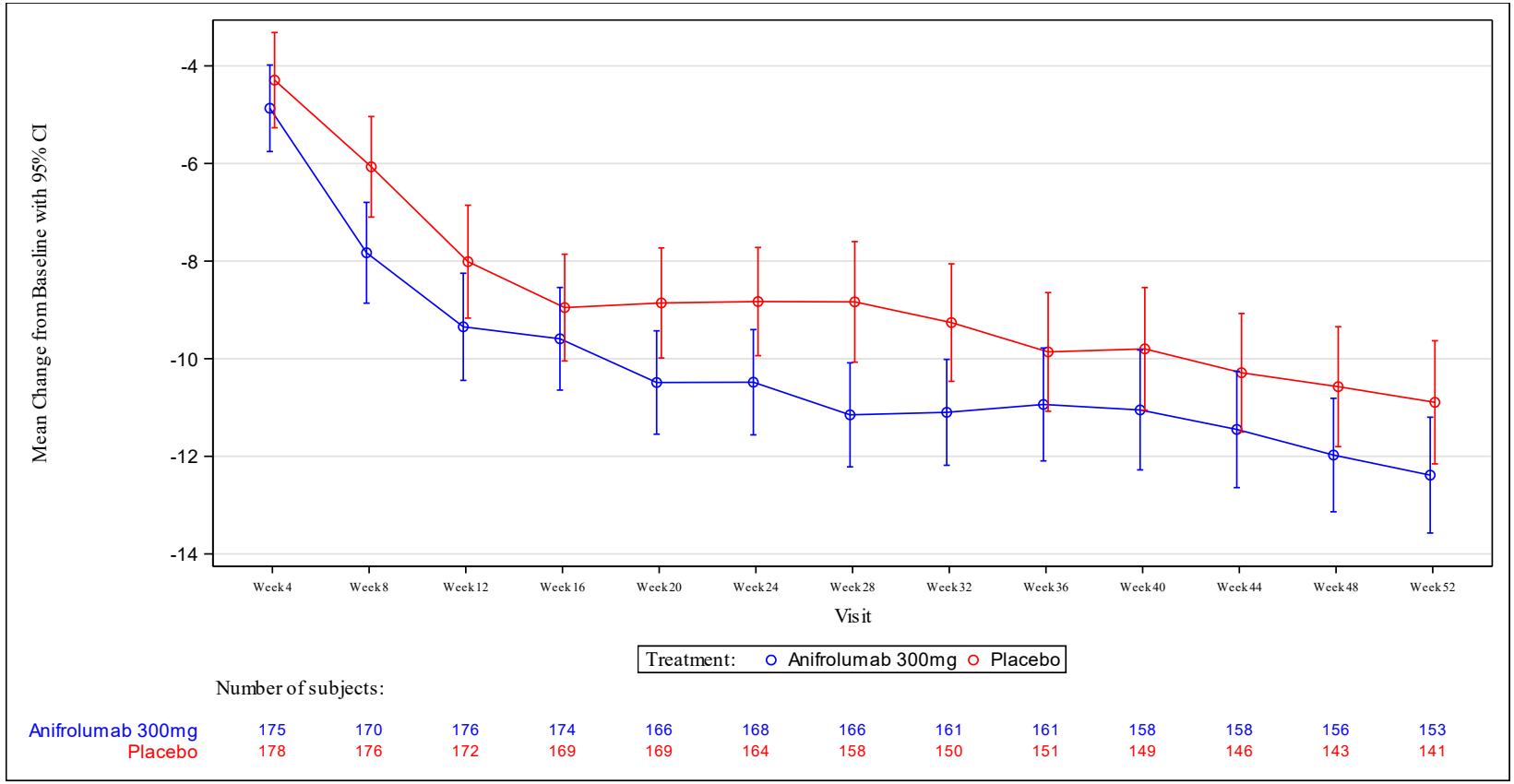
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - CLASI Total Damage Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - BILAG Global Score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=182)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	180	18.63 (4.72)	0	-	182	18.99 (5.00)	0	-
Week 4	175	13.74 (6.72)	175	-4.87 (5.94)	178	14.66 (6.48)	178	-4.29 (6.60)
Week 8	170	10.64 (6.92)	170	-7.83 (6.82)	176	12.93 (7.23)	176	-6.07 (6.93)
Week 12	176	9.20 (7.14)	176	-9.35 (7.38)	172	11.03 (6.96)	172	-8.01 (7.68)
Week 16	174	9.01 (6.97)	174	-9.59 (7.03)	169	9.99 (6.93)	169	-8.95 (7.20)
Week 20	166	8.16 (6.66)	166	-10.49 (6.91)	169	9.96 (6.96)	169	-8.86 (7.43)
Week 24	168	8.19 (6.93)	168	-10.48 (7.08)	164	10.13 (7.36)	164	-8.83 (7.19)
Week 28	166	7.42 (6.39)	166	-11.15 (6.95)	158	10.05 (7.23)	158	-8.84 (7.86)
Week 32	161	7.29 (6.55)	161	-11.10 (6.97)	150	9.77 (7.28)	150	-9.26 (7.46)
Week 36	161	7.68 (6.65)	161	-10.94 (7.43)	151	9.14 (7.19)	151	-9.86 (7.56)
Week 40	158	7.43 (6.77)	158	-11.05 (7.81)	149	9.03 (7.05)	149	-9.80 (7.76)
Week 44	158	6.99 (6.36)	158	-11.45 (7.59)	146	8.48 (6.55)	146	-10.29 (7.42)
Week 48	156	6.61 (6.27)	156	-11.97 (7.35)	143	8.15 (6.79)	143	-10.57 (7.43)
Week 52	153	6.10 (6.28)	153	-12.39 (7.43)	141	7.92 (6.72)	141	-10.89 (7.58)

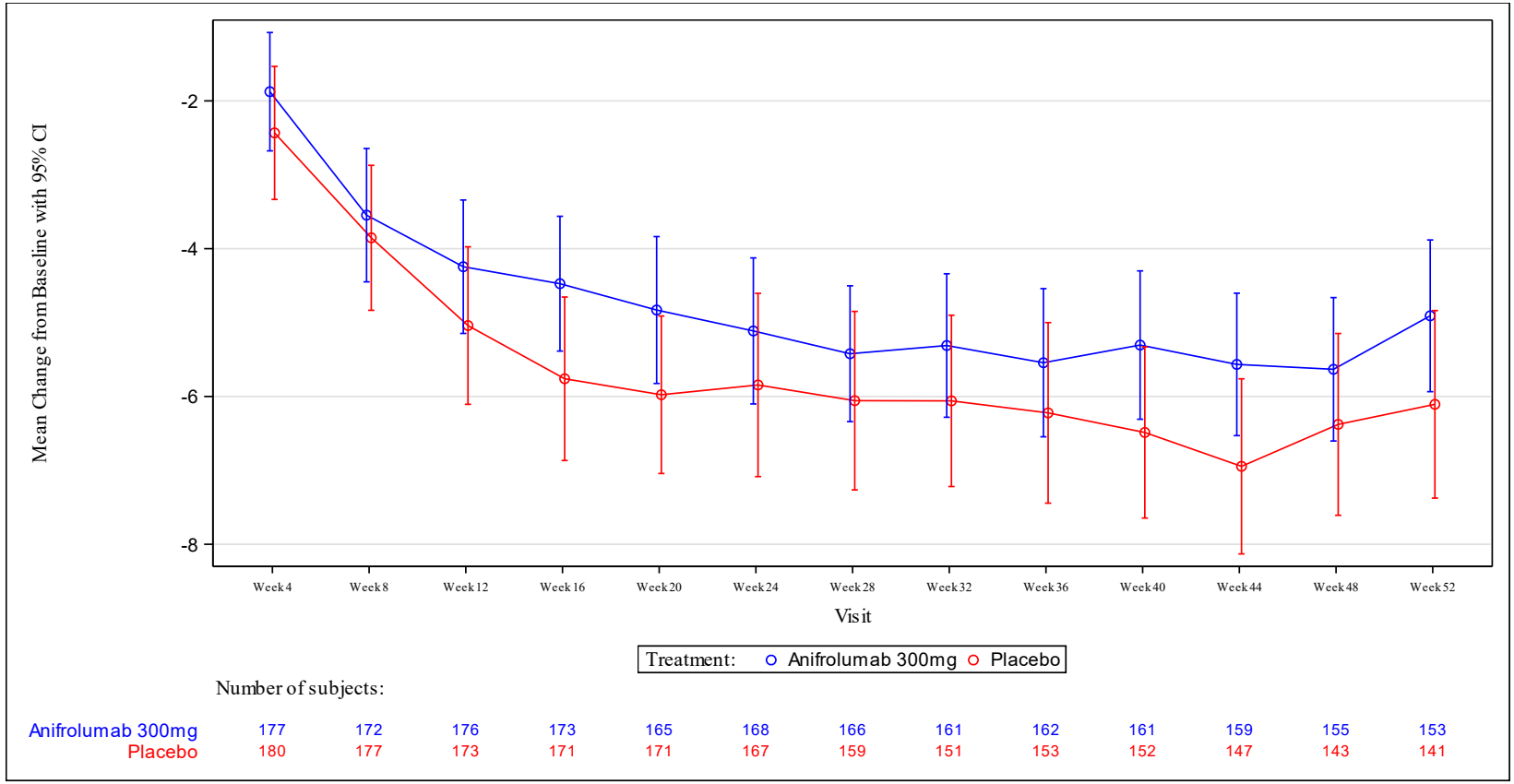
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - BILAG Global Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Tender Joint Count
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=182)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	180	8.96 (7.07)	0	-	182	11.02 (7.89)	0	-
Week 4	177	7.02 (7.28)	177	-1.88 (5.40)	180	8.58 (8.29)	180	-2.43 (6.12)
Week 8	172	5.05 (6.44)	172	-3.55 (6.00)	177	7.12 (7.84)	177	-3.85 (6.61)
Week 12	176	4.45 (6.40)	176	-4.24 (6.07)	173	6.10 (7.54)	173	-5.04 (7.10)
Week 16	173	4.38 (6.41)	173	-4.47 (6.08)	171	4.96 (6.76)	171	-5.76 (7.33)
Week 20	165	4.02 (6.35)	165	-4.83 (6.47)	171	4.97 (6.64)	171	-5.98 (7.06)
Week 24	168	3.89 (6.06)	168	-5.11 (6.49)	167	5.11 (7.20)	167	-5.84 (8.12)
Week 28	166	3.48 (5.78)	166	-5.42 (6.00)	159	4.84 (6.82)	159	-6.06 (7.71)
Week 32	161	3.29 (5.60)	161	-5.31 (6.24)	151	4.89 (6.99)	151	-6.06 (7.21)
Week 36	162	3.32 (5.76)	162	-5.54 (6.46)	153	4.65 (6.74)	153	-6.22 (7.65)
Week 40	161	3.45 (6.04)	161	-5.30 (6.45)	152	4.34 (6.57)	152	-6.49 (7.23)
Week 44	159	3.13 (5.59)	159	-5.57 (6.15)	147	3.97 (6.38)	147	-6.95 (7.27)
Week 48	155	3.40 (6.13)	155	-5.63 (6.11)	143	4.42 (7.02)	143	-6.38 (7.44)
Week 52	153	3.46 (6.19)	153	-4.91 (6.43)	141	4.67 (7.02)	141	-6.11 (7.62)

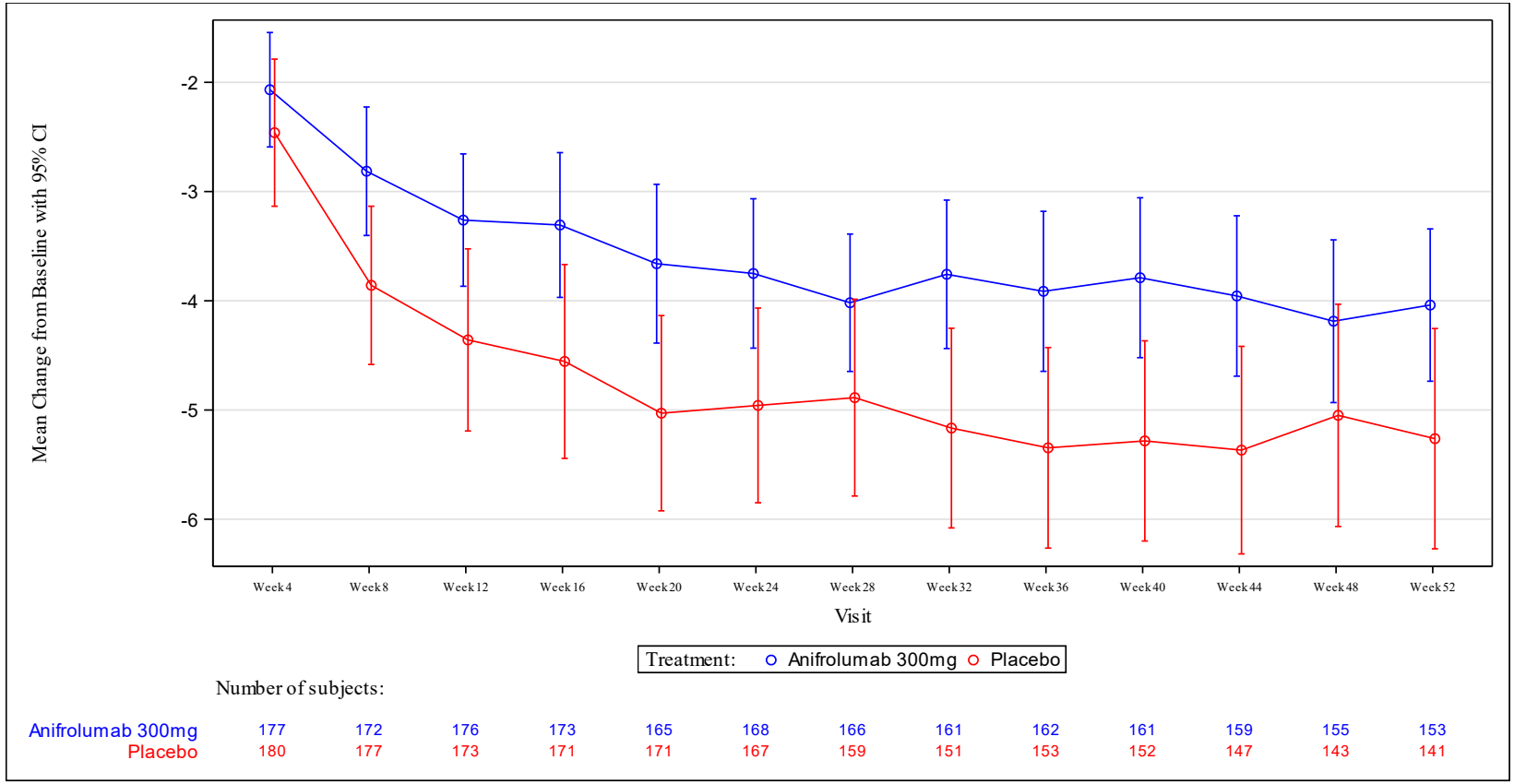
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Tender Joint Count
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Swollen Joint Count
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=182)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	180	6.19 (5.65)	0	-	182	7.43 (6.55)	0	-
Week 4	177	4.06 (5.36)	177	-2.07 (3.53)	180	4.92 (5.83)	180	-2.46 (4.58)
Week 8	172	2.98 (4.97)	172	-2.81 (3.91)	177	3.50 (5.11)	177	-3.86 (4.88)
Week 12	176	2.68 (5.14)	176	-3.26 (4.07)	173	3.17 (5.00)	173	-4.36 (5.56)
Week 16	173	2.67 (4.99)	173	-3.31 (4.42)	171	2.62 (4.86)	171	-4.56 (5.88)
Week 20	165	2.31 (4.97)	165	-3.66 (4.73)	171	2.45 (4.64)	171	-5.03 (5.92)
Week 24	168	2.36 (4.77)	168	-3.75 (4.49)	167	2.47 (4.85)	167	-4.96 (5.83)
Week 28	166	2.05 (4.39)	166	-4.02 (4.10)	159	2.57 (4.93)	159	-4.89 (5.75)
Week 32	161	2.00 (4.42)	161	-3.76 (4.36)	151	2.34 (4.78)	151	-5.17 (5.68)
Week 36	162	2.09 (4.95)	162	-3.91 (4.72)	153	2.10 (4.42)	153	-5.35 (5.75)
Week 40	161	2.12 (5.23)	161	-3.79 (4.70)	152	2.14 (4.65)	152	-5.28 (5.72)
Week 44	159	1.85 (4.72)	159	-3.96 (4.69)	147	2.03 (4.77)	147	-5.37 (5.83)
Week 48	155	1.96 (4.94)	155	-4.19 (4.69)	143	2.36 (5.31)	143	-5.05 (6.15)
Week 52	153	1.56 (3.90)	153	-4.04 (4.37)	141	2.21 (4.84)	141	-5.26 (6.06)

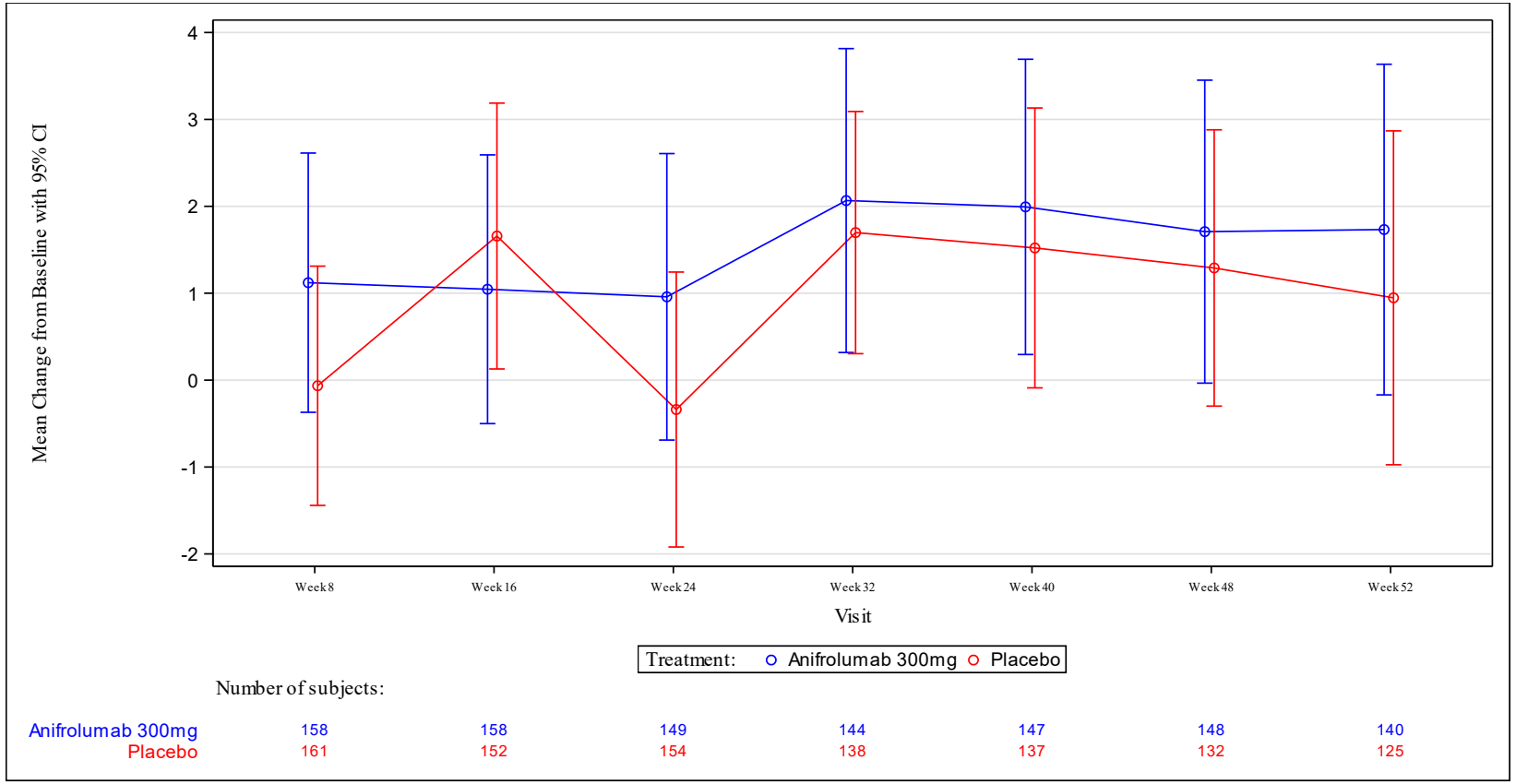
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Swollen Joint Count
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Mental Component Score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=182)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	173	44.64 (11.73)	0	-	173	43.01 (10.94)	0	-
Week 8	164	45.86 (11.69)	158	1.12 (9.49)	165	43.27 (11.35)	161	-0.07 (8.84)
Week 16	165	45.83 (11.06)	158	1.05 (9.84)	157	44.96 (10.85)	152	1.66 (9.55)
Week 24	156	45.89 (11.84)	149	0.96 (10.18)	162	43.30 (11.64)	154	-0.34 (9.94)
Week 32	150	46.96 (11.44)	144	2.07 (10.62)	142	44.74 (10.68)	138	1.70 (8.28)
Week 40	153	46.33 (11.39)	147	1.99 (10.42)	142	44.50 (10.84)	137	1.52 (9.53)
Week 48	154	46.07 (11.41)	148	1.71 (10.73)	135	44.06 (10.13)	132	1.29 (9.23)
Week 52	147	45.91 (11.97)	140	1.73 (11.38)	129	44.50 (10.83)	125	0.95 (10.85)

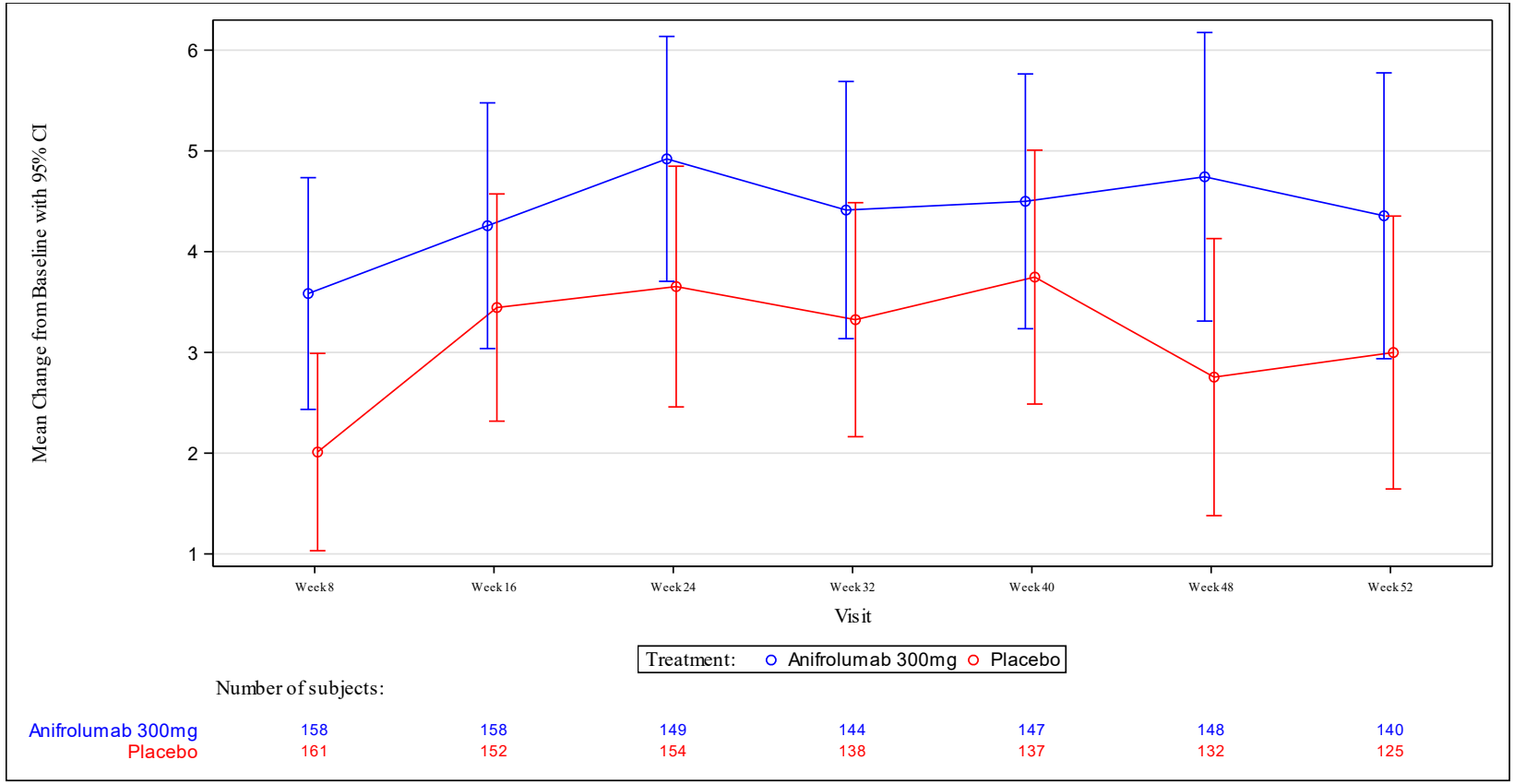
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Mental Component Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Physical Component Score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=182)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	173	37.92 (8.92)	0	-	173	38.01 (9.44)	0	-
Week 8	164	41.95 (9.13)	158	3.58 (7.32)	165	40.43 (9.01)	161	2.01 (6.29)
Week 16	165	42.29 (9.08)	158	4.26 (7.76)	157	41.64 (9.13)	152	3.45 (7.04)
Week 24	156	43.22 (9.37)	149	4.92 (7.51)	162	41.84 (8.64)	154	3.65 (7.50)
Week 32	150	42.69 (9.15)	144	4.41 (7.75)	142	41.49 (8.14)	138	3.32 (6.90)
Week 40	153	43.02 (9.32)	147	4.50 (7.76)	142	42.05 (8.64)	137	3.75 (7.46)
Week 48	154	43.06 (9.50)	148	4.74 (8.82)	135	41.32 (9.04)	132	2.75 (7.99)
Week 52	147	43.03 (9.71)	140	4.36 (8.49)	129	42.05 (8.76)	125	3.00 (7.65)

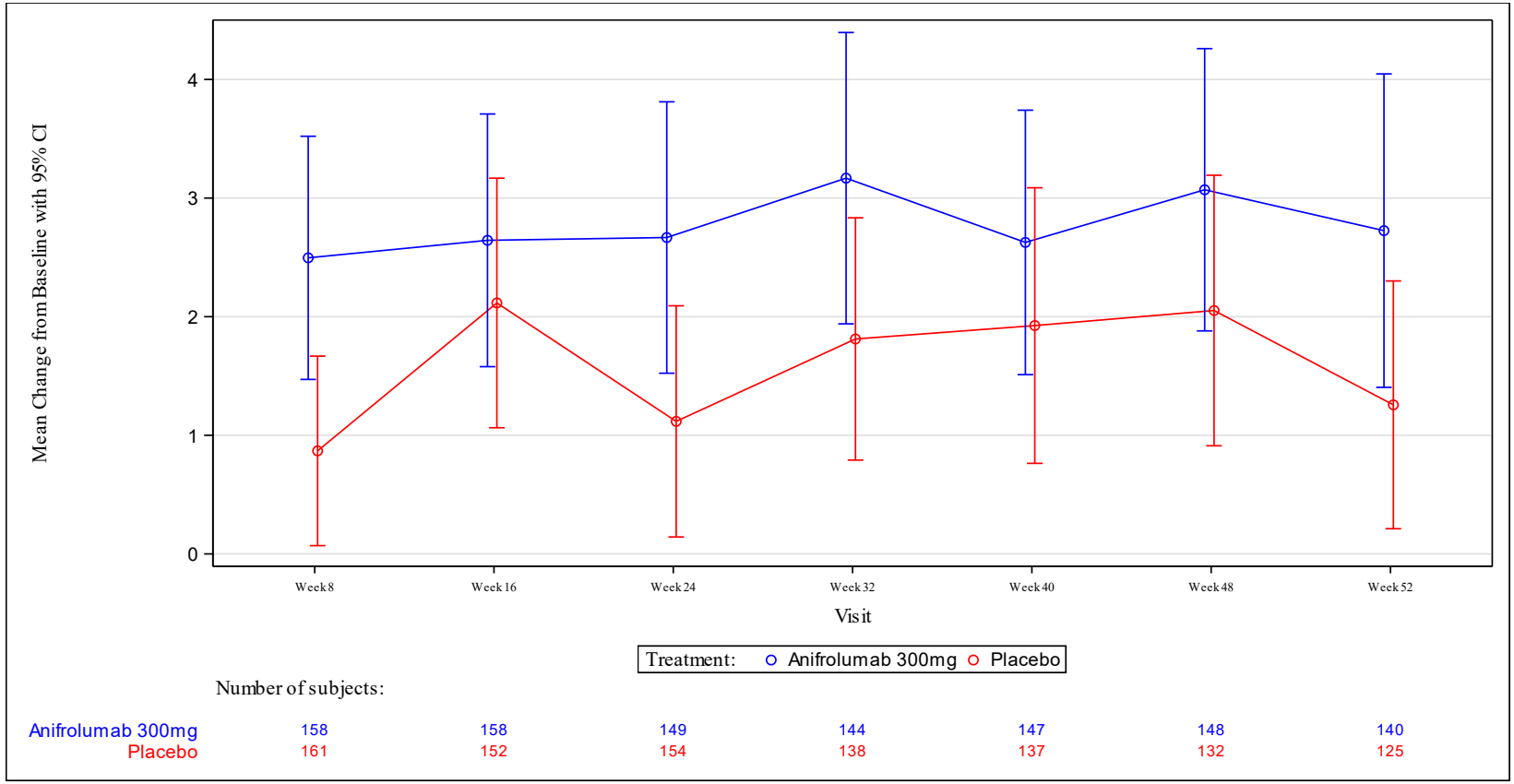
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Physical Component Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute General Health Score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=182)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	173	39.00 (8.21)	0	-	173	39.03 (7.88)	0	-
Week 8	164	41.86 (8.28)	158	2.50 (6.52)	165	40.21 (7.82)	161	0.87 (5.13)
Week 16	165	41.76 (8.86)	158	2.64 (6.78)	157	41.25 (8.38)	152	2.12 (6.56)
Week 24	156	41.82 (9.24)	149	2.67 (7.07)	162	40.63 (8.15)	154	1.12 (6.12)
Week 32	150	42.29 (9.01)	144	3.17 (7.46)	142	40.69 (8.29)	138	1.81 (6.07)
Week 40	153	41.89 (8.79)	147	2.63 (6.84)	142	41.03 (8.62)	137	1.93 (6.88)
Week 48	154	42.11 (8.99)	148	3.07 (7.32)	135	41.28 (8.27)	132	2.05 (6.62)
Week 52	147	41.93 (9.61)	140	2.73 (7.91)	129	41.00 (8.36)	125	1.26 (5.90)

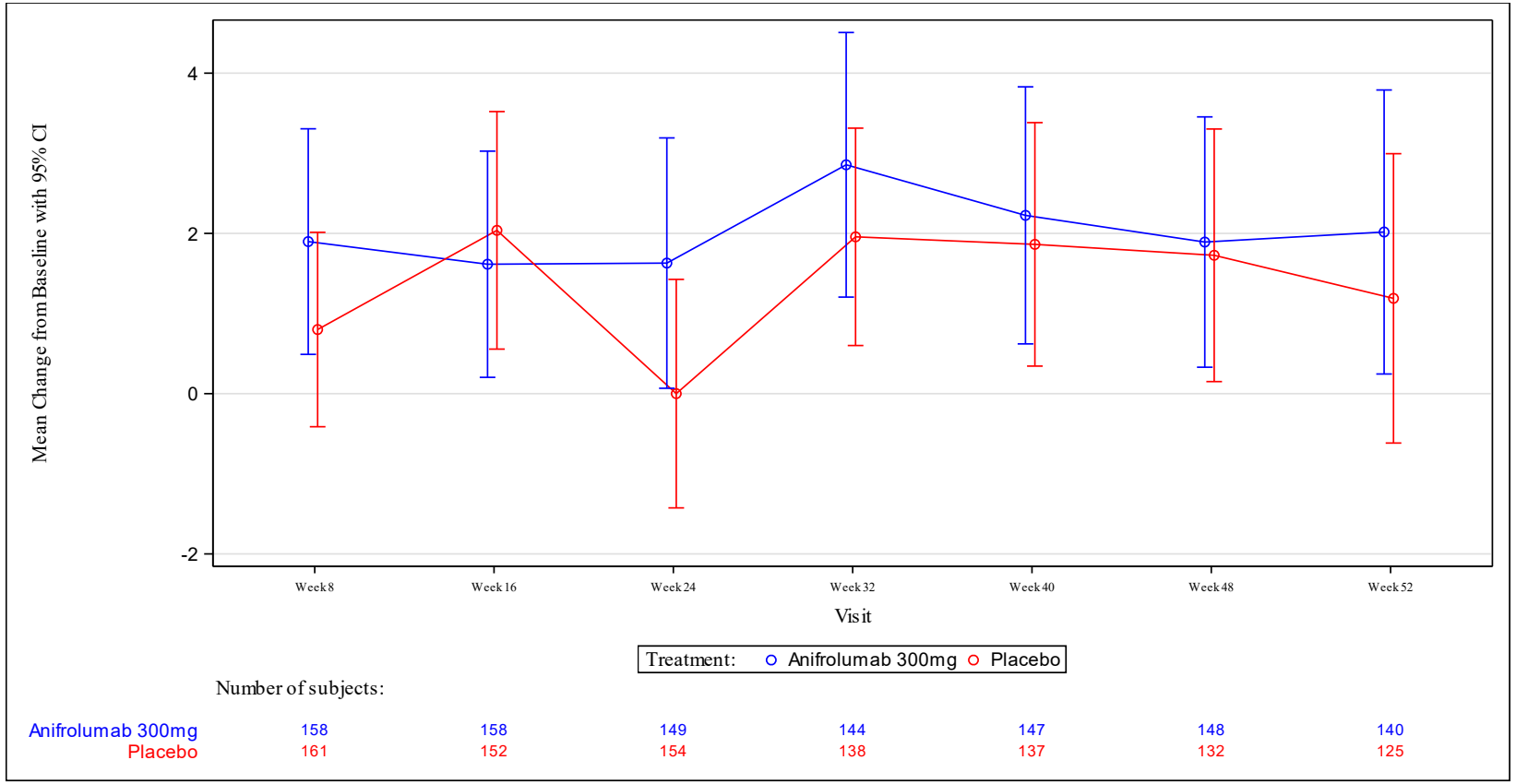
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute General Health Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Mental Health Score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=182)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	173	44.72 (10.25)	0	-	173	43.34 (10.33)	0	-
Week 8	164	46.60 (10.66)	158	1.90 (8.96)	165	44.42 (10.58)	161	0.80 (7.79)
Week 16	165	46.37 (10.23)	158	1.62 (8.98)	157	45.47 (10.39)	152	2.04 (9.25)
Week 24	156	46.52 (10.88)	149	1.63 (9.65)	162	43.89 (10.49)	154	0.00 (8.96)
Week 32	150	47.64 (10.61)	144	2.86 (10.02)	142	45.38 (10.68)	138	1.96 (8.06)
Week 40	153	46.71 (10.58)	147	2.23 (9.84)	142	45.12 (10.25)	137	1.86 (8.99)
Week 48	154	46.46 (10.13)	148	1.89 (9.62)	135	44.89 (10.27)	132	1.73 (9.15)
Week 52	147	46.41 (10.95)	140	2.02 (10.61)	129	45.33 (10.35)	125	1.19 (10.20)

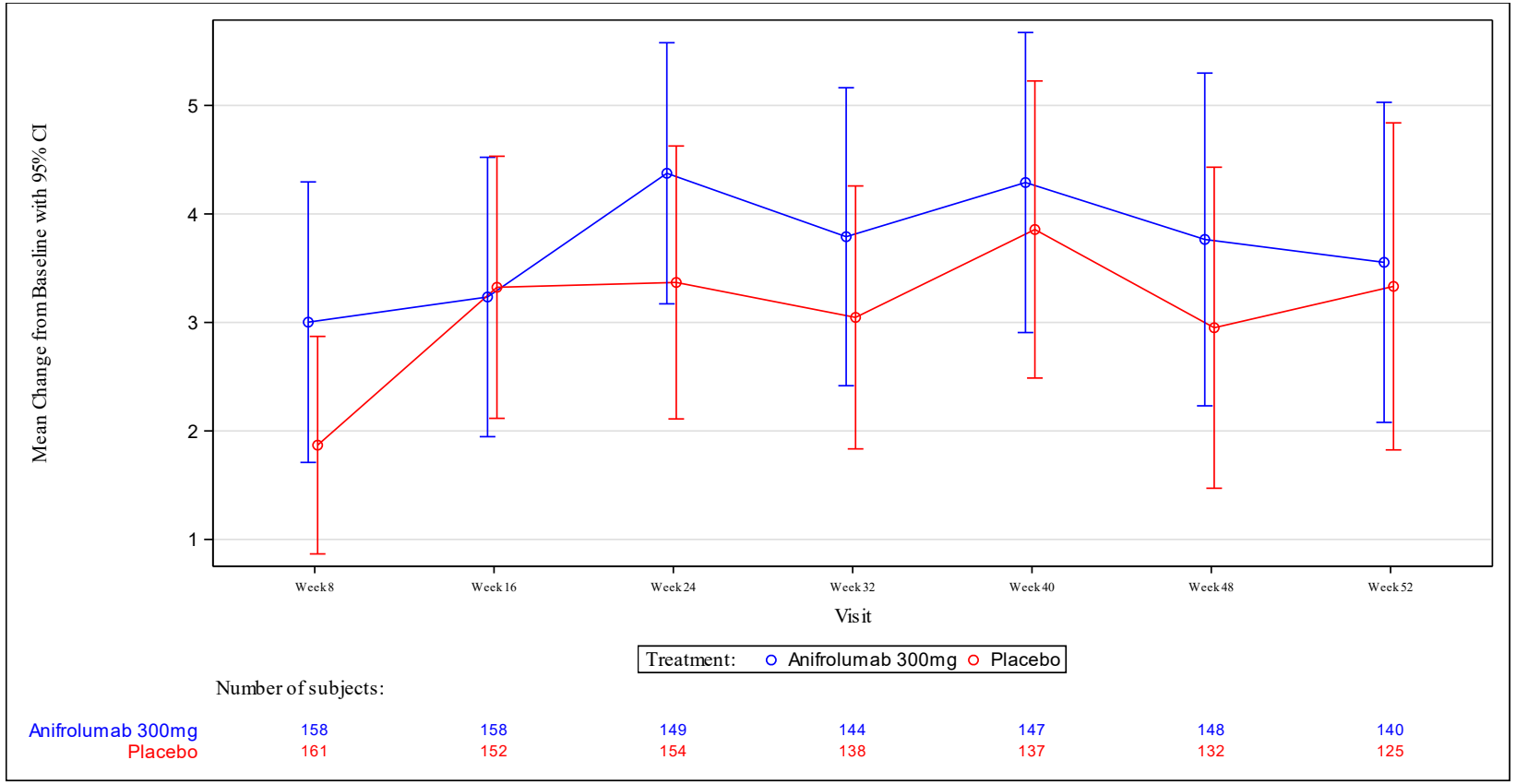
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Mental Health Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Physical Functioning Score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=182)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	173	39.72 (9.92)	0	-	173	38.69 (10.92)	0	-
Week 8	164	42.93 (9.83)	158	3.00 (8.23)	165	41.14 (10.18)	161	1.87 (6.44)
Week 16	165	43.02 (9.52)	158	3.23 (8.19)	157	42.23 (9.65)	152	3.32 (7.54)
Week 24	156	44.43 (9.63)	149	4.37 (7.43)	162	42.20 (9.79)	154	3.37 (7.90)
Week 32	150	43.85 (9.75)	144	3.79 (8.34)	142	42.09 (9.70)	138	3.05 (7.20)
Week 40	153	44.06 (9.81)	147	4.29 (8.48)	142	42.67 (9.91)	137	3.86 (8.10)
Week 48	154	43.82 (9.47)	148	3.76 (9.44)	135	41.94 (10.25)	132	2.95 (8.59)
Week 52	147	43.73 (9.96)	140	3.55 (8.83)	129	43.14 (9.86)	125	3.33 (8.51)

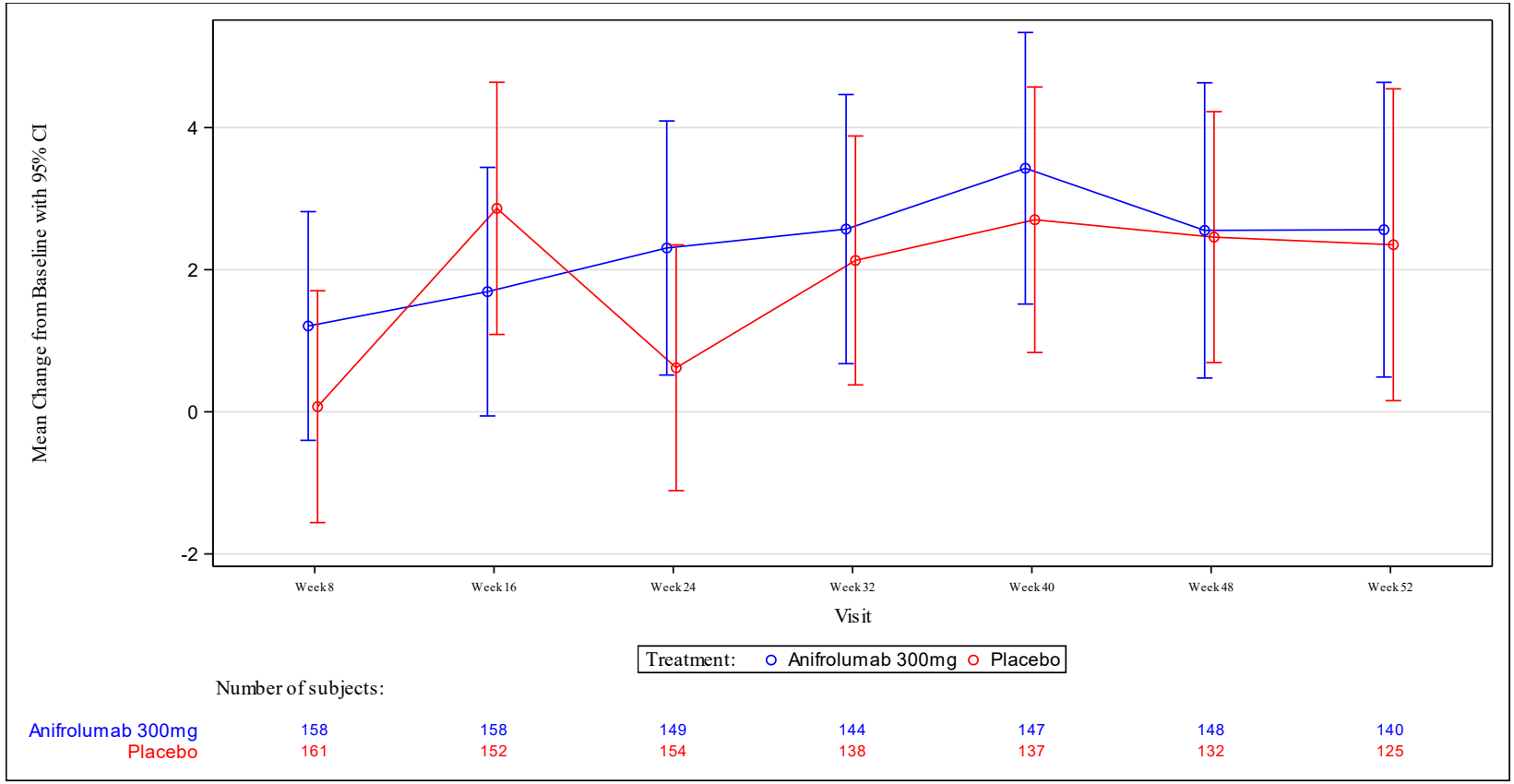
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Physical Functioning Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Role Emotional Score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=182)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	173	40.90 (13.33)	0	-	173	39.00 (12.60)	0	-
Week 8	164	42.07 (12.80)	158	1.21 (10.24)	165	39.54 (12.61)	161	0.07 (10.48)
Week 16	165	42.99 (12.05)	158	1.69 (11.13)	157	42.32 (12.08)	152	2.86 (11.07)
Week 24	156	43.55 (11.93)	149	2.31 (11.05)	162	40.14 (13.19)	154	0.62 (10.86)
Week 32	150	43.78 (11.39)	144	2.57 (11.50)	142	41.37 (12.46)	138	2.13 (10.41)
Week 40	153	43.66 (11.95)	147	3.43 (11.72)	142	41.72 (12.05)	137	2.70 (11.06)
Week 48	154	42.78 (12.34)	148	2.55 (12.79)	135	41.16 (11.48)	132	2.46 (10.26)
Week 52	147	43.10 (11.93)	140	2.56 (12.41)	129	41.73 (12.01)	125	2.35 (12.39)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Role Emotional Score
Full analysis set



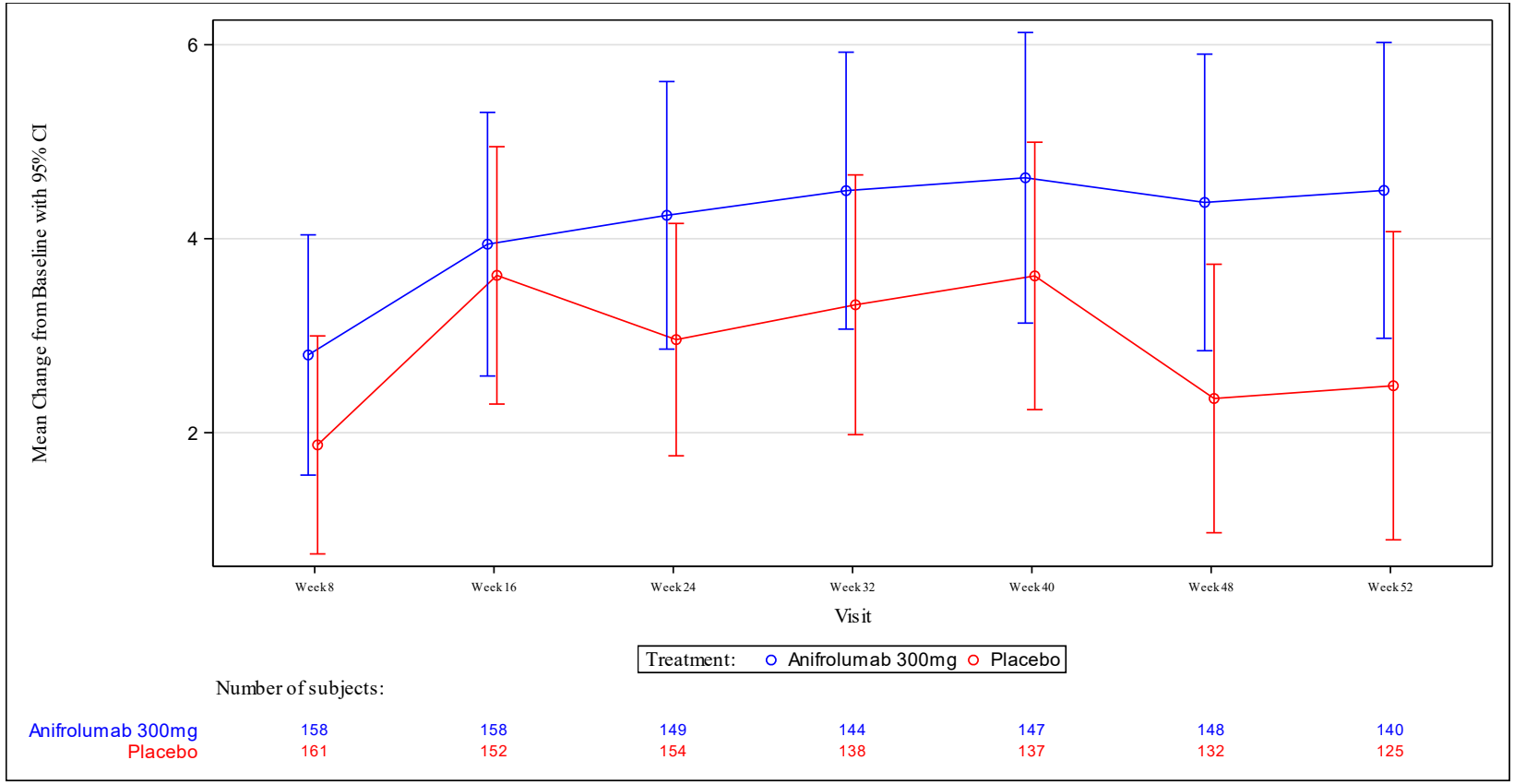
Number of subjects:

	Week 8	Week 16	Week 24	Week 32	Week 40	Week 48	Week 52
Anifrolumab 300mg	158	158	149	144	147	148	140
Placebo	161	152	154	138	137	132	125

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Role Physical Score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=182)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	173	37.70 (9.83)	0	-	173	37.86 (9.17)	0	-
Week 8	164	40.93 (9.39)	158	2.80 (7.88)	165	40.13 (9.06)	161	1.87 (7.22)
Week 16	165	42.01 (9.48)	158	3.94 (8.65)	157	41.75 (9.36)	152	3.62 (8.28)
Week 24	156	42.32 (9.29)	149	4.24 (8.52)	162	40.96 (8.74)	154	2.96 (7.52)
Week 32	150	42.55 (9.48)	144	4.50 (8.67)	142	41.37 (8.85)	138	3.32 (7.96)
Week 40	153	42.60 (9.55)	147	4.63 (9.19)	142	41.74 (8.67)	137	3.62 (8.16)
Week 48	154	42.12 (9.74)	148	4.37 (9.41)	135	40.55 (8.95)	132	2.35 (8.04)
Week 52	147	42.58 (9.11)	140	4.50 (9.13)	129	41.28 (8.94)	125	2.48 (8.97)

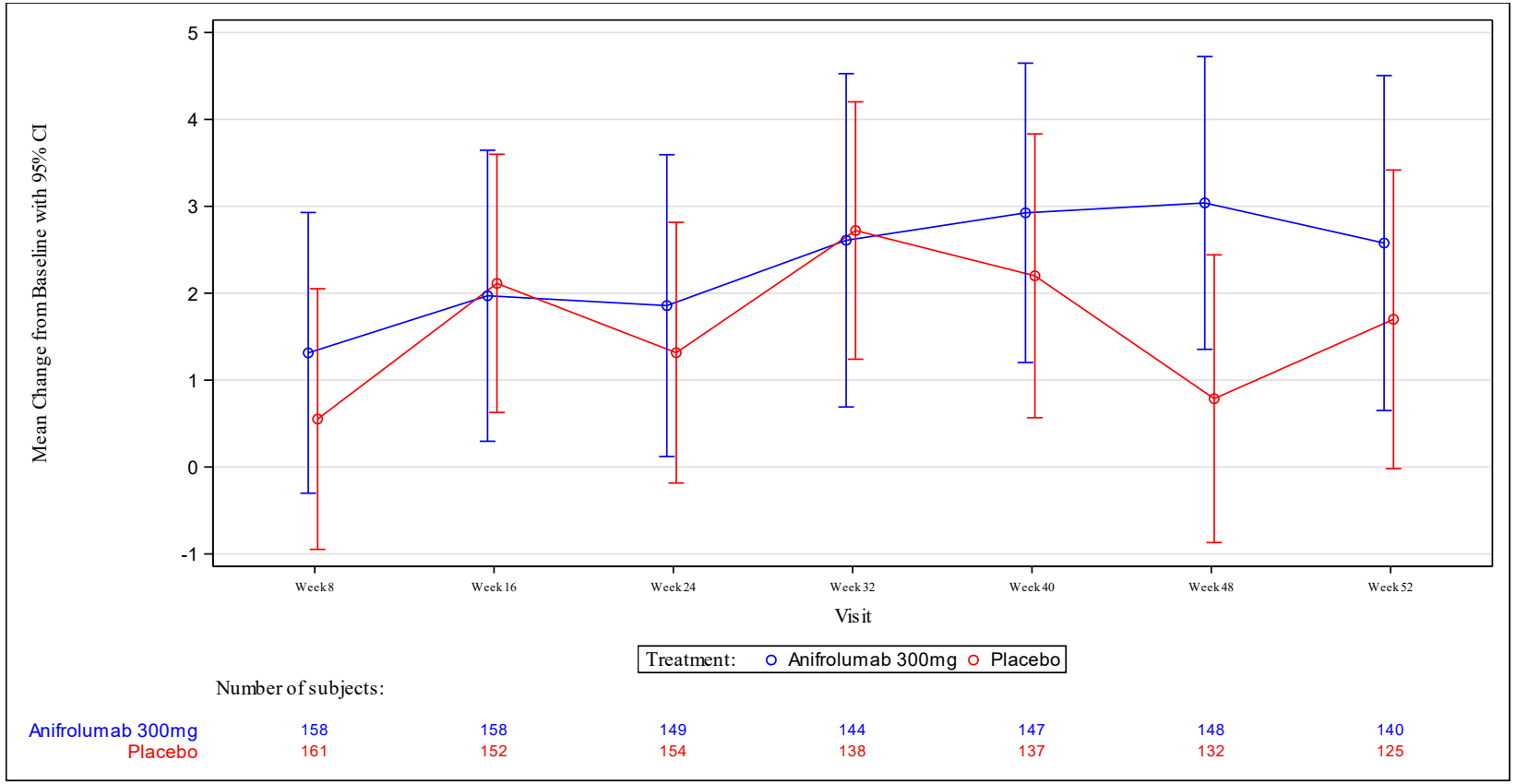
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Role Physical Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Social Functioning Score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=182)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	173	41.74 (10.78)	0	-	173	40.63 (10.09)	0	-
Week 8	164	43.45 (10.25)	158	1.31 (10.28)	165	41.61 (10.91)	161	0.55 (9.63)
Week 16	165	43.56 (10.37)	158	1.97 (10.66)	157	42.89 (9.83)	152	2.11 (9.27)
Week 24	156	43.87 (10.57)	149	1.86 (10.72)	162	42.25 (10.32)	154	1.32 (9.42)
Week 32	150	44.78 (10.50)	144	2.61 (11.64)	142	42.95 (9.93)	138	2.72 (8.80)
Week 40	153	44.72 (9.78)	147	2.92 (10.57)	142	42.64 (9.87)	137	2.20 (9.66)
Week 48	154	44.93 (9.68)	148	3.04 (10.37)	135	41.21 (10.20)	132	0.79 (9.61)
Week 52	147	44.20 (10.84)	140	2.58 (11.53)	129	42.98 (9.59)	125	1.70 (9.71)

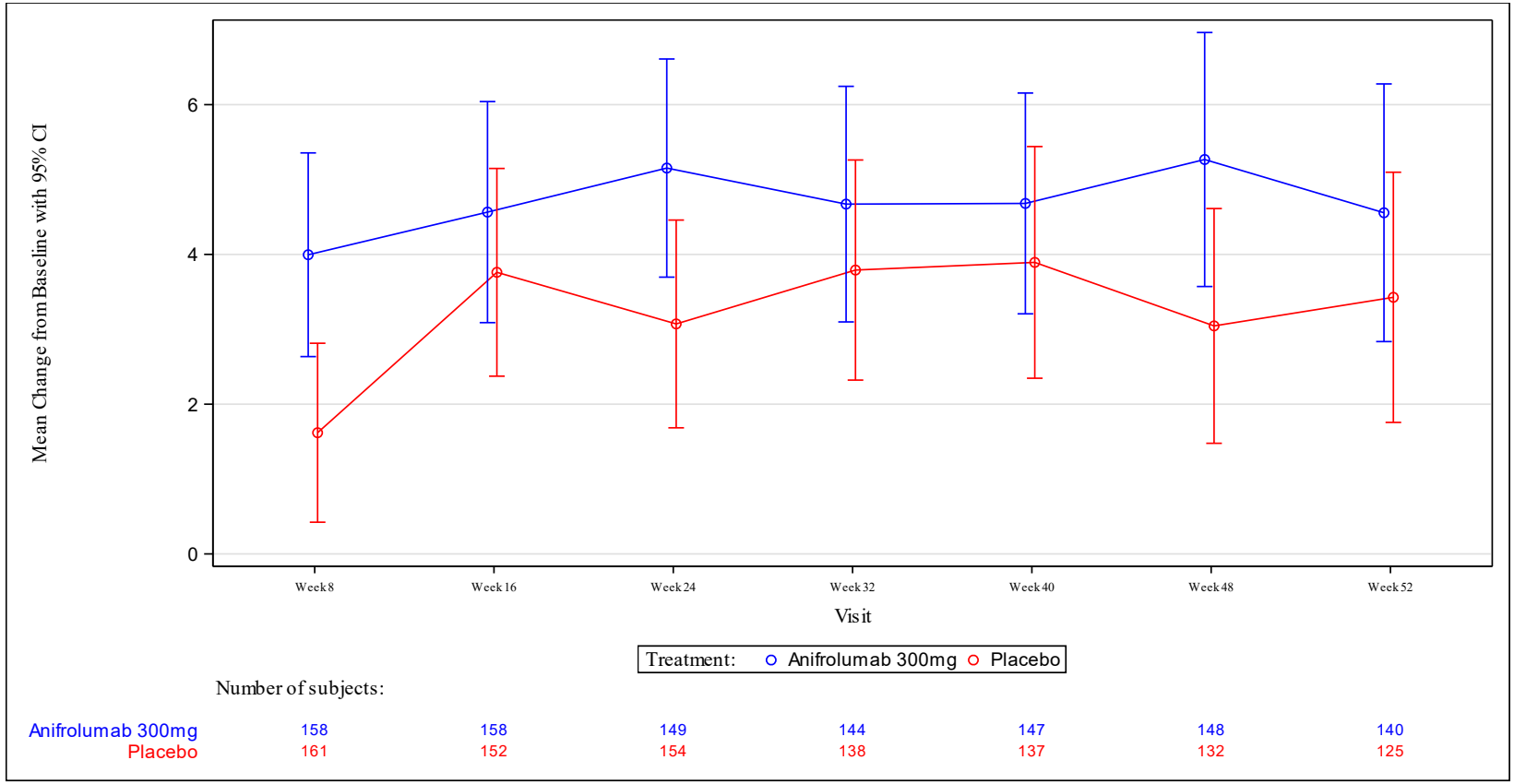
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Social Functioning Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Bodily Pain Score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=182)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	173	39.25 (8.14)	0	-	173	38.59 (8.79)	0	-
Week 8	164	43.51 (8.85)	158	4.00 (8.66)	165	40.50 (9.58)	161	1.62 (7.68)
Week 16	165	43.80 (9.43)	158	4.56 (9.39)	157	42.59 (9.49)	152	3.76 (8.65)
Week 24	156	44.88 (9.44)	149	5.15 (9.00)	162	42.14 (9.96)	154	3.07 (8.71)
Week 32	150	44.27 (9.28)	144	4.67 (9.55)	142	42.48 (9.06)	138	3.79 (8.73)
Week 40	153	44.60 (8.98)	147	4.68 (9.05)	142	42.79 (9.33)	137	3.89 (9.16)
Week 48	154	44.64 (10.34)	148	5.27 (10.44)	135	42.10 (9.56)	132	3.04 (9.10)
Week 52	147	44.49 (9.90)	140	4.56 (10.30)	129	42.92 (9.41)	125	3.43 (9.44)

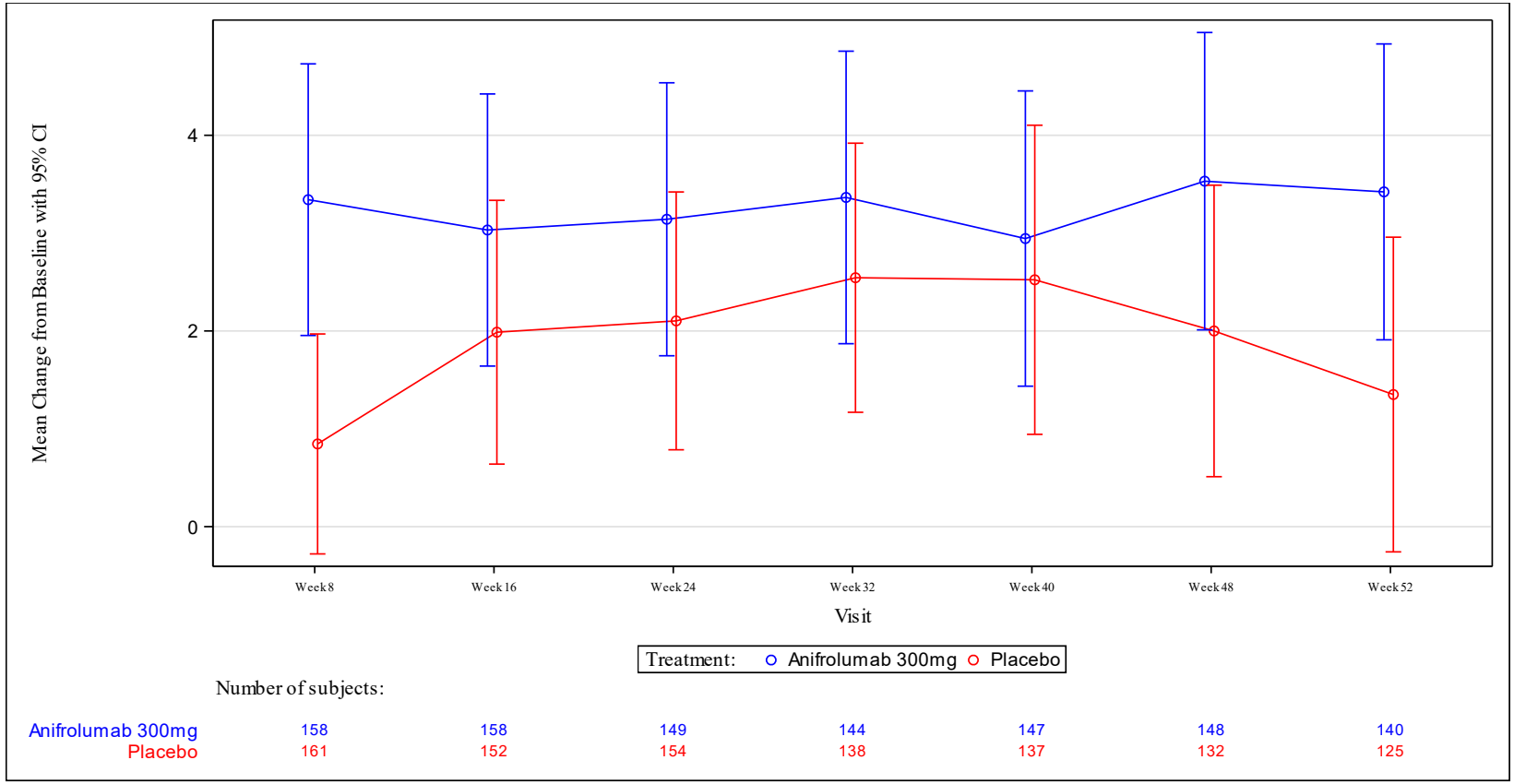
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Bodily Pain Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Vitality Score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=182)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	173	42.69 (9.87)	0	-	173	42.18 (8.74)	0	-
Week 8	164	46.65 (9.88)	158	3.34 (8.83)	165	43.40 (9.07)	161	0.85 (7.22)
Week 16	165	45.97 (9.75)	158	3.03 (8.85)	157	44.64 (8.77)	152	1.99 (8.41)
Week 24	156	46.49 (9.99)	149	3.14 (8.62)	162	44.96 (9.77)	154	2.10 (8.28)
Week 32	150	46.60 (10.30)	144	3.36 (9.08)	142	45.15 (9.35)	138	2.54 (8.17)
Week 40	153	46.47 (10.14)	147	2.94 (9.26)	142	45.31 (9.87)	137	2.52 (9.35)
Week 48	154	46.83 (9.83)	148	3.53 (9.36)	135	44.96 (9.62)	132	2.00 (8.65)
Week 52	147	46.54 (10.52)	140	3.42 (9.05)	129	44.74 (9.27)	125	1.35 (9.08)

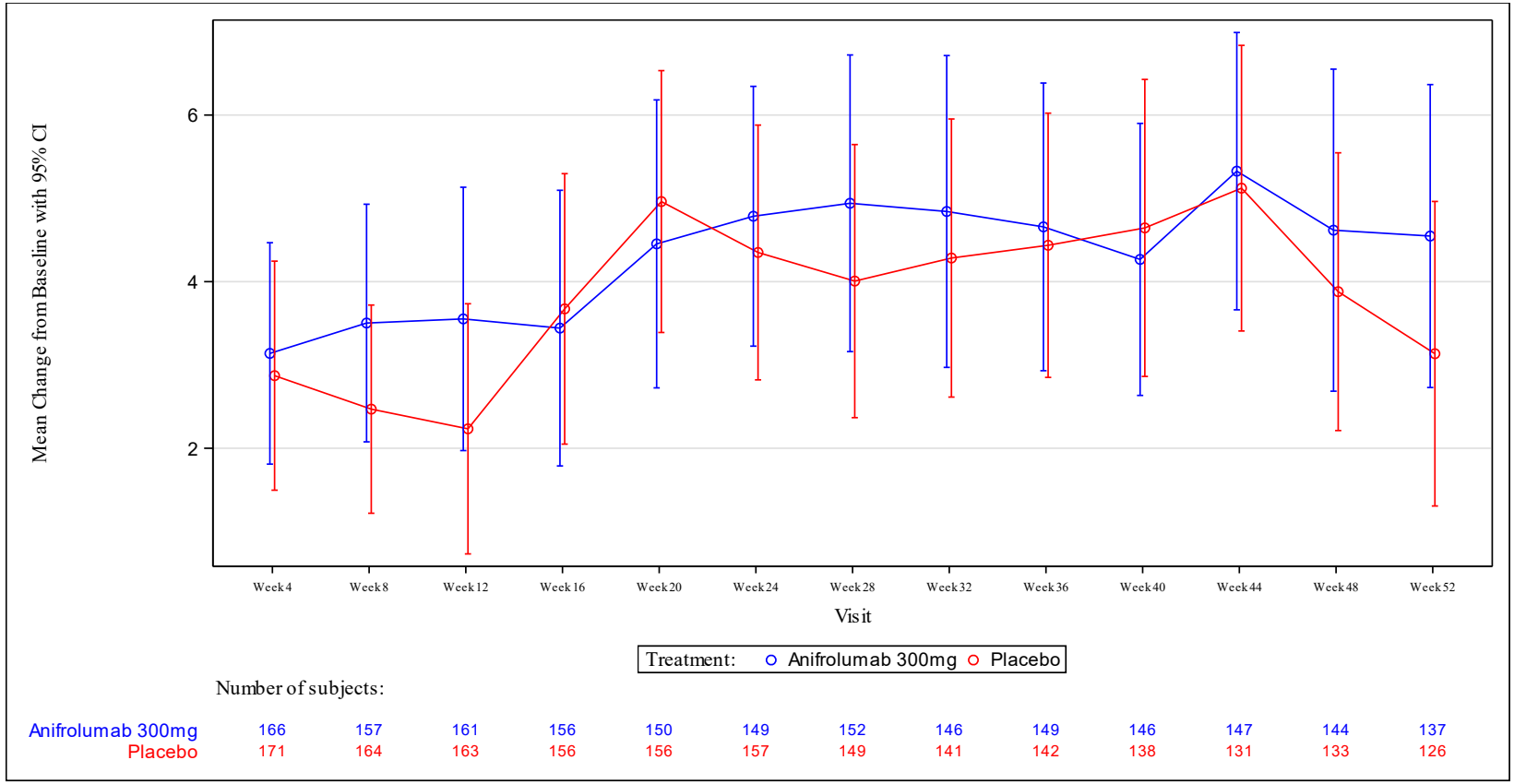
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Vitality Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - FACIT-F Total Score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=182)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	170	26.99 (12.49)	0	-	175	25.69 (11.41)	0	-
Week 4	172	30.02 (11.42)	166	3.14 (8.67)	175	28.57 (10.47)	171	2.87 (9.11)
Week 8	165	31.12 (12.07)	157	3.50 (9.05)	168	28.45 (11.65)	164	2.47 (8.10)
Week 12	171	31.05 (12.41)	161	3.55 (10.16)	167	28.07 (11.82)	163	2.23 (9.71)
Week 16	166	30.72 (12.12)	156	3.44 (10.46)	159	29.49 (11.69)	156	3.67 (10.26)
Week 20	160	31.93 (11.91)	150	4.45 (10.71)	162	31.45 (10.94)	156	4.96 (9.94)
Week 24	159	32.26 (12.10)	149	4.79 (9.63)	163	30.19 (12.19)	157	4.35 (9.70)
Week 28	162	32.48 (11.83)	152	4.94 (11.11)	155	30.20 (11.45)	149	4.01 (10.13)
Week 32	154	32.48 (12.09)	146	4.84 (11.44)	145	30.52 (11.65)	141	4.28 (10.03)
Week 36	159	32.30 (12.48)	149	4.66 (10.67)	146	30.45 (11.07)	142	4.44 (9.56)
Week 40	155	32.25 (11.98)	146	4.27 (9.98)	142	30.73 (11.60)	138	4.64 (10.59)
Week 44	157	32.83 (11.51)	147	5.33 (10.21)	134	31.19 (11.05)	131	5.12 (9.92)
Week 48	153	32.31 (12.32)	144	4.62 (11.73)	137	30.10 (11.51)	133	3.88 (9.72)
Week 52	147	31.87 (12.44)	137	4.55 (10.76)	130	30.39 (11.62)	126	3.13 (10.37)

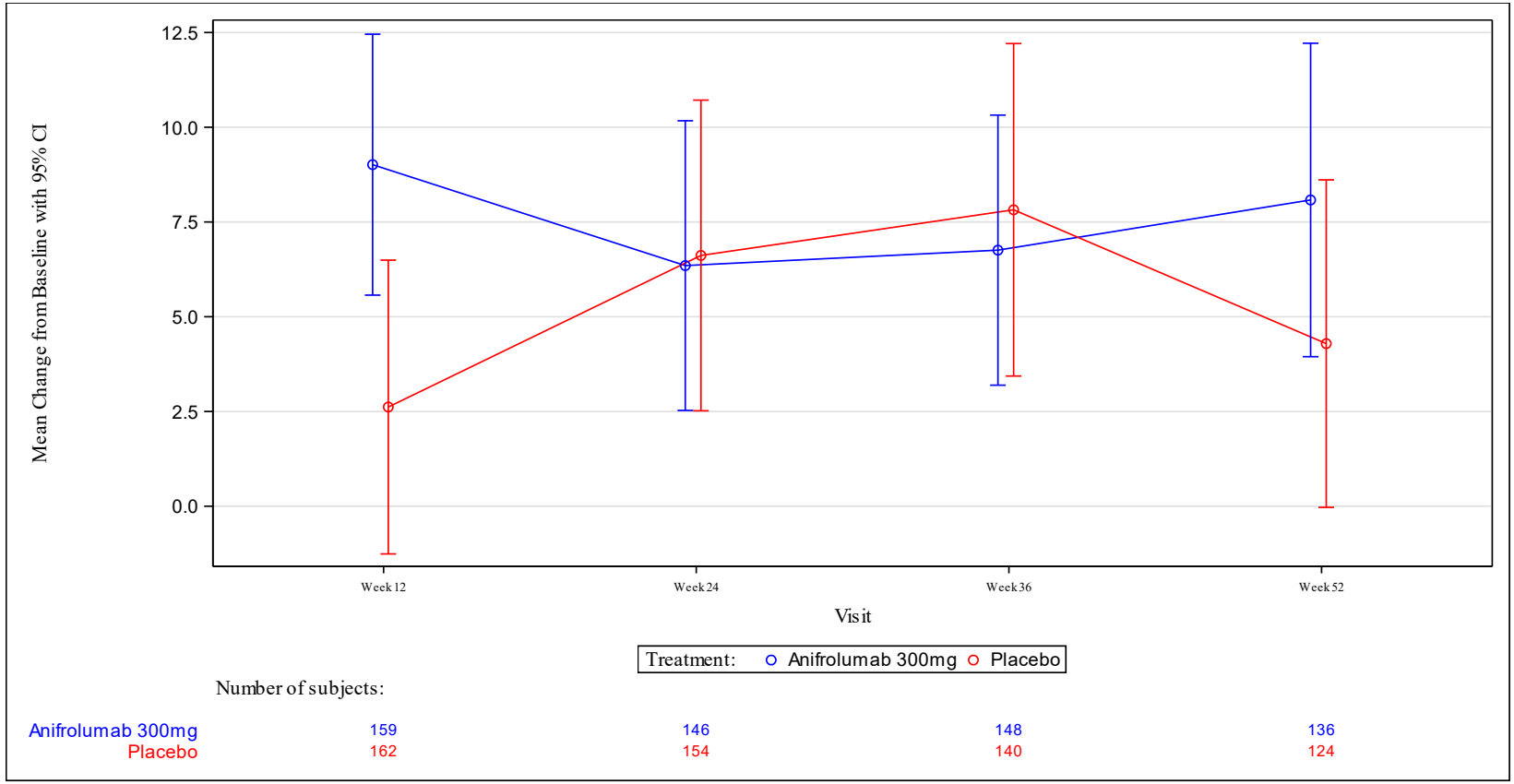
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - FACIT-F Total Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - EQ VAS Score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=182)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	170	58.07 (19.85)	0	-	175	56.60 (21.78)	0	-
Week 12	169	66.62 (20.12)	159	9.01 (21.98)	166	59.92 (21.43)	162	2.62 (24.98)
Week 24	156	64.72 (21.16)	146	6.35 (23.36)	160	63.93 (21.17)	154	6.62 (25.74)
Week 36	158	65.78 (21.74)	148	6.76 (21.93)	144	65.17 (22.06)	140	7.82 (26.25)
Week 52	146	66.73 (20.58)	136	8.08 (24.38)	128	62.53 (22.35)	124	4.29 (24.31)

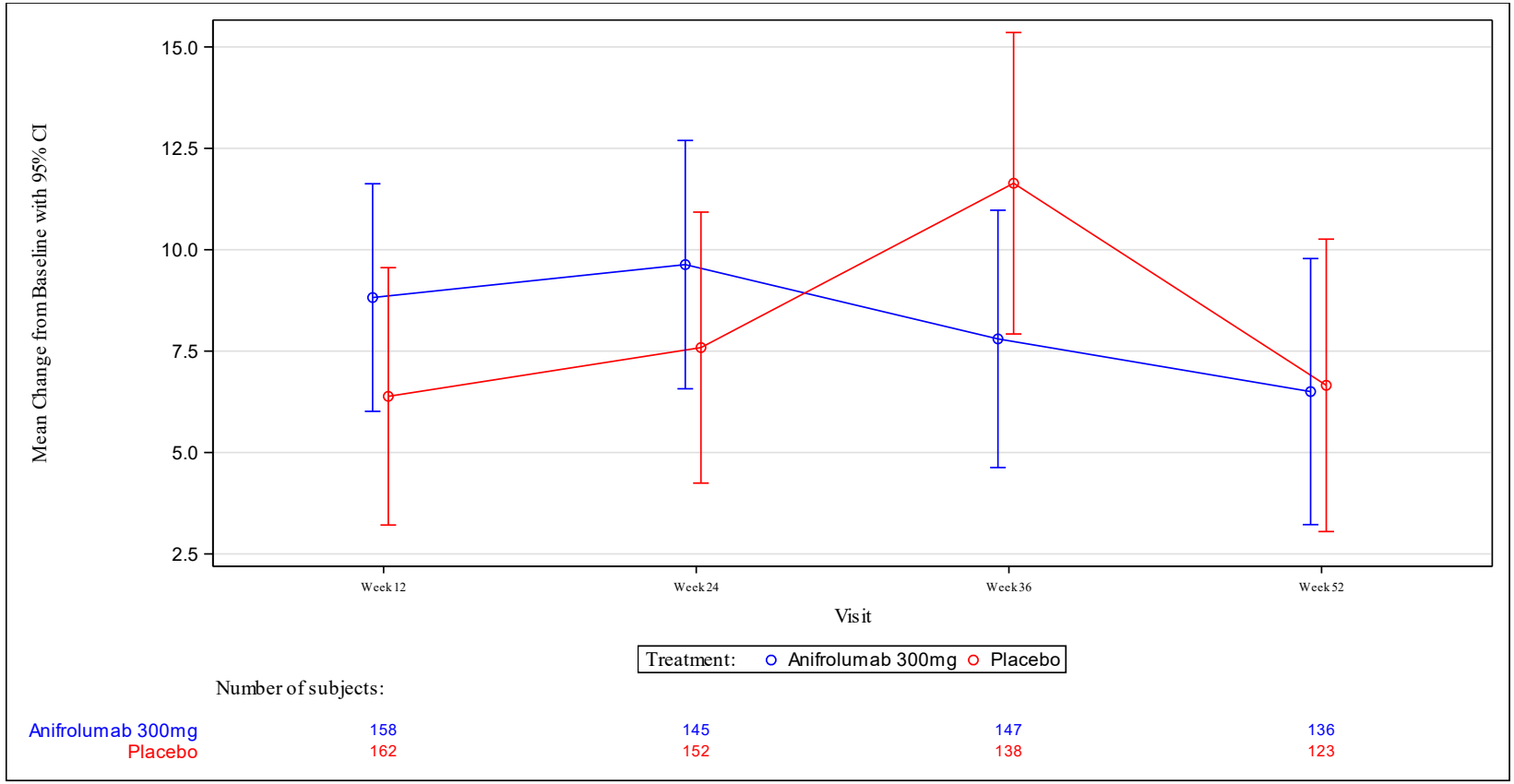
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - EQ VAS Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Physical Health domain score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=182)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	170	56.62 (26.29)	0	-	175	53.48 (26.20)	0	-
Week 12	168	66.69 (25.36)	158	8.82 (17.85)	166	60.36 (26.24)	162	6.39 (20.45)
Week 24	155	67.22 (24.96)	145	9.63 (18.65)	158	61.81 (25.13)	152	7.59 (20.85)
Week 36	157	65.33 (24.95)	147	7.80 (19.46)	142	65.61 (23.57)	138	11.64 (22.08)
Week 52	146	65.28 (24.62)	136	6.50 (19.34)	127	63.88 (22.92)	123	6.66 (20.20)

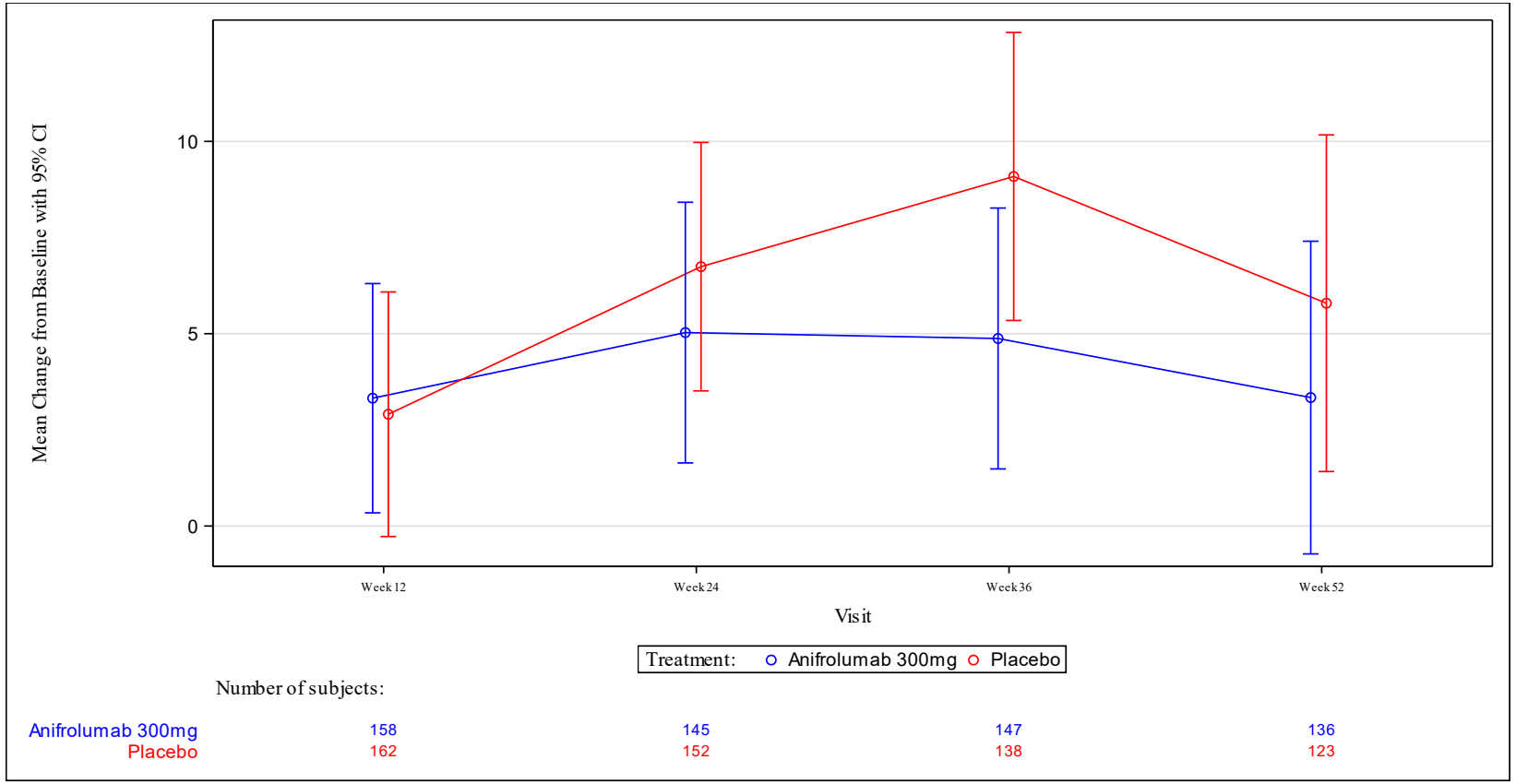
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Lupus QoL Physical Health domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Emotional Health domain score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=182)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	170	68.73 (23.87)	0	-	175	63.43 (26.22)	0	-
Week 12	168	73.19 (23.82)	158	3.32 (18.97)	166	66.79 (25.36)	162	2.91 (20.49)
Week 24	155	75.32 (21.67)	145	5.03 (20.64)	158	70.99 (24.75)	152	6.74 (20.16)
Week 36	157	74.58 (20.74)	147	4.88 (20.81)	142	73.24 (22.76)	138	9.09 (22.24)
Week 52	146	73.43 (24.11)	136	3.34 (23.97)	127	72.31 (24.12)	123	5.79 (24.52)

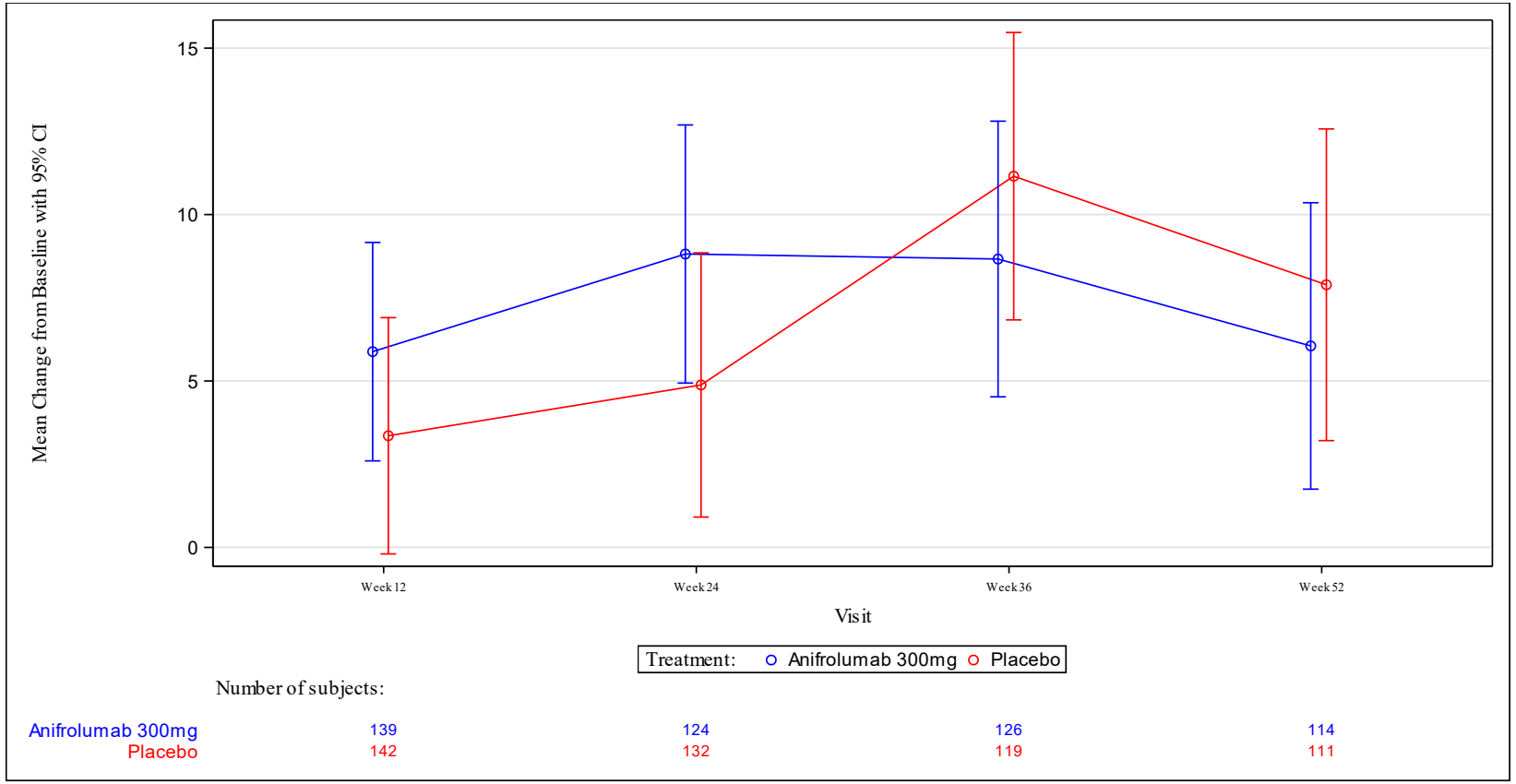
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Lupus QoL Emotional Health domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Body Image domain score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=182)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	157	61.50 (31.61)	0	-	164	62.19 (28.53)	0	-
Week 12	154	69.42 (28.24)	139	5.88 (19.56)	151	64.93 (27.68)	142	3.35 (21.39)
Week 24	136	70.29 (27.17)	124	8.81 (21.81)	142	66.56 (27.61)	132	4.88 (23.05)
Week 36	138	70.05 (27.66)	126	8.66 (23.48)	128	71.46 (24.87)	119	11.15 (23.78)
Week 52	127	68.63 (30.05)	114	6.05 (23.19)	118	70.80 (27.56)	111	7.89 (24.89)

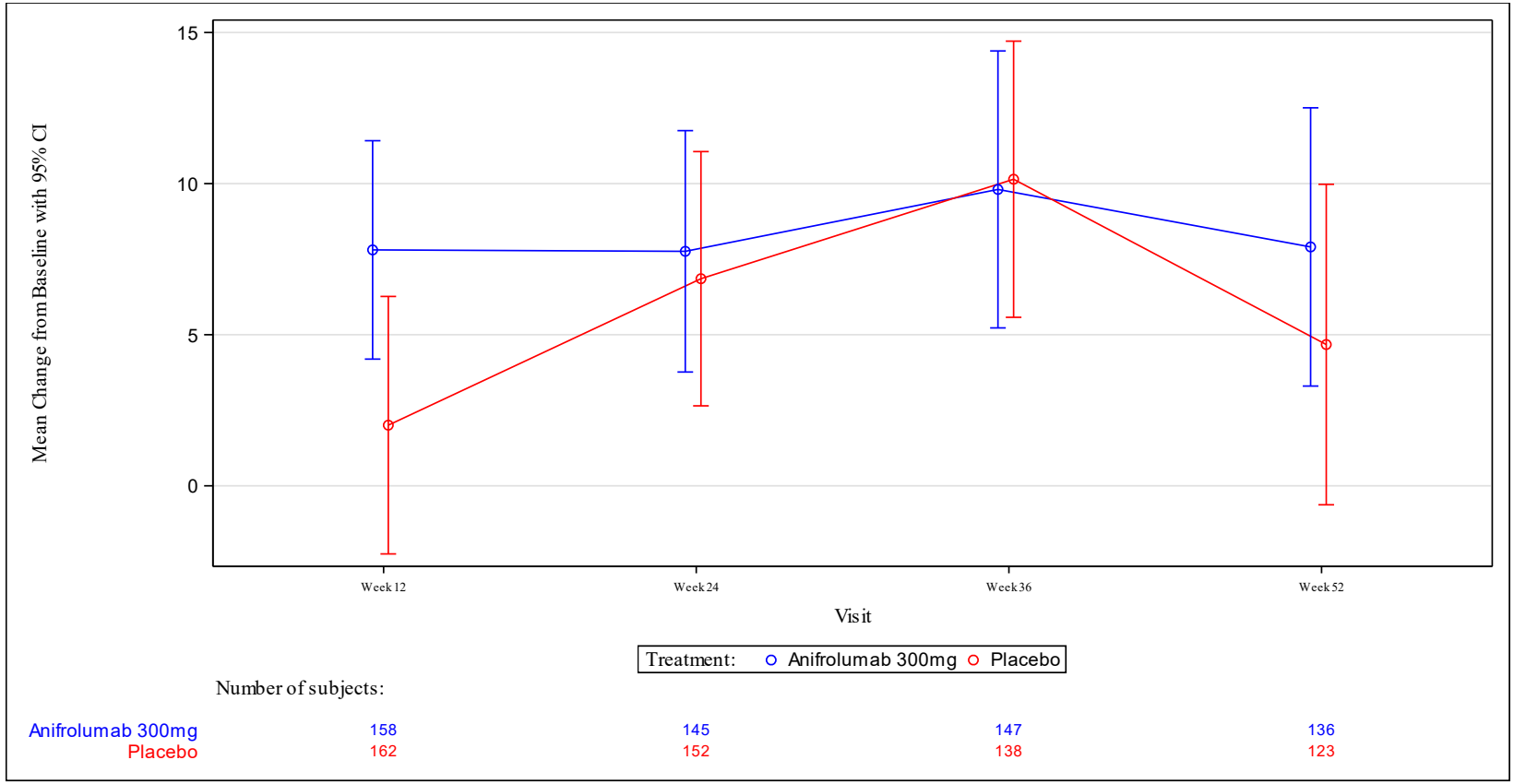
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Lupus QoL Body Image domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Burden to Others domain score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=182)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	170	53.04 (30.90)	0	-	175	52.81 (30.90)	0	-
Week 12	168	61.66 (30.85)	158	7.81 (22.99)	166	55.07 (31.65)	162	2.01 (27.46)
Week 24	155	60.97 (31.68)	145	7.76 (24.33)	158	59.18 (31.94)	152	6.85 (26.25)
Week 36	157	62.31 (30.54)	147	9.81 (28.11)	142	62.97 (28.69)	138	10.14 (27.14)
Week 52	146	61.81 (30.37)	136	7.90 (27.15)	127	58.60 (31.74)	123	4.67 (29.71)

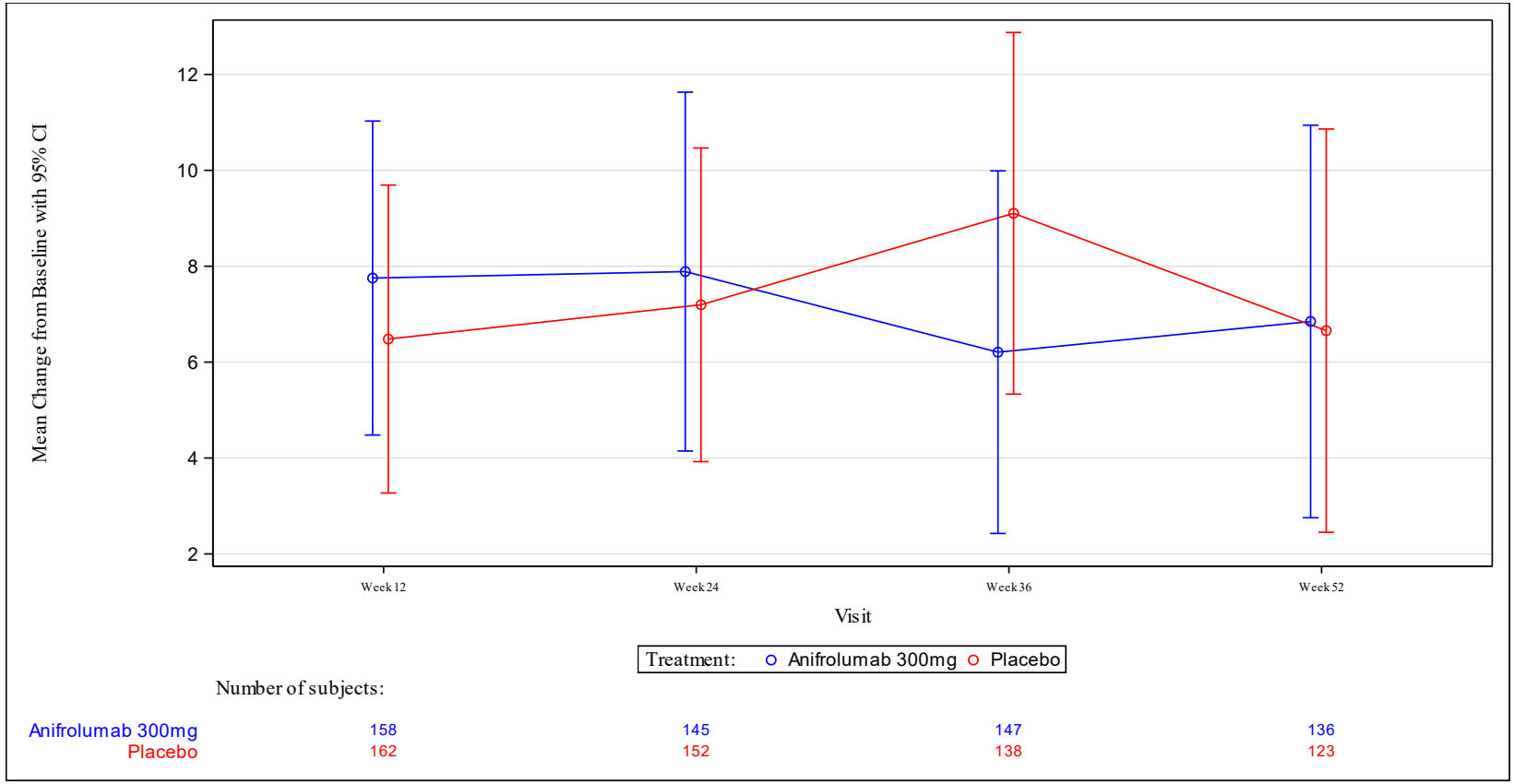
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Lupus QoL Burden to Others domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Fatigue domain score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=182)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	170	50.40 (27.53)	0	-	175	46.75 (26.22)	0	-
Week 12	168	59.90 (26.71)	158	7.75 (20.84)	166	53.80 (25.91)	162	6.48 (20.70)
Week 24	155	60.69 (26.63)	145	7.89 (22.80)	158	55.18 (26.30)	152	7.20 (20.41)
Week 36	157	58.68 (27.04)	147	6.21 (23.20)	142	57.13 (24.90)	138	9.10 (22.40)
Week 52	146	58.99 (27.33)	136	6.85 (24.14)	127	56.69 (26.14)	123	6.66 (23.56)

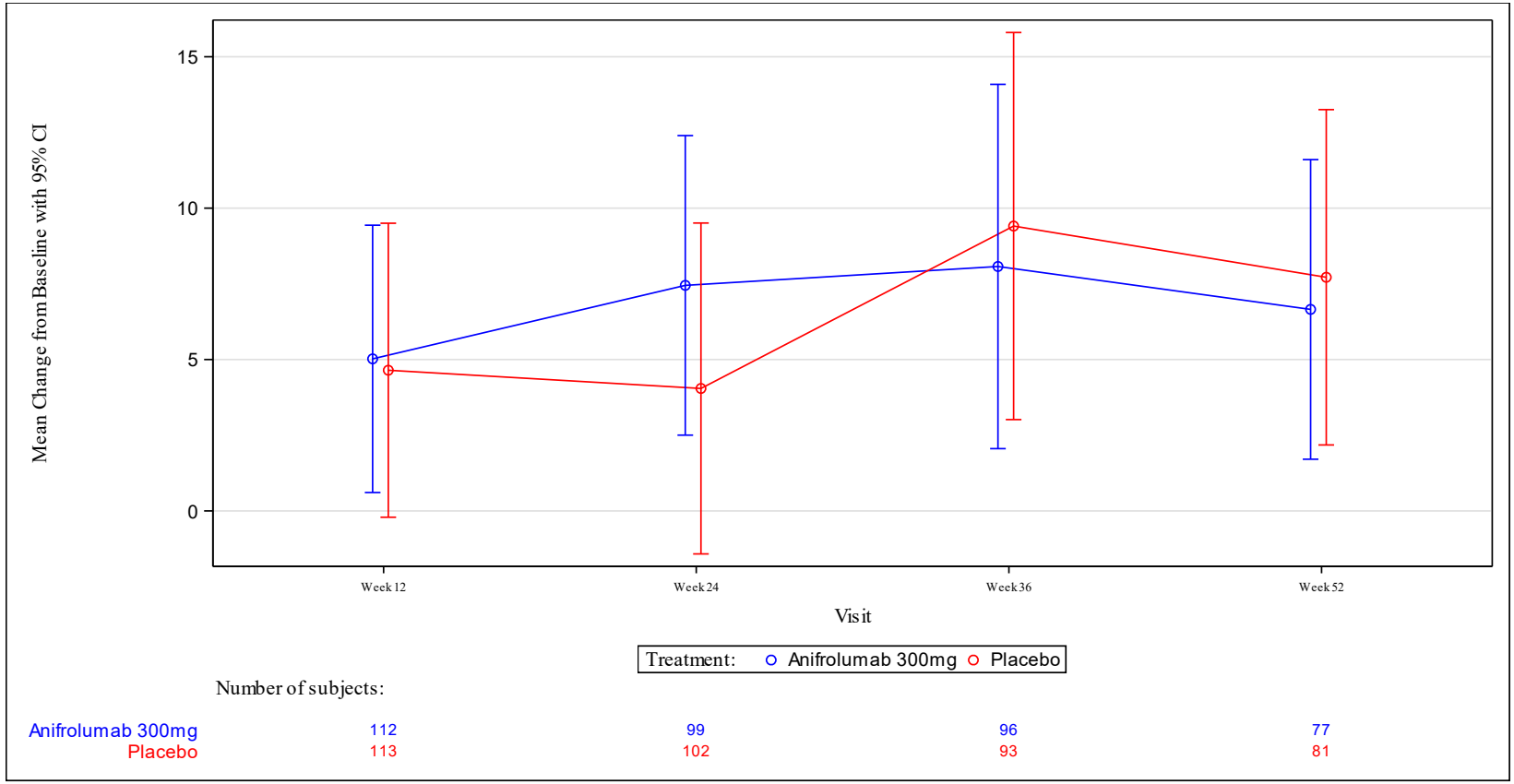
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Lupus QoL Fatigue domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Intimate Relationships domain score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=182)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	131	56.87 (33.12)	0	-	134	56.34 (31.07)	0	-
Week 12	131	64.79 (32.48)	112	5.02 (23.58)	134	59.24 (34.34)	113	4.65 (26.05)
Week 24	116	65.52 (33.57)	99	7.45 (24.80)	116	58.73 (32.61)	102	4.04 (27.82)
Week 36	120	65.42 (32.48)	96	8.07 (29.69)	103	63.35 (32.43)	93	9.41 (31.04)
Week 52	97	64.05 (32.03)	77	6.66 (21.80)	93	63.98 (31.27)	81	7.72 (25.04)

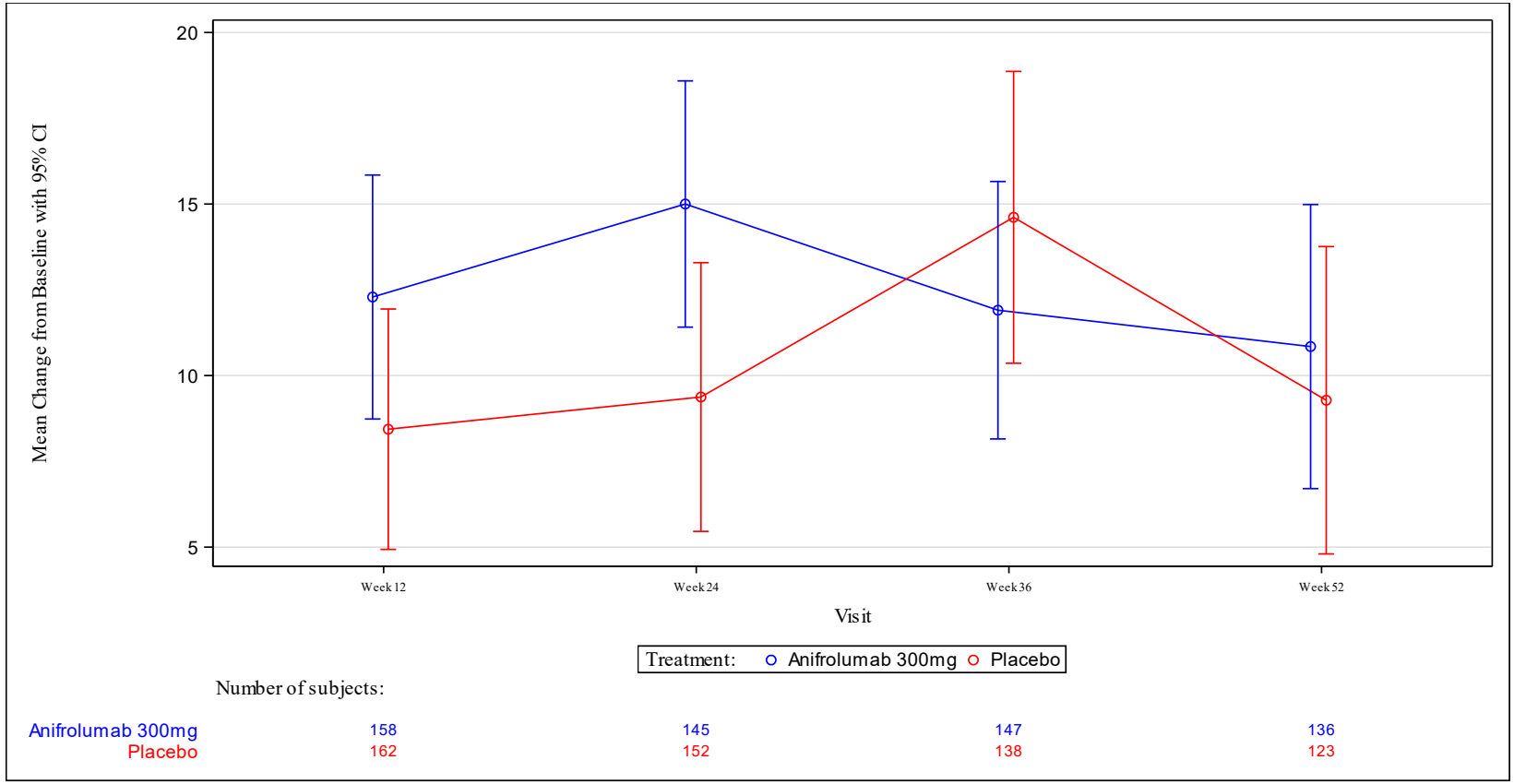
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Lupus QoL Intimate Relationships domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Pain domain score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=182)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	170	55.00 (29.07)	0	-	175	51.62 (29.76)	0	-
Week 12	168	68.50 (26.64)	158	12.29 (22.63)	166	60.89 (27.43)	162	8.44 (22.58)
Week 24	155	70.70 (24.99)	145	15.00 (21.86)	158	61.39 (28.50)	152	9.37 (24.44)
Week 36	157	67.46 (26.75)	147	11.91 (23.02)	142	66.20 (25.82)	138	14.61 (25.27)
Week 52	146	68.61 (24.78)	136	10.85 (24.41)	127	64.63 (25.21)	123	9.28 (25.10)

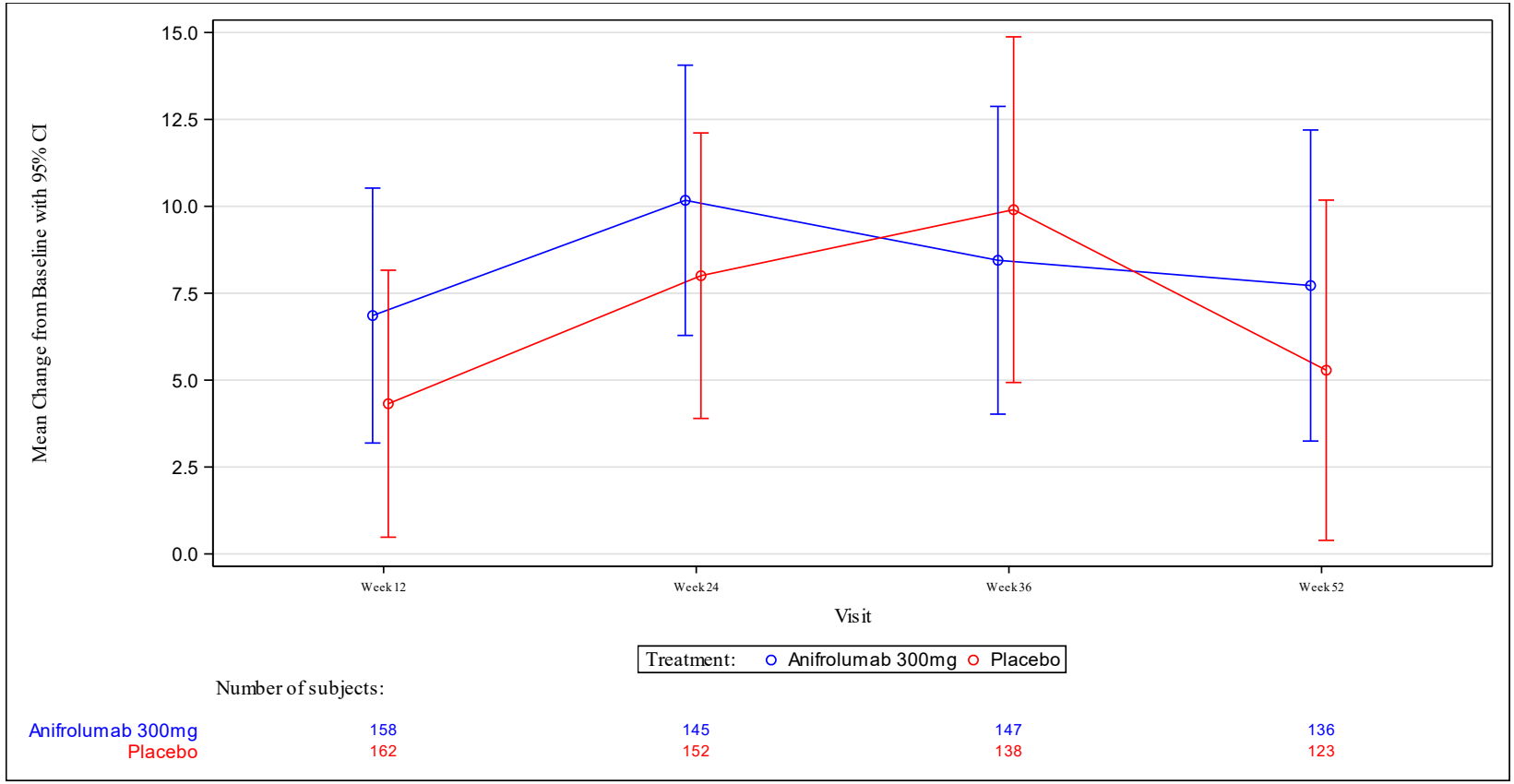
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Lupus QoL Pain domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Planning domain score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=182)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	170	60.83 (30.89)	0	-	175	58.19 (30.79)	0	-
Week 12	168	67.96 (28.77)	158	6.86 (23.33)	166	63.15 (30.46)	162	4.32 (24.75)
Week 24	155	71.45 (28.57)	145	10.17 (23.68)	158	66.19 (29.12)	152	8.00 (25.63)
Week 36	157	69.00 (28.30)	147	8.45 (27.15)	142	68.37 (27.57)	138	9.90 (29.54)
Week 52	146	69.35 (28.45)	136	7.72 (26.38)	127	67.26 (27.48)	123	5.28 (27.42)

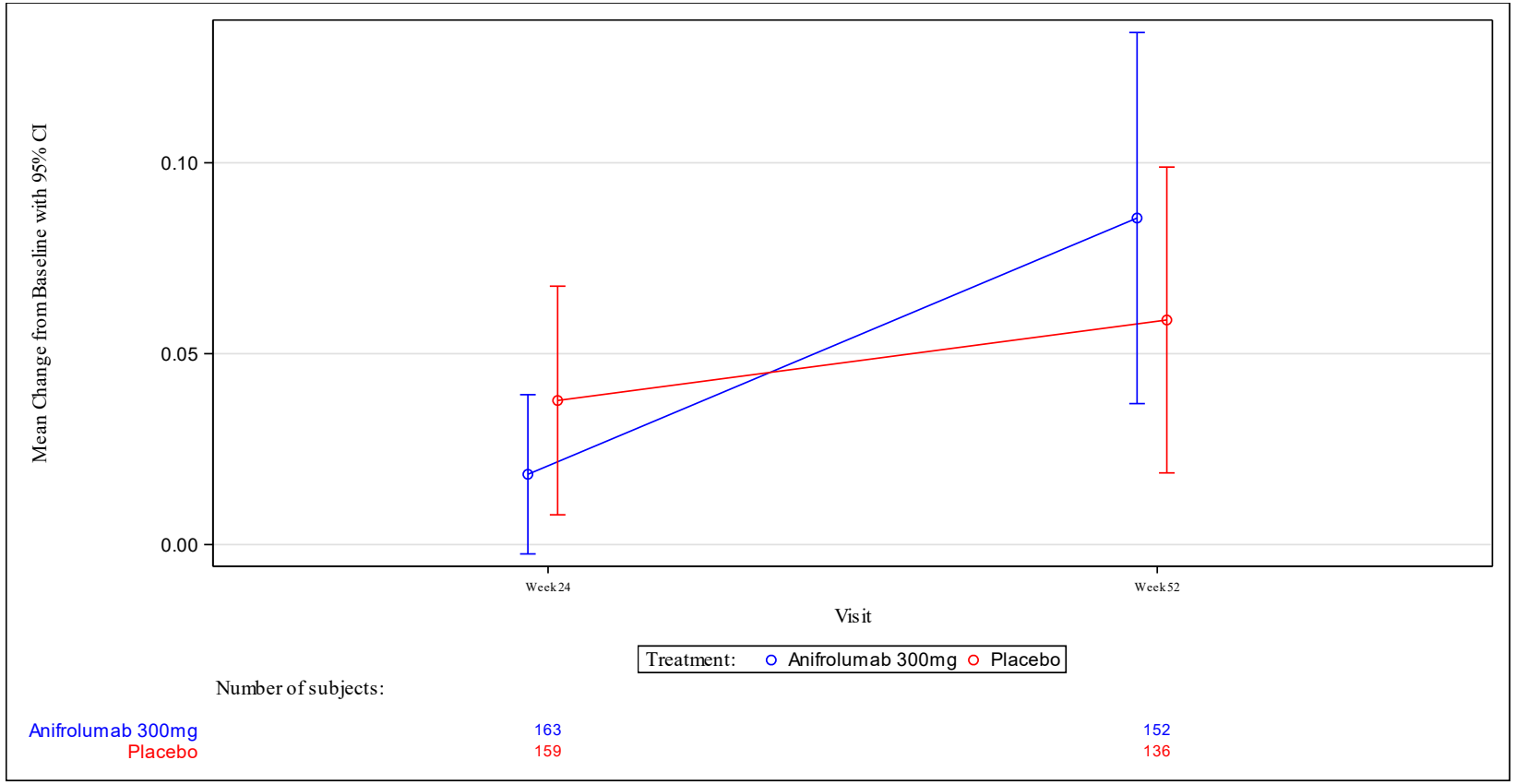
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Lupus QoL Planning domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - SDI Global Score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=182)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	180	0.50 (0.91)	0	-	182	0.47 (0.79)	0	-
Week 24	163	0.54 (0.95)	163	0.02 (0.13)	159	0.45 (0.82)	159	0.04 (0.19)
Week 52	152	0.64 (1.01)	152	0.09 (0.30)	136	0.42 (0.74)	136	0.06 (0.24)

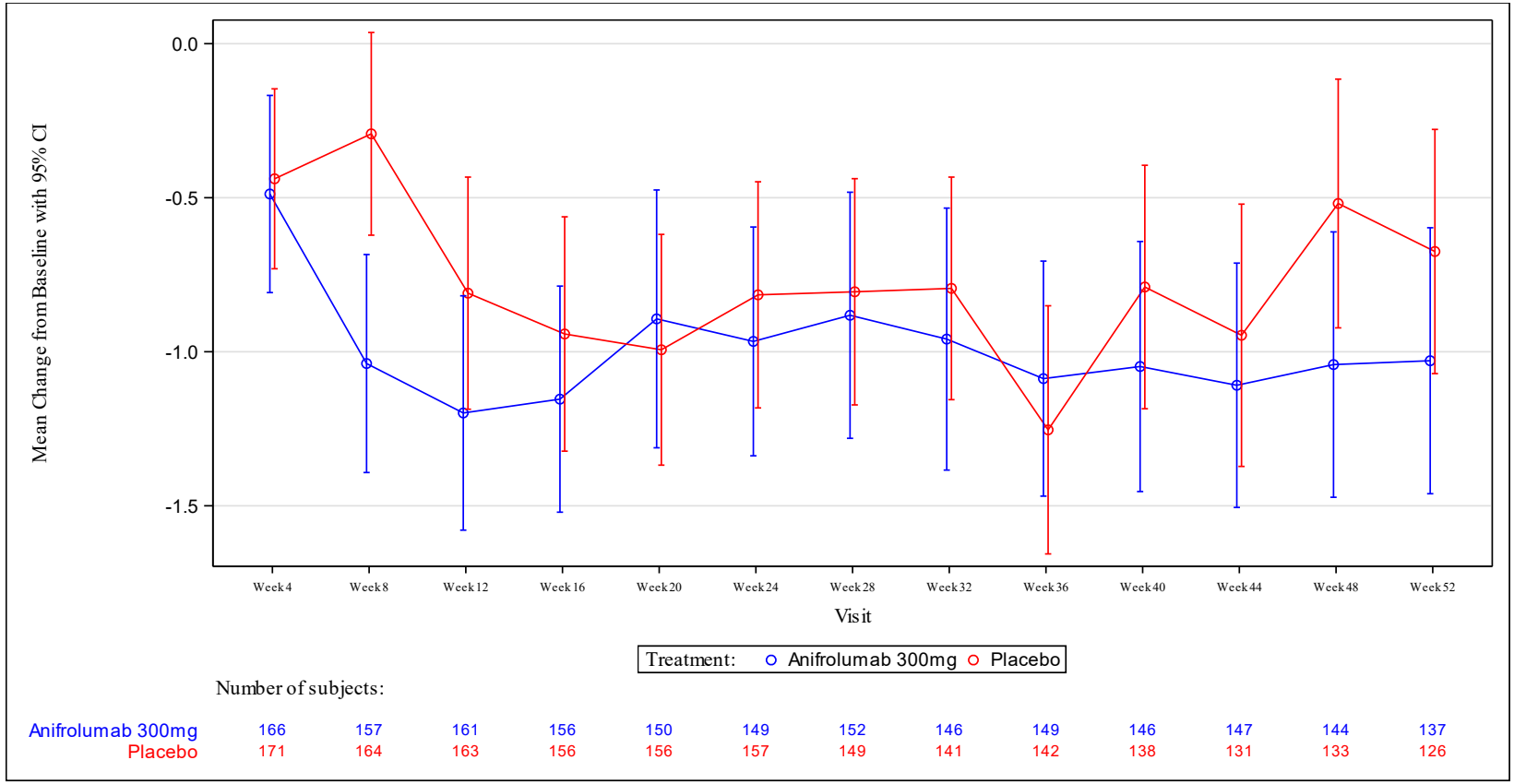
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - SDI Global Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - NRS Score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=182)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	170	5.24 (2.26)	0	-	175	5.48 (2.63)	0	-
Week 4	172	4.71 (2.40)	166	-0.49 (2.09)	175	5.03 (2.54)	171	-0.44 (1.93)
Week 8	165	4.12 (2.54)	157	-1.04 (2.24)	168	5.16 (2.72)	164	-0.29 (2.13)
Week 12	171	4.01 (2.56)	161	-1.20 (2.44)	167	4.69 (2.72)	163	-0.81 (2.44)
Week 16	166	4.04 (2.43)	156	-1.15 (2.32)	159	4.52 (2.63)	156	-0.94 (2.40)
Week 20	160	4.19 (2.54)	150	-0.89 (2.59)	162	4.39 (2.69)	156	-0.99 (2.37)
Week 24	159	4.06 (2.47)	149	-0.97 (2.29)	163	4.62 (2.70)	157	-0.82 (2.33)
Week 28	162	4.18 (2.55)	152	-0.88 (2.49)	155	4.54 (2.72)	149	-0.81 (2.27)
Week 32	154	4.12 (2.48)	146	-0.96 (2.60)	145	4.63 (2.70)	141	-0.79 (2.17)
Week 36	159	4.07 (2.60)	149	-1.09 (2.36)	146	4.18 (2.57)	142	-1.25 (2.43)
Week 40	155	3.97 (2.47)	146	-1.05 (2.48)	142	4.62 (2.86)	138	-0.79 (2.35)
Week 44	157	3.99 (2.50)	147	-1.11 (2.43)	134	4.41 (2.70)	131	-0.95 (2.46)
Week 48	153	4.11 (2.61)	144	-1.04 (2.61)	137	4.73 (2.70)	133	-0.52 (2.35)
Week 52	147	3.99 (2.57)	137	-1.03 (2.56)	130	4.54 (2.73)	126	-0.67 (2.25)

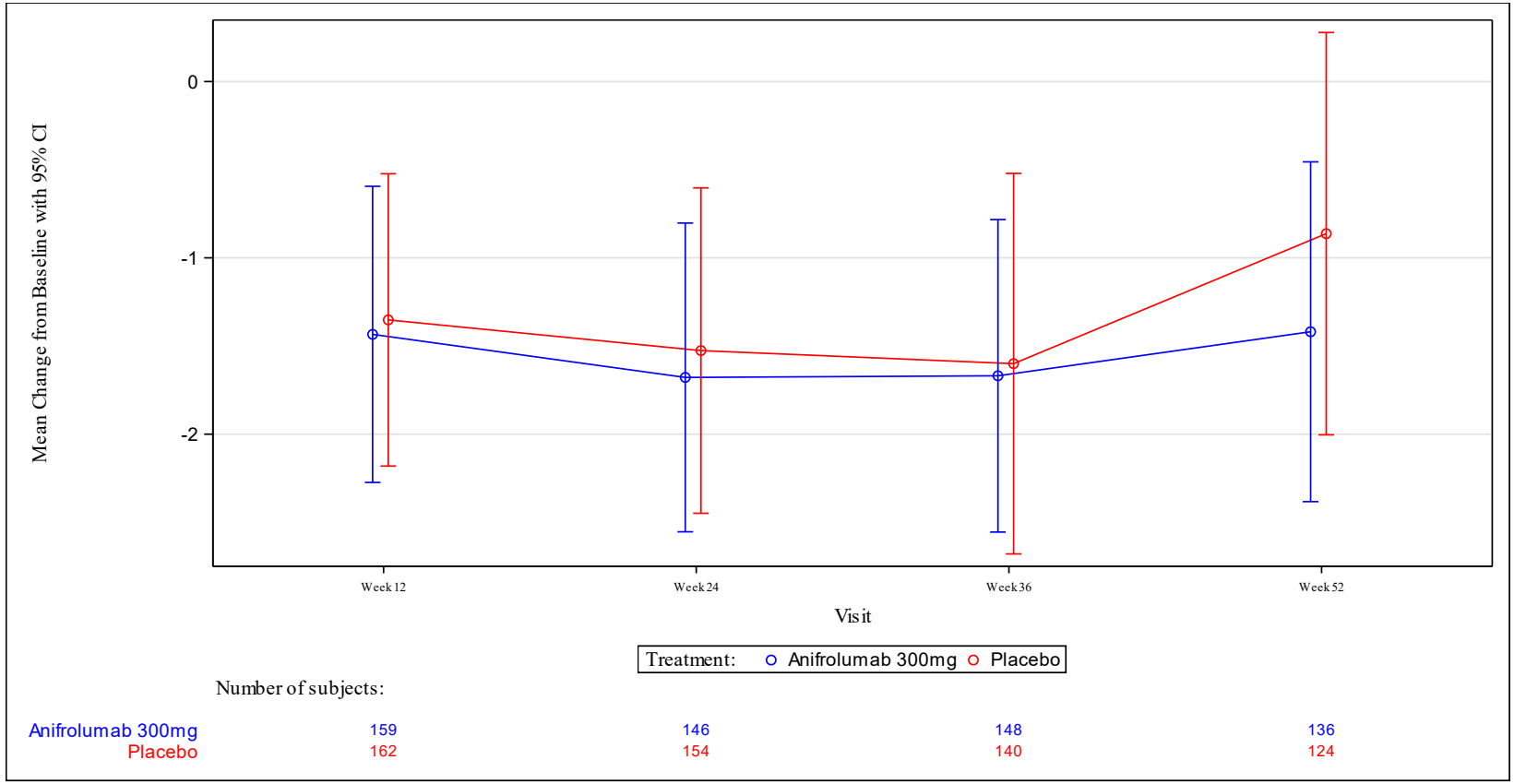
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - NRS Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - PHQ-8 Total Score
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=182)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	170	9.19 (6.30)	0	-	175	9.89 (6.17)	0	-
Week 12	169	7.49 (6.10)	159	-1.43 (5.36)	166	8.48 (5.71)	162	-1.35 (5.34)
Week 24	156	7.23 (5.77)	146	-1.68 (5.35)	160	8.17 (5.87)	154	-1.53 (5.80)
Week 36	158	7.27 (5.82)	148	-1.67 (5.46)	144	8.12 (5.58)	140	-1.60 (6.46)
Week 52	146	7.60 (5.99)	136	-1.42 (5.68)	128	8.30 (5.70)	124	-0.86 (6.42)

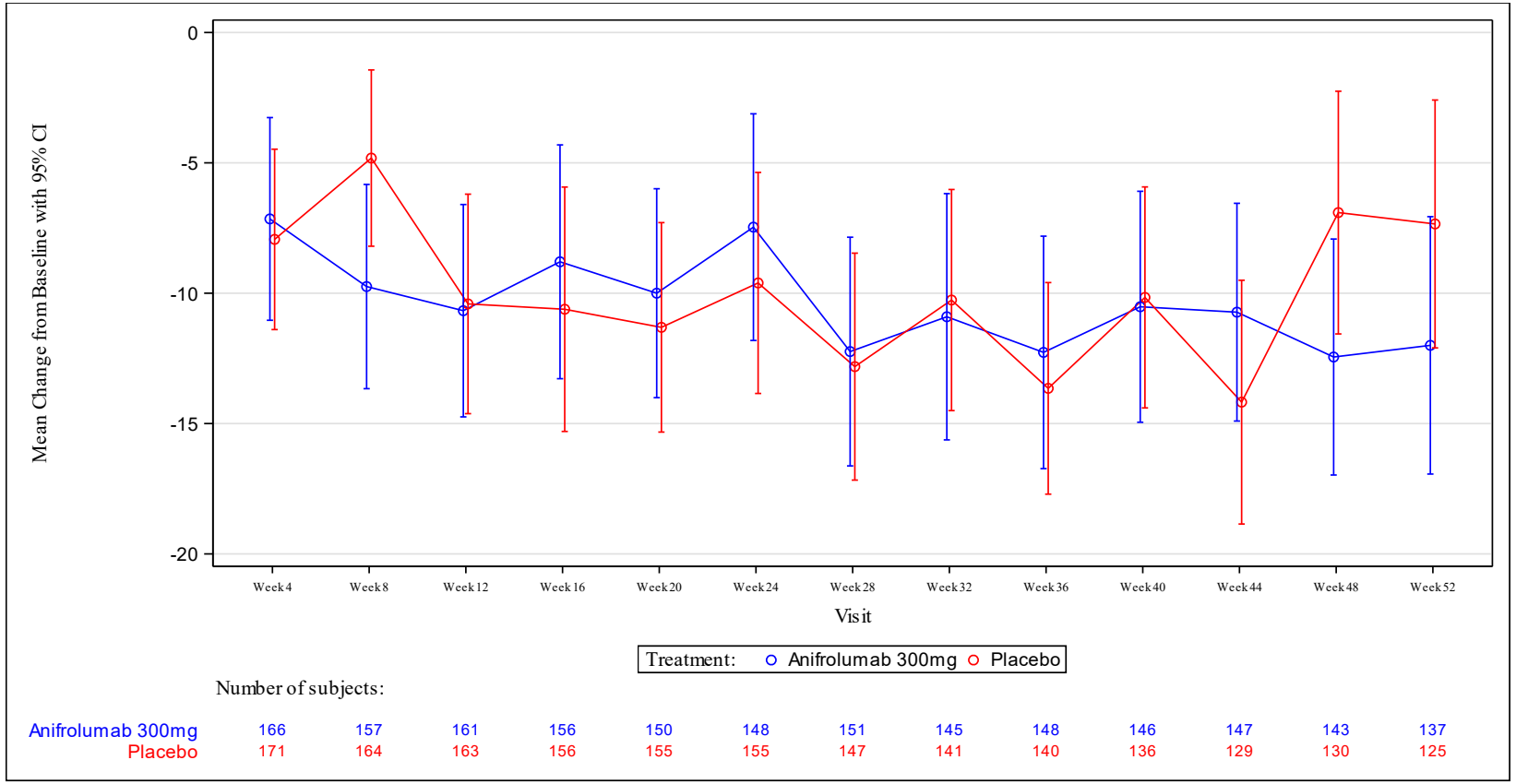
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - PHQ-8 Total Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - PtGA
Full analysis set

	Anifrolumab 300mg (N=180)				Placebo (N=182)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	170	52.76 (22.13)	0	-	175	56.57 (23.41)	0	-
Week 4	172	45.34 (22.71)	166	-7.15 (25.37)	175	48.26 (22.42)	171	-7.94 (22.92)
Week 8	165	42.95 (23.24)	157	-9.75 (24.85)	168	51.26 (23.83)	164	-4.82 (21.93)
Week 12	171	41.49 (24.61)	161	-10.67 (26.17)	167	46.78 (25.03)	163	-10.41 (27.22)
Week 16	166	43.74 (24.54)	156	-8.79 (28.35)	159	46.01 (25.13)	156	-10.62 (29.64)
Week 20	160	41.47 (23.73)	150	-10.00 (24.83)	161	44.47 (24.83)	155	-11.31 (25.32)
Week 24	158	43.30 (25.73)	148	-7.47 (26.76)	161	46.76 (25.12)	155	-9.61 (26.72)
Week 28	161	40.33 (24.08)	151	-12.24 (27.28)	152	42.87 (25.45)	147	-12.82 (26.70)
Week 32	153	41.11 (24.59)	145	-10.90 (28.78)	145	44.53 (25.77)	141	-10.26 (25.47)
Week 36	158	40.48 (24.70)	148	-12.27 (27.44)	144	41.88 (24.07)	140	-13.65 (24.29)
Week 40	155	41.24 (25.20)	146	-10.52 (27.08)	140	46.43 (25.31)	136	-10.16 (24.99)
Week 44	157	41.33 (23.80)	147	-10.73 (25.62)	132	41.76 (24.61)	129	-14.18 (26.83)
Week 48	152	40.71 (25.03)	143	-12.45 (27.38)	134	47.16 (26.35)	130	-6.91 (26.82)
Week 52	147	40.24 (26.31)	137	-12.00 (29.22)	129	46.27 (26.25)	125	-7.34 (26.85)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - PtGA
Full analysis set



Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SLEDAI-2K Total Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) N	Anifrolumab 300mg (N=180) LSMean (SE)	Placebo (N=182) N	Placebo (N=182) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-0.72 (0.18)		-0.52 (0.18)	-0.19 (0.21)	(-0.61, 0.22)	0.3596			
Week 8		-2.40 (0.27)		-1.62 (0.27)	-0.78 (0.36)	(-1.48, -0.07)	0.0317			
Week 12		-3.85 (0.30)		-2.60 (0.30)	-1.24 (0.39)	(-2.02, -0.47)	0.0017			
Week 16		-4.45 (0.31)		-3.20 (0.31)	-1.25 (0.41)	(-2.05, -0.44)	0.0027			
Week 20		-4.59 (0.29)		-3.69 (0.29)	-0.91 (0.39)	(-1.67, -0.15)	0.0193			
Week 24		-4.95 (0.31)		-3.55 (0.31)	-1.41 (0.42)	(-2.22, -0.59)	0.0008			
Week 28		-5.41 (0.31)		-3.74 (0.32)	-1.67 (0.42)	(-2.50, -0.84)	<.0001			
Week 32		-5.51 (0.31)		-3.90 (0.32)	-1.61 (0.42)	(-2.44, -0.79)	0.0001			
Week 36		-5.44 (0.33)		-4.11 (0.33)	-1.33 (0.44)	(-2.20, -0.47)	0.0027			
Week 40		-5.64 (0.33)		-4.08 (0.33)	-1.55 (0.44)	(-2.43, -0.68)	0.0005			
Week 44		-5.74 (0.32)		-4.50 (0.32)	-1.24 (0.43)	(-2.08, -0.40)	0.0040			
Week 48		-5.84 (0.31)		-4.69 (0.32)	-1.14 (0.42)	(-1.98, -0.31)	0.0073			
Week 52		-6.04 (0.31)		-4.88 (0.32)	-1.16 (0.42)	(-2.00, -0.32)	0.0067			
OVERALL	180	-4.66 (0.24)	180	-3.47 (0.24)	-1.19 (0.31)	(-1.81, -0.57)	0.0002	-0.36 (0.11)	(-0.57, -0.15)	0.0006

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SLEDAI-2K Total Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=182) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.2166
< 10 points	54	-3.10 (0.31)	52	-2.44 (0.31)	-0.66 (0.42)	(-1.50, 0.19)	0.1255	-0.29 (0.20)	(-0.67, 0.09)	0.1388	
>= 10 points	126	-5.25 (0.32)	128	-3.87 (0.32)	-1.38 (0.40)	(-2.17, -0.58)	0.0007	-0.39 (0.13)	(-0.63, -0.14)	0.0023	
OCS dose at baseline											0.1475
<10 mg/day	93	-4.50 (0.31)	98	-3.72 (0.30)	-0.78 (0.41)	(-1.59, 0.03)	0.0583	-0.26 (0.15)	(-0.54, 0.03)	0.0740	
>=10 mg/day	87	-4.91 (0.40)	82	-3.22 (0.41)	-1.70 (0.48)	(-2.65, -0.74)	0.0006	-0.46 (0.16)	(-0.76, -0.15)	0.0035	
Result of type I IFN gene signature test											0.0116
LOW	30	-3.41 (0.44)	31	-3.71 (0.44)	0.30 (0.62)	(-0.94, 1.54)	0.6248	0.12 (0.26)	(-0.38, 0.63)	0.6310	
HIGH	150	-4.92 (0.26)	149	-3.42 (0.26)	-1.49 (0.35)	(-2.19, -0.80)	<.0001	-0.47 (0.12)	(-0.70, -0.24)	<.0001	
Age (years)											NE
<= 65	175	-4.69 (0.25)	179	-3.45 (0.25)	-1.24 (0.32)	(-1.87, -0.61)	0.0001	-0.38 (0.11)	(-0.59, -0.17)	0.0005	
> 65	5	NE	1	NE	NE	NE		NE	NE		
Sex											0.5927
male	12	-4.79 (0.71)	12	-3.07 (0.77)	-1.72 (0.88)	(-3.57, 0.13)	0.0663	-0.64 (0.42)	(-1.47, 0.18)	0.1256	
female	168	-4.64 (0.26)	168	-3.43 (0.26)	-1.21 (0.33)	(-1.87, -0.56)	0.0003	-0.36 (0.11)	(-0.58, -0.15)	0.0009	
Race											NE
White	110	-4.28 (0.30)	106	-3.62 (0.31)	-0.66 (0.40)	(-1.45, 0.14)	0.1069	-0.20 (0.14)	(-0.47, 0.06)	0.1340	
Black or African American	17	NE	25	NE	NE	NE		NE	NE		
Asian	30	-5.32 (0.75)	30	-3.39 (0.73)	-1.93 (0.75)	(-3.43, -0.43)	0.0128	-0.47 (0.26)	(-0.98, 0.04)	0.0727	
American Indian or Alaska Native	4	NE	1	NE	NE	NE		NE	NE		
Other	11	NE	10	NE	NE	NE		NE	NE		
Ethnicity											0.7834
Hispanic/Latino	54	-5.10 (0.45)	54	-3.75 (0.45)	-1.35 (0.60)	(-2.53, -0.16)	0.0270	-0.41 (0.19)	(-0.79, -0.02)	0.0371	
Non-hispanic/Latino	118	-4.44 (0.29)	118	-3.29 (0.30)	-1.15 (0.37)	(-1.88, -0.42)	0.0022	-0.36 (0.13)	(-0.62, -0.10)	0.0063	
Geographic region											0.0361
EU	51	-5.06 (0.52)	45	-5.02 (0.56)	-0.04 (0.62)	(-1.27, 1.19)	0.9505	-0.01 (0.20)	(-0.41, 0.39)	0.9600	
non-EU	129	-4.56 (0.28)	135	-3.03 (0.27)	-1.54 (0.36)	(-2.25, -0.83)	<.0001	-0.48 (0.12)	(-0.73, -0.24)	0.0001	
Onset of disease											NE
Paediatric	14	NE	12	NE	NE	NE		NE	NE		
Adult	166	-4.72 (0.24)	168	-3.47 (0.24)	-1.25 (0.32)	(-1.88, -0.63)	0.0001	-0.40 (0.11)	(-0.61, -0.18)	0.0003	
ADA result											NE
Negative	172	-4.63 (0.24)	160	-3.58 (0.25)	-1.05 (0.32)	(-1.67, -0.42)	0.0011	-0.33 (0.11)	(-0.55, -0.11)	0.0030	
Positive (At any time)	8	NE	20	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.6047
< 30	125	-5.05 (0.31)	132	-3.73 (0.31)	-1.31 (0.39)	(-2.08, -0.54)	0.0009	-0.37 (0.13)	(-0.62, -0.12)	0.0033	
>= 30	55	-3.75 (0.38)	48	-2.76 (0.39)	-0.98 (0.51)	(-1.99, 0.03)	0.0574	-0.35 (0.20)	(-0.74, 0.04)	0.0756	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.1195
All negative/normal	58	-3.96 (0.37)	80	-3.36 (0.32)	-0.60 (0.47)	(-1.54, 0.33)	0.2030	-0.21 (0.17)	(-0.55, 0.13)	0.2178	
At least one positive/abnormal	122	-5.06 (0.33)	100	-3.49 (0.37)	-1.57 (0.40)	(-2.37, -0.77)	0.0001	-0.42 (0.14)	(-0.69, -0.16)	0.0019	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score CNS
Full analysis set

Visit	Anifrolumab 300mg (N=180) N	Anifrolumab 300mg (N=180) LSMean (SE)	Placebo (N=182) N	Placebo (N=182) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		NE		NE	NE	NE				
Week 8		NE		NE	NE	NE				
Week 12		NE		NE	NE	NE				
Week 16		NE		NE	NE	NE				
Week 20		NE		NE	NE	NE				
Week 24		NE		NE	NE	NE				
Week 28		NE		NE	NE	NE				
Week 32		NE		NE	NE	NE				
Week 36		NE		NE	NE	NE				
Week 40		NE		NE	NE	NE				
Week 44		NE		NE	NE	NE				
Week 48		NE		NE	NE	NE				
Week 52		NE		NE	NE	NE				
OVERALL	180	NE	180	NE	NE	NE		NE	NE	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score CNS - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=180)		Placebo (N=182)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											NE
< 10 points	54	NE	52	NE	NE	NE		NE	NE		
>= 10 points	126	NE	128	NE	NE	NE		NE	NE		
OCS dose at baseline											NE
<10 mg/day	93	NE	98	NE	NE	NE		NE	NE		
>=10 mg/day	87	NE	82	NE	NE	NE		NE	NE		
Result of type I IFN gene signature test											NE
LOW	30	NE	31	NE	NE	NE		NE	NE		
HIGH	150	NE	149	NE	NE	NE		NE	NE		
Age (years)											NE
<= 65	175	NE	179	NE	NE	NE		NE	NE		
> 65	5	NE	1	NE	NE	NE		NE	NE		
Sex											NE
male	12	NE	12	NE	NE	NE		NE	NE		
female	168	NE	168	NE	NE	NE		NE	NE		
Race											NE
White	110	NE	106	NE	NE	NE		NE	NE		
Black or African American	17	NE	25	NE	NE	NE		NE	NE		
Asian	30	NE	30	NE	NE	NE		NE	NE		
American Indian or Alaska Native	4	NE	1	NE	NE	NE		NE	NE		
Other	11	NE	10	NE	NE	NE		NE	NE		
Ethnicity											NE
Hispanic/Latino	54	NE	54	NE	NE	NE		NE	NE		
Non-hispanic/Latino	118	NE	118	NE	NE	NE		NE	NE		
Geographic region											NE
EU	51	NE	45	NE	NE	NE		NE	NE		
non-EU	129	NE	135	NE	NE	NE		NE	NE		
Onset of disease											NE
Paediatric	14	NE	12	NE	NE	NE		NE	NE		
Adult	166	NE	168	NE	NE	NE		NE	NE		
ADA result											NE
Negative	172	NE	160	NE	NE	NE		NE	NE		
Positive (At any time)	8	NE	20	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											NE
< 30	125	NE	132	NE	NE	NE		NE	NE		
>= 30	55	NE	48	NE	NE	NE		NE	NE		
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											NE
All negative/normal	58	NE	80	NE	NE	NE		NE	NE		
At least one positive/abnormal	122	NE	100	NE	NE	NE		NE	NE		

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score CVS and Respiratory
Full analysis set

Visit	Anifrolumab 300mg (N=180) N	Anifrolumab 300mg (N=180) LSMean (SE)	Placebo (N=182) N	Placebo (N=182) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		NE		NE	NE	NE				
Week 8		NE		NE	NE	NE				
Week 12		NE		NE	NE	NE				
Week 16		NE		NE	NE	NE				
Week 20		NE		NE	NE	NE				
Week 24		NE		NE	NE	NE				
Week 28		NE		NE	NE	NE				
Week 32		NE		NE	NE	NE				
Week 36		NE		NE	NE	NE				
Week 40		NE		NE	NE	NE				
Week 44		NE		NE	NE	NE				
Week 48		NE		NE	NE	NE				
Week 52		NE		NE	NE	NE				
OVERALL	180	NE	180	NE	NE	NE		NE	NE	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score CVS and Respiratory - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=180)		Placebo (N=182)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											NE
< 10 points	54	NE	52	NE	NE	NE		NE	NE		
>= 10 points	126	NE	128	NE	NE	NE		NE	NE		
OCS dose at baseline											NE
<10 mg/day	93	NE	98	NE	NE	NE		NE	NE		
>=10 mg/day	87	NE	82	NE	NE	NE		NE	NE		
Result of type I IFN gene signature test											NE
LOW	30	NE	31	NE	NE	NE		NE	NE		
HIGH	150	NE	149	NE	NE	NE		NE	NE		
Age (years)											NE
<= 65	175	NE	179	NE	NE	NE		NE	NE		
> 65	5	NE	1	NE	NE	NE		NE	NE		
Sex											NE
male	12	NE	12	NE	NE	NE		NE	NE		
female	168	NE	168	NE	NE	NE		NE	NE		
Race											NE
White	110	NE	106	NE	NE	NE		NE	NE		
Black or African American	17	NE	25	NE	NE	NE		NE	NE		
Asian	30	NE	30	NE	NE	NE		NE	NE		
American Indian or Alaska Native	4	NE	1	NE	NE	NE		NE	NE		
Other	11	NE	10	NE	NE	NE		NE	NE		
Ethnicity											NE
Hispanic/Latino	54	NE	54	NE	NE	NE		NE	NE		
Non-hispanic/Latino	118	NE	118	NE	NE	NE		NE	NE		
Geographic region											NE
EU	51	NE	45	NE	NE	NE		NE	NE		
non-EU	129	NE	135	NE	NE	NE		NE	NE		
Onset of disease											NE
Paediatric	14	NE	12	NE	NE	NE		NE	NE		
Adult	166	NE	168	NE	NE	NE		NE	NE		
ADA result											NE
Negative	172	NE	160	NE	NE	NE		NE	NE		
Positive (At any time)	8	NE	20	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											NE
< 30	125	NE	132	NE	NE	NE		NE	NE		
>= 30	55	NE	48	NE	NE	NE		NE	NE		
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											NE
All negative/normal	58	NE	80	NE	NE	NE		NE	NE		
At least one positive/abnormal	122	NE	100	NE	NE	NE		NE	NE		

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score Hematological
Full analysis set

Visit	Anifrolumab 300mg (N=180) N	Anifrolumab 300mg (N=180) LSMean (SE)	Placebo (N=182) N	Placebo (N=182) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-0.11 (0.02)		-0.05 (0.02)	-0.06 (0.03)	(-0.12, -0.00)	0.0380			
Week 8		-0.13 (0.02)		-0.05 (0.02)	-0.07 (0.03)	(-0.12, -0.02)	0.0087			
Week 12		-0.13 (0.02)		-0.07 (0.02)	-0.07 (0.03)	(-0.12, -0.01)	0.0189			
Week 16		-0.14 (0.02)		-0.07 (0.02)	-0.07 (0.02)	(-0.12, -0.02)	0.0034			
Week 20		-0.15 (0.02)		-0.05 (0.02)	-0.10 (0.03)	(-0.15, -0.04)	0.0010			
Week 24		-0.15 (0.02)		-0.03 (0.02)	-0.12 (0.03)	(-0.18, -0.07)	<.0001			
Week 28		-0.13 (0.02)		-0.08 (0.02)	-0.05 (0.03)	(-0.11, 0.00)	0.0522			
Week 32		-0.14 (0.02)		-0.06 (0.02)	-0.08 (0.03)	(-0.14, -0.03)	0.0024			
Week 36		-0.15 (0.02)		-0.06 (0.02)	-0.09 (0.03)	(-0.14, -0.04)	0.0007			
Week 40		-0.15 (0.02)		-0.09 (0.02)	-0.06 (0.03)	(-0.11, -0.01)	0.0229			
Week 44		-0.13 (0.02)		-0.05 (0.02)	-0.07 (0.03)	(-0.14, -0.01)	0.0229			
Week 48		-0.15 (0.02)		-0.07 (0.02)	-0.07 (0.03)	(-0.12, -0.02)	0.0082			
Week 52		-0.12 (0.02)		-0.08 (0.02)	-0.04 (0.03)	(-0.10, 0.02)	0.2332			
OVERALL	180	-0.14 (0.02)	180	-0.06 (0.02)	-0.07 (0.02)	(-0.11, -0.04)	<.0001	-0.35 (0.11)	(-0.56, -0.15)	0.0009

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score Hematological - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=182) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.7378
< 10 points	54	-0.14 (0.02)	52	-0.08 (0.02)	-0.06 (0.03)	(-0.12, -0.00)	0.0496	-0.35 (0.20)	(-0.74, 0.03)	0.0711	
>= 10 points	126	-0.14 (0.02)	128	-0.06 (0.02)	-0.07 (0.02)	(-0.12, -0.03)	0.0015	-0.33 (0.13)	(-0.57, -0.08)	0.0098	
OCS dose at baseline											0.2872
<10 mg/day	93	-0.11 (0.02)	98	-0.03 (0.02)	-0.08 (0.03)	(-0.14, -0.03)	0.0021	-0.41 (0.15)	(-0.70, -0.13)	0.0046	
>=10 mg/day	87	-0.15 (0.02)	82	-0.10 (0.02)	-0.05 (0.02)	(-0.09, -0.00)	0.0490	-0.24 (0.15)	(-0.55, 0.06)	0.1155	
Result of type I IFN gene signature test											NE
LOW	30	NE	31	NE	NE	NE		NE	NE		
HIGH	150	-0.15 (0.02)	149	-0.06 (0.02)	-0.08 (0.02)	(-0.13, -0.04)	0.0001	-0.43 (0.12)	(-0.66, -0.20)	0.0003	
Age (years)											NE
<= 65	175	-0.14 (0.02)	179	-0.07 (0.02)	-0.07 (0.02)	(-0.11, -0.04)	<.0001	-0.35 (0.11)	(-0.56, -0.14)	0.0010	
> 65	5	NE	1	NE	NE	NE		NE	NE		
Sex											NE
male	12	NE	12	NE	NE	NE		NE	NE		
female	168	-0.14 (0.02)	168	-0.07 (0.02)	-0.07 (0.02)	(-0.11, -0.03)	0.0002	-0.35 (0.11)	(-0.56, -0.13)	0.0016	
Race											NE
White	110	-0.08 (0.01)	106	-0.05 (0.02)	-0.03 (0.02)	(-0.06, 0.01)	0.1068	-0.19 (0.14)	(-0.46, 0.08)	0.1651	
Black or African American	17	NE	25	NE	NE	NE		NE	NE		
Asian	30	NE	30	NE	NE	NE		NE	NE		
American Indian or Alaska Native	4	NE	1	NE	NE	NE		NE	NE		
Other	11	NE	10	NE	NE	NE		NE	NE		
Ethnicity											NE
Hispanic/Latino	54	NE	54	NE	NE	NE		NE	NE		
Non-hispanic/Latino	118	-0.17 (0.02)	118	-0.07 (0.02)	-0.09 (0.02)	(-0.14, -0.05)	<.0001	-0.43 (0.13)	(-0.69, -0.17)	0.0011	
Geographic region											NE
EU	51	NE	45	NE	NE	NE		NE	NE		
non-EU	129	-0.13 (0.02)	135	-0.05 (0.02)	-0.09 (0.02)	(-0.13, -0.04)	0.0001	-0.41 (0.12)	(-0.65, -0.16)	0.0011	
Onset of disease											NE
Paediatric	14	NE	12	NE	NE	NE		NE	NE		
Adult	166	-0.12 (0.02)	168	-0.05 (0.02)	-0.07 (0.02)	(-0.11, -0.03)	0.0002	-0.35 (0.11)	(-0.56, -0.13)	0.0016	
ADA result											NE
Negative	172	-0.14 (0.02)	160	-0.06 (0.02)	-0.08 (0.02)	(-0.12, -0.04)	<.0001	-0.39 (0.11)	(-0.61, -0.18)	0.0004	
Positive (At any time)	8	NE	20	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											NE
< 30	125	-0.17 (0.02)	132	-0.08 (0.02)	-0.09 (0.02)	(-0.13, -0.04)	0.0001	-0.37 (0.13)	(-0.61, -0.12)	0.0036	
>= 30	55	NE	48	NE	NE	NE		NE	NE		
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.0072
All negative/normal	58	-0.06 (0.02)	80	-0.04 (0.02)	-0.02 (0.02)	(-0.06, 0.03)	0.4693	-0.12 (0.17)	(-0.46, 0.22)	0.4924	
At least one positive/abnormal	122	-0.20 (0.02)	100	-0.09 (0.03)	-0.11 (0.02)	(-0.16, -0.06)	<.0001	-0.40 (0.14)	(-0.67, -0.13)	0.0033	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score Immunology
Full analysis set

	Anifrolumab 300mg (N=180)		Placebo (N=182)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-0.15 (0.07)		-0.07 (0.07)	-0.08 (0.08)	(-0.24, 0.08)	0.3202			
Week 8		-0.19 (0.08)		-0.02 (0.08)	-0.17 (0.10)	(-0.36, 0.02)	0.0743			
Week 12		-0.23 (0.07)		-0.02 (0.07)	-0.21 (0.09)	(-0.39, -0.03)	0.0199			
Week 16		-0.23 (0.07)		0.03 (0.07)	-0.27 (0.09)	(-0.45, -0.08)	0.0043			
Week 20		-0.16 (0.07)		0.06 (0.08)	-0.22 (0.09)	(-0.41, -0.03)	0.0208			
Week 24		-0.26 (0.08)		0.04 (0.08)	-0.30 (0.10)	(-0.48, -0.11)	0.0021			
Week 28		-0.24 (0.07)		0.13 (0.07)	-0.37 (0.09)	(-0.55, -0.19)	<.0001			
Week 32		-0.28 (0.07)		0.08 (0.07)	-0.36 (0.09)	(-0.53, -0.19)	<.0001			
Week 36		-0.20 (0.08)		-0.01 (0.08)	-0.19 (0.10)	(-0.39, 0.00)	0.0511			
Week 40		-0.23 (0.08)		0.14 (0.08)	-0.37 (0.10)	(-0.57, -0.17)	0.0004			
Week 44		-0.16 (0.08)		0.10 (0.08)	-0.26 (0.10)	(-0.46, -0.07)	0.0079			
Week 48		-0.20 (0.08)		0.04 (0.08)	-0.24 (0.11)	(-0.45, -0.03)	0.0264			
Week 52		-0.30 (0.08)		0.03 (0.09)	-0.33 (0.11)	(-0.55, -0.12)	0.0027			
OVERALL	180	-0.22 (0.06)	182	0.04 (0.06)	-0.26 (0.07)	(-0.40, -0.12)	0.0002	-0.32 (0.11)	(-0.53, -0.11)	0.0023

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score Immunology - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=182) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.4020
< 10 points	54	-0.21 (0.09)	52	0.13 (0.10)	-0.35 (0.12)	(-0.59, -0.10)	0.0059	-0.50 (0.20)	(-0.89, -0.11)	0.0112	
>= 10 points	126	-0.16 (0.08)	130	0.06 (0.08)	-0.22 (0.09)	(-0.39, -0.05)	0.0104	-0.26 (0.13)	(-0.50, -0.01)	0.0393	
OCS dose at baseline											0.6785
<10 mg/day	93	-0.17 (0.08)	99	0.06 (0.08)	-0.23 (0.09)	(-0.42, -0.05)	0.0139	-0.32 (0.15)	(-0.60, -0.03)	0.0288	
>=10 mg/day	87	-0.29 (0.10)	83	-0.00 (0.10)	-0.29 (0.11)	(-0.50, -0.08)	0.0061	-0.31 (0.15)	(-0.61, -0.01)	0.0444	
Result of type I IFN gene signature test											0.1235
LOW	30	-0.06 (0.08)	31	0.04 (0.08)	-0.10 (0.11)	(-0.32, 0.13)	0.3897	-0.21 (0.26)	(-0.72, 0.29)	0.4071	
HIGH	150	-0.25 (0.06)	151	0.06 (0.06)	-0.31 (0.08)	(-0.46, -0.15)	0.0002	-0.41 (0.12)	(-0.64, -0.18)	0.0004	
Age (years)											NE
<= 65	175	-0.21 (0.06)	181	0.04 (0.06)	-0.25 (0.07)	(-0.39, -0.11)	0.0004	-0.32 (0.11)	(-0.53, -0.11)	0.0031	
> 65	5	NE	1	NE	NE	NE		NE	NE		
Sex											NE
male	12	NE	12	NE	NE	NE		NE	NE		
female	168	-0.21 (0.06)	170	0.06 (0.06)	-0.28 (0.07)	(-0.42, -0.13)	0.0002	-0.34 (0.11)	(-0.56, -0.13)	0.0018	
Race											NE
White	110	-0.29 (0.07)	107	0.01 (0.08)	-0.30 (0.09)	(-0.48, -0.13)	0.0009	-0.38 (0.14)	(-0.65, -0.12)	0.0050	
Black or African American	17	-0.07 (0.18)	25	-0.02 (0.18)	-0.04 (0.20)	(-0.45, 0.36)	0.8338	-0.05 (0.31)	(-0.67, 0.57)	0.8728	
Asian	30	-0.23 (0.22)	30	-0.02 (0.22)	-0.21 (0.21)	(-0.64, 0.22)	0.3286	-0.17 (0.26)	(-0.68, 0.34)	0.5112	
American Indian or Alaska Native	4	NE	1	NE	NE	NE		NE	NE		
Other	11	-0.07 (0.21)	11	0.26 (0.22)	-0.33 (0.27)	(-0.90, 0.24)	0.2385	-0.44 (0.43)	(-1.29, 0.40)	0.3054	
Ethnicity											0.5022
Hispanic/Latino	54	-0.24 (0.10)	54	-0.05 (0.09)	-0.19 (0.11)	(-0.42, 0.04)	0.0987	-0.27 (0.19)	(-0.65, 0.11)	0.1656	
Non-hispanic/Latino	118	-0.23 (0.08)	120	0.06 (0.08)	-0.29 (0.09)	(-0.47, -0.11)	0.0020	-0.34 (0.13)	(-0.59, -0.08)	0.0102	
Geographic region											0.7382
EU	51	-0.27 (0.14)	46	-0.05 (0.15)	-0.22 (0.15)	(-0.51, 0.07)	0.1328	-0.22 (0.20)	(-0.62, 0.18)	0.2799	
non-EU	129	-0.22 (0.07)	136	0.06 (0.07)	-0.28 (0.08)	(-0.44, -0.12)	0.0008	-0.35 (0.12)	(-0.60, -0.11)	0.0043	
Onset of disease											NE
Paediatric	14	NE	12	NE	NE	NE		NE	NE		
Adult	166	-0.20 (0.06)	170	0.05 (0.06)	-0.25 (0.07)	(-0.38, -0.11)	0.0005	-0.32 (0.11)	(-0.54, -0.11)	0.0034	
ADA result											NE
Negative	172	-0.18 (0.06)	162	0.05 (0.06)	-0.23 (0.07)	(-0.37, -0.09)	0.0011	-0.30 (0.11)	(-0.52, -0.09)	0.0062	
Positive (At any time)	8	NE	20	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.8072
< 30	125	-0.20 (0.08)	134	0.07 (0.08)	-0.27 (0.09)	(-0.44, -0.10)	0.0018	-0.30 (0.13)	(-0.54, -0.05)	0.0166	
>= 30	55	-0.23 (0.08)	48	0.01 (0.09)	-0.24 (0.11)	(-0.46, -0.01)	0.0375	-0.38 (0.20)	(-0.78, 0.01)	0.0539	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.4613
All negative/normal	58	0.03 (0.08)	81	0.26 (0.07)	-0.22 (0.09)	(-0.41, -0.04)	0.0181	-0.38 (0.17)	(-0.72, -0.04)	0.0272	
At least one positive/abnormal	122	-0.33 (0.10)	101	-0.01 (0.10)	-0.32 (0.10)	(-0.51, -0.13)	0.0010	-0.31 (0.14)	(-0.57, -0.04)	0.0231	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score Mucocutaneous
Full analysis set

Visit	Anifrolumab 300mg (N=180) N	Anifrolumab 300mg (N=180) LSMean (SE)	Placebo (N=182) N	Placebo (N=182) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-0.11 (0.06)		-0.20 (0.06)	0.09 (0.08)	(-0.06, 0.24)	0.2446			
Week 8		-0.54 (0.10)		-0.48 (0.10)	-0.07 (0.13)	(-0.32, 0.18)	0.6079			
Week 12		-0.99 (0.12)		-0.74 (0.12)	-0.25 (0.16)	(-0.57, 0.07)	0.1276			
Week 16		-1.40 (0.13)		-0.94 (0.13)	-0.47 (0.17)	(-0.81, -0.12)	0.0076			
Week 20		-1.52 (0.13)		-1.06 (0.13)	-0.46 (0.18)	(-0.81, -0.11)	0.0094			
Week 24		-1.63 (0.14)		-1.21 (0.14)	-0.42 (0.19)	(-0.80, -0.05)	0.0250			
Week 28		-1.88 (0.14)		-1.21 (0.14)	-0.67 (0.19)	(-1.04, -0.30)	0.0004			
Week 32		-1.96 (0.13)		-1.36 (0.13)	-0.60 (0.18)	(-0.96, -0.24)	0.0011			
Week 36		-1.99 (0.14)		-1.46 (0.14)	-0.53 (0.20)	(-0.92, -0.14)	0.0075			
Week 40		-2.06 (0.15)		-1.50 (0.15)	-0.56 (0.20)	(-0.96, -0.16)	0.0061			
Week 44		-2.20 (0.15)		-1.62 (0.15)	-0.57 (0.21)	(-0.98, -0.17)	0.0054			
Week 48		-2.12 (0.15)		-1.74 (0.15)	-0.38 (0.20)	(-0.78, 0.02)	0.0656			
Week 52		-2.22 (0.14)		-1.83 (0.15)	-0.40 (0.20)	(-0.79, -0.00)	0.0499			
OVERALL	180	-1.59 (0.11)	180	-1.18 (0.11)	-0.41 (0.14)	(-0.69, -0.13)	0.0047	-0.28 (0.11)	(-0.49, -0.08)	0.0075

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score Mucocutaneous - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=182) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.3667
< 10 points	54	-0.97 (0.16)	52	-0.73 (0.16)	-0.23 (0.22)	(-0.67, 0.21)	0.2962	-0.20 (0.19)	(-0.58, 0.18)	0.3090	
>= 10 points	126	-1.84 (0.13)	128	-1.35 (0.13)	-0.49 (0.17)	(-0.83, -0.14)	0.0056	-0.33 (0.13)	(-0.57, -0.08)	0.0101	
OCS dose at baseline											0.0076
<10 mg/day	93	-1.41 (0.14)	98	-1.34 (0.14)	-0.07 (0.20)	(-0.45, 0.32)	0.7234	-0.05 (0.14)	(-0.33, 0.23)	0.7331	
>=10 mg/day	87	-1.85 (0.16)	82	-1.02 (0.17)	-0.83 (0.21)	(-1.24, -0.42)	0.0001	-0.55 (0.16)	(-0.86, -0.25)	0.0004	
Result of type I IFN gene signature test											0.3080
LOW	30	-1.33 (0.23)	31	-1.21 (0.22)	-0.11 (0.31)	(-0.74, 0.52)	0.7246	-0.09 (0.26)	(-0.59, 0.41)	0.7317	
HIGH	150	-1.65 (0.11)	149	-1.18 (0.12)	-0.47 (0.16)	(-0.79, -0.15)	0.0037	-0.33 (0.12)	(-0.56, -0.10)	0.0043	
Age (years)											NE
<= 65	175	-1.60 (0.11)	179	-1.16 (0.11)	-0.44 (0.14)	(-0.72, -0.16)	0.0025	-0.31 (0.11)	(-0.52, -0.10)	0.0042	
> 65	5	NE	1	NE	NE	NE		NE	NE		
Sex											NE
male	12	NE	12	NE	NE	NE		NE	NE		
female	168	-1.58 (0.11)	168	-1.20 (0.11)	-0.38 (0.15)	(-0.68, -0.09)	0.0101	-0.27 (0.11)	(-0.48, -0.05)	0.0149	
Race											NE
White	110	-1.46 (0.13)	106	-1.36 (0.14)	-0.10 (0.18)	(-0.46, 0.26)	0.5789	-0.07 (0.14)	(-0.34, 0.20)	0.6022	
Black or African American	17	-1.16 (0.39)	25	-1.13 (0.33)	-0.03 (0.48)	(-1.00, 0.94)	0.9522	-0.02 (0.31)	(-0.63, 0.60)	0.9559	
Asian	30	-1.70 (0.27)	30	-0.57 (0.26)	-1.13 (0.32)	(-1.77, -0.49)	0.0009	-0.77 (0.27)	(-1.30, -0.24)	0.0041	
American Indian or Alaska Native	4	NE	1	NE	NE	NE		NE	NE		
Other	11	NE	10	NE	NE	NE		NE	NE		
Ethnicity											0.4354
Hispanic/Latino	54	-2.11 (0.21)	54	-1.53 (0.21)	-0.59 (0.27)	(-1.13, -0.04)	0.0353	-0.38 (0.19)	(-0.76, -0.00)	0.0480	
Non-hispanic/Latino	118	-1.37 (0.12)	118	-1.04 (0.12)	-0.34 (0.17)	(-0.66, -0.01)	0.0438	-0.25 (0.13)	(-0.50, 0.01)	0.0577	
Geographic region											0.0747
EU	51	-1.60 (0.20)	45	-1.61 (0.22)	0.01 (0.27)	(-0.52, 0.54)	0.9708	0.01 (0.20)	(-0.39, 0.41)	0.9736	
non-EU	129	-1.62 (0.13)	135	-1.07 (0.12)	-0.55 (0.17)	(-0.88, -0.22)	0.0011	-0.38 (0.12)	(-0.63, -0.14)	0.0020	
Onset of disease											NE
Paediatric	14	NE	12	NE	NE	NE		NE	NE		
Adult	166	-1.55 (0.11)	168	-1.19 (0.11)	-0.36 (0.15)	(-0.65, -0.07)	0.0158	-0.25 (0.11)	(-0.47, -0.04)	0.0218	
ADA result											NE
Negative	172	-1.56 (0.11)	160	-1.24 (0.11)	-0.32 (0.15)	(-0.61, -0.02)	0.0340	-0.22 (0.11)	(-0.44, -0.01)	0.0447	
Positive (At any time)	8	NE	20	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.2101
< 30	125	-1.74 (0.13)	132	-1.20 (0.13)	-0.54 (0.16)	(-0.86, -0.22)	0.0012	-0.38 (0.13)	(-0.62, -0.13)	0.0028	
>= 30	55	-1.27 (0.20)	48	-1.14 (0.22)	-0.12 (0.29)	(-0.70, 0.45)	0.6759	-0.08 (0.20)	(-0.47, 0.31)	0.6855	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.1934
All negative/normal	58	-1.40 (0.19)	80	-1.24 (0.16)	-0.16 (0.24)	(-0.64, 0.31)	0.4975	-0.11 (0.17)	(-0.45, 0.22)	0.5102	
At least one positive/abnormal	122	-1.64 (0.14)	100	-1.09 (0.15)	-0.55 (0.18)	(-0.91, -0.20)	0.0025	-0.36 (0.14)	(-0.63, -0.10)	0.0073	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score Musculoskeletal
Full analysis set

Visit	Anifrolumab 300mg (N=180) N	Anifrolumab 300mg (N=180) LSMean (SE)	Placebo (N=182) N	Placebo (N=182) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-0.12 (0.08)		-0.04 (0.08)	-0.08 (0.09)	(-0.26, 0.10)	0.3705			
Week 8		-1.03 (0.14)		-0.75 (0.14)	-0.28 (0.19)	(-0.65, 0.10)	0.1453			
Week 12		-1.76 (0.15)		-1.34 (0.15)	-0.42 (0.21)	(-0.83, -0.01)	0.0430			
Week 16		-1.97 (0.16)		-1.69 (0.16)	-0.29 (0.21)	(-0.71, 0.13)	0.1785			
Week 20		-2.06 (0.16)		-1.92 (0.16)	-0.14 (0.22)	(-0.57, 0.28)	0.5092			
Week 24		-2.14 (0.16)		-1.90 (0.16)	-0.24 (0.22)	(-0.66, 0.19)	0.2733			
Week 28		-2.25 (0.16)		-2.05 (0.16)	-0.20 (0.22)	(-0.63, 0.23)	0.3572			
Week 32		-2.23 (0.16)		-2.02 (0.16)	-0.21 (0.22)	(-0.64, 0.23)	0.3468			
Week 36		-2.25 (0.16)		-2.04 (0.16)	-0.20 (0.22)	(-0.64, 0.23)	0.3564			
Week 40		-2.33 (0.16)		-2.11 (0.16)	-0.22 (0.22)	(-0.66, 0.21)	0.3110			
Week 44		-2.38 (0.16)		-2.07 (0.16)	-0.31 (0.22)	(-0.74, 0.12)	0.1589			
Week 48		-2.59 (0.16)		-2.15 (0.16)	-0.45 (0.21)	(-0.87, -0.02)	0.0389			
Week 52		-2.56 (0.16)		-2.23 (0.16)	-0.33 (0.22)	(-0.75, 0.09)	0.1272			
OVERALL	180	-1.98 (0.12)	180	-1.72 (0.12)	-0.26 (0.15)	(-0.56, 0.04)	0.0945	-0.16 (0.11)	(-0.37, 0.04)	0.1184

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score Musculoskeletal - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=182) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.4794
< 10 points	54	-1.82 (0.21)	52	-1.73 (0.21)	-0.09 (0.29)	(-0.68, 0.49)	0.7532	-0.06 (0.19)	(-0.44, 0.32)	0.7547	
>= 10 points	126	-2.06 (0.15)	128	-1.72 (0.15)	-0.34 (0.19)	(-0.70, 0.03)	0.0715	-0.21 (0.13)	(-0.45, 0.04)	0.1031	
OCS dose at baseline											0.6103
<10 mg/day	93	-1.98 (0.16)	98	-1.79 (0.16)	-0.19 (0.21)	(-0.61, 0.23)	0.3797	-0.12 (0.14)	(-0.41, 0.16)	0.4019	
>=10 mg/day	87	-2.00 (0.18)	82	-1.65 (0.18)	-0.35 (0.23)	(-0.80, 0.11)	0.1324	-0.21 (0.15)	(-0.51, 0.10)	0.1807	
Result of type I IFN gene signature test											0.3971
LOW	30	-1.89 (0.26)	31	-1.92 (0.26)	0.03 (0.36)	(-0.69, 0.75)	0.9378	0.02 (0.26)	(-0.48, 0.52)	0.9387	
HIGH	150	-2.04 (0.12)	149	-1.73 (0.12)	-0.31 (0.17)	(-0.65, 0.03)	0.0717	-0.20 (0.12)	(-0.43, 0.02)	0.0788	
Age (years)											NE
<= 65	175	-1.98 (0.12)	179	-1.71 (0.12)	-0.28 (0.16)	(-0.59, 0.03)	0.0757	-0.18 (0.11)	(-0.39, 0.03)	0.0977	
> 65	5	NE	1	NE	NE	NE		NE	NE		
Sex											NE
male	12	NE	12	NE	NE	NE		NE	NE		
female	168	-1.92 (0.12)	168	-1.66 (0.12)	-0.26 (0.16)	(-0.57, 0.06)	0.1094	-0.16 (0.11)	(-0.38, 0.05)	0.1339	
Race											NE
White	110	-1.91 (0.14)	106	-1.61 (0.15)	-0.30 (0.20)	(-0.70, 0.10)	0.1354	-0.20 (0.14)	(-0.47, 0.07)	0.1459	
Black or African American	17	NE	25	NE	NE	NE		NE	NE		
Asian	30	-1.77 (0.37)	30	-1.91 (0.36)	0.13 (0.36)	(-0.59, 0.86)	0.7124	0.07 (0.26)	(-0.44, 0.57)	0.7969	
American Indian or Alaska Native	4	NE	1	NE	NE	NE		NE	NE		
Other	11	NE	10	NE	NE	NE		NE	NE		
Ethnicity											0.6056
Hispanic/Latino	54	-1.97 (0.20)	54	-1.56 (0.20)	-0.41 (0.27)	(-0.94, 0.13)	0.1341	-0.28 (0.19)	(-0.66, 0.10)	0.1486	
Non-hispanic/Latino	118	-1.96 (0.15)	118	-1.72 (0.15)	-0.24 (0.19)	(-0.62, 0.15)	0.2279	-0.15 (0.13)	(-0.40, 0.11)	0.2619	
Geographic region											0.1766
EU	51	-2.16 (0.20)	45	-2.24 (0.22)	0.08 (0.26)	(-0.43, 0.59)	0.7669	0.05 (0.20)	(-0.35, 0.45)	0.8022	
non-EU	129	-1.87 (0.14)	135	-1.52 (0.14)	-0.35 (0.18)	(-0.71, 0.01)	0.0589	-0.22 (0.12)	(-0.46, 0.02)	0.0733	
Onset of disease											NE
Paediatric	14	NE	12	NE	NE	NE		NE	NE		
Adult	166	-2.01 (0.12)	168	-1.72 (0.12)	-0.29 (0.16)	(-0.61, 0.03)	0.0709	-0.19 (0.11)	(-0.40, 0.03)	0.0894	
ADA result											NE
Negative	172	-1.98 (0.12)	160	-1.72 (0.12)	-0.27 (0.16)	(-0.59, 0.05)	0.1027	-0.17 (0.11)	(-0.38, 0.05)	0.1266	
Positive (At any time)	8	NE	20	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.1996
< 30	125	-1.99 (0.15)	132	-1.85 (0.15)	-0.14 (0.19)	(-0.51, 0.22)	0.4353	-0.09 (0.12)	(-0.33, 0.16)	0.4832	
>= 30	55	-1.93 (0.20)	48	-1.36 (0.21)	-0.57 (0.28)	(-1.12, -0.02)	0.0411	-0.39 (0.20)	(-0.78, -0.00)	0.0483	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.5084
All negative/normal	58	-2.06 (0.20)	80	-1.67 (0.18)	-0.39 (0.27)	(-0.92, 0.14)	0.1451	-0.25 (0.17)	(-0.59, 0.09)	0.1532	
At least one positive/abnormal	122	-1.95 (0.15)	100	-1.78 (0.17)	-0.17 (0.19)	(-0.55, 0.20)	0.3650	-0.10 (0.13)	(-0.37, 0.16)	0.4553	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score Renal
Full analysis set

	Anifrolumab 300mg (N=180)		Placebo (N=182)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		0.00 (0.08)		-0.06 (0.08)	0.06 (0.10)	(-0.13, 0.26)	0.5257			
Week 8		-0.02 (0.08)		-0.02 (0.08)	-0.00 (0.11)	(-0.21, 0.21)	0.9718			
Week 12		0.00 (0.09)		0.04 (0.09)	-0.04 (0.11)	(-0.26, 0.18)	0.7056			
Week 16		0.05 (0.09)		0.07 (0.09)	-0.02 (0.12)	(-0.26, 0.22)	0.8593			
Week 20		0.03 (0.09)		0.03 (0.09)	-0.01 (0.11)	(-0.23, 0.22)	0.9567			
Week 24		0.01 (0.11)		0.19 (0.11)	-0.19 (0.15)	(-0.48, 0.11)	0.2160			
Week 28		-0.04 (0.10)		0.04 (0.10)	-0.08 (0.13)	(-0.33, 0.17)	0.5358			
Week 32		-0.10 (0.09)		-0.01 (0.09)	-0.09 (0.11)	(-0.32, 0.14)	0.4318			
Week 36		-0.05 (0.09)		0.05 (0.09)	-0.11 (0.12)	(-0.34, 0.12)	0.3601			
Week 40		-0.05 (0.10)		0.03 (0.10)	-0.08 (0.13)	(-0.35, 0.18)	0.5411			
Week 44		-0.08 (0.10)		-0.08 (0.10)	-0.00 (0.14)	(-0.27, 0.27)	0.9734			
Week 48		-0.01 (0.12)		0.05 (0.12)	-0.05 (0.16)	(-0.37, 0.26)	0.7309			
Week 52		-0.06 (0.10)		0.01 (0.10)	-0.07 (0.14)	(-0.34, 0.20)	0.6084			
OVERALL	180	-0.03 (0.07)	182	0.03 (0.08)	-0.05 (0.09)	(-0.23, 0.13)	0.5692	-0.05 (0.11)	(-0.26, 0.15)	0.6198

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score Renal - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=182) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											NE
< 10 points	54	NE	52	NE	NE	NE		NE	NE		
>= 10 points	126	-0.06 (0.11)	130	0.04 (0.11)	-0.09 (0.13)	(-0.35, 0.17)	0.4903	-0.07 (0.13)	(-0.32, 0.17)	0.5552	
OCS dose at baseline											NE
<10 mg/day	93	NE	99	NE	NE	NE		NE	NE		
>=10 mg/day	87	-0.04 (0.15)	83	0.12 (0.16)	-0.16 (0.18)	(-0.52, 0.21)	0.3940	-0.11 (0.15)	(-0.41, 0.19)	0.4727	
Result of type I IFN gene signature test											NE
LOW	30	NE	31	NE	NE	NE		NE	NE		
HIGH	150	-0.01 (0.08)	151	0.05 (0.08)	-0.06 (0.11)	(-0.28, 0.16)	0.5972	-0.06 (0.12)	(-0.28, 0.17)	0.6135	
Age (years)											NE
<= 65	175	-0.03 (0.08)	181	0.03 (0.08)	-0.05 (0.09)	(-0.24, 0.13)	0.5816	-0.05 (0.11)	(-0.26, 0.16)	0.6318	
> 65	5	NE	1	NE	NE	NE		NE	NE		
Sex											NE
male	12	NE	12	NE	NE	NE		NE	NE		
female	168	-0.02 (0.08)	170	0.04 (0.08)	-0.06 (0.10)	(-0.26, 0.13)	0.5239	-0.06 (0.11)	(-0.27, 0.15)	0.5711	
Race											NE
White	110	NE	107	NE	NE	NE		NE	NE		
Black or African American	17	NE	25	NE	NE	NE		NE	NE		
Asian	30	NE	30	NE	NE	NE		NE	NE		
American Indian or Alaska Native	4	NE	1	NE	NE	NE		NE	NE		
Other	11	NE	11	NE	NE	NE		NE	NE		
Ethnicity											NE
Hispanic/Latino	54	NE	54	NE	NE	NE		NE	NE		
Non-hispanic/Latino	118	0.03 (0.10)	120	0.01 (0.10)	0.02 (0.13)	(-0.23, 0.27)	0.8876	0.02 (0.13)	(-0.24, 0.27)	0.9004	
Geographic region											NE
EU	51	NE	46	NE	NE	NE		NE	NE		
non-EU	129	-0.06 (0.08)	136	-0.02 (0.08)	-0.04 (0.10)	(-0.23, 0.16)	0.7161	-0.04 (0.12)	(-0.28, 0.20)	0.7439	
Onset of disease											NE
Paediatric	14	NE	12	NE	NE	NE		NE	NE		
Adult	166	-0.08 (0.07)	170	0.04 (0.07)	-0.13 (0.09)	(-0.29, 0.04)	0.1435	-0.14 (0.11)	(-0.36, 0.07)	0.1854	
ADA result											NE
Negative	172	-0.06 (0.06)	162	-0.01 (0.06)	-0.05 (0.07)	(-0.20, 0.10)	0.4982	-0.07 (0.11)	(-0.28, 0.15)	0.5525	
Positive (At any time)	8	NE	20	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											NE
< 30	125	-0.04 (0.11)	134	0.01 (0.11)	-0.05 (0.12)	(-0.30, 0.19)	0.6647	-0.04 (0.12)	(-0.29, 0.20)	0.7208	
>= 30	55	NE	48	NE	NE	NE		NE	NE		
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											NE
All negative/normal	58	NE	81	NE	NE	NE		NE	NE		
At least one positive/abnormal	122	-0.04 (0.13)	101	0.14 (0.14)	-0.18 (0.15)	(-0.47, 0.12)	0.2331	-0.13 (0.13)	(-0.39, 0.14)	0.3388	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score Vascular
Full analysis set

Visit	Anifrolumab 300mg (N=180) N	Anifrolumab 300mg (N=180) LSMean (SE)	Placebo (N=182) N	Placebo (N=182) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		NE		NE	NE	NE				
Week 8		NE		NE	NE	NE				
Week 12		NE		NE	NE	NE				
Week 16		NE		NE	NE	NE				
Week 20		NE		NE	NE	NE				
Week 24		NE		NE	NE	NE				
Week 28		NE		NE	NE	NE				
Week 32		NE		NE	NE	NE				
Week 36		NE		NE	NE	NE				
Week 40		NE		NE	NE	NE				
Week 44		NE		NE	NE	NE				
Week 48		NE		NE	NE	NE				
Week 52		NE		NE	NE	NE				
OVERALL	180	NE	180	NE	NE	NE		NE	NE	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score Vascular - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=180)		Placebo (N=182)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											NE
< 10 points	54	NE	52	NE	NE	NE		NE	NE		
>= 10 points	126	NE	128	NE	NE	NE		NE	NE		
OCS dose at baseline											NE
<10 mg/day	93	NE	98	NE	NE	NE		NE	NE		
>=10 mg/day	87	NE	82	NE	NE	NE		NE	NE		
Result of type I IFN gene signature test											NE
LOW	30	NE	31	NE	NE	NE		NE	NE		
HIGH	150	NE	149	NE	NE	NE		NE	NE		
Age (years)											NE
<= 65	175	NE	179	NE	NE	NE		NE	NE		
> 65	5	NE	1	NE	NE	NE		NE	NE		
Sex											NE
male	12	NE	12	NE	NE	NE		NE	NE		
female	168	NE	168	NE	NE	NE		NE	NE		
Race											NE
White	110	NE	106	NE	NE	NE		NE	NE		
Black or African American	17	NE	25	NE	NE	NE		NE	NE		
Asian	30	NE	30	NE	NE	NE		NE	NE		
American Indian or Alaska Native	4	NE	1	NE	NE	NE		NE	NE		
Other	11	NE	10	NE	NE	NE		NE	NE		
Ethnicity											NE
Hispanic/Latino	54	NE	54	NE	NE	NE		NE	NE		
Non-hispanic/Latino	118	NE	118	NE	NE	NE		NE	NE		
Geographic region											NE
EU	51	NE	45	NE	NE	NE		NE	NE		
non-EU	129	NE	135	NE	NE	NE		NE	NE		
Onset of disease											NE
Paediatric	14	NE	12	NE	NE	NE		NE	NE		
Adult	166	NE	168	NE	NE	NE		NE	NE		
ADA result											NE
Negative	172	NE	160	NE	NE	NE		NE	NE		
Positive (At any time)	8	NE	20	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											NE
< 30	125	NE	132	NE	NE	NE		NE	NE		
>= 30	55	NE	48	NE	NE	NE		NE	NE		
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											NE
All negative/normal	58	NE	80	NE	NE	NE		NE	NE		
At least one positive/abnormal	122	NE	100	NE	NE	NE		NE	NE		

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - PGA
Full analysis set

	Anifrolumab 300mg (N=180)		Placebo (N=182)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-0.24 (0.03)		-0.19 (0.03)	-0.04 (0.04)	(-0.12, 0.03)	0.2547			
Week 8		-0.46 (0.04)		-0.35 (0.04)	-0.11 (0.05)	(-0.20, -0.01)	0.0306			
Week 12		-0.61 (0.04)		-0.44 (0.04)	-0.17 (0.06)	(-0.28, -0.06)	0.0026			
Week 16		-0.71 (0.04)		-0.55 (0.04)	-0.16 (0.06)	(-0.27, -0.05)	0.0062			
Week 20		-0.75 (0.05)		-0.58 (0.05)	-0.18 (0.06)	(-0.29, -0.06)	0.0029			
Week 24		-0.81 (0.05)		-0.62 (0.05)	-0.19 (0.06)	(-0.31, -0.07)	0.0015			
Week 28		-0.83 (0.05)		-0.65 (0.05)	-0.18 (0.06)	(-0.30, -0.06)	0.0033			
Week 32		-0.85 (0.05)		-0.67 (0.05)	-0.18 (0.06)	(-0.31, -0.06)	0.0043			
Week 36		-0.89 (0.05)		-0.72 (0.05)	-0.18 (0.06)	(-0.30, -0.05)	0.0060			
Week 40		-0.89 (0.05)		-0.71 (0.05)	-0.17 (0.06)	(-0.30, -0.05)	0.0074			
Week 44		-0.91 (0.05)		-0.72 (0.05)	-0.19 (0.07)	(-0.32, -0.06)	0.0040			
Week 48		-0.88 (0.05)		-0.73 (0.05)	-0.15 (0.07)	(-0.28, -0.02)	0.0266			
Week 52		-0.90 (0.05)		-0.76 (0.05)	-0.15 (0.07)	(-0.28, -0.01)	0.0300			
OVERALL	180	-0.75 (0.04)	180	-0.59 (0.04)	-0.16 (0.05)	(-0.25, -0.06)	0.0013	-0.30 (0.11)	(-0.51, -0.10)	0.0043

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - PGA - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=182) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.0828
< 10 points	54	-0.70 (0.07)	52	-0.69 (0.07)	-0.02 (0.10)	(-0.21, 0.17)	0.8621	-0.03 (0.19)	(-0.41, 0.35)	0.8697	
>= 10 points	126	-0.78 (0.05)	128	-0.57 (0.05)	-0.21 (0.06)	(-0.32, -0.10)	0.0002	-0.40 (0.13)	(-0.65, -0.16)	0.0014	
OCS dose at baseline											0.3193
<10 mg/day	93	-0.69 (0.05)	98	-0.58 (0.05)	-0.10 (0.07)	(-0.24, 0.03)	0.1227	-0.21 (0.15)	(-0.49, 0.08)	0.1508	
>=10 mg/day	87	-0.80 (0.06)	82	-0.60 (0.06)	-0.20 (0.07)	(-0.34, -0.06)	0.0047	-0.36 (0.16)	(-0.66, -0.05)	0.0208	
Result of type I IFN gene signature test											0.6410
LOW	30	-0.70 (0.08)	31	-0.60 (0.09)	-0.10 (0.12)	(-0.34, 0.13)	0.3917	-0.21 (0.26)	(-0.72, 0.29)	0.4052	
HIGH	150	-0.77 (0.04)	149	-0.61 (0.04)	-0.16 (0.05)	(-0.27, -0.06)	0.0026	-0.34 (0.12)	(-0.56, -0.11)	0.0039	
Age (years)											NE
<= 65	175	-0.76 (0.04)	179	-0.59 (0.04)	-0.17 (0.05)	(-0.26, -0.07)	0.0008	-0.32 (0.11)	(-0.53, -0.11)	0.0029	
> 65	5	NE	1	NE	NE	NE		NE	NE		
Sex											0.3745
male	12	-0.90 (0.16)	12	-0.92 (0.18)	0.02 (0.20)	(-0.41, 0.45)	0.9212	0.03 (0.41)	(-0.77, 0.83)	0.9343	
female	168	-0.74 (0.04)	168	-0.57 (0.04)	-0.17 (0.05)	(-0.26, -0.07)	0.0010	-0.32 (0.11)	(-0.54, -0.11)	0.0033	
Race											NE
White	110	-0.73 (0.05)	106	-0.65 (0.05)	-0.08 (0.06)	(-0.20, 0.03)	0.1696	-0.17 (0.14)	(-0.44, 0.10)	0.2138	
Black or African American	17	-0.56 (0.15)	25	-0.55 (0.13)	-0.02 (0.18)	(-0.38, 0.35)	0.9290	-0.02 (0.31)	(-0.64, 0.59)	0.9370	
Asian	30	-0.75 (0.11)	30	-0.41 (0.11)	-0.34 (0.12)	(-0.59, -0.10)	0.0073	-0.55 (0.26)	(-1.07, -0.04)	0.0360	
American Indian or Alaska Native	4	NE	1	NE	NE	NE		NE	NE		
Other	11	NE	10	NE	NE	NE		NE	NE		
Ethnicity											0.8707
Hispanic/Latino	54	-0.83 (0.07)	54	-0.69 (0.07)	-0.14 (0.09)	(-0.31, 0.03)	0.1019	-0.28 (0.19)	(-0.66, 0.10)	0.1468	
Non-hispanic/Latino	118	-0.69 (0.05)	118	-0.53 (0.05)	-0.16 (0.06)	(-0.27, -0.04)	0.0066	-0.32 (0.13)	(-0.58, -0.06)	0.0147	
Geographic region											0.3380
EU	51	-0.83 (0.08)	45	-0.75 (0.08)	-0.08 (0.08)	(-0.25, 0.08)	0.3058	-0.15 (0.20)	(-0.56, 0.25)	0.4510	
non-EU	129	-0.74 (0.05)	135	-0.55 (0.05)	-0.18 (0.06)	(-0.30, -0.07)	0.0022	-0.35 (0.12)	(-0.59, -0.10)	0.0054	
Onset of disease											0.0585
Paediatric	14	-0.49 (0.21)	12	0.08 (0.26)	-0.57 (0.22)	(-1.02, -0.11)	0.0168	-0.65 (0.41)	(-1.45, 0.14)	0.1083	
Adult	166	-0.76 (0.04)	168	-0.62 (0.04)	-0.14 (0.05)	(-0.24, -0.05)	0.0040	-0.28 (0.11)	(-0.50, -0.07)	0.0097	
ADA result											NE
Negative	172	-0.74 (0.04)	160	-0.61 (0.04)	-0.13 (0.05)	(-0.23, -0.04)	0.0080	-0.26 (0.11)	(-0.48, -0.05)	0.0168	
Positive (At any time)	8	NE	20	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.8657
< 30	125	-0.74 (0.05)	132	-0.58 (0.05)	-0.16 (0.06)	(-0.27, -0.04)	0.0067	-0.29 (0.13)	(-0.53, -0.04)	0.0226	
>= 30	55	-0.73 (0.07)	48	-0.59 (0.07)	-0.14 (0.09)	(-0.33, 0.05)	0.1439	-0.27 (0.20)	(-0.66, 0.11)	0.1665	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.0643
All negative/normal	58	-0.70 (0.06)	80	-0.66 (0.06)	-0.04 (0.08)	(-0.21, 0.12)	0.5986	-0.09 (0.17)	(-0.43, 0.25)	0.6111	
At least one positive/abnormal	122	-0.78 (0.06)	100	-0.55 (0.06)	-0.23 (0.06)	(-0.35, -0.11)	0.0001	-0.38 (0.14)	(-0.64, -0.11)	0.0056	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - CLASI Total Activity Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) N	Anifrolumab 300mg (N=180) LSMean (SE)	Placebo (N=182) N	Placebo (N=182) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-1.57 (0.30)		-0.66 (0.30)	-0.92 (0.38)	(-1.66, -0.17)	0.0162			
Week 8		-2.90 (0.32)		-1.39 (0.32)	-1.51 (0.40)	(-2.29, -0.72)	0.0002			
Week 12		-3.59 (0.34)		-2.15 (0.35)	-1.45 (0.44)	(-2.32, -0.57)	0.0012			
Week 16		-4.02 (0.37)		-2.34 (0.37)	-1.67 (0.48)	(-2.61, -0.74)	0.0005			
Week 20		-4.21 (0.36)		-2.45 (0.36)	-1.76 (0.47)	(-2.69, -0.83)	0.0002			
Week 24		-4.41 (0.37)		-2.70 (0.37)	-1.70 (0.48)	(-2.65, -0.76)	0.0004			
Week 28		-4.73 (0.36)		-2.96 (0.36)	-1.78 (0.46)	(-2.69, -0.86)	0.0002			
Week 32		-4.86 (0.36)		-2.99 (0.36)	-1.87 (0.46)	(-2.78, -0.96)	<.0001			
Week 36		-4.92 (0.36)		-3.20 (0.36)	-1.72 (0.47)	(-2.64, -0.80)	0.0003			
Week 40		-4.99 (0.36)		-3.14 (0.37)	-1.85 (0.48)	(-2.79, -0.91)	0.0001			
Week 44		-5.03 (0.35)		-3.52 (0.36)	-1.51 (0.46)	(-2.42, -0.61)	0.0011			
Week 48		-5.06 (0.36)		-3.73 (0.37)	-1.33 (0.48)	(-2.27, -0.39)	0.0055			
Week 52		-5.32 (0.34)		-3.82 (0.35)	-1.50 (0.45)	(-2.38, -0.62)	0.0009			
OVERALL	180	-4.28 (0.31)	180	-2.70 (0.31)	-1.58 (0.38)	(-2.34, -0.83)	<.0001	-0.38 (0.11)	(-0.59, -0.17)	0.0003

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - CLASI Total Activity Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=182) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.6773
< 10 points	54	-3.96 (0.43)	52	-2.58 (0.44)	-1.38 (0.60)	(-2.57, -0.19)	0.0240	-0.43 (0.20)	(-0.82, -0.05)	0.0281	
>= 10 points	126	-4.36 (0.41)	128	-2.66 (0.41)	-1.70 (0.50)	(-2.69, -0.72)	0.0008	-0.37 (0.13)	(-0.61, -0.12)	0.0039	
OCS dose at baseline											0.7726
<10 mg/day	93	-3.85 (0.43)	98	-2.55 (0.42)	-1.30 (0.57)	(-2.43, -0.17)	0.0241	-0.31 (0.15)	(-0.59, -0.02)	0.0341	
>=10 mg/day	87	-4.41 (0.43)	82	-2.89 (0.44)	-1.52 (0.50)	(-2.51, -0.52)	0.0030	-0.38 (0.16)	(-0.68, -0.07)	0.0153	
Result of type I IFN gene signature test											0.0106
LOW	30	-2.27 (0.42)	31	-2.30 (0.41)	0.03 (0.58)	(-1.15, 1.21)	0.9571	0.01 (0.26)	(-0.49, 0.52)	0.9578	
HIGH	150	-4.94 (0.33)	149	-3.09 (0.33)	-1.85 (0.45)	(-2.74, -0.96)	<.0001	-0.46 (0.12)	(-0.69, -0.23)	<.0001	
Age (years)											NE
<= 65	175	-4.33 (0.31)	179	-2.70 (0.31)	-1.63 (0.39)	(-2.40, -0.86)	<.0001	-0.39 (0.11)	(-0.60, -0.18)	0.0003	
> 65	5	NE	1	NE	NE	NE		NE	NE		
Sex											NE
male	12	NE	12	NE	NE	NE		NE	NE		
female	168	-4.21 (0.28)	168	-2.70 (0.28)	-1.51 (0.36)	(-2.21, -0.81)	<.0001	-0.41 (0.11)	(-0.63, -0.19)	0.0002	
Race											NE
White	110	-3.65 (0.29)	106	-3.16 (0.30)	-0.48 (0.37)	(-1.21, 0.24)	0.1912	-0.16 (0.14)	(-0.42, 0.11)	0.2535	
Black or African American	17	NE	25	NE	NE	NE		NE	NE		
Asian	30	NE	30	NE	NE	NE		NE	NE		
American Indian or Alaska Native	4	NE	1	NE	NE	NE		NE	NE		
Other	11	NE	10	NE	NE	NE		NE	NE		
Ethnicity											0.1929
Hispanic/Latino	54	-3.61 (0.43)	54	-2.69 (0.42)	-0.92 (0.54)	(-1.98, 0.15)	0.0913	-0.29 (0.19)	(-0.67, 0.09)	0.1328	
Non-hispanic/Latino	118	-4.53 (0.39)	118	-2.66 (0.39)	-1.87 (0.50)	(-2.84, -0.89)	0.0002	-0.44 (0.13)	(-0.70, -0.18)	0.0008	
Geographic region											0.0531
EU	51	-3.43 (0.65)	45	-3.12 (0.70)	-0.31 (0.79)	(-1.89, 1.27)	0.7007	-0.07 (0.20)	(-0.47, 0.34)	0.7502	
non-EU	129	-4.47 (0.35)	135	-2.40 (0.35)	-2.07 (0.45)	(-2.95, -1.19)	<.0001	-0.51 (0.13)	(-0.75, -0.26)	<.0001	
Onset of disease											0.4426
Paediatric	14	-1.76 (1.07)	12	-1.07 (1.38)	-0.69 (1.11)	(-3.16, 1.78)	0.5482	-0.15 (0.39)	(-0.93, 0.62)	0.6980	
Adult	166	-4.37 (0.33)	168	-2.76 (0.33)	-1.60 (0.41)	(-2.41, -0.79)	0.0001	-0.38 (0.11)	(-0.59, -0.16)	0.0006	
ADA result											NE
Negative	172	-4.22 (0.31)	160	-2.88 (0.32)	-1.34 (0.40)	(-2.12, -0.55)	0.0009	-0.33 (0.11)	(-0.54, -0.11)	0.0031	
Positive (At any time)	8	NE	20	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.0956
< 30	125	-4.66 (0.40)	132	-2.66 (0.40)	-2.00 (0.48)	(-2.94, -1.06)	<.0001	-0.43 (0.13)	(-0.68, -0.19)	0.0006	
>= 30	55	-3.17 (0.45)	48	-2.48 (0.47)	-0.70 (0.62)	(-1.92, 0.53)	0.2613	-0.21 (0.20)	(-0.60, 0.18)	0.2857	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.0026
All negative/normal	58	-3.01 (0.35)	80	-2.72 (0.30)	-0.29 (0.44)	(-1.16, 0.58)	0.5085	-0.11 (0.17)	(-0.45, 0.23)	0.5293	
At least one positive/abnormal	122	-5.05 (0.51)	100	-2.60 (0.56)	-2.45 (0.57)	(-3.57, -1.33)	<.0001	-0.43 (0.14)	(-0.70, -0.17)	0.0015	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - CLASI Total Damage Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) N	Anifrolumab 300mg (N=180) LSMean (SE)	Placebo (N=182) N	Placebo (N=182) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-0.13 (0.11)		-0.00 (0.11)	-0.13 (0.13)	(-0.38, 0.13)	0.3347			
Week 8		-0.10 (0.13)		-0.10 (0.13)	-0.00 (0.17)	(-0.34, 0.34)	0.9924			
Week 12		-0.24 (0.13)		-0.08 (0.13)	-0.16 (0.17)	(-0.49, 0.17)	0.3391			
Week 16		-0.35 (0.13)		0.01 (0.13)	-0.37 (0.16)	(-0.69, -0.05)	0.0241			
Week 20		-0.30 (0.15)		-0.09 (0.15)	-0.21 (0.19)	(-0.59, 0.17)	0.2784			
Week 24		-0.35 (0.14)		-0.12 (0.14)	-0.23 (0.19)	(-0.59, 0.14)	0.2298			
Week 28		-0.29 (0.16)		-0.08 (0.16)	-0.20 (0.21)	(-0.61, 0.20)	0.3272			
Week 32		-0.28 (0.17)		-0.03 (0.17)	-0.25 (0.22)	(-0.68, 0.19)	0.2625			
Week 36		-0.31 (0.17)		-0.13 (0.17)	-0.17 (0.23)	(-0.63, 0.28)	0.4526			
Week 40		-0.27 (0.17)		-0.10 (0.18)	-0.17 (0.23)	(-0.63, 0.29)	0.4645			
Week 44		-0.36 (0.19)		-0.16 (0.19)	-0.21 (0.26)	(-0.71, 0.30)	0.4197			
Week 48		-0.27 (0.19)		-0.21 (0.19)	-0.06 (0.25)	(-0.56, 0.44)	0.8204			
Week 52		-0.27 (0.18)		-0.19 (0.18)	-0.08 (0.25)	(-0.56, 0.41)	0.7536			
OVERALL	180	-0.27 (0.14)	180	-0.10 (0.14)	-0.17 (0.18)	(-0.52, 0.18)	0.3326	-0.09 (0.11)	(-0.30, 0.11)	0.3783

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - CLASI Total Damage Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=182) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											NE
< 10 points	54	NE	52	NE	NE	NE		NE	NE		
>= 10 points	126	-0.43 (0.16)	128	-0.15 (0.16)	-0.29 (0.20)	(-0.69, 0.12)	0.1635	-0.15 (0.13)	(-0.40, 0.09)	0.2193	
OCS dose at baseline											0.0526
<10 mg/day	93	-0.39 (0.19)	98	0.10 (0.19)	-0.49 (0.26)	(-1.00, 0.02)	0.0588	-0.26 (0.15)	(-0.55, 0.02)	0.0720	
>=10 mg/day	87	-0.15 (0.20)	82	-0.35 (0.20)	0.19 (0.24)	(-0.28, 0.67)	0.4230	0.10 (0.15)	(-0.20, 0.41)	0.4975	
Result of type I IFN gene signature test											NE
LOW	30	NE	31	NE	NE	NE		NE	NE		
HIGH	150	-0.29 (0.15)	149	-0.14 (0.15)	-0.15 (0.21)	(-0.56, 0.26)	0.4664	-0.08 (0.12)	(-0.31, 0.15)	0.4804	
Age (years)											NE
<= 65	175	-0.28 (0.14)	179	-0.10 (0.14)	-0.18 (0.18)	(-0.53, 0.18)	0.3232	-0.10 (0.11)	(-0.30, 0.11)	0.3698	
> 65	5	NE	1	NE	NE	NE		NE	NE		
Sex											NE
male	12	NE	12	NE	NE	NE		NE	NE		
female	168	-0.25 (0.14)	168	-0.10 (0.14)	-0.15 (0.19)	(-0.51, 0.22)	0.4339	-0.08 (0.11)	(-0.29, 0.14)	0.4717	
Race											NE
White	110	-0.38 (0.11)	106	-0.14 (0.12)	-0.24 (0.15)	(-0.54, 0.07)	0.1274	-0.20 (0.14)	(-0.46, 0.07)	0.1479	
Black or African American	17	NE	25	NE	NE	NE		NE	NE		
Asian	30	NE	30	NE	NE	NE		NE	NE		
American Indian or Alaska Native	4	NE	1	NE	NE	NE		NE	NE		
Other	11	NE	10	NE	NE	NE		NE	NE		
Ethnicity											NE
Hispanic/Latino	54	NE	54	NE	NE	NE		NE	NE		
Non-hispanic/Latino	118	NE	118	NE	NE	NE		NE	NE		
Geographic region											0.3469
EU	51	-0.52 (0.22)	45	-0.09 (0.23)	-0.43 (0.27)	(-0.96, 0.09)	0.1062	-0.28 (0.21)	(-0.68, 0.13)	0.1770	
non-EU	129	-0.18 (0.16)	135	-0.07 (0.15)	-0.11 (0.21)	(-0.53, 0.30)	0.5905	-0.06 (0.12)	(-0.30, 0.18)	0.6056	
Onset of disease											NE
Paediatric	14	NE	12	NE	NE	NE		NE	NE		
Adult	166	-0.29 (0.15)	168	-0.10 (0.15)	-0.19 (0.19)	(-0.56, 0.18)	0.3160	-0.10 (0.11)	(-0.32, 0.11)	0.3593	
ADA result											NE
Negative	172	-0.26 (0.14)	160	-0.18 (0.14)	-0.08 (0.18)	(-0.44, 0.28)	0.6499	-0.05 (0.11)	(-0.26, 0.17)	0.6804	
Positive (At any time)	8	NE	20	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.7471
< 30	125	-0.33 (0.17)	132	-0.20 (0.17)	-0.14 (0.21)	(-0.54, 0.27)	0.5108	-0.07 (0.12)	(-0.32, 0.17)	0.5687	
>= 30	55	-0.13 (0.22)	48	0.12 (0.23)	-0.26 (0.31)	(-0.88, 0.37)	0.4143	-0.16 (0.20)	(-0.55, 0.23)	0.4262	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											NE
All negative/normal	58	NE	80	NE	NE	NE		NE	NE		
At least one positive/abnormal	122	NE	100	NE	NE	NE		NE	NE		

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - BILAG Global Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) N	Anifrolumab 300mg (N=180) LSMean (SE)	Placebo (N=182) N	Placebo (N=182) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-4.96 (0.51)		-4.23 (0.51)	-0.73 (0.63)	(-1.98, 0.52)	0.2502			
Week 8		-7.92 (0.55)		-6.01 (0.55)	-1.91 (0.69)	(-3.28, -0.54)	0.0063			
Week 12		-9.39 (0.57)		-8.02 (0.57)	-1.37 (0.73)	(-2.81, 0.07)	0.0621			
Week 16		-9.83 (0.55)		-8.83 (0.56)	-0.99 (0.70)	(-2.38, 0.39)	0.1594			
Week 20		-10.55 (0.55)		-8.81 (0.55)	-1.74 (0.70)	(-3.13, -0.36)	0.0134			
Week 24		-10.75 (0.57)		-8.59 (0.57)	-2.15 (0.72)	(-3.58, -0.73)	0.0031			
Week 28		-11.25 (0.56)		-8.73 (0.57)	-2.52 (0.72)	(-3.94, -1.10)	0.0005			
Week 32		-11.13 (0.57)		-8.84 (0.58)	-2.30 (0.73)	(-3.73, -0.86)	0.0018			
Week 36		-11.04 (0.58)		-9.60 (0.59)	-1.44 (0.75)	(-2.91, 0.03)	0.0549			
Week 40		-10.95 (0.60)		-9.32 (0.61)	-1.63 (0.78)	(-3.16, -0.09)	0.0377			
Week 44		-11.48 (0.57)		-9.72 (0.58)	-1.75 (0.74)	(-3.21, -0.29)	0.0188			
Week 48		-11.84 (0.57)		-10.04 (0.59)	-1.80 (0.74)	(-3.27, -0.33)	0.0162			
Week 52		-12.31 (0.57)		-10.54 (0.59)	-1.77 (0.75)	(-3.24, -0.30)	0.0185			
OVERALL	180	-10.26 (0.46)	180	-8.56 (0.46)	-1.70 (0.56)	(-2.80, -0.61)	0.0024	-0.27 (0.11)	(-0.48, -0.07)	0.0100

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - BILAG Global Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=182) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.1186
< 10 points	54	-9.71 (0.71)	52	-9.26 (0.72)	-0.45 (0.92)	(-2.27, 1.37)	0.6251	-0.09 (0.19)	(-0.47, 0.30)	0.6588	
>= 10 points	126	-10.46 (0.59)	128	-8.22 (0.59)	-2.24 (0.68)	(-3.59, -0.89)	0.0012	-0.34 (0.13)	(-0.59, -0.09)	0.0075	
OCS dose at baseline											0.8277
<10 mg/day	93	-10.72 (0.62)	98	-9.18 (0.61)	-1.55 (0.79)	(-3.11, 0.01)	0.0521	-0.26 (0.15)	(-0.54, 0.03)	0.0785	
>=10 mg/day	87	-9.63 (0.73)	82	-7.84 (0.73)	-1.79 (0.77)	(-3.31, -0.26)	0.0220	-0.26 (0.15)	(-0.57, 0.04)	0.0882	
Result of type I IFN gene signature test											0.3397
LOW	30	-9.69 (0.92)	31	-9.12 (0.90)	-0.57 (1.23)	(-3.04, 1.89)	0.6437	-0.11 (0.26)	(-0.61, 0.39)	0.6609	
HIGH	150	-10.14 (0.46)	149	-8.25 (0.47)	-1.89 (0.62)	(-3.11, -0.67)	0.0026	-0.33 (0.12)	(-0.56, -0.10)	0.0043	
Age (years)											NE
<= 65	175	-10.29 (0.47)	179	-8.60 (0.47)	-1.69 (0.56)	(-2.80, -0.59)	0.0028	-0.27 (0.11)	(-0.48, -0.06)	0.0115	
> 65	5	NE	1	NE	NE	NE		NE	NE		
Sex											0.6783
male	12	-7.26 (1.53)	12	-6.30 (1.73)	-0.96 (1.76)	(-4.61, 2.68)	0.5890	-0.16 (0.41)	(-0.97, 0.64)	0.6871	
female	168	-10.35 (0.48)	168	-8.62 (0.48)	-1.73 (0.58)	(-2.88, -0.58)	0.0032	-0.28 (0.11)	(-0.49, -0.06)	0.0119	
Race											NE
White	110	-9.80 (0.59)	106	-9.10 (0.60)	-0.71 (0.74)	(-2.16, 0.75)	0.3393	-0.11 (0.14)	(-0.38, 0.15)	0.4039	
Black or African American	17	-9.58 (1.44)	25	-7.80 (1.38)	-1.78 (1.62)	(-5.08, 1.53)	0.2821	-0.27 (0.32)	(-0.89, 0.35)	0.3979	
Asian	30	-11.32 (1.42)	30	-8.22 (1.36)	-3.10 (1.31)	(-5.73, -0.47)	0.0217	-0.40 (0.26)	(-0.91, 0.11)	0.1242	
American Indian or Alaska Native	4	NE	1	NE	NE	NE		NE	NE		
Other	11	NE	10	NE	NE	NE		NE	NE		
Ethnicity											0.5076
Hispanic/Latino	54	-12.44 (0.87)	54	-10.23 (0.86)	-2.21 (1.05)	(-4.29, -0.12)	0.0383	-0.34 (0.19)	(-0.72, 0.04)	0.0759	
Non-hispanic/Latino	118	-9.04 (0.54)	118	-7.64 (0.54)	-1.39 (0.64)	(-2.66, -0.13)	0.0313	-0.24 (0.13)	(-0.49, 0.02)	0.0695	
Geographic region											0.0845
EU	51	-10.17 (0.95)	45	-10.02 (1.03)	-0.15 (0.98)	(-2.09, 1.80)	0.8791	-0.02 (0.20)	(-0.42, 0.38)	0.9156	
non-EU	129	-10.16 (0.54)	135	-7.97 (0.53)	-2.18 (0.66)	(-3.49, -0.88)	0.0011	-0.35 (0.12)	(-0.60, -0.11)	0.0043	
Onset of disease											0.6476
Paediatric	14	-9.15 (2.30)	12	-6.22 (2.94)	-2.93 (2.64)	(-8.41, 2.56)	0.2798	-0.30 (0.40)	(-1.08, 0.47)	0.4452	
Adult	166	-10.32 (0.48)	168	-8.63 (0.47)	-1.69 (0.57)	(-2.82, -0.56)	0.0034	-0.27 (0.11)	(-0.49, -0.06)	0.0125	
ADA result											NE
Negative	172	-10.13 (0.47)	160	-8.54 (0.49)	-1.58 (0.58)	(-2.72, -0.45)	0.0062	-0.26 (0.11)	(-0.47, -0.04)	0.0197	
Positive (At any time)	8	NE	20	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.9578
< 30	125	-10.83 (0.60)	132	-8.97 (0.60)	-1.86 (0.66)	(-3.16, -0.56)	0.0052	-0.27 (0.13)	(-0.52, -0.03)	0.0298	
>= 30	55	-9.12 (0.77)	48	-7.33 (0.81)	-1.79 (1.06)	(-3.90, 0.31)	0.0934	-0.31 (0.20)	(-0.70, 0.08)	0.1143	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.5147
All negative/normal	58	-10.18 (0.77)	80	-8.91 (0.67)	-1.26 (0.97)	(-3.18, 0.65)	0.1947	-0.21 (0.17)	(-0.55, 0.13)	0.2205	
At least one positive/abnormal	122	-10.43 (0.69)	100	-8.39 (0.75)	-2.04 (0.69)	(-3.40, -0.68)	0.0034	-0.27 (0.14)	(-0.53, -0.00)	0.0469	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Tender Joint Count
Full analysis set

Visit	Anifrolumab 300mg (N=180) N	Anifrolumab 300mg (N=180) LSMean (SE)	Placebo (N=182) N	Placebo (N=182) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-1.77 (0.47)		-1.49 (0.47)	-0.28 (0.59)	(-1.44, 0.88)	0.6325			
Week 8		-3.40 (0.48)		-2.99 (0.48)	-0.42 (0.60)	(-1.60, 0.76)	0.4844			
Week 12		-4.08 (0.48)		-4.06 (0.49)	-0.02 (0.61)	(-1.21, 1.18)	0.9792			
Week 16		-4.39 (0.48)		-4.88 (0.48)	0.49 (0.60)	(-0.69, 1.68)	0.4136			
Week 20		-4.67 (0.48)		-4.98 (0.48)	0.31 (0.60)	(-0.88, 1.49)	0.6103			
Week 24		-4.92 (0.51)		-4.83 (0.51)	-0.10 (0.65)	(-1.37, 1.18)	0.8794			
Week 28		-5.24 (0.47)		-5.16 (0.48)	-0.08 (0.60)	(-1.26, 1.10)	0.8936			
Week 32		-5.01 (0.48)		-4.85 (0.49)	-0.16 (0.61)	(-1.35, 1.03)	0.7925			
Week 36		-5.24 (0.49)		-5.22 (0.50)	-0.02 (0.62)	(-1.24, 1.21)	0.9756			
Week 40		-4.90 (0.49)		-5.41 (0.50)	0.51 (0.63)	(-0.72, 1.74)	0.4183			
Week 44		-5.31 (0.47)		-5.68 (0.48)	0.37 (0.59)	(-0.79, 1.54)	0.5304			
Week 48		-5.27 (0.49)		-5.01 (0.50)	-0.26 (0.63)	(-1.50, 0.98)	0.6800			
Week 52		-4.72 (0.52)		-5.10 (0.53)	0.38 (0.68)	(-0.95, 1.72)	0.5728			
OVERALL	180	-4.53 (0.40)	180	-4.59 (0.41)	0.06 (0.48)	(-0.90, 1.01)	0.9080	0.01 (0.11)	(-0.20, 0.22)	0.9225

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Tender Joint Count - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=182) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.8924
< 10 points	54	-4.42 (0.78)	52	-4.39 (0.79)	-0.03 (1.02)	(-2.05, 1.99)	0.9749	-0.01 (0.19)	(-0.39, 0.38)	0.9770	
>= 10 points	126	-4.71 (0.46)	128	-4.84 (0.47)	0.12 (0.54)	(-0.93, 1.18)	0.8184	0.02 (0.13)	(-0.22, 0.27)	0.8518	
OCS dose at baseline											0.8303
<10 mg/day	93	-4.27 (0.55)	98	-4.41 (0.55)	0.14 (0.71)	(-1.26, 1.54)	0.8468	0.03 (0.14)	(-0.26, 0.31)	0.8614	
>=10 mg/day	87	-5.13 (0.60)	82	-5.06 (0.61)	-0.07 (0.62)	(-1.30, 1.17)	0.9169	-0.01 (0.15)	(-0.31, 0.29)	0.9397	
Result of type I IFN gene signature test											0.5977
LOW	30	-5.27 (1.07)	31	-4.62 (1.05)	-0.64 (1.42)	(-3.49, 2.21)	0.6541	-0.11 (0.26)	(-0.61, 0.39)	0.6732	
HIGH	150	-4.85 (0.37)	149	-5.01 (0.38)	0.16 (0.50)	(-0.84, 1.15)	0.7579	0.03 (0.12)	(-0.19, 0.26)	0.7699	
Age (years)											NE
<= 65	175	-4.51 (0.41)	179	-4.56 (0.41)	0.06 (0.49)	(-0.91, 1.02)	0.9103	0.01 (0.11)	(-0.20, 0.22)	0.9246	
> 65	5	NE	1	NE	NE	NE		NE	NE		
Sex											NE
male	12	NE	12	NE	NE	NE		NE	NE		
female	168	-4.57 (0.42)	168	-4.65 (0.43)	0.08 (0.51)	(-0.93, 1.08)	0.8789	0.01 (0.11)	(-0.20, 0.23)	0.8971	
Race											NE
White	110	-5.32 (0.50)	106	-6.31 (0.52)	0.99 (0.63)	(-0.24, 2.23)	0.1142	0.19 (0.14)	(-0.08, 0.45)	0.1719	
Black or African American	17	NE	25	NE	NE	NE		NE	NE		
Asian	30	-2.26 (0.71)	30	-2.23 (0.71)	-0.03 (0.81)	(-1.67, 1.61)	0.9719	-0.01 (0.26)	(-0.51, 0.50)	0.9776	
American Indian or Alaska Native	4	NE	1	NE	NE	NE		NE	NE		
Other	11	NE	10	NE	NE	NE		NE	NE		
Ethnicity											0.5000
Hispanic/Latino	54	-5.67 (0.81)	54	-5.34 (0.79)	-0.33 (0.97)	(-2.26, 1.60)	0.7367	-0.06 (0.19)	(-0.43, 0.32)	0.7736	
Non-hispanic/Latino	118	-4.20 (0.47)	118	-4.64 (0.49)	0.43 (0.57)	(-0.69, 1.56)	0.4495	0.08 (0.13)	(-0.17, 0.34)	0.5247	
Geographic region											0.7631
EU	51	-6.04 (0.54)	45	-6.05 (0.59)	0.02 (0.63)	(-1.23, 1.27)	0.9778	0.00 (0.20)	(-0.40, 0.41)	0.9827	
non-EU	129	-4.18 (0.48)	135	-4.45 (0.48)	0.28 (0.58)	(-0.87, 1.42)	0.6368	0.05 (0.12)	(-0.19, 0.29)	0.6832	
Onset of disease											NE
Paediatric	14	NE	12	NE	NE	NE		NE	NE		
Adult	166	-4.80 (0.42)	168	-4.77 (0.42)	-0.03 (0.51)	(-1.03, 0.98)	0.9560	-0.01 (0.11)	(-0.22, 0.21)	0.9627	
ADA result											NE
Negative	172	-4.55 (0.41)	160	-4.61 (0.43)	0.07 (0.51)	(-0.93, 1.06)	0.8977	0.01 (0.11)	(-0.20, 0.23)	0.9135	
Positive (At any time)	8	NE	20	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.9923
< 30	125	-4.66 (0.48)	132	-4.63 (0.49)	-0.03 (0.54)	(-1.11, 1.04)	0.9497	-0.01 (0.12)	(-0.25, 0.24)	0.9606	
>= 30	55	-4.56 (0.76)	48	-4.53 (0.79)	-0.02 (1.02)	(-2.05, 2.00)	0.9819	-0.00 (0.20)	(-0.39, 0.38)	0.9833	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.9538
All negative/normal	58	-5.29 (0.74)	80	-5.29 (0.65)	-0.01 (0.93)	(-1.85, 1.83)	0.9930	-0.00 (0.17)	(-0.34, 0.34)	0.9934	
At least one positive/abnormal	122	-4.21 (0.49)	100	-4.26 (0.55)	0.05 (0.51)	(-0.95, 1.06)	0.9170	0.01 (0.13)	(-0.25, 0.27)	0.9424	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Swollen Joint Count
Full analysis set

Visit	Anifrolumab 300mg (N=180) N	Anifrolumab 300mg (N=180) LSMean (SE)	Placebo (N=182) N	Placebo (N=182) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-2.29 (0.32)		-2.17 (0.32)	-0.12 (0.40)	(-0.90, 0.67)	0.7696			
Week 8		-3.06 (0.32)		-3.62 (0.32)	0.57 (0.40)	(-0.23, 1.36)	0.1611			
Week 12		-3.44 (0.34)		-4.02 (0.34)	0.58 (0.43)	(-0.27, 1.43)	0.1774			
Week 16		-3.57 (0.35)		-4.29 (0.35)	0.72 (0.45)	(-0.16, 1.59)	0.1097			
Week 20		-3.92 (0.35)		-4.59 (0.35)	0.67 (0.45)	(-0.22, 1.56)	0.1390			
Week 24		-3.96 (0.34)		-4.57 (0.35)	0.60 (0.44)	(-0.26, 1.46)	0.1700			
Week 28		-4.19 (0.33)		-4.47 (0.33)	0.28 (0.41)	(-0.54, 1.09)	0.5042			
Week 32		-3.88 (0.35)		-4.56 (0.35)	0.69 (0.45)	(-0.19, 1.56)	0.1239			
Week 36		-4.02 (0.35)		-4.74 (0.36)	0.72 (0.45)	(-0.17, 1.61)	0.1111			
Week 40		-3.80 (0.37)		-4.72 (0.38)	0.92 (0.48)	(-0.03, 1.88)	0.0573			
Week 44		-4.08 (0.37)		-4.56 (0.38)	0.49 (0.48)	(-0.46, 1.44)	0.3128			
Week 48		-4.16 (0.38)		-4.37 (0.39)	0.22 (0.50)	(-0.76, 1.19)	0.6632			
Week 52		-4.15 (0.36)		-4.56 (0.37)	0.42 (0.47)	(-0.51, 1.34)	0.3755			
OVERALL	180	-3.73 (0.29)	180	-4.25 (0.29)	0.52 (0.35)	(-0.17, 1.21)	0.1406	0.13 (0.11)	(-0.07, 0.34)	0.2082

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Swollen Joint Count - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=182) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.5210
< 10 points	54	-3.68 (0.56)	52	-4.55 (0.56)	0.87 (0.73)	(-0.59, 2.32)	0.2400	0.21 (0.19)	(-0.17, 0.59)	0.2789	
>= 10 points	126	-3.63 (0.33)	128	-3.96 (0.34)	0.33 (0.39)	(-0.44, 1.11)	0.3999	0.09 (0.13)	(-0.16, 0.33)	0.4825	
OCS dose at baseline											0.9836
<10 mg/day	93	-3.77 (0.42)	98	-4.19 (0.41)	0.42 (0.54)	(-0.64, 1.48)	0.4370	0.10 (0.14)	(-0.18, 0.39)	0.4783	
>=10 mg/day	87	-3.81 (0.40)	82	-4.21 (0.40)	0.40 (0.42)	(-0.42, 1.23)	0.3335	0.11 (0.15)	(-0.19, 0.41)	0.4747	
Result of type I IFN gene signature test											0.2140
LOW	30	-4.59 (0.74)	31	-3.96 (0.73)	-0.63 (1.00)	(-2.63, 1.37)	0.5280	-0.15 (0.26)	(-0.66, 0.35)	0.5479	
HIGH	150	-3.59 (0.27)	149	-4.28 (0.28)	0.69 (0.37)	(-0.04, 1.42)	0.0647	0.20 (0.12)	(-0.02, 0.43)	0.0778	
Age (years)											NE
<= 65	175	-3.66 (0.29)	179	-4.23 (0.29)	0.58 (0.35)	(-0.11, 1.27)	0.1019	0.15 (0.11)	(-0.06, 0.36)	0.1623	
> 65	5	NE	1	NE	NE	NE		NE	NE		
Sex											0.7509
male	12	-3.47 (0.67)	12	-3.64 (0.67)	0.17 (0.95)	(-1.95, 2.28)	0.8634	0.07 (0.41)	(-0.73, 0.87)	0.8648	
female	168	-3.79 (0.30)	168	-4.28 (0.30)	0.49 (0.37)	(-0.24, 1.22)	0.1860	0.12 (0.11)	(-0.09, 0.34)	0.2556	
Race											NE
White	110	-4.00 (0.35)	106	-5.25 (0.36)	1.25 (0.45)	(0.37, 2.13)	0.0057	0.33 (0.14)	(0.06, 0.60)	0.0151	
Black or African American	17	-5.10 (1.19)	25	-2.94 (1.08)	-2.16 (1.43)	(-5.14, 0.82)	0.1465	-0.41 (0.32)	(-1.03, 0.22)	0.2015	
Asian	30	-2.27 (0.73)	30	-2.42 (0.71)	0.15 (0.80)	(-1.62, 1.92)	0.8549	0.04 (0.26)	(-0.47, 0.54)	0.8849	
American Indian or Alaska Native	4	NE	1	NE	NE	NE		NE	NE		
Other	11	NE	10	NE	NE	NE		NE	NE		
Ethnicity											0.5109
Hispanic/Latino	54	-3.64 (0.55)	54	-4.73 (0.54)	1.09 (0.68)	(-0.26, 2.44)	0.1134	0.27 (0.19)	(-0.11, 0.65)	0.1637	
Non-hispanic/Latino	118	-3.81 (0.33)	118	-4.38 (0.34)	0.57 (0.41)	(-0.23, 1.37)	0.1639	0.16 (0.13)	(-0.10, 0.41)	0.2311	
Geographic region											0.8763
EU	51	-3.82 (0.43)	45	-4.23 (0.46)	0.41 (0.49)	(-0.57, 1.39)	0.4071	0.13 (0.20)	(-0.27, 0.53)	0.5176	
non-EU	129	-3.75 (0.35)	135	-4.27 (0.35)	0.51 (0.42)	(-0.33, 1.35)	0.2300	0.13 (0.12)	(-0.11, 0.37)	0.3003	
Onset of disease											NE
Paediatric	14	NE	12	NE	NE	NE		NE	NE		
Adult	166	-3.80 (0.31)	168	-4.32 (0.31)	0.51 (0.37)	(-0.22, 1.25)	0.1705	0.13 (0.11)	(-0.09, 0.34)	0.2375	
ADA result											NE
Negative	172	-3.79 (0.29)	160	-4.38 (0.30)	0.59 (0.36)	(-0.13, 1.31)	0.1056	0.15 (0.11)	(-0.06, 0.37)	0.1620	
Positive (At any time)	8	NE	20	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.2356
< 30	125	-3.21 (0.35)	132	-3.94 (0.36)	0.73 (0.39)	(-0.04, 1.50)	0.0631	0.18 (0.13)	(-0.06, 0.43)	0.1456	
>= 30	55	-4.54 (0.55)	48	-4.27 (0.57)	-0.27 (0.75)	(-1.75, 1.21)	0.7192	-0.07 (0.20)	(-0.45, 0.32)	0.7364	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.4514
All negative/normal	58	-4.14 (0.52)	80	-4.92 (0.45)	0.78 (0.66)	(-0.53, 2.09)	0.2424	0.19 (0.17)	(-0.15, 0.53)	0.2669	
At least one positive/abnormal	122	-3.79 (0.36)	100	-3.99 (0.40)	0.20 (0.38)	(-0.55, 0.96)	0.5971	0.05 (0.13)	(-0.21, 0.31)	0.7088	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Mental Component Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=182) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 8		1.60 (0.76)		-0.12 (0.76)	1.72 (0.95)	(-0.15, 3.59)	0.0712			
Week 16		1.36 (0.76)		1.42 (0.78)	-0.06 (0.96)	(-1.95, 1.83)	0.9511			
Week 24		1.46 (0.83)		-0.36 (0.83)	1.83 (1.06)	(-0.26, 3.92)	0.0867			
Week 32		2.55 (0.79)		1.06 (0.81)	1.50 (1.01)	(-0.49, 3.49)	0.1401			
Week 40		2.24 (0.80)		1.21 (0.83)	1.03 (1.03)	(-1.00, 3.06)	0.3186			
Week 48		1.86 (0.80)		0.47 (0.84)	1.39 (1.04)	(-0.65, 3.44)	0.1806			
Week 52		1.95 (0.87)		0.39 (0.90)	1.57 (1.15)	(-0.69, 3.82)	0.1729			
OVERALL	170	1.86 (0.65)	169	0.58 (0.66)	1.28 (0.78)	(-0.25, 2.81)	0.1008	0.15 (0.11)	(-0.06, 0.36)	0.1703

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Mental Component Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=182) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.0058
< 10 points	52	4.78 (1.09)	49	0.24 (1.12)	4.54 (1.42)	(1.72, 7.36)	0.0019	0.57 (0.20)	(0.17, 0.97)	0.0049	
>= 10 points	118	0.02 (0.81)	120	0.15 (0.81)	-0.13 (0.92)	(-1.94, 1.69)	0.8912	-0.01 (0.13)	(-0.27, 0.24)	0.9125	
OCS dose at baseline											0.7455
<10 mg/day	91	2.10 (0.76)	94	1.07 (0.78)	1.03 (0.97)	(-0.88, 2.94)	0.2888	0.14 (0.15)	(-0.15, 0.43)	0.3460	
>=10 mg/day	79	1.59 (1.21)	75	0.04 (1.20)	1.55 (1.29)	(-0.99, 4.09)	0.2293	0.15 (0.16)	(-0.17, 0.46)	0.3648	
Result of type I IFN gene signature test											0.8082
LOW	29	2.84 (1.44)	29	1.10 (1.40)	1.74 (1.96)	(-2.20, 5.68)	0.3798	0.22 (0.26)	(-0.29, 0.74)	0.3953	
HIGH	141	1.77 (0.64)	140	0.56 (0.65)	1.22 (0.86)	(-0.48, 2.91)	0.1586	0.16 (0.12)	(-0.08, 0.39)	0.1845	
Age (years)											NE
<= 65	165	1.71 (0.67)	169	0.52 (0.67)	1.18 (0.79)	(-0.37, 2.73)	0.1337	0.14 (0.11)	(-0.08, 0.35)	0.2118	
> 65	5	NE	0	NE	NE	NE		NE	NE		
Sex											0.6351
male	11	6.28 (5.25)	12	6.95 (7.33)	-0.66 (4.13)	(-9.28, 7.95)	0.8741	-0.03 (0.42)	(-0.85, 0.79)	0.9444	
female	159	1.66 (0.65)	157	0.33 (0.66)	1.33 (0.78)	(-0.20, 2.87)	0.0885	0.16 (0.11)	(-0.06, 0.38)	0.1511	
Race											NE
White	102	1.94 (0.86)	99	1.76 (0.89)	0.17 (1.06)	(-1.92, 2.27)	0.8713	0.02 (0.14)	(-0.26, 0.30)	0.8897	
Black or African American	16	2.26 (2.27)	22	-1.44 (2.29)	3.70 (2.74)	(-1.87, 9.26)	0.1864	0.36 (0.33)	(-0.29, 1.01)	0.2795	
Asian	29	-2.60 (1.72)	30	-3.77 (1.69)	1.18 (1.54)	(-1.91, 4.26)	0.4473	0.13 (0.26)	(-0.39, 0.64)	0.6304	
American Indian or Alaska Native	4	NE	1	NE	NE	NE		NE	NE		
Other	11	0.91 (3.42)	10	-1.32 (3.62)	2.23 (4.11)	(-6.47, 10.93)	0.5945	0.19 (0.44)	(-0.67, 1.05)	0.6678	
Ethnicity											0.5466
Hispanic/Latino	53	3.51 (1.27)	53	1.57 (1.23)	1.93 (1.54)	(-1.13, 5.00)	0.2133	0.21 (0.19)	(-0.17, 0.59)	0.2781	
Non-hispanic/Latino	109	0.98 (0.80)	109	0.13 (0.82)	0.84 (0.94)	(-1.02, 2.70)	0.3720	0.10 (0.14)	(-0.17, 0.36)	0.4646	
Geographic region											0.4113
EU	47	1.46 (1.28)	40	1.13 (1.40)	0.33 (1.38)	(-2.41, 3.08)	0.8091	0.04 (0.22)	(-0.38, 0.46)	0.8610	
non-EU	123	1.90 (0.77)	129	0.20 (0.77)	1.70 (0.94)	(-0.14, 3.55)	0.0704	0.20 (0.13)	(-0.05, 0.44)	0.1213	
Onset of disease											0.2514
Paediatric	12	-0.38 (2.47)	11	-4.79 (3.08)	4.42 (2.71)	(-1.33, 10.16)	0.1228	0.45 (0.42)	(-0.38, 1.28)	0.2846	
Adult	158	1.89 (0.69)	158	0.72 (0.69)	1.17 (0.82)	(-0.45, 2.78)	0.1568	0.13 (0.11)	(-0.09, 0.35)	0.2340	
ADA result											0.4849
Negative	163	1.85 (0.67)	150	0.83 (0.70)	1.03 (0.81)	(-0.57, 2.62)	0.2075	0.12 (0.11)	(-0.10, 0.34)	0.2910	
Positive (At any time)	7	0.60 (4.58)	19	-3.32 (3.12)	3.92 (4.06)	(-4.67, 12.51)	0.3486	0.29 (0.44)	(-0.58, 1.16)	0.5185	
BMI (kg/m2) at enrolment											0.9441
< 30	118	1.24 (0.84)	123	-0.05 (0.85)	1.29 (0.92)	(-0.52, 3.11)	0.1622	0.14 (0.13)	(-0.11, 0.39)	0.2813	
>= 30	52	2.59 (1.06)	46	1.42 (1.10)	1.18 (1.41)	(-1.64, 3.99)	0.4084	0.15 (0.20)	(-0.24, 0.55)	0.4451	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.0422
All negative/normal	56	3.50 (0.87)	76	0.23 (0.78)	3.26 (1.09)	(1.09, 5.43)	0.0035	0.49 (0.18)	(0.14, 0.84)	0.0066	
At least one positive/abnormal	114	1.03 (1.06)	93	0.88 (1.17)	0.15 (1.07)	(-1.96, 2.26)	0.8888	0.01 (0.14)	(-0.26, 0.29)	0.9246	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Physical Component Score
Full analysis set

	Anifrolumab 300mg (N=180)		Placebo (N=182)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 8		3.33 (0.57)		1.89 (0.57)	1.44 (0.69)	(0.08, 2.81)	0.0387			
Week 16		3.96 (0.59)		3.30 (0.60)	0.66 (0.74)	(-0.79, 2.11)	0.3708			
Week 24		4.81 (0.60)		3.43 (0.60)	1.38 (0.75)	(-0.10, 2.85)	0.0671			
Week 32		4.04 (0.59)		3.18 (0.60)	0.86 (0.74)	(-0.60, 2.32)	0.2488			
Week 40		4.18 (0.62)		3.55 (0.63)	0.62 (0.78)	(-0.91, 2.16)	0.4260			
Week 48		4.39 (0.67)		2.43 (0.69)	1.95 (0.87)	(0.25, 3.66)	0.0250			
Week 52		3.93 (0.65)		2.83 (0.68)	1.11 (0.85)	(-0.56, 2.77)	0.1910			
OVERALL	170	4.09 (0.52)	169	2.94 (0.52)	1.15 (0.61)	(-0.06, 2.35)	0.0625	0.17 (0.11)	(-0.04, 0.38)	0.1216

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Physical Component Score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=180)		Placebo (N=182)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											0.9256
< 10 points	52	4.55 (0.88)	49	3.35 (0.92)	1.20 (1.15)	(-1.09, 3.49)	0.2995	0.19 (0.20)	(-0.20, 0.58)	0.3488	
>= 10 points	118	4.09 (0.65)	120	3.02 (0.64)	1.07 (0.74)	(-0.37, 2.52)	0.1453	0.15 (0.13)	(-0.10, 0.41)	0.2415	
OCS dose at baseline											0.9951
<10 mg/day	91	3.56 (0.62)	94	2.40 (0.62)	1.17 (0.78)	(-0.38, 2.71)	0.1376	0.19 (0.15)	(-0.09, 0.48)	0.1864	
>=10 mg/day	79	4.52 (0.95)	75	3.36 (0.95)	1.16 (0.99)	(-0.79, 3.11)	0.2414	0.14 (0.16)	(-0.18, 0.46)	0.3891	
Result of type I IFN gene signature test											0.8618
LOW	29	4.54 (1.11)	29	3.63 (1.09)	0.91 (1.48)	(-2.06, 3.88)	0.5397	0.15 (0.26)	(-0.36, 0.67)	0.5644	
HIGH	141	3.96 (0.51)	140	2.77 (0.52)	1.20 (0.68)	(-0.15, 2.54)	0.0804	0.20 (0.12)	(-0.04, 0.43)	0.1004	
Age (years)											NE
<= 65	165	4.07 (0.53)	169	2.90 (0.53)	1.17 (0.62)	(-0.05, 2.39)	0.0591	0.17 (0.11)	(-0.04, 0.39)	0.1183	
> 65	5	NE	0	NE	NE	NE		NE	NE		
Sex											0.0039
male	11	4.29 (2.55)	12	9.85 (2.91)	-5.55 (2.39)	(-10.60, -0.51)	0.0328	-0.57 (0.43)	(-1.41, 0.27)	0.1805	
female	159	4.25 (0.52)	157	2.68 (0.53)	1.58 (0.63)	(0.34, 2.81)	0.0126	0.24 (0.11)	(0.02, 0.46)	0.0360	
Race											NE
White	102	4.20 (0.66)	99	4.18 (0.68)	0.01 (0.81)	(-1.59, 1.61)	0.9863	0.00 (0.14)	(-0.27, 0.28)	0.9882	
Black or African American	16	4.10 (1.86)	22	2.80 (1.84)	1.29 (2.09)	(-2.96, 5.55)	0.5395	0.16 (0.33)	(-0.49, 0.80)	0.6371	
Asian	29	0.99 (1.40)	30	-1.19 (1.41)	2.17 (1.24)	(-0.31, 4.66)	0.0851	0.28 (0.26)	(-0.23, 0.79)	0.2822	
American Indian or Alaska Native	4	NE	1	NE	NE	NE		NE	NE		
Other	11	6.53 (1.60)	10	2.48 (1.72)	4.04 (1.95)	(-0.15, 8.24)	0.0578	0.72 (0.45)	(-0.17, 1.61)	0.1111	
Ethnicity											0.0487
Hispanic/Latino	53	6.00 (0.96)	53	3.23 (0.93)	2.77 (1.13)	(0.52, 5.01)	0.0164	0.40 (0.20)	(0.02, 0.78)	0.0416	
Non-hispanic/Latino	109	2.88 (0.62)	109	2.78 (0.64)	0.11 (0.73)	(-1.34, 1.55)	0.8849	0.02 (0.14)	(-0.25, 0.28)	0.9054	
Geographic region											0.0392
EU	47	4.09 (1.07)	40	5.10 (1.16)	-1.01 (1.16)	(-3.31, 1.29)	0.3848	-0.14 (0.22)	(-0.56, 0.29)	0.5277	
non-EU	123	4.29 (0.60)	129	2.48 (0.60)	1.81 (0.73)	(0.37, 3.24)	0.0138	0.27 (0.13)	(0.02, 0.51)	0.0361	
Onset of disease											0.1368
Paediatric	12	1.08 (3.11)	11	-5.20 (3.96)	6.28 (3.49)	(-1.19, 13.75)	0.0932	0.51 (0.43)	(-0.33, 1.34)	0.2342	
Adult	158	4.11 (0.52)	158	3.11 (0.52)	1.00 (0.62)	(-0.22, 2.23)	0.1089	0.15 (0.11)	(-0.07, 0.37)	0.1779	
ADA result											NE
Negative	163	4.05 (0.53)	150	3.07 (0.56)	0.97 (0.64)	(-0.30, 2.24)	0.1323	0.14 (0.11)	(-0.08, 0.36)	0.2086	
Positive (At any time)	7	NE	19	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.2214
< 30	118	3.58 (0.68)	123	2.81 (0.69)	0.78 (0.74)	(-0.68, 2.23)	0.2961	0.10 (0.13)	(-0.15, 0.36)	0.4229	
>= 30	52	5.68 (0.81)	46	3.29 (0.85)	2.39 (1.09)	(0.22, 4.56)	0.0314	0.41 (0.20)	(0.01, 0.81)	0.0468	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.6096
All negative/normal	56	4.37 (0.77)	76	3.65 (0.69)	0.72 (0.97)	(-1.20, 2.65)	0.4579	0.12 (0.18)	(-0.22, 0.47)	0.4880	
At least one positive/abnormal	114	4.12 (0.81)	93	2.75 (0.89)	1.37 (0.81)	(-0.22, 2.96)	0.0916	0.16 (0.14)	(-0.12, 0.43)	0.2596	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute General Health Score
Full analysis set

	Anifrolumab 300mg (N=180)		Placebo (N=182)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 8		2.68 (0.51)		1.14 (0.50)	1.54 (0.61)	(0.34, 2.74)	0.0120			
Week 16		2.73 (0.56)		2.26 (0.56)	0.47 (0.70)	(-0.91, 1.85)	0.5042			
Week 24		2.91 (0.57)		1.40 (0.57)	1.51 (0.72)	(0.10, 2.92)	0.0365			
Week 32		3.24 (0.59)		1.78 (0.60)	1.45 (0.76)	(-0.04, 2.95)	0.0570			
Week 40		2.78 (0.59)		1.92 (0.60)	0.86 (0.76)	(-0.63, 2.34)	0.2572			
Week 48		3.10 (0.59)		1.94 (0.61)	1.16 (0.76)	(-0.34, 2.66)	0.1300			
Week 52		2.83 (0.61)		1.34 (0.63)	1.48 (0.79)	(-0.07, 3.04)	0.0618			
OVERALL	170	2.89 (0.49)	169	1.68 (0.49)	1.21 (0.59)	(0.05, 2.36)	0.0401	0.19 (0.11)	(-0.02, 0.40)	0.0830

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute General Health Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=182) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.3631
< 10 points	52	4.05 (0.73)	49	2.11 (0.75)	1.95 (0.95)	(0.07, 3.83)	0.0426	0.37 (0.20)	(-0.03, 0.76)	0.0672	
>= 10 points	118	2.41 (0.63)	120	1.55 (0.63)	0.86 (0.73)	(-0.58, 2.30)	0.2418	0.12 (0.13)	(-0.13, 0.38)	0.3358	
OCS dose at baseline											0.7527
<10 mg/day	91	2.78 (0.62)	94	1.47 (0.62)	1.32 (0.79)	(-0.25, 2.88)	0.0989	0.22 (0.15)	(-0.07, 0.51)	0.1355	
>=10 mg/day	79	2.91 (0.84)	75	1.96 (0.83)	0.94 (0.89)	(-0.81, 2.69)	0.2900	0.13 (0.16)	(-0.19, 0.44)	0.4289	
Result of type I IFN gene signature test											0.4804
LOW	29	3.62 (1.12)	29	3.39 (1.10)	0.23 (1.50)	(-2.79, 3.25)	0.8778	0.04 (0.26)	(-0.48, 0.55)	0.8839	
HIGH	141	2.51 (0.48)	140	1.12 (0.48)	1.39 (0.64)	(0.12, 2.65)	0.0314	0.24 (0.12)	(0.01, 0.48)	0.0421	
Age (years)											NE
<= 65	165	2.84 (0.50)	169	1.69 (0.50)	1.15 (0.59)	(-0.02, 2.32)	0.0540	0.18 (0.11)	(-0.04, 0.39)	0.1050	
> 65	5	NE	0	NE	NE	NE		NE	NE		
Sex											0.0052
male	11	4.41 (2.06)	12	8.49 (2.19)	-4.07 (1.92)	(-8.09, -0.06)	0.0471	-0.54 (0.43)	(-1.38, 0.29)	0.2034	
female	159	3.02 (0.50)	157	1.48 (0.51)	1.55 (0.61)	(0.35, 2.74)	0.0116	0.24 (0.11)	(0.02, 0.46)	0.0318	
Race											NE
White	102	2.95 (0.61)	99	2.62 (0.63)	0.33 (0.77)	(-1.19, 1.85)	0.6649	0.05 (0.14)	(-0.22, 0.33)	0.7041	
Black or African American	16	3.60 (1.57)	22	0.94 (1.53)	2.66 (1.80)	(-1.00, 6.32)	0.1489	0.38 (0.33)	(-0.27, 1.03)	0.2495	
Asian	29	1.34 (1.35)	30	0.53 (1.35)	0.81 (1.31)	(-1.81, 3.42)	0.5402	0.11 (0.26)	(-0.40, 0.62)	0.6783	
American Indian or Alaska Native	4	NE	1	NE	NE	NE		NE	NE		
Other	11	4.28 (1.94)	10	-1.87 (2.08)	6.15 (2.45)	(0.99, 11.30)	0.0220	0.91 (0.46)	(-0.00, 1.82)	0.0503	
Ethnicity											0.0213
Hispanic/Latino	53	4.76 (0.89)	53	1.63 (0.87)	3.13 (1.08)	(0.98, 5.28)	0.0047	0.48 (0.20)	(0.10, 0.87)	0.0142	
Non-hispanic/Latino	109	1.86 (0.59)	109	1.71 (0.61)	0.15 (0.71)	(-1.25, 1.55)	0.8301	0.02 (0.14)	(-0.24, 0.29)	0.8578	
Geographic region											0.0557
EU	47	2.44 (0.98)	40	3.08 (1.07)	-0.65 (1.06)	(-2.76, 1.47)	0.5447	-0.10 (0.22)	(-0.52, 0.33)	0.6582	
non-EU	123	3.25 (0.57)	129	1.47 (0.57)	1.78 (0.69)	(0.41, 3.15)	0.0108	0.28 (0.13)	(0.03, 0.53)	0.0279	
Onset of disease											0.0475
Paediatric	12	2.86 (1.78)	11	-2.36 (2.11)	5.21 (2.03)	(0.98, 9.45)	0.0185	0.76 (0.44)	(-0.09, 1.62)	0.0793	
Adult	158	2.81 (0.51)	158	1.80 (0.51)	1.02 (0.61)	(-0.19, 2.22)	0.0979	0.16 (0.11)	(-0.06, 0.38)	0.1593	
ADA result											NE
Negative	163	2.81 (0.50)	150	1.91 (0.52)	0.90 (0.62)	(-0.31, 2.11)	0.1454	0.14 (0.11)	(-0.08, 0.36)	0.2177	
Positive (At any time)	7	NE	19	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.5087
< 30	118	2.26 (0.63)	123	1.36 (0.64)	0.91 (0.71)	(-0.48, 2.30)	0.2001	0.13 (0.13)	(-0.12, 0.38)	0.3128	
>= 30	52	4.23 (0.81)	46	2.47 (0.84)	1.76 (1.08)	(-0.39, 3.90)	0.1068	0.30 (0.20)	(-0.10, 0.70)	0.1365	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.5016
All negative/normal	56	4.29 (0.68)	76	2.43 (0.61)	1.86 (0.86)	(0.16, 3.56)	0.0320	0.36 (0.18)	(0.01, 0.70)	0.0450	
At least one positive/abnormal	114	2.53 (0.76)	93	1.46 (0.84)	1.08 (0.80)	(-0.50, 2.65)	0.1786	0.13 (0.14)	(-0.14, 0.41)	0.3463	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Mental Health Score
Full analysis set

	Anifrolumab 300mg (N=180)		Placebo (N=182)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 8		2.56 (0.71)		1.06 (0.70)	1.50 (0.88)	(-0.22, 3.23)	0.0876			
Week 16		2.15 (0.72)		2.04 (0.74)	0.11 (0.92)	(-1.70, 1.91)	0.9073			
Week 24		2.20 (0.77)		0.27 (0.77)	1.93 (0.97)	(0.01, 3.85)	0.0485			
Week 32		3.54 (0.77)		1.69 (0.78)	1.86 (0.99)	(-0.09, 3.80)	0.0612			
Week 40		2.79 (0.76)		1.96 (0.78)	0.83 (0.97)	(-1.09, 2.74)	0.3977			
Week 48		2.36 (0.76)		1.40 (0.79)	0.96 (0.99)	(-0.99, 2.91)	0.3336			
Week 52		2.48 (0.82)		1.22 (0.85)	1.27 (1.08)	(-0.87, 3.40)	0.2438			
OVERALL	170	2.58 (0.61)	169	1.38 (0.62)	1.21 (0.73)	(-0.23, 2.65)	0.1003	0.15 (0.11)	(-0.06, 0.36)	0.1685

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Mental Health Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=182) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.0662
< 10 points	52	4.75 (1.04)	49	1.48 (1.07)	3.28 (1.35)	(0.60, 5.96)	0.0171	0.44 (0.20)	(0.04, 0.83)	0.0306	
>= 10 points	118	1.12 (0.76)	120	0.80 (0.77)	0.32 (0.88)	(-1.40, 2.05)	0.7126	0.04 (0.13)	(-0.22, 0.29)	0.7662	
OCS dose at baseline											0.9213
<10 mg/day	91	2.63 (0.72)	94	1.54 (0.74)	1.09 (0.92)	(-0.73, 2.91)	0.2384	0.15 (0.15)	(-0.13, 0.44)	0.2939	
>=10 mg/day	79	2.35 (1.12)	75	1.11 (1.10)	1.24 (1.20)	(-1.12, 3.60)	0.3015	0.13 (0.16)	(-0.19, 0.44)	0.4328	
Result of type I IFN gene signature test											0.4196
LOW	29	4.27 (1.34)	29	1.63 (1.29)	2.64 (1.80)	(-0.98, 6.26)	0.1497	0.37 (0.26)	(-0.15, 0.89)	0.1651	
HIGH	141	2.06 (0.60)	140	1.02 (0.61)	1.04 (0.81)	(-0.56, 2.64)	0.2014	0.14 (0.12)	(-0.09, 0.38)	0.2283	
Age (years)											NE
<= 65	165	2.40 (0.63)	169	1.29 (0.63)	1.11 (0.74)	(-0.35, 2.57)	0.1341	0.14 (0.11)	(-0.08, 0.35)	0.2108	
> 65	5	NE	0	NE	NE	NE		NE	NE		
Sex											0.6521
male	11	1.92 (5.21)	12	2.23 (6.96)	-0.31 (3.61)	(-7.88, 7.26)	0.9326	-0.01 (0.42)	(-0.83, 0.80)	0.9730	
female	159	2.38 (0.60)	157	1.03 (0.61)	1.35 (0.72)	(-0.07, 2.77)	0.0627	0.18 (0.11)	(-0.04, 0.40)	0.1151	
Race											NE
White	102	2.31 (0.83)	99	2.30 (0.85)	0.02 (1.03)	(-2.01, 2.04)	0.9872	0.00 (0.14)	(-0.27, 0.28)	0.9889	
Black or African American	16	2.37 (1.98)	22	-1.01 (1.99)	3.38 (2.43)	(-1.55, 8.31)	0.1734	0.38 (0.33)	(-0.27, 1.03)	0.2554	
Asian	29	0.38 (1.68)	30	-1.67 (1.65)	2.05 (1.48)	(-0.92, 5.01)	0.1721	0.22 (0.26)	(-0.29, 0.74)	0.3926	
American Indian or Alaska Native	4	NE	1	NE	NE	NE		NE	NE		
Other	11	5.09 (2.87)	10	0.87 (3.03)	4.22 (3.44)	(-3.07, 11.51)	0.2378	0.42 (0.44)	(-0.44, 1.29)	0.3376	
Ethnicity											0.6529
Hispanic/Latino	53	3.53 (1.18)	53	2.04 (1.16)	1.48 (1.48)	(-1.45, 4.41)	0.3173	0.17 (0.19)	(-0.21, 0.55)	0.3753	
Non-hispanic/Latino	109	2.00 (0.75)	109	1.29 (0.77)	0.71 (0.89)	(-1.04, 2.45)	0.4240	0.09 (0.14)	(-0.18, 0.35)	0.5129	
Geographic region											0.1797
EU	47	2.42 (1.22)	40	2.73 (1.34)	-0.31 (1.31)	(-2.91, 2.30)	0.8157	-0.04 (0.22)	(-0.46, 0.39)	0.8671	
non-EU	123	2.63 (0.72)	129	0.82 (0.72)	1.81 (0.88)	(0.08, 3.54)	0.0406	0.22 (0.13)	(-0.03, 0.47)	0.0788	
Onset of disease											0.8946
Paediatric	12	-2.06 (2.94)	11	-2.79 (3.74)	0.74 (3.29)	(-6.23, 7.70)	0.8251	0.06 (0.42)	(-0.76, 0.88)	0.8798	
Adult	158	2.77 (0.64)	158	1.58 (0.64)	1.19 (0.76)	(-0.31, 2.69)	0.1199	0.15 (0.11)	(-0.07, 0.37)	0.1903	
ADA result											NE
Negative	163	2.71 (0.62)	150	1.76 (0.65)	0.95 (0.75)	(-0.53, 2.44)	0.2068	0.12 (0.11)	(-0.10, 0.34)	0.2887	
Positive (At any time)	7	NE	19	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.6851
< 30	118	2.23 (0.79)	123	1.21 (0.81)	1.02 (0.87)	(-0.70, 2.74)	0.2424	0.12 (0.13)	(-0.14, 0.37)	0.3709	
>= 30	52	2.74 (0.97)	46	1.08 (1.01)	1.66 (1.32)	(-0.96, 4.28)	0.2108	0.24 (0.20)	(-0.16, 0.64)	0.2429	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.0966
All negative/normal	56	3.80 (0.83)	76	1.09 (0.74)	2.71 (1.05)	(0.64, 4.78)	0.0108	0.42 (0.18)	(0.07, 0.77)	0.0173	
At least one positive/abnormal	114	1.94 (1.00)	93	1.64 (1.10)	0.30 (1.01)	(-1.69, 2.29)	0.7684	0.03 (0.14)	(-0.25, 0.30)	0.8416	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Physical Functioning Score
Full analysis set

	Anifrolumab 300mg (N=180)		Placebo (N=182)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 8		2.73 (0.61)		1.45 (0.61)	1.28 (0.74)	(-0.19, 2.74)	0.0870			
Week 16		2.98 (0.61)		2.83 (0.62)	0.15 (0.76)	(-1.35, 1.65)	0.8437			
Week 24		4.17 (0.62)		2.87 (0.62)	1.30 (0.76)	(-0.20, 2.79)	0.0894			
Week 32		3.54 (0.63)		2.52 (0.64)	1.02 (0.79)	(-0.53, 2.57)	0.1978			
Week 40		3.87 (0.65)		3.15 (0.66)	0.72 (0.82)	(-0.90, 2.34)	0.3846			
Week 48		3.51 (0.69)		2.14 (0.72)	1.38 (0.90)	(-0.40, 3.15)	0.1279			
Week 52		3.24 (0.69)		2.73 (0.71)	0.51 (0.89)	(-1.24, 2.25)	0.5690			
OVERALL	170	3.43 (0.55)	169	2.53 (0.56)	0.91 (0.65)	(-0.38, 2.19)	0.1658	0.13 (0.11)	(-0.09, 0.34)	0.2485

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Physical Functioning Score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=180)		Placebo (N=182)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											0.4283
< 10 points	52	4.87 (0.93)	49	3.16 (0.97)	1.71 (1.23)	(-0.74, 4.16)	0.1698	0.25 (0.20)	(-0.14, 0.64)	0.2081	
>= 10 points	118	2.91 (0.69)	120	2.36 (0.69)	0.55 (0.78)	(-0.99, 2.09)	0.4838	0.07 (0.13)	(-0.18, 0.33)	0.5738	
OCS dose at baseline											0.7643
<10 mg/day	91	3.05 (0.64)	94	2.28 (0.65)	0.77 (0.81)	(-0.83, 2.38)	0.3430	0.12 (0.15)	(-0.16, 0.41)	0.4009	
>=10 mg/day	79	3.88 (1.00)	75	2.71 (0.99)	1.17 (1.06)	(-0.92, 3.27)	0.2691	0.13 (0.16)	(-0.18, 0.45)	0.4069	
Result of type I IFN gene signature test											0.6419
LOW	29	4.09 (1.28)	29	2.50 (1.26)	1.59 (1.72)	(-1.88, 5.05)	0.3608	0.23 (0.26)	(-0.29, 0.75)	0.3851	
HIGH	141	3.46 (0.53)	140	2.73 (0.54)	0.72 (0.71)	(-0.68, 2.12)	0.3113	0.11 (0.12)	(-0.12, 0.35)	0.3414	
Age (years)											NE
<= 65	165	3.41 (0.55)	169	2.44 (0.56)	0.96 (0.65)	(-0.32, 2.25)	0.1413	0.13 (0.11)	(-0.08, 0.35)	0.2221	
> 65	5	NE	0	NE	NE	NE		NE	NE		
Sex											0.0912
male	11	5.96 (2.78)	12	9.14 (3.24)	-3.17 (2.51)	(-8.46, 2.11)	0.2229	-0.30 (0.42)	(-1.12, 0.53)	0.4799	
female	159	3.47 (0.56)	157	2.25 (0.56)	1.22 (0.67)	(-0.10, 2.53)	0.0694	0.17 (0.11)	(-0.05, 0.39)	0.1267	
Race											NE
White	102	3.77 (0.71)	99	3.81 (0.73)	-0.04 (0.88)	(-1.77, 1.69)	0.9651	-0.01 (0.14)	(-0.28, 0.27)	0.9699	
Black or African American	16	2.62 (2.26)	22	3.92 (2.32)	-1.31 (2.66)	(-6.73, 4.12)	0.6274	-0.13 (0.33)	(-0.77, 0.52)	0.7021	
Asian	29	-0.62 (1.24)	30	-2.40 (1.23)	1.78 (1.10)	(-0.43, 4.00)	0.1121	0.26 (0.26)	(-0.25, 0.78)	0.3149	
American Indian or Alaska Native	4	NE	1	NE	NE	NE		NE	NE		
Other	11	5.47 (1.83)	10	1.37 (1.98)	4.09 (2.16)	(-0.46, 8.65)	0.0750	0.64 (0.45)	(-0.25, 1.52)	0.1572	
Ethnicity											0.2560
Hispanic/Latino	53	5.37 (1.08)	53	3.46 (1.04)	1.91 (1.28)	(-0.62, 4.45)	0.1378	0.25 (0.20)	(-0.14, 0.63)	0.2069	
Non-hispanic/Latino	109	2.21 (0.64)	109	1.98 (0.65)	0.23 (0.75)	(-1.25, 1.71)	0.7599	0.03 (0.14)	(-0.23, 0.30)	0.8016	
Geographic region											0.1144
EU	47	5.26 (1.28)	40	6.33 (1.38)	-1.07 (1.37)	(-3.80, 1.65)	0.4364	-0.12 (0.22)	(-0.54, 0.30)	0.5727	
non-EU	123	3.11 (0.61)	129	1.72 (0.61)	1.39 (0.74)	(-0.07, 2.85)	0.0625	0.20 (0.13)	(-0.05, 0.45)	0.1115	
Onset of disease											0.7797
Paediatric	12	-1.90 (3.25)	11	-1.88 (4.18)	-0.03 (3.63)	(-7.64, 7.59)	0.9940	-0.00 (0.42)	(-0.82, 0.82)	0.9959	
Adult	158	3.65 (0.56)	158	2.64 (0.56)	1.01 (0.66)	(-0.30, 2.31)	0.1305	0.14 (0.11)	(-0.08, 0.36)	0.2050	
ADA result											0.7782
Negative	163	3.52 (0.56)	150	2.72 (0.59)	0.80 (0.68)	(-0.54, 2.15)	0.2405	0.11 (0.11)	(-0.11, 0.33)	0.3267	
Positive (At any time)	7	1.85 (3.27)	19	1.85 (2.15)	0.00 (2.77)	(-5.80, 5.80)	0.9998	0.00 (0.44)	(-0.87, 0.87)	0.9999	
BMI (kg/m2) at enrolment											0.1344
< 30	118	2.88 (0.68)	123	2.48 (0.69)	0.40 (0.74)	(-1.06, 1.86)	0.5885	0.05 (0.13)	(-0.20, 0.31)	0.6807	
>= 30	52	5.22 (0.99)	46	2.54 (1.03)	2.68 (1.33)	(0.04, 5.32)	0.0469	0.38 (0.20)	(-0.02, 0.78)	0.0651	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.8618
All negative/normal	56	3.96 (0.82)	76	3.00 (0.73)	0.95 (1.04)	(-1.10, 3.00)	0.3606	0.15 (0.18)	(-0.19, 0.50)	0.3907	
At least one positive/abnormal	114	3.36 (0.86)	93	2.64 (0.95)	0.72 (0.86)	(-0.97, 2.41)	0.4039	0.08 (0.14)	(-0.20, 0.35)	0.5778	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Role Emotional Score
Full analysis set

	Anifrolumab 300mg (N=180)		Placebo (N=182)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 8		1.58 (0.84)		-0.13 (0.83)	1.71 (1.04)	(-0.34, 3.76)	0.1023			
Week 16		2.13 (0.85)		2.57 (0.86)	-0.44 (1.08)	(-2.56, 1.68)	0.6825			
Week 24		2.88 (0.88)		0.50 (0.88)	2.38 (1.12)	(0.18, 4.58)	0.0343			
Week 32		3.03 (0.86)		1.63 (0.87)	1.40 (1.09)	(-0.75, 3.55)	0.2008			
Week 40		3.47 (0.88)		2.10 (0.90)	1.36 (1.13)	(-0.86, 3.59)	0.2275			
Week 48		2.52 (0.89)		1.27 (0.93)	1.25 (1.17)	(-1.05, 3.55)	0.2848			
Week 52		2.68 (0.92)		1.37 (0.96)	1.31 (1.21)	(-1.08, 3.70)	0.2816			
OVERALL	170	2.61 (0.70)	169	1.33 (0.71)	1.28 (0.83)	(-0.34, 2.91)	0.1215	0.14 (0.11)	(-0.07, 0.35)	0.1981

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Role Emotional Score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=180)		Placebo (N=182)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											0.0020
< 10 points	52	6.09 (1.16)	49	0.94 (1.19)	5.14 (1.51)	(2.15, 8.13)	0.0009	0.61 (0.20)	(0.21, 1.01)	0.0027	
>= 10 points	118	0.62 (0.86)	120	1.02 (0.87)	-0.40 (0.97)	(-2.32, 1.52)	0.6801	-0.04 (0.13)	(-0.30, 0.21)	0.7431	
OCS dose at baseline											0.6586
<10 mg/day	91	3.34 (0.83)	94	2.43 (0.85)	0.91 (1.06)	(-1.17, 3.00)	0.3896	0.11 (0.15)	(-0.18, 0.40)	0.4452	
>=10 mg/day	79	1.53 (1.28)	75	-0.13 (1.26)	1.66 (1.32)	(-0.95, 4.27)	0.2113	0.15 (0.16)	(-0.17, 0.46)	0.3594	
Result of type I IFN gene signature test											0.7709
LOW	29	2.93 (1.59)	29	1.11 (1.55)	1.82 (2.14)	(-2.48, 6.13)	0.3982	0.21 (0.26)	(-0.30, 0.73)	0.4186	
HIGH	141	2.57 (0.67)	140	1.42 (0.68)	1.15 (0.90)	(-0.62, 2.92)	0.2025	0.14 (0.12)	(-0.09, 0.38)	0.2311	
Age (years)											NE
<= 65	165	2.55 (0.71)	169	1.32 (0.71)	1.23 (0.84)	(-0.41, 2.88)	0.1412	0.13 (0.11)	(-0.08, 0.35)	0.2232	
> 65	5	NE	0	NE	NE	NE		NE	NE		
Sex											0.3199
male	11	8.42 (4.00)	12	10.32 (5.59)	-1.89 (3.20)	(-8.59, 4.81)	0.5615	-0.11 (0.42)	(-0.93, 0.71)	0.7943	
female	159	2.57 (0.71)	157	1.16 (0.73)	1.40 (0.86)	(-0.28, 3.09)	0.1020	0.15 (0.11)	(-0.07, 0.38)	0.1699	
Race											NE
White	102	3.00 (0.90)	99	2.89 (0.94)	0.12 (1.11)	(-2.08, 2.31)	0.9175	0.01 (0.14)	(-0.26, 0.29)	0.9295	
Black or African American	16	3.28 (2.61)	22	-1.23 (2.71)	4.51 (3.11)	(-1.82, 10.84)	0.1562	0.37 (0.33)	(-0.28, 1.02)	0.2592	
Asian	29	-2.54 (1.75)	30	-2.89 (1.75)	0.35 (1.59)	(-2.84, 3.54)	0.8262	0.04 (0.26)	(-0.47, 0.55)	0.8886	
American Indian or Alaska Native	4	NE	1	NE	NE	NE		NE	NE		
Other	11	11.53 (4.77)	10	8.83 (5.04)	2.70 (5.63)	(-10.54, 15.94)	0.6458	0.16 (0.44)	(-0.69, 1.02)	0.7094	
Ethnicity											0.4822
Hispanic/Latino	53	4.94 (1.34)	53	2.81 (1.30)	2.13 (1.61)	(-1.06, 5.32)	0.1878	0.22 (0.19)	(-0.16, 0.60)	0.2577	
Non-hispanic/Latino	109	1.17 (0.85)	109	0.37 (0.87)	0.80 (1.00)	(-1.16, 2.77)	0.4202	0.09 (0.14)	(-0.18, 0.35)	0.5115	
Geographic region											0.7024
EU	47	2.46 (1.32)	40	1.55 (1.45)	0.91 (1.43)	(-1.94, 3.75)	0.5281	0.10 (0.22)	(-0.32, 0.52)	0.6467	
non-EU	123	2.58 (0.83)	129	1.01 (0.83)	1.57 (1.00)	(-0.40, 3.54)	0.1175	0.17 (0.13)	(-0.08, 0.42)	0.1837	
Onset of disease											0.4348
Paediatric	12	4.63 (2.09)	11	1.55 (2.59)	3.08 (2.32)	(-1.77, 7.94)	0.2000	0.38 (0.42)	(-0.45, 1.20)	0.3731	
Adult	158	2.48 (0.73)	158	1.33 (0.74)	1.15 (0.87)	(-0.57, 2.86)	0.1891	0.12 (0.11)	(-0.10, 0.34)	0.2724	
ADA result											NE
Negative	163	2.59 (0.71)	150	1.47 (0.75)	1.11 (0.86)	(-0.58, 2.80)	0.1962	0.12 (0.11)	(-0.10, 0.34)	0.2815	
Positive (At any time)	7	NE	19	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.4591
< 30	118	1.91 (0.87)	123	1.02 (0.89)	0.89 (0.96)	(-1.01, 2.79)	0.3553	0.09 (0.13)	(-0.16, 0.34)	0.4771	
>= 30	52	4.15 (1.18)	46	1.90 (1.22)	2.25 (1.57)	(-0.86, 5.36)	0.1537	0.27 (0.20)	(-0.13, 0.66)	0.1904	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.0319
All negative/normal	56	3.75 (1.06)	76	0.32 (0.94)	3.43 (1.33)	(0.81, 6.06)	0.0109	0.42 (0.18)	(0.07, 0.77)	0.0176	
At least one positive/abnormal	114	2.40 (1.07)	93	2.62 (1.18)	-0.22 (1.07)	(-2.32, 1.88)	0.8369	-0.02 (0.14)	(-0.29, 0.25)	0.8907	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Role Physical Score
Full analysis set

	Anifrolumab 300mg (N=180)		Placebo (N=182)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 8		2.99 (0.61)		2.16 (0.61)	0.83 (0.74)	(-0.63, 2.30)	0.2645			
Week 16		4.00 (0.66)		3.78 (0.67)	0.22 (0.83)	(-1.42, 1.86)	0.7931			
Week 24		4.43 (0.64)		3.22 (0.64)	1.21 (0.79)	(-0.34, 2.75)	0.1263			
Week 32		4.46 (0.66)		3.53 (0.67)	0.93 (0.84)	(-0.72, 2.57)	0.2673			
Week 40		4.39 (0.67)		3.80 (0.69)	0.59 (0.86)	(-1.10, 2.28)	0.4926			
Week 48		4.15 (0.69)		2.18 (0.71)	1.98 (0.89)	(0.23, 3.72)	0.0270			
Week 52		4.29 (0.69)		2.61 (0.72)	1.68 (0.90)	(-0.09, 3.45)	0.0623			
OVERALL	170	4.10 (0.55)	169	3.04 (0.56)	1.06 (0.65)	(-0.21, 2.34)	0.1026	0.15 (0.11)	(-0.07, 0.36)	0.1765

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Role Physical Score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=180)		Placebo (N=182)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											0.1390
< 10 points	52	6.14 (0.97)	49	3.54 (1.01)	2.60 (1.25)	(0.12, 5.08)	0.0403	0.37 (0.20)	(-0.03, 0.76)	0.0667	
>= 10 points	118	2.89 (0.67)	120	2.45 (0.67)	0.43 (0.76)	(-1.07, 1.93)	0.5687	0.06 (0.13)	(-0.19, 0.31)	0.6466	
OCS dose at baseline											0.5592
<10 mg/day	91	3.50 (0.68)	94	2.80 (0.69)	0.70 (0.87)	(-1.01, 2.41)	0.4190	0.11 (0.15)	(-0.18, 0.39)	0.4735	
>=10 mg/day	79	4.63 (0.96)	75	3.16 (0.97)	1.47 (1.00)	(-0.50, 3.45)	0.1424	0.17 (0.16)	(-0.14, 0.49)	0.2839	
Result of type I IFN gene signature test											0.8064
LOW	29	5.46 (1.25)	29	4.06 (1.23)	1.40 (1.66)	(-1.92, 4.72)	0.4025	0.21 (0.26)	(-0.31, 0.72)	0.4332	
HIGH	141	3.65 (0.53)	140	2.70 (0.54)	0.96 (0.71)	(-0.44, 2.36)	0.1802	0.15 (0.12)	(-0.08, 0.38)	0.2077	
Age (years)											NE
<= 65	165	4.00 (0.56)	169	3.01 (0.56)	0.99 (0.65)	(-0.29, 2.28)	0.1283	0.14 (0.11)	(-0.08, 0.35)	0.2094	
> 65	5	NE	0	NE	NE	NE		NE	NE		
Sex											0.1489
male	11	5.95 (2.91)	12	9.11 (4.08)	-3.16 (3.14)	(-10.06, 3.75)	0.3361	-0.25 (0.42)	(-1.07, 0.57)	0.5526	
female	159	4.23 (0.56)	157	2.75 (0.57)	1.48 (0.67)	(0.16, 2.80)	0.0286	0.21 (0.11)	(-0.01, 0.43)	0.0666	
Race											NE
White	102	3.96 (0.68)	99	4.14 (0.70)	-0.18 (0.84)	(-1.83, 1.48)	0.8338	-0.03 (0.14)	(-0.30, 0.25)	0.8572	
Black or African American	16	3.62 (1.86)	22	2.39 (1.95)	1.22 (2.18)	(-3.24, 5.69)	0.5782	0.14 (0.33)	(-0.50, 0.79)	0.6673	
Asian	29	2.12 (1.77)	30	-1.84 (1.78)	3.95 (1.50)	(0.94, 6.97)	0.0112	0.41 (0.26)	(-0.11, 0.92)	0.1238	
American Indian or Alaska Native	4	NE	1	NE	NE	NE		NE	NE		
Other	11	3.86 (2.01)	10	-0.24 (2.15)	4.10 (2.57)	(-1.53, 9.74)	0.1379	0.58 (0.45)	(-0.29, 1.46)	0.1919	
Ethnicity											0.3225
Hispanic/Latino	53	5.73 (1.00)	53	3.72 (0.97)	2.02 (1.20)	(-0.36, 4.39)	0.0952	0.28 (0.20)	(-0.10, 0.66)	0.1519	
Non-hispanic/Latino	109	3.07 (0.69)	109	2.48 (0.70)	0.59 (0.81)	(-1.00, 2.18)	0.4659	0.08 (0.14)	(-0.19, 0.35)	0.5526	
Geographic region											0.0356
EU	47	3.00 (1.08)	40	4.27 (1.17)	-1.27 (1.19)	(-3.64, 1.10)	0.2896	-0.17 (0.22)	(-0.59, 0.25)	0.4304	
non-EU	123	4.38 (0.65)	129	2.66 (0.65)	1.72 (0.78)	(0.19, 3.25)	0.0282	0.23 (0.13)	(-0.01, 0.48)	0.0635	
Onset of disease											0.3532
Paediatric	12	2.75 (2.37)	11	-0.67 (3.18)	3.42 (2.58)	(-1.97, 8.81)	0.2006	0.35 (0.42)	(-0.47, 1.18)	0.4050	
Adult	158	4.16 (0.57)	158	3.21 (0.57)	0.94 (0.67)	(-0.38, 2.27)	0.1628	0.13 (0.11)	(-0.09, 0.35)	0.2447	
ADA result											NE
Negative	163	4.11 (0.56)	150	3.02 (0.59)	1.09 (0.68)	(-0.25, 2.42)	0.1099	0.15 (0.11)	(-0.07, 0.37)	0.1834	
Positive (At any time)	7	NE	19	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.5563
< 30	118	3.67 (0.72)	123	2.81 (0.73)	0.86 (0.78)	(-0.68, 2.40)	0.2721	0.11 (0.13)	(-0.14, 0.36)	0.4028	
>= 30	52	4.96 (0.85)	46	3.28 (0.89)	1.67 (1.14)	(-0.59, 3.94)	0.1449	0.27 (0.20)	(-0.13, 0.67)	0.1792	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.3339
All negative/normal	56	4.68 (0.86)	76	2.92 (0.77)	1.76 (1.08)	(-0.37, 3.89)	0.1052	0.27 (0.18)	(-0.08, 0.61)	0.1323	
At least one positive/abnormal	114	3.89 (0.84)	93	3.44 (0.92)	0.45 (0.83)	(-1.18, 2.08)	0.5894	0.05 (0.14)	(-0.22, 0.32)	0.7206	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Social Functioning Score
Full analysis set

	Anifrolumab 300mg (N=180)		Placebo (N=182)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 8		1.16 (0.78)		-0.06 (0.78)	1.22 (0.98)	(-0.71, 3.15)	0.2139			
Week 16		1.51 (0.76)		1.27 (0.78)	0.25 (0.96)	(-1.64, 2.14)	0.7957			
Week 24		1.74 (0.80)		0.66 (0.80)	1.08 (1.01)	(-0.90, 3.06)	0.2835			
Week 32		2.37 (0.81)		1.36 (0.83)	1.01 (1.04)	(-1.02, 3.05)	0.3278			
Week 40		2.45 (0.79)		1.30 (0.81)	1.15 (1.00)	(-0.82, 3.11)	0.2521			
Week 48		2.79 (0.77)		-0.41 (0.81)	3.20 (0.99)	(1.25, 5.15)	0.0014			
Week 52		2.16 (0.83)		0.78 (0.86)	1.37 (1.08)	(-0.74, 3.49)	0.2027			
OVERALL	170	2.03 (0.65)	169	0.70 (0.66)	1.33 (0.76)	(-0.17, 2.83)	0.0826	0.16 (0.11)	(-0.06, 0.37)	0.1515

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Social Functioning Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=182) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.0088
< 10 points	52	5.35 (1.18)	49	0.78 (1.22)	4.57 (1.52)	(1.56, 7.59)	0.0034	0.53 (0.20)	(0.14, 0.93)	0.0086	
>= 10 points	118	0.60 (0.76)	120	0.61 (0.77)	-0.01 (0.86)	(-1.71, 1.70)	0.9946	-0.00 (0.13)	(-0.25, 0.25)	0.9957	
OCS dose at baseline											0.4278
<10 mg/day	91	1.49 (0.77)	94	0.63 (0.78)	0.85 (0.97)	(-1.07, 2.77)	0.3820	0.11 (0.15)	(-0.17, 0.40)	0.4390	
>=10 mg/day	79	2.62 (1.17)	75	0.54 (1.17)	2.08 (1.20)	(-0.30, 4.46)	0.0860	0.20 (0.16)	(-0.12, 0.52)	0.2119	
Result of type I IFN gene signature test											0.4004
LOW	29	2.78 (1.49)	29	-0.00 (1.47)	2.78 (1.99)	(-1.23, 6.80)	0.1693	0.34 (0.26)	(-0.17, 0.86)	0.1938	
HIGH	141	2.29 (0.62)	140	1.32 (0.63)	0.97 (0.83)	(-0.68, 2.61)	0.2481	0.13 (0.12)	(-0.10, 0.36)	0.2784	
Age (years)											NE
<= 65	165	1.88 (0.65)	169	0.58 (0.65)	1.30 (0.76)	(-0.19, 2.80)	0.0873	0.15 (0.11)	(-0.06, 0.37)	0.1591	
> 65	5	NE	0	NE	NE	NE		NE	NE		
Sex											0.5089
male	11	4.63 (3.52)	12	5.43 (5.34)	-0.80 (3.47)	(-8.03, 6.42)	0.8194	-0.05 (0.42)	(-0.87, 0.77)	0.9056	
female	159	1.97 (0.66)	157	0.42 (0.67)	1.55 (0.78)	(0.01, 3.08)	0.0483	0.19 (0.11)	(-0.04, 0.41)	0.0995	
Race											NE
White	102	1.98 (0.80)	99	1.80 (0.83)	0.18 (0.98)	(-1.76, 2.12)	0.8554	0.02 (0.14)	(-0.25, 0.30)	0.8767	
Black or African American	16	3.24 (2.15)	22	0.81 (2.07)	2.43 (2.55)	(-2.74, 7.61)	0.3463	0.26 (0.33)	(-0.39, 0.90)	0.4360	
Asian	29	-3.65 (1.99)	30	-6.69 (1.98)	3.04 (1.77)	(-0.52, 6.59)	0.0925	0.28 (0.26)	(-0.24, 0.79)	0.2887	
American Indian or Alaska Native	4	NE	1	NE	NE	NE		NE	NE		
Other	11	5.91 (2.02)	10	3.40 (2.16)	2.51 (2.50)	(-2.77, 7.78)	0.3306	0.36 (0.44)	(-0.51, 1.22)	0.4198	
Ethnicity											0.5412
Hispanic/Latino	53	4.45 (1.17)	53	2.43 (1.14)	2.02 (1.39)	(-0.75, 4.79)	0.1503	0.24 (0.19)	(-0.14, 0.62)	0.2213	
Non-hispanic/Latino	109	0.48 (0.81)	109	-0.52 (0.83)	0.99 (0.94)	(-0.86, 2.85)	0.2931	0.12 (0.14)	(-0.15, 0.38)	0.3934	
Geographic region											0.4752
EU	47	1.78 (1.37)	40	1.39 (1.50)	0.40 (1.42)	(-2.43, 3.22)	0.7795	0.04 (0.22)	(-0.38, 0.46)	0.8458	
non-EU	123	2.13 (0.75)	129	0.53 (0.75)	1.60 (0.91)	(-0.19, 3.39)	0.0790	0.19 (0.13)	(-0.06, 0.44)	0.1359	
Onset of disease											0.2051
Paediatric	12	-0.35 (3.06)	11	-5.71 (3.93)	5.36 (3.15)	(-1.41, 12.13)	0.1115	0.44 (0.42)	(-0.39, 1.27)	0.3025	
Adult	158	2.13 (0.67)	158	0.89 (0.68)	1.24 (0.80)	(-0.33, 2.80)	0.1206	0.15 (0.11)	(-0.08, 0.37)	0.1965	
ADA result											0.3969
Negative	163	1.88 (0.66)	150	0.73 (0.70)	1.15 (0.80)	(-0.42, 2.72)	0.1506	0.14 (0.11)	(-0.09, 0.36)	0.2331	
Positive (At any time)	7	5.62 (3.55)	19	1.77 (2.36)	3.85 (3.09)	(-2.62, 10.32)	0.2274	0.37 (0.45)	(-0.50, 1.24)	0.4059	
BMI (kg/m2) at enrolment											0.9176
< 30	118	1.17 (0.81)	123	-0.24 (0.83)	1.41 (0.88)	(-0.33, 3.15)	0.1112	0.16 (0.13)	(-0.10, 0.41)	0.2263	
>= 30	52	3.87 (1.10)	46	2.63 (1.14)	1.24 (1.47)	(-1.69, 4.16)	0.4030	0.16 (0.20)	(-0.24, 0.55)	0.4409	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.3088
All negative/normal	56	3.63 (1.02)	76	1.27 (0.91)	2.36 (1.28)	(-0.17, 4.90)	0.0672	0.30 (0.18)	(-0.05, 0.65)	0.0901	
At least one positive/abnormal	114	1.35 (0.98)	93	0.62 (1.07)	0.73 (0.97)	(-1.18, 2.64)	0.4504	0.07 (0.14)	(-0.20, 0.34)	0.6157	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Bodily Pain Score
Full analysis set

	Anifrolumab 300mg (N=180)		Placebo (N=182)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 8		3.76 (0.68)		1.22 (0.68)	2.54 (0.84)	(0.89, 4.18)	0.0026			
Week 16		4.32 (0.72)		3.32 (0.73)	1.00 (0.91)	(-0.79, 2.79)	0.2737			
Week 24		5.23 (0.74)		2.63 (0.74)	2.59 (0.93)	(0.76, 4.42)	0.0056			
Week 32		4.36 (0.73)		3.22 (0.75)	1.15 (0.93)	(-0.69, 2.98)	0.2195			
Week 40		4.53 (0.72)		3.58 (0.74)	0.95 (0.92)	(-0.87, 2.76)	0.3062			
Week 48		4.95 (0.78)		2.49 (0.82)	2.46 (1.03)	(0.44, 4.48)	0.0172			
Week 52		4.09 (0.79)		2.94 (0.82)	1.16 (1.03)	(-0.87, 3.19)	0.2629			
OVERALL	170	4.46 (0.60)	169	2.77 (0.61)	1.69 (0.71)	(0.30, 3.08)	0.0172	0.22 (0.11)	(0.00, 0.43)	0.0479

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Bodily Pain Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=182) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.3257
< 10 points	52	5.17 (1.06)	49	2.33 (1.10)	2.85 (1.38)	(0.10, 5.59)	0.0422	0.37 (0.20)	(-0.03, 0.76)	0.0672	
>= 10 points	118	4.50 (0.72)	120	3.23 (0.73)	1.27 (0.82)	(-0.36, 2.89)	0.1264	0.16 (0.13)	(-0.10, 0.41)	0.2199	
OCS dose at baseline											0.7539
<10 mg/day	91	4.49 (0.71)	94	2.63 (0.73)	1.86 (0.91)	(0.08, 3.65)	0.0412	0.27 (0.15)	(-0.02, 0.56)	0.0699	
>=10 mg/day	79	4.10 (1.08)	75	2.69 (1.07)	1.41 (1.14)	(-0.84, 3.65)	0.2179	0.15 (0.16)	(-0.17, 0.46)	0.3587	
Result of type I IFN gene signature test											0.7002
LOW	29	4.73 (1.13)	29	3.57 (1.10)	1.16 (1.50)	(-1.85, 4.18)	0.4426	0.19 (0.26)	(-0.33, 0.71)	0.4691	
HIGH	141	4.49 (0.59)	140	2.67 (0.61)	1.82 (0.80)	(0.24, 3.39)	0.0237	0.25 (0.12)	(0.02, 0.49)	0.0335	
Age (years)											NE
<= 65	165	4.46 (0.61)	169	2.70 (0.61)	1.76 (0.72)	(0.36, 3.17)	0.0142	0.22 (0.11)	(0.01, 0.44)	0.0426	
> 65	5	NE	0	NE	NE	NE		NE	NE		
Sex											0.0396
male	11	5.91 (3.62)	12	10.54 (4.46)	-4.62 (3.16)	(-11.42, 2.18)	0.1667	-0.32 (0.42)	(-1.14, 0.50)	0.4466	
female	159	4.60 (0.61)	157	2.54 (0.62)	2.06 (0.73)	(0.63, 3.50)	0.0050	0.27 (0.11)	(0.04, 0.49)	0.0184	
Race											NE
White	102	4.21 (0.68)	99	4.07 (0.70)	0.13 (0.84)	(-1.52, 1.79)	0.8726	0.02 (0.14)	(-0.26, 0.30)	0.8908	
Black or African American	16	6.85 (2.44)	22	0.34 (2.46)	6.51 (2.74)	(0.92, 12.10)	0.0239	0.59 (0.34)	(-0.07, 1.25)	0.0804	
Asian	29	-0.06 (1.71)	30	-1.75 (1.71)	1.69 (1.53)	(-1.38, 4.76)	0.2738	0.18 (0.26)	(-0.33, 0.69)	0.4908	
American Indian or Alaska Native	4	NE	1	NE	NE	NE		NE	NE		
Other	11	4.21 (2.86)	10	-0.36 (2.98)	4.57 (3.30)	(-2.42, 11.56)	0.1845	0.46 (0.44)	(-0.41, 1.33)	0.2964	
Ethnicity											0.0174
Hispanic/Latino	53	6.70 (1.06)	53	2.86 (1.03)	3.84 (1.26)	(1.34, 6.34)	0.0030	0.50 (0.20)	(0.12, 0.89)	0.0110	
Non-hispanic/Latino	109	2.95 (0.72)	109	2.72 (0.74)	0.23 (0.85)	(-1.44, 1.90)	0.7887	0.03 (0.14)	(-0.24, 0.30)	0.8262	
Geographic region											0.0614
EU	47	3.43 (1.29)	40	3.89 (1.42)	-0.46 (1.37)	(-3.19, 2.27)	0.7388	-0.05 (0.22)	(-0.47, 0.37)	0.8120	
non-EU	123	4.90 (0.68)	129	2.36 (0.69)	2.54 (0.83)	(0.91, 4.17)	0.0024	0.33 (0.13)	(0.08, 0.58)	0.0095	
Onset of disease											0.3316
Paediatric	12	3.14 (4.03)	11	-2.46 (5.10)	5.60 (4.36)	(-3.79, 14.98)	0.2207	0.35 (0.42)	(-0.48, 1.18)	0.4066	
Adult	158	4.33 (0.60)	158	3.02 (0.60)	1.31 (0.71)	(-0.09, 2.70)	0.0658	0.17 (0.11)	(-0.05, 0.39)	0.1228	
ADA result											NE
Negative	163	4.33 (0.61)	150	3.03 (0.64)	1.29 (0.74)	(-0.16, 2.74)	0.0800	0.17 (0.11)	(-0.06, 0.39)	0.1440	
Positive (At any time)	7	NE	19	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.1481
< 30	118	4.01 (0.80)	123	2.80 (0.82)	1.20 (0.88)	(-0.52, 2.93)	0.1702	0.13 (0.13)	(-0.12, 0.39)	0.2960	
>= 30	52	5.79 (0.87)	46	2.46 (0.91)	3.33 (1.18)	(0.99, 5.67)	0.0058	0.53 (0.21)	(0.13, 0.94)	0.0099	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.6919
All negative/normal	56	4.66 (0.88)	76	3.41 (0.78)	1.25 (1.11)	(-0.94, 3.44)	0.2598	0.19 (0.18)	(-0.16, 0.53)	0.2938	
At least one positive/abnormal	114	4.38 (0.95)	93	2.55 (1.04)	1.82 (0.93)	(-0.01, 3.66)	0.0518	0.18 (0.14)	(-0.09, 0.46)	0.1963	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Vitality Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=182) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 8		3.40 (0.66)		0.71 (0.66)	2.69 (0.81)	(1.09, 4.29)	0.0010			
Week 16		2.80 (0.67)		1.86 (0.68)	0.95 (0.85)	(-0.72, 2.61)	0.2643			
Week 24		3.33 (0.70)		1.80 (0.70)	1.52 (0.88)	(-0.21, 3.26)	0.0849			
Week 32		3.22 (0.72)		2.13 (0.73)	1.09 (0.92)	(-0.72, 2.89)	0.2366			
Week 40		2.94 (0.74)		2.37 (0.77)	0.57 (0.97)	(-1.33, 2.48)	0.5537			
Week 48		3.33 (0.73)		1.70 (0.77)	1.63 (0.96)	(-0.26, 3.51)	0.0909			
Week 52		3.14 (0.75)		1.14 (0.78)	2.00 (0.98)	(0.08, 3.93)	0.0411			
OVERALL	170	3.16 (0.57)	169	1.67 (0.58)	1.49 (0.68)	(0.16, 2.82)	0.0279	0.20 (0.11)	(-0.01, 0.41)	0.0675

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Vitality Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=182) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.2413
< 10 points	52	4.17 (0.97)	49	1.42 (1.01)	2.75 (1.26)	(0.25, 5.26)	0.0313	0.39 (0.20)	(-0.00, 0.78)	0.0526	
>= 10 points	118	2.54 (0.70)	120	1.53 (0.71)	1.00 (0.80)	(-0.57, 2.58)	0.2108	0.13 (0.13)	(-0.12, 0.38)	0.3159	
OCS dose at baseline											0.7821
<10 mg/day	91	2.36 (0.71)	94	1.01 (0.72)	1.35 (0.90)	(-0.43, 3.13)	0.1363	0.19 (0.15)	(-0.09, 0.48)	0.1867	
>=10 mg/day	79	4.32 (0.99)	75	2.59 (0.99)	1.73 (1.04)	(-0.32, 3.78)	0.0978	0.20 (0.16)	(-0.12, 0.51)	0.2203	
Result of type I IFN gene signature test											0.2469
LOW	29	3.85 (1.34)	29	4.36 (1.36)	-0.51 (1.87)	(-4.26, 3.25)	0.7872	-0.07 (0.26)	(-0.58, 0.45)	0.7928	
HIGH	141	3.10 (0.54)	140	1.28 (0.55)	1.82 (0.73)	(0.38, 3.26)	0.0136	0.28 (0.12)	(0.04, 0.51)	0.0201	
Age (years)											NE
<= 65	165	3.06 (0.58)	169	1.58 (0.58)	1.48 (0.68)	(0.15, 2.82)	0.0298	0.20 (0.11)	(-0.02, 0.41)	0.0722	
> 65	5	NE	0	NE	NE	NE		NE	NE		
Sex											0.4056
male	11	7.67 (3.20)	12	8.41 (4.05)	-0.73 (2.76)	(-6.80, 5.33)	0.7947	-0.06 (0.42)	(-0.87, 0.76)	0.8922	
female	159	3.04 (0.59)	157	1.41 (0.60)	1.63 (0.70)	(0.24, 3.02)	0.0213	0.22 (0.11)	(-0.00, 0.44)	0.0528	
Race											NE
White	102	3.72 (0.70)	99	3.64 (0.73)	0.09 (0.86)	(-1.62, 1.79)	0.9215	0.01 (0.14)	(-0.26, 0.29)	0.9328	
Black or African American	16	2.04 (2.15)	22	-1.36 (2.22)	3.41 (2.46)	(-1.60, 8.41)	0.1754	0.34 (0.33)	(-0.31, 0.99)	0.2994	
Asian	29	-1.25 (1.54)	30	-3.67 (1.51)	2.42 (1.39)	(-0.38, 5.21)	0.0892	0.29 (0.26)	(-0.23, 0.80)	0.2722	
American Indian or Alaska Native	4	NE	1	NE	NE	NE		NE	NE		
Other	11	3.18 (3.48)	10	-0.74 (3.77)	3.93 (3.87)	(-4.28, 12.13)	0.3251	0.32 (0.44)	(-0.54, 1.18)	0.4654	
Ethnicity											0.0272
Hispanic/Latino	53	4.83 (0.99)	53	1.32 (0.96)	3.52 (1.19)	(1.15, 5.88)	0.0040	0.49 (0.20)	(0.10, 0.88)	0.0129	
Non-hispanic/Latino	109	2.06 (0.73)	109	1.79 (0.75)	0.27 (0.86)	(-1.42, 1.96)	0.7531	0.03 (0.14)	(-0.23, 0.30)	0.7976	
Geographic region											0.0087
EU	47	3.08 (1.16)	40	4.49 (1.26)	-1.41 (1.22)	(-3.84, 1.01)	0.2498	-0.18 (0.22)	(-0.60, 0.25)	0.4158	
non-EU	123	3.28 (0.65)	129	0.88 (0.66)	2.40 (0.79)	(0.84, 3.96)	0.0028	0.33 (0.13)	(0.08, 0.57)	0.0103	
Onset of disease											0.1636
Paediatric	12	0.69 (2.78)	11	-4.74 (3.39)	5.44 (2.89)	(-0.68, 11.55)	0.0779	0.50 (0.43)	(-0.33, 1.34)	0.2372	
Adult	158	3.23 (0.59)	158	1.93 (0.60)	1.29 (0.70)	(-0.09, 2.68)	0.0668	0.17 (0.11)	(-0.05, 0.39)	0.1249	
ADA result											NE
Negative	163	3.05 (0.58)	150	1.90 (0.61)	1.15 (0.71)	(-0.24, 2.54)	0.1040	0.15 (0.11)	(-0.07, 0.38)	0.1752	
Positive (At any time)	7	NE	19	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.8609
< 30	118	2.46 (0.74)	123	0.80 (0.76)	1.66 (0.81)	(0.07, 3.26)	0.0414	0.20 (0.13)	(-0.05, 0.45)	0.1192	
>= 30	52	4.48 (0.91)	46	3.08 (0.96)	1.40 (1.24)	(-1.06, 3.86)	0.2609	0.21 (0.20)	(-0.19, 0.61)	0.2947	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.4478
All negative/normal	56	4.78 (0.83)	76	2.46 (0.74)	2.33 (1.05)	(0.25, 4.41)	0.0284	0.36 (0.18)	(0.01, 0.71)	0.0414	
At least one positive/abnormal	114	1.92 (0.88)	93	0.63 (0.96)	1.29 (0.88)	(-0.46, 3.03)	0.1476	0.14 (0.14)	(-0.14, 0.41)	0.3258	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - FACIT-F Total Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) N	Anifrolumab 300mg (N=180) LSMean (SE)	Placebo (N=182) N	Placebo (N=182) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		2.84 (0.70)		2.16 (0.70)	0.67 (0.86)	(-1.01, 2.36)	0.4312			
Week 8		3.15 (0.72)		1.87 (0.71)	1.28 (0.89)	(-0.47, 3.03)	0.1509			
Week 12		3.32 (0.78)		1.47 (0.78)	1.85 (0.99)	(-0.09, 3.79)	0.0622			
Week 16		3.08 (0.81)		2.73 (0.80)	0.34 (1.03)	(-1.68, 2.36)	0.7371			
Week 20		4.32 (0.80)		4.36 (0.79)	-0.05 (1.01)	(-2.04, 1.94)	0.9630			
Week 24		4.71 (0.80)		3.30 (0.79)	1.42 (1.01)	(-0.56, 3.40)	0.1602			
Week 28		5.02 (0.83)		3.56 (0.83)	1.46 (1.07)	(-0.64, 3.56)	0.1722			
Week 32		4.15 (0.85)		3.57 (0.86)	0.57 (1.11)	(-1.60, 2.75)	0.6040			
Week 36		4.38 (0.81)		3.29 (0.81)	1.10 (1.03)	(-0.94, 3.13)	0.2897			
Week 40		3.94 (0.83)		4.09 (0.84)	-0.15 (1.08)	(-2.28, 1.97)	0.8876			
Week 44		4.75 (0.79)		4.25 (0.81)	0.49 (1.02)	(-1.50, 2.49)	0.6264			
Week 48		3.87 (0.86)		2.86 (0.88)	1.00 (1.13)	(-1.22, 3.23)	0.3747			
Week 52		3.71 (0.86)		2.49 (0.88)	1.23 (1.13)	(-1.00, 3.45)	0.2789			
OVERALL	170	3.94 (0.65)	173	3.08 (0.65)	0.86 (0.78)	(-0.67, 2.39)	0.2677	0.10 (0.11)	(-0.11, 0.31)	0.3492

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - FACIT-F Total Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=182) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.2995
< 10 points	50	5.22 (1.10)	50	3.14 (1.09)	2.08 (1.41)	(-0.73, 4.88)	0.1446	0.27 (0.20)	(-0.13, 0.66)	0.1850	
>= 10 points	120	3.07 (0.80)	123	2.75 (0.79)	0.33 (0.92)	(-1.49, 2.15)	0.7239	0.04 (0.13)	(-0.21, 0.29)	0.7719	
OCS dose at baseline											0.8994
<10 mg/day	91	4.04 (0.81)	94	3.00 (0.80)	1.04 (1.03)	(-0.99, 3.06)	0.3140	0.13 (0.15)	(-0.16, 0.42)	0.3649	
>=10 mg/day	79	3.70 (1.13)	79	2.87 (1.11)	0.84 (1.19)	(-1.51, 3.19)	0.4825	0.08 (0.16)	(-0.23, 0.40)	0.5978	
Result of type I IFN gene signature test											0.9753
LOW	28	4.22 (1.48)	29	3.51 (1.42)	0.71 (1.98)	(-3.27, 4.69)	0.7217	0.09 (0.27)	(-0.43, 0.61)	0.7331	
HIGH	142	4.11 (0.63)	144	3.34 (0.63)	0.78 (0.85)	(-0.90, 2.45)	0.3614	0.10 (0.12)	(-0.13, 0.33)	0.3883	
Age (years)											NE
<= 65	166	3.90 (0.66)	173	3.07 (0.65)	0.83 (0.78)	(-0.72, 2.37)	0.2929	0.10 (0.11)	(-0.12, 0.31)	0.3739	
> 65	4	NE	0	NE	NE	NE		NE	NE		
Sex											NE
male	11	NE	12	NE	NE	NE		NE	NE		
female	159	3.73 (0.67)	161	2.67 (0.67)	1.06 (0.81)	(-0.53, 2.64)	0.1906	0.12 (0.11)	(-0.09, 0.34)	0.2642	
Race											NE
White	103	3.79 (0.84)	103	4.76 (0.85)	-0.97 (1.04)	(-3.02, 1.09)	0.3552	-0.11 (0.14)	(-0.39, 0.16)	0.4197	
Black or African American	17	7.25 (2.31)	22	2.64 (2.44)	4.61 (2.70)	(-0.85, 10.08)	0.0954	0.42 (0.33)	(-0.22, 1.06)	0.1944	
Asian	29	0.26 (1.68)	30	-2.74 (1.66)	3.01 (1.50)	(-0.01, 6.03)	0.0511	0.33 (0.26)	(-0.19, 0.84)	0.2132	
American Indian or Alaska Native	4	NE	1	NE	NE	NE		NE	NE		
Other	11	NE	10	NE	NE	NE		NE	NE		
Ethnicity											0.0917
Hispanic/Latino	52	5.87 (1.29)	54	2.89 (1.22)	2.98 (1.54)	(-0.07, 6.03)	0.0554	0.32 (0.20)	(-0.06, 0.71)	0.0973	
Non-hispanic/Latino	112	2.77 (0.77)	112	2.81 (0.78)	-0.04 (0.92)	(-1.86, 1.78)	0.9622	-0.01 (0.13)	(-0.27, 0.26)	0.9683	
Geographic region											0.0256
EU	45	2.43 (1.23)	43	4.31 (1.30)	-1.88 (1.36)	(-4.58, 0.83)	0.1706	-0.22 (0.21)	(-0.64, 0.20)	0.2999	
non-EU	125	4.40 (0.77)	130	2.61 (0.76)	1.79 (0.93)	(-0.04, 3.63)	0.0550	0.21 (0.13)	(-0.04, 0.45)	0.0990	
Onset of disease											NE
Paediatric	11	NE	11	NE	NE	NE		NE	NE		
Adult	159	4.15 (0.68)	162	3.32 (0.67)	0.83 (0.81)	(-0.75, 2.42)	0.3018	0.10 (0.11)	(-0.12, 0.32)	0.3809	
ADA result											NE
Negative	163	3.87 (0.65)	154	3.50 (0.67)	0.36 (0.79)	(-1.19, 1.91)	0.6452	0.04 (0.11)	(-0.18, 0.26)	0.6969	
Positive (At any time)	7	NE	19	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.8923
< 30	119	3.30 (0.84)	127	2.53 (0.84)	0.77 (0.94)	(-1.08, 2.63)	0.4127	0.08 (0.13)	(-0.17, 0.33)	0.5181	
>= 30	51	5.31 (1.06)	46	4.31 (1.08)	1.00 (1.40)	(-1.79, 3.79)	0.4772	0.13 (0.20)	(-0.27, 0.53)	0.5108	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.5591
All negative/normal	56	4.94 (0.99)	77	3.47 (0.86)	1.47 (1.23)	(-0.96, 3.90)	0.2332	0.20 (0.18)	(-0.15, 0.54)	0.2661	
At least one positive/abnormal	114	3.11 (0.98)	96	2.57 (1.07)	0.54 (1.01)	(-1.45, 2.53)	0.5914	0.05 (0.14)	(-0.22, 0.32)	0.7104	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - EQ VAS Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) N	Anifrolumab 300mg (N=180) LSMean (SE)	Placebo (N=182) N	Placebo (N=182) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 12		7.88 (1.73)		1.26 (1.71)	6.62 (2.13)	(2.43, 10.80)	0.0020			
Week 24		5.25 (1.85)		5.24 (1.82)	0.00 (2.31)	(-4.54, 4.54)	0.9991			
Week 36		6.37 (1.87)		6.47 (1.90)	-0.11 (2.38)	(-4.78, 4.57)	0.9644			
Week 52		6.85 (1.88)		3.36 (1.95)	3.49 (2.43)	(-1.29, 8.27)	0.1518			
OVERALL	168	6.58 (1.48)	169	4.08 (1.48)	2.50 (1.72)	(-0.88, 5.89)	0.1471	0.13 (0.11)	(-0.08, 0.34)	0.2332

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - EQ VAS Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=182) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.7284
< 10 points	49	9.76 (2.67)	50	6.33 (2.66)	3.43 (3.40)	(-3.32, 10.18)	0.3155	0.18 (0.20)	(-0.21, 0.58)	0.3679	
>= 10 points	119	5.23 (1.77)	119	3.17 (1.79)	2.06 (1.99)	(-1.87, 5.99)	0.3023	0.11 (0.13)	(-0.15, 0.36)	0.4142	
OCS dose at baseline											0.2710
<10 mg/day	89	6.33 (1.87)	91	5.56 (1.89)	0.77 (2.36)	(-3.89, 5.42)	0.7457	0.04 (0.15)	(-0.25, 0.34)	0.7742	
>=10 mg/day	79	6.73 (2.48)	78	2.14 (2.45)	4.59 (2.55)	(-0.45, 9.63)	0.0740	0.21 (0.16)	(-0.10, 0.52)	0.1909	
Result of type I IFN gene signature test											0.9383
LOW	28	5.54 (3.30)	29	3.37 (3.19)	2.17 (4.33)	(-6.52, 10.87)	0.6183	0.12 (0.27)	(-0.40, 0.64)	0.6408	
HIGH	140	7.49 (1.42)	140	4.95 (1.42)	2.54 (1.88)	(-1.17, 6.25)	0.1789	0.15 (0.12)	(-0.08, 0.38)	0.2093	
Age (years)											NE
<= 65	164	6.47 (1.50)	169	3.81 (1.49)	2.65 (1.74)	(-0.77, 6.08)	0.1277	0.14 (0.11)	(-0.08, 0.35)	0.2102	
> 65	4	NE	0	NE	NE	NE		NE	NE		
Sex											0.8040
male	11	-9.45 (7.69)	12	-10.36 (9.11)	0.90 (7.03)	(-13.91, 15.72)	0.8993	0.03 (0.42)	(-0.79, 0.85)	0.9424	
female	157	7.59 (1.52)	157	4.89 (1.52)	2.70 (1.80)	(-0.83, 6.24)	0.1330	0.14 (0.11)	(-0.08, 0.36)	0.2109	
Race											NE
White	101	6.36 (1.70)	101	9.30 (1.74)	-2.94 (2.06)	(-7.01, 1.12)	0.1551	-0.17 (0.14)	(-0.45, 0.11)	0.2283	
Black or African American	17	6.96 (5.42)	22	-1.20 (5.51)	8.16 (5.94)	(-3.98, 20.30)	0.1798	0.33 (0.33)	(-0.31, 0.97)	0.3135	
Asian	29	-1.52 (4.09)	29	-12.30 (4.02)	10.78 (3.67)	(3.41, 18.15)	0.0049	0.49 (0.27)	(-0.04, 1.01)	0.0680	
American Indian or Alaska Native	4	NE	1	NE	NE	NE		NE	NE		
Other	11	14.43 (6.65)	10	0.96 (7.28)	13.48 (7.80)	(-3.16, 30.12)	0.1047	0.57 (0.45)	(-0.30, 1.45)	0.1996	
Ethnicity											0.5554
Hispanic/Latino	52	11.84 (2.61)	54	8.47 (2.48)	3.37 (2.97)	(-2.53, 9.27)	0.2601	0.18 (0.19)	(-0.20, 0.56)	0.3537	
Non-hispanic/Latino	110	2.29 (1.78)	109	1.06 (1.82)	1.23 (2.08)	(-2.88, 5.34)	0.5567	0.06 (0.14)	(-0.20, 0.33)	0.6312	
Geographic region											0.1171
EU	45	4.98 (3.14)	40	6.47 (3.42)	-1.49 (3.40)	(-8.26, 5.28)	0.6618	-0.07 (0.22)	(-0.50, 0.36)	0.7499	
non-EU	123	7.39 (1.68)	129	2.72 (1.66)	4.68 (1.99)	(0.76, 8.60)	0.0196	0.25 (0.13)	(0.00, 0.50)	0.0495	
Onset of disease											0.4917
Paediatric	11	0.55 (6.49)	11	-7.04 (7.52)	7.59 (7.74)	(-8.73, 23.91)	0.3401	0.31 (0.43)	(-0.53, 1.16)	0.4653	
Adult	157	6.67 (1.53)	158	4.54 (1.52)	2.13 (1.79)	(-1.39, 5.65)	0.2344	0.11 (0.11)	(-0.11, 0.33)	0.3250	
ADA result											0.0119
Negative	161	6.11 (1.50)	151	4.07 (1.55)	2.04 (1.78)	(-1.46, 5.54)	0.2522	0.11 (0.11)	(-0.12, 0.33)	0.3449	
Positive (At any time)	7	33.24 (10.34)	18	10.85 (6.44)	22.38 (7.89)	(5.81, 38.95)	0.0109	0.79 (0.46)	(-0.11, 1.70)	0.0864	
BMI (kg/m2) at enrolment											0.6031
< 30	118	5.16 (1.89)	125	3.23 (1.91)	1.93 (2.03)	(-2.06, 5.93)	0.3418	0.09 (0.13)	(-0.16, 0.34)	0.4744	
>= 30	50	9.14 (2.51)	44	5.18 (2.55)	3.96 (3.32)	(-2.65, 10.57)	0.2373	0.23 (0.21)	(-0.18, 0.63)	0.2768	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.4266
All negative/normal	55	7.35 (2.30)	76	6.38 (2.03)	0.97 (2.87)	(-4.71, 6.65)	0.7356	0.06 (0.18)	(-0.29, 0.40)	0.7547	
At least one positive/abnormal	113	7.24 (2.24)	93	3.40 (2.44)	3.84 (2.20)	(-0.49, 8.17)	0.0818	0.16 (0.14)	(-0.11, 0.44)	0.2491	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Physical Health domain score
Full analysis set

	Anifrolumab 300mg (N=180)		Placebo (N=182)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 12		9.26 (1.63)		5.47 (1.62)	3.79 (1.98)	(-0.10, 7.68)	0.0561			
Week 24		10.00 (1.65)		7.26 (1.64)	2.74 (2.00)	(-1.19, 6.68)	0.1710			
Week 36		8.51 (1.66)		10.44 (1.69)	-1.93 (2.05)	(-5.96, 2.11)	0.3482			
Week 52		6.56 (1.67)		6.94 (1.73)	-0.38 (2.09)	(-4.49, 3.73)	0.8568			
OVERALL	166	8.58 (1.45)	169	7.53 (1.46)	1.06 (1.69)	(-2.26, 4.37)	0.5311	0.06 (0.11)	(-0.16, 0.27)	0.6079

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Physical Health domain score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=182) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.3341
< 10 points	49	11.12 (2.56)	50	12.85 (2.58)	-1.73 (3.33)	(-8.34, 4.87)	0.6039	-0.10 (0.20)	(-0.49, 0.30)	0.6366	
>= 10 points	117	7.09 (1.76)	119	5.09 (1.76)	2.00 (1.97)	(-1.88, 5.88)	0.3104	0.10 (0.13)	(-0.15, 0.36)	0.4235	
OCS dose at baseline											0.1578
<10 mg/day	89	6.90 (1.68)	91	7.96 (1.70)	-1.06 (2.11)	(-5.23, 3.10)	0.6154	-0.07 (0.15)	(-0.36, 0.23)	0.6580	
>=10 mg/day	77	9.59 (2.65)	78	5.78 (2.65)	3.81 (2.73)	(-1.58, 9.20)	0.1648	0.16 (0.16)	(-0.15, 0.48)	0.3127	
Result of type I IFN gene signature test											0.5835
LOW	28	11.31 (3.24)	29	8.24 (3.18)	3.07 (4.33)	(-5.62, 11.76)	0.4810	0.18 (0.27)	(-0.34, 0.70)	0.5052	
HIGH	138	8.15 (1.40)	140	7.66 (1.40)	0.49 (1.85)	(-3.15, 4.14)	0.7908	0.03 (0.12)	(-0.21, 0.26)	0.8046	
Age (years)											NE
<= 65	162	8.50 (1.45)	169	7.59 (1.46)	0.91 (1.69)	(-2.42, 4.24)	0.5912	0.05 (0.11)	(-0.17, 0.26)	0.6594	
> 65	4	NE	0	NE	NE	NE		NE	NE		
Sex											0.5387
male	11	11.18 (7.32)	12	13.98 (9.86)	-2.79 (6.73)	(-17.01, 11.42)	0.6832	-0.09 (0.42)	(-0.91, 0.73)	0.8292	
female	155	8.45 (1.48)	157	6.98 (1.49)	1.48 (1.75)	(-1.96, 4.91)	0.3978	0.08 (0.11)	(-0.14, 0.30)	0.4829	
Race											NE
White	100	9.47 (1.85)	101	11.84 (1.89)	-2.37 (2.25)	(-6.81, 2.06)	0.2926	-0.13 (0.14)	(-0.40, 0.15)	0.3729	
Black or African American	16	13.99 (5.48)	22	10.37 (5.62)	3.62 (6.12)	(-8.84, 16.09)	0.5581	0.14 (0.33)	(-0.50, 0.79)	0.6615	
Asian	29	-0.65 (3.37)	29	-6.19 (3.41)	5.54 (3.05)	(-0.58, 11.65)	0.0750	0.30 (0.26)	(-0.22, 0.82)	0.2577	
American Indian or Alaska Native	4	NE	1	NE	NE	NE		NE	NE		
Other	11	6.39 (5.42)	10	-6.85 (6.08)	13.25 (6.57)	(-0.69, 27.18)	0.0611	0.68 (0.45)	(-0.20, 1.57)	0.1303	
Ethnicity											0.3278
Hispanic/Latino	52	14.43 (2.88)	54	10.28 (2.72)	4.16 (3.35)	(-2.50, 10.81)	0.2181	0.20 (0.19)	(-0.18, 0.58)	0.2985	
Non-hispanic/Latino	108	5.70 (1.70)	109	5.35 (1.73)	0.35 (1.97)	(-3.54, 4.24)	0.8599	0.02 (0.14)	(-0.25, 0.29)	0.8861	
Geographic region											0.0171
EU	44	6.26 (3.10)	40	12.44 (3.28)	-6.18 (3.27)	(-12.69, 0.33)	0.0624	-0.30 (0.22)	(-0.73, 0.13)	0.1768	
non-EU	122	9.30 (1.64)	129	6.40 (1.64)	2.90 (1.95)	(-0.95, 6.74)	0.1389	0.16 (0.13)	(-0.09, 0.40)	0.2148	
Onset of disease											0.5523
Paediatric	10	-4.34 (4.84)	11	-2.25 (6.33)	-2.09 (5.65)	(-13.98, 9.80)	0.7158	-0.11 (0.44)	(-0.97, 0.75)	0.8042	
Adult	156	9.35 (1.52)	158	7.92 (1.51)	1.43 (1.77)	(-2.05, 4.91)	0.4192	0.08 (0.11)	(-0.15, 0.30)	0.5052	
ADA result											0.3045
Negative	160	8.89 (1.46)	151	8.76 (1.51)	0.13 (1.73)	(-3.27, 3.53)	0.9413	0.01 (0.11)	(-0.22, 0.23)	0.9518	
Positive (At any time)	6	8.57 (9.62)	18	-0.42 (6.20)	8.99 (8.46)	(-9.11, 27.09)	0.3054	0.34 (0.47)	(-0.59, 1.27)	0.4768	
BMI (kg/m2) at enrolment											0.2187
< 30	116	6.97 (1.78)	125	6.96 (1.80)	0.01 (1.91)	(-3.76, 3.77)	0.9964	0.00 (0.13)	(-0.25, 0.25)	0.9973	
>= 30	50	12.96 (2.59)	44	8.11 (2.66)	4.85 (3.44)	(-1.99, 11.70)	0.1625	0.27 (0.21)	(-0.14, 0.67)	0.1977	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.9885
All negative/normal	55	9.02 (2.35)	76	8.43 (2.08)	0.58 (2.94)	(-5.24, 6.41)	0.8427	0.03 (0.18)	(-0.31, 0.38)	0.8539	
At least one positive/abnormal	111	8.80 (2.15)	93	8.17 (2.34)	0.64 (2.09)	(-3.48, 4.75)	0.7604	0.03 (0.14)	(-0.25, 0.30)	0.8416	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Emotional Health domain score
Full analysis set

	Anifrolumab 300mg (N=180)		Placebo (N=182)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 12		3.70 (1.63)		0.96 (1.62)	2.75 (2.01)	(-1.20, 6.70)	0.1721			
Week 24		5.91 (1.65)		5.00 (1.64)	0.91 (2.02)	(-3.07, 4.89)	0.6525			
Week 36		5.37 (1.66)		6.91 (1.69)	-1.54 (2.06)	(-5.60, 2.52)	0.4569			
Week 52		4.15 (1.95)		4.97 (2.00)	-0.82 (2.54)	(-5.82, 4.19)	0.7487			
OVERALL	166	4.78 (1.47)	169	4.46 (1.48)	0.33 (1.74)	(-3.10, 3.76)	0.8516	0.02 (0.11)	(-0.20, 0.23)	0.8759

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Emotional Health domain score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=182) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.5594
< 10 points	49	8.11 (2.65)	50	6.22 (2.65)	1.89 (3.46)	(-4.98, 8.76)	0.5861	0.10 (0.20)	(-0.29, 0.49)	0.6173	
>= 10 points	117	2.93 (1.77)	119	3.38 (1.78)	-0.45 (2.03)	(-4.44, 3.54)	0.8245	-0.02 (0.13)	(-0.28, 0.23)	0.8587	
OCS dose at baseline											0.4276
<10 mg/day	89	3.40 (1.70)	91	4.41 (1.72)	-1.02 (2.16)	(-5.28, 3.25)	0.6387	-0.06 (0.15)	(-0.35, 0.23)	0.6762	
>=10 mg/day	77	6.35 (2.70)	78	4.53 (2.67)	1.82 (2.85)	(-3.81, 7.45)	0.5238	0.08 (0.16)	(-0.24, 0.39)	0.6333	
Result of type I IFN gene signature test											0.3896
LOW	28	6.07 (3.02)	29	2.47 (3.01)	3.59 (4.20)	(-4.84, 12.03)	0.3966	0.22 (0.27)	(-0.30, 0.74)	0.4072	
HIGH	138	5.31 (1.46)	140	5.70 (1.46)	-0.39 (1.95)	(-4.22, 3.44)	0.8404	-0.02 (0.12)	(-0.26, 0.21)	0.8499	
Age (years)											NE
<= 65	162	4.77 (1.49)	169	4.46 (1.49)	0.30 (1.76)	(-3.16, 3.77)	0.8631	0.02 (0.11)	(-0.20, 0.23)	0.8854	
> 65	4	NE	0	NE	NE	NE		NE	NE		
Sex											0.6822
male	11	4.45 (6.98)	12	6.60 (9.49)	-2.15 (6.50)	(-15.75, 11.45)	0.7448	-0.07 (0.42)	(-0.89, 0.75)	0.8627	
female	155	4.63 (1.49)	157	4.01 (1.49)	0.61 (1.78)	(-2.89, 4.11)	0.7311	0.03 (0.11)	(-0.19, 0.25)	0.7716	
Race											NE
White	100	4.45 (1.89)	101	6.60 (1.93)	-2.15 (2.32)	(-6.74, 2.43)	0.3558	-0.11 (0.14)	(-0.39, 0.16)	0.4274	
Black or African American	16	10.64 (5.27)	22	7.43 (5.27)	3.21 (5.99)	(-9.01, 15.43)	0.5956	0.14 (0.33)	(-0.51, 0.78)	0.6812	
Asian	29	-8.32 (3.64)	29	-7.39 (3.55)	-0.93 (3.52)	(-7.99, 6.13)	0.7929	-0.05 (0.26)	(-0.56, 0.47)	0.8569	
American Indian or Alaska Native	4	NE	1	NE	NE	NE		NE	NE		
Other	11	12.32 (5.69)	10	0.79 (6.23)	11.53 (6.70)	(-2.62, 25.68)	0.1036	0.57 (0.45)	(-0.30, 1.45)	0.1996	
Ethnicity											0.9658
Hispanic/Latino	52	6.08 (3.07)	54	5.88 (2.89)	0.20 (3.68)	(-7.10, 7.51)	0.9561	0.01 (0.19)	(-0.37, 0.39)	0.9618	
Non-hispanic/Latino	108	3.75 (1.74)	109	3.73 (1.77)	0.02 (2.05)	(-4.02, 4.06)	0.9912	0.00 (0.14)	(-0.26, 0.27)	0.9928	
Geographic region											0.8095
EU	44	6.51 (3.18)	40	6.94 (3.41)	-0.43 (3.43)	(-7.28, 6.42)	0.9012	-0.02 (0.22)	(-0.45, 0.41)	0.9276	
non-EU	122	3.98 (1.67)	129	3.45 (1.66)	0.53 (2.02)	(-3.45, 4.52)	0.7926	0.03 (0.13)	(-0.22, 0.28)	0.8219	
Onset of disease											0.8424
Paediatric	10	-0.46 (5.98)	11	0.34 (7.14)	-0.80 (6.46)	(-14.52, 12.93)	0.9034	-0.04 (0.44)	(-0.89, 0.82)	0.9352	
Adult	156	5.40 (1.53)	158	4.86 (1.52)	0.54 (1.81)	(-3.03, 4.11)	0.7674	0.03 (0.11)	(-0.19, 0.25)	0.8040	
ADA result											0.3326
Negative	160	4.85 (1.49)	151	5.10 (1.54)	-0.25 (1.80)	(-3.80, 3.29)	0.8878	-0.01 (0.11)	(-0.24, 0.21)	0.9060	
Positive (At any time)	6	7.48 (8.13)	18	0.84 (5.49)	6.63 (6.88)	(-8.14, 21.41)	0.3514	0.28 (0.47)	(-0.64, 1.21)	0.5487	
BMI (kg/m2) at enrolment											0.4533
< 30	116	3.44 (1.90)	125	2.16 (1.92)	1.28 (2.07)	(-2.80, 5.36)	0.5365	0.06 (0.13)	(-0.19, 0.31)	0.6371	
>= 30	50	5.85 (2.41)	44	7.45 (2.45)	-1.60 (3.24)	(-8.04, 4.84)	0.6225	-0.10 (0.21)	(-0.50, 0.31)	0.6455	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.7566
All negative/normal	55	7.05 (2.22)	76	5.93 (1.94)	1.12 (2.79)	(-4.41, 6.64)	0.6898	0.07 (0.18)	(-0.28, 0.41)	0.7078	
At least one positive/abnormal	111	4.17 (2.30)	93	4.17 (2.50)	-0.00 (2.29)	(-4.52, 4.52)	0.9993	-0.00 (0.14)	(-0.28, 0.28)	0.9995	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Body Image domain score
Full analysis set

	Anifrolumab 300mg (N=180)		Placebo (N=182)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 12		6.37 (1.84)		3.77 (1.81)	2.60 (2.22)	(-1.77, 6.97)	0.2425			
Week 24		9.57 (1.98)		5.50 (1.95)	4.08 (2.44)	(-0.73, 8.88)	0.0960			
Week 36		9.44 (1.99)		10.45 (2.01)	-1.01 (2.49)	(-5.92, 3.89)	0.6840			
Week 52		7.31 (2.19)		7.70 (2.21)	-0.39 (2.81)	(-5.92, 5.13)	0.8886			
OVERALL	152	8.17 (1.68)	158	6.86 (1.67)	1.32 (1.97)	(-2.55, 5.19)	0.5036	0.06 (0.11)	(-0.16, 0.29)	0.5803

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Body Image domain score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=182) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.8312
< 10 points	45	7.43 (2.68)	47	6.86 (2.67)	0.57 (3.39)	(-6.17, 7.30)	0.8679	0.03 (0.21)	(-0.38, 0.44)	0.8821	
>= 10 points	107	9.02 (2.13)	111	7.57 (2.11)	1.45 (2.40)	(-3.29, 6.19)	0.5464	0.07 (0.14)	(-0.20, 0.33)	0.6294	
OCS dose at baseline											0.9271
<10 mg/day	81	8.99 (1.96)	85	7.35 (1.98)	1.64 (2.48)	(-3.26, 6.53)	0.5099	0.09 (0.16)	(-0.21, 0.40)	0.5592	
>=10 mg/day	71	6.38 (3.05)	73	5.11 (2.96)	1.27 (3.12)	(-4.91, 7.45)	0.6847	0.05 (0.17)	(-0.28, 0.38)	0.7660	
Result of type I IFN gene signature test											0.8791
LOW	25	7.02 (3.19)	27	5.45 (3.08)	1.57 (4.31)	(-7.12, 10.26)	0.7177	0.10 (0.28)	(-0.45, 0.64)	0.7277	
HIGH	127	7.54 (1.67)	131	6.71 (1.65)	0.83 (2.22)	(-3.53, 5.20)	0.7079	0.04 (0.12)	(-0.20, 0.29)	0.7240	
Age (years)											NE
<= 65	148	7.92 (1.70)	158	6.73 (1.67)	1.19 (1.98)	(-2.71, 5.08)	0.5493	0.06 (0.11)	(-0.17, 0.28)	0.6202	
> 65	4	NE	0	NE	NE	NE		NE	NE		
Sex											0.4753
male	11	14.62 (6.30)	12	17.33 (7.45)	-2.72 (5.91)	(-15.55, 10.12)	0.6536	-0.11 (0.42)	(-0.93, 0.71)	0.7906	
female	141	8.28 (1.76)	146	6.53 (1.74)	1.75 (2.07)	(-2.32, 5.83)	0.3983	0.08 (0.12)	(-0.15, 0.31)	0.4800	
Race											0.0227
White	96	7.44 (2.02)	93	7.63 (2.14)	-0.20 (2.51)	(-5.16, 4.76)	0.9371	-0.01 (0.15)	(-0.29, 0.28)	0.9464	
Black or African American	16	7.01 (6.03)	21	15.24 (6.08)	-8.22 (6.66)	(-21.82, 5.38)	0.2265	-0.31 (0.33)	(-0.96, 0.35)	0.3601	
Asian	22	2.27 (5.81)	28	2.90 (5.27)	-0.63 (4.93)	(-10.55, 9.29)	0.8989	-0.02 (0.28)	(-0.58, 0.54)	0.9372	
American Indian or Alaska Native	2	NE	0	NE	NE	NE		NE	NE		
Other	11	14.62 (6.29)	10	-5.35 (6.76)	19.97 (7.01)	(5.05, 34.88)	0.0120	0.91 (0.46)	(-0.00, 1.82)	0.0501	
Ethnicity											0.4216
Hispanic/Latino	48	9.96 (3.20)	49	6.66 (3.11)	3.30 (3.71)	(-4.08, 10.68)	0.3764	0.15 (0.20)	(-0.25, 0.55)	0.4637	
Non-hispanic/Latino	99	6.52 (2.06)	103	6.78 (2.07)	-0.27 (2.44)	(-5.07, 4.54)	0.9125	-0.01 (0.14)	(-0.29, 0.26)	0.9272	
Geographic region											0.9949
EU	42	9.15 (3.51)	35	7.76 (3.72)	1.40 (3.75)	(-6.10, 8.89)	0.7112	0.06 (0.23)	(-0.39, 0.51)	0.7879	
non-EU	110	7.84 (1.94)	123	6.48 (1.89)	1.37 (2.30)	(-3.16, 5.89)	0.5520	0.07 (0.13)	(-0.19, 0.32)	0.6157	
Onset of disease											0.2351
Paediatric	9	-1.08 (8.01)	10	-14.21 (8.62)	13.13 (9.76)	(-8.89, 35.14)	0.2108	0.49 (0.47)	(-0.43, 1.40)	0.2987	
Adult	143	9.33 (1.73)	148	8.03 (1.69)	1.30 (2.00)	(-2.64, 5.25)	0.5167	0.06 (0.12)	(-0.17, 0.29)	0.5916	
ADA result											0.9221
Negative	146	8.14 (1.72)	141	7.21 (1.76)	0.93 (2.04)	(-3.08, 4.95)	0.6479	0.04 (0.12)	(-0.19, 0.28)	0.7055	
Positive (At any time)	6	1.78 (8.84)	17	1.73 (5.98)	0.05 (8.84)	(-19.09, 19.18)	0.9960	0.00 (0.47)	(-0.93, 0.93)	0.9969	
BMI (kg/m2) at enrolment											0.1673
< 30	103	8.34 (2.21)	115	5.28 (2.18)	3.06 (2.37)	(-1.61, 7.73)	0.1982	0.13 (0.14)	(-0.13, 0.40)	0.3275	
>= 30	49	8.16 (2.67)	43	10.98 (2.77)	-2.81 (3.53)	(-9.84, 4.21)	0.4278	-0.15 (0.21)	(-0.56, 0.26)	0.4704	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.9789
All negative/normal	50	8.28 (2.55)	72	6.71 (2.20)	1.57 (3.19)	(-4.75, 7.89)	0.6238	0.08 (0.18)	(-0.28, 0.45)	0.6457	
At least one positive/abnormal	102	9.85 (2.70)	86	8.39 (2.91)	1.46 (2.58)	(-3.64, 6.56)	0.5724	0.05 (0.15)	(-0.23, 0.34)	0.7143	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Burden to Others domain score
Full analysis set

Visit	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=182) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 12		9.06 (2.13)		2.88 (2.10)	6.18 (2.60)	(1.07, 11.29)	0.0179			
Week 24		8.78 (2.16)		7.73 (2.14)	1.05 (2.64)	(-4.15, 6.25)	0.6909			
Week 36		10.89 (2.22)		11.57 (2.26)	-0.68 (2.77)	(-6.13, 4.78)	0.8079			
Week 52		9.08 (2.34)		5.60 (2.40)	3.49 (2.99)	(-2.41, 9.38)	0.2453			
OVERALL	166	9.46 (1.90)	169	6.94 (1.90)	2.51 (2.22)	(-1.86, 6.88)	0.2595	0.10 (0.11)	(-0.11, 0.32)	0.3514

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Burden to Others domain score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=180)		Placebo (N=182)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											0.3295
< 10 points	49	10.16 (3.18)	50	4.42 (3.20)	5.74 (4.10)	(-2.40, 13.88)	0.1646	0.25 (0.20)	(-0.14, 0.65)	0.2089	
>= 10 points	117	9.74 (2.36)	119	8.76 (2.36)	0.98 (2.66)	(-4.27, 6.22)	0.7145	0.04 (0.13)	(-0.22, 0.29)	0.7708	
OCS dose at baseline											0.5257
<10 mg/day	89	8.42 (2.09)	91	6.98 (2.11)	1.44 (2.65)	(-3.78, 6.66)	0.5861	0.07 (0.15)	(-0.22, 0.36)	0.6286	
>=10 mg/day	77	10.19 (3.58)	78	5.86 (3.55)	4.33 (3.70)	(-2.99, 11.65)	0.2440	0.14 (0.16)	(-0.18, 0.45)	0.3931	
Result of type I IFN gene signature test											0.6845
LOW	28	12.24 (4.23)	29	11.68 (4.23)	0.56 (5.80)	(-11.07, 12.19)	0.9236	0.02 (0.26)	(-0.49, 0.54)	0.9266	
HIGH	138	6.70 (1.84)	140	3.58 (1.84)	3.11 (2.44)	(-1.69, 7.92)	0.2027	0.14 (0.12)	(-0.09, 0.38)	0.2325	
Age (years)											NE
<= 65	162	9.32 (1.92)	169	6.87 (1.91)	2.45 (2.24)	(-1.97, 6.86)	0.2760	0.10 (0.11)	(-0.12, 0.31)	0.3680	
> 65	4	NE	0	NE	NE	NE		NE	NE		
Sex											0.3436
male	11	21.51 (7.66)	12	25.80 (9.43)	-4.29 (7.37)	(-19.86, 11.27)	0.5680	-0.14 (0.42)	(-0.96, 0.68)	0.7368	
female	155	8.98 (1.95)	157	5.96 (1.95)	3.02 (2.30)	(-1.51, 7.55)	0.1911	0.12 (0.11)	(-0.10, 0.35)	0.2745	
Race											NE
White	100	9.10 (2.43)	101	10.71 (2.48)	-1.60 (2.98)	(-7.48, 4.27)	0.5909	-0.07 (0.14)	(-0.34, 0.21)	0.6449	
Black or African American	16	13.24 (7.67)	22	6.01 (7.56)	7.23 (8.42)	(-9.95, 24.41)	0.3974	0.21 (0.33)	(-0.43, 0.86)	0.5221	
Asian	29	2.74 (5.03)	29	-5.17 (5.00)	7.91 (4.53)	(-1.19, 17.02)	0.0870	0.29 (0.26)	(-0.23, 0.81)	0.2736	
American Indian or Alaska Native	4	NE	1	NE	NE	NE		NE	NE		
Other	11	9.83 (6.76)	10	-4.18 (7.31)	14.01 (7.82)	(-2.66, 30.68)	0.0934	0.59 (0.45)	(-0.29, 1.47)	0.1876	
Ethnicity											0.8559
Hispanic/Latino	52	15.03 (3.80)	54	11.16 (3.55)	3.87 (4.42)	(-4.89, 12.63)	0.3830	0.14 (0.19)	(-0.24, 0.52)	0.4603	
Non-hispanic/Latino	108	7.28 (2.28)	109	4.34 (2.31)	2.93 (2.65)	(-2.30, 8.17)	0.2705	0.12 (0.14)	(-0.14, 0.39)	0.3680	
Geographic region											0.2073
EU	44	6.87 (3.70)	40	8.86 (3.94)	-1.99 (4.16)	(-10.29, 6.31)	0.6348	-0.08 (0.22)	(-0.51, 0.35)	0.7155	
non-EU	122	10.54 (2.17)	129	6.34 (2.15)	4.20 (2.59)	(-0.90, 9.29)	0.1061	0.17 (0.13)	(-0.08, 0.42)	0.1721	
Onset of disease											0.8427
Paediatric	10	6.07 (9.12)	11	5.32 (10.56)	0.74 (10.36)	(-21.45, 22.94)	0.9438	0.02 (0.44)	(-0.83, 0.88)	0.9596	
Adult	156	10.00 (1.97)	158	7.15 (1.95)	2.85 (2.30)	(-1.69, 7.38)	0.2174	0.12 (0.11)	(-0.11, 0.34)	0.3048	
ADA result											0.0314
Negative	160	9.18 (1.93)	151	8.14 (2.00)	1.05 (2.31)	(-3.49, 5.59)	0.6498	0.04 (0.11)	(-0.18, 0.27)	0.7065	
Positive (At any time)	6	21.12 (9.87)	18	0.35 (6.63)	20.77 (8.87)	(2.12, 39.42)	0.0311	0.73 (0.49)	(-0.22, 1.69)	0.1301	
BMI (kg/m2) at enrolment											0.6695
< 30	116	6.28 (2.36)	125	3.28 (2.38)	3.00 (2.55)	(-2.03, 8.03)	0.2417	0.11 (0.13)	(-0.14, 0.37)	0.3739	
>= 30	50	13.04 (3.33)	44	12.22 (3.40)	0.82 (4.42)	(-7.97, 9.61)	0.8537	0.04 (0.21)	(-0.37, 0.44)	0.8650	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.8928
All negative/normal	55	13.31 (2.85)	76	9.92 (2.50)	3.38 (3.56)	(-3.65, 10.42)	0.3430	0.16 (0.18)	(-0.19, 0.50)	0.3785	
At least one positive/abnormal	111	6.61 (2.96)	93	3.84 (3.22)	2.76 (2.92)	(-2.99, 8.52)	0.3448	0.09 (0.14)	(-0.19, 0.36)	0.5293	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Fatigue domain score
Full analysis set

	Anifrolumab 300mg (N=180)		Placebo (N=182)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 12		7.72 (1.75)		4.85 (1.74)	2.87 (2.12)	(-1.30, 7.04)	0.1763			
Week 24		8.35 (1.81)		5.81 (1.79)	2.55 (2.20)	(-1.79, 6.88)	0.2487			
Week 36		6.81 (1.87)		6.88 (1.90)	-0.07 (2.34)	(-4.67, 4.52)	0.9746			
Week 52		7.10 (2.02)		5.80 (2.08)	1.30 (2.60)	(-3.82, 6.42)	0.6180			
OVERALL	166	7.49 (1.61)	169	5.83 (1.62)	1.66 (1.89)	(-2.07, 5.39)	0.3815	0.08 (0.11)	(-0.14, 0.29)	0.4689

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Fatigue domain score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=182) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.6461
< 10 points	49	9.28 (2.68)	50	6.40 (2.67)	2.88 (3.45)	(-3.97, 9.73)	0.4055	0.15 (0.20)	(-0.24, 0.55)	0.4502	
>= 10 points	117	6.44 (2.02)	119	5.46 (2.02)	0.98 (2.29)	(-3.53, 5.49)	0.6687	0.04 (0.13)	(-0.21, 0.30)	0.7316	
OCS dose at baseline											0.5121
<10 mg/day	89	6.00 (1.88)	91	5.39 (1.89)	0.62 (2.37)	(-4.06, 5.30)	0.7941	0.03 (0.15)	(-0.26, 0.33)	0.8170	
>=10 mg/day	77	8.84 (2.95)	78	5.70 (2.92)	3.14 (3.03)	(-2.84, 9.12)	0.3012	0.12 (0.16)	(-0.19, 0.44)	0.4523	
Result of type I IFN gene signature test											0.5816
LOW	28	9.68 (3.67)	29	5.50 (3.68)	4.19 (5.05)	(-5.94, 14.32)	0.4105	0.21 (0.27)	(-0.31, 0.73)	0.4282	
HIGH	138	7.24 (1.56)	140	6.06 (1.56)	1.18 (2.07)	(-2.89, 5.25)	0.5682	0.06 (0.12)	(-0.17, 0.30)	0.5928	
Age (years)											NE
<= 65	162	7.61 (1.62)	169	5.95 (1.62)	1.66 (1.90)	(-2.09, 5.41)	0.3840	0.08 (0.11)	(-0.14, 0.29)	0.4707	
> 65	4	NE	0	NE	NE	NE		NE	NE		
Sex											0.1985
male	11	4.52 (6.48)	12	10.89 (8.30)	-6.37 (6.37)	(-19.72, 6.98)	0.3301	-0.24 (0.42)	(-1.06, 0.58)	0.5666	
female	155	7.88 (1.68)	157	5.67 (1.68)	2.21 (2.00)	(-1.72, 6.14)	0.2687	0.10 (0.11)	(-0.12, 0.33)	0.3543	
Race											NE
White	100	6.83 (2.08)	101	8.94 (2.12)	-2.11 (2.54)	(-7.11, 2.89)	0.4064	-0.10 (0.14)	(-0.38, 0.18)	0.4792	
Black or African American	16	15.74 (5.84)	22	3.52 (5.84)	12.22 (6.53)	(-1.11, 25.55)	0.0709	0.46 (0.33)	(-0.19, 1.12)	0.1641	
Asian	29	1.63 (4.30)	29	-4.43 (4.28)	6.07 (3.95)	(-1.86, 14.00)	0.1305	0.26 (0.26)	(-0.26, 0.78)	0.3261	
American Indian or Alaska Native	4	NE	1	NE	NE	NE		NE	NE		
Other	11	7.53 (5.27)	10	-1.80 (5.68)	9.32 (6.43)	(-4.30, 22.94)	0.1662	0.51 (0.45)	(-0.37, 1.38)	0.2568	
Ethnicity											0.6703
Hispanic/Latino	52	10.40 (3.12)	54	7.01 (2.96)	3.39 (3.62)	(-3.80, 10.59)	0.3513	0.15 (0.19)	(-0.23, 0.53)	0.4330	
Non-hispanic/Latino	108	5.71 (1.96)	109	4.14 (2.00)	1.57 (2.31)	(-2.98, 6.11)	0.4981	0.08 (0.14)	(-0.19, 0.34)	0.5777	
Geographic region											0.1006
EU	44	6.15 (3.50)	40	9.93 (3.73)	-3.78 (3.73)	(-11.21, 3.65)	0.3135	-0.16 (0.22)	(-0.59, 0.27)	0.4640	
non-EU	122	8.16 (1.84)	129	4.84 (1.83)	3.32 (2.20)	(-1.01, 7.64)	0.1319	0.16 (0.13)	(-0.09, 0.41)	0.2027	
Onset of disease											0.9390
Paediatric	10	3.73 (5.90)	11	1.69 (7.28)	2.04 (6.66)	(-12.14, 16.22)	0.7636	0.09 (0.44)	(-0.77, 0.95)	0.8367	
Adult	156	8.19 (1.68)	158	6.68 (1.67)	1.51 (1.98)	(-2.39, 5.40)	0.4468	0.07 (0.11)	(-0.15, 0.29)	0.5264	
ADA result											0.3682
Negative	160	7.47 (1.61)	151	6.55 (1.67)	0.91 (1.93)	(-2.88, 4.71)	0.6362	0.04 (0.11)	(-0.18, 0.27)	0.6944	
Positive (At any time)	6	15.07 (13.45)	18	4.00 (9.16)	11.07 (11.12)	(-12.32, 34.46)	0.3329	0.28 (0.47)	(-0.64, 1.21)	0.5484	
BMI (kg/m2) at enrolment											0.6413
< 30	116	6.21 (1.99)	125	3.68 (2.02)	2.52 (2.18)	(-1.76, 6.81)	0.2470	0.11 (0.13)	(-0.14, 0.37)	0.3764	
>= 30	50	9.75 (2.89)	44	9.29 (2.94)	0.47 (3.84)	(-7.17, 8.11)	0.9033	0.02 (0.21)	(-0.38, 0.43)	0.9105	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.6651
All negative/normal	55	7.53 (2.42)	76	7.07 (2.13)	0.46 (3.02)	(-5.52, 6.44)	0.8785	0.03 (0.18)	(-0.32, 0.37)	0.8870	
At least one positive/abnormal	111	6.02 (2.53)	93	3.86 (2.75)	2.16 (2.49)	(-2.75, 7.07)	0.3873	0.08 (0.14)	(-0.19, 0.36)	0.5649	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Intimate Relationships domain score
Full analysis set

	Anifrolumab 300mg (N=180)		Placebo (N=182)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 12		4.73 (2.48)		4.06 (2.46)	0.67 (3.14)	(-5.52, 6.86)	0.8311			
Week 24		6.96 (2.61)		3.42 (2.58)	3.55 (3.32)	(-2.99, 10.09)	0.2864			
Week 36		7.71 (2.90)		7.32 (2.92)	0.39 (3.80)	(-7.10, 7.88)	0.9190			
Week 52		5.55 (2.68)		6.80 (2.66)	-1.24 (3.41)	(-7.98, 5.49)	0.7158			
OVERALL	123	6.24 (2.15)	127	5.40 (2.13)	0.84 (2.59)	(-4.26, 5.94)	0.7459	0.03 (0.13)	(-0.21, 0.28)	0.7822

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Intimate Relationships domain score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=182) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.8411
< 10 points	38	7.18 (4.19)	35	5.35 (4.25)	1.83 (5.59)	(-9.34, 12.99)	0.7449	0.07 (0.23)	(-0.39, 0.53)	0.7626	
>= 10 points	85	6.53 (2.54)	92	5.97 (2.51)	0.56 (2.93)	(-5.22, 6.34)	0.8480	0.02 (0.15)	(-0.27, 0.32)	0.8757	
OCS dose at baseline											0.0284
<10 mg/day	65	4.34 (2.61)	66	8.90 (2.60)	-4.56 (3.40)	(-11.29, 2.16)	0.1815	-0.22 (0.18)	(-0.56, 0.13)	0.2190	
>=10 mg/day	58	8.08 (3.89)	61	1.11 (3.83)	6.97 (4.02)	(-1.00, 14.95)	0.0859	0.23 (0.18)	(-0.13, 0.59)	0.2064	
Result of type I IFN gene signature test											0.9939
LOW	24	3.08 (5.22)	25	2.37 (4.95)	0.71 (6.85)	(-13.11, 14.54)	0.9178	0.03 (0.29)	(-0.53, 0.59)	0.9225	
HIGH	99	7.37 (2.15)	102	6.60 (2.17)	0.77 (2.85)	(-4.85, 6.39)	0.7876	0.04 (0.14)	(-0.24, 0.31)	0.8024	
Age (years)											NE
<= 65	120	6.50 (2.17)	127	5.33 (2.14)	1.17 (2.61)	(-3.97, 6.31)	0.6542	0.05 (0.13)	(-0.20, 0.30)	0.7022	
> 65	3	NE	0	NE	NE	NE		NE	NE		
Sex											0.8335
male	10	8.19 (5.37)	11	6.19 (6.13)	2.00 (4.66)	(-7.88, 11.88)	0.6739	0.10 (0.44)	(-0.76, 0.96)	0.8156	
female	113	6.35 (2.29)	116	5.50 (2.27)	0.86 (2.79)	(-4.64, 6.36)	0.7592	0.04 (0.13)	(-0.22, 0.29)	0.7910	
Race											NE
White	80	5.89 (2.49)	81	7.95 (2.51)	-2.05 (3.10)	(-8.19, 4.08)	0.5090	-0.09 (0.16)	(-0.40, 0.22)	0.5633	
Black or African American	14	11.13 (7.11)	18	7.27 (6.75)	3.86 (7.91)	(-12.36, 20.08)	0.6294	0.14 (0.36)	(-0.56, 0.83)	0.7041	
Asian	11	6.20 (11.56)	14	-18.36 (9.32)	24.56 (9.42)	(4.57, 44.56)	0.0192	0.65 (0.42)	(-0.16, 1.47)	0.1161	
American Indian or Alaska Native	4	NE	1	NE	NE	NE		NE	NE		
Other	9	3.19 (6.30)	9	2.32 (6.52)	0.88 (7.20)	(-15.07, 16.82)	0.9056	0.04 (0.47)	(-0.88, 0.97)	0.9267	
Ethnicity											0.5472
Hispanic/Latino	39	5.27 (3.82)	42	6.13 (3.46)	-0.86 (4.27)	(-9.38, 7.67)	0.8412	-0.04 (0.22)	(-0.47, 0.40)	0.8687	
Non-hispanic/Latino	79	6.79 (2.66)	81	4.41 (2.69)	2.38 (3.28)	(-4.11, 8.87)	0.4690	0.10 (0.16)	(-0.21, 0.41)	0.5314	
Geographic region											0.1514
EU	37	8.21 (4.71)	30	14.36 (5.33)	-6.15 (5.52)	(-17.21, 4.91)	0.2702	-0.21 (0.25)	(-0.69, 0.27)	0.3933	
non-EU	86	6.60 (2.49)	97	3.73 (2.38)	2.87 (3.01)	(-3.07, 8.80)	0.3414	0.12 (0.15)	(-0.17, 0.41)	0.4077	
Onset of disease											NE
Paediatric	7	NE	6	NE	NE	NE		NE	NE		
Adult	116	6.37 (2.24)	121	5.83 (2.19)	0.53 (2.69)	(-4.76, 5.83)	0.8426	0.02 (0.13)	(-0.23, 0.28)	0.8650	
ADA result											0.8084
Negative	119	6.25 (2.21)	116	5.92 (2.26)	0.33 (2.70)	(-4.99, 5.65)	0.9031	0.01 (0.13)	(-0.24, 0.27)	0.9172	
Positive (At any time)	4	9.58 (18.26)	11	5.42 (10.31)	4.17 (15.60)	(-37.48, 45.82)	0.8013	0.11 (0.58)	(-1.03, 1.26)	0.8468	
BMI (kg/m2) at enrolment											0.8360
< 30	86	4.14 (2.81)	92	3.15 (2.75)	1.00 (3.15)	(-5.22, 7.21)	0.7518	0.04 (0.15)	(-0.26, 0.33)	0.8008	
>= 30	37	7.84 (3.45)	35	8.01 (3.61)	-0.17 (4.67)	(-9.52, 9.18)	0.9712	-0.01 (0.24)	(-0.47, 0.45)	0.9733	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.6553
All negative/normal	41	6.68 (4.02)	59	7.59 (3.45)	-0.91 (5.03)	(-10.90, 9.08)	0.8569	-0.03 (0.20)	(-0.43, 0.36)	0.8656	
At least one positive/abnormal	82	6.61 (2.81)	68	4.92 (3.13)	1.70 (2.97)	(-4.17, 7.56)	0.5684	0.07 (0.16)	(-0.26, 0.39)	0.6883	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Pain domain score
Full analysis set

	Anifrolumab 300mg (N=180)		Placebo (N=182)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 12		12.76 (1.79)		7.64 (1.78)	5.12 (2.20)	(0.80, 9.44)	0.0204			
Week 24		15.03 (1.84)		8.78 (1.83)	6.25 (2.26)	(1.81, 10.69)	0.0060			
Week 36		12.40 (1.87)		13.57 (1.91)	-1.16 (2.34)	(-5.77, 3.44)	0.6194			
Week 52		11.47 (1.93)		10.11 (2.01)	1.36 (2.48)	(-3.52, 6.23)	0.5842			
OVERALL	166	12.92 (1.56)	169	10.02 (1.58)	2.89 (1.82)	(-0.70, 6.48)	0.1139	0.14 (0.11)	(-0.07, 0.36)	0.1949

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Pain domain score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=182) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.9394
< 10 points	49	14.07 (2.84)	50	11.40 (2.86)	2.67 (3.66)	(-4.60, 9.94)	0.4680	0.13 (0.20)	(-0.26, 0.53)	0.5123	
>= 10 points	117	12.94 (1.89)	119	9.96 (1.91)	2.99 (2.12)	(-1.19, 7.16)	0.1598	0.14 (0.13)	(-0.11, 0.40)	0.2687	
OCS dose at baseline											0.5805
<10 mg/day	89	12.76 (1.81)	91	10.52 (1.82)	2.24 (2.28)	(-2.25, 6.73)	0.3264	0.13 (0.15)	(-0.16, 0.42)	0.3848	
>=10 mg/day	77	12.67 (2.93)	78	8.35 (2.97)	4.33 (3.02)	(-1.64, 10.30)	0.1539	0.17 (0.16)	(-0.15, 0.48)	0.3024	
Result of type I IFN gene signature test											0.4895
LOW	28	19.52 (3.71)	29	13.61 (3.65)	5.91 (4.95)	(-4.03, 15.84)	0.2382	0.30 (0.27)	(-0.23, 0.82)	0.2660	
HIGH	138	10.88 (1.49)	140	8.66 (1.49)	2.22 (1.97)	(-1.66, 6.10)	0.2601	0.13 (0.12)	(-0.11, 0.36)	0.2925	
Age (years)											NE
<= 65	162	12.96 (1.58)	169	9.96 (1.59)	3.00 (1.84)	(-0.62, 6.62)	0.1036	0.15 (0.11)	(-0.07, 0.36)	0.1818	
> 65	4	NE	0	NE	NE	NE		NE	NE		
Sex											0.1603
male	11	5.39 (6.14)	12	10.32 (7.50)	-4.94 (5.71)	(-16.95, 7.07)	0.3989	-0.20 (0.42)	(-1.02, 0.62)	0.6281	
female	155	13.42 (1.62)	157	9.90 (1.63)	3.52 (1.91)	(-0.24, 7.29)	0.0665	0.17 (0.11)	(-0.05, 0.40)	0.1274	
Race											NE
White	100	12.03 (1.97)	101	14.73 (2.02)	-2.70 (2.40)	(-7.43, 2.03)	0.2619	-0.13 (0.14)	(-0.41, 0.14)	0.3410	
Black or African American	16	23.81 (5.64)	22	14.73 (5.81)	9.08 (6.40)	(-3.96, 22.11)	0.1659	0.35 (0.33)	(-0.30, 1.00)	0.2909	
Asian	29	0.16 (3.33)	29	-8.96 (3.38)	9.11 (3.06)	(2.96, 15.27)	0.0045	0.50 (0.27)	(-0.03, 1.02)	0.0621	
American Indian or Alaska Native	4	NE	1	NE	NE	NE		NE	NE		
Other	11	18.45 (6.82)	10	2.38 (7.65)	16.07 (7.86)	(-0.66, 32.80)	0.0586	0.66 (0.45)	(-0.22, 1.54)	0.1437	
Ethnicity											0.3769
Hispanic/Latino	52	16.04 (2.89)	54	10.73 (2.73)	5.30 (3.37)	(-1.38, 11.99)	0.1186	0.26 (0.20)	(-0.12, 0.64)	0.1870	
Non-hispanic/Latino	108	10.57 (1.93)	109	8.83 (1.98)	1.73 (2.24)	(-2.67, 6.14)	0.4393	0.08 (0.14)	(-0.18, 0.35)	0.5327	
Geographic region											0.1461
EU	44	10.21 (3.26)	40	12.09 (3.44)	-1.89 (3.40)	(-8.67, 4.90)	0.5814	-0.09 (0.22)	(-0.51, 0.34)	0.6936	
non-EU	122	13.42 (1.76)	129	9.50 (1.76)	3.92 (2.09)	(-0.20, 8.04)	0.0619	0.20 (0.13)	(-0.05, 0.45)	0.1170	
Onset of disease											0.8560
Paediatric	10	-1.82 (7.99)	11	-6.61 (10.61)	4.79 (9.12)	(-14.64, 24.22)	0.6073	0.15 (0.44)	(-0.71, 1.01)	0.7338	
Adult	156	13.60 (1.62)	158	10.51 (1.61)	3.10 (1.89)	(-0.62, 6.82)	0.1020	0.15 (0.11)	(-0.07, 0.37)	0.1766	
ADA result											0.5275
Negative	160	13.27 (1.59)	151	11.21 (1.65)	2.05 (1.89)	(-1.66, 5.77)	0.2775	0.10 (0.11)	(-0.12, 0.32)	0.3720	
Positive (At any time)	6	6.60 (7.71)	18	-0.10 (5.21)	6.70 (7.11)	(-8.48, 21.88)	0.3612	0.30 (0.47)	(-0.63, 1.23)	0.5238	
BMI (kg/m2) at enrolment											0.9940
< 30	116	10.80 (1.96)	125	7.86 (1.99)	2.95 (2.10)	(-1.19, 7.08)	0.1615	0.14 (0.13)	(-0.12, 0.39)	0.2951	
>= 30	50	17.49 (2.84)	44	14.58 (2.90)	2.92 (3.80)	(-4.64, 10.47)	0.4448	0.15 (0.21)	(-0.26, 0.55)	0.4776	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.4728
All negative/normal	55	14.14 (2.60)	76	13.05 (2.29)	1.09 (3.25)	(-5.35, 7.52)	0.7385	0.05 (0.18)	(-0.29, 0.40)	0.7564	
At least one positive/abnormal	111	11.64 (2.28)	93	7.73 (2.49)	3.91 (2.22)	(-0.46, 8.29)	0.0795	0.16 (0.14)	(-0.11, 0.44)	0.2493	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Planning domain score
Full analysis set

	Anifrolumab 300mg (N=180)		Placebo (N=182)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 12		7.75 (1.99)		4.36 (1.97)	3.39 (2.41)	(-1.34, 8.12)	0.1596			
Week 24		10.86 (2.02)		7.95 (2.00)	2.91 (2.44)	(-1.90, 7.71)	0.2349			
Week 36		9.11 (2.16)		9.69 (2.20)	-0.58 (2.72)	(-5.93, 4.78)	0.8324			
Week 52		8.49 (2.16)		7.10 (2.22)	1.39 (2.73)	(-3.98, 6.76)	0.6115			
OVERALL	166	9.05 (1.81)	169	7.27 (1.82)	1.78 (2.13)	(-2.40, 5.96)	0.4037	0.08 (0.11)	(-0.14, 0.29)	0.4908

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Planning domain score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=182) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.8249
< 10 points	49	11.58 (3.34)	50	10.48 (3.34)	1.10 (4.30)	(-7.44, 9.63)	0.7992	0.05 (0.20)	(-0.35, 0.44)	0.8179	
>= 10 points	117	8.34 (2.17)	119	6.15 (2.17)	2.19 (2.46)	(-2.66, 7.04)	0.3742	0.09 (0.13)	(-0.16, 0.35)	0.4769	
OCS dose at baseline											0.4540
<10 mg/day	89	7.87 (2.17)	91	6.96 (2.18)	0.90 (2.75)	(-4.52, 6.32)	0.7424	0.04 (0.15)	(-0.25, 0.34)	0.7701	
>=10 mg/day	77	10.45 (3.21)	78	6.33 (3.23)	4.12 (3.31)	(-2.41, 10.66)	0.2145	0.14 (0.16)	(-0.17, 0.46)	0.3682	
Result of type I IFN gene signature test											0.8053
LOW	28	14.82 (4.14)	29	11.90 (4.09)	2.93 (5.55)	(-8.22, 14.08)	0.6001	0.13 (0.27)	(-0.39, 0.65)	0.6201	
HIGH	138	7.29 (1.75)	140	5.84 (1.75)	1.45 (2.32)	(-3.12, 6.02)	0.5338	0.07 (0.12)	(-0.17, 0.31)	0.5599	
Age (years)											NE
<= 65	162	8.94 (1.83)	169	7.18 (1.83)	1.76 (2.14)	(-2.46, 5.97)	0.4127	0.07 (0.11)	(-0.14, 0.29)	0.4987	
> 65	4	NE	0	NE	NE	NE		NE	NE		
Sex											0.4908
male	11	19.18 (7.43)	12	12.10 (9.20)	7.08 (7.19)	(-8.38, 22.54)	0.3421	0.24 (0.42)	(-0.58, 1.06)	0.5703	
female	155	8.65 (1.85)	157	6.75 (1.86)	1.90 (2.20)	(-2.42, 6.22)	0.3884	0.08 (0.11)	(-0.14, 0.30)	0.4711	
Race											NE
White	100	10.22 (2.32)	101	13.24 (2.38)	-3.02 (2.86)	(-8.65, 2.62)	0.2921	-0.13 (0.14)	(-0.40, 0.15)	0.3663	
Black or African American	16	9.31 (6.40)	22	2.49 (6.68)	6.82 (7.10)	(-7.65, 21.30)	0.3440	0.23 (0.33)	(-0.42, 0.88)	0.4858	
Asian	29	-2.33 (4.97)	29	-8.92 (5.00)	6.60 (4.43)	(-2.30, 15.49)	0.1429	0.24 (0.26)	(-0.27, 0.76)	0.3579	
American Indian or Alaska Native	4	NE	1	NE	NE	NE		NE	NE		
Other	11	14.93 (6.39)	10	1.52 (7.34)	13.42 (7.49)	(-2.53, 29.36)	0.0932	0.58 (0.45)	(-0.30, 1.46)	0.1950	
Ethnicity											0.3063
Hispanic/Latino	52	15.05 (3.30)	54	9.55 (3.11)	5.50 (3.87)	(-2.18, 13.18)	0.1585	0.23 (0.19)	(-0.15, 0.62)	0.2300	
Non-hispanic/Latino	108	6.38 (2.28)	109	5.69 (2.32)	0.70 (2.66)	(-4.55, 5.94)	0.7943	0.03 (0.14)	(-0.24, 0.30)	0.8313	
Geographic region											0.0200
EU	44	10.45 (3.78)	40	17.12 (4.05)	-6.67 (4.05)	(-14.74, 1.39)	0.1034	-0.26 (0.22)	(-0.69, 0.17)	0.2339	
non-EU	122	9.09 (2.06)	129	4.77 (2.04)	4.32 (2.44)	(-0.49, 9.14)	0.0783	0.19 (0.13)	(-0.06, 0.44)	0.1383	
Onset of disease											0.2480
Paediatric	10	-7.90 (7.66)	11	0.54 (10.06)	-8.44 (9.03)	(-27.63, 10.75)	0.3643	-0.28 (0.44)	(-1.14, 0.59)	0.5304	
Adult	156	10.39 (1.87)	158	8.09 (1.86)	2.30 (2.19)	(-2.02, 6.61)	0.2955	0.10 (0.11)	(-0.12, 0.32)	0.3848	
ADA result											0.4291
Negative	160	9.35 (1.84)	151	8.56 (1.91)	0.79 (2.20)	(-3.54, 5.12)	0.7198	0.03 (0.11)	(-0.19, 0.26)	0.7663	
Positive (At any time)	6	8.18 (10.55)	18	0.17 (6.89)	8.00 (8.85)	(-10.79, 26.79)	0.3796	0.27 (0.47)	(-0.66, 1.20)	0.5669	
BMI (kg/m2) at enrolment											0.9490
< 30	116	7.47 (2.34)	125	5.40 (2.36)	2.08 (2.53)	(-2.90, 7.05)	0.4118	0.08 (0.13)	(-0.17, 0.33)	0.5339	
>= 30	50	12.79 (2.94)	44	11.01 (3.01)	1.78 (3.93)	(-6.03, 9.59)	0.6518	0.09 (0.21)	(-0.32, 0.49)	0.6760	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.7517
All negative/normal	55	10.73 (2.89)	76	9.91 (2.54)	0.82 (3.62)	(-6.35, 7.99)	0.8220	0.04 (0.18)	(-0.31, 0.38)	0.8337	
At least one positive/abnormal	111	7.31 (2.76)	93	5.06 (3.00)	2.25 (2.70)	(-3.08, 7.58)	0.4068	0.08 (0.14)	(-0.20, 0.35)	0.5830	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SDI Global Score
Full analysis set

	Anifrolumab 300mg (N=180)		Placebo (N=182)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 24		0.01 (0.02)		0.03 (0.02)	-0.02 (0.02)	(-0.06, 0.01)	0.1969			
Week 52		0.07 (0.02)		0.05 (0.02)	0.02 (0.03)	(-0.04, 0.08)	0.5089			
OVERALL	168	0.04 (0.02)	162	0.04 (0.02)	-0.00 (0.02)	(-0.04, 0.04)	0.9531	-0.01 (0.11)	(-0.22, 0.21)	0.9592

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SDI Global Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=182) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.7446
< 10 points	51	0.05 (0.03)	48	0.04 (0.03)	0.01 (0.04)	(-0.07, 0.09)	0.8023	0.05 (0.20)	(-0.35, 0.44)	0.8094	
>= 10 points	117	0.04 (0.02)	114	0.04 (0.02)	-0.01 (0.03)	(-0.06, 0.05)	0.8334	-0.02 (0.13)	(-0.28, 0.24)	0.8642	
OCS dose at baseline											0.7960
<10 mg/day	87	0.03 (0.02)	91	0.03 (0.02)	-0.01 (0.03)	(-0.06, 0.05)	0.7932	-0.04 (0.15)	(-0.33, 0.26)	0.8063	
>=10 mg/day	81	0.04 (0.03)	71	0.04 (0.03)	0.00 (0.04)	(-0.07, 0.08)	0.8990	0.02 (0.16)	(-0.30, 0.33)	0.9243	
Result of type I IFN gene signature test											NE
LOW	28	NE	27	NE	NE	NE		NE	NE		
HIGH	140	0.04 (0.02)	135	0.06 (0.02)	-0.01 (0.02)	(-0.06, 0.04)	0.6165	-0.06 (0.12)	(-0.29, 0.18)	0.6343	
Age (years)											NE
<= 65	164	0.04 (0.02)	161	0.04 (0.02)	0.01 (0.02)	(-0.04, 0.05)	0.7737	0.03 (0.11)	(-0.19, 0.25)	0.8024	
> 65	4	NE	1	NE	NE	NE		NE	NE		
Sex											NE
male	11	NE	12	NE	NE	NE		NE	NE		
female	157	0.04 (0.02)	150	0.04 (0.02)	0.00 (0.02)	(-0.04, 0.04)	0.9902	0.00 (0.11)	(-0.22, 0.23)	0.9914	
Race											NE
White	103	0.03 (0.02)	93	0.03 (0.02)	0.01 (0.03)	(-0.04, 0.06)	0.8159	0.03 (0.14)	(-0.25, 0.31)	0.8313	
Black or African American	16	0.13 (0.09)	23	0.16 (0.08)	-0.03 (0.10)	(-0.24, 0.17)	0.7355	-0.09 (0.33)	(-0.73, 0.55)	0.7898	
Asian	28	NE	29	NE	NE	NE		NE	NE		
American Indian or Alaska Native	4	NE	1	NE	NE	NE		NE	NE		
Other	11	NE	10	NE	NE	NE		NE	NE		
Ethnicity											0.4732
Hispanic/Latino	52	0.04 (0.04)	48	0.07 (0.04)	-0.03 (0.05)	(-0.12, 0.07)	0.5504	-0.10 (0.20)	(-0.50, 0.29)	0.6005	
Non-hispanic/Latino	110	0.04 (0.02)	108	0.03 (0.02)	0.01 (0.03)	(-0.04, 0.06)	0.6882	0.05 (0.14)	(-0.22, 0.31)	0.7284	
Geographic region											0.5376
EU	46	0.04 (0.04)	38	0.02 (0.04)	0.02 (0.04)	(-0.07, 0.11)	0.6253	0.08 (0.22)	(-0.35, 0.51)	0.7011	
non-EU	122	0.04 (0.02)	124	0.05 (0.02)	-0.01 (0.03)	(-0.06, 0.04)	0.7031	-0.04 (0.13)	(-0.29, 0.21)	0.7364	
Onset of disease											NE
Paediatric	13	NE	11	NE	NE	NE		NE	NE		
Adult	155	0.04 (0.02)	151	0.05 (0.02)	-0.01 (0.02)	(-0.05, 0.04)	0.7143	-0.04 (0.11)	(-0.26, 0.19)	0.7498	
ADA result											NE
Negative	161	0.04 (0.02)	145	0.05 (0.02)	-0.01 (0.02)	(-0.05, 0.04)	0.8222	-0.02 (0.11)	(-0.25, 0.20)	0.8446	
Positive (At any time)	7	NE	17	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.5012
< 30	117	0.04 (0.02)	119	0.05 (0.02)	-0.01 (0.03)	(-0.06, 0.05)	0.7973	-0.03 (0.13)	(-0.28, 0.23)	0.8379	
>= 30	51	0.04 (0.02)	43	0.02 (0.03)	0.02 (0.04)	(-0.05, 0.09)	0.5157	0.13 (0.21)	(-0.28, 0.54)	0.5304	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.4259
All negative/normal	54	0.01 (0.03)	74	0.03 (0.02)	-0.02 (0.03)	(-0.09, 0.04)	0.4702	-0.12 (0.18)	(-0.47, 0.23)	0.4957	
At least one positive/abnormal	114	0.05 (0.03)	88	0.04 (0.03)	0.01 (0.03)	(-0.05, 0.07)	0.7045	0.04 (0.14)	(-0.24, 0.32)	0.7809	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - NRS Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) N	Anifrolumab 300mg (N=180) LSMean (SE)	Placebo (N=182) N	Placebo (N=182) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-0.53 (0.16)		-0.39 (0.16)	-0.14 (0.20)	(-0.53, 0.26)	0.5012			
Week 8		-1.06 (0.18)		-0.23 (0.18)	-0.83 (0.23)	(-1.27, -0.38)	0.0003			
Week 12		-1.21 (0.19)		-0.73 (0.19)	-0.48 (0.24)	(-0.96, -0.00)	0.0483			
Week 16		-1.18 (0.19)		-0.89 (0.19)	-0.29 (0.24)	(-0.75, 0.18)	0.2264			
Week 20		-1.00 (0.20)		-0.99 (0.20)	-0.01 (0.25)	(-0.51, 0.49)	0.9682			
Week 24		-1.12 (0.19)		-0.72 (0.19)	-0.40 (0.24)	(-0.87, 0.07)	0.0962			
Week 28		-1.06 (0.20)		-0.84 (0.20)	-0.22 (0.25)	(-0.72, 0.28)	0.3889			
Week 32		-0.97 (0.19)		-0.75 (0.20)	-0.22 (0.25)	(-0.71, 0.28)	0.3874			
Week 36		-1.17 (0.19)		-1.15 (0.19)	-0.01 (0.25)	(-0.50, 0.47)	0.9553			
Week 40		-1.10 (0.20)		-0.81 (0.20)	-0.28 (0.25)	(-0.78, 0.22)	0.2670			
Week 44		-1.09 (0.19)		-0.94 (0.20)	-0.15 (0.25)	(-0.65, 0.35)	0.5507			
Week 48		-1.04 (0.20)		-0.58 (0.20)	-0.46 (0.26)	(-0.97, 0.05)	0.0761			
Week 52		-0.94 (0.20)		-0.69 (0.20)	-0.25 (0.26)	(-0.76, 0.26)	0.3382			
OVERALL	170	-1.04 (0.15)	173	-0.75 (0.15)	-0.29 (0.18)	(-0.63, 0.06)	0.1033	-0.15 (0.11)	(-0.36, 0.06)	0.1727

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - NRS Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=182) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.7316
< 10 points	50	-1.15 (0.29)	50	-0.77 (0.29)	-0.38 (0.37)	(-1.12, 0.37)	0.3162	-0.18 (0.20)	(-0.58, 0.21)	0.3608	
>= 10 points	120	-1.07 (0.17)	123	-0.84 (0.17)	-0.23 (0.20)	(-0.62, 0.16)	0.2423	-0.12 (0.13)	(-0.37, 0.13)	0.3430	
OCS dose at baseline											0.2416
<10 mg/day	91	-1.06 (0.19)	94	-0.56 (0.19)	-0.50 (0.23)	(-0.96, -0.04)	0.0352	-0.28 (0.15)	(-0.57, 0.01)	0.0610	
>=10 mg/day	79	-0.99 (0.25)	79	-0.91 (0.25)	-0.08 (0.27)	(-0.61, 0.45)	0.7664	-0.04 (0.16)	(-0.35, 0.28)	0.8240	
Result of type I IFN gene signature test											0.7881
LOW	28	-1.21 (0.31)	29	-1.04 (0.30)	-0.18 (0.41)	(-1.00, 0.65)	0.6698	-0.11 (0.27)	(-0.63, 0.41)	0.6853	
HIGH	142	-0.92 (0.15)	144	-0.63 (0.15)	-0.30 (0.20)	(-0.68, 0.09)	0.1275	-0.17 (0.12)	(-0.40, 0.06)	0.1509	
Age (years)											NE
<= 65	166	-1.03 (0.15)	173	-0.73 (0.15)	-0.30 (0.18)	(-0.65, 0.05)	0.0915	-0.15 (0.11)	(-0.37, 0.06)	0.1576	
> 65	4	NE	0	NE	NE	NE		NE	NE		
Sex											0.1286
male	11	-2.93 (0.83)	12	-3.93 (0.92)	1.00 (0.87)	(-0.93, 2.94)	0.2735	0.32 (0.42)	(-0.50, 1.15)	0.4407	
female	159	-1.06 (0.15)	161	-0.72 (0.15)	-0.34 (0.18)	(-0.71, 0.02)	0.0655	-0.18 (0.11)	(-0.39, 0.04)	0.1181	
Race											NE
White	103	-1.13 (0.18)	103	-0.98 (0.18)	-0.16 (0.21)	(-0.58, 0.27)	0.4662	-0.09 (0.14)	(-0.36, 0.19)	0.5336	
Black or African American	17	-1.95 (0.55)	22	-0.63 (0.54)	-1.31 (0.66)	(-2.65, 0.02)	0.0537	-0.53 (0.33)	(-1.17, 0.12)	0.1090	
Asian	29	0.08 (0.47)	30	0.06 (0.47)	0.02 (0.43)	(-0.85, 0.88)	0.9691	0.01 (0.26)	(-0.50, 0.52)	0.9800	
American Indian or Alaska Native	4	NE	1	NE	NE	NE		NE	NE		
Other	11	NE	10	NE	NE	NE		NE	NE		
Ethnicity											0.0008
Hispanic/Latino	52	-1.83 (0.26)	54	-0.71 (0.25)	-1.12 (0.31)	(-1.73, -0.51)	0.0004	-0.60 (0.20)	(-0.99, -0.21)	0.0026	
Non-hispanic/Latino	112	-0.64 (0.18)	112	-0.77 (0.18)	0.14 (0.21)	(-0.29, 0.56)	0.5288	0.07 (0.13)	(-0.19, 0.33)	0.5977	
Geographic region											0.0032
EU	45	-0.62 (0.31)	43	-1.19 (0.33)	0.56 (0.33)	(-0.09, 1.21)	0.0906	0.26 (0.21)	(-0.16, 0.68)	0.2203	
non-EU	125	-1.20 (0.17)	130	-0.62 (0.17)	-0.58 (0.21)	(-0.98, -0.17)	0.0053	-0.30 (0.13)	(-0.55, -0.05)	0.0169	
Onset of disease											NE
Paediatric	11	NE	11	NE	NE	NE		NE	NE		
Adult	159	-1.06 (0.15)	162	-0.82 (0.15)	-0.24 (0.18)	(-0.60, 0.12)	0.1912	-0.12 (0.11)	(-0.34, 0.10)	0.2703	
ADA result											NE
Negative	163	-0.99 (0.15)	154	-0.78 (0.16)	-0.22 (0.18)	(-0.58, 0.15)	0.2427	-0.11 (0.11)	(-0.33, 0.11)	0.3269	
Positive (At any time)	7	NE	19	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.1757
< 30	119	-0.95 (0.19)	127	-0.76 (0.19)	-0.19 (0.21)	(-0.60, 0.22)	0.3594	-0.09 (0.13)	(-0.34, 0.16)	0.4764	
>= 30	51	-1.36 (0.25)	46	-0.62 (0.26)	-0.74 (0.35)	(-1.44, -0.05)	0.0360	-0.41 (0.21)	(-0.81, -0.01)	0.0470	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.6324
All negative/normal	56	-1.16 (0.23)	77	-0.78 (0.20)	-0.39 (0.29)	(-0.95, 0.18)	0.1817	-0.22 (0.18)	(-0.57, 0.13)	0.2117	
At least one positive/abnormal	114	-0.91 (0.22)	96	-0.70 (0.24)	-0.21 (0.23)	(-0.66, 0.23)	0.3510	-0.09 (0.14)	(-0.36, 0.18)	0.5269	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - PHQ-8 Total Score
Full analysis set

	Anifrolumab 300mg (N=180)		Placebo (N=182)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 12		-1.68 (0.43)		-1.22 (0.42)	-0.45 (0.51)	(-1.46, 0.56)	0.3801			
Week 24		-1.88 (0.45)		-1.40 (0.44)	-0.48 (0.54)	(-1.55, 0.58)	0.3737			
Week 36		-1.99 (0.45)		-1.42 (0.46)	-0.57 (0.56)	(-1.67, 0.53)	0.3092			
Week 52		-1.64 (0.47)		-0.90 (0.49)	-0.73 (0.60)	(-1.92, 0.45)	0.2234			
OVERALL	168	-1.80 (0.39)	169	-1.24 (0.39)	-0.56 (0.46)	(-1.46, 0.35)	0.2248	-0.11 (0.11)	(-0.32, 0.10)	0.3170

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - PHQ-8 Total Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) N	LSMean (SE)	Placebo (N=182) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.2962
< 10 points	49	-2.64 (0.63)	50	-1.34 (0.63)	-1.30 (0.80)	(-2.89, 0.29)	0.1091	-0.29 (0.20)	(-0.69, 0.11)	0.1510	
>= 10 points	119	-1.28 (0.50)	119	-1.01 (0.50)	-0.27 (0.56)	(-1.38, 0.83)	0.6255	-0.05 (0.13)	(-0.30, 0.20)	0.6972	
OCS dose at baseline											0.5641
<10 mg/day	89	-1.54 (0.49)	91	-1.20 (0.50)	-0.34 (0.62)	(-1.56, 0.88)	0.5800	-0.07 (0.15)	(-0.37, 0.22)	0.6258	
>=10 mg/day	79	-1.88 (0.68)	78	-1.00 (0.66)	-0.88 (0.70)	(-2.27, 0.51)	0.2119	-0.15 (0.16)	(-0.46, 0.16)	0.3534	
Result of type I IFN gene signature test											0.4309
LOW	28	-2.94 (0.88)	29	-1.51 (0.84)	-1.43 (1.17)	(-3.78, 0.92)	0.2267	-0.31 (0.27)	(-0.83, 0.21)	0.2484	
HIGH	140	-1.48 (0.38)	140	-1.05 (0.38)	-0.43 (0.51)	(-1.42, 0.57)	0.3993	-0.09 (0.12)	(-0.33, 0.14)	0.4305	
Age (years)											NE
<= 65	164	-1.83 (0.40)	169	-1.21 (0.40)	-0.62 (0.46)	(-1.53, 0.29)	0.1789	-0.12 (0.11)	(-0.34, 0.09)	0.2676	
> 65	4	NE	0	NE	NE	NE		NE	NE		
Sex											0.8915
male	11	-1.18 (1.68)	12	-0.70 (2.19)	-0.48 (1.63)	(-3.88, 2.93)	0.7742	-0.07 (0.42)	(-0.89, 0.75)	0.8702	
female	157	-1.76 (0.40)	157	-1.05 (0.40)	-0.71 (0.48)	(-1.65, 0.23)	0.1394	-0.14 (0.11)	(-0.36, 0.08)	0.2178	
Race											NE
White	101	-1.65 (0.52)	101	-2.08 (0.53)	0.43 (0.63)	(-0.82, 1.68)	0.4987	0.08 (0.14)	(-0.19, 0.36)	0.5628	
Black or African American	17	-3.34 (1.40)	22	-1.31 (1.41)	-2.02 (1.63)	(-5.35, 1.30)	0.2250	-0.32 (0.33)	(-0.95, 0.32)	0.3302	
Asian	29	0.73 (1.02)	29	1.75 (1.01)	-1.03 (0.91)	(-2.85, 0.80)	0.2643	-0.19 (0.26)	(-0.70, 0.33)	0.4812	
American Indian or Alaska Native	4	NE	1	NE	NE	NE		NE	NE		
Other	11	-3.41 (1.44)	10	0.60 (1.50)	-4.01 (1.66)	(-7.54, -0.48)	0.0284	-0.81 (0.46)	(-1.71, 0.09)	0.0775	
Ethnicity											0.1839
Hispanic/Latino	52	-2.53 (0.80)	54	-1.02 (0.76)	-1.51 (0.94)	(-3.37, 0.36)	0.1131	-0.26 (0.20)	(-0.65, 0.12)	0.1780	
Non-hispanic/Latino	110	-1.25 (0.46)	109	-1.18 (0.47)	-0.06 (0.54)	(-1.12, 0.99)	0.9041	-0.01 (0.14)	(-0.28, 0.25)	0.9215	
Geographic region											0.2877
EU	45	-2.19 (0.74)	40	-2.41 (0.79)	0.22 (0.79)	(-1.35, 1.79)	0.7832	0.04 (0.22)	(-0.38, 0.47)	0.8416	
non-EU	123	-1.62 (0.46)	129	-0.81 (0.46)	-0.81 (0.55)	(-1.89, 0.28)	0.1451	-0.15 (0.13)	(-0.40, 0.09)	0.2197	
Onset of disease											0.5111
Paediatric	11	-0.37 (1.63)	11	1.33 (1.93)	-1.70 (1.87)	(-5.73, 2.33)	0.3788	-0.28 (0.43)	(-1.12, 0.56)	0.5195	
Adult	157	-1.79 (0.41)	158	-1.35 (0.41)	-0.43 (0.48)	(-1.38, 0.51)	0.3679	-0.08 (0.11)	(-0.31, 0.14)	0.4549	
ADA result											0.1201
Negative	161	-1.81 (0.40)	151	-1.52 (0.41)	-0.28 (0.48)	(-1.22, 0.66)	0.5529	-0.06 (0.11)	(-0.28, 0.17)	0.6235	
Positive (At any time)	7	-2.03 (2.32)	18	1.33 (1.58)	-3.36 (1.92)	(-7.39, 0.67)	0.0967	-0.49 (0.45)	(-1.38, 0.39)	0.2740	
BMI (kg/m2) at enrolment											0.9950
< 30	118	-1.27 (0.48)	125	-0.68 (0.49)	-0.60 (0.52)	(-1.62, 0.43)	0.2550	-0.11 (0.13)	(-0.36, 0.14)	0.3883	
>= 30	50	-2.52 (0.70)	44	-1.91 (0.71)	-0.60 (0.93)	(-2.44, 1.24)	0.5173	-0.12 (0.21)	(-0.53, 0.28)	0.5506	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.5949
All negative/normal	55	-2.46 (0.63)	76	-1.59 (0.55)	-0.86 (0.78)	(-2.41, 0.68)	0.2717	-0.18 (0.18)	(-0.53, 0.17)	0.3074	
At least one positive/abnormal	113	-1.32 (0.59)	93	-0.97 (0.64)	-0.35 (0.57)	(-1.48, 0.79)	0.5463	-0.06 (0.14)	(-0.33, 0.22)	0.6911	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - PtGA
Full analysis set

Visit	Anifrolumab 300mg (N=180) N	Anifrolumab 300mg (N=180) LSMean (SE)	Placebo (N=182) N	Placebo (N=182) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-8.30 (1.78)		-6.76 (1.77)	-1.55 (2.22)	(-5.91, 2.81)	0.4855			
Week 8		-10.05 (1.81)		-3.73 (1.79)	-6.32 (2.27)	(-10.79, -1.86)	0.0057			
Week 12		-11.71 (1.98)		-8.47 (1.97)	-3.24 (2.54)	(-8.24, 1.77)	0.2041			
Week 16		-9.47 (2.07)		-8.45 (2.07)	-1.02 (2.69)	(-6.31, 4.27)	0.7053			
Week 20		-11.48 (1.92)		-10.17 (1.91)	-1.31 (2.45)	(-6.14, 3.51)	0.5922			
Week 24		-9.33 (2.05)		-7.33 (2.03)	-2.00 (2.64)	(-7.19, 3.19)	0.4486			
Week 28		-13.09 (2.03)		-11.82 (2.04)	-1.27 (2.63)	(-6.45, 3.91)	0.6307			
Week 32		-10.99 (2.07)		-9.43 (2.09)	-1.56 (2.70)	(-6.87, 3.76)	0.5648			
Week 36		-13.16 (1.96)		-12.15 (1.99)	-1.00 (2.54)	(-6.01, 4.00)	0.6935			
Week 40		-10.60 (2.01)		-8.71 (2.05)	-1.88 (2.63)	(-7.05, 3.29)	0.4740			
Week 44		-10.84 (1.95)		-12.77 (2.02)	1.94 (2.56)	(-3.10, 6.97)	0.4500			
Week 48		-11.96 (2.08)		-6.35 (2.14)	-5.61 (2.75)	(-11.02, -0.21)	0.0419			
Week 52		-10.80 (2.19)		-6.17 (2.25)	-4.63 (2.91)	(-10.35, 1.10)	0.1130			
OVERALL	170	-10.91 (1.50)	173	-8.64 (1.51)	-2.27 (1.78)	(-5.77, 1.24)	0.2039	-0.11 (0.11)	(-0.33, 0.10)	0.2880

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - PtGA - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=180)		Placebo (N=182)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score at screening											0.4612
< 10 points	50	-11.74 (2.66)	50	-7.42 (2.69)	-4.32 (3.43)	(-11.13, 2.49)	0.2111	-0.23 (0.20)	(-0.62, 0.17)	0.2589	
>= 10 points	120	-10.84 (1.82)	123	-9.48 (1.81)	-1.36 (2.08)	(-5.47, 2.74)	0.5137	-0.07 (0.13)	(-0.32, 0.18)	0.5966	
OCS dose at baseline											0.4633
<10 mg/day	91	-8.68 (1.80)	94	-7.68 (1.81)	-1.01 (2.26)	(-5.47, 3.45)	0.6566	-0.06 (0.15)	(-0.35, 0.23)	0.6948	
>=10 mg/day	79	-12.77 (2.64)	79	-9.11 (2.62)	-3.66 (2.83)	(-9.25, 1.92)	0.1972	-0.16 (0.16)	(-0.47, 0.16)	0.3278	
Result of type I IFN gene signature test											0.5708
LOW	28	-11.93 (3.43)	29	-12.20 (3.42)	0.27 (4.73)	(-9.22, 9.76)	0.9549	0.01 (0.26)	(-0.50, 0.53)	0.9563	
HIGH	142	-10.10 (1.46)	144	-7.47 (1.46)	-2.63 (1.95)	(-6.47, 1.20)	0.1778	-0.15 (0.12)	(-0.38, 0.08)	0.2039	
Age (years)											NE
<= 65	166	-10.91 (1.51)	173	-8.58 (1.51)	-2.34 (1.79)	(-5.86, 1.19)	0.1938	-0.12 (0.11)	(-0.33, 0.09)	0.2762	
> 65	4	NE	0	NE	NE	NE		NE	NE		
Sex											0.0428
male	11	-15.40 (5.01)	12	-24.48 (6.75)	9.09 (5.79)	(-3.14, 21.32)	0.1351	0.43 (0.42)	(-0.40, 1.26)	0.3112	
female	159	-10.98 (1.56)	161	-7.75 (1.56)	-3.23 (1.86)	(-6.89, 0.44)	0.0840	-0.16 (0.11)	(-0.38, 0.06)	0.1439	
Race											NE
White	103	-11.47 (1.84)	103	-11.89 (1.88)	0.42 (2.26)	(-4.04, 4.87)	0.8542	0.02 (0.14)	(-0.25, 0.30)	0.8752	
Black or African American	17	-8.77 (4.13)	22	0.33 (4.16)	-9.10 (4.90)	(-19.04, 0.85)	0.0718	-0.48 (0.33)	(-1.12, 0.16)	0.1419	
Asian	29	-2.03 (4.68)	30	-0.27 (4.66)	-1.76 (4.15)	(-10.08, 6.55)	0.6724	-0.07 (0.26)	(-0.58, 0.44)	0.7923	
American Indian or Alaska Native	4	NE	1	NE	NE	NE		NE	NE		
Other	11	NE	10	NE	NE	NE		NE	NE		
Ethnicity											0.0056
Hispanic/Latino	52	-19.81 (2.83)	54	-10.35 (2.68)	-9.45 (3.21)	(-15.82, -3.08)	0.0040	-0.47 (0.20)	(-0.85, -0.08)	0.0174	
Non-hispanic/Latino	112	-6.35 (1.77)	112	-7.57 (1.81)	1.22 (2.12)	(-2.96, 5.41)	0.5655	0.06 (0.13)	(-0.20, 0.33)	0.6306	
Geographic region											<.0001
EU	45	-8.31 (2.75)	43	-17.29 (2.92)	8.98 (3.04)	(2.91, 15.05)	0.0043	0.47 (0.22)	(0.05, 0.90)	0.0284	
non-EU	125	-11.80 (1.74)	130	-5.90 (1.73)	-5.91 (2.09)	(-10.03, -1.78)	0.0052	-0.30 (0.13)	(-0.55, -0.05)	0.0172	
Onset of disease											NE
Paediatric	11	NE	11	NE	NE	NE		NE	NE		
Adult	159	-11.44 (1.57)	162	-9.33 (1.56)	-2.11 (1.86)	(-5.77, 1.55)	0.2575	-0.11 (0.11)	(-0.33, 0.11)	0.3406	
ADA result											NE
Negative	163	-10.64 (1.53)	154	-9.06 (1.58)	-1.58 (1.84)	(-5.20, 2.05)	0.3936	-0.08 (0.11)	(-0.30, 0.14)	0.4759	
Positive (At any time)	7	NE	19	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.0104
< 30	119	-8.55 (1.94)	127	-8.84 (1.94)	0.29 (2.15)	(-3.94, 4.52)	0.8924	0.01 (0.13)	(-0.24, 0.26)	0.9159	
>= 30	51	-16.85 (2.35)	46	-7.40 (2.42)	-9.45 (3.14)	(-15.69, -3.22)	0.0034	-0.57 (0.21)	(-0.97, -0.16)	0.0064	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group											0.1918
All negative/normal	56	-14.59 (2.34)	77	-9.40 (2.05)	-5.19 (2.91)	(-10.96, 0.57)	0.0769	-0.29 (0.18)	(-0.64, 0.06)	0.1001	
At least one positive/abnormal	114	-8.09 (2.22)	96	-7.71 (2.42)	-0.38 (2.27)	(-4.85, 4.09)	0.8676	-0.02 (0.14)	(-0.29, 0.26)	0.9088	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SLEDAI-2K Total Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=182) n/ N#	Placebo (N=182) Compliance
Baseline	180/ 180	100.0%	182/ 182	100.0%
Week 4	174/ 180	96.67%	176/ 182	96.70%
Week 8	167/ 180	92.78%	173/ 182	95.05%
Week 12	173/ 180	96.11%	168/ 182	92.31%
Week 16	168/ 180	93.33%	167/ 182	91.76%
Week 20	164/ 180	91.11%	165/ 182	90.66%
Week 24	166/ 180	92.22%	162/ 182	89.01%
Week 28	165/ 180	91.67%	153/ 182	84.07%
Week 32	158/ 179	88.27%	148/ 182	81.32%
Week 36	160/ 179	89.39%	152/ 182	83.52%
Week 40	157/ 179	87.71%	144/ 182	79.12%
Week 44	157/ 179	87.71%	144/ 182	79.12%
Week 48	154/ 179	86.03%	142/ 182	78.02%
Week 52	152/ 179	84.92%	141/ 182	77.47%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - PGA
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=182) n/ N#	Placebo (N=182) Compliance
Baseline	180/ 180	100.0%	182/ 182	100.0%
Week 4	177/ 180	98.33%	179/ 182	98.35%
Week 8	172/ 180	95.56%	177/ 182	97.25%
Week 12	174/ 180	96.67%	173/ 182	95.05%
Week 16	173/ 180	96.11%	172/ 182	94.51%
Week 20	166/ 180	92.22%	170/ 182	93.41%
Week 24	168/ 180	93.33%	167/ 182	91.76%
Week 28	166/ 180	92.22%	159/ 182	87.36%
Week 32	161/ 179	89.94%	151/ 182	82.97%
Week 36	163/ 179	91.06%	152/ 182	83.52%
Week 40	161/ 179	89.94%	152/ 182	83.52%
Week 44	159/ 179	88.83%	147/ 182	80.77%
Week 48	156/ 179	87.15%	142/ 182	78.02%
Week 52	153/ 179	85.47%	141/ 182	77.47%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - CLASI Total Activity Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=182) n/ N#	Placebo (N=182) Compliance
Baseline	180/ 180	100.0%	182/ 182	100.0%
Week 4	176/ 180	97.78%	180/ 182	98.90%
Week 8	172/ 180	95.56%	177/ 182	97.25%
Week 12	176/ 180	97.78%	173/ 182	95.05%
Week 16	174/ 180	96.67%	171/ 182	93.96%
Week 20	166/ 180	92.22%	171/ 182	93.96%
Week 24	168/ 180	93.33%	167/ 182	91.76%
Week 28	166/ 180	92.22%	159/ 182	87.36%
Week 32	160/ 179	89.39%	151/ 182	82.97%
Week 36	161/ 179	89.94%	153/ 182	84.07%
Week 40	159/ 179	88.83%	152/ 182	83.52%
Week 44	160/ 179	89.39%	147/ 182	80.77%
Week 48	156/ 179	87.15%	143/ 182	78.57%
Week 52	153/ 179	85.47%	141/ 182	77.47%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - CLASI Total Damage Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Compliance	Placebo (N=182) n/ N#	Compliance
Baseline	180/ 180	100.0%	182/ 182	100.0%
Week 4	177/ 180	98.33%	180/ 182	98.90%
Week 8	172/ 180	95.56%	177/ 182	97.25%
Week 12	176/ 180	97.78%	173/ 182	95.05%
Week 16	174/ 180	96.67%	171/ 182	93.96%
Week 20	166/ 180	92.22%	171/ 182	93.96%
Week 24	168/ 180	93.33%	167/ 182	91.76%
Week 28	166/ 180	92.22%	159/ 182	87.36%
Week 32	160/ 179	89.39%	151/ 182	82.97%
Week 36	161/ 179	89.94%	153/ 182	84.07%
Week 40	159/ 179	88.83%	152/ 182	83.52%
Week 44	159/ 179	88.83%	147/ 182	80.77%
Week 48	156/ 179	87.15%	143/ 182	78.57%
Week 52	153/ 179	85.47%	141/ 182	77.47%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - BILAG Global Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=182) n/ N#	Placebo (N=182) Compliance
Baseline	180/ 180	100.0%	182/ 182	100.0%
Week 4	175/ 180	97.22%	178/ 182	97.80%
Week 8	170/ 180	94.44%	176/ 182	96.70%
Week 12	176/ 180	97.78%	172/ 182	94.51%
Week 16	174/ 180	96.67%	169/ 182	92.86%
Week 20	166/ 180	92.22%	169/ 182	92.86%
Week 24	168/ 180	93.33%	164/ 182	90.11%
Week 28	166/ 180	92.22%	158/ 182	86.81%
Week 32	161/ 179	89.94%	150/ 182	82.42%
Week 36	161/ 179	89.94%	151/ 182	82.97%
Week 40	158/ 179	88.27%	149/ 182	81.87%
Week 44	158/ 179	88.27%	146/ 182	80.22%
Week 48	156/ 179	87.15%	143/ 182	78.57%
Week 52	153/ 179	85.47%	141/ 182	77.47%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Tender Joint Count
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=182) n/ N#	Placebo (N=182) Compliance
Baseline	180/ 180	100.0%	182/ 182	100.0%
Week 4	177/ 180	98.33%	180/ 182	98.90%
Week 8	172/ 180	95.56%	177/ 182	97.25%
Week 12	176/ 180	97.78%	173/ 182	95.05%
Week 16	173/ 180	96.11%	171/ 182	93.96%
Week 20	165/ 180	91.67%	171/ 182	93.96%
Week 24	168/ 180	93.33%	167/ 182	91.76%
Week 28	166/ 180	92.22%	159/ 182	87.36%
Week 32	161/ 179	89.94%	151/ 182	82.97%
Week 36	162/ 179	90.50%	153/ 182	84.07%
Week 40	161/ 179	89.94%	152/ 182	83.52%
Week 44	159/ 179	88.83%	147/ 182	80.77%
Week 48	155/ 179	86.59%	143/ 182	78.57%
Week 52	153/ 179	85.47%	141/ 182	77.47%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Swollen Joint Count
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=182) n/ N#	Placebo (N=182) Compliance
Baseline	180/ 180	100.0%	182/ 182	100.0%
Week 4	177/ 180	98.33%	180/ 182	98.90%
Week 8	172/ 180	95.56%	177/ 182	97.25%
Week 12	176/ 180	97.78%	173/ 182	95.05%
Week 16	173/ 180	96.11%	171/ 182	93.96%
Week 20	165/ 180	91.67%	171/ 182	93.96%
Week 24	168/ 180	93.33%	167/ 182	91.76%
Week 28	166/ 180	92.22%	159/ 182	87.36%
Week 32	161/ 179	89.94%	151/ 182	82.97%
Week 36	162/ 179	90.50%	153/ 182	84.07%
Week 40	161/ 179	89.94%	152/ 182	83.52%
Week 44	159/ 179	88.83%	147/ 182	80.77%
Week 48	155/ 179	86.59%	143/ 182	78.57%
Week 52	153/ 179	85.47%	141/ 182	77.47%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute Mental Component Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=182) n/ N#	Placebo (N=182) Compliance
Baseline	173/ 180	96.11%	173/ 182	95.05%
Week 8	164/ 180	91.11%	165/ 182	90.66%
Week 16	165/ 180	91.67%	157/ 182	86.26%
Week 24	156/ 180	86.67%	162/ 182	89.01%
Week 32	150/ 179	83.80%	142/ 182	78.02%
Week 40	153/ 179	85.47%	142/ 182	78.02%
Week 48	154/ 179	86.03%	135/ 182	74.18%
Week 52	147/ 179	82.12%	129/ 182	70.88%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute Physical Component Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=182) n/ N#	Placebo (N=182) Compliance
Baseline	173/ 180	96.11%	173/ 182	95.05%
Week 8	164/ 180	91.11%	165/ 182	90.66%
Week 16	165/ 180	91.67%	157/ 182	86.26%
Week 24	156/ 180	86.67%	162/ 182	89.01%
Week 32	150/ 179	83.80%	142/ 182	78.02%
Week 40	153/ 179	85.47%	142/ 182	78.02%
Week 48	154/ 179	86.03%	135/ 182	74.18%
Week 52	147/ 179	82.12%	129/ 182	70.88%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute General Health Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=182) n/ N#	Placebo (N=182) Compliance
Baseline	173/ 180	96.11%	173/ 182	95.05%
Week 8	164/ 180	91.11%	165/ 182	90.66%
Week 16	165/ 180	91.67%	157/ 182	86.26%
Week 24	156/ 180	86.67%	162/ 182	89.01%
Week 32	150/ 179	83.80%	142/ 182	78.02%
Week 40	153/ 179	85.47%	142/ 182	78.02%
Week 48	154/ 179	86.03%	135/ 182	74.18%
Week 52	147/ 179	82.12%	129/ 182	70.88%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute Mental Health Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=182) n/ N#	Placebo (N=182) Compliance
Baseline	173/ 180	96.11%	173/ 182	95.05%
Week 8	164/ 180	91.11%	165/ 182	90.66%
Week 16	165/ 180	91.67%	157/ 182	86.26%
Week 24	156/ 180	86.67%	162/ 182	89.01%
Week 32	150/ 179	83.80%	142/ 182	78.02%
Week 40	153/ 179	85.47%	142/ 182	78.02%
Week 48	154/ 179	86.03%	135/ 182	74.18%
Week 52	147/ 179	82.12%	129/ 182	70.88%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute Physical Functioning Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=182) n/ N#	Placebo (N=182) Compliance
Baseline	173/ 180	96.11%	173/ 182	95.05%
Week 8	164/ 180	91.11%	165/ 182	90.66%
Week 16	165/ 180	91.67%	157/ 182	86.26%
Week 24	156/ 180	86.67%	162/ 182	89.01%
Week 32	150/ 179	83.80%	142/ 182	78.02%
Week 40	153/ 179	85.47%	142/ 182	78.02%
Week 48	154/ 179	86.03%	135/ 182	74.18%
Week 52	147/ 179	82.12%	129/ 182	70.88%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute Role Emotional Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=182) n/ N#	Placebo (N=182) Compliance
Baseline	173/ 180	96.11%	173/ 182	95.05%
Week 8	164/ 180	91.11%	165/ 182	90.66%
Week 16	165/ 180	91.67%	157/ 182	86.26%
Week 24	156/ 180	86.67%	162/ 182	89.01%
Week 32	150/ 179	83.80%	142/ 182	78.02%
Week 40	153/ 179	85.47%	142/ 182	78.02%
Week 48	154/ 179	86.03%	135/ 182	74.18%
Week 52	147/ 179	82.12%	129/ 182	70.88%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute Role Physical Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=182) n/ N#	Placebo (N=182) Compliance
Baseline	173/ 180	96.11%	173/ 182	95.05%
Week 8	164/ 180	91.11%	165/ 182	90.66%
Week 16	165/ 180	91.67%	157/ 182	86.26%
Week 24	156/ 180	86.67%	162/ 182	89.01%
Week 32	150/ 179	83.80%	142/ 182	78.02%
Week 40	153/ 179	85.47%	142/ 182	78.02%
Week 48	154/ 179	86.03%	135/ 182	74.18%
Week 52	147/ 179	82.12%	129/ 182	70.88%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute Social Functioning Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=182) n/ N#	Placebo (N=182) Compliance
Baseline	173/ 180	96.11%	173/ 182	95.05%
Week 8	164/ 180	91.11%	165/ 182	90.66%
Week 16	165/ 180	91.67%	157/ 182	86.26%
Week 24	156/ 180	86.67%	162/ 182	89.01%
Week 32	150/ 179	83.80%	142/ 182	78.02%
Week 40	153/ 179	85.47%	142/ 182	78.02%
Week 48	154/ 179	86.03%	135/ 182	74.18%
Week 52	147/ 179	82.12%	129/ 182	70.88%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute Bodily Pain Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=182) n/ N#	Placebo (N=182) Compliance
Baseline	173/ 180	96.11%	173/ 182	95.05%
Week 8	164/ 180	91.11%	165/ 182	90.66%
Week 16	165/ 180	91.67%	157/ 182	86.26%
Week 24	156/ 180	86.67%	162/ 182	89.01%
Week 32	150/ 179	83.80%	142/ 182	78.02%
Week 40	153/ 179	85.47%	142/ 182	78.02%
Week 48	154/ 179	86.03%	135/ 182	74.18%
Week 52	147/ 179	82.12%	129/ 182	70.88%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute Vitality Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=182) n/ N#	Placebo (N=182) Compliance
Baseline	173/ 180	96.11%	173/ 182	95.05%
Week 8	164/ 180	91.11%	165/ 182	90.66%
Week 16	165/ 180	91.67%	157/ 182	86.26%
Week 24	156/ 180	86.67%	162/ 182	89.01%
Week 32	150/ 179	83.80%	142/ 182	78.02%
Week 40	153/ 179	85.47%	142/ 182	78.02%
Week 48	154/ 179	86.03%	135/ 182	74.18%
Week 52	147/ 179	82.12%	129/ 182	70.88%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - FACIT-F Total Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=182) n/ N#	Placebo (N=182) Compliance
Baseline	170/ 180	94.44%	175/ 182	96.15%
Week 4	172/ 180	95.56%	175/ 182	96.15%
Week 8	165/ 180	91.67%	168/ 182	92.31%
Week 12	171/ 180	95.00%	167/ 182	91.76%
Week 16	166/ 180	92.22%	159/ 182	87.36%
Week 20	160/ 180	88.89%	162/ 182	89.01%
Week 24	159/ 180	88.33%	163/ 182	89.56%
Week 28	162/ 180	90.00%	155/ 182	85.16%
Week 32	154/ 179	86.03%	145/ 182	79.67%
Week 36	159/ 179	88.83%	146/ 182	80.22%
Week 40	155/ 179	86.59%	142/ 182	78.02%
Week 44	157/ 179	87.71%	134/ 182	73.63%
Week 48	153/ 179	85.47%	137/ 182	75.27%
Week 52	147/ 179	82.12%	130/ 182	71.43%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - EQ VAS Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=182) n/ N#	Placebo (N=182) Compliance
Baseline	170/ 180	94.44%	175/ 182	96.15%
Week 12	169/ 180	93.89%	166/ 182	91.21%
Week 24	156/ 180	86.67%	160/ 182	87.91%
Week 36	158/ 179	88.27%	144/ 182	79.12%
Week 52	146/ 179	81.56%	128/ 182	70.33%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Lupus QoL Physical Health domain score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=182) n/ N#	Placebo (N=182) Compliance
Baseline	170/ 180	94.44%	175/ 182	96.15%
Week 12	168/ 180	93.33%	166/ 182	91.21%
Week 24	155/ 180	86.11%	158/ 182	86.81%
Week 36	157/ 179	87.71%	142/ 182	78.02%
Week 52	146/ 179	81.56%	127/ 182	69.78%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Lupus QoL Emotional Health domain score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=182) n/ N#	Placebo (N=182) Compliance
Baseline	170/ 180	94.44%	175/ 182	96.15%
Week 12	168/ 180	93.33%	166/ 182	91.21%
Week 24	155/ 180	86.11%	158/ 182	86.81%
Week 36	157/ 179	87.71%	142/ 182	78.02%
Week 52	146/ 179	81.56%	127/ 182	69.78%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Lupus QoL Body Image domain score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=182) n/ N#	Placebo (N=182) Compliance
Baseline	157/ 180	87.22%	164/ 182	90.11%
Week 12	154/ 180	85.56%	151/ 182	82.97%
Week 24	136/ 180	75.56%	142/ 182	78.02%
Week 36	138/ 179	77.09%	128/ 182	70.33%
Week 52	127/ 179	70.95%	118/ 182	64.84%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Lupus QoL Burden to Others domain score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=182) n/ N#	Placebo (N=182) Compliance
Baseline	170/ 180	94.44%	175/ 182	96.15%
Week 12	168/ 180	93.33%	166/ 182	91.21%
Week 24	155/ 180	86.11%	158/ 182	86.81%
Week 36	157/ 179	87.71%	142/ 182	78.02%
Week 52	146/ 179	81.56%	127/ 182	69.78%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Lupus QoL Fatigue domain score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=182) n/ N#	Placebo (N=182) Compliance
Baseline	170/ 180	94.44%	175/ 182	96.15%
Week 12	168/ 180	93.33%	166/ 182	91.21%
Week 24	155/ 180	86.11%	158/ 182	86.81%
Week 36	157/ 179	87.71%	142/ 182	78.02%
Week 52	146/ 179	81.56%	127/ 182	69.78%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Lupus QoL Intimate Relationships domain score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=182) n/ N#	Placebo (N=182) Compliance
Baseline	131/ 180	72.78%	134/ 182	73.63%
Week 12	131/ 180	72.78%	134/ 182	73.63%
Week 24	116/ 180	64.44%	116/ 182	63.74%
Week 36	120/ 179	67.04%	103/ 182	56.59%
Week 52	97/ 179	54.19%	93/ 182	51.10%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Lupus QoL Pain domain score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=182) n/ N#	Placebo (N=182) Compliance
Baseline	170/ 180	94.44%	175/ 182	96.15%
Week 12	168/ 180	93.33%	166/ 182	91.21%
Week 24	155/ 180	86.11%	158/ 182	86.81%
Week 36	157/ 179	87.71%	142/ 182	78.02%
Week 52	146/ 179	81.56%	127/ 182	69.78%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Lupus QoL Planning domain score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=182) n/ N#	Placebo (N=182) Compliance
Baseline	170/ 180	94.44%	175/ 182	96.15%
Week 12	168/ 180	93.33%	166/ 182	91.21%
Week 24	155/ 180	86.11%	158/ 182	86.81%
Week 36	157/ 179	87.71%	142/ 182	78.02%
Week 52	146/ 179	81.56%	127/ 182	69.78%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SDI Global Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=182) n/ N#	Placebo (N=182) Compliance
Baseline	180/ 180	100.0%	182/ 182	100.0%
Week 24	163/ 180	90.56%	159/ 182	87.36%
Week 52	152/ 179	84.92%	136/ 182	74.73%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - NRS Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=182) n/ N#	Placebo (N=182) Compliance
Baseline	170/ 180	94.44%	175/ 182	96.15%
Week 4	172/ 180	95.56%	175/ 182	96.15%
Week 8	165/ 180	91.67%	168/ 182	92.31%
Week 12	171/ 180	95.00%	167/ 182	91.76%
Week 16	166/ 180	92.22%	159/ 182	87.36%
Week 20	160/ 180	88.89%	162/ 182	89.01%
Week 24	159/ 180	88.33%	163/ 182	89.56%
Week 28	162/ 180	90.00%	155/ 182	85.16%
Week 32	154/ 179	86.03%	145/ 182	79.67%
Week 36	159/ 179	88.83%	146/ 182	80.22%
Week 40	155/ 179	86.59%	142/ 182	78.02%
Week 44	157/ 179	87.71%	134/ 182	73.63%
Week 48	153/ 179	85.47%	137/ 182	75.27%
Week 52	147/ 179	82.12%	130/ 182	71.43%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - PHQ-8 Total Score
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=182) n/ N#	Placebo (N=182) Compliance
Baseline	170/ 180	94.44%	175/ 182	96.15%
Week 12	169/ 180	93.89%	166/ 182	91.21%
Week 24	156/ 180	86.67%	160/ 182	87.91%
Week 36	158/ 179	88.27%	144/ 182	79.12%
Week 52	146/ 179	81.56%	128/ 182	70.33%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - PtGA
Full analysis set

Visit	Anifrolumab 300mg (N=180) n/ N#	Anifrolumab 300mg (N=180) Compliance	Placebo (N=182) n/ N#	Placebo (N=182) Compliance
Baseline	170/ 180	94.44%	175/ 182	96.15%
Week 4	172/ 180	95.56%	175/ 182	96.15%
Week 8	165/ 180	91.67%	168/ 182	92.31%
Week 12	171/ 180	95.00%	167/ 182	91.76%
Week 16	166/ 180	92.22%	159/ 182	87.36%
Week 20	160/ 180	88.89%	161/ 182	88.46%
Week 24	158/ 180	87.78%	161/ 182	88.46%
Week 28	161/ 180	89.44%	152/ 182	83.52%
Week 32	153/ 179	85.47%	145/ 182	79.67%
Week 36	158/ 179	88.27%	144/ 182	79.12%
Week 40	155/ 179	86.59%	140/ 182	76.92%
Week 44	157/ 179	87.71%	132/ 182	72.53%
Week 48	152/ 179	84.92%	134/ 182	73.63%
Week 52	147/ 179	82.12%	129/ 182	70.88%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Flare rate through Week 52
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) Number of flares	Anifrolumab 300mg (N=180) Total Follow-up time (years)	Anifrolumab 300mg (N=180) Annual rate (SE)	Placebo (N=182) Number of flares	Placebo (N=182) Total Follow-up time (years)	Placebo (N=182) Annual rate (SE)	Rate ratio (95% CI)	p-Value	Interaction p-Value
Overall	86	170.22	0.43 (0.16)	122	164.62	0.64 (0.15)	0.67 (0.48, 0.94)	0.0202	
SLEDAI-2K score at screening									0.0244
< 10 points	32	51.53	0.59 (0.24)	24	48.97	0.47 (0.26)	1.24 (0.68, 2.27)	0.4757	
>= 10 points	54	118.69	0.38 (0.21)	98	115.65	0.72 (0.19)	0.53 (0.35, 0.79)	0.0019	
OCS dose at baseline									0.1378
<10 mg/day	45	87.61	0.46 (0.21)	56	92.19	0.52 (0.20)	0.87 (0.54, 1.42)	0.5910	
>=10 mg/day	41	82.61	0.36 (0.28)	66	72.43	0.70 (0.26)	0.52 (0.33, 0.82)	0.0052	
Result of type I IFN gene signature test									0.5314
LOW	11	28.79	0.36 (0.41)	12	27.56	0.42 (0.39)	0.87 (0.31, 2.43)	0.7857	
HIGH	75	141.43	0.52 (0.14)	110	137.06	0.81 (0.13)	0.64 (0.45, 0.92)	0.0156	
Age (years)									0.2797
<= 65	85	165.86	0.44 (0.16)	120	163.60	0.64 (0.15)	0.69 (0.49, 0.96)	0.0296	
> 65	1	4.36	0.00 (3175.95)	2	1.02	0.00 (3175.95)	0.26 (0.02, 2.81)	0.2647	
Sex									0.7181
male	5	11.25	NE	10	12.07	NE	NE		
female	81	158.98	0.44 (0.17)	112	152.55	0.63 (0.16)	0.69 (0.48, 0.97)	0.0354	
Race									0.1409
White	57	104.64	0.42 (0.20)	72	94.42	0.61 (0.20)	0.69 (0.45, 1.05)	0.0823	
Black or African American	12	15.54	1.08 (0.32)	18	23.72	1.18 (0.30)	0.91 (0.43, 1.96)	0.8172	
Asian	6	28.64	0.11 (0.69)	22	28.58	0.53 (0.57)	0.20 (0.07, 0.57)	0.0023	
American Indian or Alaska Native	4	3.75	1.11 (0.62)	0	1.02	0.00 (0.62)	233749389596.41 (233749389596.	<.0001	
Other	5	10.97	0.26 (0.84)	8	9.90	0.52 (0.71)	0.50 (0.12, 1.99)	0.3224	
Ethnicity									0.5387
Hispanic/Latino	32	52.02	0.41 (0.32)	38	49.19	0.54 (0.30)	0.75 (0.41, 1.37)	0.3446	
Non-hispanic/Latino	52	111.52	0.43 (0.19)	82	108.45	0.70 (0.18)	0.61 (0.41, 0.92)	0.0180	
Geographic region									0.8417
EU	15	47.57	0.24 (0.44)	20	40.37	0.38 (0.45)	0.64 (0.31, 1.33)	0.2352	
non-EU	71	122.65	0.49 (0.17)	102	124.25	0.71 (0.16)	0.69 (0.48, 1.00)	0.0528	
Onset of disease									0.8428
Paediatric	11	13.45	1.10 (0.39)	14	11.43	2.36 (0.50)	0.46 (0.16, 1.32)	0.1487	
Adult	75	156.77	0.38 (0.17)	108	153.19	0.57 (0.16)	0.66 (0.46, 0.94)	0.0219	
ADA result									0.7105
Negative	80	162.72	0.43 (0.17)	100	147.81	0.60 (0.17)	0.72 (0.50, 1.03)	0.0708	
Positive (At any time)	6	7.50	0.27 (0.73)	22	16.81	0.56 (0.58)	0.49 (0.20, 1.22)	0.1256	
BMI (kg/m2) at enrolment									0.8173
< 30	54	118.32	0.39 (0.22)	81	119.64	0.58 (0.22)	0.67 (0.43, 1.03)	0.0693	
>= 30	32	51.90	0.48 (0.23)	41	44.97	0.78 (0.20)	0.62 (0.37, 1.02)	0.0616	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.0361
All negative/normal	32	55.15	NE	40	75.58	NE	NE		
At least one positive/abnormal	54	115.07	0.39 (0.25)	82	89.04	0.77 (0.26)	0.51 (0.34, 0.77)	0.0015	

Rates and rate ratio from negative binomial regression model with factors for treatment group and the stratification factors. The logarithm (to base e) of the follow-up time is used as an offset variable in the model to adjust for subjects having different exposure times.
p-Value for interaction from same negative binomial regression model with additional factors for subgroup and subgroup*treatment interaction.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Flare rate through Week 52 using modified BILAG
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) Number of flares	Anifrolumab 300mg (N=180) Total Follow-up time (years)	Anifrolumab 300mg (N=180) Annual rate (SE)	Placebo (N=182) Number of flares	Placebo (N=182) Total Follow-up time (years)	Placebo (N=182) Annual rate (SE)	Rate ratio (95% CI)	p-Value	Interaction p-Value
Overall	66	170.22	0.32 (0.18)	102	164.62	0.52 (0.17)	0.62 (0.43, 0.90)	0.0112	

Rates and rate ratio from negative binomial regression model with factors for treatment group and the stratification factors. The logarithm (to base e) of the follow-up time is used as an offset variable in the model to adjust for subjects having different exposure times.
p-Value for interaction from same negative binomial regression model with additional factors for subgroup and subgroup*treatment interaction.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Flare rate through Week 52 while on treatment
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) Number of flares	Anifrolumab 300mg (N=180) Total Follow-up time (years)	Anifrolumab 300mg (N=180) Annual rate (SE)	Placebo (N=182) Number of flares	Placebo (N=182) Total Follow-up time (years)	Placebo (N=182) Annual rate (SE)	Rate ratio (95% CI)	p-Value	Interaction p-Value
Overall	79	166.24	0.40 (0.17)	108	155.54	0.58 (0.17)	0.68 (0.48, 0.98)	0.0372	

Rates and rate ratio from negative binomial regression model with factors for treatment group and the stratification factors. The logarithm (to base e) of the follow-up time is used as an offset variable in the model to adjust for subjects having different exposure times.
p-Value for interaction from same negative binomial regression model with additional factors for subgroup and subgroup*treatment interaction.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Flare rate through Week 52 sensitivity analysis, multiple imputation and negative binomial regression model
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) Number of flares	Anifrolumab 300mg (N=180) Total Follow-up time (years)	Anifrolumab 300mg (N=180) Annual rate (SE)	Placebo (N=182) Number of flares	Placebo (N=182) Total Follow-up time (years)	Placebo (N=182) Annual rate (SE)	Rate ratio (95% CI)	p-Value
Overall	92	180.49	0.43 (0.00)	141	182.26	0.64 (0.01)	0.66 (0.47, 0.93)	0.0181

The number of flares after withdrawal from study is imputed conditional upon the observed number of flares prior to the withdrawal, a post-withdrawal model assumption, the baseline covariates included in the main analysis model and the time the subject would have remained in the study if not withdrawn (ie, date of first administration of IP + 364 days â€“ date of withdrawal). This analysis is repeated multiple times and the results combined using Rubinâ€™s formula. Full details are given in SAP
Rates and rate ratio from negative binomial regression model with factors for treatment group and the stratification factors. The logarithm (to base e) of the follow-up time is used as an offset variable in the model to adjust for subjects having different exposure times.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Flare rate through Week 52 sensitivity analysis, tipping point analysis
Full analysis set

Shift (log(Delta A)) for Anifrolumab 300 mg	Shift (log(Delta P)) for Placebo						
	0	-0.25	-0.5	-0.75	-1	-1.25	-1.5
0	0.0267	0.0321	0.0371	0.0414	0.0451	0.0481	0.0506
0.25	0.0291	0.0350	0.0403	0.0450	0.0489	0.0522	0.0549
0.5	0.0327	0.0391	0.0450	0.0500	0.0544	0.0579	0.0609
0.75	0.0378	0.0451	0.0517	0.0574	0.0622	0.0662	0.0695
1	0.0455	0.0541	0.0617	0.0683	0.0738	0.0784	0.0822
1.25	0.0576	0.0680	0.0771	0.0850	0.0916	0.0971	0.1015
1.5	0.0772	0.0903	0.1018	0.1116	0.1198	0.1265	0.1319

The response variable in the model is the number of flares up to Week 52/EDV. The model includes covariates of treatment group, and the stratification factors (SLEDAI-2K Score at Screening (<10 points vs >= 10 points), Week 0 OCS dose (<10 mg/day vs >=10 mg/day prednisone or equivalent) and Type 1 IFN test result at screening (high vs low)).
The logarithm (to base e) of the follow-up time is used as an offset variable in the model to adjust for subjects having different exposure times.
P-values of this analysis are presented.
For the scenario in the upper left corner, missing at random analysis is performed, where for each subject the rate after withdrawal y1 is assumed to be the same as their rate before withdrawal y2, which itself is calculated based on their randomised treatment group and baseline covariates. For the other scenarios, the same analyses are performed with the rate after withdrawal modified to be Deltay2 (Delta P and Delta A for placebo and anifrolumab 300 mg, respectively).

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Overall Survival
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	1 (0.6)	0 (0.0)
Number of censored subjects, n (%)	179 (99.4)	182 (100.0)
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Anifrolumab 300mg vs. Placebo (adjusted)		
Hazard Ratio (95% CI)	NE	
p-value		
Analysis Anifrolumab 300mg vs. Placebo (unadjusted)		
Hazard Ratio (95% CI)	NE	
p-value		

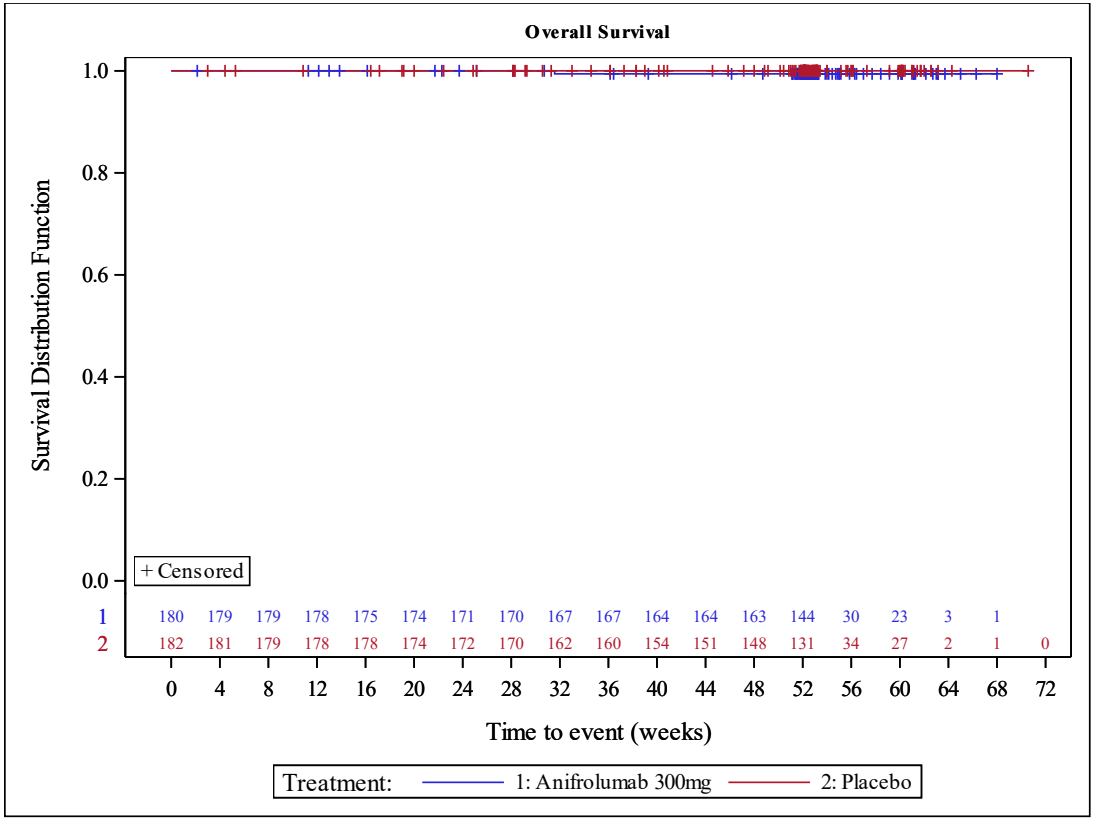
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model. Adjusted analysis also includes stratification factors in the model.
Two-sided log rank test used.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Overall Survival - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Anifrolumab 300mg (N=180) Median (95% CI)	Placebo (N=182) n/ N (%)	Placebo (N=182) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening							0.9998
< 10 points	1/ 54 (1.9)	NE (NE, NE)	0/ 52 (0.0)	NE (NE, NE)	NE		
>= 10 points	0/126 (0.0)	NE (NE, NE)	0/130 (0.0)	NE (NE, NE)	NE		
OCS dose at baseline							0.9996
<10 mg/day	0/ 93 (0.0)	NE (NE, NE)	0/ 99 (0.0)	NE (NE, NE)	NE		
>=10 mg/day	1/ 87 (1.1)	NE (NE, NE)	0/ 83 (0.0)	NE (NE, NE)	NE		
Result of type I IFN gene signature test							0.9998
LOW	0/ 30 (0.0)	NE (NE, NE)	0/ 31 (0.0)	NE (NE, NE)	NE		
HIGH	1/150 (0.7)	NE (NE, NE)	0/151 (0.0)	NE (NE, NE)	NE		
Age (years)							1.0000
<= 65	1/175 (0.6)	NE (NE, NE)	0/181 (0.0)	NE (NE, NE)	NE		
> 65	0/ 5 (0.0)	NE (NE, NE)	0/ 1 (0.0)	NE (NE, NE)	NE		
Sex							0.9998
male	0/ 12 (0.0)	NE (NE, NE)	0/ 12 (0.0)	NE (NE, NE)	NE		
female	1/168 (0.6)	NE (NE, NE)	0/170 (0.0)	NE (NE, NE)	NE		
Race							1.0000
White	1/110 (0.9)	NE (NE, NE)	0/107 (0.0)	NE (NE, NE)	NE		
Black or African American	0/ 17 (0.0)	NE (NE, NE)	0/ 25 (0.0)	NE (NE, NE)	NE		
Asian	0/ 30 (0.0)	NE (NE, NE)	0/ 30 (0.0)	NE (NE, NE)	NE		
American Indian or Alaska Native	0/ 4 (0.0)	NE (NE, NE)	0/ 1 (0.0)	NE (NE, NE)	NE		
Other	0/ 11 (0.0)	NE (NE, NE)	0/ 11 (0.0)	NE (NE, NE)	NE		
Ethnicity							0.9998
Hispanic/Latino	1/ 54 (1.9)	NE (NE, NE)	0/ 54 (0.0)	NE (NE, NE)	NE		
Non-hispanic/Latino	0/118 (0.0)	NE (NE, NE)	0/120 (0.0)	NE (NE, NE)	NE		
Geographic region							0.9997
EU	0/ 51 (0.0)	NE (NE, NE)	0/ 46 (0.0)	NE (NE, NE)	NE		
non-EU	1/129 (0.8)	NE (NE, NE)	0/136 (0.0)	NE (NE, NE)	NE		
Onset of disease							0.9998
Paediatric	0/ 14 (0.0)	NE (NE, NE)	0/ 12 (0.0)	NE (NE, NE)	NE		
Adult	1/166 (0.6)	NE (NE, NE)	0/170 (0.0)	NE (NE, NE)	NE		
ADA result							0.9998
Negative	1/172 (0.6)	NE (NE, NE)	0/162 (0.0)	NE (NE, NE)	NE		
Positive (At any time)	0/ 8 (0.0)	NE (NE, NE)	0/ 20 (0.0)	NE (NE, NE)	NE		
BMI (kg/m2) at enrolment							0.9997
< 30	1/125 (0.8)	NE (NE, NE)	0/134 (0.0)	NE (NE, NE)	NE		
>= 30	0/ 55 (0.0)	NE (NE, NE)	0/ 48 (0.0)	NE (NE, NE)	NE		
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group							0.9996
All negative/normal	0/ 58 (0.0)	NE (NE, NE)	0/ 81 (0.0)	NE (NE, NE)	NE		
At least one positive/abnormal	1/122 (0.8)	NE (NE, NE)	0/101 (0.0)	NE (NE, NE)	NE		

Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Overall Survival
Full analysis set



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Time to first Flare
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	56 (31.1)	77 (42.3)
Number of censored subjects, n (%)	124 (68.9)	105 (57.7)
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	32.71 (24.43, 48.00)	20.00 (16.00, 23.29)
Median (95% CI)	NE (NE, NE)	NE (52.00, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Anifrolumab 300mg vs. Placebo (adjusted)		
Hazard Ratio (95% CI)	0.65 (0.46, 0.91)	
p-value	0.0173	
Analysis Anifrolumab 300mg vs. Placebo (unadjusted)		
Hazard Ratio (95% CI)	0.66 (0.47, 0.93)	
p-value	0.0172	

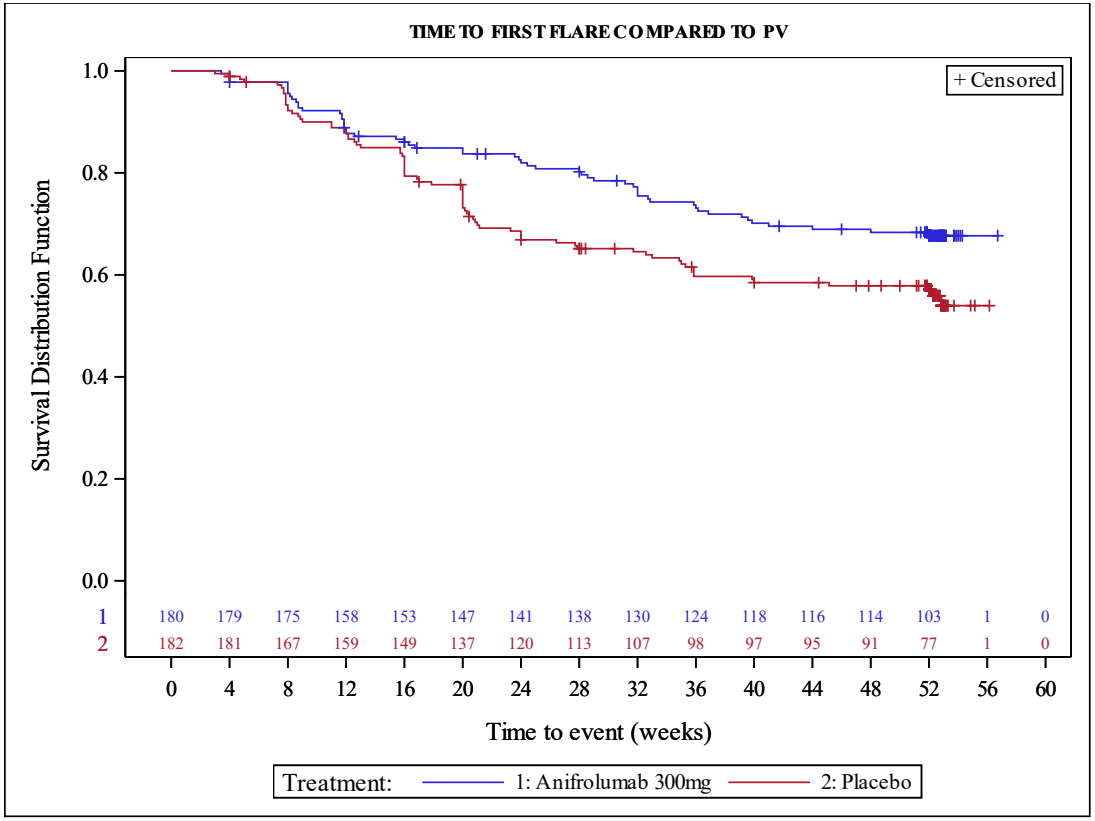
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model. Adjusted analysis also includes stratification factors in the model.
Two-sided log rank test used.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Time to first Flare - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Anifrolumab 300mg (N=180) Median (95% CI)	Placebo (N=182) n/ N (%)	Placebo (N=182) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening							0.0470
< 10 points	21/ 54 (38.9)	NE (36.00, NE)	18/ 52 (34.6)	NE (NE, NE)	1.08 (0.57, 2.02)	0.7865	
>= 10 points	35/126 (27.8)	NE (NE, NE)	59/130 (45.4)	52.86 (35.86, NE)	0.52 (0.34, 0.79)	0.0027	
OCS dose at baseline							0.4215
<10 mg/day	27/ 93 (29.0)	NE (NE, NE)	36/ 99 (36.4)	NE (52.86, NE)	0.75 (0.45, 1.23)	0.2493	
>=10 mg/day	29/ 87 (33.3)	NE (NE, NE)	41/ 83 (49.4)	39.86 (24.00, NE)	0.58 (0.36, 0.93)	0.0285	
Result of type I IFN gene signature test							0.9774
LOW	6/ 30 (20.0)	NE (NE, NE)	9/ 31 (29.0)	NE (52.29, NE)	0.62 (0.22, 1.74)	0.3863	
HIGH	50/150 (33.3)	NE (NE, NE)	68/151 (45.0)	NE (35.86, NE)	0.65 (0.45, 0.94)	0.0266	
Age (years)							0.0302
<= 65	55/175 (31.4)	NE (NE, NE)	76/181 (42.0)	NE (52.00, NE)	0.66 (0.46, 0.93)	0.0239	
> 65	1/ 5 (20.0)	NE (36.14, NE)	1/ 1 (100.0)	8.00 (NE, NE)	0.00 (0.00,)	0.1573	
Sex							0.9986
male	4/ 12 (33.3)	NE (20.00, NE)	6/ 12 (50.0)	52.86 (12.57, NE)	0.37 (0.08, 1.76)	0.3402	
female	52/168 (31.0)	NE (NE, NE)	71/170 (41.8)	NE (45.14, NE)	0.65 (0.45, 0.92)	0.0195	
Race							0.5397
White	35/110 (31.8)	NE (NE, NE)	47/107 (43.9)	NE (35.00, NE)	0.59 (0.38, 0.91)	0.0229	
Black or African American	8/ 17 (47.1)	NE (23.57, NE)	11/ 25 (44.0)	NE (20.43, NE)	1.11 (0.44, 2.80)	0.6588	
Asian	6/ 30 (20.0)	NE (NE, NE)	12/ 30 (40.0)	NE (35.29, NE)	0.29 (0.10, 0.83)	0.0418	
American Indian or Alaska Native	2/ 4 (50.0)	NE (8.00, NE)	0/ 1 (0.0)	NE (NE, NE)	NE		
Other	3/ 11 (27.3)	NE (25.00, NE)	5/ 11 (45.5)	NE (7.29, NE)	0.39 (0.09, 1.73)	0.9571	
Ethnicity							0.3134
Hispanic/Latino	15/ 54 (27.8)	NE (NE, NE)	26/ 54 (48.1)	NE (21.00, NE)	0.51 (0.27, 0.96)	0.0583	
Non-hispanic/Latino	39/118 (33.1)	NE (NE, NE)	49/120 (40.8)	NE (45.14, NE)	0.70 (0.46, 1.07)	0.1106	
Geographic region							0.9073
EU	12/ 51 (23.5)	NE (NE, NE)	15/ 46 (32.6)	NE (52.86, NE)	0.69 (0.32, 1.49)	0.2812	
non-EU	44/129 (34.1)	NE (NE, NE)	62/136 (45.6)	NE (35.29, NE)	0.64 (0.43, 0.94)	0.0248	
Onset of disease							0.8776
Paediatric	6/ 14 (42.9)	NE (11.71, NE)	7/ 12 (58.3)	31.86 (7.86, NE)	0.38 (0.10, 1.46)	0.2039	
Adult	50/166 (30.1)	NE (NE, NE)	70/170 (41.2)	NE (52.29, NE)	0.64 (0.45, 0.93)	0.0218	
ADA result							0.1596
Negative	53/172 (30.8)	NE (NE, NE)	62/162 (38.3)	NE (52.86, NE)	0.74 (0.51, 1.07)	0.1191	
Positive (At any time)	3/ 8 (37.5)	NE (4.00, NE)	15/ 20 (75.0)	17.36 (7.86, 40.00)	0.29 (0.08, 1.03)	0.0496	
BMI (kg/m2) at enrolment							0.5784
< 30	36/125 (28.8)	NE (NE, NE)	51/134 (38.1)	NE (52.86, NE)	0.68 (0.44, 1.04)	0.0985	
>= 30	20/ 55 (36.4)	NE (36.14, NE)	26/ 48 (54.2)	35.86 (21.00, NE)	0.53 (0.29, 0.95)	0.0502	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group							0.3411
All negative/normal	18/ 58 (31.0)	NE (NE, NE)	30/ 81 (37.0)	NE (52.29, NE)	0.83 (0.46, 1.50)	0.6111	
At least one positive/abnormal	38/122 (31.1)	NE (NE, NE)	47/101 (46.5)	52.86 (34.86, NE)	0.57 (0.37, 0.87)	0.0106	

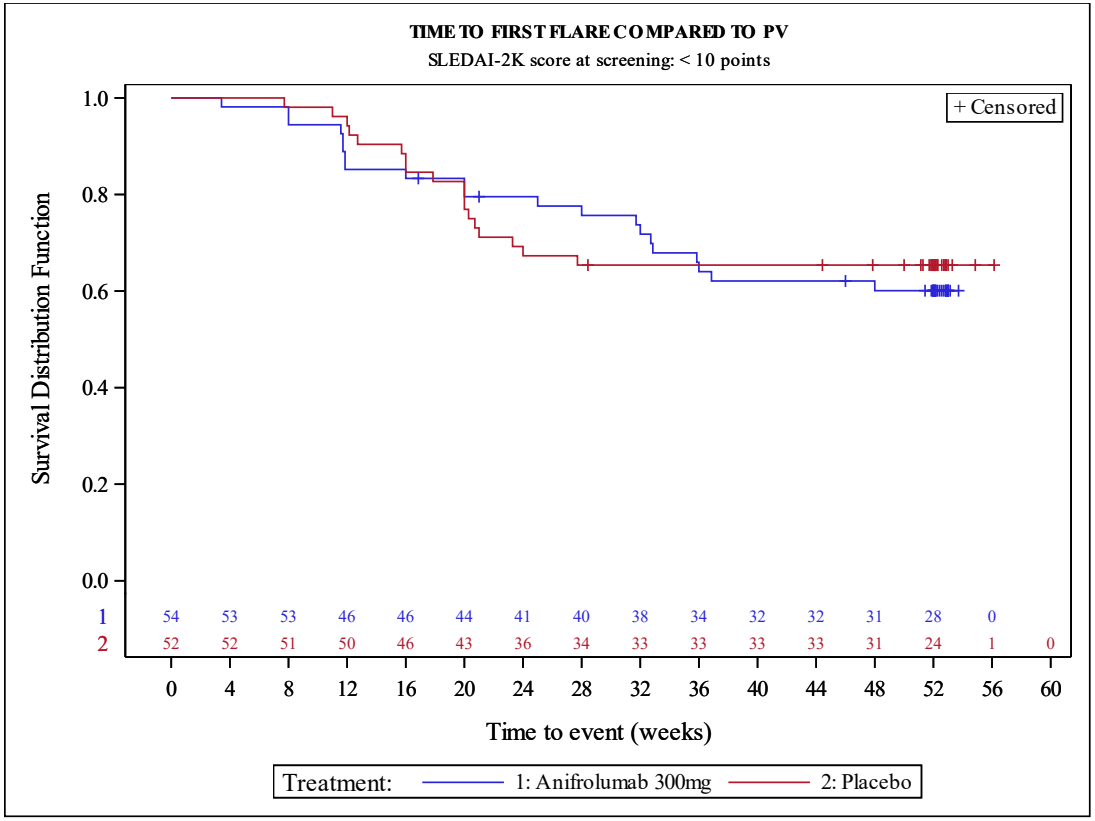
Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Time to first Flare
Full analysis set



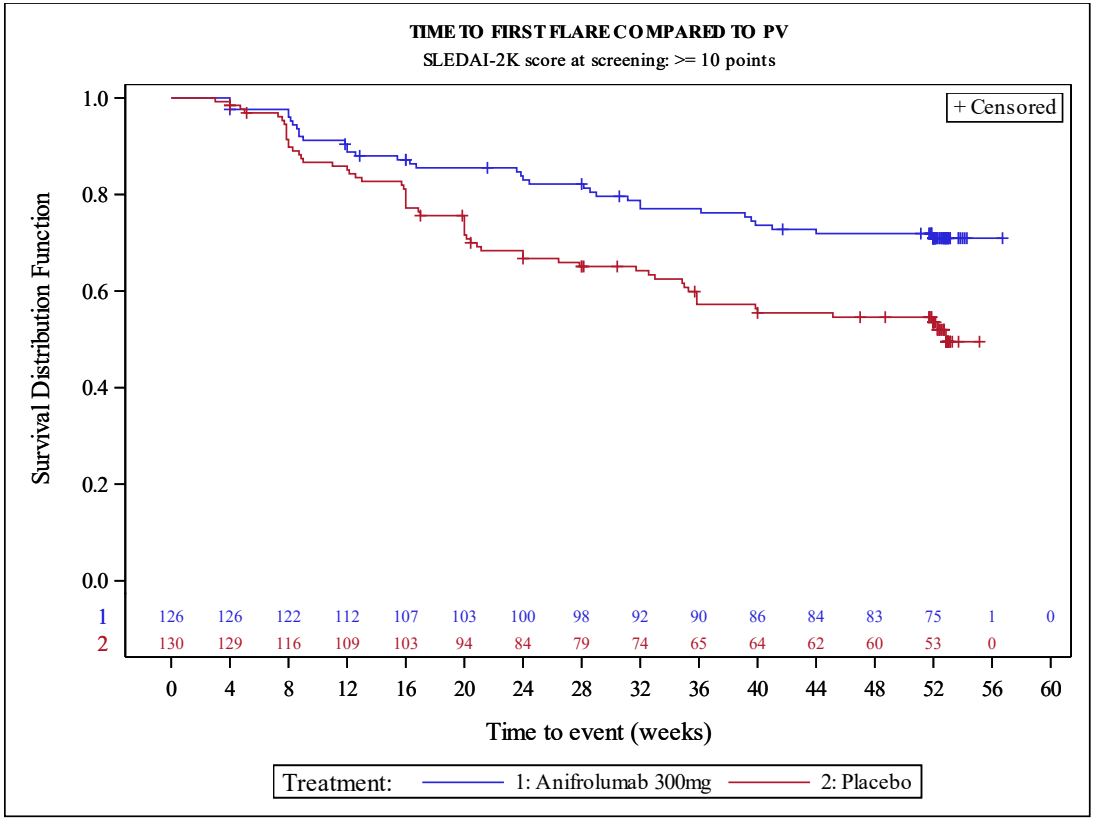
Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Time to first Flare
Full analysis set



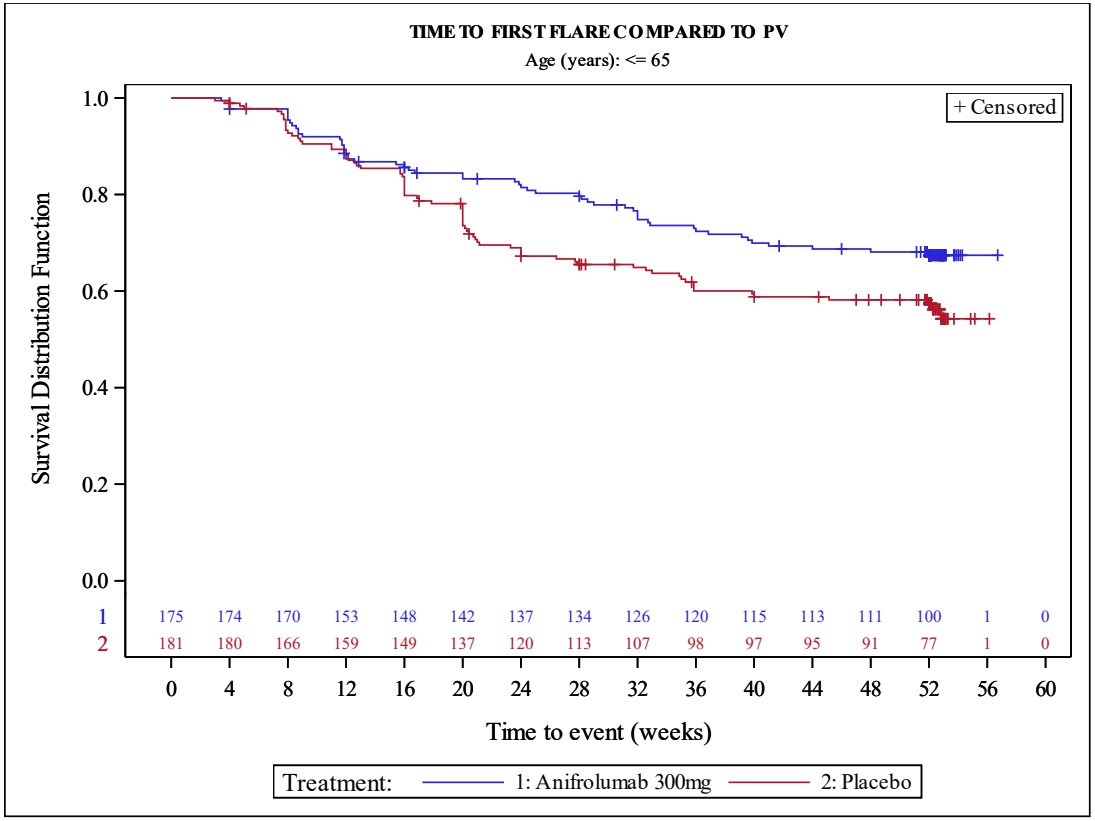
Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Time to first Flare
Full analysis set



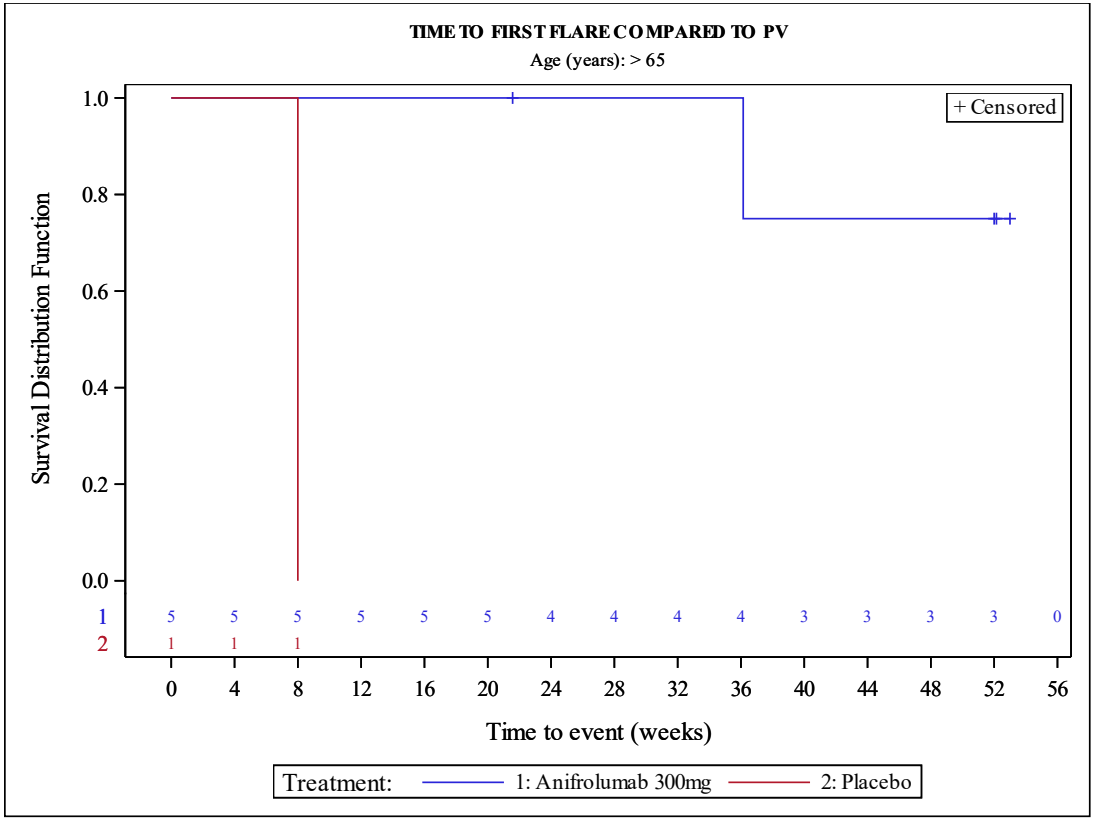
Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Time to first Flare
Full analysis set



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Time to first Flare
Full analysis set



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Time to sustained BICLA response up to week 52
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	86 (47.8)	57 (31.3)
Number of censored subjects, n (%)	94 (52.2)	125 (68.7)
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	24.86 (17.00, 32.43)	44.00 (32.29, 48.00)
Median (95% CI)	52.00 (48.00, NE)	NE (52.86, NE)
75%-ile (95% CI)	NE (53.14, NE)	NE (NE, NE)
Analysis Anifrolumab 300mg vs. Placebo (adjusted)		
Hazard Ratio (95% CI)	1.55 (1.11, 2.17)	
p-value	0.0168	
Analysis Anifrolumab 300mg vs. Placebo (unadjusted)		
Hazard Ratio (95% CI)	1.56 (1.12, 2.18)	
p-value	0.0089	

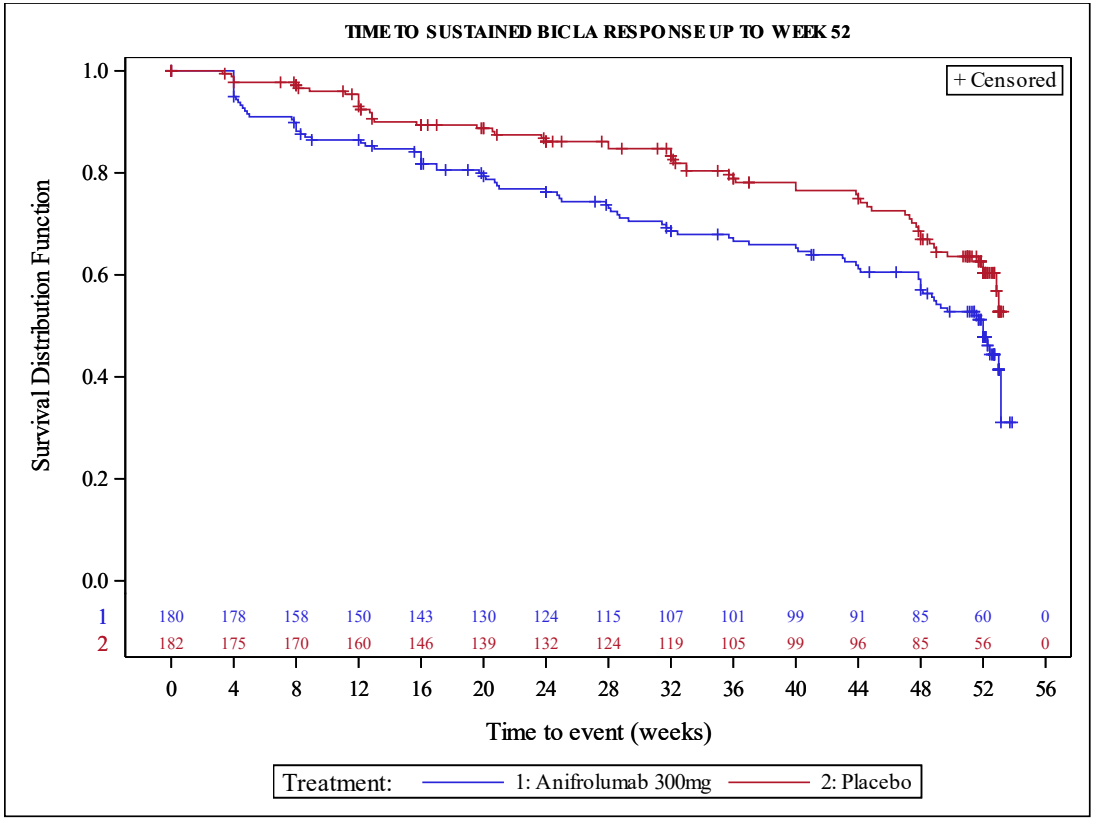
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model. Adjusted analysis also includes stratification factors in the model.
Two-sided log rank test used.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Time to sustained BICLA response up to week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Anifrolumab 300mg (N=180) Median (95% CI)	Placebo (N=182) n/ N (%)	Placebo (N=182) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening							0.6566
< 10 points	28/ 54 (51.9)	49.71 (44.14, NE)	19/ 52 (36.5)	NE (44.00, NE)	1.34 (0.74, 2.40)	0.2616	
>= 10 points	58/126 (46.0)	52.29 (44.00, NE)	38/130 (29.2)	NE (52.86, NE)	1.64 (1.09, 2.48)	0.0328	
OCS dose at baseline							0.2395
<10 mg/day	46/ 93 (49.5)	48.14 (43.86, NE)	29/ 99 (29.3)	NE (53.00, NE)	1.82 (1.14, 2.91)	0.0117	
>=10 mg/day	40/ 87 (46.0)	52.00 (49.00, NE)	28/ 83 (33.7)	52.86 (48.57, NE)	1.23 (0.76, 1.99)	0.4064	
Result of type I IFN gene signature test							0.3029
LOW	14/ 30 (46.7)	52.43 (29.29, NE)	11/ 31 (35.5)	NE (36.00, NE)	1.06 (0.48, 2.37)	0.8725	
HIGH	72/150 (48.0)	51.71 (47.86, 53.14)	46/151 (30.5)	NE (52.86, NE)	1.66 (1.14, 2.41)	0.0108	
Age (years)							0.9789
<= 65	84/175 (48.0)	52.00 (48.00, 53.14)	57/181 (31.5)	NE (52.86, NE)	1.54 (1.10, 2.15)	0.0180	
> 65	2/ 5 (40.0)	NE (8.29, NE)	0/ 1 (0.0)	NE (NE, NE)	NE		
Sex							0.3870
male	6/ 12 (50.0)	51.71 (5.00, NE)	6/ 12 (50.0)	NE (12.86, NE)	0.83 (0.24, 2.94)	0.8315	
female	80/168 (47.6)	52.00 (47.86, NE)	51/170 (30.0)	NE (52.86, NE)	1.62 (1.14, 2.31)	0.0107	
Race							0.0085
White	49/110 (44.5)	52.43 (48.86, NE)	36/107 (33.6)	53.00 (49.00, NE)	1.15 (0.74, 1.77)	0.7374	
Black or African American	9/ 17 (52.9)	44.14 (17.00, NE)	9/ 25 (36.0)	52.86 (44.86, NE)	2.34 (0.91, 6.02)	0.1314	
Asian	15/ 30 (50.0)	52.00 (27.86, NE)	6/ 30 (20.0)	NE (51.71, NE)	2.76 (1.03, 7.40)	0.0715	
American Indian or Alaska Native	3/ 4 (75.0)	24.71 (4.00, 28.57)	1/ 1 (100.0)	3.86 (NE, NE)	0.00 (0.00,)	0.0455	
Other	5/ 11 (45.5)	NE (4.43, NE)	2/ 11 (18.2)	NE (12.86, NE)	4.46 (0.71, 27.95)	0.7863	
Ethnicity							0.8855
Hispanic/Latino	30/ 54 (55.6)	47.86 (21.00, NE)	22/ 54 (40.7)	48.00 (43.86, NE)	1.49 (0.86, 2.61)	0.2524	
Non-hispanic/Latino	51/118 (43.2)	52.43 (49.29, NE)	32/120 (26.7)	NE (52.86, NE)	1.55 (1.00, 2.43)	0.0933	
Geographic region							0.0553
EU	23/ 51 (45.1)	52.29 (43.14, NE)	19/ 46 (41.3)	52.00 (36.14, NE)	0.89 (0.48, 1.64)	0.4100	
non-EU	63/129 (48.8)	49.71 (44.14, NE)	38/136 (27.9)	NE (52.86, NE)	1.93 (1.28, 2.89)	0.0018	
Onset of disease							0.4634
Paediatric	5/ 14 (35.7)	NE (27.86, NE)	2/ 12 (16.7)	NE (44.86, NE)	3.44 (0.60, 19.86)	0.2158	
Adult	81/166 (48.8)	52.00 (47.86, 53.14)	55/170 (32.4)	53.00 (52.00, NE)	1.50 (1.06, 2.11)	0.0318	
ADA result							0.6537
Negative	83/172 (48.3)	52.00 (48.00, 53.14)	54/162 (33.3)	NE (52.00, NE)	1.48 (1.05, 2.09)	0.0460	
Positive (At any time)	3/ 8 (37.5)	NE (17.00, NE)	3/ 20 (15.0)	NE (53.00, NE)	3.08 (0.48, 19.90)	0.1302	
BMI (kg/m2) at enrolment							0.4719
< 30	60/125 (48.0)	52.00 (47.86, NE)	44/134 (32.8)	NE (52.00, NE)	1.42 (0.96, 2.10)	0.1043	
>= 30	26/ 55 (47.3)	49.29 (36.00, NE)	13/ 48 (27.1)	NE (52.86, NE)	1.98 (1.00, 3.92)	0.1711	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group							0.1786
All negative/normal	26/ 58 (44.8)	52.00 (48.00, NE)	29/ 81 (35.8)	NE (47.86, NE)	1.17 (0.68, 2.01)	0.7030	
At least one positive/abnormal	60/122 (49.2)	52.00 (43.00, 53.14)	28/101 (27.7)	NE (52.00, NE)	1.87 (1.19, 2.93)	0.0057	

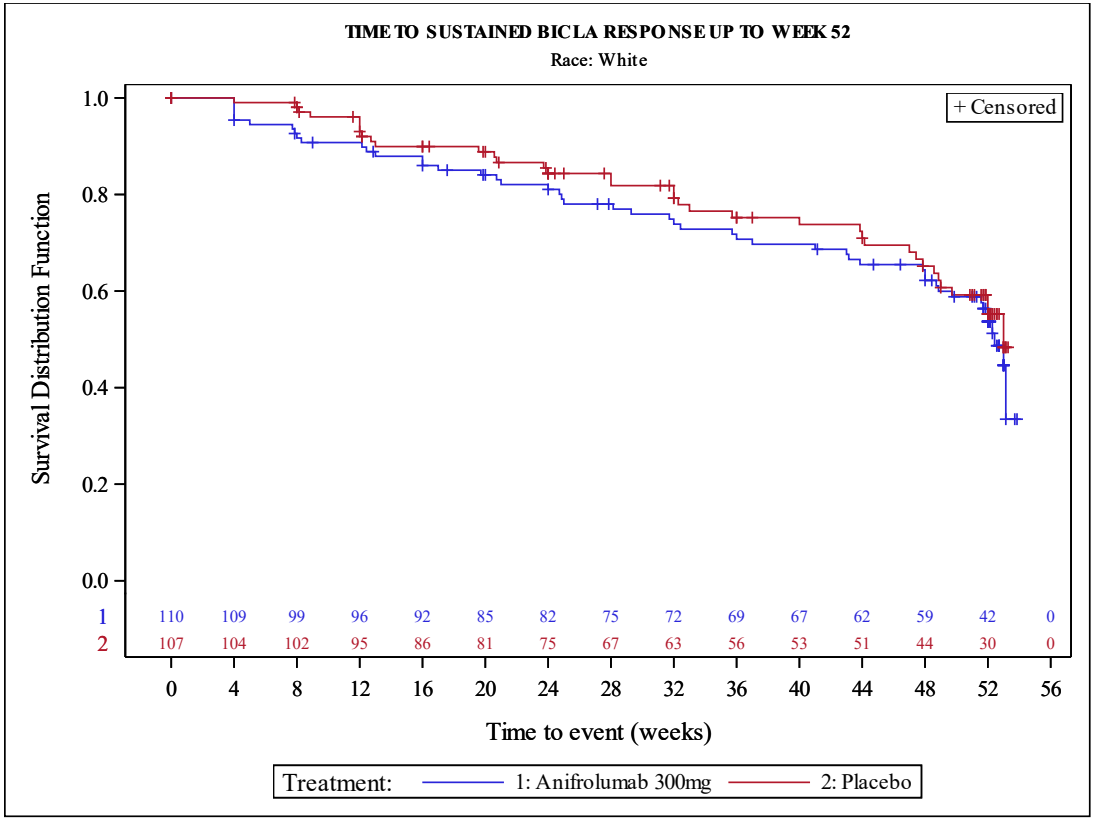
Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Time to sustained BICLA response up to week 52
Full analysis set



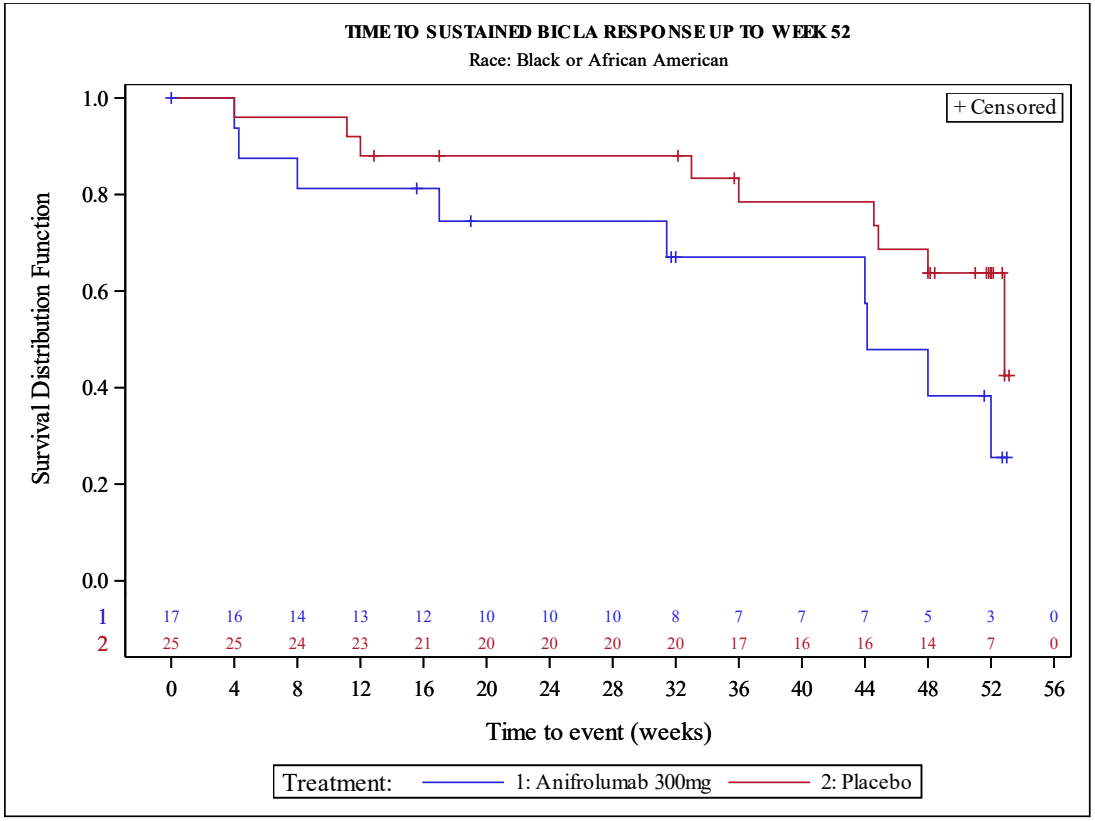
Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Time to sustained BICLA response up to week 52
Full analysis set



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Time to sustained BICLA response up to week 52
Full analysis set



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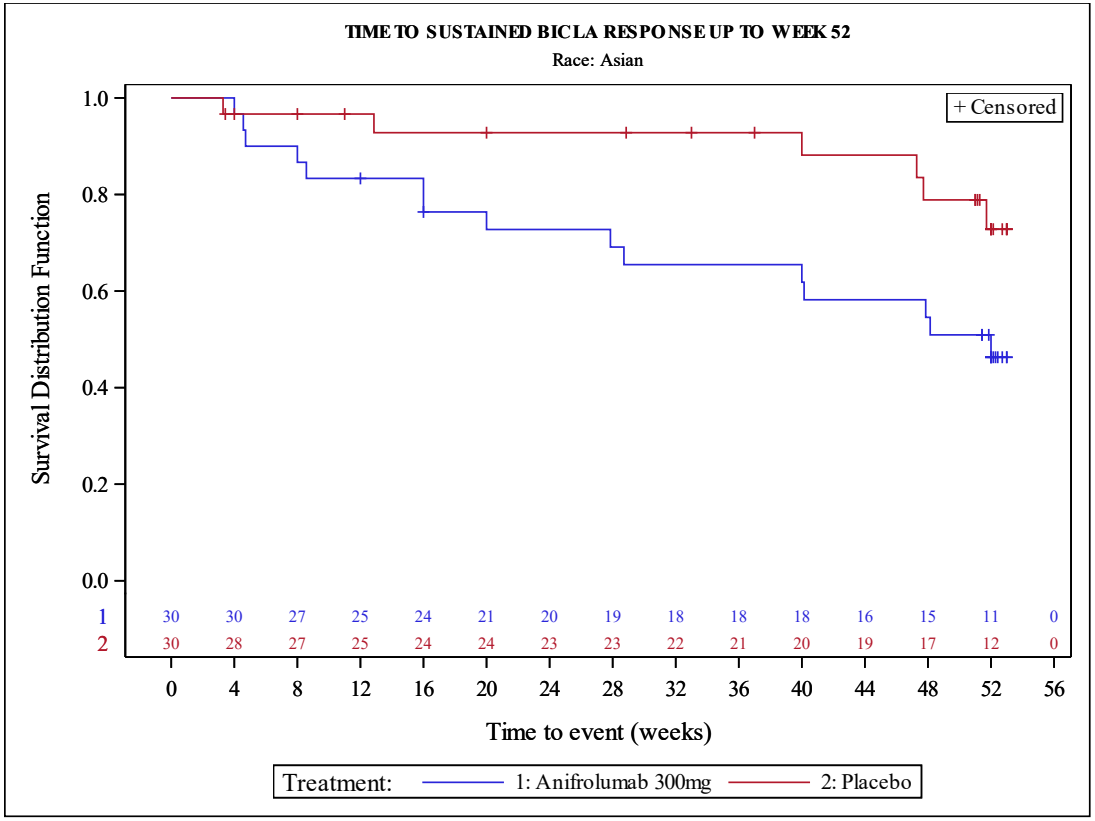
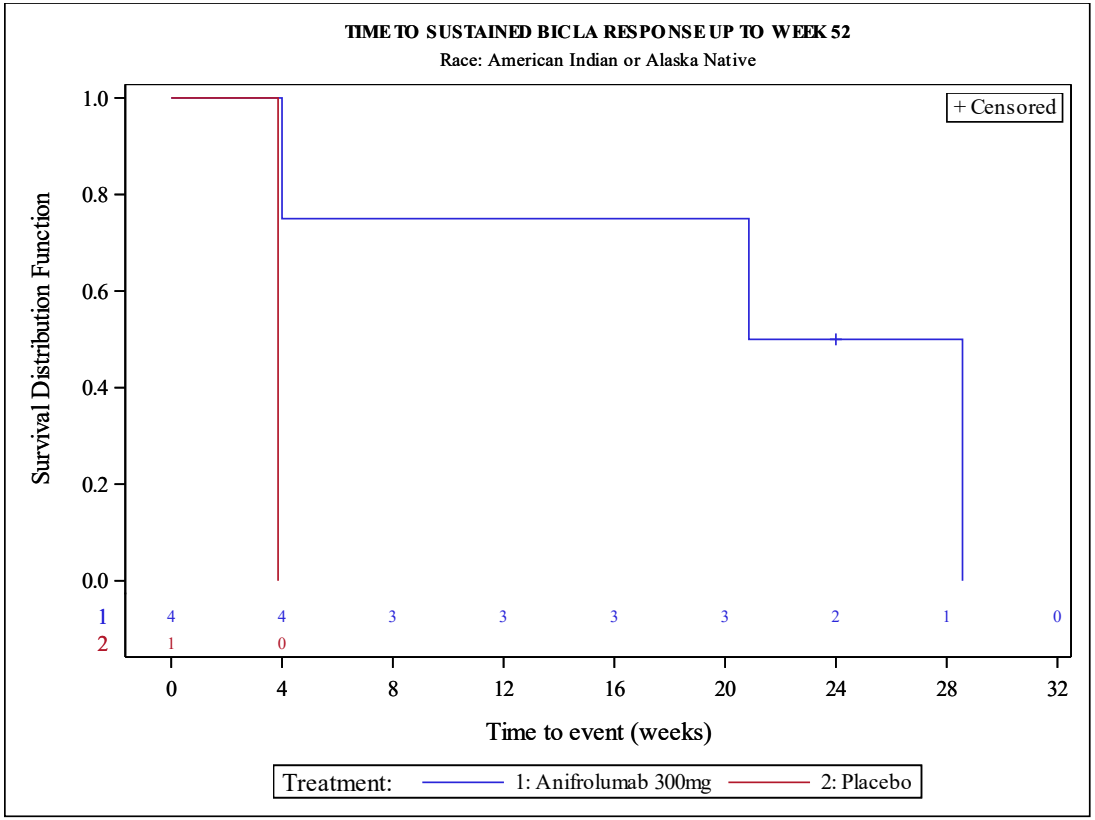
Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Time to sustained BICLA response up to week 52
Full analysis set



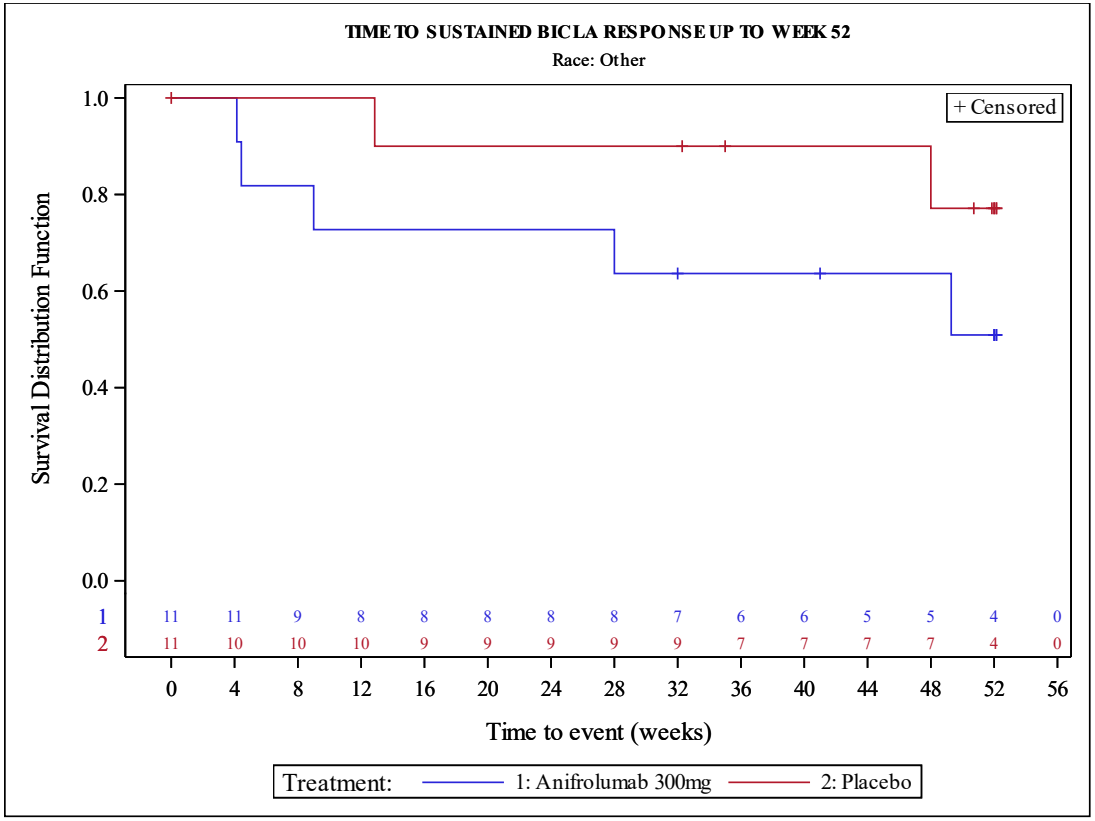
Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Time to sustained BICLA response up to week 52
Full analysis set



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Time to sustained BICLA response up to week 52
Full analysis set



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Time to OCS Reduction <=7.5 mg/day (for subjects with baseline OCS >=10 mg/day)
Full analysis set

	Anifrolumab 300mg (N=87)	Placebo (N=83)
Number of subjects with events, n (%)	58 (66.7)	44 (53.0)
Number of censored subjects, n (%)	29 (33.3)	39 (47.0)
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	14.14 (9.43, 16.71)	16.29 (10.86, 20.29)
Median (95% CI)	24.14 (20.00, 28.29)	28.29 (21.14, 40.14)
75%-ile (95% CI)	NE (33.29, NE)	NE (44.00, NE)
Analysis Anifrolumab 300mg vs. Placebo (adjusted)		
Hazard Ratio (95% CI)	1.27 (0.86, 1.88)	
p-value	0.1868	
Analysis Anifrolumab 300mg vs. Placebo (unadjusted)		
Hazard Ratio (95% CI)	1.26 (0.85, 1.86)	
p-value	0.2457	

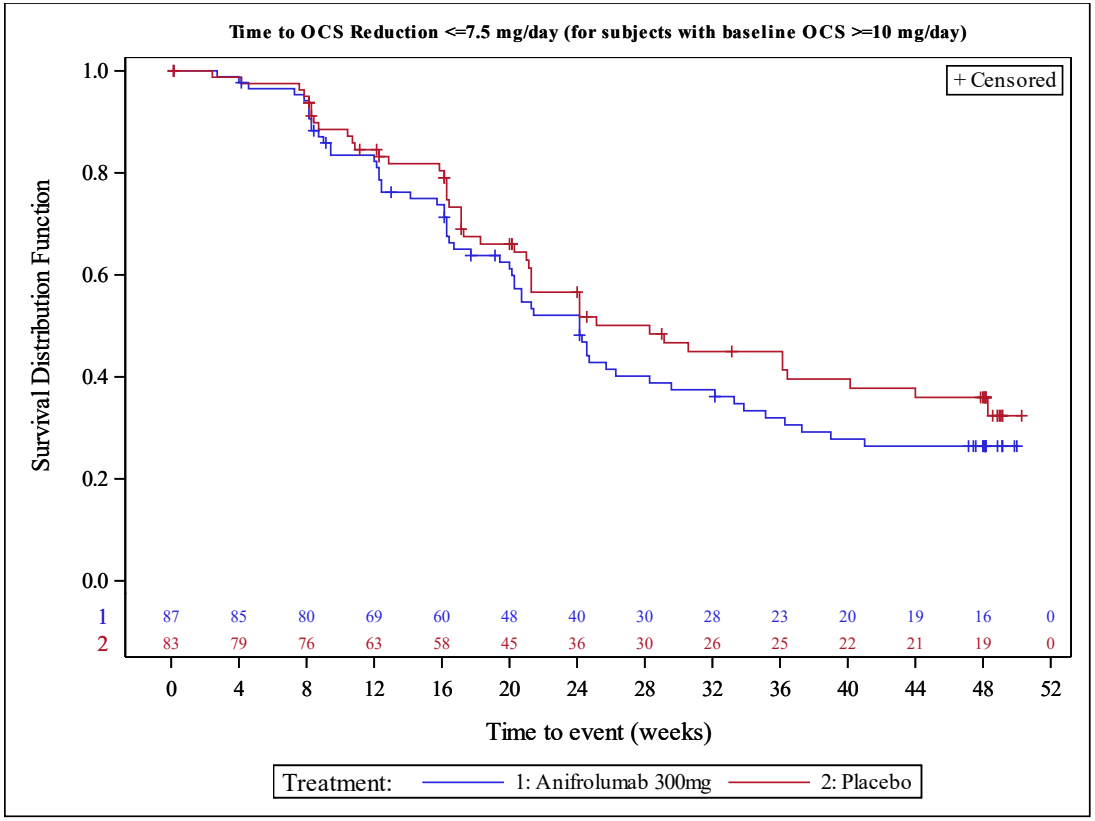
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model. Adjusted analysis also includes stratification factors in the model.
Two-sided log rank test used.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Time to OCS Reduction <=7.5 mg/day (for subjects with baseline OCS >=10 mg/day) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=87) n/ N (%)	Anifrolumab 300mg (N=87) Median (95% CI)	Placebo (N=83) n/ N (%)	Placebo (N=83) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening							0.3377
< 10 points	17/ 23 (73.9)	20.71 (16.14, 24.57)	12/ 21 (57.1)	36.14 (17.14, NE)	1.78 (0.84, 3.75)	0.1643	
>= 10 points	41/ 64 (64.1)	24.57 (20.14, 35.14)	32/ 62 (51.6)	24.14 (18.29, 48.29)	1.13 (0.71, 1.79)	0.4943	
OCS dose at baseline							NE
>=10 mg/day	58/ 87 (66.7)	24.14 (20.00, 28.29)	44/ 83 (53.0)	28.29 (21.14, 40.14)	1.27 (0.86, 1.88)	0.1868	
Result of type I IFN gene signature test							0.5243
LOW	5/ 9 (55.6)	24.14 (14.14, NE)	6/ 10 (60.0)	19.21 (16.29, NE)	1.07 (0.31, 3.72)	0.9036	
HIGH	53/ 78 (67.9)	24.14 (20.00, 28.29)	38/ 73 (52.1)	28.29 (21.14, 44.00)	1.33 (0.87, 2.02)	0.1778	
Age (years)							NE
<= 65	58/ 86 (67.4)	24.14 (20.00, 28.29)	44/ 83 (53.0)	28.29 (21.14, 40.14)	1.28 (0.86, 1.90)	0.1745	
> 65	0/ 1 (0.0)	NE (NE, NE)	0	NE (NE, NE)	NE		
Sex							0.3029
male	5/ 7 (71.4)	20.71 (8.14, NE)	2/ 5 (40.0)	NE (16.14, NE)	3.41 (0.63, 18.60)	0.2494	
female	53/ 80 (66.3)	24.14 (20.00, 28.29)	42/ 78 (53.8)	24.14 (21.00, 40.14)	1.20 (0.80, 1.80)	0.3219	
Race							0.6294
White	36/ 51 (70.6)	20.71 (16.29, 28.29)	27/ 54 (50.0)	25.14 (17.14, NE)	1.43 (0.87, 2.36)	0.1343	
Black or African American	2/ 7 (28.6)	NE (16.29, NE)	6/ 10 (60.0)	36.14 (8.29, NE)	0.55 (0.11, 2.71)	0.4514	
Asian	11/ 17 (64.7)	24.57 (15.71, NE)	5/ 11 (45.5)	36.43 (8.71, NE)	1.25 (0.42, 3.78)	0.7481	
Other	6/ 8 (75.0)	20.29 (8.14, NE)	4/ 5 (80.0)	20.29 (7.57, NE)	0.60 (0.13, 2.70)	0.3891	
Ethnicity							0.5492
Hispanic/Latino	21/ 28 (75.0)	20.00 (12.43, 24.14)	18/ 27 (66.7)	17.29 (15.86, 28.29)	1.08 (0.56, 2.07)	0.6133	
Non-hispanic/Latino	34/ 55 (61.8)	24.57 (20.71, 33.86)	24/ 53 (45.3)	36.14 (21.29, NE)	1.36 (0.80, 2.29)	0.2080	
Geographic region							0.9606
EU	20/ 29 (69.0)	24.57 (19.43, 28.29)	15/ 28 (53.6)	30.57 (16.29, NE)	1.23 (0.62, 2.45)	0.4821	
non-EU	38/ 58 (65.5)	21.29 (16.43, 36.29)	29/ 55 (52.7)	25.14 (21.00, 40.14)	1.27 (0.78, 2.07)	0.3960	
Onset of disease							0.6591
Paediatric	9/ 12 (75.0)	21.29 (9.43, 33.86)	5/ 8 (62.5)	25.14 (12.86, NE)	1.54 (0.48, 4.93)	0.4862	
Adult	49/ 75 (65.3)	24.14 (19.43, 32.14)	39/ 75 (52.0)	28.29 (20.29, 44.00)	1.22 (0.80, 1.87)	0.3052	
ADA result							0.1505
Negative	55/ 80 (68.8)	24.14 (19.43, 25.71)	36/ 69 (52.2)	29.14 (21.00, 48.29)	1.39 (0.91, 2.13)	0.0932	
Positive (At any time)	3/ 7 (42.9)	41.00 (9.43, NE)	8/ 14 (57.1)	24.14 (17.29, 36.14)	0.24 (0.05, 1.21)	0.1515	
BMI (kg/m2) at enrolment							0.1922
< 30	42/ 62 (67.7)	24.29 (20.29, 32.14)	30/ 65 (46.2)	36.14 (21.29, NE)	1.46 (0.91, 2.34)	0.1015	
>= 30	16/ 25 (64.0)	17.71 (9.43, 37.29)	14/ 18 (77.8)	21.29 (12.29, 25.14)	0.83 (0.39, 1.76)	0.6675	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group							0.0011
All negative/normal	20/ 24 (83.3)	16.43 (9.00, 20.71)	14/ 30 (46.7)	40.14 (21.29, NE)	3.35 (1.65, 6.81)	0.0007	
At least one positive/abnormal	38/ 63 (60.3)	26.29 (21.29, 36.29)	30/ 53 (56.6)	21.29 (17.14, 30.57)	0.82 (0.51, 1.34)	0.4828	

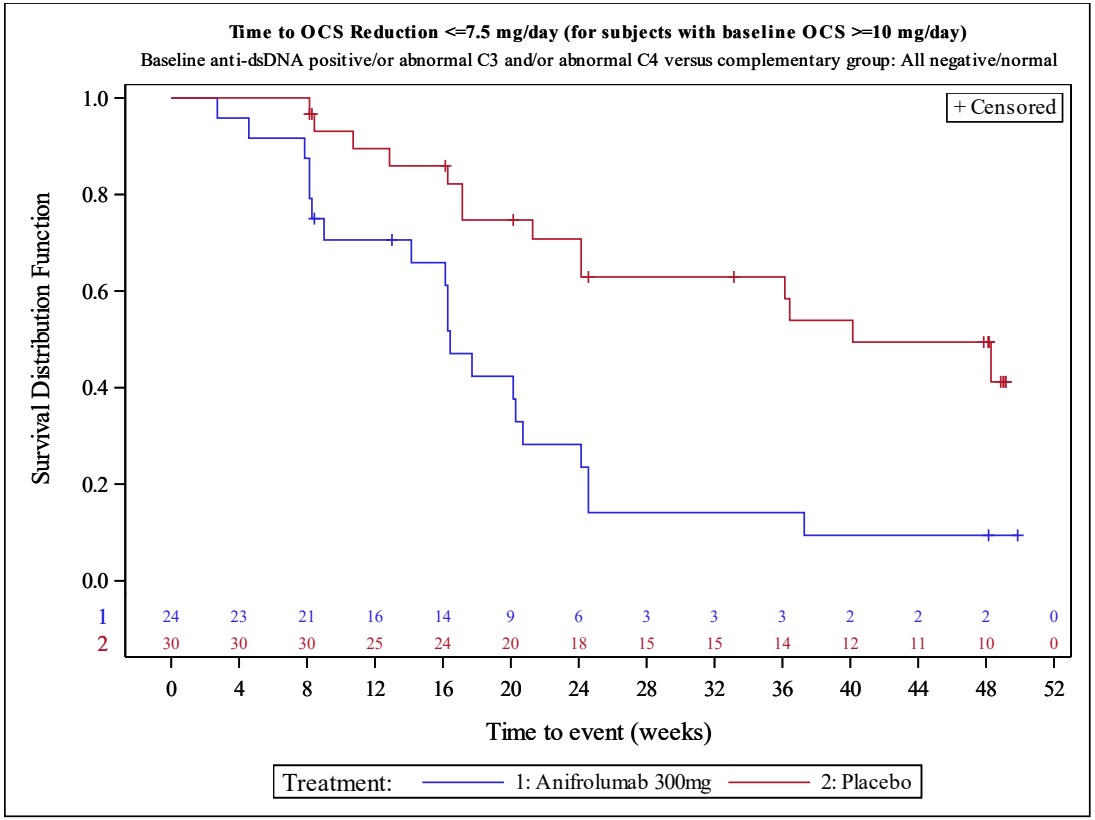
Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Time to OCS Reduction <=7.5 mg/day (for subjects with baseline OCS >=10 mg/day)
Full analysis set



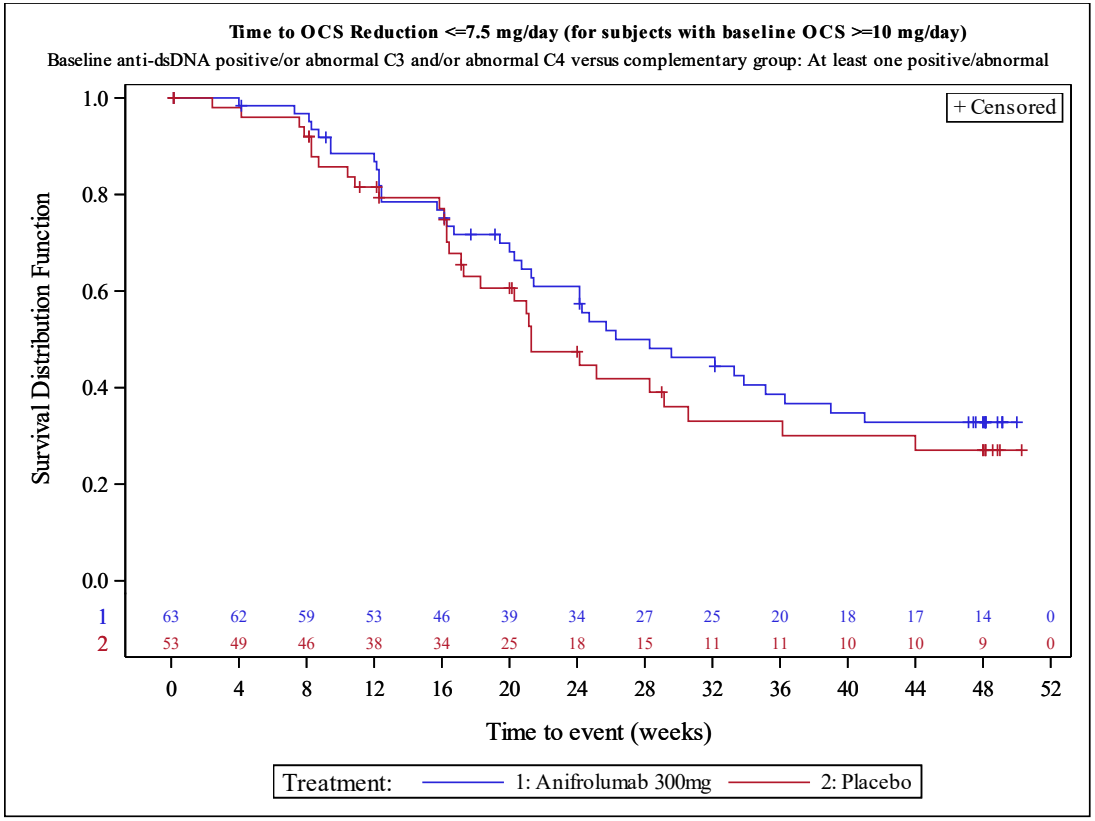
Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Time to OCS Reduction <=7.5 mg/day (for subjects with baseline OCS >=10 mg/day)
Full analysis set



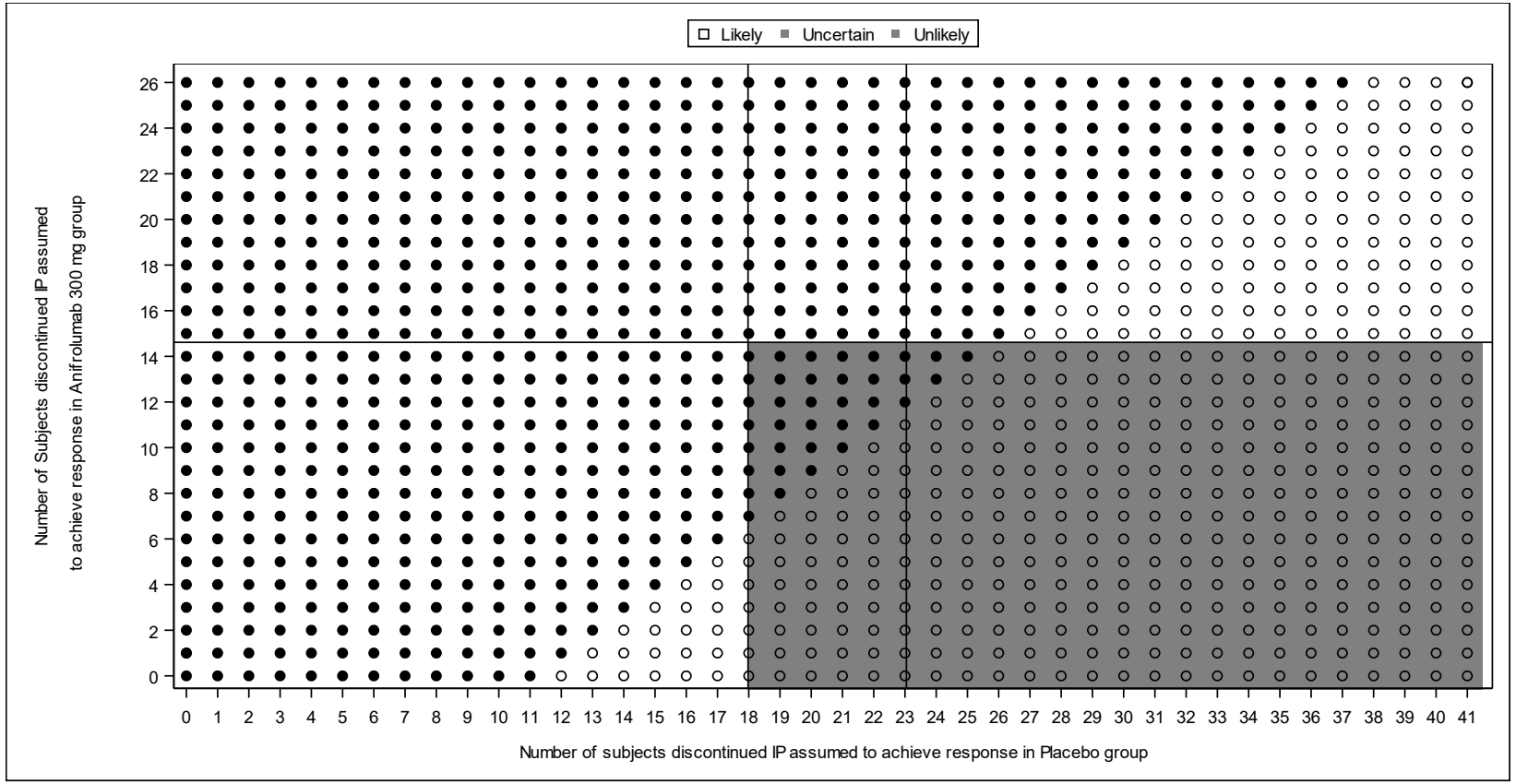
Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Time to OCS Reduction <=7.5 mg/day (for subjects with baseline OCS >=10 mg/day)
Full analysis set



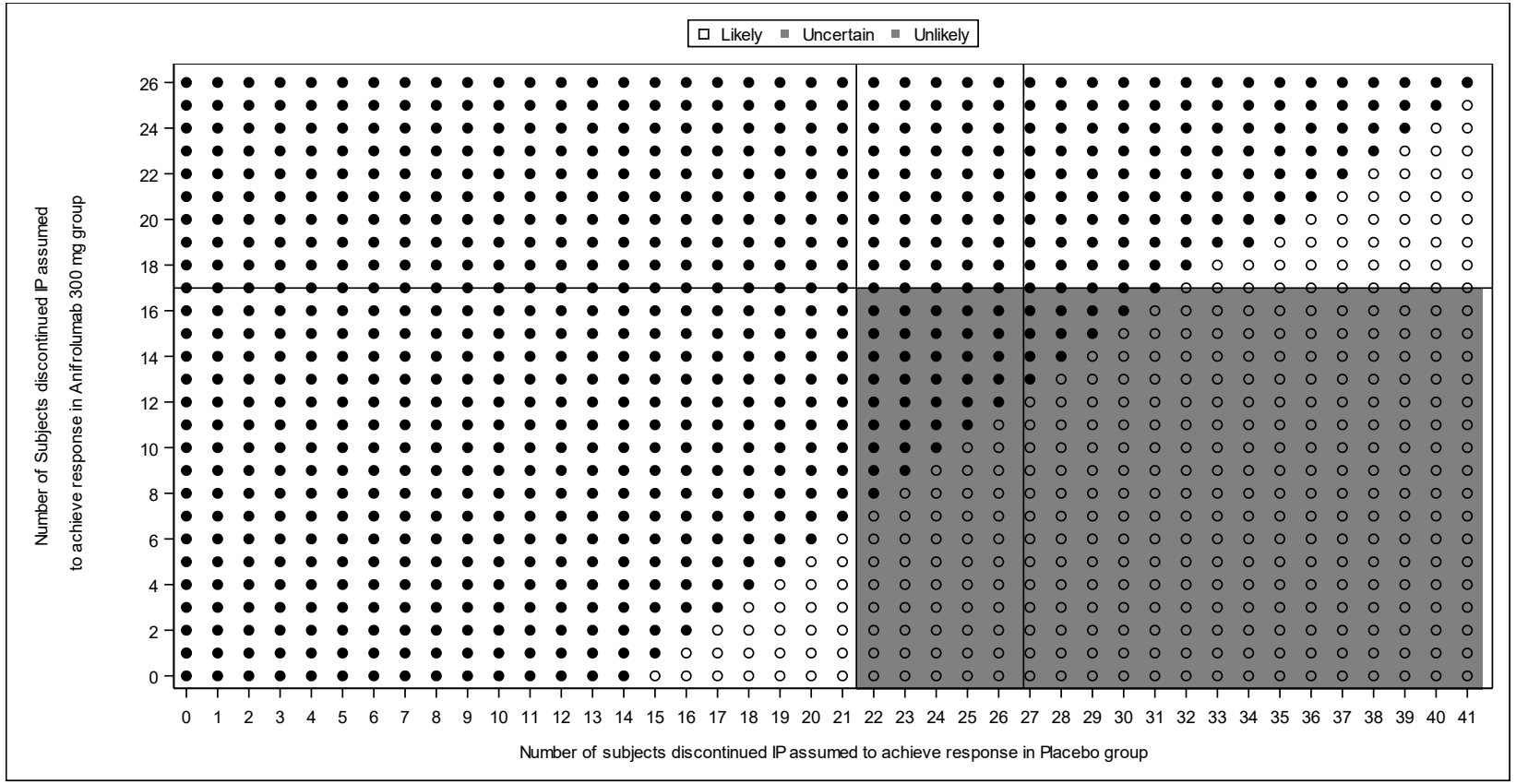
Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Plot of BICLA response rate sensitivity analysis at week 52, tipping point analysis
Full analysis set



Subjects with permanent discontinuation of IP are taken as non-responders at the bottom left grid. A certain number of such subjects from both groups are altered to be responders, while the numbers for both groups are as stated in both axes.
For each scenario, Pearson`s chi-squared test is used to compare the proportion of subjects achieving response at Week 52. The dots are presenting the results: filled = p-value <0.05, open = p-value >=0.05.
The three colors area indicate the tipping point area: white=likely, bright grey=uncertain, darker grey=Unlikely.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Plot of SRI (4) response rate sensitivity analysis at week 52, tipping point analysis
Full analysis set



Subjects with permanent discontinuation of IP are taken as non-responders at the bottom left grid. A certain number of such subjects from both groups are altered to be responders, while the numbers for both groups are as stated in both axes.
For each scenario, Pearson`s chi-squared test is used to compare the proportion of subjects achieving response at Week 52. The dots are presenting the results: filled = p-value <0.05, open = p-value >=0.05.
The three colors area indicate the tipping point area: white=likely, bright grey=uncertain, darker grey=Unlikely.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
OCS dose increases and cumulative OCS dose until week 52
Full analysis set

		Anifrolumab 300mg (N=180)	Placebo (N=182)	Total (N=362)
Number of dose increases (%)	0	135 (75.0)	116 (63.7)	251 (69.3)
	1	28 (15.6)	35 (19.2)	63 (17.4)
	2	14 (7.8)	16 (8.8)	30 (8.3)
	>2	3 (1.7)	15 (8.2)	18 (5.0)
Cumulative OCS Dose (mg/day)	n (missing)	180 (0)	182 (0)	362 (0)
	Mean (SD)	2180.0 (1704.38)	2423.2 (1820.07)	2302.3 (1765.26)
	Median	2010.5	2281.3	2180.0
	Min, Max	0, 9075	0, 9188	0, 9188
AUC up to Week 52 (mg/day)	n (missing)	180 (0)	182 (0)	362 (0)
	Mean (SD)	2364.8 (2005.10)	2787.1 (2175.20)	2577.1 (2100.13)
	Median	2257.7	2467.4	2336.7
	Min, Max	0, 13265	0, 10920	0, 13265

Subjects without any documented dose value regarded as missing values for calculation of cumulative dose and AUC.
AUC defines the cumulative dose normalized for a period of 52 weeks.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	162 (90.0)	154 (84.6)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.06 (0.98, 1.15)	
p-value	0.1249	
Odds Ratio (95% CI)	1.64 (0.87, 3.08)	
p-value	0.1266	
Risk Difference (95% CI)	5.38 (-1.45, 12.22)	
p-value	0.1224	
CMH approach		
Response rate	89.9	84.5
Difference in response rates (95% CI)	5.42 (-2.18, 13.03)	
p-value	0.1622	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.6410
< 10 points	51/ 54 (94.4)	94.4	45/ 52 (86.5)	86.5	1.09 (0.96, 1.24)	0.1711	7.88 (-6.28, 22.05)	0.2752	
>= 10 points	111/126 (88.1)	88.0	109/130 (83.8)	83.6	1.05 (0.95, 1.16)	0.3280	4.36 (-4.77, 13.50)	0.3490	
OCS dose at baseline									0.2088
<10 mg/day	84/ 93 (90.3)	90.3	88/ 99 (88.9)	88.8	1.02 (0.92, 1.12)	0.7447	1.53 (-8.64, 11.71)	0.7675	
>=10 mg/day	78/ 87 (89.7)	89.5	66/ 83 (79.5)	79.6	1.13 (0.99, 1.28)	0.0714	9.94 (-1.77, 21.64)	0.0961	
Result of type I IFN gene signature test									0.7890
LOW	25/ 30 (83.3)	83.3	25/ 31 (80.6)	80.6	1.03 (0.82, 1.31)	0.7847	2.69 (-18.00, 23.37)	0.7989	
HIGH	137/150 (91.3)	91.2	129/151 (85.4)	85.3	1.07 (0.98, 1.16)	0.1115	5.98 (-2.15, 14.11)	0.1494	
Age (years)									0.2034
<= 65	158/175 (90.3)	90.1	153/181 (84.5)	84.4	1.07 (0.99, 1.16)	0.1024	5.70 (-1.96, 13.36)	0.1448	
> 65	4/ 5 (80.0)	80.0	1/ 1 (100.0)	100.0	0.80 (0.52, 1.24)	0.3183	-20.00 (-124.53, 84.53)	0.7077	
Sex									0.4075
male	9/ 12 (75.0)	75.0	10/ 12 (83.3)	83.3	0.90 (0.60, 1.36)	0.6172	-8.33 (-44.22, 27.56)	0.6490	
female	153/168 (91.1)	91.0	144/170 (84.7)	84.6	1.08 (0.99, 1.16)	0.0741	6.39 (-1.42, 14.20)	0.1086	
Race									0.1640
White	96/110 (87.3)	86.9	85/107 (79.4)	79.7	1.10 (0.97, 1.24)	0.1243	7.21 (-3.38, 17.80)	0.1821	
Black or African American	14/ 17 (82.4)	82.4	19/ 25 (76.0)	76.0	1.08 (0.79, 1.48)	0.6133	6.35 (-20.42, 33.13)	0.6419	
Asian	29/ 30 (96.7)	96.7	30/ 30 (100.0)	100.0	0.97 (0.90, 1.03)	0.3173	-3.33 (-16.52, 9.85)	0.6203	
American Indian or Alaska Native	4/ 4 (100.0)	100.0	1/ 1 (100.0)	100.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	11/ 11 (100.0)	100.0	11/ 11 (100.0)	100.0	NE		0.00 (-28.41, 28.41)	1.0000	
Ethnicity									0.3147
Hispanic/Latino	50/ 54 (92.6)	92.3	44/ 54 (81.5)	81.4	1.14 (0.98, 1.32)	0.0901	10.97 (-3.91, 25.85)	0.1486	
Non-hispanic/Latino	104/118 (88.1)	88.0	102/120 (85.0)	84.9	1.04 (0.94, 1.15)	0.4784	3.14 (-6.74, 13.01)	0.5337	
Geographic region									0.8270
EU	43/ 51 (84.3)	84.3	37/ 46 (80.4)	80.4	1.05 (0.87, 1.26)	0.6183	3.88 (-12.10, 19.86)	0.6342	
non-EU	119/129 (92.2)	92.0	117/136 (86.0)	86.0	1.07 (0.99, 1.17)	0.1042	6.03 (-2.78, 14.85)	0.1796	
Onset of disease									0.0883
Paediatric	13/ 14 (92.9)	92.9	12/ 12 (100.0)	100.0	0.93 (0.80, 1.07)	0.3174	-7.14 (-34.18, 19.90)	0.6047	
Adult	149/166 (89.8)	89.6	142/170 (83.5)	83.5	1.07 (0.99, 1.17)	0.0942	6.16 (-1.86, 14.19)	0.1323	
ADA result									0.6343
Negative	154/172 (89.5)	89.5	136/162 (84.0)	83.7	1.07 (0.98, 1.16)	0.1353	5.80 (-2.26, 13.86)	0.1586	
Positive (At any time)	8/ 8 (100.0)	100.0	18/ 20 (90.0)	90.0	1.11 (0.96, 1.29)	0.1575	10.00 (-20.56, 40.56)	0.5212	
BMI (kg/m2) at enrolment									0.8046
< 30	114/125 (91.2)	91.5	114/134 (85.1)	84.8	1.07 (0.98, 1.17)	0.1275	6.68 (-2.30, 15.67)	0.1449	
>= 30	48/ 55 (87.3)	87.6	40/ 48 (83.3)	82.9	1.05 (0.89, 1.23)	0.5759	4.67 (-11.29, 20.62)	0.5666	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.6779
All negative/normal	52/ 58 (89.7)	89.6	67/ 81 (82.7)	82.8	1.08 (0.95, 1.24)	0.2334	6.83 (-6.41, 20.06)	0.3119	
At least one positive/abnormal	110/122 (90.2)	90.4	87/101 (86.1)	85.8	1.05 (0.95, 1.15)	0.3598	4.55 (-4.78, 13.89)	0.3389	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Serious Adverse Event
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	16 (8.9)	34 (18.7)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.48 (0.27, 0.83)	
p-value	0.0090	
Odds Ratio (95% CI)	0.42 (0.23, 0.80)	
p-value	0.0081	
Risk Difference (95% CI)	-9.79 (-16.82, -2.77)	
p-value	0.0063	
CMH approach		
Response rate	8.8	18.6
Difference in response rates (95% CI)	-9.81 (-17.48, -2.14)	
p-value	0.0122	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Serious Adverse Event - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									1.0000
< 10 points	2/ 54 (3.7)	3.7	4/ 52 (7.7)	7.7	0.48 (0.09, 2.52)	0.3865	-4.06 (-17.23, 9.11)	0.5459	
>= 10 points	14/126 (11.1)	10.9	30/130 (23.1)	23.1	0.48 (0.27, 0.86)	0.0144	-12.17 (-21.80, -2.54)	0.0132	
OCS dose at baseline									0.2606
<10 mg/day	5/ 93 (5.4)	5.5	17/ 99 (17.2)	16.8	0.31 (0.12, 0.81)	0.0173	-11.34 (-21.73, -0.95)	0.0324	
>=10 mg/day	11/ 87 (12.6)	12.6	17/ 83 (20.5)	20.6	0.62 (0.31, 1.24)	0.1745	-8.00 (-20.15, 4.14)	0.1966	
Result of type I IFN gene signature test									0.5664
LOW	1/ 30 (3.3)	3.3	1/ 31 (3.2)	3.2	1.03 (0.07, 15.78)	0.9812	0.11 (-14.04, 14.25)	0.9881	
HIGH	15/150 (10.0)	9.9	33/151 (21.9)	21.7	0.46 (0.26, 0.81)	0.0069	-11.82 (-20.59, -3.05)	0.0082	
Age (years)									0.5869
<= 65	15/175 (8.6)	8.4	34/181 (18.8)	18.8	0.46 (0.26, 0.81)	0.0071	-10.31 (-18.02, -2.60)	0.0087	
> 65	1/ 5 (20.0)	20.0	0/ 1 (0.0)	0.0	1.00 (0.06, 15.99)	1.0000	20.00 (-84.53, 124.53)	0.7077	
Sex									0.1384
male	3/ 12 (25.0)	25.0	2/ 12 (16.7)	16.7	1.50 (0.30, 7.43)	0.6195	8.33 (-27.56, 44.22)	0.6490	
female	13/168 (7.7)	7.6	32/170 (18.8)	18.9	0.41 (0.22, 0.76)	0.0042	-11.27 (-19.16, -3.37)	0.0051	
Race									0.8186
White	10/110 (9.1)	9.1	19/107 (17.8)	17.7	0.51 (0.25, 1.05)	0.0676	-8.64 (-18.62, 1.35)	0.0900	
Black or African American	1/ 17 (5.9)	5.9	5/ 25 (20.0)	20.0	0.29 (0.04, 2.30)	0.2435	-14.12 (-37.74, 9.51)	0.2415	
Asian	3/ 30 (10.0)	10.0	6/ 30 (20.0)	20.0	0.50 (0.14, 1.82)	0.2924	-10.00 (-29.77, 9.77)	0.3216	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	3/ 11 (27.3)	27.3	0.14 (0.01, 2.48)	0.1813	-27.27 (-61.62, 7.07)	0.1196	
Ethnicity									0.1716
Hispanic/Latino	2/ 54 (3.7)	3.9	11/ 54 (20.4)	21.4	0.18 (0.04, 0.78)	0.0220	-17.50 (-32.21, -2.78)	0.0198	
Non-hispanic/Latino	12/118 (10.2)	10.3	22/120 (18.3)	17.9	0.55 (0.29, 1.07)	0.0782	-7.65 (-17.56, 2.25)	0.1297	
Geographic region									0.4025
EU	6/ 51 (11.8)	11.8	8/ 46 (17.4)	17.4	0.68 (0.25, 1.80)	0.4347	-5.63 (-20.70, 9.45)	0.4644	
non-EU	10/129 (7.8)	7.7	26/136 (19.1)	19.3	0.41 (0.20, 0.81)	0.0102	-11.58 (-20.73, -2.43)	0.0131	
Onset of disease									0.0505
Paediatric	5/ 14 (35.7)	35.7	3/ 12 (25.0)	25.0	1.43 (0.43, 4.77)	0.5621	10.71 (-25.89, 47.32)	0.5662	
Adult	11/166 (6.6)	6.5	31/170 (18.2)	18.3	0.36 (0.19, 0.70)	0.0024	-11.80 (-19.56, -4.04)	0.0029	
ADA result									0.4466
Negative	16/172 (9.3)	9.2	28/162 (17.3)	17.1	0.54 (0.30, 0.96)	0.0349	-7.92 (-15.90, 0.07)	0.0520	
Positive (At any time)	0/ 8 (0.0)	0.0	6/ 20 (30.0)	30.0	0.18 (0.01, 2.86)	0.2240	-30.00 (-63.07, 3.07)	0.0754	
BMI (kg/m2) at enrolment									0.8501
< 30	10/125 (8.0)	8.1	22/134 (16.4)	16.2	0.49 (0.24, 0.99)	0.0461	-8.13 (-17.23, 0.97)	0.0800	
>= 30	6/ 55 (10.9)	11.4	12/ 48 (25.0)	26.0	0.44 (0.18, 1.07)	0.0710	-14.61 (-31.30, 2.07)	0.0861	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.0518
All negative/normal	7/ 58 (12.1)	12.6	10/ 81 (12.3)	11.9	0.98 (0.40, 2.42)	0.9609	0.74 (-12.18, 13.66)	0.9108	
At least one positive/abnormal	9/122 (7.4)	7.6	24/101 (23.8)	23.3	0.31 (0.15, 0.64)	0.0014	-15.74 (-25.99, -5.50)	0.0026	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Severe Adverse Event
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	6 (3.3)	15 (8.2)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.40 (0.16, 1.02)	
p-value	0.0549	
Odds Ratio (95% CI)	0.38 (0.15, 1.01)	
p-value	0.0531	
Risk Difference (95% CI)	-4.91 (-9.69, -0.13)	
p-value	0.0441	
CMH approach		
Response rate	3.3	8.3
Difference in response rates (95% CI)	-5.06 (-11.21, 1.10)	
p-value	0.1072	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Severe Adverse Event - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Anifrolumab 300mg (N=180) Response rate	Placebo (N=182) n/ N (%)	Placebo (N=182) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8065
< 10 points	2/ 54 (3.7)	3.7	4/ 52 (7.7)	7.7	0.48 (0.09, 2.52)	0.3865	-4.01 (-17.10, 9.08)	0.5482	
>= 10 points	4/126 (3.2)	3.1	11/130 (8.5)	8.6	0.38 (0.12, 1.15)	0.0856	-5.49 (-12.61, 1.64)	0.1312	
OCS dose at baseline									0.2521
<10 mg/day	1/ 93 (1.1)	1.1	7/ 99 (7.1)	7.1	0.15 (0.02, 1.21)	0.0754	-6.03 (-14.44, 2.39)	0.1605	
>=10 mg/day	5/ 87 (5.7)	5.8	8/ 83 (9.6)	9.6	0.60 (0.20, 1.75)	0.3463	-3.85 (-13.78, 6.08)	0.4476	
Result of type I IFN gene signature test									0.1352
LOW	2/ 30 (6.7)	6.7	1/ 31 (3.2)	3.2	2.07 (0.20, 21.61)	0.5444	3.44 (-11.73, 18.61)	0.6566	
HIGH	4/150 (2.7)	2.6	14/151 (9.3)	9.4	0.29 (0.10, 0.85)	0.0248	-6.78 (-13.52, -0.05)	0.0483	
Age (years)									NE
<= 65	6/175 (3.4)	3.4	15/181 (8.3)	8.4	0.41 (0.16, 1.04)	0.0611	-5.02 (-11.27, 1.23)	0.1154	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									0.8737
male	0/ 12 (0.0)	0.0	1/ 12 (8.3)	8.3	0.33 (0.01, 7.45)	0.4883	-8.33 (-37.28, 20.61)	0.5726	
female	6/168 (3.6)	3.5	14/170 (8.2)	8.3	0.43 (0.17, 1.10)	0.0790	-4.77 (-11.24, 1.71)	0.1493	
Race									0.8492
White	3/110 (2.7)	2.7	11/107 (10.3)	10.4	0.27 (0.08, 0.92)	0.0373	-7.79 (-16.01, 0.43)	0.0634	
Black or African American	0/ 17 (0.0)	0.0	2/ 25 (8.0)	8.0	0.29 (0.01, 5.67)	0.4135	-8.00 (-27.43, 11.43)	0.4196	
Asian	0/ 30 (0.0)	0.0	1/ 30 (3.3)	3.3	0.33 (0.01, 7.87)	0.4958	-3.33 (-16.52, 9.85)	0.6203	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	1/ 11 (9.1)	9.1	1/ 11 (9.1)	9.1	1.00 (0.07, 14.05)	1.0000	0.00 (-33.43, 33.43)	1.0000	
Ethnicity									0.9156
Hispanic/Latino	2/ 54 (3.7)	3.9	7/ 54 (13.0)	13.7	0.29 (0.06, 1.31)	0.1075	-9.87 (-23.74, 4.01)	0.1633	
Non-hispanic/Latino	2/118 (1.7)	1.7	8/120 (6.7)	6.8	0.25 (0.06, 1.17)	0.0791	-5.08 (-12.77, 2.62)	0.1962	
Geographic region									0.2247
EU	3/ 51 (5.9)	5.9	3/ 46 (6.5)	6.5	0.90 (0.19, 4.25)	0.8962	-0.64 (-12.36, 11.08)	0.9149	
non-EU	3/129 (2.3)	2.3	12/136 (8.8)	9.0	0.26 (0.08, 0.91)	0.0354	-6.70 (-14.26, 0.86)	0.0825	
Onset of disease									0.3529
Paediatric	2/ 14 (14.3)	14.3	2/ 12 (16.7)	16.7	0.86 (0.14, 5.20)	0.8668	-2.38 (-35.16, 30.40)	0.8868	
Adult	4/166 (2.4)	2.4	13/170 (7.6)	7.8	0.32 (0.10, 0.95)	0.0396	-5.36 (-11.65, 0.92)	0.0942	
ADA result									0.9640
Negative	6/172 (3.5)	3.4	13/162 (8.0)	8.0	0.43 (0.17, 1.12)	0.0834	-4.66 (-11.14, 1.83)	0.1592	
Positive (At any time)	0/ 8 (0.0)	0.0	2/ 20 (10.0)	10.0	0.47 (0.02, 8.78)	0.6107	-10.00 (-40.56, 20.56)	0.5212	
BMI (kg/m2) at enrolment									0.8323
< 30	3/125 (2.4)	2.3	9/134 (6.7)	6.6	0.36 (0.10, 1.29)	0.1161	-4.24 (-11.54, 3.06)	0.2549	
>= 30	3/ 55 (5.5)	5.9	6/ 48 (12.5)	12.8	0.44 (0.12, 1.65)	0.2219	-6.94 (-21.69, 7.81)	0.3566	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.8122
All negative/normal	2/ 58 (3.4)	3.6	6/ 81 (7.4)	7.7	0.47 (0.10, 2.23)	0.3381	-4.11 (-15.23, 7.02)	0.4694	
At least one positive/abnormal	4/122 (3.3)	3.2	9/101 (8.9)	8.8	0.37 (0.12, 1.16)	0.0878	-5.60 (-13.51, 2.31)	0.1655	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Non-Severe Adverse Event
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	162 (90.0)	153 (84.1)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.07 (0.99, 1.16)	
p-value	0.0940	
Odds Ratio (95% CI)	1.71 (0.91, 3.20)	
p-value	0.0957	
Risk Difference (95% CI)	5.93 (-0.96, 12.82)	
p-value	0.0914	
CMH approach		
Response rate	89.9	83.9
Difference in response rates (95% CI)	6.00 (-1.65, 13.64)	
p-value	0.1243	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Non-Severe Adverse Event - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.7256
< 10 points	51/ 54 (94.4)	94.4	45/ 52 (86.5)	86.5	1.09 (0.96, 1.24)	0.1711	7.88 (-6.28, 22.05)	0.2752	
>= 10 points	111/126 (88.1)	88.0	108/130 (83.1)	82.8	1.06 (0.96, 1.17)	0.2536	5.17 (-4.03, 14.38)	0.2703	
OCS dose at baseline									0.1563
<10 mg/day	84/ 93 (90.3)	90.3	88/ 99 (88.9)	88.8	1.02 (0.92, 1.12)	0.7447	1.53 (-8.64, 11.71)	0.7675	
>=10 mg/day	78/ 87 (89.7)	89.5	65/ 83 (78.3)	78.4	1.14 (1.00, 1.31)	0.0476	11.16 (-0.67, 22.98)	0.0644	
Result of type I IFN gene signature test									0.7428
LOW	25/ 30 (83.3)	83.3	25/ 31 (80.6)	80.6	1.03 (0.82, 1.31)	0.7847	2.69 (-18.00, 23.37)	0.7989	
HIGH	137/150 (91.3)	91.2	128/151 (84.8)	84.6	1.08 (0.99, 1.17)	0.0806	6.67 (-1.52, 14.85)	0.1103	
Age (years)									0.1935
<= 65	158/175 (90.3)	90.1	152/181 (84.0)	83.8	1.08 (0.99, 1.16)	0.0763	6.28 (-1.42, 13.98)	0.1101	
> 65	4/ 5 (80.0)	80.0	1/ 1 (100.0)	100.0	0.80 (0.52, 1.24)	0.3183	-20.00 (-124.53, 84.53)	0.7077	
Sex									0.3896
male	9/ 12 (75.0)	75.0	10/ 12 (83.3)	83.3	0.90 (0.60, 1.36)	0.6172	-8.33 (-44.22, 27.56)	0.6490	
female	153/168 (91.1)	91.0	143/170 (84.1)	84.0	1.08 (1.00, 1.17)	0.0536	7.01 (-0.85, 14.86)	0.0803	
Race									0.1262
White	96/110 (87.3)	86.9	84/107 (78.5)	78.8	1.11 (0.98, 1.26)	0.0894	8.12 (-2.55, 18.79)	0.1357	
Black or African American	14/ 17 (82.4)	82.4	19/ 25 (76.0)	76.0	1.08 (0.79, 1.48)	0.6133	6.35 (-20.42, 33.13)	0.6419	
Asian	29/ 30 (96.7)	96.7	30/ 30 (100.0)	100.0	0.97 (0.90, 1.03)	0.3173	-3.33 (-16.52, 9.85)	0.6203	
American Indian or Alaska Native	4/ 4 (100.0)	100.0	1/ 1 (100.0)	100.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	11/ 11 (100.0)	100.0	11/ 11 (100.0)	100.0	NE		0.00 (-28.41, 28.41)	1.0000	
Ethnicity									0.2226
Hispanic/Latino	50/ 54 (92.6)	92.3	43/ 54 (79.6)	79.4	1.16 (1.00, 1.36)	0.0558	12.98 (-2.14, 28.10)	0.0925	
Non-hispanic/Latino	104/118 (88.1)	88.0	102/120 (85.0)	84.9	1.04 (0.94, 1.15)	0.4784	3.14 (-6.74, 13.01)	0.5337	
Geographic region									0.7640
EU	43/ 51 (84.3)	84.3	37/ 46 (80.4)	80.4	1.05 (0.87, 1.26)	0.6183	3.88 (-12.10, 19.86)	0.6342	
non-EU	119/129 (92.2)	92.0	116/136 (85.3)	85.2	1.08 (0.99, 1.18)	0.0736	6.81 (-2.07, 15.69)	0.1326	
Onset of disease									0.0749
Paediatric	13/ 14 (92.9)	92.9	12/ 12 (100.0)	100.0	0.93 (0.80, 1.07)	0.3174	-7.14 (-34.18, 19.90)	0.6047	
Adult	149/166 (89.8)	89.6	141/170 (82.9)	82.9	1.08 (0.99, 1.18)	0.0697	6.77 (-1.29, 14.83)	0.0998	
ADA result									0.6976
Negative	154/172 (89.5)	89.5	135/162 (83.3)	83.0	1.07 (0.99, 1.17)	0.1009	6.44 (-1.66, 14.55)	0.1192	
Positive (At any time)	8/ 8 (100.0)	100.0	18/ 20 (90.0)	90.0	1.11 (0.96, 1.29)	0.1575	10.00 (-20.56, 40.56)	0.5212	
BMI (kg/m2) at enrolment									0.7344
< 30	114/125 (91.2)	91.5	113/134 (84.3)	84.0	1.08 (0.99, 1.18)	0.0918	7.44 (-1.61, 16.49)	0.1071	
>= 30	48/ 55 (87.3)	87.6	40/ 48 (83.3)	82.9	1.05 (0.89, 1.23)	0.5759	4.67 (-11.29, 20.62)	0.5666	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.7833
All negative/normal	52/ 58 (89.7)	89.6	67/ 81 (82.7)	82.8	1.08 (0.95, 1.24)	0.2334	6.83 (-6.41, 20.06)	0.3119	
At least one positive/abnormal	110/122 (90.2)	90.4	86/101 (85.1)	84.9	1.06 (0.96, 1.17)	0.2636	5.52 (-3.94, 14.98)	0.2525	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event leading to discontinuation of study drug
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	5 (2.8)	14 (7.7)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.36 (0.13, 0.98)	
p-value	0.0459	
Odds Ratio (95% CI)	0.34 (0.12, 0.97)	
p-value	0.0442	
Risk Difference (95% CI)	-4.91 (-9.47, -0.36)	
p-value	0.0345	
CMH approach		
Response rate	2.8	7.8
Difference in response rates (95% CI)	-5.01 (-11.10, 1.07)	
p-value	0.1061	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event leading to discontinuation of study drug - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.4404
< 10 points	0/ 54 (0.0)	0.0	3/ 52 (5.8)	5.7	0.14 (0.01, 2.60)	0.1860	-5.71 (-17.69, 6.27)	0.3500	
>= 10 points	5/126 (4.0)	4.0	11/130 (8.5)	8.7	0.47 (0.17, 1.31)	0.1490	-4.73 (-12.04, 2.58)	0.2045	
OCS dose at baseline									0.7808
<10 mg/day	2/ 93 (2.2)	2.2	5/ 99 (5.1)	5.0	0.43 (0.08, 2.14)	0.3002	-2.82 (-11.09, 5.46)	0.5048	
>=10 mg/day	3/ 87 (3.4)	3.5	9/ 83 (10.8)	11.0	0.32 (0.09, 1.13)	0.0774	-7.46 (-17.28, 2.37)	0.1369	
Result of type I IFN gene signature test									0.9616
LOW	1/ 30 (3.3)	3.3	3/ 31 (9.7)	9.7	0.34 (0.04, 3.13)	0.3438	-6.34 (-22.31, 9.62)	0.4360	
HIGH	4/150 (2.7)	2.7	11/151 (7.3)	7.4	0.37 (0.12, 1.12)	0.0791	-4.74 (-11.31, 1.82)	0.1563	
Age (years)									NE
<= 65	5/175 (2.9)	2.9	14/181 (7.7)	7.9	0.37 (0.14, 1.00)	0.0509	-4.95 (-11.12, 1.22)	0.1156	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
female	5/168 (3.0)	3.0	14/170 (8.2)	8.4	0.36 (0.13, 0.98)	0.0458	-5.38 (-11.84, 1.07)	0.1023	
Race									0.6810
White	4/110 (3.6)	3.9	9/107 (8.4)	8.3	0.43 (0.14, 1.36)	0.1520	-4.46 (-12.61, 3.68)	0.2824	
Black or African American	0/ 17 (0.0)	0.0	1/ 25 (4.0)	4.0	0.48 (0.02, 11.17)	0.6486	-4.00 (-22.36, 14.36)	0.6694	
Asian	0/ 30 (0.0)	0.0	4/ 30 (13.3)	13.3	0.11 (0.01, 1.98)	0.1347	-13.33 (-29.36, 2.70)	0.1031	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-28.41, 28.41)	1.0000	
Ethnicity									0.4295
Hispanic/Latino	2/ 54 (3.7)	3.8	4/ 54 (7.4)	7.7	0.50 (0.10, 2.62)	0.4117	-3.92 (-16.81, 8.97)	0.5508	
Non-hispanic/Latino	2/118 (1.7)	1.8	10/120 (8.3)	8.4	0.20 (0.05, 0.91)	0.0370	-6.54 (-14.57, 1.49)	0.1105	
Geographic region									0.8485
EU	1/ 51 (2.0)	2.0	3/ 46 (6.5)	6.5	0.30 (0.03, 2.79)	0.2904	-4.56 (-15.24, 6.12)	0.4025	
non-EU	4/129 (3.1)	3.2	11/136 (8.1)	8.1	0.38 (0.13, 1.17)	0.0930	-4.96 (-12.59, 2.67)	0.2025	
Onset of disease									0.1943
Paediatric	1/ 14 (7.1)	7.1	0/ 12 (0.0)	0.0	2.60 (0.12, 58.48)	0.5475	7.14 (-19.90, 34.18)	0.6047	
Adult	4/166 (2.4)	2.4	14/170 (8.2)	8.3	0.29 (0.10, 0.87)	0.0272	-5.89 (-12.26, 0.48)	0.0699	
ADA result									0.4659
Negative	4/172 (2.3)	2.4	11/162 (6.8)	6.9	0.34 (0.11, 1.05)	0.0617	-4.51 (-10.78, 1.77)	0.1592	
Positive (At any time)	1/ 8 (12.5)	12.5	3/ 20 (15.0)	15.0	0.83 (0.10, 6.87)	0.8655	-2.50 (-37.39, 32.39)	0.8883	
BMI (kg/m2) at enrolment									0.8181
< 30	4/125 (3.2)	3.2	11/134 (8.2)	8.4	0.39 (0.13, 1.19)	0.0987	-5.22 (-12.98, 2.53)	0.1869	
>= 30	1/ 55 (1.8)	1.8	3/ 48 (6.3)	6.4	0.29 (0.03, 2.70)	0.2778	-4.59 (-17.54, 8.37)	0.4879	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.3320
All negative/normal	2/ 58 (3.4)	3.7	4/ 81 (4.9)	5.0	0.70 (0.13, 3.69)	0.6722	-1.26 (-12.01, 9.49)	0.8181	
At least one positive/abnormal	3/122 (2.5)	2.4	10/101 (9.9)	9.9	0.25 (0.07, 0.88)	0.0307	-7.52 (-15.46, 0.42)	0.0636	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Serious Adverse Event leading to discontinuation of study drug
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	1 (0.6)	8 (4.4)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.13 (0.02, 1.00)	
p-value	0.0500	
Odds Ratio (95% CI)	0.12 (0.02, 0.98)	
p-value	0.0480	
Risk Difference (95% CI)	-3.84 (-7.01, -0.67)	
p-value	0.0176	
CMH approach		
Response rate	0.6	4.6
Difference in response rates (95% CI)	-3.99 (-9.30, 1.32)	
p-value	0.1407	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Serious Adverse Event leading to discontinuation of study drug - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.6878
< 10 points	0/ 54 (0.0)	0.0	1/ 52 (1.9)	1.9	0.32 (0.01, 7.71)	0.4837	-1.94 (-13.33, 9.46)	0.7392	
>= 10 points	1/126 (0.8)	0.8	7/130 (5.4)	5.7	0.15 (0.02, 1.18)	0.0713	-4.84 (-11.13, 1.45)	0.1312	
OCS dose at baseline									0.0635
<10 mg/day	1/ 93 (1.1)	1.1	0/ 99 (0.0)	0.0	3.19 (0.13, 77.38)	0.4756	1.11 (-6.17, 8.39)	0.7646	
>=10 mg/day	0/ 87 (0.0)	0.0	8/ 83 (9.6)	9.7	0.06 (0.00, 0.96)	0.0466	-9.75 (-18.81, -0.69)	0.0349	
Result of type I IFN gene signature test									NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE		0.00 (-11.73, 11.73)	1.0000	
HIGH	1/150 (0.7)	0.7	8/151 (5.3)	5.5	0.13 (0.02, 0.99)	0.0493	-4.80 (-10.73, 1.13)	0.1124	
Age (years)									NE
<= 65	1/175 (0.6)	0.6	8/181 (4.4)	4.6	0.13 (0.02, 1.02)	0.0526	-4.02 (-9.41, 1.37)	0.1438	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
female	1/168 (0.6)	0.6	8/170 (4.7)	4.9	0.13 (0.02, 1.00)	0.0500	-4.28 (-9.92, 1.36)	0.1366	
Race									0.8344
White	1/110 (0.9)	1.0	6/107 (5.6)	5.7	0.16 (0.02, 1.32)	0.0895	-4.75 (-11.97, 2.48)	0.1979	
Black or African American	0/ 17 (0.0)	0.0	1/ 25 (4.0)	4.0	0.48 (0.02, 11.17)	0.6486	-4.00 (-22.36, 14.36)	0.6694	
Asian	0/ 30 (0.0)	0.0	1/ 30 (3.3)	3.3	0.33 (0.01, 7.87)	0.4958	-3.33 (-16.52, 9.85)	0.6203	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-28.41, 28.41)	1.0000	
Ethnicity									0.8488
Hispanic/Latino	0/ 54 (0.0)	0.0	3/ 54 (5.6)	6.0	0.14 (0.01, 2.70)	0.1945	-6.03 (-18.06, 6.01)	0.3264	
Non-hispanic/Latino	1/118 (0.8)	0.9	5/120 (4.2)	4.3	0.20 (0.02, 1.71)	0.1432	-3.39 (-10.70, 3.93)	0.3647	
Geographic region									0.7912
EU	0/ 51 (0.0)	0.0	3/ 46 (6.5)	6.5	0.13 (0.01, 2.43)	0.1719	-6.52 (-16.60, 3.56)	0.2046	
non-EU	1/129 (0.8)	0.8	5/136 (3.7)	3.9	0.21 (0.02, 1.78)	0.1527	-3.06 (-9.74, 3.63)	0.3701	
Onset of disease									0.0801
Paediatric	1/ 14 (7.1)	7.1	0/ 12 (0.0)	0.0	2.60 (0.12, 58.48)	0.5475	7.14 (-19.90, 34.18)	0.6047	
Adult	0/166 (0.0)	0.0	8/170 (4.7)	4.9	0.06 (0.00, 1.04)	0.0529	-4.85 (-10.38, 0.67)	0.0853	
ADA result									0.5544
Negative	1/172 (0.6)	0.6	6/162 (3.7)	3.9	0.16 (0.02, 1.29)	0.0849	-3.27 (-8.84, 2.29)	0.2491	
Positive (At any time)	0/ 8 (0.0)	0.0	2/ 20 (10.0)	10.0	0.47 (0.02, 8.78)	0.6107	-10.00 (-40.56, 20.56)	0.5212	
BMI (kg/m2) at enrolment									0.9912
< 30	1/125 (0.8)	0.8	6/134 (4.5)	4.5	0.18 (0.02, 1.46)	0.1085	-3.72 (-10.61, 3.17)	0.2902	
>= 30	0/ 55 (0.0)	0.0	2/ 48 (4.2)	4.7	0.17 (0.01, 3.56)	0.2567	-4.66 (-16.96, 7.64)	0.4577	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.2076
All negative/normal	1/ 58 (1.7)	1.9	2/ 81 (2.5)	2.5	0.70 (0.06, 7.52)	0.7671	-0.68 (-10.67, 9.31)	0.8942	
At least one positive/abnormal	0/122 (0.0)	0.0	6/101 (5.9)	5.8	0.06 (0.00, 1.12)	0.0597	-5.81 (-12.70, 1.07)	0.0978	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with Adverse Event leading to death
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	1 (0.6)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.03 (0.12, 73.97)	
p-value	0.4959	
Odds Ratio (95% CI)	3.05 (0.12, 75.37)	
p-value	0.4956	
Risk Difference (95% CI)	0.56 (-0.53, 1.64)	
p-value	0.3160	
CMH approach		
Response rate	0.5	0.0
Difference in response rates (95% CI)	0.54 (-3.97, 5.05)	
p-value	0.8147	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with Adverse Event leading to death - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	1/ 54 (1.9)	1.8	0/ 52 (0.0)	0.0	2.89 (0.12, 69.40)	0.5127	1.84 (-9.53, 13.20)	0.7511	
>= 10 points	0/126 (0.0)	0.0	0/130 (0.0)	0.0	NE		0.00 (-4.90, 4.90)	1.0000	
OCS dose at baseline									NE
<10 mg/day	0/ 93 (0.0)	0.0	0/ 99 (0.0)	0.0	NE		0.00 (-7.00, 7.00)	1.0000	
>=10 mg/day	1/ 87 (1.1)	1.1	0/ 83 (0.0)	0.0	2.86 (0.12, 69.32)	0.5176	1.15 (-6.03, 8.33)	0.7541	
Result of type I IFN gene signature test									NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE		0.00 (-11.73, 11.73)	1.0000	
HIGH	1/150 (0.7)	0.6	0/151 (0.0)	0.0	3.02 (0.12, 73.54)	0.4975	0.65 (-4.23, 5.52)	0.7943	
Age (years)									NE
<= 65	1/175 (0.6)	0.5	0/181 (0.0)	0.0	3.10 (0.13, 75.64)	0.4872	0.55 (-4.04, 5.14)	0.8146	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
female	1/168 (0.6)	0.6	0/170 (0.0)	0.0	3.04 (0.12, 73.99)	0.4956	0.59 (-4.21, 5.40)	0.8090	
Race									NE
White	1/110 (0.9)	0.7	0/107 (0.0)	0.0	2.92 (0.12, 70.87)	0.5104	0.72 (-5.15, 6.59)	0.8109	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE		0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-28.41, 28.41)	1.0000	
Ethnicity									NE
Hispanic/Latino	1/ 54 (1.9)	2.1	0/ 54 (0.0)	0.0	3.00 (0.12, 72.05)	0.4982	2.14 (-8.79, 13.06)	0.7015	
Non-hispanic/Latino	0/118 (0.0)	0.0	0/120 (0.0)	0.0	NE		0.00 (-6.46, 6.46)	1.0000	
Geographic region									NE
EU	0/ 51 (0.0)	0.0	0/ 46 (0.0)	0.0	NE		0.00 (-7.65, 7.65)	1.0000	
non-EU	1/129 (0.8)	0.8	0/136 (0.0)	0.0	3.16 (0.13, 76.91)	0.4796	0.76 (-5.25, 6.76)	0.8048	
Onset of disease									NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-24.92, 24.92)	1.0000	
Adult	1/166 (0.6)	0.6	0/170 (0.0)	0.0	3.07 (0.13, 74.87)	0.4910	0.60 (-4.24, 5.43)	0.8091	
ADA result									NE
Negative	1/172 (0.6)	0.5	0/162 (0.0)	0.0	2.83 (0.12, 68.89)	0.5237	0.53 (-4.32, 5.37)	0.8315	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	1/125 (0.8)	0.8	0/134 (0.0)	0.0	3.21 (0.13, 78.18)	0.4733	0.80 (-5.29, 6.90)	0.7967	
>= 30	0/ 55 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-11.37, 11.37)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE		0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	1/122 (0.8)	0.8	0/101 (0.0)	0.0	2.49 (0.10, 60.41)	0.5755	0.81 (-4.76, 6.37)	0.7762	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Anaphylaxis
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.43, 4.43)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Anaphylaxis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.98, 10.98)	1.0000	
>= 10 points	0/126 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.90, 4.90)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 93 (0.0)	0.0	0/ 99 (0.0)	0.0	NE	0.00 (-7.00, 7.00)	1.0000	
>=10 mg/day	0/ 87 (0.0)	0.0	0/ 83 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE	0.00 (-11.73, 11.73)	1.0000	
HIGH	0/150 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Age (years)								NE
<= 65	0/175 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.50, 4.50)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-102.70, 102.70)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
female	0/168 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.71, 4.71)	1.0000	
Race								NE
White	0/110 (0.0)	0.0	0/107 (0.0)	0.0	NE	0.00 (-5.75, 5.75)	1.0000	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE	0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE	0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-28.41, 28.41)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	0/118 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.46, 6.46)	1.0000	
Geographic region								NE
EU	0/ 51 (0.0)	0.0	0/ 46 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
non-EU	0/129 (0.0)	0.0	0/136 (0.0)	0.0	NE	0.00 (-5.90, 5.90)	1.0000	
Onset of disease								NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-24.92, 24.92)	1.0000	
Adult	0/166 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.74, 4.74)	1.0000	
ADA result								NE
Negative	0/172 (0.0)	0.0	0/162 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE	0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/125 (0.0)	0.0	0/134 (0.0)	0.0	NE	0.00 (-5.98, 5.98)	1.0000	
>= 30	0/ 55 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-11.37, 11.37)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE	0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	0/122 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-5.42, 5.42)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Anaphylaxis
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.43, 4.43)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Anaphylaxis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.98, 10.98)	1.0000	
>= 10 points	0/126 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.90, 4.90)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 93 (0.0)	0.0	0/ 99 (0.0)	0.0	NE	0.00 (-7.00, 7.00)	1.0000	
>=10 mg/day	0/ 87 (0.0)	0.0	0/ 83 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE	0.00 (-11.73, 11.73)	1.0000	
HIGH	0/150 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Age (years)								NE
<= 65	0/175 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.50, 4.50)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-102.70, 102.70)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
female	0/168 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.71, 4.71)	1.0000	
Race								NE
White	0/110 (0.0)	0.0	0/107 (0.0)	0.0	NE	0.00 (-5.75, 5.75)	1.0000	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE	0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE	0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-28.41, 28.41)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	0/118 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.46, 6.46)	1.0000	
Geographic region								NE
EU	0/ 51 (0.0)	0.0	0/ 46 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
non-EU	0/129 (0.0)	0.0	0/136 (0.0)	0.0	NE	0.00 (-5.90, 5.90)	1.0000	
Onset of disease								NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-24.92, 24.92)	1.0000	
Adult	0/166 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.74, 4.74)	1.0000	
ADA result								NE
Negative	0/172 (0.0)	0.0	0/162 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE	0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/125 (0.0)	0.0	0/134 (0.0)	0.0	NE	0.00 (-5.98, 5.98)	1.0000	
>= 30	0/ 55 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-11.37, 11.37)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE	0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	0/122 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-5.42, 5.42)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Anaphylaxis
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.43, 4.43)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Anaphylaxis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.98, 10.98)	1.0000	
>= 10 points	0/126 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.90, 4.90)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 93 (0.0)	0.0	0/ 99 (0.0)	0.0	NE	0.00 (-7.00, 7.00)	1.0000	
>=10 mg/day	0/ 87 (0.0)	0.0	0/ 83 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE	0.00 (-11.73, 11.73)	1.0000	
HIGH	0/150 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Age (years)								NE
<= 65	0/175 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.50, 4.50)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-102.70, 102.70)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
female	0/168 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.71, 4.71)	1.0000	
Race								NE
White	0/110 (0.0)	0.0	0/107 (0.0)	0.0	NE	0.00 (-5.75, 5.75)	1.0000	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE	0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE	0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-28.41, 28.41)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	0/118 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.46, 6.46)	1.0000	
Geographic region								NE
EU	0/ 51 (0.0)	0.0	0/ 46 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
non-EU	0/129 (0.0)	0.0	0/136 (0.0)	0.0	NE	0.00 (-5.90, 5.90)	1.0000	
Onset of disease								NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-24.92, 24.92)	1.0000	
Adult	0/166 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.74, 4.74)	1.0000	
ADA result								NE
Negative	0/172 (0.0)	0.0	0/162 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE	0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/125 (0.0)	0.0	0/134 (0.0)	0.0	NE	0.00 (-5.98, 5.98)	1.0000	
>= 30	0/ 55 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-11.37, 11.37)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE	0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	0/122 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-5.42, 5.42)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Anaphylaxis
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.43, 4.43)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Anaphylaxis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.98, 10.98)	1.0000	
>= 10 points	0/126 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.90, 4.90)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 93 (0.0)	0.0	0/ 99 (0.0)	0.0	NE	0.00 (-7.00, 7.00)	1.0000	
>=10 mg/day	0/ 87 (0.0)	0.0	0/ 83 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE	0.00 (-11.73, 11.73)	1.0000	
HIGH	0/150 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Age (years)								NE
<= 65	0/175 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.50, 4.50)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-102.70, 102.70)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
female	0/168 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.71, 4.71)	1.0000	
Race								NE
White	0/110 (0.0)	0.0	0/107 (0.0)	0.0	NE	0.00 (-5.75, 5.75)	1.0000	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE	0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE	0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-28.41, 28.41)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	0/118 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.46, 6.46)	1.0000	
Geographic region								NE
EU	0/ 51 (0.0)	0.0	0/ 46 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
non-EU	0/129 (0.0)	0.0	0/136 (0.0)	0.0	NE	0.00 (-5.90, 5.90)	1.0000	
Onset of disease								NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-24.92, 24.92)	1.0000	
Adult	0/166 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.74, 4.74)	1.0000	
ADA result								NE
Negative	0/172 (0.0)	0.0	0/162 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE	0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/125 (0.0)	0.0	0/134 (0.0)	0.0	NE	0.00 (-5.98, 5.98)	1.0000	
>= 30	0/ 55 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-11.37, 11.37)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE	0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	0/122 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-5.42, 5.42)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	13 (7.2)	3 (1.6)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	4.38 (1.27, 15.12)	
p-value	0.0194	
Odds Ratio (95% CI)	4.64 (1.30, 16.59)	
p-value	0.0181	
Risk Difference (95% CI)	5.57 (1.36, 9.78)	
p-value	0.0095	
CMH approach		
Response rate	7.2	1.7
Difference in response rates (95% CI)	5.53 (-0.34, 11.40)	
p-value	0.0651	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Anifrolumab 300mg (N=180) Response rate	Placebo (N=182) n/ N (%)	Placebo (N=182) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8380
< 10 points	1/ 54 (1.9)	1.9	0/ 52 (0.0)	0.0	2.89 (0.12, 69.40)	0.5127	1.89 (-9.43, 13.20)	0.7436	
>= 10 points	12/126 (9.5)	9.4	3/130 (2.3)	2.4	4.13 (1.19, 14.28)	0.0252	7.04 (-0.13, 14.21)	0.0542	
OCS dose at baseline									0.6254
<10 mg/day	6/ 93 (6.5)	6.5	1/ 99 (1.0)	1.1	6.39 (0.78, 52.05)	0.0832	5.44 (-2.93, 13.82)	0.2027	
>=10 mg/day	7/ 87 (8.0)	8.0	2/ 83 (2.4)	2.4	3.34 (0.71, 15.61)	0.1255	5.51 (-3.68, 14.70)	0.2399	
Result of type I IFN gene signature test									0.4872
LOW	2/ 30 (6.7)	6.7	1/ 31 (3.2)	3.2	2.07 (0.20, 21.61)	0.5444	3.44 (-11.73, 18.61)	0.6566	
HIGH	11/150 (7.3)	7.3	2/151 (1.3)	1.4	5.54 (1.25, 24.56)	0.0243	5.95 (-0.41, 12.31)	0.0666	
Age (years)									NE
<= 65	13/175 (7.4)	7.4	3/181 (1.7)	1.7	4.48 (1.30, 15.46)	0.0176	5.75 (-0.23, 11.73)	0.0595	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									0.8608
male	1/ 12 (8.3)	8.3	0/ 12 (0.0)	0.0	3.00 (0.13, 67.06)	0.4883	8.33 (-20.61, 37.28)	0.5726	
female	12/168 (7.1)	7.1	3/170 (1.8)	1.8	4.05 (1.16, 14.09)	0.0280	5.31 (-0.85, 11.46)	0.0914	
Race									0.5709
White	5/110 (4.5)	4.8	2/107 (1.9)	1.8	2.43 (0.48, 12.26)	0.2817	3.02 (-4.20, 10.24)	0.4122	
Black or African American	0/ 17 (0.0)	0.0	1/ 25 (4.0)	4.0	0.48 (0.02, 11.17)	0.6486	-4.00 (-22.36, 14.36)	0.6694	
Asian	3/ 30 (10.0)	10.0	0/ 30 (0.0)	0.0	7.00 (0.38, 129.93)	0.1917	10.00 (-5.22, 25.22)	0.1977	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	3/ 11 (27.3)	27.3	0/ 11 (0.0)	0.0	7.00 (0.40, 121.39)	0.1813	27.27 (-7.07, 61.62)	0.1196	
Ethnicity									0.5236
Hispanic/Latino	6/ 54 (11.1)	10.4	1/ 54 (1.9)	2.0	6.00 (0.75, 48.18)	0.0918	8.37 (-4.68, 21.41)	0.2086	
Non-hispanic/Latino	5/118 (4.2)	4.4	2/120 (1.7)	1.7	2.54 (0.50, 12.85)	0.2589	2.75 (-4.78, 10.27)	0.4743	
Geographic region									0.9252
EU	2/ 51 (3.9)	3.9	0/ 46 (0.0)	0.0	4.52 (0.22, 91.74)	0.3261	3.92 (-5.18, 13.02)	0.3985	
non-EU	11/129 (8.5)	8.5	3/136 (2.2)	2.3	3.87 (1.10, 13.54)	0.0345	6.23 (-1.35, 13.81)	0.1071	
Onset of disease									0.9301
Paediatric	2/ 14 (14.3)	14.3	0/ 12 (0.0)	0.0	4.33 (0.23, 82.31)	0.3290	14.29 (-14.43, 43.00)	0.3295	
Adult	11/166 (6.6)	6.6	3/170 (1.8)	1.8	3.76 (1.07, 13.22)	0.0394	4.86 (-1.27, 10.99)	0.1199	
ADA result									0.9795
Negative	11/172 (6.4)	6.4	2/162 (1.2)	1.3	5.18 (1.17, 23.01)	0.0306	5.19 (-0.84, 11.23)	0.0918	
Positive (At any time)	2/ 8 (25.0)	25.0	1/ 20 (5.0)	5.0	5.00 (0.52, 47.73)	0.1621	20.00 (-15.74, 55.74)	0.2727	
BMI (kg/m2) at enrolment									0.4267
< 30	7/125 (5.6)	5.6	1/134 (0.7)	0.8	7.50 (0.94, 60.13)	0.0577	4.82 (-2.28, 11.92)	0.1831	
>= 30	6/ 55 (10.9)	11.4	2/ 48 (4.2)	3.9	2.62 (0.55, 12.37)	0.2244	7.50 (-6.63, 21.64)	0.2983	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.7324
All negative/normal	2/ 58 (3.4)	3.6	1/ 81 (1.2)	1.2	2.79 (0.26, 30.08)	0.3970	2.40 (-7.69, 12.49)	0.6412	
At least one positive/abnormal	11/122 (9.0)	9.1	2/101 (2.0)	1.9	4.55 (1.03, 20.07)	0.0452	7.20 (-0.48, 14.88)	0.0662	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	1 (0.6)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.03 (0.12, 73.97)	
p-value	0.4959	
Odds Ratio (95% CI)	3.05 (0.12, 75.37)	
p-value	0.4956	
Risk Difference (95% CI)	0.56 (-0.53, 1.64)	
p-value	0.3160	
CMH approach		
Response rate	0.5	0.0
Difference in response rates (95% CI)	0.53 (-4.00, 5.07)	
p-value	0.8175	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE		0.00 (-10.98, 10.98)	1.0000	
>= 10 points	1/126 (0.8)	0.8	0/130 (0.0)	0.0	3.09 (0.13, 75.26)	0.4878	0.76 (-4.33, 5.84)	0.7710	
OCS dose at baseline									NE
<10 mg/day	0/ 93 (0.0)	0.0	0/ 99 (0.0)	0.0	NE		0.00 (-7.00, 7.00)	1.0000	
>=10 mg/day	1/ 87 (1.1)	1.1	0/ 83 (0.0)	0.0	2.86 (0.12, 69.32)	0.5176	1.14 (-6.11, 8.38)	0.7586	
Result of type I IFN gene signature test									NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE		0.00 (-11.73, 11.73)	1.0000	
HIGH	1/150 (0.7)	0.6	0/151 (0.0)	0.0	3.02 (0.12, 73.54)	0.4975	0.64 (-4.26, 5.55)	0.7976	
Age (years)									NE
<= 65	1/175 (0.6)	0.5	0/181 (0.0)	0.0	3.10 (0.13, 75.64)	0.4872	0.55 (-4.06, 5.16)	0.8158	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
female	1/168 (0.6)	0.6	0/170 (0.0)	0.0	3.04 (0.12, 73.99)	0.4956	0.57 (-4.26, 5.40)	0.8171	
Race									NE
White	0/110 (0.0)	0.0	0/107 (0.0)	0.0	NE		0.00 (-5.75, 5.75)	1.0000	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.13, 17.13)	1.0000	
Asian	1/ 30 (3.3)	3.3	0/ 30 (0.0)	0.0	3.00 (0.13, 70.83)	0.4958	3.33 (-9.85, 16.52)	0.6203	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-28.41, 28.41)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE		0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	1/118 (0.8)	0.8	0/120 (0.0)	0.0	3.05 (0.13, 74.13)	0.4933	0.84 (-5.78, 7.47)	0.8031	
Geographic region									NE
EU	0/ 51 (0.0)	0.0	0/ 46 (0.0)	0.0	NE		0.00 (-7.65, 7.65)	1.0000	
non-EU	1/129 (0.8)	0.7	0/136 (0.0)	0.0	3.16 (0.13, 76.91)	0.4796	0.74 (-5.30, 6.77)	0.8111	
Onset of disease									NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-24.92, 24.92)	1.0000	
Adult	1/166 (0.6)	0.6	0/170 (0.0)	0.0	3.07 (0.13, 74.87)	0.4910	0.58 (-4.28, 5.44)	0.8139	
ADA result									NE
Negative	1/172 (0.6)	0.6	0/162 (0.0)	0.0	2.83 (0.12, 68.89)	0.5237	0.56 (-4.32, 5.44)	0.8225	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	1/125 (0.8)	0.8	0/134 (0.0)	0.0	3.21 (0.13, 78.18)	0.4733	0.79 (-5.35, 6.94)	0.8005	
>= 30	0/ 55 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-11.37, 11.37)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE		0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	1/122 (0.8)	0.8	0/101 (0.0)	0.0	2.49 (0.10, 60.41)	0.5755	0.85 (-4.79, 6.49)	0.7684	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.43, 4.43)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.98, 10.98)	1.0000	
>= 10 points	0/126 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.90, 4.90)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 93 (0.0)	0.0	0/ 99 (0.0)	0.0	NE	0.00 (-7.00, 7.00)	1.0000	
>=10 mg/day	0/ 87 (0.0)	0.0	0/ 83 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE	0.00 (-11.73, 11.73)	1.0000	
HIGH	0/150 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Age (years)								NE
<= 65	0/175 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.50, 4.50)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-102.70, 102.70)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
female	0/168 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.71, 4.71)	1.0000	
Race								NE
White	0/110 (0.0)	0.0	0/107 (0.0)	0.0	NE	0.00 (-5.75, 5.75)	1.0000	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE	0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE	0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-28.41, 28.41)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	0/118 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.46, 6.46)	1.0000	
Geographic region								NE
EU	0/ 51 (0.0)	0.0	0/ 46 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
non-EU	0/129 (0.0)	0.0	0/136 (0.0)	0.0	NE	0.00 (-5.90, 5.90)	1.0000	
Onset of disease								NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-24.92, 24.92)	1.0000	
Adult	0/166 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.74, 4.74)	1.0000	
ADA result								NE
Negative	0/172 (0.0)	0.0	0/162 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE	0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/125 (0.0)	0.0	0/134 (0.0)	0.0	NE	0.00 (-5.98, 5.98)	1.0000	
>= 30	0/ 55 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-11.37, 11.37)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE	0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	0/122 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-5.42, 5.42)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	13 (7.2)	3 (1.6)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	4.38 (1.27, 15.12)	
p-value	0.0194	
Odds Ratio (95% CI)	4.64 (1.30, 16.59)	
p-value	0.0181	
Risk Difference (95% CI)	5.57 (1.36, 9.78)	
p-value	0.0095	
CMH approach		
Response rate	7.2	1.7
Difference in response rates (95% CI)	5.53 (-0.34, 11.40)	
p-value	0.0651	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8380
< 10 points	1/ 54 (1.9)	1.9	0/ 52 (0.0)	0.0	2.89 (0.12, 69.40)	0.5127	1.89 (-9.43, 13.20)	0.7436	
>= 10 points	12/126 (9.5)	9.4	3/130 (2.3)	2.4	4.13 (1.19, 14.28)	0.0252	7.04 (-0.13, 14.21)	0.0542	
OCS dose at baseline									0.6254
<10 mg/day	6/ 93 (6.5)	6.5	1/ 99 (1.0)	1.1	6.39 (0.78, 52.05)	0.0832	5.44 (-2.93, 13.82)	0.2027	
>=10 mg/day	7/ 87 (8.0)	8.0	2/ 83 (2.4)	2.4	3.34 (0.71, 15.61)	0.1255	5.51 (-3.68, 14.70)	0.2399	
Result of type I IFN gene signature test									0.4872
LOW	2/ 30 (6.7)	6.7	1/ 31 (3.2)	3.2	2.07 (0.20, 21.61)	0.5444	3.44 (-11.73, 18.61)	0.6566	
HIGH	11/150 (7.3)	7.3	2/151 (1.3)	1.4	5.54 (1.25, 24.56)	0.0243	5.95 (-0.41, 12.31)	0.0666	
Age (years)									NE
<= 65	13/175 (7.4)	7.4	3/181 (1.7)	1.7	4.48 (1.30, 15.46)	0.0176	5.75 (-0.23, 11.73)	0.0595	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									0.8608
male	1/ 12 (8.3)	8.3	0/ 12 (0.0)	0.0	3.00 (0.13, 67.06)	0.4883	8.33 (-20.61, 37.28)	0.5726	
female	12/168 (7.1)	7.1	3/170 (1.8)	1.8	4.05 (1.16, 14.09)	0.0280	5.31 (-0.85, 11.46)	0.0914	
Race									0.5709
White	5/110 (4.5)	4.8	2/107 (1.9)	1.8	2.43 (0.48, 12.26)	0.2817	3.02 (-4.20, 10.24)	0.4122	
Black or African American	0/ 17 (0.0)	0.0	1/ 25 (4.0)	4.0	0.48 (0.02, 11.17)	0.6486	-4.00 (-22.36, 14.36)	0.6694	
Asian	3/ 30 (10.0)	10.0	0/ 30 (0.0)	0.0	7.00 (0.38, 129.93)	0.1917	10.00 (-5.22, 25.22)	0.1977	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	3/ 11 (27.3)	27.3	0/ 11 (0.0)	0.0	7.00 (0.40, 121.39)	0.1813	27.27 (-7.07, 61.62)	0.1196	
Ethnicity									0.5236
Hispanic/Latino	6/ 54 (11.1)	10.4	1/ 54 (1.9)	2.0	6.00 (0.75, 48.18)	0.0918	8.37 (-4.68, 21.41)	0.2086	
Non-hispanic/Latino	5/118 (4.2)	4.4	2/120 (1.7)	1.7	2.54 (0.50, 12.85)	0.2589	2.75 (-4.78, 10.27)	0.4743	
Geographic region									0.9252
EU	2/ 51 (3.9)	3.9	0/ 46 (0.0)	0.0	4.52 (0.22, 91.74)	0.3261	3.92 (-5.18, 13.02)	0.3985	
non-EU	11/129 (8.5)	8.5	3/136 (2.2)	2.3	3.87 (1.10, 13.54)	0.0345	6.23 (-1.35, 13.81)	0.1071	
Onset of disease									0.9301
Paediatric	2/ 14 (14.3)	14.3	0/ 12 (0.0)	0.0	4.33 (0.23, 82.31)	0.3290	14.29 (-14.43, 43.00)	0.3295	
Adult	11/166 (6.6)	6.6	3/170 (1.8)	1.8	3.76 (1.07, 13.22)	0.0394	4.86 (-1.27, 10.99)	0.1199	
ADA result									0.9795
Negative	11/172 (6.4)	6.4	2/162 (1.2)	1.3	5.18 (1.17, 23.01)	0.0306	5.19 (-0.84, 11.23)	0.0918	
Positive (At any time)	2/ 8 (25.0)	25.0	1/ 20 (5.0)	5.0	5.00 (0.52, 47.73)	0.1621	20.00 (-15.74, 55.74)	0.2727	
BMI (kg/m2) at enrolment									0.4267
< 30	7/125 (5.6)	5.6	1/134 (0.7)	0.8	7.50 (0.94, 60.13)	0.0577	4.82 (-2.28, 11.92)	0.1831	
>= 30	6/ 55 (10.9)	11.4	2/ 48 (4.2)	3.9	2.62 (0.55, 12.37)	0.2244	7.50 (-6.63, 21.64)	0.2983	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.7324
All negative/normal	2/ 58 (3.4)	3.6	1/ 81 (1.2)	1.2	2.79 (0.26, 30.08)	0.3970	2.40 (-7.69, 12.49)	0.6412	
At least one positive/abnormal	11/122 (9.0)	9.1	2/101 (2.0)	1.9	4.55 (1.03, 20.07)	0.0452	7.20 (-0.48, 14.88)	0.0662	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Herpes Zoster leading to discontinuation of study drug
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.43, 4.43)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Herpes Zoster leading to discontinuation of study drug - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.98, 10.98)	1.0000	
>= 10 points	0/126 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.90, 4.90)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 93 (0.0)	0.0	0/ 99 (0.0)	0.0	NE	0.00 (-7.00, 7.00)	1.0000	
>=10 mg/day	0/ 87 (0.0)	0.0	0/ 83 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE	0.00 (-11.73, 11.73)	1.0000	
HIGH	0/150 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Age (years)								NE
<= 65	0/175 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.50, 4.50)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-102.70, 102.70)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
female	0/168 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.71, 4.71)	1.0000	
Race								NE
White	0/110 (0.0)	0.0	0/107 (0.0)	0.0	NE	0.00 (-5.75, 5.75)	1.0000	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE	0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE	0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-28.41, 28.41)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	0/118 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.46, 6.46)	1.0000	
Geographic region								NE
EU	0/ 51 (0.0)	0.0	0/ 46 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
non-EU	0/129 (0.0)	0.0	0/136 (0.0)	0.0	NE	0.00 (-5.90, 5.90)	1.0000	
Onset of disease								NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-24.92, 24.92)	1.0000	
Adult	0/166 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.74, 4.74)	1.0000	
ADA result								NE
Negative	0/172 (0.0)	0.0	0/162 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE	0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/125 (0.0)	0.0	0/134 (0.0)	0.0	NE	0.00 (-5.98, 5.98)	1.0000	
>= 30	0/ 55 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-11.37, 11.37)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE	0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	0/122 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-5.42, 5.42)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Hypersensitivity
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	2 (1.1)	1 (0.5)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	2.02 (0.18, 22.10)	
p-value	0.5639	
Odds Ratio (95% CI)	2.03 (0.18, 22.63)	
p-value	0.5636	
Risk Difference (95% CI)	0.56 (-1.31, 2.43)	
p-value	0.5562	
CMH approach		
Response rate	1.1	0.5
Difference in response rates (95% CI)	0.56 (-4.15, 5.26)	
p-value	0.8173	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Hypersensitivity - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.6315
< 10 points	1/ 54 (1.9)	1.8	0/ 52 (0.0)	0.0	2.89 (0.12, 69.40)	0.5127	1.84 (-9.53, 13.20)	0.7511	
>= 10 points	1/126 (0.8)	0.8	1/130 (0.8)	0.7	1.03 (0.07, 16.32)	0.9823	0.02 (-5.23, 5.28)	0.9934	
OCS dose at baseline									0.2461
<10 mg/day	0/ 93 (0.0)	0.0	1/ 99 (1.0)	1.0	0.35 (0.01, 8.60)	0.5239	-0.98 (-8.20, 6.24)	0.7907	
>=10 mg/day	2/ 87 (2.3)	2.3	0/ 83 (0.0)	0.0	4.77 (0.23, 97.96)	0.3107	2.28 (-5.19, 9.76)	0.5491	
Result of type I IFN gene signature test									NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE		0.00 (-11.73, 11.73)	1.0000	
HIGH	2/150 (1.3)	1.3	1/151 (0.7)	0.6	2.01 (0.18, 21.97)	0.5660	0.67 (-4.47, 5.81)	0.7990	
Age (years)									NE
<= 65	2/175 (1.1)	1.1	1/181 (0.6)	0.5	2.07 (0.19, 22.61)	0.5514	0.58 (-4.21, 5.36)	0.8136	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
female	2/168 (1.2)	1.2	1/170 (0.6)	0.6	2.02 (0.19, 22.11)	0.5633	0.59 (-4.43, 5.61)	0.8168	
Race									0.3437
White	1/110 (0.9)	0.7	0/107 (0.0)	0.0	2.92 (0.12, 70.87)	0.5104	0.72 (-5.15, 6.59)	0.8109	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	1/ 30 (3.3)	3.3	0.33 (0.01, 7.87)	0.4958	-3.33 (-16.52, 9.85)	0.6203	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-28.41, 28.41)	1.0000	
Ethnicity									0.3427
Hispanic/Latino	1/ 54 (1.9)	2.1	0/ 54 (0.0)	0.0	3.00 (0.12, 72.05)	0.4982	2.14 (-8.79, 13.06)	0.7015	
Non-hispanic/Latino	0/118 (0.0)	0.0	1/120 (0.8)	0.8	0.34 (0.01, 8.24)	0.5063	-0.77 (-7.37, 5.83)	0.8189	
Geographic region									0.6600
EU	1/ 51 (2.0)	2.0	0/ 46 (0.0)	0.0	2.71 (0.11, 64.96)	0.5382	1.96 (-6.46, 10.38)	0.6481	
non-EU	1/129 (0.8)	0.8	1/136 (0.7)	0.7	1.05 (0.07, 16.68)	0.9701	0.06 (-6.08, 6.19)	0.9859	
Onset of disease									0.6609
Paediatric	1/ 14 (7.1)	7.1	0/ 12 (0.0)	0.0	2.60 (0.12, 58.48)	0.5475	7.14 (-19.90, 34.18)	0.6047	
Adult	1/166 (0.6)	0.6	1/170 (0.6)	0.6	1.02 (0.06, 16.24)	0.9865	0.02 (-4.92, 4.97)	0.9928	
ADA result									NE
Negative	2/172 (1.2)	1.1	1/162 (0.6)	0.6	1.88 (0.17, 20.58)	0.6037	0.50 (-4.56, 5.56)	0.8461	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment									0.2631
< 30	0/125 (0.0)	0.0	1/134 (0.7)	0.7	0.36 (0.01, 8.69)	0.5272	-0.73 (-6.84, 5.39)	0.8162	
>= 30	2/ 55 (3.6)	3.3	0/ 48 (0.0)	0.0	4.38 (0.22, 88.94)	0.3369	3.28 (-8.69, 15.26)	0.5911	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.4519
All negative/normal	1/ 58 (1.7)	1.6	0/ 81 (0.0)	0.0	4.17 (0.17, 100.57)	0.3793	1.56 (-7.82, 10.94)	0.7446	
At least one positive/abnormal	1/122 (0.8)	0.8	1/101 (1.0)	1.0	0.83 (0.05, 13.07)	0.8933	-0.12 (-6.04, 5.80)	0.9680	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Hypersensitivity
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	1 (0.6)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.03 (0.12, 73.97)	
p-value	0.4959	
Odds Ratio (95% CI)	3.05 (0.12, 75.37)	
p-value	0.4956	
Risk Difference (95% CI)	0.56 (-0.53, 1.64)	
p-value	0.3160	
CMH approach		
Response rate	0.5	0.0
Difference in response rates (95% CI)	0.53 (-4.00, 5.07)	
p-value	0.8175	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Hypersensitivity - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE		0.00 (-10.98, 10.98)	1.0000	
>= 10 points	1/126 (0.8)	0.8	0/130 (0.0)	0.0	3.09 (0.13, 75.26)	0.4878	0.76 (-4.33, 5.84)	0.7710	
OCS dose at baseline									NE
<10 mg/day	0/ 93 (0.0)	0.0	0/ 99 (0.0)	0.0	NE		0.00 (-7.00, 7.00)	1.0000	
>=10 mg/day	1/ 87 (1.1)	1.1	0/ 83 (0.0)	0.0	2.86 (0.12, 69.32)	0.5176	1.14 (-6.11, 8.38)	0.7586	
Result of type I IFN gene signature test									NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE		0.00 (-11.73, 11.73)	1.0000	
HIGH	1/150 (0.7)	0.6	0/151 (0.0)	0.0	3.02 (0.12, 73.54)	0.4975	0.64 (-4.26, 5.55)	0.7976	
Age (years)									NE
<= 65	1/175 (0.6)	0.5	0/181 (0.0)	0.0	3.10 (0.13, 75.64)	0.4872	0.55 (-4.06, 5.16)	0.8158	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
female	1/168 (0.6)	0.6	0/170 (0.0)	0.0	3.04 (0.12, 73.99)	0.4956	0.57 (-4.26, 5.40)	0.8171	
Race									NE
White	0/110 (0.0)	0.0	0/107 (0.0)	0.0	NE		0.00 (-5.75, 5.75)	1.0000	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE		0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-28.41, 28.41)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE		0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	0/118 (0.0)	0.0	0/120 (0.0)	0.0	NE		0.00 (-6.46, 6.46)	1.0000	
Geographic region									NE
EU	1/ 51 (2.0)	2.0	0/ 46 (0.0)	0.0	2.71 (0.11, 64.96)	0.5382	1.96 (-6.46, 10.38)	0.6481	
non-EU	0/129 (0.0)	0.0	0/136 (0.0)	0.0	NE		0.00 (-5.90, 5.90)	1.0000	
Onset of disease									NE
Paediatric	1/ 14 (7.1)	7.1	0/ 12 (0.0)	0.0	2.60 (0.12, 58.48)	0.5475	7.14 (-19.90, 34.18)	0.6047	
Adult	0/166 (0.0)	0.0	0/170 (0.0)	0.0	NE		0.00 (-4.74, 4.74)	1.0000	
ADA result									NE
Negative	1/172 (0.6)	0.6	0/162 (0.0)	0.0	2.83 (0.12, 68.89)	0.5237	0.56 (-4.32, 5.44)	0.8225	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/125 (0.0)	0.0	0/134 (0.0)	0.0	NE		0.00 (-5.98, 5.98)	1.0000	
>= 30	1/ 55 (1.8)	1.8	0/ 48 (0.0)	0.0	2.63 (0.11, 62.97)	0.5517	1.84 (-9.95, 13.63)	0.7598	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE		0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	1/122 (0.8)	0.8	0/101 (0.0)	0.0	2.49 (0.10, 60.41)	0.5755	0.85 (-4.79, 6.49)	0.7684	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Hypersensitivity
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.43, 4.43)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Hypersensitivity - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.98, 10.98)	1.0000	
>= 10 points	0/126 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.90, 4.90)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 93 (0.0)	0.0	0/ 99 (0.0)	0.0	NE	0.00 (-7.00, 7.00)	1.0000	
>=10 mg/day	0/ 87 (0.0)	0.0	0/ 83 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE	0.00 (-11.73, 11.73)	1.0000	
HIGH	0/150 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Age (years)								NE
<= 65	0/175 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.50, 4.50)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-102.70, 102.70)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
female	0/168 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.71, 4.71)	1.0000	
Race								NE
White	0/110 (0.0)	0.0	0/107 (0.0)	0.0	NE	0.00 (-5.75, 5.75)	1.0000	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE	0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE	0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-28.41, 28.41)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	0/118 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.46, 6.46)	1.0000	
Geographic region								NE
EU	0/ 51 (0.0)	0.0	0/ 46 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
non-EU	0/129 (0.0)	0.0	0/136 (0.0)	0.0	NE	0.00 (-5.90, 5.90)	1.0000	
Onset of disease								NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-24.92, 24.92)	1.0000	
Adult	0/166 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.74, 4.74)	1.0000	
ADA result								NE
Negative	0/172 (0.0)	0.0	0/162 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE	0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/125 (0.0)	0.0	0/134 (0.0)	0.0	NE	0.00 (-5.98, 5.98)	1.0000	
>= 30	0/ 55 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-11.37, 11.37)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE	0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	0/122 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-5.42, 5.42)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Hypersensitivity
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	2 (1.1)	1 (0.5)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	2.02 (0.18, 22.10)	
p-value	0.5639	
Odds Ratio (95% CI)	2.03 (0.18, 22.63)	
p-value	0.5636	
Risk Difference (95% CI)	0.56 (-1.31, 2.43)	
p-value	0.5562	
CMH approach		
Response rate	1.1	0.5
Difference in response rates (95% CI)	0.56 (-4.15, 5.26)	
p-value	0.8173	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Hypersensitivity - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.6315
< 10 points	1/ 54 (1.9)	1.8	0/ 52 (0.0)	0.0	2.89 (0.12, 69.40)	0.5127	1.84 (-9.53, 13.20)	0.7511	
>= 10 points	1/126 (0.8)	0.8	1/130 (0.8)	0.7	1.03 (0.07, 16.32)	0.9823	0.02 (-5.23, 5.28)	0.9934	
OCS dose at baseline									0.2461
<10 mg/day	0/ 93 (0.0)	0.0	1/ 99 (1.0)	1.0	0.35 (0.01, 8.60)	0.5239	-0.98 (-8.20, 6.24)	0.7907	
>=10 mg/day	2/ 87 (2.3)	2.3	0/ 83 (0.0)	0.0	4.77 (0.23, 97.96)	0.3107	2.28 (-5.19, 9.76)	0.5491	
Result of type I IFN gene signature test									NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE		0.00 (-11.73, 11.73)	1.0000	
HIGH	2/150 (1.3)	1.3	1/151 (0.7)	0.6	2.01 (0.18, 21.97)	0.5660	0.67 (-4.47, 5.81)	0.7990	
Age (years)									NE
<= 65	2/175 (1.1)	1.1	1/181 (0.6)	0.5	2.07 (0.19, 22.61)	0.5514	0.58 (-4.21, 5.36)	0.8136	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
female	2/168 (1.2)	1.2	1/170 (0.6)	0.6	2.02 (0.19, 22.11)	0.5633	0.59 (-4.43, 5.61)	0.8168	
Race									0.3437
White	1/110 (0.9)	0.7	0/107 (0.0)	0.0	2.92 (0.12, 70.87)	0.5104	0.72 (-5.15, 6.59)	0.8109	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	1/ 30 (3.3)	3.3	0.33 (0.01, 7.87)	0.4958	-3.33 (-16.52, 9.85)	0.6203	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-28.41, 28.41)	1.0000	
Ethnicity									0.3427
Hispanic/Latino	1/ 54 (1.9)	2.1	0/ 54 (0.0)	0.0	3.00 (0.12, 72.05)	0.4982	2.14 (-8.79, 13.06)	0.7015	
Non-hispanic/Latino	0/118 (0.0)	0.0	1/120 (0.8)	0.8	0.34 (0.01, 8.24)	0.5063	-0.77 (-7.37, 5.83)	0.8189	
Geographic region									0.6600
EU	1/ 51 (2.0)	2.0	0/ 46 (0.0)	0.0	2.71 (0.11, 64.96)	0.5382	1.96 (-6.46, 10.38)	0.6481	
non-EU	1/129 (0.8)	0.8	1/136 (0.7)	0.7	1.05 (0.07, 16.68)	0.9701	0.06 (-6.08, 6.19)	0.9859	
Onset of disease									0.6609
Paediatric	1/ 14 (7.1)	7.1	0/ 12 (0.0)	0.0	2.60 (0.12, 58.48)	0.5475	7.14 (-19.90, 34.18)	0.6047	
Adult	1/166 (0.6)	0.6	1/170 (0.6)	0.6	1.02 (0.06, 16.24)	0.9865	0.02 (-4.92, 4.97)	0.9928	
ADA result									NE
Negative	2/172 (1.2)	1.1	1/162 (0.6)	0.6	1.88 (0.17, 20.58)	0.6037	0.50 (-4.56, 5.56)	0.8461	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment									0.2631
< 30	0/125 (0.0)	0.0	1/134 (0.7)	0.7	0.36 (0.01, 8.69)	0.5272	-0.73 (-6.84, 5.39)	0.8162	
>= 30	2/ 55 (3.6)	3.3	0/ 48 (0.0)	0.0	4.38 (0.22, 88.94)	0.3369	3.28 (-8.69, 15.26)	0.5911	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.4519
All negative/normal	1/ 58 (1.7)	1.6	0/ 81 (0.0)	0.0	4.17 (0.17, 100.57)	0.3793	1.56 (-7.82, 10.94)	0.7446	
At least one positive/abnormal	1/122 (0.8)	0.8	1/101 (1.0)	1.0	0.83 (0.05, 13.07)	0.8933	-0.12 (-6.04, 5.80)	0.9680	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Influenza
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	4 (2.2)	7 (3.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.58 (0.17, 1.94)	
p-value	0.3747	
Odds Ratio (95% CI)	0.57 (0.16, 1.98)	
p-value	0.3739	
Risk Difference (95% CI)	-1.62 (-5.15, 1.90)	
p-value	0.3669	
CMH approach		
Response rate	2.2	3.7
Difference in response rates (95% CI)	-1.48 (-6.86, 3.90)	
p-value	0.5907	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.5091
< 10 points	2/ 54 (3.7)	3.7	2/ 52 (3.8)	3.8	0.96 (0.14, 6.59)	0.9693	-0.09 (-12.40, 12.21)	0.9880	
>= 10 points	2/126 (1.6)	1.6	5/130 (3.8)	3.7	0.41 (0.08, 2.09)	0.2847	-2.08 (-8.11, 3.95)	0.4999	
OCS dose at baseline									0.1119
<10 mg/day	2/ 93 (2.2)	2.1	7/ 99 (7.1)	6.9	0.30 (0.06, 1.43)	0.1313	-4.75 (-13.33, 3.84)	0.2784	
>=10 mg/day	2/ 87 (2.3)	2.3	0/ 83 (0.0)	0.0	4.77 (0.23, 97.96)	0.3107	2.28 (-5.19, 9.76)	0.5491	
Result of type I IFN gene signature test									0.4137
LOW	0/ 30 (0.0)	0.0	2/ 31 (6.5)	6.5	0.21 (0.01, 4.13)	0.3020	-6.45 (-20.46, 7.56)	0.3668	
HIGH	4/150 (2.7)	2.6	5/151 (3.3)	3.1	0.81 (0.22, 2.94)	0.7432	-0.47 (-6.28, 5.35)	0.8751	
Age (years)									NE
<= 65	4/175 (2.3)	2.3	7/181 (3.9)	3.7	0.59 (0.18, 1.98)	0.3946	-1.42 (-6.87, 4.03)	0.6097	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									0.6798
male	0/ 12 (0.0)	0.0	1/ 12 (8.3)	8.3	0.33 (0.01, 7.45)	0.4883	-8.33 (-37.28, 20.61)	0.5726	
female	4/168 (2.4)	2.4	6/170 (3.5)	3.4	0.67 (0.19, 2.35)	0.5361	-1.05 (-6.71, 4.61)	0.7166	
Race									0.8261
White	2/110 (1.8)	1.7	2/107 (1.9)	1.8	0.97 (0.14, 6.78)	0.9777	-0.15 (-6.71, 6.41)	0.9640	
Black or African American	0/ 17 (0.0)	0.0	1/ 25 (4.0)	4.0	0.48 (0.02, 11.17)	0.6486	-4.00 (-22.36, 14.36)	0.6694	
Asian	0/ 30 (0.0)	0.0	2/ 30 (6.7)	6.7	0.20 (0.01, 4.00)	0.2923	-6.67 (-20.94, 7.61)	0.3601	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	1/ 11 (9.1)	9.1	1/ 11 (9.1)	9.1	1.00 (0.07, 14.05)	1.0000	0.00 (-33.43, 33.43)	1.0000	
Ethnicity									0.1600
Hispanic/Latino	2/ 54 (3.7)	3.5	1/ 54 (1.9)	2.0	2.00 (0.19, 21.41)	0.5666	1.45 (-10.43, 13.33)	0.8109	
Non-hispanic/Latino	1/118 (0.8)	0.8	5/120 (4.2)	4.0	0.20 (0.02, 1.71)	0.1432	-3.21 (-10.41, 4.00)	0.3830	
Geographic region									0.8098
EU	1/ 51 (2.0)	2.0	2/ 46 (4.3)	4.3	0.45 (0.04, 4.81)	0.5097	-2.39 (-12.40, 7.63)	0.6404	
non-EU	3/129 (2.3)	2.3	5/136 (3.7)	3.5	0.63 (0.15, 2.59)	0.5247	-1.22 (-8.06, 5.63)	0.7277	
Onset of disease									NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-24.92, 24.92)	1.0000	
Adult	4/166 (2.4)	2.4	7/170 (4.1)	4.0	0.59 (0.17, 1.96)	0.3853	-1.62 (-7.39, 4.16)	0.5832	
ADA result									0.9002
Negative	4/172 (2.3)	2.3	6/162 (3.7)	3.6	0.63 (0.18, 2.18)	0.4645	-1.27 (-7.00, 4.46)	0.6648	
Positive (At any time)	0/ 8 (0.0)	0.0	1/ 20 (5.0)	5.0	0.78 (0.03, 17.33)	0.8739	-5.00 (-34.61, 24.61)	0.7407	
BMI (kg/m2) at enrolment									0.1936
< 30	4/125 (3.2)	3.3	4/134 (3.0)	2.9	1.07 (0.27, 4.19)	0.9204	0.37 (-6.62, 7.36)	0.9174	
>= 30	0/ 55 (0.0)	0.0	3/ 48 (6.3)	5.7	0.13 (0.01, 2.36)	0.1654	-5.66 (-18.10, 6.77)	0.3722	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.0717
All negative/normal	3/ 58 (5.2)	5.3	2/ 81 (2.5)	2.3	2.09 (0.36, 12.14)	0.4095	2.94 (-7.67, 13.56)	0.5868	
At least one positive/abnormal	1/122 (0.8)	0.8	5/101 (5.0)	5.0	0.17 (0.02, 1.39)	0.0981	-4.22 (-10.96, 2.51)	0.2189	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Influenza
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	0 (0.0)	1 (0.5)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.34 (0.01, 8.22)	
p-value	0.5045	
Odds Ratio (95% CI)	0.34 (0.01, 8.28)	
p-value	0.5041	
Risk Difference (95% CI)	-0.55 (-1.62, 0.52)	
p-value	0.3160	
CMH approach		
Response rate	0.0	0.5
Difference in response rates (95% CI)	-0.52 (-5.05, 4.01)	
p-value	0.8226	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE		0.00 (-10.98, 10.98)	1.0000	
>= 10 points	0/126 (0.0)	0.0	1/130 (0.8)	0.7	0.34 (0.01, 8.36)	0.5120	-0.73 (-5.81, 4.34)	0.7771	
OCS dose at baseline									NE
<10 mg/day	0/ 93 (0.0)	0.0	1/ 99 (1.0)	1.0	0.35 (0.01, 8.60)	0.5239	-0.98 (-8.20, 6.24)	0.7907	
>=10 mg/day	0/ 87 (0.0)	0.0	0/ 83 (0.0)	0.0	NE		0.00 (-6.94, 6.94)	1.0000	
Result of type I IFN gene signature test									NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE		0.00 (-11.73, 11.73)	1.0000	
HIGH	0/150 (0.0)	0.0	1/151 (0.7)	0.6	0.34 (0.01, 8.17)	0.5026	-0.62 (-5.52, 4.28)	0.8031	
Age (years)									NE
<= 65	0/175 (0.0)	0.0	1/181 (0.6)	0.5	0.34 (0.01, 8.40)	0.5134	-0.52 (-5.12, 4.08)	0.8245	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
female	0/168 (0.0)	0.0	1/170 (0.6)	0.6	0.34 (0.01, 8.22)	0.5048	-0.57 (-5.39, 4.26)	0.8173	
Race									NE
White	0/110 (0.0)	0.0	1/107 (0.9)	0.9	0.32 (0.01, 7.87)	0.4890	-0.91 (-6.90, 5.08)	0.7658	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE		0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-28.41, 28.41)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE		0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	0/118 (0.0)	0.0	1/120 (0.8)	0.8	0.34 (0.01, 8.24)	0.5063	-0.77 (-7.37, 5.83)	0.8189	
Geographic region									NE
EU	0/ 51 (0.0)	0.0	0/ 46 (0.0)	0.0	NE		0.00 (-7.65, 7.65)	1.0000	
non-EU	0/129 (0.0)	0.0	1/136 (0.7)	0.7	0.35 (0.01, 8.55)	0.5206	-0.70 (-6.73, 5.33)	0.8196	
Onset of disease									NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-24.92, 24.92)	1.0000	
Adult	0/166 (0.0)	0.0	1/170 (0.6)	0.6	0.34 (0.01, 8.32)	0.5094	-0.57 (-5.43, 4.28)	0.8171	
ADA result									NE
Negative	0/172 (0.0)	0.0	1/162 (0.6)	0.6	0.31 (0.01, 7.65)	0.4772	-0.58 (-5.47, 4.30)	0.8151	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/125 (0.0)	0.0	0/134 (0.0)	0.0	NE		0.00 (-5.98, 5.98)	1.0000	
>= 30	0/ 55 (0.0)	0.0	1/ 48 (2.1)	2.1	0.29 (0.01, 7.00)	0.4473	-2.13 (-14.04, 9.77)	0.7255	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE		0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	0/122 (0.0)	0.0	1/101 (1.0)	1.0	0.28 (0.01, 6.71)	0.4295	-0.97 (-6.67, 4.74)	0.7393	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Influenza
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	0 (0.0)	1 (0.5)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.34 (0.01, 8.22)	
p-value	0.5045	
Odds Ratio (95% CI)	0.34 (0.01, 8.28)	
p-value	0.5041	
Risk Difference (95% CI)	-0.55 (-1.62, 0.52)	
p-value	0.3160	
CMH approach		
Response rate	0.0	0.5
Difference in response rates (95% CI)	-0.52 (-5.05, 4.01)	
p-value	0.8226	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE		0.00 (-10.98, 10.98)	1.0000	
>= 10 points	0/126 (0.0)	0.0	1/130 (0.8)	0.7	0.34 (0.01, 8.36)	0.5120	-0.73 (-5.81, 4.34)	0.7771	
OCS dose at baseline									NE
<10 mg/day	0/ 93 (0.0)	0.0	1/ 99 (1.0)	1.0	0.35 (0.01, 8.60)	0.5239	-0.98 (-8.20, 6.24)	0.7907	
>=10 mg/day	0/ 87 (0.0)	0.0	0/ 83 (0.0)	0.0	NE		0.00 (-6.94, 6.94)	1.0000	
Result of type I IFN gene signature test									NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE		0.00 (-11.73, 11.73)	1.0000	
HIGH	0/150 (0.0)	0.0	1/151 (0.7)	0.6	0.34 (0.01, 8.17)	0.5026	-0.62 (-5.52, 4.28)	0.8031	
Age (years)									NE
<= 65	0/175 (0.0)	0.0	1/181 (0.6)	0.5	0.34 (0.01, 8.40)	0.5134	-0.52 (-5.12, 4.08)	0.8245	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
female	0/168 (0.0)	0.0	1/170 (0.6)	0.6	0.34 (0.01, 8.22)	0.5048	-0.57 (-5.39, 4.26)	0.8173	
Race									NE
White	0/110 (0.0)	0.0	1/107 (0.9)	0.9	0.32 (0.01, 7.87)	0.4890	-0.91 (-6.90, 5.08)	0.7658	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE		0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-28.41, 28.41)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE		0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	0/118 (0.0)	0.0	1/120 (0.8)	0.8	0.34 (0.01, 8.24)	0.5063	-0.77 (-7.37, 5.83)	0.8189	
Geographic region									NE
EU	0/ 51 (0.0)	0.0	0/ 46 (0.0)	0.0	NE		0.00 (-7.65, 7.65)	1.0000	
non-EU	0/129 (0.0)	0.0	1/136 (0.7)	0.7	0.35 (0.01, 8.55)	0.5206	-0.70 (-6.73, 5.33)	0.8196	
Onset of disease									NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-24.92, 24.92)	1.0000	
Adult	0/166 (0.0)	0.0	1/170 (0.6)	0.6	0.34 (0.01, 8.32)	0.5094	-0.57 (-5.43, 4.28)	0.8171	
ADA result									NE
Negative	0/172 (0.0)	0.0	1/162 (0.6)	0.6	0.31 (0.01, 7.65)	0.4772	-0.58 (-5.47, 4.30)	0.8151	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/125 (0.0)	0.0	0/134 (0.0)	0.0	NE		0.00 (-5.98, 5.98)	1.0000	
>= 30	0/ 55 (0.0)	0.0	1/ 48 (2.1)	2.1	0.29 (0.01, 7.00)	0.4473	-2.13 (-14.04, 9.77)	0.7255	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE		0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	0/122 (0.0)	0.0	1/101 (1.0)	1.0	0.28 (0.01, 6.71)	0.4295	-0.97 (-6.67, 4.74)	0.7393	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Influenza
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	4 (2.2)	6 (3.3)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.67 (0.19, 2.35)	
p-value	0.5357	
Odds Ratio (95% CI)	0.67 (0.18, 2.40)	
p-value	0.5354	
Risk Difference (95% CI)	-1.07 (-4.45, 2.30)	
p-value	0.5322	
CMH approach		
Response rate	2.2	3.2
Difference in response rates (95% CI)	-0.96 (-6.27, 4.35)	
p-value	0.7235	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.6318
< 10 points	2/ 54 (3.7)	3.7	2/ 52 (3.8)	3.8	0.96 (0.14, 6.59)	0.9693	-0.09 (-12.40, 12.21)	0.9880	
>= 10 points	2/126 (1.6)	1.6	4/130 (3.1)	2.9	0.52 (0.10, 2.77)	0.4399	-1.34 (-7.24, 4.56)	0.6556	
OCS dose at baseline									0.1349
<10 mg/day	2/ 93 (2.2)	2.1	6/ 99 (6.1)	5.9	0.35 (0.07, 1.71)	0.1973	-3.77 (-12.19, 4.65)	0.3805	
>=10 mg/day	2/ 87 (2.3)	2.3	0/ 83 (0.0)	0.0	4.77 (0.23, 97.96)	0.3107	2.28 (-5.19, 9.76)	0.5491	
Result of type I IFN gene signature test									0.3457
LOW	0/ 30 (0.0)	0.0	2/ 31 (6.5)	6.5	0.21 (0.01, 4.13)	0.3020	-6.45 (-20.46, 7.56)	0.3668	
HIGH	4/150 (2.7)	2.6	4/151 (2.6)	2.5	1.01 (0.26, 3.95)	0.9924	0.16 (-5.56, 5.88)	0.9572	
Age (years)									NE
<= 65	4/175 (2.3)	2.3	6/181 (3.3)	3.2	0.69 (0.20, 2.40)	0.5593	-0.90 (-6.28, 4.48)	0.7432	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									0.6055
male	0/ 12 (0.0)	0.0	1/ 12 (8.3)	8.3	0.33 (0.01, 7.45)	0.4883	-8.33 (-37.28, 20.61)	0.5726	
female	4/168 (2.4)	2.4	5/170 (2.9)	2.8	0.81 (0.22, 2.96)	0.7496	-0.48 (-6.06, 5.10)	0.8662	
Race									0.6866
White	2/110 (1.8)	1.7	1/107 (0.9)	0.9	1.95 (0.18, 21.14)	0.5846	0.76 (-5.59, 7.11)	0.8146	
Black or African American	0/ 17 (0.0)	0.0	1/ 25 (4.0)	4.0	0.48 (0.02, 11.17)	0.6486	-4.00 (-22.36, 14.36)	0.6694	
Asian	0/ 30 (0.0)	0.0	2/ 30 (6.7)	6.7	0.20 (0.01, 4.00)	0.2923	-6.67 (-20.94, 7.61)	0.3601	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	1/ 11 (9.1)	9.1	1/ 11 (9.1)	9.1	1.00 (0.07, 14.05)	1.0000	0.00 (-33.43, 33.43)	1.0000	
Ethnicity									0.2091
Hispanic/Latino	2/ 54 (3.7)	3.5	1/ 54 (1.9)	2.0	2.00 (0.19, 21.41)	0.5666	1.45 (-10.43, 13.33)	0.8109	
Non-hispanic/Latino	1/118 (0.8)	0.8	4/120 (3.3)	3.2	0.25 (0.03, 2.24)	0.2175	-2.43 (-9.52, 4.65)	0.5008	
Geographic region									0.6933
EU	1/ 51 (2.0)	2.0	2/ 46 (4.3)	4.3	0.45 (0.04, 4.81)	0.5097	-2.39 (-12.40, 7.63)	0.6404	
non-EU	3/129 (2.3)	2.3	4/136 (2.9)	2.8	0.79 (0.18, 3.46)	0.7554	-0.51 (-7.25, 6.22)	0.8812	
Onset of disease									NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-24.92, 24.92)	1.0000	
Adult	4/166 (2.4)	2.4	6/170 (3.5)	3.4	0.68 (0.20, 2.38)	0.5486	-1.04 (-6.74, 4.65)	0.7195	
ADA result									0.9853
Negative	4/172 (2.3)	2.3	5/162 (3.1)	3.0	0.75 (0.21, 2.76)	0.6689	-0.68 (-6.33, 4.96)	0.8124	
Positive (At any time)	0/ 8 (0.0)	0.0	1/ 20 (5.0)	5.0	0.78 (0.03, 17.33)	0.8739	-5.00 (-34.61, 24.61)	0.7407	
BMI (kg/m2) at enrolment									0.2827
< 30	4/125 (3.2)	3.3	4/134 (3.0)	2.9	1.07 (0.27, 4.19)	0.9204	0.37 (-6.62, 7.36)	0.9174	
>= 30	0/ 55 (0.0)	0.0	2/ 48 (4.2)	3.5	0.17 (0.01, 3.56)	0.2567	-3.53 (-15.45, 8.39)	0.5618	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.1047
All negative/normal	3/ 58 (5.2)	5.3	2/ 81 (2.5)	2.3	2.09 (0.36, 12.14)	0.4095	2.94 (-7.67, 13.56)	0.5868	
At least one positive/abnormal	1/122 (0.8)	0.8	4/101 (4.0)	4.1	0.21 (0.02, 1.82)	0.1558	-3.26 (-9.77, 3.25)	0.3271	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - MACE
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	1 (0.6)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.03 (0.12, 73.97)	
p-value	0.4959	
Odds Ratio (95% CI)	3.05 (0.12, 75.37)	
p-value	0.4956	
Risk Difference (95% CI)	0.56 (-0.53, 1.64)	
p-value	0.3160	
CMH approach		
Response rate	0.5	0.0
Difference in response rates (95% CI)	0.53 (-4.00, 5.07)	
p-value	0.8175	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - MACE - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE		0.00 (-10.98, 10.98)	1.0000	
>= 10 points	1/126 (0.8)	0.8	0/130 (0.0)	0.0	3.09 (0.13, 75.26)	0.4878	0.76 (-4.33, 5.84)	0.7710	
OCS dose at baseline									NE
<10 mg/day	0/ 93 (0.0)	0.0	0/ 99 (0.0)	0.0	NE		0.00 (-7.00, 7.00)	1.0000	
>=10 mg/day	1/ 87 (1.1)	1.1	0/ 83 (0.0)	0.0	2.86 (0.12, 69.32)	0.5176	1.14 (-6.11, 8.38)	0.7586	
Result of type I IFN gene signature test									NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE		0.00 (-11.73, 11.73)	1.0000	
HIGH	1/150 (0.7)	0.6	0/151 (0.0)	0.0	3.02 (0.12, 73.54)	0.4975	0.64 (-4.26, 5.55)	0.7976	
Age (years)									NE
<= 65	1/175 (0.6)	0.5	0/181 (0.0)	0.0	3.10 (0.13, 75.64)	0.4872	0.55 (-4.06, 5.16)	0.8158	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
female	1/168 (0.6)	0.6	0/170 (0.0)	0.0	3.04 (0.12, 73.99)	0.4956	0.57 (-4.26, 5.40)	0.8171	
Race									NE
White	1/110 (0.9)	1.0	0/107 (0.0)	0.0	2.92 (0.12, 70.87)	0.5104	0.95 (-5.06, 6.96)	0.7560	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE		0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-28.41, 28.41)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE		0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	1/118 (0.8)	0.8	0/120 (0.0)	0.0	3.05 (0.13, 74.13)	0.4933	0.84 (-5.78, 7.47)	0.8031	
Geographic region									NE
EU	1/ 51 (2.0)	2.0	0/ 46 (0.0)	0.0	2.71 (0.11, 64.96)	0.5382	1.96 (-6.46, 10.38)	0.6481	
non-EU	0/129 (0.0)	0.0	0/136 (0.0)	0.0	NE		0.00 (-5.90, 5.90)	1.0000	
Onset of disease									NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-24.92, 24.92)	1.0000	
Adult	1/166 (0.6)	0.6	0/170 (0.0)	0.0	3.07 (0.13, 74.87)	0.4910	0.58 (-4.28, 5.44)	0.8139	
ADA result									NE
Negative	1/172 (0.6)	0.6	0/162 (0.0)	0.0	2.83 (0.12, 68.89)	0.5237	0.56 (-4.32, 5.44)	0.8225	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/125 (0.0)	0.0	0/134 (0.0)	0.0	NE		0.00 (-5.98, 5.98)	1.0000	
>= 30	1/ 55 (1.8)	1.8	0/ 48 (0.0)	0.0	2.63 (0.11, 62.97)	0.5517	1.84 (-9.95, 13.63)	0.7598	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE		0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	1/122 (0.8)	0.8	0/101 (0.0)	0.0	2.49 (0.10, 60.41)	0.5755	0.85 (-4.79, 6.49)	0.7684	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious MACE
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	1 (0.6)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.03 (0.12, 73.97)	
p-value	0.4959	
Odds Ratio (95% CI)	3.05 (0.12, 75.37)	
p-value	0.4956	
Risk Difference (95% CI)	0.56 (-0.53, 1.64)	
p-value	0.3160	
CMH approach		
Response rate	0.5	0.0
Difference in response rates (95% CI)	0.53 (-4.00, 5.07)	
p-value	0.8175	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious MACE - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE		0.00 (-10.98, 10.98)	1.0000	
>= 10 points	1/126 (0.8)	0.8	0/130 (0.0)	0.0	3.09 (0.13, 75.26)	0.4878	0.76 (-4.33, 5.84)	0.7710	
OCS dose at baseline									NE
<10 mg/day	0/ 93 (0.0)	0.0	0/ 99 (0.0)	0.0	NE		0.00 (-7.00, 7.00)	1.0000	
>=10 mg/day	1/ 87 (1.1)	1.1	0/ 83 (0.0)	0.0	2.86 (0.12, 69.32)	0.5176	1.14 (-6.11, 8.38)	0.7586	
Result of type I IFN gene signature test									NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE		0.00 (-11.73, 11.73)	1.0000	
HIGH	1/150 (0.7)	0.6	0/151 (0.0)	0.0	3.02 (0.12, 73.54)	0.4975	0.64 (-4.26, 5.55)	0.7976	
Age (years)									NE
<= 65	1/175 (0.6)	0.5	0/181 (0.0)	0.0	3.10 (0.13, 75.64)	0.4872	0.55 (-4.06, 5.16)	0.8158	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
female	1/168 (0.6)	0.6	0/170 (0.0)	0.0	3.04 (0.12, 73.99)	0.4956	0.57 (-4.26, 5.40)	0.8171	
Race									NE
White	1/110 (0.9)	1.0	0/107 (0.0)	0.0	2.92 (0.12, 70.87)	0.5104	0.95 (-5.06, 6.96)	0.7560	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE		0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-28.41, 28.41)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE		0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	1/118 (0.8)	0.8	0/120 (0.0)	0.0	3.05 (0.13, 74.13)	0.4933	0.84 (-5.78, 7.47)	0.8031	
Geographic region									NE
EU	1/ 51 (2.0)	2.0	0/ 46 (0.0)	0.0	2.71 (0.11, 64.96)	0.5382	1.96 (-6.46, 10.38)	0.6481	
non-EU	0/129 (0.0)	0.0	0/136 (0.0)	0.0	NE		0.00 (-5.90, 5.90)	1.0000	
Onset of disease									NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-24.92, 24.92)	1.0000	
Adult	1/166 (0.6)	0.6	0/170 (0.0)	0.0	3.07 (0.13, 74.87)	0.4910	0.58 (-4.28, 5.44)	0.8139	
ADA result									NE
Negative	1/172 (0.6)	0.6	0/162 (0.0)	0.0	2.83 (0.12, 68.89)	0.5237	0.56 (-4.32, 5.44)	0.8225	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/125 (0.0)	0.0	0/134 (0.0)	0.0	NE		0.00 (-5.98, 5.98)	1.0000	
>= 30	1/ 55 (1.8)	1.8	0/ 48 (0.0)	0.0	2.63 (0.11, 62.97)	0.5517	1.84 (-9.95, 13.63)	0.7598	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE		0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	1/122 (0.8)	0.8	0/101 (0.0)	0.0	2.49 (0.10, 60.41)	0.5755	0.85 (-4.79, 6.49)	0.7684	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe MACE
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	1 (0.6)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.03 (0.12, 73.97)	
p-value	0.4959	
Odds Ratio (95% CI)	3.05 (0.12, 75.37)	
p-value	0.4956	
Risk Difference (95% CI)	0.56 (-0.53, 1.64)	
p-value	0.3160	
CMH approach		
Response rate	0.5	0.0
Difference in response rates (95% CI)	0.53 (-4.00, 5.07)	
p-value	0.8175	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe MACE - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE		0.00 (-10.98, 10.98)	1.0000	
>= 10 points	1/126 (0.8)	0.8	0/130 (0.0)	0.0	3.09 (0.13, 75.26)	0.4878	0.76 (-4.33, 5.84)	0.7710	
OCS dose at baseline									NE
<10 mg/day	0/ 93 (0.0)	0.0	0/ 99 (0.0)	0.0	NE		0.00 (-7.00, 7.00)	1.0000	
>=10 mg/day	1/ 87 (1.1)	1.1	0/ 83 (0.0)	0.0	2.86 (0.12, 69.32)	0.5176	1.14 (-6.11, 8.38)	0.7586	
Result of type I IFN gene signature test									NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE		0.00 (-11.73, 11.73)	1.0000	
HIGH	1/150 (0.7)	0.6	0/151 (0.0)	0.0	3.02 (0.12, 73.54)	0.4975	0.64 (-4.26, 5.55)	0.7976	
Age (years)									NE
<= 65	1/175 (0.6)	0.5	0/181 (0.0)	0.0	3.10 (0.13, 75.64)	0.4872	0.55 (-4.06, 5.16)	0.8158	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
female	1/168 (0.6)	0.6	0/170 (0.0)	0.0	3.04 (0.12, 73.99)	0.4956	0.57 (-4.26, 5.40)	0.8171	
Race									NE
White	1/110 (0.9)	1.0	0/107 (0.0)	0.0	2.92 (0.12, 70.87)	0.5104	0.95 (-5.06, 6.96)	0.7560	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE		0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-28.41, 28.41)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE		0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	1/118 (0.8)	0.8	0/120 (0.0)	0.0	3.05 (0.13, 74.13)	0.4933	0.84 (-5.78, 7.47)	0.8031	
Geographic region									NE
EU	1/ 51 (2.0)	2.0	0/ 46 (0.0)	0.0	2.71 (0.11, 64.96)	0.5382	1.96 (-6.46, 10.38)	0.6481	
non-EU	0/129 (0.0)	0.0	0/136 (0.0)	0.0	NE		0.00 (-5.90, 5.90)	1.0000	
Onset of disease									NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-24.92, 24.92)	1.0000	
Adult	1/166 (0.6)	0.6	0/170 (0.0)	0.0	3.07 (0.13, 74.87)	0.4910	0.58 (-4.28, 5.44)	0.8139	
ADA result									NE
Negative	1/172 (0.6)	0.6	0/162 (0.0)	0.0	2.83 (0.12, 68.89)	0.5237	0.56 (-4.32, 5.44)	0.8225	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/125 (0.0)	0.0	0/134 (0.0)	0.0	NE		0.00 (-5.98, 5.98)	1.0000	
>= 30	1/ 55 (1.8)	1.8	0/ 48 (0.0)	0.0	2.63 (0.11, 62.97)	0.5517	1.84 (-9.95, 13.63)	0.7598	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE		0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	1/122 (0.8)	0.8	0/101 (0.0)	0.0	2.49 (0.10, 60.41)	0.5755	0.85 (-4.79, 6.49)	0.7684	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe MACE
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.43, 4.43)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe MACE - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.98, 10.98)	1.0000	
>= 10 points	0/126 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.90, 4.90)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 93 (0.0)	0.0	0/ 99 (0.0)	0.0	NE	0.00 (-7.00, 7.00)	1.0000	
>=10 mg/day	0/ 87 (0.0)	0.0	0/ 83 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE	0.00 (-11.73, 11.73)	1.0000	
HIGH	0/150 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Age (years)								NE
<= 65	0/175 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.50, 4.50)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-102.70, 102.70)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
female	0/168 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.71, 4.71)	1.0000	
Race								NE
White	0/110 (0.0)	0.0	0/107 (0.0)	0.0	NE	0.00 (-5.75, 5.75)	1.0000	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE	0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE	0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-28.41, 28.41)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	0/118 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.46, 6.46)	1.0000	
Geographic region								NE
EU	0/ 51 (0.0)	0.0	0/ 46 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
non-EU	0/129 (0.0)	0.0	0/136 (0.0)	0.0	NE	0.00 (-5.90, 5.90)	1.0000	
Onset of disease								NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-24.92, 24.92)	1.0000	
Adult	0/166 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.74, 4.74)	1.0000	
ADA result								NE
Negative	0/172 (0.0)	0.0	0/162 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE	0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/125 (0.0)	0.0	0/134 (0.0)	0.0	NE	0.00 (-5.98, 5.98)	1.0000	
>= 30	0/ 55 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-11.37, 11.37)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE	0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	0/122 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-5.42, 5.42)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	5 (2.8)	10 (5.5)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.51 (0.18, 1.45)	
p-value	0.2045	
Odds Ratio (95% CI)	0.49 (0.16, 1.47)	
p-value	0.2031	
Risk Difference (95% CI)	-2.72 (-6.81, 1.37)	
p-value	0.1929	
CMH approach		
Response rate	2.8	5.5
Difference in response rates (95% CI)	-2.74 (-8.51, 3.04)	
p-value	0.3532	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.6383
< 10 points	1/ 54 (1.9)	1.8	3/ 52 (5.8)	5.8	0.32 (0.03, 2.99)	0.3181	-3.97 (-16.47, 8.53)	0.5340	
>= 10 points	4/126 (3.2)	3.2	7/130 (5.4)	5.4	0.59 (0.18, 1.96)	0.3896	-2.22 (-8.93, 4.50)	0.5177	
OCS dose at baseline									0.9205
<10 mg/day	2/ 93 (2.2)	2.2	4/ 99 (4.0)	4.0	0.53 (0.10, 2.84)	0.4602	-1.78 (-10.08, 6.52)	0.6742	
>=10 mg/day	3/ 87 (3.4)	3.5	6/ 83 (7.2)	7.3	0.48 (0.12, 1.85)	0.2836	-3.77 (-12.91, 5.37)	0.4185	
Result of type I IFN gene signature test									0.2341
LOW	1/ 30 (3.3)	3.3	0/ 31 (0.0)	0.0	3.10 (0.13, 73.16)	0.4836	3.33 (-9.70, 16.36)	0.6161	
HIGH	4/150 (2.7)	2.7	10/151 (6.6)	6.7	0.40 (0.13, 1.26)	0.1170	-3.97 (-10.39, 2.46)	0.2261	
Age (years)									0.5639
<= 65	4/175 (2.3)	2.3	10/181 (5.5)	5.6	0.41 (0.13, 1.29)	0.1294	-3.31 (-9.09, 2.46)	0.2605	
> 65	1/ 5 (20.0)	20.0	0/ 1 (0.0)	0.0	1.00 (0.06, 15.99)	1.0000	20.00 (-84.53, 124.53)	0.7077	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
female	5/168 (3.0)	3.0	10/170 (5.9)	5.9	0.51 (0.18, 1.45)	0.2044	-2.94 (-9.08, 3.20)	0.3485	
Race									0.5485
White	5/110 (4.5)	4.6	6/107 (5.6)	5.9	0.81 (0.25, 2.58)	0.7220	-1.37 (-9.24, 6.51)	0.7335	
Black or African American	0/ 17 (0.0)	0.0	1/ 25 (4.0)	4.0	0.48 (0.02, 11.17)	0.6486	-4.00 (-22.36, 14.36)	0.6694	
Asian	0/ 30 (0.0)	0.0	3/ 30 (10.0)	10.0	0.14 (0.01, 2.65)	0.1917	-10.00 (-25.22, 5.22)	0.1977	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-28.41, 28.41)	1.0000	
Ethnicity									0.7045
Hispanic/Latino	2/ 54 (3.7)	3.9	3/ 54 (5.6)	5.6	0.67 (0.12, 3.83)	0.6496	-1.75 (-14.25, 10.75)	0.7833	
Non-hispanic/Latino	3/118 (2.5)	2.6	7/120 (5.8)	5.9	0.44 (0.12, 1.65)	0.2205	-3.29 (-11.11, 4.53)	0.4094	
Geographic region									0.4286
EU	0/ 51 (0.0)	0.0	2/ 46 (4.3)	4.3	0.18 (0.01, 3.67)	0.2655	-4.35 (-13.72, 5.03)	0.3633	
non-EU	5/129 (3.9)	3.9	8/136 (5.9)	6.0	0.66 (0.22, 1.96)	0.4536	-2.02 (-9.44, 5.40)	0.5937	
Onset of disease									0.2261
Paediatric	2/ 14 (14.3)	14.3	1/ 12 (8.3)	8.3	1.71 (0.18, 16.65)	0.6421	5.95 (-25.06, 36.97)	0.7068	
Adult	3/166 (1.8)	1.8	9/170 (5.3)	5.3	0.34 (0.09, 1.24)	0.1022	-3.55 (-9.44, 2.35)	0.2382	
ADA result									0.6542
Negative	5/172 (2.9)	2.9	7/162 (4.3)	4.4	0.67 (0.22, 2.08)	0.4908	-1.48 (-7.46, 4.51)	0.6286	
Positive (At any time)	0/ 8 (0.0)	0.0	3/ 20 (15.0)	15.0	0.33 (0.02, 5.81)	0.4513	-15.00 (-46.36, 16.36)	0.3486	
BMI (kg/m2) at enrolment									0.5799
< 30	2/125 (1.6)	1.6	6/134 (4.5)	4.4	0.36 (0.07, 1.74)	0.2022	-2.76 (-9.73, 4.21)	0.4376	
>= 30	3/ 55 (5.5)	5.9	4/ 48 (8.3)	9.3	0.65 (0.15, 2.78)	0.5657	-3.44 (-17.50, 10.63)	0.6320	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.0334
All negative/normal	4/ 58 (6.9)	7.3	3/ 81 (3.7)	3.7	1.86 (0.43, 8.01)	0.4035	3.69 (-7.52, 14.90)	0.5189	
At least one positive/abnormal	1/122 (0.8)	0.8	7/101 (6.9)	6.9	0.12 (0.01, 0.95)	0.0441	-6.06 (-13.17, 1.06)	0.0952	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Non-opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	5 (2.8)	10 (5.5)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.51 (0.18, 1.45)	
p-value	0.2045	
Odds Ratio (95% CI)	0.49 (0.16, 1.47)	
p-value	0.2031	
Risk Difference (95% CI)	-2.72 (-6.81, 1.37)	
p-value	0.1929	
CMH approach		
Response rate	2.8	5.5
Difference in response rates (95% CI)	-2.74 (-8.51, 3.04)	
p-value	0.3532	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Non-opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.6383
< 10 points	1/ 54 (1.9)	1.8	3/ 52 (5.8)	5.8	0.32 (0.03, 2.99)	0.3181	-3.97 (-16.47, 8.53)	0.5340	
>= 10 points	4/126 (3.2)	3.2	7/130 (5.4)	5.4	0.59 (0.18, 1.96)	0.3896	-2.22 (-8.93, 4.50)	0.5177	
OCS dose at baseline									0.9205
<10 mg/day	2/ 93 (2.2)	2.2	4/ 99 (4.0)	4.0	0.53 (0.10, 2.84)	0.4602	-1.78 (-10.08, 6.52)	0.6742	
>=10 mg/day	3/ 87 (3.4)	3.5	6/ 83 (7.2)	7.3	0.48 (0.12, 1.85)	0.2836	-3.77 (-12.91, 5.37)	0.4185	
Result of type I IFN gene signature test									0.2341
LOW	1/ 30 (3.3)	3.3	0/ 31 (0.0)	0.0	3.10 (0.13, 73.16)	0.4836	3.33 (-9.70, 16.36)	0.6161	
HIGH	4/150 (2.7)	2.7	10/151 (6.6)	6.7	0.40 (0.13, 1.26)	0.1170	-3.97 (-10.39, 2.46)	0.2261	
Age (years)									0.5639
<= 65	4/175 (2.3)	2.3	10/181 (5.5)	5.6	0.41 (0.13, 1.29)	0.1294	-3.31 (-9.09, 2.46)	0.2605	
> 65	1/ 5 (20.0)	20.0	0/ 1 (0.0)	0.0	1.00 (0.06, 15.99)	1.0000	20.00 (-84.53, 124.53)	0.7077	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
female	5/168 (3.0)	3.0	10/170 (5.9)	5.9	0.51 (0.18, 1.45)	0.2044	-2.94 (-9.08, 3.20)	0.3485	
Race									0.5485
White	5/110 (4.5)	4.6	6/107 (5.6)	5.9	0.81 (0.25, 2.58)	0.7220	-1.37 (-9.24, 6.51)	0.7335	
Black or African American	0/ 17 (0.0)	0.0	1/ 25 (4.0)	4.0	0.48 (0.02, 11.17)	0.6486	-4.00 (-22.36, 14.36)	0.6694	
Asian	0/ 30 (0.0)	0.0	3/ 30 (10.0)	10.0	0.14 (0.01, 2.65)	0.1917	-10.00 (-25.22, 5.22)	0.1977	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-28.41, 28.41)	1.0000	
Ethnicity									0.7045
Hispanic/Latino	2/ 54 (3.7)	3.9	3/ 54 (5.6)	5.6	0.67 (0.12, 3.83)	0.6496	-1.75 (-14.25, 10.75)	0.7833	
Non-hispanic/Latino	3/118 (2.5)	2.6	7/120 (5.8)	5.9	0.44 (0.12, 1.65)	0.2205	-3.29 (-11.11, 4.53)	0.4094	
Geographic region									0.4286
EU	0/ 51 (0.0)	0.0	2/ 46 (4.3)	4.3	0.18 (0.01, 3.67)	0.2655	-4.35 (-13.72, 5.03)	0.3633	
non-EU	5/129 (3.9)	3.9	8/136 (5.9)	6.0	0.66 (0.22, 1.96)	0.4536	-2.02 (-9.44, 5.40)	0.5937	
Onset of disease									0.2261
Paediatric	2/ 14 (14.3)	14.3	1/ 12 (8.3)	8.3	1.71 (0.18, 16.65)	0.6421	5.95 (-25.06, 36.97)	0.7068	
Adult	3/166 (1.8)	1.8	9/170 (5.3)	5.3	0.34 (0.09, 1.24)	0.1022	-3.55 (-9.44, 2.35)	0.2382	
ADA result									0.6542
Negative	5/172 (2.9)	2.9	7/162 (4.3)	4.4	0.67 (0.22, 2.08)	0.4908	-1.48 (-7.46, 4.51)	0.6286	
Positive (At any time)	0/ 8 (0.0)	0.0	3/ 20 (15.0)	15.0	0.33 (0.02, 5.81)	0.4513	-15.00 (-46.36, 16.36)	0.3486	
BMI (kg/m2) at enrolment									0.5799
< 30	2/125 (1.6)	1.6	6/134 (4.5)	4.4	0.36 (0.07, 1.74)	0.2022	-2.76 (-9.73, 4.21)	0.4376	
>= 30	3/ 55 (5.5)	5.9	4/ 48 (8.3)	9.3	0.65 (0.15, 2.78)	0.5657	-3.44 (-17.50, 10.63)	0.6320	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.0334
All negative/normal	4/ 58 (6.9)	7.3	3/ 81 (3.7)	3.7	1.86 (0.43, 8.01)	0.4035	3.69 (-7.52, 14.90)	0.5189	
At least one positive/abnormal	1/122 (0.8)	0.8	7/101 (6.9)	6.9	0.12 (0.01, 0.95)	0.0441	-6.06 (-13.17, 1.06)	0.0952	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Non-opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	2 (1.1)	2 (1.1)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.01 (0.14, 7.10)	
p-value	0.9911	
Odds Ratio (95% CI)	1.01 (0.14, 7.26)	
p-value	0.9911	
Risk Difference (95% CI)	0.01 (-2.14, 2.17)	
p-value	0.9911	
CMH approach		
Response rate	1.1	1.1
Difference in response rates (95% CI)	-0.04 (-4.85, 4.77)	
p-value	0.9873	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Non-opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9723
< 10 points	1/ 54 (1.9)	1.8	1/ 52 (1.9)	1.9	0.96 (0.06, 15.00)	0.9785	-0.10 (-11.86, 11.67)	0.9871	
>= 10 points	1/126 (0.8)	0.8	1/130 (0.8)	0.8	1.03 (0.07, 16.32)	0.9823	-0.01 (-5.26, 5.25)	0.9983	
OCS dose at baseline									NE
<10 mg/day	0/ 93 (0.0)	0.0	0/ 99 (0.0)	0.0	NE		0.00 (-7.00, 7.00)	1.0000	
>=10 mg/day	2/ 87 (2.3)	2.4	2/ 83 (2.4)	2.4	0.95 (0.14, 6.62)	0.9620	-0.04 (-7.95, 7.87)	0.9920	
Result of type I IFN gene signature test									0.3690
LOW	1/ 30 (3.3)	3.3	0/ 31 (0.0)	0.0	3.10 (0.13, 73.16)	0.4836	3.33 (-9.70, 16.36)	0.6161	
HIGH	1/150 (0.7)	0.6	2/151 (1.3)	1.4	0.50 (0.05, 5.49)	0.5734	-0.72 (-5.87, 4.42)	0.7828	
Age (years)									NE
<= 65	2/175 (1.1)	1.1	2/181 (1.1)	1.2	1.03 (0.15, 7.26)	0.9730	-0.02 (-4.91, 4.88)	0.9951	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
female	2/168 (1.2)	1.2	2/170 (1.2)	1.2	1.01 (0.14, 7.10)	0.9905	-0.00 (-5.12, 5.12)	0.9993	
Race									NE
White	2/110 (1.8)	1.7	2/107 (1.9)	2.1	0.97 (0.14, 6.78)	0.9777	-0.35 (-6.89, 6.19)	0.9167	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE		0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-28.41, 28.41)	1.0000	
Ethnicity									0.9932
Hispanic/Latino	1/ 54 (1.9)	2.1	1/ 54 (1.9)	2.0	1.00 (0.06, 15.58)	1.0000	0.13 (-11.32, 11.58)	0.9826	
Non-hispanic/Latino	1/118 (0.8)	0.8	1/120 (0.8)	0.9	1.02 (0.06, 16.07)	0.9905	-0.08 (-6.79, 6.62)	0.9803	
Geographic region									NE
EU	0/ 51 (0.0)	0.0	0/ 46 (0.0)	0.0	NE		0.00 (-7.65, 7.65)	1.0000	
non-EU	2/129 (1.6)	1.6	2/136 (1.5)	1.5	1.05 (0.15, 7.37)	0.9575	0.04 (-6.35, 6.43)	0.9903	
Onset of disease									0.9276
Paediatric	1/ 14 (7.1)	7.1	1/ 12 (8.3)	8.3	0.86 (0.06, 12.28)	0.9097	-1.19 (-30.67, 28.28)	0.9369	
Adult	1/166 (0.6)	0.6	1/170 (0.6)	0.6	1.02 (0.06, 16.24)	0.9865	0.00 (-4.92, 4.92)	1.0000	
ADA result									0.6581
Negative	2/172 (1.2)	1.1	1/162 (0.6)	0.7	1.88 (0.17, 20.58)	0.6037	0.44 (-4.60, 5.49)	0.8641	
Positive (At any time)	0/ 8 (0.0)	0.0	1/ 20 (5.0)	5.0	0.78 (0.03, 17.33)	0.8739	-5.00 (-34.61, 24.61)	0.7407	
BMI (kg/m2) at enrolment									0.3248
< 30	1/125 (0.8)	0.8	0/134 (0.0)	0.0	3.21 (0.13, 78.18)	0.4733	0.80 (-5.29, 6.90)	0.7967	
>= 30	1/ 55 (1.8)	2.2	2/ 48 (4.2)	4.7	0.44 (0.04, 4.66)	0.4927	-2.45 (-15.14, 10.23)	0.7046	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.7925
All negative/normal	1/ 58 (1.7)	1.8	1/ 81 (1.2)	1.4	1.40 (0.09, 21.87)	0.8119	0.34 (-9.37, 10.04)	0.9460	
At least one positive/abnormal	1/122 (0.8)	0.8	1/101 (1.0)	1.0	0.83 (0.05, 13.07)	0.8933	-0.16 (-6.01, 5.69)	0.9568	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Non-opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	3 (1.7)	8 (4.4)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.38 (0.10, 1.41)	
p-value	0.1470	
Odds Ratio (95% CI)	0.37 (0.10, 1.41)	
p-value	0.1454	
Risk Difference (95% CI)	-2.73 (-6.25, 0.79)	
p-value	0.1283	
CMH approach		
Response rate	1.7	4.4
Difference in response rates (95% CI)	-2.70 (-8.18, 2.78)	
p-value	0.3349	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Non-opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.5596
< 10 points	0/ 54 (0.0)	0.0	2/ 52 (3.8)	3.9	0.19 (0.01, 3.92)	0.2841	-3.87 (-15.68, 7.94)	0.5206	
>= 10 points	3/126 (2.4)	2.4	6/130 (4.6)	4.6	0.52 (0.13, 2.02)	0.3416	-2.21 (-8.66, 4.24)	0.5019	
OCS dose at baseline									0.5660
<10 mg/day	2/ 93 (2.2)	2.2	4/ 99 (4.0)	4.0	0.53 (0.10, 2.84)	0.4602	-1.78 (-10.08, 6.52)	0.6742	
>=10 mg/day	1/ 87 (1.1)	1.1	4/ 83 (4.8)	4.9	0.24 (0.03, 2.09)	0.1956	-3.73 (-12.11, 4.64)	0.3824	
Result of type I IFN gene signature test									NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE		0.00 (-11.73, 11.73)	1.0000	
HIGH	3/150 (2.0)	2.1	8/151 (5.3)	5.3	0.38 (0.10, 1.40)	0.1442	-3.24 (-9.39, 2.90)	0.3011	
Age (years)									0.4028
<= 65	2/175 (1.1)	1.2	8/181 (4.4)	4.5	0.26 (0.06, 1.20)	0.0843	-3.30 (-8.76, 2.17)	0.2368	
> 65	1/ 5 (20.0)	20.0	0/ 1 (0.0)	0.0	1.00 (0.06, 15.99)	1.0000	20.00 (-84.53, 124.53)	0.7077	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
female	3/168 (1.8)	1.8	8/170 (4.7)	4.7	0.38 (0.10, 1.41)	0.1470	-2.93 (-8.76, 2.89)	0.3236	
Race									0.6198
White	3/110 (2.7)	2.9	4/107 (3.7)	3.9	0.73 (0.17, 3.18)	0.6748	-1.02 (-8.30, 6.26)	0.7838	
Black or African American	0/ 17 (0.0)	0.0	1/ 25 (4.0)	4.0	0.48 (0.02, 11.17)	0.6486	-4.00 (-22.36, 14.36)	0.6694	
Asian	0/ 30 (0.0)	0.0	3/ 30 (10.0)	10.0	0.14 (0.01, 2.65)	0.1917	-10.00 (-25.22, 5.22)	0.1977	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-28.41, 28.41)	1.0000	
Ethnicity									0.7892
Hispanic/Latino	1/ 54 (1.9)	1.7	2/ 54 (3.7)	3.6	0.50 (0.05, 5.35)	0.5666	-1.88 (-13.62, 9.86)	0.7534	
Non-hispanic/Latino	2/118 (1.7)	1.8	6/120 (5.0)	5.0	0.34 (0.07, 1.65)	0.1796	-3.21 (-10.82, 4.40)	0.4090	
Geographic region									0.5257
EU	0/ 51 (0.0)	0.0	2/ 46 (4.3)	4.3	0.18 (0.01, 3.67)	0.2655	-4.35 (-13.72, 5.03)	0.3633	
non-EU	3/129 (2.3)	2.4	6/136 (4.4)	4.4	0.53 (0.13, 2.06)	0.3578	-2.06 (-9.08, 4.96)	0.5654	
Onset of disease									0.1906
Paediatric	1/ 14 (7.1)	7.1	0/ 12 (0.0)	0.0	2.60 (0.12, 58.48)	0.5475	7.14 (-19.90, 34.18)	0.6047	
Adult	2/166 (1.2)	1.2	8/170 (4.7)	4.8	0.26 (0.06, 1.19)	0.0818	-3.55 (-9.30, 2.21)	0.2270	
ADA result									0.9956
Negative	3/172 (1.7)	1.8	6/162 (3.7)	3.7	0.47 (0.12, 1.85)	0.2810	-1.92 (-7.67, 3.84)	0.5139	
Positive (At any time)	0/ 8 (0.0)	0.0	2/ 20 (10.0)	10.0	0.47 (0.02, 8.78)	0.6107	-10.00 (-40.56, 20.56)	0.5212	
BMI (kg/m2) at enrolment									0.2751
< 30	1/125 (0.8)	0.8	6/134 (4.5)	4.4	0.18 (0.02, 1.46)	0.1085	-3.56 (-10.43, 3.31)	0.3095	
>= 30	2/ 55 (3.6)	3.7	2/ 48 (4.2)	4.7	0.87 (0.13, 5.96)	0.8896	-0.98 (-14.02, 12.05)	0.8825	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.0417
All negative/normal	3/ 58 (5.2)	5.6	2/ 81 (2.5)	2.2	2.09 (0.36, 12.14)	0.4095	3.35 (-7.28, 13.99)	0.5366	
At least one positive/abnormal	0/122 (0.0)	0.0	6/101 (5.9)	5.9	0.06 (0.00, 1.12)	0.0597	-5.89 (-12.68, 0.89)	0.0888	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.43, 4.43)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.98, 10.98)	1.0000	
>= 10 points	0/126 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.90, 4.90)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 93 (0.0)	0.0	0/ 99 (0.0)	0.0	NE	0.00 (-7.00, 7.00)	1.0000	
>=10 mg/day	0/ 87 (0.0)	0.0	0/ 83 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE	0.00 (-11.73, 11.73)	1.0000	
HIGH	0/150 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Age (years)								NE
<= 65	0/175 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.50, 4.50)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-102.70, 102.70)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
female	0/168 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.71, 4.71)	1.0000	
Race								NE
White	0/110 (0.0)	0.0	0/107 (0.0)	0.0	NE	0.00 (-5.75, 5.75)	1.0000	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE	0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE	0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-28.41, 28.41)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	0/118 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.46, 6.46)	1.0000	
Geographic region								NE
EU	0/ 51 (0.0)	0.0	0/ 46 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
non-EU	0/129 (0.0)	0.0	0/136 (0.0)	0.0	NE	0.00 (-5.90, 5.90)	1.0000	
Onset of disease								NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-24.92, 24.92)	1.0000	
Adult	0/166 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.74, 4.74)	1.0000	
ADA result								NE
Negative	0/172 (0.0)	0.0	0/162 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE	0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/125 (0.0)	0.0	0/134 (0.0)	0.0	NE	0.00 (-5.98, 5.98)	1.0000	
>= 30	0/ 55 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-11.37, 11.37)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE	0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	0/122 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-5.42, 5.42)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.43, 4.43)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Anifrolumab 300mg (N=180) Response rate	Placebo (N=182) n/ N (%)	Placebo (N=182) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Analysis Anifrolumab 300mg vs. Placebo Difference in response rates (95% CI)	Analysis Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.98, 10.98)	1.0000	
>= 10 points	0/126 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.90, 4.90)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 93 (0.0)	0.0	0/ 99 (0.0)	0.0	NE	0.00 (-7.00, 7.00)	1.0000	
>=10 mg/day	0/ 87 (0.0)	0.0	0/ 83 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE	0.00 (-11.73, 11.73)	1.0000	
HIGH	0/150 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Age (years)								NE
<= 65	0/175 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.50, 4.50)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-102.70, 102.70)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
female	0/168 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.71, 4.71)	1.0000	
Race								NE
White	0/110 (0.0)	0.0	0/107 (0.0)	0.0	NE	0.00 (-5.75, 5.75)	1.0000	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE	0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE	0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-28.41, 28.41)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	0/118 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.46, 6.46)	1.0000	
Geographic region								NE
EU	0/ 51 (0.0)	0.0	0/ 46 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
non-EU	0/129 (0.0)	0.0	0/136 (0.0)	0.0	NE	0.00 (-5.90, 5.90)	1.0000	
Onset of disease								NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-24.92, 24.92)	1.0000	
Adult	0/166 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.74, 4.74)	1.0000	
ADA result								NE
Negative	0/172 (0.0)	0.0	0/162 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE	0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/125 (0.0)	0.0	0/134 (0.0)	0.0	NE	0.00 (-5.98, 5.98)	1.0000	
>= 30	0/ 55 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-11.37, 11.37)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE	0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	0/122 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-5.42, 5.42)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.43, 4.43)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.98, 10.98)	1.0000	
>= 10 points	0/126 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.90, 4.90)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 93 (0.0)	0.0	0/ 99 (0.0)	0.0	NE	0.00 (-7.00, 7.00)	1.0000	
>=10 mg/day	0/ 87 (0.0)	0.0	0/ 83 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE	0.00 (-11.73, 11.73)	1.0000	
HIGH	0/150 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Age (years)								NE
<= 65	0/175 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.50, 4.50)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-102.70, 102.70)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
female	0/168 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.71, 4.71)	1.0000	
Race								NE
White	0/110 (0.0)	0.0	0/107 (0.0)	0.0	NE	0.00 (-5.75, 5.75)	1.0000	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE	0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE	0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-28.41, 28.41)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	0/118 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.46, 6.46)	1.0000	
Geographic region								NE
EU	0/ 51 (0.0)	0.0	0/ 46 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
non-EU	0/129 (0.0)	0.0	0/136 (0.0)	0.0	NE	0.00 (-5.90, 5.90)	1.0000	
Onset of disease								NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-24.92, 24.92)	1.0000	
Adult	0/166 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.74, 4.74)	1.0000	
ADA result								NE
Negative	0/172 (0.0)	0.0	0/162 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE	0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/125 (0.0)	0.0	0/134 (0.0)	0.0	NE	0.00 (-5.98, 5.98)	1.0000	
>= 30	0/ 55 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-11.37, 11.37)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE	0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	0/122 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-5.42, 5.42)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.43, 4.43)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.98, 10.98)	1.0000	
>= 10 points	0/126 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.90, 4.90)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 93 (0.0)	0.0	0/ 99 (0.0)	0.0	NE	0.00 (-7.00, 7.00)	1.0000	
>=10 mg/day	0/ 87 (0.0)	0.0	0/ 83 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE	0.00 (-11.73, 11.73)	1.0000	
HIGH	0/150 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Age (years)								NE
<= 65	0/175 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.50, 4.50)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-102.70, 102.70)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
female	0/168 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.71, 4.71)	1.0000	
Race								NE
White	0/110 (0.0)	0.0	0/107 (0.0)	0.0	NE	0.00 (-5.75, 5.75)	1.0000	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE	0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE	0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-28.41, 28.41)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	0/118 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.46, 6.46)	1.0000	
Geographic region								NE
EU	0/ 51 (0.0)	0.0	0/ 46 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
non-EU	0/129 (0.0)	0.0	0/136 (0.0)	0.0	NE	0.00 (-5.90, 5.90)	1.0000	
Onset of disease								NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-24.92, 24.92)	1.0000	
Adult	0/166 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.74, 4.74)	1.0000	
ADA result								NE
Negative	0/172 (0.0)	0.0	0/162 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE	0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/125 (0.0)	0.0	0/134 (0.0)	0.0	NE	0.00 (-5.98, 5.98)	1.0000	
>= 30	0/ 55 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-11.37, 11.37)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE	0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	0/122 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-5.42, 5.42)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	6 (3.3)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	13.14 (0.75, 231.60)	
p-value	0.0785	
Odds Ratio (95% CI)	13.60 (0.76, 243.15)	
p-value	0.0761	
Risk Difference (95% CI)	3.33 (0.71, 5.96)	
p-value	0.0127	
CMH approach		
Response rate	3.3	0.0
Difference in response rates (95% CI)	3.35 (-1.68, 8.38)	
p-value	0.1923	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.5324
< 10 points	1/ 54 (1.9)	1.8	0/ 52 (0.0)	0.0	2.89 (0.12, 69.40)	0.5127	1.84 (-9.53, 13.22)	0.7510	
>= 10 points	5/126 (4.0)	4.0	0/130 (0.0)	0.0	11.35 (0.63, 203.09)	0.0989	3.98 (-1.82, 9.78)	0.1782	
OCS dose at baseline									0.9594
<10 mg/day	3/ 93 (3.2)	3.2	0/ 99 (0.0)	0.0	7.45 (0.39, 142.25)	0.1822	3.24 (-4.47, 10.96)	0.4099	
>=10 mg/day	3/ 87 (3.4)	3.5	0/ 83 (0.0)	0.0	6.68 (0.35, 127.42)	0.2067	3.51 (-4.18, 11.20)	0.3707	
Result of type I IFN gene signature test									0.5597
LOW	1/ 30 (3.3)	3.3	0/ 31 (0.0)	0.0	3.10 (0.13, 73.16)	0.4836	3.33 (-9.70, 16.36)	0.6161	
HIGH	5/150 (3.3)	3.4	0/151 (0.0)	0.0	11.07 (0.62, 198.50)	0.1025	3.35 (-2.10, 8.80)	0.2278	
Age (years)									NE
<= 65	6/175 (3.4)	3.4	0/181 (0.0)	0.0	13.44 (0.76, 236.85)	0.0759	3.45 (-1.68, 8.58)	0.1875	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
female	6/168 (3.6)	3.6	0/170 (0.0)	0.0	13.15 (0.75, 231.66)	0.0783	3.58 (-1.78, 8.93)	0.1903	
Race									0.8259
White	3/110 (2.7)	2.7	0/107 (0.0)	0.0	6.81 (0.36, 130.30)	0.2026	2.66 (-3.67, 8.99)	0.4101	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE		0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	2/ 4 (50.0)	50.0	0/ 1 (0.0)	0.0	2.00 (0.16, 25.75)	0.5950	50.00 (-57.80, 157.80)	0.3633	
Other	1/ 11 (9.1)	9.1	0/ 11 (0.0)	0.0	3.00 (0.14, 66.53)	0.4872	9.09 (-21.93, 40.11)	0.5657	
Ethnicity									0.7893
Hispanic/Latino	4/ 54 (7.4)	7.2	0/ 54 (0.0)	0.0	9.00 (0.50, 163.20)	0.1372	7.25 (-4.77, 19.26)	0.2373	
Non-hispanic/Latino	2/118 (1.7)	1.6	0/120 (0.0)	0.0	5.08 (0.25, 104.78)	0.2922	1.64 (-5.11, 8.38)	0.6342	
Geographic region									0.7287
EU	2/ 51 (3.9)	3.9	0/ 46 (0.0)	0.0	4.52 (0.22, 91.74)	0.3261	3.92 (-5.18, 13.02)	0.3985	
non-EU	4/129 (3.1)	3.2	0/136 (0.0)	0.0	9.48 (0.52, 174.43)	0.1300	3.18 (-3.32, 9.67)	0.3374	
Onset of disease									NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-24.92, 24.92)	1.0000	
Adult	6/166 (3.6)	3.6	0/170 (0.0)	0.0	13.31 (0.76, 234.43)	0.0769	3.61 (-1.78, 9.00)	0.1891	
ADA result									NE
Negative	6/172 (3.5)	3.5	0/162 (0.0)	0.0	12.25 (0.70, 215.70)	0.0869	3.53 (-1.86, 8.92)	0.1996	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment									0.9241
< 30	3/125 (2.4)	2.4	0/134 (0.0)	0.0	7.50 (0.39, 143.76)	0.1811	2.44 (-4.02, 8.90)	0.4593	
>= 30	3/ 55 (5.5)	5.5	0/ 48 (0.0)	0.0	6.13 (0.32, 115.66)	0.2267	5.49 (-6.88, 17.86)	0.3846	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.6057
All negative/normal	4/ 58 (6.9)	7.0	0/ 81 (0.0)	0.0	12.51 (0.69, 227.90)	0.0880	7.04 (-3.54, 17.63)	0.1922	
At least one positive/abnormal	2/122 (1.6)	1.7	0/101 (0.0)	0.0	4.15 (0.20, 85.39)	0.3568	1.70 (-4.16, 7.55)	0.5703	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.43, 4.43)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.98, 10.98)	1.0000	
>= 10 points	0/126 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.90, 4.90)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 93 (0.0)	0.0	0/ 99 (0.0)	0.0	NE	0.00 (-7.00, 7.00)	1.0000	
>=10 mg/day	0/ 87 (0.0)	0.0	0/ 83 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE	0.00 (-11.73, 11.73)	1.0000	
HIGH	0/150 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Age (years)								NE
<= 65	0/175 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.50, 4.50)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-102.70, 102.70)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
female	0/168 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.71, 4.71)	1.0000	
Race								NE
White	0/110 (0.0)	0.0	0/107 (0.0)	0.0	NE	0.00 (-5.75, 5.75)	1.0000	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE	0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE	0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-28.41, 28.41)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	0/118 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.46, 6.46)	1.0000	
Geographic region								NE
EU	0/ 51 (0.0)	0.0	0/ 46 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
non-EU	0/129 (0.0)	0.0	0/136 (0.0)	0.0	NE	0.00 (-5.90, 5.90)	1.0000	
Onset of disease								NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-24.92, 24.92)	1.0000	
Adult	0/166 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.74, 4.74)	1.0000	
ADA result								NE
Negative	0/172 (0.0)	0.0	0/162 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE	0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/125 (0.0)	0.0	0/134 (0.0)	0.0	NE	0.00 (-5.98, 5.98)	1.0000	
>= 30	0/ 55 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-11.37, 11.37)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE	0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	0/122 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-5.42, 5.42)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.43, 4.43)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.98, 10.98)	1.0000	
>= 10 points	0/126 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.90, 4.90)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 93 (0.0)	0.0	0/ 99 (0.0)	0.0	NE	0.00 (-7.00, 7.00)	1.0000	
>=10 mg/day	0/ 87 (0.0)	0.0	0/ 83 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE	0.00 (-11.73, 11.73)	1.0000	
HIGH	0/150 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Age (years)								NE
<= 65	0/175 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.50, 4.50)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-102.70, 102.70)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
female	0/168 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.71, 4.71)	1.0000	
Race								NE
White	0/110 (0.0)	0.0	0/107 (0.0)	0.0	NE	0.00 (-5.75, 5.75)	1.0000	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE	0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE	0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-28.41, 28.41)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	0/118 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.46, 6.46)	1.0000	
Geographic region								NE
EU	0/ 51 (0.0)	0.0	0/ 46 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
non-EU	0/129 (0.0)	0.0	0/136 (0.0)	0.0	NE	0.00 (-5.90, 5.90)	1.0000	
Onset of disease								NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-24.92, 24.92)	1.0000	
Adult	0/166 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.74, 4.74)	1.0000	
ADA result								NE
Negative	0/172 (0.0)	0.0	0/162 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE	0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/125 (0.0)	0.0	0/134 (0.0)	0.0	NE	0.00 (-5.98, 5.98)	1.0000	
>= 30	0/ 55 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-11.37, 11.37)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE	0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	0/122 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-5.42, 5.42)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	6 (3.3)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	13.14 (0.75, 231.60)	
p-value	0.0785	
Odds Ratio (95% CI)	13.60 (0.76, 243.15)	
p-value	0.0761	
Risk Difference (95% CI)	3.33 (0.71, 5.96)	
p-value	0.0127	
CMH approach		
Response rate	3.3	0.0
Difference in response rates (95% CI)	3.35 (-1.68, 8.38)	
p-value	0.1923	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.5324
< 10 points	1/ 54 (1.9)	1.8	0/ 52 (0.0)	0.0	2.89 (0.12, 69.40)	0.5127	1.84 (-9.53, 13.22)	0.7510	
>= 10 points	5/126 (4.0)	4.0	0/130 (0.0)	0.0	11.35 (0.63, 203.09)	0.0989	3.98 (-1.82, 9.78)	0.1782	
OCS dose at baseline									0.9594
<10 mg/day	3/ 93 (3.2)	3.2	0/ 99 (0.0)	0.0	7.45 (0.39, 142.25)	0.1822	3.24 (-4.47, 10.96)	0.4099	
>=10 mg/day	3/ 87 (3.4)	3.5	0/ 83 (0.0)	0.0	6.68 (0.35, 127.42)	0.2067	3.51 (-4.18, 11.20)	0.3707	
Result of type I IFN gene signature test									0.5597
LOW	1/ 30 (3.3)	3.3	0/ 31 (0.0)	0.0	3.10 (0.13, 73.16)	0.4836	3.33 (-9.70, 16.36)	0.6161	
HIGH	5/150 (3.3)	3.4	0/151 (0.0)	0.0	11.07 (0.62, 198.50)	0.1025	3.35 (-2.10, 8.80)	0.2278	
Age (years)									NE
<= 65	6/175 (3.4)	3.4	0/181 (0.0)	0.0	13.44 (0.76, 236.85)	0.0759	3.45 (-1.68, 8.58)	0.1875	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
female	6/168 (3.6)	3.6	0/170 (0.0)	0.0	13.15 (0.75, 231.66)	0.0783	3.58 (-1.78, 8.93)	0.1903	
Race									0.8259
White	3/110 (2.7)	2.7	0/107 (0.0)	0.0	6.81 (0.36, 130.30)	0.2026	2.66 (-3.67, 8.99)	0.4101	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE		0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	2/ 4 (50.0)	50.0	0/ 1 (0.0)	0.0	2.00 (0.16, 25.75)	0.5950	50.00 (-57.80, 157.80)	0.3633	
Other	1/ 11 (9.1)	9.1	0/ 11 (0.0)	0.0	3.00 (0.14, 66.53)	0.4872	9.09 (-21.93, 40.11)	0.5657	
Ethnicity									0.7893
Hispanic/Latino	4/ 54 (7.4)	7.2	0/ 54 (0.0)	0.0	9.00 (0.50, 163.20)	0.1372	7.25 (-4.77, 19.26)	0.2373	
Non-hispanic/Latino	2/118 (1.7)	1.6	0/120 (0.0)	0.0	5.08 (0.25, 104.78)	0.2922	1.64 (-5.11, 8.38)	0.6342	
Geographic region									0.7287
EU	2/ 51 (3.9)	3.9	0/ 46 (0.0)	0.0	4.52 (0.22, 91.74)	0.3261	3.92 (-5.18, 13.02)	0.3985	
non-EU	4/129 (3.1)	3.2	0/136 (0.0)	0.0	9.48 (0.52, 174.43)	0.1300	3.18 (-3.32, 9.67)	0.3374	
Onset of disease									NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-24.92, 24.92)	1.0000	
Adult	6/166 (3.6)	3.6	0/170 (0.0)	0.0	13.31 (0.76, 234.43)	0.0769	3.61 (-1.78, 9.00)	0.1891	
ADA result									NE
Negative	6/172 (3.5)	3.5	0/162 (0.0)	0.0	12.25 (0.70, 215.70)	0.0869	3.53 (-1.86, 8.92)	0.1996	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment									0.9241
< 30	3/125 (2.4)	2.4	0/134 (0.0)	0.0	7.50 (0.39, 143.76)	0.1811	2.44 (-4.02, 8.90)	0.4593	
>= 30	3/ 55 (5.5)	5.5	0/ 48 (0.0)	0.0	6.13 (0.32, 115.66)	0.2267	5.49 (-6.88, 17.86)	0.3846	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.6057
All negative/normal	4/ 58 (6.9)	7.0	0/ 81 (0.0)	0.0	12.51 (0.69, 227.90)	0.0880	7.04 (-3.54, 17.63)	0.1922	
At least one positive/abnormal	2/122 (1.6)	1.7	0/101 (0.0)	0.0	4.15 (0.20, 85.39)	0.3568	1.70 (-4.16, 7.55)	0.5703	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Vasculitis
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.43, 4.43)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.98, 10.98)	1.0000	
>= 10 points	0/126 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.90, 4.90)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 93 (0.0)	0.0	0/ 99 (0.0)	0.0	NE	0.00 (-7.00, 7.00)	1.0000	
>=10 mg/day	0/ 87 (0.0)	0.0	0/ 83 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE	0.00 (-11.73, 11.73)	1.0000	
HIGH	0/150 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Age (years)								NE
<= 65	0/175 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.50, 4.50)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-102.70, 102.70)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
female	0/168 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.71, 4.71)	1.0000	
Race								NE
White	0/110 (0.0)	0.0	0/107 (0.0)	0.0	NE	0.00 (-5.75, 5.75)	1.0000	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE	0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE	0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-28.41, 28.41)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	0/118 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.46, 6.46)	1.0000	
Geographic region								NE
EU	0/ 51 (0.0)	0.0	0/ 46 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
non-EU	0/129 (0.0)	0.0	0/136 (0.0)	0.0	NE	0.00 (-5.90, 5.90)	1.0000	
Onset of disease								NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-24.92, 24.92)	1.0000	
Adult	0/166 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.74, 4.74)	1.0000	
ADA result								NE
Negative	0/172 (0.0)	0.0	0/162 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE	0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/125 (0.0)	0.0	0/134 (0.0)	0.0	NE	0.00 (-5.98, 5.98)	1.0000	
>= 30	0/ 55 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-11.37, 11.37)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE	0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	0/122 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-5.42, 5.42)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Vasculitis
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.43, 4.43)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.98, 10.98)	1.0000	
>= 10 points	0/126 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.90, 4.90)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 93 (0.0)	0.0	0/ 99 (0.0)	0.0	NE	0.00 (-7.00, 7.00)	1.0000	
>=10 mg/day	0/ 87 (0.0)	0.0	0/ 83 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE	0.00 (-11.73, 11.73)	1.0000	
HIGH	0/150 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Age (years)								NE
<= 65	0/175 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.50, 4.50)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-102.70, 102.70)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
female	0/168 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.71, 4.71)	1.0000	
Race								NE
White	0/110 (0.0)	0.0	0/107 (0.0)	0.0	NE	0.00 (-5.75, 5.75)	1.0000	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE	0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE	0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-28.41, 28.41)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	0/118 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.46, 6.46)	1.0000	
Geographic region								NE
EU	0/ 51 (0.0)	0.0	0/ 46 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
non-EU	0/129 (0.0)	0.0	0/136 (0.0)	0.0	NE	0.00 (-5.90, 5.90)	1.0000	
Onset of disease								NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-24.92, 24.92)	1.0000	
Adult	0/166 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.74, 4.74)	1.0000	
ADA result								NE
Negative	0/172 (0.0)	0.0	0/162 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE	0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/125 (0.0)	0.0	0/134 (0.0)	0.0	NE	0.00 (-5.98, 5.98)	1.0000	
>= 30	0/ 55 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-11.37, 11.37)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE	0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	0/122 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-5.42, 5.42)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Vasculitis
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.43, 4.43)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.98, 10.98)	1.0000	
>= 10 points	0/126 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.90, 4.90)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 93 (0.0)	0.0	0/ 99 (0.0)	0.0	NE	0.00 (-7.00, 7.00)	1.0000	
>=10 mg/day	0/ 87 (0.0)	0.0	0/ 83 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE	0.00 (-11.73, 11.73)	1.0000	
HIGH	0/150 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Age (years)								NE
<= 65	0/175 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.50, 4.50)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-102.70, 102.70)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
female	0/168 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.71, 4.71)	1.0000	
Race								NE
White	0/110 (0.0)	0.0	0/107 (0.0)	0.0	NE	0.00 (-5.75, 5.75)	1.0000	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE	0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE	0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-28.41, 28.41)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	0/118 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.46, 6.46)	1.0000	
Geographic region								NE
EU	0/ 51 (0.0)	0.0	0/ 46 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
non-EU	0/129 (0.0)	0.0	0/136 (0.0)	0.0	NE	0.00 (-5.90, 5.90)	1.0000	
Onset of disease								NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-24.92, 24.92)	1.0000	
Adult	0/166 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.74, 4.74)	1.0000	
ADA result								NE
Negative	0/172 (0.0)	0.0	0/162 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE	0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/125 (0.0)	0.0	0/134 (0.0)	0.0	NE	0.00 (-5.98, 5.98)	1.0000	
>= 30	0/ 55 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-11.37, 11.37)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE	0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	0/122 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-5.42, 5.42)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Vasculitis
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.43, 4.43)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.98, 10.98)	1.0000	
>= 10 points	0/126 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.90, 4.90)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 93 (0.0)	0.0	0/ 99 (0.0)	0.0	NE	0.00 (-7.00, 7.00)	1.0000	
>=10 mg/day	0/ 87 (0.0)	0.0	0/ 83 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE	0.00 (-11.73, 11.73)	1.0000	
HIGH	0/150 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Age (years)								NE
<= 65	0/175 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.50, 4.50)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-102.70, 102.70)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
female	0/168 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.71, 4.71)	1.0000	
Race								NE
White	0/110 (0.0)	0.0	0/107 (0.0)	0.0	NE	0.00 (-5.75, 5.75)	1.0000	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE	0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE	0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-28.41, 28.41)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	0/118 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.46, 6.46)	1.0000	
Geographic region								NE
EU	0/ 51 (0.0)	0.0	0/ 46 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
non-EU	0/129 (0.0)	0.0	0/136 (0.0)	0.0	NE	0.00 (-5.90, 5.90)	1.0000	
Onset of disease								NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-24.92, 24.92)	1.0000	
Adult	0/166 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.74, 4.74)	1.0000	
ADA result								NE
Negative	0/172 (0.0)	0.0	0/162 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE	0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/125 (0.0)	0.0	0/134 (0.0)	0.0	NE	0.00 (-5.98, 5.98)	1.0000	
>= 30	0/ 55 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-11.37, 11.37)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE	0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	0/122 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-5.42, 5.42)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Malignancy
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	1 (0.6)	1 (0.5)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.01 (0.06, 16.04)	
p-value	0.9937	
Odds Ratio (95% CI)	1.01 (0.06, 16.29)	
p-value	0.9937	
Risk Difference (95% CI)	0.01 (-1.52, 1.53)	
p-value	0.9937	
CMH approach		
Response rate	0.5	0.6
Difference in response rates (95% CI)	-0.04 (-4.69, 4.61)	
p-value	0.9867	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE		0.00 (-10.98, 10.98)	1.0000	
>= 10 points	1/126 (0.8)	0.8	1/130 (0.8)	0.8	1.03 (0.07, 16.32)	0.9823	-0.06 (-5.35, 5.24)	0.9835	
OCS dose at baseline									NE
<10 mg/day	0/ 93 (0.0)	0.0	0/ 99 (0.0)	0.0	NE		0.00 (-7.00, 7.00)	1.0000	
>=10 mg/day	1/ 87 (1.1)	1.1	1/ 83 (1.2)	1.2	0.95 (0.06, 15.00)	0.9733	-0.08 (-7.66, 7.49)	0.9826	
Result of type I IFN gene signature test									NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE		0.00 (-11.73, 11.73)	1.0000	
HIGH	1/150 (0.7)	0.6	1/151 (0.7)	0.7	1.01 (0.06, 15.95)	0.9962	-0.05 (-5.11, 5.01)	0.9853	
Age (years)									NE
<= 65	1/175 (0.6)	0.5	1/181 (0.6)	0.6	1.03 (0.07, 16.41)	0.9809	-0.03 (-4.76, 4.70)	0.9899	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									0.3364
male	1/ 12 (8.3)	8.3	0/ 12 (0.0)	0.0	3.00 (0.13, 67.06)	0.4883	8.33 (-20.61, 37.28)	0.5726	
female	0/168 (0.0)	0.0	1/170 (0.6)	0.6	0.34 (0.01, 8.22)	0.5048	-0.62 (-5.46, 4.23)	0.8034	
Race									0.2566
White	0/110 (0.0)	0.0	1/107 (0.9)	0.9	0.32 (0.01, 7.87)	0.4890	-0.91 (-6.90, 5.08)	0.7658	
Black or African American	1/ 17 (5.9)	5.9	0/ 25 (0.0)	0.0	4.33 (0.19, 100.49)	0.3606	5.88 (-13.49, 25.26)	0.5518	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE		0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-28.41, 28.41)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE		0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	1/118 (0.8)	0.8	1/120 (0.8)	0.8	1.02 (0.06, 16.07)	0.9905	0.00 (-6.79, 6.79)	1.0000	
Geographic region									0.3062
EU	0/ 51 (0.0)	0.0	1/ 46 (2.2)	2.2	0.30 (0.01, 7.22)	0.4591	-2.17 (-10.75, 6.40)	0.6192	
non-EU	1/129 (0.8)	0.7	0/136 (0.0)	0.0	3.16 (0.13, 76.91)	0.4796	0.74 (-5.30, 6.77)	0.8111	
Onset of disease									NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-24.92, 24.92)	1.0000	
Adult	1/166 (0.6)	0.6	1/170 (0.6)	0.6	1.02 (0.06, 16.24)	0.9865	-0.02 (-5.00, 4.95)	0.9922	
ADA result									NE
Negative	1/172 (0.6)	0.6	1/162 (0.6)	0.6	0.94 (0.06, 14.93)	0.9661	-0.08 (-5.10, 4.93)	0.9735	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	1/125 (0.8)	0.8	1/134 (0.7)	0.8	1.07 (0.07, 16.96)	0.9606	0.04 (-6.25, 6.32)	0.9912	
>= 30	0/ 55 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-11.37, 11.37)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE		0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	1/122 (0.8)	0.8	1/101 (1.0)	1.0	0.83 (0.05, 13.07)	0.8933	-0.12 (-6.04, 5.80)	0.9680	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Malignancy
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	1 (0.6)	1 (0.5)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.01 (0.06, 16.04)	
p-value	0.9937	
Odds Ratio (95% CI)	1.01 (0.06, 16.29)	
p-value	0.9937	
Risk Difference (95% CI)	0.01 (-1.52, 1.53)	
p-value	0.9937	
CMH approach		
Response rate	0.5	0.6
Difference in response rates (95% CI)	-0.04 (-4.69, 4.61)	
p-value	0.9867	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE		0.00 (-10.98, 10.98)	1.0000	
>= 10 points	1/126 (0.8)	0.8	1/130 (0.8)	0.8	1.03 (0.07, 16.32)	0.9823	-0.06 (-5.35, 5.24)	0.9835	
OCS dose at baseline									NE
<10 mg/day	0/ 93 (0.0)	0.0	0/ 99 (0.0)	0.0	NE		0.00 (-7.00, 7.00)	1.0000	
>=10 mg/day	1/ 87 (1.1)	1.1	1/ 83 (1.2)	1.2	0.95 (0.06, 15.00)	0.9733	-0.08 (-7.66, 7.49)	0.9826	
Result of type I IFN gene signature test									NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE		0.00 (-11.73, 11.73)	1.0000	
HIGH	1/150 (0.7)	0.6	1/151 (0.7)	0.7	1.01 (0.06, 15.95)	0.9962	-0.05 (-5.11, 5.01)	0.9853	
Age (years)									NE
<= 65	1/175 (0.6)	0.5	1/181 (0.6)	0.6	1.03 (0.07, 16.41)	0.9809	-0.03 (-4.76, 4.70)	0.9899	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									0.3364
male	1/ 12 (8.3)	8.3	0/ 12 (0.0)	0.0	3.00 (0.13, 67.06)	0.4883	8.33 (-20.61, 37.28)	0.5726	
female	0/168 (0.0)	0.0	1/170 (0.6)	0.6	0.34 (0.01, 8.22)	0.5048	-0.62 (-5.46, 4.23)	0.8034	
Race									0.2566
White	0/110 (0.0)	0.0	1/107 (0.9)	0.9	0.32 (0.01, 7.87)	0.4890	-0.91 (-6.90, 5.08)	0.7658	
Black or African American	1/ 17 (5.9)	5.9	0/ 25 (0.0)	0.0	4.33 (0.19, 100.49)	0.3606	5.88 (-13.49, 25.26)	0.5518	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE		0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-28.41, 28.41)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE		0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	1/118 (0.8)	0.8	1/120 (0.8)	0.8	1.02 (0.06, 16.07)	0.9905	0.00 (-6.79, 6.79)	1.0000	
Geographic region									0.3062
EU	0/ 51 (0.0)	0.0	1/ 46 (2.2)	2.2	0.30 (0.01, 7.22)	0.4591	-2.17 (-10.75, 6.40)	0.6192	
non-EU	1/129 (0.8)	0.7	0/136 (0.0)	0.0	3.16 (0.13, 76.91)	0.4796	0.74 (-5.30, 6.77)	0.8111	
Onset of disease									NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-24.92, 24.92)	1.0000	
Adult	1/166 (0.6)	0.6	1/170 (0.6)	0.6	1.02 (0.06, 16.24)	0.9865	-0.02 (-5.00, 4.95)	0.9922	
ADA result									NE
Negative	1/172 (0.6)	0.6	1/162 (0.6)	0.6	0.94 (0.06, 14.93)	0.9661	-0.08 (-5.10, 4.93)	0.9735	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	1/125 (0.8)	0.8	1/134 (0.7)	0.8	1.07 (0.07, 16.96)	0.9606	0.04 (-6.25, 6.32)	0.9912	
>= 30	0/ 55 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-11.37, 11.37)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE		0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	1/122 (0.8)	0.8	1/101 (1.0)	1.0	0.83 (0.05, 13.07)	0.8933	-0.12 (-6.04, 5.80)	0.9680	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Malignancy
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.43, 4.43)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.98, 10.98)	1.0000	
>= 10 points	0/126 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.90, 4.90)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 93 (0.0)	0.0	0/ 99 (0.0)	0.0	NE	0.00 (-7.00, 7.00)	1.0000	
>=10 mg/day	0/ 87 (0.0)	0.0	0/ 83 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE	0.00 (-11.73, 11.73)	1.0000	
HIGH	0/150 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Age (years)								NE
<= 65	0/175 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.50, 4.50)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-102.70, 102.70)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
female	0/168 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.71, 4.71)	1.0000	
Race								NE
White	0/110 (0.0)	0.0	0/107 (0.0)	0.0	NE	0.00 (-5.75, 5.75)	1.0000	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE	0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE	0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-28.41, 28.41)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	0/118 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.46, 6.46)	1.0000	
Geographic region								NE
EU	0/ 51 (0.0)	0.0	0/ 46 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
non-EU	0/129 (0.0)	0.0	0/136 (0.0)	0.0	NE	0.00 (-5.90, 5.90)	1.0000	
Onset of disease								NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-24.92, 24.92)	1.0000	
Adult	0/166 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.74, 4.74)	1.0000	
ADA result								NE
Negative	0/172 (0.0)	0.0	0/162 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE	0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/125 (0.0)	0.0	0/134 (0.0)	0.0	NE	0.00 (-5.98, 5.98)	1.0000	
>= 30	0/ 55 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-11.37, 11.37)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE	0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	0/122 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-5.42, 5.42)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Malignancy
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	1 (0.6)	1 (0.5)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.01 (0.06, 16.04)	
p-value	0.9937	
Odds Ratio (95% CI)	1.01 (0.06, 16.29)	
p-value	0.9937	
Risk Difference (95% CI)	0.01 (-1.52, 1.53)	
p-value	0.9937	
CMH approach		
Response rate	0.5	0.6
Difference in response rates (95% CI)	-0.04 (-4.69, 4.61)	
p-value	0.9867	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE		0.00 (-10.98, 10.98)	1.0000	
>= 10 points	1/126 (0.8)	0.8	1/130 (0.8)	0.8	1.03 (0.07, 16.32)	0.9823	-0.06 (-5.35, 5.24)	0.9835	
OCS dose at baseline									NE
<10 mg/day	0/ 93 (0.0)	0.0	0/ 99 (0.0)	0.0	NE		0.00 (-7.00, 7.00)	1.0000	
>=10 mg/day	1/ 87 (1.1)	1.1	1/ 83 (1.2)	1.2	0.95 (0.06, 15.00)	0.9733	-0.08 (-7.66, 7.49)	0.9826	
Result of type I IFN gene signature test									NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE		0.00 (-11.73, 11.73)	1.0000	
HIGH	1/150 (0.7)	0.6	1/151 (0.7)	0.7	1.01 (0.06, 15.95)	0.9962	-0.05 (-5.11, 5.01)	0.9853	
Age (years)									NE
<= 65	1/175 (0.6)	0.5	1/181 (0.6)	0.6	1.03 (0.07, 16.41)	0.9809	-0.03 (-4.76, 4.70)	0.9899	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									0.3364
male	1/ 12 (8.3)	8.3	0/ 12 (0.0)	0.0	3.00 (0.13, 67.06)	0.4883	8.33 (-20.61, 37.28)	0.5726	
female	0/168 (0.0)	0.0	1/170 (0.6)	0.6	0.34 (0.01, 8.22)	0.5048	-0.62 (-5.46, 4.23)	0.8034	
Race									0.2566
White	0/110 (0.0)	0.0	1/107 (0.9)	0.9	0.32 (0.01, 7.87)	0.4890	-0.91 (-6.90, 5.08)	0.7658	
Black or African American	1/ 17 (5.9)	5.9	0/ 25 (0.0)	0.0	4.33 (0.19, 100.49)	0.3606	5.88 (-13.49, 25.26)	0.5518	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE		0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-28.41, 28.41)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE		0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	1/118 (0.8)	0.8	1/120 (0.8)	0.8	1.02 (0.06, 16.07)	0.9905	0.00 (-6.79, 6.79)	1.0000	
Geographic region									0.3062
EU	0/ 51 (0.0)	0.0	1/ 46 (2.2)	2.2	0.30 (0.01, 7.22)	0.4591	-2.17 (-10.75, 6.40)	0.6192	
non-EU	1/129 (0.8)	0.7	0/136 (0.0)	0.0	3.16 (0.13, 76.91)	0.4796	0.74 (-5.30, 6.77)	0.8111	
Onset of disease									NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-24.92, 24.92)	1.0000	
Adult	1/166 (0.6)	0.6	1/170 (0.6)	0.6	1.02 (0.06, 16.24)	0.9865	-0.02 (-5.00, 4.95)	0.9922	
ADA result									NE
Negative	1/172 (0.6)	0.6	1/162 (0.6)	0.6	0.94 (0.06, 14.93)	0.9661	-0.08 (-5.10, 4.93)	0.9735	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	1/125 (0.8)	0.8	1/134 (0.7)	0.8	1.07 (0.07, 16.96)	0.9606	0.04 (-6.25, 6.32)	0.9912	
>= 30	0/ 55 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-11.37, 11.37)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE		0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	1/122 (0.8)	0.8	1/101 (1.0)	1.0	0.83 (0.05, 13.07)	0.8933	-0.12 (-6.04, 5.80)	0.9680	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of SOCs Cardiac disorders and/or Vascular disorders
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	9 (5.0)	10 (5.5)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.91 (0.38, 2.19)	
p-value	0.8330	
Odds Ratio (95% CI)	0.91 (0.36, 2.28)	
p-value	0.8330	
Risk Difference (95% CI)	-0.49 (-5.09, 4.10)	
p-value	0.8329	
CMH approach		
Response rate	5.1	5.5
Difference in response rates (95% CI)	-0.47 (-6.57, 5.64)	
p-value	0.8812	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of SOCs Cardiac disorders and/or Vascular disorders - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.6458
< 10 points	2/ 54 (3.7)	3.7	3/ 52 (5.8)	5.8	0.64 (0.11, 3.69)	0.6193	-2.03 (-14.76, 10.71)	0.7551	
>= 10 points	7/126 (5.6)	5.6	7/130 (5.4)	5.4	1.03 (0.37, 2.86)	0.9520	0.16 (-6.99, 7.31)	0.9658	
OCS dose at baseline									0.6706
<10 mg/day	6/ 93 (6.5)	6.6	6/ 99 (6.1)	6.1	1.06 (0.36, 3.18)	0.9109	0.49 (-8.74, 9.73)	0.9167	
>=10 mg/day	3/ 87 (3.4)	3.4	4/ 83 (4.8)	4.9	0.72 (0.17, 3.10)	0.6546	-1.47 (-10.36, 7.41)	0.7453	
Result of type I IFN gene signature test									0.9219
LOW	1/ 30 (3.3)	3.3	1/ 31 (3.2)	3.2	1.03 (0.07, 15.78)	0.9812	0.11 (-14.04, 14.25)	0.9881	
HIGH	8/150 (5.3)	5.4	9/151 (6.0)	6.0	0.89 (0.35, 2.26)	0.8139	-0.58 (-7.34, 6.18)	0.8660	
Age (years)									0.8987
<= 65	8/175 (4.6)	4.6	10/181 (5.5)	5.6	0.83 (0.33, 2.05)	0.6820	-0.96 (-7.08, 5.16)	0.7580	
> 65	1/ 5 (20.0)	20.0	0/ 1 (0.0)	0.0	1.00 (0.06, 15.99)	1.0000	20.00 (-84.53, 124.53)	0.7077	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
female	9/168 (5.4)	5.4	10/170 (5.9)	5.9	0.91 (0.38, 2.18)	0.8341	-0.55 (-7.03, 5.94)	0.8691	
Race									0.8196
White	7/110 (6.4)	6.4	6/107 (5.6)	5.4	1.13 (0.39, 3.27)	0.8146	1.01 (-7.14, 9.16)	0.8080	
Black or African American	0/ 17 (0.0)	0.0	2/ 25 (8.0)	8.0	0.29 (0.01, 5.67)	0.4135	-8.00 (-27.43, 11.43)	0.4196	
Asian	0/ 30 (0.0)	0.0	1/ 30 (3.3)	3.3	0.33 (0.01, 7.87)	0.4958	-3.33 (-16.52, 9.85)	0.6203	
American Indian or Alaska Native	1/ 4 (25.0)	25.0	0/ 1 (0.0)	0.0	1.20 (0.08, 18.75)	0.8966	25.00 (-82.10, 132.10)	0.6473	
Other	0/ 11 (0.0)	0.0	1/ 11 (9.1)	9.1	0.33 (0.02, 7.39)	0.4872	-9.09 (-40.11, 21.93)	0.5657	
Ethnicity									0.6756
Hispanic/Latino	4/ 54 (7.4)	7.3	4/ 54 (7.4)	8.0	1.00 (0.26, 3.79)	1.0000	-0.71 (-14.40, 12.98)	0.9191	
Non-hispanic/Latino	4/118 (3.4)	3.5	6/120 (5.0)	5.0	0.68 (0.20, 2.34)	0.5388	-1.50 (-9.35, 6.36)	0.7088	
Geographic region									0.1383
EU	4/ 51 (7.8)	7.8	1/ 46 (2.2)	2.2	3.61 (0.42, 31.12)	0.2432	5.67 (-5.30, 16.64)	0.3110	
non-EU	5/129 (3.9)	3.9	9/136 (6.6)	6.8	0.59 (0.20, 1.70)	0.3255	-2.86 (-10.42, 4.69)	0.4575	
Onset of disease									0.4851
Paediatric	1/ 14 (7.1)	7.1	0/ 12 (0.0)	0.0	2.60 (0.12, 58.48)	0.5475	7.14 (-19.90, 34.18)	0.6047	
Adult	8/166 (4.8)	4.8	10/170 (5.9)	5.9	0.82 (0.33, 2.02)	0.6659	-1.09 (-7.53, 5.35)	0.7405	
ADA result									0.8209
Negative	8/172 (4.7)	4.8	8/162 (4.9)	4.9	0.94 (0.36, 2.45)	0.9023	-0.11 (-6.43, 6.21)	0.9724	
Positive (At any time)	1/ 8 (12.5)	12.5	2/ 20 (10.0)	10.0	1.25 (0.13, 11.93)	0.8463	2.50 (-31.66, 36.66)	0.8860	
BMI (kg/m2) at enrolment									0.3283
< 30	6/125 (4.8)	4.8	5/134 (3.7)	3.6	1.29 (0.40, 4.11)	0.6709	1.22 (-6.11, 8.54)	0.7444	
>= 30	3/ 55 (5.5)	5.5	5/ 48 (10.4)	10.3	0.52 (0.13, 2.08)	0.3575	-4.78 (-19.16, 9.60)	0.5148	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.7471
All negative/normal	2/ 58 (3.4)	3.4	4/ 81 (4.9)	5.2	0.70 (0.13, 3.69)	0.6722	-1.77 (-12.49, 8.96)	0.7469	
At least one positive/abnormal	7/122 (5.7)	5.7	6/101 (5.9)	5.8	0.97 (0.34, 2.78)	0.9487	-0.07 (-7.97, 7.84)	0.9869	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Time to first Onset of Herpes Zoster (on-treatment)
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	13 (7.2)	2 (1.1)
Number of censored subjects, n (%)	167 (92.8)	180 (98.9)
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Anifrolumab 300mg vs. Placebo (adjusted)		
Hazard Ratio (95% CI)	6.51 (1.47, 28.87)	
p-value	0.0072	
Analysis Anifrolumab 300mg vs. Placebo (unadjusted)		
Hazard Ratio (95% CI)	6.46 (1.46, 28.62)	
p-value	0.0047	

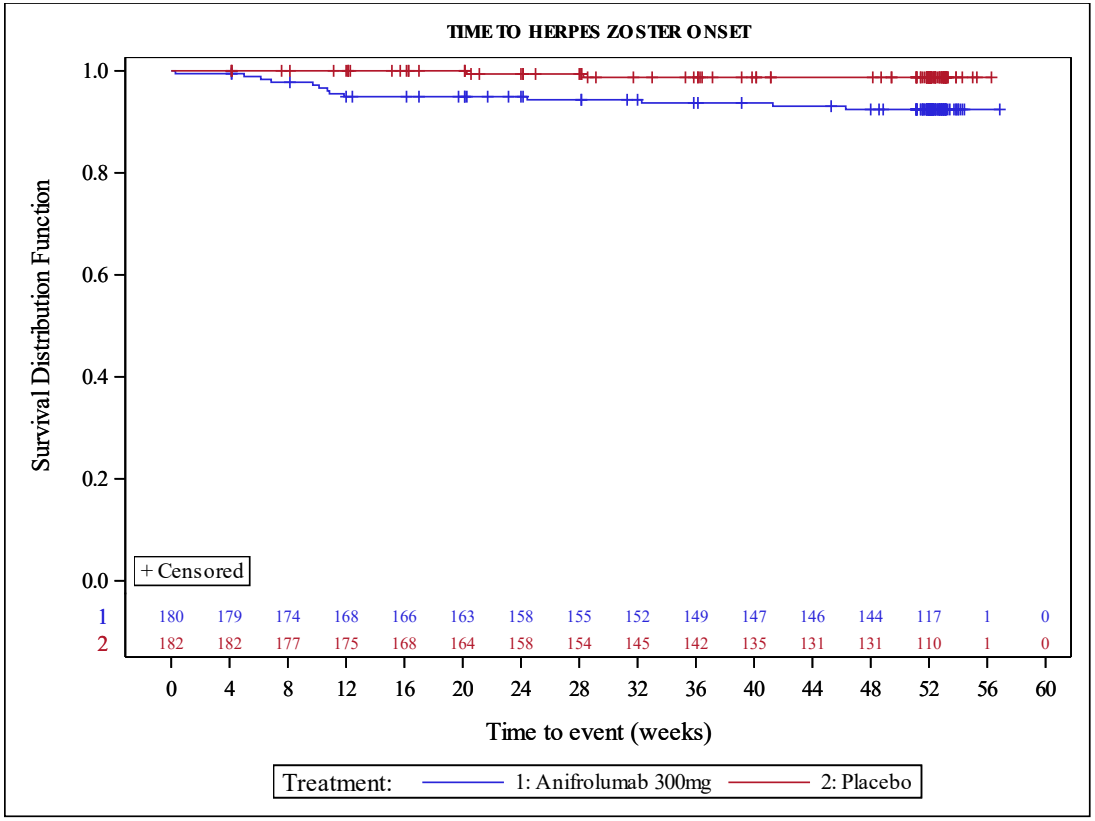
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model. Adjusted analysis also includes stratification factors in the model.
Two-sided log rank test used.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Time to first Onset of Herpes Zoster (on-treatment) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Anifrolumab 300mg (N=180) Median (95% CI)	Placebo (N=182) n/ N (%)	Placebo (N=182) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening							0.9934
< 10 points	1/ 54 (1.9)	NE (NE, NE)	0/ 52 (0.0)	NE (NE, NE)	NE		
>= 10 points	12/126 (9.5)	NE (NE, NE)	2/130 (1.5)	NE (NE, NE)	6.07 (1.36, 27.14)	0.0105	
OCS dose at baseline							0.9804
<10 mg/day	6/ 93 (6.5)	NE (NE, NE)	1/ 99 (1.0)	NE (NE, NE)	5.81 (0.69, 48.62)	0.0805	
>=10 mg/day	7/ 87 (8.0)	NE (NE, NE)	1/ 83 (1.2)	NE (NE, NE)	6.63 (0.82, 53.91)	0.0408	
Result of type I IFN gene signature test							0.2684
LOW	2/ 30 (6.7)	NE (NE, NE)	1/ 31 (3.2)	NE (NE, NE)	1.23 (0.11, 13.82)	0.8920	
HIGH	11/150 (7.3)	NE (NE, NE)	1/151 (0.7)	NE (NE, NE)	11.12 (1.43, 86.24)	0.0035	
Age (years)							0.9997
<= 65	13/175 (7.4)	NE (NE, NE)	2/181 (1.1)	NE (NE, NE)	6.68 (1.51, 29.64)	0.0060	
> 65	0/ 5 (0.0)	NE (NE, NE)	0/ 1 (0.0)	NE (NE, NE)	NE		
Sex							0.9940
male	1/ 12 (8.3)	NE (NE, NE)	0/ 12 (0.0)	NE (NE, NE)	NE		
female	12/168 (7.1)	NE (NE, NE)	2/170 (1.2)	NE (NE, NE)	5.90 (1.32, 26.38)	0.0141	
Race							1.0000
White	5/110 (4.5)	NE (NE, NE)	1/107 (0.9)	NE (NE, NE)	5.20 (0.61, 44.64)	0.1247	
Black or African American	0/ 17 (0.0)	NE (NE, NE)	1/ 25 (4.0)	NE (NE, NE)	NE		
Asian	3/ 30 (10.0)	NE (NE, NE)	0/ 30 (0.0)	NE (NE, NE)	NE		
American Indian or Alaska Native	0/ 4 (0.0)	NE (NE, NE)	0/ 1 (0.0)	NE (NE, NE)	NE		
Other	3/ 11 (27.3)	NE (10.86, NE)	0/ 11 (0.0)	NE (NE, NE)	NE		
Ethnicity							0.9955
Hispanic/Latino	6/ 54 (11.1)	NE (NE, NE)	0/ 54 (0.0)	NE (NE, NE)	NE		
Non-hispanic/Latino	5/118 (4.2)	NE (NE, NE)	2/120 (1.7)	NE (NE, NE)	2.30 (0.44, 12.05)	0.4298	
Geographic region							0.9934
EU	2/ 51 (3.9)	NE (NE, NE)	0/ 46 (0.0)	NE (NE, NE)	NE		
non-EU	11/129 (8.5)	NE (NE, NE)	2/136 (1.5)	NE (NE, NE)	5.92 (1.31, 26.78)	0.0097	
Onset of disease							0.9915
Paediatric	2/ 14 (14.3)	NE (NE, NE)	0/ 12 (0.0)	NE (NE, NE)	NE		
Adult	11/166 (6.6)	NE (NE, NE)	2/170 (1.2)	NE (NE, NE)	5.51 (1.22, 24.89)	0.0190	
ADA result							0.9912
Negative	11/172 (6.4)	NE (NE, NE)	2/162 (1.2)	NE (NE, NE)	5.13 (1.14, 23.19)	0.0272	
Positive (At any time)	2/ 8 (25.0)	NE (0.29, NE)	0/ 20 (0.0)	NE (NE, NE)	NE		
BMI (kg/m2) at enrolment							0.8688
< 30	7/125 (5.6)	NE (NE, NE)	1/134 (0.7)	NE (NE, NE)	7.30 (0.90, 59.43)	0.0355	
>= 30	6/ 55 (10.9)	NE (NE, NE)	1/ 48 (2.1)	NE (NE, NE)	5.69 (0.68, 47.34)	0.1623	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group							0.5109
All negative/normal	2/ 58 (3.4)	NE (NE, NE)	1/ 81 (1.2)	NE (NE, NE)	2.71 (0.24, 30.88)	0.7031	
At least one positive/abnormal	11/122 (9.0)	NE (NE, NE)	1/101 (1.0)	NE (NE, NE)	9.18 (1.18, 71.16)	0.0122	

Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Time to first Onset of Herpes Zoster (on-treatment)
Full analysis set



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Time to first Onset of non-opportunistic serious infection (on-treatment)
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	5 (2.8)	10 (5.5)
Number of censored subjects, n (%)	175 (97.2)	172 (94.5)
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Anifrolumab 300mg vs. Placebo (adjusted)		
Hazard Ratio (95% CI)	0.45 (0.15, 1.32)	
p-value	0.1521	
Analysis Anifrolumab 300mg vs. Placebo (unadjusted)		
Hazard Ratio (95% CI)	0.46 (0.16, 1.36)	
p-value	0.1509	

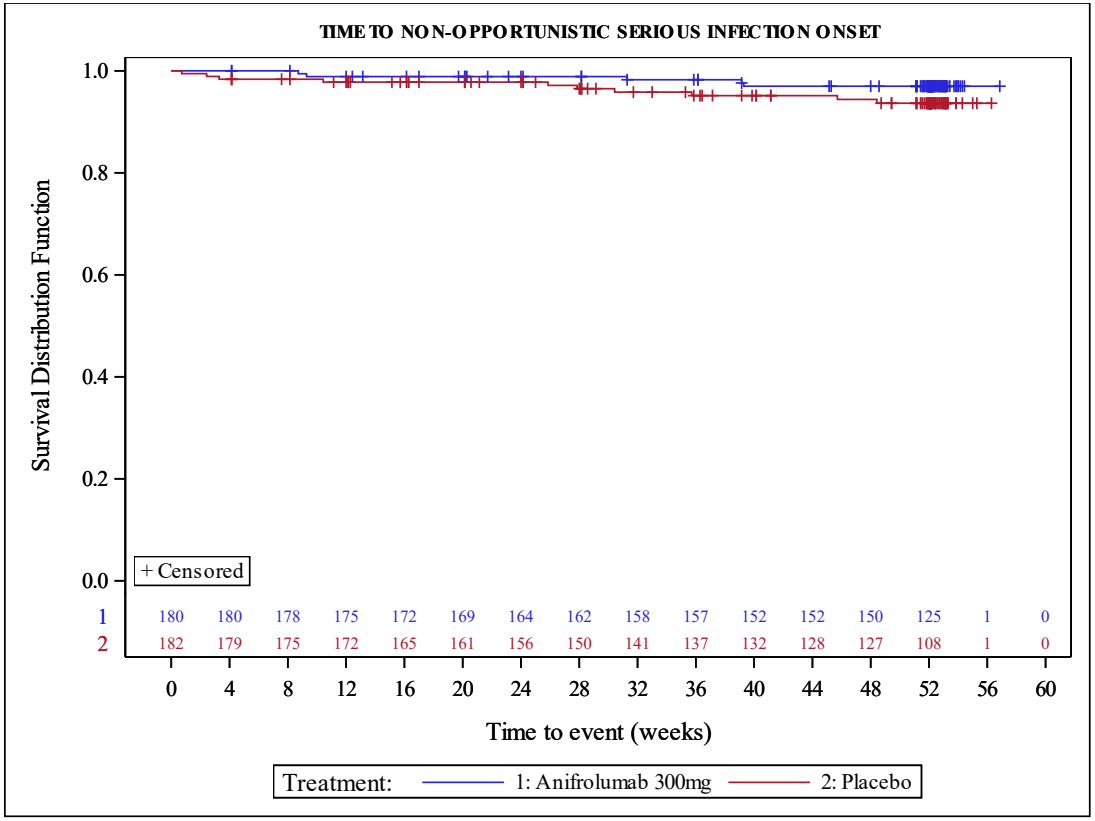
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model. Adjusted analysis also includes stratification factors in the model.
Two-sided log rank test used.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Time to first Onset of non-opportunistic serious infection (on-treatment) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Anifrolumab 300mg (N=180) Median (95% CI)	Placebo (N=182) n/ N (%)	Placebo (N=182) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening							0.6710
< 10 points	1/ 54 (1.9)	NE (NE, NE)	3/ 52 (5.8)	NE (NE, NE)	0.27 (0.03, 2.61)	0.2281	
>= 10 points	4/126 (3.2)	NE (NE, NE)	7/130 (5.4)	NE (NE, NE)	0.54 (0.16, 1.85)	0.3441	
OCS dose at baseline							0.8373
<10 mg/day	2/ 93 (2.2)	NE (NE, NE)	4/ 99 (4.0)	NE (NE, NE)	0.54 (0.10, 2.95)	0.4734	
>=10 mg/day	3/ 87 (3.4)	NE (NE, NE)	6/ 83 (7.2)	NE (NE, NE)	0.41 (0.10, 1.66)	0.2061	
Result of type I IFN gene signature test							0.9928
LOW	1/ 30 (3.3)	NE (NE, NE)	0/ 31 (0.0)	NE (NE, NE)	NE		
HIGH	4/150 (2.7)	NE (NE, NE)	10/151 (6.6)	NE (NE, NE)	0.36 (0.11, 1.15)	0.0737	
Age (years)							0.9924
<= 65	4/175 (2.3)	NE (NE, NE)	10/181 (5.5)	NE (NE, NE)	0.36 (0.11, 1.16)	0.0817	
> 65	1/ 5 (20.0)	NE (39.14, NE)	0/ 1 (0.0)	NE (NE, NE)	NE		
Sex							0.9997
male	0/ 12 (0.0)	NE (NE, NE)	0/ 12 (0.0)	NE (NE, NE)	NE		
female	5/168 (3.0)	NE (NE, NE)	10/170 (5.9)	NE (NE, NE)	0.44 (0.15, 1.30)	0.1484	
Race							1.0000
White	5/110 (4.5)	NE (NE, NE)	6/107 (5.6)	NE (NE, NE)	0.71 (0.22, 2.35)	0.6273	
Black or African American	0/ 17 (0.0)	NE (NE, NE)	1/ 25 (4.0)	NE (NE, NE)	NE		
Asian	0/ 30 (0.0)	NE (NE, NE)	3/ 30 (10.0)	NE (NE, NE)	NE		
American Indian or Alaska Native	0/ 4 (0.0)	NE (NE, NE)	0/ 1 (0.0)	NE (NE, NE)	NE		
Other	0/ 11 (0.0)	NE (NE, NE)	0/ 11 (0.0)	NE (NE, NE)	NE		
Ethnicity							0.7521
Hispanic/Latino	2/ 54 (3.7)	NE (NE, NE)	3/ 54 (5.6)	NE (NE, NE)	0.59 (0.10, 3.64)	0.5801	
Non-hispanic/Latino	3/118 (2.5)	NE (NE, NE)	7/120 (5.8)	NE (NE, NE)	0.40 (0.10, 1.55)	0.1778	
Geographic region							0.9910
EU	0/ 51 (0.0)	NE (NE, NE)	2/ 46 (4.3)	NE (NE, NE)	NE		
non-EU	5/129 (3.9)	NE (NE, NE)	8/136 (5.9)	NE (NE, NE)	0.59 (0.19, 1.80)	0.3813	
Onset of disease							0.2059
Paediatric	2/ 14 (14.3)	NE (NE, NE)	1/ 12 (8.3)	NE (NE, NE)	2.84 (0.10, 82.42)	0.6767	
Adult	3/166 (1.8)	NE (NE, NE)	9/170 (5.3)	NE (NE, NE)	0.29 (0.08, 1.09)	0.0532	
ADA result							0.9913
Negative	5/172 (2.9)	NE (NE, NE)	7/162 (4.3)	NE (NE, NE)	0.61 (0.19, 1.92)	0.4059	
Positive (At any time)	0/ 8 (0.0)	NE (NE, NE)	3/ 20 (15.0)	NE (35.71, NE)	NE		
BMI (kg/m2) at enrolment							0.6227
< 30	2/125 (1.6)	NE (NE, NE)	6/134 (4.5)	NE (NE, NE)	0.34 (0.07, 1.71)	0.1667	
>= 30	3/ 55 (5.5)	NE (NE, NE)	4/ 48 (8.3)	NE (NE, NE)	0.47 (0.10, 2.17)	0.4243	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group							0.0325
All negative/normal	4/ 58 (6.9)	NE (NE, NE)	3/ 81 (3.7)	NE (NE, NE)	2.00 (0.44, 9.01)	0.3266	
At least one positive/abnormal	1/122 (0.8)	NE (NE, NE)	7/101 (6.9)	NE (NE, NE)	0.11 (0.01, 0.87)	0.0129	

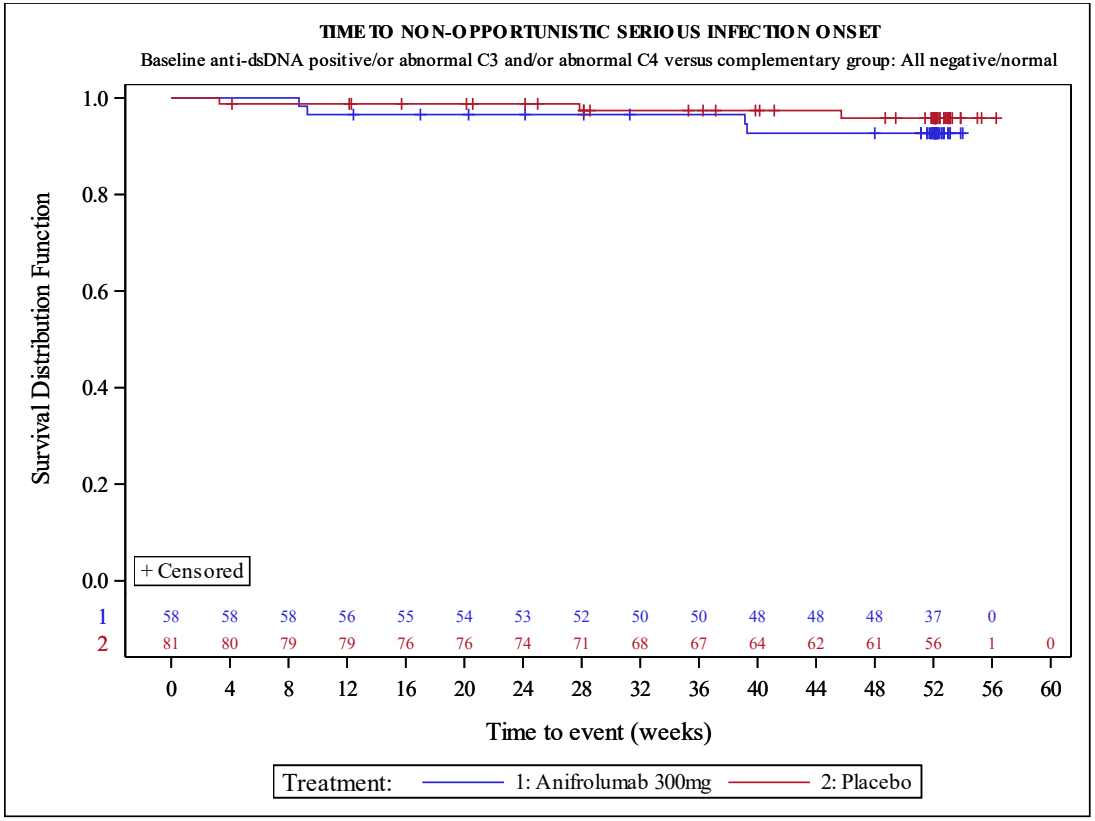
Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Time to first Onset of non-opportunistic serious infection (on-treatment)
Full analysis set



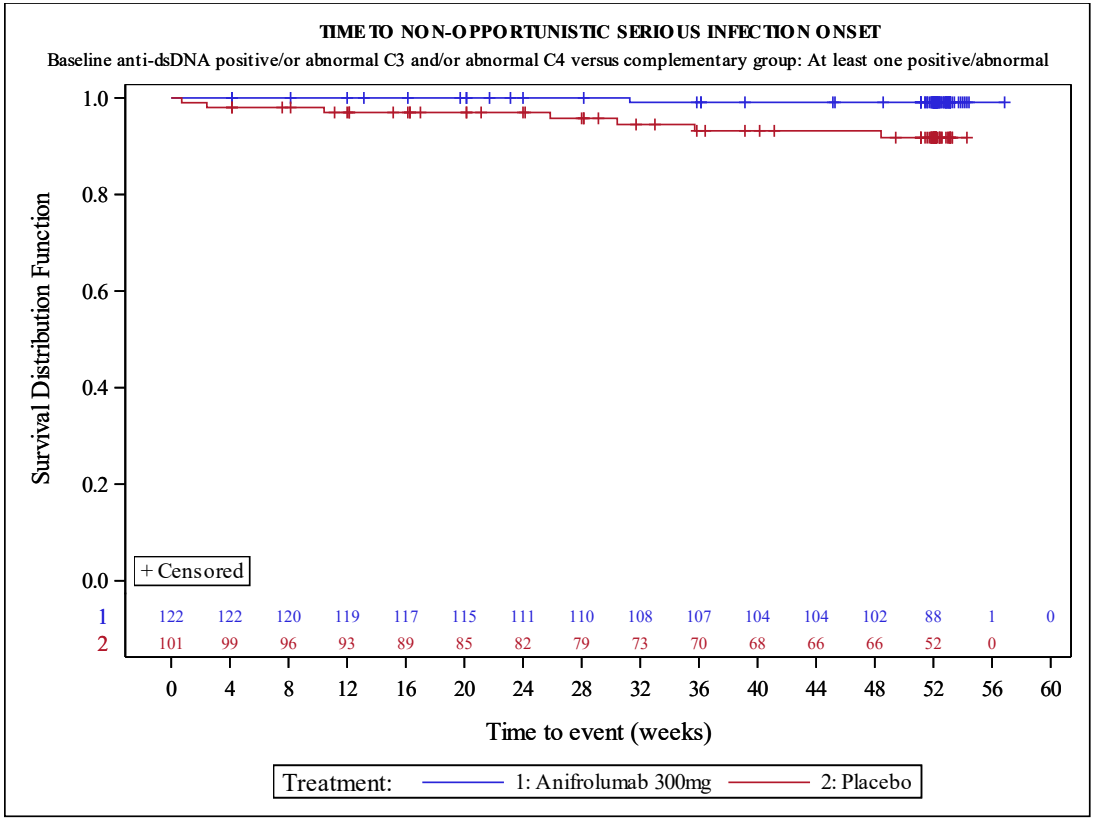
Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Time to first Onset of non-opportunistic serious infection (on-treatment)
Full analysis set



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Time to first Onset of non-opportunistic serious infection (on-treatment)
Full analysis set



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Blood and lymphatic system disorders	Number of subjects with events, n (%)	7 (3.9)	10 (5.5)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.71 (0.28, 1.82)	
	p-value	0.4728	
	Odds Ratio (95% CI)	0.70 (0.26, 1.87)	
	p-value	0.4724	
	Risk Difference (95% CI)	-1.61 (-5.96, 2.75)	
	p-value	0.4696	
	CMH approach		
	Response rate	3.9	5.5
	Difference in response rates (95% CI)	-1.63 (-7.50, 4.25)	
	p-value	0.5879	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Eye disorders	Number of subjects with events, n (%)	16 (8.9)	12 (6.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.35 (0.66, 2.77)	
	p-value	0.4158	
	Odds Ratio (95% CI)	1.38 (0.63, 3.01)	
	p-value	0.4153	
	Risk Difference (95% CI)	2.30 (-3.21, 7.80)	
	p-value	0.4136	
	CMH approach		
	Response rate	8.8	6.5
	Difference in response rates (95% CI)	2.26 (-4.21, 8.73)	
	p-value	0.4936	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Gastrointestinal disorders	Number of subjects with events, n (%)	36 (20.0)	52 (28.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.70 (0.48, 1.02)	
	p-value	0.0600	
	Odds Ratio (95% CI)	0.63 (0.38, 1.02)	
	p-value	0.0584	
	Risk Difference (95% CI)	-8.57 (-17.36, 0.22)	
	p-value	0.0559	
	CMH approach		
	Response rate	19.9	28.6
	Difference in response rates (95% CI)	-8.61 (-17.54, 0.31)	
	p-value	0.0585	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Gastrointestinal disorders, PT: Nausea	Number of subjects with events, n (%)	7 (3.9)	10 (5.5)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.71 (0.28, 1.82)	
	p-value	0.4728	
	Odds Ratio (95% CI)	0.70 (0.26, 1.87)	
	p-value	0.4724	
	Risk Difference (95% CI)	-1.61 (-5.96, 2.75)	
	p-value	0.4696	
	CMH approach		
	Response rate	3.9	5.5
	Difference in response rates (95% CI)	-1.65 (-7.52, 4.21)	
	p-value	0.5808	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: General disorders and administration site conditions	Number of subjects with events, n (%)	23 (12.8)	18 (9.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.29 (0.72, 2.31)	
	p-value	0.3878	
	Odds Ratio (95% CI)	1.33 (0.69, 2.57)	
	p-value	0.3872	
	Risk Difference (95% CI)	2.89 (-3.64, 9.41)	
	p-value	0.3858	
	CMH approach		
	Response rate	12.8	9.9
	Difference in response rates (95% CI)	2.97 (-4.38, 10.31)	
	p-value	0.4285	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Infections and infestations	Number of subjects with events, n (%)	130 (72.2)	112 (61.5)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.17 (1.01, 1.36)	
	p-value	0.0320	
	Odds Ratio (95% CI)	1.63 (1.04, 2.53)	
	p-value	0.0314	
	Risk Difference (95% CI)	10.68 (1.05, 20.32)	
	p-value	0.0297	
	CMH approach		
	Response rate	72.3	61.4
	Difference in response rates (95% CI)	10.92 (1.19, 20.66)	
	p-value	0.0279	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Infections and infestations, PT: Bronchitis	Number of subjects with events, n (%)	23 (12.8)	8 (4.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	2.91 (1.34, 6.33)	
	p-value	0.0072	
	Odds Ratio (95% CI)	3.19 (1.39, 7.33)	
	p-value	0.0064	
	Risk Difference (95% CI)	8.38 (2.67, 14.10)	
	p-value	0.0040	
	CMH approach		
	Response rate	13.0	4.5
	Difference in response rates (95% CI)	8.56 (1.76, 15.37)	
	p-value	0.0137	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Infections and infestations, PT: Herpes zoster	Number of subjects with events, n (%)	13 (7.2)	3 (1.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	4.38 (1.27, 15.12)	
	p-value	0.0194	
	Odds Ratio (95% CI)	4.64 (1.30, 16.59)	
	p-value	0.0181	
	Risk Difference (95% CI)	5.57 (1.36, 9.78)	
	p-value	0.0095	
	CMH approach		
	Response rate	7.2	1.7
	Difference in response rates (95% CI)	5.53 (-0.34, 11.40)	
	p-value	0.0651	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Infections and infestations, PT: Nasopharyngitis	Number of subjects with events, n (%)	28 (15.6)	23 (12.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.23 (0.74, 2.05)	
	p-value	0.4261	
	Odds Ratio (95% CI)	1.27 (0.70, 2.31)	
	p-value	0.4256	
	Risk Difference (95% CI)	2.92 (-4.25, 10.08)	
	p-value	0.4247	
	CMH approach		
	Response rate	15.7	12.5
	Difference in response rates (95% CI)	3.13 (-4.69, 10.95)	
	p-value	0.4327	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Infections and infestations, PT: Sinusitis	Number of subjects with events, n (%)	13 (7.2)	9 (4.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.46 (0.64, 3.33)	
	p-value	0.3679	
	Odds Ratio (95% CI)	1.50 (0.62, 3.59)	
	p-value	0.3673	
	Risk Difference (95% CI)	2.28 (-2.64, 7.20)	
	p-value	0.3645	
	CMH approach		
	Response rate	7.2	4.8
	Difference in response rates (95% CI)	2.45 (-3.74, 8.64)	
	p-value	0.4377	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Infections and infestations, PT: Upper respiratory tract infection	Number of subjects with events, n (%)	42 (23.3)	19 (10.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	2.24 (1.35, 3.69)	
	p-value	0.0017	
	Odds Ratio (95% CI)	2.61 (1.45, 4.70)	
	p-value	0.0014	
	Risk Difference (95% CI)	12.89 (5.28, 20.50)	
	p-value	0.0009	
	CMH approach		
	Response rate	23.2	10.3
	Difference in response rates (95% CI)	12.87 (4.76, 20.98)	
	p-value	0.0019	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Infections and infestations, PT: Urinary tract infection	Number of subjects with events, n (%)	21 (11.7)	26 (14.3)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.82 (0.48, 1.40)	
	p-value	0.4597	
	Odds Ratio (95% CI)	0.79 (0.43, 1.47)	
	p-value	0.4592	
	Risk Difference (95% CI)	-2.62 (-9.54, 4.30)	
	p-value	0.4580	
	CMH approach		
	Response rate	11.7	14.3
	Difference in response rates (95% CI)	-2.59 (-10.21, 5.04)	
	p-value	0.5058	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Injury, poisoning and procedural complications	Number of subjects with events, n (%)	44 (24.4)	34 (18.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.31 (0.88, 1.95)	
	p-value	0.1847	
	Odds Ratio (95% CI)	1.41 (0.85, 2.33)	
	p-value	0.1834	
	Risk Difference (95% CI)	5.76 (-2.69, 14.22)	
	p-value	0.1815	
	CMH approach		
	Response rate	24.7	18.4
	Difference in response rates (95% CI)	6.29 (-2.46, 15.04)	
	p-value	0.1588	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Injury, poisoning and procedural complications, PT: Infusion related reaction	Number of subjects with events, n (%)	25 (13.9)	14 (7.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.81 (0.97, 3.36)	
	p-value	0.0622	
	Odds Ratio (95% CI)	1.94 (0.97, 3.86)	
	p-value	0.0606	
	Risk Difference (95% CI)	6.20 (-0.17, 12.56)	
	p-value	0.0564	
	CMH approach		
	Response rate	14.1	7.5
	Difference in response rates (95% CI)	6.57 (-0.67, 13.80)	
	p-value	0.0752	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Investigations	Number of subjects with events, n (%)	10 (5.6)	9 (4.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.12 (0.47, 2.70)	
	p-value	0.7947	
	Odds Ratio (95% CI)	1.13 (0.45, 2.85)	
	p-value	0.7946	
	Risk Difference (95% CI)	0.61 (-3.99, 5.21)	
	p-value	0.7946	
	CMH approach		
	Response rate	5.6	4.9
	Difference in response rates (95% CI)	0.68 (-5.38, 6.73)	
	p-value	0.8266	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Metabolism and nutrition disorders	Number of subjects with events, n (%)	10 (5.6)	16 (8.8)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.63 (0.29, 1.35)	
	p-value	0.2383	
	Odds Ratio (95% CI)	0.61 (0.27, 1.38)	
	p-value	0.2370	
	Risk Difference (95% CI)	-3.24 (-8.54, 2.07)	
	p-value	0.2317	
	CMH approach		
	Response rate	5.6	8.7
	Difference in response rates (95% CI)	-3.14 (-9.58, 3.30)	
	p-value	0.3388	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Musculoskeletal and connective tissue disorders	Number of subjects with events, n (%)	41 (22.8)	35 (19.2)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.18 (0.79, 1.77)	
	p-value	0.4083	
	Odds Ratio (95% CI)	1.24 (0.75, 2.06)	
	p-value	0.4078	
	Risk Difference (95% CI)	3.55 (-4.84, 11.93)	
	p-value	0.4071	
	CMH approach		
	Response rate	22.9	19.3
	Difference in response rates (95% CI)	3.63 (-5.09, 12.35)	
	p-value	0.4145	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Musculoskeletal and connective tissue disorders, PT: Arthralgia	Number of subjects with events, n (%)	10 (5.6)	6 (3.3)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.69 (0.63, 4.54)	
	p-value	0.3020	
	Odds Ratio (95% CI)	1.73 (0.61, 4.85)	
	p-value	0.3010	
	Risk Difference (95% CI)	2.26 (-1.98, 6.49)	
	p-value	0.2957	
	CMH approach		
	Response rate	5.6	3.3
	Difference in response rates (95% CI)	2.28 (-3.54, 8.10)	
	p-value	0.4429	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Musculoskeletal and connective tissue disorders, PT: Back pain	Number of subjects with events, n (%)	11 (6.1)	3 (1.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	3.71 (1.05, 13.07)	
	p-value	0.0415	
	Odds Ratio (95% CI)	3.88 (1.07, 14.16)	
	p-value	0.0398	
	Risk Difference (95% CI)	4.46 (0.50, 8.42)	
	p-value	0.0271	
	CMH approach		
	Response rate	6.1	1.6
	Difference in response rates (95% CI)	4.50 (-1.11, 10.10)	
	p-value	0.1159	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Nervous system disorders	Number of subjects with events, n (%)	28 (15.6)	27 (14.8)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.05 (0.64, 1.71)	
	p-value	0.8486	
	Odds Ratio (95% CI)	1.06 (0.60, 1.88)	
	p-value	0.8486	
	Risk Difference (95% CI)	0.72 (-6.68, 8.12)	
	p-value	0.8486	
	CMH approach		
	Response rate	15.5	14.5
	Difference in response rates (95% CI)	1.00 (-6.83, 8.82)	
	p-value	0.8026	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Nervous system disorders, PT: Headache	Number of subjects with events, n (%)	11 (6.1)	18 (9.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.62 (0.30, 1.27)	
	p-value	0.1908	
	Odds Ratio (95% CI)	0.59 (0.27, 1.29)	
	p-value	0.1893	
	Risk Difference (95% CI)	-3.78 (-9.35, 1.79)	
	p-value	0.1838	
	CMH approach		
	Response rate	6.1	9.6
	Difference in response rates (95% CI)	-3.45 (-10.01, 3.12)	
	p-value	0.3033	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Psychiatric disorders	Number of subjects with events, n (%)	11 (6.1)	17 (9.3)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.65 (0.32, 1.36)	
	p-value	0.2546	
	Odds Ratio (95% CI)	0.63 (0.29, 1.39)	
	p-value	0.2534	
	Risk Difference (95% CI)	-3.23 (-8.72, 2.26)	
	p-value	0.2488	
	CMH approach		
	Response rate	6.0	9.3
	Difference in response rates (95% CI)	-3.23 (-9.80, 3.35)	
	p-value	0.3361	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Reproductive system and breast disorders	Number of subjects with events, n (%)	11 (6.1)	7 (3.8)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.59 (0.63, 4.01)	
	p-value	0.3265	
	Odds Ratio (95% CI)	1.63 (0.62, 4.30)	
	p-value	0.3257	
	Risk Difference (95% CI)	2.26 (-2.21, 6.74)	
	p-value	0.3215	
	CMH approach		
	Response rate	6.1	3.8
	Difference in response rates (95% CI)	2.32 (-3.66, 8.30)	
	p-value	0.4472	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with events, n (%)	23 (12.8)	27 (14.8)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.86 (0.51, 1.44)	
	p-value	0.5711	
	Odds Ratio (95% CI)	0.84 (0.46, 1.53)	
	p-value	0.5708	
	Risk Difference (95% CI)	-2.06 (-9.16, 5.05)	
	p-value	0.5702	
	CMH approach		
	Response rate	12.7	14.8
	Difference in response rates (95% CI)	-2.08 (-9.86, 5.70)	
	p-value	0.6009	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Respiratory, thoracic and mediastinal disorders, PT: Cough	Number of subjects with events, n (%)	10 (5.6)	7 (3.8)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.44 (0.56, 3.71)	
	p-value	0.4450	
	Odds Ratio (95% CI)	1.47 (0.55, 3.95)	
	p-value	0.4445	
	Risk Difference (95% CI)	1.71 (-2.65, 6.07)	
	p-value	0.4422	
	CMH approach		
	Response rate	5.5	3.9
	Difference in response rates (95% CI)	1.63 (-4.27, 7.53)	
	p-value	0.5873	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Skin and subcutaneous tissue disorders	Number of subjects with events, n (%)	29 (16.1)	29 (15.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.01 (0.63, 1.62)	
	p-value	0.9634	
	Odds Ratio (95% CI)	1.01 (0.58, 1.78)	
	p-value	0.9634	
	Risk Difference (95% CI)	0.18 (-7.38, 7.73)	
	p-value	0.9634	
	CMH approach		
	Response rate	16.3	15.7
	Difference in response rates (95% CI)	0.51 (-7.50, 8.52)	
	p-value	0.9008	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations	SLEDAI-2K score at screening									0.7186
	< 10 points	41/ 54 (75.9)	75.9	35/ 52 (67.3)	67.2	1.13 (0.89, 1.44)	0.3286	8.69 (-9.04, 26.41)	0.3367	
	>= 10 points	89/126 (70.6)	70.7	77/130 (59.2)	59.0	1.19 (0.99, 1.43)	0.0575	11.79 (0.15, 23.43)	0.0472	
	OCS dose at baseline									0.2680
	<10 mg/day	70/ 93 (75.3)	75.3	68/ 99 (68.7)	68.6	1.10 (0.92, 1.31)	0.3104	6.74 (-6.26, 19.74)	0.3096	
	>=10 mg/day	60/ 87 (69.0)	68.9	44/ 83 (53.0)	53.2	1.30 (1.02, 1.67)	0.0367	15.72 (1.19, 30.25)	0.0340	
	Result of type I IFN gene signature test									0.8729
	LOW	21/ 30 (70.0)	70.0	19/ 31 (61.3)	61.3	1.14 (0.79, 1.65)	0.4754	8.71 (-15.32, 32.74)	0.4775	
	HIGH	109/150 (72.7)	72.7	93/151 (61.6)	61.4	1.18 (1.01, 1.38)	0.0424	11.37 (0.73, 22.02)	0.0363	
	Age (years)									0.4484
	<= 65	126/175 (72.0)	72.0	112/181 (61.9)	61.7	1.16 (1.00, 1.35)	0.0434	10.32 (0.50, 20.15)	0.0394	
	> 65	4/ 5 (80.0)	80.0	0/ 1 (0.0)	0.0	3.00 (0.26, 34.57)	0.3784	80.00 (-24.53, 184.53)	0.1336	
	Sex									0.1175
	male	4/ 12 (33.3)	33.3	7/ 12 (58.3)	58.3	0.57 (0.22, 1.45)	0.2393	-25.00 (-64.22, 14.22)	0.2115	
	female	126/168 (75.0)	75.1	105/170 (61.8)	61.7	1.21 (1.05, 1.41)	0.0096	13.41 (3.44, 23.39)	0.0084	
	Race									0.6311
	White	74/110 (67.3)	66.8	59/107 (55.1)	55.3	1.22 (0.98, 1.51)	0.0698	11.50 (-1.51, 24.51)	0.0833	
	Black or African American	12/ 17 (70.6)	70.6	13/ 25 (52.0)	52.0	1.36 (0.84, 2.21)	0.2176	18.59 (-11.17, 48.35)	0.2209	
	Asian	24/ 30 (80.0)	80.0	23/ 30 (76.7)	76.7	1.04 (0.80, 1.36)	0.7542	3.33 (-18.57, 25.23)	0.7655	
	American Indian or Alaska Native	4/ 4 (100.0)	100.0	1/ 1 (100.0)	100.0	NE		0.00 (-104.98, 104.98)	1.0000	
	Other	9/ 11 (81.8)	81.8	9/ 11 (81.8)	81.8	1.00 (0.67, 1.48)	1.0000	0.00 (-36.96, 36.96)	1.0000	
	Ethnicity									0.9490
	Hispanic/Latino	40/ 54 (74.1)	73.7	34/ 54 (63.0)	62.8	1.18 (0.91, 1.52)	0.2176	10.91 (-6.96, 28.78)	0.2315	
	Non-hispanic/Latino	83/118 (70.3)	70.5	71/120 (59.2)	59.1	1.19 (0.98, 1.44)	0.0733	11.37 (-0.77, 23.52)	0.0663	
	Geographic region									0.6054
	EU	29/ 51 (56.9)	56.9	24/ 46 (52.2)	52.2	1.09 (0.76, 1.57)	0.6446	4.69 (-15.15, 24.53)	0.6432	
	non-EU	101/129 (78.3)	78.2	88/136 (64.7)	64.7	1.21 (1.04, 1.41)	0.0151	13.56 (2.47, 24.64)	0.0165	
	Onset of disease									0.1334
	Paediatric	10/ 14 (71.4)	71.4	10/ 12 (83.3)	83.3	0.86 (0.56, 1.30)	0.4686	-11.90 (-46.69, 22.88)	0.5024	
	Adult	120/166 (72.3)	72.3	102/170 (60.0)	59.9	1.20 (1.03, 1.41)	0.0182	12.41 (2.29, 22.53)	0.0163	
	ADA result									0.5352
	Negative	123/172 (71.5)	71.6	99/162 (61.1)	60.8	1.17 (1.00, 1.37)	0.0467	10.84 (0.67, 21.01)	0.0367	
	Positive (At any time)	7/ 8 (87.5)	87.5	13/ 20 (65.0)	65.0	1.35 (0.89, 2.04)	0.1601	22.50 (-14.25, 59.25)	0.2301	
	BMI (kg/m2) at enrolment									0.2020
	< 30	89/125 (71.2)	71.6	77/134 (57.5)	57.1	1.24 (1.03, 1.49)	0.0220	14.51 (3.00, 26.01)	0.0134	
	>= 30	41/ 55 (74.5)	75.1	35/ 48 (72.9)	72.2	1.02 (0.81, 1.29)	0.8516	2.91 (-15.05, 20.87)	0.7509	
	Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.6467
	All negative/normal	42/ 58 (72.4)	72.4	48/ 81 (59.3)	59.1	1.22 (0.96, 1.55)	0.1023	13.32 (-2.73, 29.36)	0.1039	
	At least one positive/abnormal	88/122 (72.1)	72.3	64/101 (63.4)	62.9	1.14 (0.95, 1.37)	0.1695	9.37 (-2.92, 21.65)	0.1352	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Bronchitis	SLEDAI-2K score at screening									0.0601
	< 10 points	4/ 54 (7.4)	7.4	4/ 52 (7.7)	7.7	0.96 (0.25, 3.65)	0.9557	-0.29 (-13.98, 13.41)	0.9674	
	>= 10 points	19/126 (15.1)	15.4	4/130 (3.1)	3.1	4.90 (1.71, 14.00)	0.0030	12.24 (4.25, 20.24)	0.0027	
	OCS dose at baseline									0.4900
	<10 mg/day	14/ 93 (15.1)	15.3	4/ 99 (4.0)	4.1	3.73 (1.27, 10.91)	0.0164	11.20 (1.16, 21.25)	0.0288	
	>=10 mg/day	9/ 87 (10.3)	10.5	4/ 83 (4.8)	4.9	2.15 (0.69, 6.70)	0.1886	5.60 (-4.16, 15.35)	0.2607	
	Result of type I IFN gene signature test									0.6460
	LOW	4/ 30 (13.3)	13.3	2/ 31 (6.5)	6.5	2.07 (0.41, 10.46)	0.3802	6.88 (-10.77, 24.53)	0.4448	
	HIGH	19/150 (12.7)	13.0	6/151 (4.0)	4.1	3.19 (1.31, 7.76)	0.0106	8.90 (1.54, 16.26)	0.0177	
	Age (years)									0.4769
	<= 65	22/175 (12.6)	12.8	8/181 (4.4)	4.5	2.84 (1.30, 6.22)	0.0088	8.33 (1.46, 15.21)	0.0175	
	> 65	1/ 5 (20.0)	20.0	0/ 1 (0.0)	0.0	1.00 (0.06, 15.99)	1.0000	20.00 (-84.53, 124.53)	0.7077	
	Sex									NE
	male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
	female	23/168 (13.7)	13.9	8/170 (4.7)	4.7	2.91 (1.34, 6.32)	0.0070	9.13 (1.94, 16.32)	0.0128	
	Race									0.2774
	White	16/110 (14.5)	14.9	4/107 (3.7)	3.8	3.89 (1.34, 11.26)	0.0122	11.09 (2.11, 20.07)	0.0155	
	Black or African American	4/ 17 (23.5)	23.5	1/ 25 (4.0)	4.0	5.88 (0.72, 48.18)	0.0986	19.53 (-5.04, 44.10)	0.1193	
	Asian	0/ 30 (0.0)	0.0	1/ 30 (3.3)	3.3	0.33 (0.01, 7.87)	0.4958	-3.33 (-16.52, 9.85)	0.6203	
	American Indian or Alaska Native	1/ 4 (25.0)	25.0	0/ 1 (0.0)	0.0	1.20 (0.08, 18.75)	0.8966	25.00 (-82.10, 132.10)	0.6473	
	Other	1/ 11 (9.1)	9.1	2/ 11 (18.2)	18.2	0.50 (0.05, 4.75)	0.5460	-9.09 (-44.33, 26.15)	0.6131	
	Ethnicity									0.8791
	Hispanic/Latino	5/ 54 (9.3)	9.1	2/ 54 (3.7)	3.7	2.50 (0.51, 12.33)	0.2604	5.36 (-7.66, 18.38)	0.4194	
	Non-hispanic/Latino	17/118 (14.4)	14.7	6/120 (5.0)	5.3	2.88 (1.18, 7.05)	0.0205	9.43 (0.34, 18.52)	0.0420	
	Geographic region									0.8979
	EU	7/ 51 (13.7)	13.7	2/ 46 (4.3)	4.3	3.16 (0.69, 14.44)	0.1383	9.38 (-3.45, 22.21)	0.1519	
	non-EU	16/129 (12.4)	12.7	6/136 (4.4)	4.4	2.81 (1.14, 6.96)	0.0255	8.27 (0.01, 16.53)	0.0497	
	Onset of disease									0.7588
	Paediatric	2/ 14 (14.3)	14.3	0/ 12 (0.0)	0.0	4.33 (0.23, 82.31)	0.3290	14.29 (-14.43, 43.00)	0.3295	
	Adult	21/166 (12.7)	12.8	8/170 (4.7)	4.7	2.69 (1.23, 5.90)	0.0136	8.03 (0.90, 15.17)	0.0274	
	ADA result									0.1902
	Negative	23/172 (13.4)	13.6	6/162 (3.7)	3.7	3.61 (1.51, 8.64)	0.0039	9.85 (2.75, 16.96)	0.0066	
	Positive (At any time)	0/ 8 (0.0)	0.0	2/ 20 (10.0)	10.0	0.47 (0.02, 8.78)	0.6107	-10.00 (-40.56, 20.56)	0.5212	
	BMI (kg/m2) at enrolment									0.8711
	< 30	17/125 (13.6)	13.6	6/134 (4.5)	4.5	3.04 (1.24, 7.46)	0.0153	9.12 (0.66, 17.58)	0.0346	
	>= 30	6/ 55 (10.9)	10.6	2/ 48 (4.2)	4.3	2.62 (0.55, 12.37)	0.2244	6.32 (-7.49, 20.13)	0.3699	
	Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.8033
	All negative/normal	7/ 58 (12.1)	12.4	3/ 81 (3.7)	3.9	3.26 (0.88, 12.07)	0.0771	8.55 (-3.43, 20.54)	0.1619	
	At least one positive/abnormal	16/122 (13.1)	13.3	5/101 (5.0)	4.9	2.65 (1.01, 6.98)	0.0488	8.37 (-0.30, 17.04)	0.0584	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Herpes zoster	SLEDAI-2K score at screening									0.8380
	< 10 points	1/ 54 (1.9)	1.9	0/ 52 (0.0)	0.0	2.89 (0.12, 69.40)	0.5127	1.89 (-9.43, 13.20)	0.7436	
	>= 10 points	12/126 (9.5)	9.4	3/130 (2.3)	2.4	4.13 (1.19, 14.28)	0.0252	7.04 (-0.13, 14.21)	0.0542	
	OCS dose at baseline									0.6254
	<10 mg/day	6/ 93 (6.5)	6.5	1/ 99 (1.0)	1.1	6.39 (0.78, 52.05)	0.0832	5.44 (-2.93, 13.82)	0.2027	
	>=10 mg/day	7/ 87 (8.0)	8.0	2/ 83 (2.4)	2.4	3.34 (0.71, 15.61)	0.1255	5.51 (-3.68, 14.70)	0.2399	
	Result of type I IFN gene signature test									0.4872
	LOW	2/ 30 (6.7)	6.7	1/ 31 (3.2)	3.2	2.07 (0.20, 21.61)	0.5444	3.44 (-11.73, 18.61)	0.6566	
	HIGH	11/150 (7.3)	7.3	2/151 (1.3)	1.4	5.54 (1.25, 24.56)	0.0243	5.95 (-0.41, 12.31)	0.0666	
	Age (years)									NE
	<= 65	13/175 (7.4)	7.4	3/181 (1.7)	1.7	4.48 (1.30, 15.46)	0.0176	5.75 (-0.23, 11.73)	0.0595	
	> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
	Sex									0.8608
	male	1/ 12 (8.3)	8.3	0/ 12 (0.0)	0.0	3.00 (0.13, 67.06)	0.4883	8.33 (-20.61, 37.28)	0.5726	
	female	12/168 (7.1)	7.1	3/170 (1.8)	1.8	4.05 (1.16, 14.09)	0.0280	5.31 (-0.85, 11.46)	0.0914	
	Race									0.5709
	White	5/110 (4.5)	4.8	2/107 (1.9)	1.8	2.43 (0.48, 12.26)	0.2817	3.02 (-4.20, 10.24)	0.4122	
	Black or African American	0/ 17 (0.0)	0.0	1/ 25 (4.0)	4.0	0.48 (0.02, 11.17)	0.6486	-4.00 (-22.36, 14.36)	0.6694	
	Asian	3/ 30 (10.0)	10.0	0/ 30 (0.0)	0.0	7.00 (0.38, 129.93)	0.1917	10.00 (-5.22, 25.22)	0.1977	
	American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
	Other	3/ 11 (27.3)	27.3	0/ 11 (0.0)	0.0	7.00 (0.40, 121.39)	0.1813	27.27 (-7.07, 61.62)	0.1196	
	Ethnicity									0.5236
	Hispanic/Latino	6/ 54 (11.1)	10.4	1/ 54 (1.9)	2.0	6.00 (0.75, 48.18)	0.0918	8.37 (-4.68, 21.41)	0.2086	
	Non-hispanic/Latino	5/118 (4.2)	4.4	2/120 (1.7)	1.7	2.54 (0.50, 12.85)	0.2589	2.75 (-4.78, 10.27)	0.4743	
	Geographic region									0.9252
	EU	2/ 51 (3.9)	3.9	0/ 46 (0.0)	0.0	4.52 (0.22, 91.74)	0.3261	3.92 (-5.18, 13.02)	0.3985	
	non-EU	11/129 (8.5)	8.5	3/136 (2.2)	2.3	3.87 (1.10, 13.54)	0.0345	6.23 (-1.35, 13.81)	0.1071	
	Onset of disease									0.9301
	Paediatric	2/ 14 (14.3)	14.3	0/ 12 (0.0)	0.0	4.33 (0.23, 82.31)	0.3290	14.29 (-14.43, 43.00)	0.3295	
	Adult	11/166 (6.6)	6.6	3/170 (1.8)	1.8	3.76 (1.07, 13.22)	0.0394	4.86 (-1.27, 10.99)	0.1199	
	ADA result									0.9795
	Negative	11/172 (6.4)	6.4	2/162 (1.2)	1.3	5.18 (1.17, 23.01)	0.0306	5.19 (-0.84, 11.23)	0.0918	
	Positive (At any time)	2/ 8 (25.0)	25.0	1/ 20 (5.0)	5.0	5.00 (0.52, 47.73)	0.1621	20.00 (-15.74, 55.74)	0.2727	
	BMI (kg/m2) at enrolment									0.4267
	< 30	7/125 (5.6)	5.6	1/134 (0.7)	0.8	7.50 (0.94, 60.13)	0.0577	4.82 (-2.28, 11.92)	0.1831	
	>= 30	6/ 55 (10.9)	11.4	2/ 48 (4.2)	3.9	2.62 (0.55, 12.37)	0.2244	7.50 (-6.63, 21.64)	0.2983	
	Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.7324
	All negative/normal	2/ 58 (3.4)	3.6	1/ 81 (1.2)	1.2	2.79 (0.26, 30.08)	0.3970	2.40 (-7.69, 12.49)	0.6412	
	At least one positive/abnormal	11/122 (9.0)	9.1	2/101 (2.0)	1.9	4.55 (1.03, 20.07)	0.0452	7.20 (-0.48, 14.88)	0.0662	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

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Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Upper respiratory tract infection	SLEDAI-2K score at screening									0.2723
	< 10 points	15/ 54 (27.8)	27.8	4/ 52 (7.7)	7.7	3.61 (1.28, 10.17)	0.0150	20.06 (4.25, 35.87)	0.0129	
	>= 10 points	27/126 (21.4)	21.3	15/130 (11.5)	11.4	1.86 (1.04, 3.32)	0.0370	9.88 (0.32, 19.44)	0.0428	
	OCS dose at baseline									0.5257
	<10 mg/day	22/ 93 (23.7)	23.4	12/ 99 (12.1)	12.0	1.95 (1.03, 3.72)	0.0418	11.38 (-0.19, 22.94)	0.0539	
	>=10 mg/day	20/ 87 (23.0)	23.0	7/ 83 (8.4)	8.5	2.73 (1.22, 6.11)	0.0148	14.46 (2.66, 26.26)	0.0164	
	Result of type I IFN gene signature test									0.1670
	LOW	8/ 30 (26.7)	26.7	1/ 31 (3.2)	3.2	8.27 (1.10, 62.15)	0.0402	23.44 (4.39, 42.49)	0.0159	
	HIGH	34/150 (22.7)	22.5	18/151 (11.9)	11.8	1.90 (1.13, 3.21)	0.0164	10.72 (1.77, 19.68)	0.0189	
	Age (years)									0.5764
	<= 65	41/175 (23.4)	23.3	19/181 (10.5)	10.4	2.23 (1.35, 3.69)	0.0017	12.89 (4.67, 21.10)	0.0021	
	> 65	1/ 5 (20.0)	20.0	0/ 1 (0.0)	0.0	1.00 (0.06, 15.99)	1.0000	20.00 (-84.53, 124.53)	0.7077	
	Sex									0.8432
	male	1/ 12 (8.3)	8.3	0/ 12 (0.0)	0.0	3.00 (0.13, 67.06)	0.4883	8.33 (-20.61, 37.28)	0.5726	
	female	41/168 (24.4)	24.4	19/170 (11.2)	11.1	2.18 (1.32, 3.60)	0.0022	13.23 (4.68, 21.79)	0.0024	
	Race									0.1929
	White	25/110 (22.7)	22.4	9/107 (8.4)	8.4	2.70 (1.32, 5.52)	0.0064	14.01 (3.76, 24.25)	0.0074	
	Black or African American	5/ 17 (29.4)	29.4	0/ 25 (0.0)	0.0	15.89 (0.94, 269.78)	0.0556	29.41 (4.90, 53.92)	0.0187	
	Asian	7/ 30 (23.3)	23.3	6/ 30 (20.0)	20.0	1.17 (0.44, 3.06)	0.7544	3.33 (-18.57, 25.23)	0.7655	
	American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
	Other	5/ 11 (45.5)	45.5	4/ 11 (36.4)	36.4	1.25 (0.45, 3.45)	0.6665	9.09 (-32.23, 50.41)	0.6663	
	Ethnicity									0.7137
	Hispanic/Latino	13/ 54 (24.1)	24.3	5/ 54 (9.3)	9.2	2.60 (1.00, 6.79)	0.0511	15.05 (-0.46, 30.56)	0.0573	
	Non-hispanic/Latino	29/118 (24.6)	24.4	14/120 (11.7)	11.4	2.11 (1.17, 3.78)	0.0126	13.08 (2.66, 23.51)	0.0139	
	Geographic region									0.8844
	EU	3/ 51 (5.9)	5.9	1/ 46 (2.2)	2.2	2.71 (0.29, 25.11)	0.3812	3.71 (-6.75, 14.17)	0.4870	
	non-EU	39/129 (30.2)	30.0	18/136 (13.2)	13.3	2.28 (1.38, 3.78)	0.0013	16.75 (6.48, 27.01)	0.0014	
	Onset of disease									0.8117
	Paediatric	2/ 14 (14.3)	14.3	1/ 12 (8.3)	8.3	1.71 (0.18, 16.65)	0.6421	5.95 (-25.06, 36.97)	0.7068	
	Adult	40/166 (24.1)	24.0	18/170 (10.6)	10.6	2.28 (1.36, 3.80)	0.0017	13.47 (4.94, 21.99)	0.0020	
	ADA result									0.6132
	Negative	41/172 (23.8)	23.8	17/162 (10.5)	10.3	2.27 (1.35, 3.83)	0.0021	13.41 (4.92, 21.91)	0.0020	
	Positive (At any time)	1/ 8 (12.5)	12.5	2/ 20 (10.0)	10.0	1.25 (0.13, 11.93)	0.8463	2.50 (-31.66, 36.66)	0.8860	
	BMI (kg/m2) at enrolment									0.1223
	< 30	23/125 (18.4)	18.5	15/134 (11.2)	11.1	1.64 (0.90, 3.00)	0.1063	7.40 (-2.14, 16.94)	0.1284	
	>= 30	19/ 55 (34.5)	35.2	4/ 48 (8.3)	8.9	4.15 (1.52, 11.34)	0.0056	26.27 (9.43, 43.10)	0.0022	
	Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.0625
	All negative/normal	18/ 58 (31.0)	30.6	6/ 81 (7.4)	7.3	4.19 (1.77, 9.90)	0.0011	23.26 (9.11, 37.41)	0.0013	
	At least one positive/abnormal	24/122 (19.7)	19.7	13/101 (12.9)	12.9	1.53 (0.82, 2.84)	0.1808	6.80 (-3.55, 17.15)	0.1977	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SOC: Musculoskeletal and connective tissue disorders, PT: Back pain	SLEDAI-2K score at screening									0.4831
	< 10 points	5/ 54 (9.3)	9.2	2/ 52 (3.8)	3.8	2.41 (0.49, 11.86)	0.2803	5.38 (-7.87, 18.64)	0.4261	
	>= 10 points	6/126 (4.8)	4.9	1/130 (0.8)	0.7	6.19 (0.76, 50.69)	0.0893	4.13 (-1.95, 10.22)	0.1828	
	OCS dose at baseline									0.5220
	<10 mg/day	9/ 93 (9.7)	9.4	2/ 99 (2.0)	2.0	4.79 (1.06, 21.59)	0.0414	7.43 (-1.40, 16.26)	0.0991	
	>=10 mg/day	2/ 87 (2.3)	2.3	1/ 83 (1.2)	1.2	1.91 (0.18, 20.65)	0.5949	1.08 (-6.64, 8.79)	0.7846	
	Result of type I IFN gene signature test									0.5820
	LOW	2/ 30 (6.7)	6.7	1/ 31 (3.2)	3.2	2.07 (0.20, 21.61)	0.5444	3.44 (-11.73, 18.61)	0.6566	
	HIGH	9/150 (6.0)	6.0	2/151 (1.3)	1.3	4.53 (1.00, 20.62)	0.0507	4.71 (-1.29, 10.71)	0.1238	
	Age (years)									NE
	<= 65	11/175 (6.3)	6.3	3/181 (1.7)	1.6	3.79 (1.08, 13.36)	0.0381	4.66 (-1.04, 10.37)	0.1091	
	> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
	Sex									0.9455
	male	1/ 12 (8.3)	8.3	0/ 12 (0.0)	0.0	3.00 (0.13, 67.06)	0.4883	8.33 (-20.61, 37.28)	0.5726	
	female	10/168 (6.0)	6.0	3/170 (1.8)	1.7	3.37 (0.94, 12.04)	0.0611	4.26 (-1.62, 10.14)	0.1555	
	Race									0.3529
	White	9/110 (8.2)	7.5	1/107 (0.9)	0.9	8.75 (1.13, 67.92)	0.0379	6.60 (-0.60, 13.80)	0.0723	
	Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.13, 17.13)	1.0000	
	Asian	2/ 30 (6.7)	6.7	1/ 30 (3.3)	3.3	2.00 (0.19, 20.90)	0.5626	3.33 (-12.03, 18.69)	0.6706	
	American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
	Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-28.41, 28.41)	1.0000	
	Ethnicity									0.7062
	Hispanic/Latino	4/ 54 (7.4)	8.1	1/ 54 (1.9)	1.7	4.00 (0.46, 34.64)	0.2081	6.38 (-5.72, 18.47)	0.3014	
	Non-hispanic/Latino	7/118 (5.9)	5.9	1/120 (0.8)	0.8	7.12 (0.89, 56.97)	0.0644	5.13 (-2.38, 12.64)	0.1807	
	Geographic region									0.4999
	EU	2/ 51 (3.9)	3.9	1/ 46 (2.2)	2.2	1.80 (0.17, 19.24)	0.6252	1.75 (-8.15, 11.64)	0.7292	
	non-EU	9/129 (7.0)	7.0	2/136 (1.5)	1.4	4.74 (1.04, 21.54)	0.0437	5.55 (-1.62, 12.73)	0.1293	
	Onset of disease									0.2519
	Paediatric	1/ 14 (7.1)	7.1	1/ 12 (8.3)	8.3	0.86 (0.06, 12.28)	0.9097	-1.19 (-30.67, 28.28)	0.9369	
	Adult	10/166 (6.0)	6.0	2/170 (1.2)	1.2	5.12 (1.14, 23.02)	0.0332	4.83 (-0.98, 10.65)	0.1032	
	ADA result									0.2805
	Negative	11/172 (6.4)	6.5	2/162 (1.2)	1.3	5.18 (1.17, 23.01)	0.0306	5.18 (-0.74, 11.10)	0.0864	
	Positive (At any time)	0/ 8 (0.0)	0.0	1/ 20 (5.0)	5.0	0.78 (0.03, 17.33)	0.8739	-5.00 (-34.61, 24.61)	0.7407	
	BMI (kg/m2) at enrolment									0.2553
	< 30	10/125 (8.0)	8.1	2/134 (1.5)	1.5	5.36 (1.20, 23.99)	0.0281	6.61 (-0.74, 13.97)	0.0780	
	>= 30	1/ 55 (1.8)	1.4	1/ 48 (2.1)	1.8	0.87 (0.06, 13.58)	0.9226	-0.32 (-12.18, 11.54)	0.9577	
	Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.1911
	All negative/normal	7/ 58 (12.1)	11.5	1/ 81 (1.2)	1.2	9.78 (1.24, 77.32)	0.0307	10.30 (-1.01, 21.60)	0.0742	
	At least one positive/abnormal	4/122 (3.3)	3.0	2/101 (2.0)	2.0	1.66 (0.31, 8.86)	0.5556	1.04 (-5.41, 7.49)	0.7522	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Serious Adverse Events by SOC, PT (incidence in either arm >= 5% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Infections and infestations	Number of subjects with events, n (%)	7 (3.9)	12 (6.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.59 (0.24, 1.46)	
	p-value	0.2550	
	Odds Ratio (95% CI)	0.57 (0.22, 1.49)	
	p-value	0.2539	
	Risk Difference (95% CI)	-2.70 (-7.28, 1.88)	
	p-value	0.2471	
	CMH approach		
	Response rate	3.9	6.6
	Difference in response rates (95% CI)	-2.65 (-8.72, 3.42)	
	p-value	0.3924	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Serious Adverse Events by SOC, PT (incidence in either arm >= 5% or >=10 patients) - Subgroup analysis
Full analysis set

- NO OBSERVATIONS FOR THIS ANALYSIS -

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Severe (Grade >=3) by SOC, PT (incidence in either arm >= 5% or >=10 patients)
Full analysis set

- NO OBSERVATIONS FOR THIS ANALYSIS -

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Severe (Grade >=3) by SOC, PT (incidence in either arm >= 5% or >=10 patients) - Subgroup analysis
Full analysis set

- NO OBSERVATIONS FOR THIS ANALYSIS -

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event (on-treatment)
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	159 (88.3)	153 (84.1)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.05 (0.97, 1.14)	
p-value	0.2399	
Odds Ratio (95% CI)	1.44 (0.78, 2.63)	
p-value	0.2410	
Risk Difference (95% CI)	4.27 (-2.82, 11.36)	
p-value	0.2381	
CMH approach		
Response rate	88.2	84.0
Difference in response rates (95% CI)	4.28 (-3.52, 12.09)	
p-value	0.2819	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event (on-treatment) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.5011
< 10 points	51/ 54 (94.4)	94.4	45/ 52 (86.5)	86.5	1.09 (0.96, 1.24)	0.1711	7.88 (-6.28, 22.05)	0.2752	
>= 10 points	108/126 (85.7)	85.7	108/130 (83.1)	82.9	1.03 (0.93, 1.15)	0.5610	2.75 (-6.71, 12.22)	0.5686	
OCS dose at baseline									0.3629
<10 mg/day	83/ 93 (89.2)	89.2	87/ 99 (87.9)	87.8	1.02 (0.92, 1.12)	0.7657	1.40 (-9.04, 11.84)	0.7926	
>=10 mg/day	76/ 87 (87.4)	87.3	66/ 83 (79.5)	79.6	1.10 (0.96, 1.26)	0.1733	7.67 (-4.33, 19.66)	0.2103	
Result of type I IFN gene signature test									0.8779
LOW	25/ 30 (83.3)	83.3	25/ 31 (80.6)	80.6	1.03 (0.82, 1.31)	0.7847	2.69 (-18.00, 23.37)	0.7989	
HIGH	134/150 (89.3)	89.2	128/151 (84.8)	84.6	1.05 (0.97, 1.15)	0.2392	4.61 (-3.79, 13.01)	0.2821	
Age (years)									0.2245
<= 65	155/175 (88.6)	88.4	152/181 (84.0)	83.9	1.05 (0.97, 1.15)	0.2083	4.52 (-3.35, 12.39)	0.2605	
> 65	4/ 5 (80.0)	80.0	1/ 1 (100.0)	100.0	0.80 (0.52, 1.24)	0.3183	-20.00 (-124.53, 84.53)	0.7077	
Sex									0.4431
male	9/ 12 (75.0)	75.0	10/ 12 (83.3)	83.3	0.90 (0.60, 1.36)	0.6172	-8.33 (-44.22, 27.56)	0.6490	
female	150/168 (89.3)	89.3	143/170 (84.1)	84.1	1.06 (0.98, 1.15)	0.1628	5.21 (-2.82, 13.23)	0.2036	
Race									0.2692
White	94/110 (85.5)	85.0	84/107 (78.5)	78.8	1.09 (0.96, 1.23)	0.1856	6.22 (-4.67, 17.10)	0.2630	
Black or African American	14/ 17 (82.4)	82.4	19/ 25 (76.0)	76.0	1.08 (0.79, 1.48)	0.6133	6.35 (-20.42, 33.13)	0.6419	
Asian	29/ 30 (96.7)	96.7	30/ 30 (100.0)	100.0	0.97 (0.90, 1.03)	0.3173	-3.33 (-16.52, 9.85)	0.6203	
American Indian or Alaska Native	3/ 4 (75.0)	75.0	1/ 1 (100.0)	100.0	0.75 (0.43, 1.32)	0.3190	-25.00 (-132.10, 82.10)	0.6473	
Other	11/ 11 (100.0)	100.0	11/ 11 (100.0)	100.0	NE		0.00 (-28.41, 28.41)	1.0000	
Ethnicity									0.3983
Hispanic/Latino	48/ 54 (88.9)	88.9	43/ 54 (79.6)	79.4	1.12 (0.95, 1.32)	0.1902	9.52 (-6.10, 25.14)	0.2324	
Non-hispanic/Latino	103/118 (87.3)	87.1	102/120 (85.0)	84.9	1.03 (0.93, 1.14)	0.6095	2.29 (-7.66, 12.24)	0.6517	
Geographic region									0.7247
EU	42/ 51 (82.4)	82.4	37/ 46 (80.4)	80.4	1.02 (0.85, 1.24)	0.8088	1.92 (-14.32, 18.16)	0.8170	
non-EU	117/129 (90.7)	90.4	116/136 (85.3)	85.3	1.06 (0.97, 1.16)	0.1762	5.19 (-3.86, 14.23)	0.2609	
Onset of disease									0.1260
Paediatric	13/ 14 (92.9)	92.9	12/ 12 (100.0)	100.0	0.93 (0.80, 1.07)	0.3174	-7.14 (-34.18, 19.90)	0.6047	
Adult	146/166 (88.0)	87.8	141/170 (82.9)	82.9	1.06 (0.97, 1.16)	0.1935	4.95 (-3.29, 13.19)	0.2392	
ADA result									0.5413
Negative	151/172 (87.8)	87.8	135/162 (83.3)	83.1	1.05 (0.96, 1.15)	0.2490	4.65 (-3.62, 12.92)	0.2708	
Positive (At any time)	8/ 8 (100.0)	100.0	18/ 20 (90.0)	90.0	1.11 (0.96, 1.29)	0.1575	10.00 (-20.56, 40.56)	0.5212	
BMI (kg/m2) at enrolment									0.9545
< 30	111/125 (88.8)	89.1	113/134 (84.3)	84.1	1.05 (0.96, 1.16)	0.2912	5.00 (-4.31, 14.32)	0.2926	
>= 30	48/ 55 (87.3)	87.6	40/ 48 (83.3)	82.9	1.05 (0.89, 1.23)	0.5759	4.67 (-11.29, 20.62)	0.5666	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.8002
All negative/normal	51/ 58 (87.9)	87.8	67/ 81 (82.7)	82.8	1.06 (0.93, 1.22)	0.3847	4.96 (-8.54, 18.47)	0.4711	
At least one positive/abnormal	108/122 (88.5)	88.7	86/101 (85.1)	84.9	1.04 (0.94, 1.15)	0.4616	3.83 (-5.84, 13.49)	0.4376	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Serious Adverse Event (on-treatment)
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	15 (8.3)	31 (17.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.49 (0.27, 0.87)	
p-value	0.0159	
Odds Ratio (95% CI)	0.44 (0.23, 0.85)	
p-value	0.0148	
Risk Difference (95% CI)	-8.70 (-15.49, -1.91)	
p-value	0.0121	
CMH approach		
Response rate	8.3	17.0
Difference in response rates (95% CI)	-8.73 (-16.26, -1.20)	
p-value	0.0230	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Serious Adverse Event (on-treatment) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9723
< 10 points	2/ 54 (3.7)	3.7	4/ 52 (7.7)	7.7	0.48 (0.09, 2.52)	0.3865	-4.06 (-17.23, 9.11)	0.5459	
>= 10 points	13/126 (10.3)	10.2	27/130 (20.8)	20.8	0.50 (0.27, 0.92)	0.0257	-10.65 (-20.06, -1.25)	0.0264	
OCS dose at baseline									0.4027
<10 mg/day	5/ 93 (5.4)	5.5	15/ 99 (15.2)	14.9	0.35 (0.13, 0.94)	0.0366	-9.38 (-19.61, 0.84)	0.0722	
>=10 mg/day	10/ 87 (11.5)	11.5	16/ 83 (19.3)	19.4	0.60 (0.29, 1.24)	0.1654	-7.92 (-19.83, 4.00)	0.1927	
Result of type I IFN gene signature test									0.5797
LOW	1/ 30 (3.3)	3.3	1/ 31 (3.2)	3.2	1.03 (0.07, 15.78)	0.9812	0.11 (-14.04, 14.25)	0.9881	
HIGH	14/150 (9.3)	9.3	30/151 (19.9)	19.8	0.47 (0.26, 0.85)	0.0125	-10.53 (-19.11, -1.94)	0.0163	
Age (years)									0.5987
<= 65	14/175 (8.0)	7.9	31/181 (17.1)	17.1	0.47 (0.26, 0.85)	0.0123	-9.24 (-16.81, -1.67)	0.0167	
> 65	1/ 5 (20.0)	20.0	0/ 1 (0.0)	0.0	1.00 (0.06, 15.99)	1.0000	20.00 (-84.53, 124.53)	0.7077	
Sex									0.4131
male	2/ 12 (16.7)	16.7	2/ 12 (16.7)	16.7	1.00 (0.17, 5.98)	1.0000	0.00 (-34.65, 34.65)	1.0000	
female	13/168 (7.7)	7.6	29/170 (17.1)	17.1	0.45 (0.24, 0.84)	0.0122	-9.51 (-17.30, -1.73)	0.0166	
Race									0.7401
White	10/110 (9.1)	9.1	18/107 (16.8)	16.8	0.54 (0.26, 1.12)	0.0965	-7.73 (-17.63, 2.18)	0.1264	
Black or African American	0/ 17 (0.0)	0.0	5/ 25 (20.0)	20.0	0.13 (0.01, 2.23)	0.1600	-20.00 (-41.82, 1.82)	0.0724	
Asian	3/ 30 (10.0)	10.0	6/ 30 (20.0)	20.0	0.50 (0.14, 1.82)	0.2924	-10.00 (-29.77, 9.77)	0.3216	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	2/ 11 (18.2)	18.2	0.20 (0.01, 3.74)	0.2815	-18.18 (-51.14, 14.78)	0.2796	
Ethnicity									0.3203
Hispanic/Latino	2/ 54 (3.7)	3.9	9/ 54 (16.7)	17.3	0.22 (0.05, 0.98)	0.0471	-13.48 (-27.79, 0.83)	0.0648	
Non-hispanic/Latino	11/118 (9.3)	9.4	22/120 (18.3)	17.9	0.51 (0.26, 1.00)	0.0505	-8.50 (-18.33, 1.33)	0.0902	
Geographic region									0.2925
EU	6/ 51 (11.8)	11.8	7/ 46 (15.2)	15.2	0.77 (0.28, 2.13)	0.6192	-3.45 (-18.18, 11.27)	0.6459	
non-EU	9/129 (7.0)	7.0	24/136 (17.6)	17.8	0.40 (0.19, 0.82)	0.0124	-10.84 (-19.81, -1.86)	0.0180	
Onset of disease									0.0274
Paediatric	5/ 14 (35.7)	35.7	2/ 12 (16.7)	16.7	2.14 (0.50, 9.11)	0.3020	19.05 (-16.34, 54.44)	0.2915	
Adult	10/166 (6.0)	6.0	29/170 (17.1)	17.2	0.35 (0.18, 0.70)	0.0029	-11.20 (-18.83, -3.58)	0.0040	
ADA result									0.5179
Negative	15/172 (8.7)	8.6	26/162 (16.0)	16.0	0.54 (0.30, 0.99)	0.0457	-7.31 (-15.18, 0.56)	0.0687	
Positive (At any time)	0/ 8 (0.0)	0.0	5/ 20 (25.0)	25.0	0.21 (0.01, 3.45)	0.2756	-25.00 (-57.61, 7.61)	0.1330	
BMI (kg/m2) at enrolment									0.9824
< 30	9/125 (7.2)	7.3	20/134 (14.9)	14.7	0.48 (0.23, 1.02)	0.0561	-7.44 (-16.34, 1.46)	0.1015	
>= 30	6/ 55 (10.9)	11.4	11/ 48 (22.9)	23.9	0.48 (0.19, 1.19)	0.1123	-12.48 (-29.04, 4.08)	0.1397	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.0621
All negative/normal	7/ 58 (12.1)	12.6	10/ 81 (12.3)	11.9	0.98 (0.40, 2.42)	0.9609	0.74 (-12.18, 13.66)	0.9108	
At least one positive/abnormal	8/122 (6.6)	6.7	21/101 (20.8)	20.4	0.32 (0.15, 0.68)	0.0033	-13.69 (-23.60, -3.77)	0.0068	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Severe Adverse Event (on-treatment)
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	6 (3.3)	12 (6.6)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.51 (0.19, 1.32)	
p-value	0.1629	
Odds Ratio (95% CI)	0.49 (0.18, 1.33)	
p-value	0.1613	
Risk Difference (95% CI)	-3.26 (-7.72, 1.20)	
p-value	0.1518	
CMH approach		
Response rate	3.3	6.7
Difference in response rates (95% CI)	-3.45 (-9.40, 2.50)	
p-value	0.2558	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Severe Adverse Event (on-treatment) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9469
< 10 points	2/ 54 (3.7)	3.7	4/ 52 (7.7)	7.7	0.48 (0.09, 2.52)	0.3865	-4.01 (-17.10, 9.08)	0.5482	
>= 10 points	4/126 (3.2)	3.1	8/130 (6.2)	6.3	0.52 (0.16, 1.67)	0.2695	-3.21 (-9.98, 3.56)	0.3524	
OCS dose at baseline									0.3419
<10 mg/day	1/ 93 (1.1)	1.1	5/ 99 (5.1)	5.2	0.21 (0.03, 1.79)	0.1543	-4.07 (-12.14, 4.00)	0.3225	
>=10 mg/day	5/ 87 (5.7)	5.8	7/ 83 (8.4)	8.4	0.68 (0.23, 2.06)	0.4973	-2.63 (-12.36, 7.10)	0.5965	
Result of type I IFN gene signature test									0.1922
LOW	2/ 30 (6.7)	6.7	1/ 31 (3.2)	3.2	2.07 (0.20, 21.61)	0.5444	3.44 (-11.73, 18.61)	0.6566	
HIGH	4/150 (2.7)	2.6	11/151 (7.3)	7.4	0.37 (0.12, 1.12)	0.0791	-4.85 (-11.31, 1.61)	0.1413	
Age (years)									NE
<= 65	6/175 (3.4)	3.4	12/181 (6.6)	6.8	0.52 (0.20, 1.35)	0.1772	-3.40 (-9.45, 2.65)	0.2703	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									0.7614
male	0/ 12 (0.0)	0.0	1/ 12 (8.3)	8.3	0.33 (0.01, 7.45)	0.4883	-8.33 (-37.28, 20.61)	0.5726	
female	6/168 (3.6)	3.5	11/170 (6.5)	6.5	0.55 (0.21, 1.46)	0.2306	-3.01 (-9.26, 3.23)	0.3445	
Race									0.6186
White	3/110 (2.7)	2.7	9/107 (8.4)	8.6	0.32 (0.09, 1.17)	0.0844	-5.97 (-13.91, 1.98)	0.1410	
Black or African American	0/ 17 (0.0)	0.0	2/ 25 (8.0)	8.0	0.29 (0.01, 5.67)	0.4135	-8.00 (-27.43, 11.43)	0.4196	
Asian	0/ 30 (0.0)	0.0	1/ 30 (3.3)	3.3	0.33 (0.01, 7.87)	0.4958	-3.33 (-16.52, 9.85)	0.6203	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	1/ 11 (9.1)	9.1	0/ 11 (0.0)	0.0	3.00 (0.14, 66.53)	0.4872	9.09 (-21.93, 40.11)	0.5657	
Ethnicity									0.7783
Hispanic/Latino	2/ 54 (3.7)	3.9	5/ 54 (9.3)	9.7	0.40 (0.08, 1.97)	0.2604	-5.85 (-19.12, 7.42)	0.3874	
Non-hispanic/Latino	2/118 (1.7)	1.7	7/120 (5.8)	6.0	0.29 (0.06, 1.37)	0.1183	-4.30 (-11.90, 3.29)	0.2663	
Geographic region									0.1864
EU	3/ 51 (5.9)	5.9	2/ 46 (4.3)	4.3	1.35 (0.24, 7.74)	0.7341	1.53 (-9.59, 12.66)	0.7868	
non-EU	3/129 (2.3)	2.3	10/136 (7.4)	7.5	0.32 (0.09, 1.12)	0.0751	-5.22 (-12.59, 2.15)	0.1653	
Onset of disease									0.2380
Paediatric	2/ 14 (14.3)	14.3	1/ 12 (8.3)	8.3	1.71 (0.18, 16.65)	0.6421	5.95 (-25.06, 36.97)	0.7068	
Adult	4/166 (2.4)	2.4	11/170 (6.5)	6.6	0.37 (0.12, 1.15)	0.0850	-4.18 (-10.31, 1.94)	0.1805	
ADA result									0.8026
Negative	6/172 (3.5)	3.4	11/162 (6.8)	6.9	0.51 (0.19, 1.36)	0.1790	-3.49 (-9.82, 2.84)	0.2796	
Positive (At any time)	0/ 8 (0.0)	0.0	1/ 20 (5.0)	5.0	0.78 (0.03, 17.33)	0.8739	-5.00 (-34.61, 24.61)	0.7407	
BMI (kg/m2) at enrolment									0.8325
< 30	3/125 (2.4)	2.3	6/134 (4.5)	4.4	0.54 (0.14, 2.10)	0.3703	-2.03 (-9.00, 4.93)	0.5675	
>= 30	3/ 55 (5.5)	5.9	6/ 48 (12.5)	12.8	0.44 (0.12, 1.65)	0.2219	-6.94 (-21.69, 7.81)	0.3566	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.8671
All negative/normal	2/ 58 (3.4)	3.6	6/ 81 (7.4)	7.7	0.47 (0.10, 2.23)	0.3381	-4.11 (-15.23, 7.02)	0.4694	
At least one positive/abnormal	4/122 (3.3)	3.2	6/101 (5.9)	5.9	0.55 (0.16, 1.90)	0.3465	-2.69 (-10.07, 4.69)	0.4749	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Non-Severe Adverse Event (on-treatment)
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	159 (88.3)	152 (83.5)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.06 (0.97, 1.15)	
p-value	0.1885	
Odds Ratio (95% CI)	1.49 (0.82, 2.72)	
p-value	0.1897	
Risk Difference (95% CI)	4.82 (-2.33, 11.96)	
p-value	0.1864	
CMH approach		
Response rate	88.2	83.4
Difference in response rates (95% CI)	4.86 (-2.99, 12.70)	
p-value	0.2249	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Non-Severe Adverse Event (on-treatment) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.5769
< 10 points	51/ 54 (94.4)	94.4	45/ 52 (86.5)	86.5	1.09 (0.96, 1.24)	0.1711	7.88 (-6.28, 22.05)	0.2752	
>= 10 points	108/126 (85.7)	85.7	107/130 (82.3)	82.1	1.04 (0.94, 1.16)	0.4573	3.56 (-5.97, 13.09)	0.4636	
OCS dose at baseline									0.2846
<10 mg/day	83/ 93 (89.2)	89.2	87/ 99 (87.9)	87.8	1.02 (0.92, 1.12)	0.7657	1.40 (-9.04, 11.84)	0.7926	
>=10 mg/day	76/ 87 (87.4)	87.3	65/ 83 (78.3)	78.4	1.12 (0.97, 1.28)	0.1222	8.89 (-3.23, 21.00)	0.1505	
Result of type I IFN gene signature test									0.8302
LOW	25/ 30 (83.3)	83.3	25/ 31 (80.6)	80.6	1.03 (0.82, 1.31)	0.7847	2.69 (-18.00, 23.37)	0.7989	
HIGH	134/150 (89.3)	89.2	127/151 (84.1)	83.9	1.06 (0.97, 1.16)	0.1827	5.30 (-3.15, 13.75)	0.2192	
Age (years)									0.2139
<= 65	155/175 (88.6)	88.4	151/181 (83.4)	83.3	1.06 (0.98, 1.15)	0.1623	5.10 (-2.81, 13.00)	0.2066	
> 65	4/ 5 (80.0)	80.0	1/ 1 (100.0)	100.0	0.80 (0.52, 1.24)	0.3183	-20.00 (-124.53, 84.53)	0.7077	
Sex									0.4242
male	9/ 12 (75.0)	75.0	10/ 12 (83.3)	83.3	0.90 (0.60, 1.36)	0.6172	-8.33 (-44.22, 27.56)	0.6490	
female	150/168 (89.3)	89.3	142/170 (83.5)	83.5	1.07 (0.98, 1.16)	0.1237	5.82 (-2.25, 13.89)	0.1574	
Race									0.2203
White	94/110 (85.5)	85.0	83/107 (77.6)	77.9	1.10 (0.97, 1.25)	0.1376	7.13 (-3.83, 18.08)	0.2023	
Black or African American	14/ 17 (82.4)	82.4	19/ 25 (76.0)	76.0	1.08 (0.79, 1.48)	0.6133	6.35 (-20.42, 33.13)	0.6419	
Asian	29/ 30 (96.7)	96.7	30/ 30 (100.0)	100.0	0.97 (0.90, 1.03)	0.3173	-3.33 (-16.52, 9.85)	0.6203	
American Indian or Alaska Native	3/ 4 (75.0)	75.0	1/ 1 (100.0)	100.0	0.75 (0.43, 1.32)	0.3190	-25.00 (-132.10, 82.10)	0.6473	
Other	11/ 11 (100.0)	100.0	11/ 11 (100.0)	100.0	NE		0.00 (-28.41, 28.41)	1.0000	
Ethnicity									0.2921
Hispanic/Latino	48/ 54 (88.9)	88.9	42/ 54 (77.8)	77.4	1.14 (0.96, 1.36)	0.1257	11.53 (-4.29, 27.35)	0.1533	
Non-hispanic/Latino	103/118 (87.3)	87.1	102/120 (85.0)	84.9	1.03 (0.93, 1.14)	0.6095	2.29 (-7.66, 12.24)	0.6517	
Geographic region									0.6662
EU	42/ 51 (82.4)	82.4	37/ 46 (80.4)	80.4	1.02 (0.85, 1.24)	0.8088	1.92 (-14.32, 18.16)	0.8170	
non-EU	117/129 (90.7)	90.4	115/136 (84.6)	84.5	1.07 (0.98, 1.17)	0.1296	5.97 (-3.14, 15.07)	0.1992	
Onset of disease									0.1081
Paediatric	13/ 14 (92.9)	92.9	12/ 12 (100.0)	100.0	0.93 (0.80, 1.07)	0.3174	-7.14 (-34.18, 19.90)	0.6047	
Adult	146/166 (88.0)	87.8	140/170 (82.4)	82.3	1.07 (0.98, 1.17)	0.1498	5.56 (-2.72, 13.84)	0.1883	
ADA result									0.6005
Negative	151/172 (87.8)	87.8	134/162 (82.7)	82.5	1.06 (0.97, 1.16)	0.1937	5.29 (-3.02, 13.61)	0.2122	
Positive (At any time)	8/ 8 (100.0)	100.0	18/ 20 (90.0)	90.0	1.11 (0.96, 1.29)	0.1575	10.00 (-20.56, 40.56)	0.5212	
BMI (kg/m2) at enrolment									0.8815
< 30	111/125 (88.8)	89.1	112/134 (83.6)	83.3	1.06 (0.96, 1.17)	0.2235	5.76 (-3.62, 15.14)	0.2287	
>= 30	48/ 55 (87.3)	87.6	40/ 48 (83.3)	82.9	1.05 (0.89, 1.23)	0.5759	4.67 (-11.29, 20.62)	0.5666	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.9053
All negative/normal	51/ 58 (87.9)	87.8	67/ 81 (82.7)	82.8	1.06 (0.93, 1.22)	0.3847	4.96 (-8.54, 18.47)	0.4711	
At least one positive/abnormal	108/122 (88.5)	88.7	85/101 (84.2)	83.9	1.05 (0.95, 1.17)	0.3498	4.80 (-4.98, 14.58)	0.3365	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event leading to discontinuation of study drug (on-treatment)
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	5 (2.8)	13 (7.1)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.39 (0.14, 1.07)	
p-value	0.0670	
Odds Ratio (95% CI)	0.37 (0.13, 1.06)	
p-value	0.0652	
Risk Difference (95% CI)	-4.37 (-8.81, 0.08)	
p-value	0.0543	
CMH approach		
Response rate	2.8	7.2
Difference in response rates (95% CI)	-4.44 (-10.46, 1.58)	
p-value	0.1480	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event leading to discontinuation of study drug (on-treatment) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.4065
< 10 points	0/ 54 (0.0)	0.0	3/ 52 (5.8)	5.7	0.14 (0.01, 2.60)	0.1860	-5.71 (-17.69, 6.27)	0.3500	
>= 10 points	5/126 (4.0)	4.0	10/130 (7.7)	7.9	0.52 (0.18, 1.47)	0.2145	-3.92 (-11.12, 3.28)	0.2858	
OCS dose at baseline									0.8690
<10 mg/day	2/ 93 (2.2)	2.2	5/ 99 (5.1)	5.0	0.43 (0.08, 2.14)	0.3002	-2.82 (-11.09, 5.46)	0.5048	
>=10 mg/day	3/ 87 (3.4)	3.5	8/ 83 (9.6)	9.7	0.36 (0.10, 1.30)	0.1190	-6.24 (-15.88, 3.40)	0.2048	
Result of type I IFN gene signature test									0.9019
LOW	1/ 30 (3.3)	3.3	3/ 31 (9.7)	9.7	0.34 (0.04, 3.13)	0.3438	-6.34 (-22.31, 9.62)	0.4360	
HIGH	4/150 (2.7)	2.7	10/151 (6.6)	6.8	0.40 (0.13, 1.26)	0.1170	-4.06 (-10.53, 2.42)	0.2195	
Age (years)									NE
<= 65	5/175 (2.9)	2.9	13/181 (7.2)	7.3	0.40 (0.14, 1.09)	0.0737	-4.37 (-10.47, 1.73)	0.1601	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
female	5/168 (3.0)	3.0	13/170 (7.6)	7.8	0.39 (0.14, 1.07)	0.0668	-4.77 (-11.16, 1.62)	0.1436	
Race									0.6438
White	4/110 (3.6)	3.9	8/107 (7.5)	7.4	0.49 (0.15, 1.57)	0.2274	-3.55 (-11.54, 4.43)	0.3832	
Black or African American	0/ 17 (0.0)	0.0	1/ 25 (4.0)	4.0	0.48 (0.02, 11.17)	0.6486	-4.00 (-22.36, 14.36)	0.6694	
Asian	0/ 30 (0.0)	0.0	4/ 30 (13.3)	13.3	0.11 (0.01, 1.98)	0.1347	-13.33 (-29.36, 2.70)	0.1031	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-28.41, 28.41)	1.0000	
Ethnicity									0.3121
Hispanic/Latino	2/ 54 (3.7)	3.8	3/ 54 (5.6)	5.7	0.67 (0.12, 3.83)	0.6496	-1.91 (-14.40, 10.57)	0.7639	
Non-hispanic/Latino	2/118 (1.7)	1.8	10/120 (8.3)	8.4	0.20 (0.05, 0.91)	0.0370	-6.54 (-14.57, 1.49)	0.1105	
Geographic region									0.7908
EU	1/ 51 (2.0)	2.0	3/ 46 (6.5)	6.5	0.30 (0.03, 2.79)	0.2904	-4.56 (-15.24, 6.12)	0.4025	
non-EU	4/129 (3.1)	3.2	10/136 (7.4)	7.4	0.42 (0.14, 1.31)	0.1357	-4.18 (-11.72, 3.36)	0.2768	
Onset of disease									0.2103
Paediatric	1/ 14 (7.1)	7.1	0/ 12 (0.0)	0.0	2.60 (0.12, 58.48)	0.5475	7.14 (-19.90, 34.18)	0.6047	
Adult	4/166 (2.4)	2.4	13/170 (7.6)	7.7	0.32 (0.10, 0.95)	0.0396	-5.28 (-11.59, 1.02)	0.1005	
ADA result									0.3141
Negative	4/172 (2.3)	2.4	11/162 (6.8)	6.9	0.34 (0.11, 1.05)	0.0617	-4.51 (-10.78, 1.77)	0.1592	
Positive (At any time)	1/ 8 (12.5)	12.5	2/ 20 (10.0)	10.0	1.25 (0.13, 11.93)	0.8463	2.50 (-31.66, 36.66)	0.8860	
BMI (kg/m2) at enrolment									0.7611
< 30	4/125 (3.2)	3.2	10/134 (7.5)	7.6	0.43 (0.14, 1.33)	0.1432	-4.47 (-12.13, 3.20)	0.2538	
>= 30	1/ 55 (1.8)	1.8	3/ 48 (6.3)	6.4	0.29 (0.03, 2.70)	0.2778	-4.59 (-17.54, 8.37)	0.4879	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.3860
All negative/normal	2/ 58 (3.4)	3.7	4/ 81 (4.9)	5.0	0.70 (0.13, 3.69)	0.6722	-1.26 (-12.01, 9.49)	0.8181	
At least one positive/abnormal	3/122 (2.5)	2.4	9/101 (8.9)	8.9	0.28 (0.08, 0.99)	0.0486	-6.55 (-14.33, 1.23)	0.0990	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Serious Adverse Event leading to discontinuation of study drug (on-treatment)
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	1 (0.6)	7 (3.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.14 (0.02, 1.16)	
p-value	0.0690	
Odds Ratio (95% CI)	0.14 (0.02, 1.15)	
p-value	0.0669	
Risk Difference (95% CI)	-3.29 (-6.29, -0.29)	
p-value	0.0314	
CMH approach		
Response rate	0.6	4.0
Difference in response rates (95% CI)	-3.42 (-8.65, 1.81)	
p-value	0.2004	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Serious Adverse Event leading to discontinuation of study drug (on-treatment) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.7479
< 10 points	0/ 54 (0.0)	0.0	1/ 52 (1.9)	1.9	0.32 (0.01, 7.71)	0.4837	-1.94 (-13.33, 9.46)	0.7392	
>= 10 points	1/126 (0.8)	0.8	6/130 (4.6)	4.9	0.17 (0.02, 1.41)	0.1008	-4.03 (-10.19, 2.12)	0.1992	
OCS dose at baseline									0.0726
<10 mg/day	1/ 93 (1.1)	1.1	0/ 99 (0.0)	0.0	3.19 (0.13, 77.38)	0.4756	1.11 (-6.17, 8.39)	0.7646	
>=10 mg/day	0/ 87 (0.0)	0.0	7/ 83 (8.4)	8.5	0.06 (0.00, 1.10)	0.0579	-8.53 (-17.38, 0.32)	0.0589	
Result of type I IFN gene signature test									NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE		0.00 (-11.73, 11.73)	1.0000	
HIGH	1/150 (0.7)	0.7	7/151 (4.6)	4.8	0.14 (0.02, 1.15)	0.0681	-4.11 (-9.94, 1.71)	0.1665	
Age (years)									NE
<= 65	1/175 (0.6)	0.6	7/181 (3.9)	4.0	0.15 (0.02, 1.19)	0.0722	-3.44 (-8.76, 1.87)	0.2041	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
female	1/168 (0.6)	0.6	7/170 (4.1)	4.3	0.14 (0.02, 1.16)	0.0690	-3.67 (-9.22, 1.89)	0.1958	
Race									0.8880
White	1/110 (0.9)	1.0	5/107 (4.7)	4.8	0.19 (0.02, 1.64)	0.1321	-3.84 (-10.89, 3.22)	0.2864	
Black or African American	0/ 17 (0.0)	0.0	1/ 25 (4.0)	4.0	0.48 (0.02, 11.17)	0.6486	-4.00 (-22.36, 14.36)	0.6694	
Asian	0/ 30 (0.0)	0.0	1/ 30 (3.3)	3.3	0.33 (0.01, 7.87)	0.4958	-3.33 (-16.52, 9.85)	0.6203	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-28.41, 28.41)	1.0000	
Ethnicity									0.9929
Hispanic/Latino	0/ 54 (0.0)	0.0	2/ 54 (3.7)	4.0	0.20 (0.01, 4.07)	0.2952	-4.02 (-15.62, 7.59)	0.4974	
Non-hispanic/Latino	1/118 (0.8)	0.9	5/120 (4.2)	4.3	0.20 (0.02, 1.71)	0.1432	-3.39 (-10.70, 3.93)	0.3647	
Geographic region									0.7021
EU	0/ 51 (0.0)	0.0	3/ 46 (6.5)	6.5	0.13 (0.01, 2.43)	0.1719	-6.52 (-16.60, 3.56)	0.2046	
non-EU	1/129 (0.8)	0.8	4/136 (2.9)	3.1	0.26 (0.03, 2.33)	0.2302	-2.28 (-8.85, 4.29)	0.4968	
Onset of disease									0.0912
Paediatric	1/ 14 (7.1)	7.1	0/ 12 (0.0)	0.0	2.60 (0.12, 58.48)	0.5475	7.14 (-19.90, 34.18)	0.6047	
Adult	0/166 (0.0)	0.0	7/170 (4.1)	4.2	0.07 (0.00, 1.19)	0.0653	-4.25 (-9.69, 1.20)	0.1267	
ADA result									0.4030
Negative	1/172 (0.6)	0.6	6/162 (3.7)	3.9	0.16 (0.02, 1.29)	0.0849	-3.27 (-8.84, 2.29)	0.2491	
Positive (At any time)	0/ 8 (0.0)	0.0	1/ 20 (5.0)	5.0	0.78 (0.03, 17.33)	0.8739	-5.00 (-34.61, 24.61)	0.7407	
BMI (kg/m2) at enrolment									0.9141
< 30	1/125 (0.8)	0.8	5/134 (3.7)	3.8	0.21 (0.03, 1.81)	0.1571	-2.96 (-9.75, 3.83)	0.3926	
>= 30	0/ 55 (0.0)	0.0	2/ 48 (4.2)	4.7	0.17 (0.01, 3.56)	0.2567	-4.66 (-16.96, 7.64)	0.4577	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.2430
All negative/normal	1/ 58 (1.7)	1.9	2/ 81 (2.5)	2.5	0.70 (0.06, 7.52)	0.7671	-0.68 (-10.67, 9.31)	0.8942	
At least one positive/abnormal	0/122 (0.0)	0.0	5/101 (5.0)	4.8	0.08 (0.00, 1.35)	0.0789	-4.84 (-11.52, 1.83)	0.1550	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with Adverse Event leading to death (on-treatment)
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	1 (0.6)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.03 (0.12, 73.97)	
p-value	0.4959	
Odds Ratio (95% CI)	3.05 (0.12, 75.37)	
p-value	0.4956	
Risk Difference (95% CI)	0.56 (-0.53, 1.64)	
p-value	0.3160	
CMH approach		
Response rate	0.5	0.0
Difference in response rates (95% CI)	0.54 (-3.97, 5.05)	
p-value	0.8147	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with Adverse Event leading to death (on-treatment) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	1/ 54 (1.9)	1.8	0/ 52 (0.0)	0.0	2.89 (0.12, 69.40)	0.5127	1.84 (-9.53, 13.20)	0.7511	
>= 10 points	0/126 (0.0)	0.0	0/130 (0.0)	0.0	NE		0.00 (-4.90, 4.90)	1.0000	
OCS dose at baseline									NE
<10 mg/day	0/ 93 (0.0)	0.0	0/ 99 (0.0)	0.0	NE		0.00 (-7.00, 7.00)	1.0000	
>=10 mg/day	1/ 87 (1.1)	1.1	0/ 83 (0.0)	0.0	2.86 (0.12, 69.32)	0.5176	1.15 (-6.03, 8.33)	0.7541	
Result of type I IFN gene signature test									NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE		0.00 (-11.73, 11.73)	1.0000	
HIGH	1/150 (0.7)	0.6	0/151 (0.0)	0.0	3.02 (0.12, 73.54)	0.4975	0.65 (-4.23, 5.52)	0.7943	
Age (years)									NE
<= 65	1/175 (0.6)	0.5	0/181 (0.0)	0.0	3.10 (0.13, 75.64)	0.4872	0.55 (-4.04, 5.14)	0.8146	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
female	1/168 (0.6)	0.6	0/170 (0.0)	0.0	3.04 (0.12, 73.99)	0.4956	0.59 (-4.21, 5.40)	0.8090	
Race									NE
White	1/110 (0.9)	0.7	0/107 (0.0)	0.0	2.92 (0.12, 70.87)	0.5104	0.72 (-5.15, 6.59)	0.8109	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE		0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-28.41, 28.41)	1.0000	
Ethnicity									NE
Hispanic/Latino	1/ 54 (1.9)	2.1	0/ 54 (0.0)	0.0	3.00 (0.12, 72.05)	0.4982	2.14 (-8.79, 13.06)	0.7015	
Non-hispanic/Latino	0/118 (0.0)	0.0	0/120 (0.0)	0.0	NE		0.00 (-6.46, 6.46)	1.0000	
Geographic region									NE
EU	0/ 51 (0.0)	0.0	0/ 46 (0.0)	0.0	NE		0.00 (-7.65, 7.65)	1.0000	
non-EU	1/129 (0.8)	0.8	0/136 (0.0)	0.0	3.16 (0.13, 76.91)	0.4796	0.76 (-5.25, 6.76)	0.8048	
Onset of disease									NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-24.92, 24.92)	1.0000	
Adult	1/166 (0.6)	0.6	0/170 (0.0)	0.0	3.07 (0.13, 74.87)	0.4910	0.60 (-4.24, 5.43)	0.8091	
ADA result									NE
Negative	1/172 (0.6)	0.5	0/162 (0.0)	0.0	2.83 (0.12, 68.89)	0.5237	0.53 (-4.32, 5.37)	0.8315	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	1/125 (0.8)	0.8	0/134 (0.0)	0.0	3.21 (0.13, 78.18)	0.4733	0.80 (-5.29, 6.90)	0.7967	
>= 30	0/ 55 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-11.37, 11.37)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE		0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	1/122 (0.8)	0.8	0/101 (0.0)	0.0	2.49 (0.10, 60.41)	0.5755	0.81 (-4.76, 6.37)	0.7762	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	13 (7.2)	2 (1.1)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	6.57 (1.50, 28.71)	
p-value	0.0123	
Odds Ratio (95% CI)	7.01 (1.56, 31.51)	
p-value	0.0112	
Risk Difference (95% CI)	6.12 (2.05, 10.20)	
p-value	0.0032	
CMH approach		
Response rate	7.2	1.1
Difference in response rates (95% CI)	6.10 (0.32, 11.88)	
p-value	0.0387	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Anifrolumab 300mg (N=180) Response rate	Placebo (N=182) n/ N (%)	Placebo (N=182) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.6702
< 10 points	1/ 54 (1.9)	1.9	0/ 52 (0.0)	0.0	2.89 (0.12, 69.40)	0.5127	1.89 (-9.43, 13.20)	0.7436	
>= 10 points	12/126 (9.5)	9.4	2/130 (1.5)	1.6	6.19 (1.41, 27.11)	0.0155	7.85 (0.83, 14.88)	0.0284	
OCS dose at baseline									0.9764
<10 mg/day	6/ 93 (6.5)	6.5	1/ 99 (1.0)	1.1	6.39 (0.78, 52.05)	0.0832	5.44 (-2.93, 13.82)	0.2027	
>=10 mg/day	7/ 87 (8.0)	8.0	1/ 83 (1.2)	1.2	6.68 (0.84, 53.11)	0.0727	6.73 (-2.20, 15.66)	0.1397	
Result of type I IFN gene signature test									0.2896
LOW	2/ 30 (6.7)	6.7	1/ 31 (3.2)	3.2	2.07 (0.20, 21.61)	0.5444	3.44 (-11.73, 18.61)	0.6566	
HIGH	11/150 (7.3)	7.3	1/151 (0.7)	0.7	11.07 (1.45, 84.70)	0.0205	6.64 (0.40, 12.88)	0.0370	
Age (years)									NE
<= 65	13/175 (7.4)	7.4	2/181 (1.1)	1.1	6.72 (1.54, 29.36)	0.0113	6.33 (0.44, 12.22)	0.0353	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									0.6881
male	1/ 12 (8.3)	8.3	0/ 12 (0.0)	0.0	3.00 (0.13, 67.06)	0.4883	8.33 (-20.61, 37.28)	0.5726	
female	12/168 (7.1)	7.1	2/170 (1.2)	1.2	6.07 (1.38, 26.72)	0.0170	5.92 (-0.14, 11.98)	0.0557	
Race									0.5612
White	5/110 (4.5)	4.8	1/107 (0.9)	0.9	4.86 (0.58, 40.95)	0.1456	3.93 (-3.09, 10.95)	0.2727	
Black or African American	0/ 17 (0.0)	0.0	1/ 25 (4.0)	4.0	0.48 (0.02, 11.17)	0.6486	-4.00 (-22.36, 14.36)	0.6694	
Asian	3/ 30 (10.0)	10.0	0/ 30 (0.0)	0.0	7.00 (0.38, 129.93)	0.1917	10.00 (-5.22, 25.22)	0.1977	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	3/ 11 (27.3)	27.3	0/ 11 (0.0)	0.0	7.00 (0.40, 121.39)	0.1813	27.27 (-7.07, 61.62)	0.1196	
Ethnicity									0.3295
Hispanic/Latino	6/ 54 (11.1)	10.4	0/ 54 (0.0)	0.0	13.00 (0.75, 225.20)	0.0780	10.38 (-2.21, 22.96)	0.1061	
Non-hispanic/Latino	5/118 (4.2)	4.4	2/120 (1.7)	1.7	2.54 (0.50, 12.85)	0.2589	2.75 (-4.78, 10.27)	0.4743	
Geographic region									0.8843
EU	2/ 51 (3.9)	3.9	0/ 46 (0.0)	0.0	4.52 (0.22, 91.74)	0.3261	3.92 (-5.18, 13.02)	0.3985	
non-EU	11/129 (8.5)	8.5	2/136 (1.5)	1.5	5.80 (1.31, 25.66)	0.0205	7.01 (-0.46, 14.47)	0.0657	
Onset of disease									0.8762
Paediatric	2/ 14 (14.3)	14.3	0/ 12 (0.0)	0.0	4.33 (0.23, 82.31)	0.3290	14.29 (-14.43, 43.00)	0.3295	
Adult	11/166 (6.6)	6.6	2/170 (1.2)	1.2	5.63 (1.27, 25.03)	0.0231	5.47 (-0.56, 11.51)	0.0756	
ADA result									0.6288
Negative	11/172 (6.4)	6.4	2/162 (1.2)	1.3	5.18 (1.17, 23.01)	0.0306	5.19 (-0.84, 11.23)	0.0918	
Positive (At any time)	2/ 8 (25.0)	25.0	0/ 20 (0.0)	0.0	11.67 (0.62, 219.42)	0.1008	25.00 (-9.84, 59.84)	0.1596	
BMI (kg/m2) at enrolment									0.8106
< 30	7/125 (5.6)	5.6	1/134 (0.7)	0.8	7.50 (0.94, 60.13)	0.0577	4.82 (-2.28, 11.92)	0.1831	
>= 30	6/ 55 (10.9)	11.4	1/ 48 (2.1)	1.8	5.24 (0.65, 41.97)	0.1190	9.63 (-4.05, 23.32)	0.1678	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.4586
All negative/normal	2/ 58 (3.4)	3.6	1/ 81 (1.2)	1.2	2.79 (0.26, 30.08)	0.3970	2.40 (-7.69, 12.49)	0.6412	
At least one positive/abnormal	11/122 (9.0)	9.1	1/101 (1.0)	1.0	9.11 (1.20, 69.34)	0.0329	8.17 (0.69, 15.64)	0.0322	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Serious Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	1 (0.6)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.03 (0.12, 73.97)	
p-value	0.4959	
Odds Ratio (95% CI)	3.05 (0.12, 75.37)	
p-value	0.4956	
Risk Difference (95% CI)	0.56 (-0.53, 1.64)	
p-value	0.3160	
CMH approach		
Response rate	0.5	0.0
Difference in response rates (95% CI)	0.53 (-4.00, 5.07)	
p-value	0.8175	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Serious Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE		0.00 (-10.98, 10.98)	1.0000	
>= 10 points	1/126 (0.8)	0.8	0/130 (0.0)	0.0	3.09 (0.13, 75.26)	0.4878	0.76 (-4.33, 5.84)	0.7710	
OCS dose at baseline									NE
<10 mg/day	0/ 93 (0.0)	0.0	0/ 99 (0.0)	0.0	NE		0.00 (-7.00, 7.00)	1.0000	
>=10 mg/day	1/ 87 (1.1)	1.1	0/ 83 (0.0)	0.0	2.86 (0.12, 69.32)	0.5176	1.14 (-6.11, 8.38)	0.7586	
Result of type I IFN gene signature test									NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE		0.00 (-11.73, 11.73)	1.0000	
HIGH	1/150 (0.7)	0.6	0/151 (0.0)	0.0	3.02 (0.12, 73.54)	0.4975	0.64 (-4.26, 5.55)	0.7976	
Age (years)									NE
<= 65	1/175 (0.6)	0.5	0/181 (0.0)	0.0	3.10 (0.13, 75.64)	0.4872	0.55 (-4.06, 5.16)	0.8158	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
female	1/168 (0.6)	0.6	0/170 (0.0)	0.0	3.04 (0.12, 73.99)	0.4956	0.57 (-4.26, 5.40)	0.8171	
Race									NE
White	0/110 (0.0)	0.0	0/107 (0.0)	0.0	NE		0.00 (-5.75, 5.75)	1.0000	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.13, 17.13)	1.0000	
Asian	1/ 30 (3.3)	3.3	0/ 30 (0.0)	0.0	3.00 (0.13, 70.83)	0.4958	3.33 (-9.85, 16.52)	0.6203	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-28.41, 28.41)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE		0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	1/118 (0.8)	0.8	0/120 (0.0)	0.0	3.05 (0.13, 74.13)	0.4933	0.84 (-5.78, 7.47)	0.8031	
Geographic region									NE
EU	0/ 51 (0.0)	0.0	0/ 46 (0.0)	0.0	NE		0.00 (-7.65, 7.65)	1.0000	
non-EU	1/129 (0.8)	0.7	0/136 (0.0)	0.0	3.16 (0.13, 76.91)	0.4796	0.74 (-5.30, 6.77)	0.8111	
Onset of disease									NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-24.92, 24.92)	1.0000	
Adult	1/166 (0.6)	0.6	0/170 (0.0)	0.0	3.07 (0.13, 74.87)	0.4910	0.58 (-4.28, 5.44)	0.8139	
ADA result									NE
Negative	1/172 (0.6)	0.6	0/162 (0.0)	0.0	2.83 (0.12, 68.89)	0.5237	0.56 (-4.32, 5.44)	0.8225	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	1/125 (0.8)	0.8	0/134 (0.0)	0.0	3.21 (0.13, 78.18)	0.4733	0.79 (-5.35, 6.94)	0.8005	
>= 30	0/ 55 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-11.37, 11.37)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE		0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	1/122 (0.8)	0.8	0/101 (0.0)	0.0	2.49 (0.10, 60.41)	0.5755	0.85 (-4.79, 6.49)	0.7684	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Severe Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.43, 4.43)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Severe Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Anifrolumab 300mg (N=180) Response rate	Placebo (N=182) n/ N (%)	Placebo (N=182) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Analysis Anifrolumab 300mg vs. Placebo Difference in response rates (95% CI)	Analysis Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.98, 10.98)	1.0000	
>= 10 points	0/126 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.90, 4.90)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 93 (0.0)	0.0	0/ 99 (0.0)	0.0	NE	0.00 (-7.00, 7.00)	1.0000	
>=10 mg/day	0/ 87 (0.0)	0.0	0/ 83 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE	0.00 (-11.73, 11.73)	1.0000	
HIGH	0/150 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Age (years)								NE
<= 65	0/175 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.50, 4.50)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-102.70, 102.70)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
female	0/168 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.71, 4.71)	1.0000	
Race								NE
White	0/110 (0.0)	0.0	0/107 (0.0)	0.0	NE	0.00 (-5.75, 5.75)	1.0000	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE	0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE	0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-28.41, 28.41)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	0/118 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.46, 6.46)	1.0000	
Geographic region								NE
EU	0/ 51 (0.0)	0.0	0/ 46 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
non-EU	0/129 (0.0)	0.0	0/136 (0.0)	0.0	NE	0.00 (-5.90, 5.90)	1.0000	
Onset of disease								NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-24.92, 24.92)	1.0000	
Adult	0/166 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.74, 4.74)	1.0000	
ADA result								NE
Negative	0/172 (0.0)	0.0	0/162 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE	0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/125 (0.0)	0.0	0/134 (0.0)	0.0	NE	0.00 (-5.98, 5.98)	1.0000	
>= 30	0/ 55 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-11.37, 11.37)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE	0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	0/122 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-5.42, 5.42)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Non-Severe Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	13 (7.2)	2 (1.1)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	6.57 (1.50, 28.71)	
p-value	0.0123	
Odds Ratio (95% CI)	7.01 (1.56, 31.51)	
p-value	0.0112	
Risk Difference (95% CI)	6.12 (2.05, 10.20)	
p-value	0.0032	
CMH approach		
Response rate	7.2	1.1
Difference in response rates (95% CI)	6.10 (0.32, 11.88)	
p-value	0.0387	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Non-Severe Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.6702
< 10 points	1/ 54 (1.9)	1.9	0/ 52 (0.0)	0.0	2.89 (0.12, 69.40)	0.5127	1.89 (-9.43, 13.20)	0.7436	
>= 10 points	12/126 (9.5)	9.4	2/130 (1.5)	1.6	6.19 (1.41, 27.11)	0.0155	7.85 (0.83, 14.88)	0.0284	
OCS dose at baseline									0.9764
<10 mg/day	6/ 93 (6.5)	6.5	1/ 99 (1.0)	1.1	6.39 (0.78, 52.05)	0.0832	5.44 (-2.93, 13.82)	0.2027	
>=10 mg/day	7/ 87 (8.0)	8.0	1/ 83 (1.2)	1.2	6.68 (0.84, 53.11)	0.0727	6.73 (-2.20, 15.66)	0.1397	
Result of type I IFN gene signature test									0.2896
LOW	2/ 30 (6.7)	6.7	1/ 31 (3.2)	3.2	2.07 (0.20, 21.61)	0.5444	3.44 (-11.73, 18.61)	0.6566	
HIGH	11/150 (7.3)	7.3	1/151 (0.7)	0.7	11.07 (1.45, 84.70)	0.0205	6.64 (0.40, 12.88)	0.0370	
Age (years)									NE
<= 65	13/175 (7.4)	7.4	2/181 (1.1)	1.1	6.72 (1.54, 29.36)	0.0113	6.33 (0.44, 12.22)	0.0353	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									0.6881
male	1/ 12 (8.3)	8.3	0/ 12 (0.0)	0.0	3.00 (0.13, 67.06)	0.4883	8.33 (-20.61, 37.28)	0.5726	
female	12/168 (7.1)	7.1	2/170 (1.2)	1.2	6.07 (1.38, 26.72)	0.0170	5.92 (-0.14, 11.98)	0.0557	
Race									0.5612
White	5/110 (4.5)	4.8	1/107 (0.9)	0.9	4.86 (0.58, 40.95)	0.1456	3.93 (-3.09, 10.95)	0.2727	
Black or African American	0/ 17 (0.0)	0.0	1/ 25 (4.0)	4.0	0.48 (0.02, 11.17)	0.6486	-4.00 (-22.36, 14.36)	0.6694	
Asian	3/ 30 (10.0)	10.0	0/ 30 (0.0)	0.0	7.00 (0.38, 129.93)	0.1917	10.00 (-5.22, 25.22)	0.1977	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	3/ 11 (27.3)	27.3	0/ 11 (0.0)	0.0	7.00 (0.40, 121.39)	0.1813	27.27 (-7.07, 61.62)	0.1196	
Ethnicity									0.3295
Hispanic/Latino	6/ 54 (11.1)	10.4	0/ 54 (0.0)	0.0	13.00 (0.75, 225.20)	0.0780	10.38 (-2.21, 22.96)	0.1061	
Non-hispanic/Latino	5/118 (4.2)	4.4	2/120 (1.7)	1.7	2.54 (0.50, 12.85)	0.2589	2.75 (-4.78, 10.27)	0.4743	
Geographic region									0.8843
EU	2/ 51 (3.9)	3.9	0/ 46 (0.0)	0.0	4.52 (0.22, 91.74)	0.3261	3.92 (-5.18, 13.02)	0.3985	
non-EU	11/129 (8.5)	8.5	2/136 (1.5)	1.5	5.80 (1.31, 25.66)	0.0205	7.01 (-0.46, 14.47)	0.0657	
Onset of disease									0.8762
Paediatric	2/ 14 (14.3)	14.3	0/ 12 (0.0)	0.0	4.33 (0.23, 82.31)	0.3290	14.29 (-14.43, 43.00)	0.3295	
Adult	11/166 (6.6)	6.6	2/170 (1.2)	1.2	5.63 (1.27, 25.03)	0.0231	5.47 (-0.56, 11.51)	0.0756	
ADA result									0.6288
Negative	11/172 (6.4)	6.4	2/162 (1.2)	1.3	5.18 (1.17, 23.01)	0.0306	5.19 (-0.84, 11.23)	0.0918	
Positive (At any time)	2/ 8 (25.0)	25.0	0/ 20 (0.0)	0.0	11.67 (0.62, 219.42)	0.1008	25.00 (-9.84, 59.84)	0.1596	
BMI (kg/m2) at enrolment									0.8106
< 30	7/125 (5.6)	5.6	1/134 (0.7)	0.8	7.50 (0.94, 60.13)	0.0577	4.82 (-2.28, 11.92)	0.1831	
>= 30	6/ 55 (10.9)	11.4	1/ 48 (2.1)	1.8	5.24 (0.65, 41.97)	0.1190	9.63 (-4.05, 23.32)	0.1678	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.4586
All negative/normal	2/ 58 (3.4)	3.6	1/ 81 (1.2)	1.2	2.79 (0.26, 30.08)	0.3970	2.40 (-7.69, 12.49)	0.6412	
At least one positive/abnormal	11/122 (9.0)	9.1	1/101 (1.0)	1.0	9.11 (1.20, 69.34)	0.0329	8.17 (0.69, 15.64)	0.0322	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Herpes Zoster leading to discontinuation of study drug
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.43, 4.43)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Herpes Zoster leading to discontinuation of study drug - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.98, 10.98)	1.0000	
>= 10 points	0/126 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.90, 4.90)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 93 (0.0)	0.0	0/ 99 (0.0)	0.0	NE	0.00 (-7.00, 7.00)	1.0000	
>=10 mg/day	0/ 87 (0.0)	0.0	0/ 83 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE	0.00 (-11.73, 11.73)	1.0000	
HIGH	0/150 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Age (years)								NE
<= 65	0/175 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.50, 4.50)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-102.70, 102.70)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
female	0/168 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.71, 4.71)	1.0000	
Race								NE
White	0/110 (0.0)	0.0	0/107 (0.0)	0.0	NE	0.00 (-5.75, 5.75)	1.0000	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE	0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE	0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-28.41, 28.41)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	0/118 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.46, 6.46)	1.0000	
Geographic region								NE
EU	0/ 51 (0.0)	0.0	0/ 46 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
non-EU	0/129 (0.0)	0.0	0/136 (0.0)	0.0	NE	0.00 (-5.90, 5.90)	1.0000	
Onset of disease								NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-24.92, 24.92)	1.0000	
Adult	0/166 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.74, 4.74)	1.0000	
ADA result								NE
Negative	0/172 (0.0)	0.0	0/162 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE	0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/125 (0.0)	0.0	0/134 (0.0)	0.0	NE	0.00 (-5.98, 5.98)	1.0000	
>= 30	0/ 55 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-11.37, 11.37)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE	0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	0/122 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-5.42, 5.42)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Influenza
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	4 (2.2)	6 (3.3)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.67 (0.19, 2.35)	
p-value	0.5357	
Odds Ratio (95% CI)	0.67 (0.18, 2.40)	
p-value	0.5354	
Risk Difference (95% CI)	-1.07 (-4.45, 2.30)	
p-value	0.5322	
CMH approach		
Response rate	2.2	3.1
Difference in response rates (95% CI)	-0.93 (-6.24, 4.37)	
p-value	0.7306	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.2931
< 10 points	2/ 54 (3.7)	3.7	1/ 52 (1.9)	1.9	1.93 (0.18, 20.60)	0.5878	1.79 (-10.26, 13.85)	0.7706	
>= 10 points	2/126 (1.6)	1.6	5/130 (3.8)	3.7	0.41 (0.08, 2.09)	0.2847	-2.08 (-8.11, 3.95)	0.4999	
OCS dose at baseline									0.1349
<10 mg/day	2/ 93 (2.2)	2.1	6/ 99 (6.1)	5.9	0.35 (0.07, 1.71)	0.1973	-3.75 (-12.25, 4.74)	0.3867	
>=10 mg/day	2/ 87 (2.3)	2.3	0/ 83 (0.0)	0.0	4.77 (0.23, 97.96)	0.3107	2.28 (-5.19, 9.76)	0.5491	
Result of type I IFN gene signature test									0.6257
LOW	0/ 30 (0.0)	0.0	1/ 31 (3.2)	3.2	0.34 (0.01, 8.13)	0.5085	-3.23 (-16.19, 9.74)	0.6257	
HIGH	4/150 (2.7)	2.6	5/151 (3.3)	3.1	0.81 (0.22, 2.94)	0.7432	-0.47 (-6.28, 5.35)	0.8751	
Age (years)									NE
<= 65	4/175 (2.3)	2.3	6/181 (3.3)	3.1	0.69 (0.20, 2.40)	0.5593	-0.89 (-6.27, 4.50)	0.7469	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									0.6055
male	0/ 12 (0.0)	0.0	1/ 12 (8.3)	8.3	0.33 (0.01, 7.45)	0.4883	-8.33 (-37.28, 20.61)	0.5726	
female	4/168 (2.4)	2.4	5/170 (2.9)	2.8	0.81 (0.22, 2.96)	0.7496	-0.48 (-6.06, 5.10)	0.8672	
Race									0.9315
White	2/110 (1.8)	1.7	2/107 (1.9)	1.8	0.97 (0.14, 6.78)	0.9777	-0.15 (-6.71, 6.41)	0.9640	
Black or African American	0/ 17 (0.0)	0.0	1/ 25 (4.0)	4.0	0.48 (0.02, 11.17)	0.6486	-4.00 (-22.36, 14.36)	0.6694	
Asian	0/ 30 (0.0)	0.0	1/ 30 (3.3)	3.3	0.33 (0.01, 7.87)	0.4958	-3.33 (-16.52, 9.85)	0.6203	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	1/ 11 (9.1)	9.1	1/ 11 (9.1)	9.1	1.00 (0.07, 14.05)	1.0000	0.00 (-33.43, 33.43)	1.0000	
Ethnicity									0.2091
Hispanic/Latino	2/ 54 (3.7)	3.5	1/ 54 (1.9)	2.0	2.00 (0.19, 21.41)	0.5666	1.45 (-10.43, 13.33)	0.8109	
Non-hispanic/Latino	1/118 (0.8)	0.8	4/120 (3.3)	3.2	0.25 (0.03, 2.24)	0.2175	-2.36 (-9.45, 4.73)	0.5136	
Geographic region									0.6933
EU	1/ 51 (2.0)	2.0	2/ 46 (4.3)	4.3	0.45 (0.04, 4.81)	0.5097	-2.39 (-12.40, 7.63)	0.6404	
non-EU	3/129 (2.3)	2.3	4/136 (2.9)	2.8	0.79 (0.18, 3.46)	0.7554	-0.52 (-7.27, 6.23)	0.8802	
Onset of disease									NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-24.92, 24.92)	1.0000	
Adult	4/166 (2.4)	2.4	6/170 (3.5)	3.4	0.68 (0.20, 2.38)	0.5486	-1.05 (-6.75, 4.65)	0.7177	
ADA result									0.9853
Negative	4/172 (2.3)	2.3	5/162 (3.1)	2.9	0.75 (0.21, 2.76)	0.6689	-0.66 (-6.30, 4.99)	0.8198	
Positive (At any time)	0/ 8 (0.0)	0.0	1/ 20 (5.0)	5.0	0.78 (0.03, 17.33)	0.8739	-5.00 (-34.61, 24.61)	0.7407	
BMI (kg/m2) at enrolment									0.2827
< 30	4/125 (3.2)	3.3	4/134 (3.0)	2.9	1.07 (0.27, 4.19)	0.9204	0.37 (-6.62, 7.36)	0.9174	
>= 30	0/ 55 (0.0)	0.0	2/ 48 (4.2)	3.9	0.17 (0.01, 3.56)	0.2567	-3.90 (-16.09, 8.30)	0.5310	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.1047
All negative/normal	3/ 58 (5.2)	5.3	2/ 81 (2.5)	2.3	2.09 (0.36, 12.14)	0.4095	2.94 (-7.67, 13.56)	0.5868	
At least one positive/abnormal	1/122 (0.8)	0.8	4/101 (4.0)	3.9	0.21 (0.02, 1.82)	0.1558	-3.07 (-9.65, 3.52)	0.3611	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Serious Influenza
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	0 (0.0)	1 (0.5)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.34 (0.01, 8.22)	
p-value	0.5045	
Odds Ratio (95% CI)	0.34 (0.01, 8.28)	
p-value	0.5041	
Risk Difference (95% CI)	-0.55 (-1.62, 0.52)	
p-value	0.3160	
CMH approach		
Response rate	0.0	0.5
Difference in response rates (95% CI)	-0.52 (-5.05, 4.01)	
p-value	0.8226	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Serious Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE		0.00 (-10.98, 10.98)	1.0000	
>= 10 points	0/126 (0.0)	0.0	1/130 (0.8)	0.7	0.34 (0.01, 8.36)	0.5120	-0.73 (-5.81, 4.34)	0.7771	
OCS dose at baseline									NE
<10 mg/day	0/ 93 (0.0)	0.0	1/ 99 (1.0)	1.0	0.35 (0.01, 8.60)	0.5239	-0.98 (-8.20, 6.24)	0.7907	
>=10 mg/day	0/ 87 (0.0)	0.0	0/ 83 (0.0)	0.0	NE		0.00 (-6.94, 6.94)	1.0000	
Result of type I IFN gene signature test									NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE		0.00 (-11.73, 11.73)	1.0000	
HIGH	0/150 (0.0)	0.0	1/151 (0.7)	0.6	0.34 (0.01, 8.17)	0.5026	-0.62 (-5.52, 4.28)	0.8031	
Age (years)									NE
<= 65	0/175 (0.0)	0.0	1/181 (0.6)	0.5	0.34 (0.01, 8.40)	0.5134	-0.52 (-5.12, 4.08)	0.8245	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
female	0/168 (0.0)	0.0	1/170 (0.6)	0.6	0.34 (0.01, 8.22)	0.5048	-0.57 (-5.39, 4.26)	0.8173	
Race									NE
White	0/110 (0.0)	0.0	1/107 (0.9)	0.9	0.32 (0.01, 7.87)	0.4890	-0.91 (-6.90, 5.08)	0.7658	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE		0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-28.41, 28.41)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE		0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	0/118 (0.0)	0.0	1/120 (0.8)	0.8	0.34 (0.01, 8.24)	0.5063	-0.77 (-7.37, 5.83)	0.8189	
Geographic region									NE
EU	0/ 51 (0.0)	0.0	0/ 46 (0.0)	0.0	NE		0.00 (-7.65, 7.65)	1.0000	
non-EU	0/129 (0.0)	0.0	1/136 (0.7)	0.7	0.35 (0.01, 8.55)	0.5206	-0.70 (-6.73, 5.33)	0.8196	
Onset of disease									NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-24.92, 24.92)	1.0000	
Adult	0/166 (0.0)	0.0	1/170 (0.6)	0.6	0.34 (0.01, 8.32)	0.5094	-0.57 (-5.43, 4.28)	0.8171	
ADA result									NE
Negative	0/172 (0.0)	0.0	1/162 (0.6)	0.6	0.31 (0.01, 7.65)	0.4772	-0.58 (-5.47, 4.30)	0.8151	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/125 (0.0)	0.0	0/134 (0.0)	0.0	NE		0.00 (-5.98, 5.98)	1.0000	
>= 30	0/ 55 (0.0)	0.0	1/ 48 (2.1)	2.1	0.29 (0.01, 7.00)	0.4473	-2.13 (-14.04, 9.77)	0.7255	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE		0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	0/122 (0.0)	0.0	1/101 (1.0)	1.0	0.28 (0.01, 6.71)	0.4295	-0.97 (-6.67, 4.74)	0.7393	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Severe Influenza
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	0 (0.0)	1 (0.5)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.34 (0.01, 8.22)	
p-value	0.5045	
Odds Ratio (95% CI)	0.34 (0.01, 8.28)	
p-value	0.5041	
Risk Difference (95% CI)	-0.55 (-1.62, 0.52)	
p-value	0.3160	
CMH approach		
Response rate	0.0	0.5
Difference in response rates (95% CI)	-0.52 (-5.05, 4.01)	
p-value	0.8226	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Severe Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE		0.00 (-10.98, 10.98)	1.0000	
>= 10 points	0/126 (0.0)	0.0	1/130 (0.8)	0.7	0.34 (0.01, 8.36)	0.5120	-0.73 (-5.81, 4.34)	0.7771	
OCS dose at baseline									NE
<10 mg/day	0/ 93 (0.0)	0.0	1/ 99 (1.0)	1.0	0.35 (0.01, 8.60)	0.5239	-0.98 (-8.20, 6.24)	0.7907	
>=10 mg/day	0/ 87 (0.0)	0.0	0/ 83 (0.0)	0.0	NE		0.00 (-6.94, 6.94)	1.0000	
Result of type I IFN gene signature test									NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE		0.00 (-11.73, 11.73)	1.0000	
HIGH	0/150 (0.0)	0.0	1/151 (0.7)	0.6	0.34 (0.01, 8.17)	0.5026	-0.62 (-5.52, 4.28)	0.8031	
Age (years)									NE
<= 65	0/175 (0.0)	0.0	1/181 (0.6)	0.5	0.34 (0.01, 8.40)	0.5134	-0.52 (-5.12, 4.08)	0.8245	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
female	0/168 (0.0)	0.0	1/170 (0.6)	0.6	0.34 (0.01, 8.22)	0.5048	-0.57 (-5.39, 4.26)	0.8173	
Race									NE
White	0/110 (0.0)	0.0	1/107 (0.9)	0.9	0.32 (0.01, 7.87)	0.4890	-0.91 (-6.90, 5.08)	0.7658	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE		0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-28.41, 28.41)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE		0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	0/118 (0.0)	0.0	1/120 (0.8)	0.8	0.34 (0.01, 8.24)	0.5063	-0.77 (-7.37, 5.83)	0.8189	
Geographic region									NE
EU	0/ 51 (0.0)	0.0	0/ 46 (0.0)	0.0	NE		0.00 (-7.65, 7.65)	1.0000	
non-EU	0/129 (0.0)	0.0	1/136 (0.7)	0.7	0.35 (0.01, 8.55)	0.5206	-0.70 (-6.73, 5.33)	0.8196	
Onset of disease									NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-24.92, 24.92)	1.0000	
Adult	0/166 (0.0)	0.0	1/170 (0.6)	0.6	0.34 (0.01, 8.32)	0.5094	-0.57 (-5.43, 4.28)	0.8171	
ADA result									NE
Negative	0/172 (0.0)	0.0	1/162 (0.6)	0.6	0.31 (0.01, 7.65)	0.4772	-0.58 (-5.47, 4.30)	0.8151	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/125 (0.0)	0.0	0/134 (0.0)	0.0	NE		0.00 (-5.98, 5.98)	1.0000	
>= 30	0/ 55 (0.0)	0.0	1/ 48 (2.1)	2.1	0.29 (0.01, 7.00)	0.4473	-2.13 (-14.04, 9.77)	0.7255	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE		0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	0/122 (0.0)	0.0	1/101 (1.0)	1.0	0.28 (0.01, 6.71)	0.4295	-0.97 (-6.67, 4.74)	0.7393	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Non-Severe Influenza
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	4 (2.2)	5 (2.7)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.81 (0.22, 2.96)	
p-value	0.7489	
Odds Ratio (95% CI)	0.80 (0.21, 3.05)	
p-value	0.7488	
Risk Difference (95% CI)	-0.53 (-3.73, 2.68)	
p-value	0.7482	
CMH approach		
Response rate	2.2	2.6
Difference in response rates (95% CI)	-0.41 (-5.65, 4.82)	
p-value	0.8767	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Non-Severe Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Anifrolumab 300mg (N=180) Response rate	Placebo (N=182) n/ N (%)	Placebo (N=182) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.3741
< 10 points	2/ 54 (3.7)	3.7	1/ 52 (1.9)	1.9	1.93 (0.18, 20.60)	0.5878	1.79 (-10.26, 13.85)	0.7706	
>= 10 points	2/126 (1.6)	1.6	4/130 (3.1)	2.9	0.52 (0.10, 2.77)	0.4399	-1.34 (-7.24, 4.56)	0.6556	
OCS dose at baseline									0.1668
<10 mg/day	2/ 93 (2.2)	2.1	5/ 99 (5.1)	4.9	0.43 (0.08, 2.14)	0.3002	-2.77 (-11.11, 5.56)	0.5141	
>=10 mg/day	2/ 87 (2.3)	2.3	0/ 83 (0.0)	0.0	4.77 (0.23, 97.96)	0.3107	2.28 (-5.19, 9.76)	0.5491	
Result of type I IFN gene signature test									0.5414
LOW	0/ 30 (0.0)	0.0	1/ 31 (3.2)	3.2	0.34 (0.01, 8.13)	0.5085	-3.23 (-16.19, 9.74)	0.6257	
HIGH	4/150 (2.7)	2.6	4/151 (2.6)	2.5	1.01 (0.26, 3.95)	0.9924	0.16 (-5.56, 5.88)	0.9572	
Age (years)									NE
<= 65	4/175 (2.3)	2.3	5/181 (2.8)	2.6	0.83 (0.23, 3.03)	0.7749	-0.37 (-5.68, 4.95)	0.8927	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									0.5215
male	0/ 12 (0.0)	0.0	1/ 12 (8.3)	8.3	0.33 (0.01, 7.45)	0.4883	-8.33 (-37.28, 20.61)	0.5726	
female	4/168 (2.4)	2.4	4/170 (2.4)	2.3	1.01 (0.26, 3.98)	0.9865	0.09 (-5.41, 5.59)	0.9737	
Race									0.8164
White	2/110 (1.8)	1.7	1/107 (0.9)	0.9	1.95 (0.18, 21.14)	0.5846	0.76 (-5.59, 7.11)	0.8146	
Black or African American	0/ 17 (0.0)	0.0	1/ 25 (4.0)	4.0	0.48 (0.02, 11.17)	0.6486	-4.00 (-22.36, 14.36)	0.6694	
Asian	0/ 30 (0.0)	0.0	1/ 30 (3.3)	3.3	0.33 (0.01, 7.87)	0.4958	-3.33 (-16.52, 9.85)	0.6203	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	1/ 11 (9.1)	9.1	1/ 11 (9.1)	9.1	1.00 (0.07, 14.05)	1.0000	0.00 (-33.43, 33.43)	1.0000	
Ethnicity									0.2870
Hispanic/Latino	2/ 54 (3.7)	3.5	1/ 54 (1.9)	2.0	2.00 (0.19, 21.41)	0.5666	1.45 (-10.43, 13.33)	0.8109	
Non-hispanic/Latino	1/118 (0.8)	0.8	3/120 (2.5)	2.4	0.34 (0.04, 3.21)	0.3458	-1.59 (-8.57, 5.38)	0.6547	
Geographic region									0.5588
EU	1/ 51 (2.0)	2.0	2/ 46 (4.3)	4.3	0.45 (0.04, 4.81)	0.5097	-2.39 (-12.40, 7.63)	0.6404	
non-EU	3/129 (2.3)	2.3	3/136 (2.2)	2.1	1.05 (0.22, 5.13)	0.9478	0.18 (-6.46, 6.83)	0.9570	
Onset of disease									NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-24.92, 24.92)	1.0000	
Adult	4/166 (2.4)	2.4	5/170 (2.9)	2.9	0.82 (0.22, 3.00)	0.7633	-0.48 (-6.10, 5.14)	0.8676	
ADA result									0.9119
Negative	4/172 (2.3)	2.3	4/162 (2.5)	2.4	0.94 (0.24, 3.70)	0.9317	-0.07 (-5.63, 5.48)	0.9796	
Positive (At any time)	0/ 8 (0.0)	0.0	1/ 20 (5.0)	5.0	0.78 (0.03, 17.33)	0.8739	-5.00 (-34.61, 24.61)	0.7407	
BMI (kg/m2) at enrolment									0.4607
< 30	4/125 (3.2)	3.3	4/134 (3.0)	2.9	1.07 (0.27, 4.19)	0.9204	0.37 (-6.62, 7.36)	0.9174	
>= 30	0/ 55 (0.0)	0.0	1/ 48 (2.1)	1.8	0.29 (0.01, 7.00)	0.4473	-1.76 (-13.44, 9.91)	0.7669	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.1638
All negative/normal	3/ 58 (5.2)	5.3	2/ 81 (2.5)	2.3	2.09 (0.36, 12.14)	0.4095	2.94 (-7.67, 13.56)	0.5868	
At least one positive/abnormal	1/122 (0.8)	0.8	3/101 (3.0)	2.9	0.28 (0.03, 2.61)	0.2616	-2.10 (-8.45, 4.26)	0.5173	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	3 (1.7)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	7.08 (0.37, 136.04)	
p-value	0.1945	
Odds Ratio (95% CI)	7.20 (0.37, 140.34)	
p-value	0.1928	
Risk Difference (95% CI)	1.67 (-0.20, 3.54)	
p-value	0.0807	
CMH approach		
Response rate	1.6	0.0
Difference in response rates (95% CI)	1.64 (-3.08, 6.35)	
p-value	0.4963	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.7960
< 10 points	1/ 54 (1.9)	1.8	0/ 52 (0.0)	0.0	2.89 (0.12, 69.40)	0.5127	1.84 (-9.53, 13.22)	0.7510	
>= 10 points	2/126 (1.6)	1.6	0/130 (0.0)	0.0	5.16 (0.25, 106.38)	0.2881	1.56 (-3.67, 6.79)	0.5589	
OCS dose at baseline									0.8575
<10 mg/day	1/ 93 (1.1)	1.0	0/ 99 (0.0)	0.0	3.19 (0.13, 77.38)	0.4756	1.02 (-6.17, 8.21)	0.7810	
>=10 mg/day	2/ 87 (2.3)	2.4	0/ 83 (0.0)	0.0	4.77 (0.23, 97.96)	0.3107	2.38 (-5.04, 9.79)	0.5301	
Result of type I IFN gene signature test									0.8279
LOW	1/ 30 (3.3)	3.3	0/ 31 (0.0)	0.0	3.10 (0.13, 73.16)	0.4836	3.33 (-9.70, 16.36)	0.6161	
HIGH	2/150 (1.3)	1.3	0/151 (0.0)	0.0	5.03 (0.24, 103.96)	0.2955	1.29 (-3.72, 6.31)	0.6138	
Age (years)									NE
<= 65	3/175 (1.7)	1.7	0/181 (0.0)	0.0	7.24 (0.38, 139.12)	0.1894	1.69 (-3.11, 6.49)	0.4903	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
female	3/168 (1.8)	1.8	0/170 (0.0)	0.0	7.08 (0.37, 136.08)	0.1942	1.77 (-3.25, 6.80)	0.4887	
Race									0.8268
White	2/110 (1.8)	1.7	0/107 (0.0)	0.0	4.86 (0.24, 100.17)	0.3053	1.71 (-4.38, 7.79)	0.5823	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE		0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	1/ 11 (9.1)	9.1	0/ 11 (0.0)	0.0	3.00 (0.14, 66.53)	0.4872	9.09 (-21.93, 40.11)	0.5657	
Ethnicity									0.8253
Hispanic/Latino	2/ 54 (3.7)	3.8	0/ 54 (0.0)	0.0	5.00 (0.25, 101.77)	0.2952	3.79 (-7.52, 15.09)	0.5117	
Non-hispanic/Latino	1/118 (0.8)	0.8	0/120 (0.0)	0.0	3.05 (0.13, 74.13)	0.4933	0.79 (-5.79, 7.37)	0.8131	
Geographic region									0.7666
EU	1/ 51 (2.0)	2.0	0/ 46 (0.0)	0.0	2.71 (0.11, 64.96)	0.5382	1.96 (-6.46, 10.38)	0.6481	
non-EU	2/129 (1.6)	1.6	0/136 (0.0)	0.0	5.27 (0.26, 108.72)	0.2819	1.55 (-4.63, 7.74)	0.6224	
Onset of disease									NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-24.92, 24.92)	1.0000	
Adult	3/166 (1.8)	1.8	0/170 (0.0)	0.0	7.17 (0.37, 137.70)	0.1915	1.79 (-3.27, 6.85)	0.4877	
ADA result									NE
Negative	3/172 (1.7)	1.7	0/162 (0.0)	0.0	6.60 (0.34, 126.70)	0.2109	1.74 (-3.33, 6.80)	0.5023	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/125 (0.0)	0.0	0/134 (0.0)	0.0	NE		0.00 (-5.98, 5.98)	1.0000	
>= 30	3/ 55 (5.5)	5.5	0/ 48 (0.0)	0.0	6.13 (0.32, 115.66)	0.2267	5.49 (-6.88, 17.86)	0.3846	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									NE
All negative/normal	3/ 58 (5.2)	5.2	0/ 81 (0.0)	0.0	9.73 (0.51, 184.81)	0.1299	5.18 (-5.02, 15.38)	0.3195	
At least one positive/abnormal	0/122 (0.0)	0.0	0/101 (0.0)	0.0	NE		0.00 (-5.42, 5.42)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Serious Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.43, 4.43)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Serious Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.98, 10.98)	1.0000	
>= 10 points	0/126 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.90, 4.90)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 93 (0.0)	0.0	0/ 99 (0.0)	0.0	NE	0.00 (-7.00, 7.00)	1.0000	
>=10 mg/day	0/ 87 (0.0)	0.0	0/ 83 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE	0.00 (-11.73, 11.73)	1.0000	
HIGH	0/150 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Age (years)								NE
<= 65	0/175 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.50, 4.50)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-102.70, 102.70)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
female	0/168 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.71, 4.71)	1.0000	
Race								NE
White	0/110 (0.0)	0.0	0/107 (0.0)	0.0	NE	0.00 (-5.75, 5.75)	1.0000	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE	0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE	0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-28.41, 28.41)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	0/118 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.46, 6.46)	1.0000	
Geographic region								NE
EU	0/ 51 (0.0)	0.0	0/ 46 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
non-EU	0/129 (0.0)	0.0	0/136 (0.0)	0.0	NE	0.00 (-5.90, 5.90)	1.0000	
Onset of disease								NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-24.92, 24.92)	1.0000	
Adult	0/166 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.74, 4.74)	1.0000	
ADA result								NE
Negative	0/172 (0.0)	0.0	0/162 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE	0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/125 (0.0)	0.0	0/134 (0.0)	0.0	NE	0.00 (-5.98, 5.98)	1.0000	
>= 30	0/ 55 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-11.37, 11.37)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE	0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	0/122 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-5.42, 5.42)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Severe Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.43, 4.43)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Severe Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.98, 10.98)	1.0000	
>= 10 points	0/126 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.90, 4.90)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 93 (0.0)	0.0	0/ 99 (0.0)	0.0	NE	0.00 (-7.00, 7.00)	1.0000	
>=10 mg/day	0/ 87 (0.0)	0.0	0/ 83 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE	0.00 (-11.73, 11.73)	1.0000	
HIGH	0/150 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Age (years)								NE
<= 65	0/175 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.50, 4.50)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-102.70, 102.70)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
female	0/168 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.71, 4.71)	1.0000	
Race								NE
White	0/110 (0.0)	0.0	0/107 (0.0)	0.0	NE	0.00 (-5.75, 5.75)	1.0000	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE	0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE	0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-28.41, 28.41)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	0/118 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.46, 6.46)	1.0000	
Geographic region								NE
EU	0/ 51 (0.0)	0.0	0/ 46 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
non-EU	0/129 (0.0)	0.0	0/136 (0.0)	0.0	NE	0.00 (-5.90, 5.90)	1.0000	
Onset of disease								NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-24.92, 24.92)	1.0000	
Adult	0/166 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.74, 4.74)	1.0000	
ADA result								NE
Negative	0/172 (0.0)	0.0	0/162 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE	0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/125 (0.0)	0.0	0/134 (0.0)	0.0	NE	0.00 (-5.98, 5.98)	1.0000	
>= 30	0/ 55 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-11.37, 11.37)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE	0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	0/122 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-5.42, 5.42)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Non-Severe Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	3 (1.7)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	7.08 (0.37, 136.04)	
p-value	0.1945	
Odds Ratio (95% CI)	7.20 (0.37, 140.34)	
p-value	0.1928	
Risk Difference (95% CI)	1.67 (-0.20, 3.54)	
p-value	0.0807	
CMH approach		
Response rate	1.6	0.0
Difference in response rates (95% CI)	1.64 (-3.08, 6.35)	
p-value	0.4963	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Non-Severe Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.7960
< 10 points	1/ 54 (1.9)	1.8	0/ 52 (0.0)	0.0	2.89 (0.12, 69.40)	0.5127	1.84 (-9.53, 13.22)	0.7510	
>= 10 points	2/126 (1.6)	1.6	0/130 (0.0)	0.0	5.16 (0.25, 106.38)	0.2881	1.56 (-3.67, 6.79)	0.5589	
OCS dose at baseline									0.8575
<10 mg/day	1/ 93 (1.1)	1.0	0/ 99 (0.0)	0.0	3.19 (0.13, 77.38)	0.4756	1.02 (-6.17, 8.21)	0.7810	
>=10 mg/day	2/ 87 (2.3)	2.4	0/ 83 (0.0)	0.0	4.77 (0.23, 97.96)	0.3107	2.38 (-5.04, 9.79)	0.5301	
Result of type I IFN gene signature test									0.8279
LOW	1/ 30 (3.3)	3.3	0/ 31 (0.0)	0.0	3.10 (0.13, 73.16)	0.4836	3.33 (-9.70, 16.36)	0.6161	
HIGH	2/150 (1.3)	1.3	0/151 (0.0)	0.0	5.03 (0.24, 103.96)	0.2955	1.29 (-3.72, 6.31)	0.6138	
Age (years)									NE
<= 65	3/175 (1.7)	1.7	0/181 (0.0)	0.0	7.24 (0.38, 139.12)	0.1894	1.69 (-3.11, 6.49)	0.4903	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
female	3/168 (1.8)	1.8	0/170 (0.0)	0.0	7.08 (0.37, 136.08)	0.1942	1.77 (-3.25, 6.80)	0.4887	
Race									0.8268
White	2/110 (1.8)	1.7	0/107 (0.0)	0.0	4.86 (0.24, 100.17)	0.3053	1.71 (-4.38, 7.79)	0.5823	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE		0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	1/ 11 (9.1)	9.1	0/ 11 (0.0)	0.0	3.00 (0.14, 66.53)	0.4872	9.09 (-21.93, 40.11)	0.5657	
Ethnicity									0.8253
Hispanic/Latino	2/ 54 (3.7)	3.8	0/ 54 (0.0)	0.0	5.00 (0.25, 101.77)	0.2952	3.79 (-7.52, 15.09)	0.5117	
Non-hispanic/Latino	1/118 (0.8)	0.8	0/120 (0.0)	0.0	3.05 (0.13, 74.13)	0.4933	0.79 (-5.79, 7.37)	0.8131	
Geographic region									0.7666
EU	1/ 51 (2.0)	2.0	0/ 46 (0.0)	0.0	2.71 (0.11, 64.96)	0.5382	1.96 (-6.46, 10.38)	0.6481	
non-EU	2/129 (1.6)	1.6	0/136 (0.0)	0.0	5.27 (0.26, 108.72)	0.2819	1.55 (-4.63, 7.74)	0.6224	
Onset of disease									NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-24.92, 24.92)	1.0000	
Adult	3/166 (1.8)	1.8	0/170 (0.0)	0.0	7.17 (0.37, 137.70)	0.1915	1.79 (-3.27, 6.85)	0.4877	
ADA result									NE
Negative	3/172 (1.7)	1.7	0/162 (0.0)	0.0	6.60 (0.34, 126.70)	0.2109	1.74 (-3.33, 6.80)	0.5023	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/125 (0.0)	0.0	0/134 (0.0)	0.0	NE		0.00 (-5.98, 5.98)	1.0000	
>= 30	3/ 55 (5.5)	5.5	0/ 48 (0.0)	0.0	6.13 (0.32, 115.66)	0.2267	5.49 (-6.88, 17.86)	0.3846	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									NE
All negative/normal	3/ 58 (5.2)	5.2	0/ 81 (0.0)	0.0	9.73 (0.51, 184.81)	0.1299	5.18 (-5.02, 15.38)	0.3195	
At least one positive/abnormal	0/122 (0.0)	0.0	0/101 (0.0)	0.0	NE		0.00 (-5.42, 5.42)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Vasculitis
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.43, 4.43)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.98, 10.98)	1.0000	
>= 10 points	0/126 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.90, 4.90)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 93 (0.0)	0.0	0/ 99 (0.0)	0.0	NE	0.00 (-7.00, 7.00)	1.0000	
>=10 mg/day	0/ 87 (0.0)	0.0	0/ 83 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE	0.00 (-11.73, 11.73)	1.0000	
HIGH	0/150 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Age (years)								NE
<= 65	0/175 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.50, 4.50)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-102.70, 102.70)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
female	0/168 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.71, 4.71)	1.0000	
Race								NE
White	0/110 (0.0)	0.0	0/107 (0.0)	0.0	NE	0.00 (-5.75, 5.75)	1.0000	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE	0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE	0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-28.41, 28.41)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	0/118 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.46, 6.46)	1.0000	
Geographic region								NE
EU	0/ 51 (0.0)	0.0	0/ 46 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
non-EU	0/129 (0.0)	0.0	0/136 (0.0)	0.0	NE	0.00 (-5.90, 5.90)	1.0000	
Onset of disease								NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-24.92, 24.92)	1.0000	
Adult	0/166 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.74, 4.74)	1.0000	
ADA result								NE
Negative	0/172 (0.0)	0.0	0/162 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE	0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/125 (0.0)	0.0	0/134 (0.0)	0.0	NE	0.00 (-5.98, 5.98)	1.0000	
>= 30	0/ 55 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-11.37, 11.37)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE	0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	0/122 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-5.42, 5.42)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Serious Vasculitis
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.43, 4.43)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Serious Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Anifrolumab 300mg (N=180) Response rate	Placebo (N=182) n/ N (%)	Placebo (N=182) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Analysis Anifrolumab 300mg vs. Placebo Difference in response rates (95% CI)	Analysis Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.98, 10.98)	1.0000	
>= 10 points	0/126 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.90, 4.90)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 93 (0.0)	0.0	0/ 99 (0.0)	0.0	NE	0.00 (-7.00, 7.00)	1.0000	
>=10 mg/day	0/ 87 (0.0)	0.0	0/ 83 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE	0.00 (-11.73, 11.73)	1.0000	
HIGH	0/150 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Age (years)								NE
<= 65	0/175 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.50, 4.50)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-102.70, 102.70)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
female	0/168 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.71, 4.71)	1.0000	
Race								NE
White	0/110 (0.0)	0.0	0/107 (0.0)	0.0	NE	0.00 (-5.75, 5.75)	1.0000	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE	0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE	0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-28.41, 28.41)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	0/118 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.46, 6.46)	1.0000	
Geographic region								NE
EU	0/ 51 (0.0)	0.0	0/ 46 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
non-EU	0/129 (0.0)	0.0	0/136 (0.0)	0.0	NE	0.00 (-5.90, 5.90)	1.0000	
Onset of disease								NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-24.92, 24.92)	1.0000	
Adult	0/166 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.74, 4.74)	1.0000	
ADA result								NE
Negative	0/172 (0.0)	0.0	0/162 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE	0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/125 (0.0)	0.0	0/134 (0.0)	0.0	NE	0.00 (-5.98, 5.98)	1.0000	
>= 30	0/ 55 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-11.37, 11.37)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE	0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	0/122 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-5.42, 5.42)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Severe Vasculitis
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.43, 4.43)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Severe Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Anifrolumab 300mg (N=180) Response rate	Placebo (N=182) n/ N (%)	Placebo (N=182) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Analysis Anifrolumab 300mg vs. Placebo Difference in response rates (95% CI)	Analysis Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.98, 10.98)	1.0000	
>= 10 points	0/126 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.90, 4.90)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 93 (0.0)	0.0	0/ 99 (0.0)	0.0	NE	0.00 (-7.00, 7.00)	1.0000	
>=10 mg/day	0/ 87 (0.0)	0.0	0/ 83 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE	0.00 (-11.73, 11.73)	1.0000	
HIGH	0/150 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Age (years)								NE
<= 65	0/175 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.50, 4.50)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-102.70, 102.70)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
female	0/168 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.71, 4.71)	1.0000	
Race								NE
White	0/110 (0.0)	0.0	0/107 (0.0)	0.0	NE	0.00 (-5.75, 5.75)	1.0000	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE	0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE	0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-28.41, 28.41)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	0/118 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.46, 6.46)	1.0000	
Geographic region								NE
EU	0/ 51 (0.0)	0.0	0/ 46 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
non-EU	0/129 (0.0)	0.0	0/136 (0.0)	0.0	NE	0.00 (-5.90, 5.90)	1.0000	
Onset of disease								NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-24.92, 24.92)	1.0000	
Adult	0/166 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.74, 4.74)	1.0000	
ADA result								NE
Negative	0/172 (0.0)	0.0	0/162 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE	0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/125 (0.0)	0.0	0/134 (0.0)	0.0	NE	0.00 (-5.98, 5.98)	1.0000	
>= 30	0/ 55 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-11.37, 11.37)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE	0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	0/122 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-5.42, 5.42)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Non-Severe Vasculitis
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.43, 4.43)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Non-Severe Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Anifrolumab 300mg (N=180) Response rate	Placebo (N=182) n/ N (%)	Placebo (N=182) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Analysis Anifrolumab 300mg vs. Placebo Difference in response rates (95% CI)	Analysis Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.98, 10.98)	1.0000	
>= 10 points	0/126 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.90, 4.90)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 93 (0.0)	0.0	0/ 99 (0.0)	0.0	NE	0.00 (-7.00, 7.00)	1.0000	
>=10 mg/day	0/ 87 (0.0)	0.0	0/ 83 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE	0.00 (-11.73, 11.73)	1.0000	
HIGH	0/150 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Age (years)								NE
<= 65	0/175 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.50, 4.50)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-102.70, 102.70)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
female	0/168 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.71, 4.71)	1.0000	
Race								NE
White	0/110 (0.0)	0.0	0/107 (0.0)	0.0	NE	0.00 (-5.75, 5.75)	1.0000	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE	0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE	0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-28.41, 28.41)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	0/118 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.46, 6.46)	1.0000	
Geographic region								NE
EU	0/ 51 (0.0)	0.0	0/ 46 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
non-EU	0/129 (0.0)	0.0	0/136 (0.0)	0.0	NE	0.00 (-5.90, 5.90)	1.0000	
Onset of disease								NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-24.92, 24.92)	1.0000	
Adult	0/166 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.74, 4.74)	1.0000	
ADA result								NE
Negative	0/172 (0.0)	0.0	0/162 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE	0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/125 (0.0)	0.0	0/134 (0.0)	0.0	NE	0.00 (-5.98, 5.98)	1.0000	
>= 30	0/ 55 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-11.37, 11.37)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE	0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	0/122 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-5.42, 5.42)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Malignancy
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	0 (0.0)	1 (0.5)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.34 (0.01, 8.22)	
p-value	0.5045	
Odds Ratio (95% CI)	0.34 (0.01, 8.28)	
p-value	0.5041	
Risk Difference (95% CI)	-0.55 (-1.62, 0.52)	
p-value	0.3160	
CMH approach		
Response rate	0.0	0.6
Difference in response rates (95% CI)	-0.57 (-5.12, 3.97)	
p-value	0.8049	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Anifrolumab 300mg (N=180) Response rate	Placebo (N=182) n/ N (%)	Placebo (N=182) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE		0.00 (-10.98, 10.98)	1.0000	
>= 10 points	0/126 (0.0)	0.0	1/130 (0.8)	0.8	0.34 (0.01, 8.36)	0.5120	-0.81 (-5.92, 4.30)	0.7558	
OCS dose at baseline									NE
<10 mg/day	0/ 93 (0.0)	0.0	0/ 99 (0.0)	0.0	NE		0.00 (-7.00, 7.00)	1.0000	
>=10 mg/day	0/ 87 (0.0)	0.0	1/ 83 (1.2)	1.2	0.32 (0.01, 7.70)	0.4812	-1.22 (-8.51, 6.07)	0.7428	
Result of type I IFN gene signature test									NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE		0.00 (-11.73, 11.73)	1.0000	
HIGH	0/150 (0.0)	0.0	1/151 (0.7)	0.7	0.34 (0.01, 8.17)	0.5026	-0.69 (-5.62, 4.24)	0.7838	
Age (years)									NE
<= 65	0/175 (0.0)	0.0	1/181 (0.6)	0.6	0.34 (0.01, 8.40)	0.5134	-0.58 (-5.20, 4.04)	0.8063	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
female	0/168 (0.0)	0.0	1/170 (0.6)	0.6	0.34 (0.01, 8.22)	0.5048	-0.62 (-5.46, 4.23)	0.8034	
Race									NE
White	0/110 (0.0)	0.0	1/107 (0.9)	0.9	0.32 (0.01, 7.87)	0.4890	-0.91 (-6.90, 5.08)	0.7658	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE		0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-28.41, 28.41)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE		0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	0/118 (0.0)	0.0	1/120 (0.8)	0.8	0.34 (0.01, 8.24)	0.5063	-0.84 (-7.47, 5.78)	0.8031	
Geographic region									NE
EU	0/ 51 (0.0)	0.0	1/ 46 (2.2)	2.2	0.30 (0.01, 7.22)	0.4591	-2.17 (-10.75, 6.40)	0.6192	
non-EU	0/129 (0.0)	0.0	0/136 (0.0)	0.0	NE		0.00 (-5.90, 5.90)	1.0000	
Onset of disease									NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-24.92, 24.92)	1.0000	
Adult	0/166 (0.0)	0.0	1/170 (0.6)	0.6	0.34 (0.01, 8.32)	0.5094	-0.61 (-5.48, 4.26)	0.8065	
ADA result									NE
Negative	0/172 (0.0)	0.0	1/162 (0.6)	0.6	0.31 (0.01, 7.65)	0.4772	-0.64 (-5.55, 4.27)	0.7973	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/125 (0.0)	0.0	1/134 (0.7)	0.8	0.36 (0.01, 8.69)	0.5272	-0.76 (-6.89, 5.37)	0.8088	
>= 30	0/ 55 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-11.37, 11.37)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE		0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	0/122 (0.0)	0.0	1/101 (1.0)	1.0	0.28 (0.01, 6.71)	0.4295	-0.97 (-6.67, 4.74)	0.7393	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Serious Malignancy
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	0 (0.0)	1 (0.5)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.34 (0.01, 8.22)	
p-value	0.5045	
Odds Ratio (95% CI)	0.34 (0.01, 8.28)	
p-value	0.5041	
Risk Difference (95% CI)	-0.55 (-1.62, 0.52)	
p-value	0.3160	
CMH approach		
Response rate	0.0	0.6
Difference in response rates (95% CI)	-0.57 (-5.12, 3.97)	
p-value	0.8049	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Serious Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Anifrolumab 300mg (N=180) Response rate	Placebo (N=182) n/ N (%)	Placebo (N=182) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE		0.00 (-10.98, 10.98)	1.0000	
>= 10 points	0/126 (0.0)	0.0	1/130 (0.8)	0.8	0.34 (0.01, 8.36)	0.5120	-0.81 (-5.92, 4.30)	0.7558	
OCS dose at baseline									NE
<10 mg/day	0/ 93 (0.0)	0.0	0/ 99 (0.0)	0.0	NE		0.00 (-7.00, 7.00)	1.0000	
>=10 mg/day	0/ 87 (0.0)	0.0	1/ 83 (1.2)	1.2	0.32 (0.01, 7.70)	0.4812	-1.22 (-8.51, 6.07)	0.7428	
Result of type I IFN gene signature test									NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE		0.00 (-11.73, 11.73)	1.0000	
HIGH	0/150 (0.0)	0.0	1/151 (0.7)	0.7	0.34 (0.01, 8.17)	0.5026	-0.69 (-5.62, 4.24)	0.7838	
Age (years)									NE
<= 65	0/175 (0.0)	0.0	1/181 (0.6)	0.6	0.34 (0.01, 8.40)	0.5134	-0.58 (-5.20, 4.04)	0.8063	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
female	0/168 (0.0)	0.0	1/170 (0.6)	0.6	0.34 (0.01, 8.22)	0.5048	-0.62 (-5.46, 4.23)	0.8034	
Race									NE
White	0/110 (0.0)	0.0	1/107 (0.9)	0.9	0.32 (0.01, 7.87)	0.4890	-0.91 (-6.90, 5.08)	0.7658	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE		0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-28.41, 28.41)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE		0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	0/118 (0.0)	0.0	1/120 (0.8)	0.8	0.34 (0.01, 8.24)	0.5063	-0.84 (-7.47, 5.78)	0.8031	
Geographic region									NE
EU	0/ 51 (0.0)	0.0	1/ 46 (2.2)	2.2	0.30 (0.01, 7.22)	0.4591	-2.17 (-10.75, 6.40)	0.6192	
non-EU	0/129 (0.0)	0.0	0/136 (0.0)	0.0	NE		0.00 (-5.90, 5.90)	1.0000	
Onset of disease									NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-24.92, 24.92)	1.0000	
Adult	0/166 (0.0)	0.0	1/170 (0.6)	0.6	0.34 (0.01, 8.32)	0.5094	-0.61 (-5.48, 4.26)	0.8065	
ADA result									NE
Negative	0/172 (0.0)	0.0	1/162 (0.6)	0.6	0.31 (0.01, 7.65)	0.4772	-0.64 (-5.55, 4.27)	0.7973	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/125 (0.0)	0.0	1/134 (0.7)	0.8	0.36 (0.01, 8.69)	0.5272	-0.76 (-6.89, 5.37)	0.8088	
>= 30	0/ 55 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-11.37, 11.37)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE		0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	0/122 (0.0)	0.0	1/101 (1.0)	1.0	0.28 (0.01, 6.71)	0.4295	-0.97 (-6.67, 4.74)	0.7393	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
'
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Severe Malignancy
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-4.43, 4.43)	
p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Severe Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Anifrolumab 300mg (N=180) Response rate	Placebo (N=182) n/ N (%)	Placebo (N=182) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Analysis Anifrolumab 300mg vs. Placebo Difference in response rates (95% CI)	Analysis Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE	0.00 (-10.98, 10.98)	1.0000	
>= 10 points	0/126 (0.0)	0.0	0/130 (0.0)	0.0	NE	0.00 (-4.90, 4.90)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/ 93 (0.0)	0.0	0/ 99 (0.0)	0.0	NE	0.00 (-7.00, 7.00)	1.0000	
>=10 mg/day	0/ 87 (0.0)	0.0	0/ 83 (0.0)	0.0	NE	0.00 (-6.94, 6.94)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE	0.00 (-11.73, 11.73)	1.0000	
HIGH	0/150 (0.0)	0.0	0/151 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Age (years)								NE
<= 65	0/175 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-4.50, 4.50)	1.0000	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-102.70, 102.70)	1.0000	
Sex								NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-26.46, 26.46)	1.0000	
female	0/168 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.71, 4.71)	1.0000	
Race								NE
White	0/110 (0.0)	0.0	0/107 (0.0)	0.0	NE	0.00 (-5.75, 5.75)	1.0000	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE	0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE	0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE	0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE	0.00 (-28.41, 28.41)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE	0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	0/118 (0.0)	0.0	0/120 (0.0)	0.0	NE	0.00 (-6.46, 6.46)	1.0000	
Geographic region								NE
EU	0/ 51 (0.0)	0.0	0/ 46 (0.0)	0.0	NE	0.00 (-7.65, 7.65)	1.0000	
non-EU	0/129 (0.0)	0.0	0/136 (0.0)	0.0	NE	0.00 (-5.90, 5.90)	1.0000	
Onset of disease								NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE	0.00 (-24.92, 24.92)	1.0000	
Adult	0/166 (0.0)	0.0	0/170 (0.0)	0.0	NE	0.00 (-4.74, 4.74)	1.0000	
ADA result								NE
Negative	0/172 (0.0)	0.0	0/162 (0.0)	0.0	NE	0.00 (-4.77, 4.77)	1.0000	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE	0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/125 (0.0)	0.0	0/134 (0.0)	0.0	NE	0.00 (-5.98, 5.98)	1.0000	
>= 30	0/ 55 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-11.37, 11.37)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group								NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE	0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	0/122 (0.0)	0.0	0/101 (0.0)	0.0	NE	0.00 (-5.42, 5.42)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Non-Severe Malignancy
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	0 (0.0)	1 (0.5)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.34 (0.01, 8.22)	
p-value	0.5045	
Odds Ratio (95% CI)	0.34 (0.01, 8.28)	
p-value	0.5041	
Risk Difference (95% CI)	-0.55 (-1.62, 0.52)	
p-value	0.3160	
CMH approach		
Response rate	0.0	0.6
Difference in response rates (95% CI)	-0.57 (-5.12, 3.97)	
p-value	0.8049	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) (on-treatment) - Non-Severe Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Anifrolumab 300mg (N=180) Response rate	Placebo (N=182) n/ N (%)	Placebo (N=182) Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/ 54 (0.0)	0.0	0/ 52 (0.0)	0.0	NE		0.00 (-10.98, 10.98)	1.0000	
>= 10 points	0/126 (0.0)	0.0	1/130 (0.8)	0.8	0.34 (0.01, 8.36)	0.5120	-0.81 (-5.92, 4.30)	0.7558	
OCS dose at baseline									NE
<10 mg/day	0/ 93 (0.0)	0.0	0/ 99 (0.0)	0.0	NE		0.00 (-7.00, 7.00)	1.0000	
>=10 mg/day	0/ 87 (0.0)	0.0	1/ 83 (1.2)	1.2	0.32 (0.01, 7.70)	0.4812	-1.22 (-8.51, 6.07)	0.7428	
Result of type I IFN gene signature test									NE
LOW	0/ 30 (0.0)	0.0	0/ 31 (0.0)	0.0	NE		0.00 (-11.73, 11.73)	1.0000	
HIGH	0/150 (0.0)	0.0	1/151 (0.7)	0.7	0.34 (0.01, 8.17)	0.5026	-0.69 (-5.62, 4.24)	0.7838	
Age (years)									NE
<= 65	0/175 (0.0)	0.0	1/181 (0.6)	0.6	0.34 (0.01, 8.40)	0.5134	-0.58 (-5.20, 4.04)	0.8063	
> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
female	0/168 (0.0)	0.0	1/170 (0.6)	0.6	0.34 (0.01, 8.22)	0.5048	-0.62 (-5.46, 4.23)	0.8034	
Race									NE
White	0/110 (0.0)	0.0	1/107 (0.9)	0.9	0.32 (0.01, 7.87)	0.4890	-0.91 (-6.90, 5.08)	0.7658	
Black or African American	0/ 17 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.13, 17.13)	1.0000	
Asian	0/ 30 (0.0)	0.0	0/ 30 (0.0)	0.0	NE		0.00 (-11.91, 11.91)	1.0000	
American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
Other	0/ 11 (0.0)	0.0	0/ 11 (0.0)	0.0	NE		0.00 (-28.41, 28.41)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 54 (0.0)	0.0	0/ 54 (0.0)	0.0	NE		0.00 (-10.58, 10.58)	1.0000	
Non-hispanic/Latino	0/118 (0.0)	0.0	1/120 (0.8)	0.8	0.34 (0.01, 8.24)	0.5063	-0.84 (-7.47, 5.78)	0.8031	
Geographic region									NE
EU	0/ 51 (0.0)	0.0	1/ 46 (2.2)	2.2	0.30 (0.01, 7.22)	0.4591	-2.17 (-10.75, 6.40)	0.6192	
non-EU	0/129 (0.0)	0.0	0/136 (0.0)	0.0	NE		0.00 (-5.90, 5.90)	1.0000	
Onset of disease									NE
Paediatric	0/ 14 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-24.92, 24.92)	1.0000	
Adult	0/166 (0.0)	0.0	1/170 (0.6)	0.6	0.34 (0.01, 8.32)	0.5094	-0.61 (-5.48, 4.26)	0.8065	
ADA result									NE
Negative	0/172 (0.0)	0.0	1/162 (0.6)	0.6	0.31 (0.01, 7.65)	0.4772	-0.64 (-5.55, 4.27)	0.7973	
Positive (At any time)	0/ 8 (0.0)	0.0	0/ 20 (0.0)	0.0	NE		0.00 (-28.52, 28.52)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/125 (0.0)	0.0	1/134 (0.7)	0.8	0.36 (0.01, 8.69)	0.5272	-0.76 (-6.89, 5.37)	0.8088	
>= 30	0/ 55 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-11.37, 11.37)	1.0000	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									NE
All negative/normal	0/ 58 (0.0)	0.0	0/ 81 (0.0)	0.0	NE		0.00 (-9.04, 9.04)	1.0000	
At least one positive/abnormal	0/122 (0.0)	0.0	1/101 (1.0)	1.0	0.28 (0.01, 6.71)	0.4295	-0.97 (-6.67, 4.74)	0.7393	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of SOCs Cardiac disorders and/or Vascular disorders (on-treatment)
Full analysis set

	Anifrolumab 300mg (N=180)	Placebo (N=182)
Number of subjects with events, n (%)	9 (5.0)	7 (3.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.30 (0.49, 3.42)	
p-value	0.5945	
Odds Ratio (95% CI)	1.32 (0.48, 3.61)	
p-value	0.5943	
Risk Difference (95% CI)	1.15 (-3.08, 5.39)	
p-value	0.5934	
CMH approach		
Response rate	5.1	3.9
Difference in response rates (95% CI)	1.14 (-4.74, 7.03)	
p-value	0.7032	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of SOCs Cardiac disorders and/or Vascular disorders (on-treatment) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.3397
< 10 points	2/ 54 (3.7)	3.7	3/ 52 (5.8)	5.8	0.64 (0.11, 3.69)	0.6193	-2.03 (-14.76, 10.71)	0.7551	
>= 10 points	7/126 (5.6)	5.6	4/130 (3.1)	3.2	1.81 (0.54, 6.02)	0.3360	2.43 (-4.34, 9.21)	0.4813	
OCS dose at baseline									0.6133
<10 mg/day	6/ 93 (6.5)	6.6	4/ 99 (4.0)	4.1	1.60 (0.47, 5.48)	0.4570	2.45 (-6.46, 11.35)	0.5901	
>=10 mg/day	3/ 87 (3.4)	3.4	3/ 83 (3.6)	3.7	0.95 (0.20, 4.59)	0.9532	-0.25 (-8.89, 8.39)	0.9543	
Result of type I IFN gene signature test									0.8604
LOW	1/ 30 (3.3)	3.3	1/ 31 (3.2)	3.2	1.03 (0.07, 15.78)	0.9812	0.11 (-14.04, 14.25)	0.9881	
HIGH	8/150 (5.3)	5.4	6/151 (4.0)	4.1	1.34 (0.48, 3.78)	0.5770	1.35 (-5.12, 7.82)	0.6816	
Age (years)									0.9114
<= 65	8/175 (4.6)	4.6	7/181 (3.9)	3.9	1.18 (0.44, 3.19)	0.7413	0.66 (-5.24, 6.56)	0.8269	
> 65	1/ 5 (20.0)	20.0	0/ 1 (0.0)	0.0	1.00 (0.06, 15.99)	1.0000	20.00 (-84.53, 124.53)	0.7077	
Sex									NE
male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
female	9/168 (5.4)	5.4	7/170 (4.1)	4.2	1.30 (0.50, 3.41)	0.5928	1.21 (-5.04, 7.45)	0.7047	
Race									0.5511
White	7/110 (6.4)	6.4	3/107 (2.8)	2.7	2.27 (0.60, 8.55)	0.2257	3.74 (-3.93, 11.41)	0.3391	
Black or African American	0/ 17 (0.0)	0.0	2/ 25 (8.0)	8.0	0.29 (0.01, 5.67)	0.4135	-8.00 (-27.43, 11.43)	0.4196	
Asian	0/ 30 (0.0)	0.0	1/ 30 (3.3)	3.3	0.33 (0.01, 7.87)	0.4958	-3.33 (-16.52, 9.85)	0.6203	
American Indian or Alaska Native	1/ 4 (25.0)	25.0	0/ 1 (0.0)	0.0	1.20 (0.08, 18.75)	0.8966	25.00 (-82.10, 132.10)	0.6473	
Other	0/ 11 (0.0)	0.0	1/ 11 (9.1)	9.1	0.33 (0.02, 7.39)	0.4872	-9.09 (-40.11, 21.93)	0.5657	
Ethnicity									0.4008
Hispanic/Latino	4/ 54 (7.4)	7.3	2/ 54 (3.7)	4.0	2.00 (0.38, 10.47)	0.4117	3.31 (-9.64, 16.26)	0.6166	
Non-hispanic/Latino	4/118 (3.4)	3.5	5/120 (4.2)	4.2	0.81 (0.22, 2.96)	0.7539	-0.73 (-8.47, 7.02)	0.8543	
Geographic region									0.1330
EU	4/ 51 (7.8)	7.8	0/ 46 (0.0)	0.0	8.13 (0.45, 147.10)	0.1559	7.84 (-2.42, 18.10)	0.1341	
non-EU	5/129 (3.9)	3.9	7/136 (5.1)	5.3	0.75 (0.25, 2.31)	0.6203	-1.39 (-8.74, 5.97)	0.7122	
Onset of disease									0.6321
Paediatric	1/ 14 (7.1)	7.1	0/ 12 (0.0)	0.0	2.60 (0.12, 58.48)	0.5475	7.14 (-19.90, 34.18)	0.6047	
Adult	8/166 (4.8)	4.8	7/170 (4.1)	4.2	1.17 (0.43, 3.15)	0.7558	0.67 (-5.54, 6.87)	0.8334	
ADA result									0.6351
Negative	8/172 (4.7)	4.8	6/162 (3.7)	3.7	1.26 (0.45, 3.54)	0.6667	1.05 (-5.10, 7.21)	0.7369	
Positive (At any time)	1/ 8 (12.5)	12.5	1/ 20 (5.0)	5.0	2.50 (0.18, 35.31)	0.4976	7.50 (-25.82, 40.82)	0.6591	
BMI (kg/m2) at enrolment									0.2421
< 30	6/125 (4.8)	4.8	3/134 (2.2)	2.1	2.14 (0.55, 8.39)	0.2732	2.70 (-4.39, 9.79)	0.4554	
>= 30	3/ 55 (5.5)	5.5	4/ 48 (8.3)	8.2	0.65 (0.15, 2.78)	0.5657	-2.65 (-16.70, 11.40)	0.7119	
Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.3486
All negative/normal	2/ 58 (3.4)	3.4	4/ 81 (4.9)	5.2	0.70 (0.13, 3.69)	0.6722	-1.77 (-12.49, 8.96)	0.7469	
At least one positive/abnormal	7/122 (5.7)	5.7	3/101 (3.0)	2.9	1.93 (0.51, 7.28)	0.3307	2.84 (-4.49, 10.18)	0.4478	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Blood and lymphatic system disorders	Number of subjects with events, n (%)	7 (3.9)	10 (5.5)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.71 (0.28, 1.82)	
	p-value	0.4728	
	Odds Ratio (95% CI)	0.70 (0.26, 1.87)	
	p-value	0.4724	
	Risk Difference (95% CI)	-1.61 (-5.96, 2.75)	
	p-value	0.4696	
	CMH approach		
	Response rate	3.9	5.5
	Difference in response rates (95% CI)	-1.63 (-7.50, 4.25)	
	p-value	0.5879	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Eye disorders	Number of subjects with events, n (%)	16 (8.9)	11 (6.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.47 (0.70, 3.08)	
	p-value	0.3066	
	Odds Ratio (95% CI)	1.52 (0.68, 3.37)	
	p-value	0.3057	
	Risk Difference (95% CI)	2.84 (-2.57, 8.26)	
	p-value	0.3027	
	CMH approach		
	Response rate	8.8	6.0
	Difference in response rates (95% CI)	2.83 (-3.60, 9.26)	
	p-value	0.3891	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Gastrointestinal disorders	Number of subjects with events, n (%)	35 (19.4)	51 (28.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.69 (0.48, 1.01)	
	p-value	0.0579	
	Odds Ratio (95% CI)	0.62 (0.38, 1.01)	
	p-value	0.0563	
	Risk Difference (95% CI)	-8.58 (-17.30, 0.14)	
	p-value	0.0538	
	CMH approach		
	Response rate	19.4	28.0
	Difference in response rates (95% CI)	-8.58 (-17.45, 0.29)	
	p-value	0.0579	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: General disorders and administration site conditions	Number of subjects with events, n (%)	22 (12.2)	17 (9.3)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.31 (0.72, 2.38)	
	p-value	0.3785	
	Odds Ratio (95% CI)	1.35 (0.69, 2.64)	
	p-value	0.3779	
	Risk Difference (95% CI)	2.88 (-3.50, 9.27)	
	p-value	0.3764	
	CMH approach		
	Response rate	12.3	9.3
	Difference in response rates (95% CI)	2.95 (-4.29, 10.19)	
	p-value	0.4245	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Infections and infestations	Number of subjects with events, n (%)	124 (68.9)	107 (58.8)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.17 (1.00, 1.37)	
	p-value	0.0469	
	Odds Ratio (95% CI)	1.55 (1.01, 2.39)	
	p-value	0.0462	
	Risk Difference (95% CI)	10.10 (0.26, 19.94)	
	p-value	0.0443	
	CMH approach		
	Response rate	69.0	58.6
	Difference in response rates (95% CI)	10.33 (0.44, 20.23)	
	p-value	0.0406	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Infections and infestations, PT: Bronchitis	Number of subjects with events, n (%)	22 (12.2)	7 (3.8)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	3.18 (1.39, 7.25)	
	p-value	0.0060	
	Odds Ratio (95% CI)	3.48 (1.45, 8.37)	
	p-value	0.0053	
	Risk Difference (95% CI)	8.38 (2.84, 13.92)	
	p-value	0.0030	
	CMH approach		
	Response rate	12.5	3.9
	Difference in response rates (95% CI)	8.57 (1.87, 15.26)	
	p-value	0.0122	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Infections and infestations, PT: Herpes zoster	Number of subjects with events, n (%)	13 (7.2)	2 (1.1)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	6.57 (1.50, 28.71)	
	p-value	0.0123	
	Odds Ratio (95% CI)	7.01 (1.56, 31.51)	
	p-value	0.0112	
	Risk Difference (95% CI)	6.12 (2.05, 10.20)	
	p-value	0.0032	
	CMH approach		
	Response rate	7.2	1.1
	Difference in response rates (95% CI)	6.10 (0.32, 11.88)	
	p-value	0.0387	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Infections and infestations, PT: Nasopharyngitis	Number of subjects with events, n (%)	28 (15.6)	20 (11.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.42 (0.83, 2.42)	
	p-value	0.2034	
	Odds Ratio (95% CI)	1.49 (0.81, 2.76)	
	p-value	0.2022	
	Risk Difference (95% CI)	4.57 (-2.41, 11.54)	
	p-value	0.1996	
	CMH approach		
	Response rate	15.7	10.9
	Difference in response rates (95% CI)	4.79 (-2.88, 12.47)	
	p-value	0.2207	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Infections and infestations, PT: Sinusitis	Number of subjects with events, n (%)	12 (6.7)	9 (4.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.35 (0.58, 3.12)	
	p-value	0.4854	
	Odds Ratio (95% CI)	1.37 (0.56, 3.34)	
	p-value	0.4851	
	Risk Difference (95% CI)	1.72 (-3.10, 6.54)	
	p-value	0.4836	
	CMH approach		
	Response rate	6.7	4.8
	Difference in response rates (95% CI)	1.91 (-4.22, 8.04)	
	p-value	0.5416	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Infections and infestations, PT: Upper respiratory tract infection	Number of subjects with events, n (%)	39 (21.7)	18 (9.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	2.19 (1.30, 3.68)	
	p-value	0.0031	
	Odds Ratio (95% CI)	2.52 (1.38, 4.60)	
	p-value	0.0026	
	Risk Difference (95% CI)	11.78 (4.36, 19.19)	
	p-value	0.0019	
	CMH approach		
	Response rate	21.6	9.8
	Difference in response rates (95% CI)	11.77 (3.82, 19.73)	
	p-value	0.0037	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Infections and infestations, PT: Urinary tract infection	Number of subjects with events, n (%)	20 (11.1)	25 (13.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.81 (0.47, 1.40)	
	p-value	0.4503	
	Odds Ratio (95% CI)	0.79 (0.42, 1.47)	
	p-value	0.4499	
	Risk Difference (95% CI)	-2.63 (-9.41, 4.16)	
	p-value	0.4485	
	CMH approach		
	Response rate	11.2	13.8
	Difference in response rates (95% CI)	-2.60 (-10.13, 4.92)	
	p-value	0.4978	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Injury, poisoning and procedural complications	Number of subjects with events, n (%)	43 (23.9)	34 (18.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.28 (0.86, 1.91)	
	p-value	0.2281	
	Odds Ratio (95% CI)	1.37 (0.82, 2.27)	
	p-value	0.2270	
	Risk Difference (95% CI)	5.21 (-3.21, 13.63)	
	p-value	0.2253	
	CMH approach		
	Response rate	24.1	18.4
	Difference in response rates (95% CI)	5.76 (-2.96, 14.47)	
	p-value	0.1956	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Injury, poisoning and procedural complications, PT: Infusion related reaction	Number of subjects with events, n (%)	25 (13.9)	14 (7.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.81 (0.97, 3.36)	
	p-value	0.0622	
	Odds Ratio (95% CI)	1.94 (0.97, 3.86)	
	p-value	0.0606	
	Risk Difference (95% CI)	6.20 (-0.17, 12.56)	
	p-value	0.0564	
	CMH approach		
	Response rate	14.1	7.5
	Difference in response rates (95% CI)	6.57 (-0.67, 13.80)	
	p-value	0.0752	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Metabolism and nutrition disorders	Number of subjects with events, n (%)	10 (5.6)	16 (8.8)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.63 (0.29, 1.35)	
	p-value	0.2383	
	Odds Ratio (95% CI)	0.61 (0.27, 1.38)	
	p-value	0.2370	
	Risk Difference (95% CI)	-3.24 (-8.54, 2.07)	
	p-value	0.2317	
	CMH approach		
	Response rate	5.6	8.7
	Difference in response rates (95% CI)	-3.14 (-9.58, 3.30)	
	p-value	0.3388	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Musculoskeletal and connective tissue disorders	Number of subjects with events, n (%)	40 (22.2)	35 (19.2)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.16 (0.77, 1.73)	
	p-value	0.4832	
	Odds Ratio (95% CI)	1.20 (0.72, 2.00)	
	p-value	0.4829	
	Risk Difference (95% CI)	2.99 (-5.36, 11.34)	
	p-value	0.4824	
	CMH approach		
	Response rate	22.3	19.3
	Difference in response rates (95% CI)	3.09 (-5.61, 11.79)	
	p-value	0.4862	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Musculoskeletal and connective tissue disorders, PT: Arthralgia	Number of subjects with events, n (%)	10 (5.6)	6 (3.3)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.69 (0.63, 4.54)	
	p-value	0.3020	
	Odds Ratio (95% CI)	1.73 (0.61, 4.85)	
	p-value	0.3010	
	Risk Difference (95% CI)	2.26 (-1.98, 6.49)	
	p-value	0.2957	
	CMH approach		
	Response rate	5.6	3.3
	Difference in response rates (95% CI)	2.28 (-3.54, 8.10)	
	p-value	0.4429	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Musculoskeletal and connective tissue disorders, PT: Back pain	Number of subjects with events, n (%)	10 (5.6)	3 (1.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	3.37 (0.94, 12.05)	
	p-value	0.0615	
	Odds Ratio (95% CI)	3.51 (0.95, 12.97)	
	p-value	0.0598	
	Risk Difference (95% CI)	3.91 (0.08, 7.73)	
	p-value	0.0452	
	CMH approach		
	Response rate	5.6	1.6
	Difference in response rates (95% CI)	3.96 (-1.60, 9.51)	
	p-value	0.1630	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Nervous system disorders	Number of subjects with events, n (%)	27 (15.0)	25 (13.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.09 (0.66, 1.81)	
	p-value	0.7319	
	Odds Ratio (95% CI)	1.11 (0.62, 1.99)	
	p-value	0.7318	
	Risk Difference (95% CI)	1.26 (-5.96, 8.49)	
	p-value	0.7318	
	CMH approach		
	Response rate	15.0	13.4
	Difference in response rates (95% CI)	1.55 (-6.17, 9.26)	
	p-value	0.6940	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Nervous system disorders, PT: Headache	Number of subjects with events, n (%)	9 (5.0)	16 (8.8)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.57 (0.26, 1.25)	
	p-value	0.1616	
	Odds Ratio (95% CI)	0.55 (0.23, 1.27)	
	p-value	0.1601	
	Risk Difference (95% CI)	-3.79 (-8.99, 1.41)	
	p-value	0.1532	
	CMH approach		
	Response rate	5.1	8.5
	Difference in response rates (95% CI)	-3.43 (-9.76, 2.90)	
	p-value	0.2882	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Psychiatric disorders	Number of subjects with events, n (%)	11 (6.1)	16 (8.8)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.70 (0.33, 1.46)	
	p-value	0.3352	
	Odds Ratio (95% CI)	0.68 (0.30, 1.50)	
	p-value	0.3343	
	Risk Difference (95% CI)	-2.68 (-8.08, 2.72)	
	p-value	0.3308	
	CMH approach		
	Response rate	6.0	8.7
	Difference in response rates (95% CI)	-2.68 (-9.20, 3.84)	
	p-value	0.4203	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Reproductive system and breast disorders	Number of subjects with events, n (%)	11 (6.1)	7 (3.8)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.59 (0.63, 4.01)	
	p-value	0.3265	
	Odds Ratio (95% CI)	1.63 (0.62, 4.30)	
	p-value	0.3257	
	Risk Difference (95% CI)	2.26 (-2.21, 6.74)	
	p-value	0.3215	
	CMH approach		
	Response rate	6.1	3.8
	Difference in response rates (95% CI)	2.32 (-3.66, 8.30)	
	p-value	0.4472	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with events, n (%)	22 (12.2)	25 (13.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.89 (0.52, 1.52)	
	p-value	0.6686	
	Odds Ratio (95% CI)	0.87 (0.47, 1.62)	
	p-value	0.6684	
	Risk Difference (95% CI)	-1.51 (-8.44, 5.41)	
	p-value	0.6681	
	CMH approach		
	Response rate	12.2	13.7
	Difference in response rates (95% CI)	-1.52 (-9.18, 6.13)	
	p-value	0.6962	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Respiratory, thoracic and mediastinal disorders, PT: Cough	Number of subjects with events, n (%)	10 (5.6)	6 (3.3)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.69 (0.63, 4.54)	
	p-value	0.3020	
	Odds Ratio (95% CI)	1.73 (0.61, 4.85)	
	p-value	0.3010	
	Risk Difference (95% CI)	2.26 (-1.98, 6.49)	
	p-value	0.2957	
	CMH approach		
	Response rate	5.5	3.3
	Difference in response rates (95% CI)	2.15 (-3.67, 7.98)	
	p-value	0.4692	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Skin and subcutaneous tissue disorders	Number of subjects with events, n (%)	28 (15.6)	25 (13.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.13 (0.69, 1.86)	
	p-value	0.6248	
	Odds Ratio (95% CI)	1.16 (0.65, 2.07)	
	p-value	0.6246	
	Risk Difference (95% CI)	1.82 (-5.46, 9.10)	
	p-value	0.6244	
	CMH approach		
	Response rate	15.7	13.6
	Difference in response rates (95% CI)	2.07 (-5.76, 9.90)	
	p-value	0.6045	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations	SLEDAI-2K score									0.5783
	< 10 points	40/ 54 (74.1)	74.1	35/ 52 (67.3)	67.2	1.10 (0.86, 1.41)	0.4463	6.85 (-10.96, 24.66)	0.4511	
	>= 10 points	84/126 (66.7)	66.8	72/130 (55.4)	55.1	1.20 (0.99, 1.47)	0.0659	11.70 (-0.16, 23.56)	0.0531	
	OCS dose									0.4215
	<10 mg/day	68/ 93 (73.1)	73.1	65/ 99 (65.7)	65.5	1.11 (0.92, 1.34)	0.2627	7.57 (-5.66, 20.79)	0.2622	
	>=10 mg/day	56/ 87 (64.4)	64.4	42/ 83 (50.6)	50.8	1.27 (0.98, 1.66)	0.0739	13.60 (-1.13, 28.33)	0.0703	
	Result of type I IFN gene signature test									0.8722
	LOW	21/ 30 (70.0)	70.0	18/ 31 (58.1)	58.1	1.21 (0.82, 1.76)	0.3349	11.94 (-12.22, 36.10)	0.3329	
	HIGH	103/150 (68.7)	68.7	89/151 (58.9)	58.7	1.17 (0.98, 1.38)	0.0809	10.01 (-0.84, 20.85)	0.0705	
	Age (years)									0.4471
	<= 65	120/175 (68.6)	68.6	107/181 (59.1)	58.9	1.16 (0.99, 1.36)	0.0645	9.65 (-0.34, 19.64)	0.0582	
	> 65	4/ 5 (80.0)	80.0	0/ 1 (0.0)	0.0	3.00 (0.26, 34.57)	0.3784	80.00 (-24.53, 184.53)	0.1336	
	Sex									0.1181
	male	4/ 12 (33.3)	33.3	7/ 12 (58.3)	58.3	0.57 (0.22, 1.45)	0.2393	-25.00 (-64.22, 14.22)	0.2115	
	female	120/168 (71.4)	71.5	100/170 (58.8)	58.7	1.21 (1.04, 1.42)	0.0160	12.82 (2.66, 22.98)	0.0134	
	Race									0.5535
	White	71/110 (64.5)	64.1	57/107 (53.3)	53.5	1.21 (0.97, 1.52)	0.0946	10.66 (-2.47, 23.79)	0.1115	
	Black or African American	11/ 17 (64.7)	64.7	13/ 25 (52.0)	52.0	1.24 (0.74, 2.08)	0.4053	12.71 (-17.57, 42.98)	0.4108	
	Asian	24/ 30 (80.0)	80.0	20/ 30 (66.7)	66.7	1.20 (0.88, 1.64)	0.2489	13.33 (-9.53, 36.20)	0.2531	
	American Indian or Alaska Native	3/ 4 (75.0)	75.0	1/ 1 (100.0)	100.0	0.75 (0.43, 1.32)	0.3190	-25.00 (-132.10, 82.10)	0.6473	
	Other	9/ 11 (81.8)	81.8	9/ 11 (81.8)	81.8	1.00 (0.67, 1.48)	1.0000	0.00 (-36.96, 36.96)	1.0000	
	Ethnicity									0.5993
	Hispanic/Latino	37/ 54 (68.5)	68.1	33/ 54 (61.1)	60.7	1.12 (0.85, 1.48)	0.4219	7.32 (-10.97, 25.61)	0.4329	
	Non-hispanic/Latino	81/118 (68.6)	68.8	67/120 (55.8)	55.8	1.23 (1.01, 1.50)	0.0434	12.92 (0.68, 25.15)	0.0386	
	Geographic region									0.3581
	EU	27/ 51 (52.9)	52.9	24/ 46 (52.2)	52.2	1.01 (0.69, 1.48)	0.9398	0.77 (-19.14, 20.67)	0.9398	
	non-EU	97/129 (75.2)	75.1	83/136 (61.0)	61.0	1.23 (1.04, 1.46)	0.0143	14.10 (2.77, 25.42)	0.0147	
	Onset of disease									0.1382
	Paediatric	10/ 14 (71.4)	71.4	10/ 12 (83.3)	83.3	0.86 (0.56, 1.30)	0.4686	-11.90 (-46.69, 22.88)	0.5024	
	Adult	114/166 (68.7)	68.7	97/170 (57.1)	56.9	1.20 (1.02, 1.42)	0.0287	11.75 (1.47, 22.03)	0.0250	
	ADA result									0.3430
	Negative	117/172 (68.0)	68.2	95/162 (58.6)	58.4	1.16 (0.98, 1.37)	0.0779	9.83 (-0.50, 20.15)	0.0623	
	Positive (At any time)	7/ 8 (87.5)	87.5	12/ 20 (60.0)	60.0	1.46 (0.94, 2.27)	0.0954	27.50 (-9.48, 64.48)	0.1449	
	BMI (kg/m2)									0.1515
	< 30	84/125 (67.2)	67.6	72/134 (53.7)	53.3	1.25 (1.02, 1.53)	0.0278	14.29 (2.65, 25.93)	0.0161	
	>= 30	40/ 55 (72.7)	73.3	35/ 48 (72.9)	72.2	1.00 (0.79, 1.26)	0.9828	1.07 (-17.00, 19.14)	0.9077	
	Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.7637
	All negative/normal	39/ 58 (67.2)	67.1	48/ 81 (59.3)	59.1	1.13 (0.88, 1.46)	0.3308	8.03 (-8.29, 24.35)	0.3348	
	At least one positive/abnormal	85/122 (69.7)	69.7	59/101 (58.4)	57.9	1.19 (0.97, 1.46)	0.0872	11.85 (-0.61, 24.32)	0.0624	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Bronchitis	SLEDAI-2K score									0.0214
	< 10 points	3/ 54 (5.6)	5.6	4/ 52 (7.7)	7.7	0.72 (0.17, 3.07)	0.6595	-2.12 (-15.53, 11.28)	0.7561	
	>= 10 points	19/126 (15.1)	15.4	3/130 (2.3)	2.4	6.53 (1.98, 21.54)	0.0020	13.01 (5.10, 20.91)	0.0013	
	OCS dose									0.2645
	<10 mg/day	14/ 93 (15.1)	15.3	3/ 99 (3.0)	3.0	4.97 (1.47, 16.73)	0.0097	12.30 (2.36, 22.23)	0.0153	
	>=10 mg/day	8/ 87 (9.2)	9.3	4/ 83 (4.8)	4.9	1.91 (0.60, 6.10)	0.2758	4.45 (-5.15, 14.05)	0.3636	
	Result of type I IFN gene signature test									0.7903
	LOW	4/ 30 (13.3)	13.3	1/ 31 (3.2)	3.2	4.13 (0.49, 34.89)	0.1923	10.11 (-6.72, 26.94)	0.2391	
	HIGH	18/150 (12.0)	12.3	6/151 (4.0)	4.1	3.02 (1.23, 7.40)	0.0156	8.25 (0.96, 15.55)	0.0266	
	Age (years)									0.4431
	<= 65	21/175 (12.0)	12.3	7/181 (3.9)	3.9	3.10 (1.35, 7.11)	0.0075	8.32 (1.55, 15.09)	0.0160	
	> 65	1/ 5 (20.0)	20.0	0/ 1 (0.0)	0.0	1.00 (0.06, 15.99)	1.0000	20.00 (-84.53, 124.53)	0.7077	
	Sex									NE
	male	0/ 12 (0.0)	0.0	0/ 12 (0.0)	0.0	NE		0.00 (-26.46, 26.46)	1.0000	
	female	22/168 (13.1)	13.3	7/170 (4.1)	4.1	3.18 (1.40, 7.25)	0.0059	9.11 (2.04, 16.19)	0.0116	
	Race									0.2422
	White	16/110 (14.5)	14.9	3/107 (2.8)	2.9	5.19 (1.56, 17.29)	0.0074	11.96 (3.09, 20.83)	0.0082	
	Black or African American	3/ 17 (17.6)	17.6	1/ 25 (4.0)	4.0	4.41 (0.50, 38.94)	0.1816	13.65 (-9.86, 37.15)	0.2551	
	Asian	0/ 30 (0.0)	0.0	1/ 30 (3.3)	3.3	0.33 (0.01, 7.87)	0.4958	-3.33 (-16.52, 9.85)	0.6203	
	American Indian or Alaska Native	1/ 4 (25.0)	25.0	0/ 1 (0.0)	0.0	1.20 (0.08, 18.75)	0.8966	25.00 (-82.10, 132.10)	0.6473	
	Other	1/ 11 (9.1)	9.1	2/ 11 (18.2)	18.2	0.50 (0.05, 4.75)	0.5460	-9.09 (-44.33, 26.15)	0.6131	
	Ethnicity									0.7821
	Hispanic/Latino	5/ 54 (9.3)	9.1	2/ 54 (3.7)	3.7	2.50 (0.51, 12.33)	0.2604	5.36 (-7.66, 18.38)	0.4194	
	Non-hispanic/Latino	16/118 (13.6)	13.9	5/120 (4.2)	4.4	3.25 (1.23, 8.60)	0.0173	9.51 (0.59, 18.44)	0.0368	
	Geographic region									0.9984
	EU	7/ 51 (13.7)	13.7	2/ 46 (4.3)	4.3	3.16 (0.69, 14.44)	0.1383	9.38 (-3.45, 22.21)	0.1519	
	non-EU	15/129 (11.6)	11.9	5/136 (3.7)	3.7	3.16 (1.18, 8.45)	0.0217	8.21 (0.09, 16.33)	0.0475	
	Onset of disease									0.8014
	Paediatric	2/ 14 (14.3)	14.3	0/ 12 (0.0)	0.0	4.33 (0.23, 82.31)	0.3290	14.29 (-14.43, 43.00)	0.3295	
	Adult	20/166 (12.0)	12.2	7/170 (4.1)	4.2	2.93 (1.27, 6.74)	0.0116	8.00 (0.98, 15.03)	0.0255	
	ADA result									0.1651
	Negative	22/172 (12.8)	13.1	5/162 (3.1)	3.1	4.14 (1.61, 10.68)	0.0033	9.94 (2.95, 16.93)	0.0053	
	Positive (At any time)	0/ 8 (0.0)	0.0	2/ 20 (10.0)	10.0	0.47 (0.02, 8.78)	0.6107	-10.00 (-40.56, 20.56)	0.5212	
	BMI (kg/m2)									0.5895
	< 30	17/125 (13.6)	13.6	5/134 (3.7)	3.7	3.64 (1.39, 9.58)	0.0088	9.94 (1.57, 18.31)	0.0199	
	>= 30	5/ 55 (9.1)	9.2	2/ 48 (4.2)	4.3	2.18 (0.44, 10.74)	0.3373	4.87 (-8.80, 18.54)	0.4847	
	Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.4658
	All negative/normal	7/ 58 (12.1)	12.4	2/ 81 (2.5)	2.6	4.89 (1.05, 22.68)	0.0427	9.78 (-2.06, 21.61)	0.1054	
	At least one positive/abnormal	15/122 (12.3)	12.5	5/101 (5.0)	4.9	2.48 (0.93, 6.60)	0.0681	7.56 (-1.02, 16.15)	0.0842	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Herpes zoster	SLEDAI-2K score									0.6702
	< 10 points	1/ 54 (1.9)	1.9	0/ 52 (0.0)	0.0	2.89 (0.12, 69.40)	0.5127	1.89 (-9.43, 13.20)	0.7436	
	>= 10 points	12/126 (9.5)	9.4	2/130 (1.5)	1.6	6.19 (1.41, 27.11)	0.0155	7.85 (0.83, 14.88)	0.0284	
	OCS dose									0.9764
	<10 mg/day	6/ 93 (6.5)	6.5	1/ 99 (1.0)	1.1	6.39 (0.78, 52.05)	0.0832	5.44 (-2.93, 13.82)	0.2027	
	>=10 mg/day	7/ 87 (8.0)	8.0	1/ 83 (1.2)	1.2	6.68 (0.84, 53.11)	0.0727	6.73 (-2.20, 15.66)	0.1397	
	Result of type I IFN gene signature test									0.2896
	LOW	2/ 30 (6.7)	6.7	1/ 31 (3.2)	3.2	2.07 (0.20, 21.61)	0.5444	3.44 (-11.73, 18.61)	0.6566	
	HIGH	11/150 (7.3)	7.3	1/151 (0.7)	0.7	11.07 (1.45, 84.70)	0.0205	6.64 (0.40, 12.88)	0.0370	
	Age (years)									NE
	<= 65	13/175 (7.4)	7.4	2/181 (1.1)	1.1	6.72 (1.54, 29.36)	0.0113	6.33 (0.44, 12.22)	0.0353	
	> 65	0/ 5 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-102.70, 102.70)	1.0000	
	Sex									0.6881
	male	1/ 12 (8.3)	8.3	0/ 12 (0.0)	0.0	3.00 (0.13, 67.06)	0.4883	8.33 (-20.61, 37.28)	0.5726	
	female	12/168 (7.1)	7.1	2/170 (1.2)	1.2	6.07 (1.38, 26.72)	0.0170	5.92 (-0.14, 11.98)	0.0557	
	Race									0.5612
	White	5/110 (4.5)	4.8	1/107 (0.9)	0.9	4.86 (0.58, 40.95)	0.1456	3.93 (-3.09, 10.95)	0.2727	
	Black or African American	0/ 17 (0.0)	0.0	1/ 25 (4.0)	4.0	0.48 (0.02, 11.17)	0.6486	-4.00 (-22.36, 14.36)	0.6694	
	Asian	3/ 30 (10.0)	10.0	0/ 30 (0.0)	0.0	7.00 (0.38, 129.93)	0.1917	10.00 (-5.22, 25.22)	0.1977	
	American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
	Other	3/ 11 (27.3)	27.3	0/ 11 (0.0)	0.0	7.00 (0.40, 121.39)	0.1813	27.27 (-7.07, 61.62)	0.1196	
	Ethnicity									0.3295
	Hispanic/Latino	6/ 54 (11.1)	10.4	0/ 54 (0.0)	0.0	13.00 (0.75, 225.20)	0.0780	10.38 (-2.21, 22.96)	0.1061	
	Non-hispanic/Latino	5/118 (4.2)	4.4	2/120 (1.7)	1.7	2.54 (0.50, 12.85)	0.2589	2.75 (-4.78, 10.27)	0.4743	
	Geographic region									0.8843
	EU	2/ 51 (3.9)	3.9	0/ 46 (0.0)	0.0	4.52 (0.22, 91.74)	0.3261	3.92 (-5.18, 13.02)	0.3985	
	non-EU	11/129 (8.5)	8.5	2/136 (1.5)	1.5	5.80 (1.31, 25.66)	0.0205	7.01 (-0.46, 14.47)	0.0657	
	Onset of disease									0.8762
	Paediatric	2/ 14 (14.3)	14.3	0/ 12 (0.0)	0.0	4.33 (0.23, 82.31)	0.3290	14.29 (-14.43, 43.00)	0.3295	
	Adult	11/166 (6.6)	6.6	2/170 (1.2)	1.2	5.63 (1.27, 25.03)	0.0231	5.47 (-0.56, 11.51)	0.0756	
	ADA result									0.6288
	Negative	11/172 (6.4)	6.4	2/162 (1.2)	1.3	5.18 (1.17, 23.01)	0.0306	5.19 (-0.84, 11.23)	0.0918	
	Positive (At any time)	2/ 8 (25.0)	25.0	0/ 20 (0.0)	0.0	11.67 (0.62, 219.42)	0.1008	25.00 (-9.84, 59.84)	0.1596	
	BMI (kg/m2)									0.8106
	< 30	7/125 (5.6)	5.6	1/134 (0.7)	0.8	7.50 (0.94, 60.13)	0.0577	4.82 (-2.28, 11.92)	0.1831	
	>= 30	6/ 55 (10.9)	11.4	1/ 48 (2.1)	1.8	5.24 (0.65, 41.97)	0.1190	9.63 (-4.05, 23.32)	0.1678	
	Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.4586
	All negative/normal	2/ 58 (3.4)	3.6	1/ 81 (1.2)	1.2	2.79 (0.26, 30.08)	0.3970	2.40 (-7.69, 12.49)	0.6412	
	At least one positive/abnormal	11/122 (9.0)	9.1	1/101 (1.0)	1.0	9.11 (1.20, 69.34)	0.0329	8.17 (0.69, 15.64)	0.0322	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) (on-treatment) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=180) n/ N (%)	Response rate	Placebo (N=182) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Upper respiratory tract infection	SLEDAI-2K score									0.5497
	< 10 points	12/ 54 (22.2)	22.2	4/ 52 (7.7)	7.7	2.89 (1.00, 8.39)	0.0510	14.49 (-0.80, 29.78)	0.0632	
	>= 10 points	27/126 (21.4)	21.3	14/130 (10.8)	10.7	1.99 (1.10, 3.62)	0.0239	10.64 (1.16, 20.13)	0.0279	
	OCS dose									0.8760
	<10 mg/day	22/ 93 (23.7)	23.4	11/ 99 (11.1)	10.9	2.13 (1.09, 4.14)	0.0262	12.47 (0.99, 23.95)	0.0332	
	>=10 mg/day	17/ 87 (19.5)	19.4	7/ 83 (8.4)	8.5	2.32 (1.01, 5.30)	0.0465	10.92 (-0.59, 22.43)	0.0629	
	Result of type I IFN gene signature test									0.1405
	LOW	7/ 30 (23.3)	23.3	0/ 31 (0.0)	0.0	15.48 (0.92, 259.71)	0.0569	23.33 (5.56, 41.11)	0.0101	
	HIGH	32/150 (21.3)	21.2	18/151 (11.9)	11.8	1.79 (1.05, 3.04)	0.0318	9.43 (0.56, 18.29)	0.0372	
	Age (years)									0.5873
	<= 65	38/175 (21.7)	21.6	18/181 (9.9)	9.9	2.18 (1.30, 3.68)	0.0033	11.73 (3.67, 19.79)	0.0043	
	> 65	1/ 5 (20.0)	20.0	0/ 1 (0.0)	0.0	1.00 (0.06, 15.99)	1.0000	20.00 (-84.53, 124.53)	0.7077	
	Sex									0.8327
	male	1/ 12 (8.3)	8.3	0/ 12 (0.0)	0.0	3.00 (0.13, 67.06)	0.4883	8.33 (-20.61, 37.28)	0.5726	
	female	38/168 (22.6)	22.6	18/170 (10.6)	10.6	2.14 (1.27, 3.59)	0.0041	12.01 (3.61, 20.40)	0.0051	
	Race									0.2072
	White	22/110 (20.0)	20.0	8/107 (7.5)	7.5	2.68 (1.25, 5.74)	0.0116	12.46 (2.45, 22.46)	0.0147	
	Black or African American	5/ 17 (29.4)	29.4	0/ 25 (0.0)	0.0	15.89 (0.94, 269.78)	0.0556	29.41 (4.90, 53.92)	0.0187	
	Asian	7/ 30 (23.3)	23.3	6/ 30 (20.0)	20.0	1.17 (0.44, 3.06)	0.7544	3.33 (-18.57, 25.23)	0.7655	
	American Indian or Alaska Native	0/ 4 (0.0)	0.0	0/ 1 (0.0)	0.0	NE		0.00 (-104.98, 104.98)	1.0000	
	Other	5/ 11 (45.5)	45.5	4/ 11 (36.4)	36.4	1.25 (0.45, 3.45)	0.6665	9.09 (-32.23, 50.41)	0.6663	
	Ethnicity									0.8274
	Hispanic/Latino	12/ 54 (22.2)	22.1	5/ 54 (9.3)	9.2	2.40 (0.91, 6.35)	0.0777	12.91 (-2.42, 28.24)	0.0988	
	Non-hispanic/Latino	27/118 (22.9)	22.8	13/120 (10.8)	10.5	2.11 (1.15, 3.89)	0.0164	12.32 (2.08, 22.57)	0.0183	
	Geographic region									0.8458
	EU	2/ 51 (3.9)	3.9	1/ 46 (2.2)	2.2	1.80 (0.17, 19.24)	0.6252	1.75 (-8.15, 11.64)	0.7292	
	non-EU	37/129 (28.7)	28.4	17/136 (12.5)	12.6	2.29 (1.36, 3.86)	0.0018	15.87 (5.74, 25.99)	0.0021	
	Onset of disease									0.8256
	Paediatric	2/ 14 (14.3)	14.3	1/ 12 (8.3)	8.3	1.71 (0.18, 16.65)	0.6421	5.95 (-25.06, 36.97)	0.7068	
	Adult	37/166 (22.3)	22.2	17/170 (10.0)	10.0	2.23 (1.31, 3.80)	0.0032	12.21 (3.85, 20.58)	0.0042	
	ADA result									0.6231
	Negative	38/172 (22.1)	22.1	16/162 (9.9)	9.7	2.24 (1.30, 3.85)	0.0037	12.38 (4.04, 20.73)	0.0036	
	Positive (At any time)	1/ 8 (12.5)	12.5	2/ 20 (10.0)	10.0	1.25 (0.13, 11.93)	0.8463	2.50 (-31.66, 36.66)	0.8860	
	BMI (kg/m2)									0.1422
	< 30	21/125 (16.8)	16.9	14/134 (10.4)	10.2	1.61 (0.86, 3.02)	0.1400	6.62 (-2.73, 15.97)	0.1651	
	>= 30	18/ 55 (32.7)	33.0	4/ 48 (8.3)	8.9	3.93 (1.43, 10.80)	0.0081	24.06 (7.31, 40.81)	0.0049	
	Baseline anti-dsDNA positive/or abnormal C3 and/or abnormal C4 versus complementary group									0.1244
	All negative/normal	16/ 58 (27.6)	27.3	6/ 81 (7.4)	7.3	3.72 (1.55, 8.94)	0.0032	19.94 (5.98, 33.91)	0.0051	
	At least one positive/abnormal	23/122 (18.9)	18.9	12/101 (11.9)	11.7	1.59 (0.83, 3.03)	0.1614	7.15 (-3.04, 17.34)	0.1690	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Serious Adverse Events by SOC, PT (incidence in either arm >= 5% or >=10 patients) (on-treatment)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=180)	Placebo (N=182)
SOC: Infections and infestations	Number of subjects with events, n (%)	7 (3.9)	12 (6.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.59 (0.24, 1.46)	
	p-value	0.2550	
	Odds Ratio (95% CI)	0.57 (0.22, 1.49)	
	p-value	0.2539	
	Risk Difference (95% CI)	-2.70 (-7.28, 1.88)	
	p-value	0.2471	
	CMH approach		
	Response rate	3.9	6.6
	Difference in response rates (95% CI)	-2.65 (-8.72, 3.42)	
	p-value	0.3924	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Serious Adverse Events by SOC, PT (incidence in either arm >= 5% or >=10 patients) (on-treatment) - Subgroup analysis
Full analysis set

- NO OBSERVATIONS FOR THIS ANALYSIS -

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Severe (Grade >=3) by SOC, PT (incidence in either arm >= 5% or >=10 patients) (on-treatment)
Full analysis set

- NO OBSERVATIONS FOR THIS ANALYSIS -

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
Stratification factors CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00004 (TULIP SLE Study 2) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Severe (Grade >=3) by SOC, PT (incidence in either arm >= 5% or >=10 patients) (on-treatment) - Subgroup analysis
Full analysis set

- NO OBSERVATIONS FOR THIS ANALYSIS -

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Subject disposition and summary of treatment exposure
Full analysis set

		Anifrolumab 300mg (N=360)	Placebo (N=366)
Patients who completed the study		302 (83.9)	284 (77.6)
Patients withdrawn from the study		58 (16.1)	82 (22.4)
WITHDRAWAL BY SUBJECT		26 (7.2)	34 (9.3)
ADVERSE EVENT		15 (4.2)	12 (3.3)
LACK OF EFFICACY		6 (1.7)	15 (4.1)
OTHER		7 (1.9)	8 (2.2)
CONDITION UNDER INVESTIGATION WORSENED		2 (0.6)	5 (1.4)
LOST TO FOLLOW-UP		1 (0.3)	5 (1.4)
SEVERE NON-COMPLIANCE TO PROTOCOL		0	2 (0.5)
DEVELOPMENT OF STUDY-SPECIFIC WITHDRAWAL CRITERIA		1 (0.3)	0
Duration of study (weeks)	n (missing)	360 (0)	366 (0)
	Mean (SD)	50.8 (10.77)	49.8 (11.19)
	Median	52.4	52.3
	Min, Max	0, 78	3, 71
Patients who completed investigational product		298 (82.8)	276 (75.4)
Patients discontinued investigational product		62 (17.2)	90 (24.6)
Withdrawal By Subject		22 (6.1)	29 (7.9)
Adverse Event		18 (5.0)	22 (6.0)
Lack Of Efficacy		5 (1.4)	21 (5.7)
Other		12 (3.3)	2 (0.5)
Condition Under Investigation Worsened		3 (0.8)	8 (2.2)
Lost To Follow-Up		2 (0.6)	5 (1.4)
Severe Non-Compliance To Protocol		0	3 (0.8)
Duration of exposure (weeks)	n (missing)	360 (0)	366 (0)
	Mean (SD)	47.4 (12.24)	45.7 (13.37)
	Median	52.1	52.1
	Min, Max	4, 60	4, 56
Number of Infusions	n (missing)	360 (0)	366 (0)
	Mean (SD)	11.5 (3.04)	11.1 (3.34)
	Median	13.0	13.0
	Min, Max	1, 13	1, 13
Subjects enrolled to the LTE study		259 (71.9)	233 (63.7)

Duration of study defined as time from randomization until end of participation date.
Duration of exposure defined as difference of date of first exposure to treatment and date of last exposure to treatment + 28 days.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Demographic and baseline characteristics
Full analysis set

		Anifrolumab 300mg (N=360)	Placebo (N=366)	Total (N=726)
Age	n (missing)	360 (0)	366 (0)	726 (0)
	Mean (SD)	42.6 (11.97)	41.0 (11.88)	41.8 (11.94)
	Median	42.0	41.0	42.0
	Min, Max	18, 69	18, 69	18, 69
Age subgroups (%)	<= 65	348 (96.7)	362 (98.9)	710 (97.8)
	> 65	12 (3.3)	4 (1.1)	16 (2.2)
Sex (%)	female	333 (92.5)	341 (93.2)	674 (92.8)
	male	27 (7.5)	25 (6.8)	52 (7.2)
Race (%)	American Indian or Alaska Native	4 (1.1)	2 (0.5)	6 (0.8)
	Asian	41 (11.4)	35 (9.6)	76 (10.5)
	Black or African American	46 (12.8)	48 (13.1)	94 (12.9)
	Other	26 (7.2)	29 (7.9)	55 (7.6)
	White	235 (65.3)	244 (66.7)	479 (66.0)
	Missing	8 (2.2)	8 (2.2)	16 (2.2)
Ethnicity (%)	Hispanic/Latino	86 (23.9)	89 (24.3)	175 (24.1)
	Non-hispanic/Latino	266 (73.9)	269 (73.5)	535 (73.7)
	Missing	8 (2.2)	8 (2.2)	16 (2.2)
Geographic region (%)	Asia Pacific	38 (10.6)	32 (8.7)	70 (9.6)
	Europe	115 (31.9)	122 (33.3)	237 (32.6)
	Latin America	59 (16.4)	57 (15.6)	116 (16.0)
	North America	139 (38.6)	140 (38.3)	279 (38.4)
	Rest Of World	9 (2.5)	15 (4.1)	24 (3.3)
Geographic region subgroup (%)	EU	115 (31.9)	122 (33.3)	237 (32.6)
	non-EU	245 (68.1)	244 (66.7)	489 (67.4)
Height (cm)	n (missing)	360 (0)	366 (0)	726 (0)
	Mean (SD)	162.32 (8.405)	162.86 (8.031)	162.59 (8.218)
	Median	161.90	162.60	162.00
	Min, Max	138.0, 198.0	130.0, 195.0	130.0, 198.0
Weight (cm)	n (missing)	360 (0)	366 (0)	726 (0)
	Mean (SD)	73.47 (19.615)	72.83 (18.380)	73.14 (18.992)
	Median	69.90	67.85	68.90
	Min, Max	42.0, 132.7	42.2, 138.0	42.0, 138.0
BMI (kg/m^2)	n (missing)	360 (0)	366 (0)	726 (0)
	Mean (SD)	27.82 (6.870)	27.47 (6.761)	27.64 (6.812)
	Median	26.04	25.67	25.81
	Min, Max	16.0, 49.8	17.2, 57.5	16.0, 57.5
BMI subgroup (%)	<=28 kg/m2	205 (56.9)	223 (60.9)	428 (59.0)
	>28 kg/m2	155 (43.1)	143 (39.1)	298 (41.0)

[a] Asia Pacific: Australia, New Zealand, South Korea, Taiwan. Europe: Germany, Hungary, Italy, Poland, Romania, Ukraine, United Kingdom. Latin America: Argentinia, Brazil, Chile, Colombia, Peru. Rest of World: Israel.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SLE disease characteristics
Full analysis set

		Anifrolumab 300mg (N=360)	Placebo (N=366)	Total (N=726)
SLEDAI-2K score at screening	n (missing)	360 (0)	366 (0)	726 (0)
	Mean (SD)	11.4 (3.87)	11.3 (3.61)	11.3 (3.74)
	Median	10.0	10.0	10.0
	Min, Max	6, 26	6, 26	6, 26
SLEDAI-2K score at screening, categorisation (%)	< 10 points	109 (30.3)	106 (29.0)	215 (29.6)
	>= 10 points	251 (69.7)	260 (71.0)	511 (70.4)
Clinical SLEDAI-2K score at screening	n (missing)	360 (0)	366 (0)	726 (0)
	Mean (SD)	8.8 (2.96)	8.7 (2.73)	8.8 (2.85)
	Median	8.0	8.0	8.0
	Min, Max	4, 20	4, 18	4, 20
SLEDAI-2K score at baseline	n (missing)	360 (0)	366 (0)	726 (0)
	Mean (SD)	11.4 (3.84)	11.5 (3.69)	11.4 (3.76)
	Median	10.0	10.0	10.0
	Min, Max	4, 32	4, 26	4, 32
SLEDAI-2K score at baseline, categorisation (%)	< 10 points	106 (29.4)	100 (27.3)	206 (28.4)
	>= 10 points	254 (70.6)	266 (72.7)	520 (71.6)
Clinical SLEDAI-2K score at baseline	n (missing)	360 (0)	366 (0)	726 (0)
	Mean (SD)	8.9 (2.93)	8.9 (2.72)	8.9 (2.83)
	Median	8.0	8.0	8.0
	Min, Max	4, 20	4, 18	4, 20
Total Organ Score CNS	n (missing)	360 (0)	366 (0)	726 (0)
	Mean (SD)	0.0 (0.60)	0.0 (0.59)	0.0 (0.59)
	Median	0.0	0.0	0.0
	Min, Max	0, 8	0, 8	0, 8
Total Organ Score CVS and Respiratory	n (missing)	360 (0)	366 (0)	726 (0)
	Mean (SD)	0.2 (0.55)	0.2 (0.57)	0.2 (0.56)
	Median	0.0	0.0	0.0
	Min, Max	0, 2	0, 4	0, 4
Total Organ Score Hematological	n (missing)	360 (0)	366 (0)	726 (0)
	Mean (SD)	0.2 (0.37)	0.1 (0.38)	0.1 (0.38)
	Median	0.0	0.0	0.0
	Min, Max	0, 2	0, 2	0, 2
Total Organ Score Immunology	n (missing)	360 (0)	366 (0)	726 (0)
	Mean (SD)	1.9 (1.61)	1.9 (1.66)	1.9 (1.64)
	Median	2.0	2.0	2.0
	Min, Max	0, 4	0, 4	0, 4
Total Organ Score Mucocutaneous	n (missing)	360 (0)	366 (0)	726 (0)
	Mean (SD)	4.2 (1.57)	4.0 (1.59)	4.1 (1.58)
	Median	4.0	4.0	4.0
	Min, Max	0, 6	0, 6	0, 6
Total Organ Score Musculoskeletal	n (missing)	360 (0)	366 (0)	726 (0)
	Mean (SD)	3.8 (1.09)	3.9 (1.04)	3.8 (1.07)
	Median	4.0	4.0	4.0
	Min, Max	0, 8	0, 8	0, 8
Total Organ Score Renal	n (missing)	360 (0)	366 (0)	726 (0)
	Mean (SD)	0.4 (1.42)	0.5 (1.70)	0.4 (1.57)
	Median	0.0	0.0	0.0
	Min, Max	0, 12	0, 12	0, 12

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Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SLE disease characteristics
Full analysis set

		Anifrolumab 300mg (N=360)	Placebo (N=366)	Total (N=726)
Total Organ Score Vascular	n (missing)	360 (0)	366 (0)	726 (0)
	Mean (SD)	0.9 (2.49)	0.9 (2.50)	0.9 (2.49)
	Median	0.0	0.0	0.0
	Min, Max	0, 8	0, 8	0, 8
Adjudication Scoring (BILAG) at baseline Overall (%)	At least one A	174 (48.3)	179 (48.9)	353 (48.6)
	No A and <2Bs	16 (4.4)	25 (6.8)	41 (5.6)
	No A and at least 2 Bs	170 (47.2)	162 (44.3)	332 (45.7)
Adjudication Scoring (BILAG) at baseline Constitutional (%)	A	1 (0.3)	0	1 (0.1)
	B	24 (6.7)	17 (4.6)	41 (5.6)
	C, D or E	335 (93.1)	349 (95.4)	684 (94.2)
Adjudication Scoring (BILAG) at baseline Mucocutaneous (%)	A	84 (23.3)	75 (20.5)	159 (21.9)
	B	231 (64.2)	237 (64.8)	468 (64.5)
	C, D or E	45 (12.5)	54 (14.8)	99 (13.6)
Adjudication Scoring (BILAG) at baseline Neuropsychiatric (%)	A	1 (0.3)	1 (0.3)	2 (0.3)
	B	8 (2.2)	4 (1.1)	12 (1.7)
	C, D or E	351 (97.5)	361 (98.6)	712 (98.1)
Adjudication Scoring (BILAG) at baseline Musculoskeletal (%)	A	114 (31.7)	115 (31.4)	229 (31.5)
	B	203 (56.4)	213 (58.2)	416 (57.3)
	C, D or E	43 (11.9)	38 (10.4)	81 (11.2)
Adjudication Scoring (BILAG) at baseline Cardiorespiratory (%)	A	3 (0.8)	4 (1.1)	7 (1.0)
	B	27 (7.5)	23 (6.3)	50 (6.9)
	C, D or E	330 (91.7)	339 (92.6)	669 (92.1)
Adjudication Scoring (BILAG) at baseline Gastrointestinal (%)	A	0	1 (0.3)	1 (0.1)
	B	1 (0.3)	3 (0.8)	4 (0.6)
	C, D or E	359 (99.7)	362 (98.9)	721 (99.3)
Adjudication Scoring (BILAG) at baseline Ophthalmic (%)	A	1 (0.3)	0	1 (0.1)
	B	0	1 (0.3)	1 (0.1)
	C, D or E	359 (99.7)	365 (99.7)	724 (99.7)
Adjudication Scoring (BILAG) at baseline Renal (%)	A	2 (0.6)	7 (1.9)	9 (1.2)
	B	23 (6.4)	25 (6.8)	48 (6.6)
	C, D or E	335 (93.1)	334 (91.3)	669 (92.1)
Adjudication Scoring (BILAG) at baseline Haematological (%)	B	2 (0.6)	1 (0.3)	3 (0.4)
	C, D or E	358 (99.4)	365 (99.7)	723 (99.6)
BILAG-2004 global score at baseline	n (missing)	360 (0)	366 (0)	726 (0)
	Mean (SD)	19.2 (5.58)	18.9 (5.23)	19.1 (5.40)
	Median	17.0	18.0	18.0
	Min, Max	2, 40	4, 33	2, 40
Physician Global Assessment (PGA) score at baseline	n (missing)	360 (0)	366 (0)	726 (0)
	Mean (SD)	1.8 (0.41)	1.8 (0.39)	1.8 (0.40)
	Median	1.7	1.8	1.8
	Min, Max	1, 3	1, 3	1, 3
CLASI activity score at baseline	n (missing)	360 (0)	366 (0)	726 (0)
	Mean (SD)	8.4 (7.60)	7.8 (7.22)	8.1 (7.41)
	Median	6.0	6.0	6.0
	Min, Max	0, 51	0, 52	0, 52
CLASI activity score at baseline, categorisation 1 (%)	0	12 (3.3)	18 (4.9)	30 (4.1)

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Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SLE disease characteristics
Full analysis set

		Anifrolumab 300mg (N=360)	Placebo (N=366)	Total (N=726)
CLASI activity score at baseline, categorisation 1 (%)	> 0	348 (96.7)	348 (95.1)	696 (95.9)
CLASI activity score at baseline, categorisation 2 (%)	<10	253 (70.3)	272 (74.3)	525 (72.3)
	>=10	107 (29.7)	94 (25.7)	201 (27.7)
CLASI damage score at baseline	n (missing)	360 (0)	366 (0)	726 (0)
	Mean (SD)	2.1 (4.88)	1.9 (4.36)	2.0 (4.62)
	Median	0.0	0.0	0.0
	Min, Max	0, 30	0, 35	0, 35
CLASI damage score at baseline, categorisation 1 (%)	0	240 (66.7)	239 (65.3)	479 (66.0)
	> 0	120 (33.3)	127 (34.7)	247 (34.0)
CLASI damage score at baseline, categorisation 2 (%)	<10	333 (92.5)	350 (95.6)	683 (94.1)
	>=10	27 (7.5)	16 (4.4)	43 (5.9)
Tender Joint Count at Baseline	n (missing)	360 (0)	366 (0)	726 (0)
	Mean (SD)	10.3 (7.41)	10.8 (7.53)	10.5 (7.47)
	Median	9.0	10.0	9.0
	Min, Max	0, 28	0, 28	0, 28
Tender Joint Count at Baseline, categorisation (%)	0	23 (6.4)	18 (4.9)	41 (5.6)
	> 0	337 (93.6)	348 (95.1)	685 (94.4)
Swollen Joint Count at Baseline	n (missing)	360 (0)	366 (0)	726 (0)
	Mean (SD)	6.8 (5.75)	7.2 (5.74)	7.0 (5.74)
	Median	5.0	6.0	6.0
	Min, Max	0, 28	0, 28	0, 28
Swollen Joint Count at Baseline, categorisation (%)	0	36 (10.0)	32 (8.7)	68 (9.4)
	> 0	324 (90.0)	334 (91.3)	658 (90.6)
Active Joint Count at Baseline	n (missing)	360 (0)	366 (0)	726 (0)
	Mean (SD)	6.4 (5.70)	6.7 (5.58)	6.5 (5.64)
	Median	5.0	5.0	5.0
	Min, Max	0, 28	0, 28	0, 28
Active Joint Count at Baseline, categorisation (%)	0	40 (11.1)	34 (9.3)	74 (10.2)
	> 0	320 (88.9)	332 (90.7)	652 (89.8)
SDI global score at baseline	n (missing)	359 (1)	363 (3)	722 (4)
	Mean (SD)	0.6 (1.04)	0.6 (0.89)	0.6 (0.97)
	Median	0.0	0.0	0.0
	Min, Max	0, 5	0, 5	0, 5
SDI global score at baseline, categorisation (%)	0 (no damage)	245 (68.1)	232 (63.4)	477 (65.7)
	>=1 (damage)	114 (31.7)	131 (35.8)	245 (33.7)
	Missing	1 (0.3)	3 (0.8)	4 (0.6)
Time from initial SLE diagnosis to randomisation (months)	n (missing)	360 (0)	366 (0)	726 (0)
	Mean (SD)	123.2 (103.42)	105.5 (94.70)	114.3 (99.45)
	Median	91.0	78.5	84.5
	Min, Max	0, 555	4, 503	0, 555
Cushingoid features (%)	Any Cushingoid Feature	108 (30.0)	127 (34.7)	235 (32.4)
	Moon Face	57 (15.8)	66 (18.0)	123 (16.9)
	Buffalo Hump	28 (7.8)	24 (6.6)	52 (7.2)
	Purple or Violaceous Striae	27 (7.5)	28 (7.7)	55 (7.6)
	Central Obesity	50 (13.9)	54 (14.8)	104 (14.3)
	Hirsutisim	20 (5.6)	12 (3.3)	32 (4.4)
	Acne	24 (6.7)	16 (4.4)	40 (5.5)

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Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SLE disease characteristics
Full analysis set

		Anifrolumab 300mg (N=360)	Placebo (N=366)	Total (N=726)
Cushingoid features (%)	Easy Bruising	53 (14.7)	52 (14.2)	105 (14.5)
	Fragile Skin	35 (9.7)	43 (11.7)	78 (10.7)
Results of 4-gene Type 1 Interferon (IFN) test (%)	High	298 (82.8)	302 (82.5)	600 (82.6)
	Low	62 (17.2)	64 (17.5)	126 (17.4)
Anti-dsDNA levels at baseline	n (missing)	167 (0)	155 (0)	322 (0)
	Mean (SD)	129.3 (261.40)	212.0 (549.65)	169.1 (426.60)
	Median	50.1	53.0	51.2
	Min, Max	15, 1897	15, 3790	15, 3790
Anti-dsDNA levels at baseline, categorisation (%)	Negative	193 (53.6)	211 (57.7)	404 (55.6)
	Positive	167 (46.4)	155 (42.3)	322 (44.4)
ANA (%)	Abnormal (titre >= 1:80)	324 (90.0)	330 (90.2)	654 (90.1)
	Normal (titre < 1:80)	23 (6.4)	26 (7.1)	49 (6.7)
	Missing	13 (3.6)	10 (2.7)	23 (3.2)
Complement C3 level at baseline	n (missing)	130 (0)	137 (0)	267 (0)
	Mean (SD)	0.69 (0.150)	0.70 (0.140)	0.70 (0.145)
	Median	0.72	0.72	0.72
	Min, Max	0.2, 0.9	0.4, 0.9	0.2, 0.9
Complement C3 level at baseline, categorisation (%)	Abnormal	130 (36.1)	137 (37.4)	267 (36.8)
	Normal	230 (63.9)	229 (62.6)	459 (63.2)
Complement C4 level at baseline	n (missing)	84 (0)	85 (0)	169 (0)
	Mean (SD)	0.07 (0.016)	0.07 (0.015)	0.07 (0.015)
	Median	0.07	0.07	0.07
	Min, Max	0.1, 0.1	0.1, 0.1	0.1, 0.1
Complement C4 level at baseline, categorisation (%)	Abnormal	84 (23.3)	85 (23.2)	169 (23.3)
	Normal	276 (76.7)	281 (76.8)	557 (76.7)
Complement CH50 level at baseline	n (missing)	35 (0)	31 (0)	66 (0)
	Mean (SD)	45.51 (29.029)	49.13 (28.827)	47.21 (28.768)
	Median	43.00	55.00	47.00
	Min, Max	5.0, 90.0	5.0, 90.0	5.0, 90.0
Complement CH50 level at baseline, categorisation (%)	Abnormal	35 (9.7)	31 (8.5)	66 (9.1)
	Normal	325 (90.3)	335 (91.5)	660 (90.9)

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Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Observation times for Efficacy endpoints
Full analysis set

		Anifrolumab 300mg (N=360)	Placebo (N=366)
SRI4: Observation time (weeks)	n (missing)	360 (0)	366 (0)
	Mean (SD)	48.8 (10.05)	47.8 (11.03)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
CLASI activity score: Observation time (weeks)	n (missing)	360 (0)	366 (0)
	Mean (SD)	48.8 (10.03)	47.8 (11.04)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
CLASI damage score: Observation time (weeks)	n (missing)	360 (0)	366 (0)
	Mean (SD)	48.8 (10.03)	47.8 (11.04)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
BICLA: Observation time (weeks)	n (missing)	360 (0)	366 (0)
	Mean (SD)	48.8 (10.03)	47.8 (11.02)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
SLEDAI-2K Total Score: Observation time (weeks)	n (missing)	360 (0)	366 (0)
	Mean (SD)	48.5 (10.26)	47.3 (11.59)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
PGA: Observation time (weeks)	n (missing)	360 (0)	366 (0)
	Mean (SD)	48.8 (10.22)	47.8 (11.03)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
BILAG Global Score: Observation time (weeks)	n (missing)	360 (0)	366 (0)
	Mean (SD)	48.8 (10.18)	47.8 (11.02)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
Tender Joint Count: Observation time (weeks)	n (missing)	360 (0)	366 (0)
	Mean (SD)	48.8 (10.05)	47.8 (11.04)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
Swollen Joint Count: Observation time (weeks)	n (missing)	360 (0)	366 (0)
	Mean (SD)	48.8 (10.05)	47.8 (11.04)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
FACIT-F Total Score: Observation time (weeks)	n (missing)	360 (0)	366 (0)
	Mean (SD)	48.4 (10.76)	47.2 (11.80)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
SF-36 v2.0 Acute - Mental Component Score: Observation time (weeks)	n (missing)	360 (0)	366 (0)
	Mean (SD)	47.7 (12.40)	46.4 (13.08)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
SF-36 v2.0 Acute - Physical Component Score: Observation time (weeks)	n (missing)	360 (0)	366 (0)
	Mean (SD)	47.7 (12.40)	46.4 (13.08)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
EQ-5D VAS Score: Observation time (weeks)	n (missing)	360 (0)	366 (0)

Observation duration defined as time from randomization until last non-missing assessment after randomization. Subjects without assessment are censored at day 1.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Observation times for Efficacy endpoints
Full analysis set

		Anifrolumab 300mg (N=360)	Placebo (N=366)
EQ-5D VAS Score: Observation time (weeks)	Mean (SD)	46.2 (13.44)	45.0 (14.36)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
SDI Global Score: Observation time (weeks)	n (missing)	360 (0)	366 (0)
	Mean (SD)	44.5 (16.53)	43.7 (17.19)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
PtGA: Observation time (weeks)	n (missing)	360 (0)	366 (0)
	Mean (SD)	48.1 (11.33)	46.5 (12.63)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54

Observation duration defined as time from randomization until last non-missing assessment after randomization. Subjects without assessment are censored at day 1.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 4	Number of subjects with events, n (%)	34 (9.4)	29 (7.9)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.22 (0.76, 1.95)	
	p-value	0.4210	
	Odds Ratio (95% CI)	1.24 (0.73, 2.10)	
	p-value	0.4191	
	Risk Difference (95% CI)	1.68 (-2.39, 5.74)	
	p-value	0.4186	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.19 (0.74, 1.91)	
	p-value	0.4696	
	Odds Ratio (95% CI)	1.21 (0.72, 2.04)	
	p-value	0.4680	
	Risk Difference (95% CI)	1.52 (-2.57, 5.62)	
	p-value	0.4662	
	CMH approach		
	Response rate	9.5	7.8
	Difference in response rates (95% CI)	1.67 (-3.18, 6.51)	
	p-value	0.5003	
	p-Value for test for heterogenity between studies	0.6849	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 8	Number of subjects with events, n (%)	98 (27.2)	78 (21.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.29 (1.00, 1.66)	
	p-value	0.0515	
	Odds Ratio (95% CI)	1.42 (1.00, 2.01)	
	p-value	0.0504	
	Risk Difference (95% CI)	6.12 (0.01, 12.23)	
	p-value	0.0496	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.28 (0.99, 1.66)	
	p-value	0.0621	
	Odds Ratio (95% CI)	1.38 (0.98, 1.95)	
	p-value	0.0639	
	Risk Difference (95% CI)	5.89 (-0.31, 12.10)	
	p-value	0.0628	
	CMH approach		
	Response rate	27.3	21.2
	Difference in response rates (95% CI)	6.19 (-0.16, 12.53)	
	p-value	0.0559	
	p-Value for test for heterogenity between studies	0.6739	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 12	Number of subjects with events, n (%)	149 (41.4)	116 (31.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.31 (1.08, 1.59)	
	p-value	0.0055	
	Odds Ratio (95% CI)	1.55 (1.14, 2.11)	
	p-value	0.0053	
	Risk Difference (95% CI)	9.92 (3.01, 16.84)	
	p-value	0.0049	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.31 (1.08, 1.59)	
	p-value	0.0060	
	Odds Ratio (95% CI)	1.52 (1.12, 2.07)	
	p-value	0.0070	
	Risk Difference (95% CI)	9.67 (2.71, 16.63)	
	p-value	0.0064	
	CMH approach		
	Response rate	41.6	31.6
	Difference in response rates (95% CI)	9.94 (3.03, 16.85)	
	p-value	0.0048	
	p-Value for test for heterogenity between studies	0.1962	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 16	Number of subjects with events, n (%)	164 (45.6)	140 (38.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.19 (1.00, 1.41)	
	p-value	0.0451	
	Odds Ratio (95% CI)	1.35 (1.01, 1.82)	
	p-value	0.0452	
	Risk Difference (95% CI)	7.34 (0.18, 14.50)	
	p-value	0.0444	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.20 (1.01, 1.42)	
	p-value	0.0422	
	Odds Ratio (95% CI)	1.35 (1.00, 1.82)	
	p-value	0.0474	
	Risk Difference (95% CI)	7.29 (0.13, 14.45)	
	p-value	0.0460	
	CMH approach		
	Response rate	45.8	38.3
	Difference in response rates (95% CI)	7.46 (0.35, 14.56)	
	p-value	0.0397	
	p-Value for test for heterogenity between studies	0.1855	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 20	Number of subjects with events, n (%)	182 (50.6)	156 (42.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.19 (1.02, 1.39)	
	p-value	0.0284	
	Odds Ratio (95% CI)	1.39 (1.04, 1.86)	
	p-value	0.0282	
	Risk Difference (95% CI)	8.14 (0.91, 15.37)	
	p-value	0.0274	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.19 (1.02, 1.39)	
	p-value	0.0302	
	Odds Ratio (95% CI)	1.38 (1.03, 1.85)	
	p-value	0.0328	
	Risk Difference (95% CI)	7.92 (0.69, 15.15)	
	p-value	0.0318	
	CMH approach		
	Response rate	50.8	42.6
	Difference in response rates (95% CI)	8.22 (1.05, 15.39)	
	p-value	0.0246	
	p-Value for test for heterogenity between studies	0.3840	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 24	Number of subjects with events, n (%)	190 (52.8)	158 (43.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.23 (1.05, 1.43)	
	p-value	0.0091	
	Odds Ratio (95% CI)	1.48 (1.10, 1.98)	
	p-value	0.0090	
	Risk Difference (95% CI)	9.73 (2.48, 16.99)	
	p-value	0.0086	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.23 (1.05, 1.43)	
	p-value	0.0088	
	Odds Ratio (95% CI)	1.47 (1.10, 1.97)	
	p-value	0.0101	
	Risk Difference (95% CI)	9.59 (2.36, 16.83)	
	p-value	0.0094	
	CMH approach		
	Response rate	53.0	43.2
	Difference in response rates (95% CI)	9.83 (2.72, 16.94)	
	p-value	0.0067	
	p-Value for test for heterogenity between studies	0.1499	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 28	Number of subjects with events, n (%)	191 (53.1)	165 (45.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.18 (1.01, 1.37)	
	p-value	0.0312	
	Odds Ratio (95% CI)	1.38 (1.03, 1.85)	
	p-value	0.0310	
	Risk Difference (95% CI)	8.04 (0.77, 15.31)	
	p-value	0.0303	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.18 (1.02, 1.37)	
	p-value	0.0298	
	Odds Ratio (95% CI)	1.38 (1.03, 1.84)	
	p-value	0.0327	
	Risk Difference (95% CI)	7.96 (0.71, 15.22)	
	p-value	0.0315	
	CMH approach		
	Response rate	53.2	45.1
	Difference in response rates (95% CI)	8.09 (0.88, 15.29)	
	p-value	0.0278	
	p-Value for test for heterogenity between studies	0.1818	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 32	Number of subjects with events, n (%)	195 (54.2)	166 (45.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.20 (1.03, 1.39)	
	p-value	0.0163	
	Odds Ratio (95% CI)	1.43 (1.07, 1.92)	
	p-value	0.0161	
	Risk Difference (95% CI)	8.97 (1.71, 16.24)	
	p-value	0.0155	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.20 (1.03, 1.39)	
	p-value	0.0168	
	Odds Ratio (95% CI)	1.42 (1.06, 1.91)	
	p-value	0.0186	
	Risk Difference (95% CI)	8.80 (1.54, 16.06)	
	p-value	0.0175	
	CMH approach		
	Response rate	54.3	45.3
	Difference in response rates (95% CI)	8.97 (1.77, 16.16)	
	p-value	0.0146	
	p-Value for test for heterogenity between studies	0.0889	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 36	Number of subjects with events, n (%)	192 (53.3)	166 (45.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.18 (1.02, 1.37)	
	p-value	0.0305	
	Odds Ratio (95% CI)	1.38 (1.03, 1.85)	
	p-value	0.0304	
	Risk Difference (95% CI)	8.08 (0.80, 15.37)	
	p-value	0.0296	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.18 (1.01, 1.37)	
	p-value	0.0314	
	Odds Ratio (95% CI)	1.38 (1.03, 1.84)	
	p-value	0.0326	
	Risk Difference (95% CI)	7.97 (0.71, 15.23)	
	p-value	0.0314	
	CMH approach		
	Response rate	53.4	45.4
	Difference in response rates (95% CI)	8.03 (0.82, 15.24)	
	p-value	0.0290	
	p-Value for test for heterogenity between studies	0.1716	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 40	Number of subjects with events, n (%)	193 (53.6)	158 (43.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.24 (1.06, 1.44)	
	p-value	0.0061	
	Odds Ratio (95% CI)	1.51 (1.13, 2.02)	
	p-value	0.0058	
	Risk Difference (95% CI)	10.31 (3.04, 17.58)	
	p-value	0.0055	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.24 (1.06, 1.44)	
	p-value	0.0061	
	Odds Ratio (95% CI)	1.52 (1.13, 2.04)	
	p-value	0.0054	
	Risk Difference (95% CI)	10.44 (3.19, 17.69)	
	p-value	0.0048	
	CMH approach		
	Response rate	53.5	43.2
	Difference in response rates (95% CI)	10.32 (3.14, 17.50)	
	p-value	0.0048	
	p-Value for test for heterogenity between studies	0.0387	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 44	Number of subjects with events, n (%)	193 (53.6)	153 (41.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.29 (1.10, 1.50)	
	p-value	0.0015	
	Odds Ratio (95% CI)	1.61 (1.20, 2.15)	
	p-value	0.0014	
	Risk Difference (95% CI)	11.98 (4.70, 19.26)	
	p-value	0.0013	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.28 (1.10, 1.50)	
	p-value	0.0017	
	Odds Ratio (95% CI)	1.61 (1.20, 2.15)	
	p-value	0.0016	
	Risk Difference (95% CI)	11.80 (4.57, 19.03)	
	p-value	0.0014	
	CMH approach		
	Response rate	53.7	41.8
	Difference in response rates (95% CI)	11.83 (4.68, 18.99)	
	p-value	0.0012	
	p-Value for test for heterogenity between studies	0.0970	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 48	Number of subjects with events, n (%)	188 (52.2)	153 (41.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.26 (1.08, 1.47)	
	p-value	0.0040	
	Odds Ratio (95% CI)	1.54 (1.15, 2.07)	
	p-value	0.0039	
	Risk Difference (95% CI)	10.73 (3.51, 17.94)	
	p-value	0.0036	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.25 (1.07, 1.46)	
	p-value	0.0050	
	Odds Ratio (95% CI)	1.52 (1.13, 2.04)	
	p-value	0.0050	
	Risk Difference (95% CI)	10.41 (3.19, 17.62)	
	p-value	0.0047	
	CMH approach		
	Response rate	52.3	41.8
	Difference in response rates (95% CI)	10.55 (3.36, 17.74)	
	p-value	0.0040	
	p-Value for test for heterogenity between studies	0.6265	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 52	Number of subjects with events, n (%)	188 (52.2)	147 (40.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.30 (1.11, 1.53)	
	p-value	0.0012	
	Odds Ratio (95% CI)	1.63 (1.21, 2.18)	
	p-value	0.0011	
	Risk Difference (95% CI)	12.18 (4.92, 19.43)	
	p-value	0.0010	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.30 (1.11, 1.52)	
	p-value	0.0014	
	Odds Ratio (95% CI)	1.63 (1.21, 2.18)	
	p-value	0.0012	
	Risk Difference (95% CI)	12.06 (4.84, 19.27)	
	p-value	0.0011	
	CMH approach		
	Response rate	52.2	40.1
	Difference in response rates (95% CI)	12.09 (4.91, 19.27)	
	p-value	0.0010	
	p-Value for test for heterogenity between studies	0.1024	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.6978
< 10 points	54/109 (49.5)	49.7	38/106 (35.8)	36.0	1.37 (1.00, 1.88)	0.0507	13.64 (0.53, 26.75)	0.0414	
>= 10 points	134/251 (53.4)	53.3	109/260 (41.9)	41.9	1.28 (1.06, 1.53)	0.0100	11.44 (2.88, 20.00)	0.0088	
OCS dose at baseline									0.5213
<10 mg/day	87/170 (51.2)	51.4	75/181 (41.4)	41.5	1.23 (0.98, 1.54)	0.0771	9.89 (-0.41, 20.20)	0.0599	
>=10 mg/day	101/190 (53.2)	53.2	72/185 (38.9)	39.0	1.36 (1.09, 1.71)	0.0068	14.22 (4.24, 24.19)	0.0052	
Result of type I IFN gene signature test									0.1457
LOW	28/ 62 (45.2)	45.2	29/ 64 (45.3)	45.3	1.00 (0.68, 1.47)	0.9974	-0.15 (-17.51, 17.20)	0.9864	
HIGH	160/298 (53.7)	53.7	118/302 (39.1)	39.0	1.37 (1.15, 1.63)	0.0005	14.67 (6.78, 22.55)	0.0003	
Age (years)									0.5838
<= 65	181/348 (52.0)	52.0	145/362 (40.1)	40.0	1.30 (1.10, 1.52)	0.0017	12.02 (4.75, 19.28)	0.0012	
> 65	7/ 12 (58.3)	58.0	2/ 4 (50.0)	47.7	0.99 (0.38, 2.56)	0.9847	10.23 (-46.36, 66.81)	0.7231	
Sex									0.2042
male	14/ 27 (51.9)	52.3	13/ 25 (52.0)	51.2	0.96 (0.61, 1.52)	0.8626	1.10 (-25.03, 27.23)	0.9341	
female	174/333 (52.3)	52.2	134/341 (39.3)	39.2	1.32 (1.12, 1.56)	0.0012	12.92 (5.50, 20.35)	0.0006	
Race									0.0779
White	122/235 (51.9)	52.4	108/244 (44.3)	44.0	1.17 (0.97, 1.41)	0.0975	8.39 (-0.50, 17.27)	0.0643	
Black	21/ 46 (45.7)	46.5	16/ 48 (33.3)	34.2	1.36 (0.82, 2.25)	0.2369	12.26 (-7.76, 32.27)	0.2301	
Other	41/ 71 (57.7)	57.8	19/ 66 (28.8)	28.8	2.01 (1.31, 3.08)	0.0015	28.97 (12.99, 44.96)	0.0004	
Ethnicity									0.7654
Hispanic/Latino	47/ 86 (54.7)	54.3	39/ 89 (43.8)	44.1	1.25 (0.92, 1.69)	0.1539	10.22 (-4.49, 24.92)	0.1734	
Non-hispanic/Latino	137/266 (51.5)	51.6	104/269 (38.7)	38.9	1.32 (1.09, 1.59)	0.0049	12.68 (4.33, 21.02)	0.0029	
Geographic region									0.4113
EU	72/115 (62.6)	62.7	63/122 (51.6)	51.4	1.22 (0.97, 1.52)	0.0845	11.28 (-1.28, 23.84)	0.0783	
non-EU	116/245 (47.3)	47.7	84/244 (34.4)	34.3	1.39 (1.11, 1.72)	0.0033	13.48 (4.83, 22.13)	0.0023	
Onset of disease									0.8113
Paediatric	9/ 26 (34.6)	34.3	7/ 24 (29.2)	29.3	1.18 (0.52, 2.66)	0.6908	4.94 (-21.57, 31.45)	0.7150	
Adult	179/334 (53.6)	53.6	140/342 (40.9)	40.9	1.30 (1.11, 1.53)	0.0013	12.72 (5.28, 20.16)	0.0008	
ADA result									0.3615
Negative	176/334 (52.7)	52.6	138/331 (41.7)	41.8	1.26 (1.07, 1.49)	0.0055	10.87 (3.36, 18.38)	0.0046	
Positive (At any time)	12/ 25 (48.0)	48.3	9/ 35 (25.7)	27.8	1.75 (0.88, 3.49)	0.1098	20.52 (-5.27, 46.32)	0.1189	
BMI (kg/m2) at enrolment									0.6662
< 30	128/233 (54.9)	55.1	112/261 (42.9)	43.2	1.28 (1.07, 1.54)	0.0083	11.83 (3.15, 20.50)	0.0076	
>= 30	60/127 (47.2)	47.7	35/105 (33.3)	34.0	1.39 (1.00, 1.93)	0.0487	13.67 (1.16, 26.17)	0.0322	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SRI (4) - individual components at week 52 (Full analysis set)
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
>=4 point reduction in SLEDAI-2k [a]	190 (52.8)	151 (41.3)
No discontinuation of IP	298 (82.8)	276 (75.4)
No use of medication beyond protocol allowed threshold	284 (78.9)	251 (68.6)
No worsening of BILAG [a]	244 (67.8)	199 (54.4)
No worsening of PGA [a]	239 (66.4)	200 (54.6)

[a] Subjects who discontinued IP or used medications beyond protocol allowed threshold are considered non-responders and not included in this category.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate at week 52 sensitivity analysis, multiple imputation
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 52	Number of subjects with events, n (%)	188 (52.3)	146 (39.9)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.32 (1.12, 1.55)	
	p-value	0.0009	
	Odds Ratio (95% CI)	1.65 (1.23, 2.22)	
	p-value	0.0009	
	Risk Difference (95% CI)	12.58 (5.27, 19.89)	
	p-value	0.0007	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.31 (1.11, 1.54)	
	p-value	0.0011	
	Odds Ratio (95% CI)	1.65 (1.23, 2.22)	
	p-value	0.0009	
	Risk Difference (95% CI)	12.44 (5.18, 19.70)	
	p-value	0.0008	
	p-Value for test for heterogenity between studies	0.1072	

For each outcome and visit, 100 imputations were generated by randomised treatment group. Each imputed dataset was analysed separately, and the single estimates are combined using PROC MIANALYZE. The estimated number of responders and non-responders are rounded to an integer. Therefore, there might be slight mismatches between number of subjects and corresponding percentage.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SRI (8) response rate at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=339)	Placebo (N=341)
Week 52	Number of subjects with events, n (%)	101 (29.8)	62 (18.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.65 (1.25, 2.18)	
	p-value	0.0004	
	Odds Ratio (95% CI)	1.92 (1.34, 2.76)	
	p-value	0.0004	
	Risk Difference (95% CI)	11.81 (5.42, 18.20)	
	p-value	0.0003	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.64 (1.24, 2.16)	
	p-value	0.0005	
	Odds Ratio (95% CI)	1.91 (1.33, 2.74)	
	p-value	0.0004	
	Risk Difference (95% CI)	11.61 (5.25, 17.97)	
	p-value	0.0003	
	CMH approach		
	Response rate	29.9	18.0
	Difference in response rates (95% CI)	11.88 (5.31, 18.45)	
	p-value	0.0004	
	p-Value for test for heterogenity between studies	0.6008	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SRI (8) response rate at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=339) n/ N (%)	Response rate	Placebo (N=341) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.5061
< 10 points	16/ 88 (18.2)	18.2	11/ 81 (13.6)	13.6	1.32 (0.64, 2.74)	0.4548	4.59 (-7.12, 16.31)	0.4420	
>= 10 points	85/251 (33.9)	33.8	51/260 (19.6)	19.5	1.73 (1.28, 2.33)	0.0004	14.30 (6.56, 22.03)	0.0003	
OCS dose at baseline									0.0174
<10 mg/day	42/158 (26.6)	26.9	38/167 (22.8)	22.8	1.17 (0.80, 1.71)	0.4173	4.12 (-5.61, 13.84)	0.4065	
>=10 mg/day	59/181 (32.6)	32.8	24/174 (13.8)	13.9	2.34 (1.53, 3.59)	<.0001	18.89 (10.01, 27.78)	<.0001	
Result of type I IFN gene signature test									0.0759
LOW	10/ 57 (17.5)	17.5	12/ 59 (20.3)	20.3	0.87 (0.40, 1.85)	0.7094	-2.80 (-18.02, 12.43)	0.7190	
HIGH	91/282 (32.3)	32.4	50/282 (17.7)	17.5	1.82 (1.34, 2.46)	0.0001	14.91 (7.63, 22.18)	<.0001	
Age (years)									0.5143
<= 65	99/327 (30.3)	30.4	61/337 (18.1)	17.9	1.67 (1.26, 2.21)	0.0003	12.48 (5.81, 19.16)	0.0002	
> 65	2/ 12 (16.7)	20.5	1/ 4 (25.0)	23.9	0.86 (0.12, 6.23)	0.8789	-3.41 (-59.17, 52.35)	0.9046	
Sex									0.8227
male	8/ 25 (32.0)	31.8	5/ 23 (21.7)	21.3	1.47 (0.54, 3.95)	0.4499	10.46 (-16.10, 37.02)	0.4401	
female	93/314 (29.6)	29.6	57/318 (17.9)	17.7	1.65 (1.23, 2.20)	0.0007	11.85 (5.07, 18.63)	0.0006	
Race									0.0562
White	61/223 (27.4)	28.0	46/228 (20.2)	19.8	1.35 (0.97, 1.89)	0.0781	8.24 (0.06, 16.43)	0.0484	
Black	10/ 41 (24.4)	24.8	7/ 44 (15.9)	15.5	1.59 (0.66, 3.83)	0.2969	9.32 (-9.13, 27.76)	0.3221	
Other	29/ 68 (42.6)	42.7	7/ 61 (11.5)	11.5	3.69 (1.75, 7.81)	0.0006	31.20 (16.26, 46.14)	<.0001	
Ethnicity									0.2622
Hispanic/Latino	25/ 81 (30.9)	30.8	18/ 83 (21.7)	21.9	1.23 (0.72, 2.09)	0.4424	8.95 (-4.62, 22.51)	0.1962	
Non-hispanic/Latino	75/251 (29.9)	30.4	42/250 (16.8)	16.9	1.76 (1.26, 2.46)	0.0009	13.51 (5.85, 21.17)	0.0005	
Geographic region									0.6091
EU	43/108 (39.8)	40.1	26/118 (22.0)	22.1	1.81 (1.20, 2.73)	0.0045	17.97 (5.92, 30.03)	0.0035	
non-EU	58/231 (25.1)	25.3	36/223 (16.1)	15.9	1.57 (1.08, 2.28)	0.0177	9.44 (1.68, 17.20)	0.0171	
Onset of disease									0.5808
Paediatric	7/ 26 (26.9)	26.9	2/ 24 (8.3)	8.6	2.33 (0.61, 8.87)	0.2149	18.21 (-5.58, 42.00)	0.1335	
Adult	94/313 (30.0)	30.2	60/317 (18.9)	18.8	1.59 (1.19, 2.11)	0.0015	11.39 (4.51, 18.28)	0.0012	
ADA result									0.5651
Negative	93/314 (29.6)	29.8	57/307 (18.6)	18.5	1.59 (1.19, 2.12)	0.0018	11.34 (4.43, 18.26)	0.0013	
Positive (At any time)	8/ 24 (33.3)	33.9	5/ 34 (14.7)	16.0	2.14 (0.80, 5.70)	0.1283	17.87 (-6.79, 42.53)	0.1555	
BMI (kg/m2) at enrolment									0.4028
< 30	72/222 (32.4)	32.6	51/245 (20.8)	20.9	1.56 (1.14, 2.12)	0.0051	11.78 (3.57, 19.99)	0.0049	
>= 30	29/117 (24.8)	24.2	11/ 96 (11.5)	11.5	2.11 (1.11, 4.03)	0.0234	12.67 (1.51, 23.83)	0.0260	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
>=4 reduction in SLEDAI-2K at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 52	Number of subjects with events, n (%)	190 (52.8)	151 (41.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.28 (1.10, 1.50)	
	p-value	0.0019	
	Odds Ratio (95% CI)	1.59 (1.19, 2.14)	
	p-value	0.0018	
	Risk Difference (95% CI)	11.68 (4.42, 18.94)	
	p-value	0.0016	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.28 (1.09, 1.50)	
	p-value	0.0022	
	Odds Ratio (95% CI)	1.59 (1.18, 2.13)	
	p-value	0.0020	
	Risk Difference (95% CI)	11.52 (4.29, 18.74)	
	p-value	0.0018	
	CMH approach		
	Response rate	52.8	41.2
	Difference in response rates (95% CI)	11.59 (4.40, 18.77)	
	p-value	0.0016	
	p-Value for test for heterogenity between studies	0.1427	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
>=4 reduction in SLEDAI-2K at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.6331
< 10 points	55/109 (50.5)	50.5	39/106 (36.8)	37.0	1.37 (1.00, 1.86)	0.0485	13.55 (0.43, 26.68)	0.0429	
>= 10 points	135/251 (53.8)	53.8	112/260 (43.1)	43.0	1.25 (1.04, 1.50)	0.0153	10.75 (2.19, 19.32)	0.0139	
OCS dose at baseline									0.3445
<10 mg/day	88/170 (51.8)	52.0	79/181 (43.6)	43.6	1.18 (0.95, 1.48)	0.1352	8.34 (-1.98, 18.67)	0.1131	
>=10 mg/day	102/190 (53.7)	53.7	72/185 (38.9)	39.0	1.38 (1.10, 1.72)	0.0051	14.70 (4.73, 24.68)	0.0039	
Result of type I IFN gene signature test									0.1149
LOW	28/ 62 (45.2)	45.2	30/ 64 (46.9)	46.9	0.97 (0.66, 1.42)	0.8665	-1.71 (-19.09, 15.67)	0.8469	
HIGH	162/298 (54.4)	54.4	121/302 (40.1)	40.0	1.35 (1.14, 1.61)	0.0006	14.39 (6.50, 22.28)	0.0004	
Age (years)									0.6049
<= 65	183/348 (52.6)	52.6	149/362 (41.2)	41.0	1.28 (1.09, 1.50)	0.0026	11.52 (4.25, 18.79)	0.0019	
> 65	7/ 12 (58.3)	58.0	2/ 4 (50.0)	47.7	0.99 (0.38, 2.56)	0.9847	10.23 (-46.36, 66.81)	0.7231	
Sex									0.2264
male	14/ 27 (51.9)	52.3	13/ 25 (52.0)	51.2	0.96 (0.61, 1.52)	0.8626	1.10 (-25.03, 27.23)	0.9341	
female	176/333 (52.9)	52.7	138/341 (40.5)	40.4	1.30 (1.10, 1.53)	0.0019	12.37 (4.94, 19.80)	0.0011	
Race									0.1549
White	123/235 (52.3)	52.8	109/244 (44.7)	44.4	1.17 (0.97, 1.41)	0.0966	8.40 (-0.47, 17.28)	0.0635	
Black	22/ 46 (47.8)	48.4	17/ 48 (35.4)	36.0	1.35 (0.83, 2.19)	0.2257	12.42 (-7.72, 32.56)	0.2269	
Other	41/ 71 (57.7)	57.8	21/ 66 (31.8)	31.8	1.81 (1.21, 2.72)	0.0042	25.94 (9.79, 42.09)	0.0016	
Ethnicity									0.7023
Hispanic/Latino	47/ 86 (54.7)	54.3	40/ 89 (44.9)	45.2	1.22 (0.90, 1.64)	0.1975	9.12 (-5.61, 23.85)	0.2251	
Non-hispanic/Latino	139/266 (52.3)	52.3	107/269 (39.8)	39.9	1.30 (1.08, 1.57)	0.0054	12.31 (3.95, 20.67)	0.0039	
Geographic region									0.4104
EU	72/115 (62.6)	62.7	64/122 (52.5)	52.3	1.20 (0.96, 1.49)	0.1085	10.39 (-2.17, 22.95)	0.1050	
non-EU	118/245 (48.2)	48.5	87/244 (35.7)	35.4	1.36 (1.10, 1.69)	0.0044	13.14 (4.47, 21.81)	0.0030	
Onset of disease									0.8397
Paediatric	9/ 26 (34.6)	34.3	7/ 24 (29.2)	29.3	1.18 (0.52, 2.66)	0.6908	4.94 (-21.57, 31.45)	0.7150	
Adult	181/334 (54.2)	54.2	144/342 (42.1)	42.0	1.28 (1.10, 1.51)	0.0020	12.18 (4.74, 19.63)	0.0013	
ADA result									0.3374
Negative	178/334 (53.3)	53.2	142/331 (42.9)	42.9	1.24 (1.06, 1.46)	0.0084	10.26 (2.75, 17.78)	0.0074	
Positive (At any time)	12/ 25 (48.0)	48.3	9/ 35 (25.7)	27.8	1.75 (0.88, 3.49)	0.1098	20.52 (-5.27, 46.32)	0.1189	
BMI (kg/m2) at enrolment									0.6091
< 30	129/233 (55.4)	55.5	115/261 (44.1)	44.4	1.26 (1.05, 1.50)	0.0127	11.13 (2.45, 19.81)	0.0119	
>= 30	61/127 (48.0)	48.6	36/105 (34.3)	34.8	1.38 (1.00, 1.91)	0.0472	13.74 (1.25, 26.23)	0.0311	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
>=8 reduction in SLEDAI-2K at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 52	Number of subjects with events, n (%)	101 (28.1)	62 (16.9)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.67 (1.26, 2.21)	
	p-value	0.0003	
	Odds Ratio (95% CI)	1.94 (1.36, 2.78)	
	p-value	0.0003	
	Risk Difference (95% CI)	11.29 (5.29, 17.30)	
	p-value	0.0002	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.65 (1.25, 2.19)	
	p-value	0.0005	
	Odds Ratio (95% CI)	1.91 (1.34, 2.73)	
	p-value	0.0004	
	Risk Difference (95% CI)	11.11 (5.09, 17.14)	
	p-value	0.0003	
	CMH approach		
	Response rate	28.1	16.8
	Difference in response rates (95% CI)	11.33 (5.10, 17.55)	
	p-value	0.0004	
	p-Value for test for heterogenity between studies	0.5773	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
>=8 reduction in SLEDAI-2K at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.6119
< 10 points	16/109 (14.7)	14.6	11/106 (10.4)	10.4	1.40 (0.67, 2.95)	0.3714	4.25 (-6.25, 14.74)	0.4279	
>= 10 points	85/251 (33.9)	33.8	51/260 (19.6)	19.5	1.73 (1.28, 2.33)	0.0004	14.30 (6.56, 22.03)	0.0003	
OCS dose at baseline									0.0169
<10 mg/day	42/170 (24.7)	25.0	38/181 (21.0)	21.0	1.18 (0.80, 1.73)	0.4073	3.97 (-5.21, 13.15)	0.3966	
>=10 mg/day	59/190 (31.1)	31.2	24/185 (13.0)	13.0	2.38 (1.55, 3.66)	<.0001	18.20 (9.71, 26.70)	<.0001	
Result of type I IFN gene signature test									0.0730
LOW	10/ 62 (16.1)	16.1	12/ 64 (18.8)	18.7	0.86 (0.40, 1.86)	0.7105	-2.62 (-16.85, 11.61)	0.7180	
HIGH	91/298 (30.5)	30.7	50/302 (16.6)	16.4	1.84 (1.36, 2.50)	<.0001	14.26 (7.35, 21.17)	<.0001	
Age (years)									0.5085
<= 65	99/348 (28.4)	28.6	61/362 (16.9)	16.7	1.68 (1.27, 2.24)	0.0003	11.85 (5.54, 18.17)	0.0002	
> 65	2/ 12 (16.7)	20.5	1/ 4 (25.0)	23.9	0.86 (0.12, 6.23)	0.8789	-3.41 (-59.17, 52.35)	0.9046	
Sex									0.7844
male	8/ 27 (29.6)	29.5	5/ 25 (20.0)	19.8	1.44 (0.53, 3.94)	0.4758	9.64 (-15.26, 34.54)	0.4479	
female	93/333 (27.9)	27.9	57/341 (16.7)	16.6	1.67 (1.24, 2.24)	0.0006	11.28 (4.85, 17.71)	0.0006	
Race									0.0523
White	61/235 (26.0)	26.5	46/244 (18.9)	18.6	1.38 (0.98, 1.93)	0.0653	7.89 (0.11, 15.67)	0.0470	
Black	10/ 46 (21.7)	21.9	7/ 48 (14.6)	14.3	1.53 (0.63, 3.71)	0.3515	7.59 (-9.54, 24.73)	0.3849	
Other	29/ 71 (40.8)	40.9	7/ 66 (10.6)	10.6	3.82 (1.80, 8.12)	0.0005	30.25 (15.92, 44.57)	<.0001	
Ethnicity									0.2657
Hispanic/Latino	25/ 86 (29.1)	28.3	18/ 89 (20.2)	21.0	1.25 (0.73, 2.14)	0.4259	7.33 (-5.69, 20.34)	0.2697	
Non-hispanic/Latino	75/266 (28.2)	28.7	42/269 (15.6)	15.7	1.79 (1.27, 2.51)	0.0008	12.96 (5.63, 20.29)	0.0005	
Geographic region									0.7719
EU	43/115 (37.4)	37.6	26/122 (21.3)	21.5	1.75 (1.16, 2.65)	0.0081	16.18 (4.53, 27.83)	0.0065	
non-EU	58/245 (23.7)	23.7	36/244 (14.8)	14.5	1.61 (1.11, 2.35)	0.0127	9.21 (1.84, 16.57)	0.0143	
Onset of disease									0.5918
Paediatric	7/ 26 (26.9)	26.9	2/ 24 (8.3)	8.6	2.33 (0.61, 8.87)	0.2149	18.21 (-5.58, 42.00)	0.1335	
Adult	94/334 (28.1)	28.2	60/342 (17.5)	17.4	1.60 (1.20, 2.14)	0.0013	10.81 (4.32, 17.31)	0.0011	
ADA result									0.6080
Negative	93/334 (27.8)	28.0	57/331 (17.2)	17.2	1.61 (1.20, 2.16)	0.0015	10.88 (4.35, 17.42)	0.0011	
Positive (At any time)	8/ 25 (32.0)	32.8	5/ 35 (14.3)	15.8	2.10 (0.79, 5.63)	0.1383	16.97 (-7.30, 41.23)	0.1706	
BMI (kg/m2) at enrolment									0.4195
< 30	72/233 (30.9)	31.1	51/261 (19.5)	19.5	1.58 (1.16, 2.16)	0.0041	11.53 (3.69, 19.37)	0.0039	
>= 30	29/127 (22.8)	22.5	11/105 (10.5)	10.7	2.13 (1.11, 4.08)	0.0232	11.79 (1.21, 22.37)	0.0290	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
No worsening in BILAG-2004 (>=1A or >=2B compared to BL) at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 52	Number of subjects with events, n (%)	244 (67.8)	199 (54.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.25 (1.11, 1.40)	
	p-value	0.0002	
	Odds Ratio (95% CI)	1.77 (1.30, 2.39)	
	p-value	0.0002	
	Risk Difference (95% CI)	13.44 (6.40, 20.49)	
	p-value	0.0002	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.24 (1.11, 1.40)	
	p-value	0.0003	
	Odds Ratio (95% CI)	1.76 (1.30, 2.39)	
	p-value	0.0002	
	Risk Difference (95% CI)	13.41 (6.38, 20.44)	
	p-value	0.0002	
	CMH approach		
	Response rate	67.8	54.4
	Difference in response rates (95% CI)	13.39 (6.37, 20.42)	
	p-value	0.0002	
	p-Value for test for heterogenity between studies	0.2166	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
No worsening in BILAG-2004 (>=1A or >=2B compared to BL) at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.7411
< 10 points	76/109 (69.7)	69.8	61/106 (57.5)	57.6	1.21 (0.98, 1.48)	0.0701	12.22 (-0.65, 25.09)	0.0628	
>= 10 points	168/251 (66.9)	67.0	138/260 (53.1)	53.1	1.26 (1.09, 1.45)	0.0017	13.88 (5.52, 22.24)	0.0011	
OCS dose at baseline									0.8531
<10 mg/day	121/170 (71.2)	71.0	104/181 (57.5)	57.6	1.23 (1.05, 1.44)	0.0093	13.41 (3.39, 23.43)	0.0087	
>=10 mg/day	123/190 (64.7)	64.7	95/185 (51.4)	51.4	1.26 (1.06, 1.50)	0.0100	13.37 (3.50, 23.24)	0.0079	
Result of type I IFN gene signature test									0.3954
LOW	45/ 62 (72.6)	72.6	40/ 64 (62.5)	62.5	1.13 (0.88, 1.43)	0.3375	10.08 (-6.28, 26.43)	0.2272	
HIGH	199/298 (66.8)	66.8	159/302 (52.6)	52.7	1.27 (1.11, 1.45)	0.0005	14.09 (6.32, 21.86)	0.0004	
Age (years)									0.0335
<= 65	234/348 (67.2)	67.2	196/362 (54.1)	54.1	1.24 (1.10, 1.40)	0.0004	13.10 (5.98, 20.23)	0.0003	
> 65	10/ 12 (83.3)	84.1	3/ 4 (75.0)	71.6	0.87 (0.65, 1.18)	0.3771	12.50 (-40.22, 65.22)	0.6421	
Sex									0.7270
male	18/ 27 (66.7)	66.9	13/ 25 (52.0)	51.2	1.15 (0.76, 1.73)	0.5184	15.70 (-10.17, 41.58)	0.2343	
female	226/333 (67.9)	67.8	186/341 (54.5)	54.5	1.24 (1.09, 1.40)	0.0006	13.31 (6.02, 20.59)	0.0003	
Race									0.1889
White	164/235 (69.8)	69.9	140/244 (57.4)	57.4	1.21 (1.06, 1.39)	0.0058	12.54 (3.94, 21.14)	0.0043	
Black	27/ 46 (58.7)	58.7	27/ 48 (56.3)	56.3	1.04 (0.73, 1.48)	0.8144	2.42 (-17.87, 22.70)	0.8152	
Other	48/ 71 (67.6)	67.6	28/ 66 (42.4)	42.4	1.59 (1.15, 2.20)	0.0048	25.19 (8.93, 41.44)	0.0024	
Ethnicity									0.8874
Hispanic/Latino	58/ 86 (67.4)	67.5	49/ 89 (55.1)	55.2	1.22 (0.96, 1.55)	0.0997	12.34 (-2.14, 26.82)	0.0950	
Non-hispanic/Latino	181/266 (68.0)	67.8	146/269 (54.3)	54.4	1.25 (1.09, 1.43)	0.0017	13.36 (5.14, 21.59)	0.0015	
Geographic region									0.3869
EU	84/115 (73.0)	73.1	76/122 (62.3)	62.0	1.17 (0.98, 1.40)	0.0824	11.09 (-0.86, 23.04)	0.0690	
non-EU	160/245 (65.3)	65.9	123/244 (50.4)	50.3	1.30 (1.11, 1.52)	0.0009	15.64 (7.04, 24.24)	0.0004	
Onset of disease									0.9493
Paediatric	12/ 26 (46.2)	46.0	9/ 24 (37.5)	37.7	1.22 (0.63, 2.36)	0.5547	8.33 (-19.10, 35.77)	0.5517	
Adult	232/334 (69.5)	69.5	190/342 (55.6)	55.7	1.25 (1.11, 1.40)	0.0003	13.85 (6.61, 21.08)	0.0002	
ADA result									0.7440
Negative	230/334 (68.9)	68.7	187/331 (56.5)	56.7	1.22 (1.08, 1.37)	0.0012	12.03 (4.70, 19.35)	0.0013	
Positive (At any time)	14/ 25 (56.0)	55.1	12/ 35 (34.3)	39.4	1.34 (0.78, 2.30)	0.2937	15.73 (-10.28, 41.73)	0.2360	
BMI (kg/m2) at enrolment									0.3540
< 30	162/233 (69.5)	69.6	141/261 (54.0)	54.2	1.29 (1.12, 1.48)	0.0004	15.42 (6.93, 23.91)	0.0004	
>= 30	82/127 (64.6)	65.3	58/105 (55.2)	55.6	1.14 (0.92, 1.41)	0.2233	9.73 (-2.84, 22.29)	0.1293	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Maintained OCS Reduction at week 52 (for subjects with baseline OCS >=10 mg/day)
Full analysis set

Timepoint		Anifrolumab 300mg (N=190)	Placebo (N=185)
Week 52	Number of subjects with events, n (%)	96 (50.5)	59 (31.9)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.59 (1.24, 2.05)	
	p-value	0.0003	
	Odds Ratio (95% CI)	2.21 (1.45, 3.38)	
	p-value	0.0002	
	Risk Difference (95% CI)	18.79 (9.04, 28.54)	
	p-value	0.0002	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.58 (1.23, 2.04)	
	p-value	0.0004	
	Odds Ratio (95% CI)	2.18 (1.43, 3.32)	
	p-value	0.0003	
	Risk Difference (95% CI)	18.64 (8.86, 28.42)	
	p-value	0.0002	
	CMH approach		
	Response rate	50.6	31.8
	Difference in response rates (95% CI)	18.86 (9.11, 28.61)	
	p-value	0.0001	
	p-Value for test for heterogenity between studies	0.5787	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Maintained OCS Reduction at week 52 (for subjects with baseline OCS >=10 mg/day) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=190) n/ N (%)	Response rate	Placebo (N=185) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8586
< 10 points	26/ 52 (50.0)	50.0	15/ 46 (32.6)	32.7	1.52 (0.92, 2.50)	0.0990	17.37 (-1.98, 36.72)	0.0785	
>= 10 points	70/138 (50.7)	50.7	44/139 (31.7)	31.6	1.60 (1.19, 2.15)	0.0017	19.07 (7.66, 30.49)	0.0011	
OCS dose at baseline									NE
>=10 mg/day	96/190 (50.5)	50.6	59/185 (31.9)	31.8	1.58 (1.23, 2.04)	0.0004	18.86 (9.11, 28.61)	0.0001	
Result of type I IFN gene signature test									0.1190
LOW	10/ 22 (45.5)	45.6	11/ 25 (44.0)	43.8	1.03 (0.59, 1.82)	0.9067	1.82 (-25.61, 29.24)	0.8968	
HIGH	86/168 (51.2)	51.2	48/160 (30.0)	30.1	1.71 (1.29, 2.25)	0.0002	21.10 (10.67, 31.54)	<.0001	
Age (years)									0.1040
<= 65	95/187 (50.8)	51.0	58/184 (31.5)	31.3	1.61 (1.25, 2.08)	0.0003	19.68 (9.89, 29.47)	<.0001	
> 65	1/ 3 (33.3)	50.0	1/ 1 (100.0)	100.0	0.50 (0.13, 2.00)	0.3270	-50.00 (-168.41, 68.41)	0.4079	
Sex									0.9199
male	10/ 18 (55.6)	54.7	5/ 15 (33.3)	33.6	1.64 (0.72, 3.73)	0.2356	21.17 (-12.41, 54.75)	0.2166	
female	86/172 (50.0)	50.0	54/170 (31.8)	31.6	1.57 (1.20, 2.05)	0.0009	18.37 (8.19, 28.55)	0.0004	
Race									0.6654
White	60/116 (51.7)	51.8	41/131 (31.3)	31.0	1.63 (1.20, 2.23)	0.0021	20.74 (8.71, 32.77)	0.0007	
Black	10/ 27 (37.0)	32.8	5/ 19 (26.3)	25.3	1.33 (0.44, 4.01)	0.6164	7.43 (-21.11, 35.96)	0.6100	
Other	23/ 43 (53.5)	53.7	13/ 32 (40.6)	41.3	1.26 (0.76, 2.07)	0.3671	12.37 (-10.31, 35.04)	0.2851	
Ethnicity									0.9987
Hispanic/Latino	25/ 49 (51.0)	51.2	15/ 45 (33.3)	33.2	1.54 (0.94, 2.52)	0.0833	18.03 (-1.68, 37.74)	0.0730	
Non-hispanic/Latino	68/137 (49.6)	49.6	44/137 (32.1)	32.2	1.54 (1.15, 2.07)	0.0040	17.43 (5.94, 28.92)	0.0029	
Geographic region									0.6926
EU	45/ 74 (60.8)	60.7	30/ 85 (35.3)	34.8	1.68 (1.19, 2.38)	0.0031	25.95 (10.85, 41.05)	0.0008	
non-EU	51/116 (44.0)	44.1	29/100 (29.0)	28.8	1.52 (1.05, 2.20)	0.0262	15.30 (2.55, 28.05)	0.0187	
Onset of disease									0.8867
Paediatric	11/ 22 (50.0)	50.0	4/ 15 (26.7)	26.8	1.67 (0.66, 4.22)	0.2778	23.22 (-8.51, 54.95)	0.1515	
Adult	85/168 (50.6)	50.7	55/170 (32.4)	32.3	1.56 (1.20, 2.03)	0.0010	18.43 (8.16, 28.69)	0.0004	
ADA result									0.2964
Negative	90/171 (52.6)	52.7	57/163 (35.0)	35.0	1.50 (1.17, 1.94)	0.0016	17.71 (7.23, 28.18)	0.0009	
Positive (At any time)	6/ 18 (33.3)	32.5	2/ 22 (9.1)	9.8	3.35 (0.76, 14.78)	0.1100	22.64 (-6.47, 51.75)	0.1274	
BMI (kg/m2) at enrolment									0.9891
< 30	70/129 (54.3)	54.2	48/143 (33.6)	33.5	1.62 (1.22, 2.14)	0.0008	20.71 (9.11, 32.32)	0.0005	
>= 30	26/ 61 (42.6)	42.6	11/ 42 (26.2)	26.2	1.61 (0.90, 2.89)	0.1114	16.40 (-2.22, 35.03)	0.0843	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
>=50% Reduction in CLASI activity score at week 52 (for subjects with baseline CLASI activity score >=10)
Full analysis set

Timepoint		Anifrolumab 300mg (N=107)	Placebo (N=94)
Week 52	Number of subjects with events, n (%)	68 (63.6)	42 (44.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.41 (1.08, 1.83)	
	p-value	0.0106	
	Odds Ratio (95% CI)	2.17 (1.21, 3.88)	
	p-value	0.0090	
	Risk Difference (95% CI)	18.36 (4.90, 31.82)	
	p-value	0.0075	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.42 (1.09, 1.86)	
	p-value	0.0097	
	Odds Ratio (95% CI)	2.16 (1.23, 3.80)	
	p-value	0.0077	
	Risk Difference (95% CI)	18.87 (5.29, 32.45)	
	p-value	0.0064	
	CMH approach		
	Response rate	63.6	44.7
	Difference in response rates (95% CI)	18.87 (5.26, 32.49)	
	p-value	0.0066	
	p-Value for test for heterogenity between studies	0.9398	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
>=50% Reduction in CLASI activity score at week 52 (for subjects with baseline CLASI activity score >=10) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=107) n/ N (%)	Response rate	Placebo (N=94) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.4455
< 10 points	16/ 21 (76.2)	77.2	10/ 22 (45.5)	45.2	1.72 (1.03, 2.87)	0.0384	32.00 (3.13, 60.87)	0.0298	
>= 10 points	52/ 86 (60.5)	60.5	32/ 72 (44.4)	44.4	1.36 (1.00, 1.85)	0.0512	16.03 (0.55, 31.51)	0.0424	
OCS dose at baseline									0.0277
<10 mg/day	27/ 38 (71.1)	71.1	11/ 35 (31.4)	31.5	2.26 (1.33, 3.83)	0.0026	39.60 (17.90, 61.31)	0.0003	
>=10 mg/day	41/ 69 (59.4)	59.4	31/ 59 (52.5)	52.5	1.13 (0.83, 1.54)	0.4380	6.90 (-10.37, 24.16)	0.4337	
Result of type I IFN gene signature test									0.0087
LOW	8/ 14 (57.1)	55.0	10/ 13 (76.9)	78.3	0.77 (0.48, 1.22)	0.2660	-23.33 (-58.73, 12.06)	0.1964	
HIGH	60/ 93 (64.5)	64.8	32/ 81 (39.5)	39.4	1.62 (1.19, 2.21)	0.0021	25.44 (10.95, 39.93)	0.0006	
Age (years)									NE
<= 65	65/104 (62.5)	62.5	41/ 93 (44.1)	44.1	1.42 (1.08, 1.86)	0.0126	18.35 (4.58, 32.13)	0.0090	
> 65	3/ 3 (100.0)	100.0	1/ 1 (100.0)	100.0	NE		0.00 (-108.78, 108.78)	1.0000	
Sex									0.4640
male	4/ 9 (44.4)	43.5	5/ 10 (50.0)	49.4	0.98 (0.34, 2.83)	0.9762	-5.88 (-50.40, 38.64)	0.7957	
female	64/ 98 (65.3)	65.2	37/ 84 (44.0)	44.0	1.48 (1.12, 1.96)	0.0063	21.24 (6.97, 35.51)	0.0035	
Race									0.2056
White	46/ 74 (62.2)	62.1	35/ 71 (49.3)	49.8	1.24 (0.92, 1.66)	0.1515	12.30 (-3.86, 28.45)	0.1357	
Black	9/ 16 (56.3)	52.7	1/ 5 (20.0)	18.1	2.13 (0.48, 9.44)	0.3206	34.62 (-18.23, 87.46)	0.1992	
Other	13/ 16 (81.3)	81.2	4/ 14 (28.6)	28.7	2.66 (1.15, 6.17)	0.0228	52.50 (19.11, 85.89)	0.0021	
Ethnicity									0.8403
Hispanic/Latino	9/ 17 (52.9)	51.1	4/ 11 (36.4)	37.6	1.33 (0.57, 3.08)	0.5059	13.51 (-23.82, 50.84)	0.4781	
Non-hispanic/Latino	59/ 89 (66.3)	66.3	36/ 79 (45.6)	45.5	1.46 (1.10, 1.93)	0.0092	20.83 (6.03, 35.63)	0.0058	
Geographic region									0.1262
EU	26/ 39 (66.7)	66.5	25/ 44 (56.8)	57.0	1.17 (0.83, 1.64)	0.3730	9.48 (-11.54, 30.51)	0.3768	
non-EU	42/ 68 (61.8)	61.6	17/ 50 (34.0)	34.3	1.78 (1.16, 2.73)	0.0078	27.30 (9.60, 45.01)	0.0025	
Onset of disease									0.9135
Paediatric	3/ 7 (42.9)	41.4	2/ 6 (33.3)	32.8	1.31 (0.28, 6.08)	0.7295	8.62 (-44.73, 61.97)	0.7515	
Adult	65/100 (65.0)	65.0	40/ 88 (45.5)	45.4	1.43 (1.09, 1.87)	0.0098	19.53 (5.48, 33.58)	0.0064	
ADA result									0.7300
Negative	66/ 98 (67.3)	67.5	41/ 88 (46.6)	46.7	1.44 (1.11, 1.88)	0.0060	20.78 (6.76, 34.80)	0.0037	
Positive (At any time)	2/ 9 (22.2)	23.8	1/ 6 (16.7)	19.0	1.04 (0.16, 6.59)	0.9662	4.76 (-45.43, 54.95)	0.8525	
BMI (kg/m2) at enrolment									0.5171
< 30	44/ 66 (66.7)	66.7	29/ 66 (43.9)	43.9	1.52 (1.10, 2.10)	0.0108	22.78 (6.14, 39.42)	0.0073	
>= 30	24/ 41 (58.5)	58.6	13/ 28 (46.4)	46.5	1.26 (0.78, 2.02)	0.3430	12.07 (-11.85, 36.00)	0.3226	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 4	Number of subjects with events, n (%)	91 (25.3)	72 (19.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.27 (0.97, 1.67)	
	p-value	0.0824	
	Odds Ratio (95% CI)	1.36 (0.96, 1.94)	
	p-value	0.0828	
	Risk Difference (95% CI)	5.40 (-0.67, 11.48)	
	p-value	0.0815	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.28 (0.98, 1.69)	
	p-value	0.0727	
	Odds Ratio (95% CI)	1.38 (0.97, 1.96)	
	p-value	0.0712	
	Risk Difference (95% CI)	5.60 (-0.46, 11.65)	
	p-value	0.0701	
	CMH approach		
	Response rate	25.3	19.8
	Difference in response rates (95% CI)	5.52 (-0.76, 11.80)	
	p-value	0.0848	
	p-Value for test for heterogenity between studies	0.8077	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 8	Number of subjects with events, n (%)	126 (35.0)	83 (22.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.54 (1.22, 1.94)	
	p-value	0.0003	
	Odds Ratio (95% CI)	1.85 (1.33, 2.59)	
	p-value	0.0003	
	Risk Difference (95% CI)	12.20 (5.74, 18.66)	
	p-value	0.0002	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.54 (1.22, 1.95)	
	p-value	0.0003	
	Odds Ratio (95% CI)	1.84 (1.32, 2.55)	
	p-value	0.0003	
	Risk Difference (95% CI)	12.32 (5.79, 18.86)	
	p-value	0.0002	
	CMH approach		
	Response rate	35.0	22.7
	Difference in response rates (95% CI)	12.32 (5.76, 18.88)	
	p-value	0.0002	
	p-Value for test for heterogenity between studies	0.7987	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 12	Number of subjects with events, n (%)	144 (40.0)	108 (29.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.35 (1.10, 1.65)	
	p-value	0.0038	
	Odds Ratio (95% CI)	1.58 (1.16, 2.16)	
	p-value	0.0036	
	Risk Difference (95% CI)	10.30 (3.42, 17.17)	
	p-value	0.0033	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.35 (1.11, 1.66)	
	p-value	0.0033	
	Odds Ratio (95% CI)	1.59 (1.17, 2.17)	
	p-value	0.0031	
	Risk Difference (95% CI)	10.48 (3.60, 17.36)	
	p-value	0.0028	
	CMH approach		
	Response rate	39.9	29.7
	Difference in response rates (95% CI)	10.27 (3.37, 17.18)	
	p-value	0.0036	
	p-Value for test for heterogenity between studies	0.9224	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 16	Number of subjects with events, n (%)	155 (43.1)	117 (32.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.34 (1.11, 1.63)	
	p-value	0.0026	
	Odds Ratio (95% CI)	1.59 (1.18, 2.16)	
	p-value	0.0025	
	Risk Difference (95% CI)	10.98 (3.93, 18.02)	
	p-value	0.0023	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.35 (1.11, 1.63)	
	p-value	0.0022	
	Odds Ratio (95% CI)	1.61 (1.19, 2.18)	
	p-value	0.0021	
	Risk Difference (95% CI)	11.09 (4.09, 18.09)	
	p-value	0.0019	
	CMH approach		
	Response rate	43.1	32.0
	Difference in response rates (95% CI)	11.08 (4.07, 18.08)	
	p-value	0.0019	
	p-Value for test for heterogenity between studies	0.6348	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 20	Number of subjects with events, n (%)	158 (43.9)	130 (35.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.24 (1.03, 1.49)	
	p-value	0.0209	
	Odds Ratio (95% CI)	1.42 (1.06, 1.92)	
	p-value	0.0204	
	Risk Difference (95% CI)	8.47 (1.35, 15.59)	
	p-value	0.0197	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.23 (1.03, 1.48)	
	p-value	0.0224	
	Odds Ratio (95% CI)	1.42 (1.05, 1.91)	
	p-value	0.0216	
	Risk Difference (95% CI)	8.37 (1.27, 15.47)	
	p-value	0.0208	
	CMH approach		
	Response rate	44.0	35.5
	Difference in response rates (95% CI)	8.52 (1.41, 15.63)	
	p-value	0.0188	
	p-Value for test for heterogenity between studies	0.3942	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 24	Number of subjects with events, n (%)	175 (48.6)	123 (33.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.45 (1.21, 1.74)	
	p-value	<.0001	
	Odds Ratio (95% CI)	1.87 (1.39, 2.53)	
	p-value	<.0001	
	Risk Difference (95% CI)	15.11 (8.01, 22.21)	
	p-value	<.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.44 (1.20, 1.72)	
	p-value	<.0001	
	Odds Ratio (95% CI)	1.87 (1.38, 2.52)	
	p-value	<.0001	
	Risk Difference (95% CI)	15.01 (7.92, 22.09)	
	p-value	<.0001	
	CMH approach		
	Response rate	48.6	33.6
	Difference in response rates (95% CI)	15.03 (7.98, 22.07)	
	p-value	<.0001	
	p-Value for test for heterogenity between studies	0.1755	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 28	Number of subjects with events, n (%)	168 (46.7)	128 (35.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.33 (1.12, 1.59)	
	p-value	0.0015	
	Odds Ratio (95% CI)	1.62 (1.20, 2.19)	
	p-value	0.0015	
	Risk Difference (95% CI)	11.70 (4.57, 18.83)	
	p-value	0.0013	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.33 (1.11, 1.59)	
	p-value	0.0017	
	Odds Ratio (95% CI)	1.62 (1.20, 2.19)	
	p-value	0.0015	
	Risk Difference (95% CI)	11.69 (4.58, 18.81)	
	p-value	0.0013	
	CMH approach		
	Response rate	46.7	35.1
	Difference in response rates (95% CI)	11.67 (4.60, 18.74)	
	p-value	0.0012	
	p-Value for test for heterogenity between studies	0.1467	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 32	Number of subjects with events, n (%)	170 (47.2)	127 (34.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.37 (1.14, 1.63)	
	p-value	0.0006	
	Odds Ratio (95% CI)	1.69 (1.26, 2.28)	
	p-value	0.0006	
	Risk Difference (95% CI)	12.68 (5.57, 19.79)	
	p-value	0.0005	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.35 (1.13, 1.62)	
	p-value	0.0009	
	Odds Ratio (95% CI)	1.68 (1.25, 2.27)	
	p-value	0.0007	
	Risk Difference (95% CI)	12.53 (5.43, 19.63)	
	p-value	0.0005	
	CMH approach		
	Response rate	47.2	34.7
	Difference in response rates (95% CI)	12.56 (5.51, 19.60)	
	p-value	0.0005	
	p-Value for test for heterogenity between studies	0.1858	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 36	Number of subjects with events, n (%)	169 (46.9)	131 (35.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.31 (1.10, 1.56)	
	p-value	0.0025	
	Odds Ratio (95% CI)	1.58 (1.18, 2.13)	
	p-value	0.0024	
	Risk Difference (95% CI)	11.19 (4.03, 18.35)	
	p-value	0.0022	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.31 (1.09, 1.56)	
	p-value	0.0030	
	Odds Ratio (95% CI)	1.59 (1.18, 2.14)	
	p-value	0.0024	
	Risk Difference (95% CI)	11.16 (4.05, 18.28)	
	p-value	0.0021	
	CMH approach		
	Response rate	47.0	35.8
	Difference in response rates (95% CI)	11.17 (4.09, 18.26)	
	p-value	0.0020	
	p-Value for test for heterogenity between studies	0.2508	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 40	Number of subjects with events, n (%)	161 (44.7)	118 (32.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.38 (1.15, 1.66)	
	p-value	0.0007	
	Odds Ratio (95% CI)	1.69 (1.25, 2.29)	
	p-value	0.0007	
	Risk Difference (95% CI)	12.33 (5.30, 19.36)	
	p-value	0.0006	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.38 (1.15, 1.67)	
	p-value	0.0007	
	Odds Ratio (95% CI)	1.70 (1.26, 2.31)	
	p-value	0.0006	
	Risk Difference (95% CI)	12.50 (5.48, 19.51)	
	p-value	0.0005	
	CMH approach		
	Response rate	44.7	32.4
	Difference in response rates (95% CI)	12.29 (5.31, 19.26)	
	p-value	0.0006	
	p-Value for test for heterogenity between studies	0.5816	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 44	Number of subjects with events, n (%)	160 (44.4)	116 (31.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.40 (1.16, 1.70)	
	p-value	0.0005	
	Odds Ratio (95% CI)	1.71 (1.27, 2.31)	
	p-value	0.0005	
	Risk Difference (95% CI)	12.86 (5.77, 19.95)	
	p-value	0.0004	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.40 (1.16, 1.69)	
	p-value	0.0005	
	Odds Ratio (95% CI)	1.72 (1.27, 2.34)	
	p-value	0.0004	
	Risk Difference (95% CI)	12.76 (5.75, 19.76)	
	p-value	0.0004	
	CMH approach		
	Response rate	44.5	31.8
	Difference in response rates (95% CI)	12.76 (5.79, 19.73)	
	p-value	0.0003	
	p-Value for test for heterogenity between studies	0.7271	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 48	Number of subjects with events, n (%)	162 (45.0)	116 (31.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.42 (1.17, 1.71)	
	p-value	0.0003	
	Odds Ratio (95% CI)	1.76 (1.30, 2.38)	
	p-value	0.0003	
	Risk Difference (95% CI)	13.30 (6.26, 20.33)	
	p-value	0.0002	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.42 (1.17, 1.71)	
	p-value	0.0003	
	Odds Ratio (95% CI)	1.76 (1.30, 2.39)	
	p-value	0.0002	
	Risk Difference (95% CI)	13.30 (6.29, 20.31)	
	p-value	0.0002	
	CMH approach		
	Response rate	45.0	31.8
	Difference in response rates (95% CI)	13.21 (6.20, 20.22)	
	p-value	0.0002	
	p-Value for test for heterogenity between studies	0.5530	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 52	Number of subjects with events, n (%)	171 (47.5)	112 (30.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.54 (1.28, 1.86)	
	p-value	<.0001	
	Odds Ratio (95% CI)	2.03 (1.50, 2.75)	
	p-value	<.0001	
	Risk Difference (95% CI)	16.80 (9.76, 23.83)	
	p-value	<.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.55 (1.29, 1.87)	
	p-value	<.0001	
	Odds Ratio (95% CI)	2.05 (1.51, 2.78)	
	p-value	<.0001	
	Risk Difference (95% CI)	16.90 (9.90, 23.89)	
	p-value	<.0001	
	CMH approach		
	Response rate	47.5	30.8
	Difference in response rates (95% CI)	16.64 (9.65, 23.63)	
	p-value	<.0001	
	p-Value for test for heterogenity between studies	0.8560	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BICLA response rate at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.6989
< 10 points	59/109 (54.1)	54.2	39/106 (36.8)	37.2	1.47 (1.09, 1.99)	0.0125	16.96 (3.91, 30.02)	0.0109	
>= 10 points	112/251 (44.6)	44.7	73/260 (28.1)	28.2	1.59 (1.25, 2.02)	0.0001	16.51 (8.26, 24.76)	<.0001	
OCS dose at baseline									0.6727
<10 mg/day	82/170 (48.2)	48.3	54/181 (29.8)	30.0	1.62 (1.23, 2.12)	0.0006	18.32 (8.22, 28.42)	0.0004	
>=10 mg/day	89/190 (46.8)	46.8	58/185 (31.4)	31.6	1.49 (1.15, 1.94)	0.0028	15.20 (5.52, 24.89)	0.0021	
Result of type I IFN gene signature test									0.2526
LOW	29/ 62 (46.8)	46.8	24/ 64 (37.5)	37.5	1.25 (0.82, 1.88)	0.2969	9.27 (-7.96, 26.50)	0.2915	
HIGH	142/298 (47.7)	47.6	88/302 (29.1)	29.4	1.63 (1.32, 2.02)	<.0001	18.19 (10.55, 25.83)	<.0001	
Age (years)									0.5753
<= 65	163/348 (46.8)	46.8	111/362 (30.7)	30.9	1.53 (1.26, 1.85)	<.0001	15.85 (8.78, 22.92)	<.0001	
> 65	8/ 12 (66.7)	72.7	1/ 4 (25.0)	23.9	2.27 (0.57, 9.01)	0.2427	48.86 (-6.47, 104.20)	0.0835	
Sex									0.2747
male	12/ 27 (44.4)	44.6	10/ 25 (40.0)	39.7	1.10 (0.59, 2.08)	0.7573	4.96 (-21.83, 31.75)	0.7168	
female	159/333 (47.7)	47.7	102/341 (29.9)	30.0	1.60 (1.31, 1.94)	<.0001	17.67 (10.44, 24.91)	<.0001	
Race									0.3057
White	110/235 (46.8)	47.1	79/244 (32.4)	32.3	1.45 (1.15, 1.81)	0.0014	14.83 (6.15, 23.51)	0.0008	
Black	22/ 46 (47.8)	48.4	16/ 48 (33.3)	32.9	1.47 (0.89, 2.43)	0.1325	15.52 (-4.45, 35.48)	0.1277	
Other	34/ 71 (47.9)	47.9	14/ 66 (21.2)	21.2	2.26 (1.34, 3.82)	0.0023	26.69 (11.15, 42.23)	0.0008	
Ethnicity									0.2820
Hispanic/Latino	42/ 86 (48.8)	48.8	33/ 89 (37.1)	36.8	1.32 (0.93, 1.85)	0.1166	12.04 (-2.47, 26.54)	0.1038	
Non-hispanic/Latino	124/266 (46.6)	46.4	76/269 (28.3)	28.8	1.65 (1.31, 2.08)	<.0001	17.68 (9.56, 25.81)	<.0001	
Geographic region									0.5932
EU	62/115 (53.9)	54.4	45/122 (36.9)	37.1	1.47 (1.10, 1.96)	0.0085	17.31 (4.84, 29.79)	0.0065	
non-EU	109/245 (44.5)	44.9	67/244 (27.5)	27.5	1.63 (1.27, 2.09)	0.0001	17.47 (9.05, 25.89)	<.0001	
Onset of disease									0.4297
Paediatric	10/ 26 (38.5)	38.6	4/ 24 (16.7)	16.7	2.32 (0.84, 6.41)	0.1057	21.91 (-3.75, 47.57)	0.0942	
Adult	161/334 (48.2)	48.2	108/342 (31.6)	31.8	1.53 (1.26, 1.85)	<.0001	16.47 (9.19, 23.75)	<.0001	
ADA result									0.5179
Negative	162/334 (48.5)	48.4	106/331 (32.0)	32.5	1.51 (1.25, 1.83)	<.0001	15.87 (8.53, 23.20)	<.0001	
Positive (At any time)	9/ 25 (36.0)	36.2	6/ 35 (17.1)	17.9	2.05 (0.83, 5.06)	0.1191	18.30 (-6.35, 42.96)	0.1457	
BMI (kg/m2) at enrolment									0.7625
< 30	115/233 (49.4)	49.5	81/261 (31.0)	31.5	1.59 (1.27, 1.98)	<.0001	18.04 (9.54, 26.54)	<.0001	
>= 30	56/127 (44.1)	44.9	31/105 (29.5)	30.0	1.49 (1.04, 2.12)	0.0282	14.90 (2.53, 27.26)	0.0182	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BICLA - individual components at week 52 (Full analysis set)
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
BILAG improvement [a]	173 (48.1)	117 (32.0)
No discontinuation of IP	298 (82.8)	276 (75.4)
No use of medication beyond protocol allowed threshold	284 (78.9)	251 (68.6)
No worsening of PGA [a]	239 (66.4)	200 (54.6)
No worsening of SLEDAI-2K [a]	243 (67.5)	198 (54.1)

[a] Subjects who discontinued IP or used medications beyond protocol allowed threshold are considered non-responders and not included in this category.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BICLA response rate at week 52 sensitivity analysis, multiple imputation
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 52	Number of subjects with events, n (%)	170 (47.3)	112 (30.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.54 (1.27, 1.86)	
	p-value	<.0001	
	Odds Ratio (95% CI)	2.01 (1.48, 2.73)	
	p-value	<.0001	
	Risk Difference (95% CI)	16.58 (9.49, 23.68)	
	p-value	<.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.55 (1.28, 1.87)	
	p-value	<.0001	
	Odds Ratio (95% CI)	2.04 (1.50, 2.76)	
	p-value	<.0001	
	Risk Difference (95% CI)	16.69 (9.65, 23.74)	
	p-value	<.0001	
	p-Value for test for heterogenity between studies	0.8862	

For each outcome and visit, 100 imputations were generated by randomised treatment group. Each imputed dataset was analysed separately, and the single estimates are combined using PROC MIANALYZE. The estimated number of responders and non-responders are rounded to an integer. Therefore, there might be slight mismatches between number of subjects and corresponding percentage.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Change from baseline in PGA VAS < 0.3 at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 52	Number of subjects with events, n (%)	239 (66.4)	200 (54.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.22 (1.08, 1.37)	
	p-value	0.0013	
	Odds Ratio (95% CI)	1.63 (1.21, 2.21)	
	p-value	0.0013	
	Risk Difference (95% CI)	11.81 (4.70, 18.92)	
	p-value	0.0011	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.21 (1.08, 1.37)	
	p-value	0.0015	
	Odds Ratio (95% CI)	1.64 (1.21, 2.21)	
	p-value	0.0013	
	Risk Difference (95% CI)	11.75 (4.68, 18.81)	
	p-value	0.0011	
	CMH approach		
	Response rate	66.4	54.7
	Difference in response rates (95% CI)	11.68 (4.63, 18.73)	
	p-value	0.0012	
	p-Value for test for heterogenity between studies	0.2808	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Change from baseline in PGA VAS < 0.3 at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8603
< 10 points	74/109 (67.9)	68.1	60/106 (56.6)	56.8	1.19 (0.97, 1.47)	0.0991	11.29 (-1.64, 24.22)	0.0871	
>= 10 points	165/251 (65.7)	65.7	140/260 (53.8)	53.9	1.22 (1.06, 1.41)	0.0066	11.84 (3.44, 20.25)	0.0057	
OCS dose at baseline									0.7059
<10 mg/day	117/170 (68.8)	68.8	100/181 (55.2)	55.4	1.24 (1.05, 1.47)	0.0099	13.36 (3.25, 23.47)	0.0096	
>=10 mg/day	122/190 (64.2)	64.2	100/185 (54.1)	54.1	1.19 (1.00, 1.41)	0.0486	10.14 (0.28, 20.01)	0.0439	
Result of type I IFN gene signature test									0.4277
LOW	44/ 62 (71.0)	71.0	40/ 64 (62.5)	62.5	1.10 (0.86, 1.41)	0.4418	8.46 (-7.99, 24.91)	0.3132	
HIGH	195/298 (65.4)	65.4	160/302 (53.0)	53.1	1.24 (1.08, 1.41)	0.0021	12.36 (4.56, 20.16)	0.0019	
Age (years)									0.0495
<= 65	229/348 (65.8)	65.8	197/362 (54.4)	54.5	1.21 (1.07, 1.36)	0.0022	11.33 (4.17, 18.48)	0.0019	
> 65	10/ 12 (83.3)	84.1	3/ 4 (75.0)	71.6	0.87 (0.65, 1.18)	0.3771	12.50 (-40.22, 65.22)	0.6421	
Sex									0.7045
male	18/ 27 (66.7)	66.9	14/ 25 (56.0)	55.4	1.12 (0.75, 1.67)	0.5877	11.57 (-14.53, 37.67)	0.3850	
female	221/333 (66.4)	66.4	186/341 (54.5)	54.6	1.21 (1.07, 1.37)	0.0023	11.75 (4.44, 19.07)	0.0016	
Race									0.1957
White	161/235 (68.5)	68.7	141/244 (57.8)	57.7	1.18 (1.03, 1.36)	0.0174	11.05 (2.41, 19.68)	0.0121	
Black	25/ 46 (54.3)	54.2	26/ 48 (54.2)	54.5	0.99 (0.68, 1.44)	0.9708	-0.34 (-20.73, 20.05)	0.9740	
Other	48/ 71 (67.6)	67.6	29/ 66 (43.9)	43.9	1.53 (1.11, 2.09)	0.0085	23.68 (7.43, 39.94)	0.0043	
Ethnicity									0.6613
Hispanic/Latino	59/ 86 (68.6)	68.8	48/ 89 (53.9)	54.1	1.26 (1.00, 1.60)	0.0535	14.70 (0.29, 29.12)	0.0456	
Non-hispanic/Latino	175/266 (65.8)	65.6	148/269 (55.0)	55.2	1.19 (1.03, 1.37)	0.0145	10.40 (2.14, 18.67)	0.0136	
Geographic region									0.3698
EU	83/115 (72.2)	72.3	77/122 (63.1)	62.6	1.14 (0.95, 1.36)	0.1512	9.62 (-2.32, 21.56)	0.1142	
non-EU	156/245 (63.7)	64.3	123/244 (50.4)	50.3	1.27 (1.08, 1.48)	0.0029	14.04 (5.43, 22.65)	0.0014	
Onset of disease									0.9891
Paediatric	12/ 26 (46.2)	46.0	9/ 24 (37.5)	37.7	1.22 (0.63, 2.36)	0.5547	8.33 (-19.10, 35.77)	0.5517	
Adult	227/334 (68.0)	68.0	191/342 (55.8)	56.0	1.21 (1.08, 1.37)	0.0015	12.05 (4.79, 19.31)	0.0011	
ADA result									0.7715
Negative	225/334 (67.4)	67.2	187/331 (56.5)	56.7	1.19 (1.06, 1.34)	0.0043	10.49 (3.14, 17.84)	0.0051	
Positive (At any time)	14/ 25 (56.0)	55.1	13/ 35 (37.1)	41.5	1.29 (0.76, 2.19)	0.3434	13.64 (-12.49, 39.77)	0.3063	
BMI (kg/m2) at enrolment									0.5927
< 30	159/233 (68.2)	68.3	144/261 (55.2)	55.4	1.24 (1.07, 1.42)	0.0030	12.84 (4.33, 21.35)	0.0031	
>= 30	80/127 (63.0)	63.8	56/105 (53.3)	53.9	1.15 (0.92, 1.44)	0.2086	9.91 (-2.71, 22.54)	0.1239	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Change from baseline in PGA VAS < 0.45 at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 52	Number of subjects with events, n (%)	242 (67.2)	207 (56.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.19 (1.06, 1.33)	
	p-value	0.0031	
	Odds Ratio (95% CI)	1.58 (1.16, 2.13)	
	p-value	0.0032	
	Risk Difference (95% CI)	10.71 (3.67, 17.75)	
	p-value	0.0029	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.19 (1.06, 1.33)	
	p-value	0.0035	
	Odds Ratio (95% CI)	1.58 (1.16, 2.13)	
	p-value	0.0032	
	Risk Difference (95% CI)	10.67 (3.65, 17.69)	
	p-value	0.0029	
	CMH approach		
	Response rate	67.2	56.6
	Difference in response rates (95% CI)	10.62 (3.59, 17.64)	
	p-value	0.0031	
	p-Value for test for heterogenity between studies	0.4313	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Change from baseline in PGA VAS < 0.45 at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8849
< 10 points	75/109 (68.8)	68.9	62/106 (58.5)	58.6	1.17 (0.96, 1.43)	0.1262	10.31 (-2.57, 23.19)	0.1166	
>= 10 points	167/251 (66.5)	66.5	145/260 (55.8)	55.8	1.19 (1.04, 1.37)	0.0131	10.73 (2.35, 19.11)	0.0121	
OCS dose at baseline									0.9286
<10 mg/day	118/170 (69.4)	69.3	106/181 (58.6)	58.7	1.18 (1.01, 1.38)	0.0368	10.61 (0.54, 20.68)	0.0389	
>=10 mg/day	124/190 (65.3)	65.3	101/185 (54.6)	54.6	1.20 (1.01, 1.41)	0.0373	10.62 (0.77, 20.47)	0.0345	
Result of type I IFN gene signature test									0.4458
LOW	45/ 62 (72.6)	72.6	42/ 64 (65.6)	65.6	1.09 (0.86, 1.38)	0.4685	6.95 (-9.36, 23.26)	0.4034	
HIGH	197/298 (66.1)	66.1	165/302 (54.6)	54.7	1.21 (1.06, 1.38)	0.0044	11.39 (3.61, 19.17)	0.0041	
Age (years)									0.0657
<= 65	232/348 (66.7)	66.7	204/362 (56.4)	56.4	1.18 (1.05, 1.33)	0.0052	10.28 (3.16, 17.41)	0.0047	
> 65	10/ 12 (83.3)	84.1	3/ 4 (75.0)	71.6	0.87 (0.65, 1.18)	0.3771	12.50 (-40.22, 65.22)	0.6421	
Sex									0.7836
male	18/ 27 (66.7)	66.9	14/ 25 (56.0)	55.4	1.12 (0.75, 1.67)	0.5877	11.57 (-14.53, 37.67)	0.3850	
female	224/333 (67.3)	67.2	193/341 (56.6)	56.6	1.18 (1.05, 1.33)	0.0054	10.62 (3.33, 17.91)	0.0043	
Race									0.1759
White	162/235 (68.9)	69.1	146/244 (59.8)	59.7	1.15 (1.01, 1.32)	0.0405	9.43 (0.83, 18.03)	0.0317	
Black	26/ 46 (56.5)	56.1	27/ 48 (56.3)	56.3	1.00 (0.70, 1.43)	0.9941	-0.18 (-20.51, 20.16)	0.9865	
Other	49/ 71 (69.0)	69.0	30/ 66 (45.5)	45.4	1.51 (1.11, 2.06)	0.0081	23.57 (7.33, 39.80)	0.0044	
Ethnicity									0.6651
Hispanic/Latino	60/ 86 (69.8)	70.0	50/ 89 (56.2)	56.4	1.24 (0.98, 1.55)	0.0711	13.57 (-0.76, 27.90)	0.0635	
Non-hispanic/Latino	177/266 (66.5)	66.3	153/269 (56.9)	57.0	1.16 (1.02, 1.33)	0.0261	9.23 (0.99, 17.48)	0.0281	
Geographic region									0.3499
EU	83/115 (72.2)	72.3	79/122 (64.8)	64.3	1.11 (0.93, 1.32)	0.2338	7.96 (-3.94, 19.85)	0.1900	
non-EU	159/245 (64.9)	65.5	128/244 (52.5)	52.3	1.24 (1.07, 1.44)	0.0052	13.21 (4.60, 21.82)	0.0026	
Onset of disease									0.7624
Paediatric	12/ 26 (46.2)	46.0	10/ 24 (41.7)	42.0	1.08 (0.58, 2.01)	0.8032	4.01 (-23.49, 31.51)	0.7749	
Adult	230/334 (68.9)	68.9	197/342 (57.6)	57.7	1.19 (1.06, 1.34)	0.0029	11.23 (3.99, 18.46)	0.0023	
ADA result									0.8231
Negative	228/334 (68.3)	68.1	193/331 (58.3)	58.5	1.17 (1.04, 1.32)	0.0083	9.61 (2.29, 16.93)	0.0101	
Positive (At any time)	14/ 25 (56.0)	55.1	14/ 35 (40.0)	43.6	1.24 (0.74, 2.09)	0.4107	11.55 (-14.68, 37.78)	0.3881	
BMI (kg/m2) at enrolment									0.3596
< 30	160/233 (68.7)	68.7	146/261 (55.9)	56.2	1.23 (1.07, 1.41)	0.0037	12.55 (4.06, 21.04)	0.0038	
>= 30	82/127 (64.6)	65.4	61/105 (58.1)	58.4	1.09 (0.89, 1.34)	0.3904	7.04 (-5.50, 19.58)	0.2709	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Constitutional
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 52	Number of subjects with events, n (%)	3 (0.8)	4 (1.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.76 (0.18, 3.32)	
	p-value	0.7186	
	Odds Ratio (95% CI)	0.76 (0.17, 3.45)	
	p-value	0.7207	
	Risk Difference (95% CI)	-0.26 (-1.68, 1.16)	
	p-value	0.7190	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.76 (0.17, 3.40)	
	p-value	0.7208	
	Odds Ratio (95% CI)	0.76 (0.17, 3.44)	
	p-value	0.7213	
	Risk Difference (95% CI)	-0.26 (-1.68, 1.16)	
	p-value	0.7176	
	CMH approach		
	Response rate	0.8	1.1
	Difference in response rates (95% CI)	-0.24 (-3.61, 3.12)	
	p-value	0.8870	
	p-Value for test for heterogenity between studies	0.8039	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Constitutional - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.3617
< 10 points	1/109 (0.9)	0.9	0/106 (0.0)	0.0	2.89 (0.12, 69.40)	0.5127	0.91 (-6.89, 8.71)	0.8191	
>= 10 points	2/251 (0.8)	0.8	4/260 (1.5)	1.5	0.53 (0.09, 3.06)	0.4819	-0.74 (-4.57, 3.09)	0.7062	
OCS dose at baseline									0.8646
<10 mg/day	2/170 (1.2)	1.1	3/181 (1.7)	1.7	0.72 (0.12, 4.34)	0.7168	-0.54 (-6.10, 5.02)	0.8483	
>=10 mg/day	1/190 (0.5)	0.5	1/185 (0.5)	0.5	0.95 (0.06, 15.00)	0.9733	-0.03 (-4.09, 4.04)	0.9903	
Result of type I IFN gene signature test									0.3072
LOW	2/ 62 (3.2)	3.2	1/ 64 (1.6)	1.6	1.65 (0.21, 13.01)	0.6352	1.66 (-7.68, 11.00)	0.7272	
HIGH	1/298 (0.3)	0.3	3/302 (1.0)	1.0	0.34 (0.04, 3.19)	0.3419	-0.65 (-4.22, 2.93)	0.7233	
Age (years)									0.2980
<= 65	3/348 (0.9)	0.9	3/362 (0.8)	0.8	0.99 (0.21, 4.66)	0.9864	0.05 (-3.36, 3.46)	0.9762	
> 65	0/ 12 (0.0)	0.0	1/ 4 (25.0)	23.9	0.17 (0.01, 3.24)	0.2366	-23.86 (-77.50, 29.77)	0.3832	
Sex									NE
male	0/ 27 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.55, 17.55)	1.0000	
female	3/333 (0.9)	0.9	4/341 (1.2)	1.2	0.76 (0.17, 3.41)	0.7251	-0.26 (-3.87, 3.34)	0.8856	
Race									0.3654
White	2/235 (0.9)	0.9	4/244 (1.6)	1.7	0.53 (0.09, 3.01)	0.4711	-0.82 (-5.36, 3.73)	0.7248	
Black	0/ 46 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-10.79, 10.79)	1.0000	
Other	1/ 71 (1.4)	1.4	0/ 66 (0.0)	0.0	2.80 (0.12, 67.00)	0.5242	1.41 (-6.43, 9.25)	0.7243	
Ethnicity									0.3332
Hispanic/Latino	1/ 86 (1.2)	1.2	0/ 89 (0.0)	0.0	3.27 (0.14, 77.57)	0.4629	1.20 (-6.79, 9.19)	0.7681	
Non-hispanic/Latino	2/266 (0.8)	0.7	4/269 (1.5)	1.4	0.57 (0.12, 2.70)	0.4831	-0.70 (-5.10, 3.70)	0.7538	
Geographic region									0.1300
EU	0/115 (0.0)	0.0	3/122 (2.5)	2.7	0.13 (0.01, 2.43)	0.1719	-2.68 (-7.91, 2.55)	0.3157	
non-EU	3/245 (1.2)	1.3	1/244 (0.4)	0.4	2.04 (0.27, 15.71)	0.4918	0.84 (-3.86, 5.55)	0.7255	
Onset of disease									0.2178
Paediatric	0/ 26 (0.0)	0.0	2/ 24 (8.3)	8.6	0.17 (0.01, 3.29)	0.2433	-8.64 (-28.56, 11.27)	0.3950	
Adult	3/334 (0.9)	0.9	2/342 (0.6)	0.6	1.52 (0.25, 9.28)	0.6488	0.31 (-3.22, 3.83)	0.8648	
ADA result									0.5258
Negative	3/334 (0.9)	0.9	3/331 (0.9)	0.9	0.92 (0.19, 4.33)	0.9137	-0.02 (-3.64, 3.61)	0.9930	
Positive (At any time)	0/ 25 (0.0)	0.0	1/ 35 (2.9)	3.9	0.30 (0.01, 6.77)	0.4461	-3.88 (-21.87, 14.10)	0.6722	
BMI (kg/m2) at enrolment									0.9511
< 30	2/233 (0.9)	0.8	3/261 (1.1)	1.2	0.71 (0.12, 4.21)	0.7103	-0.33 (-4.62, 3.96)	0.8807	
>= 30	1/127 (0.8)	0.8	1/105 (1.0)	1.0	0.79 (0.05, 12.38)	0.8678	-0.18 (-7.68, 7.31)	0.9620	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Mucocutaneous
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 52	Number of subjects with events, n (%)	97 (26.9)	126 (34.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.78 (0.63, 0.98)	
	p-value	0.0300	
	Odds Ratio (95% CI)	0.70 (0.51, 0.96)	
	p-value	0.0292	
	Risk Difference (95% CI)	-7.47 (-14.14, -0.80)	
	p-value	0.0282	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.79 (0.63, 0.98)	
	p-value	0.0335	
	Odds Ratio (95% CI)	0.70 (0.51, 0.97)	
	p-value	0.0315	
	Risk Difference (95% CI)	-7.48 (-14.18, -0.78)	
	p-value	0.0288	
	CMH approach		
	Response rate	26.9	34.4
	Difference in response rates (95% CI)	-7.45 (-14.18, -0.72)	
	p-value	0.0301	
	p-Value for test for heterogenity between studies	0.0586	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Mucocutaneous - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.2246
< 10 points	21/109 (19.3)	19.3	34/106 (32.1)	31.8	0.61 (0.38, 0.99)	0.0464	-12.47 (-24.40, -0.54)	0.0405	
>= 10 points	76/251 (30.3)	30.1	92/260 (35.4)	35.4	0.86 (0.67, 1.10)	0.2275	-5.32 (-13.46, 2.82)	0.2002	
OCS dose at baseline									0.3363
<10 mg/day	42/170 (24.7)	24.5	64/181 (35.4)	35.4	0.70 (0.50, 0.97)	0.0316	-10.86 (-20.51, -1.20)	0.0275	
>=10 mg/day	55/190 (28.9)	29.1	62/185 (33.5)	33.3	0.87 (0.64, 1.19)	0.3811	-4.23 (-13.63, 5.17)	0.3780	
Result of type I IFN gene signature test									0.4851
LOW	19/ 62 (30.6)	30.6	21/ 64 (32.8)	32.8	0.93 (0.55, 1.56)	0.7786	-2.17 (-18.61, 14.27)	0.7959	
HIGH	78/298 (26.2)	26.1	105/302 (34.8)	34.7	0.76 (0.59, 0.97)	0.0265	-8.56 (-15.94, -1.18)	0.0230	
Age (years)									0.3142
<= 65	93/348 (26.7)	26.7	124/362 (34.3)	34.2	0.78 (0.62, 0.98)	0.0345	-7.47 (-14.27, -0.67)	0.0313	
> 65	4/ 12 (33.3)	31.8	2/ 4 (50.0)	52.3	0.48 (0.18, 1.22)	0.1227	-20.45 (-76.63, 35.72)	0.4754	
Sex									0.7414
male	6/ 27 (22.2)	22.9	11/ 25 (44.0)	44.1	0.70 (0.30, 1.64)	0.4097	-21.21 (-46.67, 4.25)	0.1025	
female	91/333 (27.3)	27.3	115/341 (33.7)	33.7	0.81 (0.64, 1.02)	0.0745	-6.41 (-13.41, 0.58)	0.0722	
Race									0.4070
White	74/235 (31.5)	31.3	87/244 (35.7)	35.3	0.88 (0.68, 1.14)	0.3467	-3.97 (-12.46, 4.52)	0.3591	
Black	6/ 46 (13.0)	14.2	11/ 48 (22.9)	24.1	0.68 (0.26, 1.75)	0.4195	-9.84 (-27.12, 7.45)	0.2647	
Other	17/ 71 (23.9)	23.9	26/ 66 (39.4)	39.4	0.61 (0.36, 1.01)	0.0558	-15.44 (-31.09, 0.22)	0.0533	
Ethnicity									0.1173
Hispanic/Latino	25/ 86 (29.1)	29.0	23/ 89 (25.8)	26.0	1.13 (0.70, 1.83)	0.6169	3.01 (-10.74, 16.75)	0.6681	
Non-hispanic/Latino	72/266 (27.1)	27.1	101/269 (37.5)	37.3	0.73 (0.57, 0.94)	0.0160	-10.24 (-18.20, -2.28)	0.0117	
Geographic region									0.9258
EU	29/115 (25.2)	25.3	40/122 (32.8)	32.1	0.78 (0.51, 1.17)	0.2320	-6.76 (-18.28, 4.76)	0.2502	
non-EU	68/245 (27.8)	27.8	86/244 (35.2)	35.3	0.80 (0.61, 1.04)	0.0909	-7.48 (-15.77, 0.82)	0.0773	
Onset of disease									0.6416
Paediatric	6/ 26 (23.1)	22.5	10/ 24 (41.7)	41.7	0.65 (0.27, 1.55)	0.3304	-19.14 (-45.27, 7.00)	0.1512	
Adult	91/334 (27.2)	27.3	116/342 (33.9)	33.9	0.80 (0.64, 1.01)	0.0630	-6.66 (-13.64, 0.33)	0.0618	
ADA result									0.3635
Negative	89/334 (26.6)	26.6	116/331 (35.0)	34.8	0.76 (0.60, 0.96)	0.0237	-8.18 (-15.24, -1.13)	0.0229	
Positive (At any time)	8/ 25 (32.0)	32.8	10/ 35 (28.6)	29.9	1.11 (0.51, 2.41)	0.7900	2.94 (-22.46, 28.34)	0.8208	
BMI (kg/m2) at enrolment									0.1730
< 30	54/233 (23.2)	23.2	89/261 (34.1)	33.9	0.69 (0.51, 0.92)	0.0127	-10.76 (-18.77, -2.74)	0.0085	
>= 30	43/127 (33.9)	33.7	37/105 (35.2)	35.0	0.95 (0.67, 1.36)	0.7803	-1.33 (-13.76, 11.09)	0.8334	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Neuropsychiatric
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 52	Number of subjects with events, n (%)	4 (1.1)	1 (0.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	4.23 (0.45, 39.32)	
	p-value	0.2054	
	Odds Ratio (95% CI)	4.23 (0.46, 38.53)	
	p-value	0.2013	
	Risk Difference (95% CI)	0.85 (-0.36, 2.06)	
	p-value	0.1680	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	4.09 (0.46, 36.23)	
	p-value	0.2058	
	Odds Ratio (95% CI)	4.16 (0.46, 37.58)	
	p-value	0.2044	
	Risk Difference (95% CI)	0.84 (-0.36, 2.05)	
	p-value	0.1714	
	CMH approach		
	Response rate	1.1	0.3
	Difference in response rates (95% CI)	0.88 (-2.43, 4.18)	
	p-value	0.6043	
	p-Value for test for heterogenity between studies	NE	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Neuropsychiatric - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.1274
< 10 points	0/109 (0.0)	0.0	1/106 (0.9)	0.9	0.33 (0.01, 7.86)	0.4912	-0.89 (-8.69, 6.91)	0.8230	
>= 10 points	4/251 (1.6)	1.6	0/260 (0.0)	0.0	9.36 (0.51, 172.02)	0.1322	1.61 (-2.13, 5.35)	0.3986	
OCS dose at baseline									0.9709
<10 mg/day	3/170 (1.8)	1.8	1/181 (0.6)	0.5	3.19 (0.34, 30.06)	0.3098	1.21 (-4.30, 6.72)	0.6664	
>=10 mg/day	1/190 (0.5)	0.5	0/185 (0.0)	0.0	2.97 (0.12, 72.09)	0.5033	0.54 (-3.41, 4.48)	0.7891	
Result of type I IFN gene signature test									0.9961
LOW	1/ 62 (1.6)	1.6	0/ 64 (0.0)	0.0	3.09 (0.13, 73.19)	0.4846	1.61 (-6.90, 10.13)	0.7106	
HIGH	3/298 (1.0)	1.0	1/302 (0.3)	0.3	3.06 (0.32, 29.09)	0.3302	0.72 (-2.86, 4.30)	0.6937	
Age (years)									NE
<= 65	4/348 (1.1)	1.2	1/362 (0.3)	0.3	4.18 (0.47, 37.07)	0.1984	0.93 (-2.46, 4.31)	0.5921	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE		0.00 (-51.08, 51.08)	1.0000	
Sex									0.9313
male	1/ 27 (3.7)	3.6	0/ 25 (0.0)	0.0	2.63 (0.12, 59.40)	0.5442	3.58 (-14.77, 21.93)	0.7021	
female	3/333 (0.9)	0.9	1/341 (0.3)	0.3	3.11 (0.33, 29.59)	0.3238	0.63 (-2.87, 4.14)	0.7240	
Race									0.9320
White	3/235 (1.3)	1.3	1/244 (0.4)	0.4	3.29 (0.35, 31.20)	0.2998	0.89 (-3.52, 5.29)	0.6930	
Black	0/ 46 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-10.79, 10.79)	1.0000	
Other	1/ 71 (1.4)	1.4	0/ 66 (0.0)	0.0	2.78 (0.12, 65.08)	0.5255	1.40 (-6.39, 9.19)	0.7240	
Ethnicity									0.9677
Hispanic/Latino	1/ 86 (1.2)	1.2	0/ 89 (0.0)	0.0	3.27 (0.14, 77.57)	0.4629	1.20 (-6.79, 9.19)	0.7681	
Non-hispanic/Latino	3/266 (1.1)	1.1	1/269 (0.4)	0.3	3.02 (0.32, 28.70)	0.3360	0.75 (-3.56, 5.07)	0.7329	
Geographic region									0.9036
EU	1/115 (0.9)	0.9	0/122 (0.0)	0.0	3.55 (0.15, 85.76)	0.4350	0.92 (-3.87, 5.71)	0.7061	
non-EU	3/245 (1.2)	1.2	1/244 (0.4)	0.4	2.79 (0.29, 26.45)	0.3705	0.80 (-3.90, 5.49)	0.7398	
Onset of disease									NE
Paediatric	0/ 26 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-18.15, 18.15)	1.0000	
Adult	4/334 (1.2)	1.2	1/342 (0.3)	0.3	4.10 (0.46, 36.26)	0.2052	0.92 (-2.61, 4.46)	0.6089	
ADA result									NE
Negative	4/334 (1.2)	1.2	1/331 (0.3)	0.3	4.17 (0.47, 36.94)	0.1991	0.97 (-2.62, 4.56)	0.5968	
Positive (At any time)	0/ 25 (0.0)	0.0	0/ 35 (0.0)	0.0	NE		0.00 (-17.02, 17.02)	1.0000	
BMI (kg/m2) at enrolment									0.1867
< 30	0/233 (0.0)	0.0	1/261 (0.4)	0.4	0.39 (0.02, 9.51)	0.5645	-0.42 (-4.50, 3.67)	0.8419	
>= 30	4/127 (3.1)	3.0	0/105 (0.0)	0.0	7.15 (0.39, 130.13)	0.1839	2.95 (-4.71, 10.61)	0.4501	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Musculoskeletal
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 52	Number of subjects with events, n (%)	68 (18.9)	75 (20.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.93 (0.69, 1.24)	
	p-value	0.6098	
	Odds Ratio (95% CI)	0.91 (0.63, 1.32)	
	p-value	0.6086	
	Risk Difference (95% CI)	-1.50 (-7.22, 4.23)	
	p-value	0.6084	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.92 (0.69, 1.24)	
	p-value	0.5929	
	Odds Ratio (95% CI)	0.90 (0.63, 1.30)	
	p-value	0.5889	
	Risk Difference (95% CI)	-1.60 (-7.38, 4.19)	
	p-value	0.5884	
	CMH approach		
	Response rate	18.9	20.4
	Difference in response rates (95% CI)	-1.44 (-7.44, 4.56)	
	p-value	0.6379	
	p-Value for test for heterogenity between studies	0.7203	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Musculoskeletal - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.5928
< 10 points	22/109 (20.2)	20.2	26/106 (24.5)	24.3	0.82 (0.50, 1.36)	0.4439	-4.11 (-15.92, 7.69)	0.4944	
>= 10 points	46/251 (18.3)	18.4	49/260 (18.8)	18.7	0.97 (0.68, 1.40)	0.8857	-0.34 (-7.32, 6.63)	0.9232	
OCS dose at baseline									0.6692
<10 mg/day	38/170 (22.4)	22.2	46/181 (25.4)	25.5	0.88 (0.61, 1.29)	0.5186	-3.29 (-12.51, 5.94)	0.4850	
>=10 mg/day	30/190 (15.8)	15.8	29/185 (15.7)	15.6	1.01 (0.63, 1.61)	0.9759	0.17 (-7.54, 7.89)	0.9650	
Result of type I IFN gene signature test									0.2633
LOW	17/ 62 (27.4)	27.4	14/ 64 (21.9)	21.9	1.26 (0.68, 2.33)	0.4555	5.54 (-9.95, 21.03)	0.4834	
HIGH	51/298 (17.1)	17.1	61/302 (20.2)	20.1	0.85 (0.61, 1.19)	0.3338	-2.91 (-9.39, 3.58)	0.3794	
Age (years)									0.6654
<= 65	66/348 (19.0)	19.0	74/362 (20.4)	20.3	0.93 (0.69, 1.25)	0.6286	-1.28 (-7.35, 4.79)	0.6799	
> 65	2/ 12 (16.7)	15.9	1/ 4 (25.0)	23.9	0.62 (0.10, 3.83)	0.6051	-7.95 (-63.15, 47.24)	0.7776	
Sex									0.6711
male	3/ 27 (11.1)	10.7	2/ 25 (8.0)	8.0	1.34 (0.23, 7.82)	0.7423	2.75 (-18.38, 23.89)	0.7984	
female	65/333 (19.5)	19.6	73/341 (21.4)	21.4	0.91 (0.68, 1.23)	0.5471	-1.78 (-8.09, 4.54)	0.5810	
Race									0.0200
White	51/235 (21.7)	21.7	44/244 (18.0)	18.1	1.20 (0.84, 1.73)	0.3148	3.65 (-3.92, 11.21)	0.3450	
Black	6/ 46 (13.0)	12.2	17/ 48 (35.4)	36.7	0.35 (0.15, 0.82)	0.0154	-24.42 (-42.19, -6.65)	0.0071	
Other	10/ 71 (14.1)	14.1	14/ 66 (21.2)	21.2	0.66 (0.32, 1.39)	0.2792	-7.13 (-20.75, 6.49)	0.3050	
Ethnicity									0.4640
Hispanic/Latino	12/ 86 (14.0)	13.8	17/ 89 (19.1)	19.2	0.72 (0.37, 1.42)	0.3499	-5.40 (-17.52, 6.71)	0.3822	
Non-hispanic/Latino	55/266 (20.7)	20.6	58/269 (21.6)	21.3	0.96 (0.69, 1.33)	0.8024	-0.73 (-7.93, 6.46)	0.8415	
Geographic region									0.0792
EU	18/115 (15.7)	15.8	12/122 (9.8)	9.5	1.58 (0.78, 3.17)	0.2034	6.22 (-2.85, 15.30)	0.1789	
non-EU	50/245 (20.4)	20.7	63/244 (25.8)	25.7	0.79 (0.57, 1.09)	0.1538	-5.08 (-12.84, 2.68)	0.1991	
Onset of disease									0.7328
Paediatric	3/ 26 (11.5)	11.4	4/ 24 (16.7)	16.4	0.71 (0.15, 3.36)	0.6689	-4.94 (-27.98, 18.11)	0.6745	
Adult	65/334 (19.5)	19.4	71/342 (20.8)	20.8	0.94 (0.69, 1.27)	0.6813	-1.37 (-7.66, 4.92)	0.6691	
ADA result									0.4048
Negative	63/334 (18.9)	18.9	65/331 (19.6)	19.5	0.96 (0.71, 1.32)	0.8160	-0.63 (-6.89, 5.63)	0.8443	
Positive (At any time)	5/ 25 (20.0)	20.7	10/ 35 (28.6)	33.4	0.63 (0.25, 1.62)	0.3395	-12.72 (-37.16, 11.71)	0.3074	
BMI (kg/m2) at enrolment									0.2382
< 30	40/233 (17.2)	17.1	43/261 (16.5)	16.4	1.04 (0.70, 1.55)	0.8354	0.65 (-6.39, 7.69)	0.8565	
>= 30	28/127 (22.0)	22.0	32/105 (30.5)	30.1	0.73 (0.47, 1.14)	0.1630	-8.07 (-19.74, 3.60)	0.1754	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Cardiorespiratory
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 52	Number of subjects with events, n (%)	4 (1.1)	3 (0.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.46 (0.32, 6.55)	
	p-value	0.6241	
	Odds Ratio (95% CI)	1.46 (0.32, 6.57)	
	p-value	0.6247	
	Risk Difference (95% CI)	0.36 (-1.07, 1.79)	
	p-value	0.6233	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.36 (0.30, 6.05)	
	p-value	0.6886	
	Odds Ratio (95% CI)	1.36 (0.30, 6.17)	
	p-value	0.6892	
	Risk Difference (95% CI)	0.29 (-1.13, 1.72)	
	p-value	0.6857	
	CMH approach		
	Response rate	1.1	0.8
	Difference in response rates (95% CI)	0.33 (-3.06, 3.71)	
	p-value	0.8497	
	p-Value for test for heterogenity between studies	0.8039	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Cardiorespiratory - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.3271
< 10 points	0/109 (0.0)	0.0	1/106 (0.9)	0.9	0.33 (0.01, 7.86)	0.4912	-0.89 (-8.65, 6.87)	0.8224	
>= 10 points	4/251 (1.6)	1.6	2/260 (0.8)	0.8	2.01 (0.35, 11.48)	0.4340	0.84 (-3.00, 4.69)	0.6671	
OCS dose at baseline									0.1224
<10 mg/day	3/170 (1.8)	1.8	0/181 (0.0)	0.0	4.18 (0.47, 37.43)	0.2012	1.76 (-3.69, 7.22)	0.5259	
>=10 mg/day	1/190 (0.5)	0.6	3/185 (1.6)	1.6	0.42 (0.06, 2.85)	0.3764	-1.00 (-5.22, 3.22)	0.6420	
Result of type I IFN gene signature test									0.7816
LOW	2/ 62 (3.2)	3.2	2/ 64 (3.1)	3.1	1.09 (0.17, 7.19)	0.9283	0.10 (-9.60, 9.80)	0.9840	
HIGH	2/298 (0.7)	0.7	1/302 (0.3)	0.3	1.62 (0.20, 13.11)	0.6493	0.38 (-3.18, 3.93)	0.8360	
Age (years)									NE
<= 65	4/348 (1.1)	1.2	3/362 (0.8)	0.8	1.39 (0.31, 6.19)	0.6664	0.37 (-3.08, 3.83)	0.8325	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE		0.00 (-51.08, 51.08)	1.0000	
Sex									0.2929
male	0/ 27 (0.0)	0.0	1/ 25 (4.0)	4.1	0.29 (0.01, 6.60)	0.4388	-4.13 (-22.67, 14.40)	0.6621	
female	4/333 (1.2)	1.2	2/341 (0.6)	0.6	1.99 (0.35, 11.39)	0.4412	0.65 (-2.93, 4.23)	0.7217	
Race									0.3182
White	4/235 (1.7)	1.7	2/244 (0.8)	0.8	1.88 (0.40, 8.86)	0.4236	0.85 (-3.69, 5.39)	0.7142	
Black	0/ 46 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-10.79, 10.79)	1.0000	
Other	0/ 71 (0.0)	0.0	1/ 66 (1.5)	1.5	0.31 (0.01, 7.44)	0.4714	-1.51 (-9.41, 6.38)	0.7074	
Ethnicity									0.5155
Hispanic/Latino	1/ 86 (1.2)	1.2	0/ 89 (0.0)	0.0	3.27 (0.14, 77.57)	0.4629	1.20 (-6.79, 9.19)	0.7681	
Non-hispanic/Latino	3/266 (1.1)	1.2	3/269 (1.1)	1.1	1.01 (0.21, 4.96)	0.9901	0.08 (-4.35, 4.51)	0.9716	
Geographic region									0.7275
EU	2/115 (1.7)	1.7	1/122 (0.8)	0.8	1.69 (0.21, 13.54)	0.6202	0.95 (-4.25, 6.15)	0.7205	
non-EU	2/245 (0.8)	0.8	2/244 (0.8)	0.8	1.02 (0.15, 6.92)	0.9806	0.06 (-4.65, 4.76)	0.9816	
Onset of disease									NE
Paediatric	0/ 26 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-18.15, 18.15)	1.0000	
Adult	4/334 (1.2)	1.2	3/342 (0.9)	0.9	1.36 (0.31, 6.08)	0.6838	0.34 (-3.27, 3.94)	0.8553	
ADA result									0.6357
Negative	4/334 (1.2)	1.2	2/331 (0.6)	0.6	1.80 (0.38, 8.50)	0.4582	0.64 (-2.99, 4.27)	0.7296	
Positive (At any time)	0/ 25 (0.0)	0.0	1/ 35 (2.9)	2.1	0.78 (0.03, 17.33)	0.8739	-2.09 (-19.43, 15.26)	0.8135	
BMI (kg/m2) at enrolment									0.6538
< 30	3/233 (1.3)	1.3	2/261 (0.8)	0.8	1.68 (0.28, 10.22)	0.5730	0.54 (-3.80, 4.88)	0.8068	
>= 30	1/127 (0.8)	0.8	1/105 (1.0)	1.0	0.79 (0.05, 12.38)	0.8678	-0.18 (-7.68, 7.31)	0.9620	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Gastrointestinal
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 52	Number of subjects with events, n (%)	0 (0.0)	3 (0.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.00 (NE, NE)	
	p-value	NE	
	Odds Ratio (95% CI)	0.00 (NE, NE)	
	p-value	NE	
	Risk Difference (95% CI)	-0.84 (-1.78, 0.10)	
	p-value	0.0786	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.26 (0.03, 2.33)	
	p-value	0.2282	
	Odds Ratio (95% CI)	0.26 (0.03, 2.34)	
	p-value	0.2274	
	Risk Difference (95% CI)	-0.82 (-1.74, 0.10)	
	p-value	0.0819	
	CMH approach		
	Response rate	0.0	0.8
	Difference in response rates (95% CI)	-0.84 (-4.07, 2.39)	
	p-value	0.6104	
	p-Value for test for heterogenity between studies	0.8163	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Gastrointestinal - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.7933
< 10 points	0/109 (0.0)	0.0	2/106 (1.9)	1.9	0.19 (0.01, 3.92)	0.2841	-1.91 (-9.87, 6.04)	0.6376	
>= 10 points	0/251 (0.0)	0.0	1/260 (0.4)	0.4	0.35 (0.01, 8.43)	0.5152	-0.39 (-3.93, 3.16)	0.8297	
OCS dose at baseline									0.9640
<10 mg/day	0/170 (0.0)	0.0	1/181 (0.6)	0.6	0.35 (0.01, 8.60)	0.5239	-0.59 (-5.83, 4.66)	0.8270	
>=10 mg/day	0/190 (0.0)	0.0	2/185 (1.1)	1.1	0.32 (0.03, 3.09)	0.3272	-1.08 (-5.15, 2.99)	0.6040	
Result of type I IFN gene signature test									NE
LOW	0/ 62 (0.0)	0.0	0/ 64 (0.0)	0.0	NE		0.00 (-8.05, 8.05)	1.0000	
HIGH	0/298 (0.0)	0.0	3/302 (1.0)	1.0	0.26 (0.03, 2.32)	0.2269	-1.02 (-4.54, 2.51)	0.5718	
Age (years)									NE
<= 65	0/348 (0.0)	0.0	3/362 (0.8)	0.9	0.26 (0.03, 2.39)	0.2361	-0.86 (-4.16, 2.44)	0.6107	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE		0.00 (-51.08, 51.08)	1.0000	
Sex									NE
male	0/ 27 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.55, 17.55)	1.0000	
female	0/333 (0.0)	0.0	3/341 (0.9)	0.9	0.26 (0.03, 2.35)	0.2305	-0.89 (-4.34, 2.57)	0.6146	
Race									0.9815
White	0/235 (0.0)	0.0	1/244 (0.4)	0.4	0.37 (0.02, 8.88)	0.5360	-0.40 (-4.64, 3.84)	0.8523	
Black	0/ 46 (0.0)	0.0	1/ 48 (2.1)	1.8	0.48 (0.02, 11.17)	0.6486	-1.76 (-12.94, 9.41)	0.7571	
Other	0/ 71 (0.0)	0.0	1/ 66 (1.5)	1.5	0.31 (0.01, 7.44)	0.4714	-1.51 (-9.41, 6.38)	0.7074	
Ethnicity									NE
Hispanic/Latino	0/ 86 (0.0)	0.0	0/ 89 (0.0)	0.0	NE		0.00 (-7.72, 7.72)	1.0000	
Non-hispanic/Latino	0/266 (0.0)	0.0	3/269 (1.1)	1.2	0.26 (0.03, 2.32)	0.2263	-1.16 (-5.43, 3.11)	0.5939	
Geographic region									0.7794
EU	0/115 (0.0)	0.0	1/122 (0.8)	0.8	0.39 (0.02, 9.53)	0.5673	-0.78 (-5.48, 3.93)	0.7466	
non-EU	0/245 (0.0)	0.0	2/244 (0.8)	0.8	0.21 (0.01, 4.35)	0.3134	-0.83 (-5.43, 3.76)	0.7217	
Onset of disease									0.9323
Paediatric	0/ 26 (0.0)	0.0	1/ 24 (4.2)	4.3	0.29 (0.01, 6.50)	0.4344	-4.32 (-23.46, 14.82)	0.6581	
Adult	0/334 (0.0)	0.0	2/342 (0.6)	0.6	0.34 (0.04, 3.26)	0.3508	-0.59 (-4.01, 2.82)	0.7339	
ADA result									NE
Negative	0/334 (0.0)	0.0	3/331 (0.9)	0.9	0.25 (0.03, 2.27)	0.2187	-0.94 (-4.44, 2.57)	0.6012	
Positive (At any time)	0/ 25 (0.0)	0.0	0/ 35 (0.0)	0.0	NE		0.00 (-17.02, 17.02)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/233 (0.0)	0.0	3/261 (1.1)	1.1	0.29 (0.03, 2.56)	0.2626	-1.12 (-5.28, 3.04)	0.5971	
>= 30	0/127 (0.0)	0.0	0/105 (0.0)	0.0	NE		0.00 (-7.26, 7.26)	1.0000	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Ophthalmic
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 52	Number of subjects with events, n (%)	0 (0.0)	1 (0.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.00 (NE, NE)	
	p-value	NE	
	Odds Ratio (95% CI)	0.00 (NE, NE)	
	p-value	NE	
	Risk Difference (95% CI)	-0.26 (-0.78, 0.26)	
	p-value	0.3308	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.34 (0.01, 8.22)	
	p-value	0.5045	
	Odds Ratio (95% CI)	0.34 (0.01, 8.28)	
	p-value	0.5041	
	Risk Difference (95% CI)	-0.27 (-0.81, 0.26)	
	p-value	0.3160	
	CMH approach		
	Response rate	0.0	0.3
	Difference in response rates (95% CI)	-0.26 (-3.42, 2.90)	
	p-value	0.8728	
	p-Value for test for heterogenity between studies	NE	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Ophthalmic - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/109 (0.0)	0.0	0/106 (0.0)	0.0	NE		0.00 (-7.66, 7.66)	1.0000	
>= 10 points	0/251 (0.0)	0.0	1/260 (0.4)	0.4	0.34 (0.01, 8.36)	0.5120	-0.37 (-3.90, 3.17)	0.8389	
OCS dose at baseline									NE
<10 mg/day	0/170 (0.0)	0.0	1/181 (0.6)	0.5	0.35 (0.01, 8.60)	0.5239	-0.53 (-5.79, 4.72)	0.8419	
>=10 mg/day	0/190 (0.0)	0.0	0/185 (0.0)	0.0	NE		0.00 (-3.82, 3.82)	1.0000	
Result of type I IFN gene signature test									NE
LOW	0/ 62 (0.0)	0.0	0/ 64 (0.0)	0.0	NE		0.00 (-8.05, 8.05)	1.0000	
HIGH	0/298 (0.0)	0.0	1/302 (0.3)	0.3	0.34 (0.01, 8.17)	0.5026	-0.31 (-3.74, 3.12)	0.8583	
Age (years)									NE
<= 65	0/348 (0.0)	0.0	1/362 (0.3)	0.3	0.34 (0.01, 8.40)	0.5134	-0.26 (-3.49, 2.97)	0.8741	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE		0.00 (-51.08, 51.08)	1.0000	
Sex									NE
male	0/ 27 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.55, 17.55)	1.0000	
female	0/333 (0.0)	0.0	1/341 (0.3)	0.3	0.34 (0.01, 8.22)	0.5048	-0.29 (-3.67, 3.10)	0.8688	
Race									NE
White	0/235 (0.0)	0.0	1/244 (0.4)	0.4	0.32 (0.01, 7.87)	0.4890	-0.41 (-4.66, 3.84)	0.8494	
Black	0/ 46 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-10.79, 10.79)	1.0000	
Other	0/ 71 (0.0)	0.0	0/ 66 (0.0)	0.0	NE		0.00 (-7.43, 7.43)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 86 (0.0)	0.0	0/ 89 (0.0)	0.0	NE		0.00 (-7.72, 7.72)	1.0000	
Non-hispanic/Latino	0/266 (0.0)	0.0	1/269 (0.4)	0.3	0.34 (0.01, 8.24)	0.5063	-0.34 (-4.53, 3.84)	0.8720	
Geographic region									NE
EU	0/115 (0.0)	0.0	1/122 (0.8)	0.9	0.30 (0.01, 7.22)	0.4591	-0.89 (-5.65, 3.86)	0.7131	
non-EU	0/245 (0.0)	0.0	0/244 (0.0)	0.0	NE		0.00 (-4.51, 4.51)	1.0000	
Onset of disease									NE
Paediatric	0/ 26 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-18.15, 18.15)	1.0000	
Adult	0/334 (0.0)	0.0	1/342 (0.3)	0.3	0.34 (0.01, 8.32)	0.5094	-0.28 (-3.66, 3.09)	0.8687	
ADA result									NE
Negative	0/334 (0.0)	0.0	1/331 (0.3)	0.3	0.31 (0.01, 7.65)	0.4772	-0.29 (-3.73, 3.14)	0.8673	
Positive (At any time)	0/ 25 (0.0)	0.0	0/ 35 (0.0)	0.0	NE		0.00 (-17.02, 17.02)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/233 (0.0)	0.0	1/261 (0.4)	0.4	0.36 (0.01, 8.69)	0.5272	-0.38 (-4.46, 3.70)	0.8547	
>= 30	0/127 (0.0)	0.0	0/105 (0.0)	0.0	NE		0.00 (-7.26, 7.26)	1.0000	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Renal
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 52	Number of subjects with events, n (%)	12 (3.3)	18 (4.9)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.67 (0.33, 1.36)	
	p-value	0.2689	
	Odds Ratio (95% CI)	0.65 (0.30, 1.39)	
	p-value	0.2679	
	Risk Difference (95% CI)	-1.62 (-4.46, 1.22)	
	p-value	0.2640	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.68 (0.33, 1.40)	
	p-value	0.2937	
	Odds Ratio (95% CI)	0.67 (0.32, 1.41)	
	p-value	0.2920	
	Risk Difference (95% CI)	-1.58 (-4.47, 1.31)	
	p-value	0.2828	
	CMH approach		
	Response rate	3.3	4.9
	Difference in response rates (95% CI)	-1.62 (-5.71, 2.48)	
	p-value	0.4389	
	p-Value for test for heterogenity between studies	0.6373	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Renal - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.6265
< 10 points	0/109 (0.0)	0.0	1/106 (0.9)	0.9	0.33 (0.01, 7.86)	0.4912	-0.89 (-8.69, 6.91)	0.8230	
>= 10 points	12/251 (4.8)	4.7	17/260 (6.5)	6.6	0.74 (0.36, 1.52)	0.4050	-1.92 (-6.99, 3.15)	0.4579	
OCS dose at baseline									0.5473
<10 mg/day	2/170 (1.2)	1.2	5/181 (2.8)	2.7	0.43 (0.08, 2.20)	0.3106	-1.48 (-7.26, 4.30)	0.6151	
>=10 mg/day	10/190 (5.3)	5.3	13/185 (7.0)	7.0	0.75 (0.34, 1.67)	0.4832	-1.68 (-7.63, 4.28)	0.5812	
Result of type I IFN gene signature test									NE
LOW	0/ 62 (0.0)	0.0	0/ 64 (0.0)	0.0	NE		0.00 (-8.05, 8.05)	1.0000	
HIGH	12/298 (4.0)	4.0	18/302 (6.0)	6.0	0.68 (0.33, 1.39)	0.2880	-1.96 (-6.61, 2.70)	0.4101	
Age (years)									NE
<= 65	12/348 (3.4)	3.4	18/362 (5.0)	5.0	0.70 (0.34, 1.43)	0.3233	-1.57 (-5.75, 2.61)	0.4626	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE		0.00 (-51.08, 51.08)	1.0000	
Sex									0.6295
male	1/ 27 (3.7)	3.6	3/ 25 (12.0)	11.8	0.45 (0.06, 3.22)	0.4237	-8.26 (-28.90, 12.37)	0.4324	
female	11/333 (3.3)	3.3	15/341 (4.4)	4.5	0.75 (0.35, 1.61)	0.4638	-1.18 (-5.44, 3.08)	0.5877	
Race									0.7901
White	6/235 (2.6)	2.6	9/244 (3.7)	3.7	0.81 (0.27, 2.45)	0.7093	-1.04 (-6.09, 4.01)	0.6862	
Black	2/ 46 (4.3)	3.9	1/ 48 (2.1)	2.4	1.59 (0.15, 16.42)	0.6988	1.42 (-10.93, 13.78)	0.8212	
Other	4/ 71 (5.6)	5.6	8/ 66 (12.1)	12.1	0.63 (0.19, 2.11)	0.4581	-6.48 (-17.75, 4.78)	0.2594	
Ethnicity									0.9815
Hispanic/Latino	4/ 86 (4.7)	4.4	6/ 89 (6.7)	7.0	0.72 (0.20, 2.56)	0.6071	-2.61 (-12.42, 7.20)	0.6021	
Non-hispanic/Latino	8/266 (3.0)	3.2	12/269 (4.5)	4.3	0.70 (0.28, 1.74)	0.4467	-1.16 (-6.20, 3.88)	0.6517	
Geographic region									0.7374
EU	4/115 (3.5)	3.7	6/122 (4.9)	4.9	0.87 (0.25, 2.96)	0.8214	-1.20 (-7.82, 5.41)	0.7216	
non-EU	8/245 (3.3)	3.2	12/244 (4.9)	5.0	0.67 (0.28, 1.61)	0.3719	-1.86 (-7.32, 3.59)	0.5032	
Onset of disease									0.5663
Paediatric	4/ 26 (15.4)	15.4	4/ 24 (16.7)	16.7	0.93 (0.26, 3.30)	0.9060	-1.23 (-25.05, 22.58)	0.9191	
Adult	8/334 (2.4)	2.4	14/342 (4.1)	4.1	0.59 (0.25, 1.40)	0.2320	-1.70 (-5.82, 2.42)	0.4186	
ADA result									0.9630
Negative	10/334 (3.0)	3.0	14/331 (4.2)	4.2	0.71 (0.32, 1.57)	0.3959	-1.15 (-5.41, 3.10)	0.5953	
Positive (At any time)	2/ 25 (8.0)	6.9	4/ 35 (11.4)	11.9	0.74 (0.16, 3.49)	0.7016	-5.09 (-25.71, 15.54)	0.6286	
BMI (kg/m2) at enrolment									0.6138
< 30	8/233 (3.4)	3.5	11/261 (4.2)	4.1	0.82 (0.33, 2.03)	0.6739	-0.64 (-5.72, 4.44)	0.8059	
>= 30	4/127 (3.1)	3.0	7/105 (6.7)	6.7	0.54 (0.14, 2.09)	0.3746	-3.69 (-12.30, 4.93)	0.4019	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Haematological
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 52	Number of subjects with events, n (%)	2 (0.6)	0 (0.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	NE	
	p-value		
	Odds Ratio (95% CI)	NE	
	p-value		
	Risk Difference (95% CI)	0.56 (-0.21, 1.33)	
	p-value	0.1557	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	3.05 (0.32, 29.18)	
	p-value	0.3332	
	Odds Ratio (95% CI)	3.07 (0.32, 29.62)	
	p-value	0.3328	
	Risk Difference (95% CI)	0.56 (-0.21, 1.32)	
	p-value	0.1561	
	CMH approach		
	Response rate	0.6	0.0
	Difference in response rates (95% CI)	0.56 (-2.63, 3.75)	
	p-value	0.7319	
	p-Value for test for heterogenity between studies	0.9962	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score A or B at week 52 - Haematological - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	2/109 (1.8)	1.9	0/106 (0.0)	0.0	2.92 (0.31, 27.62)	0.3503	1.88 (-6.07, 9.84)	0.6424	
>= 10 points	0/251 (0.0)	0.0	0/260 (0.0)	0.0	NE		0.00 (-3.47, 3.47)	1.0000	
OCS dose at baseline									NE
<10 mg/day	2/170 (1.2)	1.2	0/181 (0.0)	0.0	3.19 (0.34, 30.39)	0.3128	1.15 (-4.17, 6.48)	0.6710	
>=10 mg/day	0/190 (0.0)	0.0	0/185 (0.0)	0.0	NE		0.00 (-3.82, 3.82)	1.0000	
Result of type I IFN gene signature test									NE
LOW	0/ 62 (0.0)	0.0	0/ 64 (0.0)	0.0	NE		0.00 (-8.05, 8.05)	1.0000	
HIGH	2/298 (0.7)	0.7	0/302 (0.0)	0.0	3.04 (0.32, 29.06)	0.3344	0.68 (-2.80, 4.15)	0.7030	
Age (years)									NE
<= 65	2/348 (0.6)	0.6	0/362 (0.0)	0.0	3.12 (0.33, 29.85)	0.3234	0.58 (-2.69, 3.84)	0.7285	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE		0.00 (-51.08, 51.08)	1.0000	
Sex									NE
male	0/ 27 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.55, 17.55)	1.0000	
female	2/333 (0.6)	0.6	0/341 (0.0)	0.0	3.07 (0.32, 29.38)	0.3300	0.60 (-2.81, 4.01)	0.7297	
Race									0.9036
White	1/235 (0.4)	0.4	0/244 (0.0)	0.0	3.29 (0.14, 79.92)	0.4651	0.43 (-3.80, 4.66)	0.8404	
Black	1/ 46 (2.2)	2.6	0/ 48 (0.0)	0.0	4.33 (0.19, 100.49)	0.3606	2.59 (-8.91, 14.10)	0.6585	
Other	0/ 71 (0.0)	0.0	0/ 66 (0.0)	0.0	NE		0.00 (-7.43, 7.43)	1.0000	
Ethnicity									0.9755
Hispanic/Latino	1/ 86 (1.2)	1.2	0/ 89 (0.0)	0.0	3.27 (0.14, 77.57)	0.4629	1.20 (-6.79, 9.19)	0.7681	
Non-hispanic/Latino	1/266 (0.4)	0.4	0/269 (0.0)	0.0	3.05 (0.13, 74.13)	0.4933	0.35 (-3.82, 4.53)	0.8680	
Geographic region									NE
EU	0/115 (0.0)	0.0	0/122 (0.0)	0.0	NE		0.00 (-4.48, 4.48)	1.0000	
non-EU	2/245 (0.8)	0.8	0/244 (0.0)	0.0	2.97 (0.31, 28.38)	0.3440	0.82 (-3.78, 5.42)	0.7261	
Onset of disease									NE
Paediatric	0/ 26 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-18.15, 18.15)	1.0000	
Adult	2/334 (0.6)	0.6	0/342 (0.0)	0.0	3.07 (0.32, 29.38)	0.3301	0.58 (-2.83, 3.98)	0.7392	
ADA result									NE
Negative	2/334 (0.6)	0.6	0/331 (0.0)	0.0	2.97 (0.31, 28.44)	0.3442	0.62 (-2.85, 4.09)	0.7261	
Positive (At any time)	0/ 25 (0.0)	0.0	0/ 35 (0.0)	0.0	NE		0.00 (-17.02, 17.02)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/233 (0.0)	0.0	0/261 (0.0)	0.0	NE		0.00 (-4.03, 4.03)	1.0000	
>= 30	2/127 (1.6)	1.5	0/105 (0.0)	0.0	2.50 (0.26, 23.70)	0.4241	1.50 (-5.95, 8.95)	0.6938	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Major clinical response at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 52	Number of subjects with events, n (%)	77 (21.4)	49 (13.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.61 (1.16, 2.22)	
	p-value	0.0042	
	Odds Ratio (95% CI)	1.79 (1.20, 2.66)	
	p-value	0.0040	
	Risk Difference (95% CI)	8.10 (2.65, 13.56)	
	p-value	0.0036	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.59 (1.15, 2.21)	
	p-value	0.0056	
	Odds Ratio (95% CI)	1.76 (1.19, 2.61)	
	p-value	0.0049	
	Risk Difference (95% CI)	8.01 (2.53, 13.49)	
	p-value	0.0042	
	CMH approach		
	Response rate	21.5	13.4
	Difference in response rates (95% CI)	8.06 (2.25, 13.86)	
	p-value	0.0065	
	p-Value for test for heterogenity between studies	0.4034	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Major clinical response at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.5836
< 10 points	31/109 (28.4)	28.3	17/106 (16.0)	16.2	1.77 (1.04, 3.00)	0.0343	12.18 (0.42, 23.95)	0.0424	
>= 10 points	46/251 (18.3)	18.5	32/260 (12.3)	12.2	1.46 (0.96, 2.23)	0.0743	6.29 (-0.36, 12.95)	0.0637	
OCS dose at baseline									0.4620
<10 mg/day	42/170 (24.7)	24.9	25/181 (13.8)	13.8	1.79 (1.14, 2.80)	0.0111	11.05 (2.27, 19.83)	0.0136	
>=10 mg/day	35/190 (18.4)	18.3	24/185 (13.0)	12.9	1.40 (0.87, 2.26)	0.1688	5.34 (-2.32, 12.99)	0.1718	
Result of type I IFN gene signature test									0.4743
LOW	12/ 62 (19.4)	19.4	10/ 64 (15.6)	15.6	1.23 (0.56, 2.68)	0.6017	3.73 (-10.49, 17.95)	0.6071	
HIGH	65/298 (21.8)	21.9	39/302 (12.9)	12.9	1.68 (1.17, 2.42)	0.0049	8.97 (2.61, 15.32)	0.0057	
Age (years)									0.2816
<= 65	76/348 (21.8)	21.9	48/362 (13.3)	13.2	1.64 (1.18, 2.28)	0.0034	8.65 (2.75, 14.55)	0.0040	
> 65	1/ 12 (8.3)	10.2	1/ 4 (25.0)	23.9	0.43 (0.04, 4.82)	0.4925	-13.64 (-68.56, 41.29)	0.6265	
Sex									0.3722
male	6/ 27 (22.2)	22.0	1/ 25 (4.0)	3.9	3.41 (0.58, 19.99)	0.1737	18.18 (-3.75, 40.12)	0.1043	
female	71/333 (21.3)	21.4	48/341 (14.1)	14.0	1.50 (1.08, 2.10)	0.0169	7.32 (1.28, 13.36)	0.0175	
Race									0.9786
White	48/235 (20.4)	20.8	32/244 (13.1)	13.1	1.57 (1.04, 2.36)	0.0305	7.79 (0.63, 14.95)	0.0330	
Black	12/ 46 (26.1)	25.8	7/ 48 (14.6)	15.7	1.60 (0.70, 3.67)	0.2674	10.12 (-7.57, 27.81)	0.2623	
Other	14/ 71 (19.7)	19.7	9/ 66 (13.6)	13.6	1.44 (0.65, 3.19)	0.3703	6.09 (-7.25, 19.43)	0.3706	
Ethnicity									0.2643
Hispanic/Latino	16/ 86 (18.6)	18.4	16/ 89 (18.0)	17.8	1.16 (0.58, 2.32)	0.6679	0.58 (-11.60, 12.76)	0.9253	
Non-hispanic/Latino	58/266 (21.8)	21.6	32/269 (11.9)	12.1	1.83 (1.23, 2.72)	0.0027	9.51 (2.71, 16.31)	0.0061	
Geographic region									0.6849
EU	32/115 (27.8)	28.3	20/122 (16.4)	16.2	1.76 (1.07, 2.88)	0.0253	12.10 (1.32, 22.88)	0.0279	
non-EU	45/245 (18.4)	18.9	29/244 (11.9)	12.0	1.53 (0.99, 2.37)	0.0545	6.89 (-0.18, 13.97)	0.0562	
Onset of disease									0.4016
Paediatric	5/ 26 (19.2)	19.1	1/ 24 (4.2)	4.3	3.23 (0.58, 18.11)	0.1820	14.81 (-7.53, 37.16)	0.1938	
Adult	72/334 (21.6)	21.6	48/342 (14.0)	14.0	1.53 (1.09, 2.13)	0.0130	7.59 (1.50, 13.67)	0.0145	
ADA result									0.4800
Negative	71/334 (21.3)	21.3	46/331 (13.9)	13.9	1.53 (1.09, 2.15)	0.0139	7.41 (1.30, 13.51)	0.0174	
Positive (At any time)	6/ 25 (24.0)	24.1	3/ 35 (8.6)	9.9	2.46 (0.69, 8.83)	0.1664	14.29 (-8.59, 37.17)	0.2209	
BMI (kg/m2) at enrolment									0.8495
< 30	54/233 (23.2)	23.2	38/261 (14.6)	14.4	1.59 (1.09, 2.32)	0.0160	8.78 (1.53, 16.03)	0.0177	
>= 30	23/127 (18.1)	18.7	11/105 (10.5)	10.8	1.71 (0.88, 3.34)	0.1155	7.89 (-2.42, 18.21)	0.1336	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Partial clinical response at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 52	Number of subjects with events, n (%)	166 (46.1)	144 (39.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.18 (0.99, 1.39)	
	p-value	0.0587	
	Odds Ratio (95% CI)	1.33 (0.99, 1.79)	
	p-value	0.0584	
	Risk Difference (95% CI)	6.96 (-0.22, 14.13)	
	p-value	0.0574	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.17 (0.99, 1.39)	
	p-value	0.0665	
	Odds Ratio (95% CI)	1.32 (0.98, 1.77)	
	p-value	0.0656	
	Risk Difference (95% CI)	6.77 (-0.41, 13.95)	
	p-value	0.0647	
	CMH approach		
	Response rate	46.1	39.3
	Difference in response rates (95% CI)	6.79 (-0.36, 13.95)	
	p-value	0.0628	
	p-Value for test for heterogenity between studies	0.6908	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Partial clinical response at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9124
< 10 points	56/109 (51.4)	51.4	46/106 (43.4)	43.3	1.19 (0.90, 1.57)	0.2333	8.03 (-5.23, 21.29)	0.2352	
>= 10 points	110/251 (43.8)	43.9	98/260 (37.7)	37.6	1.16 (0.94, 1.44)	0.1560	6.34 (-2.13, 14.81)	0.1424	
OCS dose at baseline									0.3023
<10 mg/day	80/170 (47.1)	47.1	79/181 (43.6)	43.8	1.08 (0.85, 1.36)	0.5304	3.37 (-7.01, 13.74)	0.5248	
>=10 mg/day	86/190 (45.3)	45.1	65/185 (35.1)	35.3	1.29 (1.00, 1.66)	0.0477	9.79 (-0.08, 19.67)	0.0518	
Result of type I IFN gene signature test									0.2253
LOW	27/ 62 (43.5)	43.6	30/ 64 (46.9)	46.9	0.95 (0.65, 1.39)	0.7874	-3.32 (-20.58, 13.94)	0.7061	
HIGH	139/298 (46.6)	46.6	114/302 (37.7)	37.7	1.24 (1.02, 1.49)	0.0281	8.92 (1.06, 16.78)	0.0261	
Age (years)									0.4985
<= 65	159/348 (45.7)	45.6	143/362 (39.5)	39.4	1.16 (0.97, 1.37)	0.0966	6.23 (-1.00, 13.47)	0.0914	
> 65	7/ 12 (58.3)	58.0	1/ 4 (25.0)	23.9	1.89 (0.46, 7.82)	0.3774	34.09 (-22.49, 90.67)	0.2377	
Sex									0.6005
male	15/ 27 (55.6)	55.6	10/ 25 (40.0)	39.7	1.36 (0.76, 2.43)	0.3044	15.98 (-10.84, 42.79)	0.2429	
female	151/333 (45.3)	45.4	134/341 (39.3)	39.2	1.15 (0.97, 1.38)	0.1145	6.19 (-1.23, 13.60)	0.1019	
Race									0.2466
White	101/235 (43.0)	43.4	99/244 (40.6)	40.5	1.05 (0.85, 1.30)	0.6218	2.88 (-5.92, 11.68)	0.5209	
Black	20/ 46 (43.5)	43.2	16/ 48 (33.3)	35.6	1.16 (0.70, 1.91)	0.5661	7.66 (-12.22, 27.54)	0.4500	
Other	40/ 71 (56.3)	56.3	24/ 66 (36.4)	36.4	1.52 (1.05, 2.21)	0.0278	19.95 (3.60, 36.29)	0.0168	
Ethnicity									0.4616
Hispanic/Latino	42/ 86 (48.8)	48.5	41/ 89 (46.1)	45.8	1.07 (0.78, 1.46)	0.6955	2.70 (-12.01, 17.40)	0.7194	
Non-hispanic/Latino	119/266 (44.7)	44.6	98/269 (36.4)	36.7	1.23 (1.00, 1.51)	0.0513	7.89 (-0.42, 16.20)	0.0629	
Geographic region									0.5780
EU	63/115 (54.8)	54.9	53/122 (43.4)	43.9	1.24 (0.95, 1.60)	0.1113	10.98 (-1.66, 23.63)	0.0887	
non-EU	103/245 (42.0)	42.3	91/244 (37.3)	37.2	1.12 (0.90, 1.40)	0.3051	5.05 (-3.63, 13.73)	0.2540	
Onset of disease									0.1457
Paediatric	12/ 26 (46.2)	46.3	5/ 24 (20.8)	20.7	2.21 (0.92, 5.33)	0.0779	25.62 (-0.62, 51.86)	0.0557	
Adult	154/334 (46.1)	46.1	139/342 (40.6)	40.6	1.13 (0.95, 1.35)	0.1525	5.52 (-1.91, 12.95)	0.1454	
ADA result									0.3947
Negative	157/334 (47.0)	46.9	137/331 (41.4)	41.4	1.14 (0.96, 1.35)	0.1469	5.54 (-1.96, 13.04)	0.1475	
Positive (At any time)	9/ 25 (36.0)	34.4	7/ 35 (20.0)	18.2	1.76 (0.65, 4.80)	0.2659	16.22 (-8.02, 40.45)	0.1897	
BMI (kg/m2) at enrolment									0.1646
< 30	115/233 (49.4)	49.2	101/261 (38.7)	38.9	1.28 (1.04, 1.56)	0.0172	10.36 (1.67, 19.05)	0.0195	
>= 30	51/127 (40.2)	40.9	43/105 (41.0)	41.0	0.98 (0.72, 1.34)	0.9025	-0.13 (-12.87, 12.61)	0.9842	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
>=50% Joint reduction at week 52 (for subjects with at least 6 tender joints and swollen joints at baseline)
Full analysis set

Timepoint		Anifrolumab 300mg (N=164)	Placebo (N=190)
Week 52	Number of subjects with events, n (%)	81 (49.4)	71 (37.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.36 (1.07, 1.73)	
	p-value	0.0135	
	Odds Ratio (95% CI)	1.72 (1.12, 2.65)	
	p-value	0.0135	
	Risk Difference (95% CI)	13.23 (2.86, 23.60)	
	p-value	0.0124	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.32 (1.04, 1.68)	
	p-value	0.0244	
	Odds Ratio (95% CI)	1.62 (1.06, 2.48)	
	p-value	0.0265	
	Risk Difference (95% CI)	11.80 (1.50, 22.11)	
	p-value	0.0248	
	CMH approach		
	Response rate	49.4	36.8
	Difference in response rates (95% CI)	12.63 (2.36, 22.91)	
	p-value	0.0160	
	p-Value for test for heterogenity between studies	0.2637	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
>=50% Joint reduction at week 52 (for subjects with at least 6 tender joints and swollen joints at baseline) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=164) n/ N (%)	Response rate	Placebo (N=190) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9260
< 10 points	26/ 52 (50.0)	49.5	21/ 54 (38.9)	38.9	1.30 (0.84, 2.01)	0.2350	10.51 (-8.09, 29.11)	0.2681	
>= 10 points	55/112 (49.1)	49.8	50/136 (36.8)	36.2	1.33 (1.00, 1.79)	0.0524	13.58 (1.24, 25.93)	0.0310	
OCS dose at baseline									0.6933
<10 mg/day	42/ 81 (51.9)	52.4	35/ 93 (37.6)	37.0	1.39 (0.99, 1.94)	0.0561	15.44 (0.79, 30.09)	0.0389	
>=10 mg/day	39/ 83 (47.0)	46.4	36/ 97 (37.1)	37.1	1.26 (0.88, 1.79)	0.2014	9.31 (-5.14, 23.75)	0.2066	
Result of type I IFN gene signature test									0.5264
LOW	17/ 35 (48.6)	48.5	10/ 33 (30.3)	30.4	1.59 (0.86, 2.95)	0.1407	18.14 (-5.01, 41.29)	0.1247	
HIGH	64/129 (49.6)	49.7	61/157 (38.9)	38.4	1.28 (0.98, 1.67)	0.0683	11.29 (-0.17, 22.76)	0.0536	
Age (years)									0.0910
<= 65	77/158 (48.7)	48.8	69/187 (36.9)	36.3	1.32 (1.03, 1.69)	0.0285	12.46 (2.04, 22.89)	0.0191	
> 65	4/ 6 (66.7)	66.7	2/ 3 (66.7)	66.7	0.78 (0.45, 1.36)	0.3854	0.00 (-66.75, 66.75)	1.0000	
Sex									0.4281
male	4/ 11 (36.4)	30.8	5/ 10 (50.0)	46.2	0.85 (0.27, 2.72)	0.7842	-15.38 (-60.12, 29.35)	0.5003	
female	77/153 (50.3)	50.1	66/180 (36.7)	36.6	1.37 (1.07, 1.76)	0.0122	13.47 (2.89, 24.06)	0.0126	
Race									0.4473
White	57/115 (49.6)	50.4	57/138 (41.3)	40.8	1.22 (0.93, 1.60)	0.1536	9.63 (-2.63, 21.89)	0.1238	
Black	9/ 24 (37.5)	37.9	6/ 24 (25.0)	22.5	1.61 (0.61, 4.24)	0.3318	15.44 (-12.93, 43.81)	0.2861	
Other	12/ 21 (57.1)	55.9	7/ 25 (28.0)	27.9	1.99 (0.93, 4.25)	0.0765	27.94 (0.08, 55.80)	0.0494	
Ethnicity									0.8008
Hispanic/Latino	22/ 45 (48.9)	48.6	14/ 40 (35.0)	34.9	1.38 (0.82, 2.34)	0.2280	13.76 (-7.14, 34.65)	0.1970	
Non-hispanic/Latino	56/115 (48.7)	48.6	56/147 (38.1)	38.1	1.28 (0.96, 1.70)	0.0874	10.48 (-1.65, 22.61)	0.0902	
Geographic region									0.5790
EU	32/ 46 (69.6)	69.7	33/ 59 (55.9)	56.0	1.25 (0.93, 1.67)	0.1471	13.63 (-4.92, 32.19)	0.1498	
non-EU	49/118 (41.5)	41.0	38/131 (29.0)	28.6	1.42 (1.00, 2.02)	0.0518	12.44 (0.50, 24.37)	0.0411	
Onset of disease									0.6616
Paediatric	3/ 7 (42.9)	43.6	2/ 9 (22.2)	23.1	1.83 (0.40, 8.34)	0.4330	20.51 (-27.92, 68.95)	0.4065	
Adult	78/157 (49.7)	49.9	69/181 (38.1)	37.7	1.30 (1.02, 1.66)	0.0353	12.23 (1.68, 22.78)	0.0231	
ADA result									0.3104
Negative	76/152 (50.0)	49.9	69/178 (38.8)	38.6	1.30 (1.01, 1.66)	0.0381	11.28 (0.62, 21.94)	0.0381	
Positive (At any time)	5/ 11 (45.5)	46.1	2/ 12 (16.7)	16.7	2.80 (0.64, 12.18)	0.1693	29.41 (-12.18, 71.01)	0.1658	
BMI (kg/m2) at enrolment									0.3682
< 30	54/ 98 (55.1)	55.0	50/131 (38.2)	38.2	1.47 (1.10, 1.94)	0.0082	16.88 (4.12, 29.63)	0.0095	
>= 30	27/ 66 (40.9)	40.7	21/ 59 (35.6)	35.6	1.15 (0.73, 1.80)	0.5519	5.12 (-12.01, 22.26)	0.5579	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
>=50% Joint reduction at week 52 (for subjects with at least 8 tender joints and swollen joints at baseline)
Full analysis set

Timepoint		Anifrolumab 300mg (N=115)	Placebo (N=140)
Week 52	Number of subjects with events, n (%)	55 (47.8)	48 (34.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.50 (1.10, 2.04)	
	p-value	0.0096	
	Odds Ratio (95% CI)	2.06 (1.20, 3.55)	
	p-value	0.0090	
	Risk Difference (95% CI)	16.52 (4.36, 28.68)	
	p-value	0.0077	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.38 (1.01, 1.87)	
	p-value	0.0419	
	Odds Ratio (95% CI)	1.70 (1.02, 2.84)	
	p-value	0.0437	
	Risk Difference (95% CI)	12.71 (0.56, 24.87)	
	p-value	0.0404	
	CMH approach		
	Response rate	47.2	33.5
	Difference in response rates (95% CI)	13.71 (1.65, 25.77)	
	p-value	0.0259	
	p-Value for test for heterogenity between studies	0.2269	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
>=50% Joint reduction at week 52 (for subjects with at least 8 tender joints and swollen joints at baseline) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=115) n/ N (%)	Response rate	Placebo (N=140) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8414
< 10 points	20/ 37 (54.1)	53.9	17/ 41 (41.5)	41.5	1.34 (0.85, 2.12)	0.2073	12.39 (-9.20, 33.97)	0.2607	
>= 10 points	35/ 78 (44.9)	45.4	31/ 99 (31.3)	30.9	1.43 (0.96, 2.13)	0.0816	14.55 (-0.05, 29.15)	0.0508	
OCS dose at baseline									0.4359
<10 mg/day	30/ 57 (52.6)	51.8	22/ 66 (33.3)	32.9	1.55 (1.00, 2.40)	0.0507	18.83 (1.48, 36.17)	0.0334	
>=10 mg/day	25/ 58 (43.1)	41.9	26/ 74 (35.1)	35.4	1.21 (0.78, 1.88)	0.3982	6.49 (-10.32, 23.30)	0.4495	
Result of type I IFN gene signature test									0.4860
LOW	14/ 31 (45.2)	44.8	6/ 25 (24.0)	24.4	1.80 (0.82, 3.96)	0.1410	20.39 (-4.74, 45.52)	0.1118	
HIGH	41/ 84 (48.8)	47.9	42/115 (36.5)	36.1	1.33 (0.94, 1.87)	0.1022	11.77 (-1.98, 25.51)	0.0934	
Age (years)									0.2641
<= 65	53/111 (47.7)	47.1	47/138 (34.1)	33.2	1.39 (1.01, 1.90)	0.0422	13.88 (1.66, 26.10)	0.0260	
> 65	2/ 4 (50.0)	50.0	1/ 2 (50.0)	50.0	0.67 (0.20, 2.30)	0.5274	0.00 (-83.73, 83.73)	1.0000	
Sex									0.1736
male	3/ 9 (33.3)	30.8	4/ 6 (66.7)	64.1	0.64 (0.20, 2.04)	0.4486	-33.33 (-84.50, 17.83)	0.2017	
female	52/106 (49.1)	48.7	44/134 (32.8)	32.2	1.47 (1.07, 2.03)	0.0173	16.45 (3.99, 28.91)	0.0096	
Race									0.4955
White	41/ 83 (49.4)	49.2	39/100 (39.0)	37.4	1.26 (0.90, 1.77)	0.1719	11.79 (-2.58, 26.16)	0.1078	
Black	7/ 19 (36.8)	36.2	4/ 18 (22.2)	17.8	1.79 (0.47, 6.84)	0.3962	18.46 (-14.50, 51.41)	0.2723	
Other	6/ 12 (50.0)	51.2	5/ 21 (23.8)	24.0	2.24 (0.87, 5.76)	0.0951	27.24 (-6.95, 61.42)	0.1184	
Ethnicity									0.7630
Hispanic/Latino	16/ 35 (45.7)	45.7	12/ 33 (36.4)	36.2	1.25 (0.70, 2.24)	0.4517	9.47 (-13.96, 32.91)	0.4282	
Non-hispanic/Latino	38/ 79 (48.1)	45.6	36/106 (34.0)	34.8	1.39 (0.96, 2.02)	0.0827	10.83 (-3.50, 25.16)	0.1384	
Geographic region									0.9548
EU	18/ 23 (78.3)	78.0	20/ 37 (54.1)	54.3	1.44 (0.98, 2.10)	0.0633	23.76 (-1.58, 49.09)	0.0661	
non-EU	37/ 92 (40.2)	39.9	28/103 (27.2)	25.8	1.46 (0.96, 2.22)	0.0755	14.11 (0.67, 27.56)	0.0396	
Onset of disease									0.8251
Paediatric	1/ 4 (25.0)	23.8	2/ 8 (25.0)	23.8	1.12 (0.19, 6.69)	0.9008	0.00 (-58.99, 58.99)	1.0000	
Adult	54/111 (48.6)	47.9	46/132 (34.8)	34.2	1.37 (1.01, 1.88)	0.0448	13.74 (1.34, 26.14)	0.0298	
ADA result									0.1646
Negative	51/105 (48.6)	48.1	46/129 (35.7)	34.3	1.35 (0.99, 1.85)	0.0591	13.77 (1.21, 26.34)	0.0317	
Positive (At any time)	4/ 9 (44.4)	49.7	2/ 11 (18.2)	17.3	3.53 (0.95, 13.21)	0.0605	32.40 (-12.80, 77.60)	0.1600	
BMI (kg/m2) at enrolment									0.3874
< 30	33/ 62 (53.2)	52.2	33/ 97 (34.0)	33.9	1.56 (1.07, 2.28)	0.0211	18.33 (2.85, 33.81)	0.0203	
>= 30	22/ 53 (41.5)	41.0	15/ 43 (34.9)	35.0	1.17 (0.70, 1.98)	0.5475	6.03 (-13.69, 25.75)	0.5488	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Low Disease Activity State at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 52	Number of subjects with events, n (%)	63 (17.5)	39 (10.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.65 (1.14, 2.39)	
	p-value	0.0085	
	Odds Ratio (95% CI)	1.79 (1.16, 2.77)	
	p-value	0.0082	
	Risk Difference (95% CI)	6.87 (1.85, 11.89)	
	p-value	0.0073	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.64 (1.13, 2.38)	
	p-value	0.0088	
	Odds Ratio (95% CI)	1.78 (1.16, 2.74)	
	p-value	0.0083	
	Risk Difference (95% CI)	6.86 (1.83, 11.89)	
	p-value	0.0075	
	CMH approach		
	Response rate	17.5	10.6
	Difference in response rates (95% CI)	6.83 (1.39, 12.27)	
	p-value	0.0139	
	p-Value for test for heterogenity between studies	0.8676	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Low Disease Activity State at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.2241
< 10 points	23/109 (21.1)	21.2	18/106 (17.0)	16.8	1.24 (0.71, 2.17)	0.4449	4.33 (-7.07, 15.73)	0.4567	
>= 10 points	40/251 (15.9)	15.9	21/260 (8.1)	8.0	1.97 (1.20, 3.24)	0.0074	7.86 (1.73, 13.99)	0.0119	
OCS dose at baseline									0.3300
<10 mg/day	30/170 (17.6)	17.7	23/181 (12.7)	12.8	1.39 (0.84, 2.28)	0.2009	4.87 (-3.28, 13.01)	0.2420	
>=10 mg/day	33/190 (17.4)	17.4	16/185 (8.6)	8.6	2.01 (1.15, 3.53)	0.0146	8.71 (1.47, 15.96)	0.0184	
Result of type I IFN gene signature test									0.0525
LOW	11/ 62 (17.7)	17.7	13/ 64 (20.3)	20.3	0.87 (0.42, 1.80)	0.7143	-2.57 (-17.13, 11.99)	0.7296	
HIGH	52/298 (17.4)	17.4	26/302 (8.6)	8.6	2.02 (1.30, 3.14)	0.0018	8.81 (2.98, 14.64)	0.0031	
Age (years)									0.7241
<= 65	62/348 (17.8)	17.8	39/362 (10.8)	10.7	1.65 (1.14, 2.40)	0.0079	7.08 (1.54, 12.62)	0.0122	
> 65	1/ 12 (8.3)	5.7	0/ 4 (0.0)	0.0	1.00 (0.06, 15.99)	1.0000	5.68 (-45.70, 57.06)	0.8284	
Sex									0.3413
male	7/ 27 (25.9)	26.2	2/ 25 (8.0)	8.0	3.26 (0.74, 14.25)	0.1168	18.18 (-4.89, 41.26)	0.1225	
female	56/333 (16.8)	16.8	37/341 (10.9)	10.8	1.55 (1.06, 2.28)	0.0252	6.00 (0.34, 11.66)	0.0376	
Race									0.4207
White	39/235 (16.6)	16.7	28/244 (11.5)	11.3	1.45 (0.93, 2.28)	0.1042	5.42 (-1.36, 12.19)	0.1169	
Black	11/ 46 (23.9)	23.9	8/ 48 (16.7)	16.1	1.45 (0.62, 3.39)	0.3856	7.76 (-9.71, 25.23)	0.3841	
Other	11/ 71 (15.5)	15.5	2/ 66 (3.0)	3.0	3.76 (0.97, 14.59)	0.0559	12.46 (1.25, 23.67)	0.0294	
Ethnicity									0.7500
Hispanic/Latino	13/ 86 (15.1)	15.7	7/ 89 (7.9)	7.5	1.82 (0.74, 4.48)	0.1901	8.23 (-2.65, 19.11)	0.1384	
Non-hispanic/Latino	48/266 (18.0)	17.9	31/269 (11.5)	11.7	1.55 (1.02, 2.36)	0.0393	6.21 (-0.42, 12.84)	0.0662	
Geographic region									0.6234
EU	28/115 (24.3)	24.6	20/122 (16.4)	16.1	1.52 (0.91, 2.54)	0.1117	8.53 (-2.02, 19.08)	0.1130	
non-EU	35/245 (14.3)	14.2	19/244 (7.8)	7.5	1.83 (1.07, 3.11)	0.0266	6.71 (0.30, 13.12)	0.0403	
Onset of disease									0.8630
Paediatric	3/ 26 (11.5)	11.4	1/ 24 (4.2)	4.0	1.93 (0.27, 13.85)	0.5134	7.41 (-13.75, 28.57)	0.4926	
Adult	60/334 (18.0)	18.0	38/342 (11.1)	11.1	1.62 (1.11, 2.36)	0.0124	6.85 (1.13, 12.58)	0.0190	
ADA result									0.5933
Negative	59/334 (17.7)	17.6	38/331 (11.5)	11.4	1.55 (1.06, 2.26)	0.0240	6.23 (0.46, 12.01)	0.0344	
Positive (At any time)	4/ 25 (16.0)	13.7	1/ 35 (2.9)	2.1	2.76 (0.34, 22.48)	0.3422	11.62 (-8.16, 31.39)	0.2497	
BMI (kg/m2) at enrolment									0.7370
< 30	41/233 (17.6)	17.7	27/261 (10.3)	10.6	1.71 (1.09, 2.69)	0.0196	7.14 (0.40, 13.88)	0.0378	
>= 30	22/127 (17.3)	17.7	12/105 (11.4)	11.3	1.49 (0.78, 2.87)	0.2268	6.40 (-3.87, 16.68)	0.2218	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Mental Component Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 52	Number of subjects with events, n (%)	96 (26.7)	75 (20.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.31 (1.00, 1.72)	
	p-value	0.0478	
	Odds Ratio (95% CI)	1.42 (1.01, 2.00)	
	p-value	0.0461	
	Risk Difference (95% CI)	6.34 (0.14, 12.53)	
	p-value	0.0450	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.30 (1.00, 1.70)	
	p-value	0.0513	
	Odds Ratio (95% CI)	1.41 (1.00, 1.99)	
	p-value	0.0506	
	Risk Difference (95% CI)	6.17 (0.01, 12.33)	
	p-value	0.0497	
	CMH approach		
	Response rate	26.5	20.3
	Difference in response rates (95% CI)	6.12 (-0.14, 12.38)	
	p-value	0.0553	
	p-Value for test for heterogenity between studies	0.9776	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Mental Component Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.0581
< 10 points	40/109 (36.7)	36.6	19/106 (17.9)	17.6	1.82 (1.11, 2.98)	0.0168	19.02 (7.04, 31.01)	0.0019	
>= 10 points	56/251 (22.3)	22.2	56/260 (21.5)	21.5	1.03 (0.74, 1.43)	0.8679	0.74 (-6.59, 8.07)	0.8428	
OCS dose at baseline									0.2599
<10 mg/day	43/170 (25.3)	25.1	41/181 (22.7)	22.6	1.12 (0.77, 1.62)	0.5627	2.56 (-6.62, 11.75)	0.5844	
>=10 mg/day	53/190 (27.9)	27.8	34/185 (18.4)	18.2	1.52 (1.04, 2.22)	0.0318	9.62 (1.06, 18.18)	0.0277	
Result of type I IFN gene signature test									0.1403
LOW	15/ 62 (24.2)	24.2	18/ 64 (28.1)	28.1	0.88 (0.49, 1.58)	0.6602	-3.94 (-19.66, 11.79)	0.6237	
HIGH	81/298 (27.2)	26.9	57/302 (18.9)	18.7	1.44 (1.07, 1.94)	0.0166	8.23 (1.42, 15.05)	0.0179	
Age (years)									0.8404
<= 65	92/348 (26.4)	26.1	74/362 (20.4)	20.2	1.29 (0.99, 1.69)	0.0607	5.96 (-0.35, 12.27)	0.0642	
> 65	4/ 12 (33.3)	31.8	1/ 4 (25.0)	23.9	1.10 (0.23, 5.29)	0.9079	7.95 (-48.22, 64.13)	0.7814	
Sex									0.8198
male	7/ 27 (25.9)	25.9	4/ 25 (16.0)	15.7	1.47 (0.47, 4.65)	0.5097	10.19 (-13.85, 34.24)	0.4061	
female	89/333 (26.7)	26.6	71/341 (20.8)	20.8	1.28 (0.98, 1.69)	0.0731	5.80 (-0.73, 12.33)	0.0819	
Race									0.7611
White	60/235 (25.5)	25.2	52/244 (21.3)	21.4	1.19 (0.86, 1.65)	0.3012	3.79 (-4.05, 11.64)	0.3432	
Black	16/ 46 (34.8)	35.5	12/ 48 (25.0)	26.5	1.29 (0.69, 2.42)	0.4239	9.01 (-10.24, 28.25)	0.3589	
Other	17/ 71 (23.9)	24.0	10/ 66 (15.2)	15.1	1.59 (0.78, 3.21)	0.1984	8.82 (-5.11, 22.74)	0.2147	
Ethnicity									0.6620
Hispanic/Latino	21/ 86 (24.4)	24.9	19/ 89 (21.3)	21.4	1.15 (0.66, 1.99)	0.6194	3.47 (-9.46, 16.40)	0.5987	
Non-hispanic/Latino	72/266 (27.1)	26.7	55/269 (20.4)	20.1	1.32 (0.97, 1.80)	0.0748	6.59 (-0.80, 13.98)	0.0805	
Geographic region									0.6939
EU	32/115 (27.8)	28.1	28/122 (23.0)	23.0	1.22 (0.79, 1.90)	0.3647	5.08 (-6.26, 16.42)	0.3801	
non-EU	64/245 (26.1)	26.2	47/244 (19.3)	19.0	1.37 (0.98, 1.90)	0.0643	7.15 (-0.49, 14.80)	0.0666	
Onset of disease									0.4680
Paediatric	5/ 26 (19.2)	19.1	2/ 24 (8.3)	8.3	2.29 (0.48, 10.77)	0.2960	10.80 (-12.25, 33.85)	0.3583	
Adult	91/334 (27.2)	27.1	73/342 (21.3)	21.4	1.28 (0.98, 1.67)	0.0748	5.74 (-0.84, 12.31)	0.0873	
ADA result									0.2799
Negative	92/334 (27.5)	27.1	68/331 (20.5)	20.5	1.34 (1.02, 1.76)	0.0383	6.65 (0.06, 13.24)	0.0479	
Positive (At any time)	4/ 25 (16.0)	15.5	7/ 35 (20.0)	21.8	0.71 (0.23, 2.17)	0.5440	-6.30 (-29.51, 16.92)	0.5950	
BMI (kg/m2) at enrolment									0.8743
< 30	61/233 (26.2)	26.4	52/261 (19.9)	20.0	1.31 (0.94, 1.81)	0.1070	6.40 (-1.16, 13.95)	0.0972	
>= 30	35/127 (27.6)	27.7	23/105 (21.9)	21.5	1.25 (0.79, 1.98)	0.3442	6.22 (-5.33, 17.77)	0.2912	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Physical Component Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 52	Number of subjects with events, n (%)	118 (32.8)	95 (26.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.27 (1.01, 1.59)	
	p-value	0.0385	
	Odds Ratio (95% CI)	1.40 (1.02, 1.93)	
	p-value	0.0391	
	Risk Difference (95% CI)	7.03 (0.38, 13.68)	
	p-value	0.0382	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.26 (1.00, 1.58)	
	p-value	0.0457	
	Odds Ratio (95% CI)	1.39 (1.01, 1.92)	
	p-value	0.0440	
	Risk Difference (95% CI)	6.83 (0.22, 13.44)	
	p-value	0.0429	
	CMH approach		
	Response rate	32.8	26.1
	Difference in response rates (95% CI)	6.73 (0.02, 13.45)	
	p-value	0.0494	
	p-Value for test for heterogenity between studies	0.5570	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Physical Component Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.1067
< 10 points	38/109 (34.9)	35.2	21/106 (19.8)	20.1	1.73 (1.09, 2.76)	0.0205	15.04 (2.87, 27.21)	0.0155	
>= 10 points	80/251 (31.9)	31.9	74/260 (28.5)	28.7	1.11 (0.85, 1.45)	0.4221	3.20 (-4.84, 11.24)	0.4351	
OCS dose at baseline									0.0674
<10 mg/day	56/170 (32.9)	33.2	37/181 (20.4)	20.4	1.61 (1.12, 2.30)	0.0097	12.77 (3.36, 22.18)	0.0078	
>=10 mg/day	62/190 (32.6)	32.7	58/185 (31.4)	31.3	1.04 (0.77, 1.40)	0.7911	1.43 (-8.09, 10.95)	0.7680	
Result of type I IFN gene signature test									0.7011
LOW	20/ 62 (32.3)	32.3	18/ 64 (28.1)	28.1	1.15 (0.67, 1.95)	0.6135	4.13 (-12.20, 20.47)	0.6199	
HIGH	98/298 (32.9)	33.0	77/302 (25.5)	25.7	1.29 (1.00, 1.66)	0.0496	7.28 (-0.08, 14.65)	0.0527	
Age (years)									0.4336
<= 65	112/348 (32.2)	32.2	93/362 (25.7)	25.8	1.25 (0.99, 1.58)	0.0579	6.44 (-0.34, 13.21)	0.0627	
> 65	6/ 12 (50.0)	47.7	2/ 4 (50.0)	47.7	0.81 (0.28, 2.34)	0.6994	0.00 (-56.58, 56.58)	1.0000	
Sex									0.5402
male	8/ 27 (29.6)	29.2	8/ 25 (32.0)	31.7	0.96 (0.39, 2.38)	0.9356	-2.48 (-28.06, 23.10)	0.8494	
female	110/333 (33.0)	33.0	87/341 (25.5)	25.6	1.29 (1.02, 1.64)	0.0354	7.46 (0.50, 14.42)	0.0357	
Race									0.7521
White	81/235 (34.5)	35.0	71/244 (29.1)	28.9	1.19 (0.91, 1.55)	0.1966	6.10 (-2.36, 14.56)	0.1578	
Black	12/ 46 (26.1)	27.8	11/ 48 (22.9)	22.7	1.26 (0.63, 2.54)	0.5109	5.06 (-13.29, 23.41)	0.5888	
Other	20/ 71 (28.2)	28.2	12/ 66 (18.2)	18.2	1.55 (0.82, 2.91)	0.1759	9.98 (-4.58, 24.54)	0.1793	
Ethnicity									0.8497
Hispanic/Latino	32/ 86 (37.2)	37.0	28/ 89 (31.5)	31.5	1.18 (0.78, 1.78)	0.4287	5.51 (-8.71, 19.72)	0.4478	
Non-hispanic/Latino	81/266 (30.5)	30.7	66/269 (24.5)	24.5	1.24 (0.94, 1.63)	0.1296	6.18 (-1.60, 13.95)	0.1195	
Geographic region									0.7436
EU	47/115 (40.9)	41.2	41/122 (33.6)	33.0	1.22 (0.88, 1.70)	0.2365	8.23 (-3.99, 20.45)	0.1869	
non-EU	71/245 (29.0)	29.4	54/244 (22.1)	22.2	1.32 (0.97, 1.79)	0.0779	7.25 (-0.72, 15.23)	0.0747	
Onset of disease									0.6319
Paediatric	5/ 26 (19.2)	19.1	2/ 24 (8.3)	8.6	1.76 (0.43, 7.25)	0.4327	10.49 (-12.52, 33.51)	0.3715	
Adult	113/334 (33.8)	33.9	93/342 (27.2)	27.2	1.24 (0.99, 1.56)	0.0648	6.68 (-0.34, 13.70)	0.0620	
ADA result									0.6440
Negative	113/334 (33.8)	33.9	88/331 (26.6)	26.8	1.27 (1.01, 1.61)	0.0433	7.13 (0.07, 14.19)	0.0479	
Positive (At any time)	5/ 25 (20.0)	18.9	7/ 35 (20.0)	20.0	0.97 (0.32, 2.96)	0.9628	-1.08 (-24.41, 22.26)	0.9280	
BMI (kg/m2) at enrolment									0.8801
< 30	77/233 (33.0)	33.1	69/261 (26.4)	26.6	1.25 (0.95, 1.64)	0.1064	6.56 (-1.65, 14.77)	0.1173	
>= 30	41/127 (32.3)	32.6	26/105 (24.8)	24.8	1.30 (0.86, 1.98)	0.2176	7.76 (-4.22, 19.74)	0.2044	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - General Health Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 52	Number of subjects with events, n (%)	64 (17.8)	39 (10.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.70 (1.17, 2.47)	
	p-value	0.0050	
	Odds Ratio (95% CI)	1.87 (1.21, 2.88)	
	p-value	0.0047	
	Risk Difference (95% CI)	7.38 (2.34, 12.41)	
	p-value	0.0041	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.67 (1.15, 2.41)	
	p-value	0.0069	
	Odds Ratio (95% CI)	1.81 (1.18, 2.79)	
	p-value	0.0064	
	Risk Difference (95% CI)	7.13 (2.07, 12.18)	
	p-value	0.0057	
	CMH approach		
	Response rate	17.8	10.6
	Difference in response rates (95% CI)	7.16 (1.65, 12.67)	
	p-value	0.0109	
	p-Value for test for heterogenity between studies	0.7492	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - General Health Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.0804
< 10 points	22/109 (20.2)	20.3	7/106 (6.6)	6.7	3.06 (1.37, 6.86)	0.0066	13.64 (3.09, 24.18)	0.0113	
>= 10 points	42/251 (16.7)	16.8	32/260 (12.3)	12.3	1.36 (0.89, 2.08)	0.1614	4.42 (-2.11, 10.95)	0.1849	
OCS dose at baseline									0.1463
<10 mg/day	32/170 (18.8)	18.9	15/181 (8.3)	8.2	2.27 (1.28, 4.04)	0.0052	10.72 (2.70, 18.74)	0.0088	
>=10 mg/day	32/190 (16.8)	16.8	24/185 (13.0)	12.8	1.30 (0.79, 2.12)	0.2975	4.02 (-3.52, 11.57)	0.2958	
Result of type I IFN gene signature test									0.5119
LOW	13/ 62 (21.0)	21.0	10/ 64 (15.6)	15.6	1.34 (0.63, 2.82)	0.4472	5.34 (-9.07, 19.75)	0.4676	
HIGH	51/298 (17.1)	17.1	29/302 (9.6)	9.6	1.78 (1.16, 2.73)	0.0080	7.54 (1.60, 13.48)	0.0129	
Age (years)									0.6608
<= 65	59/348 (17.0)	17.0	39/362 (10.8)	10.7	1.57 (1.08, 2.29)	0.0183	6.22 (0.67, 11.77)	0.0281	
> 65	5/ 12 (41.7)	37.5	0/ 4 (0.0)	0.0	2.41 (0.37, 15.44)	0.3547	37.50 (-16.23, 91.23)	0.1714	
Sex									0.9325
male	4/ 27 (14.8)	14.6	2/ 25 (8.0)	8.0	1.79 (0.34, 9.43)	0.4951	6.61 (-15.21, 28.43)	0.5526	
female	60/333 (18.0)	18.0	37/341 (10.9)	10.8	1.66 (1.13, 2.43)	0.0093	7.20 (1.44, 12.96)	0.0143	
Race									0.5727
White	43/235 (18.3)	18.5	26/244 (10.7)	10.6	1.72 (1.09, 2.71)	0.0187	7.97 (1.05, 14.89)	0.0240	
Black	6/ 46 (13.0)	12.9	6/ 48 (12.5)	12.6	1.03 (0.35, 3.00)	0.9635	0.32 (-15.52, 16.15)	0.9689	
Other	14/ 71 (19.7)	19.7	6/ 66 (9.1)	9.1	2.15 (0.88, 5.25)	0.0940	10.61 (-2.09, 23.32)	0.1015	
Ethnicity									0.1120
Hispanic/Latino	24/ 86 (27.9)	28.0	9/ 89 (10.1)	10.1	2.70 (1.32, 5.52)	0.0064	17.89 (5.63, 30.14)	0.0042	
Non-hispanic/Latino	39/266 (14.7)	14.6	29/269 (10.8)	10.7	1.36 (0.87, 2.14)	0.1781	3.87 (-2.55, 10.29)	0.2374	
Geographic region									0.0839
EU	18/115 (15.7)	16.0	18/122 (14.8)	14.4	1.11 (0.61, 2.01)	0.7354	1.57 (-8.07, 11.21)	0.7496	
non-EU	46/245 (18.8)	19.0	21/244 (8.6)	8.6	2.18 (1.34, 3.55)	0.0016	10.45 (3.55, 17.34)	0.0030	
Onset of disease									0.4574
Paediatric	3/ 26 (11.5)	11.4	0/ 24 (0.0)	0.0	3.64 (0.43, 30.86)	0.2359	11.42 (-8.97, 31.81)	0.2724	
Adult	61/334 (18.3)	18.3	39/342 (11.4)	11.4	1.60 (1.10, 2.32)	0.0133	6.90 (1.08, 12.71)	0.0201	
ADA result									0.8255
Negative	60/334 (18.0)	17.9	37/331 (11.2)	11.2	1.61 (1.10, 2.36)	0.0139	6.70 (0.86, 12.54)	0.0246	
Positive (At any time)	4/ 25 (16.0)	15.5	2/ 35 (5.7)	7.8	1.91 (0.45, 8.19)	0.3839	7.73 (-13.85, 29.32)	0.4826	
BMI (kg/m2) at enrolment									0.9468
< 30	41/233 (17.6)	17.6	28/261 (10.7)	10.7	1.65 (1.06, 2.58)	0.0276	6.89 (0.14, 13.64)	0.0455	
>= 30	23/127 (18.1)	18.8	11/105 (10.5)	10.4	1.70 (0.86, 3.33)	0.1242	8.41 (-1.97, 18.79)	0.1123	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Mental Health Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 52	Number of subjects with events, n (%)	86 (23.9)	46 (12.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.92 (1.37, 2.67)	
	p-value	0.0001	
	Odds Ratio (95% CI)	2.17 (1.47, 3.21)	
	p-value	<.0001	
	Risk Difference (95% CI)	11.42 (5.80, 17.03)	
	p-value	<.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.90 (1.37, 2.64)	
	p-value	0.0001	
	Odds Ratio (95% CI)	2.18 (1.47, 3.23)	
	p-value	<.0001	
	Risk Difference (95% CI)	11.32 (5.76, 16.88)	
	p-value	<.0001	
	CMH approach		
	Response rate	23.8	12.5
	Difference in response rates (95% CI)	11.24 (5.43, 17.05)	
	p-value	0.0002	
	p-Value for test for heterogenity between studies	0.9739	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Mental Health Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.0109
< 10 points	37/109 (33.9)	33.9	8/106 (7.5)	7.6	3.89 (1.88, 8.05)	0.0003	26.31 (15.04, 37.59)	<.0001	
>= 10 points	49/251 (19.5)	19.6	38/260 (14.6)	14.7	1.33 (0.90, 1.96)	0.1479	4.90 (-1.94, 11.74)	0.1603	
OCS dose at baseline									0.5320
<10 mg/day	42/170 (24.7)	24.7	21/181 (11.6)	11.5	2.10 (1.30, 3.41)	0.0026	13.16 (4.62, 21.70)	0.0025	
>=10 mg/day	44/190 (23.2)	23.1	25/185 (13.5)	13.4	1.70 (1.09, 2.67)	0.0204	9.71 (1.74, 17.68)	0.0170	
Result of type I IFN gene signature test									0.0800
LOW	11/ 62 (17.7)	17.7	11/ 64 (17.2)	17.2	1.01 (0.47, 2.17)	0.9857	0.55 (-13.63, 14.73)	0.9394	
HIGH	75/298 (25.2)	25.1	35/302 (11.6)	11.6	2.16 (1.49, 3.12)	<.0001	13.49 (7.12, 19.86)	<.0001	
Age (years)									0.8639
<= 65	83/348 (23.9)	23.7	46/362 (12.7)	12.7	1.88 (1.35, 2.61)	0.0002	11.03 (5.13, 16.92)	0.0002	
> 65	3/ 12 (25.0)	26.1	0/ 4 (0.0)	0.0	1.58 (0.22, 11.26)	0.6499	26.14 (-27.46, 79.73)	0.3391	
Sex									0.3840
male	7/ 27 (25.9)	26.2	5/ 25 (20.0)	19.6	1.23 (0.45, 3.35)	0.6819	6.61 (-17.65, 30.87)	0.5933	
female	79/333 (23.7)	23.7	41/341 (12.0)	12.0	1.97 (1.40, 2.79)	0.0001	11.63 (5.59, 17.68)	0.0002	
Race									0.7015
White	53/235 (22.6)	22.0	32/244 (13.1)	13.1	1.70 (1.14, 2.54)	0.0098	8.93 (1.75, 16.10)	0.0147	
Black	14/ 46 (30.4)	30.3	8/ 48 (16.7)	17.4	1.72 (0.80, 3.70)	0.1620	12.87 (-5.36, 31.11)	0.1664	
Other	16/ 71 (22.5)	22.5	5/ 66 (7.6)	7.6	2.66 (1.00, 7.05)	0.0493	14.96 (2.20, 27.72)	0.0216	
Ethnicity									0.2821
Hispanic/Latino	17/ 86 (19.8)	20.0	13/ 89 (14.6)	15.0	1.35 (0.68, 2.67)	0.3843	5.00 (-7.22, 17.22)	0.4223	
Non-hispanic/Latino	66/266 (24.8)	24.4	32/269 (11.9)	11.8	2.08 (1.41, 3.06)	0.0002	12.63 (5.74, 19.52)	0.0003	
Geographic region									0.1561
EU	28/115 (24.3)	24.6	21/122 (17.2)	17.2	1.43 (0.87, 2.38)	0.1607	7.41 (-3.28, 18.09)	0.1744	
non-EU	58/245 (23.7)	23.9	25/244 (10.2)	10.3	2.32 (1.51, 3.58)	0.0001	13.58 (6.46, 20.71)	0.0002	
Onset of disease									0.7015
Paediatric	4/ 26 (15.4)	15.4	1/ 24 (4.2)	4.0	2.67 (0.44, 16.03)	0.2842	11.42 (-10.35, 33.19)	0.3038	
Adult	82/334 (24.6)	24.5	45/342 (13.2)	13.2	1.87 (1.34, 2.60)	0.0002	11.29 (5.16, 17.41)	0.0003	
ADA result									0.9615
Negative	81/334 (24.3)	24.0	43/331 (13.0)	13.0	1.86 (1.33, 2.61)	0.0003	10.99 (4.86, 17.12)	0.0004	
Positive (At any time)	5/ 25 (20.0)	18.9	3/ 35 (8.6)	9.9	1.93 (0.51, 7.34)	0.3356	9.07 (-13.17, 31.31)	0.4240	
BMI (kg/m2) at enrolment									0.9696
< 30	54/233 (23.2)	23.3	32/261 (12.3)	12.2	1.88 (1.26, 2.81)	0.0019	11.13 (4.05, 18.21)	0.0021	
>= 30	32/127 (25.2)	25.1	14/105 (13.3)	13.2	1.86 (1.05, 3.29)	0.0342	11.87 (1.03, 22.71)	0.0318	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Physical Functioning Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 52	Number of subjects with events, n (%)	91 (25.3)	78 (21.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.19 (0.91, 1.54)	
	p-value	0.2022	
	Odds Ratio (95% CI)	1.25 (0.89, 1.77)	
	p-value	0.2033	
	Risk Difference (95% CI)	4.00 (-2.15, 10.14)	
	p-value	0.2023	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.18 (0.91, 1.54)	
	p-value	0.2161	
	Odds Ratio (95% CI)	1.25 (0.88, 1.76)	
	p-value	0.2081	
	Risk Difference (95% CI)	3.97 (-2.17, 10.12)	
	p-value	0.2051	
	CMH approach		
	Response rate	25.3	21.4
	Difference in response rates (95% CI)	3.89 (-2.45, 10.23)	
	p-value	0.2292	
	p-Value for test for heterogenity between studies	0.3231	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Physical Functioning Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.2864
< 10 points	28/109 (25.7)	25.8	18/106 (17.0)	17.2	1.51 (0.89, 2.56)	0.1243	8.54 (-3.14, 20.22)	0.1519	
>= 10 points	63/251 (25.1)	25.1	60/260 (23.1)	23.2	1.08 (0.80, 1.48)	0.6078	1.90 (-5.68, 9.48)	0.6229	
OCS dose at baseline									0.1490
<10 mg/day	43/170 (25.3)	25.5	31/181 (17.1)	17.1	1.48 (0.98, 2.23)	0.0631	8.36 (-0.61, 17.33)	0.0678	
>=10 mg/day	48/190 (25.3)	25.3	47/185 (25.4)	25.3	0.99 (0.70, 1.41)	0.9646	-0.00 (-8.90, 8.90)	0.9996	
Result of type I IFN gene signature test									0.1650
LOW	14/ 62 (22.6)	22.6	18/ 64 (28.1)	28.1	0.80 (0.44, 1.47)	0.4778	-5.55 (-21.21, 10.12)	0.4879	
HIGH	77/298 (25.8)	25.9	60/302 (19.9)	20.0	1.30 (0.96, 1.75)	0.0884	5.88 (-1.06, 12.81)	0.0966	
Age (years)									0.6728
<= 65	85/348 (24.4)	24.4	77/362 (21.3)	21.3	1.15 (0.87, 1.50)	0.3261	3.10 (-3.28, 9.48)	0.3415	
> 65	6/ 12 (50.0)	47.7	1/ 4 (25.0)	23.9	1.58 (0.36, 6.85)	0.5410	23.86 (-32.72, 80.45)	0.4085	
Sex									0.7437
male	8/ 27 (29.6)	29.8	7/ 25 (28.0)	27.5	1.02 (0.43, 2.42)	0.9581	2.20 (-23.14, 27.55)	0.8647	
female	83/333 (24.9)	24.9	71/341 (20.8)	20.8	1.19 (0.90, 1.57)	0.2224	4.07 (-2.48, 10.62)	0.2235	
Race									0.5455
White	66/235 (28.1)	28.4	60/244 (24.6)	24.4	1.14 (0.85, 1.54)	0.3887	3.97 (-4.10, 12.04)	0.3347	
Black	8/ 46 (17.4)	16.8	10/ 48 (20.8)	21.6	0.78 (0.34, 1.80)	0.5545	-4.88 (-22.25, 12.48)	0.5815	
Other	14/ 71 (19.7)	19.7	7/ 66 (10.6)	10.6	1.54 (0.61, 3.89)	0.3557	9.10 (-3.72, 21.92)	0.1641	
Ethnicity									0.3151
Hispanic/Latino	22/ 86 (25.6)	25.3	25/ 89 (28.1)	28.4	0.94 (0.57, 1.55)	0.8122	-3.09 (-16.51, 10.32)	0.6514	
Non-hispanic/Latino	66/266 (24.8)	24.7	52/269 (19.3)	19.3	1.27 (0.93, 1.75)	0.1380	5.40 (-1.96, 12.76)	0.1505	
Geographic region									0.7899
EU	38/115 (33.0)	33.0	35/122 (28.7)	28.2	1.14 (0.78, 1.69)	0.4965	4.83 (-6.98, 16.64)	0.4232	
non-EU	53/245 (21.6)	22.0	43/244 (17.6)	17.5	1.23 (0.86, 1.77)	0.2598	4.42 (-3.11, 11.96)	0.2501	
Onset of disease									0.5391
Paediatric	3/ 26 (11.5)	11.4	1/ 24 (4.2)	4.3	2.08 (0.33, 13.05)	0.4329	7.10 (-14.18, 28.38)	0.5132	
Adult	88/334 (26.3)	26.4	77/342 (22.5)	22.5	1.17 (0.89, 1.52)	0.2602	3.85 (-2.81, 10.52)	0.2567	
ADA result									0.6890
Negative	88/334 (26.3)	26.3	74/331 (22.4)	22.5	1.18 (0.90, 1.54)	0.2310	3.78 (-2.94, 10.50)	0.2699	
Positive (At any time)	3/ 25 (12.0)	12.1	4/ 35 (11.4)	13.7	0.88 (0.22, 3.57)	0.8597	-1.66 (-23.58, 20.25)	0.8817	
BMI (kg/m2) at enrolment									0.5248
< 30	58/233 (24.9)	25.0	58/261 (22.2)	22.2	1.12 (0.81, 1.54)	0.4846	2.77 (-5.00, 10.53)	0.4852	
>= 30	33/127 (26.0)	26.5	20/105 (19.0)	18.8	1.36 (0.83, 2.22)	0.2256	7.71 (-3.69, 19.11)	0.1849	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Role Emotional Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 52	Number of subjects with events, n (%)	89 (24.7)	62 (16.9)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.47 (1.10, 1.97)	
	p-value	0.0089	
	Odds Ratio (95% CI)	1.64 (1.14, 2.36)	
	p-value	0.0084	
	Risk Difference (95% CI)	7.94 (2.09, 13.79)	
	p-value	0.0078	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.46 (1.09, 1.94)	
	p-value	0.0108	
	Odds Ratio (95% CI)	1.61 (1.12, 2.32)	
	p-value	0.0101	
	Risk Difference (95% CI)	7.77 (1.90, 13.64)	
	p-value	0.0095	
	CMH approach		
	Response rate	24.7	16.9
	Difference in response rates (95% CI)	7.75 (1.69, 13.81)	
	p-value	0.0122	
	p-Value for test for heterogenity between studies	0.7693	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Role Emotional Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.3339
< 10 points	33/109 (30.3)	30.4	18/106 (17.0)	16.8	1.78 (1.06, 2.97)	0.0289	13.61 (1.86, 25.35)	0.0231	
>= 10 points	56/251 (22.3)	22.3	44/260 (16.9)	16.9	1.30 (0.91, 1.86)	0.1449	5.32 (-1.78, 12.41)	0.1420	
OCS dose at baseline									0.9881
<10 mg/day	44/170 (25.9)	25.8	32/181 (17.7)	17.8	1.46 (0.97, 2.19)	0.0665	8.03 (-0.95, 17.00)	0.0797	
>=10 mg/day	45/190 (23.7)	23.8	30/185 (16.2)	16.1	1.45 (0.96, 2.20)	0.0747	7.68 (-0.56, 15.92)	0.0676	
Result of type I IFN gene signature test									0.0351
LOW	13/ 62 (21.0)	21.0	17/ 64 (26.6)	26.6	0.79 (0.42, 1.49)	0.4635	-5.60 (-21.02, 9.83)	0.4770	
HIGH	76/298 (25.5)	25.5	45/302 (14.9)	14.9	1.70 (1.22, 2.37)	0.0017	10.56 (3.98, 17.14)	0.0017	
Age (years)									0.8798
<= 65	84/348 (24.1)	24.1	61/362 (16.9)	16.8	1.43 (1.06, 1.92)	0.0178	7.31 (1.21, 13.40)	0.0188	
> 65	5/ 12 (41.7)	37.5	1/ 4 (25.0)	23.9	1.26 (0.27, 5.97)	0.7678	13.64 (-42.54, 69.81)	0.6342	
Sex									0.6092
male	6/ 27 (22.2)	22.3	5/ 25 (20.0)	19.8	1.12 (0.39, 3.21)	0.8377	2.48 (-21.84, 26.80)	0.8416	
female	83/333 (24.9)	24.9	57/341 (16.7)	16.7	1.49 (1.10, 2.01)	0.0097	8.20 (1.89, 14.50)	0.0109	
Race									0.8197
White	60/235 (25.5)	25.0	43/244 (17.6)	17.9	1.42 (1.01, 2.01)	0.0460	7.14 (-0.53, 14.80)	0.0679	
Black	12/ 46 (26.1)	27.1	11/ 48 (22.9)	22.7	1.21 (0.60, 2.45)	0.5962	4.39 (-14.03, 22.82)	0.6403	
Other	13/ 71 (18.3)	18.3	7/ 66 (10.6)	10.6	1.73 (0.73, 4.05)	0.2106	7.71 (-5.14, 20.56)	0.2393	
Ethnicity									0.4685
Hispanic/Latino	21/ 86 (24.4)	24.9	18/ 89 (20.2)	20.3	1.18 (0.69, 2.04)	0.5437	4.60 (-8.16, 17.35)	0.4802	
Non-hispanic/Latino	64/266 (24.1)	24.1	43/269 (16.0)	15.9	1.50 (1.06, 2.13)	0.0211	8.19 (1.06, 15.32)	0.0244	
Geographic region									0.6562
EU	35/115 (30.4)	30.4	23/122 (18.9)	19.0	1.60 (1.01, 2.53)	0.0462	11.37 (0.20, 22.55)	0.0461	
non-EU	54/245 (22.0)	22.4	39/244 (16.0)	15.8	1.40 (0.96, 2.02)	0.0769	6.62 (-0.74, 13.98)	0.0780	
Onset of disease									0.9626
Paediatric	5/ 26 (19.2)	18.8	3/ 24 (12.5)	12.7	1.50 (0.40, 5.59)	0.5439	6.17 (-17.31, 29.66)	0.6064	
Adult	84/334 (25.1)	25.1	59/342 (17.3)	17.3	1.45 (1.08, 1.96)	0.0131	7.84 (1.49, 14.18)	0.0155	
ADA result									0.4227
Negative	84/334 (25.1)	25.0	55/331 (16.6)	16.8	1.49 (1.10, 2.02)	0.0095	8.24 (1.88, 14.61)	0.0112	
Positive (At any time)	5/ 25 (20.0)	20.7	7/ 35 (20.0)	21.8	0.97 (0.35, 2.68)	0.9479	-1.08 (-24.91, 22.76)	0.9294	
BMI (kg/m2) at enrolment									0.1270
< 30	53/233 (22.7)	23.0	48/261 (18.4)	18.5	1.23 (0.87, 1.75)	0.2400	4.58 (-2.79, 11.96)	0.2234	
>= 30	36/127 (28.3)	28.4	14/105 (13.3)	12.9	2.06 (1.18, 3.62)	0.0116	15.52 (4.58, 26.46)	0.0054	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Role Physical Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 52	Number of subjects with events, n (%)	126 (35.0)	93 (25.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.39 (1.11, 1.74)	
	p-value	0.0036	
	Odds Ratio (95% CI)	1.62 (1.17, 2.23)	
	p-value	0.0035	
	Risk Difference (95% CI)	9.97 (3.35, 16.59)	
	p-value	0.0032	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.37 (1.10, 1.72)	
	p-value	0.0057	
	Odds Ratio (95% CI)	1.58 (1.15, 2.18)	
	p-value	0.0051	
	Risk Difference (95% CI)	9.60 (2.95, 16.24)	
	p-value	0.0047	
	CMH approach		
	Response rate	35.0	25.4
	Difference in response rates (95% CI)	9.65 (2.93, 16.37)	
	p-value	0.0049	
	p-Value for test for heterogenity between studies	0.4266	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Role Physical Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.2930
< 10 points	40/109 (36.7)	36.9	23/106 (21.7)	21.4	1.68 (1.08, 2.60)	0.0219	15.51 (3.28, 27.73)	0.0129	
>= 10 points	86/251 (34.3)	34.3	70/260 (26.9)	27.1	1.27 (0.98, 1.65)	0.0737	7.22 (-0.81, 15.26)	0.0781	
OCS dose at baseline									0.1994
<10 mg/day	62/170 (36.5)	36.4	41/181 (22.7)	22.6	1.61 (1.15, 2.25)	0.0053	13.75 (4.18, 23.32)	0.0049	
>=10 mg/day	64/190 (33.7)	33.8	52/185 (28.1)	27.8	1.20 (0.88, 1.62)	0.2517	6.04 (-3.31, 15.38)	0.2057	
Result of type I IFN gene signature test									0.2627
LOW	23/ 62 (37.1)	37.1	22/ 64 (34.4)	34.4	1.08 (0.67, 1.74)	0.7581	2.72 (-14.08, 19.52)	0.7508	
HIGH	103/298 (34.6)	34.6	71/302 (23.5)	23.5	1.47 (1.14, 1.90)	0.0033	11.11 (3.78, 18.43)	0.0030	
Age (years)									0.9603
<= 65	120/348 (34.5)	34.5	92/362 (25.4)	25.3	1.35 (1.08, 1.70)	0.0091	9.22 (2.45, 16.00)	0.0076	
> 65	6/ 12 (50.0)	43.2	1/ 4 (25.0)	23.9	1.41 (0.30, 6.57)	0.6624	19.32 (-36.72, 75.35)	0.4992	
Sex									0.6404
male	10/ 27 (37.0)	36.6	8/ 25 (32.0)	31.7	1.13 (0.50, 2.57)	0.7624	4.96 (-21.07, 30.98)	0.7088	
female	116/333 (34.8)	34.9	85/341 (24.9)	24.8	1.39 (1.10, 1.76)	0.0063	10.04 (3.07, 17.00)	0.0047	
Race									0.3597
White	86/235 (36.6)	36.6	69/244 (28.3)	28.3	1.30 (1.00, 1.69)	0.0502	8.34 (-0.12, 16.81)	0.0533	
Black	16/ 46 (34.8)	35.5	15/ 48 (31.3)	31.1	1.15 (0.65, 2.04)	0.6380	4.38 (-15.19, 23.95)	0.6608	
Other	19/ 71 (26.8)	26.8	7/ 66 (10.6)	10.6	2.32 (1.02, 5.26)	0.0445	16.15 (2.61, 29.69)	0.0194	
Ethnicity									0.7075
Hispanic/Latino	24/ 86 (27.9)	28.0	20/ 89 (22.5)	22.6	1.23 (0.74, 2.05)	0.4321	5.40 (-7.96, 18.77)	0.4281	
Non-hispanic/Latino	97/266 (36.5)	36.5	71/269 (26.4)	26.1	1.37 (1.06, 1.77)	0.0155	10.39 (2.46, 18.32)	0.0102	
Geographic region									0.3192
EU	52/115 (45.2)	45.5	45/122 (36.9)	36.4	1.23 (0.91, 1.68)	0.1804	9.03 (-3.43, 21.50)	0.1556	
non-EU	74/245 (30.2)	30.6	48/244 (19.7)	19.7	1.54 (1.12, 2.12)	0.0073	10.93 (3.03, 18.83)	0.0067	
Onset of disease									0.4540
Paediatric	7/ 26 (26.9)	27.2	3/ 24 (12.5)	12.3	2.17 (0.64, 7.39)	0.2139	14.81 (-9.52, 39.15)	0.2328	
Adult	119/334 (35.6)	35.8	90/342 (26.3)	26.3	1.35 (1.07, 1.70)	0.0100	9.46 (2.46, 16.47)	0.0081	
ADA result									0.9896
Negative	120/334 (35.9)	35.9	87/331 (26.3)	26.3	1.36 (1.08, 1.72)	0.0084	9.67 (2.60, 16.74)	0.0074	
Positive (At any time)	6/ 25 (24.0)	20.6	6/ 35 (17.1)	17.9	1.38 (0.45, 4.16)	0.5725	2.64 (-20.18, 25.46)	0.8204	
BMI (kg/m2) at enrolment									0.4257
< 30	80/233 (34.3)	34.6	69/261 (26.4)	26.4	1.30 (0.99, 1.70)	0.0601	8.15 (-0.02, 16.32)	0.0507	
>= 30	46/127 (36.2)	36.7	24/105 (22.9)	22.9	1.59 (1.04, 2.42)	0.0312	13.90 (1.91, 25.88)	0.0230	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Social Functioning Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 52	Number of subjects with events, n (%)	81 (22.5)	55 (15.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.51 (1.11, 2.07)	
	p-value	0.0096	
	Odds Ratio (95% CI)	1.65 (1.13, 2.40)	
	p-value	0.0092	
	Risk Difference (95% CI)	7.65 (1.95, 13.36)	
	p-value	0.0086	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.49 (1.09, 2.04)	
	p-value	0.0116	
	Odds Ratio (95% CI)	1.64 (1.12, 2.40)	
	p-value	0.0107	
	Risk Difference (95% CI)	7.48 (1.82, 13.14)	
	p-value	0.0096	
	CMH approach		
	Response rate	22.4	15.0
	Difference in response rates (95% CI)	7.43 (1.52, 13.35)	
	p-value	0.0138	
	p-Value for test for heterogenity between studies	0.3967	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Social Functioning Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.0366
< 10 points	34/109 (31.2)	31.3	12/106 (11.3)	11.3	2.44 (1.32, 4.52)	0.0044	20.02 (8.52, 31.52)	0.0006	
>= 10 points	47/251 (18.7)	18.7	43/260 (16.5)	16.5	1.13 (0.78, 1.65)	0.5165	2.14 (-4.78, 9.07)	0.5439	
OCS dose at baseline									0.5231
<10 mg/day	35/170 (20.6)	20.7	28/181 (15.5)	15.5	1.33 (0.85, 2.09)	0.2122	5.21 (-3.44, 13.86)	0.2380	
>=10 mg/day	46/190 (24.2)	24.2	27/185 (14.6)	14.4	1.63 (1.06, 2.52)	0.0272	9.75 (1.60, 17.89)	0.0190	
Result of type I IFN gene signature test									0.2374
LOW	12/ 62 (19.4)	19.4	12/ 64 (18.8)	18.8	1.00 (0.49, 2.07)	0.9953	0.60 (-13.87, 15.06)	0.9353	
HIGH	69/298 (23.2)	23.0	43/302 (14.2)	14.2	1.63 (1.15, 2.30)	0.0059	8.87 (2.39, 15.35)	0.0073	
Age (years)									0.0993
<= 65	78/348 (22.4)	22.3	53/362 (14.6)	14.5	1.53 (1.11, 2.10)	0.0088	7.75 (1.77, 13.72)	0.0110	
> 65	3/ 12 (25.0)	26.1	2/ 4 (50.0)	47.7	0.51 (0.14, 1.81)	0.2973	-21.59 (-77.63, 34.44)	0.4501	
Sex									0.7786
male	6/ 27 (22.2)	22.0	4/ 25 (16.0)	15.7	1.24 (0.35, 4.39)	0.7396	6.34 (-17.32, 29.99)	0.5996	
female	75/333 (22.5)	22.4	51/341 (15.0)	14.9	1.49 (1.08, 2.07)	0.0151	7.50 (1.35, 13.66)	0.0169	
Race									0.6391
White	54/235 (23.0)	22.8	41/244 (16.8)	16.9	1.37 (0.95, 1.97)	0.0917	5.92 (-1.61, 13.46)	0.1233	
Black	11/ 46 (23.9)	23.9	9/ 48 (18.8)	19.9	1.18 (0.54, 2.56)	0.6764	3.99 (-13.98, 21.97)	0.6632	
Other	14/ 71 (19.7)	19.7	5/ 66 (7.6)	7.6	2.23 (0.75, 6.69)	0.1514	12.16 (-0.23, 24.55)	0.0545	
Ethnicity									0.9630
Hispanic/Latino	19/ 86 (22.1)	22.3	14/ 89 (15.7)	16.0	1.51 (0.77, 2.96)	0.2325	6.27 (-5.98, 18.52)	0.3155	
Non-hispanic/Latino	60/266 (22.6)	22.4	41/269 (15.2)	15.1	1.48 (1.03, 2.12)	0.0319	7.35 (0.31, 14.39)	0.0406	
Geographic region									0.9228
EU	27/115 (23.5)	23.9	20/122 (16.4)	16.2	1.49 (0.89, 2.49)	0.1312	7.73 (-2.78, 18.24)	0.1495	
non-EU	54/245 (22.0)	22.4	35/244 (14.3)	14.4	1.53 (1.04, 2.26)	0.0308	7.98 (0.63, 15.32)	0.0334	
Onset of disease									0.5152
Paediatric	4/ 26 (15.4)	15.4	1/ 24 (4.2)	4.0	2.67 (0.44, 16.03)	0.2842	11.42 (-10.35, 33.19)	0.3038	
Adult	77/334 (23.1)	23.0	54/342 (15.8)	15.8	1.46 (1.06, 1.99)	0.0191	7.15 (0.91, 13.38)	0.0247	
ADA result									0.1309
Negative	78/334 (23.4)	23.1	49/331 (14.8)	14.7	1.58 (1.14, 2.18)	0.0057	8.39 (2.16, 14.61)	0.0083	
Positive (At any time)	3/ 25 (12.0)	12.1	6/ 35 (17.1)	21.5	0.56 (0.15, 2.06)	0.3863	-9.43 (-32.10, 13.24)	0.4150	
BMI (kg/m2) at enrolment									0.2150
< 30	52/233 (22.3)	22.4	34/261 (13.0)	13.1	1.70 (1.15, 2.54)	0.0085	9.33 (2.20, 16.45)	0.0103	
>= 30	29/127 (22.8)	23.0	21/105 (20.0)	20.4	1.14 (0.69, 1.87)	0.6091	2.63 (-8.77, 14.03)	0.6515	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Bodily Pain Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 52	Number of subjects with events, n (%)	99 (27.5)	81 (22.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.25 (0.97, 1.61)	
	p-value	0.0839	
	Odds Ratio (95% CI)	1.35 (0.96, 1.89)	
	p-value	0.0843	
	Risk Difference (95% CI)	5.56 (-0.73, 11.86)	
	p-value	0.0834	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.24 (0.96, 1.60)	
	p-value	0.0956	
	Odds Ratio (95% CI)	1.33 (0.95, 1.87)	
	p-value	0.0945	
	Risk Difference (95% CI)	5.37 (-0.90, 11.64)	
	p-value	0.0934	
	CMH approach		
	Response rate	27.5	22.2
	Difference in response rates (95% CI)	5.30 (-1.14, 11.74)	
	p-value	0.1065	
	p-Value for test for heterogenity between studies	0.7488	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Bodily Pain Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.0705
< 10 points	38/109 (34.9)	35.1	21/106 (19.8)	20.0	1.76 (1.11, 2.79)	0.0160	15.15 (2.89, 27.41)	0.0154	
>= 10 points	61/251 (24.3)	24.3	60/260 (23.1)	23.2	1.05 (0.77, 1.44)	0.7411	1.17 (-6.40, 8.74)	0.7621	
OCS dose at baseline									0.2974
<10 mg/day	51/170 (30.0)	30.1	38/181 (21.0)	21.0	1.43 (0.99, 2.05)	0.0566	9.04 (-0.34, 18.43)	0.0590	
>=10 mg/day	48/190 (25.3)	25.3	43/185 (23.2)	23.3	1.09 (0.76, 1.55)	0.6505	2.00 (-6.83, 10.82)	0.6573	
Result of type I IFN gene signature test									0.8149
LOW	17/ 62 (27.4)	27.4	15/ 64 (23.4)	23.4	1.16 (0.64, 2.12)	0.6219	3.98 (-11.71, 19.66)	0.6190	
HIGH	82/298 (27.5)	27.5	66/302 (21.9)	22.0	1.26 (0.95, 1.67)	0.1092	5.58 (-1.48, 12.64)	0.1213	
Age (years)									0.3148
<= 65	94/348 (27.0)	27.0	79/362 (21.8)	21.9	1.24 (0.95, 1.61)	0.1085	5.12 (-1.38, 11.62)	0.1224	
> 65	5/ 12 (41.7)	37.5	2/ 4 (50.0)	47.7	0.65 (0.19, 2.23)	0.4912	-10.23 (-66.40, 45.94)	0.7212	
Sex									0.1273
male	4/ 27 (14.8)	14.6	8/ 25 (32.0)	31.7	0.53 (0.17, 1.68)	0.2806	-17.08 (-41.44, 7.28)	0.1694	
female	95/333 (28.5)	28.5	73/341 (21.4)	21.5	1.33 (1.02, 1.74)	0.0347	6.99 (0.31, 13.68)	0.0403	
Race									0.5789
White	68/235 (28.9)	29.0	60/244 (24.6)	24.3	1.18 (0.88, 1.59)	0.2742	4.72 (-3.40, 12.83)	0.2547	
Black	13/ 46 (28.3)	29.1	8/ 48 (16.7)	16.1	1.80 (0.82, 3.94)	0.1424	12.95 (-4.92, 30.81)	0.1555	
Other	14/ 71 (19.7)	19.7	12/ 66 (18.2)	18.2	1.09 (0.54, 2.18)	0.8122	1.55 (-12.37, 15.47)	0.8274	
Ethnicity									0.9905
Hispanic/Latino	28/ 86 (32.6)	32.6	24/ 89 (27.0)	27.1	1.21 (0.76, 1.91)	0.4235	5.52 (-8.38, 19.41)	0.4364	
Non-hispanic/Latino	67/266 (25.2)	25.2	56/269 (20.8)	20.8	1.21 (0.89, 1.65)	0.2308	4.41 (-3.07, 11.88)	0.2479	
Geographic region									0.8316
EU	35/115 (30.4)	30.7	31/122 (25.4)	24.9	1.21 (0.80, 1.83)	0.3622	5.86 (-5.63, 17.36)	0.3173	
non-EU	64/245 (26.1)	26.6	50/244 (20.5)	20.4	1.28 (0.93, 1.77)	0.1341	6.21 (-1.60, 14.03)	0.1193	
Onset of disease									0.1455
Paediatric	5/ 26 (19.2)	19.1	0/ 24 (0.0)	0.0	5.52 (0.71, 42.98)	0.1028	19.14 (-2.37, 40.64)	0.0811	
Adult	94/334 (28.1)	28.1	81/342 (23.7)	23.8	1.19 (0.92, 1.53)	0.1873	4.31 (-2.45, 11.07)	0.2112	
ADA result									0.4257
Negative	95/334 (28.4)	28.5	75/331 (22.7)	22.9	1.26 (0.97, 1.63)	0.0891	5.60 (-1.20, 12.40)	0.1066	
Positive (At any time)	4/ 25 (16.0)	15.5	6/ 35 (17.1)	19.7	0.78 (0.25, 2.44)	0.6688	-4.21 (-27.24, 18.82)	0.7202	
BMI (kg/m2) at enrolment									0.2400
< 30	60/233 (25.8)	25.9	61/261 (23.4)	23.5	1.10 (0.81, 1.50)	0.5486	2.34 (-5.51, 10.19)	0.5586	
>= 30	39/127 (30.7)	31.2	20/105 (19.0)	19.0	1.54 (0.96, 2.48)	0.0728	12.24 (0.66, 23.82)	0.0383	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Vitality Score
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 52	Number of subjects with events, n (%)	90 (25.0)	61 (16.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.50 (1.12, 2.01)	
	p-value	0.0060	
	Odds Ratio (95% CI)	1.67 (1.16, 2.40)	
	p-value	0.0058	
	Risk Difference (95% CI)	8.40 (2.50, 14.31)	
	p-value	0.0053	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.49 (1.12, 2.00)	
	p-value	0.0068	
	Odds Ratio (95% CI)	1.67 (1.16, 2.40)	
	p-value	0.0060	
	Risk Difference (95% CI)	8.35 (2.47, 14.22)	
	p-value	0.0053	
	CMH approach		
	Response rate	24.9	16.7
	Difference in response rates (95% CI)	8.26 (2.15, 14.38)	
	p-value	0.0081	
	p-Value for test for heterogenity between studies	0.4639	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SF-36 v2.0 Acute response rate at week 52 - Vitality Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.0720
< 10 points	35/109 (32.1)	32.3	15/106 (14.2)	14.1	2.23 (1.30, 3.83)	0.0036	18.17 (6.49, 29.85)	0.0023	
>= 10 points	55/251 (21.9)	21.9	46/260 (17.7)	17.7	1.24 (0.87, 1.76)	0.2382	4.14 (-3.06, 11.34)	0.2598	
OCS dose at baseline									0.3013
<10 mg/day	43/170 (25.3)	25.2	26/181 (14.4)	14.4	1.76 (1.14, 2.74)	0.0113	10.87 (2.04, 19.70)	0.0159	
>=10 mg/day	47/190 (24.7)	24.7	35/185 (18.9)	18.7	1.29 (0.87, 1.91)	0.1974	5.97 (-2.50, 14.45)	0.1672	
Result of type I IFN gene signature test									0.2024
LOW	15/ 62 (24.2)	24.2	15/ 64 (23.4)	23.4	1.05 (0.57, 1.93)	0.8814	0.75 (-14.47, 15.97)	0.9233	
HIGH	75/298 (25.2)	25.1	46/302 (15.2)	15.3	1.64 (1.18, 2.29)	0.0032	9.84 (3.17, 16.52)	0.0038	
Age (years)									0.5426
<= 65	87/348 (25.0)	24.9	60/362 (16.6)	16.5	1.50 (1.12, 2.02)	0.0066	8.37 (2.18, 14.55)	0.0080	
> 65	3/ 12 (25.0)	26.1	1/ 4 (25.0)	23.9	0.90 (0.18, 4.53)	0.9014	2.27 (-53.76, 58.31)	0.9366	
Sex									0.7628
male	7/ 27 (25.9)	25.6	5/ 25 (20.0)	19.8	1.27 (0.43, 3.73)	0.6670	5.79 (-18.74, 30.31)	0.6438	
female	83/333 (24.9)	24.8	56/341 (16.4)	16.4	1.51 (1.11, 2.04)	0.0082	8.40 (2.06, 14.73)	0.0094	
Race									0.8679
White	62/235 (26.4)	26.3	45/244 (18.4)	18.4	1.44 (1.03, 2.03)	0.0329	7.89 (0.13, 15.65)	0.0462	
Black	14/ 46 (30.4)	31.0	8/ 48 (16.7)	17.4	1.75 (0.81, 3.76)	0.1531	13.54 (-4.73, 31.81)	0.1464	
Other	13/ 71 (18.3)	18.3	7/ 66 (10.6)	10.6	1.72 (0.70, 4.23)	0.2401	7.72 (-5.04, 20.49)	0.2358	
Ethnicity									0.7494
Hispanic/Latino	20/ 86 (23.3)	23.2	12/ 89 (13.5)	13.4	1.66 (0.81, 3.40)	0.1694	9.77 (-2.48, 22.02)	0.1179	
Non-hispanic/Latino	69/266 (25.9)	25.8	48/269 (17.8)	17.6	1.46 (1.05, 2.02)	0.0243	8.21 (0.90, 15.53)	0.0278	
Geographic region									0.1391
EU	28/115 (24.3)	25.0	27/122 (22.1)	21.8	1.16 (0.74, 1.83)	0.5189	3.22 (-7.73, 14.17)	0.5645	
non-EU	62/245 (25.3)	25.7	34/244 (13.9)	14.0	1.81 (1.24, 2.65)	0.0021	11.68 (4.22, 19.14)	0.0022	
Onset of disease									0.7938
Paediatric	3/ 26 (11.5)	11.4	1/ 24 (4.2)	4.0	1.93 (0.27, 13.85)	0.5134	7.41 (-13.75, 28.57)	0.4926	
Adult	87/334 (26.0)	25.9	60/342 (17.5)	17.6	1.48 (1.10, 1.98)	0.0085	8.35 (1.91, 14.79)	0.0111	
ADA result									0.7157
Negative	86/334 (25.7)	25.6	59/331 (17.8)	17.8	1.45 (1.08, 1.94)	0.0135	7.80 (1.31, 14.30)	0.0185	
Positive (At any time)	4/ 25 (16.0)	15.5	2/ 35 (5.7)	7.8	1.91 (0.45, 8.19)	0.3839	7.73 (-13.85, 29.32)	0.4826	
BMI (kg/m2) at enrolment									0.7255
< 30	55/233 (23.6)	23.8	43/261 (16.5)	16.3	1.43 (1.00, 2.05)	0.0516	7.51 (0.13, 14.89)	0.0461	
>= 30	35/127 (27.6)	27.9	18/105 (17.1)	17.0	1.60 (0.96, 2.65)	0.0693	10.86 (-0.45, 22.16)	0.0598	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
C-SSRS Suicidal ideation or behaviour
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
On-treatment/Follow-Up	Number of subjects with events, n (%)	5 (1.4)	11 (3.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.47 (0.16, 1.37)	
	p-value	0.1679	
	Odds Ratio (95% CI)	0.47 (0.16, 1.36)	
	p-value	0.1630	
	Risk Difference (95% CI)	-1.55 (-3.67, 0.57)	
	p-value	0.1523	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.47 (0.16, 1.34)	
	p-value	0.1562	
	Odds Ratio (95% CI)	0.46 (0.16, 1.35)	
	p-value	0.1556	
	Risk Difference (95% CI)	-1.62 (-3.75, 0.50)	
	p-value	0.1349	
	CMH approach		
	Response rate	1.4	3.0
	Difference in response rates (95% CI)	-1.60 (-5.23, 2.03)	
	p-value	0.3883	
	p-Value for test for heterogenity between studies	0.6028	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
C-SSRS Suicidal ideation or behaviour - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.4128
< 10 points	1/109 (0.9)	0.9	5/106 (4.7)	4.6	0.27 (0.04, 1.62)	0.1521	-3.72 (-12.16, 4.73)	0.3884	
>= 10 points	4/251 (1.6)	1.6	6/260 (2.3)	2.3	0.69 (0.18, 2.63)	0.5841	-0.71 (-4.77, 3.35)	0.7306	
OCS dose at baseline									0.9939
<10 mg/day	3/170 (1.8)	1.8	7/181 (3.9)	3.9	0.48 (0.12, 1.89)	0.2946	-2.12 (-8.05, 3.82)	0.4844	
>=10 mg/day	2/190 (1.1)	1.0	4/185 (2.2)	2.2	0.48 (0.09, 2.54)	0.3851	-1.14 (-5.66, 3.38)	0.6199	
Result of type I IFN gene signature test									0.3328
LOW	0/ 62 (0.0)	0.0	4/ 64 (6.3)	6.2	0.22 (0.03, 1.86)	0.1638	-6.25 (-15.84, 3.34)	0.2017	
HIGH	5/298 (1.7)	1.7	7/302 (2.3)	2.3	0.72 (0.23, 2.27)	0.5797	-0.62 (-4.53, 3.29)	0.7553	
Age (years)									NE
<= 65	5/348 (1.4)	1.4	11/362 (3.0)	3.0	0.48 (0.17, 1.37)	0.1689	-1.56 (-5.27, 2.15)	0.4095	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE		0.00 (-51.08, 51.08)	1.0000	
Sex									0.7326
male	0/ 27 (0.0)	0.0	1/ 25 (4.0)	4.1	0.29 (0.01, 6.60)	0.4388	-4.13 (-22.67, 14.40)	0.6621	
female	5/333 (1.5)	1.5	10/341 (2.9)	2.9	0.52 (0.17, 1.54)	0.2366	-1.41 (-5.28, 2.45)	0.4731	
Race									0.5961
White	4/235 (1.7)	1.6	5/244 (2.0)	2.1	0.80 (0.22, 2.93)	0.7342	-0.50 (-5.18, 4.18)	0.8353	
Black	1/ 46 (2.2)	1.9	4/ 48 (8.3)	8.4	0.35 (0.06, 2.21)	0.2648	-6.46 (-19.63, 6.71)	0.3363	
Other	0/ 71 (0.0)	0.0	2/ 66 (3.0)	3.0	0.19 (0.01, 3.78)	0.2745	-3.02 (-11.34, 5.29)	0.4759	
Ethnicity									0.5259
Hispanic/Latino	0/ 86 (0.0)	0.0	2/ 89 (2.2)	2.3	0.20 (0.01, 4.07)	0.2952	-2.27 (-10.40, 5.86)	0.5838	
Non-hispanic/Latino	5/266 (1.9)	1.8	9/269 (3.3)	3.3	0.56 (0.19, 1.66)	0.2984	-1.50 (-6.19, 3.20)	0.5324	
Geographic region									0.2547
EU	1/115 (0.9)	0.8	0/122 (0.0)	0.0	2.71 (0.11, 64.96)	0.5382	0.80 (-3.91, 5.51)	0.7377	
non-EU	4/245 (1.6)	1.7	11/244 (4.5)	4.4	0.38 (0.12, 1.21)	0.1016	-2.70 (-7.87, 2.47)	0.3059	
Onset of disease									0.2164
Paediatric	1/ 26 (3.8)	4.0	0/ 24 (0.0)	0.0	3.00 (0.13, 67.06)	0.4883	4.01 (-14.99, 23.02)	0.6790	
Adult	4/334 (1.2)	1.2	11/342 (3.2)	3.2	0.37 (0.12, 1.16)	0.0876	-2.04 (-5.89, 1.81)	0.2992	
ADA result									NE
Negative	5/334 (1.5)	1.5	11/331 (3.3)	3.3	0.45 (0.16, 1.29)	0.1358	-1.85 (-5.80, 2.10)	0.3578	
Positive (At any time)	0/ 25 (0.0)	0.0	0/ 35 (0.0)	0.0	NE		0.00 (-17.02, 17.02)	1.0000	
BMI (kg/m2) at enrolment									0.7391
< 30	2/233 (0.9)	0.9	4/261 (1.5)	1.6	0.54 (0.10, 2.88)	0.4668	-0.71 (-5.05, 3.63)	0.7487	
>= 30	3/127 (2.4)	2.3	7/105 (6.7)	6.4	0.37 (0.10, 1.45)	0.1537	-4.15 (-12.53, 4.24)	0.3326	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Modified SELENA Flare Index based flares - mild/moderate flare
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
at least once during study	Number of subjects with events, n (%)	114 (31.7)	127 (34.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.91 (0.74, 1.12)	
	p-value	0.3839	
	Odds Ratio (95% CI)	0.87 (0.64, 1.19)	
	p-value	0.3830	
	Risk Difference (95% CI)	-3.07 (-9.95, 3.82)	
	p-value	0.3824	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.91 (0.74, 1.12)	
	p-value	0.3809	
	Odds Ratio (95% CI)	0.87 (0.64, 1.19)	
	p-value	0.3847	
	Risk Difference (95% CI)	-3.04 (-9.88, 3.80)	
	p-value	0.3840	
	CMH approach		
	Response rate	31.6	34.7
	Difference in response rates (95% CI)	-3.10 (-9.97, 3.76)	
	p-value	0.3757	
	p-Value for test for heterogenity between studies	0.6834	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Modified SELENA Flare Index based flares - mild/moderate flare - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.0343
< 10 points	43/109 (39.4)	39.4	33/106 (31.1)	31.2	1.27 (0.88, 1.83)	0.2036	8.21 (-4.62, 21.05)	0.2097	
>= 10 points	71/251 (28.3)	28.3	94/260 (36.2)	36.2	0.78 (0.61, 1.01)	0.0602	-7.86 (-16.01, 0.29)	0.0586	
OCS dose at baseline									0.9780
<10 mg/day	52/170 (30.6)	30.4	61/181 (33.7)	33.5	0.91 (0.67, 1.23)	0.5336	-3.11 (-12.96, 6.74)	0.5360	
>=10 mg/day	62/190 (32.6)	32.7	66/185 (35.7)	35.7	0.91 (0.69, 1.21)	0.5267	-3.03 (-12.69, 6.63)	0.5387	
Result of type I IFN gene signature test									0.8804
LOW	20/ 62 (32.3)	32.3	22/ 64 (34.4)	34.4	0.94 (0.58, 1.55)	0.8205	-2.12 (-18.75, 14.51)	0.8026	
HIGH	94/298 (31.5)	31.4	105/302 (34.8)	34.7	0.91 (0.72, 1.14)	0.3943	-3.31 (-10.85, 4.23)	0.3895	
Age (years)									0.0814
<= 65	112/348 (32.2)	32.1	125/362 (34.5)	34.5	0.93 (0.76, 1.15)	0.5025	-2.49 (-9.45, 4.47)	0.4839	
> 65	2/ 12 (16.7)	15.9	2/ 4 (50.0)	52.3	0.26 (0.06, 1.08)	0.0629	-36.36 (-91.56, 18.84)	0.1966	
Sex									0.2377
male	5/ 27 (18.5)	18.5	9/ 25 (36.0)	35.8	0.52 (0.20, 1.37)	0.1854	-17.36 (-42.56, 7.85)	0.1772	
female	109/333 (32.7)	32.7	118/341 (34.6)	34.7	0.94 (0.76, 1.17)	0.6005	-1.98 (-9.13, 5.17)	0.5878	
Race									0.7073
White	74/235 (31.5)	31.0	83/244 (34.0)	34.0	0.92 (0.71, 1.19)	0.5401	-2.99 (-11.44, 5.46)	0.4878	
Black	19/ 46 (41.3)	41.3	18/ 48 (37.5)	37.7	1.09 (0.66, 1.81)	0.7285	3.54 (-16.59, 23.67)	0.7303	
Other	18/ 71 (25.4)	25.4	21/ 66 (31.8)	31.8	0.80 (0.47, 1.37)	0.4181	-6.45 (-21.89, 9.00)	0.4132	
Ethnicity									0.5487
Hispanic/Latino	23/ 86 (26.7)	27.2	29/ 89 (32.6)	33.1	0.82 (0.52, 1.29)	0.3882	-5.89 (-19.69, 7.91)	0.4031	
Non-hispanic/Latino	88/266 (33.1)	32.8	93/269 (34.6)	34.4	0.96 (0.75, 1.21)	0.7157	-1.58 (-9.64, 6.48)	0.7005	
Geographic region									0.0629
EU	24/115 (20.9)	20.8	39/122 (32.0)	32.6	0.63 (0.41, 0.98)	0.0417	-11.76 (-23.05, -0.47)	0.0413	
non-EU	90/245 (36.7)	36.5	88/244 (36.1)	36.2	1.02 (0.80, 1.28)	0.8931	0.30 (-8.22, 8.82)	0.9450	
Onset of disease									0.5228
Paediatric	11/ 26 (42.3)	42.6	9/ 24 (37.5)	37.7	1.13 (0.57, 2.25)	0.7267	4.94 (-22.39, 32.26)	0.7232	
Adult	103/334 (30.8)	30.7	118/342 (34.5)	34.5	0.89 (0.72, 1.11)	0.3084	-3.84 (-10.93, 3.24)	0.2875	
ADA result									0.1715
Negative	108/334 (32.3)	32.2	110/331 (33.2)	33.3	0.97 (0.78, 1.21)	0.7917	-1.04 (-8.22, 6.14)	0.7771	
Positive (At any time)	6/ 25 (24.0)	25.9	17/ 35 (48.6)	48.1	0.56 (0.26, 1.19)	0.1339	-22.12 (-47.48, 3.23)	0.0873	
BMI (kg/m2) at enrolment									0.6807
< 30	63/233 (27.0)	27.0	82/261 (31.4)	31.3	0.86 (0.65, 1.13)	0.2787	-4.27 (-12.36, 3.82)	0.3007	
>= 30	51/127 (40.2)	39.4	45/105 (42.9)	42.1	0.94 (0.69, 1.27)	0.6748	-2.64 (-15.22, 9.93)	0.6804	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Modified SELENA Flare Index based flares - severe flare
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
at least once during study	Number of subjects with events, n (%)	8 (2.2)	17 (4.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.47 (0.21, 1.08)	
	p-value	0.0753	
	Odds Ratio (95% CI)	0.46 (0.19, 1.08)	
	p-value	0.0734	
	Risk Difference (95% CI)	-2.46 (-5.09, 0.16)	
	p-value	0.0661	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.48 (0.21, 1.10)	
	p-value	0.0819	
	Odds Ratio (95% CI)	0.47 (0.20, 1.10)	
	p-value	0.0808	
	Risk Difference (95% CI)	-2.42 (-5.06, 0.22)	
	p-value	0.0723	
	CMH approach		
	Response rate	2.2	4.7
	Difference in response rates (95% CI)	-2.49 (-6.43, 1.45)	
	p-value	0.2147	
	p-Value for test for heterogenity between studies	0.8492	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Modified SELENA Flare Index based flares - severe flare - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.4412
< 10 points	2/109 (1.8)	1.8	2/106 (1.9)	2.0	0.97 (0.14, 6.78)	0.9774	-0.22 (-8.44, 8.01)	0.9589	
>= 10 points	6/251 (2.4)	2.4	15/260 (5.8)	5.8	0.42 (0.16, 1.06)	0.0657	-3.45 (-8.14, 1.24)	0.1496	
OCS dose at baseline									0.7177
<10 mg/day	2/170 (1.2)	1.2	4/181 (2.2)	2.2	0.75 (0.12, 4.78)	0.7605	-1.00 (-6.67, 4.68)	0.7311	
>=10 mg/day	6/190 (3.2)	3.2	13/185 (7.0)	7.0	0.51 (0.19, 1.36)	0.1786	-3.88 (-9.52, 1.76)	0.1771	
Result of type I IFN gene signature test									0.8157
LOW	0/ 62 (0.0)	0.0	1/ 64 (1.6)	1.6	0.34 (0.01, 8.13)	0.5085	-1.56 (-10.05, 6.92)	0.7183	
HIGH	8/298 (2.7)	2.7	16/302 (5.3)	5.3	0.51 (0.22, 1.17)	0.1104	-2.69 (-7.11, 1.73)	0.2332	
Age (years)									NE
<= 65	8/348 (2.3)	2.3	17/362 (4.7)	4.7	0.49 (0.21, 1.12)	0.0919	-2.49 (-6.51, 1.53)	0.2239	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE		0.00 (-51.08, 51.08)	1.0000	
Sex									0.7661
male	2/ 27 (7.4)	7.4	3/ 25 (12.0)	12.4	0.61 (0.11, 3.57)	0.5858	-4.96 (-26.28, 16.37)	0.6486	
female	6/333 (1.8)	1.8	14/341 (4.1)	4.1	0.45 (0.17, 1.18)	0.1034	-2.33 (-6.39, 1.73)	0.2602	
Race									0.4840
White	3/235 (1.3)	1.2	11/244 (4.5)	4.4	0.29 (0.08, 1.04)	0.0575	-3.18 (-8.10, 1.74)	0.2056	
Black	2/ 46 (4.3)	3.9	2/ 48 (4.2)	4.2	1.04 (0.16, 6.77)	0.9692	-0.34 (-13.04, 12.36)	0.9582	
Other	3/ 71 (4.2)	4.2	4/ 66 (6.1)	6.1	0.71 (0.14, 3.54)	0.6749	-1.85 (-11.71, 8.02)	0.7136	
Ethnicity									0.8507
Hispanic/Latino	2/ 86 (2.3)	2.3	5/ 89 (5.6)	5.7	0.42 (0.08, 2.13)	0.2955	-3.44 (-12.65, 5.78)	0.4645	
Non-hispanic/Latino	6/266 (2.3)	2.3	12/269 (4.5)	4.5	0.51 (0.19, 1.32)	0.1651	-2.24 (-7.17, 2.69)	0.3733	
Geographic region									0.5206
EU	1/115 (0.9)	0.9	5/122 (4.1)	4.0	0.30 (0.05, 1.79)	0.1852	-3.07 (-8.85, 2.70)	0.2969	
non-EU	7/245 (2.9)	2.7	12/244 (4.9)	5.1	0.58 (0.23, 1.44)	0.2391	-2.47 (-7.84, 2.89)	0.3664	
Onset of disease									0.5733
Paediatric	1/ 26 (3.8)	4.0	1/ 24 (4.2)	4.0	1.00 (0.07, 14.21)	1.0000	0.00 (-19.83, 19.83)	1.0000	
Adult	7/334 (2.1)	2.1	16/342 (4.7)	4.7	0.45 (0.19, 1.07)	0.0721	-2.58 (-6.71, 1.55)	0.2210	
ADA result									0.3707
Negative	8/334 (2.4)	2.4	12/331 (3.6)	3.6	0.67 (0.28, 1.62)	0.3721	-1.23 (-5.36, 2.90)	0.5593	
Positive (At any time)	0/ 25 (0.0)	0.0	5/ 35 (14.3)	15.8	0.24 (0.03, 1.88)	0.1750	-15.82 (-35.76, 4.11)	0.1197	
BMI (kg/m2) at enrolment									0.3556
< 30	7/233 (3.0)	3.1	12/261 (4.6)	4.5	0.66 (0.26, 1.66)	0.3814	-1.45 (-6.48, 3.58)	0.5726	
>= 30	1/127 (0.8)	0.7	5/105 (4.8)	4.6	0.25 (0.04, 1.59)	0.1425	-3.89 (-11.97, 4.19)	0.3456	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Modified SELENA Flare Index based flares - mild/moderate or severe flare
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
at least once during study	Number of subjects with events, n (%)	118 (32.8)	137 (37.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.87 (0.71, 1.07)	
	p-value	0.1832	
	Odds Ratio (95% CI)	0.81 (0.60, 1.10)	
	p-value	0.1821	
	Risk Difference (95% CI)	-4.76 (-11.73, 2.21)	
	p-value	0.1811	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.88 (0.72, 1.07)	
	p-value	0.1891	
	Odds Ratio (95% CI)	0.81 (0.60, 1.11)	
	p-value	0.1888	
	Risk Difference (95% CI)	-4.66 (-11.59, 2.28)	
	p-value	0.1879	
	CMH approach		
	Response rate	32.7	37.5
	Difference in response rates (95% CI)	-4.79 (-11.73, 2.15)	
	p-value	0.1762	
	p-Value for test for heterogenity between studies	0.9181	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Modified SELENA Flare Index based flares - mild/moderate or severe flare - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.0266
< 10 points	44/109 (40.4)	40.3	35/106 (33.0)	33.2	1.22 (0.86, 1.75)	0.2645	7.09 (-5.83, 20.00)	0.2821	
>= 10 points	74/251 (29.5)	29.5	102/260 (39.2)	39.3	0.75 (0.59, 0.96)	0.0220	-9.78 (-18.03, -1.53)	0.0201	
OCS dose at baseline									0.8126
<10 mg/day	53/170 (31.2)	31.0	63/181 (34.8)	34.6	0.90 (0.67, 1.21)	0.4771	-3.59 (-13.49, 6.32)	0.4778	
>=10 mg/day	65/190 (34.2)	34.2	74/185 (40.0)	40.0	0.85 (0.66, 1.11)	0.2454	-5.83 (-15.64, 3.98)	0.2442	
Result of type I IFN gene signature test									0.7446
LOW	20/ 62 (32.3)	32.3	22/ 64 (34.4)	34.4	0.94 (0.58, 1.55)	0.8205	-2.12 (-18.75, 14.51)	0.8026	
HIGH	98/298 (32.9)	32.8	115/302 (38.1)	38.1	0.86 (0.70, 1.07)	0.1844	-5.35 (-12.99, 2.29)	0.1697	
Age (years)									0.0914
<= 65	116/348 (33.3)	33.2	135/362 (37.3)	37.4	0.89 (0.73, 1.09)	0.2700	-4.19 (-11.23, 2.85)	0.2431	
> 65	2/ 12 (16.7)	15.9	2/ 4 (50.0)	52.3	0.26 (0.06, 1.08)	0.0629	-36.36 (-91.56, 18.84)	0.1966	
Sex									0.0986
male	5/ 27 (18.5)	18.5	11/ 25 (44.0)	44.1	0.42 (0.17, 1.04)	0.0603	-25.62 (-51.17, -0.06)	0.0494	
female	113/333 (33.9)	33.8	126/341 (37.0)	37.0	0.92 (0.75, 1.13)	0.4105	-3.15 (-10.37, 4.07)	0.3919	
Race									0.6236
White	74/235 (31.5)	31.0	88/244 (36.1)	35.9	0.87 (0.68, 1.12)	0.2856	-4.94 (-13.44, 3.56)	0.2543	
Black	20/ 46 (43.5)	43.2	19/ 48 (39.6)	39.5	1.09 (0.67, 1.78)	0.7198	3.70 (-16.51, 23.92)	0.7196	
Other	21/ 71 (29.6)	29.6	25/ 66 (37.9)	37.9	0.79 (0.49, 1.27)	0.3345	-8.30 (-24.25, 7.66)	0.3083	
Ethnicity									0.4966
Hispanic/Latino	24/ 86 (27.9)	28.3	32/ 89 (36.0)	36.6	0.78 (0.50, 1.20)	0.2555	-8.26 (-22.25, 5.73)	0.2473	
Non-hispanic/Latino	91/266 (34.2)	33.9	100/269 (37.2)	37.1	0.92 (0.73, 1.16)	0.4752	-3.18 (-11.32, 4.97)	0.4448	
Geographic region									0.0578
EU	24/115 (20.9)	20.8	41/122 (33.6)	34.1	0.61 (0.39, 0.93)	0.0235	-13.31 (-24.68, -1.93)	0.0219	
non-EU	94/245 (38.4)	38.0	96/244 (39.3)	39.6	0.97 (0.78, 1.21)	0.7950	-1.58 (-10.17, 7.01)	0.7189	
Onset of disease									0.3932
Paediatric	12/ 26 (46.2)	46.6	10/ 24 (41.7)	41.7	1.14 (0.61, 2.14)	0.6816	4.94 (-22.49, 32.37)	0.7242	
Adult	106/334 (31.7)	31.5	127/342 (37.1)	37.1	0.85 (0.69, 1.05)	0.1416	-5.60 (-12.75, 1.55)	0.1250	
ADA result									0.0726
Negative	112/334 (33.5)	33.4	117/331 (35.3)	35.4	0.95 (0.77, 1.17)	0.6182	-2.01 (-9.26, 5.24)	0.5863	
Positive (At any time)	6/ 25 (24.0)	25.9	20/ 35 (57.1)	57.9	0.47 (0.23, 0.98)	0.0444	-31.97 (-57.22, -6.73)	0.0131	
BMI (kg/m2) at enrolment									0.7235
< 30	67/233 (28.8)	28.7	90/261 (34.5)	34.3	0.83 (0.64, 1.08)	0.1759	-5.55 (-13.78, 2.68)	0.1865	
>= 30	51/127 (40.2)	39.4	47/105 (44.8)	43.9	0.90 (0.66, 1.21)	0.4786	-4.49 (-17.07, 8.09)	0.4842	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score Improvement >=15% (of maxmimum value =40)
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
at least once during study	Number of subjects with events, n (%)	310 (86.1)	291 (79.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.09 (1.02, 1.16)	
	p-value	0.0149	
	Odds Ratio (95% CI)	1.63 (1.10, 2.43)	
	p-value	0.0155	
	Risk Difference (95% CI)	6.78 (1.36, 12.20)	
	p-value	0.0143	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.09 (1.02, 1.16)	
	p-value	0.0110	
	Odds Ratio (95% CI)	1.58 (1.06, 2.35)	
	p-value	0.0238	
	Risk Difference (95% CI)	6.59 (1.13, 12.05)	
	p-value	0.0181	
	p-Value for test for heterogenity between studies	0.1452	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BILAG-2004 Score Improvement >=15% (of maxmimum value =40) at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 52	Number of subjects with events, n (%)	207 (57.5)	159 (43.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.33 (1.15, 1.54)	
	p-value	0.0001	
	Odds Ratio (95% CI)	1.78 (1.33, 2.40)	
	p-value	0.0001	
	Risk Difference (95% CI)	14.29 (7.11, 21.48)	
	p-value	<.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.32 (1.14, 1.53)	
	p-value	0.0002	
	Odds Ratio (95% CI)	1.76 (1.31, 2.36)	
	p-value	0.0002	
	Risk Difference (95% CI)	14.06 (6.85, 21.26)	
	p-value	0.0001	
	p-Value for test for heterogenity between studies	0.7096	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SRI (5) response rate at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=365)
Week 52	Number of subjects with events, n (%)	153 (42.5)	109 (29.9)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.43 (1.17, 1.74)	
	p-value	0.0004	
	Odds Ratio (95% CI)	1.76 (1.29, 2.39)	
	p-value	0.0003	
	Risk Difference (95% CI)	12.84 (5.92, 19.76)	
	p-value	0.0003	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.42 (1.17, 1.73)	
	p-value	0.0005	
	Odds Ratio (95% CI)	1.73 (1.28, 2.36)	
	p-value	0.0004	
	Risk Difference (95% CI)	12.64 (5.70, 19.58)	
	p-value	0.0004	
	CMH approach		
	Response rate	42.6	29.9
	Difference in response rates (95% CI)	12.70 (5.75, 19.65)	
	p-value	0.0003	
	p-Value for test for heterogenity between studies	0.3802	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SRI (6) response rate at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=365)
Week 52	Number of subjects with events, n (%)	150 (41.7)	106 (29.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.44 (1.18, 1.76)	
	p-value	0.0004	
	Odds Ratio (95% CI)	1.76 (1.29, 2.40)	
	p-value	0.0003	
	Risk Difference (95% CI)	12.82 (5.92, 19.72)	
	p-value	0.0003	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.43 (1.17, 1.75)	
	p-value	0.0005	
	Odds Ratio (95% CI)	1.74 (1.28, 2.37)	
	p-value	0.0004	
	Risk Difference (95% CI)	12.63 (5.72, 19.54)	
	p-value	0.0003	
	CMH approach		
	Response rate	41.8	29.1
	Difference in response rates (95% CI)	12.69 (5.77, 19.61)	
	p-value	0.0003	
	p-Value for test for heterogenity between studies	0.1763	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SRI (7) response rate at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=340)	Placebo (N=345)
Week 52	Number of subjects with events, n (%)	108 (31.8)	65 (18.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.69 (1.29, 2.21)	
	p-value	0.0001	
	Odds Ratio (95% CI)	2.01 (1.41, 2.86)	
	p-value	0.0001	
	Risk Difference (95% CI)	12.97 (6.51, 19.43)	
	p-value	<.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.69 (1.29, 2.20)	
	p-value	0.0001	
	Odds Ratio (95% CI)	2.01 (1.41, 2.86)	
	p-value	0.0001	
	Risk Difference (95% CI)	12.92 (6.48, 19.36)	
	p-value	<.0001	
	CMH approach		
	Response rate	31.8	18.7
	Difference in response rates (95% CI)	13.06 (6.44, 19.69)	
	p-value	0.0001	
	p-Value for test for heterogenity between studies	0.9316	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BICLA response rate sensitivity analysis using modified BILAG at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 52	Number of subjects with events, n (%)	184 (51.1)	124 (33.9)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.50 (1.26, 1.79)	
	p-value	<.0001	
	Odds Ratio (95% CI)	2.03 (1.51, 2.75)	
	p-value	<.0001	
	Risk Difference (95% CI)	17.21 (10.11, 24.32)	
	p-value	<.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.51 (1.27, 1.80)	
	p-value	<.0001	
	Odds Ratio (95% CI)	2.04 (1.51, 2.75)	
	p-value	<.0001	
	Risk Difference (95% CI)	17.23 (10.15, 24.31)	
	p-value	<.0001	
	CMH approach		
	Response rate	51.1	34.1
	Difference in response rates (95% CI)	17.05 (9.99, 24.11)	
	p-value	<.0001	
	p-Value for test for heterogenity between studies	0.9518	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BICLA response rate sensitivity analysis excluding subjects with no BILAG A or B or PGA VAS score >2.7 at baseline at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=356)	Placebo (N=363)
Week 52	Number of subjects with events, n (%)	170 (47.8)	112 (30.9)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.54 (1.28, 1.86)	
	p-value	<.0001	
	Odds Ratio (95% CI)	2.03 (1.50, 2.74)	
	p-value	<.0001	
	Risk Difference (95% CI)	16.86 (9.77, 23.96)	
	p-value	<.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.55 (1.28, 1.87)	
	p-value	<.0001	
	Odds Ratio (95% CI)	2.05 (1.51, 2.78)	
	p-value	<.0001	
	Risk Difference (95% CI)	16.90 (9.87, 23.94)	
	p-value	<.0001	
	CMH approach		
	Response rate	47.8	31.1
	Difference in response rates (95% CI)	16.69 (9.66, 23.72)	
	p-value	<.0001	
	p-Value for test for heterogenity between studies	0.9723	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BICLA response rate sensitivity analysis excluding criterion of no restricted medications at week 52
Full analysis set

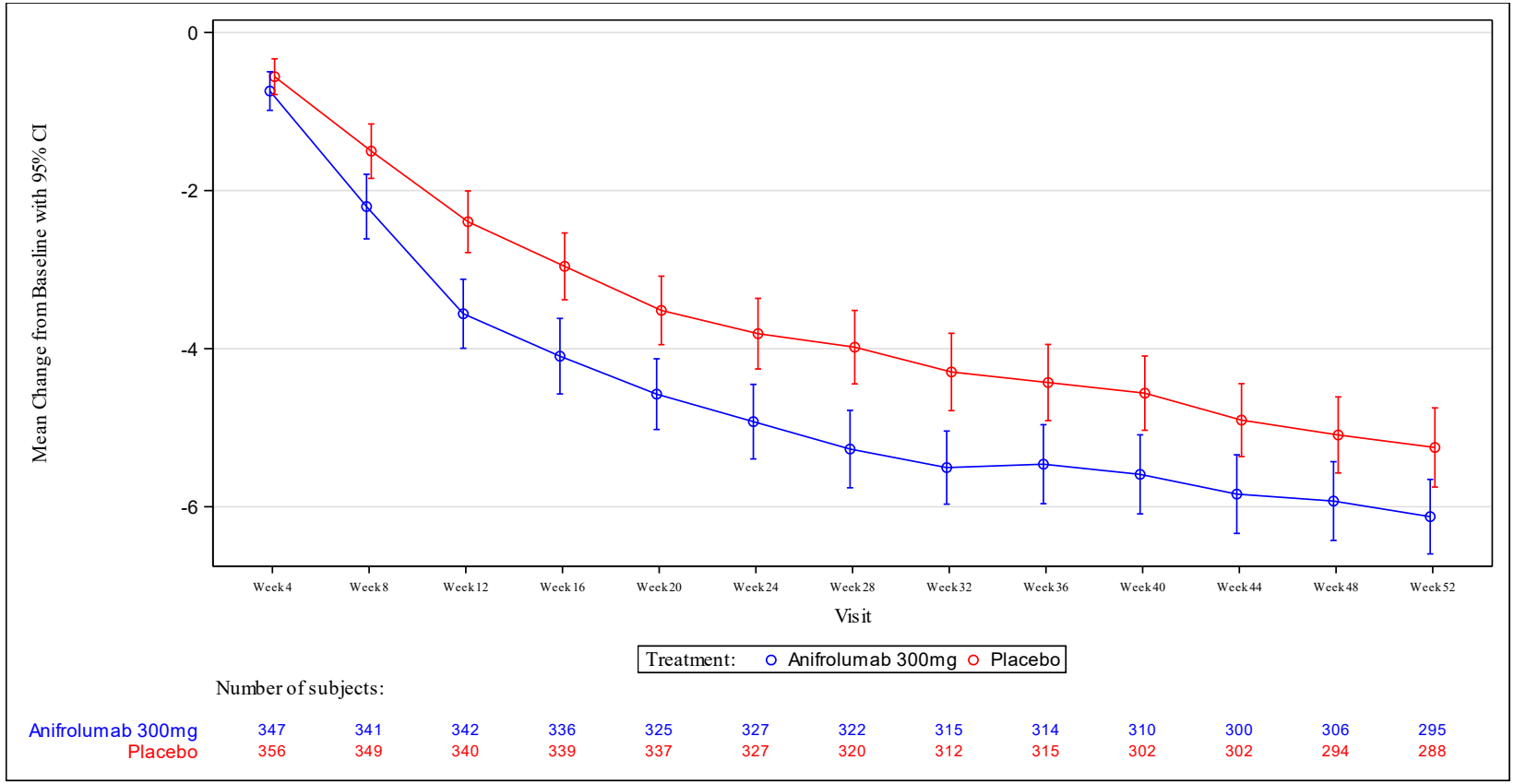
Timepoint		Anifrolumab 300mg (N=360)	Placebo (N=366)
Week 52	Number of subjects with events, n (%)	197 (54.7)	142 (38.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.41 (1.20, 1.65)	
	p-value	<.0001	
	Odds Ratio (95% CI)	1.89 (1.41, 2.53)	
	p-value	<.0001	
	Risk Difference (95% CI)	15.90 (8.67, 23.14)	
	p-value	<.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.41 (1.20, 1.65)	
	p-value	<.0001	
	Odds Ratio (95% CI)	1.91 (1.42, 2.56)	
	p-value	<.0001	
	Risk Difference (95% CI)	15.92 (8.76, 23.09)	
	p-value	<.0001	
	CMH approach		
	Response rate	54.8	39.0
	Difference in response rates (95% CI)	15.77 (8.63, 22.92)	
	p-value	<.0001	
	p-Value for test for heterogenity between studies	0.8662	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - SLEDAI-2K Total Score
Full analysis set

	Anifrolumab 300mg (N=360)				Placebo (N=366)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	360	11.42 (3.83)	0	-	366	11.51 (3.73)	0	-
Week 4	347	10.71 (3.62)	347	-0.74 (2.31)	356	10.89 (3.85)	356	-0.56 (2.17)
Week 8	341	9.27 (4.15)	341	-2.20 (3.84)	349	10.03 (4.11)	349	-1.50 (3.27)
Week 12	342	7.86 (4.02)	342	-3.56 (4.10)	340	9.08 (4.27)	340	-2.39 (3.66)
Week 16	336	7.27 (4.48)	336	-4.10 (4.45)	339	8.52 (4.51)	339	-2.96 (3.95)
Week 20	325	6.73 (4.06)	325	-4.58 (4.10)	337	7.91 (4.33)	337	-3.52 (4.04)
Week 24	327	6.52 (4.09)	327	-4.92 (4.34)	327	7.56 (4.30)	327	-3.81 (4.11)
Week 28	322	6.20 (4.19)	322	-5.27 (4.47)	320	7.37 (4.24)	320	-3.98 (4.22)
Week 32	315	5.91 (3.98)	315	-5.50 (4.17)	312	7.09 (4.45)	312	-4.29 (4.39)
Week 36	314	5.98 (4.25)	314	-5.46 (4.50)	315	6.88 (4.37)	315	-4.43 (4.35)
Week 40	310	5.69 (3.98)	310	-5.59 (4.48)	302	6.61 (4.16)	302	-4.56 (4.15)
Week 44	300	5.46 (3.98)	300	-5.84 (4.38)	302	6.29 (3.97)	302	-4.90 (4.07)
Week 48	306	5.41 (3.99)	306	-5.93 (4.43)	294	6.15 (3.89)	294	-5.09 (4.19)
Week 52	295	5.18 (3.55)	295	-6.13 (4.11)	288	5.98 (3.91)	288	-5.25 (4.32)

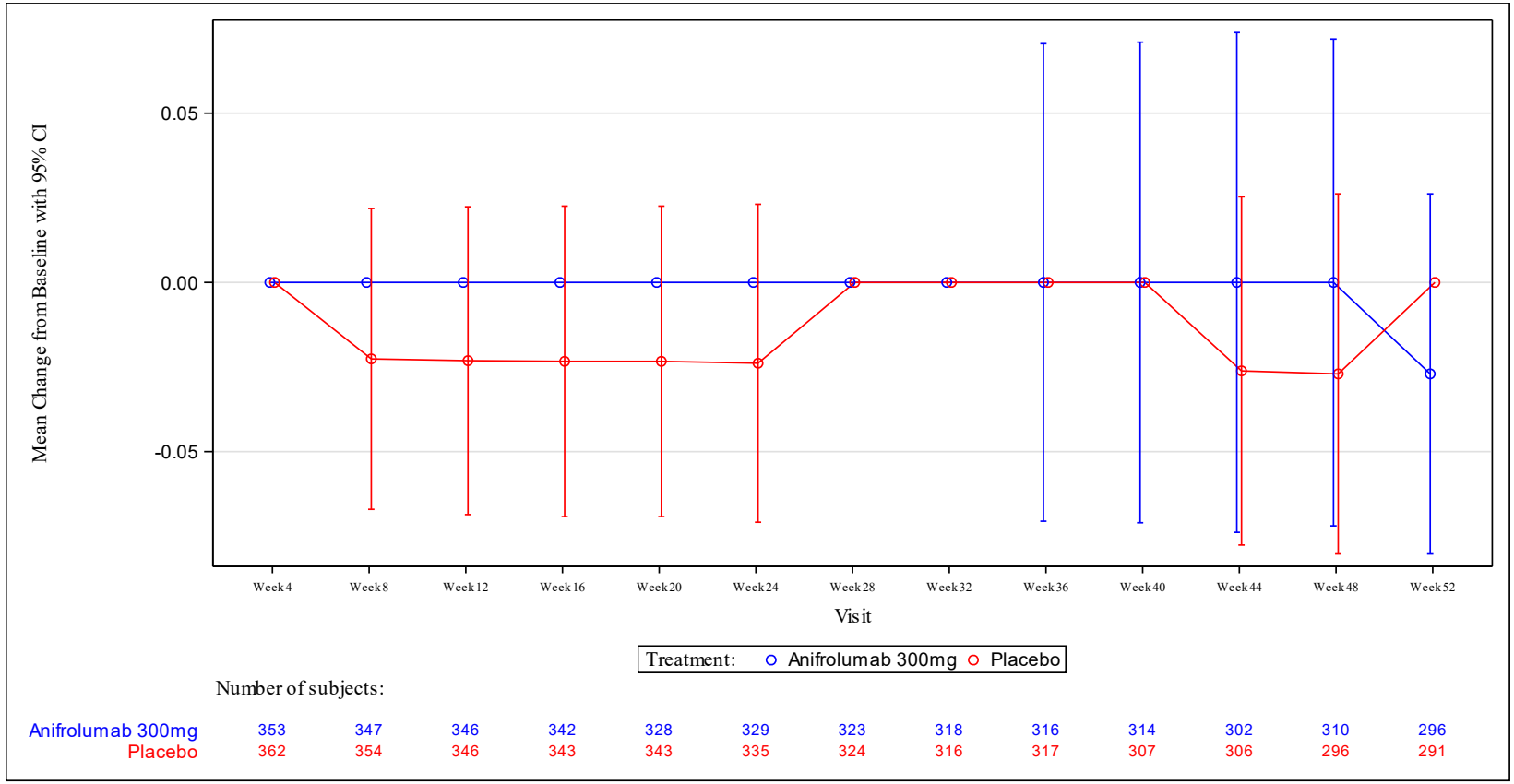
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - SLEDAI-2K Total Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score CNS
Full analysis set

	Anifrolumab 300mg (N=360)				Placebo (N=366)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	360	0.04 (0.60)	0	-	366	0.04 (0.59)	0	-
Week 4	353	0.05 (0.60)	353	0.00 (0.00)	362	0.04 (0.59)	362	0.00 (0.00)
Week 8	347	0.05 (0.61)	347	0.00 (0.00)	354	0.02 (0.43)	354	-0.02 (0.43)
Week 12	346	0.05 (0.61)	346	0.00 (0.00)	346	0.02 (0.43)	346	-0.02 (0.43)
Week 16	342	0.05 (0.61)	342	0.00 (0.00)	343	0.02 (0.43)	343	-0.02 (0.43)
Week 20	328	0.05 (0.62)	328	0.00 (0.00)	343	0.02 (0.43)	343	-0.02 (0.43)
Week 24	329	0.05 (0.62)	329	0.00 (0.00)	335	0.02 (0.44)	335	-0.02 (0.44)
Week 28	323	0.05 (0.63)	323	0.00 (0.00)	324	0.02 (0.44)	324	0.00 (0.00)
Week 32	318	0.05 (0.63)	318	0.00 (0.00)	316	0.00 (0.00)	316	0.00 (0.00)
Week 36	316	0.05 (0.64)	316	0.00 (0.64)	317	0.03 (0.45)	317	0.00 (0.00)
Week 40	314	0.03 (0.45)	314	0.00 (0.64)	307	0.03 (0.46)	307	0.00 (0.00)
Week 44	302	0.05 (0.65)	302	0.00 (0.65)	306	0.00 (0.00)	306	-0.03 (0.46)
Week 48	310	0.05 (0.64)	310	0.00 (0.64)	296	0.00 (0.00)	296	-0.03 (0.46)
Week 52	296	0.03 (0.46)	296	-0.03 (0.46)	291	0.00 (0.00)	291	0.00 (0.00)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Total Organ Score CNS
Full analysis set



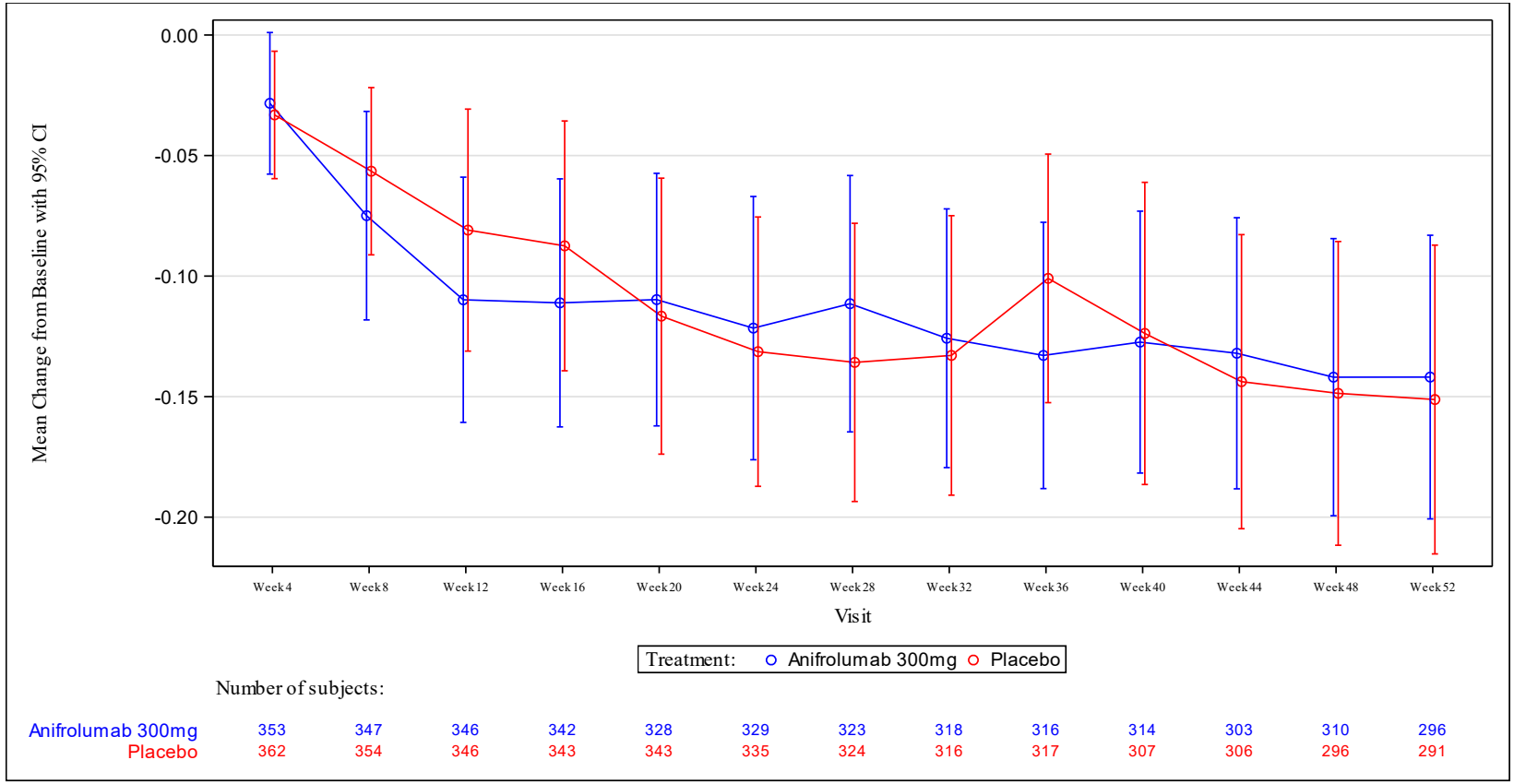
Number of subjects:

	Week 4	Week 8	Week 12	Week 16	Week 20	Week 24	Week 28	Week 32	Week 36	Week 40	Week 44	Week 48	Week 52
Anifrolumab 300mg	353	347	346	342	328	329	323	318	316	314	302	310	296
Placebo	362	354	346	343	343	335	324	316	317	307	306	296	291

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score CVS and Respiratory
Full analysis set

	Anifrolumab 300mg (N=360)				Placebo (N=366)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	360	0.17 (0.55)	0	-	366	0.16 (0.57)	0	-
Week 4	353	0.14 (0.51)	353	-0.03 (0.28)	362	0.13 (0.49)	362	-0.03 (0.26)
Week 8	347	0.09 (0.42)	347	-0.07 (0.41)	354	0.10 (0.43)	354	-0.06 (0.33)
Week 12	346	0.05 (0.32)	346	-0.11 (0.48)	346	0.08 (0.38)	346	-0.08 (0.47)
Week 16	342	0.05 (0.32)	342	-0.11 (0.48)	343	0.05 (0.32)	343	-0.09 (0.49)
Week 20	328	0.05 (0.33)	328	-0.11 (0.48)	343	0.03 (0.26)	343	-0.12 (0.54)
Week 24	329	0.04 (0.27)	329	-0.12 (0.50)	335	0.02 (0.22)	335	-0.13 (0.52)
Week 28	323	0.04 (0.29)	323	-0.11 (0.49)	324	0.02 (0.22)	324	-0.14 (0.53)
Week 32	318	0.03 (0.25)	318	-0.13 (0.49)	316	0.03 (0.22)	316	-0.13 (0.52)
Week 36	316	0.04 (0.27)	316	-0.13 (0.50)	317	0.03 (0.25)	317	-0.10 (0.47)
Week 40	314	0.03 (0.22)	314	-0.13 (0.49)	307	0.03 (0.25)	307	-0.12 (0.56)
Week 44	303	0.03 (0.23)	303	-0.13 (0.50)	306	0.01 (0.16)	306	-0.14 (0.54)
Week 48	310	0.02 (0.20)	310	-0.14 (0.51)	296	0.01 (0.16)	296	-0.15 (0.55)
Week 52	296	0.01 (0.16)	296	-0.14 (0.51)	291	0.01 (0.17)	291	-0.15 (0.56)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Total Organ Score CVS and Respiratory
Full analysis set



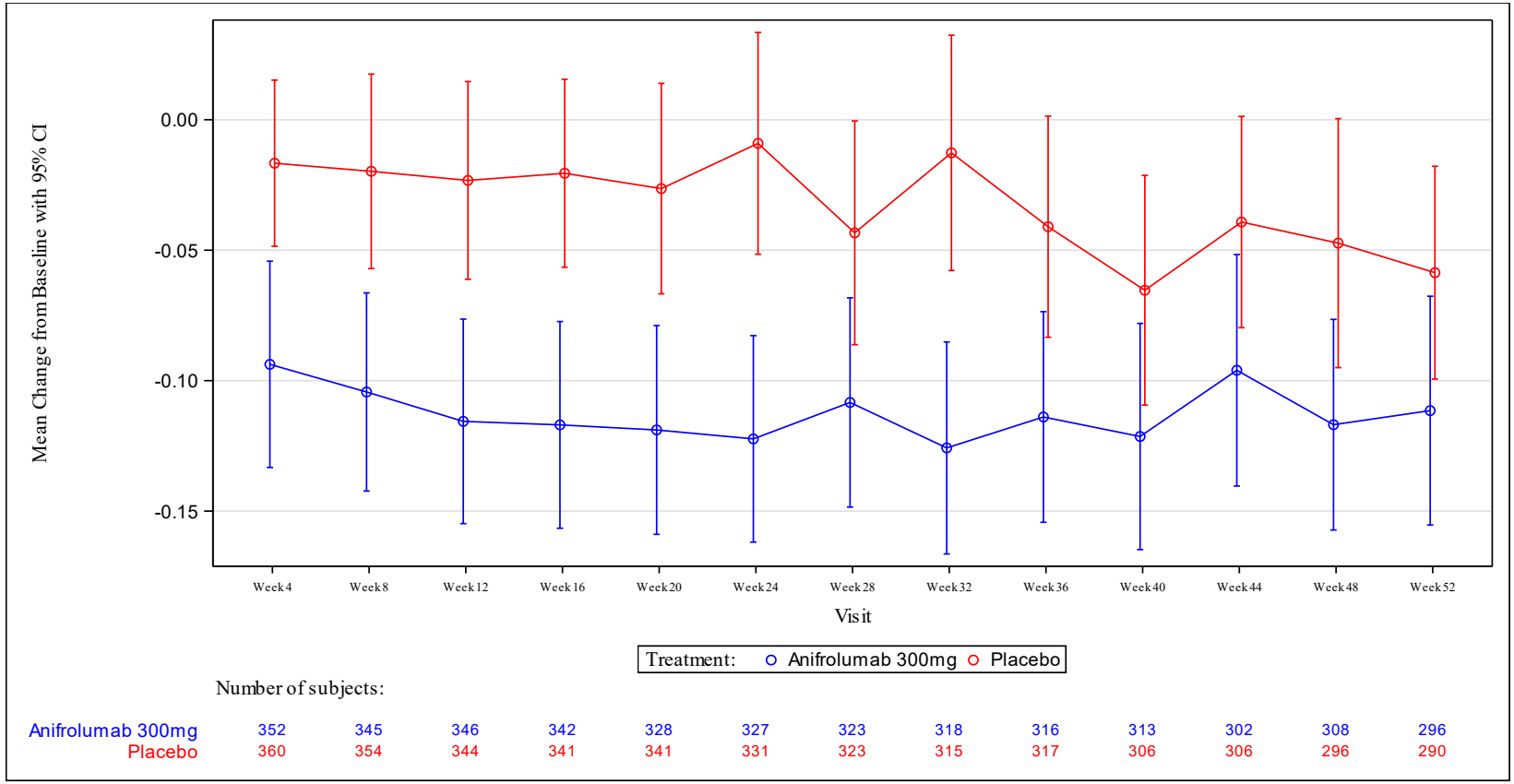
Number of subjects:

	Week 4	Week 8	Week 12	Week 16	Week 20	Week 24	Week 28	Week 32	Week 36	Week 40	Week 44	Week 48	Week 52
Anifrolumab 300mg	353	347	346	342	328	329	323	318	316	314	303	310	296
Placebo	362	354	346	343	343	335	324	316	317	307	306	296	291

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score Hematological
Full analysis set

	Anifrolumab 300mg (N=360)				Placebo (N=366)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	360	0.16 (0.37)	0	-	366	0.14 (0.38)	0	-
Week 4	352	0.07 (0.26)	352	-0.09 (0.38)	360	0.12 (0.35)	360	-0.02 (0.31)
Week 8	345	0.05 (0.22)	345	-0.10 (0.36)	354	0.11 (0.32)	354	-0.02 (0.36)
Week 12	346	0.04 (0.20)	346	-0.12 (0.37)	344	0.11 (0.35)	344	-0.02 (0.36)
Week 16	342	0.04 (0.20)	342	-0.12 (0.37)	341	0.10 (0.30)	341	-0.02 (0.34)
Week 20	328	0.04 (0.19)	328	-0.12 (0.37)	341	0.11 (0.35)	341	-0.03 (0.38)
Week 24	327	0.03 (0.17)	327	-0.12 (0.36)	331	0.12 (0.35)	331	-0.01 (0.39)
Week 28	323	0.04 (0.20)	323	-0.11 (0.37)	323	0.09 (0.30)	323	-0.04 (0.39)
Week 32	318	0.03 (0.17)	318	-0.13 (0.37)	315	0.12 (0.34)	315	-0.01 (0.41)
Week 36	316	0.03 (0.17)	316	-0.11 (0.36)	317	0.09 (0.30)	317	-0.04 (0.38)
Week 40	313	0.03 (0.17)	313	-0.12 (0.39)	306	0.07 (0.27)	306	-0.07 (0.39)
Week 44	302	0.05 (0.24)	302	-0.10 (0.39)	306	0.09 (0.31)	306	-0.04 (0.36)
Week 48	308	0.03 (0.18)	308	-0.12 (0.36)	296	0.08 (0.32)	296	-0.05 (0.42)
Week 52	296	0.04 (0.22)	296	-0.11 (0.38)	290	0.07 (0.27)	290	-0.06 (0.35)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Total Organ Score Hematological
Full analysis set



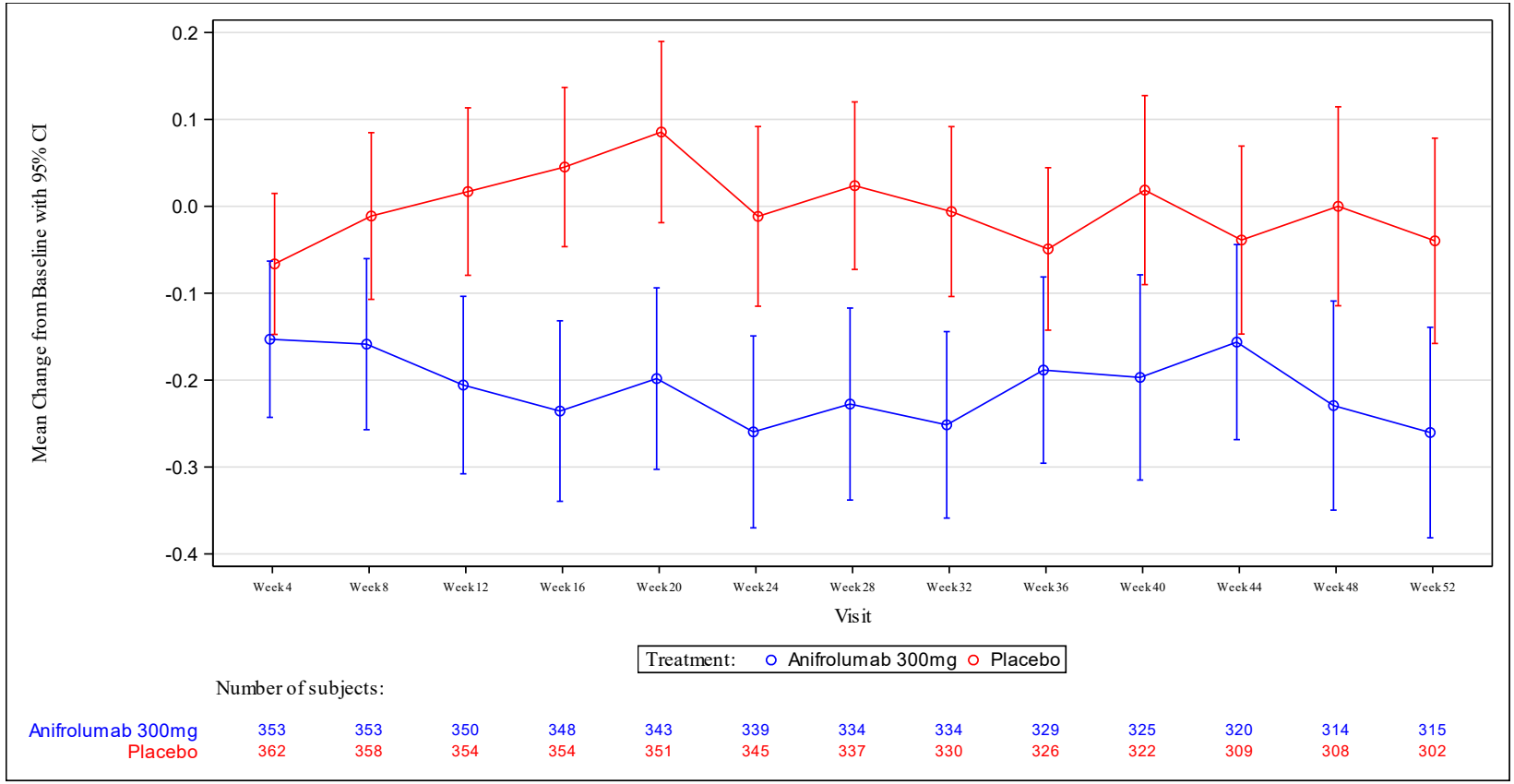
Number of subjects:

	Week 4	Week 8	Week 12	Week 16	Week 20	Week 24	Week 28	Week 32	Week 36	Week 40	Week 44	Week 48	Week 52
Anifrolumab 300mg	352	345	346	342	328	327	323	318	316	313	302	308	296
Placebo	360	354	344	341	341	331	323	315	317	306	306	296	290

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score Immunology
Full analysis set

	Anifrolumab 300mg (N=360)				Placebo (N=366)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	360	1.93 (1.61)	0	-	366	1.90 (1.66)	0	-
Week 4	353	1.77 (1.56)	353	-0.15 (0.86)	362	1.81 (1.61)	362	-0.07 (0.78)
Week 8	353	1.76 (1.56)	353	-0.16 (0.94)	358	1.89 (1.64)	358	-0.01 (0.92)
Week 12	350	1.71 (1.54)	350	-0.21 (0.97)	354	1.90 (1.63)	354	0.02 (0.92)
Week 16	348	1.68 (1.58)	348	-0.24 (0.99)	354	1.93 (1.66)	354	0.05 (0.88)
Week 20	343	1.75 (1.54)	343	-0.20 (0.98)	351	1.97 (1.68)	351	0.09 (0.99)
Week 24	339	1.69 (1.56)	339	-0.26 (1.03)	345	1.85 (1.66)	345	-0.01 (0.98)
Week 28	334	1.71 (1.56)	334	-0.23 (1.03)	337	1.90 (1.67)	337	0.02 (0.90)
Week 32	334	1.66 (1.58)	334	-0.25 (1.00)	330	1.84 (1.62)	330	-0.01 (0.90)
Week 36	329	1.72 (1.55)	329	-0.19 (0.99)	326	1.79 (1.66)	326	-0.05 (0.86)
Week 40	325	1.74 (1.57)	325	-0.20 (1.08)	322	1.84 (1.62)	322	0.02 (0.99)
Week 44	320	1.79 (1.59)	320	-0.16 (1.02)	309	1.77 (1.64)	309	-0.04 (0.97)
Week 48	314	1.73 (1.57)	314	-0.23 (1.08)	308	1.81 (1.63)	308	0.00 (1.02)
Week 52	315	1.68 (1.57)	315	-0.26 (1.09)	302	1.78 (1.62)	302	-0.04 (1.04)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Total Organ Score Immunology
Full analysis set



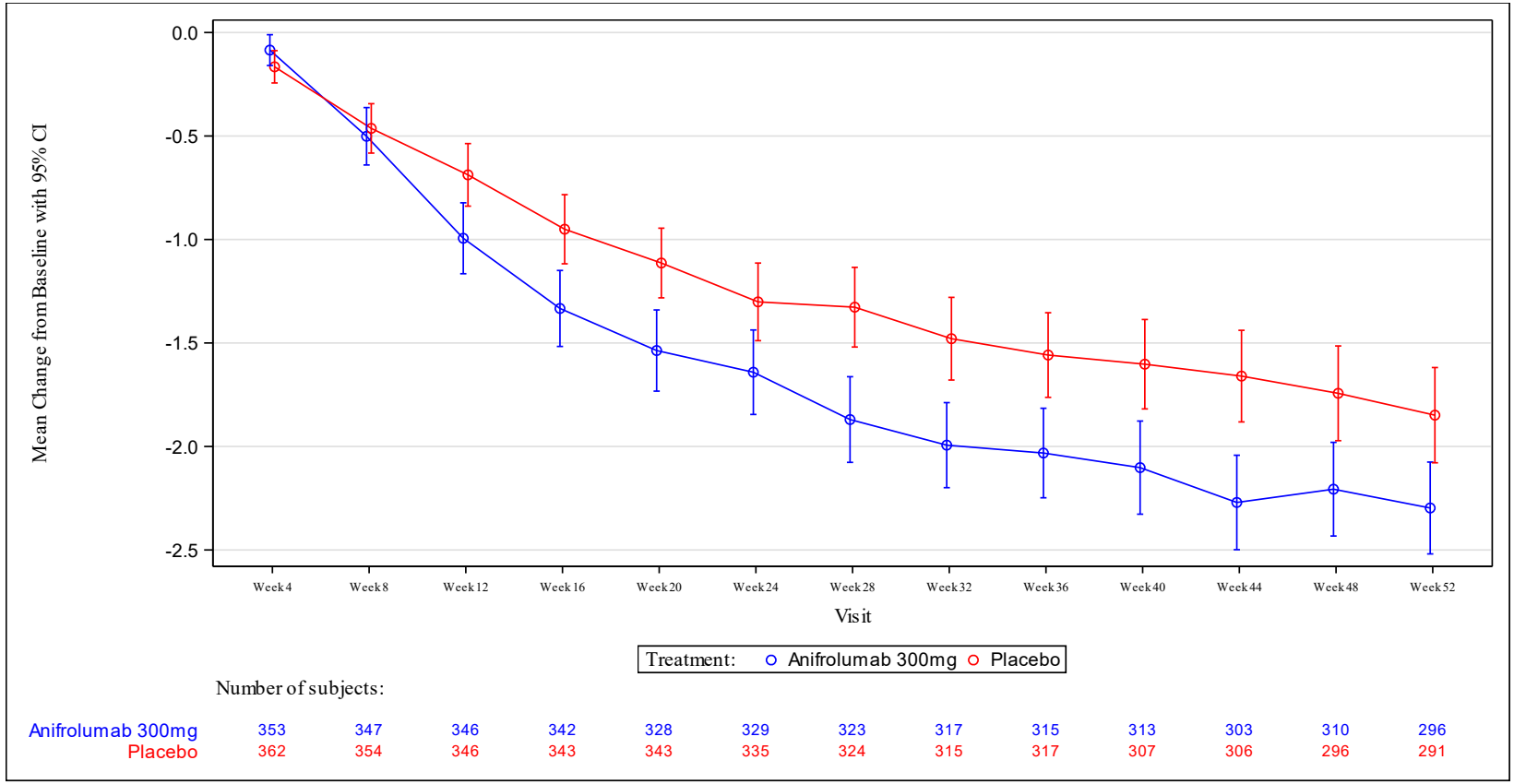
Number of subjects:

	Week 4	Week 8	Week 12	Week 16	Week 20	Week 24	Week 28	Week 32	Week 36	Week 40	Week 44	Week 48	Week 52
Anifrolumab 300mg	353	353	350	348	343	339	334	334	329	325	320	314	315
Placebo	362	358	354	354	351	345	337	330	326	322	309	308	302

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score Mucocutaneous
Full analysis set

	Anifrolumab 300mg (N=360)				Placebo (N=366)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	360	4.15 (1.57)	0	-	366	3.99 (1.59)	0	-
Week 4	353	4.08 (1.61)	353	-0.08 (0.71)	362	3.82 (1.60)	362	-0.17 (0.76)
Week 8	347	3.64 (1.68)	347	-0.50 (1.31)	354	3.53 (1.67)	354	-0.46 (1.14)
Week 12	346	3.16 (1.83)	346	-0.99 (1.62)	346	3.27 (1.79)	346	-0.69 (1.43)
Week 16	342	2.85 (1.82)	342	-1.33 (1.73)	343	3.04 (1.81)	343	-0.95 (1.57)
Week 20	328	2.63 (1.79)	328	-1.54 (1.81)	343	2.89 (1.72)	343	-1.11 (1.58)
Week 24	329	2.56 (1.84)	329	-1.64 (1.88)	335	2.72 (1.74)	335	-1.30 (1.74)
Week 28	323	2.32 (1.78)	323	-1.87 (1.89)	324	2.67 (1.76)	324	-1.33 (1.76)
Week 32	317	2.20 (1.74)	317	-1.99 (1.86)	315	2.54 (1.76)	315	-1.48 (1.80)
Week 36	315	2.14 (1.81)	315	-2.03 (1.95)	317	2.43 (1.75)	317	-1.56 (1.85)
Week 40	313	2.03 (1.79)	313	-2.10 (2.02)	307	2.34 (1.74)	307	-1.60 (1.92)
Week 44	303	1.90 (1.78)	303	-2.27 (2.02)	306	2.31 (1.77)	306	-1.66 (1.97)
Week 48	310	1.94 (1.78)	310	-2.21 (2.02)	296	2.24 (1.75)	296	-1.74 (2.00)
Week 52	296	1.89 (1.74)	296	-2.30 (1.94)	291	2.12 (1.72)	291	-1.85 (1.99)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Total Organ Score Mucocutaneous
Full analysis set



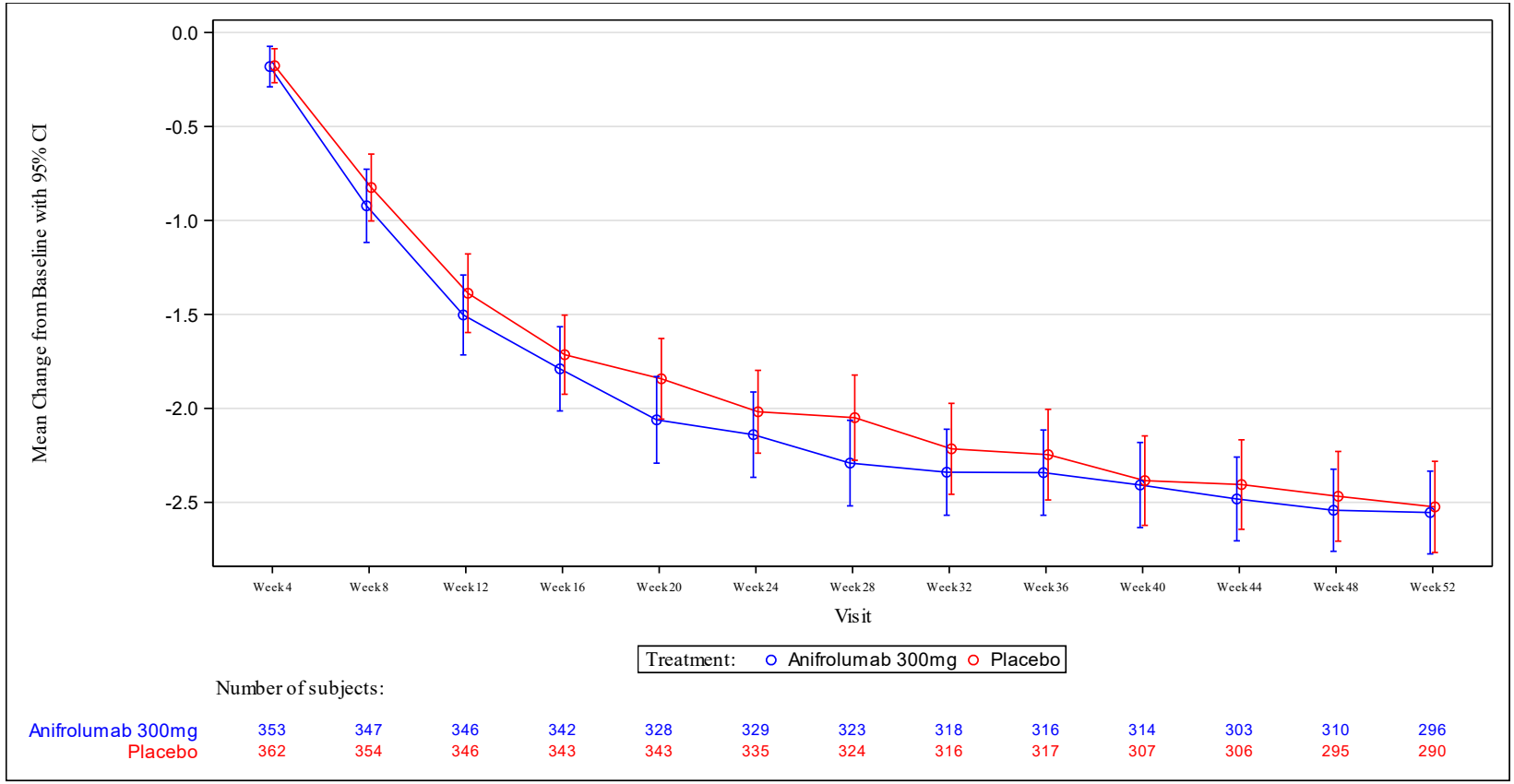
Number of subjects:

	Week 4	Week 8	Week 12	Week 16	Week 20	Week 24	Week 28	Week 32	Week 36	Week 40	Week 44	Week 48	Week 52
Anifrolumab 300mg	353	347	346	342	328	329	323	317	315	313	303	310	296
Placebo	362	354	346	343	343	335	324	315	317	307	306	296	291

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score Musculoskeletal
Full analysis set

	Anifrolumab 300mg (N=360)				Placebo (N=366)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	360	3.76 (1.09)	0	-	366	3.90 (1.04)	0	-
Week 4	353	3.57 (1.31)	353	-0.18 (1.03)	362	3.72 (1.29)	362	-0.18 (0.88)
Week 8	347	2.82 (1.82)	347	-0.92 (1.84)	354	3.07 (1.79)	354	-0.82 (1.70)
Week 12	346	2.25 (1.99)	346	-1.50 (2.01)	346	2.52 (2.03)	346	-1.39 (1.98)
Week 16	342	1.95 (2.05)	342	-1.79 (2.11)	343	2.20 (2.06)	343	-1.71 (1.98)
Week 20	328	1.68 (2.00)	328	-2.06 (2.12)	343	2.05 (2.07)	343	-1.84 (2.02)
Week 24	329	1.62 (1.99)	329	-2.14 (2.09)	335	1.89 (2.07)	335	-2.02 (2.05)
Week 28	323	1.47 (1.96)	323	-2.29 (2.08)	324	1.86 (2.05)	324	-2.05 (2.08)
Week 32	318	1.38 (1.91)	318	-2.34 (2.07)	316	1.70 (2.06)	316	-2.22 (2.19)
Week 36	316	1.39 (1.91)	316	-2.34 (2.05)	317	1.67 (2.10)	317	-2.25 (2.18)
Week 40	314	1.31 (1.91)	314	-2.41 (2.04)	307	1.55 (2.03)	307	-2.38 (2.12)
Week 44	303	1.23 (1.85)	303	-2.48 (1.97)	306	1.52 (2.02)	306	-2.41 (2.12)
Week 48	310	1.19 (1.83)	310	-2.54 (1.95)	295	1.45 (2.01)	295	-2.47 (2.08)
Week 52	296	1.18 (1.83)	296	-2.55 (1.92)	290	1.39 (1.99)	290	-2.52 (2.10)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Total Organ Score Musculoskeletal
Full analysis set



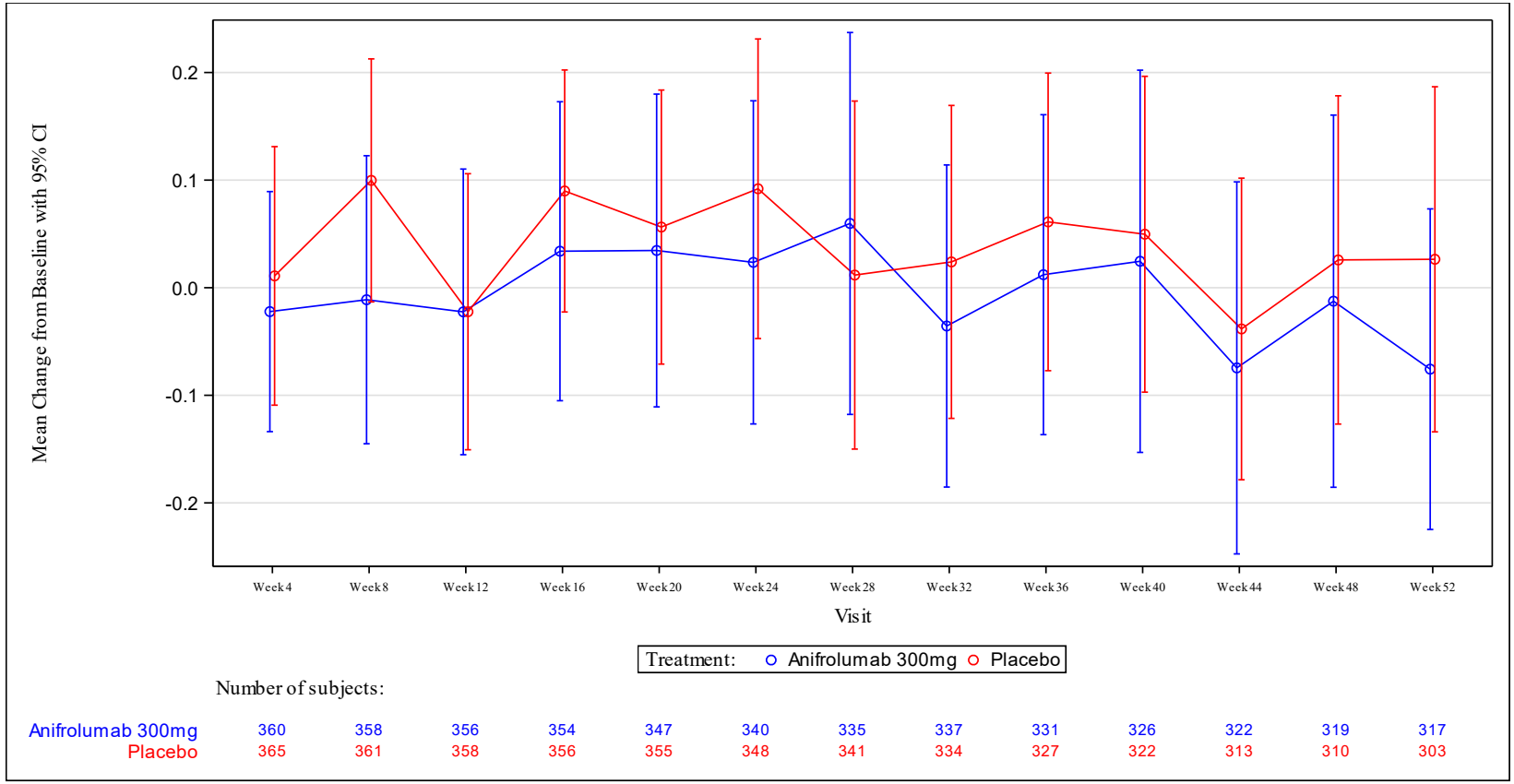
Number of subjects:

	Week 4	Week 8	Week 12	Week 16	Week 20	Week 24	Week 28	Week 32	Week 36	Week 40	Week 44	Week 48	Week 52
Anifrolumab 300mg	353	347	346	342	328	329	323	318	316	314	303	310	296
Placebo	362	354	346	343	343	335	324	316	317	307	306	295	290

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score Renal
Full analysis set

	Anifrolumab 300mg (N=360)				Placebo (N=366)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	360	0.36 (1.42)	0	-	366	0.50 (1.70)	0	-
Week 4	360	0.33 (1.42)	360	-0.02 (1.08)	365	0.52 (1.91)	365	0.01 (1.17)
Week 8	358	0.35 (1.47)	358	-0.01 (1.29)	361	0.61 (1.94)	361	0.10 (1.09)
Week 12	356	0.34 (1.46)	356	-0.02 (1.27)	358	0.46 (1.53)	358	-0.02 (1.23)
Week 16	354	0.40 (1.64)	354	0.03 (1.33)	356	0.54 (1.74)	356	0.09 (1.08)
Week 20	347	0.37 (1.51)	347	0.03 (1.38)	355	0.51 (1.72)	355	0.06 (1.22)
Week 24	340	0.34 (1.48)	340	0.02 (1.41)	348	0.55 (1.84)	348	0.09 (1.32)
Week 28	335	0.37 (1.73)	335	0.06 (1.65)	341	0.48 (1.68)	341	0.01 (1.52)
Week 32	337	0.27 (1.18)	337	-0.04 (1.40)	334	0.46 (1.64)	334	0.02 (1.35)
Week 36	331	0.33 (1.41)	331	0.01 (1.38)	327	0.50 (1.66)	327	0.06 (1.27)
Week 40	326	0.32 (1.50)	326	0.02 (1.63)	322	0.50 (1.74)	322	0.05 (1.34)
Week 44	322	0.25 (1.32)	322	-0.07 (1.58)	313	0.36 (1.56)	313	-0.04 (1.26)
Week 48	319	0.30 (1.49)	319	-0.01 (1.57)	310	0.43 (1.66)	310	0.03 (1.37)
Week 52	317	0.24 (1.27)	317	-0.08 (1.35)	303	0.41 (1.56)	303	0.03 (1.42)

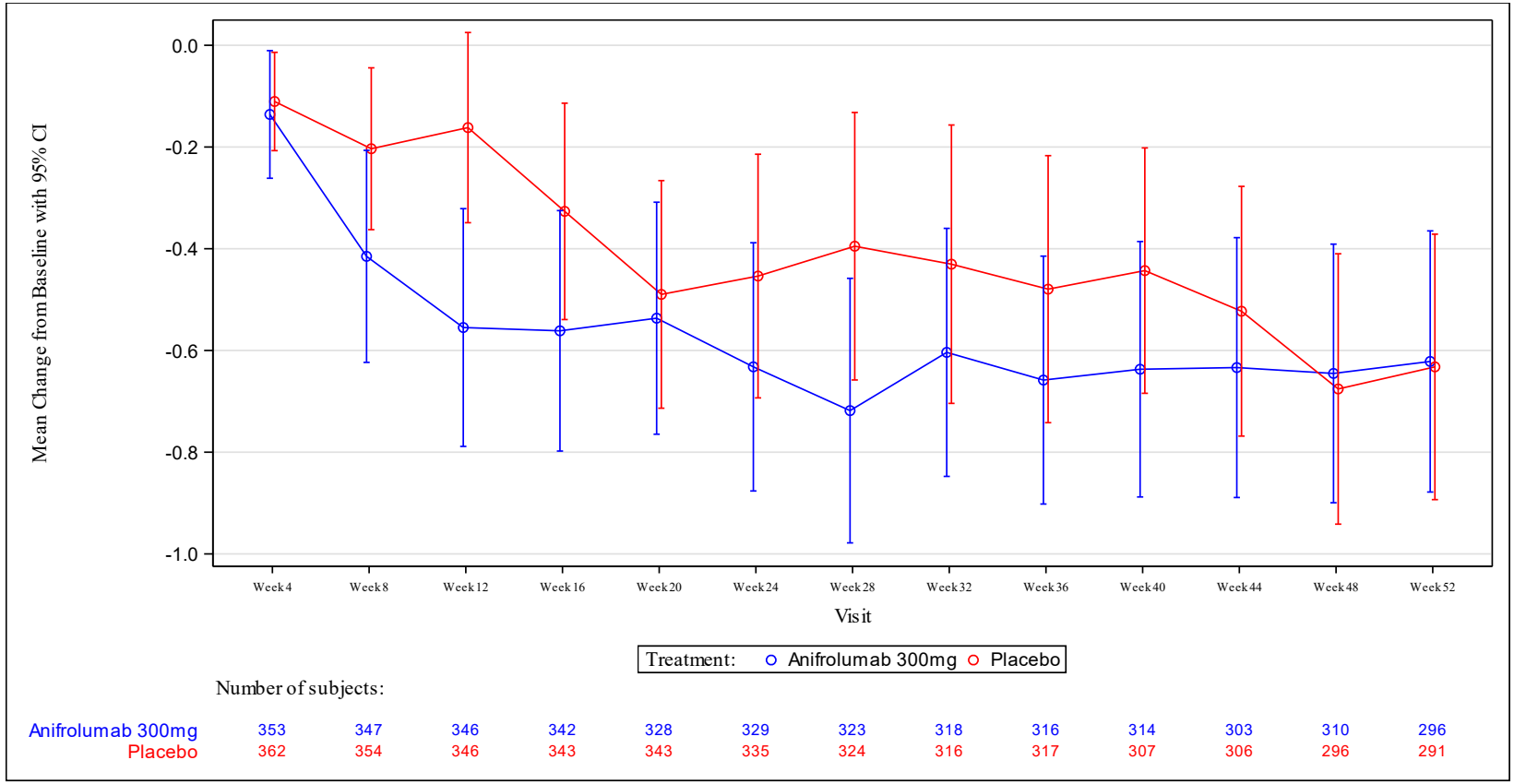
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Total Organ Score Renal
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Total Organ Score Vascular
Full analysis set

	Anifrolumab 300mg (N=360)				Placebo (N=366)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	360	0.87 (2.49)	0	-	366	0.87 (2.50)	0	-
Week 4	353	0.75 (2.33)	353	-0.14 (1.20)	362	0.77 (2.37)	362	-0.11 (0.93)
Week 8	347	0.48 (1.91)	347	-0.41 (1.97)	354	0.70 (2.26)	354	-0.20 (1.52)
Week 12	346	0.30 (1.52)	346	-0.55 (2.21)	346	0.69 (2.25)	346	-0.16 (1.77)
Week 16	342	0.30 (1.53)	342	-0.56 (2.22)	343	0.58 (2.08)	343	-0.33 (2.00)
Week 20	328	0.27 (1.44)	328	-0.54 (2.10)	343	0.42 (1.79)	343	-0.49 (2.11)
Week 24	329	0.27 (1.44)	329	-0.63 (2.25)	335	0.36 (1.66)	335	-0.45 (2.23)
Week 28	323	0.20 (1.25)	323	-0.72 (2.38)	324	0.47 (1.88)	324	-0.40 (2.41)
Week 32	318	0.28 (1.46)	318	-0.60 (2.21)	316	0.41 (1.76)	316	-0.43 (2.47)
Week 36	316	0.25 (1.40)	316	-0.66 (2.20)	317	0.35 (1.65)	317	-0.48 (2.38)
Week 40	314	0.20 (1.26)	314	-0.64 (2.26)	307	0.34 (1.61)	307	-0.44 (2.15)
Week 44	303	0.18 (1.20)	303	-0.63 (2.26)	306	0.24 (1.35)	306	-0.52 (2.18)
Week 48	310	0.21 (1.27)	310	-0.65 (2.27)	296	0.16 (1.13)	296	-0.68 (2.32)
Week 52	296	0.16 (1.13)	296	-0.62 (2.24)	291	0.19 (1.23)	291	-0.63 (2.26)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Total Organ Score Vascular
Full analysis set



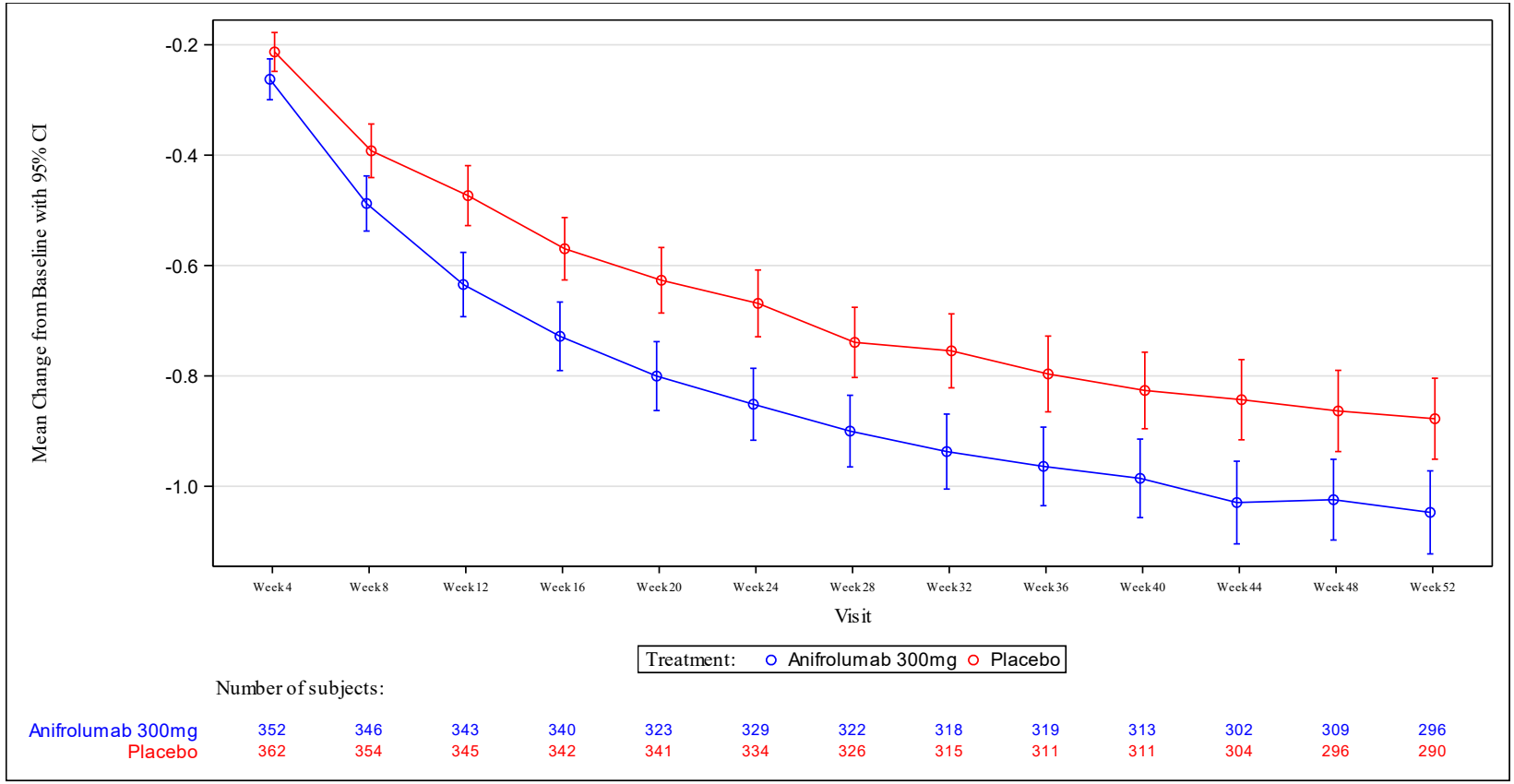
Number of subjects:

	Week 4	Week 8	Week 12	Week 16	Week 20	Week 24	Week 28	Week 32	Week 36	Week 40	Week 44	Week 48	Week 52
Anifrolumab 300mg	353	347	346	342	328	329	323	318	316	314	303	310	296
Placebo	362	354	346	343	343	335	324	316	317	307	306	296	291

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - PGA
Full analysis set

	Anifrolumab 300mg (N=360)				Placebo (N=366)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	360	1.77 (0.41)	0	-	366	1.80 (0.39)	0	-
Week 4	352	1.51 (0.51)	352	-0.26 (0.35)	362	1.59 (0.47)	362	-0.21 (0.34)
Week 8	346	1.28 (0.54)	346	-0.49 (0.47)	354	1.41 (0.54)	354	-0.39 (0.46)
Week 12	343	1.14 (0.58)	343	-0.63 (0.55)	345	1.33 (0.55)	345	-0.47 (0.51)
Week 16	340	1.04 (0.60)	340	-0.73 (0.58)	342	1.23 (0.55)	342	-0.57 (0.53)
Week 20	323	0.96 (0.57)	323	-0.80 (0.57)	341	1.18 (0.58)	341	-0.63 (0.56)
Week 24	329	0.92 (0.60)	329	-0.85 (0.60)	334	1.12 (0.56)	334	-0.67 (0.56)
Week 28	322	0.87 (0.59)	322	-0.90 (0.59)	326	1.06 (0.58)	326	-0.74 (0.58)
Week 32	318	0.84 (0.58)	318	-0.94 (0.62)	315	1.04 (0.60)	315	-0.75 (0.60)
Week 36	319	0.81 (0.60)	319	-0.96 (0.65)	311	0.99 (0.61)	311	-0.80 (0.62)
Week 40	313	0.78 (0.59)	313	-0.99 (0.64)	311	0.96 (0.57)	311	-0.83 (0.62)
Week 44	302	0.73 (0.59)	302	-1.03 (0.66)	304	0.95 (0.59)	304	-0.84 (0.64)
Week 48	309	0.74 (0.59)	309	-1.02 (0.65)	296	0.92 (0.59)	296	-0.86 (0.64)
Week 52	296	0.70 (0.59)	296	-1.05 (0.66)	290	0.90 (0.59)	290	-0.88 (0.63)

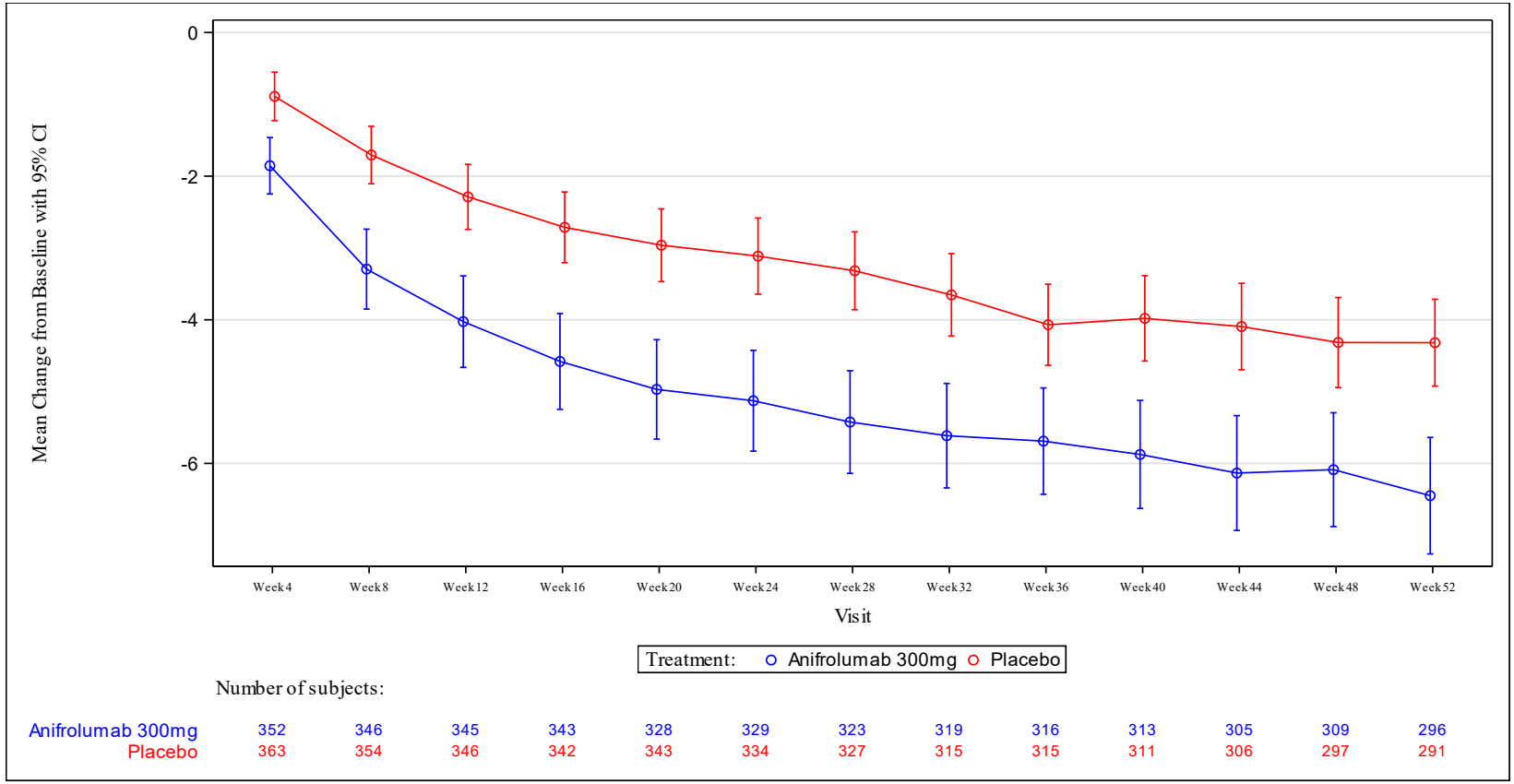
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - PGA
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - CLASI Total Activity Score
Full analysis set

	Anifrolumab 300mg (N=360)				Placebo (N=366)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	360	8.42 (7.60)	0	-	366	7.82 (7.22)	0	-
Week 4	352	6.64 (6.00)	352	-1.86 (3.75)	363	6.96 (6.98)	363	-0.89 (3.27)
Week 8	346	5.20 (4.89)	346	-3.29 (5.26)	354	6.20 (6.96)	354	-1.71 (3.83)
Week 12	345	4.50 (4.54)	345	-4.03 (6.02)	346	5.55 (6.55)	346	-2.29 (4.28)
Week 16	343	4.02 (4.31)	343	-4.58 (6.28)	342	5.10 (6.22)	342	-2.71 (4.63)
Week 20	328	3.64 (4.14)	328	-4.97 (6.37)	343	5.06 (6.45)	343	-2.96 (4.77)
Week 24	329	3.50 (4.31)	329	-5.13 (6.47)	334	4.89 (6.62)	334	-3.11 (4.93)
Week 28	323	3.17 (3.76)	323	-5.42 (6.53)	327	4.59 (6.35)	327	-3.32 (4.99)
Week 32	319	2.94 (3.63)	319	-5.61 (6.61)	315	4.36 (6.10)	315	-3.65 (5.17)
Week 36	316	2.83 (3.59)	316	-5.69 (6.69)	315	3.99 (5.67)	315	-4.07 (5.10)
Week 40	313	2.54 (3.33)	313	-5.88 (6.76)	311	3.94 (5.78)	311	-3.98 (5.32)
Week 44	305	2.62 (3.82)	305	-6.13 (7.10)	306	3.87 (5.80)	306	-4.09 (5.35)
Week 48	309	2.46 (3.26)	309	-6.09 (7.08)	297	3.70 (5.46)	297	-4.32 (5.49)
Week 52	296	2.44 (3.65)	296	-6.45 (7.09)	291	3.60 (5.47)	291	-4.32 (5.24)

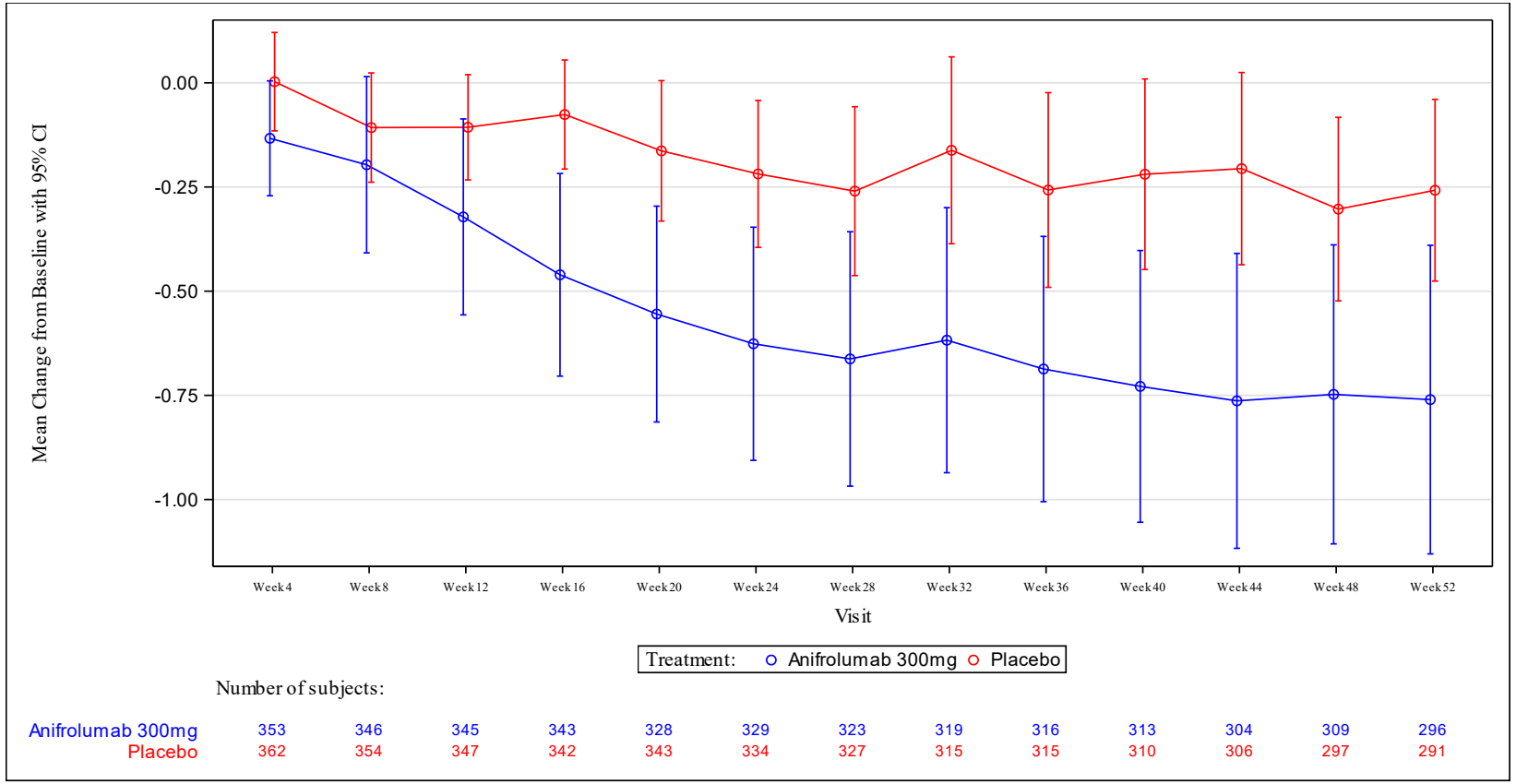
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - CLASI Total Activity Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - CLASI Total Damage Score
Full analysis set

	Anifrolumab 300mg (N=360)				Placebo (N=366)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	360	2.15 (4.88)	0	-	366	1.88 (4.36)	0	-
Week 4	353	2.03 (4.73)	353	-0.13 (1.32)	362	1.87 (4.43)	362	0.00 (1.14)
Week 8	346	1.97 (4.69)	346	-0.20 (2.00)	354	1.81 (4.30)	354	-0.11 (1.25)
Week 12	345	1.86 (4.61)	345	-0.32 (2.22)	347	1.77 (4.37)	347	-0.11 (1.20)
Week 16	343	1.75 (4.37)	343	-0.46 (2.29)	342	1.73 (4.21)	342	-0.08 (1.23)
Week 20	328	1.66 (4.08)	328	-0.55 (2.38)	343	1.72 (4.30)	343	-0.16 (1.59)
Week 24	329	1.54 (3.94)	329	-0.63 (2.58)	334	1.71 (4.11)	334	-0.22 (1.64)
Week 28	323	1.52 (4.03)	323	-0.66 (2.79)	327	1.61 (4.04)	327	-0.26 (1.86)
Week 32	319	1.54 (4.03)	319	-0.62 (2.89)	315	1.61 (3.99)	315	-0.16 (2.02)
Week 36	316	1.49 (3.98)	316	-0.69 (2.88)	315	1.55 (3.80)	315	-0.26 (2.11)
Week 40	313	1.35 (3.75)	313	-0.73 (2.93)	310	1.46 (3.78)	310	-0.22 (2.05)
Week 44	304	1.55 (4.28)	304	-0.76 (3.14)	306	1.49 (3.85)	306	-0.21 (2.05)
Week 48	309	1.45 (3.99)	309	-0.75 (3.21)	297	1.45 (3.79)	297	-0.30 (1.93)
Week 52	296	1.63 (4.46)	296	-0.76 (3.24)	291	1.44 (3.79)	291	-0.26 (1.89)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - CLASI Total Damage Score
Full analysis set



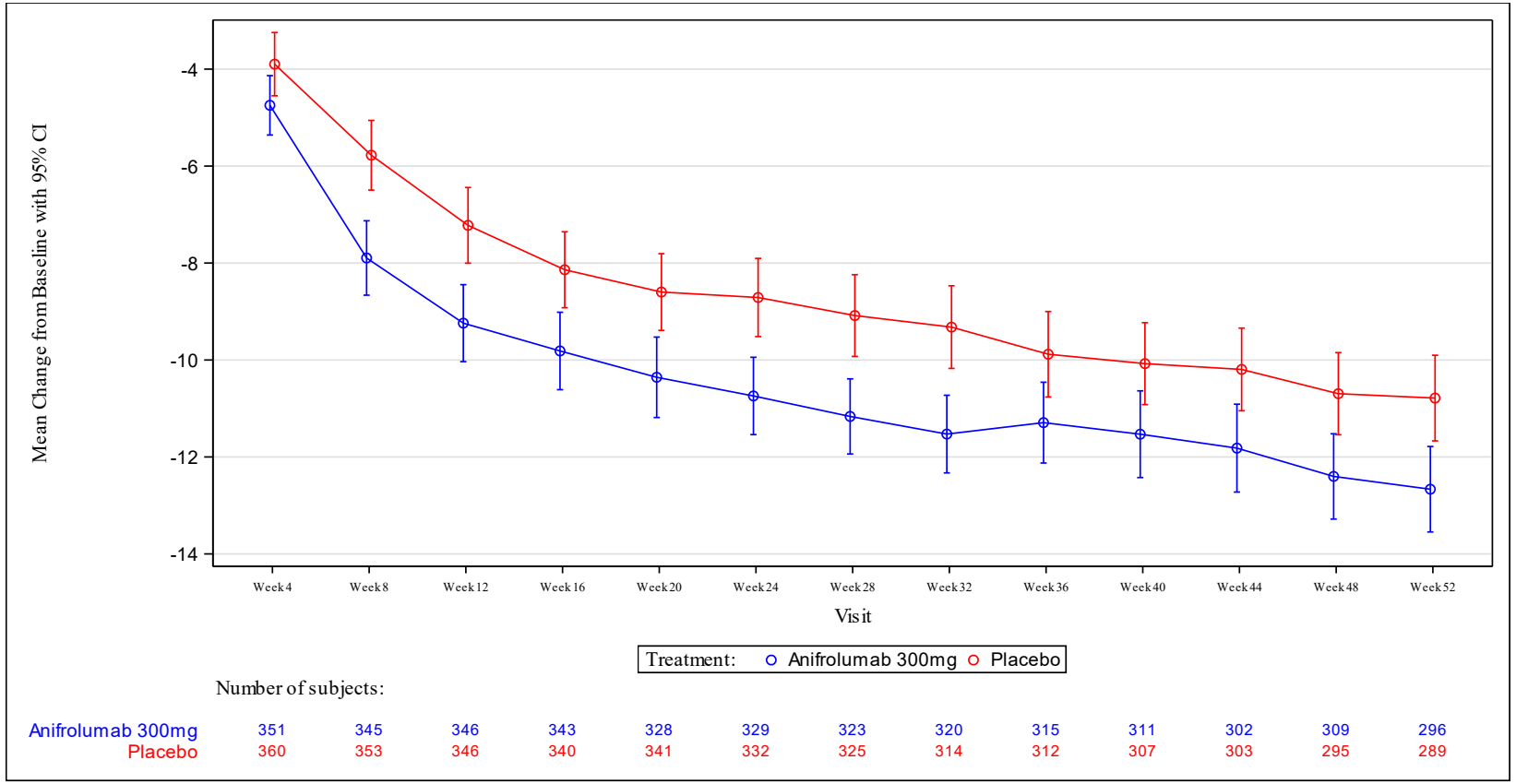
Number of subjects:

	Week 4	Week 8	Week 12	Week 16	Week 20	Week 24	Week 28	Week 32	Week 36	Week 40	Week 44	Week 48	Week 52
Anifrolumab 300mg	353	346	345	343	328	329	323	319	316	313	304	309	296
Placebo	362	354	347	342	343	334	327	315	315	310	306	297	291

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - BILAG Global Score
Full analysis set

	Anifrolumab 300mg (N=360)				Placebo (N=366)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	360	19.23 (5.58)	0	-	366	18.95 (5.23)	0	-
Week 4	351	14.50 (7.03)	351	-4.75 (5.83)	360	15.01 (6.64)	360	-3.90 (6.30)
Week 8	345	11.23 (7.33)	345	-7.90 (7.25)	353	13.18 (7.25)	353	-5.78 (6.87)
Week 12	346	9.88 (7.43)	346	-9.24 (7.51)	346	11.74 (7.11)	346	-7.22 (7.39)
Week 16	343	9.34 (7.60)	343	-9.81 (7.52)	340	10.85 (7.29)	340	-8.14 (7.35)
Week 20	328	8.79 (7.45)	328	-10.36 (7.64)	341	10.28 (7.26)	341	-8.60 (7.43)
Week 24	329	8.49 (7.46)	329	-10.74 (7.36)	332	10.23 (7.40)	332	-8.71 (7.47)
Week 28	323	7.99 (7.13)	323	-11.16 (7.08)	325	9.81 (7.42)	325	-9.08 (7.73)
Week 32	320	7.62 (6.97)	320	-11.53 (7.29)	314	9.68 (7.40)	314	-9.32 (7.68)
Week 36	315	7.97 (7.27)	315	-11.29 (7.51)	312	9.01 (7.41)	312	-9.88 (7.91)
Week 40	311	7.55 (7.31)	311	-11.53 (8.01)	307	8.90 (7.06)	307	-10.07 (7.52)
Week 44	302	7.23 (7.08)	302	-11.82 (8.01)	303	8.70 (6.86)	303	-10.19 (7.54)
Week 48	309	6.78 (6.90)	309	-12.40 (7.86)	295	8.18 (6.75)	295	-10.69 (7.39)
Week 52	296	6.46 (6.73)	296	-12.67 (7.71)	289	8.11 (6.79)	289	-10.79 (7.63)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - BILAG Global Score
Full analysis set



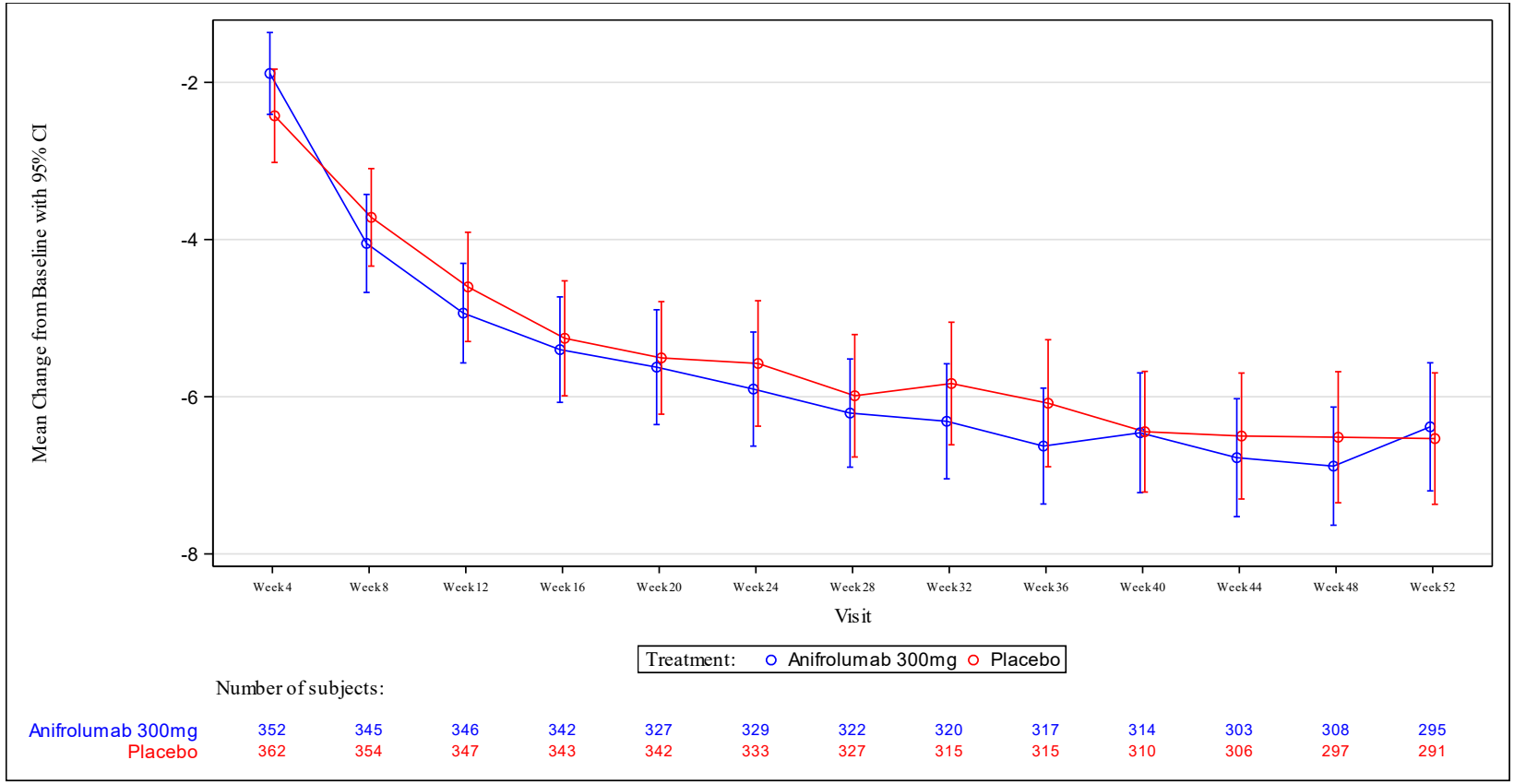
Number of subjects:

	Week 4	Week 8	Week 12	Week 16	Week 20	Week 24	Week 28	Week 32	Week 36	Week 40	Week 44	Week 48	Week 52
Anifrolumab 300mg	351	345	346	343	328	329	323	320	315	311	302	309	296
Placebo	360	353	346	340	341	332	325	314	312	307	303	295	289

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Tender Joint Count
Full analysis set

	Anifrolumab 300mg (N=360)				Placebo (N=366)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	360	10.31 (7.41)	0	-	366	10.79 (7.53)	0	-
Week 4	352	8.37 (7.68)	352	-1.89 (4.97)	362	8.35 (7.78)	362	-2.43 (5.74)
Week 8	345	6.13 (6.90)	345	-4.05 (5.89)	354	7.07 (7.34)	354	-3.72 (5.94)
Week 12	346	5.28 (6.72)	346	-4.94 (5.99)	347	6.20 (7.35)	347	-4.60 (6.58)
Week 16	342	4.85 (6.84)	342	-5.40 (6.31)	343	5.41 (6.75)	343	-5.26 (6.89)
Week 20	327	4.59 (6.95)	327	-5.62 (6.71)	342	5.22 (6.69)	342	-5.51 (6.73)
Week 24	329	4.46 (6.79)	329	-5.90 (6.69)	333	5.01 (6.95)	333	-5.58 (7.40)
Week 28	322	4.04 (6.36)	322	-6.21 (6.28)	327	4.66 (6.63)	327	-5.99 (7.16)
Week 32	320	3.88 (6.17)	320	-6.31 (6.65)	315	4.85 (7.01)	315	-5.83 (7.03)
Week 36	317	3.69 (6.05)	317	-6.63 (6.67)	315	4.57 (6.93)	315	-6.08 (7.29)
Week 40	314	3.68 (6.21)	314	-6.46 (6.86)	310	4.23 (6.41)	310	-6.45 (6.87)
Week 44	303	3.24 (5.52)	303	-6.78 (6.63)	306	4.02 (6.44)	306	-6.50 (7.12)
Week 48	308	3.52 (6.00)	308	-6.88 (6.71)	297	4.08 (6.42)	297	-6.52 (7.30)
Week 52	295	3.75 (6.46)	295	-6.38 (7.11)	291	3.99 (6.39)	291	-6.53 (7.25)

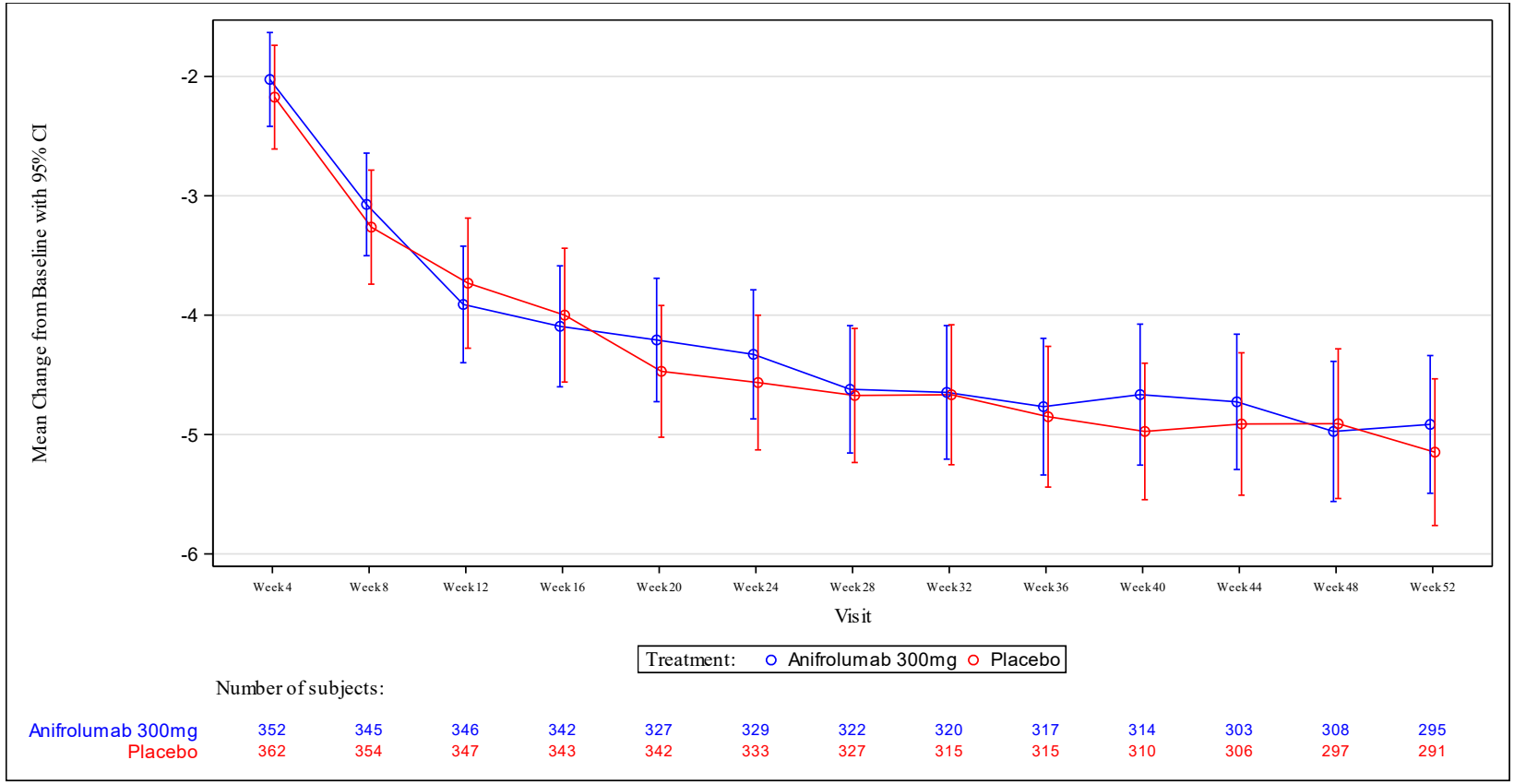
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Tender Joint Count
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Swollen Joint Count
Full analysis set

	Anifrolumab 300mg (N=360)				Placebo (N=366)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	360	6.78 (5.75)	0	-	366	7.22 (5.74)	0	-
Week 4	352	4.71 (5.39)	352	-2.03 (3.75)	362	5.01 (5.52)	362	-2.17 (4.20)
Week 8	345	3.51 (4.93)	345	-3.07 (4.06)	354	3.91 (5.05)	354	-3.26 (4.57)
Week 12	346	2.80 (4.56)	346	-3.91 (4.62)	347	3.46 (4.96)	347	-3.73 (5.16)
Week 16	342	2.61 (4.61)	342	-4.09 (4.76)	343	3.11 (4.77)	343	-4.00 (5.28)
Week 20	327	2.35 (4.69)	327	-4.21 (4.75)	342	2.77 (4.49)	342	-4.47 (5.19)
Week 24	329	2.42 (4.74)	329	-4.33 (4.98)	333	2.52 (4.40)	333	-4.56 (5.23)
Week 28	322	2.10 (4.31)	322	-4.62 (4.87)	327	2.56 (4.43)	327	-4.67 (5.16)
Week 32	320	1.94 (4.08)	320	-4.65 (5.09)	315	2.54 (4.52)	315	-4.67 (5.29)
Week 36	317	1.97 (4.30)	317	-4.77 (5.18)	315	2.31 (4.31)	315	-4.85 (5.32)
Week 40	314	1.94 (4.50)	314	-4.67 (5.32)	310	2.14 (3.97)	310	-4.97 (5.11)
Week 44	303	1.75 (4.15)	303	-4.73 (5.01)	306	2.19 (4.35)	306	-4.91 (5.30)
Week 48	308	1.83 (4.32)	308	-4.97 (5.23)	297	2.20 (4.49)	297	-4.91 (5.49)
Week 52	295	1.63 (3.66)	295	-4.92 (5.03)	291	2.01 (4.05)	291	-5.15 (5.32)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Swollen Joint Count
Full analysis set



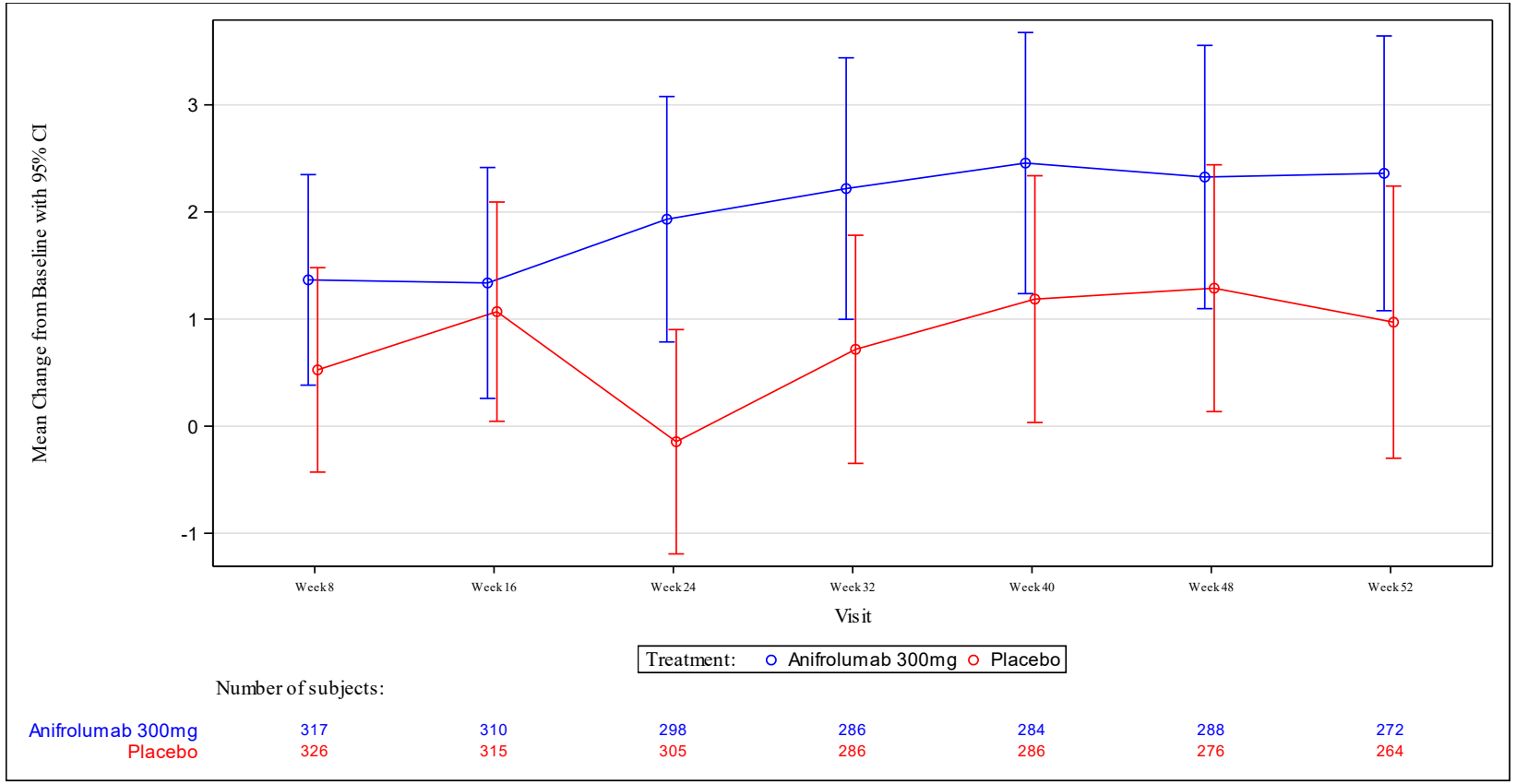
Number of subjects:

	Week 4	Week 8	Week 12	Week 16	Week 20	Week 24	Week 28	Week 32	Week 36	Week 40	Week 44	Week 48	Week 52
Anifrolumab 300mg	352	345	346	342	327	329	322	320	317	314	303	308	295
Placebo	362	354	347	343	342	333	327	315	315	310	306	297	291

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Mental Component Score
Full analysis set

	Anifrolumab 300mg (N=360)				Placebo (N=366)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	345	43.99 (11.60)	0	-	348	44.01 (11.12)	0	-
Week 8	326	45.57 (11.34)	317	1.37 (8.89)	338	44.54 (11.06)	326	0.53 (8.76)
Week 16	321	45.49 (11.30)	310	1.34 (9.65)	327	45.11 (10.79)	315	1.07 (9.23)
Week 24	311	45.71 (11.85)	298	1.93 (10.05)	320	44.05 (11.17)	305	-0.15 (9.30)
Week 32	298	45.99 (11.42)	286	2.22 (10.49)	296	44.71 (11.00)	286	0.72 (9.15)
Week 40	296	46.17 (11.34)	284	2.46 (10.44)	297	45.28 (11.15)	286	1.19 (9.90)
Week 48	300	45.99 (11.23)	288	2.33 (10.60)	283	45.20 (10.59)	276	1.29 (9.72)
Week 52	285	46.00 (11.55)	272	2.36 (10.74)	273	45.21 (11.20)	264	0.97 (10.49)

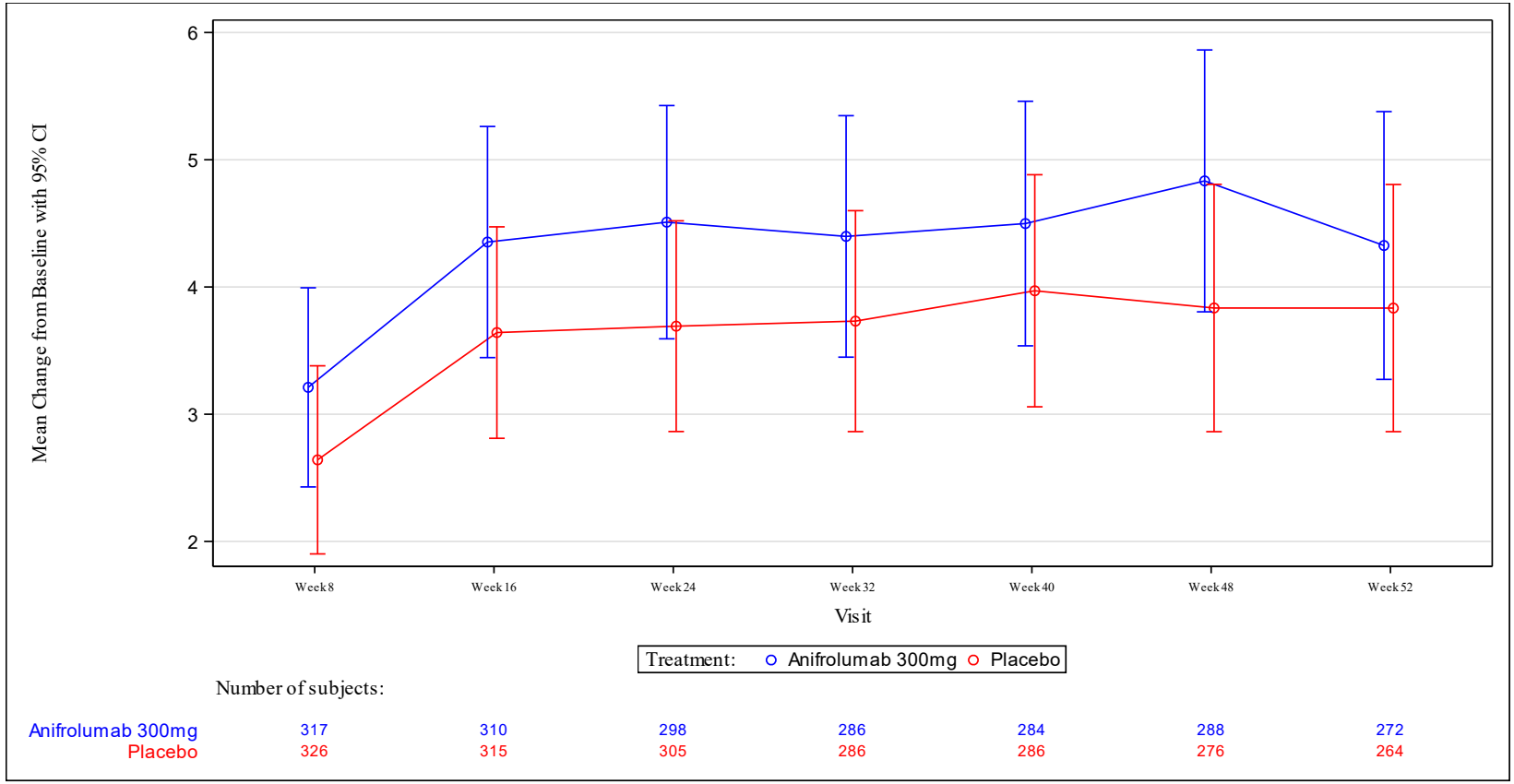
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Mental Component Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Physical Component Score
Full analysis set

	Anifrolumab 300mg (N=360)				Placebo (N=366)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	345	37.43 (9.19)	0	-	348	37.57 (9.28)	0	-
Week 8	326	41.03 (9.07)	317	3.21 (7.08)	338	40.28 (8.84)	326	2.64 (6.78)
Week 16	321	42.04 (9.56)	310	4.35 (8.13)	327	41.13 (9.24)	315	3.64 (7.50)
Week 24	311	42.29 (9.67)	298	4.51 (8.04)	320	41.52 (8.77)	305	3.69 (7.35)
Week 32	298	42.23 (9.43)	286	4.40 (8.15)	296	41.51 (8.63)	286	3.73 (7.46)
Week 40	296	42.69 (9.83)	284	4.50 (8.23)	297	41.53 (9.17)	286	3.97 (7.84)
Week 48	300	42.89 (9.90)	288	4.83 (8.87)	283	41.63 (9.47)	276	3.83 (8.20)
Week 52	285	42.46 (9.79)	272	4.33 (8.82)	273	41.93 (8.97)	264	3.83 (8.01)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Physical Component Score
Full analysis set



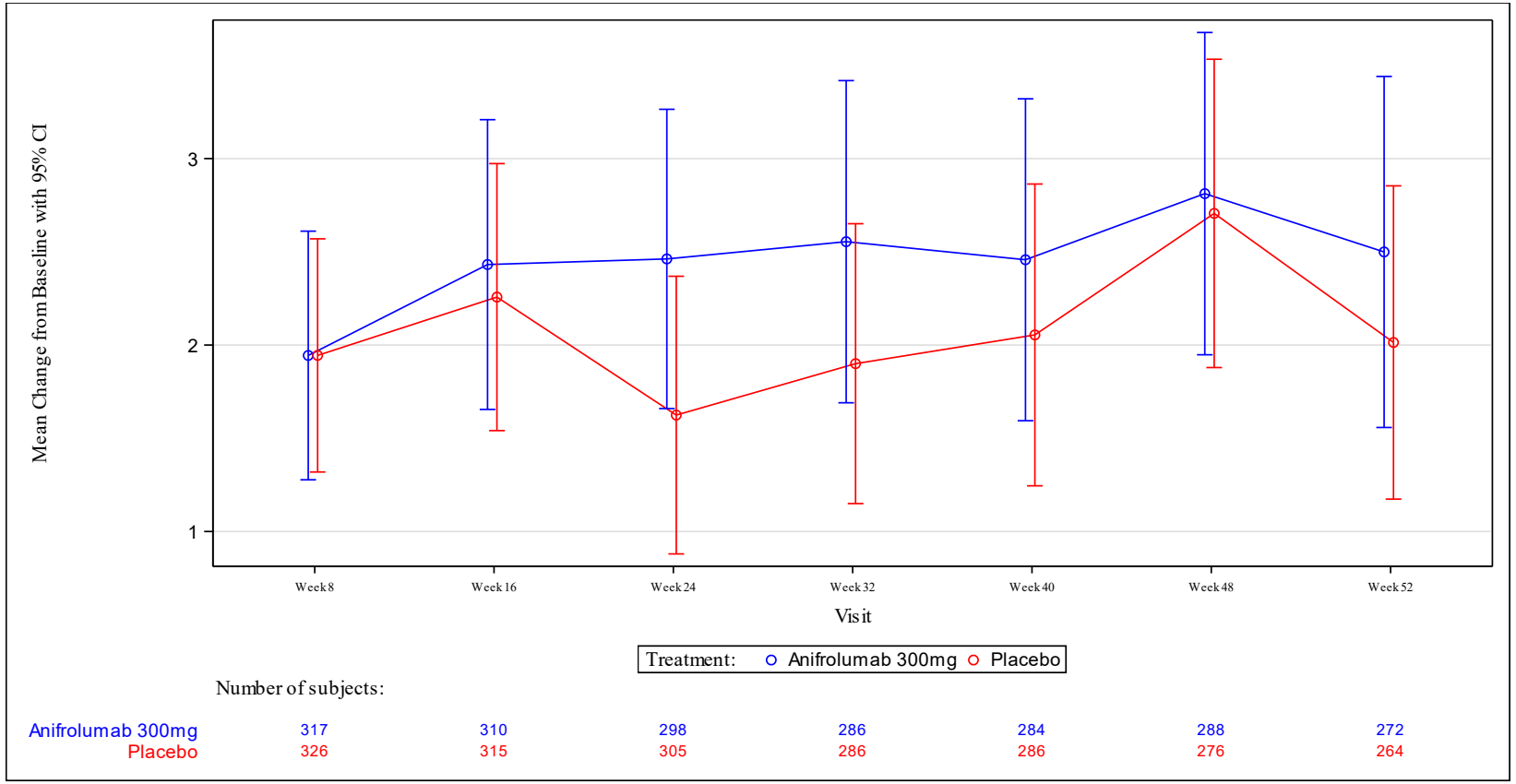
Number of subjects:

	Week 8	Week 16	Week 24	Week 32	Week 40	Week 48	Week 52
Anifrolumab 300mg	317	310	298	286	284	288	272
Placebo	326	315	305	286	286	276	264

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute General Health Score
Full analysis set

	Anifrolumab 300mg (N=360)				Placebo (N=366)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	345	38.29 (8.19)	0	-	348	38.83 (8.04)	0	-
Week 8	326	40.60 (8.13)	317	1.94 (6.03)	338	40.78 (8.18)	326	1.94 (5.74)
Week 16	321	41.00 (8.98)	310	2.43 (6.95)	327	40.96 (8.32)	315	2.26 (6.46)
Week 24	311	40.81 (9.37)	298	2.46 (7.04)	320	40.80 (8.30)	305	1.62 (6.61)
Week 32	298	41.01 (9.44)	286	2.55 (7.42)	296	40.92 (8.39)	286	1.90 (6.45)
Week 40	296	41.25 (9.19)	284	2.46 (7.39)	297	41.07 (8.82)	286	2.05 (6.95)
Week 48	300	41.37 (9.18)	288	2.81 (7.45)	283	41.79 (8.82)	276	2.71 (6.98)
Week 52	285	41.04 (9.46)	272	2.50 (7.89)	273	41.51 (8.82)	264	2.01 (6.93)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute General Health Score
Full analysis set

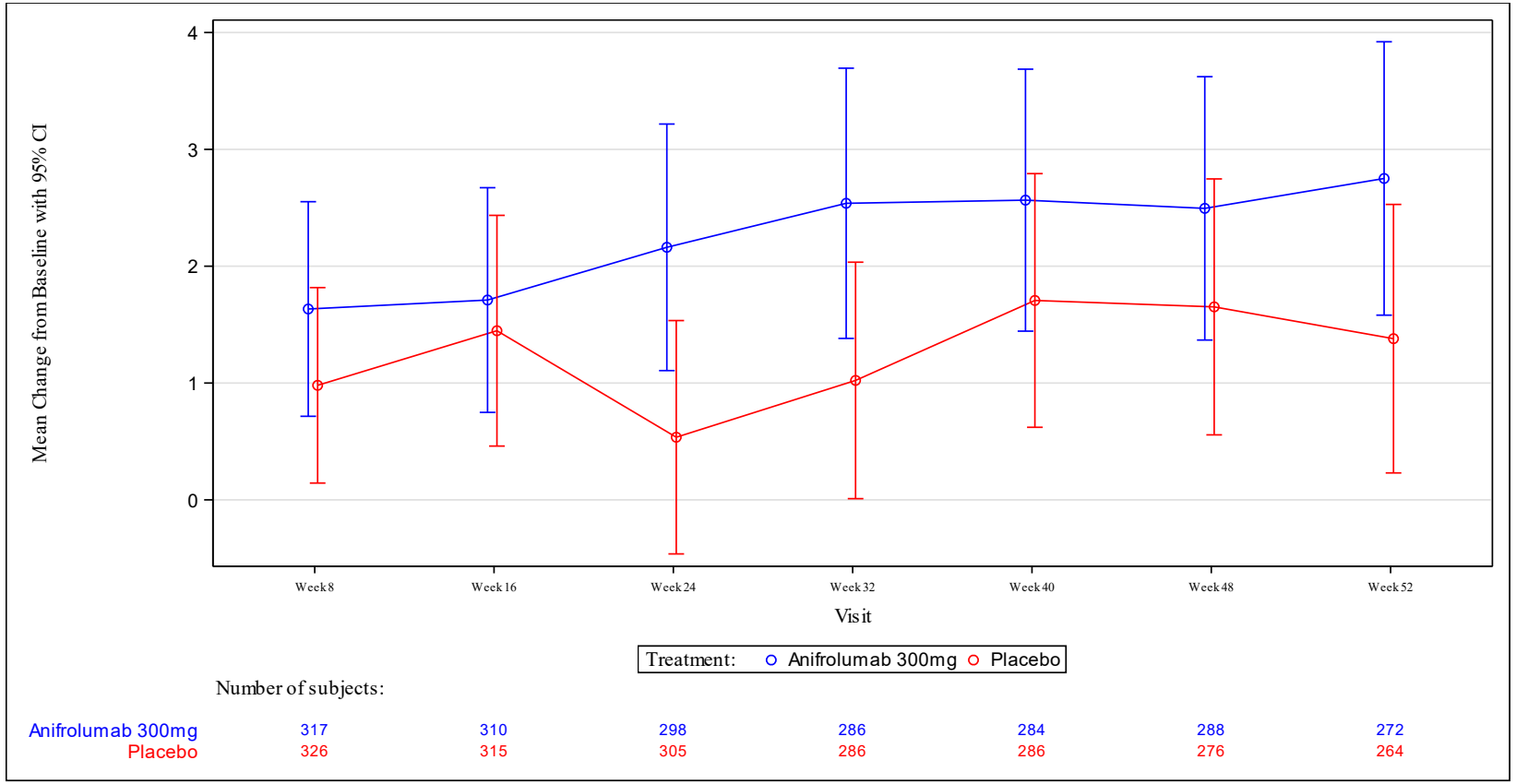


Number of subjects:							
Anifrolumab 300mg	317	310	298	286	284	288	272
Placebo	326	315	305	286	286	276	264

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Mental Health Score
Full analysis set

	Anifrolumab 300mg (N=360)				Placebo (N=366)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	345	44.16 (10.45)	0	-	348	43.89 (10.39)	0	-
Week 8	326	45.93 (10.42)	317	1.63 (8.31)	338	44.97 (10.20)	326	0.98 (7.68)
Week 16	321	45.99 (10.63)	310	1.71 (8.60)	327	45.31 (10.46)	315	1.45 (8.91)
Week 24	311	46.10 (11.10)	298	2.16 (9.26)	320	44.60 (10.23)	305	0.54 (8.86)
Week 32	298	46.40 (10.74)	286	2.54 (9.93)	296	45.04 (10.41)	286	1.02 (8.69)
Week 40	296	46.50 (10.41)	284	2.57 (9.60)	297	45.70 (10.33)	286	1.71 (9.33)
Week 48	300	46.33 (10.09)	288	2.49 (9.72)	283	45.41 (10.46)	276	1.65 (9.24)
Week 52	285	46.48 (10.76)	272	2.75 (9.80)	273	45.58 (10.47)	264	1.38 (9.48)

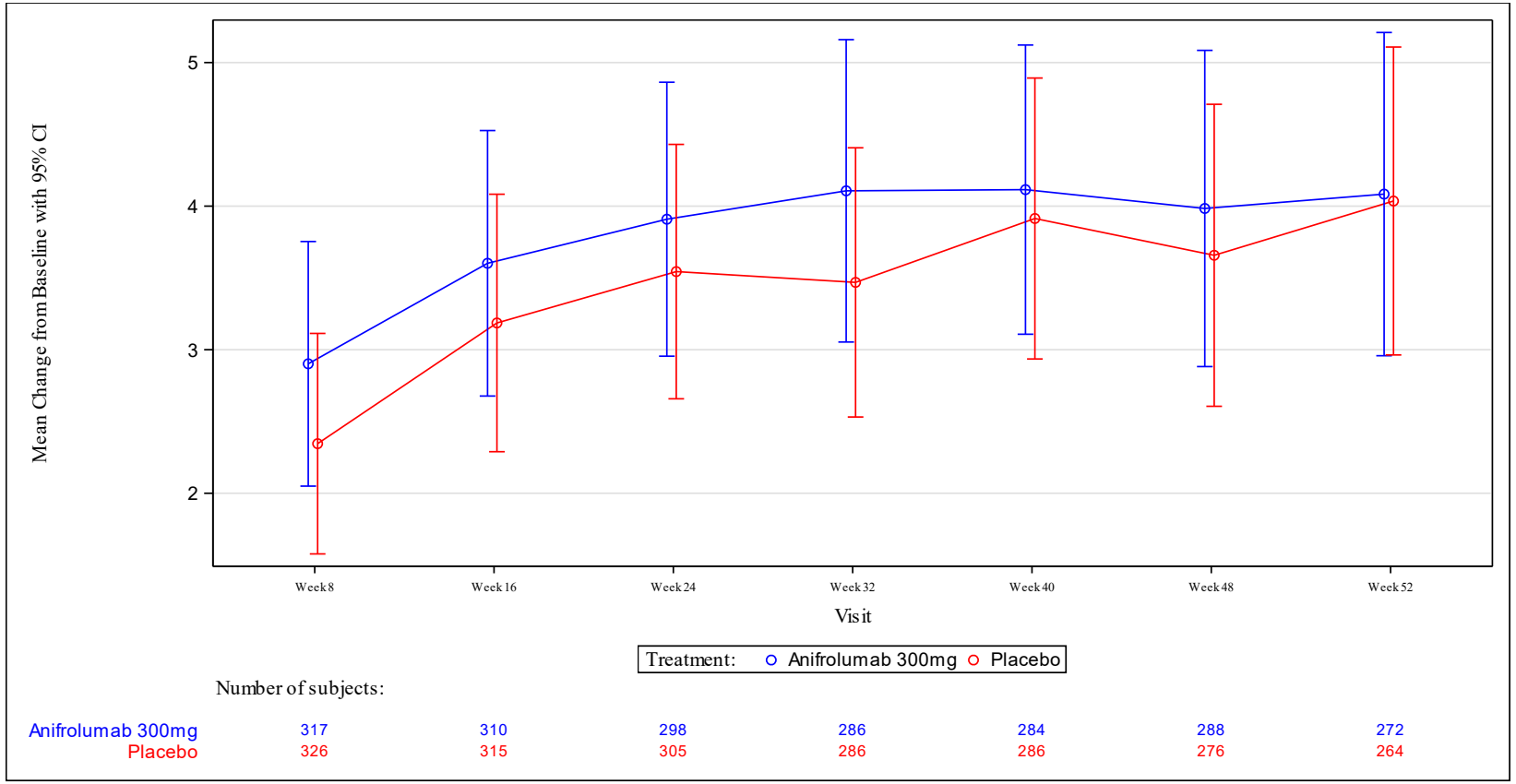
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Mental Health Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Physical Functioning Score
Full analysis set

	Anifrolumab 300mg (N=360)				Placebo (N=366)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	345	39.14 (10.18)	0	-	348	38.67 (10.37)	0	-
Week 8	326	42.44 (9.78)	317	2.90 (7.71)	338	41.20 (9.63)	326	2.35 (7.05)
Week 16	321	42.94 (10.07)	310	3.60 (8.27)	327	41.87 (9.91)	315	3.19 (8.09)
Week 24	311	43.36 (10.36)	298	3.91 (8.37)	320	42.37 (9.69)	305	3.54 (7.86)
Week 32	298	43.58 (10.00)	286	4.11 (9.05)	296	42.39 (9.61)	286	3.47 (8.06)
Week 40	296	43.74 (10.31)	284	4.11 (8.62)	297	42.42 (10.14)	286	3.91 (8.41)
Week 48	300	43.74 (10.08)	288	3.98 (9.49)	283	42.29 (10.60)	276	3.66 (8.88)
Week 52	285	43.83 (10.11)	272	4.08 (9.43)	273	43.08 (9.91)	264	4.04 (8.85)

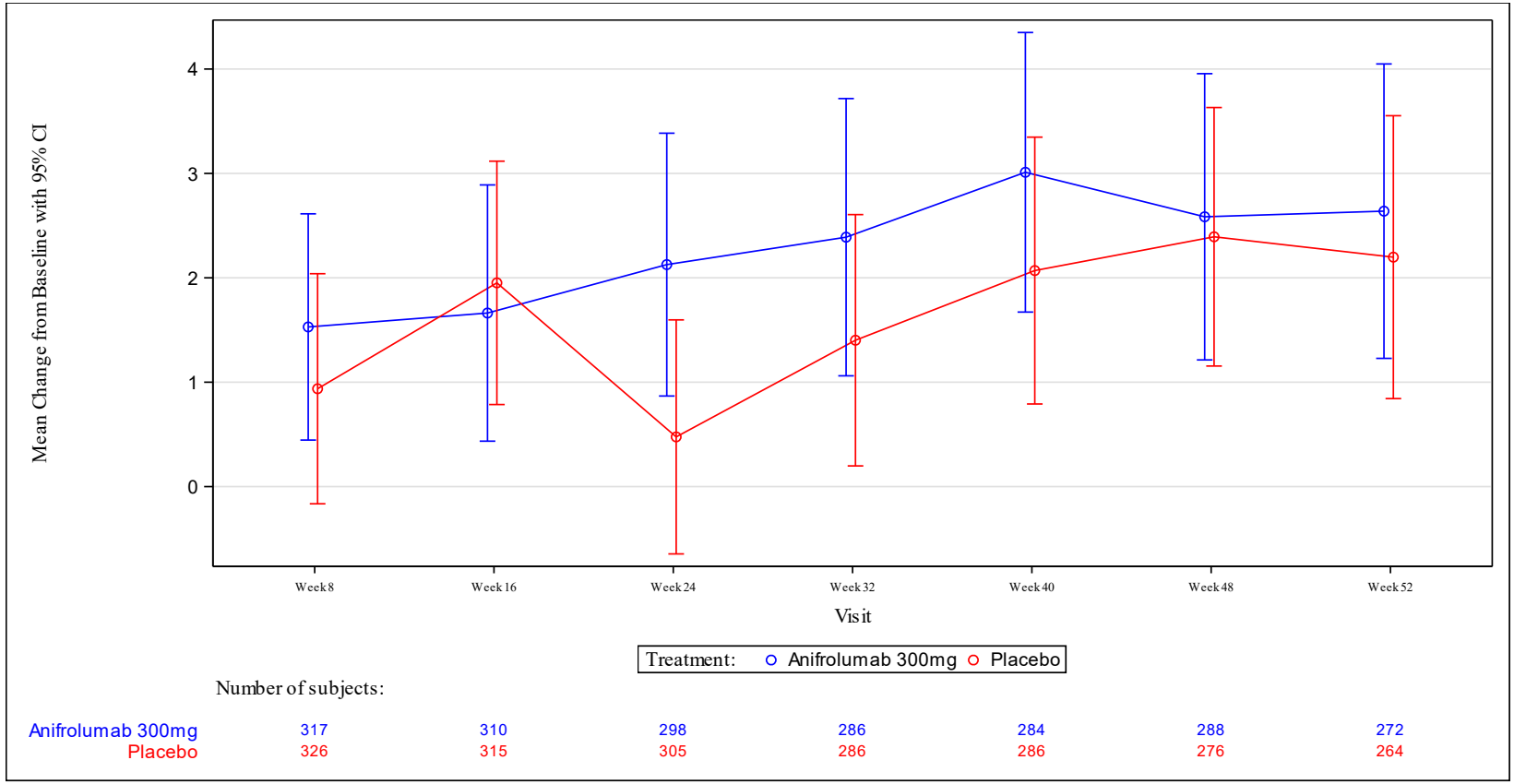
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Physical Functioning Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Role Emotional Score
Full analysis set

	Anifrolumab 300mg (N=360)				Placebo (N=366)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	345	40.88 (12.85)	0	-	348	40.33 (12.14)	0	-
Week 8	326	42.65 (12.44)	317	1.53 (9.81)	338	41.18 (12.14)	326	0.94 (10.11)
Week 16	321	42.86 (12.01)	310	1.66 (10.98)	327	42.30 (11.97)	315	1.95 (10.51)
Week 24	311	43.03 (12.34)	298	2.13 (11.04)	320	40.88 (12.33)	305	0.48 (9.95)
Week 32	298	43.25 (11.64)	286	2.39 (11.41)	296	41.66 (12.46)	286	1.40 (10.34)
Week 40	296	43.61 (11.81)	284	3.01 (11.46)	297	42.33 (12.14)	286	2.07 (10.98)
Week 48	300	43.13 (12.03)	288	2.58 (11.82)	283	42.38 (11.64)	276	2.39 (10.45)
Week 52	285	43.43 (11.78)	272	2.64 (11.81)	273	42.58 (11.92)	264	2.20 (11.18)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Role Emotional Score
Full analysis set



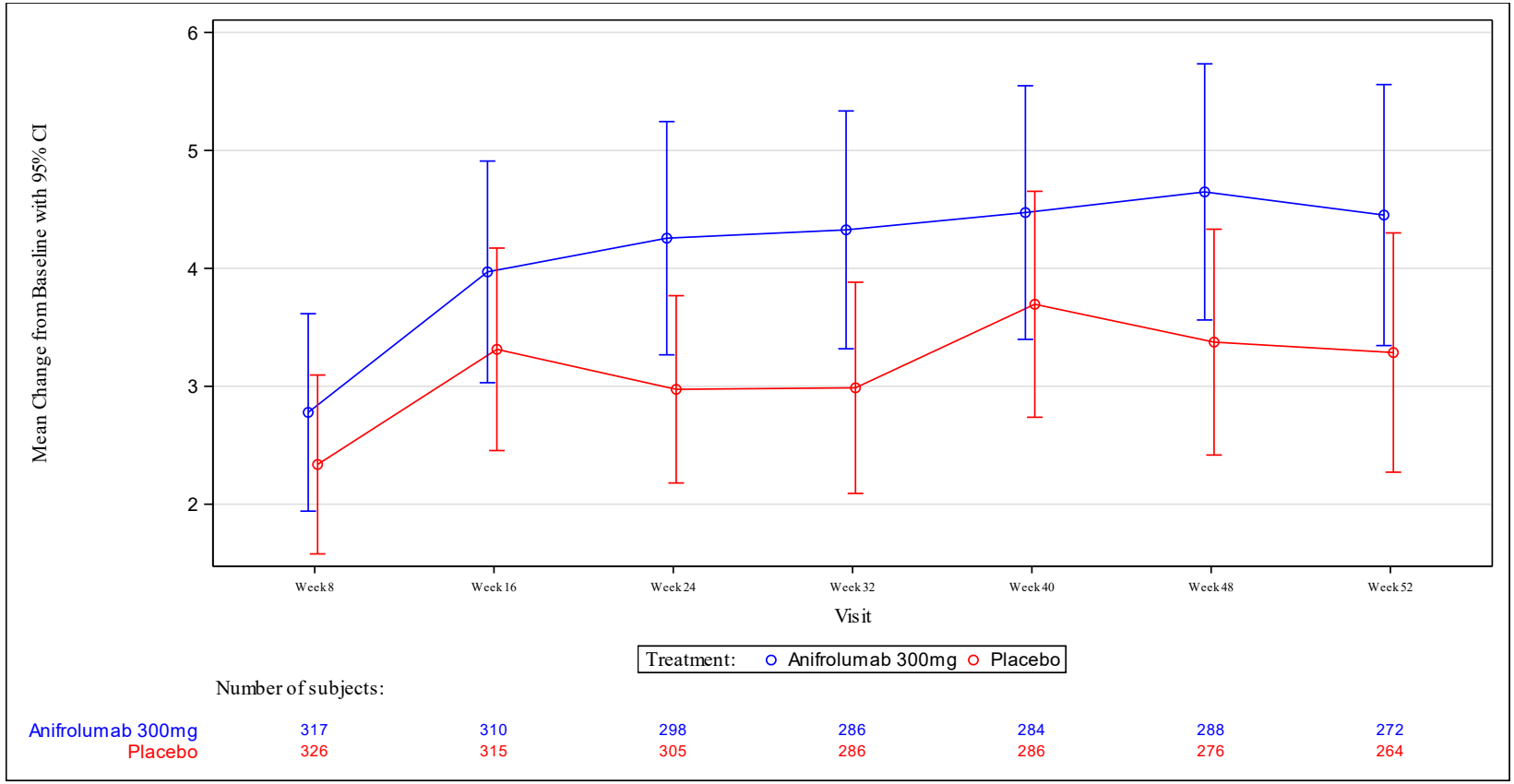
Number of subjects:

	Week 8	Week 16	Week 24	Week 32	Week 40	Week 48	Week 52
Anifrolumab 300mg	317	310	298	286	284	288	272
Placebo	326	315	305	286	286	276	264

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Role Physical Score
Full analysis set

	Anifrolumab 300mg (N=360)				Placebo (N=366)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	345	37.65 (9.60)	0	-	348	37.72 (8.65)	0	-
Week 8	326	40.76 (9.29)	317	2.78 (7.58)	338	40.15 (8.72)	326	2.34 (6.96)
Week 16	321	41.91 (9.53)	310	3.97 (8.41)	327	41.03 (9.19)	315	3.31 (7.74)
Week 24	311	42.05 (9.82)	298	4.26 (8.68)	320	40.87 (8.86)	305	2.97 (7.05)
Week 32	298	42.11 (9.49)	286	4.33 (8.66)	296	40.96 (8.87)	286	2.99 (7.69)
Week 40	296	42.40 (9.56)	284	4.47 (9.21)	297	41.59 (8.93)	286	3.70 (8.23)
Week 48	300	42.46 (9.70)	288	4.65 (9.36)	283	41.25 (9.20)	276	3.37 (8.08)
Week 52	285	42.35 (9.42)	272	4.45 (9.27)	273	41.57 (8.92)	264	3.29 (8.37)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Role Physical Score
Full analysis set



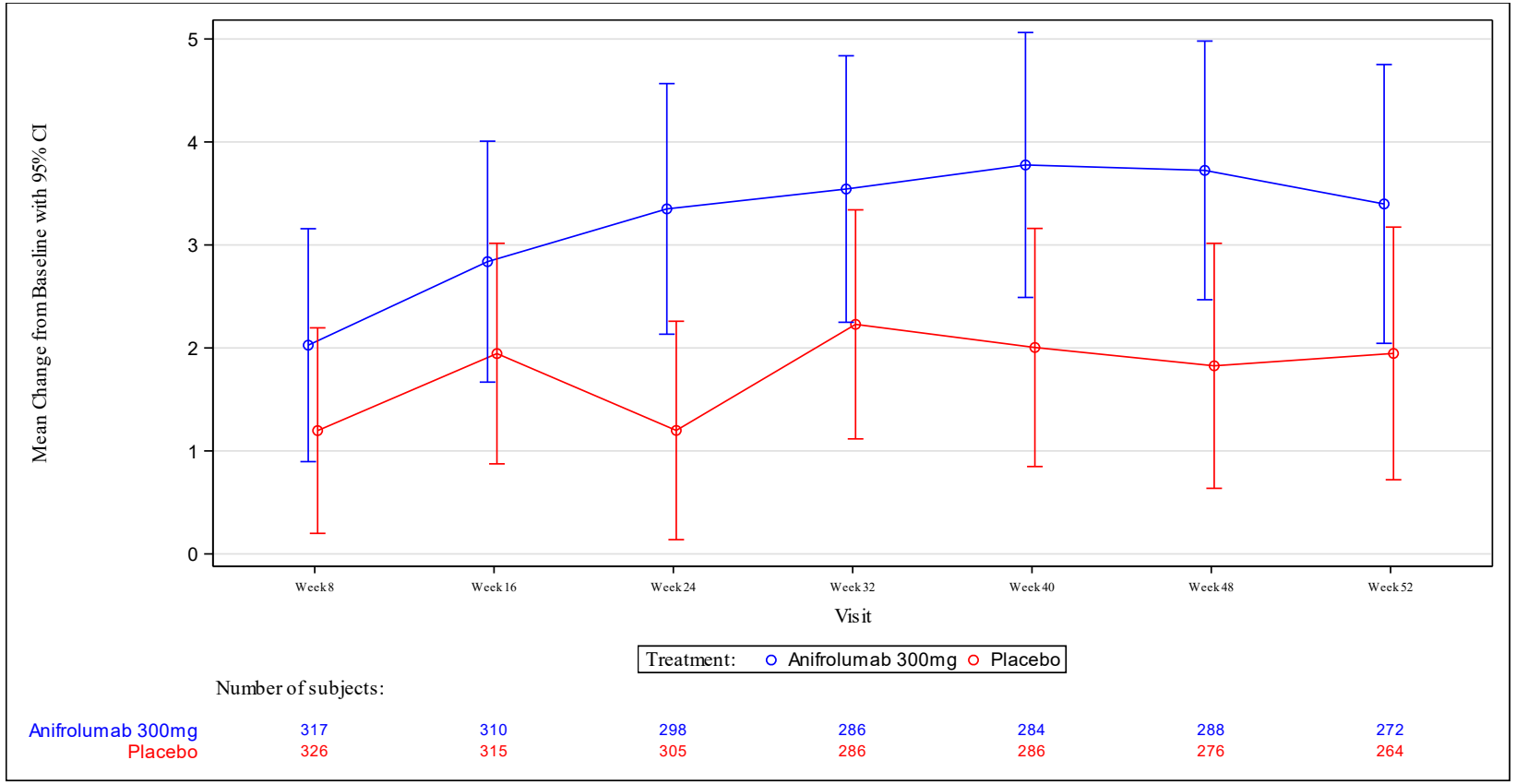
Number of subjects:

	Week 8	Week 16	Week 24	Week 32	Week 40	Week 48	Week 52
Anifrolumab 300mg	317	310	298	286	284	288	272
Placebo	326	315	305	286	286	276	264

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Social Functioning Score
Full analysis set

	Anifrolumab 300mg (N=360)				Placebo (N=366)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	345	40.41 (10.82)	0	-	348	40.77 (10.23)	0	-
Week 8	326	42.82 (10.29)	317	2.03 (10.23)	338	42.04 (10.33)	326	1.20 (9.16)
Week 16	321	43.30 (10.38)	310	2.84 (10.47)	327	42.64 (9.58)	315	1.95 (9.66)
Week 24	311	43.64 (10.53)	298	3.35 (10.67)	320	42.20 (10.14)	305	1.20 (9.41)
Week 32	298	43.92 (10.46)	286	3.54 (11.12)	296	42.80 (10.14)	286	2.23 (9.55)
Week 40	296	44.33 (10.31)	284	3.78 (11.01)	297	42.61 (9.94)	286	2.00 (9.93)
Week 48	300	44.23 (10.23)	288	3.72 (10.83)	283	42.61 (10.10)	276	1.83 (10.04)
Week 52	285	43.89 (10.71)	272	3.40 (11.34)	273	43.05 (9.90)	264	1.95 (10.12)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Social Functioning Score
Full analysis set



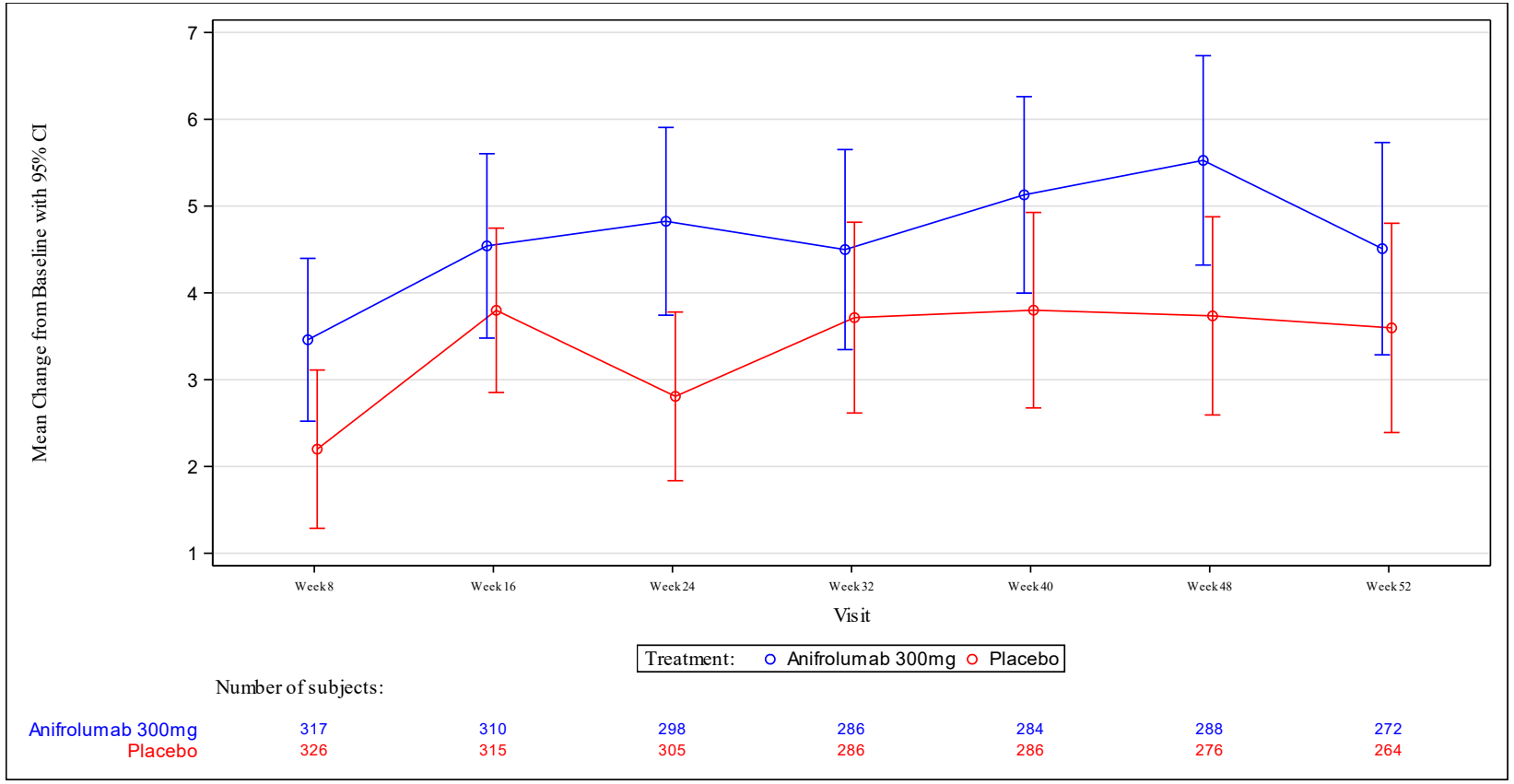
Number of subjects:

	Week 8	Week 16	Week 24	Week 32	Week 40	Week 48	Week 52
Anifrolumab 300mg	317	310	298	286	284	288	272
Placebo	326	315	305	286	286	276	264

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Bodily Pain Score
Full analysis set

	Anifrolumab 300mg (N=360)				Placebo (N=366)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	345	38.72 (8.44)	0	-	348	38.69 (8.94)	0	-
Week 8	326	42.43 (9.07)	317	3.46 (8.49)	338	40.79 (9.11)	326	2.20 (8.37)
Week 16	321	43.52 (9.72)	310	4.54 (9.50)	327	42.32 (9.32)	315	3.80 (8.54)
Week 24	311	43.89 (9.91)	298	4.82 (9.49)	320	41.77 (9.37)	305	2.81 (8.62)
Week 32	298	43.52 (9.76)	286	4.50 (9.90)	296	42.32 (9.33)	286	3.71 (9.44)
Week 40	296	44.52 (9.65)	284	5.13 (9.69)	297	42.35 (9.22)	286	3.80 (9.67)
Week 48	300	44.55 (10.41)	288	5.53 (10.40)	283	42.49 (9.47)	276	3.73 (9.63)
Week 52	285	43.78 (9.85)	272	4.51 (10.24)	273	42.51 (9.03)	264	3.60 (9.95)

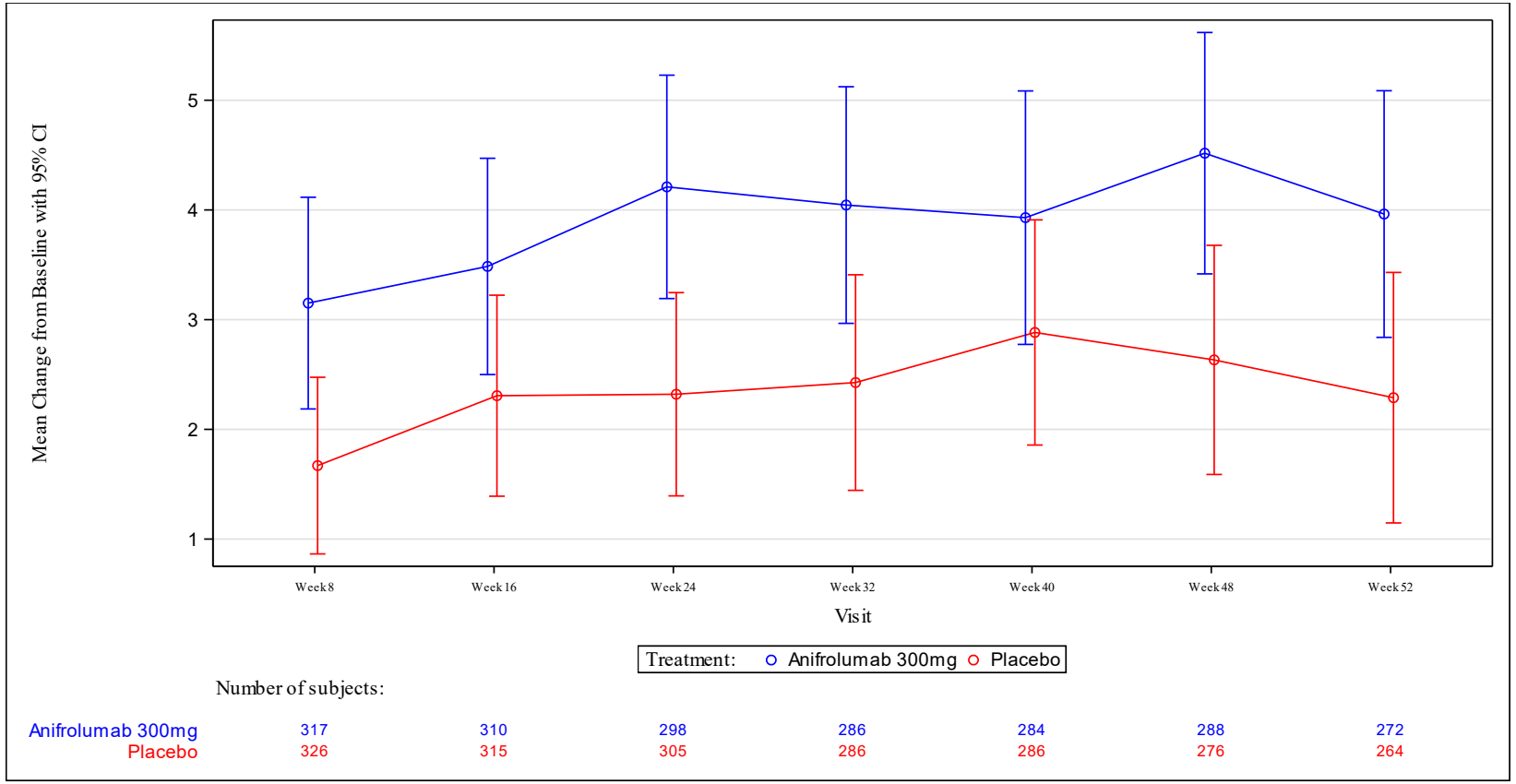
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Bodily Pain Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - SF-36 v2.0 Acute Vitality Score
Full analysis set

	Anifrolumab 300mg (N=360)				Placebo (N=366)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	345	41.78 (9.56)	0	-	348	42.59 (8.94)	0	-
Week 8	326	45.34 (9.75)	317	3.15 (8.73)	338	44.34 (9.39)	326	1.67 (7.39)
Week 16	321	45.54 (10.19)	310	3.49 (8.82)	327	45.09 (9.40)	315	2.31 (8.26)
Week 24	311	46.12 (10.28)	298	4.21 (8.93)	320	45.31 (9.89)	305	2.32 (8.22)
Week 32	298	46.07 (10.30)	286	4.04 (9.27)	296	45.43 (9.58)	286	2.43 (8.44)
Week 40	296	46.27 (10.58)	284	3.93 (9.89)	297	45.83 (9.99)	286	2.88 (8.82)
Week 48	300	46.87 (10.44)	288	4.52 (9.49)	283	45.78 (9.85)	276	2.63 (8.81)
Week 52	285	46.18 (10.37)	272	3.96 (9.42)	273	45.57 (9.90)	264	2.29 (9.42)

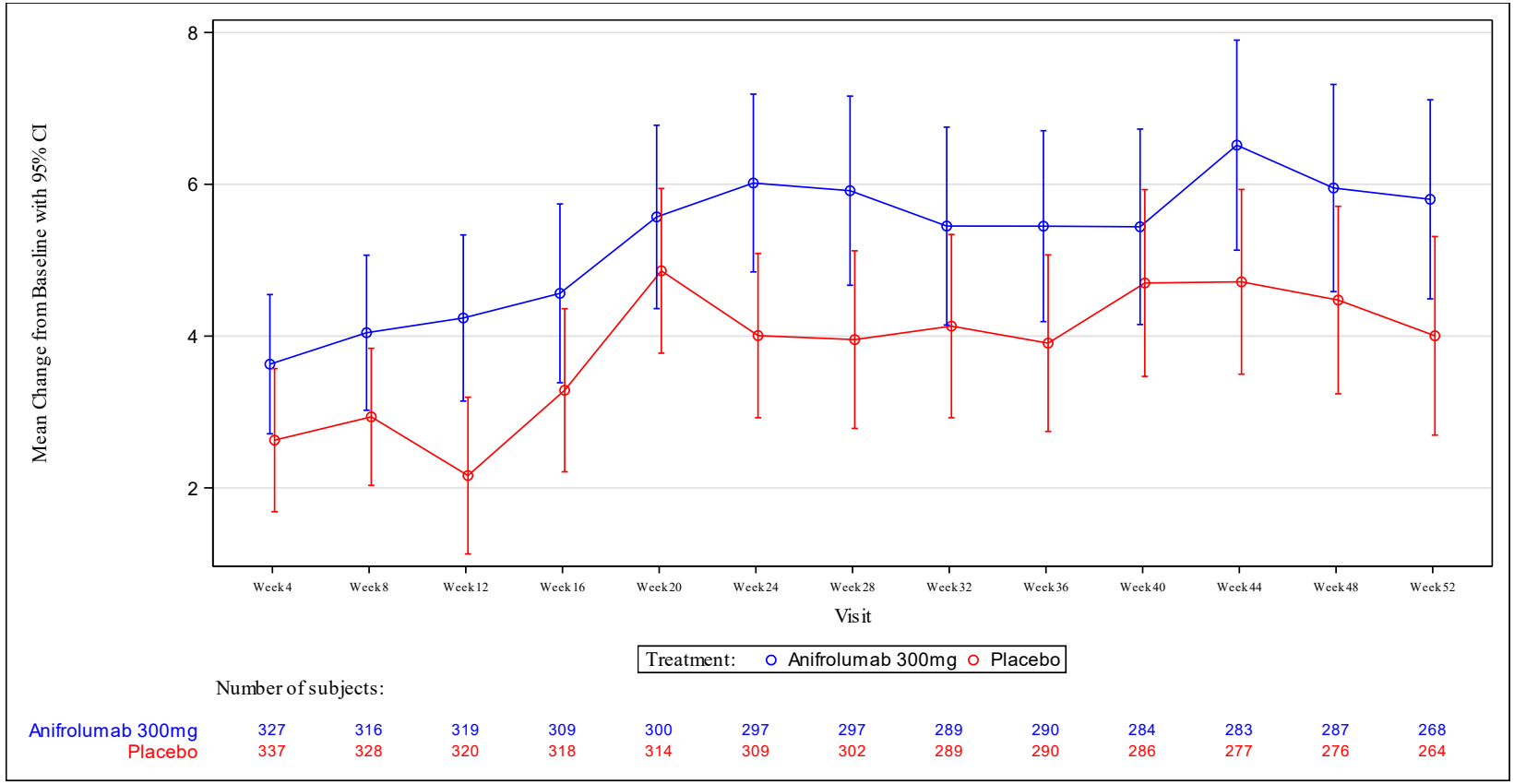
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - SF-36 v2.0 Acute Vitality Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - FACIT-F Total Score
Full analysis set

	Anifrolumab 300mg (N=360)				Placebo (N=366)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	341	25.72 (12.24)	0	-	349	25.85 (11.98)	0	-
Week 4	338	29.22 (11.35)	327	3.63 (8.43)	349	28.07 (11.54)	337	2.63 (8.80)
Week 8	328	30.27 (11.74)	316	4.04 (9.23)	341	28.79 (12.23)	328	2.94 (8.31)
Week 12	333	30.19 (12.84)	319	4.24 (9.94)	333	28.13 (12.64)	320	2.16 (9.39)
Week 16	324	30.71 (12.32)	309	4.56 (10.52)	329	29.23 (12.29)	318	3.29 (9.74)
Week 20	314	31.71 (12.16)	300	5.57 (10.63)	329	31.16 (11.90)	314	4.86 (9.77)
Week 24	314	31.79 (12.64)	297	6.02 (10.26)	323	29.99 (12.83)	309	4.01 (9.67)
Week 28	313	32.20 (12.21)	297	5.92 (10.92)	316	30.29 (12.19)	302	3.95 (10.33)
Week 32	304	31.44 (12.59)	289	5.45 (11.26)	300	30.56 (12.71)	289	4.13 (10.43)
Week 36	307	31.69 (12.78)	290	5.45 (10.88)	300	30.27 (12.60)	290	3.91 (10.07)
Week 40	300	31.85 (12.38)	284	5.44 (11.02)	298	30.80 (12.72)	286	4.70 (10.57)
Week 44	298	32.78 (12.70)	283	6.52 (11.83)	286	30.99 (12.22)	277	4.71 (10.29)
Week 48	303	32.16 (12.87)	287	5.95 (11.75)	286	31.00 (12.48)	276	4.47 (10.42)
Week 52	285	31.80 (12.64)	268	5.80 (10.90)	274	30.90 (12.73)	264	4.00 (10.79)

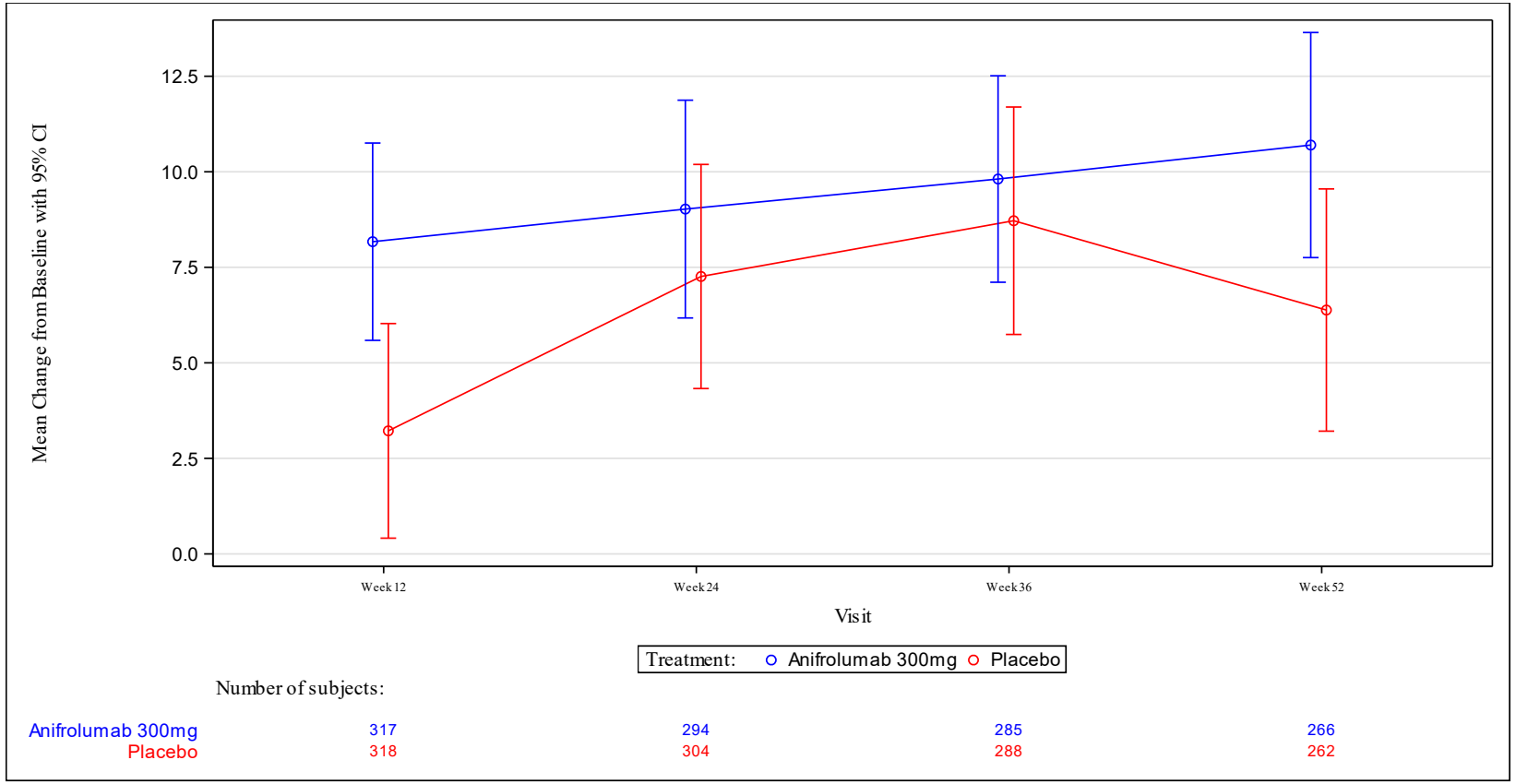
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - FACIT-F Total Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - EQ VAS Score
Full analysis set

	Anifrolumab 300mg (N=360)				Placebo (N=366)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	341	55.69 (20.17)	0	-	349	55.59 (21.48)	0	-
Week 12	331	63.67 (21.07)	317	8.17 (23.37)	331	59.07 (20.86)	318	3.22 (25.45)
Week 24	311	64.52 (21.46)	294	9.02 (24.82)	318	63.12 (20.55)	304	7.26 (25.98)
Week 36	302	65.77 (21.38)	285	9.81 (23.17)	297	65.34 (21.49)	288	8.72 (25.66)
Week 52	283	66.25 (20.80)	266	10.70 (24.40)	272	63.03 (21.75)	262	6.38 (26.05)

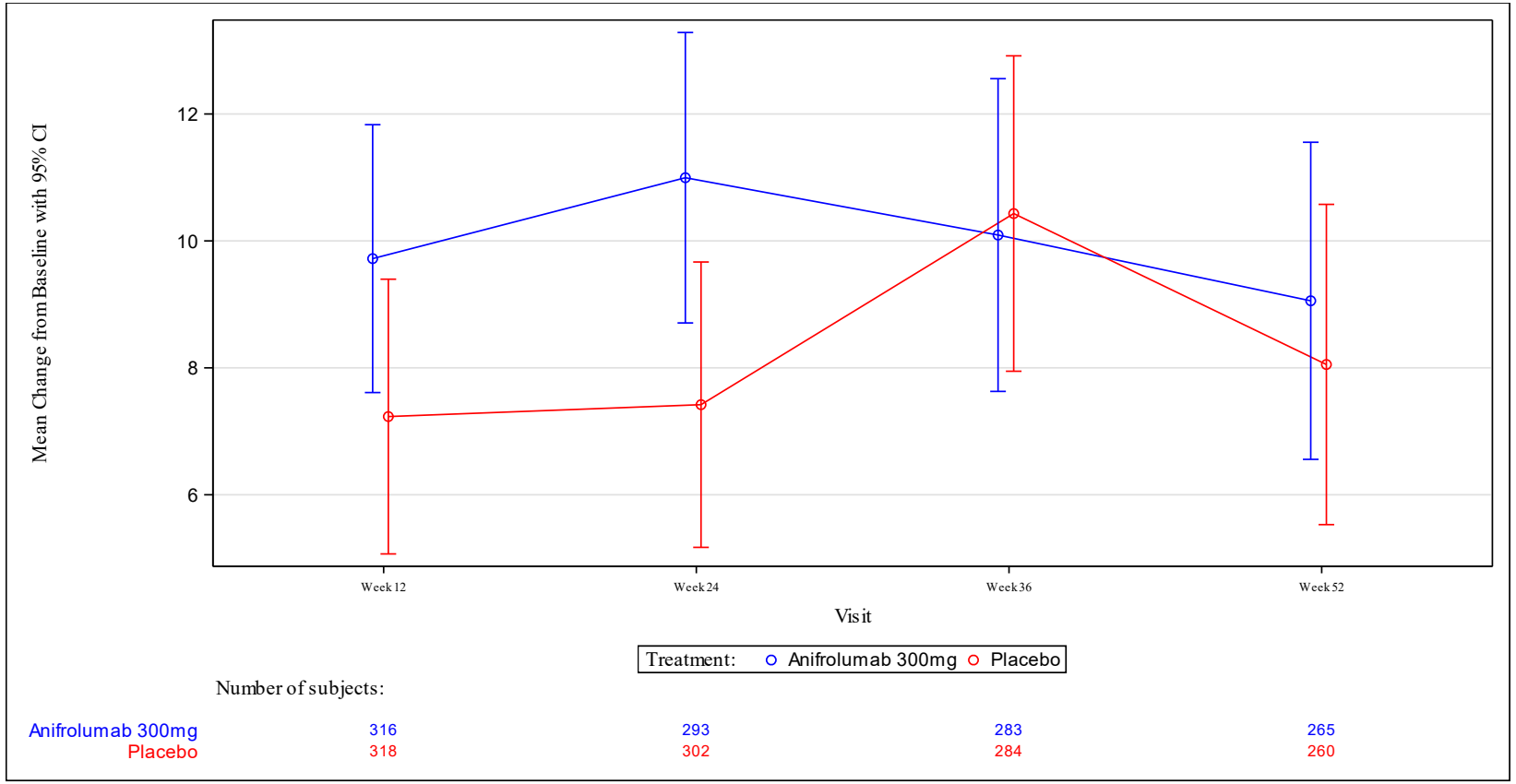
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - EQ VAS Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Physical Health domain score
Full analysis set

	Anifrolumab 300mg (N=360)				Placebo (N=366)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	341	54.12 (25.74)	0	-	349	53.41 (25.72)	0	-
Week 12	330	64.42 (25.37)	316	9.72 (19.07)	331	60.44 (25.81)	318	7.23 (19.62)
Week 24	310	65.25 (25.50)	293	11.00 (19.90)	316	61.46 (24.80)	302	7.42 (19.85)
Week 36	300	64.85 (24.99)	283	10.09 (21.06)	293	64.29 (23.99)	284	10.43 (21.28)
Week 52	282	64.66 (25.38)	265	9.06 (20.66)	270	63.36 (23.85)	260	8.05 (20.66)

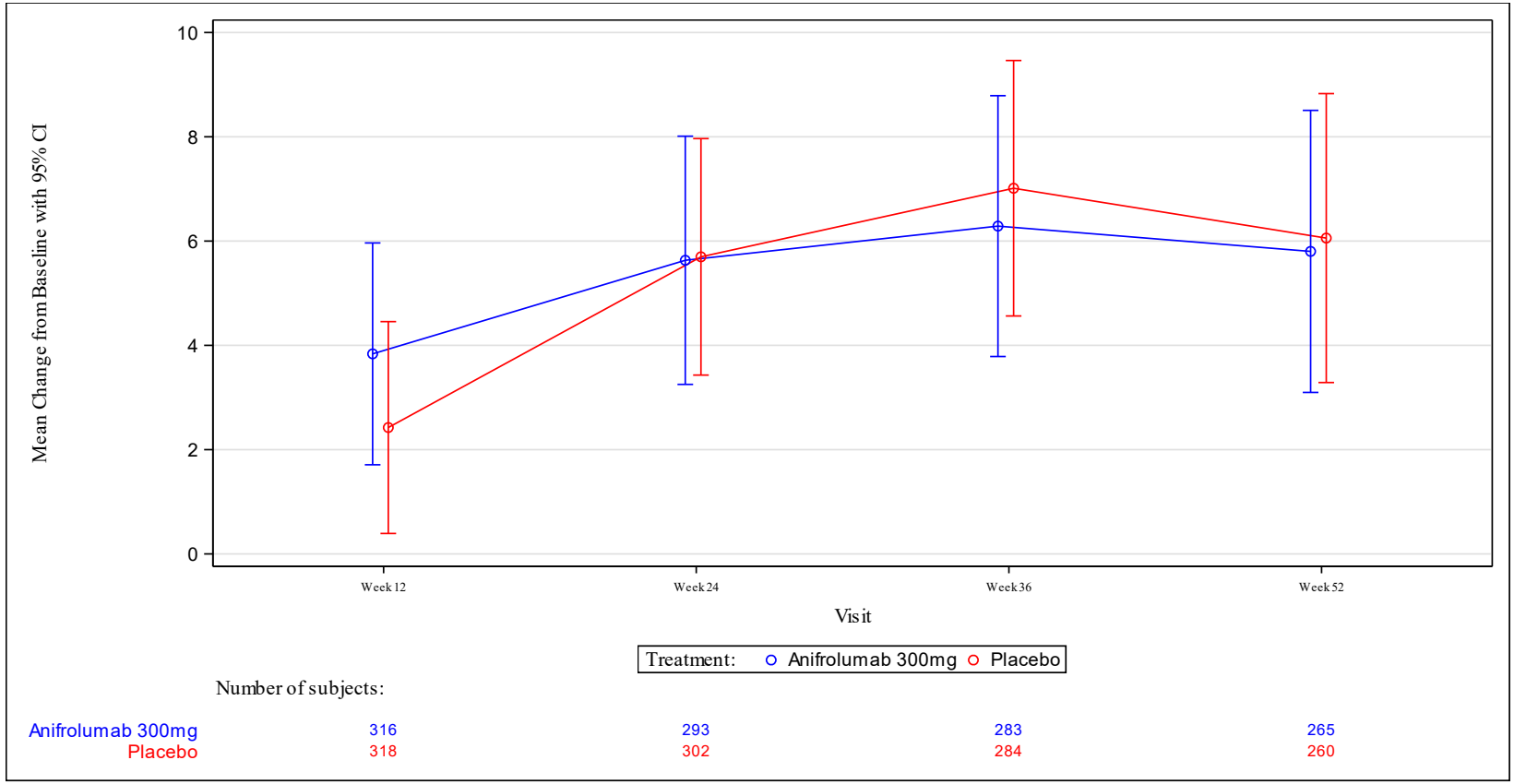
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Lupus QoL Physical Health domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Emotional Health domain score
Full analysis set

	Anifrolumab 300mg (N=360)				Placebo (N=366)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	341	67.34 (24.06)	0	-	349	64.57 (25.52)	0	-
Week 12	330	71.57 (23.44)	316	3.84 (19.22)	331	67.28 (24.70)	318	2.42 (18.41)
Week 24	310	73.55 (22.91)	293	5.63 (20.70)	316	70.62 (24.32)	302	5.70 (20.03)
Week 36	300	73.79 (21.92)	283	6.29 (21.37)	293	72.70 (23.01)	284	7.01 (20.97)
Week 52	282	73.58 (23.76)	265	5.80 (22.36)	270	72.79 (23.57)	260	6.06 (22.69)

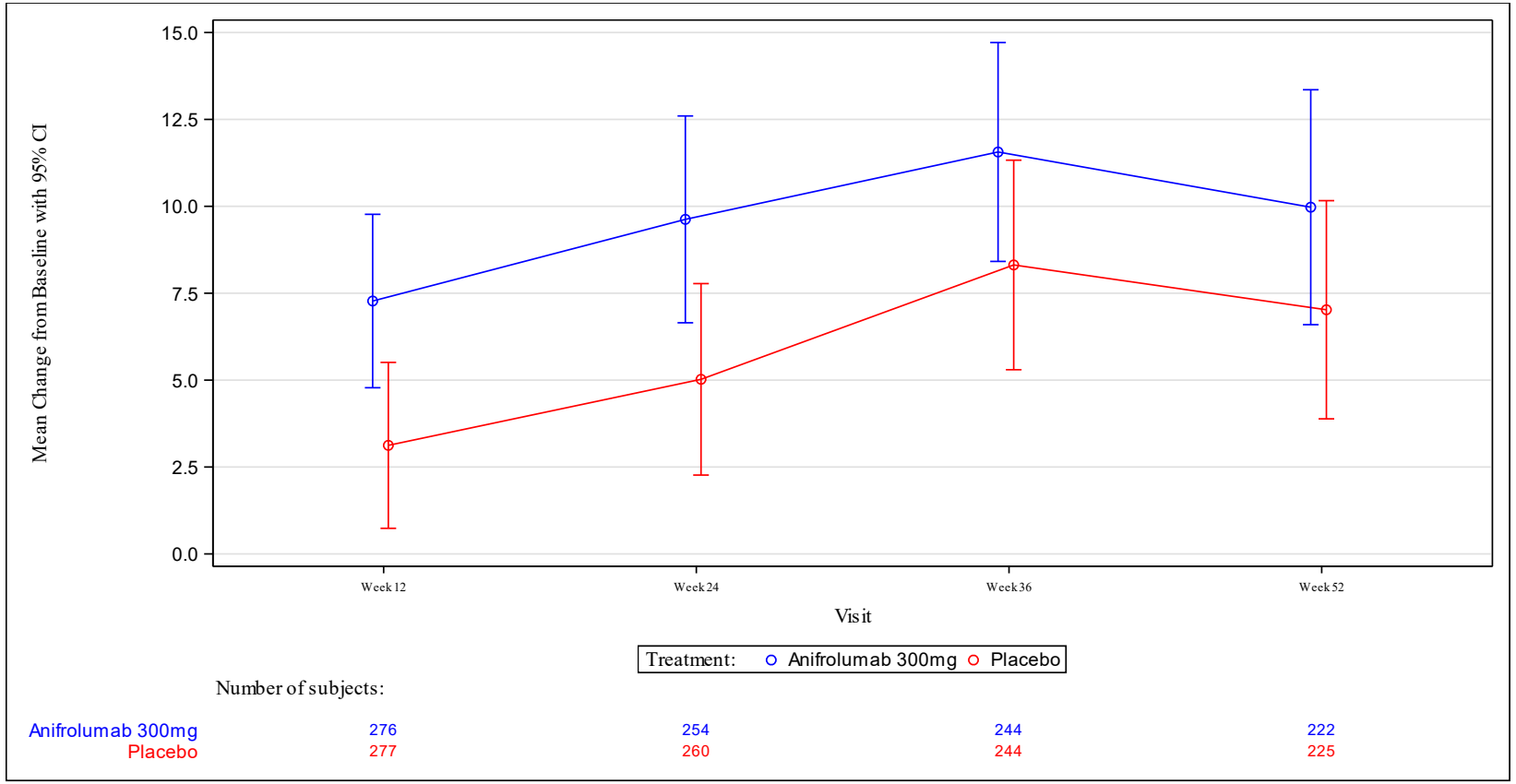
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Lupus QoL Emotional Health domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Body Image domain score
Full analysis set

	Anifrolumab 300mg (N=360)				Placebo (N=366)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	319	59.39 (29.81)	0	-	324	62.00 (28.17)	0	-
Week 12	299	66.85 (27.59)	276	7.28 (21.05)	299	64.88 (26.80)	277	3.12 (20.18)
Week 24	277	68.21 (27.54)	254	9.62 (24.07)	284	66.19 (27.17)	260	5.02 (22.55)
Week 36	268	69.93 (27.10)	244	11.56 (24.96)	264	69.79 (24.95)	244	8.31 (23.90)
Week 52	245	68.22 (27.72)	222	9.97 (25.55)	242	69.71 (26.62)	225	7.02 (23.89)

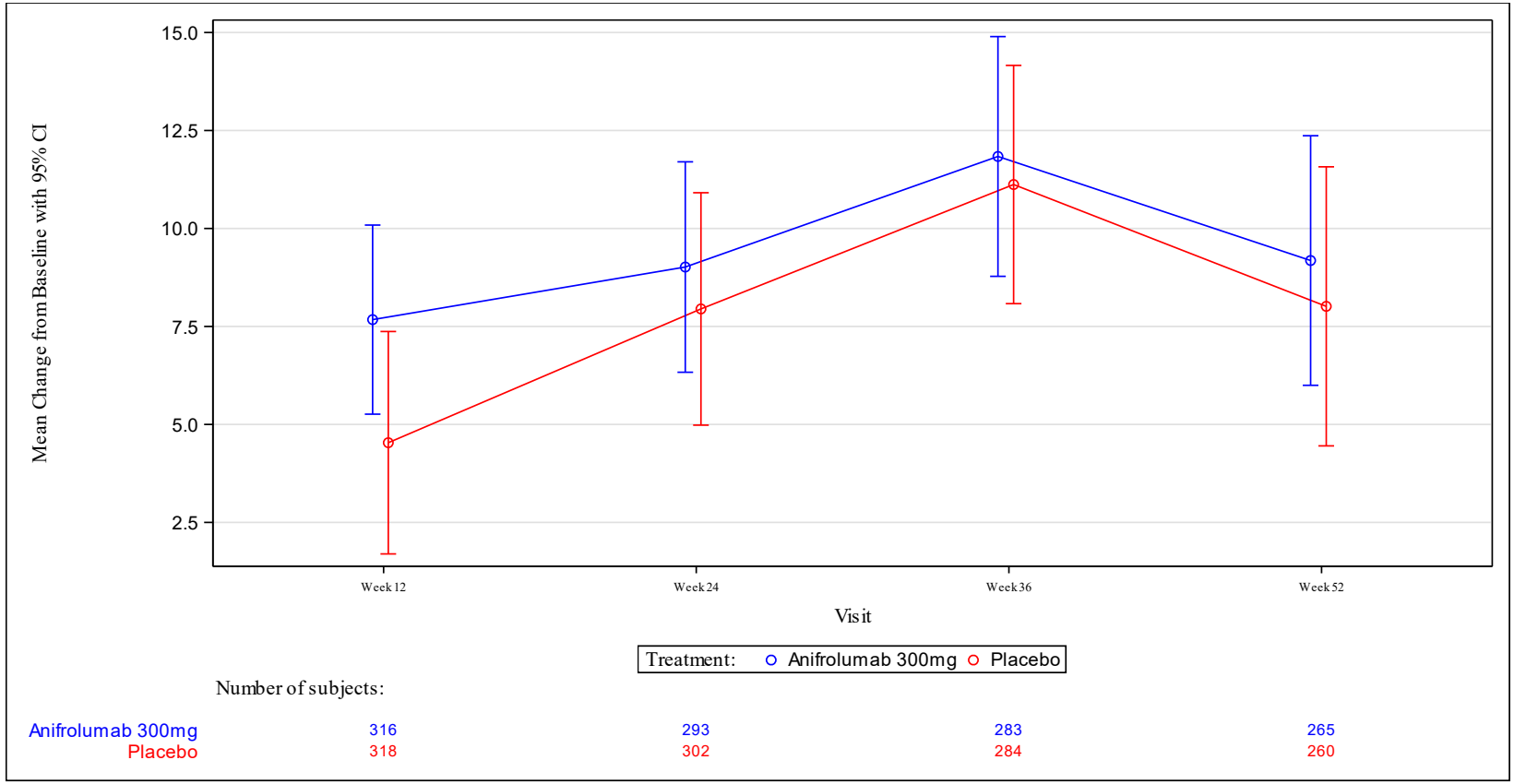
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Lupus QoL Body Image domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Burden to Others domain score
Full analysis set

	Anifrolumab 300mg (N=360)				Placebo (N=366)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	341	51.86 (30.41)	0	-	349	50.95 (31.12)	0	-
Week 12	330	59.34 (30.46)	316	7.67 (21.80)	331	55.94 (30.88)	318	4.53 (25.72)
Week 24	310	60.40 (31.23)	293	9.02 (23.35)	316	58.83 (31.05)	302	7.95 (26.18)
Week 36	300	63.03 (30.03)	283	11.84 (26.14)	293	62.91 (28.71)	284	11.12 (26.02)
Week 52	282	61.47 (30.51)	265	9.18 (26.32)	270	60.83 (30.23)	260	8.01 (29.15)

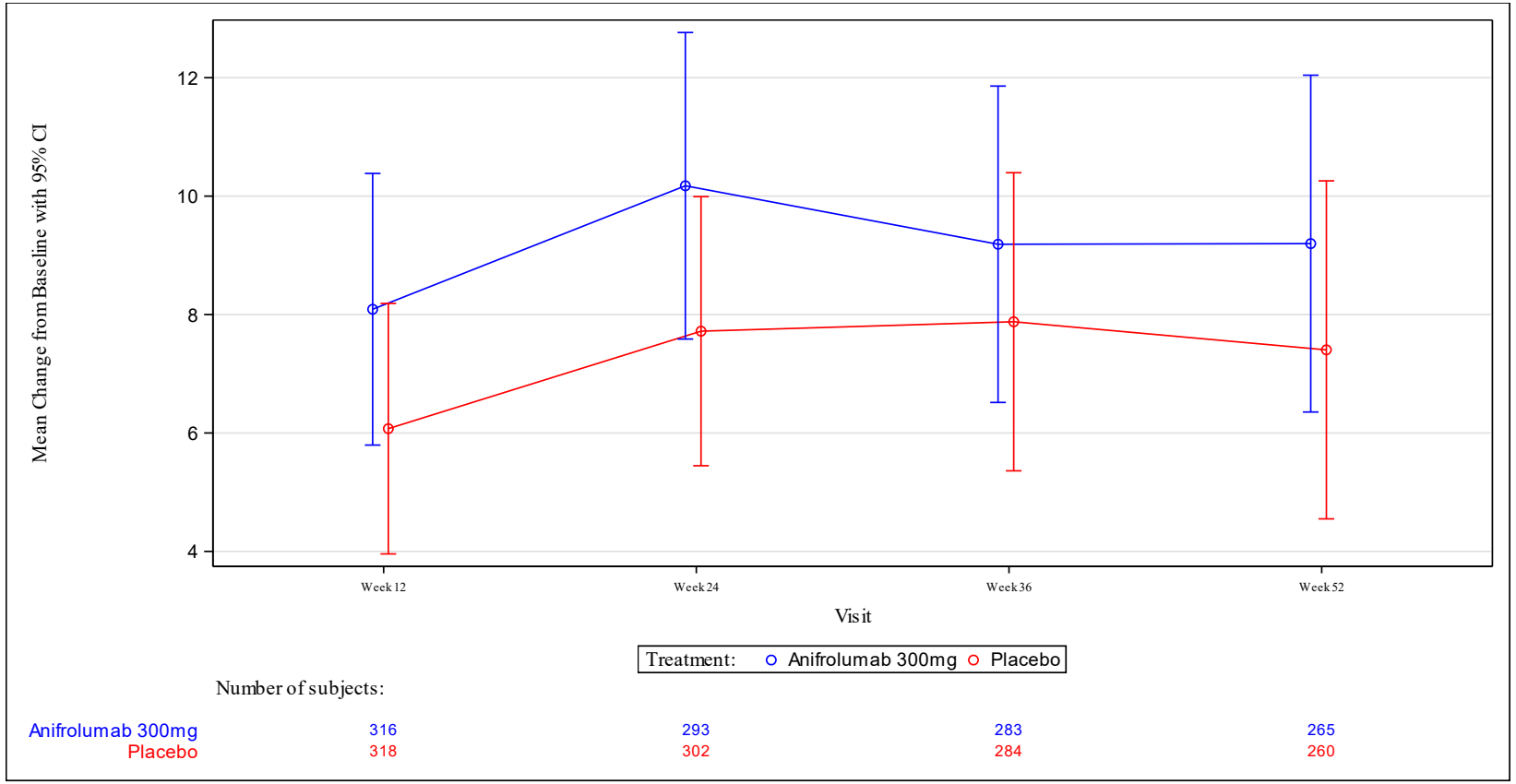
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Lupus QoL Burden to Others domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Fatigue domain score
Full analysis set

	Anifrolumab 300mg (N=360)				Placebo (N=366)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	341	48.86 (26.74)	0	-	349	47.71 (26.40)	0	-
Week 12	330	57.41 (27.09)	316	8.09 (20.72)	331	54.10 (26.64)	318	6.07 (19.17)
Week 24	310	59.62 (27.12)	293	10.17 (22.51)	316	56.37 (27.04)	302	7.72 (20.07)
Week 36	300	59.25 (27.03)	283	9.19 (22.83)	293	57.19 (26.02)	284	7.88 (21.55)
Week 52	282	58.89 (27.88)	265	9.20 (23.51)	270	57.52 (26.41)	260	7.40 (23.37)

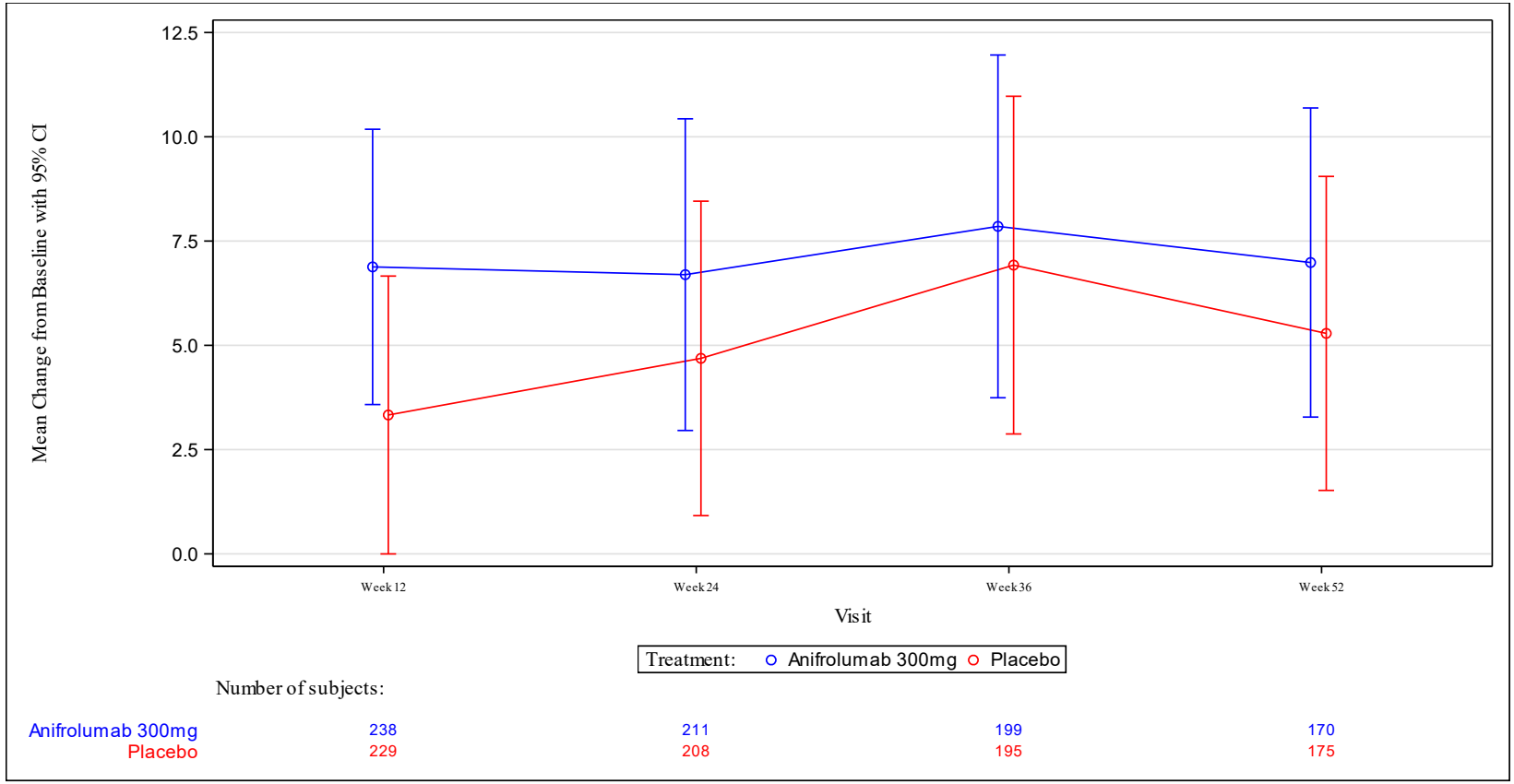
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Lupus QoL Fatigue domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Intimate Relationships domain score
Full analysis set

	Anifrolumab 300mg (N=360)				Placebo (N=366)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	280	55.63 (32.97)	0	-	280	57.77 (30.10)	0	-
Week 12	269	64.17 (32.46)	238	6.88 (25.84)	264	59.85 (32.81)	229	3.33 (25.58)
Week 24	241	63.69 (32.74)	211	6.69 (27.53)	236	60.86 (32.01)	208	4.69 (27.57)
Week 36	236	64.83 (32.55)	199	7.85 (29.39)	215	63.60 (31.34)	195	6.92 (28.66)
Week 52	205	65.30 (31.14)	170	6.99 (24.48)	198	63.26 (31.83)	175	5.29 (25.23)

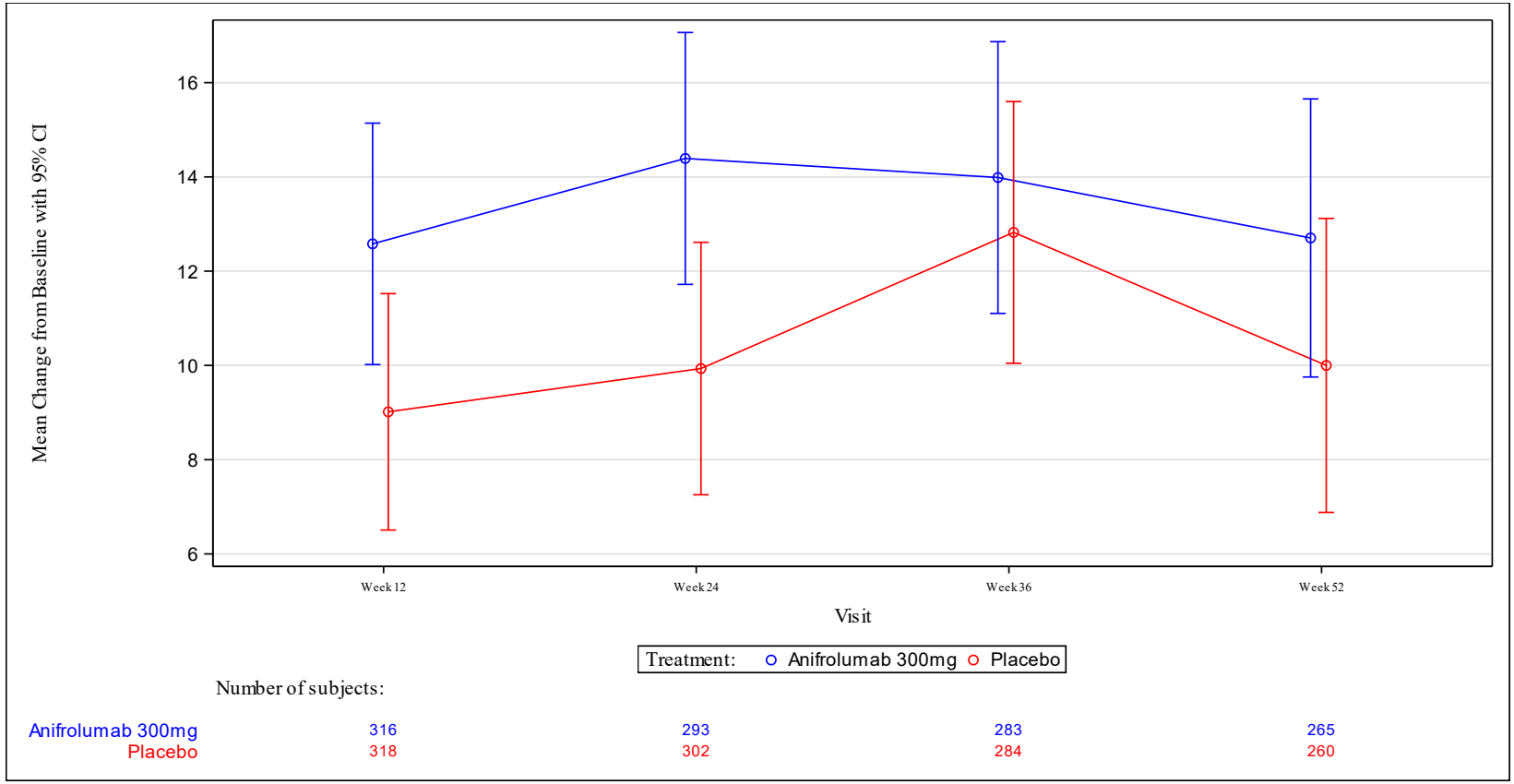
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Lupus QoL Intimate Relationships domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Pain domain score
Full analysis set

	Anifrolumab 300mg (N=360)				Placebo (N=366)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	341	52.52 (28.71)	0	-	349	51.53 (28.96)	0	-
Week 12	330	65.38 (27.38)	316	12.58 (23.14)	331	60.70 (28.04)	318	9.01 (22.74)
Week 24	310	67.04 (26.71)	293	14.39 (23.25)	316	62.21 (27.99)	302	9.93 (23.65)
Week 36	300	67.19 (26.61)	283	13.99 (24.64)	293	64.65 (26.79)	284	12.82 (23.78)
Week 52	282	67.52 (25.87)	265	12.70 (24.39)	270	63.95 (26.30)	260	10.00 (25.53)

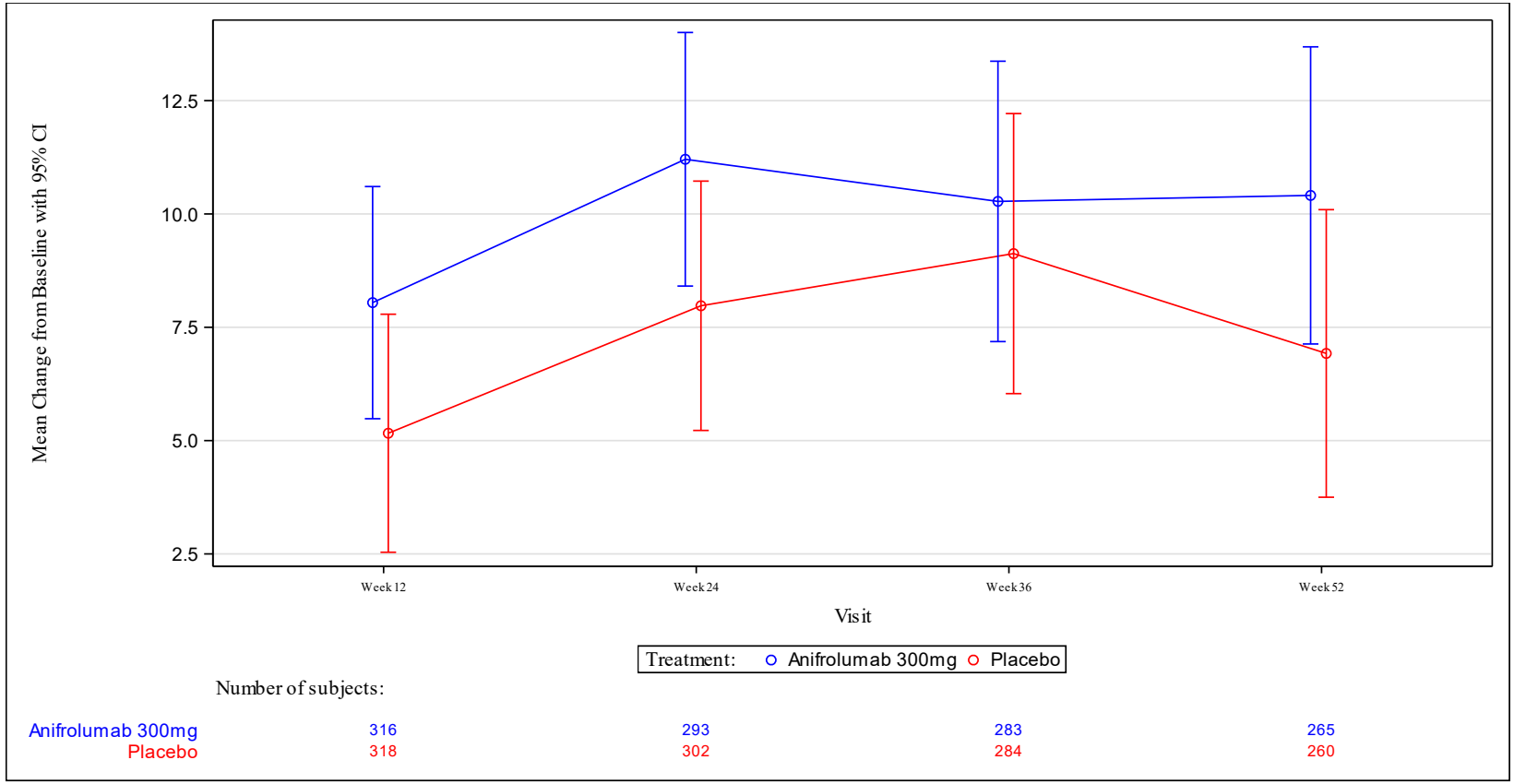
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Lupus QoL Pain domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - Lupus QoL Planning domain score
Full analysis set

	Anifrolumab 300mg (N=360)				Placebo (N=366)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	341	58.36 (30.63)	0	-	349	57.76 (30.42)	0	-
Week 12	330	66.19 (28.57)	316	8.04 (23.14)	331	62.92 (29.74)	318	5.16 (23.80)
Week 24	310	69.22 (28.85)	293	11.21 (24.33)	316	65.61 (29.14)	302	7.97 (24.29)
Week 36	300	68.36 (28.42)	283	10.28 (26.43)	293	67.61 (27.54)	284	9.13 (26.45)
Week 52	282	68.79 (28.56)	265	10.41 (27.10)	270	66.60 (27.65)	260	6.92 (25.98)

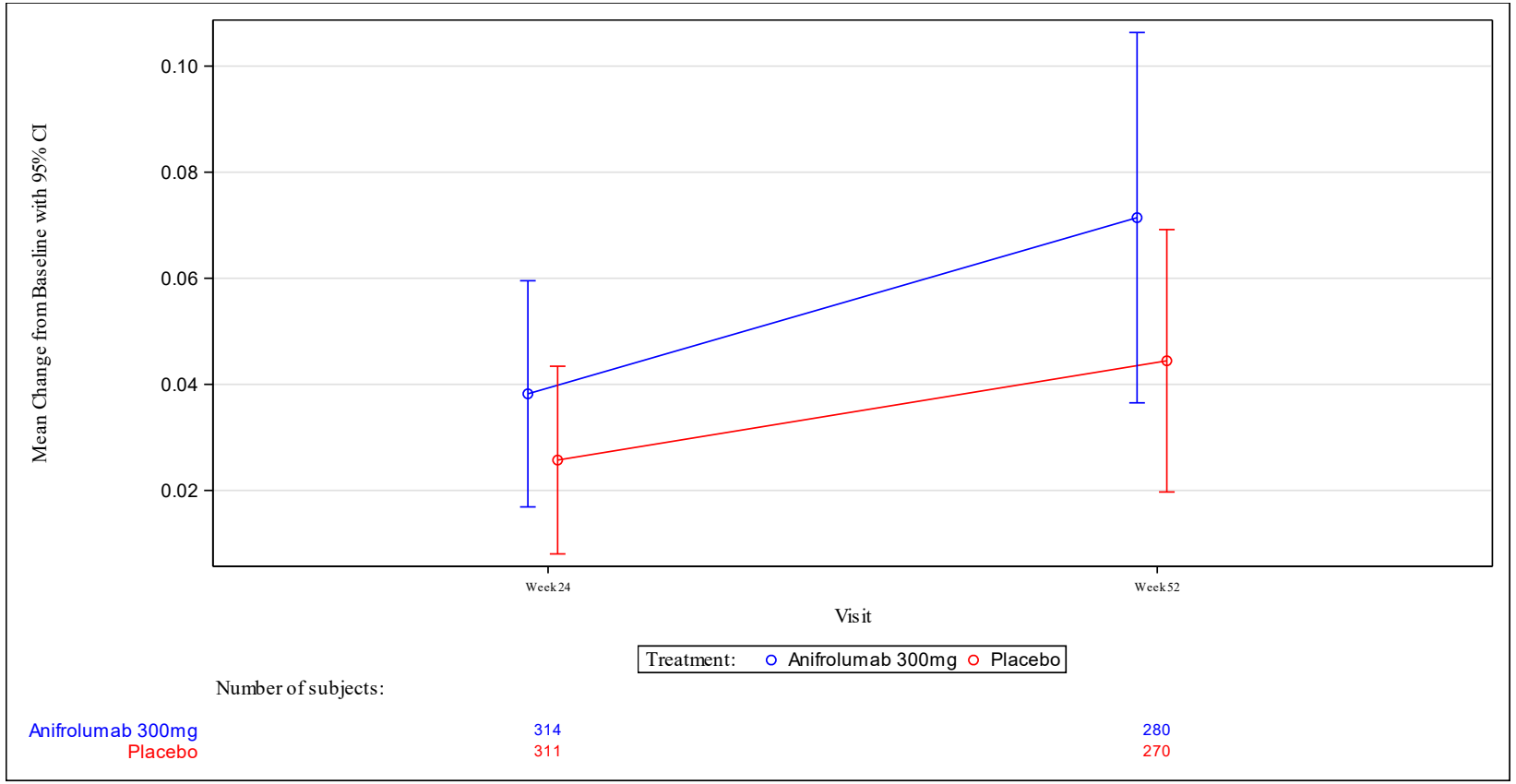
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - Lupus QoL Planning domain score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - SDI Global Score
Full analysis set

	Anifrolumab 300mg (N=360)				Placebo (N=366)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	350	0.58 (1.04)	0	-	351	0.56 (0.89)	0	-
Week 24	317	0.63 (1.08)	314	0.04 (0.19)	318	0.57 (0.93)	311	0.03 (0.16)
Week 52	286	0.67 (1.05)	280	0.07 (0.30)	283	0.54 (0.88)	270	0.04 (0.21)

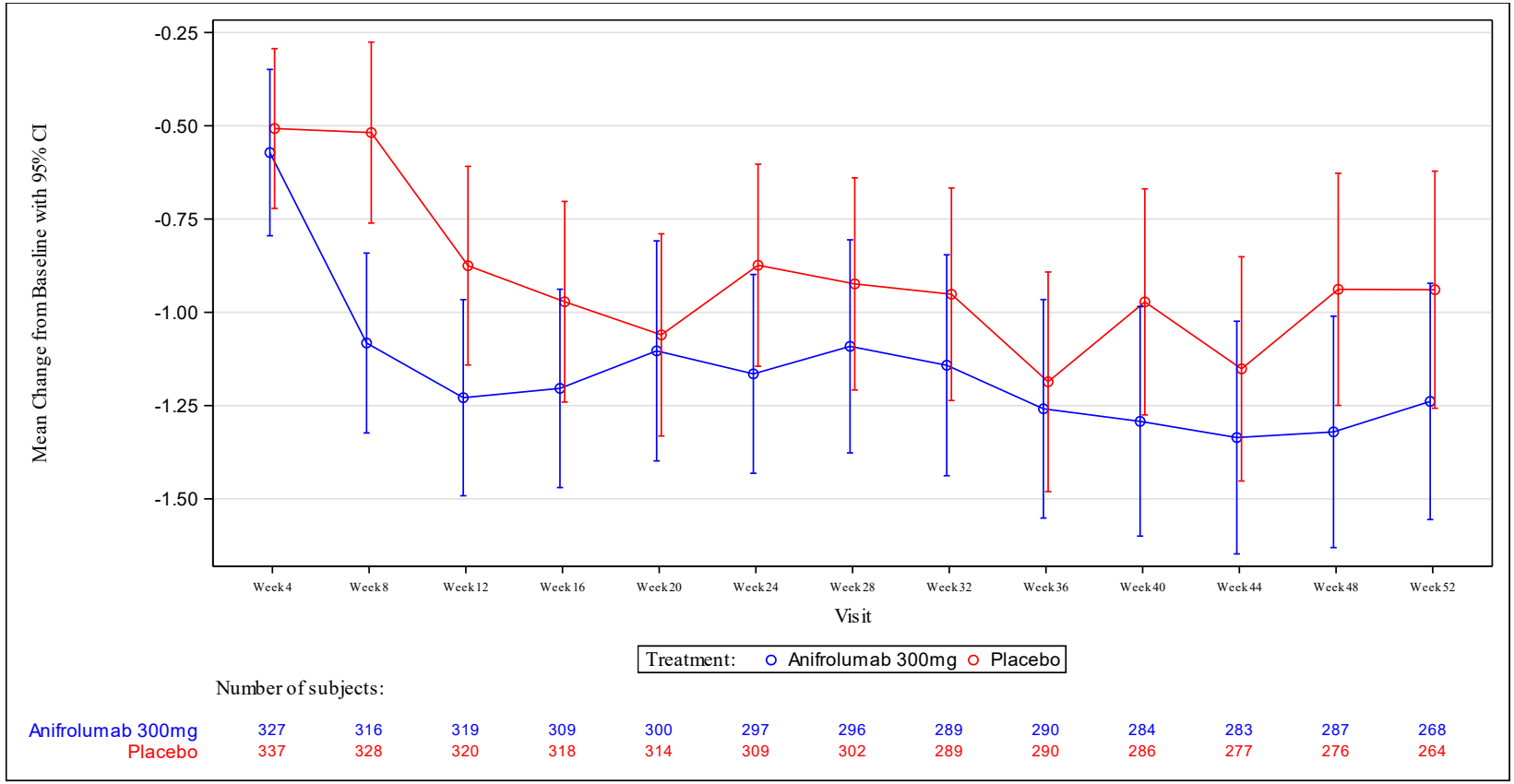
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - SDI Global Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - NRS Score
Full analysis set

	Anifrolumab 300mg (N=360)				Placebo (N=366)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	341	5.46 (2.34)	0	-	349	5.46 (2.53)	0	-
Week 4	338	4.88 (2.38)	327	-0.57 (2.05)	349	5.02 (2.55)	337	-0.51 (2.00)
Week 8	328	4.33 (2.49)	316	-1.08 (2.18)	341	5.00 (2.62)	328	-0.52 (2.23)
Week 12	333	4.21 (2.59)	319	-1.23 (2.39)	333	4.64 (2.69)	320	-0.88 (2.42)
Week 16	324	4.15 (2.52)	309	-1.20 (2.37)	329	4.56 (2.53)	318	-0.97 (2.44)
Week 20	314	4.21 (2.59)	300	-1.10 (2.60)	329	4.40 (2.60)	314	-1.06 (2.44)
Week 24	314	4.14 (2.54)	297	-1.16 (2.33)	323	4.60 (2.60)	309	-0.87 (2.42)
Week 28	312	4.19 (2.60)	296	-1.09 (2.50)	316	4.51 (2.60)	302	-0.92 (2.51)
Week 32	304	4.23 (2.50)	289	-1.14 (2.56)	300	4.50 (2.65)	289	-0.95 (2.46)
Week 36	307	4.08 (2.57)	290	-1.26 (2.53)	300	4.25 (2.56)	290	-1.19 (2.55)
Week 40	300	3.97 (2.57)	284	-1.29 (2.63)	298	4.53 (2.73)	286	-0.97 (2.60)
Week 44	298	3.95 (2.59)	283	-1.34 (2.67)	286	4.31 (2.61)	277	-1.15 (2.54)
Week 48	303	4.03 (2.64)	287	-1.32 (2.67)	286	4.42 (2.69)	276	-0.94 (2.63)
Week 52	285	4.04 (2.59)	268	-1.24 (2.63)	274	4.42 (2.67)	264	-0.94 (2.62)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - NRS Score
Full analysis set



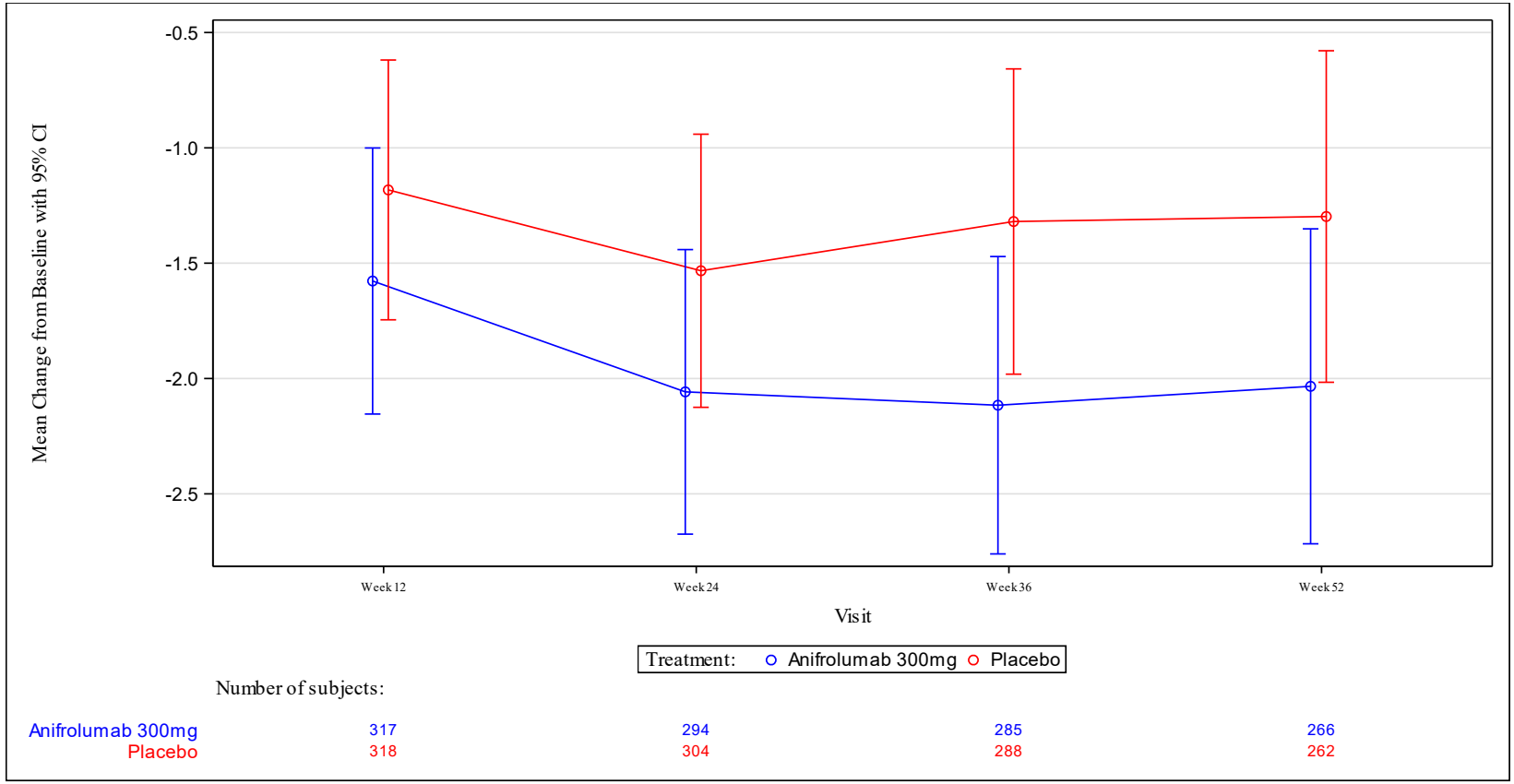
Number of subjects:

	Week 4	Week 8	Week 12	Week 16	Week 20	Week 24	Week 28	Week 32	Week 36	Week 40	Week 44	Week 48	Week 52
Anifrolumab 300mg	327	316	319	309	300	297	296	289	290	284	283	287	268
Placebo	337	328	320	318	314	309	302	289	290	286	277	276	264

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - PHQ-8 Total Score
Full analysis set

	Anifrolumab 300mg (N=360)				Placebo (N=366)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	341	9.65 (6.26)	0	-	349	9.66 (6.11)	0	-
Week 12	331	8.03 (6.18)	317	-1.58 (5.22)	331	8.45 (5.98)	318	-1.18 (5.10)
Week 24	311	7.57 (5.90)	294	-2.06 (5.37)	318	8.13 (6.04)	304	-1.53 (5.25)
Week 36	302	7.52 (5.81)	285	-2.12 (5.53)	297	8.12 (5.96)	288	-1.32 (5.70)
Week 52	283	7.63 (6.02)	266	-2.03 (5.65)	272	7.90 (6.03)	262	-1.30 (5.91)

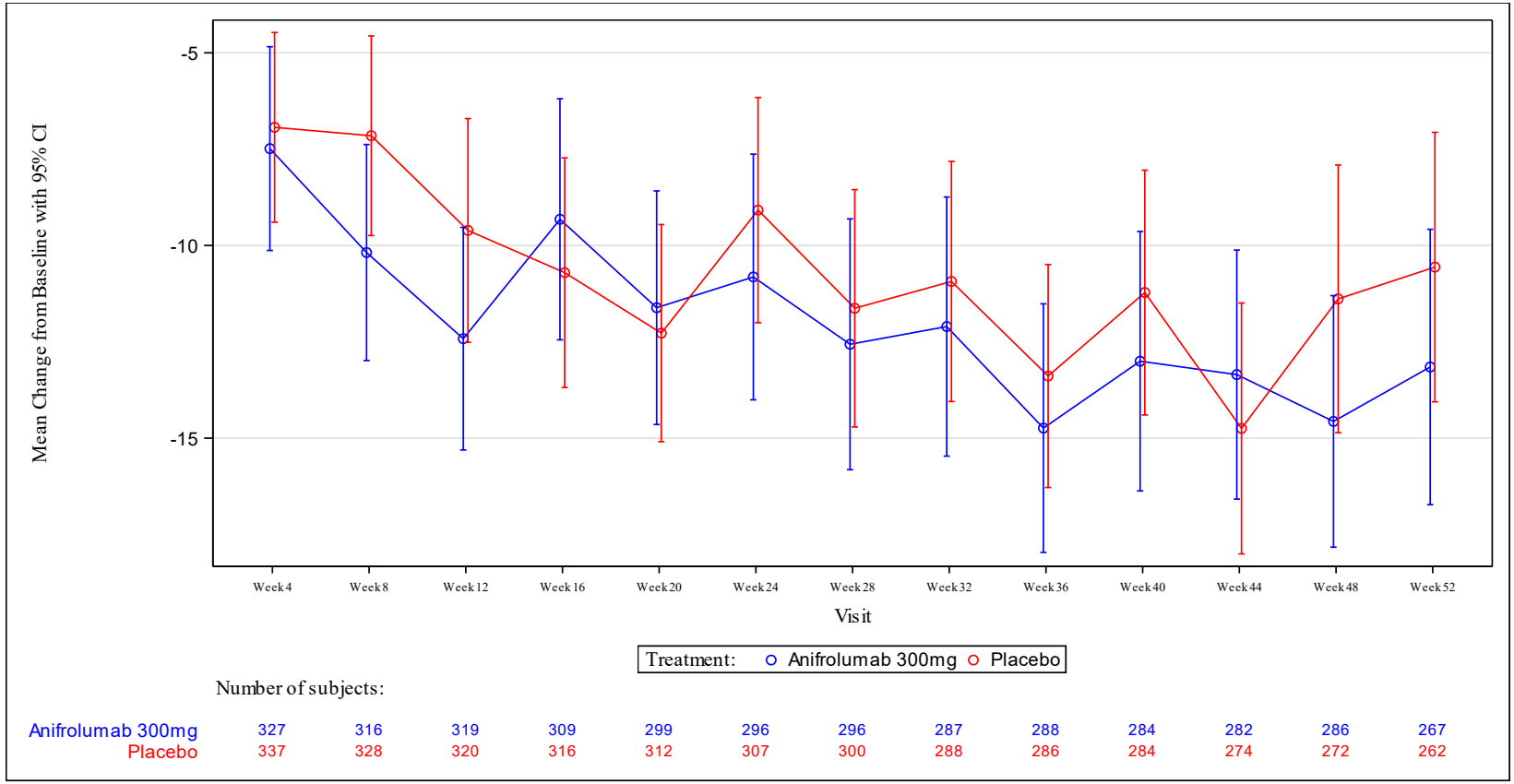
Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - PHQ-8 Total Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - PtGA
Full analysis set

	Anifrolumab 300mg (N=360)				Placebo (N=366)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	341	54.98 (21.76)	0	-	349	55.33 (22.35)	0	-
Week 4	338	47.21 (21.98)	327	-7.49 (24.31)	349	48.89 (22.47)	337	-6.93 (22.98)
Week 8	328	44.52 (23.45)	316	-10.18 (25.33)	341	48.65 (23.55)	328	-7.15 (23.84)
Week 12	333	42.19 (24.00)	319	-12.42 (26.22)	333	46.37 (24.72)	320	-9.61 (26.40)
Week 16	324	45.09 (25.30)	309	-9.32 (27.95)	327	45.11 (24.58)	316	-10.71 (26.92)
Week 20	313	42.14 (24.23)	299	-11.62 (26.64)	326	42.75 (24.47)	312	-12.28 (25.30)
Week 24	313	43.37 (25.68)	296	-10.82 (27.87)	321	46.28 (24.81)	307	-9.08 (26.02)
Week 28	312	41.90 (24.91)	296	-12.56 (28.46)	313	42.99 (24.77)	300	-11.63 (27.11)
Week 32	302	42.32 (25.03)	287	-12.10 (28.94)	299	43.37 (25.28)	288	-10.93 (26.86)
Week 36	305	40.19 (24.39)	288	-14.74 (27.82)	296	40.81 (24.22)	286	-13.39 (24.86)
Week 40	300	41.22 (25.40)	284	-13.00 (28.82)	295	44.25 (26.00)	284	-11.22 (27.20)
Week 44	297	40.75 (24.72)	282	-13.35 (27.57)	283	40.59 (25.19)	274	-14.75 (27.38)
Week 48	302	40.12 (25.19)	286	-14.57 (28.05)	282	42.80 (26.18)	272	-11.39 (29.11)
Week 52	284	41.13 (26.37)	267	-13.15 (29.66)	272	43.84 (26.19)	262	-10.56 (28.74)

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - PtGA
Full analysis set



Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SLEDAI-2K Total Score
Full analysis set

Visit	Anifrolumab 300mg (N=360) N	Anifrolumab 300mg (N=360) LSMean (SE)	Placebo (N=366) N	Placebo (N=366) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		-0.78 (0.14)		-0.61 (0.14)	-0.17 (0.16)	(-0.49, 0.15)	0.2948				
Week 8		-2.21 (0.19)		-1.56 (0.19)	-0.64 (0.25)	(-1.14, -0.15)	0.0106				
Week 12		-3.55 (0.21)		-2.48 (0.21)	-1.07 (0.27)	(-1.61, -0.53)	<.0001				
Week 16		-4.17 (0.22)		-3.00 (0.22)	-1.16 (0.30)	(-1.75, -0.58)	0.0001				
Week 20		-4.61 (0.22)		-3.55 (0.22)	-1.06 (0.29)	(-1.63, -0.49)	0.0003				
Week 24		-4.97 (0.23)		-3.86 (0.23)	-1.12 (0.30)	(-1.70, -0.53)	0.0002				
Week 28		-5.29 (0.23)		-4.01 (0.23)	-1.29 (0.31)	(-1.89, -0.68)	<.0001				
Week 32		-5.56 (0.23)		-4.22 (0.23)	-1.33 (0.31)	(-1.94, -0.73)	<.0001				
Week 36		-5.50 (0.24)		-4.41 (0.24)	-1.09 (0.32)	(-1.71, -0.46)	0.0006				
Week 40		-5.55 (0.24)		-4.49 (0.24)	-1.06 (0.32)	(-1.68, -0.43)	0.0009				
Week 44		-5.72 (0.23)		-4.78 (0.23)	-0.94 (0.31)	(-1.55, -0.33)	0.0026				
Week 48		-5.82 (0.24)		-4.92 (0.24)	-0.90 (0.32)	(-1.52, -0.28)	0.0045				
Week 52		-6.07 (0.23)		-5.10 (0.23)	-0.98 (0.31)	(-1.58, -0.37)	0.0016				
OVERALL	359	-4.60 (0.18)	362	-3.62 (0.18)	-0.98 (0.23)	(-1.44, -0.53)	<.0001	-0.29 (0.07)	(-0.43, -0.14)	0.0001	0.3642

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SLEDAI-2K Total Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) N	LSMean (SE)	Placebo (N=366) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.5065
< 10 points	108	-3.33 (0.23)	105	-2.54 (0.23)	-0.78 (0.31)	(-1.40, -0.17)	0.0133	-0.33 (0.14)	(-0.60, -0.06)	0.0165	
>= 10 points	251	-4.98 (0.23)	257	-3.91 (0.23)	-1.07 (0.30)	(-1.65, -0.49)	0.0003	-0.29 (0.09)	(-0.47, -0.12)	0.0011	
OCS dose at baseline											0.3261
<10 mg/day	170	-4.51 (0.23)	180	-3.77 (0.23)	-0.74 (0.30)	(-1.34, -0.15)	0.0150	-0.25 (0.11)	(-0.46, -0.04)	0.0216	
>=10 mg/day	189	-4.68 (0.28)	182	-3.48 (0.29)	-1.19 (0.34)	(-1.86, -0.53)	0.0005	-0.31 (0.10)	(-0.51, -0.10)	0.0033	
Result of type I IFN gene signature test											0.0487
LOW	62	-3.42 (0.36)	64	-3.34 (0.35)	-0.08 (0.50)	(-1.06, 0.90)	0.8745	-0.03 (0.18)	(-0.38, 0.32)	0.8762	
HIGH	297	-4.88 (0.19)	298	-3.70 (0.19)	-1.18 (0.26)	(-1.69, -0.67)	<.0001	-0.36 (0.08)	(-0.52, -0.20)	<.0001	
Age (years)											NE
<= 65	347	-4.64 (0.19)	358	-3.62 (0.18)	-1.02 (0.23)	(-1.48, -0.56)	<.0001	-0.29 (0.08)	(-0.44, -0.15)	0.0001	
> 65	12	NE	4	NE	NE	NE		NE	NE		
Sex											0.1475
male	27	-5.53 (0.61)	24	-3.46 (0.65)	-2.07 (0.78)	(-3.65, -0.50)	0.0110	-0.64 (0.29)	(-1.21, -0.08)	0.0258	
female	332	-4.51 (0.19)	338	-3.63 (0.19)	-0.89 (0.24)	(-1.36, -0.41)	0.0003	-0.26 (0.08)	(-0.41, -0.11)	0.0009	
Race											0.0641
White	235	-4.28 (0.21)	241	-3.71 (0.21)	-0.57 (0.28)	(-1.12, -0.02)	0.0415	-0.17 (0.09)	(-0.35, 0.01)	0.0602	
Black	45	-4.96 (0.49)	48	-3.39 (0.46)	-1.57 (0.59)	(-2.76, -0.39)	0.0098	-0.48 (0.21)	(-0.90, -0.07)	0.0215	
Other	71	-4.96 (0.54)	65	-3.08 (0.55)	-1.88 (0.58)	(-3.04, -0.72)	0.0017	-0.42 (0.17)	(-0.76, -0.08)	0.0166	
Ethnicity											0.9869
Hispanic/Latino	86	-4.80 (0.39)	88	-3.81 (0.39)	-1.00 (0.49)	(-1.96, -0.03)	0.0431	-0.27 (0.15)	(-0.57, 0.03)	0.0731	
Non-hispanic/Latino	265	-4.55 (0.21)	266	-3.57 (0.21)	-0.99 (0.26)	(-1.51, -0.47)	0.0002	-0.29 (0.09)	(-0.47, -0.12)	0.0008	
Geographic region											0.4714
EU	115	-5.21 (0.34)	120	-4.49 (0.34)	-0.73 (0.40)	(-1.52, 0.07)	0.0724	-0.20 (0.13)	(-0.45, 0.06)	0.1346	
non-EU	244	-4.34 (0.22)	242	-3.26 (0.22)	-1.08 (0.28)	(-1.63, -0.53)	0.0001	-0.32 (0.09)	(-0.50, -0.14)	0.0004	
Onset of disease											0.3706
Paediatric	26	-5.26 (1.05)	24	-3.19 (1.10)	-2.08 (1.25)	(-4.59, 0.44)	0.1041	-0.38 (0.29)	(-0.94, 0.18)	0.1830	
Adult	333	-4.59 (0.18)	338	-3.65 (0.18)	-0.94 (0.23)	(-1.39, -0.48)	<.0001	-0.28 (0.08)	(-0.44, -0.13)	0.0002	
ADA result											0.1225
Negative	334	-4.59 (0.18)	327	-3.69 (0.19)	-0.90 (0.24)	(-1.37, -0.44)	0.0001	-0.27 (0.08)	(-0.42, -0.12)	0.0006	
Positive (At any time)	25	-5.33 (0.92)	35	-3.00 (0.70)	-2.33 (0.89)	(-4.12, -0.53)	0.0124	-0.53 (0.27)	(-1.05, -0.01)	0.0461	
BMI (kg/m2) at enrolment											0.6993
< 30	232	-4.95 (0.24)	257	-3.87 (0.23)	-1.07 (0.29)	(-1.65, -0.50)	0.0003	-0.29 (0.09)	(-0.47, -0.11)	0.0016	
>= 30	127	-3.93 (0.27)	105	-3.05 (0.29)	-0.89 (0.37)	(-1.62, -0.16)	0.0174	-0.30 (0.13)	(-0.56, -0.04)	0.0241	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score CNS
Full analysis set

Visit	Anifrolumab 300mg (N=360) N	Anifrolumab 300mg (N=360) LSMean (SE)	Placebo (N=366) N	Placebo (N=366) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		NE		NE	NE	NE					
Week 8		NE		NE	NE	NE					
Week 12		NE		NE	NE	NE					
Week 16		NE		NE	NE	NE					
Week 20		NE		NE	NE	NE					
Week 24		NE		NE	NE	NE					
Week 28		NE		NE	NE	NE					
Week 32		NE		NE	NE	NE					
Week 36		NE		NE	NE	NE					
Week 40		NE		NE	NE	NE					
Week 44		NE		NE	NE	NE					
Week 48		NE		NE	NE	NE					
Week 52		NE		NE	NE	NE					
OVERALL	359	NE	363	NE	NE	NE		NE	NE		NE

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score CNS - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) N	LSMean (SE)	Placebo (N=366) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											NE
< 10 points	108	NE	105	NE	NE	NE		NE	NE		
>= 10 points	251	NE	258	NE	NE	NE		NE	NE		
OCS dose at baseline											NE
<10 mg/day	170	NE	180	NE	NE	NE		NE	NE		
>=10 mg/day	189	NE	183	NE	NE	NE		NE	NE		
Result of type I IFN gene signature test											NE
LOW	62	NE	64	NE	NE	NE		NE	NE		
HIGH	297	NE	299	NE	NE	NE		NE	NE		
Age (years)											NE
<= 65	347	NE	359	NE	NE	NE		NE	NE		
> 65	12	NE	4	NE	NE	NE		NE	NE		
Sex											NE
male	27	NE	25	NE	NE	NE		NE	NE		
female	332	NE	338	NE	NE	NE		NE	NE		
Race											NE
White	235	NE	242	NE	NE	NE		NE	NE		
Black	45	NE	48	NE	NE	NE		NE	NE		
Other	71	NE	65	NE	NE	NE		NE	NE		
Ethnicity											NE
Hispanic/Latino	86	NE	88	NE	NE	NE		NE	NE		
Non-hispanic/Latino	265	NE	267	NE	NE	NE		NE	NE		
Geographic region											NE
EU	115	NE	121	NE	NE	NE		NE	NE		
non-EU	244	NE	242	NE	NE	NE		NE	NE		
Onset of disease											NE
Paediatric	26	NE	24	NE	NE	NE		NE	NE		
Adult	333	NE	339	NE	NE	NE		NE	NE		
ADA result											NE
Negative	334	NE	328	NE	NE	NE		NE	NE		
Positive (At any time)	25	NE	35	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											NE
< 30	232	NE	258	NE	NE	NE		NE	NE		
>= 30	127	NE	105	NE	NE	NE		NE	NE		

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score CVS and Respiratory
Full analysis set

	Anifrolumab 300mg (N=360)		Placebo (N=366)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 4		NE		NE	NE	NE					
Week 8		NE		NE	NE	NE					
Week 12		NE		NE	NE	NE					
Week 16		NE		NE	NE	NE					
Week 20		NE		NE	NE	NE					
Week 24		NE		NE	NE	NE					
Week 28		NE		NE	NE	NE					
Week 32		NE		NE	NE	NE					
Week 36		NE		NE	NE	NE					
Week 40		NE		NE	NE	NE					
Week 44		NE		NE	NE	NE					
Week 48		NE		NE	NE	NE					
Week 52		NE		NE	NE	NE					
OVERALL	359	NE	363	NE	NE	NE		NE	NE		NE

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score CVS and Respiratory - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) N	LSMean (SE)	Placebo (N=366) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											NE
< 10 points	108	NE	105	NE	NE	NE		NE	NE		
>= 10 points	251	NE	258	NE	NE	NE		NE	NE		
OCS dose at baseline											NE
<10 mg/day	170	NE	180	NE	NE	NE		NE	NE		
>=10 mg/day	189	NE	183	NE	NE	NE		NE	NE		
Result of type I IFN gene signature test											NE
LOW	62	NE	64	NE	NE	NE		NE	NE		
HIGH	297	NE	299	NE	NE	NE		NE	NE		
Age (years)											NE
<= 65	347	NE	359	NE	NE	NE		NE	NE		
> 65	12	NE	4	NE	NE	NE		NE	NE		
Sex											NE
male	27	NE	25	NE	NE	NE		NE	NE		
female	332	NE	338	NE	NE	NE		NE	NE		
Race											NE
White	235	NE	242	NE	NE	NE		NE	NE		
Black	45	NE	48	NE	NE	NE		NE	NE		
Other	71	NE	65	NE	NE	NE		NE	NE		
Ethnicity											NE
Hispanic/Latino	86	NE	88	NE	NE	NE		NE	NE		
Non-hispanic/Latino	265	NE	267	NE	NE	NE		NE	NE		
Geographic region											NE
EU	115	NE	121	NE	NE	NE		NE	NE		
non-EU	244	NE	242	NE	NE	NE		NE	NE		
Onset of disease											NE
Paediatric	26	NE	24	NE	NE	NE		NE	NE		
Adult	333	NE	339	NE	NE	NE		NE	NE		
ADA result											NE
Negative	334	NE	328	NE	NE	NE		NE	NE		
Positive (At any time)	25	NE	35	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											NE
< 30	232	NE	258	NE	NE	NE		NE	NE		
>= 30	127	NE	105	NE	NE	NE		NE	NE		

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score Hematological
Full analysis set

	Anifrolumab 300mg (N=360)		Placebo (N=366)		Difference of						
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		-0.09 (0.02)		-0.03 (0.02)	-0.06 (0.02)	(-0.10, -0.02)	0.0062				
Week 8		-0.10 (0.01)		-0.04 (0.01)	-0.07 (0.02)	(-0.10, -0.03)	0.0004				
Week 12		-0.11 (0.01)		-0.04 (0.01)	-0.07 (0.02)	(-0.11, -0.03)	0.0003				
Week 16		-0.11 (0.01)		-0.04 (0.01)	-0.07 (0.02)	(-0.11, -0.04)	<.0001				
Week 20		-0.12 (0.02)		-0.04 (0.01)	-0.08 (0.02)	(-0.11, -0.04)	0.0001				
Week 24		-0.12 (0.02)		-0.03 (0.02)	-0.09 (0.02)	(-0.13, -0.05)	<.0001				
Week 28		-0.11 (0.01)		-0.06 (0.01)	-0.05 (0.02)	(-0.09, -0.01)	0.0060				
Week 32		-0.12 (0.02)		-0.03 (0.02)	-0.09 (0.02)	(-0.13, -0.05)	<.0001				
Week 36		-0.12 (0.01)		-0.06 (0.01)	-0.06 (0.02)	(-0.09, -0.02)	0.0024				
Week 40		-0.12 (0.01)		-0.08 (0.01)	-0.04 (0.02)	(-0.07, -0.01)	0.0248				
Week 44		-0.10 (0.02)		-0.06 (0.02)	-0.04 (0.02)	(-0.08, 0.00)	0.0673				
Week 48		-0.11 (0.02)		-0.07 (0.02)	-0.05 (0.02)	(-0.09, -0.01)	0.0253				
Week 52		-0.11 (0.01)		-0.08 (0.01)	-0.03 (0.02)	(-0.07, 0.01)	0.1093				
OVERALL	359	-0.11 (0.01)	363	-0.05 (0.01)	-0.06 (0.01)	(-0.08, -0.04)	<.0001	-0.32 (0.07)	(-0.46, -0.17)	<.0001	0.3047

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score Hematological - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) N	LSMean (SE)	Placebo (N=366) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.9183
< 10 points	108	-0.10 (0.01)	105	-0.03 (0.01)	-0.06 (0.02)	(-0.10, -0.02)	0.0012	-0.41 (0.14)	(-0.69, -0.14)	0.0027	
>= 10 points	251	-0.12 (0.01)	258	-0.06 (0.01)	-0.06 (0.02)	(-0.09, -0.03)	0.0001	-0.29 (0.09)	(-0.46, -0.12)	0.0011	
OCS dose at baseline											0.6448
<10 mg/day	170	-0.10 (0.01)	180	-0.04 (0.01)	-0.05 (0.02)	(-0.09, -0.02)	0.0032	-0.29 (0.11)	(-0.50, -0.07)	0.0079	
>=10 mg/day	189	-0.13 (0.01)	183	-0.06 (0.01)	-0.06 (0.02)	(-0.10, -0.03)	<.0001	-0.32 (0.10)	(-0.52, -0.11)	0.0024	
Result of type I IFN gene signature test											NE
LOW	62	NE	64	NE	NE	NE		NE	NE		
HIGH	297	-0.11 (0.01)	299	-0.05 (0.01)	-0.07 (0.01)	(-0.10, -0.04)	<.0001	-0.37 (0.08)	(-0.54, -0.21)	<.0001	
Age (years)											NE
<= 65	347	-0.11 (0.01)	359	-0.05 (0.01)	-0.06 (0.01)	(-0.08, -0.04)	<.0001	-0.31 (0.08)	(-0.46, -0.16)	<.0001	
> 65	12	NE	4	NE	NE	NE		NE	NE		
Sex											NE
male	27	NE	25	NE	NE	NE		NE	NE		
female	332	-0.11 (0.01)	338	-0.05 (0.01)	-0.06 (0.01)	(-0.08, -0.03)	<.0001	-0.31 (0.08)	(-0.46, -0.15)	<.0001	
Race											0.0139
White	235	-0.08 (0.01)	242	-0.04 (0.01)	-0.04 (0.01)	(-0.06, -0.01)	0.0030	-0.24 (0.09)	(-0.42, -0.06)	0.0103	
Black	45	-0.11 (0.03)	48	-0.05 (0.03)	-0.06 (0.03)	(-0.13, 0.01)	0.0959	-0.32 (0.21)	(-0.73, 0.09)	0.1289	
Other	71	-0.20 (0.04)	65	-0.05 (0.04)	-0.15 (0.04)	(-0.22, -0.08)	<.0001	-0.50 (0.17)	(-0.84, -0.16)	0.0039	
Ethnicity											0.8369
Hispanic/Latino	86	-0.07 (0.02)	88	-0.01 (0.02)	-0.06 (0.03)	(-0.11, -0.01)	0.0304	-0.29 (0.15)	(-0.59, 0.01)	0.0588	
Non-hispanic/Latino	265	-0.12 (0.01)	267	-0.06 (0.01)	-0.06 (0.01)	(-0.09, -0.04)	<.0001	-0.34 (0.09)	(-0.51, -0.17)	<.0001	
Geographic region											0.7182
EU	115	-0.11 (0.02)	121	-0.05 (0.02)	-0.07 (0.02)	(-0.10, -0.03)	0.0002	-0.37 (0.13)	(-0.62, -0.11)	0.0053	
non-EU	244	-0.11 (0.01)	242	-0.05 (0.01)	-0.06 (0.02)	(-0.09, -0.03)	0.0002	-0.29 (0.09)	(-0.47, -0.11)	0.0014	
Onset of disease											NE
Paediatric	26	NE	24	NE	NE	NE		NE	NE		
Adult	333	-0.11 (0.01)	339	-0.04 (0.01)	-0.06 (0.01)	(-0.09, -0.04)	<.0001	-0.33 (0.08)	(-0.49, -0.18)	<.0001	
ADA result											NE
Negative	334	-0.11 (0.01)	328	-0.04 (0.01)	-0.07 (0.01)	(-0.09, -0.04)	<.0001	-0.35 (0.08)	(-0.51, -0.20)	<.0001	
Positive (At any time)	25	NE	35	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.0411
< 30	232	-0.14 (0.01)	258	-0.06 (0.01)	-0.07 (0.02)	(-0.11, -0.04)	<.0001	-0.33 (0.09)	(-0.50, -0.15)	0.0004	
>= 30	127	-0.06 (0.01)	105	-0.03 (0.01)	-0.03 (0.02)	(-0.06, 0.00)	0.0634	-0.23 (0.13)	(-0.49, 0.03)	0.0849	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score Immunology
Full analysis set

	Anifrolumab 300mg (N=360)		Placebo (N=366)		Difference of						
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		-0.17 (0.05)		-0.10 (0.05)	-0.07 (0.06)	(-0.19, 0.04)	0.2253				
Week 8		-0.18 (0.05)		-0.04 (0.05)	-0.14 (0.07)	(-0.27, -0.01)	0.0362				
Week 12		-0.23 (0.05)		-0.02 (0.05)	-0.22 (0.07)	(-0.35, -0.09)	0.0012				
Week 16		-0.26 (0.05)		0.01 (0.05)	-0.27 (0.07)	(-0.40, -0.14)	<.0001				
Week 20		-0.22 (0.06)		0.04 (0.06)	-0.26 (0.07)	(-0.40, -0.12)	0.0002				
Week 24		-0.30 (0.06)		-0.05 (0.06)	-0.25 (0.07)	(-0.39, -0.10)	0.0006				
Week 28		-0.27 (0.05)		-0.02 (0.05)	-0.26 (0.07)	(-0.39, -0.12)	0.0002				
Week 32		-0.29 (0.05)		-0.05 (0.05)	-0.24 (0.07)	(-0.38, -0.11)	0.0004				
Week 36		-0.23 (0.05)		-0.08 (0.05)	-0.15 (0.07)	(-0.29, -0.02)	0.0244				
Week 40		-0.23 (0.06)		-0.01 (0.06)	-0.22 (0.08)	(-0.37, -0.07)	0.0039				
Week 44		-0.19 (0.06)		-0.07 (0.06)	-0.12 (0.07)	(-0.26, 0.02)	0.1016				
Week 48		-0.25 (0.06)		-0.04 (0.06)	-0.22 (0.08)	(-0.37, -0.06)	0.0061				
Week 52		-0.28 (0.06)		-0.07 (0.06)	-0.22 (0.08)	(-0.37, -0.06)	0.0058				
OVERALL	359	-0.24 (0.04)	366	-0.04 (0.04)	-0.20 (0.05)	(-0.30, -0.10)	<.0001	-0.25 (0.07)	(-0.39, -0.10)	0.0010	0.2891

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score Immunology - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) N	LSMean (SE)	Placebo (N=366) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.8494
< 10 points	108	-0.14 (0.06)	106	0.07 (0.06)	-0.22 (0.08)	(-0.37, -0.06)	0.0073	-0.34 (0.14)	(-0.61, -0.07)	0.0142	
>= 10 points	251	-0.22 (0.05)	260	-0.03 (0.05)	-0.20 (0.06)	(-0.32, -0.07)	0.0021	-0.23 (0.09)	(-0.40, -0.05)	0.0109	
OCS dose at baseline											0.3063
<10 mg/day	170	-0.15 (0.05)	181	0.00 (0.05)	-0.15 (0.07)	(-0.28, -0.02)	0.0238	-0.21 (0.11)	(-0.42, -0.00)	0.0453	
>=10 mg/day	189	-0.36 (0.07)	185	-0.10 (0.07)	-0.26 (0.07)	(-0.40, -0.11)	0.0007	-0.26 (0.10)	(-0.46, -0.06)	0.0122	
Result of type I IFN gene signature test											0.9470
LOW	62	-0.09 (0.06)	64	0.12 (0.06)	-0.21 (0.09)	(-0.38, -0.04)	0.0147	-0.43 (0.18)	(-0.78, -0.07)	0.0182	
HIGH	297	-0.27 (0.04)	302	-0.07 (0.04)	-0.20 (0.06)	(-0.32, -0.09)	0.0005	-0.27 (0.08)	(-0.43, -0.11)	0.0011	
Age (years)											NE
<= 65	347	-0.23 (0.04)	362	-0.05 (0.04)	-0.19 (0.05)	(-0.29, -0.09)	0.0002	-0.23 (0.08)	(-0.38, -0.08)	0.0024	
> 65	12	NE	4	NE	NE	NE		NE	NE		
Sex											0.5752
male	27	-0.36 (0.19)	25	-0.26 (0.20)	-0.09 (0.20)	(-0.50, 0.31)	0.6421	-0.09 (0.28)	(-0.64, 0.45)	0.7356	
female	332	-0.23 (0.04)	341	-0.02 (0.04)	-0.21 (0.05)	(-0.31, -0.11)	<.0001	-0.26 (0.08)	(-0.41, -0.11)	0.0009	
Race											0.4321
White	235	-0.24 (0.05)	244	-0.07 (0.05)	-0.18 (0.06)	(-0.30, -0.06)	0.0034	-0.23 (0.09)	(-0.41, -0.05)	0.0135	
Black	45	-0.23 (0.12)	48	-0.11 (0.11)	-0.13 (0.14)	(-0.40, 0.15)	0.3673	-0.15 (0.21)	(-0.56, 0.25)	0.4608	
Other	71	-0.40 (0.15)	66	-0.04 (0.15)	-0.36 (0.14)	(-0.63, -0.08)	0.0120	-0.28 (0.17)	(-0.62, 0.05)	0.0987	
Ethnicity											0.9969
Hispanic/Latino	86	-0.30 (0.10)	89	-0.09 (0.09)	-0.21 (0.11)	(-0.41, 0.00)	0.0530	-0.23 (0.15)	(-0.53, 0.07)	0.1281	
Non-hispanic/Latino	265	-0.23 (0.05)	269	-0.02 (0.05)	-0.20 (0.06)	(-0.32, -0.09)	0.0006	-0.25 (0.09)	(-0.42, -0.08)	0.0043	
Geographic region											0.2761
EU	115	-0.26 (0.09)	122	-0.14 (0.09)	-0.12 (0.09)	(-0.30, 0.05)	0.1718	-0.13 (0.13)	(-0.38, 0.13)	0.3240	
non-EU	244	-0.23 (0.05)	244	0.01 (0.05)	-0.24 (0.06)	(-0.36, -0.12)	<.0001	-0.30 (0.09)	(-0.48, -0.12)	0.0009	
Onset of disease											0.4537
Paediatric	26	-0.72 (0.25)	24	-0.32 (0.26)	-0.40 (0.27)	(-0.95, 0.15)	0.1471	-0.31 (0.28)	(-0.87, 0.25)	0.2782	
Adult	333	-0.22 (0.04)	342	-0.02 (0.04)	-0.19 (0.05)	(-0.29, -0.09)	0.0002	-0.24 (0.08)	(-0.39, -0.09)	0.0017	
ADA result											0.3162
Negative	334	-0.22 (0.04)	331	-0.04 (0.04)	-0.19 (0.05)	(-0.29, -0.08)	0.0004	-0.23 (0.08)	(-0.38, -0.08)	0.0029	
Positive (At any time)	25	-0.72 (0.26)	35	-0.31 (0.21)	-0.41 (0.21)	(-0.83, 0.02)	0.0606	-0.32 (0.26)	(-0.84, 0.20)	0.2251	
BMI (kg/m2) at enrolment											0.7615
< 30	232	-0.25 (0.06)	261	-0.06 (0.06)	-0.18 (0.07)	(-0.31, -0.05)	0.0054	-0.19 (0.09)	(-0.37, -0.02)	0.0320	
>= 30	127	-0.20 (0.05)	105	0.01 (0.06)	-0.21 (0.07)	(-0.35, -0.07)	0.0028	-0.36 (0.13)	(-0.62, -0.10)	0.0069	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score Mucocutaneous
Full analysis set

	Anifrolumab 300mg (N=360)		Placebo (N=366)		Difference of						
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		-0.06 (0.05)		-0.17 (0.05)	0.11 (0.05)	(-0.00, 0.21)	0.0503				
Week 8		-0.49 (0.07)		-0.48 (0.07)	-0.01 (0.09)	(-0.18, 0.16)	0.9146				
Week 12		-0.96 (0.08)		-0.71 (0.08)	-0.25 (0.11)	(-0.46, -0.03)	0.0259				
Week 16		-1.30 (0.09)		-0.95 (0.09)	-0.34 (0.12)	(-0.57, -0.11)	0.0038				
Week 20		-1.49 (0.09)		-1.11 (0.09)	-0.38 (0.12)	(-0.62, -0.14)	0.0017				
Week 24		-1.63 (0.10)		-1.27 (0.09)	-0.36 (0.13)	(-0.62, -0.11)	0.0057				
Week 28		-1.83 (0.10)		-1.31 (0.10)	-0.52 (0.13)	(-0.78, -0.26)	<.0001				
Week 32		-1.96 (0.10)		-1.43 (0.10)	-0.53 (0.13)	(-0.79, -0.27)	<.0001				
Week 36		-2.02 (0.10)		-1.52 (0.10)	-0.50 (0.14)	(-0.76, -0.23)	0.0003				
Week 40		-2.05 (0.10)		-1.57 (0.10)	-0.48 (0.14)	(-0.76, -0.20)	0.0009				
Week 44		-2.16 (0.11)		-1.62 (0.11)	-0.55 (0.14)	(-0.83, -0.26)	0.0002				
Week 48		-2.16 (0.11)		-1.70 (0.11)	-0.46 (0.15)	(-0.75, -0.17)	0.0018				
Week 52		-2.25 (0.10)		-1.78 (0.10)	-0.47 (0.14)	(-0.75, -0.19)	0.0012				
OVERALL	359	-1.57 (0.07)	363	-1.20 (0.07)	-0.36 (0.10)	(-0.56, -0.17)	0.0003	-0.26 (0.07)	(-0.40, -0.11)	0.0006	0.6501

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score Mucocutaneous - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) N	LSMean (SE)	Placebo (N=366) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.9001
< 10 points	108	-1.15 (0.12)	105	-0.80 (0.12)	-0.35 (0.17)	(-0.68, -0.02)	0.0370	-0.28 (0.14)	(-0.55, -0.01)	0.0447	
>= 10 points	251	-1.73 (0.09)	258	-1.36 (0.09)	-0.38 (0.12)	(-0.62, -0.14)	0.0021	-0.26 (0.09)	(-0.43, -0.08)	0.0036	
OCS dose at baseline											0.0255
<10 mg/day	170	-1.46 (0.11)	180	-1.31 (0.11)	-0.15 (0.15)	(-0.43, 0.14)	0.3123	-0.10 (0.11)	(-0.31, 0.11)	0.3320	
>=10 mg/day	189	-1.69 (0.11)	183	-1.09 (0.11)	-0.60 (0.14)	(-0.87, -0.32)	<.0001	-0.41 (0.10)	(-0.62, -0.21)	<.0001	
Result of type I IFN gene signature test											0.3239
LOW	62	-1.35 (0.17)	64	-1.20 (0.17)	-0.15 (0.23)	(-0.62, 0.31)	0.5109	-0.12 (0.18)	(-0.46, 0.23)	0.5176	
HIGH	297	-1.64 (0.08)	299	-1.23 (0.08)	-0.41 (0.11)	(-0.63, -0.19)	0.0002	-0.30 (0.08)	(-0.46, -0.14)	0.0003	
Age (years)											NE
<= 65	347	-1.58 (0.08)	359	-1.20 (0.08)	-0.38 (0.10)	(-0.58, -0.18)	0.0002	-0.27 (0.08)	(-0.41, -0.12)	0.0004	
> 65	12	NE	4	NE	NE	NE		NE	NE		
Sex											0.1131
male	27	-1.61 (0.27)	25	-0.68 (0.28)	-0.93 (0.37)	(-1.67, -0.19)	0.0152	-0.65 (0.29)	(-1.21, -0.09)	0.0228	
female	332	-1.55 (0.08)	338	-1.23 (0.08)	-0.32 (0.10)	(-0.53, -0.12)	0.0020	-0.23 (0.08)	(-0.38, -0.07)	0.0035	
Race											0.0097
White	235	-1.47 (0.09)	242	-1.27 (0.09)	-0.20 (0.12)	(-0.44, 0.04)	0.1095	-0.14 (0.09)	(-0.32, 0.04)	0.1294	
Black	45	-1.52 (0.21)	48	-1.20 (0.20)	-0.32 (0.28)	(-0.86, 0.23)	0.2533	-0.22 (0.21)	(-0.63, 0.18)	0.2798	
Other	71	-1.90 (0.18)	65	-0.93 (0.19)	-0.98 (0.22)	(-1.42, -0.53)	<.0001	-0.64 (0.18)	(-0.99, -0.30)	0.0003	
Ethnicity											0.7300
Hispanic/Latino	86	-1.86 (0.17)	88	-1.43 (0.16)	-0.43 (0.22)	(-0.86, -0.00)	0.0485	-0.28 (0.15)	(-0.58, 0.02)	0.0682	
Non-hispanic/Latino	265	-1.48 (0.08)	267	-1.14 (0.08)	-0.35 (0.11)	(-0.57, -0.12)	0.0023	-0.25 (0.09)	(-0.42, -0.08)	0.0038	
Geographic region											0.2983
EU	115	-1.57 (0.13)	121	-1.36 (0.13)	-0.22 (0.17)	(-0.55, 0.12)	0.2044	-0.15 (0.13)	(-0.41, 0.10)	0.2426	
non-EU	244	-1.56 (0.09)	242	-1.12 (0.09)	-0.43 (0.12)	(-0.68, -0.19)	0.0006	-0.30 (0.09)	(-0.48, -0.12)	0.0010	
Onset of disease											NE
Paediatric	26	NE	24	NE	NE	NE		NE	NE		
Adult	333	-1.55 (0.08)	339	-1.21 (0.08)	-0.34 (0.10)	(-0.54, -0.14)	0.0011	-0.24 (0.08)	(-0.39, -0.09)	0.0020	
ADA result											0.2038
Negative	334	-1.57 (0.08)	328	-1.23 (0.08)	-0.33 (0.10)	(-0.54, -0.12)	0.0017	-0.23 (0.08)	(-0.38, -0.08)	0.0030	
Positive (At any time)	25	-1.56 (0.29)	35	-0.79 (0.24)	-0.77 (0.33)	(-1.43, -0.11)	0.0231	-0.54 (0.27)	(-1.06, -0.01)	0.0445	
BMI (kg/m2) at enrolment											0.2594
< 30	232	-1.72 (0.09)	258	-1.26 (0.09)	-0.46 (0.12)	(-0.69, -0.22)	0.0002	-0.32 (0.09)	(-0.50, -0.14)	0.0004	
>= 30	127	-1.33 (0.13)	105	-1.12 (0.14)	-0.21 (0.18)	(-0.57, 0.15)	0.2559	-0.14 (0.13)	(-0.40, 0.11)	0.2729	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score Musculoskeletal
Full analysis set

	Anifrolumab 300mg (N=360)		Placebo (N=366)		Difference of						
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		-0.12 (0.06)		-0.07 (0.06)	-0.05 (0.07)	(-0.19, 0.09)	0.5131				
Week 8		-0.84 (0.10)		-0.73 (0.10)	-0.10 (0.13)	(-0.36, 0.15)	0.4242				
Week 12		-1.43 (0.11)		-1.29 (0.11)	-0.14 (0.15)	(-0.42, 0.15)	0.3497				
Week 16		-1.72 (0.11)		-1.59 (0.11)	-0.13 (0.15)	(-0.43, 0.17)	0.3889				
Week 20		-1.99 (0.11)		-1.75 (0.11)	-0.24 (0.15)	(-0.54, 0.06)	0.1192				
Week 24		-2.08 (0.11)		-1.89 (0.11)	-0.19 (0.15)	(-0.49, 0.11)	0.2114				
Week 28		-2.20 (0.11)		-1.97 (0.11)	-0.23 (0.15)	(-0.54, 0.07)	0.1262				
Week 32		-2.26 (0.12)		-2.08 (0.12)	-0.18 (0.16)	(-0.49, 0.13)	0.2444				
Week 36		-2.29 (0.11)		-2.13 (0.11)	-0.17 (0.16)	(-0.47, 0.14)	0.2909				
Week 40		-2.30 (0.11)		-2.21 (0.11)	-0.09 (0.16)	(-0.39, 0.22)	0.5653				
Week 44		-2.35 (0.11)		-2.22 (0.11)	-0.13 (0.15)	(-0.44, 0.17)	0.3787				
Week 48		-2.43 (0.11)		-2.29 (0.11)	-0.14 (0.15)	(-0.43, 0.16)	0.3643				
Week 52		-2.45 (0.11)		-2.36 (0.11)	-0.09 (0.15)	(-0.39, 0.21)	0.5503				
OVERALL	359	-1.88 (0.08)	363	-1.74 (0.08)	-0.14 (0.11)	(-0.36, 0.07)	0.1874	-0.09 (0.07)	(-0.24, 0.05)	0.2204	0.3338

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score Musculoskeletal - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) N	LSMean (SE)	Placebo (N=366) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.9562
< 10 points	108	-1.81 (0.15)	105	-1.65 (0.15)	-0.15 (0.21)	(-0.56, 0.25)	0.4559	-0.10 (0.14)	(-0.37, 0.17)	0.4660	
>= 10 points	251	-1.93 (0.10)	258	-1.79 (0.10)	-0.14 (0.13)	(-0.40, 0.12)	0.2799	-0.09 (0.09)	(-0.26, 0.09)	0.3220	
OCS dose at baseline											0.8701
<10 mg/day	170	-1.94 (0.12)	180	-1.77 (0.11)	-0.17 (0.16)	(-0.48, 0.14)	0.2845	-0.11 (0.11)	(-0.32, 0.10)	0.3063	
>=10 mg/day	189	-1.82 (0.12)	183	-1.69 (0.12)	-0.13 (0.15)	(-0.43, 0.17)	0.3865	-0.08 (0.10)	(-0.28, 0.12)	0.4432	
Result of type I IFN gene signature test											0.2384
LOW	62	-1.50 (0.19)	64	-1.64 (0.18)	0.14 (0.26)	(-0.38, 0.65)	0.5961	0.09 (0.18)	(-0.26, 0.44)	0.5998	
HIGH	297	-2.02 (0.09)	299	-1.82 (0.09)	-0.20 (0.12)	(-0.44, 0.04)	0.0981	-0.13 (0.08)	(-0.29, 0.03)	0.1063	
Age (years)											NE
<= 65	347	-1.89 (0.09)	359	-1.73 (0.08)	-0.16 (0.11)	(-0.37, 0.06)	0.1594	-0.10 (0.08)	(-0.25, 0.05)	0.1931	
> 65	12	NE	4	NE	NE	NE		NE	NE		
Sex											NE
male	27	NE	25	NE	NE	NE		NE	NE		
female	332	-1.85 (0.09)	338	-1.70 (0.09)	-0.15 (0.11)	(-0.37, 0.07)	0.1875	-0.09 (0.08)	(-0.25, 0.06)	0.2208	
Race											0.1448
White	235	-1.85 (0.10)	242	-1.77 (0.10)	-0.08 (0.14)	(-0.35, 0.19)	0.5760	-0.05 (0.09)	(-0.23, 0.13)	0.5917	
Black	45	-2.08 (0.26)	48	-1.38 (0.24)	-0.70 (0.31)	(-1.31, -0.09)	0.0255	-0.41 (0.21)	(-0.82, 0.00)	0.0519	
Other	71	-1.70 (0.23)	65	-1.70 (0.24)	0.00 (0.24)	(-0.48, 0.49)	0.9878	0.00 (0.17)	(-0.33, 0.34)	0.9911	
Ethnicity											0.7150
Hispanic/Latino	86	-1.97 (0.17)	88	-1.74 (0.16)	-0.23 (0.22)	(-0.66, 0.19)	0.2810	-0.15 (0.15)	(-0.45, 0.15)	0.3256	
Non-hispanic/Latino	265	-1.87 (0.10)	267	-1.73 (0.10)	-0.14 (0.13)	(-0.40, 0.11)	0.2742	-0.09 (0.09)	(-0.26, 0.08)	0.3075	
Geographic region											0.5034
EU	115	-2.22 (0.14)	121	-2.17 (0.14)	-0.04 (0.17)	(-0.38, 0.30)	0.8016	-0.03 (0.13)	(-0.28, 0.23)	0.8255	
non-EU	244	-1.74 (0.10)	242	-1.55 (0.10)	-0.19 (0.14)	(-0.46, 0.08)	0.1649	-0.12 (0.09)	(-0.30, 0.06)	0.1934	
Onset of disease											0.5500
Paediatric	26	-1.28 (0.39)	24	-1.35 (0.39)	0.08 (0.39)	(-0.72, 0.87)	0.8452	0.04 (0.28)	(-0.52, 0.59)	0.8908	
Adult	333	-1.91 (0.09)	339	-1.74 (0.09)	-0.17 (0.11)	(-0.39, 0.06)	0.1421	-0.11 (0.08)	(-0.26, 0.05)	0.1702	
ADA result											0.1915
Negative	334	-1.89 (0.09)	328	-1.78 (0.09)	-0.11 (0.11)	(-0.33, 0.12)	0.3439	-0.07 (0.08)	(-0.22, 0.08)	0.3783	
Positive (At any time)	25	-1.87 (0.30)	35	-1.25 (0.25)	-0.62 (0.37)	(-1.36, 0.13)	0.1032	-0.41 (0.26)	(-0.92, 0.11)	0.1259	
BMI (kg/m2) at enrolment											0.2873
< 30	232	-1.98 (0.11)	258	-1.89 (0.10)	-0.09 (0.13)	(-0.35, 0.17)	0.5003	-0.05 (0.09)	(-0.23, 0.12)	0.5476	
>= 30	127	-1.75 (0.14)	105	-1.41 (0.15)	-0.34 (0.19)	(-0.72, 0.04)	0.0832	-0.22 (0.13)	(-0.48, 0.04)	0.0940	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score Renal
Full analysis set

	Anifrolumab 300mg (N=360)		Placebo (N=366)		Difference of						
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		-0.10 (0.07)		-0.02 (0.07)	-0.07 (0.08)	(-0.23, 0.08)	0.3583				
Week 8		-0.08 (0.07)		0.07 (0.07)	-0.15 (0.09)	(-0.32, 0.02)	0.0762				
Week 12		-0.10 (0.07)		-0.05 (0.07)	-0.04 (0.08)	(-0.21, 0.13)	0.6365				
Week 16		-0.04 (0.07)		0.04 (0.07)	-0.08 (0.09)	(-0.26, 0.09)	0.3526				
Week 20		-0.05 (0.07)		0.00 (0.07)	-0.05 (0.09)	(-0.23, 0.13)	0.5808				
Week 24		-0.05 (0.08)		0.06 (0.08)	-0.11 (0.10)	(-0.31, 0.08)	0.2612				
Week 28		-0.03 (0.09)		-0.02 (0.09)	-0.01 (0.11)	(-0.23, 0.22)	0.9629				
Week 32		-0.09 (0.08)		-0.00 (0.08)	-0.09 (0.10)	(-0.29, 0.11)	0.3882				
Week 36		-0.04 (0.08)		0.04 (0.08)	-0.08 (0.10)	(-0.28, 0.11)	0.3983				
Week 40		-0.04 (0.09)		0.03 (0.09)	-0.07 (0.11)	(-0.29, 0.15)	0.5518				
Week 44		-0.09 (0.09)		-0.02 (0.09)	-0.07 (0.12)	(-0.30, 0.16)	0.5609				
Week 48		-0.02 (0.09)		0.05 (0.09)	-0.07 (0.13)	(-0.32, 0.18)	0.5676				
Week 52		-0.08 (0.09)		0.04 (0.09)	-0.13 (0.11)	(-0.35, 0.09)	0.2599				
OVERALL	360	-0.06 (0.06)	366	0.02 (0.06)	-0.08 (0.08)	(-0.23, 0.08)	0.3172	-0.06 (0.07)	(-0.21, 0.08)	0.3860	0.7667

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score Renal - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) N	LSMean (SE)	Placebo (N=366) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											NE
< 10 points	109	NE	106	NE	NE	NE		NE	NE		
>= 10 points	251	-0.05 (0.09)	260	0.08 (0.09)	-0.13 (0.11)	(-0.35, 0.08)	0.2311	-0.09 (0.09)	(-0.27, 0.08)	0.3002	
OCS dose at baseline											0.8517
<10 mg/day	170	-0.04 (0.05)	181	0.02 (0.05)	-0.06 (0.07)	(-0.19, 0.07)	0.3489	-0.09 (0.11)	(-0.30, 0.11)	0.3741	
>=10 mg/day	190	-0.12 (0.12)	185	-0.03 (0.12)	-0.09 (0.14)	(-0.37, 0.19)	0.5193	-0.05 (0.10)	(-0.26, 0.15)	0.6085	
Result of type I IFN gene signature test											NE
LOW	62	NE	64	NE	NE	NE		NE	NE		
HIGH	298	-0.04 (0.07)	302	0.05 (0.07)	-0.09 (0.09)	(-0.28, 0.09)	0.3234	-0.08 (0.08)	(-0.24, 0.08)	0.3444	
Age (years)											NE
<= 65	348	-0.07 (0.07)	362	0.01 (0.07)	-0.08 (0.08)	(-0.24, 0.08)	0.3250	-0.06 (0.08)	(-0.21, 0.08)	0.3972	
> 65	12	NE	4	NE	NE	NE		NE	NE		
Sex											NE
male	27	NE	25	NE	NE	NE		NE	NE		
female	333	-0.04 (0.07)	341	0.04 (0.07)	-0.08 (0.08)	(-0.24, 0.08)	0.3316	-0.07 (0.08)	(-0.22, 0.08)	0.3905	
Race											NE
White	235	-0.06 (0.08)	244	0.04 (0.08)	-0.10 (0.10)	(-0.30, 0.10)	0.3233	-0.08 (0.09)	(-0.26, 0.10)	0.3747	
Black	46	NE	48	NE	NE	NE		NE	NE		
Other	71	0.16 (0.20)	66	0.12 (0.20)	0.03 (0.21)	(-0.37, 0.44)	0.8691	0.02 (0.17)	(-0.31, 0.36)	0.9035	
Ethnicity											0.4250
Hispanic/Latino	86	0.04 (0.13)	89	0.24 (0.13)	-0.20 (0.18)	(-0.55, 0.16)	0.2741	-0.16 (0.15)	(-0.46, 0.13)	0.2764	
Non-hispanic/Latino	266	-0.06 (0.08)	269	-0.02 (0.08)	-0.04 (0.09)	(-0.22, 0.15)	0.7071	-0.03 (0.09)	(-0.20, 0.14)	0.7430	
Geographic region											0.2552
EU	115	-0.05 (0.14)	122	0.18 (0.14)	-0.23 (0.17)	(-0.56, 0.10)	0.1741	-0.15 (0.13)	(-0.41, 0.10)	0.2439	
non-EU	245	-0.01 (0.07)	244	0.00 (0.07)	-0.02 (0.08)	(-0.18, 0.15)	0.8551	-0.01 (0.09)	(-0.19, 0.16)	0.8688	
Onset of disease											NE
Paediatric	26	NE	24	NE	NE	NE		NE	NE		
Adult	334	-0.10 (0.06)	342	-0.01 (0.05)	-0.08 (0.07)	(-0.22, 0.05)	0.2091	-0.08 (0.08)	(-0.23, 0.07)	0.2767	
ADA result											NE
Negative	334	-0.07 (0.05)	331	-0.02 (0.05)	-0.05 (0.07)	(-0.18, 0.08)	0.4623	-0.05 (0.08)	(-0.20, 0.10)	0.5223	
Positive (At any time)	25	NE	35	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.8938
< 30	233	-0.01 (0.09)	261	0.05 (0.09)	-0.06 (0.10)	(-0.26, 0.14)	0.5533	-0.04 (0.09)	(-0.22, 0.13)	0.6235	
>= 30	127	-0.18 (0.08)	105	-0.10 (0.09)	-0.08 (0.11)	(-0.30, 0.14)	0.4734	-0.09 (0.13)	(-0.35, 0.17)	0.5014	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score Vascular
Full analysis set

Visit	Anifrolumab 300mg (N=360) N	Anifrolumab 300mg (N=360) LSMean (SE)	Placebo (N=366) N	Placebo (N=366) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		NE		NE	NE	NE					
Week 8		NE		NE	NE	NE					
Week 12		NE		NE	NE	NE					
Week 16		NE		NE	NE	NE					
Week 20		NE		NE	NE	NE					
Week 24		NE		NE	NE	NE					
Week 28		NE		NE	NE	NE					
Week 32		NE		NE	NE	NE					
Week 36		NE		NE	NE	NE					
Week 40		NE		NE	NE	NE					
Week 44		NE		NE	NE	NE					
Week 48		NE		NE	NE	NE					
Week 52		NE		NE	NE	NE					
OVERALL	359	NE	363	NE	NE	NE		NE	NE		NE

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Total Organ Score Vascular - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) N	LSMean (SE)	Placebo (N=366) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											NE
< 10 points	108	NE	105	NE	NE	NE		NE	NE		
>= 10 points	251	NE	258	NE	NE	NE		NE	NE		
OCS dose at baseline											NE
<10 mg/day	170	NE	180	NE	NE	NE		NE	NE		
>=10 mg/day	189	-0.55 (0.11)	183	-0.41 (0.11)	-0.14 (0.14)	(-0.42, 0.14)	0.3124	-0.09 (0.10)	(-0.30, 0.11)	0.3694	
Result of type I IFN gene signature test											NE
LOW	62	NE	64	NE	NE	NE		NE	NE		
HIGH	297	NE	299	NE	NE	NE		NE	NE		
Age (years)											NE
<= 65	347	NE	359	NE	NE	NE		NE	NE		
> 65	12	NE	4	NE	NE	NE		NE	NE		
Sex											NE
male	27	NE	25	NE	NE	NE		NE	NE		
female	332	NE	338	NE	NE	NE		NE	NE		
Race											NE
White	235	-0.38 (0.08)	242	-0.34 (0.08)	-0.04 (0.10)	(-0.23, 0.16)	0.7067	-0.03 (0.09)	(-0.21, 0.15)	0.7280	
Black	45	NE	48	NE	NE	NE		NE	NE		
Other	71	NE	65	NE	NE	NE		NE	NE		
Ethnicity											NE
Hispanic/Latino	86	NE	88	NE	NE	NE		NE	NE		
Non-hispanic/Latino	265	-0.61 (0.08)	267	-0.42 (0.08)	-0.20 (0.11)	(-0.41, 0.01)	0.0628	-0.15 (0.09)	(-0.32, 0.02)	0.0921	
Geographic region											NE
EU	115	-0.76 (0.14)	121	-0.66 (0.15)	-0.10 (0.18)	(-0.46, 0.25)	0.5567	-0.07 (0.13)	(-0.32, 0.19)	0.6107	
non-EU	244	NE	242	NE	NE	NE		NE	NE		
Onset of disease											NE
Paediatric	26	NE	24	NE	NE	NE		NE	NE		
Adult	333	NE	339	NE	NE	NE		NE	NE		
ADA result											NE
Negative	334	-0.56 (0.07)	328	-0.37 (0.07)	-0.19 (0.09)	(-0.37, -0.00)	0.0456	-0.14 (0.08)	(-0.30, 0.01)	0.0670	
Positive (At any time)	25	NE	35	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											NE
< 30	232	NE	258	NE	NE	NE		NE	NE		
>= 30	127	NE	105	NE	NE	NE		NE	NE		

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - PGA
Full analysis set

Visit	Anifrolumab 300mg (N=360) N	Anifrolumab 300mg (N=360) LSMean (SE)	Placebo (N=366) N	Placebo (N=366) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		-0.24 (0.02)		-0.19 (0.02)	-0.05 (0.03)	(-0.10, -0.00)	0.0414				
Week 8		-0.46 (0.03)		-0.37 (0.03)	-0.09 (0.03)	(-0.16, -0.02)	0.0074				
Week 12		-0.61 (0.03)		-0.44 (0.03)	-0.16 (0.04)	(-0.24, -0.09)	<.0001				
Week 16		-0.70 (0.03)		-0.54 (0.03)	-0.16 (0.04)	(-0.24, -0.08)	<.0001				
Week 20		-0.77 (0.03)		-0.59 (0.03)	-0.18 (0.04)	(-0.26, -0.10)	<.0001				
Week 24		-0.83 (0.03)		-0.64 (0.03)	-0.19 (0.04)	(-0.27, -0.11)	<.0001				
Week 28		-0.87 (0.03)		-0.69 (0.03)	-0.18 (0.04)	(-0.27, -0.10)	<.0001				
Week 32		-0.89 (0.03)		-0.71 (0.03)	-0.18 (0.04)	(-0.27, -0.10)	<.0001				
Week 36		-0.92 (0.03)		-0.75 (0.03)	-0.18 (0.05)	(-0.27, -0.08)	0.0002				
Week 40		-0.93 (0.04)		-0.77 (0.04)	-0.16 (0.05)	(-0.25, -0.07)	0.0007				
Week 44		-0.96 (0.04)		-0.77 (0.04)	-0.19 (0.05)	(-0.28, -0.09)	0.0001				
Week 48		-0.97 (0.04)		-0.80 (0.04)	-0.17 (0.05)	(-0.26, -0.07)	0.0005				
Week 52		-1.00 (0.04)		-0.82 (0.04)	-0.18 (0.05)	(-0.28, -0.08)	0.0003				
OVERALL	359	-0.78 (0.03)	363	-0.62 (0.03)	-0.16 (0.03)	(-0.23, -0.09)	<.0001	-0.31 (0.07)	(-0.46, -0.17)	<.0001	0.8884

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - PGA - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) N	LSMean (SE)	Placebo (N=366) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.5912
< 10 points	108	-0.77 (0.05)	105	-0.65 (0.05)	-0.13 (0.07)	(-0.26, 0.00)	0.0563	-0.25 (0.14)	(-0.52, 0.02)	0.0719	
>= 10 points	251	-0.78 (0.03)	258	-0.61 (0.03)	-0.17 (0.04)	(-0.25, -0.09)	<.0001	-0.33 (0.09)	(-0.51, -0.16)	0.0002	
OCS dose at baseline											0.6360
<10 mg/day	170	-0.72 (0.04)	180	-0.58 (0.04)	-0.14 (0.05)	(-0.24, -0.04)	0.0042	-0.29 (0.11)	(-0.50, -0.08)	0.0075	
>=10 mg/day	189	-0.85 (0.04)	183	-0.67 (0.04)	-0.17 (0.05)	(-0.27, -0.08)	0.0004	-0.32 (0.10)	(-0.52, -0.11)	0.0024	
Result of type I IFN gene signature test											0.0911
LOW	62	-0.69 (0.06)	64	-0.65 (0.06)	-0.04 (0.08)	(-0.19, 0.12)	0.6579	-0.08 (0.18)	(-0.43, 0.27)	0.6642	
HIGH	297	-0.83 (0.03)	299	-0.64 (0.03)	-0.19 (0.04)	(-0.26, -0.11)	<.0001	-0.39 (0.08)	(-0.55, -0.23)	<.0001	
Age (years)											NE
<= 65	347	-0.79 (0.03)	359	-0.62 (0.03)	-0.16 (0.03)	(-0.23, -0.10)	<.0001	-0.32 (0.08)	(-0.47, -0.17)	<.0001	
> 65	12	NE	4	NE	NE	NE		NE	NE		
Sex											0.7208
male	27	-1.02 (0.10)	25	-0.82 (0.10)	-0.20 (0.12)	(-0.45, 0.04)	0.1038	-0.39 (0.28)	(-0.94, 0.16)	0.1688	
female	332	-0.76 (0.03)	338	-0.61 (0.03)	-0.16 (0.04)	(-0.23, -0.09)	<.0001	-0.31 (0.08)	(-0.46, -0.15)	<.0001	
Race											0.0301
White	235	-0.75 (0.03)	242	-0.66 (0.03)	-0.10 (0.04)	(-0.18, -0.02)	0.0193	-0.20 (0.09)	(-0.38, -0.02)	0.0320	
Black	45	-0.77 (0.08)	48	-0.57 (0.07)	-0.20 (0.10)	(-0.39, -0.01)	0.0425	-0.38 (0.21)	(-0.79, 0.03)	0.0719	
Other	71	-0.86 (0.08)	65	-0.52 (0.08)	-0.34 (0.09)	(-0.51, -0.17)	0.0001	-0.51 (0.17)	(-0.86, -0.17)	0.0032	
Ethnicity											0.4704
Hispanic/Latino	86	-0.78 (0.06)	88	-0.67 (0.06)	-0.11 (0.07)	(-0.25, 0.03)	0.1105	-0.21 (0.15)	(-0.51, 0.09)	0.1671	
Non-hispanic/Latino	265	-0.77 (0.03)	267	-0.59 (0.03)	-0.17 (0.04)	(-0.25, -0.10)	<.0001	-0.35 (0.09)	(-0.52, -0.18)	<.0001	
Geographic region											0.8380
EU	115	-0.84 (0.05)	121	-0.69 (0.05)	-0.15 (0.06)	(-0.26, -0.04)	0.0071	-0.29 (0.13)	(-0.55, -0.03)	0.0264	
non-EU	244	-0.76 (0.03)	242	-0.59 (0.03)	-0.16 (0.04)	(-0.25, -0.08)	0.0002	-0.32 (0.09)	(-0.50, -0.14)	0.0005	
Onset of disease											0.1434
Paediatric	26	-0.68 (0.14)	24	-0.33 (0.14)	-0.36 (0.14)	(-0.63, -0.08)	0.0135	-0.51 (0.29)	(-1.08, 0.05)	0.0751	
Adult	333	-0.79 (0.03)	339	-0.64 (0.03)	-0.15 (0.04)	(-0.22, -0.08)	<.0001	-0.29 (0.08)	(-0.44, -0.14)	0.0002	
ADA result											0.2736
Negative	334	-0.78 (0.03)	328	-0.63 (0.03)	-0.15 (0.04)	(-0.22, -0.08)	<.0001	-0.29 (0.08)	(-0.44, -0.13)	0.0002	
Positive (At any time)	25	-0.81 (0.14)	35	-0.52 (0.11)	-0.29 (0.13)	(-0.55, -0.03)	0.0280	-0.42 (0.26)	(-0.94, 0.10)	0.1149	
BMI (kg/m2) at enrolment											0.6284
< 30	232	-0.80 (0.03)	258	-0.62 (0.03)	-0.17 (0.04)	(-0.26, -0.09)	<.0001	-0.33 (0.09)	(-0.51, -0.15)	0.0003	
>= 30	127	-0.74 (0.04)	105	-0.60 (0.05)	-0.14 (0.06)	(-0.26, -0.02)	0.0265	-0.28 (0.13)	(-0.54, -0.02)	0.0361	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - CLASI Total Activity Score
Full analysis set

Visit	Anifrolumab 300mg (N=360) N	Anifrolumab 300mg (N=360) LSMean (SE)	Placebo (N=366) N	Placebo (N=366) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		-1.64 (0.20)		-0.93 (0.20)	-0.71 (0.24)	(-1.19, -0.23)	0.0035				
Week 8		-3.06 (0.22)		-1.74 (0.22)	-1.31 (0.27)	(-1.85, -0.78)	<.0001				
Week 12		-3.79 (0.23)		-2.32 (0.23)	-1.48 (0.30)	(-2.06, -0.89)	<.0001				
Week 16		-4.28 (0.24)		-2.71 (0.24)	-1.57 (0.31)	(-2.18, -0.97)	<.0001				
Week 20		-4.62 (0.24)		-2.90 (0.24)	-1.73 (0.31)	(-2.34, -1.11)	<.0001				
Week 24		-4.85 (0.25)		-3.00 (0.25)	-1.85 (0.33)	(-2.50, -1.20)	<.0001				
Week 28		-5.17 (0.25)		-3.30 (0.25)	-1.86 (0.33)	(-2.50, -1.22)	<.0001				
Week 32		-5.32 (0.25)		-3.50 (0.25)	-1.81 (0.33)	(-2.46, -1.17)	<.0001				
Week 36		-5.46 (0.25)		-3.84 (0.25)	-1.61 (0.32)	(-2.25, -0.98)	<.0001				
Week 40		-5.56 (0.26)		-3.83 (0.26)	-1.73 (0.34)	(-2.39, -1.07)	<.0001				
Week 44		-5.61 (0.26)		-4.01 (0.26)	-1.60 (0.34)	(-2.27, -0.94)	<.0001				
Week 48		-5.69 (0.26)		-4.20 (0.26)	-1.48 (0.34)	(-2.15, -0.82)	<.0001				
Week 52		-5.86 (0.25)		-4.24 (0.26)	-1.62 (0.33)	(-2.28, -0.96)	<.0001				
OVERALL	359	-4.69 (0.21)	363	-3.12 (0.21)	-1.57 (0.26)	(-2.09, -1.05)	<.0001	-0.39 (0.08)	(-0.54, -0.24)	<.0001	0.9730

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - CLASI Total Activity Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) N	LSMean (SE)	Placebo (N=366) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.1263
< 10 points	108	-3.93 (0.30)	105	-2.91 (0.30)	-1.02 (0.40)	(-1.82, -0.23)	0.0118	-0.33 (0.14)	(-0.60, -0.06)	0.0165	
>= 10 points	251	-4.92 (0.27)	258	-3.09 (0.27)	-1.83 (0.34)	(-2.49, -1.16)	<.0001	-0.42 (0.09)	(-0.60, -0.25)	<.0001	
OCS dose at baseline											0.3262
<10 mg/day	170	-3.95 (0.29)	180	-2.77 (0.28)	-1.17 (0.38)	(-1.92, -0.43)	0.0022	-0.31 (0.11)	(-0.52, -0.10)	0.0039	
>=10 mg/day	189	-5.10 (0.30)	183	-3.42 (0.31)	-1.68 (0.35)	(-2.38, -0.98)	<.0001	-0.40 (0.10)	(-0.61, -0.20)	0.0001	
Result of type I IFN gene signature test											0.0002
LOW	62	-3.00 (0.30)	64	-3.05 (0.29)	0.06 (0.41)	(-0.77, 0.89)	0.8877	0.02 (0.18)	(-0.32, 0.37)	0.8892	
HIGH	297	-5.21 (0.23)	299	-3.34 (0.23)	-1.88 (0.31)	(-2.48, -1.27)	<.0001	-0.48 (0.08)	(-0.64, -0.31)	<.0001	
Age (years)											NE
<= 65	347	-4.68 (0.22)	359	-3.09 (0.21)	-1.59 (0.27)	(-2.12, -1.06)	<.0001	-0.39 (0.08)	(-0.54, -0.24)	<.0001	
> 65	12	NE	4	NE	NE	NE		NE	NE		
Sex											NE
male	27	NE	25	NE	NE	NE		NE	NE		
female	332	-4.47 (0.20)	338	-2.99 (0.20)	-1.49 (0.25)	(-1.98, -0.99)	<.0001	-0.40 (0.08)	(-0.55, -0.25)	<.0001	
Race											NE
White	235	-4.31 (0.22)	242	-3.46 (0.22)	-0.85 (0.28)	(-1.39, -0.31)	0.0022	-0.25 (0.09)	(-0.43, -0.07)	0.0064	
Black	45	-5.37 (0.44)	48	-3.46 (0.42)	-1.90 (0.54)	(-2.98, -0.82)	0.0008	-0.64 (0.21)	(-1.06, -0.22)	0.0026	
Other	71	NE	65	NE	NE	NE		NE	NE		
Ethnicity											0.0593
Hispanic/Latino	86	-3.50 (0.34)	88	-2.65 (0.33)	-0.85 (0.39)	(-1.63, -0.07)	0.0327	-0.27 (0.15)	(-0.57, 0.03)	0.0730	
Non-hispanic/Latino	265	-5.05 (0.25)	267	-3.24 (0.25)	-1.82 (0.33)	(-2.46, -1.17)	<.0001	-0.44 (0.09)	(-0.61, -0.27)	<.0001	
Geographic region											0.3597
EU	115	-4.78 (0.41)	121	-3.58 (0.42)	-1.20 (0.50)	(-2.18, -0.21)	0.0175	-0.26 (0.13)	(-0.52, -0.01)	0.0447	
non-EU	244	-4.57 (0.25)	242	-2.84 (0.25)	-1.74 (0.31)	(-2.35, -1.12)	<.0001	-0.45 (0.09)	(-0.63, -0.27)	<.0001	
Onset of disease											NE
Paediatric	26	NE	24	NE	NE	NE		NE	NE		
Adult	333	-4.63 (0.22)	339	-3.14 (0.22)	-1.49 (0.27)	(-2.03, -0.96)	<.0001	-0.38 (0.08)	(-0.53, -0.22)	<.0001	
ADA result											NE
Negative	334	-4.67 (0.21)	328	-3.25 (0.22)	-1.43 (0.27)	(-1.96, -0.89)	<.0001	-0.36 (0.08)	(-0.52, -0.21)	<.0001	
Positive (At any time)	25	NE	35	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.0628
< 30	232	-5.03 (0.28)	258	-3.10 (0.27)	-1.94 (0.33)	(-2.59, -1.28)	<.0001	-0.44 (0.09)	(-0.62, -0.27)	<.0001	
>= 30	127	-4.05 (0.30)	105	-3.10 (0.32)	-0.94 (0.42)	(-1.77, -0.12)	0.0248	-0.28 (0.13)	(-0.54, -0.02)	0.0343	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - CLASI Total Damage Score
Full analysis set

Visit	Anifrolumab 300mg (N=360) N	Anifrolumab 300mg (N=360) LSMean (SE)	Placebo (N=366) N	Placebo (N=366) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		-0.13 (0.08)		-0.02 (0.08)	-0.11 (0.09)	(-0.29, 0.07)	0.2143				
Week 8		-0.19 (0.09)		-0.13 (0.09)	-0.06 (0.12)	(-0.29, 0.17)	0.6115				
Week 12		-0.33 (0.10)		-0.12 (0.10)	-0.21 (0.13)	(-0.45, 0.04)	0.1054				
Week 16		-0.45 (0.10)		-0.10 (0.10)	-0.35 (0.13)	(-0.61, -0.09)	0.0077				
Week 20		-0.45 (0.11)		-0.19 (0.11)	-0.27 (0.15)	(-0.55, 0.02)	0.0657				
Week 24		-0.58 (0.12)		-0.24 (0.12)	-0.35 (0.15)	(-0.65, -0.04)	0.0245				
Week 28		-0.58 (0.13)		-0.27 (0.13)	-0.31 (0.17)	(-0.65, 0.02)	0.0657				
Week 32		-0.57 (0.13)		-0.21 (0.13)	-0.36 (0.18)	(-0.71, -0.01)	0.0431				
Week 36		-0.59 (0.14)		-0.28 (0.14)	-0.32 (0.18)	(-0.68, 0.05)	0.0876				
Week 40		-0.62 (0.14)		-0.28 (0.14)	-0.34 (0.19)	(-0.71, 0.03)	0.0731				
Week 44		-0.67 (0.14)		-0.33 (0.14)	-0.34 (0.20)	(-0.73, 0.04)	0.0803				
Week 48		-0.63 (0.15)		-0.35 (0.15)	-0.29 (0.20)	(-0.68, 0.10)	0.1468				
Week 52		-0.66 (0.14)		-0.35 (0.14)	-0.31 (0.19)	(-0.70, 0.07)	0.1074				
OVERALL	359	-0.50 (0.11)	363	-0.22 (0.11)	-0.28 (0.14)	(-0.55, -0.00)	0.0466	-0.14 (0.07)	(-0.28, 0.01)	0.0653	0.4036

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - CLASI Total Damage Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) N	LSMean (SE)	Placebo (N=366) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											NE
< 10 points	108	NE	105	NE	NE	NE		NE	NE		
>= 10 points	251	-0.59 (0.13)	258	-0.29 (0.13)	-0.30 (0.17)	(-0.63, 0.04)	0.0795	-0.15 (0.09)	(-0.32, 0.03)	0.1019	
OCS dose at baseline											0.3079
<10 mg/day	170	-0.62 (0.15)	180	-0.21 (0.14)	-0.41 (0.20)	(-0.80, -0.03)	0.0368	-0.21 (0.11)	(-0.42, -0.00)	0.0455	
>=10 mg/day	189	-0.33 (0.16)	183	-0.20 (0.16)	-0.13 (0.20)	(-0.52, 0.26)	0.5116	-0.06 (0.10)	(-0.26, 0.14)	0.5630	
Result of type I IFN gene signature test											0.4849
LOW	62	-0.28 (0.12)	64	-0.15 (0.12)	-0.13 (0.17)	(-0.48, 0.21)	0.4369	-0.14 (0.18)	(-0.49, 0.21)	0.4427	
HIGH	297	-0.54 (0.12)	299	-0.24 (0.12)	-0.30 (0.16)	(-0.62, 0.02)	0.0688	-0.15 (0.08)	(-0.31, 0.01)	0.0754	
Age (years)											NE
<= 65	347	-0.49 (0.11)	359	-0.20 (0.11)	-0.29 (0.14)	(-0.57, -0.01)	0.0433	-0.14 (0.08)	(-0.29, 0.01)	0.0625	
> 65	12	NE	4	NE	NE	NE		NE	NE		
Sex											NE
male	27	NE	25	NE	NE	NE		NE	NE		
female	332	-0.43 (0.11)	338	-0.24 (0.11)	-0.18 (0.14)	(-0.45, 0.09)	0.1832	-0.09 (0.08)	(-0.25, 0.06)	0.2202	
Race											NE
White	235	-0.53 (0.11)	242	-0.29 (0.11)	-0.24 (0.15)	(-0.53, 0.04)	0.0956	-0.14 (0.09)	(-0.32, 0.04)	0.1206	
Black	45	NE	48	NE	NE	NE		NE	NE		
Other	71	NE	65	NE	NE	NE		NE	NE		
Ethnicity											NE
Hispanic/Latino	86	NE	88	NE	NE	NE		NE	NE		
Non-hispanic/Latino	265	-0.63 (0.13)	267	-0.32 (0.13)	-0.31 (0.17)	(-0.64, 0.02)	0.0672	-0.15 (0.09)	(-0.32, 0.02)	0.0847	
Geographic region											0.0983
EU	115	-0.78 (0.19)	121	-0.17 (0.20)	-0.61 (0.22)	(-1.04, -0.18)	0.0057	-0.29 (0.13)	(-0.55, -0.03)	0.0272	
non-EU	244	-0.39 (0.13)	242	-0.24 (0.13)	-0.15 (0.17)	(-0.49, 0.19)	0.3800	-0.08 (0.09)	(-0.25, 0.10)	0.3990	
Onset of disease											NE
Paediatric	26	NE	24	NE	NE	NE		NE	NE		
Adult	333	-0.47 (0.11)	339	-0.19 (0.11)	-0.28 (0.14)	(-0.56, 0.01)	0.0549	-0.14 (0.08)	(-0.29, 0.01)	0.0747	
ADA result											NE
Negative	334	NE	328	NE	NE	NE		NE	NE		
Positive (At any time)	25	NE	35	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.3990
< 30	232	-0.57 (0.13)	258	-0.19 (0.13)	-0.38 (0.16)	(-0.69, -0.07)	0.0175	-0.19 (0.09)	(-0.37, -0.01)	0.0369	
>= 30	127	-0.34 (0.20)	105	-0.24 (0.22)	-0.10 (0.29)	(-0.68, 0.48)	0.7409	-0.04 (0.13)	(-0.30, 0.22)	0.7451	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - BILAG Global Score
Full analysis set

Visit	Anifrolumab 300mg (N=360) N	Anifrolumab 300mg (N=360) LSMean (SE)	Placebo (N=366) N	Placebo (N=366) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		-4.64 (0.35)		-3.97 (0.35)	-0.67 (0.44)	(-1.53, 0.19)	0.1251				
Week 8		-7.84 (0.39)		-5.84 (0.39)	-1.99 (0.50)	(-2.97, -1.01)	<.0001				
Week 12		-9.12 (0.40)		-7.29 (0.40)	-1.83 (0.52)	(-2.85, -0.82)	0.0004				
Week 16		-9.82 (0.41)		-8.09 (0.41)	-1.73 (0.52)	(-2.76, -0.70)	0.0010				
Week 20		-10.28 (0.41)		-8.64 (0.41)	-1.63 (0.53)	(-2.67, -0.60)	0.0021				
Week 24		-10.72 (0.41)		-8.67 (0.41)	-2.05 (0.53)	(-3.09, -1.01)	0.0001				
Week 28		-11.09 (0.41)		-9.08 (0.41)	-2.01 (0.52)	(-3.04, -0.98)	0.0001				
Week 32		-11.29 (0.41)		-9.24 (0.41)	-2.04 (0.53)	(-3.08, -1.01)	0.0001				
Week 36		-11.10 (0.42)		-9.80 (0.42)	-1.30 (0.55)	(-2.38, -0.22)	0.0181				
Week 40		-11.18 (0.43)		-9.73 (0.43)	-1.46 (0.56)	(-2.55, -0.36)	0.0090				
Week 44		-11.50 (0.42)		-9.85 (0.42)	-1.65 (0.55)	(-2.73, -0.57)	0.0028				
Week 48		-11.92 (0.42)		-10.27 (0.43)	-1.65 (0.55)	(-2.73, -0.57)	0.0027				
Week 52		-12.29 (0.42)		-10.45 (0.42)	-1.84 (0.54)	(-2.90, -0.77)	0.0008				
OVERALL	359	-10.21 (0.34)	363	-8.53 (0.34)	-1.68 (0.41)	(-2.48, -0.88)	<.0001	-0.26 (0.07)	(-0.41, -0.12)	0.0004	0.9700

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - BILAG Global Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) N	LSMean (SE)	Placebo (N=366) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.9026
< 10 points	108	-10.12 (0.53)	105	-8.51 (0.53)	-1.62 (0.69)	(-2.97, -0.26)	0.0194	-0.29 (0.14)	(-0.56, -0.02)	0.0326	
>= 10 points	251	-10.17 (0.42)	258	-8.45 (0.41)	-1.72 (0.50)	(-2.71, -0.73)	0.0007	-0.26 (0.09)	(-0.43, -0.08)	0.0036	
OCS dose at baseline											0.7185
<10 mg/day	170	-10.39 (0.46)	180	-8.89 (0.45)	-1.50 (0.59)	(-2.65, -0.35)	0.0110	-0.25 (0.11)	(-0.46, -0.04)	0.0208	
>=10 mg/day	189	-9.85 (0.51)	183	-8.06 (0.51)	-1.79 (0.57)	(-2.91, -0.68)	0.0017	-0.26 (0.10)	(-0.46, -0.05)	0.0133	
Result of type I IFN gene signature test											0.0251
LOW	62	-9.41 (0.73)	64	-9.75 (0.71)	0.34 (0.98)	(-1.61, 2.29)	0.7309	0.06 (0.18)	(-0.29, 0.41)	0.7403	
HIGH	297	-10.32 (0.33)	299	-8.24 (0.33)	-2.08 (0.45)	(-2.96, -1.20)	<.0001	-0.36 (0.08)	(-0.53, -0.20)	<.0001	
Age (years)											NE
<= 65	347	-10.24 (0.35)	359	-8.57 (0.34)	-1.67 (0.41)	(-2.48, -0.86)	<.0001	-0.26 (0.08)	(-0.41, -0.11)	0.0006	
> 65	12	NE	4	NE	NE	NE		NE	NE		
Sex											0.2014
male	27	-11.22 (1.09)	25	-7.96 (1.15)	-3.26 (1.26)	(-5.80, -0.72)	0.0131	-0.56 (0.28)	(-1.12, -0.01)	0.0475	
female	332	-10.12 (0.35)	338	-8.57 (0.35)	-1.56 (0.43)	(-2.40, -0.71)	0.0003	-0.24 (0.08)	(-0.39, -0.09)	0.0018	
Race											0.1105
White	235	-10.14 (0.41)	242	-9.03 (0.41)	-1.11 (0.51)	(-2.12, -0.10)	0.0307	-0.17 (0.09)	(-0.35, 0.01)	0.0574	
Black	45	-10.21 (0.88)	48	-6.97 (0.82)	-3.23 (1.01)	(-5.25, -1.22)	0.0020	-0.56 (0.21)	(-0.97, -0.14)	0.0086	
Other	71	-10.63 (1.01)	65	-8.09 (1.03)	-2.54 (0.94)	(-4.40, -0.69)	0.0076	-0.30 (0.17)	(-0.64, 0.04)	0.0817	
Ethnicity											0.5857
Hispanic/Latino	86	-10.90 (0.74)	88	-9.64 (0.72)	-1.27 (0.85)	(-2.94, 0.41)	0.1371	-0.18 (0.15)	(-0.48, 0.11)	0.2250	
Non-hispanic/Latino	265	-9.85 (0.38)	267	-8.05 (0.38)	-1.79 (0.46)	(-2.70, -0.88)	0.0001	-0.29 (0.09)	(-0.46, -0.12)	0.0009	
Geographic region											0.3800
EU	115	-10.94 (0.64)	121	-9.77 (0.66)	-1.17 (0.69)	(-2.54, 0.19)	0.0916	-0.17 (0.13)	(-0.42, 0.09)	0.2028	
non-EU	244	-9.95 (0.40)	242	-8.03 (0.40)	-1.92 (0.50)	(-2.91, -0.94)	0.0001	-0.31 (0.09)	(-0.49, -0.13)	0.0007	
Onset of disease											0.8994
Paediatric	26	-9.01 (1.89)	24	-7.15 (1.84)	-1.86 (1.74)	(-5.37, 1.65)	0.2907	-0.20 (0.28)	(-0.75, 0.36)	0.4897	
Adult	333	-10.25 (0.35)	339	-8.61 (0.34)	-1.64 (0.42)	(-2.47, -0.80)	0.0001	-0.26 (0.08)	(-0.41, -0.11)	0.0009	
ADA result											0.1151
Negative	334	-10.12 (0.34)	328	-8.59 (0.35)	-1.53 (0.43)	(-2.36, -0.69)	0.0004	-0.24 (0.08)	(-0.39, -0.09)	0.0019	
Positive (At any time)	25	-12.33 (1.63)	35	-8.29 (1.33)	-4.04 (1.54)	(-7.13, -0.96)	0.0112	-0.50 (0.27)	(-1.02, 0.02)	0.0602	
BMI (kg/m2) at enrolment											0.9551
< 30	232	-10.89 (0.43)	258	-9.11 (0.43)	-1.79 (0.49)	(-2.75, -0.82)	0.0003	-0.26 (0.09)	(-0.44, -0.09)	0.0036	
>= 30	127	-9.42 (0.54)	105	-7.59 (0.57)	-1.83 (0.74)	(-3.28, -0.39)	0.0133	-0.31 (0.13)	(-0.57, -0.05)	0.0211	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Tender Joint Count
Full analysis set

	Anifrolumab 300mg (N=360)		Placebo (N=366)		Difference of						
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		-1.50 (0.31)		-1.83 (0.31)	0.33 (0.39)	(-0.44, 1.10)	0.3981				
Week 8		-3.58 (0.32)		-3.13 (0.31)	-0.44 (0.40)	(-1.22, 0.33)	0.2639				
Week 12		-4.45 (0.33)		-4.01 (0.33)	-0.44 (0.41)	(-1.25, 0.37)	0.2857				
Week 16		-5.00 (0.33)		-4.69 (0.33)	-0.31 (0.42)	(-1.14, 0.52)	0.4618				
Week 20		-5.26 (0.34)		-4.86 (0.34)	-0.40 (0.43)	(-1.24, 0.45)	0.3588				
Week 24		-5.48 (0.35)		-4.97 (0.35)	-0.52 (0.45)	(-1.41, 0.38)	0.2566				
Week 28		-5.81 (0.33)		-5.38 (0.33)	-0.43 (0.42)	(-1.26, 0.40)	0.3081				
Week 32		-5.78 (0.34)		-5.11 (0.34)	-0.68 (0.44)	(-1.54, 0.19)	0.1237				
Week 36		-6.06 (0.34)		-5.41 (0.34)	-0.64 (0.44)	(-1.51, 0.22)	0.1460				
Week 40		-5.84 (0.34)		-5.70 (0.34)	-0.13 (0.44)	(-1.00, 0.73)	0.7592				
Week 44		-6.28 (0.34)		-5.70 (0.34)	-0.57 (0.43)	(-1.42, 0.28)	0.1862				
Week 48		-6.24 (0.34)		-5.60 (0.35)	-0.64 (0.44)	(-1.51, 0.24)	0.1529				
Week 52		-5.92 (0.36)		-5.77 (0.36)	-0.14 (0.46)	(-1.05, 0.77)	0.7619				
OVERALL	359	-5.17 (0.28)	363	-4.78 (0.28)	-0.39 (0.33)	(-1.04, 0.27)	0.2498	-0.07 (0.07)	(-0.22, 0.07)	0.3259	0.1454

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Tender Joint Count - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) N	LSMean (SE)	Placebo (N=366) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.8229
< 10 points	108	-5.59 (0.52)	105	-5.10 (0.52)	-0.50 (0.67)	(-1.83, 0.83)	0.4615	-0.09 (0.14)	(-0.36, 0.18)	0.5030	
>= 10 points	251	-4.92 (0.32)	258	-4.60 (0.31)	-0.32 (0.38)	(-1.07, 0.42)	0.3946	-0.06 (0.09)	(-0.24, 0.11)	0.4668	
OCS dose at baseline											0.5032
<10 mg/day	170	-5.12 (0.40)	180	-4.53 (0.39)	-0.58 (0.51)	(-1.58, 0.42)	0.2511	-0.11 (0.11)	(-0.32, 0.10)	0.3004	
>=10 mg/day	189	-5.35 (0.39)	183	-5.21 (0.39)	-0.14 (0.43)	(-0.99, 0.72)	0.7538	-0.03 (0.10)	(-0.23, 0.18)	0.8054	
Result of type I IFN gene signature test											0.1464
LOW	62	-5.60 (0.71)	64	-3.93 (0.70)	-1.67 (0.96)	(-3.58, 0.24)	0.0864	-0.30 (0.18)	(-0.65, 0.05)	0.0975	
HIGH	297	-5.66 (0.26)	299	-5.48 (0.26)	-0.18 (0.35)	(-0.86, 0.50)	0.6047	-0.04 (0.08)	(-0.20, 0.12)	0.6220	
Age (years)											NE
<= 65	347	-5.10 (0.28)	359	-4.72 (0.28)	-0.38 (0.34)	(-1.04, 0.29)	0.2648	-0.07 (0.08)	(-0.22, 0.08)	0.3451	
> 65	12	NE	4	NE	NE	NE		NE	NE		
Sex											0.4028
male	27	-6.15 (0.91)	25	-4.86 (0.95)	-1.29 (1.14)	(-3.62, 1.04)	0.2659	-0.27 (0.28)	(-0.82, 0.28)	0.3343	
female	332	-5.14 (0.29)	338	-4.84 (0.29)	-0.29 (0.35)	(-0.98, 0.39)	0.4002	-0.06 (0.08)	(-0.21, 0.10)	0.4720	
Race											0.3247
White	235	-5.82 (0.34)	242	-5.83 (0.34)	0.02 (0.42)	(-0.81, 0.84)	0.9682	0.00 (0.09)	(-0.18, 0.18)	0.9721	
Black	45	-4.44 (0.95)	48	-2.79 (0.89)	-1.65 (1.08)	(-3.79, 0.49)	0.1286	-0.26 (0.21)	(-0.67, 0.15)	0.2106	
Other	71	-3.00 (0.66)	65	-2.50 (0.68)	-0.50 (0.61)	(-1.71, 0.71)	0.4175	-0.09 (0.17)	(-0.43, 0.25)	0.6009	
Ethnicity											0.9415
Hispanic/Latino	86	-5.54 (0.63)	88	-5.28 (0.61)	-0.26 (0.72)	(-1.68, 1.16)	0.7195	-0.04 (0.15)	(-0.34, 0.25)	0.7698	
Non-hispanic/Latino	265	-5.09 (0.31)	267	-4.77 (0.32)	-0.32 (0.38)	(-1.07, 0.43)	0.4061	-0.06 (0.09)	(-0.23, 0.11)	0.4744	
Geographic region											0.5220
EU	115	-6.10 (0.43)	121	-6.09 (0.44)	-0.00 (0.46)	(-0.91, 0.91)	0.9996	-0.00 (0.13)	(-0.26, 0.26)	0.9997	
non-EU	244	-4.88 (0.34)	242	-4.48 (0.35)	-0.40 (0.43)	(-1.24, 0.43)	0.3448	-0.08 (0.09)	(-0.25, 0.10)	0.4085	
Onset of disease											0.5203
Paediatric	26	-2.68 (0.91)	24	-2.86 (0.90)	0.18 (0.99)	(-1.82, 2.17)	0.8576	0.04 (0.28)	(-0.52, 0.59)	0.8914	
Adult	333	-5.40 (0.29)	339	-4.91 (0.29)	-0.49 (0.35)	(-1.18, 0.19)	0.1593	-0.09 (0.08)	(-0.24, 0.06)	0.2264	
ADA result											0.3461
Negative	334	-5.15 (0.28)	328	-4.91 (0.29)	-0.24 (0.35)	(-0.93, 0.45)	0.4910	-0.05 (0.08)	(-0.20, 0.11)	0.5536	
Positive (At any time)	25	-5.28 (1.40)	35	-3.76 (1.12)	-1.52 (1.31)	(-4.15, 1.12)	0.2526	-0.22 (0.26)	(-0.74, 0.29)	0.4011	
BMI (kg/m2) at enrolment											0.6792
< 30	232	-5.20 (0.33)	258	-4.68 (0.32)	-0.52 (0.38)	(-1.26, 0.22)	0.1695	-0.10 (0.09)	(-0.28, 0.08)	0.2648	
>= 30	127	-5.43 (0.50)	105	-5.23 (0.53)	-0.20 (0.67)	(-1.51, 1.11)	0.7608	-0.04 (0.13)	(-0.30, 0.22)	0.7814	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Swollen Joint Count
Full analysis set

Visit	Anifrolumab 300mg (N=360) N	Anifrolumab 300mg (N=360) LSMean (SE)	Placebo (N=366) N	Placebo (N=366) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		-2.01 (0.22)		-1.96 (0.22)	-0.05 (0.28)	(-0.61, 0.50)	0.8488				
Week 8		-3.06 (0.22)		-3.07 (0.22)	0.01 (0.28)	(-0.54, 0.56)	0.9648				
Week 12		-3.82 (0.23)		-3.50 (0.23)	-0.32 (0.30)	(-0.90, 0.27)	0.2855				
Week 16		-4.03 (0.24)		-3.76 (0.24)	-0.28 (0.30)	(-0.87, 0.32)	0.3597				
Week 20		-4.25 (0.24)		-4.13 (0.23)	-0.12 (0.30)	(-0.71, 0.47)	0.6908				
Week 24		-4.25 (0.24)		-4.28 (0.24)	0.03 (0.31)	(-0.57, 0.63)	0.9237				
Week 28		-4.54 (0.23)		-4.27 (0.23)	-0.27 (0.29)	(-0.85, 0.30)	0.3466				
Week 32		-4.54 (0.24)		-4.27 (0.24)	-0.28 (0.31)	(-0.88, 0.33)	0.3707				
Week 36		-4.60 (0.24)		-4.42 (0.24)	-0.18 (0.31)	(-0.79, 0.43)	0.5622				
Week 40		-4.44 (0.25)		-4.58 (0.25)	0.14 (0.32)	(-0.48, 0.76)	0.6567				
Week 44		-4.64 (0.24)		-4.43 (0.24)	-0.21 (0.31)	(-0.82, 0.41)	0.5084				
Week 48		-4.75 (0.25)		-4.45 (0.25)	-0.30 (0.32)	(-0.93, 0.33)	0.3514				
Week 52		-4.76 (0.23)		-4.66 (0.24)	-0.11 (0.30)	(-0.70, 0.48)	0.7218				
OVERALL	359	-4.13 (0.19)	363	-3.98 (0.19)	-0.15 (0.24)	(-0.61, 0.31)	0.5283	-0.04 (0.07)	(-0.19, 0.11)	0.5905	0.0062

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Swollen Joint Count - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) N	LSMean (SE)	Placebo (N=366) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.6033
< 10 points	108	-4.27 (0.37)	105	-3.89 (0.37)	-0.37 (0.48)	(-1.32, 0.57)	0.4370	-0.10 (0.14)	(-0.37, 0.17)	0.4766	
>= 10 points	251	-4.04 (0.22)	258	-3.95 (0.22)	-0.09 (0.27)	(-0.61, 0.43)	0.7391	-0.03 (0.09)	(-0.20, 0.15)	0.7764	
OCS dose at baseline											0.9964
<10 mg/day	170	-4.24 (0.28)	180	-4.10 (0.28)	-0.13 (0.35)	(-0.83, 0.57)	0.7110	-0.04 (0.11)	(-0.25, 0.17)	0.7387	
>=10 mg/day	189	-4.04 (0.27)	183	-3.91 (0.27)	-0.13 (0.31)	(-0.74, 0.47)	0.6636	-0.04 (0.10)	(-0.24, 0.17)	0.7305	
Result of type I IFN gene signature test											0.1791
LOW	62	-4.98 (0.42)	64	-4.11 (0.42)	-0.86 (0.58)	(-2.00, 0.28)	0.1367	-0.26 (0.18)	(-0.61, 0.09)	0.1502	
HIGH	297	-4.05 (0.19)	299	-4.03 (0.19)	-0.02 (0.25)	(-0.52, 0.48)	0.9452	-0.01 (0.08)	(-0.17, 0.16)	0.9477	
Age (years)											NE
<= 65	347	-4.12 (0.20)	359	-3.98 (0.20)	-0.14 (0.24)	(-0.61, 0.33)	0.5611	-0.04 (0.08)	(-0.18, 0.11)	0.6220	
> 65	12	NE	4	NE	NE	NE		NE	NE		
Sex											0.5197
male	27	-4.70 (0.68)	25	-4.07 (0.73)	-0.63 (0.77)	(-2.36, 1.10)	0.4324	-0.17 (0.28)	(-0.72, 0.37)	0.5354	
female	332	-4.10 (0.20)	338	-3.99 (0.20)	-0.11 (0.25)	(-0.59, 0.37)	0.6538	-0.03 (0.08)	(-0.18, 0.12)	0.7014	
Race											0.1195
White	235	-4.31 (0.23)	242	-4.42 (0.23)	0.11 (0.29)	(-0.45, 0.67)	0.6979	0.03 (0.09)	(-0.15, 0.21)	0.7354	
Black	45	-4.94 (0.63)	48	-3.49 (0.59)	-1.45 (0.71)	(-2.86, -0.04)	0.0433	-0.35 (0.21)	(-0.76, 0.06)	0.0984	
Other	71	-2.91 (0.52)	65	-2.92 (0.53)	0.02 (0.49)	(-0.96, 0.99)	0.9709	0.00 (0.17)	(-0.33, 0.34)	0.9808	
Ethnicity											0.1057
Hispanic/Latino	86	-4.09 (0.45)	88	-4.71 (0.43)	0.61 (0.51)	(-0.39, 1.61)	0.2295	0.15 (0.15)	(-0.15, 0.45)	0.3262	
Non-hispanic/Latino	265	-4.19 (0.22)	267	-3.87 (0.22)	-0.31 (0.26)	(-0.83, 0.21)	0.2360	-0.09 (0.09)	(-0.26, 0.08)	0.3098	
Geographic region											0.8469
EU	115	-4.35 (0.25)	121	-4.13 (0.25)	-0.23 (0.28)	(-0.79, 0.34)	0.4277	-0.08 (0.13)	(-0.34, 0.17)	0.5256	
non-EU	244	-4.13 (0.25)	242	-3.98 (0.25)	-0.15 (0.31)	(-0.75, 0.46)	0.6338	-0.04 (0.09)	(-0.22, 0.14)	0.6799	
Onset of disease											NE
Paediatric	26	NE	24	NE	NE	NE		NE	NE		
Adult	333	-4.23 (0.20)	339	-4.01 (0.20)	-0.22 (0.25)	(-0.70, 0.26)	0.3732	-0.06 (0.08)	(-0.21, 0.09)	0.4439	
ADA result											NE
Negative	334	-4.14 (0.20)	328	-4.09 (0.20)	-0.06 (0.25)	(-0.54, 0.42)	0.8097	-0.02 (0.08)	(-0.17, 0.14)	0.8354	
Positive (At any time)	25	NE	35	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.3350
< 30	232	-3.98 (0.23)	258	-3.93 (0.23)	-0.05 (0.27)	(-0.57, 0.48)	0.8646	-0.01 (0.09)	(-0.19, 0.16)	0.8912	
>= 30	127	-4.62 (0.35)	105	-4.06 (0.37)	-0.56 (0.46)	(-1.47, 0.35)	0.2280	-0.15 (0.13)	(-0.40, 0.11)	0.2696	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Mental Component Score
Full analysis set

	Anifrolumab 300mg (N=360)		Placebo (N=366)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 8		1.37 (0.51)		0.57 (0.51)	0.80 (0.63)	(-0.45, 2.05)	0.2074				
Week 16		1.14 (0.53)		0.99 (0.53)	0.14 (0.67)	(-1.18, 1.47)	0.8299				
Week 24		1.72 (0.56)		-0.07 (0.55)	1.79 (0.71)	(0.40, 3.17)	0.0119				
Week 32		2.12 (0.56)		0.40 (0.57)	1.72 (0.72)	(0.30, 3.13)	0.0178				
Week 40		2.03 (0.58)		1.12 (0.58)	0.91 (0.74)	(-0.54, 2.37)	0.2169				
Week 48		1.99 (0.57)		0.82 (0.58)	1.17 (0.74)	(-0.28, 2.63)	0.1142				
Week 52		2.05 (0.60)		0.72 (0.61)	1.33 (0.78)	(-0.21, 2.86)	0.0908				
OVERALL	338	1.77 (0.45)	341	0.65 (0.46)	1.12 (0.54)	(0.05, 2.19)	0.0396	0.13 (0.08)	(-0.02, 0.28)	0.0818	0.7683

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Mental Component Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) N	LSMean (SE)	Placebo (N=366) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.0061
< 10 points	102	3.65 (0.74)	100	0.32 (0.75)	3.34 (0.95)	(1.46, 5.21)	0.0006	0.45 (0.14)	(0.17, 0.73)	0.0017	
>= 10 points	236	0.62 (0.56)	241	0.45 (0.55)	0.17 (0.66)	(-1.13, 1.46)	0.8019	0.02 (0.09)	(-0.16, 0.20)	0.8332	
OCS dose at baseline											0.6881
<10 mg/day	163	2.22 (0.59)	170	0.90 (0.59)	1.33 (0.75)	(-0.15, 2.81)	0.0788	0.17 (0.11)	(-0.04, 0.39)	0.1148	
>=10 mg/day	175	1.28 (0.72)	171	0.39 (0.72)	0.89 (0.79)	(-0.66, 2.44)	0.2608	0.09 (0.11)	(-0.12, 0.30)	0.3850	
Result of type I IFN gene signature test											0.7718
LOW	59	2.51 (0.97)	60	1.05 (0.96)	1.46 (1.33)	(-1.17, 4.09)	0.2729	0.20 (0.18)	(-0.16, 0.56)	0.2864	
HIGH	279	1.82 (0.45)	281	0.78 (0.45)	1.04 (0.60)	(-0.14, 2.22)	0.0851	0.14 (0.08)	(-0.03, 0.30)	0.1022	
Age (years)											NE
<= 65	326	1.65 (0.47)	339	0.64 (0.46)	1.01 (0.55)	(-0.08, 2.09)	0.0684	0.12 (0.08)	(-0.03, 0.27)	0.1265	
> 65	12	NE	2	NE	NE	NE		NE	NE		
Sex											0.9964
male	26	5.72 (1.97)	24	4.63 (2.14)	1.09 (2.09)	(-3.12, 5.30)	0.6044	0.10 (0.28)	(-0.45, 0.66)	0.7122	
female	312	1.48 (0.47)	317	0.39 (0.46)	1.10 (0.56)	(-0.00, 2.20)	0.0505	0.13 (0.08)	(-0.02, 0.29)	0.0959	
Race											0.2985
White	219	1.71 (0.56)	225	0.91 (0.56)	0.81 (0.69)	(-0.54, 2.15)	0.2403	0.10 (0.09)	(-0.09, 0.28)	0.3088	
Black	42	2.54 (1.46)	44	-0.66 (1.41)	3.19 (1.70)	(-0.19, 6.58)	0.0639	0.34 (0.22)	(-0.09, 0.76)	0.1204	
Other	69	-0.46 (1.25)	65	-0.49 (1.28)	0.03 (1.14)	(-2.23, 2.29)	0.9778	0.00 (0.17)	(-0.34, 0.34)	0.9859	
Ethnicity											0.2038
Hispanic/Latino	83	1.97 (1.01)	86	2.18 (0.97)	-0.21 (1.16)	(-2.50, 2.09)	0.8593	-0.02 (0.15)	(-0.32, 0.28)	0.8833	
Non-hispanic/Latino	247	1.57 (0.53)	248	0.09 (0.53)	1.47 (0.63)	(0.24, 2.71)	0.0197	0.18 (0.09)	(0.00, 0.35)	0.0490	
Geographic region											0.9075
EU	108	1.95 (0.82)	112	0.87 (0.84)	1.08 (0.87)	(-0.65, 2.80)	0.2199	0.12 (0.13)	(-0.14, 0.39)	0.3626	
non-EU	230	1.52 (0.56)	229	0.31 (0.57)	1.20 (0.69)	(-0.16, 2.57)	0.0832	0.14 (0.09)	(-0.04, 0.32)	0.1320	
Onset of disease											0.4034
Paediatric	23	0.73 (2.08)	22	1.39 (2.00)	-0.67 (2.20)	(-5.13, 3.80)	0.7640	-0.07 (0.30)	(-0.65, 0.52)	0.8212	
Adult	315	1.84 (0.47)	319	0.60 (0.47)	1.23 (0.57)	(0.12, 2.34)	0.0299	0.15 (0.08)	(-0.01, 0.30)	0.0654	
ADA result											0.5030
Negative	315	1.62 (0.47)	307	0.62 (0.48)	1.00 (0.57)	(-0.13, 2.12)	0.0818	0.12 (0.08)	(-0.04, 0.28)	0.1387	
Positive (At any time)	23	3.19 (1.95)	34	0.84 (1.54)	2.35 (1.94)	(-1.56, 6.26)	0.2316	0.25 (0.27)	(-0.28, 0.79)	0.3482	
BMI (kg/m2) at enrolment											0.4666
< 30	218	1.50 (0.58)	241	0.64 (0.57)	0.86 (0.64)	(-0.41, 2.12)	0.1840	0.10 (0.09)	(-0.08, 0.28)	0.2924	
>= 30	120	2.07 (0.77)	100	0.33 (0.81)	1.74 (1.02)	(-0.28, 3.75)	0.0906	0.21 (0.14)	(-0.06, 0.48)	0.1227	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Physical Component Score
Full analysis set

	Anifrolumab 300mg (N=360)		Placebo (N=366)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 8		2.66 (0.41)		2.14 (0.40)	0.52 (0.49)	(-0.44, 1.48)	0.2865				
Week 16		3.83 (0.45)		3.01 (0.44)	0.82 (0.56)	(-0.27, 1.91)	0.1391				
Week 24		4.11 (0.45)		3.19 (0.44)	0.92 (0.55)	(-0.16, 2.01)	0.0956				
Week 32		3.80 (0.45)		3.24 (0.45)	0.56 (0.56)	(-0.54, 1.66)	0.3154				
Week 40		4.00 (0.47)		3.33 (0.47)	0.67 (0.59)	(-0.49, 1.83)	0.2550				
Week 48		4.24 (0.49)		3.15 (0.49)	1.10 (0.63)	(-0.13, 2.32)	0.0803				
Week 52		3.79 (0.48)		3.15 (0.48)	0.64 (0.61)	(-0.55, 1.84)	0.2911				
OVERALL	338	3.78 (0.39)	341	3.03 (0.39)	0.75 (0.47)	(-0.16, 1.66)	0.1076	0.10 (0.08)	(-0.05, 0.25)	0.1752	0.4276

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Physical Component Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) N	LSMean (SE)	Placebo (N=366) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.0582
< 10 points	102	4.44 (0.64)	100	2.38 (0.65)	2.06 (0.82)	(0.44, 3.68)	0.0128	0.32 (0.14)	(0.04, 0.59)	0.0254	
>= 10 points	236	3.61 (0.48)	241	3.43 (0.47)	0.18 (0.56)	(-0.93, 1.28)	0.7561	0.02 (0.09)	(-0.16, 0.20)	0.7943	
OCS dose at baseline											0.6151
<10 mg/day	163	3.38 (0.48)	170	2.38 (0.48)	1.00 (0.61)	(-0.20, 2.21)	0.1033	0.16 (0.11)	(-0.05, 0.38)	0.1436	
>=10 mg/day	175	4.11 (0.65)	171	3.57 (0.65)	0.53 (0.70)	(-0.84, 1.91)	0.4453	0.06 (0.11)	(-0.15, 0.27)	0.5601	
Result of type I IFN gene signature test											0.0806
LOW	59	3.35 (0.77)	60	4.27 (0.76)	-0.92 (1.05)	(-3.00, 1.16)	0.3832	-0.15 (0.18)	(-0.51, 0.21)	0.4000	
HIGH	279	4.25 (0.38)	281	3.13 (0.38)	1.13 (0.52)	(0.11, 2.14)	0.0296	0.17 (0.08)	(0.01, 0.34)	0.0391	
Age (years)											NE
<= 65	326	3.80 (0.40)	339	3.00 (0.39)	0.80 (0.47)	(-0.12, 1.72)	0.0880	0.11 (0.08)	(-0.04, 0.26)	0.1541	
> 65	12	NE	2	NE	NE	NE		NE	NE		
Sex											0.9973
male	26	3.22 (1.86)	24	2.47 (2.00)	0.75 (1.88)	(-3.04, 4.54)	0.6923	0.08 (0.28)	(-0.48, 0.63)	0.7874	
female	312	3.76 (0.40)	317	3.02 (0.40)	0.74 (0.48)	(-0.21, 1.69)	0.1247	0.10 (0.08)	(-0.05, 0.26)	0.1922	
Race											0.2034
White	219	3.75 (0.47)	225	3.71 (0.47)	0.04 (0.58)	(-1.10, 1.18)	0.9505	0.01 (0.09)	(-0.18, 0.19)	0.9570	
Black	42	4.23 (1.24)	44	2.21 (1.17)	2.02 (1.40)	(-0.76, 4.80)	0.1520	0.25 (0.22)	(-0.17, 0.68)	0.2415	
Other	69	3.57 (1.11)	65	1.89 (1.13)	1.69 (0.99)	(-0.27, 3.64)	0.0901	0.18 (0.17)	(-0.16, 0.52)	0.2927	
Ethnicity											0.3457
Hispanic/Latino	83	4.90 (0.84)	86	3.46 (0.81)	1.44 (0.94)	(-0.42, 3.30)	0.1278	0.19 (0.15)	(-0.11, 0.49)	0.2187	
Non-hispanic/Latino	247	3.27 (0.45)	248	2.85 (0.45)	0.42 (0.54)	(-0.65, 1.48)	0.4426	0.06 (0.09)	(-0.12, 0.23)	0.5159	
Geographic region											0.0124
EU	108	3.73 (0.74)	112	4.64 (0.76)	-0.90 (0.80)	(-2.49, 0.68)	0.2627	-0.11 (0.13)	(-0.38, 0.15)	0.3989	
non-EU	230	3.93 (0.46)	229	2.39 (0.46)	1.55 (0.56)	(0.45, 2.65)	0.0061	0.22 (0.09)	(0.04, 0.41)	0.0179	
Onset of disease											0.5817
Paediatric	23	2.03 (2.33)	22	0.11 (2.24)	1.91 (2.19)	(-2.51, 6.34)	0.3873	0.17 (0.30)	(-0.41, 0.76)	0.5619	
Adult	315	3.80 (0.40)	319	3.12 (0.40)	0.68 (0.48)	(-0.26, 1.62)	0.1549	0.10 (0.08)	(-0.06, 0.25)	0.2270	
ADA result											0.0137
Negative	315	3.63 (0.41)	307	3.17 (0.41)	0.46 (0.49)	(-0.51, 1.43)	0.3483	0.06 (0.08)	(-0.09, 0.22)	0.4251	
Positive (At any time)	23	6.94 (1.51)	34	2.94 (1.17)	4.00 (1.35)	(1.30, 6.69)	0.0044	0.56 (0.28)	(0.02, 1.10)	0.0407	
BMI (kg/m2) at enrolment											0.0480
< 30	218	3.62 (0.50)	241	3.40 (0.49)	0.22 (0.55)	(-0.86, 1.29)	0.6943	0.03 (0.09)	(-0.15, 0.21)	0.7572	
>= 30	120	4.63 (0.64)	100	2.41 (0.68)	2.22 (0.85)	(0.54, 3.90)	0.0099	0.32 (0.14)	(0.05, 0.59)	0.0184	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute General Health Score
Full analysis set

	Anifrolumab 300mg (N=360)		Placebo (N=366)		Difference of						
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 8		1.67 (0.36)		1.78 (0.35)	-0.11 (0.43)	(-0.96, 0.73)	0.7936				
Week 16		2.15 (0.40)		1.96 (0.40)	0.19 (0.50)	(-0.78, 1.16)	0.7004				
Week 24		2.13 (0.41)		1.56 (0.41)	0.57 (0.51)	(-0.44, 1.57)	0.2705				
Week 32		2.17 (0.42)		1.75 (0.42)	0.42 (0.54)	(-0.64, 1.47)	0.4356				
Week 40		2.27 (0.43)		1.86 (0.43)	0.40 (0.55)	(-0.69, 1.49)	0.4687				
Week 48		2.41 (0.43)		2.40 (0.44)	0.01 (0.56)	(-1.08, 1.11)	0.9829				
Week 52		2.23 (0.45)		1.87 (0.45)	0.36 (0.58)	(-0.78, 1.50)	0.5325				
OVERALL	338	2.15 (0.36)	341	1.89 (0.36)	0.26 (0.43)	(-0.58, 1.11)	0.5409	0.04 (0.08)	(-0.11, 0.19)	0.6018	0.0264

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute General Health Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) N	LSMean (SE)	Placebo (N=366) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.1423
< 10 points	102	2.95 (0.58)	100	1.74 (0.59)	1.21 (0.75)	(-0.26, 2.68)	0.1051	0.21 (0.14)	(-0.07, 0.48)	0.1432	
>= 10 points	236	1.86 (0.44)	241	1.99 (0.43)	-0.12 (0.52)	(-1.16, 0.91)	0.8134	-0.02 (0.09)	(-0.20, 0.16)	0.8404	
OCS dose at baseline											0.3803
<10 mg/day	163	1.99 (0.48)	170	1.36 (0.48)	0.63 (0.62)	(-0.59, 1.85)	0.3108	0.10 (0.11)	(-0.11, 0.32)	0.3569	
>=10 mg/day	175	2.21 (0.55)	171	2.34 (0.54)	-0.13 (0.60)	(-1.30, 1.05)	0.8327	-0.02 (0.11)	(-0.23, 0.19)	0.8698	
Result of type I IFN gene signature test											0.2269
LOW	59	2.26 (0.79)	60	3.18 (0.78)	-0.91 (1.07)	(-3.04, 1.22)	0.3972	-0.15 (0.18)	(-0.51, 0.21)	0.4123	
HIGH	279	2.31 (0.35)	281	1.81 (0.35)	0.50 (0.47)	(-0.41, 1.42)	0.2822	0.09 (0.08)	(-0.08, 0.25)	0.3058	
Age (years)											NE
<= 65	326	2.16 (0.37)	339	1.96 (0.36)	0.20 (0.43)	(-0.65, 1.05)	0.6486	0.03 (0.08)	(-0.12, 0.18)	0.6996	
> 65	12	NE	2	NE	NE	NE		NE	NE		
Sex											0.2338
male	26	1.56 (1.33)	24	3.03 (1.43)	-1.46 (1.44)	(-4.37, 1.44)	0.3156	-0.21 (0.28)	(-0.77, 0.35)	0.4609	
female	312	2.13 (0.37)	317	1.80 (0.37)	0.33 (0.45)	(-0.55, 1.21)	0.4561	0.05 (0.08)	(-0.11, 0.21)	0.5224	
Race											0.3448
White	219	1.94 (0.44)	225	2.25 (0.43)	-0.31 (0.54)	(-1.38, 0.75)	0.5625	-0.05 (0.09)	(-0.23, 0.14)	0.6099	
Black	42	2.98 (1.06)	44	1.61 (1.01)	1.38 (1.22)	(-1.05, 3.81)	0.2627	0.20 (0.22)	(-0.22, 0.63)	0.3521	
Other	69	2.67 (1.01)	65	1.94 (1.03)	0.73 (0.93)	(-1.11, 2.56)	0.4346	0.09 (0.17)	(-0.25, 0.43)	0.6162	
Ethnicity											0.1230
Hispanic/Latino	83	3.96 (0.75)	86	2.61 (0.73)	1.35 (0.85)	(-0.33, 3.03)	0.1152	0.20 (0.15)	(-0.10, 0.50)	0.1987	
Non-hispanic/Latino	247	1.46 (0.41)	248	1.63 (0.41)	-0.17 (0.50)	(-1.15, 0.81)	0.7284	-0.03 (0.09)	(-0.20, 0.15)	0.7659	
Geographic region											0.1406
EU	108	1.94 (0.69)	112	2.60 (0.70)	-0.66 (0.76)	(-2.15, 0.83)	0.3841	-0.09 (0.13)	(-0.35, 0.17)	0.5039	
non-EU	230	2.31 (0.42)	229	1.62 (0.42)	0.69 (0.52)	(-0.33, 1.72)	0.1836	0.11 (0.09)	(-0.07, 0.29)	0.2462	
Onset of disease											0.1003
Paediatric	23	2.82 (1.56)	22	0.11 (1.49)	2.71 (1.51)	(-0.34, 5.76)	0.0805	0.37 (0.30)	(-0.22, 0.96)	0.2226	
Adult	315	2.09 (0.37)	319	1.97 (0.37)	0.12 (0.45)	(-0.75, 1.00)	0.7818	0.02 (0.08)	(-0.14, 0.17)	0.8119	
ADA result											0.0154
Negative	315	1.94 (0.37)	307	2.03 (0.37)	-0.09 (0.45)	(-0.97, 0.79)	0.8423	-0.01 (0.08)	(-0.17, 0.14)	0.8641	
Positive (At any time)	23	4.15 (1.50)	34	0.63 (1.19)	3.53 (1.42)	(0.67, 6.39)	0.0166	0.49 (0.27)	(-0.04, 1.03)	0.0711	
BMI (kg/m2) at enrolment											0.7016
< 30	218	2.17 (0.46)	241	1.99 (0.45)	0.18 (0.52)	(-0.84, 1.21)	0.7263	0.03 (0.09)	(-0.16, 0.21)	0.7779	
>= 30	120	2.48 (0.56)	100	1.94 (0.60)	0.53 (0.75)	(-0.95, 2.02)	0.4792	0.09 (0.14)	(-0.18, 0.35)	0.5161	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Mental Health Score
Full analysis set

	Anifrolumab 300mg (N=360)		Placebo (N=366)		Difference of							
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 8		1.71 (0.47)		1.08 (0.46)	0.63 (0.58)	(-0.50, 1.77)	0.2748				
Week 16		1.61 (0.50)		1.36 (0.50)	0.24 (0.64)	(-1.01, 1.49)	0.7020				
Week 24		1.96 (0.52)		0.58 (0.52)	1.38 (0.66)	(0.09, 2.68)	0.0368				
Week 32		2.46 (0.54)		0.84 (0.54)	1.62 (0.69)	(0.26, 2.98)	0.0197				
Week 40		2.32 (0.54)		1.72 (0.54)	0.60 (0.69)	(-0.76, 1.95)	0.3861				
Week 48		2.24 (0.54)		1.27 (0.55)	0.97 (0.70)	(-0.41, 2.35)	0.1689				
Week 52		2.43 (0.56)		1.22 (0.56)	1.21 (0.72)	(-0.21, 2.63)	0.0956				
OVERALL	338	2.10 (0.42)	341	1.15 (0.42)	0.95 (0.50)	(-0.04, 1.94)	0.0599	0.12 (0.08)	(-0.03, 0.27)	0.1109	0.6051

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Mental Health Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) N	LSMean (SE)	Placebo (N=366) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.0113
< 10 points	102	3.72 (0.67)	100	0.89 (0.68)	2.83 (0.87)	(1.13, 4.54)	0.0013	0.42 (0.14)	(0.14, 0.69)	0.0035	
>= 10 points	236	1.04 (0.52)	241	0.90 (0.52)	0.14 (0.62)	(-1.08, 1.35)	0.8234	0.02 (0.09)	(-0.16, 0.20)	0.8506	
OCS dose at baseline											0.3913
<10 mg/day	163	2.38 (0.55)	170	1.01 (0.54)	1.37 (0.69)	(0.00, 2.73)	0.0496	0.19 (0.11)	(-0.02, 0.41)	0.0779	
>=10 mg/day	175	1.71 (0.67)	171	1.21 (0.67)	0.50 (0.74)	(-0.95, 1.95)	0.4981	0.06 (0.11)	(-0.15, 0.27)	0.5980	
Result of type I IFN gene signature test											0.5241
LOW	59	2.60 (0.85)	60	0.97 (0.84)	1.63 (1.16)	(-0.68, 3.93)	0.1643	0.25 (0.18)	(-0.11, 0.61)	0.1775	
HIGH	279	2.19 (0.42)	281	1.38 (0.42)	0.81 (0.56)	(-0.30, 1.91)	0.1518	0.12 (0.08)	(-0.05, 0.28)	0.1735	
Age (years)											NE
<= 65	326	2.03 (0.43)	339	1.16 (0.43)	0.87 (0.51)	(-0.13, 1.87)	0.0895	0.11 (0.08)	(-0.04, 0.26)	0.1535	
> 65	12	NE	2	NE	NE	NE		NE	NE		
Sex											0.7100
male	26	4.66 (2.00)	24	4.44 (2.17)	0.21 (2.06)	(-3.93, 4.36)	0.9178	0.02 (0.28)	(-0.53, 0.57)	0.9432	
female	312	1.89 (0.43)	317	0.89 (0.43)	1.00 (0.52)	(-0.01, 2.01)	0.0523	0.13 (0.08)	(-0.02, 0.29)	0.0978	
Race											0.2759
White	219	1.88 (0.52)	225	1.40 (0.53)	0.47 (0.65)	(-0.80, 1.74)	0.4648	0.06 (0.09)	(-0.13, 0.25)	0.5248	
Black	42	2.55 (1.26)	44	-0.41 (1.22)	2.96 (1.46)	(0.06, 5.87)	0.0458	0.36 (0.22)	(-0.06, 0.79)	0.0965	
Other	69	1.07 (1.17)	65	0.64 (1.19)	0.43 (1.06)	(-1.66, 2.52)	0.6862	0.04 (0.17)	(-0.29, 0.38)	0.7987	
Ethnicity											0.2300
Hispanic/Latino	83	2.20 (0.96)	86	2.49 (0.93)	-0.29 (1.12)	(-2.51, 1.93)	0.7939	-0.03 (0.15)	(-0.34, 0.27)	0.8271	
Non-hispanic/Latino	247	1.91 (0.48)	248	0.69 (0.48)	1.22 (0.57)	(0.09, 2.34)	0.0337	0.16 (0.09)	(-0.01, 0.34)	0.0727	
Geographic region											0.4279
EU	108	2.45 (0.77)	112	2.00 (0.79)	0.45 (0.82)	(-1.15, 2.06)	0.5779	0.06 (0.13)	(-0.21, 0.32)	0.6807	
non-EU	230	1.84 (0.52)	229	0.57 (0.52)	1.28 (0.64)	(0.02, 2.53)	0.0466	0.16 (0.09)	(-0.02, 0.35)	0.0833	
Onset of disease											0.2401
Paediatric	23	-0.67 (2.16)	22	0.90 (2.09)	-1.57 (2.26)	(-6.16, 3.02)	0.4920	-0.15 (0.30)	(-0.74, 0.43)	0.6087	
Adult	315	2.29 (0.43)	319	1.14 (0.43)	1.15 (0.52)	(0.13, 2.17)	0.0266	0.15 (0.08)	(-0.01, 0.31)	0.0595	
ADA result											0.8017
Negative	315	2.01 (0.43)	307	1.21 (0.44)	0.80 (0.53)	(-0.23, 1.83)	0.1281	0.10 (0.08)	(-0.05, 0.26)	0.1946	
Positive (At any time)	23	1.79 (2.11)	34	0.46 (1.65)	1.32 (2.01)	(-2.72, 5.36)	0.5132	0.13 (0.27)	(-0.40, 0.66)	0.6233	
BMI (kg/m2) at enrolment											0.1751
< 30	218	1.88 (0.55)	241	1.39 (0.54)	0.49 (0.61)	(-0.71, 1.69)	0.4217	0.06 (0.09)	(-0.12, 0.24)	0.5245	
>= 30	120	2.40 (0.68)	100	0.43 (0.72)	1.97 (0.91)	(0.18, 3.76)	0.0309	0.27 (0.14)	(0.00, 0.54)	0.0480	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Physical Functioning Score
Full analysis set

	Anifrolumab 300mg (N=360)		Placebo (N=366)		Difference of						
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 8		2.41 (0.43)		1.71 (0.43)	0.69 (0.52)	(-0.33, 1.71)	0.1835				
Week 16		3.05 (0.46)		2.46 (0.46)	0.59 (0.58)	(-0.54, 1.72)	0.3074				
Week 24		3.42 (0.47)		2.83 (0.47)	0.59 (0.59)	(-0.56, 1.74)	0.3172				
Week 32		3.58 (0.48)		2.68 (0.48)	0.90 (0.60)	(-0.29, 2.08)	0.1376				
Week 40		3.53 (0.49)		2.98 (0.49)	0.55 (0.62)	(-0.66, 1.76)	0.3713				
Week 48		3.50 (0.51)		2.60 (0.52)	0.91 (0.66)	(-0.39, 2.21)	0.1702				
Week 52		3.55 (0.51)		3.06 (0.52)	0.49 (0.66)	(-0.80, 1.77)	0.4581				
OVERALL	338	3.29 (0.42)	341	2.62 (0.42)	0.67 (0.50)	(-0.31, 1.65)	0.1779	0.09 (0.08)	(-0.06, 0.24)	0.2538	0.6608

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Physical Functioning Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) N	LSMean (SE)	Placebo (N=366) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.0097
< 10 points	102	4.29 (0.67)	100	1.70 (0.69)	2.58 (0.87)	(0.87, 4.30)	0.0034	0.38 (0.14)	(0.10, 0.65)	0.0081	
>= 10 points	236	2.98 (0.51)	241	3.14 (0.50)	-0.16 (0.61)	(-1.35, 1.03)	0.7957	-0.02 (0.09)	(-0.20, 0.16)	0.8270	
OCS dose at baseline											0.7323
<10 mg/day	163	3.10 (0.51)	170	2.23 (0.51)	0.87 (0.64)	(-0.40, 2.14)	0.1766	0.13 (0.11)	(-0.08, 0.35)	0.2252	
>=10 mg/day	175	3.41 (0.69)	171	2.87 (0.69)	0.53 (0.76)	(-0.96, 2.02)	0.4828	0.06 (0.11)	(-0.15, 0.27)	0.5871	
Result of type I IFN gene signature test											0.2679
LOW	59	2.65 (0.87)	60	3.18 (0.87)	-0.53 (1.19)	(-2.89, 1.82)	0.6556	-0.08 (0.18)	(-0.44, 0.28)	0.6677	
HIGH	279	3.86 (0.41)	281	2.94 (0.41)	0.92 (0.55)	(-0.16, 2.00)	0.0950	0.13 (0.08)	(-0.03, 0.30)	0.1126	
Age (years)											NE
<= 65	326	3.27 (0.43)	339	2.53 (0.42)	0.74 (0.50)	(-0.25, 1.73)	0.1421	0.10 (0.08)	(-0.06, 0.25)	0.2173	
> 65	12	NE	2	NE	NE	NE		NE	NE		
Sex											0.8494
male	26	4.71 (1.86)	24	3.70 (2.01)	1.01 (1.89)	(-2.81, 4.83)	0.5968	0.10 (0.28)	(-0.45, 0.66)	0.7171	
female	312	3.21 (0.43)	317	2.57 (0.43)	0.64 (0.52)	(-0.38, 1.65)	0.2190	0.08 (0.08)	(-0.07, 0.24)	0.2944	
Race											0.5745
White	219	3.41 (0.50)	225	3.28 (0.50)	0.13 (0.62)	(-1.08, 1.35)	0.8323	0.02 (0.09)	(-0.17, 0.20)	0.8539	
Black	42	3.37 (1.39)	44	1.89 (1.35)	1.48 (1.62)	(-1.74, 4.70)	0.3634	0.16 (0.22)	(-0.26, 0.59)	0.4499	
Other	69	2.80 (1.14)	65	1.66 (1.16)	1.14 (1.03)	(-0.90, 3.19)	0.2716	0.12 (0.17)	(-0.22, 0.46)	0.4842	
Ethnicity											0.9812
Hispanic/Latino	83	4.15 (0.94)	86	3.47 (0.90)	0.69 (1.07)	(-1.43, 2.80)	0.5226	0.08 (0.15)	(-0.22, 0.38)	0.6012	
Non-hispanic/Latino	247	2.92 (0.47)	248	2.27 (0.47)	0.66 (0.57)	(-0.46, 1.77)	0.2468	0.09 (0.09)	(-0.09, 0.26)	0.3255	
Geographic region											0.0532
EU	108	3.95 (0.80)	112	4.62 (0.82)	-0.68 (0.86)	(-2.37, 1.02)	0.4331	-0.08 (0.13)	(-0.34, 0.19)	0.5564	
non-EU	230	3.08 (0.48)	229	1.73 (0.49)	1.35 (0.60)	(0.17, 2.52)	0.0244	0.18 (0.09)	(-0.00, 0.37)	0.0502	
Onset of disease											0.5783
Paediatric	23	1.23 (2.57)	22	1.86 (2.49)	-0.63 (2.44)	(-5.57, 4.31)	0.7978	-0.05 (0.30)	(-0.64, 0.53)	0.8629	
Adult	315	3.44 (0.42)	319	2.68 (0.42)	0.76 (0.51)	(-0.25, 1.76)	0.1387	0.10 (0.08)	(-0.06, 0.26)	0.2062	
ADA result											0.0877
Negative	315	3.21 (0.43)	307	2.78 (0.44)	0.43 (0.53)	(-0.60, 1.46)	0.4152	0.06 (0.08)	(-0.10, 0.21)	0.4867	
Positive (At any time)	23	5.67 (1.84)	34	2.17 (1.45)	3.49 (1.72)	(0.05, 6.94)	0.0468	0.40 (0.27)	(-0.13, 0.93)	0.1424	
BMI (kg/m2) at enrolment											0.0430
< 30	218	3.06 (0.52)	241	2.97 (0.51)	0.09 (0.57)	(-1.03, 1.22)	0.8732	0.01 (0.09)	(-0.17, 0.19)	0.8997	
>= 30	120	4.33 (0.71)	100	1.98 (0.76)	2.35 (0.96)	(0.46, 4.24)	0.0150	0.30 (0.14)	(0.04, 0.57)	0.0258	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Role Emotional Score
Full analysis set

	Anifrolumab 300mg (N=360)		Placebo (N=366)		Difference of						
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 8		1.52 (0.57)		0.69 (0.56)	0.84 (0.71)	(-0.55, 2.23)	0.2366				
Week 16		1.58 (0.59)		1.62 (0.59)	-0.04 (0.75)	(-1.52, 1.43)	0.9560				
Week 24		2.06 (0.60)		0.34 (0.59)	1.71 (0.76)	(0.23, 3.20)	0.0239				
Week 32		2.39 (0.61)		0.85 (0.61)	1.54 (0.78)	(0.01, 3.07)	0.0483				
Week 40		2.55 (0.62)		1.59 (0.62)	0.96 (0.80)	(-0.61, 2.52)	0.2315				
Week 48		2.26 (0.62)		1.48 (0.63)	0.79 (0.80)	(-0.79, 2.36)	0.3281				
Week 52		2.38 (0.63)		1.47 (0.64)	0.91 (0.82)	(-0.70, 2.52)	0.2682				
OVERALL	338	2.11 (0.48)	341	1.15 (0.49)	0.96 (0.58)	(-0.18, 2.09)	0.0981	0.11 (0.08)	(-0.04, 0.26)	0.1642	0.5700

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Role Emotional Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) N	LSMean (SE)	Placebo (N=366) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.0013
< 10 points	102	4.11 (0.80)	100	0.36 (0.81)	3.75 (1.03)	(1.72, 5.78)	0.0003	0.46 (0.14)	(0.18, 0.74)	0.0012	
>= 10 points	236	0.93 (0.59)	241	1.17 (0.58)	-0.24 (0.69)	(-1.60, 1.12)	0.7280	-0.03 (0.09)	(-0.21, 0.15)	0.7718	
OCS dose at baseline											0.4423
<10 mg/day	163	3.04 (0.64)	170	1.64 (0.64)	1.40 (0.81)	(-0.20, 3.00)	0.0862	0.17 (0.11)	(-0.05, 0.38)	0.1250	
>=10 mg/day	175	1.03 (0.76)	171	0.51 (0.76)	0.51 (0.82)	(-1.11, 2.13)	0.5351	0.05 (0.11)	(-0.16, 0.26)	0.6366	
Result of type I IFN gene signature test											0.8906
LOW	59	2.40 (1.08)	60	1.62 (1.07)	0.78 (1.49)	(-2.17, 3.73)	0.6001	0.09 (0.18)	(-0.27, 0.45)	0.6108	
HIGH	279	2.31 (0.47)	281	1.31 (0.47)	1.00 (0.63)	(-0.23, 2.24)	0.1109	0.13 (0.08)	(-0.04, 0.29)	0.1311	
Age (years)											NE
<= 65	326	2.00 (0.50)	339	1.11 (0.49)	0.89 (0.59)	(-0.26, 2.04)	0.1292	0.10 (0.08)	(-0.05, 0.25)	0.2059	
> 65	12	NE	2	NE	NE	NE		NE	NE		
Sex											0.9225
male	26	6.09 (1.91)	24	4.97 (2.10)	1.11 (1.94)	(-2.81, 5.03)	0.5706	0.11 (0.28)	(-0.45, 0.66)	0.6994	
female	312	1.88 (0.50)	317	0.97 (0.50)	0.91 (0.60)	(-0.27, 2.10)	0.1300	0.10 (0.08)	(-0.05, 0.26)	0.1998	
Race											0.3277
White	219	2.15 (0.57)	225	1.46 (0.58)	0.68 (0.70)	(-0.70, 2.07)	0.3317	0.08 (0.09)	(-0.11, 0.27)	0.4019	
Black	42	3.08 (1.79)	44	-0.32 (1.77)	3.40 (2.09)	(-0.75, 7.55)	0.1073	0.29 (0.22)	(-0.14, 0.71)	0.1846	
Other	69	-0.27 (1.35)	65	-0.09 (1.38)	-0.18 (1.18)	(-2.51, 2.15)	0.8787	-0.02 (0.17)	(-0.35, 0.32)	0.9261	
Ethnicity											0.5459
Hispanic/Latino	83	2.86 (1.06)	86	2.59 (1.02)	0.27 (1.21)	(-2.11, 2.66)	0.8215	0.03 (0.15)	(-0.27, 0.33)	0.8535	
Non-hispanic/Latino	247	1.54 (0.56)	248	0.43 (0.56)	1.10 (0.66)	(-0.20, 2.41)	0.0972	0.13 (0.09)	(-0.05, 0.30)	0.1645	
Geographic region											0.8506
EU	108	1.97 (0.79)	112	1.07 (0.81)	0.89 (0.84)	(-0.77, 2.55)	0.2892	0.11 (0.13)	(-0.16, 0.37)	0.4295	
non-EU	230	1.84 (0.61)	229	0.73 (0.62)	1.11 (0.75)	(-0.37, 2.59)	0.1423	0.12 (0.09)	(-0.06, 0.30)	0.2057	
Onset of disease											0.8218
Paediatric	23	2.87 (2.15)	22	2.42 (2.08)	0.46 (2.20)	(-4.01, 4.92)	0.8374	0.04 (0.30)	(-0.54, 0.63)	0.8814	
Adult	315	2.07 (0.50)	319	1.10 (0.50)	0.97 (0.60)	(-0.22, 2.15)	0.1086	0.11 (0.08)	(-0.05, 0.26)	0.1754	
ADA result											0.3645
Negative	315	1.90 (0.50)	307	1.10 (0.51)	0.80 (0.61)	(-0.39, 1.99)	0.1884	0.09 (0.08)	(-0.07, 0.25)	0.2655	
Positive (At any time)	23	4.23 (2.24)	34	1.41 (1.78)	2.82 (2.14)	(-1.50, 7.13)	0.1948	0.26 (0.27)	(-0.27, 0.80)	0.3306	
BMI (kg/m2) at enrolment											0.1982
< 30	218	1.76 (0.60)	241	1.27 (0.59)	0.50 (0.67)	(-0.82, 1.81)	0.4580	0.05 (0.09)	(-0.13, 0.24)	0.5578	
>= 30	120	2.57 (0.84)	100	0.40 (0.89)	2.18 (1.12)	(-0.04, 4.39)	0.0537	0.24 (0.14)	(-0.03, 0.50)	0.0796	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Role Physical Score
Full analysis set

	Anifrolumab 300mg (N=360)		Placebo (N=366)		Difference of						
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 8		2.52 (0.42)		2.14 (0.42)	0.39 (0.51)	(-0.62, 1.39)	0.4529				
Week 16		3.68 (0.46)		2.92 (0.46)	0.75 (0.58)	(-0.38, 1.89)	0.1933				
Week 24		4.08 (0.46)		2.80 (0.46)	1.28 (0.57)	(0.16, 2.40)	0.0257				
Week 32		3.96 (0.47)		2.79 (0.47)	1.17 (0.59)	(0.01, 2.34)	0.0475				
Week 40		3.86 (0.49)		3.36 (0.49)	0.51 (0.63)	(-0.73, 1.74)	0.4206				
Week 48		4.14 (0.50)		2.75 (0.50)	1.39 (0.64)	(0.14, 2.64)	0.0289				
Week 52		4.00 (0.50)		2.80 (0.50)	1.21 (0.64)	(-0.04, 2.45)	0.0581				
OVERALL	338	3.75 (0.40)	341	2.79 (0.40)	0.96 (0.48)	(0.02, 1.89)	0.0444	0.13 (0.08)	(-0.02, 0.28)	0.0907	0.8261

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Role Physical Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) N	LSMean (SE)	Placebo (N=366) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.0274
< 10 points	102	4.95 (0.68)	100	2.38 (0.69)	2.57 (0.87)	(0.85, 4.29)	0.0036	0.37 (0.14)	(0.09, 0.65)	0.0090	
>= 10 points	236	2.97 (0.48)	241	2.69 (0.47)	0.28 (0.57)	(-0.83, 1.39)	0.6217	0.04 (0.09)	(-0.14, 0.22)	0.6785	
OCS dose at baseline											0.7058
<10 mg/day	163	3.28 (0.53)	170	2.49 (0.53)	0.79 (0.67)	(-0.52, 2.11)	0.2361	0.12 (0.11)	(-0.10, 0.33)	0.2883	
>=10 mg/day	175	4.05 (0.63)	171	2.90 (0.63)	1.15 (0.68)	(-0.18, 2.48)	0.0890	0.14 (0.11)	(-0.07, 0.35)	0.1959	
Result of type I IFN gene signature test											0.2187
LOW	59	3.82 (0.78)	60	4.08 (0.78)	-0.26 (1.06)	(-2.36, 1.85)	0.8100	-0.04 (0.18)	(-0.40, 0.32)	0.8176	
HIGH	279	4.05 (0.39)	281	2.84 (0.39)	1.20 (0.53)	(0.16, 2.24)	0.0233	0.18 (0.08)	(0.02, 0.35)	0.0312	
Age (years)											NE
<= 65	326	3.73 (0.41)	339	2.79 (0.40)	0.94 (0.48)	(-0.00, 1.88)	0.0505	0.13 (0.08)	(-0.03, 0.28)	0.1026	
> 65	12	NE	2	NE	NE	NE		NE	NE		
Sex											0.8933
male	26	5.63 (1.72)	24	4.46 (1.90)	1.18 (1.74)	(-2.35, 4.70)	0.5032	0.13 (0.28)	(-0.43, 0.68)	0.6507	
female	312	3.63 (0.41)	317	2.70 (0.41)	0.93 (0.49)	(-0.04, 1.90)	0.0590	0.13 (0.08)	(-0.03, 0.28)	0.1091	
Race											0.3314
White	219	3.62 (0.47)	225	3.23 (0.47)	0.39 (0.58)	(-0.74, 1.52)	0.4958	0.06 (0.09)	(-0.13, 0.24)	0.5543	
Black	42	4.59 (1.34)	44	2.55 (1.30)	2.03 (1.51)	(-0.98, 5.05)	0.1824	0.23 (0.22)	(-0.19, 0.66)	0.2820	
Other	69	2.30 (1.22)	65	0.43 (1.24)	1.88 (1.05)	(-0.19, 3.95)	0.0751	0.19 (0.17)	(-0.15, 0.52)	0.2853	
Ethnicity											0.9342
Hispanic/Latino	83	4.34 (0.85)	86	3.42 (0.82)	0.92 (0.96)	(-0.98, 2.82)	0.3404	0.12 (0.15)	(-0.18, 0.42)	0.4373	
Non-hispanic/Latino	247	3.50 (0.47)	248	2.49 (0.47)	1.01 (0.56)	(-0.09, 2.11)	0.0707	0.14 (0.09)	(-0.04, 0.31)	0.1268	
Geographic region											0.0616
EU	108	3.31 (0.70)	112	3.53 (0.71)	-0.22 (0.76)	(-1.72, 1.27)	0.7700	-0.03 (0.13)	(-0.29, 0.23)	0.8242	
non-EU	230	3.86 (0.49)	229	2.28 (0.49)	1.58 (0.60)	(0.41, 2.76)	0.0083	0.21 (0.09)	(0.03, 0.40)	0.0232	
Onset of disease											0.9943
Paediatric	23	2.21 (1.91)	22	1.27 (1.85)	0.94 (1.88)	(-2.87, 4.74)	0.6224	0.10 (0.30)	(-0.48, 0.69)	0.7308	
Adult	315	3.80 (0.41)	319	2.85 (0.41)	0.95 (0.49)	(-0.02, 1.92)	0.0551	0.13 (0.08)	(-0.03, 0.28)	0.1045	
ADA result											0.1592
Negative	315	3.59 (0.41)	307	2.78 (0.42)	0.81 (0.50)	(-0.18, 1.79)	0.1081	0.11 (0.08)	(-0.05, 0.27)	0.1725	
Positive (At any time)	23	7.23 (1.73)	34	4.07 (1.36)	3.16 (1.59)	(-0.04, 6.36)	0.0528	0.39 (0.27)	(-0.15, 0.92)	0.1569	
BMI (kg/m2) at enrolment											0.1039
< 30	218	3.63 (0.50)	241	3.11 (0.49)	0.51 (0.55)	(-0.57, 1.60)	0.3509	0.07 (0.09)	(-0.11, 0.25)	0.4645	
>= 30	120	4.29 (0.67)	100	2.06 (0.71)	2.23 (0.90)	(0.46, 4.00)	0.0139	0.31 (0.14)	(0.04, 0.57)	0.0247	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Social Functioning Score
Full analysis set

	Anifrolumab 300mg (N=360)		Placebo (N=366)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 8		1.55 (0.54)		0.89 (0.53)	0.66 (0.66)	(-0.65, 1.97)	0.3212				
Week 16		2.12 (0.54)		1.42 (0.54)	0.71 (0.68)	(-0.62, 2.03)	0.2968				
Week 24		2.79 (0.56)		0.94 (0.55)	1.84 (0.70)	(0.47, 3.22)	0.0086				
Week 32		2.94 (0.57)		1.52 (0.57)	1.42 (0.72)	(-0.00, 2.84)	0.0504				
Week 40		2.96 (0.58)		1.48 (0.58)	1.48 (0.73)	(0.04, 2.91)	0.0442				
Week 48		3.08 (0.57)		1.09 (0.57)	1.99 (0.72)	(0.57, 3.41)	0.0061				
Week 52		2.67 (0.59)		1.41 (0.60)	1.27 (0.76)	(-0.23, 2.76)	0.0975				
OVERALL	338	2.59 (0.46)	341	1.25 (0.46)	1.34 (0.54)	(0.27, 2.41)	0.0143	0.16 (0.08)	(0.01, 0.31)	0.0401	0.9937

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Social Functioning Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) N	LSMean (SE)	Placebo (N=366) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.0078
< 10 points	102	4.06 (0.81)	100	0.45 (0.83)	3.61 (1.04)	(1.56, 5.66)	0.0006	0.44 (0.14)	(0.16, 0.72)	0.0022	
>= 10 points	236	2.04 (0.54)	241	1.67 (0.54)	0.37 (0.64)	(-0.88, 1.62)	0.5594	0.04 (0.09)	(-0.13, 0.22)	0.6264	
OCS dose at baseline											0.5158
<10 mg/day	163	2.24 (0.58)	170	1.25 (0.58)	0.99 (0.73)	(-0.45, 2.44)	0.1774	0.13 (0.11)	(-0.08, 0.35)	0.2281	
>=10 mg/day	175	2.92 (0.75)	171	1.22 (0.75)	1.70 (0.80)	(0.12, 3.28)	0.0351	0.17 (0.11)	(-0.04, 0.38)	0.1111	
Result of type I IFN gene signature test											0.7518
LOW	59	3.02 (0.92)	60	2.07 (0.91)	0.96 (1.25)	(-1.52, 3.43)	0.4452	0.13 (0.18)	(-0.23, 0.49)	0.4635	
HIGH	279	2.89 (0.45)	281	1.50 (0.45)	1.40 (0.61)	(0.21, 2.59)	0.0217	0.18 (0.08)	(0.02, 0.35)	0.0296	
Age (years)											NE
<= 65	326	2.46 (0.47)	339	1.19 (0.46)	1.27 (0.55)	(0.20, 2.34)	0.0206	0.15 (0.08)	(-0.00, 0.30)	0.0544	
> 65	12	NE	2	NE	NE	NE		NE	NE		
Sex											0.6096
male	26	6.01 (1.73)	24	3.79 (1.87)	2.21 (1.80)	(-1.42, 5.85)	0.2258	0.24 (0.28)	(-0.31, 0.80)	0.3931	
female	312	2.32 (0.47)	317	1.07 (0.47)	1.25 (0.56)	(0.14, 2.36)	0.0271	0.15 (0.08)	(-0.01, 0.31)	0.0621	
Race											0.4186
White	219	2.47 (0.54)	225	1.61 (0.55)	0.87 (0.67)	(-0.44, 2.18)	0.1940	0.11 (0.09)	(-0.08, 0.29)	0.2627	
Black	42	4.19 (1.48)	44	0.97 (1.39)	3.22 (1.67)	(-0.11, 6.55)	0.0578	0.34 (0.22)	(-0.09, 0.77)	0.1185	
Other	69	-0.51 (1.39)	65	-1.93 (1.41)	1.42 (1.22)	(-0.99, 3.82)	0.2456	0.12 (0.17)	(-0.22, 0.46)	0.4774	
Ethnicity											0.2761
Hispanic/Latino	83	3.24 (0.97)	86	2.91 (0.93)	0.33 (1.09)	(-1.82, 2.48)	0.7598	0.04 (0.15)	(-0.26, 0.34)	0.8048	
Non-hispanic/Latino	247	2.28 (0.54)	248	0.57 (0.54)	1.71 (0.64)	(0.45, 2.97)	0.0078	0.20 (0.09)	(0.02, 0.38)	0.0256	
Geographic region											0.7002
EU	108	2.87 (0.83)	112	1.83 (0.85)	1.04 (0.88)	(-0.70, 2.78)	0.2400	0.12 (0.13)	(-0.15, 0.38)	0.3854	
non-EU	230	2.45 (0.56)	229	0.98 (0.57)	1.47 (0.69)	(0.12, 2.82)	0.0331	0.17 (0.09)	(-0.01, 0.35)	0.0664	
Onset of disease											0.7190
Paediatric	23	4.42 (2.31)	22	3.87 (2.24)	0.55 (2.32)	(-4.16, 5.26)	0.8137	0.05 (0.30)	(-0.53, 0.63)	0.8667	
Adult	315	2.59 (0.47)	319	1.18 (0.47)	1.41 (0.56)	(0.30, 2.52)	0.0127	0.17 (0.08)	(0.01, 0.32)	0.0357	
ADA result											0.2145
Negative	315	2.38 (0.48)	307	1.21 (0.49)	1.17 (0.58)	(0.03, 2.31)	0.0441	0.14 (0.08)	(-0.02, 0.29)	0.0889	
Positive (At any time)	23	6.01 (1.75)	34	2.79 (1.37)	3.22 (1.55)	(0.12, 6.32)	0.0424	0.39 (0.27)	(-0.14, 0.92)	0.1531	
BMI (kg/m2) at enrolment											0.4928
< 30	218	2.32 (0.57)	241	1.19 (0.56)	1.13 (0.62)	(-0.09, 2.35)	0.0690	0.13 (0.09)	(-0.05, 0.32)	0.1562	
>= 30	120	3.42 (0.82)	100	1.43 (0.87)	1.99 (1.09)	(-0.17, 4.15)	0.0702	0.22 (0.14)	(-0.04, 0.49)	0.0994	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Bodily Pain Score
Full analysis set

	Anifrolumab 300mg (N=360)		Placebo (N=366)		Difference of						
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 8		2.83 (0.48)		1.58 (0.48)	1.25 (0.59)	(0.09, 2.41)	0.0350				
Week 16		3.97 (0.51)		3.01 (0.51)	0.96 (0.64)	(-0.30, 2.22)	0.1365				
Week 24		4.39 (0.52)		2.26 (0.52)	2.13 (0.66)	(0.84, 3.42)	0.0013				
Week 32		3.84 (0.54)		2.93 (0.54)	0.90 (0.69)	(-0.45, 2.25)	0.1887				
Week 40		4.60 (0.54)		3.10 (0.54)	1.50 (0.69)	(0.15, 2.85)	0.0291				
Week 48		4.78 (0.56)		2.93 (0.57)	1.84 (0.72)	(0.42, 3.26)	0.0113				
Week 52		3.80 (0.56)		2.77 (0.56)	1.03 (0.72)	(-0.39, 2.44)	0.1536				
OVERALL	338	4.03 (0.43)	341	2.66 (0.43)	1.37 (0.51)	(0.38, 2.37)	0.0070	0.17 (0.08)	(0.02, 0.32)	0.0237	0.5248

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Bodily Pain Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) N	LSMean (SE)	Placebo (N=366) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.0099
< 10 points	102	5.05 (0.72)	100	1.66 (0.73)	3.39 (0.92)	(1.57, 5.20)	0.0003	0.46 (0.14)	(0.18, 0.74)	0.0012	
>= 10 points	236	3.69 (0.51)	241	3.15 (0.51)	0.55 (0.61)	(-0.64, 1.74)	0.3676	0.07 (0.09)	(-0.11, 0.25)	0.4519	
OCS dose at baseline											0.1168
<10 mg/day	163	4.28 (0.53)	170	2.16 (0.53)	2.13 (0.67)	(0.80, 3.45)	0.0018	0.31 (0.11)	(0.09, 0.52)	0.0052	
>=10 mg/day	175	3.71 (0.70)	171	3.18 (0.70)	0.53 (0.76)	(-0.97, 2.03)	0.4867	0.06 (0.11)	(-0.15, 0.27)	0.5942	
Result of type I IFN gene signature test											0.1195
LOW	59	3.57 (0.77)	60	3.73 (0.76)	-0.16 (1.05)	(-2.24, 1.91)	0.8763	-0.03 (0.18)	(-0.39, 0.33)	0.8809	
HIGH	279	4.58 (0.43)	281	2.88 (0.43)	1.70 (0.57)	(0.57, 2.83)	0.0033	0.24 (0.08)	(0.07, 0.40)	0.0053	
Age (years)											NE
<= 65	326	4.07 (0.44)	339	2.62 (0.43)	1.44 (0.51)	(0.44, 2.45)	0.0050	0.18 (0.08)	(0.03, 0.33)	0.0195	
> 65	12	NE	2	NE	NE	NE		NE	NE		
Sex											0.9291
male	26	4.88 (2.09)	24	3.70 (2.27)	1.18 (2.04)	(-2.92, 5.28)	0.5651	0.11 (0.28)	(-0.45, 0.66)	0.7060	
female	312	3.97 (0.44)	317	2.61 (0.44)	1.37 (0.53)	(0.33, 2.40)	0.0096	0.18 (0.08)	(0.02, 0.33)	0.0284	
Race											0.0639
White	219	3.87 (0.49)	225	3.31 (0.49)	0.56 (0.60)	(-0.63, 1.74)	0.3568	0.08 (0.09)	(-0.11, 0.26)	0.4258	
Black	42	5.06 (1.46)	44	0.46 (1.38)	4.61 (1.63)	(1.37, 7.85)	0.0059	0.49 (0.22)	(0.06, 0.92)	0.0249	
Other	69	2.22 (1.29)	65	0.87 (1.32)	1.35 (1.13)	(-0.89, 3.59)	0.2366	0.13 (0.17)	(-0.21, 0.46)	0.4687	
Ethnicity											0.3438
Hispanic/Latino	83	5.59 (0.92)	86	3.50 (0.89)	2.10 (1.02)	(0.07, 4.12)	0.0422	0.25 (0.15)	(-0.05, 0.55)	0.1035	
Non-hispanic/Latino	247	3.38 (0.49)	248	2.40 (0.49)	0.98 (0.59)	(-0.17, 2.13)	0.0959	0.13 (0.09)	(-0.05, 0.30)	0.1601	
Geographic region											0.0329
EU	108	3.90 (0.83)	112	4.03 (0.86)	-0.14 (0.89)	(-1.90, 1.62)	0.8787	-0.02 (0.13)	(-0.28, 0.25)	0.9095	
non-EU	230	4.11 (0.50)	229	1.93 (0.51)	2.18 (0.62)	(0.97, 3.39)	0.0004	0.28 (0.09)	(0.10, 0.47)	0.0026	
Onset of disease											0.7719
Paediatric	23	3.60 (2.70)	22	1.55 (2.59)	2.06 (2.59)	(-3.18, 7.29)	0.4314	0.16 (0.30)	(-0.42, 0.75)	0.5897	
Adult	315	4.02 (0.43)	319	2.73 (0.43)	1.29 (0.52)	(0.27, 2.31)	0.0130	0.17 (0.08)	(0.01, 0.32)	0.0357	
ADA result											0.0526
Negative	315	3.83 (0.44)	307	2.76 (0.45)	1.07 (0.53)	(0.02, 2.12)	0.0455	0.14 (0.08)	(-0.02, 0.29)	0.0909	
Positive (At any time)	23	7.81 (1.91)	34	3.13 (1.50)	4.67 (1.78)	(1.10, 8.25)	0.0114	0.52 (0.27)	(-0.02, 1.05)	0.0599	
BMI (kg/m2) at enrolment											0.0092
< 30	218	3.68 (0.56)	241	3.11 (0.56)	0.57 (0.62)	(-0.65, 1.78)	0.3607	0.07 (0.09)	(-0.12, 0.25)	0.4755	
>= 30	120	5.02 (0.66)	100	1.65 (0.70)	3.37 (0.88)	(1.64, 5.10)	0.0002	0.47 (0.14)	(0.20, 0.74)	0.0006	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Vitality Score
Full analysis set

	Anifrolumab 300mg (N=360)		Placebo (N=366)		Difference of						
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 8		2.65 (0.47)		1.49 (0.47)	1.16 (0.58)	(0.03, 2.29)	0.0441				
Week 16		2.82 (0.50)		2.07 (0.49)	0.75 (0.62)	(-0.46, 1.97)	0.2257				
Week 24		3.65 (0.51)		2.07 (0.50)	1.59 (0.64)	(0.34, 2.84)	0.0129				
Week 32		3.38 (0.52)		2.11 (0.52)	1.27 (0.66)	(-0.02, 2.57)	0.0540				
Week 40		3.30 (0.54)		2.70 (0.54)	0.61 (0.70)	(-0.76, 1.98)	0.3829				
Week 48		3.87 (0.54)		2.35 (0.54)	1.52 (0.69)	(0.16, 2.88)	0.0290				
Week 52		3.43 (0.55)		2.05 (0.56)	1.39 (0.71)	(-0.01, 2.79)	0.0522				
OVERALL	338	3.30 (0.43)	341	2.12 (0.42)	1.18 (0.51)	(0.19, 2.18)	0.0198	0.15 (0.08)	(0.00, 0.30)	0.0496	0.5877

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SF-36 v2.0 Acute Vitality Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) N	LSMean (SE)	Placebo (N=366) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.0412
< 10 points	102	4.67 (0.73)	100	1.86 (0.74)	2.81 (0.93)	(0.97, 4.65)	0.0030	0.38 (0.14)	(0.10, 0.66)	0.0077	
>= 10 points	236	2.66 (0.51)	241	2.12 (0.50)	0.54 (0.60)	(-0.64, 1.72)	0.3695	0.07 (0.09)	(-0.11, 0.25)	0.4517	
OCS dose at baseline											0.9811
<10 mg/day	163	2.95 (0.57)	170	1.80 (0.57)	1.15 (0.72)	(-0.27, 2.57)	0.1116	0.16 (0.11)	(-0.06, 0.37)	0.1546	
>=10 mg/day	175	3.59 (0.67)	171	2.41 (0.66)	1.17 (0.72)	(-0.24, 2.58)	0.1023	0.13 (0.11)	(-0.08, 0.35)	0.2112	
Result of type I IFN gene signature test											0.3280
LOW	59	4.03 (0.90)	60	3.94 (0.90)	0.09 (1.23)	(-2.36, 2.53)	0.9452	0.01 (0.18)	(-0.35, 0.37)	0.9472	
HIGH	279	3.46 (0.41)	281	2.05 (0.41)	1.41 (0.56)	(0.32, 2.50)	0.0117	0.20 (0.08)	(0.04, 0.37)	0.0165	
Age (years)											NE
<= 65	326	3.27 (0.44)	339	2.12 (0.43)	1.15 (0.51)	(0.15, 2.16)	0.0239	0.15 (0.08)	(-0.01, 0.30)	0.0593	
> 65	12	NE	2	NE	NE	NE		NE	NE		
Sex											0.7446
male	26	5.90 (1.63)	24	4.24 (1.74)	1.66 (1.62)	(-1.60, 4.92)	0.3094	0.19 (0.28)	(-0.36, 0.75)	0.4934	
female	312	3.07 (0.44)	317	1.96 (0.44)	1.11 (0.53)	(0.07, 2.15)	0.0368	0.14 (0.08)	(-0.01, 0.30)	0.0761	
Race											0.3274
White	219	3.61 (0.52)	225	3.06 (0.51)	0.55 (0.63)	(-0.69, 1.79)	0.3861	0.07 (0.09)	(-0.11, 0.26)	0.4527	
Black	42	3.29 (1.27)	44	0.43 (1.22)	2.86 (1.44)	(-0.01, 5.73)	0.0509	0.35 (0.22)	(-0.08, 0.77)	0.1098	
Other	69	0.59 (1.25)	65	-0.68 (1.28)	1.27 (1.13)	(-0.97, 3.52)	0.2639	0.12 (0.17)	(-0.22, 0.46)	0.4797	
Ethnicity											0.8009
Hispanic/Latino	83	3.84 (0.87)	86	2.49 (0.84)	1.35 (1.00)	(-0.62, 3.32)	0.1767	0.17 (0.15)	(-0.13, 0.47)	0.2659	
Non-hispanic/Latino	247	2.98 (0.51)	248	1.93 (0.51)	1.06 (0.61)	(-0.13, 2.25)	0.0815	0.13 (0.09)	(-0.04, 0.31)	0.1418	
Geographic region											0.0276
EU	108	2.98 (0.83)	112	3.41 (0.84)	-0.43 (0.88)	(-2.16, 1.30)	0.6222	-0.05 (0.13)	(-0.31, 0.21)	0.7142	
non-EU	230	3.48 (0.50)	229	1.55 (0.51)	1.93 (0.62)	(0.72, 3.14)	0.0019	0.25 (0.09)	(0.07, 0.44)	0.0072	
Onset of disease											0.6977
Paediatric	23	3.10 (2.22)	22	1.09 (2.12)	2.01 (2.15)	(-2.35, 6.38)	0.3561	0.19 (0.30)	(-0.39, 0.78)	0.5213	
Adult	315	3.38 (0.44)	319	2.22 (0.44)	1.15 (0.52)	(0.12, 2.18)	0.0284	0.15 (0.08)	(-0.01, 0.30)	0.0634	
ADA result											0.1271
Negative	315	3.18 (0.44)	307	2.25 (0.45)	0.93 (0.53)	(-0.12, 1.98)	0.0810	0.12 (0.08)	(-0.04, 0.28)	0.1388	
Positive (At any time)	23	5.25 (2.00)	34	1.42 (1.58)	3.84 (1.83)	(0.16, 7.52)	0.0412	0.40 (0.27)	(-0.13, 0.94)	0.1382	
BMI (kg/m2) at enrolment											0.3098
< 30	218	3.10 (0.55)	241	2.21 (0.54)	0.89 (0.61)	(-0.31, 2.08)	0.1447	0.11 (0.09)	(-0.08, 0.29)	0.2526	
>= 30	120	4.06 (0.69)	100	2.05 (0.73)	2.01 (0.92)	(0.19, 3.82)	0.0305	0.27 (0.14)	(0.00, 0.54)	0.0469	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - FACIT-F Total Score
Full analysis set

	Anifrolumab 300mg (N=360)		Placebo (N=366)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 4		2.81 (0.49)		1.93 (0.49)	0.88 (0.60)	(-0.30, 2.05)	0.1420				
Week 8		3.27 (0.51)		2.32 (0.51)	0.95 (0.63)	(-0.29, 2.19)	0.1335				
Week 12		3.52 (0.55)		1.49 (0.55)	2.02 (0.70)	(0.65, 3.40)	0.0040				
Week 16		3.88 (0.57)		2.47 (0.56)	1.42 (0.72)	(-0.00, 2.83)	0.0503				
Week 20		4.91 (0.57)		4.25 (0.56)	0.66 (0.72)	(-0.76, 2.08)	0.3606				
Week 24		5.33 (0.58)		3.11 (0.57)	2.21 (0.74)	(0.77, 3.66)	0.0027				
Week 28		5.50 (0.60)		3.43 (0.59)	2.07 (0.77)	(0.56, 3.58)	0.0071				
Week 32		4.53 (0.62)		3.62 (0.61)	0.92 (0.80)	(-0.65, 2.48)	0.2517				
Week 36		4.75 (0.61)		2.98 (0.60)	1.77 (0.78)	(0.23, 3.31)	0.0239				
Week 40		4.53 (0.62)		4.02 (0.62)	0.51 (0.81)	(-1.07, 2.10)	0.5237				
Week 44		5.51 (0.63)		3.89 (0.63)	1.62 (0.82)	(-0.00, 3.23)	0.0505				
Week 48		4.86 (0.63)		3.49 (0.64)	1.37 (0.83)	(-0.26, 2.99)	0.0991				
Week 52		4.89 (0.63)		3.35 (0.63)	1.54 (0.82)	(-0.08, 3.15)	0.0630				
OVERALL	340	4.48 (0.48)	345	3.10 (0.48)	1.38 (0.58)	(0.23, 2.53)	0.0186	0.16 (0.08)	(0.01, 0.31)	0.0427	0.3414

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - FACIT-F Total Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) N	LSMean (SE)	Placebo (N=366) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.0518
< 10 points	102	5.87 (0.81)	101	2.77 (0.82)	3.10 (1.05)	(1.03, 5.17)	0.0036	0.38 (0.14)	(0.10, 0.65)	0.0078	
>= 10 points	238	3.95 (0.58)	244	3.31 (0.57)	0.65 (0.70)	(-0.73, 2.02)	0.3566	0.07 (0.09)	(-0.11, 0.25)	0.4285	
OCS dose at baseline											0.6320
<10 mg/day	163	4.53 (0.64)	169	2.83 (0.63)	1.70 (0.82)	(0.08, 3.32)	0.0395	0.21 (0.11)	(-0.01, 0.42)	0.0596	
>=10 mg/day	177	4.25 (0.75)	176	3.12 (0.75)	1.14 (0.83)	(-0.50, 2.78)	0.1733	0.11 (0.11)	(-0.10, 0.32)	0.2859	
Result of type I IFN gene signature test											0.5155
LOW	58	5.23 (1.11)	60	4.76 (1.10)	0.47 (1.52)	(-2.54, 3.48)	0.7569	0.06 (0.18)	(-0.31, 0.42)	0.7645	
HIGH	282	4.83 (0.47)	285	3.29 (0.47)	1.54 (0.63)	(0.30, 2.79)	0.0153	0.20 (0.08)	(0.03, 0.36)	0.0202	
Age (years)											NE
<= 65	329	4.48 (0.49)	343	3.15 (0.48)	1.33 (0.59)	(0.17, 2.49)	0.0251	0.15 (0.08)	(-0.00, 0.30)	0.0552	
> 65	11	NE	2	NE	NE	NE		NE	NE		
Sex											0.6903
male	26	6.76 (1.64)	24	4.74 (1.80)	2.03 (1.70)	(-1.41, 5.46)	0.2414	0.23 (0.28)	(-0.32, 0.79)	0.4142	
female	314	4.33 (0.50)	321	3.03 (0.50)	1.30 (0.61)	(0.10, 2.51)	0.0338	0.15 (0.08)	(-0.01, 0.30)	0.0654	
Race											0.1227
White	220	4.22 (0.59)	230	3.52 (0.58)	0.70 (0.74)	(-0.75, 2.14)	0.3437	0.08 (0.09)	(-0.11, 0.26)	0.4018	
Black	44	8.12 (1.51)	43	3.83 (1.46)	4.29 (1.73)	(0.84, 7.73)	0.0154	0.43 (0.22)	(0.01, 0.86)	0.0460	
Other	70	2.66 (1.32)	65	0.38 (1.36)	2.28 (1.21)	(-0.12, 4.68)	0.0621	0.21 (0.17)	(-0.13, 0.54)	0.2323	
Ethnicity											0.6104
Hispanic/Latino	83	5.00 (1.08)	87	3.00 (1.04)	2.00 (1.23)	(-0.43, 4.44)	0.1065	0.20 (0.15)	(-0.10, 0.51)	0.1831	
Non-hispanic/Latino	251	4.40 (0.55)	251	3.11 (0.54)	1.29 (0.67)	(-0.03, 2.60)	0.0550	0.15 (0.09)	(-0.03, 0.32)	0.0957	
Geographic region											0.0249
EU	107	4.28 (0.82)	116	4.61 (0.82)	-0.32 (0.92)	(-2.13, 1.48)	0.7239	-0.04 (0.13)	(-0.30, 0.23)	0.7806	
non-EU	233	4.65 (0.59)	229	2.33 (0.60)	2.31 (0.74)	(0.86, 3.77)	0.0018	0.26 (0.09)	(0.07, 0.44)	0.0063	
Onset of disease											0.8941
Paediatric	22	5.11 (2.25)	22	3.95 (2.18)	1.16 (2.34)	(-3.60, 5.91)	0.6238	0.11 (0.30)	(-0.48, 0.70)	0.7172	
Adult	318	4.66 (0.50)	323	3.18 (0.49)	1.48 (0.60)	(0.29, 2.67)	0.0147	0.17 (0.08)	(0.01, 0.32)	0.0346	
ADA result											0.0664
Negative	316	4.33 (0.50)	311	3.23 (0.50)	1.10 (0.61)	(-0.10, 2.29)	0.0724	0.12 (0.08)	(-0.03, 0.28)	0.1197	
Positive (At any time)	24	7.82 (2.40)	34	2.45 (1.94)	5.38 (2.25)	(0.86, 9.89)	0.0204	0.46 (0.27)	(-0.07, 0.99)	0.0880	
BMI (kg/m2) at enrolment											0.3542
< 30	221	4.23 (0.61)	245	3.19 (0.60)	1.04 (0.69)	(-0.32, 2.40)	0.1332	0.11 (0.09)	(-0.07, 0.29)	0.2261	
>= 30	119	5.26 (0.81)	100	3.02 (0.85)	2.24 (1.10)	(0.08, 4.41)	0.0425	0.26 (0.14)	(-0.01, 0.52)	0.0591	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - EQ VAS Score
Full analysis set

	Anifrolumab 300mg (N=360)		Placebo (N=366)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 12		6.41 (1.24)		1.85 (1.24)	4.56 (1.55)	(1.52, 7.60)	0.0034				
Week 24		6.84 (1.30)		5.88 (1.29)	0.96 (1.63)	(-2.24, 4.15)	0.5559				
Week 36		7.94 (1.31)		7.43 (1.31)	0.51 (1.65)	(-2.73, 3.76)	0.7564				
Week 52		8.28 (1.35)		4.95 (1.35)	3.33 (1.72)	(-0.05, 6.70)	0.0532				
OVERALL	332	7.37 (1.06)	337	5.03 (1.06)	2.34 (1.25)	(-0.12, 4.79)	0.0620	0.12 (0.08)	(-0.03, 0.27)	0.1199	0.8989

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - EQ VAS Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) N	LSMean (SE)	Placebo (N=366) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.4474
< 10 points	98	8.15 (1.86)	99	4.32 (1.86)	3.83 (2.36)	(-0.84, 8.49)	0.1072	0.21 (0.14)	(-0.07, 0.49)	0.1489	
>= 10 points	234	7.16 (1.26)	238	5.45 (1.26)	1.71 (1.48)	(-1.20, 4.61)	0.2488	0.09 (0.09)	(-0.09, 0.27)	0.3390	
OCS dose at baseline											0.6531
<10 mg/day	159	6.52 (1.46)	165	4.69 (1.45)	1.83 (1.83)	(-1.78, 5.44)	0.3191	0.10 (0.11)	(-0.12, 0.32)	0.3758	
>=10 mg/day	173	7.91 (1.60)	172	4.95 (1.59)	2.96 (1.71)	(-0.40, 6.31)	0.0839	0.14 (0.11)	(-0.07, 0.35)	0.1911	
Result of type I IFN gene signature test											0.3435
LOW	58	4.75 (2.18)	60	4.99 (2.14)	-0.24 (2.94)	(-6.07, 5.58)	0.9345	-0.01 (0.18)	(-0.38, 0.35)	0.9372	
HIGH	274	9.20 (1.04)	277	6.37 (1.03)	2.83 (1.38)	(0.12, 5.55)	0.0410	0.16 (0.09)	(-0.00, 0.33)	0.0541	
Age (years)											0.9498
<= 65	321	7.44 (1.09)	335	5.00 (1.07)	2.45 (1.26)	(-0.04, 4.93)	0.0535	0.13 (0.08)	(-0.03, 0.28)	0.1097	
> 65	11	9.79 (4.30)	2	6.73 (8.88)	3.06 (9.74)	(-19.15, 25.27)	0.7607	0.20 (0.77)	(-1.31, 1.71)	0.7930	
Sex											0.4020
male	26	1.48 (4.63)	24	-4.58 (5.03)	6.06 (4.59)	(-3.21, 15.33)	0.1940	0.25 (0.28)	(-0.31, 0.80)	0.3838	
female	306	7.76 (1.10)	313	5.70 (1.09)	2.06 (1.30)	(-0.49, 4.62)	0.1134	0.11 (0.08)	(-0.05, 0.26)	0.1834	
Race											0.0280
White	215	7.72 (1.24)	226	8.28 (1.25)	-0.57 (1.50)	(-3.52, 2.39)	0.7065	-0.03 (0.10)	(-0.22, 0.16)	0.7482	
Black	43	7.49 (3.19)	43	1.40 (2.99)	6.09 (3.66)	(-1.20, 13.38)	0.1002	0.30 (0.22)	(-0.13, 0.72)	0.1698	
Other	68	2.86 (3.32)	62	-4.34 (3.37)	7.20 (2.96)	(1.33, 13.07)	0.0166	0.27 (0.18)	(-0.08, 0.61)	0.1325	
Ethnicity											0.9834
Hispanic/Latino	81	10.59 (2.33)	86	8.60 (2.21)	1.99 (2.53)	(-3.01, 6.99)	0.4328	0.10 (0.15)	(-0.21, 0.40)	0.5370	
Non-hispanic/Latino	245	5.65 (1.20)	245	3.72 (1.21)	1.93 (1.43)	(-0.88, 4.74)	0.1785	0.10 (0.09)	(-0.08, 0.28)	0.2596	
Geographic region											0.0726
EU	106	9.14 (2.00)	112	9.59 (2.04)	-0.45 (2.12)	(-4.64, 3.74)	0.8323	-0.02 (0.14)	(-0.29, 0.24)	0.8753	
non-EU	226	6.39 (1.25)	225	2.15 (1.26)	4.24 (1.52)	(1.25, 7.22)	0.0055	0.22 (0.09)	(0.04, 0.41)	0.0176	
Onset of disease											0.4209
Paediatric	21	7.15 (5.11)	21	0.63 (4.79)	6.52 (5.37)	(-4.41, 17.45)	0.2334	0.28 (0.31)	(-0.33, 0.89)	0.3637	
Adult	311	7.41 (1.10)	316	5.33 (1.09)	2.07 (1.30)	(-0.47, 4.62)	0.1100	0.11 (0.08)	(-0.05, 0.26)	0.1804	
ADA result											0.0858
Negative	309	6.94 (1.09)	304	5.10 (1.11)	1.84 (1.31)	(-0.72, 4.41)	0.1591	0.10 (0.08)	(-0.06, 0.25)	0.2366	
Positive (At any time)	23	16.83 (5.35)	33	6.56 (4.12)	10.27 (4.72)	(0.76, 19.77)	0.0349	0.41 (0.27)	(-0.12, 0.95)	0.1321	
BMI (kg/m2) at enrolment											0.4690
< 30	216	7.54 (1.39)	240	5.52 (1.36)	2.02 (1.51)	(-0.96, 4.99)	0.1840	0.10 (0.09)	(-0.09, 0.28)	0.3018	
>= 30	116	7.82 (1.69)	97	3.86 (1.76)	3.96 (2.22)	(-0.42, 8.34)	0.0760	0.22 (0.14)	(-0.05, 0.49)	0.1074	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Physical Health domain score
Full analysis set

	Anifrolumab 300mg (N=360)		Placebo (N=366)		Difference of						
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 12		9.04 (1.15)		6.19 (1.15)	2.84 (1.40)	(0.09, 5.59)	0.0428				
Week 24		9.84 (1.18)		6.82 (1.17)	3.03 (1.44)	(0.19, 5.86)	0.0364				
Week 36		9.15 (1.22)		9.09 (1.22)	0.05 (1.51)	(-2.92, 3.02)	0.9728				
Week 52		7.88 (1.25)		7.44 (1.25)	0.44 (1.56)	(-2.62, 3.49)	0.7779				
OVERALL	330	8.98 (1.07)	337	7.39 (1.06)	1.59 (1.25)	(-0.87, 4.05)	0.2050	0.08 (0.08)	(-0.07, 0.23)	0.2912	0.6488

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Physical Health domain score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) N	LSMean (SE)	Placebo (N=366) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.4384
< 10 points	98	10.90 (1.75)	99	7.86 (1.76)	3.04 (2.23)	(-1.36, 7.43)	0.1748	0.17 (0.14)	(-0.11, 0.45)	0.2232	
>= 10 points	232	8.15 (1.30)	238	7.20 (1.29)	0.95 (1.52)	(-2.03, 3.93)	0.5329	0.05 (0.09)	(-0.13, 0.23)	0.6050	
OCS dose at baseline											0.6707
<10 mg/day	159	8.25 (1.35)	165	7.11 (1.34)	1.14 (1.69)	(-2.19, 4.47)	0.5020	0.07 (0.11)	(-0.15, 0.28)	0.5507	
>=10 mg/day	171	9.48 (1.73)	172	7.28 (1.73)	2.20 (1.85)	(-1.43, 5.84)	0.2338	0.10 (0.11)	(-0.11, 0.31)	0.3691	
Result of type I IFN gene signature test											0.5896
LOW	58	9.90 (2.25)	60	9.82 (2.21)	0.08 (3.04)	(-5.96, 6.11)	0.9803	0.00 (0.18)	(-0.36, 0.37)	0.9811	
HIGH	272	9.44 (1.04)	277	7.56 (1.03)	1.88 (1.38)	(-0.83, 4.59)	0.1743	0.11 (0.09)	(-0.06, 0.28)	0.2003	
Age (years)											0.8288
<= 65	319	9.20 (1.09)	335	7.65 (1.07)	1.56 (1.26)	(-0.92, 4.04)	0.2175	0.08 (0.08)	(-0.07, 0.23)	0.3073	
> 65	11	4.88 (10.40)	2	-0.30 (17.53)	5.17 (16.67)	(-40.95, 51.30)	0.7717	0.14 (0.77)	(-1.37, 1.65)	0.8529	
Sex											0.2908
male	26	13.69 (4.29)	24	7.81 (4.66)	5.88 (4.26)	(-2.71, 14.47)	0.1747	0.26 (0.28)	(-0.30, 0.82)	0.3622	
female	304	8.63 (1.11)	313	7.46 (1.09)	1.17 (1.31)	(-1.40, 3.74)	0.3705	0.06 (0.08)	(-0.10, 0.22)	0.4519	
Race											0.2741
White	214	8.99 (1.30)	226	8.74 (1.30)	0.25 (1.58)	(-2.86, 3.36)	0.8753	0.01 (0.10)	(-0.17, 0.20)	0.8929	
Black	42	12.45 (3.32)	43	8.57 (3.23)	3.88 (3.82)	(-3.72, 11.48)	0.3127	0.18 (0.22)	(-0.25, 0.61)	0.4076	
Other	68	4.66 (2.94)	62	-0.09 (2.99)	4.74 (2.55)	(-0.31, 9.80)	0.0655	0.20 (0.18)	(-0.15, 0.54)	0.2624	
Ethnicity											0.8974
Hispanic/Latino	81	11.38 (2.42)	86	9.69 (2.29)	1.69 (2.68)	(-3.60, 6.98)	0.5285	0.08 (0.15)	(-0.23, 0.38)	0.6130	
Non-hispanic/Latino	243	8.22 (1.21)	245	6.14 (1.21)	2.08 (1.44)	(-0.74, 4.90)	0.1477	0.11 (0.09)	(-0.07, 0.29)	0.2251	
Geographic region											0.1164
EU	105	9.38 (1.93)	112	10.58 (1.95)	-1.19 (2.05)	(-5.23, 2.85)	0.5615	-0.06 (0.14)	(-0.32, 0.21)	0.6660	
non-EU	225	8.52 (1.26)	225	5.70 (1.27)	2.82 (1.53)	(-0.18, 5.83)	0.0657	0.15 (0.09)	(-0.04, 0.33)	0.1158	
Onset of disease											0.0740
Paediatric	20	1.32 (4.36)	21	7.64 (4.18)	-6.32 (4.49)	(-15.48, 2.85)	0.1696	-0.32 (0.31)	(-0.94, 0.30)	0.3081	
Adult	310	9.43 (1.11)	316	7.39 (1.10)	2.04 (1.31)	(-0.53, 4.61)	0.1200	0.10 (0.08)	(-0.05, 0.26)	0.1930	
ADA result											0.2695
Negative	308	8.93 (1.10)	304	7.91 (1.11)	1.02 (1.31)	(-1.56, 3.60)	0.4396	0.05 (0.08)	(-0.11, 0.21)	0.5163	
Positive (At any time)	22	10.62 (4.82)	33	4.39 (3.75)	6.23 (4.53)	(-2.89, 15.34)	0.1760	0.28 (0.28)	(-0.26, 0.82)	0.3127	
BMI (kg/m2) at enrolment											0.5846
< 30	214	9.33 (1.28)	240	7.95 (1.25)	1.37 (1.40)	(-1.37, 4.11)	0.3260	0.07 (0.09)	(-0.11, 0.26)	0.4449	
>= 30	116	9.87 (1.95)	97	6.89 (2.05)	2.98 (2.58)	(-2.12, 8.07)	0.2506	0.14 (0.14)	(-0.13, 0.41)	0.2956	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Emotional Health domain score
Full analysis set

	Anifrolumab 300mg (N=360)		Placebo (N=366)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 12		3.16 (1.10)		0.89 (1.09)	2.27 (1.35)	(-0.37, 4.91)	0.0922				
Week 24		4.99 (1.15)		4.18 (1.14)	0.81 (1.43)	(-1.99, 3.62)	0.5697				
Week 36		5.62 (1.18)		5.37 (1.18)	0.25 (1.48)	(-2.66, 3.16)	0.8679				
Week 52		5.28 (1.29)		5.08 (1.30)	0.20 (1.66)	(-3.07, 3.46)	0.9055				
OVERALL	330	4.76 (1.00)	337	3.88 (1.00)	0.88 (1.19)	(-1.46, 3.22)	0.4599	0.05 (0.08)	(-0.10, 0.20)	0.5345	0.6156

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Emotional Health domain score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) N	LSMean (SE)	Placebo (N=366) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.1540
< 10 points	98	7.32 (1.63)	99	3.98 (1.64)	3.34 (2.09)	(-0.78, 7.47)	0.1115	0.21 (0.14)	(-0.07, 0.49)	0.1506	
>= 10 points	232	3.30 (1.22)	238	3.58 (1.22)	-0.28 (1.45)	(-3.13, 2.56)	0.8458	-0.02 (0.09)	(-0.20, 0.17)	0.8707	
OCS dose at baseline											0.8493
<10 mg/day	159	3.91 (1.28)	165	3.24 (1.27)	0.67 (1.61)	(-2.51, 3.84)	0.6798	0.04 (0.11)	(-0.18, 0.26)	0.7127	
>=10 mg/day	171	5.53 (1.62)	172	4.41 (1.61)	1.12 (1.76)	(-2.33, 4.57)	0.5239	0.05 (0.11)	(-0.16, 0.26)	0.6252	
Result of type I IFN gene signature test											0.9503
LOW	58	3.94 (1.97)	60	3.34 (1.96)	0.60 (2.71)	(-4.76, 5.97)	0.8244	0.04 (0.18)	(-0.32, 0.40)	0.8295	
HIGH	272	6.10 (1.00)	277	5.31 (0.99)	0.79 (1.33)	(-1.83, 3.41)	0.5537	0.05 (0.09)	(-0.12, 0.22)	0.5755	
Age (years)											0.5985
<= 65	319	4.66 (1.03)	335	3.99 (1.01)	0.66 (1.21)	(-1.71, 3.04)	0.5825	0.04 (0.08)	(-0.12, 0.19)	0.6462	
> 65	11	8.70 (4.17)	2	3.21 (8.16)	5.49 (9.09)	(-16.09, 27.07)	0.5651	0.37 (0.77)	(-1.14, 1.89)	0.6280	
Sex											0.3461
male	26	10.33 (4.95)	24	4.80 (5.54)	5.53 (5.16)	(-4.88, 15.94)	0.2900	0.21 (0.28)	(-0.35, 0.76)	0.4640	
female	304	4.41 (1.02)	313	3.87 (1.01)	0.53 (1.22)	(-1.86, 2.93)	0.6630	0.03 (0.08)	(-0.13, 0.19)	0.7121	
Race											0.8753
White	214	4.67 (1.20)	226	4.04 (1.20)	0.64 (1.47)	(-2.25, 3.52)	0.6656	0.04 (0.10)	(-0.15, 0.22)	0.7097	
Black	42	9.01 (3.30)	43	6.72 (3.19)	2.29 (3.84)	(-5.37, 9.95)	0.5531	0.11 (0.22)	(-0.32, 0.53)	0.6214	
Other	68	-0.16 (2.91)	62	-0.05 (2.97)	-0.11 (2.62)	(-5.30, 5.08)	0.9664	-0.00 (0.18)	(-0.35, 0.34)	0.9789	
Ethnicity											0.1426
Hispanic/Latino	81	4.98 (2.45)	86	7.54 (2.32)	-2.56 (2.76)	(-8.02, 2.89)	0.3547	-0.12 (0.15)	(-0.42, 0.19)	0.4491	
Non-hispanic/Latino	243	4.65 (1.11)	245	2.73 (1.11)	1.93 (1.32)	(-0.67, 4.52)	0.1459	0.11 (0.09)	(-0.07, 0.29)	0.2214	
Geographic region											0.8625
EU	105	6.63 (1.78)	112	5.46 (1.81)	1.18 (1.89)	(-2.54, 4.90)	0.5333	0.06 (0.14)	(-0.20, 0.33)	0.6452	
non-EU	225	3.62 (1.22)	225	2.86 (1.23)	0.76 (1.50)	(-2.19, 3.71)	0.6131	0.04 (0.09)	(-0.14, 0.23)	0.6616	
Onset of disease											0.1456
Paediatric	20	0.32 (5.06)	21	6.72 (4.76)	-6.40 (5.17)	(-16.90, 4.11)	0.2242	-0.28 (0.31)	(-0.90, 0.33)	0.3686	
Adult	310	5.17 (1.03)	316	3.83 (1.03)	1.33 (1.23)	(-1.09, 3.75)	0.2798	0.07 (0.08)	(-0.08, 0.23)	0.3614	
ADA result											0.4587
Negative	308	4.80 (1.03)	304	3.97 (1.05)	0.84 (1.25)	(-1.61, 3.28)	0.5015	0.05 (0.08)	(-0.11, 0.20)	0.5696	
Positive (At any time)	22	1.43 (5.13)	33	4.34 (4.23)	-2.91 (4.90)	(-12.85, 7.03)	0.5565	-0.12 (0.28)	(-0.66, 0.42)	0.6672	
BMI (kg/m2) at enrolment											0.8997
< 30	214	4.64 (1.28)	240	3.76 (1.26)	0.88 (1.40)	(-1.88, 3.64)	0.5310	0.05 (0.09)	(-0.14, 0.23)	0.6244	
>= 30	116	4.92 (1.72)	97	3.70 (1.79)	1.22 (2.29)	(-3.29, 5.73)	0.5947	0.07 (0.14)	(-0.20, 0.34)	0.6263	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Body Image domain score
Full analysis set

	Anifrolumab 300mg (N=360)		Placebo (N=366)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 12		6.43 (1.27)		3.44 (1.27)	3.00 (1.55)	(-0.06, 6.05)	0.0544				
Week 24		8.92 (1.41)		4.95 (1.41)	3.96 (1.77)	(0.49, 7.43)	0.0254				
Week 36		9.86 (1.44)		8.16 (1.44)	1.70 (1.82)	(-1.88, 5.28)	0.3507				
Week 52		8.52 (1.52)		6.98 (1.52)	1.54 (1.94)	(-2.27, 5.35)	0.4283				
OVERALL	304	8.43 (1.20)	311	5.88 (1.20)	2.55 (1.43)	(-0.27, 5.37)	0.0760	0.12 (0.08)	(-0.04, 0.28)	0.1352	0.4249

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Body Image domain score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) N	LSMean (SE)	Placebo (N=366) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.3927
< 10 points	91	7.10 (1.78)	92	6.70 (1.82)	0.40 (2.27)	(-4.08, 4.89)	0.8597	0.02 (0.15)	(-0.27, 0.31)	0.8748	
>= 10 points	213	8.82 (1.50)	219	5.94 (1.49)	2.88 (1.80)	(-0.65, 6.41)	0.1097	0.13 (0.10)	(-0.06, 0.32)	0.1739	
OCS dose at baseline											0.9300
<10 mg/day	146	7.68 (1.56)	149	5.29 (1.56)	2.39 (1.98)	(-1.50, 6.28)	0.2280	0.13 (0.12)	(-0.10, 0.35)	0.2803	
>=10 mg/day	158	8.68 (1.92)	162	6.04 (1.90)	2.64 (2.07)	(-1.44, 6.72)	0.2037	0.11 (0.11)	(-0.11, 0.33)	0.3306	
Result of type I IFN gene signature test											0.4176
LOW	55	6.13 (2.29)	55	6.28 (2.35)	-0.15 (3.17)	(-6.45, 6.15)	0.9622	-0.01 (0.19)	(-0.38, 0.37)	0.9637	
HIGH	249	9.36 (1.20)	256	6.63 (1.18)	2.73 (1.61)	(-0.42, 5.89)	0.0896	0.14 (0.09)	(-0.03, 0.32)	0.1063	
Age (years)											NE
<= 65	294	8.44 (1.23)	309	6.02 (1.22)	2.42 (1.45)	(-0.43, 5.27)	0.0963	0.11 (0.08)	(-0.05, 0.27)	0.1641	
> 65	10	NE	2	NE	NE	NE		NE	NE		
Sex											0.6871
male	23	15.62 (4.15)	22	11.41 (4.52)	4.21 (4.38)	(-4.65, 13.08)	0.3417	0.20 (0.30)	(-0.38, 0.79)	0.5004	
female	281	8.05 (1.25)	289	5.70 (1.25)	2.35 (1.50)	(-0.60, 5.30)	0.1177	0.11 (0.08)	(-0.05, 0.28)	0.1846	
Race											0.5911
White	202	8.44 (1.38)	208	5.59 (1.41)	2.85 (1.70)	(-0.50, 6.20)	0.0949	0.14 (0.10)	(-0.05, 0.34)	0.1492	
Black	39	6.52 (4.07)	39	8.21 (3.88)	-1.69 (4.69)	(-11.04, 7.65)	0.7190	-0.07 (0.23)	(-0.51, 0.38)	0.7657	
Other	58	8.52 (3.86)	58	4.43 (3.86)	4.09 (3.40)	(-2.65, 10.83)	0.2319	0.14 (0.19)	(-0.23, 0.50)	0.4575	
Ethnicity											0.3616
Hispanic/Latino	74	9.22 (2.68)	78	9.14 (2.62)	0.09 (3.01)	(-5.87, 6.04)	0.9772	0.00 (0.16)	(-0.31, 0.32)	0.9818	
Non-hispanic/Latino	225	8.20 (1.38)	227	4.97 (1.39)	3.23 (1.66)	(-0.05, 6.50)	0.0533	0.15 (0.09)	(-0.03, 0.34)	0.1002	
Geographic region											0.2058
EU	99	12.36 (2.19)	100	7.29 (2.27)	5.07 (2.36)	(0.41, 9.73)	0.0332	0.23 (0.14)	(-0.05, 0.51)	0.1111	
non-EU	205	6.31 (1.42)	211	4.96 (1.43)	1.35 (1.75)	(-2.08, 4.79)	0.4394	0.07 (0.10)	(-0.13, 0.26)	0.5038	
Onset of disease											0.7752
Paediatric	19	-4.41 (7.70)	20	-4.81 (7.19)	0.39 (7.94)	(-15.75, 16.54)	0.9609	0.01 (0.32)	(-0.62, 0.64)	0.9708	
Adult	285	9.07 (1.21)	291	6.37 (1.21)	2.70 (1.44)	(-0.13, 5.53)	0.0618	0.13 (0.08)	(-0.03, 0.30)	0.1143	
ADA result											0.6299
Negative	285	8.42 (1.25)	280	5.94 (1.27)	2.49 (1.51)	(-0.48, 5.45)	0.1004	0.12 (0.08)	(-0.05, 0.28)	0.1642	
Positive (At any time)	19	4.89 (5.17)	31	4.96 (4.05)	-0.07 (5.08)	(-10.37, 10.23)	0.9894	-0.00 (0.29)	(-0.57, 0.57)	0.9919	
BMI (kg/m2) at enrolment											0.3828
< 30	193	8.88 (1.59)	219	5.28 (1.55)	3.59 (1.76)	(0.13, 7.06)	0.0420	0.16 (0.10)	(-0.03, 0.35)	0.1074	
>= 30	111	8.31 (1.89)	92	7.39 (2.00)	0.92 (2.50)	(-4.02, 5.86)	0.7134	0.05 (0.14)	(-0.23, 0.32)	0.7399	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Burden to Others domain score
Full analysis set

	Anifrolumab 300mg (N=360)		Placebo (N=366)		Difference of						
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 12		8.06 (1.41)		4.99 (1.40)	3.07 (1.73)	(-0.33, 6.47)	0.0769				
Week 24		9.23 (1.47)		7.88 (1.46)	1.35 (1.82)	(-2.24, 4.93)	0.4611				
Week 36		11.81 (1.49)		11.33 (1.49)	0.48 (1.87)	(-3.19, 4.15)	0.7976				
Week 52		9.43 (1.61)		8.07 (1.61)	1.36 (2.06)	(-2.68, 5.40)	0.5090				
OVERALL	330	9.63 (1.26)	337	8.07 (1.26)	1.56 (1.49)	(-1.36, 4.49)	0.2949	0.07 (0.08)	(-0.08, 0.22)	0.3802	0.5381

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Burden to Others domain score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) N	LSMean (SE)	Placebo (N=366) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.0881
< 10 points	98	10.86 (1.96)	99	5.72 (1.97)	5.14 (2.50)	(0.21, 10.07)	0.0411	0.26 (0.14)	(-0.02, 0.54)	0.0664	
>= 10 points	232	9.18 (1.56)	238	9.32 (1.54)	-0.14 (1.83)	(-3.74, 3.45)	0.9376	-0.01 (0.09)	(-0.19, 0.17)	0.9479	
OCS dose at baseline											0.5480
<10 mg/day	159	8.73 (1.56)	165	7.93 (1.55)	0.80 (1.96)	(-3.06, 4.67)	0.6823	0.04 (0.11)	(-0.18, 0.26)	0.7153	
>=10 mg/day	171	10.57 (2.07)	172	7.98 (2.07)	2.59 (2.23)	(-1.80, 6.98)	0.2470	0.10 (0.11)	(-0.12, 0.31)	0.3778	
Result of type I IFN gene signature test											0.9796
LOW	58	13.40 (2.70)	60	11.62 (2.67)	1.78 (3.67)	(-5.50, 9.05)	0.6294	0.09 (0.18)	(-0.28, 0.45)	0.6423	
HIGH	272	7.87 (1.22)	277	6.20 (1.21)	1.67 (1.63)	(-1.53, 4.87)	0.3044	0.08 (0.09)	(-0.08, 0.25)	0.3320	
Age (years)											0.1380
<= 65	319	9.30 (1.29)	335	8.12 (1.27)	1.18 (1.51)	(-1.78, 4.14)	0.4352	0.05 (0.08)	(-0.10, 0.20)	0.5160	
> 65	11	18.51 (6.26)	2	0.59 (10.83)	17.91 (11.18)	(-9.92, 45.75)	0.1638	0.82 (0.79)	(-0.73, 2.37)	0.3010	
Sex											0.9086
male	26	17.50 (4.23)	24	15.34 (4.69)	2.16 (4.62)	(-7.15, 11.47)	0.6426	0.10 (0.28)	(-0.46, 0.65)	0.7359	
female	304	9.17 (1.31)	313	7.57 (1.30)	1.60 (1.56)	(-1.47, 4.66)	0.3062	0.07 (0.08)	(-0.09, 0.23)	0.3875	
Race											0.2774
White	214	9.61 (1.52)	226	9.65 (1.52)	-0.04 (1.85)	(-3.68, 3.61)	0.9849	-0.00 (0.10)	(-0.19, 0.19)	0.9870	
Black	42	11.63 (4.24)	43	7.02 (4.01)	4.61 (4.84)	(-5.03, 14.26)	0.3441	0.17 (0.22)	(-0.26, 0.60)	0.4340	
Other	68	7.01 (3.44)	62	1.81 (3.49)	5.19 (3.03)	(-0.81, 11.20)	0.0893	0.18 (0.18)	(-0.16, 0.53)	0.2941	
Ethnicity											0.2209
Hispanic/Latino	81	12.62 (2.92)	86	14.13 (2.76)	-1.52 (3.23)	(-7.90, 4.87)	0.6393	-0.06 (0.15)	(-0.36, 0.25)	0.7068	
Non-hispanic/Latino	243	8.89 (1.43)	245	5.94 (1.43)	2.95 (1.70)	(-0.39, 6.29)	0.0829	0.13 (0.09)	(-0.05, 0.31)	0.1453	
Geographic region											0.1582
EU	105	8.94 (2.22)	112	10.05 (2.26)	-1.11 (2.41)	(-5.87, 3.65)	0.6460	-0.05 (0.14)	(-0.31, 0.22)	0.7276	
non-EU	225	10.14 (1.51)	225	6.97 (1.52)	3.17 (1.84)	(-0.45, 6.80)	0.0856	0.14 (0.09)	(-0.05, 0.32)	0.1399	
Onset of disease											0.7119
Paediatric	20	6.92 (6.10)	21	7.42 (5.64)	-0.50 (6.09)	(-12.87, 11.87)	0.9349	-0.02 (0.31)	(-0.63, 0.59)	0.9528	
Adult	310	9.96 (1.30)	316	8.14 (1.29)	1.82 (1.55)	(-1.21, 4.85)	0.2392	0.08 (0.08)	(-0.08, 0.24)	0.3212	
ADA result											0.3471
Negative	308	9.72 (1.31)	304	8.73 (1.33)	0.99 (1.58)	(-2.10, 4.09)	0.5296	0.04 (0.08)	(-0.12, 0.20)	0.5956	
Positive (At any time)	22	7.71 (5.04)	33	2.05 (3.99)	5.67 (4.72)	(-3.83, 15.17)	0.2357	0.24 (0.28)	(-0.30, 0.78)	0.3833	
BMI (kg/m2) at enrolment											0.9822
< 30	214	8.12 (1.61)	240	6.36 (1.59)	1.76 (1.77)	(-1.71, 5.24)	0.3192	0.07 (0.09)	(-0.11, 0.26)	0.4376	
>= 30	116	12.24 (2.09)	97	10.55 (2.18)	1.69 (2.78)	(-3.79, 7.18)	0.5441	0.08 (0.14)	(-0.19, 0.35)	0.5789	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Fatigue domain score
Full analysis set

	Anifrolumab 300mg (N=360)		Placebo (N=366)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 12		6.91 (1.21)		4.68 (1.20)	2.23 (1.46)	(-0.64, 5.10)	0.1276				
Week 24		9.03 (1.27)		6.17 (1.26)	2.86 (1.56)	(-0.20, 5.92)	0.0671				
Week 36		8.05 (1.32)		6.21 (1.32)	1.83 (1.64)	(-1.39, 5.06)	0.2650				
Week 52		8.27 (1.42)		6.14 (1.42)	2.13 (1.80)	(-1.41, 5.67)	0.2373				
OVERALL	330	8.06 (1.14)	337	5.80 (1.14)	2.26 (1.35)	(-0.39, 4.92)	0.0944	0.11 (0.08)	(-0.04, 0.26)	0.1616	0.6022

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Fatigue domain score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) N	LSMean (SE)	Placebo (N=366) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.3085
< 10 points	98	9.88 (1.87)	99	5.63 (1.88)	4.25 (2.38)	(-0.46, 8.95)	0.0764	0.23 (0.14)	(-0.05, 0.51)	0.1118	
>= 10 points	232	7.20 (1.39)	238	5.90 (1.38)	1.30 (1.64)	(-1.91, 4.52)	0.4265	0.06 (0.09)	(-0.12, 0.24)	0.5070	
OCS dose at baseline											0.8281
<10 mg/day	159	8.53 (1.41)	165	5.96 (1.39)	2.57 (1.77)	(-0.91, 6.06)	0.1468	0.14 (0.11)	(-0.07, 0.36)	0.1947	
>=10 mg/day	171	7.39 (1.89)	172	5.40 (1.88)	1.99 (2.02)	(-1.98, 5.96)	0.3245	0.08 (0.11)	(-0.13, 0.29)	0.4562	
Result of type I IFN gene signature test											0.8315
LOW	58	9.87 (2.58)	60	8.27 (2.55)	1.60 (3.51)	(-5.37, 8.56)	0.6504	0.08 (0.18)	(-0.28, 0.44)	0.6620	
HIGH	272	8.50 (1.10)	277	6.09 (1.09)	2.41 (1.47)	(-0.47, 5.28)	0.1010	0.13 (0.09)	(-0.04, 0.30)	0.1212	
Age (years)											0.3327
<= 65	319	8.24 (1.17)	335	6.03 (1.15)	2.21 (1.36)	(-0.46, 4.88)	0.1052	0.11 (0.08)	(-0.05, 0.26)	0.1777	
> 65	11	4.93 (5.02)	2	12.87 (9.52)	-7.93 (10.38)	(-39.80, 23.93)	0.4971	-0.45 (0.78)	(-1.97, 1.07)	0.5616	
Sex											0.1459
male	26	9.13 (4.53)	24	0.40 (4.95)	8.73 (4.62)	(-0.59, 18.05)	0.0656	0.36 (0.29)	(-0.20, 0.92)	0.2036	
female	304	7.79 (1.19)	313	6.09 (1.18)	1.70 (1.41)	(-1.08, 4.48)	0.2296	0.08 (0.08)	(-0.08, 0.24)	0.3106	
Race											0.2787
White	214	8.06 (1.39)	226	7.08 (1.39)	0.98 (1.69)	(-2.35, 4.31)	0.5622	0.05 (0.10)	(-0.14, 0.23)	0.6186	
Black	42	8.64 (3.60)	43	4.48 (3.46)	4.16 (4.12)	(-4.05, 12.37)	0.3159	0.18 (0.22)	(-0.25, 0.61)	0.4098	
Other	68	6.30 (3.13)	62	0.29 (3.18)	6.01 (2.78)	(0.50, 11.52)	0.0327	0.23 (0.18)	(-0.11, 0.58)	0.1826	
Ethnicity											0.6956
Hispanic/Latino	81	9.82 (2.64)	86	8.20 (2.51)	1.62 (2.92)	(-4.15, 7.38)	0.5799	0.07 (0.15)	(-0.23, 0.37)	0.6579	
Non-hispanic/Latino	243	7.65 (1.29)	245	4.74 (1.30)	2.91 (1.54)	(-0.12, 5.94)	0.0597	0.14 (0.09)	(-0.03, 0.32)	0.1132	
Geographic region											0.2498
EU	105	9.32 (2.01)	112	9.00 (2.04)	0.32 (2.14)	(-3.90, 4.54)	0.8818	0.02 (0.14)	(-0.25, 0.28)	0.9120	
non-EU	225	7.52 (1.38)	225	4.06 (1.39)	3.46 (1.69)	(0.14, 6.78)	0.0414	0.17 (0.09)	(-0.02, 0.35)	0.0796	
Onset of disease											0.9932
Paediatric	20	6.75 (5.55)	21	4.30 (5.22)	2.45 (5.57)	(-8.88, 13.79)	0.6625	0.10 (0.31)	(-0.51, 0.71)	0.7522	
Adult	310	8.49 (1.18)	316	6.09 (1.17)	2.41 (1.40)	(-0.34, 5.15)	0.0859	0.12 (0.08)	(-0.04, 0.27)	0.1485	
ADA result											0.5525
Negative	308	7.79 (1.18)	304	5.95 (1.19)	1.83 (1.41)	(-0.94, 4.61)	0.1954	0.09 (0.08)	(-0.07, 0.25)	0.2745	
Positive (At any time)	22	11.12 (5.67)	33	6.10 (4.55)	5.02 (5.17)	(-5.38, 15.42)	0.3368	0.19 (0.28)	(-0.35, 0.73)	0.4957	
BMI (kg/m2) at enrolment											0.5787
< 30	214	8.44 (1.41)	240	5.52 (1.38)	2.92 (1.54)	(-0.11, 5.95)	0.0592	0.14 (0.09)	(-0.05, 0.32)	0.1406	
>= 30	116	8.23 (2.05)	97	7.05 (2.15)	1.18 (2.73)	(-4.21, 6.56)	0.6671	0.05 (0.14)	(-0.22, 0.32)	0.6946	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Intimate Relationships domain score
Full analysis set

	Anifrolumab 300mg (N=360)		Placebo (N=366)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 12		5.47 (1.72)		2.79 (1.73)	2.68 (2.18)	(-1.60, 6.97)	0.2195				
Week 24		5.49 (1.86)		4.33 (1.86)	1.16 (2.39)	(-3.53, 5.85)	0.6283				
Week 36		6.76 (1.93)		5.49 (1.93)	1.27 (2.49)	(-3.63, 6.16)	0.6106				
Week 52		6.46 (1.87)		4.46 (1.86)	1.99 (2.38)	(-2.70, 6.68)	0.4038				
OVERALL	259	6.05 (1.53)	262	4.27 (1.53)	1.77 (1.85)	(-1.86, 5.41)	0.3373	0.07 (0.09)	(-0.10, 0.24)	0.4117	0.6420

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Intimate Relationships domain score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) N	LSMean (SE)	Placebo (N=366) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.5319
< 10 points	76	7.36 (2.74)	74	3.78 (2.76)	3.59 (3.57)	(-3.46, 10.64)	0.3160	0.15 (0.16)	(-0.17, 0.47)	0.3593	
>= 10 points	183	5.74 (1.77)	188	4.76 (1.77)	0.98 (2.16)	(-3.27, 5.24)	0.6503	0.04 (0.10)	(-0.16, 0.24)	0.6953	
OCS dose at baseline											0.2632
<10 mg/day	123	4.59 (1.96)	122	5.06 (1.96)	-0.47 (2.54)	(-5.47, 4.54)	0.8544	-0.02 (0.13)	(-0.27, 0.23)	0.8666	
>=10 mg/day	136	6.62 (2.49)	140	2.96 (2.46)	3.67 (2.68)	(-1.62, 8.95)	0.1730	0.13 (0.12)	(-0.11, 0.36)	0.2958	
Result of type I IFN gene signature test											0.6396
LOW	51	3.29 (3.47)	52	3.39 (3.38)	-0.11 (4.61)	(-9.27, 9.05)	0.9817	-0.00 (0.20)	(-0.39, 0.38)	0.9827	
HIGH	208	7.89 (1.51)	210	5.64 (1.51)	2.25 (2.01)	(-1.71, 6.21)	0.2640	0.10 (0.10)	(-0.09, 0.29)	0.2931	
Age (years)											NE
<= 65	253	5.69 (1.54)	261	4.13 (1.53)	1.56 (1.85)	(-2.08, 5.20)	0.4009	0.06 (0.09)	(-0.11, 0.24)	0.4738	
> 65	6	NE	1	NE	NE	NE		NE	NE		
Sex											0.4114
male	21	10.85 (3.51)	21	5.85 (3.89)	4.99 (3.89)	(-2.91, 12.89)	0.2081	0.29 (0.31)	(-0.32, 0.90)	0.3524	
female	238	5.96 (1.63)	241	4.56 (1.61)	1.41 (1.97)	(-2.47, 5.29)	0.4768	0.06 (0.09)	(-0.12, 0.24)	0.5402	
Race											0.4231
White	177	6.35 (1.77)	182	5.22 (1.77)	1.13 (2.17)	(-3.14, 5.40)	0.6028	0.05 (0.11)	(-0.16, 0.25)	0.6530	
Black	36	4.30 (4.87)	35	2.95 (4.66)	1.35 (5.93)	(-10.49, 13.19)	0.8209	0.05 (0.24)	(-0.42, 0.51)	0.8434	
Other	41	4.07 (4.86)	41	-3.69 (4.79)	7.76 (4.61)	(-1.43, 16.95)	0.0966	0.25 (0.22)	(-0.19, 0.68)	0.2619	
Ethnicity											0.0340
Hispanic/Latino	62	3.51 (3.10)	64	8.08 (2.89)	-4.57 (3.42)	(-11.35, 2.21)	0.1842	-0.19 (0.18)	(-0.54, 0.16)	0.2840	
Non-hispanic/Latino	192	6.95 (1.80)	194	2.89 (1.81)	4.06 (2.21)	(-0.28, 8.40)	0.0667	0.16 (0.10)	(-0.04, 0.36)	0.1135	
Geographic region											0.1894
EU	86	10.38 (2.85)	87	12.06 (3.00)	-1.67 (3.17)	(-7.93, 4.58)	0.5980	-0.06 (0.15)	(-0.36, 0.24)	0.6871	
non-EU	173	4.83 (1.81)	175	1.40 (1.80)	3.43 (2.25)	(-1.00, 7.85)	0.1289	0.14 (0.11)	(-0.07, 0.35)	0.1817	
Onset of disease											0.0738
Paediatric	15	-0.05 (6.66)	13	11.81 (7.40)	-11.86 (7.65)	(-28.13, 4.41)	0.1413	-0.44 (0.38)	(-1.19, 0.31)	0.2526	
Adult	244	6.29 (1.58)	249	4.06 (1.57)	2.23 (1.91)	(-1.53, 5.99)	0.2444	0.09 (0.09)	(-0.09, 0.27)	0.3177	
ADA result											0.9383
Negative	243	6.15 (1.58)	240	4.65 (1.60)	1.50 (1.93)	(-2.30, 5.31)	0.4376	0.06 (0.09)	(-0.12, 0.24)	0.5048	
Positive (At any time)	16	0.45 (7.19)	22	-0.49 (5.33)	0.94 (6.98)	(-13.37, 15.25)	0.8937	0.03 (0.33)	(-0.61, 0.68)	0.9160	
BMI (kg/m2) at enrolment											0.1835
< 30	164	5.20 (1.88)	183	4.98 (1.83)	0.22 (2.16)	(-4.03, 4.46)	0.9207	0.01 (0.11)	(-0.20, 0.22)	0.9350	
>= 30	95	7.87 (2.65)	79	2.19 (2.80)	5.68 (3.50)	(-1.22, 12.58)	0.1062	0.22 (0.15)	(-0.08, 0.52)	0.1450	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Pain domain score
Full analysis set

	Anifrolumab 300mg (N=360)		Placebo (N=366)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 12		11.85 (1.31)		8.12 (1.31)	3.73 (1.61)	(0.57, 6.89)	0.0208				
Week 24		13.01 (1.35)		9.37 (1.34)	3.64 (1.66)	(0.39, 6.89)	0.0282				
Week 36		12.98 (1.37)		11.94 (1.37)	1.04 (1.70)	(-2.29, 4.37)	0.5406				
Week 52		12.07 (1.43)		9.90 (1.43)	2.17 (1.80)	(-1.36, 5.70)	0.2269				
OVERALL	330	12.48 (1.18)	337	9.83 (1.18)	2.65 (1.38)	(-0.07, 5.36)	0.0563	0.12 (0.08)	(-0.03, 0.27)	0.1128	0.8863

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Pain domain score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) N	LSMean (SE)	Placebo (N=366) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.0952
< 10 points	98	14.46 (2.05)	99	8.17 (2.05)	6.28 (2.60)	(1.15, 11.42)	0.0168	0.31 (0.14)	(0.03, 0.59)	0.0320	
>= 10 points	232	11.91 (1.40)	238	10.76 (1.40)	1.15 (1.64)	(-2.07, 4.37)	0.4832	0.05 (0.09)	(-0.13, 0.23)	0.5623	
OCS dose at baseline											0.7650
<10 mg/day	159	12.72 (1.54)	165	9.63 (1.52)	3.09 (1.93)	(-0.70, 6.88)	0.1093	0.16 (0.11)	(-0.06, 0.38)	0.1548	
>=10 mg/day	171	12.17 (1.88)	172	9.91 (1.89)	2.26 (2.01)	(-1.69, 6.21)	0.2613	0.09 (0.11)	(-0.12, 0.30)	0.3978	
Result of type I IFN gene signature test											0.8953
LOW	58	16.22 (2.58)	60	14.02 (2.54)	2.21 (3.49)	(-4.71, 9.12)	0.5285	0.11 (0.18)	(-0.25, 0.47)	0.5449	
HIGH	272	11.85 (1.14)	277	9.15 (1.13)	2.71 (1.51)	(-0.26, 5.68)	0.0740	0.14 (0.09)	(-0.02, 0.31)	0.0922	
Age (years)											0.4349
<= 65	319	12.53 (1.20)	335	9.92 (1.19)	2.61 (1.40)	(-0.13, 5.35)	0.0618	0.12 (0.08)	(-0.03, 0.27)	0.1230	
> 65	11	13.23 (8.74)	2	24.00 (16.78)	-10.77 (17.07)	(-54.48, 32.95)	0.5557	-0.35 (0.77)	(-1.87, 1.16)	0.6501	
Sex											0.3276
male	26	11.63 (4.54)	24	4.68 (4.98)	6.96 (4.59)	(-2.31, 16.22)	0.1371	0.29 (0.28)	(-0.27, 0.85)	0.3110	
female	304	12.43 (1.23)	313	10.18 (1.22)	2.25 (1.45)	(-0.61, 5.10)	0.1228	0.10 (0.08)	(-0.05, 0.26)	0.1959	
Race											0.0086
White	214	11.57 (1.40)	226	11.90 (1.40)	-0.33 (1.69)	(-3.65, 3.00)	0.8458	-0.02 (0.10)	(-0.20, 0.17)	0.8683	
Black	42	17.94 (4.03)	43	10.21 (3.83)	7.73 (4.52)	(-1.28, 16.73)	0.0915	0.30 (0.22)	(-0.13, 0.73)	0.1708	
Other	68	10.85 (3.23)	62	1.81 (3.31)	9.04 (2.81)	(3.47, 14.61)	0.0017	0.34 (0.18)	(-0.01, 0.69)	0.0540	
Ethnicity											0.9392
Hispanic/Latino	81	15.12 (2.59)	86	12.25 (2.46)	2.86 (2.86)	(-2.79, 8.52)	0.3191	0.12 (0.15)	(-0.18, 0.43)	0.4250	
Non-hispanic/Latino	243	11.27 (1.36)	245	8.66 (1.36)	2.61 (1.61)	(-0.55, 5.78)	0.1054	0.12 (0.09)	(-0.06, 0.30)	0.1769	
Geographic region											0.0388
EU	105	11.66 (2.01)	112	12.87 (2.03)	-1.21 (2.12)	(-5.40, 2.98)	0.5706	-0.06 (0.14)	(-0.32, 0.21)	0.6743	
non-EU	225	12.79 (1.40)	225	8.38 (1.41)	4.40 (1.69)	(1.08, 7.73)	0.0095	0.21 (0.09)	(0.02, 0.39)	0.0271	
Onset of disease											0.1095
Paediatric	20	1.50 (5.48)	21	7.49 (5.12)	-5.99 (5.55)	(-17.28, 5.30)	0.2882	-0.24 (0.31)	(-0.86, 0.37)	0.4354	
Adult	310	13.02 (1.22)	316	9.84 (1.21)	3.18 (1.44)	(0.36, 6.00)	0.0271	0.15 (0.08)	(-0.01, 0.30)	0.0647	
ADA result											0.3836
Negative	308	12.35 (1.21)	304	10.37 (1.23)	1.98 (1.45)	(-0.86, 4.82)	0.1716	0.09 (0.08)	(-0.07, 0.25)	0.2521	
Positive (At any time)	22	14.00 (5.97)	33	7.15 (4.73)	6.85 (5.40)	(-4.05, 17.75)	0.2116	0.25 (0.28)	(-0.30, 0.79)	0.3744	
BMI (kg/m2) at enrolment											0.9758
< 30	214	12.12 (1.46)	240	9.36 (1.43)	2.76 (1.58)	(-0.35, 5.87)	0.0818	0.13 (0.09)	(-0.06, 0.31)	0.1787	
>= 30	116	14.16 (2.08)	97	11.30 (2.18)	2.85 (2.77)	(-2.60, 8.31)	0.3032	0.13 (0.14)	(-0.14, 0.40)	0.3479	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

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Repeated measures model analysis - Lupus QoL Planning domain score
Full analysis set

	Anifrolumab 300mg (N=360)		Placebo (N=366)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 12		7.59 (1.35)		4.58 (1.34)	3.02 (1.65)	(-0.22, 6.25)	0.0675				
Week 24		10.26 (1.39)		7.39 (1.38)	2.87 (1.71)	(-0.48, 6.22)	0.0933				
Week 36		9.37 (1.46)		8.37 (1.46)	1.01 (1.83)	(-2.58, 4.59)	0.5823				
Week 52		9.21 (1.51)		6.83 (1.51)	2.38 (1.90)	(-1.36, 6.11)	0.2117				
OVERALL	330	9.11 (1.25)	337	6.79 (1.24)	2.32 (1.47)	(-0.57, 5.21)	0.1157	0.10 (0.08)	(-0.05, 0.25)	0.1883	0.6995

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

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D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - Lupus QoL Planning domain score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) N	LSMean (SE)	Placebo (N=366) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.2898
< 10 points	98	10.30 (2.14)	99	5.62 (2.16)	4.68 (2.74)	(-0.72, 10.08)	0.0891	0.22 (0.14)	(-0.06, 0.50)	0.1271	
>= 10 points	232	8.67 (1.49)	238	7.43 (1.48)	1.24 (1.75)	(-2.21, 4.68)	0.4801	0.05 (0.09)	(-0.13, 0.24)	0.5556	
OCS dose at baseline											0.9651
<10 mg/day	159	8.29 (1.61)	165	5.75 (1.59)	2.54 (2.03)	(-1.45, 6.53)	0.2108	0.12 (0.11)	(-0.09, 0.34)	0.2635	
>=10 mg/day	171	9.97 (2.00)	172	7.56 (1.99)	2.41 (2.12)	(-1.77, 6.59)	0.2569	0.09 (0.11)	(-0.12, 0.30)	0.3935	
Result of type I IFN gene signature test											0.1844
LOW	58	10.42 (2.64)	60	12.40 (2.61)	-1.98 (3.59)	(-9.10, 5.13)	0.5818	-0.10 (0.18)	(-0.46, 0.26)	0.5965	
HIGH	272	9.23 (1.21)	277	5.99 (1.20)	3.24 (1.61)	(0.07, 6.41)	0.0450	0.16 (0.09)	(-0.01, 0.33)	0.0581	
Age (years)											0.6666
<= 65	319	8.86 (1.27)	335	6.74 (1.25)	2.12 (1.49)	(-0.80, 5.03)	0.1548	0.09 (0.08)	(-0.06, 0.25)	0.2368	
> 65	11	18.53 (5.61)	2	12.04 (8.70)	6.49 (10.05)	(-27.53, 40.52)	0.5688	0.33 (0.77)	(-1.18, 1.85)	0.6663	
Sex											0.1249
male	26	17.90 (4.83)	24	8.03 (5.25)	9.87 (5.07)	(-0.35, 20.09)	0.0580	0.39 (0.29)	(-0.17, 0.95)	0.1767	
female	304	8.55 (1.29)	313	6.80 (1.27)	1.75 (1.52)	(-1.25, 4.74)	0.2518	0.08 (0.08)	(-0.08, 0.24)	0.3339	
Race											0.3698
White	214	9.37 (1.52)	226	8.66 (1.52)	0.71 (1.86)	(-2.94, 4.36)	0.7023	0.03 (0.10)	(-0.16, 0.22)	0.7418	
Black	42	12.00 (3.82)	43	7.06 (3.72)	4.94 (4.40)	(-3.81, 13.70)	0.2646	0.20 (0.22)	(-0.23, 0.63)	0.3598	
Other	68	5.76 (3.55)	62	0.54 (3.60)	5.21 (3.07)	(-0.87, 11.29)	0.0924	0.18 (0.18)	(-0.17, 0.52)	0.3073	
Ethnicity											0.8700
Hispanic/Latino	81	11.76 (2.82)	86	9.63 (2.68)	2.13 (3.14)	(-4.07, 8.32)	0.4985	0.08 (0.15)	(-0.22, 0.39)	0.5864	
Non-hispanic/Latino	243	8.34 (1.42)	245	5.63 (1.42)	2.71 (1.69)	(-0.60, 6.03)	0.1088	0.12 (0.09)	(-0.06, 0.30)	0.1771	
Geographic region											0.1121
EU	105	11.74 (2.14)	112	12.56 (2.17)	-0.82 (2.29)	(-5.33, 3.68)	0.7188	-0.04 (0.14)	(-0.30, 0.23)	0.7881	
non-EU	225	8.16 (1.50)	225	4.34 (1.51)	3.83 (1.83)	(0.23, 7.42)	0.0369	0.17 (0.09)	(-0.02, 0.35)	0.0738	
Onset of disease											0.0711
Paediatric	20	-1.71 (5.38)	21	5.72 (5.05)	-7.43 (5.45)	(-18.52, 3.66)	0.1820	-0.31 (0.31)	(-0.93, 0.31)	0.3260	
Adult	310	9.62 (1.29)	316	6.84 (1.28)	2.78 (1.53)	(-0.21, 5.78)	0.0687	0.12 (0.08)	(-0.03, 0.28)	0.1257	
ADA result											0.9533
Negative	308	9.20 (1.29)	304	7.20 (1.30)	2.01 (1.55)	(-1.03, 5.05)	0.1948	0.09 (0.08)	(-0.07, 0.25)	0.2742	
Positive (At any time)	22	7.77 (5.52)	33	5.45 (4.39)	2.32 (5.15)	(-8.04, 12.69)	0.6538	0.09 (0.28)	(-0.45, 0.63)	0.7441	
BMI (kg/m2) at enrolment											0.8359
< 30	214	8.65 (1.58)	240	6.25 (1.55)	2.39 (1.73)	(-1.00, 5.79)	0.1665	0.10 (0.09)	(-0.08, 0.29)	0.2814	
>= 30	116	11.02 (2.10)	97	7.95 (2.20)	3.07 (2.79)	(-2.43, 8.58)	0.2721	0.14 (0.14)	(-0.13, 0.41)	0.3158	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SDI Global Score
Full analysis set

	Anifrolumab 300mg (N=360)		Placebo (N=366)		Difference of						
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 24		0.03 (0.01)		0.02 (0.01)	0.01 (0.01)	(-0.01, 0.04)	0.3535				
Week 52		0.07 (0.02)		0.04 (0.02)	0.03 (0.02)	(-0.01, 0.07)	0.1839				
OVERALL	322	0.05 (0.01)	317	0.03 (0.01)	0.02 (0.02)	(-0.01, 0.05)	0.1924	0.09 (0.08)	(-0.07, 0.24)	0.2667	0.1938

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SDI Global Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) N	LSMean (SE)	Placebo (N=366) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.0469
< 10 points	95	0.08 (0.03)	91	0.01 (0.02)	0.07 (0.03)	(0.01, 0.14)	0.0262	0.30 (0.15)	(0.01, 0.59)	0.0414	
>= 10 points	227	0.03 (0.01)	226	0.03 (0.02)	-0.00 (0.02)	(-0.04, 0.03)	0.9673	-0.00 (0.09)	(-0.19, 0.18)	0.9726	
OCS dose at baseline											0.9538
<10 mg/day	156	0.05 (0.02)	161	0.03 (0.02)	0.02 (0.02)	(-0.02, 0.06)	0.3411	0.10 (0.11)	(-0.12, 0.32)	0.3890	
>=10 mg/day	166	0.04 (0.02)	156	0.02 (0.02)	0.02 (0.02)	(-0.03, 0.06)	0.4066	0.07 (0.11)	(-0.15, 0.29)	0.5222	
Result of type I IFN gene signature test											0.6962
LOW	54	0.02 (0.02)	51	0.02 (0.03)	0.01 (0.04)	(-0.06, 0.08)	0.8505	0.04 (0.20)	(-0.35, 0.42)	0.8527	
HIGH	268	0.06 (0.01)	266	0.04 (0.01)	0.02 (0.02)	(-0.01, 0.06)	0.2169	0.10 (0.09)	(-0.07, 0.27)	0.2417	
Age (years)											NE
<= 65	314	0.05 (0.01)	314	0.03 (0.01)	0.02 (0.02)	(-0.01, 0.06)	0.1172	0.11 (0.08)	(-0.05, 0.26)	0.1829	
> 65	8	NE	3	NE	NE	NE		NE	NE		
Sex											0.7531
male	25	0.02 (0.05)	24	0.02 (0.06)	0.00 (0.06)	(-0.12, 0.13)	0.9753	0.01 (0.29)	(-0.55, 0.57)	0.9807	
female	297	0.05 (0.01)	293	0.03 (0.01)	0.02 (0.02)	(-0.01, 0.05)	0.1819	0.09 (0.08)	(-0.07, 0.26)	0.2509	
Race											0.9428
White	212	0.04 (0.01)	205	0.02 (0.01)	0.02 (0.02)	(-0.01, 0.06)	0.1691	0.12 (0.10)	(-0.07, 0.31)	0.2245	
Black	37	0.14 (0.06)	46	0.11 (0.05)	0.03 (0.06)	(-0.10, 0.16)	0.6416	0.08 (0.22)	(-0.35, 0.51)	0.7119	
Other	67	0.04 (0.04)	60	0.03 (0.04)	0.01 (0.04)	(-0.07, 0.09)	0.7998	0.03 (0.18)	(-0.32, 0.38)	0.8676	
Ethnicity											0.8923
Hispanic/Latino	78	0.06 (0.03)	77	0.05 (0.03)	0.02 (0.04)	(-0.06, 0.09)	0.6301	0.06 (0.16)	(-0.25, 0.38)	0.6875	
Non-hispanic/Latino	238	0.05 (0.01)	234	0.02 (0.01)	0.02 (0.02)	(-0.01, 0.06)	0.1867	0.10 (0.09)	(-0.08, 0.28)	0.2622	
Geographic region											0.3466
EU	107	0.05 (0.02)	105	0.01 (0.02)	0.04 (0.02)	(-0.01, 0.09)	0.1004	0.18 (0.14)	(-0.09, 0.45)	0.2023	
non-EU	215	0.05 (0.02)	212	0.04 (0.02)	0.01 (0.02)	(-0.03, 0.05)	0.6038	0.04 (0.10)	(-0.15, 0.23)	0.6525	
Onset of disease											NE
Paediatric	22	NE	18	NE	NE	NE		NE	NE		
Adult	300	0.05 (0.01)	299	0.03 (0.01)	0.02 (0.02)	(-0.01, 0.05)	0.2662	0.08 (0.08)	(-0.08, 0.24)	0.3422	
ADA result											NE
Negative	302	0.05 (0.01)	288	0.03 (0.01)	0.02 (0.02)	(-0.02, 0.05)	0.2995	0.07 (0.08)	(-0.09, 0.23)	0.3727	
Positive (At any time)	20	NE	29	NE	NE	NE		NE	NE		
BMI (kg/m2) at enrolment											0.2886
< 30	213	0.03 (0.02)	226	0.03 (0.02)	0.01 (0.02)	(-0.03, 0.04)	0.6562	0.03 (0.10)	(-0.15, 0.22)	0.7146	
>= 30	109	0.07 (0.02)	91	0.03 (0.03)	0.05 (0.03)	(-0.02, 0.11)	0.1389	0.19 (0.14)	(-0.09, 0.47)	0.1821	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - NRS Score
Full analysis set

Visit	Anifrolumab 300mg (N=360) N	Anifrolumab 300mg (N=360) LSMean (SE)	Placebo (N=366) N	Placebo (N=366) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		-0.38 (0.12)		-0.33 (0.12)	-0.06 (0.14)	(-0.34, 0.22)	0.6945				
Week 8		-0.88 (0.13)		-0.32 (0.12)	-0.56 (0.16)	(-0.87, -0.25)	0.0004				
Week 12		-1.04 (0.13)		-0.66 (0.13)	-0.38 (0.17)	(-0.71, -0.05)	0.0255				
Week 16		-1.06 (0.13)		-0.76 (0.13)	-0.30 (0.17)	(-0.63, 0.03)	0.0786				
Week 20		-0.95 (0.14)		-0.88 (0.14)	-0.07 (0.18)	(-0.42, 0.28)	0.6885				
Week 24		-1.07 (0.13)		-0.64 (0.13)	-0.43 (0.17)	(-0.76, -0.09)	0.0120				
Week 28		-1.04 (0.14)		-0.77 (0.14)	-0.27 (0.18)	(-0.62, 0.08)	0.1342				
Week 32		-0.94 (0.14)		-0.77 (0.14)	-0.17 (0.18)	(-0.52, 0.18)	0.3452				
Week 36		-1.12 (0.14)		-0.97 (0.14)	-0.16 (0.18)	(-0.51, 0.20)	0.3867				
Week 40		-1.11 (0.15)		-0.80 (0.14)	-0.32 (0.19)	(-0.69, 0.06)	0.0953				
Week 44		-1.12 (0.14)		-0.96 (0.14)	-0.16 (0.19)	(-0.53, 0.20)	0.3865				
Week 48		-1.09 (0.15)		-0.77 (0.15)	-0.33 (0.19)	(-0.70, 0.04)	0.0821				
Week 52		-0.98 (0.15)		-0.72 (0.15)	-0.26 (0.19)	(-0.63, 0.12)	0.1760				
OVERALL	340	-0.98 (0.11)	345	-0.72 (0.11)	-0.27 (0.13)	(-0.52, -0.01)	0.0415	-0.13 (0.08)	(-0.28, 0.02)	0.0833	0.8670

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - NRS Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) N	LSMean (SE)	Placebo (N=366) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.1477
< 10 points	102	-1.17 (0.20)	101	-0.61 (0.20)	-0.56 (0.25)	(-1.06, -0.07)	0.0261	-0.28 (0.14)	(-0.56, -0.01)	0.0447	
>= 10 points	238	-0.96 (0.13)	244	-0.82 (0.13)	-0.14 (0.15)	(-0.44, 0.16)	0.3644	-0.07 (0.09)	(-0.25, 0.11)	0.4408	
OCS dose at baseline											0.0776
<10 mg/day	163	-1.08 (0.14)	169	-0.58 (0.14)	-0.50 (0.18)	(-0.86, -0.15)	0.0056	-0.27 (0.11)	(-0.49, -0.06)	0.0128	
>=10 mg/day	177	-0.88 (0.17)	176	-0.84 (0.17)	-0.04 (0.19)	(-0.41, 0.33)	0.8174	-0.02 (0.11)	(-0.23, 0.19)	0.8574	
Result of type I IFN gene signature test											0.1807
LOW	58	-0.87 (0.22)	60	-0.97 (0.21)	0.10 (0.29)	(-0.48, 0.67)	0.7455	0.06 (0.18)	(-0.30, 0.42)	0.7542	
HIGH	282	-1.15 (0.11)	285	-0.81 (0.11)	-0.34 (0.14)	(-0.63, -0.06)	0.0184	-0.19 (0.08)	(-0.35, -0.02)	0.0249	
Age (years)											NE
<= 65	329	-0.98 (0.11)	343	-0.70 (0.11)	-0.28 (0.13)	(-0.54, -0.02)	0.0327	-0.14 (0.08)	(-0.29, 0.01)	0.0713	
> 65	11	NE	2	NE	NE	NE		NE	NE		
Sex											0.8624
male	26	-0.96 (0.45)	24	-0.77 (0.49)	-0.19 (0.43)	(-1.06, 0.67)	0.6571	-0.08 (0.28)	(-0.64, 0.47)	0.7751	
female	314	-0.99 (0.11)	321	-0.72 (0.11)	-0.27 (0.14)	(-0.54, -0.00)	0.0494	-0.13 (0.08)	(-0.29, 0.02)	0.0920	
Race											0.1032
White	220	-1.00 (0.13)	230	-0.85 (0.13)	-0.16 (0.16)	(-0.47, 0.15)	0.3182	-0.08 (0.09)	(-0.27, 0.10)	0.3845	
Black	44	-1.38 (0.35)	43	-0.33 (0.33)	-1.05 (0.41)	(-1.87, -0.24)	0.0119	-0.46 (0.22)	(-0.89, -0.04)	0.0330	
Other	70	-0.48 (0.31)	65	-0.40 (0.32)	-0.08 (0.28)	(-0.63, 0.47)	0.7787	-0.03 (0.17)	(-0.37, 0.31)	0.8623	
Ethnicity											0.0804
Hispanic/Latino	83	-1.69 (0.23)	87	-1.05 (0.22)	-0.64 (0.25)	(-1.13, -0.14)	0.0119	-0.31 (0.15)	(-0.61, -0.01)	0.0439	
Non-hispanic/Latino	251	-0.79 (0.13)	251	-0.66 (0.13)	-0.12 (0.15)	(-0.42, 0.18)	0.4173	-0.06 (0.09)	(-0.24, 0.11)	0.4855	
Geographic region											0.0055
EU	107	-0.91 (0.21)	116	-1.16 (0.21)	0.24 (0.23)	(-0.21, 0.69)	0.2888	0.11 (0.13)	(-0.15, 0.37)	0.4183	
non-EU	233	-1.04 (0.13)	229	-0.52 (0.13)	-0.52 (0.16)	(-0.83, -0.22)	0.0008	-0.27 (0.09)	(-0.46, -0.09)	0.0036	
Onset of disease											0.1207
Paediatric	22	-0.66 (0.48)	22	0.33 (0.46)	-0.99 (0.47)	(-1.93, -0.05)	0.0405	-0.44 (0.31)	(-1.04, 0.16)	0.1520	
Adult	318	-1.01 (0.11)	323	-0.78 (0.11)	-0.24 (0.14)	(-0.50, 0.03)	0.0823	-0.12 (0.08)	(-0.27, 0.04)	0.1372	
ADA result											0.0984
Negative	316	-0.91 (0.11)	311	-0.70 (0.11)	-0.20 (0.14)	(-0.47, 0.07)	0.1392	-0.10 (0.08)	(-0.26, 0.06)	0.2054	
Positive (At any time)	24	-2.24 (0.48)	34	-1.23 (0.39)	-1.01 (0.47)	(-1.96, -0.07)	0.0364	-0.44 (0.27)	(-0.97, 0.09)	0.1047	
BMI (kg/m2) at enrolment											0.0430
< 30	221	-0.96 (0.14)	245	-0.86 (0.14)	-0.10 (0.16)	(-0.41, 0.21)	0.5221	-0.05 (0.09)	(-0.23, 0.13)	0.6102	
>= 30	119	-1.14 (0.18)	100	-0.47 (0.19)	-0.67 (0.24)	(-1.14, -0.21)	0.0050	-0.35 (0.14)	(-0.62, -0.09)	0.0096	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - PHQ-8 Total Score
Full analysis set

	Anifrolumab 300mg (N=360)		Placebo (N=366)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 12		-1.48 (0.30)		-1.14 (0.30)	-0.35 (0.36)	(-1.06, 0.37)	0.3383				
Week 24		-1.88 (0.30)		-1.42 (0.30)	-0.46 (0.37)	(-1.20, 0.27)	0.2152				
Week 36		-2.00 (0.31)		-1.35 (0.31)	-0.65 (0.39)	(-1.42, 0.12)	0.0957				
Week 52		-1.90 (0.33)		-1.35 (0.33)	-0.55 (0.42)	(-1.38, 0.28)	0.1930				
OVERALL	332	-1.82 (0.27)	337	-1.31 (0.27)	-0.50 (0.32)	(-1.13, 0.12)	0.1137	-0.10 (0.08)	(-0.25, 0.05)	0.1873	0.9790

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - PHQ-8 Total Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) N	LSMean (SE)	Placebo (N=366) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.0290
< 10 points	98	-2.45 (0.43)	99	-0.92 (0.43)	-1.53 (0.55)	(-2.61, -0.45)	0.0059	-0.35 (0.14)	(-0.64, -0.07)	0.0135	
>= 10 points	234	-1.53 (0.33)	238	-1.47 (0.33)	-0.06 (0.39)	(-0.82, 0.70)	0.8706	-0.01 (0.09)	(-0.19, 0.17)	0.8924	
OCS dose at baseline											0.8721
<10 mg/day	159	-1.71 (0.36)	165	-1.14 (0.36)	-0.57 (0.45)	(-1.46, 0.32)	0.2078	-0.12 (0.11)	(-0.34, 0.09)	0.2633	
>=10 mg/day	173	-1.91 (0.42)	172	-1.44 (0.42)	-0.47 (0.45)	(-1.35, 0.42)	0.2988	-0.08 (0.11)	(-0.30, 0.13)	0.4310	
Result of type I IFN gene signature test											0.7245
LOW	58	-2.73 (0.60)	60	-1.96 (0.59)	-0.77 (0.81)	(-2.38, 0.83)	0.3434	-0.17 (0.18)	(-0.53, 0.19)	0.3613	
HIGH	274	-1.63 (0.26)	277	-1.17 (0.26)	-0.46 (0.35)	(-1.14, 0.22)	0.1854	-0.11 (0.09)	(-0.27, 0.06)	0.2118	
Age (years)											0.6047
<= 65	321	-1.81 (0.28)	335	-1.31 (0.27)	-0.49 (0.32)	(-1.13, 0.14)	0.1244	-0.10 (0.08)	(-0.25, 0.05)	0.2031	
> 65	11	-2.79 (0.95)	2	-1.20 (1.90)	-1.59 (2.09)	(-6.35, 3.17)	0.4673	-0.48 (0.78)	(-2.00, 1.05)	0.5403	
Sex											0.6670
male	26	-3.32 (1.18)	24	-2.34 (1.32)	-0.99 (1.20)	(-3.41, 1.44)	0.4174	-0.16 (0.28)	(-0.71, 0.40)	0.5840	
female	306	-1.72 (0.28)	313	-1.28 (0.28)	-0.45 (0.33)	(-1.10, 0.20)	0.1743	-0.09 (0.08)	(-0.25, 0.07)	0.2535	
Race											0.2877
White	215	-1.63 (0.33)	226	-1.52 (0.33)	-0.11 (0.40)	(-0.89, 0.67)	0.7791	-0.02 (0.10)	(-0.21, 0.16)	0.8101	
Black	43	-3.15 (0.86)	43	-1.79 (0.83)	-1.35 (1.00)	(-3.34, 0.64)	0.1807	-0.24 (0.22)	(-0.67, 0.18)	0.2641	
Other	68	-1.62 (0.76)	62	-0.52 (0.76)	-1.10 (0.67)	(-2.42, 0.22)	0.1006	-0.18 (0.18)	(-0.52, 0.17)	0.3117	
Ethnicity											0.9096
Hispanic/Latino	81	-2.12 (0.66)	86	-1.68 (0.63)	-0.44 (0.73)	(-1.89, 1.01)	0.5501	-0.07 (0.15)	(-0.38, 0.23)	0.6309	
Non-hispanic/Latino	245	-1.69 (0.30)	245	-1.16 (0.30)	-0.53 (0.35)	(-1.22, 0.16)	0.1302	-0.11 (0.09)	(-0.29, 0.06)	0.2053	
Geographic region											0.3016
EU	106	-2.16 (0.46)	112	-2.07 (0.46)	-0.09 (0.48)	(-1.04, 0.87)	0.8600	-0.02 (0.14)	(-0.28, 0.25)	0.8966	
non-EU	226	-1.69 (0.34)	225	-0.95 (0.34)	-0.74 (0.41)	(-1.54, 0.06)	0.0710	-0.15 (0.09)	(-0.33, 0.04)	0.1219	
Onset of disease											0.7547
Paediatric	21	-1.93 (1.32)	21	-1.02 (1.23)	-0.91 (1.29)	(-3.54, 1.73)	0.4893	-0.15 (0.31)	(-0.76, 0.45)	0.6226	
Adult	311	-1.85 (0.28)	316	-1.36 (0.28)	-0.49 (0.33)	(-1.14, 0.16)	0.1401	-0.10 (0.08)	(-0.26, 0.06)	0.2160	
ADA result											0.4807
Negative	309	-1.78 (0.28)	304	-1.38 (0.28)	-0.40 (0.34)	(-1.06, 0.26)	0.2360	-0.08 (0.08)	(-0.24, 0.08)	0.3193	
Positive (At any time)	23	-1.92 (1.12)	33	-0.75 (0.90)	-1.17 (1.05)	(-3.28, 0.93)	0.2679	-0.22 (0.27)	(-0.75, 0.31)	0.4186	
BMI (kg/m2) at enrolment											0.8121
< 30	216	-1.77 (0.33)	240	-1.27 (0.32)	-0.50 (0.36)	(-1.21, 0.21)	0.1661	-0.10 (0.09)	(-0.28, 0.08)	0.2825	
>= 30	116	-2.04 (0.48)	97	-1.37 (0.50)	-0.67 (0.64)	(-1.93, 0.58)	0.2910	-0.13 (0.14)	(-0.40, 0.14)	0.3366	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - PtGA
Full analysis set

Visit	Anifrolumab 300mg (N=360) N	Anifrolumab 300mg (N=360) LSMean (SE)	Placebo (N=366) N	Placebo (N=366) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		-6.43 (1.24)		-5.67 (1.23)	-0.76 (1.54)	(-3.80, 2.27)	0.6215				
Week 8		-8.75 (1.32)		-5.76 (1.30)	-2.99 (1.66)	(-6.25, 0.28)	0.0730				
Week 12		-11.44 (1.38)		-7.83 (1.37)	-3.61 (1.77)	(-7.08, -0.14)	0.0417				
Week 16		-8.39 (1.44)		-8.65 (1.42)	0.26 (1.85)	(-3.38, 3.90)	0.8877				
Week 20		-10.63 (1.39)		-10.69 (1.37)	0.06 (1.78)	(-3.43, 3.56)	0.9719				
Week 24		-9.89 (1.46)		-7.17 (1.44)	-2.72 (1.88)	(-6.41, 0.98)	0.1490				
Week 28		-11.49 (1.47)		-10.19 (1.46)	-1.30 (1.90)	(-5.03, 2.43)	0.4944				
Week 32		-10.25 (1.48)		-9.73 (1.48)	-0.53 (1.93)	(-4.32, 3.27)	0.7850				
Week 36		-13.48 (1.41)		-11.75 (1.41)	-1.73 (1.82)	(-5.31, 1.85)	0.3421				
Week 40		-10.97 (1.51)		-9.46 (1.50)	-1.51 (1.97)	(-5.38, 2.36)	0.4433				
Week 44		-11.41 (1.46)		-12.93 (1.47)	1.52 (1.91)	(-2.23, 5.27)	0.4260				
Week 48		-12.32 (1.52)		-9.54 (1.53)	-2.78 (2.00)	(-6.70, 1.14)	0.1641				
Week 52		-10.86 (1.58)		-8.26 (1.59)	-2.60 (2.09)	(-6.70, 1.50)	0.2130				
OVERALL	340	-10.49 (1.10)	345	-9.05 (1.09)	-1.44 (1.32)	(-4.02, 1.15)	0.2755	-0.07 (0.08)	(-0.22, 0.08)	0.3537	0.5248

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - PtGA - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) N	LSMean (SE)	Placebo (N=366) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.1206
< 10 points	102	-11.22 (1.93)	101	-6.53 (1.95)	-4.69 (2.46)	(-9.54, 0.16)	0.0578	-0.24 (0.14)	(-0.52, 0.04)	0.0893	
>= 10 points	238	-10.56 (1.30)	244	-10.38 (1.29)	-0.18 (1.55)	(-3.23, 2.88)	0.9091	-0.01 (0.09)	(-0.19, 0.17)	0.9227	
OCS dose at baseline											0.6663
<10 mg/day	163	-9.31 (1.42)	169	-8.47 (1.41)	-0.84 (1.80)	(-4.37, 2.70)	0.6416	-0.05 (0.11)	(-0.26, 0.17)	0.6769	
>=10 mg/day	177	-11.48 (1.73)	176	-9.51 (1.73)	-1.97 (1.92)	(-5.74, 1.80)	0.3049	-0.09 (0.11)	(-0.29, 0.12)	0.4219	
Result of type I IFN gene signature test											0.0238
LOW	58	-7.32 (2.24)	60	-12.32 (2.23)	5.00 (3.08)	(-1.09, 11.10)	0.1067	0.29 (0.19)	(-0.07, 0.65)	0.1176	
HIGH	282	-12.08 (1.08)	285	-9.39 (1.08)	-2.69 (1.46)	(-5.55, 0.17)	0.0652	-0.15 (0.08)	(-0.31, 0.02)	0.0792	
Age (years)											NE
<= 65	329	-10.48 (1.12)	343	-9.00 (1.10)	-1.48 (1.33)	(-4.08, 1.13)	0.2667	-0.07 (0.08)	(-0.22, 0.08)	0.3473	
> 65	11	NE	2	NE	NE	NE		NE	NE		
Sex											0.4402
male	26	-15.77 (4.22)	24	-17.70 (4.61)	1.93 (4.35)	(-6.85, 10.71)	0.6590	0.09 (0.28)	(-0.47, 0.64)	0.7605	
female	314	-10.30 (1.14)	321	-8.71 (1.13)	-1.59 (1.37)	(-4.29, 1.11)	0.2485	-0.08 (0.08)	(-0.23, 0.08)	0.3217	
Race											0.0636
White	220	-10.30 (1.34)	230	-11.00 (1.33)	0.70 (1.64)	(-2.53, 3.93)	0.6710	0.03 (0.09)	(-0.15, 0.22)	0.7118	
Black	44	-10.47 (2.86)	43	-2.66 (2.72)	-7.81 (3.32)	(-14.43, -1.19)	0.0214	-0.42 (0.22)	(-0.85, 0.00)	0.0527	
Other	70	-8.22 (3.29)	65	-5.57 (3.37)	-2.64 (3.05)	(-8.68, 3.40)	0.3884	-0.10 (0.17)	(-0.43, 0.24)	0.5777	
Ethnicity											0.1466
Hispanic/Latino	83	-17.62 (2.40)	87	-12.91 (2.30)	-4.71 (2.65)	(-9.95, 0.53)	0.0780	-0.22 (0.15)	(-0.52, 0.09)	0.1600	
Non-hispanic/Latino	251	-8.37 (1.25)	251	-8.11 (1.26)	-0.27 (1.52)	(-3.26, 2.73)	0.8619	-0.01 (0.09)	(-0.19, 0.16)	0.8814	
Geographic region											0.0017
EU	107	-11.58 (2.03)	116	-15.86 (2.05)	4.28 (2.20)	(-0.07, 8.62)	0.0536	0.20 (0.13)	(-0.07, 0.46)	0.1418	
non-EU	233	-10.27 (1.30)	229	-5.99 (1.31)	-4.28 (1.60)	(-7.43, -1.14)	0.0078	-0.22 (0.09)	(-0.40, -0.03)	0.0209	
Onset of disease											0.3412
Paediatric	22	-11.74 (4.88)	22	-5.33 (4.67)	-6.41 (5.11)	(-16.87, 4.05)	0.2198	-0.28 (0.30)	(-0.88, 0.31)	0.3537	
Adult	318	-10.77 (1.13)	323	-9.39 (1.13)	-1.38 (1.37)	(-4.06, 1.31)	0.3147	-0.07 (0.08)	(-0.22, 0.09)	0.3899	
ADA result											0.0632
Negative	316	-10.08 (1.14)	311	-9.39 (1.15)	-0.69 (1.39)	(-3.41, 2.04)	0.6209	-0.03 (0.08)	(-0.19, 0.12)	0.6723	
Positive (At any time)	24	-17.21 (4.19)	34	-8.09 (3.26)	-9.12 (4.33)	(-17.80, -0.44)	0.0397	-0.46 (0.27)	(-0.99, 0.07)	0.0900	
BMI (kg/m2) at enrolment											0.0017
< 30	221	-9.80 (1.40)	245	-10.94 (1.37)	1.14 (1.57)	(-1.95, 4.23)	0.4684	0.05 (0.09)	(-0.13, 0.24)	0.5617	
>= 30	119	-12.93 (1.76)	100	-5.25 (1.84)	-7.68 (2.33)	(-12.27, -3.10)	0.0011	-0.41 (0.14)	(-0.68, -0.14)	0.0030	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SLEDAI-2K Total Score
Full analysis set

Visit	Anifrolumab 300mg (N=360) n/ N#	Anifrolumab 300mg (N=360) Compliance	Placebo (N=366) n/ N#	Placebo (N=366) Compliance
Baseline	360/ 360	100.0%	366/ 366	100.0%
Week 4	347/ 360	96.39%	356/ 366	97.27%
Week 8	341/ 360	94.72%	349/ 366	95.36%
Week 12	342/ 359	95.26%	340/ 366	92.90%
Week 16	336/ 359	93.59%	339/ 366	92.62%
Week 20	325/ 359	90.53%	337/ 366	92.08%
Week 24	327/ 359	91.09%	327/ 366	89.34%
Week 28	322/ 359	89.69%	320/ 366	87.43%
Week 32	315/ 358	87.99%	312/ 366	85.25%
Week 36	314/ 358	87.71%	315/ 366	86.07%
Week 40	310/ 358	86.59%	302/ 365	82.74%
Week 44	300/ 358	83.80%	302/ 365	82.74%
Week 48	306/ 358	85.47%	294/ 365	80.55%
Week 52	295/ 358	82.40%	288/ 365	78.90%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - PGA
Full analysis set

Visit	Anifrolumab 300mg (N=360) n/ N#	Anifrolumab 300mg (N=360) Compliance	Placebo (N=366) n/ N#	Placebo (N=366) Compliance
Baseline	360/ 360	100.0%	366/ 366	100.0%
Week 4	352/ 360	97.78%	362/ 366	98.91%
Week 8	346/ 360	96.11%	354/ 366	96.72%
Week 12	343/ 359	95.54%	345/ 366	94.26%
Week 16	340/ 359	94.71%	342/ 366	93.44%
Week 20	323/ 359	89.97%	341/ 366	93.17%
Week 24	329/ 359	91.64%	334/ 366	91.26%
Week 28	322/ 359	89.69%	326/ 366	89.07%
Week 32	318/ 358	88.83%	315/ 366	86.07%
Week 36	319/ 358	89.11%	311/ 366	84.97%
Week 40	313/ 358	87.43%	311/ 365	85.21%
Week 44	302/ 358	84.36%	304/ 365	83.29%
Week 48	309/ 358	86.31%	296/ 365	81.10%
Week 52	296/ 358	82.68%	290/ 365	79.45%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - CLASI Total Activity Score
Full analysis set

Visit	Anifrolumab 300mg (N=360) n/ N#	Anifrolumab 300mg (N=360) Compliance	Placebo (N=366) n/ N#	Placebo (N=366) Compliance
Baseline	360/ 360	100.0%	366/ 366	100.0%
Week 4	352/ 360	97.78%	363/ 366	99.18%
Week 8	346/ 360	96.11%	354/ 366	96.72%
Week 12	345/ 359	96.10%	346/ 366	94.54%
Week 16	343/ 359	95.54%	342/ 366	93.44%
Week 20	328/ 359	91.36%	343/ 366	93.72%
Week 24	329/ 359	91.64%	334/ 366	91.26%
Week 28	323/ 359	89.97%	327/ 366	89.34%
Week 32	319/ 358	89.11%	315/ 366	86.07%
Week 36	316/ 358	88.27%	315/ 366	86.07%
Week 40	313/ 358	87.43%	311/ 365	85.21%
Week 44	305/ 358	85.20%	306/ 365	83.84%
Week 48	309/ 358	86.31%	297/ 365	81.37%
Week 52	296/ 358	82.68%	291/ 365	79.73%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - CLASI Total Damage Score
Full analysis set

Visit	Anifrolumab 300mg (N=360) n/ N#	Anifrolumab 300mg (N=360) Compliance	Placebo (N=366) n/ N#	Placebo (N=366) Compliance
Baseline	360/ 360	100.0%	366/ 366	100.0%
Week 4	353/ 360	98.06%	362/ 366	98.91%
Week 8	346/ 360	96.11%	354/ 366	96.72%
Week 12	345/ 359	96.10%	347/ 366	94.81%
Week 16	343/ 359	95.54%	342/ 366	93.44%
Week 20	328/ 359	91.36%	343/ 366	93.72%
Week 24	329/ 359	91.64%	334/ 366	91.26%
Week 28	323/ 359	89.97%	327/ 366	89.34%
Week 32	319/ 358	89.11%	315/ 366	86.07%
Week 36	316/ 358	88.27%	315/ 366	86.07%
Week 40	313/ 358	87.43%	310/ 365	84.93%
Week 44	304/ 358	84.92%	306/ 365	83.84%
Week 48	309/ 358	86.31%	297/ 365	81.37%
Week 52	296/ 358	82.68%	291/ 365	79.73%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - BILAG Global Score
Full analysis set

Visit	Anifrolumab 300mg (N=360) n/ N#	Anifrolumab 300mg (N=360) Compliance	Placebo (N=366) n/ N#	Placebo (N=366) Compliance
Baseline	360/ 360	100.0%	366/ 366	100.0%
Week 4	351/ 360	97.50%	360/ 366	98.36%
Week 8	345/ 360	95.83%	353/ 366	96.45%
Week 12	346/ 359	96.38%	346/ 366	94.54%
Week 16	343/ 359	95.54%	340/ 366	92.90%
Week 20	328/ 359	91.36%	341/ 366	93.17%
Week 24	329/ 359	91.64%	332/ 366	90.71%
Week 28	323/ 359	89.97%	325/ 366	88.80%
Week 32	320/ 358	89.39%	314/ 366	85.79%
Week 36	315/ 358	87.99%	312/ 366	85.25%
Week 40	311/ 358	86.87%	307/ 365	84.11%
Week 44	302/ 358	84.36%	303/ 365	83.01%
Week 48	309/ 358	86.31%	295/ 365	80.82%
Week 52	296/ 358	82.68%	289/ 365	79.18%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Tender Joint Count
Full analysis set

Visit	Anifrolumab 300mg (N=360) n/ N#	Anifrolumab 300mg (N=360) Compliance	Placebo (N=366) n/ N#	Placebo (N=366) Compliance
Baseline	360/ 360	100.0%	366/ 366	100.0%
Week 4	352/ 360	97.78%	362/ 366	98.91%
Week 8	345/ 360	95.83%	354/ 366	96.72%
Week 12	346/ 359	96.38%	347/ 366	94.81%
Week 16	342/ 359	95.26%	343/ 366	93.72%
Week 20	327/ 359	91.09%	342/ 366	93.44%
Week 24	329/ 359	91.64%	333/ 366	90.98%
Week 28	322/ 359	89.69%	327/ 366	89.34%
Week 32	320/ 358	89.39%	315/ 366	86.07%
Week 36	317/ 358	88.55%	315/ 366	86.07%
Week 40	314/ 358	87.71%	310/ 365	84.93%
Week 44	303/ 358	84.64%	306/ 365	83.84%
Week 48	308/ 358	86.03%	297/ 365	81.37%
Week 52	295/ 358	82.40%	291/ 365	79.73%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Swollen Joint Count
Full analysis set

Visit	Anifrolumab 300mg (N=360) n/ N#	Anifrolumab 300mg (N=360) Compliance	Placebo (N=366) n/ N#	Placebo (N=366) Compliance
Baseline	360/ 360	100.0%	366/ 366	100.0%
Week 4	352/ 360	97.78%	362/ 366	98.91%
Week 8	345/ 360	95.83%	354/ 366	96.72%
Week 12	346/ 359	96.38%	347/ 366	94.81%
Week 16	342/ 359	95.26%	343/ 366	93.72%
Week 20	327/ 359	91.09%	342/ 366	93.44%
Week 24	329/ 359	91.64%	333/ 366	90.98%
Week 28	322/ 359	89.69%	327/ 366	89.34%
Week 32	320/ 358	89.39%	315/ 366	86.07%
Week 36	317/ 358	88.55%	315/ 366	86.07%
Week 40	314/ 358	87.71%	310/ 365	84.93%
Week 44	303/ 358	84.64%	306/ 365	83.84%
Week 48	308/ 358	86.03%	297/ 365	81.37%
Week 52	295/ 358	82.40%	291/ 365	79.73%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute Mental Component Score
Full analysis set

Visit	Anifrolumab 300mg (N=360) n/ N#	Anifrolumab 300mg (N=360) Compliance	Placebo (N=366) n/ N#	Placebo (N=366) Compliance
Baseline	345/ 360	95.83%	348/ 366	95.08%
Week 8	326/ 360	90.56%	338/ 366	92.35%
Week 16	321/ 359	89.42%	327/ 366	89.34%
Week 24	311/ 359	86.63%	320/ 366	87.43%
Week 32	298/ 358	83.24%	296/ 366	80.87%
Week 40	296/ 358	82.68%	297/ 365	81.37%
Week 48	300/ 358	83.80%	283/ 365	77.53%
Week 52	285/ 358	79.61%	273/ 365	74.79%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute Physical Component Score
Full analysis set

Visit	Anifrolumab 300mg (N=360) n/ N#	Anifrolumab 300mg (N=360) Compliance	Placebo (N=366) n/ N#	Placebo (N=366) Compliance
Baseline	345/ 360	95.83%	348/ 366	95.08%
Week 8	326/ 360	90.56%	338/ 366	92.35%
Week 16	321/ 359	89.42%	327/ 366	89.34%
Week 24	311/ 359	86.63%	320/ 366	87.43%
Week 32	298/ 358	83.24%	296/ 366	80.87%
Week 40	296/ 358	82.68%	297/ 365	81.37%
Week 48	300/ 358	83.80%	283/ 365	77.53%
Week 52	285/ 358	79.61%	273/ 365	74.79%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute General Health Score
Full analysis set

Visit	Anifrolumab 300mg (N=360) n/ N#	Anifrolumab 300mg (N=360) Compliance	Placebo (N=366) n/ N#	Placebo (N=366) Compliance
Baseline	345/ 360	95.83%	348/ 366	95.08%
Week 8	326/ 360	90.56%	338/ 366	92.35%
Week 16	321/ 359	89.42%	327/ 366	89.34%
Week 24	311/ 359	86.63%	320/ 366	87.43%
Week 32	298/ 358	83.24%	296/ 366	80.87%
Week 40	296/ 358	82.68%	297/ 365	81.37%
Week 48	300/ 358	83.80%	283/ 365	77.53%
Week 52	285/ 358	79.61%	273/ 365	74.79%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute Mental Health Score
Full analysis set

Visit	Anifrolumab 300mg (N=360) n/ N#	Anifrolumab 300mg (N=360) Compliance	Placebo (N=366) n/ N#	Placebo (N=366) Compliance
Baseline	345/ 360	95.83%	348/ 366	95.08%
Week 8	326/ 360	90.56%	338/ 366	92.35%
Week 16	321/ 359	89.42%	327/ 366	89.34%
Week 24	311/ 359	86.63%	320/ 366	87.43%
Week 32	298/ 358	83.24%	296/ 366	80.87%
Week 40	296/ 358	82.68%	297/ 365	81.37%
Week 48	300/ 358	83.80%	283/ 365	77.53%
Week 52	285/ 358	79.61%	273/ 365	74.79%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute Physical Functioning Score
Full analysis set

Visit	Anifrolumab 300mg (N=360) n/ N#	Anifrolumab 300mg (N=360) Compliance	Placebo (N=366) n/ N#	Placebo (N=366) Compliance
Baseline	345/ 360	95.83%	348/ 366	95.08%
Week 8	326/ 360	90.56%	338/ 366	92.35%
Week 16	321/ 359	89.42%	327/ 366	89.34%
Week 24	311/ 359	86.63%	320/ 366	87.43%
Week 32	298/ 358	83.24%	296/ 366	80.87%
Week 40	296/ 358	82.68%	297/ 365	81.37%
Week 48	300/ 358	83.80%	283/ 365	77.53%
Week 52	285/ 358	79.61%	273/ 365	74.79%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute Role Emotional Score
Full analysis set

Visit	Anifrolumab 300mg (N=360) n/ N#	Anifrolumab 300mg (N=360) Compliance	Placebo (N=366) n/ N#	Placebo (N=366) Compliance
Baseline	345/ 360	95.83%	348/ 366	95.08%
Week 8	326/ 360	90.56%	338/ 366	92.35%
Week 16	321/ 359	89.42%	327/ 366	89.34%
Week 24	311/ 359	86.63%	320/ 366	87.43%
Week 32	298/ 358	83.24%	296/ 366	80.87%
Week 40	296/ 358	82.68%	297/ 365	81.37%
Week 48	300/ 358	83.80%	283/ 365	77.53%
Week 52	285/ 358	79.61%	273/ 365	74.79%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute Role Physical Score
Full analysis set

Visit	Anifrolumab 300mg (N=360) n/ N#	Anifrolumab 300mg (N=360) Compliance	Placebo (N=366) n/ N#	Placebo (N=366) Compliance
Baseline	345/ 360	95.83%	348/ 366	95.08%
Week 8	326/ 360	90.56%	338/ 366	92.35%
Week 16	321/ 359	89.42%	327/ 366	89.34%
Week 24	311/ 359	86.63%	320/ 366	87.43%
Week 32	298/ 358	83.24%	296/ 366	80.87%
Week 40	296/ 358	82.68%	297/ 365	81.37%
Week 48	300/ 358	83.80%	283/ 365	77.53%
Week 52	285/ 358	79.61%	273/ 365	74.79%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute Social Functioning Score
Full analysis set

Visit	Anifrolumab 300mg (N=360) n/ N#	Anifrolumab 300mg (N=360) Compliance	Placebo (N=366) n/ N#	Placebo (N=366) Compliance
Baseline	345/ 360	95.83%	348/ 366	95.08%
Week 8	326/ 360	90.56%	338/ 366	92.35%
Week 16	321/ 359	89.42%	327/ 366	89.34%
Week 24	311/ 359	86.63%	320/ 366	87.43%
Week 32	298/ 358	83.24%	296/ 366	80.87%
Week 40	296/ 358	82.68%	297/ 365	81.37%
Week 48	300/ 358	83.80%	283/ 365	77.53%
Week 52	285/ 358	79.61%	273/ 365	74.79%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute Bodily Pain Score
Full analysis set

Visit	Anifrolumab 300mg (N=360) n/ N#	Anifrolumab 300mg (N=360) Compliance	Placebo (N=366) n/ N#	Placebo (N=366) Compliance
Baseline	345/ 360	95.83%	348/ 366	95.08%
Week 8	326/ 360	90.56%	338/ 366	92.35%
Week 16	321/ 359	89.42%	327/ 366	89.34%
Week 24	311/ 359	86.63%	320/ 366	87.43%
Week 32	298/ 358	83.24%	296/ 366	80.87%
Week 40	296/ 358	82.68%	297/ 365	81.37%
Week 48	300/ 358	83.80%	283/ 365	77.53%
Week 52	285/ 358	79.61%	273/ 365	74.79%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute Vitality Score
Full analysis set

Visit	Anifrolumab 300mg (N=360) n/ N#	Anifrolumab 300mg (N=360) Compliance	Placebo (N=366) n/ N#	Placebo (N=366) Compliance
Baseline	345/ 360	95.83%	348/ 366	95.08%
Week 8	326/ 360	90.56%	338/ 366	92.35%
Week 16	321/ 359	89.42%	327/ 366	89.34%
Week 24	311/ 359	86.63%	320/ 366	87.43%
Week 32	298/ 358	83.24%	296/ 366	80.87%
Week 40	296/ 358	82.68%	297/ 365	81.37%
Week 48	300/ 358	83.80%	283/ 365	77.53%
Week 52	285/ 358	79.61%	273/ 365	74.79%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - FACIT-F Total Score
Full analysis set

Visit	Anifrolumab 300mg (N=360) n/ N#	Anifrolumab 300mg (N=360) Compliance	Placebo (N=366) n/ N#	Placebo (N=366) Compliance
Baseline	341/ 360	94.72%	349/ 366	95.36%
Week 4	338/ 360	93.89%	349/ 366	95.36%
Week 8	328/ 360	91.11%	341/ 366	93.17%
Week 12	333/ 359	92.76%	333/ 366	90.98%
Week 16	324/ 359	90.25%	329/ 366	89.89%
Week 20	314/ 359	87.47%	329/ 366	89.89%
Week 24	314/ 359	87.47%	323/ 366	88.25%
Week 28	313/ 359	87.19%	316/ 366	86.34%
Week 32	304/ 358	84.92%	300/ 366	81.97%
Week 36	307/ 358	85.75%	300/ 366	81.97%
Week 40	300/ 358	83.80%	298/ 365	81.64%
Week 44	298/ 358	83.24%	286/ 365	78.36%
Week 48	303/ 358	84.64%	286/ 365	78.36%
Week 52	285/ 358	79.61%	274/ 365	75.07%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - EQ VAS Score
Full analysis set

Visit	Anifrolumab 300mg (N=360) n/ N#	Anifrolumab 300mg (N=360) Compliance	Placebo (N=366) n/ N#	Placebo (N=366) Compliance
Baseline	341/ 360	94.72%	349/ 366	95.36%
Week 12	331/ 359	92.20%	331/ 366	90.44%
Week 24	311/ 359	86.63%	318/ 366	86.89%
Week 36	302/ 358	84.36%	297/ 366	81.15%
Week 52	283/ 358	79.05%	272/ 365	74.52%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Lupus QoL Physical Health domain score
Full analysis set

Visit	Anifrolumab 300mg (N=360) n/ N#	Anifrolumab 300mg (N=360) Compliance	Placebo (N=366) n/ N#	Placebo (N=366) Compliance
Baseline	341/ 360	94.72%	349/ 366	95.36%
Week 12	330/ 359	91.92%	331/ 366	90.44%
Week 24	310/ 359	86.35%	316/ 366	86.34%
Week 36	300/ 358	83.80%	293/ 366	80.05%
Week 52	282/ 358	78.77%	270/ 365	73.97%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Lupus QoL Emotional Health domain score
Full analysis set

Visit	Anifrolumab 300mg (N=360) n/ N#	Anifrolumab 300mg (N=360) Compliance	Placebo (N=366) n/ N#	Placebo (N=366) Compliance
Baseline	341/ 360	94.72%	349/ 366	95.36%
Week 12	330/ 359	91.92%	331/ 366	90.44%
Week 24	310/ 359	86.35%	316/ 366	86.34%
Week 36	300/ 358	83.80%	293/ 366	80.05%
Week 52	282/ 358	78.77%	270/ 365	73.97%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Lupus QoL Body Image domain score
Full analysis set

Visit	Anifrolumab 300mg (N=360) n/ N#	Anifrolumab 300mg (N=360) Compliance	Placebo (N=366) n/ N#	Placebo (N=366) Compliance
Baseline	319/ 360	88.61%	324/ 366	88.52%
Week 12	299/ 359	83.29%	299/ 366	81.69%
Week 24	277/ 359	77.16%	284/ 366	77.60%
Week 36	268/ 358	74.86%	264/ 366	72.13%
Week 52	245/ 358	68.44%	242/ 365	66.30%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Lupus QoL Burden to Others domain score
Full analysis set

Visit	Anifrolumab 300mg (N=360) n/ N#	Anifrolumab 300mg (N=360) Compliance	Placebo (N=366) n/ N#	Placebo (N=366) Compliance
Baseline	341/ 360	94.72%	349/ 366	95.36%
Week 12	330/ 359	91.92%	331/ 366	90.44%
Week 24	310/ 359	86.35%	316/ 366	86.34%
Week 36	300/ 358	83.80%	293/ 366	80.05%
Week 52	282/ 358	78.77%	270/ 365	73.97%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Lupus QoL Fatigue domain score
Full analysis set

Visit	Anifrolumab 300mg (N=360) n/ N#	Anifrolumab 300mg (N=360) Compliance	Placebo (N=366) n/ N#	Placebo (N=366) Compliance
Baseline	341/ 360	94.72%	349/ 366	95.36%
Week 12	330/ 359	91.92%	331/ 366	90.44%
Week 24	310/ 359	86.35%	316/ 366	86.34%
Week 36	300/ 358	83.80%	293/ 366	80.05%
Week 52	282/ 358	78.77%	270/ 365	73.97%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Lupus QoL Intimate Relationships domain score
Full analysis set

Visit	Anifrolumab 300mg (N=360) n/ N#	Anifrolumab 300mg (N=360) Compliance	Placebo (N=366) n/ N#	Placebo (N=366) Compliance
Baseline	280/ 360	77.78%	280/ 366	76.50%
Week 12	269/ 359	74.93%	264/ 366	72.13%
Week 24	241/ 359	67.13%	236/ 366	64.48%
Week 36	236/ 358	65.92%	215/ 366	58.74%
Week 52	205/ 358	57.26%	198/ 365	54.25%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Lupus QoL Pain domain score
Full analysis set

Visit	Anifrolumab 300mg (N=360) n/ N#	Anifrolumab 300mg (N=360) Compliance	Placebo (N=366) n/ N#	Placebo (N=366) Compliance
Baseline	341/ 360	94.72%	349/ 366	95.36%
Week 12	330/ 359	91.92%	331/ 366	90.44%
Week 24	310/ 359	86.35%	316/ 366	86.34%
Week 36	300/ 358	83.80%	293/ 366	80.05%
Week 52	282/ 358	78.77%	270/ 365	73.97%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Lupus QoL Planning domain score
Full analysis set

Visit	Anifrolumab 300mg (N=360) n/ N#	Anifrolumab 300mg (N=360) Compliance	Placebo (N=366) n/ N#	Placebo (N=366) Compliance
Baseline	341/ 360	94.72%	349/ 366	95.36%
Week 12	330/ 359	91.92%	331/ 366	90.44%
Week 24	310/ 359	86.35%	316/ 366	86.34%
Week 36	300/ 358	83.80%	293/ 366	80.05%
Week 52	282/ 358	78.77%	270/ 365	73.97%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SDI Global Score
Full analysis set

Visit	Anifrolumab 300mg (N=360) n/ N#	Anifrolumab 300mg (N=360) Compliance	Placebo (N=366) n/ N#	Placebo (N=366) Compliance
Baseline	350/ 360	97.22%	351/ 366	95.90%
Week 24	317/ 359	88.30%	318/ 366	86.89%
Week 52	286/ 358	79.89%	283/ 365	77.53%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - NRS Score
Full analysis set

Visit	Anifrolumab 300mg (N=360) n/ N#	Anifrolumab 300mg (N=360) Compliance	Placebo (N=366) n/ N#	Placebo (N=366) Compliance
Baseline	341/ 360	94.72%	349/ 366	95.36%
Week 4	338/ 360	93.89%	349/ 366	95.36%
Week 8	328/ 360	91.11%	341/ 366	93.17%
Week 12	333/ 359	92.76%	333/ 366	90.98%
Week 16	324/ 359	90.25%	329/ 366	89.89%
Week 20	314/ 359	87.47%	329/ 366	89.89%
Week 24	314/ 359	87.47%	323/ 366	88.25%
Week 28	312/ 359	86.91%	316/ 366	86.34%
Week 32	304/ 358	84.92%	300/ 366	81.97%
Week 36	307/ 358	85.75%	300/ 366	81.97%
Week 40	300/ 358	83.80%	298/ 365	81.64%
Week 44	298/ 358	83.24%	286/ 365	78.36%
Week 48	303/ 358	84.64%	286/ 365	78.36%
Week 52	285/ 358	79.61%	274/ 365	75.07%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - PHQ-8 Total Score
Full analysis set

Visit	Anifrolumab 300mg (N=360) n/ N#	Anifrolumab 300mg (N=360) Compliance	Placebo (N=366) n/ N#	Placebo (N=366) Compliance
Baseline	341/ 360	94.72%	349/ 366	95.36%
Week 12	331/ 359	92.20%	331/ 366	90.44%
Week 24	311/ 359	86.63%	318/ 366	86.89%
Week 36	302/ 358	84.36%	297/ 366	81.15%
Week 52	283/ 358	79.05%	272/ 365	74.52%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - PtGA
Full analysis set

Visit	Anifrolumab 300mg (N=360) n/ N#	Anifrolumab 300mg (N=360) Compliance	Placebo (N=366) n/ N#	Placebo (N=366) Compliance
Baseline	341/ 360	94.72%	349/ 366	95.36%
Week 4	338/ 360	93.89%	349/ 366	95.36%
Week 8	328/ 360	91.11%	341/ 366	93.17%
Week 12	333/ 359	92.76%	333/ 366	90.98%
Week 16	324/ 359	90.25%	327/ 366	89.34%
Week 20	313/ 359	87.19%	326/ 366	89.07%
Week 24	313/ 359	87.19%	321/ 366	87.70%
Week 28	312/ 359	86.91%	313/ 366	85.52%
Week 32	302/ 358	84.36%	299/ 366	81.69%
Week 36	305/ 358	85.20%	296/ 366	80.87%
Week 40	300/ 358	83.80%	295/ 365	80.82%
Week 44	297/ 358	82.96%	283/ 365	77.53%
Week 48	302/ 358	84.36%	282/ 365	77.26%
Week 52	284/ 358	79.33%	272/ 365	74.52%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Flare rate through Week 52
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) Number of flares	Anifrolumab 300mg (N=360) Total Follow-up time (years)	Anifrolumab 300mg (N=360) Annual rate (SE)	Placebo (N=366) Number of flares	Placebo (N=366) Total Follow-up time (years)	Placebo (N=366) Annual rate (SE)	Rate ratio (95% CI)	p-Value	Heterogenity/ Interaction p-Value
									0.3704
Overall	195	336.88	0.51 (0.11)	255	335.46	0.67 (0.10)	0.75 (0.60, 0.95)	0.0170	
SLEDAI-2K score at screening									0.1359
< 10 points	55	100.93	0.51 (0.18)	52	98.21	0.51 (0.18)	1.00 (0.64, 1.54)	0.9839	
>= 10 points	140	235.95	0.54 (0.13)	203	237.26	0.80 (0.12)	0.67 (0.51, 0.88)	0.0040	
OCS dose at baseline									0.1960
<10 mg/day	87	160.16	0.47 (0.15)	106	170.44	0.53 (0.15)	0.90 (0.62, 1.29)	0.5557	
>=10 mg/day	108	176.72	0.55 (0.15)	149	165.02	0.85 (0.14)	0.65 (0.48, 0.88)	0.0051	
Result of type I IFN gene signature test									0.1189
LOW	35	59.88	0.55 (0.22)	30	59.65	0.49 (0.22)	1.12 (0.62, 2.01)	0.7048	
HIGH	160	277.00	0.54 (0.10)	225	275.82	0.77 (0.10)	0.70 (0.54, 0.90)	0.0054	
Age (years)									0.2117
<= 65	191	325.65	0.51 (0.11)	250	331.52	0.66 (0.11)	0.77 (0.61, 0.97)	0.0284	
> 65	4	11.23	NE	5	3.94	NE	NE		
Sex									0.5142
male	14	25.57	0.27 (0.56)	23	24.47	0.45 (0.54)	0.59 (0.29, 1.21)	0.1511	
female	181	311.30	0.51 (0.11)	232	311.00	0.67 (0.11)	0.77 (0.60, 0.98)	0.0368	
Race									0.6152
White	133	222.19	0.51 (0.13)	174	221.32	0.67 (0.12)	0.77 (0.58, 1.02)	0.0636	
Black	30	41.22	0.79 (0.26)	33	45.90	0.87 (0.24)	0.91 (0.49, 1.67)	0.7546	
Other	30	66.78	0.25 (0.46)	46	61.26	0.39 (0.44)	0.63 (0.35, 1.14)	0.1291	
Ethnicity									0.8336
Hispanic/Latino	44	79.89	0.33 (0.29)	63	81.39	0.50 (0.27)	0.66 (0.39, 1.13)	0.1312	
Non-hispanic/Latino	149	250.30	0.53 (0.12)	190	247.09	0.71 (0.11)	0.74 (0.57, 0.97)	0.0294	
Geographic region									0.8731
EU	50	110.29	0.35 (0.23)	70	111.55	0.49 (0.24)	0.72 (0.45, 1.16)	0.1735	
non-EU	145	226.59	0.56 (0.12)	185	223.91	0.74 (0.12)	0.76 (0.58, 1.00)	0.0476	
Onset of disease									0.9215
Paediatric	20	23.89	0.86 (0.39)	23	21.24	1.12 (0.40)	0.77 (0.37, 1.62)	0.4950	
Adult	175	312.99	0.49 (0.11)	232	314.22	0.65 (0.11)	0.75 (0.59, 0.95)	0.0197	
ADA result									0.2222
Negative	180	314.65	0.52 (0.11)	217	304.68	0.65 (0.11)	0.80 (0.62, 1.03)	0.0785	
Positive (At any time)	15	22.23	0.21 (0.53)	38	30.78	0.50 (0.42)	0.42 (0.22, 0.82)	0.0108	
BMI (kg/m2) at enrolment									0.1105
< 30	110	218.21	0.46 (0.15)	186	236.42	0.71 (0.14)	0.65 (0.48, 0.87)	0.0041	
>= 30	85	118.66	0.57 (0.15)	69	99.04	0.60 (0.16)	0.95 (0.65, 1.37)	0.7660	

Rates and rate ratio from negative binomial regression model with factors for treatment group and the stratification factors. The logarithm (to base e) of the follow-up time is used as an offset variable in the model to adjust for subjects having different exposure times.
Study*treatment interaction also included to assess heterogenity between studies.
p-Value for interaction from same negative binomial regression model with additional factors for subgroup and subgroup*treatment interaction.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Flare rate through Week 52 using modified BILAG
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) Number of flares	Anifrolumab 300mg (N=360) Total Follow-up time (years)	Anifrolumab 300mg (N=360) Annual rate (SE)	Placebo (N=366) Number of flares	Placebo (N=366) Total Follow-up time (years)	Placebo (N=366) Annual rate (SE)	Rate ratio (95% CI)	p-Value	Heterogenity/ Interaction p-Value
Overall	132	336.88	0.31 (0.13)	198	335.46	0.47 (0.12)	0.67 (0.51, 0.87)	0.0034	0.6412

Rates and rate ratio from negative binomial regression model with factors for treatment group and the stratification factors. The logarithm (to base e) of the follow-up time is used as an offset variable in the model to adjust for subjects having different exposure times.
Study*treatment interaction also included to assess heterogenity between studies.
p-Value for interaction from same negative binomial regression model with additional factors for subgroup and subgroup*treatment interaction.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Flare rate through Week 52 while on treatment
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) Number of flares	Anifrolumab 300mg (N=360) Total Follow-up time (years)	Anifrolumab 300mg (N=360) Annual rate (SE)	Placebo (N=366) Number of flares	Placebo (N=366) Total Follow-up time (years)	Placebo (N=366) Annual rate (SE)	Rate ratio (95% CI)	p-Value	Heterogenity/ Interaction p-Value
Overall	176	327.12	0.48 (0.11)	226	320.61	0.63 (0.11)	0.76 (0.60, 0.97)	0.0282	0.4248

Rates and rate ratio from negative binomial regression model with factors for treatment group and the stratification factors. The logarithm (to base e) of the follow-up time is used as an offset variable in the model to adjust for subjects having different exposure times.
Study*treatment interaction also included to assess heterogenity between studies.
p-Value for interaction from same negative binomial regression model with additional factors for subgroup and subgroup*treatment interaction.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Flare rate through Week 52 sensitivity analysis, multiple imputation and negative binomial regression model
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) Number of flares	Anifrolumab 300mg (N=360) Total Follow-up time (years)	Anifrolumab 300mg (N=360) Annual rate (SE)	Placebo (N=366) Number of flares	Placebo (N=366) Total Follow-up time (years)	Placebo (N=366) Annual rate (SE)	Rate ratio (95% CI)	p-Value
Overall	210	361.13	0.51 (0.00)	286	367.04	0.67 (0.00)	0.76 (0.60, 0.95)	0.0182

The number of flares after withdrawal from study is imputed conditional upon the observed number of flares prior to the withdrawal, a post-withdrawal model assumption, the baseline covariates included in the main analysis model and the time the subject would have remained in the study if not withdrawn (ie, date of first administration of IP + 364 days â€“ date of withdrawal). This analysis is repeated multiple times and the results combined using Rubinâ€™s formula. Full details are given in SAP
Rates and rate ratio from negative binomial regression model with factors for treatment group and the stratification factors. The logarithm (to base e) of the follow-up time is used as an offset variable in the model to adjust for subjects having different exposure times.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Flare rate through Week 52 sensitivity analysis, tipping point analysis
Full analysis set

Shift (log(Delta A)) for Anifrolumab 300 mg	Shift (log(Delta P)) for Placebo						
	0	-0.25	-0.5	-0.75	-1	-1.25	-1.5
0	0.0232	0.0293	0.0349	0.0400	0.0444	0.0481	0.0512
0.25	0.0273	0.0342	0.0407	0.0464	0.0514	0.0556	0.0591
0.5	0.0335	0.0417	0.0493	0.0561	0.0619	0.0668	0.0708
0.75	0.0433	0.0535	0.0629	0.0711	0.0781	0.0840	0.0888
1	0.0597	0.0730	0.0850	0.0954	0.1043	0.1117	0.1177
1.25	0.0885	0.1066	0.1227	0.1365	0.1482	0.1578	0.1657
1.5	0.1412	0.1670	0.1895	0.2086	0.2244	0.2374	0.2478

The response variable in the model is the number of flares up to Week 52/EDV. The model includes covariates of treatment group, and the stratification factors (SLEDAI-2K Score at Screening (<10 points vs >= 10 points), Week 0 OCS dose (<10 mg/day vs >=10 mg/day prednisone or equivalent) and Type 1 IFN test result at screening (high vs low)).
The logarithm (to base e) of the follow-up time is used as an offset variable in the model to adjust for subjects having different exposure times.
P-values of this analysis are presented.
For the scenario in the upper left corner, missing at random analysis is performed, where for each subject the rate after withdrawal y1 is assumed to be the same as their rate before withdrawal y2, which itself is calculated based on their randomised treatment group and baseline covariates. For the other scenarios, the same analyses are performed with the rate after withdrawal modified to be Deltay2 (Delta P and Delta A for placebo and anifrolumab 300 mg, respectively).

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Overall Survival
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	2 (0.6)	1 (0.3)
Number of censored subjects, n (%)	358 (99.4)	365 (99.7)
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Anifrolumab 300mg vs. Placebo (adjusted)		
Hazard Ratio (95% CI)	1.74 (0.16, 19.26)	
p-value	0.6652	
Analysis Anifrolumab 300mg vs. Placebo (unadjusted)		
Hazard Ratio (95% CI)	2.02 (0.18, 22.30)	
p-value	0.5604	
p-Value for test for heterogenity between studies	0.9978	

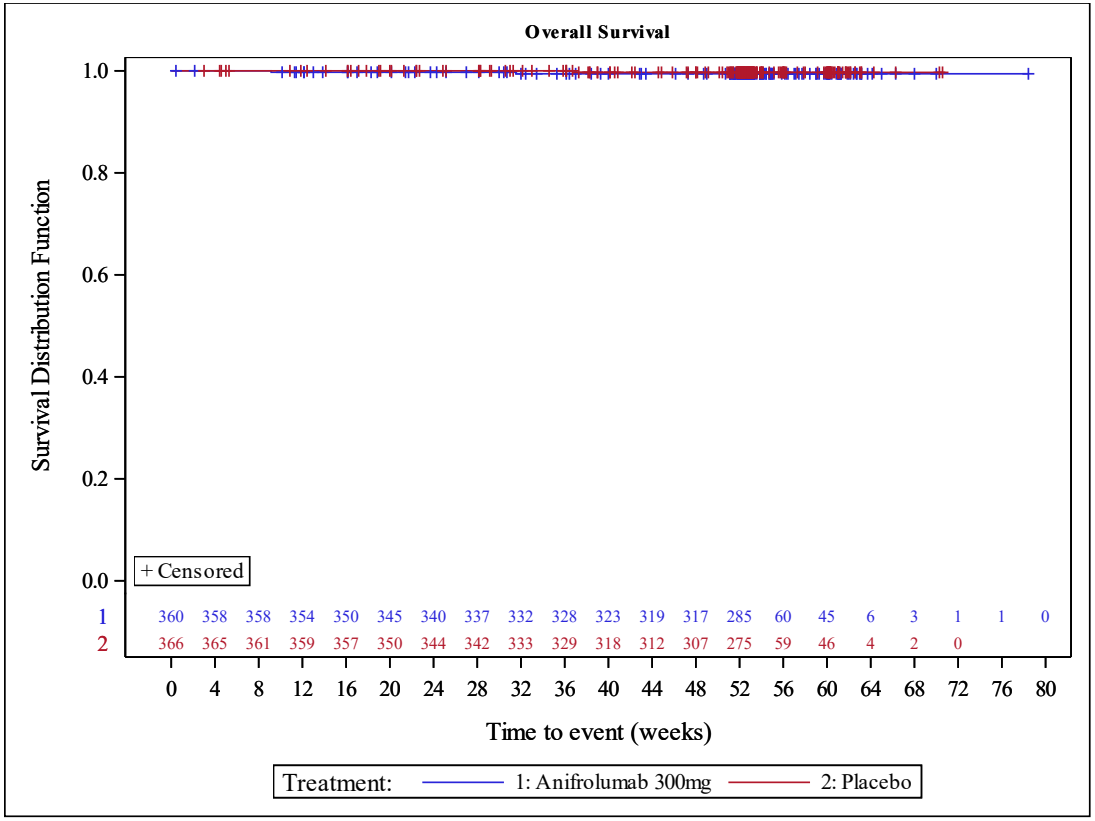
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model. Adjusted analysis also includes stratification factors in the model.
Two-sided log rank test used.
p-Value for heterogenity between studies from Cox proportional hazards model with factors for treatment, study, treatment*study interaction and stratfication factors.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unadjusted analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Overall Survival - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Anifrolumab 300mg (N=360) Median (95% CI)	Placebo (N=366) n/ N (%)	Placebo (N=366) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening							0.9983
< 10 points	2/109 (1.8)	NE (NE, NE)	0/106 (0.0)	NE (NE, NE)	NE		
>= 10 points	0/251 (0.0)	NE (NE, NE)	1/260 (0.4)	NE (NE, NE)	NE		
OCS dose at baseline							0.9999
<10 mg/day	0/170 (0.0)	NE (NE, NE)	0/181 (0.0)	NE (NE, NE)	NE		
>=10 mg/day	2/190 (1.1)	NE (NE, NE)	1/185 (0.5)	NE (NE, NE)	1.74 (0.16, 19.26)	0.6652	
Result of type I IFN gene signature test							1.0000
LOW	0/ 62 (0.0)	NE (NE, NE)	0/ 64 (0.0)	NE (NE, NE)	NE		
HIGH	2/298 (0.7)	NE (NE, NE)	1/302 (0.3)	NE (NE, NE)	1.74 (0.16, 19.26)	0.6652	
Age (years)							1.0000
<= 65	2/348 (0.6)	NE (NE, NE)	1/362 (0.3)	NE (NE, NE)	1.71 (0.15, 18.88)	0.6721	
> 65	0/ 12 (0.0)	NE (NE, NE)	0/ 4 (0.0)	NE (NE, NE)	NE		
Sex							1.0000
male	0/ 27 (0.0)	NE (NE, NE)	0/ 25 (0.0)	NE (NE, NE)	NE		
female	2/333 (0.6)	NE (NE, NE)	1/341 (0.3)	NE (NE, NE)	1.76 (0.16, 19.46)	0.6456	
Race							1.0000
White	1/235 (0.4)	NE (NE, NE)	0/244 (0.0)	NE (NE, NE)	NE		
Black	0/ 46 (0.0)	NE (NE, NE)	1/ 48 (2.1)	NE (NE, NE)	NE		
Other	1/ 71 (1.4)	NE (NE, NE)	0/ 66 (0.0)	NE (NE, NE)	NE		
Ethnicity							0.9979
Hispanic/Latino	2/ 86 (2.3)	NE (NE, NE)	0/ 89 (0.0)	NE (NE, NE)	NE		
Non-hispanic/Latino	0/266 (0.0)	NE (NE, NE)	1/269 (0.4)	NE (NE, NE)	NE		
Geographic region							1.0000
EU	0/115 (0.0)	NE (NE, NE)	0/122 (0.0)	NE (NE, NE)	NE		
non-EU	2/245 (0.8)	NE (NE, NE)	1/244 (0.4)	NE (NE, NE)	1.70 (0.15, 18.81)	0.6647	
Onset of disease							1.0000
Paediatric	0/ 26 (0.0)	NE (NE, NE)	0/ 24 (0.0)	NE (NE, NE)	NE		
Adult	2/334 (0.6)	NE (NE, NE)	1/342 (0.3)	NE (NE, NE)	1.86 (0.17, 20.53)	0.6333	
ADA result							1.0000
Negative	2/334 (0.6)	NE (NE, NE)	1/331 (0.3)	NE (NE, NE)	1.60 (0.14, 17.81)	0.7108	
Positive (At any time)	0/ 25 (0.0)	NE (NE, NE)	0/ 35 (0.0)	NE (NE, NE)	NE		
BMI (kg/m2) at enrolment							0.9974
< 30	2/233 (0.9)	NE (NE, NE)	0/261 (0.0)	NE (NE, NE)	NE		
>= 30	0/127 (0.0)	NE (NE, NE)	1/105 (1.0)	NE (NE, NE)	NE		

Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Overall Survival
Full analysis set



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Time to first Flare
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	121 (33.6)	157 (42.9)
Number of censored subjects, n (%)	239 (66.4)	209 (57.1)
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	31.14 (24.00, 36.29)	20.00 (16.14, 23.71)
Median (95% CI)	NE (NE, NE)	NE (52.29, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Anifrolumab 300mg vs. Placebo (adjusted)		
Hazard Ratio (95% CI)	0.70 (0.55, 0.89)	
p-value	0.0054	
Analysis Anifrolumab 300mg vs. Placebo (unadjusted)		
Hazard Ratio (95% CI)	0.72 (0.57, 0.91)	
p-value	0.0059	
p-Value for test for heterogenity between studies	0.5072	

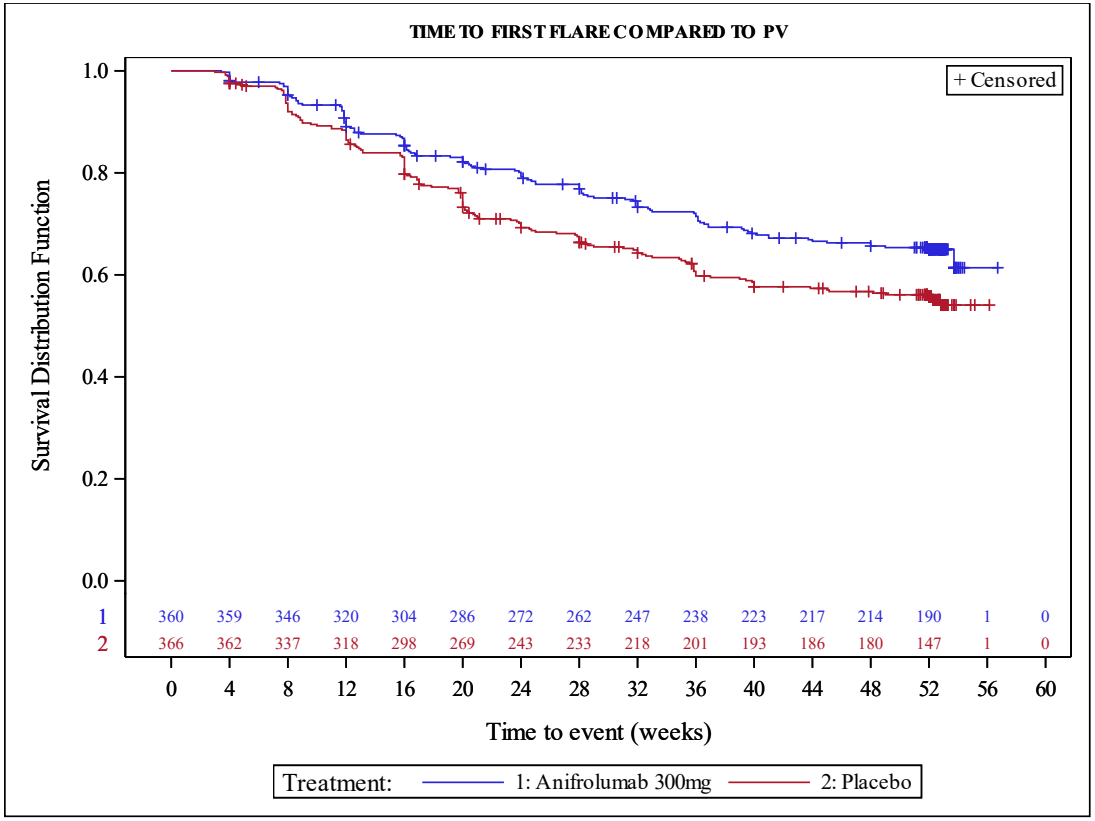
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model. Adjusted analysis also includes stratification factors in the model.
Two-sided log rank test used.
p-Value for heterogenity between studies from Cox proportional hazards model with factors for treatment, study, treatment*study interaction and stratfication factors.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unadjusted analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Time to first Flare - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Anifrolumab 300mg (N=360) Median (95% CI)	Placebo (N=366) n/ N (%)	Placebo (N=366) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening							0.1397
< 10 points	37/109 (33.9)	NE (53.71, NE)	38/106 (35.8)	NE (NE, NE)	0.90 (0.57, 1.42)	0.7011	
>= 10 points	84/251 (33.5)	NE (NE, NE)	119/260 (45.8)	NE (37.00, NE)	0.63 (0.48, 0.84)	0.0026	
OCS dose at baseline							0.1485
<10 mg/day	54/170 (31.8)	NE (NE, NE)	65/181 (35.9)	NE (NE, NE)	0.85 (0.59, 1.22)	0.3881	
>=10 mg/day	67/190 (35.3)	NE (53.71, NE)	92/185 (49.7)	40.00 (32.00, NE)	0.61 (0.44, 0.83)	0.0033	
Result of type I IFN gene signature test							0.1707
LOW	21/ 62 (33.9)	NE (NE, NE)	22/ 64 (34.4)	NE (52.29, NE)	1.09 (0.60, 1.99)	0.7208	
HIGH	100/298 (33.6)	NE (NE, NE)	135/302 (44.7)	NE (40.00, NE)	0.66 (0.51, 0.85)	0.0015	
Age (years)							0.7797
<= 65	117/348 (33.6)	NE (NE, NE)	155/362 (42.8)	NE (52.29, NE)	0.70 (0.55, 0.89)	0.0062	
> 65	4/ 12 (33.3)	NE (16.14, NE)	2/ 4 (50.0)	NE (8.00, NE)	0.39 (0.04, 3.66)	0.1573	
Sex							0.6271
male	10/ 27 (37.0)	NE (32.00, NE)	14/ 25 (56.0)	48.14 (16.43, NE)	0.65 (0.28, 1.50)	0.0311	
female	111/333 (33.3)	NE (NE, NE)	143/341 (41.9)	NE (52.29, NE)	0.71 (0.56, 0.91)	0.0113	
Race							0.6043
White	81/235 (34.5)	NE (53.71, NE)	109/244 (44.7)	NE (39.43, NE)	0.68 (0.51, 0.90)	0.0061	
Black	18/ 46 (39.1)	NE (32.00, NE)	20/ 48 (41.7)	NE (32.57, NE)	0.99 (0.51, 1.90)	0.9917	
Other	20/ 71 (28.2)	NE (NE, NE)	26/ 66 (39.4)	NE (39.86, NE)	0.62 (0.34, 1.13)	0.1443	
Ethnicity							0.6820
Hispanic/Latino	26/ 86 (30.2)	NE (NE, NE)	37/ 89 (41.6)	NE (32.29, NE)	0.64 (0.38, 1.06)	0.1347	
Non-hispanic/Latino	93/266 (35.0)	NE (53.71, NE)	118/269 (43.9)	NE (45.00, NE)	0.71 (0.54, 0.93)	0.0175	
Geographic region							0.6261
EU	31/115 (27.0)	NE (53.71, NE)	46/122 (37.7)	NE (52.86, NE)	0.63 (0.40, 1.00)	0.0601	
non-EU	90/245 (36.7)	NE (NE, NE)	111/244 (45.5)	NE (39.00, NE)	0.72 (0.54, 0.95)	0.0239	
Onset of disease							0.7348
Paediatric	12/ 26 (46.2)	NE (25.00, NE)	13/ 24 (54.2)	35.86 (12.00, NE)	0.54 (0.23, 1.28)	0.0115	
Adult	109/334 (32.6)	NE (NE, NE)	144/342 (42.1)	NE (52.86, NE)	0.70 (0.55, 0.90)	0.0083	
ADA result							0.0829
Negative	112/334 (33.5)	NE (NE, NE)	133/331 (40.2)	NE (NE, NE)	0.76 (0.59, 0.98)	0.0465	
Positive (At any time)	9/ 25 (36.0)	NE (24.14, NE)	24/ 35 (68.6)	23.29 (15.71, 40.00)	0.32 (0.14, 0.74)	0.0061	
BMI (kg/m2) at enrolment							0.3579
< 30	72/233 (30.9)	NE (53.71, NE)	109/261 (41.8)	NE (52.00, NE)	0.64 (0.48, 0.87)	0.0048	
>= 30	49/127 (38.6)	NE (NE, NE)	48/105 (45.7)	NE (35.86, NE)	0.78 (0.52, 1.16)	0.2821	

Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Time to first Flare
Full analysis set



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Time to sustained BICLA response up to week 52
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	171 (47.5)	112 (30.6)
Number of censored subjects, n (%)	189 (52.5)	254 (69.4)
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	23.14 (16.00, 28.00)	43.86 (32.14, 48.00)
Median (95% CI)	51.86 (48.00, 52.57)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Anifrolumab 300mg vs. Placebo (adjusted)		
Hazard Ratio (95% CI)	1.73 (1.36, 2.20)	
p-value	<.0001	
Analysis Anifrolumab 300mg vs. Placebo (unadjusted)		
Hazard Ratio (95% CI)	1.74 (1.37, 2.21)	
p-value	<.0001	
p-Value for test for heterogenity between studies	0.3292	

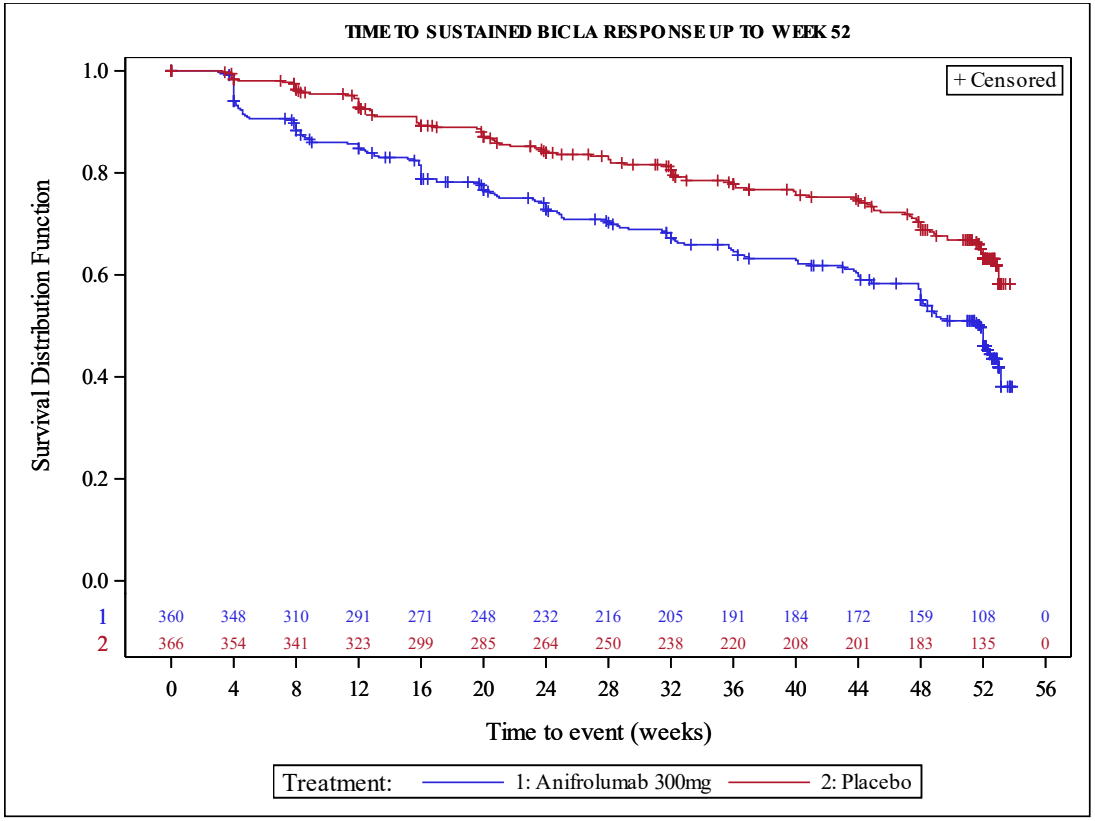
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model. Adjusted analysis also includes stratification factors in the model.
Two-sided log rank test used.
p-Value for heterogenity between studies from Cox proportional hazards model with factors for treatment, study, treatment*study interaction and stratfication factors.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unadjusted analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Time to sustained BICLA response up to week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Anifrolumab 300mg (N=360) Median (95% CI)	Placebo (N=366) n/ N (%)	Placebo (N=366) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening							0.9873
< 10 points	59/109 (54.1)	48.14 (35.71, 52.00)	39/106 (36.8)	NE (48.00, NE)	1.73 (1.15, 2.59)	0.0091	
>= 10 points	112/251 (44.6)	52.29 (48.14, NE)	73/260 (28.1)	NE (NE, NE)	1.74 (1.29, 2.33)	0.0004	
OCS dose at baseline							0.4803
<10 mg/day	82/170 (48.2)	48.86 (44.00, NE)	54/181 (29.8)	NE (53.00, NE)	1.86 (1.32, 2.62)	0.0003	
>=10 mg/day	89/190 (46.8)	52.00 (48.00, 53.14)	58/185 (31.4)	NE (52.86, NE)	1.60 (1.15, 2.23)	0.0081	
Result of type I IFN gene signature test							0.1559
LOW	29/ 62 (46.8)	52.00 (32.86, NE)	24/ 64 (37.5)	NE (40.00, NE)	1.22 (0.71, 2.11)	0.5021	
HIGH	142/298 (47.7)	51.57 (48.00, 52.57)	88/302 (29.1)	NE (NE, NE)	1.87 (1.43, 2.45)	<.0001	
Age (years)							0.5456
<= 65	163/348 (46.8)	51.86 (48.00, 53.00)	111/362 (30.7)	NE (53.00, NE)	1.69 (1.33, 2.16)	<.0001	
> 65	8/ 12 (66.7)	32.00 (8.29, 52.57)	1/ 4 (25.0)	NE (8.29, NE)	2.54 (0.24, 27.04)	0.4795	
Sex							0.3904
male	12/ 27 (44.4)	51.71 (20.43, NE)	10/ 25 (40.0)	NE (32.29, NE)	1.13 (0.48, 2.64)	0.9431	
female	159/333 (47.7)	51.86 (48.00, 52.57)	102/341 (29.9)	NE (53.00, NE)	1.79 (1.39, 2.30)	<.0001	
Race							0.2814
White	110/235 (46.8)	52.00 (48.14, 53.14)	79/244 (32.4)	NE (53.00, NE)	1.55 (1.16, 2.07)	0.0036	
Black	22/ 46 (47.8)	48.00 (32.00, NE)	16/ 48 (33.3)	NE (49.71, NE)	2.18 (1.12, 4.25)	0.0300	
Other	34/ 71 (47.9)	49.29 (36.71, NE)	14/ 66 (21.2)	NE (NE, NE)	2.57 (1.36, 4.86)	0.0055	
Ethnicity							0.2769
Hispanic/Latino	42/ 86 (48.8)	49.00 (31.71, NE)	33/ 89 (37.1)	NE (47.43, NE)	1.38 (0.87, 2.19)	0.1540	
Non-hispanic/Latino	124/266 (46.6)	52.00 (48.00, 53.14)	76/269 (28.3)	NE (NE, NE)	1.89 (1.42, 2.51)	<.0001	
Geographic region							0.5477
EU	62/115 (53.9)	49.00 (35.86, 52.57)	45/122 (36.9)	53.00 (51.86, NE)	1.64 (1.11, 2.43)	0.0231	
non-EU	109/245 (44.5)	52.00 (48.00, NE)	67/244 (27.5)	NE (NE, NE)	1.84 (1.35, 2.49)	<.0001	
Onset of disease							0.3279
Paediatric	10/ 26 (38.5)	NE (27.86, NE)	4/ 24 (16.7)	NE (51.86, NE)	3.24 (0.94, 11.19)	0.0456	
Adult	161/334 (48.2)	51.86 (48.00, 52.57)	108/342 (31.6)	NE (53.00, NE)	1.68 (1.32, 2.15)	<.0001	
ADA result							0.5376
Negative	162/334 (48.5)	51.71 (48.00, 52.43)	106/331 (32.0)	NE (NE, NE)	1.68 (1.32, 2.15)	<.0001	
Positive (At any time)	9/ 25 (36.0)	NE (17.00, NE)	6/ 35 (17.1)	NE (53.00, NE)	2.56 (0.87, 7.52)	0.0737	
BMI (kg/m2) at enrolment							0.8602
< 30	115/233 (49.4)	51.71 (44.86, 52.57)	81/261 (31.0)	NE (53.00, NE)	1.71 (1.29, 2.28)	0.0004	
>= 30	56/127 (44.1)	52.00 (48.00, NE)	31/105 (29.5)	NE (52.86, NE)	1.88 (1.21, 2.92)	0.0241	

Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Time to sustained BICLA response up to week 52
Full analysis set



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Time to OCS Reduction <=7.5 mg/day (for subjects with baseline OCS >=10 mg/day)
Full analysis set

	Anifrolumab 300mg (N=190)	Placebo (N=185)
Number of subjects with events, n (%)	128 (67.4)	99 (53.5)
Number of censored subjects, n (%)	62 (32.6)	86 (46.5)
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	12.71 (12.00, 16.14)	16.00 (12.00, 17.14)
Median (95% CI)	21.43 (18.71, 24.29)	28.29 (21.29, 36.14)
75%-ile (95% CI)	48.14 (32.14, NE)	NE (NE, NE)
Analysis Anifrolumab 300mg vs. Placebo (adjusted)		
Hazard Ratio (95% CI)	1.39 (1.07, 1.80)	
p-value	0.0108	
Analysis Anifrolumab 300mg vs. Placebo (unadjusted)		
Hazard Ratio (95% CI)	1.38 (1.06, 1.80)	
p-value	0.0160	
p-Value for test for heterogenity between studies	0.5341	

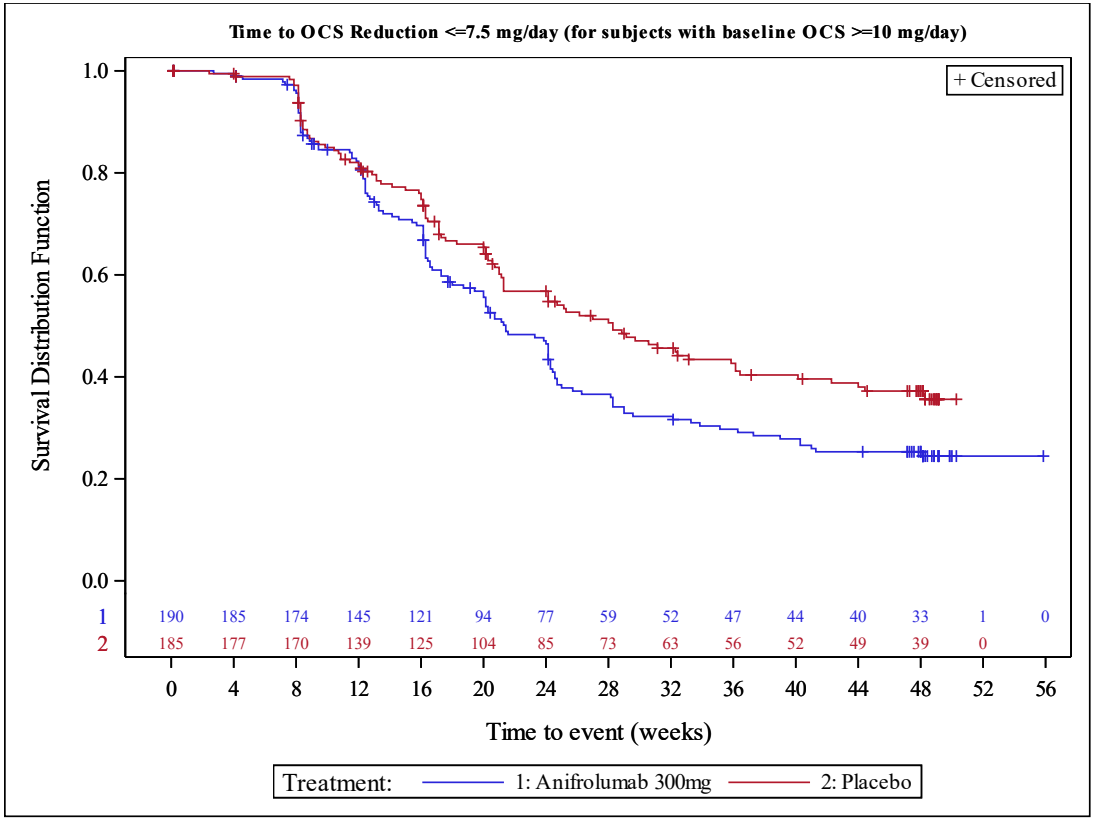
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model. Adjusted analysis also includes stratification factors in the model.
Two-sided log rank test used.
p-Value for heterogenity between studies from Cox proportional hazards model with factors for treatment, study, treatment*study interaction and stratfication factors.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unadjusted analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Time to OCS Reduction <=7.5 mg/day (for subjects with baseline OCS >=10 mg/day) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=190) n/ N (%)	 Median (95% CI)	Placebo (N=185) n/ N (%)	 Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	 p-Value	Interaction p-Value
SLEDAI-2K score at screening							0.1898
< 10 points	39/ 52 (75.0)	20.71 (16.14, 24.57)	26/ 46 (56.5)	29.71 (24.14, 44.43)	1.97 (1.19, 3.25)	0.0084	
>= 10 points	89/138 (64.5)	21.43 (19.43, 24.57)	73/139 (52.5)	25.14 (20.71, 36.14)	1.23 (0.90, 1.68)	0.1747	
OCS dose at baseline							NE
>=10 mg/day	128/190 (67.4)	21.43 (18.71, 24.29)	99/185 (53.5)	28.29 (21.29, 36.14)	1.39 (1.07, 1.80)	0.0108	
Result of type I IFN gene signature test							0.1237
LOW	14/ 22 (63.6)	25.00 (16.29, 40.29)	18/ 25 (72.0)	20.71 (17.14, 28.86)	0.86 (0.42, 1.73)	0.7306	
HIGH	114/168 (67.9)	21.14 (18.00, 24.29)	81/160 (50.6)	29.71 (24.14, 42.29)	1.50 (1.13, 2.00)	0.0040	
Age (years)							0.4693
<= 65	127/187 (67.9)	21.29 (18.71, 24.29)	98/184 (53.3)	28.29 (21.29, 36.14)	1.40 (1.07, 1.82)	0.0088	
> 65	1/ 3 (33.3)	NE (11.57, NE)	1/ 1 (100.0)	20.29 (NE, NE)	1.00 (0.00,)	<.0001	
Sex							0.1397
male	16/ 18 (88.9)	16.14 (8.86, 23.86)	8/ 15 (53.3)	28.86 (13.43, NE)	3.22 (1.29, 7.99)	0.0160	
female	112/172 (65.1)	21.57 (20.00, 24.57)	91/170 (53.5)	27.00 (21.29, 36.14)	1.29 (0.98, 1.70)	0.0561	
Race							0.9930
White	77/116 (66.4)	20.71 (16.43, 24.29)	68/131 (51.9)	28.86 (20.57, 40.14)	1.34 (0.97, 1.87)	0.0762	
Black	16/ 27 (59.3)	24.14 (13.00, NE)	11/ 19 (57.9)	36.14 (16.43, NE)	1.15 (0.52, 2.58)	0.5776	
Other	32/ 43 (74.4)	21.21 (16.57, 24.57)	18/ 32 (56.3)	26.14 (17.14, NE)	1.62 (0.88, 2.95)	0.1780	
Ethnicity							0.6611
Hispanic/Latino	35/ 49 (71.4)	16.57 (12.71, 20.29)	27/ 45 (60.0)	24.14 (16.43, 29.14)	1.50 (0.88, 2.56)	0.1541	
Non-hispanic/Latino	90/137 (65.7)	24.00 (20.00, 25.71)	70/137 (51.1)	31.14 (21.29, 44.43)	1.34 (0.98, 1.83)	0.0636	
Geographic region							0.3730
EU	51/ 74 (68.9)	23.86 (19.43, 25.00)	48/ 85 (56.5)	21.29 (18.29, 35.86)	1.20 (0.81, 1.79)	0.3613	
non-EU	77/116 (66.4)	20.29 (16.57, 24.29)	51/100 (51.0)	29.14 (24.14, 42.29)	1.56 (1.09, 2.23)	0.0123	
Onset of disease							0.4050
Paediatric	17/ 22 (77.3)	21.29 (12.57, 28.29)	7/ 15 (46.7)	26.14 (20.14, NE)	2.06 (0.81, 5.25)	0.1640	
Adult	111/168 (66.1)	21.43 (17.71, 24.29)	92/170 (54.1)	28.29 (21.00, 36.14)	1.33 (1.01, 1.75)	0.0423	
ADA result							0.7215
Negative	118/171 (69.0)	21.43 (18.71, 24.29)	90/163 (55.2)	28.00 (21.00, 33.14)	1.36 (1.03, 1.79)	0.0203	
Positive (At any time)	10/ 18 (55.6)	21.14 (9.43, NE)	9/ 22 (40.9)	36.14 (21.14, NE)	1.77 (0.69, 4.56)	0.9918	
BMI (kg/m2) at enrolment							0.1656
< 30	93/129 (72.1)	21.14 (17.29, 24.29)	72/143 (50.3)	29.14 (21.29, 40.14)	1.62 (1.19, 2.21)	0.0011	
>= 30	35/ 61 (57.4)	21.57 (16.29, 41.29)	27/ 42 (64.3)	25.14 (17.29, 42.29)	1.00 (0.60, 1.66)	0.9426	

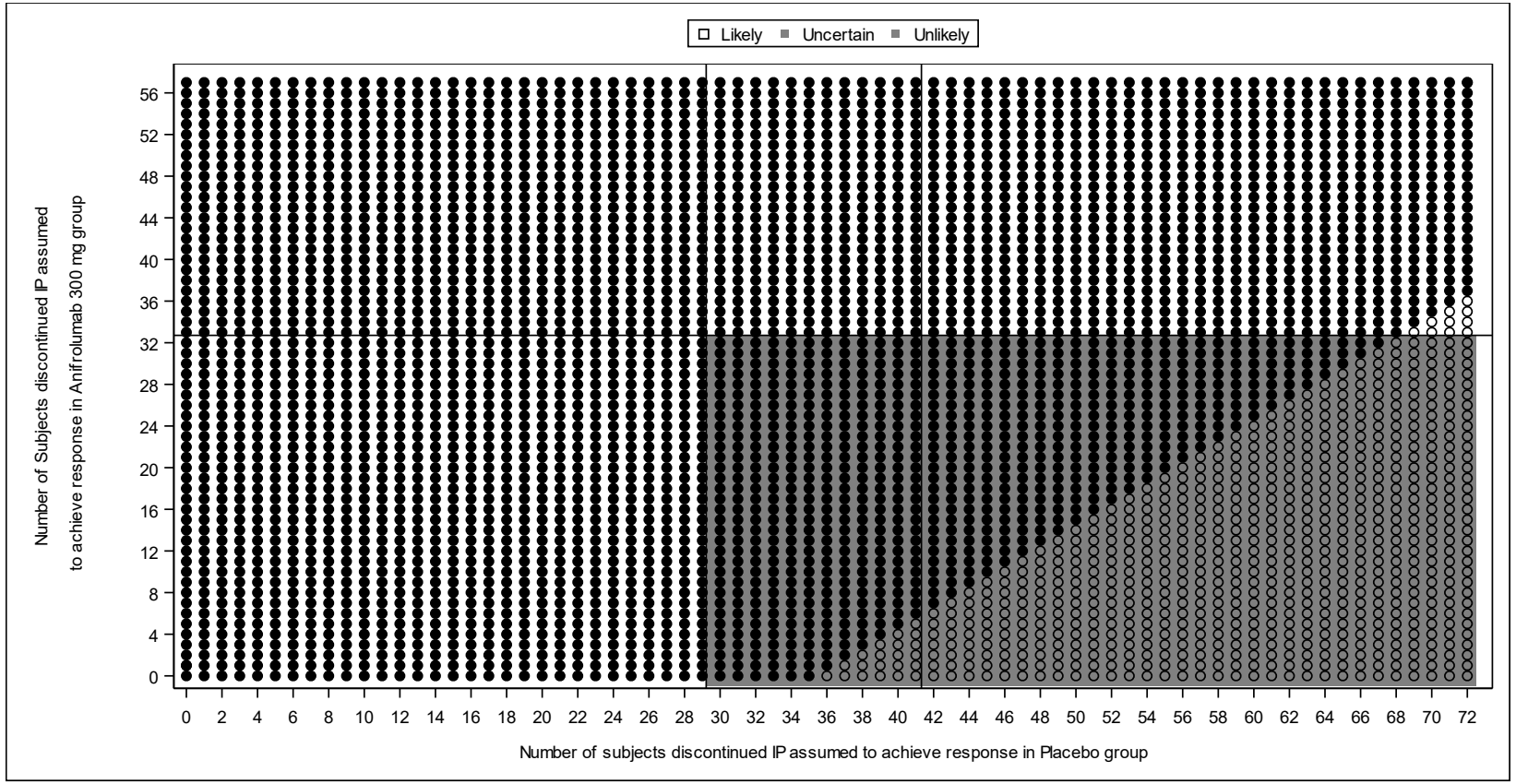
Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Time to OCS Reduction <=7.5 mg/day (for subjects with baseline OCS >=10 mg/day)
Full analysis set



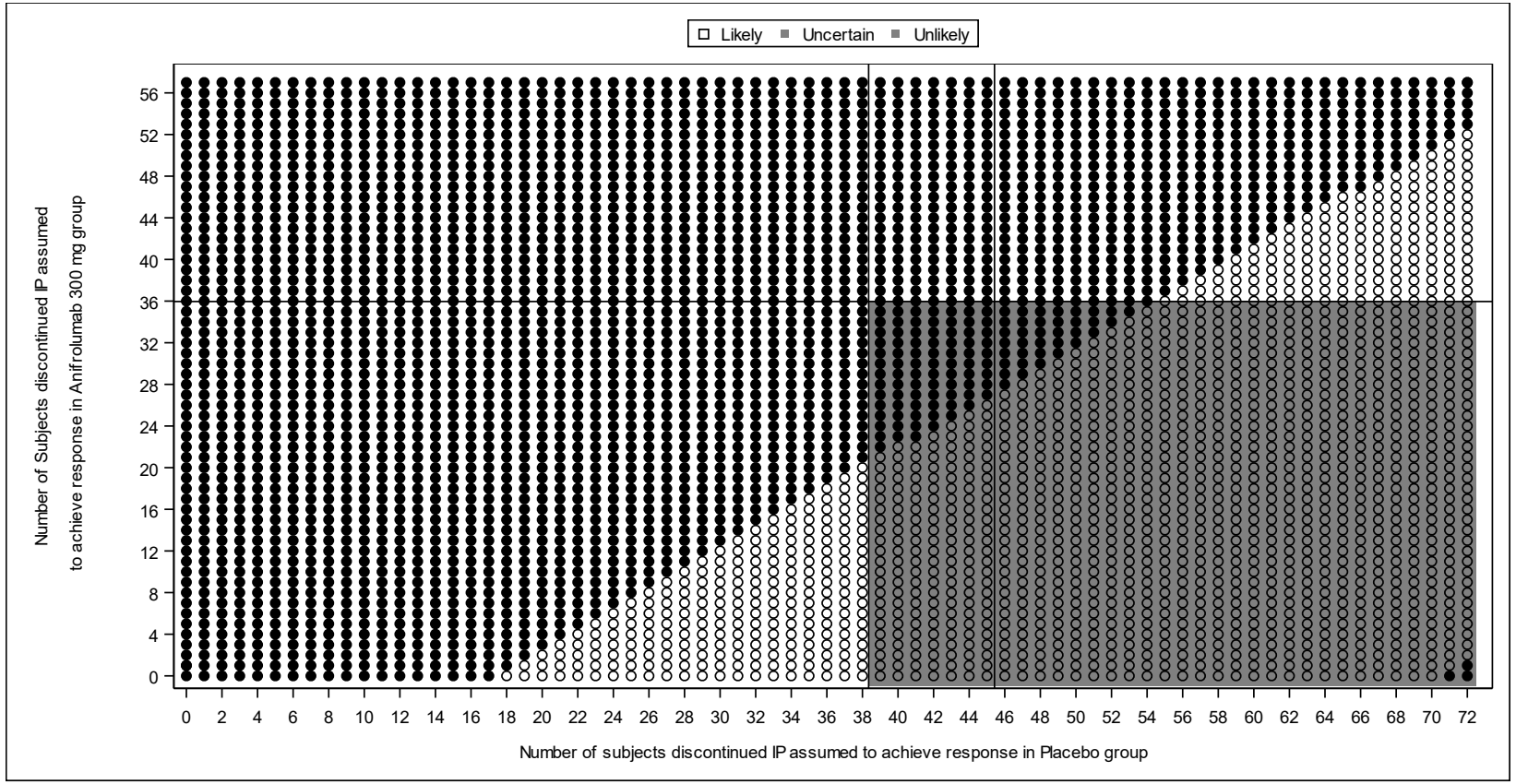
Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Plot of BICLA response rate sensitivity analysis at week 52, tipping point analysis
Full analysis set



Subjects with permanent discontinuation of IP are taken as non-responders at the bottom left grid. A certain number of such subjects from both groups are altered to be responders, while the numbers for both groups are as stated in both axes.
For each scenario, Pearson`s chi-squared test is used to compare the proportion of subjects achieving response at Week 52. The dots are presenting the results: filled = p-value <0.05, open = p-value >=0.05.
The three colors area indicate the tipping point area: white=likely, bright grey=uncertain, darker grey=Unlikely.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Plot of SRI (4) response rate sensitivity analysis at week 52, tipping point analysis
Full analysis set



Subjects with permanent discontinuation of IP are taken as non-responders at the bottom left grid. A certain number of such subjects from both groups are altered to be responders, while the numbers for both groups are as stated in both axes.
For each scenario, Pearson`s chi-squared test is used to compare the proportion of subjects achieving response at Week 52. The dots are presenting the results: filled = p-value <0.05, open = p-value >=0.05.
The three colors area indicate the tipping point area: white=likely, bright grey=uncertain, darker grey=Unlikely.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	323 (89.7)	299 (81.7)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.09 (1.03, 1.16)	
p-value	0.0030	
Odds Ratio (95% CI)	1.95 (1.27, 3.01)	
p-value	0.0024	
Risk Difference (95% CI)	8.02 (2.97, 13.07)	
p-value	0.0019	
CMH approach		
Response rate	89.8	81.6
Difference in response rates (95% CI)	8.17 (2.67, 13.68)	
p-value	0.0036	
p-Value for test for heterogenity between studies	0.2878	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8058
< 10 points	99/109 (90.8)	91.1	89/106 (84.0)	83.8	1.08 (0.98, 1.20)	0.1118	7.24 (-3.17, 17.64)	0.1730	
>= 10 points	224/251 (89.2)	89.2	210/260 (80.8)	80.7	1.10 (1.02, 1.18)	0.0102	8.54 (1.97, 15.12)	0.0109	
OCS dose at baseline									0.4605
<10 mg/day	157/170 (92.4)	92.3	155/181 (85.6)	85.6	1.07 (1.00, 1.16)	0.0605	6.76 (-0.85, 14.36)	0.0817	
>=10 mg/day	166/190 (87.4)	87.4	144/185 (77.8)	77.9	1.12 (1.02, 1.23)	0.0154	9.45 (1.35, 17.54)	0.0222	
Result of type I IFN gene signature test									0.4542
LOW	55/ 62 (88.7)	88.7	49/ 64 (76.6)	76.6	1.16 (0.98, 1.36)	0.0776	12.15 (-1.87, 26.17)	0.0895	
HIGH	268/298 (89.9)	90.0	250/302 (82.8)	82.7	1.08 (1.02, 1.15)	0.0127	7.34 (1.36, 13.32)	0.0161	
Age (years)									0.0382
<= 65	313/348 (89.9)	90.0	295/362 (81.5)	81.4	1.10 (1.04, 1.17)	0.0020	8.62 (3.05, 14.19)	0.0024	
> 65	10/ 12 (83.3)	84.1	4/ 4 (100.0)	100.0	0.84 (0.65, 1.08)	0.1648	-15.91 (-68.63, 36.81)	0.5542	
Sex									0.8269
male	22/ 27 (81.5)	81.3	19/ 25 (76.0)	75.8	1.06 (0.79, 1.42)	0.6891	5.51 (-18.85, 29.87)	0.6576	
female	301/333 (90.4)	90.5	280/341 (82.1)	82.1	1.10 (1.03, 1.17)	0.0025	8.38 (2.70, 14.05)	0.0038	
Race									0.0067
White	208/235 (88.5)	88.2	190/244 (77.9)	78.1	1.14 (1.05, 1.23)	0.0020	10.17 (2.99, 17.34)	0.0055	
Black	40/ 46 (87.0)	86.4	39/ 48 (81.3)	82.1	1.05 (0.88, 1.24)	0.5999	4.31 (-12.16, 20.78)	0.6081	
Other	67/ 71 (94.4)	94.4	62/ 66 (93.9)	93.9	0.98 (0.94, 1.02)	0.3773	0.46 (-9.46, 10.38)	0.9276	
Ethnicity									0.3705
Hispanic/Latino	80/ 86 (93.0)	92.9	72/ 89 (80.9)	80.8	1.15 (1.02, 1.29)	0.0186	12.04 (0.63, 23.45)	0.0387	
Non-hispanic/Latino	235/266 (88.3)	88.5	219/269 (81.4)	81.2	1.08 (1.01, 1.16)	0.0343	7.25 (0.58, 13.93)	0.0332	
Geographic region									0.4488
EU	96/115 (83.5)	83.4	88/122 (72.1)	72.6	1.13 (0.99, 1.30)	0.0659	10.85 (0.15, 21.56)	0.0469	
non-EU	227/245 (92.7)	92.6	211/244 (86.5)	86.6	1.07 (1.01, 1.14)	0.0270	6.06 (-0.36, 12.48)	0.0643	
Onset of disease									0.1457
Paediatric	25/ 26 (96.2)	96.3	22/ 24 (91.7)	92.0	0.99 (0.87, 1.12)	0.8699	4.32 (-16.10, 24.74)	0.6783	
Adult	298/334 (89.2)	89.2	277/342 (81.0)	81.0	1.10 (1.03, 1.17)	0.0035	8.22 (2.43, 14.01)	0.0054	
ADA result									0.9295
Negative	301/334 (90.1)	90.2	269/331 (81.3)	81.1	1.11 (1.04, 1.18)	0.0017	9.11 (3.31, 14.90)	0.0021	
Positive (At any time)	22/ 25 (88.0)	89.7	30/ 35 (85.7)	84.2	1.10 (0.96, 1.25)	0.1727	5.55 (-16.14, 27.23)	0.6162	
BMI (kg/m2) at enrolment									0.6353
< 30	207/233 (88.8)	89.1	209/261 (80.1)	80.1	1.10 (1.02, 1.18)	0.0122	9.00 (2.17, 15.83)	0.0098	
>= 30	116/127 (91.3)	91.6	90/105 (85.7)	85.5	1.07 (0.97, 1.17)	0.1676	6.11 (-3.80, 16.02)	0.2267	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Serious Adverse Event
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	43 (11.9)	69 (18.9)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.64 (0.45, 0.92)	
p-value	0.0145	
Odds Ratio (95% CI)	0.59 (0.39, 0.89)	
p-value	0.0123	
Risk Difference (95% CI)	-6.90 (-12.12, -1.68)	
p-value	0.0096	
CMH approach		
Response rate	11.9	18.8
Difference in response rates (95% CI)	-6.94 (-12.57, -1.31)	
p-value	0.0157	
p-Value for test for heterogenity between studies	0.1699	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Serious Adverse Event - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8709
< 10 points	9/109 (8.3)	8.1	13/106 (12.3)	12.2	0.69 (0.31, 1.53)	0.3549	-4.07 (-14.12, 5.97)	0.4264	
>= 10 points	34/251 (13.5)	13.5	56/260 (21.5)	21.6	0.64 (0.43, 0.94)	0.0241	-8.13 (-15.05, -1.20)	0.0214	
OCS dose at baseline									0.4220
<10 mg/day	16/170 (9.4)	9.4	33/181 (18.2)	18.1	0.54 (0.31, 0.96)	0.0348	-8.73 (-16.76, -0.70)	0.0332	
>=10 mg/day	27/190 (14.2)	14.2	36/185 (19.5)	19.6	0.73 (0.46, 1.16)	0.1820	-5.43 (-13.60, 2.75)	0.1933	
Result of type I IFN gene signature test									0.5084
LOW	6/ 62 (9.7)	9.7	7/ 64 (10.9)	10.9	0.88 (0.32, 2.41)	0.8055	-1.27 (-13.49, 10.96)	0.8390	
HIGH	37/298 (12.4)	12.3	62/302 (20.5)	20.5	0.61 (0.42, 0.89)	0.0111	-8.13 (-14.44, -1.82)	0.0115	
Age (years)									0.6587
<= 65	40/348 (11.5)	11.4	68/362 (18.8)	18.8	0.62 (0.43, 0.90)	0.0106	-7.39 (-13.06, -1.72)	0.0106	
> 65	3/ 12 (25.0)	26.1	1/ 4 (25.0)	23.9	0.90 (0.18, 4.53)	0.9014	2.27 (-53.76, 58.31)	0.9366	
Sex									0.3097
male	5/ 27 (18.5)	18.7	4/ 25 (16.0)	16.0	1.18 (0.36, 3.92)	0.7871	2.75 (-20.74, 26.25)	0.8183	
female	38/333 (11.4)	11.4	65/341 (19.1)	19.1	0.62 (0.42, 0.89)	0.0108	-7.73 (-13.58, -1.88)	0.0096	
Race									0.2797
White	29/235 (12.3)	12.4	40/244 (16.4)	16.4	0.77 (0.49, 1.20)	0.2458	-4.05 (-11.00, 2.91)	0.2544	
Black	5/ 46 (10.9)	10.3	13/ 48 (27.1)	28.3	0.37 (0.14, 0.96)	0.0410	-17.96 (-35.04, -0.88)	0.0393	
Other	7/ 71 (9.9)	9.8	15/ 66 (22.7)	22.7	0.45 (0.19, 1.04)	0.0618	-12.88 (-26.06, 0.29)	0.0553	
Ethnicity									0.9976
Hispanic/Latino	9/ 86 (10.5)	10.8	18/ 89 (20.2)	20.8	0.65 (0.30, 1.43)	0.2828	-10.05 (-22.05, 1.96)	0.1009	
Non-hispanic/Latino	32/266 (12.0)	12.0	50/269 (18.6)	18.4	0.65 (0.43, 0.98)	0.0395	-6.41 (-13.12, 0.30)	0.0613	
Geographic region									0.8252
EU	12/115 (10.4)	10.4	21/122 (17.2)	17.2	0.60 (0.31, 1.18)	0.1381	-6.87 (-16.18, 2.44)	0.1483	
non-EU	31/245 (12.7)	12.2	48/244 (19.7)	20.0	0.66 (0.43, 1.01)	0.0548	-7.79 (-14.90, -0.68)	0.0319	
Onset of disease									0.3889
Paediatric	8/ 26 (30.8)	30.6	8/ 24 (33.3)	33.0	0.92 (0.39, 2.14)	0.8457	-2.47 (-28.97, 24.03)	0.8551	
Adult	35/334 (10.5)	10.4	61/342 (17.8)	17.9	0.61 (0.41, 0.90)	0.0139	-7.42 (-13.13, -1.70)	0.0110	
ADA result									0.0672
Negative	42/334 (12.6)	12.6	57/331 (17.2)	17.1	0.74 (0.51, 1.08)	0.1177	-4.54 (-10.42, 1.34)	0.1298	
Positive (At any time)	1/ 25 (4.0)	3.4	12/ 35 (34.3)	35.8	0.16 (0.03, 0.80)	0.0254	-32.40 (-54.68, -10.12)	0.0044	
BMI (kg/m2) at enrolment									0.6160
< 30	25/233 (10.7)	10.8	48/261 (18.4)	18.2	0.59 (0.38, 0.93)	0.0228	-7.48 (-14.29, -0.68)	0.0311	
>= 30	18/127 (14.2)	14.0	21/105 (20.0)	20.4	0.72 (0.40, 1.30)	0.2751	-6.42 (-17.18, 4.34)	0.2421	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Severe Adverse Event
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	30 (8.3)	35 (9.6)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.91 (0.57, 1.47)	
p-value	0.7079	
Odds Ratio (95% CI)	0.88 (0.52, 1.50)	
p-value	0.6504	
Risk Difference (95% CI)	-1.21 (-5.35, 2.92)	
p-value	0.5655	
CMH approach		
Response rate	8.3	9.6
Difference in response rates (95% CI)	-1.34 (-6.19, 3.51)	
p-value	0.5889	
p-Value for test for heterogenity between studies	0.0438	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Severe Adverse Event - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9360
< 10 points	8/109 (7.3)	7.3	9/106 (8.5)	8.5	0.89 (0.35, 2.25)	0.8016	-1.22 (-10.89, 8.45)	0.8053	
>= 10 points	22/251 (8.8)	8.7	26/260 (10.0)	10.1	0.93 (0.53, 1.62)	0.7913	-1.40 (-7.14, 4.34)	0.6319	
OCS dose at baseline									0.9975
<10 mg/day	10/170 (5.9)	5.9	14/181 (7.7)	7.8	0.94 (0.40, 2.22)	0.8942	-1.97 (-8.78, 4.84)	0.5708	
>=10 mg/day	20/190 (10.5)	10.5	21/185 (11.4)	11.4	0.95 (0.53, 1.69)	0.8494	-0.83 (-8.09, 6.43)	0.8232	
Result of type I IFN gene signature test									0.6212
LOW	5/ 62 (8.1)	8.1	4/ 64 (6.3)	6.3	1.27 (0.35, 4.55)	0.7164	1.81 (-9.52, 13.14)	0.7539	
HIGH	25/298 (8.4)	8.3	31/302 (10.3)	10.3	0.89 (0.53, 1.51)	0.6771	-2.00 (-7.36, 3.36)	0.4649	
Age (years)									NE
<= 65	30/348 (8.6)	8.6	35/362 (9.7)	9.8	0.93 (0.58, 1.50)	0.7814	-1.19 (-6.14, 3.76)	0.6383	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE		0.00 (-51.08, 51.08)	1.0000	
Sex									0.9421
male	2/ 27 (7.4)	7.2	2/ 25 (8.0)	8.0	0.97 (0.15, 6.12)	0.9763	-0.83 (-21.47, 19.82)	0.9375	
female	28/333 (8.4)	8.4	33/341 (9.7)	9.7	0.91 (0.56, 1.48)	0.6936	-1.30 (-6.39, 3.79)	0.6170	
Race									0.5151
White	20/235 (8.5)	8.6	22/244 (9.0)	9.1	1.07 (0.57, 1.99)	0.8363	-0.50 (-6.60, 5.60)	0.8715	
Black	5/ 46 (10.9)	9.6	8/ 48 (16.7)	18.1	0.60 (0.22, 1.63)	0.3176	-8.47 (-24.33, 7.38)	0.2949	
Other	3/ 71 (4.2)	4.2	5/ 66 (7.6)	7.6	0.56 (0.14, 2.23)	0.4104	-3.37 (-13.52, 6.79)	0.5157	
Ethnicity									0.9174
Hispanic/Latino	8/ 86 (9.3)	9.6	11/ 89 (12.4)	12.8	0.86 (0.34, 2.17)	0.7471	-3.26 (-14.43, 7.91)	0.5676	
Non-hispanic/Latino	20/266 (7.5)	7.6	24/269 (8.9)	8.9	0.91 (0.51, 1.63)	0.7512	-1.29 (-7.06, 4.49)	0.6622	
Geographic region									0.6761
EU	9/115 (7.8)	7.9	9/122 (7.4)	7.3	1.09 (0.45, 2.63)	0.8566	0.61 (-7.18, 8.40)	0.8779	
non-EU	21/245 (8.6)	8.1	26/244 (10.7)	11.1	0.87 (0.49, 1.54)	0.6243	-2.93 (-9.20, 3.33)	0.3582	
Onset of disease									0.4725
Paediatric	4/ 26 (15.4)	15.4	6/ 24 (25.0)	24.7	0.62 (0.20, 1.97)	0.4207	-9.26 (-33.79, 15.28)	0.4595	
Adult	26/334 (7.8)	7.8	29/342 (8.5)	8.5	0.99 (0.58, 1.69)	0.9760	-0.78 (-5.72, 4.17)	0.7579	
ADA result									0.3038
Negative	27/334 (8.1)	8.2	28/331 (8.5)	8.5	1.01 (0.60, 1.70)	0.9768	-0.32 (-5.36, 4.72)	0.9022	
Positive (At any time)	3/ 25 (12.0)	10.3	7/ 35 (20.0)	23.6	0.52 (0.16, 1.64)	0.2645	-13.31 (-35.76, 9.14)	0.2452	
BMI (kg/m2) at enrolment									0.6216
< 30	17/233 (7.3)	7.3	21/261 (8.0)	7.9	0.99 (0.53, 1.86)	0.9739	-0.59 (-6.37, 5.19)	0.8408	
>= 30	13/127 (10.2)	10.2	14/105 (13.3)	13.6	0.78 (0.38, 1.60)	0.4939	-3.35 (-13.46, 6.75)	0.5153	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Non-Severe Adverse Event
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	321 (89.2)	296 (80.9)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.10 (1.03, 1.17)	
p-value	0.0026	
Odds Ratio (95% CI)	1.95 (1.27, 2.97)	
p-value	0.0020	
Risk Difference (95% CI)	8.28 (3.14, 13.43)	
p-value	0.0016	
CMH approach		
Response rate	89.2	80.8
Difference in response rates (95% CI)	8.48 (2.90, 14.05)	
p-value	0.0029	
p-Value for test for heterogenity between studies	0.3412	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Non-Severe Adverse Event - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.6234
< 10 points	98/109 (89.9)	90.2	89/106 (84.0)	83.8	1.08 (0.97, 1.19)	0.1528	6.39 (-4.07, 16.85)	0.2313	
>= 10 points	223/251 (88.8)	88.8	207/260 (79.6)	79.5	1.11 (1.03, 1.20)	0.0065	9.33 (2.66, 16.01)	0.0061	
OCS dose at baseline									0.3824
<10 mg/day	157/170 (92.4)	92.3	155/181 (85.6)	85.6	1.07 (1.00, 1.16)	0.0605	6.76 (-0.85, 14.36)	0.0817	
>=10 mg/day	164/190 (86.3)	86.4	141/185 (76.2)	76.3	1.13 (1.03, 1.25)	0.0118	10.04 (1.77, 18.30)	0.0173	
Result of type I IFN gene signature test									0.4883
LOW	55/ 62 (88.7)	88.7	49/ 64 (76.6)	76.6	1.16 (0.98, 1.36)	0.0776	12.15 (-1.87, 26.17)	0.0895	
HIGH	266/298 (89.3)	89.4	247/302 (81.8)	81.6	1.09 (1.02, 1.16)	0.0104	7.71 (1.64, 13.78)	0.0128	
Age (years)									0.0360
<= 65	311/348 (89.4)	89.5	292/362 (80.7)	80.5	1.10 (1.04, 1.17)	0.0018	8.93 (3.29, 14.56)	0.0019	
> 65	10/ 12 (83.3)	84.1	4/ 4 (100.0)	100.0	0.84 (0.65, 1.08)	0.1648	-15.91 (-68.63, 36.81)	0.5542	
Sex									0.8072
male	22/ 27 (81.5)	81.3	19/ 25 (76.0)	75.8	1.06 (0.79, 1.42)	0.6891	5.51 (-18.85, 29.87)	0.6576	
female	299/333 (89.8)	89.9	277/341 (81.2)	81.2	1.10 (1.04, 1.17)	0.0021	8.70 (2.95, 14.44)	0.0030	
Race									0.0038
White	207/235 (88.1)	87.8	187/244 (76.6)	76.8	1.15 (1.06, 1.25)	0.0012	10.94 (3.69, 18.20)	0.0031	
Black	40/ 46 (87.0)	86.4	39/ 48 (81.3)	82.1	1.05 (0.88, 1.24)	0.5999	4.31 (-12.16, 20.78)	0.6081	
Other	66/ 71 (93.0)	93.0	62/ 66 (93.9)	93.9	0.98 (0.94, 1.02)	0.3361	-0.94 (-11.07, 9.18)	0.8550	
Ethnicity									0.4018
Hispanic/Latino	79/ 86 (91.9)	91.7	71/ 89 (79.8)	79.6	1.15 (1.02, 1.30)	0.0237	12.07 (0.38, 23.76)	0.0429	
Non-hispanic/Latino	234/266 (88.0)	88.1	217/269 (80.7)	80.5	1.08 (1.01, 1.17)	0.0308	7.54 (0.81, 14.28)	0.0281	
Geographic region									0.4231
EU	95/115 (82.6)	82.5	86/122 (70.5)	71.0	1.14 (0.99, 1.31)	0.0628	11.48 (0.63, 22.33)	0.0381	
non-EU	226/245 (92.2)	92.3	210/244 (86.1)	86.2	1.07 (1.01, 1.14)	0.0301	6.12 (-0.34, 12.57)	0.0635	
Onset of disease									0.1462
Paediatric	25/ 26 (96.2)	96.3	21/ 24 (87.5)	88.0	0.99 (0.86, 1.13)	0.8321	8.33 (-12.58, 29.24)	0.4347	
Adult	296/334 (88.6)	88.6	275/342 (80.4)	80.4	1.10 (1.03, 1.17)	0.0038	8.23 (2.38, 14.07)	0.0058	
ADA result									0.9350
Negative	299/334 (89.5)	89.6	267/331 (80.7)	80.5	1.11 (1.04, 1.18)	0.0020	9.13 (3.28, 14.99)	0.0022	
Positive (At any time)	22/ 25 (88.0)	89.7	29/ 35 (82.9)	80.3	1.11 (0.97, 1.27)	0.1244	9.43 (-12.70, 31.55)	0.4036	
BMI (kg/m2) at enrolment									0.5841
< 30	205/233 (88.0)	88.2	206/261 (78.9)	78.9	1.10 (1.02, 1.19)	0.0105	9.28 (2.34, 16.22)	0.0088	
>= 30	116/127 (91.3)	91.6	90/105 (85.7)	85.5	1.07 (0.97, 1.17)	0.1676	6.11 (-3.80, 16.02)	0.2267	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event leading to discontinuation of study drug
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	18 (5.0)	22 (6.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.87 (0.45, 1.67)	
p-value	0.6773	
Odds Ratio (95% CI)	0.86 (0.43, 1.70)	
p-value	0.6596	
Risk Difference (95% CI)	-1.01 (-4.34, 2.32)	
p-value	0.5524	
CMH approach		
Response rate	5.0	6.1
Difference in response rates (95% CI)	-1.06 (-5.40, 3.28)	
p-value	0.6321	
p-Value for test for heterogenity between studies	0.0231	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event leading to discontinuation of study drug - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.4966
< 10 points	5/109 (4.6)	4.6	4/106 (3.8)	3.7	1.45 (0.26, 8.07)	0.6705	0.91 (-7.83, 9.65)	0.8382	
>= 10 points	13/251 (5.2)	5.2	18/260 (6.9)	7.1	0.76 (0.37, 1.55)	0.4536	-1.88 (-7.04, 3.27)	0.4737	
OCS dose at baseline									0.6252
<10 mg/day	7/170 (4.1)	4.2	7/181 (3.9)	3.8	1.07 (0.34, 3.34)	0.9102	0.32 (-5.91, 6.56)	0.9188	
>=10 mg/day	11/190 (5.8)	5.8	15/185 (8.1)	8.2	0.75 (0.34, 1.67)	0.4893	-2.33 (-8.82, 4.16)	0.4817	
Result of type I IFN gene signature test									0.9514
LOW	3/ 62 (4.8)	4.8	3/ 64 (4.7)	4.7	0.89 (0.15, 5.27)	0.8988	0.15 (-10.20, 10.50)	0.9769	
HIGH	15/298 (5.0)	5.0	19/302 (6.3)	6.4	0.84 (0.42, 1.68)	0.6214	-1.31 (-6.09, 3.46)	0.5896	
Age (years)									0.7092
<= 65	17/348 (4.9)	4.9	22/362 (6.1)	6.1	0.84 (0.44, 1.62)	0.6060	-1.24 (-5.64, 3.17)	0.5818	
> 65	1/ 12 (8.3)	10.2	0/ 4 (0.0)	0.0	1.50 (0.08, 29.15)	0.7888	10.23 (-42.20, 62.65)	0.7022	
Sex									NE
male	0/ 27 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.55, 17.55)	1.0000	
female	18/333 (5.4)	5.4	22/341 (6.5)	6.5	0.88 (0.46, 1.68)	0.6965	-1.12 (-5.75, 3.51)	0.6359	
Race									0.8868
White	13/235 (5.5)	5.7	14/244 (5.7)	5.8	0.98 (0.45, 2.13)	0.9523	-0.07 (-5.66, 5.52)	0.9798	
Black	1/ 46 (2.2)	1.9	2/ 48 (4.2)	4.2	0.64 (0.08, 5.01)	0.6712	-2.27 (-14.57, 10.04)	0.7180	
Other	3/ 71 (4.2)	4.2	6/ 66 (9.1)	9.1	0.71 (0.16, 3.08)	0.6492	-4.88 (-15.31, 5.55)	0.3591	
Ethnicity									0.5677
Hispanic/Latino	5/ 86 (5.8)	5.9	8/ 89 (9.0)	9.1	0.67 (0.23, 1.95)	0.4581	-3.20 (-13.46, 7.06)	0.5405	
Non-hispanic/Latino	12/266 (4.5)	4.6	14/269 (5.2)	5.1	1.00 (0.41, 2.48)	0.9956	-0.52 (-5.73, 4.70)	0.8460	
Geographic region									0.8460
EU	5/115 (4.3)	4.5	6/122 (4.9)	5.0	0.96 (0.28, 3.26)	0.9496	-0.51 (-7.32, 6.29)	0.8822	
non-EU	13/245 (5.3)	5.3	16/244 (6.6)	6.6	0.83 (0.39, 1.80)	0.6424	-1.36 (-7.13, 4.42)	0.6450	
Onset of disease									0.9949
Paediatric	2/ 26 (7.7)	7.7	2/ 24 (8.3)	8.0	0.88 (0.14, 5.51)	0.8951	-0.31 (-21.49, 20.88)	0.9772	
Adult	16/334 (4.8)	4.8	20/342 (5.8)	5.9	0.88 (0.43, 1.80)	0.7241	-1.08 (-5.57, 3.41)	0.6374	
ADA result									0.9370
Negative	15/334 (4.5)	4.6	17/331 (5.1)	5.2	0.92 (0.44, 1.91)	0.8173	-0.62 (-5.11, 3.87)	0.7864	
Positive (At any time)	3/ 25 (12.0)	12.1	5/ 35 (14.3)	14.0	0.86 (0.22, 3.43)	0.8320	-1.96 (-23.75, 19.83)	0.8602	
BMI (kg/m2) at enrolment									0.9024
< 30	14/233 (6.0)	6.0	18/261 (6.9)	7.0	0.92 (0.45, 1.89)	0.8276	-0.99 (-6.60, 4.62)	0.7292	
>= 30	4/127 (3.1)	3.2	4/105 (3.8)	3.9	0.83 (0.17, 4.02)	0.8155	-0.70 (-8.96, 7.55)	0.8674	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Serious Adverse Event leading to discontinuation of study drug
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	7 (1.9)	13 (3.6)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.71 (0.26, 1.96)	
p-value	0.5055	
Odds Ratio (95% CI)	0.69 (0.24, 1.97)	
p-value	0.4895	
Risk Difference (95% CI)	-1.61 (-3.99, 0.77)	
p-value	0.1858	
CMH approach		
Response rate	1.9	3.7
Difference in response rates (95% CI)	-1.71 (-5.50, 2.08)	
p-value	0.3770	
p-Value for test for heterogenity between studies	0.0608	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Serious Adverse Event leading to discontinuation of study drug - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.1267
< 10 points	4/109 (3.7)	3.6	1/106 (0.9)	1.0	1.96 (0.23, 16.71)	0.5371	2.69 (-5.61, 10.99)	0.5249	
>= 10 points	3/251 (1.2)	1.2	12/260 (4.6)	4.8	0.28 (0.08, 1.01)	0.0518	-3.55 (-7.95, 0.86)	0.1143	
OCS dose at baseline									0.0416
<10 mg/day	4/170 (2.4)	2.4	0/181 (0.0)	0.0	5.04 (0.58, 43.89)	0.1429	2.41 (-3.15, 7.97)	0.3963	
>=10 mg/day	3/190 (1.6)	1.5	13/185 (7.0)	7.1	0.37 (0.11, 1.31)	0.1250	-5.53 (-11.34, 0.28)	0.0620	
Result of type I IFN gene signature test									0.3325
LOW	1/ 62 (1.6)	1.6	0/ 64 (0.0)	0.0	3.09 (0.13, 73.19)	0.4846	1.61 (-6.90, 10.13)	0.7106	
HIGH	6/298 (2.0)	2.0	13/302 (4.3)	4.4	0.59 (0.21, 1.70)	0.3316	-2.41 (-6.63, 1.82)	0.2640	
Age (years)									0.5747
<= 65	6/348 (1.7)	1.7	13/362 (3.6)	3.7	0.61 (0.21, 1.74)	0.3557	-2.00 (-5.84, 1.84)	0.3082	
> 65	1/ 12 (8.3)	10.2	0/ 4 (0.0)	0.0	1.50 (0.08, 29.15)	0.7888	10.23 (-42.20, 62.65)	0.7022	
Sex									NE
male	0/ 27 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.55, 17.55)	1.0000	
female	7/333 (2.1)	2.1	13/341 (3.8)	3.9	0.72 (0.26, 1.98)	0.5192	-1.82 (-5.87, 2.22)	0.3772	
Race									0.8320
White	5/235 (2.1)	2.2	8/244 (3.3)	3.4	0.79 (0.21, 2.95)	0.7296	-1.15 (-6.09, 3.78)	0.6464	
Black	0/ 46 (0.0)	0.0	2/ 48 (4.2)	4.2	0.36 (0.04, 3.33)	0.3669	-4.19 (-16.06, 7.67)	0.4883	
Other	2/ 71 (2.8)	2.8	3/ 66 (4.5)	4.6	0.70 (0.14, 3.51)	0.6608	-1.75 (-10.95, 7.46)	0.7102	
Ethnicity									0.3686
Hispanic/Latino	1/ 86 (1.2)	1.2	5/ 89 (5.6)	5.9	0.32 (0.05, 2.03)	0.2289	-4.70 (-13.83, 4.43)	0.3125	
Non-hispanic/Latino	6/266 (2.3)	2.2	8/269 (3.0)	3.0	0.88 (0.27, 2.86)	0.8332	-0.76 (-5.50, 3.97)	0.7521	
Geographic region									0.3904
EU	1/115 (0.9)	0.9	5/122 (4.1)	4.2	0.32 (0.05, 2.06)	0.2326	-3.31 (-9.16, 2.55)	0.2681	
non-EU	6/245 (2.4)	2.5	8/244 (3.3)	3.5	0.85 (0.26, 2.74)	0.7822	-1.01 (-6.22, 4.20)	0.7041	
Onset of disease									0.9876
Paediatric	1/ 26 (3.8)	3.7	1/ 24 (4.2)	4.0	0.93 (0.10, 8.38)	0.9477	-0.31 (-20.08, 19.46)	0.9756	
Adult	6/334 (1.8)	1.8	12/342 (3.5)	3.6	0.91 (0.29, 2.85)	0.8728	-1.79 (-5.75, 2.16)	0.3741	
ADA result									0.3200
Negative	7/334 (2.1)	2.1	9/331 (2.7)	2.8	0.97 (0.31, 3.05)	0.9550	-0.72 (-4.70, 3.26)	0.7237	
Positive (At any time)	0/ 25 (0.0)	0.0	4/ 35 (11.4)	11.9	0.29 (0.04, 2.33)	0.2434	-11.94 (-31.26, 7.38)	0.2257	
BMI (kg/m2) at enrolment									0.9930
< 30	5/233 (2.1)	2.1	10/261 (3.8)	3.8	0.67 (0.21, 2.11)	0.4985	-1.76 (-6.57, 3.04)	0.4722	
>= 30	2/127 (1.6)	1.5	3/105 (2.9)	3.1	0.68 (0.11, 4.39)	0.6858	-1.59 (-9.53, 6.35)	0.6942	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with Adverse Event leading to death
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	2 (0.6)	1 (0.3)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.63 (0.20, 13.17)	
p-value	0.6474	
Odds Ratio (95% CI)	1.63 (0.20, 13.35)	
p-value	0.6469	
Risk Difference (95% CI)	0.28 (-0.65, 1.22)	
p-value	0.5530	
CMH approach		
Response rate	0.5	0.3
Difference in response rates (95% CI)	0.25 (-2.98, 3.47)	
p-value	0.8811	
p-Value for test for heterogenity between studies	0.6138	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with Adverse Event leading to death - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.2847
< 10 points	2/109 (1.8)	1.8	0/106 (0.0)	0.0	2.92 (0.31, 27.62)	0.3503	1.76 (-6.16, 9.68)	0.6638	
>= 10 points	0/251 (0.0)	0.0	1/260 (0.4)	0.4	0.35 (0.01, 8.43)	0.5152	-0.39 (-3.93, 3.16)	0.8297	
OCS dose at baseline									NE
<10 mg/day	0/170 (0.0)	0.0	0/181 (0.0)	0.0	NE		0.00 (-5.16, 5.16)	1.0000	
>=10 mg/day	2/190 (1.1)	1.0	1/185 (0.5)	0.5	1.56 (0.19, 12.56)	0.6758	0.48 (-4.29, 5.24)	0.8447	
Result of type I IFN gene signature test									NE
LOW	0/ 62 (0.0)	0.0	0/ 64 (0.0)	0.0	NE		0.00 (-8.05, 8.05)	1.0000	
HIGH	2/298 (0.7)	0.6	1/302 (0.3)	0.3	1.62 (0.20, 13.11)	0.6493	0.30 (-3.22, 3.81)	0.8681	
Age (years)									NE
<= 65	2/348 (0.6)	0.5	1/362 (0.3)	0.3	1.67 (0.21, 13.47)	0.6320	0.25 (-3.05, 3.54)	0.8832	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE		0.00 (-51.08, 51.08)	1.0000	
Sex									NE
male	0/ 27 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.55, 17.55)	1.0000	
female	2/333 (0.6)	0.6	1/341 (0.3)	0.3	1.64 (0.20, 13.27)	0.6419	0.28 (-3.17, 3.72)	0.8744	
Race									0.4873
White	1/235 (0.4)	0.3	0/244 (0.0)	0.0	2.92 (0.12, 70.87)	0.5104	0.32 (-3.89, 4.54)	0.8802	
Black	0/ 46 (0.0)	0.0	1/ 48 (2.1)	2.4	0.27 (0.01, 6.26)	0.4116	-2.43 (-13.93, 9.07)	0.6786	
Other	1/ 71 (1.4)	1.4	0/ 66 (0.0)	0.0	2.78 (0.12, 65.08)	0.5255	1.40 (-6.39, 9.19)	0.7240	
Ethnicity									0.2617
Hispanic/Latino	2/ 86 (2.3)	2.5	0/ 89 (0.0)	0.0	3.13 (0.33, 29.53)	0.3182	2.52 (-5.65, 10.68)	0.5458	
Non-hispanic/Latino	0/266 (0.0)	0.0	1/269 (0.4)	0.3	0.34 (0.01, 8.17)	0.5026	-0.35 (-4.54, 3.84)	0.8707	
Geographic region									NE
EU	0/115 (0.0)	0.0	0/122 (0.0)	0.0	NE		0.00 (-4.48, 4.48)	1.0000	
non-EU	2/245 (0.8)	0.8	1/244 (0.4)	0.5	1.57 (0.19, 12.67)	0.6716	0.30 (-4.34, 4.95)	0.8977	
Onset of disease									NE
Paediatric	0/ 26 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-18.15, 18.15)	1.0000	
Adult	2/334 (0.6)	0.6	1/342 (0.3)	0.3	1.64 (0.20, 13.25)	0.6431	0.29 (-3.15, 3.73)	0.8694	
ADA result									NE
Negative	2/334 (0.6)	0.5	1/331 (0.3)	0.3	1.60 (0.20, 12.92)	0.6599	0.24 (-3.24, 3.73)	0.8915	
Positive (At any time)	0/ 25 (0.0)	0.0	0/ 35 (0.0)	0.0	NE		0.00 (-17.02, 17.02)	1.0000	
BMI (kg/m2) at enrolment									0.2015
< 30	2/233 (0.9)	0.8	0/261 (0.0)	0.0	3.37 (0.35, 32.13)	0.2918	0.82 (-3.31, 4.95)	0.6968	
>= 30	0/127 (0.0)	0.0	1/105 (1.0)	1.0	0.26 (0.01, 6.38)	0.4131	-1.04 (-8.50, 6.43)	0.7852	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Anaphylaxis
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-3.13, 3.13)	
p-value	1.0000	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Anaphylaxis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/109 (0.0)	0.0	0/106 (0.0)	0.0	NE	0.00 (-7.66, 7.66)	1.0000	
>= 10 points	0/251 (0.0)	0.0	0/260 (0.0)	0.0	NE	0.00 (-3.47, 3.47)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/170 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-5.16, 5.16)	1.0000	
>=10 mg/day	0/190 (0.0)	0.0	0/185 (0.0)	0.0	NE	0.00 (-4.52, 4.52)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 62 (0.0)	0.0	0/ 64 (0.0)	0.0	NE	0.00 (-8.05, 8.05)	1.0000	
HIGH	0/298 (0.0)	0.0	0/302 (0.0)	0.0	NE	0.00 (-3.38, 3.38)	1.0000	
Age (years)								NE
<= 65	0/348 (0.0)	0.0	0/362 (0.0)	0.0	NE	0.00 (-3.20, 3.20)	1.0000	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE	0.00 (-51.08, 51.08)	1.0000	
Sex								NE
male	0/ 27 (0.0)	0.0	0/ 25 (0.0)	0.0	NE	0.00 (-17.55, 17.55)	1.0000	
female	0/333 (0.0)	0.0	0/341 (0.0)	0.0	NE	0.00 (-3.35, 3.35)	1.0000	
Race								NE
White	0/235 (0.0)	0.0	0/244 (0.0)	0.0	NE	0.00 (-4.18, 4.18)	1.0000	
Black	0/ 46 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-10.79, 10.79)	1.0000	
Other	0/ 71 (0.0)	0.0	0/ 66 (0.0)	0.0	NE	0.00 (-7.43, 7.43)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 86 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-7.72, 7.72)	1.0000	
Non-hispanic/Latino	0/266 (0.0)	0.0	0/269 (0.0)	0.0	NE	0.00 (-4.14, 4.14)	1.0000	
Geographic region								NE
EU	0/115 (0.0)	0.0	0/122 (0.0)	0.0	NE	0.00 (-4.48, 4.48)	1.0000	
non-EU	0/245 (0.0)	0.0	0/244 (0.0)	0.0	NE	0.00 (-4.51, 4.51)	1.0000	
Onset of disease								NE
Paediatric	0/ 26 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-18.15, 18.15)	1.0000	
Adult	0/334 (0.0)	0.0	0/342 (0.0)	0.0	NE	0.00 (-3.34, 3.34)	1.0000	
ADA result								NE
Negative	0/334 (0.0)	0.0	0/331 (0.0)	0.0	NE	0.00 (-3.40, 3.40)	1.0000	
Positive (At any time)	0/ 25 (0.0)	0.0	0/ 35 (0.0)	0.0	NE	0.00 (-17.02, 17.02)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/233 (0.0)	0.0	0/261 (0.0)	0.0	NE	0.00 (-4.03, 4.03)	1.0000	
>= 30	0/127 (0.0)	0.0	0/105 (0.0)	0.0	NE	0.00 (-7.26, 7.26)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Anaphylaxis
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-3.13, 3.13)	
p-value	1.0000	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Anaphylaxis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/109 (0.0)	0.0	0/106 (0.0)	0.0	NE	0.00 (-7.66, 7.66)	1.0000	
>= 10 points	0/251 (0.0)	0.0	0/260 (0.0)	0.0	NE	0.00 (-3.47, 3.47)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/170 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-5.16, 5.16)	1.0000	
>=10 mg/day	0/190 (0.0)	0.0	0/185 (0.0)	0.0	NE	0.00 (-4.52, 4.52)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 62 (0.0)	0.0	0/ 64 (0.0)	0.0	NE	0.00 (-8.05, 8.05)	1.0000	
HIGH	0/298 (0.0)	0.0	0/302 (0.0)	0.0	NE	0.00 (-3.38, 3.38)	1.0000	
Age (years)								NE
<= 65	0/348 (0.0)	0.0	0/362 (0.0)	0.0	NE	0.00 (-3.20, 3.20)	1.0000	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE	0.00 (-51.08, 51.08)	1.0000	
Sex								NE
male	0/ 27 (0.0)	0.0	0/ 25 (0.0)	0.0	NE	0.00 (-17.55, 17.55)	1.0000	
female	0/333 (0.0)	0.0	0/341 (0.0)	0.0	NE	0.00 (-3.35, 3.35)	1.0000	
Race								NE
White	0/235 (0.0)	0.0	0/244 (0.0)	0.0	NE	0.00 (-4.18, 4.18)	1.0000	
Black	0/ 46 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-10.79, 10.79)	1.0000	
Other	0/ 71 (0.0)	0.0	0/ 66 (0.0)	0.0	NE	0.00 (-7.43, 7.43)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 86 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-7.72, 7.72)	1.0000	
Non-hispanic/Latino	0/266 (0.0)	0.0	0/269 (0.0)	0.0	NE	0.00 (-4.14, 4.14)	1.0000	
Geographic region								NE
EU	0/115 (0.0)	0.0	0/122 (0.0)	0.0	NE	0.00 (-4.48, 4.48)	1.0000	
non-EU	0/245 (0.0)	0.0	0/244 (0.0)	0.0	NE	0.00 (-4.51, 4.51)	1.0000	
Onset of disease								NE
Paediatric	0/ 26 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-18.15, 18.15)	1.0000	
Adult	0/334 (0.0)	0.0	0/342 (0.0)	0.0	NE	0.00 (-3.34, 3.34)	1.0000	
ADA result								NE
Negative	0/334 (0.0)	0.0	0/331 (0.0)	0.0	NE	0.00 (-3.40, 3.40)	1.0000	
Positive (At any time)	0/ 25 (0.0)	0.0	0/ 35 (0.0)	0.0	NE	0.00 (-17.02, 17.02)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/233 (0.0)	0.0	0/261 (0.0)	0.0	NE	0.00 (-4.03, 4.03)	1.0000	
>= 30	0/127 (0.0)	0.0	0/105 (0.0)	0.0	NE	0.00 (-7.26, 7.26)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Anaphylaxis
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-3.13, 3.13)	
p-value	1.0000	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Anaphylaxis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/109 (0.0)	0.0	0/106 (0.0)	0.0	NE	0.00 (-7.66, 7.66)	1.0000	
>= 10 points	0/251 (0.0)	0.0	0/260 (0.0)	0.0	NE	0.00 (-3.47, 3.47)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/170 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-5.16, 5.16)	1.0000	
>=10 mg/day	0/190 (0.0)	0.0	0/185 (0.0)	0.0	NE	0.00 (-4.52, 4.52)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 62 (0.0)	0.0	0/ 64 (0.0)	0.0	NE	0.00 (-8.05, 8.05)	1.0000	
HIGH	0/298 (0.0)	0.0	0/302 (0.0)	0.0	NE	0.00 (-3.38, 3.38)	1.0000	
Age (years)								NE
<= 65	0/348 (0.0)	0.0	0/362 (0.0)	0.0	NE	0.00 (-3.20, 3.20)	1.0000	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE	0.00 (-51.08, 51.08)	1.0000	
Sex								NE
male	0/ 27 (0.0)	0.0	0/ 25 (0.0)	0.0	NE	0.00 (-17.55, 17.55)	1.0000	
female	0/333 (0.0)	0.0	0/341 (0.0)	0.0	NE	0.00 (-3.35, 3.35)	1.0000	
Race								NE
White	0/235 (0.0)	0.0	0/244 (0.0)	0.0	NE	0.00 (-4.18, 4.18)	1.0000	
Black	0/ 46 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-10.79, 10.79)	1.0000	
Other	0/ 71 (0.0)	0.0	0/ 66 (0.0)	0.0	NE	0.00 (-7.43, 7.43)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 86 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-7.72, 7.72)	1.0000	
Non-hispanic/Latino	0/266 (0.0)	0.0	0/269 (0.0)	0.0	NE	0.00 (-4.14, 4.14)	1.0000	
Geographic region								NE
EU	0/115 (0.0)	0.0	0/122 (0.0)	0.0	NE	0.00 (-4.48, 4.48)	1.0000	
non-EU	0/245 (0.0)	0.0	0/244 (0.0)	0.0	NE	0.00 (-4.51, 4.51)	1.0000	
Onset of disease								NE
Paediatric	0/ 26 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-18.15, 18.15)	1.0000	
Adult	0/334 (0.0)	0.0	0/342 (0.0)	0.0	NE	0.00 (-3.34, 3.34)	1.0000	
ADA result								NE
Negative	0/334 (0.0)	0.0	0/331 (0.0)	0.0	NE	0.00 (-3.40, 3.40)	1.0000	
Positive (At any time)	0/ 25 (0.0)	0.0	0/ 35 (0.0)	0.0	NE	0.00 (-17.02, 17.02)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/233 (0.0)	0.0	0/261 (0.0)	0.0	NE	0.00 (-4.03, 4.03)	1.0000	
>= 30	0/127 (0.0)	0.0	0/105 (0.0)	0.0	NE	0.00 (-7.26, 7.26)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Anaphylaxis
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-3.13, 3.13)	
p-value	1.0000	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Anaphylaxis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/109 (0.0)	0.0	0/106 (0.0)	0.0	NE	0.00 (-7.66, 7.66)	1.0000	
>= 10 points	0/251 (0.0)	0.0	0/260 (0.0)	0.0	NE	0.00 (-3.47, 3.47)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/170 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-5.16, 5.16)	1.0000	
>=10 mg/day	0/190 (0.0)	0.0	0/185 (0.0)	0.0	NE	0.00 (-4.52, 4.52)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 62 (0.0)	0.0	0/ 64 (0.0)	0.0	NE	0.00 (-8.05, 8.05)	1.0000	
HIGH	0/298 (0.0)	0.0	0/302 (0.0)	0.0	NE	0.00 (-3.38, 3.38)	1.0000	
Age (years)								NE
<= 65	0/348 (0.0)	0.0	0/362 (0.0)	0.0	NE	0.00 (-3.20, 3.20)	1.0000	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE	0.00 (-51.08, 51.08)	1.0000	
Sex								NE
male	0/ 27 (0.0)	0.0	0/ 25 (0.0)	0.0	NE	0.00 (-17.55, 17.55)	1.0000	
female	0/333 (0.0)	0.0	0/341 (0.0)	0.0	NE	0.00 (-3.35, 3.35)	1.0000	
Race								NE
White	0/235 (0.0)	0.0	0/244 (0.0)	0.0	NE	0.00 (-4.18, 4.18)	1.0000	
Black	0/ 46 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-10.79, 10.79)	1.0000	
Other	0/ 71 (0.0)	0.0	0/ 66 (0.0)	0.0	NE	0.00 (-7.43, 7.43)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 86 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-7.72, 7.72)	1.0000	
Non-hispanic/Latino	0/266 (0.0)	0.0	0/269 (0.0)	0.0	NE	0.00 (-4.14, 4.14)	1.0000	
Geographic region								NE
EU	0/115 (0.0)	0.0	0/122 (0.0)	0.0	NE	0.00 (-4.48, 4.48)	1.0000	
non-EU	0/245 (0.0)	0.0	0/244 (0.0)	0.0	NE	0.00 (-4.51, 4.51)	1.0000	
Onset of disease								NE
Paediatric	0/ 26 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-18.15, 18.15)	1.0000	
Adult	0/334 (0.0)	0.0	0/342 (0.0)	0.0	NE	0.00 (-3.34, 3.34)	1.0000	
ADA result								NE
Negative	0/334 (0.0)	0.0	0/331 (0.0)	0.0	NE	0.00 (-3.40, 3.40)	1.0000	
Positive (At any time)	0/ 25 (0.0)	0.0	0/ 35 (0.0)	0.0	NE	0.00 (-17.02, 17.02)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/233 (0.0)	0.0	0/261 (0.0)	0.0	NE	0.00 (-4.03, 4.03)	1.0000	
>= 30	0/127 (0.0)	0.0	0/105 (0.0)	0.0	NE	0.00 (-7.26, 7.26)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	23 (6.4)	6 (1.6)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.88 (1.60, 9.42)	
p-value	0.0028	
Odds Ratio (95% CI)	4.07 (1.64, 10.14)	
p-value	0.0025	
Risk Difference (95% CI)	4.75 (1.91, 7.59)	
p-value	0.0011	
CMH approach		
Response rate	6.4	1.7
Difference in response rates (95% CI)	4.74 (0.67, 8.80)	
p-value	0.0224	
p-Value for test for heterogenity between studies	0.7815	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.1826
< 10 points	3/109 (2.8)	2.9	2/106 (1.9)	1.9	1.31 (0.25, 6.80)	0.7467	0.98 (-7.35, 9.31)	0.8182	
>= 10 points	20/251 (8.0)	7.9	4/260 (1.5)	1.6	4.97 (1.72, 14.40)	0.0031	6.33 (1.50, 11.16)	0.0102	
OCS dose at baseline									0.4608
<10 mg/day	11/170 (6.5)	6.5	2/181 (1.1)	1.1	5.84 (1.31, 25.98)	0.0205	5.34 (-0.85, 11.53)	0.0907	
>=10 mg/day	12/190 (6.3)	6.3	4/185 (2.2)	2.2	2.90 (0.95, 8.84)	0.0619	4.08 (-1.77, 9.93)	0.1720	
Result of type I IFN gene signature test									0.8244
LOW	4/ 62 (6.5)	6.5	1/ 64 (1.6)	1.6	2.92 (0.46, 18.57)	0.2552	4.89 (-5.18, 14.96)	0.3410	
HIGH	19/298 (6.4)	6.4	5/302 (1.7)	1.7	3.71 (1.39, 9.90)	0.0090	4.70 (0.26, 9.15)	0.0379	
Age (years)									NE
<= 65	23/348 (6.6)	6.7	6/362 (1.7)	1.7	3.97 (1.63, 9.64)	0.0023	4.96 (0.79, 9.13)	0.0196	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE		0.00 (-51.08, 51.08)	1.0000	
Sex									0.9459
male	3/ 27 (11.1)	11.0	0/ 25 (0.0)	0.0	3.66 (0.43, 31.08)	0.2348	11.02 (-8.75, 30.79)	0.2746	
female	20/333 (6.0)	6.0	6/341 (1.8)	1.8	3.38 (1.37, 8.33)	0.0083	4.19 (-0.06, 8.44)	0.0534	
Race									0.3455
White	13/235 (5.5)	5.6	5/244 (2.0)	1.9	2.72 (0.98, 7.51)	0.0536	3.68 (-1.49, 8.84)	0.1627	
Black	0/ 46 (0.0)	0.0	1/ 48 (2.1)	1.8	0.48 (0.02, 11.17)	0.6486	-1.76 (-12.94, 9.41)	0.7571	
Other	8/ 71 (11.3)	11.3	0/ 66 (0.0)	0.0	7.68 (0.98, 60.28)	0.0525	11.28 (1.31, 21.24)	0.0265	
Ethnicity									0.4340
Hispanic/Latino	8/ 86 (9.3)	8.8	1/ 89 (1.1)	1.2	5.82 (1.05, 32.19)	0.0437	7.55 (-1.93, 17.04)	0.1184	
Non-hispanic/Latino	13/266 (4.9)	5.1	5/269 (1.9)	1.9	2.63 (0.95, 7.27)	0.0627	3.21 (-1.77, 8.20)	0.2061	
Geographic region									0.4752
EU	5/115 (4.3)	4.4	2/122 (1.6)	1.6	2.26 (0.49, 10.30)	0.2933	2.82 (-3.22, 8.86)	0.3601	
non-EU	18/245 (7.3)	7.4	4/244 (1.6)	1.6	4.44 (1.52, 13.00)	0.0065	5.80 (0.29, 11.31)	0.0393	
Onset of disease									0.5992
Paediatric	5/ 26 (19.2)	19.4	0/ 24 (0.0)	0.0	5.55 (0.71, 43.16)	0.1018	19.44 (-2.06, 40.94)	0.0763	
Adult	18/334 (5.4)	5.4	6/342 (1.8)	1.8	3.04 (1.21, 7.59)	0.0175	3.63 (-0.56, 7.81)	0.0894	
ADA result									0.8761
Negative	21/334 (6.3)	6.4	5/331 (1.5)	1.5	4.11 (1.56, 10.83)	0.0042	4.85 (0.53, 9.16)	0.0276	
Positive (At any time)	2/ 25 (8.0)	10.4	1/ 35 (2.9)	2.1	5.00 (0.52, 47.73)	0.1621	8.35 (-10.90, 27.60)	0.3951	
BMI (kg/m2) at enrolment									0.3245
< 30	15/233 (6.4)	6.5	3/261 (1.1)	1.2	5.54 (1.62, 18.99)	0.0064	5.36 (0.28, 10.45)	0.0386	
>= 30	8/127 (6.3)	6.6	3/105 (2.9)	2.6	2.25 (0.61, 8.26)	0.2208	4.00 (-4.49, 12.49)	0.3559	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	1 (0.3)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.03 (0.12, 73.97)	
p-value	0.4959	
Odds Ratio (95% CI)	3.05 (0.12, 75.37)	
p-value	0.4956	
Risk Difference (95% CI)	0.28 (-0.27, 0.82)	
p-value	0.3173	
CMH approach		
Response rate	0.3	0.0
Difference in response rates (95% CI)	0.27 (-2.90, 3.43)	
p-value	0.8691	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/109 (0.0)	0.0	0/106 (0.0)	0.0	NE		0.00 (-7.66, 7.66)	1.0000	
>= 10 points	1/251 (0.4)	0.4	0/260 (0.0)	0.0	3.09 (0.13, 75.26)	0.4878	0.38 (-3.16, 3.92)	0.8342	
OCS dose at baseline									NE
<10 mg/day	0/170 (0.0)	0.0	0/181 (0.0)	0.0	NE		0.00 (-5.16, 5.16)	1.0000	
>=10 mg/day	1/190 (0.5)	0.5	0/185 (0.0)	0.0	2.86 (0.12, 69.32)	0.5176	0.52 (-4.10, 5.13)	0.8268	
Result of type I IFN gene signature test									NE
LOW	0/ 62 (0.0)	0.0	0/ 64 (0.0)	0.0	NE		0.00 (-8.05, 8.05)	1.0000	
HIGH	1/298 (0.3)	0.3	0/302 (0.0)	0.0	3.02 (0.12, 73.54)	0.4975	0.32 (-3.11, 3.76)	0.8542	
Age (years)									NE
<= 65	1/348 (0.3)	0.3	0/362 (0.0)	0.0	3.10 (0.13, 75.64)	0.4872	0.27 (-2.96, 3.51)	0.8677	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE		0.00 (-51.08, 51.08)	1.0000	
Sex									NE
male	0/ 27 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.55, 17.55)	1.0000	
female	1/333 (0.3)	0.3	0/341 (0.0)	0.0	3.04 (0.12, 73.99)	0.4956	0.29 (-3.10, 3.67)	0.8686	
Race									NE
White	0/235 (0.0)	0.0	0/244 (0.0)	0.0	NE		0.00 (-4.18, 4.18)	1.0000	
Black	0/ 46 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-10.79, 10.79)	1.0000	
Other	1/ 71 (1.4)	1.4	0/ 66 (0.0)	0.0	2.80 (0.12, 67.00)	0.5242	1.41 (-6.43, 9.25)	0.7243	
Ethnicity									NE
Hispanic/Latino	0/ 86 (0.0)	0.0	0/ 89 (0.0)	0.0	NE		0.00 (-7.72, 7.72)	1.0000	
Non-hispanic/Latino	1/266 (0.4)	0.4	0/269 (0.0)	0.0	3.05 (0.13, 74.13)	0.4933	0.38 (-3.82, 4.57)	0.8604	
Geographic region									NE
EU	0/115 (0.0)	0.0	0/122 (0.0)	0.0	NE		0.00 (-4.48, 4.48)	1.0000	
non-EU	1/245 (0.4)	0.4	0/244 (0.0)	0.0	3.16 (0.13, 76.91)	0.4796	0.40 (-4.16, 4.96)	0.8636	
Onset of disease									NE
Paediatric	0/ 26 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-18.15, 18.15)	1.0000	
Adult	1/334 (0.3)	0.3	0/342 (0.0)	0.0	3.07 (0.13, 74.87)	0.4910	0.29 (-3.09, 3.67)	0.8664	
ADA result									NE
Negative	1/334 (0.3)	0.3	0/331 (0.0)	0.0	2.83 (0.12, 68.89)	0.5237	0.28 (-3.15, 3.71)	0.8728	
Positive (At any time)	0/ 25 (0.0)	0.0	0/ 35 (0.0)	0.0	NE		0.00 (-17.02, 17.02)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	1/233 (0.4)	0.4	0/261 (0.0)	0.0	3.21 (0.13, 78.18)	0.4733	0.42 (-3.68, 4.51)	0.8419	
>= 30	0/127 (0.0)	0.0	0/105 (0.0)	0.0	NE		0.00 (-7.26, 7.26)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	1 (0.3)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.07 (0.13, 74.78)	
p-value	0.4917	
Odds Ratio (95% CI)	3.08 (0.12, 76.19)	
p-value	0.4913	
Risk Difference (95% CI)	0.28 (-0.27, 0.82)	
p-value	0.3160	
CMH approach		
Response rate	0.3	0.0
Difference in response rates (95% CI)	0.29 (-2.88, 3.46)	
p-value	0.8575	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/109 (0.0)	0.0	0/106 (0.0)	0.0	NE		0.00 (-7.66, 7.66)	1.0000	
>= 10 points	1/251 (0.4)	0.4	0/260 (0.0)	0.0	3.12 (0.13, 75.85)	0.4848	0.41 (-3.13, 3.96)	0.8198	
OCS dose at baseline									NE
<10 mg/day	1/170 (0.6)	0.6	0/181 (0.0)	0.0	3.19 (0.13, 77.20)	0.4751	0.60 (-4.67, 5.87)	0.8232	
>=10 mg/day	0/190 (0.0)	0.0	0/185 (0.0)	0.0	NE		0.00 (-4.52, 4.52)	1.0000	
Result of type I IFN gene signature test									NE
LOW	0/ 62 (0.0)	0.0	0/ 64 (0.0)	0.0	NE		0.00 (-8.05, 8.05)	1.0000	
HIGH	1/298 (0.3)	0.4	0/302 (0.0)	0.0	3.06 (0.13, 74.53)	0.4923	0.35 (-3.09, 3.79)	0.8414	
Age (years)									NE
<= 65	1/348 (0.3)	0.3	0/362 (0.0)	0.0	3.14 (0.13, 76.51)	0.4828	0.30 (-2.94, 3.55)	0.8537	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE		0.00 (-51.08, 51.08)	1.0000	
Sex									NE
male	0/ 27 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.55, 17.55)	1.0000	
female	1/333 (0.3)	0.3	0/341 (0.0)	0.0	3.11 (0.13, 75.76)	0.4864	0.32 (-3.07, 3.71)	0.8546	
Race									NE
White	1/235 (0.4)	0.4	0/244 (0.0)	0.0	3.29 (0.14, 79.92)	0.4651	0.44 (-3.80, 4.69)	0.8375	
Black	0/ 46 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-10.79, 10.79)	1.0000	
Other	0/ 71 (0.0)	0.0	0/ 66 (0.0)	0.0	NE		0.00 (-7.43, 7.43)	1.0000	
Ethnicity									NE
Hispanic/Latino	1/ 86 (1.2)	1.2	0/ 89 (0.0)	0.0	3.27 (0.14, 77.57)	0.4629	1.20 (-6.79, 9.19)	0.7681	
Non-hispanic/Latino	0/266 (0.0)	0.0	0/269 (0.0)	0.0	NE		0.00 (-4.14, 4.14)	1.0000	
Geographic region									NE
EU	0/115 (0.0)	0.0	0/122 (0.0)	0.0	NE		0.00 (-4.48, 4.48)	1.0000	
non-EU	1/245 (0.4)	0.4	0/244 (0.0)	0.0	2.79 (0.12, 67.88)	0.5277	0.43 (-4.13, 5.00)	0.8523	
Onset of disease									NE
Paediatric	0/ 26 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-18.15, 18.15)	1.0000	
Adult	1/334 (0.3)	0.3	0/342 (0.0)	0.0	3.07 (0.13, 74.86)	0.4911	0.32 (-3.07, 3.70)	0.8548	
ADA result									NE
Negative	1/334 (0.3)	0.3	0/331 (0.0)	0.0	3.13 (0.13, 76.25)	0.4839	0.31 (-3.12, 3.75)	0.8577	
Positive (At any time)	0/ 25 (0.0)	0.0	0/ 35 (0.0)	0.0	NE		0.00 (-17.02, 17.02)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/233 (0.0)	0.0	0/261 (0.0)	0.0	NE		0.00 (-4.03, 4.03)	1.0000	
>= 30	1/127 (0.8)	0.7	0/105 (0.0)	0.0	2.38 (0.10, 57.43)	0.5926	0.72 (-6.65, 8.09)	0.8480	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	22 (6.1)	6 (1.6)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.69 (1.51, 9.02)	
p-value	0.0042	
Odds Ratio (95% CI)	3.87 (1.55, 9.68)	
p-value	0.0038	
Risk Difference (95% CI)	4.47 (1.67, 7.26)	
p-value	0.0017	
CMH approach		
Response rate	6.1	1.7
Difference in response rates (95% CI)	4.45 (0.41, 8.48)	
p-value	0.0308	
p-Value for test for heterogenity between studies	0.6958	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.1954
< 10 points	3/109 (2.8)	2.9	2/106 (1.9)	1.9	1.31 (0.25, 6.80)	0.7467	0.98 (-7.35, 9.31)	0.8182	
>= 10 points	19/251 (7.6)	7.5	4/260 (1.5)	1.6	4.79 (1.65, 13.91)	0.0040	5.92 (1.14, 10.69)	0.0152	
OCS dose at baseline									0.5340
<10 mg/day	10/170 (5.9)	5.9	2/181 (1.1)	1.1	5.25 (1.16, 23.72)	0.0311	4.74 (-1.36, 10.84)	0.1279	
>=10 mg/day	12/190 (6.3)	6.3	4/185 (2.2)	2.2	2.90 (0.95, 8.84)	0.0619	4.08 (-1.77, 9.93)	0.1720	
Result of type I IFN gene signature test									0.8740
LOW	4/ 62 (6.5)	6.5	1/ 64 (1.6)	1.6	2.92 (0.46, 18.57)	0.2552	4.89 (-5.18, 14.96)	0.3410	
HIGH	18/298 (6.0)	6.1	5/302 (1.7)	1.7	3.47 (1.28, 9.36)	0.0142	4.35 (-0.05, 8.75)	0.0525	
Age (years)									NE
<= 65	22/348 (6.3)	6.4	6/362 (1.7)	1.7	3.78 (1.55, 9.23)	0.0035	4.65 (0.52, 8.79)	0.0274	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE		0.00 (-51.08, 51.08)	1.0000	
Sex									0.9069
male	3/ 27 (11.1)	11.0	0/ 25 (0.0)	0.0	3.66 (0.43, 31.08)	0.2348	11.02 (-8.75, 30.79)	0.2746	
female	19/333 (5.7)	5.7	6/341 (1.8)	1.8	3.18 (1.28, 7.92)	0.0128	3.87 (-0.34, 8.09)	0.0717	
Race									0.3390
White	12/235 (5.1)	5.2	5/244 (2.0)	1.9	2.51 (0.90, 7.00)	0.0798	3.23 (-1.88, 8.35)	0.2152	
Black	0/ 46 (0.0)	0.0	1/ 48 (2.1)	1.8	0.48 (0.02, 11.17)	0.6486	-1.76 (-12.94, 9.41)	0.7571	
Other	8/ 71 (11.3)	11.3	0/ 66 (0.0)	0.0	7.68 (0.98, 60.28)	0.0525	11.28 (1.31, 21.24)	0.0265	
Ethnicity									0.5321
Hispanic/Latino	7/ 86 (8.1)	7.6	1/ 89 (1.1)	1.2	5.00 (0.88, 28.47)	0.0700	6.35 (-2.92, 15.62)	0.1792	
Non-hispanic/Latino	13/266 (4.9)	5.1	5/269 (1.9)	1.9	2.63 (0.95, 7.27)	0.0627	3.21 (-1.77, 8.20)	0.2061	
Geographic region									0.5038
EU	5/115 (4.3)	4.4	2/122 (1.6)	1.6	2.26 (0.49, 10.30)	0.2933	2.82 (-3.22, 8.86)	0.3601	
non-EU	17/245 (6.9)	7.0	4/244 (1.6)	1.6	4.26 (1.45, 12.50)	0.0083	5.37 (-0.10, 10.84)	0.0545	
Onset of disease									0.5612
Paediatric	5/ 26 (19.2)	19.4	0/ 24 (0.0)	0.0	5.55 (0.71, 43.16)	0.1018	19.44 (-2.06, 40.94)	0.0763	
Adult	17/334 (5.1)	5.1	6/342 (1.8)	1.8	2.84 (1.13, 7.19)	0.0270	3.31 (-0.84, 7.46)	0.1180	
ADA result									0.8401
Negative	20/334 (6.0)	6.1	5/331 (1.5)	1.5	3.88 (1.46, 10.29)	0.0064	4.53 (0.25, 8.82)	0.0379	
Positive (At any time)	2/ 25 (8.0)	10.4	1/ 35 (2.9)	2.1	5.00 (0.52, 47.73)	0.1621	8.35 (-10.90, 27.60)	0.3951	
BMI (kg/m2) at enrolment									0.2657
< 30	15/233 (6.4)	6.5	3/261 (1.1)	1.2	5.54 (1.62, 18.99)	0.0064	5.36 (0.28, 10.45)	0.0386	
>= 30	7/127 (5.5)	5.9	3/105 (2.9)	2.6	1.96 (0.51, 7.58)	0.3291	3.28 (-5.12, 11.67)	0.4442	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Herpes Zoster leading to discontinuation of study drug
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	2 (0.6)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	5.11 (0.25, 105.71)	
p-value	0.2912	
Odds Ratio (95% CI)	5.17 (0.25, 108.40)	
p-value	0.2901	
Risk Difference (95% CI)	0.56 (-0.21, 1.33)	
p-value	0.1556	
CMH approach		
Response rate	0.6	0.0
Difference in response rates (95% CI)	0.56 (-2.65, 3.76)	
p-value	0.7340	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Herpes Zoster leading to discontinuation of study drug - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/109 (0.0)	0.0	0/106 (0.0)	0.0	NE		0.00 (-7.66, 7.66)	1.0000	
>= 10 points	2/251 (0.8)	0.8	0/260 (0.0)	0.0	5.20 (0.25, 107.22)	0.2858	0.79 (-2.83, 4.41)	0.6688	
OCS dose at baseline									NE
<10 mg/day	0/170 (0.0)	0.0	0/181 (0.0)	0.0	NE		0.00 (-5.16, 5.16)	1.0000	
>=10 mg/day	2/190 (1.1)	1.1	0/185 (0.0)	0.0	4.95 (0.24, 101.89)	0.2998	1.08 (-3.65, 5.80)	0.6552	
Result of type I IFN gene signature test									NE
LOW	0/ 62 (0.0)	0.0	0/ 64 (0.0)	0.0	NE		0.00 (-8.05, 8.05)	1.0000	
HIGH	2/298 (0.7)	0.7	0/302 (0.0)	0.0	5.10 (0.25, 105.35)	0.2916	0.67 (-2.82, 4.17)	0.7057	
Age (years)									NE
<= 65	2/348 (0.6)	0.6	0/362 (0.0)	0.0	5.23 (0.25, 108.16)	0.2844	0.57 (-2.71, 3.85)	0.7318	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE		0.00 (-51.08, 51.08)	1.0000	
Sex									NE
male	0/ 27 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.55, 17.55)	1.0000	
female	2/333 (0.6)	0.6	0/341 (0.0)	0.0	5.18 (0.25, 107.11)	0.2871	0.60 (-2.83, 4.04)	0.7302	
Race									NE
White	2/235 (0.9)	0.9	0/244 (0.0)	0.0	5.48 (0.27, 112.97)	0.2709	0.88 (-3.44, 5.20)	0.6901	
Black	0/ 46 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-10.79, 10.79)	1.0000	
Other	0/ 71 (0.0)	0.0	0/ 66 (0.0)	0.0	NE		0.00 (-7.43, 7.43)	1.0000	
Ethnicity									0.9721
Hispanic/Latino	1/ 86 (1.2)	1.2	0/ 89 (0.0)	0.0	3.27 (0.14, 77.57)	0.4629	1.20 (-6.79, 9.19)	0.7681	
Non-hispanic/Latino	1/266 (0.4)	0.4	0/269 (0.0)	0.0	3.02 (0.12, 73.54)	0.4974	0.40 (-3.80, 4.61)	0.8504	
Geographic region									0.9168
EU	1/115 (0.9)	0.9	0/122 (0.0)	0.0	3.55 (0.15, 85.76)	0.4350	0.92 (-3.87, 5.71)	0.7061	
non-EU	1/245 (0.4)	0.4	0/244 (0.0)	0.0	2.79 (0.12, 67.88)	0.5277	0.35 (-4.20, 4.90)	0.8800	
Onset of disease									0.9918
Paediatric	1/ 26 (3.8)	4.0	0/ 24 (0.0)	0.0	3.00 (0.13, 67.06)	0.4883	4.01 (-14.99, 23.02)	0.6790	
Adult	1/334 (0.3)	0.3	0/342 (0.0)	0.0	3.07 (0.13, 74.86)	0.4911	0.30 (-3.08, 3.69)	0.8604	
ADA result									NE
Negative	2/334 (0.6)	0.6	0/331 (0.0)	0.0	5.21 (0.25, 107.80)	0.2852	0.63 (-2.86, 4.12)	0.7217	
Positive (At any time)	0/ 25 (0.0)	0.0	0/ 35 (0.0)	0.0	NE		0.00 (-17.02, 17.02)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	2/233 (0.9)	0.9	0/261 (0.0)	0.0	5.87 (0.28, 120.99)	0.2515	0.90 (-3.29, 5.09)	0.6733	
>= 30	0/127 (0.0)	0.0	0/105 (0.0)	0.0	NE		0.00 (-7.26, 7.26)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Hypersensitivity
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	13 (3.6)	3 (0.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	4.22 (1.19, 14.97)	
p-value	0.0258	
Odds Ratio (95% CI)	4.37 (1.21, 15.81)	
p-value	0.0247	
Risk Difference (95% CI)	2.80 (0.66, 4.93)	
p-value	0.0102	
CMH approach		
Response rate	3.7	0.8
Difference in response rates (95% CI)	2.85 (-0.77, 6.48)	
p-value	0.1223	
p-Value for test for heterogenity between studies	0.4771	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Hypersensitivity - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8348
< 10 points	6/109 (5.5)	5.8	1/106 (0.9)	0.9	4.17 (0.72, 24.26)	0.1116	4.90 (-3.62, 13.41)	0.2597	
>= 10 points	7/251 (2.8)	2.8	2/260 (0.8)	0.8	3.22 (0.61, 17.17)	0.1703	2.00 (-1.99, 5.99)	0.3264	
OCS dose at baseline									0.9695
<10 mg/day	8/170 (4.7)	4.6	2/181 (1.1)	1.1	3.35 (0.60, 18.85)	0.1702	3.54 (-2.34, 9.41)	0.2383	
>=10 mg/day	5/190 (2.6)	2.7	1/185 (0.5)	0.5	3.52 (0.58, 21.34)	0.1716	2.19 (-2.83, 7.20)	0.3923	
Result of type I IFN gene signature test									0.2791
LOW	6/ 62 (9.7)	9.7	0/ 64 (0.0)	0.0	13.39 (0.79, 228.40)	0.0730	9.67 (-0.49, 19.84)	0.0622	
HIGH	7/298 (2.3)	2.4	3/302 (1.0)	1.0	2.37 (0.62, 9.07)	0.2087	1.42 (-2.41, 5.25)	0.4669	
Age (years)									0.9860
<= 65	10/348 (2.9)	2.9	3/362 (0.8)	0.8	3.41 (0.94, 12.40)	0.0630	2.11 (-1.52, 5.75)	0.2545	
> 65	3/ 12 (25.0)	30.7	0/ 4 (0.0)	0.0	3.50 (0.23, 52.56)	0.3648	30.68 (-23.06, 84.42)	0.2631	
Sex									0.2557
male	1/ 27 (3.7)	3.6	1/ 25 (4.0)	4.1	0.87 (0.06, 12.52)	0.9164	-0.55 (-19.84, 18.74)	0.9554	
female	12/333 (3.6)	3.6	2/341 (0.6)	0.6	5.20 (1.10, 24.59)	0.0376	3.05 (-0.77, 6.87)	0.1179	
Race									0.2157
White	11/235 (4.7)	4.5	2/244 (0.8)	0.8	4.89 (1.26, 18.98)	0.0218	3.70 (-1.06, 8.45)	0.1275	
Black	0/ 46 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-10.79, 10.79)	1.0000	
Other	1/ 71 (1.4)	1.4	1/ 66 (1.5)	1.5	0.94 (0.10, 8.77)	0.9543	-0.11 (-8.34, 8.13)	0.9793	
Ethnicity									0.9910
Hispanic/Latino	2/ 86 (2.3)	2.5	0/ 89 (0.0)	0.0	3.13 (0.33, 29.53)	0.3182	2.52 (-5.65, 10.68)	0.5458	
Non-hispanic/Latino	10/266 (3.8)	3.9	3/269 (1.1)	1.0	3.09 (0.79, 12.01)	0.1038	2.85 (-1.83, 7.54)	0.2326	
Geographic region									0.6548
EU	4/115 (3.5)	3.6	0/122 (0.0)	0.0	4.95 (0.57, 42.87)	0.1468	3.57 (-1.95, 9.09)	0.2049	
non-EU	9/245 (3.7)	3.7	3/244 (1.2)	1.3	2.77 (0.73, 10.54)	0.1350	2.41 (-2.61, 7.43)	0.3461	
Onset of disease									0.8555
Paediatric	2/ 26 (7.7)	7.7	0/ 24 (0.0)	0.0	2.79 (0.31, 25.19)	0.3599	7.72 (-12.05, 27.49)	0.4443	
Adult	11/334 (3.3)	3.2	3/342 (0.9)	0.9	3.55 (0.95, 13.28)	0.0603	2.35 (-1.43, 6.13)	0.2226	
ADA result									NE
Negative	13/334 (3.9)	4.0	3/331 (0.9)	0.9	4.20 (1.19, 14.89)	0.0262	3.10 (-0.81, 7.02)	0.1204	
Positive (At any time)	0/ 25 (0.0)	0.0	0/ 35 (0.0)	0.0	NE		0.00 (-17.02, 17.02)	1.0000	
BMI (kg/m2) at enrolment									0.4732
< 30	4/233 (1.7)	1.8	2/261 (0.8)	0.8	2.08 (0.34, 12.53)	0.4261	1.01 (-3.35, 5.38)	0.6497	
>= 30	9/127 (7.1)	7.1	1/105 (1.0)	1.0	5.14 (0.93, 28.23)	0.0598	6.07 (-2.22, 14.37)	0.1513	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Hypersensitivity
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	1 (0.3)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.03 (0.12, 73.97)	
p-value	0.4959	
Odds Ratio (95% CI)	3.05 (0.12, 75.37)	
p-value	0.4956	
Risk Difference (95% CI)	0.28 (-0.27, 0.82)	
p-value	0.3173	
CMH approach		
Response rate	0.3	0.0
Difference in response rates (95% CI)	0.27 (-2.90, 3.43)	
p-value	0.8691	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Hypersensitivity - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/109 (0.0)	0.0	0/106 (0.0)	0.0	NE		0.00 (-7.66, 7.66)	1.0000	
>= 10 points	1/251 (0.4)	0.4	0/260 (0.0)	0.0	3.09 (0.13, 75.26)	0.4878	0.38 (-3.16, 3.92)	0.8342	
OCS dose at baseline									NE
<10 mg/day	0/170 (0.0)	0.0	0/181 (0.0)	0.0	NE		0.00 (-5.16, 5.16)	1.0000	
>=10 mg/day	1/190 (0.5)	0.5	0/185 (0.0)	0.0	2.86 (0.12, 69.32)	0.5176	0.52 (-4.10, 5.13)	0.8268	
Result of type I IFN gene signature test									NE
LOW	0/ 62 (0.0)	0.0	0/ 64 (0.0)	0.0	NE		0.00 (-8.05, 8.05)	1.0000	
HIGH	1/298 (0.3)	0.3	0/302 (0.0)	0.0	3.02 (0.12, 73.54)	0.4975	0.32 (-3.11, 3.76)	0.8542	
Age (years)									NE
<= 65	1/348 (0.3)	0.3	0/362 (0.0)	0.0	3.10 (0.13, 75.64)	0.4872	0.27 (-2.96, 3.51)	0.8677	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE		0.00 (-51.08, 51.08)	1.0000	
Sex									NE
male	0/ 27 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.55, 17.55)	1.0000	
female	1/333 (0.3)	0.3	0/341 (0.0)	0.0	3.04 (0.12, 73.99)	0.4956	0.29 (-3.10, 3.67)	0.8686	
Race									NE
White	0/235 (0.0)	0.0	0/244 (0.0)	0.0	NE		0.00 (-4.18, 4.18)	1.0000	
Black	0/ 46 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-10.79, 10.79)	1.0000	
Other	0/ 71 (0.0)	0.0	0/ 66 (0.0)	0.0	NE		0.00 (-7.43, 7.43)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 86 (0.0)	0.0	0/ 89 (0.0)	0.0	NE		0.00 (-7.72, 7.72)	1.0000	
Non-hispanic/Latino	0/266 (0.0)	0.0	0/269 (0.0)	0.0	NE		0.00 (-4.14, 4.14)	1.0000	
Geographic region									NE
EU	1/115 (0.9)	0.8	0/122 (0.0)	0.0	2.71 (0.11, 64.96)	0.5382	0.80 (-3.91, 5.51)	0.7377	
non-EU	0/245 (0.0)	0.0	0/244 (0.0)	0.0	NE		0.00 (-4.51, 4.51)	1.0000	
Onset of disease									NE
Paediatric	1/ 26 (3.8)	3.7	0/ 24 (0.0)	0.0	2.60 (0.12, 58.48)	0.5475	3.70 (-15.24, 22.65)	0.7016	
Adult	0/334 (0.0)	0.0	0/342 (0.0)	0.0	NE		0.00 (-3.34, 3.34)	1.0000	
ADA result									NE
Negative	1/334 (0.3)	0.3	0/331 (0.0)	0.0	2.83 (0.12, 68.89)	0.5237	0.28 (-3.15, 3.71)	0.8728	
Positive (At any time)	0/ 25 (0.0)	0.0	0/ 35 (0.0)	0.0	NE		0.00 (-17.02, 17.02)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/233 (0.0)	0.0	0/261 (0.0)	0.0	NE		0.00 (-4.03, 4.03)	1.0000	
>= 30	1/127 (0.8)	0.8	0/105 (0.0)	0.0	2.63 (0.11, 62.97)	0.5517	0.81 (-6.58, 8.21)	0.8291	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Hypersensitivity
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-3.13, 3.13)	
p-value	1.0000	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Hypersensitivity - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/109 (0.0)	0.0	0/106 (0.0)	0.0	NE	0.00 (-7.66, 7.66)	1.0000	
>= 10 points	0/251 (0.0)	0.0	0/260 (0.0)	0.0	NE	0.00 (-3.47, 3.47)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/170 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-5.16, 5.16)	1.0000	
>=10 mg/day	0/190 (0.0)	0.0	0/185 (0.0)	0.0	NE	0.00 (-4.52, 4.52)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 62 (0.0)	0.0	0/ 64 (0.0)	0.0	NE	0.00 (-8.05, 8.05)	1.0000	
HIGH	0/298 (0.0)	0.0	0/302 (0.0)	0.0	NE	0.00 (-3.38, 3.38)	1.0000	
Age (years)								NE
<= 65	0/348 (0.0)	0.0	0/362 (0.0)	0.0	NE	0.00 (-3.20, 3.20)	1.0000	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE	0.00 (-51.08, 51.08)	1.0000	
Sex								NE
male	0/ 27 (0.0)	0.0	0/ 25 (0.0)	0.0	NE	0.00 (-17.55, 17.55)	1.0000	
female	0/333 (0.0)	0.0	0/341 (0.0)	0.0	NE	0.00 (-3.35, 3.35)	1.0000	
Race								NE
White	0/235 (0.0)	0.0	0/244 (0.0)	0.0	NE	0.00 (-4.18, 4.18)	1.0000	
Black	0/ 46 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-10.79, 10.79)	1.0000	
Other	0/ 71 (0.0)	0.0	0/ 66 (0.0)	0.0	NE	0.00 (-7.43, 7.43)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 86 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-7.72, 7.72)	1.0000	
Non-hispanic/Latino	0/266 (0.0)	0.0	0/269 (0.0)	0.0	NE	0.00 (-4.14, 4.14)	1.0000	
Geographic region								NE
EU	0/115 (0.0)	0.0	0/122 (0.0)	0.0	NE	0.00 (-4.48, 4.48)	1.0000	
non-EU	0/245 (0.0)	0.0	0/244 (0.0)	0.0	NE	0.00 (-4.51, 4.51)	1.0000	
Onset of disease								NE
Paediatric	0/ 26 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-18.15, 18.15)	1.0000	
Adult	0/334 (0.0)	0.0	0/342 (0.0)	0.0	NE	0.00 (-3.34, 3.34)	1.0000	
ADA result								NE
Negative	0/334 (0.0)	0.0	0/331 (0.0)	0.0	NE	0.00 (-3.40, 3.40)	1.0000	
Positive (At any time)	0/ 25 (0.0)	0.0	0/ 35 (0.0)	0.0	NE	0.00 (-17.02, 17.02)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/233 (0.0)	0.0	0/261 (0.0)	0.0	NE	0.00 (-4.03, 4.03)	1.0000	
>= 30	0/127 (0.0)	0.0	0/105 (0.0)	0.0	NE	0.00 (-7.26, 7.26)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Hypersensitivity
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	13 (3.6)	3 (0.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	4.22 (1.19, 14.97)	
p-value	0.0258	
Odds Ratio (95% CI)	4.37 (1.21, 15.81)	
p-value	0.0247	
Risk Difference (95% CI)	2.80 (0.66, 4.93)	
p-value	0.0102	
CMH approach		
Response rate	3.7	0.8
Difference in response rates (95% CI)	2.85 (-0.77, 6.48)	
p-value	0.1223	
p-Value for test for heterogenity between studies	0.4771	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Hypersensitivity - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8348
< 10 points	6/109 (5.5)	5.8	1/106 (0.9)	0.9	4.17 (0.72, 24.26)	0.1116	4.90 (-3.62, 13.41)	0.2597	
>= 10 points	7/251 (2.8)	2.8	2/260 (0.8)	0.8	3.22 (0.61, 17.17)	0.1703	2.00 (-1.99, 5.99)	0.3264	
OCS dose at baseline									0.9695
<10 mg/day	8/170 (4.7)	4.6	2/181 (1.1)	1.1	3.35 (0.60, 18.85)	0.1702	3.54 (-2.34, 9.41)	0.2383	
>=10 mg/day	5/190 (2.6)	2.7	1/185 (0.5)	0.5	3.52 (0.58, 21.34)	0.1716	2.19 (-2.83, 7.20)	0.3923	
Result of type I IFN gene signature test									0.2791
LOW	6/ 62 (9.7)	9.7	0/ 64 (0.0)	0.0	13.39 (0.79, 228.40)	0.0730	9.67 (-0.49, 19.84)	0.0622	
HIGH	7/298 (2.3)	2.4	3/302 (1.0)	1.0	2.37 (0.62, 9.07)	0.2087	1.42 (-2.41, 5.25)	0.4669	
Age (years)									0.9860
<= 65	10/348 (2.9)	2.9	3/362 (0.8)	0.8	3.41 (0.94, 12.40)	0.0630	2.11 (-1.52, 5.75)	0.2545	
> 65	3/ 12 (25.0)	30.7	0/ 4 (0.0)	0.0	3.50 (0.23, 52.56)	0.3648	30.68 (-23.06, 84.42)	0.2631	
Sex									0.2557
male	1/ 27 (3.7)	3.6	1/ 25 (4.0)	4.1	0.87 (0.06, 12.52)	0.9164	-0.55 (-19.84, 18.74)	0.9554	
female	12/333 (3.6)	3.6	2/341 (0.6)	0.6	5.20 (1.10, 24.59)	0.0376	3.05 (-0.77, 6.87)	0.1179	
Race									0.2157
White	11/235 (4.7)	4.5	2/244 (0.8)	0.8	4.89 (1.26, 18.98)	0.0218	3.70 (-1.06, 8.45)	0.1275	
Black	0/ 46 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-10.79, 10.79)	1.0000	
Other	1/ 71 (1.4)	1.4	1/ 66 (1.5)	1.5	0.94 (0.10, 8.77)	0.9543	-0.11 (-8.34, 8.13)	0.9793	
Ethnicity									0.9910
Hispanic/Latino	2/ 86 (2.3)	2.5	0/ 89 (0.0)	0.0	3.13 (0.33, 29.53)	0.3182	2.52 (-5.65, 10.68)	0.5458	
Non-hispanic/Latino	10/266 (3.8)	3.9	3/269 (1.1)	1.0	3.09 (0.79, 12.01)	0.1038	2.85 (-1.83, 7.54)	0.2326	
Geographic region									0.6548
EU	4/115 (3.5)	3.6	0/122 (0.0)	0.0	4.95 (0.57, 42.87)	0.1468	3.57 (-1.95, 9.09)	0.2049	
non-EU	9/245 (3.7)	3.7	3/244 (1.2)	1.3	2.77 (0.73, 10.54)	0.1350	2.41 (-2.61, 7.43)	0.3461	
Onset of disease									0.8555
Paediatric	2/ 26 (7.7)	7.7	0/ 24 (0.0)	0.0	2.79 (0.31, 25.19)	0.3599	7.72 (-12.05, 27.49)	0.4443	
Adult	11/334 (3.3)	3.2	3/342 (0.9)	0.9	3.55 (0.95, 13.28)	0.0603	2.35 (-1.43, 6.13)	0.2226	
ADA result									NE
Negative	13/334 (3.9)	4.0	3/331 (0.9)	0.9	4.20 (1.19, 14.89)	0.0262	3.10 (-0.81, 7.02)	0.1204	
Positive (At any time)	0/ 25 (0.0)	0.0	0/ 35 (0.0)	0.0	NE		0.00 (-17.02, 17.02)	1.0000	
BMI (kg/m2) at enrolment									0.4732
< 30	4/233 (1.7)	1.8	2/261 (0.8)	0.8	2.08 (0.34, 12.53)	0.4261	1.01 (-3.35, 5.38)	0.6497	
>= 30	9/127 (7.1)	7.1	1/105 (1.0)	1.0	5.14 (0.93, 28.23)	0.0598	6.07 (-2.22, 14.37)	0.1513	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Influenza
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	6 (1.7)	9 (2.5)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.68 (0.24, 1.89)	
p-value	0.4578	
Odds Ratio (95% CI)	0.67 (0.23, 1.93)	
p-value	0.4595	
Risk Difference (95% CI)	-0.80 (-2.86, 1.26)	
p-value	0.4484	
CMH approach		
Response rate	1.7	2.4
Difference in response rates (95% CI)	-0.72 (-4.33, 2.89)	
p-value	0.6952	
p-Value for test for heterogenity between studies	0.6260	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.5660
< 10 points	3/109 (2.8)	2.8	3/106 (2.8)	2.8	0.97 (0.20, 4.68)	0.9689	0.04 (-8.29, 8.37)	0.9921	
>= 10 points	3/251 (1.2)	1.2	6/260 (2.3)	2.2	0.52 (0.13, 2.12)	0.3637	-1.04 (-5.05, 2.97)	0.6126	
OCS dose at baseline									0.6606
<10 mg/day	4/170 (2.4)	2.3	7/181 (3.9)	3.8	0.55 (0.14, 2.18)	0.3957	-1.48 (-7.44, 4.47)	0.6254	
>=10 mg/day	2/190 (1.1)	1.0	2/185 (1.1)	1.0	0.97 (0.11, 8.25)	0.9804	0.01 (-4.84, 4.86)	0.9970	
Result of type I IFN gene signature test									0.8692
LOW	2/ 62 (3.2)	3.2	3/ 64 (4.7)	4.7	0.86 (0.14, 5.45)	0.8711	-1.46 (-11.49, 8.57)	0.7751	
HIGH	4/298 (1.3)	1.3	6/302 (2.0)	1.9	0.71 (0.21, 2.37)	0.5806	-0.57 (-4.39, 3.26)	0.7719	
Age (years)									NE
<= 65	6/348 (1.7)	1.7	9/362 (2.5)	2.4	0.69 (0.25, 1.94)	0.4845	-0.68 (-4.36, 3.00)	0.7172	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE		0.00 (-51.08, 51.08)	1.0000	
Sex									0.6200
male	0/ 27 (0.0)	0.0	1/ 25 (4.0)	3.9	0.33 (0.01, 7.45)	0.4883	-3.86 (-22.23, 14.52)	0.6808	
female	6/333 (1.8)	1.8	8/341 (2.3)	2.3	0.76 (0.27, 2.18)	0.6159	-0.51 (-4.34, 3.33)	0.7958	
Race									0.3512
White	4/235 (1.7)	1.6	2/244 (0.8)	0.8	1.61 (0.31, 8.25)	0.5679	0.74 (-3.77, 5.26)	0.7469	
Black	0/ 46 (0.0)	0.0	2/ 48 (4.2)	4.2	0.36 (0.04, 3.33)	0.3669	-4.19 (-16.06, 7.67)	0.4883	
Other	1/ 71 (1.4)	1.4	4/ 66 (6.1)	6.1	0.31 (0.05, 1.91)	0.2069	-4.65 (-14.03, 4.74)	0.3322	
Ethnicity									0.3176
Hispanic/Latino	2/ 86 (2.3)	2.1	1/ 89 (1.1)	1.2	2.00 (0.19, 21.41)	0.5666	0.89 (-7.52, 9.30)	0.8351	
Non-hispanic/Latino	3/266 (1.1)	1.1	7/269 (2.6)	2.5	0.49 (0.12, 2.05)	0.3260	-1.38 (-5.94, 3.17)	0.5520	
Geographic region									0.6790
EU	2/115 (1.7)	1.7	2/122 (1.6)	1.8	0.94 (0.14, 6.29)	0.9495	-0.06 (-5.53, 5.42)	0.9833	
non-EU	4/245 (1.6)	1.7	7/244 (2.9)	2.8	0.58 (0.17, 1.97)	0.3858	-1.13 (-6.17, 3.91)	0.6597	
Onset of disease									NE
Paediatric	0/ 26 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-18.15, 18.15)	1.0000	
Adult	6/334 (1.8)	1.8	9/342 (2.6)	2.6	0.68 (0.24, 1.91)	0.4684	-0.81 (-4.66, 3.04)	0.6802	
ADA result									0.9683
Negative	6/334 (1.8)	1.8	8/331 (2.4)	2.4	0.73 (0.25, 2.08)	0.5530	-0.62 (-4.51, 3.27)	0.7543	
Positive (At any time)	0/ 25 (0.0)	0.0	1/ 35 (2.9)	2.1	0.78 (0.03, 17.33)	0.8739	-2.09 (-19.43, 15.26)	0.8135	
BMI (kg/m2) at enrolment									0.1119
< 30	6/233 (2.6)	2.6	5/261 (1.9)	1.9	1.30 (0.40, 4.25)	0.6634	0.74 (-3.86, 5.34)	0.7539	
>= 30	0/127 (0.0)	0.0	4/105 (3.8)	3.5	0.18 (0.02, 1.53)	0.1154	-3.48 (-11.20, 4.25)	0.3776	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Influenza
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	0 (0.0)	1 (0.3)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.34 (0.01, 8.22)	
p-value	0.5045	
Odds Ratio (95% CI)	0.34 (0.01, 8.28)	
p-value	0.5041	
Risk Difference (95% CI)	-0.27 (-0.81, 0.26)	
p-value	0.3160	
CMH approach		
Response rate	0.0	0.3
Difference in response rates (95% CI)	-0.26 (-3.42, 2.90)	
p-value	0.8728	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/109 (0.0)	0.0	0/106 (0.0)	0.0	NE		0.00 (-7.66, 7.66)	1.0000	
>= 10 points	0/251 (0.0)	0.0	1/260 (0.4)	0.4	0.34 (0.01, 8.36)	0.5120	-0.37 (-3.90, 3.17)	0.8389	
OCS dose at baseline									NE
<10 mg/day	0/170 (0.0)	0.0	1/181 (0.6)	0.5	0.35 (0.01, 8.60)	0.5239	-0.53 (-5.79, 4.72)	0.8419	
>=10 mg/day	0/190 (0.0)	0.0	0/185 (0.0)	0.0	NE		0.00 (-4.52, 4.52)	1.0000	
Result of type I IFN gene signature test									NE
LOW	0/ 62 (0.0)	0.0	0/ 64 (0.0)	0.0	NE		0.00 (-8.05, 8.05)	1.0000	
HIGH	0/298 (0.0)	0.0	1/302 (0.3)	0.3	0.34 (0.01, 8.17)	0.5026	-0.31 (-3.74, 3.12)	0.8583	
Age (years)									NE
<= 65	0/348 (0.0)	0.0	1/362 (0.3)	0.3	0.34 (0.01, 8.40)	0.5134	-0.26 (-3.49, 2.97)	0.8741	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE		0.00 (-51.08, 51.08)	1.0000	
Sex									NE
male	0/ 27 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.55, 17.55)	1.0000	
female	0/333 (0.0)	0.0	1/341 (0.3)	0.3	0.34 (0.01, 8.22)	0.5048	-0.29 (-3.67, 3.10)	0.8688	
Race									NE
White	0/235 (0.0)	0.0	1/244 (0.4)	0.4	0.32 (0.01, 7.87)	0.4890	-0.41 (-4.66, 3.84)	0.8494	
Black	0/ 46 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-10.79, 10.79)	1.0000	
Other	0/ 71 (0.0)	0.0	0/ 66 (0.0)	0.0	NE		0.00 (-7.43, 7.43)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 86 (0.0)	0.0	0/ 89 (0.0)	0.0	NE		0.00 (-7.72, 7.72)	1.0000	
Non-hispanic/Latino	0/266 (0.0)	0.0	1/269 (0.4)	0.3	0.34 (0.01, 8.24)	0.5063	-0.34 (-4.53, 3.84)	0.8720	
Geographic region									NE
EU	0/115 (0.0)	0.0	0/122 (0.0)	0.0	NE		0.00 (-4.48, 4.48)	1.0000	
non-EU	0/245 (0.0)	0.0	1/244 (0.4)	0.4	0.35 (0.01, 8.55)	0.5206	-0.38 (-4.94, 4.18)	0.8699	
Onset of disease									NE
Paediatric	0/ 26 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-18.15, 18.15)	1.0000	
Adult	0/334 (0.0)	0.0	1/342 (0.3)	0.3	0.34 (0.01, 8.32)	0.5094	-0.28 (-3.66, 3.09)	0.8687	
ADA result									NE
Negative	0/334 (0.0)	0.0	1/331 (0.3)	0.3	0.31 (0.01, 7.65)	0.4772	-0.29 (-3.73, 3.14)	0.8673	
Positive (At any time)	0/ 25 (0.0)	0.0	0/ 35 (0.0)	0.0	NE		0.00 (-17.02, 17.02)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/233 (0.0)	0.0	0/261 (0.0)	0.0	NE		0.00 (-4.03, 4.03)	1.0000	
>= 30	0/127 (0.0)	0.0	1/105 (1.0)	0.9	0.29 (0.01, 7.00)	0.4473	-0.94 (-8.37, 6.49)	0.8032	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Influenza
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	0 (0.0)	1 (0.3)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.34 (0.01, 8.22)	
p-value	0.5045	
Odds Ratio (95% CI)	0.34 (0.01, 8.28)	
p-value	0.5041	
Risk Difference (95% CI)	-0.27 (-0.81, 0.26)	
p-value	0.3160	
CMH approach		
Response rate	0.0	0.3
Difference in response rates (95% CI)	-0.26 (-3.42, 2.90)	
p-value	0.8728	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/109 (0.0)	0.0	0/106 (0.0)	0.0	NE		0.00 (-7.66, 7.66)	1.0000	
>= 10 points	0/251 (0.0)	0.0	1/260 (0.4)	0.4	0.34 (0.01, 8.36)	0.5120	-0.37 (-3.90, 3.17)	0.8389	
OCS dose at baseline									NE
<10 mg/day	0/170 (0.0)	0.0	1/181 (0.6)	0.5	0.35 (0.01, 8.60)	0.5239	-0.53 (-5.79, 4.72)	0.8419	
>=10 mg/day	0/190 (0.0)	0.0	0/185 (0.0)	0.0	NE		0.00 (-4.52, 4.52)	1.0000	
Result of type I IFN gene signature test									NE
LOW	0/ 62 (0.0)	0.0	0/ 64 (0.0)	0.0	NE		0.00 (-8.05, 8.05)	1.0000	
HIGH	0/298 (0.0)	0.0	1/302 (0.3)	0.3	0.34 (0.01, 8.17)	0.5026	-0.31 (-3.74, 3.12)	0.8583	
Age (years)									NE
<= 65	0/348 (0.0)	0.0	1/362 (0.3)	0.3	0.34 (0.01, 8.40)	0.5134	-0.26 (-3.49, 2.97)	0.8741	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE		0.00 (-51.08, 51.08)	1.0000	
Sex									NE
male	0/ 27 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.55, 17.55)	1.0000	
female	0/333 (0.0)	0.0	1/341 (0.3)	0.3	0.34 (0.01, 8.22)	0.5048	-0.29 (-3.67, 3.10)	0.8688	
Race									NE
White	0/235 (0.0)	0.0	1/244 (0.4)	0.4	0.32 (0.01, 7.87)	0.4890	-0.41 (-4.66, 3.84)	0.8494	
Black	0/ 46 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-10.79, 10.79)	1.0000	
Other	0/ 71 (0.0)	0.0	0/ 66 (0.0)	0.0	NE		0.00 (-7.43, 7.43)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 86 (0.0)	0.0	0/ 89 (0.0)	0.0	NE		0.00 (-7.72, 7.72)	1.0000	
Non-hispanic/Latino	0/266 (0.0)	0.0	1/269 (0.4)	0.3	0.34 (0.01, 8.24)	0.5063	-0.34 (-4.53, 3.84)	0.8720	
Geographic region									NE
EU	0/115 (0.0)	0.0	0/122 (0.0)	0.0	NE		0.00 (-4.48, 4.48)	1.0000	
non-EU	0/245 (0.0)	0.0	1/244 (0.4)	0.4	0.35 (0.01, 8.55)	0.5206	-0.38 (-4.94, 4.18)	0.8699	
Onset of disease									NE
Paediatric	0/ 26 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-18.15, 18.15)	1.0000	
Adult	0/334 (0.0)	0.0	1/342 (0.3)	0.3	0.34 (0.01, 8.32)	0.5094	-0.28 (-3.66, 3.09)	0.8687	
ADA result									NE
Negative	0/334 (0.0)	0.0	1/331 (0.3)	0.3	0.31 (0.01, 7.65)	0.4772	-0.29 (-3.73, 3.14)	0.8673	
Positive (At any time)	0/ 25 (0.0)	0.0	0/ 35 (0.0)	0.0	NE		0.00 (-17.02, 17.02)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/233 (0.0)	0.0	0/261 (0.0)	0.0	NE		0.00 (-4.03, 4.03)	1.0000	
>= 30	0/127 (0.0)	0.0	1/105 (1.0)	0.9	0.29 (0.01, 7.00)	0.4473	-0.94 (-8.37, 6.49)	0.8032	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Influenza
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	6 (1.7)	8 (2.2)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.76 (0.27, 2.18)	
p-value	0.6103	
Odds Ratio (95% CI)	0.76 (0.26, 2.22)	
p-value	0.6119	
Risk Difference (95% CI)	-0.52 (-2.52, 1.47)	
p-value	0.6070	
CMH approach		
Response rate	1.7	2.1
Difference in response rates (95% CI)	-0.46 (-4.05, 3.12)	
p-value	0.8000	
p-Value for test for heterogenity between studies	0.7244	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.6849
< 10 points	3/109 (2.8)	2.8	3/106 (2.8)	2.8	0.97 (0.20, 4.68)	0.9689	0.04 (-8.29, 8.37)	0.9921	
>= 10 points	3/251 (1.2)	1.2	5/260 (1.9)	1.9	0.62 (0.15, 2.62)	0.5187	-0.67 (-4.63, 3.29)	0.7406	
OCS dose at baseline									0.7411
<10 mg/day	4/170 (2.4)	2.3	6/181 (3.3)	3.2	0.63 (0.16, 2.56)	0.5211	-0.95 (-6.84, 4.94)	0.7520	
>=10 mg/day	2/190 (1.1)	1.0	2/185 (1.1)	1.0	0.97 (0.11, 8.25)	0.9804	0.01 (-4.84, 4.86)	0.9970	
Result of type I IFN gene signature test									0.9941
LOW	2/ 62 (3.2)	3.2	3/ 64 (4.7)	4.7	0.86 (0.14, 5.45)	0.8711	-1.46 (-11.49, 8.57)	0.7751	
HIGH	4/298 (1.3)	1.3	5/302 (1.7)	1.6	0.85 (0.24, 2.99)	0.8011	-0.25 (-4.04, 3.53)	0.8959	
Age (years)									NE
<= 65	6/348 (1.7)	1.7	8/362 (2.2)	2.1	0.78 (0.27, 2.23)	0.6404	-0.42 (-4.07, 3.24)	0.8222	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE		0.00 (-51.08, 51.08)	1.0000	
Sex									0.5660
male	0/ 27 (0.0)	0.0	1/ 25 (4.0)	3.9	0.33 (0.01, 7.45)	0.4883	-3.86 (-22.23, 14.52)	0.6808	
female	6/333 (1.8)	1.8	7/341 (2.1)	2.0	0.87 (0.30, 2.57)	0.8058	-0.22 (-4.02, 3.58)	0.9093	
Race									0.1905
White	4/235 (1.7)	1.6	1/244 (0.4)	0.4	2.89 (0.44, 18.83)	0.2666	1.16 (-3.30, 5.61)	0.6113	
Black	0/ 46 (0.0)	0.0	2/ 48 (4.2)	4.2	0.36 (0.04, 3.33)	0.3669	-4.19 (-16.06, 7.67)	0.4883	
Other	1/ 71 (1.4)	1.4	4/ 66 (6.1)	6.1	0.31 (0.05, 1.91)	0.2069	-4.65 (-14.03, 4.74)	0.3322	
Ethnicity									0.3600
Hispanic/Latino	2/ 86 (2.3)	2.1	1/ 89 (1.1)	1.2	2.00 (0.19, 21.41)	0.5666	0.89 (-7.52, 9.30)	0.8351	
Non-hispanic/Latino	3/266 (1.1)	1.1	6/269 (2.2)	2.2	0.55 (0.13, 2.33)	0.4139	-1.04 (-5.56, 3.48)	0.6525	
Geographic region									0.7828
EU	2/115 (1.7)	1.7	2/122 (1.6)	1.8	0.94 (0.14, 6.29)	0.9495	-0.06 (-5.53, 5.42)	0.9833	
non-EU	4/245 (1.6)	1.7	6/244 (2.5)	2.4	0.68 (0.19, 2.40)	0.5515	-0.75 (-5.75, 4.25)	0.7684	
Onset of disease									NE
Paediatric	0/ 26 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-18.15, 18.15)	1.0000	
Adult	6/334 (1.8)	1.8	8/342 (2.3)	2.3	0.77 (0.27, 2.20)	0.6224	-0.53 (-4.35, 3.30)	0.7877	
ADA result									0.9675
Negative	6/334 (1.8)	1.8	7/331 (2.1)	2.1	0.83 (0.28, 2.45)	0.7396	-0.33 (-4.18, 3.53)	0.8676	
Positive (At any time)	0/ 25 (0.0)	0.0	1/ 35 (2.9)	2.1	0.78 (0.03, 17.33)	0.8739	-2.09 (-19.43, 15.26)	0.8135	
BMI (kg/m2) at enrolment									0.1538
< 30	6/233 (2.6)	2.6	5/261 (1.9)	1.9	1.30 (0.40, 4.25)	0.6634	0.74 (-3.86, 5.34)	0.7539	
>= 30	0/127 (0.0)	0.0	3/105 (2.9)	2.5	0.21 (0.02, 1.90)	0.1657	-2.53 (-10.10, 5.03)	0.5116	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - MACE
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	1 (0.3)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.03 (0.12, 73.97)	
p-value	0.4959	
Odds Ratio (95% CI)	3.05 (0.12, 75.37)	
p-value	0.4956	
Risk Difference (95% CI)	0.28 (-0.27, 0.82)	
p-value	0.3173	
CMH approach		
Response rate	0.3	0.0
Difference in response rates (95% CI)	0.27 (-2.90, 3.43)	
p-value	0.8691	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - MACE - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/109 (0.0)	0.0	0/106 (0.0)	0.0	NE		0.00 (-7.66, 7.66)	1.0000	
>= 10 points	1/251 (0.4)	0.4	0/260 (0.0)	0.0	3.09 (0.13, 75.26)	0.4878	0.38 (-3.16, 3.92)	0.8342	
OCS dose at baseline									NE
<10 mg/day	0/170 (0.0)	0.0	0/181 (0.0)	0.0	NE		0.00 (-5.16, 5.16)	1.0000	
>=10 mg/day	1/190 (0.5)	0.5	0/185 (0.0)	0.0	2.86 (0.12, 69.32)	0.5176	0.52 (-4.10, 5.13)	0.8268	
Result of type I IFN gene signature test									NE
LOW	0/ 62 (0.0)	0.0	0/ 64 (0.0)	0.0	NE		0.00 (-8.05, 8.05)	1.0000	
HIGH	1/298 (0.3)	0.3	0/302 (0.0)	0.0	3.02 (0.12, 73.54)	0.4975	0.32 (-3.11, 3.76)	0.8542	
Age (years)									NE
<= 65	1/348 (0.3)	0.3	0/362 (0.0)	0.0	3.10 (0.13, 75.64)	0.4872	0.27 (-2.96, 3.51)	0.8677	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE		0.00 (-51.08, 51.08)	1.0000	
Sex									NE
male	0/ 27 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.55, 17.55)	1.0000	
female	1/333 (0.3)	0.3	0/341 (0.0)	0.0	3.04 (0.12, 73.99)	0.4956	0.29 (-3.10, 3.67)	0.8686	
Race									NE
White	1/235 (0.4)	0.4	0/244 (0.0)	0.0	2.92 (0.12, 70.87)	0.5104	0.43 (-3.82, 4.68)	0.8427	
Black	0/ 46 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-10.79, 10.79)	1.0000	
Other	0/ 71 (0.0)	0.0	0/ 66 (0.0)	0.0	NE		0.00 (-7.43, 7.43)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 86 (0.0)	0.0	0/ 89 (0.0)	0.0	NE		0.00 (-7.72, 7.72)	1.0000	
Non-hispanic/Latino	1/266 (0.4)	0.4	0/269 (0.0)	0.0	3.05 (0.13, 74.13)	0.4933	0.38 (-3.82, 4.57)	0.8604	
Geographic region									NE
EU	1/115 (0.9)	0.8	0/122 (0.0)	0.0	2.71 (0.11, 64.96)	0.5382	0.80 (-3.91, 5.51)	0.7377	
non-EU	0/245 (0.0)	0.0	0/244 (0.0)	0.0	NE		0.00 (-4.51, 4.51)	1.0000	
Onset of disease									NE
Paediatric	0/ 26 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-18.15, 18.15)	1.0000	
Adult	1/334 (0.3)	0.3	0/342 (0.0)	0.0	3.07 (0.13, 74.87)	0.4910	0.29 (-3.09, 3.67)	0.8664	
ADA result									NE
Negative	1/334 (0.3)	0.3	0/331 (0.0)	0.0	2.83 (0.12, 68.89)	0.5237	0.28 (-3.15, 3.71)	0.8728	
Positive (At any time)	0/ 25 (0.0)	0.0	0/ 35 (0.0)	0.0	NE		0.00 (-17.02, 17.02)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/233 (0.0)	0.0	0/261 (0.0)	0.0	NE		0.00 (-4.03, 4.03)	1.0000	
>= 30	1/127 (0.8)	0.8	0/105 (0.0)	0.0	2.63 (0.11, 62.97)	0.5517	0.81 (-6.58, 8.21)	0.8291	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious MACE
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	1 (0.3)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.03 (0.12, 73.97)	
p-value	0.4959	
Odds Ratio (95% CI)	3.05 (0.12, 75.37)	
p-value	0.4956	
Risk Difference (95% CI)	0.28 (-0.27, 0.82)	
p-value	0.3173	
CMH approach		
Response rate	0.3	0.0
Difference in response rates (95% CI)	0.27 (-2.90, 3.43)	
p-value	0.8691	
p-Value for test for heterogenity between studies	NE	

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Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
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Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious MACE - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/109 (0.0)	0.0	0/106 (0.0)	0.0	NE		0.00 (-7.66, 7.66)	1.0000	
>= 10 points	1/251 (0.4)	0.4	0/260 (0.0)	0.0	3.09 (0.13, 75.26)	0.4878	0.38 (-3.16, 3.92)	0.8342	
OCS dose at baseline									NE
<10 mg/day	0/170 (0.0)	0.0	0/181 (0.0)	0.0	NE		0.00 (-5.16, 5.16)	1.0000	
>=10 mg/day	1/190 (0.5)	0.5	0/185 (0.0)	0.0	2.86 (0.12, 69.32)	0.5176	0.52 (-4.10, 5.13)	0.8268	
Result of type I IFN gene signature test									NE
LOW	0/ 62 (0.0)	0.0	0/ 64 (0.0)	0.0	NE		0.00 (-8.05, 8.05)	1.0000	
HIGH	1/298 (0.3)	0.3	0/302 (0.0)	0.0	3.02 (0.12, 73.54)	0.4975	0.32 (-3.11, 3.76)	0.8542	
Age (years)									NE
<= 65	1/348 (0.3)	0.3	0/362 (0.0)	0.0	3.10 (0.13, 75.64)	0.4872	0.27 (-2.96, 3.51)	0.8677	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE		0.00 (-51.08, 51.08)	1.0000	
Sex									NE
male	0/ 27 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.55, 17.55)	1.0000	
female	1/333 (0.3)	0.3	0/341 (0.0)	0.0	3.04 (0.12, 73.99)	0.4956	0.29 (-3.10, 3.67)	0.8686	
Race									NE
White	1/235 (0.4)	0.4	0/244 (0.0)	0.0	2.92 (0.12, 70.87)	0.5104	0.43 (-3.82, 4.68)	0.8427	
Black	0/ 46 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-10.79, 10.79)	1.0000	
Other	0/ 71 (0.0)	0.0	0/ 66 (0.0)	0.0	NE		0.00 (-7.43, 7.43)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 86 (0.0)	0.0	0/ 89 (0.0)	0.0	NE		0.00 (-7.72, 7.72)	1.0000	
Non-hispanic/Latino	1/266 (0.4)	0.4	0/269 (0.0)	0.0	3.05 (0.13, 74.13)	0.4933	0.38 (-3.82, 4.57)	0.8604	
Geographic region									NE
EU	1/115 (0.9)	0.8	0/122 (0.0)	0.0	2.71 (0.11, 64.96)	0.5382	0.80 (-3.91, 5.51)	0.7377	
non-EU	0/245 (0.0)	0.0	0/244 (0.0)	0.0	NE		0.00 (-4.51, 4.51)	1.0000	
Onset of disease									NE
Paediatric	0/ 26 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-18.15, 18.15)	1.0000	
Adult	1/334 (0.3)	0.3	0/342 (0.0)	0.0	3.07 (0.13, 74.87)	0.4910	0.29 (-3.09, 3.67)	0.8664	
ADA result									NE
Negative	1/334 (0.3)	0.3	0/331 (0.0)	0.0	2.83 (0.12, 68.89)	0.5237	0.28 (-3.15, 3.71)	0.8728	
Positive (At any time)	0/ 25 (0.0)	0.0	0/ 35 (0.0)	0.0	NE		0.00 (-17.02, 17.02)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/233 (0.0)	0.0	0/261 (0.0)	0.0	NE		0.00 (-4.03, 4.03)	1.0000	
>= 30	1/127 (0.8)	0.8	0/105 (0.0)	0.0	2.63 (0.11, 62.97)	0.5517	0.81 (-6.58, 8.21)	0.8291	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

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D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe MACE
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	1 (0.3)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.03 (0.12, 73.97)	
p-value	0.4959	
Odds Ratio (95% CI)	3.05 (0.12, 75.37)	
p-value	0.4956	
Risk Difference (95% CI)	0.28 (-0.27, 0.82)	
p-value	0.3173	
CMH approach		
Response rate	0.3	0.0
Difference in response rates (95% CI)	0.27 (-2.90, 3.43)	
p-value	0.8691	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe MACE - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/109 (0.0)	0.0	0/106 (0.0)	0.0	NE		0.00 (-7.66, 7.66)	1.0000	
>= 10 points	1/251 (0.4)	0.4	0/260 (0.0)	0.0	3.09 (0.13, 75.26)	0.4878	0.38 (-3.16, 3.92)	0.8342	
OCS dose at baseline									NE
<10 mg/day	0/170 (0.0)	0.0	0/181 (0.0)	0.0	NE		0.00 (-5.16, 5.16)	1.0000	
>=10 mg/day	1/190 (0.5)	0.5	0/185 (0.0)	0.0	2.86 (0.12, 69.32)	0.5176	0.52 (-4.10, 5.13)	0.8268	
Result of type I IFN gene signature test									NE
LOW	0/ 62 (0.0)	0.0	0/ 64 (0.0)	0.0	NE		0.00 (-8.05, 8.05)	1.0000	
HIGH	1/298 (0.3)	0.3	0/302 (0.0)	0.0	3.02 (0.12, 73.54)	0.4975	0.32 (-3.11, 3.76)	0.8542	
Age (years)									NE
<= 65	1/348 (0.3)	0.3	0/362 (0.0)	0.0	3.10 (0.13, 75.64)	0.4872	0.27 (-2.96, 3.51)	0.8677	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE		0.00 (-51.08, 51.08)	1.0000	
Sex									NE
male	0/ 27 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.55, 17.55)	1.0000	
female	1/333 (0.3)	0.3	0/341 (0.0)	0.0	3.04 (0.12, 73.99)	0.4956	0.29 (-3.10, 3.67)	0.8686	
Race									NE
White	1/235 (0.4)	0.4	0/244 (0.0)	0.0	2.92 (0.12, 70.87)	0.5104	0.43 (-3.82, 4.68)	0.8427	
Black	0/ 46 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-10.79, 10.79)	1.0000	
Other	0/ 71 (0.0)	0.0	0/ 66 (0.0)	0.0	NE		0.00 (-7.43, 7.43)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 86 (0.0)	0.0	0/ 89 (0.0)	0.0	NE		0.00 (-7.72, 7.72)	1.0000	
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Paediatric	0/ 26 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-18.15, 18.15)	1.0000	
Adult	1/334 (0.3)	0.3	0/342 (0.0)	0.0	3.07 (0.13, 74.87)	0.4910	0.29 (-3.09, 3.67)	0.8664	
ADA result									NE
Negative	1/334 (0.3)	0.3	0/331 (0.0)	0.0	2.83 (0.12, 68.89)	0.5237	0.28 (-3.15, 3.71)	0.8728	
Positive (At any time)	0/ 25 (0.0)	0.0	0/ 35 (0.0)	0.0	NE		0.00 (-17.02, 17.02)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	0/233 (0.0)	0.0	0/261 (0.0)	0.0	NE		0.00 (-4.03, 4.03)	1.0000	
>= 30	1/127 (0.8)	0.8	0/105 (0.0)	0.0	2.63 (0.11, 62.97)	0.5517	0.81 (-6.58, 8.21)	0.8291	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
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Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe MACE
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-3.13, 3.13)	
p-value	1.0000	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe MACE - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/109 (0.0)	0.0	0/106 (0.0)	0.0	NE	0.00 (-7.66, 7.66)	1.0000	
>= 10 points	0/251 (0.0)	0.0	0/260 (0.0)	0.0	NE	0.00 (-3.47, 3.47)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/170 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-5.16, 5.16)	1.0000	
>=10 mg/day	0/190 (0.0)	0.0	0/185 (0.0)	0.0	NE	0.00 (-4.52, 4.52)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 62 (0.0)	0.0	0/ 64 (0.0)	0.0	NE	0.00 (-8.05, 8.05)	1.0000	
HIGH	0/298 (0.0)	0.0	0/302 (0.0)	0.0	NE	0.00 (-3.38, 3.38)	1.0000	
Age (years)								NE
<= 65	0/348 (0.0)	0.0	0/362 (0.0)	0.0	NE	0.00 (-3.20, 3.20)	1.0000	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE	0.00 (-51.08, 51.08)	1.0000	
Sex								NE
male	0/ 27 (0.0)	0.0	0/ 25 (0.0)	0.0	NE	0.00 (-17.55, 17.55)	1.0000	
female	0/333 (0.0)	0.0	0/341 (0.0)	0.0	NE	0.00 (-3.35, 3.35)	1.0000	
Race								NE
White	0/235 (0.0)	0.0	0/244 (0.0)	0.0	NE	0.00 (-4.18, 4.18)	1.0000	
Black	0/ 46 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-10.79, 10.79)	1.0000	
Other	0/ 71 (0.0)	0.0	0/ 66 (0.0)	0.0	NE	0.00 (-7.43, 7.43)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 86 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-7.72, 7.72)	1.0000	
Non-hispanic/Latino	0/266 (0.0)	0.0	0/269 (0.0)	0.0	NE	0.00 (-4.14, 4.14)	1.0000	
Geographic region								NE
EU	0/115 (0.0)	0.0	0/122 (0.0)	0.0	NE	0.00 (-4.48, 4.48)	1.0000	
non-EU	0/245 (0.0)	0.0	0/244 (0.0)	0.0	NE	0.00 (-4.51, 4.51)	1.0000	
Onset of disease								NE
Paediatric	0/ 26 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-18.15, 18.15)	1.0000	
Adult	0/334 (0.0)	0.0	0/342 (0.0)	0.0	NE	0.00 (-3.34, 3.34)	1.0000	
ADA result								NE
Negative	0/334 (0.0)	0.0	0/331 (0.0)	0.0	NE	0.00 (-3.40, 3.40)	1.0000	
Positive (At any time)	0/ 25 (0.0)	0.0	0/ 35 (0.0)	0.0	NE	0.00 (-17.02, 17.02)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/233 (0.0)	0.0	0/261 (0.0)	0.0	NE	0.00 (-4.03, 4.03)	1.0000	
>= 30	0/127 (0.0)	0.0	0/105 (0.0)	0.0	NE	0.00 (-7.26, 7.26)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	14 (3.9)	20 (5.5)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.72 (0.37, 1.41)	
p-value	0.3396	
Odds Ratio (95% CI)	0.71 (0.35, 1.43)	
p-value	0.3350	
Risk Difference (95% CI)	-1.57 (-4.64, 1.50)	
p-value	0.3151	
CMH approach		
Response rate	3.9	5.5
Difference in response rates (95% CI)	-1.61 (-5.78, 2.56)	
p-value	0.4489	
p-Value for test for heterogenity between studies	0.3919	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.7868
< 10 points	3/109 (2.8)	2.6	5/106 (4.7)	4.6	0.61 (0.14, 2.62)	0.5053	-2.04 (-10.69, 6.60)	0.6433	
>= 10 points	11/251 (4.4)	4.4	15/260 (5.8)	5.8	0.76 (0.36, 1.64)	0.4902	-1.43 (-6.35, 3.49)	0.5686	
OCS dose at baseline									0.3839
<10 mg/day	4/170 (2.4)	2.3	9/181 (5.0)	5.0	0.47 (0.15, 1.51)	0.2074	-2.66 (-8.84, 3.52)	0.3982	
>=10 mg/day	10/190 (5.3)	5.3	11/185 (5.9)	6.0	0.90 (0.38, 2.13)	0.8116	-0.70 (-6.86, 5.46)	0.8238	
Result of type I IFN gene signature test									0.3943
LOW	3/ 62 (4.8)	4.8	2/ 64 (3.1)	3.1	1.38 (0.27, 7.03)	0.6981	1.71 (-8.35, 11.77)	0.7388	
HIGH	11/298 (3.7)	3.6	18/302 (6.0)	6.0	0.63 (0.30, 1.34)	0.2308	-2.31 (-6.89, 2.27)	0.3231	
Age (years)									0.8022
<= 65	13/348 (3.7)	3.7	20/362 (5.5)	5.5	0.69 (0.35, 1.39)	0.3028	-1.87 (-6.09, 2.36)	0.3865	
> 65	1/ 12 (8.3)	5.7	0/ 4 (0.0)	0.0	1.00 (0.06, 15.99)	1.0000	5.68 (-45.70, 57.06)	0.8284	
Sex									0.8864
male	1/ 27 (3.7)	3.6	1/ 25 (4.0)	4.1	0.87 (0.06, 12.52)	0.9164	-0.55 (-19.84, 18.74)	0.9554	
female	13/333 (3.9)	3.9	19/341 (5.6)	5.6	0.71 (0.35, 1.42)	0.3323	-1.70 (-6.11, 2.71)	0.4503	
Race									0.5125
White	10/235 (4.3)	4.2	10/244 (4.1)	4.4	1.02 (0.43, 2.42)	0.9575	-0.17 (-5.45, 5.12)	0.9509	
Black	2/ 46 (4.3)	3.9	4/ 48 (8.3)	9.1	0.52 (0.12, 2.31)	0.3888	-5.20 (-18.93, 8.53)	0.4578	
Other	2/ 71 (2.8)	2.8	6/ 66 (9.1)	9.1	0.42 (0.10, 1.83)	0.2466	-6.29 (-16.45, 3.87)	0.2249	
Ethnicity									0.7018
Hispanic/Latino	4/ 86 (4.7)	4.8	7/ 89 (7.9)	7.9	0.60 (0.18, 1.97)	0.4002	-3.07 (-12.96, 6.82)	0.5429	
Non-hispanic/Latino	10/266 (3.8)	3.8	13/269 (4.8)	4.8	0.80 (0.35, 1.83)	0.5916	-0.95 (-6.08, 4.18)	0.7161	
Geographic region									0.4568
EU	1/115 (0.9)	0.9	4/122 (3.3)	3.3	0.38 (0.06, 2.43)	0.3042	-2.41 (-8.07, 3.24)	0.4024	
non-EU	13/245 (5.3)	5.1	16/244 (6.6)	6.8	0.80 (0.39, 1.64)	0.5468	-1.69 (-7.43, 4.05)	0.5640	
Onset of disease									0.4115
Paediatric	4/ 26 (15.4)	15.4	3/ 24 (12.5)	12.3	1.23 (0.30, 5.01)	0.7738	3.09 (-20.09, 26.26)	0.7940	
Adult	10/334 (3.0)	3.0	17/342 (5.0)	5.0	0.63 (0.29, 1.37)	0.2425	-2.02 (-6.26, 2.22)	0.3508	
ADA result									0.4250
Negative	13/334 (3.9)	3.9	15/331 (4.5)	4.5	0.87 (0.42, 1.80)	0.7043	-0.66 (-5.01, 3.69)	0.7665	
Positive (At any time)	1/ 25 (4.0)	3.4	5/ 35 (14.3)	14.0	0.40 (0.07, 2.37)	0.3096	-10.60 (-30.85, 9.64)	0.3046	
BMI (kg/m2) at enrolment									0.3740
< 30	7/233 (3.0)	3.0	15/261 (5.7)	5.6	0.54 (0.22, 1.31)	0.1729	-2.62 (-7.75, 2.50)	0.3155	
>= 30	7/127 (5.5)	5.6	5/105 (4.8)	5.2	1.06 (0.32, 3.54)	0.9183	0.46 (-8.20, 9.11)	0.9173	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Non-opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	14 (3.9)	20 (5.5)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.72 (0.37, 1.41)	
p-value	0.3396	
Odds Ratio (95% CI)	0.71 (0.35, 1.43)	
p-value	0.3350	
Risk Difference (95% CI)	-1.57 (-4.64, 1.50)	
p-value	0.3151	
CMH approach		
Response rate	3.9	5.5
Difference in response rates (95% CI)	-1.61 (-5.78, 2.56)	
p-value	0.4489	
p-Value for test for heterogenity between studies	0.3919	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
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Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Non-opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.7868
< 10 points	3/109 (2.8)	2.6	5/106 (4.7)	4.6	0.61 (0.14, 2.62)	0.5053	-2.04 (-10.69, 6.60)	0.6433	
>= 10 points	11/251 (4.4)	4.4	15/260 (5.8)	5.8	0.76 (0.36, 1.64)	0.4902	-1.43 (-6.35, 3.49)	0.5686	
OCS dose at baseline									0.3839
<10 mg/day	4/170 (2.4)	2.3	9/181 (5.0)	5.0	0.47 (0.15, 1.51)	0.2074	-2.66 (-8.84, 3.52)	0.3982	
>=10 mg/day	10/190 (5.3)	5.3	11/185 (5.9)	6.0	0.90 (0.38, 2.13)	0.8116	-0.70 (-6.86, 5.46)	0.8238	
Result of type I IFN gene signature test									0.3943
LOW	3/ 62 (4.8)	4.8	2/ 64 (3.1)	3.1	1.38 (0.27, 7.03)	0.6981	1.71 (-8.35, 11.77)	0.7388	
HIGH	11/298 (3.7)	3.6	18/302 (6.0)	6.0	0.63 (0.30, 1.34)	0.2308	-2.31 (-6.89, 2.27)	0.3231	
Age (years)									0.8022
<= 65	13/348 (3.7)	3.7	20/362 (5.5)	5.5	0.69 (0.35, 1.39)	0.3028	-1.87 (-6.09, 2.36)	0.3865	
> 65	1/ 12 (8.3)	5.7	0/ 4 (0.0)	0.0	1.00 (0.06, 15.99)	1.0000	5.68 (-45.70, 57.06)	0.8284	
Sex									0.8864
male	1/ 27 (3.7)	3.6	1/ 25 (4.0)	4.1	0.87 (0.06, 12.52)	0.9164	-0.55 (-19.84, 18.74)	0.9554	
female	13/333 (3.9)	3.9	19/341 (5.6)	5.6	0.71 (0.35, 1.42)	0.3323	-1.70 (-6.11, 2.71)	0.4503	
Race									0.5125
White	10/235 (4.3)	4.2	10/244 (4.1)	4.4	1.02 (0.43, 2.42)	0.9575	-0.17 (-5.45, 5.12)	0.9509	
Black	2/ 46 (4.3)	3.9	4/ 48 (8.3)	9.1	0.52 (0.12, 2.31)	0.3888	-5.20 (-18.93, 8.53)	0.4578	
Other	2/ 71 (2.8)	2.8	6/ 66 (9.1)	9.1	0.42 (0.10, 1.83)	0.2466	-6.29 (-16.45, 3.87)	0.2249	
Ethnicity									0.7018
Hispanic/Latino	4/ 86 (4.7)	4.8	7/ 89 (7.9)	7.9	0.60 (0.18, 1.97)	0.4002	-3.07 (-12.96, 6.82)	0.5429	
Non-hispanic/Latino	10/266 (3.8)	3.8	13/269 (4.8)	4.8	0.80 (0.35, 1.83)	0.5916	-0.95 (-6.08, 4.18)	0.7161	
Geographic region									0.4568
EU	1/115 (0.9)	0.9	4/122 (3.3)	3.3	0.38 (0.06, 2.43)	0.3042	-2.41 (-8.07, 3.24)	0.4024	
non-EU	13/245 (5.3)	5.1	16/244 (6.6)	6.8	0.80 (0.39, 1.64)	0.5468	-1.69 (-7.43, 4.05)	0.5640	
Onset of disease									0.4115
Paediatric	4/ 26 (15.4)	15.4	3/ 24 (12.5)	12.3	1.23 (0.30, 5.01)	0.7738	3.09 (-20.09, 26.26)	0.7940	
Adult	10/334 (3.0)	3.0	17/342 (5.0)	5.0	0.63 (0.29, 1.37)	0.2425	-2.02 (-6.26, 2.22)	0.3508	
ADA result									0.4250
Negative	13/334 (3.9)	3.9	15/331 (4.5)	4.5	0.87 (0.42, 1.80)	0.7043	-0.66 (-5.01, 3.69)	0.7665	
Positive (At any time)	1/ 25 (4.0)	3.4	5/ 35 (14.3)	14.0	0.40 (0.07, 2.37)	0.3096	-10.60 (-30.85, 9.64)	0.3046	
BMI (kg/m2) at enrolment									0.3740
< 30	7/233 (3.0)	3.0	15/261 (5.7)	5.6	0.54 (0.22, 1.31)	0.1729	-2.62 (-7.75, 2.50)	0.3155	
>= 30	7/127 (5.5)	5.6	5/105 (4.8)	5.2	1.06 (0.32, 3.54)	0.9183	0.46 (-8.20, 9.11)	0.9173	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Non-opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	8 (2.2)	7 (1.9)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.17 (0.43, 3.18)	
p-value	0.7646	
Odds Ratio (95% CI)	1.17 (0.42, 3.27)	
p-value	0.7656	
Risk Difference (95% CI)	0.31 (-1.75, 2.38)	
p-value	0.7652	
CMH approach		
Response rate	2.2	1.9
Difference in response rates (95% CI)	0.27 (-3.36, 3.90)	
p-value	0.8844	
p-Value for test for heterogenity between studies	0.8676	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Non-opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.8296
< 10 points	2/109 (1.8)	1.8	2/106 (1.9)	1.8	0.97 (0.14, 6.78)	0.9774	-0.09 (-8.28, 8.10)	0.9828	
>= 10 points	6/251 (2.4)	2.4	5/260 (1.9)	2.0	1.25 (0.39, 4.02)	0.7114	0.41 (-3.74, 4.55)	0.8474	
OCS dose at baseline									0.9337
<10 mg/day	2/170 (1.2)	1.1	2/181 (1.1)	1.1	1.06 (0.15, 7.37)	0.9492	-0.02 (-5.47, 5.43)	0.9942	
>=10 mg/day	6/190 (3.2)	3.2	5/185 (2.7)	2.7	1.17 (0.36, 3.78)	0.7903	0.49 (-4.95, 5.93)	0.8595	
Result of type I IFN gene signature test									0.3684
LOW	3/ 62 (4.8)	4.8	1/ 64 (1.6)	1.6	2.38 (0.36, 15.72)	0.3669	3.27 (-6.44, 12.99)	0.5089	
HIGH	5/298 (1.7)	1.6	6/302 (2.0)	2.0	0.86 (0.26, 2.81)	0.7990	-0.36 (-4.25, 3.52)	0.8547	
Age (years)									NE
<= 65	8/348 (2.3)	2.3	7/362 (1.9)	2.0	1.19 (0.44, 3.25)	0.7303	0.32 (-3.39, 4.02)	0.8675	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE		0.00 (-51.08, 51.08)	1.0000	
Sex									NE
male	0/ 27 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.55, 17.55)	1.0000	
female	8/333 (2.4)	2.4	7/341 (2.1)	2.1	1.18 (0.43, 3.21)	0.7489	0.32 (-3.56, 4.20)	0.8704	
Race									0.5987
White	6/235 (2.6)	2.5	4/244 (1.6)	1.8	1.55 (0.43, 5.52)	0.5002	0.69 (-4.05, 5.43)	0.7756	
Black	1/ 46 (2.2)	1.9	2/ 48 (4.2)	4.9	0.40 (0.04, 4.11)	0.4380	-2.93 (-15.47, 9.60)	0.6465	
Other	1/ 71 (1.4)	1.4	1/ 66 (1.5)	1.5	0.92 (0.06, 13.95)	0.9539	-0.12 (-8.30, 8.06)	0.9776	
Ethnicity									0.8686
Hispanic/Latino	3/ 86 (3.5)	3.7	3/ 89 (3.4)	3.4	1.06 (0.22, 5.07)	0.9394	0.28 (-8.78, 9.35)	0.9509	
Non-hispanic/Latino	5/266 (1.9)	2.0	4/269 (1.5)	1.5	1.26 (0.34, 4.65)	0.7268	0.49 (-4.06, 5.05)	0.8314	
Geographic region									0.4892
EU	0/115 (0.0)	0.0	1/122 (0.8)	0.8	0.39 (0.02, 9.53)	0.5673	-0.78 (-5.48, 3.93)	0.7466	
non-EU	8/245 (3.3)	3.1	6/244 (2.5)	2.7	1.29 (0.45, 3.66)	0.6349	0.43 (-4.71, 5.58)	0.8686	
Onset of disease									0.8022
Paediatric	2/ 26 (7.7)	7.7	2/ 24 (8.3)	8.3	0.93 (0.14, 6.07)	0.9361	-0.62 (-22.06, 20.82)	0.9550	
Adult	6/334 (1.8)	1.8	5/342 (1.5)	1.5	1.23 (0.38, 3.98)	0.7305	0.30 (-3.43, 4.04)	0.8732	
ADA result									0.2911
Negative	7/334 (2.1)	2.1	4/331 (1.2)	1.2	1.78 (0.53, 6.00)	0.3556	0.86 (-2.92, 4.64)	0.6567	
Positive (At any time)	1/ 25 (4.0)	3.4	3/ 35 (8.6)	9.9	0.54 (0.09, 3.42)	0.5122	-6.43 (-26.21, 13.35)	0.5242	
BMI (kg/m2) at enrolment									0.9738
< 30	4/233 (1.7)	1.7	4/261 (1.5)	1.5	1.11 (0.29, 4.22)	0.8814	0.22 (-4.26, 4.70)	0.9246	
>= 30	4/127 (3.1)	3.3	3/105 (2.9)	3.1	1.07 (0.21, 5.43)	0.9360	0.17 (-7.96, 8.31)	0.9667	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Non-opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	6 (1.7)	14 (3.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.44 (0.17, 1.13)	
p-value	0.0870	
Odds Ratio (95% CI)	0.43 (0.16, 1.13)	
p-value	0.0861	
Risk Difference (95% CI)	-2.16 (-4.53, 0.21)	
p-value	0.0739	
CMH approach		
Response rate	1.7	3.8
Difference in response rates (95% CI)	-2.15 (-5.95, 1.64)	
p-value	0.2662	
p-Value for test for heterogenity between studies	0.7576	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Non-opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.9958
< 10 points	1/109 (0.9)	0.8	3/106 (2.8)	2.8	0.47 (0.06, 3.57)	0.4646	-1.95 (-10.12, 6.22)	0.6394	
>= 10 points	5/251 (2.0)	2.0	11/260 (4.2)	4.2	0.47 (0.17, 1.34)	0.1584	-2.23 (-6.68, 2.23)	0.3270	
OCS dose at baseline									0.6597
<10 mg/day	2/170 (1.2)	1.2	7/181 (3.9)	3.9	0.39 (0.09, 1.68)	0.2074	-2.64 (-8.58, 3.29)	0.3826	
>=10 mg/day	4/190 (2.1)	2.1	7/185 (3.8)	3.8	0.61 (0.17, 2.17)	0.4410	-1.72 (-7.22, 3.78)	0.5395	
Result of type I IFN gene signature test									0.8507
LOW	0/ 62 (0.0)	0.0	1/ 64 (1.6)	1.6	0.34 (0.01, 8.13)	0.5080	-1.56 (-10.05, 6.93)	0.7182	
HIGH	6/298 (2.0)	2.0	13/302 (4.3)	4.3	0.47 (0.18, 1.23)	0.1250	-2.28 (-6.51, 1.96)	0.2916	
Age (years)									0.5241
<= 65	5/348 (1.4)	1.4	14/362 (3.9)	3.9	0.38 (0.14, 1.06)	0.0656	-2.46 (-6.30, 1.38)	0.2091	
> 65	1/ 12 (8.3)	5.7	0/ 4 (0.0)	0.0	1.00 (0.06, 15.99)	1.0000	5.68 (-45.70, 57.06)	0.8284	
Sex									0.5875
male	1/ 27 (3.7)	3.6	1/ 25 (4.0)	4.1	0.87 (0.06, 12.52)	0.9164	-0.55 (-19.84, 18.74)	0.9554	
female	5/333 (1.5)	1.5	13/341 (3.8)	3.8	0.39 (0.14, 1.09)	0.0726	-2.31 (-6.32, 1.69)	0.2575	
Race									0.5943
White	4/235 (1.7)	1.7	6/244 (2.5)	2.6	0.67 (0.19, 2.36)	0.5377	-0.86 (-5.67, 3.95)	0.7274	
Black	1/ 46 (2.2)	1.9	2/ 48 (4.2)	4.2	0.64 (0.08, 5.01)	0.6712	-2.27 (-14.57, 10.04)	0.7180	
Other	1/ 71 (1.4)	1.4	6/ 66 (9.1)	9.1	0.23 (0.04, 1.32)	0.0992	-7.69 (-17.60, 2.21)	0.1280	
Ethnicity									0.5751
Hispanic/Latino	1/ 86 (1.2)	1.1	5/ 89 (5.6)	5.5	0.31 (0.05, 1.99)	0.2189	-4.45 (-13.38, 4.47)	0.3279	
Non-hispanic/Latino	5/266 (1.9)	1.9	9/269 (3.3)	3.3	0.58 (0.19, 1.79)	0.3450	-1.45 (-6.23, 3.34)	0.5533	
Geographic region									0.9318
EU	1/115 (0.9)	0.9	3/122 (2.5)	2.6	0.50 (0.07, 3.84)	0.5086	-1.64 (-7.11, 3.83)	0.5571	
non-EU	5/245 (2.0)	2.0	11/244 (4.5)	4.6	0.46 (0.16, 1.30)	0.1405	-2.60 (-7.87, 2.68)	0.3347	
Onset of disease									0.1899
Paediatric	2/ 26 (7.7)	7.7	1/ 24 (4.2)	4.0	1.49 (0.20, 11.27)	0.6964	3.70 (-16.86, 24.26)	0.7240	
Adult	4/334 (1.2)	1.2	13/342 (3.8)	3.8	0.32 (0.10, 0.98)	0.0451	-2.61 (-6.56, 1.33)	0.1946	
ADA result									0.7650
Negative	6/334 (1.8)	1.8	11/331 (3.3)	3.3	0.54 (0.20, 1.45)	0.2202	-1.52 (-5.55, 2.52)	0.4613	
Positive (At any time)	0/ 25 (0.0)	0.0	3/ 35 (8.6)	8.1	0.38 (0.04, 3.21)	0.3721	-8.06 (-26.62, 10.50)	0.3947	
BMI (kg/m2) at enrolment									0.2012
< 30	3/233 (1.3)	1.3	12/261 (4.6)	4.5	0.30 (0.08, 1.04)	0.0583	-3.20 (-8.00, 1.59)	0.1903	
>= 30	3/127 (2.4)	2.3	2/105 (1.9)	2.1	1.14 (0.22, 5.91)	0.8747	0.29 (-7.61, 8.18)	0.9435	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	1 (0.3)	1 (0.3)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.02 (0.06, 16.22)	
p-value	0.9876	
Odds Ratio (95% CI)	1.02 (0.06, 16.47)	
p-value	0.9876	
Risk Difference (95% CI)	0.01 (-0.76, 0.77)	
p-value	0.9876	
CMH approach		
Response rate	0.3	0.3
Difference in response rates (95% CI)	0.02 (-3.19, 3.22)	
p-value	0.9921	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/109 (0.0)	0.0	0/106 (0.0)	0.0	NE		0.00 (-7.66, 7.66)	1.0000	
>= 10 points	1/251 (0.4)	0.4	1/260 (0.4)	0.4	1.04 (0.07, 16.45)	0.9778	0.02 (-3.58, 3.63)	0.9900	
OCS dose at baseline									0.3554
<10 mg/day	0/170 (0.0)	0.0	1/181 (0.6)	0.5	0.35 (0.01, 8.58)	0.5237	-0.54 (-5.79, 4.71)	0.8397	
>=10 mg/day	1/190 (0.5)	0.5	0/185 (0.0)	0.0	2.97 (0.12, 72.09)	0.5033	0.54 (-4.09, 5.16)	0.8195	
Result of type I IFN gene signature test									NE
LOW	0/ 62 (0.0)	0.0	0/ 64 (0.0)	0.0	NE		0.00 (-8.05, 8.05)	1.0000	
HIGH	1/298 (0.3)	0.3	1/302 (0.3)	0.3	1.02 (0.06, 16.16)	0.9886	0.02 (-3.47, 3.51)	0.9912	
Age (years)									NE
<= 65	1/348 (0.3)	0.3	1/362 (0.3)	0.3	1.05 (0.07, 16.60)	0.9744	0.03 (-3.25, 3.30)	0.9873	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE		0.00 (-51.08, 51.08)	1.0000	
Sex									NE
male	0/ 27 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.55, 17.55)	1.0000	
female	1/333 (0.3)	0.3	1/341 (0.3)	0.3	1.04 (0.07, 16.43)	0.9798	0.02 (-3.40, 3.45)	0.9887	
Race									0.3032
White	0/235 (0.0)	0.0	0/244 (0.0)	0.0	NE		0.00 (-4.18, 4.18)	1.0000	
Black	0/ 46 (0.0)	0.0	1/ 48 (2.1)	2.4	0.27 (0.01, 6.26)	0.4116	-2.43 (-13.93, 9.07)	0.6786	
Other	1/ 71 (1.4)	1.4	0/ 66 (0.0)	0.0	2.78 (0.12, 65.08)	0.5255	1.40 (-6.39, 9.19)	0.7240	
Ethnicity									NE
Hispanic/Latino	0/ 86 (0.0)	0.0	0/ 89 (0.0)	0.0	NE		0.00 (-7.72, 7.72)	1.0000	
Non-hispanic/Latino	1/266 (0.4)	0.4	1/269 (0.4)	0.4	1.01 (0.06, 15.95)	0.9962	0.01 (-4.25, 4.27)	0.9964	
Geographic region									NE
EU	0/115 (0.0)	0.0	0/122 (0.0)	0.0	NE		0.00 (-4.48, 4.48)	1.0000	
non-EU	1/245 (0.4)	0.4	1/244 (0.4)	0.4	0.93 (0.06, 14.70)	0.9595	-0.04 (-4.64, 4.56)	0.9870	
Onset of disease									NE
Paediatric	0/ 26 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-18.15, 18.15)	1.0000	
Adult	1/334 (0.3)	0.3	1/342 (0.3)	0.3	1.02 (0.06, 16.24)	0.9867	0.03 (-3.39, 3.45)	0.9876	
ADA result									0.3015
Negative	1/334 (0.3)	0.3	0/331 (0.0)	0.0	3.13 (0.13, 76.25)	0.4839	0.32 (-3.13, 3.76)	0.8568	
Positive (At any time)	0/ 25 (0.0)	0.0	1/ 35 (2.9)	3.9	0.30 (0.01, 6.77)	0.4461	-3.88 (-21.87, 14.10)	0.6722	
BMI (kg/m2) at enrolment									0.2603
< 30	1/233 (0.4)	0.5	0/261 (0.0)	0.0	3.52 (0.14, 85.60)	0.4392	0.45 (-3.66, 4.56)	0.8298	
>= 30	0/127 (0.0)	0.0	1/105 (1.0)	1.0	0.26 (0.01, 6.38)	0.4131	-1.04 (-8.50, 6.43)	0.7852	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	0 (0.0)	1 (0.3)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.34 (0.01, 8.31)	
p-value	0.5088	
Odds Ratio (95% CI)	0.34 (0.01, 8.37)	
p-value	0.5084	
Risk Difference (95% CI)	-0.27 (-0.81, 0.26)	
p-value	0.3173	
CMH approach		
Response rate	0.0	0.3
Difference in response rates (95% CI)	-0.26 (-3.42, 2.90)	
p-value	0.8710	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/109 (0.0)	0.0	0/106 (0.0)	0.0	NE		0.00 (-7.66, 7.66)	1.0000	
>= 10 points	0/251 (0.0)	0.0	1/260 (0.4)	0.4	0.35 (0.01, 8.43)	0.5152	-0.37 (-3.91, 3.16)	0.8366	
OCS dose at baseline									NE
<10 mg/day	0/170 (0.0)	0.0	1/181 (0.6)	0.5	0.35 (0.01, 8.58)	0.5237	-0.54 (-5.79, 4.71)	0.8397	
>=10 mg/day	0/190 (0.0)	0.0	0/185 (0.0)	0.0	NE		0.00 (-4.52, 4.52)	1.0000	
Result of type I IFN gene signature test									NE
LOW	0/ 62 (0.0)	0.0	0/ 64 (0.0)	0.0	NE		0.00 (-8.05, 8.05)	1.0000	
HIGH	0/298 (0.0)	0.0	1/302 (0.3)	0.3	0.34 (0.01, 8.28)	0.5078	-0.32 (-3.75, 3.11)	0.8563	
Age (years)									NE
<= 65	0/348 (0.0)	0.0	1/362 (0.3)	0.3	0.35 (0.01, 8.50)	0.5179	-0.26 (-3.49, 2.97)	0.8745	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE		0.00 (-51.08, 51.08)	1.0000	
Sex									NE
male	0/ 27 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.55, 17.55)	1.0000	
female	0/333 (0.0)	0.0	1/341 (0.3)	0.3	0.35 (0.01, 8.42)	0.5141	-0.28 (-3.66, 3.10)	0.8722	
Race									NE
White	0/235 (0.0)	0.0	0/244 (0.0)	0.0	NE		0.00 (-4.18, 4.18)	1.0000	
Black	0/ 46 (0.0)	0.0	1/ 48 (2.1)	2.4	0.27 (0.01, 6.26)	0.4116	-2.43 (-13.93, 9.07)	0.6786	
Other	0/ 71 (0.0)	0.0	0/ 66 (0.0)	0.0	NE		0.00 (-7.43, 7.43)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 86 (0.0)	0.0	0/ 89 (0.0)	0.0	NE		0.00 (-7.72, 7.72)	1.0000	
Non-hispanic/Latino	0/266 (0.0)	0.0	1/269 (0.4)	0.4	0.34 (0.01, 8.17)	0.5026	-0.39 (-4.59, 3.80)	0.8536	
Geographic region									NE
EU	0/115 (0.0)	0.0	0/122 (0.0)	0.0	NE		0.00 (-4.48, 4.48)	1.0000	
non-EU	0/245 (0.0)	0.0	1/244 (0.4)	0.4	0.31 (0.01, 7.54)	0.4724	-0.39 (-4.95, 4.17)	0.8672	
Onset of disease									NE
Paediatric	0/ 26 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-18.15, 18.15)	1.0000	
Adult	0/334 (0.0)	0.0	1/342 (0.3)	0.3	0.34 (0.01, 8.32)	0.5093	-0.28 (-3.65, 3.10)	0.8724	
ADA result									NE
Negative	0/334 (0.0)	0.0	0/331 (0.0)	0.0	NE		0.00 (-3.40, 3.40)	1.0000	
Positive (At any time)	0/ 25 (0.0)	0.0	1/ 35 (2.9)	3.9	0.30 (0.01, 6.77)	0.4461	-3.88 (-21.87, 14.10)	0.6722	
BMI (kg/m2) at enrolment									NE
< 30	0/233 (0.0)	0.0	0/261 (0.0)	0.0	NE		0.00 (-4.03, 4.03)	1.0000	
>= 30	0/127 (0.0)	0.0	1/105 (1.0)	1.0	0.26 (0.01, 6.38)	0.4131	-1.04 (-8.50, 6.43)	0.7852	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	0 (0.0)	1 (0.3)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.34 (0.01, 8.31)	
p-value	0.5088	
Odds Ratio (95% CI)	0.34 (0.01, 8.37)	
p-value	0.5084	
Risk Difference (95% CI)	-0.27 (-0.81, 0.26)	
p-value	0.3173	
CMH approach		
Response rate	0.0	0.3
Difference in response rates (95% CI)	-0.26 (-3.42, 2.90)	
p-value	0.8710	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/109 (0.0)	0.0	0/106 (0.0)	0.0	NE		0.00 (-7.66, 7.66)	1.0000	
>= 10 points	0/251 (0.0)	0.0	1/260 (0.4)	0.4	0.35 (0.01, 8.43)	0.5152	-0.37 (-3.91, 3.16)	0.8366	
OCS dose at baseline									NE
<10 mg/day	0/170 (0.0)	0.0	1/181 (0.6)	0.5	0.35 (0.01, 8.58)	0.5237	-0.54 (-5.79, 4.71)	0.8397	
>=10 mg/day	0/190 (0.0)	0.0	0/185 (0.0)	0.0	NE		0.00 (-4.52, 4.52)	1.0000	
Result of type I IFN gene signature test									NE
LOW	0/ 62 (0.0)	0.0	0/ 64 (0.0)	0.0	NE		0.00 (-8.05, 8.05)	1.0000	
HIGH	0/298 (0.0)	0.0	1/302 (0.3)	0.3	0.34 (0.01, 8.28)	0.5078	-0.32 (-3.75, 3.11)	0.8563	
Age (years)									NE
<= 65	0/348 (0.0)	0.0	1/362 (0.3)	0.3	0.35 (0.01, 8.50)	0.5179	-0.26 (-3.49, 2.97)	0.8745	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE		0.00 (-51.08, 51.08)	1.0000	
Sex									NE
male	0/ 27 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.55, 17.55)	1.0000	
female	0/333 (0.0)	0.0	1/341 (0.3)	0.3	0.35 (0.01, 8.42)	0.5141	-0.28 (-3.66, 3.10)	0.8722	
Race									NE
White	0/235 (0.0)	0.0	0/244 (0.0)	0.0	NE		0.00 (-4.18, 4.18)	1.0000	
Black	0/ 46 (0.0)	0.0	1/ 48 (2.1)	2.4	0.27 (0.01, 6.26)	0.4116	-2.43 (-13.93, 9.07)	0.6786	
Other	0/ 71 (0.0)	0.0	0/ 66 (0.0)	0.0	NE		0.00 (-7.43, 7.43)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 86 (0.0)	0.0	0/ 89 (0.0)	0.0	NE		0.00 (-7.72, 7.72)	1.0000	
Non-hispanic/Latino	0/266 (0.0)	0.0	1/269 (0.4)	0.4	0.34 (0.01, 8.17)	0.5026	-0.39 (-4.59, 3.80)	0.8536	
Geographic region									NE
EU	0/115 (0.0)	0.0	0/122 (0.0)	0.0	NE		0.00 (-4.48, 4.48)	1.0000	
non-EU	0/245 (0.0)	0.0	1/244 (0.4)	0.4	0.31 (0.01, 7.54)	0.4724	-0.39 (-4.95, 4.17)	0.8672	
Onset of disease									NE
Paediatric	0/ 26 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-18.15, 18.15)	1.0000	
Adult	0/334 (0.0)	0.0	1/342 (0.3)	0.3	0.34 (0.01, 8.32)	0.5093	-0.28 (-3.65, 3.10)	0.8724	
ADA result									NE
Negative	0/334 (0.0)	0.0	0/331 (0.0)	0.0	NE		0.00 (-3.40, 3.40)	1.0000	
Positive (At any time)	0/ 25 (0.0)	0.0	1/ 35 (2.9)	3.9	0.30 (0.01, 6.77)	0.4461	-3.88 (-21.87, 14.10)	0.6722	
BMI (kg/m2) at enrolment									NE
< 30	0/233 (0.0)	0.0	0/261 (0.0)	0.0	NE		0.00 (-4.03, 4.03)	1.0000	
>= 30	0/127 (0.0)	0.0	1/105 (1.0)	1.0	0.26 (0.01, 6.38)	0.4131	-1.04 (-8.50, 6.43)	0.7852	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	1 (0.3)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.07 (0.13, 74.78)	
p-value	0.4917	
Odds Ratio (95% CI)	3.08 (0.12, 76.19)	
p-value	0.4913	
Risk Difference (95% CI)	0.28 (-0.27, 0.82)	
p-value	0.3160	
CMH approach		
Response rate	0.3	0.0
Difference in response rates (95% CI)	0.28 (-2.89, 3.45)	
p-value	0.8634	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	0/109 (0.0)	0.0	0/106 (0.0)	0.0	NE		0.00 (-7.66, 7.66)	1.0000	
>= 10 points	1/251 (0.4)	0.4	0/260 (0.0)	0.0	3.12 (0.13, 75.85)	0.4848	0.39 (-3.15, 3.94)	0.8273	
OCS dose at baseline									NE
<10 mg/day	0/170 (0.0)	0.0	0/181 (0.0)	0.0	NE		0.00 (-5.16, 5.16)	1.0000	
>=10 mg/day	1/190 (0.5)	0.5	0/185 (0.0)	0.0	2.97 (0.12, 72.09)	0.5033	0.54 (-4.09, 5.16)	0.8195	
Result of type I IFN gene signature test									NE
LOW	0/ 62 (0.0)	0.0	0/ 64 (0.0)	0.0	NE		0.00 (-8.05, 8.05)	1.0000	
HIGH	1/298 (0.3)	0.3	0/302 (0.0)	0.0	3.06 (0.13, 74.53)	0.4923	0.34 (-3.10, 3.78)	0.8480	
Age (years)									NE
<= 65	1/348 (0.3)	0.3	0/362 (0.0)	0.0	3.14 (0.13, 76.51)	0.4828	0.29 (-2.95, 3.53)	0.8622	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE		0.00 (-51.08, 51.08)	1.0000	
Sex									NE
male	0/ 27 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.55, 17.55)	1.0000	
female	1/333 (0.3)	0.3	0/341 (0.0)	0.0	3.11 (0.13, 75.76)	0.4864	0.30 (-3.09, 3.69)	0.8614	
Race									NE
White	0/235 (0.0)	0.0	0/244 (0.0)	0.0	NE		0.00 (-4.18, 4.18)	1.0000	
Black	0/ 46 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-10.79, 10.79)	1.0000	
Other	1/ 71 (1.4)	1.4	0/ 66 (0.0)	0.0	2.78 (0.12, 65.08)	0.5255	1.40 (-6.39, 9.19)	0.7240	
Ethnicity									NE
Hispanic/Latino	0/ 86 (0.0)	0.0	0/ 89 (0.0)	0.0	NE		0.00 (-7.72, 7.72)	1.0000	
Non-hispanic/Latino	1/266 (0.4)	0.4	0/269 (0.0)	0.0	3.02 (0.12, 73.54)	0.4974	0.40 (-3.80, 4.61)	0.8504	
Geographic region									NE
EU	0/115 (0.0)	0.0	0/122 (0.0)	0.0	NE		0.00 (-4.48, 4.48)	1.0000	
non-EU	1/245 (0.4)	0.4	0/244 (0.0)	0.0	2.79 (0.12, 67.88)	0.5277	0.35 (-4.20, 4.90)	0.8800	
Onset of disease									NE
Paediatric	0/ 26 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-18.15, 18.15)	1.0000	
Adult	1/334 (0.3)	0.3	0/342 (0.0)	0.0	3.07 (0.13, 74.86)	0.4911	0.30 (-3.08, 3.69)	0.8604	
ADA result									NE
Negative	1/334 (0.3)	0.3	0/331 (0.0)	0.0	3.13 (0.13, 76.25)	0.4839	0.32 (-3.13, 3.76)	0.8568	
Positive (At any time)	0/ 25 (0.0)	0.0	0/ 35 (0.0)	0.0	NE		0.00 (-17.02, 17.02)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	1/233 (0.4)	0.5	0/261 (0.0)	0.0	3.52 (0.14, 85.60)	0.4392	0.45 (-3.66, 4.56)	0.8298	
>= 30	0/127 (0.0)	0.0	0/105 (0.0)	0.0	NE		0.00 (-7.26, 7.26)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	7 (1.9)	2 (0.5)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.93 (0.31, 12.15)	
p-value	0.4813	
Odds Ratio (95% CI)	1.96 (0.31, 12.47)	
p-value	0.4747	
Risk Difference (95% CI)	1.40 (-0.22, 3.01)	
p-value	0.0907	
CMH approach		
Response rate	2.0	0.5
Difference in response rates (95% CI)	1.42 (-2.03, 4.87)	
p-value	0.4190	
p-Value for test for heterogenity between studies	0.0884	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.4304
< 10 points	1/109 (0.9)	0.9	1/106 (0.9)	0.9	0.97 (0.10, 9.21)	0.9810	0.02 (-7.91, 7.95)	0.9961	
>= 10 points	6/251 (2.4)	2.4	1/260 (0.4)	0.4	3.26 (0.44, 23.96)	0.2456	2.02 (-1.92, 5.95)	0.3155	
OCS dose at baseline									0.7627
<10 mg/day	4/170 (2.4)	2.4	1/181 (0.6)	0.5	2.63 (0.35, 19.73)	0.3456	1.83 (-3.80, 7.46)	0.5244	
>=10 mg/day	3/190 (1.6)	1.6	1/185 (0.5)	0.5	1.67 (0.19, 14.56)	0.6420	1.06 (-3.80, 5.92)	0.6682	
Result of type I IFN gene signature test									0.7676
LOW	1/ 62 (1.6)	1.6	0/ 64 (0.0)	0.0	3.10 (0.13, 73.16)	0.4836	1.61 (-6.89, 10.12)	0.7101	
HIGH	6/298 (2.0)	2.0	2/302 (0.7)	0.7	1.78 (0.28, 11.24)	0.5378	1.38 (-2.39, 5.15)	0.4726	
Age (years)									NE
<= 65	7/348 (2.0)	2.0	2/362 (0.6)	0.5	1.98 (0.32, 12.43)	0.4662	1.49 (-2.04, 5.02)	0.4068	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE		0.00 (-51.08, 51.08)	1.0000	
Sex									NE
male	0/ 27 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.55, 17.55)	1.0000	
female	7/333 (2.1)	2.1	2/341 (0.6)	0.6	1.95 (0.31, 12.24)	0.4757	1.53 (-2.16, 5.22)	0.4166	
Race									0.4026
White	4/235 (1.7)	1.6	2/244 (0.8)	0.8	1.49 (0.23, 9.51)	0.6762	0.84 (-3.68, 5.35)	0.7163	
Black	0/ 46 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-10.79, 10.79)	1.0000	
Other	3/ 71 (4.2)	4.2	0/ 66 (0.0)	0.0	6.54 (0.35, 123.02)	0.2095	4.23 (-4.33, 12.79)	0.3323	
Ethnicity									0.2642
Hispanic/Latino	5/ 86 (5.8)	5.7	0/ 89 (0.0)	0.0	5.67 (0.67, 48.11)	0.1114	5.66 (-3.07, 14.39)	0.2036	
Non-hispanic/Latino	2/266 (0.8)	0.7	2/269 (0.7)	0.7	1.01 (0.12, 8.61)	0.9907	0.04 (-4.28, 4.35)	0.9872	
Geographic region									0.2837
EU	2/115 (1.7)	1.6	2/122 (1.6)	1.6	1.04 (0.12, 8.75)	0.9722	0.06 (-5.26, 5.37)	0.9829	
non-EU	5/245 (2.0)	2.2	0/244 (0.0)	0.0	5.44 (0.63, 46.75)	0.1226	2.16 (-2.64, 6.96)	0.3776	
Onset of disease									NE
Paediatric	0/ 26 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-18.15, 18.15)	1.0000	
Adult	7/334 (2.1)	2.1	2/342 (0.6)	0.6	1.95 (0.31, 12.22)	0.4772	1.52 (-2.17, 5.20)	0.4190	
ADA result									NE
Negative	7/334 (2.1)	2.1	2/331 (0.6)	0.6	1.90 (0.30, 11.93)	0.4926	1.52 (-2.20, 5.25)	0.4233	
Positive (At any time)	0/ 25 (0.0)	0.0	0/ 35 (0.0)	0.0	NE		0.00 (-17.02, 17.02)	1.0000	
BMI (kg/m2) at enrolment									0.9633
< 30	3/233 (1.3)	1.3	1/261 (0.4)	0.4	1.92 (0.22, 16.77)	0.5552	0.87 (-3.41, 5.15)	0.6914	
>= 30	4/127 (3.1)	3.2	1/105 (1.0)	1.0	2.06 (0.28, 15.33)	0.4811	2.11 (-5.76, 9.99)	0.5986	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-3.13, 3.13)	
p-value	1.0000	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/109 (0.0)	0.0	0/106 (0.0)	0.0	NE	0.00 (-7.66, 7.66)	1.0000	
>= 10 points	0/251 (0.0)	0.0	0/260 (0.0)	0.0	NE	0.00 (-3.47, 3.47)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/170 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-5.16, 5.16)	1.0000	
>=10 mg/day	0/190 (0.0)	0.0	0/185 (0.0)	0.0	NE	0.00 (-4.52, 4.52)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 62 (0.0)	0.0	0/ 64 (0.0)	0.0	NE	0.00 (-8.05, 8.05)	1.0000	
HIGH	0/298 (0.0)	0.0	0/302 (0.0)	0.0	NE	0.00 (-3.38, 3.38)	1.0000	
Age (years)								NE
<= 65	0/348 (0.0)	0.0	0/362 (0.0)	0.0	NE	0.00 (-3.20, 3.20)	1.0000	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE	0.00 (-51.08, 51.08)	1.0000	
Sex								NE
male	0/ 27 (0.0)	0.0	0/ 25 (0.0)	0.0	NE	0.00 (-17.55, 17.55)	1.0000	
female	0/333 (0.0)	0.0	0/341 (0.0)	0.0	NE	0.00 (-3.35, 3.35)	1.0000	
Race								NE
White	0/235 (0.0)	0.0	0/244 (0.0)	0.0	NE	0.00 (-4.18, 4.18)	1.0000	
Black	0/ 46 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-10.79, 10.79)	1.0000	
Other	0/ 71 (0.0)	0.0	0/ 66 (0.0)	0.0	NE	0.00 (-7.43, 7.43)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 86 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-7.72, 7.72)	1.0000	
Non-hispanic/Latino	0/266 (0.0)	0.0	0/269 (0.0)	0.0	NE	0.00 (-4.14, 4.14)	1.0000	
Geographic region								NE
EU	0/115 (0.0)	0.0	0/122 (0.0)	0.0	NE	0.00 (-4.48, 4.48)	1.0000	
non-EU	0/245 (0.0)	0.0	0/244 (0.0)	0.0	NE	0.00 (-4.51, 4.51)	1.0000	
Onset of disease								NE
Paediatric	0/ 26 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-18.15, 18.15)	1.0000	
Adult	0/334 (0.0)	0.0	0/342 (0.0)	0.0	NE	0.00 (-3.34, 3.34)	1.0000	
ADA result								NE
Negative	0/334 (0.0)	0.0	0/331 (0.0)	0.0	NE	0.00 (-3.40, 3.40)	1.0000	
Positive (At any time)	0/ 25 (0.0)	0.0	0/ 35 (0.0)	0.0	NE	0.00 (-17.02, 17.02)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/233 (0.0)	0.0	0/261 (0.0)	0.0	NE	0.00 (-4.03, 4.03)	1.0000	
>= 30	0/127 (0.0)	0.0	0/105 (0.0)	0.0	NE	0.00 (-7.26, 7.26)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-3.13, 3.13)	
p-value	1.0000	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/109 (0.0)	0.0	0/106 (0.0)	0.0	NE	0.00 (-7.66, 7.66)	1.0000	
>= 10 points	0/251 (0.0)	0.0	0/260 (0.0)	0.0	NE	0.00 (-3.47, 3.47)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/170 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-5.16, 5.16)	1.0000	
>=10 mg/day	0/190 (0.0)	0.0	0/185 (0.0)	0.0	NE	0.00 (-4.52, 4.52)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 62 (0.0)	0.0	0/ 64 (0.0)	0.0	NE	0.00 (-8.05, 8.05)	1.0000	
HIGH	0/298 (0.0)	0.0	0/302 (0.0)	0.0	NE	0.00 (-3.38, 3.38)	1.0000	
Age (years)								NE
<= 65	0/348 (0.0)	0.0	0/362 (0.0)	0.0	NE	0.00 (-3.20, 3.20)	1.0000	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE	0.00 (-51.08, 51.08)	1.0000	
Sex								NE
male	0/ 27 (0.0)	0.0	0/ 25 (0.0)	0.0	NE	0.00 (-17.55, 17.55)	1.0000	
female	0/333 (0.0)	0.0	0/341 (0.0)	0.0	NE	0.00 (-3.35, 3.35)	1.0000	
Race								NE
White	0/235 (0.0)	0.0	0/244 (0.0)	0.0	NE	0.00 (-4.18, 4.18)	1.0000	
Black	0/ 46 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-10.79, 10.79)	1.0000	
Other	0/ 71 (0.0)	0.0	0/ 66 (0.0)	0.0	NE	0.00 (-7.43, 7.43)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 86 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-7.72, 7.72)	1.0000	
Non-hispanic/Latino	0/266 (0.0)	0.0	0/269 (0.0)	0.0	NE	0.00 (-4.14, 4.14)	1.0000	
Geographic region								NE
EU	0/115 (0.0)	0.0	0/122 (0.0)	0.0	NE	0.00 (-4.48, 4.48)	1.0000	
non-EU	0/245 (0.0)	0.0	0/244 (0.0)	0.0	NE	0.00 (-4.51, 4.51)	1.0000	
Onset of disease								NE
Paediatric	0/ 26 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-18.15, 18.15)	1.0000	
Adult	0/334 (0.0)	0.0	0/342 (0.0)	0.0	NE	0.00 (-3.34, 3.34)	1.0000	
ADA result								NE
Negative	0/334 (0.0)	0.0	0/331 (0.0)	0.0	NE	0.00 (-3.40, 3.40)	1.0000	
Positive (At any time)	0/ 25 (0.0)	0.0	0/ 35 (0.0)	0.0	NE	0.00 (-17.02, 17.02)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/233 (0.0)	0.0	0/261 (0.0)	0.0	NE	0.00 (-4.03, 4.03)	1.0000	
>= 30	0/127 (0.0)	0.0	0/105 (0.0)	0.0	NE	0.00 (-7.26, 7.26)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	7 (1.9)	2 (0.5)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.93 (0.31, 12.15)	
p-value	0.4813	
Odds Ratio (95% CI)	1.96 (0.31, 12.47)	
p-value	0.4747	
Risk Difference (95% CI)	1.40 (-0.22, 3.01)	
p-value	0.0907	
CMH approach		
Response rate	2.0	0.5
Difference in response rates (95% CI)	1.42 (-2.03, 4.87)	
p-value	0.4190	
p-Value for test for heterogenity between studies	0.0884	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.4304
< 10 points	1/109 (0.9)	0.9	1/106 (0.9)	0.9	0.97 (0.10, 9.21)	0.9810	0.02 (-7.91, 7.95)	0.9961	
>= 10 points	6/251 (2.4)	2.4	1/260 (0.4)	0.4	3.26 (0.44, 23.96)	0.2456	2.02 (-1.92, 5.95)	0.3155	
OCS dose at baseline									0.7627
<10 mg/day	4/170 (2.4)	2.4	1/181 (0.6)	0.5	2.63 (0.35, 19.73)	0.3456	1.83 (-3.80, 7.46)	0.5244	
>=10 mg/day	3/190 (1.6)	1.6	1/185 (0.5)	0.5	1.67 (0.19, 14.56)	0.6420	1.06 (-3.80, 5.92)	0.6682	
Result of type I IFN gene signature test									0.7676
LOW	1/ 62 (1.6)	1.6	0/ 64 (0.0)	0.0	3.10 (0.13, 73.16)	0.4836	1.61 (-6.89, 10.12)	0.7101	
HIGH	6/298 (2.0)	2.0	2/302 (0.7)	0.7	1.78 (0.28, 11.24)	0.5378	1.38 (-2.39, 5.15)	0.4726	
Age (years)									NE
<= 65	7/348 (2.0)	2.0	2/362 (0.6)	0.5	1.98 (0.32, 12.43)	0.4662	1.49 (-2.04, 5.02)	0.4068	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE		0.00 (-51.08, 51.08)	1.0000	
Sex									NE
male	0/ 27 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.55, 17.55)	1.0000	
female	7/333 (2.1)	2.1	2/341 (0.6)	0.6	1.95 (0.31, 12.24)	0.4757	1.53 (-2.16, 5.22)	0.4166	
Race									0.4026
White	4/235 (1.7)	1.6	2/244 (0.8)	0.8	1.49 (0.23, 9.51)	0.6762	0.84 (-3.68, 5.35)	0.7163	
Black	0/ 46 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-10.79, 10.79)	1.0000	
Other	3/ 71 (4.2)	4.2	0/ 66 (0.0)	0.0	6.54 (0.35, 123.02)	0.2095	4.23 (-4.33, 12.79)	0.3323	
Ethnicity									0.2642
Hispanic/Latino	5/ 86 (5.8)	5.7	0/ 89 (0.0)	0.0	5.67 (0.67, 48.11)	0.1114	5.66 (-3.07, 14.39)	0.2036	
Non-hispanic/Latino	2/266 (0.8)	0.7	2/269 (0.7)	0.7	1.01 (0.12, 8.61)	0.9907	0.04 (-4.28, 4.35)	0.9872	
Geographic region									0.2837
EU	2/115 (1.7)	1.6	2/122 (1.6)	1.6	1.04 (0.12, 8.75)	0.9722	0.06 (-5.26, 5.37)	0.9829	
non-EU	5/245 (2.0)	2.2	0/244 (0.0)	0.0	5.44 (0.63, 46.75)	0.1226	2.16 (-2.64, 6.96)	0.3776	
Onset of disease									NE
Paediatric	0/ 26 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-18.15, 18.15)	1.0000	
Adult	7/334 (2.1)	2.1	2/342 (0.6)	0.6	1.95 (0.31, 12.22)	0.4772	1.52 (-2.17, 5.20)	0.4190	
ADA result									NE
Negative	7/334 (2.1)	2.1	2/331 (0.6)	0.6	1.90 (0.30, 11.93)	0.4926	1.52 (-2.20, 5.25)	0.4233	
Positive (At any time)	0/ 25 (0.0)	0.0	0/ 35 (0.0)	0.0	NE		0.00 (-17.02, 17.02)	1.0000	
BMI (kg/m2) at enrolment									0.9633
< 30	3/233 (1.3)	1.3	1/261 (0.4)	0.4	1.92 (0.22, 16.77)	0.5552	0.87 (-3.41, 5.15)	0.6914	
>= 30	4/127 (3.1)	3.2	1/105 (1.0)	1.0	2.06 (0.28, 15.33)	0.4811	2.11 (-5.76, 9.99)	0.5986	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Vasculitis
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-3.13, 3.13)	
p-value	1.0000	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/109 (0.0)	0.0	0/106 (0.0)	0.0	NE	0.00 (-7.66, 7.66)	1.0000	
>= 10 points	0/251 (0.0)	0.0	0/260 (0.0)	0.0	NE	0.00 (-3.47, 3.47)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/170 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-5.16, 5.16)	1.0000	
>=10 mg/day	0/190 (0.0)	0.0	0/185 (0.0)	0.0	NE	0.00 (-4.52, 4.52)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 62 (0.0)	0.0	0/ 64 (0.0)	0.0	NE	0.00 (-8.05, 8.05)	1.0000	
HIGH	0/298 (0.0)	0.0	0/302 (0.0)	0.0	NE	0.00 (-3.38, 3.38)	1.0000	
Age (years)								NE
<= 65	0/348 (0.0)	0.0	0/362 (0.0)	0.0	NE	0.00 (-3.20, 3.20)	1.0000	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE	0.00 (-51.08, 51.08)	1.0000	
Sex								NE
male	0/ 27 (0.0)	0.0	0/ 25 (0.0)	0.0	NE	0.00 (-17.55, 17.55)	1.0000	
female	0/333 (0.0)	0.0	0/341 (0.0)	0.0	NE	0.00 (-3.35, 3.35)	1.0000	
Race								NE
White	0/235 (0.0)	0.0	0/244 (0.0)	0.0	NE	0.00 (-4.18, 4.18)	1.0000	
Black	0/ 46 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-10.79, 10.79)	1.0000	
Other	0/ 71 (0.0)	0.0	0/ 66 (0.0)	0.0	NE	0.00 (-7.43, 7.43)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 86 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-7.72, 7.72)	1.0000	
Non-hispanic/Latino	0/266 (0.0)	0.0	0/269 (0.0)	0.0	NE	0.00 (-4.14, 4.14)	1.0000	
Geographic region								NE
EU	0/115 (0.0)	0.0	0/122 (0.0)	0.0	NE	0.00 (-4.48, 4.48)	1.0000	
non-EU	0/245 (0.0)	0.0	0/244 (0.0)	0.0	NE	0.00 (-4.51, 4.51)	1.0000	
Onset of disease								NE
Paediatric	0/ 26 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-18.15, 18.15)	1.0000	
Adult	0/334 (0.0)	0.0	0/342 (0.0)	0.0	NE	0.00 (-3.34, 3.34)	1.0000	
ADA result								NE
Negative	0/334 (0.0)	0.0	0/331 (0.0)	0.0	NE	0.00 (-3.40, 3.40)	1.0000	
Positive (At any time)	0/ 25 (0.0)	0.0	0/ 35 (0.0)	0.0	NE	0.00 (-17.02, 17.02)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/233 (0.0)	0.0	0/261 (0.0)	0.0	NE	0.00 (-4.03, 4.03)	1.0000	
>= 30	0/127 (0.0)	0.0	0/105 (0.0)	0.0	NE	0.00 (-7.26, 7.26)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Vasculitis
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-3.13, 3.13)	
p-value	1.0000	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/109 (0.0)	0.0	0/106 (0.0)	0.0	NE	0.00 (-7.66, 7.66)	1.0000	
>= 10 points	0/251 (0.0)	0.0	0/260 (0.0)	0.0	NE	0.00 (-3.47, 3.47)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/170 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-5.16, 5.16)	1.0000	
>=10 mg/day	0/190 (0.0)	0.0	0/185 (0.0)	0.0	NE	0.00 (-4.52, 4.52)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 62 (0.0)	0.0	0/ 64 (0.0)	0.0	NE	0.00 (-8.05, 8.05)	1.0000	
HIGH	0/298 (0.0)	0.0	0/302 (0.0)	0.0	NE	0.00 (-3.38, 3.38)	1.0000	
Age (years)								NE
<= 65	0/348 (0.0)	0.0	0/362 (0.0)	0.0	NE	0.00 (-3.20, 3.20)	1.0000	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE	0.00 (-51.08, 51.08)	1.0000	
Sex								NE
male	0/ 27 (0.0)	0.0	0/ 25 (0.0)	0.0	NE	0.00 (-17.55, 17.55)	1.0000	
female	0/333 (0.0)	0.0	0/341 (0.0)	0.0	NE	0.00 (-3.35, 3.35)	1.0000	
Race								NE
White	0/235 (0.0)	0.0	0/244 (0.0)	0.0	NE	0.00 (-4.18, 4.18)	1.0000	
Black	0/ 46 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-10.79, 10.79)	1.0000	
Other	0/ 71 (0.0)	0.0	0/ 66 (0.0)	0.0	NE	0.00 (-7.43, 7.43)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 86 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-7.72, 7.72)	1.0000	
Non-hispanic/Latino	0/266 (0.0)	0.0	0/269 (0.0)	0.0	NE	0.00 (-4.14, 4.14)	1.0000	
Geographic region								NE
EU	0/115 (0.0)	0.0	0/122 (0.0)	0.0	NE	0.00 (-4.48, 4.48)	1.0000	
non-EU	0/245 (0.0)	0.0	0/244 (0.0)	0.0	NE	0.00 (-4.51, 4.51)	1.0000	
Onset of disease								NE
Paediatric	0/ 26 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-18.15, 18.15)	1.0000	
Adult	0/334 (0.0)	0.0	0/342 (0.0)	0.0	NE	0.00 (-3.34, 3.34)	1.0000	
ADA result								NE
Negative	0/334 (0.0)	0.0	0/331 (0.0)	0.0	NE	0.00 (-3.40, 3.40)	1.0000	
Positive (At any time)	0/ 25 (0.0)	0.0	0/ 35 (0.0)	0.0	NE	0.00 (-17.02, 17.02)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/233 (0.0)	0.0	0/261 (0.0)	0.0	NE	0.00 (-4.03, 4.03)	1.0000	
>= 30	0/127 (0.0)	0.0	0/105 (0.0)	0.0	NE	0.00 (-7.26, 7.26)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Vasculitis
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-3.13, 3.13)	
p-value	1.0000	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/109 (0.0)	0.0	0/106 (0.0)	0.0	NE	0.00 (-7.66, 7.66)	1.0000	
>= 10 points	0/251 (0.0)	0.0	0/260 (0.0)	0.0	NE	0.00 (-3.47, 3.47)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/170 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-5.16, 5.16)	1.0000	
>=10 mg/day	0/190 (0.0)	0.0	0/185 (0.0)	0.0	NE	0.00 (-4.52, 4.52)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 62 (0.0)	0.0	0/ 64 (0.0)	0.0	NE	0.00 (-8.05, 8.05)	1.0000	
HIGH	0/298 (0.0)	0.0	0/302 (0.0)	0.0	NE	0.00 (-3.38, 3.38)	1.0000	
Age (years)								NE
<= 65	0/348 (0.0)	0.0	0/362 (0.0)	0.0	NE	0.00 (-3.20, 3.20)	1.0000	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE	0.00 (-51.08, 51.08)	1.0000	
Sex								NE
male	0/ 27 (0.0)	0.0	0/ 25 (0.0)	0.0	NE	0.00 (-17.55, 17.55)	1.0000	
female	0/333 (0.0)	0.0	0/341 (0.0)	0.0	NE	0.00 (-3.35, 3.35)	1.0000	
Race								NE
White	0/235 (0.0)	0.0	0/244 (0.0)	0.0	NE	0.00 (-4.18, 4.18)	1.0000	
Black	0/ 46 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-10.79, 10.79)	1.0000	
Other	0/ 71 (0.0)	0.0	0/ 66 (0.0)	0.0	NE	0.00 (-7.43, 7.43)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 86 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-7.72, 7.72)	1.0000	
Non-hispanic/Latino	0/266 (0.0)	0.0	0/269 (0.0)	0.0	NE	0.00 (-4.14, 4.14)	1.0000	
Geographic region								NE
EU	0/115 (0.0)	0.0	0/122 (0.0)	0.0	NE	0.00 (-4.48, 4.48)	1.0000	
non-EU	0/245 (0.0)	0.0	0/244 (0.0)	0.0	NE	0.00 (-4.51, 4.51)	1.0000	
Onset of disease								NE
Paediatric	0/ 26 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-18.15, 18.15)	1.0000	
Adult	0/334 (0.0)	0.0	0/342 (0.0)	0.0	NE	0.00 (-3.34, 3.34)	1.0000	
ADA result								NE
Negative	0/334 (0.0)	0.0	0/331 (0.0)	0.0	NE	0.00 (-3.40, 3.40)	1.0000	
Positive (At any time)	0/ 25 (0.0)	0.0	0/ 35 (0.0)	0.0	NE	0.00 (-17.02, 17.02)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/233 (0.0)	0.0	0/261 (0.0)	0.0	NE	0.00 (-4.03, 4.03)	1.0000	
>= 30	0/127 (0.0)	0.0	0/105 (0.0)	0.0	NE	0.00 (-7.26, 7.26)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Vasculitis
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
CMH approach		
Response rate	0.0	0.0
Difference in response rates (95% CI)	0.00 (-3.13, 3.13)	
p-value	1.0000	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI) p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening								NE
< 10 points	0/109 (0.0)	0.0	0/106 (0.0)	0.0	NE	0.00 (-7.66, 7.66)	1.0000	
>= 10 points	0/251 (0.0)	0.0	0/260 (0.0)	0.0	NE	0.00 (-3.47, 3.47)	1.0000	
OCS dose at baseline								NE
<10 mg/day	0/170 (0.0)	0.0	0/181 (0.0)	0.0	NE	0.00 (-5.16, 5.16)	1.0000	
>=10 mg/day	0/190 (0.0)	0.0	0/185 (0.0)	0.0	NE	0.00 (-4.52, 4.52)	1.0000	
Result of type I IFN gene signature test								NE
LOW	0/ 62 (0.0)	0.0	0/ 64 (0.0)	0.0	NE	0.00 (-8.05, 8.05)	1.0000	
HIGH	0/298 (0.0)	0.0	0/302 (0.0)	0.0	NE	0.00 (-3.38, 3.38)	1.0000	
Age (years)								NE
<= 65	0/348 (0.0)	0.0	0/362 (0.0)	0.0	NE	0.00 (-3.20, 3.20)	1.0000	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE	0.00 (-51.08, 51.08)	1.0000	
Sex								NE
male	0/ 27 (0.0)	0.0	0/ 25 (0.0)	0.0	NE	0.00 (-17.55, 17.55)	1.0000	
female	0/333 (0.0)	0.0	0/341 (0.0)	0.0	NE	0.00 (-3.35, 3.35)	1.0000	
Race								NE
White	0/235 (0.0)	0.0	0/244 (0.0)	0.0	NE	0.00 (-4.18, 4.18)	1.0000	
Black	0/ 46 (0.0)	0.0	0/ 48 (0.0)	0.0	NE	0.00 (-10.79, 10.79)	1.0000	
Other	0/ 71 (0.0)	0.0	0/ 66 (0.0)	0.0	NE	0.00 (-7.43, 7.43)	1.0000	
Ethnicity								NE
Hispanic/Latino	0/ 86 (0.0)	0.0	0/ 89 (0.0)	0.0	NE	0.00 (-7.72, 7.72)	1.0000	
Non-hispanic/Latino	0/266 (0.0)	0.0	0/269 (0.0)	0.0	NE	0.00 (-4.14, 4.14)	1.0000	
Geographic region								NE
EU	0/115 (0.0)	0.0	0/122 (0.0)	0.0	NE	0.00 (-4.48, 4.48)	1.0000	
non-EU	0/245 (0.0)	0.0	0/244 (0.0)	0.0	NE	0.00 (-4.51, 4.51)	1.0000	
Onset of disease								NE
Paediatric	0/ 26 (0.0)	0.0	0/ 24 (0.0)	0.0	NE	0.00 (-18.15, 18.15)	1.0000	
Adult	0/334 (0.0)	0.0	0/342 (0.0)	0.0	NE	0.00 (-3.34, 3.34)	1.0000	
ADA result								NE
Negative	0/334 (0.0)	0.0	0/331 (0.0)	0.0	NE	0.00 (-3.40, 3.40)	1.0000	
Positive (At any time)	0/ 25 (0.0)	0.0	0/ 35 (0.0)	0.0	NE	0.00 (-17.02, 17.02)	1.0000	
BMI (kg/m2) at enrolment								NE
< 30	0/233 (0.0)	0.0	0/261 (0.0)	0.0	NE	0.00 (-4.03, 4.03)	1.0000	
>= 30	0/127 (0.0)	0.0	0/105 (0.0)	0.0	NE	0.00 (-7.26, 7.26)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Malignancy
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	5 (1.4)	2 (0.5)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	2.39 (0.43, 13.26)	
p-value	0.3183	
Odds Ratio (95% CI)	2.41 (0.43, 13.54)	
p-value	0.3174	
Risk Difference (95% CI)	0.84 (-0.58, 2.27)	
p-value	0.2457	
CMH approach		
Response rate	1.4	0.6
Difference in response rates (95% CI)	0.82 (-2.56, 4.19)	
p-value	0.6357	
p-Value for test for heterogenity between studies	0.4368	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.5179
< 10 points	2/109 (1.8)	1.8	0/106 (0.0)	0.0	4.91 (0.24, 99.97)	0.3006	1.82 (-6.12, 9.77)	0.6529	
>= 10 points	3/251 (1.2)	1.2	2/260 (0.8)	0.8	1.54 (0.25, 9.38)	0.6389	0.39 (-3.42, 4.20)	0.8421	
OCS dose at baseline									0.2586
<10 mg/day	3/170 (1.8)	1.8	0/181 (0.0)	0.0	7.45 (0.39, 141.89)	0.1817	1.75 (-3.67, 7.18)	0.5265	
>=10 mg/day	2/190 (1.1)	1.0	2/185 (1.1)	1.1	0.97 (0.14, 6.83)	0.9772	-0.08 (-4.97, 4.80)	0.9735	
Result of type I IFN gene signature test									0.8056
LOW	1/ 62 (1.6)	1.6	0/ 64 (0.0)	0.0	3.09 (0.13, 73.19)	0.4846	1.61 (-6.90, 10.13)	0.7106	
HIGH	4/298 (1.3)	1.3	2/302 (0.7)	0.7	1.96 (0.34, 11.25)	0.4486	0.65 (-3.03, 4.32)	0.7293	
Age (years)									NE
<= 65	5/348 (1.4)	1.4	2/362 (0.6)	0.6	2.45 (0.44, 13.56)	0.3056	0.86 (-2.60, 4.31)	0.6274	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE		0.00 (-51.08, 51.08)	1.0000	
Sex									0.7957
male	1/ 27 (3.7)	3.9	0/ 25 (0.0)	0.0	3.00 (0.13, 67.06)	0.4883	3.86 (-14.52, 22.23)	0.6808	
female	4/333 (1.2)	1.2	2/341 (0.6)	0.6	1.87 (0.31, 11.30)	0.4970	0.60 (-2.98, 4.17)	0.7439	
Race									0.6587
White	4/235 (1.7)	1.8	2/244 (0.8)	0.8	1.92 (0.32, 11.57)	0.4788	0.98 (-3.55, 5.51)	0.6708	
Black	1/ 46 (2.2)	2.6	0/ 48 (0.0)	0.0	4.33 (0.19, 100.49)	0.3606	2.59 (-8.91, 14.10)	0.6585	
Other	0/ 71 (0.0)	0.0	0/ 66 (0.0)	0.0	NE		0.00 (-7.43, 7.43)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 86 (0.0)	0.0	0/ 89 (0.0)	0.0	NE		0.00 (-7.72, 7.72)	1.0000	
Non-hispanic/Latino	5/266 (1.9)	1.8	2/269 (0.7)	0.7	2.37 (0.43, 13.13)	0.3219	1.09 (-3.37, 5.54)	0.6326	
Geographic region									0.4061
EU	2/115 (1.7)	1.8	2/122 (1.6)	1.7	1.13 (0.17, 7.59)	0.8987	0.17 (-5.33, 5.68)	0.9504	
non-EU	3/245 (1.2)	1.2	0/244 (0.0)	0.0	3.88 (0.43, 34.84)	0.2264	1.23 (-3.42, 5.89)	0.6035	
Onset of disease									NE
Paediatric	0/ 26 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-18.15, 18.15)	1.0000	
Adult	5/334 (1.5)	1.5	2/342 (0.6)	0.6	2.41 (0.43, 13.33)	0.3149	0.88 (-2.72, 4.48)	0.6331	
ADA result									NE
Negative	5/334 (1.5)	1.5	2/331 (0.6)	0.6	2.36 (0.43, 13.06)	0.3263	0.88 (-2.78, 4.54)	0.6385	
Positive (At any time)	0/ 25 (0.0)	0.0	0/ 35 (0.0)	0.0	NE		0.00 (-17.02, 17.02)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	5/233 (2.1)	2.1	2/261 (0.8)	0.8	2.67 (0.48, 14.74)	0.2603	1.36 (-3.08, 5.80)	0.5494	
>= 30	0/127 (0.0)	0.0	0/105 (0.0)	0.0	NE		0.00 (-7.26, 7.26)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Malignancy
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	3 (0.8)	1 (0.3)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	2.11 (0.27, 16.27)	
p-value	0.4733	
Odds Ratio (95% CI)	2.12 (0.27, 16.53)	
p-value	0.4721	
Risk Difference (95% CI)	0.56 (-0.52, 1.64)	
p-value	0.3104	
CMH approach		
Response rate	0.8	0.3
Difference in response rates (95% CI)	0.52 (-2.75, 3.79)	
p-value	0.7551	
p-Value for test for heterogenity between studies	0.4387	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.4543
< 10 points	2/109 (1.8)	1.8	0/106 (0.0)	0.0	4.91 (0.24, 99.97)	0.3006	1.82 (-6.12, 9.77)	0.6529	
>= 10 points	1/251 (0.4)	0.4	1/260 (0.4)	0.4	1.03 (0.07, 16.32)	0.9823	-0.03 (-3.64, 3.59)	0.9879	
OCS dose at baseline									0.7100
<10 mg/day	1/170 (0.6)	0.6	0/181 (0.0)	0.0	3.19 (0.13, 77.20)	0.4751	0.60 (-4.65, 5.85)	0.8236	
>=10 mg/day	2/190 (1.1)	1.0	1/185 (0.5)	0.6	1.55 (0.19, 12.47)	0.6802	0.45 (-4.34, 5.24)	0.8546	
Result of type I IFN gene signature test									NE
LOW	0/ 62 (0.0)	0.0	0/ 64 (0.0)	0.0	NE		0.00 (-8.05, 8.05)	1.0000	
HIGH	3/298 (1.0)	1.0	1/302 (0.3)	0.3	2.10 (0.27, 16.19)	0.4750	0.63 (-2.94, 4.20)	0.7299	
Age (years)									NE
<= 65	3/348 (0.9)	0.8	1/362 (0.3)	0.3	2.16 (0.28, 16.64)	0.4598	0.54 (-2.80, 3.88)	0.7527	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE		0.00 (-51.08, 51.08)	1.0000	
Sex									0.7003
male	1/ 27 (3.7)	3.9	0/ 25 (0.0)	0.0	3.00 (0.13, 67.06)	0.4883	3.86 (-14.52, 22.23)	0.6808	
female	2/333 (0.6)	0.6	1/341 (0.3)	0.3	1.42 (0.16, 12.79)	0.7541	0.27 (-3.18, 3.72)	0.8787	
Race									0.5722
White	2/235 (0.9)	0.9	1/244 (0.4)	0.4	1.44 (0.16, 12.89)	0.7471	0.53 (-3.82, 4.89)	0.8098	
Black	1/ 46 (2.2)	2.6	0/ 48 (0.0)	0.0	4.33 (0.19, 100.49)	0.3606	2.59 (-8.91, 14.10)	0.6585	
Other	0/ 71 (0.0)	0.0	0/ 66 (0.0)	0.0	NE		0.00 (-7.43, 7.43)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 86 (0.0)	0.0	0/ 89 (0.0)	0.0	NE		0.00 (-7.72, 7.72)	1.0000	
Non-hispanic/Latino	3/266 (1.1)	1.1	1/269 (0.4)	0.4	2.10 (0.27, 16.16)	0.4755	0.69 (-3.62, 5.01)	0.7530	
Geographic region									0.5150
EU	1/115 (0.9)	0.9	1/122 (0.8)	0.9	1.03 (0.11, 9.77)	0.9782	0.03 (-5.02, 5.07)	0.9910	
non-EU	2/245 (0.8)	0.8	0/244 (0.0)	0.0	2.97 (0.31, 28.38)	0.3440	0.82 (-3.79, 5.43)	0.7264	
Onset of disease									NE
Paediatric	0/ 26 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-18.15, 18.15)	1.0000	
Adult	3/334 (0.9)	0.9	1/342 (0.3)	0.3	2.13 (0.28, 16.38)	0.4687	0.56 (-2.93, 4.04)	0.7535	
ADA result									NE
Negative	3/334 (0.9)	0.9	1/331 (0.3)	0.3	2.05 (0.27, 15.78)	0.4909	0.55 (-3.00, 4.09)	0.7621	
Positive (At any time)	0/ 25 (0.0)	0.0	0/ 35 (0.0)	0.0	NE		0.00 (-17.02, 17.02)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	3/233 (1.3)	1.2	1/261 (0.4)	0.4	2.32 (0.30, 17.85)	0.4183	0.82 (-3.44, 5.07)	0.7067	
>= 30	0/127 (0.0)	0.0	0/105 (0.0)	0.0	NE		0.00 (-7.26, 7.26)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Malignancy
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	1 (0.3)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.07 (0.13, 74.78)	
p-value	0.4917	
Odds Ratio (95% CI)	3.08 (0.12, 76.19)	
p-value	0.4913	
Risk Difference (95% CI)	0.28 (-0.27, 0.82)	
p-value	0.3160	
CMH approach		
Response rate	0.3	0.0
Difference in response rates (95% CI)	0.29 (-2.87, 3.45)	
p-value	0.8580	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									NE
< 10 points	1/109 (0.9)	1.0	0/106 (0.0)	0.0	2.95 (0.12, 70.77)	0.5053	0.98 (-6.85, 8.80)	0.8069	
>= 10 points	0/251 (0.0)	0.0	0/260 (0.0)	0.0	NE		0.00 (-3.47, 3.47)	1.0000	
OCS dose at baseline									NE
<10 mg/day	1/170 (0.6)	0.6	0/181 (0.0)	0.0	3.19 (0.13, 77.20)	0.4751	0.60 (-4.65, 5.85)	0.8236	
>=10 mg/day	0/190 (0.0)	0.0	0/185 (0.0)	0.0	NE		0.00 (-4.52, 4.52)	1.0000	
Result of type I IFN gene signature test									NE
LOW	0/ 62 (0.0)	0.0	0/ 64 (0.0)	0.0	NE		0.00 (-8.05, 8.05)	1.0000	
HIGH	1/298 (0.3)	0.3	0/302 (0.0)	0.0	3.06 (0.13, 74.53)	0.4923	0.35 (-3.08, 3.78)	0.8419	
Age (years)									NE
<= 65	1/348 (0.3)	0.3	0/362 (0.0)	0.0	3.14 (0.13, 76.51)	0.4828	0.30 (-2.93, 3.54)	0.8546	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE		0.00 (-51.08, 51.08)	1.0000	
Sex									NE
male	0/ 27 (0.0)	0.0	0/ 25 (0.0)	0.0	NE		0.00 (-17.55, 17.55)	1.0000	
female	1/333 (0.3)	0.3	0/341 (0.0)	0.0	3.11 (0.13, 75.76)	0.4864	0.30 (-3.08, 3.68)	0.8599	
Race									NE
White	1/235 (0.4)	0.4	0/244 (0.0)	0.0	3.29 (0.14, 79.92)	0.4651	0.43 (-3.80, 4.66)	0.8404	
Black	0/ 46 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-10.79, 10.79)	1.0000	
Other	0/ 71 (0.0)	0.0	0/ 66 (0.0)	0.0	NE		0.00 (-7.43, 7.43)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 86 (0.0)	0.0	0/ 89 (0.0)	0.0	NE		0.00 (-7.72, 7.72)	1.0000	
Non-hispanic/Latino	1/266 (0.4)	0.4	0/269 (0.0)	0.0	3.02 (0.12, 73.54)	0.4974	0.41 (-3.79, 4.60)	0.8496	
Geographic region									NE
EU	0/115 (0.0)	0.0	0/122 (0.0)	0.0	NE		0.00 (-4.48, 4.48)	1.0000	
non-EU	1/245 (0.4)	0.4	0/244 (0.0)	0.0	2.79 (0.12, 67.88)	0.5277	0.42 (-4.13, 4.98)	0.8556	
Onset of disease									NE
Paediatric	0/ 26 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-18.15, 18.15)	1.0000	
Adult	1/334 (0.3)	0.3	0/342 (0.0)	0.0	3.07 (0.13, 74.86)	0.4911	0.29 (-3.08, 3.66)	0.8666	
ADA result									NE
Negative	1/334 (0.3)	0.3	0/331 (0.0)	0.0	3.13 (0.13, 76.25)	0.4839	0.33 (-3.11, 3.76)	0.8528	
Positive (At any time)	0/ 25 (0.0)	0.0	0/ 35 (0.0)	0.0	NE		0.00 (-17.02, 17.02)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	1/233 (0.4)	0.4	0/261 (0.0)	0.0	3.52 (0.14, 85.60)	0.4392	0.40 (-3.68, 4.48)	0.8480	
>= 30	0/127 (0.0)	0.0	0/105 (0.0)	0.0	NE		0.00 (-7.26, 7.26)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Malignancy
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	4 (1.1)	2 (0.5)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.97 (0.34, 11.29)	
p-value	0.4471	
Odds Ratio (95% CI)	1.98 (0.34, 11.50)	
p-value	0.4468	
Risk Difference (95% CI)	0.57 (-0.75, 1.89)	
p-value	0.4008	
CMH approach		
Response rate	1.1	0.6
Difference in response rates (95% CI)	0.53 (-2.82, 3.87)	
p-value	0.7572	
p-Value for test for heterogenity between studies	0.5420	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.7282
< 10 points	1/109 (0.9)	0.8	0/106 (0.0)	0.0	2.95 (0.12, 70.77)	0.5053	0.85 (-6.94, 8.64)	0.8310	
>= 10 points	3/251 (1.2)	1.2	2/260 (0.8)	0.8	1.54 (0.25, 9.38)	0.6389	0.39 (-3.42, 4.20)	0.8421	
OCS dose at baseline									0.3540
<10 mg/day	2/170 (1.2)	1.2	0/181 (0.0)	0.0	5.32 (0.26, 109.09)	0.2781	1.16 (-4.18, 6.50)	0.6713	
>=10 mg/day	2/190 (1.1)	1.0	2/185 (1.1)	1.1	0.97 (0.14, 6.83)	0.9772	-0.08 (-4.97, 4.80)	0.9735	
Result of type I IFN gene signature test									0.6995
LOW	1/ 62 (1.6)	1.6	0/ 64 (0.0)	0.0	3.09 (0.13, 73.19)	0.4846	1.61 (-6.90, 10.13)	0.7106	
HIGH	3/298 (1.0)	1.0	2/302 (0.7)	0.7	1.51 (0.25, 9.19)	0.6560	0.30 (-3.33, 3.93)	0.8716	
Age (years)									NE
<= 65	4/348 (1.1)	1.1	2/362 (0.6)	0.6	2.01 (0.35, 11.56)	0.4318	0.55 (-2.87, 3.97)	0.7513	
> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE		0.00 (-51.08, 51.08)	1.0000	
Sex									0.7030
male	1/ 27 (3.7)	3.9	0/ 25 (0.0)	0.0	3.00 (0.13, 67.06)	0.4883	3.86 (-14.52, 22.23)	0.6808	
female	3/333 (0.9)	0.9	2/341 (0.6)	0.6	1.49 (0.24, 9.37)	0.6732	0.29 (-3.25, 3.83)	0.8719	
Race									0.5736
White	3/235 (1.3)	1.4	2/244 (0.8)	0.8	1.52 (0.24, 9.58)	0.6539	0.55 (-3.93, 5.03)	0.8108	
Black	1/ 46 (2.2)	2.6	0/ 48 (0.0)	0.0	4.33 (0.19, 100.49)	0.3606	2.59 (-8.91, 14.10)	0.6585	
Other	0/ 71 (0.0)	0.0	0/ 66 (0.0)	0.0	NE		0.00 (-7.43, 7.43)	1.0000	
Ethnicity									NE
Hispanic/Latino	0/ 86 (0.0)	0.0	0/ 89 (0.0)	0.0	NE		0.00 (-7.72, 7.72)	1.0000	
Non-hispanic/Latino	4/266 (1.5)	1.4	2/269 (0.7)	0.7	1.95 (0.34, 11.19)	0.4514	0.68 (-3.73, 5.09)	0.7621	
Geographic region									0.5214
EU	2/115 (1.7)	1.8	2/122 (1.6)	1.7	1.13 (0.17, 7.59)	0.8987	0.17 (-5.33, 5.68)	0.9504	
non-EU	2/245 (0.8)	0.8	0/244 (0.0)	0.0	2.97 (0.31, 28.38)	0.3440	0.81 (-3.80, 5.42)	0.7303	
Onset of disease									NE
Paediatric	0/ 26 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-18.15, 18.15)	1.0000	
Adult	4/334 (1.2)	1.2	2/342 (0.6)	0.6	1.98 (0.35, 11.36)	0.4430	0.59 (-2.98, 4.16)	0.7469	
ADA result									NE
Negative	4/334 (1.2)	1.2	2/331 (0.6)	0.6	1.94 (0.34, 11.11)	0.4578	0.55 (-3.07, 4.18)	0.7653	
Positive (At any time)	0/ 25 (0.0)	0.0	0/ 35 (0.0)	0.0	NE		0.00 (-17.02, 17.02)	1.0000	
BMI (kg/m2) at enrolment									NE
< 30	4/233 (1.7)	1.7	2/261 (0.8)	0.8	2.19 (0.38, 12.54)	0.3771	0.96 (-3.44, 5.35)	0.6695	
>= 30	0/127 (0.0)	0.0	0/105 (0.0)	0.0	NE		0.00 (-7.26, 7.26)	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of SOCs Cardiac disorders and/or Vascular disorders
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	18 (5.0)	32 (8.7)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.58 (0.33, 1.02)	
p-value	0.0608	
Odds Ratio (95% CI)	0.56 (0.30, 1.03)	
p-value	0.0601	
Risk Difference (95% CI)	-3.73 (-7.40, -0.07)	
p-value	0.0459	
CMH approach		
Response rate	5.0	8.8
Difference in response rates (95% CI)	-3.74 (-8.29, 0.81)	
p-value	0.1074	
p-Value for test for heterogenity between studies	0.1860	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of SOCs Cardiac disorders and/or Vascular disorders - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening									0.7349
< 10 points	5/109 (4.6)	4.6	7/106 (6.6)	6.7	0.70 (0.23, 2.12)	0.5249	-2.02 (-11.21, 7.17)	0.6668	
>= 10 points	13/251 (5.2)	5.2	25/260 (9.6)	9.7	0.56 (0.28, 1.09)	0.0863	-4.50 (-9.90, 0.91)	0.1030	
OCS dose at baseline									0.4114
<10 mg/day	9/170 (5.3)	5.4	13/181 (7.2)	7.2	0.75 (0.32, 1.75)	0.5084	-1.83 (-8.61, 4.96)	0.5981	
>=10 mg/day	9/190 (4.7)	4.8	19/185 (10.3)	10.3	0.47 (0.22, 1.01)	0.0525	-5.52 (-12.11, 1.08)	0.1011	
Result of type I IFN gene signature test									0.8345
LOW	2/ 62 (3.2)	3.2	3/ 64 (4.7)	4.7	0.69 (0.12, 4.11)	0.6871	-1.46 (-11.52, 8.60)	0.7757	
HIGH	16/298 (5.4)	5.4	29/302 (9.6)	9.6	0.57 (0.31, 1.03)	0.0643	-4.22 (-9.31, 0.87)	0.1041	
Age (years)									0.7923
<= 65	17/348 (4.9)	4.9	31/362 (8.6)	8.6	0.58 (0.32, 1.03)	0.0616	-3.71 (-8.31, 0.89)	0.1135	
> 65	1/ 12 (8.3)	5.7	1/ 4 (25.0)	23.9	0.43 (0.06, 3.29)	0.4191	-18.18 (-72.10, 35.74)	0.5087	
Sex									0.1573
male	3/ 27 (11.1)	10.7	1/ 25 (4.0)	4.1	2.60 (0.31, 22.05)	0.3810	6.61 (-13.81, 27.04)	0.5258	
female	15/333 (4.5)	4.5	31/341 (9.1)	9.1	0.52 (0.28, 0.97)	0.0399	-4.57 (-9.32, 0.18)	0.0591	
Race									0.5640
White	15/235 (6.4)	6.5	23/244 (9.4)	9.2	0.69 (0.36, 1.31)	0.2536	-2.76 (-8.71, 3.18)	0.3623	
Black	1/ 46 (2.2)	1.9	4/ 48 (8.3)	8.4	0.35 (0.06, 2.21)	0.2648	-6.46 (-19.63, 6.71)	0.3363	
Other	1/ 71 (1.4)	1.4	5/ 66 (7.6)	7.6	0.28 (0.05, 1.77)	0.1775	-6.17 (-15.80, 3.45)	0.2085	
Ethnicity									0.8881
Hispanic/Latino	5/ 86 (5.8)	5.7	10/ 89 (11.2)	11.5	0.61 (0.20, 1.85)	0.3796	-5.83 (-16.36, 4.71)	0.2782	
Non-hispanic/Latino	12/266 (4.5)	4.6	22/269 (8.2)	8.1	0.55 (0.28, 1.09)	0.0869	-3.49 (-8.97, 2.00)	0.2131	
Geographic region									0.9022
EU	7/115 (6.1)	6.0	12/122 (9.8)	9.4	0.59 (0.20, 1.71)	0.3287	-3.44 (-11.08, 4.20)	0.3772	
non-EU	11/245 (4.5)	4.5	20/244 (8.2)	8.4	0.54 (0.27, 1.10)	0.0917	-3.88 (-9.75, 1.98)	0.1945	
Onset of disease									0.9039
Paediatric	1/ 26 (3.8)	3.7	2/ 24 (8.3)	8.0	0.67 (0.08, 5.67)	0.7127	-4.32 (-24.74, 16.10)	0.6783	
Adult	17/334 (5.1)	5.1	30/342 (8.8)	8.8	0.58 (0.33, 1.04)	0.0695	-3.68 (-8.46, 1.09)	0.1303	
ADA result									0.4837
Negative	16/334 (4.8)	4.9	29/331 (8.8)	8.6	0.56 (0.31, 1.03)	0.0632	-3.71 (-8.49, 1.07)	0.1285	
Positive (At any time)	2/ 25 (8.0)	8.6	3/ 35 (8.6)	8.1	1.08 (0.19, 6.08)	0.9286	0.59 (-19.73, 20.91)	0.9548	
BMI (kg/m2) at enrolment									0.4906
< 30	8/233 (3.4)	3.5	22/261 (8.4)	8.2	0.54 (0.22, 1.32)	0.1756	-4.80 (-10.20, 0.61)	0.0818	
>= 30	10/127 (7.9)	8.0	10/105 (9.5)	9.5	0.83 (0.35, 1.95)	0.6689	-1.58 (-11.12, 7.95)	0.7451	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Time to first Onset of Herpes Zoster (on-treatment)
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	23 (6.4)	5 (1.4)
Number of censored subjects, n (%)	337 (93.6)	361 (98.6)
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Anifrolumab 300mg vs. Placebo (adjusted)		
Hazard Ratio (95% CI)	4.66 (1.77, 12.27)	
p-value	0.0009	
Analysis Anifrolumab 300mg vs. Placebo (unadjusted)		
Hazard Ratio (95% CI)	4.64 (1.76, 12.20)	
p-value	0.0006	
p-Value for test for heterogenity between studies	0.5369	

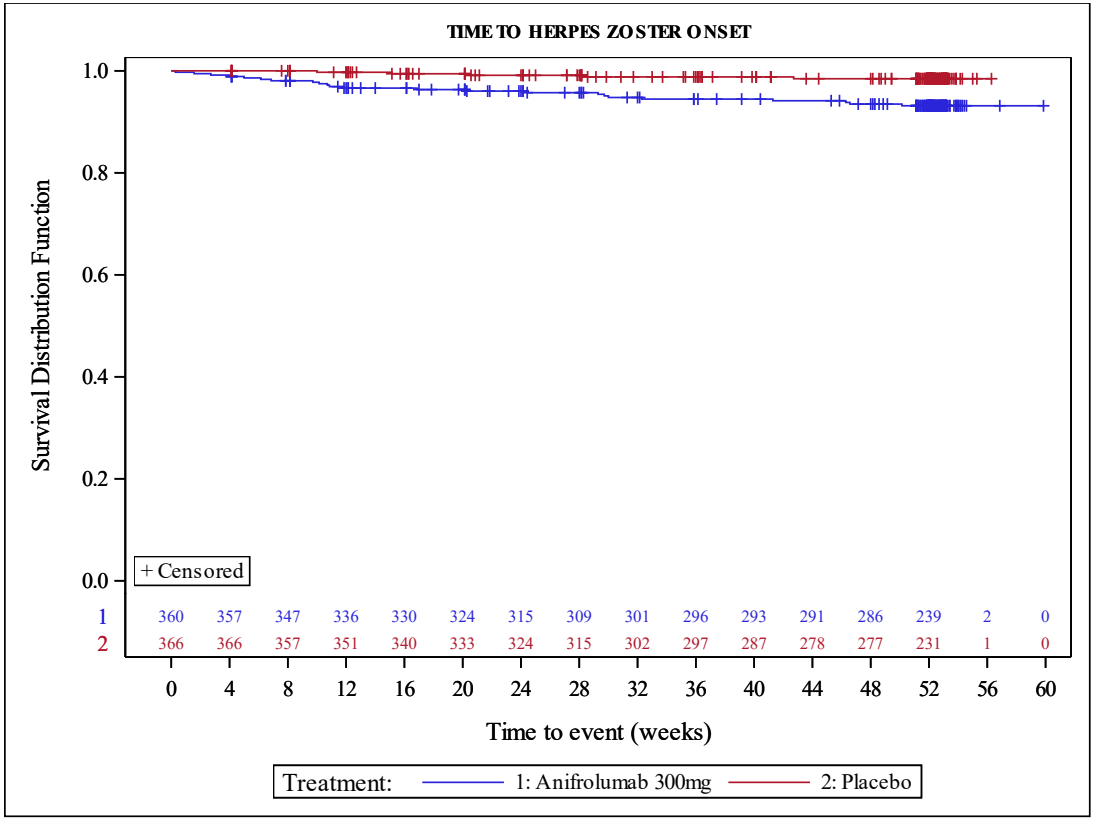
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model. Adjusted analysis also includes stratification factors in the model.
Two-sided log rank test used.
p-Value for heterogenity between studies from Cox proportional hazards model with factors for treatment, study, treatment*study interaction and stratfication factors.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unadjusted analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Time to first Onset of Herpes Zoster (on-treatment) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Anifrolumab 300mg (N=360) Median (95% CI)	Placebo (N=366) n/ N (%)	Placebo (N=366) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening							0.1597
< 10 points	3/109 (2.8)	NE (NE, NE)	2/106 (1.9)	NE (NE, NE)	1.59 (0.26, 9.51)	0.6960	
>= 10 points	20/251 (8.0)	NE (NE, NE)	3/260 (1.2)	NE (NE, NE)	6.79 (2.02, 22.85)	0.0005	
OCS dose at baseline							0.6645
<10 mg/day	11/170 (6.5)	NE (NE, NE)	2/181 (1.1)	NE (NE, NE)	5.72 (1.27, 25.83)	0.0141	
>=10 mg/day	12/190 (6.3)	NE (NE, NE)	3/185 (1.6)	NE (NE, NE)	3.83 (1.08, 13.57)	0.0253	
Result of type I IFN gene signature test							0.8752
LOW	4/ 62 (6.5)	NE (NE, NE)	1/ 64 (1.6)	NE (NE, NE)	3.52 (0.39, 31.83)	0.3172	
HIGH	19/298 (6.4)	NE (NE, NE)	4/302 (1.3)	NE (NE, NE)	4.79 (1.63, 14.10)	0.0015	
Age (years)							0.9994
<= 65	23/348 (6.6)	NE (NE, NE)	5/362 (1.4)	NE (NE, NE)	4.76 (1.81, 12.54)	0.0006	
> 65	0/ 12 (0.0)	NE (NE, NE)	0/ 4 (0.0)	NE (NE, NE)	NE		
Sex							0.9911
male	3/ 27 (11.1)	NE (NE, NE)	0/ 25 (0.0)	NE (NE, NE)	NE		
female	20/333 (6.0)	NE (NE, NE)	5/341 (1.5)	NE (NE, NE)	4.06 (1.52, 10.82)	0.0038	
Race							0.9999
White	13/235 (5.5)	NE (NE, NE)	4/244 (1.6)	NE (NE, NE)	3.37 (1.10, 10.34)	0.0267	
Black	0/ 46 (0.0)	NE (NE, NE)	1/ 48 (2.1)	NE (NE, NE)	NE		
Other	8/ 71 (11.3)	NE (NE, NE)	0/ 66 (0.0)	NE (NE, NE)	NE		
Ethnicity							0.9899
Hispanic/Latino	8/ 86 (9.3)	NE (NE, NE)	0/ 89 (0.0)	NE (NE, NE)	NE		
Non-hispanic/Latino	13/266 (4.9)	NE (NE, NE)	5/269 (1.9)	NE (NE, NE)	2.59 (0.92, 7.26)	0.0828	
Geographic region							0.4159
EU	5/115 (4.3)	NE (NE, NE)	2/122 (1.6)	NE (NE, NE)	2.70 (0.52, 14.04)	0.3398	
non-EU	18/245 (7.3)	NE (NE, NE)	3/244 (1.2)	NE (NE, NE)	6.20 (1.82, 21.10)	0.0008	
Onset of disease							0.9902
Paediatric	5/ 26 (19.2)	NE (NE, NE)	0/ 24 (0.0)	NE (NE, NE)	NE		
Adult	18/334 (5.4)	NE (NE, NE)	5/342 (1.5)	NE (NE, NE)	3.68 (1.37, 9.92)	0.0087	
ADA result							0.9900
Negative	21/334 (6.3)	NE (NE, NE)	5/331 (1.5)	NE (NE, NE)	4.17 (1.57, 11.06)	0.0028	
Positive (At any time)	2/ 25 (8.0)	NE (NE, NE)	0/ 35 (0.0)	NE (NE, NE)	NE		
BMI (kg/m2) at enrolment							0.6220
< 30	15/233 (6.4)	NE (NE, NE)	3/261 (1.1)	NE (NE, NE)	5.63 (1.63, 19.47)	0.0025	
>= 30	8/127 (6.3)	NE (NE, NE)	2/105 (1.9)	NE (NE, NE)	3.60 (0.76, 17.06)	0.1278	

Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Time to first Onset of Herpes Zoster (on-treatment)
Full analysis set



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Time to first Onset of non-opportunistic serious infection (on-treatment)
Full analysis set

	Anifrolumab 300mg (N=360)	Placebo (N=366)
Number of subjects with events, n (%)	14 (3.9)	18 (4.9)
Number of censored subjects, n (%)	346 (96.1)	348 (95.1)
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Anifrolumab 300mg vs. Placebo (adjusted)		
Hazard Ratio (95% CI)	0.75 (0.37, 1.52)	
p-value	0.3981	
Analysis Anifrolumab 300mg vs. Placebo (unadjusted)		
Hazard Ratio (95% CI)	0.76 (0.38, 1.53)	
p-value	0.4451	
p-Value for test for heterogenity between studies	0.2018	

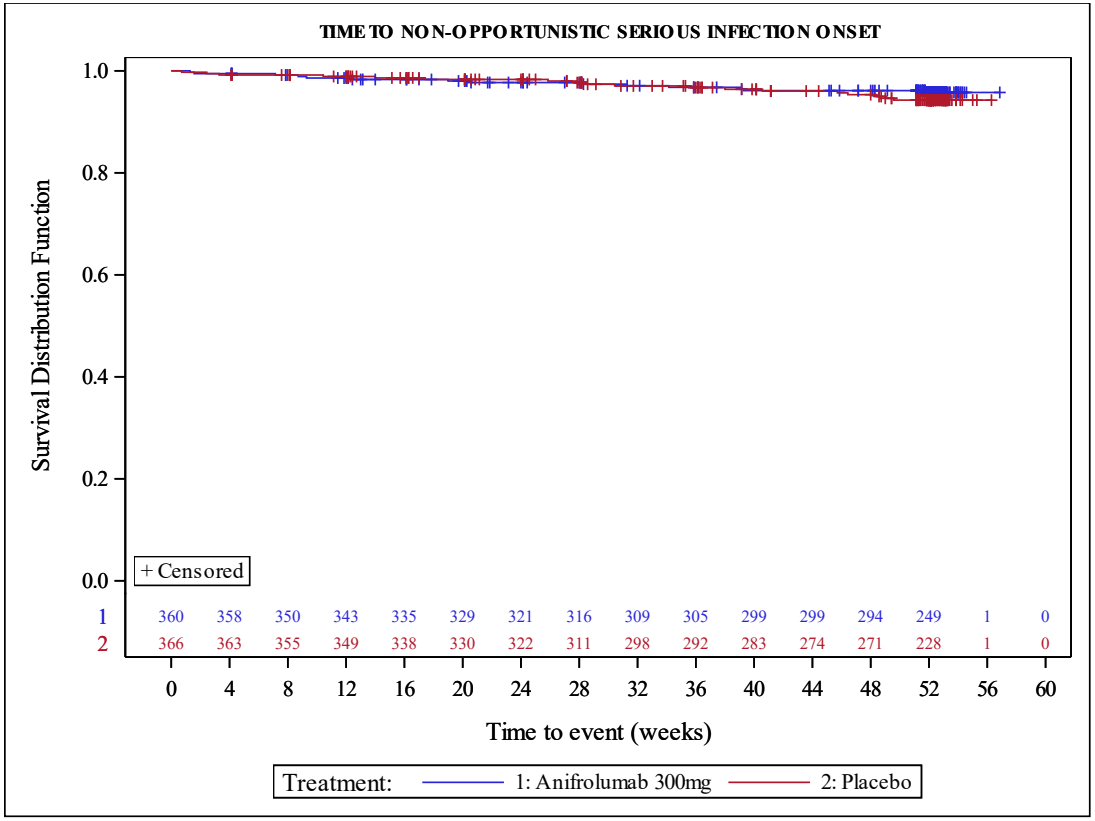
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model. Adjusted analysis also includes stratification factors in the model.
Two-sided log rank test used.
p-Value for heterogenity between studies from Cox proportional hazards model with factors for treatment, study, treatment*study interaction and stratfication factors.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unadjusted analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Time to first Onset of non-opportunistic serious infection (on-treatment) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Anifrolumab 300mg (N=360) Median (95% CI)	Placebo (N=366) n/ N (%)	Placebo (N=366) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score at screening							0.6472
< 10 points	3/109 (2.8)	NE (NE, NE)	5/106 (4.7)	NE (NE, NE)	0.54 (0.13, 2.28)	0.3180	
>= 10 points	11/251 (4.4)	NE (NE, NE)	13/260 (5.0)	NE (NE, NE)	0.84 (0.37, 1.87)	0.6883	
OCS dose at baseline							0.2847
<10 mg/day	4/170 (2.4)	NE (NE, NE)	9/181 (5.0)	NE (NE, NE)	0.45 (0.14, 1.47)	0.1817	
>=10 mg/day	10/190 (5.3)	NE (NE, NE)	9/185 (4.9)	NE (NE, NE)	1.00 (0.41, 2.47)	0.9931	
Result of type I IFN gene signature test							0.4020
LOW	3/ 62 (4.8)	NE (NE, NE)	2/ 64 (3.1)	NE (NE, NE)	1.46 (0.24, 8.79)	0.6633	
HIGH	11/298 (3.7)	NE (NE, NE)	16/302 (5.3)	NE (NE, NE)	0.65 (0.30, 1.40)	0.2692	
Age (years)							0.9887
<= 65	13/348 (3.7)	NE (NE, NE)	18/362 (5.0)	NE (NE, NE)	0.71 (0.35, 1.46)	0.3118	
> 65	1/ 12 (8.3)	NE (39.14, NE)	0/ 4 (0.0)	NE (NE, NE)	NE		
Sex							0.9006
male	1/ 27 (3.7)	NE (NE, NE)	1/ 25 (4.0)	NE (NE, NE)	0.89 (0.05, 15.65)	0.7276	
female	13/333 (3.9)	NE (NE, NE)	17/341 (5.0)	NE (NE, NE)	0.74 (0.36, 1.53)	0.4159	
Race							0.4812
White	10/235 (4.3)	NE (NE, NE)	10/244 (4.1)	NE (NE, NE)	0.97 (0.40, 2.34)	0.8458	
Black	2/ 46 (4.3)	NE (NE, NE)	3/ 48 (6.3)	NE (NE, NE)	0.50 (0.08, 3.21)	0.2467	
Other	2/ 71 (2.8)	NE (NE, NE)	5/ 66 (7.6)	NE (NE, NE)	0.36 (0.07, 1.85)	0.2475	
Ethnicity							0.7509
Hispanic/Latino	4/ 86 (4.7)	NE (NE, NE)	6/ 89 (6.7)	NE (NE, NE)	0.67 (0.19, 2.42)	0.5849	
Non-hispanic/Latino	10/266 (3.8)	NE (NE, NE)	12/269 (4.5)	NE (NE, NE)	0.81 (0.35, 1.88)	0.6392	
Geographic region							0.3164
EU	1/115 (0.9)	NE (NE, NE)	4/122 (3.3)	NE (NE, NE)	0.23 (0.03, 2.11)	0.1877	
non-EU	13/245 (5.3)	NE (NE, NE)	14/244 (5.7)	NE (NE, NE)	0.85 (0.40, 1.82)	0.6744	
Onset of disease							0.5288
Paediatric	4/ 26 (15.4)	NE (NE, NE)	3/ 24 (12.5)	NE (NE, NE)	1.50 (0.30, 7.49)	0.7483	
Adult	10/334 (3.0)	NE (NE, NE)	15/342 (4.4)	NE (NE, NE)	0.65 (0.29, 1.44)	0.2352	
ADA result							0.3707
Negative	13/334 (3.9)	NE (NE, NE)	14/331 (4.2)	NE (NE, NE)	0.89 (0.42, 1.90)	0.6848	
Positive (At any time)	1/ 25 (4.0)	NE (NE, NE)	4/ 35 (11.4)	NE (NE, NE)	0.23 (0.02, 2.29)	0.1897	
BMI (kg/m2) at enrolment							0.2116
< 30	7/233 (3.0)	NE (NE, NE)	14/261 (5.4)	NE (NE, NE)	0.55 (0.22, 1.35)	0.1768	
>= 30	7/127 (5.5)	NE (NE, NE)	4/105 (3.8)	NE (NE, NE)	1.33 (0.39, 4.62)	0.6832	

Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Time to first Onset of non-opportunistic serious infection (on-treatment)
Full analysis set



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Blood and lymphatic system disorders	Number of subjects with events, n (%)	16 (4.4)	25 (6.8)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.65 (0.35, 1.20)	
	p-value	0.1685	
	Odds Ratio (95% CI)	0.63 (0.33, 1.21)	
	p-value	0.1681	
	Risk Difference (95% CI)	-2.38 (-5.73, 0.96)	
	p-value	0.1631	
	CMH approach		
	Response rate	4.4	6.8
	Difference in response rates (95% CI)	-2.41 (-6.74, 1.92)	
	p-value	0.2750	
	p-Value for test for heterogenity between studies	0.8205	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Cardiac disorders	Number of subjects with events, n (%)	6 (1.7)	17 (4.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.36 (0.14, 0.90)	
	p-value	0.0291	
	Odds Ratio (95% CI)	0.35 (0.14, 0.89)	
	p-value	0.0283	
	Risk Difference (95% CI)	-2.98 (-5.51, -0.45)	
	p-value	0.0210	
	CMH approach		
	Response rate	1.7	4.7
	Difference in response rates (95% CI)	-3.04 (-6.92, 0.84)	
	p-value	0.1248	
	p-Value for test for heterogenity between studies	0.9093	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Ear and labyrinth disorders	Number of subjects with events, n (%)	12 (3.3)	16 (4.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.77 (0.37, 1.60)	
	p-value	0.4788	
	Odds Ratio (95% CI)	0.76 (0.35, 1.63)	
	p-value	0.4751	
	Risk Difference (95% CI)	-1.04 (-3.84, 1.75)	
	p-value	0.4646	
	CMH approach		
	Response rate	3.3	4.3
	Difference in response rates (95% CI)	-1.03 (-4.99, 2.94)	
	p-value	0.6116	
	p-Value for test for heterogenity between studies	0.5802	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Eye disorders	Number of subjects with events, n (%)	26 (7.2)	17 (4.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.54 (0.85, 2.79)	
	p-value	0.1550	
	Odds Ratio (95% CI)	1.59 (0.84, 3.00)	
	p-value	0.1506	
	Risk Difference (95% CI)	2.57 (-0.86, 5.99)	
	p-value	0.1418	
	CMH approach		
	Response rate	7.2	4.7
	Difference in response rates (95% CI)	2.52 (-1.82, 6.86)	
	p-value	0.2545	
	p-Value for test for heterogenity between studies	0.5224	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Gastrointestinal disorders	Number of subjects with events, n (%)	82 (22.8)	95 (26.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.88 (0.68, 1.14)	
	p-value	0.3352	
	Odds Ratio (95% CI)	0.84 (0.60, 1.19)	
	p-value	0.3266	
	Risk Difference (95% CI)	-3.18 (-9.43, 3.08)	
	p-value	0.3192	
	CMH approach		
	Response rate	22.9	26.1
	Difference in response rates (95% CI)	-3.17 (-9.48, 3.14)	
	p-value	0.3244	
	p-Value for test for heterogenity between studies	0.0917	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Gastrointestinal disorders, PT: Abdominal pain upper	Number of subjects with events, n (%)	7 (1.9)	11 (3.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.65 (0.25, 1.68)	
	p-value	0.3768	
	Odds Ratio (95% CI)	0.65 (0.24, 1.71)	
	p-value	0.3779	
	Risk Difference (95% CI)	-1.06 (-3.31, 1.20)	
	p-value	0.3584	
	CMH approach		
	Response rate	1.9	3.1
	Difference in response rates (95% CI)	-1.15 (-4.85, 2.56)	
	p-value	0.5445	
	p-Value for test for heterogenity between studies	0.4993	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Gastrointestinal disorders, PT: Diarrhoea	Number of subjects with events, n (%)	14 (3.9)	22 (6.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.66 (0.34, 1.29)	
	p-value	0.2208	
	Odds Ratio (95% CI)	0.64 (0.32, 1.30)	
	p-value	0.2186	
	Risk Difference (95% CI)	-2.12 (-5.27, 1.03)	
	p-value	0.1875	
	CMH approach		
	Response rate	3.9	6.0
	Difference in response rates (95% CI)	-2.08 (-6.27, 2.10)	
	p-value	0.3294	
	p-Value for test for heterogenity between studies	0.2205	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Gastrointestinal disorders, PT: Gastrooesophageal reflux disease	Number of subjects with events, n (%)	8 (2.2)	11 (3.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.76 (0.30, 1.91)	
	p-value	0.5594	
	Odds Ratio (95% CI)	0.75 (0.29, 1.93)	
	p-value	0.5533	
	Risk Difference (95% CI)	-0.78 (-3.10, 1.54)	
	p-value	0.5099	
	CMH approach		
	Response rate	2.3	3.0
	Difference in response rates (95% CI)	-0.75 (-4.52, 3.01)	
	p-value	0.6952	
	p-Value for test for heterogenity between studies	0.3565	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Gastrointestinal disorders, PT: Nausea	Number of subjects with events, n (%)	16 (4.4)	24 (6.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.68 (0.37, 1.25)	
	p-value	0.2162	
	Odds Ratio (95% CI)	0.66 (0.35, 1.27)	
	p-value	0.2158	
	Risk Difference (95% CI)	-2.11 (-5.42, 1.20)	
	p-value	0.2117	
	CMH approach		
	Response rate	4.4	6.6
	Difference in response rates (95% CI)	-2.19 (-6.49, 2.10)	
	p-value	0.3166	
	p-Value for test for heterogenity between studies	0.9070	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Gastrointestinal disorders, PT: Vomiting	Number of subjects with events, n (%)	18 (5.0)	10 (2.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.82 (0.85, 3.89)	
	p-value	0.1252	
	Odds Ratio (95% CI)	1.86 (0.84, 4.11)	
	p-value	0.1236	
	Risk Difference (95% CI)	2.27 (-0.54, 5.07)	
	p-value	0.1131	
	CMH approach		
	Response rate	5.0	2.8
	Difference in response rates (95% CI)	2.22 (-1.76, 6.19)	
	p-value	0.2750	
	p-Value for test for heterogenity between studies	0.5960	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: General disorders and administration site conditions	Number of subjects with events, n (%)	51 (14.2)	38 (10.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.37 (0.92, 2.02)	
	p-value	0.1213	
	Odds Ratio (95% CI)	1.43 (0.91, 2.23)	
	p-value	0.1210	
	Risk Difference (95% CI)	3.79 (-0.98, 8.56)	
	p-value	0.1193	
	CMH approach		
	Response rate	14.2	10.4
	Difference in response rates (95% CI)	3.82 (-1.49, 9.13)	
	p-value	0.1586	
	p-Value for test for heterogenity between studies	0.7998	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Immune system disorders	Number of subjects with events, n (%)	23 (6.4)	10 (2.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	2.32 (1.12, 4.82)	
	p-value	0.0243	
	Odds Ratio (95% CI)	2.41 (1.13, 5.16)	
	p-value	0.0235	
	Risk Difference (95% CI)	3.66 (0.63, 6.69)	
	p-value	0.0179	
	CMH approach		
	Response rate	6.4	2.7
	Difference in response rates (95% CI)	3.77 (-0.32, 7.87)	
	p-value	0.0710	
	p-Value for test for heterogenity between studies	0.5453	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Immune system disorders, PT: Hypersensitivity	Number of subjects with events, n (%)	13 (3.6)	3 (0.8)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	4.22 (1.19, 14.97)	
	p-value	0.0258	
	Odds Ratio (95% CI)	4.37 (1.21, 15.81)	
	p-value	0.0247	
	Risk Difference (95% CI)	2.80 (0.66, 4.93)	
	p-value	0.0102	
	CMH approach		
	Response rate	3.7	0.8
	Difference in response rates (95% CI)	2.85 (-0.77, 6.48)	
	p-value	0.1223	
	p-Value for test for heterogenity between studies	0.4771	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Infections and infestations	Number of subjects with events, n (%)	267 (74.2)	218 (59.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.24 (1.12, 1.38)	
	p-value	<.0001	
	Odds Ratio (95% CI)	1.95 (1.42, 2.67)	
	p-value	<.0001	
	Risk Difference (95% CI)	14.60 (7.84, 21.37)	
	p-value	<.0001	
	CMH approach		
	Response rate	74.3	59.5
	Difference in response rates (95% CI)	14.76 (7.95, 21.57)	
	p-value	<.0001	
	p-Value for test for heterogenity between studies	0.2655	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Infections and infestations, PT: Bronchitis	Number of subjects with events, n (%)	39 (10.8)	18 (4.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	2.17 (1.26, 3.74)	
	p-value	0.0053	
	Odds Ratio (95% CI)	2.31 (1.29, 4.15)	
	p-value	0.0049	
	Risk Difference (95% CI)	5.91 (2.01, 9.81)	
	p-value	0.0030	
	CMH approach		
	Response rate	11.0	5.0
	Difference in response rates (95% CI)	5.96 (1.27, 10.65)	
	p-value	0.0127	
	p-Value for test for heterogenity between studies	0.3008	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Infections and infestations, PT: Gastroenteritis	Number of subjects with events, n (%)	9 (2.5)	10 (2.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.91 (0.36, 2.29)	
	p-value	0.8448	
	Odds Ratio (95% CI)	0.91 (0.35, 2.34)	
	p-value	0.8478	
	Risk Difference (95% CI)	-0.23 (-2.56, 2.09)	
	p-value	0.8432	
	CMH approach		
	Response rate	2.5	2.7
	Difference in response rates (95% CI)	-0.28 (-4.02, 3.45)	
	p-value	0.8814	
	p-Value for test for heterogenity between studies	0.2554	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Infections and infestations, PT: Gastroenteritis viral	Number of subjects with events, n (%)	11 (3.1)	6 (1.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.81 (0.64, 5.15)	
	p-value	0.2646	
	Odds Ratio (95% CI)	1.83 (0.63, 5.33)	
	p-value	0.2647	
	Risk Difference (95% CI)	1.41 (-0.79, 3.61)	
	p-value	0.2091	
	CMH approach		
	Response rate	3.1	1.6
	Difference in response rates (95% CI)	1.54 (-2.15, 5.23)	
	p-value	0.4136	
	p-Value for test for heterogenity between studies	0.1827	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Infections and infestations, PT: Herpes zoster	Number of subjects with events, n (%)	23 (6.4)	6 (1.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	3.88 (1.60, 9.42)	
	p-value	0.0028	
	Odds Ratio (95% CI)	4.07 (1.64, 10.14)	
	p-value	0.0025	
	Risk Difference (95% CI)	4.75 (1.91, 7.59)	
	p-value	0.0011	
	CMH approach		
	Response rate	6.4	1.7
	Difference in response rates (95% CI)	4.74 (0.67, 8.80)	
	p-value	0.0224	
	p-Value for test for heterogenity between studies	0.7815	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Infections and infestations, PT: Nasopharyngitis	Number of subjects with events, n (%)	64 (17.8)	47 (12.8)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.39 (0.98, 1.96)	
	p-value	0.0661	
	Odds Ratio (95% CI)	1.47 (0.97, 2.21)	
	p-value	0.0661	
	Risk Difference (95% CI)	4.94 (-0.29, 10.17)	
	p-value	0.0639	
	CMH approach		
	Response rate	17.8	12.9
	Difference in response rates (95% CI)	4.97 (-0.67, 10.61)	
	p-value	0.0841	
	p-Value for test for heterogenity between studies	0.5370	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Infections and infestations, PT: Oral herpes	Number of subjects with events, n (%)	15 (4.2)	11 (3.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.38 (0.64, 2.98)	
	p-value	0.4069	
	Odds Ratio (95% CI)	1.40 (0.63, 3.10)	
	p-value	0.4062	
	Risk Difference (95% CI)	1.16 (-1.55, 3.87)	
	p-value	0.4004	
	CMH approach		
	Response rate	4.1	3.0
	Difference in response rates (95% CI)	1.11 (-2.84, 5.05)	
	p-value	0.5817	
	p-Value for test for heterogenity between studies	0.6763	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Infections and infestations, PT: Pharyngitis	Number of subjects with events, n (%)	14 (3.9)	16 (4.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.90 (0.45, 1.80)	
	p-value	0.7575	
	Odds Ratio (95% CI)	0.89 (0.42, 1.86)	
	p-value	0.7520	
	Risk Difference (95% CI)	-0.47 (-3.33, 2.40)	
	p-value	0.7491	
	CMH approach		
	Response rate	3.9	4.4
	Difference in response rates (95% CI)	-0.45 (-4.50, 3.59)	
	p-value	0.8267	
	p-Value for test for heterogenity between studies	0.7329	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Infections and infestations, PT: Pneumonia	Number of subjects with events, n (%)	13 (3.6)	12 (3.3)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.07 (0.48, 2.39)	
	p-value	0.8725	
	Odds Ratio (95% CI)	1.08 (0.47, 2.48)	
	p-value	0.8615	
	Risk Difference (95% CI)	0.33 (-2.33, 2.99)	
	p-value	0.8084	
	CMH approach		
	Response rate	3.6	3.3
	Difference in response rates (95% CI)	0.27 (-3.65, 4.19)	
	p-value	0.8917	
	p-Value for test for heterogenity between studies	0.1397	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Infections and infestations, PT: Respiratory tract infection	Number of subjects with events, n (%)	13 (3.6)	3 (0.8)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	2.70 (0.76, 9.58)	
	p-value	0.1252	
	Odds Ratio (95% CI)	2.78 (0.76, 10.10)	
	p-value	0.1206	
	Risk Difference (95% CI)	2.79 (0.65, 4.93)	
	p-value	0.0106	
	CMH approach		
	Response rate	3.6	0.8
	Difference in response rates (95% CI)	2.84 (-0.82, 6.51)	
	p-value	0.1278	
	p-Value for test for heterogenity between studies	0.1540	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Infections and infestations, PT: Sinusitis	Number of subjects with events, n (%)	21 (5.8)	22 (6.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.97 (0.54, 1.76)	
	p-value	0.9306	
	Odds Ratio (95% CI)	0.97 (0.52, 1.82)	
	p-value	0.9275	
	Risk Difference (95% CI)	-0.18 (-3.62, 3.26)	
	p-value	0.9190	
	CMH approach		
	Response rate	5.9	5.9
	Difference in response rates (95% CI)	-0.01 (-4.32, 4.30)	
	p-value	0.9961	
	p-Value for test for heterogenity between studies	0.1649	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Infections and infestations, PT: Upper respiratory tract infection	Number of subjects with events, n (%)	64 (17.8)	38 (10.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.70 (1.17, 2.49)	
	p-value	0.0059	
	Odds Ratio (95% CI)	1.85 (1.20, 2.86)	
	p-value	0.0058	
	Risk Difference (95% CI)	7.38 (2.35, 12.41)	
	p-value	0.0041	
	CMH approach		
	Response rate	17.7	10.4
	Difference in response rates (95% CI)	7.32 (1.89, 12.76)	
	p-value	0.0082	
	p-Value for test for heterogenity between studies	0.1035	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Infections and infestations, PT: Urinary tract infection	Number of subjects with events, n (%)	44 (12.2)	54 (14.8)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.83 (0.57, 1.20)	
	p-value	0.3200	
	Odds Ratio (95% CI)	0.80 (0.52, 1.23)	
	p-value	0.3193	
	Risk Difference (95% CI)	-2.53 (-7.49, 2.44)	
	p-value	0.3180	
	CMH approach		
	Response rate	12.2	14.8
	Difference in response rates (95% CI)	-2.56 (-8.01, 2.90)	
	p-value	0.3581	
	p-Value for test for heterogenity between studies	0.9415	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Injury, poisoning and procedural complications	Number of subjects with events, n (%)	86 (23.9)	68 (18.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.29 (0.97, 1.71)	
	p-value	0.0816	
	Odds Ratio (95% CI)	1.38 (0.96, 1.97)	
	p-value	0.0809	
	Risk Difference (95% CI)	5.31 (-0.63, 11.25)	
	p-value	0.0799	
	CMH approach		
	Response rate	24.1	18.4
	Difference in response rates (95% CI)	5.66 (-0.46, 11.79)	
	p-value	0.0697	
	p-Value for test for heterogenity between studies	0.9019	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Injury, poisoning and procedural complications, PT: Infusion related reaction	Number of subjects with events, n (%)	41 (11.4)	27 (7.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.54 (0.97, 2.45)	
	p-value	0.0685	
	Odds Ratio (95% CI)	1.61 (0.96, 2.68)	
	p-value	0.0685	
	Risk Difference (95% CI)	4.00 (-0.23, 8.24)	
	p-value	0.0637	
	CMH approach		
	Response rate	11.5	7.3
	Difference in response rates (95% CI)	4.18 (-0.70, 9.06)	
	p-value	0.0929	
	p-Value for test for heterogenity between studies	0.4501	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Investigations	Number of subjects with events, n (%)	21 (5.8)	21 (5.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.02 (0.56, 1.83)	
	p-value	0.9561	
	Odds Ratio (95% CI)	1.02 (0.55, 1.90)	
	p-value	0.9548	
	Risk Difference (95% CI)	0.10 (-3.30, 3.49)	
	p-value	0.9546	
	CMH approach		
	Response rate	5.8	5.7
	Difference in response rates (95% CI)	0.11 (-4.26, 4.49)	
	p-value	0.9593	
	p-Value for test for heterogenity between studies	0.7634	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Metabolism and nutrition disorders	Number of subjects with events, n (%)	19 (5.3)	32 (8.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.60 (0.35, 1.05)	
	p-value	0.0716	
	Odds Ratio (95% CI)	0.58 (0.32, 1.05)	
	p-value	0.0707	
	Risk Difference (95% CI)	-3.47 (-7.17, 0.24)	
	p-value	0.0665	
	CMH approach		
	Response rate	5.2	8.7
	Difference in response rates (95% CI)	-3.53 (-8.05, 1.00)	
	p-value	0.1266	
	p-Value for test for heterogenity between studies	0.8662	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Musculoskeletal and connective tissue disorders	Number of subjects with events, n (%)	84 (23.3)	83 (22.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.03 (0.79, 1.34)	
	p-value	0.8512	
	Odds Ratio (95% CI)	1.04 (0.73, 1.47)	
	p-value	0.8317	
	Risk Difference (95% CI)	0.67 (-5.45, 6.79)	
	p-value	0.8309	
	CMH approach		
	Response rate	23.5	22.7
	Difference in response rates (95% CI)	0.79 (-5.53, 7.10)	
	p-value	0.8066	
	p-Value for test for heterogenity between studies	0.3475	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Musculoskeletal and connective tissue disorders, PT: Arthralgia	Number of subjects with events, n (%)	21 (5.8)	9 (2.5)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	2.29 (1.05, 4.98)	
	p-value	0.0373	
	Odds Ratio (95% CI)	2.38 (1.06, 5.33)	
	p-value	0.0356	
	Risk Difference (95% CI)	3.37 (0.48, 6.27)	
	p-value	0.0225	
	CMH approach		
	Response rate	5.9	2.5
	Difference in response rates (95% CI)	3.42 (-0.65, 7.49)	
	p-value	0.0993	
	p-Value for test for heterogenity between studies	0.3284	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Musculoskeletal and connective tissue disorders, PT: Back pain	Number of subjects with events, n (%)	21 (5.8)	16 (4.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.23 (0.62, 2.41)	
	p-value	0.5534	
	Odds Ratio (95% CI)	1.26 (0.62, 2.57)	
	p-value	0.5245	
	Risk Difference (95% CI)	1.47 (-1.73, 4.67)	
	p-value	0.3688	
	CMH approach		
	Response rate	5.9	4.4
	Difference in response rates (95% CI)	1.54 (-2.67, 5.76)	
	p-value	0.4728	
	p-Value for test for heterogenity between studies	0.0416	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Musculoskeletal and connective tissue disorders, PT: Systemic lupus erythematosus	Number of subjects with events, n (%)	7 (1.9)	12 (3.3)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.60 (0.24, 1.50)	
	p-value	0.2705	
	Odds Ratio (95% CI)	0.59 (0.23, 1.51)	
	p-value	0.2695	
	Risk Difference (95% CI)	-1.33 (-3.65, 0.98)	
	p-value	0.2591	
	CMH approach		
	Response rate	1.9	3.3
	Difference in response rates (95% CI)	-1.39 (-5.16, 2.39)	
	p-value	0.4712	
	p-Value for test for heterogenity between studies	0.7522	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Number of subjects with events, n (%)	15 (4.2)	6 (1.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	2.30 (0.86, 6.13)	
	p-value	0.0976	
	Odds Ratio (95% CI)	2.36 (0.86, 6.45)	
	p-value	0.0941	
	Risk Difference (95% CI)	2.53 (0.09, 4.97)	
	p-value	0.0425	
	CMH approach		
	Response rate	4.1	1.6
	Difference in response rates (95% CI)	2.47 (-1.34, 6.28)	
	p-value	0.2032	
	p-Value for test for heterogenity between studies	0.1682	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Nervous system disorders	Number of subjects with events, n (%)	71 (19.7)	62 (16.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.17 (0.86, 1.59)	
	p-value	0.3197	
	Odds Ratio (95% CI)	1.21 (0.83, 1.76)	
	p-value	0.3294	
	Risk Difference (95% CI)	2.80 (-2.81, 8.41)	
	p-value	0.3281	
	CMH approach		
	Response rate	19.7	16.8
	Difference in response rates (95% CI)	2.94 (-2.89, 8.78)	
	p-value	0.3231	
	p-Value for test for heterogenity between studies	0.5732	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Nervous system disorders, PT: Dizziness	Number of subjects with events, n (%)	8 (2.2)	11 (3.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.74 (0.30, 1.82)	
	p-value	0.5119	
	Odds Ratio (95% CI)	0.73 (0.29, 1.85)	
	p-value	0.5119	
	Risk Difference (95% CI)	-0.78 (-3.10, 1.54)	
	p-value	0.5096	
	CMH approach		
	Response rate	2.2	3.0
	Difference in response rates (95% CI)	-0.79 (-4.53, 2.95)	
	p-value	0.6790	
	p-Value for test for heterogenity between studies	0.9682	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Nervous system disorders, PT: Headache	Number of subjects with events, n (%)	28 (7.8)	36 (9.8)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.80 (0.50, 1.28)	
	p-value	0.3456	
	Odds Ratio (95% CI)	0.78 (0.46, 1.31)	
	p-value	0.3390	
	Risk Difference (95% CI)	-2.05 (-6.17, 2.07)	
	p-value	0.3284	
	CMH approach		
	Response rate	7.8	9.7
	Difference in response rates (95% CI)	-1.84 (-6.62, 2.94)	
	p-value	0.4504	
	p-Value for test for heterogenity between studies	0.3611	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Psychiatric disorders	Number of subjects with events, n (%)	25 (6.9)	37 (10.1)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.69 (0.42, 1.12)	
	p-value	0.1310	
	Odds Ratio (95% CI)	0.66 (0.39, 1.13)	
	p-value	0.1298	
	Risk Difference (95% CI)	-3.16 (-7.21, 0.89)	
	p-value	0.1264	
	CMH approach		
	Response rate	6.9	10.1
	Difference in response rates (95% CI)	-3.21 (-7.97, 1.55)	
	p-value	0.1860	
	p-Value for test for heterogenity between studies	0.8576	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Psychiatric disorders, PT: Depression	Number of subjects with events, n (%)	11 (3.1)	8 (2.2)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.40 (0.57, 3.44)	
	p-value	0.4692	
	Odds Ratio (95% CI)	1.41 (0.56, 3.56)	
	p-value	0.4679	
	Risk Difference (95% CI)	0.87 (-1.45, 3.20)	
	p-value	0.4621	
	CMH approach		
	Response rate	3.0	2.2
	Difference in response rates (95% CI)	0.85 (-2.86, 4.57)	
	p-value	0.6522	
	p-Value for test for heterogenity between studies	0.7347	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Psychiatric disorders, PT: Insomnia	Number of subjects with events, n (%)	6 (1.7)	17 (4.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.37 (0.15, 0.95)	
	p-value	0.0392	
	Odds Ratio (95% CI)	0.36 (0.14, 0.94)	
	p-value	0.0377	
	Risk Difference (95% CI)	-2.98 (-5.51, -0.45)	
	p-value	0.0211	
	CMH approach		
	Response rate	1.7	4.6
	Difference in response rates (95% CI)	-2.93 (-6.79, 0.93)	
	p-value	0.1365	
	p-Value for test for heterogenity between studies	0.4026	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Renal and urinary disorders	Number of subjects with events, n (%)	15 (4.2)	16 (4.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.96 (0.48, 1.92)	
	p-value	0.9099	
	Odds Ratio (95% CI)	0.96 (0.46, 1.98)	
	p-value	0.9018	
	Risk Difference (95% CI)	-0.20 (-3.13, 2.74)	
	p-value	0.8954	
	CMH approach		
	Response rate	4.2	4.4
	Difference in response rates (95% CI)	-0.19 (-4.25, 3.88)	
	p-value	0.9289	
	p-Value for test for heterogenity between studies	0.5037	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Reproductive system and breast disorders	Number of subjects with events, n (%)	19 (5.3)	17 (4.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.13 (0.59, 2.16)	
	p-value	0.7067	
	Odds Ratio (95% CI)	1.14 (0.58, 2.25)	
	p-value	0.7053	
	Risk Difference (95% CI)	0.63 (-2.53, 3.79)	
	p-value	0.6948	
	CMH approach		
	Response rate	5.3	4.6
	Difference in response rates (95% CI)	0.73 (-3.50, 4.96)	
	p-value	0.7346	
	p-Value for test for heterogenity between studies	0.3149	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with events, n (%)	55 (15.3)	53 (14.5)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.06 (0.75, 1.50)	
	p-value	0.7534	
	Odds Ratio (95% CI)	1.07 (0.71, 1.61)	
	p-value	0.7626	
	Risk Difference (95% CI)	0.80 (-4.38, 5.98)	
	p-value	0.7613	
	CMH approach		
	Response rate	15.2	14.5
	Difference in response rates (95% CI)	0.75 (-4.85, 6.36)	
	p-value	0.7920	
	p-Value for test for heterogenity between studies	0.2899	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Respiratory, thoracic and mediastinal disorders, PT: Cough	Number of subjects with events, n (%)	21 (5.8)	14 (3.8)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.52 (0.79, 2.95)	
	p-value	0.2107	
	Odds Ratio (95% CI)	1.56 (0.78, 3.11)	
	p-value	0.2101	
	Risk Difference (95% CI)	2.01 (-1.11, 5.13)	
	p-value	0.2067	
	CMH approach		
	Response rate	5.8	3.8
	Difference in response rates (95% CI)	1.97 (-2.21, 6.15)	
	p-value	0.3556	
	p-Value for test for heterogenity between studies	0.8748	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Skin and subcutaneous tissue disorders	Number of subjects with events, n (%)	56 (15.6)	44 (12.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.27 (0.88, 1.84)	
	p-value	0.2013	
	Odds Ratio (95% CI)	1.34 (0.87, 2.06)	
	p-value	0.1826	
	Risk Difference (95% CI)	3.52 (-1.49, 8.53)	
	p-value	0.1681	
	CMH approach		
	Response rate	15.7	12.0
	Difference in response rates (95% CI)	3.70 (-1.74, 9.14)	
	p-value	0.1827	
	p-Value for test for heterogenity between studies	0.1229	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Vascular disorders	Number of subjects with events, n (%)	12 (3.3)	18 (4.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.68 (0.32, 1.45)	
	p-value	0.3198	
	Odds Ratio (95% CI)	0.68 (0.31, 1.47)	
	p-value	0.3236	
	Risk Difference (95% CI)	-1.58 (-4.47, 1.31)	
	p-value	0.2844	
	CMH approach		
	Response rate	3.4	4.9
	Difference in response rates (95% CI)	-1.53 (-5.59, 2.53)	
	p-value	0.4603	
	p-Value for test for heterogenity between studies	0.1185	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Vascular disorders, PT: Hypertension	Number of subjects with events, n (%)	6 (1.7)	12 (3.3)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.51 (0.19, 1.35)	
	p-value	0.1756	
	Odds Ratio (95% CI)	0.50 (0.19, 1.36)	
	p-value	0.1753	
	Risk Difference (95% CI)	-1.61 (-3.85, 0.64)	
	p-value	0.1615	
	CMH approach		
	Response rate	1.7	3.3
	Difference in response rates (95% CI)	-1.58 (-5.31, 2.15)	
	p-value	0.4062	
	p-Value for test for heterogenity between studies	0.7156	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SOC: Cardiac disorders	SLEDAI-2K score at screening									0.2312
	< 10 points	0/109 (0.0)	0.0	6/106 (5.7)	5.8	0.14 (0.02, 1.11)	0.0628	-5.77 (-14.25, 2.72)	0.1826	
	>= 10 points	6/251 (2.4)	2.4	11/260 (4.2)	4.3	0.57 (0.21, 1.51)	0.2548	-1.92 (-6.41, 2.57)	0.4018	
	OCS dose at baseline									0.6224
	<10 mg/day	2/170 (1.2)	1.2	8/181 (4.4)	4.5	0.27 (0.06, 1.27)	0.0976	-3.29 (-9.24, 2.65)	0.2777	
	>=10 mg/day	4/190 (2.1)	2.1	9/185 (4.9)	4.9	0.44 (0.14, 1.43)	0.1731	-2.81 (-8.46, 2.85)	0.3304	
	Result of type I IFN gene signature test									0.8544
	LOW	1/ 62 (1.6)	1.6	3/ 64 (4.7)	4.7	0.45 (0.07, 2.95)	0.4022	-3.08 (-12.75, 6.60)	0.5333	
	HIGH	5/298 (1.7)	1.7	14/302 (4.6)	4.7	0.37 (0.13, 1.01)	0.0513	-3.03 (-7.27, 1.20)	0.1604	
	Age (years)									0.5918
	<= 65	6/348 (1.7)	1.7	16/362 (4.4)	4.5	0.39 (0.15, 0.99)	0.0465	-2.78 (-6.72, 1.16)	0.1662	
	> 65	0/ 12 (0.0)	0.0	1/ 4 (25.0)	23.9	0.17 (0.01, 3.24)	0.2366	-23.86 (-77.50, 29.77)	0.3832	
	Sex									0.1581
	male	2/ 27 (7.4)	7.2	1/ 25 (4.0)	4.1	1.73 (0.18, 16.99)	0.6367	3.03 (-16.89, 22.95)	0.7656	
	female	4/333 (1.2)	1.2	16/341 (4.7)	4.7	0.28 (0.09, 0.84)	0.0237	-3.56 (-7.61, 0.49)	0.0850	
	Race									0.8262
	White	6/235 (2.6)	2.6	12/244 (4.9)	4.8	0.52 (0.20, 1.37)	0.1854	-2.21 (-7.35, 2.93)	0.4004	
	Black	0/ 46 (0.0)	0.0	3/ 48 (6.3)	6.0	0.28 (0.03, 2.42)	0.2468	-5.96 (-18.15, 6.23)	0.3379	
	Other	0/ 71 (0.0)	0.0	2/ 66 (3.0)	3.0	0.31 (0.03, 2.90)	0.3050	-3.03 (-11.31, 5.25)	0.4730	
	Ethnicity									0.7810
	Hispanic/Latino	1/ 86 (1.2)	1.1	5/ 89 (5.6)	5.8	0.31 (0.05, 1.99)	0.2189	-4.70 (-13.75, 4.34)	0.3082	
	Non-hispanic/Latino	5/266 (1.9)	1.9	12/269 (4.5)	4.6	0.42 (0.15, 1.19)	0.1047	-2.65 (-7.55, 2.24)	0.2883	
	Geographic region									0.4900
	EU	2/115 (1.7)	1.6	4/122 (3.3)	3.2	0.71 (0.11, 4.51)	0.7188	-1.61 (-7.33, 4.11)	0.5813	
	non-EU	4/245 (1.6)	1.6	13/244 (5.3)	5.5	0.33 (0.11, 1.04)	0.0578	-3.90 (-9.21, 1.40)	0.1495	
	Onset of disease									0.5871
	Paediatric	1/ 26 (3.8)	3.7	2/ 24 (8.3)	8.0	0.67 (0.08, 5.67)	0.7127	-4.32 (-24.74, 16.10)	0.6783	
	Adult	5/334 (1.5)	1.5	15/342 (4.4)	4.5	0.35 (0.13, 0.95)	0.0400	-2.95 (-7.00, 1.10)	0.1536	
	ADA result									0.4769
	Negative	5/334 (1.5)	1.5	14/331 (4.2)	4.2	0.36 (0.13, 0.98)	0.0460	-2.71 (-6.79, 1.36)	0.1922	
	Positive (At any time)	1/ 25 (4.0)	5.2	3/ 35 (8.6)	8.1	0.76 (0.12, 4.76)	0.7731	-2.84 (-22.46, 16.79)	0.7768	
	BMI (kg/m2) at enrolment									0.1617
	< 30	1/233 (0.4)	0.4	11/261 (4.2)	4.2	0.16 (0.03, 0.87)	0.0343	-3.76 (-8.38, 0.86)	0.1108	
	>= 30	5/127 (3.9)	3.9	6/105 (5.7)	5.6	0.69 (0.22, 2.21)	0.5329	-1.72 (-10.32, 6.87)	0.6945	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SOC: Immune system disorders	SLEDAI-2K score at screening									0.1213
	< 10 points	12/109 (11.0)	11.3	2/106 (1.9)	1.8	5.78 (1.32, 25.26)	0.0198	9.47 (0.23, 18.70)	0.0444	
	>= 10 points	11/251 (4.4)	4.4	8/260 (3.1)	3.0	1.44 (0.56, 3.73)	0.4496	1.36 (-3.17, 5.90)	0.5564	
	OCS dose at baseline									0.7527
	<10 mg/day	14/170 (8.2)	8.1	7/181 (3.9)	3.8	2.13 (0.88, 5.14)	0.0938	4.36 (-2.26, 10.98)	0.1966	
	>=10 mg/day	9/190 (4.7)	4.9	3/185 (1.6)	1.6	2.74 (0.74, 10.21)	0.1323	3.25 (-2.22, 8.71)	0.2443	
	Result of type I IFN gene signature test									0.0809
	LOW	9/ 62 (14.5)	14.5	0/ 64 (0.0)	0.0	9.93 (1.30, 75.98)	0.0271	14.51 (3.36, 25.67)	0.0107	
	HIGH	14/298 (4.7)	4.7	10/302 (3.3)	3.2	1.42 (0.64, 3.15)	0.3911	1.51 (-2.85, 5.88)	0.4973	
	Age (years)									0.8141
	<= 65	18/348 (5.2)	5.2	10/362 (2.8)	2.7	1.86 (0.87, 3.99)	0.1105	2.53 (-1.54, 6.59)	0.2229	
	> 65	5/ 12 (41.7)	42.0	0/ 4 (0.0)	0.0	2.37 (0.37, 15.37)	0.3649	42.05 (-12.12, 96.21)	0.1282	
	Sex									0.4622
	male	1/ 27 (3.7)	3.6	1/ 25 (4.0)	4.1	0.87 (0.06, 12.52)	0.9164	-0.55 (-19.84, 18.74)	0.9554	
	female	22/333 (6.6)	6.7	9/341 (2.6)	2.6	2.46 (1.14, 5.30)	0.0217	4.08 (-0.25, 8.42)	0.0650	
	Race									0.4561
	White	18/235 (7.7)	7.4	6/244 (2.5)	2.5	2.98 (1.18, 7.52)	0.0210	4.81 (-0.50, 10.11)	0.0756	
	Black	1/ 46 (2.2)	2.6	1/ 48 (2.1)	2.4	1.08 (0.12, 10.02)	0.9457	0.16 (-12.01, 12.33)	0.9790	
	Other	2/ 71 (2.8)	2.8	2/ 66 (3.0)	3.0	0.93 (0.13, 6.39)	0.9396	-0.22 (-9.18, 8.75)	0.9620	
	Ethnicity									0.8579
	Hispanic/Latino	4/ 86 (4.7)	4.8	2/ 89 (2.2)	2.1	2.00 (0.36, 11.27)	0.4308	2.76 (-6.08, 11.61)	0.5407	
	Non-hispanic/Latino	17/266 (6.4)	6.5	7/269 (2.6)	2.6	2.39 (0.99, 5.77)	0.0523	3.94 (-1.17, 9.04)	0.1310	
	Geographic region									0.5033
	EU	6/115 (5.2)	5.3	1/122 (0.8)	0.9	3.67 (0.59, 22.97)	0.1650	4.40 (-1.73, 10.53)	0.1592	
	non-EU	17/245 (6.9)	7.0	9/244 (3.7)	3.6	1.85 (0.84, 4.08)	0.1243	3.35 (-2.23, 8.94)	0.2394	
	Onset of disease									0.8192
	Paediatric	2/ 26 (7.7)	7.7	0/ 24 (0.0)	0.0	2.79 (0.31, 25.19)	0.3599	7.72 (-12.05, 27.49)	0.4443	
	Adult	21/334 (6.3)	6.3	10/342 (2.9)	2.9	2.13 (1.01, 4.48)	0.0459	3.39 (-0.91, 7.69)	0.1222	
	ADA result									0.1387
	Negative	23/334 (6.9)	7.0	8/331 (2.4)	2.4	2.83 (1.28, 6.25)	0.0103	4.57 (0.19, 8.95)	0.0407	
	Positive (At any time)	0/ 25 (0.0)	0.0	2/ 35 (5.7)	6.0	0.48 (0.05, 4.36)	0.5162	-5.97 (-24.26, 12.32)	0.5223	
	BMI (kg/m2) at enrolment									0.8108
	< 30	11/233 (4.7)	4.8	5/261 (1.9)	2.0	2.36 (0.81, 6.89)	0.1148	2.87 (-2.00, 7.74)	0.2474	
	>= 30	12/127 (9.4)	9.5	5/105 (4.8)	5.0	1.98 (0.72, 5.43)	0.1868	4.54 (-4.57, 13.65)	0.3290	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SOC: Immune system disorders, PT: Hypersensitivity	SLEDAI-2K score at screening									0.8348
	< 10 points	6/109 (5.5)	5.8	1/106 (0.9)	0.9	4.17 (0.72, 24.26)	0.1116	4.90 (-3.62, 13.41)	0.2597	
	>= 10 points	7/251 (2.8)	2.8	2/260 (0.8)	0.8	3.22 (0.61, 17.17)	0.1703	2.00 (-1.99, 5.99)	0.3264	
	OCS dose at baseline									0.9695
	<10 mg/day	8/170 (4.7)	4.6	2/181 (1.1)	1.1	3.35 (0.60, 18.85)	0.1702	3.54 (-2.34, 9.41)	0.2383	
	>=10 mg/day	5/190 (2.6)	2.7	1/185 (0.5)	0.5	3.52 (0.58, 21.34)	0.1716	2.19 (-2.83, 7.20)	0.3923	
	Result of type I IFN gene signature test									0.2791
	LOW	6/ 62 (9.7)	9.7	0/ 64 (0.0)	0.0	13.39 (0.79, 228.40)	0.0730	9.67 (-0.49, 19.84)	0.0622	
	HIGH	7/298 (2.3)	2.4	3/302 (1.0)	1.0	2.37 (0.62, 9.07)	0.2087	1.42 (-2.41, 5.25)	0.4669	
	Age (years)									0.9860
	<= 65	10/348 (2.9)	2.9	3/362 (0.8)	0.8	3.41 (0.94, 12.40)	0.0630	2.11 (-1.52, 5.75)	0.2545	
	> 65	3/ 12 (25.0)	30.7	0/ 4 (0.0)	0.0	3.50 (0.23, 52.56)	0.3648	30.68 (-23.06, 84.42)	0.2631	
	Sex									0.2557
	male	1/ 27 (3.7)	3.6	1/ 25 (4.0)	4.1	0.87 (0.06, 12.52)	0.9164	-0.55 (-19.84, 18.74)	0.9554	
	female	12/333 (3.6)	3.6	2/341 (0.6)	0.6	5.20 (1.10, 24.59)	0.0376	3.05 (-0.77, 6.87)	0.1179	
	Race									0.2157
	White	11/235 (4.7)	4.5	2/244 (0.8)	0.8	4.89 (1.26, 18.98)	0.0218	3.70 (-1.06, 8.45)	0.1275	
	Black	0/ 46 (0.0)	0.0	0/ 48 (0.0)	0.0	NE		0.00 (-10.79, 10.79)	1.0000	
	Other	1/ 71 (1.4)	1.4	1/ 66 (1.5)	1.5	0.94 (0.10, 8.77)	0.9543	-0.11 (-8.34, 8.13)	0.9793	
	Ethnicity									0.9910
	Hispanic/Latino	2/ 86 (2.3)	2.5	0/ 89 (0.0)	0.0	3.13 (0.33, 29.53)	0.3182	2.52 (-5.65, 10.68)	0.5458	
	Non-hispanic/Latino	10/266 (3.8)	3.9	3/269 (1.1)	1.0	3.09 (0.79, 12.01)	0.1038	2.85 (-1.83, 7.54)	0.2326	
	Geographic region									0.6548
	EU	4/115 (3.5)	3.6	0/122 (0.0)	0.0	4.95 (0.57, 42.87)	0.1468	3.57 (-1.95, 9.09)	0.2049	
	non-EU	9/245 (3.7)	3.7	3/244 (1.2)	1.3	2.77 (0.73, 10.54)	0.1350	2.41 (-2.61, 7.43)	0.3461	
	Onset of disease									0.8555
	Paediatric	2/ 26 (7.7)	7.7	0/ 24 (0.0)	0.0	2.79 (0.31, 25.19)	0.3599	7.72 (-12.05, 27.49)	0.4443	
	Adult	11/334 (3.3)	3.2	3/342 (0.9)	0.9	3.55 (0.95, 13.28)	0.0603	2.35 (-1.43, 6.13)	0.2226	
	ADA result									NE
	Negative	13/334 (3.9)	4.0	3/331 (0.9)	0.9	4.20 (1.19, 14.89)	0.0262	3.10 (-0.81, 7.02)	0.1204	
	Positive (At any time)	0/ 25 (0.0)	0.0	0/ 35 (0.0)	0.0	NE		0.00 (-17.02, 17.02)	1.0000	
	BMI (kg/m2) at enrolment									0.4732
	< 30	4/233 (1.7)	1.8	2/261 (0.8)	0.8	2.08 (0.34, 12.53)	0.4261	1.01 (-3.35, 5.38)	0.6497	
	>= 30	9/127 (7.1)	7.1	1/105 (1.0)	1.0	5.14 (0.93, 28.23)	0.0598	6.07 (-2.22, 14.37)	0.1513	

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SOC / PT	Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations	SLEDAI-2K score at screening									0.2481
	< 10 points	82/109 (75.2)	75.3	70/106 (66.0)	66.0	1.14 (0.96, 1.35)	0.1430	9.32 (-3.09, 21.73)	0.1411	
	>= 10 points	185/251 (73.7)	73.8	148/260 (56.9)	56.8	1.29 (1.14, 1.47)	<.0001	17.00 (8.86, 25.13)	<.0001	
	OCS dose at baseline									0.4186
	<10 mg/day	132/170 (77.6)	77.7	117/181 (64.6)	64.6	1.19 (1.04, 1.37)	0.0098	13.09 (3.56, 22.62)	0.0071	
	>=10 mg/day	135/190 (71.1)	71.1	101/185 (54.6)	54.8	1.30 (1.11, 1.53)	0.0012	16.28 (6.58, 25.98)	0.0010	
	Result of type I IFN gene signature test									0.8794
	LOW	45/ 62 (72.6)	72.6	38/ 64 (59.4)	59.4	1.22 (0.95, 1.58)	0.1223	13.21 (-3.39, 29.80)	0.1189	
	HIGH	222/298 (74.5)	74.6	180/302 (59.6)	59.5	1.25 (1.11, 1.40)	0.0001	15.09 (7.62, 22.56)	<.0001	
	Age (years)									0.7512
	<= 65	257/348 (73.9)	74.0	216/362 (59.7)	59.6	1.24 (1.11, 1.37)	<.0001	14.35 (7.46, 21.25)	<.0001	
	> 65	10/ 12 (83.3)	84.1	2/ 4 (50.0)	47.7	1.41 (0.63, 3.16)	0.4040	36.36 (-18.84, 91.56)	0.1966	
	Sex									0.8696
	male	17/ 27 (63.0)	62.0	13/ 25 (52.0)	51.8	1.30 (0.78, 2.18)	0.3136	10.19 (-15.59, 35.98)	0.4384	
	female	250/333 (75.1)	75.2	205/341 (60.1)	60.2	1.25 (1.12, 1.39)	<.0001	15.06 (8.03, 22.10)	<.0001	
	Race									0.5230
	White	168/235 (71.5)	71.4	136/244 (55.7)	55.7	1.29 (1.12, 1.48)	0.0003	15.67 (7.10, 24.23)	0.0003	
	Black	33/ 46 (71.7)	71.6	28/ 48 (58.3)	59.4	1.20 (0.89, 1.61)	0.2352	12.22 (-7.31, 31.75)	0.2201	
	Other	59/ 71 (83.1)	83.1	47/ 66 (71.2)	71.2	1.13 (0.94, 1.36)	0.1887	11.91 (-2.47, 26.29)	0.1045	
	Ethnicity									0.6277
	Hispanic/Latino	66/ 86 (76.7)	76.6	57/ 89 (64.0)	63.9	1.20 (0.99, 1.46)	0.0616	12.69 (-1.06, 26.43)	0.0705	
	Non-hispanic/Latino	194/266 (72.9)	72.9	154/269 (57.2)	57.2	1.27 (1.12, 1.45)	0.0002	15.72 (7.68, 23.76)	0.0001	
	Geographic region									0.2027
	EU	76/115 (66.1)	66.6	58/122 (47.5)	47.8	1.40 (1.12, 1.76)	0.0036	18.85 (6.52, 31.17)	0.0027	
	non-EU	191/245 (78.0)	78.1	160/244 (65.6)	65.8	1.19 (1.06, 1.33)	0.0027	12.29 (4.17, 20.41)	0.0030	
	Onset of disease									0.6872
	Paediatric	22/ 26 (84.6)	85.2	16/ 24 (66.7)	67.3	1.15 (0.83, 1.62)	0.4005	17.90 (-6.43, 42.23)	0.1493	
	Adult	245/334 (73.4)	73.4	202/342 (59.1)	59.2	1.24 (1.11, 1.39)	0.0001	14.28 (7.20, 21.36)	<.0001	
	ADA result									0.8414
	Negative	249/334 (74.6)	74.7	197/331 (59.5)	59.4	1.25 (1.13, 1.40)	<.0001	15.36 (8.24, 22.48)	<.0001	
	Positive (At any time)	18/ 25 (72.0)	74.2	21/ 35 (60.0)	58.2	1.30 (0.93, 1.83)	0.1288	16.02 (-9.14, 41.18)	0.2120	
	BMI (kg/m2) at enrolment									0.1214
	< 30	169/233 (72.5)	72.8	145/261 (55.6)	55.6	1.30 (1.14, 1.49)	0.0001	17.28 (8.98, 25.57)	<.0001	
	>= 30	98/127 (77.2)	77.3	73/105 (69.5)	68.9	1.11 (0.94, 1.30)	0.2115	8.43 (-3.49, 20.35)	0.1655	

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SOC: Infections and infestations, PT: Bronchitis	SLEDAI-2K score at screening									0.0123
	< 10 points	9/109 (8.3)	8.4	10/106 (9.4)	9.5	0.88 (0.37, 2.07)	0.7621	-1.11 (-11.00, 8.78)	0.8256	
	>= 10 points	30/251 (12.0)	12.1	8/260 (3.1)	3.1	3.81 (1.77, 8.18)	0.0006	8.94 (3.57, 14.30)	0.0011	
	OCS dose at baseline									0.3146
	<10 mg/day	22/170 (12.9)	13.0	8/181 (4.4)	4.5	2.88 (1.31, 6.33)	0.0086	8.52 (1.31, 15.73)	0.0205	
	>=10 mg/day	17/190 (8.9)	9.0	10/185 (5.4)	5.5	1.64 (0.77, 3.51)	0.2024	3.52 (-2.90, 9.94)	0.2820	
	Result of type I IFN gene signature test									0.1984
	LOW	7/ 62 (11.3)	11.3	6/ 64 (9.4)	9.4	1.18 (0.41, 3.44)	0.7571	1.91 (-10.47, 14.30)	0.7618	
	HIGH	32/298 (10.7)	10.9	12/302 (4.0)	4.1	2.68 (1.41, 5.12)	0.0028	6.81 (1.77, 11.85)	0.0081	
	Age (years)									0.3136
	<= 65	36/348 (10.3)	10.5	17/362 (4.7)	4.8	2.17 (1.24, 3.82)	0.0069	5.68 (0.97, 10.40)	0.0182	
	> 65	3/ 12 (25.0)	26.1	1/ 4 (25.0)	23.9	0.90 (0.18, 4.53)	0.9014	2.27 (-53.76, 58.31)	0.9366	
	Sex									0.8954
	male	1/ 27 (3.7)	3.6	0/ 25 (0.0)	0.0	2.63 (0.12, 59.40)	0.5442	3.58 (-14.77, 21.93)	0.7021	
	female	38/333 (11.4)	11.5	18/341 (5.3)	5.4	2.12 (1.23, 3.67)	0.0070	6.12 (1.15, 11.08)	0.0158	
	Race									0.2671
	White	29/235 (12.3)	12.3	11/244 (4.5)	4.4	2.66 (1.34, 5.24)	0.0049	7.94 (1.95, 13.94)	0.0094	
	Black	6/ 46 (13.0)	14.2	3/ 48 (6.3)	6.6	1.93 (0.48, 7.86)	0.3568	7.61 (-7.47, 22.69)	0.3228	
	Other	3/ 71 (4.2)	4.2	4/ 66 (6.1)	6.1	0.70 (0.16, 3.02)	0.6302	-1.83 (-11.81, 8.15)	0.7192	
	Ethnicity									0.5180
	Hispanic/Latino	9/ 86 (10.5)	10.4	3/ 89 (3.4)	3.4	3.05 (0.85, 10.97)	0.0871	7.01 (-3.01, 17.03)	0.1703	
	Non-hispanic/Latino	29/266 (10.9)	11.2	15/269 (5.6)	5.9	1.91 (1.04, 3.52)	0.0370	5.29 (-0.49, 11.07)	0.0728	
	Geographic region									0.1469
	EU	14/115 (12.2)	12.1	3/122 (2.5)	2.6	4.43 (1.30, 15.09)	0.0172	9.52 (1.90, 17.14)	0.0143	
	non-EU	25/245 (10.2)	10.4	15/244 (6.1)	6.2	1.60 (0.85, 3.01)	0.1475	4.18 (-1.93, 10.29)	0.1801	
	Onset of disease									0.4310
	Paediatric	4/ 26 (15.4)	15.4	0/ 24 (0.0)	0.0	4.66 (0.58, 37.24)	0.1471	15.43 (-5.59, 36.46)	0.1502	
	Adult	35/334 (10.5)	10.5	18/342 (5.3)	5.4	1.96 (1.13, 3.41)	0.0173	5.16 (0.25, 10.06)	0.0392	
	ADA result									0.0705
	Negative	38/334 (11.4)	11.5	14/331 (4.2)	4.4	2.62 (1.43, 4.78)	0.0017	7.15 (2.21, 12.09)	0.0045	
	Positive (At any time)	1/ 25 (4.0)	3.4	4/ 35 (11.4)	11.9	0.45 (0.07, 2.75)	0.3879	-8.52 (-28.54, 11.51)	0.4046	
	BMI (kg/m2) at enrolment									0.2291
	< 30	27/233 (11.6)	11.6	11/261 (4.2)	4.3	2.72 (1.38, 5.38)	0.0039	7.28 (1.47, 13.09)	0.0140	
	>= 30	12/127 (9.4)	9.4	7/105 (6.7)	6.5	1.35 (0.54, 3.38)	0.5187	2.88 (-6.23, 12.00)	0.5351	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Herpes zoster	SLEDAI-2K score at screening									0.1826
	< 10 points	3/109 (2.8)	2.9	2/106 (1.9)	1.9	1.31 (0.25, 6.80)	0.7467	0.98 (-7.35, 9.31)	0.8182	
	>= 10 points	20/251 (8.0)	7.9	4/260 (1.5)	1.6	4.97 (1.72, 14.40)	0.0031	6.33 (1.50, 11.16)	0.0102	
	OCS dose at baseline									0.4608
	<10 mg/day	11/170 (6.5)	6.5	2/181 (1.1)	1.1	5.84 (1.31, 25.98)	0.0205	5.34 (-0.85, 11.53)	0.0907	
	>=10 mg/day	12/190 (6.3)	6.3	4/185 (2.2)	2.2	2.90 (0.95, 8.84)	0.0619	4.08 (-1.77, 9.93)	0.1720	
	Result of type I IFN gene signature test									0.8244
	LOW	4/ 62 (6.5)	6.5	1/ 64 (1.6)	1.6	2.92 (0.46, 18.57)	0.2552	4.89 (-5.18, 14.96)	0.3410	
	HIGH	19/298 (6.4)	6.4	5/302 (1.7)	1.7	3.71 (1.39, 9.90)	0.0090	4.70 (0.26, 9.15)	0.0379	
	Age (years)									NE
	<= 65	23/348 (6.6)	6.7	6/362 (1.7)	1.7	3.97 (1.63, 9.64)	0.0023	4.96 (0.79, 9.13)	0.0196	
	> 65	0/ 12 (0.0)	0.0	0/ 4 (0.0)	0.0	NE		0.00 (-51.08, 51.08)	1.0000	
	Sex									0.9459
	male	3/ 27 (11.1)	11.0	0/ 25 (0.0)	0.0	3.66 (0.43, 31.08)	0.2348	11.02 (-8.75, 30.79)	0.2746	
	female	20/333 (6.0)	6.0	6/341 (1.8)	1.8	3.38 (1.37, 8.33)	0.0083	4.19 (-0.06, 8.44)	0.0534	
	Race									0.3455
	White	13/235 (5.5)	5.6	5/244 (2.0)	1.9	2.72 (0.98, 7.51)	0.0536	3.68 (-1.49, 8.84)	0.1627	
	Black	0/ 46 (0.0)	0.0	1/ 48 (2.1)	1.8	0.48 (0.02, 11.17)	0.6486	-1.76 (-12.94, 9.41)	0.7571	
	Other	8/ 71 (11.3)	11.3	0/ 66 (0.0)	0.0	7.68 (0.98, 60.28)	0.0525	11.28 (1.31, 21.24)	0.0265	
	Ethnicity									0.4340
	Hispanic/Latino	8/ 86 (9.3)	8.8	1/ 89 (1.1)	1.2	5.82 (1.05, 32.19)	0.0437	7.55 (-1.93, 17.04)	0.1184	
	Non-hispanic/Latino	13/266 (4.9)	5.1	5/269 (1.9)	1.9	2.63 (0.95, 7.27)	0.0627	3.21 (-1.77, 8.20)	0.2061	
	Geographic region									0.4752
	EU	5/115 (4.3)	4.4	2/122 (1.6)	1.6	2.26 (0.49, 10.30)	0.2933	2.82 (-3.22, 8.86)	0.3601	
	non-EU	18/245 (7.3)	7.4	4/244 (1.6)	1.6	4.44 (1.52, 13.00)	0.0065	5.80 (0.29, 11.31)	0.0393	
	Onset of disease									0.5992
	Paediatric	5/ 26 (19.2)	19.4	0/ 24 (0.0)	0.0	5.55 (0.71, 43.16)	0.1018	19.44 (-2.06, 40.94)	0.0763	
	Adult	18/334 (5.4)	5.4	6/342 (1.8)	1.8	3.04 (1.21, 7.59)	0.0175	3.63 (-0.56, 7.81)	0.0894	
	ADA result									0.8761
	Negative	21/334 (6.3)	6.4	5/331 (1.5)	1.5	4.11 (1.56, 10.83)	0.0042	4.85 (0.53, 9.16)	0.0276	
	Positive (At any time)	2/ 25 (8.0)	10.4	1/ 35 (2.9)	2.1	5.00 (0.52, 47.73)	0.1621	8.35 (-10.90, 27.60)	0.3951	
	BMI (kg/m2) at enrolment									0.3245
	< 30	15/233 (6.4)	6.5	3/261 (1.1)	1.2	5.54 (1.62, 18.99)	0.0064	5.36 (0.28, 10.45)	0.0386	
	>= 30	8/127 (6.3)	6.6	3/105 (2.9)	2.6	2.25 (0.61, 8.26)	0.2208	4.00 (-4.49, 12.49)	0.3559	

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Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Upper respiratory tract infection	SLEDAI-2K score at screening									0.8814
	< 10 points	25/109 (22.9)	23.1	14/106 (13.2)	13.2	1.59 (0.85, 2.98)	0.1495	9.88 (-1.32, 21.07)	0.0839	
	>= 10 points	39/251 (15.5)	15.5	24/260 (9.2)	9.2	1.69 (1.05, 2.71)	0.0314	6.28 (0.07, 12.48)	0.0473	
	OCS dose at baseline									0.9350
	<10 mg/day	33/170 (19.4)	19.2	21/181 (11.6)	11.5	1.67 (1.01, 2.78)	0.0466	7.70 (-0.51, 15.90)	0.0662	
	>=10 mg/day	31/190 (16.3)	16.2	17/185 (9.2)	9.3	1.73 (0.98, 3.06)	0.0609	6.91 (-0.53, 14.35)	0.0686	
	Result of type I IFN gene signature test									0.3179
	LOW	13/ 62 (21.0)	21.0	4/ 64 (6.3)	6.3	2.79 (0.91, 8.54)	0.0727	14.72 (1.63, 27.81)	0.0275	
	HIGH	51/298 (17.1)	17.0	34/302 (11.3)	11.2	1.52 (1.01, 2.28)	0.0438	5.77 (-0.20, 11.74)	0.0584	
	Age (years)									0.9596
	<= 65	61/348 (17.5)	17.5	38/362 (10.5)	10.5	1.66 (1.13, 2.44)	0.0095	6.93 (1.42, 12.44)	0.0136	
	> 65	3/ 12 (25.0)	26.1	0/ 4 (0.0)	0.0	1.58 (0.22, 11.26)	0.6499	26.14 (-27.46, 79.73)	0.3391	
	Sex									0.6495
	male	3/ 27 (11.1)	11.0	2/ 25 (8.0)	8.3	1.19 (0.25, 5.69)	0.8291	2.75 (-18.59, 24.10)	0.8003	
	female	61/333 (18.3)	18.3	36/341 (10.6)	10.6	1.73 (1.17, 2.54)	0.0056	7.67 (1.97, 13.38)	0.0084	
	Race									0.6590
	White	44/235 (18.7)	18.5	26/244 (10.7)	10.5	1.71 (1.08, 2.71)	0.0234	7.99 (1.12, 14.85)	0.0226	
	Black	5/ 46 (10.9)	13.0	1/ 48 (2.1)	2.4	2.57 (0.31, 21.11)	0.3810	10.54 (-3.31, 24.39)	0.1360	
	Other	15/ 71 (21.1)	21.1	11/ 66 (16.7)	16.6	1.22 (0.61, 2.44)	0.5644	4.50 (-9.25, 18.26)	0.5209	
	Ethnicity									0.1320
	Hispanic/Latino	20/ 86 (23.3)	23.4	7/ 89 (7.9)	7.9	2.91 (1.30, 6.53)	0.0096	15.48 (3.67, 27.28)	0.0102	
	Non-hispanic/Latino	44/266 (16.5)	16.4	31/269 (11.5)	11.6	1.44 (0.93, 2.22)	0.1037	4.82 (-1.64, 11.27)	0.1439	
	Geographic region									0.9861
	EU	8/115 (7.0)	7.0	5/122 (4.1)	4.0	1.72 (0.57, 5.19)	0.3357	3.03 (-4.04, 10.09)	0.4012	
	non-EU	56/245 (22.9)	23.0	33/244 (13.5)	13.6	1.70 (1.15, 2.53)	0.0085	9.45 (2.14, 16.77)	0.0113	
	Onset of disease									0.8948
	Paediatric	5/ 26 (19.2)	19.4	3/ 24 (12.5)	12.3	1.57 (0.42, 5.80)	0.5006	7.10 (-16.51, 30.70)	0.5556	
	Adult	59/334 (17.7)	17.6	35/342 (10.2)	10.3	1.72 (1.16, 2.55)	0.0072	7.29 (1.64, 12.95)	0.0114	
	ADA result									0.3830
	Negative	63/334 (18.9)	18.7	35/331 (10.6)	10.5	1.76 (1.19, 2.59)	0.0046	8.18 (2.40, 13.96)	0.0055	
	Positive (At any time)	1/ 25 (4.0)	5.2	3/ 35 (8.6)	8.1	0.76 (0.12, 4.76)	0.7731	-2.84 (-22.46, 16.79)	0.7768	
	BMI (kg/m2) at enrolment									0.8862
	< 30	35/233 (15.0)	14.9	25/261 (9.6)	9.7	1.56 (0.96, 2.52)	0.0722	5.15 (-1.30, 11.60)	0.1177	
	>= 30	29/127 (22.8)	23.2	13/105 (12.4)	12.5	1.65 (0.87, 3.13)	0.1260	10.72 (0.07, 21.38)	0.0485	

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Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
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Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
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Summary of Incidence and Time to First Frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SOC: Musculoskeletal and connective tissue disorders, PT: Arthralgia	SLEDAI-2K score at screening									0.0405
	< 10 points	5/109 (4.6)	4.7	6/106 (5.7)	5.7	0.82 (0.26, 2.62)	0.7364	-1.00 (-9.95, 7.94)	0.8257	
	>= 10 points	16/251 (6.4)	6.4	3/260 (1.2)	1.2	4.88 (1.40, 17.02)	0.0130	5.23 (0.64, 9.83)	0.0256	
	OCS dose at baseline									0.8111
	<10 mg/day	10/170 (5.9)	6.0	5/181 (2.8)	2.8	2.07 (0.71, 6.06)	0.1828	3.22 (-3.10, 9.55)	0.3181	
	>=10 mg/day	11/190 (5.8)	5.9	4/185 (2.2)	2.2	2.51 (0.80, 7.86)	0.1142	3.69 (-1.99, 9.36)	0.2033	
	Result of type I IFN gene signature test									0.1648
	LOW	4/ 62 (6.5)	6.5	4/ 64 (6.3)	6.2	1.01 (0.25, 4.04)	0.9899	0.20 (-10.81, 11.22)	0.9711	
	HIGH	17/298 (5.7)	5.8	5/302 (1.7)	1.7	3.38 (1.25, 9.08)	0.0160	4.10 (-0.25, 8.45)	0.0645	
	Age (years)									0.0852
	<= 65	21/348 (6.0)	6.1	8/362 (2.2)	2.2	2.49 (1.09, 5.69)	0.0301	3.91 (-0.23, 8.05)	0.0642	
	> 65	0/ 12 (0.0)	0.0	1/ 4 (25.0)	23.9	0.17 (0.01, 3.24)	0.2366	-23.86 (-77.50, 29.77)	0.3832	
	Sex									0.8037
	male	2/ 27 (7.4)	7.4	0/ 25 (0.0)	0.0	2.81 (0.31, 25.36)	0.3581	7.44 (-11.70, 26.58)	0.4462	
	female	19/333 (5.7)	5.8	9/341 (2.6)	2.7	2.09 (0.95, 4.60)	0.0685	3.11 (-1.17, 7.40)	0.1547	
	Race									0.2138
	White	15/235 (6.4)	6.5	4/244 (1.6)	1.6	3.84 (1.29, 11.43)	0.0158	4.95 (-0.26, 10.17)	0.0627	
	Black	1/ 46 (2.2)	1.9	3/ 48 (6.3)	6.0	0.50 (0.07, 3.73)	0.4998	-4.03 (-16.65, 8.58)	0.5312	
	Other	5/ 71 (7.0)	7.0	2/ 66 (3.0)	3.0	2.03 (0.47, 8.73)	0.3405	4.02 (-5.88, 13.93)	0.4259	
	Ethnicity									0.5391
	Hispanic/Latino	1/ 86 (1.2)	1.1	1/ 89 (1.1)	1.0	1.00 (0.06, 15.58)	1.0000	0.03 (-8.03, 8.09)	0.9943	
	Non-hispanic/Latino	20/266 (7.5)	7.6	8/269 (3.0)	3.1	2.45 (1.09, 5.52)	0.0302	4.56 (-0.72, 9.84)	0.0904	
	Geographic region									0.2739
	EU	5/115 (4.3)	4.4	0/122 (0.0)	0.0	6.16 (0.75, 50.59)	0.0904	4.37 (-1.32, 10.07)	0.1324	
	non-EU	16/245 (6.5)	6.6	9/244 (3.7)	3.6	1.75 (0.78, 3.93)	0.1743	3.02 (-2.57, 8.62)	0.2894	
	Onset of disease									0.8084
	Paediatric	2/ 26 (7.7)	7.7	0/ 24 (0.0)	0.0	2.79 (0.31, 25.19)	0.3599	7.72 (-12.05, 27.49)	0.4443	
	Adult	19/334 (5.7)	5.8	9/342 (2.6)	2.6	2.09 (0.95, 4.62)	0.0676	3.12 (-1.16, 7.40)	0.1528	
	ADA result									0.0357
	Negative	21/334 (6.3)	6.4	5/331 (1.5)	1.6	3.44 (1.27, 9.29)	0.0150	4.80 (0.51, 9.09)	0.0283	
	Positive (At any time)	0/ 25 (0.0)	0.0	4/ 35 (11.4)	11.9	0.29 (0.04, 2.33)	0.2434	-11.94 (-31.26, 7.38)	0.2257	
	BMI (kg/m2) at enrolment									0.2142
	< 30	12/233 (5.2)	5.2	3/261 (1.1)	1.2	3.34 (1.00, 11.17)	0.0506	3.96 (-0.92, 8.84)	0.1118	
	>= 30	9/127 (7.1)	7.1	6/105 (5.7)	5.3	1.23 (0.44, 3.39)	0.6924	1.85 (-6.99, 10.69)	0.6813	

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SOC / PT	Subgroup Level	Anifrolumab 300mg (N=360) n/ N (%)	Response rate	Placebo (N=366) n/ N (%)	Response rate	Analysis Anifrolumab 300mg vs. Placebo: Relative Risk (95% CI)	p-Value	Difference in response rates (95% CI)	p-Value	Interaction p-Value
SOC: Psychiatric disorders, PT: Insomnia	SLEDAI-2K score at screening									0.6558
	< 10 points	2/109 (1.8)	1.8	8/106 (7.5)	7.5	0.31 (0.08, 1.26)	0.1011	-5.70 (-14.55, 3.15)	0.2070	
	>= 10 points	4/251 (1.6)	1.7	9/260 (3.5)	3.4	0.47 (0.14, 1.53)	0.2089	-1.75 (-6.03, 2.52)	0.4212	
	OCS dose at baseline									0.8550
	<10 mg/day	4/170 (2.4)	2.4	10/181 (5.5)	5.4	0.43 (0.14, 1.35)	0.1483	-2.98 (-9.23, 3.26)	0.3491	
	>=10 mg/day	2/190 (1.1)	1.1	7/185 (3.8)	3.8	0.36 (0.08, 1.55)	0.1709	-2.79 (-8.04, 2.46)	0.2979	
	Result of type I IFN gene signature test									0.7904
	LOW	1/ 62 (1.6)	1.6	3/ 64 (4.7)	4.7	0.50 (0.07, 3.74)	0.4973	-3.07 (-12.74, 6.60)	0.5332	
	HIGH	5/298 (1.7)	1.7	14/302 (4.6)	4.6	0.37 (0.13, 1.01)	0.0517	-2.90 (-7.10, 1.30)	0.1762	
	Age (years)									0.3255
	<= 65	5/348 (1.4)	1.5	17/362 (4.7)	4.7	0.31 (0.12, 0.84)	0.0215	-3.23 (-7.13, 0.67)	0.1050	
	> 65	1/ 12 (8.3)	10.2	0/ 4 (0.0)	0.0	1.50 (0.08, 29.15)	0.7888	10.23 (-42.20, 62.65)	0.7022	
	Sex									0.8418
	male	0/ 27 (0.0)	0.0	1/ 25 (4.0)	4.1	0.29 (0.01, 6.60)	0.4388	-4.13 (-22.67, 14.40)	0.6621	
	female	6/333 (1.8)	1.8	16/341 (4.7)	4.7	0.41 (0.16, 1.05)	0.0621	-2.89 (-6.98, 1.21)	0.1668	
	Race									0.8013
	White	3/235 (1.3)	1.4	8/244 (3.3)	3.1	0.40 (0.11, 1.47)	0.1667	-1.70 (-6.45, 3.04)	0.4823	
	Black	1/ 46 (2.2)	1.9	5/ 48 (10.4)	10.8	0.27 (0.05, 1.60)	0.1496	-8.89 (-22.54, 4.76)	0.2017	
	Other	2/ 71 (2.8)	2.8	3/ 66 (4.5)	4.5	0.64 (0.10, 3.96)	0.6346	-1.72 (-11.07, 7.63)	0.7181	
	Ethnicity									0.9054
	Hispanic/Latino	1/ 86 (1.2)	1.2	4/ 89 (4.5)	4.5	0.37 (0.06, 2.39)	0.2981	-3.27 (-12.06, 5.53)	0.4665	
	Non-hispanic/Latino	5/266 (1.9)	1.8	12/269 (4.5)	4.5	0.42 (0.15, 1.19)	0.1047	-2.65 (-7.49, 2.19)	0.2831	
	Geographic region									0.2642
	EU	2/115 (1.7)	1.7	2/122 (1.6)	1.7	1.03 (0.15, 7.22)	0.9727	0.06 (-5.38, 5.50)	0.9833	
	non-EU	4/245 (1.6)	1.7	15/244 (6.1)	6.1	0.29 (0.09, 0.88)	0.0291	-4.34 (-9.69, 1.01)	0.1121	
	Onset of disease									NE
	Paediatric	0/ 26 (0.0)	0.0	0/ 24 (0.0)	0.0	NE		0.00 (-18.15, 18.15)	1.0000	
	Adult	6/334 (1.8)	1.8	17/342 (5.0)	5.0	0.38 (0.15, 0.96)	0.0402	-3.15 (-7.27, 0.96)	0.1328	
	ADA result									0.2203
	Negative	5/334 (1.5)	1.5	16/331 (4.8)	4.8	0.32 (0.12, 0.86)	0.0233	-3.33 (-7.46, 0.79)	0.1129	
	Positive (At any time)	1/ 25 (4.0)	3.4	1/ 35 (2.9)	2.1	1.43 (0.16, 12.98)	0.7490	1.34 (-16.79, 19.47)	0.8850	
	BMI (kg/m2) at enrolment									0.1735
	< 30	5/233 (2.1)	2.2	9/261 (3.4)	3.5	0.64 (0.21, 1.89)	0.4167	-1.24 (-6.05, 3.57)	0.6137	
	>= 30	1/127 (0.8)	0.9	8/105 (7.6)	7.1	0.15 (0.03, 0.87)	0.0340	-6.27 (-14.59, 2.05)	0.1394	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Serious Adverse Events by SOC, PT (incidence in either arm >= 5% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Infections and infestations	Number of subjects with events, n (%)	16 (4.4)	24 (6.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.68 (0.37, 1.26)	
	p-value	0.2195	
	Odds Ratio (95% CI)	0.66 (0.35, 1.27)	
	p-value	0.2180	
	Risk Difference (95% CI)	-2.11 (-5.42, 1.20)	
	p-value	0.2114	
	CMH approach		
	Response rate	4.4	6.5
	Difference in response rates (95% CI)	-2.09 (-6.42, 2.23)	
	p-value	0.3431	
	p-Value for test for heterogenity between studies	0.6779	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Serious Adverse Events by SOC, PT (incidence in either arm >= 5% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Musculoskeletal and connective tissue disorders	Number of subjects with events, n (%)	8 (2.2)	12 (3.3)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.73 (0.29, 1.86)	
	p-value	0.5070	
	Odds Ratio (95% CI)	0.72 (0.28, 1.87)	
	p-value	0.4982	
	Risk Difference (95% CI)	-1.06 (-3.44, 1.33)	
	p-value	0.3850	
	CMH approach		
	Response rate	2.2	3.3
	Difference in response rates (95% CI)	-1.13 (-4.94, 2.69)	
	p-value	0.5627	
	p-Value for test for heterogenity between studies	0.1456	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Serious Adverse Events by SOC, PT (incidence in either arm >= 5% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Musculoskeletal and connective tissue disorders, PT: Systemic lupus erythematosus	Number of subjects with events, n (%)	5 (1.4)	11 (3.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.53 (0.18, 1.60)	
	p-value	0.2595	
	Odds Ratio (95% CI)	0.52 (0.17, 1.60)	
	p-value	0.2537	
	Risk Difference (95% CI)	-1.62 (-3.74, 0.51)	
	p-value	0.1369	
	CMH approach		
	Response rate	1.4	3.1
	Difference in response rates (95% CI)	-1.68 (-5.36, 2.01)	
	p-value	0.3734	
	p-Value for test for heterogenity between studies	0.2110	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Serious Adverse Events by SOC, PT (incidence in either arm >= 5% or >=10 patients) - Subgroup analysis
Full analysis set

- NO OBSERVATIONS FOR THIS ANALYSIS -

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Severe (Grade >=3) by SOC, PT (incidence in either arm >= 5% or >=10 patients)
Full analysis set

SOC / PT		Anifrolumab 300mg (N=360)	Placebo (N=366)
SOC: Infections and infestations	Number of subjects with events, n (%)	12 (3.3)	10 (2.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.22 (0.54, 2.79)	
	p-value	0.6308	
	Odds Ratio (95% CI)	1.23 (0.52, 2.90)	
	p-value	0.6330	
	Risk Difference (95% CI)	0.61 (-1.88, 3.10)	
	p-value	0.6317	
	CMH approach		
	Response rate	3.3	2.7
	Difference in response rates (95% CI)	0.56 (-3.28, 4.40)	
	p-value	0.7741	
	p-Value for test for heterogenity between studies	0.7821	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and Time to First Frequent Severe (Grade >=3) by SOC, PT (incidence in either arm >= 5% or >=10 patients) - Subgroup analysis
Full analysis set

- NO OBSERVATIONS FOR THIS ANALYSIS -

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 84 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
The responder rates (percentages), the difference in estimates and associated 95% CI are weighted and are calculated using a stratified CMH approach, with stratification factors.
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Stratification factors for CMH approach: Study [Tulip1, Tulip2], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Subject disposition and summary of treatment exposure
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

		Anifrolumab 300mg (N=99)	Placebo (N=102)
Patients who completed the study		84 (84.8)	77 (75.5)
Patients withdrawn from the study		15 (15.2)	25 (24.5)
OTHER		13 (13.1)	20 (19.6)
LOST TO FOLLOW-UP		2 (2.0)	4 (3.9)
ADVERSE EVENT		0	1 (1.0)
Duration of study (weeks)	n (missing)	99 (0)	102 (0)
	Mean (SD)	57.5 (11.52)	51.7 (16.31)
	Median	60.3	60.1
	Min, Max	6, 71	4, 71
Patients who completed investigational product		87 (87.9)	71 (69.6)
Patients discontinued investigational product		12 (12.1)	31 (30.4)
Withdrawal Of Consent		3 (3.0)	13 (12.7)
Adverse Event		2 (2.0)	8 (7.8)
Sponsor Decision, Regional Political Circumstances Preclude Site Activities		0	3 (2.9)
Lost To Follow-Up		0	2 (2.0)
Inadequate Venous Access.		1 (1.0)	0
Investigator Decision Due To Exacerbation Of Her Disease.		0	1 (1.0)
Lack Of Efficacy		1 (1.0)	0
Medical Decision, The Patient Has Been Presenting Various Infections In A Relatively Short Amount Of Time.		1 (1.0)	0
Patient Is Moving Away		0	1 (1.0)
Patient Withdrawn Consent, She Has Decided To Finish Treatment And Participation In The Study Due To Sae.		1 (1.0)	0
Pregnancy		0	1 (1.0)
Prohibited Concomitant Medications (Steroid Pulses)		1 (1.0)	0
Subject Called Did Not Want To Come In And See The Pi Any Longer Has Found A New Doctor. She Never Said She Wanted To Withdraw Consent.		0	1 (1.0)
Subject Complete The Treatment Period, However This Patient Missed Dose For Visit Day 337		0	1 (1.0)
Subject Missed Visit Day 337, But Was Approved To Continue On Study By Sponsor And Completed Remaining Visits.		1 (1.0)	0
The Patient Left The Country		1 (1.0)	0
Duration of exposure (weeks)	n (missing)	99 (0)	102 (0)
	Mean (SD)	49.2 (10.59)	43.6 (15.17)
	Median	52.1	52.1
	Min, Max	4, 55	4, 54

Duration of study defined as time from randomization until end of participation date.
Duration of exposure defined as difference of date of first exposure to treatment and date of last exposure to treatment + 28 days.
'Full Analysis Set' Referred to as 'mITT population' in the study 1013 CSR

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Demographic and baseline characteristics
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

		Anifrolumab 300mg (N=99)	Placebo (N=102)	Total (N=201)
Age	n (missing)	99 (0)	102 (0)	201 (0)
	Mean (SD)	39.1 (11.93)	39.3 (12.89)	39.2 (12.40)
	Median	38.0	39.0	38.0
	Min, Max	19, 65	18, 65	18, 65
Age (years) (%)	<= 65	99 (100.0)	102 (100.0)	201 (100.0)
Sex (%) (%)	female	93 (93.9)	93 (91.2)	186 (92.5)
	male	6 (6.1)	9 (8.8)	15 (7.5)
Race (%) (%)	American Indian or Alaska Native	4 (4.0)	0	4 (2.0)
	Asian	3 (3.0)	13 (12.7)	16 (8.0)
	Black or African American	19 (19.2)	12 (11.8)	31 (15.4)
	Other	38 (38.4)	36 (35.3)	74 (36.8)
	White	35 (35.4)	41 (40.2)	76 (37.8)
Ethnicity (%) (%)	Hispanic/Latino	46 (46.5)	42 (41.2)	88 (43.8)
	Non-hispanic/Latino	53 (53.5)	60 (58.8)	113 (56.2)
Geographic region (%) (%)	Asia Pacific	2 (2.0)	10 (9.8)	12 (6.0)
	Europe	20 (20.2)	25 (24.5)	45 (22.4)
	Latin America	39 (39.4)	37 (36.3)	76 (37.8)
	North America	37 (37.4)	28 (27.5)	65 (32.3)
	Rest Of World	1 (1.0)	2 (2.0)	3 (1.5)
Geographic region subgroup (%)	EU	20 (20.2)	25 (24.5)	45 (22.4)
	non-EU	79 (79.8)	77 (75.5)	156 (77.6)
Height (cm)	n (missing)	99 (0)	102 (0)	201 (0)
	Mean (SD)	161.57 (8.539)	161.22 (8.072)	161.39 (8.287)
	Median	162.00	160.00	161.00
	Min, Max	137.2, 188.0	142.0, 182.0	137.2, 188.0
Weight (kg)	n (missing)	99 (0)	102 (0)	201 (0)
	Mean (SD)	69.54 (17.152)	68.13 (19.068)	68.82 (18.118)
	Median	67.59	64.60	65.00
	Min, Max	44.7, 132.9	40.0, 139.3	40.0, 139.3
BMI (kg/m2)	n (missing)	99 (0)	102 (0)	201 (0)
	Mean (SD)	26.58 (5.866)	26.12 (6.639)	26.34 (6.259)
	Median	25.72	24.95	25.34
	Min, Max	17.0, 44.6	16.1, 46.7	16.1, 46.7
BMI subgroup (%)	<=28 kg/m2	62 (62.6)	75 (73.5)	137 (68.2)
	>28 kg/m2	37 (37.4)	27 (26.5)	64 (31.8)

[a] Asia Pacific: Australia, New Zealand, South Korea, Taiwan. Europe: Germany, Hungary, Italy, Poland, Romania, Ukraine, United Kingdom. Latin America: Argentinia, Brazil, Chile, Colombia, Peru. Rest of World: India, Israel, South Africa.
Missing/multiple categories checked for Race grouped as 'Other'.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
SLE disease characteristics
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

		Anifrolumab 300mg (N=99)	Placebo (N=102)	Total (N=201)
SLEDAI-2K score at screening	n (missing)	99 (0)	102 (0)	201 (0)
	Mean (SD)	10.6 (3.57)	11.0 (4.45)	10.8 (4.03)
	Median	10.0	10.0	10.0
	Min, Max	6, 24	6, 37	6, 37
SLEDAI-2K score at screening, categorisation (%)	<10	39 (39.4)	40 (39.2)	79 (39.3)
	>=10	60 (60.6)	62 (60.8)	122 (60.7)
Clinical SLEDAI-2K score at screening	n (missing)	99 (0)	102 (0)	201 (0)
	Mean (SD)	8.8 (2.56)	8.9 (2.83)	8.9 (2.70)
	Median	8.0	8.0	8.0
	Min, Max	4, 18	4, 21	4, 21
SLEDAI-2K score at baseline	n (missing)	99 (0)	102 (0)	201 (0)
	Mean (SD)	10.7 (3.73)	11.1 (4.35)	10.9 (4.05)
	Median	10.0	10.0	10.0
	Min, Max	6, 24	6, 29	6, 29
SLEDAI-2K score at baseline, categorisation (%)	<10	40 (40.4)	41 (40.2)	81 (40.3)
	>=10	59 (59.6)	61 (59.8)	120 (59.7)
Clinical SLEDAI-2K score at baseline	n (missing)	99 (0)	102 (0)	201 (0)
	Mean (SD)	8.9 (2.48)	9.0 (2.88)	9.0 (2.68)
	Median	8.0	8.0	8.0
	Min, Max	6, 18	4, 20	4, 20
Adjudication Scoring (BILAG) at baseline Overall (%)	At least one A	52 (52.5)	49 (48.0)	101 (50.2)
	No A and <2Bs	6 (6.1)	5 (4.9)	11 (5.5)
	No A and at least 2 Bs	41 (41.4)	48 (47.1)	89 (44.3)
Adjudication Scoring (BILAG) at baseline Constitutional (%)	A	1 (1.0)	1 (1.0)	2 (1.0)
	B	6 (6.1)	10 (9.8)	16 (8.0)
	C, D or E	92 (92.9)	91 (89.2)	183 (91.0)
Adjudication Scoring (BILAG) at baseline Mucocutaneous (%)	A	22 (22.2)	18 (17.6)	40 (19.9)
	B	62 (62.6)	69 (67.6)	131 (65.2)
	C, D or E	15 (15.2)	15 (14.7)	30 (14.9)
Adjudication Scoring (BILAG) at baseline Neuropsychiatric (%)	B	0	2 (2.0)	2 (1.0)
	C, D or E	99 (100.0)	100 (98.0)	199 (99.0)
Adjudication Scoring (BILAG) at baseline Musculoskeletal (%)	A	36 (36.4)	29 (28.4)	65 (32.3)
	B	58 (58.6)	66 (64.7)	124 (61.7)
	C, D or E	5 (5.1)	7 (6.9)	12 (6.0)
Adjudication Scoring (BILAG) at baseline Cardiorespiratory (%)	B	4 (4.0)	8 (7.8)	12 (6.0)
	C, D or E	95 (96.0)	94 (92.2)	189 (94.0)
Adjudication Scoring (BILAG) at baseline Gastrointestinal (%)	C, D or E	99 (100.0)	102 (100.0)	201 (100.0)
Adjudication Scoring (BILAG) at baseline Ophthalmic (%)	B	1 (1.0)	0	1 (0.5)
	C, D or E	98 (99.0)	102 (100.0)	200 (99.5)
Adjudication Scoring (BILAG) at baseline Renal (%)	A	1 (1.0)	2 (2.0)	3 (1.5)
	B	10 (10.1)	9 (8.8)	19 (9.5)
	C, D or E	88 (88.9)	91 (89.2)	179 (89.1)
Adjudication Scoring (BILAG) at baseline Haematological (%)	B	0	4 (3.9)	4 (2.0)
	C, D or E	99 (100.0)	98 (96.1)	197 (98.0)

Baseline is defined as the last measurement prior to randomisation and dose administration on Day 1.
Only subjects with baseline positive anti-dsDNA and abnormal complement level, respectively, are included in the summary statistics for the respective variables.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
SLE disease characteristics
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

		Anifrolumab 300mg (N=99)	Placebo (N=102)	Total (N=201)
BILAG-2004 global score at baseline	n (missing)	99 (0)	102 (0)	201 (0)
	Mean (SD)	19.6 (5.73)	19.8 (5.76)	19.7 (5.73)
	Median	18.0	20.0	20.0
	Min, Max	9, 36	2, 36	2, 36
Physician Global Assessment (PGA) score at baseline	n (missing)	99 (0)	102 (0)	201 (0)
	Mean (SD)	1.9 (0.39)	1.8 (0.44)	1.8 (0.42)
	Median	1.9	1.8	1.9
	Min, Max	1, 3	1, 3	1, 3
CLASI activity score at baseline	n (missing)	99 (0)	102 (0)	201 (0)
	Mean (SD)	7.5 (6.30)	6.7 (5.08)	7.1 (5.72)
	Median	5.0	5.0	5.0
	Min, Max	1, 36	0, 26	0, 36
CLASI activity score at baseline, categorisation 1 (%)	0	0	1 (1.0)	1 (0.5)
	> 0	99 (100.0)	101 (99.0)	200 (99.5)
CLASI activity score at baseline, categorisation 2 (%)	<10	72 (72.7)	76 (74.5)	148 (73.6)
	>=10	27 (27.3)	26 (25.5)	53 (26.4)
CLASI damage score at baseline	n (missing)	99 (0)	102 (0)	201 (0)
	Mean (SD)	2.1 (4.40)	2.5 (5.95)	2.3 (5.23)
	Median	0.0	0.0	0.0
	Min, Max	0, 25	0, 37	0, 37
CLASI damage score at baseline, categorisation 1 (%)	0	67 (67.7)	70 (68.6)	137 (68.2)
	> 0	32 (32.3)	32 (31.4)	64 (31.8)
CLASI damage score at baseline, categorisation 2 (%)	<10	93 (93.9)	93 (91.2)	186 (92.5)
	>=10	6 (6.1)	9 (8.8)	15 (7.5)
Tender Joint Count at Baseline	n (missing)	99 (0)	102 (0)	201 (0)
	Mean (SD)	12.2 (7.10)	10.5 (7.44)	11.3 (7.31)
	Median	11.0	8.0	10.0
	Min, Max	2, 28	0, 28	0, 28
Tender Joint Count at Baseline, categorisation (%)	0	0	4 (3.9)	4 (2.0)
	> 0	99 (100.0)	98 (96.1)	197 (98.0)
Swollen Joint Count at Baseline	n (missing)	99 (0)	102 (0)	201 (0)
	Mean (SD)	8.6 (6.04)	8.3 (6.35)	8.4 (6.19)
	Median	7.0	6.0	7.0
	Min, Max	0, 25	0, 26	0, 26
Swollen Joint Count at Baseline, categorisation (%)	0	3 (3.0)	4 (3.9)	7 (3.5)
	> 0	96 (97.0)	98 (96.1)	194 (96.5)
Active Joint Count at Baseline	n (missing)	99 (0)	102 (0)	201 (0)
	Mean (SD)	11.4 (7.19)	10.0 (7.00)	10.7 (7.11)
	Median	11.0	7.5	10.0
	Min, Max	0, 28	0, 28	0, 28
Active Joint Count at Baseline, categorisation (%)	0	4 (4.0)	4 (3.9)	8 (4.0)
	> 0	95 (96.0)	98 (96.1)	193 (96.0)
SDI global score at baseline	n (missing)	99 (0)	102 (0)	201 (0)
	Mean (SD)	0.7 (0.96)	0.7 (1.21)	0.7 (1.09)
	Median	0.0	0.0	0.0
	Min, Max	0, 3	0, 7	0, 7

Baseline is defined as the last measurement prior to randomisation and dose administration on Day 1.
Only subjects with baseline positive anti-dsDNA and abnormal complement level, respectively, are included in the summary statistics for the respective variables.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
SLE disease characteristics
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

		Anifrolumab 300mg (N=99)	Placebo (N=102)	Total (N=201)
SDI global score at baseline, categorisation (%)	0 (no damage)	62 (62.6)	66 (64.7)	128 (63.7)
	>=1 (damage)	37 (37.4)	36 (35.3)	73 (36.3)
Time from initial SLE diagnosis to randomisation (months)	n (missing)	99 (0)	102 (0)	201 (0)
	Mean (SD)	95.9 (76.77)	90.6 (86.29)	93.2 (81.58)
	Median	71.4	65.8	67.0
	Min, Max	7, 361	7, 404	7, 404
Cushingoid features (%)	Any Cushingoid Feature	45 (45.5)	40 (39.2)	85 (42.3)
	Moon Face	30 (30.3)	22 (21.6)	52 (25.9)
	Buffalo Hump	12 (12.1)	10 (9.8)	22 (10.9)
	Purple or Violaceous Striae	6 (6.1)	5 (4.9)	11 (5.5)
	Central Obesity	20 (20.2)	11 (10.8)	31 (15.4)
	Hirsutisim	8 (8.1)	6 (5.9)	14 (7.0)
	Acne	5 (5.1)	8 (7.8)	13 (6.5)
	Easy Bruising	27 (27.3)	20 (19.6)	47 (23.4)
	Fragile Skin	21 (21.2)	18 (17.6)	39 (19.4)
Results of 4-gene Type 1 Interferon (IFN) test (%)	High	75 (75.8)	76 (74.5)	151 (75.1)
	Low	24 (24.2)	26 (25.5)	50 (24.9)
Anti-dsDNA levels at baseline	n (missing)	56 (0)	66 (0)	122 (0)
	Mean (SD)	139.7 (209.76)	140.7 (206.28)	140.2 (207.02)
	Median	54.5	46.5	49.5
	Min, Max	14, 814	14, 890	14, 890
Anti-dsDNA levels at baseline, categorisation (%)	Negative	21 (21.2)	16 (15.7)	37 (18.4)
	Positive	56 (56.6)	66 (64.7)	122 (60.7)
	Missing	22 (22.2)	20 (19.6)	42 (20.9)
ANA (%)	Abnormal (titre >= 1:80)	98 (99.0)	99 (97.1)	197 (98.0)
	Normal (titre < 1:80)	1 (1.0)	3 (2.9)	4 (2.0)
Complement C3 level at baseline	n (missing)	28 (0)	43 (0)	71 (0)
	Mean (SD)	0.67 (0.172)	0.69 (0.154)	0.68 (0.161)
	Median	0.70	0.72	0.71
	Min, Max	0.2, 0.9	0.3, 0.9	0.2, 0.9
Complement C3 level at baseline, categorisation (%)	Abnormal	28 (28.3)	43 (42.2)	71 (35.3)
	Normal	71 (71.7)	59 (57.8)	130 (64.7)
Complement C4 level at baseline	n (missing)	21 (0)	25 (0)	46 (0)
	Mean (SD)	0.06 (0.027)	0.07 (0.019)	0.07 (0.023)
	Median	0.07	0.07	0.07
	Min, Max	0.0, 0.1	0.0, 0.1	0.0, 0.1
Complement C4 level at baseline, categorisation (%)	Abnormal	21 (21.2)	25 (24.5)	46 (22.9)
	Normal	78 (78.8)	77 (75.5)	155 (77.1)
Complement CH50 level at baseline	n (missing)	13 (0)	13 (0)	26 (0)
	Mean (SD)	38.73 (32.432)	51.50 (30.627)	45.12 (31.584)
	Median	33.00	55.00	37.50
	Min, Max	2.5, 94.0	2.5, 98.0	2.5, 98.0
Complement CH50 level at baseline, categorisation (%)	Abnormal	13 (13.1)	13 (12.7)	26 (12.9)
	Normal	86 (86.9)	89 (87.3)	175 (87.1)

Baseline is defined as the last measurement prior to randomisation and dose administration on Day 1.
Only subjects with baseline positive anti-dsDNA and abnormal complement level, respectively, are included in the summary statistics for the respective variables.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Observation times for Efficacy endpoints
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

		Anifrolumab 300mg (N=99)	Placebo (N=102)
SRI4: Observation time (weeks)	n (missing)	99 (0)	102 (0)
	Mean (SD)	49.3 (10.30)	43.5 (15.30)
	Median	52.1	52.1
	Min, Max	6, 57	4, 54
CLASI activity score: Observation time (weeks)	n (missing)	99 (0)	102 (0)
	Mean (SD)	49.3 (10.30)	43.5 (15.30)
	Median	52.1	52.1
	Min, Max	6, 57	4, 54
CLASI damage score: Observation time (weeks)	n (missing)	99 (0)	102 (0)
	Mean (SD)	49.3 (10.30)	43.5 (15.30)
	Median	52.1	52.1
	Min, Max	6, 57	4, 54
BICLA: Observation time (weeks)	n (missing)	99 (0)	102 (0)
	Mean (SD)	49.3 (10.30)	43.0 (15.87)
	Median	52.1	52.1
	Min, Max	6, 57	0, 54
SLEDAI-2K Total Score: Observation time (weeks)	n (missing)	99 (0)	102 (0)
	Mean (SD)	49.3 (10.30)	43.5 (15.30)
	Median	52.1	52.1
	Min, Max	6, 57	4, 54
PGA: Observation time (weeks)	n (missing)	99 (0)	102 (0)
	Mean (SD)	49.3 (10.30)	43.5 (15.30)
	Median	52.1	52.1
	Min, Max	6, 57	4, 54
BILAG Global Score: Observation time (weeks)	n (missing)	99 (0)	102 (0)
	Mean (SD)	49.3 (10.30)	43.5 (15.30)
	Median	52.1	52.1
	Min, Max	6, 57	4, 54
Tender Joint Count: Observation time (weeks)	n (missing)	99 (0)	102 (0)
	Mean (SD)	49.3 (10.30)	43.5 (15.30)
	Median	52.1	52.1
	Min, Max	6, 57	4, 54
Swollen Joint Count: Observation time (weeks)	n (missing)	99 (0)	102 (0)
	Mean (SD)	49.3 (10.30)	43.5 (15.30)
	Median	52.1	52.1
	Min, Max	6, 57	4, 54
FACIT-F Total Score: Observation time (weeks)	n (missing)	99 (0)	102 (0)
	Mean (SD)	49.0 (10.75)	42.4 (16.13)
	Median	52.1	52.1
	Min, Max	4, 57	4, 54
SF-36 v2.0 Acute - Mental Component Score: Observation time (weeks)	n (missing)	99 (0)	102 (0)
	Mean (SD)	49.0 (10.75)	42.4 (16.13)
	Median	52.1	52.1
	Min, Max	4, 57	4, 54
SF-36 v2.0 Acute - Physical Component Score: Observation time (weeks)	n (missing)	99 (0)	102 (0)
	Mean (SD)	49.0 (10.75)	42.4 (16.13)
	Median	52.1	52.1
	Min, Max	4, 57	4, 54
EQ-5D VAS Score: Observation time (weeks)	n (missing)	99 (0)	102 (0)

Observation duration defined as time from randomization until last non-missing assessment after randomization. Subjects without assessment are censored at day 1.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Observation times for Efficacy endpoints
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

		Anifrolumab 300mg (N=99)	Placebo (N=102)
EQ-5D VAS Score: Observation time (weeks)	Mean (SD)	49.0 (10.75)	42.4 (16.13)
	Median	52.1	52.1
	Min, Max	4, 57	4, 54
SDI Global Score: Observation time (weeks)	n (missing)	99 (0)	102 (0)
	Mean (SD)	47.8 (13.07)	40.3 (19.30)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
PtGA: Observation time (weeks)	n (missing)	99 (0)	102 (0)
	Mean (SD)	49.4 (10.25)	43.5 (15.30)
	Median	52.1	52.1
	Min, Max	6, 57	4, 54

Observation duration defined as time from randomization until last non-missing assessment after randomization. Subjects without assessment are censored at day 1.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=99)	Placebo (N=102)
Week 4	Number of subjects with events, n (%)	10 (10.1)	12 (11.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.87 (0.37, 2.09)	
	p-value	0.7620	
	Odds Ratio (95% CI)	0.86 (0.35, 2.15)	
	p-value	0.7530	
	Risk Difference (95% CI)	-1.37 (-9.92, 7.17)	
	p-value	0.7528	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.86 (0.39, 1.90)	
	p-value	0.7061	
	Odds Ratio (95% CI)	0.84 (0.35, 2.05)	
	p-value	0.7059	
	Risk Difference (95% CI)	-1.66 (-10.29, 6.96)	
	p-value	0.7053	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=99)	Placebo (N=102)
Week 8	Number of subjects with events, n (%)	28 (28.3)	32 (31.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.90 (0.58, 1.40)	
	p-value	0.6403	
	Odds Ratio (95% CI)	0.86 (0.47, 1.58)	
	p-value	0.6373	
	Risk Difference (95% CI)	-3.09 (-15.95, 9.76)	
	p-value	0.6374	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.90 (0.59, 1.38)	
	p-value	0.6327	
	Odds Ratio (95% CI)	0.86 (0.47, 1.58)	
	p-value	0.6324	
	Risk Difference (95% CI)	-3.09 (-15.73, 9.55)	
	p-value	0.6319	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=99)	Placebo (N=102)
Week 12	Number of subjects with events, n (%)	40 (40.4)	43 (42.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	0.99 (0.70, 1.39)	
	p-value	0.9381	
	Odds Ratio (95% CI)	0.98 (0.56, 1.72)	
	p-value	0.9371	
	Risk Difference (95% CI)	-0.56 (-14.35, 13.24)	
	p-value	0.9371	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	0.96 (0.69, 1.33)	
	p-value	0.8009	
	Odds Ratio (95% CI)	0.93 (0.53, 1.63)	
	p-value	0.8008	
	Risk Difference (95% CI)	-1.75 (-15.36, 11.86)	
	p-value	0.8007	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=99)	Placebo (N=102)
Week 16	Number of subjects with events, n (%)	49 (49.5)	43 (42.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.19 (0.88, 1.61)	
	p-value	0.2642	
	Odds Ratio (95% CI)	1.39 (0.78, 2.48)	
	p-value	0.2584	
	Risk Difference (95% CI)	7.82 (-5.66, 21.30)	
	p-value	0.2555	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.17 (0.87, 1.59)	
	p-value	0.2978	
	Odds Ratio (95% CI)	1.34 (0.77, 2.35)	
	p-value	0.2969	
	Risk Difference (95% CI)	7.34 (-6.40, 21.08)	
	p-value	0.2953	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=99)	Placebo (N=102)
Week 20	Number of subjects with events, n (%)	53 (53.5)	44 (43.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.25 (0.93, 1.68)	
	p-value	0.1351	
	Odds Ratio (95% CI)	1.55 (0.88, 2.72)	
	p-value	0.1306	
	Risk Difference (95% CI)	10.69 (-3.05, 24.42)	
	p-value	0.1272	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.24 (0.93, 1.66)	
	p-value	0.1426	
	Odds Ratio (95% CI)	1.52 (0.87, 2.65)	
	p-value	0.1410	
	Risk Difference (95% CI)	10.40 (-3.35, 24.14)	
	p-value	0.1381	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=99)	Placebo (N=102)
Week 24	Number of subjects with events, n (%)	53 (53.5)	41 (40.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.34 (0.99, 1.83)	
	p-value	0.0602	
	Odds Ratio (95% CI)	1.73 (0.99, 3.04)	
	p-value	0.0563	
	Risk Difference (95% CI)	13.65 (-0.16, 27.45)	
	p-value	0.0527	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.33 (0.99, 1.80)	
	p-value	0.0608	
	Odds Ratio (95% CI)	1.71 (0.98, 3.00)	
	p-value	0.0589	
	Risk Difference (95% CI)	13.34 (-0.34, 27.02)	
	p-value	0.0559	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=99)	Placebo (N=102)
Week 28	Number of subjects with events, n (%)	56 (56.6)	42 (41.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.37 (1.03, 1.83)	
	p-value	0.0300	
	Odds Ratio (95% CI)	1.91 (1.07, 3.39)	
	p-value	0.0283	
	Risk Difference (95% CI)	15.37 (1.87, 28.87)	
	p-value	0.0256	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.37 (1.03, 1.83)	
	p-value	0.0314	
	Odds Ratio (95% CI)	1.86 (1.06, 3.26)	
	p-value	0.0297	
	Risk Difference (95% CI)	15.39 (1.73, 29.05)	
	p-value	0.0272	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=99)	Placebo (N=102)
Week 32	Number of subjects with events, n (%)	57 (57.6)	45 (44.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.32 (1.00, 1.74)	
	p-value	0.0518	
	Odds Ratio (95% CI)	1.77 (1.00, 3.14)	
	p-value	0.0497	
	Risk Difference (95% CI)	13.86 (0.24, 27.48)	
	p-value	0.0461	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.31 (0.99, 1.72)	
	p-value	0.0589	
	Odds Ratio (95% CI)	1.72 (0.98, 3.00)	
	p-value	0.0571	
	Risk Difference (95% CI)	13.46 (-0.24, 27.16)	
	p-value	0.0541	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=99)	Placebo (N=102)
Week 36	Number of subjects with events, n (%)	56 (56.6)	42 (41.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.39 (1.04, 1.86)	
	p-value	0.0243	
	Odds Ratio (95% CI)	1.96 (1.10, 3.48)	
	p-value	0.0228	
	Risk Difference (95% CI)	16.03 (2.53, 29.52)	
	p-value	0.0200	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.37 (1.03, 1.83)	
	p-value	0.0314	
	Odds Ratio (95% CI)	1.86 (1.06, 3.26)	
	p-value	0.0297	
	Risk Difference (95% CI)	15.39 (1.73, 29.05)	
	p-value	0.0272	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=99)	Placebo (N=102)
Week 40	Number of subjects with events, n (%)	59 (59.6)	39 (38.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.60 (1.18, 2.17)	
	p-value	0.0022	
	Odds Ratio (95% CI)	2.56 (1.43, 4.60)	
	p-value	0.0017	
	Risk Difference (95% CI)	22.37 (9.04, 35.70)	
	p-value	0.0010	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.56 (1.16, 2.09)	
	p-value	0.0032	
	Odds Ratio (95% CI)	2.38 (1.35, 4.20)	
	p-value	0.0027	
	Risk Difference (95% CI)	21.36 (7.86, 34.87)	
	p-value	0.0019	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=99)	Placebo (N=102)
Week 44	Number of subjects with events, n (%)	59 (59.6)	43 (42.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.45 (1.09, 1.93)	
	p-value	0.0115	
	Odds Ratio (95% CI)	2.15 (1.20, 3.85)	
	p-value	0.0097	
	Risk Difference (95% CI)	18.32 (4.88, 31.76)	
	p-value	0.0075	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.41 (1.07, 1.87)	
	p-value	0.0151	
	Odds Ratio (95% CI)	2.02 (1.15, 3.55)	
	p-value	0.0139	
	Risk Difference (95% CI)	17.44 (3.83, 31.05)	
	p-value	0.0120	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=99)	Placebo (N=102)
Week 48	Number of subjects with events, n (%)	60 (60.6)	41 (40.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.54 (1.15, 2.05)	
	p-value	0.0033	
	Odds Ratio (95% CI)	2.48 (1.37, 4.48)	
	p-value	0.0026	
	Risk Difference (95% CI)	21.16 (7.93, 34.38)	
	p-value	0.0017	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.51 (1.13, 2.01)	
	p-value	0.0048	
	Odds Ratio (95% CI)	2.29 (1.30, 4.03)	
	p-value	0.0041	
	Risk Difference (95% CI)	20.41 (6.88, 33.94)	
	p-value	0.0031	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=99)	Placebo (N=102)
Week 52	Number of subjects with events, n (%)	62 (62.6)	41 (40.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.62 (1.21, 2.16)	
	p-value	0.0012	
	Odds Ratio (95% CI)	2.74 (1.52, 4.94)	
	p-value	0.0008	
	Risk Difference (95% CI)	23.92 (10.65, 37.18)	
	p-value	0.0004	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.56 (1.18, 2.06)	
	p-value	0.0020	
	Odds Ratio (95% CI)	2.49 (1.41, 4.40)	
	p-value	0.0016	
	Risk Difference (95% CI)	22.43 (8.96, 35.90)	
	p-value	0.0011	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate at week 52 - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=102) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.0558
< 10 points	22/ 39 (56.4)	20/ 40 (50.0)	1.13 (0.75, 1.71)	0.5688	
>= 10 points	40/ 60 (66.7)	21/ 62 (33.9)	1.97 (1.33, 2.91)	0.0007	
OCS dose					0.1960
<10 mg/day	25/ 44 (56.8)	10/ 38 (26.3)	2.16 (1.20, 3.90)	0.0107	
>=10 mg/day	37/ 55 (67.3)	31/ 64 (48.4)	1.39 (1.02, 1.90)	0.0396	
Result of type I IFN gene signature test					0.3855
LOW	17/ 24 (70.8)	14/ 26 (53.8)	1.32 (0.85, 2.04)	0.2207	
HIGH	45/ 75 (60.0)	27/ 76 (35.5)	1.69 (1.18, 2.41)	0.0038	
Age (years)					0.2115
<= 45	43/ 67 (64.2)	33/ 72 (45.8)	1.40 (1.03, 1.91)	0.0323	
> 45	19/ 32 (59.4)	8/ 30 (26.7)	2.23 (1.15, 4.30)	0.0173	
Sex					0.0356
male	3/ 6 (50.0)	7/ 9 (77.8)	0.64 (0.27, 1.54)	0.3212	
female	59/ 93 (63.4)	34/ 93 (36.6)	1.74 (1.27, 2.36)	0.0005	
Race					0.9331
White	23/ 35 (65.7)	16/ 41 (39.0)	1.68 (1.07, 2.64)	0.0236	
Black	10/ 19 (52.6)	4/ 12 (33.3)	1.58 (0.64, 3.91)	0.3235	
Other	29/ 45 (64.4)	21/ 49 (42.9)	1.50 (1.02, 2.22)	0.0400	
Ethnicity					0.0861
Hispanic/Latino	29/ 46 (63.0)	22/ 42 (52.4)	1.20 (0.84, 1.73)	0.3177	
Non-hispanic/Latino	33/ 53 (62.3)	19/ 60 (31.7)	1.97 (1.28, 3.01)	0.0019	
Geographic region					0.5355
Latin America, Eastern Europe and Asia	40/ 62 (64.5)	32/ 74 (43.2)	1.49 (1.08, 2.05)	0.0142	
North America	22/ 37 (59.5)	9/ 28 (32.1)	1.85 (1.01, 3.37)	0.0446	
Baseline weight					0.0514
<60 kg	23/ 32 (71.9)	12/ 39 (30.8)	2.34 (1.39, 3.92)	0.0013	
>=60 kg	39/ 67 (58.2)	29/ 63 (46.0)	1.26 (0.90, 1.77)	0.1705	
Low CH50					0.0546
Yes	5/ 13 (38.5)	7/ 13 (53.8)	0.71 (0.30, 1.67)	0.4390	
No	57/ 86 (66.3)	34/ 89 (38.2)	1.73 (1.28, 2.35)	0.0004	
Low C3 or C4					0.8950
Yes	20/ 33 (60.6)	18/ 47 (38.3)	1.58 (1.00, 2.50)	0.0482	
No	42/ 66 (63.6)	23/ 55 (41.8)	1.52 (1.06, 2.18)	0.0227	
Baseline FARR anti-dsDNA					0.4683
<5 IU/mL	14/ 21 (66.7)	9/ 16 (56.3)	1.19 (0.70, 2.01)	0.5278	
>=5 IU/mL	32/ 56 (57.1)	25/ 66 (37.9)	1.51 (1.03, 2.21)	0.0355	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.7994
Yes	42/ 70 (60.0)	31/ 81 (38.3)	1.57 (1.12, 2.19)	0.0088	
No	20/ 29 (69.0)	10/ 21 (47.6)	1.45 (0.87, 2.41)	0.1552	
OCS use					0.7566
Yes	52/ 79 (65.8)	36/ 88 (40.9)	1.61 (1.20, 2.17)	0.0017	
No	10/ 20 (50.0)	5/ 14 (35.7)	1.40 (0.61, 3.20)	0.4259	
SLICC score					0.1939
0	40/ 62 (64.5)	31/ 66 (47.0)	1.37 (1.00, 1.88)	0.0489	
>=1	22/ 37 (59.5)	10/ 36 (27.8)	2.14 (1.19, 3.86)	0.0115	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
SRI (8) response rate at week 52
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=99)	Placebo (N=102)
Week 52	Number of subjects with events, n (%)	32 (32.3)	16 (15.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	2.18 (1.26, 3.77)	
	p-value	0.0054	
	Odds Ratio (95% CI)	2.80 (1.38, 5.68)	
	p-value	0.0044	
	Risk Difference (95% CI)	17.53 (6.05, 29.01)	
	p-value	0.0028	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	2.06 (1.21, 3.51)	
	p-value	0.0078	
	Odds Ratio (95% CI)	2.57 (1.30, 5.07)	
	p-value	0.0066	
	Risk Difference (95% CI)	16.64 (5.03, 28.24)	
	p-value	0.0050	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
SRI (8) response rate at week 52 - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=102) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.9908
< 10 points	8/ 39 (20.5)	4/ 40 (10.0)	2.05 (0.67, 6.26)	0.2071	
>= 10 points	24/ 60 (40.0)	12/ 62 (19.4)	2.07 (1.14, 3.75)	0.0168	
OCS dose					0.3714
<10 mg/day	14/ 44 (31.8)	4/ 38 (10.5)	3.02 (1.09, 8.41)	0.0341	
>=10 mg/day	18/ 55 (32.7)	12/ 64 (18.8)	1.75 (0.92, 3.29)	0.0857	
Result of type I IFN gene signature test					0.0785
LOW	5/ 24 (20.8)	6/ 26 (23.1)	0.90 (0.32, 2.58)	0.8485	
HIGH	27/ 75 (36.0)	10/ 76 (13.2)	2.74 (1.43, 5.25)	0.0025	
Age (years)					0.2734
<= 45	23/ 67 (34.3)	14/ 72 (19.4)	1.77 (0.99, 3.14)	0.0527	
> 45	9/ 32 (28.1)	2/ 30 (6.7)	4.22 (0.99, 17.97)	0.0515	
Sex					0.8112
male	1/ 6 (16.7)	1/ 9 (11.1)	1.50 (0.11, 19.64)	0.7573	
female	31/ 93 (33.3)	15/ 93 (16.1)	2.07 (1.20, 3.57)	0.0091	
Race					0.9893
White	10/ 35 (28.6)	6/ 41 (14.6)	1.95 (0.79, 4.83)	0.1478	
Black	7/ 19 (36.8)	2/ 12 (16.7)	2.21 (0.55, 8.92)	0.2652	
Other	15/ 45 (33.3)	8/ 49 (16.3)	2.04 (0.96, 4.35)	0.0645	
Ethnicity					0.3913
Hispanic/Latino	14/ 46 (30.4)	8/ 42 (19.0)	1.60 (0.75, 3.42)	0.2276	
Non-hispanic/Latino	18/ 53 (34.0)	8/ 60 (13.3)	2.55 (1.21, 5.37)	0.0141	
Geographic region					0.5888
Latin America, Eastern Europe and Asia	21/ 62 (33.9)	11/ 74 (14.9)	2.28 (1.19, 4.35)	0.0126	
North America	11/ 37 (29.7)	5/ 28 (17.9)	1.66 (0.65, 4.25)	0.2859	
Baseline weight					0.1624
<60 kg	16/ 32 (50.0)	6/ 39 (15.4)	3.25 (1.44, 7.33)	0.0045	
>=60 kg	16/ 67 (23.9)	10/ 63 (15.9)	1.50 (0.74, 3.06)	0.2604	
Low CH50					0.0963
Yes	3/ 13 (23.1)	4/ 13 (30.8)	0.75 (0.21, 2.71)	0.6607	
No	29/ 86 (33.7)	12/ 89 (13.5)	2.50 (1.37, 4.58)	0.0029	
Low C3 or C4					0.5140
Yes	11/ 33 (33.3)	9/ 47 (19.1)	1.74 (0.81, 3.72)	0.1530	
No	21/ 66 (31.8)	7/ 55 (12.7)	2.50 (1.15, 5.44)	0.0208	
Baseline FARR anti-dsDNA					0.6822
<5 IU/mL	6/ 21 (28.6)	3/ 16 (18.8)	1.52 (0.45, 5.18)	0.4999	
>=5 IU/mL	19/ 56 (33.9)	11/ 66 (16.7)	2.04 (1.06, 3.91)	0.0325	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.9300
Yes	23/ 70 (32.9)	13/ 81 (16.0)	2.05 (1.12, 3.73)	0.0193	
No	9/ 29 (31.0)	3/ 21 (14.3)	2.17 (0.67, 7.07)	0.1974	
OCS use					0.6047
Yes	27/ 79 (34.2)	15/ 88 (17.0)	2.01 (1.15, 3.49)	0.0137	
No	5/ 20 (25.0)	1/ 14 (7.1)	3.50 (0.46, 26.80)	0.2277	
SLICC score					0.4196
0	20/ 62 (32.3)	12/ 66 (18.2)	1.77 (0.95, 3.32)	0.0727	
>=1	12/ 37 (32.4)	4/ 36 (11.1)	2.92 (1.04, 8.21)	0.0424	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
>=4 reduction in SLEDAI-2K at week 52
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=99)	Placebo (N=102)
Week 52	Number of subjects with events, n (%)	62 (62.6)	41 (40.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.62 (1.21, 2.16)	
	p-value	0.0012	
	Odds Ratio (95% CI)	2.74 (1.52, 4.94)	
	p-value	0.0008	
	Risk Difference (95% CI)	23.92 (10.65, 37.18)	
	p-value	0.0004	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.56 (1.18, 2.06)	
	p-value	0.0020	
	Odds Ratio (95% CI)	2.49 (1.41, 4.40)	
	p-value	0.0016	
	Risk Difference (95% CI)	22.43 (8.96, 35.90)	
	p-value	0.0011	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
>=4 reduction in SLEDAI-2K at week 52 - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=102) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	 p-Value	Interaction p-Value
SLEDAI-2K score					0.0558
< 10 points	22/ 39 (56.4)	20/ 40 (50.0)	1.13 (0.75, 1.71)	0.5688	
>= 10 points	40/ 60 (66.7)	21/ 62 (33.9)	1.97 (1.33, 2.91)	0.0007	
OCS dose					0.1960
<10 mg/day	25/ 44 (56.8)	10/ 38 (26.3)	2.16 (1.20, 3.90)	0.0107	
>=10 mg/day	37/ 55 (67.3)	31/ 64 (48.4)	1.39 (1.02, 1.90)	0.0396	
Result of type I IFN gene signature test					0.3855
LOW	17/ 24 (70.8)	14/ 26 (53.8)	1.32 (0.85, 2.04)	0.2207	
HIGH	45/ 75 (60.0)	27/ 76 (35.5)	1.69 (1.18, 2.41)	0.0038	
Age (years)					0.2115
<= 45	43/ 67 (64.2)	33/ 72 (45.8)	1.40 (1.03, 1.91)	0.0323	
> 45	19/ 32 (59.4)	8/ 30 (26.7)	2.23 (1.15, 4.30)	0.0173	
Sex					0.0356
male	3/ 6 (50.0)	7/ 9 (77.8)	0.64 (0.27, 1.54)	0.3212	
female	59/ 93 (63.4)	34/ 93 (36.6)	1.74 (1.27, 2.36)	0.0005	
Race					0.9331
White	23/ 35 (65.7)	16/ 41 (39.0)	1.68 (1.07, 2.64)	0.0236	
Black	10/ 19 (52.6)	4/ 12 (33.3)	1.58 (0.64, 3.91)	0.3235	
Other	29/ 45 (64.4)	21/ 49 (42.9)	1.50 (1.02, 2.22)	0.0400	
Ethnicity					0.0861
Hispanic/Latino	29/ 46 (63.0)	22/ 42 (52.4)	1.20 (0.84, 1.73)	0.3177	
Non-hispanic/Latino	33/ 53 (62.3)	19/ 60 (31.7)	1.97 (1.28, 3.01)	0.0019	
Geographic region					0.5355
Latin America, Eastern Europe and Asia	40/ 62 (64.5)	32/ 74 (43.2)	1.49 (1.08, 2.05)	0.0142	
North America	22/ 37 (59.5)	9/ 28 (32.1)	1.85 (1.01, 3.37)	0.0446	
Baseline weight					0.0514
<60 kg	23/ 32 (71.9)	12/ 39 (30.8)	2.34 (1.39, 3.92)	0.0013	
>=60 kg	39/ 67 (58.2)	29/ 63 (46.0)	1.26 (0.90, 1.77)	0.1705	
Low CH50					0.0546
Yes	5/ 13 (38.5)	7/ 13 (53.8)	0.71 (0.30, 1.67)	0.4390	
No	57/ 86 (66.3)	34/ 89 (38.2)	1.73 (1.28, 2.35)	0.0004	
Low C3 or C4					0.8950
Yes	20/ 33 (60.6)	18/ 47 (38.3)	1.58 (1.00, 2.50)	0.0482	
No	42/ 66 (63.6)	23/ 55 (41.8)	1.52 (1.06, 2.18)	0.0227	
Baseline FARR anti-dsDNA					0.4683
<5 IU/mL	14/ 21 (66.7)	9/ 16 (56.3)	1.19 (0.70, 2.01)	0.5278	
>=5 IU/mL	32/ 56 (57.1)	25/ 66 (37.9)	1.51 (1.03, 2.21)	0.0355	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.7994
Yes	42/ 70 (60.0)	31/ 81 (38.3)	1.57 (1.12, 2.19)	0.0088	
No	20/ 29 (69.0)	10/ 21 (47.6)	1.45 (0.87, 2.41)	0.1552	
OCS use					0.7566
Yes	52/ 79 (65.8)	36/ 88 (40.9)	1.61 (1.20, 2.17)	0.0017	
No	10/ 20 (50.0)	5/ 14 (35.7)	1.40 (0.61, 3.20)	0.4259	
SLICC score					0.1939
0	40/ 62 (64.5)	31/ 66 (47.0)	1.37 (1.00, 1.88)	0.0489	
>=1	22/ 37 (59.5)	10/ 36 (27.8)	2.14 (1.19, 3.86)	0.0115	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
>=8 reduction in SLEDAI-2K at week 52
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=99)	Placebo (N=102)
Week 52	Number of subjects with events, n (%)	32 (32.3)	16 (15.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	2.18 (1.26, 3.77)	
	p-value	0.0054	
	Odds Ratio (95% CI)	2.80 (1.38, 5.68)	
	p-value	0.0044	
	Risk Difference (95% CI)	17.53 (6.05, 29.01)	
	p-value	0.0028	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	2.06 (1.21, 3.51)	
	p-value	0.0078	
	Odds Ratio (95% CI)	2.57 (1.30, 5.07)	
	p-value	0.0066	
	Risk Difference (95% CI)	16.64 (5.03, 28.24)	
	p-value	0.0050	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
>=8 reduction in SLEDAI-2K at week 52 - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=102) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.9908
< 10 points	8/ 39 (20.5)	4/ 40 (10.0)	2.05 (0.67, 6.26)	0.2071	
>= 10 points	24/ 60 (40.0)	12/ 62 (19.4)	2.07 (1.14, 3.75)	0.0168	
OCS dose					0.3714
<10 mg/day	14/ 44 (31.8)	4/ 38 (10.5)	3.02 (1.09, 8.41)	0.0341	
>=10 mg/day	18/ 55 (32.7)	12/ 64 (18.8)	1.75 (0.92, 3.29)	0.0857	
Result of type I IFN gene signature test					0.0785
LOW	5/ 24 (20.8)	6/ 26 (23.1)	0.90 (0.32, 2.58)	0.8485	
HIGH	27/ 75 (36.0)	10/ 76 (13.2)	2.74 (1.43, 5.25)	0.0025	
Age (years)					0.2734
<= 45	23/ 67 (34.3)	14/ 72 (19.4)	1.77 (0.99, 3.14)	0.0527	
> 45	9/ 32 (28.1)	2/ 30 (6.7)	4.22 (0.99, 17.97)	0.0515	
Sex					0.8112
male	1/ 6 (16.7)	1/ 9 (11.1)	1.50 (0.11, 19.64)	0.7573	
female	31/ 93 (33.3)	15/ 93 (16.1)	2.07 (1.20, 3.57)	0.0091	
Race					0.9893
White	10/ 35 (28.6)	6/ 41 (14.6)	1.95 (0.79, 4.83)	0.1478	
Black	7/ 19 (36.8)	2/ 12 (16.7)	2.21 (0.55, 8.92)	0.2652	
Other	15/ 45 (33.3)	8/ 49 (16.3)	2.04 (0.96, 4.35)	0.0645	
Ethnicity					0.3913
Hispanic/Latino	14/ 46 (30.4)	8/ 42 (19.0)	1.60 (0.75, 3.42)	0.2276	
Non-hispanic/Latino	18/ 53 (34.0)	8/ 60 (13.3)	2.55 (1.21, 5.37)	0.0141	
Geographic region					0.5888
Latin America, Eastern Europe and Asia	21/ 62 (33.9)	11/ 74 (14.9)	2.28 (1.19, 4.35)	0.0126	
North America	11/ 37 (29.7)	5/ 28 (17.9)	1.66 (0.65, 4.25)	0.2859	
Baseline weight					0.1624
<60 kg	16/ 32 (50.0)	6/ 39 (15.4)	3.25 (1.44, 7.33)	0.0045	
>=60 kg	16/ 67 (23.9)	10/ 63 (15.9)	1.50 (0.74, 3.06)	0.2604	
Low CH50					0.0963
Yes	3/ 13 (23.1)	4/ 13 (30.8)	0.75 (0.21, 2.71)	0.6607	
No	29/ 86 (33.7)	12/ 89 (13.5)	2.50 (1.37, 4.58)	0.0029	
Low C3 or C4					0.5140
Yes	11/ 33 (33.3)	9/ 47 (19.1)	1.74 (0.81, 3.72)	0.1530	
No	21/ 66 (31.8)	7/ 55 (12.7)	2.50 (1.15, 5.44)	0.0208	
Baseline FARR anti-dsDNA					0.6822
<5 IU/mL	6/ 21 (28.6)	3/ 16 (18.8)	1.52 (0.45, 5.18)	0.4999	
>=5 IU/mL	19/ 56 (33.9)	11/ 66 (16.7)	2.04 (1.06, 3.91)	0.0325	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.9300
Yes	23/ 70 (32.9)	13/ 81 (16.0)	2.05 (1.12, 3.73)	0.0193	
No	9/ 29 (31.0)	3/ 21 (14.3)	2.17 (0.67, 7.07)	0.1974	
OCS use					0.6047
Yes	27/ 79 (34.2)	15/ 88 (17.0)	2.01 (1.15, 3.49)	0.0137	
No	5/ 20 (25.0)	1/ 14 (7.1)	3.50 (0.46, 26.80)	0.2277	
SLICC score					0.4196
0	20/ 62 (32.3)	12/ 66 (18.2)	1.77 (0.95, 3.32)	0.0727	
>=1	12/ 37 (32.4)	4/ 36 (11.1)	2.92 (1.04, 8.21)	0.0424	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
No worsening in BILAG-2004 (>=1A or >=2B compared to BL) at week 52
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=99)	Placebo (N=102)
Week 52	Number of subjects with events, n (%)	75 (75.8)	61 (59.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.28 (1.06, 1.55)	
	p-value	0.0122	
	Odds Ratio (95% CI)	2.24 (1.20, 4.20)	
	p-value	0.0115	
	Risk Difference (95% CI)	16.68 (4.14, 29.22)	
	p-value	0.0091	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.27 (1.04, 1.54)	
	p-value	0.0170	
	Odds Ratio (95% CI)	2.10 (1.15, 3.85)	
	p-value	0.0165	
	Risk Difference (95% CI)	15.95 (3.23, 28.67)	
	p-value	0.0140	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
No worsening in BILAG-2004 (>=1A or >=2B compared to BL) at week 52 - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=102) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	 p-Value	Interaction p-Value
SLEDAI-2K score					0.1060
< 10 points	30/ 39 (76.9)	29/ 40 (72.5)	1.06 (0.82, 1.37)	0.6514	
>= 10 points	45/ 60 (75.0)	32/ 62 (51.6)	1.45 (1.10, 1.93)	0.0094	
OCS dose					0.7807
<10 mg/day	30/ 44 (68.2)	21/ 38 (55.3)	1.23 (0.87, 1.75)	0.2396	
>=10 mg/day	45/ 55 (81.8)	40/ 64 (62.5)	1.31 (1.04, 1.64)	0.0201	
Result of type I IFN gene signature test					0.7175
LOW	21/ 24 (87.5)	17/ 26 (65.4)	1.34 (0.97, 1.84)	0.0725	
HIGH	54/ 75 (72.0)	44/ 76 (57.9)	1.24 (0.98, 1.58)	0.0726	
Age (years)					0.9955
<= 45	52/ 67 (77.6)	44/ 72 (61.1)	1.27 (1.01, 1.59)	0.0371	
> 45	23/ 32 (71.9)	17/ 30 (56.7)	1.27 (0.87, 1.86)	0.2209	
Sex					0.0441
male	3/ 6 (50.0)	8/ 9 (88.9)	0.56 (0.24, 1.29)	0.1757	
female	72/ 93 (77.4)	53/ 93 (57.0)	1.36 (1.10, 1.67)	0.0039	
Race					0.3850
White	26/ 35 (74.3)	25/ 41 (61.0)	1.22 (0.89, 1.67)	0.2163	
Black	14/ 19 (73.7)	4/ 12 (33.3)	2.21 (0.95, 5.14)	0.0655	
Other	35/ 45 (77.8)	32/ 49 (65.3)	1.19 (0.92, 1.54)	0.1825	
Ethnicity					0.4624
Hispanic/Latino	37/ 46 (80.4)	29/ 42 (69.0)	1.16 (0.91, 1.49)	0.2269	
Non-hispanic/Latino	38/ 53 (71.7)	32/ 60 (53.3)	1.34 (1.00, 1.80)	0.0462	
Geographic region					0.2737
Latin America, Eastern Europe and Asia	48/ 62 (77.4)	48/ 74 (64.9)	1.19 (0.96, 1.48)	0.1066	
North America	27/ 37 (73.0)	13/ 28 (46.4)	1.57 (1.01, 2.45)	0.0457	
Baseline weight					0.2067
<60 kg	27/ 32 (84.4)	22/ 39 (56.4)	1.50 (1.09, 2.05)	0.0119	
>=60 kg	48/ 67 (71.6)	39/ 63 (61.9)	1.16 (0.91, 1.48)	0.2433	
Low CH50					0.1282
Yes	6/ 13 (46.2)	8/ 13 (61.5)	0.75 (0.36, 1.55)	0.4384	
No	69/ 86 (80.2)	53/ 89 (59.6)	1.35 (1.10, 1.65)	0.0036	
Low C3 or C4					0.6126
Yes	21/ 33 (63.6)	26/ 47 (55.3)	1.15 (0.80, 1.66)	0.4508	
No	54/ 66 (81.8)	35/ 55 (63.6)	1.29 (1.02, 1.62)	0.0321	
Baseline FARR anti-dsDNA					0.9724
<5 IU/mL	16/ 21 (76.2)	10/ 16 (62.5)	1.22 (0.78, 1.91)	0.3868	
>=5 IU/mL	41/ 56 (73.2)	40/ 66 (60.6)	1.21 (0.94, 1.55)	0.1398	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.9572
Yes	51/ 70 (72.9)	47/ 81 (58.0)	1.26 (0.99, 1.59)	0.0566	
No	24/ 29 (82.8)	14/ 21 (66.7)	1.24 (0.88, 1.75)	0.2194	
OCS use					0.0684
Yes	63/ 79 (79.7)	51/ 88 (58.0)	1.38 (1.12, 1.70)	0.0029	
No	12/ 20 (60.0)	10/ 14 (71.4)	0.84 (0.52, 1.37)	0.4835	
SLICC score					0.7538
0	49/ 62 (79.0)	42/ 66 (63.6)	1.24 (0.99, 1.55)	0.0568	
>=1	26/ 37 (70.3)	19/ 36 (52.8)	1.33 (0.92, 1.93)	0.1329	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Maintained OCS Reduction at week 52 (for subjects with baseline OCS >=10 mg/day)
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=55)	Placebo (N=64)
Week 52	Number of subjects with events, n (%)	31 (56.4)	17 (26.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	2.08 (1.32, 3.29)	
	p-value	0.0016	
	Odds Ratio (95% CI)	3.57 (1.64, 7.79)	
	p-value	0.0014	
	Risk Difference (95% CI)	29.55 (12.55, 46.54)	
	p-value	0.0007	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	2.12 (1.33, 3.39)	
	p-value	0.0017	
	Odds Ratio (95% CI)	3.57 (1.65, 7.71)	
	p-value	0.0012	
	Risk Difference (95% CI)	29.80 (12.80, 46.80)	
	p-value	0.0006	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Maintained OCS Reduction at week 52 (for subjects with baseline OCS >=10 mg/day) - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=55) n/ N (%)	Placebo (N=64) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.2967
< 10 points	12/ 18 (66.7)	8/ 19 (42.1)	1.58 (0.85, 2.94)	0.1465	
>= 10 points	19/ 37 (51.4)	9/ 45 (20.0)	2.57 (1.32, 4.98)	0.0053	
OCS dose					NE
>=10 mg/day	31/ 55 (56.4)	17/ 64 (26.6)	2.12 (1.33, 3.39)	0.0017	
Result of type I IFN gene signature test					0.2619
LOW	5/ 11 (45.5)	4/ 11 (36.4)	1.25 (0.45, 3.45)	0.6665	
HIGH	26/ 44 (59.1)	13/ 53 (24.5)	2.41 (1.41, 4.10)	0.0012	
Age (years)					0.3685
<= 45	22/ 42 (52.4)	14/ 50 (28.0)	1.87 (1.10, 3.18)	0.0205	
> 45	9/ 13 (69.2)	3/ 14 (21.4)	3.23 (1.11, 9.39)	0.0311	
Sex					0.2505
male	1/ 3 (33.3)	3/ 7 (42.9)	0.78 (0.13, 4.77)	0.7860	
female	30/ 52 (57.7)	14/ 57 (24.6)	2.35 (1.41, 3.92)	0.0011	
Race					0.3244
White	9/ 21 (42.9)	5/ 24 (20.8)	2.06 (0.82, 5.18)	0.1256	
Black	6/ 7 (85.7)	0/ 7 (0.0)	13.00 (0.87, 194.28)	0.0630	
Other	16/ 27 (59.3)	12/ 33 (36.4)	1.63 (0.94, 2.82)	0.0813	
Ethnicity					0.4093
Hispanic/Latino	16/ 29 (55.2)	10/ 32 (31.3)	1.77 (0.96, 3.25)	0.0676	
Non-hispanic/Latino	15/ 26 (57.7)	7/ 32 (21.9)	2.64 (1.27, 5.49)	0.0095	
Geographic region					0.5880
Latin America, Eastern Europe and Asia	25/ 44 (56.8)	15/ 53 (28.3)	2.01 (1.22, 3.31)	0.0063	
North America	6/ 11 (54.5)	2/ 11 (18.2)	3.00 (0.77, 11.74)	0.1146	
Baseline weight					0.7091
<60 kg	11/ 20 (55.0)	6/ 26 (23.1)	2.38 (1.06, 5.34)	0.0347	
>=60 kg	20/ 35 (57.1)	11/ 38 (28.9)	1.97 (1.11, 3.51)	0.0204	
Low CH50					0.8388
Yes	4/ 7 (57.1)	3/ 10 (30.0)	1.90 (0.61, 5.98)	0.2695	
No	27/ 48 (56.3)	14/ 54 (25.9)	2.17 (1.30, 3.63)	0.0032	
Low C3 or C4					0.8722
Yes	12/ 21 (57.1)	8/ 31 (25.8)	2.21 (1.10, 4.47)	0.0266	
No	19/ 34 (55.9)	9/ 33 (27.3)	2.05 (1.09, 3.86)	0.0261	
Baseline FARR anti-dsDNA					0.4698
<5 IU/mL	5/ 7 (71.4)	2/ 9 (22.2)	3.21 (0.87, 11.90)	0.0804	
>=5 IU/mL	18/ 34 (52.9)	12/ 43 (27.9)	1.90 (1.07, 3.37)	0.0292	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.3922
Yes	22/ 42 (52.4)	15/ 54 (27.8)	1.89 (1.12, 3.16)	0.0164	
No	9/ 13 (69.2)	2/ 10 (20.0)	3.46 (0.95, 12.59)	0.0595	
OCS use					NE
Yes	31/ 55 (56.4)	17/ 64 (26.6)	2.12 (1.33, 3.39)	0.0017	
SLICC score					0.3527
0	22/ 38 (57.9)	14/ 45 (31.1)	1.86 (1.11, 3.11)	0.0175	
>=1	9/ 17 (52.9)	3/ 19 (15.8)	3.35 (1.08, 10.39)	0.0360	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
>=50% Reduction in CLASI activity score at week 52 (for subjects with baseline CLASI activity score >=10)
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=27)	Placebo (N=26)
Week 52	Number of subjects with events, n (%)	17 (63.0)	8 (30.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	2.22 (1.12, 4.37)	
	p-value	0.0216	
	Odds Ratio (95% CI)	4.79 (1.38, 16.67)	
	p-value	0.0138	
	Risk Difference (95% CI)	34.88 (10.07, 59.68)	
	p-value	0.0059	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	2.05 (1.07, 3.90)	
	p-value	0.0296	
	Odds Ratio (95% CI)	3.83 (1.22, 11.98)	
	p-value	0.0213	
	Risk Difference (95% CI)	32.19 (6.77, 57.62)	
	p-value	0.0131	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
>=50% Reduction in CLASI activity score at week 52 (for subjects with baseline CLASI activity score >=10) - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=27) n/ N (%)	Placebo (N=26) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	 p-Value	Interaction p-Value
SLEDAI-2K score					0.8176
< 10 points	3/ 6 (50.0)	2/ 7 (28.6)	1.75 (0.42, 7.23)	0.4394	
>= 10 points	14/ 21 (66.7)	6/ 19 (31.6)	2.11 (1.02, 4.37)	0.0442	
OCS dose					0.2972
<10 mg/day	7/ 11 (63.6)	2/ 11 (18.2)	3.50 (0.92, 13.24)	0.0650	
>=10 mg/day	10/ 16 (62.5)	6/ 15 (40.0)	1.56 (0.76, 3.23)	0.2288	
Result of type I IFN gene signature test					NE
LOW	0	1/ 2 (50.0)	NE		
HIGH	17/ 27 (63.0)	7/ 24 (29.2)	2.16 (1.09, 4.29)	0.0282	
Age (years)					0.8607
<= 45	13/ 18 (72.2)	5/ 14 (35.7)	2.02 (0.95, 4.32)	0.0690	
> 45	4/ 9 (44.4)	3/ 12 (25.0)	1.78 (0.52, 6.04)	0.3562	
Sex					0.0157
male	1/ 3 (33.3)	3/ 3 (100.0)	0.33 (0.07, 1.65)	0.1785	
female	16/ 24 (66.7)	5/ 23 (21.7)	3.07 (1.34, 7.00)	0.0078	
Race					0.5106
White	4/ 9 (44.4)	5/ 14 (35.7)	1.24 (0.45, 3.43)	0.6724	
Black	5/ 7 (71.4)	0/ 3 (0.0)	5.50 (0.39, 76.65)	0.2047	
Other	8/ 11 (72.7)	3/ 9 (33.3)	2.18 (0.81, 5.89)	0.1233	
Ethnicity					0.9252
Hispanic/Latino	7/ 10 (70.0)	2/ 6 (33.3)	2.10 (0.63, 6.99)	0.2264	
Non-hispanic/Latino	10/ 17 (58.8)	6/ 20 (30.0)	1.96 (0.90, 4.27)	0.0901	
Geographic region					0.2174
Latin America, Eastern Europe and Asia	11/ 19 (57.9)	8/ 21 (38.1)	1.52 (0.78, 2.96)	0.2184	
North America	6/ 8 (75.0)	0/ 5 (0.0)	8.67 (0.59, 126.98)	0.1149	
Baseline weight					0.0928
<60 kg	8/ 11 (72.7)	1/ 10 (10.0)	7.27 (1.09, 48.35)	0.0401	
>=60 kg	9/ 16 (56.3)	7/ 16 (43.8)	1.29 (0.64, 2.60)	0.4841	
Low CH50					0.1270
Yes	1/ 4 (25.0)	2/ 4 (50.0)	0.50 (0.07, 3.55)	0.4882	
No	16/ 23 (69.6)	6/ 22 (27.3)	2.55 (1.22, 5.31)	0.0124	
Low C3 or C4					0.9667
Yes	7/ 13 (53.8)	4/ 15 (26.7)	2.02 (0.76, 5.37)	0.1593	
No	10/ 14 (71.4)	4/ 11 (36.4)	1.96 (0.84, 4.59)	0.1191	
Baseline FARR anti-dsDNA					0.3141
<5 IU/mL	3/ 4 (75.0)	0/ 3 (0.0)	5.60 (0.39, 79.70)	0.2035	
>=5 IU/mL	11/ 19 (57.9)	8/ 19 (42.1)	1.38 (0.72, 2.64)	0.3384	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.4043
Yes	14/ 23 (60.9)	8/ 23 (34.8)	1.75 (0.91, 3.35)	0.0908	
No	3/ 4 (75.0)	0/ 3 (0.0)	5.60 (0.39, 79.70)	0.2035	
OCS use					0.4704
Yes	15/ 24 (62.5)	6/ 22 (27.3)	2.29 (1.08, 4.85)	0.0301	
No	2/ 3 (66.7)	2/ 4 (50.0)	1.33 (0.38, 4.72)	0.6558	
SLICC score					0.8671
0	10/ 12 (83.3)	4/ 10 (40.0)	2.08 (0.94, 4.64)	0.0722	
>=1	7/ 15 (46.7)	4/ 16 (25.0)	1.87 (0.68, 5.11)	0.2242	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=99)	Placebo (N=102)
Week 4	Number of subjects with events, n (%)	20 (20.2)	20 (19.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.02 (0.57, 1.82)	
	p-value	0.9573	
	Odds Ratio (95% CI)	1.02 (0.51, 2.05)	
	p-value	0.9566	
	Risk Difference (95% CI)	0.31 (-10.81, 11.43)	
	p-value	0.9566	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.03 (0.59, 1.79)	
	p-value	0.9160	
	Odds Ratio (95% CI)	1.04 (0.52, 2.07)	
	p-value	0.9160	
	Risk Difference (95% CI)	0.59 (-10.45, 11.64)	
	p-value	0.9160	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=99)	Placebo (N=102)
Week 8	Number of subjects with events, n (%)	36 (36.4)	30 (29.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.26 (0.84, 1.88)	
	p-value	0.2619	
	Odds Ratio (95% CI)	1.41 (0.77, 2.58)	
	p-value	0.2591	
	Risk Difference (95% CI)	7.52 (-5.45, 20.48)	
	p-value	0.2557	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.24 (0.83, 1.84)	
	p-value	0.2959	
	Odds Ratio (95% CI)	1.37 (0.76, 2.48)	
	p-value	0.2947	
	Risk Difference (95% CI)	6.95 (-6.01, 19.91)	
	p-value	0.2931	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=99)	Placebo (N=102)
Week 12	Number of subjects with events, n (%)	35 (35.4)	28 (27.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.32 (0.87, 2.00)	
	p-value	0.1897	
	Odds Ratio (95% CI)	1.52 (0.82, 2.83)	
	p-value	0.1858	
	Risk Difference (95% CI)	8.58 (-4.00, 21.15)	
	p-value	0.1813	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.29 (0.85, 1.95)	
	p-value	0.2298	
	Odds Ratio (95% CI)	1.45 (0.79, 2.63)	
	p-value	0.2282	
	Risk Difference (95% CI)	7.90 (-4.89, 20.70)	
	p-value	0.2260	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=99)	Placebo (N=102)
Week 16	Number of subjects with events, n (%)	43 (43.4)	28 (27.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.62 (1.09, 2.39)	
	p-value	0.0167	
	Odds Ratio (95% CI)	2.12 (1.16, 3.88)	
	p-value	0.0150	
	Risk Difference (95% CI)	16.57 (3.59, 29.56)	
	p-value	0.0124	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.58 (1.07, 2.33)	
	p-value	0.0203	
	Odds Ratio (95% CI)	2.03 (1.13, 3.66)	
	p-value	0.0185	
	Risk Difference (95% CI)	15.98 (2.93, 29.03)	
	p-value	0.0164	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=99)	Placebo (N=102)
Week 20	Number of subjects with events, n (%)	45 (45.5)	29 (28.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.65 (1.13, 2.41)	
	p-value	0.0095	
	Odds Ratio (95% CI)	2.24 (1.23, 4.09)	
	p-value	0.0084	
	Risk Difference (95% CI)	18.11 (5.06, 31.16)	
	p-value	0.0065	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.60 (1.10, 2.33)	
	p-value	0.0144	
	Odds Ratio (95% CI)	2.10 (1.17, 3.76)	
	p-value	0.0130	
	Risk Difference (95% CI)	17.02 (3.88, 30.17)	
	p-value	0.0112	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=99)	Placebo (N=102)
Week 24	Number of subjects with events, n (%)	45 (45.5)	26 (25.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.84 (1.23, 2.76)	
	p-value	0.0028	
	Odds Ratio (95% CI)	2.63 (1.42, 4.88)	
	p-value	0.0022	
	Risk Difference (95% CI)	20.89 (8.11, 33.66)	
	p-value	0.0014	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.78 (1.20, 2.65)	
	p-value	0.0042	
	Odds Ratio (95% CI)	2.44 (1.34, 4.42)	
	p-value	0.0034	
	Risk Difference (95% CI)	19.96 (7.01, 32.92)	
	p-value	0.0025	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=99)	Placebo (N=102)
Week 28	Number of subjects with events, n (%)	43 (43.4)	32 (31.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.43 (0.99, 2.05)	
	p-value	0.0554	
	Odds Ratio (95% CI)	1.80 (0.99, 3.26)	
	p-value	0.0534	
	Risk Difference (95% CI)	13.14 (0.03, 26.25)	
	p-value	0.0495	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.38 (0.96, 1.99)	
	p-value	0.0803	
	Odds Ratio (95% CI)	1.68 (0.94, 2.99)	
	p-value	0.0781	
	Risk Difference (95% CI)	12.06 (-1.22, 25.34)	
	p-value	0.0751	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=99)	Placebo (N=102)
Week 32	Number of subjects with events, n (%)	47 (47.5)	30 (29.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.63 (1.12, 2.38)	
	p-value	0.0104	
	Odds Ratio (95% CI)	2.17 (1.21, 3.89)	
	p-value	0.0092	
	Risk Difference (95% CI)	18.40 (4.98, 31.83)	
	p-value	0.0072	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.61 (1.12, 2.33)	
	p-value	0.0102	
	Odds Ratio (95% CI)	2.17 (1.21, 3.88)	
	p-value	0.0089	
	Risk Difference (95% CI)	18.06 (4.84, 31.29)	
	p-value	0.0074	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=99)	Placebo (N=102)
Week 36	Number of subjects with events, n (%)	51 (51.5)	30 (29.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.81 (1.27, 2.59)	
	p-value	0.0010	
	Odds Ratio (95% CI)	2.83 (1.54, 5.20)	
	p-value	0.0008	
	Risk Difference (95% CI)	23.39 (10.44, 36.34)	
	p-value	0.0004	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.75 (1.23, 2.50)	
	p-value	0.0020	
	Odds Ratio (95% CI)	2.55 (1.43, 4.56)	
	p-value	0.0016	
	Risk Difference (95% CI)	22.10 (8.87, 35.34)	
	p-value	0.0011	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=99)	Placebo (N=102)
Week 40	Number of subjects with events, n (%)	48 (48.5)	30 (29.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.70 (1.17, 2.45)	
	p-value	0.0049	
	Odds Ratio (95% CI)	2.38 (1.32, 4.31)	
	p-value	0.0042	
	Risk Difference (95% CI)	20.04 (6.84, 33.24)	
	p-value	0.0029	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.65 (1.15, 2.37)	
	p-value	0.0069	
	Odds Ratio (95% CI)	2.26 (1.26, 4.04)	
	p-value	0.0059	
	Risk Difference (95% CI)	19.07 (5.84, 32.31)	
	p-value	0.0047	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=99)	Placebo (N=102)
Week 44	Number of subjects with events, n (%)	42 (42.4)	27 (26.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.64 (1.10, 2.46)	
	p-value	0.0156	
	Odds Ratio (95% CI)	2.14 (1.17, 3.93)	
	p-value	0.0142	
	Risk Difference (95% CI)	16.72 (3.77, 29.68)	
	p-value	0.0114	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.60 (1.08, 2.38)	
	p-value	0.0197	
	Odds Ratio (95% CI)	2.05 (1.13, 3.71)	
	p-value	0.0180	
	Risk Difference (95% CI)	15.95 (2.99, 28.92)	
	p-value	0.0159	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=99)	Placebo (N=102)
Week 48	Number of subjects with events, n (%)	49 (49.5)	30 (29.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.73 (1.20, 2.49)	
	p-value	0.0034	
	Odds Ratio (95% CI)	2.50 (1.37, 4.54)	
	p-value	0.0027	
	Risk Difference (95% CI)	20.91 (7.79, 34.04)	
	p-value	0.0018	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.68 (1.17, 2.41)	
	p-value	0.0047	
	Odds Ratio (95% CI)	2.35 (1.32, 4.20)	
	p-value	0.0039	
	Risk Difference (95% CI)	20.08 (6.85, 33.32)	
	p-value	0.0029	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=99)	Placebo (N=102)
Week 52	Number of subjects with events, n (%)	53 (53.5)	26 (25.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	2.17 (1.47, 3.18)	
	p-value	<.0001	
	Odds Ratio (95% CI)	3.72 (1.99, 6.97)	
	p-value	<.0001	
	Risk Difference (95% CI)	28.80 (16.10, 41.49)	
	p-value	<.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	2.10 (1.44, 3.07)	
	p-value	0.0001	
	Odds Ratio (95% CI)	3.37 (1.86, 6.11)	
	p-value	<.0001	
	Risk Difference (95% CI)	28.05 (15.08, 41.01)	
	p-value	<.0001	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
BICLA response rate at week 52 - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=102) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	 p-Value	Interaction p-Value
SLEDAI-2K score					0.1333
< 10 points	23/ 39 (59.0)	15/ 40 (37.5)	1.57 (0.97, 2.54)	0.0634	
>= 10 points	30/ 60 (50.0)	11/ 62 (17.7)	2.82 (1.56, 5.10)	0.0006	
OCS dose					0.4126
<10 mg/day	22/ 44 (50.0)	7/ 38 (18.4)	2.71 (1.31, 5.64)	0.0075	
>=10 mg/day	31/ 55 (56.4)	19/ 64 (29.7)	1.90 (1.22, 2.96)	0.0046	
Result of type I IFN gene signature test					0.7226
LOW	14/ 24 (58.3)	8/ 26 (30.8)	1.90 (0.97, 3.70)	0.0607	
HIGH	39/ 75 (52.0)	18/ 76 (23.7)	2.20 (1.39, 3.47)	0.0008	
Age (years)					0.1394
<= 45	40/ 67 (59.7)	17/ 72 (23.6)	2.53 (1.60, 4.00)	<.0001	
> 45	13/ 32 (40.6)	9/ 30 (30.0)	1.35 (0.68, 2.70)	0.3882	
Sex					0.6899
male	2/ 6 (33.3)	2/ 9 (22.2)	1.50 (0.28, 7.93)	0.6333	
female	51/ 93 (54.8)	24/ 93 (25.8)	2.13 (1.44, 3.14)	0.0002	
Race					0.8998
White	16/ 35 (45.7)	9/ 41 (22.0)	2.08 (1.05, 4.11)	0.0347	
Black	9/ 19 (47.4)	2/ 12 (16.7)	2.84 (0.74, 10.97)	0.1297	
Other	28/ 45 (62.2)	15/ 49 (30.6)	2.03 (1.26, 3.28)	0.0037	
Ethnicity					0.2921
Hispanic/Latino	26/ 46 (56.5)	14/ 42 (33.3)	1.70 (1.03, 2.79)	0.0374	
Non-hispanic/Latino	27/ 53 (50.9)	12/ 60 (20.0)	2.55 (1.44, 4.51)	0.0013	
Geographic region					0.2115
Latin America, Eastern Europe and Asia	34/ 62 (54.8)	22/ 74 (29.7)	1.84 (1.22, 2.80)	0.0040	
North America	19/ 37 (51.4)	4/ 28 (14.3)	3.59 (1.38, 9.39)	0.0090	
Baseline weight					0.9840
<60 kg	21/ 32 (65.6)	12/ 39 (30.8)	2.13 (1.25, 3.64)	0.0054	
>=60 kg	32/ 67 (47.8)	14/ 63 (22.2)	2.15 (1.27, 3.63)	0.0043	
Low CH50					0.0325
Yes	5/ 13 (38.5)	6/ 13 (46.2)	0.83 (0.34, 2.06)	0.6927	
No	48/ 86 (55.8)	20/ 89 (22.5)	2.48 (1.62, 3.82)	<.0001	
Low C3 or C4					0.4475
Yes	16/ 33 (48.5)	13/ 47 (27.7)	1.75 (0.98, 3.13)	0.0583	
No	37/ 66 (56.1)	13/ 55 (23.6)	2.37 (1.41, 3.99)	0.0012	
Baseline FARR anti-dsDNA					0.3681
<5 IU/mL	12/ 21 (57.1)	3/ 16 (18.8)	3.05 (1.03, 9.02)	0.0441	
>=5 IU/mL	27/ 56 (48.2)	18/ 66 (27.3)	1.77 (1.10, 2.85)	0.0196	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.6491
Yes	36/ 70 (51.4)	21/ 81 (25.9)	1.98 (1.29, 3.06)	0.0019	
No	17/ 29 (58.6)	5/ 21 (23.8)	2.46 (1.08, 5.61)	0.0321	
OCS use					0.3717
Yes	45/ 79 (57.0)	22/ 88 (25.0)	2.28 (1.51, 3.43)	<.0001	
No	8/ 20 (40.0)	4/ 14 (28.6)	1.40 (0.52, 3.76)	0.5040	
SLICC score					0.4553
0	34/ 62 (54.8)	19/ 66 (28.8)	1.90 (1.22, 2.96)	0.0042	
>=1	19/ 37 (51.4)	7/ 36 (19.4)	2.64 (1.27, 5.51)	0.0096	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Change from baseline in PGA VAS < 0.3 at week 52
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=99)	Placebo (N=102)
Week 52	Number of subjects with events, n (%)	76 (76.8)	62 (60.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.29 (1.06, 1.56)	
	p-value	0.0100	
	Odds Ratio (95% CI)	2.31 (1.23, 4.35)	
	p-value	0.0094	
	Risk Difference (95% CI)	17.13 (4.67, 29.59)	
	p-value	0.0070	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.26 (1.04, 1.53)	
	p-value	0.0159	
	Odds Ratio (95% CI)	2.13 (1.16, 3.93)	
	p-value	0.0155	
	Risk Difference (95% CI)	15.98 (3.37, 28.59)	
	p-value	0.0130	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Change from baseline in PGA VAS < 0.3 at week 52 - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=102) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	 p-Value	Interaction p-Value
SLEDAI-2K score					0.0516
< 10 points	30/ 39 (76.9)	30/ 40 (75.0)	1.03 (0.80, 1.31)	0.8415	
>= 10 points	46/ 60 (76.7)	32/ 62 (51.6)	1.49 (1.12, 1.96)	0.0054	
OCS dose					0.7880
<10 mg/day	30/ 44 (68.2)	21/ 38 (55.3)	1.23 (0.87, 1.75)	0.2396	
>=10 mg/day	46/ 55 (83.6)	41/ 64 (64.1)	1.31 (1.05, 1.62)	0.0163	
Result of type I IFN gene signature test					0.6994
LOW	21/ 24 (87.5)	17/ 26 (65.4)	1.34 (0.97, 1.84)	0.0725	
HIGH	55/ 75 (73.3)	45/ 76 (59.2)	1.24 (0.98, 1.56)	0.0697	
Age (years)					0.9408
<= 45	52/ 67 (77.6)	44/ 72 (61.1)	1.27 (1.01, 1.59)	0.0371	
> 45	24/ 32 (75.0)	18/ 30 (60.0)	1.25 (0.88, 1.78)	0.2168	
Sex					0.0450
male	3/ 6 (50.0)	8/ 9 (88.9)	0.56 (0.24, 1.29)	0.1757	
female	73/ 93 (78.5)	54/ 93 (58.1)	1.35 (1.10, 1.66)	0.0036	
Race					0.6267
White	27/ 35 (77.1)	26/ 41 (63.4)	1.22 (0.91, 1.63)	0.1918	
Black	14/ 19 (73.7)	5/ 12 (41.7)	1.77 (0.86, 3.64)	0.1214	
Other	35/ 45 (77.8)	31/ 49 (63.3)	1.23 (0.94, 1.60)	0.1258	
Ethnicity					0.4678
Hispanic/Latino	37/ 46 (80.4)	29/ 42 (69.0)	1.16 (0.91, 1.49)	0.2269	
Non-hispanic/Latino	39/ 53 (73.6)	33/ 60 (55.0)	1.34 (1.01, 1.77)	0.0416	
Geographic region					0.2705
Latin America, Eastern Europe and Asia	49/ 62 (79.0)	49/ 74 (66.2)	1.19 (0.97, 1.47)	0.0942	
North America	27/ 37 (73.0)	13/ 28 (46.4)	1.57 (1.01, 2.45)	0.0457	
Baseline weight					0.1085
<60 kg	28/ 32 (87.5)	22/ 39 (56.4)	1.55 (1.14, 2.11)	0.0048	
>=60 kg	48/ 67 (71.6)	40/ 63 (63.5)	1.13 (0.89, 1.43)	0.3247	
Low CH50					0.1304
Yes	6/ 13 (46.2)	8/ 13 (61.5)	0.75 (0.36, 1.55)	0.4384	
No	70/ 86 (81.4)	54/ 89 (60.7)	1.34 (1.10, 1.63)	0.0032	
Low C3 or C4					0.8886
Yes	22/ 33 (66.7)	25/ 47 (53.2)	1.25 (0.87, 1.80)	0.2199	
No	54/ 66 (81.8)	37/ 55 (67.3)	1.22 (0.98, 1.51)	0.0765	
Baseline FARR anti-dsDNA					0.8962
<5 IU/mL	16/ 21 (76.2)	10/ 16 (62.5)	1.22 (0.78, 1.91)	0.3868	
>=5 IU/mL	42/ 56 (75.0)	42/ 66 (63.6)	1.18 (0.93, 1.49)	0.1741	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.9630
Yes	52/ 70 (74.3)	48/ 81 (59.3)	1.25 (1.00, 1.57)	0.0512	
No	24/ 29 (82.8)	14/ 21 (66.7)	1.24 (0.88, 1.75)	0.2194	
OCS use					0.0693
Yes	64/ 79 (81.0)	52/ 88 (59.1)	1.37 (1.12, 1.68)	0.0024	
No	12/ 20 (60.0)	10/ 14 (71.4)	0.84 (0.52, 1.37)	0.4835	
SLICC score					0.9929
0	50/ 62 (80.6)	42/ 66 (63.6)	1.27 (1.02, 1.58)	0.0343	
>=1	26/ 37 (70.3)	20/ 36 (55.6)	1.26 (0.88, 1.81)	0.2003	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Change from baseline in PGA VAS < 0.45 at week 52
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=99)	Placebo (N=102)
Week 52	Number of subjects with events, n (%)	76 (76.8)	62 (60.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.29 (1.06, 1.56)	
	p-value	0.0100	
	Odds Ratio (95% CI)	2.31 (1.23, 4.35)	
	p-value	0.0094	
	Risk Difference (95% CI)	17.13 (4.67, 29.59)	
	p-value	0.0070	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.26 (1.04, 1.53)	
	p-value	0.0159	
	Odds Ratio (95% CI)	2.13 (1.16, 3.93)	
	p-value	0.0155	
	Risk Difference (95% CI)	15.98 (3.37, 28.59)	
	p-value	0.0130	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Change from baseline in PGA VAS < 0.45 at week 52 - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=102) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.0516
< 10 points	30/ 39 (76.9)	30/ 40 (75.0)	1.03 (0.80, 1.31)	0.8415	
>= 10 points	46/ 60 (76.7)	32/ 62 (51.6)	1.49 (1.12, 1.96)	0.0054	
OCS dose					0.7880
<10 mg/day	30/ 44 (68.2)	21/ 38 (55.3)	1.23 (0.87, 1.75)	0.2396	
>=10 mg/day	46/ 55 (83.6)	41/ 64 (64.1)	1.31 (1.05, 1.62)	0.0163	
Result of type I IFN gene signature test					0.6994
LOW	21/ 24 (87.5)	17/ 26 (65.4)	1.34 (0.97, 1.84)	0.0725	
HIGH	55/ 75 (73.3)	45/ 76 (59.2)	1.24 (0.98, 1.56)	0.0697	
Age (years)					0.9408
<= 45	52/ 67 (77.6)	44/ 72 (61.1)	1.27 (1.01, 1.59)	0.0371	
> 45	24/ 32 (75.0)	18/ 30 (60.0)	1.25 (0.88, 1.78)	0.2168	
Sex					0.0450
male	3/ 6 (50.0)	8/ 9 (88.9)	0.56 (0.24, 1.29)	0.1757	
female	73/ 93 (78.5)	54/ 93 (58.1)	1.35 (1.10, 1.66)	0.0036	
Race					0.6267
White	27/ 35 (77.1)	26/ 41 (63.4)	1.22 (0.91, 1.63)	0.1918	
Black	14/ 19 (73.7)	5/ 12 (41.7)	1.77 (0.86, 3.64)	0.1214	
Other	35/ 45 (77.8)	31/ 49 (63.3)	1.23 (0.94, 1.60)	0.1258	
Ethnicity					0.4678
Hispanic/Latino	37/ 46 (80.4)	29/ 42 (69.0)	1.16 (0.91, 1.49)	0.2269	
Non-hispanic/Latino	39/ 53 (73.6)	33/ 60 (55.0)	1.34 (1.01, 1.77)	0.0416	
Geographic region					0.2705
Latin America, Eastern Europe and Asia	49/ 62 (79.0)	49/ 74 (66.2)	1.19 (0.97, 1.47)	0.0942	
North America	27/ 37 (73.0)	13/ 28 (46.4)	1.57 (1.01, 2.45)	0.0457	
Baseline weight					0.1085
<60 kg	28/ 32 (87.5)	22/ 39 (56.4)	1.55 (1.14, 2.11)	0.0048	
>=60 kg	48/ 67 (71.6)	40/ 63 (63.5)	1.13 (0.89, 1.43)	0.3247	
Low CH50					0.1304
Yes	6/ 13 (46.2)	8/ 13 (61.5)	0.75 (0.36, 1.55)	0.4384	
No	70/ 86 (81.4)	54/ 89 (60.7)	1.34 (1.10, 1.63)	0.0032	
Low C3 or C4					0.8886
Yes	22/ 33 (66.7)	25/ 47 (53.2)	1.25 (0.87, 1.80)	0.2199	
No	54/ 66 (81.8)	37/ 55 (67.3)	1.22 (0.98, 1.51)	0.0765	
Baseline FARR anti-dsDNA					0.8962
<5 IU/mL	16/ 21 (76.2)	10/ 16 (62.5)	1.22 (0.78, 1.91)	0.3868	
>=5 IU/mL	42/ 56 (75.0)	42/ 66 (63.6)	1.18 (0.93, 1.49)	0.1741	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.9630
Yes	52/ 70 (74.3)	48/ 81 (59.3)	1.25 (1.00, 1.57)	0.0512	
No	24/ 29 (82.8)	14/ 21 (66.7)	1.24 (0.88, 1.75)	0.2194	
OCS use					0.0693
Yes	64/ 79 (81.0)	52/ 88 (59.1)	1.37 (1.12, 1.68)	0.0024	
No	12/ 20 (60.0)	10/ 14 (71.4)	0.84 (0.52, 1.37)	0.4835	
SLICC score					0.9929
0	50/ 62 (80.6)	42/ 66 (63.6)	1.27 (1.02, 1.58)	0.0343	
>=1	26/ 37 (70.3)	20/ 36 (55.6)	1.26 (0.88, 1.81)	0.2003	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Major clinical response at week 52
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=99)	Placebo (N=102)
Week 52	Number of subjects with events, n (%)	19 (19.2)	7 (6.9)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	2.81 (1.23, 6.43)	
	p-value	0.0145	
	Odds Ratio (95% CI)	3.24 (1.28, 8.20)	
	p-value	0.0134	
	Risk Difference (95% CI)	12.41 (3.15, 21.68)	
	p-value	0.0087	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	2.80 (1.23, 6.36)	
	p-value	0.0141	
	Odds Ratio (95% CI)	3.22 (1.29, 8.06)	
	p-value	0.0123	
	Risk Difference (95% CI)	12.33 (3.15, 21.51)	
	p-value	0.0085	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Major clinical response at week 52 - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=102) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.1734
< 10 points	8/ 39 (20.5)	5/ 40 (12.5)	1.64 (0.59, 4.58)	0.3443	
>= 10 points	11/ 60 (18.3)	2/ 62 (3.2)	5.68 (1.31, 24.58)	0.0200	
OCS dose					0.3026
<10 mg/day	8/ 44 (18.2)	1/ 38 (2.6)	6.91 (0.90, 52.77)	0.0624	
>=10 mg/day	11/ 55 (20.0)	6/ 64 (9.4)	2.13 (0.84, 5.39)	0.1092	
Result of type I IFN gene signature test					0.1578
LOW	3/ 24 (12.5)	3/ 26 (11.5)	1.08 (0.24, 4.86)	0.9168	
HIGH	16/ 75 (21.3)	4/ 76 (5.3)	4.05 (1.42, 11.56)	0.0089	
Age (years)					0.7919
<= 45	12/ 67 (17.9)	5/ 72 (6.9)	2.58 (0.96, 6.93)	0.0604	
> 45	7/ 32 (21.9)	2/ 30 (6.7)	3.28 (0.74, 14.57)	0.1182	
Sex					0.6172
male	1/ 6 (16.7)	1/ 9 (11.1)	1.50 (0.11, 19.64)	0.7573	
female	18/ 93 (19.4)	6/ 93 (6.5)	3.00 (1.25, 7.22)	0.0142	
Race					0.7823
White	5/ 35 (14.3)	3/ 41 (7.3)	1.95 (0.50, 7.59)	0.3344	
Black	4/ 19 (21.1)	0/ 12 (0.0)	5.85 (0.34, 99.83)	0.2223	
Other	10/ 45 (22.2)	4/ 49 (8.2)	2.72 (0.92, 8.07)	0.0709	
Ethnicity					0.2601
Hispanic/Latino	10/ 46 (21.7)	5/ 42 (11.9)	1.83 (0.68, 4.91)	0.2326	
Non-hispanic/Latino	9/ 53 (17.0)	2/ 60 (3.3)	5.09 (1.15, 22.54)	0.0319	
Geographic region					0.3703
Latin America, Eastern Europe and Asia	11/ 62 (17.7)	6/ 74 (8.1)	2.19 (0.86, 5.58)	0.1010	
North America	8/ 37 (21.6)	1/ 28 (3.6)	6.05 (0.80, 45.64)	0.0806	
Baseline weight					0.5043
<60 kg	7/ 32 (21.9)	4/ 39 (10.3)	2.13 (0.68, 6.64)	0.1913	
>=60 kg	12/ 67 (17.9)	3/ 63 (4.8)	3.76 (1.11, 12.71)	0.0330	
Low CH50					0.4283
Yes	1/ 13 (7.7)	1/ 13 (7.7)	1.00 (0.07, 14.34)	1.0000	
No	18/ 86 (20.9)	6/ 89 (6.7)	3.10 (1.29, 7.45)	0.0112	
Low C3 or C4					0.6535
Yes	5/ 33 (15.2)	2/ 47 (4.3)	3.56 (0.73, 17.26)	0.1148	
No	14/ 66 (21.2)	5/ 55 (9.1)	2.33 (0.90, 6.07)	0.0825	
Baseline FARR anti-dsDNA					0.6103
<5 IU/mL	5/ 21 (23.8)	1/ 16 (6.3)	3.81 (0.49, 29.48)	0.2001	
>=5 IU/mL	7/ 56 (12.5)	4/ 66 (6.1)	2.06 (0.64, 6.68)	0.2275	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.8857
Yes	11/ 70 (15.7)	5/ 81 (6.2)	2.55 (0.93, 6.97)	0.0691	
No	8/ 29 (27.6)	2/ 21 (9.5)	2.90 (0.68, 12.28)	0.1489	
OCS use					0.5130
Yes	15/ 79 (19.0)	7/ 88 (8.0)	2.39 (1.03, 5.55)	0.0434	
No	4/ 20 (20.0)	0/ 14 (0.0)	6.43 (0.37, 110.65)	0.2000	
SLICC score					0.9126
0	10/ 62 (16.1)	4/ 66 (6.1)	2.66 (0.88, 8.05)	0.0830	
>=1	9/ 37 (24.3)	3/ 36 (8.3)	2.92 (0.86, 9.92)	0.0861	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Partial clinical response at week 52
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=99)	Placebo (N=102)
Week 52	Number of subjects with events, n (%)	44 (44.4)	32 (31.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.45 (1.01, 2.09)	
	p-value	0.0443	
	Odds Ratio (95% CI)	1.86 (1.02, 3.37)	
	p-value	0.0422	
	Risk Difference (95% CI)	13.92 (0.79, 27.05)	
	p-value	0.0377	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.42 (0.99, 2.03)	
	p-value	0.0592	
	Odds Ratio (95% CI)	1.75 (0.98, 3.11)	
	p-value	0.0570	
	Risk Difference (95% CI)	13.07 (-0.23, 26.37)	
	p-value	0.0541	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Partial clinical response at week 52 - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=102) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	 p-Value	Interaction p-Value
SLEDAI-2K score					0.0758
< 10 points	19/ 39 (48.7)	19/ 40 (47.5)	1.03 (0.65, 1.62)	0.9137	
>= 10 points	25/ 60 (41.7)	13/ 62 (21.0)	1.99 (1.13, 3.51)	0.0179	
OCS dose					0.5035
<10 mg/day	18/ 44 (40.9)	9/ 38 (23.7)	1.73 (0.88, 3.38)	0.1110	
>=10 mg/day	26/ 55 (47.3)	23/ 64 (35.9)	1.32 (0.86, 2.02)	0.2114	
Result of type I IFN gene signature test					0.0464
LOW	10/ 24 (41.7)	13/ 26 (50.0)	0.83 (0.45, 1.53)	0.5579	
HIGH	34/ 75 (45.3)	19/ 76 (25.0)	1.81 (1.14, 2.88)	0.0116	
Age (years)					0.4683
<= 45	29/ 67 (43.3)	24/ 72 (33.3)	1.30 (0.85, 1.99)	0.2299	
> 45	15/ 32 (46.9)	8/ 30 (26.7)	1.76 (0.87, 3.54)	0.1136	
Sex					0.3359
male	3/ 6 (50.0)	5/ 9 (55.6)	0.90 (0.33, 2.42)	0.8349	
female	41/ 93 (44.1)	27/ 93 (29.0)	1.52 (1.03, 2.25)	0.0366	
Race					0.4320
White	12/ 35 (34.3)	11/ 41 (26.8)	1.28 (0.65, 2.53)	0.4813	
Black	6/ 19 (31.6)	0/ 12 (0.0)	8.45 (0.52, 137.63)	0.1339	
Other	26/ 45 (57.8)	21/ 49 (42.9)	1.35 (0.90, 2.03)	0.1518	
Ethnicity					0.0311
Hispanic/Latino	25/ 46 (54.3)	23/ 42 (54.8)	0.99 (0.68, 1.45)	0.9689	
Non-hispanic/Latino	19/ 53 (35.8)	9/ 60 (15.0)	2.39 (1.18, 4.82)	0.0150	
Geographic region					0.7636
Latin America, Eastern Europe and Asia	31/ 62 (50.0)	26/ 74 (35.1)	1.42 (0.96, 2.12)	0.0817	
North America	13/ 37 (35.1)	6/ 28 (21.4)	1.64 (0.71, 3.77)	0.2449	
Baseline weight					0.3696
<60 kg	16/ 32 (50.0)	11/ 39 (28.2)	1.77 (0.96, 3.26)	0.0654	
>=60 kg	28/ 67 (41.8)	21/ 63 (33.3)	1.25 (0.80, 1.96)	0.3239	
Low CH50					0.5281
Yes	4/ 13 (30.8)	4/ 13 (30.8)	1.00 (0.32, 3.17)	1.0000	
No	40/ 86 (46.5)	28/ 89 (31.5)	1.48 (1.01, 2.16)	0.0445	
Low C3 or C4					0.6543
Yes	13/ 33 (39.4)	12/ 47 (25.5)	1.54 (0.81, 2.94)	0.1883	
No	31/ 66 (47.0)	20/ 55 (36.4)	1.29 (0.84, 1.99)	0.2472	
Baseline FARR anti-dsDNA					0.7532
<5 IU/mL	11/ 21 (52.4)	7/ 16 (43.8)	1.20 (0.60, 2.39)	0.6086	
>=5 IU/mL	21/ 56 (37.5)	18/ 66 (27.3)	1.38 (0.82, 2.31)	0.2293	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.6208
Yes	29/ 70 (41.4)	23/ 81 (28.4)	1.46 (0.94, 2.27)	0.0954	
No	15/ 29 (51.7)	9/ 21 (42.9)	1.21 (0.66, 2.21)	0.5432	
OCS use					0.8242
Yes	37/ 79 (46.8)	29/ 88 (33.0)	1.42 (0.97, 2.08)	0.0694	
No	7/ 20 (35.0)	3/ 14 (21.4)	1.63 (0.51, 5.25)	0.4101	
SLICC score					0.4124
0	29/ 62 (46.8)	24/ 66 (36.4)	1.29 (0.85, 1.95)	0.2346	
>=1	15/ 37 (40.5)	8/ 36 (22.2)	1.82 (0.88, 3.77)	0.1041	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
>=50% Joint reduction at week 52 (for subjects with at least 6 tender joints and at least 6 swollen joints at baseline)
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=58)	Placebo (N=58)
Week 52	Number of subjects with events, n (%)	42 (72.4)	24 (41.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.72 (1.21, 2.44)	
	p-value	0.0024	
	Odds Ratio (95% CI)	4.16 (1.75, 9.85)	
	p-value	0.0012	
	Risk Difference (95% CI)	29.37 (12.82, 45.93)	
	p-value	0.0005	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.75 (1.24, 2.47)	
	p-value	0.0015	
	Odds Ratio (95% CI)	3.72 (1.71, 8.09)	
	p-value	0.0009	
	Risk Difference (95% CI)	31.03 (13.92, 48.15)	
	p-value	0.0004	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
>=50% Joint reduction at week 52 (for subjects with at least 6 tender joints and at least 6 swollen joints at baseline) - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=58) n/ N (%)	Placebo (N=58) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.0942
< 10 points	16/ 20 (80.0)	12/ 19 (63.2)	1.27 (0.84, 1.90)	0.2554	
>= 10 points	26/ 38 (68.4)	12/ 39 (30.8)	2.22 (1.32, 3.73)	0.0025	
OCS dose					0.5696
<10 mg/day	12/ 20 (60.0)	5/ 18 (27.8)	2.16 (0.95, 4.94)	0.0678	
>=10 mg/day	30/ 38 (78.9)	19/ 40 (47.5)	1.66 (1.15, 2.39)	0.0063	
Result of type I IFN gene signature test					0.8745
LOW	13/ 16 (81.3)	8/ 18 (44.4)	1.83 (1.04, 3.22)	0.0372	
HIGH	29/ 42 (69.0)	16/ 40 (40.0)	1.73 (1.12, 2.65)	0.0129	
Age (years)					0.5272
<= 45	29/ 41 (70.7)	17/ 39 (43.6)	1.62 (1.08, 2.44)	0.0200	
> 45	13/ 17 (76.5)	7/ 19 (36.8)	2.08 (1.09, 3.96)	0.0265	
Sex					0.0896
male	0/ 2 (0.0)	2/ 2 (100.0)	0.20 (0.02, 2.64)	0.2215	
female	42/ 56 (75.0)	22/ 56 (39.3)	1.91 (1.33, 2.73)	0.0004	
Race					0.5859
White	15/ 21 (71.4)	8/ 25 (32.0)	2.23 (1.19, 4.20)	0.0128	
Black	6/ 10 (60.0)	2/ 6 (33.3)	1.80 (0.52, 6.22)	0.3527	
Other	21/ 27 (77.8)	14/ 27 (51.9)	1.50 (0.99, 2.27)	0.0559	
Ethnicity					0.1648
Hispanic/Latino	22/ 28 (78.6)	16/ 29 (55.2)	1.42 (0.97, 2.08)	0.0688	
Non-hispanic/Latino	20/ 30 (66.7)	8/ 29 (27.6)	2.42 (1.27, 4.59)	0.0070	
Geographic region					0.2307
Latin America, Eastern Europe and Asia	32/ 42 (76.2)	21/ 43 (48.8)	1.56 (1.10, 2.21)	0.0126	
North America	10/ 16 (62.5)	3/ 15 (20.0)	3.13 (1.06, 9.21)	0.0388	
Baseline weight					0.9528
<60 kg	15/ 19 (78.9)	11/ 25 (44.0)	1.79 (1.09, 2.96)	0.0218	
>=60 kg	27/ 39 (69.2)	13/ 33 (39.4)	1.76 (1.10, 2.82)	0.0192	
Low CH50					0.5727
Yes	4/ 8 (50.0)	2/ 5 (40.0)	1.25 (0.35, 4.49)	0.7321	
No	38/ 50 (76.0)	22/ 53 (41.5)	1.83 (1.28, 2.61)	0.0009	
Low C3 or C4					0.4623
Yes	14/ 21 (66.7)	12/ 27 (44.4)	1.50 (0.89, 2.52)	0.1257	
No	28/ 37 (75.7)	12/ 31 (38.7)	1.95 (1.21, 3.16)	0.0061	
Baseline FARR anti-dsDNA					0.4948
<5 IU/mL	7/ 10 (70.0)	3/ 9 (33.3)	2.10 (0.77, 5.76)	0.1496	
>=5 IU/mL	21/ 34 (61.8)	16/ 37 (43.2)	1.43 (0.91, 2.25)	0.1239	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.4231
Yes	27/ 40 (67.5)	20/ 47 (42.6)	1.59 (1.07, 2.36)	0.0223	
No	15/ 18 (83.3)	4/ 11 (36.4)	2.29 (1.02, 5.14)	0.0444	
OCS use					0.8352
Yes	38/ 51 (74.5)	22/ 51 (43.1)	1.73 (1.21, 2.46)	0.0025	
No	4/ 7 (57.1)	2/ 7 (28.6)	2.00 (0.53, 7.60)	0.3090	
SLICC score					0.3904
0	30/ 40 (75.0)	17/ 35 (48.6)	1.54 (1.05, 2.27)	0.0270	
>=1	12/ 18 (66.7)	7/ 23 (30.4)	2.19 (1.09, 4.41)	0.0279	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
>=50% Joint reduction at week 52 (for subjects with at least 8 tender joints and at least 8 swollen joints at baseline)
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=46)	Placebo (N=37)
Week 52	Number of subjects with events, n (%)	32 (69.6)	18 (48.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.45 (0.99, 2.11)	
	p-value	0.0577	
	Odds Ratio (95% CI)	2.83 (1.01, 7.91)	
	p-value	0.0474	
	Risk Difference (95% CI)	21.79 (1.14, 42.43)	
	p-value	0.0386	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.43 (0.98, 2.10)	
	p-value	0.0667	
	Odds Ratio (95% CI)	2.41 (0.98, 5.93)	
	p-value	0.0551	
	Risk Difference (95% CI)	20.92 (0.03, 41.80)	
	p-value	0.0497	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
>=50% Joint reduction at week 52 (for subjects with at least 8 tender joints and at least 8 swollen joints at baseline) - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=46) n/ N (%)	Placebo (N=37) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	 p-Value	Interaction p-Value
SLEDAI-2K score					0.1172
< 10 points	12/ 16 (75.0)	10/ 14 (71.4)	1.05 (0.68, 1.62)	0.8263	
>= 10 points	20/ 30 (66.7)	8/ 23 (34.8)	1.92 (1.04, 3.54)	0.0379	
OCS dose					0.6046
<10 mg/day	8/ 15 (53.3)	4/ 9 (44.4)	1.20 (0.50, 2.87)	0.6814	
>=10 mg/day	24/ 31 (77.4)	14/ 28 (50.0)	1.55 (1.02, 2.35)	0.0396	
Result of type I IFN gene signature test					0.7187
LOW	10/ 13 (76.9)	7/ 12 (58.3)	1.32 (0.75, 2.32)	0.3358	
HIGH	22/ 33 (66.7)	11/ 25 (44.0)	1.52 (0.92, 2.51)	0.1060	
Age (years)					0.4937
<= 45	21/ 31 (67.7)	13/ 25 (52.0)	1.30 (0.83, 2.04)	0.2474	
> 45	11/ 15 (73.3)	5/ 12 (41.7)	1.76 (0.84, 3.67)	0.1321	
Sex					NE
male	0/ 2 (0.0)	0	NE		
female	32/ 44 (72.7)	18/ 37 (48.6)	1.49 (1.03, 2.18)	0.0367	
Race					0.7821
White	12/ 18 (66.7)	4/ 11 (36.4)	1.83 (0.79, 4.28)	0.1609	
Black	5/ 8 (62.5)	2/ 5 (40.0)	1.56 (0.47, 5.19)	0.4661	
Other	15/ 20 (75.0)	12/ 21 (57.1)	1.31 (0.84, 2.06)	0.2348	
Ethnicity					0.3759
Hispanic/Latino	16/ 21 (76.2)	13/ 22 (59.1)	1.29 (0.85, 1.97)	0.2378	
Non-hispanic/Latino	16/ 25 (64.0)	5/ 15 (33.3)	1.92 (0.89, 4.16)	0.0984	
Geographic region					0.9823
Latin America, Eastern Europe and Asia	26/ 35 (74.3)	15/ 29 (51.7)	1.44 (0.96, 2.15)	0.0776	
North America	6/ 11 (54.5)	3/ 8 (37.5)	1.45 (0.51, 4.13)	0.4821	
Baseline weight					0.8961
<60 kg	12/ 16 (75.0)	10/ 19 (52.6)	1.43 (0.85, 2.38)	0.1750	
>=60 kg	20/ 30 (66.7)	8/ 18 (44.4)	1.50 (0.84, 2.67)	0.1671	
Low CH50					0.4018
Yes	3/ 7 (42.9)	2/ 4 (50.0)	0.86 (0.23, 3.15)	0.8163	
No	29/ 39 (74.4)	16/ 33 (48.5)	1.53 (1.03, 2.28)	0.0348	
Low C3 or C4					0.3049
Yes	11/ 16 (68.8)	9/ 15 (60.0)	1.15 (0.68, 1.94)	0.6140	
No	21/ 30 (70.0)	9/ 22 (40.9)	1.71 (0.98, 2.98)	0.0575	
Baseline FARR anti-dsDNA					0.4079
<5 IU/mL	5/ 8 (62.5)	3/ 8 (37.5)	1.67 (0.59, 4.73)	0.3372	
>=5 IU/mL	16/ 27 (59.3)	11/ 19 (57.9)	1.02 (0.62, 1.68)	0.9265	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.2234
Yes	21/ 32 (65.6)	15/ 28 (53.6)	1.23 (0.80, 1.88)	0.3509	
No	11/ 14 (78.6)	3/ 9 (33.3)	2.36 (0.90, 6.18)	0.0811	
OCS use					0.3813
Yes	29/ 41 (70.7)	16/ 34 (47.1)	1.50 (1.00, 2.26)	0.0499	
No	3/ 5 (60.0)	2/ 3 (66.7)	0.90 (0.31, 2.63)	0.8475	
SLICC score					0.7531
0	25/ 34 (73.5)	14/ 26 (53.8)	1.37 (0.91, 2.06)	0.1355	
>=1	7/ 12 (58.3)	4/ 11 (36.4)	1.60 (0.64, 4.01)	0.3121	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
>=0.22 point Improvement in HAQ Score at week 52 (for subjects with baseline HAQ Score >= 0.25)
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=81)	Placebo (N=80)
Week 52	Number of subjects with events, n (%)	34 (42.0)	33 (41.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.14 (0.78, 1.67)	
	p-value	0.4929	
	Odds Ratio (95% CI)	1.27 (0.65, 2.47)	
	p-value	0.4829	
	Risk Difference (95% CI)	5.42 (-9.58, 20.41)	
	p-value	0.4791	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.02 (0.71, 1.47)	
	p-value	0.9256	
	Odds Ratio (95% CI)	1.03 (0.55, 1.93)	
	p-value	0.9256	
	Risk Difference (95% CI)	0.73 (-14.50, 15.95)	
	p-value	0.9256	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
>=0.22 point Improvement in HAQ Score at week 52 (for subjects with baseline HAQ Score >= 0.25) - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=81) n/ N (%)	Placebo (N=80) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.9542
< 10 points	14/ 30 (46.7)	14/ 31 (45.2)	1.03 (0.60, 1.78)	0.9061	
>= 10 points	20/ 51 (39.2)	19/ 49 (38.8)	1.01 (0.62, 1.65)	0.9640	
OCS dose					0.2264
<10 mg/day	12/ 37 (32.4)	5/ 27 (18.5)	1.75 (0.70, 4.38)	0.2314	
>=10 mg/day	22/ 44 (50.0)	28/ 53 (52.8)	0.95 (0.64, 1.40)	0.7820	
Result of type I IFN gene signature test					0.6115
LOW	8/ 20 (40.0)	8/ 24 (33.3)	1.20 (0.55, 2.62)	0.6468	
HIGH	26/ 61 (42.6)	25/ 56 (44.6)	0.95 (0.63, 1.44)	0.8257	
Age (years)					0.5323
<= 45	24/ 53 (45.3)	26/ 55 (47.3)	0.96 (0.64, 1.44)	0.8359	
> 45	10/ 28 (35.7)	7/ 25 (28.0)	1.28 (0.57, 2.84)	0.5517	
Sex					0.3521
male	2/ 4 (50.0)	4/ 5 (80.0)	0.63 (0.21, 1.83)	0.3908	
female	32/ 77 (41.6)	29/ 75 (38.7)	1.07 (0.73, 1.59)	0.7164	
Race					0.3523
White	10/ 31 (32.3)	15/ 36 (41.7)	0.77 (0.41, 1.47)	0.4332	
Black	6/ 14 (42.9)	2/ 11 (18.2)	2.36 (0.59, 9.48)	0.2273	
Other	18/ 36 (50.0)	16/ 33 (48.5)	1.03 (0.64, 1.67)	0.9000	
Ethnicity					0.6336
Hispanic/Latino	19/ 37 (51.4)	18/ 32 (56.3)	0.91 (0.59, 1.41)	0.6834	
Non-hispanic/Latino	15/ 44 (34.1)	15/ 48 (31.3)	1.09 (0.61, 1.96)	0.7715	
Geographic region					0.5647
Latin America, Eastern Europe and Asia	25/ 50 (50.0)	27/ 53 (50.9)	0.98 (0.67, 1.44)	0.9238	
North America	9/ 31 (29.0)	6/ 27 (22.2)	1.31 (0.53, 3.20)	0.5582	
Baseline weight					0.0498
<60 kg	16/ 26 (61.5)	12/ 31 (38.7)	1.59 (0.93, 2.72)	0.0908	
>=60 kg	18/ 55 (32.7)	21/ 49 (42.9)	0.76 (0.46, 1.26)	0.2886	
Low CH50					0.3288
Yes	4/ 10 (40.0)	6/ 10 (60.0)	0.67 (0.27, 1.66)	0.3837	
No	30/ 71 (42.3)	27/ 70 (38.6)	1.10 (0.73, 1.64)	0.6564	
Low C3 or C4					0.7749
Yes	9/ 26 (34.6)	14/ 37 (37.8)	0.91 (0.47, 1.79)	0.7947	
No	25/ 55 (45.5)	19/ 43 (44.2)	1.03 (0.66, 1.60)	0.9004	
Baseline FARR anti-dsDNA					0.0867
<5 IU/mL	9/ 17 (52.9)	3/ 11 (27.3)	1.94 (0.67, 5.63)	0.2218	
>=5 IU/mL	15/ 46 (32.6)	24/ 51 (47.1)	0.69 (0.42, 1.15)	0.1564	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.2857
Yes	20/ 57 (35.1)	26/ 64 (40.6)	0.86 (0.54, 1.37)	0.5332	
No	14/ 24 (58.3)	7/ 16 (43.8)	1.33 (0.70, 2.56)	0.3860	
OCS use					0.4325
Yes	31/ 65 (47.7)	30/ 70 (42.9)	1.11 (0.77, 1.61)	0.5727	
No	3/ 16 (18.8)	3/ 10 (30.0)	0.63 (0.16, 2.51)	0.5080	
SLICC score					0.5896
0	24/ 47 (51.1)	23/ 50 (46.0)	1.11 (0.74, 1.67)	0.6180	
>=1	10/ 34 (29.4)	10/ 30 (33.3)	0.88 (0.43, 1.82)	0.7355	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
SRI (5) response rate at week 52
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=99)	Placebo (N=102)
Week 52	Number of subjects with events, n (%)	49 (49.5)	30 (29.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.77 (1.22, 2.57)	
	p-value	0.0026	
	Odds Ratio (95% CI)	2.59 (1.42, 4.74)	
	p-value	0.0020	
	Risk Difference (95% CI)	21.59 (8.55, 34.62)	
	p-value	0.0012	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.68 (1.17, 2.41)	
	p-value	0.0047	
	Odds Ratio (95% CI)	2.35 (1.32, 4.20)	
	p-value	0.0039	
	Risk Difference (95% CI)	20.08 (6.85, 33.32)	
	p-value	0.0029	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
SRI (6) response rate at week 52
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=99)	Placebo (N=102)
Week 52	Number of subjects with events, n (%)	49 (49.5)	29 (28.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.83 (1.25, 2.67)	
	p-value	0.0018	
	Odds Ratio (95% CI)	2.70 (1.47, 4.96)	
	p-value	0.0013	
	Risk Difference (95% CI)	22.47 (9.47, 35.46)	
	p-value	0.0007	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.74 (1.21, 2.51)	
	p-value	0.0030	
	Odds Ratio (95% CI)	2.47 (1.38, 4.42)	
	p-value	0.0024	
	Risk Difference (95% CI)	21.06 (7.89, 34.24)	
	p-value	0.0017	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
SRI (7) response rate at week 52
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Timepoint		Anifrolumab 300mg (N=99)	Placebo (N=102)
Week 52	Number of subjects with events, n (%)	33 (33.3)	16 (15.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	2.23 (1.29, 3.87)	
	p-value	0.0042	
	Odds Ratio (95% CI)	2.88 (1.43, 5.81)	
	p-value	0.0032	
	Risk Difference (95% CI)	18.31 (6.75, 29.88)	
	p-value	0.0019	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	2.13 (1.25, 3.61)	
	p-value	0.0052	
	Odds Ratio (95% CI)	2.69 (1.36, 5.29)	
	p-value	0.0043	
	Risk Difference (95% CI)	17.65 (5.98, 29.31)	
	p-value	0.0030	

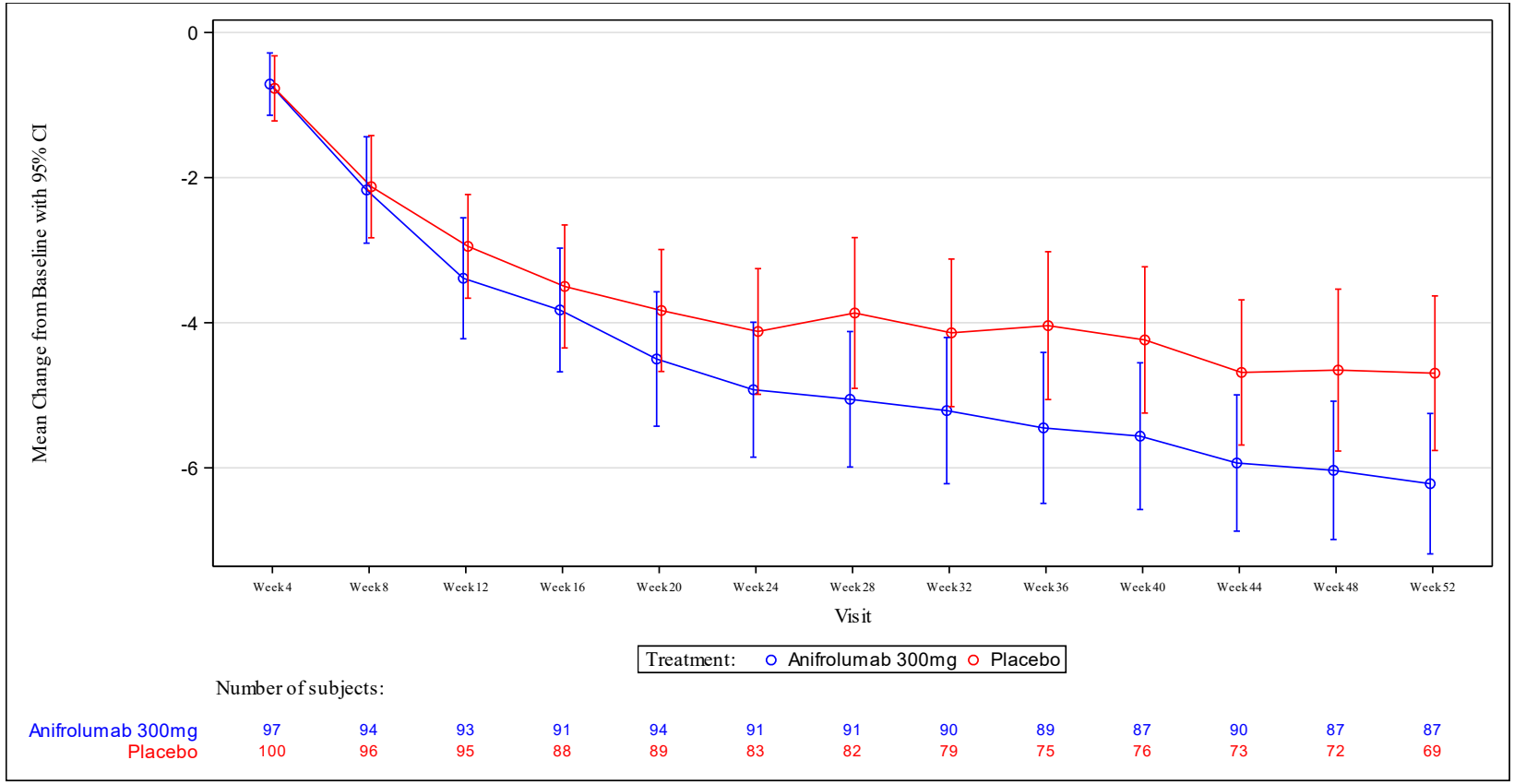
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - SLEDAI-2K Total Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)				Placebo (N=102)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	99	10.65 (3.88)	0	-	102	11.13 (4.35)	0	-
Week 4	97	10.04 (3.41)	97	-0.71 (2.13)	100	10.36 (3.97)	100	-0.77 (2.26)
Week 8	94	8.68 (4.30)	94	-2.17 (3.58)	96	9.09 (4.89)	96	-2.13 (3.48)
Week 12	93	7.37 (4.39)	93	-3.39 (4.05)	95	8.16 (4.59)	95	-2.95 (3.51)
Week 16	91	6.86 (4.35)	91	-3.82 (4.09)	88	7.50 (4.86)	88	-3.50 (4.00)
Week 20	94	6.24 (4.53)	94	-4.50 (4.52)	89	7.17 (4.60)	89	-3.83 (3.99)
Week 24	91	5.84 (4.45)	91	-4.92 (4.47)	83	6.87 (4.48)	83	-4.12 (3.97)
Week 28	91	5.70 (4.20)	91	-5.05 (4.48)	82	7.06 (5.44)	82	-3.87 (4.73)
Week 32	90	5.63 (4.44)	90	-5.21 (4.81)	79	6.86 (5.32)	79	-4.14 (4.54)
Week 36	89	5.34 (4.51)	89	-5.45 (4.94)	75	6.88 (5.32)	75	-4.04 (4.43)
Week 40	87	5.17 (4.19)	87	-5.56 (4.74)	76	6.76 (5.06)	76	-4.24 (4.41)
Week 44	90	4.89 (3.85)	90	-5.93 (4.48)	73	5.79 (4.40)	73	-4.68 (4.29)
Week 48	87	4.63 (3.61)	87	-6.03 (4.47)	72	6.06 (4.71)	72	-4.65 (4.75)
Week 52	87	4.48 (4.07)	87	-6.22 (4.54)	69	5.81 (4.55)	69	-4.70 (4.43)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - SLEDAI-2K Total Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)



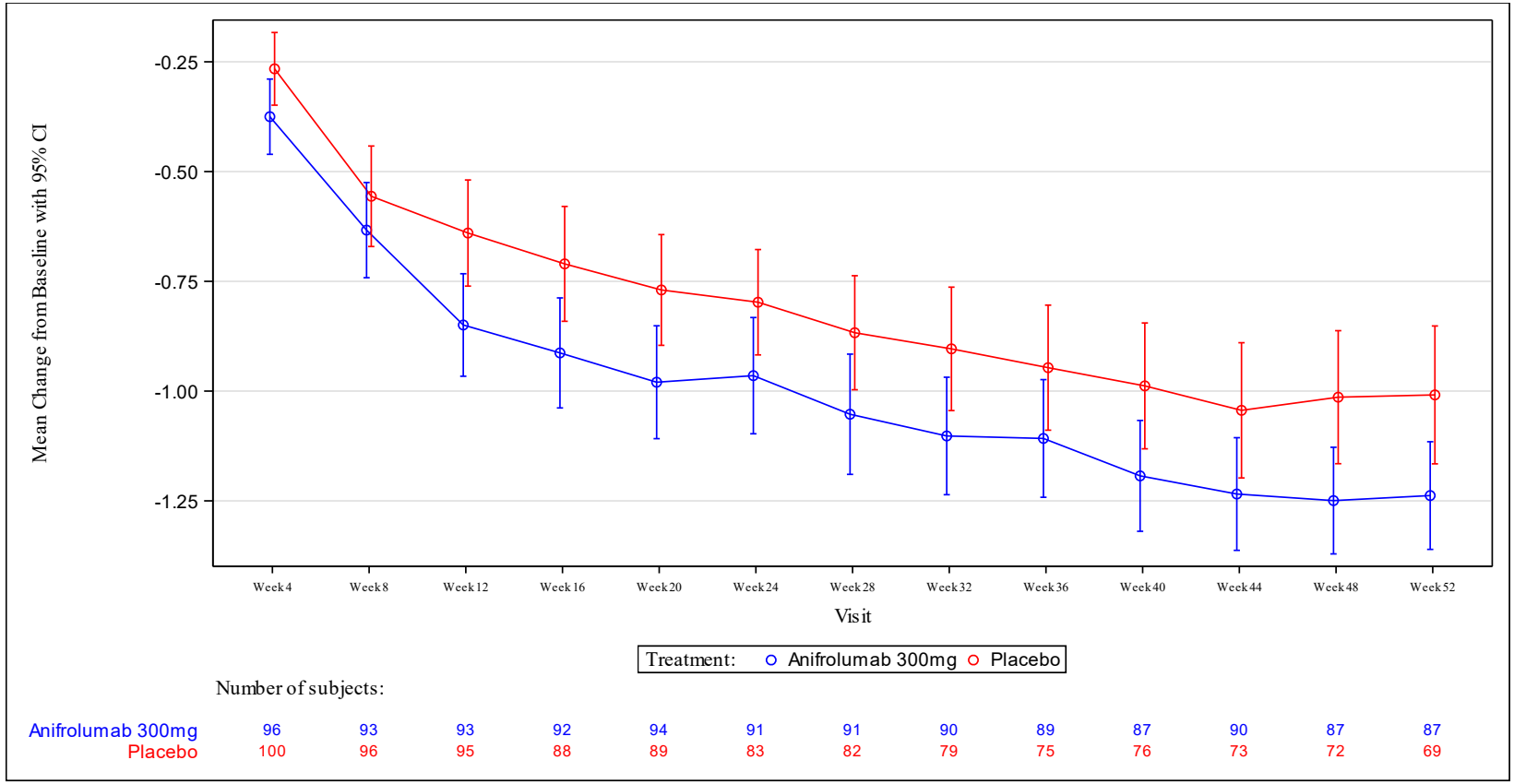
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - PGA
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)				Placebo (N=102)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	99	1.86 (0.39)	0	-	102	1.77 (0.44)	0	-
Week 4	96	1.48 (0.51)	96	-0.37 (0.42)	100	1.49 (0.47)	100	-0.27 (0.42)
Week 8	93	1.23 (0.52)	93	-0.63 (0.53)	96	1.22 (0.51)	96	-0.56 (0.56)
Week 12	93	1.00 (0.53)	93	-0.85 (0.57)	95	1.12 (0.54)	95	-0.64 (0.59)
Week 16	92	0.92 (0.54)	92	-0.91 (0.60)	88	1.04 (0.56)	88	-0.71 (0.62)
Week 20	94	0.86 (0.57)	94	-0.98 (0.63)	89	1.00 (0.56)	89	-0.77 (0.60)
Week 24	91	0.87 (0.59)	91	-0.96 (0.64)	83	0.95 (0.55)	83	-0.80 (0.55)
Week 28	91	0.79 (0.61)	91	-1.05 (0.66)	82	0.91 (0.59)	82	-0.87 (0.59)
Week 32	90	0.74 (0.56)	90	-1.10 (0.64)	79	0.85 (0.58)	79	-0.90 (0.63)
Week 36	89	0.74 (0.55)	89	-1.11 (0.64)	75	0.80 (0.56)	75	-0.95 (0.62)
Week 40	87	0.65 (0.53)	87	-1.19 (0.59)	76	0.76 (0.58)	76	-0.99 (0.63)
Week 44	90	0.60 (0.51)	90	-1.23 (0.61)	73	0.71 (0.59)	73	-1.04 (0.66)
Week 48	87	0.60 (0.52)	87	-1.25 (0.57)	72	0.74 (0.58)	72	-1.01 (0.64)
Week 52	87	0.61 (0.54)	87	-1.24 (0.58)	69	0.74 (0.63)	69	-1.01 (0.65)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - PGA
Full analysis set



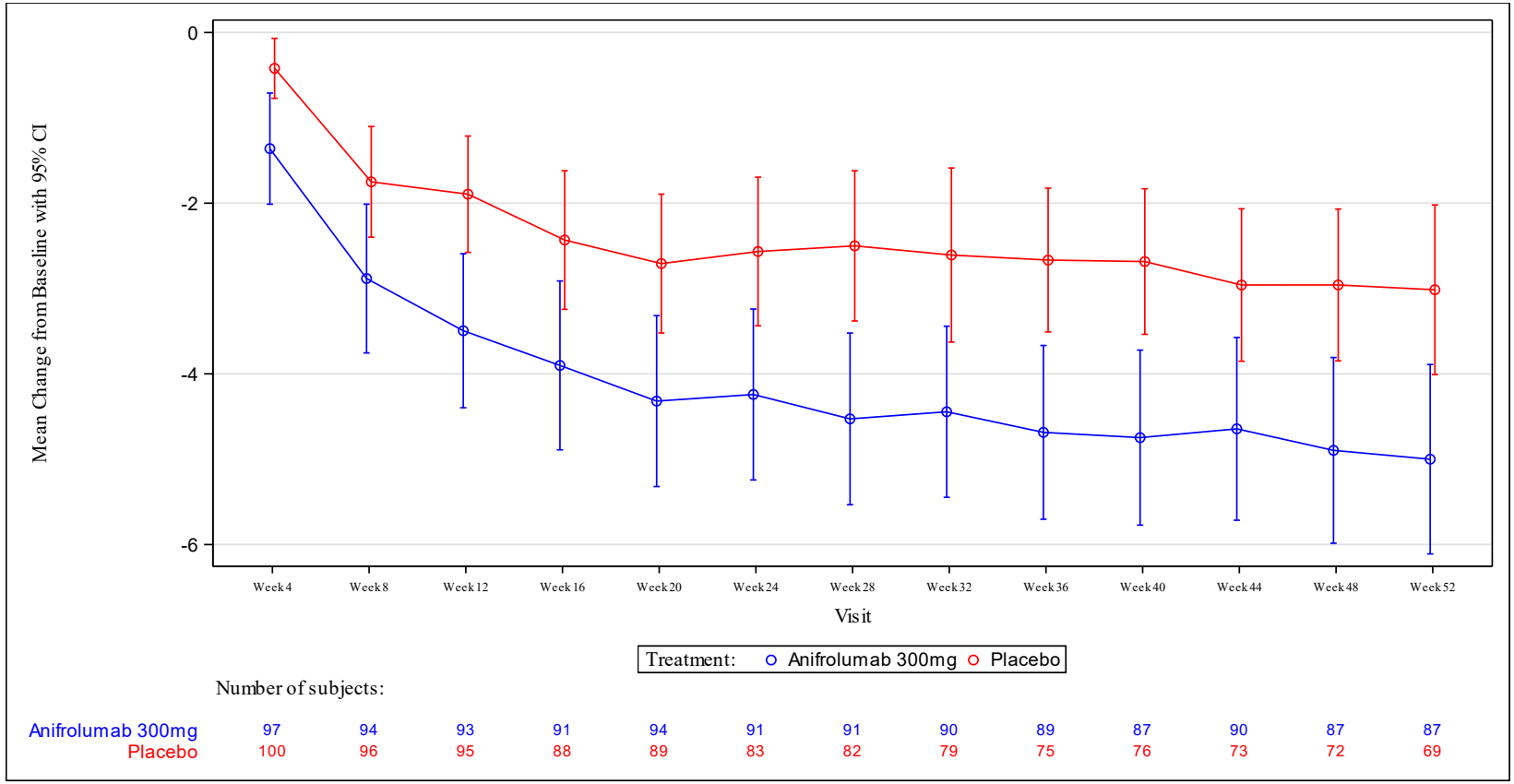
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - CLASI Total Activity Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)				Placebo (N=102)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	99	7.52 (6.30)	0	-	102	6.71 (5.08)	0	-
Week 4	97	6.18 (5.91)	97	-1.36 (3.23)	100	6.03 (4.76)	100	-0.42 (1.77)
Week 8	94	4.68 (4.97)	94	-2.88 (4.25)	96	5.08 (4.24)	96	-1.75 (3.20)
Week 12	93	3.84 (4.05)	93	-3.49 (4.38)	95	4.89 (4.19)	95	-1.89 (3.35)
Week 16	91	3.45 (4.10)	91	-3.90 (4.75)	88	4.38 (4.01)	88	-2.43 (3.83)
Week 20	94	3.00 (3.88)	94	-4.32 (4.89)	89	4.08 (4.09)	89	-2.71 (3.86)
Week 24	91	2.87 (3.84)	91	-4.24 (4.81)	83	4.33 (4.12)	83	-2.57 (3.99)
Week 28	91	2.91 (4.05)	91	-4.53 (4.83)	82	4.54 (4.35)	82	-2.50 (4.01)
Week 32	90	2.68 (3.97)	90	-4.44 (4.79)	79	4.16 (4.46)	79	-2.61 (4.55)
Week 36	89	2.51 (3.78)	89	-4.69 (4.83)	75	4.08 (4.19)	75	-2.67 (3.66)
Week 40	87	2.47 (3.84)	87	-4.75 (4.81)	76	4.09 (4.35)	76	-2.68 (3.73)
Week 44	90	2.52 (3.95)	90	-4.64 (5.11)	73	3.88 (4.10)	73	-2.96 (3.83)
Week 48	87	2.20 (3.55)	87	-4.90 (5.11)	72	3.92 (4.05)	72	-2.96 (3.78)
Week 52	87	2.16 (3.76)	87	-5.00 (5.21)	69	3.94 (4.29)	69	-3.01 (4.14)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - CLASI Total Activity Score
Full analysis set



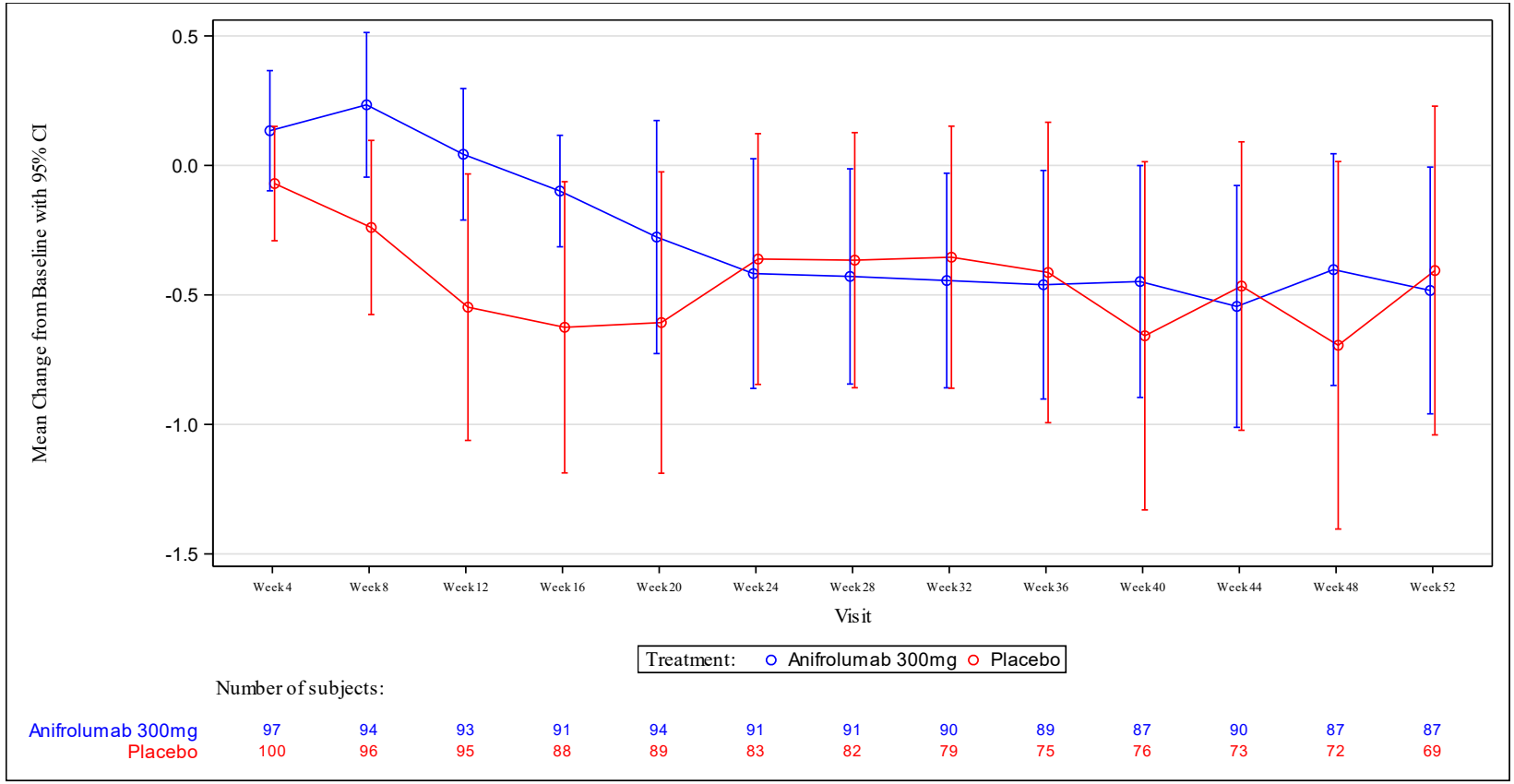
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - CLASI Total Damage Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)				Placebo (N=102)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	99	2.10 (4.40)	0	-	102	2.50 (5.95)	0	-
Week 4	97	2.28 (4.40)	97	0.13 (1.15)	100	2.47 (6.18)	100	-0.07 (1.11)
Week 8	94	2.33 (4.38)	94	0.23 (1.36)	96	2.39 (6.09)	96	-0.24 (1.66)
Week 12	93	2.14 (4.28)	93	0.04 (1.23)	95	2.09 (5.30)	95	-0.55 (2.53)
Week 16	91	2.07 (4.07)	91	-0.10 (1.03)	88	2.18 (5.52)	88	-0.63 (2.65)
Week 20	94	1.82 (3.64)	94	-0.28 (2.20)	89	2.18 (5.63)	89	-0.61 (2.76)
Week 24	91	1.68 (3.52)	91	-0.42 (2.13)	83	2.45 (6.07)	83	-0.36 (2.22)
Week 28	91	1.74 (3.54)	91	-0.43 (2.00)	82	2.56 (6.12)	82	-0.37 (2.24)
Week 32	90	1.63 (3.54)	90	-0.44 (1.98)	79	2.44 (6.04)	79	-0.35 (2.26)
Week 36	89	1.63 (3.56)	89	-0.46 (2.09)	75	2.51 (6.19)	75	-0.41 (2.52)
Week 40	87	1.68 (3.54)	87	-0.45 (2.10)	76	2.13 (5.79)	76	-0.66 (2.94)
Week 44	90	1.58 (3.42)	90	-0.54 (2.23)	73	2.22 (5.89)	73	-0.47 (2.39)
Week 48	87	1.66 (3.62)	87	-0.40 (2.10)	72	2.25 (5.92)	72	-0.69 (3.02)
Week 52	87	1.64 (3.70)	87	-0.48 (2.24)	69	2.38 (6.42)	69	-0.41 (2.64)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - CLASI Total Damage Score
Full analysis set



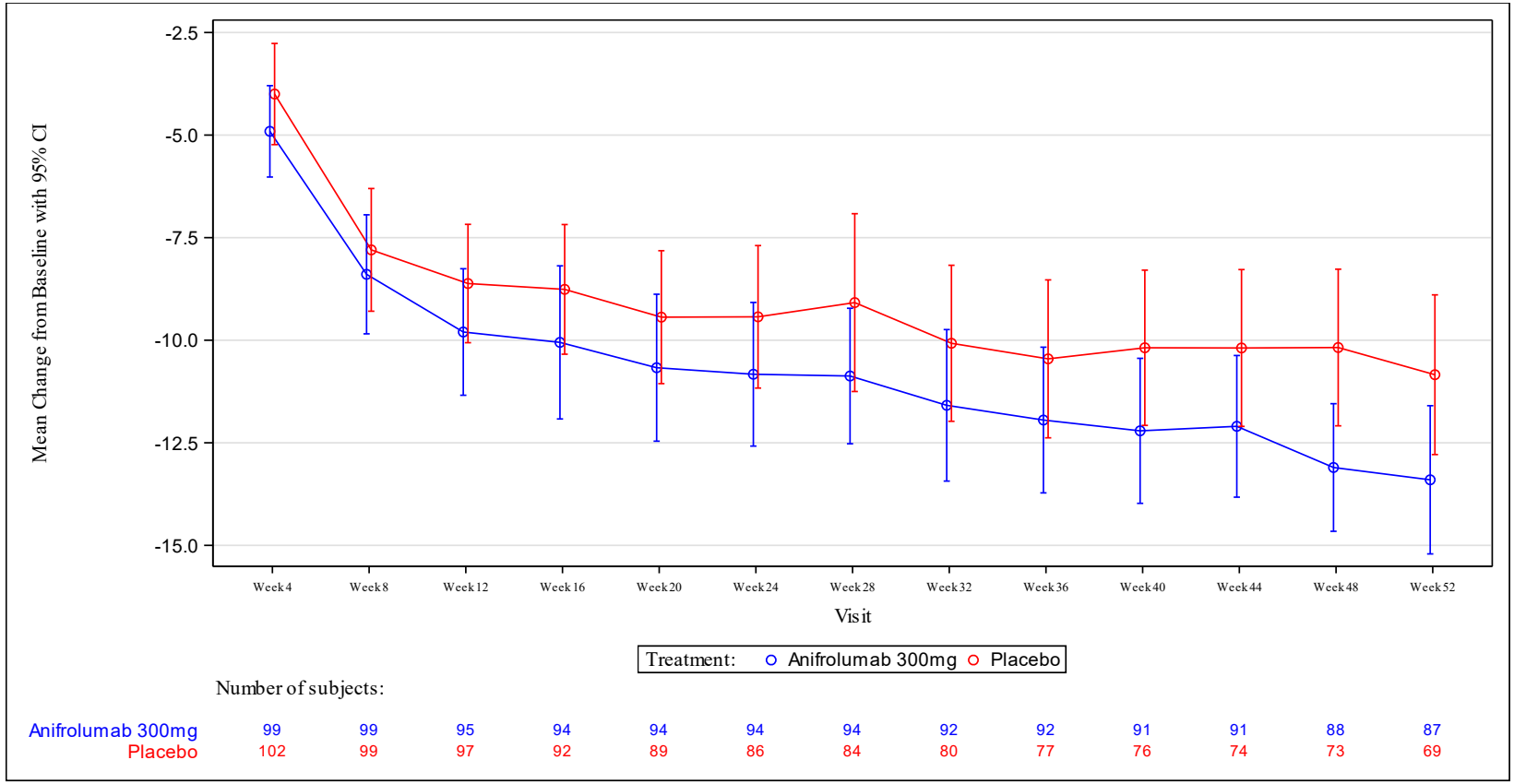
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - BILAG Global Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)				Placebo (N=102)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	99	19.60 (5.73)	0	-	102	19.82 (5.76)	0	-
Week 4	99	14.69 (6.71)	99	-4.91 (5.58)	102	15.82 (7.06)	102	-4.00 (6.28)
Week 8	99	11.20 (6.73)	99	-8.39 (7.27)	99	12.01 (7.83)	99	-7.80 (7.50)
Week 12	95	9.72 (6.99)	95	-9.80 (7.57)	97	11.20 (7.29)	97	-8.62 (7.16)
Week 16	94	9.53 (8.57)	94	-10.05 (9.11)	92	11.18 (7.73)	92	-8.76 (7.63)
Week 20	94	8.91 (7.62)	94	-10.67 (8.74)	89	10.46 (7.80)	89	-9.44 (7.69)
Week 24	94	8.76 (7.76)	94	-10.83 (8.55)	86	10.35 (7.14)	86	-9.43 (8.10)
Week 28	94	8.71 (7.15)	94	-10.87 (8.06)	84	10.77 (9.84)	84	-9.08 (9.98)
Week 32	92	7.97 (7.81)	92	-11.59 (8.91)	80	9.75 (8.15)	80	-10.08 (8.54)
Week 36	92	7.61 (7.42)	92	-11.95 (8.57)	77	9.18 (7.31)	77	-10.45 (8.48)
Week 40	91	7.38 (7.44)	91	-12.21 (8.48)	76	9.49 (7.76)	76	-10.18 (8.28)
Week 44	91	7.49 (6.91)	91	-12.10 (8.29)	74	9.32 (7.21)	74	-10.19 (8.25)
Week 48	88	6.61 (6.10)	88	-13.10 (7.34)	73	9.27 (6.97)	73	-10.18 (8.18)
Week 52	87	6.38 (7.41)	87	-13.40 (8.47)	69	8.61 (6.93)	69	-10.84 (8.10)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - BILAG Global Score
Full analysis set



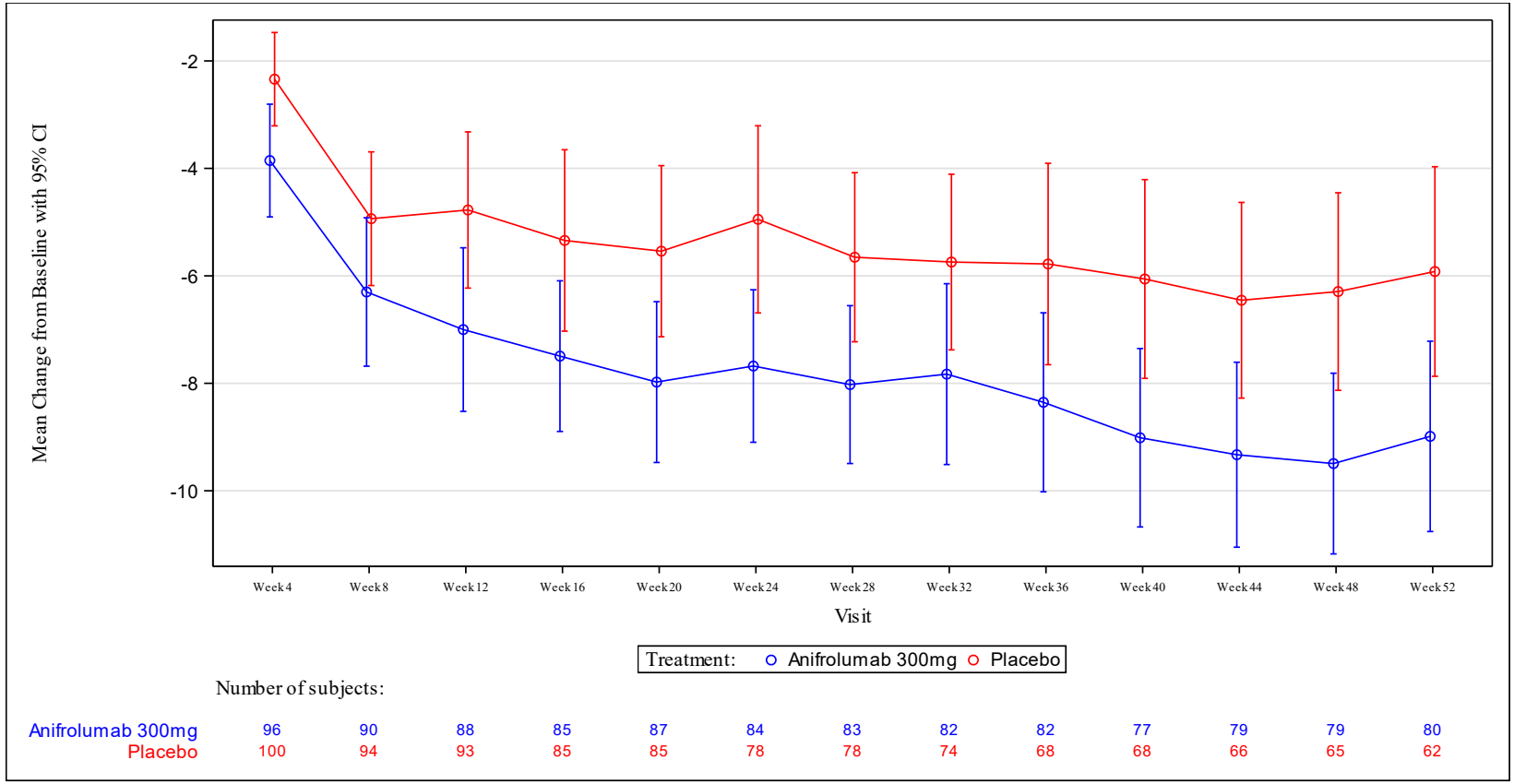
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - Tender Joint Count
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)				Placebo (N=102)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	99	12.23 (7.10)	0	-	102	10.49 (7.44)	0	-
Week 4	97	8.34 (7.54)	96	-3.85 (5.17)	100	8.03 (7.42)	100	-2.34 (4.38)
Week 8	94	5.96 (6.87)	90	-6.30 (6.59)	96	5.45 (6.17)	94	-4.94 (6.07)
Week 12	93	5.17 (6.95)	88	-7.00 (7.18)	95	5.36 (6.94)	93	-4.77 (7.06)
Week 16	91	4.52 (6.88)	85	-7.49 (6.50)	88	4.75 (7.37)	85	-5.34 (7.83)
Week 20	94	4.10 (6.57)	87	-7.98 (7.02)	89	4.56 (7.12)	85	-5.54 (7.38)
Week 24	91	4.36 (6.74)	84	-7.68 (6.54)	83	4.73 (7.27)	78	-4.95 (7.73)
Week 28	91	4.13 (7.03)	83	-8.02 (6.73)	82	4.21 (6.88)	78	-5.65 (6.98)
Week 32	90	4.21 (6.92)	82	-7.83 (7.66)	79	4.11 (6.83)	74	-5.74 (7.05)
Week 36	89	3.78 (6.37)	82	-8.35 (7.58)	75	3.73 (6.65)	68	-5.78 (7.74)
Week 40	87	3.14 (5.70)	77	-9.01 (7.32)	76	3.24 (5.97)	68	-6.06 (7.64)
Week 44	90	2.76 (5.32)	79	-9.33 (7.68)	73	3.05 (5.66)	66	-6.45 (7.41)
Week 48	87	2.72 (5.02)	79	-9.49 (7.51)	72	3.07 (5.66)	65	-6.29 (7.42)
Week 52	87	3.06 (5.50)	80	-8.99 (7.96)	69	3.67 (6.24)	62	-5.92 (7.68)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - Tender Joint Count
Full analysis set



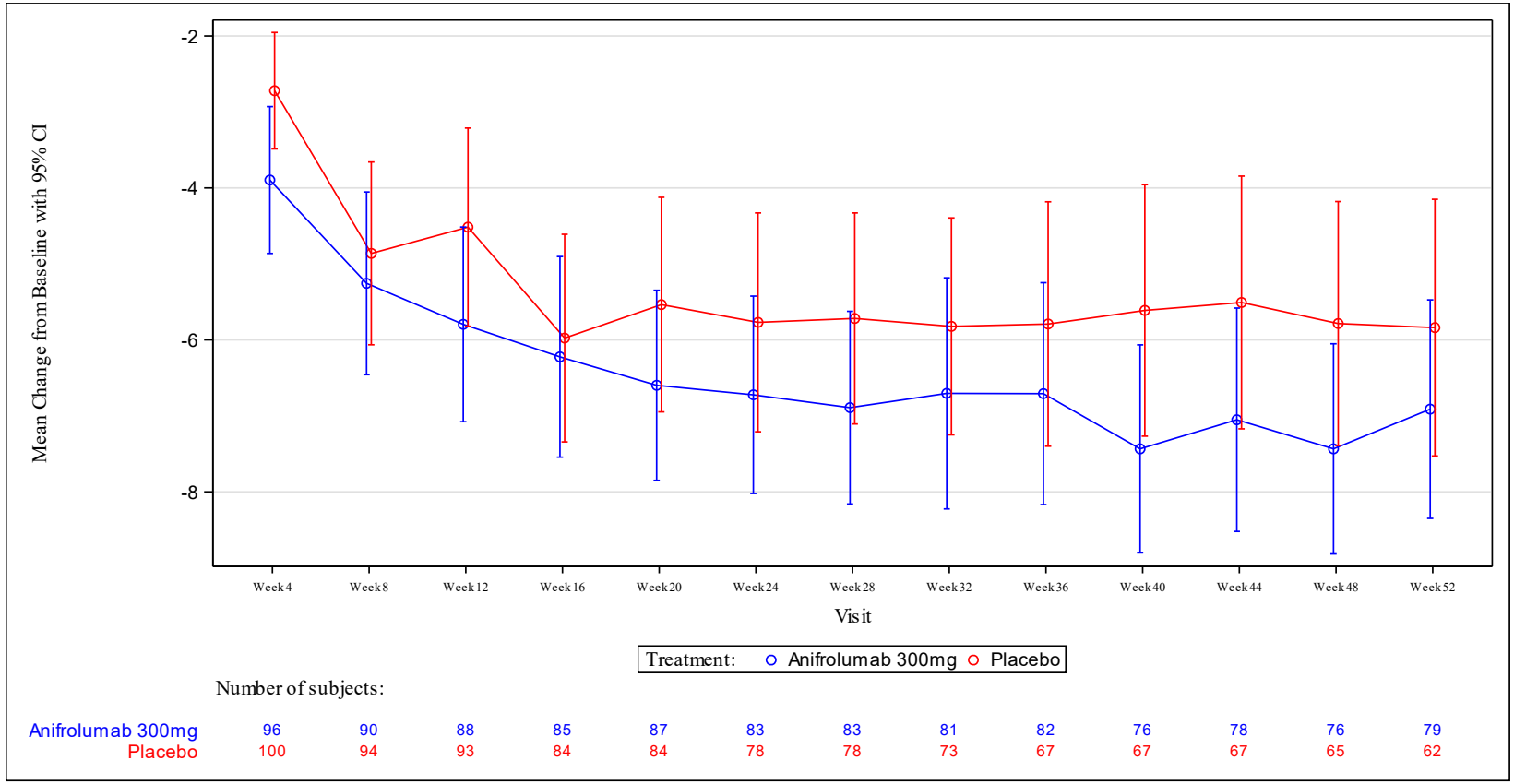
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - Swollen Joint Count
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)				Placebo (N=102)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	99	8.64 (6.04)	0	-	102	8.25 (6.35)	0	-
Week 4	97	4.60 (5.08)	96	-3.90 (4.77)	100	5.38 (5.70)	100	-2.72 (3.86)
Week 8	94	3.35 (4.83)	90	-5.26 (5.74)	96	3.11 (4.53)	94	-4.86 (5.87)
Week 12	93	2.78 (4.28)	88	-5.80 (6.05)	95	3.28 (4.88)	93	-4.52 (6.33)
Week 16	91	2.35 (3.53)	85	-6.22 (6.12)	88	2.01 (3.35)	84	-5.98 (6.30)
Week 20	94	1.95 (3.24)	87	-6.60 (5.87)	89	2.43 (4.83)	84	-5.54 (6.51)
Week 24	91	1.87 (3.26)	83	-6.72 (5.95)	83	2.17 (3.56)	78	-5.77 (6.39)
Week 28	91	1.71 (3.45)	83	-6.89 (5.81)	82	2.46 (5.13)	78	-5.72 (6.16)
Week 32	90	1.78 (3.18)	81	-6.70 (6.88)	79	2.25 (4.39)	73	-5.82 (6.12)
Week 36	89	1.96 (3.77)	82	-6.71 (6.65)	75	1.96 (4.21)	67	-5.79 (6.60)
Week 40	87	1.21 (2.35)	76	-7.43 (5.99)	76	1.89 (3.80)	67	-5.61 (6.79)
Week 44	90	1.51 (3.68)	78	-7.05 (6.52)	73	1.90 (3.94)	67	-5.51 (6.82)
Week 48	87	1.29 (2.75)	76	-7.43 (6.05)	72	1.81 (3.54)	65	-5.78 (6.48)
Week 52	87	1.60 (3.89)	79	-6.91 (6.42)	69	1.70 (3.47)	62	-5.84 (6.65)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - Swollen Joint Count
Full analysis set



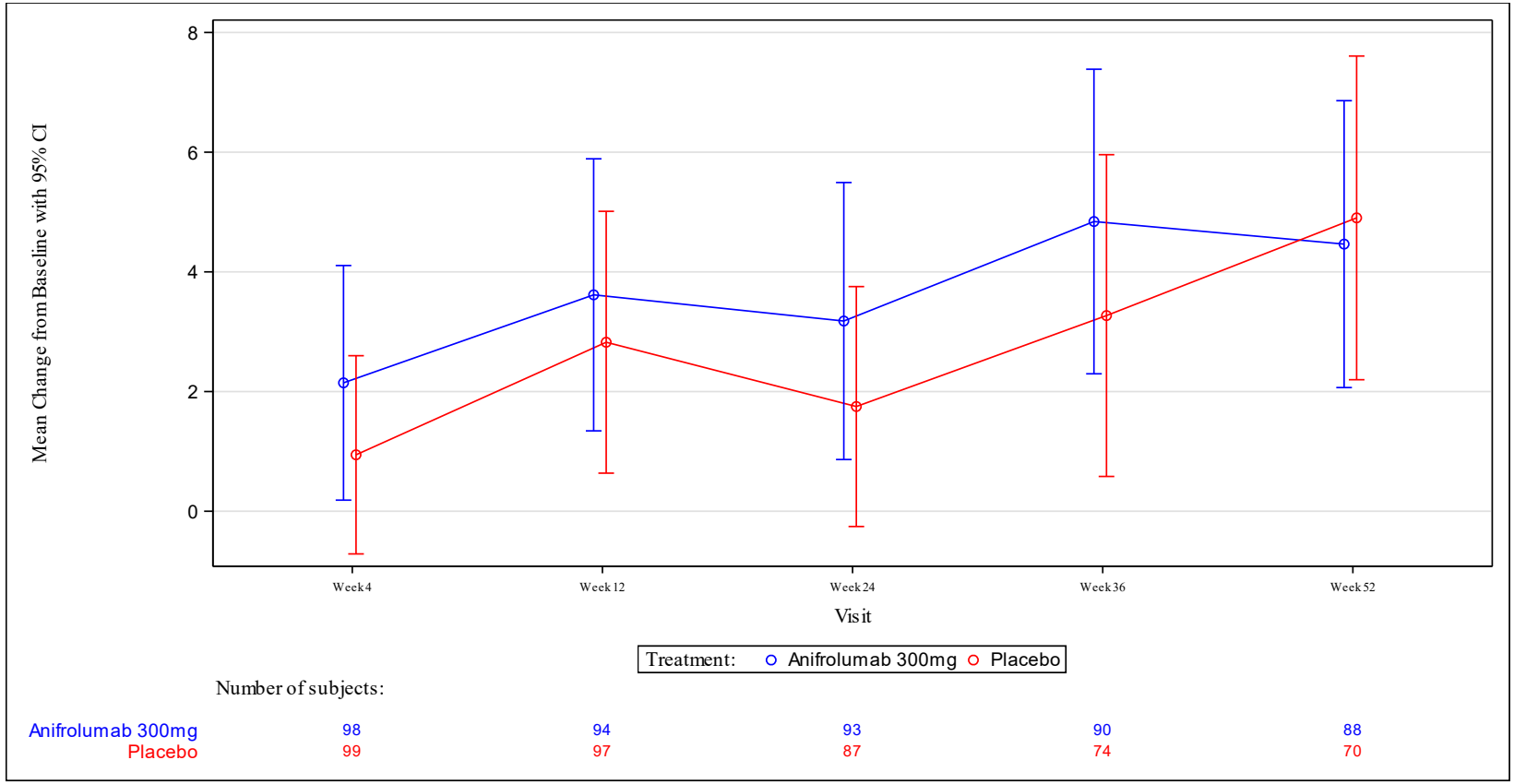
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Mental Component Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)				Placebo (N=102)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	99	37.66 (11.96)	0	-	102	37.92 (12.35)	0	-
Week 4	98	39.65 (11.68)	98	2.15 (9.78)	99	39.18 (11.64)	99	0.94 (8.30)
Week 12	94	41.24 (12.49)	94	3.62 (11.10)	97	40.83 (12.30)	97	2.82 (10.85)
Week 24	93	40.55 (11.65)	93	3.18 (11.24)	87	40.27 (11.84)	87	1.75 (9.41)
Week 36	90	42.86 (11.62)	90	4.84 (12.15)	74	42.63 (12.17)	74	3.27 (11.60)
Week 52	88	42.48 (11.20)	88	4.46 (11.31)	70	43.72 (12.44)	70	4.90 (11.34)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Mental Component Score
Full analysis set



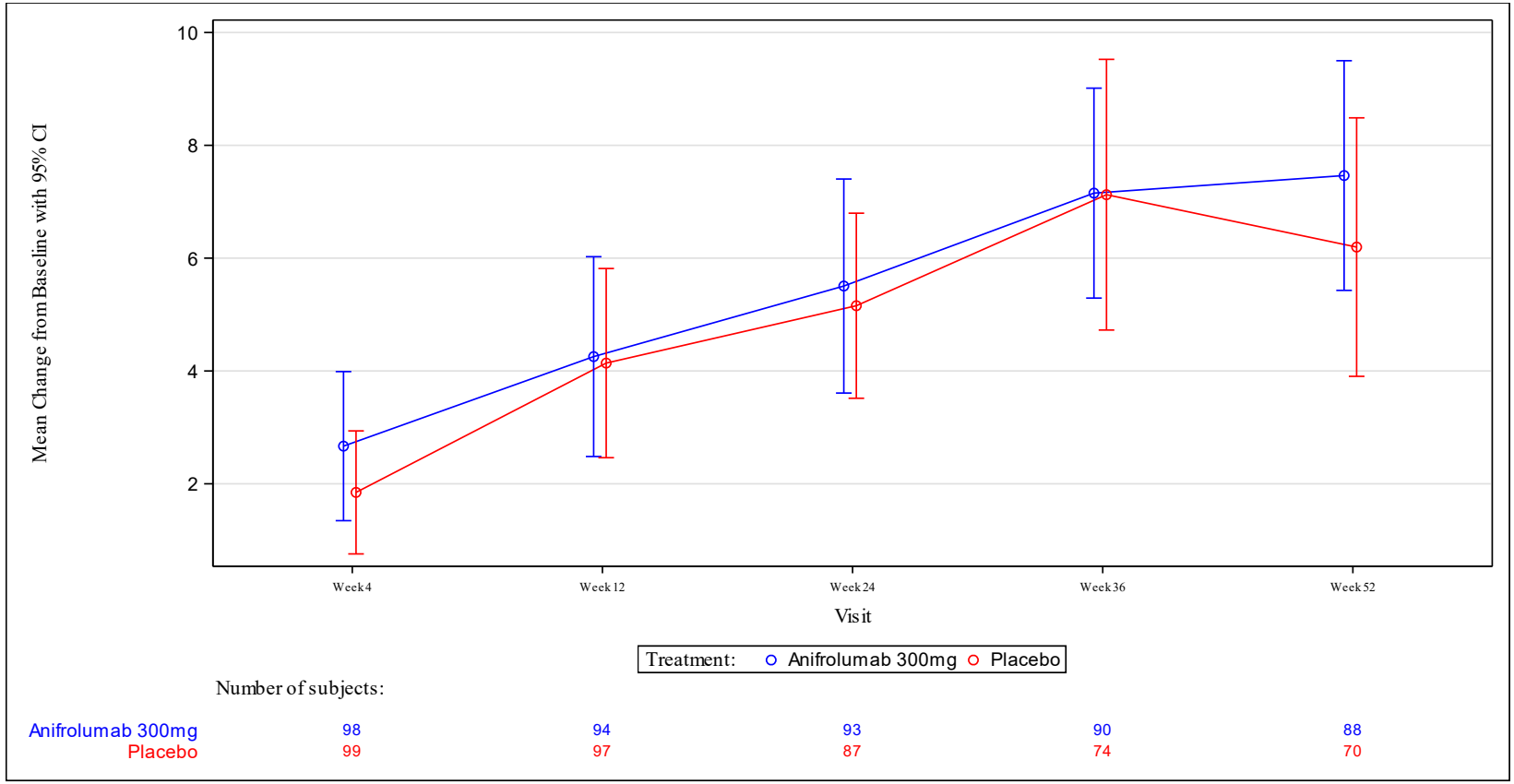
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Physical Component Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)				Placebo (N=102)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	99	34.88 (9.30)	0	-	102	35.07 (10.58)	0	-
Week 4	98	37.67 (8.32)	98	2.67 (6.59)	99	37.01 (9.99)	99	1.85 (5.47)
Week 12	94	39.47 (9.46)	94	4.25 (8.65)	97	39.20 (11.15)	97	4.14 (8.32)
Week 24	93	40.76 (9.80)	93	5.51 (9.21)	87	40.64 (11.33)	87	5.16 (7.70)
Week 36	90	42.24 (10.56)	90	7.15 (8.88)	74	43.21 (11.27)	74	7.12 (10.36)
Week 52	88	42.45 (10.72)	88	7.46 (9.61)	70	42.43 (11.15)	70	6.20 (9.61)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Physical Component Score
Full analysis set



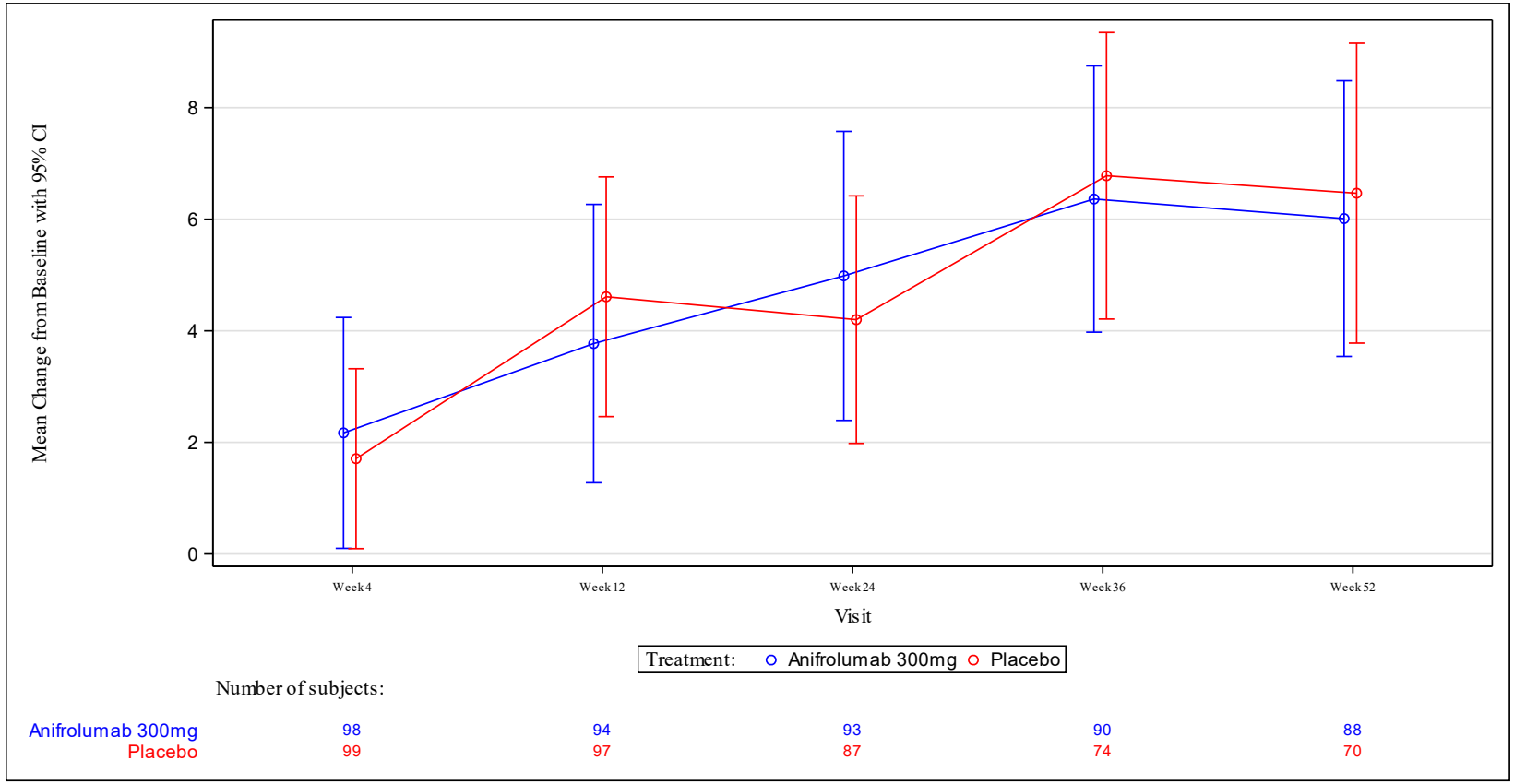
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - SF-36 v2.0 Acute General Health Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)				Placebo (N=102)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	99	34.87 (11.70)	0	-	102	34.66 (11.75)	0	-
Week 4	98	37.04 (10.66)	98	2.17 (10.32)	99	36.69 (11.54)	99	1.71 (8.08)
Week 12	94	38.92 (11.55)	94	3.77 (12.18)	97	39.14 (11.62)	97	4.61 (10.66)
Week 24	93	39.84 (11.54)	93	4.98 (12.58)	87	39.30 (12.06)	87	4.20 (10.41)
Week 36	90	41.76 (11.51)	90	6.36 (11.39)	74	42.62 (11.34)	74	6.78 (11.09)
Week 52	88	41.11 (11.85)	88	6.01 (11.67)	70	41.89 (11.73)	70	6.47 (11.27)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - SF-36 v2.0 Acute General Health Score
Full analysis set



Number of subjects:

	Week 4	Week 12	Week 24	Week 36	Week 52
Anifrolumab 300mg	98	94	93	90	88
Placebo	99	97	87	74	70

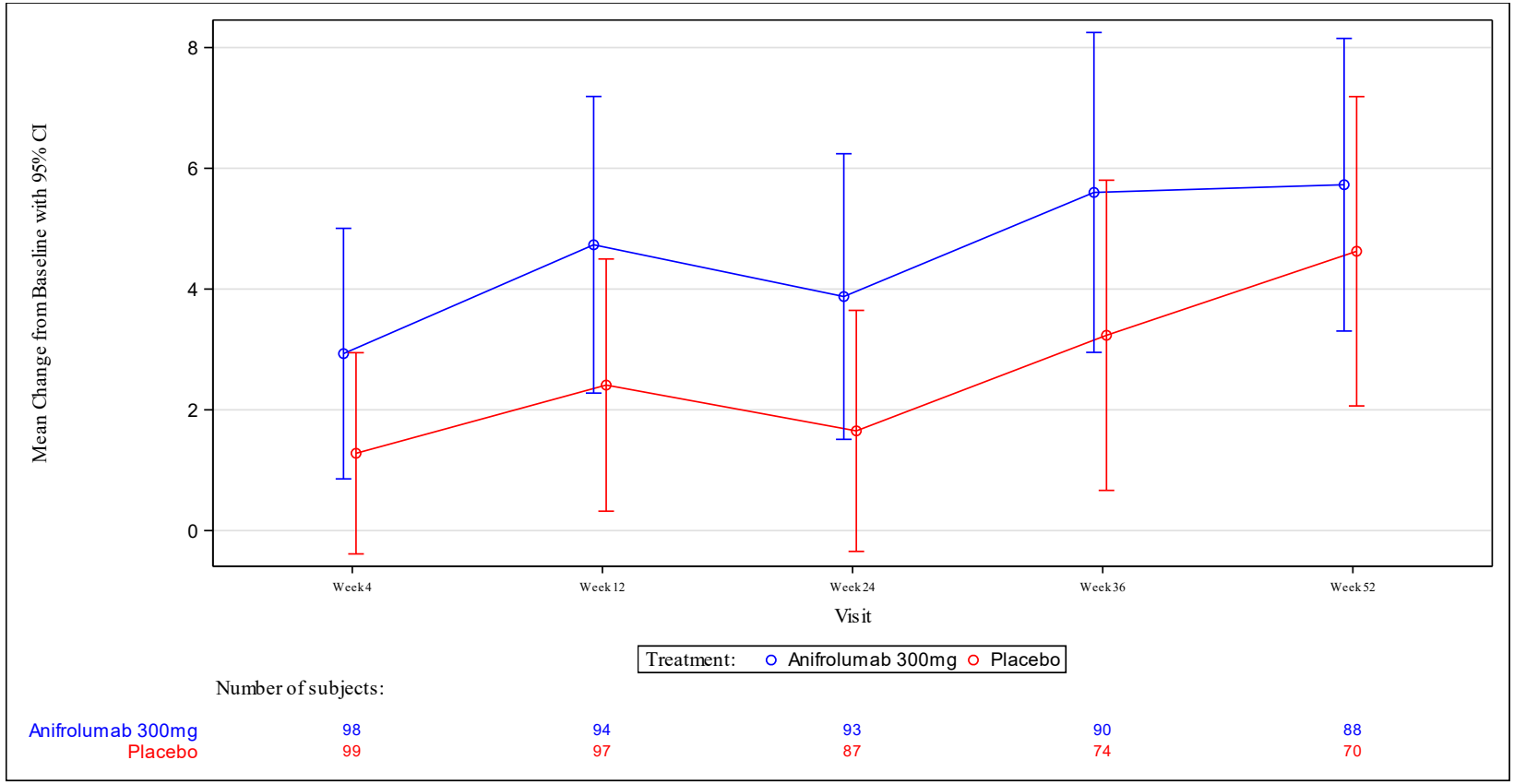
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Mental Health Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)				Placebo (N=102)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	99	37.69 (12.27)	0	-	102	38.61 (12.20)	0	-
Week 4	98	40.50 (11.64)	98	2.93 (10.35)	99	40.17 (11.83)	99	1.28 (8.35)
Week 12	94	42.22 (12.08)	94	4.73 (11.99)	97	41.21 (12.13)	97	2.41 (10.36)
Week 24	93	41.35 (11.97)	93	3.88 (11.48)	87	40.82 (11.94)	87	1.65 (9.36)
Week 36	90	43.37 (11.32)	90	5.60 (12.65)	74	43.35 (11.91)	74	3.23 (11.09)
Week 52	88	43.61 (10.95)	88	5.73 (11.44)	70	44.42 (11.96)	70	4.63 (10.74)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Mental Health Score
Full analysis set



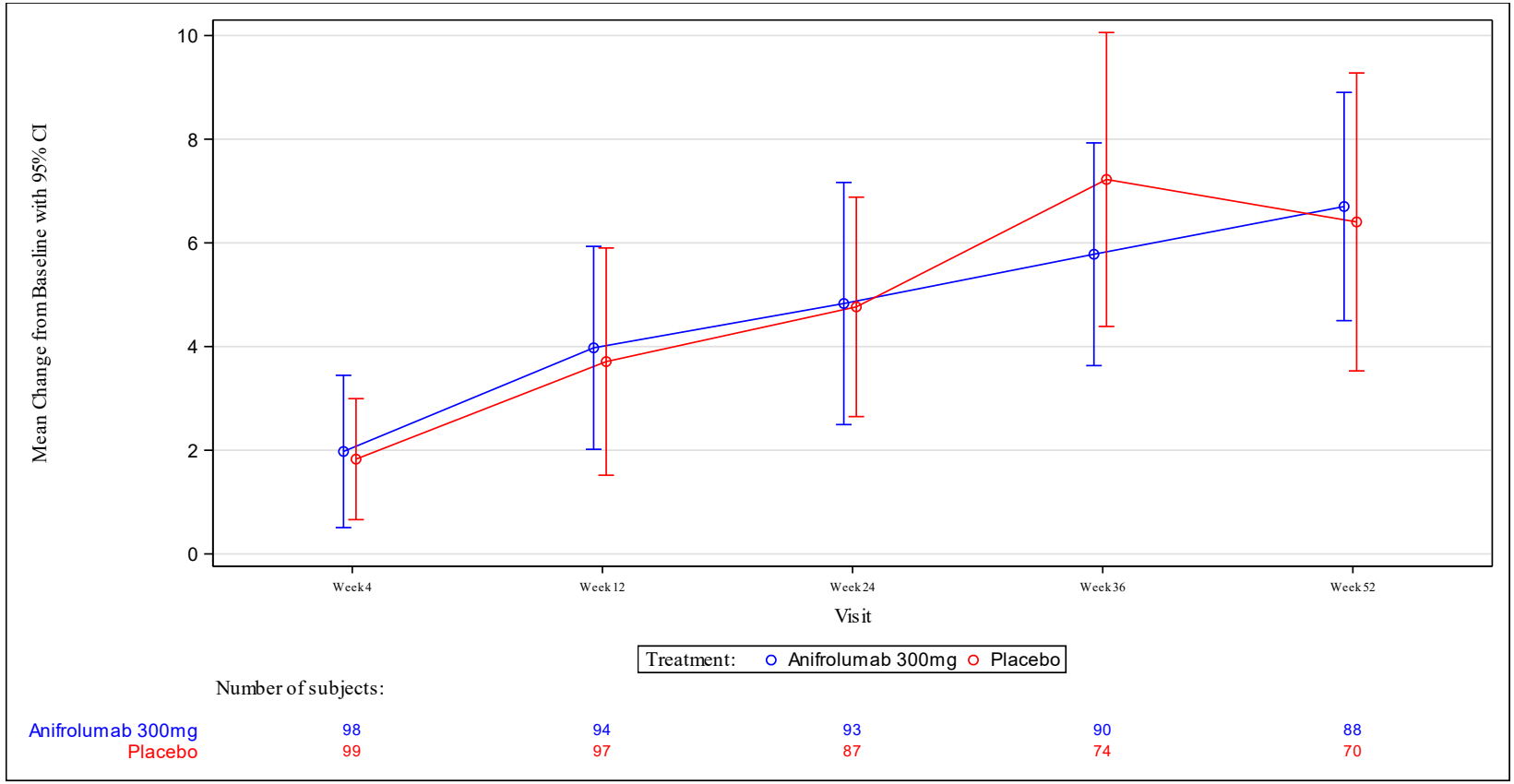
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Physical Functioning Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)				Placebo (N=102)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	99	35.47 (11.50)	0	-	102	33.99 (11.82)	0	-
Week 4	98	37.49 (10.10)	98	1.98 (7.33)	99	35.84 (11.86)	99	1.83 (5.85)
Week 12	94	39.55 (10.52)	94	3.98 (9.56)	97	37.88 (11.98)	97	3.71 (10.87)
Week 24	93	40.73 (11.12)	93	4.83 (11.34)	87	39.35 (12.34)	87	4.77 (9.93)
Week 36	90	41.53 (11.75)	90	5.78 (10.25)	74	42.47 (11.62)	74	7.22 (12.24)
Week 52	88	42.52 (10.83)	88	6.70 (10.39)	70	42.03 (11.67)	70	6.40 (12.05)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Physical Functioning Score
Full analysis set



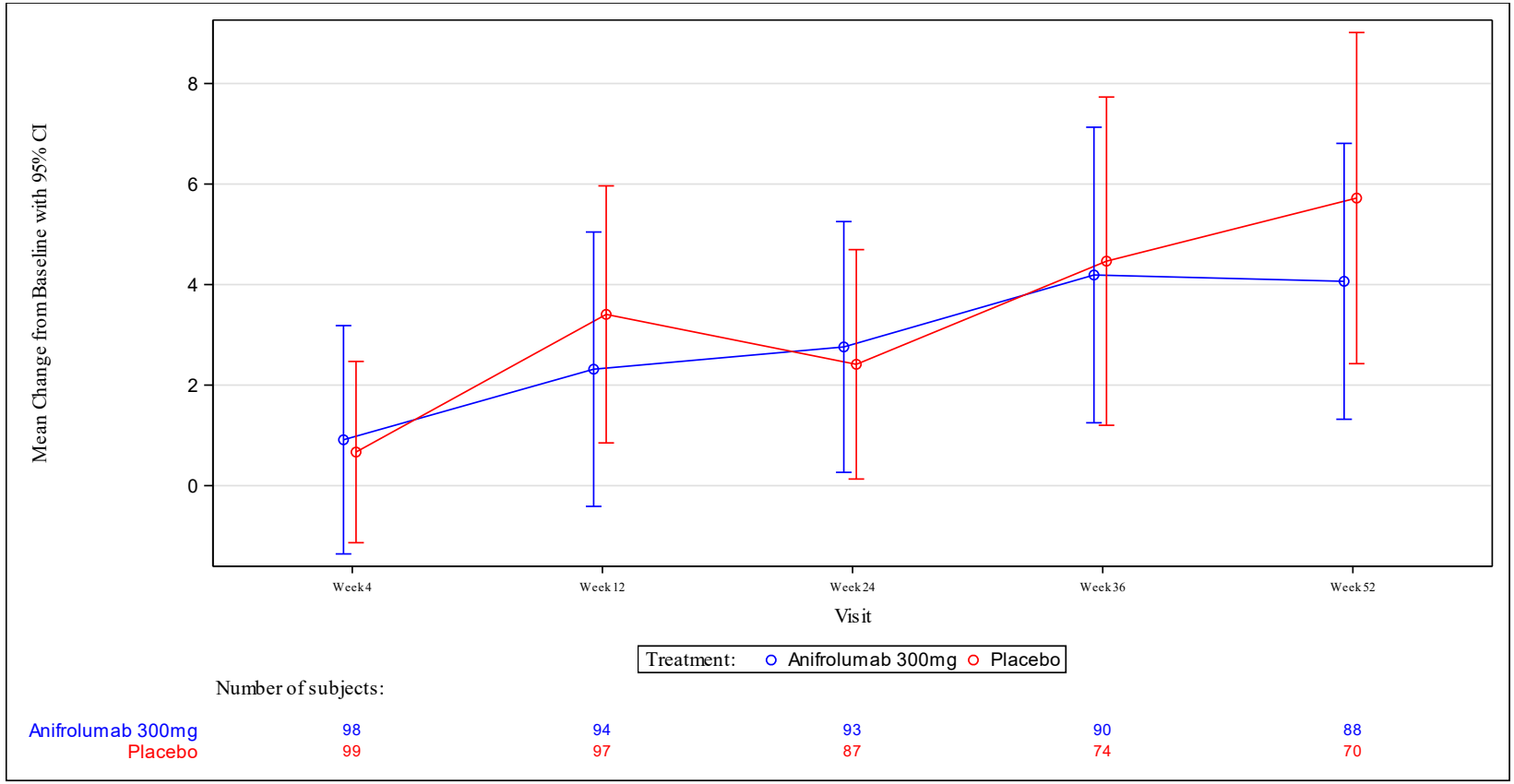
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Role Emotional Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)				Placebo (N=102)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	99	35.11 (12.89)	0	-	102	33.62 (12.90)	0	-
Week 4	98	35.81 (12.42)	98	0.91 (11.33)	99	34.48 (12.48)	99	0.67 (9.04)
Week 12	94	37.52 (13.72)	94	2.32 (13.32)	97	37.32 (13.22)	97	3.41 (12.69)
Week 24	93	37.74 (12.78)	93	2.76 (12.11)	87	37.02 (13.41)	87	2.41 (10.71)
Week 36	90	39.81 (13.01)	90	4.19 (14.04)	74	39.49 (13.45)	74	4.47 (14.09)
Week 52	88	39.67 (12.90)	88	4.06 (12.95)	70	40.78 (13.21)	70	5.72 (13.81)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Role Emotional Score
Full analysis set



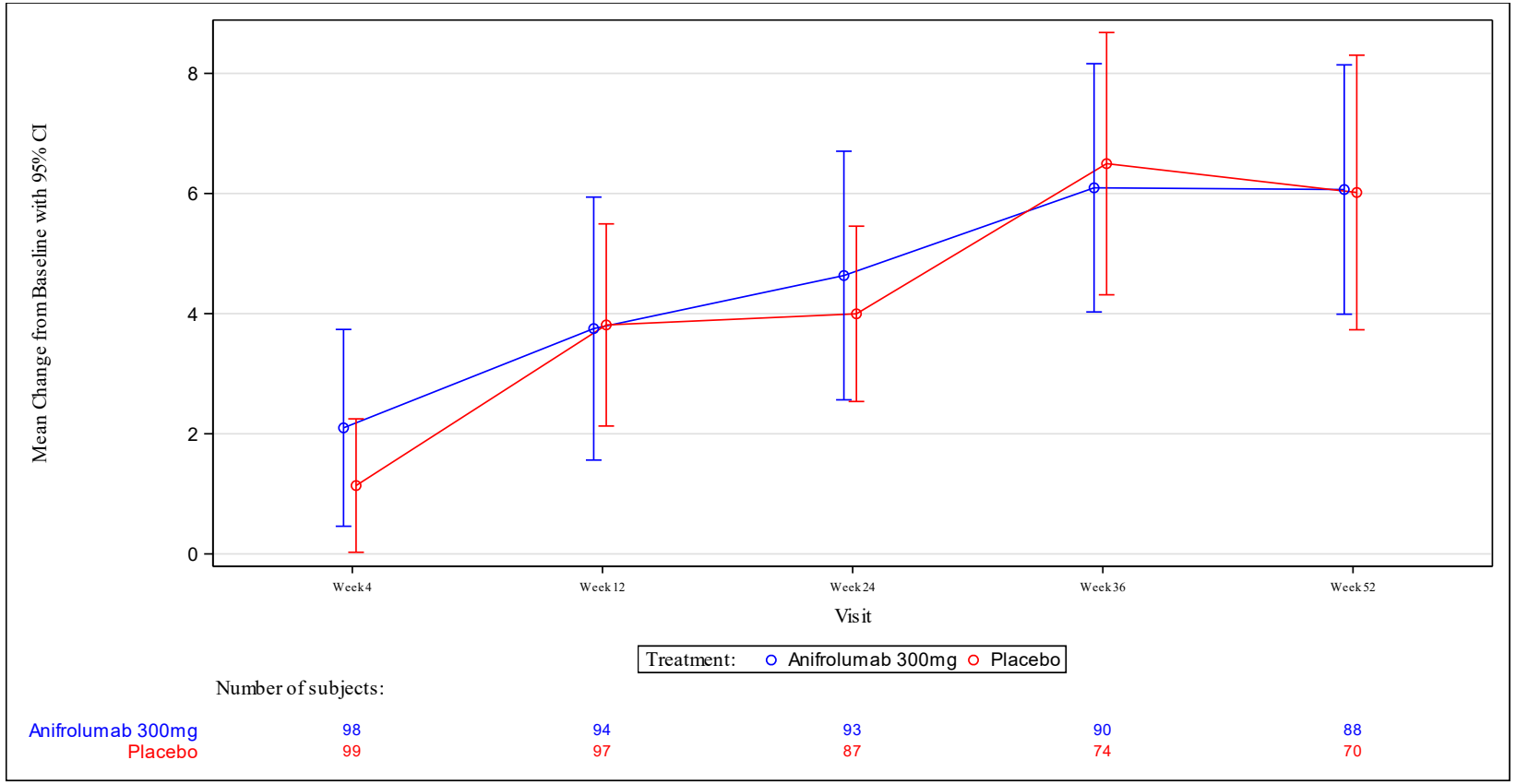
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Role Physical Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)				Placebo (N=102)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	99	34.47 (10.34)	0	-	102	33.85 (10.05)	0	-
Week 4	98	36.64 (9.59)	98	2.10 (8.17)	99	35.18 (9.54)	99	1.14 (5.57)
Week 12	94	38.72 (10.81)	94	3.75 (10.69)	97	37.74 (10.85)	97	3.81 (8.35)
Week 24	93	39.53 (10.66)	93	4.63 (10.05)	87	38.16 (11.01)	87	4.00 (6.85)
Week 36	90	41.21 (10.83)	90	6.09 (9.87)	74	41.54 (10.78)	74	6.50 (9.42)
Week 52	88	40.88 (11.23)	88	6.07 (9.80)	70	41.00 (11.33)	70	6.02 (9.59)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Role Physical Score
Full analysis set



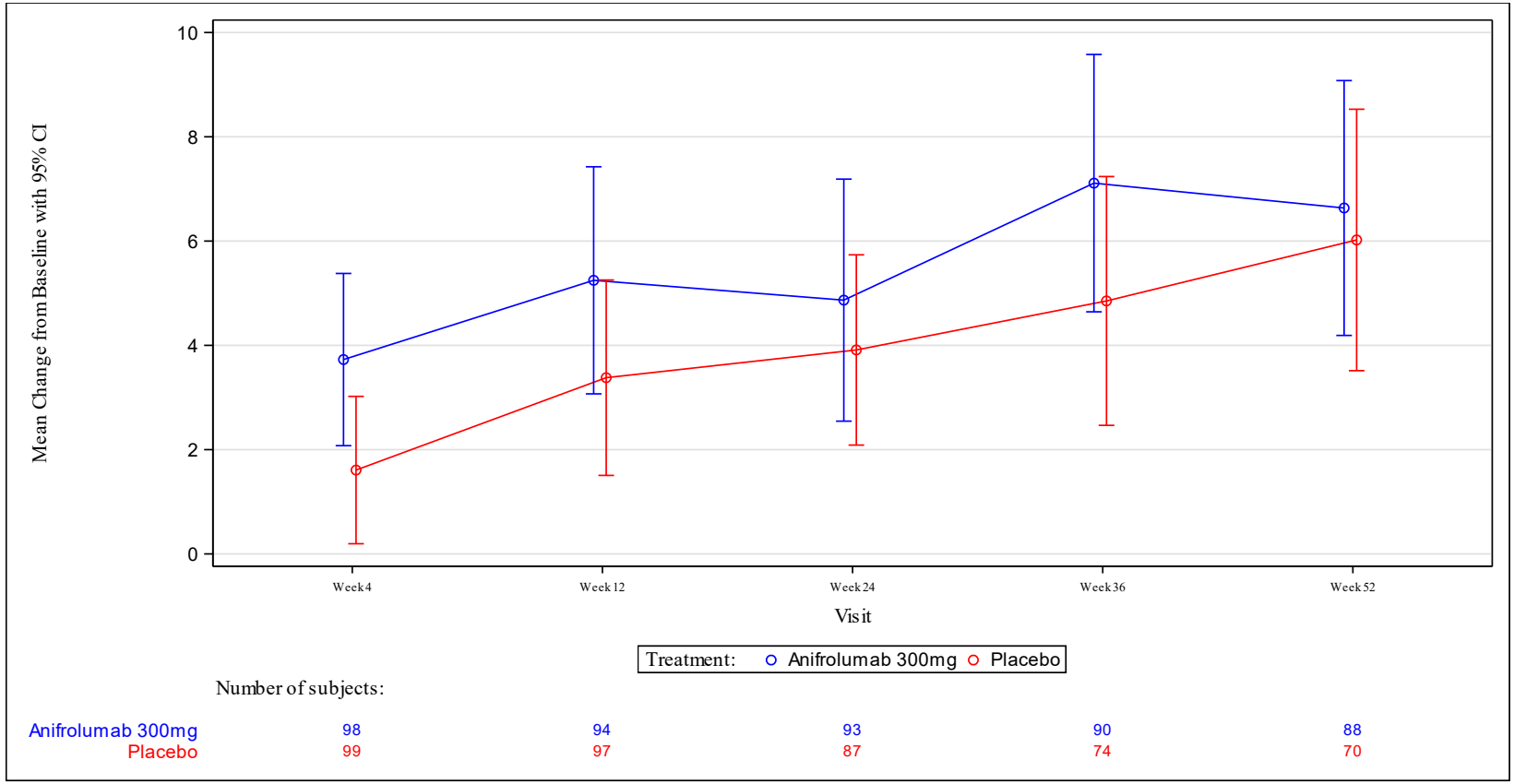
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Social Functioning Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)				Placebo (N=102)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	99	38.47 (10.35)	0	-	102	39.57 (11.34)	0	-
Week 4	98	42.25 (10.82)	98	3.73 (8.24)	99	41.49 (10.78)	99	1.61 (7.09)
Week 12	94	43.99 (11.93)	94	5.25 (10.63)	97	42.72 (12.58)	97	3.38 (9.30)
Week 24	93	43.43 (12.01)	93	4.87 (11.27)	87	43.62 (12.05)	87	3.91 (8.56)
Week 36	90	46.02 (12.83)	90	7.11 (11.78)	74	45.85 (12.20)	74	4.85 (10.30)
Week 52	88	45.56 (12.65)	88	6.63 (11.53)	70	46.11 (13.32)	70	6.02 (10.51)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Social Functioning Score
Full analysis set



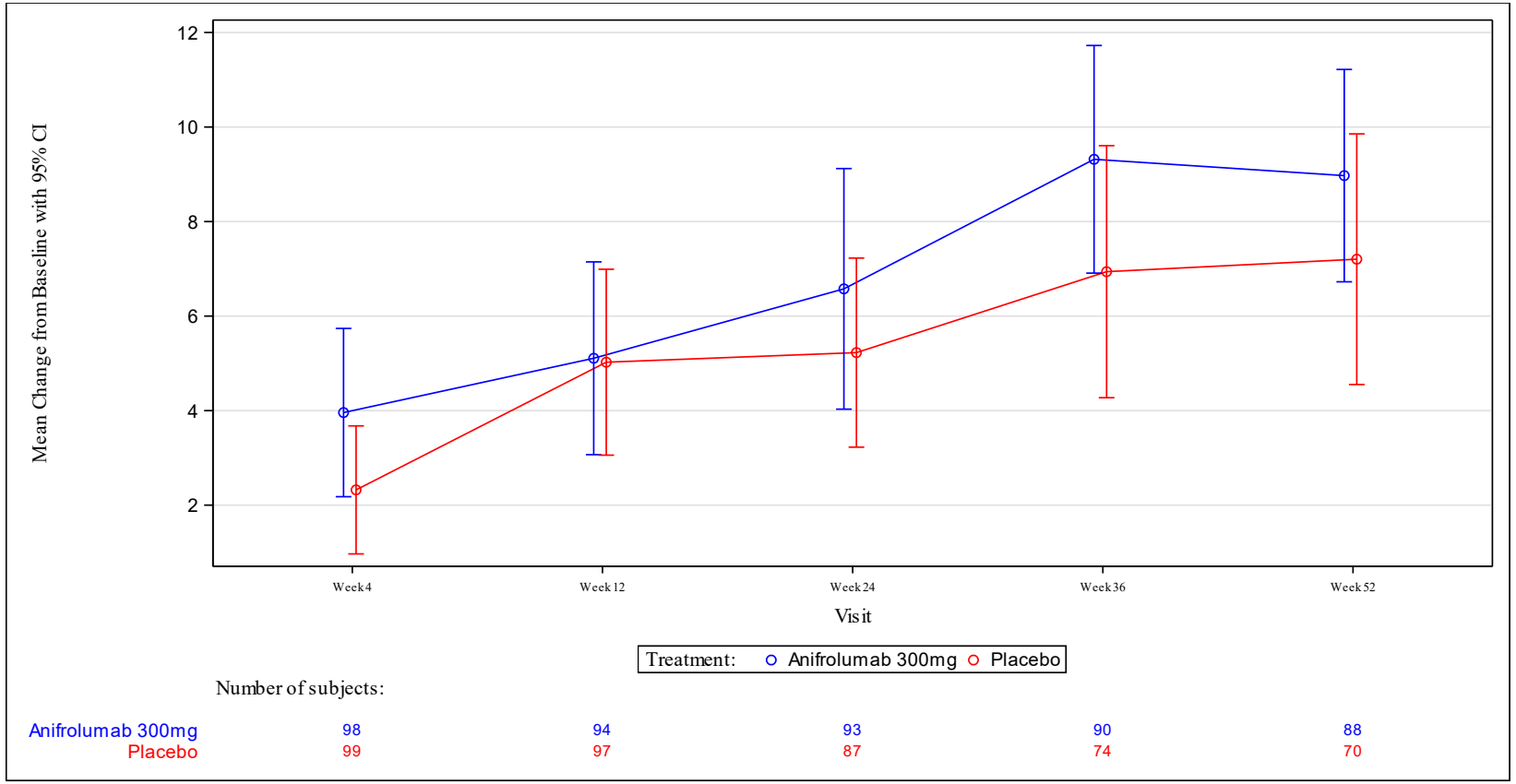
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Bodily Pain Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)				Placebo (N=102)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	99	36.16 (9.13)	0	-	102	37.47 (10.50)	0	-
Week 4	98	40.11 (9.23)	98	3.96 (8.88)	99	40.10 (10.25)	99	2.32 (6.79)
Week 12	94	41.53 (10.18)	94	5.11 (9.96)	97	42.49 (10.96)	97	5.02 (9.76)
Week 24	93	42.65 (11.60)	93	6.58 (12.36)	87	43.32 (11.45)	87	5.23 (9.39)
Week 36	90	45.58 (11.31)	90	9.32 (11.50)	74	45.39 (11.29)	74	6.94 (11.51)
Week 52	88	45.12 (11.27)	88	8.97 (10.60)	70	45.66 (11.01)	70	7.20 (11.12)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Bodily Pain Score
Full analysis set



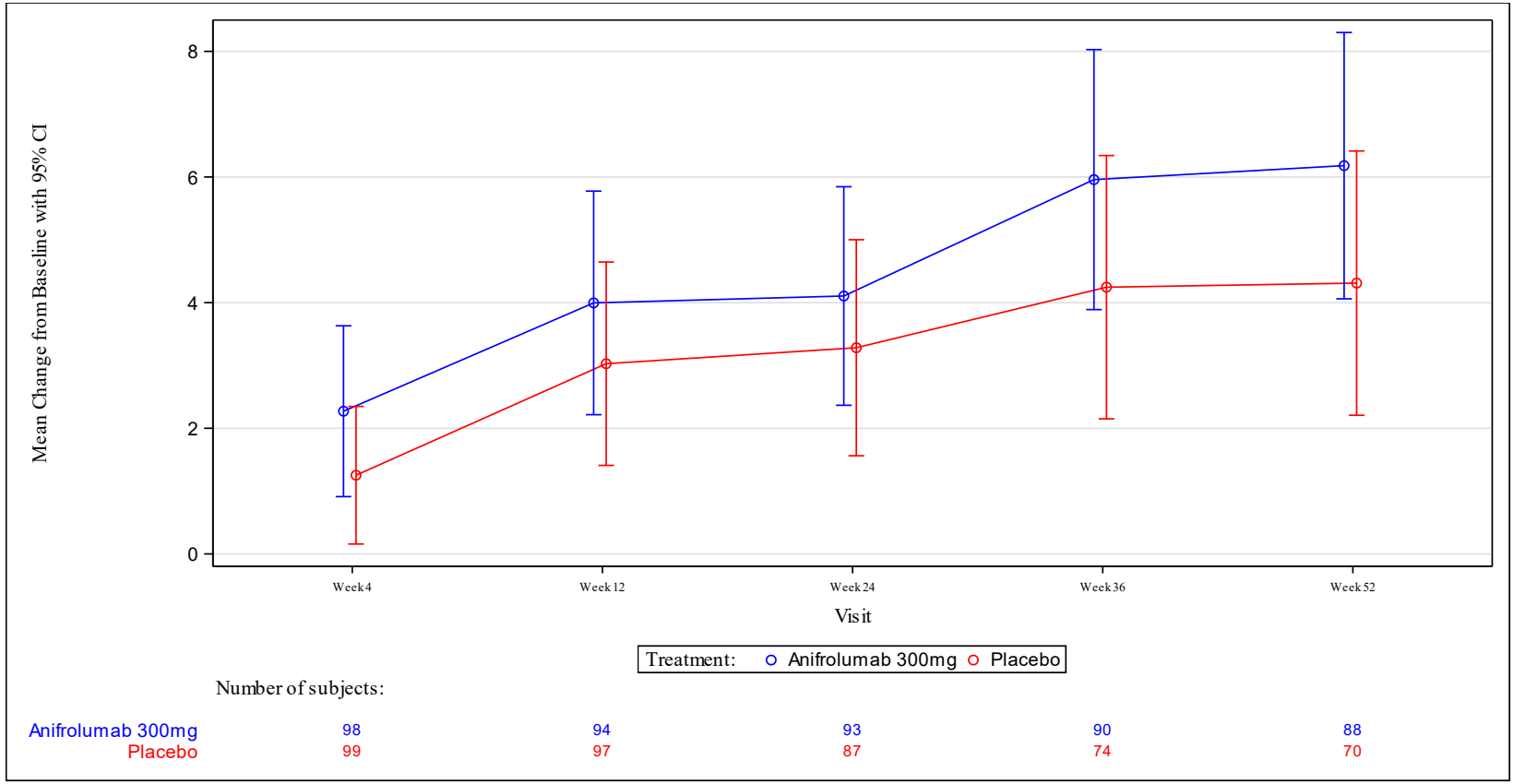
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Vitality Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)				Placebo (N=102)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	99	32.10 (8.38)	0	-	102	34.09 (9.41)	0	-
Week 4	98	34.42 (8.24)	98	2.27 (6.78)	99	35.38 (9.65)	99	1.25 (5.49)
Week 12	94	36.08 (9.55)	94	4.00 (8.69)	97	37.10 (10.50)	97	3.03 (8.03)
Week 24	93	36.17 (9.05)	93	4.11 (8.45)	87	38.05 (10.81)	87	3.28 (8.07)
Week 36	90	37.81 (10.09)	90	5.96 (9.88)	74	39.65 (10.79)	74	4.25 (9.05)
Week 52	88	38.15 (11.32)	88	6.18 (10.00)	70	39.57 (10.70)	70	4.31 (8.82)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Vitality Score
Full analysis set



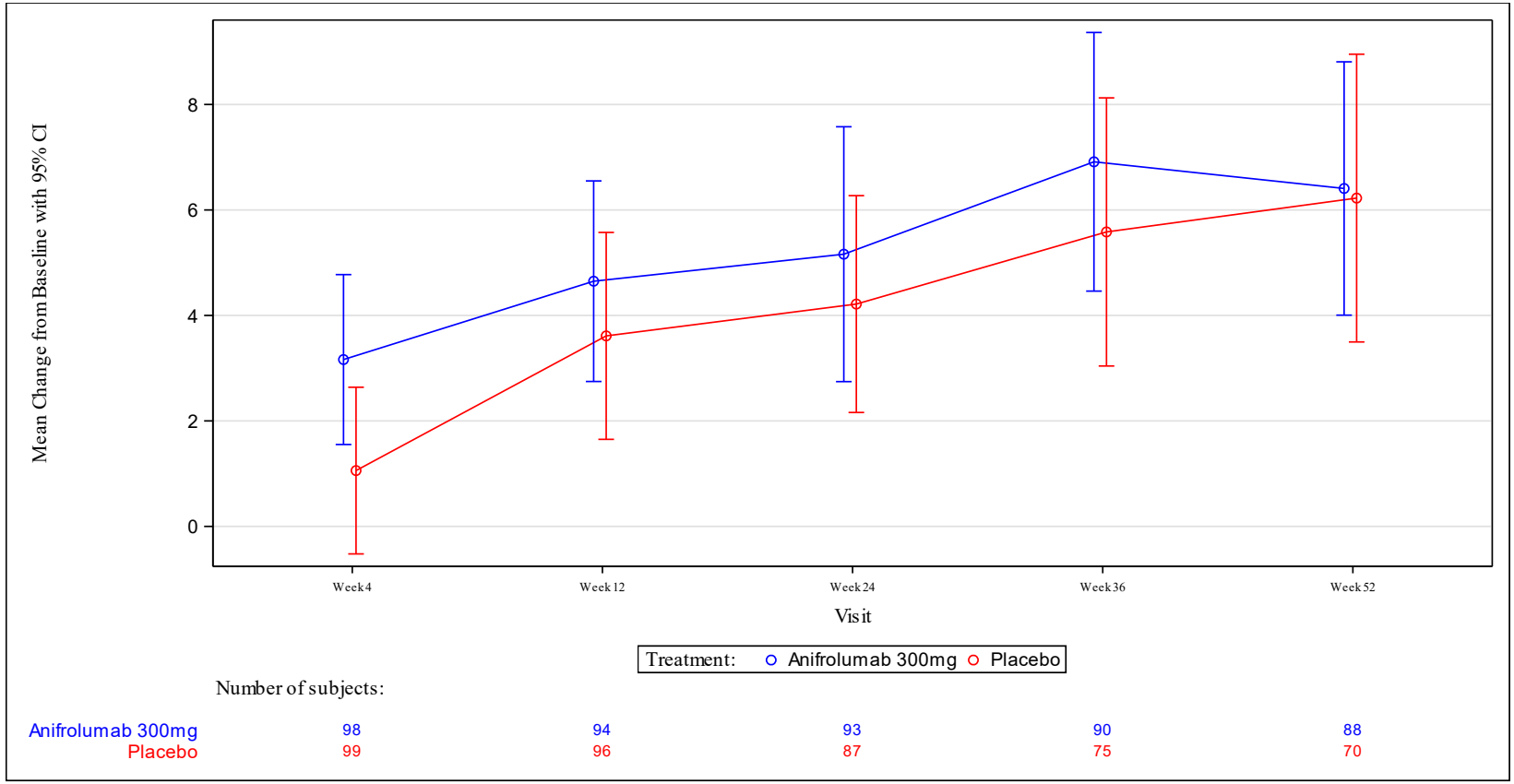
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - FACIT-F Total Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)				Placebo (N=102)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	99	25.62 (12.04)	0	-	102	26.12 (13.55)	0	-
Week 4	98	28.82 (12.16)	98	3.16 (8.03)	99	27.56 (13.08)	99	1.06 (7.92)
Week 12	94	30.60 (13.11)	94	4.65 (9.28)	96	29.67 (13.36)	96	3.61 (9.68)
Week 24	93	31.01 (13.91)	93	5.16 (11.73)	87	30.56 (14.04)	87	4.22 (9.65)
Week 36	90	32.91 (13.71)	90	6.91 (11.71)	75	33.03 (13.79)	75	5.58 (11.05)
Week 52	88	32.57 (13.84)	88	6.41 (11.33)	70	33.31 (13.89)	70	6.23 (11.44)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - FACIT-F Total Score
Full analysis set



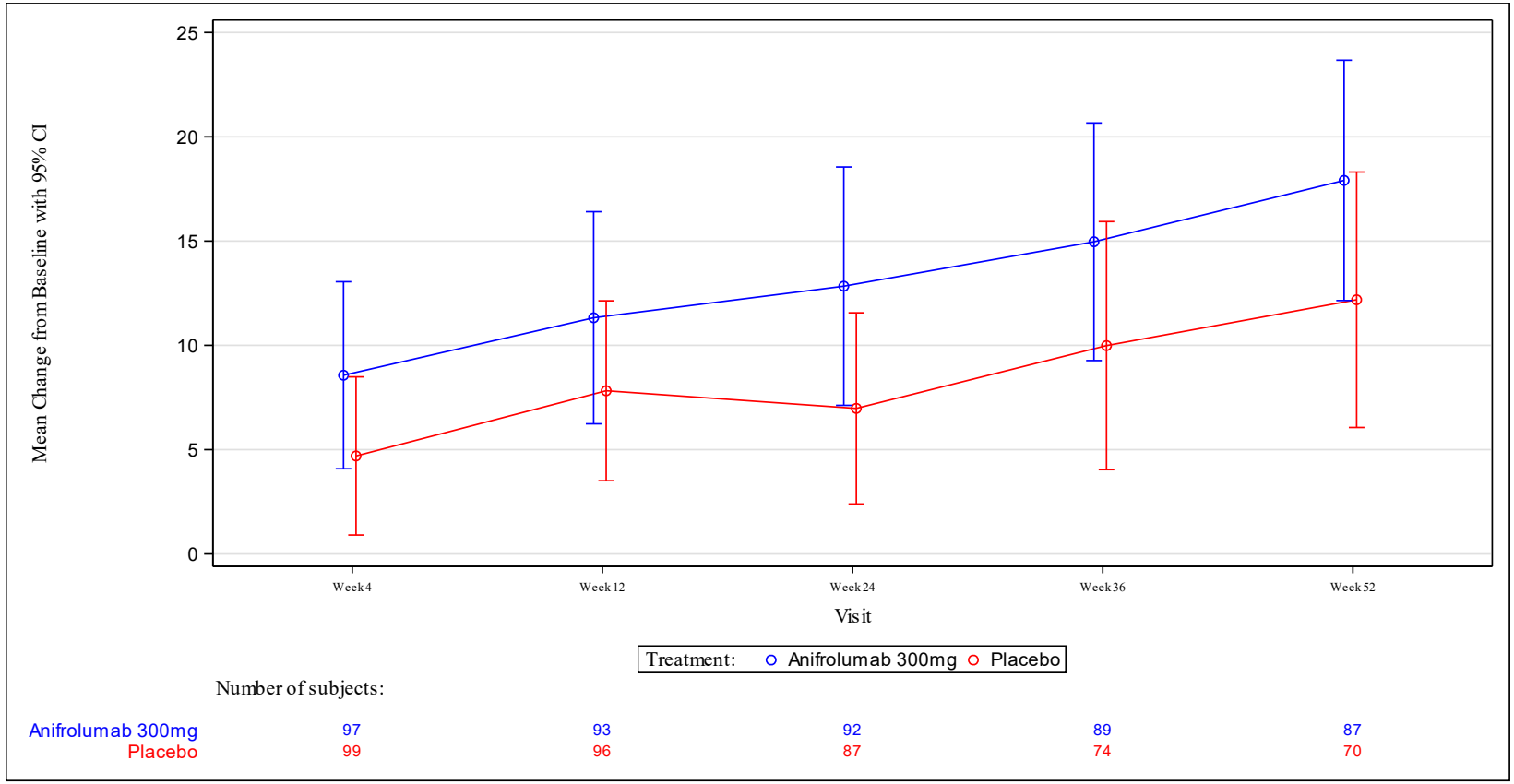
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - EQ VAS Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)				Placebo (N=102)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	98	52.14 (22.13)	0	-	102	56.80 (20.88)	0	-
Week 4	98	61.20 (19.45)	97	8.57 (22.24)	99	62.01 (19.48)	99	4.70 (19.01)
Week 12	94	63.35 (21.23)	93	11.32 (24.69)	96	63.95 (20.77)	96	7.82 (21.29)
Week 24	93	65.55 (22.38)	92	12.84 (27.59)	87	63.62 (22.95)	87	6.98 (21.50)
Week 36	90	67.57 (22.74)	89	14.97 (27.04)	74	68.09 (21.61)	74	9.99 (25.67)
Week 52	88	69.98 (22.61)	87	17.91 (27.03)	70	70.60 (21.01)	70	12.19 (25.68)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - EQ VAS Score
Full analysis set



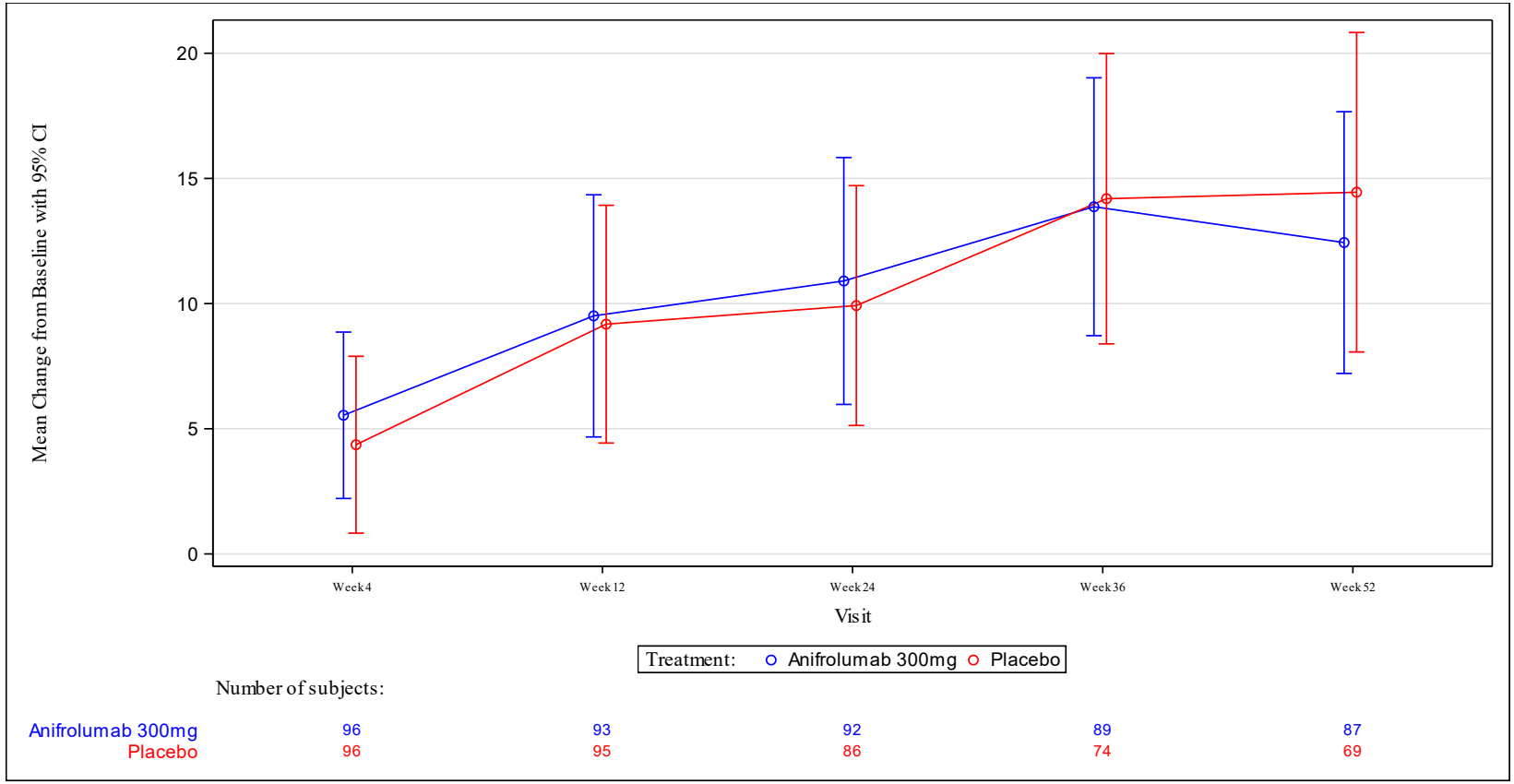
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - Lupus QoL Physical Health domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)				Placebo (N=102)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	98	54.02 (27.54)	0	-	100	51.91 (27.21)	0	-
Week 4	97	59.77 (25.76)	96	5.54 (16.40)	98	56.38 (25.22)	96	4.36 (17.44)
Week 12	94	63.87 (26.33)	93	9.51 (23.48)	97	60.99 (27.08)	95	9.18 (23.31)
Week 24	93	65.66 (26.01)	92	10.90 (23.81)	87	61.60 (28.00)	86	9.92 (22.35)
Week 36	90	68.68 (27.04)	89	13.87 (24.45)	75	68.17 (27.01)	74	14.19 (25.03)
Week 52	88	67.38 (27.25)	87	12.44 (24.53)	70	67.73 (26.69)	69	14.45 (26.56)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - Lupus QoL Physical Health domain score
Full analysis set



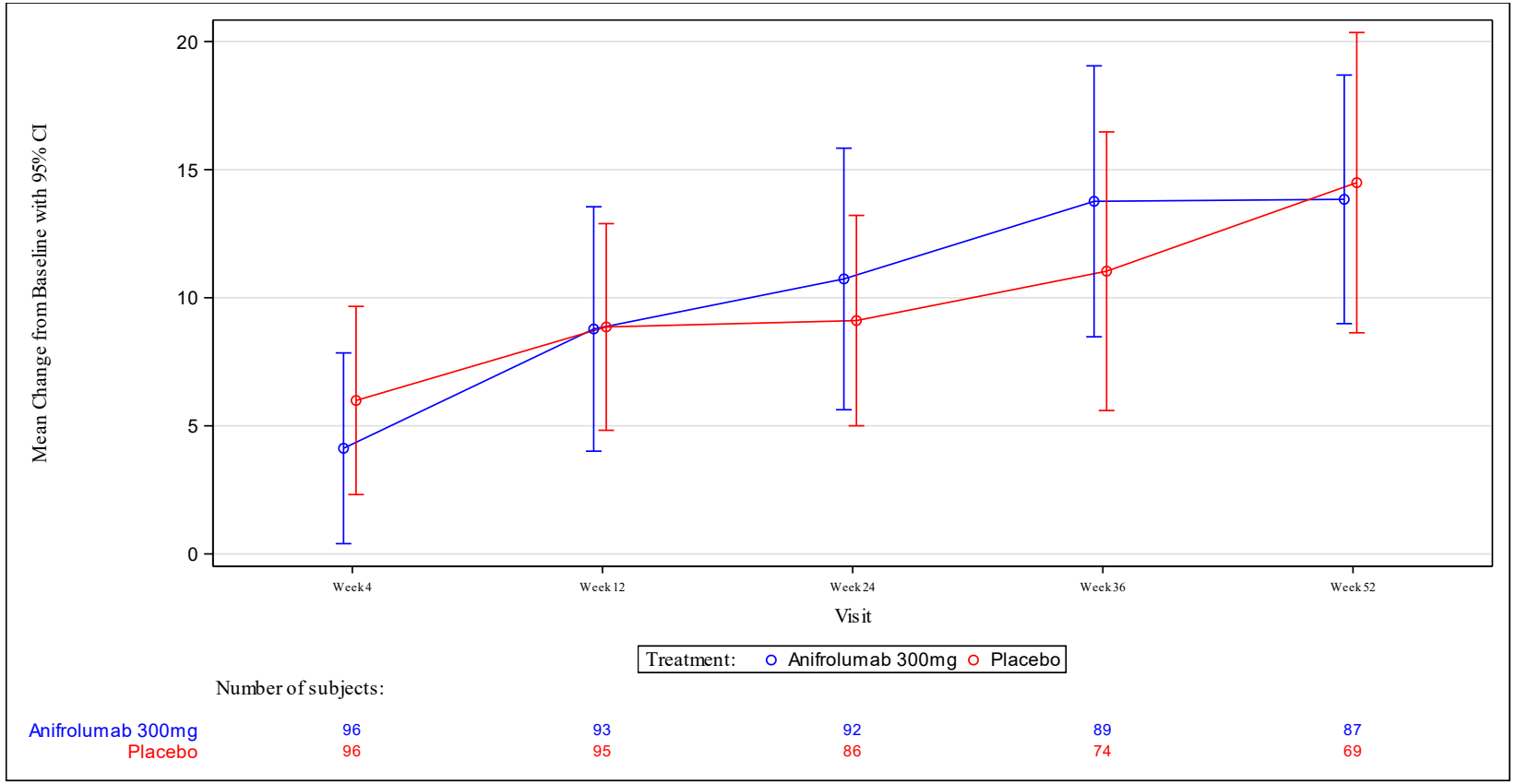
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - Lupus QoL Emotional Health domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)				Placebo (N=102)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	98	56.76 (26.65)	0	-	100	58.54 (27.48)	0	-
Week 4	97	60.82 (24.32)	96	4.12 (18.37)	98	64.37 (26.42)	96	5.99 (18.13)
Week 12	94	64.94 (24.60)	93	8.78 (23.16)	97	67.74 (25.39)	95	8.86 (19.80)
Week 24	93	66.85 (24.47)	92	10.73 (24.65)	87	68.96 (26.42)	86	9.11 (19.15)
Week 36	90	70.19 (24.97)	89	13.76 (25.11)	75	72.06 (24.12)	74	11.04 (23.47)
Week 52	88	70.93 (23.52)	87	13.84 (22.76)	70	74.17 (24.97)	69	14.49 (24.40)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - Lupus QoL Emotional Health domain score
Full analysis set



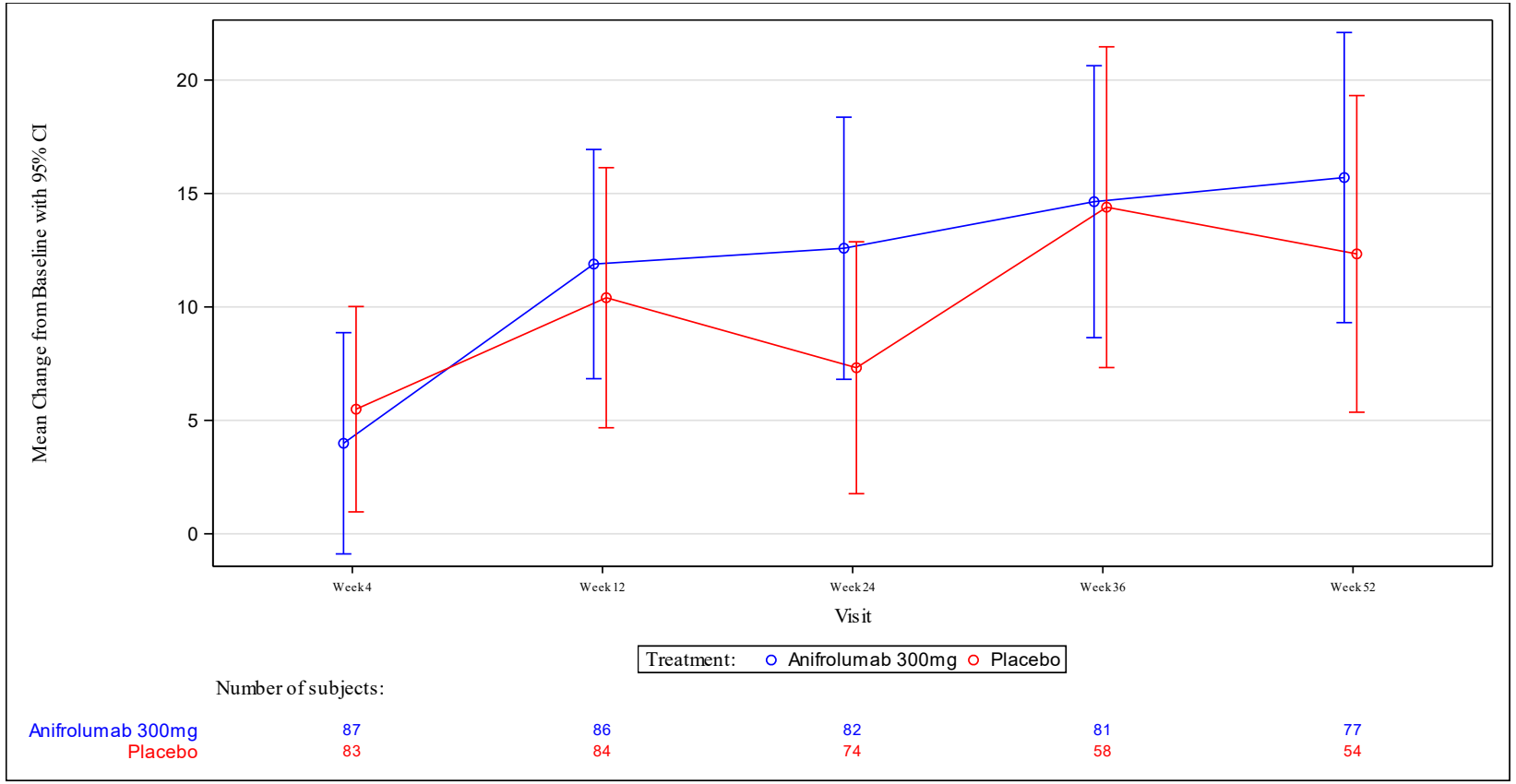
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - Lupus QoL Body Image domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)				Placebo (N=102)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	95	53.57 (31.78)	0	-	91	55.59 (28.10)	0	-
Week 4	90	56.18 (29.73)	87	3.99 (22.88)	89	61.11 (29.33)	83	5.49 (20.73)
Week 12	90	64.82 (27.09)	86	11.89 (23.57)	90	67.28 (26.19)	84	10.41 (26.41)
Week 24	84	64.64 (27.97)	82	12.59 (26.29)	79	62.93 (31.25)	74	7.32 (23.96)
Week 36	84	67.21 (30.30)	81	14.64 (27.10)	63	69.87 (27.82)	58	14.40 (26.88)
Week 52	80	68.93 (27.66)	77	15.70 (28.17)	57	66.22 (31.47)	54	12.34 (25.57)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - Lupus QoL Body Image domain score
Full analysis set



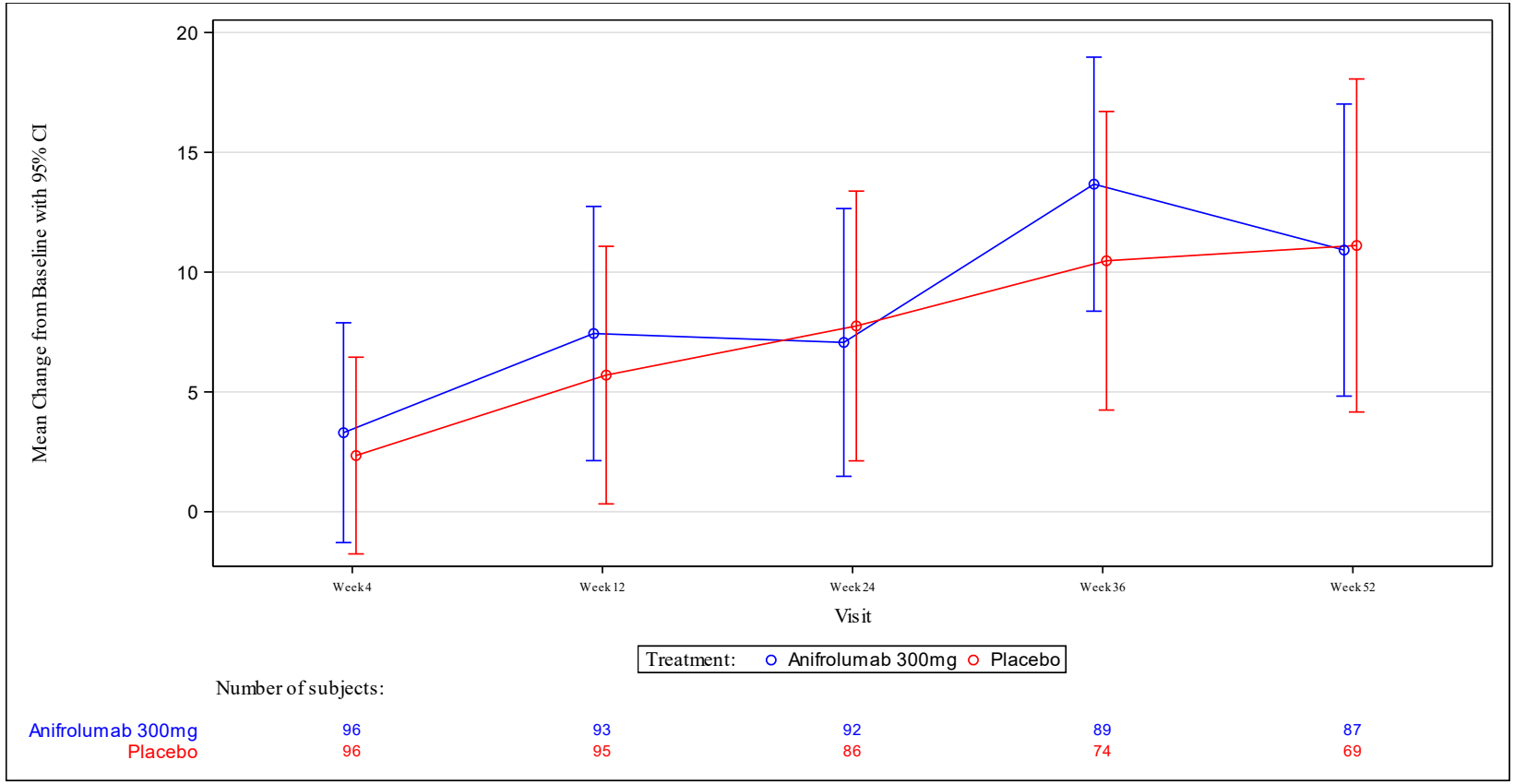
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - Lupus QoL Burden to Others domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)				Placebo (N=102)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	98	44.13 (29.82)	0	-	100	49.75 (30.85)	0	-
Week 4	97	47.59 (30.78)	96	3.30 (22.64)	98	50.77 (30.95)	96	2.34 (20.26)
Week 12	94	52.22 (31.40)	93	7.44 (25.76)	97	54.98 (31.54)	95	5.70 (26.39)
Week 24	93	51.79 (32.97)	92	7.07 (26.98)	87	57.18 (30.08)	86	7.75 (26.25)
Week 36	90	58.43 (31.49)	89	13.67 (25.16)	75	61.67 (29.64)	74	10.47 (26.89)
Week 52	88	57.39 (32.17)	87	10.92 (28.60)	70	59.76 (31.66)	69	11.11 (28.93)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - Lupus QoL Burden to Others domain score
Full analysis set



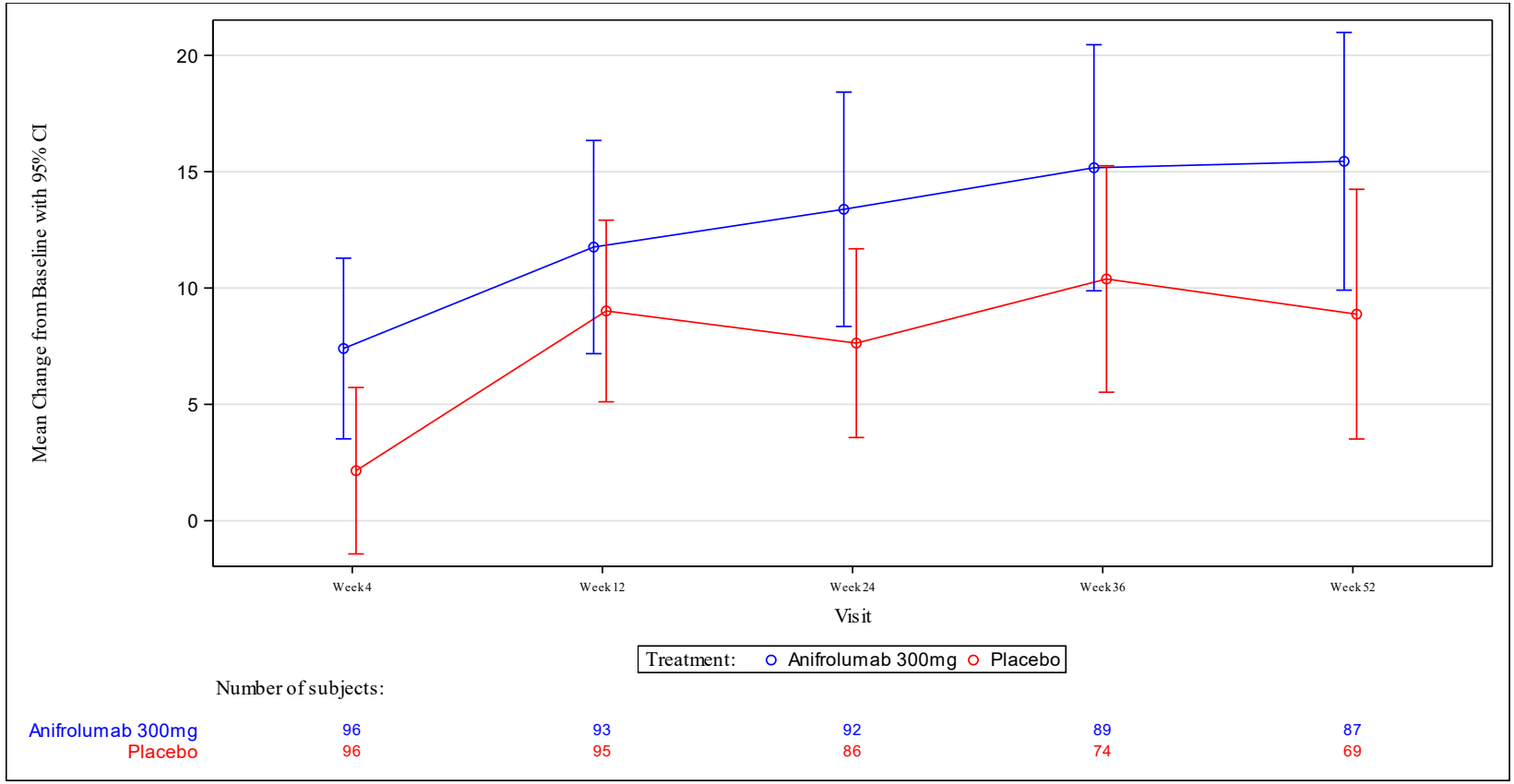
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - Lupus QoL Fatigue domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)				Placebo (N=102)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	98	45.47 (27.32)	0	-	100	50.00 (28.45)	0	-
Week 4	97	52.88 (25.58)	96	7.40 (19.16)	98	51.79 (29.68)	96	2.15 (17.65)
Week 12	94	57.78 (28.08)	93	11.76 (22.25)	97	58.57 (27.44)	95	9.01 (19.16)
Week 24	93	58.80 (27.98)	92	13.38 (24.31)	87	57.54 (29.70)	86	7.63 (18.92)
Week 36	90	61.53 (27.68)	89	15.17 (25.10)	75	63.50 (29.74)	74	10.39 (21.01)
Week 52	88	61.29 (29.19)	87	15.45 (25.98)	70	62.14 (30.65)	69	8.88 (22.34)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - Lupus QoL Fatigue domain score
Full analysis set



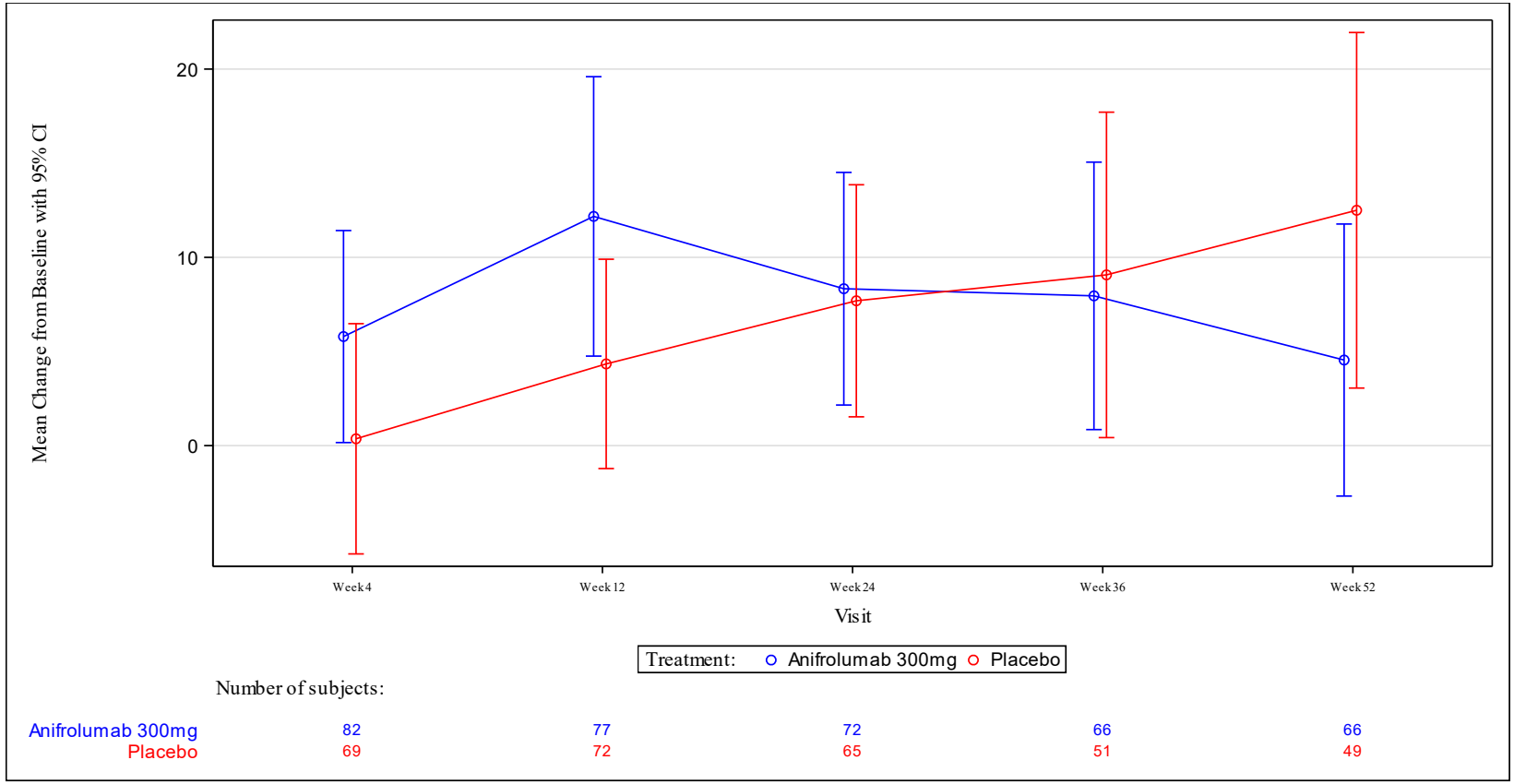
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - Lupus QoL Intimate Relationships domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)				Placebo (N=102)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	87	54.60 (34.00)	0	-	82	56.71 (35.31)	0	-
Week 4	85	60.44 (32.72)	82	5.79 (25.62)	77	59.90 (34.13)	69	0.36 (25.45)
Week 12	79	66.14 (32.04)	77	12.18 (32.70)	82	63.41 (33.15)	72	4.34 (23.66)
Week 24	78	62.98 (33.43)	72	8.33 (26.29)	71	64.61 (32.94)	65	7.69 (24.87)
Week 36	71	63.20 (33.80)	66	7.95 (28.89)	55	67.50 (32.06)	51	9.07 (30.73)
Week 52	71	60.92 (34.39)	66	4.55 (29.39)	52	66.83 (36.12)	49	12.50 (32.87)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - Lupus QoL Intimate Relationships domain score
Full analysis set



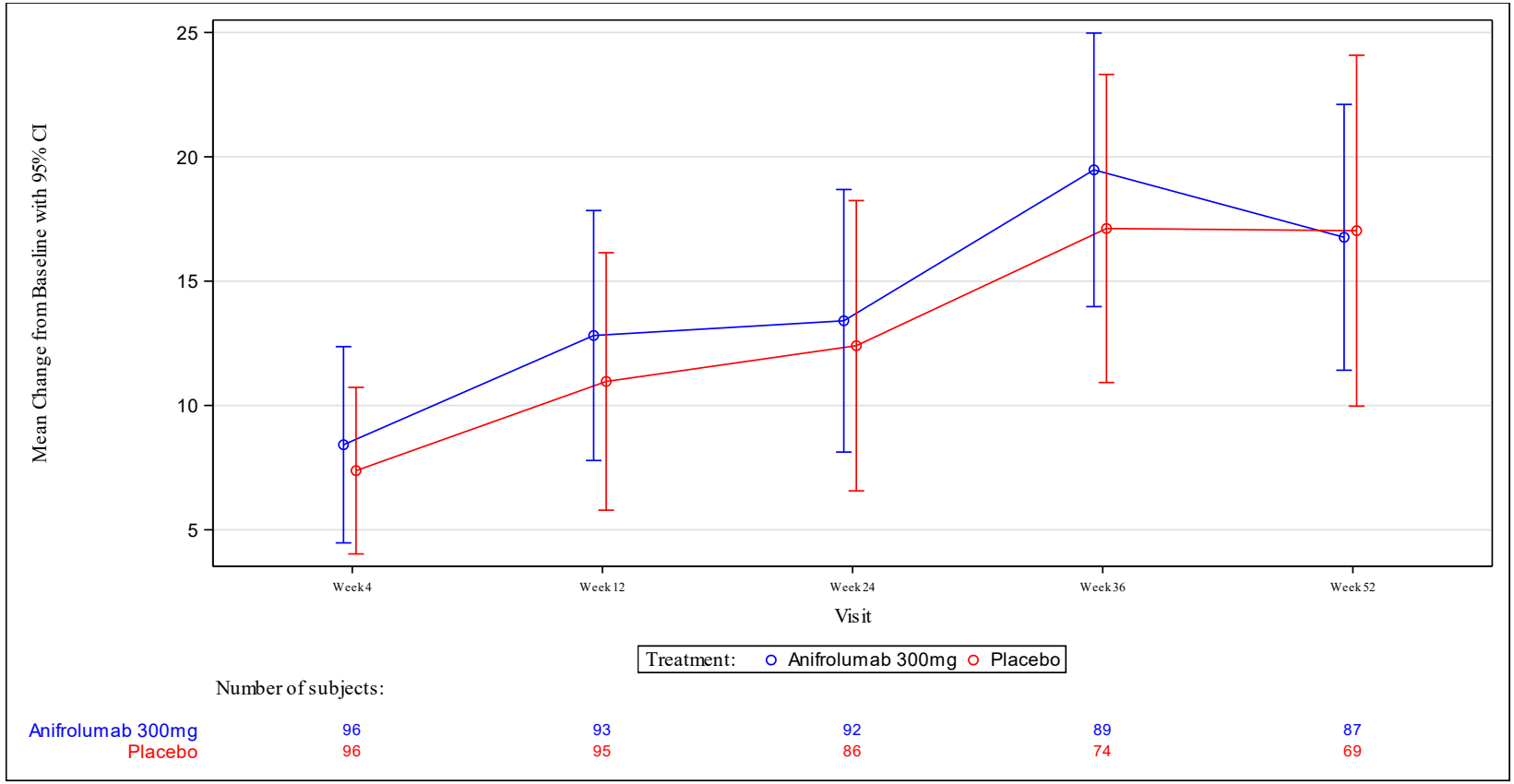
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - Lupus QoL Pain domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)				Placebo (N=102)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	98	48.72 (26.23)	0	-	100	49.33 (30.49)	0	-
Week 4	97	57.13 (26.71)	96	8.42 (19.48)	98	56.63 (27.68)	96	7.38 (16.53)
Week 12	94	61.52 (27.84)	93	12.81 (24.41)	97	60.05 (29.14)	95	10.97 (25.42)
Week 24	93	62.10 (28.70)	92	13.41 (25.50)	87	61.69 (31.86)	86	12.40 (27.23)
Week 36	90	67.87 (28.20)	89	19.48 (26.11)	75	68.89 (27.17)	74	17.12 (26.74)
Week 52	88	65.91 (28.07)	87	16.76 (25.08)	70	68.21 (27.81)	69	17.03 (29.37)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - Lupus QoL Pain domain score
Full analysis set



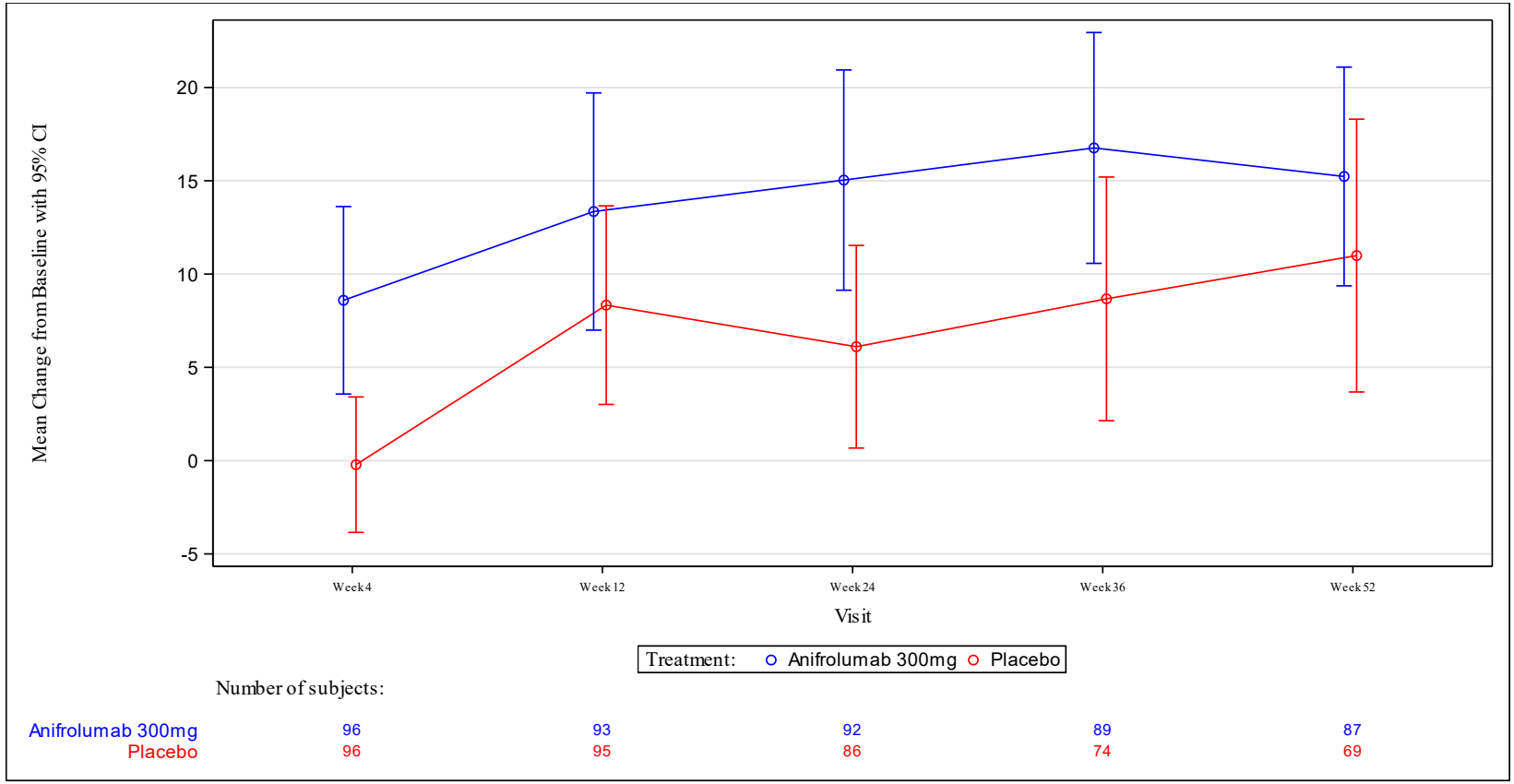
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - Lupus QoL Planning domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)				Placebo (N=102)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	98	51.79 (30.54)	0	-	100	55.25 (33.26)	0	-
Week 4	97	60.31 (29.14)	96	8.59 (24.79)	98	55.65 (32.66)	96	-0.22 (17.92)
Week 12	94	66.22 (28.85)	93	13.35 (30.87)	97	64.00 (30.04)	95	8.33 (26.13)
Week 24	93	66.94 (29.65)	92	15.04 (28.50)	87	62.16 (32.32)	86	6.10 (25.32)
Week 36	90	69.63 (30.61)	89	16.76 (29.37)	75	67.44 (31.90)	74	8.67 (28.18)
Week 52	88	67.90 (29.38)	87	15.23 (27.50)	70	68.45 (30.26)	69	10.99 (30.43)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - Lupus QoL Planning domain score
Full analysis set



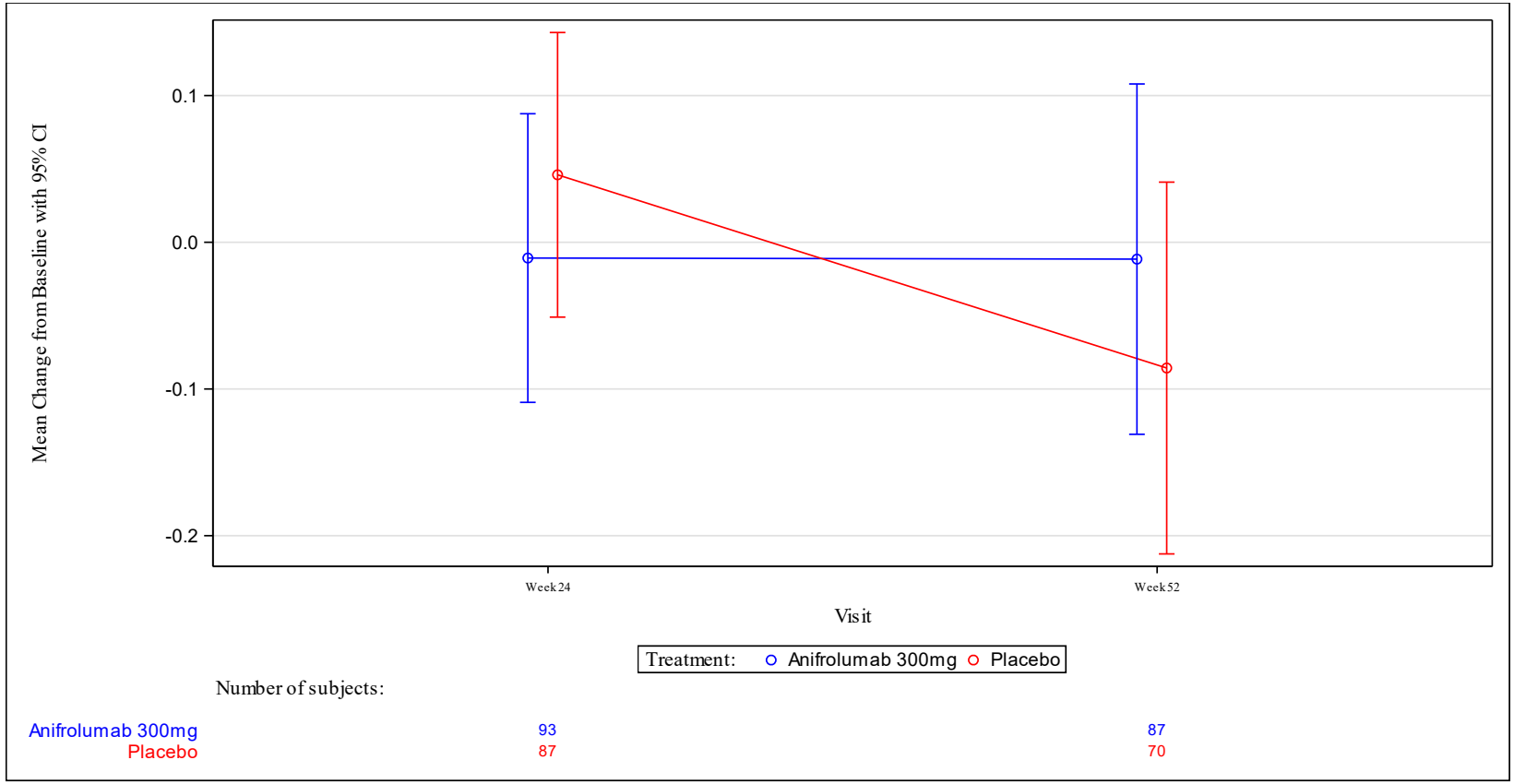
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - SDI Global Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)				Placebo (N=102)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	99	0.66 (0.96)	0	-	102	0.67 (1.21)	0	-
Week 24	93	0.63 (0.99)	93	-0.01 (0.48)	87	0.77 (1.36)	87	0.05 (0.46)
Week 52	87	0.64 (0.98)	87	-0.01 (0.56)	70	0.54 (1.13)	70	-0.09 (0.53)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - SDI Global Score
Full analysis set



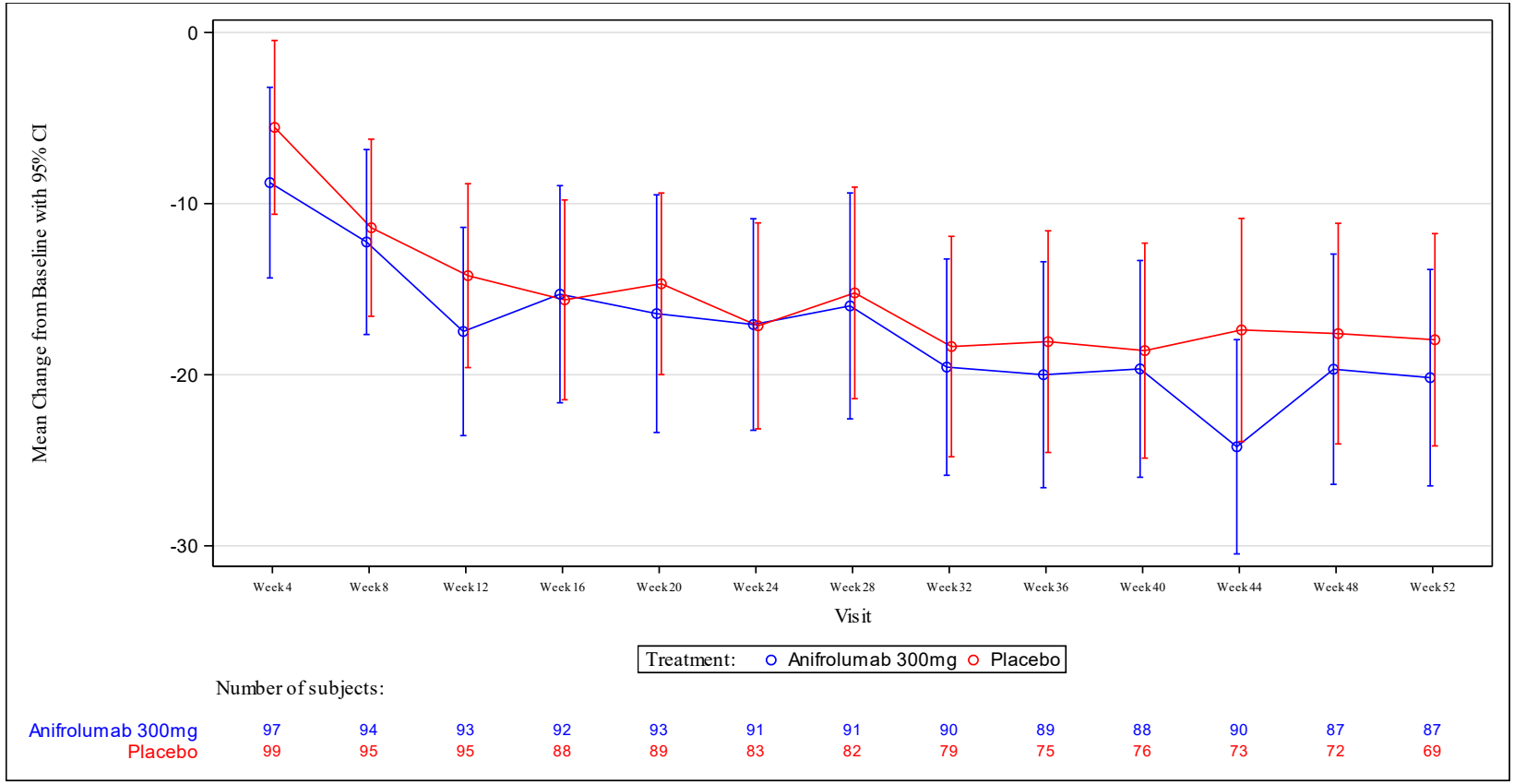
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - PtGA
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)				Placebo (N=102)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	99	54.20 (24.75)	0	-	102	55.58 (23.32)	0	-
Week 4	97	45.42 (24.53)	97	-8.77 (27.64)	99	49.47 (26.63)	99	-5.55 (25.46)
Week 8	94	42.41 (22.15)	94	-12.24 (26.39)	95	43.06 (24.37)	95	-11.41 (25.41)
Week 12	93	37.24 (24.58)	93	-17.47 (29.54)	95	40.54 (24.97)	95	-14.21 (26.38)
Week 16	92	38.79 (25.44)	92	-15.29 (30.63)	88	39.13 (24.37)	88	-15.63 (27.56)
Week 20	93	38.01 (24.00)	93	-16.43 (33.72)	89	41.43 (25.08)	89	-14.69 (25.19)
Week 24	91	37.68 (24.19)	91	-17.07 (29.68)	83	37.66 (24.70)	83	-17.14 (27.56)
Week 28	91	38.32 (23.92)	91	-15.98 (31.70)	82	39.52 (24.48)	82	-15.22 (28.13)
Week 32	90	34.92 (23.09)	90	-19.56 (30.18)	79	35.53 (24.32)	79	-18.35 (28.76)
Week 36	89	33.85 (25.59)	89	-20.00 (31.34)	75	35.17 (24.32)	75	-18.07 (28.15)
Week 40	88	34.31 (23.29)	88	-19.66 (29.89)	76	35.38 (23.04)	76	-18.59 (27.49)
Week 44	90	30.23 (22.68)	90	-24.21 (29.89)	73	37.05 (25.44)	73	-17.38 (27.94)
Week 48	87	34.47 (23.79)	87	-19.68 (31.57)	72	35.94 (22.94)	72	-17.60 (27.43)
Week 52	87	34.82 (25.60)	87	-20.17 (29.67)	69	36.54 (26.90)	69	-17.96 (25.83)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - PtGA
Full analysis set



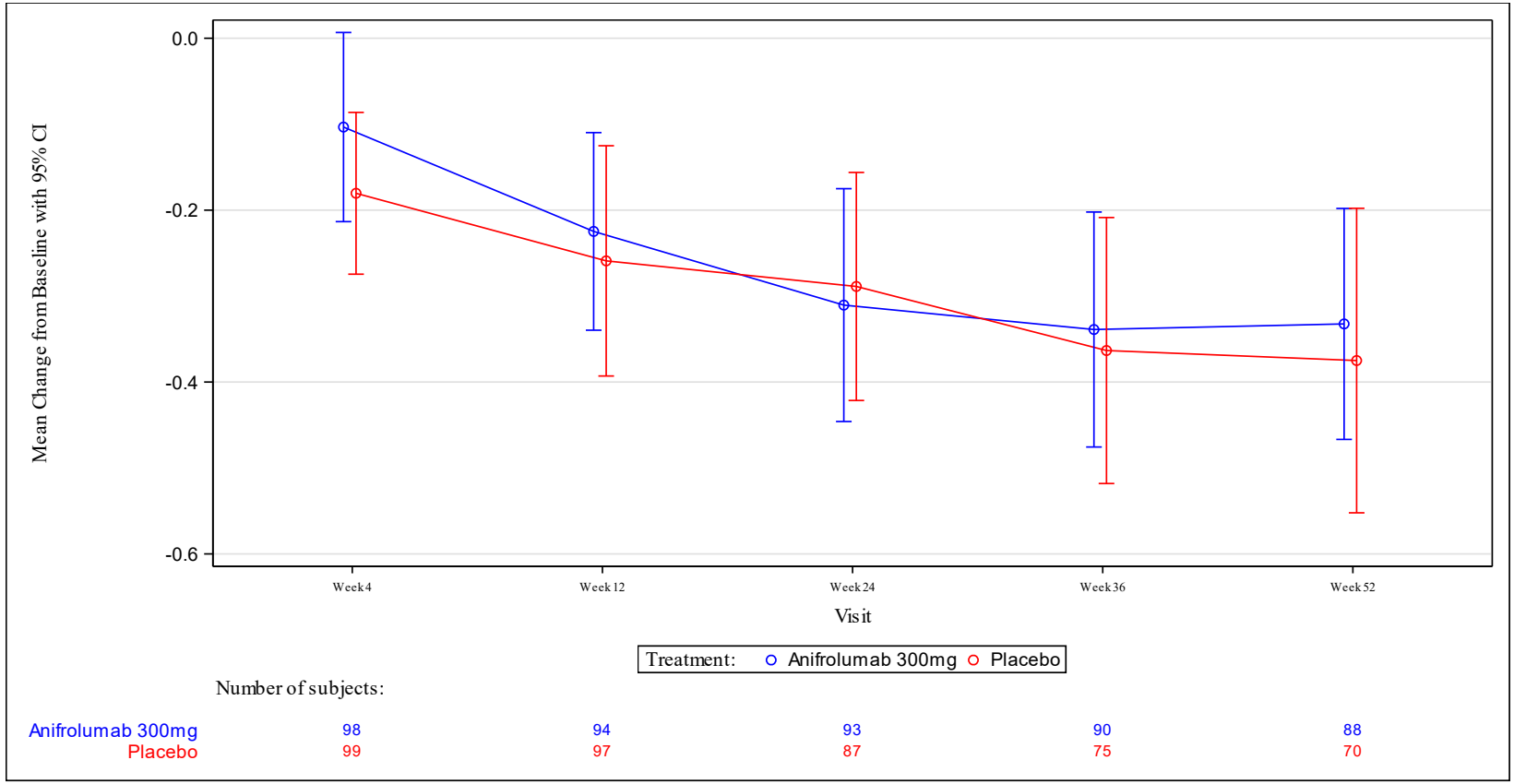
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - Total HAQ Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)				Placebo (N=102)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	99	1.00 (0.74)	0	-	102	1.02 (0.75)	0	-
Week 4	98	0.91 (0.68)	98	-0.10 (0.55)	99	0.83 (0.70)	99	-0.18 (0.47)
Week 12	94	0.78 (0.65)	94	-0.22 (0.56)	97	0.75 (0.70)	97	-0.26 (0.66)
Week 24	93	0.69 (0.67)	93	-0.31 (0.66)	87	0.70 (0.70)	87	-0.29 (0.62)
Week 36	90	0.67 (0.70)	90	-0.34 (0.65)	75	0.56 (0.63)	75	-0.36 (0.67)
Week 52	88	0.67 (0.66)	88	-0.33 (0.63)	70	0.56 (0.65)	70	-0.38 (0.74)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - Total HAQ Score
Full analysis set



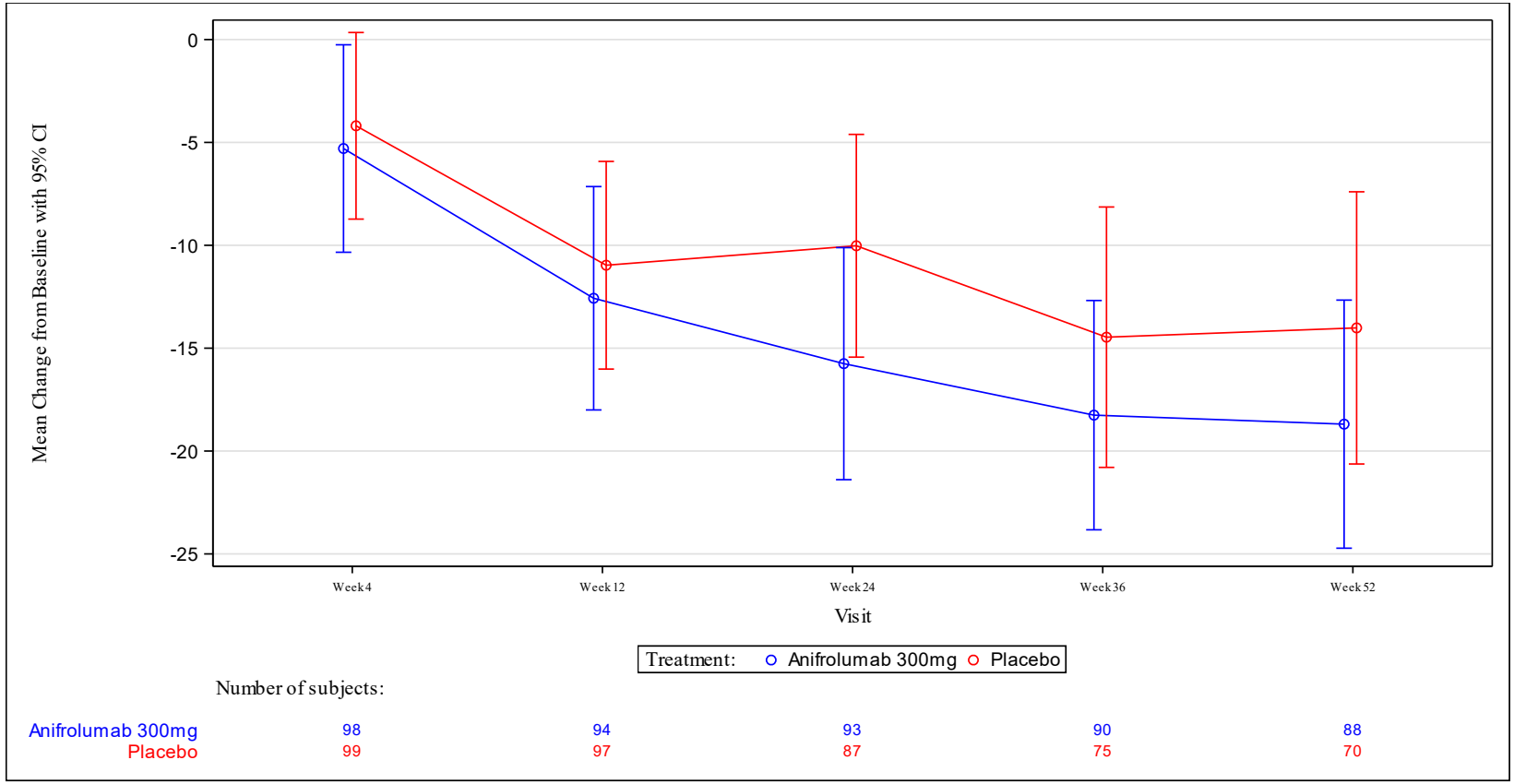
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - Pain Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)				Placebo (N=102)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	99	51.93 (24.95)	0	-	102	51.22 (24.96)	0	-
Week 4	98	46.63 (24.44)	98	-5.30 (25.15)	99	46.48 (25.72)	99	-4.19 (22.74)
Week 12	94	39.79 (24.76)	94	-12.57 (26.50)	97	40.22 (26.69)	97	-10.97 (25.04)
Week 24	93	36.59 (26.57)	93	-15.75 (27.38)	87	39.92 (27.87)	87	-10.02 (25.40)
Week 36	90	33.96 (26.17)	90	-18.26 (26.60)	75	32.81 (26.50)	75	-14.47 (27.50)
Week 52	88	33.63 (25.65)	88	-18.69 (28.46)	70	34.27 (28.18)	70	-14.01 (27.74)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - Pain Score
Full analysis set



N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SLEDAI-2K Total Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-0.85 (0.22)		-0.76 (0.21)	-0.09 (0.28)	(-0.65, 0.47)	0.7527			
Week 8		-2.24 (0.35)		-2.08 (0.35)	-0.16 (0.48)	(-1.11, 0.79)	0.7391			
Week 12		-3.58 (0.38)		-2.77 (0.38)	-0.81 (0.52)	(-1.84, 0.22)	0.1232			
Week 16		-3.95 (0.41)		-3.28 (0.41)	-0.67 (0.57)	(-1.79, 0.45)	0.2406			
Week 20		-4.69 (0.43)		-3.63 (0.43)	-1.06 (0.59)	(-2.23, 0.11)	0.0754			
Week 24		-5.09 (0.42)		-3.94 (0.43)	-1.14 (0.59)	(-2.31, 0.02)	0.0536			
Week 28		-5.24 (0.46)		-3.45 (0.47)	-1.79 (0.65)	(-3.08, -0.50)	0.0068			
Week 32		-5.29 (0.47)		-3.86 (0.49)	-1.43 (0.66)	(-2.74, -0.12)	0.0331			
Week 36		-5.51 (0.47)		-3.74 (0.49)	-1.77 (0.67)	(-3.09, -0.44)	0.0091			
Week 40		-5.64 (0.45)		-4.00 (0.47)	-1.65 (0.64)	(-2.91, -0.38)	0.0111			
Week 44		-5.92 (0.43)		-4.61 (0.45)	-1.30 (0.61)	(-2.51, -0.10)	0.0346			
Week 48		-6.00 (0.45)		-4.60 (0.47)	-1.40 (0.64)	(-2.66, -0.14)	0.0302			
Week 52		-6.32 (0.44)		-4.59 (0.47)	-1.72 (0.64)	(-2.98, -0.47)	0.0075			
OVERALL	99	-4.64 (0.33)	102	-3.49 (0.34)	-1.15 (0.46)	(-2.07, -0.24)	0.0136	-0.34 (0.14)	(-0.62, -0.06)	0.0168

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SLEDAI-2K Total Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.6508
< 10 points	39	-3.42 (0.41)	40	-2.54 (0.41)	-0.88 (0.57)	(-2.02, 0.26)	0.1292	-0.34 (0.23)	(-0.78, 0.11)	0.1346	
>= 10 points	60	-5.52 (0.49)	62	-4.25 (0.51)	-1.28 (0.66)	(-2.59, 0.04)	0.0568	-0.32 (0.18)	(-0.68, 0.03)	0.0749	
OCS dose											0.6393
<10 mg/day	44	-4.70 (0.52)	38	-3.23 (0.57)	-1.47 (0.77)	(-3.00, 0.06)	0.0602	-0.42 (0.22)	(-0.86, 0.02)	0.0628	
>=10 mg/day	55	-4.56 (0.45)	64	-3.55 (0.44)	-1.01 (0.59)	(-2.19, 0.16)	0.0907	-0.29 (0.18)	(-0.65, 0.07)	0.1164	
Result of type I IFN gene signature test											0.0143
LOW	24	-3.46 (0.51)	26	-3.94 (0.51)	0.48 (0.72)	(-0.98, 1.94)	0.5103	0.19 (0.28)	(-0.37, 0.74)	0.5130	
HIGH	75	-5.02 (0.40)	76	-3.25 (0.41)	-1.76 (0.56)	(-2.88, -0.65)	0.0021	-0.50 (0.17)	(-0.82, -0.18)	0.0025	
Age (years)											0.4785
<= 45	67	-5.01 (0.43)	72	-3.65 (0.43)	-1.36 (0.58)	(-2.50, -0.22)	0.0197	-0.38 (0.17)	(-0.71, -0.04)	0.0269	
> 45	32	-3.59 (0.55)	30	-2.92 (0.58)	-0.67 (0.79)	(-2.25, 0.91)	0.3969	-0.21 (0.25)	(-0.71, 0.29)	0.4082	
Sex											NE
male	6	NE	9	NE	NE	NE		NE	NE		
female	93	-4.69 (0.35)	93	-3.42 (0.37)	-1.27 (0.50)	(-2.25, -0.29)	0.0116	-0.36 (0.15)	(-0.65, -0.07)	0.0140	
Race											0.6911
White	35	-4.42 (0.55)	41	-3.76 (0.51)	-0.66 (0.73)	(-2.13, 0.80)	0.3681	-0.20 (0.23)	(-0.65, 0.25)	0.3813	
Black	19	-5.67 (1.02)	12	-4.06 (1.02)	-1.61 (1.30)	(-4.28, 1.07)	0.2280	-0.38 (0.37)	(-1.11, 0.35)	0.3094	
Other	45	-4.75 (0.49)	49	-3.32 (0.50)	-1.43 (0.67)	(-2.77, -0.09)	0.0369	-0.42 (0.21)	(-0.83, -0.01)	0.0463	
Ethnicity											0.1802
Hispanic/Latino	46	-4.34 (0.42)	42	-3.93 (0.47)	-0.42 (0.61)	(-1.64, 0.80)	0.4965	-0.14 (0.21)	(-0.56, 0.28)	0.5115	
Non-hispanic/Latino	53	-4.86 (0.51)	60	-3.21 (0.49)	-1.65 (0.69)	(-3.01, -0.29)	0.0183	-0.43 (0.19)	(-0.81, -0.06)	0.0230	
Geographic region											0.4212
Latin America, Eastern Europe and Asia	62	-4.70 (0.45)	74	-3.16 (0.44)	-1.54 (0.58)	(-2.69, -0.38)	0.0096	-0.42 (0.17)	(-0.76, -0.08)	0.0166	
North America	37	-4.76 (0.58)	28	-4.05 (0.64)	-0.70 (0.86)	(-2.42, 1.01)	0.4145	-0.20 (0.25)	(-0.69, 0.29)	0.4225	
Baseline weight											0.0198
<60 kg	32	-5.62 (0.67)	39	-2.85 (0.66)	-2.77 (0.90)	(-4.58, -0.96)	0.0033	-0.69 (0.25)	(-1.17, -0.21)	0.0050	
>=60 kg	67	-4.11 (0.37)	63	-3.77 (0.38)	-0.34 (0.52)	(-1.37, 0.69)	0.5138	-0.11 (0.18)	(-0.46, 0.23)	0.5262	
Low CH50											NE
Yes	13	NE	13	NE	NE	NE		NE	NE		
No	86	-4.45 (0.35)	89	-3.26 (0.35)	-1.19 (0.48)	(-2.14, -0.23)	0.0150	-0.36 (0.15)	(-0.66, -0.06)	0.0171	
Low C3 or C4											0.4296
Yes	33	-6.61 (0.84)	47	-4.86 (0.72)	-1.75 (0.84)	(-3.43, -0.07)	0.0416	-0.35 (0.23)	(-0.80, 0.09)	0.1223	
No	66	-3.76 (0.37)	55	-2.80 (0.41)	-0.96 (0.55)	(-2.04, 0.13)	0.0838	-0.31 (0.18)	(-0.67, 0.05)	0.0869	
Baseline FARR anti-dsDNA											0.3796
<5 IU/mL	21	-3.85 (0.68)	16	-3.52 (0.78)	-0.34 (1.04)	(-2.46, 1.78)	0.7463	-0.11 (0.33)	(-0.76, 0.54)	0.7485	
>=5 IU/mL	56	-4.89 (0.49)	66	-3.48 (0.47)	-1.41 (0.64)	(-2.68, -0.14)	0.0298	-0.37 (0.18)	(-0.73, -0.01)	0.0418	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.5646
Yes	70	-5.04 (0.44)	81	-3.70 (0.42)	-1.34 (0.57)	(-2.47, -0.22)	0.0193	-0.36 (0.16)	(-0.68, -0.03)	0.0305	
No	29	-3.68 (0.50)	21	-2.88 (0.59)	-0.79 (0.77)	(-2.35, 0.76)	0.3091	-0.29 (0.29)	(-0.85, 0.28)	0.3147	
OCS use											NE
Yes	79	-4.68 (0.39)	88	-3.63 (0.39)	-1.04 (0.52)	(-2.07, -0.02)	0.0455	-0.29 (0.16)	(-0.60, 0.01)	0.0588	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SLEDAI-2K Total Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) N	LSMean (SE)	Placebo (N=102) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
No	20	NE	14	NE	NE	NE		NE	NE		
SLICC score											0.4134
0	62	-4.22 (0.44)	66	-3.41 (0.44)	-0.81 (0.61)	(-2.01, 0.39)	0.1838	-0.23 (0.18)	(-0.58, 0.12)	0.1980	
>=1	37	-5.24 (0.49)	36	-3.68 (0.50)	-1.56 (0.68)	(-2.93, -0.19)	0.0265	-0.51 (0.24)	(-0.98, -0.05)	0.0308	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - PGA
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-0.36 (0.05)		-0.28 (0.04)	-0.09 (0.06)	(-0.20, 0.03)	0.1490			
Week 8		-0.61 (0.05)		-0.55 (0.05)	-0.06 (0.07)	(-0.21, 0.08)	0.3762			
Week 12		-0.82 (0.06)		-0.63 (0.06)	-0.19 (0.08)	(-0.34, -0.04)	0.0159			
Week 16		-0.88 (0.06)		-0.70 (0.06)	-0.18 (0.08)	(-0.34, -0.02)	0.0274			
Week 20		-0.95 (0.06)		-0.72 (0.06)	-0.23 (0.08)	(-0.39, -0.06)	0.0065			
Week 24		-0.93 (0.06)		-0.78 (0.06)	-0.15 (0.08)	(-0.32, 0.02)	0.0761			
Week 28		-1.01 (0.06)		-0.81 (0.06)	-0.21 (0.09)	(-0.38, -0.03)	0.0189			
Week 32		-1.06 (0.06)		-0.85 (0.06)	-0.21 (0.09)	(-0.38, -0.04)	0.0158			
Week 36		-1.06 (0.06)		-0.89 (0.06)	-0.17 (0.09)	(-0.33, 0.00)	0.0520			
Week 40		-1.13 (0.06)		-0.93 (0.06)	-0.20 (0.08)	(-0.36, -0.03)	0.0189			
Week 44		-1.18 (0.06)		-0.99 (0.06)	-0.19 (0.09)	(-0.36, -0.02)	0.0266			
Week 48		-1.17 (0.06)		-0.96 (0.06)	-0.21 (0.08)	(-0.37, -0.04)	0.0148			
Week 52		-1.16 (0.06)		-0.93 (0.06)	-0.23 (0.09)	(-0.40, -0.06)	0.0084			
OVERALL	99	-0.95 (0.05)	102	-0.77 (0.05)	-0.18 (0.07)	(-0.31, -0.05)	0.0085	-0.35 (0.14)	(-0.63, -0.08)	0.0126

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - PGA - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.8500
< 10 points	39	-0.95 (0.07)	40	-0.80 (0.07)	-0.16 (0.10)	(-0.36, 0.05)	0.1285	-0.34 (0.23)	(-0.78, 0.11)	0.1346	
>= 10 points	60	-0.94 (0.07)	62	-0.76 (0.07)	-0.18 (0.09)	(-0.36, -0.01)	0.0383	-0.34 (0.18)	(-0.69, 0.02)	0.0653	
OCS dose											0.6606
<10 mg/day	44	-0.89 (0.07)	38	-0.67 (0.07)	-0.22 (0.10)	(-0.42, -0.02)	0.0316	-0.47 (0.22)	(-0.91, -0.03)	0.0349	
>=10 mg/day	55	-1.01 (0.07)	64	-0.85 (0.07)	-0.16 (0.09)	(-0.34, 0.02)	0.0760	-0.29 (0.18)	(-0.66, 0.07)	0.1117	
Result of type I IFN gene signature test											0.0466
LOW	24	-0.86 (0.09)	26	-0.90 (0.09)	0.04 (0.13)	(-0.22, 0.30)	0.7367	0.09 (0.28)	(-0.46, 0.65)	0.7401	
HIGH	75	-0.98 (0.05)	76	-0.72 (0.06)	-0.26 (0.08)	(-0.41, -0.10)	0.0011	-0.52 (0.17)	(-0.85, -0.20)	0.0015	
Age (years)											0.8369
<= 45	67	-0.95 (0.06)	72	-0.78 (0.06)	-0.17 (0.08)	(-0.33, -0.01)	0.0331	-0.34 (0.17)	(-0.67, -0.00)	0.0495	
> 45	32	-0.92 (0.09)	30	-0.72 (0.09)	-0.20 (0.12)	(-0.44, 0.04)	0.0997	-0.41 (0.26)	(-0.91, 0.10)	0.1131	
Sex											NE
male	6	NE	9	NE	NE	NE		NE	NE		
female	93	-0.97 (0.05)	93	-0.76 (0.05)	-0.21 (0.07)	(-0.34, -0.07)	0.0034	-0.42 (0.15)	(-0.71, -0.13)	0.0050	
Race											0.8538
White	35	-0.84 (0.08)	41	-0.66 (0.07)	-0.18 (0.11)	(-0.39, 0.03)	0.0921	-0.38 (0.23)	(-0.83, 0.08)	0.1037	
Black	19	-0.59 (0.20)	12	-0.50 (0.16)	-0.09 (0.22)	(-0.54, 0.36)	0.6803	-0.11 (0.37)	(-0.84, 0.61)	0.7579	
Other	45	-1.01 (0.07)	49	-0.90 (0.07)	-0.11 (0.09)	(-0.30, 0.08)	0.2541	-0.22 (0.21)	(-0.62, 0.19)	0.2927	
Ethnicity											0.0177
Hispanic/Latino	46	-0.97 (0.07)	42	-0.98 (0.07)	0.01 (0.09)	(-0.18, 0.20)	0.9398	0.02 (0.21)	(-0.40, 0.43)	0.9435	
Non-hispanic/Latino	53	-0.91 (0.07)	60	-0.61 (0.06)	-0.29 (0.09)	(-0.46, -0.13)	0.0008	-0.61 (0.19)	(-0.99, -0.23)	0.0016	
Geographic region											0.5326
Latin America, Eastern Europe and Asia	62	-0.97 (0.07)	74	-0.82 (0.07)	-0.15 (0.09)	(-0.32, 0.02)	0.0745	-0.27 (0.17)	(-0.61, 0.07)	0.1144	
North America	37	-0.89 (0.08)	28	-0.64 (0.09)	-0.24 (0.12)	(-0.48, -0.01)	0.0408	-0.50 (0.25)	(-1.00, -0.01)	0.0475	
Baseline weight											0.8301
<60 kg	32	-1.01 (0.09)	39	-0.81 (0.09)	-0.20 (0.12)	(-0.43, 0.04)	0.1066	-0.35 (0.24)	(-0.83, 0.12)	0.1409	
>=60 kg	67	-0.90 (0.06)	63	-0.73 (0.06)	-0.16 (0.08)	(-0.32, -0.01)	0.0420	-0.34 (0.18)	(-0.69, 0.00)	0.0513	
Low CH50											NE
Yes	13	NE	13	NE	NE	NE		NE	NE		
No	86	-0.95 (0.05)	89	-0.74 (0.05)	-0.20 (0.07)	(-0.34, -0.06)	0.0053	-0.41 (0.15)	(-0.71, -0.11)	0.0072	
Low C3 or C4											0.9947
Yes	33	-1.08 (0.12)	47	-0.90 (0.10)	-0.18 (0.11)	(-0.39, 0.03)	0.0917	-0.26 (0.23)	(-0.70, 0.19)	0.2618	
No	66	-0.95 (0.06)	55	-0.77 (0.07)	-0.18 (0.09)	(-0.35, -0.01)	0.0394	-0.37 (0.18)	(-0.73, -0.01)	0.0424	
Baseline FARR anti-dsDNA											NE
<5 IU/mL	21	NE	16	NE	NE	NE		NE	NE		
>=5 IU/mL	56	-0.90 (0.07)	66	-0.72 (0.07)	-0.18 (0.08)	(-0.35, -0.01)	0.0334	-0.35 (0.18)	(-0.71, 0.01)	0.0584	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.9577
Yes	70	-0.89 (0.06)	81	-0.71 (0.06)	-0.18 (0.08)	(-0.34, -0.03)	0.0191	-0.34 (0.16)	(-0.66, -0.01)	0.0413	
No	29	-1.08 (0.09)	21	-0.90 (0.11)	-0.18 (0.14)	(-0.45, 0.10)	0.2032	-0.36 (0.29)	(-0.93, 0.20)	0.2077	
OCS use											0.4085
Yes	79	-0.92 (0.06)	88	-0.76 (0.06)	-0.16 (0.07)	(-0.31, -0.02)	0.0284	-0.31 (0.16)	(-0.62, -0.01)	0.0445	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - PGA - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) N	LSMean (SE)	Placebo (N=102) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
No	20	-1.09 (0.11)	14	-0.78 (0.12)	-0.31 (0.17)	(-0.65, 0.02)	0.0676	-0.63 (0.36)	(-1.33, 0.07)	0.0779	
SLICC score											0.5948
0	62	-0.94 (0.06)	66	-0.78 (0.06)	-0.15 (0.08)	(-0.32, 0.01)	0.0678	-0.31 (0.18)	(-0.66, 0.04)	0.0826	
>=1	37	-0.94 (0.09)	36	-0.71 (0.09)	-0.23 (0.12)	(-0.47, 0.01)	0.0595	-0.42 (0.24)	(-0.89, 0.04)	0.0740	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - CLASI Total Activity Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-1.25 (0.29)		-0.69 (0.29)	-0.56 (0.39)	(-1.34, 0.21)	0.1535			
Week 8		-2.65 (0.33)		-1.71 (0.33)	-0.94 (0.44)	(-1.81, -0.07)	0.0342			
Week 12		-3.39 (0.31)		-1.99 (0.31)	-1.41 (0.42)	(-2.23, -0.58)	0.0010			
Week 16		-3.81 (0.34)		-2.46 (0.34)	-1.34 (0.46)	(-2.26, -0.43)	0.0043			
Week 20		-4.25 (0.35)		-2.82 (0.35)	-1.43 (0.47)	(-2.36, -0.49)	0.0030			
Week 24		-4.30 (0.36)		-2.69 (0.36)	-1.61 (0.49)	(-2.57, -0.65)	0.0012			
Week 28		-4.41 (0.35)		-2.55 (0.36)	-1.85 (0.49)	(-2.81, -0.89)	0.0002			
Week 32		-4.48 (0.39)		-2.77 (0.40)	-1.71 (0.54)	(-2.77, -0.64)	0.0018			
Week 36		-4.62 (0.36)		-2.77 (0.37)	-1.84 (0.49)	(-2.82, -0.87)	0.0003			
Week 40		-4.69 (0.35)		-2.86 (0.36)	-1.83 (0.48)	(-2.78, -0.87)	0.0002			
Week 44		-4.59 (0.37)		-3.09 (0.38)	-1.50 (0.51)	(-2.51, -0.48)	0.0040			
Week 48		-4.75 (0.36)		-3.14 (0.37)	-1.61 (0.50)	(-2.60, -0.62)	0.0016			
Week 52		-4.90 (0.39)		-3.02 (0.40)	-1.88 (0.54)	(-2.95, -0.82)	0.0006			
OVERALL	99	-4.01 (0.30)	102	-2.51 (0.31)	-1.50 (0.41)	(-2.31, -0.70)	0.0003	-0.49 (0.14)	(-0.77, -0.21)	0.0006

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - CLASI Total Activity Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) N	LSMean (SE)	Placebo (N=102) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.5547
< 10 points	39	-3.18 (0.43)	40	-1.93 (0.43)	-1.25 (0.60)	(-2.45, -0.04)	0.0429	-0.45 (0.23)	(-0.90, -0.01)	0.0464	
>= 10 points	60	-4.56 (0.43)	62	-2.83 (0.44)	-1.73 (0.55)	(-2.81, -0.64)	0.0022	-0.51 (0.18)	(-0.87, -0.14)	0.0060	
OCS dose											0.5441
<10 mg/day	44	-4.08 (0.50)	38	-2.28 (0.54)	-1.81 (0.73)	(-3.26, -0.35)	0.0155	-0.53 (0.23)	(-0.98, -0.09)	0.0177	
>=10 mg/day	55	-3.94 (0.36)	64	-2.66 (0.36)	-1.28 (0.46)	(-2.20, -0.36)	0.0068	-0.46 (0.19)	(-0.82, -0.09)	0.0142	
Result of type I IFN gene signature test											0.0062
LOW	24	-2.03 (0.25)	26	-1.80 (0.25)	-0.23 (0.35)	(-0.94, 0.47)	0.5113	-0.18 (0.28)	(-0.74, 0.37)	0.5162	
HIGH	75	-4.60 (0.37)	76	-2.65 (0.39)	-1.95 (0.52)	(-2.98, -0.91)	0.0003	-0.59 (0.17)	(-0.92, -0.26)	0.0004	
Age (years)											NE
<= 45	67	-3.93 (0.35)	72	-2.22 (0.35)	-1.71 (0.46)	(-2.61, -0.80)	0.0003	-0.59 (0.17)	(-0.93, -0.25)	0.0007	
> 45	32	NE	30	NE	NE	NE		NE	NE		
Sex											NE
male	6	NE	9	NE	NE	NE		NE	NE		
female	93	-3.95 (0.31)	93	-2.28 (0.31)	-1.66 (0.42)	(-2.49, -0.83)	0.0001	-0.55 (0.15)	(-0.85, -0.26)	0.0002	
Race											NE
White	35	-3.73 (0.58)	41	-2.88 (0.54)	-0.85 (0.77)	(-2.40, 0.70)	0.2762	-0.24 (0.23)	(-0.70, 0.21)	0.2914	
Black	19	NE	12	NE	NE	NE		NE	NE		
Other	45	-3.86 (0.38)	49	-2.05 (0.39)	-1.81 (0.51)	(-2.82, -0.79)	0.0007	-0.67 (0.21)	(-1.09, -0.26)	0.0015	
Ethnicity											0.5246
Hispanic/Latino	46	-3.46 (0.31)	42	-2.22 (0.34)	-1.25 (0.42)	(-2.09, -0.41)	0.0042	-0.58 (0.22)	(-1.01, -0.15)	0.0079	
Non-hispanic/Latino	53	-4.40 (0.52)	60	-2.64 (0.50)	-1.77 (0.70)	(-3.15, -0.38)	0.0133	-0.45 (0.19)	(-0.83, -0.08)	0.0173	
Geographic region											NE
Latin America, Eastern Europe and Asia	62	-3.90 (0.40)	74	-2.52 (0.40)	-1.37 (0.51)	(-2.38, -0.37)	0.0078	-0.41 (0.17)	(-0.75, -0.07)	0.0181	
North America	37	NE	28	NE	NE	NE		NE	NE		
Baseline weight											NE
<60 kg	32	NE	39	NE	NE	NE		NE	NE		
>=60 kg	67	-3.75 (0.38)	63	-2.66 (0.39)	-1.09 (0.52)	(-2.13, -0.05)	0.0402	-0.35 (0.18)	(-0.69, -0.00)	0.0491	
Low CH50											NE
Yes	13	NE	13	NE	NE	NE		NE	NE		
No	86	-4.08 (0.33)	89	-2.31 (0.33)	-1.77 (0.45)	(-2.67, -0.88)	0.0001	-0.57 (0.15)	(-0.87, -0.27)	0.0002	
Low C3 or C4											0.4381
Yes	33	-4.38 (0.77)	47	-3.26 (0.66)	-1.12 (0.68)	(-2.47, 0.24)	0.1056	-0.25 (0.23)	(-0.69, 0.20)	0.2789	
No	66	-3.79 (0.34)	55	-2.02 (0.37)	-1.77 (0.50)	(-2.75, -0.78)	0.0006	-0.64 (0.19)	(-1.01, -0.27)	0.0006	
Baseline FARR anti-dsDNA											NE
<5 IU/mL	21	NE	16	NE	NE	NE		NE	NE		
>=5 IU/mL	56	-4.40 (0.46)	66	-2.64 (0.44)	-1.76 (0.58)	(-2.92, -0.60)	0.0033	-0.50 (0.18)	(-0.86, -0.13)	0.0072	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.8779
Yes	70	-4.28 (0.41)	81	-2.69 (0.39)	-1.59 (0.50)	(-2.58, -0.59)	0.0020	-0.45 (0.17)	(-0.78, -0.13)	0.0063	
No	29	-3.26 (0.41)	21	-1.80 (0.50)	-1.46 (0.64)	(-2.75, -0.17)	0.0274	-0.64 (0.29)	(-1.22, -0.07)	0.0291	
OCS use											NE
Yes	79	-3.94 (0.35)	88	-2.44 (0.35)	-1.50 (0.46)	(-2.40, -0.59)	0.0013	-0.46 (0.16)	(-0.77, -0.16)	0.0031	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - CLASI Total Activity Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) N	LSMean (SE)	Placebo (N=102) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
No	20	NE	14	NE	NE	NE		NE	NE		
SLICC score											NE
0	62	-3.46 (0.29)	66	-2.41 (0.30)	-1.05 (0.40)	(-1.84, -0.27)	0.0093	-0.45 (0.18)	(-0.80, -0.09)	0.0129	
>=1	37	NE	36	NE	NE	NE		NE	NE		

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - CLASI Total Damage Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		0.09 (0.16)		-0.06 (0.16)	0.15 (0.22)	(-0.29, 0.58)	0.5065			
Week 8		0.15 (0.24)		-0.22 (0.24)	0.36 (0.33)	(-0.28, 1.01)	0.2685			
Week 12		0.04 (0.25)		-0.52 (0.25)	0.56 (0.35)	(-0.13, 1.26)	0.1099			
Week 16		-0.10 (0.22)		-0.55 (0.22)	0.45 (0.30)	(-0.14, 1.05)	0.1360			
Week 20		-0.28 (0.26)		-0.57 (0.27)	0.29 (0.37)	(-0.44, 1.02)	0.4315			
Week 24		-0.41 (0.20)		-0.31 (0.20)	-0.10 (0.27)	(-0.64, 0.44)	0.7061			
Week 28		-0.43 (0.17)		-0.31 (0.17)	-0.12 (0.24)	(-0.58, 0.35)	0.6236			
Week 32		-0.47 (0.17)		-0.29 (0.17)	-0.18 (0.23)	(-0.64, 0.28)	0.4303			
Week 36		-0.47 (0.20)		-0.29 (0.21)	-0.18 (0.28)	(-0.73, 0.38)	0.5316			
Week 40		-0.51 (0.22)		-0.52 (0.22)	0.02 (0.31)	(-0.59, 0.62)	0.9607			
Week 44		-0.56 (0.20)		-0.54 (0.21)	-0.01 (0.29)	(-0.58, 0.56)	0.9707			
Week 48		-0.45 (0.20)		-0.53 (0.21)	0.08 (0.28)	(-0.46, 0.63)	0.7668			
Week 52		-0.46 (0.20)		-0.40 (0.21)	-0.06 (0.29)	(-0.62, 0.50)	0.8242			
OVERALL	99	-0.30 (0.17)	102	-0.39 (0.17)	0.10 (0.23)	(-0.35, 0.55)	0.6719	0.06 (0.14)	(-0.22, 0.33)	0.6843

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - CLASI Total Damage Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) N	LSMean (SE)	Placebo (N=102) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											NE
< 10 points	39	-0.04 (0.17)	40	-0.29 (0.17)	0.25 (0.23)	(-0.23, 0.72)	0.2992	0.23 (0.23)	(-0.21, 0.67)	0.3064	
>= 10 points	60	NE	62	NE	NE	NE		NE	NE		
OCS dose											NE
<10 mg/day	44	NE	38	NE	NE	NE		NE	NE		
>=10 mg/day	55	-0.34 (0.21)	64	-0.41 (0.20)	0.06 (0.27)	(-0.47, 0.60)	0.8138	0.04 (0.18)	(-0.32, 0.40)	0.8255	
Result of type I IFN gene signature test											NE
LOW	24	NE	26	NE	NE	NE		NE	NE		
HIGH	75	NE	76	NE	NE	NE		NE	NE		
Age (years)											0.8264
<= 45	67	-0.33 (0.18)	72	-0.43 (0.18)	0.10 (0.24)	(-0.37, 0.58)	0.6678	0.07 (0.17)	(-0.26, 0.40)	0.6857	
> 45	32	-0.27 (0.36)	30	-0.25 (0.37)	-0.02 (0.51)	(-1.04, 1.00)	0.9698	-0.01 (0.25)	(-0.51, 0.49)	0.9706	
Sex											NE
male	6	NE	9	NE	NE	NE		NE	NE		
female	93	-0.33 (0.17)	93	-0.33 (0.17)	0.00 (0.23)	(-0.46, 0.46)	0.9987	0.00 (0.15)	(-0.29, 0.29)	0.9988	
Race											NE
White	35	NE	41	NE	NE	NE		NE	NE		
Black	19	-0.67 (0.54)	12	-0.29 (0.52)	-0.39 (0.67)	(-1.75, 0.98)	0.5683	-0.17 (0.37)	(-0.90, 0.55)	0.6393	
Other	45	-0.16 (0.19)	49	-0.41 (0.19)	0.25 (0.26)	(-0.26, 0.76)	0.3354	0.19 (0.21)	(-0.22, 0.60)	0.3584	
Ethnicity											0.3820
Hispanic/Latino	46	-0.17 (0.21)	42	-0.49 (0.22)	0.32 (0.29)	(-0.26, 0.90)	0.2822	0.22 (0.21)	(-0.20, 0.64)	0.2994	
Non-hispanic/Latino	53	-0.39 (0.26)	60	-0.31 (0.25)	-0.08 (0.35)	(-0.77, 0.61)	0.8158	-0.04 (0.19)	(-0.41, 0.33)	0.8242	
Geographic region											NE
Latin America, Eastern Europe and Asia	62	-0.28 (0.29)	74	-0.38 (0.27)	0.10 (0.38)	(-0.64, 0.85)	0.7868	0.04 (0.17)	(-0.29, 0.38)	0.7977	
North America	37	NE	28	NE	NE	NE		NE	NE		
Baseline weight											0.0751
<60 kg	32	-0.21 (0.24)	39	-0.86 (0.24)	0.65 (0.33)	(-0.01, 1.30)	0.0518	0.44 (0.24)	(-0.03, 0.92)	0.0659	
>=60 kg	67	-0.33 (0.20)	63	-0.21 (0.20)	-0.12 (0.28)	(-0.66, 0.43)	0.6748	-0.07 (0.18)	(-0.42, 0.27)	0.6847	
Low CH50											NE
Yes	13	NE	13	NE	NE	NE		NE	NE		
No	86	-0.32 (0.18)	89	-0.35 (0.18)	0.03 (0.25)	(-0.46, 0.53)	0.8942	0.02 (0.15)	(-0.28, 0.32)	0.8961	
Low C3 or C4											NE
Yes	33	-0.64 (0.37)	47	-0.60 (0.32)	-0.04 (0.38)	(-0.80, 0.72)	0.9203	-0.02 (0.23)	(-0.46, 0.43)	0.9391	
No	66	NE	55	NE	NE	NE		NE	NE		
Baseline FARR anti-dsDNA											0.3338
<5 IU/mL	21	-0.50 (0.19)	16	-0.17 (0.21)	-0.32 (0.28)	(-0.90, 0.25)	0.2594	-0.37 (0.34)	(-1.03, 0.28)	0.2650	
>=5 IU/mL	56	-0.27 (0.29)	66	-0.40 (0.27)	0.13 (0.37)	(-0.61, 0.87)	0.7309	0.06 (0.18)	(-0.30, 0.42)	0.7446	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.9691
Yes	70	-0.21 (0.23)	81	-0.33 (0.22)	0.12 (0.29)	(-0.46, 0.70)	0.6783	0.06 (0.16)	(-0.26, 0.38)	0.7016	
No	29	-0.53 (0.20)	21	-0.67 (0.24)	0.14 (0.32)	(-0.52, 0.79)	0.6675	0.12 (0.29)	(-0.44, 0.68)	0.6691	
OCS use											0.4600
Yes	79	-0.27 (0.16)	88	-0.32 (0.16)	0.05 (0.21)	(-0.37, 0.46)	0.8172	0.03 (0.16)	(-0.27, 0.34)	0.8282	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - CLASI Total Damage Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) N	LSMean (SE)	Placebo (N=102) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
No	20	-0.13 (0.48)	14	-0.73 (0.55)	0.61 (0.73)	(-0.87, 2.08)	0.4090	0.28 (0.35)	(-0.40, 0.97)	0.4207	
SLICC score											0.7607
0	62	-0.11 (0.11)	66	-0.17 (0.11)	0.06 (0.15)	(-0.23, 0.35)	0.6937	0.07 (0.18)	(-0.28, 0.41)	0.7076	
>=1	37	-0.59 (0.44)	36	-0.84 (0.44)	0.25 (0.60)	(-0.95, 1.44)	0.6830	0.09 (0.23)	(-0.37, 0.55)	0.6971	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - BILAG Global Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-5.26 (0.61)		-4.22 (0.61)	-1.04 (0.81)	(-2.64, 0.56)	0.2009			
Week 8		-8.75 (0.71)		-7.92 (0.71)	-0.83 (0.96)	(-2.73, 1.07)	0.3889			
Week 12		-10.31 (0.72)		-8.60 (0.71)	-1.71 (0.97)	(-3.62, 0.21)	0.0800			
Week 16		-10.46 (0.82)		-8.50 (0.83)	-1.96 (1.13)	(-4.18, 0.27)	0.0849			
Week 20		-11.07 (0.80)		-9.05 (0.81)	-2.02 (1.10)	(-4.19, 0.15)	0.0680			
Week 24		-11.21 (0.79)		-9.16 (0.80)	-2.05 (1.09)	(-4.20, 0.10)	0.0612			
Week 28		-11.29 (0.88)		-8.77 (0.91)	-2.52 (1.23)	(-4.94, -0.10)	0.0417			
Week 32		-11.81 (0.84)		-9.81 (0.88)	-2.00 (1.18)	(-4.33, 0.34)	0.0933			
Week 36		-12.18 (0.80)		-10.31 (0.84)	-1.87 (1.12)	(-4.09, 0.34)	0.0971			
Week 40		-12.27 (0.80)		-10.03 (0.84)	-2.24 (1.12)	(-4.46, -0.02)	0.0476			
Week 44		-12.21 (0.77)		-9.93 (0.81)	-2.28 (1.08)	(-4.42, -0.14)	0.0367			
Week 48		-12.92 (0.73)		-10.08 (0.77)	-2.84 (1.02)	(-4.86, -0.83)	0.0060			
Week 52		-13.16 (0.80)		-10.49 (0.85)	-2.67 (1.13)	(-4.90, -0.44)	0.0193			
OVERALL	99	-10.99 (0.62)	102	-8.99 (0.62)	-2.00 (0.82)	(-3.63, -0.38)	0.0161	-0.32 (0.14)	(-0.60, -0.04)	0.0236

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - BILAG Global Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.5068
< 10 points	39	-10.05 (0.84)	40	-8.80 (0.83)	-1.26 (1.17)	(-3.59, 1.08)	0.2866	-0.24 (0.23)	(-0.68, 0.21)	0.2964	
>= 10 points	60	-11.70 (0.91)	62	-9.36 (0.94)	-2.34 (1.15)	(-4.62, -0.07)	0.0438	-0.32 (0.18)	(-0.68, 0.04)	0.0771	
OCS dose											0.2876
<10 mg/day	44	-10.28 (0.85)	38	-7.22 (0.91)	-3.06 (1.21)	(-5.49, -0.64)	0.0140	-0.54 (0.23)	(-0.98, -0.10)	0.0164	
>=10 mg/day	55	-11.45 (0.87)	64	-10.12 (0.86)	-1.33 (1.09)	(-3.49, 0.83)	0.2260	-0.20 (0.18)	(-0.56, 0.17)	0.2872	
Result of type I IFN gene signature test											0.0158
LOW	24	-9.55 (1.01)	26	-10.78 (1.00)	1.23 (1.43)	(-1.66, 4.11)	0.3962	0.24 (0.28)	(-0.32, 0.80)	0.3994	
HIGH	75	-11.03 (0.69)	76	-8.08 (0.72)	-2.94 (0.97)	(-4.87, -1.02)	0.0029	-0.48 (0.17)	(-0.80, -0.15)	0.0039	
Age (years)											0.2037
<= 45	67	-11.50 (0.70)	72	-8.89 (0.71)	-2.61 (0.90)	(-4.39, -0.84)	0.0043	-0.44 (0.17)	(-0.78, -0.10)	0.0104	
> 45	32	-8.85 (1.20)	30	-8.70 (1.25)	-0.16 (1.71)	(-3.58, 3.27)	0.9278	-0.02 (0.25)	(-0.52, 0.48)	0.9293	
Sex											NE
male	6	NE	9	NE	NE	NE		NE	NE		
female	93	-10.99 (0.65)	93	-8.87 (0.66)	-2.12 (0.88)	(-3.86, -0.38)	0.0170	-0.33 (0.15)	(-0.62, -0.04)	0.0237	
Race											NE
White	35	-10.01 (1.05)	41	-9.18 (0.98)	-0.83 (1.39)	(-3.61, 1.95)	0.5541	-0.13 (0.23)	(-0.58, 0.32)	0.5690	
Black	19	NE	12	NE	NE	NE		NE	NE		
Other	45	-11.80 (0.88)	49	-9.23 (0.92)	-2.56 (1.17)	(-4.89, -0.24)	0.0308	-0.41 (0.21)	(-0.82, -0.00)	0.0497	
Ethnicity											0.1684
Hispanic/Latino	46	-11.14 (0.82)	42	-10.43 (0.90)	-0.71 (1.14)	(-2.98, 1.56)	0.5324	-0.12 (0.21)	(-0.54, 0.29)	0.5607	
Non-hispanic/Latino	53	-11.08 (0.86)	60	-8.18 (0.82)	-2.90 (1.10)	(-5.09, -0.71)	0.0101	-0.46 (0.19)	(-0.83, -0.08)	0.0166	
Geographic region											0.7093
Latin America, Eastern Europe and Asia	62	-11.32 (0.85)	74	-9.11 (0.86)	-2.22 (1.03)	(-4.27, -0.17)	0.0340	-0.31 (0.17)	(-0.65, 0.03)	0.0729	
North America	37	-9.63 (0.99)	28	-8.07 (1.08)	-1.56 (1.44)	(-4.44, 1.32)	0.2835	-0.26 (0.25)	(-0.75, 0.23)	0.3011	
Baseline weight											0.4220
<60 kg	32	-12.10 (1.25)	39	-8.97 (1.24)	-3.13 (1.59)	(-6.31, 0.05)	0.0536	-0.42 (0.24)	(-0.89, 0.06)	0.0846	
>=60 kg	67	-10.50 (0.70)	63	-8.86 (0.72)	-1.64 (0.96)	(-3.54, 0.26)	0.0899	-0.29 (0.18)	(-0.63, 0.06)	0.1050	
Low CH50											0.9414
Yes	13	-11.50 (1.54)	13	-9.04 (1.65)	-2.45 (2.23)	(-7.13, 2.23)	0.2860	-0.41 (0.40)	(-1.19, 0.36)	0.2977	
No	86	-10.98 (0.66)	89	-8.71 (0.66)	-2.27 (0.90)	(-4.05, -0.50)	0.0123	-0.37 (0.15)	(-0.67, -0.07)	0.0162	
Low C3 or C4											0.5662
Yes	33	-13.31 (1.71)	47	-10.69 (1.48)	-2.62 (1.38)	(-5.38, 0.14)	0.0622	-0.26 (0.23)	(-0.71, 0.19)	0.2546	
No	66	-10.48 (0.72)	55	-8.85 (0.80)	-1.63 (1.06)	(-3.72, 0.47)	0.1272	-0.28 (0.18)	(-0.64, 0.08)	0.1332	
Baseline FARR anti-dsDNA											0.9741
<5 IU/mL	21	-10.40 (1.37)	16	-9.18 (1.51)	-1.21 (2.08)	(-5.52, 3.10)	0.5655	-0.19 (0.33)	(-0.84, 0.46)	0.5637	
>=5 IU/mL	56	-10.25 (0.90)	66	-8.96 (0.86)	-1.29 (1.09)	(-3.45, 0.88)	0.2410	-0.19 (0.18)	(-0.54, 0.17)	0.3050	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.8440
Yes	70	-10.59 (0.82)	81	-8.79 (0.78)	-1.81 (0.98)	(-3.74, 0.13)	0.0670	-0.26 (0.16)	(-0.58, 0.06)	0.1144	
No	29	-11.72 (1.02)	21	-10.28 (1.23)	-1.44 (1.60)	(-4.70, 1.82)	0.3751	-0.25 (0.29)	(-0.82, 0.31)	0.3762	
OCS use											0.2777
Yes	79	-11.11 (0.72)	88	-9.38 (0.72)	-1.73 (0.91)	(-3.53, 0.07)	0.0600	-0.26 (0.16)	(-0.57, 0.04)	0.0927	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - BILAG Global Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
No	20	-10.86 (1.32)	14	-6.80 (1.47)	-4.07 (1.95)	(-8.05, -0.08)	0.0458	-0.69 (0.36)	(-1.39, 0.02)	0.0553	
SLICC score											0.2679
0	62	-10.54 (0.74)	66	-9.14 (0.77)	-1.40 (1.00)	(-3.38, 0.57)	0.1622	-0.23 (0.18)	(-0.58, 0.12)	0.1913	
>=1	37	-11.78 (1.15)	36	-8.36 (1.13)	-3.42 (1.52)	(-6.46, -0.38)	0.0283	-0.49 (0.24)	(-0.96, -0.03)	0.0387	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Tender Joint Count
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-3.56 (0.53)		-2.65 (0.52)	-0.92 (0.70)	(-2.30, 0.47)	0.1922			
Week 8		-5.70 (0.59)		-5.04 (0.57)	-0.66 (0.79)	(-2.21, 0.89)	0.4042			
Week 12		-6.55 (0.66)		-5.19 (0.65)	-1.36 (0.89)	(-3.11, 0.40)	0.1299			
Week 16		-6.96 (0.69)		-5.50 (0.68)	-1.46 (0.94)	(-3.32, 0.40)	0.1232			
Week 20		-7.38 (0.68)		-5.79 (0.68)	-1.59 (0.93)	(-3.43, 0.25)	0.0900			
Week 24		-6.96 (0.70)		-5.58 (0.70)	-1.39 (0.96)	(-3.29, 0.52)	0.1524			
Week 28		-7.29 (0.67)		-5.86 (0.67)	-1.43 (0.91)	(-3.23, 0.37)	0.1185			
Week 32		-7.16 (0.72)		-5.85 (0.73)	-1.31 (1.00)	(-3.29, 0.66)	0.1917			
Week 36		-7.64 (0.72)		-5.87 (0.74)	-1.77 (1.01)	(-3.76, 0.22)	0.0808			
Week 40		-7.97 (0.71)		-6.38 (0.74)	-1.59 (0.99)	(-3.55, 0.38)	0.1130			
Week 44		-8.36 (0.72)		-6.44 (0.76)	-1.92 (1.03)	(-3.95, 0.11)	0.0633			
Week 48		-8.71 (0.67)		-6.69 (0.72)	-2.03 (0.96)	(-3.92, -0.13)	0.0361			
Week 52		-8.45 (0.74)		-5.83 (0.79)	-2.62 (1.05)	(-4.71, -0.54)	0.0141			
OVERALL	98	-7.13 (0.55)	100	-5.59 (0.54)	-1.54 (0.73)	(-2.99, -0.10)	0.0367	-0.28 (0.14)	(-0.56, -0.00)	0.0471

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Tender Joint Count - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) N	LSMean (SE)	Placebo (N=102) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.6772
< 10 points	39	-7.17 (0.73)	40	-6.12 (0.70)	-1.05 (0.99)	(-3.03, 0.92)	0.2923	-0.23 (0.23)	(-0.67, 0.21)	0.3046	
>= 10 points	59	-7.19 (0.73)	60	-5.57 (0.75)	-1.62 (0.95)	(-3.52, 0.27)	0.0919	-0.28 (0.18)	(-0.64, 0.08)	0.1269	
OCS dose											0.5645
<10 mg/day	43	-5.90 (0.74)	38	-3.98 (0.77)	-1.92 (1.05)	(-4.01, 0.17)	0.0714	-0.40 (0.22)	(-0.84, 0.05)	0.0786	
>=10 mg/day	55	-8.07 (0.76)	62	-6.97 (0.74)	-1.10 (0.96)	(-3.00, 0.80)	0.2527	-0.19 (0.19)	(-0.55, 0.17)	0.3057	
Result of type I IFN gene signature test											0.8918
LOW	24	-8.24 (1.30)	26	-6.55 (1.29)	-1.69 (1.83)	(-5.41, 2.04)	0.3624	-0.26 (0.28)	(-0.81, 0.30)	0.3667	
HIGH	74	-6.67 (0.55)	74	-5.25 (0.57)	-1.42 (0.77)	(-2.95, 0.11)	0.0688	-0.29 (0.17)	(-0.62, 0.03)	0.0757	
Age (years)											0.3847
<= 45	66	-7.77 (0.71)	70	-5.73 (0.69)	-2.04 (0.92)	(-3.86, -0.23)	0.0277	-0.35 (0.17)	(-0.69, -0.01)	0.0411	
> 45	32	-5.70 (0.89)	30	-5.01 (0.94)	-0.69 (1.26)	(-3.22, 1.84)	0.5843	-0.13 (0.25)	(-0.63, 0.36)	0.5973	
Sex											NE
male	6	NE	9	NE	NE	NE		NE	NE		
female	92	-7.44 (0.56)	91	-5.78 (0.58)	-1.66 (0.77)	(-3.18, -0.13)	0.0333	-0.30 (0.15)	(-0.59, -0.01)	0.0419	
Race											NE
White	35	-6.53 (0.89)	39	-4.12 (0.81)	-2.41 (1.19)	(-4.79, -0.04)	0.0462	-0.46 (0.24)	(-0.93, -0.00)	0.0499	
Black	19	NE	12	NE	NE	NE		NE	NE		
Other	44	-8.17 (0.79)	49	-7.14 (0.80)	-1.03 (1.05)	(-3.12, 1.07)	0.3325	-0.19 (0.21)	(-0.59, 0.22)	0.3694	
Ethnicity											0.1136
Hispanic/Latino	45	-8.06 (0.80)	42	-7.80 (0.86)	-0.26 (1.12)	(-2.48, 1.96)	0.8194	-0.05 (0.21)	(-0.47, 0.37)	0.8294	
Non-hispanic/Latino	53	-6.27 (0.74)	58	-3.68 (0.68)	-2.58 (0.96)	(-4.49, -0.68)	0.0084	-0.49 (0.19)	(-0.86, -0.11)	0.0117	
Geographic region											0.0524
Latin America, Eastern Europe and Asia	61	-7.53 (0.63)	72	-7.14 (0.62)	-0.39 (0.78)	(-1.92, 1.15)	0.6202	-0.08 (0.17)	(-0.42, 0.27)	0.6657	
North America	37	-6.12 (0.99)	28	-2.52 (1.12)	-3.61 (1.47)	(-6.55, -0.67)	0.0171	-0.60 (0.26)	(-1.10, -0.10)	0.0196	
Baseline weight											0.8034
<60 kg	32	-7.67 (0.96)	38	-6.22 (0.98)	-1.44 (1.26)	(-3.98, 1.09)	0.2575	-0.25 (0.24)	(-0.72, 0.22)	0.3042	
>=60 kg	66	-6.89 (0.69)	62	-5.06 (0.67)	-1.83 (0.93)	(-3.68, 0.01)	0.0513	-0.34 (0.18)	(-0.69, 0.01)	0.0593	
Low CH50											NE
Yes	13	NE	13	NE	NE	NE		NE	NE		
No	85	-7.37 (0.59)	87	-5.46 (0.58)	-1.91 (0.80)	(-3.50, -0.33)	0.0182	-0.35 (0.15)	(-0.65, -0.05)	0.0223	
Low C3 or C4											0.2573
Yes	32	-7.58 (1.06)	45	-7.07 (0.91)	-0.51 (0.97)	(-2.46, 1.44)	0.6023	-0.08 (0.23)	(-0.54, 0.37)	0.7190	
No	66	-7.42 (0.68)	55	-5.33 (0.76)	-2.09 (1.00)	(-4.08, -0.11)	0.0391	-0.37 (0.18)	(-0.74, -0.01)	0.0422	
Baseline FARR anti-dsDNA											NE
<5 IU/mL	21	NE	15	NE	NE	NE		NE	NE		
>=5 IU/mL	55	-5.97 (0.67)	65	-5.27 (0.62)	-0.71 (0.83)	(-2.36, 0.95)	0.3978	-0.14 (0.18)	(-0.50, 0.22)	0.4434	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.1347
Yes	69	-6.55 (0.65)	79	-5.70 (0.61)	-0.85 (0.79)	(-2.42, 0.72)	0.2861	-0.16 (0.17)	(-0.48, 0.17)	0.3435	
No	29	-9.05 (1.17)	21	-5.20 (1.43)	-3.85 (1.84)	(-7.59, -0.11)	0.0437	-0.59 (0.29)	(-1.16, -0.02)	0.0440	
OCS use											0.6316
Yes	79	-6.99 (0.64)	86	-5.71 (0.63)	-1.28 (0.83)	(-2.91, 0.35)	0.1232	-0.22 (0.16)	(-0.53, 0.09)	0.1570	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Tender Joint Count - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
No	19	-6.59 (1.29)	14	-4.35 (1.36)	-2.24 (1.82)	(-6.01, 1.54)	0.2315	-0.40 (0.36)	(-1.10, 0.29)	0.2574	
SLICC score											0.4504
0	62	-7.23 (0.62)	65	-6.52 (0.63)	-0.71 (0.85)	(-2.39, 0.97)	0.4023	-0.14 (0.18)	(-0.49, 0.21)	0.4263	
>=1	36	-6.86 (1.04)	35	-4.93 (1.00)	-1.93 (1.38)	(-4.69, 0.83)	0.1664	-0.31 (0.24)	(-0.78, 0.15)	0.1884	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Swollen Joint Count
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-3.84 (0.45)		-2.88 (0.44)	-0.96 (0.61)	(-2.16, 0.24)	0.1150			
Week 8		-4.97 (0.46)		-4.98 (0.45)	0.00 (0.62)	(-1.22, 1.23)	0.9956			
Week 12		-5.54 (0.47)		-4.83 (0.47)	-0.70 (0.64)	(-1.97, 0.57)	0.2763			
Week 16		-5.99 (0.40)		-6.10 (0.40)	0.11 (0.54)	(-0.97, 1.18)	0.8439			
Week 20		-6.25 (0.46)		-5.44 (0.47)	-0.81 (0.64)	(-2.07, 0.44)	0.2036			
Week 24		-6.36 (0.41)		-5.79 (0.41)	-0.57 (0.56)	(-1.67, 0.53)	0.3075			
Week 28		-6.42 (0.47)		-5.28 (0.48)	-1.14 (0.65)	(-2.43, 0.15)	0.0834			
Week 32		-6.13 (0.48)		-5.47 (0.49)	-0.67 (0.67)	(-1.99, 0.66)	0.3204			
Week 36		-6.18 (0.48)		-5.63 (0.50)	-0.55 (0.67)	(-1.87, 0.77)	0.4136			
Week 40		-6.76 (0.43)		-5.74 (0.44)	-1.02 (0.59)	(-2.19, 0.15)	0.0874			
Week 44		-6.58 (0.49)		-5.62 (0.50)	-0.96 (0.68)	(-2.31, 0.39)	0.1601			
Week 48		-6.58 (0.45)		-6.00 (0.47)	-0.58 (0.63)	(-1.82, 0.67)	0.3617			
Week 52		-6.65 (0.46)		-5.75 (0.49)	-0.91 (0.66)	(-2.20, 0.39)	0.1688			
OVERALL	98	-6.02 (0.34)	100	-5.35 (0.34)	-0.67 (0.45)	(-1.57, 0.22)	0.1388	-0.20 (0.14)	(-0.48, 0.08)	0.1646

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Swollen Joint Count - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) N	LSMean (SE)	Placebo (N=102) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.3715
< 10 points	39	-6.02 (0.50)	40	-5.92 (0.49)	-0.10 (0.69)	(-1.47, 1.28)	0.8886	-0.03 (0.23)	(-0.47, 0.41)	0.8908	
>= 10 points	59	-5.88 (0.47)	60	-4.97 (0.49)	-0.91 (0.61)	(-2.12, 0.29)	0.1346	-0.25 (0.18)	(-0.61, 0.11)	0.1794	
OCS dose											0.6426
<10 mg/day	43	-4.15 (0.50)	38	-3.70 (0.52)	-0.45 (0.71)	(-1.86, 0.96)	0.5244	-0.14 (0.22)	(-0.57, 0.30)	0.5374	
>=10 mg/day	55	-7.56 (0.47)	62	-6.69 (0.46)	-0.87 (0.57)	(-2.00, 0.26)	0.1282	-0.24 (0.19)	(-0.61, 0.12)	0.1889	
Result of type I IFN gene signature test											0.9542
LOW	24	-6.61 (0.70)	26	-6.02 (0.70)	-0.59 (0.99)	(-2.61, 1.42)	0.5526	-0.17 (0.28)	(-0.72, 0.39)	0.5553	
HIGH	74	-5.65 (0.34)	74	-5.12 (0.35)	-0.53 (0.47)	(-1.47, 0.41)	0.2652	-0.18 (0.16)	(-0.50, 0.15)	0.2810	
Age (years)											0.2577
<= 45	66	-6.37 (0.48)	70	-5.36 (0.47)	-1.01 (0.60)	(-2.20, 0.19)	0.0986	-0.26 (0.17)	(-0.60, 0.08)	0.1351	
> 45	32	-5.11 (0.47)	30	-5.12 (0.52)	0.01 (0.66)	(-1.33, 1.35)	0.9905	0.00 (0.25)	(-0.50, 0.50)	0.9911	
Sex											NE
male	6	NE	9	NE	NE	NE		NE	NE		
female	92	-6.31 (0.34)	91	-5.56 (0.34)	-0.74 (0.45)	(-1.64, 0.15)	0.1026	-0.23 (0.15)	(-0.52, 0.06)	0.1237	
Race											NE
White	35	-5.05 (0.51)	39	-4.37 (0.46)	-0.69 (0.67)	(-2.04, 0.67)	0.3100	-0.23 (0.23)	(-0.69, 0.23)	0.3238	
Black	19	NE	12	NE	NE	NE		NE	NE		
Other	44	-7.67 (0.44)	49	-6.88 (0.45)	-0.78 (0.59)	(-1.97, 0.40)	0.1899	-0.26 (0.21)	(-0.66, 0.15)	0.2197	
Ethnicity											0.4076
Hispanic/Latino	45	-7.98 (0.47)	42	-7.48 (0.51)	-0.50 (0.65)	(-1.79, 0.79)	0.4416	-0.15 (0.21)	(-0.58, 0.27)	0.4708	
Non-hispanic/Latino	53	-4.91 (0.46)	58	-3.68 (0.43)	-1.23 (0.59)	(-2.41, -0.05)	0.0417	-0.37 (0.19)	(-0.74, 0.01)	0.0546	
Geographic region											0.0644
Latin America, Eastern Europe and Asia	61	-7.05 (0.39)	72	-6.90 (0.39)	-0.15 (0.47)	(-1.08, 0.78)	0.7492	-0.05 (0.17)	(-0.39, 0.29)	0.7876	
North America	37	-4.40 (0.61)	28	-2.39 (0.67)	-2.01 (0.89)	(-3.79, -0.22)	0.0281	-0.54 (0.26)	(-1.04, -0.04)	0.0331	
Baseline weight											0.9652
<60 kg	32	-7.41 (0.62)	38	-6.66 (0.63)	-0.75 (0.77)	(-2.29, 0.79)	0.3352	-0.20 (0.24)	(-0.67, 0.27)	0.4042	
>=60 kg	66	-5.43 (0.42)	62	-4.64 (0.42)	-0.79 (0.57)	(-1.92, 0.34)	0.1695	-0.23 (0.18)	(-0.58, 0.12)	0.1907	
Low CH50											NE
Yes	13	NE	13	NE	NE	NE		NE	NE		
No	85	-5.95 (0.36)	87	-5.21 (0.36)	-0.74 (0.49)	(-1.71, 0.24)	0.1380	-0.22 (0.15)	(-0.52, 0.08)	0.1550	
Low C3 or C4											0.5738
Yes	32	-6.59 (0.63)	45	-6.16 (0.54)	-0.43 (0.55)	(-1.55, 0.68)	0.4392	-0.12 (0.23)	(-0.57, 0.34)	0.6090	
No	66	-5.78 (0.43)	55	-4.87 (0.49)	-0.91 (0.64)	(-2.18, 0.36)	0.1587	-0.25 (0.18)	(-0.61, 0.11)	0.1665	
Baseline FARR anti-dsDNA											NE
<5 IU/mL	21	NE	15	NE	NE	NE		NE	NE		
>=5 IU/mL	55	-4.97 (0.44)	65	-4.51 (0.42)	-0.46 (0.54)	(-1.53, 0.61)	0.3925	-0.14 (0.18)	(-0.50, 0.22)	0.4556	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.4244
Yes	69	-5.50 (0.43)	79	-4.93 (0.41)	-0.58 (0.50)	(-1.58, 0.43)	0.2572	-0.16 (0.17)	(-0.48, 0.16)	0.3346	
No	29	-7.17 (0.72)	21	-5.61 (0.86)	-1.55 (1.12)	(-3.81, 0.70)	0.1716	-0.39 (0.29)	(-0.96, 0.17)	0.1747	
OCS use											NE
Yes	79	-6.22 (0.41)	86	-5.52 (0.41)	-0.70 (0.52)	(-1.73, 0.33)	0.1836	-0.19 (0.16)	(-0.49, 0.12)	0.2333	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Swollen Joint Count - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
No	19	NE	14	NE	NE	NE		NE	NE		
SLICC score											0.9195
0	62	-6.77 (0.39)	65	-6.26 (0.41)	-0.51 (0.53)	(-1.57, 0.55)	0.3396	-0.16 (0.18)	(-0.51, 0.19)	0.3695	
>=1	36	-4.59 (0.71)	35	-3.97 (0.69)	-0.62 (0.92)	(-2.47, 1.23)	0.5057	-0.15 (0.24)	(-0.61, 0.32)	0.5357	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Mental Component Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		1.92 (0.90)		1.03 (0.89)	0.89 (1.18)	(-1.45, 3.22)	0.4541			
Week 12		3.51 (1.06)		2.53 (1.05)	0.98 (1.42)	(-1.82, 3.79)	0.4901			
Week 24		2.90 (1.01)		1.24 (1.02)	1.66 (1.37)	(-1.04, 4.36)	0.2266			
Week 36		4.83 (1.14)		2.63 (1.20)	2.20 (1.59)	(-0.94, 5.34)	0.1686			
Week 52		4.08 (1.10)		3.85 (1.18)	0.22 (1.55)	(-2.83, 3.28)	0.8851			
OVERALL	99	3.45 (0.85)	102	2.26 (0.85)	1.19 (1.12)	(-1.01, 3.40)	0.2880	0.14 (0.14)	(-0.14, 0.42)	0.3241

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Mental Component Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.7336
< 10 points	39	3.63 (1.28)	40	2.96 (1.25)	0.67 (1.75)	(-2.82, 4.15)	0.7028	0.08 (0.23)	(-0.36, 0.52)	0.7113	
>= 10 points	60	2.56 (1.15)	62	1.12 (1.20)	1.44 (1.44)	(-1.42, 4.30)	0.3204	0.16 (0.18)	(-0.20, 0.51)	0.3888	
OCS dose											0.2867
<10 mg/day	44	2.32 (1.17)	38	2.42 (1.26)	-0.10 (1.68)	(-3.46, 3.26)	0.9532	-0.01 (0.22)	(-0.45, 0.42)	0.9545	
>=10 mg/day	55	3.97 (1.24)	64	1.66 (1.22)	2.30 (1.50)	(-0.67, 5.27)	0.1274	0.24 (0.18)	(-0.12, 0.60)	0.1922	
Result of type I IFN gene signature test											0.3249
LOW	24	2.24 (1.56)	26	2.80 (1.54)	-0.55 (2.18)	(-4.99, 3.89)	0.8014	-0.07 (0.28)	(-0.63, 0.48)	0.8038	
HIGH	75	3.33 (0.92)	76	1.39 (0.97)	1.94 (1.29)	(-0.60, 4.49)	0.1338	0.24 (0.16)	(-0.08, 0.56)	0.1495	
Age (years)											0.6276
<= 45	67	3.77 (1.10)	72	2.18 (1.08)	1.59 (1.37)	(-1.13, 4.30)	0.2491	0.17 (0.17)	(-0.16, 0.51)	0.3065	
> 45	32	2.50 (1.44)	30	2.08 (1.51)	0.42 (1.99)	(-3.57, 4.41)	0.8349	0.05 (0.25)	(-0.45, 0.55)	0.8434	
Sex											0.0670
male	6	14.25 (7.08)	9	1.51 (5.13)	12.73 (6.23)	(-1.58, 27.05)	0.0744	0.74 (0.55)	(-0.34, 1.82)	0.1779	
female	93	3.56 (0.87)	93	2.43 (0.89)	1.13 (1.17)	(-1.19, 3.44)	0.3374	0.13 (0.15)	(-0.16, 0.42)	0.3693	
Race											0.8396
White	35	3.47 (1.30)	41	2.09 (1.21)	1.39 (1.72)	(-2.04, 4.81)	0.4219	0.18 (0.23)	(-0.27, 0.63)	0.4415	
Black	19	0.77 (2.99)	12	-2.35 (2.72)	3.12 (3.40)	(-3.86, 10.10)	0.3667	0.26 (0.37)	(-0.47, 0.98)	0.4860	
Other	45	4.48 (1.29)	49	3.59 (1.33)	0.88 (1.68)	(-2.46, 4.22)	0.6003	0.10 (0.21)	(-0.31, 0.50)	0.6376	
Ethnicity											0.5982
Hispanic/Latino	46	5.22 (1.25)	42	3.40 (1.37)	1.81 (1.71)	(-1.60, 5.22)	0.2931	0.21 (0.21)	(-0.21, 0.63)	0.3318	
Non-hispanic/Latino	53	1.62 (1.17)	60	1.00 (1.11)	0.62 (1.49)	(-2.34, 3.58)	0.6801	0.07 (0.19)	(-0.30, 0.44)	0.7043	
Geographic region											0.7716
Latin America, Eastern Europe and Asia	62	4.31 (1.12)	74	3.43 (1.14)	0.88 (1.33)	(-1.76, 3.52)	0.5098	0.09 (0.17)	(-0.24, 0.43)	0.5877	
North America	37	2.17 (1.50)	28	0.55 (1.64)	1.62 (2.16)	(-2.71, 5.95)	0.4570	0.18 (0.25)	(-0.31, 0.67)	0.4757	
Baseline weight											0.7788
<60 kg	32	4.35 (1.67)	39	2.45 (1.66)	1.90 (2.12)	(-2.33, 6.14)	0.3715	0.19 (0.24)	(-0.28, 0.66)	0.4288	
>=60 kg	67	3.28 (0.99)	63	2.07 (1.00)	1.20 (1.33)	(-1.43, 3.84)	0.3678	0.15 (0.18)	(-0.20, 0.49)	0.3960	
Low CH50											0.4156
Yes	13	3.66 (2.47)	13	-0.94 (3.77)	4.60 (4.13)	(-3.96, 13.16)	0.2770	0.39 (0.40)	(-0.39, 1.17)	0.3280	
No	86	3.36 (0.88)	89	2.26 (0.88)	1.11 (1.18)	(-1.23, 3.44)	0.3511	0.13 (0.15)	(-0.16, 0.43)	0.3766	
Low C3 or C4											0.9827
Yes	33	5.50 (2.17)	47	4.04 (1.87)	1.47 (1.88)	(-2.29, 5.23)	0.4387	0.11 (0.23)	(-0.33, 0.56)	0.6143	
No	66	2.86 (1.00)	55	1.34 (1.10)	1.52 (1.46)	(-1.37, 4.41)	0.3002	0.19 (0.18)	(-0.17, 0.54)	0.3109	
Baseline FARR anti-dsDNA											0.6718
<5 IU/mL	21	1.61 (1.83)	16	1.46 (2.04)	0.15 (2.80)	(-5.58, 5.87)	0.9585	0.02 (0.33)	(-0.63, 0.67)	0.9584	
>=5 IU/mL	56	3.01 (1.17)	66	1.53 (1.11)	1.47 (1.42)	(-1.33, 4.28)	0.2996	0.16 (0.18)	(-0.19, 0.52)	0.3670	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.4347
Yes	70	3.10 (1.08)	81	1.57 (1.03)	1.53 (1.27)	(-0.98, 4.05)	0.2302	0.17 (0.16)	(-0.15, 0.49)	0.3081	
No	29	3.56 (1.43)	21	4.06 (1.77)	-0.50 (2.27)	(-5.08, 4.08)	0.8269	-0.06 (0.29)	(-0.62, 0.50)	0.8280	
OCS use											0.9293
Yes	79	3.15 (0.99)	88	1.89 (0.99)	1.26 (1.24)	(-1.18, 3.70)	0.3091	0.14 (0.16)	(-0.17, 0.44)	0.3723	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Mental Component Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
No	20	2.27 (1.84)	14	1.27 (2.05)	1.00 (2.70)	(-4.55, 6.55)	0.7144	0.12 (0.35)	(-0.56, 0.81)	0.7272	
SLICC score											0.2995
0	62	2.81 (1.05)	66	2.55 (1.09)	0.27 (1.43)	(-2.56, 3.09)	0.8530	0.03 (0.18)	(-0.32, 0.38)	0.8626	
>=1	37	4.75 (1.51)	36	1.96 (1.47)	2.79 (1.97)	(-1.14, 6.71)	0.1611	0.31 (0.24)	(-0.16, 0.77)	0.1937	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Physical Component Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		2.30 (0.60)		1.43 (0.59)	0.87 (0.78)	(-0.67, 2.41)	0.2647			
Week 12		4.02 (0.84)		3.70 (0.82)	0.32 (1.13)	(-1.91, 2.54)	0.7799			
Week 24		5.04 (0.86)		4.85 (0.86)	0.19 (1.17)	(-2.13, 2.51)	0.8716			
Week 36		6.48 (0.96)		5.81 (1.00)	0.67 (1.34)	(-1.98, 3.33)	0.6172			
Week 52		6.64 (0.94)		5.34 (0.99)	1.30 (1.33)	(-1.33, 3.93)	0.3300			
OVERALL	99	4.90 (0.71)	102	4.23 (0.71)	0.67 (0.95)	(-1.20, 2.54)	0.4812	0.09 (0.14)	(-0.18, 0.37)	0.5057

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Physical Component Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) N	LSMean (SE)	Placebo (N=102) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.4123
< 10 points	39	4.05 (1.04)	40	4.38 (1.02)	-0.33 (1.43)	(-3.18, 2.53)	0.8207	-0.05 (0.23)	(-0.49, 0.39)	0.8253	
>= 10 points	60	5.27 (0.97)	62	4.03 (1.00)	1.24 (1.26)	(-1.26, 3.73)	0.3279	0.16 (0.18)	(-0.20, 0.51)	0.3793	
OCS dose											0.5470
<10 mg/day	44	4.60 (1.03)	38	3.00 (1.08)	1.60 (1.48)	(-1.34, 4.54)	0.2809	0.23 (0.22)	(-0.20, 0.67)	0.2913	
>=10 mg/day	55	5.62 (0.98)	64	5.17 (0.96)	0.44 (1.23)	(-2.00, 2.89)	0.7203	0.06 (0.18)	(-0.30, 0.42)	0.7485	
Result of type I IFN gene signature test											0.8388
LOW	24	4.17 (1.36)	26	3.95 (1.33)	0.23 (1.90)	(-3.60, 4.06)	0.9057	0.03 (0.28)	(-0.52, 0.59)	0.9069	
HIGH	75	5.58 (0.78)	76	4.91 (0.81)	0.67 (1.09)	(-1.49, 2.83)	0.5394	0.10 (0.16)	(-0.22, 0.42)	0.5514	
Age (years)											0.6905
<= 45	67	5.69 (0.87)	72	4.73 (0.86)	0.96 (1.11)	(-1.24, 3.17)	0.3883	0.13 (0.17)	(-0.20, 0.47)	0.4335	
> 45	32	3.21 (1.25)	30	3.07 (1.30)	0.14 (1.75)	(-3.37, 3.64)	0.9372	0.02 (0.25)	(-0.48, 0.52)	0.9395	
Sex											0.6677
male	6	6.78 (3.03)	9	7.29 (2.55)	-0.51 (2.94)	(-7.02, 6.00)	0.8657	-0.06 (0.53)	(-1.10, 0.97)	0.9044	
female	93	5.01 (0.73)	93	4.19 (0.75)	0.82 (1.00)	(-1.15, 2.80)	0.4123	0.11 (0.15)	(-0.17, 0.40)	0.4357	
Race											0.5288
White	35	4.08 (1.07)	41	4.05 (0.99)	0.03 (1.40)	(-2.77, 2.82)	0.9849	0.00 (0.23)	(-0.45, 0.46)	0.9856	
Black	19	4.78 (2.43)	12	1.17 (2.48)	3.61 (2.95)	(-2.43, 9.66)	0.2313	0.36 (0.37)	(-0.37, 1.09)	0.3380	
Other	45	5.65 (1.01)	49	5.45 (1.04)	0.19 (1.35)	(-2.50, 2.89)	0.8869	0.03 (0.21)	(-0.38, 0.43)	0.8954	
Ethnicity											0.4108
Hispanic/Latino	46	5.39 (1.04)	42	5.69 (1.13)	-0.30 (1.45)	(-3.19, 2.60)	0.8387	-0.04 (0.21)	(-0.46, 0.38)	0.8478	
Non-hispanic/Latino	53	4.62 (0.94)	60	3.36 (0.89)	1.26 (1.22)	(-1.15, 3.68)	0.3022	0.18 (0.19)	(-0.19, 0.55)	0.3347	
Geographic region											0.4464
Latin America, Eastern Europe and Asia	62	5.70 (0.92)	74	5.43 (0.92)	0.28 (1.13)	(-1.97, 2.52)	0.8074	0.04 (0.17)	(-0.30, 0.37)	0.8343	
North America	37	4.47 (1.10)	28	2.69 (1.24)	1.79 (1.63)	(-1.47, 5.05)	0.2771	0.27 (0.25)	(-0.23, 0.76)	0.2904	
Baseline weight											0.5753
<60 kg	32	8.05 (1.52)	39	6.34 (1.50)	1.70 (1.99)	(-2.28, 5.69)	0.3959	0.19 (0.24)	(-0.28, 0.65)	0.4358	
>=60 kg	67	3.63 (0.72)	63	3.17 (0.73)	0.46 (0.98)	(-1.49, 2.40)	0.6413	0.08 (0.18)	(-0.27, 0.42)	0.6578	
Low CH50											0.2949
Yes	13	5.82 (1.82)	13	1.74 (2.52)	4.08 (2.95)	(-2.09, 10.26)	0.1822	0.50 (0.40)	(-0.28, 1.28)	0.2119	
No	86	4.89 (0.73)	89	4.07 (0.73)	0.82 (1.00)	(-1.15, 2.79)	0.4121	0.12 (0.15)	(-0.18, 0.42)	0.4309	
Low C3 or C4											0.9038
Yes	33	5.69 (1.77)	47	4.98 (1.51)	0.71 (1.65)	(-2.58, 4.00)	0.6678	0.07 (0.23)	(-0.38, 0.51)	0.7630	
No	66	4.44 (0.81)	55	3.49 (0.90)	0.96 (1.19)	(-1.39, 3.31)	0.4222	0.14 (0.18)	(-0.21, 0.50)	0.4315	
Baseline FARR anti-dsDNA											0.0054
<5 IU/mL	21	5.89 (0.97)	16	1.13 (1.08)	4.76 (1.47)	(1.75, 7.77)	0.0030	1.06 (0.36)	(0.36, 1.76)	0.0029	
>=5 IU/mL	56	4.20 (0.96)	66	4.73 (0.91)	-0.53 (1.20)	(-2.91, 1.85)	0.6586	-0.07 (0.18)	(-0.43, 0.28)	0.6892	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.1893
Yes	70	4.51 (0.87)	81	4.60 (0.82)	-0.10 (1.07)	(-2.20, 2.01)	0.9280	-0.01 (0.16)	(-0.33, 0.31)	0.9361	
No	29	6.69 (1.34)	21	3.70 (1.64)	2.99 (2.10)	(-1.23, 7.22)	0.1607	0.40 (0.29)	(-0.17, 0.97)	0.1659	
OCS use											0.2091
Yes	79	5.30 (0.80)	88	4.60 (0.79)	0.70 (1.02)	(-1.33, 2.72)	0.4965	0.10 (0.16)	(-0.21, 0.40)	0.5378	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
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An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Physical Component Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) N	LSMean (SE)	Placebo (N=102) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
No	20	4.62 (1.47)	14	0.88 (1.61)	3.75 (2.20)	(-0.76, 8.26)	0.0999	0.57 (0.36)	(-0.12, 1.27)	0.1069	
SLICC score											0.2448
0	62	5.47 (0.87)	66	4.08 (0.89)	1.39 (1.18)	(-0.96, 3.73)	0.2444	0.20 (0.18)	(-0.15, 0.54)	0.2711	
>=1	37	4.02 (1.19)	36	4.94 (1.19)	-0.93 (1.60)	(-4.12, 2.26)	0.5632	-0.13 (0.23)	(-0.59, 0.33)	0.5846	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute General Health Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		2.12 (0.90)		1.66 (0.89)	0.46 (1.18)	(-1.87, 2.79)	0.6984			
Week 12		3.94 (1.08)		4.09 (1.06)	-0.16 (1.44)	(-3.00, 2.69)	0.9143			
Week 24		4.80 (1.10)		3.65 (1.11)	1.14 (1.49)	(-1.81, 4.09)	0.4457			
Week 36		6.47 (1.09)		5.72 (1.15)	0.75 (1.51)	(-2.23, 3.74)	0.6191			
Week 52		5.57 (1.12)		5.33 (1.20)	0.23 (1.57)	(-2.87, 3.34)	0.8821			
OVERALL	99	4.58 (0.85)	102	4.09 (0.86)	0.49 (1.12)	(-1.73, 2.70)	0.6656	0.06 (0.14)	(-0.22, 0.33)	0.6887

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
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An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute General Health Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) N	LSMean (SE)	Placebo (N=102) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.1106
< 10 points	39	4.33 (1.19)	40	6.00 (1.16)	-1.67 (1.62)	(-4.90, 1.57)	0.3072	-0.22 (0.23)	(-0.67, 0.22)	0.3232	
>= 10 points	60	3.86 (1.19)	62	2.01 (1.24)	1.85 (1.50)	(-1.11, 4.82)	0.2186	0.19 (0.18)	(-0.16, 0.55)	0.2873	
OCS dose											0.5153
<10 mg/day	44	3.80 (1.23)	38	4.03 (1.31)	-0.23 (1.76)	(-3.75, 3.28)	0.8961	-0.03 (0.22)	(-0.46, 0.41)	0.8988	
>=10 mg/day	55	5.17 (1.23)	64	3.89 (1.21)	1.27 (1.50)	(-1.69, 4.24)	0.3965	0.13 (0.18)	(-0.23, 0.50)	0.4653	
Result of type I IFN gene signature test											0.3930
LOW	24	3.85 (1.77)	26	5.06 (1.74)	-1.21 (2.47)	(-6.21, 3.80)	0.6282	-0.14 (0.28)	(-0.69, 0.42)	0.6331	
HIGH	75	4.65 (0.88)	76	3.49 (0.92)	1.15 (1.23)	(-1.29, 3.59)	0.3513	0.15 (0.16)	(-0.17, 0.47)	0.3701	
Age (years)											0.4104
<= 45	67	5.55 (1.06)	72	4.33 (1.05)	1.22 (1.33)	(-1.42, 3.86)	0.3634	0.14 (0.17)	(-0.20, 0.47)	0.4190	
> 45	32	2.57 (1.51)	30	3.39 (1.59)	-0.82 (2.09)	(-5.02, 3.37)	0.6949	-0.09 (0.25)	(-0.59, 0.40)	0.7106	
Sex											0.8190
male	6	10.14 (5.72)	9	10.61 (4.54)	-0.47 (4.73)	(-11.21, 10.26)	0.9229	-0.03 (0.53)	(-1.07, 1.00)	0.9513	
female	93	4.65 (0.88)	93	4.01 (0.90)	0.64 (1.18)	(-1.69, 2.98)	0.5865	0.07 (0.15)	(-0.21, 0.36)	0.6110	
Race											0.5032
White	35	6.16 (1.33)	41	4.48 (1.23)	1.67 (1.72)	(-1.76, 5.11)	0.3342	0.21 (0.23)	(-0.24, 0.66)	0.3619	
Black	19	2.33 (2.78)	12	-0.52 (2.56)	2.85 (3.23)	(-3.82, 9.51)	0.3874	0.25 (0.37)	(-0.47, 0.98)	0.4957	
Other	45	4.70 (1.28)	49	5.32 (1.32)	-0.62 (1.67)	(-3.94, 2.71)	0.7140	-0.07 (0.21)	(-0.47, 0.34)	0.7411	
Ethnicity											0.8120
Hispanic/Latino	46	5.41 (1.31)	42	5.15 (1.44)	0.26 (1.81)	(-3.33, 3.86)	0.8838	0.03 (0.21)	(-0.39, 0.45)	0.8925	
Non-hispanic/Latino	53	3.91 (1.12)	60	3.10 (1.06)	0.81 (1.41)	(-2.00, 3.62)	0.5680	0.10 (0.19)	(-0.27, 0.47)	0.6018	
Geographic region											0.3658
Latin America, Eastern Europe and Asia	62	5.25 (1.12)	74	5.47 (1.14)	-0.22 (1.32)	(-2.84, 2.40)	0.8689	-0.02 (0.17)	(-0.36, 0.31)	0.8926	
North America	37	4.44 (1.46)	28	2.40 (1.62)	2.04 (2.12)	(-2.21, 6.29)	0.3398	0.23 (0.25)	(-0.26, 0.72)	0.3595	
Baseline weight											0.4412
<60 kg	32	7.26 (1.64)	39	5.29 (1.64)	1.97 (2.08)	(-2.20, 6.14)	0.3477	0.20 (0.24)	(-0.27, 0.67)	0.4057	
>=60 kg	67	3.67 (0.96)	63	3.59 (0.97)	0.09 (1.29)	(-2.46, 2.63)	0.9470	0.01 (0.18)	(-0.33, 0.35)	0.9502	
Low CH50											0.3281
Yes	13	4.01 (2.09)	13	-0.23 (3.31)	4.25 (3.60)	(-3.35, 11.85)	0.2547	0.41 (0.40)	(-0.37, 1.19)	0.2991	
No	86	4.72 (0.89)	89	4.18 (0.89)	0.53 (1.20)	(-1.83, 2.90)	0.6572	0.06 (0.15)	(-0.23, 0.36)	0.6737	
Low C3 or C4											0.4501
Yes	33	7.37 (2.37)	47	5.40 (2.04)	1.96 (1.98)	(-1.98, 5.91)	0.3244	0.14 (0.23)	(-0.31, 0.59)	0.5362	
No	66	3.89 (0.95)	55	3.75 (1.06)	0.14 (1.39)	(-2.62, 2.89)	0.9215	0.02 (0.18)	(-0.34, 0.38)	0.9233	
Baseline FARR anti-dsDNA											0.7438
<5 IU/mL	21	2.49 (1.60)	16	2.77 (1.82)	-0.28 (2.45)	(-5.28, 4.72)	0.9098	-0.04 (0.33)	(-0.69, 0.61)	0.9101	
>=5 IU/mL	56	4.65 (1.20)	66	4.00 (1.13)	0.65 (1.44)	(-2.20, 3.50)	0.6533	0.07 (0.18)	(-0.29, 0.43)	0.6963	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.5341
Yes	70	4.81 (1.12)	81	3.83 (1.06)	0.98 (1.31)	(-1.61, 3.58)	0.4540	0.10 (0.16)	(-0.22, 0.42)	0.5262	
No	29	4.42 (1.40)	21	5.03 (1.74)	-0.61 (2.21)	(-5.06, 3.84)	0.7831	-0.08 (0.29)	(-0.64, 0.48)	0.7855	
OCS use											0.8097
Yes	79	4.29 (0.98)	88	3.81 (0.98)	0.48 (1.22)	(-1.93, 2.89)	0.6939	0.05 (0.16)	(-0.25, 0.36)	0.7300	

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Repeated measures model analysis (observed values) - SF-36 v2.0 Acute General Health Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) N	LSMean (SE)	Placebo (N=102) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
No	20	3.55 (2.01)	14	2.30 (2.21)	1.25 (2.95)	(-4.79, 7.29)	0.6749	0.14 (0.35)	(-0.54, 0.82)	0.6874	
SLICC score											0.4322
0	62	4.43 (1.04)	66	4.78 (1.08)	-0.35 (1.41)	(-3.14, 2.44)	0.8033	-0.04 (0.18)	(-0.39, 0.31)	0.8167	
>=1	37	4.77 (1.57)	36	3.18 (1.52)	1.59 (2.04)	(-2.48, 5.66)	0.4369	0.17 (0.23)	(-0.29, 0.63)	0.4723	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Mental Health Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		2.55 (0.92)		1.31 (0.91)	1.23 (1.22)	(-1.17, 3.63)	0.3127			
Week 12		4.34 (1.06)		2.21 (1.05)	2.13 (1.42)	(-0.67, 4.94)	0.1357			
Week 24		3.56 (1.04)		1.13 (1.05)	2.43 (1.41)	(-0.35, 5.20)	0.0860			
Week 36		5.15 (1.12)		2.78 (1.18)	2.36 (1.57)	(-0.73, 5.45)	0.1330			
Week 52		5.21 (1.06)		3.86 (1.14)	1.34 (1.49)	(-1.60, 4.29)	0.3689			
OVERALL	99	4.16 (0.84)	102	2.26 (0.84)	1.90 (1.10)	(-0.28, 4.08)	0.0865	0.22 (0.14)	(-0.05, 0.50)	0.1123

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Mental Health Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.9670
< 10 points	39	4.31 (1.26)	40	2.49 (1.24)	1.82 (1.73)	(-1.64, 5.28)	0.2974	0.23 (0.23)	(-0.21, 0.67)	0.3103	
>= 10 points	60	3.33 (1.15)	62	1.42 (1.20)	1.91 (1.44)	(-0.94, 4.76)	0.1860	0.21 (0.18)	(-0.15, 0.56)	0.2531	
OCS dose											0.3812
<10 mg/day	44	2.94 (1.12)	38	2.18 (1.19)	0.76 (1.60)	(-2.42, 3.94)	0.6351	0.10 (0.22)	(-0.33, 0.54)	0.6458	
>=10 mg/day	55	4.87 (1.24)	64	2.19 (1.22)	2.68 (1.50)	(-0.30, 5.65)	0.0772	0.28 (0.18)	(-0.08, 0.64)	0.1288	
Result of type I IFN gene signature test											0.0849
LOW	24	2.14 (1.28)	26	3.18 (1.27)	-1.04 (1.80)	(-4.69, 2.61)	0.5652	-0.16 (0.28)	(-0.72, 0.39)	0.5702	
HIGH	75	4.55 (0.94)	76	1.76 (0.98)	2.79 (1.31)	(0.20, 5.38)	0.0352	0.33 (0.16)	(0.01, 0.65)	0.0427	
Age (years)											0.3512
<= 45	67	5.08 (1.02)	72	2.41 (1.01)	2.67 (1.28)	(0.15, 5.20)	0.0379	0.31 (0.17)	(-0.02, 0.65)	0.0658	
> 45	32	2.63 (1.58)	30	2.31 (1.65)	0.32 (2.18)	(-4.06, 4.69)	0.8843	0.04 (0.25)	(-0.46, 0.53)	0.8904	
Sex											0.9423
male	6	7.43 (8.34)	9	6.09 (5.68)	1.34 (7.31)	(-15.59, 18.28)	0.8589	0.07 (0.53)	(-0.96, 1.10)	0.8964	
female	93	4.27 (0.86)	93	2.39 (0.88)	1.88 (1.16)	(-0.40, 4.16)	0.1058	0.22 (0.15)	(-0.07, 0.51)	0.1310	
Race											0.9350
White	35	3.41 (1.32)	41	1.95 (1.23)	1.46 (1.73)	(-2.01, 4.92)	0.4037	0.18 (0.23)	(-0.27, 0.64)	0.4240	
Black	19	3.91 (2.76)	12	1.40 (2.52)	2.51 (3.13)	(-3.92, 8.94)	0.4296	0.22 (0.37)	(-0.50, 0.95)	0.5446	
Other	45	5.26 (1.33)	49	3.05 (1.36)	2.21 (1.73)	(-1.24, 5.65)	0.2058	0.24 (0.21)	(-0.17, 0.64)	0.2528	
Ethnicity											0.8165
Hispanic/Latino	46	5.51 (1.30)	42	3.45 (1.42)	2.06 (1.78)	(-1.49, 5.61)	0.2514	0.23 (0.21)	(-0.19, 0.65)	0.2887	
Non-hispanic/Latino	53	2.70 (1.11)	60	1.17 (1.06)	1.53 (1.42)	(-1.28, 4.35)	0.2829	0.19 (0.19)	(-0.18, 0.56)	0.3238	
Geographic region											0.9212
Latin America, Eastern Europe and Asia	62	4.51 (1.19)	74	2.83 (1.21)	1.68 (1.41)	(-1.11, 4.47)	0.2358	0.17 (0.17)	(-0.17, 0.51)	0.3291	
North America	37	3.94 (1.25)	28	2.48 (1.39)	1.45 (1.83)	(-2.20, 5.11)	0.4301	0.19 (0.25)	(-0.30, 0.68)	0.4468	
Baseline weight											0.6864
<60 kg	32	5.41 (1.73)	39	2.66 (1.69)	2.75 (2.18)	(-1.61, 7.11)	0.2117	0.27 (0.24)	(-0.20, 0.74)	0.2667	
>=60 kg	67	3.84 (0.94)	63	2.11 (0.95)	1.73 (1.26)	(-0.77, 4.24)	0.1733	0.23 (0.18)	(-0.12, 0.57)	0.1993	
Low CH50											0.3548
Yes	13	5.90 (2.36)	13	0.43 (3.61)	5.47 (3.94)	(-2.69, 13.63)	0.1784	0.48 (0.40)	(-0.30, 1.26)	0.2273	
No	86	3.92 (0.87)	89	2.25 (0.87)	1.67 (1.17)	(-0.64, 3.98)	0.1558	0.20 (0.15)	(-0.09, 0.50)	0.1786	
Low C3 or C4											0.8897
Yes	33	5.41 (2.18)	47	3.02 (1.88)	2.39 (1.93)	(-1.46, 6.24)	0.2196	0.19 (0.23)	(-0.26, 0.63)	0.4146	
No	66	3.53 (0.97)	55	1.48 (1.08)	2.06 (1.42)	(-0.76, 4.87)	0.1505	0.26 (0.18)	(-0.10, 0.62)	0.1598	
Baseline FARR anti-dsDNA											0.2042
<5 IU/mL	21	2.21 (1.45)	16	2.83 (1.63)	-0.62 (2.23)	(-5.19, 3.95)	0.7818	-0.09 (0.33)	(-0.74, 0.56)	0.7803	
>=5 IU/mL	56	3.58 (1.17)	66	0.86 (1.11)	2.72 (1.41)	(-0.07, 5.50)	0.0556	0.30 (0.18)	(-0.06, 0.66)	0.0972	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.2352
Yes	70	3.41 (1.07)	81	0.95 (1.01)	2.47 (1.26)	(-0.02, 4.95)	0.0514	0.27 (0.16)	(-0.05, 0.59)	0.0982	
No	29	4.51 (1.35)	21	4.99 (1.67)	-0.48 (2.14)	(-4.79, 3.83)	0.8243	-0.06 (0.29)	(-0.62, 0.50)	0.8256	
OCS use											0.9262
Yes	79	3.93 (1.00)	88	2.09 (1.00)	1.84 (1.24)	(-0.60, 4.29)	0.1387	0.20 (0.16)	(-0.10, 0.51)	0.1952	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Mental Health Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) N	LSMean (SE)	Placebo (N=102) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
No	20	2.90 (1.58)	14	1.30 (1.75)	1.60 (2.30)	(-3.11, 6.31)	0.4912	0.23 (0.35)	(-0.46, 0.91)	0.5155	
SLICC score											0.5977
0	62	3.32 (1.03)	66	1.87 (1.07)	1.45 (1.39)	(-1.31, 4.20)	0.3005	0.17 (0.18)	(-0.18, 0.52)	0.3350	
>=1	37	5.92 (1.52)	36	3.21 (1.48)	2.72 (1.97)	(-1.21, 6.65)	0.1719	0.30 (0.24)	(-0.16, 0.76)	0.2079	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Physical Functioning Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		1.66 (0.67)		1.04 (0.67)	0.62 (0.88)	(-1.12, 2.36)	0.4854			
Week 12		3.78 (0.97)		2.92 (0.96)	0.86 (1.32)	(-1.75, 3.47)	0.5158			
Week 24		4.61 (1.02)		4.09 (1.03)	0.52 (1.40)	(-2.25, 3.28)	0.7127			
Week 36		5.31 (1.07)		5.61 (1.12)	-0.30 (1.51)	(-3.28, 2.68)	0.8422			
Week 52		6.31 (1.06)		5.21 (1.12)	1.10 (1.50)	(-1.86, 4.06)	0.4638			
OVERALL	99	4.33 (0.79)	102	3.77 (0.79)	0.56 (1.06)	(-1.53, 2.65)	0.5989	0.07 (0.14)	(-0.21, 0.35)	0.6180

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Physical Functioning Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.3217
< 10 points	39	2.81 (1.19)	40	3.44 (1.16)	-0.63 (1.63)	(-3.88, 2.62)	0.7006	-0.08 (0.23)	(-0.53, 0.36)	0.7074	
>= 10 points	60	4.97 (1.03)	62	3.51 (1.07)	1.46 (1.34)	(-1.19, 4.11)	0.2774	0.18 (0.18)	(-0.18, 0.53)	0.3299	
OCS dose											0.6743
<10 mg/day	44	4.11 (1.07)	38	2.81 (1.15)	1.30 (1.55)	(-1.78, 4.39)	0.4026	0.18 (0.22)	(-0.25, 0.62)	0.4129	
>=10 mg/day	55	4.99 (1.12)	64	4.57 (1.10)	0.42 (1.42)	(-2.40, 3.24)	0.7680	0.05 (0.18)	(-0.31, 0.41)	0.7912	
Result of type I IFN gene signature test											0.7224
LOW	24	3.43 (1.50)	26	3.59 (1.47)	-0.16 (2.10)	(-4.40, 4.07)	0.9382	-0.02 (0.28)	(-0.58, 0.53)	0.9388	
HIGH	75	4.82 (0.86)	76	4.12 (0.89)	0.70 (1.20)	(-1.68, 3.07)	0.5632	0.09 (0.16)	(-0.23, 0.41)	0.5749	
Age (years)											0.1189
<= 45	67	5.27 (0.92)	72	3.50 (0.92)	1.77 (1.20)	(-0.61, 4.15)	0.1434	0.23 (0.17)	(-0.10, 0.56)	0.1784	
> 45	32	2.34 (1.48)	30	4.31 (1.55)	-1.98 (2.08)	(-6.15, 2.20)	0.3464	-0.23 (0.26)	(-0.73, 0.27)	0.3638	
Sex											0.6651
male	6	7.74 (4.75)	9	8.64 (4.15)	-0.90 (3.51)	(-9.55, 7.75)	0.8066	-0.07 (0.53)	(-1.10, 0.96)	0.8947	
female	93	4.44 (0.81)	93	3.74 (0.83)	0.70 (1.11)	(-1.50, 2.89)	0.5327	0.09 (0.15)	(-0.20, 0.37)	0.5514	
Race											0.3516
White	35	3.56 (1.08)	41	3.43 (1.00)	0.13 (1.42)	(-2.70, 2.96)	0.9256	0.02 (0.23)	(-0.43, 0.47)	0.9288	
Black	19	4.58 (2.36)	12	0.20 (2.23)	4.38 (2.72)	(-1.20, 9.96)	0.1192	0.45 (0.37)	(-0.28, 1.19)	0.2249	
Other	45	5.34 (1.25)	49	5.18 (1.29)	0.15 (1.69)	(-3.21, 3.52)	0.9285	0.02 (0.21)	(-0.39, 0.42)	0.9333	
Ethnicity											0.3136
Hispanic/Latino	46	5.03 (1.24)	42	5.59 (1.35)	-0.56 (1.76)	(-4.06, 2.94)	0.7513	-0.06 (0.21)	(-0.48, 0.35)	0.7622	
Non-hispanic/Latino	53	3.99 (0.96)	60	2.39 (0.91)	1.60 (1.23)	(-0.83, 4.03)	0.1947	0.23 (0.19)	(-0.14, 0.60)	0.2296	
Geographic region											0.3000
Latin America, Eastern Europe and Asia	62	5.49 (1.07)	74	5.49 (1.07)	-0.00 (1.33)	(-2.63, 2.63)	0.9983	-0.00 (0.17)	(-0.34, 0.34)	0.9985	
North America	37	3.39 (0.94)	28	1.39 (1.06)	2.00 (1.40)	(-0.80, 4.80)	0.1588	0.35 (0.25)	(-0.15, 0.84)	0.1684	
Baseline weight											0.9065
<60 kg	32	7.78 (1.72)	39	6.78 (1.68)	1.01 (2.25)	(-3.49, 5.50)	0.6558	0.10 (0.24)	(-0.37, 0.57)	0.6807	
>=60 kg	67	2.84 (0.77)	63	2.13 (0.78)	0.71 (1.04)	(-1.35, 2.78)	0.4950	0.11 (0.18)	(-0.23, 0.46)	0.5180	
Low CH50											0.0695
Yes	13	5.15 (2.09)	13	-1.92 (2.97)	7.06 (3.42)	(-0.01, 14.14)	0.0503	0.74 (0.41)	(-0.06, 1.54)	0.0700	
No	86	4.30 (0.81)	89	3.76 (0.81)	0.54 (1.11)	(-1.65, 2.72)	0.6287	0.07 (0.15)	(-0.23, 0.37)	0.6405	
Low C3 or C4											0.8905
Yes	33	5.37 (2.01)	47	4.78 (1.72)	0.59 (1.85)	(-3.10, 4.27)	0.7515	0.05 (0.23)	(-0.40, 0.49)	0.8267	
No	66	3.71 (0.90)	55	2.81 (1.01)	0.90 (1.33)	(-1.73, 3.53)	0.4994	0.12 (0.18)	(-0.24, 0.48)	0.5066	
Baseline FARR anti-dsDNA											0.1811
<5 IU/mL	21	3.15 (1.00)	16	0.34 (1.13)	2.81 (1.53)	(-0.31, 5.92)	0.0756	0.60 (0.34)	(-0.06, 1.27)	0.0766	
>=5 IU/mL	56	3.99 (1.05)	66	3.86 (1.00)	0.13 (1.30)	(-2.44, 2.70)	0.9209	0.02 (0.18)	(-0.34, 0.37)	0.9298	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.6407
Yes	70	4.06 (0.97)	81	3.76 (0.91)	0.31 (1.17)	(-2.00, 2.62)	0.7930	0.04 (0.16)	(-0.28, 0.36)	0.8183	
No	29	5.23 (1.60)	21	3.62 (1.95)	1.60 (2.52)	(-3.50, 6.71)	0.5283	0.18 (0.29)	(-0.38, 0.74)	0.5300	
OCS use											0.2413
Yes	79	4.55 (0.91)	88	4.00 (0.92)	0.55 (1.19)	(-1.80, 2.89)	0.6449	0.07 (0.16)	(-0.24, 0.37)	0.6743	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
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p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Physical Functioning Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) N	LSMean (SE)	Placebo (N=102) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
No	20	4.10 (1.32)	14	0.89 (1.45)	3.21 (1.93)	(-0.75, 7.16)	0.1079	0.55 (0.36)	(-0.15, 1.25)	0.1222	
SLICC score											0.3806
0	62	4.42 (0.95)	66	3.01 (0.98)	1.41 (1.30)	(-1.17, 3.99)	0.2811	0.18 (0.18)	(-0.17, 0.53)	0.3061	
>=1	37	4.31 (1.44)	36	4.95 (1.43)	-0.63 (1.94)	(-4.50, 3.23)	0.7443	-0.07 (0.23)	(-0.53, 0.39)	0.7576	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Role Emotional Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		0.63 (1.00)		0.10 (1.00)	0.54 (1.33)	(-2.08, 3.15)	0.6860			
Week 12		2.26 (1.25)		2.64 (1.23)	-0.38 (1.68)	(-3.69, 2.93)	0.8203			
Week 24		2.39 (1.13)		1.55 (1.15)	0.84 (1.53)	(-2.18, 3.87)	0.5832			
Week 36		4.10 (1.33)		3.06 (1.41)	1.03 (1.87)	(-2.67, 4.73)	0.5822			
Week 52		3.59 (1.28)		4.18 (1.38)	-0.59 (1.81)	(-4.17, 3.00)	0.7470			
OVERALL	99	2.59 (0.96)	102	2.30 (0.97)	0.29 (1.27)	(-2.22, 2.80)	0.8205	0.03 (0.14)	(-0.25, 0.31)	0.8330

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Role Emotional Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) N	LSMean (SE)	Placebo (N=102) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.6307
< 10 points	39	2.22 (1.51)	40	2.69 (1.47)	-0.47 (2.05)	(-4.56, 3.61)	0.8176	-0.05 (0.23)	(-0.49, 0.39)	0.8237	
>= 10 points	60	2.32 (1.25)	62	1.56 (1.30)	0.77 (1.58)	(-2.36, 3.89)	0.6271	0.08 (0.18)	(-0.28, 0.43)	0.6726	
OCS dose											0.2619
<10 mg/day	44	1.41 (1.38)	38	2.55 (1.48)	-1.13 (1.98)	(-5.08, 2.81)	0.5687	-0.12 (0.22)	(-0.56, 0.31)	0.5799	
>=10 mg/day	55	3.43 (1.36)	64	1.67 (1.33)	1.76 (1.65)	(-1.51, 5.02)	0.2888	0.17 (0.18)	(-0.19, 0.53)	0.3614	
Result of type I IFN gene signature test											0.6476
LOW	24	1.46 (2.06)	26	2.09 (2.02)	-0.63 (2.88)	(-6.46, 5.19)	0.8271	-0.06 (0.28)	(-0.62, 0.49)	0.8293	
HIGH	75	2.67 (0.98)	76	1.84 (1.03)	0.83 (1.38)	(-1.89, 3.55)	0.5494	0.09 (0.16)	(-0.23, 0.41)	0.5648	
Age (years)											0.9081
<= 45	67	2.50 (1.30)	72	2.34 (1.27)	0.16 (1.62)	(-3.05, 3.37)	0.9224	0.01 (0.17)	(-0.32, 0.35)	0.9309	
> 45	32	2.31 (1.40)	30	1.86 (1.50)	0.45 (1.96)	(-3.50, 4.40)	0.8187	0.06 (0.25)	(-0.44, 0.55)	0.8273	
Sex											0.9107
male	6	2.25 (5.86)	9	1.43 (4.89)	0.82 (5.29)	(-11.55, 13.20)	0.8807	0.05 (0.53)	(-0.98, 1.09)	0.9197	
female	93	2.80 (1.00)	93	2.59 (1.02)	0.21 (1.34)	(-2.43, 2.85)	0.8755	0.02 (0.15)	(-0.27, 0.31)	0.8833	
Race											0.4169
White	35	1.90 (1.47)	41	1.60 (1.36)	0.29 (1.92)	(-3.55, 4.14)	0.8787	0.03 (0.23)	(-0.42, 0.48)	0.8840	
Black	19	3.05 (4.27)	12	-3.00 (3.80)	6.05 (4.74)	(-3.69, 15.79)	0.2129	0.35 (0.37)	(-0.38, 1.08)	0.3447	
Other	45	3.93 (1.32)	49	4.55 (1.36)	-0.62 (1.73)	(-4.06, 2.82)	0.7227	-0.07 (0.21)	(-0.47, 0.34)	0.7484	
Ethnicity											0.3891
Hispanic/Latino	46	4.93 (1.30)	42	3.46 (1.42)	1.48 (1.80)	(-2.10, 5.05)	0.4129	0.16 (0.21)	(-0.26, 0.58)	0.4459	
Non-hispanic/Latino	53	0.32 (1.42)	60	1.04 (1.34)	-0.71 (1.80)	(-4.29, 2.86)	0.6930	-0.07 (0.19)	(-0.44, 0.30)	0.7166	
Geographic region											0.5008
Latin America, Eastern Europe and Asia	62	3.92 (1.12)	74	4.27 (1.14)	-0.35 (1.34)	(-3.00, 2.29)	0.7913	-0.04 (0.17)	(-0.38, 0.30)	0.8271	
North America	37	-0.05 (1.97)	28	-1.81 (2.16)	1.76 (2.85)	(-3.93, 7.46)	0.5381	0.15 (0.25)	(-0.34, 0.64)	0.5542	
Baseline weight											0.8093
<60 kg	32	4.65 (1.74)	39	4.48 (1.72)	0.17 (2.20)	(-4.23, 4.57)	0.9382	0.02 (0.24)	(-0.45, 0.48)	0.9453	
>=60 kg	67	1.86 (1.18)	63	1.04 (1.20)	0.83 (1.59)	(-2.32, 3.97)	0.6038	0.09 (0.18)	(-0.26, 0.43)	0.6259	
Low CH50											0.2836
Yes	13	1.58 (2.93)	13	-4.20 (4.33)	5.78 (4.82)	(-4.17, 15.74)	0.2422	0.42 (0.40)	(-0.36, 1.20)	0.2904	
No	86	2.65 (0.98)	89	2.23 (0.98)	0.42 (1.32)	(-2.18, 3.02)	0.7503	0.05 (0.15)	(-0.25, 0.34)	0.7625	
Low C3 or C4											0.3975
Yes	33	5.00 (2.27)	47	5.80 (1.93)	-0.80 (1.89)	(-4.58, 2.98)	0.6740	-0.06 (0.23)	(-0.51, 0.38)	0.7905	
No	66	2.20 (1.20)	55	0.82 (1.33)	1.38 (1.75)	(-2.09, 4.86)	0.4317	0.14 (0.18)	(-0.22, 0.50)	0.4417	
Baseline FARR anti-dsDNA											0.2837
<5 IU/mL	21	2.85 (2.41)	16	-0.84 (2.70)	3.69 (3.67)	(-3.80, 11.18)	0.3228	0.33 (0.33)	(-0.33, 0.99)	0.3238	
>=5 IU/mL	56	1.82 (1.34)	66	2.43 (1.27)	-0.61 (1.62)	(-3.82, 2.59)	0.7055	-0.06 (0.18)	(-0.42, 0.30)	0.7415	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.5580
Yes	70	2.09 (1.22)	81	2.44 (1.16)	-0.34 (1.43)	(-3.18, 2.49)	0.8108	-0.03 (0.16)	(-0.35, 0.29)	0.8387	
No	29	3.67 (1.81)	21	2.15 (2.21)	1.52 (2.84)	(-4.20, 7.23)	0.5952	0.15 (0.29)	(-0.41, 0.71)	0.5989	
OCS use											0.9938
Yes	79	2.60 (1.10)	88	2.09 (1.10)	0.51 (1.38)	(-2.22, 3.24)	0.7119	0.05 (0.16)	(-0.25, 0.35)	0.7448	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Role Emotional Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) N	LSMean (SE)	Placebo (N=102) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
No	20	1.41 (2.42)	14	0.93 (2.68)	0.48 (3.53)	(-6.80, 7.76)	0.8928	0.04 (0.35)	(-0.64, 0.73)	0.8980	
SLICC score											0.5686
0	62	2.37 (1.25)	66	2.34 (1.29)	0.02 (1.69)	(-3.33, 3.38)	0.9900	0.00 (0.18)	(-0.34, 0.35)	0.9906	
>=1	37	3.23 (1.57)	36	1.70 (1.54)	1.54 (2.05)	(-2.55, 5.63)	0.4559	0.16 (0.23)	(-0.30, 0.62)	0.4904	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Role Physical Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		1.81 (0.69)		0.64 (0.68)	1.17 (0.90)	(-0.60, 2.95)	0.1939			
Week 12		3.61 (0.93)		3.17 (0.92)	0.44 (1.26)	(-2.04, 2.93)	0.7267			
Week 24		4.19 (0.89)		3.13 (0.89)	1.06 (1.21)	(-1.32, 3.44)	0.3809			
Week 36		5.66 (0.98)		5.13 (1.03)	0.53 (1.37)	(-2.18, 3.24)	0.6984			
Week 52		5.27 (0.99)		4.73 (1.07)	0.54 (1.41)	(-2.25, 3.33)	0.7017			
OVERALL	99	4.11 (0.72)	102	3.36 (0.73)	0.75 (0.96)	(-1.14, 2.64)	0.4361	0.10 (0.14)	(-0.17, 0.38)	0.4666

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Role Physical Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) N	LSMean (SE)	Placebo (N=102) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.7676
< 10 points	39	4.14 (1.10)	40	3.77 (1.07)	0.38 (1.50)	(-2.60, 3.36)	0.8016	0.05 (0.23)	(-0.39, 0.50)	0.8073	
>= 10 points	60	3.67 (0.97)	62	2.71 (1.02)	0.95 (1.25)	(-1.52, 3.43)	0.4469	0.12 (0.18)	(-0.23, 0.48)	0.5023	
OCS dose											0.9693
<10 mg/day	44	3.84 (1.06)	38	2.75 (1.11)	1.09 (1.51)	(-1.92, 4.10)	0.4725	0.16 (0.22)	(-0.28, 0.59)	0.4831	
>=10 mg/day	55	4.56 (1.00)	64	3.39 (0.99)	1.17 (1.26)	(-1.32, 3.65)	0.3545	0.15 (0.18)	(-0.21, 0.51)	0.4137	
Result of type I IFN gene signature test											0.9441
LOW	24	4.25 (1.48)	26	3.48 (1.45)	0.77 (2.07)	(-3.40, 4.94)	0.7103	0.10 (0.28)	(-0.45, 0.66)	0.7142	
HIGH	75	4.34 (0.76)	76	3.40 (0.80)	0.94 (1.06)	(-1.17, 3.04)	0.3802	0.14 (0.16)	(-0.18, 0.46)	0.3976	
Age (years)											0.6325
<= 45	67	4.05 (0.90)	72	3.58 (0.90)	0.47 (1.15)	(-1.80, 2.74)	0.6842	0.06 (0.17)	(-0.27, 0.39)	0.7155	
> 45	32	3.88 (1.32)	30	2.38 (1.36)	1.50 (1.83)	(-2.18, 5.18)	0.4163	0.20 (0.25)	(-0.30, 0.70)	0.4368	
Sex											0.3379
male	6	10.06 (2.84)	9	6.44 (2.29)	3.62 (2.90)	(-2.71, 9.94)	0.2365	0.49 (0.54)	(-0.56, 1.55)	0.3586	
female	93	4.22 (0.74)	93	3.55 (0.76)	0.67 (1.00)	(-1.31, 2.65)	0.5039	0.09 (0.15)	(-0.20, 0.38)	0.5290	
Race											0.1556
White	35	4.40 (1.06)	41	2.98 (0.97)	1.42 (1.38)	(-1.33, 4.16)	0.3071	0.23 (0.23)	(-0.23, 0.68)	0.3295	
Black	19	7.48 (2.70)	12	1.92 (2.44)	5.57 (3.09)	(-0.80, 11.93)	0.0837	0.51 (0.38)	(-0.23, 1.24)	0.1747	
Other	45	3.77 (1.09)	49	4.50 (1.12)	-0.74 (1.43)	(-3.59, 2.12)	0.6097	-0.10 (0.21)	(-0.50, 0.31)	0.6429	
Ethnicity											0.6284
Hispanic/Latino	46	4.39 (1.15)	42	4.14 (1.27)	0.25 (1.60)	(-2.93, 3.44)	0.8750	0.03 (0.21)	(-0.39, 0.45)	0.8836	
Non-hispanic/Latino	53	3.65 (0.94)	60	2.43 (0.89)	1.22 (1.20)	(-1.17, 3.61)	0.3128	0.18 (0.19)	(-0.19, 0.55)	0.3477	
Geographic region											0.3107
Latin America, Eastern Europe and Asia	62	4.24 (0.92)	74	4.38 (0.93)	-0.14 (1.11)	(-2.33, 2.05)	0.9003	-0.02 (0.17)	(-0.36, 0.32)	0.9167	
North America	37	5.22 (1.31)	28	3.12 (1.46)	2.10 (1.91)	(-1.72, 5.92)	0.2762	0.26 (0.25)	(-0.23, 0.76)	0.2934	
Baseline weight											0.4376
<60 kg	32	5.95 (1.39)	39	3.86 (1.40)	2.09 (1.78)	(-1.48, 5.65)	0.2465	0.25 (0.24)	(-0.22, 0.72)	0.3026	
>=60 kg	67	3.50 (0.83)	63	3.05 (0.84)	0.45 (1.12)	(-1.77, 2.67)	0.6887	0.07 (0.18)	(-0.28, 0.41)	0.7040	
Low CH50											0.1544
Yes	13	3.67 (2.26)	13	-2.41 (2.88)	6.09 (3.52)	(-1.23, 13.40)	0.0983	0.63 (0.40)	(-0.16, 1.42)	0.1181	
No	86	4.20 (0.73)	89	3.32 (0.74)	0.88 (0.99)	(-1.08, 2.84)	0.3772	0.13 (0.15)	(-0.17, 0.42)	0.4008	
Low C3 or C4											0.6808
Yes	33	4.78 (1.79)	47	4.35 (1.52)	0.44 (1.57)	(-2.70, 3.58)	0.7819	0.04 (0.23)	(-0.40, 0.49)	0.8542	
No	66	4.07 (0.85)	55	2.81 (0.95)	1.26 (1.25)	(-1.21, 3.73)	0.3138	0.18 (0.18)	(-0.18, 0.54)	0.3254	
Baseline FARR anti-dsDNA											0.1899
<5 IU/mL	21	5.98 (1.54)	16	2.35 (1.70)	3.63 (2.33)	(-1.12, 8.38)	0.1297	0.51 (0.34)	(-0.15, 1.17)	0.1311	
>=5 IU/mL	56	3.60 (0.93)	66	3.38 (0.89)	0.21 (1.16)	(-2.08, 2.51)	0.8533	0.03 (0.18)	(-0.33, 0.39)	0.8685	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.3230
Yes	70	3.57 (0.87)	81	3.50 (0.83)	0.07 (1.05)	(-2.01, 2.15)	0.9470	0.01 (0.16)	(-0.31, 0.33)	0.9537	
No	29	6.05 (1.41)	21	3.56 (1.73)	2.48 (2.20)	(-1.95, 6.92)	0.2658	0.32 (0.29)	(-0.25, 0.88)	0.2732	
OCS use											0.3257
Yes	79	4.14 (0.80)	88	3.44 (0.81)	0.70 (1.02)	(-1.32, 2.72)	0.4949	0.09 (0.16)	(-0.21, 0.40)	0.5425	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Role Physical Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
No	20	4.13 (1.82)	14	0.55 (1.99)	3.58 (2.74)	(-2.04, 9.19)	0.2026	0.44 (0.35)	(-0.25, 1.14)	0.2087	
SLICC score											0.8735
0	62	4.14 (0.90)	66	3.79 (0.93)	0.35 (1.22)	(-2.06, 2.77)	0.7721	0.05 (0.18)	(-0.30, 0.39)	0.7860	
>=1	37	3.80 (1.26)	36	3.11 (1.24)	0.68 (1.66)	(-2.64, 4.00)	0.6823	0.09 (0.23)	(-0.37, 0.55)	0.7037	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Social Functioning Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		3.48 (0.79)		1.65 (0.78)	1.83 (1.03)	(-0.20, 3.87)	0.0776			
Week 12		5.07 (1.02)		3.15 (1.00)	1.92 (1.36)	(-0.76, 4.59)	0.1593			
Week 24		4.64 (1.01)		3.51 (1.02)	1.13 (1.37)	(-1.58, 3.83)	0.4123			
Week 36		6.96 (1.11)		4.24 (1.16)	2.73 (1.55)	(-0.33, 5.79)	0.0803			
Week 52		6.22 (1.13)		5.15 (1.20)	1.08 (1.59)	(-2.07, 4.22)	0.5001			
OVERALL	99	5.28 (0.85)	102	3.54 (0.85)	1.74 (1.12)	(-0.48, 3.95)	0.1239	0.20 (0.14)	(-0.07, 0.48)	0.1512

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Social Functioning Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) N	LSMean (SE)	Placebo (N=102) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.9105
< 10 points	39	5.33 (1.15)	40	3.42 (1.12)	1.91 (1.57)	(-1.22, 5.04)	0.2270	0.27 (0.23)	(-0.18, 0.71)	0.2394	
>= 10 points	60	4.85 (1.23)	62	3.19 (1.27)	1.67 (1.55)	(-1.41, 4.74)	0.2851	0.17 (0.18)	(-0.19, 0.52)	0.3514	
OCS dose											0.8773
<10 mg/day	44	4.49 (1.14)	38	2.40 (1.21)	2.09 (1.63)	(-1.16, 5.34)	0.2048	0.27 (0.22)	(-0.16, 0.71)	0.2170	
>=10 mg/day	55	5.80 (1.25)	64	4.06 (1.23)	1.74 (1.54)	(-1.30, 4.79)	0.2593	0.18 (0.18)	(-0.18, 0.54)	0.3260	
Result of type I IFN gene signature test											0.7368
LOW	24	5.56 (1.44)	26	3.21 (1.42)	2.35 (2.01)	(-1.70, 6.40)	0.2488	0.32 (0.29)	(-0.24, 0.88)	0.2566	
HIGH	75	4.88 (0.94)	76	3.34 (0.98)	1.54 (1.31)	(-1.05, 4.14)	0.2418	0.18 (0.16)	(-0.14, 0.50)	0.2586	
Age (years)											0.4799
<= 45	67	5.44 (1.11)	72	3.18 (1.09)	2.27 (1.40)	(-0.50, 5.04)	0.1077	0.25 (0.17)	(-0.09, 0.58)	0.1477	
> 45	32	4.28 (1.35)	30	3.65 (1.39)	0.63 (1.84)	(-3.06, 4.32)	0.7323	0.08 (0.25)	(-0.42, 0.58)	0.7471	
Sex											0.8836
male	6	10.39 (3.54)	9	8.02 (2.85)	2.36 (3.45)	(-5.16, 9.89)	0.5066	0.26 (0.53)	(-0.78, 1.30)	0.6254	
female	93	5.32 (0.88)	93	3.49 (0.90)	1.83 (1.19)	(-0.51, 4.17)	0.1251	0.21 (0.15)	(-0.08, 0.50)	0.1498	
Race											0.9866
White	35	4.73 (1.22)	41	3.13 (1.12)	1.60 (1.59)	(-1.56, 4.77)	0.3159	0.22 (0.23)	(-0.23, 0.67)	0.3392	
Black	19	0.81 (3.59)	12	-0.28 (3.15)	1.09 (3.77)	(-6.66, 8.84)	0.7748	0.08 (0.37)	(-0.65, 0.80)	0.8377	
Other	45	7.06 (1.25)	49	5.30 (1.27)	1.76 (1.65)	(-1.52, 5.03)	0.2890	0.20 (0.21)	(-0.20, 0.61)	0.3308	
Ethnicity											0.6986
Hispanic/Latino	46	6.69 (1.23)	42	5.70 (1.33)	0.98 (1.69)	(-2.39, 4.36)	0.5636	0.11 (0.21)	(-0.30, 0.53)	0.5905	
Non-hispanic/Latino	53	3.72 (1.13)	60	1.88 (1.07)	1.84 (1.43)	(-1.00, 4.68)	0.2015	0.22 (0.19)	(-0.15, 0.59)	0.2415	
Geographic region											0.9743
Latin America, Eastern Europe and Asia	62	6.98 (1.05)	74	5.03 (1.06)	1.94 (1.28)	(-0.60, 4.48)	0.1323	0.22 (0.17)	(-0.12, 0.56)	0.2009	
North America	37	3.31 (1.45)	28	1.44 (1.58)	1.87 (2.07)	(-2.28, 6.01)	0.3721	0.21 (0.25)	(-0.28, 0.71)	0.3961	
Baseline weight											0.3687
<60 kg	32	6.25 (1.72)	39	2.83 (1.70)	3.42 (2.22)	(-1.02, 7.87)	0.1290	0.33 (0.24)	(-0.14, 0.80)	0.1692	
>=60 kg	67	4.89 (0.95)	63	3.78 (0.96)	1.11 (1.28)	(-1.42, 3.65)	0.3852	0.14 (0.18)	(-0.20, 0.49)	0.4130	
Low CH50											0.3145
Yes	13	6.75 (1.94)	13	1.74 (2.50)	5.01 (3.03)	(-1.26, 11.28)	0.1118	0.60 (0.40)	(-0.19, 1.39)	0.1354	
No	86	5.11 (0.90)	89	3.38 (0.89)	1.73 (1.21)	(-0.65, 4.11)	0.1538	0.21 (0.15)	(-0.09, 0.50)	0.1753	
Low C3 or C4											0.5275
Yes	33	8.83 (1.85)	47	5.70 (1.60)	3.13 (1.76)	(-0.39, 6.64)	0.0805	0.29 (0.23)	(-0.16, 0.73)	0.2113	
No	66	4.12 (1.03)	55	2.46 (1.13)	1.67 (1.49)	(-1.29, 4.63)	0.2673	0.20 (0.18)	(-0.16, 0.56)	0.2797	
Baseline FARR anti-dsDNA											0.2349
<5 IU/mL	21	4.88 (1.61)	16	0.35 (1.81)	4.54 (2.44)	(-0.44, 9.52)	0.0728	0.61 (0.34)	(-0.06, 1.27)	0.0749	
>=5 IU/mL	56	5.05 (1.18)	66	3.88 (1.11)	1.17 (1.44)	(-1.69, 4.03)	0.4196	0.13 (0.18)	(-0.23, 0.49)	0.4755	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.7494
Yes	70	5.37 (1.05)	81	3.69 (0.99)	1.68 (1.25)	(-0.80, 4.16)	0.1819	0.19 (0.16)	(-0.13, 0.51)	0.2461	
No	29	5.76 (1.67)	21	3.15 (2.04)	2.61 (2.61)	(-2.65, 7.87)	0.3231	0.28 (0.29)	(-0.28, 0.85)	0.3301	
OCS use											0.5804
Yes	79	5.37 (0.99)	88	3.56 (0.98)	1.82 (1.25)	(-0.65, 4.28)	0.1475	0.20 (0.16)	(-0.10, 0.51)	0.1964	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Social Functioning Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
No	20	4.95 (1.80)	14	1.50 (1.98)	3.45 (2.67)	(-2.02, 8.91)	0.2072	0.43 (0.35)	(-0.26, 1.12)	0.2215	
SLICC score											0.8862
0	62	5.10 (1.08)	66	3.72 (1.11)	1.38 (1.46)	(-1.51, 4.28)	0.3453	0.16 (0.18)	(-0.19, 0.50)	0.3753	
>=1	37	5.52 (1.47)	36	3.79 (1.41)	1.72 (1.87)	(-2.00, 5.45)	0.3592	0.20 (0.23)	(-0.26, 0.66)	0.4041	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Bodily Pain Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		3.22 (0.79)		2.05 (0.78)	1.17 (1.04)	(-0.88, 3.21)	0.2618			
Week 12		4.58 (0.96)		4.60 (0.95)	-0.02 (1.29)	(-2.56, 2.52)	0.9877			
Week 24		5.56 (1.08)		4.81 (1.09)	0.75 (1.48)	(-2.17, 3.67)	0.6111			
Week 36		8.25 (1.10)		5.78 (1.15)	2.46 (1.54)	(-0.57, 5.50)	0.1111			
Week 52		7.70 (1.05)		6.45 (1.12)	1.26 (1.48)	(-1.67, 4.18)	0.3977			
OVERALL	99	5.86 (0.82)	102	4.74 (0.82)	1.12 (1.09)	(-1.03, 3.28)	0.3041	0.14 (0.14)	(-0.14, 0.41)	0.3352

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Bodily Pain Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.6748
< 10 points	39	5.69 (1.19)	40	5.19 (1.17)	0.50 (1.63)	(-2.75, 3.76)	0.7590	0.07 (0.23)	(-0.37, 0.51)	0.7653	
>= 10 points	60	5.89 (1.14)	62	4.47 (1.19)	1.42 (1.47)	(-1.48, 4.33)	0.3335	0.15 (0.18)	(-0.20, 0.51)	0.3930	
OCS dose											0.6794
<10 mg/day	44	4.56 (1.29)	38	3.99 (1.37)	0.58 (1.85)	(-3.11, 4.27)	0.7563	0.07 (0.22)	(-0.37, 0.50)	0.7618	
>=10 mg/day	55	7.19 (1.09)	64	5.66 (1.07)	1.53 (1.37)	(-1.19, 4.25)	0.2666	0.18 (0.18)	(-0.18, 0.54)	0.3223	
Result of type I IFN gene signature test											0.8364
LOW	24	3.80 (1.69)	26	3.10 (1.65)	0.70 (2.35)	(-4.06, 5.46)	0.7672	0.08 (0.28)	(-0.47, 0.64)	0.7702	
HIGH	75	7.07 (0.87)	76	5.82 (0.91)	1.25 (1.22)	(-1.17, 3.67)	0.3091	0.16 (0.16)	(-0.16, 0.48)	0.3254	
Age (years)											0.7255
<= 45	67	6.51 (0.99)	72	5.58 (0.99)	0.93 (1.26)	(-1.56, 3.43)	0.4618	0.11 (0.17)	(-0.22, 0.45)	0.5095	
> 45	32	3.92 (1.50)	30	2.13 (1.55)	1.79 (2.09)	(-2.40, 5.98)	0.3961	0.21 (0.25)	(-0.29, 0.71)	0.4135	
Sex											0.9735
male	6	7.43 (3.23)	9	6.23 (2.69)	1.20 (3.17)	(-5.75, 8.15)	0.7119	0.14 (0.53)	(-0.89, 1.18)	0.7894	
female	93	5.99 (0.85)	93	4.68 (0.87)	1.31 (1.15)	(-0.95, 3.58)	0.2546	0.16 (0.15)	(-0.13, 0.45)	0.2831	
Race											0.6630
White	35	4.46 (1.28)	41	4.50 (1.18)	-0.05 (1.67)	(-3.38, 3.29)	0.9778	-0.01 (0.23)	(-0.46, 0.44)	0.9788	
Black	19	4.81 (3.07)	12	1.80 (2.88)	3.01 (3.51)	(-4.18, 10.19)	0.3986	0.24 (0.37)	(-0.49, 0.97)	0.5163	
Other	45	7.35 (1.18)	49	5.84 (1.24)	1.51 (1.59)	(-1.65, 4.67)	0.3451	0.18 (0.21)	(-0.23, 0.59)	0.3843	
Ethnicity											0.5011
Hispanic/Latino	46	7.37 (1.21)	42	5.79 (1.35)	1.57 (1.72)	(-1.84, 4.99)	0.3618	0.18 (0.21)	(-0.23, 0.60)	0.3887	
Non-hispanic/Latino	53	4.34 (1.10)	60	4.26 (1.04)	0.09 (1.40)	(-2.69, 2.86)	0.9515	0.01 (0.19)	(-0.36, 0.38)	0.9554	
Geographic region											0.8076
Latin America, Eastern Europe and Asia	62	7.28 (1.05)	74	5.77 (1.06)	1.51 (1.29)	(-1.04, 4.06)	0.2431	0.17 (0.17)	(-0.17, 0.51)	0.3202	
North America	37	4.32 (1.45)	28	3.41 (1.62)	0.91 (2.11)	(-3.32, 5.14)	0.6691	0.10 (0.25)	(-0.39, 0.59)	0.6811	
Baseline weight											0.6568
<60 kg	32	9.00 (1.71)	39	6.75 (1.69)	2.25 (2.20)	(-2.15, 6.65)	0.3105	0.22 (0.24)	(-0.25, 0.69)	0.3605	
>=60 kg	67	4.76 (0.88)	63	3.62 (0.90)	1.14 (1.20)	(-1.24, 3.52)	0.3459	0.16 (0.18)	(-0.19, 0.50)	0.3695	
Low CH50											0.8015
Yes	13	9.31 (2.33)	13	8.98 (3.32)	0.32 (3.78)	(-7.61, 8.26)	0.9331	0.03 (0.39)	(-0.74, 0.80)	0.9389	
No	86	5.62 (0.85)	89	4.31 (0.85)	1.32 (1.15)	(-0.96, 3.59)	0.2562	0.16 (0.15)	(-0.13, 0.46)	0.2779	
Low C3 or C4											0.8994
Yes	33	8.32 (2.00)	47	6.69 (1.71)	1.63 (1.89)	(-2.13, 5.39)	0.3901	0.14 (0.23)	(-0.31, 0.58)	0.5423	
No	66	5.04 (0.93)	55	3.71 (1.04)	1.34 (1.37)	(-1.39, 4.06)	0.3334	0.17 (0.18)	(-0.18, 0.53)	0.3419	
Baseline FARR anti-dsDNA											0.0046
<5 IU/mL	21	7.35 (1.41)	16	0.72 (1.57)	6.63 (2.17)	(2.21, 11.05)	0.0046	1.01 (0.35)	(0.32, 1.71)	0.0042	
>=5 IU/mL	56	4.82 (1.14)	66	5.51 (1.09)	-0.69 (1.40)	(-3.47, 2.08)	0.6215	-0.08 (0.18)	(-0.44, 0.28)	0.6630	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.2215
Yes	70	5.24 (1.03)	81	5.14 (0.97)	0.10 (1.24)	(-2.35, 2.55)	0.9358	0.01 (0.16)	(-0.31, 0.33)	0.9441	
No	29	7.71 (1.54)	21	4.26 (1.89)	3.45 (2.45)	(-1.47, 8.37)	0.1651	0.40 (0.29)	(-0.17, 0.97)	0.1654	
OCS use											0.8780
Yes	79	6.34 (0.90)	88	5.08 (0.90)	1.26 (1.15)	(-1.01, 3.53)	0.2738	0.15 (0.16)	(-0.15, 0.46)	0.3249	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Bodily Pain Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) N	LSMean (SE)	Placebo (N=102) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
No	20	3.75 (2.26)	14	1.94 (2.51)	1.81 (3.36)	(-5.05, 8.66)	0.5944	0.18 (0.35)	(-0.51, 0.86)	0.6079	
SLICC score											0.2397
0	62	6.08 (1.04)	66	3.90 (1.07)	2.18 (1.41)	(-0.61, 4.97)	0.1241	0.26 (0.18)	(-0.09, 0.61)	0.1469	
>=1	37	5.97 (1.35)	36	6.45 (1.33)	-0.48 (1.77)	(-4.02, 3.06)	0.7876	-0.06 (0.23)	(-0.52, 0.40)	0.8019	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Vitality Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		1.85 (0.64)		1.29 (0.63)	0.56 (0.83)	(-1.07, 2.20)	0.4994			
Week 12		3.50 (0.85)		2.99 (0.84)	0.51 (1.14)	(-1.74, 2.77)	0.6533			
Week 24		3.69 (0.83)		3.31 (0.84)	0.37 (1.14)	(-1.87, 2.61)	0.7441			
Week 36		5.34 (0.95)		3.76 (0.99)	1.57 (1.33)	(-1.06, 4.21)	0.2395			
Week 52		5.47 (0.97)		3.85 (1.04)	1.62 (1.38)	(-1.11, 4.34)	0.2429			
OVERALL	99	3.97 (0.71)	102	3.04 (0.71)	0.93 (0.94)	(-0.94, 2.79)	0.3273	0.13 (0.14)	(-0.15, 0.41)	0.3563

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Vitality Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) N	LSMean (SE)	Placebo (N=102) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.4907
< 10 points	39	4.17 (1.11)	40	4.02 (1.08)	0.15 (1.52)	(-2.88, 3.18)	0.9203	0.02 (0.23)	(-0.42, 0.46)	0.9222	
>= 10 points	60	3.43 (0.94)	62	1.94 (0.98)	1.49 (1.21)	(-0.90, 3.88)	0.2191	0.20 (0.18)	(-0.16, 0.55)	0.2772	
OCS dose											0.7609
<10 mg/day	44	3.38 (0.99)	38	2.68 (1.05)	0.70 (1.42)	(-2.13, 3.52)	0.6262	0.11 (0.22)	(-0.33, 0.54)	0.6336	
>=10 mg/day	55	4.40 (1.02)	64	3.13 (1.00)	1.27 (1.26)	(-1.22, 3.77)	0.3143	0.16 (0.18)	(-0.20, 0.52)	0.3790	
Result of type I IFN gene signature test											0.1818
LOW	24	2.64 (1.27)	26	3.78 (1.24)	-1.13 (1.76)	(-4.69, 2.42)	0.5237	-0.18 (0.28)	(-0.73, 0.38)	0.5297	
HIGH	75	4.60 (0.79)	76	2.95 (0.83)	1.65 (1.11)	(-0.55, 3.85)	0.1407	0.23 (0.16)	(-0.09, 0.55)	0.1524	
Age (years)											0.6260
<= 45	67	5.11 (0.87)	72	3.83 (0.86)	1.28 (1.13)	(-0.95, 3.51)	0.2590	0.18 (0.17)	(-0.16, 0.51)	0.2994	
> 45	32	1.99 (1.25)	30	1.72 (1.30)	0.27 (1.74)	(-3.21, 3.75)	0.8771	0.04 (0.25)	(-0.46, 0.54)	0.8830	
Sex											0.7002
male	6	7.42 (4.04)	9	5.11 (3.16)	2.31 (3.43)	(-5.13, 9.76)	0.5123	0.23 (0.53)	(-0.81, 1.26)	0.6695	
female	93	4.07 (0.73)	93	3.13 (0.75)	0.94 (0.99)	(-1.02, 2.90)	0.3452	0.13 (0.15)	(-0.16, 0.42)	0.3716	
Race											0.0347
White	35	1.53 (0.93)	41	2.65 (0.86)	-1.11 (1.22)	(-3.55, 1.33)	0.3655	-0.20 (0.23)	(-0.65, 0.25)	0.3847	
Black	19	5.63 (1.92)	12	0.22 (1.83)	5.41 (2.20)	(0.89, 9.93)	0.0208	0.69 (0.38)	(-0.06, 1.43)	0.0710	
Other	45	5.51 (1.10)	49	4.82 (1.13)	0.69 (1.48)	(-2.25, 3.63)	0.6429	0.09 (0.21)	(-0.32, 0.49)	0.6677	
Ethnicity											0.6393
Hispanic/Latino	46	4.94 (1.12)	42	4.83 (1.22)	0.11 (1.56)	(-2.98, 3.21)	0.9424	0.01 (0.21)	(-0.40, 0.43)	0.9462	
Non-hispanic/Latino	53	2.76 (0.84)	60	1.75 (0.80)	1.00 (1.09)	(-1.16, 3.17)	0.3604	0.16 (0.19)	(-0.21, 0.53)	0.3914	
Geographic region											0.5129
Latin America, Eastern Europe and Asia	62	4.51 (1.00)	74	4.10 (1.00)	0.41 (1.23)	(-2.02, 2.84)	0.7408	0.05 (0.17)	(-0.29, 0.39)	0.7767	
North America	37	3.53 (0.90)	28	1.94 (1.01)	1.59 (1.32)	(-1.05, 4.22)	0.2332	0.29 (0.25)	(-0.20, 0.78)	0.2511	
Baseline weight											0.9532
<60 kg	32	5.33 (1.42)	39	4.13 (1.43)	1.20 (1.83)	(-2.45, 4.85)	0.5138	0.14 (0.24)	(-0.33, 0.61)	0.5615	
>=60 kg	67	3.56 (0.79)	63	2.48 (0.80)	1.08 (1.09)	(-1.08, 3.23)	0.3256	0.17 (0.18)	(-0.18, 0.51)	0.3446	
Low CH50											0.2824
Yes	13	5.11 (1.54)	13	1.19 (2.27)	3.92 (2.60)	(-1.53, 9.37)	0.1479	0.54 (0.40)	(-0.24, 1.33)	0.1752	
No	86	3.92 (0.75)	89	3.00 (0.75)	0.92 (1.02)	(-1.08, 2.93)	0.3644	0.13 (0.15)	(-0.16, 0.43)	0.3839	
Low C3 or C4											0.8045
Yes	33	5.57 (1.74)	47	4.73 (1.51)	0.84 (1.50)	(-2.16, 3.84)	0.5802	0.08 (0.23)	(-0.36, 0.53)	0.7217	
No	66	3.58 (0.85)	55	2.26 (0.94)	1.32 (1.25)	(-1.15, 3.79)	0.2925	0.19 (0.18)	(-0.17, 0.55)	0.3006	
Baseline FARR anti-dsDNA											0.1182
<5 IU/mL	21	5.03 (1.15)	16	1.87 (1.31)	3.16 (1.76)	(-0.42, 6.74)	0.0819	0.59 (0.34)	(-0.08, 1.25)	0.0837	
>=5 IU/mL	56	2.54 (0.94)	66	2.67 (0.89)	-0.13 (1.16)	(-2.42, 2.16)	0.9097	-0.02 (0.18)	(-0.37, 0.34)	0.9201	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.6966
Yes	70	3.17 (0.87)	81	2.67 (0.82)	0.50 (1.05)	(-1.57, 2.57)	0.6364	0.07 (0.16)	(-0.25, 0.39)	0.6807	
No	29	6.12 (1.33)	21	4.72 (1.62)	1.40 (2.08)	(-2.78, 5.59)	0.5030	0.19 (0.29)	(-0.37, 0.75)	0.5077	
OCS use											0.9233
Yes	79	4.22 (0.84)	88	3.20 (0.83)	1.02 (1.07)	(-1.09, 3.12)	0.3413	0.13 (0.16)	(-0.17, 0.44)	0.3929	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Vitality Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) N	LSMean (SE)	Placebo (N=102) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
No	20	2.87 (1.21)	14	1.65 (1.36)	1.22 (1.80)	(-2.47, 4.91)	0.5040	0.22 (0.35)	(-0.46, 0.91)	0.5203	
SLICC score											0.9891
0	62	4.65 (0.85)	66	3.96 (0.88)	0.69 (1.17)	(-1.63, 3.01)	0.5566	0.10 (0.18)	(-0.25, 0.45)	0.5770	
>=1	37	2.70 (1.24)	36	1.99 (1.18)	0.72 (1.59)	(-2.46, 3.90)	0.6542	0.10 (0.23)	(-0.36, 0.56)	0.6790	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - FACIT-F Total Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		2.62 (0.83)		0.62 (0.82)	2.01 (1.08)	(-0.13, 4.14)	0.0649			
Week 12		4.32 (0.96)		3.02 (0.95)	1.31 (1.28)	(-1.22, 3.83)	0.3090			
Week 24		4.84 (1.09)		3.63 (1.10)	1.21 (1.49)	(-1.72, 4.15)	0.4159			
Week 36		6.31 (1.14)		4.41 (1.19)	1.90 (1.59)	(-1.23, 5.03)	0.2319			
Week 52		5.70 (1.13)		4.77 (1.20)	0.92 (1.59)	(-2.22, 4.06)	0.5622			
OVERALL	99	4.76 (0.86)	102	3.29 (0.87)	1.47 (1.15)	(-0.79, 3.73)	0.2007	0.17 (0.14)	(-0.11, 0.45)	0.2328

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - FACIT-F Total Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) N	LSMean (SE)	Placebo (N=102) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.9035
< 10 points	39	5.15 (1.26)	40	3.84 (1.23)	1.32 (1.72)	(-2.12, 4.75)	0.4468	0.17 (0.23)	(-0.28, 0.61)	0.4607	
>= 10 points	60	3.88 (1.18)	62	2.29 (1.23)	1.59 (1.49)	(-1.36, 4.55)	0.2872	0.17 (0.18)	(-0.19, 0.52)	0.3529	
OCS dose											0.2485
<10 mg/day	44	4.56 (1.20)	38	1.18 (1.27)	3.37 (1.72)	(-0.06, 6.80)	0.0538	0.42 (0.22)	(-0.02, 0.86)	0.0598	
>=10 mg/day	55	5.28 (1.21)	64	4.55 (1.19)	0.73 (1.51)	(-2.26, 3.72)	0.6305	0.08 (0.18)	(-0.28, 0.44)	0.6724	
Result of type I IFN gene signature test											0.7922
LOW	24	3.77 (1.57)	26	2.77 (1.55)	1.00 (2.19)	(-3.43, 5.43)	0.6508	0.13 (0.28)	(-0.43, 0.68)	0.6557	
HIGH	75	5.10 (0.93)	76	3.43 (0.97)	1.67 (1.30)	(-0.89, 4.24)	0.1996	0.20 (0.16)	(-0.12, 0.52)	0.2158	
Age (years)											0.6166
<= 45	67	5.33 (1.05)	72	3.37 (1.04)	1.96 (1.33)	(-0.67, 4.59)	0.1427	0.22 (0.17)	(-0.11, 0.56)	0.1887	
> 45	32	3.12 (1.64)	30	2.46 (1.68)	0.65 (2.25)	(-3.85, 5.16)	0.7720	0.07 (0.25)	(-0.43, 0.57)	0.7832	
Sex											0.3540
male	6	6.10 (2.61)	9	6.87 (2.09)	-0.77 (2.45)	(-6.30, 4.77)	0.7615	-0.11 (0.53)	(-1.15, 0.92)	0.8282	
female	93	5.08 (0.90)	93	3.31 (0.92)	1.77 (1.21)	(-0.62, 4.16)	0.1457	0.20 (0.15)	(-0.09, 0.49)	0.1715	
Race											0.6922
White	35	4.92 (1.28)	41	2.87 (1.18)	2.05 (1.67)	(-1.28, 5.38)	0.2227	0.27 (0.23)	(-0.18, 0.72)	0.2450	
Black	19	4.93 (2.85)	12	1.19 (2.70)	3.73 (3.29)	(-2.99, 10.46)	0.2660	0.32 (0.37)	(-0.41, 1.05)	0.3890	
Other	45	5.47 (1.32)	49	4.73 (1.36)	0.74 (1.73)	(-2.71, 4.18)	0.6726	0.08 (0.21)	(-0.33, 0.48)	0.7017	
Ethnicity											0.2543
Hispanic/Latino	46	5.61 (1.30)	42	5.61 (1.44)	-0.00 (1.80)	(-3.59, 3.59)	0.9995	-0.00 (0.21)	(-0.42, 0.42)	0.9996	
Non-hispanic/Latino	53	4.36 (1.14)	60	1.73 (1.06)	2.63 (1.44)	(-0.23, 5.50)	0.0711	0.32 (0.19)	(-0.05, 0.69)	0.0945	
Geographic region											0.5877
Latin America, Eastern Europe and Asia	62	6.17 (1.14)	74	4.86 (1.15)	1.30 (1.38)	(-1.44, 4.04)	0.3483	0.14 (0.17)	(-0.20, 0.47)	0.4290	
North America	37	4.01 (1.29)	28	1.44 (1.44)	2.56 (1.87)	(-1.18, 6.30)	0.1753	0.33 (0.25)	(-0.17, 0.82)	0.1946	
Baseline weight											0.9730
<60 kg	32	7.40 (1.90)	39	5.42 (1.90)	1.98 (2.44)	(-2.91, 6.86)	0.4216	0.17 (0.24)	(-0.30, 0.64)	0.4718	
>=60 kg	67	4.01 (0.87)	63	2.13 (0.88)	1.89 (1.18)	(-0.45, 4.22)	0.1122	0.26 (0.18)	(-0.08, 0.61)	0.1330	
Low CH50											0.2750
Yes	13	5.10 (2.41)	13	-0.89 (3.80)	5.98 (4.12)	(-2.56, 14.52)	0.1605	0.51 (0.40)	(-0.28, 1.29)	0.2062	
No	86	4.71 (0.89)	89	3.41 (0.90)	1.29 (1.21)	(-1.10, 3.68)	0.2871	0.15 (0.15)	(-0.14, 0.45)	0.3101	
Low C3 or C4											0.9697
Yes	33	5.30 (2.24)	47	3.49 (1.93)	1.80 (1.97)	(-2.13, 5.74)	0.3633	0.14 (0.23)	(-0.31, 0.58)	0.5480	
No	66	4.40 (0.98)	55	2.51 (1.09)	1.90 (1.43)	(-0.95, 4.74)	0.1889	0.24 (0.18)	(-0.12, 0.59)	0.1992	
Baseline FARR anti-dsDNA											0.5394
<5 IU/mL	21	5.00 (1.36)	16	2.17 (1.56)	2.83 (2.09)	(-1.48, 7.13)	0.1885	0.44 (0.34)	(-0.22, 1.10)	0.1879	
>=5 IU/mL	56	4.27 (1.25)	66	3.04 (1.18)	1.24 (1.53)	(-1.79, 4.27)	0.4207	0.13 (0.18)	(-0.23, 0.49)	0.4773	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.8446
Yes	70	4.10 (1.10)	81	2.83 (1.04)	1.27 (1.31)	(-1.31, 3.85)	0.3319	0.14 (0.16)	(-0.18, 0.46)	0.4034	
No	29	6.43 (1.62)	21	4.60 (2.00)	1.83 (2.54)	(-3.30, 6.96)	0.4752	0.20 (0.29)	(-0.36, 0.77)	0.4817	
OCS use											0.4293
Yes	79	4.59 (1.00)	88	3.05 (0.99)	1.54 (1.26)	(-0.96, 4.04)	0.2250	0.17 (0.16)	(-0.14, 0.47)	0.2788	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - FACIT-F Total Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) N	LSMean (SE)	Placebo (N=102) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
No	20	5.15 (1.67)	14	1.42 (1.83)	3.73 (2.46)	(-1.32, 8.77)	0.1415	0.50 (0.35)	(-0.19, 1.20)	0.1561	
SLICC score											0.9213
0	62	4.52 (1.02)	66	2.89 (1.06)	1.63 (1.38)	(-1.11, 4.37)	0.2402	0.19 (0.18)	(-0.15, 0.54)	0.2726	
>=1	37	5.23 (1.64)	36	3.85 (1.60)	1.38 (2.14)	(-2.88, 5.64)	0.5197	0.14 (0.23)	(-0.32, 0.60)	0.5513	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - EQ VAS Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		6.64 (1.85)		5.41 (1.84)	1.23 (2.46)	(-3.62, 6.08)	0.6177			
Week 12		9.04 (2.07)		8.16 (2.05)	0.88 (2.77)	(-4.59, 6.36)	0.7502			
Week 24		10.87 (2.25)		7.38 (2.27)	3.49 (3.07)	(-2.56, 9.54)	0.2564			
Week 36		12.55 (2.35)		9.13 (2.46)	3.42 (3.28)	(-3.06, 9.89)	0.2994			
Week 52		14.81 (2.31)		12.03 (2.45)	2.79 (3.25)	(-3.62, 9.19)	0.3920			
OVERALL	98	10.78 (1.77)	102	8.42 (1.79)	2.36 (2.35)	(-2.28, 7.00)	0.3170	0.13 (0.14)	(-0.15, 0.41)	0.3508

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - EQ VAS Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.4070
< 10 points	38	10.34 (2.38)	40	10.23 (2.31)	0.11 (3.24)	(-6.34, 6.57)	0.9719	0.01 (0.23)	(-0.44, 0.45)	0.9728	
>= 10 points	60	9.87 (2.49)	62	6.01 (2.61)	3.86 (3.15)	(-2.38, 10.10)	0.2230	0.19 (0.18)	(-0.16, 0.55)	0.2894	
OCS dose											0.5587
<10 mg/day	44	8.58 (2.56)	38	4.30 (2.75)	4.28 (3.68)	(-3.05, 11.61)	0.2483	0.25 (0.22)	(-0.19, 0.69)	0.2613	
>=10 mg/day	54	12.28 (2.51)	64	10.81 (2.50)	1.48 (3.08)	(-4.63, 7.58)	0.6327	0.08 (0.18)	(-0.29, 0.44)	0.6811	
Result of type I IFN gene signature test											0.4185
LOW	24	3.28 (3.34)	26	3.94 (3.29)	-0.66 (4.68)	(-10.13, 8.81)	0.8887	-0.04 (0.28)	(-0.59, 0.52)	0.8901	
HIGH	74	13.23 (1.88)	76	9.55 (1.96)	3.69 (2.63)	(-1.51, 8.88)	0.1629	0.22 (0.16)	(-0.10, 0.54)	0.1783	
Age (years)											0.5152
<= 45	66	12.16 (2.20)	72	8.50 (2.18)	3.66 (2.77)	(-1.82, 9.14)	0.1889	0.20 (0.17)	(-0.13, 0.53)	0.2420	
> 45	32	5.53 (3.11)	30	5.23 (3.27)	0.30 (4.36)	(-8.43, 9.03)	0.9456	0.02 (0.25)	(-0.48, 0.51)	0.9479	
Sex											0.5367
male	6	18.59 (10.54)	9	21.25 (9.12)	-2.67 (8.54)	(-22.44, 17.11)	0.7631	-0.09 (0.53)	(-1.13, 0.94)	0.8589	
female	92	11.23 (1.82)	93	8.41 (1.86)	2.82 (2.45)	(-2.01, 7.65)	0.2501	0.16 (0.15)	(-0.13, 0.45)	0.2802	
Race											0.5533
White	35	6.52 (2.86)	41	6.32 (2.62)	0.20 (3.73)	(-7.24, 7.63)	0.9580	0.01 (0.23)	(-0.44, 0.46)	0.9599	
Black	19	11.69 (5.67)	12	3.56 (5.01)	8.13 (6.27)	(-4.74, 20.99)	0.2059	0.36 (0.37)	(-0.37, 1.09)	0.3376	
Other	44	15.70 (2.48)	49	13.63 (2.61)	2.07 (3.29)	(-4.49, 8.63)	0.5309	0.12 (0.21)	(-0.29, 0.53)	0.5703	
Ethnicity											0.8573
Hispanic/Latino	45	13.26 (2.60)	42	10.81 (2.91)	2.45 (3.67)	(-4.87, 9.76)	0.5073	0.13 (0.21)	(-0.29, 0.55)	0.5339	
Non-hispanic/Latino	53	8.14 (2.31)	60	6.53 (2.18)	1.60 (2.93)	(-4.20, 7.41)	0.5853	0.09 (0.19)	(-0.28, 0.46)	0.6165	
Geographic region											0.9561
Latin America, Eastern Europe and Asia	61	16.18 (2.40)	74	13.82 (2.46)	2.36 (2.88)	(-3.34, 8.06)	0.4146	0.12 (0.17)	(-0.22, 0.46)	0.5002	
North America	37	2.10 (2.52)	28	-0.00 (2.83)	2.10 (3.70)	(-5.31, 9.51)	0.5730	0.14 (0.25)	(-0.35, 0.63)	0.5856	
Baseline weight											0.8197
<60 kg	32	16.79 (3.65)	39	13.20 (3.63)	3.59 (4.69)	(-5.78, 12.97)	0.4467	0.16 (0.24)	(-0.31, 0.63)	0.4953	
>=60 kg	66	8.36 (1.96)	63	6.00 (1.99)	2.36 (2.65)	(-2.89, 7.61)	0.3746	0.15 (0.18)	(-0.20, 0.49)	0.4013	
Low CH50											0.3550
Yes	13	13.21 (5.16)	13	2.24 (8.70)	10.97 (9.32)	(-8.45, 30.39)	0.2528	0.41 (0.40)	(-0.37, 1.19)	0.2996	
No	85	10.72 (1.83)	89	8.67 (1.84)	2.05 (2.49)	(-2.86, 6.96)	0.4116	0.12 (0.15)	(-0.18, 0.42)	0.4330	
Low C3 or C4											0.2951
Yes	33	16.41 (4.74)	47	10.44 (4.07)	5.97 (3.87)	(-1.75, 13.70)	0.1277	0.21 (0.23)	(-0.23, 0.66)	0.3471	
No	65	8.07 (2.03)	55	7.23 (2.26)	0.85 (2.99)	(-5.08, 6.77)	0.7774	0.05 (0.18)	(-0.31, 0.41)	0.7809	
Baseline FARR anti-dsDNA											0.9742
<5 IU/mL	21	7.10 (3.10)	16	5.38 (3.50)	1.72 (4.75)	(-7.97, 11.41)	0.7192	0.12 (0.33)	(-0.53, 0.77)	0.7192	
>=5 IU/mL	56	9.24 (2.50)	66	7.34 (2.41)	1.91 (3.07)	(-4.18, 7.99)	0.5366	0.10 (0.18)	(-0.26, 0.46)	0.5868	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.6279
Yes	70	10.52 (2.34)	81	7.31 (2.24)	3.21 (2.78)	(-2.28, 8.70)	0.2493	0.16 (0.16)	(-0.16, 0.48)	0.3258	
No	28	12.35 (2.99)	21	11.79 (3.66)	0.56 (4.71)	(-8.93, 10.05)	0.9056	0.03 (0.29)	(-0.53, 0.60)	0.9061	
OCS use											0.3085
Yes	78	11.42 (2.08)	88	9.88 (2.09)	1.54 (2.62)	(-3.64, 6.71)	0.5586	0.08 (0.16)	(-0.22, 0.39)	0.6054	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - EQ VAS Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) N	LSMean (SE)	Placebo (N=102) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
No	20	6.67 (3.96)	14	-1.29 (4.32)	7.96 (5.74)	(-3.81, 19.74)	0.1766	0.45 (0.35)	(-0.24, 1.15)	0.1984	
SLICC score											0.6945
0	62	12.70 (2.19)	66	9.80 (2.27)	2.90 (2.97)	(-2.98, 8.79)	0.3304	0.16 (0.18)	(-0.19, 0.51)	0.3619	
>=1	36	7.45 (3.06)	36	6.49 (2.96)	0.96 (3.96)	(-6.94, 8.86)	0.8090	0.05 (0.24)	(-0.41, 0.51)	0.8233	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Lupus QoL Physical Health domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		5.31 (1.69)		3.60 (1.69)	1.71 (2.22)	(-2.66, 6.08)	0.4418			
Week 12		9.51 (2.24)		8.04 (2.23)	1.47 (3.02)	(-4.48, 7.43)	0.6262			
Week 24		10.37 (2.29)		7.69 (2.32)	2.68 (3.13)	(-3.49, 8.86)	0.3927			
Week 36		13.33 (2.39)		10.39 (2.48)	2.94 (3.32)	(-3.61, 9.50)	0.3771			
Week 52		11.51 (2.44)		9.98 (2.57)	1.53 (3.43)	(-5.23, 8.29)	0.6554			
OVERALL	98	10.01 (1.92)	100	7.94 (1.94)	2.07 (2.57)	(-3.00, 7.13)	0.4215	0.11 (0.14)	(-0.17, 0.39)	0.4500

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Lupus QoL Physical Health domain score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.8112
< 10 points	39	11.79 (2.63)	39	10.36 (2.61)	1.43 (3.62)	(-5.80, 8.66)	0.6942	0.09 (0.23)	(-0.36, 0.53)	0.7026	
>= 10 points	59	7.68 (2.68)	61	5.06 (2.79)	2.62 (3.44)	(-4.20, 9.45)	0.4478	0.12 (0.18)	(-0.24, 0.48)	0.5010	
OCS dose											0.5365
<10 mg/day	44	9.11 (2.84)	37	4.06 (3.05)	5.06 (4.10)	(-3.11, 13.22)	0.2212	0.27 (0.22)	(-0.17, 0.71)	0.2324	
>=10 mg/day	54	11.06 (2.60)	63	9.23 (2.55)	1.83 (3.24)	(-4.60, 8.25)	0.5743	0.09 (0.19)	(-0.27, 0.46)	0.6197	
Result of type I IFN gene signature test											0.3619
LOW	24	7.21 (3.94)	25	9.28 (3.90)	-2.08 (5.55)	(-13.30, 9.15)	0.7104	-0.11 (0.29)	(-0.67, 0.46)	0.7128	
HIGH	74	10.68 (2.01)	75	7.07 (2.09)	3.60 (2.82)	(-1.98, 9.18)	0.2039	0.20 (0.16)	(-0.12, 0.52)	0.2187	
Age (years)											0.2593
<= 45	66	11.70 (2.31)	70	7.32 (2.32)	4.38 (2.96)	(-1.48, 10.25)	0.1417	0.23 (0.17)	(-0.11, 0.57)	0.1853	
> 45	32	5.81 (3.75)	30	8.18 (3.85)	-2.37 (5.20)	(-12.82, 8.08)	0.6505	-0.11 (0.25)	(-0.61, 0.39)	0.6633	
Sex											0.4916
male	6	16.45 (10.00)	9	20.02 (8.39)	-3.57 (8.91)	(-24.18, 17.04)	0.6991	-0.13 (0.53)	(-1.17, 0.90)	0.7982	
female	92	10.45 (2.00)	91	7.61 (2.06)	2.84 (2.73)	(-2.55, 8.23)	0.3001	0.15 (0.15)	(-0.14, 0.44)	0.3262	
Race											0.8628
White	35	8.60 (2.39)	40	4.91 (2.23)	3.69 (3.14)	(-2.58, 9.96)	0.2442	0.26 (0.23)	(-0.20, 0.71)	0.2653	
Black	19	8.85 (6.70)	11	3.80 (6.97)	5.05 (8.37)	(-12.16, 22.26)	0.5515	0.18 (0.38)	(-0.56, 0.92)	0.6343	
Other	44	13.74 (3.04)	49	12.48 (3.09)	1.27 (4.01)	(-6.71, 9.24)	0.7527	0.06 (0.21)	(-0.35, 0.47)	0.7728	
Ethnicity											0.2879
Hispanic/Latino	45	11.88 (3.12)	42	12.58 (3.38)	-0.70 (4.33)	(-9.33, 7.93)	0.8728	-0.03 (0.21)	(-0.45, 0.39)	0.8806	
Non-hispanic/Latino	53	9.12 (2.24)	58	4.28 (2.15)	4.85 (2.90)	(-0.91, 10.60)	0.0980	0.29 (0.19)	(-0.08, 0.67)	0.1234	
Geographic region											0.3599
Latin America, Eastern Europe and Asia	61	14.01 (2.41)	74	12.27 (2.42)	1.75 (2.92)	(-4.03, 7.52)	0.5499	0.09 (0.17)	(-0.25, 0.43)	0.6146	
North America	37	5.73 (2.75)	26	-0.65 (3.19)	6.38 (4.13)	(-1.90, 14.66)	0.1282	0.38 (0.26)	(-0.13, 0.89)	0.1403	
Baseline weight											0.8994
<60 kg	32	15.51 (3.96)	39	11.97 (3.92)	3.54 (5.11)	(-6.67, 13.76)	0.4904	0.15 (0.24)	(-0.32, 0.62)	0.5332	
>=60 kg	66	8.48 (2.02)	61	5.67 (2.07)	2.81 (2.75)	(-2.63, 8.25)	0.3082	0.17 (0.18)	(-0.18, 0.52)	0.3350	
Low CH50											0.5253
Yes	12	9.60 (6.00)	13	0.54 (7.91)	9.06 (9.57)	(-10.84, 28.96)	0.3545	0.35 (0.40)	(-0.44, 1.14)	0.3878	
No	86	10.18 (1.95)	87	7.42 (1.97)	2.75 (2.65)	(-2.49, 7.99)	0.3011	0.15 (0.15)	(-0.15, 0.45)	0.3237	
Low C3 or C4											0.7984
Yes	32	8.73 (4.98)	46	7.41 (4.23)	1.32 (4.62)	(-7.90, 10.55)	0.7757	0.05 (0.23)	(-0.41, 0.50)	0.8420	
No	66	9.88 (2.18)	54	7.13 (2.45)	2.76 (3.22)	(-3.61, 9.13)	0.3931	0.15 (0.18)	(-0.21, 0.51)	0.4039	
Baseline FARR anti-dsDNA											0.2122
<5 IU/mL	21	11.21 (3.18)	14	3.44 (3.79)	7.76 (5.02)	(-2.48, 18.01)	0.1322	0.53 (0.35)	(-0.16, 1.21)	0.1346	
>=5 IU/mL	55	8.47 (2.55)	66	8.09 (2.41)	0.38 (3.15)	(-5.85, 6.61)	0.9042	0.02 (0.18)	(-0.34, 0.38)	0.9146	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.9525
Yes	69	8.28 (2.33)	80	6.82 (2.20)	1.46 (2.81)	(-4.10, 7.02)	0.6044	0.07 (0.16)	(-0.25, 0.40)	0.6509	
No	29	13.61 (3.89)	20	11.75 (4.82)	1.86 (6.14)	(-10.55, 14.27)	0.7633	0.09 (0.29)	(-0.48, 0.66)	0.7663	
OCS use											0.3239
Yes	78	10.91 (2.19)	87	7.01 (2.19)	3.90 (2.81)	(-1.64, 9.45)	0.1660	0.20 (0.16)	(-0.11, 0.50)	0.2121	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Lupus QoL Physical Health domain score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) N	LSMean (SE)	Placebo (N=102) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
No	20	5.48 (3.44)	13	7.35 (3.92)	-1.87 (5.14)	(-12.64, 8.89)	0.7198	-0.12 (0.36)	(-0.82, 0.58)	0.7312	
SLICC score											0.8809
0	61	9.22 (2.49)	65	7.88 (2.58)	1.34 (3.38)	(-5.36, 8.04)	0.6924	0.07 (0.18)	(-0.28, 0.42)	0.7104	
>=1	37	10.95 (3.15)	35	8.80 (3.14)	2.15 (4.24)	(-6.31, 10.62)	0.6129	0.11 (0.24)	(-0.35, 0.58)	0.6326	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Lupus QoL Emotional Health domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		2.87 (1.81)		5.65 (1.81)	-2.77 (2.41)	(-7.54, 1.99)	0.2517			
Week 12		7.77 (2.04)		8.72 (2.02)	-0.95 (2.73)	(-6.34, 4.44)	0.7289			
Week 24		9.75 (2.12)		8.07 (2.16)	1.68 (2.90)	(-4.05, 7.41)	0.5636			
Week 36		12.55 (2.27)		9.38 (2.38)	3.16 (3.17)	(-3.09, 9.42)	0.3198			
Week 52		12.03 (2.22)		12.21 (2.39)	-0.19 (3.14)	(-6.40, 6.02)	0.9527			
OVERALL	98	8.99 (1.68)	100	8.81 (1.70)	0.19 (2.22)	(-4.20, 4.58)	0.9333	0.01 (0.14)	(-0.27, 0.29)	0.9380

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Lupus QoL Emotional Health domain score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.7498
< 10 points	39	11.19 (2.11)	39	11.58 (2.10)	-0.39 (2.92)	(-6.23, 5.44)	0.8935	-0.03 (0.23)	(-0.47, 0.41)	0.8962	
>= 10 points	59	6.39 (2.53)	61	5.41 (2.63)	0.98 (3.17)	(-5.29, 7.26)	0.7572	0.05 (0.18)	(-0.31, 0.41)	0.7896	
OCS dose											0.3489
<10 mg/day	44	6.85 (2.39)	37	9.05 (2.59)	-2.20 (3.45)	(-9.07, 4.66)	0.5245	-0.14 (0.22)	(-0.58, 0.30)	0.5361	
>=10 mg/day	54	10.29 (2.39)	63	8.28 (2.36)	2.01 (2.90)	(-3.73, 7.76)	0.4885	0.11 (0.19)	(-0.25, 0.47)	0.5535	
Result of type I IFN gene signature test											0.3373
LOW	24	4.40 (2.97)	25	7.61 (2.95)	-3.20 (4.18)	(-11.63, 5.22)	0.4472	-0.22 (0.29)	(-0.78, 0.35)	0.4527	
HIGH	74	11.05 (1.84)	75	9.54 (1.93)	1.50 (2.57)	(-3.59, 6.59)	0.5600	0.09 (0.16)	(-0.23, 0.41)	0.5743	
Age (years)											0.1801
<= 45	66	12.08 (2.08)	70	9.81 (2.09)	2.27 (2.62)	(-2.91, 7.46)	0.3873	0.13 (0.17)	(-0.21, 0.47)	0.4438	
> 45	32	2.93 (3.01)	30	7.26 (3.13)	-4.33 (4.17)	(-12.69, 4.03)	0.3039	-0.25 (0.26)	(-0.75, 0.25)	0.3264	
Sex											0.6308
male	6	2.62 (11.01)	9	6.57 (8.43)	-3.96 (8.74)	(-25.30, 17.38)	0.6666	-0.14 (0.53)	(-1.18, 0.89)	0.7857	
female	92	9.64 (1.77)	91	9.24 (1.82)	0.40 (2.38)	(-4.30, 5.10)	0.8673	0.02 (0.15)	(-0.27, 0.31)	0.8756	
Race											0.9428
White	35	6.65 (2.15)	40	5.60 (2.02)	1.05 (2.83)	(-4.59, 6.70)	0.7112	0.08 (0.23)	(-0.37, 0.54)	0.7245	
Black	19	8.47 (5.56)	11	6.86 (5.02)	1.61 (6.41)	(-11.56, 14.77)	0.8038	0.07 (0.38)	(-0.67, 0.81)	0.8500	
Other	44	11.74 (2.97)	49	12.15 (3.05)	-0.42 (3.89)	(-8.15, 7.32)	0.9149	-0.02 (0.21)	(-0.43, 0.39)	0.9230	
Ethnicity											0.7211
Hispanic/Latino	45	11.14 (2.93)	42	11.55 (3.19)	-0.41 (4.03)	(-8.45, 7.62)	0.9184	-0.02 (0.21)	(-0.44, 0.40)	0.9243	
Non-hispanic/Latino	53	7.45 (1.90)	58	6.18 (1.83)	1.27 (2.44)	(-3.58, 6.12)	0.6046	0.09 (0.19)	(-0.28, 0.46)	0.6339	
Geographic region											0.5363
Latin America, Eastern Europe and Asia	61	10.03 (2.41)	74	10.29 (2.44)	-0.26 (2.87)	(-5.94, 5.41)	0.9278	-0.01 (0.17)	(-0.35, 0.33)	0.9405	
North America	37	8.97 (2.37)	26	6.39 (2.77)	2.57 (3.58)	(-4.58, 9.73)	0.4746	0.18 (0.26)	(-0.32, 0.68)	0.4884	
Baseline weight											0.8399
<60 kg	32	14.31 (3.92)	39	12.40 (3.86)	1.92 (4.87)	(-7.85, 11.68)	0.6959	0.08 (0.24)	(-0.39, 0.55)	0.7326	
>=60 kg	66	7.80 (1.67)	61	6.97 (1.71)	0.83 (2.28)	(-3.69, 5.35)	0.7174	0.06 (0.18)	(-0.29, 0.41)	0.7305	
Low CH50											0.4118
Yes	12	18.05 (5.73)	13	9.88 (8.87)	8.16 (10.00)	(-12.55, 28.88)	0.4229	0.29 (0.40)	(-0.50, 1.08)	0.4660	
No	86	8.08 (1.68)	87	8.33 (1.71)	-0.26 (2.28)	(-4.77, 4.26)	0.9110	-0.02 (0.15)	(-0.31, 0.28)	0.9154	
Low C3 or C4											0.9380
Yes	32	13.09 (4.91)	46	12.43 (4.18)	0.66 (4.20)	(-7.72, 9.04)	0.8761	0.02 (0.23)	(-0.43, 0.47)	0.9199	
No	66	8.34 (1.78)	54	7.30 (2.01)	1.04 (2.64)	(-4.18, 6.26)	0.6932	0.07 (0.18)	(-0.29, 0.43)	0.6997	
Baseline FARR anti-dsDNA											0.9479
<5 IU/mL	21	9.66 (2.17)	14	9.39 (2.64)	0.27 (3.50)	(-6.88, 7.42)	0.9387	0.03 (0.35)	(-0.65, 0.70)	0.9381	
>=5 IU/mL	55	7.84 (2.43)	66	7.86 (2.30)	-0.03 (2.92)	(-5.82, 5.77)	0.9928	-0.00 (0.18)	(-0.36, 0.36)	0.9937	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.6708
Yes	69	7.46 (2.27)	80	7.41 (2.14)	0.05 (2.68)	(-5.26, 5.36)	0.9845	0.00 (0.16)	(-0.32, 0.32)	0.9867	
No	29	10.40 (2.34)	20	12.33 (2.99)	-1.93 (3.81)	(-9.60, 5.74)	0.6152	-0.15 (0.29)	(-0.72, 0.42)	0.6144	
OCS use											0.9817
Yes	78	9.22 (1.98)	87	8.49 (1.98)	0.73 (2.49)	(-4.19, 5.64)	0.7698	0.04 (0.16)	(-0.27, 0.35)	0.7962	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Lupus QoL Emotional Health domain score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) N	LSMean (SE)	Placebo (N=102) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
No	20	5.83 (2.78)	13	4.99 (3.15)	0.84 (4.15)	(-7.64, 9.32)	0.8409	0.07 (0.36)	(-0.63, 0.77)	0.8484	
SLICC score											0.2062
0	61	7.71 (2.10)	65	9.66 (2.20)	-1.95 (2.85)	(-7.59, 3.70)	0.4959	-0.11 (0.18)	(-0.46, 0.24)	0.5261	
>=1	37	12.09 (2.95)	35	7.94 (2.90)	4.15 (3.89)	(-3.63, 11.93)	0.2904	0.23 (0.24)	(-0.23, 0.70)	0.3234	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Lupus QoL Body Image domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		2.54 (2.27)		5.05 (2.32)	-2.51 (3.09)	(-8.61, 3.59)	0.4175			
Week 12		11.14 (2.35)		10.82 (2.38)	0.32 (3.17)	(-5.94, 6.59)	0.9187			
Week 24		12.18 (2.52)		5.72 (2.61)	6.46 (3.47)	(-0.40, 13.31)	0.0646			
Week 36		13.35 (2.60)		13.08 (2.88)	0.27 (3.74)	(-7.11, 7.65)	0.9419			
Week 52		14.41 (2.64)		10.92 (2.97)	3.49 (3.83)	(-4.08, 11.07)	0.3639			
OVERALL	95	10.72 (1.97)	91	9.12 (2.04)	1.61 (2.64)	(-3.60, 6.81)	0.5430	0.08 (0.15)	(-0.20, 0.37)	0.5720

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Lupus QoL Body Image domain score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.2229
< 10 points	38	9.76 (2.65)	33	11.57 (2.86)	-1.81 (3.85)	(-9.50, 5.87)	0.6388	-0.11 (0.24)	(-0.58, 0.36)	0.6454	
>= 10 points	57	10.27 (2.84)	58	5.75 (2.92)	4.52 (3.49)	(-2.41, 11.45)	0.1986	0.21 (0.19)	(-0.16, 0.57)	0.2720	
OCS dose											0.2266
<10 mg/day	42	6.28 (2.89)	34	8.20 (3.20)	-1.92 (4.24)	(-10.38, 6.54)	0.6520	-0.10 (0.23)	(-0.55, 0.35)	0.6597	
>=10 mg/day	53	15.20 (2.72)	57	10.59 (2.75)	4.61 (3.35)	(-2.02, 11.25)	0.1710	0.23 (0.19)	(-0.15, 0.60)	0.2387	
Result of type I IFN gene signature test											0.2852
LOW	23	4.38 (3.31)	25	7.16 (3.24)	-2.78 (4.68)	(-12.23, 6.66)	0.5554	-0.17 (0.29)	(-0.74, 0.40)	0.5561	
HIGH	72	13.19 (2.18)	66	9.95 (2.44)	3.24 (3.14)	(-2.97, 9.44)	0.3039	0.17 (0.17)	(-0.17, 0.50)	0.3249	
Age (years)											0.8669
<= 45	64	11.16 (2.59)	64	9.77 (2.64)	1.39 (3.29)	(-5.13, 7.91)	0.6741	0.07 (0.18)	(-0.28, 0.41)	0.7087	
> 45	31	10.00 (3.14)	27	7.68 (3.38)	2.31 (4.44)	(-6.59, 11.22)	0.6043	0.13 (0.26)	(-0.39, 0.65)	0.6205	
Sex											NE
male	6	NE	6	NE	NE	NE		NE	NE		
female	89	11.18 (2.05)	85	9.27 (2.14)	1.91 (2.78)	(-3.57, 7.39)	0.4924	0.10 (0.15)	(-0.20, 0.39)	0.5212	
Race											0.1953
White	34	12.68 (2.92)	35	6.13 (2.89)	6.55 (3.97)	(-1.38, 14.48)	0.1035	0.38 (0.24)	(-0.10, 0.86)	0.1183	
Black	18	10.51 (7.21)	11	2.87 (6.33)	7.64 (8.18)	(-9.19, 24.47)	0.3591	0.27 (0.38)	(-0.48, 1.02)	0.4815	
Other	43	9.78 (3.27)	45	13.00 (3.35)	-3.23 (4.24)	(-11.66, 5.20)	0.4484	-0.15 (0.21)	(-0.56, 0.27)	0.4951	
Ethnicity											0.4141
Hispanic/Latino	44	12.22 (3.24)	39	12.89 (3.57)	-0.67 (4.46)	(-9.56, 8.21)	0.8804	-0.03 (0.22)	(-0.46, 0.40)	0.8897	
Non-hispanic/Latino	51	9.92 (2.44)	52	6.09 (2.44)	3.82 (3.22)	(-2.58, 10.22)	0.2386	0.22 (0.20)	(-0.17, 0.60)	0.2732	
Geographic region											0.2988
Latin America, Eastern Europe and Asia	59	12.20 (2.81)	65	11.53 (2.90)	0.66 (3.28)	(-5.82, 7.15)	0.8397	0.03 (0.18)	(-0.32, 0.38)	0.8708	
North America	36	12.52 (3.12)	26	5.92 (3.62)	6.60 (4.68)	(-2.76, 15.96)	0.1636	0.35 (0.26)	(-0.16, 0.86)	0.1771	
Baseline weight											0.4160
<60 kg	31	23.05 (3.83)	37	17.40 (3.83)	5.65 (4.70)	(-3.76, 15.07)	0.2338	0.25 (0.24)	(-0.23, 0.73)	0.3079	
>=60 kg	64	6.46 (2.14)	54	5.35 (2.30)	1.11 (3.02)	(-4.88, 7.11)	0.7138	0.06 (0.18)	(-0.30, 0.43)	0.7252	
Low CH50											0.7917
Yes	12	19.04 (6.54)	12	20.27 (9.30)	-1.23 (10.87)	(-23.67, 21.22)	0.9111	-0.04 (0.41)	(-0.84, 0.76)	0.9170	
No	83	9.83 (1.96)	79	8.10 (2.04)	1.73 (2.70)	(-3.59, 7.06)	0.5217	0.10 (0.16)	(-0.21, 0.40)	0.5425	
Low C3 or C4											0.7774
Yes	32	16.56 (5.45)	42	13.08 (4.74)	3.48 (4.63)	(-5.77, 12.73)	0.4558	0.11 (0.23)	(-0.35, 0.57)	0.6339	
No	63	10.13 (2.21)	49	8.27 (2.54)	1.87 (3.32)	(-4.72, 8.45)	0.5756	0.10 (0.19)	(-0.27, 0.48)	0.5824	
Baseline FARR anti-dsDNA											0.8094
<5 IU/mL	20	11.69 (3.16)	12	8.39 (4.26)	3.30 (5.44)	(-7.84, 14.44)	0.5493	0.22 (0.37)	(-0.49, 0.94)	0.5415	
>=5 IU/mL	54	11.51 (2.95)	60	9.79 (2.90)	1.72 (3.62)	(-5.46, 8.90)	0.6359	0.08 (0.19)	(-0.29, 0.45)	0.6800	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.5788
Yes	68	9.78 (2.69)	73	8.00 (2.60)	1.77 (3.21)	(-4.57, 8.11)	0.5812	0.08 (0.17)	(-0.25, 0.41)	0.6376	
No	27	8.63 (2.63)	18	9.83 (3.35)	-1.20 (4.28)	(-9.89, 7.50)	0.7816	-0.08 (0.30)	(-0.68, 0.51)	0.7811	
OCS use											0.5599
Yes	75	11.23 (2.29)	80	8.25 (2.31)	2.98 (2.85)	(-2.65, 8.62)	0.2968	0.15 (0.16)	(-0.17, 0.46)	0.3623	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Lupus QoL Body Image domain score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) N	Anifrolumab 300mg (N=99) LSMean (SE)	Placebo (N=102) N	Placebo (N=102) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
No	20	6.42 (4.13)	11	7.67 (5.16)	-1.25 (6.68)	(-14.96, 12.46)	0.8528	-0.07 (0.38)	(-0.80, 0.67)	0.8570	
SLICC score											0.3768
0	59	9.92 (2.44)	57	9.94 (2.60)	-0.03 (3.32)	(-6.61, 6.56)	0.9937	-0.00 (0.19)	(-0.37, 0.36)	0.9941	
>=1	36	12.48 (3.42)	34	7.54 (3.45)	4.94 (4.53)	(-4.11, 13.99)	0.2797	0.24 (0.24)	(-0.23, 0.71)	0.3163	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Lupus QoL Burden to Others domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		0.73 (2.21)		1.03 (2.20)	-0.30 (2.91)	(-6.05, 5.45)	0.9180			
Week 12		5.58 (2.58)		4.54 (2.56)	1.04 (3.45)	(-5.77, 7.86)	0.7630			
Week 24		5.07 (2.63)		5.02 (2.66)	0.05 (3.57)	(-7.00, 7.09)	0.9895			
Week 36		10.66 (2.64)		7.15 (2.76)	3.52 (3.66)	(-3.70, 10.73)	0.3374			
Week 52		8.31 (2.88)		5.72 (3.05)	2.59 (4.05)	(-5.39, 10.58)	0.5225			
OVERALL	98	6.07 (2.20)	100	4.69 (2.21)	1.38 (2.92)	(-4.37, 7.13)	0.6366	0.06 (0.14)	(-0.22, 0.34)	0.6597

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Lupus QoL Burden to Others domain score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) N	LSMean (SE)	Placebo (N=102) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.1657
< 10 points	39	3.03 (3.31)	39	6.85 (3.24)	-3.82 (4.52)	(-12.83, 5.20)	0.4010	-0.18 (0.23)	(-0.63, 0.26)	0.4156	
>= 10 points	59	8.97 (2.92)	61	4.66 (3.04)	4.30 (3.73)	(-3.09, 11.69)	0.2511	0.18 (0.18)	(-0.17, 0.54)	0.3125	
OCS dose											0.9417
<10 mg/day	44	3.20 (3.45)	37	2.33 (3.68)	0.86 (4.94)	(-8.98, 10.71)	0.8616	0.04 (0.22)	(-0.40, 0.48)	0.8655	
>=10 mg/day	54	9.15 (2.90)	63	7.85 (2.86)	1.31 (3.55)	(-5.74, 8.35)	0.7133	0.06 (0.19)	(-0.30, 0.42)	0.7510	
Result of type I IFN gene signature test											0.5422
LOW	24	2.38 (4.00)	25	4.03 (3.98)	-1.65 (5.63)	(-13.11, 9.81)	0.7714	-0.08 (0.29)	(-0.64, 0.48)	0.7738	
HIGH	74	8.00 (2.43)	75	5.64 (2.55)	2.36 (3.42)	(-4.39, 9.12)	0.4903	0.11 (0.16)	(-0.21, 0.43)	0.5049	
Age (years)											0.8753
<= 45	66	8.25 (2.72)	70	6.42 (2.71)	1.83 (3.42)	(-4.94, 8.60)	0.5938	0.08 (0.17)	(-0.26, 0.42)	0.6366	
> 45	32	2.31 (4.06)	30	1.51 (4.14)	0.80 (5.57)	(-10.38, 11.98)	0.8859	0.03 (0.25)	(-0.46, 0.53)	0.8913	
Sex											0.1033
male	6	-22.77 (16.59)	9	-5.02 (14.86)	-17.75 (12.44)	(-45.62, 10.11)	0.1852	-0.39 (0.53)	(-1.43, 0.66)	0.4676	
female	92	7.53 (2.25)	91	4.42 (2.31)	3.11 (3.04)	(-2.89, 9.11)	0.3075	0.14 (0.15)	(-0.15, 0.43)	0.3377	
Race											0.8093
White	35	1.82 (3.07)	40	1.23 (2.87)	0.59 (4.00)	(-7.42, 8.60)	0.8835	0.03 (0.23)	(-0.42, 0.49)	0.8895	
Black	19	7.31 (10.47)	11	-0.67 (9.31)	7.98 (11.19)	(-15.12, 31.08)	0.4826	0.19 (0.38)	(-0.55, 0.93)	0.6178	
Other	44	8.79 (3.34)	49	8.47 (3.43)	0.32 (4.43)	(-8.49, 9.13)	0.9424	0.01 (0.21)	(-0.39, 0.42)	0.9472	
Ethnicity											0.9536
Hispanic/Latino	45	10.41 (3.22)	42	9.70 (3.53)	0.71 (4.48)	(-8.22, 9.64)	0.8753	0.03 (0.21)	(-0.39, 0.45)	0.8834	
Non-hispanic/Latino	53	1.65 (3.04)	58	0.60 (2.90)	1.05 (3.87)	(-6.62, 8.73)	0.7864	0.05 (0.19)	(-0.33, 0.42)	0.8039	
Geographic region											0.7560
Latin America, Eastern Europe and Asia	61	8.67 (2.71)	74	7.93 (2.75)	0.73 (3.27)	(-5.74, 7.21)	0.8232	0.03 (0.17)	(-0.31, 0.37)	0.8522	
North America	37	3.74 (4.32)	26	0.78 (4.94)	2.96 (6.39)	(-9.85, 15.78)	0.6448	0.11 (0.26)	(-0.39, 0.62)	0.6582	
Baseline weight											0.2141
<60 kg	32	14.79 (4.20)	39	8.02 (4.28)	6.77 (5.31)	(-3.88, 17.42)	0.2079	0.26 (0.24)	(-0.21, 0.73)	0.2722	
>=60 kg	66	2.38 (2.51)	61	3.46 (2.55)	-1.07 (3.41)	(-7.83, 5.68)	0.7534	-0.05 (0.18)	(-0.40, 0.30)	0.7660	
Low CH50											0.9383
Yes	12	7.18 (7.53)	13	4.06 (11.03)	3.12 (12.63)	(-23.00, 29.23)	0.8073	0.09 (0.40)	(-0.70, 0.87)	0.8245	
No	86	5.97 (2.16)	87	3.86 (2.17)	2.11 (2.92)	(-3.65, 7.88)	0.4702	0.10 (0.15)	(-0.19, 0.40)	0.4918	
Low C3 or C4											0.8597
Yes	32	8.31 (5.78)	46	7.13 (4.98)	1.18 (4.99)	(-8.79, 11.16)	0.8134	0.04 (0.23)	(-0.42, 0.49)	0.8786	
No	66	5.10 (2.50)	54	2.82 (2.78)	2.28 (3.67)	(-5.00, 9.56)	0.5361	0.11 (0.18)	(-0.25, 0.47)	0.5451	
Baseline FARR anti-dsDNA											0.4695
<5 IU/mL	21	7.02 (4.94)	14	0.74 (5.84)	6.28 (7.79)	(-9.69, 22.24)	0.4272	0.27 (0.35)	(-0.41, 0.95)	0.4283	
>=5 IU/mL	55	4.60 (3.23)	66	4.64 (3.04)	-0.04 (3.94)	(-7.84, 7.77)	0.9928	-0.00 (0.18)	(-0.36, 0.36)	0.9937	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.7054
Yes	69	4.48 (2.86)	80	3.49 (2.68)	1.00 (3.39)	(-5.71, 7.70)	0.7692	0.04 (0.16)	(-0.28, 0.36)	0.8001	
No	29	8.99 (3.68)	20	5.43 (4.63)	3.56 (5.86)	(-8.28, 15.40)	0.5474	0.17 (0.29)	(-0.40, 0.74)	0.5515	
OCS use											0.5359
Yes	78	6.91 (2.48)	87	4.25 (2.46)	2.66 (3.11)	(-3.48, 8.80)	0.3935	0.12 (0.16)	(-0.19, 0.42)	0.4496	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Lupus QoL Burden to Others domain score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) N	LSMean (SE)	Placebo (N=102) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
No	20	0.91 (5.32)	13	3.51 (6.09)	-2.60 (7.91)	(-18.84, 13.64)	0.7449	-0.11 (0.36)	(-0.81, 0.59)	0.7581	
SLICC score											0.7344
0	61	6.42 (2.75)	65	6.11 (2.84)	0.31 (3.73)	(-7.08, 7.69)	0.9344	0.01 (0.18)	(-0.34, 0.36)	0.9385	
>=1	37	4.60 (3.84)	35	2.17 (3.75)	2.43 (5.01)	(-7.59, 12.44)	0.6299	0.11 (0.24)	(-0.36, 0.57)	0.6553	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Lupus QoL Fatigue domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		5.03 (1.90)		1.33 (1.88)	3.70 (2.50)	(-1.24, 8.63)	0.1411			
Week 12		10.38 (2.10)		8.19 (2.07)	2.19 (2.79)	(-3.32, 7.69)	0.4347			
Week 24		11.56 (2.23)		6.30 (2.27)	5.26 (3.04)	(-0.74, 11.26)	0.0852			
Week 36		13.63 (2.38)		8.58 (2.48)	5.05 (3.30)	(-1.47, 11.57)	0.1282			
Week 52		12.73 (2.49)		7.16 (2.64)	5.58 (3.51)	(-1.34, 12.49)	0.1135			
OVERALL	98	10.66 (1.85)	100	6.31 (1.85)	4.35 (2.44)	(-0.46, 9.17)	0.0760	0.24 (0.14)	(-0.04, 0.52)	0.0986

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Lupus QoL Fatigue domain score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) N	LSMean (SE)	Placebo (N=102) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.5740
< 10 points	39	13.56 (2.62)	39	7.68 (2.58)	5.88 (3.61)	(-1.32, 13.07)	0.1078	0.36 (0.23)	(-0.09, 0.81)	0.1165	
>= 10 points	59	7.52 (2.56)	61	4.37 (2.66)	3.15 (3.23)	(-3.25, 9.56)	0.3309	0.15 (0.18)	(-0.20, 0.51)	0.3978	
OCS dose											0.9508
<10 mg/day	44	11.37 (2.55)	37	5.90 (2.74)	5.47 (3.70)	(-1.90, 12.83)	0.1436	0.32 (0.22)	(-0.12, 0.76)	0.1515	
>=10 mg/day	54	10.23 (2.59)	63	5.06 (2.56)	5.17 (3.15)	(-1.08, 11.42)	0.1041	0.26 (0.19)	(-0.11, 0.63)	0.1627	
Result of type I IFN gene signature test											0.5637
LOW	24	10.03 (2.98)	25	3.31 (2.95)	6.72 (4.19)	(-1.74, 15.18)	0.1164	0.45 (0.29)	(-0.12, 1.02)	0.1203	
HIGH	74	11.49 (1.99)	75	7.68 (2.09)	3.81 (2.80)	(-1.72, 9.34)	0.1750	0.22 (0.16)	(-0.11, 0.54)	0.1901	
Age (years)											0.4700
<= 45	66	11.95 (2.30)	70	6.20 (2.28)	5.75 (2.88)	(0.04, 11.45)	0.0484	0.30 (0.17)	(-0.04, 0.64)	0.0799	
> 45	32	7.36 (3.41)	30	5.60 (3.51)	1.77 (4.69)	(-7.64, 11.17)	0.7081	0.09 (0.25)	(-0.41, 0.59)	0.7218	
Sex											0.8725
male	6	4.16 (5.92)	9	-1.68 (5.04)	5.84 (6.19)	(-7.54, 19.23)	0.3626	0.37 (0.53)	(-0.67, 1.41)	0.4882	
female	92	11.52 (1.92)	91	6.76 (1.97)	4.77 (2.59)	(-0.34, 9.87)	0.0672	0.25 (0.15)	(-0.04, 0.55)	0.0862	
Race											0.2701
White	35	11.74 (2.84)	40	2.58 (2.59)	9.17 (3.70)	(1.78, 16.55)	0.0157	0.55 (0.24)	(0.08, 1.01)	0.0204	
Black	19	12.21 (7.63)	11	6.03 (6.74)	6.18 (8.20)	(-10.65, 23.01)	0.4576	0.20 (0.38)	(-0.54, 0.95)	0.5958	
Other	44	11.09 (2.80)	49	10.34 (2.88)	0.75 (3.69)	(-6.58, 8.09)	0.8388	0.04 (0.21)	(-0.37, 0.45)	0.8532	
Ethnicity											0.6185
Hispanic/Latino	45	12.36 (2.89)	42	9.34 (3.17)	3.01 (3.99)	(-4.94, 10.96)	0.4530	0.15 (0.21)	(-0.27, 0.57)	0.4861	
Non-hispanic/Latino	53	9.62 (2.44)	58	4.10 (2.28)	5.52 (3.08)	(-0.59, 11.64)	0.0761	0.31 (0.19)	(-0.06, 0.69)	0.1020	
Geographic region											0.3651
Latin America, Eastern Europe and Asia	61	12.76 (2.30)	74	9.12 (2.33)	3.65 (2.76)	(-1.83, 9.12)	0.1897	0.19 (0.17)	(-0.15, 0.53)	0.2751	
North America	37	10.76 (3.22)	26	2.17 (3.62)	8.59 (4.71)	(-0.84, 18.03)	0.0734	0.44 (0.26)	(-0.06, 0.95)	0.0868	
Baseline weight											0.3395
<60 kg	32	15.95 (3.83)	39	7.26 (3.84)	8.68 (4.83)	(-0.98, 18.35)	0.0774	0.37 (0.24)	(-0.10, 0.85)	0.1203	
>=60 kg	66	9.09 (1.98)	61	5.68 (2.00)	3.41 (2.68)	(-1.90, 8.71)	0.2061	0.21 (0.18)	(-0.14, 0.56)	0.2310	
Low CH50											0.9330
Yes	12	13.46 (5.48)	13	9.62 (7.36)	3.84 (8.84)	(-14.43, 22.12)	0.6679	0.16 (0.40)	(-0.63, 0.95)	0.6902	
No	86	10.59 (1.93)	87	5.97 (1.93)	4.62 (2.59)	(-0.50, 9.74)	0.0768	0.26 (0.15)	(-0.04, 0.56)	0.0930	
Low C3 or C4											0.5179
Yes	32	7.45 (4.58)	46	5.26 (3.92)	2.18 (4.15)	(-6.11, 10.47)	0.6004	0.08 (0.23)	(-0.37, 0.53)	0.7212	
No	66	10.68 (2.19)	54	5.11 (2.42)	5.57 (3.20)	(-0.77, 11.91)	0.0844	0.31 (0.18)	(-0.05, 0.67)	0.0919	
Baseline FARR anti-dsDNA											0.2248
<5 IU/mL	21	13.80 (3.53)	14	2.41 (4.25)	11.40 (5.58)	(-0.01, 22.80)	0.0501	0.69 (0.36)	(-0.01, 1.39)	0.0517	
>=5 IU/mL	55	9.83 (2.59)	66	6.22 (2.42)	3.61 (3.16)	(-2.66, 9.88)	0.2568	0.18 (0.18)	(-0.17, 0.54)	0.3144	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.7511
Yes	69	9.10 (2.35)	80	5.26 (2.21)	3.84 (2.80)	(-1.71, 9.38)	0.1735	0.19 (0.16)	(-0.13, 0.52)	0.2383	
No	29	12.88 (3.42)	20	7.10 (4.27)	5.77 (5.43)	(-5.18, 16.73)	0.2936	0.30 (0.29)	(-0.27, 0.88)	0.2985	
OCS use											0.6842
Yes	78	10.09 (2.10)	87	4.50 (2.09)	5.59 (2.63)	(0.38, 10.79)	0.0355	0.29 (0.16)	(-0.02, 0.60)	0.0627	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Lupus QoL Fatigue domain score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) N	LSMean (SE)	Placebo (N=102) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
No	20	13.59 (3.50)	13	5.55 (4.07)	8.05 (5.45)	(-3.07, 19.17)	0.1499	0.51 (0.36)	(-0.20, 1.22)	0.1562	
SLICC score											0.8822
0	61	10.48 (2.30)	65	6.62 (2.39)	3.86 (3.12)	(-2.32, 10.03)	0.2185	0.21 (0.18)	(-0.14, 0.56)	0.2503	
>=1	37	10.40 (3.35)	35	5.76 (3.21)	4.64 (4.31)	(-3.96, 13.24)	0.2853	0.23 (0.24)	(-0.23, 0.70)	0.3247	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Lupus QoL Intimate Relationships domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		4.79 (2.83)		0.79 (3.03)	3.99 (3.88)	(-3.67, 11.65)	0.3046			
Week 12		11.24 (3.09)		4.03 (3.22)	7.21 (4.19)	(-1.08, 15.49)	0.0877			
Week 24		7.52 (2.92)		6.67 (3.06)	0.85 (3.96)	(-6.97, 8.67)	0.8300			
Week 36		7.38 (3.33)		7.42 (3.69)	-0.04 (4.74)	(-9.43, 9.35)	0.9933			
Week 52		4.15 (3.50)		8.77 (3.96)	-4.62 (5.08)	(-14.68, 5.43)	0.3646			
OVERALL	85	7.02 (2.46)	78	5.54 (2.61)	1.48 (3.26)	(-4.97, 7.93)	0.6515	0.06 (0.16)	(-0.24, 0.37)	0.6816

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Lupus QoL Intimate Relationships domain score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) N	LSMean (SE)	Placebo (N=102) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.1904
< 10 points	32	5.48 (3.54)	28	9.94 (3.78)	-4.46 (4.96)	(-14.39, 5.47)	0.3725	-0.22 (0.26)	(-0.73, 0.29)	0.3969	
>= 10 points	53	8.42 (3.31)	50	4.27 (3.54)	4.15 (4.32)	(-4.44, 12.74)	0.3391	0.17 (0.20)	(-0.22, 0.55)	0.3956	
OCS dose											0.4400
<10 mg/day	41	5.03 (3.65)	23	-0.23 (4.59)	5.26 (5.60)	(-5.94, 16.46)	0.3507	0.23 (0.26)	(-0.29, 0.74)	0.3846	
>=10 mg/day	44	10.30 (3.31)	55	10.34 (3.10)	-0.04 (3.98)	(-7.94, 7.87)	0.9927	-0.00 (0.20)	(-0.40, 0.39)	0.9936	
Result of type I IFN gene signature test											0.9986
LOW	18	7.40 (4.94)	18	5.81 (5.01)	1.59 (7.15)	(-13.11, 16.29)	0.8255	0.07 (0.33)	(-0.58, 0.73)	0.8250	
HIGH	67	7.41 (2.48)	60	5.84 (2.83)	1.58 (3.65)	(-5.66, 8.81)	0.6667	0.07 (0.18)	(-0.27, 0.42)	0.6756	
Age (years)											0.5197
<= 45	58	8.52 (2.88)	59	8.20 (2.91)	0.32 (3.58)	(-6.79, 7.43)	0.9290	0.01 (0.18)	(-0.35, 0.38)	0.9381	
> 45	27	6.00 (4.96)	19	0.30 (6.09)	5.70 (7.54)	(-9.62, 21.01)	0.4551	0.21 (0.30)	(-0.37, 0.80)	0.4747	
Sex											NE
male	6	NE	7	NE	NE	NE		NE	NE		
female	79	6.10 (2.53)	71	5.17 (2.73)	0.92 (3.41)	(-5.81, 7.66)	0.7864	0.04 (0.16)	(-0.28, 0.36)	0.8045	
Race											0.4988
White	27	2.75 (3.75)	34	1.39 (3.46)	1.36 (4.85)	(-8.37, 11.08)	0.7808	0.07 (0.26)	(-0.44, 0.57)	0.7935	
Black	19	2.80 (7.04)	10	-9.32 (7.56)	12.12 (9.51)	(-7.38, 31.63)	0.2131	0.41 (0.39)	(-0.36, 1.19)	0.2969	
Other	39	13.20 (3.57)	34	13.57 (4.11)	-0.36 (4.79)	(-9.98, 9.25)	0.9396	-0.02 (0.23)	(-0.48, 0.44)	0.9469	
Ethnicity											0.3836
Hispanic/Latino	38	9.84 (4.09)	31	12.91 (4.77)	-3.08 (5.63)	(-14.37, 8.21)	0.5870	-0.12 (0.24)	(-0.59, 0.36)	0.6267	
Non-hispanic/Latino	47	3.81 (2.86)	47	1.02 (2.91)	2.79 (3.70)	(-4.56, 10.14)	0.4521	0.14 (0.21)	(-0.26, 0.54)	0.4974	
Geographic region											0.2261
Latin America, Eastern Europe and Asia	52	12.75 (2.96)	56	13.51 (3.25)	-0.76 (3.43)	(-7.59, 6.06)	0.8241	-0.03 (0.19)	(-0.41, 0.34)	0.8635	
North America	33	3.34 (4.32)	22	-4.82 (4.99)	8.16 (6.52)	(-4.92, 21.24)	0.2166	0.33 (0.28)	(-0.21, 0.87)	0.2318	
Baseline weight											0.5308
<60 kg	25	21.64 (5.45)	27	15.46 (5.97)	6.19 (6.37)	(-6.75, 19.12)	0.3381	0.21 (0.28)	(-0.34, 0.75)	0.4547	
>=60 kg	60	4.05 (2.68)	51	2.49 (2.85)	1.56 (3.72)	(-5.80, 8.93)	0.6745	0.08 (0.19)	(-0.30, 0.45)	0.6914	
Low CH50											0.1930
Yes	12	9.76 (6.67)	9	-8.95 (12.22)	18.71 (13.25)	(-9.69, 47.11)	0.1796	0.61 (0.45)	(-0.28, 1.50)	0.1801	
No	73	6.59 (2.52)	69	5.68 (2.63)	0.91 (3.41)	(-5.84, 7.66)	0.7908	0.04 (0.17)	(-0.29, 0.37)	0.8044	
Low C3 or C4											0.3533
Yes	26	11.24 (7.08)	36	5.38 (5.83)	5.86 (5.47)	(-5.13, 16.85)	0.2890	0.16 (0.26)	(-0.34, 0.67)	0.5267	
No	59	5.93 (2.87)	42	6.57 (3.47)	-0.65 (4.39)	(-9.37, 8.07)	0.8832	-0.03 (0.20)	(-0.42, 0.37)	0.8863	
Baseline FARR anti-dsDNA											0.1637
<5 IU/mL	18	13.41 (4.29)	11	4.90 (5.75)	8.51 (7.74)	(-7.51, 24.53)	0.2830	0.45 (0.39)	(-0.31, 1.21)	0.2497	
>=5 IU/mL	50	3.81 (3.33)	53	7.46 (3.41)	-3.65 (4.05)	(-11.69, 4.38)	0.3692	-0.15 (0.20)	(-0.54, 0.24)	0.4479	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.8285
Yes	61	5.21 (3.14)	65	5.63 (3.10)	-0.42 (3.70)	(-7.74, 6.91)	0.9101	-0.02 (0.18)	(-0.37, 0.33)	0.9250	
No	24	11.79 (3.97)	13	13.97 (5.73)	-2.18 (7.24)	(-17.13, 12.77)	0.7660	-0.11 (0.34)	(-0.78, 0.57)	0.7554	
OCS use											0.2634
Yes	67	9.48 (2.77)	69	6.31 (2.94)	3.17 (3.44)	(-3.64, 9.98)	0.3590	0.13 (0.17)	(-0.20, 0.47)	0.4370	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Lupus QoL Intimate Relationships domain score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) N	LSMean (SE)	Placebo (N=102) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
No	18	-4.98 (6.21)	9	3.63 (7.91)	-8.61 (9.95)	(-29.24, 12.02)	0.3961	-0.33 (0.41)	(-1.13, 0.48)	0.4262	
SLICC score											0.3445
0	51	5.31 (3.21)	50	5.59 (3.49)	-0.28 (4.25)	(-8.74, 8.17)	0.9471	-0.01 (0.20)	(-0.40, 0.38)	0.9528	
>=1	34	11.26 (4.06)	28	4.92 (4.26)	6.35 (5.58)	(-4.82, 17.51)	0.2598	0.27 (0.26)	(-0.23, 0.77)	0.2915	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Lupus QoL Pain domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		6.95 (1.82)		6.04 (1.82)	0.91 (2.39)	(-3.80, 5.62)	0.7036			
Week 12		11.42 (2.40)		9.62 (2.38)	1.80 (3.24)	(-4.59, 8.20)	0.5793			
Week 24		11.94 (2.54)		10.51 (2.58)	1.43 (3.48)	(-5.44, 8.30)	0.6821			
Week 36		17.54 (2.47)		13.24 (2.56)	4.30 (3.42)	(-2.45, 11.05)	0.2104			
Week 52		14.56 (2.55)		12.39 (2.70)	2.18 (3.58)	(-4.90, 9.25)	0.5445			
OVERALL	98	12.48 (2.00)	100	10.36 (2.01)	2.12 (2.66)	(-3.13, 7.38)	0.4266	0.11 (0.14)	(-0.17, 0.38)	0.4558

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Lupus QoL Pain domain score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) N	LSMean (SE)	Placebo (N=102) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.7457
< 10 points	39	14.47 (3.07)	39	13.63 (3.03)	0.84 (4.21)	(-7.55, 9.23)	0.8417	0.04 (0.23)	(-0.40, 0.49)	0.8467	
>= 10 points	59	10.47 (2.60)	61	7.89 (2.70)	2.59 (3.35)	(-4.05, 9.23)	0.4415	0.13 (0.18)	(-0.23, 0.48)	0.4931	
OCS dose											0.3175
<10 mg/day	44	11.05 (2.76)	37	4.98 (2.96)	6.07 (3.97)	(-1.84, 13.97)	0.1308	0.33 (0.22)	(-0.11, 0.77)	0.1415	
>=10 mg/day	54	14.42 (2.79)	63	13.64 (2.73)	0.78 (3.48)	(-6.12, 7.69)	0.8221	0.04 (0.19)	(-0.33, 0.40)	0.8423	
Result of type I IFN gene signature test											0.9789
LOW	24	10.43 (3.97)	25	7.98 (3.93)	2.46 (5.57)	(-8.81, 13.73)	0.6615	0.12 (0.29)	(-0.44, 0.68)	0.6653	
HIGH	74	13.75 (2.14)	75	11.46 (2.22)	2.29 (2.99)	(-3.63, 8.21)	0.4453	0.12 (0.16)	(-0.20, 0.44)	0.4603	
Age (years)											0.7414
<= 45	66	14.78 (2.37)	70	11.80 (2.37)	2.98 (3.03)	(-3.01, 8.97)	0.3263	0.15 (0.17)	(-0.19, 0.49)	0.3773	
> 45	32	7.55 (3.85)	30	6.59 (3.99)	0.95 (5.36)	(-9.80, 11.70)	0.8599	0.04 (0.25)	(-0.46, 0.54)	0.8657	
Sex											0.3902
male	6	24.18 (11.61)	9	31.14 (9.18)	-6.96 (10.75)	(-31.07, 17.16)	0.5328	-0.23 (0.53)	(-1.27, 0.80)	0.6575	
female	92	12.64 (2.05)	91	10.06 (2.10)	2.58 (2.78)	(-2.90, 8.07)	0.3539	0.13 (0.15)	(-0.16, 0.42)	0.3813	
Race											0.5506
White	35	8.63 (2.80)	40	4.90 (2.62)	3.73 (3.68)	(-3.63, 11.09)	0.3147	0.22 (0.23)	(-0.23, 0.68)	0.3370	
Black	19	15.64 (6.65)	11	7.18 (6.87)	8.45 (7.93)	(-7.86, 24.77)	0.2966	0.31 (0.38)	(-0.44, 1.05)	0.4233	
Other	44	16.68 (3.23)	49	17.29 (3.28)	-0.61 (4.31)	(-9.18, 7.96)	0.8880	-0.03 (0.21)	(-0.43, 0.38)	0.8961	
Ethnicity											0.2582
Hispanic/Latino	45	15.87 (3.21)	42	17.65 (3.48)	-1.79 (4.48)	(-10.70, 7.13)	0.6912	-0.08 (0.21)	(-0.50, 0.34)	0.7086	
Non-hispanic/Latino	53	9.93 (2.39)	58	5.57 (2.31)	4.36 (3.08)	(-1.75, 10.47)	0.1601	0.25 (0.19)	(-0.13, 0.62)	0.1941	
Geographic region											0.2801
Latin America, Eastern Europe and Asia	61	17.21 (2.53)	74	16.11 (2.54)	1.10 (3.09)	(-5.02, 7.22)	0.7219	0.05 (0.17)	(-0.29, 0.39)	0.7623	
North America	37	8.57 (2.88)	26	1.76 (3.32)	6.81 (4.28)	(-1.76, 15.38)	0.1173	0.39 (0.26)	(-0.12, 0.90)	0.1324	
Baseline weight											0.7947
<60 kg	32	20.48 (4.04)	39	18.56 (4.01)	1.92 (5.20)	(-8.49, 12.33)	0.7135	0.08 (0.24)	(-0.39, 0.55)	0.7412	
>=60 kg	66	9.31 (2.14)	61	5.84 (2.18)	3.47 (2.90)	(-2.27, 9.20)	0.2335	0.20 (0.18)	(-0.15, 0.55)	0.2605	
Low CH50											0.2659
Yes	12	27.28 (5.35)	13	15.40 (7.83)	11.87 (9.07)	(-7.04, 30.79)	0.2053	0.48 (0.41)	(-0.32, 1.27)	0.2416	
No	86	10.92 (2.06)	87	9.61 (2.08)	1.31 (2.80)	(-4.23, 6.85)	0.6406	0.07 (0.15)	(-0.23, 0.37)	0.6555	
Low C3 or C4											0.5123
Yes	32	17.60 (4.71)	46	12.51 (4.03)	5.09 (4.45)	(-3.81, 13.98)	0.2577	0.19 (0.23)	(-0.27, 0.64)	0.4195	
No	66	10.82 (2.34)	54	9.43 (2.63)	1.39 (3.45)	(-5.44, 8.22)	0.6868	0.07 (0.18)	(-0.29, 0.43)	0.6937	
Baseline FARR anti-dsDNA											0.1192
<5 IU/mL	21	15.46 (3.48)	14	4.82 (4.15)	10.64 (5.51)	(-0.64, 21.92)	0.0634	0.66 (0.36)	(-0.04, 1.35)	0.0636	
>=5 IU/mL	55	10.59 (2.80)	66	10.07 (2.64)	0.52 (3.45)	(-6.32, 7.35)	0.8814	0.02 (0.18)	(-0.33, 0.38)	0.8942	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.9656
Yes	69	11.04 (2.49)	80	9.22 (2.34)	1.82 (3.01)	(-4.13, 7.76)	0.5465	0.09 (0.16)	(-0.24, 0.41)	0.5975	
No	29	16.92 (3.78)	20	14.82 (4.71)	2.11 (5.98)	(-9.95, 14.16)	0.7264	0.10 (0.29)	(-0.47, 0.67)	0.7299	
OCS use											0.6395
Yes	78	13.44 (2.30)	87	10.07 (2.29)	3.36 (2.94)	(-2.44, 9.17)	0.2540	0.16 (0.16)	(-0.15, 0.47)	0.3042	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Lupus QoL Pain domain score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) N	LSMean (SE)	Placebo (N=102) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
No	20	7.41 (3.51)	13	6.85 (4.00)	0.57 (5.19)	(-10.10, 11.24)	0.9137	0.04 (0.36)	(-0.66, 0.73)	0.9185	
SLICC score											0.7928
0	61	11.08 (2.51)	65	9.56 (2.59)	1.52 (3.41)	(-5.23, 8.27)	0.6573	0.07 (0.18)	(-0.28, 0.42)	0.6766	
>=1	37	15.23 (3.52)	35	12.20 (3.46)	3.03 (4.64)	(-6.24, 12.29)	0.5163	0.14 (0.24)	(-0.32, 0.61)	0.5448	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Lupus QoL Planning domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		5.99 (2.21)		-1.16 (2.20)	7.15 (2.92)	(1.38, 12.92)	0.0154			
Week 12		11.86 (2.67)		7.27 (2.65)	4.59 (3.59)	(-2.49, 11.67)	0.2026			
Week 24		12.91 (2.59)		4.32 (2.61)	8.59 (3.51)	(1.67, 15.50)	0.0152			
Week 36		14.81 (2.71)		6.57 (2.81)	8.24 (3.75)	(0.84, 15.64)	0.0293			
Week 52		12.25 (2.66)		7.77 (2.79)	4.48 (3.70)	(-2.81, 11.78)	0.2268			
OVERALL	98	11.56 (2.18)	100	4.95 (2.19)	6.61 (2.89)	(0.91, 12.31)	0.0232	0.30 (0.14)	(0.02, 0.58)	0.0342

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Lupus QoL Planning domain score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) N	LSMean (SE)	Placebo (N=102) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.8707
< 10 points	39	13.46 (3.15)	39	7.62 (3.10)	5.84 (4.32)	(-2.78, 14.46)	0.1813	0.30 (0.23)	(-0.15, 0.74)	0.1931	
>= 10 points	59	8.84 (2.99)	61	2.07 (3.09)	6.77 (3.78)	(-0.72, 14.26)	0.0758	0.29 (0.18)	(-0.07, 0.65)	0.1195	
OCS dose											0.9221
<10 mg/day	44	10.90 (3.11)	37	3.33 (3.33)	7.57 (4.46)	(-1.32, 16.46)	0.0938	0.37 (0.23)	(-0.07, 0.81)	0.1032	
>=10 mg/day	54	11.87 (3.06)	63	4.87 (2.99)	7.00 (3.76)	(-0.45, 14.45)	0.0653	0.30 (0.19)	(-0.07, 0.67)	0.1076	
Result of type I IFN gene signature test											0.3256
LOW	24	12.30 (4.47)	25	0.06 (4.40)	12.24 (6.28)	(-0.43, 24.91)	0.0578	0.55 (0.29)	(-0.02, 1.12)	0.0598	
HIGH	74	12.42 (2.29)	75	7.11 (2.38)	5.31 (3.20)	(-1.01, 11.64)	0.0991	0.26 (0.16)	(-0.06, 0.58)	0.1112	
Age (years)											0.2634
<= 45	66	13.13 (2.68)	70	4.13 (2.67)	9.00 (3.36)	(2.34, 15.65)	0.0085	0.41 (0.17)	(0.07, 0.75)	0.0192	
> 45	32	7.76 (4.09)	30	6.13 (4.21)	1.64 (5.66)	(-9.71, 12.99)	0.7736	0.07 (0.25)	(-0.43, 0.57)	0.7834	
Sex											0.3641
male	6	12.97 (9.63)	9	14.45 (7.78)	-1.48 (9.42)	(-21.78, 18.82)	0.8776	-0.06 (0.53)	(-1.09, 0.97)	0.9103	
female	92	12.24 (2.24)	91	4.74 (2.29)	7.50 (3.02)	(1.55, 13.46)	0.0139	0.34 (0.15)	(0.05, 0.64)	0.0208	
Race											0.6733
White	35	12.70 (3.38)	40	3.63 (3.13)	9.08 (4.38)	(0.33, 17.83)	0.0423	0.45 (0.23)	(-0.01, 0.91)	0.0540	
Black	19	-0.55 (6.86)	11	-10.51 (6.87)	9.95 (8.40)	(-7.24, 27.15)	0.2458	0.35 (0.38)	(-0.40, 1.10)	0.3576	
Other	44	14.84 (3.21)	49	10.66 (3.30)	4.18 (4.24)	(-4.26, 12.61)	0.3274	0.19 (0.21)	(-0.22, 0.59)	0.3710	
Ethnicity											0.9565
Hispanic/Latino	45	15.16 (3.26)	42	8.68 (3.53)	6.48 (4.51)	(-2.50, 15.46)	0.1551	0.29 (0.22)	(-0.14, 0.71)	0.1834	
Non-hispanic/Latino	53	8.00 (2.95)	58	1.20 (2.81)	6.80 (3.75)	(-0.65, 14.24)	0.0731	0.32 (0.19)	(-0.06, 0.69)	0.0995	
Geographic region											0.1813
Latin America, Eastern Europe and Asia	61	16.78 (2.66)	74	11.47 (2.71)	5.31 (3.19)	(-1.02, 11.63)	0.0991	0.24 (0.17)	(-0.10, 0.58)	0.1707	
North America	37	5.52 (3.51)	26	-7.90 (3.98)	13.43 (5.16)	(3.09, 23.76)	0.0118	0.63 (0.26)	(0.12, 1.15)	0.0158	
Baseline weight											0.8006
<60 kg	32	18.64 (4.40)	39	9.03 (4.40)	9.60 (5.70)	(-1.79, 21.00)	0.0971	0.36 (0.24)	(-0.11, 0.83)	0.1338	
>=60 kg	66	8.84 (2.44)	61	0.90 (2.48)	7.94 (3.32)	(1.36, 14.51)	0.0185	0.40 (0.18)	(0.05, 0.75)	0.0249	
Low CH50											0.3521
Yes	12	18.12 (7.01)	13	0.31 (9.79)	17.81 (11.55)	(-6.02, 41.64)	0.1360	0.56 (0.41)	(-0.24, 1.37)	0.1683	
No	86	11.03 (2.19)	87	4.31 (2.20)	6.72 (2.96)	(0.88, 12.56)	0.0244	0.33 (0.15)	(0.03, 0.63)	0.0324	
Low C3 or C4											0.7301
Yes	32	12.10 (5.89)	46	6.47 (4.97)	5.63 (5.25)	(-4.86, 16.12)	0.2880	0.17 (0.23)	(-0.29, 0.62)	0.4715	
No	66	10.58 (2.44)	54	2.76 (2.71)	7.82 (3.59)	(0.72, 14.93)	0.0312	0.39 (0.19)	(0.03, 0.75)	0.0350	
Baseline FARR anti-dsDNA											0.3367
<5 IU/mL	21	10.08 (3.86)	14	-2.25 (4.57)	12.33 (6.11)	(-0.16, 24.81)	0.0527	0.69 (0.36)	(-0.01, 1.39)	0.0526	
>=5 IU/mL	55	12.53 (3.18)	66	7.16 (2.99)	5.37 (3.88)	(-2.32, 13.07)	0.1693	0.22 (0.18)	(-0.14, 0.58)	0.2239	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.8756
Yes	69	11.34 (2.86)	80	4.89 (2.68)	6.45 (3.40)	(-0.26, 13.16)	0.0595	0.27 (0.17)	(-0.05, 0.59)	0.1031	
No	29	11.73 (3.71)	20	6.35 (4.61)	5.39 (5.89)	(-6.49, 17.26)	0.3652	0.26 (0.29)	(-0.31, 0.83)	0.3698	
OCS use											0.6854
Yes	78	12.24 (2.48)	87	3.86 (2.47)	8.38 (3.13)	(2.19, 14.57)	0.0083	0.37 (0.16)	(0.06, 0.68)	0.0186	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Lupus QoL Planning domain score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) N	LSMean (SE)	Placebo (N=102) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
No	20	7.77 (4.84)	13	2.68 (5.61)	5.09 (7.50)	(-10.23, 20.40)	0.5026	0.24 (0.36)	(-0.47, 0.94)	0.5109	
SLICC score											0.5502
0	61	10.16 (2.64)	65	5.12 (2.74)	5.04 (3.58)	(-2.05, 12.12)	0.1621	0.23 (0.18)	(-0.12, 0.58)	0.1909	
>=1	37	14.71 (4.11)	35	5.81 (4.02)	8.89 (5.37)	(-1.85, 19.63)	0.1029	0.36 (0.24)	(-0.11, 0.83)	0.1296	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SDI Global Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 24		-0.01 (0.05)		0.04 (0.05)	-0.06 (0.07)	(-0.19, 0.08)	0.4155			
Week 52		-0.01 (0.06)		-0.05 (0.07)	0.03 (0.09)	(-0.14, 0.21)	0.7076			
OVERALL	94	-0.01 (0.05)	88	-0.00 (0.06)	-0.01 (0.07)	(-0.16, 0.13)	0.8752	-0.02 (0.15)	(-0.31, 0.27)	0.8839

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SDI Global Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) N	LSMean (SE)	Placebo (N=102) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.2007
< 10 points	36	0.03 (0.08)	36	-0.11 (0.08)	0.14 (0.12)	(-0.09, 0.37)	0.2184	0.29 (0.24)	(-0.18, 0.75)	0.2279	
>= 10 points	58	-0.00 (0.08)	52	0.05 (0.08)	-0.05 (0.10)	(-0.25, 0.15)	0.6019	-0.09 (0.19)	(-0.46, 0.29)	0.6405	
OCS dose											0.6373
<10 mg/day	40	-0.07 (0.08)	33	-0.02 (0.08)	-0.05 (0.11)	(-0.27, 0.17)	0.6328	-0.11 (0.24)	(-0.57, 0.35)	0.6424	
>=10 mg/day	54	0.06 (0.08)	55	0.05 (0.08)	0.02 (0.10)	(-0.18, 0.21)	0.8659	0.03 (0.19)	(-0.35, 0.40)	0.8844	
Result of type I IFN gene signature test											0.3894
LOW	23	0.04 (0.05)	23	-0.03 (0.06)	0.07 (0.08)	(-0.09, 0.22)	0.4032	0.25 (0.30)	(-0.33, 0.83)	0.4046	
HIGH	71	-0.05 (0.07)	65	-0.01 (0.07)	-0.04 (0.10)	(-0.23, 0.15)	0.6721	-0.07 (0.17)	(-0.41, 0.27)	0.6832	
Age (years)											0.0932
<= 45	65	-0.06 (0.05)	61	0.06 (0.05)	-0.12 (0.06)	(-0.24, 0.01)	0.0739	-0.29 (0.18)	(-0.64, 0.07)	0.1111	
> 45	29	0.14 (0.14)	27	-0.08 (0.15)	0.22 (0.19)	(-0.16, 0.61)	0.2497	0.29 (0.27)	(-0.23, 0.82)	0.2737	
Sex											NE
male	6	NE	9	NE	NE	NE		NE	NE		
female	88	-0.02 (0.06)	79	0.01 (0.06)	-0.03 (0.08)	(-0.19, 0.13)	0.7128	-0.05 (0.16)	(-0.36, 0.25)	0.7297	
Race											0.9150
White	32	0.02 (0.06)	37	0.01 (0.06)	0.02 (0.08)	(-0.15, 0.18)	0.8542	0.04 (0.24)	(-0.43, 0.52)	0.8619	
Black	18	-0.02 (0.15)	12	0.04 (0.13)	-0.06 (0.17)	(-0.42, 0.29)	0.7137	-0.11 (0.37)	(-0.84, 0.62)	0.7728	
Other	44	-0.05 (0.09)	39	-0.07 (0.10)	0.01 (0.13)	(-0.24, 0.27)	0.9273	0.02 (0.22)	(-0.41, 0.45)	0.9342	
Ethnicity											0.8365
Hispanic/Latino	45	-0.08 (0.08)	35	-0.06 (0.10)	-0.02 (0.12)	(-0.25, 0.22)	0.8841	-0.03 (0.23)	(-0.47, 0.41)	0.8927	
Non-hispanic/Latino	49	0.02 (0.06)	53	0.01 (0.06)	0.01 (0.07)	(-0.14, 0.16)	0.8774	0.03 (0.20)	(-0.36, 0.42)	0.8874	
Geographic region											0.4139
Latin America, Eastern Europe and Asia	60	-0.07 (0.08)	63	-0.03 (0.08)	-0.04 (0.10)	(-0.23, 0.15)	0.6603	-0.07 (0.18)	(-0.42, 0.29)	0.7135	
North America	34	0.07 (0.06)	25	-0.00 (0.07)	0.07 (0.09)	(-0.12, 0.26)	0.4760	0.18 (0.26)	(-0.33, 0.70)	0.4861	
Baseline weight											0.1129
<60 kg	31	-0.19 (0.12)	30	0.03 (0.12)	-0.22 (0.16)	(-0.54, 0.10)	0.1682	-0.32 (0.26)	(-0.83, 0.18)	0.2117	
>=60 kg	63	0.05 (0.05)	58	-0.00 (0.06)	0.06 (0.07)	(-0.09, 0.20)	0.4538	0.13 (0.18)	(-0.23, 0.49)	0.4806	
Low CH50											0.2461
Yes	11	-0.01 (0.28)	11	0.43 (0.39)	-0.44 (0.45)	(-1.39, 0.51)	0.3400	-0.38 (0.43)	(-1.22, 0.47)	0.3833	
No	83	0.03 (0.04)	77	-0.06 (0.05)	0.08 (0.06)	(-0.04, 0.21)	0.1763	0.21 (0.16)	(-0.11, 0.52)	0.1943	
Low C3 or C4											0.5857
Yes	31	0.05 (0.20)	38	0.11 (0.17)	-0.06 (0.17)	(-0.39, 0.27)	0.7192	-0.05 (0.24)	(-0.53, 0.42)	0.8205	
No	63	0.02 (0.04)	50	-0.02 (0.05)	0.04 (0.06)	(-0.09, 0.16)	0.5538	0.11 (0.19)	(-0.26, 0.48)	0.5604	
Baseline FARR anti-dsDNA											0.6709
<5 IU/mL	19	-0.06 (0.12)	14	0.00 (0.14)	-0.07 (0.19)	(-0.46, 0.32)	0.7247	-0.12 (0.35)	(-0.81, 0.57)	0.7258	
>=5 IU/mL	54	0.01 (0.07)	58	-0.01 (0.07)	0.02 (0.09)	(-0.15, 0.20)	0.8086	0.04 (0.19)	(-0.33, 0.41)	0.8318	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.2909
Yes	67	-0.01 (0.08)	69	0.02 (0.08)	-0.04 (0.10)	(-0.23, 0.16)	0.7195	-0.05 (0.17)	(-0.39, 0.28)	0.7611	
No	27	0.00 (0.04)	19	-0.09 (0.05)	0.09 (0.06)	(-0.04, 0.22)	0.1760	0.41 (0.30)	(-0.18, 1.01)	0.1731	
OCS use											0.6699
Yes	77	-0.02 (0.07)	75	0.00 (0.07)	-0.03 (0.09)	(-0.19, 0.14)	0.7633	-0.04 (0.16)	(-0.36, 0.27)	0.7900	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SDI Global Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
No	17	-0.04 (0.08)	13	-0.07 (0.09)	0.04 (0.12)	(-0.21, 0.28)	0.7603	0.11 (0.37)	(-0.61, 0.83)	0.7675	
SLICC score											0.9542
0	60	0.06 (0.05)	56	0.04 (0.05)	0.02 (0.07)	(-0.12, 0.16)	0.7637	0.05 (0.19)	(-0.31, 0.42)	0.7790	
>=1	34	-0.10 (0.13)	32	-0.13 (0.13)	0.03 (0.17)	(-0.31, 0.37)	0.8515	0.04 (0.25)	(-0.44, 0.53)	0.8624	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - PtGA
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-9.23 (2.51)		-4.90 (2.48)	-4.32 (3.35)	(-10.94, 2.29)	0.1988			
Week 8		-12.11 (2.31)		-10.87 (2.30)	-1.23 (3.07)	(-7.29, 4.82)	0.6887			
Week 12		-17.51 (2.51)		-13.68 (2.49)	-3.83 (3.36)	(-10.47, 2.80)	0.2554			
Week 16		-15.33 (2.59)		-14.28 (2.61)	-1.05 (3.52)	(-7.99, 5.88)	0.7646			
Week 20		-16.48 (2.59)		-12.24 (2.62)	-4.24 (3.52)	(-11.20, 2.71)	0.2300			
Week 24		-15.96 (2.61)		-15.86 (2.66)	-0.11 (3.56)	(-7.14, 6.93)	0.9760			
Week 28		-15.68 (2.60)		-12.64 (2.66)	-3.04 (3.56)	(-10.07, 3.99)	0.3946			
Week 32		-19.43 (2.58)		-16.00 (2.66)	-3.43 (3.55)	(-10.43, 3.57)	0.3349			
Week 36		-20.06 (2.66)		-15.91 (2.76)	-4.15 (3.68)	(-11.41, 3.11)	0.2606			
Week 40		-19.96 (2.49)		-16.58 (2.59)	-3.38 (3.43)	(-10.14, 3.39)	0.3257			
Week 44		-22.91 (2.58)		-14.37 (2.69)	-8.55 (3.57)	(-15.59, -1.50)	0.0177			
Week 48		-19.03 (2.55)		-15.11 (2.68)	-3.92 (3.54)	(-10.91, 3.07)	0.2694			
Week 52		-19.15 (2.65)		-14.35 (2.81)	-4.79 (3.71)	(-12.12, 2.53)	0.1979			
OVERALL	99	-17.14 (2.03)	102	-13.60 (2.04)	-3.54 (2.67)	(-8.81, 1.73)	0.1865	-0.17 (0.14)	(-0.45, 0.10)	0.2217

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - PtGA - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) N	LSMean (SE)	Placebo (N=102) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.3262
< 10 points	39	-19.46 (3.16)	40	-18.75 (3.10)	-0.71 (4.30)	(-9.29, 7.86)	0.8689	-0.04 (0.23)	(-0.48, 0.41)	0.8735	
>= 10 points	60	-13.39 (2.61)	62	-7.38 (2.72)	-6.01 (3.26)	(-12.48, 0.46)	0.0682	-0.29 (0.18)	(-0.64, 0.07)	0.1157	
OCS dose											0.6751
<10 mg/day	44	-16.14 (2.88)	38	-10.55 (3.08)	-5.59 (4.12)	(-13.80, 2.62)	0.1793	-0.29 (0.22)	(-0.73, 0.15)	0.1924	
>=10 mg/day	55	-16.75 (2.91)	64	-13.45 (2.89)	-3.31 (3.56)	(-10.36, 3.75)	0.3548	-0.15 (0.18)	(-0.51, 0.21)	0.4262	
Result of type I IFN gene signature test											0.1520
LOW	24	-11.82 (3.55)	26	-14.93 (3.56)	3.11 (5.08)	(-7.12, 13.34)	0.5435	0.17 (0.28)	(-0.38, 0.73)	0.5446	
HIGH	75	-18.02 (2.20)	76	-12.63 (2.30)	-5.39 (3.07)	(-11.46, 0.68)	0.0815	-0.27 (0.16)	(-0.59, 0.05)	0.0941	
Age (years)											0.9416
<= 45	67	-16.49 (2.56)	72	-12.71 (2.53)	-3.78 (3.20)	(-10.11, 2.56)	0.2404	-0.18 (0.17)	(-0.51, 0.16)	0.2985	
> 45	32	-16.26 (3.53)	30	-12.91 (3.78)	-3.35 (4.92)	(-13.21, 6.52)	0.4991	-0.16 (0.25)	(-0.66, 0.34)	0.5234	
Sex											NE
male	6	NE	9	NE	NE	NE		NE	NE		
female	93	-16.65 (2.04)	93	-12.63 (2.08)	-4.02 (2.72)	(-9.39, 1.34)	0.1409	-0.20 (0.15)	(-0.49, 0.09)	0.1701	
Race											NE
White	35	-15.61 (3.13)	41	-15.86 (2.88)	0.25 (4.08)	(-7.89, 8.38)	0.9515	0.01 (0.23)	(-0.44, 0.46)	0.9537	
Black	19	NE	12	NE	NE	NE		NE	NE		
Other	45	-18.68 (3.09)	49	-15.35 (3.23)	-3.33 (4.07)	(-11.44, 4.78)	0.4159	-0.15 (0.21)	(-0.56, 0.25)	0.4621	
Ethnicity											0.4712
Hispanic/Latino	46	-18.26 (3.22)	42	-17.43 (3.55)	-0.84 (4.43)	(-9.67, 7.99)	0.8506	-0.04 (0.21)	(-0.46, 0.38)	0.8621	
Non-hispanic/Latino	53	-15.89 (2.46)	60	-11.15 (2.34)	-4.74 (3.10)	(-10.89, 1.42)	0.1301	-0.26 (0.19)	(-0.63, 0.11)	0.1679	
Geographic region											0.2051
Latin America, Eastern Europe and Asia	62	-19.78 (2.79)	74	-18.11 (2.85)	-1.67 (3.33)	(-8.26, 4.92)	0.6168	-0.07 (0.17)	(-0.41, 0.27)	0.6807	
North America	37	-15.81 (2.90)	28	-7.41 (3.18)	-8.40 (4.14)	(-16.68, -0.11)	0.0471	-0.48 (0.25)	(-0.98, 0.02)	0.0591	
Baseline weight											0.7895
<60 kg	32	-18.10 (3.98)	39	-14.91 (4.00)	-3.20 (5.09)	(-13.37, 6.98)	0.5326	-0.13 (0.24)	(-0.60, 0.34)	0.5796	
>=60 kg	67	-17.07 (2.35)	63	-12.28 (2.37)	-4.79 (3.14)	(-11.00, 1.42)	0.1291	-0.25 (0.18)	(-0.60, 0.10)	0.1554	
Low CH50											0.4928
Yes	13	-20.17 (5.22)	13	-10.20 (8.62)	-9.97 (9.09)	(-29.10, 9.16)	0.2876	-0.38 (0.40)	(-1.15, 0.40)	0.3427	
No	86	-16.66 (2.14)	89	-13.23 (2.14)	-3.43 (2.87)	(-9.10, 2.24)	0.2340	-0.17 (0.15)	(-0.47, 0.13)	0.2598	
Low C3 or C4											0.0943
Yes	33	-21.57 (5.55)	47	-11.80 (4.75)	-9.76 (4.49)	(-18.73, -0.80)	0.0333	-0.30 (0.23)	(-0.75, 0.15)	0.1897	
No	66	-15.24 (2.35)	55	-14.95 (2.63)	-0.29 (3.46)	(-7.13, 6.56)	0.9338	-0.01 (0.18)	(-0.37, 0.34)	0.9354	
Baseline FARR anti-dsDNA											0.6407
<5 IU/mL	21	-19.86 (3.49)	16	-15.45 (3.93)	-4.41 (5.38)	(-15.37, 6.55)	0.4188	-0.27 (0.33)	(-0.93, 0.38)	0.4155	
>=5 IU/mL	56	-15.02 (2.88)	66	-13.61 (2.75)	-1.41 (3.51)	(-8.36, 5.54)	0.6887	-0.06 (0.18)	(-0.42, 0.29)	0.7259	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.7529
Yes	70	-15.87 (2.64)	81	-11.79 (2.50)	-4.08 (3.11)	(-10.22, 2.07)	0.1920	-0.18 (0.16)	(-0.50, 0.14)	0.2668	
No	29	-20.88 (3.55)	21	-18.81 (4.34)	-2.07 (5.57)	(-13.29, 9.16)	0.7123	-0.10 (0.29)	(-0.67, 0.46)	0.7149	
OCS use											0.7481
Yes	79	-16.59 (2.39)	88	-13.36 (2.40)	-3.23 (2.99)	(-9.15, 2.69)	0.2826	-0.15 (0.16)	(-0.45, 0.16)	0.3448	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - PtGA - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) N	LSMean (SE)	Placebo (N=102) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
No	20	-14.01 (4.26)	14	-8.60 (4.56)	-5.41 (6.09)	(-17.84, 7.03)	0.3816	-0.29 (0.35)	(-0.98, 0.40)	0.4092	
SLICC score											0.6499
0	62	-16.67 (2.51)	66	-12.67 (2.61)	-4.01 (3.40)	(-10.74, 2.73)	0.2410	-0.19 (0.18)	(-0.54, 0.15)	0.2729	
>=1	37	-16.55 (3.73)	36	-15.19 (3.61)	-1.36 (4.75)	(-10.85, 8.13)	0.7761	-0.06 (0.23)	(-0.52, 0.40)	0.7962	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Total HAQ Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-0.06 (0.05)		-0.12 (0.05)	0.07 (0.07)	(-0.06, 0.20)	0.3082			
Week 12		-0.17 (0.06)		-0.19 (0.06)	0.02 (0.07)	(-0.13, 0.17)	0.7689			
Week 24		-0.26 (0.06)		-0.23 (0.06)	-0.03 (0.08)	(-0.18, 0.13)	0.7530			
Week 36		-0.26 (0.06)		-0.27 (0.06)	0.01 (0.08)	(-0.16, 0.18)	0.9096			
Week 52		-0.26 (0.06)		-0.28 (0.07)	0.02 (0.09)	(-0.15, 0.19)	0.7932			
OVERALL	99	-0.20 (0.05)	102	-0.22 (0.05)	0.02 (0.06)	(-0.11, 0.15)	0.7659	0.04 (0.14)	(-0.24, 0.32)	0.7812

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Total HAQ Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.9660
< 10 points	39	-0.20 (0.07)	40	-0.22 (0.07)	0.03 (0.10)	(-0.17, 0.22)	0.7983	0.06 (0.23)	(-0.39, 0.50)	0.8036	
>= 10 points	60	-0.17 (0.07)	62	-0.19 (0.07)	0.02 (0.09)	(-0.15, 0.19)	0.8187	0.04 (0.18)	(-0.32, 0.39)	0.8426	
OCS dose											0.3478
<10 mg/day	44	-0.15 (0.07)	38	-0.07 (0.07)	-0.08 (0.10)	(-0.27, 0.11)	0.4174	-0.18 (0.22)	(-0.61, 0.26)	0.4279	
>=10 mg/day	55	-0.30 (0.07)	64	-0.34 (0.07)	0.04 (0.08)	(-0.13, 0.21)	0.6221	0.08 (0.18)	(-0.28, 0.44)	0.6700	
Result of type I IFN gene signature test											0.8474
LOW	24	-0.11 (0.08)	26	-0.12 (0.08)	0.01 (0.12)	(-0.22, 0.24)	0.9205	0.03 (0.28)	(-0.53, 0.58)	0.9213	
HIGH	75	-0.27 (0.05)	76	-0.31 (0.06)	0.04 (0.08)	(-0.11, 0.19)	0.6147	0.08 (0.16)	(-0.24, 0.40)	0.6282	
Age (years)											0.9777
<= 45	67	-0.24 (0.06)	72	-0.24 (0.06)	0.00 (0.07)	(-0.14, 0.15)	0.9472	0.01 (0.17)	(-0.32, 0.34)	0.9530	
> 45	32	-0.15 (0.09)	30	-0.15 (0.10)	0.00 (0.13)	(-0.26, 0.26)	0.9955	0.00 (0.25)	(-0.50, 0.50)	0.9957	
Sex											0.8055
male	6	-0.85 (0.21)	9	-0.82 (0.19)	-0.04 (0.15)	(-0.40, 0.33)	0.8155	-0.06 (0.53)	(-1.10, 0.97)	0.9029	
female	93	-0.21 (0.05)	93	-0.22 (0.05)	0.00 (0.07)	(-0.13, 0.14)	0.9522	0.01 (0.15)	(-0.28, 0.30)	0.9550	
Race											0.5464
White	35	-0.12 (0.07)	41	-0.18 (0.06)	0.07 (0.09)	(-0.11, 0.24)	0.4551	0.16 (0.23)	(-0.29, 0.62)	0.4753	
Black	19	-0.18 (0.17)	12	-0.02 (0.15)	-0.16 (0.19)	(-0.55, 0.23)	0.4006	-0.24 (0.37)	(-0.96, 0.49)	0.5246	
Other	45	-0.30 (0.07)	49	-0.31 (0.08)	0.01 (0.10)	(-0.19, 0.20)	0.9372	0.01 (0.21)	(-0.39, 0.42)	0.9429	
Ethnicity											0.8064
Hispanic/Latino	46	-0.31 (0.08)	42	-0.34 (0.08)	0.03 (0.10)	(-0.18, 0.24)	0.7787	0.06 (0.21)	(-0.36, 0.47)	0.7932	
Non-hispanic/Latino	53	-0.15 (0.06)	60	-0.15 (0.06)	-0.00 (0.08)	(-0.15, 0.15)	0.9773	-0.00 (0.19)	(-0.37, 0.36)	0.9791	
Geographic region											0.0645
Latin America, Eastern Europe and Asia	62	-0.29 (0.07)	74	-0.38 (0.07)	0.09 (0.08)	(-0.07, 0.24)	0.2608	0.16 (0.17)	(-0.18, 0.50)	0.3497	
North America	37	-0.09 (0.06)	28	0.04 (0.07)	-0.13 (0.09)	(-0.31, 0.05)	0.1479	-0.36 (0.25)	(-0.85, 0.14)	0.1595	
Baseline weight											0.1696
<60 kg	32	-0.50 (0.11)	39	-0.35 (0.10)	-0.14 (0.13)	(-0.41, 0.13)	0.2955	-0.22 (0.24)	(-0.69, 0.25)	0.3532	
>=60 kg	67	-0.08 (0.05)	63	-0.14 (0.05)	0.06 (0.06)	(-0.06, 0.18)	0.3235	0.16 (0.18)	(-0.18, 0.51)	0.3513	
Low CH50											0.8218
Yes	13	-0.44 (0.18)	13	-0.40 (0.25)	-0.04 (0.28)	(-0.63, 0.55)	0.8977	-0.05 (0.39)	(-0.81, 0.72)	0.9068	
No	86	-0.19 (0.05)	89	-0.22 (0.05)	0.03 (0.07)	(-0.10, 0.16)	0.6670	0.06 (0.15)	(-0.23, 0.36)	0.6816	
Low C3 or C4											0.8977
Yes	33	-0.31 (0.13)	47	-0.31 (0.11)	0.00 (0.11)	(-0.22, 0.22)	0.9998	0.00 (0.23)	(-0.45, 0.45)	0.9999	
No	66	-0.19 (0.06)	55	-0.21 (0.06)	0.02 (0.08)	(-0.15, 0.18)	0.8298	0.04 (0.18)	(-0.32, 0.40)	0.8332	
Baseline FARR anti-dsDNA											0.0358
<5 IU/mL	21	-0.21 (0.07)	16	-0.02 (0.08)	-0.19 (0.11)	(-0.42, 0.04)	0.0984	-0.56 (0.34)	(-1.23, 0.10)	0.0976	
>=5 IU/mL	56	-0.12 (0.07)	66	-0.22 (0.06)	0.10 (0.08)	(-0.06, 0.25)	0.2219	0.19 (0.18)	(-0.16, 0.55)	0.2872	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.4716
Yes	70	-0.13 (0.06)	81	-0.20 (0.06)	0.07 (0.07)	(-0.08, 0.21)	0.3590	0.13 (0.16)	(-0.19, 0.45)	0.4320	
No	29	-0.36 (0.09)	21	-0.31 (0.11)	-0.05 (0.15)	(-0.35, 0.24)	0.7295	-0.10 (0.29)	(-0.66, 0.46)	0.7324	
OCS use											0.8362
Yes	79	-0.24 (0.06)	88	-0.23 (0.06)	-0.01 (0.07)	(-0.15, 0.14)	0.9431	-0.01 (0.15)	(-0.31, 0.29)	0.9496	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Total HAQ Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) N	LSMean (SE)	Placebo (N=102) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
No	20	-0.06 (0.06)	14	-0.03 (0.07)	-0.03 (0.09)	(-0.22, 0.16)	0.7504	-0.11 (0.35)	(-0.79, 0.58)	0.7613	
SLICC score											0.3998
0	62	-0.24 (0.06)	66	-0.21 (0.06)	-0.02 (0.08)	(-0.19, 0.14)	0.7840	-0.05 (0.18)	(-0.39, 0.30)	0.7985	
>=1	37	-0.14 (0.08)	36	-0.23 (0.08)	0.09 (0.11)	(-0.12, 0.30)	0.3958	0.19 (0.23)	(-0.27, 0.65)	0.4219	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Pain Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)		Placebo (N=102)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 4		-4.00 (2.28)		-3.06 (2.26)	-0.94 (3.03)	(-6.91, 5.03)	0.7561			
Week 12		-11.12 (2.44)		-9.59 (2.40)	-1.54 (3.24)	(-7.94, 4.86)	0.6364			
Week 24		-14.16 (2.58)		-9.53 (2.62)	-4.63 (3.51)	(-11.55, 2.29)	0.1882			
Week 36		-16.55 (2.59)		-13.64 (2.71)	-2.91 (3.59)	(-10.00, 4.18)	0.4192			
Week 52		-16.30 (2.65)		-12.56 (2.80)	-3.75 (3.70)	(-11.05, 3.56)	0.3128			
OVERALL	99	-12.43 (2.04)	102	-9.67 (2.04)	-2.75 (2.68)	(-8.03, 2.53)	0.3050	-0.13 (0.14)	(-0.41, 0.14)	0.3426

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Pain Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) N	LSMean (SE)	Placebo (N=102) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.9568
< 10 points	39	-13.67 (2.66)	40	-10.77 (2.61)	-2.90 (3.62)	(-10.12, 4.33)	0.4269	-0.17 (0.23)	(-0.62, 0.27)	0.4427	
>= 10 points	60	-10.95 (2.93)	62	-8.33 (3.04)	-2.62 (3.66)	(-9.86, 4.63)	0.4758	-0.11 (0.18)	(-0.47, 0.24)	0.5387	
OCS dose											0.6454
<10 mg/day	44	-11.40 (2.97)	38	-7.06 (3.17)	-4.35 (4.24)	(-12.80, 4.10)	0.3089	-0.22 (0.22)	(-0.65, 0.22)	0.3234	
>=10 mg/day	55	-13.28 (2.85)	64	-11.46 (2.81)	-1.83 (3.46)	(-8.68, 5.03)	0.5986	-0.08 (0.18)	(-0.44, 0.28)	0.6521	
Result of type I IFN gene signature test											0.5005
LOW	24	-6.76 (4.13)	26	-7.24 (4.10)	0.48 (5.88)	(-11.40, 12.35)	0.9355	0.02 (0.28)	(-0.53, 0.58)	0.9355	
HIGH	75	-14.40 (2.14)	76	-10.43 (2.24)	-3.97 (2.99)	(-9.88, 1.95)	0.1869	-0.21 (0.16)	(-0.53, 0.11)	0.2041	
Age (years)											0.6128
<= 45	67	-13.28 (2.59)	72	-9.70 (2.55)	-3.58 (3.21)	(-9.93, 2.77)	0.2668	-0.17 (0.17)	(-0.50, 0.17)	0.3288	
> 45	32	-9.04 (3.55)	30	-8.44 (3.71)	-0.60 (4.93)	(-10.53, 9.32)	0.9033	-0.03 (0.25)	(-0.53, 0.47)	0.9077	
Sex											0.8025
male	6	0.91 (15.40)	9	1.00 (12.36)	-0.09 (12.08)	(-29.05, 28.86)	0.9942	-0.00 (0.53)	(-1.04, 1.03)	0.9965	
female	93	-13.26 (2.09)	93	-10.07 (2.13)	-3.19 (2.79)	(-8.71, 2.32)	0.2549	-0.16 (0.15)	(-0.44, 0.13)	0.2881	
Race											0.4918
White	35	-4.83 (3.38)	41	-6.58 (3.10)	1.75 (4.38)	(-6.99, 10.49)	0.6904	0.09 (0.23)	(-0.36, 0.54)	0.7053	
Black	19	-8.69 (7.06)	12	-3.54 (6.52)	-5.15 (7.95)	(-21.46, 11.16)	0.5223	-0.18 (0.37)	(-0.90, 0.54)	0.6271	
Other	45	-18.83 (2.76)	49	-14.14 (2.87)	-4.68 (3.61)	(-11.85, 2.49)	0.1979	-0.24 (0.21)	(-0.65, 0.17)	0.2475	
Ethnicity											0.9529
Hispanic/Latino	46	-15.76 (2.97)	42	-13.63 (3.30)	-2.12 (4.11)	(-10.31, 6.06)	0.6067	-0.10 (0.21)	(-0.52, 0.32)	0.6344	
Non-hispanic/Latino	53	-8.48 (2.68)	60	-6.67 (2.54)	-1.81 (3.40)	(-8.55, 4.93)	0.5952	-0.09 (0.19)	(-0.46, 0.28)	0.6266	
Geographic region											0.9701
Latin America, Eastern Europe and Asia	62	-16.30 (2.59)	74	-12.78 (2.65)	-3.51 (3.07)	(-9.59, 2.56)	0.2546	-0.16 (0.17)	(-0.50, 0.18)	0.3517	
North America	37	-8.67 (3.69)	28	-4.92 (4.05)	-3.74 (5.33)	(-14.43, 6.94)	0.4854	-0.17 (0.25)	(-0.66, 0.32)	0.5030	
Baseline weight											0.5304
<60 kg	32	-16.81 (4.10)	39	-14.95 (4.01)	-1.86 (5.17)	(-12.18, 8.46)	0.7197	-0.08 (0.24)	(-0.54, 0.39)	0.7499	
>=60 kg	67	-11.58 (2.26)	63	-5.96 (2.28)	-5.62 (3.04)	(-11.65, 0.40)	0.0669	-0.31 (0.18)	(-0.65, 0.04)	0.0836	
Low CH50											0.6843
Yes	13	-23.45 (4.75)	13	-23.24 (7.37)	-0.21 (8.08)	(-17.10, 16.67)	0.9791	-0.01 (0.39)	(-0.78, 0.76)	0.9811	
No	86	-11.68 (2.11)	89	-7.98 (2.10)	-3.70 (2.83)	(-9.29, 1.90)	0.1936	-0.19 (0.15)	(-0.48, 0.11)	0.2175	
Low C3 or C4											0.2998
Yes	33	-16.57 (5.16)	47	-9.32 (4.42)	-7.25 (4.23)	(-15.70, 1.19)	0.0911	-0.24 (0.23)	(-0.69, 0.21)	0.2939	
No	66	-9.52 (2.37)	55	-7.94 (2.63)	-1.58 (3.47)	(-8.46, 5.29)	0.6491	-0.08 (0.18)	(-0.44, 0.28)	0.6566	
Baseline FARR anti-dsDNA											0.1300
<5 IU/mL	21	-11.00 (3.43)	16	-2.31 (3.86)	-8.69 (5.23)	(-19.42, 2.03)	0.1080	-0.55 (0.34)	(-1.21, 0.12)	0.1071	
>=5 IU/mL	56	-10.72 (2.82)	66	-11.47 (2.69)	0.74 (3.38)	(-5.96, 7.45)	0.8266	0.03 (0.18)	(-0.32, 0.39)	0.8502	
Low complement (C3 or C4) and positive FARR anti-dsDNA											0.8292
Yes	70	-12.73 (2.60)	81	-10.19 (2.45)	-2.54 (3.03)	(-8.53, 3.44)	0.4023	-0.12 (0.16)	(-0.44, 0.20)	0.4802	
No	29	-14.05 (3.95)	21	-10.02 (4.87)	-4.03 (6.20)	(-16.51, 8.45)	0.5187	-0.18 (0.29)	(-0.75, 0.38)	0.5243	
OCS use											0.4507
Yes	79	-12.90 (2.35)	88	-9.21 (2.34)	-3.70 (2.93)	(-9.49, 2.09)	0.2090	-0.17 (0.16)	(-0.48, 0.13)	0.2695	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Pain Score - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) N	LSMean (SE)	Placebo (N=102) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
No	20	-6.72 (4.46)	14	-8.36 (4.91)	1.65 (6.45)	(-11.61, 14.90)	0.8006	0.08 (0.35)	(-0.60, 0.77)	0.8116	
SLICC score											0.0677
0	62	-14.85 (2.59)	66	-8.23 (2.67)	-6.62 (3.49)	(-13.52, 0.28)	0.0598	-0.31 (0.18)	(-0.66, 0.04)	0.0793	
>=1	37	-8.95 (3.38)	36	-12.47 (3.28)	3.53 (4.33)	(-5.11, 12.17)	0.4178	0.17 (0.23)	(-0.29, 0.63)	0.4598	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SLEDAI-2K Total Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Visit	Anifrolumab 300mg (N=99) n/ N#	Compliance	Placebo (N=102) n/ N#	Compliance
Baseline	99/ 99	100.0%	102/ 102	100.0%
Week 4	97/ 99	97.98%	100/ 102	98.04%
Week 8	94/ 99	94.95%	96/ 102	94.12%
Week 12	93/ 99	93.94%	95/ 102	93.14%
Week 16	91/ 99	91.92%	88/ 102	86.27%
Week 20	94/ 99	94.95%	89/ 102	87.25%
Week 24	91/ 99	91.92%	83/ 102	81.37%
Week 28	91/ 99	91.92%	82/ 102	80.39%
Week 32	90/ 99	90.91%	79/ 102	77.45%
Week 36	89/ 99	89.90%	75/ 102	73.53%
Week 40	87/ 99	87.88%	76/ 102	74.51%
Week 44	90/ 99	90.91%	73/ 102	71.57%
Week 48	87/ 99	87.88%	72/ 102	70.59%
Week 52	87/ 99	87.88%	69/ 102	67.65%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - PGA
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Visit	Anifrolumab 300mg (N=99) n/ N#	Compliance	Placebo (N=102) n/ N#	Compliance
Baseline	99/ 99	100.0%	102/ 102	100.0%
Week 4	96/ 99	96.97%	100/ 102	98.04%
Week 8	93/ 99	93.94%	96/ 102	94.12%
Week 12	93/ 99	93.94%	95/ 102	93.14%
Week 16	92/ 99	92.93%	88/ 102	86.27%
Week 20	94/ 99	94.95%	89/ 102	87.25%
Week 24	91/ 99	91.92%	83/ 102	81.37%
Week 28	91/ 99	91.92%	82/ 102	80.39%
Week 32	90/ 99	90.91%	79/ 102	77.45%
Week 36	89/ 99	89.90%	75/ 102	73.53%
Week 40	87/ 99	87.88%	76/ 102	74.51%
Week 44	90/ 99	90.91%	73/ 102	71.57%
Week 48	87/ 99	87.88%	72/ 102	70.59%
Week 52	87/ 99	87.88%	69/ 102	67.65%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - CLASI Total Activity Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Visit	Anifrolumab 300mg (N=99) n/ N#	Compliance	Placebo (N=102) n/ N#	Compliance
Baseline	99/ 99	100.0%	102/ 102	100.0%
Week 4	97/ 99	97.98%	100/ 102	98.04%
Week 8	94/ 99	94.95%	96/ 102	94.12%
Week 12	93/ 99	93.94%	95/ 102	93.14%
Week 16	91/ 99	91.92%	88/ 102	86.27%
Week 20	94/ 99	94.95%	89/ 102	87.25%
Week 24	91/ 99	91.92%	83/ 102	81.37%
Week 28	91/ 99	91.92%	82/ 102	80.39%
Week 32	90/ 99	90.91%	79/ 102	77.45%
Week 36	89/ 99	89.90%	75/ 102	73.53%
Week 40	87/ 99	87.88%	76/ 102	74.51%
Week 44	90/ 99	90.91%	73/ 102	71.57%
Week 48	87/ 99	87.88%	72/ 102	70.59%
Week 52	87/ 99	87.88%	69/ 102	67.65%

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Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - CLASI Total Damage Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Visit	Anifrolumab 300mg (N=99) n/ N#	Compliance	Placebo (N=102) n/ N#	Compliance
Baseline	99/ 99	100.0%	102/ 102	100.0%
Week 4	97/ 99	97.98%	100/ 102	98.04%
Week 8	94/ 99	94.95%	96/ 102	94.12%
Week 12	93/ 99	93.94%	95/ 102	93.14%
Week 16	91/ 99	91.92%	88/ 102	86.27%
Week 20	94/ 99	94.95%	89/ 102	87.25%
Week 24	91/ 99	91.92%	83/ 102	81.37%
Week 28	91/ 99	91.92%	82/ 102	80.39%
Week 32	90/ 99	90.91%	79/ 102	77.45%
Week 36	89/ 99	89.90%	75/ 102	73.53%
Week 40	87/ 99	87.88%	76/ 102	74.51%
Week 44	90/ 99	90.91%	73/ 102	71.57%
Week 48	87/ 99	87.88%	72/ 102	70.59%
Week 52	87/ 99	87.88%	69/ 102	67.65%

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Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - BILAG Global Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Visit	Anifrolumab 300mg (N=99) n/ N#	Compliance	Placebo (N=102) n/ N#	Compliance
Baseline	99/ 99	100.0%	102/ 102	100.0%
Week 4	99/ 99	100.0%	102/ 102	100.0%
Week 8	99/ 99	100.0%	99/ 102	97.06%
Week 12	95/ 99	95.96%	97/ 102	95.10%
Week 16	94/ 99	94.95%	92/ 102	90.20%
Week 20	94/ 99	94.95%	89/ 102	87.25%
Week 24	94/ 99	94.95%	86/ 102	84.31%
Week 28	94/ 99	94.95%	84/ 102	82.35%
Week 32	92/ 99	92.93%	80/ 102	78.43%
Week 36	92/ 99	92.93%	77/ 102	75.49%
Week 40	91/ 99	91.92%	76/ 102	74.51%
Week 44	91/ 99	91.92%	74/ 102	72.55%
Week 48	88/ 99	88.89%	73/ 102	71.57%
Week 52	87/ 99	87.88%	69/ 102	67.65%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Tender Joint Count
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Visit	Anifrolumab 300mg (N=99) n/ N#	Compliance	Placebo (N=102) n/ N#	Compliance
Baseline	99/ 99	100.0%	102/ 102	100.0%
Week 4	97/ 99	97.98%	100/ 102	98.04%
Week 8	94/ 99	94.95%	96/ 102	94.12%
Week 12	93/ 99	93.94%	95/ 102	93.14%
Week 16	91/ 99	91.92%	88/ 102	86.27%
Week 20	94/ 99	94.95%	89/ 102	87.25%
Week 24	91/ 99	91.92%	83/ 102	81.37%
Week 28	91/ 99	91.92%	82/ 102	80.39%
Week 32	90/ 99	90.91%	79/ 102	77.45%
Week 36	89/ 99	89.90%	75/ 102	73.53%
Week 40	87/ 99	87.88%	76/ 102	74.51%
Week 44	90/ 99	90.91%	73/ 102	71.57%
Week 48	87/ 99	87.88%	72/ 102	70.59%
Week 52	87/ 99	87.88%	69/ 102	67.65%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Swollen Joint Count
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Visit	Anifrolumab 300mg (N=99) n/ N#	Compliance	Placebo (N=102) n/ N#	Compliance
Baseline	99/ 99	100.0%	102/ 102	100.0%
Week 4	97/ 99	97.98%	100/ 102	98.04%
Week 8	94/ 99	94.95%	96/ 102	94.12%
Week 12	93/ 99	93.94%	95/ 102	93.14%
Week 16	91/ 99	91.92%	88/ 102	86.27%
Week 20	94/ 99	94.95%	89/ 102	87.25%
Week 24	91/ 99	91.92%	83/ 102	81.37%
Week 28	91/ 99	91.92%	82/ 102	80.39%
Week 32	90/ 99	90.91%	79/ 102	77.45%
Week 36	89/ 99	89.90%	75/ 102	73.53%
Week 40	87/ 99	87.88%	76/ 102	74.51%
Week 44	90/ 99	90.91%	73/ 102	71.57%
Week 48	87/ 99	87.88%	72/ 102	70.59%
Week 52	87/ 99	87.88%	69/ 102	67.65%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute Mental Component Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Visit	Anifrolumab 300mg (N=99) n/ N#	Compliance	Placebo (N=102) n/ N#	Compliance
Baseline	99/ 99	100.0%	102/ 102	100.0%
Week 4	98/ 99	98.99%	99/ 102	97.06%
Week 12	94/ 99	94.95%	97/ 102	95.10%
Week 24	93/ 99	93.94%	87/ 102	85.29%
Week 36	90/ 99	90.91%	74/ 102	72.55%
Week 52	88/ 99	88.89%	70/ 102	68.63%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute Physical Component Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Visit	Anifrolumab 300mg (N=99) n/ N#	Compliance	Placebo (N=102) n/ N#	Compliance
Baseline	99/ 99	100.0%	102/ 102	100.0%
Week 4	98/ 99	98.99%	99/ 102	97.06%
Week 12	94/ 99	94.95%	97/ 102	95.10%
Week 24	93/ 99	93.94%	87/ 102	85.29%
Week 36	90/ 99	90.91%	74/ 102	72.55%
Week 52	88/ 99	88.89%	70/ 102	68.63%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute General Health Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Visit	Anifrolumab 300mg (N=99) n/ N#	Compliance	Placebo (N=102) n/ N#	Compliance
Baseline	99/ 99	100.0%	102/ 102	100.0%
Week 4	98/ 99	98.99%	99/ 102	97.06%
Week 12	94/ 99	94.95%	97/ 102	95.10%
Week 24	93/ 99	93.94%	87/ 102	85.29%
Week 36	90/ 99	90.91%	74/ 102	72.55%
Week 52	88/ 99	88.89%	70/ 102	68.63%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute Mental Health Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Visit	Anifrolumab 300mg (N=99) n/ N#	Compliance	Placebo (N=102) n/ N#	Compliance
Baseline	99/ 99	100.0%	102/ 102	100.0%
Week 4	98/ 99	98.99%	99/ 102	97.06%
Week 12	94/ 99	94.95%	97/ 102	95.10%
Week 24	93/ 99	93.94%	87/ 102	85.29%
Week 36	90/ 99	90.91%	74/ 102	72.55%
Week 52	88/ 99	88.89%	70/ 102	68.63%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute Physical Functioning Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Visit	Anifrolumab 300mg (N=99) n/ N#	Compliance	Placebo (N=102) n/ N#	Compliance
Baseline	99/ 99	100.0%	102/ 102	100.0%
Week 4	98/ 99	98.99%	99/ 102	97.06%
Week 12	94/ 99	94.95%	97/ 102	95.10%
Week 24	93/ 99	93.94%	87/ 102	85.29%
Week 36	90/ 99	90.91%	74/ 102	72.55%
Week 52	88/ 99	88.89%	70/ 102	68.63%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute Role Emotional Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Visit	Anifrolumab 300mg (N=99) n/ N#	Compliance	Placebo (N=102) n/ N#	Compliance
Baseline	99/ 99	100.0%	102/ 102	100.0%
Week 4	98/ 99	98.99%	99/ 102	97.06%
Week 12	94/ 99	94.95%	97/ 102	95.10%
Week 24	93/ 99	93.94%	87/ 102	85.29%
Week 36	90/ 99	90.91%	74/ 102	72.55%
Week 52	88/ 99	88.89%	70/ 102	68.63%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute Role Physical Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)			Placebo (N=102)		
Visit	n/	N#	Compliance	n/	N#	Compliance
Baseline	99/	99	100.0%	102/	102	100.0%
Week 4	98/	99	98.99%	99/	102	97.06%
Week 12	94/	99	94.95%	97/	102	95.10%
Week 24	93/	99	93.94%	87/	102	85.29%
Week 36	90/	99	90.91%	74/	102	72.55%
Week 52	88/	99	88.89%	70/	102	68.63%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute Social Functioning Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Visit	Anifrolumab 300mg (N=99) n/ N#	Compliance	Placebo (N=102) n/ N#	Compliance
Baseline	99/ 99	100.0%	102/ 102	100.0%
Week 4	98/ 99	98.99%	99/ 102	97.06%
Week 12	94/ 99	94.95%	97/ 102	95.10%
Week 24	93/ 99	93.94%	87/ 102	85.29%
Week 36	90/ 99	90.91%	74/ 102	72.55%
Week 52	88/ 99	88.89%	70/ 102	68.63%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute Bodily Pain Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Visit	Anifrolumab 300mg (N=99) n/ N#	Compliance	Placebo (N=102) n/ N#	Compliance
Baseline	99/ 99	100.0%	102/ 102	100.0%
Week 4	98/ 99	98.99%	99/ 102	97.06%
Week 12	94/ 99	94.95%	97/ 102	95.10%
Week 24	93/ 99	93.94%	87/ 102	85.29%
Week 36	90/ 99	90.91%	74/ 102	72.55%
Week 52	88/ 99	88.89%	70/ 102	68.63%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute Vitality Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Visit	Anifrolumab 300mg (N=99) n/ N#	Anifrolumab 300mg (N=99) Compliance	Placebo (N=102) n/ N#	Placebo (N=102) Compliance
Baseline	99/ 99	100.0%	102/ 102	100.0%
Week 4	98/ 99	98.99%	99/ 102	97.06%
Week 12	94/ 99	94.95%	97/ 102	95.10%
Week 24	93/ 99	93.94%	87/ 102	85.29%
Week 36	90/ 99	90.91%	74/ 102	72.55%
Week 52	88/ 99	88.89%	70/ 102	68.63%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - FACIT-F Total Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Visit	Anifrolumab 300mg (N=99) n/ N#	Compliance	Placebo (N=102) n/ N#	Compliance
Baseline	99/ 99	100.0%	102/ 102	100.0%
Week 4	98/ 99	98.99%	99/ 102	97.06%
Week 12	94/ 99	94.95%	96/ 102	94.12%
Week 24	93/ 99	93.94%	87/ 102	85.29%
Week 36	90/ 99	90.91%	75/ 102	73.53%
Week 52	88/ 99	88.89%	70/ 102	68.63%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - EQ VAS Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Visit	Anifrolumab 300mg (N=99) n/ N#	Anifrolumab 300mg (N=99) Compliance	Placebo (N=102) n/ N#	Placebo (N=102) Compliance
Baseline	98/ 99	98.99%	102/ 102	100.0%
Week 4	98/ 99	98.99%	99/ 102	97.06%
Week 12	94/ 99	94.95%	96/ 102	94.12%
Week 24	93/ 99	93.94%	87/ 102	85.29%
Week 36	90/ 99	90.91%	74/ 102	72.55%
Week 52	88/ 99	88.89%	70/ 102	68.63%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Lupus QoL Physical Health domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Visit	Anifrolumab 300mg (N=99) n/ N#	Anifrolumab 300mg (N=99) Compliance	Placebo (N=102) n/ N#	Placebo (N=102) Compliance
Baseline	98/ 99	98.99%	100/ 102	98.04%
Week 4	97/ 99	97.98%	98/ 102	96.08%
Week 12	94/ 99	94.95%	97/ 102	95.10%
Week 24	93/ 99	93.94%	87/ 102	85.29%
Week 36	90/ 99	90.91%	75/ 102	73.53%
Week 52	88/ 99	88.89%	70/ 102	68.63%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Lupus QoL Emotional Health domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Visit	Anifrolumab 300mg (N=99) n/ N#	Compliance	Placebo (N=102) n/ N#	Compliance
Baseline	98/ 99	98.99%	100/ 102	98.04%
Week 4	97/ 99	97.98%	98/ 102	96.08%
Week 12	94/ 99	94.95%	97/ 102	95.10%
Week 24	93/ 99	93.94%	87/ 102	85.29%
Week 36	90/ 99	90.91%	75/ 102	73.53%
Week 52	88/ 99	88.89%	70/ 102	68.63%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Lupus QoL Body Image domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Visit	Anifrolumab 300mg (N=99) n/ N#	Compliance	Placebo (N=102) n/ N#	Compliance
Baseline	95/ 99	95.96%	91/ 102	89.22%
Week 4	90/ 99	90.91%	89/ 102	87.25%
Week 12	90/ 99	90.91%	90/ 102	88.24%
Week 24	84/ 99	84.85%	79/ 102	77.45%
Week 36	84/ 99	84.85%	63/ 102	61.76%
Week 52	80/ 99	80.81%	57/ 102	55.88%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Lupus QoL Burden to Others domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Visit	Anifrolumab 300mg (N=99) n/ N#	Anifrolumab 300mg (N=99) Compliance	Placebo (N=102) n/ N#	Placebo (N=102) Compliance
Baseline	98/ 99	98.99%	100/ 102	98.04%
Week 4	97/ 99	97.98%	98/ 102	96.08%
Week 12	94/ 99	94.95%	97/ 102	95.10%
Week 24	93/ 99	93.94%	87/ 102	85.29%
Week 36	90/ 99	90.91%	75/ 102	73.53%
Week 52	88/ 99	88.89%	70/ 102	68.63%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Lupus QoL Fatigue domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Visit	Anifrolumab 300mg (N=99) n/ N#	Compliance	Placebo (N=102) n/ N#	Compliance
Baseline	98/ 99	98.99%	100/ 102	98.04%
Week 4	97/ 99	97.98%	98/ 102	96.08%
Week 12	94/ 99	94.95%	97/ 102	95.10%
Week 24	93/ 99	93.94%	87/ 102	85.29%
Week 36	90/ 99	90.91%	75/ 102	73.53%
Week 52	88/ 99	88.89%	70/ 102	68.63%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Lupus QoL Intimate Relationships domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Visit	Anifrolumab 300mg (N=99) n/ N#	Compliance	Placebo (N=102) n/ N#	Compliance
Baseline	87/ 99	87.88%	82/ 102	80.39%
Week 4	85/ 99	85.86%	77/ 102	75.49%
Week 12	79/ 99	79.80%	82/ 102	80.39%
Week 24	78/ 99	78.79%	71/ 102	69.61%
Week 36	71/ 99	71.72%	55/ 102	53.92%
Week 52	71/ 99	71.72%	52/ 102	50.98%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Lupus QoL Pain domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Visit	Anifrolumab 300mg (N=99) n/ N#	Compliance	Placebo (N=102) n/ N#	Compliance
Baseline	98/ 99	98.99%	100/ 102	98.04%
Week 4	97/ 99	97.98%	98/ 102	96.08%
Week 12	94/ 99	94.95%	97/ 102	95.10%
Week 24	93/ 99	93.94%	87/ 102	85.29%
Week 36	90/ 99	90.91%	75/ 102	73.53%
Week 52	88/ 99	88.89%	70/ 102	68.63%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Lupus QoL Planning domain score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Visit	Anifrolumab 300mg (N=99) n/ N#	Compliance	Placebo (N=102) n/ N#	Compliance
Baseline	98/ 99	98.99%	100/ 102	98.04%
Week 4	97/ 99	97.98%	98/ 102	96.08%
Week 12	94/ 99	94.95%	97/ 102	95.10%
Week 24	93/ 99	93.94%	87/ 102	85.29%
Week 36	90/ 99	90.91%	75/ 102	73.53%
Week 52	88/ 99	88.89%	70/ 102	68.63%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SDI Global Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Visit	Anifrolumab 300mg (N=99) n/ N#	Anifrolumab 300mg (N=99) Compliance	Placebo (N=102) n/ N#	Placebo (N=102) Compliance
Baseline	99/ 99	100.0%	102/ 102	100.0%
Week 24	93/ 99	93.94%	87/ 102	85.29%
Week 52	87/ 99	87.88%	70/ 102	68.63%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - PtGA
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Visit	Anifrolumab 300mg (N=99) n/ N#	Compliance	Placebo (N=102) n/ N#	Compliance
Baseline	99/ 99	100.0%	102/ 102	100.0%
Week 4	97/ 99	97.98%	99/ 102	97.06%
Week 8	94/ 99	94.95%	95/ 102	93.14%
Week 12	93/ 99	93.94%	95/ 102	93.14%
Week 16	92/ 99	92.93%	88/ 102	86.27%
Week 20	93/ 99	93.94%	89/ 102	87.25%
Week 24	91/ 99	91.92%	83/ 102	81.37%
Week 28	91/ 99	91.92%	82/ 102	80.39%
Week 32	90/ 99	90.91%	79/ 102	77.45%
Week 36	89/ 99	89.90%	75/ 102	73.53%
Week 40	88/ 99	88.89%	76/ 102	74.51%
Week 44	90/ 99	90.91%	73/ 102	71.57%
Week 48	87/ 99	87.88%	72/ 102	70.59%
Week 52	87/ 99	87.88%	69/ 102	67.65%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Total HAQ Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Visit	Anifrolumab 300mg (N=99) n/ N#	Compliance	Placebo (N=102) n/ N#	Compliance
Baseline	99/ 99	100.0%	102/ 102	100.0%
Week 4	98/ 99	98.99%	99/ 102	97.06%
Week 12	94/ 99	94.95%	97/ 102	95.10%
Week 24	93/ 99	93.94%	87/ 102	85.29%
Week 36	90/ 99	90.91%	75/ 102	73.53%
Week 52	88/ 99	88.89%	70/ 102	68.63%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Pain Score
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Visit	Anifrolumab 300mg (N=99) n/ N#	Compliance	Placebo (N=102) n/ N#	Compliance
Baseline	99/ 99	100.0%	102/ 102	100.0%
Week 4	98/ 99	98.99%	99/ 102	97.06%
Week 12	94/ 99	94.95%	97/ 102	95.10%
Week 24	93/ 99	93.94%	87/ 102	85.29%
Week 36	90/ 99	90.91%	75/ 102	73.53%
Week 52	88/ 99	88.89%	70/ 102	68.63%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Flare rate through Week 52
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) Number of flares	Anifrolumab 300mg (N=99) Total Follow-up time (years)	Anifrolumab 300mg (N=99) Annual rate (SE)	Placebo (N=102) Number of flares	Placebo (N=102) Total Follow-up time (years)	Placebo (N=102) Annual rate (SE)	Rate ratio (95% CI)	p-Value	Interaction p-Value
Overall	50	93.83	0.42 (0.21)	61	85.10	0.58 (0.21)	0.73 (0.44, 1.20)	0.2149	
SLEDAI-2K score									0.8430
< 10 points	16	36.42	0.39 (0.34)	21	35.31	0.56 (0.34)	0.69 (0.28, 1.70)	0.4226	
>= 10 points	34	57.41	0.35 (0.33)	40	49.79	0.49 (0.33)	0.71 (0.39, 1.30)	0.2691	
OCS dose									0.7337
<10 mg/day	23	40.68	0.51 (0.29)	28	30.55	0.77 (0.30)	0.66 (0.30, 1.41)	0.2819	
>=10 mg/day	27	53.15	0.29 (0.35)	33	54.55	0.37 (0.35)	0.79 (0.41, 1.53)	0.4821	
Result of type I IFN gene signature test									0.0072
LOW	12	22.92	NE	3	22.20	NE	NE		
HIGH	38	70.90	0.49 (0.22)	58	62.91	0.92 (0.19)	0.53 (0.31, 0.91)	0.0217	
Age (years)									0.6744
<= 45	36	64.70	0.43 (0.25)	42	60.54	0.58 (0.25)	0.74 (0.42, 1.30)	0.2930	
> 45	14	29.13	0.37 (0.42)	19	24.56	0.64 (0.42)	0.59 (0.21, 1.68)	0.3227	
Sex									0.6661
male	3	6.11	NE	7	8.84	NE	NE		
female	47	87.72	0.44 (0.22)	54	76.27	0.58 (0.23)	0.76 (0.44, 1.30)	0.3099	
Race									0.2776
White	21	32.08	0.62 (0.29)	24	35.31	0.59 (0.29)	1.06 (0.49, 2.27)	0.8835	
Black	9	18.09	0.00 (85267.27)	14	10.48	0.00 (85267.27)	0.24 (0.10, 0.60)	0.0022	
Other	20	43.66	0.38 (0.35)	23	39.32	0.49 (0.37)	0.76 (0.34, 1.71)	0.5058	
Ethnicity									0.2450
Hispanic/Latino	23	44.73	0.44 (0.32)	15	36.15	0.38 (0.39)	1.17 (0.49, 2.79)	0.7289	
Non-hispanic/Latino	27	49.10	0.40 (0.28)	46	48.96	0.68 (0.26)	0.59 (0.32, 1.09)	0.0921	
Geographic region									0.7615
Latin America, Eastern Europe and Asia	30	59.28	0.33 (0.33)	40	62.15	0.44 (0.34)	0.76 (0.41, 1.42)	0.3947	
North America	20	34.55	0.45 (0.33)	21	22.96	0.73 (0.34)	0.63 (0.26, 1.48)	0.2882	
Baseline weight									0.1563
<60 kg	16	30.68	0.47 (0.33)	29	29.33	0.92 (0.32)	0.51 (0.24, 1.11)	0.0904	
>=60 kg	34	63.15	0.39 (0.27)	32	55.77	0.39 (0.29)	1.01 (0.52, 1.96)	0.9702	
Low CH50									0.6911
Yes	9	11.30	0.76 (0.39)	13	10.63	1.14 (0.51)	0.66 (0.22, 2.02)	0.4680	
No	41	82.53	0.42 (0.23)	48	74.47	0.55 (0.23)	0.77 (0.43, 1.37)	0.3741	
Low C3 or C4									0.8234
Yes	25	30.59	0.00 (50557.08)	39	37.29	0.00 (50557.08)	0.68 (0.35, 1.32)	0.2535	
No	25	63.24	0.35 (0.26)	22	47.81	0.44 (0.29)	0.80 (0.38, 1.68)	0.5597	
Baseline FARR anti-dsDNA									0.0949
<5 IU/mL	12	19.49	0.47 (0.40)	3	13.95	0.18 (0.64)	2.67 (0.65, 10.95)	0.1719	
>=5 IU/mL	26	53.22	0.31 (0.33)	43	55.22	0.52 (0.30)	0.60 (0.32, 1.12)	0.1096	
Low complement (C3 or C4) and positive FARR anti-dsDNA									0.1717
Yes	38	66.19	0.31 (0.31)	56	66.75	0.50 (0.29)	0.63 (0.36, 1.09)	0.1013	
No	12	27.64	0.38 (0.34)	5	18.35	0.21 (0.53)	1.83 (0.59, 5.70)	0.2983	
OCS use									0.5651

Rates and rate ratio from negative binomial regression model with factors for treatment group and the stratification factors. The logarithm (to base e) of the follow-up time is used as an offset variable in the model to adjust for subjects having different exposure times.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Flare rate through Week 52
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) Number of flares	Anifrolumab 300mg (N=99) Total Follow-up time (years)	Anifrolumab 300mg (N=99) Annual rate (SE)	Placebo (N=102) Number of flares	Placebo (N=102) Total Follow-up time (years)	Placebo (N=102) Annual rate (SE)	Rate ratio (95% CI)	p-Value	Interaction p-Value
Yes	43	76.16	0.41 (0.25)	50	72.39	0.53 (0.25)	0.78 (0.46, 1.34)	0.3723	
No	7	17.67	0.40 (0.53)	11	12.72	0.85 (0.53)	0.47 (0.11, 1.97)	0.3005	
SLICC score									0.4297
0	31	60.13	0.34 (0.29)	30	54.60	0.40 (0.30)	0.85 (0.44, 1.62)	0.6175	
>=1	19	33.70	0.51 (0.33)	31	30.51	0.99 (0.33)	0.51 (0.22, 1.18)	0.1172	

Rates and rate ratio from negative binomial regression model with factors for treatment group and the stratification factors. The logarithm (to base e) of the follow-up time is used as an offset variable in the model to adjust for subjects having different exposure times.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Overall Survival
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)	Placebo (N=102)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	99 (100.0)	102 (100.0)
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Anifrolumab 300mg vs. Placebo (adjusted)		
Hazard Ratio (95% CI)	NE	
p-value		
Analysis Anifrolumab 300mg vs. Placebo (unadjusted)		
Hazard Ratio (95% CI)	NE	
p-value		

Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model. Adjusted analysis also includes stratification factors in the model.
Two-sided log rank test used.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Overall Survival - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Anifrolumab 300mg (N=99) Median (95% CI)	Placebo (N=102) n/ N (%)	Placebo (N=102) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score							NE
< 10 points	0/ 39 (0.0)	NE (NE, NE)	0/ 40 (0.0)	NE (NE, NE)	NE		
>= 10 points	0/ 60 (0.0)	NE (NE, NE)	0/ 62 (0.0)	NE (NE, NE)	NE		
OCS dose							NE
<10 mg/day	0/ 44 (0.0)	NE (NE, NE)	0/ 38 (0.0)	NE (NE, NE)	NE		
>=10 mg/day	0/ 55 (0.0)	NE (NE, NE)	0/ 64 (0.0)	NE (NE, NE)	NE		
Result of type I IFN gene signature test							NE
LOW	0/ 24 (0.0)	NE (NE, NE)	0/ 26 (0.0)	NE (NE, NE)	NE		
HIGH	0/ 75 (0.0)	NE (NE, NE)	0/ 76 (0.0)	NE (NE, NE)	NE		
Age (years)							NE
<= 45	0/ 67 (0.0)	NE (NE, NE)	0/ 72 (0.0)	NE (NE, NE)	NE		
> 45	0/ 32 (0.0)	NE (NE, NE)	0/ 30 (0.0)	NE (NE, NE)	NE		
Sex							NE
male	0/ 6 (0.0)	NE (NE, NE)	0/ 9 (0.0)	NE (NE, NE)	NE		
female	0/ 93 (0.0)	NE (NE, NE)	0/ 93 (0.0)	NE (NE, NE)	NE		
Race							NE
White	0/ 35 (0.0)	NE (NE, NE)	0/ 41 (0.0)	NE (NE, NE)	NE		
Black	0/ 19 (0.0)	NE (NE, NE)	0/ 12 (0.0)	NE (NE, NE)	NE		
Other	0/ 45 (0.0)	NE (NE, NE)	0/ 49 (0.0)	NE (NE, NE)	NE		
Ethnicity							NE
Hispanic/Latino	0/ 46 (0.0)	NE (NE, NE)	0/ 42 (0.0)	NE (NE, NE)	NE		
Non-hispanic/Latino	0/ 53 (0.0)	NE (NE, NE)	0/ 60 (0.0)	NE (NE, NE)	NE		
Geographic region							NE
Latin America, Eastern Europe and Asia	0/ 62 (0.0)	NE (NE, NE)	0/ 74 (0.0)	NE (NE, NE)	NE		
North America	0/ 37 (0.0)	NE (NE, NE)	0/ 28 (0.0)	NE (NE, NE)	NE		
Baseline weight							NE
<60 kg	0/ 32 (0.0)	NE (NE, NE)	0/ 39 (0.0)	NE (NE, NE)	NE		
>=60 kg	0/ 67 (0.0)	NE (NE, NE)	0/ 63 (0.0)	NE (NE, NE)	NE		
Low CH50							NE
Yes	0/ 13 (0.0)	NE (NE, NE)	0/ 13 (0.0)	NE (NE, NE)	NE		
No	0/ 86 (0.0)	NE (NE, NE)	0/ 89 (0.0)	NE (NE, NE)	NE		
Low C3 or C4							NE
Yes	0/ 33 (0.0)	NE (NE, NE)	0/ 47 (0.0)	NE (NE, NE)	NE		
No	0/ 66 (0.0)	NE (NE, NE)	0/ 55 (0.0)	NE (NE, NE)	NE		
Baseline FARR anti-dsDNA							NE
<5 IU/mL	0/ 21 (0.0)	NE (NE, NE)	0/ 16 (0.0)	NE (NE, NE)	NE		
>=5 IU/mL	0/ 56 (0.0)	NE (NE, NE)	0/ 66 (0.0)	NE (NE, NE)	NE		
Low complement (C3 or C4) and positive FARR anti-dsDNA							NE
Yes	0/ 70 (0.0)	NE (NE, NE)	0/ 81 (0.0)	NE (NE, NE)	NE		
No	0/ 29 (0.0)	NE (NE, NE)	0/ 21 (0.0)	NE (NE, NE)	NE		
OCS use							NE
Yes	0/ 79 (0.0)	NE (NE, NE)	0/ 88 (0.0)	NE (NE, NE)	NE		
No	0/ 20 (0.0)	NE (NE, NE)	0/ 14 (0.0)	NE (NE, NE)	NE		

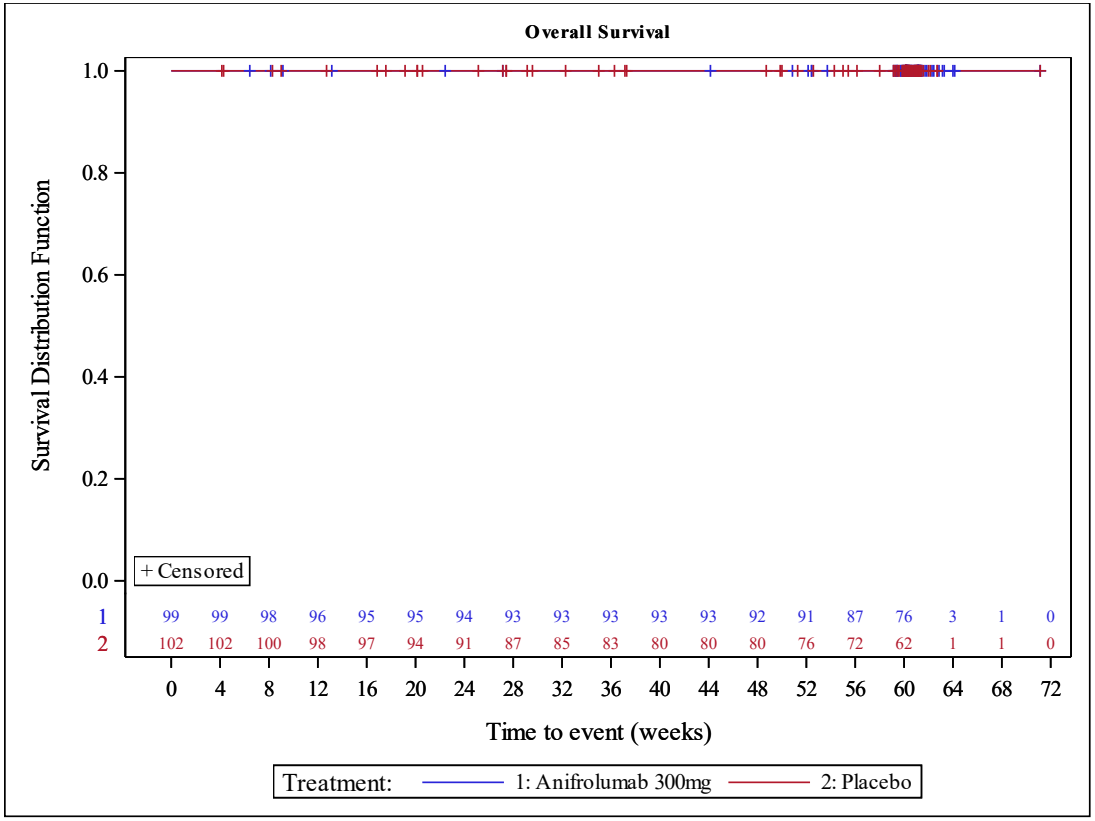
Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Overall Survival - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Anifrolumab 300mg (N=99) Median (95% CI)	Placebo (N=102) n/ N (%)	Placebo (N=102) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLICC score							NE
0	0/ 62 (0.0)	NE (NE, NE)	0/ 66 (0.0)	NE (NE, NE)	NE		
>=1	0/ 37 (0.0)	NE (NE, NE)	0/ 36 (0.0)	NE (NE, NE)	NE		

Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Overall Survival
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Time to first Flare
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

	Anifrolumab 300mg (N=99)	Placebo (N=102)
Number of subjects with events, n (%)	30 (30.3)	36 (35.3)
Number of censored subjects, n (%)	69 (69.7)	66 (64.7)
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	32.00 (16.29, NE)	21.14 (16.86, 30.00)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Anifrolumab 300mg vs. Placebo (adjusted)		
Hazard Ratio (95% CI)	0.72 (0.44, 1.18)	
p-value	0.2581	
Analysis Anifrolumab 300mg vs. Placebo (unadjusted)		
Hazard Ratio (95% CI)	0.78 (0.48, 1.27)	
p-value	0.3121	

Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model. Adjusted analysis also includes stratification factors in the model.
Two-sided log rank test used.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Time to first Flare - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Anifrolumab 300mg (N=99) Median (95% CI)	Placebo (N=102) n/ N (%)	Placebo (N=102) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score							0.7723
< 10 points	9/ 39 (23.1)	NE (NE, NE)	13/ 40 (32.5)	NE (40.14, NE)	0.68 (0.29, 1.61)	0.3581	
>= 10 points	21/ 60 (35.0)	NE (45.14, NE)	23/ 62 (37.1)	NE (28.00, NE)	0.78 (0.43, 1.43)	0.4636	
OCS dose							0.9025
<10 mg/day	14/ 44 (31.8)	NE (44.00, NE)	13/ 38 (34.2)	NE (24.14, NE)	0.74 (0.34, 1.61)	0.4188	
>=10 mg/day	16/ 55 (29.1)	NE (NE, NE)	23/ 64 (35.9)	NE (37.00, NE)	0.76 (0.40, 1.43)	0.4227	
Result of type I IFN gene signature test							0.0397
LOW	7/ 24 (29.2)	NE (35.29, NE)	3/ 26 (11.5)	NE (NE, NE)	2.93 (0.75, 11.44)	0.1124	
HIGH	23/ 75 (30.7)	NE (NE, NE)	33/ 76 (43.4)	NE (28.00, NE)	0.58 (0.34, 1.00)	0.0563	
Age (years)							0.8447
<= 45	22/ 67 (32.8)	NE (NE, NE)	27/ 72 (37.5)	NE (33.14, NE)	0.67 (0.38, 1.19)	0.1994	
> 45	8/ 32 (25.0)	NE (NE, NE)	9/ 30 (30.0)	NE (24.14, NE)	0.78 (0.30, 2.02)	0.8964	
Sex							0.3431
male	3/ 6 (50.0)	NE (4.14, NE)	4/ 9 (44.4)	NE (8.14, NE)	6.19 (0.72, 52.92)	0.2593	
female	27/ 93 (29.0)	NE (NE, NE)	32/ 93 (34.4)	NE (NE, NE)	0.69 (0.41, 1.15)	0.1793	
Race							0.8229
White	12/ 35 (34.3)	NE (35.29, NE)	15/ 41 (36.6)	NE (24.14, NE)	0.84 (0.39, 1.83)	0.6325	
Black	6/ 19 (31.6)	NE (24.14, NE)	5/ 12 (41.7)	NE (12.14, NE)	0.30 (0.08, 1.17)	0.1387	
Other	12/ 45 (26.7)	NE (NE, NE)	16/ 49 (32.7)	NE (31.43, NE)	0.73 (0.34, 1.57)	0.5623	
Ethnicity							0.2979
Hispanic/Latino	14/ 46 (30.4)	NE (NE, NE)	12/ 42 (28.6)	NE (NE, NE)	1.11 (0.51, 2.41)	0.6558	
Non-hispanic/Latino	16/ 53 (30.2)	NE (NE, NE)	24/ 60 (40.0)	NE (28.00, NE)	0.55 (0.29, 1.05)	0.0916	
Geographic region							0.8566
Latin America, Eastern Europe and Asia	18/ 62 (29.0)	NE (NE, NE)	27/ 74 (36.5)	NE (37.00, NE)	0.72 (0.39, 1.31)	0.4125	
North America	12/ 37 (32.4)	NE (39.57, NE)	9/ 28 (32.1)	NE (33.14, NE)	0.55 (0.21, 1.49)	0.3763	
Baseline weight							0.0193
<60 kg	9/ 32 (28.1)	NE (NE, NE)	20/ 39 (51.3)	31.43 (20.14, NE)	0.37 (0.16, 0.83)	0.0234	
>=60 kg	21/ 67 (31.3)	NE (NE, NE)	16/ 63 (25.4)	NE (NE, NE)	1.25 (0.65, 2.42)	0.4518	
Low CH50							0.6886
Yes	6/ 13 (46.2)	44.14 (8.14, NE)	7/ 13 (53.8)	26.07 (8.43, NE)	1.22 (0.36, 4.19)	0.7595	
No	24/ 86 (27.9)	NE (NE, NE)	29/ 89 (32.6)	NE (NE, NE)	0.72 (0.42, 1.25)	0.2786	
Low C3 or C4							0.9643
Yes	14/ 33 (42.4)	NE (16.29, NE)	21/ 47 (44.7)	37.00 (21.14, NE)	0.79 (0.40, 1.58)	0.5001	
No	16/ 66 (24.2)	NE (NE, NE)	15/ 55 (27.3)	NE (NE, NE)	0.79 (0.38, 1.61)	0.4991	
Baseline FARR anti-dsDNA							0.2319
<5 IU/mL	7/ 21 (33.3)	NE (16.29, NE)	3/ 16 (18.8)	NE (24.14, NE)	2.13 (0.50, 9.05)	0.0718	
>=5 IU/mL	16/ 56 (28.6)	NE (NE, NE)	24/ 66 (36.4)	NE (30.00, NE)	0.61 (0.32, 1.16)	0.1443	
Low complement (C3 or C4) and positive FARR anti-dsDNA							0.3860
Yes	22/ 70 (31.4)	NE (NE, NE)	31/ 81 (38.3)	NE (30.00, NE)	0.65 (0.37, 1.13)	0.1587	
No	8/ 29 (27.6)	NE (24.71, NE)	5/ 21 (23.8)	NE (40.14, NE)	1.62 (0.51, 5.13)	0.4324	
OCS use							0.3273
Yes	26/ 79 (32.9)	NE (NE, NE)	31/ 88 (35.2)	NE (NE, NE)	0.81 (0.48, 1.37)	0.5373	
No	4/ 20 (20.0)	NE (44.00, NE)	5/ 14 (35.7)	NE (16.86, NE)	0.49 (0.12, 1.97)	0.3430	

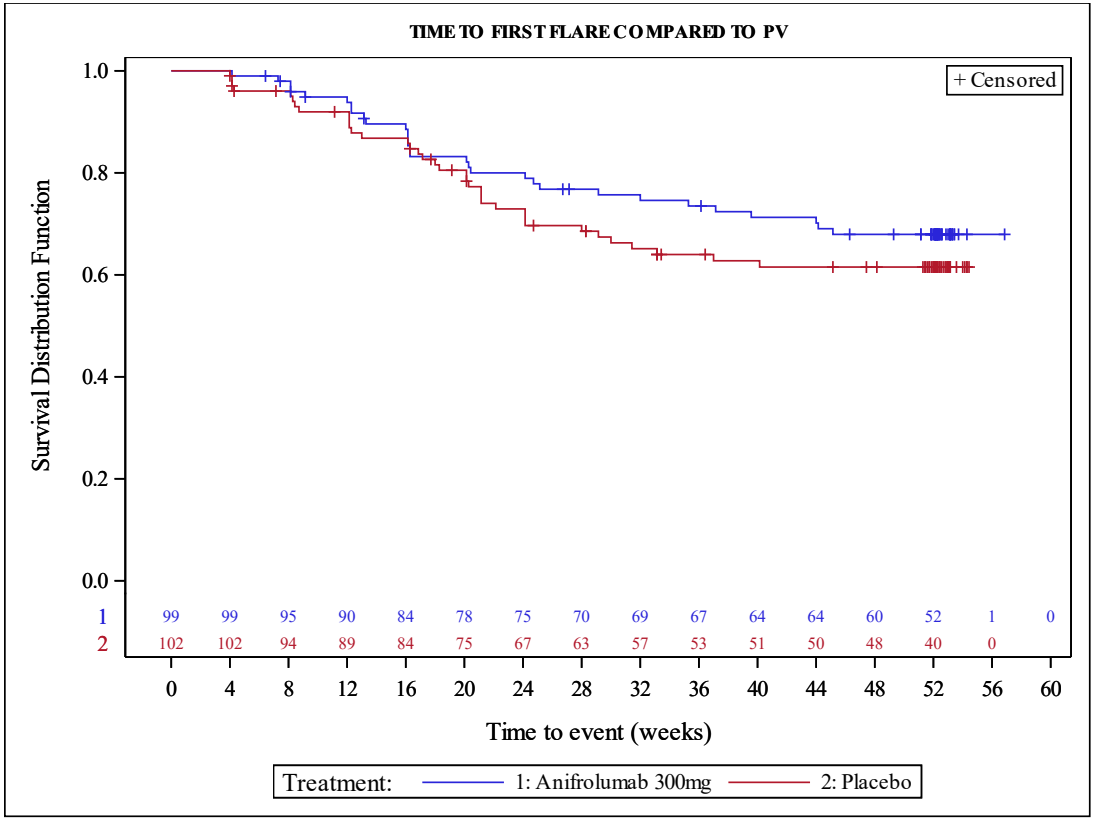
Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Time to first Flare - Subgroup analysis
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Anifrolumab 300mg (N=99) Median (95% CI)	Placebo (N=102) n/ N (%)	Placebo (N=102) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLICC score							0.9029
0	18/ 62 (29.0)	NE (NE, NE)	23/ 66 (34.8)	NE (37.00, NE)	0.73 (0.39, 1.38)	0.4827	
>=1	12/ 37 (32.4)	NE (44.14, NE)	13/ 36 (36.1)	NE (21.14, NE)	0.74 (0.33, 1.66)	0.5051	

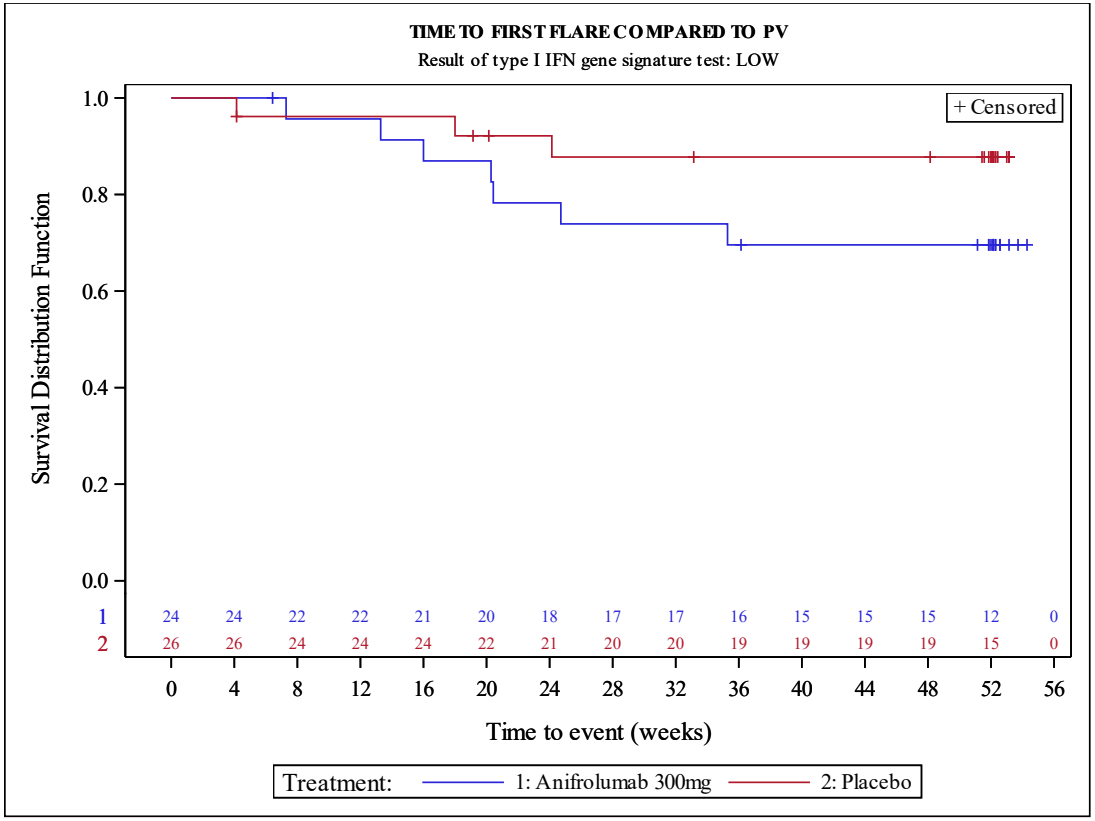
Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Time to first Flare
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)



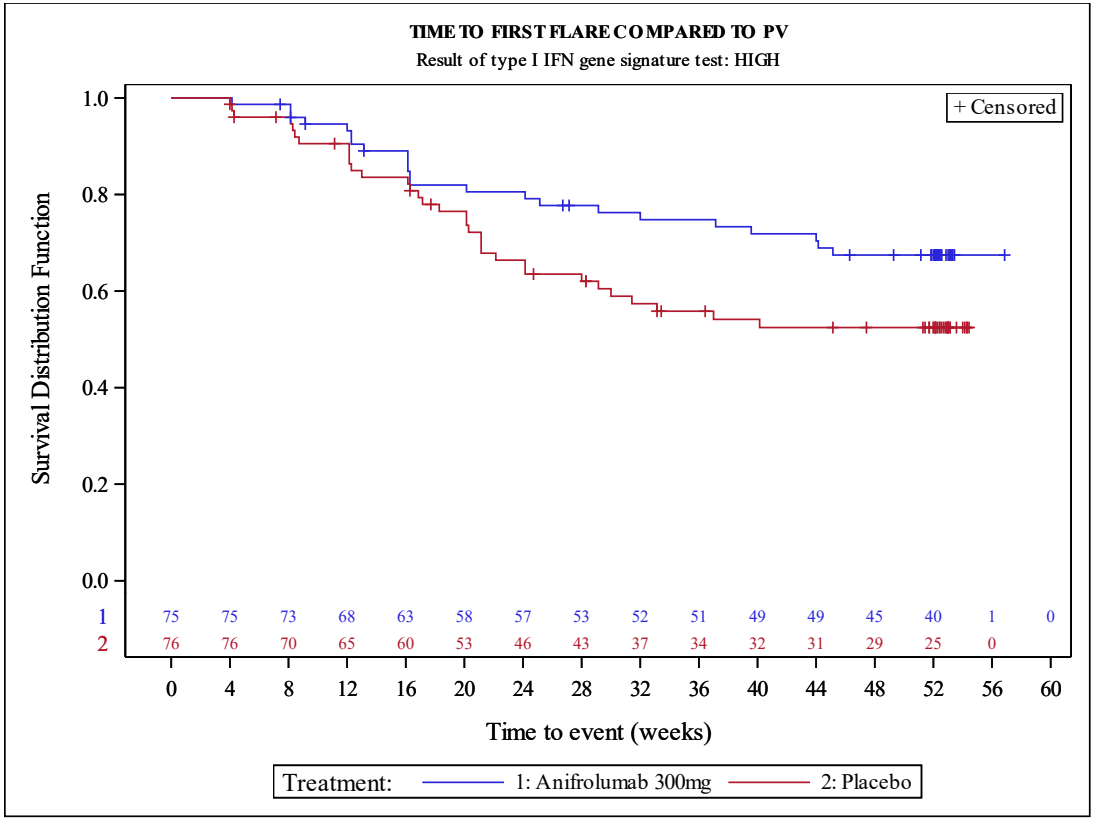
Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Time to first Flare
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)



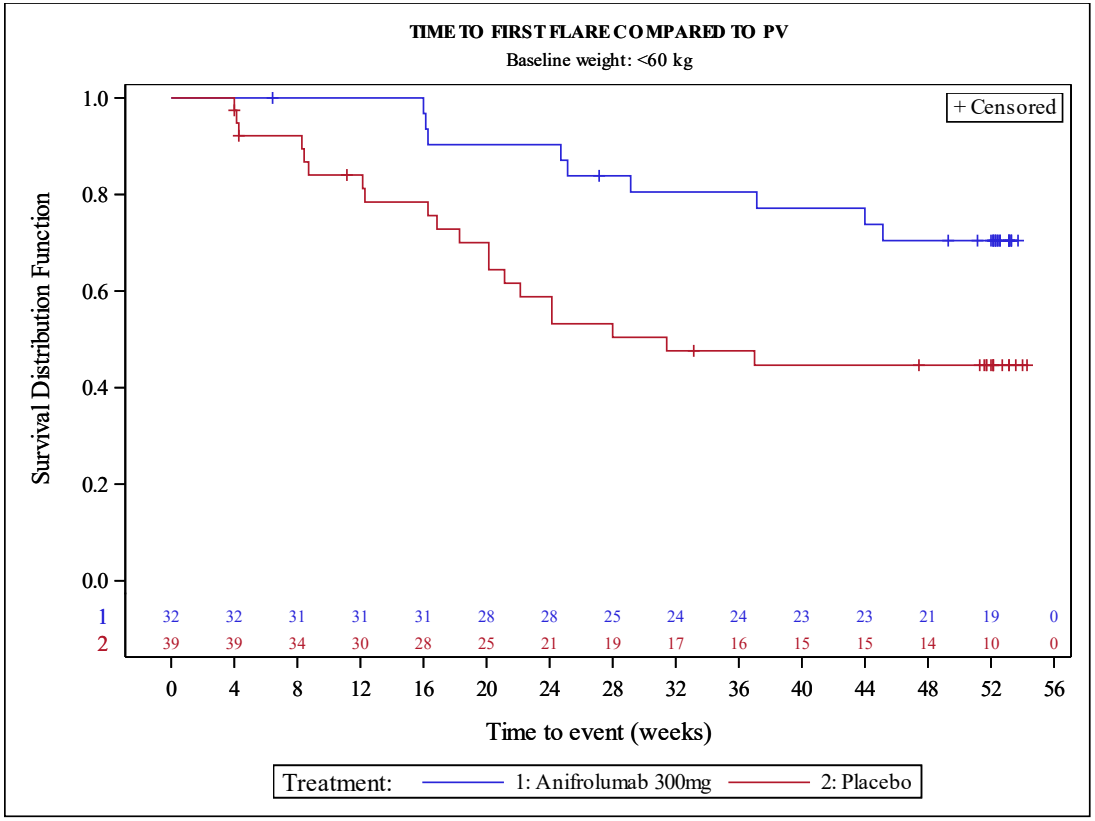
Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Time to first Flare
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)



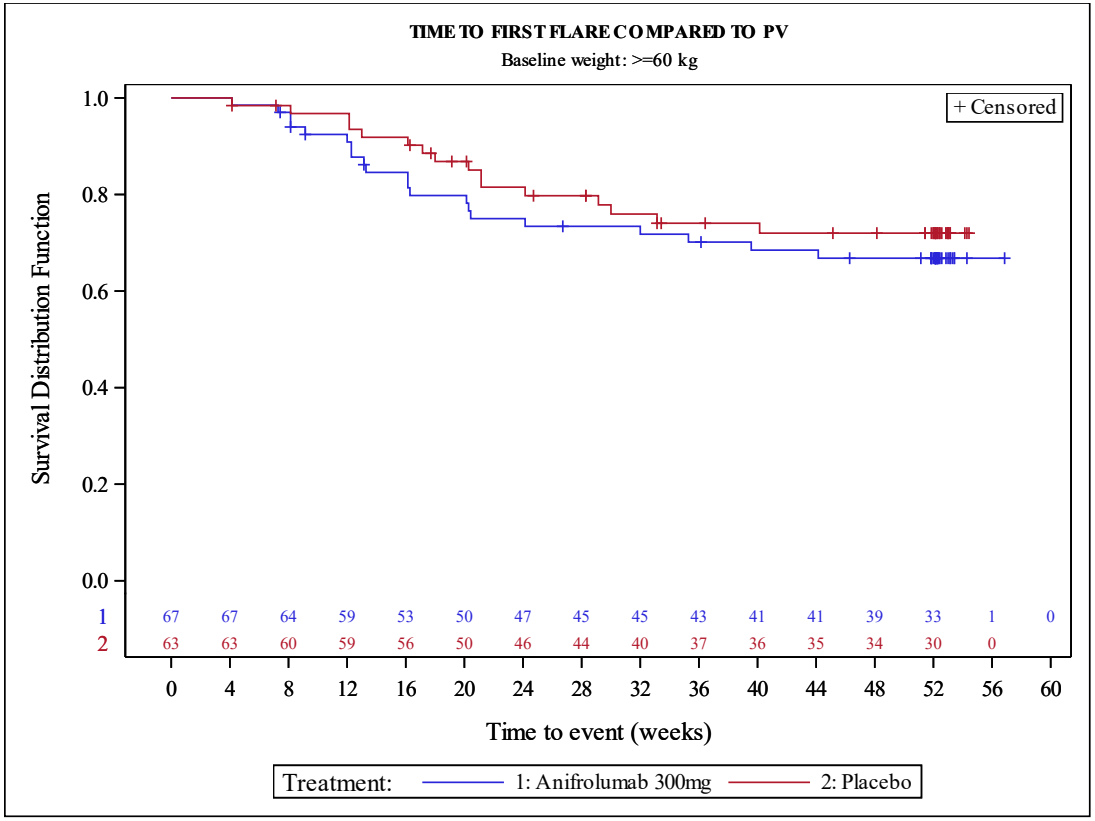
Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Time to first Flare
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Time to first Flare
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
OCS dose increases and cumulative OCS dose until week 52
Full analysis set (referred to as a 'modified Intent-to-treat' population in study CSR)

		Anifrolumab 300mg (N=99)	Placebo (N=102)	Total (N=201)
Number of dose increases (%)	0	81 (81.8)	79 (77.5)	160 (79.6)
	1	12 (12.1)	15 (14.7)	27 (13.4)
	2	4 (4.0)	5 (4.9)	9 (4.5)
	>2	2 (2.0)	3 (2.9)	5 (2.5)
Cumulative OCS Dose (mg/day)	n (missing)	86 (13)	91 (11)	177 (24)
	Mean (SD)	2991.1 (1713.46)	3537.9 (2371.63)	3272.2 (2090.28)
	Median	2732.5	3142.5	2845.0
	Min, Max	84, 7480	100, 10581	84, 10581
AUC up to Week 52 (mg/day)	n (missing)	86 (13)	91 (11)	177 (24)
	Mean (SD)	3345.2 (2102.16)	4290.8 (3228.02)	3831.4 (2772.60)
	Median	2809.9	3640.0	3229.8
	Min, Max	130, 12858	141, 21809	130, 21809

Subjects without any documented dose value regarded as missing values for calculation of cumulative dose and AUC.
AUC defines the cumulative dose normalized for a period of 52 weeks.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event
Safety analysis set

	Anifrolumab 300mg (N=99)	Placebo (N=101)
Number of subjects with events, n (%)	84 (84.8)	78 (77.2)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.10 (0.96, 1.26)	
p-value	0.1709	
Odds Ratio (95% CI)	1.65 (0.80, 3.39)	
p-value	0.1720	
Risk Difference (95% CI)	7.62 (-3.19, 18.43)	
p-value	0.1669	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	 p-Value	Interaction p-Value
SLEDAI-2K score					0.3036
< 10 points	34/ 39 (87.2)	29/ 40 (72.5)	1.20 (0.96, 1.51)	0.1092	
>= 10 points	50/ 60 (83.3)	49/ 61 (80.3)	1.04 (0.88, 1.23)	0.6683	
OCS dose					0.0892
<10 mg/day	34/ 44 (77.3)	30/ 37 (81.1)	0.95 (0.76, 1.19)	0.6730	
>=10 mg/day	50/ 55 (90.9)	48/ 64 (75.0)	1.21 (1.03, 1.43)	0.0217	
Result of type I IFN gene signature test					0.1142
LOW	23/ 24 (95.8)	19/ 26 (73.1)	1.31 (1.02, 1.68)	0.0320	
HIGH	61/ 75 (81.3)	59/ 75 (78.7)	1.03 (0.88, 1.21)	0.6833	
Age (years)					0.6861
<= 45	57/ 67 (85.1)	54/ 71 (76.1)	1.12 (0.95, 1.32)	0.1821	
> 45	27/ 32 (84.4)	24/ 30 (80.0)	1.05 (0.84, 1.33)	0.6541	
Sex					0.1721
male	6/ 6 (100.0)	6/ 9 (66.7)	1.50 (0.95, 2.38)	0.0854	
female	78/ 93 (83.9)	72/ 92 (78.3)	1.07 (0.93, 1.23)	0.3317	
Race					0.6179
White	29/ 35 (82.9)	33/ 41 (80.5)	1.03 (0.83, 1.27)	0.7896	
Black	16/ 19 (84.2)	9/ 11 (81.8)	1.03 (0.73, 1.45)	0.8680	
Other	39/ 45 (86.7)	36/ 49 (73.5)	1.18 (0.96, 1.45)	0.1117	
Ethnicity					0.0237
Hispanic/Latino	39/ 46 (84.8)	26/ 42 (61.9)	1.37 (1.05, 1.79)	0.0210	
Non-hispanic/Latino	45/ 53 (84.9)	52/ 59 (88.1)	0.96 (0.83, 1.12)	0.6190	
Geographic region					0.0700
Latin America, Eastern Europe and Asia	55/ 62 (88.7)	55/ 74 (74.3)	1.19 (1.02, 1.40)	0.0309	
North America	29/ 37 (78.4)	23/ 27 (85.2)	0.92 (0.73, 1.16)	0.4799	
Baseline weight					0.9908
<60 kg	28/ 32 (87.5)	31/ 39 (79.5)	1.10 (0.90, 1.35)	0.3616	
>=60 kg	56/ 67 (83.6)	47/ 62 (75.8)	1.10 (0.92, 1.31)	0.2773	
Low CH50					0.5116
Yes	12/ 13 (92.3)	9/ 12 (75.0)	1.23 (0.86, 1.77)	0.2614	
No	72/ 86 (83.7)	69/ 89 (77.5)	1.08 (0.93, 1.25)	0.3009	
Low C3 or C4					0.3273
Yes	30/ 33 (90.9)	35/ 46 (76.1)	1.19 (0.98, 1.45)	0.0731	
No	54/ 66 (81.8)	43/ 55 (78.2)	1.05 (0.87, 1.25)	0.6207	
Baseline FARR anti-dsDNA					0.4241
<5 IU/mL	16/ 21 (76.2)	13/ 16 (81.3)	0.94 (0.67, 1.31)	0.7072	
>=5 IU/mL	48/ 56 (85.7)	51/ 65 (78.5)	1.09 (0.93, 1.29)	0.2974	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.1350
Yes	61/ 70 (87.1)	60/ 80 (75.0)	1.16 (0.99, 1.36)	0.0582	
No	23/ 29 (79.3)	18/ 21 (85.7)	0.93 (0.72, 1.19)	0.5507	
OCS use					0.1370
Yes	69/ 79 (87.3)	66/ 87 (75.9)	1.15 (1.00, 1.33)	0.0572	
No	15/ 20 (75.0)	12/ 14 (85.7)	0.88 (0.63, 1.22)	0.4295	
SLICC score					0.5609
0	52/ 62 (83.9)	49/ 66 (74.2)	1.13 (0.94, 1.35)	0.1823	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
>=1	32/ 37 (86.5)	29/ 35 (82.9)	1.04 (0.86, 1.27)	0.6702	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Serious Adverse Event
Safety analysis set

	Anifrolumab 300mg (N=99)	Placebo (N=101)
Number of subjects with events, n (%)	16 (16.2)	19 (18.8)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.86 (0.47, 1.57)	
p-value	0.6225	
Odds Ratio (95% CI)	0.83 (0.40, 1.73)	
p-value	0.6222	
Risk Difference (95% CI)	-2.65 (-13.17, 7.87)	
p-value	0.6215	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Serious Adverse Event - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.4539
< 10 points	5/ 39 (12.8)	4/ 40 (10.0)	1.28 (0.37, 4.42)	0.6942	
>= 10 points	11/ 60 (18.3)	15/ 61 (24.6)	0.75 (0.37, 1.49)	0.4053	
OCS dose					0.7594
<10 mg/day	7/ 44 (15.9)	6/ 37 (16.2)	0.98 (0.36, 2.66)	0.9701	
>=10 mg/day	9/ 55 (16.4)	13/ 64 (20.3)	0.81 (0.37, 1.74)	0.5820	
Result of type I IFN gene signature test					0.1970
LOW	3/ 24 (12.5)	1/ 26 (3.8)	3.25 (0.36, 29.16)	0.2924	
HIGH	13/ 75 (17.3)	18/ 75 (24.0)	0.72 (0.38, 1.37)	0.3171	
Age (years)					0.3183
<= 45	9/ 67 (13.4)	14/ 71 (19.7)	0.68 (0.32, 1.47)	0.3273	
> 45	7/ 32 (21.9)	5/ 30 (16.7)	1.31 (0.47, 3.69)	0.6062	
Sex					0.6575
male	1/ 6 (16.7)	1/ 9 (11.1)	1.50 (0.11, 19.64)	0.7573	
female	15/ 93 (16.1)	18/ 92 (19.6)	0.82 (0.44, 1.53)	0.5426	
Race					0.6014
White	3/ 35 (8.6)	7/ 41 (17.1)	0.50 (0.14, 1.80)	0.2895	
Black	4/ 19 (21.1)	3/ 11 (27.3)	0.77 (0.21, 2.83)	0.6963	
Other	9/ 45 (20.0)	9/ 49 (18.4)	1.09 (0.47, 2.50)	0.8407	
Ethnicity					0.0973
Hispanic/Latino	10/ 46 (21.7)	6/ 42 (14.3)	1.52 (0.61, 3.82)	0.3719	
Non-hispanic/Latino	6/ 53 (11.3)	13/ 59 (22.0)	0.51 (0.21, 1.26)	0.1440	
Geographic region					0.6094
Latin America, Eastern Europe and Asia	11/ 62 (17.7)	16/ 74 (21.6)	0.82 (0.41, 1.64)	0.5740	
North America	5/ 37 (13.5)	3/ 27 (11.1)	1.22 (0.32, 4.66)	0.7751	
Baseline weight					0.1989
<60 kg	5/ 32 (15.6)	11/ 39 (28.2)	0.55 (0.21, 1.43)	0.2221	
>=60 kg	11/ 67 (16.4)	8/ 62 (12.9)	1.27 (0.55, 2.96)	0.5753	
Low CH50					0.7255
Yes	3/ 13 (23.1)	4/ 12 (33.3)	0.69 (0.19, 2.48)	0.5718	
No	13/ 86 (15.1)	15/ 89 (16.9)	0.90 (0.45, 1.77)	0.7542	
Low C3 or C4					0.5045
Yes	8/ 33 (24.2)	10/ 46 (21.7)	1.12 (0.49, 2.52)	0.7933	
No	8/ 66 (12.1)	9/ 55 (16.4)	0.74 (0.31, 1.79)	0.5051	
Baseline FARR anti-dsDNA					0.9500
<5 IU/mL	2/ 21 (9.5)	2/ 16 (12.5)	0.76 (0.12, 4.84)	0.7731	
>=5 IU/mL	8/ 56 (14.3)	13/ 65 (20.0)	0.71 (0.32, 1.60)	0.4126	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.7658
Yes	13/ 70 (18.6)	16/ 80 (20.0)	0.93 (0.48, 1.79)	0.8252	
No	3/ 29 (10.3)	3/ 21 (14.3)	0.72 (0.16, 3.24)	0.6729	
OCS use					0.8079
Yes	13/ 79 (16.5)	17/ 87 (19.5)	0.84 (0.44, 1.62)	0.6070	
No	3/ 20 (15.0)	2/ 14 (14.3)	1.05 (0.20, 5.49)	0.9539	
SLICC score					0.1572
0	7/ 62 (11.3)	13/ 66 (19.7)	0.57 (0.24, 1.34)	0.1999	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Serious Adverse Event - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
>=1	9/ 37 (24.3)	6/ 35 (17.1)	1.42 (0.56, 3.57)	0.4579	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Severe Adverse Event
Safety analysis set

	Anifrolumab 300mg (N=99)	Placebo (N=101)
Number of subjects with events, n (%)	19 (19.2)	12 (11.9)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.62 (0.83, 3.15)	
p-value	0.1591	
Odds Ratio (95% CI)	1.76 (0.80, 3.86)	
p-value	0.1566	
Risk Difference (95% CI)	7.31 (-2.69, 17.31)	
p-value	0.1519	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Severe Adverse Event - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.0590
< 10 points	8/ 39 (20.5)	1/ 40 (2.5)	8.21 (1.08, 62.57)	0.0423	
>= 10 points	11/ 60 (18.3)	11/ 61 (18.0)	1.02 (0.48, 2.17)	0.9658	
OCS dose					0.1126
<10 mg/day	8/ 44 (18.2)	1/ 37 (2.7)	6.73 (0.88, 51.34)	0.0660	
>=10 mg/day	11/ 55 (20.0)	11/ 64 (17.2)	1.16 (0.55, 2.47)	0.6936	
Result of type I IFN gene signature test					0.1204
LOW	5/ 24 (20.8)	0/ 26 (0.0)	11.88 (0.69, 204.05)	0.0880	
HIGH	14/ 75 (18.7)	12/ 75 (16.0)	1.17 (0.58, 2.35)	0.6667	
Age (years)					0.8782
<= 45	11/ 67 (16.4)	7/ 71 (9.9)	1.67 (0.69, 4.04)	0.2597	
> 45	8/ 32 (25.0)	5/ 30 (16.7)	1.50 (0.55, 4.08)	0.4269	
Sex					0.5058
male	1/ 6 (16.7)	0/ 9 (0.0)	4.29 (0.20, 90.62)	0.3499	
female	18/ 93 (19.4)	12/ 92 (13.0)	1.48 (0.76, 2.90)	0.2491	
Race					0.2808
White	5/ 35 (14.3)	7/ 41 (17.1)	0.84 (0.29, 2.40)	0.7406	
Black	6/ 19 (31.6)	0/ 11 (0.0)	7.80 (0.48, 126.48)	0.1484	
Other	8/ 45 (17.8)	5/ 49 (10.2)	1.74 (0.61, 4.94)	0.2961	
Ethnicity					0.7231
Hispanic/Latino	10/ 46 (21.7)	5/ 42 (11.9)	1.83 (0.68, 4.91)	0.2326	
Non-hispanic/Latino	9/ 53 (17.0)	7/ 59 (11.9)	1.43 (0.57, 3.58)	0.4427	
Geographic region					0.1792
Latin America, Eastern Europe and Asia	13/ 62 (21.0)	12/ 74 (16.2)	1.29 (0.64, 2.63)	0.4771	
North America	6/ 37 (16.2)	0/ 27 (0.0)	9.58 (0.56, 163.09)	0.1182	
Baseline weight					0.7011
<60 kg	7/ 32 (21.9)	6/ 39 (15.4)	1.42 (0.53, 3.81)	0.4838	
>=60 kg	12/ 67 (17.9)	6/ 62 (9.7)	1.85 (0.74, 4.63)	0.1883	
Low CH50					0.6571
Yes	4/ 13 (30.8)	3/ 12 (25.0)	1.23 (0.34, 4.40)	0.7496	
No	15/ 86 (17.4)	9/ 89 (10.1)	1.72 (0.80, 3.73)	0.1661	
Low C3 or C4					0.4844
Yes	8/ 33 (24.2)	8/ 46 (17.4)	1.39 (0.58, 3.33)	0.4554	
No	11/ 66 (16.7)	4/ 55 (7.3)	2.29 (0.77, 6.80)	0.1348	
Baseline FARR anti-dsDNA					0.9543
<5 IU/mL	2/ 21 (9.5)	1/ 16 (6.3)	1.52 (0.15, 15.36)	0.7209	
>=5 IU/mL	11/ 56 (19.6)	9/ 65 (13.8)	1.42 (0.63, 3.17)	0.3946	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.1696
Yes	13/ 70 (18.6)	12/ 80 (15.0)	1.24 (0.61, 2.53)	0.5588	
No	6/ 29 (20.7)	0/ 21 (0.0)	9.53 (0.57, 160.47)	0.1175	
OCS use					0.3025
Yes	15/ 79 (19.0)	12/ 87 (13.8)	1.38 (0.69, 2.76)	0.3676	
No	4/ 20 (20.0)	0/ 14 (0.0)	6.43 (0.37, 110.65)	0.2000	
SLICC score					0.8687
0	10/ 62 (16.1)	7/ 66 (10.6)	1.52 (0.62, 3.75)	0.3621	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Severe Adverse Event - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
>=1	9/ 37 (24.3)	5/ 35 (14.3)	1.70 (0.63, 4.59)	0.2924	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Non-Severe Adverse Event
Safety analysis set

	Anifrolumab 300mg (N=99)	Placebo (N=101)
Number of subjects with events, n (%)	83 (83.8)	77 (76.2)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.10 (0.96, 1.26)	
p-value	0.1804	
Odds Ratio (95% CI)	1.62 (0.80, 3.27)	
p-value	0.1813	
Risk Difference (95% CI)	7.60 (-3.42, 18.62)	
p-value	0.1765	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Non-Severe Adverse Event - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	 p-Value	Interaction p-Value
SLEDAI-2K score					0.3146
< 10 points	34/ 39 (87.2)	29/ 40 (72.5)	1.20 (0.96, 1.51)	0.1092	
>= 10 points	49/ 60 (81.7)	48/ 61 (78.7)	1.04 (0.87, 1.24)	0.6813	
OCS dose					0.0948
<10 mg/day	34/ 44 (77.3)	30/ 37 (81.1)	0.95 (0.76, 1.19)	0.6730	
>=10 mg/day	49/ 55 (89.1)	47/ 64 (73.4)	1.21 (1.02, 1.44)	0.0295	
Result of type I IFN gene signature test					0.1196
LOW	23/ 24 (95.8)	19/ 26 (73.1)	1.31 (1.02, 1.68)	0.0320	
HIGH	60/ 75 (80.0)	58/ 75 (77.3)	1.03 (0.88, 1.22)	0.6903	
Age (years)					0.6857
<= 45	56/ 67 (83.6)	53/ 71 (74.6)	1.12 (0.94, 1.33)	0.1981	
> 45	27/ 32 (84.4)	24/ 30 (80.0)	1.05 (0.84, 1.33)	0.6541	
Sex					0.1748
male	6/ 6 (100.0)	6/ 9 (66.7)	1.50 (0.95, 2.38)	0.0854	
female	77/ 93 (82.8)	71/ 92 (77.2)	1.07 (0.93, 1.24)	0.3408	
Race					0.5907
White	29/ 35 (82.9)	32/ 41 (78.0)	1.06 (0.85, 1.32)	0.5968	
Black	15/ 19 (78.9)	9/ 11 (81.8)	0.96 (0.67, 1.39)	0.8469	
Other	39/ 45 (86.7)	36/ 49 (73.5)	1.18 (0.96, 1.45)	0.1117	
Ethnicity					0.0250
Hispanic/Latino	39/ 46 (84.8)	26/ 42 (61.9)	1.37 (1.05, 1.79)	0.0210	
Non-hispanic/Latino	44/ 53 (83.0)	51/ 59 (86.4)	0.96 (0.82, 1.13)	0.6169	
Geographic region					0.0745
Latin America, Eastern Europe and Asia	54/ 62 (87.1)	54/ 74 (73.0)	1.19 (1.01, 1.41)	0.0396	
North America	29/ 37 (78.4)	23/ 27 (85.2)	0.92 (0.73, 1.16)	0.4799	
Baseline weight					0.9719
<60 kg	27/ 32 (84.4)	30/ 39 (76.9)	1.10 (0.87, 1.38)	0.4258	
>=60 kg	56/ 67 (83.6)	47/ 62 (75.8)	1.10 (0.92, 1.31)	0.2773	
Low CH50					0.5157
Yes	12/ 13 (92.3)	9/ 12 (75.0)	1.23 (0.86, 1.77)	0.2614	
No	71/ 86 (82.6)	68/ 89 (76.4)	1.08 (0.93, 1.26)	0.3143	
Low C3 or C4					0.3704
Yes	29/ 33 (87.9)	34/ 46 (73.9)	1.19 (0.96, 1.47)	0.1119	
No	54/ 66 (81.8)	43/ 55 (78.2)	1.05 (0.87, 1.25)	0.6207	
Baseline FARR anti-dsDNA					0.4332
<5 IU/mL	16/ 21 (76.2)	13/ 16 (81.3)	0.94 (0.67, 1.31)	0.7072	
>=5 IU/mL	47/ 56 (83.9)	50/ 65 (76.9)	1.09 (0.92, 1.30)	0.3309	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.1391
Yes	60/ 70 (85.7)	59/ 80 (73.8)	1.16 (0.99, 1.37)	0.0689	
No	23/ 29 (79.3)	18/ 21 (85.7)	0.93 (0.72, 1.19)	0.5507	
OCS use					0.1386
Yes	68/ 79 (86.1)	65/ 87 (74.7)	1.15 (0.99, 1.34)	0.0662	
No	15/ 20 (75.0)	12/ 14 (85.7)	0.88 (0.63, 1.22)	0.4295	
SLICC score					0.3518
0	52/ 62 (83.9)	48/ 66 (72.7)	1.15 (0.96, 1.39)	0.1282	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Non-Severe Adverse Event - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
>=1	31/ 37 (83.8)	29/ 35 (82.9)	1.01 (0.82, 1.24)	0.9161	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event leading to discontinuation of study drug
Safety analysis set

	Anifrolumab 300mg (N=99)	Placebo (N=101)
Number of subjects with events, n (%)	3 (3.0)	8 (7.9)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.38 (0.10, 1.40)	
p-value	0.1467	
Odds Ratio (95% CI)	0.36 (0.09, 1.41)	
p-value	0.1437	
Risk Difference (95% CI)	-4.89 (-11.15, 1.37)	
p-value	0.1255	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event leading to discontinuation of study drug - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.1640
< 10 points	1/ 39 (2.6)	0/ 40 (0.0)	3.08 (0.13, 73.27)	0.4875	
>= 10 points	2/ 60 (3.3)	8/ 61 (13.1)	0.25 (0.06, 1.15)	0.0750	
OCS dose					0.1480
<10 mg/day	2/ 44 (4.5)	1/ 37 (2.7)	1.68 (0.16, 17.82)	0.6660	
>=10 mg/day	1/ 55 (1.8)	7/ 64 (10.9)	0.17 (0.02, 1.31)	0.0884	
Result of type I IFN gene signature test					0.4026
LOW	1/ 24 (4.2)	1/ 26 (3.8)	1.08 (0.07, 16.38)	0.9539	
HIGH	2/ 75 (2.7)	7/ 75 (9.3)	0.29 (0.06, 1.33)	0.1105	
Age (years)					0.2463
<= 45	1/ 67 (1.5)	6/ 71 (8.5)	0.18 (0.02, 1.43)	0.1041	
> 45	2/ 32 (6.3)	2/ 30 (6.7)	0.94 (0.14, 6.24)	0.9468	
Sex					NE
male	0/ 6 (0.0)	0/ 9 (0.0)	NE		
female	3/ 93 (3.2)	8/ 92 (8.7)	0.37 (0.10, 1.35)	0.1335	
Race					0.4479
White	2/ 35 (5.7)	4/ 41 (9.8)	0.59 (0.11, 3.01)	0.5217	
Black	1/ 19 (5.3)	0/ 11 (0.0)	1.80 (0.08, 40.75)	0.7119	
Other	0/ 45 (0.0)	4/ 49 (8.2)	0.12 (0.01, 2.18)	0.1523	
Ethnicity					0.2021
Hispanic/Latino	0/ 46 (0.0)	4/ 42 (9.5)	0.10 (0.01, 1.83)	0.1213	
Non-hispanic/Latino	3/ 53 (5.7)	4/ 59 (6.8)	0.83 (0.20, 3.56)	0.8073	
Geographic region					0.1787
Latin America, Eastern Europe and Asia	1/ 62 (1.6)	7/ 74 (9.5)	0.17 (0.02, 1.35)	0.0936	
North America	2/ 37 (5.4)	1/ 27 (3.7)	1.46 (0.14, 15.28)	0.7524	
Baseline weight					0.9281
<60 kg	2/ 32 (6.3)	6/ 39 (15.4)	0.41 (0.09, 1.88)	0.2487	
>=60 kg	1/ 67 (1.5)	2/ 62 (3.2)	0.46 (0.04, 4.98)	0.5248	
Low CH50					0.8362
Yes	1/ 13 (7.7)	2/ 12 (16.7)	0.46 (0.05, 4.46)	0.5041	
No	2/ 86 (2.3)	6/ 89 (6.7)	0.34 (0.07, 1.66)	0.1847	
Low C3 or C4					0.6213
Yes	1/ 33 (3.0)	5/ 46 (10.9)	0.28 (0.03, 2.28)	0.2332	
No	2/ 66 (3.0)	3/ 55 (5.5)	0.56 (0.10, 3.21)	0.5111	
Baseline FARR anti-dsDNA					0.7567
<5 IU/mL	1/ 21 (4.8)	1/ 16 (6.3)	0.76 (0.05, 11.27)	0.8432	
>=5 IU/mL	2/ 56 (3.6)	5/ 65 (7.7)	0.46 (0.09, 2.30)	0.3474	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.6168
Yes	2/ 70 (2.9)	7/ 80 (8.8)	0.33 (0.07, 1.52)	0.1539	
No	1/ 29 (3.4)	1/ 21 (4.8)	0.72 (0.05, 10.93)	0.8157	
OCS use					0.0768
Yes	1/ 79 (1.3)	8/ 87 (9.2)	0.14 (0.02, 1.08)	0.0588	
No	2/ 20 (10.0)	0/ 14 (0.0)	3.57 (0.18, 69.14)	0.3998	
SLICC score					0.6776
0	1/ 62 (1.6)	4/ 66 (6.1)	0.27 (0.03, 2.32)	0.2305	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event leading to discontinuation of study drug - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
>=1	2/ 37 (5.4)	4/ 35 (11.4)	0.47 (0.09, 2.42)	0.3689	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Serious Adverse Event leading to discontinuation of study drug
Safety analysis set

	Anifrolumab 300mg (N=99)	Placebo (N=101)
Number of subjects with events, n (%)	2 (2.0)	5 (5.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.41 (0.08, 2.05)	
p-value	0.2771	
Odds Ratio (95% CI)	0.40 (0.07, 2.09)	
p-value	0.2750	
Risk Difference (95% CI)	-2.93 (-7.99, 2.13)	
p-value	0.2561	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Serious Adverse Event leading to discontinuation of study drug - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					NE
< 10 points	0/ 39 (0.0)	0/ 40 (0.0)	NE		
>= 10 points	2/ 60 (3.3)	5/ 61 (8.2)	0.41 (0.08, 2.02)	0.2706	
OCS dose					0.5508
<10 mg/day	1/ 44 (2.3)	1/ 37 (2.7)	0.84 (0.05, 12.99)	0.9013	
>=10 mg/day	1/ 55 (1.8)	4/ 64 (6.3)	0.29 (0.03, 2.53)	0.2629	
Result of type I IFN gene signature test					NE
LOW	0/ 24 (0.0)	0/ 26 (0.0)	NE		
HIGH	2/ 75 (2.7)	5/ 75 (6.7)	0.40 (0.08, 2.00)	0.2641	
Age (years)					0.8643
<= 45	1/ 67 (1.5)	3/ 71 (4.2)	0.35 (0.04, 3.31)	0.3622	
> 45	1/ 32 (3.1)	2/ 30 (6.7)	0.47 (0.04, 4.91)	0.5271	
Sex					NE
male	0/ 6 (0.0)	0/ 9 (0.0)	NE		
female	2/ 93 (2.2)	5/ 92 (5.4)	0.40 (0.08, 1.99)	0.2603	
Race					0.6100
White	1/ 35 (2.9)	3/ 41 (7.3)	0.39 (0.04, 3.59)	0.4059	
Black	1/ 19 (5.3)	0/ 11 (0.0)	1.80 (0.08, 40.75)	0.7119	
Other	0/ 45 (0.0)	2/ 49 (4.1)	0.22 (0.01, 4.41)	0.3203	
Ethnicity					0.4304
Hispanic/Latino	0/ 46 (0.0)	2/ 42 (4.8)	0.18 (0.01, 3.70)	0.2685	
Non-hispanic/Latino	2/ 53 (3.8)	3/ 59 (5.1)	0.74 (0.13, 4.27)	0.7384	
Geographic region					0.2520
Latin America, Eastern Europe and Asia	1/ 62 (1.6)	5/ 74 (6.8)	0.24 (0.03, 1.99)	0.1855	
North America	1/ 37 (2.7)	0/ 27 (0.0)	2.21 (0.09, 52.27)	0.6231	
Baseline weight					0.5321
<60 kg	1/ 32 (3.1)	4/ 39 (10.3)	0.30 (0.04, 2.59)	0.2766	
>=60 kg	1/ 67 (1.5)	1/ 62 (1.6)	0.93 (0.06, 14.48)	0.9559	
Low CH50					0.8581
Yes	1/ 13 (7.7)	2/ 12 (16.7)	0.46 (0.05, 4.46)	0.5041	
No	1/ 86 (1.2)	3/ 89 (3.4)	0.34 (0.04, 3.25)	0.3525	
Low C3 or C4					0.6241
Yes	1/ 33 (3.0)	4/ 46 (8.7)	0.35 (0.04, 2.98)	0.3355	
No	1/ 66 (1.5)	1/ 55 (1.8)	0.83 (0.05, 13.02)	0.8966	
Baseline FARR anti-dsDNA					NE
<5 IU/mL	0/ 21 (0.0)	0/ 16 (0.0)	NE		
>=5 IU/mL	2/ 56 (3.6)	3/ 65 (4.6)	0.77 (0.13, 4.47)	0.7744	
Low complement (C3 or C4) and positive FARR anti-dsDNA					NE
Yes	2/ 70 (2.9)	5/ 80 (6.3)	0.46 (0.09, 2.28)	0.3401	
No	0/ 29 (0.0)	0/ 21 (0.0)	NE		
OCS use					0.2387
Yes	1/ 79 (1.3)	5/ 87 (5.7)	0.22 (0.03, 1.84)	0.1629	
No	1/ 20 (5.0)	0/ 14 (0.0)	2.14 (0.09, 49.08)	0.6333	
SLICC score					0.5401
0	0/ 62 (0.0)	2/ 66 (3.0)	0.21 (0.01, 4.34)	0.3146	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Serious Adverse Event leading to discontinuation of study drug - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
>=1	2/ 37 (5.4)	3/ 35 (8.6)	0.63 (0.11, 3.55)	0.6011	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with Adverse Event leading to death
Safety analysis set

	Anifrolumab 300mg (N=99)	Placebo (N=101)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with Adverse Event leading to death - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
SLEDAI-2K score				NE
< 10 points	0/ 39 (0.0)	0/ 40 (0.0)	NE	
>= 10 points	0/ 60 (0.0)	0/ 61 (0.0)	NE	
OCS dose				NE
<10 mg/day	0/ 44 (0.0)	0/ 37 (0.0)	NE	
>=10 mg/day	0/ 55 (0.0)	0/ 64 (0.0)	NE	
Result of type I IFN gene signature test				NE
LOW	0/ 24 (0.0)	0/ 26 (0.0)	NE	
HIGH	0/ 75 (0.0)	0/ 75 (0.0)	NE	
Age (years)				NE
<= 45	0/ 67 (0.0)	0/ 71 (0.0)	NE	
> 45	0/ 32 (0.0)	0/ 30 (0.0)	NE	
Sex				NE
male	0/ 6 (0.0)	0/ 9 (0.0)	NE	
female	0/ 93 (0.0)	0/ 92 (0.0)	NE	
Race				NE
White	0/ 35 (0.0)	0/ 41 (0.0)	NE	
Black	0/ 19 (0.0)	0/ 11 (0.0)	NE	
Other	0/ 45 (0.0)	0/ 49 (0.0)	NE	
Ethnicity				NE
Hispanic/Latino	0/ 46 (0.0)	0/ 42 (0.0)	NE	
Non-hispanic/Latino	0/ 53 (0.0)	0/ 59 (0.0)	NE	
Geographic region				NE
Latin America, Eastern Europe and Asia	0/ 62 (0.0)	0/ 74 (0.0)	NE	
North America	0/ 37 (0.0)	0/ 27 (0.0)	NE	
Baseline weight				NE
<60 kg	0/ 32 (0.0)	0/ 39 (0.0)	NE	
>=60 kg	0/ 67 (0.0)	0/ 62 (0.0)	NE	
Low CH50				NE
Yes	0/ 13 (0.0)	0/ 12 (0.0)	NE	
No	0/ 86 (0.0)	0/ 89 (0.0)	NE	
Low C3 or C4				NE
Yes	0/ 33 (0.0)	0/ 46 (0.0)	NE	
No	0/ 66 (0.0)	0/ 55 (0.0)	NE	
Baseline FARR anti-dsDNA				NE
<5 IU/mL	0/ 21 (0.0)	0/ 16 (0.0)	NE	
>=5 IU/mL	0/ 56 (0.0)	0/ 65 (0.0)	NE	
Low complement (C3 or C4) and positive FARR anti-dsDNA				NE
Yes	0/ 70 (0.0)	0/ 80 (0.0)	NE	
No	0/ 29 (0.0)	0/ 21 (0.0)	NE	
OCS use				NE
Yes	0/ 79 (0.0)	0/ 87 (0.0)	NE	
No	0/ 20 (0.0)	0/ 14 (0.0)	NE	
SLICC score				NE
0	0/ 62 (0.0)	0/ 66 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with Adverse Event leading to death - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
>=1	0/ 37 (0.0)	0/ 35 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Herpes Zoster
Safety analysis set

	Anifrolumab 300mg (N=99)	Placebo (N=101)
Number of subjects with events, n (%)	5 (5.1)	2 (2.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	2.55 (0.51, 12.84)	
p-value	0.2562	
Odds Ratio (95% CI)	2.63 (0.50, 13.90)	
p-value	0.2541	
Risk Difference (95% CI)	3.07 (-2.03, 8.17)	
p-value	0.2378	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Herpes Zoster - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.4389
< 10 points	1/ 39 (2.6)	1/ 40 (2.5)	1.03 (0.07, 15.83)	0.9855	
>= 10 points	4/ 60 (6.7)	1/ 61 (1.6)	4.07 (0.47, 35.34)	0.2035	
OCS dose					0.3363
<10 mg/day	1/ 44 (2.3)	1/ 37 (2.7)	0.84 (0.05, 12.99)	0.9013	
>=10 mg/day	4/ 55 (7.3)	1/ 64 (1.6)	4.65 (0.54, 40.42)	0.1632	
Result of type I IFN gene signature test					NE
LOW	0/ 24 (0.0)	0/ 26 (0.0)	NE		
HIGH	5/ 75 (6.7)	2/ 75 (2.7)	2.50 (0.50, 12.49)	0.2641	
Age (years)					0.8758
<= 45	4/ 67 (6.0)	2/ 71 (2.8)	2.12 (0.40, 11.19)	0.3764	
> 45	1/ 32 (3.1)	0/ 30 (0.0)	2.82 (0.12, 66.62)	0.5208	
Sex					0.6633
male	1/ 6 (16.7)	0/ 9 (0.0)	4.29 (0.20, 90.62)	0.3499	
female	4/ 93 (4.3)	2/ 92 (2.2)	1.98 (0.37, 10.54)	0.4240	
Race					0.9912
White	2/ 35 (5.7)	1/ 41 (2.4)	2.34 (0.22, 24.76)	0.4791	
Black	1/ 19 (5.3)	0/ 11 (0.0)	1.80 (0.08, 40.75)	0.7119	
Other	2/ 45 (4.4)	1/ 49 (2.0)	2.18 (0.20, 23.21)	0.5191	
Ethnicity					0.7159
Hispanic/Latino	2/ 46 (4.3)	1/ 42 (2.4)	1.83 (0.17, 19.41)	0.6176	
Non-hispanic/Latino	3/ 53 (5.7)	1/ 59 (1.7)	3.34 (0.36, 31.14)	0.2898	
Geographic region					0.9664
Latin America, Eastern Europe and Asia	4/ 62 (6.5)	2/ 74 (2.7)	2.39 (0.45, 12.60)	0.3053	
North America	1/ 37 (2.7)	0/ 27 (0.0)	2.21 (0.09, 52.27)	0.6231	
Baseline weight					0.7113
<60 kg	1/ 32 (3.1)	0/ 39 (0.0)	3.64 (0.15, 86.33)	0.4244	
>=60 kg	4/ 67 (6.0)	2/ 62 (3.2)	1.85 (0.35, 9.75)	0.4678	
Low CH50					0.5313
Yes	2/ 13 (15.4)	0/ 12 (0.0)	4.64 (0.25, 87.91)	0.3062	
No	3/ 86 (3.5)	2/ 89 (2.2)	1.55 (0.27, 9.06)	0.6252	
Low C3 or C4					0.9476
Yes	2/ 33 (6.1)	1/ 46 (2.2)	2.79 (0.26, 29.48)	0.3942	
No	3/ 66 (4.5)	1/ 55 (1.8)	2.50 (0.27, 23.36)	0.4216	
Baseline FARR anti-dsDNA					NE
<5 IU/mL	0/ 21 (0.0)	0/ 16 (0.0)	NE		
>=5 IU/mL	5/ 56 (8.9)	2/ 65 (3.1)	2.90 (0.59, 14.38)	0.1920	
Low complement (C3 or C4) and positive FARR anti-dsDNA					NE
Yes	5/ 70 (7.1)	2/ 80 (2.5)	2.86 (0.57, 14.27)	0.2007	
No	0/ 29 (0.0)	0/ 21 (0.0)	NE		
OCS use					0.2965
Yes	4/ 79 (5.1)	1/ 87 (1.1)	4.41 (0.50, 38.58)	0.1805	
No	1/ 20 (5.0)	1/ 14 (7.1)	0.70 (0.05, 10.27)	0.7947	
SLICC score					0.8623
0	2/ 62 (3.2)	1/ 66 (1.5)	2.13 (0.20, 22.90)	0.5329	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Herpes Zoster - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
>=1	3/ 37 (8.1)	1/ 35 (2.9)	2.84 (0.31, 26.01)	0.3561	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Herpes Zoster
Safety analysis set

	Anifrolumab 300mg (N=99)	Placebo (N=101)
Number of subjects with events, n (%)	1 (1.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.06 (0.13, 74.23)	
p-value	0.4918	
Odds Ratio (95% CI)	3.09 (0.12, 76.80)	
p-value	0.4911	
Risk Difference (95% CI)	1.01 (-0.96, 2.98)	
p-value	0.3149	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Herpes Zoster - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					NE
< 10 points	0/ 39 (0.0)	0/ 40 (0.0)	NE		
>= 10 points	1/ 60 (1.7)	0/ 61 (0.0)	3.05 (0.13, 73.40)	0.4921	
OCS dose					NE
<10 mg/day	1/ 44 (2.3)	0/ 37 (0.0)	2.53 (0.11, 60.39)	0.5656	
>=10 mg/day	0/ 55 (0.0)	0/ 64 (0.0)	NE		
Result of type I IFN gene signature test					NE
LOW	0/ 24 (0.0)	0/ 26 (0.0)	NE		
HIGH	1/ 75 (1.3)	0/ 75 (0.0)	3.00 (0.12, 72.49)	0.4990	
Age (years)					NE
<= 45	0/ 67 (0.0)	0/ 71 (0.0)	NE		
> 45	1/ 32 (3.1)	0/ 30 (0.0)	2.82 (0.12, 66.62)	0.5208	
Sex					NE
male	0/ 6 (0.0)	0/ 9 (0.0)	NE		
female	1/ 93 (1.1)	0/ 92 (0.0)	2.97 (0.12, 71.93)	0.5036	
Race					NE
White	0/ 35 (0.0)	0/ 41 (0.0)	NE		
Black	1/ 19 (5.3)	0/ 11 (0.0)	1.80 (0.08, 40.75)	0.7119	
Other	0/ 45 (0.0)	0/ 49 (0.0)	NE		
Ethnicity					NE
Hispanic/Latino	0/ 46 (0.0)	0/ 42 (0.0)	NE		
Non-hispanic/Latino	1/ 53 (1.9)	0/ 59 (0.0)	3.33 (0.14, 80.11)	0.4580	
Geographic region					NE
Latin America, Eastern Europe and Asia	0/ 62 (0.0)	0/ 74 (0.0)	NE		
North America	1/ 37 (2.7)	0/ 27 (0.0)	2.21 (0.09, 52.27)	0.6231	
Baseline weight					NE
<60 kg	0/ 32 (0.0)	0/ 39 (0.0)	NE		
>=60 kg	1/ 67 (1.5)	0/ 62 (0.0)	2.78 (0.12, 66.98)	0.5289	
Low CH50					NE
Yes	1/ 13 (7.7)	0/ 12 (0.0)	2.79 (0.12, 62.48)	0.5185	
No	0/ 86 (0.0)	0/ 89 (0.0)	NE		
Low C3 or C4					NE
Yes	1/ 33 (3.0)	0/ 46 (0.0)	4.15 (0.17, 98.74)	0.3792	
No	0/ 66 (0.0)	0/ 55 (0.0)	NE		
Baseline FARR anti-dsDNA					NE
<5 IU/mL	0/ 21 (0.0)	0/ 16 (0.0)	NE		
>=5 IU/mL	1/ 56 (1.8)	0/ 65 (0.0)	3.47 (0.14, 83.61)	0.4429	
Low complement (C3 or C4) and positive FARR anti-dsDNA					NE
Yes	1/ 70 (1.4)	0/ 80 (0.0)	3.42 (0.14, 82.69)	0.4489	
No	0/ 29 (0.0)	0/ 21 (0.0)	NE		
OCS use					NE
Yes	0/ 79 (0.0)	0/ 87 (0.0)	NE		
No	1/ 20 (5.0)	0/ 14 (0.0)	2.14 (0.09, 49.08)	0.6333	
SLICC score					NE
0	0/ 62 (0.0)	0/ 66 (0.0)	NE		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Herpes Zoster - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
>=1	1/ 37 (2.7)	0/ 35 (0.0)	2.84 (0.12, 67.53)	0.5181	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Herpes Zoster
Safety analysis set

	Anifrolumab 300mg (N=99)	Placebo (N=101)
Number of subjects with events, n (%)	1 (1.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.06 (0.13, 74.23)	
p-value	0.4918	
Odds Ratio (95% CI)	3.09 (0.12, 76.80)	
p-value	0.4911	
Risk Difference (95% CI)	1.01 (-0.96, 2.98)	
p-value	0.3149	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Herpes Zoster - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					NE
< 10 points	0/ 39 (0.0)	0/ 40 (0.0)	NE		
>= 10 points	1/ 60 (1.7)	0/ 61 (0.0)	3.05 (0.13, 73.40)	0.4921	
OCS dose					NE
<10 mg/day	1/ 44 (2.3)	0/ 37 (0.0)	2.53 (0.11, 60.39)	0.5656	
>=10 mg/day	0/ 55 (0.0)	0/ 64 (0.0)	NE		
Result of type I IFN gene signature test					NE
LOW	0/ 24 (0.0)	0/ 26 (0.0)	NE		
HIGH	1/ 75 (1.3)	0/ 75 (0.0)	3.00 (0.12, 72.49)	0.4990	
Age (years)					NE
<= 45	0/ 67 (0.0)	0/ 71 (0.0)	NE		
> 45	1/ 32 (3.1)	0/ 30 (0.0)	2.82 (0.12, 66.62)	0.5208	
Sex					NE
male	0/ 6 (0.0)	0/ 9 (0.0)	NE		
female	1/ 93 (1.1)	0/ 92 (0.0)	2.97 (0.12, 71.93)	0.5036	
Race					NE
White	0/ 35 (0.0)	0/ 41 (0.0)	NE		
Black	1/ 19 (5.3)	0/ 11 (0.0)	1.80 (0.08, 40.75)	0.7119	
Other	0/ 45 (0.0)	0/ 49 (0.0)	NE		
Ethnicity					NE
Hispanic/Latino	0/ 46 (0.0)	0/ 42 (0.0)	NE		
Non-hispanic/Latino	1/ 53 (1.9)	0/ 59 (0.0)	3.33 (0.14, 80.11)	0.4580	
Geographic region					NE
Latin America, Eastern Europe and Asia	0/ 62 (0.0)	0/ 74 (0.0)	NE		
North America	1/ 37 (2.7)	0/ 27 (0.0)	2.21 (0.09, 52.27)	0.6231	
Baseline weight					NE
<60 kg	0/ 32 (0.0)	0/ 39 (0.0)	NE		
>=60 kg	1/ 67 (1.5)	0/ 62 (0.0)	2.78 (0.12, 66.98)	0.5289	
Low CH50					NE
Yes	1/ 13 (7.7)	0/ 12 (0.0)	2.79 (0.12, 62.48)	0.5185	
No	0/ 86 (0.0)	0/ 89 (0.0)	NE		
Low C3 or C4					NE
Yes	1/ 33 (3.0)	0/ 46 (0.0)	4.15 (0.17, 98.74)	0.3792	
No	0/ 66 (0.0)	0/ 55 (0.0)	NE		
Baseline FARR anti-dsDNA					NE
<5 IU/mL	0/ 21 (0.0)	0/ 16 (0.0)	NE		
>=5 IU/mL	1/ 56 (1.8)	0/ 65 (0.0)	3.47 (0.14, 83.61)	0.4429	
Low complement (C3 or C4) and positive FARR anti-dsDNA					NE
Yes	1/ 70 (1.4)	0/ 80 (0.0)	3.42 (0.14, 82.69)	0.4489	
No	0/ 29 (0.0)	0/ 21 (0.0)	NE		
OCS use					NE
Yes	0/ 79 (0.0)	0/ 87 (0.0)	NE		
No	1/ 20 (5.0)	0/ 14 (0.0)	2.14 (0.09, 49.08)	0.6333	
SLICC score					NE
0	0/ 62 (0.0)	0/ 66 (0.0)	NE		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Herpes Zoster - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
>=1	1/ 37 (2.7)	0/ 35 (0.0)	2.84 (0.12, 67.53)	0.5181	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Herpes Zoster
Safety analysis set

	Anifrolumab 300mg (N=99)	Placebo (N=101)
Number of subjects with events, n (%)	4 (4.0)	2 (2.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	2.04 (0.38, 10.89)	
p-value	0.4039	
Odds Ratio (95% CI)	2.08 (0.37, 11.65)	
p-value	0.4028	
Risk Difference (95% CI)	2.06 (-2.68, 6.80)	
p-value	0.3938	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Herpes Zoster - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.5455
< 10 points	1/ 39 (2.6)	1/ 40 (2.5)	1.03 (0.07, 15.83)	0.9855	
>= 10 points	3/ 60 (5.0)	1/ 61 (1.6)	3.05 (0.33, 28.50)	0.3281	
OCS dose					0.1519
<10 mg/day	0/ 44 (0.0)	1/ 37 (2.7)	0.28 (0.01, 6.71)	0.4334	
>=10 mg/day	4/ 55 (7.3)	1/ 64 (1.6)	4.65 (0.54, 40.42)	0.1632	
Result of type I IFN gene signature test					NE
LOW	0/ 24 (0.0)	0/ 26 (0.0)	NE		
HIGH	4/ 75 (5.3)	2/ 75 (2.7)	2.00 (0.38, 10.59)	0.4151	
Age (years)					NE
<= 45	4/ 67 (6.0)	2/ 71 (2.8)	2.12 (0.40, 11.19)	0.3764	
> 45	0/ 32 (0.0)	0/ 30 (0.0)	NE		
Sex					0.5554
male	1/ 6 (16.7)	0/ 9 (0.0)	4.29 (0.20, 90.62)	0.3499	
female	3/ 93 (3.2)	2/ 92 (2.2)	1.48 (0.25, 8.68)	0.6614	
Race					0.9658
White	2/ 35 (5.7)	1/ 41 (2.4)	2.34 (0.22, 24.76)	0.4791	
Black	0/ 19 (0.0)	0/ 11 (0.0)	NE		
Other	2/ 45 (4.4)	1/ 49 (2.0)	2.18 (0.20, 23.21)	0.5191	
Ethnicity					0.9076
Hispanic/Latino	2/ 46 (4.3)	1/ 42 (2.4)	1.83 (0.17, 19.41)	0.6176	
Non-hispanic/Latino	2/ 53 (3.8)	1/ 59 (1.7)	2.23 (0.21, 23.86)	0.5083	
Geographic region					NE
Latin America, Eastern Europe and Asia	4/ 62 (6.5)	2/ 74 (2.7)	2.39 (0.45, 12.60)	0.3053	
North America	0/ 37 (0.0)	0/ 27 (0.0)	NE		
Baseline weight					0.6022
<60 kg	1/ 32 (3.1)	0/ 39 (0.0)	3.64 (0.15, 86.33)	0.4244	
>=60 kg	3/ 67 (4.5)	2/ 62 (3.2)	1.39 (0.24, 8.03)	0.7143	
Low CH50					0.7486
Yes	1/ 13 (7.7)	0/ 12 (0.0)	2.79 (0.12, 62.48)	0.5185	
No	3/ 86 (3.5)	2/ 89 (2.2)	1.55 (0.27, 9.06)	0.6252	
Low C3 or C4					0.7458
Yes	1/ 33 (3.0)	1/ 46 (2.2)	1.39 (0.09, 21.49)	0.8119	
No	3/ 66 (4.5)	1/ 55 (1.8)	2.50 (0.27, 23.36)	0.4216	
Baseline FARR anti-dsDNA					NE
<5 IU/mL	0/ 21 (0.0)	0/ 16 (0.0)	NE		
>=5 IU/mL	4/ 56 (7.1)	2/ 65 (3.1)	2.32 (0.44, 12.20)	0.3199	
Low complement (C3 or C4) and positive FARR anti-dsDNA					NE
Yes	4/ 70 (5.7)	2/ 80 (2.5)	2.29 (0.43, 12.10)	0.3310	
No	0/ 29 (0.0)	0/ 21 (0.0)	NE		
OCS use					0.1333
Yes	4/ 79 (5.1)	1/ 87 (1.1)	4.41 (0.50, 38.58)	0.1805	
No	0/ 20 (0.0)	1/ 14 (7.1)	0.24 (0.01, 5.45)	0.3690	
SLICC score					0.9448
0	2/ 62 (3.2)	1/ 66 (1.5)	2.13 (0.20, 22.90)	0.5329	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Herpes Zoster - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
>=1	2/ 37 (5.4)	1/ 35 (2.9)	1.89 (0.18, 19.95)	0.5958	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Herpes Zoster leading to discontinuation of study drug
Safety analysis set

	Anifrolumab 300mg (N=99)	Placebo (N=101)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Herpes Zoster leading to discontinuation of study drug - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
SLEDAI-2K score				NE
< 10 points	0/ 39 (0.0)	0/ 40 (0.0)	NE	
>= 10 points	0/ 60 (0.0)	0/ 61 (0.0)	NE	
OCS dose				NE
<10 mg/day	0/ 44 (0.0)	0/ 37 (0.0)	NE	
>=10 mg/day	0/ 55 (0.0)	0/ 64 (0.0)	NE	
Result of type I IFN gene signature test				NE
LOW	0/ 24 (0.0)	0/ 26 (0.0)	NE	
HIGH	0/ 75 (0.0)	0/ 75 (0.0)	NE	
Age (years)				NE
<= 45	0/ 67 (0.0)	0/ 71 (0.0)	NE	
> 45	0/ 32 (0.0)	0/ 30 (0.0)	NE	
Sex				NE
male	0/ 6 (0.0)	0/ 9 (0.0)	NE	
female	0/ 93 (0.0)	0/ 92 (0.0)	NE	
Race				NE
White	0/ 35 (0.0)	0/ 41 (0.0)	NE	
Black	0/ 19 (0.0)	0/ 11 (0.0)	NE	
Other	0/ 45 (0.0)	0/ 49 (0.0)	NE	
Ethnicity				NE
Hispanic/Latino	0/ 46 (0.0)	0/ 42 (0.0)	NE	
Non-hispanic/Latino	0/ 53 (0.0)	0/ 59 (0.0)	NE	
Geographic region				NE
Latin America, Eastern Europe and Asia	0/ 62 (0.0)	0/ 74 (0.0)	NE	
North America	0/ 37 (0.0)	0/ 27 (0.0)	NE	
Baseline weight				NE
<60 kg	0/ 32 (0.0)	0/ 39 (0.0)	NE	
>=60 kg	0/ 67 (0.0)	0/ 62 (0.0)	NE	
Low CH50				NE
Yes	0/ 13 (0.0)	0/ 12 (0.0)	NE	
No	0/ 86 (0.0)	0/ 89 (0.0)	NE	
Low C3 or C4				NE
Yes	0/ 33 (0.0)	0/ 46 (0.0)	NE	
No	0/ 66 (0.0)	0/ 55 (0.0)	NE	
Baseline FARR anti-dsDNA				NE
<5 IU/mL	0/ 21 (0.0)	0/ 16 (0.0)	NE	
>=5 IU/mL	0/ 56 (0.0)	0/ 65 (0.0)	NE	
Low complement (C3 or C4) and positive FARR anti-dsDNA				NE
Yes	0/ 70 (0.0)	0/ 80 (0.0)	NE	
No	0/ 29 (0.0)	0/ 21 (0.0)	NE	
OCS use				NE
Yes	0/ 79 (0.0)	0/ 87 (0.0)	NE	
No	0/ 20 (0.0)	0/ 14 (0.0)	NE	
SLICC score				NE
0	0/ 62 (0.0)	0/ 66 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Herpes Zoster leading to discontinuation of study drug - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
>=1	0/ 37 (0.0)	0/ 35 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Influenza
Safety analysis set

	Anifrolumab 300mg (N=99)	Placebo (N=101)
Number of subjects with events, n (%)	6 (6.1)	2 (2.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.06 (0.63, 14.80)	
p-value	0.1642	
Odds Ratio (95% CI)	3.19 (0.63, 16.22)	
p-value	0.1614	
Risk Difference (95% CI)	4.08 (-1.35, 9.51)	
p-value	0.1407	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Influenza - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.6751
< 10 points	2/ 39 (5.1)	1/ 40 (2.5)	2.05 (0.19, 21.72)	0.5507	
>= 10 points	4/ 60 (6.7)	1/ 61 (1.6)	4.07 (0.47, 35.34)	0.2035	
OCS dose					0.8398
<10 mg/day	3/ 44 (6.8)	1/ 37 (2.7)	2.52 (0.27, 23.24)	0.4141	
>=10 mg/day	3/ 55 (5.5)	1/ 64 (1.6)	3.49 (0.37, 32.60)	0.2728	
Result of type I IFN gene signature test					0.5693
LOW	2/ 24 (8.3)	0/ 26 (0.0)	5.40 (0.27, 107.09)	0.2685	
HIGH	4/ 75 (5.3)	2/ 75 (2.7)	2.00 (0.38, 10.59)	0.4151	
Age (years)					0.0421
<= 45	6/ 67 (9.0)	0/ 71 (0.0)	13.76 (0.79, 239.70)	0.0721	
> 45	0/ 32 (0.0)	2/ 30 (6.7)	0.19 (0.01, 3.76)	0.2741	
Sex					NE
male	0/ 6 (0.0)	0/ 9 (0.0)	NE		
female	6/ 93 (6.5)	2/ 92 (2.2)	2.97 (0.61, 14.32)	0.1756	
Race					0.3832
White	1/ 35 (2.9)	1/ 41 (2.4)	1.17 (0.08, 18.05)	0.9097	
Black	0/ 19 (0.0)	0/ 11 (0.0)	NE		
Other	5/ 45 (11.1)	1/ 49 (2.0)	5.44 (0.66, 44.84)	0.1152	
Ethnicity					0.7619
Hispanic/Latino	4/ 46 (8.7)	1/ 42 (2.4)	3.65 (0.42, 31.39)	0.2379	
Non-hispanic/Latino	2/ 53 (3.8)	1/ 59 (1.7)	2.23 (0.21, 23.86)	0.5083	
Geographic region					0.8040
Latin America, Eastern Europe and Asia	4/ 62 (6.5)	2/ 74 (2.7)	2.39 (0.45, 12.60)	0.3053	
North America	2/ 37 (5.4)	0/ 27 (0.0)	3.68 (0.18, 73.77)	0.3937	
Baseline weight					0.4495
<60 kg	1/ 32 (3.1)	1/ 39 (2.6)	1.22 (0.08, 18.73)	0.8871	
>=60 kg	5/ 67 (7.5)	1/ 62 (1.6)	4.63 (0.56, 38.51)	0.1565	
Low CH50					0.9670
Yes	1/ 13 (7.7)	0/ 12 (0.0)	2.79 (0.12, 62.48)	0.5185	
No	5/ 86 (5.8)	2/ 89 (2.2)	2.59 (0.52, 12.98)	0.2480	
Low C3 or C4					0.2401
Yes	3/ 33 (9.1)	0/ 46 (0.0)	9.68 (0.52, 181.24)	0.1290	
No	3/ 66 (4.5)	2/ 55 (3.6)	1.25 (0.22, 7.22)	0.8030	
Baseline FARR anti-dsDNA					0.2454
<5 IU/mL	1/ 21 (4.8)	1/ 16 (6.3)	0.76 (0.05, 11.27)	0.8432	
>=5 IU/mL	3/ 56 (5.4)	0/ 65 (0.0)	8.11 (0.43, 153.61)	0.1633	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.1329
Yes	4/ 70 (5.7)	0/ 80 (0.0)	10.27 (0.56, 187.41)	0.1160	
No	2/ 29 (6.9)	2/ 21 (9.5)	0.72 (0.11, 4.74)	0.7362	
OCS use					0.8891
Yes	5/ 79 (6.3)	2/ 87 (2.3)	2.75 (0.55, 13.79)	0.2180	
No	1/ 20 (5.0)	0/ 14 (0.0)	2.14 (0.09, 49.08)	0.6333	
SLICC score					0.7246
0	2/ 62 (3.2)	1/ 66 (1.5)	2.13 (0.20, 22.90)	0.5329	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Influenza - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
>=1	4/ 37 (10.8)	1/ 35 (2.9)	3.78 (0.44, 32.23)	0.2234	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Influenza
Safety analysis set

	Anifrolumab 300mg (N=99)	Placebo (N=101)
Number of subjects with events, n (%)	2 (2.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	5.10 (0.25, 104.90)	
p-value	0.2910	
Odds Ratio (95% CI)	5.21 (0.25, 109.80)	
p-value	0.2890	
Risk Difference (95% CI)	2.02 (-0.75, 4.79)	
p-value	0.1531	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Influenza - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.9971
< 10 points	1/ 39 (2.6)	0/ 40 (0.0)	3.08 (0.13, 73.27)	0.4875	
>= 10 points	1/ 60 (1.7)	0/ 61 (0.0)	3.05 (0.13, 73.40)	0.4921	
OCS dose					0.8896
<10 mg/day	1/ 44 (2.3)	0/ 37 (0.0)	2.53 (0.11, 60.39)	0.5656	
>=10 mg/day	1/ 55 (1.8)	0/ 64 (0.0)	3.48 (0.14, 83.78)	0.4420	
Result of type I IFN gene signature test					NE
LOW	0/ 24 (0.0)	0/ 26 (0.0)	NE		
HIGH	2/ 75 (2.7)	0/ 75 (0.0)	5.00 (0.24, 102.42)	0.2962	
Age (years)					NE
<= 45	2/ 67 (3.0)	0/ 71 (0.0)	5.29 (0.26, 108.29)	0.2791	
> 45	0/ 32 (0.0)	0/ 30 (0.0)	NE		
Sex					NE
male	0/ 6 (0.0)	0/ 9 (0.0)	NE		
female	2/ 93 (2.2)	0/ 92 (0.0)	4.95 (0.24, 101.65)	0.2999	
Race					NE
White	0/ 35 (0.0)	0/ 41 (0.0)	NE		
Black	0/ 19 (0.0)	0/ 11 (0.0)	NE		
Other	2/ 45 (4.4)	0/ 49 (0.0)	5.43 (0.27, 110.24)	0.2703	
Ethnicity					NE
Hispanic/Latino	2/ 46 (4.3)	0/ 42 (0.0)	4.57 (0.23, 92.62)	0.3218	
Non-hispanic/Latino	0/ 53 (0.0)	0/ 59 (0.0)	NE		
Geographic region					NE
Latin America, Eastern Europe and Asia	2/ 62 (3.2)	0/ 74 (0.0)	5.95 (0.29, 121.71)	0.2467	
North America	0/ 37 (0.0)	0/ 27 (0.0)	NE		
Baseline weight					NE
<60 kg	0/ 32 (0.0)	0/ 39 (0.0)	NE		
>=60 kg	2/ 67 (3.0)	0/ 62 (0.0)	4.63 (0.23, 94.63)	0.3193	
Low CH50					NE
Yes	0/ 13 (0.0)	0/ 12 (0.0)	NE		
No	2/ 86 (2.3)	0/ 89 (0.0)	5.17 (0.25, 106.20)	0.2865	
Low C3 or C4					0.8262
Yes	1/ 33 (3.0)	0/ 46 (0.0)	4.15 (0.17, 98.74)	0.3792	
No	1/ 66 (1.5)	0/ 55 (0.0)	2.51 (0.10, 60.35)	0.5711	
Baseline FARR anti-dsDNA					NE
<5 IU/mL	0/ 21 (0.0)	0/ 16 (0.0)	NE		
>=5 IU/mL	2/ 56 (3.6)	0/ 65 (0.0)	5.79 (0.28, 118.11)	0.2537	
Low complement (C3 or C4) and positive FARR anti-dsDNA					NE
Yes	2/ 70 (2.9)	0/ 80 (0.0)	5.70 (0.28, 116.84)	0.2584	
No	0/ 29 (0.0)	0/ 21 (0.0)	NE		
OCS use					0.8498
Yes	1/ 79 (1.3)	0/ 87 (0.0)	3.30 (0.14, 79.85)	0.4627	
No	1/ 20 (5.0)	0/ 14 (0.0)	2.14 (0.09, 49.08)	0.6333	
SLICC score					NE
0	0/ 62 (0.0)	0/ 66 (0.0)	NE		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Influenza - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
>=1	2/ 37 (5.4)	0/ 35 (0.0)	4.74 (0.24, 95.33)	0.3099	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Influenza
Safety analysis set

	Anifrolumab 300mg (N=99)	Placebo (N=101)
Number of subjects with events, n (%)	1 (1.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.06 (0.13, 74.23)	
p-value	0.4918	
Odds Ratio (95% CI)	3.09 (0.12, 76.80)	
p-value	0.4911	
Risk Difference (95% CI)	1.01 (-0.96, 2.98)	
p-value	0.3149	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Influenza - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					NE
< 10 points	0/ 39 (0.0)	0/ 40 (0.0)	NE		
>= 10 points	1/ 60 (1.7)	0/ 61 (0.0)	3.05 (0.13, 73.40)	0.4921	
OCS dose					NE
<10 mg/day	1/ 44 (2.3)	0/ 37 (0.0)	2.53 (0.11, 60.39)	0.5656	
>=10 mg/day	0/ 55 (0.0)	0/ 64 (0.0)	NE		
Result of type I IFN gene signature test					NE
LOW	0/ 24 (0.0)	0/ 26 (0.0)	NE		
HIGH	1/ 75 (1.3)	0/ 75 (0.0)	3.00 (0.12, 72.49)	0.4990	
Age (years)					NE
<= 45	1/ 67 (1.5)	0/ 71 (0.0)	3.18 (0.13, 76.64)	0.4767	
> 45	0/ 32 (0.0)	0/ 30 (0.0)	NE		
Sex					NE
male	0/ 6 (0.0)	0/ 9 (0.0)	NE		
female	1/ 93 (1.1)	0/ 92 (0.0)	2.97 (0.12, 71.93)	0.5036	
Race					NE
White	0/ 35 (0.0)	0/ 41 (0.0)	NE		
Black	0/ 19 (0.0)	0/ 11 (0.0)	NE		
Other	1/ 45 (2.2)	0/ 49 (0.0)	3.26 (0.14, 78.06)	0.4657	
Ethnicity					NE
Hispanic/Latino	1/ 46 (2.2)	0/ 42 (0.0)	2.74 (0.11, 65.59)	0.5329	
Non-hispanic/Latino	0/ 53 (0.0)	0/ 59 (0.0)	NE		
Geographic region					NE
Latin America, Eastern Europe and Asia	1/ 62 (1.6)	0/ 74 (0.0)	3.57 (0.15, 86.14)	0.4331	
North America	0/ 37 (0.0)	0/ 27 (0.0)	NE		
Baseline weight					NE
<60 kg	0/ 32 (0.0)	0/ 39 (0.0)	NE		
>=60 kg	1/ 67 (1.5)	0/ 62 (0.0)	2.78 (0.12, 66.98)	0.5289	
Low CH50					NE
Yes	0/ 13 (0.0)	0/ 12 (0.0)	NE		
No	1/ 86 (1.2)	0/ 89 (0.0)	3.10 (0.13, 75.15)	0.4861	
Low C3 or C4					NE
Yes	1/ 33 (3.0)	0/ 46 (0.0)	4.15 (0.17, 98.74)	0.3792	
No	0/ 66 (0.0)	0/ 55 (0.0)	NE		
Baseline FARR anti-dsDNA					NE
<5 IU/mL	0/ 21 (0.0)	0/ 16 (0.0)	NE		
>=5 IU/mL	1/ 56 (1.8)	0/ 65 (0.0)	3.47 (0.14, 83.61)	0.4429	
Low complement (C3 or C4) and positive FARR anti-dsDNA					NE
Yes	1/ 70 (1.4)	0/ 80 (0.0)	3.42 (0.14, 82.69)	0.4489	
No	0/ 29 (0.0)	0/ 21 (0.0)	NE		
OCS use					NE
Yes	0/ 79 (0.0)	0/ 87 (0.0)	NE		
No	1/ 20 (5.0)	0/ 14 (0.0)	2.14 (0.09, 49.08)	0.6333	
SLICC score					NE
0	0/ 62 (0.0)	0/ 66 (0.0)	NE		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Influenza - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
>=1	1/ 37 (2.7)	0/ 35 (0.0)	2.84 (0.12, 67.53)	0.5181	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Influenza
Safety analysis set

	Anifrolumab 300mg (N=99)	Placebo (N=101)
Number of subjects with events, n (%)	6 (6.1)	2 (2.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.06 (0.63, 14.80)	
p-value	0.1642	
Odds Ratio (95% CI)	3.19 (0.63, 16.22)	
p-value	0.1614	
Risk Difference (95% CI)	4.08 (-1.35, 9.51)	
p-value	0.1407	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Influenza - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.6751
< 10 points	2/ 39 (5.1)	1/ 40 (2.5)	2.05 (0.19, 21.72)	0.5507	
>= 10 points	4/ 60 (6.7)	1/ 61 (1.6)	4.07 (0.47, 35.34)	0.2035	
OCS dose					0.8398
<10 mg/day	3/ 44 (6.8)	1/ 37 (2.7)	2.52 (0.27, 23.24)	0.4141	
>=10 mg/day	3/ 55 (5.5)	1/ 64 (1.6)	3.49 (0.37, 32.60)	0.2728	
Result of type I IFN gene signature test					0.5693
LOW	2/ 24 (8.3)	0/ 26 (0.0)	5.40 (0.27, 107.09)	0.2685	
HIGH	4/ 75 (5.3)	2/ 75 (2.7)	2.00 (0.38, 10.59)	0.4151	
Age (years)					0.0421
<= 45	6/ 67 (9.0)	0/ 71 (0.0)	13.76 (0.79, 239.70)	0.0721	
> 45	0/ 32 (0.0)	2/ 30 (6.7)	0.19 (0.01, 3.76)	0.2741	
Sex					NE
male	0/ 6 (0.0)	0/ 9 (0.0)	NE		
female	6/ 93 (6.5)	2/ 92 (2.2)	2.97 (0.61, 14.32)	0.1756	
Race					0.3832
White	1/ 35 (2.9)	1/ 41 (2.4)	1.17 (0.08, 18.05)	0.9097	
Black	0/ 19 (0.0)	0/ 11 (0.0)	NE		
Other	5/ 45 (11.1)	1/ 49 (2.0)	5.44 (0.66, 44.84)	0.1152	
Ethnicity					0.7619
Hispanic/Latino	4/ 46 (8.7)	1/ 42 (2.4)	3.65 (0.42, 31.39)	0.2379	
Non-hispanic/Latino	2/ 53 (3.8)	1/ 59 (1.7)	2.23 (0.21, 23.86)	0.5083	
Geographic region					0.8040
Latin America, Eastern Europe and Asia	4/ 62 (6.5)	2/ 74 (2.7)	2.39 (0.45, 12.60)	0.3053	
North America	2/ 37 (5.4)	0/ 27 (0.0)	3.68 (0.18, 73.77)	0.3937	
Baseline weight					0.4495
<60 kg	1/ 32 (3.1)	1/ 39 (2.6)	1.22 (0.08, 18.73)	0.8871	
>=60 kg	5/ 67 (7.5)	1/ 62 (1.6)	4.63 (0.56, 38.51)	0.1565	
Low CH50					0.9670
Yes	1/ 13 (7.7)	0/ 12 (0.0)	2.79 (0.12, 62.48)	0.5185	
No	5/ 86 (5.8)	2/ 89 (2.2)	2.59 (0.52, 12.98)	0.2480	
Low C3 or C4					0.2401
Yes	3/ 33 (9.1)	0/ 46 (0.0)	9.68 (0.52, 181.24)	0.1290	
No	3/ 66 (4.5)	2/ 55 (3.6)	1.25 (0.22, 7.22)	0.8030	
Baseline FARR anti-dsDNA					0.2454
<5 IU/mL	1/ 21 (4.8)	1/ 16 (6.3)	0.76 (0.05, 11.27)	0.8432	
>=5 IU/mL	3/ 56 (5.4)	0/ 65 (0.0)	8.11 (0.43, 153.61)	0.1633	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.1329
Yes	4/ 70 (5.7)	0/ 80 (0.0)	10.27 (0.56, 187.41)	0.1160	
No	2/ 29 (6.9)	2/ 21 (9.5)	0.72 (0.11, 4.74)	0.7362	
OCS use					0.8891
Yes	5/ 79 (6.3)	2/ 87 (2.3)	2.75 (0.55, 13.79)	0.2180	
No	1/ 20 (5.0)	0/ 14 (0.0)	2.14 (0.09, 49.08)	0.6333	
SLICC score					0.7246
0	2/ 62 (3.2)	1/ 66 (1.5)	2.13 (0.20, 22.90)	0.5329	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Influenza - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
>=1	4/ 37 (10.8)	1/ 35 (2.9)	3.78 (0.44, 32.23)	0.2234	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Tuberculosis (including latent TB)
Safety analysis set

	Anifrolumab 300mg (N=99)	Placebo (N=101)
Number of subjects with events, n (%)	2 (2.0)	1 (1.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	2.04 (0.19, 22.14)	
p-value	0.5577	
Odds Ratio (95% CI)	2.06 (0.18, 23.11)	
p-value	0.5573	
Risk Difference (95% CI)	1.03 (-2.35, 4.41)	
p-value	0.5500	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Tuberculosis (including latent TB) - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.2266
< 10 points	0/ 39 (0.0)	1/ 40 (2.5)	0.34 (0.01, 8.14)	0.5068	
>= 10 points	2/ 60 (3.3)	0/ 61 (0.0)	5.08 (0.25, 103.69)	0.2907	
OCS dose					0.7163
<10 mg/day	1/ 44 (2.3)	0/ 37 (0.0)	2.53 (0.11, 60.39)	0.5656	
>=10 mg/day	1/ 55 (1.8)	1/ 64 (1.6)	1.16 (0.07, 18.17)	0.9139	
Result of type I IFN gene signature test					NE
LOW	0/ 24 (0.0)	0/ 26 (0.0)	NE		
HIGH	2/ 75 (2.7)	1/ 75 (1.3)	2.00 (0.19, 21.59)	0.5680	
Age (years)					NE
<= 45	2/ 67 (3.0)	1/ 71 (1.4)	2.12 (0.20, 22.83)	0.5357	
> 45	0/ 32 (0.0)	0/ 30 (0.0)	NE		
Sex					NE
male	0/ 6 (0.0)	0/ 9 (0.0)	NE		
female	2/ 93 (2.2)	1/ 92 (1.1)	1.98 (0.18, 21.44)	0.5747	
Race					NE
White	0/ 35 (0.0)	0/ 41 (0.0)	NE		
Black	0/ 19 (0.0)	0/ 11 (0.0)	NE		
Other	2/ 45 (4.4)	1/ 49 (2.0)	2.18 (0.20, 23.21)	0.5191	
Ethnicity					0.5454
Hispanic/Latino	1/ 46 (2.2)	1/ 42 (2.4)	0.91 (0.06, 14.14)	0.9481	
Non-hispanic/Latino	1/ 53 (1.9)	0/ 59 (0.0)	3.33 (0.14, 80.11)	0.4580	
Geographic region					NE
Latin America, Eastern Europe and Asia	2/ 62 (3.2)	1/ 74 (1.4)	2.39 (0.22, 25.71)	0.4730	
North America	0/ 37 (0.0)	0/ 27 (0.0)	NE		
Baseline weight					0.5225
<60 kg	1/ 32 (3.1)	0/ 39 (0.0)	3.64 (0.15, 86.33)	0.4244	
>=60 kg	1/ 67 (1.5)	1/ 62 (1.6)	0.93 (0.06, 14.48)	0.9559	
Low CH50					NE
Yes	0/ 13 (0.0)	0/ 12 (0.0)	NE		
No	2/ 86 (2.3)	1/ 89 (1.1)	2.07 (0.19, 22.41)	0.5495	
Low C3 or C4					0.4535
Yes	1/ 33 (3.0)	0/ 46 (0.0)	4.15 (0.17, 98.74)	0.3792	
No	1/ 66 (1.5)	1/ 55 (1.8)	0.83 (0.05, 13.02)	0.8966	
Baseline FARR anti-dsDNA					0.7451
<5 IU/mL	1/ 21 (4.8)	0/ 16 (0.0)	2.32 (0.10, 53.42)	0.5994	
>=5 IU/mL	1/ 56 (1.8)	1/ 65 (1.5)	1.16 (0.07, 18.13)	0.9154	
Low complement (C3 or C4) and positive FARR anti-dsDNA					NE
Yes	2/ 70 (2.9)	1/ 80 (1.3)	2.29 (0.21, 24.67)	0.4958	
No	0/ 29 (0.0)	0/ 21 (0.0)	NE		
OCS use					NE
Yes	2/ 79 (2.5)	1/ 87 (1.1)	2.20 (0.20, 23.82)	0.5157	
No	0/ 20 (0.0)	0/ 14 (0.0)	NE		
SLICC score					NE
0	2/ 62 (3.2)	1/ 66 (1.5)	2.13 (0.20, 22.90)	0.5329	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Tuberculosis (including latent TB) - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
>=1	0/ 37 (0.0)	0/ 35 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Tuberculosis (including latent TB)
Safety analysis set

	Anifrolumab 300mg (N=99)	Placebo (N=101)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Tuberculosis (including latent TB) - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
SLEDAI-2K score				NE
< 10 points	0/ 39 (0.0)	0/ 40 (0.0)	NE	
>= 10 points	0/ 60 (0.0)	0/ 61 (0.0)	NE	
OCS dose				NE
<10 mg/day	0/ 44 (0.0)	0/ 37 (0.0)	NE	
>=10 mg/day	0/ 55 (0.0)	0/ 64 (0.0)	NE	
Result of type I IFN gene signature test				NE
LOW	0/ 24 (0.0)	0/ 26 (0.0)	NE	
HIGH	0/ 75 (0.0)	0/ 75 (0.0)	NE	
Age (years)				NE
<= 45	0/ 67 (0.0)	0/ 71 (0.0)	NE	
> 45	0/ 32 (0.0)	0/ 30 (0.0)	NE	
Sex				NE
male	0/ 6 (0.0)	0/ 9 (0.0)	NE	
female	0/ 93 (0.0)	0/ 92 (0.0)	NE	
Race				NE
White	0/ 35 (0.0)	0/ 41 (0.0)	NE	
Black	0/ 19 (0.0)	0/ 11 (0.0)	NE	
Other	0/ 45 (0.0)	0/ 49 (0.0)	NE	
Ethnicity				NE
Hispanic/Latino	0/ 46 (0.0)	0/ 42 (0.0)	NE	
Non-hispanic/Latino	0/ 53 (0.0)	0/ 59 (0.0)	NE	
Geographic region				NE
Latin America, Eastern Europe and Asia	0/ 62 (0.0)	0/ 74 (0.0)	NE	
North America	0/ 37 (0.0)	0/ 27 (0.0)	NE	
Baseline weight				NE
<60 kg	0/ 32 (0.0)	0/ 39 (0.0)	NE	
>=60 kg	0/ 67 (0.0)	0/ 62 (0.0)	NE	
Low CH50				NE
Yes	0/ 13 (0.0)	0/ 12 (0.0)	NE	
No	0/ 86 (0.0)	0/ 89 (0.0)	NE	
Low C3 or C4				NE
Yes	0/ 33 (0.0)	0/ 46 (0.0)	NE	
No	0/ 66 (0.0)	0/ 55 (0.0)	NE	
Baseline FARR anti-dsDNA				NE
<5 IU/mL	0/ 21 (0.0)	0/ 16 (0.0)	NE	
>=5 IU/mL	0/ 56 (0.0)	0/ 65 (0.0)	NE	
Low complement (C3 or C4) and positive FARR anti-dsDNA				NE
Yes	0/ 70 (0.0)	0/ 80 (0.0)	NE	
No	0/ 29 (0.0)	0/ 21 (0.0)	NE	
OCS use				NE
Yes	0/ 79 (0.0)	0/ 87 (0.0)	NE	
No	0/ 20 (0.0)	0/ 14 (0.0)	NE	
SLICC score				NE
0	0/ 62 (0.0)	0/ 66 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Tuberculosis (including latent TB) - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
>=1	0/ 37 (0.0)	0/ 35 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Tuberculosis (including latent TB)
Safety analysis set

	Anifrolumab 300mg (N=99)	Placebo (N=101)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Tuberculosis (including latent TB) - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
SLEDAI-2K score				NE
< 10 points	0/ 39 (0.0)	0/ 40 (0.0)	NE	
>= 10 points	0/ 60 (0.0)	0/ 61 (0.0)	NE	
OCS dose				NE
<10 mg/day	0/ 44 (0.0)	0/ 37 (0.0)	NE	
>=10 mg/day	0/ 55 (0.0)	0/ 64 (0.0)	NE	
Result of type I IFN gene signature test				NE
LOW	0/ 24 (0.0)	0/ 26 (0.0)	NE	
HIGH	0/ 75 (0.0)	0/ 75 (0.0)	NE	
Age (years)				NE
<= 45	0/ 67 (0.0)	0/ 71 (0.0)	NE	
> 45	0/ 32 (0.0)	0/ 30 (0.0)	NE	
Sex				NE
male	0/ 6 (0.0)	0/ 9 (0.0)	NE	
female	0/ 93 (0.0)	0/ 92 (0.0)	NE	
Race				NE
White	0/ 35 (0.0)	0/ 41 (0.0)	NE	
Black	0/ 19 (0.0)	0/ 11 (0.0)	NE	
Other	0/ 45 (0.0)	0/ 49 (0.0)	NE	
Ethnicity				NE
Hispanic/Latino	0/ 46 (0.0)	0/ 42 (0.0)	NE	
Non-hispanic/Latino	0/ 53 (0.0)	0/ 59 (0.0)	NE	
Geographic region				NE
Latin America, Eastern Europe and Asia	0/ 62 (0.0)	0/ 74 (0.0)	NE	
North America	0/ 37 (0.0)	0/ 27 (0.0)	NE	
Baseline weight				NE
<60 kg	0/ 32 (0.0)	0/ 39 (0.0)	NE	
>=60 kg	0/ 67 (0.0)	0/ 62 (0.0)	NE	
Low CH50				NE
Yes	0/ 13 (0.0)	0/ 12 (0.0)	NE	
No	0/ 86 (0.0)	0/ 89 (0.0)	NE	
Low C3 or C4				NE
Yes	0/ 33 (0.0)	0/ 46 (0.0)	NE	
No	0/ 66 (0.0)	0/ 55 (0.0)	NE	
Baseline FARR anti-dsDNA				NE
<5 IU/mL	0/ 21 (0.0)	0/ 16 (0.0)	NE	
>=5 IU/mL	0/ 56 (0.0)	0/ 65 (0.0)	NE	
Low complement (C3 or C4) and positive FARR anti-dsDNA				NE
Yes	0/ 70 (0.0)	0/ 80 (0.0)	NE	
No	0/ 29 (0.0)	0/ 21 (0.0)	NE	
OCS use				NE
Yes	0/ 79 (0.0)	0/ 87 (0.0)	NE	
No	0/ 20 (0.0)	0/ 14 (0.0)	NE	
SLICC score				NE
0	0/ 62 (0.0)	0/ 66 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Tuberculosis (including latent TB) - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
>=1	0/ 37 (0.0)	0/ 35 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Tuberculosis (including latent TB)
Safety analysis set

	Anifrolumab 300mg (N=99)	Placebo (N=101)
Number of subjects with events, n (%)	2 (2.0)	1 (1.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	2.04 (0.19, 22.14)	
p-value	0.5577	
Odds Ratio (95% CI)	2.06 (0.18, 23.11)	
p-value	0.5573	
Risk Difference (95% CI)	1.03 (-2.35, 4.41)	
p-value	0.5500	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Tuberculosis (including latent TB) - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.2266
< 10 points	0/ 39 (0.0)	1/ 40 (2.5)	0.34 (0.01, 8.14)	0.5068	
>= 10 points	2/ 60 (3.3)	0/ 61 (0.0)	5.08 (0.25, 103.69)	0.2907	
OCS dose					0.7163
<10 mg/day	1/ 44 (2.3)	0/ 37 (0.0)	2.53 (0.11, 60.39)	0.5656	
>=10 mg/day	1/ 55 (1.8)	1/ 64 (1.6)	1.16 (0.07, 18.17)	0.9139	
Result of type I IFN gene signature test					NE
LOW	0/ 24 (0.0)	0/ 26 (0.0)	NE		
HIGH	2/ 75 (2.7)	1/ 75 (1.3)	2.00 (0.19, 21.59)	0.5680	
Age (years)					NE
<= 45	2/ 67 (3.0)	1/ 71 (1.4)	2.12 (0.20, 22.83)	0.5357	
> 45	0/ 32 (0.0)	0/ 30 (0.0)	NE		
Sex					NE
male	0/ 6 (0.0)	0/ 9 (0.0)	NE		
female	2/ 93 (2.2)	1/ 92 (1.1)	1.98 (0.18, 21.44)	0.5747	
Race					NE
White	0/ 35 (0.0)	0/ 41 (0.0)	NE		
Black	0/ 19 (0.0)	0/ 11 (0.0)	NE		
Other	2/ 45 (4.4)	1/ 49 (2.0)	2.18 (0.20, 23.21)	0.5191	
Ethnicity					0.5454
Hispanic/Latino	1/ 46 (2.2)	1/ 42 (2.4)	0.91 (0.06, 14.14)	0.9481	
Non-hispanic/Latino	1/ 53 (1.9)	0/ 59 (0.0)	3.33 (0.14, 80.11)	0.4580	
Geographic region					NE
Latin America, Eastern Europe and Asia	2/ 62 (3.2)	1/ 74 (1.4)	2.39 (0.22, 25.71)	0.4730	
North America	0/ 37 (0.0)	0/ 27 (0.0)	NE		
Baseline weight					0.5225
<60 kg	1/ 32 (3.1)	0/ 39 (0.0)	3.64 (0.15, 86.33)	0.4244	
>=60 kg	1/ 67 (1.5)	1/ 62 (1.6)	0.93 (0.06, 14.48)	0.9559	
Low CH50					NE
Yes	0/ 13 (0.0)	0/ 12 (0.0)	NE		
No	2/ 86 (2.3)	1/ 89 (1.1)	2.07 (0.19, 22.41)	0.5495	
Low C3 or C4					0.4535
Yes	1/ 33 (3.0)	0/ 46 (0.0)	4.15 (0.17, 98.74)	0.3792	
No	1/ 66 (1.5)	1/ 55 (1.8)	0.83 (0.05, 13.02)	0.8966	
Baseline FARR anti-dsDNA					0.7451
<5 IU/mL	1/ 21 (4.8)	0/ 16 (0.0)	2.32 (0.10, 53.42)	0.5994	
>=5 IU/mL	1/ 56 (1.8)	1/ 65 (1.5)	1.16 (0.07, 18.13)	0.9154	
Low complement (C3 or C4) and positive FARR anti-dsDNA					NE
Yes	2/ 70 (2.9)	1/ 80 (1.3)	2.29 (0.21, 24.67)	0.4958	
No	0/ 29 (0.0)	0/ 21 (0.0)	NE		
OCS use					NE
Yes	2/ 79 (2.5)	1/ 87 (1.1)	2.20 (0.20, 23.82)	0.5157	
No	0/ 20 (0.0)	0/ 14 (0.0)	NE		
SLICC score					NE
0	2/ 62 (3.2)	1/ 66 (1.5)	2.13 (0.20, 22.90)	0.5329	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Tuberculosis (including latent TB) - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
>=1	0/ 37 (0.0)	0/ 35 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Vasculitis
Safety analysis set

	Anifrolumab 300mg (N=99)	Placebo (N=101)
Number of subjects with events, n (%)	0 (0.0)	3 (3.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.15 (0.01, 2.78)	
p-value	0.2007	
Odds Ratio (95% CI)	0.14 (0.01, 2.77)	
p-value	0.1977	
Risk Difference (95% CI)	-2.97 (-6.28, 0.34)	
p-value	0.0787	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Vasculitis - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.8161
< 10 points	0/ 39 (0.0)	1/ 40 (2.5)	0.34 (0.01, 8.14)	0.5068	
>= 10 points	0/ 60 (0.0)	2/ 61 (3.3)	0.20 (0.01, 4.15)	0.3005	
OCS dose					0.9312
<10 mg/day	0/ 44 (0.0)	1/ 37 (2.7)	0.28 (0.01, 6.71)	0.4334	
>=10 mg/day	0/ 55 (0.0)	2/ 64 (3.1)	0.23 (0.01, 4.73)	0.3425	
Result of type I IFN gene signature test					NE
LOW	0/ 24 (0.0)	0/ 26 (0.0)	NE		
HIGH	0/ 75 (0.0)	3/ 75 (4.0)	0.14 (0.01, 2.72)	0.1955	
Age (years)					0.8608
<= 45	0/ 67 (0.0)	2/ 71 (2.8)	0.21 (0.01, 4.33)	0.3134	
> 45	0/ 32 (0.0)	1/ 30 (3.3)	0.31 (0.01, 7.40)	0.4718	
Sex					NE
male	0/ 6 (0.0)	0/ 9 (0.0)	NE		
female	0/ 93 (0.0)	3/ 92 (3.3)	0.14 (0.01, 2.70)	0.1935	
Race					0.9699
White	0/ 35 (0.0)	0/ 41 (0.0)	NE		
Black	0/ 19 (0.0)	1/ 11 (9.1)	0.20 (0.01, 4.53)	0.3119	
Other	0/ 45 (0.0)	2/ 49 (4.1)	0.22 (0.01, 4.41)	0.3203	
Ethnicity					0.8873
Hispanic/Latino	0/ 46 (0.0)	1/ 42 (2.4)	0.30 (0.01, 7.29)	0.4633	
Non-hispanic/Latino	0/ 53 (0.0)	2/ 59 (3.4)	0.22 (0.01, 4.53)	0.3280	
Geographic region					0.9889
Latin America, Eastern Europe and Asia	0/ 62 (0.0)	2/ 74 (2.7)	0.24 (0.01, 4.87)	0.3513	
North America	0/ 37 (0.0)	1/ 27 (3.7)	0.25 (0.01, 5.81)	0.3843	
Baseline weight					0.9136
<60 kg	0/ 32 (0.0)	2/ 39 (5.1)	0.24 (0.01, 4.87)	0.3547	
>=60 kg	0/ 67 (0.0)	1/ 62 (1.6)	0.31 (0.01, 7.44)	0.4693	
Low CH50					NE
Yes	0/ 13 (0.0)	0/ 12 (0.0)	NE		
No	0/ 86 (0.0)	3/ 89 (3.4)	0.15 (0.01, 2.82)	0.2037	
Low C3 or C4					0.9972
Yes	0/ 33 (0.0)	2/ 46 (4.3)	0.28 (0.01, 5.58)	0.4016	
No	0/ 66 (0.0)	1/ 55 (1.8)	0.28 (0.01, 6.71)	0.4310	
Baseline FARR anti-dsDNA					NE
<5 IU/mL	0/ 21 (0.0)	0/ 16 (0.0)	NE		
>=5 IU/mL	0/ 56 (0.0)	2/ 65 (3.1)	0.23 (0.01, 4.72)	0.3417	
Low complement (C3 or C4) and positive FARR anti-dsDNA					NE
Yes	0/ 70 (0.0)	3/ 80 (3.8)	0.16 (0.01, 3.10)	0.2275	
No	0/ 29 (0.0)	0/ 21 (0.0)	NE		
OCS use					NE
Yes	0/ 79 (0.0)	3/ 87 (3.4)	0.16 (0.01, 3.00)	0.2185	
No	0/ 20 (0.0)	0/ 14 (0.0)	NE		
SLICC score					NE
0	0/ 62 (0.0)	3/ 66 (4.5)	0.15 (0.01, 2.88)	0.2095	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Vasculitis - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
>=1	0/ 37 (0.0)	0/ 35 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Vasculitis
Safety analysis set

	Anifrolumab 300mg (N=99)	Placebo (N=101)
Number of subjects with events, n (%)	0 (0.0)	2 (2.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.20 (0.01, 4.20)	
p-value	0.3028	
Odds Ratio (95% CI)	0.20 (0.01, 4.22)	
p-value	0.3009	
Risk Difference (95% CI)	-1.98 (-4.70, 0.74)	
p-value	0.1532	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Vasculitis - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.9971
< 10 points	0/ 39 (0.0)	1/ 40 (2.5)	0.34 (0.01, 8.14)	0.5068	
>= 10 points	0/ 60 (0.0)	1/ 61 (1.6)	0.34 (0.01, 8.16)	0.5048	
OCS dose					0.8896
<10 mg/day	0/ 44 (0.0)	1/ 37 (2.7)	0.28 (0.01, 6.71)	0.4334	
>=10 mg/day	0/ 55 (0.0)	1/ 64 (1.6)	0.39 (0.02, 9.31)	0.5584	
Result of type I IFN gene signature test					NE
LOW	0/ 24 (0.0)	0/ 26 (0.0)	NE		
HIGH	0/ 75 (0.0)	2/ 75 (2.7)	0.20 (0.01, 4.10)	0.2962	
Age (years)					0.9583
<= 45	0/ 67 (0.0)	1/ 71 (1.4)	0.35 (0.01, 8.52)	0.5214	
> 45	0/ 32 (0.0)	1/ 30 (3.3)	0.31 (0.01, 7.40)	0.4718	
Sex					NE
male	0/ 6 (0.0)	0/ 9 (0.0)	NE		
female	0/ 93 (0.0)	2/ 92 (2.2)	0.20 (0.01, 4.07)	0.2935	
Race					0.7936
White	0/ 35 (0.0)	0/ 41 (0.0)	NE		
Black	0/ 19 (0.0)	1/ 11 (9.1)	0.20 (0.01, 4.53)	0.3119	
Other	0/ 45 (0.0)	1/ 49 (2.0)	0.36 (0.02, 8.67)	0.5309	
Ethnicity					NE
Hispanic/Latino	0/ 46 (0.0)	0/ 42 (0.0)	NE		
Non-hispanic/Latino	0/ 53 (0.0)	2/ 59 (3.4)	0.22 (0.01, 4.53)	0.3280	
Geographic region					0.8340
Latin America, Eastern Europe and Asia	0/ 62 (0.0)	1/ 74 (1.4)	0.40 (0.02, 9.57)	0.5693	
North America	0/ 37 (0.0)	1/ 27 (3.7)	0.25 (0.01, 5.81)	0.3843	
Baseline weight					0.9066
<60 kg	0/ 32 (0.0)	1/ 39 (2.6)	0.40 (0.02, 9.59)	0.5749	
>=60 kg	0/ 67 (0.0)	1/ 62 (1.6)	0.31 (0.01, 7.44)	0.4693	
Low CH50					NE
Yes	0/ 13 (0.0)	0/ 12 (0.0)	NE		
No	0/ 86 (0.0)	2/ 89 (2.2)	0.21 (0.01, 4.25)	0.3069	
Low C3 or C4					0.8262
Yes	0/ 33 (0.0)	1/ 46 (2.2)	0.46 (0.02, 10.97)	0.6319	
No	0/ 66 (0.0)	1/ 55 (1.8)	0.28 (0.01, 6.71)	0.4310	
Baseline FARR anti-dsDNA					NE
<5 IU/mL	0/ 21 (0.0)	0/ 16 (0.0)	NE		
>=5 IU/mL	0/ 56 (0.0)	2/ 65 (3.1)	0.23 (0.01, 4.72)	0.3417	
Low complement (C3 or C4) and positive FARR anti-dsDNA					NE
Yes	0/ 70 (0.0)	2/ 80 (2.5)	0.23 (0.01, 4.67)	0.3375	
No	0/ 29 (0.0)	0/ 21 (0.0)	NE		
OCS use					NE
Yes	0/ 79 (0.0)	2/ 87 (2.3)	0.22 (0.01, 4.51)	0.3260	
No	0/ 20 (0.0)	0/ 14 (0.0)	NE		
SLICC score					NE
0	0/ 62 (0.0)	2/ 66 (3.0)	0.21 (0.01, 4.34)	0.3146	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Vasculitis - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
>=1	0/ 37 (0.0)	0/ 35 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Vasculitis
Safety analysis set

	Anifrolumab 300mg (N=99)	Placebo (N=101)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Vasculitis - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
SLEDAI-2K score				NE
< 10 points	0/ 39 (0.0)	0/ 40 (0.0)	NE	
>= 10 points	0/ 60 (0.0)	0/ 61 (0.0)	NE	
OCS dose				NE
<10 mg/day	0/ 44 (0.0)	0/ 37 (0.0)	NE	
>=10 mg/day	0/ 55 (0.0)	0/ 64 (0.0)	NE	
Result of type I IFN gene signature test				NE
LOW	0/ 24 (0.0)	0/ 26 (0.0)	NE	
HIGH	0/ 75 (0.0)	0/ 75 (0.0)	NE	
Age (years)				NE
<= 45	0/ 67 (0.0)	0/ 71 (0.0)	NE	
> 45	0/ 32 (0.0)	0/ 30 (0.0)	NE	
Sex				NE
male	0/ 6 (0.0)	0/ 9 (0.0)	NE	
female	0/ 93 (0.0)	0/ 92 (0.0)	NE	
Race				NE
White	0/ 35 (0.0)	0/ 41 (0.0)	NE	
Black	0/ 19 (0.0)	0/ 11 (0.0)	NE	
Other	0/ 45 (0.0)	0/ 49 (0.0)	NE	
Ethnicity				NE
Hispanic/Latino	0/ 46 (0.0)	0/ 42 (0.0)	NE	
Non-hispanic/Latino	0/ 53 (0.0)	0/ 59 (0.0)	NE	
Geographic region				NE
Latin America, Eastern Europe and Asia	0/ 62 (0.0)	0/ 74 (0.0)	NE	
North America	0/ 37 (0.0)	0/ 27 (0.0)	NE	
Baseline weight				NE
<60 kg	0/ 32 (0.0)	0/ 39 (0.0)	NE	
>=60 kg	0/ 67 (0.0)	0/ 62 (0.0)	NE	
Low CH50				NE
Yes	0/ 13 (0.0)	0/ 12 (0.0)	NE	
No	0/ 86 (0.0)	0/ 89 (0.0)	NE	
Low C3 or C4				NE
Yes	0/ 33 (0.0)	0/ 46 (0.0)	NE	
No	0/ 66 (0.0)	0/ 55 (0.0)	NE	
Baseline FARR anti-dsDNA				NE
<5 IU/mL	0/ 21 (0.0)	0/ 16 (0.0)	NE	
>=5 IU/mL	0/ 56 (0.0)	0/ 65 (0.0)	NE	
Low complement (C3 or C4) and positive FARR anti-dsDNA				NE
Yes	0/ 70 (0.0)	0/ 80 (0.0)	NE	
No	0/ 29 (0.0)	0/ 21 (0.0)	NE	
OCS use				NE
Yes	0/ 79 (0.0)	0/ 87 (0.0)	NE	
No	0/ 20 (0.0)	0/ 14 (0.0)	NE	
SLICC score				NE
0	0/ 62 (0.0)	0/ 66 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Vasculitis - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
>=1	0/ 37 (0.0)	0/ 35 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Vasculitis
Safety analysis set

	Anifrolumab 300mg (N=99)	Placebo (N=101)
Number of subjects with events, n (%)	0 (0.0)	3 (3.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.15 (0.01, 2.78)	
p-value	0.2007	
Odds Ratio (95% CI)	0.14 (0.01, 2.77)	
p-value	0.1977	
Risk Difference (95% CI)	-2.97 (-6.28, 0.34)	
p-value	0.0787	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Vasculitis - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.8161
< 10 points	0/ 39 (0.0)	1/ 40 (2.5)	0.34 (0.01, 8.14)	0.5068	
>= 10 points	0/ 60 (0.0)	2/ 61 (3.3)	0.20 (0.01, 4.15)	0.3005	
OCS dose					0.9312
<10 mg/day	0/ 44 (0.0)	1/ 37 (2.7)	0.28 (0.01, 6.71)	0.4334	
>=10 mg/day	0/ 55 (0.0)	2/ 64 (3.1)	0.23 (0.01, 4.73)	0.3425	
Result of type I IFN gene signature test					NE
LOW	0/ 24 (0.0)	0/ 26 (0.0)	NE		
HIGH	0/ 75 (0.0)	3/ 75 (4.0)	0.14 (0.01, 2.72)	0.1955	
Age (years)					0.8608
<= 45	0/ 67 (0.0)	2/ 71 (2.8)	0.21 (0.01, 4.33)	0.3134	
> 45	0/ 32 (0.0)	1/ 30 (3.3)	0.31 (0.01, 7.40)	0.4718	
Sex					NE
male	0/ 6 (0.0)	0/ 9 (0.0)	NE		
female	0/ 93 (0.0)	3/ 92 (3.3)	0.14 (0.01, 2.70)	0.1935	
Race					0.9699
White	0/ 35 (0.0)	0/ 41 (0.0)	NE		
Black	0/ 19 (0.0)	1/ 11 (9.1)	0.20 (0.01, 4.53)	0.3119	
Other	0/ 45 (0.0)	2/ 49 (4.1)	0.22 (0.01, 4.41)	0.3203	
Ethnicity					0.8873
Hispanic/Latino	0/ 46 (0.0)	1/ 42 (2.4)	0.30 (0.01, 7.29)	0.4633	
Non-hispanic/Latino	0/ 53 (0.0)	2/ 59 (3.4)	0.22 (0.01, 4.53)	0.3280	
Geographic region					0.9889
Latin America, Eastern Europe and Asia	0/ 62 (0.0)	2/ 74 (2.7)	0.24 (0.01, 4.87)	0.3513	
North America	0/ 37 (0.0)	1/ 27 (3.7)	0.25 (0.01, 5.81)	0.3843	
Baseline weight					0.9136
<60 kg	0/ 32 (0.0)	2/ 39 (5.1)	0.24 (0.01, 4.87)	0.3547	
>=60 kg	0/ 67 (0.0)	1/ 62 (1.6)	0.31 (0.01, 7.44)	0.4693	
Low CH50					NE
Yes	0/ 13 (0.0)	0/ 12 (0.0)	NE		
No	0/ 86 (0.0)	3/ 89 (3.4)	0.15 (0.01, 2.82)	0.2037	
Low C3 or C4					0.9972
Yes	0/ 33 (0.0)	2/ 46 (4.3)	0.28 (0.01, 5.58)	0.4016	
No	0/ 66 (0.0)	1/ 55 (1.8)	0.28 (0.01, 6.71)	0.4310	
Baseline FARR anti-dsDNA					NE
<5 IU/mL	0/ 21 (0.0)	0/ 16 (0.0)	NE		
>=5 IU/mL	0/ 56 (0.0)	2/ 65 (3.1)	0.23 (0.01, 4.72)	0.3417	
Low complement (C3 or C4) and positive FARR anti-dsDNA					NE
Yes	0/ 70 (0.0)	3/ 80 (3.8)	0.16 (0.01, 3.10)	0.2275	
No	0/ 29 (0.0)	0/ 21 (0.0)	NE		
OCS use					NE
Yes	0/ 79 (0.0)	3/ 87 (3.4)	0.16 (0.01, 3.00)	0.2185	
No	0/ 20 (0.0)	0/ 14 (0.0)	NE		
SLICC score					NE
0	0/ 62 (0.0)	3/ 66 (4.5)	0.15 (0.01, 2.88)	0.2095	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Vasculitis - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
>=1	0/ 37 (0.0)	0/ 35 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Malignancy
Safety analysis set

	Anifrolumab 300mg (N=99)	Placebo (N=101)
Number of subjects with events, n (%)	1 (1.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.06 (0.13, 74.23)	
p-value	0.4918	
Odds Ratio (95% CI)	3.09 (0.12, 76.80)	
p-value	0.4911	
Risk Difference (95% CI)	1.01 (-0.96, 2.98)	
p-value	0.3149	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Malignancy - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					NE
< 10 points	1/ 39 (2.6)	0/ 40 (0.0)	3.08 (0.13, 73.27)	0.4875	
>= 10 points	0/ 60 (0.0)	0/ 61 (0.0)	NE		
OCS dose					NE
<10 mg/day	1/ 44 (2.3)	0/ 37 (0.0)	2.53 (0.11, 60.39)	0.5656	
>=10 mg/day	0/ 55 (0.0)	0/ 64 (0.0)	NE		
Result of type I IFN gene signature test					NE
LOW	1/ 24 (4.2)	0/ 26 (0.0)	3.24 (0.14, 75.91)	0.4651	
HIGH	0/ 75 (0.0)	0/ 75 (0.0)	NE		
Age (years)					NE
<= 45	0/ 67 (0.0)	0/ 71 (0.0)	NE		
> 45	1/ 32 (3.1)	0/ 30 (0.0)	2.82 (0.12, 66.62)	0.5208	
Sex					NE
male	0/ 6 (0.0)	0/ 9 (0.0)	NE		
female	1/ 93 (1.1)	0/ 92 (0.0)	2.97 (0.12, 71.93)	0.5036	
Race					NE
White	1/ 35 (2.9)	0/ 41 (0.0)	3.50 (0.15, 83.28)	0.4385	
Black	0/ 19 (0.0)	0/ 11 (0.0)	NE		
Other	0/ 45 (0.0)	0/ 49 (0.0)	NE		
Ethnicity					NE
Hispanic/Latino	0/ 46 (0.0)	0/ 42 (0.0)	NE		
Non-hispanic/Latino	1/ 53 (1.9)	0/ 59 (0.0)	3.33 (0.14, 80.11)	0.4580	
Geographic region					NE
Latin America, Eastern Europe and Asia	0/ 62 (0.0)	0/ 74 (0.0)	NE		
North America	1/ 37 (2.7)	0/ 27 (0.0)	2.21 (0.09, 52.27)	0.6231	
Baseline weight					NE
<60 kg	0/ 32 (0.0)	0/ 39 (0.0)	NE		
>=60 kg	1/ 67 (1.5)	0/ 62 (0.0)	2.78 (0.12, 66.98)	0.5289	
Low CH50					NE
Yes	0/ 13 (0.0)	0/ 12 (0.0)	NE		
No	1/ 86 (1.2)	0/ 89 (0.0)	3.10 (0.13, 75.15)	0.4861	
Low C3 or C4					NE
Yes	0/ 33 (0.0)	0/ 46 (0.0)	NE		
No	1/ 66 (1.5)	0/ 55 (0.0)	2.51 (0.10, 60.35)	0.5711	
Baseline FARR anti-dsDNA					NE
<5 IU/mL	0/ 21 (0.0)	0/ 16 (0.0)	NE		
>=5 IU/mL	1/ 56 (1.8)	0/ 65 (0.0)	3.47 (0.14, 83.61)	0.4429	
Low complement (C3 or C4) and positive FARR anti-dsDNA					NE
Yes	1/ 70 (1.4)	0/ 80 (0.0)	3.42 (0.14, 82.69)	0.4489	
No	0/ 29 (0.0)	0/ 21 (0.0)	NE		
OCS use					NE
Yes	0/ 79 (0.0)	0/ 87 (0.0)	NE		
No	1/ 20 (5.0)	0/ 14 (0.0)	2.14 (0.09, 49.08)	0.6333	
SLICC score					NE
0	0/ 62 (0.0)	0/ 66 (0.0)	NE		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Malignancy - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
>=1	1/ 37 (2.7)	0/ 35 (0.0)	2.84 (0.12, 67.53)	0.5181	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Malignancy
Safety analysis set

	Anifrolumab 300mg (N=99)	Placebo (N=101)
Number of subjects with events, n (%)	1 (1.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.06 (0.13, 74.23)	
p-value	0.4918	
Odds Ratio (95% CI)	3.09 (0.12, 76.80)	
p-value	0.4911	
Risk Difference (95% CI)	1.01 (-0.96, 2.98)	
p-value	0.3149	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Malignancy - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					NE
< 10 points	1/ 39 (2.6)	0/ 40 (0.0)	3.08 (0.13, 73.27)	0.4875	
>= 10 points	0/ 60 (0.0)	0/ 61 (0.0)	NE		
OCS dose					NE
<10 mg/day	1/ 44 (2.3)	0/ 37 (0.0)	2.53 (0.11, 60.39)	0.5656	
>=10 mg/day	0/ 55 (0.0)	0/ 64 (0.0)	NE		
Result of type I IFN gene signature test					NE
LOW	1/ 24 (4.2)	0/ 26 (0.0)	3.24 (0.14, 75.91)	0.4651	
HIGH	0/ 75 (0.0)	0/ 75 (0.0)	NE		
Age (years)					NE
<= 45	0/ 67 (0.0)	0/ 71 (0.0)	NE		
> 45	1/ 32 (3.1)	0/ 30 (0.0)	2.82 (0.12, 66.62)	0.5208	
Sex					NE
male	0/ 6 (0.0)	0/ 9 (0.0)	NE		
female	1/ 93 (1.1)	0/ 92 (0.0)	2.97 (0.12, 71.93)	0.5036	
Race					NE
White	1/ 35 (2.9)	0/ 41 (0.0)	3.50 (0.15, 83.28)	0.4385	
Black	0/ 19 (0.0)	0/ 11 (0.0)	NE		
Other	0/ 45 (0.0)	0/ 49 (0.0)	NE		
Ethnicity					NE
Hispanic/Latino	0/ 46 (0.0)	0/ 42 (0.0)	NE		
Non-hispanic/Latino	1/ 53 (1.9)	0/ 59 (0.0)	3.33 (0.14, 80.11)	0.4580	
Geographic region					NE
Latin America, Eastern Europe and Asia	0/ 62 (0.0)	0/ 74 (0.0)	NE		
North America	1/ 37 (2.7)	0/ 27 (0.0)	2.21 (0.09, 52.27)	0.6231	
Baseline weight					NE
<60 kg	0/ 32 (0.0)	0/ 39 (0.0)	NE		
>=60 kg	1/ 67 (1.5)	0/ 62 (0.0)	2.78 (0.12, 66.98)	0.5289	
Low CH50					NE
Yes	0/ 13 (0.0)	0/ 12 (0.0)	NE		
No	1/ 86 (1.2)	0/ 89 (0.0)	3.10 (0.13, 75.15)	0.4861	
Low C3 or C4					NE
Yes	0/ 33 (0.0)	0/ 46 (0.0)	NE		
No	1/ 66 (1.5)	0/ 55 (0.0)	2.51 (0.10, 60.35)	0.5711	
Baseline FARR anti-dsDNA					NE
<5 IU/mL	0/ 21 (0.0)	0/ 16 (0.0)	NE		
>=5 IU/mL	1/ 56 (1.8)	0/ 65 (0.0)	3.47 (0.14, 83.61)	0.4429	
Low complement (C3 or C4) and positive FARR anti-dsDNA					NE
Yes	1/ 70 (1.4)	0/ 80 (0.0)	3.42 (0.14, 82.69)	0.4489	
No	0/ 29 (0.0)	0/ 21 (0.0)	NE		
OCS use					NE
Yes	0/ 79 (0.0)	0/ 87 (0.0)	NE		
No	1/ 20 (5.0)	0/ 14 (0.0)	2.14 (0.09, 49.08)	0.6333	
SLICC score					NE
0	0/ 62 (0.0)	0/ 66 (0.0)	NE		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Malignancy - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
>=1	1/ 37 (2.7)	0/ 35 (0.0)	2.84 (0.12, 67.53)	0.5181	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Malignancy
Safety analysis set

	Anifrolumab 300mg (N=99)	Placebo (N=101)
Number of subjects with events, n (%)	1 (1.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.06 (0.13, 74.23)	
p-value	0.4918	
Odds Ratio (95% CI)	3.09 (0.12, 76.80)	
p-value	0.4911	
Risk Difference (95% CI)	1.01 (-0.96, 2.98)	
p-value	0.3149	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Malignancy - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					NE
< 10 points	1/ 39 (2.6)	0/ 40 (0.0)	3.08 (0.13, 73.27)	0.4875	
>= 10 points	0/ 60 (0.0)	0/ 61 (0.0)	NE		
OCS dose					NE
<10 mg/day	1/ 44 (2.3)	0/ 37 (0.0)	2.53 (0.11, 60.39)	0.5656	
>=10 mg/day	0/ 55 (0.0)	0/ 64 (0.0)	NE		
Result of type I IFN gene signature test					NE
LOW	1/ 24 (4.2)	0/ 26 (0.0)	3.24 (0.14, 75.91)	0.4651	
HIGH	0/ 75 (0.0)	0/ 75 (0.0)	NE		
Age (years)					NE
<= 45	0/ 67 (0.0)	0/ 71 (0.0)	NE		
> 45	1/ 32 (3.1)	0/ 30 (0.0)	2.82 (0.12, 66.62)	0.5208	
Sex					NE
male	0/ 6 (0.0)	0/ 9 (0.0)	NE		
female	1/ 93 (1.1)	0/ 92 (0.0)	2.97 (0.12, 71.93)	0.5036	
Race					NE
White	1/ 35 (2.9)	0/ 41 (0.0)	3.50 (0.15, 83.28)	0.4385	
Black	0/ 19 (0.0)	0/ 11 (0.0)	NE		
Other	0/ 45 (0.0)	0/ 49 (0.0)	NE		
Ethnicity					NE
Hispanic/Latino	0/ 46 (0.0)	0/ 42 (0.0)	NE		
Non-hispanic/Latino	1/ 53 (1.9)	0/ 59 (0.0)	3.33 (0.14, 80.11)	0.4580	
Geographic region					NE
Latin America, Eastern Europe and Asia	0/ 62 (0.0)	0/ 74 (0.0)	NE		
North America	1/ 37 (2.7)	0/ 27 (0.0)	2.21 (0.09, 52.27)	0.6231	
Baseline weight					NE
<60 kg	0/ 32 (0.0)	0/ 39 (0.0)	NE		
>=60 kg	1/ 67 (1.5)	0/ 62 (0.0)	2.78 (0.12, 66.98)	0.5289	
Low CH50					NE
Yes	0/ 13 (0.0)	0/ 12 (0.0)	NE		
No	1/ 86 (1.2)	0/ 89 (0.0)	3.10 (0.13, 75.15)	0.4861	
Low C3 or C4					NE
Yes	0/ 33 (0.0)	0/ 46 (0.0)	NE		
No	1/ 66 (1.5)	0/ 55 (0.0)	2.51 (0.10, 60.35)	0.5711	
Baseline FARR anti-dsDNA					NE
<5 IU/mL	0/ 21 (0.0)	0/ 16 (0.0)	NE		
>=5 IU/mL	1/ 56 (1.8)	0/ 65 (0.0)	3.47 (0.14, 83.61)	0.4429	
Low complement (C3 or C4) and positive FARR anti-dsDNA					NE
Yes	1/ 70 (1.4)	0/ 80 (0.0)	3.42 (0.14, 82.69)	0.4489	
No	0/ 29 (0.0)	0/ 21 (0.0)	NE		
OCS use					NE
Yes	0/ 79 (0.0)	0/ 87 (0.0)	NE		
No	1/ 20 (5.0)	0/ 14 (0.0)	2.14 (0.09, 49.08)	0.6333	
SLICC score					NE
0	0/ 62 (0.0)	0/ 66 (0.0)	NE		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Malignancy - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
>=1	1/ 37 (2.7)	0/ 35 (0.0)	2.84 (0.12, 67.53)	0.5181	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Malignancy
Safety analysis set

	Anifrolumab 300mg (N=99)	Placebo (N=101)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Malignancy - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
SLEDAI-2K score				NE
< 10 points	0/ 39 (0.0)	0/ 40 (0.0)	NE	
>= 10 points	0/ 60 (0.0)	0/ 61 (0.0)	NE	
OCS dose				NE
<10 mg/day	0/ 44 (0.0)	0/ 37 (0.0)	NE	
>=10 mg/day	0/ 55 (0.0)	0/ 64 (0.0)	NE	
Result of type I IFN gene signature test				NE
LOW	0/ 24 (0.0)	0/ 26 (0.0)	NE	
HIGH	0/ 75 (0.0)	0/ 75 (0.0)	NE	
Age (years)				NE
<= 45	0/ 67 (0.0)	0/ 71 (0.0)	NE	
> 45	0/ 32 (0.0)	0/ 30 (0.0)	NE	
Sex				NE
male	0/ 6 (0.0)	0/ 9 (0.0)	NE	
female	0/ 93 (0.0)	0/ 92 (0.0)	NE	
Race				NE
White	0/ 35 (0.0)	0/ 41 (0.0)	NE	
Black	0/ 19 (0.0)	0/ 11 (0.0)	NE	
Other	0/ 45 (0.0)	0/ 49 (0.0)	NE	
Ethnicity				NE
Hispanic/Latino	0/ 46 (0.0)	0/ 42 (0.0)	NE	
Non-hispanic/Latino	0/ 53 (0.0)	0/ 59 (0.0)	NE	
Geographic region				NE
Latin America, Eastern Europe and Asia	0/ 62 (0.0)	0/ 74 (0.0)	NE	
North America	0/ 37 (0.0)	0/ 27 (0.0)	NE	
Baseline weight				NE
<60 kg	0/ 32 (0.0)	0/ 39 (0.0)	NE	
>=60 kg	0/ 67 (0.0)	0/ 62 (0.0)	NE	
Low CH50				NE
Yes	0/ 13 (0.0)	0/ 12 (0.0)	NE	
No	0/ 86 (0.0)	0/ 89 (0.0)	NE	
Low C3 or C4				NE
Yes	0/ 33 (0.0)	0/ 46 (0.0)	NE	
No	0/ 66 (0.0)	0/ 55 (0.0)	NE	
Baseline FARR anti-dsDNA				NE
<5 IU/mL	0/ 21 (0.0)	0/ 16 (0.0)	NE	
>=5 IU/mL	0/ 56 (0.0)	0/ 65 (0.0)	NE	
Low complement (C3 or C4) and positive FARR anti-dsDNA				NE
Yes	0/ 70 (0.0)	0/ 80 (0.0)	NE	
No	0/ 29 (0.0)	0/ 21 (0.0)	NE	
OCS use				NE
Yes	0/ 79 (0.0)	0/ 87 (0.0)	NE	
No	0/ 20 (0.0)	0/ 14 (0.0)	NE	
SLICC score				NE
0	0/ 62 (0.0)	0/ 66 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Malignancy - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
>=1	0/ 37 (0.0)	0/ 35 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of SOCs Cardiac disorders and/or Vascular disorders
Safety analysis set

	Anifrolumab 300mg (N=99)	Placebo (N=101)
Number of subjects with events, n (%)	7 (7.1)	15 (14.9)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.48 (0.20, 1.12)	
p-value	0.0882	
Odds Ratio (95% CI)	0.44 (0.17, 1.12)	
p-value	0.0850	
Risk Difference (95% CI)	-7.78 (-16.36, 0.80)	
p-value	0.0755	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of SOCs Cardiac disorders and/or Vascular disorders - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.9153
< 10 points	2/ 39 (5.1)	4/ 40 (10.0)	0.51 (0.10, 2.64)	0.4245	
>= 10 points	5/ 60 (8.3)	11/ 61 (18.0)	0.46 (0.17, 1.25)	0.1285	
OCS dose					0.2918
<10 mg/day	5/ 44 (11.4)	6/ 37 (16.2)	0.70 (0.23, 2.11)	0.5276	
>=10 mg/day	2/ 55 (3.6)	9/ 64 (14.1)	0.26 (0.06, 1.15)	0.0751	
Result of type I IFN gene signature test					0.3824
LOW	1/ 24 (4.2)	5/ 26 (19.2)	0.22 (0.03, 1.72)	0.1484	
HIGH	6/ 75 (8.0)	10/ 75 (13.3)	0.60 (0.23, 1.57)	0.2971	
Age (years)					0.1245
<= 45	5/ 67 (7.5)	6/ 71 (8.5)	0.88 (0.28, 2.76)	0.8306	
> 45	2/ 32 (6.3)	9/ 30 (30.0)	0.21 (0.05, 0.89)	0.0339	
Sex					0.9813
male	0/ 6 (0.0)	1/ 9 (11.1)	0.48 (0.02, 10.07)	0.6337	
female	7/ 93 (7.5)	14/ 92 (15.2)	0.49 (0.21, 1.17)	0.1088	
Race					0.1258
White	0/ 35 (0.0)	10/ 41 (24.4)	0.06 (0.00, 0.92)	0.0432	
Black	3/ 19 (15.8)	2/ 11 (18.2)	0.87 (0.17, 4.42)	0.8651	
Other	4/ 45 (8.9)	3/ 49 (6.1)	1.45 (0.34, 6.14)	0.6121	
Ethnicity					0.1236
Hispanic/Latino	4/ 46 (8.7)	3/ 42 (7.1)	1.22 (0.29, 5.12)	0.7885	
Non-hispanic/Latino	3/ 53 (5.7)	12/ 59 (20.3)	0.28 (0.08, 0.93)	0.0382	
Geographic region					0.2862
Latin America, Eastern Europe and Asia	5/ 62 (8.1)	9/ 74 (12.2)	0.66 (0.23, 1.88)	0.4387	
North America	2/ 37 (5.4)	6/ 27 (22.2)	0.24 (0.05, 1.11)	0.0686	
Baseline weight					0.2334
<60 kg	1/ 32 (3.1)	7/ 39 (17.9)	0.17 (0.02, 1.34)	0.0935	
>=60 kg	6/ 67 (9.0)	8/ 62 (12.9)	0.69 (0.26, 1.89)	0.4743	
Low CH50					0.7128
Yes	2/ 13 (15.4)	3/ 12 (25.0)	0.62 (0.12, 3.07)	0.5540	
No	5/ 86 (5.8)	12/ 89 (13.5)	0.43 (0.16, 1.17)	0.0993	
Low C3 or C4					0.0477
Yes	4/ 33 (12.1)	4/ 46 (8.7)	1.39 (0.38, 5.18)	0.6197	
No	3/ 66 (4.5)	11/ 55 (20.0)	0.23 (0.07, 0.77)	0.0178	
Baseline FARR anti-dsDNA					0.2516
<5 IU/mL	0/ 21 (0.0)	4/ 16 (25.0)	0.09 (0.00, 1.49)	0.0916	
>=5 IU/mL	4/ 56 (7.1)	9/ 65 (13.8)	0.52 (0.17, 1.58)	0.2477	
Low complement (C3 or C4) and positive FARR anti-dsDNA					0.2958
Yes	6/ 70 (8.6)	11/ 80 (13.8)	0.62 (0.24, 1.60)	0.3252	
No	1/ 29 (3.4)	4/ 21 (19.0)	0.18 (0.02, 1.51)	0.1138	
OCS use					0.6367
Yes	5/ 79 (6.3)	13/ 87 (14.9)	0.42 (0.16, 1.13)	0.0875	
No	2/ 20 (10.0)	2/ 14 (14.3)	0.70 (0.11, 4.39)	0.7036	
SLICC score					0.3565
0	4/ 62 (6.5)	6/ 66 (9.1)	0.71 (0.21, 2.40)	0.5807	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of SOCs Cardiac disorders and/or Vascular disorders - Subgroup analysis
Safety analysis set

Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
>=1	3/ 37 (8.1)	9/ 35 (25.7)	0.32 (0.09, 1.07)	0.0642	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Safety analysis set

SOC / PT		Anifrolumab 300mg (N=99)	Placebo (N=101)
SOC: Gastrointestinal disorders	Number of subjects with events, n (%)	22 (22.2)	19 (18.8)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.18 (0.68, 2.04)	
	p-value	0.5510	
	Odds Ratio (95% CI)	1.23 (0.62, 2.45)	
	p-value	0.5507	
	Risk Difference (95% CI)	3.41 (-7.78, 14.60)	
	p-value	0.5502	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Safety analysis set

SOC / PT		Anifrolumab 300mg (N=99)	Placebo (N=101)
SOC: General disorders and administration site conditions	Number of subjects with events, n (%)	8 (8.1)	12 (11.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.68 (0.29, 1.59)	
	p-value	0.3744	
	Odds Ratio (95% CI)	0.65 (0.25, 1.67)	
	p-value	0.3731	
	Risk Difference (95% CI)	-3.80 (-12.09, 4.48)	
	p-value	0.3686	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Safety analysis set

SOC / PT		Anifrolumab 300mg (N=99)	Placebo (N=101)
SOC: Infections and infestations	Number of subjects with events, n (%)	63 (63.6)	52 (51.5)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.24 (0.97, 1.57)	
	p-value	0.0847	
	Odds Ratio (95% CI)	1.65 (0.94, 2.90)	
	p-value	0.0831	
	Risk Difference (95% CI)	12.15 (-1.44, 25.75)	
	p-value	0.0798	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Safety analysis set

SOC / PT		Anifrolumab 300mg (N=99)	Placebo (N=101)
SOC: Infections and infestations, PT: Nasopharyngitis	Number of subjects with events, n (%)	12 (12.1)	4 (4.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	3.06 (1.02, 9.17)	
	p-value	0.0457	
	Odds Ratio (95% CI)	3.34 (1.04, 10.76)	
	p-value	0.0428	
	Risk Difference (95% CI)	8.16 (0.69, 15.63)	
	p-value	0.0323	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Safety analysis set

SOC / PT		Anifrolumab 300mg (N=99)	Placebo (N=101)
SOC: Infections and infestations, PT: Upper respiratory tract infection	Number of subjects with events, n (%)	13 (13.1)	10 (9.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.33 (0.61, 2.88)	
	p-value	0.4760	
	Odds Ratio (95% CI)	1.38 (0.57, 3.30)	
	p-value	0.4753	
	Risk Difference (95% CI)	3.23 (-5.61, 12.07)	
	p-value	0.4740	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Safety analysis set

SOC / PT		Anifrolumab 300mg (N=99)	Placebo (N=101)
SOC: Infections and infestations, PT: Urinary tract infection	Number of subjects with events, n (%)	15 (15.2)	11 (10.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.39 (0.67, 2.88)	
	p-value	0.3734	
	Odds Ratio (95% CI)	1.46 (0.64, 3.36)	
	p-value	0.3723	
	Risk Difference (95% CI)	4.26 (-5.06, 13.58)	
	p-value	0.3701	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Safety analysis set

SOC / PT		Anifrolumab 300mg (N=99)	Placebo (N=101)
SOC: Injury, poisoning and procedural complications	Number of subjects with events, n (%)	11 (11.1)	12 (11.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.94 (0.43, 2.02)	
	p-value	0.8645	
	Odds Ratio (95% CI)	0.93 (0.39, 2.21)	
	p-value	0.8645	
	Risk Difference (95% CI)	-0.77 (-9.61, 8.07)	
	p-value	0.8644	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Safety analysis set

SOC / PT		Anifrolumab 300mg (N=99)	Placebo (N=101)
SOC: Metabolism and nutrition disorders	Number of subjects with events, n (%)	11 (11.1)	9 (8.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.25 (0.54, 2.88)	
	p-value	0.6050	
	Odds Ratio (95% CI)	1.28 (0.51, 3.23)	
	p-value	0.6047	
	Risk Difference (95% CI)	2.20 (-6.12, 10.52)	
	p-value	0.6042	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Safety analysis set

SOC / PT		Anifrolumab 300mg (N=99)	Placebo (N=101)
SOC: Musculoskeletal and connective tissue disorders	Number of subjects with events, n (%)	24 (24.2)	25 (24.8)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.98 (0.60, 1.59)	
	p-value	0.9332	
	Odds Ratio (95% CI)	0.97 (0.51, 1.85)	
	p-value	0.9332	
	Risk Difference (95% CI)	-0.51 (-12.43, 11.41)	
	p-value	0.9332	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Safety analysis set

SOC / PT		Anifrolumab 300mg (N=99)	Placebo (N=101)
SOC: Nervous system disorders	Number of subjects with events, n (%)	21 (21.2)	24 (23.8)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.89 (0.53, 1.50)	
	p-value	0.6662	
	Odds Ratio (95% CI)	0.86 (0.44, 1.68)	
	p-value	0.6660	
	Risk Difference (95% CI)	-2.55 (-14.12, 9.01)	
	p-value	0.6656	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Safety analysis set

SOC / PT		Anifrolumab 300mg (N=99)	Placebo (N=101)
SOC: Nervous system disorders, PT: Headache	Number of subjects with events, n (%)	12 (12.1)	13 (12.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.94 (0.45, 1.96)	
	p-value	0.8726	
	Odds Ratio (95% CI)	0.93 (0.40, 2.16)	
	p-value	0.8726	
	Risk Difference (95% CI)	-0.75 (-9.91, 8.41)	
	p-value	0.8726	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Safety analysis set

SOC / PT		Anifrolumab 300mg (N=99)	Placebo (N=101)
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with events, n (%)	10 (10.1)	9 (8.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.13 (0.48, 2.67)	
	p-value	0.7743	
	Odds Ratio (95% CI)	1.15 (0.45, 2.96)	
	p-value	0.7742	
	Risk Difference (95% CI)	1.19 (-6.94, 9.32)	
	p-value	0.7742	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Safety analysis set

SOC / PT		Anifrolumab 300mg (N=99)	Placebo (N=101)
SOC: Skin and subcutaneous tissue disorders	Number of subjects with events, n (%)	8 (8.1)	10 (9.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.82 (0.34, 1.98)	
	p-value	0.6537	
	Odds Ratio (95% CI)	0.80 (0.30, 2.12)	
	p-value	0.6534	
	Risk Difference (95% CI)	-1.82 (-9.74, 6.10)	
	p-value	0.6525	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Safety analysis set

SOC / PT		Anifrolumab 300mg (N=99)	Placebo (N=101)
SOC: Vascular disorders	Number of subjects with events, n (%)	4 (4.0)	12 (11.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.34 (0.11, 1.02)	
	p-value	0.0540	
	Odds Ratio (95% CI)	0.31 (0.10, 1.00)	
	p-value	0.0508	
	Risk Difference (95% CI)	-7.84 (-15.25, -0.43)	
	p-value	0.0380	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Safety analysis set

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Nasopharyngitis	SLEDAI-2K score					0.5413
	< 10 points	5/ 39 (12.8)	1/ 40 (2.5)	5.13 (0.63, 41.93)	0.1273	
	>= 10 points	7/ 60 (11.7)	3/ 61 (4.9)	2.37 (0.64, 8.75)	0.1944	
	OCS dose					0.9496
	<10 mg/day	4/ 44 (9.1)	1/ 37 (2.7)	3.36 (0.39, 28.80)	0.2682	
	>=10 mg/day	8/ 55 (14.5)	3/ 64 (4.7)	3.10 (0.87, 11.13)	0.0822	
	Result of type I IFN gene signature test					0.7012
	LOW	4/ 24 (16.7)	1/ 26 (3.8)	4.33 (0.52, 36.10)	0.1752	
	HIGH	8/ 75 (10.7)	3/ 75 (4.0)	2.67 (0.74, 9.67)	0.1355	
	Age (years)					0.2757
	<= 45	7/ 67 (10.4)	4/ 71 (5.6)	1.85 (0.57, 6.05)	0.3059	
	> 45	5/ 32 (15.6)	0/ 30 (0.0)	10.33 (0.60, 179.22)	0.1087	
	Sex					0.1387
	male	1/ 6 (16.7)	2/ 9 (22.2)	0.75 (0.09, 6.55)	0.7947	
	female	11/ 93 (11.8)	2/ 92 (2.2)	5.44 (1.24, 23.87)	0.0248	
	Race					0.6133
	White	5/ 35 (14.3)	3/ 41 (7.3)	1.95 (0.50, 7.59)	0.3344	
	Black	1/ 19 (5.3)	0/ 11 (0.0)	1.80 (0.08, 40.75)	0.7119	
	Other	6/ 45 (13.3)	1/ 49 (2.0)	6.53 (0.82, 52.19)	0.0767	
	Ethnicity					0.2985
	Hispanic/Latino	5/ 46 (10.9)	0/ 42 (0.0)	10.06 (0.57, 176.67)	0.1143	
	Non-hispanic/Latino	7/ 53 (13.2)	4/ 59 (6.8)	1.95 (0.60, 6.28)	0.2644	
	Geographic region					0.8169
	Latin America, Eastern Europe and Asia	11/ 62 (17.7)	4/ 74 (5.4)	3.28 (1.10, 9.80)	0.0331	
	North America	1/ 37 (2.7)	0/ 27 (0.0)	2.21 (0.09, 52.27)	0.6231	
	Baseline weight					0.1814
	<60 kg	5/ 32 (15.6)	0/ 39 (0.0)	13.33 (0.77, 232.39)	0.0757	
	>=60 kg	7/ 67 (10.4)	4/ 62 (6.5)	1.62 (0.50, 5.26)	0.4229	
	Low CH50					0.9279
	Yes	3/ 13 (23.1)	1/ 12 (8.3)	2.77 (0.33, 23.14)	0.3470	
	No	9/ 86 (10.5)	3/ 89 (3.4)	3.10 (0.87, 11.08)	0.0810	
	Low C3 or C4					0.8750
	Yes	4/ 33 (12.1)	2/ 46 (4.3)	2.79 (0.54, 14.34)	0.2197	
	No	8/ 66 (12.1)	2/ 55 (3.6)	3.33 (0.74, 15.05)	0.1175	
	Baseline FARR anti-dsDNA					0.9993
	<5 IU/mL	1/ 21 (4.8)	0/ 16 (0.0)	2.32 (0.10, 53.42)	0.5994	
	>=5 IU/mL	8/ 56 (14.3)	4/ 65 (6.2)	2.32 (0.74, 7.30)	0.1497	
	Low complement (C3 or C4) and positive FARR anti-dsDNA					0.6645
	Yes	9/ 70 (12.9)	4/ 80 (5.0)	2.57 (0.83, 7.99)	0.1024	
	No	3/ 29 (10.3)	0/ 21 (0.0)	5.13 (0.28, 94.39)	0.2709	
	OCS use					0.8382
	Yes	11/ 79 (13.9)	4/ 87 (4.6)	3.03 (1.00, 9.13)	0.0490	
	No	1/ 20 (5.0)	0/ 14 (0.0)	2.14 (0.09, 49.08)	0.6333	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Safety analysis set

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=99) n/ N (%)	Placebo (N=101) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Nasopharyngitis	SLICC score					0.2752
	0	7/ 62 (11.3)	4/ 66 (6.1)	1.86 (0.57, 6.05)	0.3008	
	>=1	5/ 37 (13.5)	0/ 35 (0.0)	10.42 (0.60, 181.78)	0.1081	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Serious Adverse Events by SOC, PT (incidence in either arm >= 5% or >=10 patients)
Safety analysis set

SOC / PT		Anifrolumab 300mg (N=99)	Placebo (N=101)
SOC: Infections and infestations	Number of subjects with events, n (%)	7 (7.1)	8 (7.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.89 (0.34, 2.37)	
	p-value	0.8196	
	Odds Ratio (95% CI)	0.88 (0.31, 2.54)	
	p-value	0.8196	
	Risk Difference (95% CI)	-0.85 (-8.15, 6.45)	
	p-value	0.8194	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Serious Adverse Events by SOC, PT (incidence in either arm >= 5% or >=10 patients)
Safety analysis set

SOC / PT		Anifrolumab 300mg (N=99)	Placebo (N=101)
SOC: Musculoskeletal and connective tissue disorders	Number of subjects with events, n (%)	3 (3.0)	6 (5.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.51 (0.13, 1.98)	
	p-value	0.3312	
	Odds Ratio (95% CI)	0.49 (0.12, 2.04)	
	p-value	0.3296	
	Risk Difference (95% CI)	-2.91 (-8.62, 2.80)	
	p-value	0.3182	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Serious Adverse Events by SOC, PT (incidence in either arm >= 5% or >=10 patients)
Safety analysis set

SOC / PT		Anifrolumab 300mg (N=99)	Placebo (N=101)
SOC: Musculoskeletal and connective tissue disorders, PT: Systemic lupus erythematosus	Number of subjects with events, n (%)	3 (3.0)	6 (5.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.51 (0.13, 1.98)	
	p-value	0.3312	
	Odds Ratio (95% CI)	0.49 (0.12, 2.04)	
	p-value	0.3296	
	Risk Difference (95% CI)	-2.91 (-8.62, 2.80)	
	p-value	0.3182	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Serious Adverse Events by SOC, PT (incidence in either arm >= 5% or >=10 patients) - Subgroup analysis
Safety analysis set

- NO OBSERVATIONS FOR THIS ANALYSIS -

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Severe (Grade >=3) by SOC, PT (incidence in either arm >= 5% or >=10 patients)
Safety analysis set

SOC / PT		Anifrolumab 300mg (N=99)	Placebo (N=101)
SOC: Infections and infestations	Number of subjects with events, n (%)	11 (11.1)	4 (4.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	2.81 (0.92, 8.52)	
	p-value	0.0686	
	Odds Ratio (95% CI)	3.03 (0.93, 9.87)	
	p-value	0.0655	
	Risk Difference (95% CI)	7.15 (-0.11, 14.42)	
	p-value	0.0537	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00001 (MUSE) - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Severe (Grade >=3) by SOC, PT (incidence in either arm >= 5% or >=10 patients) - Subgroup analysis
Safety analysis set

- NO OBSERVATIONS FOR THIS ANALYSIS -

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Subject disposition and summary of treatment exposure
Full analysis set

		Anifrolumab 300mg (N=459)	Placebo (N=468)
Patients who completed the study		386 (84.1)	361 (77.1)
Patients withdrawn from the study		73 (15.9)	107 (22.9)
WITHDRAWAL BY SUBJECT		26 (5.7)	34 (7.3)
OTHER		20 (4.4)	28 (6.0)
ADVERSE EVENT		15 (3.3)	13 (2.8)
LACK OF EFFICACY		6 (1.3)	15 (3.2)
LOST TO FOLLOW-UP		3 (0.7)	9 (1.9)
CONDITION UNDER INVESTIGATION WORSENED		2 (0.4)	5 (1.1)
SEVERE NON-COMPLIANCE TO PROTOCOL		0	2 (0.4)
DEVELOPMENT OF STUDY-SPECIFIC WITHDRAWAL CRITERIA		1 (0.2)	0
Duration of study (weeks)	n (missing)	459 (0)	468 (0)
	Mean (SD)	52.2 (11.26)	50.3 (12.49)
	Median	52.9	52.4
	Min, Max	0, 78	3, 71
Patients who completed investigational product		385 (83.9)	347 (74.1)
Patients discontinued investigational product		74 (16.1)	121 (25.9)
Withdrawal By Subject		22 (4.8)	29 (6.2)
Adverse Event		20 (4.4)	30 (6.4)
Lack Of Efficacy		6 (1.3)	21 (4.5)
Withdrawal Of Consent		3 (0.7)	13 (2.8)
Other		12 (2.6)	2 (0.4)
Condition Under Investigation Worsened		3 (0.7)	8 (1.7)
Lost To Follow-Up		2 (0.4)	7 (1.5)
Severe Non-Compliance To Protocol		0	3 (0.6)
Sponsor Decision, Regional Political Circumstances Preclude Site Activities		0	3 (0.6)
Inadequate Venous Access.		1 (0.2)	0
Investigator Decision Due To Exacerbation Of Her Disease.		0	1 (0.2)
Medical Decision, The Patient Has Been Presenting Various Infections In A Relatively Short Amount Of Time.		1 (0.2)	0
Patient Is Moving Away		0	1 (0.2)
Patient Withdrawn Consent, She Has Decided To Finish Treatment And Participation In The Study Due To Sae.		1 (0.2)	0
Pregnancy		0	1 (0.2)
Prohibited Concomitant Medications (Steroid Pulses)		1 (0.2)	0
Subject Called Did Not Want To Come In And See The Pi Any Longer Has Found A New Doctor. She Never Said She Wanted To Withdraw Consent.		0	1 (0.2)
Subject Complete The Treatment Period, However This Patient Missed Dose For Visit Day 337		0	1 (0.2)
Subject Missed Visit Day 337, But Was Approved To Continue On Study By Sponsor And Completed Remaining Visits.		1 (0.2)	0
The Patient Left The Country		1 (0.2)	0
Duration of exposure (weeks)	n (missing)	459 (0)	468 (0)
	Mean (SD)	47.8 (11.92)	45.3 (13.79)
	Median	52.1	52.1
	Min, Max	4, 60	4, 56

Duration of study defined as time from randomization until end of participation date.
Duration of exposure defined as difference of date of first exposure to treatment and date of last exposure to treatment + 28 days.
'Full Analysis Set' Referred to as 'mITT population' in the study 1013 CSR

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Demographic and baseline characteristics
Full analysis set

		Anifrolumab 300mg (N=459)	Placebo (N=468)	Total (N=927)
Age	n (missing)	459 (0)	468 (0)	927 (0)
	Mean (SD)	41.8 (12.03)	40.6 (12.11)	41.2 (12.08)
	Median	41.0	40.5	41.0
	Min, Max	18, 69	18, 69	18, 69
Age (years) (%)	<= 65	447 (97.4)	464 (99.1)	911 (98.3)
	> 65	12 (2.6)	4 (0.9)	16 (1.7)
Sex (%) (%)	female	426 (92.8)	434 (92.7)	860 (92.8)
	male	33 (7.2)	34 (7.3)	67 (7.2)
Race (%) (%)	American Indian or Alaska Native	8 (1.7)	2 (0.4)	10 (1.1)
	Asian	44 (9.6)	48 (10.3)	92 (9.9)
	Black or African American	65 (14.2)	60 (12.8)	125 (13.5)
	Other	64 (13.9)	65 (13.9)	129 (13.9)
	White	270 (58.8)	285 (60.9)	555 (59.9)
	Missing	8 (1.7)	8 (1.7)	16 (1.7)
Ethnicity (%) (%)	Hispanic/Latino	132 (28.8)	131 (28.0)	263 (28.4)
	Non-hispanic/Latino	319 (69.5)	329 (70.3)	648 (69.9)
	Missing	8 (1.7)	8 (1.7)	16 (1.7)
Geographic region (%) (%)	Asia Pacific	40 (8.7)	42 (9.0)	82 (8.8)
	Europe	135 (29.4)	147 (31.4)	282 (30.4)
	Latin America	98 (21.4)	94 (20.1)	192 (20.7)
	North America	176 (38.3)	168 (35.9)	344 (37.1)
	Rest Of World	10 (2.2)	17 (3.6)	27 (2.9)
Geographic region subgroup (%)	EU	135 (29.4)	147 (31.4)	282 (30.4)
	non-EU	324 (70.6)	321 (68.6)	645 (69.6)
Height (cm)	n (missing)	459 (0)	468 (0)	927 (0)
	Mean (SD)	162.16 (8.431)	162.50 (8.060)	162.33 (8.243)
	Median	161.90	162.50	162.00
	Min, Max	137.2, 198.0	130.0, 195.0	130.0, 198.0
Weight (kg)	n (missing)	459 (0)	468 (0)	927 (0)
	Mean (SD)	72.62 (19.161)	71.80 (18.613)	72.21 (18.881)
	Median	69.30	67.20	68.00
	Min, Max	42.0, 132.9	40.0, 139.3	40.0, 139.3
BMI (kg/m2)	n (missing)	459 (0)	468 (0)	927 (0)
	Mean (SD)	27.55 (6.679)	27.18 (6.750)	27.36 (6.714)
	Median	25.94	25.59	25.72
	Min, Max	16.0, 49.8	16.1, 57.5	16.0, 57.5
BMI subgroup (%)	<=28 kg/m2	267 (58.2)	298 (63.7)	565 (60.9)
	>28 kg/m2	192 (41.8)	170 (36.3)	362 (39.1)

[a] Asia Pacific: Australia, New Zealand, South Korea, Taiwan. Europe: Germany, Hungary, Italy, Poland, Romania, Ukraine, United Kingdom. Latin America: Argentinia, Brazil, Chile, Colombia, Peru. Rest of World: India, Israel, South Africa.
Missing/multiple categories checked for Race grouped as 'Other'.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SLE disease characteristics
Full analysis set

		Anifrolumab 300mg (N=459)	Placebo (N=468)	Total (N=927)
SLEDAI-2K score at screening	n (missing)	459 (0)	468 (0)	927 (0)
	Mean (SD)	11.3 (3.82)	11.2 (3.81)	11.2 (3.81)
	Median	10.0	10.0	10.0
	Min, Max	6, 26	6, 37	6, 37
SLEDAI-2K score at screening, categorisation (%)	<10	148 (32.2)	146 (31.2)	294 (31.7)
	>=10	311 (67.8)	322 (68.8)	633 (68.3)
Clinical SLEDAI-2K score at screening	n (missing)	459 (0)	468 (0)	927 (0)
	Mean (SD)	8.8 (2.88)	8.7 (2.75)	8.8 (2.81)
	Median	8.0	8.0	8.0
	Min, Max	4, 20	4, 21	4, 21
SLEDAI-2K score at baseline	n (missing)	459 (0)	468 (0)	927 (0)
	Mean (SD)	11.2 (3.82)	11.4 (3.84)	11.3 (3.83)
	Median	10.0	10.0	10.0
	Min, Max	4, 32	4, 29	4, 32
SLEDAI-2K score at baseline, categorisation (%)	<10	146 (31.8)	141 (30.1)	287 (31.0)
	>=10	313 (68.2)	327 (69.9)	640 (69.0)
Clinical SLEDAI-2K score at baseline	n (missing)	459 (0)	468 (0)	927 (0)
	Mean (SD)	8.9 (2.84)	8.9 (2.76)	8.9 (2.79)
	Median	8.0	8.0	8.0
	Min, Max	4, 20	4, 20	4, 20
Adjudication Scoring (BILAG) at baseline Overall (%)	At least one A	226 (49.2)	228 (48.7)	454 (49.0)
	No A and <2Bs	22 (4.8)	30 (6.4)	52 (5.6)
	No A and at least 2 Bs	211 (46.0)	210 (44.9)	421 (45.4)
Adjudication Scoring (BILAG) at baseline Constitutional (%)	A	2 (0.4)	1 (0.2)	3 (0.3)
	B	30 (6.5)	27 (5.8)	57 (6.1)
	C, D or E	427 (93.0)	440 (94.0)	867 (93.5)
Adjudication Scoring (BILAG) at baseline Mucocutaneous (%)	A	106 (23.1)	93 (19.9)	199 (21.5)
	B	293 (63.8)	306 (65.4)	599 (64.6)
	C, D or E	60 (13.1)	69 (14.7)	129 (13.9)
Adjudication Scoring (BILAG) at baseline Neuropsychiatric (%)	A	1 (0.2)	1 (0.2)	2 (0.2)
	B	8 (1.7)	6 (1.3)	14 (1.5)
	C, D or E	450 (98.0)	461 (98.5)	911 (98.3)
Adjudication Scoring (BILAG) at baseline Musculoskeletal (%)	A	150 (32.7)	144 (30.8)	294 (31.7)
	B	261 (56.9)	279 (59.6)	540 (58.3)
	C, D or E	48 (10.5)	45 (9.6)	93 (10.0)
Adjudication Scoring (BILAG) at baseline Cardiorespiratory (%)	A	3 (0.7)	4 (0.9)	7 (0.8)
	B	31 (6.8)	31 (6.6)	62 (6.7)
	C, D or E	425 (92.6)	433 (92.5)	858 (92.6)
Adjudication Scoring (BILAG) at baseline Gastrointestinal (%)	A	0	1 (0.2)	1 (0.1)
	B	1 (0.2)	3 (0.6)	4 (0.4)
	C, D or E	458 (99.8)	464 (99.1)	922 (99.5)
Adjudication Scoring (BILAG) at baseline Ophthalmic (%)	A	1 (0.2)	0	1 (0.1)
	B	1 (0.2)	1 (0.2)	2 (0.2)
	C, D or E	457 (99.6)	467 (99.8)	924 (99.7)
Adjudication Scoring (BILAG) at baseline Renal (%)	A	3 (0.7)	9 (1.9)	12 (1.3)
	B	33 (7.2)	34 (7.3)	67 (7.2)

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Only subjects with baseline positive anti-dsDNA and abnormal complement level, respectively, are included in the summary statistics for the respective variables.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SLE disease characteristics
Full analysis set

		Anifrolumab 300mg (N=459)	Placebo (N=468)	Total (N=927)
Adjudication Scoring (BILAG) at baseline Renal (%)	C, D or E	423 (92.2)	425 (90.8)	848 (91.5)
Adjudication Scoring (BILAG) at baseline Haematological (%)	B	2 (0.4)	5 (1.1)	7 (0.8)
	C, D or E	457 (99.6)	463 (98.9)	920 (99.2)
BILAG-2004 global score at baseline	n (missing)	459 (0)	468 (0)	927 (0)
	Mean (SD)	19.3 (5.61)	19.1 (5.35)	19.2 (5.48)
	Median	17.0	18.0	18.0
	Min, Max	2, 40	2, 36	2, 40
Physician Global Assessment (PGA) score at baseline	n (missing)	459 (0)	468 (0)	927 (0)
	Mean (SD)	1.8 (0.41)	1.8 (0.40)	1.8 (0.41)
	Median	1.8	1.8	1.8
	Min, Max	1, 3	1, 3	1, 3
CLASI activity score at baseline	n (missing)	459 (0)	468 (0)	927 (0)
	Mean (SD)	8.2 (7.34)	7.6 (6.82)	7.9 (7.09)
	Median	6.0	6.0	6.0
	Min, Max	0, 51	0, 52	0, 52
CLASI activity score at baseline, categorisation 1 (%)	0	12 (2.6)	19 (4.1)	31 (3.3)
	> 0	447 (97.4)	449 (95.9)	896 (96.7)
CLASI activity score at baseline, categorisation 2 (%)	<10	325 (70.8)	348 (74.4)	673 (72.6)
	>=10	134 (29.2)	120 (25.6)	254 (27.4)
CLASI damage score at baseline	n (missing)	459 (0)	468 (0)	927 (0)
	Mean (SD)	2.1 (4.78)	2.0 (4.75)	2.1 (4.76)
	Median	0.0	0.0	0.0
	Min, Max	0, 30	0, 37	0, 37
CLASI damage score at baseline, categorisation 1 (%)	0	307 (66.9)	309 (66.0)	616 (66.5)
	> 0	152 (33.1)	159 (34.0)	311 (33.5)
CLASI damage score at baseline, categorisation 2 (%)	<10	426 (92.8)	443 (94.7)	869 (93.7)
	>=10	33 (7.2)	25 (5.3)	58 (6.3)
Tender Joint Count at Baseline	n (missing)	459 (0)	468 (0)	927 (0)
	Mean (SD)	10.7 (7.38)	10.7 (7.50)	10.7 (7.44)
	Median	9.0	9.5	9.0
	Min, Max	0, 28	0, 28	0, 28
Tender Joint Count at Baseline, categorisation (%)	0	23 (5.0)	22 (4.7)	45 (4.9)
	> 0	436 (95.0)	446 (95.3)	882 (95.1)
Swollen Joint Count at Baseline	n (missing)	459 (0)	468 (0)	927 (0)
	Mean (SD)	7.2 (5.85)	7.4 (5.88)	7.3 (5.87)
	Median	6.0	6.0	6.0
	Min, Max	0, 28	0, 28	0, 28
Swollen Joint Count at Baseline, categorisation (%)	0	39 (8.5)	36 (7.7)	75 (8.1)
	> 0	420 (91.5)	432 (92.3)	852 (91.9)
Active Joint Count at Baseline	n (missing)	459 (0)	468 (0)	927 (0)
	Mean (SD)	7.5 (6.39)	7.4 (6.06)	7.4 (6.22)
	Median	6.0	6.0	6.0
	Min, Max	0, 28	0, 28	0, 28
Active Joint Count at Baseline, categorisation (%)	0	44 (9.6)	38 (8.1)	82 (8.8)
	> 0	415 (90.4)	430 (91.9)	845 (91.2)

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Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SLE disease characteristics
Full analysis set

		Anifrolumab 300mg (N=459)	Placebo (N=468)	Total (N=927)
SDI global score at baseline	n (missing)	458 (1)	465 (3)	923 (4)
	Mean (SD)	0.6 (1.03)	0.6 (0.97)	0.6 (1.00)
	Median	0.0	0.0	0.0
	Min, Max	0, 5	0, 7	0, 7
SDI global score at baseline, categorisation (%)	0 (no damage)	307 (66.9)	298 (63.7)	605 (65.3)
	>=1 (damage)	151 (32.9)	167 (35.7)	318 (34.3)
	Missing	1 (0.2)	3 (0.6)	4 (0.4)
Time from initial SLE diagnosis to randomisation (months)	n (missing)	459 (0)	468 (0)	927 (0)
	Mean (SD)	117.3 (98.85)	102.3 (93.05)	109.7 (96.21)
	Median	85.0	75.0	82.0
	Min, Max	0, 555	4, 503	0, 555
Cushingoid features (%)	Any Cushingoid Feature	153 (33.3)	167 (35.7)	320 (34.5)
	Moon Face	87 (19.0)	88 (18.8)	175 (18.9)
	Buffalo Hump	40 (8.7)	34 (7.3)	74 (8.0)
	Purple or Violaceous Striae	33 (7.2)	33 (7.1)	66 (7.1)
	Central Obesity	70 (15.3)	65 (13.9)	135 (14.6)
	Hirsutisim	28 (6.1)	18 (3.8)	46 (5.0)
	Acne	29 (6.3)	24 (5.1)	53 (5.7)
	Easy Bruising	80 (17.4)	72 (15.4)	152 (16.4)
	Fragile Skin	56 (12.2)	61 (13.0)	117 (12.6)
Results of 4-gene Type 1 Interferon (IFN) test (%)	High	373 (81.3)	378 (80.8)	751 (81.0)
	Low	86 (18.7)	90 (19.2)	176 (19.0)
Anti-dsDNA levels at baseline	n (missing)	223 (0)	221 (0)	444 (0)
	Mean (SD)	131.9 (249.03)	190.7 (474.47)	161.2 (379.13)
	Median	51.0	52.3	51.1
	Min, Max	14, 1897	14, 3790	14, 3790
Anti-dsDNA levels at baseline, categorisation (%)	Negative	214 (46.6)	227 (48.5)	441 (47.6)
	Positive	223 (48.6)	221 (47.2)	444 (47.9)
	Missing	22 (4.8)	20 (4.3)	42 (4.5)
ANA (%)	Abnormal (titre >= 1:80)	422 (91.9)	429 (91.7)	851 (91.8)
	Normal (titre < 1:80)	24 (5.2)	29 (6.2)	53 (5.7)
	Missing	13 (2.8)	10 (2.1)	23 (2.5)
Complement C3 level at baseline	n (missing)	158 (0)	180 (0)	338 (0)
	Mean (SD)	0.69 (0.154)	0.70 (0.143)	0.69 (0.148)
	Median	0.72	0.72	0.72
	Min, Max	0.2, 0.9	0.3, 0.9	0.2, 0.9
Complement C3 level at baseline, categorisation (%)	Abnormal	158 (34.4)	180 (38.5)	338 (36.5)
	Normal	301 (65.6)	288 (61.5)	589 (63.5)
Complement C4 level at baseline	n (missing)	105 (0)	110 (0)	215 (0)
	Mean (SD)	0.07 (0.019)	0.07 (0.016)	0.07 (0.017)
	Median	0.07	0.07	0.07
	Min, Max	0.0, 0.1	0.0, 0.1	0.0, 0.1
Complement C4 level at baseline, categorisation (%)	Abnormal	105 (22.9)	110 (23.5)	215 (23.2)
	Normal	354 (77.1)	358 (76.5)	712 (76.8)
Complement CH50 level at baseline	n (missing)	48 (0)	44 (0)	92 (0)
	Mean (SD)	43.68 (29.790)	49.83 (29.030)	46.62 (29.430)
	Median	39.00	55.00	43.00
	Min, Max	2.5, 94.0	2.5, 98.0	2.5, 98.0

Baseline is defined as the last measurement prior to randomisation and dose administration on Day 1.
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Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SLE disease characteristics
Full analysis set

		Anifrolumab 300mg (N=459)	Placebo (N=468)	Total (N=927)
Complement CH50 level at baseline, categorisation (%)	Abnormal	48 (10.5)	44 (9.4)	92 (9.9)
	Normal	411 (89.5)	424 (90.6)	835 (90.1)

Baseline is defined as the last measurement prior to randomisation and dose administration on Day 1.
Only subjects with baseline positive anti-dsDNA and abnormal complement level, respectively, are included in the summary statistics for the respective variables.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Observation times for Efficacy endpoints
Full analysis set

		Anifrolumab 300mg (N=459)	Placebo (N=468)
SRI4: Observation time (weeks)	n (missing)	459 (0)	468 (0)
	Mean (SD)	48.9 (10.09)	46.9 (12.20)
	Median	52.1	52.1
	Min, Max	0, 57	0, 54
CLASI activity score: Observation time (weeks)	n (missing)	459 (0)	468 (0)
	Mean (SD)	48.9 (10.08)	46.9 (12.21)
	Median	52.1	52.1
	Min, Max	0, 57	0, 54
CLASI damage score: Observation time (weeks)	n (missing)	459 (0)	468 (0)
	Mean (SD)	48.9 (10.08)	46.9 (12.21)
	Median	52.1	52.1
	Min, Max	0, 57	0, 54
BICLA: Observation time (weeks)	n (missing)	459 (0)	468 (0)
	Mean (SD)	49.0 (10.08)	46.8 (12.38)
	Median	52.1	52.1
	Min, Max	0, 57	0, 54
SLEDAI-2K Total Score: Observation time (weeks)	n (missing)	459 (0)	468 (0)
	Mean (SD)	48.7 (10.26)	46.5 (12.57)
	Median	52.1	52.1
	Min, Max	0, 57	0, 54
PGA: Observation time (weeks)	n (missing)	459 (0)	468 (0)
	Mean (SD)	48.9 (10.23)	46.9 (12.20)
	Median	52.1	52.1
	Min, Max	0, 57	0, 54
BILAG Global Score: Observation time (weeks)	n (missing)	459 (0)	468 (0)
	Mean (SD)	48.9 (10.20)	46.9 (12.20)
	Median	52.1	52.1
	Min, Max	0, 57	0, 54
Tender Joint Count: Observation time (weeks)	n (missing)	459 (0)	468 (0)
	Mean (SD)	48.9 (10.10)	46.9 (12.21)
	Median	52.1	52.1
	Min, Max	0, 57	0, 54
Swollen Joint Count: Observation time (weeks)	n (missing)	459 (0)	468 (0)
	Mean (SD)	48.9 (10.10)	46.9 (12.21)
	Median	52.1	52.1
	Min, Max	0, 57	0, 54
FACIT-F Total Score: Observation time (weeks)	n (missing)	459 (0)	468 (0)
	Mean (SD)	48.5 (10.75)	46.1 (13.00)
	Median	52.1	52.1
	Min, Max	0, 57	0, 54
SF-36 v2.0 Acute - Mental Component Score: Observation time (weeks)	n (missing)	459 (0)	468 (0)
	Mean (SD)	48.0 (12.06)	45.5 (13.88)
	Median	52.1	52.1
	Min, Max	0, 57	0, 54
SF-36 v2.0 Acute - Physical Component Score: Observation time (weeks)	n (missing)	459 (0)	468 (0)
	Mean (SD)	48.0 (12.06)	45.5 (13.88)
	Median	52.1	52.1
	Min, Max	0, 57	0, 54
EQ-5D VAS Score: Observation time (weeks)	n (missing)	459 (0)	468 (0)

Observation duration defined as time from randomization until last non-missing assessment after randomization. Subjects without assessment are censored at day 1.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Observation times for Efficacy endpoints
Full analysis set

		Anifrolumab 300mg (N=459)	Placebo (N=468)
EQ-5D VAS Score: Observation time (weeks)	Mean (SD)	46.8 (12.95)	44.4 (14.79)
	Median	52.1	52.1
	Min, Max	0, 57	0, 54
SDI Global Score: Observation time (weeks)	n (missing)	459 (0)	468 (0)
	Mean (SD)	45.2 (15.90)	42.9 (17.71)
	Median	52.1	52.1
	Min, Max	0, 54	0, 54
PtGA: Observation time (weeks)	n (missing)	459 (0)	468 (0)
	Mean (SD)	48.4 (11.11)	45.9 (13.30)
	Median	52.1	52.1
	Min, Max	0, 57	0, 54

Observation duration defined as time from randomization until last non-missing assessment after randomization. Subjects without assessment are censored at day 1.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=459)	Placebo (N=468)
Week 4	Number of subjects with events, n (%)	44 (9.6)	41 (8.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.12 (0.74, 1.70)	
	p-value	0.5911	
	Odds Ratio (95% CI)	1.13 (0.72, 1.78)	
	p-value	0.5866	
	Risk Difference (95% CI)	1.02 (-2.66, 4.71)	
	p-value	0.5864	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.09 (0.73, 1.64)	
	p-value	0.6695	
	Odds Ratio (95% CI)	1.10 (0.71, 1.73)	
	p-value	0.6625	
	Risk Difference (95% CI)	0.83 (-2.88, 4.55)	
	p-value	0.6607	
	p-Value for test for heterogenity between studies	0.7234	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=459)	Placebo (N=468)
Week 8	Number of subjects with events, n (%)	126 (27.5)	110 (23.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.18 (0.94, 1.47)	
	p-value	0.1454	
	Odds Ratio (95% CI)	1.25 (0.93, 1.69)	
	p-value	0.1441	
	Risk Difference (95% CI)	4.14 (-1.40, 9.69)	
	p-value	0.1432	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.16 (0.93, 1.45)	
	p-value	0.1785	
	Odds Ratio (95% CI)	1.23 (0.92, 1.66)	
	p-value	0.1685	
	Risk Difference (95% CI)	3.95 (-1.65, 9.54)	
	p-value	0.1667	
	p-Value for test for heterogenity between studies	0.3543	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=459)	Placebo (N=468)
Week 12	Number of subjects with events, n (%)	189 (41.2)	159 (34.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.23 (1.04, 1.45)	
	p-value	0.0164	
	Odds Ratio (95% CI)	1.39 (1.06, 1.82)	
	p-value	0.0159	
	Risk Difference (95% CI)	7.67 (1.48, 13.87)	
	p-value	0.0152	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.21 (1.02, 1.43)	
	p-value	0.0251	
	Odds Ratio (95% CI)	1.36 (1.04, 1.78)	
	p-value	0.0246	
	Risk Difference (95% CI)	7.20 (0.98, 13.41)	
	p-value	0.0232	
	p-Value for test for heterogenity between studies	0.1185	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=459)	Placebo (N=468)
Week 16	Number of subjects with events, n (%)	213 (46.4)	183 (39.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.19 (1.03, 1.38)	
	p-value	0.0219	
	Odds Ratio (95% CI)	1.36 (1.05, 1.77)	
	p-value	0.0215	
	Risk Difference (95% CI)	7.44 (1.12, 13.76)	
	p-value	0.0210	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.19 (1.02, 1.38)	
	p-value	0.0226	
	Odds Ratio (95% CI)	1.35 (1.04, 1.75)	
	p-value	0.0251	
	Risk Difference (95% CI)	7.30 (0.95, 13.65)	
	p-value	0.0242	
	p-Value for test for heterogenity between studies	0.4141	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=459)	Placebo (N=468)
Week 20	Number of subjects with events, n (%)	235 (51.2)	200 (42.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.20 (1.05, 1.38)	
	p-value	0.0084	
	Odds Ratio (95% CI)	1.42 (1.10, 1.84)	
	p-value	0.0082	
	Risk Difference (95% CI)	8.69 (2.29, 15.09)	
	p-value	0.0078	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.20 (1.05, 1.38)	
	p-value	0.0092	
	Odds Ratio (95% CI)	1.41 (1.08, 1.82)	
	p-value	0.0100	
	Risk Difference (95% CI)	8.46 (2.06, 14.86)	
	p-value	0.0096	
	p-Value for test for heterogenity between studies	0.6627	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=459)	Placebo (N=468)
Week 24	Number of subjects with events, n (%)	243 (52.9)	199 (42.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.25 (1.09, 1.43)	
	p-value	0.0014	
	Odds Ratio (95% CI)	1.53 (1.18, 1.98)	
	p-value	0.0014	
	Risk Difference (95% CI)	10.57 (4.15, 17.00)	
	p-value	0.0013	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.25 (1.09, 1.43)	
	p-value	0.0014	
	Odds Ratio (95% CI)	1.52 (1.17, 1.97)	
	p-value	0.0016	
	Risk Difference (95% CI)	10.41 (4.01, 16.80)	
	p-value	0.0014	
	p-Value for test for heterogenity between studies	0.3164	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=459)	Placebo (N=468)
Week 28	Number of subjects with events, n (%)	247 (53.8)	207 (44.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.22 (1.07, 1.39)	
	p-value	0.0036	
	Odds Ratio (95% CI)	1.47 (1.14, 1.91)	
	p-value	0.0035	
	Risk Difference (95% CI)	9.61 (3.20, 16.02)	
	p-value	0.0033	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.22 (1.07, 1.39)	
	p-value	0.0035	
	Odds Ratio (95% CI)	1.47 (1.13, 1.90)	
	p-value	0.0037	
	Risk Difference (95% CI)	9.57 (3.16, 15.99)	
	p-value	0.0034	
	p-Value for test for heterogenity between studies	0.2697	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=459)	Placebo (N=468)
Week 32	Number of subjects with events, n (%)	252 (54.9)	211 (45.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.22 (1.07, 1.39)	
	p-value	0.0024	
	Odds Ratio (95% CI)	1.50 (1.15, 1.94)	
	p-value	0.0024	
	Risk Difference (95% CI)	10.02 (3.61, 16.44)	
	p-value	0.0022	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.22 (1.07, 1.39)	
	p-value	0.0027	
	Odds Ratio (95% CI)	1.48 (1.14, 1.92)	
	p-value	0.0030	
	Risk Difference (95% CI)	9.81 (3.40, 16.23)	
	p-value	0.0027	
	p-Value for test for heterogenity between studies	0.2035	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=459)	Placebo (N=468)
Week 36	Number of subjects with events, n (%)	248 (54.0)	208 (44.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.22 (1.07, 1.39)	
	p-value	0.0031	
	Odds Ratio (95% CI)	1.48 (1.14, 1.92)	
	p-value	0.0030	
	Risk Difference (95% CI)	9.79 (3.37, 16.21)	
	p-value	0.0028	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.22 (1.07, 1.39)	
	p-value	0.0038	
	Odds Ratio (95% CI)	1.47 (1.13, 1.90)	
	p-value	0.0037	
	Risk Difference (95% CI)	9.58 (3.16, 16.00)	
	p-value	0.0034	
	p-Value for test for heterogenity between studies	0.2548	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=459)	Placebo (N=468)
Week 40	Number of subjects with events, n (%)	252 (54.9)	197 (42.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.31 (1.14, 1.50)	
	p-value	0.0001	
	Odds Ratio (95% CI)	1.68 (1.29, 2.18)	
	p-value	<.0001	
	Risk Difference (95% CI)	12.90 (6.49, 19.30)	
	p-value	<.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.30 (1.13, 1.49)	
	p-value	0.0002	
	Odds Ratio (95% CI)	1.67 (1.29, 2.17)	
	p-value	0.0001	
	Risk Difference (95% CI)	12.81 (6.40, 19.21)	
	p-value	<.0001	
	p-Value for test for heterogenity between studies	0.0470	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=459)	Placebo (N=468)
Week 44	Number of subjects with events, n (%)	252 (54.9)	196 (41.9)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.32 (1.15, 1.51)	
	p-value	<.0001	
	Odds Ratio (95% CI)	1.71 (1.32, 2.21)	
	p-value	<.0001	
	Risk Difference (95% CI)	13.34 (6.93, 19.75)	
	p-value	<.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.31 (1.15, 1.50)	
	p-value	<.0001	
	Odds Ratio (95% CI)	1.69 (1.30, 2.19)	
	p-value	<.0001	
	Risk Difference (95% CI)	13.02 (6.64, 19.41)	
	p-value	<.0001	
	p-Value for test for heterogenity between studies	0.2107	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=459)	Placebo (N=468)
Week 48	Number of subjects with events, n (%)	248 (54.0)	194 (41.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.31 (1.15, 1.51)	
	p-value	<.0001	
	Odds Ratio (95% CI)	1.70 (1.31, 2.21)	
	p-value	<.0001	
	Risk Difference (95% CI)	12.97 (6.62, 19.32)	
	p-value	<.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.31 (1.14, 1.50)	
	p-value	0.0001	
	Odds Ratio (95% CI)	1.66 (1.28, 2.15)	
	p-value	0.0001	
	Risk Difference (95% CI)	12.58 (6.20, 18.96)	
	p-value	0.0001	
	p-Value for test for heterogenity between studies	0.4702	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=459)	Placebo (N=468)
Week 52	Number of subjects with events, n (%)	250 (54.5)	188 (40.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.37 (1.19, 1.57)	
	p-value	<.0001	
	Odds Ratio (95% CI)	1.81 (1.39, 2.35)	
	p-value	<.0001	
	Risk Difference (95% CI)	14.70 (8.31, 21.08)	
	p-value	<.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.36 (1.18, 1.56)	
	p-value	<.0001	
	Odds Ratio (95% CI)	1.78 (1.37, 2.31)	
	p-value	<.0001	
	Risk Difference (95% CI)	14.31 (7.93, 20.68)	
	p-value	<.0001	
	p-Value for test for heterogenity between studies	0.1423	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SRI (4) response rate at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=468) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	 p-Value	Interaction p-Value
SLEDAI-2K score					0.6110
< 10 points	76/148 (51.4)	58/146 (39.7)	1.28 (0.99, 1.64)	0.0576	
>= 10 points	174/311 (55.9)	130/322 (40.4)	1.38 (1.17, 1.63)	0.0002	
OCS dose					0.7918
<10 mg/day	112/214 (52.3)	85/219 (38.8)	1.32 (1.07, 1.64)	0.0102	
>=10 mg/day	138/245 (56.3)	103/249 (41.4)	1.37 (1.14, 1.65)	0.0007	
Result of type I IFN gene signature test					0.1599
LOW	45/ 86 (52.3)	43/ 90 (47.8)	1.13 (0.84, 1.51)	0.4193	
HIGH	205/373 (55.0)	145/378 (38.4)	1.43 (1.22, 1.67)	<.0001	
Age (years)					0.5200
<= 65	243/447 (54.4)	186/464 (40.1)	1.36 (1.18, 1.56)	<.0001	
> 65	7/ 12 (58.3)	2/ 4 (50.0)	0.99 (0.38, 2.56)	0.9847	
Sex					0.0344
male	17/ 33 (51.5)	20/ 34 (58.8)	0.88 (0.59, 1.32)	0.5377	
female	233/426 (54.7)	168/434 (38.7)	1.40 (1.21, 1.63)	<.0001	
Race					0.1623
White	145/270 (53.7)	124/285 (43.5)	1.24 (1.04, 1.47)	0.0164	
Black	31/ 65 (47.7)	20/ 60 (33.3)	1.41 (0.90, 2.19)	0.1301	
Other	70/116 (60.3)	40/115 (34.8)	1.71 (1.28, 2.29)	0.0003	
Ethnicity					0.3594
Hispanic/Latino	76/132 (57.6)	61/131 (46.6)	1.23 (0.97, 1.55)	0.0827	
Non-hispanic/Latino	170/319 (53.3)	123/329 (37.4)	1.41 (1.18, 1.68)	0.0001	
Geographic region					0.3684
EU	85/135 (63.0)	73/147 (49.7)	1.26 (1.03, 1.55)	0.0277	
non-EU	165/324 (50.9)	115/321 (35.8)	1.43 (1.20, 1.72)	<.0001	
Onset of disease					0.7969
Paediatric	15/ 36 (41.7)	10/ 35 (28.6)	1.47 (0.77, 2.83)	0.2433	
Adult	235/423 (55.6)	178/433 (41.1)	1.35 (1.17, 1.56)	<.0001	
ADA result					0.3215
Negative	235/427 (55.0)	179/429 (41.7)	1.32 (1.15, 1.52)	0.0001	
Positive (At any time)	15/ 31 (48.4)	9/ 39 (23.1)	1.87 (0.96, 3.64)	0.0668	
BMI (kg/m2)					0.8007
< 30	176/309 (57.0)	143/339 (42.2)	1.35 (1.15, 1.58)	0.0002	
>= 30	74/150 (49.3)	45/129 (34.9)	1.41 (1.06, 1.87)	0.0187	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SRI (8) response rate at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=438)	Placebo (N=443)
Week 52	Number of subjects with events, n (%)	133 (30.4)	78 (17.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.75 (1.37, 2.25)	
	p-value	<.0001	
	Odds Ratio (95% CI)	2.08 (1.51, 2.87)	
	p-value	<.0001	
	Risk Difference (95% CI)	13.10 (7.51, 18.69)	
	p-value	<.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.72 (1.34, 2.20)	
	p-value	<.0001	
	Odds Ratio (95% CI)	2.04 (1.48, 2.80)	
	p-value	<.0001	
	Risk Difference (95% CI)	12.76 (7.18, 18.34)	
	p-value	<.0001	
	p-Value for test for heterogenity between studies	0.6566	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SRI (8) response rate at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=438) n/ N (%)	Placebo (N=443) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	 p-Value	Interaction p-Value
SLEDAI-2K score					0.6123
< 10 points	24/127 (18.9)	15/121 (12.4)	1.51 (0.82, 2.77)	0.1882	
>= 10 points	109/311 (35.0)	63/322 (19.6)	1.79 (1.37, 2.34)	<.0001	
OCS dose					0.0578
<10 mg/day	56/202 (27.7)	42/205 (20.5)	1.31 (0.92, 1.88)	0.1336	
>=10 mg/day	77/236 (32.6)	36/238 (15.1)	2.14 (1.50, 3.05)	<.0001	
Result of type I IFN gene signature test					0.0201
LOW	15/ 81 (18.5)	18/ 85 (21.2)	0.88 (0.47, 1.63)	0.6790	
HIGH	118/357 (33.1)	60/358 (16.8)	1.95 (1.48, 2.57)	<.0001	
Age (years)					0.4849
<= 65	131/426 (30.8)	77/439 (17.5)	1.75 (1.36, 2.24)	<.0001	
> 65	2/ 12 (16.7)	1/ 4 (25.0)	0.86 (0.12, 6.23)	0.8789	
Sex					0.7362
male	9/ 31 (29.0)	6/ 32 (18.8)	1.47 (0.58, 3.71)	0.4144	
female	124/407 (30.5)	72/411 (17.5)	1.73 (1.34, 2.24)	<.0001	
Race					0.1065
White	71/258 (27.5)	52/269 (19.3)	1.41 (1.03, 1.94)	0.0312	
Black	17/ 60 (28.3)	9/ 56 (16.1)	1.75 (0.83, 3.67)	0.1400	
Other	44/113 (38.9)	15/110 (13.6)	2.75 (1.62, 4.69)	0.0002	
Ethnicity					0.2162
Hispanic/Latino	39/127 (30.7)	26/125 (20.8)	1.34 (0.87, 2.07)	0.1870	
Non-hispanic/Latino	93/304 (30.6)	50/310 (16.1)	1.87 (1.38, 2.54)	<.0001	
Geographic region					0.6974
EU	50/128 (39.1)	30/143 (21.0)	1.86 (1.26, 2.73)	0.0016	
non-EU	83/310 (26.8)	48/300 (16.0)	1.68 (1.22, 2.31)	0.0014	
Onset of disease					0.6776
Paediatric	12/ 36 (33.3)	5/ 35 (14.3)	2.03 (0.85, 4.85)	0.1110	
Adult	121/402 (30.1)	73/408 (17.9)	1.67 (1.30, 2.16)	<.0001	
ADA result					0.4671
Negative	122/407 (30.0)	73/405 (18.0)	1.65 (1.28, 2.13)	0.0001	
Positive (At any time)	11/ 30 (36.7)	5/ 38 (13.2)	2.36 (0.94, 5.93)	0.0685	
BMI (kg/m2)					0.4759
< 30	100/298 (33.6)	65/323 (20.1)	1.66 (1.27, 2.18)	0.0002	
>= 30	33/140 (23.6)	13/120 (10.8)	2.11 (1.16, 3.84)	0.0147	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
>=4 reduction in SLEDAI-2K at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=459)	Placebo (N=468)
Week 52	Number of subjects with events, n (%)	252 (54.9)	192 (41.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.35 (1.18, 1.55)	
	p-value	<.0001	
	Odds Ratio (95% CI)	1.78 (1.37, 2.31)	
	p-value	<.0001	
	Risk Difference (95% CI)	14.31 (7.92, 20.70)	
	p-value	<.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.34 (1.17, 1.54)	
	p-value	<.0001	
	Odds Ratio (95% CI)	1.75 (1.35, 2.27)	
	p-value	<.0001	
	Risk Difference (95% CI)	13.88 (7.50, 20.26)	
	p-value	<.0001	
	p-Value for test for heterogenity between studies	0.1651	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
>=4 reduction in SLEDAI-2K at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=468) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.6865
< 10 points	77/148 (52.0)	59/146 (40.4)	1.28 (1.00, 1.64)	0.0547	
>= 10 points	175/311 (56.3)	133/322 (41.3)	1.36 (1.15, 1.60)	0.0003	
OCS dose					0.5661
<10 mg/day	113/214 (52.8)	89/219 (40.6)	1.27 (1.04, 1.57)	0.0218	
>=10 mg/day	139/245 (56.7)	103/249 (41.4)	1.38 (1.15, 1.66)	0.0005	
Result of type I IFN gene signature test					0.1384
LOW	45/ 86 (52.3)	44/ 90 (48.9)	1.10 (0.83, 1.47)	0.5001	
HIGH	207/373 (55.5)	148/378 (39.2)	1.41 (1.21, 1.65)	<.0001	
Age (years)					0.5369
<= 65	245/447 (54.8)	190/464 (40.9)	1.34 (1.17, 1.54)	<.0001	
> 65	7/ 12 (58.3)	2/ 4 (50.0)	0.99 (0.38, 2.56)	0.9847	
Sex					0.0399
male	17/ 33 (51.5)	20/ 34 (58.8)	0.88 (0.59, 1.32)	0.5377	
female	235/426 (55.2)	172/434 (39.6)	1.38 (1.20, 1.60)	<.0001	
Race					0.2296
White	146/270 (54.1)	125/285 (43.9)	1.23 (1.04, 1.47)	0.0164	
Black	32/ 65 (49.2)	21/ 60 (35.0)	1.40 (0.91, 2.14)	0.1251	
Other	70/116 (60.3)	42/115 (36.5)	1.64 (1.24, 2.18)	0.0005	
Ethnicity					0.3408
Hispanic/Latino	76/132 (57.6)	62/131 (47.3)	1.21 (0.96, 1.53)	0.1031	
Non-hispanic/Latino	172/319 (53.9)	126/329 (38.3)	1.39 (1.17, 1.65)	0.0001	
Geographic region					0.3589
EU	85/135 (63.0)	74/147 (50.3)	1.25 (1.01, 1.53)	0.0369	
non-EU	167/324 (51.5)	118/321 (36.8)	1.41 (1.18, 1.69)	0.0001	
Onset of disease					0.7675
Paediatric	15/ 36 (41.7)	10/ 35 (28.6)	1.47 (0.77, 2.83)	0.2433	
Adult	237/423 (56.0)	182/433 (42.0)	1.33 (1.16, 1.53)	<.0001	
ADA result					0.3022
Negative	237/427 (55.5)	183/429 (42.7)	1.30 (1.13, 1.50)	0.0002	
Positive (At any time)	15/ 31 (48.4)	9/ 39 (23.1)	1.87 (0.96, 3.64)	0.0668	
BMI (kg/m2)					0.7454
< 30	177/309 (57.3)	146/339 (43.1)	1.33 (1.14, 1.55)	0.0004	
>= 30	75/150 (50.0)	46/129 (35.7)	1.40 (1.06, 1.85)	0.0182	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
>=8 reduction in SLEDAI-2K at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=459)	Placebo (N=468)
Week 52	Number of subjects with events, n (%)	133 (29.0)	78 (16.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.77 (1.38, 2.27)	
	p-value	<.0001	
	Odds Ratio (95% CI)	2.10 (1.52, 2.89)	
	p-value	<.0001	
	Risk Difference (95% CI)	12.63 (7.30, 17.96)	
	p-value	<.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.73 (1.35, 2.22)	
	p-value	<.0001	
	Odds Ratio (95% CI)	2.04 (1.48, 2.79)	
	p-value	<.0001	
	Risk Difference (95% CI)	12.31 (6.96, 17.66)	
	p-value	<.0001	
	p-Value for test for heterogenity between studies	0.6622	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
>=8 reduction in SLEDAI-2K at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=468) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.7109
< 10 points	24/148 (16.2)	15/146 (10.3)	1.58 (0.85, 2.92)	0.1491	
>= 10 points	109/311 (35.0)	63/322 (19.6)	1.79 (1.37, 2.34)	<.0001	
OCS dose					0.0585
<10 mg/day	56/214 (26.2)	42/219 (19.2)	1.32 (0.92, 1.90)	0.1277	
>=10 mg/day	77/245 (31.4)	36/249 (14.5)	2.16 (1.51, 3.08)	<.0001	
Result of type I IFN gene signature test					0.0190
LOW	15/ 86 (17.4)	18/ 90 (20.0)	0.88 (0.47, 1.63)	0.6801	
HIGH	118/373 (31.6)	60/378 (15.9)	1.98 (1.50, 2.61)	<.0001	
Age (years)					0.4801
<= 65	131/447 (29.3)	77/464 (16.6)	1.76 (1.37, 2.26)	<.0001	
> 65	2/ 12 (16.7)	1/ 4 (25.0)	0.86 (0.12, 6.23)	0.8789	
Sex					0.7032
male	9/ 33 (27.3)	6/ 34 (17.6)	1.45 (0.57, 3.70)	0.4374	
female	124/426 (29.1)	72/434 (16.6)	1.75 (1.35, 2.27)	<.0001	
Race					0.1091
White	71/270 (26.3)	52/285 (18.2)	1.44 (1.05, 1.97)	0.0255	
Black	17/ 65 (26.2)	9/ 60 (15.0)	1.70 (0.80, 3.59)	0.1662	
Other	44/116 (37.9)	15/115 (13.0)	2.80 (1.64, 4.77)	0.0002	
Ethnicity					0.2168
Hispanic/Latino	39/132 (29.5)	26/131 (19.8)	1.35 (0.87, 2.10)	0.1779	
Non-hispanic/Latino	93/319 (29.2)	50/329 (15.2)	1.90 (1.40, 2.58)	<.0001	
Geographic region					0.8503
EU	50/135 (37.0)	30/147 (20.4)	1.80 (1.22, 2.66)	0.0028	
non-EU	83/324 (25.6)	48/321 (15.0)	1.72 (1.25, 2.37)	0.0009	
Onset of disease					0.6934
Paediatric	12/ 36 (33.3)	5/ 35 (14.3)	2.03 (0.85, 4.85)	0.1110	
Adult	121/423 (28.6)	73/433 (16.9)	1.69 (1.31, 2.19)	<.0001	
ADA result					0.5021
Negative	122/427 (28.6)	73/429 (17.0)	1.67 (1.29, 2.16)	<.0001	
Positive (At any time)	11/ 31 (35.5)	5/ 39 (12.8)	2.32 (0.92, 5.86)	0.0742	
BMI (kg/m2)					0.4912
< 30	100/309 (32.4)	65/339 (19.2)	1.68 (1.28, 2.21)	0.0002	
>= 30	33/150 (22.0)	13/129 (10.1)	2.12 (1.16, 3.88)	0.0146	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
No worsening in BILAG-2004 (>=1A or >=2B compared to BL) at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=459)	Placebo (N=468)
Week 52	Number of subjects with events, n (%)	319 (69.5)	260 (55.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.25 (1.13, 1.39)	
	p-value	<.0001	
	Odds Ratio (95% CI)	1.85 (1.41, 2.43)	
	p-value	<.0001	
	Risk Difference (95% CI)	14.14 (7.99, 20.29)	
	p-value	<.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.25 (1.13, 1.38)	
	p-value	<.0001	
	Odds Ratio (95% CI)	1.83 (1.39, 2.39)	
	p-value	<.0001	
	Risk Difference (95% CI)	13.96 (7.80, 20.12)	
	p-value	<.0001	
	p-Value for test for heterogenity between studies	0.4603	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
No worsening in BILAG-2004 (>=1A or >=2B compared to BL) at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=468) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	 p-Value	Interaction p-Value
SLEDAI-2K score					0.2436
< 10 points	106/148 (71.6)	90/146 (61.6)	1.15 (0.98, 1.35)	0.0894	
>= 10 points	213/311 (68.5)	170/322 (52.8)	1.30 (1.14, 1.48)	<.0001	
OCS dose					0.7207
<10 mg/day	151/214 (70.6)	125/219 (57.1)	1.23 (1.07, 1.42)	0.0043	
>=10 mg/day	168/245 (68.6)	135/249 (54.2)	1.28 (1.11, 1.47)	0.0005	
Result of type I IFN gene signature test					0.6529
LOW	66/ 86 (76.7)	57/ 90 (63.3)	1.20 (0.99, 1.45)	0.0643	
HIGH	253/373 (67.8)	203/378 (53.7)	1.26 (1.12, 1.42)	<.0001	
Age (years)					0.0275
<= 65	309/447 (69.1)	257/464 (55.4)	1.25 (1.13, 1.38)	<.0001	
> 65	10/ 12 (83.3)	3/ 4 (75.0)	0.87 (0.65, 1.18)	0.3771	
Sex					0.2196
male	21/ 33 (63.6)	21/ 34 (61.8)	1.00 (0.69, 1.44)	0.9825	
female	298/426 (70.0)	239/434 (55.1)	1.27 (1.14, 1.41)	<.0001	
Race					0.6909
White	190/270 (70.4)	165/285 (57.9)	1.21 (1.07, 1.38)	0.0025	
Black	41/ 65 (63.1)	31/ 60 (51.7)	1.17 (0.84, 1.61)	0.3550	
Other	83/116 (71.6)	60/115 (52.2)	1.33 (1.09, 1.63)	0.0051	
Ethnicity					0.6023
Hispanic/Latino	95/132 (72.0)	78/131 (59.5)	1.19 (1.01, 1.42)	0.0429	
Non-hispanic/Latino	219/319 (68.7)	178/329 (54.1)	1.26 (1.12, 1.43)	0.0002	
Geographic region					0.2546
EU	98/135 (72.6)	92/147 (62.6)	1.16 (0.98, 1.36)	0.0778	
non-EU	221/324 (68.2)	168/321 (52.3)	1.31 (1.15, 1.48)	<.0001	
Onset of disease					0.7617
Paediatric	19/ 36 (52.8)	14/ 35 (40.0)	1.35 (0.82, 2.22)	0.2417	
Adult	300/423 (70.9)	246/433 (56.8)	1.25 (1.12, 1.38)	<.0001	
ADA result					0.8993
Negative	302/427 (70.7)	246/429 (57.3)	1.24 (1.12, 1.37)	<.0001	
Positive (At any time)	17/ 31 (54.8)	14/ 39 (35.9)	1.28 (0.78, 2.10)	0.3343	
BMI (kg/m2)					0.3136
< 30	220/309 (71.2)	187/339 (55.2)	1.29 (1.14, 1.45)	<.0001	
>= 30	99/150 (66.0)	73/129 (56.6)	1.15 (0.95, 1.39)	0.1421	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Maintained OCS Reduction at week 52 (for subjects with baseline OCS >=10 mg/day)
Full analysis set

Timepoint		Anifrolumab 300mg (N=245)	Placebo (N=249)
Week 52	Number of subjects with events, n (%)	127 (51.8)	76 (30.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.69 (1.36, 2.11)	
	p-value	<.0001	
	Odds Ratio (95% CI)	2.47 (1.70, 3.58)	
	p-value	<.0001	
	Risk Difference (95% CI)	21.37 (12.89, 29.84)	
	p-value	<.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.69 (1.35, 2.11)	
	p-value	<.0001	
	Odds Ratio (95% CI)	2.44 (1.69, 3.53)	
	p-value	<.0001	
	Risk Difference (95% CI)	21.32 (12.82, 29.82)	
	p-value	<.0001	
	p-Value for test for heterogenity between studies	0.4783	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Maintained OCS Reduction at week 52 (for subjects with baseline OCS >=10 mg/day) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=245) n/ N (%)	Placebo (N=249) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	 p-Value	Interaction p-Value
SLEDAI-2K score					0.6352
< 10 points	38/ 70 (54.3)	23/ 65 (35.4)	1.54 (1.05, 2.28)	0.0281	
>= 10 points	89/175 (50.9)	53/184 (28.8)	1.73 (1.32, 2.27)	<.0001	
OCS dose					NE
>=10 mg/day	127/245 (51.8)	76/249 (30.5)	1.69 (1.35, 2.11)	<.0001	
Result of type I IFN gene signature test					0.0596
LOW	15/ 33 (45.5)	15/ 36 (41.7)	1.08 (0.66, 1.77)	0.7553	
HIGH	112/212 (52.8)	61/213 (28.6)	1.84 (1.44, 2.35)	<.0001	
Age (years)					0.0853
<= 65	126/242 (52.1)	75/248 (30.2)	1.71 (1.37, 2.15)	<.0001	
> 65	1/ 3 (33.3)	1/ 1 (100.0)	0.50 (0.13, 2.00)	0.3270	
Sex					0.6737
male	11/ 21 (52.4)	8/ 22 (36.4)	1.45 (0.69, 3.05)	0.3324	
female	116/224 (51.8)	68/227 (30.0)	1.71 (1.35, 2.17)	<.0001	
Race					0.7491
White	69/137 (50.4)	46/155 (29.7)	1.67 (1.24, 2.25)	0.0007	
Black	16/ 34 (47.1)	5/ 26 (19.2)	1.84 (0.66, 5.12)	0.2430	
Other	39/ 70 (55.7)	25/ 65 (38.5)	1.41 (0.98, 2.04)	0.0660	
Ethnicity					0.9254
Hispanic/Latino	41/ 78 (52.6)	25/ 77 (32.5)	1.63 (1.11, 2.38)	0.0126	
Non-hispanic/Latino	83/163 (50.9)	51/169 (30.2)	1.66 (1.26, 2.19)	0.0003	
Geographic region					0.7141
EU	52/ 89 (58.4)	32/103 (31.1)	1.77 (1.27, 2.48)	0.0008	
non-EU	75/156 (48.1)	44/146 (30.1)	1.63 (1.21, 2.19)	0.0011	
Onset of disease					0.6387
Paediatric	14/ 27 (51.9)	5/ 23 (21.7)	2.02 (0.87, 4.68)	0.0995	
Adult	113/218 (51.8)	71/226 (31.4)	1.64 (1.30, 2.07)	<.0001	
ADA result					0.3602
Negative	120/220 (54.5)	74/223 (33.2)	1.64 (1.31, 2.04)	<.0001	
Positive (At any time)	7/ 24 (29.2)	2/ 26 (7.7)	3.07 (0.81, 11.59)	0.0982	
BMI (kg/m2)					0.9872
< 30	95/172 (55.2)	62/194 (32.0)	1.72 (1.34, 2.20)	<.0001	
>= 30	32/ 73 (43.8)	14/ 55 (25.5)	1.71 (1.02, 2.88)	0.0432	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
>=50% Reduction in CLASI activity score at week 52 (for subjects with baseline CLASI activity score >=10)
Full analysis set

Timepoint		Anifrolumab 300mg (N=134)	Placebo (N=120)
Week 52	Number of subjects with events, n (%)	85 (63.4)	50 (41.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.52 (1.19, 1.94)	
	p-value	0.0008	
	Odds Ratio (95% CI)	2.51 (1.49, 4.24)	
	p-value	0.0006	
	Risk Difference (95% CI)	21.73 (9.81, 33.65)	
	p-value	0.0004	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.50 (1.17, 1.92)	
	p-value	0.0013	
	Odds Ratio (95% CI)	2.42 (1.46, 4.01)	
	p-value	0.0007	
	Risk Difference (95% CI)	21.66 (9.64, 33.68)	
	p-value	0.0004	
	p-Value for test for heterogenity between studies	0.5921	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
>=50% Reduction in CLASI activity score at week 52 (for subjects with baseline CLASI activity score >=10) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=134) n/ N (%)	Placebo (N=120) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.5568
< 10 points	19/ 27 (70.4)	12/ 29 (41.4)	1.72 (1.06, 2.79)	0.0271	
>= 10 points	66/107 (61.7)	38/ 91 (41.8)	1.46 (1.09, 1.93)	0.0098	
OCS dose					0.0159
<10 mg/day	34/ 49 (69.4)	13/ 46 (28.3)	2.39 (1.46, 3.92)	0.0005	
>=10 mg/day	51/ 85 (60.0)	37/ 74 (50.0)	1.19 (0.89, 1.58)	0.2352	
Result of type I IFN gene signature test					0.0042
LOW	8/ 14 (57.1)	11/ 15 (73.3)	0.77 (0.48, 1.22)	0.2660	
HIGH	77/120 (64.2)	39/105 (37.1)	1.70 (1.28, 2.25)	0.0002	
Age (years)					NE
<= 65	82/131 (62.6)	49/119 (41.2)	1.50 (1.16, 1.93)	0.0017	
> 65	3/ 3 (100.0)	1/ 1 (100.0)	NE		
Sex					0.0836
male	5/ 12 (41.7)	8/ 13 (61.5)	0.71 (0.29, 1.71)	0.4434	
female	80/122 (65.6)	42/107 (39.3)	1.60 (1.22, 2.09)	0.0006	
Race					0.1017
White	50/ 83 (60.2)	40/ 85 (47.1)	1.24 (0.94, 1.64)	0.1349	
Black	14/ 23 (60.9)	1/ 8 (12.5)	2.68 (0.73, 9.80)	0.1366	
Other	21/ 27 (77.8)	7/ 23 (30.4)	2.45 (1.29, 4.65)	0.0063	
Ethnicity					0.9490
Hispanic/Latino	16/ 27 (59.3)	6/ 17 (35.3)	1.54 (0.78, 3.07)	0.2158	
Non-hispanic/Latino	69/106 (65.1)	42/ 99 (42.4)	1.51 (1.16, 1.97)	0.0025	
Geographic region					0.0437
EU	29/ 47 (61.7)	30/ 57 (52.6)	1.15 (0.83, 1.59)	0.4005	
non-EU	56/ 87 (64.4)	20/ 63 (31.7)	1.94 (1.31, 2.88)	0.0009	
Onset of disease					0.9283
Paediatric	4/ 9 (44.4)	2/ 8 (25.0)	1.59 (0.42, 6.09)	0.4973	
Adult	81/125 (64.8)	48/112 (42.9)	1.50 (1.17, 1.92)	0.0016	
ADA result					0.6813
Negative	83/123 (67.5)	49/114 (43.0)	1.54 (1.21, 1.96)	0.0005	
Positive (At any time)	2/ 11 (18.2)	1/ 6 (16.7)	1.04 (0.16, 6.59)	0.9662	
BMI (kg/m2)					0.3053
< 30	59/ 88 (67.0)	35/ 87 (40.2)	1.63 (1.22, 2.19)	0.0011	
>= 30	26/ 46 (56.5)	15/ 33 (45.5)	1.23 (0.78, 1.94)	0.3653	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=459)	Placebo (N=468)
Week 4	Number of subjects with events, n (%)	111 (24.2)	92 (19.7)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.22 (0.95, 1.56)	
	p-value	0.1154	
	Odds Ratio (95% CI)	1.29 (0.94, 1.76)	
	p-value	0.1147	
	Risk Difference (95% CI)	4.31 (-1.03, 9.65)	
	p-value	0.1138	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.23 (0.96, 1.57)	
	p-value	0.0974	
	Odds Ratio (95% CI)	1.30 (0.95, 1.78)	
	p-value	0.0975	
	Risk Difference (95% CI)	4.51 (-0.81, 9.83)	
	p-value	0.0963	
	p-Value for test for heterogenity between studies	0.7616	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=459)	Placebo (N=468)
Week 8	Number of subjects with events, n (%)	162 (35.3)	113 (24.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.46 (1.20, 1.79)	
	p-value	0.0002	
	Odds Ratio (95% CI)	1.74 (1.30, 2.33)	
	p-value	0.0002	
	Risk Difference (95% CI)	11.19 (5.40, 16.98)	
	p-value	0.0002	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.46 (1.19, 1.78)	
	p-value	0.0003	
	Odds Ratio (95% CI)	1.71 (1.29, 2.28)	
	p-value	0.0002	
	Risk Difference (95% CI)	11.16 (5.32, 17.00)	
	p-value	0.0002	
	p-Value for test for heterogenity between studies	0.6230	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=459)	Placebo (N=468)
Week 12	Number of subjects with events, n (%)	179 (39.0)	136 (29.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.34 (1.12, 1.61)	
	p-value	0.0015	
	Odds Ratio (95% CI)	1.57 (1.19, 2.07)	
	p-value	0.0014	
	Risk Difference (95% CI)	9.93 (3.89, 15.96)	
	p-value	0.0013	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.34 (1.12, 1.61)	
	p-value	0.0015	
	Odds Ratio (95% CI)	1.56 (1.19, 2.05)	
	p-value	0.0015	
	Risk Difference (95% CI)	9.92 (3.86, 15.98)	
	p-value	0.0013	
	p-Value for test for heterogenity between studies	0.9725	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=459)	Placebo (N=468)
Week 16	Number of subjects with events, n (%)	198 (43.1)	145 (31.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.39 (1.17, 1.66)	
	p-value	0.0002	
	Odds Ratio (95% CI)	1.69 (1.29, 2.21)	
	p-value	0.0001	
	Risk Difference (95% CI)	12.18 (5.98, 18.38)	
	p-value	0.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.39 (1.17, 1.65)	
	p-value	0.0002	
	Odds Ratio (95% CI)	1.69 (1.29, 2.21)	
	p-value	0.0001	
	Risk Difference (95% CI)	12.15 (5.98, 18.32)	
	p-value	0.0001	
	p-Value for test for heterogenity between studies	0.6841	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=459)	Placebo (N=468)
Week 20	Number of subjects with events, n (%)	203 (44.2)	159 (34.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.31 (1.11, 1.55)	
	p-value	0.0012	
	Odds Ratio (95% CI)	1.56 (1.19, 2.04)	
	p-value	0.0011	
	Risk Difference (95% CI)	10.54 (4.27, 16.81)	
	p-value	0.0010	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.30 (1.10, 1.53)	
	p-value	0.0018	
	Odds Ratio (95% CI)	1.54 (1.18, 2.01)	
	p-value	0.0015	
	Risk Difference (95% CI)	10.25 (3.99, 16.50)	
	p-value	0.0013	
	p-Value for test for heterogenity between studies	0.3334	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=459)	Placebo (N=468)
Week 24	Number of subjects with events, n (%)	220 (47.9)	149 (31.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.52 (1.29, 1.79)	
	p-value	<.0001	
	Odds Ratio (95% CI)	2.00 (1.53, 2.62)	
	p-value	<.0001	
	Risk Difference (95% CI)	16.35 (10.14, 22.57)	
	p-value	<.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.49 (1.27, 1.76)	
	p-value	<.0001	
	Odds Ratio (95% CI)	1.97 (1.51, 2.57)	
	p-value	<.0001	
	Risk Difference (95% CI)	16.08 (9.86, 22.30)	
	p-value	<.0001	
	p-Value for test for heterogenity between studies	0.2515	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=459)	Placebo (N=468)
Week 28	Number of subjects with events, n (%)	211 (46.0)	160 (34.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.35 (1.15, 1.59)	
	p-value	0.0002	
	Odds Ratio (95% CI)	1.66 (1.27, 2.16)	
	p-value	0.0002	
	Risk Difference (95% CI)	12.01 (5.74, 18.27)	
	p-value	0.0002	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.34 (1.14, 1.57)	
	p-value	0.0003	
	Odds Ratio (95% CI)	1.64 (1.25, 2.13)	
	p-value	0.0003	
	Risk Difference (95% CI)	11.77 (5.50, 18.04)	
	p-value	0.0002	
	p-Value for test for heterogenity between studies	0.3425	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=459)	Placebo (N=468)
Week 32	Number of subjects with events, n (%)	217 (47.3)	157 (33.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.42 (1.21, 1.66)	
	p-value	<.0001	
	Odds Ratio (95% CI)	1.78 (1.37, 2.33)	
	p-value	<.0001	
	Risk Difference (95% CI)	13.91 (7.62, 20.19)	
	p-value	<.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.40 (1.19, 1.64)	
	p-value	<.0001	
	Odds Ratio (95% CI)	1.77 (1.36, 2.32)	
	p-value	<.0001	
	Risk Difference (95% CI)	13.73 (7.47, 19.99)	
	p-value	<.0001	
	p-Value for test for heterogenity between studies	0.2915	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=459)	Placebo (N=468)
Week 36	Number of subjects with events, n (%)	220 (47.9)	161 (34.4)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.40 (1.20, 1.64)	
	p-value	<.0001	
	Odds Ratio (95% CI)	1.78 (1.36, 2.32)	
	p-value	<.0001	
	Risk Difference (95% CI)	13.81 (7.52, 20.10)	
	p-value	<.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.38 (1.18, 1.62)	
	p-value	<.0001	
	Odds Ratio (95% CI)	1.75 (1.34, 2.29)	
	p-value	<.0001	
	Risk Difference (95% CI)	13.54 (7.25, 19.82)	
	p-value	<.0001	
	p-Value for test for heterogenity between studies	0.1803	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=459)	Placebo (N=468)
Week 40	Number of subjects with events, n (%)	209 (45.5)	148 (31.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.44 (1.22, 1.70)	
	p-value	<.0001	
	Odds Ratio (95% CI)	1.82 (1.39, 2.38)	
	p-value	<.0001	
	Risk Difference (95% CI)	13.98 (7.77, 20.20)	
	p-value	<.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.44 (1.22, 1.70)	
	p-value	<.0001	
	Odds Ratio (95% CI)	1.81 (1.38, 2.37)	
	p-value	<.0001	
	Risk Difference (95% CI)	13.92 (7.72, 20.12)	
	p-value	<.0001	
	p-Value for test for heterogenity between studies	0.6042	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=459)	Placebo (N=468)
Week 44	Number of subjects with events, n (%)	202 (44.0)	143 (30.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.45 (1.22, 1.72)	
	p-value	<.0001	
	Odds Ratio (95% CI)	1.79 (1.37, 2.34)	
	p-value	<.0001	
	Risk Difference (95% CI)	13.69 (7.46, 19.92)	
	p-value	<.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.44 (1.21, 1.70)	
	p-value	<.0001	
	Odds Ratio (95% CI)	1.79 (1.36, 2.34)	
	p-value	<.0001	
	Risk Difference (95% CI)	13.45 (7.28, 19.61)	
	p-value	<.0001	
	p-Value for test for heterogenity between studies	0.7868	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=459)	Placebo (N=468)
Week 48	Number of subjects with events, n (%)	211 (46.0)	146 (31.2)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.48 (1.25, 1.75)	
	p-value	<.0001	
	Odds Ratio (95% CI)	1.89 (1.44, 2.48)	
	p-value	<.0001	
	Risk Difference (95% CI)	14.93 (8.72, 21.14)	
	p-value	<.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.47 (1.24, 1.74)	
	p-value	<.0001	
	Odds Ratio (95% CI)	1.88 (1.43, 2.45)	
	p-value	<.0001	
	Risk Difference (95% CI)	14.77 (8.57, 20.97)	
	p-value	<.0001	
	p-Value for test for heterogenity between studies	0.5964	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BICLA response rate by timepoint
Full analysis set

Timepoint		Anifrolumab 300mg (N=459)	Placebo (N=468)
Week 52	Number of subjects with events, n (%)	224 (48.8)	138 (29.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.65 (1.40, 1.96)	
	p-value	<.0001	
	Odds Ratio (95% CI)	2.28 (1.74, 3.00)	
	p-value	<.0001	
	Risk Difference (95% CI)	19.37 (13.19, 25.55)	
	p-value	<.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.65 (1.39, 1.95)	
	p-value	<.0001	
	Odds Ratio (95% CI)	2.27 (1.73, 2.98)	
	p-value	<.0001	
	Risk Difference (95% CI)	19.31 (13.14, 25.48)	
	p-value	<.0001	
	p-Value for test for heterogenity between studies	0.3689	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
BICLA response rate at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=468) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	 p-Value	Interaction p-Value
SLEDAI-2K score					0.4277
< 10 points	82/148 (55.4)	54/146 (37.0)	1.50 (1.16, 1.94)	0.0019	
>= 10 points	142/311 (45.7)	84/322 (26.1)	1.72 (1.38, 2.15)	<.0001	
OCS dose					0.6374
<10 mg/day	104/214 (48.6)	61/219 (27.9)	1.72 (1.33, 2.22)	<.0001	
>=10 mg/day	120/245 (49.0)	77/249 (30.9)	1.59 (1.27, 1.99)	<.0001	
Result of type I IFN gene signature test					0.3106
LOW	43/ 86 (50.0)	32/ 90 (35.6)	1.40 (0.98, 1.99)	0.0610	
HIGH	181/373 (48.5)	106/378 (28.0)	1.72 (1.42, 2.09)	<.0001	
Age (years)					0.6382
<= 65	216/447 (48.3)	137/464 (29.5)	1.63 (1.37, 1.93)	<.0001	
> 65	8/ 12 (66.7)	1/ 4 (25.0)	2.27 (0.57, 9.01)	0.2427	
Sex					0.2165
male	14/ 33 (42.4)	12/ 34 (35.3)	1.15 (0.64, 2.07)	0.6470	
female	210/426 (49.3)	126/434 (29.0)	1.69 (1.42, 2.02)	<.0001	
Race					0.2479
White	126/270 (46.7)	88/285 (30.9)	1.50 (1.21, 1.86)	0.0002	
Black	31/ 65 (47.7)	18/ 60 (30.0)	1.59 (0.99, 2.56)	0.0525	
Other	62/116 (53.4)	29/115 (25.2)	2.13 (1.50, 3.04)	<.0001	
Ethnicity					0.2555
Hispanic/Latino	68/132 (51.5)	47/131 (35.9)	1.43 (1.08, 1.89)	0.0134	
Non-hispanic/Latino	151/319 (47.3)	88/329 (26.7)	1.75 (1.42, 2.17)	<.0001	
Geographic region					0.1845
EU	69/135 (51.1)	53/147 (36.1)	1.42 (1.09, 1.87)	0.0106	
non-EU	155/324 (47.8)	85/321 (26.5)	1.80 (1.45, 2.24)	<.0001	
Onset of disease					0.4723
Paediatric	17/ 36 (47.2)	8/ 35 (22.9)	2.08 (1.07, 4.06)	0.0307	
Adult	207/423 (48.9)	130/433 (30.0)	1.62 (1.36, 1.93)	<.0001	
ADA result					0.4555
Negative	212/427 (49.6)	132/429 (30.8)	1.61 (1.35, 1.91)	<.0001	
Positive (At any time)	12/ 31 (38.7)	6/ 39 (15.4)	2.24 (0.95, 5.28)	0.0654	
BMI (kg/m2)					0.8459
< 30	157/309 (50.8)	103/339 (30.4)	1.67 (1.37, 2.03)	<.0001	
>= 30	67/150 (44.7)	35/129 (27.1)	1.60 (1.15, 2.24)	0.0056	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Change from baseline in PGA VAS < 0.3 at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=459)	Placebo (N=468)
Week 52	Number of subjects with events, n (%)	315 (68.6)	262 (56.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.23 (1.11, 1.36)	
	p-value	<.0001	
	Odds Ratio (95% CI)	1.74 (1.33, 2.28)	
	p-value	<.0001	
	Risk Difference (95% CI)	12.95 (6.76, 19.15)	
	p-value	<.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.23 (1.11, 1.36)	
	p-value	<.0001	
	Odds Ratio (95% CI)	1.72 (1.32, 2.26)	
	p-value	<.0001	
	Risk Difference (95% CI)	12.67 (6.49, 18.84)	
	p-value	<.0001	
	p-Value for test for heterogenity between studies	0.5252	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Change from baseline in PGA VAS < 0.3 at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=468) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	 p-Value	Interaction p-Value
SLEDAI-2K score					0.2235
< 10 points	104/148 (70.3)	90/146 (61.6)	1.12 (0.95, 1.31)	0.1651	
>= 10 points	211/311 (67.8)	172/322 (53.4)	1.27 (1.12, 1.45)	0.0002	
OCS dose					0.9359
<10 mg/day	147/214 (68.7)	121/219 (55.3)	1.24 (1.07, 1.44)	0.0046	
>=10 mg/day	168/245 (68.6)	141/249 (56.6)	1.23 (1.08, 1.41)	0.0024	
Result of type I IFN gene signature test					0.7209
LOW	65/ 86 (75.6)	57/ 90 (63.3)	1.19 (0.98, 1.44)	0.0872	
HIGH	250/373 (67.0)	205/378 (54.2)	1.24 (1.10, 1.39)	0.0004	
Age (years)					0.0371
<= 65	305/447 (68.2)	259/464 (55.8)	1.22 (1.11, 1.36)	0.0001	
> 65	10/ 12 (83.3)	3/ 4 (75.0)	0.87 (0.65, 1.18)	0.3771	
Sex					0.2117
male	21/ 33 (63.6)	22/ 34 (64.7)	0.98 (0.68, 1.41)	0.9220	
female	294/426 (69.0)	240/434 (55.3)	1.25 (1.12, 1.39)	<.0001	
Race					0.5245
White	188/270 (69.6)	167/285 (58.6)	1.19 (1.05, 1.35)	0.0068	
Black	39/ 65 (60.0)	31/ 60 (51.7)	1.12 (0.81, 1.56)	0.4964	
Other	83/116 (71.6)	60/115 (52.2)	1.34 (1.10, 1.65)	0.0042	
Ethnicity					0.9930
Hispanic/Latino	96/132 (72.7)	77/131 (58.8)	1.22 (1.02, 1.44)	0.0258	
Non-hispanic/Latino	214/319 (67.1)	181/329 (55.0)	1.22 (1.07, 1.38)	0.0020	
Geographic region					0.2222
EU	98/135 (72.6)	94/147 (63.9)	1.13 (0.96, 1.33)	0.1287	
non-EU	217/324 (67.0)	168/321 (52.3)	1.28 (1.13, 1.46)	0.0001	
Onset of disease					0.7038
Paediatric	19/ 36 (52.8)	14/ 35 (40.0)	1.35 (0.82, 2.22)	0.2417	
Adult	296/423 (70.0)	248/433 (57.3)	1.22 (1.10, 1.35)	0.0001	
ADA result					0.9332
Negative	298/427 (69.8)	247/429 (57.6)	1.22 (1.10, 1.35)	0.0002	
Positive (At any time)	17/ 31 (54.8)	15/ 39 (38.5)	1.24 (0.76, 2.03)	0.3821	
BMI (kg/m2)					0.5031
< 30	218/309 (70.6)	191/339 (56.3)	1.25 (1.11, 1.41)	0.0002	
>= 30	97/150 (64.7)	71/129 (55.0)	1.16 (0.96, 1.40)	0.1323	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Change from baseline in PGA VAS < 0.45 at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=459)	Placebo (N=468)
Week 52	Number of subjects with events, n (%)	318 (69.3)	269 (57.5)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.21 (1.10, 1.34)	
	p-value	0.0001	
	Odds Ratio (95% CI)	1.70 (1.29, 2.23)	
	p-value	0.0001	
	Risk Difference (95% CI)	12.09 (5.94, 18.23)	
	p-value	0.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.21 (1.09, 1.33)	
	p-value	0.0002	
	Odds Ratio (95% CI)	1.67 (1.27, 2.19)	
	p-value	0.0002	
	Risk Difference (95% CI)	11.82 (5.68, 17.97)	
	p-value	0.0002	
	p-Value for test for heterogenity between studies	0.6318	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Change from baseline in PGA VAS < 0.45 at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=468) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	 p-Value	Interaction p-Value
SLEDAI-2K score					0.2594
< 10 points	105/148 (70.9)	92/146 (63.0)	1.11 (0.95, 1.30)	0.1901	
>= 10 points	213/311 (68.5)	177/322 (55.0)	1.25 (1.10, 1.41)	0.0005	
OCS dose					0.7157
<10 mg/day	148/214 (69.2)	127/219 (58.0)	1.19 (1.03, 1.37)	0.0170	
>=10 mg/day	170/245 (69.4)	142/249 (57.0)	1.24 (1.08, 1.41)	0.0018	
Result of type I IFN gene signature test					0.7345
LOW	66/ 86 (76.7)	59/ 90 (65.6)	1.17 (0.97, 1.41)	0.0996	
HIGH	252/373 (67.6)	210/378 (55.6)	1.22 (1.09, 1.36)	0.0008	
Age (years)					0.0468
<= 65	308/447 (68.9)	266/464 (57.3)	1.20 (1.09, 1.33)	0.0003	
> 65	10/ 12 (83.3)	3/ 4 (75.0)	0.87 (0.65, 1.18)	0.3771	
Sex					0.2477
male	21/ 33 (63.6)	22/ 34 (64.7)	0.98 (0.68, 1.41)	0.9220	
female	297/426 (69.7)	247/434 (56.9)	1.23 (1.11, 1.36)	0.0001	
Race					0.4363
White	189/270 (70.0)	172/285 (60.4)	1.16 (1.03, 1.31)	0.0161	
Black	40/ 65 (61.5)	32/ 60 (53.3)	1.12 (0.81, 1.55)	0.4910	
Other	84/116 (72.4)	61/115 (53.0)	1.34 (1.10, 1.64)	0.0039	
Ethnicity					0.9570
Hispanic/Latino	97/132 (73.5)	79/131 (60.3)	1.20 (1.02, 1.42)	0.0319	
Non-hispanic/Latino	216/319 (67.7)	186/329 (56.5)	1.20 (1.06, 1.35)	0.0039	
Geographic region					0.2010
EU	98/135 (72.6)	96/147 (65.3)	1.11 (0.95, 1.30)	0.1940	
non-EU	220/324 (67.9)	173/321 (53.9)	1.26 (1.12, 1.43)	0.0002	
Onset of disease					0.8951
Paediatric	19/ 36 (52.8)	15/ 35 (42.9)	1.24 (0.77, 2.01)	0.3727	
Adult	299/423 (70.7)	254/433 (58.7)	1.20 (1.09, 1.33)	0.0003	
ADA result					0.9864
Negative	301/427 (70.5)	253/429 (59.0)	1.20 (1.09, 1.33)	0.0003	
Positive (At any time)	17/ 31 (54.8)	16/ 39 (41.0)	1.21 (0.74, 1.95)	0.4468	
BMI (kg/m2)					0.3053
< 30	219/309 (70.9)	193/339 (56.9)	1.24 (1.11, 1.40)	0.0002	
>= 30	99/150 (66.0)	76/129 (58.9)	1.11 (0.93, 1.33)	0.2514	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Major clinical response at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=459)	Placebo (N=468)
Week 52	Number of subjects with events, n (%)	96 (20.9)	56 (12.0)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.75 (1.30, 2.37)	
	p-value	0.0003	
	Odds Ratio (95% CI)	1.98 (1.37, 2.84)	
	p-value	0.0002	
	Risk Difference (95% CI)	9.03 (4.30, 13.75)	
	p-value	0.0002	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.72 (1.27, 2.33)	
	p-value	0.0005	
	Odds Ratio (95% CI)	1.93 (1.35, 2.78)	
	p-value	0.0004	
	Risk Difference (95% CI)	8.95 (4.21, 13.68)	
	p-value	0.0002	
	p-Value for test for heterogenity between studies	0.3219	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Major clinical response at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=468) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	 p-Value	Interaction p-Value
SLEDAI-2K score					0.8240
< 10 points	39/148 (26.4)	22/146 (15.1)	1.74 (1.09, 2.78)	0.0207	
>= 10 points	57/311 (18.3)	34/322 (10.6)	1.62 (1.08, 2.43)	0.0185	
OCS dose					0.4796
<10 mg/day	50/214 (23.4)	26/219 (11.9)	1.90 (1.23, 2.95)	0.0039	
>=10 mg/day	46/245 (18.8)	30/249 (12.0)	1.53 (1.00, 2.34)	0.0503	
Result of type I IFN gene signature test					0.2695
LOW	15/ 86 (17.4)	13/ 90 (14.4)	1.20 (0.60, 2.39)	0.6091	
HIGH	81/373 (21.7)	43/378 (11.4)	1.85 (1.31, 2.61)	0.0004	
Age (years)					0.2551
<= 65	95/447 (21.3)	55/464 (11.9)	1.77 (1.30, 2.40)	0.0003	
> 65	1/ 12 (8.3)	1/ 4 (25.0)	0.43 (0.04, 4.82)	0.4925	
Sex					0.5382
male	7/ 33 (21.2)	2/ 34 (5.9)	2.62 (0.61, 11.25)	0.1949	
female	89/426 (20.9)	54/434 (12.4)	1.64 (1.20, 2.24)	0.0019	
Race					0.9429
White	53/270 (19.6)	35/285 (12.3)	1.60 (1.08, 2.37)	0.0187	
Black	16/ 65 (24.6)	7/ 60 (11.7)	1.77 (0.80, 3.93)	0.1594	
Other	24/116 (20.7)	13/115 (11.3)	1.80 (0.95, 3.41)	0.0735	
Ethnicity					0.2847
Hispanic/Latino	26/132 (19.7)	21/131 (16.0)	1.35 (0.77, 2.38)	0.3004	
Non-hispanic/Latino	67/319 (21.0)	34/329 (10.3)	1.96 (1.34, 2.87)	0.0006	
Geographic region					0.9484
EU	34/135 (25.2)	22/147 (15.0)	1.72 (1.07, 2.77)	0.0262	
non-EU	62/324 (19.1)	34/321 (10.6)	1.75 (1.18, 2.60)	0.0054	
Onset of disease					0.8353
Paediatric	7/ 36 (19.4)	3/ 35 (8.6)	1.91 (0.56, 6.55)	0.3038	
Adult	89/423 (21.0)	53/433 (12.2)	1.67 (1.22, 2.28)	0.0014	
ADA result					0.5485
Negative	89/427 (20.8)	53/429 (12.4)	1.66 (1.21, 2.27)	0.0015	
Positive (At any time)	7/ 31 (22.6)	3/ 39 (7.7)	2.41 (0.75, 7.80)	0.1418	
BMI (kg/m2)					0.9093
< 30	70/309 (22.7)	44/339 (13.0)	1.73 (1.22, 2.44)	0.0020	
>= 30	26/150 (17.3)	12/129 (9.3)	1.80 (0.95, 3.42)	0.0713	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Partial clinical response at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=459)	Placebo (N=468)
Week 52	Number of subjects with events, n (%)	210 (45.8)	176 (37.6)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.23 (1.05, 1.43)	
	p-value	0.0093	
	Odds Ratio (95% CI)	1.42 (1.09, 1.85)	
	p-value	0.0091	
	Risk Difference (95% CI)	8.45 (2.15, 14.76)	
	p-value	0.0086	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.21 (1.04, 1.41)	
	p-value	0.0138	
	Odds Ratio (95% CI)	1.40 (1.08, 1.82)	
	p-value	0.0122	
	Risk Difference (95% CI)	8.13 (1.81, 14.46)	
	p-value	0.0117	
	p-Value for test for heterogenity between studies	0.5989	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Partial clinical response at week 52 - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=468) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.5929
< 10 points	75/148 (50.7)	65/146 (44.5)	1.14 (0.90, 1.45)	0.2840	
>= 10 points	135/311 (43.4)	111/322 (34.5)	1.24 (1.02, 1.51)	0.0315	
OCS dose					0.3902
<10 mg/day	98/214 (45.8)	88/219 (40.2)	1.13 (0.91, 1.41)	0.2666	
>=10 mg/day	112/245 (45.7)	88/249 (35.3)	1.30 (1.04, 1.61)	0.0193	
Result of type I IFN gene signature test					0.0584
LOW	37/ 86 (43.0)	43/ 90 (47.8)	0.91 (0.66, 1.27)	0.5891	
HIGH	173/373 (46.4)	133/378 (35.2)	1.31 (1.10, 1.55)	0.0028	
Age (years)					0.5309
<= 65	203/447 (45.4)	175/464 (37.7)	1.20 (1.03, 1.40)	0.0209	
> 65	7/ 12 (58.3)	1/ 4 (25.0)	1.89 (0.46, 7.82)	0.3774	
Sex					0.9689
male	18/ 33 (54.5)	15/ 34 (44.1)	1.22 (0.74, 2.02)	0.4355	
female	192/426 (45.1)	161/434 (37.1)	1.21 (1.03, 1.42)	0.0215	
Race					0.2376
White	113/270 (41.9)	110/285 (38.6)	1.07 (0.88, 1.31)	0.4969	
Black	26/ 65 (40.0)	16/ 60 (26.7)	1.23 (0.75, 2.02)	0.4064	
Other	66/116 (56.9)	45/115 (39.1)	1.44 (1.09, 1.90)	0.0096	
Ethnicity					0.1620
Hispanic/Latino	67/132 (50.8)	64/131 (48.9)	1.03 (0.81, 1.32)	0.7825	
Non-hispanic/Latino	138/319 (43.3)	107/329 (32.5)	1.30 (1.06, 1.58)	0.0106	
Geographic region					0.6388
EU	69/135 (51.1)	57/147 (38.8)	1.26 (0.98, 1.63)	0.0719	
non-EU	141/324 (43.5)	119/321 (37.1)	1.17 (0.97, 1.41)	0.1037	
Onset of disease					0.2797
Paediatric	15/ 36 (41.7)	8/ 35 (22.9)	1.79 (0.86, 3.75)	0.1205	
Adult	195/423 (46.1)	168/433 (38.8)	1.18 (1.01, 1.38)	0.0353	
ADA result					0.3208
Negative	199/427 (46.6)	169/429 (39.4)	1.18 (1.01, 1.38)	0.0391	
Positive (At any time)	11/ 31 (35.5)	7/ 39 (17.9)	1.91 (0.74, 4.90)	0.1784	
BMI (kg/m2)					0.1596
< 30	150/309 (48.5)	126/339 (37.2)	1.31 (1.09, 1.56)	0.0036	
>= 30	60/150 (40.0)	50/129 (38.8)	1.02 (0.76, 1.37)	0.8849	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
>=50% Joint reduction at week 52 (for subjects with at least 6 tender joints and at least 6 swollen joints at baseline)
Full analysis set

Timepoint		Anifrolumab 300mg (N=222)	Placebo (N=248)
Week 52	Number of subjects with events, n (%)	123 (55.4)	95 (38.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.45 (1.19, 1.78)	
	p-value	0.0002	
	Odds Ratio (95% CI)	2.07 (1.41, 3.03)	
	p-value	0.0002	
	Risk Difference (95% CI)	17.19 (8.33, 26.05)	
	p-value	0.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.45 (1.19, 1.77)	
	p-value	0.0002	
	Odds Ratio (95% CI)	1.96 (1.35, 2.85)	
	p-value	0.0004	
	Risk Difference (95% CI)	16.58 (7.67, 25.48)	
	p-value	0.0003	
	p-Value for test for heterogenity between studies	0.2283	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
>=50% Joint reduction at week 52 (for subjects with at least 6 tender joints and at least 6 swollen joints at baseline) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=222) n/ N (%)	Placebo (N=248) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.4162
< 10 points	42/ 72 (58.3)	33/ 73 (45.2)	1.28 (0.95, 1.73)	0.1006	
>= 10 points	81/150 (54.0)	62/175 (35.4)	1.51 (1.17, 1.95)	0.0015	
OCS dose					0.8976
<10 mg/day	54/101 (53.5)	40/111 (36.0)	1.48 (1.08, 2.02)	0.0140	
>=10 mg/day	69/121 (57.0)	55/137 (40.1)	1.44 (1.12, 1.85)	0.0049	
Result of type I IFN gene signature test					0.3860
LOW	30/ 51 (58.8)	18/ 51 (35.3)	1.72 (1.13, 2.61)	0.0114	
HIGH	93/171 (54.4)	77/197 (39.1)	1.39 (1.11, 1.74)	0.0043	
Age (years)					0.0392
<= 65	119/216 (55.1)	93/245 (38.0)	1.45 (1.19, 1.78)	0.0003	
> 65	4/ 6 (66.7)	2/ 3 (66.7)	0.78 (0.45, 1.36)	0.3854	
Sex					0.1311
male	4/ 13 (30.8)	7/ 12 (58.3)	0.67 (0.23, 1.92)	0.4520	
female	119/209 (56.9)	88/236 (37.3)	1.53 (1.25, 1.88)	<.0001	
Race					0.6664
White	72/136 (52.9)	65/163 (39.9)	1.34 (1.04, 1.72)	0.0219	
Black	15/ 34 (44.1)	8/ 30 (26.7)	1.68 (0.78, 3.60)	0.1813	
Other	33/ 48 (68.8)	21/ 52 (40.4)	1.60 (1.11, 2.30)	0.0115	
Ethnicity					0.9745
Hispanic/Latino	44/ 73 (60.3)	30/ 69 (43.5)	1.41 (1.04, 1.92)	0.0292	
Non-hispanic/Latino	76/145 (52.4)	64/176 (36.4)	1.42 (1.10, 1.84)	0.0080	
Geographic region					0.4453
EU	42/ 60 (70.0)	39/ 75 (52.0)	1.33 (1.01, 1.74)	0.0437	
non-EU	81/162 (50.0)	56/173 (32.4)	1.54 (1.18, 2.00)	0.0013	
Onset of disease					0.7887
Paediatric	7/ 13 (53.8)	6/ 16 (37.5)	1.30 (0.62, 2.74)	0.4883	
Adult	116/209 (55.5)	89/232 (38.4)	1.45 (1.18, 1.78)	0.0004	
ADA result					0.3643
Negative	116/206 (56.3)	92/232 (39.7)	1.43 (1.17, 1.75)	0.0005	
Positive (At any time)	7/ 15 (46.7)	3/ 16 (18.8)	2.48 (0.77, 8.04)	0.1297	
BMI (kg/m2)					0.7009
< 30	85/142 (59.9)	69/174 (39.7)	1.51 (1.20, 1.90)	0.0004	
>= 30	38/ 80 (47.5)	26/ 74 (35.1)	1.38 (0.94, 2.04)	0.1038	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
>=50% Joint reduction at week 52 (for subjects with at least 8 tender joints and at least 8 swollen joints at baseline)
Full analysis set

Timepoint		Anifrolumab 300mg (N=161)	Placebo (N=177)
Week 52	Number of subjects with events, n (%)	87 (54.0)	66 (37.3)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.48 (1.16, 1.89)	
	p-value	0.0014	
	Odds Ratio (95% CI)	2.21 (1.37, 3.57)	
	p-value	0.0012	
	Risk Difference (95% CI)	17.79 (7.31, 28.28)	
	p-value	0.0009	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.40 (1.10, 1.78)	
	p-value	0.0062	
	Odds Ratio (95% CI)	1.85 (1.18, 2.89)	
	p-value	0.0069	
	Risk Difference (95% CI)	14.75 (4.22, 25.27)	
	p-value	0.0060	
	p-Value for test for heterogenity between studies	0.4764	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
>=50% Joint reduction at week 52 (for subjects with at least 8 tender joints and at least 8 swollen joints at baseline) - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=161) n/ N (%)	Placebo (N=177) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	 p-Value	Interaction p-Value
SLEDAI-2K score					0.2355
< 10 points	32/ 53 (60.4)	27/ 55 (49.1)	1.18 (0.86, 1.62)	0.3038	
>= 10 points	55/108 (50.9)	39/122 (32.0)	1.56 (1.11, 2.18)	0.0095	
OCS dose					0.7971
<10 mg/day	38/ 72 (52.8)	26/ 75 (34.7)	1.47 (0.99, 2.18)	0.0537	
>=10 mg/day	49/ 89 (55.1)	40/102 (39.2)	1.38 (1.02, 1.87)	0.0378	
Result of type I IFN gene signature test					0.8368
LOW	24/ 44 (54.5)	13/ 37 (35.1)	1.47 (0.93, 2.32)	0.1010	
HIGH	63/117 (53.8)	53/140 (37.9)	1.39 (1.04, 1.84)	0.0238	
Age (years)					0.2499
<= 65	85/157 (54.1)	65/175 (37.1)	1.40 (1.10, 1.79)	0.0063	
> 65	2/ 4 (50.0)	1/ 2 (50.0)	0.67 (0.20, 2.30)	0.5274	
Sex					0.1642
male	3/ 11 (27.3)	4/ 6 (66.7)	0.64 (0.20, 2.04)	0.4486	
female	84/150 (56.0)	62/171 (36.3)	1.48 (1.16, 1.89)	0.0015	
Race					0.8752
White	53/101 (52.5)	43/111 (38.7)	1.33 (0.97, 1.82)	0.0739	
Black	12/ 27 (44.4)	6/ 23 (26.1)	1.66 (0.68, 4.06)	0.2675	
Other	21/ 32 (65.6)	17/ 42 (40.5)	1.45 (0.97, 2.17)	0.0736	
Ethnicity					0.5482
Hispanic/Latino	32/ 56 (57.1)	25/ 55 (45.5)	1.28 (0.91, 1.80)	0.1623	
Non-hispanic/Latino	54/104 (51.9)	41/121 (33.9)	1.48 (1.06, 2.07)	0.0226	
Geographic region					0.8065
EU	27/ 36 (75.0)	23/ 45 (51.1)	1.49 (1.04, 2.12)	0.0289	
non-EU	60/125 (48.0)	43/132 (32.6)	1.40 (1.04, 1.88)	0.0246	
Onset of disease					0.4218
Paediatric	3/ 8 (37.5)	6/ 15 (40.0)	0.94 (0.35, 2.51)	0.9057	
Adult	84/153 (54.9)	60/162 (37.0)	1.43 (1.11, 1.83)	0.0056	
ADA result					0.3667
Negative	83/149 (55.7)	63/163 (38.7)	1.39 (1.09, 1.77)	0.0074	
Positive (At any time)	4/ 11 (36.4)	3/ 14 (21.4)	2.44 (0.74, 8.07)	0.1432	
BMI (kg/m2)					0.7425
< 30	57/ 98 (58.2)	47/125 (37.6)	1.46 (1.10, 1.94)	0.0097	
>= 30	30/ 63 (47.6)	19/ 52 (36.5)	1.34 (0.86, 2.07)	0.1930	

Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SRI (5) response rate at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=459)	Placebo (N=467)
Week 52	Number of subjects with events, n (%)	202 (44.0)	139 (29.8)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.50 (1.26, 1.78)	
	p-value	<.0001	
	Odds Ratio (95% CI)	1.91 (1.45, 2.51)	
	p-value	<.0001	
	Risk Difference (95% CI)	14.72 (8.60, 20.84)	
	p-value	<.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.48 (1.24, 1.76)	
	p-value	<.0001	
	Odds Ratio (95% CI)	1.85 (1.41, 2.43)	
	p-value	<.0001	
	Risk Difference (95% CI)	14.25 (8.10, 20.41)	
	p-value	<.0001	
	p-Value for test for heterogenity between studies	0.4918	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SRI (6) response rate at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=459)	Placebo (N=467)
Week 52	Number of subjects with events, n (%)	199 (43.4)	135 (28.9)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.52 (1.27, 1.81)	
	p-value	<.0001	
	Odds Ratio (95% CI)	1.93 (1.47, 2.54)	
	p-value	<.0001	
	Risk Difference (95% CI)	14.89 (8.79, 21.00)	
	p-value	<.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.50 (1.25, 1.79)	
	p-value	<.0001	
	Odds Ratio (95% CI)	1.88 (1.43, 2.47)	
	p-value	<.0001	
	Risk Difference (95% CI)	14.46 (8.33, 20.59)	
	p-value	<.0001	
	p-Value for test for heterogenity between studies	0.2618	

Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
SRI (7) response rate at week 52
Full analysis set

Timepoint		Anifrolumab 300mg (N=439)	Placebo (N=447)
Week 52	Number of subjects with events, n (%)	141 (32.1)	81 (18.1)
	Analysis Anifrolumab 300mg vs. Placebo (stratified)		
	Relative Risk (95% CI)	1.79 (1.40, 2.28)	
	p-value	<.0001	
	Odds Ratio (95% CI)	2.16 (1.58, 2.97)	
	p-value	<.0001	
	Risk Difference (95% CI)	14.17 (8.52, 19.82)	
	p-value	<.0001	
	Analysis Anifrolumab 300mg vs. Placebo (unstratified)		
	Relative Risk (95% CI)	1.77 (1.39, 2.25)	
	p-value	<.0001	
	Odds Ratio (95% CI)	2.14 (1.56, 2.92)	
	p-value	<.0001	
	Risk Difference (95% CI)	13.99 (8.35, 19.63)	
	p-value	<.0001	
	p-Value for test for heterogenity between studies	0.7432	

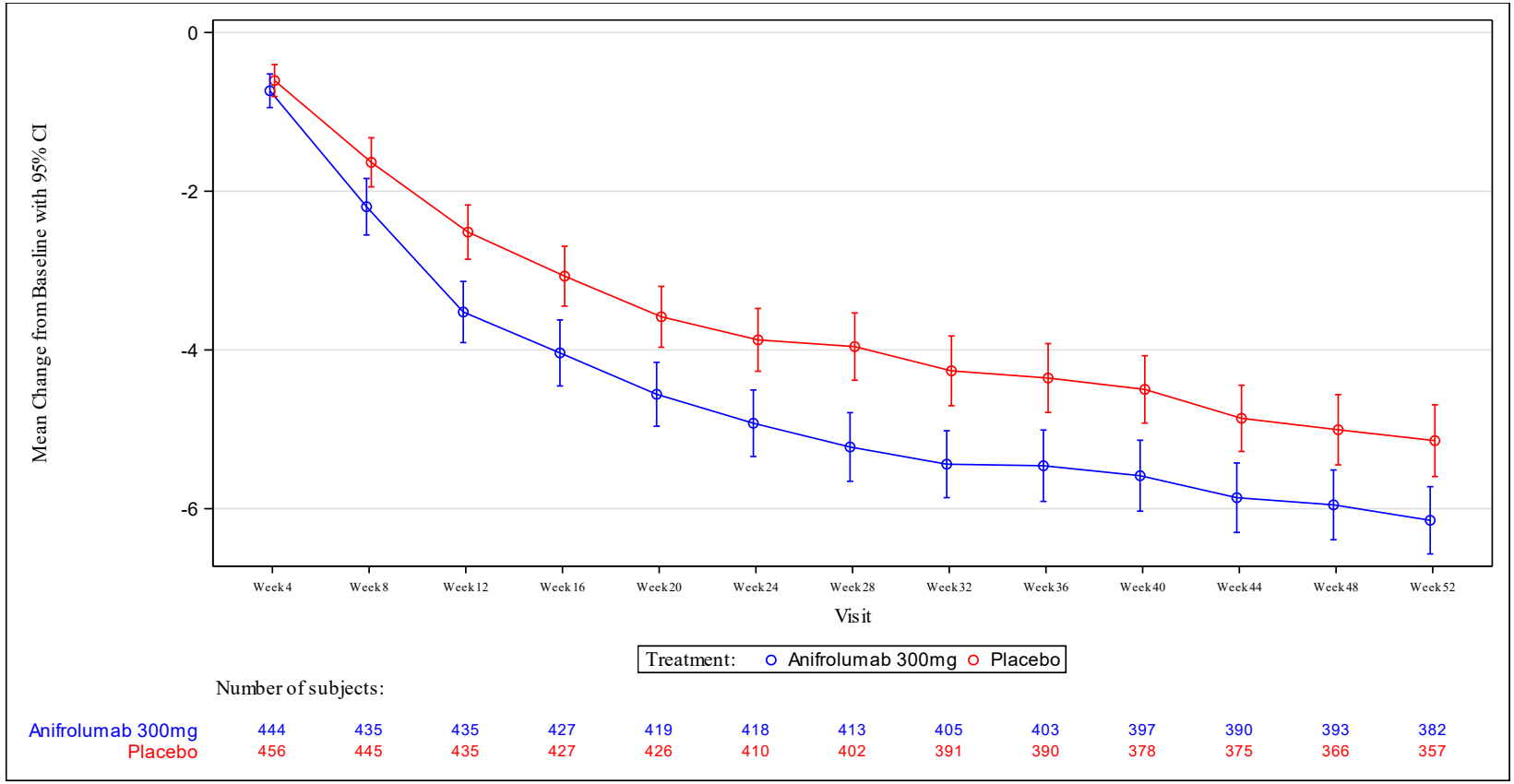
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unstratified analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - SLEDAI-2K Total Score
Full analysis set

	Anifrolumab 300mg (N=459)				Placebo (N=468)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	459	11.25 (3.85)	0	-	468	11.43 (3.87)	0	-
Week 4	444	10.56 (3.58)	444	-0.73 (2.27)	456	10.77 (3.87)	456	-0.61 (2.19)
Week 8	435	9.14 (4.19)	435	-2.20 (3.78)	445	9.82 (4.30)	445	-1.64 (3.32)
Week 12	435	7.75 (4.10)	435	-3.52 (4.09)	435	8.88 (4.35)	435	-2.51 (3.63)
Week 16	427	7.19 (4.45)	427	-4.04 (4.37)	427	8.31 (4.60)	427	-3.07 (3.96)
Week 20	419	6.62 (4.17)	419	-4.56 (4.19)	426	7.75 (4.39)	426	-3.58 (4.03)
Week 24	418	6.37 (4.17)	418	-4.92 (4.36)	410	7.42 (4.34)	410	-3.87 (4.08)
Week 28	413	6.09 (4.19)	413	-5.22 (4.47)	402	7.31 (4.51)	402	-3.96 (4.32)
Week 32	405	5.85 (4.08)	405	-5.44 (4.32)	391	7.05 (4.63)	391	-4.26 (4.42)
Week 36	403	5.84 (4.31)	403	-5.46 (4.59)	390	6.88 (4.56)	390	-4.35 (4.36)
Week 40	397	5.58 (4.03)	397	-5.58 (4.53)	378	6.64 (4.35)	378	-4.50 (4.20)
Week 44	390	5.33 (3.95)	390	-5.86 (4.40)	375	6.19 (4.05)	375	-4.86 (4.11)
Week 48	393	5.23 (3.92)	393	-5.95 (4.43)	366	6.13 (4.06)	366	-5.01 (4.30)
Week 52	382	5.02 (3.68)	382	-6.15 (4.21)	357	5.95 (4.04)	357	-5.14 (4.34)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - SLEDAI-2K Total Score
Full analysis set



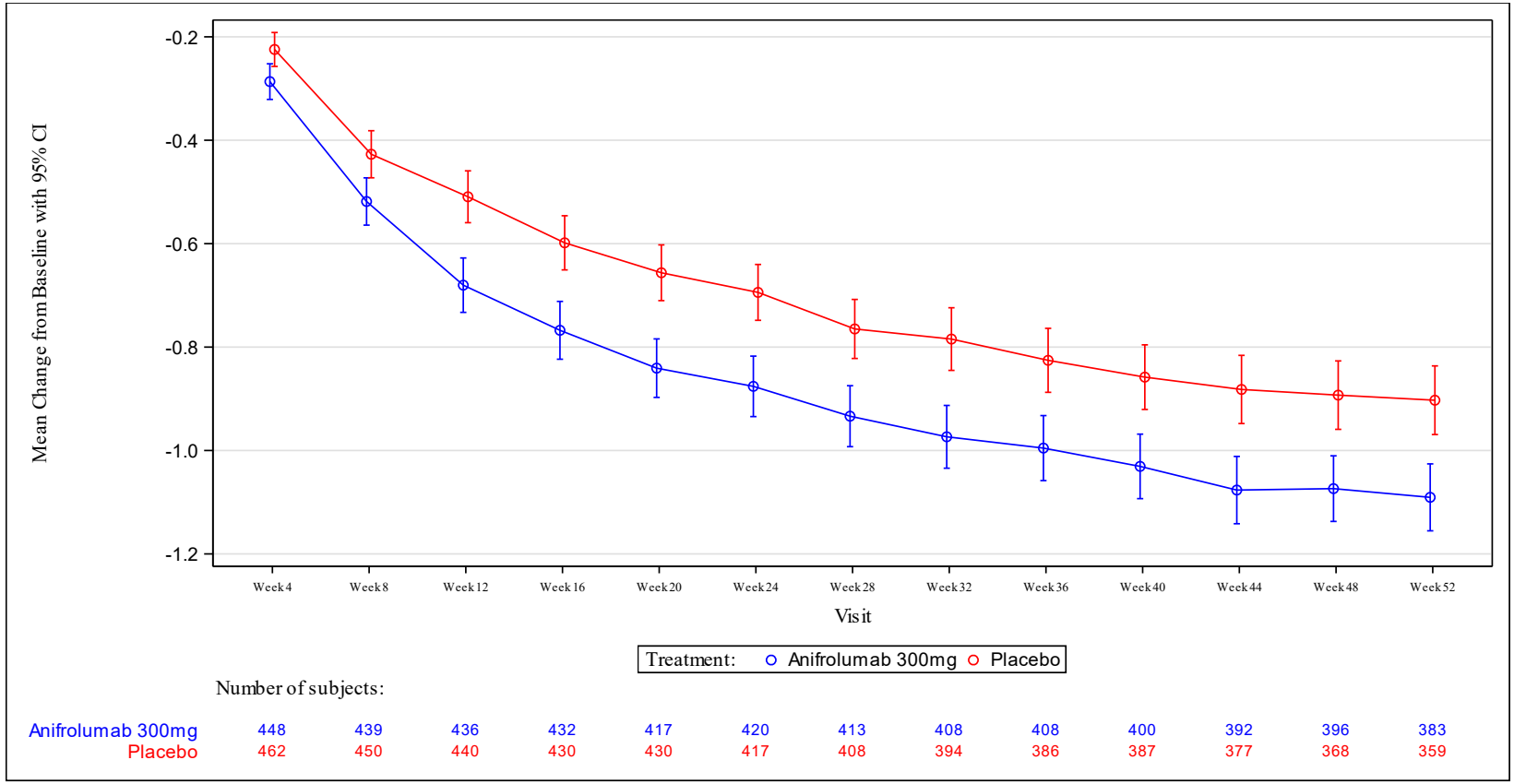
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - PGA
Full analysis set

	Anifrolumab 300mg (N=459)				Placebo (N=468)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	459	1.79 (0.41)	0	-	468	1.79 (0.40)	0	-
Week 4	448	1.51 (0.51)	448	-0.29 (0.37)	462	1.57 (0.47)	462	-0.22 (0.36)
Week 8	439	1.27 (0.53)	439	-0.52 (0.49)	450	1.37 (0.54)	450	-0.43 (0.49)
Week 12	436	1.11 (0.57)	436	-0.68 (0.56)	440	1.29 (0.55)	440	-0.51 (0.54)
Week 16	432	1.02 (0.59)	432	-0.77 (0.59)	430	1.19 (0.56)	430	-0.60 (0.55)
Week 20	417	0.94 (0.58)	417	-0.84 (0.59)	430	1.14 (0.58)	430	-0.66 (0.57)
Week 24	420	0.91 (0.60)	420	-0.88 (0.61)	417	1.09 (0.56)	417	-0.69 (0.56)
Week 28	413	0.86 (0.60)	413	-0.93 (0.61)	408	1.03 (0.59)	408	-0.76 (0.59)
Week 32	408	0.82 (0.57)	408	-0.97 (0.62)	394	1.01 (0.60)	394	-0.78 (0.61)
Week 36	408	0.80 (0.59)	408	-1.00 (0.65)	386	0.96 (0.60)	386	-0.83 (0.62)
Week 40	400	0.76 (0.58)	400	-1.03 (0.63)	387	0.92 (0.58)	387	-0.86 (0.63)
Week 44	392	0.70 (0.57)	392	-1.08 (0.66)	377	0.90 (0.60)	377	-0.88 (0.65)
Week 48	396	0.71 (0.57)	396	-1.07 (0.64)	368	0.89 (0.59)	368	-0.89 (0.65)
Week 52	383	0.68 (0.58)	383	-1.09 (0.64)	359	0.87 (0.60)	359	-0.90 (0.64)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - PGA
Full analysis set



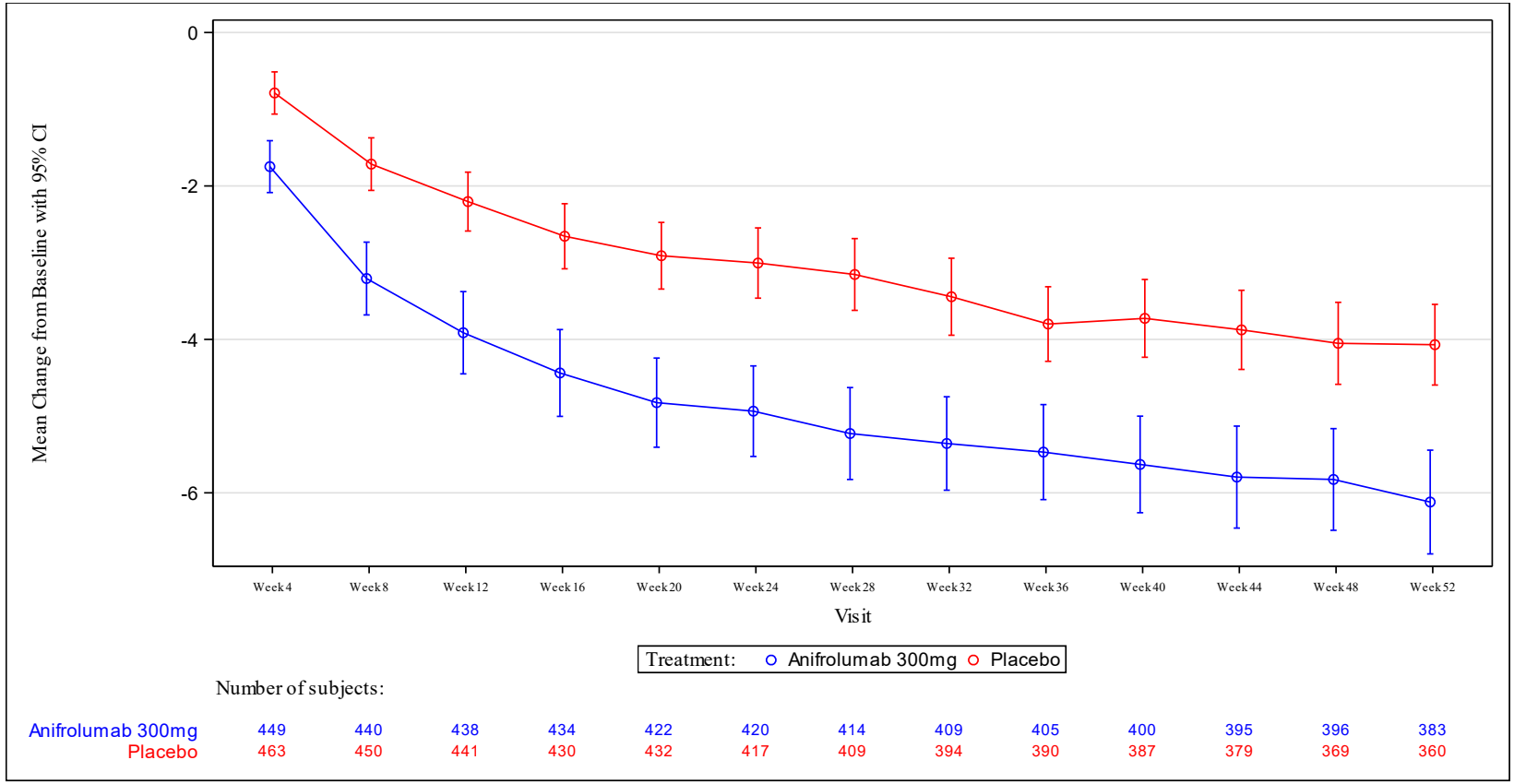
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - CLASI Total Activity Score
Full analysis set

	Anifrolumab 300mg (N=459)				Placebo (N=468)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	459	8.22 (7.34)	0	-	468	7.58 (6.82)	0	-
Week 4	449	6.54 (5.98)	449	-1.75 (3.64)	463	6.76 (6.57)	463	-0.79 (3.01)
Week 8	440	5.09 (4.91)	440	-3.21 (5.06)	450	5.96 (6.49)	450	-1.72 (3.70)
Week 12	438	4.36 (4.44)	438	-3.91 (5.71)	441	5.41 (6.12)	441	-2.20 (4.10)
Week 16	434	3.90 (4.27)	434	-4.44 (6.00)	430	4.95 (5.84)	430	-2.66 (4.48)
Week 20	422	3.50 (4.09)	422	-4.82 (6.07)	432	4.86 (6.05)	432	-2.91 (4.59)
Week 24	420	3.36 (4.22)	420	-4.94 (6.15)	417	4.78 (6.20)	417	-3.00 (4.76)
Week 28	414	3.11 (3.82)	414	-5.23 (6.20)	409	4.58 (6.00)	409	-3.15 (4.81)
Week 32	409	2.88 (3.70)	409	-5.36 (6.26)	394	4.32 (5.81)	394	-3.44 (5.07)
Week 36	405	2.76 (3.63)	405	-5.47 (6.34)	390	4.01 (5.41)	390	-3.80 (4.88)
Week 40	400	2.53 (3.44)	400	-5.63 (6.40)	387	3.97 (5.53)	387	-3.73 (5.07)
Week 44	395	2.60 (3.85)	395	-5.79 (6.72)	379	3.87 (5.51)	379	-3.88 (5.11)
Week 48	396	2.40 (3.32)	396	-5.83 (6.71)	369	3.75 (5.21)	369	-4.05 (5.22)
Week 52	383	2.38 (3.67)	383	-6.12 (6.73)	360	3.67 (5.26)	360	-4.07 (5.07)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - CLASI Total Activity Score
Full analysis set



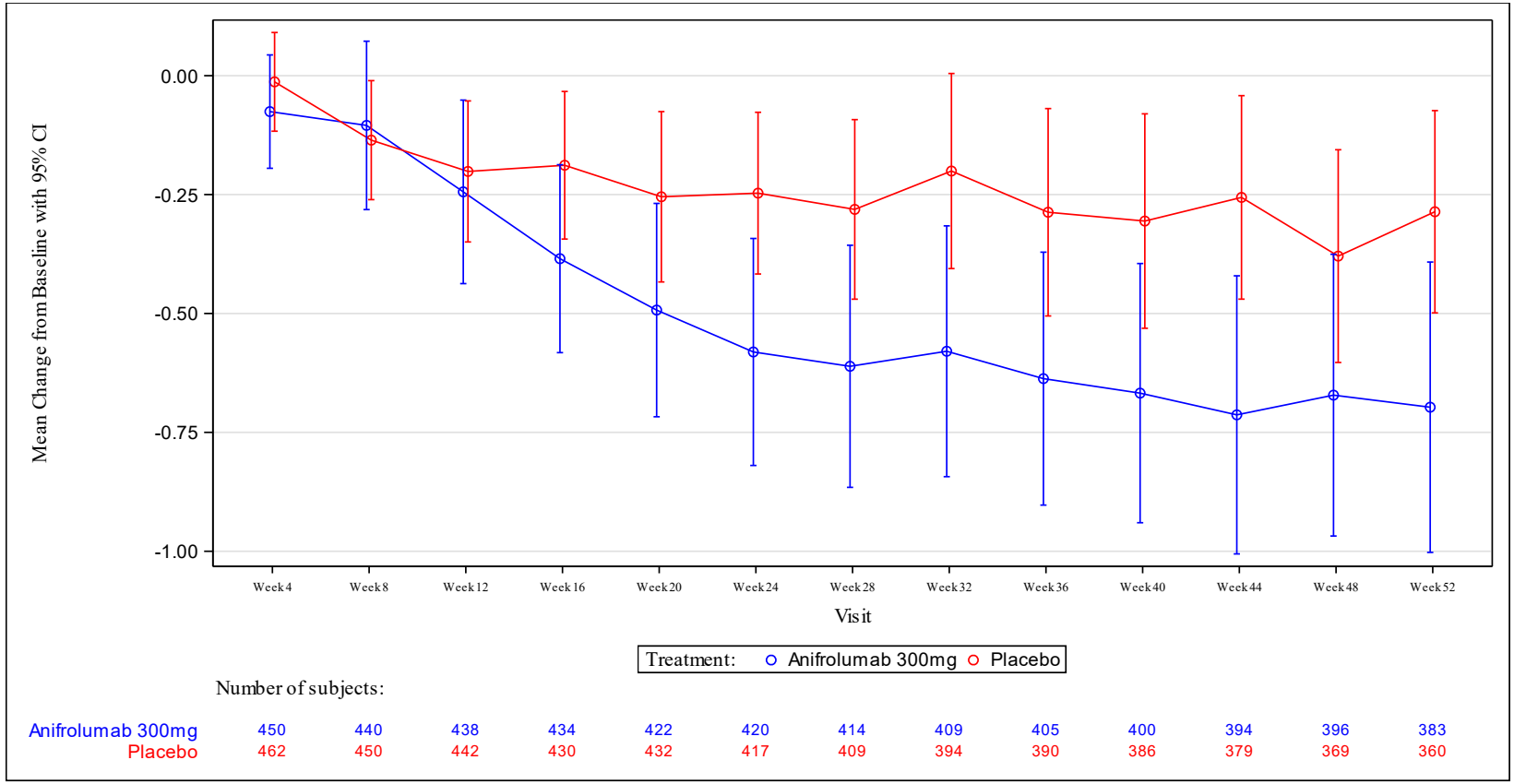
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - CLASI Total Damage Score
Full analysis set

	Anifrolumab 300mg (N=459)				Placebo (N=468)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	459	2.14 (4.78)	0	-	468	2.02 (4.75)	0	-
Week 4	450	2.08 (4.66)	450	-0.08 (1.29)	462	2.00 (4.86)	462	-0.01 (1.14)
Week 8	440	2.05 (4.62)	440	-0.10 (1.89)	450	1.93 (4.74)	450	-0.14 (1.35)
Week 12	438	1.92 (4.54)	438	-0.24 (2.05)	442	1.84 (4.58)	442	-0.20 (1.59)
Week 16	434	1.82 (4.31)	434	-0.38 (2.09)	430	1.82 (4.50)	430	-0.19 (1.64)
Week 20	422	1.69 (3.98)	422	-0.49 (2.34)	432	1.82 (4.60)	432	-0.25 (1.89)
Week 24	420	1.57 (3.85)	420	-0.58 (2.49)	417	1.86 (4.57)	417	-0.25 (1.77)
Week 28	414	1.57 (3.92)	414	-0.61 (2.63)	409	1.80 (4.54)	409	-0.28 (1.94)
Week 32	409	1.56 (3.93)	409	-0.58 (2.71)	394	1.78 (4.48)	394	-0.20 (2.07)
Week 36	405	1.52 (3.89)	405	-0.64 (2.72)	390	1.73 (4.37)	390	-0.29 (2.19)
Week 40	400	1.42 (3.70)	400	-0.67 (2.77)	386	1.59 (4.25)	386	-0.31 (2.25)
Week 44	394	1.56 (4.10)	394	-0.71 (2.95)	379	1.63 (4.31)	379	-0.26 (2.12)
Week 48	396	1.50 (3.91)	396	-0.67 (3.00)	369	1.60 (4.29)	369	-0.38 (2.18)
Week 52	383	1.63 (4.30)	383	-0.70 (3.04)	360	1.62 (4.42)	360	-0.29 (2.05)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - CLASI Total Damage Score
Full analysis set



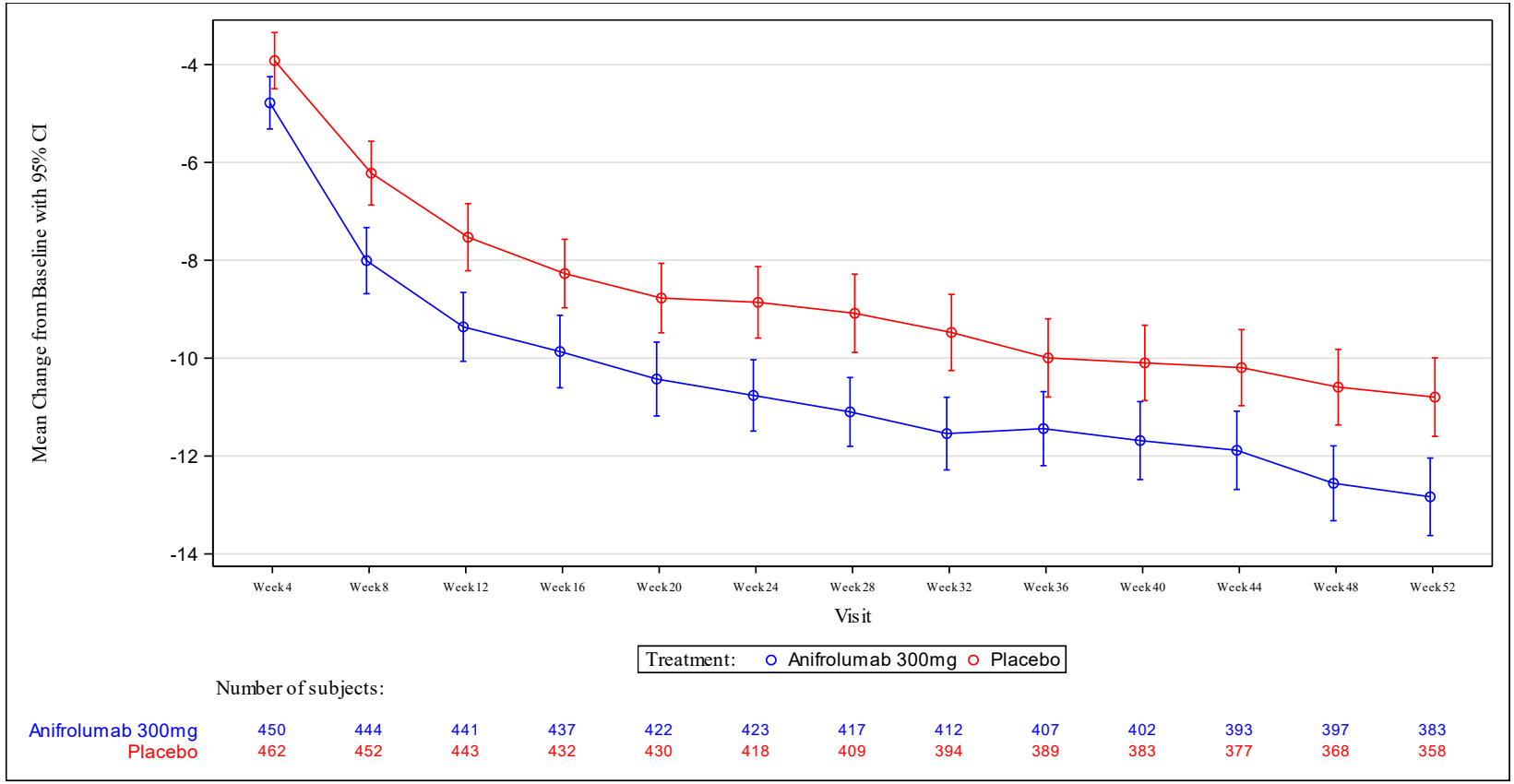
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - BILAG Global Score
Full analysis set

	Anifrolumab 300mg (N=459)				Placebo (N=468)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	459	19.31 (5.61)	0	-	468	19.14 (5.35)	0	-
Week 4	450	14.54 (6.95)	450	-4.78 (5.77)	462	15.19 (6.74)	462	-3.92 (6.29)
Week 8	444	11.23 (7.19)	444	-8.01 (7.25)	452	12.93 (7.39)	452	-6.22 (7.05)
Week 12	441	9.85 (7.33)	441	-9.36 (7.52)	443	11.62 (7.15)	443	-7.53 (7.35)
Week 16	437	9.38 (7.81)	437	-9.86 (7.88)	432	10.92 (7.38)	432	-8.27 (7.40)
Week 20	422	8.82 (7.48)	422	-10.43 (7.89)	430	10.32 (7.36)	430	-8.77 (7.48)
Week 24	423	8.55 (7.52)	423	-10.76 (7.63)	418	10.26 (7.34)	418	-8.86 (7.60)
Week 28	417	8.15 (7.13)	417	-11.10 (7.30)	409	10.01 (7.97)	409	-9.08 (8.23)
Week 32	412	7.69 (7.16)	412	-11.54 (7.67)	394	9.69 (7.54)	394	-9.47 (7.86)
Week 36	407	7.89 (7.29)	407	-11.44 (7.76)	389	9.04 (7.38)	389	-9.99 (8.02)
Week 40	402	7.51 (7.33)	402	-11.68 (8.12)	383	9.02 (7.20)	383	-10.10 (7.67)
Week 44	393	7.29 (7.04)	393	-11.88 (8.06)	377	8.82 (6.92)	377	-10.19 (7.67)
Week 48	397	6.74 (6.72)	397	-12.56 (7.74)	368	8.40 (6.80)	368	-10.59 (7.55)
Week 52	383	6.44 (6.88)	383	-12.83 (7.88)	358	8.21 (6.81)	358	-10.80 (7.71)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - BILAG Global Score
Full analysis set



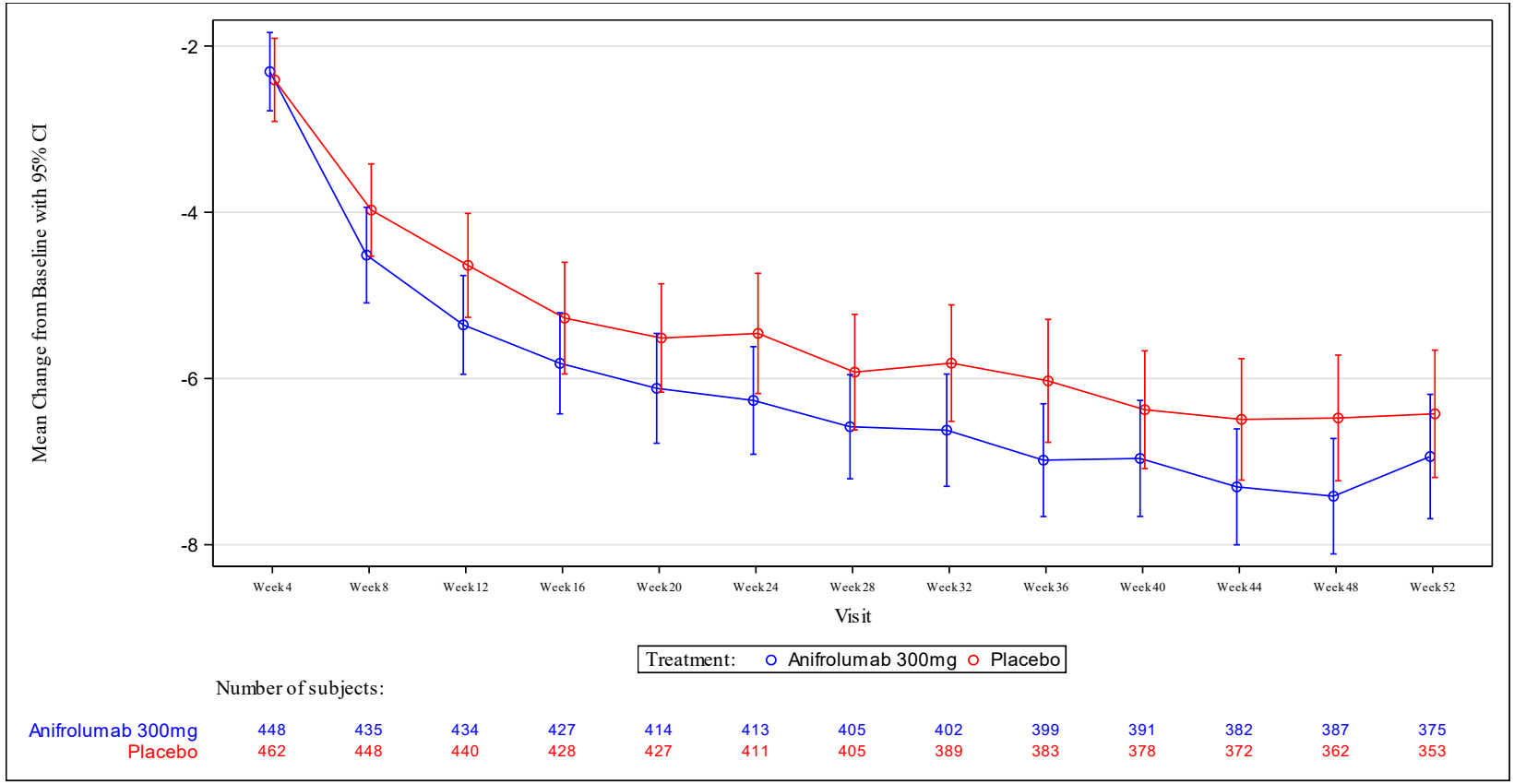
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - Tender Joint Count
Full analysis set

	Anifrolumab 300mg (N=459)				Placebo (N=468)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	459	10.72 (7.38)	0	-	468	10.72 (7.50)	0	-
Week 4	449	8.36 (7.64)	448	-2.31 (5.07)	462	8.28 (7.70)	462	-2.41 (5.47)
Week 8	439	6.10 (6.88)	435	-4.51 (6.10)	450	6.72 (7.13)	448	-3.97 (5.98)
Week 12	439	5.26 (6.76)	434	-5.35 (6.30)	442	6.02 (7.26)	440	-4.64 (6.68)
Week 16	433	4.78 (6.84)	427	-5.82 (6.39)	431	5.28 (6.88)	428	-5.27 (7.07)
Week 20	421	4.48 (6.86)	414	-6.12 (6.84)	431	5.09 (6.77)	427	-5.51 (6.86)
Week 24	420	4.44 (6.77)	413	-6.26 (6.69)	416	4.95 (7.01)	411	-5.46 (7.46)
Week 28	413	4.06 (6.50)	405	-6.58 (6.41)	409	4.57 (6.67)	405	-5.92 (7.12)
Week 32	410	3.95 (6.33)	402	-6.62 (6.89)	394	4.70 (6.97)	389	-5.81 (7.03)
Week 36	406	3.71 (6.11)	399	-6.98 (6.89)	390	4.41 (6.88)	383	-6.03 (7.36)
Week 40	401	3.56 (6.10)	391	-6.96 (7.02)	386	4.03 (6.33)	378	-6.38 (7.01)
Week 44	393	3.13 (5.47)	382	-7.30 (6.93)	379	3.83 (6.30)	372	-6.49 (7.16)
Week 48	395	3.35 (5.80)	387	-7.42 (6.95)	369	3.88 (6.29)	362	-6.48 (7.31)
Week 52	382	3.59 (6.26)	375	-6.94 (7.37)	360	3.93 (6.35)	353	-6.42 (7.32)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - Tender Joint Count
Full analysis set



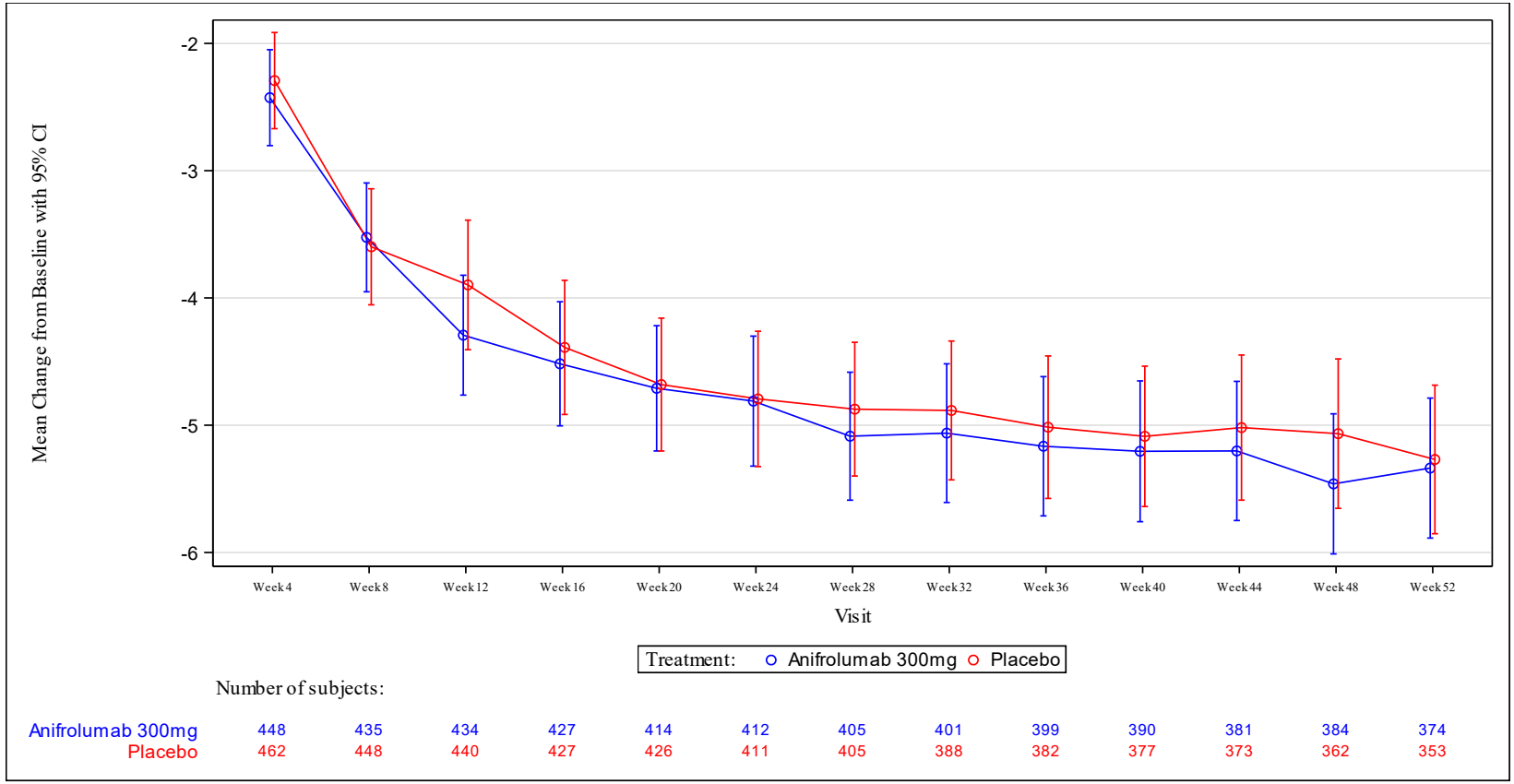
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - Swollen Joint Count
Full analysis set

	Anifrolumab 300mg (N=459)				Placebo (N=468)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	459	7.18 (5.85)	0	-	468	7.44 (5.88)	0	-
Week 4	449	4.69 (5.32)	448	-2.43 (4.06)	462	5.09 (5.56)	462	-2.29 (4.13)
Week 8	439	3.48 (4.90)	435	-3.52 (4.54)	450	3.74 (4.95)	448	-3.60 (4.91)
Week 12	439	2.79 (4.49)	434	-4.29 (4.99)	442	3.43 (4.94)	440	-3.90 (5.43)
Week 16	433	2.55 (4.40)	427	-4.52 (5.13)	431	2.89 (4.54)	427	-4.39 (5.54)
Week 20	421	2.26 (4.40)	414	-4.71 (5.09)	431	2.70 (4.56)	426	-4.68 (5.48)
Week 24	420	2.30 (4.47)	412	-4.81 (5.27)	416	2.45 (4.24)	411	-4.79 (5.48)
Week 28	413	2.01 (4.13)	405	-5.09 (5.15)	409	2.54 (4.57)	405	-4.87 (5.38)
Week 32	410	1.90 (3.90)	401	-5.06 (5.55)	394	2.48 (4.49)	388	-4.88 (5.46)
Week 36	406	1.97 (4.18)	399	-5.17 (5.56)	390	2.24 (4.29)	382	-5.02 (5.56)
Week 40	401	1.78 (4.14)	390	-5.21 (5.56)	386	2.09 (3.93)	377	-5.09 (5.44)
Week 44	393	1.69 (4.04)	381	-5.20 (5.43)	379	2.14 (4.27)	373	-5.02 (5.60)
Week 48	395	1.71 (4.03)	384	-5.46 (5.49)	369	2.12 (4.32)	362	-5.07 (5.68)
Week 52	382	1.63 (3.71)	374	-5.34 (5.41)	360	1.95 (3.95)	353	-5.27 (5.58)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - Swollen Joint Count
Full analysis set



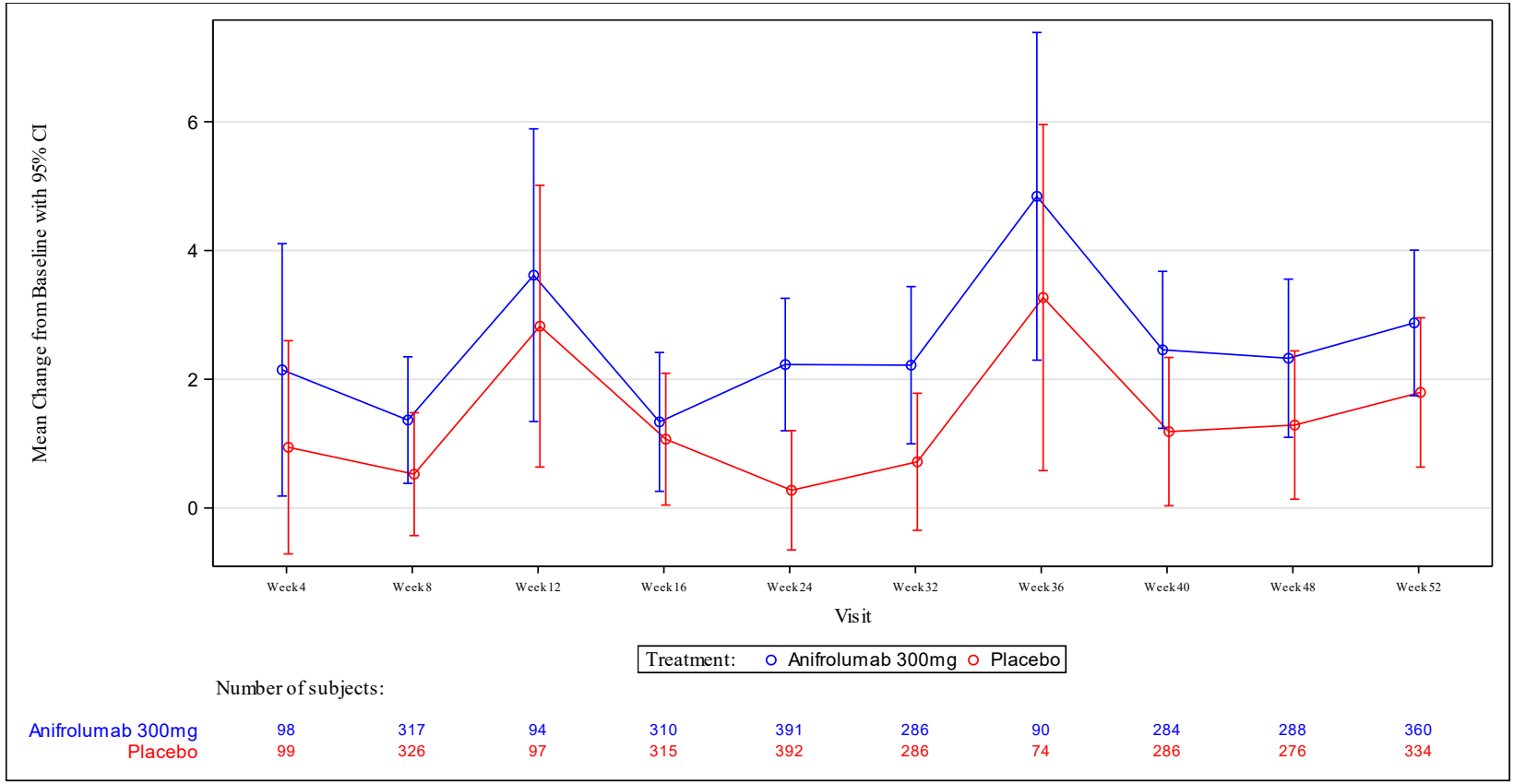
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Mental Component Score
Full analysis set

	Anifrolumab 300mg (N=459)				Placebo (N=468)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	444	42.58 (11.96)	0	-	450	42.63 (11.68)	0	-
Week 4	98	39.65 (11.68)	98	2.15 (9.78)	99	39.18 (11.64)	99	0.94 (8.30)
Week 8	326	45.57 (11.34)	317	1.37 (8.89)	338	44.54 (11.06)	326	0.53 (8.76)
Week 12	94	41.24 (12.49)	94	3.62 (11.10)	97	40.83 (12.30)	97	2.82 (10.85)
Week 16	321	45.49 (11.30)	310	1.34 (9.65)	327	45.11 (10.79)	315	1.07 (9.23)
Week 24	404	44.52 (11.99)	391	2.23 (10.34)	407	43.24 (11.41)	392	0.28 (9.34)
Week 32	298	45.99 (11.42)	286	2.22 (10.49)	296	44.71 (11.00)	286	0.72 (9.15)
Week 36	90	42.86 (11.62)	90	4.84 (12.15)	74	42.63 (12.17)	74	3.27 (11.60)
Week 40	296	46.17 (11.34)	284	2.46 (10.44)	297	45.28 (11.15)	286	1.19 (9.90)
Week 48	300	45.99 (11.23)	288	2.33 (10.60)	283	45.20 (10.59)	276	1.29 (9.72)
Week 52	373	45.17 (11.55)	360	2.88 (10.91)	343	44.91 (11.46)	334	1.79 (10.77)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Mental Component Score
Full analysis set



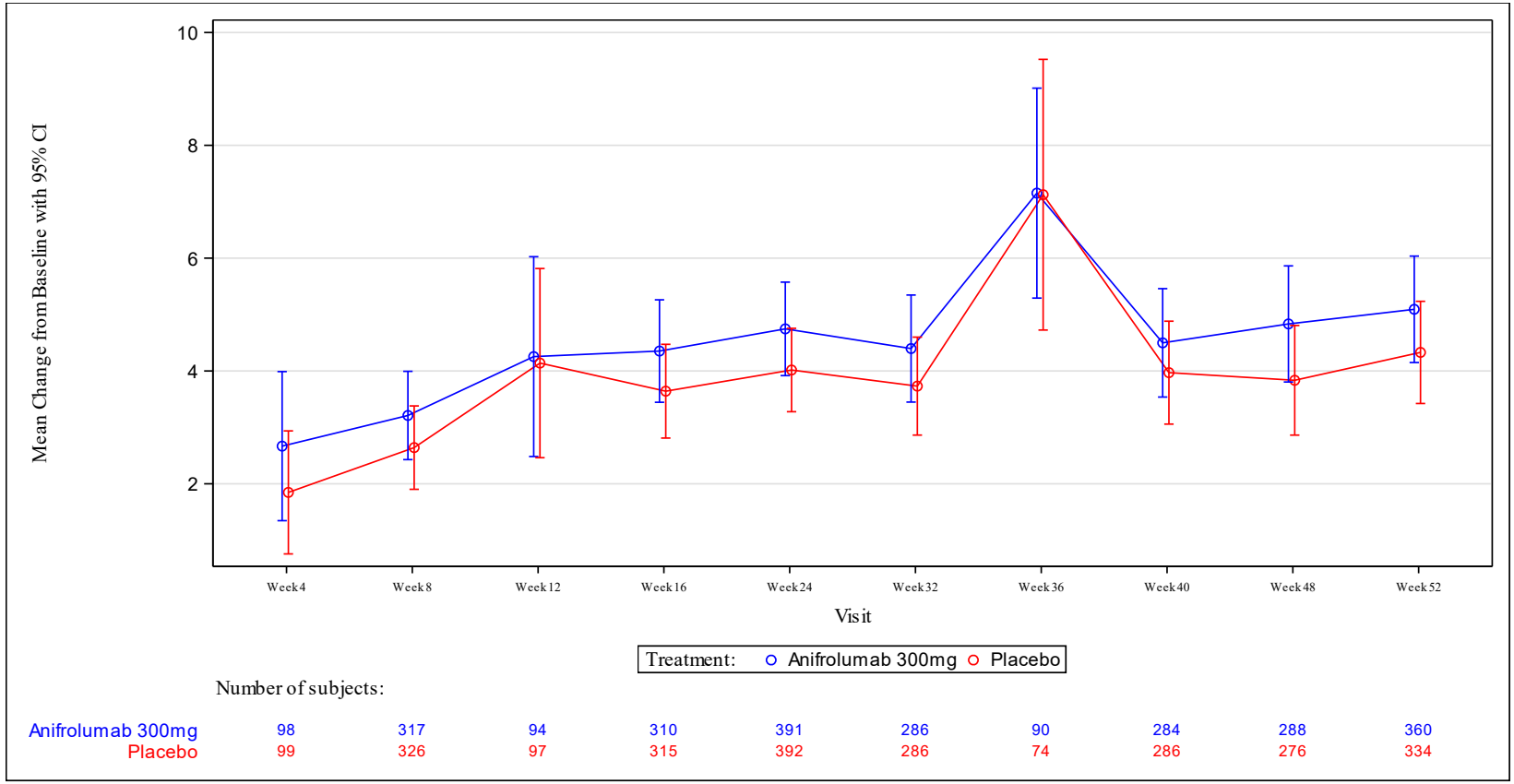
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Physical Component Score
Full analysis set

	Anifrolumab 300mg (N=459)				Placebo (N=468)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	444	36.86 (9.27)	0	-	450	37.00 (9.64)	0	-
Week 4	98	37.67 (8.32)	98	2.67 (6.59)	99	37.01 (9.99)	99	1.85 (5.47)
Week 8	326	41.03 (9.07)	317	3.21 (7.08)	338	40.28 (8.84)	326	2.64 (6.78)
Week 12	94	39.47 (9.46)	94	4.25 (8.65)	97	39.20 (11.15)	97	4.14 (8.32)
Week 16	321	42.04 (9.56)	310	4.35 (8.13)	327	41.13 (9.24)	315	3.64 (7.50)
Week 24	404	41.94 (9.71)	391	4.75 (8.33)	407	41.33 (9.37)	392	4.02 (7.44)
Week 32	298	42.23 (9.43)	286	4.40 (8.15)	296	41.51 (8.63)	286	3.73 (7.46)
Week 36	90	42.24 (10.56)	90	7.15 (8.88)	74	43.21 (11.27)	74	7.12 (10.36)
Week 40	296	42.69 (9.83)	284	4.50 (8.23)	297	41.53 (9.17)	286	3.97 (7.84)
Week 48	300	42.89 (9.90)	288	4.83 (8.87)	283	41.63 (9.47)	276	3.83 (8.20)
Week 52	373	42.46 (10.00)	360	5.09 (9.10)	343	42.04 (9.44)	334	4.33 (8.41)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Physical Component Score
Full analysis set



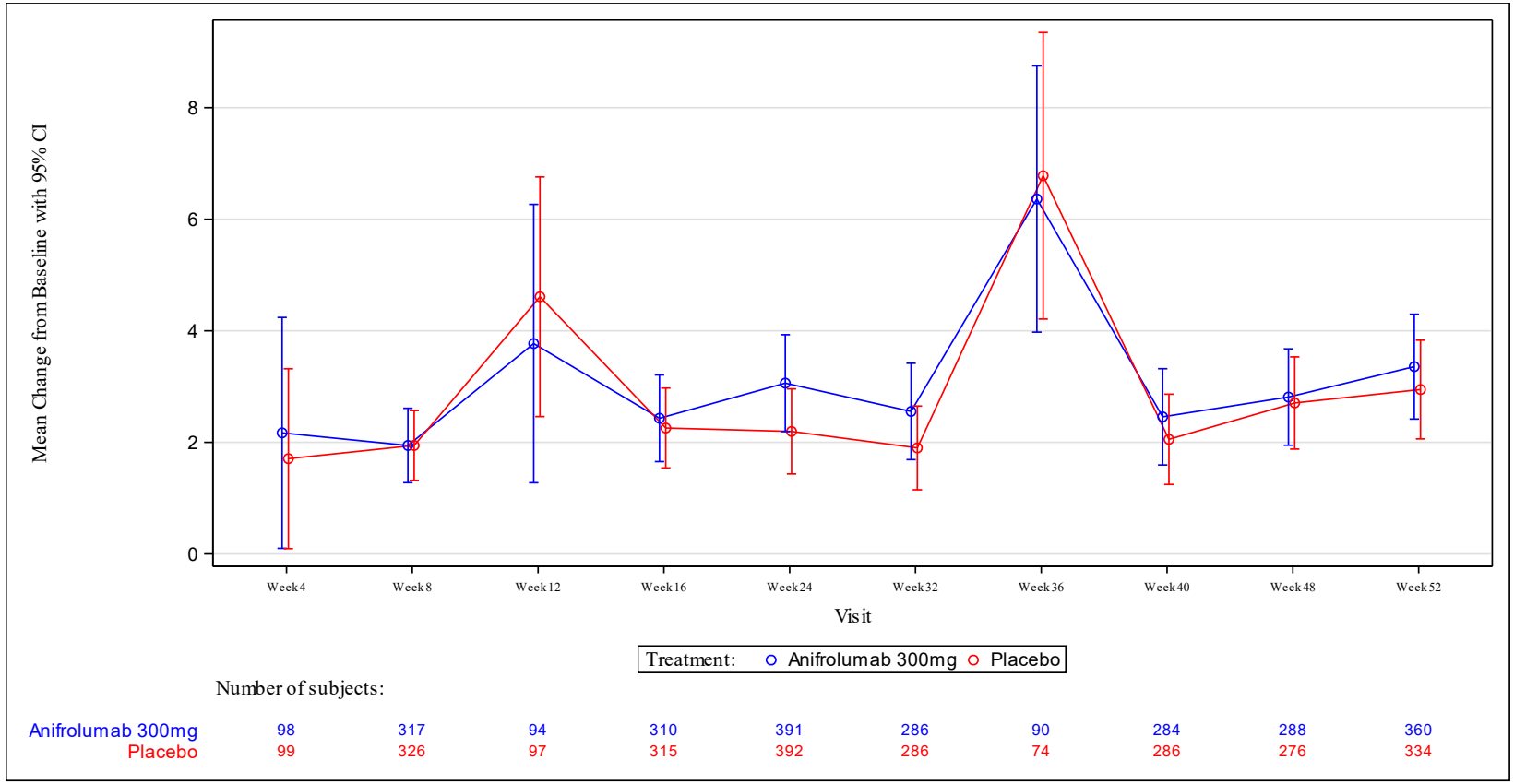
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - SF-36 v2.0 Acute General Health Score
Full analysis set

	Anifrolumab 300mg (N=459)				Placebo (N=468)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	444	37.52 (9.19)	0	-	450	37.88 (9.17)	0	-
Week 4	98	37.04 (10.66)	98	2.17 (10.32)	99	36.69 (11.54)	99	1.71 (8.08)
Week 8	326	40.60 (8.13)	317	1.94 (6.03)	338	40.78 (8.18)	326	1.94 (5.74)
Week 12	94	38.92 (11.55)	94	3.77 (12.18)	97	39.14 (11.62)	97	4.61 (10.66)
Week 16	321	41.00 (8.98)	310	2.43 (6.95)	327	40.96 (8.32)	315	2.26 (6.46)
Week 24	404	40.59 (9.91)	391	3.06 (8.73)	407	40.48 (9.24)	392	2.20 (7.68)
Week 32	298	41.01 (9.44)	286	2.55 (7.42)	296	40.92 (8.39)	286	1.90 (6.45)
Week 36	90	41.76 (11.51)	90	6.36 (11.39)	74	42.62 (11.34)	74	6.78 (11.09)
Week 40	296	41.25 (9.19)	284	2.46 (7.39)	297	41.07 (8.82)	286	2.05 (6.95)
Week 48	300	41.37 (9.18)	288	2.81 (7.45)	283	41.79 (8.82)	276	2.71 (6.98)
Week 52	373	41.06 (10.06)	360	3.36 (9.07)	343	41.59 (9.47)	334	2.95 (8.22)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - SF-36 v2.0 Acute General Health Score
Full analysis set



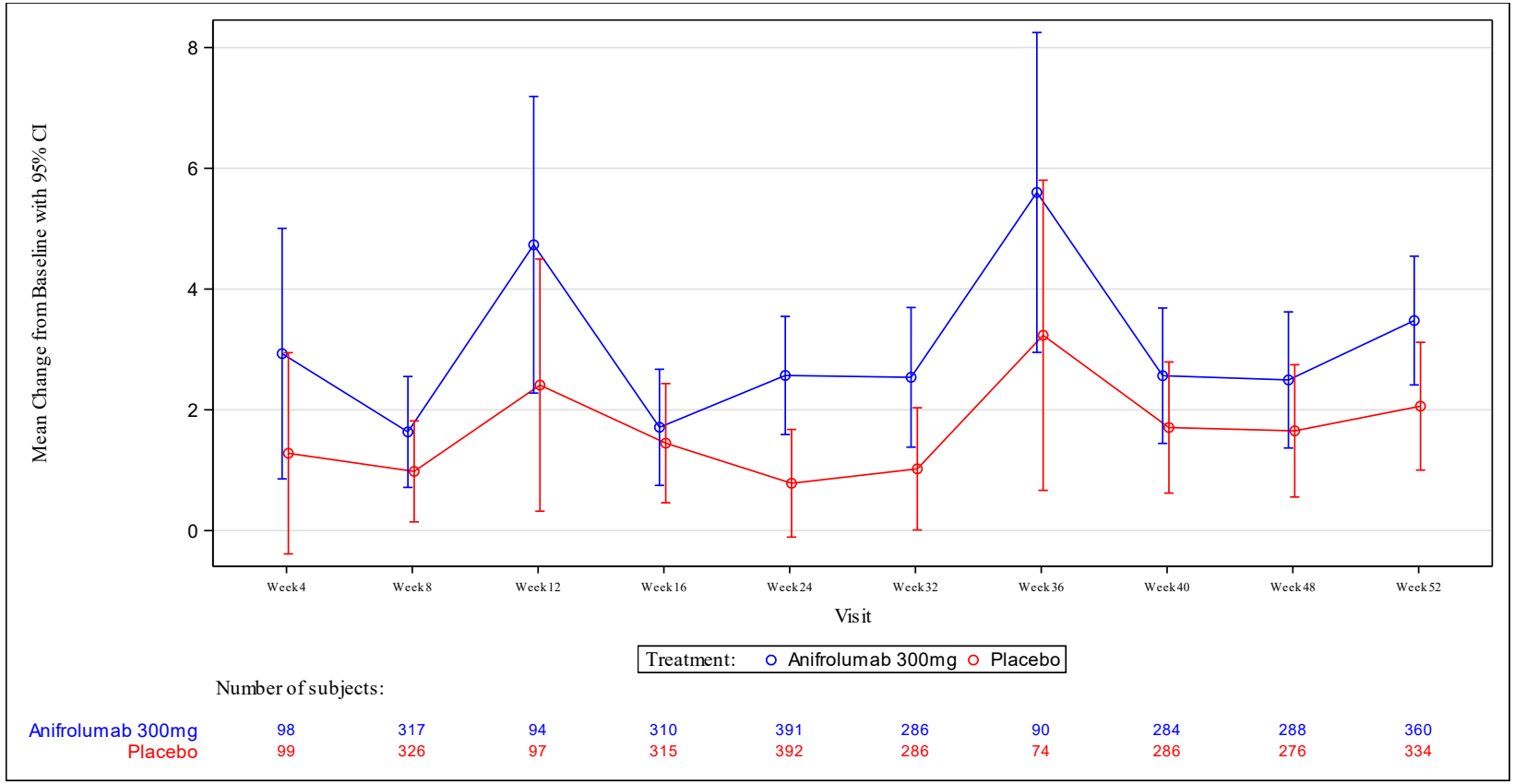
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Mental Health Score
Full analysis set

	Anifrolumab 300mg (N=459)				Placebo (N=468)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	444	42.72 (11.20)	0	-	450	42.69 (11.04)	0	-
Week 4	98	40.50 (11.64)	98	2.93 (10.35)	99	40.17 (11.83)	99	1.28 (8.35)
Week 8	326	45.93 (10.42)	317	1.63 (8.31)	338	44.97 (10.20)	326	0.98 (7.68)
Week 12	94	42.22 (12.08)	94	4.73 (11.99)	97	41.21 (12.13)	97	2.41 (10.36)
Week 16	321	45.99 (10.63)	310	1.71 (8.60)	327	45.31 (10.46)	315	1.45 (8.91)
Week 24	404	45.00 (11.47)	391	2.57 (9.84)	407	43.79 (10.72)	392	0.78 (8.98)
Week 32	298	46.40 (10.74)	286	2.54 (9.93)	296	45.04 (10.41)	286	1.02 (8.69)
Week 36	90	43.37 (11.32)	90	5.60 (12.65)	74	43.35 (11.91)	74	3.23 (11.09)
Week 40	296	46.50 (10.41)	284	2.57 (9.60)	297	45.70 (10.33)	286	1.71 (9.33)
Week 48	300	46.33 (10.09)	288	2.49 (9.72)	283	45.41 (10.46)	276	1.65 (9.24)
Week 52	373	45.80 (10.86)	360	3.48 (10.29)	343	45.34 (10.78)	334	2.06 (9.83)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Mental Health Score
Full analysis set



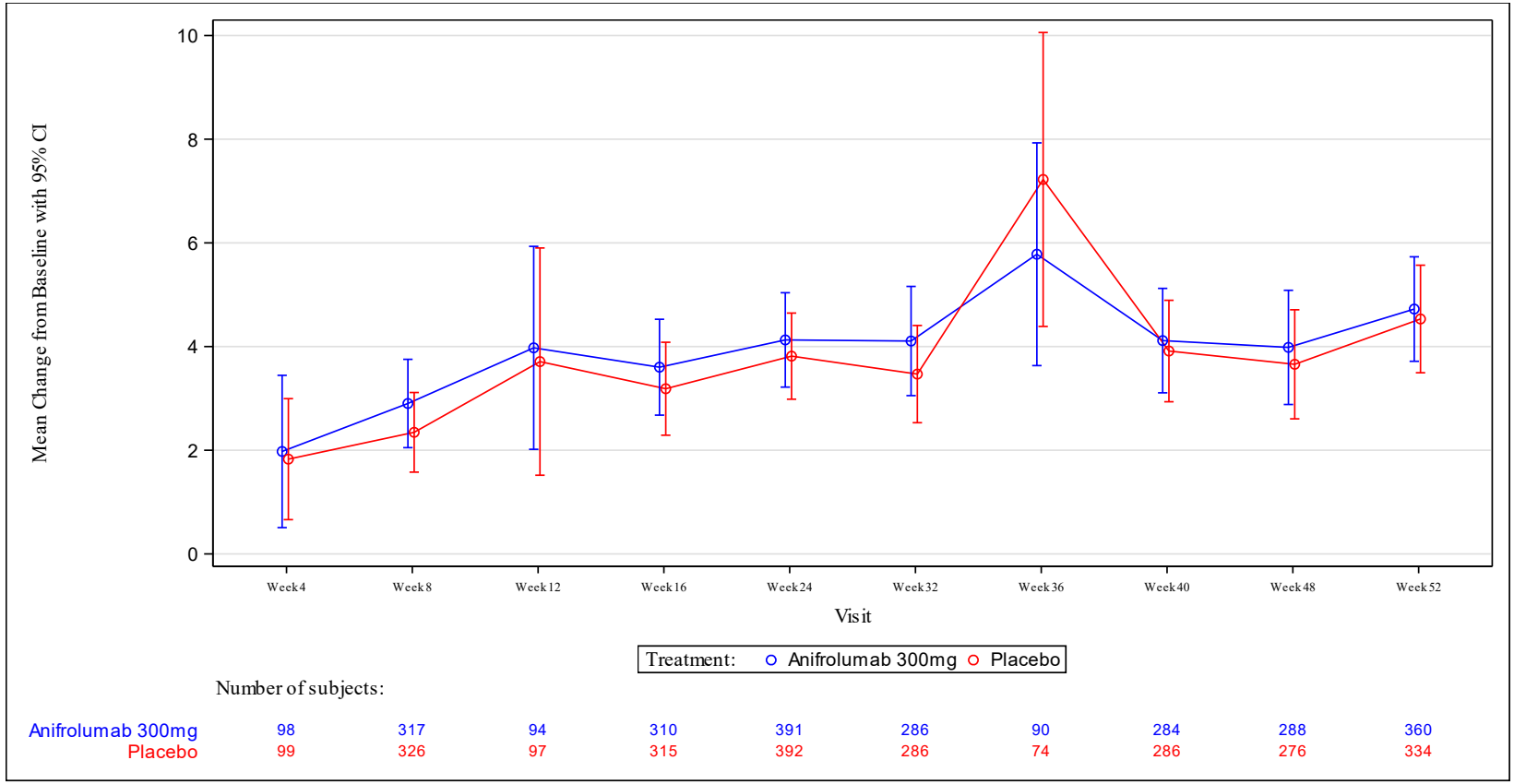
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Physical Functioning Score
Full analysis set

	Anifrolumab 300mg (N=459)				Placebo (N=468)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	444	38.32 (10.59)	0	-	450	37.61 (10.89)	0	-
Week 4	98	37.49 (10.10)	98	1.98 (7.33)	99	35.84 (11.86)	99	1.83 (5.85)
Week 8	326	42.44 (9.78)	317	2.90 (7.71)	338	41.20 (9.63)	326	2.35 (7.05)
Week 12	94	39.55 (10.52)	94	3.98 (9.56)	97	37.88 (11.98)	97	3.71 (10.87)
Week 16	321	42.94 (10.07)	310	3.60 (8.27)	327	41.87 (9.91)	315	3.19 (8.09)
Week 24	404	42.75 (10.58)	391	4.13 (9.16)	407	41.73 (10.37)	392	3.82 (8.37)
Week 32	298	43.58 (10.00)	286	4.11 (9.05)	296	42.39 (9.61)	286	3.47 (8.06)
Week 36	90	41.53 (11.75)	90	5.78 (10.25)	74	42.47 (11.62)	74	7.22 (12.24)
Week 40	296	43.74 (10.31)	284	4.11 (8.62)	297	42.42 (10.14)	286	3.91 (8.41)
Week 48	300	43.74 (10.08)	288	3.98 (9.49)	283	42.29 (10.60)	276	3.66 (8.88)
Week 52	373	43.52 (10.29)	360	4.72 (9.72)	343	42.86 (10.28)	334	4.53 (9.64)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Physical Functioning Score
Full analysis set



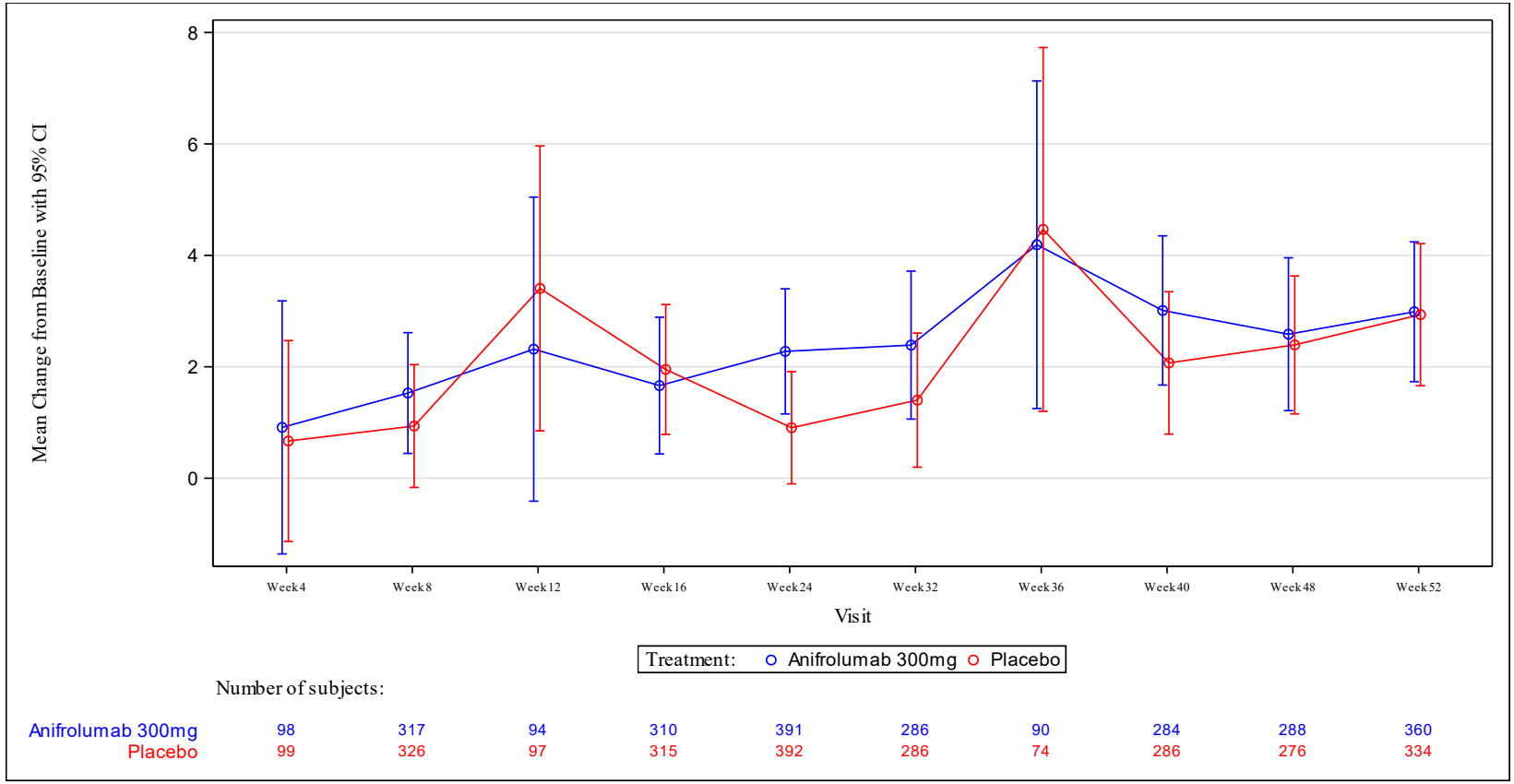
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Role Emotional Score
Full analysis set

	Anifrolumab 300mg (N=459)				Placebo (N=468)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	444	39.59 (13.07)	0	-	450	38.81 (12.62)	0	-
Week 4	98	35.81 (12.42)	98	0.91 (11.33)	99	34.48 (12.48)	99	0.67 (9.04)
Week 8	326	42.65 (12.44)	317	1.53 (9.81)	338	41.18 (12.14)	326	0.94 (10.11)
Week 12	94	37.52 (13.72)	94	2.32 (13.32)	97	37.32 (13.22)	97	3.41 (12.69)
Week 16	321	42.86 (12.01)	310	1.66 (10.98)	327	42.30 (11.97)	315	1.95 (10.51)
Week 24	404	41.82 (12.62)	391	2.28 (11.29)	407	40.06 (12.65)	392	0.91 (10.14)
Week 32	298	43.25 (11.64)	286	2.39 (11.41)	296	41.66 (12.46)	286	1.40 (10.34)
Week 36	90	39.81 (13.01)	90	4.19 (14.04)	74	39.49 (13.45)	74	4.47 (14.09)
Week 40	296	43.61 (11.81)	284	3.01 (11.46)	297	42.33 (12.14)	286	2.07 (10.98)
Week 48	300	43.13 (12.03)	288	2.58 (11.82)	283	42.38 (11.64)	276	2.39 (10.45)
Week 52	373	42.54 (12.14)	360	2.99 (12.10)	343	42.21 (12.20)	334	2.94 (11.85)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Role Emotional Score
Full analysis set



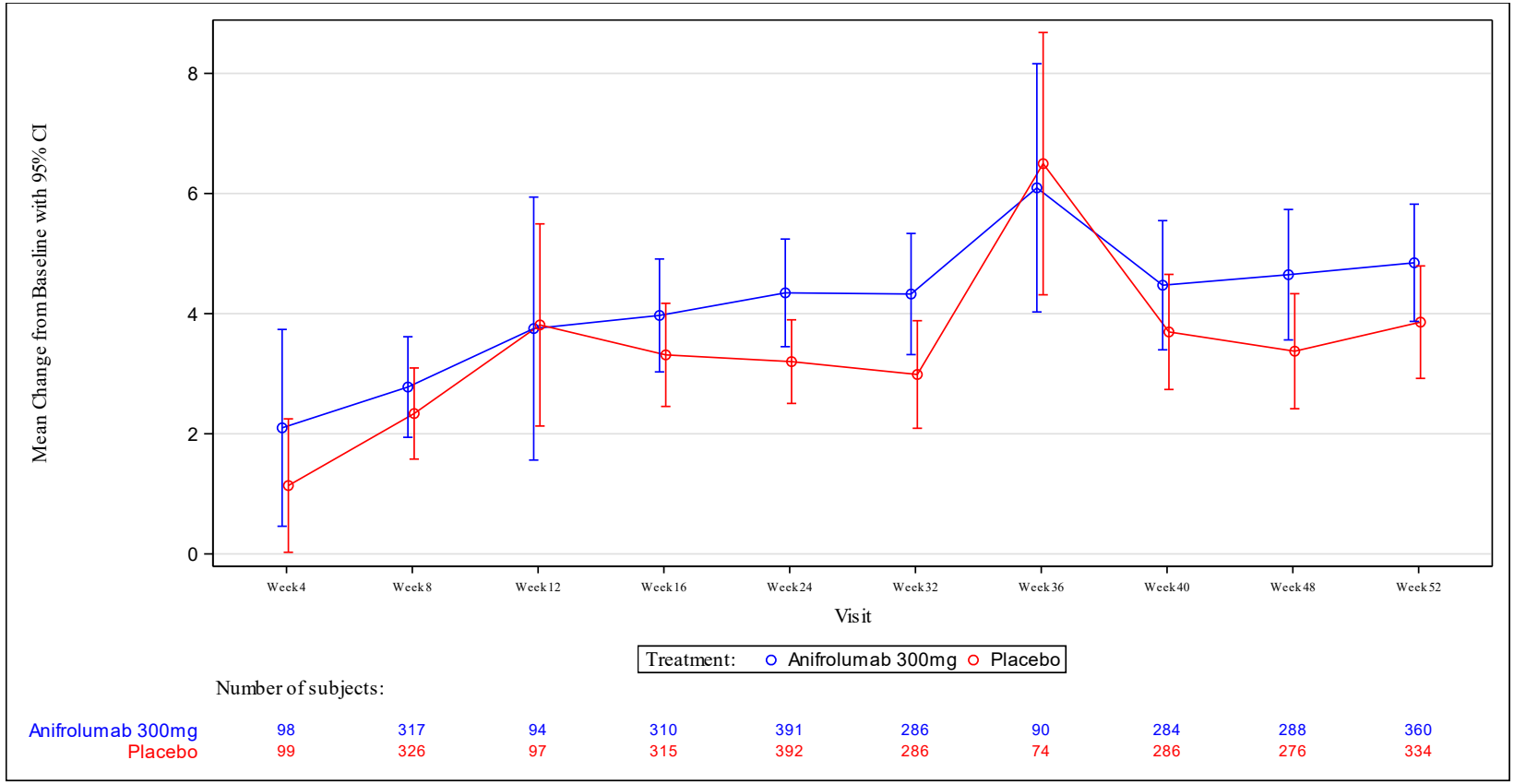
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Role Physical Score
Full analysis set

	Anifrolumab 300mg (N=459)				Placebo (N=468)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	444	36.94 (9.84)	0	-	450	36.85 (9.12)	0	-
Week 4	98	36.64 (9.59)	98	2.10 (8.17)	99	35.18 (9.54)	99	1.14 (5.57)
Week 8	326	40.76 (9.29)	317	2.78 (7.58)	338	40.15 (8.72)	326	2.34 (6.96)
Week 12	94	38.72 (10.81)	94	3.75 (10.69)	97	37.74 (10.85)	97	3.81 (8.35)
Week 16	321	41.91 (9.53)	310	3.97 (8.41)	327	41.03 (9.19)	315	3.31 (7.74)
Week 24	404	41.47 (10.06)	391	4.35 (9.01)	407	40.29 (9.41)	392	3.20 (7.01)
Week 32	298	42.11 (9.49)	286	4.33 (8.66)	296	40.96 (8.87)	286	2.99 (7.69)
Week 36	90	41.21 (10.83)	90	6.09 (9.87)	74	41.54 (10.78)	74	6.50 (9.42)
Week 40	296	42.40 (9.56)	284	4.47 (9.21)	297	41.59 (8.93)	286	3.70 (8.23)
Week 48	300	42.46 (9.70)	288	4.65 (9.36)	283	41.25 (9.20)	276	3.37 (8.08)
Week 52	373	42.00 (9.88)	360	4.85 (9.41)	343	41.46 (9.45)	334	3.86 (8.70)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Role Physical Score
Full analysis set



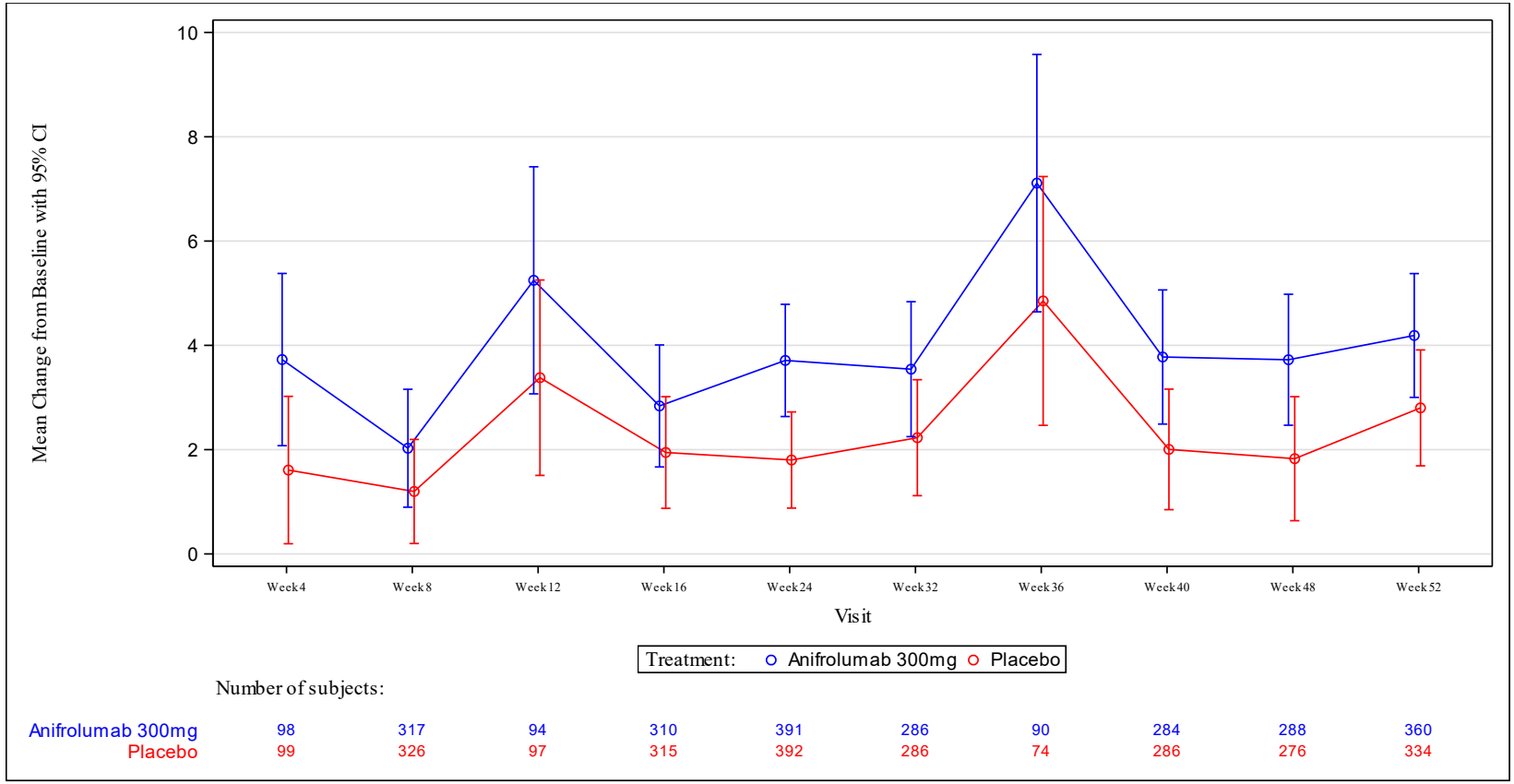
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Social Functioning Score
Full analysis set

	Anifrolumab 300mg (N=459)				Placebo (N=468)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	444	39.97 (10.74)	0	-	450	40.50 (10.49)	0	-
Week 4	98	42.25 (10.82)	98	3.73 (8.24)	99	41.49 (10.78)	99	1.61 (7.09)
Week 8	326	42.82 (10.29)	317	2.03 (10.23)	338	42.04 (10.33)	326	1.20 (9.16)
Week 12	94	43.99 (11.93)	94	5.25 (10.63)	97	42.72 (12.58)	97	3.38 (9.30)
Week 16	321	43.30 (10.38)	310	2.84 (10.47)	327	42.64 (9.58)	315	1.95 (9.66)
Week 24	404	43.59 (10.87)	391	3.71 (10.82)	407	42.51 (10.58)	392	1.80 (9.29)
Week 32	298	43.92 (10.46)	286	3.54 (11.12)	296	42.80 (10.14)	286	2.23 (9.55)
Week 36	90	46.02 (12.83)	90	7.11 (11.78)	74	45.85 (12.20)	74	4.85 (10.30)
Week 40	296	44.33 (10.31)	284	3.78 (11.01)	297	42.61 (9.94)	286	2.00 (9.93)
Week 48	300	44.23 (10.23)	288	3.72 (10.83)	283	42.61 (10.10)	276	1.83 (10.04)
Week 52	373	44.28 (11.21)	360	4.19 (11.46)	343	43.68 (10.73)	334	2.80 (10.32)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Social Functioning Score
Full analysis set



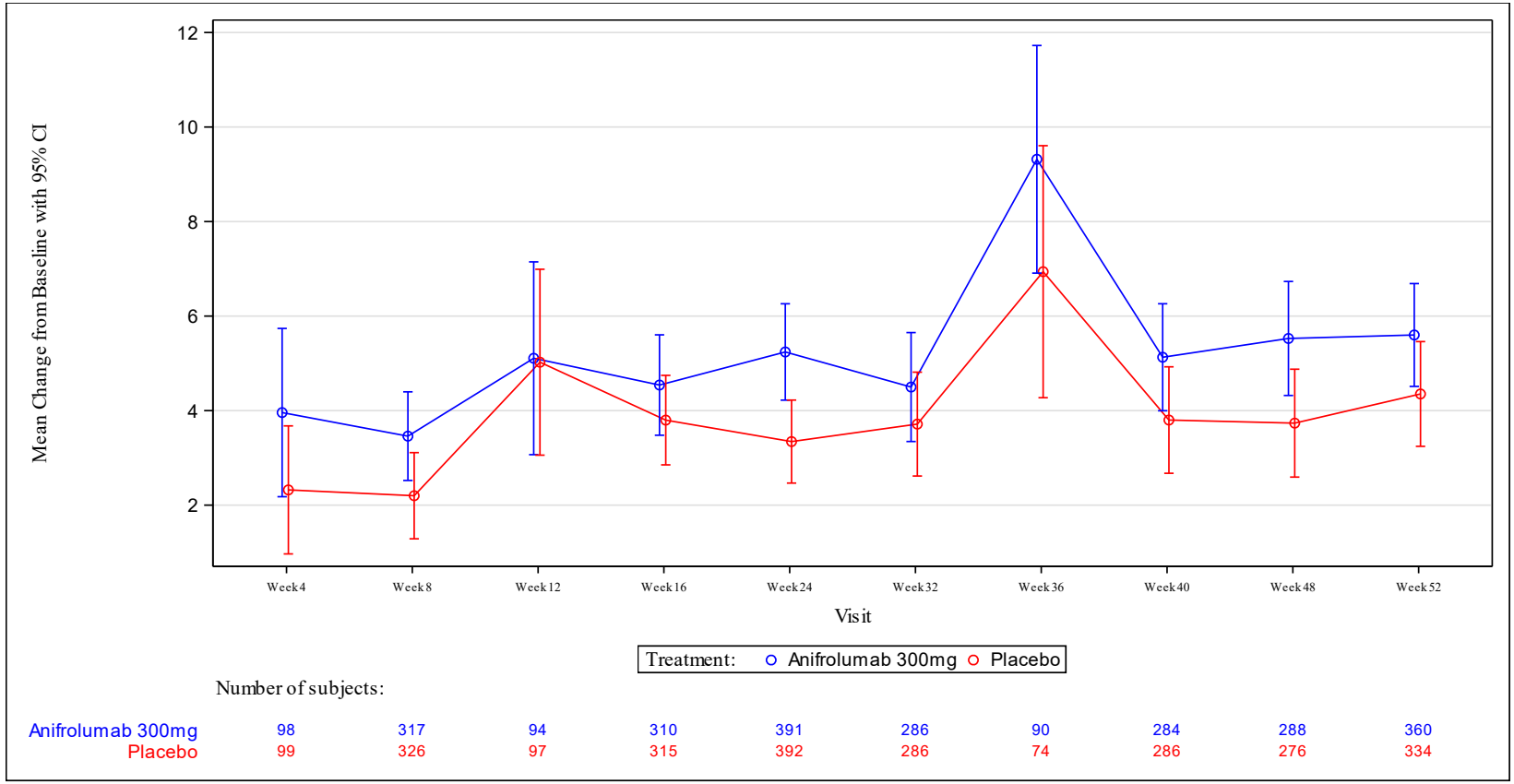
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Bodily Pain Score
Full analysis set

	Anifrolumab 300mg (N=459)				Placebo (N=468)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	444	38.15 (8.66)	0	-	450	38.41 (9.32)	0	-
Week 4	98	40.11 (9.23)	98	3.96 (8.88)	99	40.10 (10.25)	99	2.32 (6.79)
Week 8	326	42.43 (9.07)	317	3.46 (8.49)	338	40.79 (9.11)	326	2.20 (8.37)
Week 12	94	41.53 (10.18)	94	5.11 (9.96)	97	42.49 (10.96)	97	5.02 (9.76)
Week 16	321	43.52 (9.72)	310	4.54 (9.50)	327	42.32 (9.32)	315	3.80 (8.54)
Week 24	404	43.60 (10.32)	391	5.24 (10.25)	407	42.10 (9.86)	392	3.34 (8.84)
Week 32	298	43.52 (9.76)	286	4.50 (9.90)	296	42.32 (9.33)	286	3.71 (9.44)
Week 36	90	45.58 (11.31)	90	9.32 (11.50)	74	45.39 (11.29)	74	6.94 (11.51)
Week 40	296	44.52 (9.65)	284	5.13 (9.69)	297	42.35 (9.22)	286	3.80 (9.67)
Week 48	300	44.55 (10.41)	288	5.53 (10.40)	283	42.49 (9.47)	276	3.73 (9.63)
Week 52	373	44.10 (10.20)	360	5.60 (10.49)	343	43.15 (9.54)	334	4.35 (10.29)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Bodily Pain Score
Full analysis set



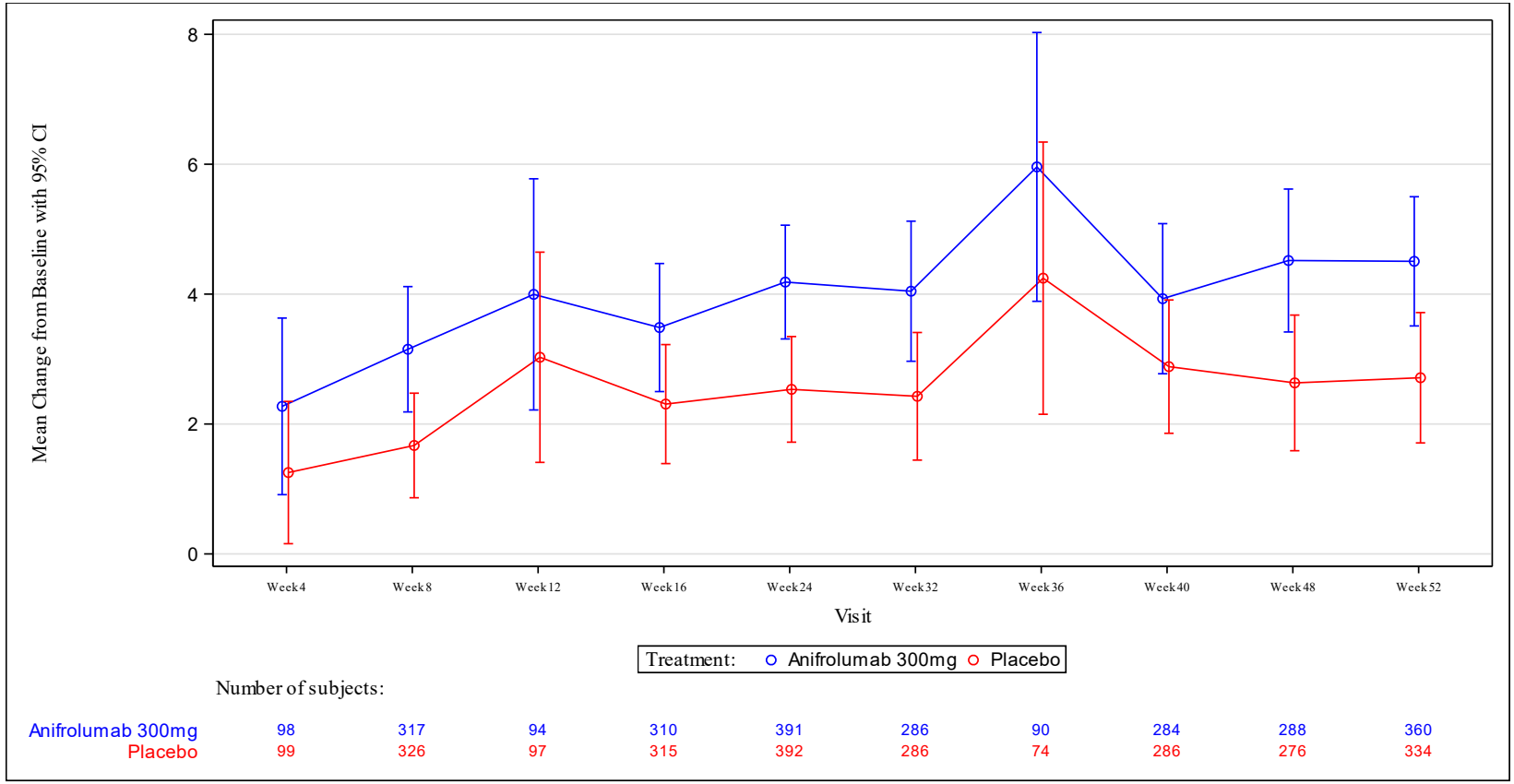
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Vitality Score
Full analysis set

	Anifrolumab 300mg (N=459)				Placebo (N=468)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	444	39.62 (10.14)	0	-	450	40.66 (9.72)	0	-
Week 4	98	34.42 (8.24)	98	2.27 (6.78)	99	35.38 (9.65)	99	1.25 (5.49)
Week 8	326	45.34 (9.75)	317	3.15 (8.73)	338	44.34 (9.39)	326	1.67 (7.39)
Week 12	94	36.08 (9.55)	94	4.00 (8.69)	97	37.10 (10.50)	97	3.03 (8.03)
Week 16	321	45.54 (10.19)	310	3.49 (8.82)	327	45.09 (9.40)	315	2.31 (8.26)
Week 24	404	43.83 (10.84)	391	4.19 (8.81)	407	43.76 (10.52)	392	2.53 (8.19)
Week 32	298	46.07 (10.30)	286	4.04 (9.27)	296	45.43 (9.58)	286	2.43 (8.44)
Week 36	90	37.81 (10.09)	90	5.96 (9.88)	74	39.65 (10.79)	74	4.25 (9.05)
Week 40	296	46.27 (10.58)	284	3.93 (9.89)	297	45.83 (9.99)	286	2.88 (8.82)
Week 48	300	46.87 (10.44)	288	4.52 (9.49)	283	45.78 (9.85)	276	2.63 (8.81)
Week 52	373	44.29 (11.13)	360	4.50 (9.60)	343	44.35 (10.34)	334	2.71 (9.32)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - SF-36 v2.0 Acute Vitality Score
Full analysis set



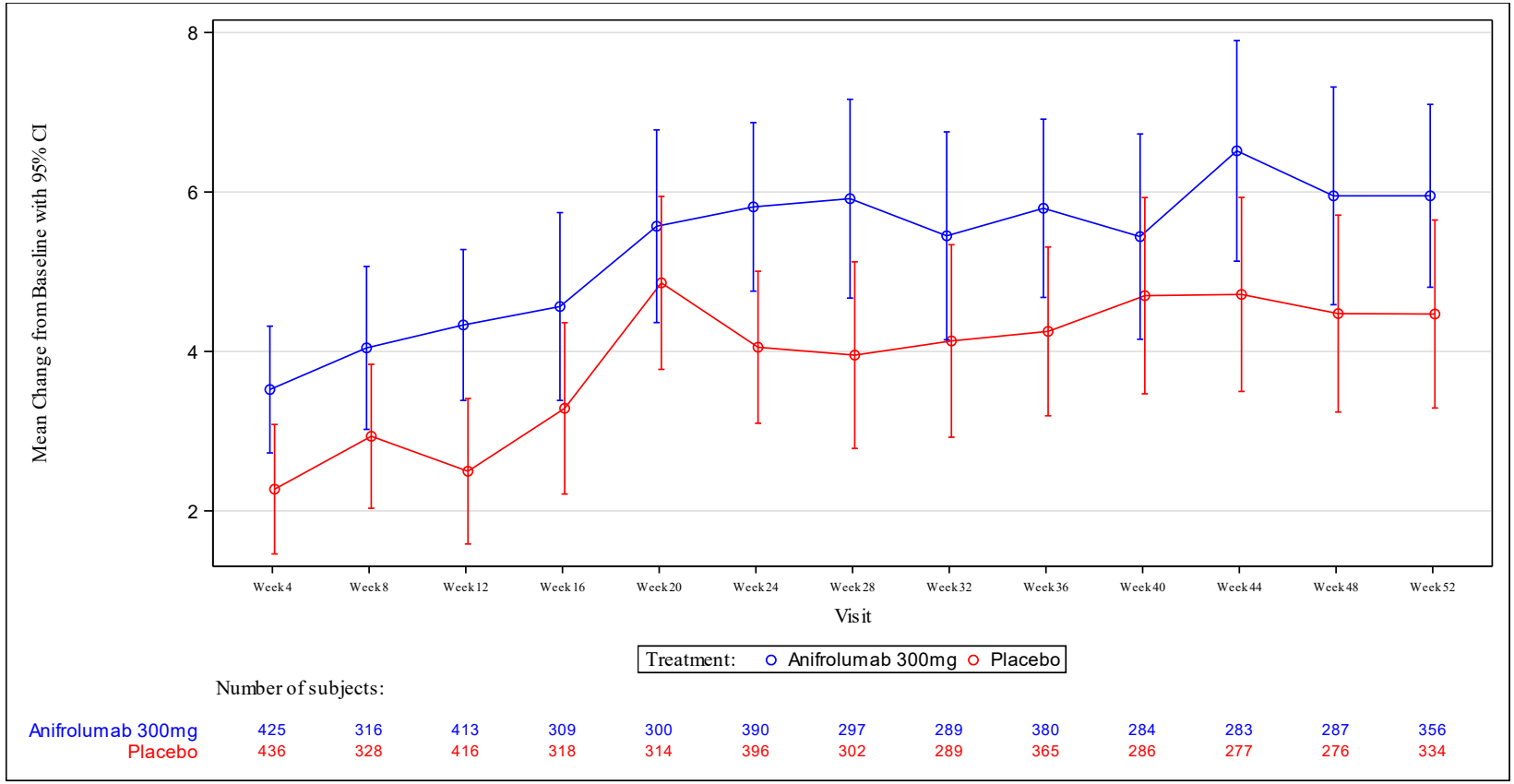
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - FACIT-F Total Score
Full analysis set

	Anifrolumab 300mg (N=459)				Placebo (N=468)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	440	25.70 (12.18)	0	-	451	25.91 (12.34)	0	-
Week 4	436	29.13 (11.52)	425	3.52 (8.34)	448	27.96 (11.88)	436	2.27 (8.62)
Week 8	328	30.27 (11.74)	316	4.04 (9.23)	341	28.79 (12.23)	328	2.94 (8.31)
Week 12	427	30.28 (12.88)	413	4.33 (9.78)	429	28.47 (12.80)	416	2.50 (9.46)
Week 16	324	30.71 (12.32)	309	4.56 (10.52)	329	29.23 (12.29)	318	3.29 (9.74)
Week 20	314	31.71 (12.16)	300	5.57 (10.63)	329	31.16 (11.90)	314	4.86 (9.77)
Week 24	407	31.61 (12.93)	390	5.81 (10.62)	410	30.11 (13.08)	396	4.05 (9.65)
Week 28	313	32.20 (12.21)	297	5.92 (10.92)	316	30.29 (12.19)	302	3.95 (10.33)
Week 32	304	31.44 (12.59)	289	5.45 (11.26)	300	30.56 (12.71)	289	4.13 (10.43)
Week 36	397	31.97 (12.99)	380	5.80 (11.08)	375	30.82 (12.87)	365	4.25 (10.28)
Week 40	300	31.85 (12.38)	284	5.44 (11.02)	298	30.80 (12.72)	286	4.70 (10.57)
Week 44	298	32.78 (12.70)	283	6.52 (11.83)	286	30.99 (12.22)	277	4.71 (10.29)
Week 48	303	32.16 (12.87)	287	5.95 (11.75)	286	31.00 (12.48)	276	4.47 (10.42)
Week 52	373	31.98 (12.92)	356	5.95 (11.00)	344	31.39 (12.99)	334	4.47 (10.95)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - FACIT-F Total Score
Full analysis set



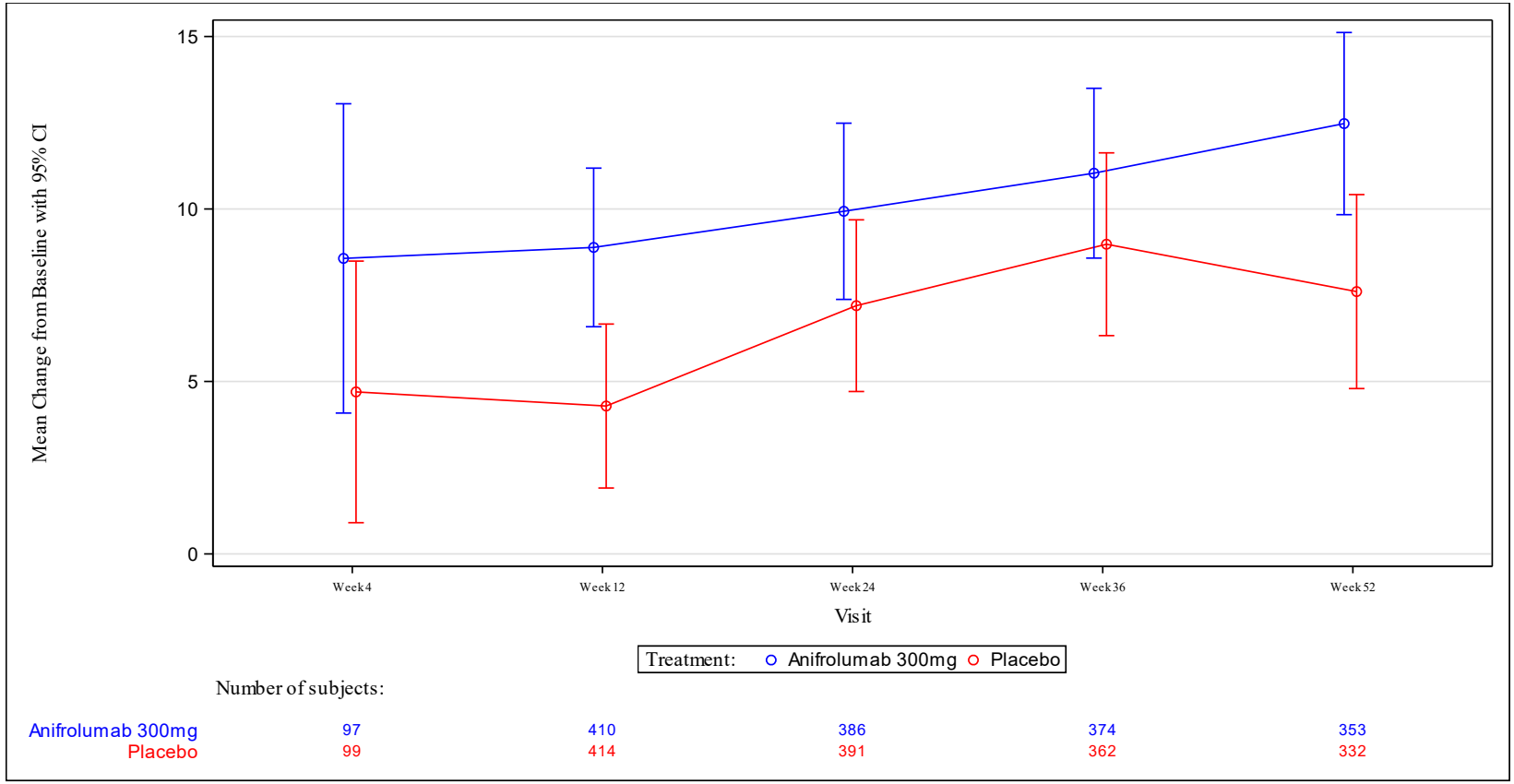
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - EQ VAS Score
Full analysis set

	Anifrolumab 300mg (N=459)				Placebo (N=468)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	439	54.90 (20.65)	0	-	451	55.86 (21.33)	0	-
Week 4	98	61.20 (19.45)	97	8.57 (22.24)	99	62.01 (19.48)	99	4.70 (19.01)
Week 12	425	63.60 (21.08)	410	8.89 (23.68)	427	60.16 (20.91)	414	4.29 (24.60)
Week 24	404	64.76 (21.65)	386	9.93 (25.52)	405	63.22 (21.06)	391	7.20 (25.03)
Week 36	392	66.18 (21.68)	374	11.04 (24.21)	371	65.89 (21.51)	362	8.98 (25.63)
Week 52	371	67.13 (21.27)	353	12.48 (25.22)	342	64.58 (21.78)	332	7.61 (26.04)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - EQ VAS Score
Full analysis set



Number of subjects:					
Anifrolumab 300mg	97	410	386	374	353
Placebo	99	414	391	362	332

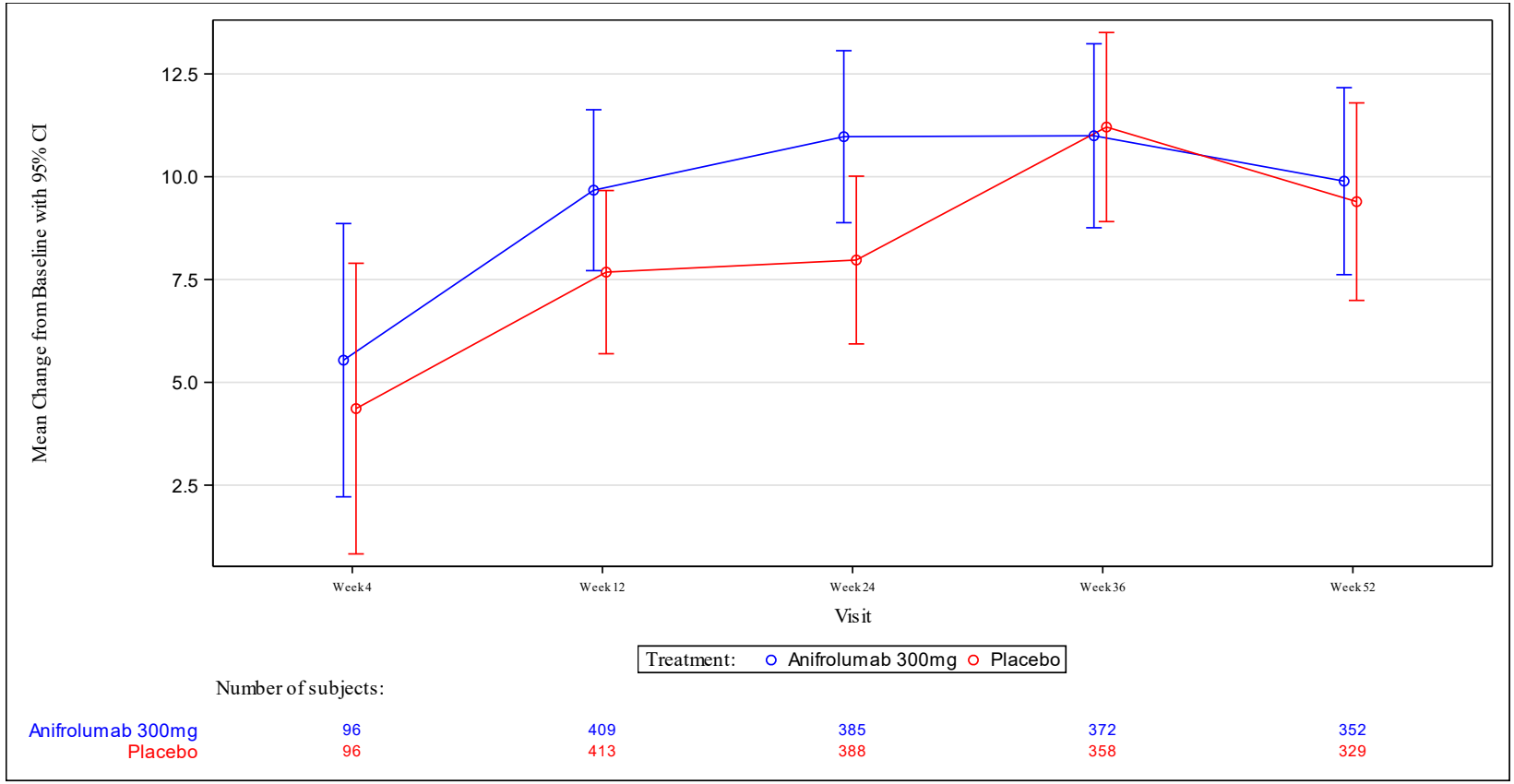
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - Lupus QoL Physical Health domain score
Full analysis set

	Anifrolumab 300mg (N=459)				Placebo (N=468)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	439	54.10 (26.12)	0	-	449	53.08 (26.04)	0	-
Week 4	97	59.77 (25.76)	96	5.54 (16.40)	98	56.38 (25.22)	96	4.36 (17.44)
Week 12	424	64.29 (25.55)	409	9.67 (20.13)	428	60.57 (26.07)	413	7.68 (20.51)
Week 24	403	65.35 (25.59)	385	10.97 (20.87)	403	61.49 (25.49)	388	7.97 (20.43)
Week 36	390	65.73 (25.50)	372	11.00 (21.94)	368	65.08 (24.65)	358	11.21 (22.12)
Week 52	370	65.31 (25.82)	352	9.89 (21.69)	340	64.26 (24.48)	329	9.39 (22.14)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - Lupus QoL Physical Health domain score
Full analysis set



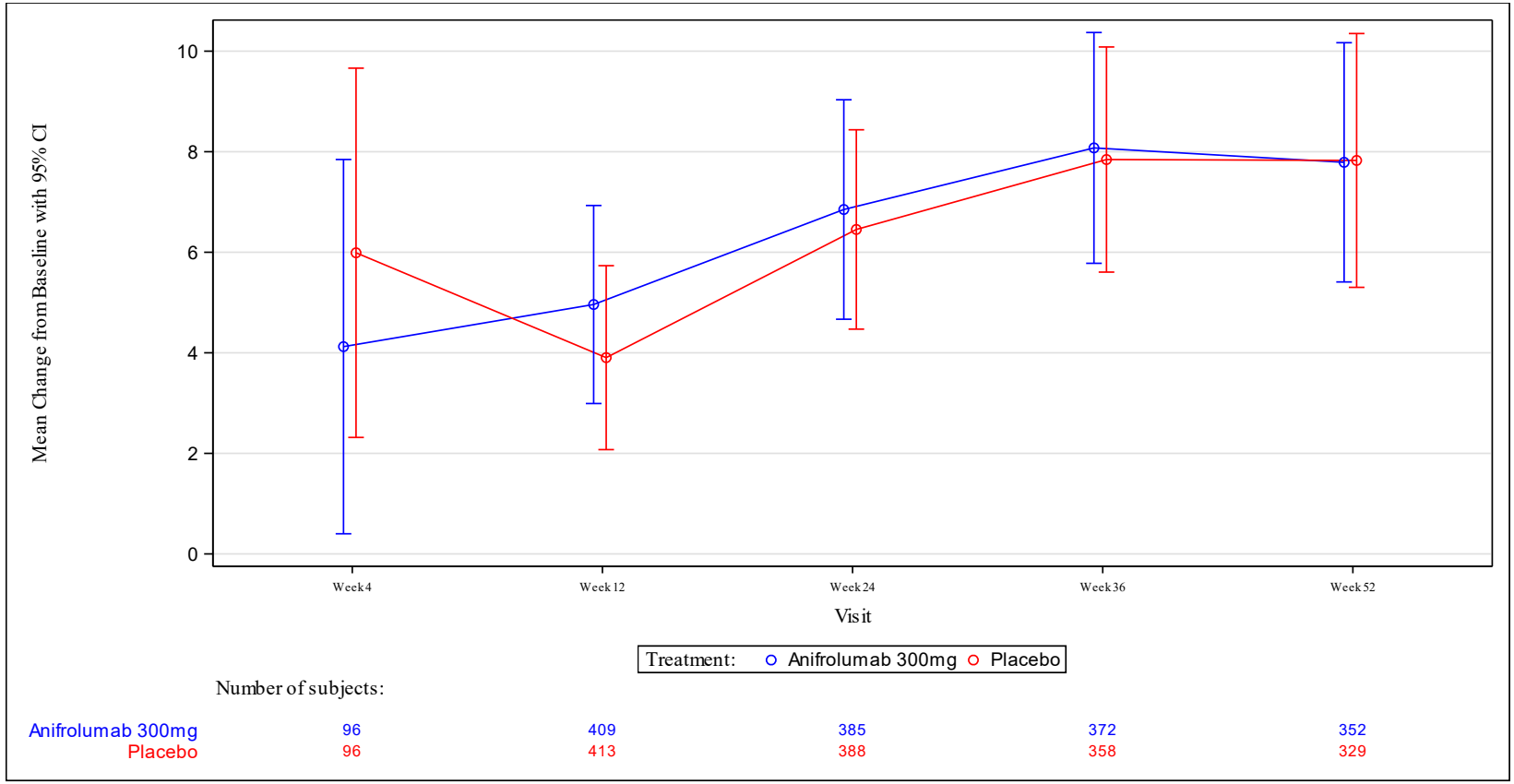
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - Lupus QoL Emotional Health domain score
Full analysis set

	Anifrolumab 300mg (N=459)				Placebo (N=468)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	439	64.98 (25.02)	0	-	449	63.22 (26.06)	0	-
Week 4	97	60.82 (24.32)	96	4.12 (18.37)	98	64.37 (26.42)	96	5.99 (18.13)
Week 12	424	70.10 (23.84)	409	4.96 (20.26)	428	67.39 (24.83)	413	3.90 (18.91)
Week 24	403	72.00 (23.42)	385	6.85 (21.78)	403	70.26 (24.76)	388	6.45 (19.86)
Week 36	390	72.96 (22.68)	372	8.08 (22.52)	368	72.57 (23.21)	358	7.84 (21.54)
Week 52	370	72.95 (23.70)	352	7.79 (22.70)	340	73.08 (23.83)	329	7.83 (23.27)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - Lupus QoL Emotional Health domain score
Full analysis set



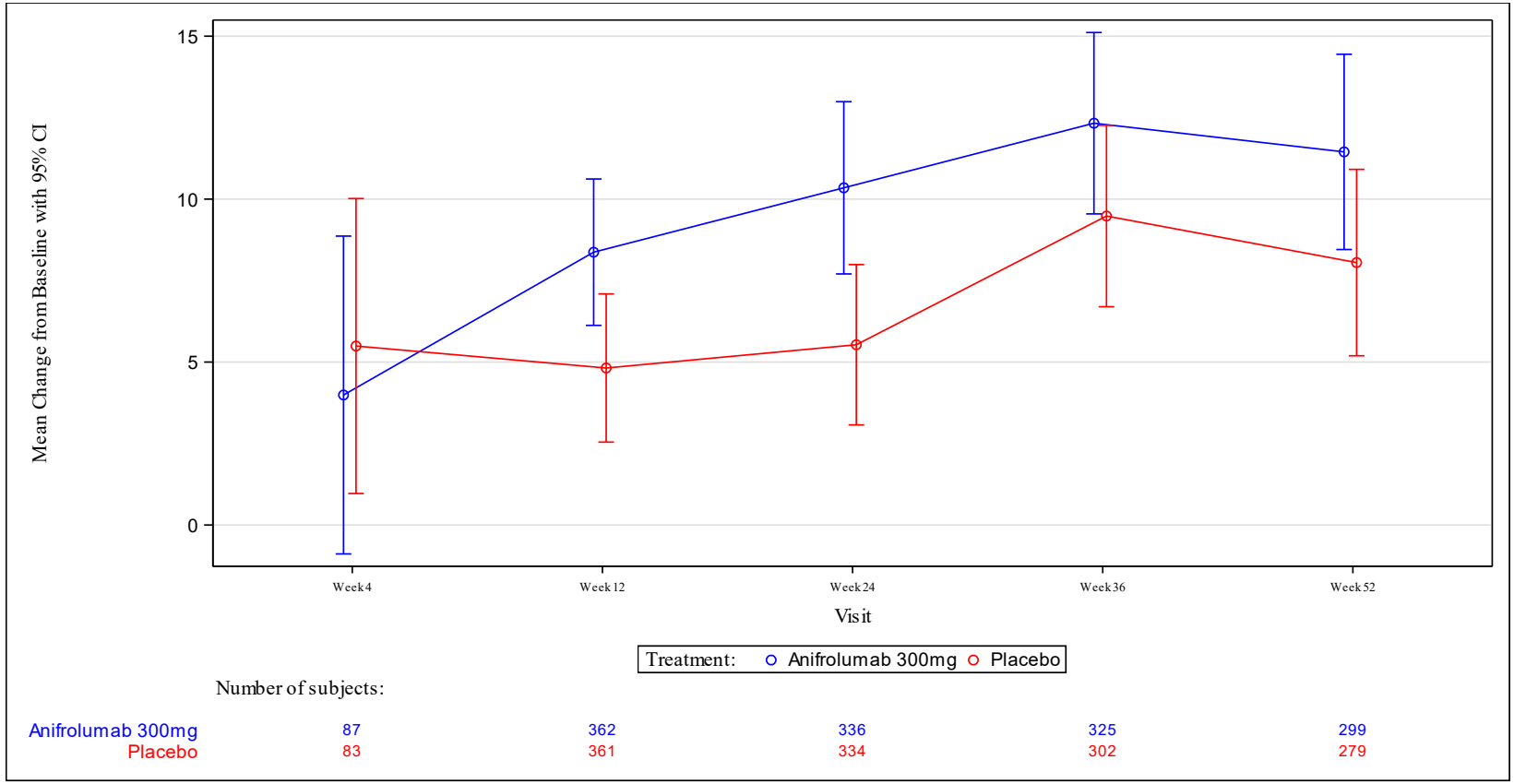
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - Lupus QoL Body Image domain score
Full analysis set

	Anifrolumab 300mg (N=459)				Placebo (N=468)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	414	58.05 (30.33)	0	-	415	60.59 (28.24)	0	-
Week 4	90	56.18 (29.73)	87	3.99 (22.88)	89	61.11 (29.33)	83	5.49 (20.73)
Week 12	389	66.38 (27.45)	362	8.37 (21.73)	389	65.43 (26.65)	361	4.82 (21.97)
Week 24	361	67.38 (27.64)	336	10.35 (24.63)	363	65.48 (28.10)	334	5.53 (22.85)
Week 36	352	69.28 (27.88)	325	12.33 (25.51)	327	69.81 (25.48)	302	9.48 (24.57)
Week 52	325	68.39 (27.67)	299	11.45 (26.32)	299	69.04 (27.59)	279	8.05 (24.27)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - Lupus QoL Body Image domain score
Full analysis set



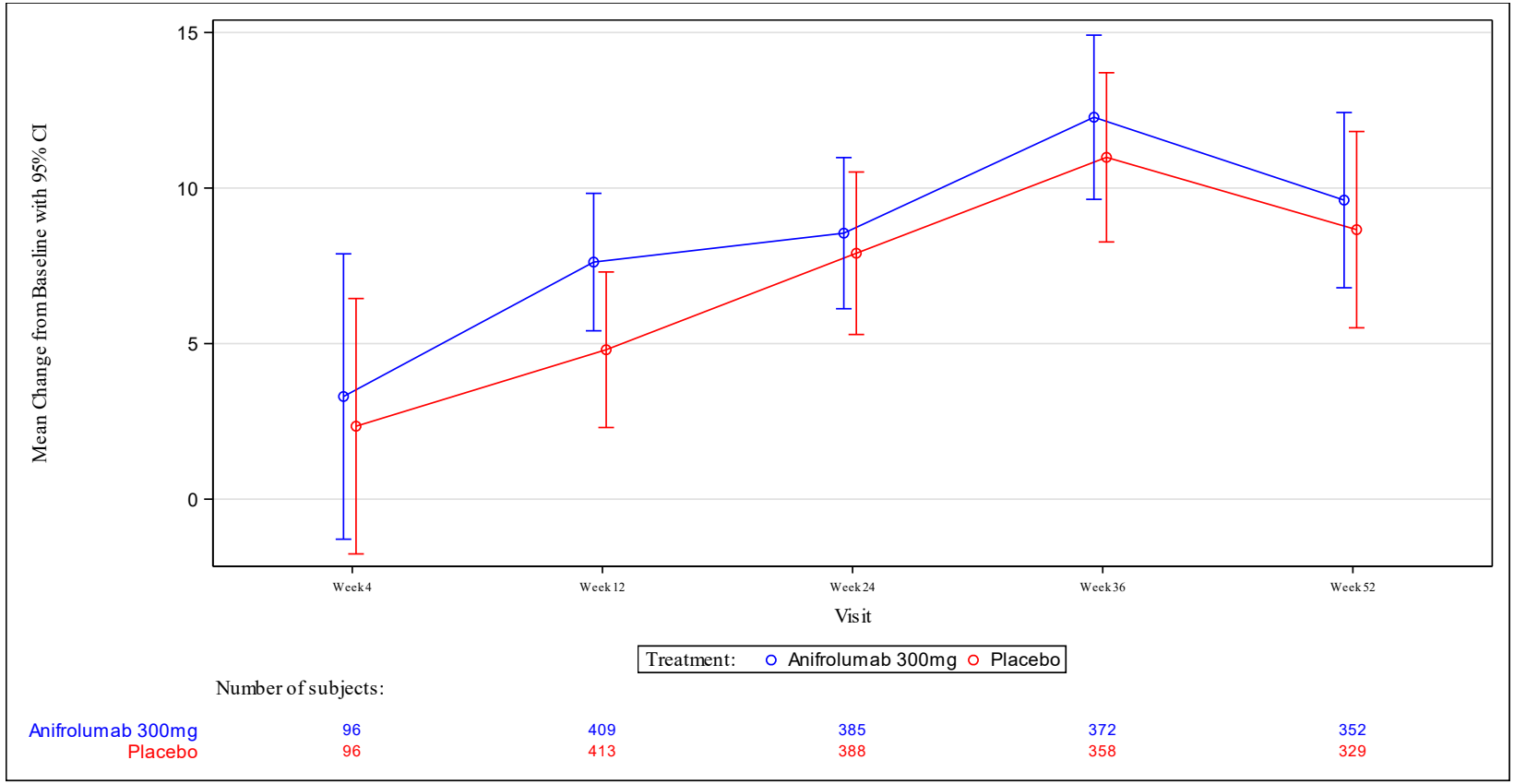
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - Lupus QoL Burden to Others domain score
Full analysis set

	Anifrolumab 300mg (N=459)				Placebo (N=468)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	439	50.13 (30.42)	0	-	449	50.69 (31.03)	0	-
Week 4	97	47.59 (30.78)	96	3.30 (22.64)	98	50.77 (30.95)	96	2.34 (20.26)
Week 12	424	57.76 (30.78)	409	7.62 (22.72)	428	55.72 (31.00)	413	4.80 (25.84)
Week 24	403	58.42 (31.81)	385	8.55 (24.24)	403	58.48 (30.82)	388	7.90 (26.16)
Week 36	390	61.97 (30.39)	372	12.28 (25.89)	368	62.66 (28.87)	358	10.99 (26.17)
Week 52	370	60.50 (30.92)	352	9.61 (26.87)	340	60.61 (30.49)	329	8.66 (29.09)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - Lupus QoL Burden to Others domain score
Full analysis set



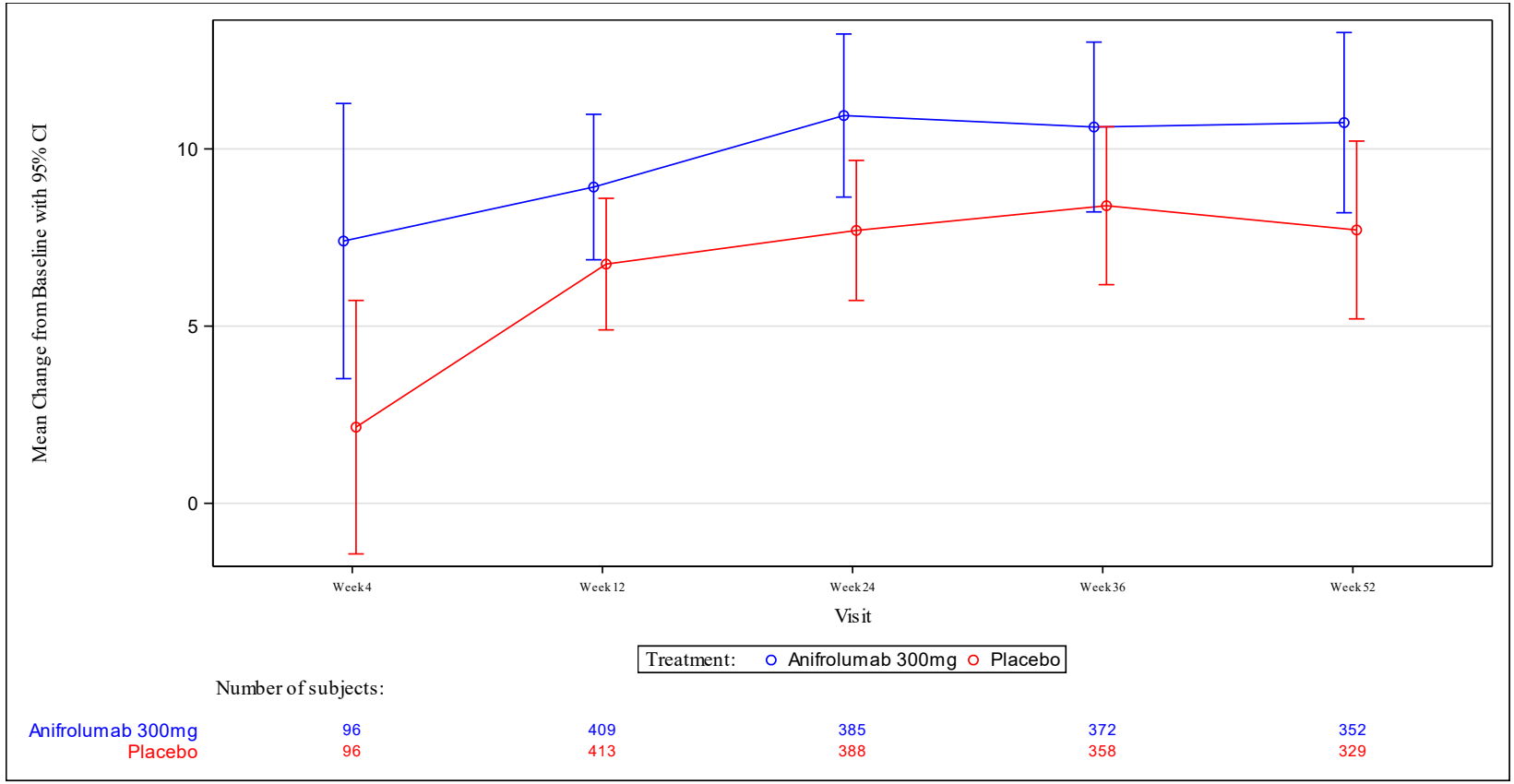
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - Lupus QoL Fatigue domain score
Full analysis set

	Anifrolumab 300mg (N=459)				Placebo (N=468)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	439	48.11 (26.88)	0	-	449	48.22 (26.85)	0	-
Week 4	97	52.88 (25.58)	96	7.40 (19.16)	98	51.79 (29.68)	96	2.15 (17.65)
Week 12	424	57.49 (27.28)	409	8.92 (21.11)	428	55.11 (26.86)	413	6.75 (19.19)
Week 24	403	59.43 (27.29)	385	10.94 (22.96)	403	56.62 (27.60)	388	7.70 (19.79)
Week 36	390	59.78 (27.16)	372	10.62 (23.50)	368	58.47 (26.90)	358	8.40 (21.43)
Week 52	370	59.46 (28.18)	352	10.74 (24.26)	340	58.47 (27.35)	329	7.71 (23.13)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - Lupus QoL Fatigue domain score
Full analysis set



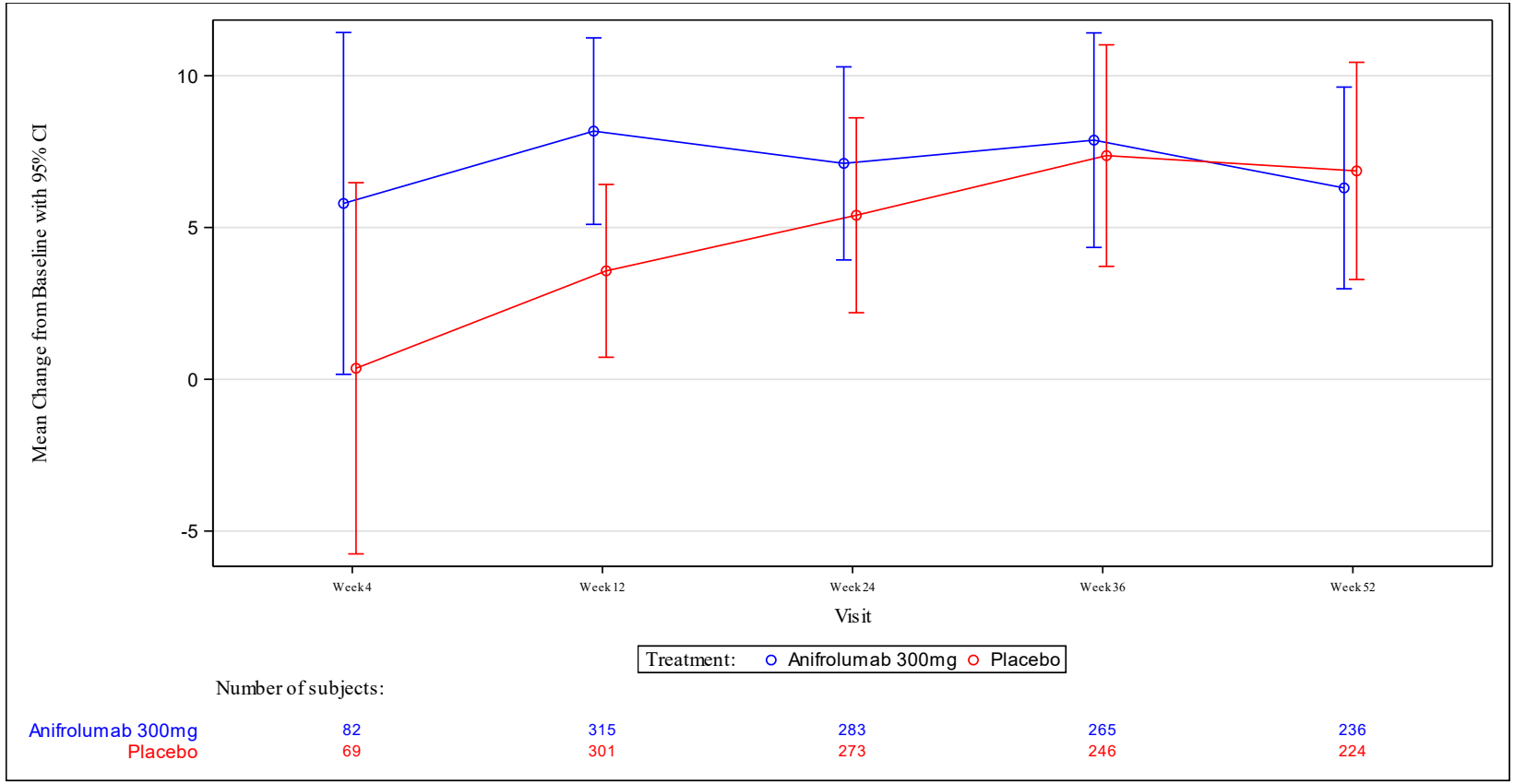
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - Lupus QoL Intimate Relationships domain score
Full analysis set

	Anifrolumab 300mg (N=459)				Placebo (N=468)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	367	55.38 (33.17)	0	-	362	57.53 (31.31)	0	-
Week 4	85	60.44 (32.72)	82	5.79 (25.62)	77	59.90 (34.13)	69	0.36 (25.45)
Week 12	348	64.62 (32.33)	315	8.17 (27.71)	346	60.69 (32.88)	301	3.57 (25.10)
Week 24	319	63.52 (32.86)	283	7.11 (27.18)	307	61.73 (32.21)	273	5.40 (26.94)
Week 36	307	64.45 (32.80)	265	7.88 (29.21)	270	64.40 (31.47)	246	7.37 (29.05)
Week 52	276	64.18 (32.00)	236	6.30 (25.90)	250	64.00 (32.72)	224	6.86 (27.17)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - Lupus QoL Intimate Relationships domain score
Full analysis set



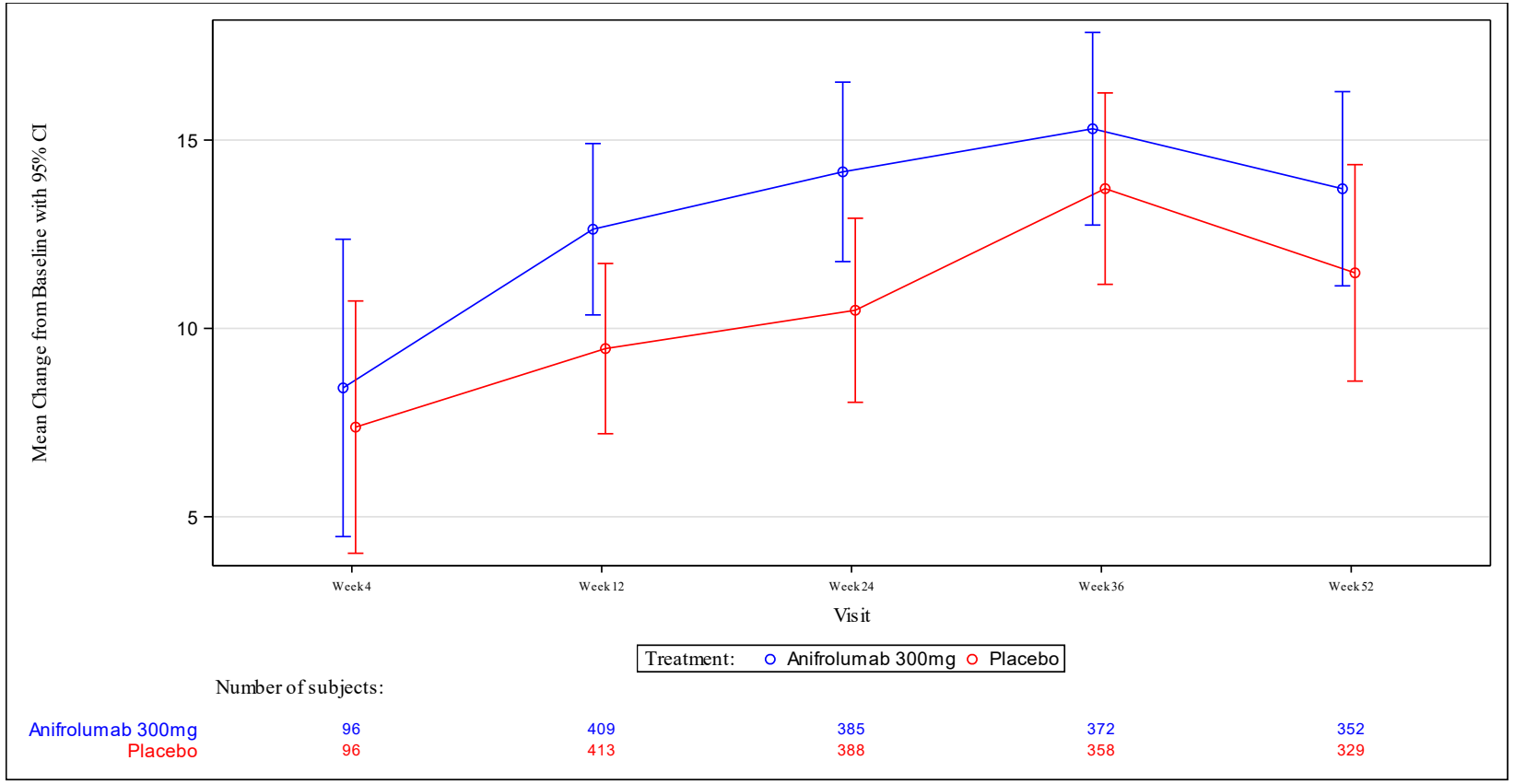
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - Lupus QoL Pain domain score
Full analysis set

	Anifrolumab 300mg (N=459)				Placebo (N=468)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	439	51.67 (28.19)	0	-	449	51.04 (29.29)	0	-
Week 4	97	57.13 (26.71)	96	8.42 (19.48)	98	56.63 (27.68)	96	7.38 (16.53)
Week 12	424	64.52 (27.50)	409	12.63 (23.40)	428	60.55 (28.26)	413	9.46 (23.36)
Week 24	403	65.90 (27.23)	385	14.16 (23.77)	403	62.10 (28.83)	388	10.48 (24.48)
Week 36	390	67.35 (26.95)	372	15.30 (25.08)	368	65.51 (26.89)	358	13.71 (24.45)
Week 52	370	67.14 (26.38)	352	13.71 (24.59)	340	64.83 (26.63)	329	11.47 (26.49)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - Lupus QoL Pain domain score
Full analysis set



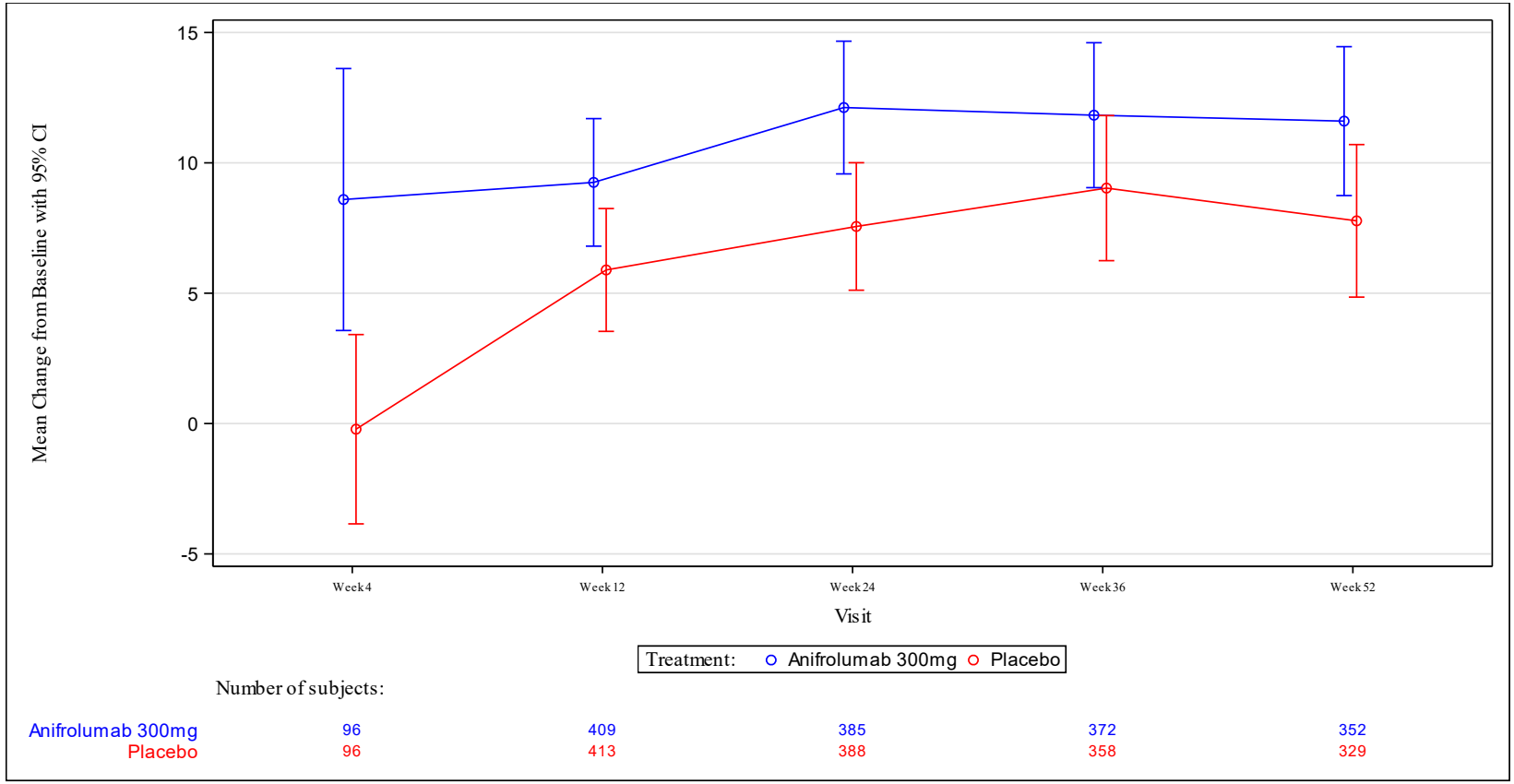
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - Lupus QoL Planning domain score
Full analysis set

	Anifrolumab 300mg (N=459)				Placebo (N=468)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	439	56.89 (30.70)	0	-	449	57.20 (31.05)	0	-
Week 4	97	60.31 (29.14)	96	8.59 (24.79)	98	55.65 (32.66)	96	-0.22 (17.92)
Week 12	424	66.20 (28.60)	409	9.25 (25.16)	428	63.16 (29.78)	413	5.89 (24.36)
Week 24	403	68.69 (29.02)	385	12.12 (25.40)	403	64.87 (29.85)	388	7.56 (24.50)
Week 36	390	68.65 (28.91)	372	11.83 (27.26)	368	67.57 (28.44)	358	9.03 (26.78)
Week 52	370	68.58 (28.72)	352	11.60 (27.24)	340	66.99 (28.17)	329	7.78 (26.97)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - Lupus QoL Planning domain score
Full analysis set



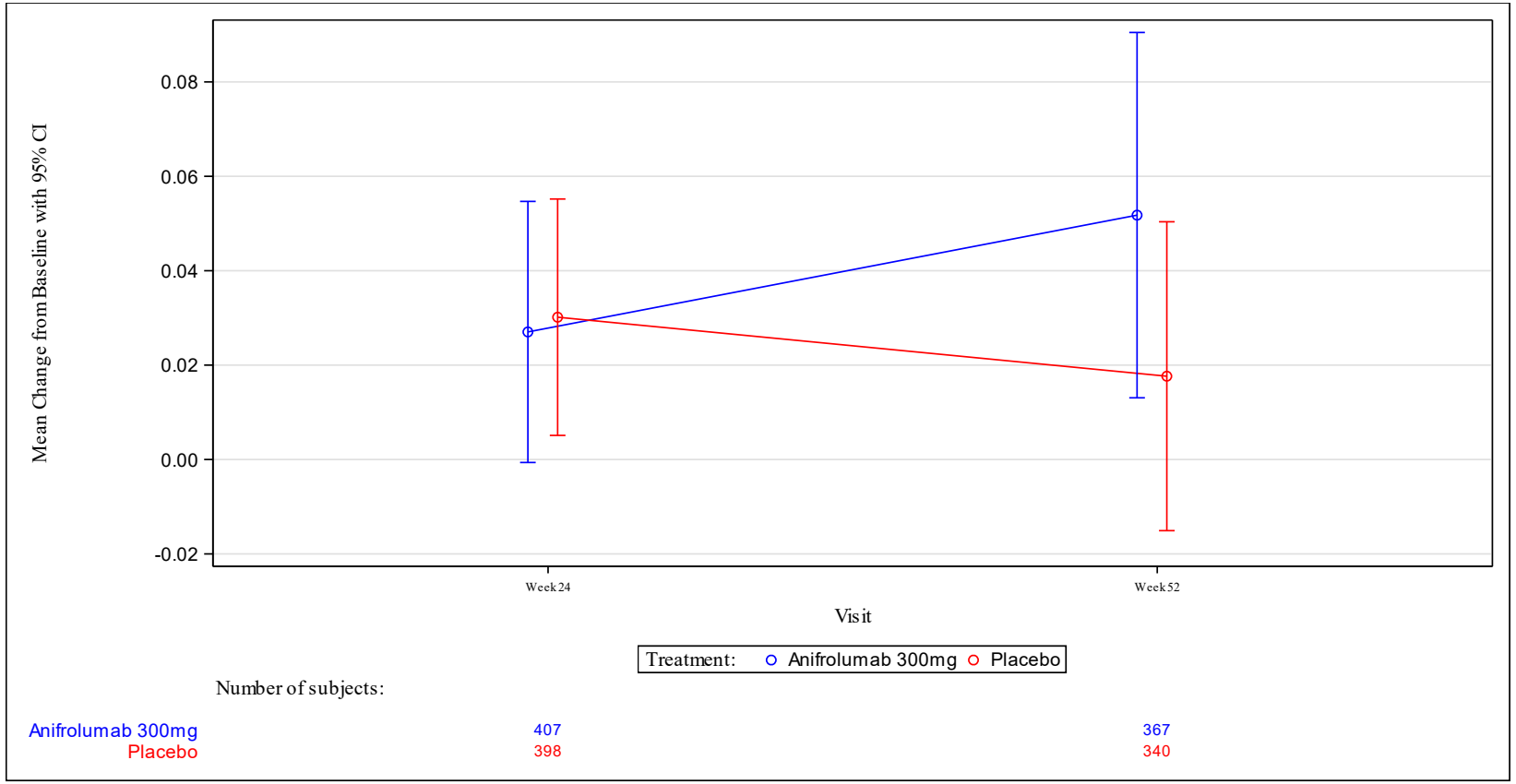
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - SDI Global Score
Full analysis set

	Anifrolumab 300mg (N=459)				Placebo (N=468)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	449	0.59 (1.02)	0	-	453	0.58 (0.97)	0	-
Week 24	410	0.63 (1.06)	407	0.03 (0.28)	405	0.61 (1.04)	398	0.03 (0.25)
Week 52	373	0.67 (1.03)	367	0.05 (0.38)	353	0.54 (0.93)	340	0.02 (0.31)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - SDI Global Score
Full analysis set



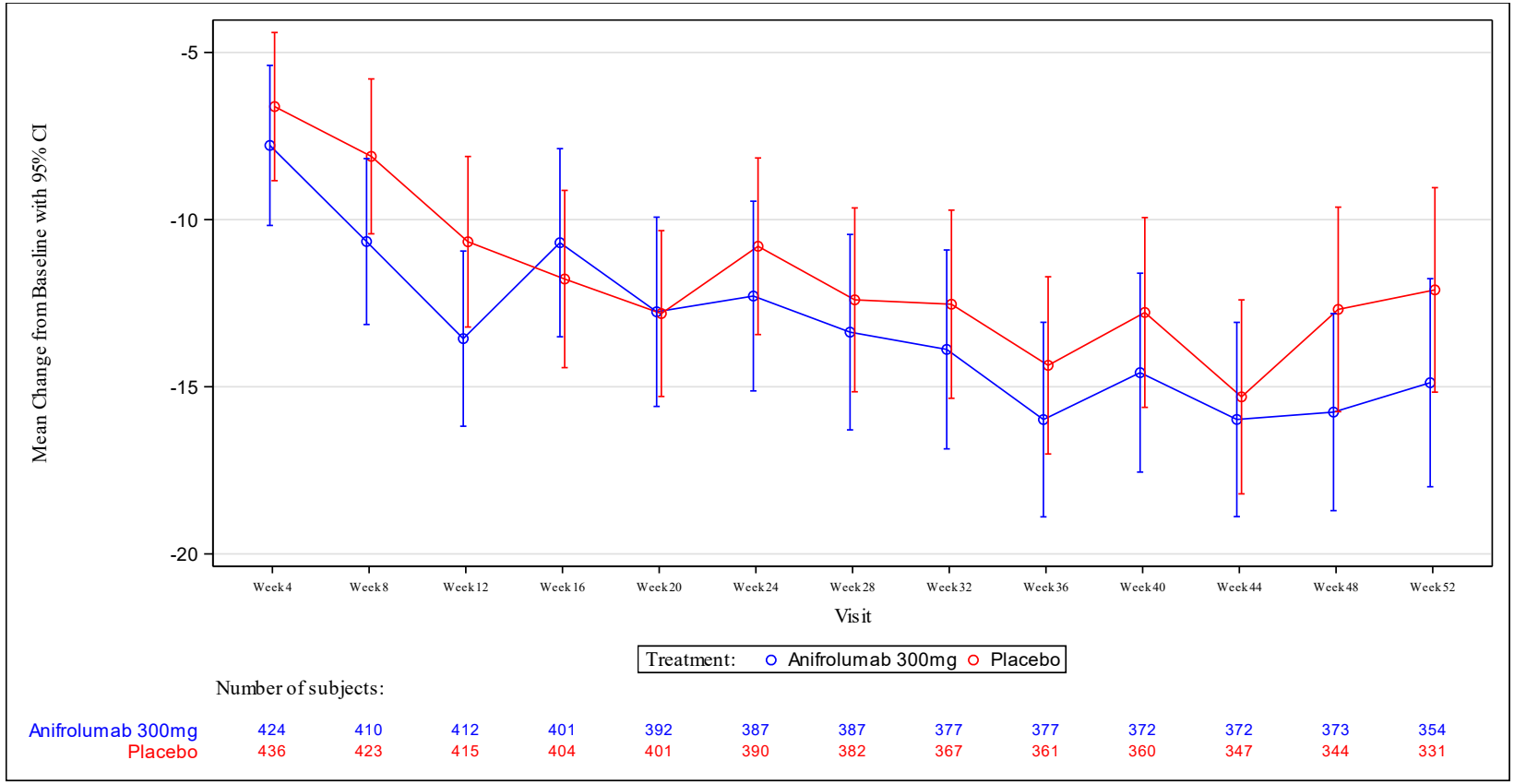
N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint (observed values) - PtGA
Full analysis set

	Anifrolumab 300mg (N=459)				Placebo (N=468)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	440	54.81 (22.44)	0	-	451	55.38 (22.54)	0	-
Week 4	435	46.81 (22.56)	424	-7.78 (25.08)	448	49.02 (23.42)	436	-6.62 (23.54)
Week 8	422	44.05 (23.16)	410	-10.66 (25.56)	436	47.44 (23.82)	423	-8.11 (24.24)
Week 12	426	41.11 (24.18)	412	-13.56 (27.05)	428	45.07 (24.87)	415	-10.66 (26.43)
Week 16	416	43.70 (25.44)	401	-10.69 (28.66)	415	43.84 (24.63)	404	-11.78 (27.10)
Week 20	406	41.20 (24.21)	392	-12.76 (28.51)	415	42.46 (24.57)	401	-12.81 (25.26)
Week 24	404	42.09 (25.44)	387	-12.29 (28.39)	404	44.51 (25.00)	390	-10.80 (26.53)
Week 28	403	41.09 (24.70)	387	-13.37 (29.25)	395	42.27 (24.72)	382	-12.40 (27.33)
Week 32	392	40.62 (24.76)	377	-13.88 (29.37)	378	41.74 (25.25)	367	-12.53 (27.41)
Week 36	394	38.76 (24.78)	377	-15.98 (28.73)	371	39.67 (24.31)	361	-14.36 (25.61)
Week 40	388	39.65 (25.08)	372	-14.58 (29.17)	371	42.43 (25.64)	360	-12.78 (27.39)
Week 44	387	38.31 (24.64)	372	-15.98 (28.49)	356	39.87 (25.24)	347	-15.30 (27.48)
Week 48	389	38.86 (24.97)	373	-15.76 (28.94)	354	41.41 (25.67)	344	-12.69 (28.84)
Week 52	371	39.65 (26.30)	354	-14.88 (29.77)	341	42.36 (26.46)	331	-12.10 (28.28)

N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint (observed values) - PtGA
Full analysis set



N defines number of subjects with non-missing value at the respective visit.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SLEDAI-2K Total Score
Full analysis set

	Anifrolumab 300mg (N=459)		Placebo (N=468)		Difference of						
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		-0.82 (0.12)		-0.68 (0.12)	-0.15 (0.14)	(-0.42, 0.13)	0.2934				
Week 8		-2.24 (0.17)		-1.71 (0.17)	-0.53 (0.22)	(-0.97, -0.09)	0.0171				
Week 12		-3.59 (0.18)		-2.57 (0.18)	-1.02 (0.24)	(-1.49, -0.54)	<.0001				
Week 16		-4.15 (0.20)		-3.10 (0.20)	-1.05 (0.26)	(-1.57, -0.53)	<.0001				
Week 20		-4.66 (0.19)		-3.61 (0.19)	-1.05 (0.26)	(-1.56, -0.54)	<.0001				
Week 24		-5.02 (0.20)		-3.92 (0.20)	-1.10 (0.27)	(-1.62, -0.58)	<.0001				
Week 28		-5.30 (0.21)		-3.94 (0.21)	-1.36 (0.28)	(-1.91, -0.81)	<.0001				
Week 32		-5.52 (0.21)		-4.19 (0.21)	-1.33 (0.28)	(-1.88, -0.78)	<.0001				
Week 36		-5.52 (0.21)		-4.34 (0.21)	-1.19 (0.29)	(-1.75, -0.63)	<.0001				
Week 40		-5.60 (0.21)		-4.43 (0.21)	-1.16 (0.28)	(-1.72, -0.61)	<.0001				
Week 44		-5.80 (0.20)		-4.78 (0.21)	-1.02 (0.28)	(-1.56, -0.48)	0.0002				
Week 48		-5.90 (0.21)		-4.89 (0.21)	-1.00 (0.28)	(-1.56, -0.45)	0.0004				
Week 52		-6.15 (0.20)		-5.04 (0.21)	-1.11 (0.28)	(-1.65, -0.57)	<.0001				
OVERALL	458	-4.64 (0.16)	464	-3.63 (0.16)	-1.00 (0.21)	(-1.41, -0.60)	<.0001	-0.30 (0.07)	(-0.43, -0.17)	<.0001	0.6336

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SLEDAI-2K Total Score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=459)		Placebo (N=468)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.4729
< 10 points	147	-3.33 (0.20)	145	-2.52 (0.20)	-0.81 (0.28)	(-1.35, -0.27)	0.0034	-0.34 (0.12)	(-0.57, -0.11)	0.0044	
>= 10 points	311	-5.09 (0.21)	319	-4.01 (0.21)	-1.09 (0.27)	(-1.62, -0.56)	<.0001	-0.29 (0.08)	(-0.45, -0.13)	0.0003	
OCS dose											0.4573
<10 mg/day	214	-4.57 (0.21)	218	-3.73 (0.21)	-0.85 (0.28)	(-1.41, -0.29)	0.0030	-0.27 (0.10)	(-0.46, -0.08)	0.0046	
>=10 mg/day	244	-4.64 (0.24)	246	-3.49 (0.24)	-1.15 (0.29)	(-1.72, -0.58)	<.0001	-0.31 (0.09)	(-0.49, -0.13)	0.0007	
Result of type I IFN gene signature test											0.0024
LOW	86	-3.42 (0.29)	90	-3.58 (0.29)	0.16 (0.41)	(-0.65, 0.97)	0.6983	0.06 (0.15)	(-0.24, 0.35)	0.7010	
HIGH	372	-4.94 (0.17)	374	-3.67 (0.17)	-1.27 (0.23)	(-1.73, -0.81)	<.0001	-0.38 (0.07)	(-0.53, -0.24)	<.0001	
Age (years)											NE
<= 65	446	-4.66 (0.16)	460	-3.63 (0.16)	-1.03 (0.21)	(-1.44, -0.62)	<.0001	-0.30 (0.07)	(-0.43, -0.17)	<.0001	
> 65	12	NE	4	NE	NE	NE		NE	NE		
Sex											0.2674
male	33	-5.49 (0.54)	33	-3.78 (0.53)	-1.72 (0.66)	(-3.03, -0.40)	0.0113	-0.55 (0.25)	(-1.05, -0.06)	0.0276	
female	425	-4.58 (0.16)	431	-3.63 (0.16)	-0.95 (0.22)	(-1.37, -0.53)	<.0001	-0.28 (0.07)	(-0.41, -0.14)	<.0001	
Race											0.0699
White	270	-4.33 (0.20)	282	-3.72 (0.20)	-0.61 (0.26)	(-1.12, -0.10)	0.0195	-0.18 (0.09)	(-0.35, -0.02)	0.0322	
Black	64	-4.91 (0.44)	60	-3.49 (0.43)	-1.42 (0.54)	(-2.50, -0.35)	0.0099	-0.41 (0.18)	(-0.77, -0.06)	0.0225	
Other	116	-4.98 (0.34)	114	-3.31 (0.35)	-1.68 (0.43)	(-2.52, -0.83)	0.0001	-0.45 (0.13)	(-0.71, -0.19)	0.0008	
Ethnicity											0.4662
Hispanic/Latino	132	-4.62 (0.29)	130	-3.85 (0.29)	-0.77 (0.38)	(-1.51, -0.03)	0.0417	-0.23 (0.12)	(-0.48, 0.01)	0.0596	
Non-hispanic/Latino	318	-4.63 (0.19)	326	-3.53 (0.19)	-1.10 (0.25)	(-1.58, -0.61)	<.0001	-0.32 (0.08)	(-0.47, -0.16)	<.0001	
Geographic region											0.6573
EU	135	-5.14 (0.32)	145	-4.27 (0.32)	-0.86 (0.37)	(-1.60, -0.13)	0.0209	-0.23 (0.12)	(-0.46, 0.01)	0.0587	
non-EU	323	-4.44 (0.18)	319	-3.38 (0.19)	-1.06 (0.25)	(-1.55, -0.58)	<.0001	-0.32 (0.08)	(-0.48, -0.16)	<.0001	
Onset of disease											0.3534
Paediatric	36	-5.06 (0.82)	35	-3.22 (0.83)	-1.84 (0.96)	(-3.77, 0.08)	0.0607	-0.37 (0.24)	(-0.84, 0.10)	0.1226	
Adult	422	-4.56 (0.16)	429	-3.63 (0.16)	-0.93 (0.21)	(-1.33, -0.52)	<.0001	-0.28 (0.07)	(-0.42, -0.15)	<.0001	
ADA result											0.0912
Negative	427	-4.61 (0.16)	425	-3.70 (0.16)	-0.90 (0.21)	(-1.32, -0.49)	<.0001	-0.27 (0.07)	(-0.41, -0.14)	<.0001	
Positive (At any time)	31	-5.66 (0.92)	39	-3.24 (0.77)	-2.42 (0.87)	(-4.18, -0.67)	0.0079	-0.48 (0.24)	(-0.96, -0.00)	0.0480	
BMI (kg/m2)											0.3305
< 30	308	-4.95 (0.21)	335	-3.81 (0.20)	-1.14 (0.26)	(-1.65, -0.63)	<.0001	-0.31 (0.08)	(-0.47, -0.15)	<.0001	
>= 30	150	-4.02 (0.24)	129	-3.29 (0.25)	-0.73 (0.33)	(-1.38, -0.08)	0.0275	-0.25 (0.12)	(-0.49, -0.02)	0.0351	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - PGA
Full analysis set

Visit	Anifrolumab 300mg (N=459) N	Anifrolumab 300mg (N=459) LSMean (SE)	Placebo (N=468) N	Placebo (N=468) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		-0.29 (0.02)		-0.22 (0.02)	-0.06 (0.02)	(-0.11, -0.02)	0.0085				
Week 8		-0.51 (0.02)		-0.42 (0.02)	-0.09 (0.03)	(-0.15, -0.03)	0.0042				
Week 12		-0.67 (0.03)		-0.50 (0.03)	-0.17 (0.03)	(-0.24, -0.10)	<.0001				
Week 16		-0.76 (0.03)		-0.59 (0.03)	-0.17 (0.04)	(-0.24, -0.10)	<.0001				
Week 20		-0.83 (0.03)		-0.63 (0.03)	-0.19 (0.04)	(-0.27, -0.12)	<.0001				
Week 24		-0.87 (0.03)		-0.68 (0.03)	-0.19 (0.04)	(-0.26, -0.11)	<.0001				
Week 28		-0.92 (0.03)		-0.73 (0.03)	-0.19 (0.04)	(-0.27, -0.12)	<.0001				
Week 32		-0.95 (0.03)		-0.75 (0.03)	-0.19 (0.04)	(-0.27, -0.11)	<.0001				
Week 36		-0.97 (0.03)		-0.79 (0.03)	-0.18 (0.04)	(-0.26, -0.10)	<.0001				
Week 40		-0.99 (0.03)		-0.82 (0.03)	-0.17 (0.04)	(-0.25, -0.09)	<.0001				
Week 44		-1.03 (0.03)		-0.83 (0.03)	-0.20 (0.04)	(-0.28, -0.11)	<.0001				
Week 48		-1.03 (0.03)		-0.85 (0.03)	-0.18 (0.04)	(-0.26, -0.10)	<.0001				
Week 52		-1.05 (0.03)		-0.86 (0.03)	-0.19 (0.04)	(-0.27, -0.11)	<.0001				
OVERALL	458	-0.84 (0.02)	465	-0.67 (0.02)	-0.17 (0.03)	(-0.23, -0.11)	<.0001	-0.33 (0.07)	(-0.46, -0.20)	<.0001	0.9700

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - PGA - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=459)		Placebo (N=468)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.8396
< 10 points	147	-0.84 (0.04)	145	-0.69 (0.04)	-0.16 (0.06)	(-0.27, -0.05)	0.0047	-0.32 (0.12)	(-0.55, -0.09)	0.0070	
>= 10 points	311	-0.83 (0.03)	320	-0.66 (0.03)	-0.17 (0.04)	(-0.24, -0.10)	<.0001	-0.33 (0.08)	(-0.49, -0.17)	<.0001	
OCS dose											0.8303
<10 mg/day	214	-0.77 (0.03)	218	-0.61 (0.03)	-0.16 (0.04)	(-0.24, -0.07)	0.0003	-0.33 (0.10)	(-0.52, -0.14)	0.0007	
>=10 mg/day	244	-0.90 (0.03)	247	-0.73 (0.03)	-0.17 (0.04)	(-0.26, -0.09)	<.0001	-0.32 (0.09)	(-0.49, -0.14)	0.0005	
Result of type I IFN gene signature test											0.0185
LOW	86	-0.74 (0.05)	90	-0.72 (0.05)	-0.02 (0.07)	(-0.16, 0.11)	0.7140	-0.05 (0.15)	(-0.35, 0.24)	0.7176	
HIGH	372	-0.87 (0.03)	375	-0.67 (0.03)	-0.20 (0.03)	(-0.27, -0.14)	<.0001	-0.42 (0.07)	(-0.56, -0.27)	<.0001	
Age (years)											NE
<= 65	446	-0.84 (0.02)	461	-0.67 (0.02)	-0.17 (0.03)	(-0.23, -0.11)	<.0001	-0.33 (0.07)	(-0.46, -0.20)	<.0001	
> 65	12	NE	4	NE	NE	NE		NE	NE		
Sex											0.7793
male	33	-0.94 (0.10)	34	-0.80 (0.09)	-0.14 (0.11)	(-0.35, 0.08)	0.1997	-0.25 (0.25)	(-0.73, 0.23)	0.3153	
female	425	-0.83 (0.02)	431	-0.66 (0.02)	-0.17 (0.03)	(-0.23, -0.11)	<.0001	-0.34 (0.07)	(-0.47, -0.20)	<.0001	
Race											0.1337
White	270	-0.77 (0.03)	283	-0.66 (0.03)	-0.11 (0.04)	(-0.18, -0.03)	0.0041	-0.22 (0.09)	(-0.39, -0.05)	0.0096	
Black	64	-0.82 (0.07)	60	-0.64 (0.07)	-0.18 (0.08)	(-0.35, -0.02)	0.0310	-0.34 (0.18)	(-0.69, 0.02)	0.0617	
Other	116	-0.92 (0.05)	114	-0.66 (0.06)	-0.26 (0.06)	(-0.38, -0.13)	0.0001	-0.44 (0.13)	(-0.70, -0.18)	0.0010	
Ethnicity											0.0750
Hispanic/Latino	132	-0.86 (0.04)	130	-0.78 (0.05)	-0.08 (0.06)	(-0.19, 0.04)	0.1854	-0.15 (0.12)	(-0.39, 0.09)	0.2301	
Non-hispanic/Latino	318	-0.81 (0.03)	327	-0.61 (0.03)	-0.20 (0.04)	(-0.27, -0.13)	<.0001	-0.40 (0.08)	(-0.55, -0.24)	<.0001	
Geographic region											0.9389
EU	135	-0.81 (0.04)	146	-0.65 (0.04)	-0.16 (0.05)	(-0.26, -0.06)	0.0018	-0.30 (0.12)	(-0.54, -0.07)	0.0112	
non-EU	323	-0.83 (0.03)	319	-0.66 (0.03)	-0.17 (0.04)	(-0.24, -0.09)	<.0001	-0.33 (0.08)	(-0.48, -0.17)	<.0001	
Onset of disease											0.6674
Paediatric	36	-0.76 (0.11)	35	-0.54 (0.11)	-0.22 (0.13)	(-0.47, 0.03)	0.0859	-0.33 (0.24)	(-0.80, 0.14)	0.1698	
Adult	422	-0.84 (0.02)	430	-0.68 (0.02)	-0.16 (0.03)	(-0.22, -0.10)	<.0001	-0.33 (0.07)	(-0.46, -0.19)	<.0001	
ADA result											0.3374
Negative	427	-0.83 (0.02)	426	-0.67 (0.02)	-0.16 (0.03)	(-0.22, -0.10)	<.0001	-0.31 (0.07)	(-0.45, -0.18)	<.0001	
Positive (At any time)	31	-0.84 (0.14)	39	-0.56 (0.12)	-0.28 (0.13)	(-0.53, -0.03)	0.0280	-0.35 (0.24)	(-0.83, 0.12)	0.1452	
BMI (kg/m2)											0.5325
< 30	308	-0.86 (0.03)	336	-0.67 (0.03)	-0.18 (0.04)	(-0.25, -0.11)	<.0001	-0.34 (0.08)	(-0.50, -0.19)	<.0001	
>= 30	150	-0.79 (0.04)	129	-0.65 (0.04)	-0.14 (0.05)	(-0.25, -0.03)	0.0107	-0.29 (0.12)	(-0.53, -0.06)	0.0156	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - CLASI Total Activity Score
Full analysis set

	Anifrolumab 300mg (N=459)		Placebo (N=468)		Difference of						
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		-1.56 (0.17)		-0.90 (0.17)	-0.66 (0.21)	(-1.07, -0.25)	0.0016				
Week 8		-2.98 (0.18)		-1.76 (0.18)	-1.22 (0.23)	(-1.68, -0.76)	<.0001				
Week 12		-3.71 (0.19)		-2.26 (0.19)	-1.45 (0.25)	(-1.94, -0.96)	<.0001				
Week 16		-4.19 (0.20)		-2.67 (0.20)	-1.52 (0.26)	(-2.03, -1.00)	<.0001				
Week 20		-4.55 (0.20)		-2.89 (0.20)	-1.66 (0.27)	(-2.18, -1.13)	<.0001				
Week 24		-4.74 (0.21)		-2.96 (0.21)	-1.79 (0.28)	(-2.33, -1.24)	<.0001				
Week 28		-5.01 (0.21)		-3.17 (0.21)	-1.84 (0.28)	(-2.38, -1.30)	<.0001				
Week 32		-5.14 (0.21)		-3.37 (0.21)	-1.77 (0.28)	(-2.32, -1.22)	<.0001				
Week 36		-5.28 (0.21)		-3.65 (0.21)	-1.63 (0.28)	(-2.17, -1.09)	<.0001				
Week 40		-5.38 (0.21)		-3.65 (0.22)	-1.73 (0.28)	(-2.28, -1.17)	<.0001				
Week 44		-5.39 (0.22)		-3.83 (0.22)	-1.56 (0.29)	(-2.13, -0.99)	<.0001				
Week 48		-5.49 (0.22)		-3.99 (0.22)	-1.50 (0.29)	(-2.06, -0.93)	<.0001				
Week 52		-5.65 (0.22)		-4.00 (0.22)	-1.65 (0.29)	(-2.21, -1.08)	<.0001				
OVERALL	458	-4.54 (0.18)	465	-3.01 (0.18)	-1.54 (0.23)	(-1.98, -1.09)	<.0001	-0.40 (0.07)	(-0.53, -0.27)	<.0001	0.9821

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - CLASI Total Activity Score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=459)		Placebo (N=468)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.1074
< 10 points	147	-3.72 (0.25)	145	-2.67 (0.25)	-1.06 (0.34)	(-1.72, -0.39)	0.0020	-0.35 (0.12)	(-0.58, -0.12)	0.0029	
>= 10 points	311	-4.88 (0.24)	320	-3.10 (0.24)	-1.78 (0.29)	(-2.35, -1.20)	<.0001	-0.42 (0.08)	(-0.58, -0.26)	<.0001	
OCS dose											0.4662
<10 mg/day	214	-3.94 (0.25)	218	-2.67 (0.25)	-1.27 (0.34)	(-1.93, -0.60)	0.0002	-0.34 (0.10)	(-0.53, -0.15)	0.0004	
>=10 mg/day	244	-4.89 (0.25)	247	-3.30 (0.25)	-1.59 (0.29)	(-2.16, -1.02)	<.0001	-0.41 (0.09)	(-0.59, -0.23)	<.0001	
Result of type I IFN gene signature test											<.0001
LOW	86	-2.73 (0.22)	90	-2.69 (0.22)	-0.04 (0.30)	(-0.64, 0.56)	0.8936	-0.02 (0.15)	(-0.32, 0.28)	0.8947	
HIGH	372	-5.04 (0.20)	375	-3.17 (0.20)	-1.86 (0.27)	(-2.39, -1.34)	<.0001	-0.48 (0.07)	(-0.63, -0.34)	<.0001	
Age (years)											NE
<= 65	446	-4.54 (0.18)	461	-2.99 (0.18)	-1.55 (0.23)	(-2.00, -1.10)	<.0001	-0.40 (0.07)	(-0.53, -0.27)	<.0001	
> 65	12	NE	4	NE	NE	NE		NE	NE		
Sex											0.8680
male	33	-6.31 (1.27)	34	-4.55 (1.25)	-1.77 (1.57)	(-4.93, 1.40)	0.2661	-0.24 (0.25)	(-0.72, 0.24)	0.3288	
female	425	-4.37 (0.17)	431	-2.86 (0.17)	-1.50 (0.22)	(-1.93, -1.07)	<.0001	-0.42 (0.07)	(-0.56, -0.29)	<.0001	
Race											0.0038
White	270	-4.19 (0.21)	283	-3.35 (0.21)	-0.83 (0.26)	(-1.34, -0.33)	0.0014	-0.24 (0.09)	(-0.41, -0.07)	0.0050	
Black	64	-5.18 (0.43)	60	-3.08 (0.42)	-2.09 (0.53)	(-3.15, -1.04)	0.0002	-0.62 (0.18)	(-0.98, -0.26)	0.0007	
Other	116	-4.85 (0.42)	114	-2.31 (0.43)	-2.54 (0.52)	(-3.57, -1.51)	<.0001	-0.56 (0.13)	(-0.82, -0.29)	<.0001	
Ethnicity											0.0540
Hispanic/Latino	132	-3.49 (0.25)	130	-2.53 (0.25)	-0.96 (0.31)	(-1.57, -0.36)	0.0019	-0.34 (0.12)	(-0.58, -0.09)	0.0066	
Non-hispanic/Latino	318	-4.91 (0.23)	327	-3.12 (0.23)	-1.78 (0.29)	(-2.36, -1.20)	<.0001	-0.43 (0.08)	(-0.59, -0.28)	<.0001	
Geographic region											0.2693
EU	135	-4.50 (0.41)	146	-3.41 (0.41)	-1.09 (0.46)	(-2.01, -0.18)	0.0193	-0.23 (0.12)	(-0.46, 0.01)	0.0582	
non-EU	323	-4.45 (0.20)	319	-2.77 (0.20)	-1.68 (0.26)	(-2.19, -1.17)	<.0001	-0.47 (0.08)	(-0.63, -0.32)	<.0001	
Onset of disease											NE
Paediatric	36	NE	35	NE	NE	NE		NE	NE		
Adult	422	-4.51 (0.18)	430	-3.03 (0.18)	-1.48 (0.23)	(-1.94, -1.03)	<.0001	-0.39 (0.07)	(-0.53, -0.26)	<.0001	
ADA result											0.0056
Negative	427	-4.51 (0.18)	426	-3.12 (0.18)	-1.39 (0.23)	(-1.85, -0.93)	<.0001	-0.37 (0.07)	(-0.51, -0.24)	<.0001	
Positive (At any time)	31	-5.08 (0.91)	39	-1.23 (0.79)	-3.85 (0.86)	(-5.58, -2.13)	<.0001	-0.77 (0.25)	(-1.26, -0.28)	0.0021	
BMI (kg/m2)											0.0199
< 30	308	-4.90 (0.23)	336	-3.01 (0.23)	-1.89 (0.28)	(-2.44, -1.34)	<.0001	-0.46 (0.08)	(-0.61, -0.30)	<.0001	
>= 30	150	-3.76 (0.26)	129	-2.93 (0.27)	-0.84 (0.36)	(-1.54, -0.13)	0.0197	-0.27 (0.12)	(-0.50, -0.03)	0.0279	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - CLASI Total Damage Score
Full analysis set

	Anifrolumab 300mg (N=459)		Placebo (N=468)		Difference of						
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		-0.07 (0.07)		-0.02 (0.06)	-0.05 (0.08)	(-0.21, 0.10)	0.5034				
Week 8		-0.10 (0.08)		-0.14 (0.08)	0.04 (0.10)	(-0.17, 0.24)	0.7315				
Week 12		-0.24 (0.09)		-0.20 (0.09)	-0.04 (0.12)	(-0.26, 0.19)	0.7451				
Week 16		-0.36 (0.09)		-0.19 (0.09)	-0.17 (0.12)	(-0.40, 0.06)	0.1543				
Week 20		-0.40 (0.10)		-0.26 (0.10)	-0.15 (0.14)	(-0.41, 0.12)	0.2847				
Week 24		-0.53 (0.10)		-0.25 (0.10)	-0.28 (0.14)	(-0.55, -0.02)	0.0376				
Week 28		-0.53 (0.11)		-0.27 (0.11)	-0.26 (0.15)	(-0.55, 0.03)	0.0747				
Week 32		-0.54 (0.11)		-0.22 (0.11)	-0.32 (0.15)	(-0.62, -0.02)	0.0355				
Week 36		-0.55 (0.12)		-0.28 (0.12)	-0.27 (0.16)	(-0.58, 0.04)	0.0890				
Week 40		-0.58 (0.12)		-0.32 (0.12)	-0.26 (0.17)	(-0.59, 0.07)	0.1220				
Week 44		-0.63 (0.13)		-0.35 (0.13)	-0.28 (0.17)	(-0.62, 0.06)	0.1033				
Week 48		-0.58 (0.13)		-0.37 (0.13)	-0.21 (0.17)	(-0.55, 0.13)	0.2179				
Week 52		-0.60 (0.12)		-0.35 (0.13)	-0.25 (0.17)	(-0.59, 0.08)	0.1393				
OVERALL	458	-0.44 (0.09)	465	-0.25 (0.09)	-0.19 (0.12)	(-0.43, 0.05)	0.1140	-0.10 (0.07)	(-0.23, 0.03)	0.1394	0.2735

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - CLASI Total Damage Score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=459)		Placebo (N=468)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.5339
< 10 points	147	-0.21 (0.14)	145	-0.13 (0.14)	-0.08 (0.19)	(-0.46, 0.30)	0.6751	-0.05 (0.12)	(-0.28, 0.18)	0.6867	
>= 10 points	311	-0.53 (0.12)	320	-0.30 (0.12)	-0.23 (0.16)	(-0.54, 0.07)	0.1353	-0.11 (0.08)	(-0.27, 0.05)	0.1672	
OCS dose											NE
<10 mg/day	214	NE	218	NE	NE	NE		NE	NE		
>=10 mg/day	244	-0.34 (0.13)	247	-0.26 (0.13)	-0.08 (0.17)	(-0.41, 0.25)	0.6274	-0.04 (0.09)	(-0.22, 0.14)	0.6630	
Result of type I IFN gene signature test											0.7480
LOW	86	-0.26 (0.10)	90	-0.12 (0.10)	-0.14 (0.14)	(-0.41, 0.14)	0.3257	-0.15 (0.15)	(-0.44, 0.15)	0.3292	
HIGH	372	-0.47 (0.11)	375	-0.27 (0.11)	-0.20 (0.15)	(-0.49, 0.09)	0.1725	-0.10 (0.07)	(-0.24, 0.05)	0.1856	
Age (years)											NE
<= 65	446	-0.43 (0.09)	461	-0.23 (0.09)	-0.20 (0.12)	(-0.44, 0.04)	0.1062	-0.10 (0.07)	(-0.23, 0.03)	0.1318	
> 65	12	NE	4	NE	NE	NE		NE	NE		
Sex											NE
male	33	NE	34	NE	NE	NE		NE	NE		
female	425	-0.40 (0.09)	431	-0.25 (0.09)	-0.14 (0.12)	(-0.38, 0.10)	0.2412	-0.07 (0.07)	(-0.21, 0.06)	0.2730	
Race											NE
White	270	-0.52 (0.11)	283	-0.27 (0.11)	-0.25 (0.14)	(-0.54, 0.03)	0.0834	-0.14 (0.09)	(-0.30, 0.03)	0.1094	
Black	64	-0.62 (0.34)	60	-0.67 (0.34)	0.05 (0.45)	(-0.83, 0.93)	0.9110	0.02 (0.18)	(-0.33, 0.37)	0.9183	
Other	116	NE	114	NE	NE	NE		NE	NE		
Ethnicity											0.1724
Hispanic/Latino	132	-0.14 (0.13)	130	-0.18 (0.14)	0.04 (0.18)	(-0.31, 0.39)	0.8225	0.03 (0.12)	(-0.22, 0.27)	0.8326	
Non-hispanic/Latino	318	-0.58 (0.12)	327	-0.30 (0.12)	-0.28 (0.16)	(-0.59, 0.02)	0.0682	-0.13 (0.08)	(-0.29, 0.02)	0.0877	
Geographic region											0.0442
EU	135	-0.70 (0.20)	146	-0.12 (0.20)	-0.58 (0.23)	(-1.03, -0.14)	0.0109	-0.25 (0.12)	(-0.48, -0.01)	0.0405	
non-EU	323	-0.33 (0.10)	319	-0.29 (0.11)	-0.04 (0.14)	(-0.32, 0.24)	0.7724	-0.02 (0.08)	(-0.18, 0.13)	0.7801	
Onset of disease											NE
Paediatric	36	NE	35	NE	NE	NE		NE	NE		
Adult	422	-0.39 (0.10)	430	-0.22 (0.09)	-0.16 (0.13)	(-0.41, 0.08)	0.1959	-0.08 (0.07)	(-0.22, 0.05)	0.2263	
ADA result											NE
Negative	427	-0.48 (0.09)	426	-0.27 (0.10)	-0.21 (0.13)	(-0.45, 0.04)	0.1051	-0.10 (0.07)	(-0.24, 0.03)	0.1276	
Positive (At any time)	31	NE	39	NE	NE	NE		NE	NE		
BMI (kg/m2)											0.7400
< 30	308	-0.49 (0.11)	336	-0.26 (0.11)	-0.23 (0.14)	(-0.50, 0.04)	0.1008	-0.12 (0.08)	(-0.27, 0.04)	0.1414	
>= 30	150	-0.30 (0.18)	129	-0.16 (0.19)	-0.13 (0.25)	(-0.63, 0.37)	0.6066	-0.06 (0.12)	(-0.30, 0.17)	0.6137	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - BILAG Global Score
Full analysis set

Visit	Anifrolumab 300mg (N=459) N	Anifrolumab 300mg (N=459) LSMean (SE)	Placebo (N=468) N	Placebo (N=468) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		-4.84 (0.31)		-4.11 (0.30)	-0.74 (0.38)	(-1.49, 0.02)	0.0562				
Week 8		-8.10 (0.34)		-6.38 (0.34)	-1.72 (0.44)	(-2.59, -0.85)	0.0001				
Week 12		-9.43 (0.35)		-7.65 (0.35)	-1.79 (0.46)	(-2.68, -0.89)	<.0001				
Week 16		-10.02 (0.36)		-8.27 (0.36)	-1.75 (0.48)	(-2.68, -0.81)	0.0003				
Week 20		-10.51 (0.37)		-8.82 (0.36)	-1.69 (0.48)	(-2.63, -0.76)	0.0004				
Week 24		-10.89 (0.36)		-8.88 (0.36)	-2.01 (0.48)	(-2.94, -1.08)	<.0001				
Week 28		-11.19 (0.37)		-9.12 (0.37)	-2.07 (0.49)	(-3.03, -1.11)	<.0001				
Week 32		-11.45 (0.37)		-9.46 (0.37)	-1.99 (0.49)	(-2.94, -1.04)	<.0001				
Week 36		-11.40 (0.37)		-10.02 (0.38)	-1.38 (0.49)	(-2.35, -0.41)	0.0052				
Week 40		-11.49 (0.38)		-9.90 (0.38)	-1.59 (0.50)	(-2.57, -0.61)	0.0015				
Week 44		-11.72 (0.37)		-9.98 (0.37)	-1.73 (0.49)	(-2.69, -0.77)	0.0004				
Week 48		-12.21 (0.36)		-10.35 (0.37)	-1.86 (0.48)	(-2.80, -0.91)	0.0001				
Week 52		-12.56 (0.37)		-10.56 (0.38)	-1.99 (0.49)	(-2.95, -1.03)	<.0001				
OVERALL	458	-10.45 (0.29)	465	-8.73 (0.29)	-1.72 (0.37)	(-2.43, -1.00)	<.0001	-0.27 (0.07)	(-0.40, -0.14)	<.0001	0.9519

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - BILAG Global Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=459) N	LSMean (SE)	Placebo (N=468) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.7127
< 10 points	147	-10.13 (0.44)	145	-8.60 (0.44)	-1.53 (0.58)	(-2.68, -0.38)	0.0092	-0.29 (0.12)	(-0.52, -0.06)	0.0142	
>= 10 points	311	-10.54 (0.38)	320	-8.74 (0.38)	-1.80 (0.46)	(-2.71, -0.90)	0.0001	-0.26 (0.08)	(-0.42, -0.11)	0.0009	
OCS dose											0.9361
<10 mg/day	214	-10.37 (0.40)	218	-8.64 (0.41)	-1.73 (0.53)	(-2.77, -0.70)	0.0011	-0.29 (0.10)	(-0.48, -0.10)	0.0027	
>=10 mg/day	244	-10.32 (0.43)	247	-8.65 (0.43)	-1.67 (0.50)	(-2.66, -0.68)	0.0010	-0.25 (0.09)	(-0.42, -0.07)	0.0067	
Result of type I IFN gene signature test											0.0034
LOW	86	-9.54 (0.60)	90	-10.01 (0.59)	0.47 (0.82)	(-1.15, 2.09)	0.5675	0.08 (0.15)	(-0.21, 0.38)	0.5751	
HIGH	372	-10.46 (0.30)	375	-8.24 (0.31)	-2.22 (0.41)	(-3.01, -1.42)	<.0001	-0.38 (0.07)	(-0.52, -0.23)	<.0001	
Age (years)											NE
<= 65	446	-10.47 (0.30)	461	-8.76 (0.30)	-1.71 (0.37)	(-2.44, -0.99)	<.0001	-0.27 (0.07)	(-0.40, -0.14)	<.0001	
> 65	12	NE	4	NE	NE	NE		NE	NE		
Sex											0.3265
male	33	-11.46 (1.00)	34	-8.68 (0.98)	-2.78 (1.09)	(-4.97, -0.59)	0.0137	-0.48 (0.25)	(-0.97, 0.01)	0.0528	
female	425	-10.37 (0.31)	431	-8.73 (0.31)	-1.64 (0.39)	(-2.40, -0.88)	<.0001	-0.26 (0.07)	(-0.39, -0.12)	0.0002	
Race											0.1071
White	270	-10.05 (0.40)	283	-8.95 (0.39)	-1.09 (0.48)	(-2.04, -0.15)	0.0235	-0.17 (0.09)	(-0.33, -0.00)	0.0494	
Black	64	-10.19 (0.78)	60	-7.33 (0.75)	-2.86 (0.91)	(-4.67, -1.05)	0.0022	-0.47 (0.18)	(-0.83, -0.11)	0.0097	
Other	116	-11.04 (0.63)	114	-8.53 (0.66)	-2.52 (0.73)	(-3.95, -1.09)	0.0006	-0.36 (0.13)	(-0.62, -0.10)	0.0064	
Ethnicity											0.2266
Hispanic/Latino	132	-10.98 (0.55)	130	-9.98 (0.55)	-0.99 (0.68)	(-2.33, 0.34)	0.1434	-0.16 (0.12)	(-0.40, 0.08)	0.2003	
Non-hispanic/Latino	318	-10.02 (0.35)	327	-8.06 (0.35)	-1.96 (0.43)	(-2.80, -1.12)	<.0001	-0.31 (0.08)	(-0.47, -0.16)	<.0001	
Geographic region											0.3897
EU	135	-10.35 (0.62)	146	-9.12 (0.63)	-1.22 (0.65)	(-2.51, 0.06)	0.0621	-0.16 (0.12)	(-0.40, 0.07)	0.1688	
non-EU	323	-10.34 (0.34)	319	-8.45 (0.34)	-1.90 (0.44)	(-2.75, -1.04)	<.0001	-0.31 (0.08)	(-0.47, -0.16)	<.0001	
Onset of disease											0.9223
Paediatric	36	-11.11 (1.32)	35	-9.27 (1.28)	-1.83 (1.37)	(-4.58, 0.91)	0.1868	-0.23 (0.24)	(-0.70, 0.23)	0.3249	
Adult	422	-10.41 (0.30)	430	-8.71 (0.30)	-1.70 (0.38)	(-2.44, -0.95)	<.0001	-0.27 (0.07)	(-0.41, -0.14)	<.0001	
ADA result											0.0364
Negative	427	-10.35 (0.30)	426	-8.80 (0.30)	-1.55 (0.38)	(-2.29, -0.80)	<.0001	-0.25 (0.07)	(-0.38, -0.11)	0.0003	
Positive (At any time)	31	-13.01 (1.65)	39	-8.36 (1.45)	-4.64 (1.43)	(-7.50, -1.78)	0.0019	-0.50 (0.24)	(-0.98, -0.02)	0.0396	
BMI (kg/m2)											0.6664
< 30	308	-11.00 (0.37)	336	-9.11 (0.37)	-1.89 (0.44)	(-2.74, -1.04)	<.0001	-0.28 (0.08)	(-0.44, -0.13)	0.0003	
>= 30	150	-9.71 (0.50)	129	-8.16 (0.52)	-1.54 (0.68)	(-2.87, -0.21)	0.0232	-0.26 (0.12)	(-0.49, -0.02)	0.0337	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Tender Joint Count
Full analysis set

Visit	Anifrolumab 300mg (N=459) N	Anifrolumab 300mg (N=459) LSMean (SE)	Placebo (N=468) N	Placebo (N=468) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		-2.06 (0.27)		-2.14 (0.27)	0.08 (0.34)	(-0.59, 0.75)	0.8177				
Week 8		-4.16 (0.28)		-3.67 (0.27)	-0.48 (0.35)	(-1.17, 0.21)	0.1727				
Week 12		-5.02 (0.29)		-4.40 (0.29)	-0.61 (0.37)	(-1.35, 0.12)	0.1010				
Week 16		-5.53 (0.30)		-5.02 (0.30)	-0.51 (0.39)	(-1.27, 0.24)	0.1840				
Week 20		-5.83 (0.30)		-5.21 (0.30)	-0.62 (0.39)	(-1.39, 0.15)	0.1125				
Week 24		-5.93 (0.31)		-5.24 (0.31)	-0.69 (0.41)	(-1.50, 0.11)	0.0905				
Week 28		-6.26 (0.30)		-5.62 (0.30)	-0.64 (0.38)	(-1.39, 0.11)	0.0950				
Week 32		-6.20 (0.31)		-5.44 (0.31)	-0.76 (0.40)	(-1.55, 0.03)	0.0596				
Week 36		-6.52 (0.31)		-5.67 (0.31)	-0.85 (0.41)	(-1.65, -0.06)	0.0360				
Week 40		-6.42 (0.31)		-6.02 (0.31)	-0.40 (0.40)	(-1.19, 0.39)	0.3202				
Week 44		-6.84 (0.30)		-6.04 (0.31)	-0.80 (0.40)	(-1.58, -0.02)	0.0445				
Week 48		-6.88 (0.31)		-6.01 (0.31)	-0.87 (0.40)	(-1.66, -0.08)	0.0305				
Week 52		-6.57 (0.32)		-5.95 (0.33)	-0.62 (0.43)	(-1.45, 0.22)	0.1488				
OVERALL	457	-5.71 (0.25)	463	-5.11 (0.24)	-0.60 (0.30)	(-1.19, -0.00)	0.0488	-0.11 (0.07)	(-0.24, 0.02)	0.0846	0.1384

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Tender Joint Count - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=459) N	LSMean (SE)	Placebo (N=468) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.6772
< 10 points	147	-6.24 (0.44)	145	-5.45 (0.44)	-0.79 (0.58)	(-1.92, 0.35)	0.1732	-0.15 (0.12)	(-0.38, 0.08)	0.2031	
>= 10 points	310	-5.45 (0.29)	318	-4.95 (0.29)	-0.51 (0.35)	(-1.20, 0.19)	0.1530	-0.10 (0.08)	(-0.25, 0.06)	0.2249	
OCS dose											0.4450
<10 mg/day	213	-5.35 (0.35)	218	-4.53 (0.35)	-0.81 (0.46)	(-1.71, 0.09)	0.0769	-0.16 (0.10)	(-0.34, 0.03)	0.1067	
>=10 mg/day	244	-6.18 (0.34)	245	-5.83 (0.34)	-0.35 (0.40)	(-1.13, 0.44)	0.3828	-0.06 (0.09)	(-0.24, 0.11)	0.4743	
Result of type I IFN gene signature test											0.1299
LOW	86	-6.48 (0.62)	90	-4.73 (0.61)	-1.75 (0.86)	(-3.45, -0.05)	0.0432	-0.30 (0.15)	(-0.60, -0.00)	0.0467	
HIGH	371	-5.92 (0.24)	373	-5.55 (0.24)	-0.37 (0.31)	(-0.98, 0.25)	0.2441	-0.08 (0.07)	(-0.22, 0.06)	0.2748	
Age (years)											NE
<= 65	445	-5.67 (0.25)	459	-5.07 (0.25)	-0.60 (0.31)	(-1.20, 0.00)	0.0509	-0.11 (0.07)	(-0.24, 0.02)	0.0885	
> 65	12	NE	4	NE	NE	NE		NE	NE		
Sex											0.9921
male	33	-5.18 (0.79)	34	-4.61 (0.77)	-0.57 (0.91)	(-2.39, 1.25)	0.5322	-0.12 (0.24)	(-0.60, 0.36)	0.6110	
female	424	-5.76 (0.26)	429	-5.20 (0.26)	-0.56 (0.32)	(-1.19, 0.07)	0.0793	-0.11 (0.07)	(-0.24, 0.03)	0.1232	
Race											0.6240
White	270	-5.85 (0.32)	281	-5.57 (0.32)	-0.29 (0.39)	(-1.06, 0.49)	0.4661	-0.05 (0.09)	(-0.22, 0.11)	0.5294	
Black	64	-4.27 (0.81)	60	-3.18 (0.77)	-1.08 (0.92)	(-2.90, 0.74)	0.2413	-0.17 (0.18)	(-0.53, 0.18)	0.3364	
Other	115	-5.44 (0.48)	114	-4.65 (0.50)	-0.78 (0.56)	(-1.89, 0.33)	0.1658	-0.15 (0.13)	(-0.41, 0.11)	0.2639	
Ethnicity											0.4988
Hispanic/Latino	131	-6.44 (0.49)	130	-6.26 (0.49)	-0.18 (0.60)	(-1.37, 1.01)	0.7648	-0.03 (0.12)	(-0.28, 0.21)	0.7928	
Non-hispanic/Latino	318	-5.31 (0.29)	325	-4.66 (0.29)	-0.65 (0.35)	(-1.35, 0.04)	0.0634	-0.13 (0.08)	(-0.28, 0.03)	0.1105	
Geographic region											0.1733
EU	135	-5.74 (0.42)	144	-5.81 (0.42)	0.07 (0.43)	(-0.79, 0.93)	0.8728	0.01 (0.12)	(-0.22, 0.25)	0.9074	
non-EU	322	-5.65 (0.30)	319	-4.93 (0.30)	-0.72 (0.38)	(-1.48, 0.04)	0.0616	-0.13 (0.08)	(-0.29, 0.02)	0.0907	
Onset of disease											0.0624
Paediatric	36	-3.10 (0.90)	35	-4.18 (0.87)	1.08 (0.92)	(-0.77, 2.94)	0.2453	0.20 (0.24)	(-0.26, 0.67)	0.3921	
Adult	421	-5.89 (0.26)	428	-5.16 (0.26)	-0.74 (0.32)	(-1.36, -0.11)	0.0209	-0.14 (0.07)	(-0.27, -0.00)	0.0423	
ADA result											0.6000
Negative	426	-5.70 (0.25)	424	-5.18 (0.25)	-0.52 (0.32)	(-1.14, 0.10)	0.0999	-0.10 (0.07)	(-0.23, 0.03)	0.1460	
Positive (At any time)	31	-5.83 (1.43)	39	-4.62 (1.25)	-1.21 (1.29)	(-3.80, 1.37)	0.3501	-0.15 (0.24)	(-0.62, 0.32)	0.5269	
BMI (kg/m2)											0.8973
< 30	307	-5.64 (0.29)	334	-5.00 (0.29)	-0.64 (0.34)	(-1.32, 0.03)	0.0624	-0.12 (0.08)	(-0.28, 0.03)	0.1179	
>= 30	150	-6.23 (0.46)	129	-5.68 (0.48)	-0.55 (0.61)	(-1.76, 0.65)	0.3676	-0.10 (0.12)	(-0.33, 0.14)	0.4080	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Swollen Joint Count
Full analysis set

	Anifrolumab 300mg (N=459)		Placebo (N=468)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 4		-2.55 (0.20)		-2.28 (0.20)	-0.27 (0.25)	(-0.77, 0.23)	0.2848				
Week 8		-3.60 (0.20)		-3.58 (0.20)	-0.02 (0.26)	(-0.53, 0.49)	0.9452				
Week 12		-4.33 (0.21)		-3.91 (0.21)	-0.42 (0.27)	(-0.96, 0.11)	0.1226				
Week 16		-4.59 (0.21)		-4.34 (0.21)	-0.25 (0.27)	(-0.79, 0.28)	0.3471				
Week 20		-4.84 (0.21)		-4.55 (0.21)	-0.29 (0.27)	(-0.83, 0.24)	0.2832				
Week 24		-4.85 (0.21)		-4.74 (0.21)	-0.11 (0.27)	(-0.65, 0.42)	0.6756				
Week 28		-5.11 (0.21)		-4.64 (0.21)	-0.47 (0.27)	(-0.99, 0.06)	0.0801				
Week 32		-5.03 (0.22)		-4.66 (0.22)	-0.37 (0.28)	(-0.93, 0.18)	0.1889				
Week 36		-5.10 (0.22)		-4.80 (0.22)	-0.30 (0.28)	(-0.86, 0.25)	0.2881				
Week 40		-5.08 (0.22)		-4.92 (0.22)	-0.16 (0.29)	(-0.72, 0.40)	0.5732				
Week 44		-5.18 (0.22)		-4.79 (0.22)	-0.39 (0.29)	(-0.96, 0.18)	0.1765				
Week 48		-5.27 (0.22)		-4.88 (0.22)	-0.39 (0.29)	(-0.96, 0.18)	0.1792				
Week 52		-5.29 (0.21)		-5.03 (0.21)	-0.25 (0.28)	(-0.80, 0.29)	0.3613				
OVERALL	457	-4.68 (0.17)	463	-4.39 (0.17)	-0.29 (0.21)	(-0.70, 0.13)	0.1802	-0.08 (0.07)	(-0.21, 0.05)	0.2427	0.0154

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Swollen Joint Count - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=459)		Placebo (N=468)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.8981
< 10 points	147	-4.93 (0.31)	145	-4.61 (0.31)	-0.32 (0.41)	(-1.12, 0.48)	0.4270	-0.09 (0.12)	(-0.32, 0.14)	0.4592	
>= 10 points	310	-4.47 (0.21)	318	-4.21 (0.21)	-0.26 (0.25)	(-0.75, 0.22)	0.2880	-0.07 (0.08)	(-0.23, 0.08)	0.3681	
OCS dose											0.5968
<10 mg/day	213	-4.28 (0.25)	218	-4.10 (0.25)	-0.18 (0.32)	(-0.80, 0.45)	0.5765	-0.05 (0.10)	(-0.24, 0.14)	0.6120	
>=10 mg/day	244	-5.06 (0.24)	245	-4.66 (0.24)	-0.40 (0.28)	(-0.94, 0.14)	0.1490	-0.11 (0.09)	(-0.28, 0.07)	0.2393	
Result of type I IFN gene signature test											0.1889
LOW	86	-5.63 (0.38)	90	-4.73 (0.37)	-0.90 (0.52)	(-1.93, 0.13)	0.0855	-0.26 (0.15)	(-0.55, 0.04)	0.0911	
HIGH	371	-4.41 (0.17)	373	-4.26 (0.17)	-0.15 (0.23)	(-0.60, 0.30)	0.5037	-0.05 (0.07)	(-0.19, 0.10)	0.5310	
Age (years)											NE
<= 65	445	-4.68 (0.18)	459	-4.40 (0.17)	-0.28 (0.22)	(-0.71, 0.14)	0.1880	-0.08 (0.07)	(-0.21, 0.05)	0.2522	
> 65	12	NE	4	NE	NE	NE		NE	NE		
Sex											0.7571
male	33	-4.32 (0.58)	34	-3.83 (0.57)	-0.49 (0.69)	(-1.88, 0.90)	0.4803	-0.15 (0.24)	(-0.62, 0.33)	0.5527	
female	424	-4.71 (0.18)	429	-4.44 (0.18)	-0.27 (0.22)	(-0.70, 0.17)	0.2292	-0.07 (0.07)	(-0.21, 0.06)	0.2931	
Race											0.2376
White	270	-4.44 (0.22)	281	-4.44 (0.22)	0.01 (0.26)	(-0.51, 0.52)	0.9797	0.00 (0.09)	(-0.17, 0.17)	0.9827	
Black	64	-4.64 (0.57)	60	-3.71 (0.55)	-0.93 (0.65)	(-2.22, 0.36)	0.1552	-0.21 (0.18)	(-0.56, 0.14)	0.2441	
Other	115	-5.12 (0.35)	114	-4.51 (0.37)	-0.61 (0.40)	(-1.41, 0.18)	0.1290	-0.16 (0.13)	(-0.42, 0.10)	0.2330	
Ethnicity											0.1023
Hispanic/Latino	131	-5.41 (0.34)	130	-5.75 (0.34)	0.34 (0.41)	(-0.48, 1.16)	0.4139	0.09 (0.12)	(-0.15, 0.33)	0.4770	
Non-hispanic/Latino	318	-4.33 (0.20)	325	-3.88 (0.20)	-0.44 (0.24)	(-0.91, 0.03)	0.0653	-0.12 (0.08)	(-0.28, 0.03)	0.1144	
Geographic region											0.5631
EU	135	-4.16 (0.25)	144	-4.05 (0.25)	-0.12 (0.27)	(-0.66, 0.42)	0.6660	-0.04 (0.12)	(-0.27, 0.20)	0.7429	
non-EU	322	-4.81 (0.22)	319	-4.47 (0.22)	-0.34 (0.27)	(-0.88, 0.20)	0.2136	-0.09 (0.08)	(-0.24, 0.07)	0.2641	
Onset of disease											0.0960
Paediatric	36	-3.71 (0.76)	35	-4.78 (0.74)	1.07 (0.85)	(-0.64, 2.78)	0.2139	0.24 (0.24)	(-0.23, 0.70)	0.3200	
Adult	421	-4.78 (0.18)	428	-4.39 (0.18)	-0.39 (0.22)	(-0.82, 0.04)	0.0763	-0.11 (0.07)	(-0.24, 0.03)	0.1213	
ADA result											0.6138
Negative	426	-4.68 (0.18)	424	-4.45 (0.18)	-0.23 (0.22)	(-0.66, 0.20)	0.2893	-0.06 (0.07)	(-0.20, 0.07)	0.3504	
Positive (At any time)	31	-3.45 (1.15)	39	-2.73 (1.02)	-0.72 (0.94)	(-2.59, 1.16)	0.4464	-0.11 (0.24)	(-0.58, 0.36)	0.6437	
BMI (kg/m2)											0.2430
< 30	307	-4.60 (0.20)	334	-4.44 (0.20)	-0.17 (0.24)	(-0.63, 0.30)	0.4818	-0.05 (0.08)	(-0.20, 0.11)	0.5627	
>= 30	150	-5.03 (0.32)	129	-4.28 (0.33)	-0.74 (0.43)	(-1.59, 0.11)	0.0865	-0.19 (0.12)	(-0.43, 0.05)	0.1128	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Mental Component Score
Full analysis set

	Anifrolumab 300mg (N=459)		Placebo (N=468)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 4		0.54 (0.79)		-0.43 (0.79)	0.97 (1.05)	(-1.10, 3.04)	0.3550				
Week 8		1.65 (0.52)		0.92 (0.51)	0.73 (0.65)	(-0.54, 2.00)	0.2604				
Week 12		2.24 (0.88)		1.15 (0.88)	1.09 (1.21)	(-1.29, 3.46)	0.3690				
Week 16		1.40 (0.52)		1.32 (0.52)	0.08 (0.66)	(-1.22, 1.39)	0.9011				
Week 24		1.91 (0.50)		0.19 (0.49)	1.72 (0.64)	(0.47, 2.97)	0.0069				
Week 32		2.41 (0.53)		0.79 (0.53)	1.62 (0.68)	(0.28, 2.97)	0.0179				
Week 36		3.46 (0.89)		1.05 (0.96)	2.42 (1.28)	(-0.10, 4.94)	0.0599				
Week 40		2.37 (0.54)		1.56 (0.54)	0.80 (0.69)	(-0.55, 2.16)	0.2456				
Week 48		2.36 (0.52)		1.34 (0.53)	1.02 (0.67)	(-0.30, 2.34)	0.1312				
Week 52		2.48 (0.51)		1.44 (0.52)	1.03 (0.67)	(-0.28, 2.35)	0.1237				
OVERALL	437	2.08 (0.41)	443	0.93 (0.41)	1.15 (0.50)	(0.17, 2.13)	0.0220	0.13 (0.07)	(0.00, 0.27)	0.0460	0.9559

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Mental Component Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=459) N	LSMean (SE)	Placebo (N=468) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.0954
< 10 points	141	3.50 (0.64)	140	1.14 (0.64)	2.36 (0.84)	(0.72, 4.01)	0.0051	0.31 (0.12)	(0.08, 0.55)	0.0093	
>= 10 points	296	1.04 (0.52)	303	0.41 (0.52)	0.63 (0.62)	(-0.60, 1.85)	0.3148	0.07 (0.08)	(-0.09, 0.23)	0.3962	
OCS dose											0.7000
<10 mg/day	207	1.98 (0.54)	208	1.07 (0.55)	0.92 (0.71)	(-0.48, 2.31)	0.1987	0.12 (0.10)	(-0.08, 0.31)	0.2351	
>=10 mg/day	230	2.07 (0.63)	235	0.77 (0.62)	1.30 (0.71)	(-0.09, 2.69)	0.0662	0.14 (0.09)	(-0.05, 0.32)	0.1420	
Result of type I IFN gene signature test											0.6151
LOW	83	2.39 (0.79)	86	1.75 (0.78)	0.64 (1.10)	(-1.53, 2.80)	0.5609	0.09 (0.15)	(-0.21, 0.39)	0.5682	
HIGH	354	2.04 (0.42)	357	0.78 (0.42)	1.26 (0.57)	(0.15, 2.37)	0.0267	0.16 (0.08)	(0.01, 0.30)	0.0359	
Age (years)											0.5955
<= 65	425	2.00 (0.41)	441	0.94 (0.41)	1.06 (0.51)	(0.07, 2.05)	0.0366	0.12 (0.07)	(-0.01, 0.26)	0.0698	
> 65	12	4.49 (2.14)	2	0.92 (4.51)	3.57 (4.70)	(-7.92, 15.05)	0.4764	0.46 (0.77)	(-1.05, 1.97)	0.5541	
Sex											0.7584
male	32	5.44 (1.91)	33	4.87 (1.80)	0.57 (1.80)	(-3.02, 4.17)	0.7508	0.05 (0.25)	(-0.43, 0.54)	0.8292	
female	405	1.92 (0.42)	410	0.77 (0.42)	1.15 (0.52)	(0.13, 2.17)	0.0274	0.14 (0.07)	(-0.00, 0.27)	0.0526	
Race											0.4270
White	254	1.93 (0.55)	266	0.81 (0.54)	1.12 (0.68)	(-0.23, 2.46)	0.1029	0.13 (0.09)	(-0.05, 0.30)	0.1478	
Black	61	2.24 (1.31)	56	-0.43 (1.25)	2.67 (1.48)	(-0.26, 5.60)	0.0739	0.27 (0.19)	(-0.09, 0.63)	0.1469	
Other	114	1.69 (0.86)	114	1.31 (0.89)	0.39 (0.94)	(-1.47, 2.24)	0.6822	0.04 (0.13)	(-0.22, 0.30)	0.7552	
Ethnicity											0.5155
Hispanic/Latino	129	3.17 (0.77)	128	2.62 (0.77)	0.55 (0.94)	(-1.29, 2.39)	0.5566	0.06 (0.12)	(-0.18, 0.31)	0.6133	
Non-hispanic/Latino	300	1.32 (0.50)	308	0.04 (0.49)	1.27 (0.60)	(0.09, 2.46)	0.0353	0.15 (0.08)	(-0.01, 0.31)	0.0692	
Geographic region											0.9239
EU	128	1.68 (0.82)	137	0.56 (0.82)	1.12 (0.87)	(-0.59, 2.83)	0.1974	0.12 (0.12)	(-0.12, 0.36)	0.3360	
non-EU	309	1.99 (0.48)	306	0.77 (0.49)	1.22 (0.62)	(0.01, 2.43)	0.0476	0.14 (0.08)	(-0.01, 0.30)	0.0756	
Onset of disease											0.6002
Paediatric	33	2.42 (1.87)	33	2.26 (1.78)	0.17 (1.94)	(-3.71, 4.04)	0.9311	0.02 (0.25)	(-0.47, 0.50)	0.9487	
Adult	404	2.10 (0.42)	410	0.88 (0.42)	1.22 (0.52)	(0.20, 2.24)	0.0190	0.14 (0.07)	(0.01, 0.28)	0.0398	
ADA result											0.6949
Negative	408	1.89 (0.42)	405	0.88 (0.42)	1.01 (0.52)	(-0.01, 2.03)	0.0516	0.12 (0.07)	(-0.02, 0.26)	0.0874	
Positive (At any time)	29	4.22 (2.21)	38	2.26 (2.12)	1.95 (2.35)	(-2.78, 6.69)	0.4103	0.15 (0.25)	(-0.33, 0.64)	0.5339	
BMI (kg/m2)											0.7369
< 30	294	2.05 (0.50)	319	1.03 (0.50)	1.02 (0.58)	(-0.12, 2.15)	0.0790	0.12 (0.08)	(-0.04, 0.27)	0.1509	
>= 30	143	1.86 (0.76)	124	0.45 (0.77)	1.41 (1.01)	(-0.58, 3.40)	0.1651	0.16 (0.12)	(-0.08, 0.40)	0.1959	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Physical Component Score
Full analysis set

	Anifrolumab 300mg (N=459)		Placebo (N=468)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 4		0.98 (0.55)		-0.09 (0.55)	1.07 (0.72)	(-0.34, 2.48)	0.1367				
Week 8		3.09 (0.39)		2.59 (0.39)	0.49 (0.48)	(-0.45, 1.44)	0.3036				
Week 12		2.74 (0.67)		2.27 (0.67)	0.47 (0.92)	(-1.34, 2.29)	0.6095				
Week 16		4.25 (0.42)		3.46 (0.42)	0.79 (0.54)	(-0.26, 1.85)	0.1410				
Week 24		4.39 (0.40)		3.58 (0.40)	0.81 (0.50)	(-0.18, 1.80)	0.1067				
Week 32		4.25 (0.41)		3.69 (0.41)	0.57 (0.52)	(-0.46, 1.59)	0.2797				
Week 36		5.13 (0.69)		4.41 (0.75)	0.72 (0.99)	(-1.23, 2.67)	0.4696				
Week 40		4.50 (0.43)		3.82 (0.43)	0.68 (0.56)	(-0.41, 1.77)	0.2202				
Week 48		4.81 (0.44)		3.67 (0.45)	1.14 (0.58)	(0.01, 2.27)	0.0479				
Week 52		4.54 (0.42)		3.76 (0.42)	0.79 (0.54)	(-0.27, 1.85)	0.1451				
OVERALL	437	3.87 (0.34)	443	3.12 (0.34)	0.75 (0.42)	(-0.08, 1.58)	0.0747	0.10 (0.07)	(-0.03, 0.24)	0.1206	0.7222

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Physical Component Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=459) N	LSMean (SE)	Placebo (N=468) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.1285
< 10 points	141	4.34 (0.54)	140	2.77 (0.54)	1.57 (0.71)	(0.17, 2.97)	0.0278	0.24 (0.12)	(0.01, 0.48)	0.0408	
>= 10 points	296	3.50 (0.44)	303	3.27 (0.44)	0.23 (0.53)	(-0.80, 1.26)	0.6628	0.03 (0.08)	(-0.13, 0.19)	0.7134	
OCS dose											0.3006
<10 mg/day	207	3.57 (0.44)	208	2.28 (0.45)	1.29 (0.58)	(0.15, 2.43)	0.0272	0.20 (0.10)	(0.01, 0.39)	0.0421	
>=10 mg/day	230	4.26 (0.54)	235	3.84 (0.53)	0.42 (0.61)	(-0.78, 1.61)	0.4939	0.05 (0.09)	(-0.13, 0.23)	0.5825	
Result of type I IFN gene signature test											0.1624
LOW	83	3.60 (0.66)	86	4.01 (0.65)	-0.40 (0.91)	(-2.20, 1.39)	0.6578	-0.07 (0.15)	(-0.37, 0.23)	0.6639	
HIGH	354	4.35 (0.36)	357	3.32 (0.36)	1.03 (0.48)	(0.10, 1.97)	0.0308	0.15 (0.08)	(0.01, 0.30)	0.0412	
Age (years)											0.0467
<= 65	425	3.88 (0.35)	441	3.09 (0.34)	0.79 (0.42)	(-0.04, 1.63)	0.0625	0.11 (0.07)	(-0.02, 0.24)	0.1062	
> 65	12	4.34 (1.74)	2	11.30 (3.72)	-6.96 (3.88)	(-15.90, 1.98)	0.1102	-1.09 (0.80)	(-2.66, 0.48)	0.1741	
Sex											0.8557
male	32	3.81 (1.63)	33	3.33 (1.56)	0.48 (1.57)	(-2.67, 3.62)	0.7633	0.05 (0.25)	(-0.43, 0.54)	0.8351	
female	405	3.88 (0.35)	410	3.11 (0.35)	0.77 (0.44)	(-0.09, 1.64)	0.0800	0.11 (0.07)	(-0.03, 0.25)	0.1242	
Race											0.0553
White	254	3.23 (0.45)	266	3.42 (0.44)	-0.19 (0.56)	(-1.28, 0.90)	0.7331	-0.03 (0.09)	(-0.20, 0.15)	0.7647	
Black	61	4.07 (1.09)	56	1.25 (1.06)	2.82 (1.23)	(0.38, 5.26)	0.0240	0.34 (0.19)	(-0.03, 0.71)	0.0682	
Other	114	4.01 (0.70)	114	2.84 (0.72)	1.16 (0.77)	(-0.35, 2.68)	0.1316	0.15 (0.13)	(-0.11, 0.41)	0.2471	
Ethnicity											0.7331
Hispanic/Latino	129	4.93 (0.63)	128	4.08 (0.62)	0.84 (0.77)	(-0.67, 2.36)	0.2733	0.12 (0.12)	(-0.13, 0.36)	0.3424	
Non-hispanic/Latino	300	3.16 (0.42)	308	2.63 (0.42)	0.53 (0.51)	(-0.47, 1.53)	0.2999	0.07 (0.08)	(-0.09, 0.23)	0.3737	
Geographic region											0.0031
EU	128	2.89 (0.73)	137	4.14 (0.73)	-1.24 (0.77)	(-2.77, 0.28)	0.1091	-0.15 (0.12)	(-0.39, 0.09)	0.2306	
non-EU	309	4.17 (0.39)	306	2.69 (0.40)	1.48 (0.50)	(0.50, 2.47)	0.0033	0.21 (0.08)	(0.05, 0.37)	0.0083	
Onset of disease											0.8093
Paediatric	33	3.06 (1.74)	33	1.92 (1.63)	1.15 (1.75)	(-2.35, 4.65)	0.5143	0.12 (0.25)	(-0.37, 0.60)	0.6349	
Adult	404	3.85 (0.35)	410	3.13 (0.35)	0.71 (0.44)	(-0.15, 1.57)	0.1040	0.10 (0.07)	(-0.04, 0.24)	0.1535	
ADA result											0.0174
Negative	408	3.71 (0.35)	405	3.21 (0.35)	0.49 (0.44)	(-0.37, 1.36)	0.2624	0.07 (0.07)	(-0.07, 0.21)	0.3242	
Positive (At any time)	29	8.07 (1.71)	38	3.67 (1.56)	4.40 (1.58)	(1.23, 7.57)	0.0073	0.46 (0.25)	(-0.03, 0.95)	0.0655	
BMI (kg/m2)											0.1120
< 30	294	3.86 (0.43)	319	3.49 (0.43)	0.37 (0.50)	(-0.60, 1.35)	0.4501	0.05 (0.08)	(-0.11, 0.21)	0.5359	
>= 30	143	4.29 (0.58)	124	2.45 (0.59)	1.84 (0.78)	(0.31, 3.37)	0.0186	0.27 (0.12)	(0.03, 0.51)	0.0272	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute General Health Score
Full analysis set

	Anifrolumab 300mg (N=459)		Placebo (N=468)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 4		-0.03 (0.75)		-0.27 (0.75)	0.23 (1.03)	(-1.80, 2.27)	0.8199				
Week 8		2.39 (0.37)		2.48 (0.37)	-0.09 (0.44)	(-0.95, 0.77)	0.8403				
Week 12		1.79 (0.85)		2.18 (0.85)	-0.39 (1.18)	(-2.71, 1.93)	0.7407				
Week 16		2.87 (0.40)		2.63 (0.40)	0.24 (0.50)	(-0.74, 1.21)	0.6350				
Week 24		2.83 (0.41)		2.15 (0.41)	0.69 (0.53)	(-0.35, 1.72)	0.1946				
Week 32		2.93 (0.40)		2.45 (0.40)	0.48 (0.51)	(-0.51, 1.47)	0.3433				
Week 36		4.16 (0.79)		3.42 (0.85)	0.74 (1.14)	(-1.50, 2.98)	0.5148				
Week 40		3.02 (0.41)		2.63 (0.41)	0.39 (0.52)	(-0.62, 1.40)	0.4468				
Week 48		3.19 (0.40)		3.20 (0.41)	-0.00 (0.51)	(-1.01, 1.00)	0.9944				
Week 52		3.06 (0.42)		2.78 (0.43)	0.29 (0.55)	(-0.79, 1.36)	0.6043				
OVERALL	437	2.62 (0.36)	443	2.36 (0.36)	0.26 (0.45)	(-0.63, 1.14)	0.5689	0.03 (0.07)	(-0.10, 0.17)	0.6161	0.0841

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute General Health Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=459) N	LSMean (SE)	Placebo (N=468) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.5480
< 10 points	141	3.40 (0.57)	140	2.75 (0.57)	0.65 (0.76)	(-0.84, 2.14)	0.3916	0.10 (0.12)	(-0.14, 0.33)	0.4240	
>= 10 points	296	2.10 (0.46)	303	2.01 (0.46)	0.08 (0.56)	(-1.01, 1.18)	0.8801	0.01 (0.08)	(-0.15, 0.17)	0.8973	
OCS dose											0.5491
<10 mg/day	207	2.50 (0.52)	208	1.93 (0.53)	0.57 (0.69)	(-0.77, 1.92)	0.4030	0.08 (0.10)	(-0.12, 0.27)	0.4429	
>=10 mg/day	230	2.66 (0.53)	235	2.64 (0.53)	0.02 (0.61)	(-1.18, 1.23)	0.9699	0.00 (0.09)	(-0.18, 0.18)	0.9755	
Result of type I IFN gene signature test											0.2162
LOW	83	2.81 (0.79)	86	3.76 (0.77)	-0.95 (1.08)	(-3.09, 1.19)	0.3838	-0.13 (0.15)	(-0.43, 0.17)	0.3947	
HIGH	354	2.72 (0.37)	357	2.19 (0.37)	0.53 (0.49)	(-0.44, 1.50)	0.2868	0.08 (0.08)	(-0.07, 0.22)	0.3150	
Age (years)											0.8964
<= 65	425	2.63 (0.37)	441	2.42 (0.36)	0.21 (0.45)	(-0.69, 1.10)	0.6516	0.03 (0.07)	(-0.11, 0.16)	0.6921	
> 65	12	2.71 (2.35)	2	1.84 (4.83)	0.88 (5.14)	(-11.16, 12.91)	0.8691	0.10 (0.76)	(-1.40, 1.60)	0.8937	
Sex											0.3072
male	32	2.56 (1.53)	33	3.93 (1.43)	-1.37 (1.62)	(-4.62, 1.88)	0.4018	-0.16 (0.25)	(-0.65, 0.33)	0.5185	
female	405	2.63 (0.38)	410	2.28 (0.38)	0.35 (0.47)	(-0.57, 1.28)	0.4523	0.05 (0.07)	(-0.09, 0.18)	0.5059	
Race											0.2500
White	254	2.63 (0.50)	266	3.01 (0.48)	-0.38 (0.61)	(-1.58, 0.82)	0.5351	-0.05 (0.09)	(-0.22, 0.12)	0.5867	
Black	61	2.29 (0.99)	56	0.51 (0.99)	1.78 (1.18)	(-0.55, 4.11)	0.1338	0.23 (0.19)	(-0.13, 0.60)	0.2081	
Other	114	2.73 (0.77)	114	2.29 (0.79)	0.44 (0.85)	(-1.24, 2.12)	0.6053	0.05 (0.13)	(-0.21, 0.31)	0.6904	
Ethnicity											0.3033
Hispanic/Latino	129	4.24 (0.67)	128	3.40 (0.67)	0.85 (0.83)	(-0.79, 2.49)	0.3092	0.11 (0.12)	(-0.13, 0.36)	0.3744	
Non-hispanic/Latino	300	1.78 (0.45)	308	1.95 (0.44)	-0.18 (0.54)	(-1.24, 0.89)	0.7473	-0.02 (0.08)	(-0.18, 0.14)	0.7801	
Geographic region											0.0939
EU	128	2.14 (0.73)	137	3.01 (0.72)	-0.86 (0.78)	(-2.40, 0.68)	0.2701	-0.10 (0.12)	(-0.34, 0.14)	0.4013	
non-EU	309	2.84 (0.43)	306	2.10 (0.43)	0.74 (0.55)	(-0.34, 1.81)	0.1806	0.10 (0.08)	(-0.06, 0.26)	0.2255	
Onset of disease											0.2198
Paediatric	33	3.74 (1.55)	33	1.50 (1.48)	2.24 (1.64)	(-1.04, 5.52)	0.1775	0.25 (0.25)	(-0.23, 0.74)	0.3037	
Adult	404	2.53 (0.38)	410	2.39 (0.38)	0.14 (0.47)	(-0.78, 1.07)	0.7587	0.02 (0.07)	(-0.12, 0.16)	0.7861	
ADA result											0.1043
Negative	408	2.36 (0.37)	405	2.43 (0.37)	-0.07 (0.46)	(-0.98, 0.84)	0.8851	-0.01 (0.07)	(-0.15, 0.13)	0.8980	
Positive (At any time)	29	6.99 (1.89)	38	3.73 (1.82)	3.27 (2.00)	(-0.76, 7.30)	0.1092	0.30 (0.25)	(-0.19, 0.79)	0.2273	
BMI (kg/m2)											0.4092
< 30	294	2.65 (0.45)	319	2.57 (0.44)	0.08 (0.53)	(-0.96, 1.12)	0.8769	0.01 (0.08)	(-0.15, 0.17)	0.8967	
>= 30	143	2.91 (0.65)	124	1.99 (0.66)	0.92 (0.87)	(-0.79, 2.63)	0.2890	0.12 (0.12)	(-0.12, 0.36)	0.3272	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Mental Health Score
Full analysis set

	Anifrolumab 300mg (N=459)		Placebo (N=468)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 4		0.90 (0.80)		-0.04 (0.80)	0.95 (1.08)	(-1.18, 3.07)	0.3801				
Week 8		2.04 (0.48)		1.35 (0.47)	0.69 (0.59)	(-0.47, 1.85)	0.2424				
Week 12		2.80 (0.88)		1.08 (0.88)	1.72 (1.21)	(-0.67, 4.10)	0.1572				
Week 16		1.94 (0.50)		1.58 (0.50)	0.36 (0.63)	(-0.88, 1.60)	0.5721				
Week 24		2.22 (0.47)		0.66 (0.47)	1.56 (0.61)	(0.36, 2.76)	0.0108				
Week 32		2.83 (0.51)		1.11 (0.52)	1.72 (0.66)	(0.42, 3.03)	0.0097				
Week 36		3.45 (0.88)		1.45 (0.95)	2.00 (1.27)	(-0.51, 4.50)	0.1184				
Week 40		2.74 (0.51)		2.05 (0.51)	0.69 (0.65)	(-0.59, 1.97)	0.2884				
Week 48		2.69 (0.50)		1.69 (0.51)	1.00 (0.64)	(-0.26, 2.26)	0.1190				
Week 52		3.03 (0.48)		1.81 (0.49)	1.22 (0.63)	(-0.01, 2.45)	0.0519				
OVERALL	437	2.46 (0.39)	443	1.27 (0.39)	1.19 (0.48)	(0.25, 2.13)	0.0133	0.15 (0.07)	(0.01, 0.28)	0.0302	0.6365

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Mental Health Score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=459)		Placebo (N=468)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.0771
< 10 points	141	3.75 (0.60)	140	1.33 (0.60)	2.42 (0.79)	(0.87, 3.97)	0.0024	0.34 (0.12)	(0.10, 0.57)	0.0047	
>= 10 points	296	1.53 (0.50)	303	0.87 (0.50)	0.66 (0.60)	(-0.52, 1.85)	0.2722	0.08 (0.08)	(-0.08, 0.24)	0.3503	
OCS dose											0.9317
<10 mg/day	207	2.19 (0.51)	208	1.08 (0.52)	1.11 (0.67)	(-0.21, 2.43)	0.1002	0.15 (0.10)	(-0.04, 0.34)	0.1289	
>=10 mg/day	230	2.65 (0.60)	235	1.46 (0.59)	1.19 (0.68)	(-0.15, 2.53)	0.0818	0.13 (0.09)	(-0.05, 0.31)	0.1602	
Result of type I IFN gene signature test											0.6164
LOW	83	2.37 (0.72)	86	1.66 (0.71)	0.71 (0.99)	(-1.25, 2.68)	0.4741	0.11 (0.15)	(-0.19, 0.41)	0.4817	
HIGH	354	2.60 (0.41)	357	1.32 (0.41)	1.28 (0.55)	(0.20, 2.36)	0.0198	0.17 (0.08)	(0.02, 0.31)	0.0273	
Age (years)											0.7776
<= 65	425	2.43 (0.39)	441	1.30 (0.39)	1.13 (0.48)	(0.18, 2.07)	0.0202	0.14 (0.07)	(0.00, 0.27)	0.0431	
> 65	12	2.48 (2.41)	2	-0.13 (5.02)	2.61 (5.23)	(-9.68, 14.90)	0.6328	0.30 (0.77)	(-1.21, 1.80)	0.6995	
Sex											0.4575
male	32	4.37 (1.91)	33	4.50 (1.77)	-0.13 (1.76)	(-3.64, 3.39)	0.9422	-0.01 (0.25)	(-0.50, 0.47)	0.9612	
female	405	2.35 (0.40)	410	1.12 (0.40)	1.23 (0.50)	(0.25, 2.20)	0.0135	0.15 (0.07)	(0.02, 0.29)	0.0292	
Race											0.4717
White	254	1.90 (0.53)	266	1.23 (0.51)	0.67 (0.66)	(-0.62, 1.96)	0.3060	0.08 (0.09)	(-0.09, 0.25)	0.3624	
Black	61	3.12 (1.14)	56	0.65 (1.11)	2.47 (1.31)	(-0.13, 5.07)	0.0621	0.28 (0.19)	(-0.08, 0.65)	0.1276	
Other	114	2.71 (0.83)	114	1.63 (0.86)	1.08 (0.91)	(-0.72, 2.88)	0.2399	0.12 (0.13)	(-0.14, 0.38)	0.3678	
Ethnicity											0.6682
Hispanic/Latino	129	3.37 (0.76)	128	2.63 (0.76)	0.75 (0.93)	(-1.08, 2.57)	0.4215	0.09 (0.12)	(-0.16, 0.33)	0.4880	
Non-hispanic/Latino	300	1.80 (0.47)	308	0.59 (0.46)	1.21 (0.57)	(0.10, 2.32)	0.0329	0.15 (0.08)	(-0.01, 0.31)	0.0644	
Geographic region											0.3909
EU	128	1.79 (0.80)	137	1.18 (0.80)	0.61 (0.85)	(-1.06, 2.28)	0.4735	0.07 (0.12)	(-0.18, 0.31)	0.5929	
non-EU	309	2.45 (0.46)	306	0.96 (0.46)	1.49 (0.58)	(0.35, 2.64)	0.0106	0.19 (0.08)	(0.03, 0.34)	0.0214	
Onset of disease											0.6190
Paediatric	33	3.22 (1.87)	33	2.93 (1.78)	0.29 (1.93)	(-3.57, 4.16)	0.8796	0.03 (0.25)	(-0.45, 0.51)	0.9106	
Adult	404	2.48 (0.40)	410	1.20 (0.40)	1.28 (0.49)	(0.31, 2.25)	0.0097	0.16 (0.07)	(0.02, 0.30)	0.0227	
ADA result											0.8293
Negative	408	2.30 (0.39)	405	1.25 (0.40)	1.04 (0.49)	(0.08, 2.01)	0.0340	0.13 (0.07)	(-0.01, 0.27)	0.0617	
Positive (At any time)	29	4.40 (2.29)	38	2.86 (2.13)	1.54 (2.26)	(-2.99, 6.08)	0.4975	0.12 (0.25)	(-0.36, 0.60)	0.6292	
BMI (kg/m2)											0.6081
< 30	294	2.43 (0.49)	319	1.43 (0.49)	1.00 (0.57)	(-0.13, 2.12)	0.0816	0.12 (0.08)	(-0.04, 0.27)	0.1527	
>= 30	143	2.36 (0.68)	124	0.81 (0.69)	1.55 (0.91)	(-0.25, 3.35)	0.0909	0.19 (0.12)	(-0.05, 0.44)	0.1138	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Physical Functioning Score
Full analysis set

	Anifrolumab 300mg (N=459)		Placebo (N=468)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 4		0.26 (0.65)		-0.52 (0.66)	0.78 (0.87)	(-0.94, 2.49)	0.3735				
Week 8		2.70 (0.42)		1.98 (0.42)	0.72 (0.51)	(-0.29, 1.73)	0.1611				
Week 12		2.36 (0.78)		1.52 (0.78)	0.84 (1.08)	(-1.28, 2.96)	0.4355				
Week 16		3.36 (0.44)		2.73 (0.44)	0.63 (0.56)	(-0.47, 1.73)	0.2590				
Week 24		3.63 (0.44)		2.99 (0.44)	0.65 (0.56)	(-0.45, 1.74)	0.2461				
Week 32		3.93 (0.44)		2.99 (0.44)	0.94 (0.55)	(-0.15, 2.03)	0.0903				
Week 36		3.78 (0.78)		4.00 (0.84)	-0.23 (1.11)	(-2.42, 1.97)	0.8398				
Week 40		3.94 (0.45)		3.32 (0.45)	0.61 (0.56)	(-0.49, 1.72)	0.2781				
Week 48		3.95 (0.46)		2.96 (0.47)	0.99 (0.60)	(-0.18, 2.17)	0.0975				
Week 52		4.15 (0.44)		3.54 (0.45)	0.61 (0.58)	(-0.52, 1.75)	0.2914				
OVERALL	437	3.21 (0.38)	443	2.55 (0.38)	0.65 (0.47)	(-0.26, 1.57)	0.1604	0.08 (0.07)	(-0.05, 0.21)	0.2205	0.8998

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Physical Functioning Score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=459)		Placebo (N=468)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.0551
< 10 points	141	3.82 (0.59)	140	2.01 (0.59)	1.81 (0.78)	(0.28, 3.35)	0.0204	0.26 (0.12)	(0.02, 0.49)	0.0306	
>= 10 points	296	2.91 (0.49)	303	2.96 (0.49)	-0.05 (0.59)	(-1.20, 1.10)	0.9282	-0.01 (0.08)	(-0.17, 0.15)	0.9392	
OCS dose											0.6429
<10 mg/day	207	2.95 (0.47)	208	2.02 (0.48)	0.93 (0.62)	(-0.28, 2.14)	0.1331	0.14 (0.10)	(-0.06, 0.33)	0.1692	
>=10 mg/day	230	3.44 (0.60)	235	2.94 (0.59)	0.50 (0.68)	(-0.84, 1.84)	0.4607	0.06 (0.09)	(-0.13, 0.24)	0.5506	
Result of type I IFN gene signature test											0.3391
LOW	83	2.93 (0.75)	86	3.19 (0.74)	-0.27 (1.04)	(-2.31, 1.78)	0.7977	-0.04 (0.15)	(-0.34, 0.26)	0.8014	
HIGH	354	3.74 (0.39)	357	2.90 (0.39)	0.84 (0.52)	(-0.18, 1.87)	0.1074	0.11 (0.08)	(-0.03, 0.26)	0.1288	
Age (years)											0.1277
<= 65	425	3.20 (0.38)	441	2.49 (0.38)	0.70 (0.47)	(-0.22, 1.62)	0.1339	0.09 (0.07)	(-0.04, 0.22)	0.1924	
> 65	12	3.86 (2.40)	2	11.54 (5.34)	-7.68 (5.48)	(-20.47, 5.12)	0.2015	-0.87 (0.79)	(-2.42, 0.67)	0.2692	
Sex											0.9241
male	32	4.45 (1.74)	33	3.64 (1.69)	0.81 (1.72)	(-2.64, 4.26)	0.6399	0.08 (0.25)	(-0.40, 0.57)	0.7419	
female	405	3.16 (0.39)	410	2.52 (0.39)	0.64 (0.49)	(-0.31, 1.59)	0.1885	0.08 (0.07)	(-0.06, 0.22)	0.2475	
Race											0.2049
White	254	2.70 (0.50)	266	2.84 (0.49)	-0.13 (0.61)	(-1.33, 1.07)	0.8281	-0.02 (0.09)	(-0.19, 0.16)	0.8494	
Black	61	3.22 (1.17)	56	0.84 (1.15)	2.39 (1.34)	(-0.27, 5.04)	0.0779	0.27 (0.19)	(-0.10, 0.63)	0.1503	
Other	114	2.78 (0.77)	114	1.97 (0.79)	0.81 (0.86)	(-0.88, 2.49)	0.3471	0.10 (0.13)	(-0.16, 0.36)	0.4662	
Ethnicity											0.6115
Hispanic/Latino	129	4.19 (0.72)	128	3.95 (0.72)	0.24 (0.89)	(-1.51, 1.99)	0.7883	0.03 (0.12)	(-0.22, 0.27)	0.8147	
Non-hispanic/Latino	300	2.57 (0.45)	308	1.80 (0.44)	0.77 (0.54)	(-0.29, 1.82)	0.1547	0.10 (0.08)	(-0.06, 0.26)	0.2226	
Geographic region											0.0120
EU	128	2.63 (0.81)	137	3.88 (0.81)	-1.25 (0.87)	(-2.96, 0.45)	0.1494	-0.13 (0.12)	(-0.38, 0.11)	0.2769	
non-EU	309	3.32 (0.43)	306	2.00 (0.43)	1.32 (0.55)	(0.25, 2.40)	0.0161	0.18 (0.08)	(0.02, 0.33)	0.0300	
Onset of disease											0.7507
Paediatric	33	2.34 (1.88)	33	2.32 (1.80)	0.03 (1.94)	(-3.87, 3.92)	0.9897	0.00 (0.25)	(-0.48, 0.48)	0.9924	
Adult	404	3.21 (0.39)	410	2.55 (0.39)	0.66 (0.48)	(-0.29, 1.61)	0.1709	0.08 (0.07)	(-0.05, 0.22)	0.2288	
ADA result											0.0444
Negative	408	3.05 (0.39)	405	2.66 (0.39)	0.39 (0.48)	(-0.56, 1.34)	0.4184	0.05 (0.07)	(-0.09, 0.19)	0.4763	
Positive (At any time)	29	6.26 (2.00)	38	2.05 (1.83)	4.21 (1.84)	(0.53, 7.89)	0.0256	0.38 (0.25)	(-0.11, 0.86)	0.1301	
BMI (kg/m2)											0.0636
< 30	294	3.28 (0.46)	319	3.09 (0.46)	0.18 (0.54)	(-0.87, 1.24)	0.7343	0.02 (0.08)	(-0.14, 0.18)	0.7796	
>= 30	143	3.54 (0.65)	124	1.46 (0.66)	2.08 (0.87)	(0.37, 3.79)	0.0175	0.27 (0.12)	(0.03, 0.52)	0.0265	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Role Emotional Score
Full analysis set

	Anifrolumab 300mg (N=459)		Placebo (N=468)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 4		-0.31 (0.89)		-1.25 (0.89)	0.94 (1.19)	(-1.41, 3.29)	0.4313				
Week 8		1.59 (0.57)		0.90 (0.57)	0.69 (0.72)	(-0.73, 2.10)	0.3394				
Week 12		1.49 (1.05)		1.27 (1.04)	0.23 (1.44)	(-2.61, 3.07)	0.8745				
Week 16		1.63 (0.58)		1.85 (0.58)	-0.22 (0.74)	(-1.68, 1.24)	0.7646				
Week 24		2.01 (0.53)		0.53 (0.53)	1.48 (0.68)	(0.13, 2.82)	0.0311				
Week 32		2.48 (0.58)		1.13 (0.58)	1.34 (0.74)	(-0.11, 2.80)	0.0702				
Week 36		3.33 (1.04)		1.56 (1.13)	1.77 (1.51)	(-1.21, 4.75)	0.2428				
Week 40		2.67 (0.58)		1.93 (0.59)	0.74 (0.75)	(-0.74, 2.21)	0.3263				
Week 48		2.43 (0.58)		1.85 (0.59)	0.58 (0.75)	(-0.89, 2.05)	0.4398				
Week 52		2.59 (0.56)		2.08 (0.57)	0.52 (0.73)	(-0.92, 1.95)	0.4784				
OVERALL	437	1.99 (0.45)	443	1.18 (0.45)	0.81 (0.55)	(-0.28, 1.89)	0.1459	0.09 (0.07)	(-0.05, 0.22)	0.2040	0.7615

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Role Emotional Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=459) N	LSMean (SE)	Placebo (N=468) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.0341
< 10 points	141	3.37 (0.73)	140	0.89 (0.73)	2.48 (0.97)	(0.58, 4.38)	0.0108	0.28 (0.12)	(0.05, 0.52)	0.0177	
>= 10 points	296	1.03 (0.56)	303	1.04 (0.56)	-0.02 (0.67)	(-1.34, 1.30)	0.9784	-0.00 (0.08)	(-0.16, 0.16)	0.9817	
OCS dose											0.8297
<10 mg/day	207	2.29 (0.60)	208	1.33 (0.62)	0.96 (0.79)	(-0.61, 2.52)	0.2295	0.11 (0.10)	(-0.08, 0.30)	0.2682	
>=10 mg/day	230	1.47 (0.68)	235	0.76 (0.67)	0.72 (0.77)	(-0.80, 2.23)	0.3528	0.07 (0.09)	(-0.11, 0.25)	0.4548	
Result of type I IFN gene signature test											0.6333
LOW	83	1.99 (0.96)	86	1.77 (0.95)	0.22 (1.33)	(-2.41, 2.85)	0.8702	0.02 (0.15)	(-0.28, 0.33)	0.8725	
HIGH	354	2.11 (0.45)	357	1.19 (0.46)	0.92 (0.61)	(-0.28, 2.12)	0.1341	0.11 (0.08)	(-0.04, 0.25)	0.1561	
Age (years)											0.5053
<= 65	425	1.92 (0.46)	441	1.18 (0.45)	0.75 (0.56)	(-0.35, 1.85)	0.1816	0.08 (0.07)	(-0.05, 0.21)	0.2453	
> 65	12	6.07 (1.38)	2	3.43 (2.43)	2.63 (2.77)	(-3.63, 8.90)	0.3669	0.53 (0.77)	(-0.99, 2.04)	0.4948	
Sex											0.9560
male	32	5.04 (1.81)	33	4.18 (1.74)	0.86 (1.73)	(-2.60, 4.33)	0.6199	0.08 (0.25)	(-0.40, 0.57)	0.7342	
female	405	1.88 (0.47)	410	1.12 (0.47)	0.76 (0.58)	(-0.38, 1.90)	0.1901	0.08 (0.07)	(-0.06, 0.22)	0.2485	
Race											0.1731
White	254	1.85 (0.59)	266	0.91 (0.57)	0.94 (0.73)	(-0.48, 2.37)	0.1951	0.10 (0.09)	(-0.07, 0.27)	0.2499	
Black	61	2.83 (1.68)	56	-0.59 (1.64)	3.41 (1.92)	(-0.40, 7.23)	0.0787	0.27 (0.19)	(-0.10, 0.63)	0.1523	
Other	114	1.03 (0.89)	114	1.48 (0.92)	-0.46 (0.98)	(-2.38, 1.47)	0.6392	-0.05 (0.13)	(-0.31, 0.21)	0.7208	
Ethnicity											0.8204
Hispanic/Latino	129	3.54 (0.81)	128	2.97 (0.81)	0.57 (1.00)	(-1.39, 2.53)	0.5694	0.06 (0.12)	(-0.18, 0.31)	0.6220	
Non-hispanic/Latino	300	0.93 (0.56)	308	0.09 (0.55)	0.84 (0.67)	(-0.48, 2.16)	0.2132	0.09 (0.08)	(-0.07, 0.25)	0.2826	
Geographic region											0.7416
EU	128	1.67 (0.80)	137	1.08 (0.80)	0.59 (0.86)	(-1.10, 2.28)	0.4930	0.06 (0.12)	(-0.18, 0.30)	0.6051	
non-EU	309	1.87 (0.55)	306	0.92 (0.55)	0.95 (0.70)	(-0.42, 2.33)	0.1741	0.10 (0.08)	(-0.06, 0.26)	0.2217	
Onset of disease											0.5992
Paediatric	33	2.91 (1.84)	33	3.10 (1.76)	-0.19 (1.97)	(-4.13, 3.75)	0.9233	-0.02 (0.25)	(-0.50, 0.46)	0.9412	
Adult	404	2.01 (0.46)	410	1.12 (0.47)	0.89 (0.58)	(-0.25, 2.02)	0.1251	0.09 (0.07)	(-0.04, 0.23)	0.1780	
ADA result											0.4915
Negative	408	1.80 (0.46)	405	1.12 (0.46)	0.68 (0.58)	(-0.45, 1.81)	0.2387	0.07 (0.07)	(-0.06, 0.21)	0.2993	
Positive (At any time)	29	4.70 (2.38)	38	2.37 (2.22)	2.33 (2.33)	(-2.34, 7.01)	0.3218	0.17 (0.25)	(-0.31, 0.66)	0.4836	
BMI (kg/m2)											0.3079
< 30	294	2.13 (0.53)	319	1.68 (0.53)	0.44 (0.62)	(-0.77, 1.66)	0.4718	0.05 (0.08)	(-0.11, 0.21)	0.5537	
>= 30	143	1.55 (0.88)	124	-0.25 (0.89)	1.80 (1.17)	(-0.51, 4.11)	0.1271	0.17 (0.12)	(-0.07, 0.42)	0.1557	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Role Physical Score
Full analysis set

	Anifrolumab 300mg (N=459)		Placebo (N=468)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 4		1.17 (0.62)		-0.17 (0.62)	1.34 (0.82)	(-0.28, 2.96)	0.1036				
Week 8		2.58 (0.41)		2.23 (0.41)	0.35 (0.50)	(-0.64, 1.34)	0.4837				
Week 12		3.09 (0.77)		2.42 (0.76)	0.67 (1.05)	(-1.41, 2.74)	0.5282				
Week 16		3.73 (0.44)		3.02 (0.44)	0.71 (0.56)	(-0.39, 1.81)	0.2034				
Week 24		4.04 (0.41)		2.79 (0.41)	1.25 (0.52)	(0.22, 2.28)	0.0171				
Week 32		4.05 (0.44)		2.87 (0.44)	1.17 (0.56)	(0.08, 2.27)	0.0354				
Week 36		5.12 (0.76)		4.15 (0.81)	0.97 (1.09)	(-1.17, 3.10)	0.3743				
Week 40		3.97 (0.46)		3.53 (0.46)	0.44 (0.58)	(-0.71, 1.59)	0.4504				
Week 48		4.30 (0.45)		3.00 (0.46)	1.29 (0.58)	(0.15, 2.43)	0.0264				
Week 52		4.25 (0.44)		3.18 (0.45)	1.08 (0.57)	(-0.04, 2.19)	0.0595				
OVERALL	437	3.63 (0.36)	443	2.70 (0.36)	0.93 (0.44)	(0.07, 1.79)	0.0351	0.12 (0.07)	(-0.01, 0.26)	0.0666	0.9567

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Role Physical Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=459) N	LSMean (SE)	Placebo (N=468) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.0690
< 10 points	141	4.71 (0.58)	140	2.71 (0.58)	2.00 (0.76)	(0.50, 3.50)	0.0092	0.29 (0.12)	(0.05, 0.52)	0.0157	
>= 10 points	296	2.72 (0.45)	303	2.42 (0.45)	0.30 (0.54)	(-0.76, 1.36)	0.5788	0.04 (0.08)	(-0.12, 0.20)	0.6399	
OCS dose											0.9226
<10 mg/day	207	3.17 (0.48)	208	2.20 (0.49)	0.97 (0.63)	(-0.27, 2.21)	0.1264	0.14 (0.10)	(-0.05, 0.33)	0.1606	
>=10 mg/day	230	3.96 (0.54)	235	2.91 (0.54)	1.05 (0.61)	(-0.15, 2.25)	0.0851	0.13 (0.09)	(-0.05, 0.31)	0.1670	
Result of type I IFN gene signature test											0.3069
LOW	83	3.76 (0.70)	86	3.74 (0.69)	0.02 (0.96)	(-1.87, 1.92)	0.9799	0.00 (0.15)	(-0.30, 0.31)	0.9803	
HIGH	354	3.88 (0.37)	357	2.75 (0.37)	1.13 (0.50)	(0.15, 2.11)	0.0239	0.16 (0.08)	(0.01, 0.31)	0.0327	
Age (years)											0.2384
<= 65	425	3.62 (0.36)	441	2.70 (0.36)	0.91 (0.44)	(0.05, 1.78)	0.0389	0.12 (0.07)	(-0.01, 0.26)	0.0734	
> 65	12	6.54 (1.45)	2	9.15 (2.77)	-2.61 (2.96)	(-9.28, 4.05)	0.3994	-0.50 (0.77)	(-2.01, 1.02)	0.5202	
Sex											0.7593
male	32	5.10 (1.61)	33	3.73 (1.56)	1.36 (1.54)	(-1.72, 4.45)	0.3798	0.15 (0.25)	(-0.34, 0.64)	0.5477	
female	405	3.57 (0.37)	410	2.70 (0.37)	0.87 (0.46)	(-0.03, 1.77)	0.0579	0.12 (0.07)	(-0.02, 0.25)	0.0962	
Race											0.5068
White	254	3.44 (0.45)	266	2.83 (0.44)	0.60 (0.55)	(-0.48, 1.69)	0.2745	0.08 (0.09)	(-0.09, 0.26)	0.3371	
Black	61	4.64 (1.19)	56	2.32 (1.18)	2.32 (1.37)	(-0.40, 5.05)	0.0940	0.25 (0.19)	(-0.11, 0.62)	0.1721	
Other	114	3.30 (0.76)	114	2.34 (0.79)	0.96 (0.84)	(-0.69, 2.62)	0.2534	0.12 (0.13)	(-0.14, 0.38)	0.3810	
Ethnicity											0.6502
Hispanic/Latino	129	4.27 (0.67)	128	3.67 (0.67)	0.59 (0.83)	(-1.03, 2.22)	0.4726	0.08 (0.12)	(-0.17, 0.32)	0.5320	
Non-hispanic/Latino	300	3.19 (0.44)	308	2.15 (0.43)	1.04 (0.52)	(0.01, 2.07)	0.0480	0.14 (0.08)	(-0.02, 0.30)	0.0896	
Geographic region											0.0609
EU	128	2.79 (0.67)	137	3.02 (0.67)	-0.23 (0.71)	(-1.63, 1.17)	0.7438	-0.03 (0.12)	(-0.27, 0.21)	0.8070	
non-EU	309	3.80 (0.43)	306	2.35 (0.43)	1.45 (0.55)	(0.37, 2.52)	0.0083	0.19 (0.08)	(0.03, 0.35)	0.0178	
Onset of disease											0.9717
Paediatric	33	3.14 (1.62)	33	2.17 (1.55)	0.97 (1.68)	(-2.39, 4.33)	0.5654	0.11 (0.25)	(-0.38, 0.59)	0.6691	
Adult	404	3.65 (0.37)	410	2.74 (0.37)	0.91 (0.46)	(0.01, 1.81)	0.0480	0.12 (0.07)	(-0.02, 0.26)	0.0835	
ADA result											0.3709
Negative	408	3.49 (0.37)	405	2.67 (0.37)	0.82 (0.45)	(-0.07, 1.71)	0.0718	0.11 (0.07)	(-0.03, 0.25)	0.1138	
Positive (At any time)	29	8.21 (1.98)	38	5.63 (1.84)	2.59 (1.92)	(-1.26, 6.43)	0.1833	0.23 (0.25)	(-0.25, 0.72)	0.3500	
BMI (kg/m2)											0.3572
< 30	294	3.64 (0.44)	319	2.97 (0.44)	0.67 (0.51)	(-0.33, 1.66)	0.1878	0.09 (0.08)	(-0.07, 0.25)	0.2800	
>= 30	143	3.90 (0.63)	124	2.32 (0.64)	1.58 (0.85)	(-0.10, 3.26)	0.0645	0.21 (0.12)	(-0.03, 0.45)	0.0836	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Social Functioning Score
Full analysis set

	Anifrolumab 300mg (N=459)		Placebo (N=468)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 4		1.52 (0.69)		-0.36 (0.70)	1.88 (0.91)	(0.10, 3.66)	0.0386				
Week 8		2.27 (0.53)		1.73 (0.53)	0.53 (0.67)	(-0.78, 1.85)	0.4266				
Week 12		3.27 (0.82)		1.15 (0.82)	2.12 (1.12)	(-0.08, 4.32)	0.0589				
Week 16		2.89 (0.52)		2.29 (0.52)	0.60 (0.66)	(-0.71, 1.90)	0.3694				
Week 24		3.37 (0.49)		1.75 (0.49)	1.62 (0.63)	(0.39, 2.86)	0.0102				
Week 32		3.73 (0.54)		2.39 (0.54)	1.34 (0.70)	(-0.03, 2.71)	0.0550				
Week 36		5.05 (0.84)		2.20 (0.90)	2.85 (1.20)	(0.49, 5.21)	0.0182				
Week 40		3.77 (0.54)		2.39 (0.54)	1.38 (0.70)	(0.01, 2.75)	0.0490				
Week 48		3.93 (0.53)		2.03 (0.54)	1.90 (0.69)	(0.55, 3.24)	0.0058				
Week 52		3.71 (0.52)		2.54 (0.53)	1.16 (0.68)	(-0.16, 2.49)	0.0851				
OVERALL	437	3.35 (0.41)	443	1.81 (0.41)	1.54 (0.50)	(0.56, 2.52)	0.0021	0.18 (0.07)	(0.05, 0.31)	0.0076	0.9490

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Social Functioning Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=459) N	LSMean (SE)	Placebo (N=468) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.0539
< 10 points	141	4.53 (0.66)	140	1.63 (0.66)	2.90 (0.87)	(1.19, 4.61)	0.0009	0.37 (0.12)	(0.13, 0.61)	0.0022	
>= 10 points	296	2.70 (0.52)	303	1.85 (0.52)	0.85 (0.61)	(-0.35, 2.06)	0.1650	0.10 (0.08)	(-0.06, 0.26)	0.2429	
OCS dose											0.6221
<10 mg/day	207	2.82 (0.52)	208	1.51 (0.52)	1.30 (0.68)	(-0.03, 2.64)	0.0561	0.17 (0.10)	(-0.02, 0.37)	0.0780	
>=10 mg/day	230	3.87 (0.65)	235	2.08 (0.64)	1.79 (0.72)	(0.37, 3.22)	0.0137	0.18 (0.09)	(-0.00, 0.36)	0.0503	
Result of type I IFN gene signature test											0.8819
LOW	83	3.91 (0.77)	86	2.53 (0.76)	1.37 (1.06)	(-0.73, 3.47)	0.1983	0.19 (0.15)	(-0.11, 0.50)	0.2079	
HIGH	354	3.55 (0.42)	357	2.00 (0.42)	1.55 (0.57)	(0.44, 2.66)	0.0062	0.19 (0.08)	(0.05, 0.34)	0.0095	
Age (years)											0.8530
<= 65	425	3.25 (0.41)	441	1.77 (0.41)	1.48 (0.50)	(0.50, 2.46)	0.0032	0.17 (0.07)	(0.04, 0.31)	0.0108	
> 65	12	6.39 (3.45)	2	6.48 (8.06)	-0.09 (8.45)	(-21.14, 20.96)	0.9921	-0.01 (0.76)	(-1.50, 1.49)	0.9928	
Sex											0.6645
male	32	6.10 (1.77)	33	5.30 (1.69)	0.80 (1.68)	(-2.56, 4.17)	0.6350	0.08 (0.25)	(-0.41, 0.57)	0.7458	
female	405	3.21 (0.42)	410	1.65 (0.42)	1.57 (0.52)	(0.55, 2.59)	0.0027	0.18 (0.07)	(0.05, 0.32)	0.0085	
Race											0.6793
White	254	2.88 (0.53)	266	1.64 (0.52)	1.24 (0.66)	(-0.05, 2.53)	0.0604	0.15 (0.09)	(-0.03, 0.32)	0.0962	
Black	61	2.77 (1.37)	56	0.07 (1.30)	2.71 (1.54)	(-0.34, 5.76)	0.0814	0.26 (0.19)	(-0.10, 0.63)	0.1580	
Other	114	3.60 (0.88)	114	2.11 (0.90)	1.49 (0.97)	(-0.43, 3.40)	0.1271	0.16 (0.13)	(-0.10, 0.42)	0.2390	
Ethnicity											0.1951
Hispanic/Latino	129	4.36 (0.74)	128	3.95 (0.74)	0.41 (0.91)	(-1.37, 2.19)	0.6509	0.05 (0.12)	(-0.20, 0.29)	0.6970	
Non-hispanic/Latino	300	2.39 (0.50)	308	0.57 (0.49)	1.82 (0.60)	(0.64, 3.00)	0.0026	0.21 (0.08)	(0.05, 0.37)	0.0095	
Geographic region											0.6715
EU	128	3.25 (0.82)	137	2.08 (0.82)	1.18 (0.87)	(-0.54, 2.90)	0.1788	0.12 (0.12)	(-0.12, 0.37)	0.3123	
non-EU	309	3.35 (0.48)	306	1.72 (0.49)	1.63 (0.61)	(0.42, 2.84)	0.0081	0.19 (0.08)	(0.03, 0.35)	0.0179	
Onset of disease											0.8669
Paediatric	33	2.54 (1.98)	33	0.66 (1.90)	1.88 (2.08)	(-2.27, 6.04)	0.3684	0.17 (0.25)	(-0.32, 0.65)	0.4993	
Adult	404	3.37 (0.42)	410	1.84 (0.42)	1.52 (0.52)	(0.51, 2.54)	0.0034	0.18 (0.07)	(0.04, 0.32)	0.0103	
ADA result											0.0987
Negative	408	3.11 (0.42)	405	1.80 (0.42)	1.31 (0.52)	(0.28, 2.33)	0.0125	0.15 (0.07)	(0.02, 0.29)	0.0286	
Positive (At any time)	29	8.09 (2.01)	38	3.72 (1.81)	4.38 (1.78)	(0.81, 7.95)	0.0171	0.39 (0.25)	(-0.10, 0.88)	0.1152	
BMI (kg/m2)											0.8790
< 30	294	3.33 (0.49)	319	1.75 (0.49)	1.58 (0.57)	(0.47, 2.70)	0.0054	0.18 (0.08)	(0.02, 0.34)	0.0235	
>= 30	143	3.49 (0.76)	124	2.08 (0.77)	1.41 (1.02)	(-0.59, 3.41)	0.1675	0.16 (0.12)	(-0.08, 0.40)	0.1953	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Bodily Pain Score
Full analysis set

	Anifrolumab 300mg (N=459)		Placebo (N=468)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 4		1.36 (0.71)		-0.07 (0.71)	1.43 (0.94)	(-0.43, 3.29)	0.1303				
Week 8		3.55 (0.47)		2.44 (0.47)	1.11 (0.58)	(-0.04, 2.25)	0.0587				
Week 12		2.86 (0.80)		2.52 (0.79)	0.34 (1.08)	(-1.79, 2.47)	0.7544				
Week 16		4.70 (0.50)		3.87 (0.50)	0.84 (0.63)	(-0.41, 2.08)	0.1871				
Week 24		4.83 (0.48)		3.05 (0.47)	1.78 (0.61)	(0.58, 2.98)	0.0037				
Week 32		4.60 (0.51)		3.82 (0.51)	0.79 (0.66)	(-0.51, 2.08)	0.2334				
Week 36		6.44 (0.83)		3.75 (0.89)	2.69 (1.19)	(0.35, 5.03)	0.0246				
Week 40		5.39 (0.51)		4.02 (0.51)	1.37 (0.66)	(0.07, 2.67)	0.0384				
Week 48		5.62 (0.53)		3.87 (0.53)	1.75 (0.69)	(0.40, 3.10)	0.0111				
Week 52		4.91 (0.48)		3.86 (0.50)	1.05 (0.64)	(-0.20, 2.29)	0.1008				
OVERALL	437	4.43 (0.38)	443	3.11 (0.38)	1.31 (0.47)	(0.39, 2.24)	0.0055	0.16 (0.07)	(0.03, 0.30)	0.0156	0.7988

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Bodily Pain Score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=459)		Placebo (N=468)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.0490
< 10 points	141	5.35 (0.63)	140	2.70 (0.63)	2.65 (0.83)	(1.02, 4.28)	0.0015	0.36 (0.12)	(0.12, 0.59)	0.0031	
>= 10 points	296	3.87 (0.48)	303	3.21 (0.48)	0.67 (0.58)	(-0.46, 1.80)	0.2455	0.08 (0.08)	(-0.08, 0.24)	0.3281	
OCS dose											0.1327
<10 mg/day	207	4.43 (0.52)	208	2.35 (0.53)	2.08 (0.68)	(0.73, 3.42)	0.0025	0.28 (0.10)	(0.08, 0.47)	0.0052	
>=10 mg/day	230	4.47 (0.59)	235	3.82 (0.58)	0.64 (0.66)	(-0.66, 1.95)	0.3333	0.07 (0.09)	(-0.11, 0.25)	0.4389	
Result of type I IFN gene signature test											0.1981
LOW	83	3.74 (0.74)	86	3.63 (0.73)	0.11 (1.03)	(-1.92, 2.13)	0.9157	0.02 (0.15)	(-0.29, 0.32)	0.9173	
HIGH	354	5.11 (0.39)	357	3.52 (0.40)	1.59 (0.53)	(0.55, 2.64)	0.0028	0.21 (0.08)	(0.07, 0.36)	0.0046	
Age (years)											NE
<= 65	425	4.44 (0.39)	441	3.08 (0.38)	1.36 (0.48)	(0.42, 2.29)	0.0044	0.17 (0.07)	(0.03, 0.30)	0.0135	
> 65	12	NE	2	NE	NE	NE		NE	NE		
Sex											0.5732
male	32	5.73 (1.82)	33	5.36 (1.75)	0.37 (1.74)	(-3.12, 3.85)	0.8328	0.04 (0.25)	(-0.45, 0.52)	0.8852	
female	405	4.42 (0.40)	410	3.04 (0.40)	1.39 (0.49)	(0.42, 2.35)	0.0049	0.17 (0.07)	(0.04, 0.31)	0.0135	
Race											0.0907
White	254	3.74 (0.49)	266	3.32 (0.48)	0.42 (0.60)	(-0.77, 1.61)	0.4899	0.05 (0.09)	(-0.12, 0.23)	0.5409	
Black	61	4.81 (1.30)	56	0.98 (1.25)	3.83 (1.47)	(0.92, 6.74)	0.0104	0.39 (0.19)	(0.02, 0.76)	0.0373	
Other	114	4.33 (0.82)	114	2.96 (0.84)	1.37 (0.90)	(-0.40, 3.14)	0.1280	0.15 (0.13)	(-0.11, 0.41)	0.2444	
Ethnicity											0.3557
Hispanic/Latino	129	5.97 (0.71)	128	4.22 (0.71)	1.75 (0.86)	(0.05, 3.45)	0.0439	0.22 (0.13)	(-0.03, 0.46)	0.0834	
Non-hispanic/Latino	300	3.40 (0.47)	308	2.60 (0.46)	0.80 (0.56)	(-0.31, 1.90)	0.1570	0.10 (0.08)	(-0.06, 0.26)	0.2225	
Geographic region											0.0398
EU	128	3.67 (0.80)	137	3.83 (0.81)	-0.17 (0.85)	(-1.84, 1.51)	0.8459	-0.02 (0.12)	(-0.26, 0.22)	0.8852	
non-EU	309	4.60 (0.45)	306	2.66 (0.45)	1.93 (0.57)	(0.82, 3.05)	0.0007	0.25 (0.08)	(0.09, 0.41)	0.0023	
Onset of disease											0.9957
Paediatric	33	4.66 (2.06)	33	3.31 (1.95)	1.35 (2.04)	(-2.72, 5.43)	0.5095	0.12 (0.25)	(-0.37, 0.60)	0.6377	
Adult	404	4.41 (0.39)	410	3.07 (0.39)	1.34 (0.49)	(0.39, 2.29)	0.0059	0.17 (0.07)	(0.03, 0.31)	0.0156	
ADA result											0.0664
Negative	408	4.22 (0.39)	405	3.18 (0.39)	1.04 (0.49)	(0.08, 2.00)	0.0337	0.13 (0.07)	(-0.01, 0.27)	0.0618	
Positive (At any time)	29	9.78 (2.12)	38	4.95 (1.94)	4.83 (2.00)	(0.81, 8.85)	0.0193	0.41 (0.25)	(-0.08, 0.89)	0.1032	
BMI (kg/m2)											0.1065
< 30	294	4.42 (0.48)	319	3.54 (0.48)	0.88 (0.56)	(-0.22, 1.98)	0.1175	0.10 (0.08)	(-0.06, 0.26)	0.2016	
>= 30	143	4.68 (0.66)	124	2.11 (0.67)	2.57 (0.89)	(0.82, 4.31)	0.0041	0.33 (0.12)	(0.09, 0.58)	0.0069	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Vitality Score
Full analysis set

	Anifrolumab 300mg (N=459)		Placebo (N=468)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 4		0.79 (0.59)		-0.01 (0.59)	0.80 (0.74)	(-0.65, 2.26)	0.2779				
Week 8		2.52 (0.47)		1.48 (0.46)	1.04 (0.58)	(-0.10, 2.18)	0.0732				
Week 12		2.55 (0.70)		1.68 (0.70)	0.87 (0.94)	(-0.99, 2.73)	0.3586				
Week 16		2.68 (0.48)		2.06 (0.48)	0.62 (0.61)	(-0.58, 1.81)	0.3102				
Week 24		3.37 (0.44)		2.04 (0.44)	1.32 (0.56)	(0.22, 2.43)	0.0189				
Week 32		3.29 (0.49)		2.12 (0.49)	1.17 (0.63)	(-0.06, 2.39)	0.0626				
Week 36		4.23 (0.73)		2.45 (0.78)	1.78 (1.04)	(-0.26, 3.82)	0.0876				
Week 40		3.25 (0.51)		2.73 (0.50)	0.52 (0.65)	(-0.76, 1.80)	0.4265				
Week 48		3.88 (0.49)		2.43 (0.49)	1.45 (0.63)	(0.21, 2.70)	0.0220				
Week 52		3.62 (0.47)		2.18 (0.48)	1.43 (0.61)	(0.23, 2.64)	0.0197				
OVERALL	437	3.02 (0.36)	443	1.92 (0.36)	1.10 (0.44)	(0.24, 1.96)	0.0127	0.15 (0.07)	(0.01, 0.28)	0.0313	0.8253

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SF-36 v2.0 Acute Vitality Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=459) N	LSMean (SE)	Placebo (N=468) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.2065
< 10 points	141	4.21 (0.60)	140	2.30 (0.59)	1.91 (0.78)	(0.37, 3.45)	0.0152	0.27 (0.12)	(0.03, 0.50)	0.0245	
>= 10 points	296	2.14 (0.46)	303	1.43 (0.45)	0.71 (0.54)	(-0.34, 1.76)	0.1836	0.09 (0.08)	(-0.07, 0.25)	0.2713	
OCS dose											0.8591
<10 mg/day	207	2.54 (0.49)	208	1.53 (0.49)	1.01 (0.63)	(-0.23, 2.25)	0.1110	0.14 (0.10)	(-0.05, 0.34)	0.1450	
>=10 mg/day	230	3.40 (0.55)	235	2.24 (0.54)	1.16 (0.61)	(-0.04, 2.37)	0.0591	0.14 (0.09)	(-0.04, 0.32)	0.1355	
Result of type I IFN gene signature test											0.0609
LOW	83	3.15 (0.71)	86	3.73 (0.71)	-0.58 (0.99)	(-2.53, 1.37)	0.5590	-0.09 (0.15)	(-0.39, 0.21)	0.5668	
HIGH	354	3.18 (0.37)	357	1.68 (0.37)	1.49 (0.50)	(0.52, 2.47)	0.0027	0.21 (0.08)	(0.07, 0.36)	0.0046	
Age (years)											0.8557
<= 65	425	3.01 (0.37)	441	1.93 (0.36)	1.08 (0.44)	(0.21, 1.95)	0.0148	0.14 (0.07)	(0.01, 0.28)	0.0361	
> 65	12	6.49 (1.91)	2	6.22 (4.07)	0.27 (4.44)	(-9.54, 10.08)	0.9528	0.04 (0.76)	(-1.46, 1.54)	0.9598	
Sex											0.9994
male	32	4.40 (1.49)	33	3.32 (1.38)	1.08 (1.39)	(-1.70, 3.86)	0.4399	0.13 (0.25)	(-0.36, 0.62)	0.5992	
female	405	2.90 (0.38)	410	1.82 (0.37)	1.08 (0.46)	(0.17, 1.99)	0.0197	0.14 (0.07)	(0.00, 0.28)	0.0423	
Race											0.0118
White	254	2.13 (0.46)	266	2.21 (0.44)	-0.08 (0.55)	(-1.17, 1.01)	0.8866	-0.01 (0.09)	(-0.18, 0.16)	0.9010	
Black	61	3.74 (1.08)	56	0.01 (1.03)	3.73 (1.18)	(1.40, 6.06)	0.0020	0.46 (0.19)	(0.09, 0.82)	0.0148	
Other	114	3.10 (0.78)	114	1.94 (0.81)	1.16 (0.88)	(-0.56, 2.89)	0.1859	0.14 (0.13)	(-0.12, 0.40)	0.3026	
Ethnicity											0.9904
Hispanic/Latino	129	3.94 (0.67)	128	3.01 (0.66)	0.93 (0.81)	(-0.68, 2.53)	0.2560	0.12 (0.12)	(-0.12, 0.37)	0.3271	
Non-hispanic/Latino	300	2.21 (0.44)	308	1.27 (0.43)	0.94 (0.52)	(-0.08, 1.96)	0.0721	0.12 (0.08)	(-0.04, 0.28)	0.1277	
Geographic region											0.0030
EU	128	1.18 (0.76)	137	2.12 (0.76)	-0.94 (0.76)	(-2.44, 0.56)	0.2182	-0.11 (0.12)	(-0.35, 0.13)	0.3829	
non-EU	309	3.49 (0.42)	306	1.68 (0.42)	1.81 (0.53)	(0.77, 2.85)	0.0006	0.25 (0.08)	(0.09, 0.41)	0.0023	
Onset of disease											0.8244
Paediatric	33	3.00 (1.67)	33	2.22 (1.57)	0.78 (1.69)	(-2.60, 4.16)	0.6452	0.08 (0.25)	(-0.40, 0.57)	0.7363	
Adult	404	3.07 (0.37)	410	1.90 (0.37)	1.17 (0.46)	(0.27, 2.07)	0.0109	0.16 (0.07)	(0.02, 0.29)	0.0268	
ADA result											0.0964
Negative	408	2.92 (0.37)	405	2.06 (0.37)	0.86 (0.46)	(-0.03, 1.75)	0.0593	0.12 (0.07)	(-0.02, 0.25)	0.1002	
Positive (At any time)	29	4.53 (2.15)	38	0.40 (1.94)	4.13 (1.91)	(0.29, 7.97)	0.0353	0.35 (0.25)	(-0.14, 0.83)	0.1637	
BMI (kg/m2)											0.3440
< 30	294	2.90 (0.46)	319	2.06 (0.45)	0.84 (0.52)	(-0.18, 1.87)	0.1076	0.11 (0.08)	(-0.05, 0.26)	0.1920	
>= 30	143	3.41 (0.61)	124	1.65 (0.61)	1.76 (0.81)	(0.16, 3.35)	0.0313	0.25 (0.12)	(0.01, 0.49)	0.0448	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - FACIT-F Total Score
Full analysis set

	Anifrolumab 300mg (N=459)		Placebo (N=468)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 4		2.76 (0.42)		1.64 (0.42)	1.12 (0.52)	(0.09, 2.14)	0.0334				
Week 8		3.33 (0.48)		2.37 (0.47)	0.96 (0.60)	(-0.23, 2.14)	0.1134				
Week 12		3.69 (0.48)		1.83 (0.48)	1.85 (0.62)	(0.65, 3.06)	0.0027				
Week 16		3.96 (0.53)		2.65 (0.52)	1.31 (0.68)	(-0.03, 2.65)	0.0557				
Week 20		4.97 (0.53)		4.40 (0.52)	0.56 (0.68)	(-0.78, 1.91)	0.4118				
Week 24		5.19 (0.51)		3.23 (0.50)	1.96 (0.66)	(0.66, 3.25)	0.0031				
Week 28		5.59 (0.55)		3.59 (0.55)	1.99 (0.72)	(0.57, 3.41)	0.0060				
Week 32		4.69 (0.57)		3.81 (0.57)	0.88 (0.75)	(-0.60, 2.35)	0.2440				
Week 36		5.10 (0.53)		3.29 (0.54)	1.81 (0.70)	(0.43, 3.19)	0.0102				
Week 40		4.74 (0.57)		4.27 (0.57)	0.48 (0.76)	(-1.01, 1.96)	0.5289				
Week 44		5.68 (0.58)		4.11 (0.59)	1.57 (0.78)	(0.04, 3.10)	0.0443				
Week 48		5.04 (0.58)		3.75 (0.58)	1.28 (0.77)	(-0.24, 2.80)	0.0976				
Week 52		5.06 (0.55)		3.64 (0.56)	1.42 (0.73)	(-0.02, 2.85)	0.0533				
OVERALL	439	4.60 (0.43)	447	3.28 (0.42)	1.32 (0.53)	(0.28, 2.36)	0.0128	0.15 (0.07)	(0.02, 0.28)	0.0282	0.6334

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - FACIT-F Total Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=459) N	LSMean (SE)	Placebo (N=468) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.1399
< 10 points	141	6.00 (0.70)	141	3.56 (0.69)	2.44 (0.92)	(0.63, 4.25)	0.0084	0.30 (0.12)	(0.06, 0.53)	0.0134	
>= 10 points	298	3.76 (0.53)	306	2.97 (0.53)	0.79 (0.64)	(-0.48, 2.05)	0.2216	0.08 (0.08)	(-0.07, 0.24)	0.2972	
OCS dose											0.4717
<10 mg/day	207	4.46 (0.58)	207	2.67 (0.57)	1.79 (0.75)	(0.31, 3.27)	0.0177	0.22 (0.10)	(0.02, 0.41)	0.0282	
>=10 mg/day	232	4.59 (0.64)	240	3.56 (0.64)	1.03 (0.74)	(-0.43, 2.49)	0.1653	0.10 (0.09)	(-0.08, 0.28)	0.2573	
Result of type I IFN gene signature test											0.3517
LOW	82	4.78 (0.93)	86	4.57 (0.92)	0.21 (1.28)	(-2.32, 2.75)	0.8686	0.03 (0.15)	(-0.28, 0.33)	0.8709	
HIGH	357	4.97 (0.43)	361	3.44 (0.43)	1.52 (0.58)	(0.39, 2.66)	0.0085	0.19 (0.07)	(0.04, 0.33)	0.0128	
Age (years)											NE
<= 65	428	4.58 (0.43)	445	3.30 (0.43)	1.28 (0.53)	(0.23, 2.33)	0.0169	0.14 (0.07)	(0.01, 0.28)	0.0357	
> 65	11	NE	2	NE	NE	NE		NE	NE		
Sex											0.6206
male	32	5.73 (1.52)	33	5.19 (1.51)	0.54 (1.52)	(-2.50, 3.58)	0.7221	0.06 (0.25)	(-0.42, 0.55)	0.8027	
female	407	4.56 (0.44)	414	3.22 (0.44)	1.34 (0.56)	(0.25, 2.43)	0.0161	0.15 (0.07)	(0.01, 0.29)	0.0325	
Race											0.2427
White	255	4.14 (0.56)	271	3.32 (0.55)	0.82 (0.68)	(-0.52, 2.16)	0.2293	0.09 (0.09)	(-0.08, 0.26)	0.2949	
Black	63	6.73 (1.37)	55	3.03 (1.32)	3.71 (1.57)	(0.59, 6.82)	0.0203	0.35 (0.19)	(-0.01, 0.72)	0.0565	
Other	115	3.88 (0.89)	114	2.61 (0.93)	1.26 (1.02)	(-0.76, 3.28)	0.2190	0.13 (0.13)	(-0.13, 0.39)	0.3280	
Ethnicity											0.9160
Hispanic/Latino	129	5.24 (0.83)	129	3.96 (0.83)	1.28 (1.03)	(-0.75, 3.31)	0.2159	0.14 (0.12)	(-0.11, 0.38)	0.2782	
Non-hispanic/Latino	304	4.11 (0.50)	311	2.71 (0.50)	1.40 (0.62)	(0.20, 2.61)	0.0228	0.16 (0.08)	(0.00, 0.32)	0.0475	
Geographic region											0.0407
EU	127	4.01 (0.78)	141	4.20 (0.77)	-0.18 (0.86)	(-1.87, 1.50)	0.8299	-0.02 (0.12)	(-0.26, 0.22)	0.8677	
non-EU	312	4.85 (0.52)	306	2.82 (0.52)	2.03 (0.66)	(0.73, 3.33)	0.0022	0.22 (0.08)	(0.07, 0.38)	0.0057	
Onset of disease											0.8345
Paediatric	32	5.12 (1.92)	33	4.13 (1.85)	0.99 (2.07)	(-3.15, 5.13)	0.6334	0.09 (0.25)	(-0.40, 0.58)	0.7142	
Adult	407	4.69 (0.44)	414	3.25 (0.44)	1.44 (0.55)	(0.36, 2.51)	0.0089	0.16 (0.07)	(0.02, 0.30)	0.0206	
ADA result											0.0614
Negative	409	4.45 (0.44)	409	3.36 (0.44)	1.08 (0.55)	(0.01, 2.16)	0.0488	0.12 (0.07)	(-0.01, 0.26)	0.0799	
Positive (At any time)	30	8.31 (2.44)	38	3.10 (2.12)	5.21 (2.14)	(0.94, 9.48)	0.0176	0.39 (0.25)	(-0.09, 0.87)	0.1142	
BMI (kg/m2)											0.5393
< 30	297	4.58 (0.53)	323	3.44 (0.52)	1.14 (0.62)	(-0.09, 2.37)	0.0682	0.12 (0.08)	(-0.04, 0.28)	0.1273	
>= 30	142	4.62 (0.73)	124	2.76 (0.75)	1.85 (0.98)	(-0.08, 3.79)	0.0602	0.22 (0.12)	(-0.03, 0.46)	0.0804	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - EQ VAS Score
Full analysis set

	Anifrolumab 300mg (N=459)		Placebo (N=468)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 4		3.67 (1.67)		1.88 (1.66)	1.80 (2.21)	(-2.56, 6.15)	0.4170				
Week 12		7.47 (1.06)		3.86 (1.05)	3.61 (1.35)	(0.96, 6.26)	0.0077				
Week 24		8.21 (1.12)		6.78 (1.11)	1.42 (1.44)	(-1.40, 4.24)	0.3225				
Week 36		9.46 (1.13)		8.51 (1.14)	0.94 (1.47)	(-1.94, 3.83)	0.5215				
Week 52		10.30 (1.16)		7.14 (1.18)	3.15 (1.51)	(0.18, 6.13)	0.0376				
OVERALL	430	7.82 (0.89)	439	5.64 (0.89)	2.18 (1.10)	(0.03, 4.34)	0.0465	0.12 (0.07)	(-0.02, 0.25)	0.0833	0.9920

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - EQ VAS Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=459) N	LSMean (SE)	Placebo (N=468) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.7405
< 10 points	136	8.68 (1.44)	139	5.98 (1.42)	2.70 (1.88)	(-1.00, 6.40)	0.1526	0.16 (0.12)	(-0.08, 0.40)	0.1851	
>= 10 points	294	6.83 (1.13)	300	4.90 (1.13)	1.93 (1.35)	(-0.71, 4.57)	0.1519	0.10 (0.08)	(-0.06, 0.26)	0.2265	
OCS dose											0.8514
<10 mg/day	203	6.79 (1.26)	203	4.91 (1.27)	1.88 (1.66)	(-1.37, 5.14)	0.2556	0.10 (0.10)	(-0.09, 0.30)	0.2922	
>=10 mg/day	227	8.49 (1.32)	236	6.19 (1.30)	2.30 (1.47)	(-0.60, 5.20)	0.1196	0.11 (0.09)	(-0.07, 0.30)	0.2166	
Result of type I IFN gene signature test											0.1385
LOW	82	4.28 (1.80)	86	5.26 (1.77)	-0.98 (2.46)	(-5.84, 3.89)	0.6916	-0.06 (0.15)	(-0.36, 0.24)	0.6991	
HIGH	348	9.63 (0.91)	353	6.54 (0.91)	3.10 (1.22)	(0.69, 5.50)	0.0117	0.18 (0.08)	(0.03, 0.33)	0.0168	
Age (years)											0.9344
<= 65	419	7.88 (0.91)	437	5.62 (0.89)	2.26 (1.10)	(0.09, 4.42)	0.0412	0.12 (0.07)	(-0.01, 0.26)	0.0767	
> 65	11	9.79 (4.30)	2	6.73 (8.88)	3.06 (9.74)	(-19.15, 25.27)	0.7607	0.20 (0.77)	(-1.31, 1.71)	0.7930	
Sex											0.8117
male	32	3.97 (4.44)	33	2.69 (4.23)	1.28 (3.86)	(-6.45, 9.02)	0.7408	0.05 (0.25)	(-0.44, 0.54)	0.8362	
female	398	8.29 (0.92)	406	6.05 (0.92)	2.24 (1.14)	(0.00, 4.48)	0.0497	0.12 (0.07)	(-0.02, 0.26)	0.0851	
Race											0.0118
White	250	6.35 (1.15)	267	7.65 (1.12)	-1.30 (1.44)	(-4.12, 1.53)	0.3676	-0.07 (0.09)	(-0.24, 0.10)	0.4206	
Black	62	6.50 (2.70)	55	0.35 (2.56)	6.16 (3.10)	(0.01, 12.30)	0.0495	0.30 (0.19)	(-0.06, 0.67)	0.1046	
Other	112	8.98 (1.97)	111	3.84 (2.05)	5.14 (2.16)	(0.88, 9.40)	0.0182	0.24 (0.13)	(-0.02, 0.50)	0.0725	
Ethnicity											0.5829
Hispanic/Latino	126	10.25 (1.68)	128	7.73 (1.67)	2.51 (2.01)	(-1.44, 6.47)	0.2117	0.13 (0.13)	(-0.11, 0.38)	0.2902	
Non-hispanic/Latino	298	5.43 (1.07)	305	4.23 (1.05)	1.20 (1.30)	(-1.36, 3.76)	0.3565	0.07 (0.08)	(-0.09, 0.22)	0.4245	
Geographic region											0.0066
EU	126	7.32 (1.88)	137	9.53 (1.90)	-2.21 (1.97)	(-6.09, 1.67)	0.2635	-0.10 (0.12)	(-0.34, 0.14)	0.4108	
non-EU	304	7.37 (1.02)	302	3.16 (1.02)	4.20 (1.30)	(1.66, 6.75)	0.0013	0.24 (0.08)	(0.08, 0.40)	0.0038	
Onset of disease											0.2763
Paediatric	31	10.59 (4.17)	32	4.10 (3.89)	6.50 (4.20)	(-1.94, 14.93)	0.1283	0.28 (0.25)	(-0.21, 0.78)	0.2632	
Adult	399	7.62 (0.92)	407	5.86 (0.92)	1.76 (1.14)	(-0.49, 4.00)	0.1251	0.09 (0.07)	(-0.04, 0.23)	0.1790	
ADA result											0.0224
Negative	401	7.35 (0.92)	402	5.66 (0.91)	1.68 (1.14)	(-0.55, 3.92)	0.1393	0.09 (0.07)	(-0.05, 0.23)	0.1940	
Positive (At any time)	29	19.87 (5.33)	37	7.74 (4.83)	12.12 (4.43)	(3.21, 21.04)	0.0088	0.41 (0.25)	(-0.08, 0.90)	0.1006	
BMI (kg/m2)											0.7693
< 30	291	9.01 (1.13)	318	6.57 (1.13)	2.43 (1.30)	(-0.12, 4.99)	0.0619	0.12 (0.08)	(-0.04, 0.28)	0.1295	
>= 30	139	5.79 (1.49)	121	4.07 (1.50)	1.73 (2.03)	(-2.27, 5.72)	0.3948	0.10 (0.12)	(-0.14, 0.34)	0.4170	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Lupus QoL Physical Health domain score
Full analysis set

	Anifrolumab 300mg (N=459)		Placebo (N=468)		Difference of						
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		4.62 (1.50)		2.65 (1.50)	1.97 (1.93)	(-1.83, 5.77)	0.3076				
Week 12		9.40 (1.02)		6.88 (1.01)	2.52 (1.28)	(0.01, 5.03)	0.0488				
Week 24		10.23 (1.04)		7.30 (1.04)	2.93 (1.31)	(0.35, 5.51)	0.0260				
Week 36		10.39 (1.08)		9.69 (1.09)	0.70 (1.39)	(-2.02, 3.42)	0.6139				
Week 52		8.99 (1.11)		8.31 (1.12)	0.68 (1.43)	(-2.13, 3.49)	0.6334				
OVERALL	428	8.73 (0.89)	437	6.97 (0.89)	1.76 (1.09)	(-0.38, 3.90)	0.1072	0.10 (0.07)	(-0.04, 0.23)	0.1623	0.8880

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Lupus QoL Physical Health domain score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=459)		Placebo (N=468)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.8484
< 10 points	137	10.61 (1.39)	138	8.63 (1.39)	1.98 (1.83)	(-1.62, 5.58)	0.2795	0.12 (0.12)	(-0.12, 0.36)	0.3162	
>= 10 points	291	7.14 (1.15)	299	5.59 (1.14)	1.55 (1.36)	(-1.13, 4.22)	0.2565	0.08 (0.08)	(-0.08, 0.24)	0.3412	
OCS dose											0.7550
<10 mg/day	203	8.26 (1.18)	202	6.68 (1.18)	1.57 (1.54)	(-1.45, 4.60)	0.3066	0.09 (0.10)	(-0.10, 0.29)	0.3455	
>=10 mg/day	225	9.17 (1.37)	235	6.91 (1.37)	2.25 (1.54)	(-0.78, 5.28)	0.1446	0.11 (0.09)	(-0.07, 0.29)	0.2461	
Result of type I IFN gene signature test											0.3177
LOW	82	8.54 (1.87)	85	9.10 (1.85)	-0.56 (2.59)	(-5.67, 4.55)	0.8294	-0.03 (0.15)	(-0.34, 0.27)	0.8327	
HIGH	346	9.00 (0.90)	352	6.70 (0.90)	2.30 (1.21)	(-0.08, 4.67)	0.0582	0.14 (0.08)	(-0.01, 0.29)	0.0715	
Age (years)											0.8374
<= 65	417	8.86 (0.90)	435	7.11 (0.89)	1.74 (1.10)	(-0.41, 3.90)	0.1124	0.09 (0.07)	(-0.04, 0.23)	0.1698	
> 65	11	4.88 (10.40)	2	-0.30 (17.53)	5.17 (16.67)	(-40.95, 51.30)	0.7717	0.14 (0.77)	(-1.37, 1.65)	0.8529	
Sex											0.6514
male	32	13.53 (5.35)	33	14.18 (5.25)	-0.65 (5.05)	(-10.92, 9.63)	0.8989	-0.02 (0.25)	(-0.51, 0.47)	0.9321	
female	396	8.61 (0.93)	404	6.92 (0.92)	1.69 (1.15)	(-0.56, 3.95)	0.1403	0.09 (0.07)	(-0.05, 0.23)	0.1967	
Race											0.5747
White	249	8.02 (1.12)	266	6.83 (1.09)	1.19 (1.37)	(-1.50, 3.88)	0.3838	0.07 (0.09)	(-0.11, 0.24)	0.4459	
Black	61	10.64 (2.94)	54	6.04 (2.87)	4.60 (3.35)	(-2.04, 11.24)	0.1725	0.21 (0.19)	(-0.16, 0.57)	0.2697	
Other	112	8.21 (1.97)	111	5.35 (2.05)	2.86 (2.17)	(-1.42, 7.15)	0.1892	0.13 (0.13)	(-0.13, 0.40)	0.3160	
Ethnicity											0.2817
Hispanic/Latino	126	9.87 (1.84)	128	9.63 (1.81)	0.24 (2.21)	(-4.11, 4.60)	0.9126	0.01 (0.13)	(-0.23, 0.26)	0.9253	
Non-hispanic/Latino	296	7.98 (1.02)	303	5.01 (1.00)	2.97 (1.23)	(0.55, 5.39)	0.0162	0.17 (0.08)	(0.01, 0.33)	0.0390	
Geographic region											0.3896
EU	125	8.89 (1.74)	137	8.57 (1.74)	0.32 (1.80)	(-3.23, 3.86)	0.8606	0.02 (0.12)	(-0.23, 0.26)	0.8982	
non-EU	303	8.39 (1.07)	300	6.14 (1.07)	2.25 (1.35)	(-0.40, 4.91)	0.0964	0.12 (0.08)	(-0.04, 0.28)	0.1367	
Onset of disease											0.2274
Paediatric	30	3.80 (3.71)	32	6.64 (3.47)	-2.84 (3.81)	(-10.47, 4.80)	0.4598	-0.14 (0.25)	(-0.64, 0.36)	0.5810	
Adult	398	8.91 (0.92)	405	6.95 (0.92)	1.96 (1.14)	(-0.28, 4.20)	0.0856	0.11 (0.07)	(-0.03, 0.24)	0.1330	
ADA result											0.0853
Negative	400	8.48 (0.91)	400	7.38 (0.91)	1.11 (1.13)	(-1.11, 3.32)	0.3284	0.06 (0.07)	(-0.08, 0.20)	0.3916	
Positive (At any time)	28	17.32 (5.23)	37	8.31 (4.61)	9.01 (4.45)	(0.10, 17.92)	0.0476	0.32 (0.25)	(-0.17, 0.81)	0.2054	
BMI (kg/m2)											0.8754
< 30	289	9.46 (1.09)	317	7.37 (1.09)	2.09 (1.25)	(-0.37, 4.54)	0.0953	0.11 (0.08)	(-0.05, 0.27)	0.1762	
>= 30	139	8.47 (1.61)	120	6.77 (1.65)	1.69 (2.19)	(-2.62, 6.00)	0.4402	0.09 (0.12)	(-0.15, 0.34)	0.4666	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Lupus QoL Emotional Health domain score
Full analysis set

	Anifrolumab 300mg (N=459)		Placebo (N=468)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 4		-0.99 (1.65)		1.68 (1.65)	-2.67 (2.20)	(-7.01, 1.67)	0.2264				
Week 12		4.64 (0.96)		3.14 (0.95)	1.50 (1.21)	(-0.87, 3.87)	0.2141				
Week 24		6.51 (1.01)		5.56 (1.00)	0.95 (1.28)	(-1.57, 3.47)	0.4601				
Week 36		7.66 (1.04)		6.82 (1.05)	0.85 (1.35)	(-1.79, 3.49)	0.5291				
Week 52		7.21 (1.11)		7.05 (1.13)	0.16 (1.47)	(-2.72, 3.04)	0.9125				
OVERALL	428	5.01 (0.85)	437	4.85 (0.84)	0.16 (1.05)	(-1.89, 2.21)	0.8800	0.01 (0.07)	(-0.12, 0.14)	0.8951	0.8407

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Lupus QoL Emotional Health domain score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=459) N	LSMean (SE)	Placebo (N=468) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.5351
< 10 points	137	7.35 (1.23)	138	6.30 (1.22)	1.04 (1.61)	(-2.12, 4.21)	0.5176	0.07 (0.12)	(-0.16, 0.31)	0.5494	
>= 10 points	291	3.19 (1.12)	299	3.45 (1.12)	-0.26 (1.35)	(-2.92, 2.40)	0.8466	-0.01 (0.08)	(-0.17, 0.15)	0.8691	
OCS dose											0.5698
<10 mg/day	203	4.35 (1.11)	202	4.85 (1.12)	-0.50 (1.46)	(-3.37, 2.38)	0.7334	-0.03 (0.10)	(-0.23, 0.16)	0.7524	
>=10 mg/day	225	5.56 (1.32)	235	4.87 (1.31)	0.69 (1.49)	(-2.24, 3.61)	0.6444	0.03 (0.09)	(-0.15, 0.22)	0.7120	
Result of type I IFN gene signature test											0.5430
LOW	82	3.31 (1.61)	85	4.51 (1.60)	-1.20 (2.23)	(-5.60, 3.21)	0.5932	-0.08 (0.15)	(-0.38, 0.22)	0.6002	
HIGH	346	6.26 (0.88)	352	5.92 (0.88)	0.34 (1.19)	(-1.99, 2.67)	0.7728	0.02 (0.08)	(-0.13, 0.17)	0.7832	
Age (years)											0.5492
<= 65	417	4.95 (0.86)	435	4.94 (0.85)	0.01 (1.05)	(-2.06, 2.08)	0.9908	0.00 (0.07)	(-0.13, 0.14)	0.9920	
> 65	11	8.70 (4.17)	2	3.21 (8.16)	5.49 (9.09)	(-16.09, 27.07)	0.5651	0.37 (0.77)	(-1.14, 1.89)	0.6280	
Sex											0.9499
male	32	5.71 (4.45)	33	5.34 (4.17)	0.37 (3.97)	(-7.70, 8.44)	0.9263	0.01 (0.25)	(-0.47, 0.50)	0.9522	
female	396	5.02 (0.87)	404	4.91 (0.87)	0.11 (1.08)	(-2.02, 2.24)	0.9183	0.01 (0.07)	(-0.13, 0.14)	0.9280	
Race											0.8879
White	249	4.31 (1.05)	266	3.76 (1.04)	0.56 (1.31)	(-2.02, 3.13)	0.6708	0.03 (0.09)	(-0.14, 0.21)	0.7066	
Black	61	6.96 (2.75)	54	7.28 (2.62)	-0.32 (3.11)	(-6.50, 5.86)	0.9192	-0.02 (0.19)	(-0.38, 0.35)	0.9344	
Other	112	5.35 (1.97)	111	5.95 (2.04)	-0.60 (2.17)	(-4.88, 3.68)	0.7822	-0.03 (0.13)	(-0.29, 0.23)	0.8331	
Ethnicity											0.1388
Hispanic/Latino	126	6.21 (1.85)	128	8.58 (1.82)	-2.37 (2.23)	(-6.76, 2.02)	0.2891	-0.11 (0.13)	(-0.36, 0.13)	0.3631	
Non-hispanic/Latino	296	4.55 (0.95)	303	3.21 (0.94)	1.35 (1.15)	(-0.92, 3.61)	0.2431	0.08 (0.08)	(-0.08, 0.24)	0.3148	
Geographic region											0.8551
EU	125	4.27 (1.59)	137	3.87 (1.61)	0.40 (1.65)	(-2.85, 3.64)	0.8096	0.02 (0.12)	(-0.22, 0.26)	0.8616	
non-EU	303	4.73 (1.02)	300	4.71 (1.02)	0.01 (1.30)	(-2.54, 2.57)	0.9916	0.00 (0.08)	(-0.16, 0.16)	0.9924	
Onset of disease											0.7114
Paediatric	30	6.01 (4.55)	32	7.50 (4.17)	-1.49 (4.52)	(-10.56, 7.58)	0.7432	-0.06 (0.25)	(-0.56, 0.44)	0.8113	
Adult	398	5.07 (0.86)	405	4.84 (0.86)	0.23 (1.08)	(-1.88, 2.34)	0.8304	0.01 (0.07)	(-0.13, 0.15)	0.8507	
ADA result											0.8121
Negative	400	4.78 (0.87)	400	4.89 (0.87)	-0.11 (1.08)	(-2.23, 2.02)	0.9217	-0.01 (0.07)	(-0.14, 0.13)	0.9311	
Positive (At any time)	28	4.83 (5.89)	37	6.66 (6.20)	-1.83 (7.19)	(-17.22, 13.56)	0.8022	-0.05 (0.25)	(-0.54, 0.44)	0.8365	
BMI (kg/m2)											0.8974
< 30	289	4.94 (1.08)	317	4.59 (1.08)	0.34 (1.25)	(-2.10, 2.79)	0.7828	0.02 (0.08)	(-0.14, 0.18)	0.8222	
>= 30	139	4.97 (1.40)	120	4.93 (1.42)	0.05 (1.92)	(-3.73, 3.83)	0.9796	0.00 (0.12)	(-0.24, 0.25)	0.9805	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Lupus QoL Body Image domain score
Full analysis set

	Anifrolumab 300mg (N=459)		Placebo (N=468)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 4		-0.60 (1.97)		1.64 (2.02)	-2.25 (2.71)	(-7.59, 3.10)	0.4083				
Week 12		7.92 (1.11)		5.60 (1.12)	2.31 (1.40)	(-0.44, 5.07)	0.1000				
Week 24		10.03 (1.23)		5.60 (1.23)	4.44 (1.58)	(1.34, 7.53)	0.0050				
Week 36		11.05 (1.25)		9.73 (1.28)	1.32 (1.64)	(-1.90, 4.54)	0.4215				
Week 52		10.32 (1.31)		8.36 (1.34)	1.96 (1.73)	(-1.44, 5.35)	0.2579				
OVERALL	399	7.74 (1.02)	402	6.19 (1.03)	1.56 (1.27)	(-0.95, 4.06)	0.2226	0.08 (0.07)	(-0.06, 0.21)	0.2841	0.7029

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Lupus QoL Body Image domain score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=459)		Placebo (N=468)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.1046
< 10 points	129	6.40 (1.42)	125	7.83 (1.45)	-1.43 (1.89)	(-5.15, 2.29)	0.4510	-0.09 (0.13)	(-0.33, 0.16)	0.4841	
>= 10 points	270	8.04 (1.36)	277	5.40 (1.35)	2.65 (1.65)	(-0.60, 5.89)	0.1097	0.12 (0.09)	(-0.05, 0.29)	0.1684	
OCS dose											0.5333
<10 mg/day	188	6.16 (1.36)	183	5.43 (1.40)	0.73 (1.82)	(-2.85, 4.31)	0.6882	0.04 (0.10)	(-0.16, 0.24)	0.7090	
>=10 mg/day	211	8.98 (1.57)	219	6.66 (1.56)	2.32 (1.79)	(-1.19, 5.83)	0.1952	0.10 (0.10)	(-0.09, 0.29)	0.2959	
Result of type I IFN gene signature test											0.2470
LOW	78	5.06 (1.80)	80	6.36 (1.81)	-1.31 (2.50)	(-6.25, 3.64)	0.6022	-0.08 (0.16)	(-0.39, 0.23)	0.6109	
HIGH	321	8.93 (1.08)	322	6.87 (1.10)	2.05 (1.47)	(-0.84, 4.95)	0.1640	0.10 (0.08)	(-0.05, 0.26)	0.1849	
Age (years)											NE
<= 65	389	7.72 (1.04)	400	6.27 (1.04)	1.45 (1.29)	(-1.07, 3.97)	0.2592	0.07 (0.07)	(-0.07, 0.21)	0.3235	
> 65	10	NE	2	NE	NE	NE		NE	NE		
Sex											0.3075
male	29	6.68 (4.58)	28	9.79 (4.46)	-3.11 (4.46)	(-12.13, 5.91)	0.4891	-0.13 (0.27)	(-0.65, 0.39)	0.6314	
female	370	7.67 (1.07)	374	6.03 (1.07)	1.63 (1.34)	(-0.99, 4.26)	0.2214	0.08 (0.07)	(-0.06, 0.22)	0.2800	
Race											0.4695
White	236	8.10 (1.23)	243	4.99 (1.25)	3.11 (1.56)	(0.05, 6.17)	0.0464	0.16 (0.09)	(-0.02, 0.34)	0.0778	
Black	57	5.55 (3.53)	50	6.20 (3.41)	-0.64 (4.11)	(-8.80, 7.51)	0.8760	-0.03 (0.19)	(-0.40, 0.35)	0.8972	
Other	101	7.11 (2.41)	103	7.12 (2.43)	-0.01 (2.61)	(-5.16, 5.14)	0.9980	-0.00 (0.14)	(-0.27, 0.27)	0.9985	
Ethnicity											0.2157
Hispanic/Latino	118	8.63 (2.06)	117	9.59 (2.07)	-0.96 (2.51)	(-5.90, 3.98)	0.7011	-0.04 (0.13)	(-0.30, 0.21)	0.7420	
Non-hispanic/Latino	276	7.35 (1.20)	279	4.71 (1.19)	2.64 (1.48)	(-0.26, 5.54)	0.0744	0.13 (0.08)	(-0.03, 0.30)	0.1192	
Geographic region											0.1044
EU	118	9.45 (2.06)	120	4.90 (2.13)	4.55 (2.22)	(0.17, 8.93)	0.0419	0.20 (0.13)	(-0.06, 0.45)	0.1273	
non-EU	281	6.44 (1.20)	282	6.27 (1.20)	0.17 (1.54)	(-2.85, 3.18)	0.9145	0.01 (0.08)	(-0.16, 0.17)	0.9227	
Onset of disease											0.7142
Paediatric	29	4.57 (5.38)	31	1.22 (5.13)	3.35 (5.48)	(-7.67, 14.37)	0.5440	0.12 (0.26)	(-0.39, 0.62)	0.6564	
Adult	370	7.99 (1.04)	371	6.71 (1.05)	1.29 (1.31)	(-1.28, 3.85)	0.3255	0.06 (0.07)	(-0.08, 0.21)	0.3848	
ADA result											NE
Negative	375	7.70 (1.06)	367	6.25 (1.07)	1.44 (1.33)	(-1.17, 4.06)	0.2785	0.07 (0.07)	(-0.07, 0.21)	0.3376	
Positive (At any time)	24	NE	35	NE	NE	NE		NE	NE		
BMI (kg/m2)											0.1871
< 30	265	8.55 (1.33)	288	5.96 (1.33)	2.59 (1.55)	(-0.46, 5.64)	0.0959	0.12 (0.09)	(-0.05, 0.28)	0.1704	
>= 30	134	6.22 (1.63)	114	7.22 (1.67)	-0.99 (2.23)	(-5.39, 3.40)	0.6558	-0.05 (0.13)	(-0.30, 0.20)	0.6718	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Lupus QoL Burden to Others domain score
Full analysis set

	Anifrolumab 300mg (N=459)		Placebo (N=468)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 4		2.08 (1.88)		1.97 (1.88)	0.11 (2.50)	(-4.82, 5.04)	0.9651				
Week 12		6.95 (1.23)		4.48 (1.22)	2.47 (1.55)	(-0.57, 5.51)	0.1106				
Week 24		7.75 (1.28)		6.82 (1.27)	0.93 (1.62)	(-2.26, 4.12)	0.5674				
Week 36		11.06 (1.29)		10.04 (1.30)	1.02 (1.66)	(-2.25, 4.28)	0.5413				
Week 52		8.67 (1.40)		7.22 (1.42)	1.45 (1.83)	(-2.15, 5.05)	0.4289				
OVERALL	428	7.30 (1.07)	437	6.11 (1.06)	1.20 (1.31)	(-1.38, 3.78)	0.3634	0.05 (0.07)	(-0.08, 0.19)	0.4290	0.8268

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Lupus QoL Burden to Others domain score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=459)		Placebo (N=468)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.7136
< 10 points	137	7.10 (1.68)	138	5.21 (1.67)	1.89 (2.19)	(-2.43, 6.21)	0.3892	0.10 (0.12)	(-0.14, 0.33)	0.4254	
>= 10 points	291	8.15 (1.35)	299	7.25 (1.35)	0.89 (1.61)	(-2.27, 4.06)	0.5799	0.04 (0.08)	(-0.12, 0.20)	0.6403	
OCS dose											0.7702
<10 mg/day	203	6.02 (1.41)	202	5.26 (1.43)	0.76 (1.85)	(-2.88, 4.40)	0.6829	0.04 (0.10)	(-0.16, 0.23)	0.7064	
>=10 mg/day	225	8.57 (1.65)	235	7.05 (1.64)	1.52 (1.86)	(-2.13, 5.17)	0.4127	0.06 (0.09)	(-0.12, 0.24)	0.5138	
Result of type I IFN gene signature test											0.6909
LOW	82	9.02 (2.13)	85	8.91 (2.11)	0.11 (2.95)	(-5.73, 5.94)	0.9711	0.01 (0.15)	(-0.30, 0.31)	0.9716	
HIGH	346	6.73 (1.10)	352	5.31 (1.10)	1.42 (1.48)	(-1.48, 4.32)	0.3365	0.07 (0.08)	(-0.08, 0.22)	0.3604	
Age (years)											0.1311
<= 65	417	7.04 (1.09)	435	6.13 (1.07)	0.91 (1.32)	(-1.69, 3.51)	0.4923	0.04 (0.07)	(-0.09, 0.18)	0.5516	
> 65	11	18.51 (6.26)	2	0.59 (10.83)	17.91 (11.18)	(-9.92, 45.75)	0.1638	0.82 (0.79)	(-0.73, 2.37)	0.3010	
Sex											0.3139
male	32	8.83 (4.43)	33	11.84 (4.30)	-3.01 (4.48)	(-11.98, 5.97)	0.5045	-0.12 (0.25)	(-0.61, 0.37)	0.6303	
female	396	7.34 (1.11)	404	5.63 (1.10)	1.71 (1.37)	(-0.99, 4.40)	0.2141	0.08 (0.07)	(-0.06, 0.22)	0.2755	
Race											0.5640
White	249	7.12 (1.36)	266	6.33 (1.34)	0.79 (1.68)	(-2.52, 4.10)	0.6387	0.04 (0.09)	(-0.14, 0.21)	0.6802	
Black	61	10.33 (4.00)	54	4.39 (3.86)	5.94 (4.57)	(-3.11, 15.00)	0.1960	0.20 (0.19)	(-0.17, 0.56)	0.2927	
Other	112	6.71 (2.23)	111	4.84 (2.31)	1.87 (2.45)	(-2.97, 6.71)	0.4473	0.08 (0.13)	(-0.18, 0.34)	0.5612	
Ethnicity											0.0854
Hispanic/Latino	126	10.18 (2.12)	128	12.17 (2.09)	-1.99 (2.54)	(-7.00, 3.01)	0.4332	-0.08 (0.13)	(-0.33, 0.16)	0.5039	
Non-hispanic/Latino	296	6.11 (1.28)	303	2.99 (1.26)	3.12 (1.54)	(0.09, 6.15)	0.0439	0.14 (0.08)	(-0.02, 0.30)	0.0842	
Geographic region											0.3262
EU	125	6.44 (2.02)	137	6.92 (2.03)	-0.49 (2.13)	(-4.69, 3.71)	0.8194	-0.02 (0.12)	(-0.26, 0.22)	0.8656	
non-EU	303	7.97 (1.28)	300	5.83 (1.28)	2.14 (1.63)	(-1.05, 5.34)	0.1876	0.10 (0.08)	(-0.06, 0.26)	0.2373	
Onset of disease											0.6771
Paediatric	30	3.37 (4.58)	32	4.08 (4.25)	-0.72 (4.67)	(-10.10, 8.67)	0.8783	-0.03 (0.25)	(-0.53, 0.47)	0.9095	
Adult	398	7.43 (1.11)	405	6.12 (1.11)	1.31 (1.38)	(-1.39, 4.01)	0.3421	0.06 (0.07)	(-0.08, 0.20)	0.4055	
ADA result											0.3943
Negative	400	7.22 (1.11)	400	6.53 (1.11)	0.69 (1.38)	(-2.02, 3.40)	0.6183	0.03 (0.07)	(-0.11, 0.17)	0.6617	
Positive (At any time)	28	7.93 (5.22)	37	3.27 (4.57)	4.65 (4.45)	(-4.27, 13.58)	0.3002	0.17 (0.25)	(-0.33, 0.66)	0.5085	
BMI (kg/m2)											0.3280
< 30	289	7.07 (1.34)	317	4.91 (1.34)	2.16 (1.54)	(-0.86, 5.19)	0.1611	0.09 (0.08)	(-0.07, 0.25)	0.2555	
>= 30	139	7.84 (1.88)	120	8.59 (1.91)	-0.75 (2.54)	(-5.76, 4.27)	0.7695	-0.03 (0.12)	(-0.28, 0.21)	0.7820	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Lupus QoL Fatigue domain score
Full analysis set

	Anifrolumab 300mg (N=459)		Placebo (N=468)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 4		2.32 (1.60)		-0.53 (1.60)	2.85 (2.13)	(-1.34, 7.04)	0.1817				
Week 12		7.98 (1.04)		5.82 (1.03)	2.16 (1.29)	(-0.37, 4.69)	0.0940				
Week 24		9.85 (1.10)		6.55 (1.09)	3.30 (1.39)	(0.58, 6.03)	0.0175				
Week 36		9.63 (1.15)		7.08 (1.15)	2.54 (1.47)	(-0.35, 5.43)	0.0849				
Week 52		9.58 (1.23)		6.70 (1.24)	2.88 (1.60)	(-0.27, 6.02)	0.0728				
OVERALL	428	7.87 (0.95)	437	5.12 (0.94)	2.75 (1.16)	(0.46, 5.03)	0.0186	0.14 (0.07)	(0.01, 0.27)	0.0407	0.6747

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Lupus QoL Fatigue domain score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=459) N	LSMean (SE)	Placebo (N=468) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.4516
< 10 points	137	9.71 (1.48)	138	5.69 (1.47)	4.03 (1.94)	(0.21, 7.84)	0.0388	0.23 (0.12)	(-0.01, 0.47)	0.0554	
>= 10 points	291	6.51 (1.21)	299	4.31 (1.21)	2.21 (1.44)	(-0.62, 5.04)	0.1263	0.11 (0.08)	(-0.06, 0.27)	0.1978	
OCS dose											0.9652
<10 mg/day	203	8.64 (1.18)	202	5.77 (1.18)	2.87 (1.55)	(-0.17, 5.92)	0.0644	0.17 (0.10)	(-0.02, 0.37)	0.0865	
>=10 mg/day	225	6.92 (1.51)	235	4.14 (1.50)	2.77 (1.70)	(-0.56, 6.11)	0.1030	0.12 (0.09)	(-0.06, 0.30)	0.1942	
Result of type I IFN gene signature test											0.8332
LOW	82	9.09 (1.97)	85	5.94 (1.94)	3.15 (2.72)	(-2.23, 8.53)	0.2490	0.18 (0.16)	(-0.13, 0.48)	0.2583	
HIGH	346	8.44 (0.96)	352	5.92 (0.96)	2.52 (1.29)	(-0.01, 5.05)	0.0510	0.14 (0.08)	(-0.01, 0.29)	0.0633	
Age (years)											0.3084
<= 65	417	7.97 (0.96)	435	5.26 (0.95)	2.71 (1.17)	(0.41, 5.01)	0.0210	0.14 (0.07)	(0.00, 0.27)	0.0453	
> 65	11	4.93 (5.02)	2	12.87 (9.52)	-7.93 (10.38)	(-39.80, 23.93)	0.4971	-0.45 (0.78)	(-1.97, 1.07)	0.5616	
Sex											0.3811
male	32	8.14 (4.38)	33	2.17 (4.14)	5.98 (3.79)	(-1.68, 13.64)	0.1226	0.24 (0.25)	(-0.24, 0.73)	0.3287	
female	396	7.84 (0.99)	404	5.35 (0.99)	2.49 (1.23)	(0.08, 4.90)	0.0427	0.13 (0.07)	(-0.01, 0.26)	0.0754	
Race											0.8332
White	249	7.63 (1.23)	266	5.33 (1.21)	2.30 (1.51)	(-0.67, 5.27)	0.1280	0.12 (0.09)	(-0.06, 0.29)	0.1825	
Black	61	8.01 (3.16)	54	4.01 (3.06)	4.01 (3.61)	(-3.15, 11.17)	0.2697	0.17 (0.19)	(-0.20, 0.53)	0.3691	
Other	112	7.76 (1.95)	111	4.12 (2.02)	3.64 (2.17)	(-0.63, 7.91)	0.0947	0.17 (0.13)	(-0.09, 0.44)	0.1985	
Ethnicity											0.6678
Hispanic/Latino	126	9.03 (1.90)	128	6.91 (1.88)	2.12 (2.29)	(-2.40, 6.64)	0.3557	0.10 (0.13)	(-0.15, 0.35)	0.4292	
Non-hispanic/Latino	296	7.20 (1.12)	303	3.94 (1.10)	3.26 (1.35)	(0.61, 5.92)	0.0161	0.17 (0.08)	(0.01, 0.33)	0.0388	
Geographic region											0.2387
EU	125	7.99 (1.78)	137	7.15 (1.79)	0.84 (1.87)	(-2.84, 4.52)	0.6533	0.04 (0.12)	(-0.20, 0.28)	0.7414	
non-EU	303	7.83 (1.14)	300	4.21 (1.13)	3.62 (1.44)	(0.79, 6.45)	0.0123	0.18 (0.08)	(0.02, 0.34)	0.0247	
Onset of disease											0.7668
Paediatric	30	8.42 (4.13)	32	6.98 (3.91)	1.44 (4.44)	(-7.47, 10.36)	0.7466	0.06 (0.25)	(-0.43, 0.56)	0.8020	
Adult	398	8.07 (0.98)	405	5.26 (0.98)	2.81 (1.22)	(0.42, 5.20)	0.0213	0.14 (0.07)	(0.00, 0.28)	0.0437	
ADA result											NE
Negative	400	7.50 (0.98)	400	5.17 (0.98)	2.33 (1.22)	(-0.06, 4.72)	0.0558	0.12 (0.07)	(-0.02, 0.26)	0.0929	
Positive (At any time)	28	NE	37	NE	NE	NE		NE	NE		
BMI (kg/m2)											0.5298
< 30	289	8.31 (1.16)	317	4.94 (1.16)	3.37 (1.33)	(0.75, 5.99)	0.0117	0.17 (0.08)	(0.01, 0.33)	0.0403	
>= 30	139	7.95 (1.75)	120	6.29 (1.78)	1.66 (2.37)	(-3.01, 6.34)	0.4833	0.08 (0.12)	(-0.16, 0.33)	0.5085	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Lupus QoL Intimate Relationships domain score
Full analysis set

	Anifrolumab 300mg (N=459)		Placebo (N=468)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 4		2.17 (2.43)		-0.18 (2.60)	2.36 (3.40)	(-4.35, 9.06)	0.4887				
Week 12		7.14 (1.50)		3.48 (1.52)	3.66 (1.93)	(-0.14, 7.46)	0.0589				
Week 24		6.25 (1.57)		5.29 (1.59)	0.96 (2.04)	(-3.04, 4.96)	0.6372				
Week 36		7.17 (1.66)		6.37 (1.70)	0.80 (2.20)	(-3.52, 5.11)	0.7162				
Week 52		5.98 (1.65)		5.84 (1.69)	0.14 (2.18)	(-4.14, 4.43)	0.9479				
OVERALL	344	5.74 (1.29)	340	4.16 (1.31)	1.58 (1.61)	(-1.58, 4.75)	0.3262	0.07 (0.08)	(-0.08, 0.22)	0.3893	0.8963

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Lupus QoL Intimate Relationships domain score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=459)		Placebo (N=468)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.4677
< 10 points	108	5.83 (2.23)	102	5.88 (2.28)	-0.05 (2.97)	(-5.92, 5.81)	0.9857	-0.00 (0.14)	(-0.27, 0.27)	0.9868	
>= 10 points	236	5.79 (1.53)	238	3.29 (1.55)	2.51 (1.90)	(-1.22, 6.23)	0.1869	0.11 (0.09)	(-0.07, 0.29)	0.2503	
OCS dose											0.5674
<10 mg/day	164	4.26 (1.74)	145	3.90 (1.96)	0.36 (2.45)	(-4.47, 5.19)	0.8842	0.02 (0.11)	(-0.21, 0.24)	0.8914	
>=10 mg/day	180	7.16 (1.95)	195	4.93 (1.89)	2.23 (2.17)	(-2.04, 6.51)	0.3051	0.08 (0.10)	(-0.12, 0.29)	0.4114	
Result of type I IFN gene signature test											0.4380
LOW	69	3.60 (2.89)	70	4.44 (2.82)	-0.84 (3.96)	(-8.69, 7.00)	0.8322	-0.04 (0.17)	(-0.37, 0.30)	0.8359	
HIGH	275	7.25 (1.27)	270	4.74 (1.33)	2.52 (1.75)	(-0.92, 5.96)	0.1513	0.12 (0.09)	(-0.05, 0.29)	0.1722	
Age (years)											NE
<= 65	338	5.49 (1.30)	339	4.06 (1.31)	1.42 (1.61)	(-1.74, 4.59)	0.3777	0.06 (0.08)	(-0.09, 0.21)	0.4404	
> 65	6	NE	1	NE	NE	NE		NE	NE		
Sex											0.2121
male	27	14.10 (3.40)	28	8.08 (3.24)	6.02 (3.46)	(-0.94, 12.99)	0.0884	0.34 (0.27)	(-0.19, 0.87)	0.2095	
female	317	5.48 (1.36)	312	4.28 (1.39)	1.20 (1.72)	(-2.17, 4.58)	0.4838	0.05 (0.08)	(-0.11, 0.21)	0.5364	
Race											0.9071
White	204	5.25 (1.56)	216	3.46 (1.53)	1.79 (1.95)	(-2.04, 5.62)	0.3581	0.08 (0.10)	(-0.11, 0.27)	0.4134	
Black	55	1.51 (4.03)	45	-1.62 (3.95)	3.13 (4.89)	(-6.59, 12.85)	0.5237	0.11 (0.20)	(-0.28, 0.50)	0.5868	
Other	80	8.13 (2.98)	75	4.80 (3.09)	3.33 (3.29)	(-3.18, 9.85)	0.3136	0.12 (0.16)	(-0.19, 0.44)	0.4397	
Ethnicity											0.0561
Hispanic/Latino	100	5.97 (2.51)	95	9.03 (2.48)	-3.05 (2.97)	(-8.91, 2.80)	0.3050	-0.12 (0.14)	(-0.40, 0.16)	0.3896	
Non-hispanic/Latino	239	5.38 (1.55)	241	1.68 (1.56)	3.70 (1.93)	(-0.08, 7.49)	0.0552	0.15 (0.09)	(-0.03, 0.33)	0.0924	
Geographic region											0.6293
EU	102	8.58 (2.39)	109	8.03 (2.47)	0.56 (2.60)	(-4.58, 5.69)	0.8309	0.02 (0.14)	(-0.25, 0.29)	0.8720	
non-EU	242	4.97 (1.54)	231	2.84 (1.56)	2.14 (1.99)	(-1.77, 6.04)	0.2829	0.09 (0.09)	(-0.09, 0.27)	0.3312	
Onset of disease											0.6044
Paediatric	24	3.99 (4.96)	21	5.32 (5.63)	-1.33 (5.49)	(-12.49, 9.83)	0.8098	-0.05 (0.30)	(-0.64, 0.53)	0.8612	
Adult	320	5.82 (1.35)	319	4.18 (1.37)	1.64 (1.70)	(-1.69, 4.98)	0.3331	0.07 (0.08)	(-0.09, 0.22)	0.3930	
ADA result											NE
Negative	324	5.67 (1.33)	314	4.14 (1.36)	1.53 (1.68)	(-1.76, 4.82)	0.3624	0.06 (0.08)	(-0.09, 0.22)	0.4215	
Positive (At any time)	20	NE	26	NE	NE	NE		NE	NE		
BMI (kg/m2)											0.7196
< 30	227	5.37 (1.60)	244	4.57 (1.59)	0.80 (1.86)	(-2.85, 4.46)	0.6662	0.03 (0.09)	(-0.15, 0.21)	0.7229	
>= 30	117	6.70 (2.25)	96	4.58 (2.42)	2.12 (3.15)	(-4.11, 8.34)	0.5030	0.09 (0.14)	(-0.18, 0.36)	0.5251	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Lupus QoL Pain domain score
Full analysis set

	Anifrolumab 300mg (N=459)		Placebo (N=468)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 4		6.62 (1.64)		5.21 (1.64)	1.41 (2.12)	(-2.76, 5.58)	0.5060				
Week 12		11.85 (1.14)		8.63 (1.13)	3.22 (1.44)	(0.39, 6.04)	0.0256				
Week 24		12.80 (1.18)		9.80 (1.18)	3.00 (1.50)	(0.05, 5.96)	0.0464				
Week 36		14.14 (1.19)		12.49 (1.20)	1.65 (1.53)	(-1.35, 4.65)	0.2813				
Week 52		12.74 (1.24)		10.63 (1.26)	2.10 (1.62)	(-1.07, 5.28)	0.1934				
OVERALL	428	11.63 (0.98)	437	9.35 (0.97)	2.28 (1.19)	(-0.07, 4.62)	0.0569	0.11 (0.07)	(-0.02, 0.25)	0.0990	0.9704

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Lupus QoL Pain domain score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=459) N	LSMean (SE)	Placebo (N=468) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.1950
< 10 points	137	13.95 (1.67)	138	9.42 (1.66)	4.53 (2.18)	(0.25, 8.81)	0.0383	0.23 (0.12)	(-0.01, 0.47)	0.0553	
>= 10 points	291	10.17 (1.20)	299	9.01 (1.20)	1.16 (1.43)	(-1.64, 3.96)	0.4168	0.06 (0.08)	(-0.11, 0.22)	0.4960	
OCS dose											0.5824
<10 mg/day	203	11.32 (1.31)	202	8.19 (1.32)	3.13 (1.71)	(-0.23, 6.50)	0.0678	0.17 (0.10)	(-0.03, 0.36)	0.0933	
>=10 mg/day	225	11.88 (1.49)	235	10.06 (1.49)	1.82 (1.67)	(-1.47, 5.11)	0.2782	0.08 (0.09)	(-0.10, 0.26)	0.3887	
Result of type I IFN gene signature test											0.7553
LOW	82	13.29 (2.05)	85	11.82 (2.03)	1.47 (2.83)	(-4.12, 7.06)	0.6042	0.08 (0.15)	(-0.23, 0.38)	0.6123	
HIGH	346	11.58 (0.98)	352	9.13 (0.98)	2.44 (1.32)	(-0.15, 5.04)	0.0644	0.13 (0.08)	(-0.02, 0.28)	0.0788	
Age (years)											0.4477
<= 65	417	11.62 (0.99)	435	9.39 (0.98)	2.23 (1.20)	(-0.13, 4.59)	0.0637	0.11 (0.07)	(-0.02, 0.24)	0.1093	
> 65	11	13.23 (8.74)	2	24.00 (16.78)	-10.77 (17.07)	(-54.48, 32.95)	0.5557	-0.35 (0.77)	(-1.87, 1.16)	0.6501	
Sex											0.8375
male	32	11.41 (4.45)	33	8.34 (4.22)	3.07 (4.07)	(-5.09, 11.23)	0.4538	0.12 (0.25)	(-0.36, 0.61)	0.6206	
female	396	11.66 (1.01)	404	9.46 (1.01)	2.20 (1.25)	(-0.26, 4.66)	0.0795	0.11 (0.07)	(-0.03, 0.25)	0.1252	
Race											0.3002
White	249	10.02 (1.24)	266	9.08 (1.22)	0.93 (1.52)	(-2.05, 3.92)	0.5394	0.05 (0.09)	(-0.13, 0.22)	0.5917	
Black	61	15.36 (3.36)	54	8.93 (3.28)	6.42 (3.80)	(-1.12, 13.97)	0.0943	0.25 (0.19)	(-0.12, 0.62)	0.1781	
Other	112	12.40 (2.11)	111	8.58 (2.19)	3.81 (2.33)	(-0.78, 8.41)	0.1032	0.17 (0.13)	(-0.10, 0.43)	0.2112	
Ethnicity											0.2098
Hispanic/Latino	126	13.48 (1.95)	128	13.55 (1.92)	-0.07 (2.33)	(-4.66, 4.51)	0.9749	-0.00 (0.13)	(-0.25, 0.24)	0.9787	
Non-hispanic/Latino	296	10.15 (1.15)	303	6.83 (1.13)	3.32 (1.38)	(0.60, 6.04)	0.0167	0.17 (0.08)	(0.01, 0.33)	0.0406	
Geographic region											0.3191
EU	125	10.92 (1.81)	137	10.39 (1.82)	0.53 (1.88)	(-3.18, 4.23)	0.7801	0.03 (0.12)	(-0.22, 0.27)	0.8388	
non-EU	303	11.75 (1.15)	300	8.85 (1.15)	2.90 (1.46)	(0.03, 5.76)	0.0478	0.14 (0.08)	(-0.02, 0.30)	0.0769	
Onset of disease											0.0287
Paediatric	30	3.17 (4.46)	32	10.52 (4.13)	-7.35 (4.49)	(-16.37, 1.67)	0.1079	-0.30 (0.26)	(-0.81, 0.20)	0.2343	
Adult	398	11.91 (1.01)	405	9.06 (1.01)	2.84 (1.24)	(0.41, 5.28)	0.0223	0.14 (0.07)	(0.00, 0.28)	0.0462	
ADA result											0.0846
Negative	400	11.28 (1.00)	400	9.70 (1.00)	1.58 (1.24)	(-0.85, 4.01)	0.2025	0.08 (0.07)	(-0.06, 0.22)	0.2649	
Positive (At any time)	28	22.68 (6.06)	37	12.67 (5.42)	10.00 (4.73)	(0.52, 19.49)	0.0391	0.30 (0.25)	(-0.19, 0.80)	0.2285	
BMI (kg/m2)											0.4173
< 30	289	12.38 (1.18)	317	9.41 (1.18)	2.97 (1.35)	(0.31, 5.62)	0.0286	0.14 (0.08)	(-0.02, 0.30)	0.0765	
>= 30	139	11.05 (1.77)	120	10.32 (1.80)	0.74 (2.39)	(-3.97, 5.45)	0.7580	0.04 (0.12)	(-0.21, 0.28)	0.7716	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Lupus QoL Planning domain score
Full analysis set

	Anifrolumab 300mg (N=459)		Placebo (N=468)		Difference of						Heterogenity
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
Week 4		4.40 (1.90)		-1.63 (1.90)	6.04 (2.51)	(1.09, 10.98)	0.0169				
Week 12		8.72 (1.20)		5.41 (1.19)	3.31 (1.50)	(0.36, 6.26)	0.0280				
Week 24		10.98 (1.22)		6.92 (1.22)	4.07 (1.54)	(1.05, 7.09)	0.0084				
Week 36		10.78 (1.28)		8.24 (1.29)	2.54 (1.65)	(-0.70, 5.78)	0.1240				
Week 52		9.99 (1.31)		7.24 (1.32)	2.75 (1.69)	(-0.57, 6.07)	0.1038				
OVERALL	428	8.98 (1.05)	437	5.24 (1.05)	3.74 (1.29)	(1.21, 6.27)	0.0038	0.17 (0.07)	(0.04, 0.30)	0.0120	0.3945

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - Lupus QoL Planning domain score - Subgroup analysis
Full analysis set

Subgroup	Anifrolumab 300mg (N=459)		Placebo (N=468)		Difference of						Interaction
Level	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	p-Value
SLEDAI-2K score											0.5278
< 10 points	137	10.70 (1.71)	138	5.78 (1.70)	4.92 (2.24)	(0.51, 9.33)	0.0289	0.24 (0.12)	(0.01, 0.48)	0.0431	
>= 10 points	291	7.59 (1.33)	299	4.41 (1.32)	3.19 (1.58)	(0.08, 6.30)	0.0446	0.14 (0.08)	(-0.02, 0.30)	0.0902	
OCS dose											0.9402
<10 mg/day	203	8.44 (1.40)	202	4.57 (1.41)	3.87 (1.83)	(0.28, 7.47)	0.0349	0.19 (0.10)	(-0.00, 0.39)	0.0521	
>=10 mg/day	225	9.14 (1.63)	235	5.46 (1.62)	3.68 (1.82)	(0.11, 7.25)	0.0436	0.15 (0.09)	(-0.03, 0.33)	0.1102	
Result of type I IFN gene signature test											0.6512
LOW	82	10.34 (2.25)	85	7.95 (2.22)	2.39 (3.11)	(-3.75, 8.53)	0.4426	0.12 (0.15)	(-0.19, 0.42)	0.4521	
HIGH	346	9.31 (1.05)	352	5.37 (1.05)	3.94 (1.42)	(1.16, 6.72)	0.0056	0.20 (0.08)	(0.05, 0.35)	0.0083	
Age (years)											0.7751
<= 65	417	8.79 (1.07)	435	5.19 (1.05)	3.60 (1.30)	(1.05, 6.15)	0.0057	0.16 (0.07)	(0.03, 0.30)	0.0168	
> 65	11	18.53 (5.61)	2	12.04 (8.70)	6.49 (10.05)	(-27.53, 40.52)	0.5688	0.33 (0.77)	(-1.18, 1.85)	0.6663	
Sex											0.9037
male	32	12.18 (4.64)	33	7.97 (4.34)	4.22 (4.37)	(-4.58, 13.01)	0.3397	0.16 (0.25)	(-0.32, 0.65)	0.5122	
female	396	8.85 (1.09)	404	5.19 (1.08)	3.66 (1.35)	(1.02, 6.30)	0.0066	0.17 (0.07)	(0.03, 0.31)	0.0173	
Race											0.4460
White	249	8.94 (1.41)	266	6.06 (1.38)	2.89 (1.73)	(-0.51, 6.29)	0.0960	0.13 (0.09)	(-0.04, 0.30)	0.1453	
Black	61	8.21 (3.32)	54	0.18 (3.19)	8.03 (3.75)	(0.60, 15.46)	0.0343	0.32 (0.19)	(-0.05, 0.69)	0.0875	
Other	112	9.27 (2.21)	111	4.76 (2.30)	4.51 (2.43)	(-0.28, 9.30)	0.0648	0.19 (0.13)	(-0.07, 0.45)	0.1596	
Ethnicity											0.6495
Hispanic/Latino	126	11.09 (2.07)	128	7.99 (2.04)	3.10 (2.47)	(-1.77, 7.98)	0.2113	0.13 (0.13)	(-0.11, 0.38)	0.2886	
Non-hispanic/Latino	296	7.73 (1.27)	303	3.31 (1.25)	4.42 (1.53)	(1.42, 7.42)	0.0039	0.20 (0.08)	(0.04, 0.36)	0.0135	
Geographic region											0.2477
EU	125	11.32 (2.00)	137	9.75 (2.01)	1.58 (2.09)	(-2.54, 5.69)	0.4513	0.07 (0.12)	(-0.17, 0.31)	0.5811	
non-EU	303	8.15 (1.25)	300	3.54 (1.25)	4.61 (1.59)	(1.49, 7.72)	0.0038	0.21 (0.08)	(0.05, 0.37)	0.0096	
Onset of disease											0.3743
Paediatric	30	0.26 (4.93)	32	0.82 (4.57)	-0.56 (4.92)	(-10.44, 9.31)	0.9098	-0.02 (0.25)	(-0.52, 0.48)	0.9343	
Adult	398	9.27 (1.08)	405	5.30 (1.08)	3.97 (1.34)	(1.34, 6.60)	0.0031	0.18 (0.07)	(0.04, 0.32)	0.0097	
ADA result											0.8203
Negative	400	8.75 (1.08)	400	5.41 (1.08)	3.34 (1.34)	(0.71, 5.96)	0.0128	0.15 (0.07)	(0.02, 0.29)	0.0289	
Positive (At any time)	28	17.05 (6.14)	37	12.33 (5.81)	4.72 (5.92)	(-7.21, 16.64)	0.4301	0.14 (0.25)	(-0.36, 0.63)	0.5863	
BMI (kg/m2)											0.8322
< 30	289	9.19 (1.30)	317	5.47 (1.30)	3.72 (1.49)	(0.79, 6.64)	0.0130	0.16 (0.08)	(0.00, 0.32)	0.0442	
>= 30	139	9.73 (1.91)	120	5.39 (1.94)	4.35 (2.58)	(-0.74, 9.44)	0.0936	0.20 (0.12)	(-0.05, 0.44)	0.1132	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SDI Global Score
Full analysis set

	Anifrolumab 300mg (N=459)		Placebo (N=468)		Difference of						
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 24		0.02 (0.02)		0.02 (0.02)	-0.00 (0.02)	(-0.04, 0.03)	0.9072				
Week 52		0.05 (0.02)		0.02 (0.02)	0.03 (0.03)	(-0.02, 0.08)	0.2885				
OVERALL	416	0.03 (0.02)	405	0.02 (0.02)	0.01 (0.02)	(-0.03, 0.05)	0.5387	0.04 (0.07)	(-0.10, 0.17)	0.5942	0.3967

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - SDI Global Score - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=459) N	LSMean (SE)	Placebo (N=468) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.0552
< 10 points	131	0.06 (0.03)	127	-0.01 (0.03)	0.08 (0.04)	(-0.00, 0.15)	0.0542	0.22 (0.12)	(-0.02, 0.47)	0.0746	
>= 10 points	285	0.03 (0.02)	278	0.04 (0.02)	-0.01 (0.02)	(-0.06, 0.03)	0.6114	-0.04 (0.08)	(-0.20, 0.13)	0.6672	
OCS dose											0.7075
<10 mg/day	196	0.01 (0.02)	194	0.01 (0.02)	0.01 (0.03)	(-0.05, 0.06)	0.8521	0.02 (0.10)	(-0.18, 0.22)	0.8655	
>=10 mg/day	220	0.05 (0.03)	211	0.03 (0.03)	0.02 (0.03)	(-0.04, 0.08)	0.5048	0.05 (0.10)	(-0.14, 0.24)	0.5941	
Result of type I IFN gene signature test											0.5119
LOW	77	0.03 (0.02)	74	-0.00 (0.02)	0.04 (0.03)	(-0.03, 0.10)	0.3108	0.16 (0.16)	(-0.16, 0.48)	0.3180	
HIGH	339	0.03 (0.02)	331	0.03 (0.02)	0.01 (0.02)	(-0.04, 0.05)	0.7575	0.02 (0.08)	(-0.13, 0.17)	0.7719	
Age (years)											NE
<= 65	408	0.04 (0.02)	402	0.02 (0.02)	0.02 (0.02)	(-0.02, 0.06)	0.4494	0.05 (0.07)	(-0.09, 0.18)	0.5128	
> 65	8	NE	3	NE	NE	NE		NE	NE		
Sex											0.7446
male	31	-0.00 (0.05)	33	-0.03 (0.05)	0.03 (0.06)	(-0.08, 0.14)	0.6088	0.10 (0.25)	(-0.39, 0.59)	0.6963	
female	385	0.04 (0.02)	372	0.03 (0.02)	0.01 (0.02)	(-0.03, 0.05)	0.6671	0.03 (0.07)	(-0.12, 0.17)	0.7074	
Race											0.9012
White	244	0.04 (0.02)	242	0.02 (0.02)	0.02 (0.02)	(-0.01, 0.06)	0.2135	0.10 (0.09)	(-0.08, 0.28)	0.2805	
Black	55	0.09 (0.06)	58	0.09 (0.05)	0.00 (0.06)	(-0.12, 0.12)	0.9390	0.01 (0.19)	(-0.36, 0.38)	0.9512	
Other	111	0.00 (0.05)	99	0.00 (0.05)	0.00 (0.06)	(-0.12, 0.12)	0.9904	0.00 (0.14)	(-0.27, 0.27)	0.9925	
Ethnicity											0.5109
Hispanic/Latino	123	0.01 (0.04)	112	0.02 (0.04)	-0.02 (0.05)	(-0.12, 0.09)	0.7603	-0.03 (0.13)	(-0.29, 0.22)	0.7909	
Non-hispanic/Latino	287	0.04 (0.02)	287	0.02 (0.02)	0.02 (0.02)	(-0.02, 0.06)	0.2809	0.08 (0.08)	(-0.09, 0.24)	0.3606	
Geographic region											0.5837
EU	126	0.04 (0.02)	128	0.02 (0.03)	0.03 (0.03)	(-0.03, 0.08)	0.3222	0.10 (0.13)	(-0.15, 0.34)	0.4484	
non-EU	290	0.03 (0.02)	277	0.03 (0.02)	0.01 (0.03)	(-0.05, 0.06)	0.8274	0.02 (0.08)	(-0.15, 0.18)	0.8459	
Onset of disease											NE
Paediatric	32	NE	27	NE	NE	NE		NE	NE		
Adult	384	0.04 (0.02)	378	0.02 (0.02)	0.01 (0.02)	(-0.03, 0.06)	0.5589	0.04 (0.07)	(-0.11, 0.18)	0.6113	
ADA result											NE
Negative	391	0.03 (0.02)	372	0.02 (0.02)	0.01 (0.02)	(-0.03, 0.05)	0.6399	0.03 (0.07)	(-0.11, 0.17)	0.6822	
Positive (At any time)	25	NE	33	NE	NE	NE		NE	NE		
BMI (kg/m2)											0.2626
< 30	285	0.02 (0.02)	292	0.02 (0.02)	-0.00 (0.03)	(-0.05, 0.05)	0.9255	-0.01 (0.08)	(-0.17, 0.16)	0.9388	
>= 30	131	0.07 (0.02)	113	0.02 (0.03)	0.04 (0.03)	(-0.02, 0.11)	0.1782	0.16 (0.13)	(-0.09, 0.41)	0.2118	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - PtGA
Full analysis set

Visit	Anifrolumab 300mg (N=459) N	Anifrolumab 300mg (N=459) LSMean (SE)	Placebo (N=468) N	Placebo (N=468) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Heterogenity p-Value
Week 4		-7.42 (1.11)		-5.94 (1.10)	-1.48 (1.41)	(-4.25, 1.29)	0.2934				
Week 8		-9.89 (1.14)		-7.29 (1.13)	-2.60 (1.46)	(-5.47, 0.27)	0.0755				
Week 12		-13.15 (1.21)		-9.56 (1.20)	-3.60 (1.56)	(-6.66, -0.53)	0.0215				
Week 16		-10.28 (1.26)		-10.33 (1.25)	0.05 (1.64)	(-3.17, 3.26)	0.9779				
Week 20		-12.35 (1.23)		-11.50 (1.21)	-0.85 (1.59)	(-3.97, 2.27)	0.5944				
Week 24		-11.66 (1.27)		-9.46 (1.26)	-2.20 (1.66)	(-5.46, 1.06)	0.1859				
Week 28		-12.81 (1.27)		-11.20 (1.27)	-1.62 (1.67)	(-4.90, 1.67)	0.3337				
Week 32		-12.71 (1.29)		-11.59 (1.30)	-1.12 (1.70)	(-4.46, 2.22)	0.5099				
Week 36		-15.33 (1.25)		-13.18 (1.26)	-2.15 (1.64)	(-5.36, 1.07)	0.1901				
Week 40		-13.41 (1.30)		-11.43 (1.31)	-1.98 (1.72)	(-5.35, 1.39)	0.2501				
Week 44		-14.50 (1.28)		-13.70 (1.29)	-0.80 (1.69)	(-4.12, 2.52)	0.6366				
Week 48		-14.20 (1.31)		-11.25 (1.33)	-2.95 (1.74)	(-6.37, 0.47)	0.0908				
Week 52		-13.09 (1.36)		-10.03 (1.38)	-3.06 (1.82)	(-6.64, 0.51)	0.0931				
OVERALL	439	-12.37 (0.96)	447	-10.50 (0.96)	-1.87 (1.19)	(-4.20, 0.45)	0.1144	-0.09 (0.07)	(-0.22, 0.04)	0.1694	0.6456

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for heterogenity between studies from test for heterogeneity of the mean differences in the studies using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis (observed values) - PtGA - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=459) N	LSMean (SE)	Placebo (N=468) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score											0.3673
< 10 points	141	-14.00 (1.65)	141	-10.46 (1.65)	-3.54 (2.16)	(-7.79, 0.71)	0.1024	-0.18 (0.12)	(-0.41, 0.05)	0.1312	
>= 10 points	298	-11.10 (1.18)	306	-9.89 (1.18)	-1.21 (1.41)	(-3.98, 1.55)	0.3894	-0.06 (0.08)	(-0.22, 0.10)	0.4676	
OCS dose											0.7058
<10 mg/day	207	-11.34 (1.29)	207	-10.01 (1.30)	-1.32 (1.66)	(-4.59, 1.95)	0.4276	-0.07 (0.10)	(-0.26, 0.12)	0.4720	
>=10 mg/day	232	-12.86 (1.47)	240	-10.65 (1.46)	-2.22 (1.68)	(-5.52, 1.09)	0.1890	-0.10 (0.09)	(-0.28, 0.08)	0.2874	
Result of type I IFN gene signature test											0.0086
LOW	82	-9.16 (1.93)	86	-13.79 (1.91)	4.63 (2.69)	(-0.68, 9.95)	0.0869	0.26 (0.16)	(-0.04, 0.57)	0.0908	
HIGH	357	-13.64 (0.99)	361	-10.39 (0.99)	-3.24 (1.32)	(-5.83, -0.66)	0.0140	-0.17 (0.07)	(-0.32, -0.03)	0.0208	
Age (years)											NE
<= 65	428	-12.39 (0.98)	445	-10.46 (0.96)	-1.93 (1.19)	(-4.27, 0.41)	0.1067	-0.09 (0.07)	(-0.23, 0.04)	0.1613	
> 65	11	NE	2	NE	NE	NE		NE	NE		
Sex											0.3695
male	32	-16.75 (4.43)	33	-18.59 (4.37)	1.83 (4.22)	(-6.62, 10.28)	0.6658	0.07 (0.25)	(-0.41, 0.56)	0.7711	
female	407	-12.15 (0.99)	414	-10.04 (0.99)	-2.11 (1.23)	(-4.53, 0.30)	0.0862	-0.11 (0.07)	(-0.24, 0.03)	0.1321	
Race											0.0090
White	255	-11.49 (1.26)	271	-12.30 (1.24)	0.81 (1.52)	(-2.18, 3.79)	0.5955	0.04 (0.09)	(-0.13, 0.21)	0.6492	
Black	63	-10.80 (2.64)	55	-1.52 (2.53)	-9.28 (3.03)	(-15.28, -3.28)	0.0027	-0.46 (0.19)	(-0.83, -0.10)	0.0135	
Other	115	-14.26 (2.15)	114	-10.94 (2.25)	-3.31 (2.44)	(-8.13, 1.51)	0.1770	-0.14 (0.13)	(-0.40, 0.12)	0.2896	
Ethnicity											0.2811
Hispanic/Latino	129	-17.28 (1.89)	129	-13.57 (1.87)	-3.71 (2.28)	(-8.21, 0.79)	0.1054	-0.17 (0.12)	(-0.42, 0.07)	0.1648	
Non-hispanic/Latino	304	-9.79 (1.14)	311	-8.95 (1.13)	-0.84 (1.38)	(-3.54, 1.87)	0.5443	-0.04 (0.08)	(-0.20, 0.12)	0.6036	
Geographic region											0.0004
EU	127	-11.14 (1.93)	141	-15.30 (1.93)	4.15 (2.00)	(0.22, 8.09)	0.0387	0.18 (0.12)	(-0.06, 0.43)	0.1314	
non-EU	312	-12.72 (1.13)	306	-8.19 (1.13)	-4.53 (1.44)	(-7.35, -1.70)	0.0017	-0.23 (0.08)	(-0.39, -0.07)	0.0049	
Onset of disease											0.9174
Paediatric	32	-11.88 (4.10)	33	-9.50 (3.92)	-2.38 (4.36)	(-11.14, 6.38)	0.5876	-0.10 (0.25)	(-0.59, 0.38)	0.6787	
Adult	407	-12.57 (1.00)	414	-10.66 (1.00)	-1.91 (1.24)	(-4.34, 0.52)	0.1232	-0.09 (0.07)	(-0.23, 0.04)	0.1777	
ADA result											0.0849
Negative	409	-12.04 (0.99)	409	-10.74 (1.00)	-1.30 (1.24)	(-3.73, 1.12)	0.2921	-0.06 (0.07)	(-0.20, 0.07)	0.3551	
Positive (At any time)	30	-21.19 (4.60)	38	-12.10 (3.91)	-9.09 (4.35)	(-17.79, -0.39)	0.0408	-0.37 (0.25)	(-0.85, 0.12)	0.1377	
BMI (kg/m2)											0.0119
< 30	297	-12.06 (1.21)	323	-11.96 (1.20)	-0.11 (1.40)	(-2.86, 2.65)	0.9401	-0.00 (0.08)	(-0.16, 0.15)	0.9507	
>= 30	142	-14.07 (1.63)	124	-7.48 (1.67)	-6.59 (2.17)	(-10.86, -2.33)	0.0026	-0.34 (0.12)	(-0.59, -0.10)	0.0054	

A repeated measures model with fixed effects for baseline value, treatment group, visit, treatment*visit interaction and stratification factors was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model, e.g. subjects with non-missing baseline and at least one non-missing post-baseline value.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochranes Q statistic.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SLEDAI-2K Total Score
Full analysis set

Visit	Anifrolumab 300mg (N=459) n/ N#	Anifrolumab 300mg (N=459) Compliance	Placebo (N=468) n/ N#	Placebo (N=468) Compliance
Baseline	459/ 459	100.0%	468/ 468	100.0%
Week 4	444/ 459	96.73%	456/ 468	97.44%
Week 8	435/ 459	94.77%	445/ 468	95.09%
Week 12	435/ 458	94.98%	435/ 468	92.95%
Week 16	427/ 458	93.23%	427/ 468	91.24%
Week 20	419/ 458	91.48%	426/ 468	91.03%
Week 24	418/ 458	91.27%	410/ 468	87.61%
Week 28	413/ 458	90.17%	402/ 468	85.90%
Week 32	405/ 457	88.62%	391/ 468	83.55%
Week 36	403/ 457	88.18%	390/ 468	83.33%
Week 40	397/ 457	86.87%	378/ 467	80.94%
Week 44	390/ 457	85.34%	375/ 467	80.30%
Week 48	393/ 457	86.00%	366/ 467	78.37%
Week 52	382/ 457	83.59%	357/ 467	76.45%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - PGA
Full analysis set

Visit	Anifrolumab 300mg (N=459) n/ N#	Anifrolumab 300mg (N=459) Compliance	Placebo (N=468) n/ N#	Placebo (N=468) Compliance
Baseline	459/ 459	100.0%	468/ 468	100.0%
Week 4	448/ 459	97.60%	462/ 468	98.72%
Week 8	439/ 459	95.64%	450/ 468	96.15%
Week 12	436/ 458	95.20%	440/ 468	94.02%
Week 16	432/ 458	94.32%	430/ 468	91.88%
Week 20	417/ 458	91.05%	430/ 468	91.88%
Week 24	420/ 458	91.70%	417/ 468	89.10%
Week 28	413/ 458	90.17%	408/ 468	87.18%
Week 32	408/ 457	89.28%	394/ 468	84.19%
Week 36	408/ 457	89.28%	386/ 468	82.48%
Week 40	400/ 457	87.53%	387/ 467	82.87%
Week 44	392/ 457	85.78%	377/ 467	80.73%
Week 48	396/ 457	86.65%	368/ 467	78.80%
Week 52	383/ 457	83.81%	359/ 467	76.87%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - CLASI Total Activity Score
Full analysis set

Visit	Anifrolumab 300mg (N=459) n/ N#	Anifrolumab 300mg (N=459) Compliance	Placebo (N=468) n/ N#	Placebo (N=468) Compliance
Baseline	459/ 459	100.0%	468/ 468	100.0%
Week 4	449/ 459	97.82%	463/ 468	98.93%
Week 8	440/ 459	95.86%	450/ 468	96.15%
Week 12	438/ 458	95.63%	441/ 468	94.23%
Week 16	434/ 458	94.76%	430/ 468	91.88%
Week 20	422/ 458	92.14%	432/ 468	92.31%
Week 24	420/ 458	91.70%	417/ 468	89.10%
Week 28	414/ 458	90.39%	409/ 468	87.39%
Week 32	409/ 457	89.50%	394/ 468	84.19%
Week 36	405/ 457	88.62%	390/ 468	83.33%
Week 40	400/ 457	87.53%	387/ 467	82.87%
Week 44	395/ 457	86.43%	379/ 467	81.16%
Week 48	396/ 457	86.65%	369/ 467	79.01%
Week 52	383/ 457	83.81%	360/ 467	77.09%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - CLASI Total Damage Score
Full analysis set

Visit	Anifrolumab 300mg (N=459) n/ N#	Anifrolumab 300mg (N=459) Compliance	Placebo (N=468) n/ N#	Placebo (N=468) Compliance
Baseline	459/ 459	100.0%	468/ 468	100.0%
Week 4	450/ 459	98.04%	462/ 468	98.72%
Week 8	440/ 459	95.86%	450/ 468	96.15%
Week 12	438/ 458	95.63%	442/ 468	94.44%
Week 16	434/ 458	94.76%	430/ 468	91.88%
Week 20	422/ 458	92.14%	432/ 468	92.31%
Week 24	420/ 458	91.70%	417/ 468	89.10%
Week 28	414/ 458	90.39%	409/ 468	87.39%
Week 32	409/ 457	89.50%	394/ 468	84.19%
Week 36	405/ 457	88.62%	390/ 468	83.33%
Week 40	400/ 457	87.53%	386/ 467	82.66%
Week 44	394/ 457	86.21%	379/ 467	81.16%
Week 48	396/ 457	86.65%	369/ 467	79.01%
Week 52	383/ 457	83.81%	360/ 467	77.09%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - BILAG Global Score
Full analysis set

Visit	Anifrolumab 300mg (N=459) n/ N#	Anifrolumab 300mg (N=459) Compliance	Placebo (N=468) n/ N#	Placebo (N=468) Compliance
Baseline	459/ 459	100.0%	468/ 468	100.0%
Week 4	450/ 459	98.04%	462/ 468	98.72%
Week 8	444/ 459	96.73%	452/ 468	96.58%
Week 12	441/ 458	96.29%	443/ 468	94.66%
Week 16	437/ 458	95.41%	432/ 468	92.31%
Week 20	422/ 458	92.14%	430/ 468	91.88%
Week 24	423/ 458	92.36%	418/ 468	89.32%
Week 28	417/ 458	91.05%	409/ 468	87.39%
Week 32	412/ 457	90.15%	394/ 468	84.19%
Week 36	407/ 457	89.06%	389/ 468	83.12%
Week 40	402/ 457	87.96%	383/ 467	82.01%
Week 44	393/ 457	86.00%	377/ 467	80.73%
Week 48	397/ 457	86.87%	368/ 467	78.80%
Week 52	383/ 457	83.81%	358/ 467	76.66%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Tender Joint Count
Full analysis set

Visit	Anifrolumab 300mg (N=459) n/ N#	Anifrolumab 300mg (N=459) Compliance	Placebo (N=468) n/ N#	Placebo (N=468) Compliance
Baseline	459/ 459	100.0%	468/ 468	100.0%
Week 4	449/ 459	97.82%	462/ 468	98.72%
Week 8	439/ 459	95.64%	450/ 468	96.15%
Week 12	439/ 458	95.85%	442/ 468	94.44%
Week 16	433/ 458	94.54%	431/ 468	92.09%
Week 20	421/ 458	91.92%	431/ 468	92.09%
Week 24	420/ 458	91.70%	416/ 468	88.89%
Week 28	413/ 458	90.17%	409/ 468	87.39%
Week 32	410/ 457	89.72%	394/ 468	84.19%
Week 36	406/ 457	88.84%	390/ 468	83.33%
Week 40	401/ 457	87.75%	386/ 467	82.66%
Week 44	393/ 457	86.00%	379/ 467	81.16%
Week 48	395/ 457	86.43%	369/ 467	79.01%
Week 52	382/ 457	83.59%	360/ 467	77.09%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Swollen Joint Count
Full analysis set

Visit	Anifrolumab 300mg (N=459) n/ N#	Anifrolumab 300mg (N=459) Compliance	Placebo (N=468) n/ N#	Placebo (N=468) Compliance
Baseline	459/ 459	100.0%	468/ 468	100.0%
Week 4	449/ 459	97.82%	462/ 468	98.72%
Week 8	439/ 459	95.64%	450/ 468	96.15%
Week 12	439/ 458	95.85%	442/ 468	94.44%
Week 16	433/ 458	94.54%	431/ 468	92.09%
Week 20	421/ 458	91.92%	431/ 468	92.09%
Week 24	420/ 458	91.70%	416/ 468	88.89%
Week 28	413/ 458	90.17%	409/ 468	87.39%
Week 32	410/ 457	89.72%	394/ 468	84.19%
Week 36	406/ 457	88.84%	390/ 468	83.33%
Week 40	401/ 457	87.75%	386/ 467	82.66%
Week 44	393/ 457	86.00%	379/ 467	81.16%
Week 48	395/ 457	86.43%	369/ 467	79.01%
Week 52	382/ 457	83.59%	360/ 467	77.09%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute Mental Component Score
Full analysis set

Visit	Anifrolumab 300mg (N=459) n/ N#	Anifrolumab 300mg (N=459) Compliance	Placebo (N=468) n/ N#	Placebo (N=468) Compliance
Baseline	444/ 459	96.73%	450/ 468	96.15%
Week 4	98/ 459	21.35%	99/ 468	21.15%
Week 8	326/ 459	71.02%	338/ 468	72.22%
Week 12	94/ 458	20.52%	97/ 468	20.73%
Week 16	321/ 458	70.09%	327/ 468	69.87%
Week 24	404/ 458	88.21%	407/ 468	86.97%
Week 32	298/ 457	65.21%	296/ 468	63.25%
Week 36	90/ 457	19.69%	74/ 468	15.81%
Week 40	296/ 457	64.77%	297/ 467	63.60%
Week 48	300/ 457	65.65%	283/ 467	60.60%
Week 52	373/ 457	81.62%	343/ 467	73.45%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute Physical Component Score
Full analysis set

Visit	Anifrolumab 300mg (N=459) n/ N#	Anifrolumab 300mg (N=459) Compliance	Placebo (N=468) n/ N#	Placebo (N=468) Compliance
Baseline	444/ 459	96.73%	450/ 468	96.15%
Week 4	98/ 459	21.35%	99/ 468	21.15%
Week 8	326/ 459	71.02%	338/ 468	72.22%
Week 12	94/ 458	20.52%	97/ 468	20.73%
Week 16	321/ 458	70.09%	327/ 468	69.87%
Week 24	404/ 458	88.21%	407/ 468	86.97%
Week 32	298/ 457	65.21%	296/ 468	63.25%
Week 36	90/ 457	19.69%	74/ 468	15.81%
Week 40	296/ 457	64.77%	297/ 467	63.60%
Week 48	300/ 457	65.65%	283/ 467	60.60%
Week 52	373/ 457	81.62%	343/ 467	73.45%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute General Health Score
Full analysis set

Visit	Anifrolumab 300mg (N=459) n/ N#	Anifrolumab 300mg (N=459) Compliance	Placebo (N=468) n/ N#	Placebo (N=468) Compliance
Baseline	444/ 459	96.73%	450/ 468	96.15%
Week 4	98/ 459	21.35%	99/ 468	21.15%
Week 8	326/ 459	71.02%	338/ 468	72.22%
Week 12	94/ 458	20.52%	97/ 468	20.73%
Week 16	321/ 458	70.09%	327/ 468	69.87%
Week 24	404/ 458	88.21%	407/ 468	86.97%
Week 32	298/ 457	65.21%	296/ 468	63.25%
Week 36	90/ 457	19.69%	74/ 468	15.81%
Week 40	296/ 457	64.77%	297/ 467	63.60%
Week 48	300/ 457	65.65%	283/ 467	60.60%
Week 52	373/ 457	81.62%	343/ 467	73.45%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute Mental Health Score
Full analysis set

Visit	Anifrolumab 300mg (N=459) n/ N#	Anifrolumab 300mg (N=459) Compliance	Placebo (N=468) n/ N#	Placebo (N=468) Compliance
Baseline	444/ 459	96.73%	450/ 468	96.15%
Week 4	98/ 459	21.35%	99/ 468	21.15%
Week 8	326/ 459	71.02%	338/ 468	72.22%
Week 12	94/ 458	20.52%	97/ 468	20.73%
Week 16	321/ 458	70.09%	327/ 468	69.87%
Week 24	404/ 458	88.21%	407/ 468	86.97%
Week 32	298/ 457	65.21%	296/ 468	63.25%
Week 36	90/ 457	19.69%	74/ 468	15.81%
Week 40	296/ 457	64.77%	297/ 467	63.60%
Week 48	300/ 457	65.65%	283/ 467	60.60%
Week 52	373/ 457	81.62%	343/ 467	73.45%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute Physical Functioning Score
Full analysis set

Visit	Anifrolumab 300mg (N=459) n/ N#	Anifrolumab 300mg (N=459) Compliance	Placebo (N=468) n/ N#	Placebo (N=468) Compliance
Baseline	444/ 459	96.73%	450/ 468	96.15%
Week 4	98/ 459	21.35%	99/ 468	21.15%
Week 8	326/ 459	71.02%	338/ 468	72.22%
Week 12	94/ 458	20.52%	97/ 468	20.73%
Week 16	321/ 458	70.09%	327/ 468	69.87%
Week 24	404/ 458	88.21%	407/ 468	86.97%
Week 32	298/ 457	65.21%	296/ 468	63.25%
Week 36	90/ 457	19.69%	74/ 468	15.81%
Week 40	296/ 457	64.77%	297/ 467	63.60%
Week 48	300/ 457	65.65%	283/ 467	60.60%
Week 52	373/ 457	81.62%	343/ 467	73.45%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute Role Emotional Score
Full analysis set

Visit	Anifrolumab 300mg (N=459) n/ N#	Anifrolumab 300mg (N=459) Compliance	Placebo (N=468) n/ N#	Placebo (N=468) Compliance
Baseline	444/ 459	96.73%	450/ 468	96.15%
Week 4	98/ 459	21.35%	99/ 468	21.15%
Week 8	326/ 459	71.02%	338/ 468	72.22%
Week 12	94/ 458	20.52%	97/ 468	20.73%
Week 16	321/ 458	70.09%	327/ 468	69.87%
Week 24	404/ 458	88.21%	407/ 468	86.97%
Week 32	298/ 457	65.21%	296/ 468	63.25%
Week 36	90/ 457	19.69%	74/ 468	15.81%
Week 40	296/ 457	64.77%	297/ 467	63.60%
Week 48	300/ 457	65.65%	283/ 467	60.60%
Week 52	373/ 457	81.62%	343/ 467	73.45%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute Role Physical Score
Full analysis set

Visit	Anifrolumab 300mg (N=459) n/ N#	Anifrolumab 300mg (N=459) Compliance	Placebo (N=468) n/ N#	Placebo (N=468) Compliance
Baseline	444/ 459	96.73%	450/ 468	96.15%
Week 4	98/ 459	21.35%	99/ 468	21.15%
Week 8	326/ 459	71.02%	338/ 468	72.22%
Week 12	94/ 458	20.52%	97/ 468	20.73%
Week 16	321/ 458	70.09%	327/ 468	69.87%
Week 24	404/ 458	88.21%	407/ 468	86.97%
Week 32	298/ 457	65.21%	296/ 468	63.25%
Week 36	90/ 457	19.69%	74/ 468	15.81%
Week 40	296/ 457	64.77%	297/ 467	63.60%
Week 48	300/ 457	65.65%	283/ 467	60.60%
Week 52	373/ 457	81.62%	343/ 467	73.45%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute Social Functioning Score
Full analysis set

Visit	Anifrolumab 300mg (N=459) n/ N#	Anifrolumab 300mg (N=459) Compliance	Placebo (N=468) n/ N#	Placebo (N=468) Compliance
Baseline	444/ 459	96.73%	450/ 468	96.15%
Week 4	98/ 459	21.35%	99/ 468	21.15%
Week 8	326/ 459	71.02%	338/ 468	72.22%
Week 12	94/ 458	20.52%	97/ 468	20.73%
Week 16	321/ 458	70.09%	327/ 468	69.87%
Week 24	404/ 458	88.21%	407/ 468	86.97%
Week 32	298/ 457	65.21%	296/ 468	63.25%
Week 36	90/ 457	19.69%	74/ 468	15.81%
Week 40	296/ 457	64.77%	297/ 467	63.60%
Week 48	300/ 457	65.65%	283/ 467	60.60%
Week 52	373/ 457	81.62%	343/ 467	73.45%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute Bodily Pain Score
Full analysis set

Visit	Anifrolumab 300mg (N=459) n/ N#	Anifrolumab 300mg (N=459) Compliance	Placebo (N=468) n/ N#	Placebo (N=468) Compliance
Baseline	444/ 459	96.73%	450/ 468	96.15%
Week 4	98/ 459	21.35%	99/ 468	21.15%
Week 8	326/ 459	71.02%	338/ 468	72.22%
Week 12	94/ 458	20.52%	97/ 468	20.73%
Week 16	321/ 458	70.09%	327/ 468	69.87%
Week 24	404/ 458	88.21%	407/ 468	86.97%
Week 32	298/ 457	65.21%	296/ 468	63.25%
Week 36	90/ 457	19.69%	74/ 468	15.81%
Week 40	296/ 457	64.77%	297/ 467	63.60%
Week 48	300/ 457	65.65%	283/ 467	60.60%
Week 52	373/ 457	81.62%	343/ 467	73.45%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SF-36 v2.0 Acute Vitality Score
Full analysis set

Visit	Anifrolumab 300mg (N=459) n/ N#	Anifrolumab 300mg (N=459) Compliance	Placebo (N=468) n/ N#	Placebo (N=468) Compliance
Baseline	444/ 459	96.73%	450/ 468	96.15%
Week 4	98/ 459	21.35%	99/ 468	21.15%
Week 8	326/ 459	71.02%	338/ 468	72.22%
Week 12	94/ 458	20.52%	97/ 468	20.73%
Week 16	321/ 458	70.09%	327/ 468	69.87%
Week 24	404/ 458	88.21%	407/ 468	86.97%
Week 32	298/ 457	65.21%	296/ 468	63.25%
Week 36	90/ 457	19.69%	74/ 468	15.81%
Week 40	296/ 457	64.77%	297/ 467	63.60%
Week 48	300/ 457	65.65%	283/ 467	60.60%
Week 52	373/ 457	81.62%	343/ 467	73.45%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - FACIT-F Total Score
Full analysis set

Visit	Anifrolumab 300mg (N=459) n/ N#	Anifrolumab 300mg (N=459) Compliance	Placebo (N=468) n/ N#	Placebo (N=468) Compliance
Baseline	440/ 459	95.86%	451/ 468	96.37%
Week 4	436/ 459	94.99%	448/ 468	95.73%
Week 8	328/ 459	71.46%	341/ 468	72.86%
Week 12	427/ 458	93.23%	429/ 468	91.67%
Week 16	324/ 458	70.74%	329/ 468	70.30%
Week 20	314/ 458	68.56%	329/ 468	70.30%
Week 24	407/ 458	88.86%	410/ 468	87.61%
Week 28	313/ 458	68.34%	316/ 468	67.52%
Week 32	304/ 457	66.52%	300/ 468	64.10%
Week 36	397/ 457	86.87%	375/ 468	80.13%
Week 40	300/ 457	65.65%	298/ 467	63.81%
Week 44	298/ 457	65.21%	286/ 467	61.24%
Week 48	303/ 457	66.30%	286/ 467	61.24%
Week 52	373/ 457	81.62%	344/ 467	73.66%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - EQ VAS Score
Full analysis set

Visit	Anifrolumab 300mg (N=459) n/ N#	Anifrolumab 300mg (N=459) Compliance	Placebo (N=468) n/ N#	Placebo (N=468) Compliance
Baseline	439/ 459	95.64%	451/ 468	96.37%
Week 4	98/ 459	21.35%	99/ 468	21.15%
Week 12	425/ 458	92.79%	427/ 468	91.24%
Week 24	404/ 458	88.21%	405/ 468	86.54%
Week 36	392/ 457	85.78%	371/ 468	79.27%
Week 52	371/ 457	81.18%	342/ 467	73.23%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Lupus QoL Physical Health domain score
Full analysis set

Visit	Anifrolumab 300mg (N=459) n/ N#	Anifrolumab 300mg (N=459) Compliance	Placebo (N=468) n/ N#	Placebo (N=468) Compliance
Baseline	439/ 459	95.64%	449/ 468	95.94%
Week 4	97/ 459	21.13%	98/ 468	20.94%
Week 12	424/ 458	92.58%	428/ 468	91.45%
Week 24	403/ 458	87.99%	403/ 468	86.11%
Week 36	390/ 457	85.34%	368/ 468	78.63%
Week 52	370/ 457	80.96%	340/ 467	72.81%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Lupus QoL Emotional Health domain score
Full analysis set

Visit	Anifrolumab 300mg (N=459) n/ N#	Anifrolumab 300mg (N=459) Compliance	Placebo (N=468) n/ N#	Placebo (N=468) Compliance
Baseline	439/ 459	95.64%	449/ 468	95.94%
Week 4	97/ 459	21.13%	98/ 468	20.94%
Week 12	424/ 458	92.58%	428/ 468	91.45%
Week 24	403/ 458	87.99%	403/ 468	86.11%
Week 36	390/ 457	85.34%	368/ 468	78.63%
Week 52	370/ 457	80.96%	340/ 467	72.81%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Lupus QoL Body Image domain score
Full analysis set

Visit	Anifrolumab 300mg (N=459) n/ N#	Anifrolumab 300mg (N=459) Compliance	Placebo (N=468) n/ N#	Placebo (N=468) Compliance
Baseline	414/ 459	90.20%	415/ 468	88.68%
Week 4	90/ 459	19.61%	89/ 468	19.02%
Week 12	389/ 458	84.93%	389/ 468	83.12%
Week 24	361/ 458	78.82%	363/ 468	77.56%
Week 36	352/ 457	77.02%	327/ 468	69.87%
Week 52	325/ 457	71.12%	299/ 467	64.03%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Lupus QoL Burden to Others domain score
Full analysis set

Visit	Anifrolumab 300mg (N=459) n/ N#	Anifrolumab 300mg (N=459) Compliance	Placebo (N=468) n/ N#	Placebo (N=468) Compliance
Baseline	439/ 459	95.64%	449/ 468	95.94%
Week 4	97/ 459	21.13%	98/ 468	20.94%
Week 12	424/ 458	92.58%	428/ 468	91.45%
Week 24	403/ 458	87.99%	403/ 468	86.11%
Week 36	390/ 457	85.34%	368/ 468	78.63%
Week 52	370/ 457	80.96%	340/ 467	72.81%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Lupus QoL Fatigue domain score
Full analysis set

Visit	Anifrolumab 300mg (N=459) n/ N#	Anifrolumab 300mg (N=459) Compliance	Placebo (N=468) n/ N#	Placebo (N=468) Compliance
Baseline	439/ 459	95.64%	449/ 468	95.94%
Week 4	97/ 459	21.13%	98/ 468	20.94%
Week 12	424/ 458	92.58%	428/ 468	91.45%
Week 24	403/ 458	87.99%	403/ 468	86.11%
Week 36	390/ 457	85.34%	368/ 468	78.63%
Week 52	370/ 457	80.96%	340/ 467	72.81%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Lupus QoL Intimate Relationships domain score
Full analysis set

Visit	Anifrolumab 300mg (N=459) n/ N#	Anifrolumab 300mg (N=459) Compliance	Placebo (N=468) n/ N#	Placebo (N=468) Compliance
Baseline	367/ 459	79.96%	362/ 468	77.35%
Week 4	85/ 459	18.52%	77/ 468	16.45%
Week 12	348/ 458	75.98%	346/ 468	73.93%
Week 24	319/ 458	69.65%	307/ 468	65.60%
Week 36	307/ 457	67.18%	270/ 468	57.69%
Week 52	276/ 457	60.39%	250/ 467	53.53%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Lupus QoL Pain domain score
Full analysis set

Visit	Anifrolumab 300mg (N=459) n/ N#	Anifrolumab 300mg (N=459) Compliance	Placebo (N=468) n/ N#	Placebo (N=468) Compliance
Baseline	439/ 459	95.64%	449/ 468	95.94%
Week 4	97/ 459	21.13%	98/ 468	20.94%
Week 12	424/ 458	92.58%	428/ 468	91.45%
Week 24	403/ 458	87.99%	403/ 468	86.11%
Week 36	390/ 457	85.34%	368/ 468	78.63%
Week 52	370/ 457	80.96%	340/ 467	72.81%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Lupus QoL Planning domain score
Full analysis set

Visit	Anifrolumab 300mg (N=459) n/ N#	Anifrolumab 300mg (N=459) Compliance	Placebo (N=468) n/ N#	Placebo (N=468) Compliance
Baseline	439/ 459	95.64%	449/ 468	95.94%
Week 4	97/ 459	21.13%	98/ 468	20.94%
Week 12	424/ 458	92.58%	428/ 468	91.45%
Week 24	403/ 458	87.99%	403/ 468	86.11%
Week 36	390/ 457	85.34%	368/ 468	78.63%
Week 52	370/ 457	80.96%	340/ 467	72.81%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - SDI Global Score
Full analysis set

Visit	Anifrolumab 300mg (N=459) n/ N#	Anifrolumab 300mg (N=459) Compliance	Placebo (N=468) n/ N#	Placebo (N=468) Compliance
Baseline	449/ 459	97.82%	453/ 468	96.79%
Week 24	410/ 458	89.52%	405/ 468	86.54%
Week 52	373/ 457	81.62%	353/ 467	75.59%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - PtGA
Full analysis set

Visit	Anifrolumab 300mg (N=459) n/ N#	Anifrolumab 300mg (N=459) Compliance	Placebo (N=468) n/ N#	Placebo (N=468) Compliance
Baseline	440/ 459	95.86%	451/ 468	96.37%
Week 4	435/ 459	94.77%	448/ 468	95.73%
Week 8	422/ 459	91.94%	436/ 468	93.16%
Week 12	426/ 458	93.01%	428/ 468	91.45%
Week 16	416/ 458	90.83%	415/ 468	88.68%
Week 20	406/ 458	88.65%	415/ 468	88.68%
Week 24	404/ 458	88.21%	404/ 468	86.32%
Week 28	403/ 458	87.99%	395/ 468	84.40%
Week 32	392/ 457	85.78%	378/ 468	80.77%
Week 36	394/ 457	86.21%	371/ 468	79.27%
Week 40	388/ 457	84.90%	371/ 467	79.44%
Week 44	387/ 457	84.68%	356/ 467	76.23%
Week 48	389/ 457	85.12%	354/ 467	75.80%
Week 52	371/ 457	81.18%	341/ 467	73.02%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Total HAQ Score
Full analysis set

Visit	Anifrolumab 300mg (N=459) n/ N#	Anifrolumab 300mg (N=459) Compliance	Placebo (N=468) n/ N#	Placebo (N=468) Compliance
Baseline	99/ 459	21.57%	102/ 468	21.79%
Week 4	98/ 459	21.35%	99/ 468	21.15%
Week 12	94/ 458	20.52%	97/ 468	20.73%
Week 24	93/ 458	20.31%	87/ 468	18.59%
Week 36	90/ 457	19.69%	75/ 468	16.03%
Week 52	88/ 457	19.26%	70/ 467	14.99%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Compliance rates by timepoint - Pain Score
Full analysis set

Visit	Anifrolumab 300mg (N=459) n/ N#	Anifrolumab 300mg (N=459) Compliance	Placebo (N=468) n/ N#	Placebo (N=468) Compliance
Baseline	99/ 459	21.57%	102/ 468	21.79%
Week 4	98/ 459	21.35%	99/ 468	21.15%
Week 12	94/ 458	20.52%	97/ 468	20.73%
Week 24	93/ 458	20.31%	87/ 468	18.59%
Week 36	90/ 457	19.69%	75/ 468	16.03%
Week 52	88/ 457	19.26%	70/ 467	14.99%

N defines number of subjects still alive at planned study day.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Flare rate through Week 52
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=459) Number of flares	Anifrolumab 300mg (N=459) Total Follow-up time (years)	Anifrolumab 300mg (N=459) Annual rate (SE)	Placebo (N=468) Number of flares	Placebo (N=468) Total Follow-up time (years)	Placebo (N=468) Annual rate (SE)	Rate ratio (95% CI)	p-Value	Heterogenity/ Interaction p-Value
									0.6636
Overall	245	430.70	0.48 (0.10)	316	420.57	0.65 (0.10)	0.74 (0.60, 0.93)	0.0094	
SLEDAI-2K score									0.1852
< 10 points	71	137.35	0.48 (0.16)	73	133.52	0.53 (0.16)	0.90 (0.60, 1.35)	0.6228	
>= 10 points	174	293.36	0.50 (0.12)	243	287.05	0.74 (0.12)	0.68 (0.52, 0.89)	0.0056	
OCS dose									0.3248
<10 mg/day	110	200.84	0.49 (0.14)	134	200.99	0.61 (0.14)	0.80 (0.56, 1.13)	0.2046	
>=10 mg/day	135	229.87	0.48 (0.14)	182	219.57	0.69 (0.13)	0.69 (0.52, 0.93)	0.0130	
Result of type I IFN gene signature test									0.0120
LOW	47	82.80	0.54 (0.19)	33	81.84	0.33 (0.25)	1.66 (0.91, 3.04)	0.1010	
HIGH	198	347.90	0.52 (0.10)	283	338.72	0.81 (0.09)	0.65 (0.51, 0.82)	0.0004	
Age (years)									0.2141
<= 65	241	419.48	0.48 (0.10)	311	416.63	0.64 (0.10)	0.76 (0.60, 0.95)	0.0142	
> 65	4	11.23	NE	5	3.94	NE	NE		
Sex									0.5247
male	17	31.68	0.21 (0.56)	30	33.30	0.36 (0.53)	0.58 (0.31, 1.11)	0.1023	
female	228	399.02	0.49 (0.10)	286	387.26	0.65 (0.10)	0.76 (0.60, 0.96)	0.0209	
Race									0.8205
White	154	254.28	0.54 (0.13)	198	256.62	0.65 (0.12)	0.82 (0.61, 1.12)	0.2134	
Black	39	59.30	0.65 (0.26)	47	56.38	0.92 (0.24)	0.71 (0.40, 1.25)	0.2382	
Other	50	110.44	0.32 (0.27)	69	100.58	0.46 (0.26)	0.68 (0.42, 1.11)	0.1233	
Ethnicity									0.6120
Hispanic/Latino	67	124.62	0.38 (0.21)	78	117.54	0.48 (0.21)	0.80 (0.51, 1.25)	0.3230	
Non-hispanic/Latino	176	299.40	0.50 (0.12)	236	296.04	0.74 (0.11)	0.68 (0.52, 0.89)	0.0049	
Geographic region									0.6816
EU	62	129.02	0.40 (0.22)	91	133.54	0.58 (0.22)	0.69 (0.44, 1.07)	0.0997	
non-EU	183	301.68	0.51 (0.11)	225	287.03	0.66 (0.11)	0.77 (0.60, 1.00)	0.0520	
Onset of disease									0.7825
Paediatric	25	33.95	0.78 (0.32)	28	30.52	0.94 (0.33)	0.83 (0.42, 1.64)	0.5910	
Adult	220	396.76	0.47 (0.10)	288	390.05	0.63 (0.10)	0.73 (0.58, 0.93)	0.0101	
ADA result									0.1709
Negative	228	403.70	0.49 (0.10)	274	385.93	0.63 (0.10)	0.78 (0.62, 0.99)	0.0413	
Positive (At any time)	17	27.01	0.17 (0.55)	42	34.64	0.38 (0.47)	0.45 (0.22, 0.94)	0.0347	
BMI (kg/m2)									0.1624
< 30	150	290.07	0.45 (0.13)	232	300.06	0.67 (0.12)	0.67 (0.51, 0.88)	0.0044	
>= 30	95	140.63	0.51 (0.16)	84	120.51	0.60 (0.15)	0.85 (0.57, 1.27)	0.4203	

Rates and rate ratio from negative binomial regression model with factors for treatment group and the stratification factors. The logarithm (to base e) of the follow-up time is used as an offset variable in the model to adjust for subjects having different exposure times.
Study*treatment interaction also included to assess heterogenity between studies.
p-Value for interaction from same negative binomial regression model with additional factors for subgroup and subgroup*treatment interaction.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Overall Survival
Full analysis set

	Anifrolumab 300mg (N=459)	Placebo (N=468)
Number of subjects with events, n (%)	2 (0.4)	1 (0.2)
Number of censored subjects, n (%)	457 (99.6)	467 (99.8)
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Anifrolumab 300mg vs. Placebo (adjusted)		
Hazard Ratio (95% CI)	1.74 (0.16, 19.26)	
p-value	0.6652	
Analysis Anifrolumab 300mg vs. Placebo (unadjusted)		
Hazard Ratio (95% CI)	2.02 (0.18, 22.31)	
p-value	0.5604	
p-Value for test for heterogenity between studies	1.0000	

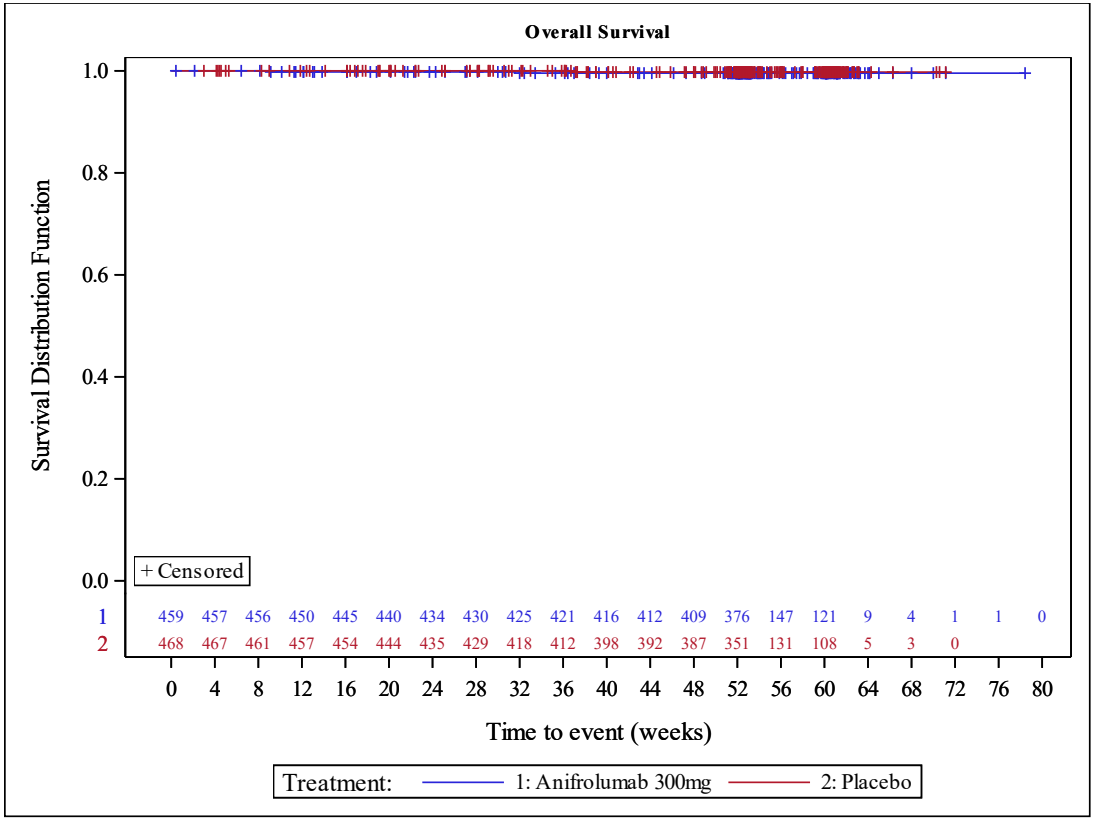
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model. Adjusted analysis also includes stratification factors in the model.
Two-sided log rank test used.
p-Value for heterogenity between studies from Cox proportional hazards model with factors for treatment, study, treatment*study interaction and stratfication factors.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unadjusted analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Overall Survival - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Anifrolumab 300mg (N=459) Median (95% CI)	Placebo (N=468) n/ N (%)	Placebo (N=468) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score							0.9990
< 10 points	2/148 (1.4)	NE (NE, NE)	0/146 (0.0)	NE (NE, NE)	NE		
>= 10 points	0/311 (0.0)	NE (NE, NE)	1/322 (0.3)	NE (NE, NE)	NE		
OCS dose							1.0000
<10 mg/day	0/214 (0.0)	NE (NE, NE)	0/219 (0.0)	NE (NE, NE)	NE		
>=10 mg/day	2/245 (0.8)	NE (NE, NE)	1/249 (0.4)	NE (NE, NE)	1.74 (0.16, 19.26)	0.6652	
Result of type I IFN gene signature test							1.0000
LOW	0/ 86 (0.0)	NE (NE, NE)	0/ 90 (0.0)	NE (NE, NE)	NE		
HIGH	2/373 (0.5)	NE (NE, NE)	1/378 (0.3)	NE (NE, NE)	1.74 (0.16, 19.26)	0.6652	
Age (years)							1.0000
<= 65	2/447 (0.4)	NE (NE, NE)	1/464 (0.2)	NE (NE, NE)	1.71 (0.15, 18.88)	0.6721	
> 65	0/ 12 (0.0)	NE (NE, NE)	0/ 4 (0.0)	NE (NE, NE)	NE		
Sex							1.0000
male	0/ 33 (0.0)	NE (NE, NE)	0/ 34 (0.0)	NE (NE, NE)	NE		
female	2/426 (0.5)	NE (NE, NE)	1/434 (0.2)	NE (NE, NE)	1.76 (0.16, 19.46)	0.6456	
Race							1.0000
White	1/270 (0.4)	NE (NE, NE)	0/285 (0.0)	NE (NE, NE)	NE		
Black	0/ 65 (0.0)	NE (NE, NE)	1/ 60 (1.7)	NE (NE, NE)	NE		
Other	1/116 (0.9)	NE (NE, NE)	0/115 (0.0)	NE (NE, NE)	NE		
Ethnicity							0.9980
Hispanic/Latino	2/132 (1.5)	NE (NE, NE)	0/131 (0.0)	NE (NE, NE)	NE		
Non-hispanic/Latino	0/319 (0.0)	NE (NE, NE)	1/329 (0.3)	NE (NE, NE)	NE		
Geographic region							1.0000
EU	0/135 (0.0)	NE (NE, NE)	0/147 (0.0)	NE (NE, NE)	NE		
non-EU	2/324 (0.6)	NE (NE, NE)	1/321 (0.3)	NE (NE, NE)	1.70 (0.15, 18.81)	0.6647	
Onset of disease							1.0000
Paediatric	0/ 36 (0.0)	NE (NE, NE)	0/ 35 (0.0)	NE (NE, NE)	NE		
Adult	2/423 (0.5)	NE (NE, NE)	1/433 (0.2)	NE (NE, NE)	1.86 (0.17, 20.53)	0.6333	
ADA result							1.0000
Negative	2/427 (0.5)	NE (NE, NE)	1/429 (0.2)	NE (NE, NE)	1.60 (0.14, 17.81)	0.7108	
Positive (At any time)	0/ 31 (0.0)	NE (NE, NE)	0/ 39 (0.0)	NE (NE, NE)	NE		
BMI (kg/m2)							0.9975
< 30	2/309 (0.6)	NE (NE, NE)	0/339 (0.0)	NE (NE, NE)	NE		
>= 30	0/150 (0.0)	NE (NE, NE)	1/129 (0.8)	NE (NE, NE)	NE		

Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Overall Survival
Full analysis set



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Time to first Flare
Full analysis set

	Anifrolumab 300mg (N=459)	Placebo (N=468)
Number of subjects with events, n (%)	151 (32.9)	193 (41.2)
Number of censored subjects, n (%)	308 (67.1)	275 (58.8)
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	31.14 (24.14, 36.29)	20.00 (17.14, 23.71)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Anifrolumab 300mg vs. Placebo (adjusted)		
Hazard Ratio (95% CI)	0.72 (0.58, 0.89)	
p-value	0.0027	
Analysis Anifrolumab 300mg vs. Placebo (unadjusted)		
Hazard Ratio (95% CI)	0.73 (0.59, 0.90)	
p-value	0.0035	
p-Value for test for heterogenity between studies	0.7584	

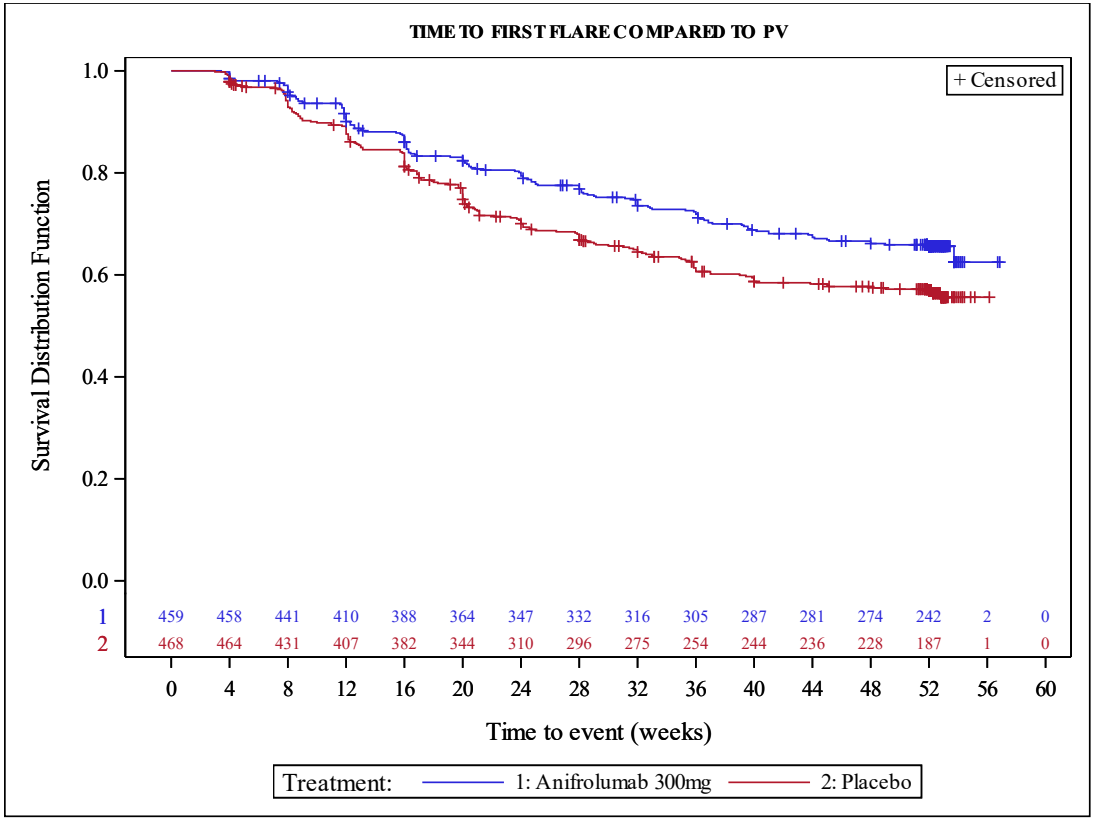
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model. Adjusted analysis also includes stratification factors in the model.
Two-sided log rank test used.
p-Value for heterogenity between studies from Cox proportional hazards model with factors for treatment, study, treatment*study interaction and stratfication factors.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].
Unadjusted analysis also includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Time to first Flare - Subgroup analysis
Full analysis set

Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Anifrolumab 300mg (N=459) Median (95% CI)	Placebo (N=468) n/ N (%)	Placebo (N=468) Median (95% CI)	Anifrolumab 300mg vs. Placebo Hazard Ratio (95% CI)	Anifrolumab 300mg vs. Placebo p-Value	Interaction p-Value
SLEDAI-2K score							0.2298
< 10 points	46/148 (31.1)	NE (53.71, NE)	51/146 (34.9)	NE (NE, NE)	0.87 (0.58, 1.29)	0.4377	
>= 10 points	105/311 (33.8)	NE (NE, NE)	142/322 (44.1)	NE (40.00, NE)	0.66 (0.51, 0.85)	0.0023	
OCS dose							0.1682
<10 mg/day	68/214 (31.8)	NE (NE, NE)	78/219 (35.6)	NE (NE, NE)	0.83 (0.60, 1.15)	0.2624	
>=10 mg/day	83/245 (33.9)	NE (NE, NE)	115/249 (46.2)	NE (35.86, NE)	0.63 (0.47, 0.83)	0.0028	
Result of type I IFN gene signature test							0.0372
LOW	28/ 86 (32.6)	NE (NE, NE)	25/ 90 (27.8)	NE (NE, NE)	1.25 (0.73, 2.15)	0.3097	
HIGH	123/373 (33.0)	NE (NE, NE)	168/378 (44.4)	NE (40.14, NE)	0.65 (0.52, 0.82)	0.0002	
Age (years)							0.7298
<= 65	147/447 (32.9)	NE (NE, NE)	191/464 (41.2)	NE (NE, NE)	0.72 (0.58, 0.89)	0.0031	
> 65	4/ 12 (33.3)	NE (16.14, NE)	2/ 4 (50.0)	NE (8.00, NE)	0.39 (0.04, 3.66)	0.1573	
Sex							0.9412
male	13/ 33 (39.4)	NE (32.00, NE)	18/ 34 (52.9)	48.14 (21.14, NE)	0.71 (0.34, 1.48)	0.1219	
female	138/426 (32.4)	NE (NE, NE)	175/434 (40.3)	NE (NE, NE)	0.72 (0.58, 0.90)	0.0042	
Race							0.7554
White	93/270 (34.4)	NE (53.71, NE)	124/285 (43.5)	NE (43.86, NE)	0.69 (0.53, 0.91)	0.0062	
Black	24/ 65 (36.9)	NE (39.57, NE)	25/ 60 (41.7)	NE (33.14, NE)	0.95 (0.53, 1.70)	0.4879	
Other	32/116 (27.6)	NE (NE, NE)	42/115 (36.5)	NE (NE, NE)	0.68 (0.43, 1.07)	0.1317	
Ethnicity							0.8225
Hispanic/Latino	40/132 (30.3)	NE (NE, NE)	49/131 (37.4)	NE (NE, NE)	0.74 (0.49, 1.12)	0.3120	
Non-hispanic/Latino	109/319 (34.2)	NE (53.71, NE)	142/329 (43.2)	NE (45.00, NE)	0.70 (0.54, 0.90)	0.0044	
Geographic region							0.4388
EU	38/135 (28.1)	NE (53.71, NE)	58/147 (39.5)	NE (52.86, NE)	0.63 (0.42, 0.95)	0.0339	
non-EU	113/324 (34.9)	NE (NE, NE)	135/321 (42.1)	NE (52.29, NE)	0.75 (0.58, 0.96)	0.0174	
Onset of disease							0.8227
Paediatric	16/ 36 (44.4)	NE (25.14, NE)	16/ 35 (45.7)	NE (24.57, NE)	0.75 (0.36, 1.58)	0.0419	
Adult	135/423 (31.9)	NE (NE, NE)	177/433 (40.9)	NE (NE, NE)	0.71 (0.56, 0.88)	0.0036	
ADA result							0.1217
Negative	140/427 (32.8)	NE (NE, NE)	167/429 (38.9)	NE (NE, NE)	0.76 (0.61, 0.96)	0.0201	
Positive (At any time)	11/ 31 (35.5)	NE (25.14, NE)	26/ 39 (66.7)	27.71 (16.00, 40.00)	0.38 (0.18, 0.80)	0.0194	
BMI (kg/m2)							0.3942
< 30	96/309 (31.1)	NE (53.71, NE)	138/339 (40.7)	NE (52.86, NE)	0.67 (0.52, 0.87)	0.0030	
>= 30	55/150 (36.7)	NE (NE, NE)	55/129 (42.6)	NE (40.14, NE)	0.79 (0.54, 1.15)	0.2219	

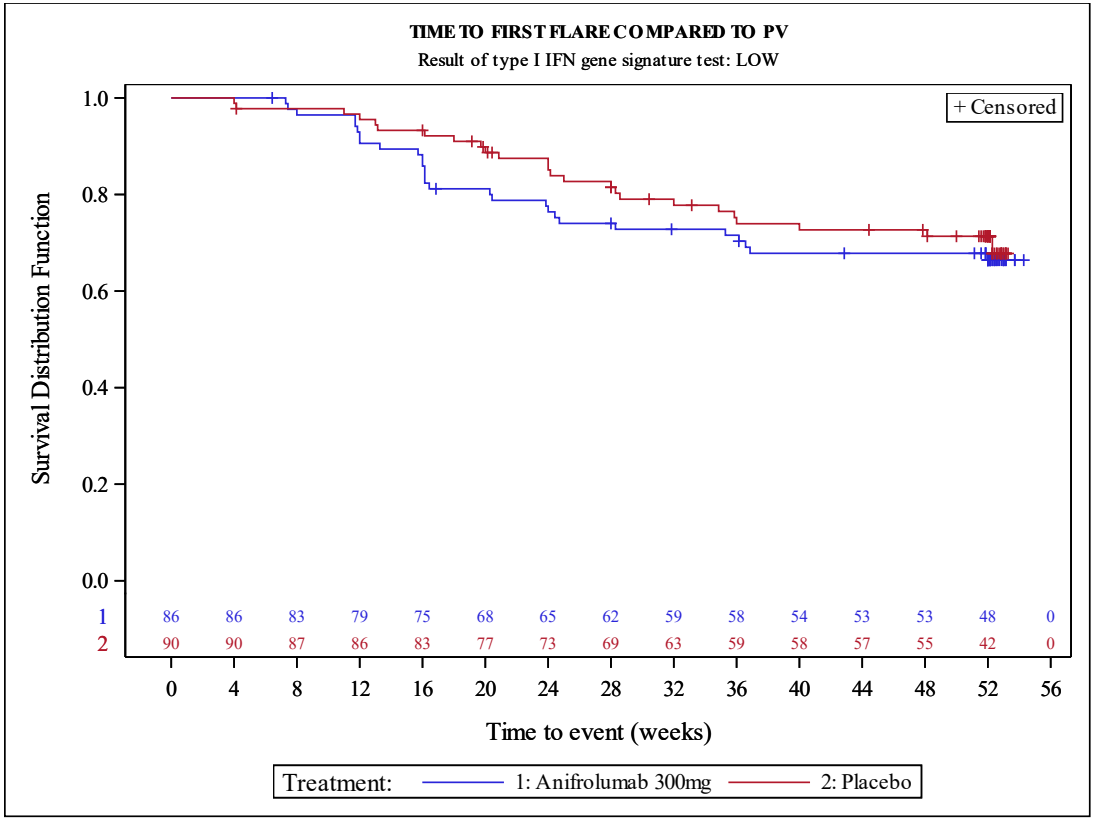
Kaplan-Meier median with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratios, confidence intervals and 2-sided p-value are calculated from Cox proportional hazards model with factors for treatment and stratification factors.
Two-sided log rank test used.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup, treatment*subgroup interaction and stratfication factors.
Stratification factors: Study [Tulip1, Tulip2, MUSE], SLEDAI-2K score at screening [<10 points vs >= 10 points], Week 0 OCS dose [<10 mg/day vs >=10 mg/day prednisone or equivalent] and type I IFN gene signature test result at screening [high vs low].

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Time to first Flare
Full analysis set



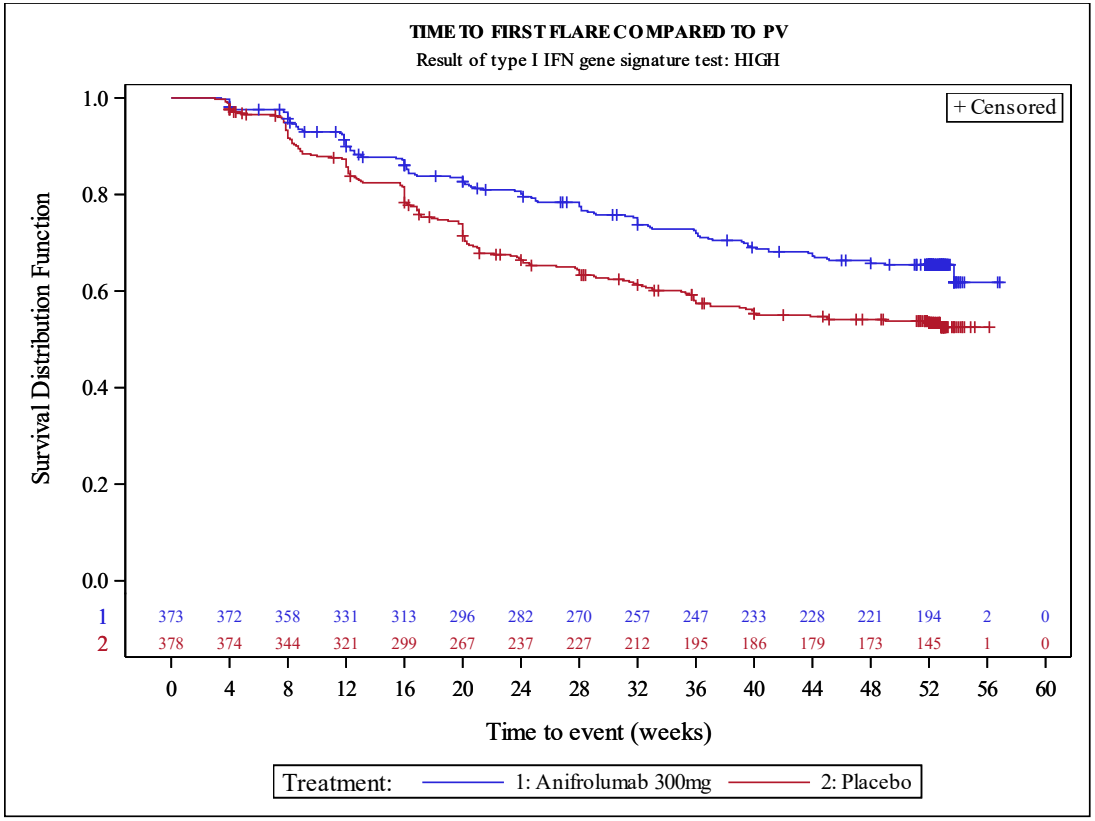
Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Time to first Flare
Full analysis set



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Time to first Flare
Full analysis set



Kaplan-Meier Plots for subgroups are generated if p-value for interaction <0.05.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
OCS dose increases and cumulative OCS dose until week 52
Full analysis set

		Anifrolumab 300mg (N=459)	Placebo (N=468)	Total (N=927)
Number of dose increases (%)	0	337 (73.4)	313 (66.9)	650 (70.1)
	1	82 (17.9)	78 (16.7)	160 (17.3)
	2	26 (5.7)	38 (8.1)	64 (6.9)
	>2	14 (3.1)	39 (8.3)	53 (5.7)
Cumulative OCS Dose (mg/day)	n (missing)	446 (13)	457 (11)	903 (24)
	Mean (SD)	2541.8 (2809.02)	2733.9 (2041.66)	2639.0 (2451.40)
	Median	2146.3	2455.0	2274.0
	Min, Max	0, 35466	0, 10581	0, 35466
AUC up to Week 52 (mg/day)	n (missing)	446 (13)	457 (11)	903 (24)
	Mean (SD)	2772.6 (2934.91)	3137.5 (2468.84)	2957.3 (2713.71)
	Median	2332.5	2824.1	2573.4
	Min, Max	0, 35369	0, 21809	0, 35369

Subjects without any documented dose value regarded as missing values for calculation of cumulative dose and AUC.
AUC defines the cumulative dose normalized for a period of 52 weeks.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=459)	Placebo (N=467)
Number of subjects with events, n (%)	404 (88.0)	375 (80.3)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.09 (1.03, 1.16)	
p-value	0.0018	
Odds Ratio (95% CI)	1.80 (1.25, 2.58)	
p-value	0.0016	
Risk Difference (95% CI)	7.71 (3.04, 12.38)	
p-value	0.0012	
p-Value for test for heterogenity between studies	0.4064	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=467) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.6824
< 10 points	133/148 (89.9)	117/146 (80.1)	1.11 (1.01, 1.22)	0.0254	
>= 10 points	271/311 (87.1)	258/321 (80.4)	1.08 (1.01, 1.16)	0.0216	
OCS dose					0.2191
<10 mg/day	190/214 (88.8)	184/218 (84.4)	1.06 (0.99, 1.14)	0.0962	
>=10 mg/day	214/245 (87.3)	191/249 (76.7)	1.14 (1.05, 1.24)	0.0021	
Result of type I IFN gene signature test					0.1330
LOW	78/ 86 (90.7)	68/ 90 (75.6)	1.20 (1.05, 1.38)	0.0080	
HIGH	326/373 (87.4)	307/377 (81.4)	1.07 (1.01, 1.14)	0.0235	
Age (years)					0.0391
<= 65	394/447 (88.1)	371/463 (80.1)	1.10 (1.04, 1.16)	0.0013	
> 65	10/ 12 (83.3)	4/ 4 (100.0)	0.84 (0.65, 1.08)	0.1648	
Sex					0.5785
male	28/ 33 (84.8)	25/ 34 (73.5)	1.17 (0.92, 1.50)	0.2085	
female	376/426 (88.3)	350/433 (80.8)	1.09 (1.03, 1.15)	0.0028	
Race					0.0204
White	235/270 (87.0)	221/285 (77.5)	1.12 (1.04, 1.21)	0.0033	
Black	56/ 65 (86.2)	48/ 59 (81.4)	1.04 (0.90, 1.21)	0.5866	
Other	105/116 (90.5)	98/115 (85.2)	0.98 (0.92, 1.04)	0.4726	
Ethnicity					0.0994
Hispanic/Latino	117/132 (88.6)	97/131 (74.0)	1.18 (1.05, 1.32)	0.0043	
Non-hispanic/Latino	279/319 (87.5)	270/328 (82.3)	1.06 (0.99, 1.13)	0.1017	
Geographic region					0.6762
EU	111/135 (82.2)	107/147 (72.8)	1.11 (0.98, 1.25)	0.1088	
non-EU	293/324 (90.4)	268/320 (83.8)	1.08 (1.01, 1.14)	0.0143	
Onset of disease					0.1681
Paediatric	33/ 36 (91.7)	30/ 35 (85.7)	1.00 (0.88, 1.13)	0.9536	
Adult	371/423 (87.7)	345/432 (79.9)	1.10 (1.03, 1.16)	0.0024	
ADA result					0.5660
Negative	377/427 (88.3)	341/428 (79.7)	1.11 (1.04, 1.17)	0.0008	
Positive (At any time)	27/ 31 (87.1)	34/ 39 (87.2)	1.06 (0.94, 1.20)	0.3539	
BMI (kg/m2)					0.7380
< 30	268/309 (86.7)	267/339 (78.8)	1.09 (1.02, 1.17)	0.0121	
>= 30	136/150 (90.7)	108/128 (84.4)	1.07 (0.98, 1.17)	0.1196	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Serious Adverse Event
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=459)	Placebo (N=467)
Number of subjects with events, n (%)	56 (12.2)	80 (17.1)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.72 (0.53, 0.99)	
p-value	0.0458	
Odds Ratio (95% CI)	0.68 (0.47, 0.98)	
p-value	0.0401	
Risk Difference (95% CI)	-4.92 (-9.47, -0.38)	
p-value	0.0336	
p-Value for test for heterogenity between studies	0.2894	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Serious Adverse Event - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=467) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	 p-Value	Interaction p-Value
SLEDAI-2K score					0.5642
< 10 points	13/148 (8.8)	15/146 (10.3)	0.87 (0.43, 1.78)	0.7065	
>= 10 points	43/311 (13.8)	65/321 (20.2)	0.69 (0.48, 0.98)	0.0401	
OCS dose					0.6256
<10 mg/day	22/214 (10.3)	35/218 (16.1)	0.66 (0.40, 1.10)	0.1088	
>=10 mg/day	34/245 (13.9)	45/249 (18.1)	0.78 (0.51, 1.17)	0.2245	
Result of type I IFN gene signature test					0.3108
LOW	9/ 86 (10.5)	8/ 90 (8.9)	1.11 (0.44, 2.76)	0.8298	
HIGH	47/373 (12.6)	72/377 (19.1)	0.67 (0.47, 0.94)	0.0199	
Age (years)					0.7698
<= 65	53/447 (11.9)	79/463 (17.1)	0.71 (0.51, 0.98)	0.0361	
> 65	3/ 12 (25.0)	1/ 4 (25.0)	0.90 (0.18, 4.53)	0.9014	
Sex					0.5366
male	5/ 33 (15.2)	5/ 34 (14.7)	1.02 (0.33, 3.20)	0.9683	
female	51/426 (12.0)	75/433 (17.3)	0.70 (0.50, 0.98)	0.0379	
Race					0.6675
White	30/270 (11.1)	43/285 (15.1)	0.75 (0.48, 1.16)	0.1943	
Black	8/ 65 (12.3)	15/ 59 (25.4)	0.50 (0.22, 1.12)	0.0943	
Other	16/116 (13.8)	22/115 (19.1)	0.76 (0.42, 1.39)	0.3766	
Ethnicity					0.1947
Hispanic/Latino	18/132 (13.6)	20/131 (15.3)	1.02 (0.54, 1.92)	0.9574	
Non-hispanic/Latino	36/319 (11.3)	60/328 (18.3)	0.62 (0.42, 0.92)	0.0159	
Geographic region					0.5465
EU	14/135 (10.4)	25/147 (17.0)	0.62 (0.33, 1.16)	0.1337	
non-EU	42/324 (13.0)	55/320 (17.2)	0.78 (0.53, 1.14)	0.1952	
Onset of disease					0.4204
Paediatric	8/ 36 (22.2)	7/ 35 (20.0)	1.07 (0.40, 2.81)	0.8970	
Adult	48/423 (11.3)	73/432 (16.9)	0.70 (0.50, 0.99)	0.0413	
ADA result					0.1035
Negative	54/427 (12.6)	68/428 (15.9)	0.81 (0.58, 1.13)	0.2124	
Positive (At any time)	2/ 31 (6.5)	12/ 39 (30.8)	0.25 (0.07, 0.98)	0.0474	
BMI (kg/m2)					0.4699
< 30	35/309 (11.3)	59/339 (17.4)	0.66 (0.45, 0.97)	0.0345	
>= 30	21/150 (14.0)	21/128 (16.4)	0.85 (0.48, 1.51)	0.5801	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Severe Adverse Event
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=459)	Placebo (N=467)
Number of subjects with events, n (%)	46 (10.0)	40 (8.6)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.20 (0.80, 1.81)	
p-value	0.3749	
Odds Ratio (95% CI)	1.21 (0.76, 1.91)	
p-value	0.4155	
Risk Difference (95% CI)	1.47 (-2.24, 5.19)	
p-value	0.4373	
p-Value for test for heterogenity between studies	0.1344	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Severe Adverse Event - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=467) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.8474
< 10 points	15/148 (10.1)	10/146 (6.8)	1.19 (0.50, 2.84)	0.6956	
>= 10 points	31/311 (10.0)	30/321 (9.3)	1.08 (0.67, 1.74)	0.7555	
OCS dose					0.9524
<10 mg/day	16/214 (7.5)	13/218 (6.0)	1.13 (0.50, 2.59)	0.7669	
>=10 mg/day	30/245 (12.2)	27/249 (10.8)	1.17 (0.72, 1.90)	0.5367	
Result of type I IFN gene signature test					0.3798
LOW	10/ 86 (11.6)	4/ 90 (4.4)	1.85 (0.58, 5.93)	0.3026	
HIGH	36/373 (9.7)	36/377 (9.5)	1.06 (0.68, 1.65)	0.8132	
Age (years)					NE
<= 65	46/447 (10.3)	40/463 (8.6)	1.22 (0.81, 1.84)	0.3386	
> 65	0/ 12 (0.0)	0/ 4 (0.0)	NE		
Sex					0.8020
male	3/ 33 (9.1)	2/ 34 (5.9)	1.44 (0.30, 6.98)	0.6476	
female	43/426 (10.1)	38/433 (8.8)	1.17 (0.77, 1.78)	0.4571	
Race					0.7543
White	22/270 (8.1)	25/285 (8.8)	0.99 (0.56, 1.76)	0.9840	
Black	11/ 65 (16.9)	7/ 59 (11.9)	0.94 (0.35, 2.50)	0.9042	
Other	11/116 (9.5)	8/115 (7.0)	1.43 (0.60, 3.40)	0.4161	
Ethnicity					0.6554
Hispanic/Latino	17/132 (12.9)	13/131 (9.9)	1.35 (0.66, 2.75)	0.4124	
Non-hispanic/Latino	27/319 (8.5)	27/328 (8.2)	1.10 (0.65, 1.86)	0.7151	
Geographic region					0.5271
EU	11/135 (8.1)	13/147 (8.8)	0.95 (0.43, 2.09)	0.9053	
non-EU	35/324 (10.8)	27/320 (8.4)	1.29 (0.77, 2.16)	0.3316	
Onset of disease					0.9342
Paediatric	7/ 36 (19.4)	5/ 35 (14.3)	1.12 (0.29, 4.24)	0.8721	
Adult	39/423 (9.2)	35/432 (8.1)	1.18 (0.76, 1.85)	0.4600	
ADA result					0.5959
Negative	41/427 (9.6)	35/428 (8.2)	1.22 (0.79, 1.89)	0.3685	
Positive (At any time)	5/ 31 (16.1)	5/ 39 (12.8)	0.88 (0.29, 2.70)	0.8269	
BMI (kg/m2)					0.5010
< 30	30/309 (9.7)	27/339 (8.0)	1.23 (0.75, 2.01)	0.4119	
>= 30	16/150 (10.7)	13/128 (10.2)	0.91 (0.44, 1.89)	0.7955	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Non-Severe Adverse Event
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=459)	Placebo (N=467)
Number of subjects with events, n (%)	400 (87.1)	371 (79.4)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.09 (1.03, 1.16)	
p-value	0.0024	
Odds Ratio (95% CI)	1.75 (1.23, 2.50)	
p-value	0.0019	
Risk Difference (95% CI)	7.69 (2.92, 12.46)	
p-value	0.0016	
p-Value for test for heterogenity between studies	0.5307	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Non-Severe Adverse Event - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=467) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.9298
< 10 points	131/148 (88.5)	117/146 (80.1)	1.10 (1.00, 1.21)	0.0495	
>= 10 points	269/311 (86.5)	254/321 (79.1)	1.09 (1.02, 1.17)	0.0151	
OCS dose					0.1536
<10 mg/day	189/214 (88.3)	184/218 (84.4)	1.06 (0.98, 1.14)	0.1454	
>=10 mg/day	211/245 (86.1)	187/249 (75.1)	1.15 (1.05, 1.25)	0.0020	
Result of type I IFN gene signature test					0.1382
LOW	78/ 86 (90.7)	68/ 90 (75.6)	1.20 (1.05, 1.38)	0.0080	
HIGH	322/373 (86.3)	303/377 (80.4)	1.07 (1.01, 1.14)	0.0267	
Age (years)					0.0393
<= 65	390/447 (87.2)	367/463 (79.3)	1.10 (1.04, 1.16)	0.0018	
> 65	10/ 12 (83.3)	4/ 4 (100.0)	0.84 (0.65, 1.08)	0.1648	
Sex					0.5815
male	28/ 33 (84.8)	25/ 34 (73.5)	1.17 (0.92, 1.50)	0.2085	
female	372/426 (87.3)	346/433 (79.9)	1.09 (1.03, 1.16)	0.0036	
Race					0.0093
White	234/270 (86.7)	217/285 (76.1)	1.14 (1.05, 1.23)	0.0015	
Black	54/ 65 (83.1)	48/ 59 (81.4)	1.01 (0.86, 1.18)	0.9084	
Other	104/116 (89.7)	98/115 (85.2)	0.98 (0.92, 1.03)	0.4094	
Ethnicity					0.1073
Hispanic/Latino	116/132 (87.9)	96/131 (73.3)	1.18 (1.05, 1.33)	0.0056	
Non-hispanic/Latino	276/319 (86.5)	267/328 (81.4)	1.06 (0.99, 1.13)	0.1125	
Geographic region					0.5002
EU	110/135 (81.5)	104/147 (70.7)	1.12 (0.99, 1.28)	0.0791	
non-EU	290/324 (89.5)	267/320 (83.4)	1.07 (1.01, 1.13)	0.0294	
Onset of disease					0.1836
Paediatric	33/ 36 (91.7)	29/ 35 (82.9)	0.99 (0.87, 1.13)	0.9211	
Adult	367/423 (86.8)	342/432 (79.2)	1.09 (1.03, 1.16)	0.0038	
ADA result					0.5968
Negative	374/427 (87.6)	338/428 (79.0)	1.11 (1.04, 1.17)	0.0010	
Positive (At any time)	26/ 31 (83.9)	33/ 39 (84.6)	1.06 (0.94, 1.21)	0.3433	
BMI (kg/m2)					0.5887
< 30	265/309 (85.8)	263/339 (77.6)	1.10 (1.02, 1.18)	0.0114	
>= 30	135/150 (90.0)	108/128 (84.4)	1.06 (0.97, 1.16)	0.1834	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event leading to discontinuation of study drug
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=459)	Placebo (N=467)
Number of subjects with events, n (%)	20 (4.4)	26 (5.6)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.78 (0.41, 1.46)	
p-value	0.4320	
Odds Ratio (95% CI)	0.77 (0.40, 1.48)	
p-value	0.4300	
Risk Difference (95% CI)	-1.21 (-4.02, 1.60)	
p-value	0.3983	
p-Value for test for heterogenity between studies	0.0202	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event leading to discontinuation of study drug - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=467) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.3902
< 10 points	5/148 (3.4)	4/146 (2.7)	1.50 (0.33, 6.92)	0.5995	
>= 10 points	15/311 (4.8)	22/321 (6.9)	0.72 (0.36, 1.44)	0.3570	
OCS dose					0.5938
<10 mg/day	8/214 (3.7)	8/218 (3.7)	1.04 (0.37, 2.95)	0.9388	
>=10 mg/day	12/245 (4.9)	18/249 (7.2)	0.72 (0.31, 1.67)	0.4498	
Result of type I IFN gene signature test					0.7914
LOW	4/ 86 (4.7)	4/ 90 (4.4)	0.94 (0.21, 4.18)	0.9404	
HIGH	16/373 (4.3)	22/377 (5.8)	0.76 (0.38, 1.51)	0.4294	
Age (years)					0.6585
<= 65	19/447 (4.3)	26/463 (5.6)	0.76 (0.40, 1.42)	0.3876	
> 65	1/ 12 (8.3)	0/ 4 (0.0)	1.50 (0.08, 29.15)	0.7888	
Sex					NE
male	0/ 33 (0.0)	0/ 34 (0.0)	NE		
female	20/426 (4.7)	26/433 (6.0)	0.78 (0.41, 1.45)	0.4282	
Race					0.6961
White	14/270 (5.2)	16/285 (5.6)	0.92 (0.44, 1.92)	0.8188	
Black	2/ 65 (3.1)	1/ 59 (1.7)	1.28 (0.21, 7.82)	0.7916	
Other	3/116 (2.6)	9/115 (7.8)	0.50 (0.11, 2.22)	0.3609	
Ethnicity					0.6498
Hispanic/Latino	5/132 (3.8)	10/131 (7.6)	0.66 (0.23, 1.91)	0.4415	
Non-hispanic/Latino	14/319 (4.4)	16/328 (4.9)	0.90 (0.38, 2.13)	0.8156	
Geographic region					0.8411
EU	6/135 (4.4)	8/147 (5.4)	0.86 (0.28, 2.70)	0.8006	
non-EU	14/324 (4.3)	18/320 (5.6)	0.75 (0.35, 1.60)	0.4572	
Onset of disease					0.8283
Paediatric	2/ 36 (5.6)	2/ 35 (5.7)	0.88 (0.14, 5.51)	0.8951	
Adult	18/423 (4.3)	24/432 (5.6)	0.71 (0.35, 1.43)	0.3396	
ADA result					0.9815
Negative	17/427 (4.0)	21/428 (4.9)	0.76 (0.37, 1.55)	0.4535	
Positive (At any time)	3/ 31 (9.7)	5/ 39 (12.8)	0.78 (0.21, 2.80)	0.6979	
BMI (kg/m2)					0.8378
< 30	16/309 (5.2)	22/339 (6.5)	0.81 (0.42, 1.58)	0.5386	
>= 30	4/150 (2.7)	4/128 (3.1)	0.68 (0.14, 3.20)	0.6254	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Serious Adverse Event leading to discontinuation of study drug
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=459)	Placebo (N=467)
Number of subjects with events, n (%)	8 (1.7)	14 (3.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.65 (0.24, 1.76)	
p-value	0.3931	
Odds Ratio (95% CI)	0.64 (0.23, 1.78)	
p-value	0.3891	
Risk Difference (95% CI)	-1.25 (-3.22, 0.71)	
p-value	0.2099	
p-Value for test for heterogenity between studies	0.0806	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Serious Adverse Event leading to discontinuation of study drug - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=467) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.2701
< 10 points	3/148 (2.0)	1/146 (0.7)	1.67 (0.19, 14.49)	0.6397	
>= 10 points	5/311 (1.6)	13/321 (4.0)	0.43 (0.15, 1.25)	0.1228	
OCS dose					0.1552
<10 mg/day	4/214 (1.9)	1/218 (0.5)	2.23 (0.40, 12.36)	0.3576	
>=10 mg/day	4/245 (1.6)	13/249 (5.2)	0.48 (0.14, 1.66)	0.2483	
Result of type I IFN gene signature test					0.3177
LOW	1/ 86 (1.2)	0/ 90 (0.0)	3.09 (0.13, 73.19)	0.4846	
HIGH	7/373 (1.9)	14/377 (3.7)	0.57 (0.21, 1.57)	0.2746	
Age (years)					0.5540
<= 65	7/447 (1.6)	14/463 (3.0)	0.58 (0.21, 1.61)	0.2970	
> 65	1/ 12 (8.3)	0/ 4 (0.0)	1.50 (0.08, 29.15)	0.7888	
Sex					NE
male	0/ 33 (0.0)	0/ 34 (0.0)	NE		
female	8/426 (1.9)	14/433 (3.2)	0.64 (0.24, 1.75)	0.3858	
Race					0.9430
White	5/270 (1.9)	9/285 (3.2)	0.60 (0.17, 2.14)	0.4308	
Black	1/ 65 (1.5)	1/ 59 (1.7)	0.94 (0.10, 8.57)	0.9531	
Other	2/116 (1.7)	4/115 (3.5)	0.65 (0.13, 3.18)	0.5911	
Ethnicity					0.4463
Hispanic/Latino	1/132 (0.8)	5/131 (3.8)	0.37 (0.07, 1.98)	0.2455	
Non-hispanic/Latino	7/319 (2.2)	9/328 (2.7)	0.82 (0.26, 2.57)	0.7278	
Geographic region					0.5174
EU	2/135 (1.5)	7/147 (4.8)	0.42 (0.10, 1.84)	0.2488	
non-EU	6/324 (1.9)	7/320 (2.2)	0.80 (0.22, 2.92)	0.7371	
Onset of disease					0.7734
Paediatric	1/ 36 (2.8)	1/ 35 (2.9)	0.93 (0.10, 8.38)	0.9477	
Adult	7/423 (1.7)	13/432 (3.0)	0.64 (0.20, 2.08)	0.4626	
ADA result					0.7524
Negative	8/427 (1.9)	11/428 (2.6)	0.53 (0.16, 1.72)	0.2910	
Positive (At any time)	0/ 31 (0.0)	3/ 39 (7.7)	0.36 (0.04, 3.06)	0.3488	
BMI (kg/m2)					0.7675
< 30	6/309 (1.9)	12/339 (3.5)	0.58 (0.21, 1.65)	0.3070	
>= 30	2/150 (1.3)	2/128 (1.6)	0.83 (0.10, 7.01)	0.8655	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with Adverse Event leading to death
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=459)	Placebo (N=467)
Number of subjects with events, n (%)	2 (0.4)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.05 (0.32, 29.18)	
p-value	0.3332	
Odds Ratio (95% CI)	3.07 (0.32, 29.62)	
p-value	0.3328	
Risk Difference (95% CI)	0.44 (-0.17, 1.04)	
p-value	0.1565	
p-Value for test for heterogenity between studies	0.9962	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with Adverse Event leading to death - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=467) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					NE
< 10 points	2/148 (1.4)	0/146 (0.0)	2.92 (0.31, 27.62)	0.3503	
>= 10 points	0/311 (0.0)	0/321 (0.0)	NE		
OCS dose					NE
<10 mg/day	0/214 (0.0)	0/218 (0.0)	NE		
>=10 mg/day	2/245 (0.8)	0/249 (0.0)	2.92 (0.31, 27.79)	0.3520	
Result of type I IFN gene signature test					NE
LOW	0/ 86 (0.0)	0/ 90 (0.0)	NE		
HIGH	2/373 (0.5)	0/377 (0.0)	3.04 (0.32, 29.06)	0.3344	
Age (years)					NE
<= 65	2/447 (0.4)	0/463 (0.0)	3.12 (0.33, 29.85)	0.3234	
> 65	0/ 12 (0.0)	0/ 4 (0.0)	NE		
Sex					NE
male	0/ 33 (0.0)	0/ 34 (0.0)	NE		
female	2/426 (0.5)	0/433 (0.0)	3.07 (0.32, 29.38)	0.3300	
Race					0.9827
White	1/270 (0.4)	0/285 (0.0)	2.92 (0.12, 70.87)	0.5104	
Black	0/ 65 (0.0)	0/ 59 (0.0)	NE		
Other	1/116 (0.9)	0/115 (0.0)	2.78 (0.12, 65.08)	0.5255	
Ethnicity					NE
Hispanic/Latino	2/132 (1.5)	0/131 (0.0)	3.13 (0.33, 29.53)	0.3182	
Non-hispanic/Latino	0/319 (0.0)	0/328 (0.0)	NE		
Geographic region					NE
EU	0/135 (0.0)	0/147 (0.0)	NE		
non-EU	2/324 (0.6)	0/320 (0.0)	2.97 (0.31, 28.38)	0.3440	
Onset of disease					NE
Paediatric	0/ 36 (0.0)	0/ 35 (0.0)	NE		
Adult	2/423 (0.5)	0/432 (0.0)	3.07 (0.32, 29.38)	0.3301	
ADA result					NE
Negative	2/427 (0.5)	0/428 (0.0)	2.97 (0.31, 28.44)	0.3442	
Positive (At any time)	0/ 31 (0.0)	0/ 39 (0.0)	NE		
BMI (kg/m2)					NE
< 30	2/309 (0.6)	0/339 (0.0)	3.37 (0.35, 32.13)	0.2918	
>= 30	0/150 (0.0)	0/128 (0.0)	NE		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Herpes Zoster
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=459)	Placebo (N=467)
Number of subjects with events, n (%)	28 (6.1)	7 (1.5)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.88 (1.70, 8.89)	
p-value	0.0013	
Odds Ratio (95% CI)	4.08 (1.75, 9.53)	
p-value	0.0012	
Risk Difference (95% CI)	4.60 (2.15, 7.05)	
p-value	0.0002	
p-Value for test for heterogenity between studies	0.6738	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Herpes Zoster - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=467) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.0755
< 10 points	4/148 (2.7)	3/146 (2.1)	1.23 (0.30, 5.03)	0.7748	
>= 10 points	24/311 (7.7)	4/321 (1.2)	6.05 (2.12, 17.29)	0.0008	
OCS dose					0.9748
<10 mg/day	12/214 (5.6)	3/218 (1.4)	3.74 (1.01, 13.88)	0.0483	
>=10 mg/day	16/245 (6.5)	4/249 (1.6)	3.85 (1.28, 11.54)	0.0162	
Result of type I IFN gene signature test					0.8637
LOW	4/ 86 (4.7)	1/ 90 (1.1)	2.92 (0.46, 18.57)	0.2552	
HIGH	24/373 (6.4)	6/377 (1.6)	3.50 (1.41, 8.68)	0.0068	
Age (years)					NE
<= 65	28/447 (6.3)	7/463 (1.5)	3.95 (1.73, 9.04)	0.0011	
> 65	0/ 12 (0.0)	0/ 4 (0.0)	NE		
Sex					0.8709
male	4/ 33 (12.1)	0/ 34 (0.0)	3.85 (0.67, 22.22)	0.1312	
female	24/426 (5.6)	7/433 (1.6)	3.28 (1.41, 7.65)	0.0059	
Race					0.5169
White	15/270 (5.6)	5/285 (1.8)	3.15 (1.15, 8.60)	0.0256	
Black	1/ 65 (1.5)	1/ 59 (1.7)	0.94 (0.10, 8.57)	0.9531	
Other	10/116 (8.6)	1/115 (0.9)	4.46 (0.94, 21.09)	0.0594	
Ethnicity					0.6083
Hispanic/Latino	10/132 (7.6)	1/131 (0.8)	4.40 (0.93, 20.84)	0.0621	
Non-hispanic/Latino	16/319 (5.0)	6/328 (1.8)	2.74 (1.08, 6.91)	0.0330	
Geographic region					0.3527
EU	7/135 (5.2)	3/147 (2.0)	2.33 (0.65, 8.30)	0.1930	
non-EU	21/324 (6.5)	4/320 (1.3)	5.11 (1.76, 14.81)	0.0027	
Onset of disease					0.6570
Paediatric	5/ 36 (13.9)	1/ 35 (2.9)	2.41 (0.44, 13.34)	0.3128	
Adult	23/423 (5.4)	6/432 (1.4)	3.74 (1.52, 9.21)	0.0041	
ADA result					0.5635
Negative	24/427 (5.6)	7/428 (1.6)	3.29 (1.41, 7.69)	0.0060	
Positive (At any time)	4/ 31 (12.9)	0/ 39 (0.0)	6.29 (0.83, 47.91)	0.0757	
BMI (kg/m2)					0.7903
< 30	19/309 (6.1)	5/339 (1.5)	3.90 (1.45, 10.51)	0.0071	
>= 30	9/150 (6.0)	2/128 (1.6)	3.09 (0.76, 12.56)	0.1145	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Herpes Zoster
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=459)	Placebo (N=467)
Number of subjects with events, n (%)	2 (0.4)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.05 (0.32, 29.10)	
p-value	0.3333	
Odds Ratio (95% CI)	3.07 (0.32, 29.71)	
p-value	0.3327	
Risk Difference (95% CI)	0.44 (-0.17, 1.04)	
p-value	0.1566	
p-Value for test for heterogenity between studies	0.9969	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Herpes Zoster - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=467) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					NE
< 10 points	0/148 (0.0)	0/146 (0.0)	NE		
>= 10 points	2/311 (0.6)	0/321 (0.0)	3.07 (0.32, 29.23)	0.3289	
OCS dose					0.9574
<10 mg/day	1/214 (0.5)	0/218 (0.0)	2.53 (0.11, 60.39)	0.5656	
>=10 mg/day	1/245 (0.4)	0/249 (0.0)	2.86 (0.12, 69.32)	0.5176	
Result of type I IFN gene signature test					NE
LOW	0/ 86 (0.0)	0/ 90 (0.0)	NE		
HIGH	2/373 (0.5)	0/377 (0.0)	3.01 (0.32, 28.69)	0.3381	
Age (years)					NE
<= 65	2/447 (0.4)	0/463 (0.0)	3.08 (0.32, 29.43)	0.3284	
> 65	0/ 12 (0.0)	0/ 4 (0.0)	NE		
Sex					NE
male	0/ 33 (0.0)	0/ 34 (0.0)	NE		
female	2/426 (0.5)	0/433 (0.0)	3.00 (0.31, 28.65)	0.3397	
Race					0.8452
White	0/270 (0.0)	0/285 (0.0)	NE		
Black	1/ 65 (1.5)	0/ 59 (0.0)	1.80 (0.08, 40.75)	0.7119	
Other	1/116 (0.9)	0/115 (0.0)	2.80 (0.12, 67.00)	0.5242	
Ethnicity					NE
Hispanic/Latino	0/132 (0.0)	0/131 (0.0)	NE		
Non-hispanic/Latino	2/319 (0.6)	0/328 (0.0)	3.19 (0.34, 30.32)	0.3128	
Geographic region					NE
EU	0/135 (0.0)	0/147 (0.0)	NE		
non-EU	2/324 (0.6)	0/320 (0.0)	3.02 (0.32, 28.79)	0.3365	
Onset of disease					NE
Paediatric	0/ 36 (0.0)	0/ 35 (0.0)	NE		
Adult	2/423 (0.5)	0/432 (0.0)	3.05 (0.32, 29.13)	0.3323	
ADA result					NE
Negative	2/427 (0.5)	0/428 (0.0)	2.97 (0.31, 28.39)	0.3438	
Positive (At any time)	0/ 31 (0.0)	0/ 39 (0.0)	NE		
BMI (kg/m2)					NE
< 30	2/309 (0.6)	0/339 (0.0)	3.15 (0.33, 29.97)	0.3192	
>= 30	0/150 (0.0)	0/128 (0.0)	NE		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Herpes Zoster
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=459)	Placebo (N=467)
Number of subjects with events, n (%)	2 (0.4)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.06 (0.32, 29.26)	
p-value	0.3309	
Odds Ratio (95% CI)	3.09 (0.32, 29.88)	
p-value	0.3303	
Risk Difference (95% CI)	0.44 (-0.17, 1.04)	
p-value	0.1560	
p-Value for test for heterogenity between studies	0.9993	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Herpes Zoster - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=467) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					NE
< 10 points	0/148 (0.0)	0/146 (0.0)	NE		
>= 10 points	2/311 (0.6)	0/321 (0.0)	3.08 (0.32, 29.34)	0.3272	
OCS dose					NE
<10 mg/day	2/214 (0.9)	0/218 (0.0)	2.84 (0.30, 26.90)	0.3623	
>=10 mg/day	0/245 (0.0)	0/249 (0.0)	NE		
Result of type I IFN gene signature test					NE
LOW	0/ 86 (0.0)	0/ 90 (0.0)	NE		
HIGH	2/373 (0.5)	0/377 (0.0)	3.03 (0.32, 28.88)	0.3352	
Age (years)					NE
<= 65	2/447 (0.4)	0/463 (0.0)	3.10 (0.32, 29.59)	0.3259	
> 65	0/ 12 (0.0)	0/ 4 (0.0)	NE		
Sex					NE
male	0/ 33 (0.0)	0/ 34 (0.0)	NE		
female	2/426 (0.5)	0/433 (0.0)	3.04 (0.32, 28.99)	0.3345	
Race					0.7916
White	1/270 (0.4)	0/285 (0.0)	3.29 (0.14, 79.92)	0.4651	
Black	1/ 65 (1.5)	0/ 59 (0.0)	1.80 (0.08, 40.75)	0.7119	
Other	0/116 (0.0)	0/115 (0.0)	NE		
Ethnicity					0.9936
Hispanic/Latino	1/132 (0.8)	0/131 (0.0)	3.27 (0.14, 77.57)	0.4629	
Non-hispanic/Latino	1/319 (0.3)	0/328 (0.0)	3.33 (0.14, 80.11)	0.4580	
Geographic region					NE
EU	0/135 (0.0)	0/147 (0.0)	NE		
non-EU	2/324 (0.6)	0/320 (0.0)	2.84 (0.30, 27.06)	0.3639	
Onset of disease					NE
Paediatric	0/ 36 (0.0)	0/ 35 (0.0)	NE		
Adult	2/423 (0.5)	0/432 (0.0)	3.05 (0.32, 29.13)	0.3323	
ADA result					NE
Negative	2/427 (0.5)	0/428 (0.0)	3.13 (0.33, 29.86)	0.3218	
Positive (At any time)	0/ 31 (0.0)	0/ 39 (0.0)	NE		
BMI (kg/m2)					0.9114
< 30	1/309 (0.3)	0/339 (0.0)	3.08 (0.13, 74.40)	0.4891	
>= 30	1/150 (0.7)	0/128 (0.0)	2.38 (0.10, 57.43)	0.5926	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Herpes Zoster
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=459)	Placebo (N=467)
Number of subjects with events, n (%)	26 (5.7)	7 (1.5)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.54 (1.53, 8.21)	
p-value	0.0031	
Odds Ratio (95% CI)	3.70 (1.57, 8.75)	
p-value	0.0029	
Risk Difference (95% CI)	4.16 (1.78, 6.55)	
p-value	0.0006	
p-Value for test for heterogenity between studies	0.5656	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Herpes Zoster - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=467) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.0957
< 10 points	4/148 (2.7)	3/146 (2.1)	1.23 (0.30, 5.03)	0.7748	
>= 10 points	22/311 (7.1)	4/321 (1.2)	5.51 (1.91, 15.89)	0.0016	
OCS dose					0.7975
<10 mg/day	10/214 (4.7)	3/218 (1.4)	3.06 (0.78, 11.95)	0.1074	
>=10 mg/day	16/245 (6.5)	4/249 (1.6)	3.85 (1.28, 11.54)	0.0162	
Result of type I IFN gene signature test					0.9550
LOW	4/ 86 (4.7)	1/ 90 (1.1)	2.92 (0.46, 18.57)	0.2552	
HIGH	22/373 (5.9)	6/377 (1.6)	3.10 (1.23, 7.84)	0.0166	
Age (years)					NE
<= 65	26/447 (5.8)	7/463 (1.5)	3.61 (1.56, 8.35)	0.0028	
> 65	0/ 12 (0.0)	0/ 4 (0.0)	NE		
Sex					0.7868
male	4/ 33 (12.1)	0/ 34 (0.0)	3.85 (0.67, 22.22)	0.1312	
female	22/426 (5.2)	7/433 (1.6)	2.94 (1.24, 6.99)	0.0144	
Race					0.4612
White	14/270 (5.2)	5/285 (1.8)	2.91 (1.05, 8.06)	0.0395	
Black	0/ 65 (0.0)	1/ 59 (1.7)	0.48 (0.02, 11.17)	0.6486	
Other	10/116 (8.6)	1/115 (0.9)	4.46 (0.94, 21.09)	0.0594	
Ethnicity					0.6632
Hispanic/Latino	9/132 (6.8)	1/131 (0.8)	3.85 (0.79, 18.64)	0.0941	
Non-hispanic/Latino	15/319 (4.7)	6/328 (1.8)	2.56 (1.01, 6.52)	0.0487	
Geographic region					0.4277
EU	7/135 (5.2)	3/147 (2.0)	2.33 (0.65, 8.30)	0.1930	
non-EU	19/324 (5.9)	4/320 (1.3)	4.57 (1.55, 13.48)	0.0059	
Onset of disease					0.7330
Paediatric	5/ 36 (13.9)	1/ 35 (2.9)	2.41 (0.44, 13.34)	0.3128	
Adult	21/423 (5.0)	6/432 (1.4)	3.38 (1.35, 8.44)	0.0091	
ADA result					0.5067
Negative	22/427 (5.2)	7/428 (1.6)	2.98 (1.25, 7.12)	0.0141	
Positive (At any time)	4/ 31 (12.9)	0/ 39 (0.0)	6.29 (0.83, 47.91)	0.0757	
BMI (kg/m2)					0.7453
< 30	18/309 (5.8)	5/339 (1.5)	3.64 (1.33, 9.98)	0.0122	
>= 30	8/150 (5.3)	2/128 (1.6)	2.71 (0.62, 11.76)	0.1837	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Herpes Zoster leading to discontinuation of study drug
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=459)	Placebo (N=467)
Number of subjects with events, n (%)	2 (0.4)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	5.11 (0.25, 105.71)	
p-value	0.2912	
Odds Ratio (95% CI)	5.17 (0.25, 108.40)	
p-value	0.2901	
Risk Difference (95% CI)	0.44 (-0.17, 1.04)	
p-value	0.1559	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Herpes Zoster leading to discontinuation of study drug - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=467) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
SLEDAI-2K score				NE
< 10 points	0/148 (0.0)	0/146 (0.0)	NE	
>= 10 points	2/311 (0.6)	0/321 (0.0)	5.20 (0.25, 107.22) 0.2858	
OCS dose				NE
<10 mg/day	0/214 (0.0)	0/218 (0.0)	NE	
>=10 mg/day	2/245 (0.8)	0/249 (0.0)	4.95 (0.24, 101.89) 0.2998	
Result of type I IFN gene signature test				NE
LOW	0/ 86 (0.0)	0/ 90 (0.0)	NE	
HIGH	2/373 (0.5)	0/377 (0.0)	5.10 (0.25, 105.35) 0.2916	
Age (years)				NE
<= 65	2/447 (0.4)	0/463 (0.0)	5.23 (0.25, 108.16) 0.2844	
> 65	0/ 12 (0.0)	0/ 4 (0.0)	NE	
Sex				NE
male	0/ 33 (0.0)	0/ 34 (0.0)	NE	
female	2/426 (0.5)	0/433 (0.0)	5.18 (0.25, 107.11) 0.2871	
Race				NE
White	2/270 (0.7)	0/285 (0.0)	5.48 (0.27, 112.97) 0.2709	
Black	0/ 65 (0.0)	0/ 59 (0.0)	NE	
Other	0/116 (0.0)	0/115 (0.0)	NE	
Ethnicity				0.9721
Hispanic/Latino	1/132 (0.8)	0/131 (0.0)	3.27 (0.14, 77.57) 0.4629	
Non-hispanic/Latino	1/319 (0.3)	0/328 (0.0)	3.02 (0.12, 73.54) 0.4974	
Geographic region				0.9168
EU	1/135 (0.7)	0/147 (0.0)	3.55 (0.15, 85.76) 0.4350	
non-EU	1/324 (0.3)	0/320 (0.0)	2.79 (0.12, 67.88) 0.5277	
Onset of disease				0.9918
Paediatric	1/ 36 (2.8)	0/ 35 (0.0)	3.00 (0.13, 67.06) 0.4883	
Adult	1/423 (0.2)	0/432 (0.0)	3.07 (0.13, 74.86) 0.4911	
ADA result				NE
Negative	2/427 (0.5)	0/428 (0.0)	5.21 (0.25, 107.80) 0.2852	
Positive (At any time)	0/ 31 (0.0)	0/ 39 (0.0)	NE	
BMI (kg/m2)				NE
< 30	2/309 (0.6)	0/339 (0.0)	5.87 (0.28, 120.99) 0.2515	
>= 30	0/150 (0.0)	0/128 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Influenza
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=459)	Placebo (N=467)
Number of subjects with events, n (%)	12 (2.6)	10 (2.1)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.17 (0.49, 2.80)	
p-value	0.7279	
Odds Ratio (95% CI)	1.17 (0.48, 2.88)	
p-value	0.7269	
Risk Difference (95% CI)	0.47 (-1.49, 2.43)	
p-value	0.6383	
p-Value for test for heterogenity between studies	0.3332	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Influenza - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=467) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.5673
< 10 points	5/148 (3.4)	3/146 (2.1)	1.64 (0.39, 6.85)	0.4958	
>= 10 points	7/311 (2.3)	7/321 (2.2)	0.96 (0.30, 3.10)	0.9424	
OCS dose					0.5133
<10 mg/day	7/214 (3.3)	7/218 (3.2)	0.94 (0.29, 3.06)	0.9137	
>=10 mg/day	5/245 (2.0)	3/249 (1.2)	1.79 (0.38, 8.40)	0.4591	
Result of type I IFN gene signature test					0.5791
LOW	4/ 86 (4.7)	2/ 90 (2.2)	1.72 (0.35, 8.48)	0.5049	
HIGH	8/373 (2.1)	8/377 (2.1)	1.01 (0.38, 2.69)	0.9778	
Age (years)					NE
<= 65	12/447 (2.7)	10/463 (2.2)	1.19 (0.49, 2.84)	0.7017	
> 65	0/ 12 (0.0)	0/ 4 (0.0)	NE		
Sex					0.4114
male	0/ 33 (0.0)	1/ 34 (2.9)	0.33 (0.01, 7.45)	0.4883	
female	12/426 (2.8)	9/433 (2.1)	1.29 (0.53, 3.15)	0.5731	
Race					0.5511
White	5/270 (1.9)	3/285 (1.1)	1.48 (0.36, 6.02)	0.5834	
Black	0/ 65 (0.0)	2/ 59 (3.4)	0.36 (0.04, 3.33)	0.3669	
Other	6/116 (5.2)	4/115 (3.5)	1.29 (0.31, 5.25)	0.7270	
Ethnicity					0.2262
Hispanic/Latino	6/132 (4.5)	2/131 (1.5)	2.78 (0.57, 13.69)	0.2080	
Non-hispanic/Latino	5/319 (1.6)	7/328 (2.1)	0.80 (0.23, 2.76)	0.7250	
Geographic region					0.6406
EU	2/135 (1.5)	3/147 (2.0)	0.75 (0.15, 3.84)	0.7348	
non-EU	10/324 (3.1)	7/320 (2.2)	1.20 (0.41, 3.53)	0.7385	
Onset of disease					NE
Paediatric	0/ 36 (0.0)	0/ 35 (0.0)	NE		
Adult	12/423 (2.8)	10/432 (2.3)	1.17 (0.49, 2.81)	0.7203	
ADA result					0.9295
Negative	11/427 (2.6)	9/428 (2.1)	1.18 (0.48, 2.91)	0.7113	
Positive (At any time)	1/ 31 (3.2)	1/ 39 (2.6)	1.32 (0.15, 11.33)	0.8025	
BMI (kg/m2)					0.5571
< 30	9/309 (2.9)	7/339 (2.1)	1.37 (0.51, 3.66)	0.5293	
>= 30	3/150 (2.0)	3/128 (2.3)	0.75 (0.13, 4.32)	0.7491	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Influenza
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=459)	Placebo (N=467)
Number of subjects with events, n (%)	2 (0.4)	1 (0.2)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.41 (0.16, 12.69)	
p-value	0.7580	
Odds Ratio (95% CI)	1.42 (0.16, 12.90)	
p-value	0.7579	
Risk Difference (95% CI)	0.22 (-0.51, 0.96)	
p-value	0.5552	
p-Value for test for heterogenity between studies	0.2260	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Influenza - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=467) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.5807
< 10 points	1/148 (0.7)	0/146 (0.0)	3.08 (0.13, 73.27)	0.4875	
>= 10 points	1/311 (0.3)	1/321 (0.3)	1.03 (0.11, 9.78)	0.9812	
OCS dose					0.5143
<10 mg/day	1/214 (0.5)	1/218 (0.5)	0.95 (0.10, 9.03)	0.9664	
>=10 mg/day	1/245 (0.4)	0/249 (0.0)	3.48 (0.14, 83.78)	0.4420	
Result of type I IFN gene signature test					NE
LOW	0/ 86 (0.0)	0/ 90 (0.0)	NE		
HIGH	2/373 (0.5)	1/377 (0.3)	1.40 (0.16, 12.53)	0.7655	
Age (years)					NE
<= 65	2/447 (0.4)	1/463 (0.2)	1.43 (0.16, 12.83)	0.7509	
> 65	0/ 12 (0.0)	0/ 4 (0.0)	NE		
Sex					NE
male	0/ 33 (0.0)	0/ 34 (0.0)	NE		
female	2/426 (0.5)	1/433 (0.2)	1.39 (0.15, 12.49)	0.7685	
Race					0.2077
White	0/270 (0.0)	1/285 (0.4)	0.32 (0.01, 7.87)	0.4890	
Black	0/ 65 (0.0)	0/ 59 (0.0)	NE		
Other	2/116 (1.7)	0/115 (0.0)	5.43 (0.27, 110.24)	0.2703	
Ethnicity					0.2447
Hispanic/Latino	2/132 (1.5)	0/131 (0.0)	4.57 (0.23, 92.62)	0.3218	
Non-hispanic/Latino	0/319 (0.0)	1/328 (0.3)	0.34 (0.01, 8.24)	0.5063	
Geographic region					NE
EU	0/135 (0.0)	0/147 (0.0)	NE		
non-EU	2/324 (0.6)	1/320 (0.3)	1.40 (0.16, 12.53)	0.7649	
Onset of disease					NE
Paediatric	0/ 36 (0.0)	0/ 35 (0.0)	NE		
Adult	2/423 (0.5)	1/432 (0.2)	1.41 (0.16, 12.71)	0.7567	
ADA result					0.6872
Negative	1/427 (0.2)	1/428 (0.2)	0.99 (0.10, 9.48)	0.9951	
Positive (At any time)	1/ 31 (3.2)	0/ 39 (0.0)	2.14 (0.11, 42.52)	0.6171	
BMI (kg/m2)					0.1999
< 30	2/309 (0.6)	0/339 (0.0)	5.13 (0.25, 105.13)	0.2886	
>= 30	0/150 (0.0)	1/128 (0.8)	0.29 (0.01, 7.00)	0.4473	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Influenza
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=459)	Placebo (N=467)
Number of subjects with events, n (%)	1 (0.2)	1 (0.2)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.02 (0.11, 9.72)	
p-value	0.9881	
Odds Ratio (95% CI)	1.02 (0.10, 9.83)	
p-value	0.9890	
Risk Difference (95% CI)	0.00 (-0.60, 0.60)	
p-value	0.9913	
p-Value for test for heterogenity between studies	0.3381	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Influenza - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=467) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					NE
< 10 points	0/148 (0.0)	0/146 (0.0)	NE		
>= 10 points	1/311 (0.3)	1/321 (0.3)	1.03 (0.11, 9.78)	0.9812	
OCS dose					NE
<10 mg/day	1/214 (0.5)	1/218 (0.5)	0.95 (0.10, 9.03)	0.9664	
>=10 mg/day	0/245 (0.0)	0/249 (0.0)	NE		
Result of type I IFN gene signature test					NE
LOW	0/ 86 (0.0)	0/ 90 (0.0)	NE		
HIGH	1/373 (0.3)	1/377 (0.3)	1.01 (0.11, 9.59)	0.9958	
Age (years)					NE
<= 65	1/447 (0.2)	1/463 (0.2)	1.03 (0.11, 9.83)	0.9803	
> 65	0/ 12 (0.0)	0/ 4 (0.0)	NE		
Sex					NE
male	0/ 33 (0.0)	0/ 34 (0.0)	NE		
female	1/426 (0.2)	1/433 (0.2)	1.00 (0.11, 9.57)	0.9983	
Race					0.3149
White	0/270 (0.0)	1/285 (0.4)	0.32 (0.01, 7.87)	0.4890	
Black	0/ 65 (0.0)	0/ 59 (0.0)	NE		
Other	1/116 (0.9)	0/115 (0.0)	3.26 (0.14, 78.06)	0.4657	
Ethnicity					0.3623
Hispanic/Latino	1/132 (0.8)	0/131 (0.0)	2.74 (0.11, 65.59)	0.5329	
Non-hispanic/Latino	0/319 (0.0)	1/328 (0.3)	0.34 (0.01, 8.24)	0.5063	
Geographic region					NE
EU	0/135 (0.0)	0/147 (0.0)	NE		
non-EU	1/324 (0.3)	1/320 (0.3)	1.01 (0.11, 9.62)	0.9936	
Onset of disease					NE
Paediatric	0/ 36 (0.0)	0/ 35 (0.0)	NE		
Adult	1/423 (0.2)	1/432 (0.2)	1.02 (0.11, 9.73)	0.9865	
ADA result					NE
Negative	1/427 (0.2)	1/428 (0.2)	0.99 (0.10, 9.48)	0.9951	
Positive (At any time)	0/ 31 (0.0)	0/ 39 (0.0)	NE		
BMI (kg/m2)					0.3046
< 30	1/309 (0.3)	0/339 (0.0)	3.08 (0.13, 74.40)	0.4891	
>= 30	0/150 (0.0)	1/128 (0.8)	0.29 (0.01, 7.00)	0.4473	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Influenza
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=459)	Placebo (N=467)
Number of subjects with events, n (%)	12 (2.6)	9 (1.9)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.30 (0.53, 3.17)	
p-value	0.5639	
Odds Ratio (95% CI)	1.31 (0.53, 3.26)	
p-value	0.5638	
Risk Difference (95% CI)	0.69 (-1.23, 2.60)	
p-value	0.4837	
p-Value for test for heterogenity between studies	0.4263	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Influenza - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=467) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.6774
< 10 points	5/148 (3.4)	3/146 (2.1)	1.64 (0.39, 6.85)	0.4958	
>= 10 points	7/311 (2.3)	6/321 (1.9)	1.11 (0.33, 3.66)	0.8686	
OCS dose					0.6017
<10 mg/day	7/214 (3.3)	6/218 (2.8)	1.06 (0.32, 3.53)	0.9184	
>=10 mg/day	5/245 (2.0)	3/249 (1.2)	1.79 (0.38, 8.40)	0.4591	
Result of type I IFN gene signature test					0.6816
LOW	4/ 86 (4.7)	2/ 90 (2.2)	1.72 (0.35, 8.48)	0.5049	
HIGH	8/373 (2.1)	7/377 (1.9)	1.16 (0.43, 3.16)	0.7722	
Age (years)					NE
<= 65	12/447 (2.7)	9/463 (1.9)	1.32 (0.54, 3.22)	0.5412	
> 65	0/ 12 (0.0)	0/ 4 (0.0)	NE		
Sex					0.3712
male	0/ 33 (0.0)	1/ 34 (2.9)	0.33 (0.01, 7.45)	0.4883	
female	12/426 (2.8)	8/433 (1.8)	1.46 (0.59, 3.64)	0.4159	
Race					0.4285
White	5/270 (1.9)	2/285 (0.7)	2.17 (0.46, 10.17)	0.3268	
Black	0/ 65 (0.0)	2/ 59 (3.4)	0.36 (0.04, 3.33)	0.3669	
Other	6/116 (5.2)	4/115 (3.5)	1.29 (0.31, 5.25)	0.7270	
Ethnicity					0.2730
Hispanic/Latino	6/132 (4.5)	2/131 (1.5)	2.78 (0.57, 13.69)	0.2080	
Non-hispanic/Latino	5/319 (1.6)	6/328 (1.8)	0.90 (0.26, 3.13)	0.8641	
Geographic region					0.5260
EU	2/135 (1.5)	3/147 (2.0)	0.75 (0.15, 3.84)	0.7348	
non-EU	10/324 (3.1)	6/320 (1.9)	1.43 (0.47, 4.36)	0.5305	
Onset of disease					NE
Paediatric	0/ 36 (0.0)	0/ 35 (0.0)	NE		
Adult	12/423 (2.8)	9/432 (2.1)	1.31 (0.54, 3.18)	0.5575	
ADA result					0.9873
Negative	11/427 (2.6)	8/428 (1.9)	1.34 (0.53, 3.37)	0.5317	
Positive (At any time)	1/ 31 (3.2)	1/ 39 (2.6)	1.32 (0.15, 11.33)	0.8025	
BMI (kg/m2)					0.7075
< 30	9/309 (2.9)	7/339 (2.1)	1.37 (0.51, 3.66)	0.5293	
>= 30	3/150 (2.0)	2/128 (1.6)	0.93 (0.16, 5.50)	0.9354	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Tuberculosis (including latent TB)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=459)	Placebo (N=467)
Number of subjects with events, n (%)	6 (1.3)	2 (0.4)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	2.31 (0.49, 10.77)	
p-value	0.2874	
Odds Ratio (95% CI)	2.33 (0.49, 11.03)	
p-value	0.2857	
Risk Difference (95% CI)	0.88 (-0.32, 2.07)	
p-value	0.1497	
p-Value for test for heterogenity between studies	0.6390	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=467) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.4661
< 10 points	1/148 (0.7)	1/146 (0.7)	0.99 (0.11, 9.36)	0.9939	
>= 10 points	5/311 (1.6)	1/321 (0.3)	2.82 (0.52, 15.27)	0.2294	
OCS dose					0.5117
<10 mg/day	3/214 (1.4)	0/218 (0.0)	2.95 (0.47, 18.54)	0.2478	
>=10 mg/day	3/245 (1.2)	2/249 (0.8)	1.27 (0.23, 7.07)	0.7822	
Result of type I IFN gene signature test					0.8206
LOW	1/ 86 (1.2)	0/ 90 (0.0)	3.10 (0.13, 73.16)	0.4836	
HIGH	5/373 (1.3)	2/377 (0.5)	2.06 (0.44, 9.70)	0.3603	
Age (years)					NE
<= 65	6/447 (1.3)	2/463 (0.4)	2.34 (0.50, 10.92)	0.2798	
> 65	0/ 12 (0.0)	0/ 4 (0.0)	NE		
Sex					NE
male	0/ 33 (0.0)	0/ 34 (0.0)	NE		
female	6/426 (1.4)	2/433 (0.5)	2.29 (0.49, 10.68)	0.2922	
Race					0.9441
White	3/270 (1.1)	1/285 (0.4)	2.16 (0.28, 16.58)	0.4598	
Black	0/ 65 (0.0)	0/ 59 (0.0)	NE		
Other	3/116 (2.6)	1/115 (0.9)	2.38 (0.36, 15.89)	0.3694	
Ethnicity					0.7462
Hispanic/Latino	4/132 (3.0)	1/131 (0.8)	2.28 (0.41, 12.59)	0.3429	
Non-hispanic/Latino	2/319 (0.6)	1/328 (0.3)	1.51 (0.24, 9.51)	0.6611	
Geographic region					0.4789
EU	1/135 (0.7)	1/147 (0.7)	1.04 (0.11, 9.82)	0.9747	
non-EU	5/324 (1.5)	1/320 (0.3)	2.82 (0.56, 14.15)	0.2081	
Onset of disease					NE
Paediatric	0/ 36 (0.0)	0/ 35 (0.0)	NE		
Adult	6/423 (1.4)	2/432 (0.5)	2.31 (0.49, 10.77)	0.2871	
ADA result					NE
Negative	6/427 (1.4)	2/428 (0.5)	2.30 (0.49, 10.73)	0.2894	
Positive (At any time)	0/ 31 (0.0)	0/ 39 (0.0)	NE		
BMI (kg/m2)					0.9987
< 30	2/309 (0.6)	1/339 (0.3)	2.05 (0.19, 22.17)	0.5536	
>= 30	4/150 (2.7)	1/128 (0.8)	2.06 (0.28, 15.33)	0.4811	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Tuberculosis (including latent TB)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=459)	Placebo (N=467)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=467) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
SLEDAI-2K score				NE
< 10 points	0/148 (0.0)	0/146 (0.0)	NE	
>= 10 points	0/311 (0.0)	0/321 (0.0)	NE	
OCS dose				NE
<10 mg/day	0/214 (0.0)	0/218 (0.0)	NE	
>=10 mg/day	0/245 (0.0)	0/249 (0.0)	NE	
Result of type I IFN gene signature test				NE
LOW	0/ 86 (0.0)	0/ 90 (0.0)	NE	
HIGH	0/373 (0.0)	0/377 (0.0)	NE	
Age (years)				NE
<= 65	0/447 (0.0)	0/463 (0.0)	NE	
> 65	0/ 12 (0.0)	0/ 4 (0.0)	NE	
Sex				NE
male	0/ 33 (0.0)	0/ 34 (0.0)	NE	
female	0/426 (0.0)	0/433 (0.0)	NE	
Race				NE
White	0/270 (0.0)	0/285 (0.0)	NE	
Black	0/ 65 (0.0)	0/ 59 (0.0)	NE	
Other	0/116 (0.0)	0/115 (0.0)	NE	
Ethnicity				NE
Hispanic/Latino	0/132 (0.0)	0/131 (0.0)	NE	
Non-hispanic/Latino	0/319 (0.0)	0/328 (0.0)	NE	
Geographic region				NE
EU	0/135 (0.0)	0/147 (0.0)	NE	
non-EU	0/324 (0.0)	0/320 (0.0)	NE	
Onset of disease				NE
Paediatric	0/ 36 (0.0)	0/ 35 (0.0)	NE	
Adult	0/423 (0.0)	0/432 (0.0)	NE	
ADA result				NE
Negative	0/427 (0.0)	0/428 (0.0)	NE	
Positive (At any time)	0/ 31 (0.0)	0/ 39 (0.0)	NE	
BMI (kg/m2)				NE
< 30	0/309 (0.0)	0/339 (0.0)	NE	
>= 30	0/150 (0.0)	0/128 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Tuberculosis (including latent TB)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=459)	Placebo (N=467)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=467) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
SLEDAI-2K score				NE
< 10 points	0/148 (0.0)	0/146 (0.0)	NE	
>= 10 points	0/311 (0.0)	0/321 (0.0)	NE	
OCS dose				NE
<10 mg/day	0/214 (0.0)	0/218 (0.0)	NE	
>=10 mg/day	0/245 (0.0)	0/249 (0.0)	NE	
Result of type I IFN gene signature test				NE
LOW	0/ 86 (0.0)	0/ 90 (0.0)	NE	
HIGH	0/373 (0.0)	0/377 (0.0)	NE	
Age (years)				NE
<= 65	0/447 (0.0)	0/463 (0.0)	NE	
> 65	0/ 12 (0.0)	0/ 4 (0.0)	NE	
Sex				NE
male	0/ 33 (0.0)	0/ 34 (0.0)	NE	
female	0/426 (0.0)	0/433 (0.0)	NE	
Race				NE
White	0/270 (0.0)	0/285 (0.0)	NE	
Black	0/ 65 (0.0)	0/ 59 (0.0)	NE	
Other	0/116 (0.0)	0/115 (0.0)	NE	
Ethnicity				NE
Hispanic/Latino	0/132 (0.0)	0/131 (0.0)	NE	
Non-hispanic/Latino	0/319 (0.0)	0/328 (0.0)	NE	
Geographic region				NE
EU	0/135 (0.0)	0/147 (0.0)	NE	
non-EU	0/324 (0.0)	0/320 (0.0)	NE	
Onset of disease				NE
Paediatric	0/ 36 (0.0)	0/ 35 (0.0)	NE	
Adult	0/423 (0.0)	0/432 (0.0)	NE	
ADA result				NE
Negative	0/427 (0.0)	0/428 (0.0)	NE	
Positive (At any time)	0/ 31 (0.0)	0/ 39 (0.0)	NE	
BMI (kg/m2)				NE
< 30	0/309 (0.0)	0/339 (0.0)	NE	
>= 30	0/150 (0.0)	0/128 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Tuberculosis (including latent TB)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=459)	Placebo (N=467)
Number of subjects with events, n (%)	6 (1.3)	2 (0.4)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	2.31 (0.49, 10.77)	
p-value	0.2874	
Odds Ratio (95% CI)	2.33 (0.49, 11.03)	
p-value	0.2857	
Risk Difference (95% CI)	0.88 (-0.32, 2.07)	
p-value	0.1497	
p-Value for test for heterogenity between studies	0.6390	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=467) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.4661
< 10 points	1/148 (0.7)	1/146 (0.7)	0.99 (0.11, 9.36)	0.9939	
>= 10 points	5/311 (1.6)	1/321 (0.3)	2.82 (0.52, 15.27)	0.2294	
OCS dose					0.5117
<10 mg/day	3/214 (1.4)	0/218 (0.0)	2.95 (0.47, 18.54)	0.2478	
>=10 mg/day	3/245 (1.2)	2/249 (0.8)	1.27 (0.23, 7.07)	0.7822	
Result of type I IFN gene signature test					0.8206
LOW	1/ 86 (1.2)	0/ 90 (0.0)	3.10 (0.13, 73.16)	0.4836	
HIGH	5/373 (1.3)	2/377 (0.5)	2.06 (0.44, 9.70)	0.3603	
Age (years)					NE
<= 65	6/447 (1.3)	2/463 (0.4)	2.34 (0.50, 10.92)	0.2798	
> 65	0/ 12 (0.0)	0/ 4 (0.0)	NE		
Sex					NE
male	0/ 33 (0.0)	0/ 34 (0.0)	NE		
female	6/426 (1.4)	2/433 (0.5)	2.29 (0.49, 10.68)	0.2922	
Race					0.9441
White	3/270 (1.1)	1/285 (0.4)	2.16 (0.28, 16.58)	0.4598	
Black	0/ 65 (0.0)	0/ 59 (0.0)	NE		
Other	3/116 (2.6)	1/115 (0.9)	2.38 (0.36, 15.89)	0.3694	
Ethnicity					0.7462
Hispanic/Latino	4/132 (3.0)	1/131 (0.8)	2.28 (0.41, 12.59)	0.3429	
Non-hispanic/Latino	2/319 (0.6)	1/328 (0.3)	1.51 (0.24, 9.51)	0.6611	
Geographic region					0.4789
EU	1/135 (0.7)	1/147 (0.7)	1.04 (0.11, 9.82)	0.9747	
non-EU	5/324 (1.5)	1/320 (0.3)	2.82 (0.56, 14.15)	0.2081	
Onset of disease					NE
Paediatric	0/ 36 (0.0)	0/ 35 (0.0)	NE		
Adult	6/423 (1.4)	2/432 (0.5)	2.31 (0.49, 10.77)	0.2871	
ADA result					NE
Negative	6/427 (1.4)	2/428 (0.5)	2.30 (0.49, 10.73)	0.2894	
Positive (At any time)	0/ 31 (0.0)	0/ 39 (0.0)	NE		
BMI (kg/m2)					0.9987
< 30	2/309 (0.6)	1/339 (0.3)	2.05 (0.19, 22.17)	0.5536	
>= 30	4/150 (2.7)	1/128 (0.8)	2.06 (0.28, 15.33)	0.4811	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Vasculitis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=459)	Placebo (N=467)
Number of subjects with events, n (%)	0 (0.0)	3 (0.6)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.15 (0.01, 2.78)	
p-value	0.2007	
Odds Ratio (95% CI)	0.14 (0.01, 2.77)	
p-value	0.1977	
Risk Difference (95% CI)	-0.64 (-1.37, 0.08)	
p-value	0.0825	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Vasculitis - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=467) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.8161
< 10 points	0/148 (0.0)	1/146 (0.7)	0.34 (0.01, 8.14)	0.5068	
>= 10 points	0/311 (0.0)	2/321 (0.6)	0.20 (0.01, 4.15)	0.3005	
OCS dose					0.9312
<10 mg/day	0/214 (0.0)	1/218 (0.5)	0.28 (0.01, 6.71)	0.4334	
>=10 mg/day	0/245 (0.0)	2/249 (0.8)	0.23 (0.01, 4.73)	0.3425	
Result of type I IFN gene signature test					NE
LOW	0/ 86 (0.0)	0/ 90 (0.0)	NE		
HIGH	0/373 (0.0)	3/377 (0.8)	0.14 (0.01, 2.72)	0.1955	
Age (years)					NE
<= 65	0/447 (0.0)	3/463 (0.6)	0.15 (0.01, 2.78)	0.2007	
> 65	0/ 12 (0.0)	0/ 4 (0.0)	NE		
Sex					NE
male	0/ 33 (0.0)	0/ 34 (0.0)	NE		
female	0/426 (0.0)	3/433 (0.7)	0.14 (0.01, 2.70)	0.1935	
Race					0.9699
White	0/270 (0.0)	0/285 (0.0)	NE		
Black	0/ 65 (0.0)	1/ 59 (1.7)	0.20 (0.01, 4.53)	0.3119	
Other	0/116 (0.0)	2/115 (1.7)	0.22 (0.01, 4.41)	0.3203	
Ethnicity					0.8873
Hispanic/Latino	0/132 (0.0)	1/131 (0.8)	0.30 (0.01, 7.29)	0.4633	
Non-hispanic/Latino	0/319 (0.0)	2/328 (0.6)	0.22 (0.01, 4.53)	0.3280	
Geographic region					NE
EU	0/135 (0.0)	0/147 (0.0)	NE		
non-EU	0/324 (0.0)	3/320 (0.9)	0.14 (0.01, 2.62)	0.1869	
Onset of disease					0.7903
Paediatric	0/ 36 (0.0)	1/ 35 (2.9)	0.36 (0.02, 8.03)	0.5217	
Adult	0/423 (0.0)	2/432 (0.5)	0.20 (0.01, 4.15)	0.3000	
ADA result					0.9512
Negative	0/427 (0.0)	2/428 (0.5)	0.21 (0.01, 4.29)	0.3094	
Positive (At any time)	0/ 31 (0.0)	1/ 39 (2.6)	0.24 (0.01, 4.72)	0.3465	
BMI (kg/m2)					NE
< 30	0/309 (0.0)	3/339 (0.9)	0.15 (0.01, 2.79)	0.2015	
>= 30	0/150 (0.0)	0/128 (0.0)	NE		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Vasculitis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=459)	Placebo (N=467)
Number of subjects with events, n (%)	0 (0.0)	2 (0.4)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.20 (0.01, 4.20)	
p-value	0.3028	
Odds Ratio (95% CI)	0.20 (0.01, 4.22)	
p-value	0.3009	
Risk Difference (95% CI)	-0.43 (-1.02, 0.16)	
p-value	0.1567	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Vasculitis - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=467) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.9971
< 10 points	0/148 (0.0)	1/146 (0.7)	0.34 (0.01, 8.14)	0.5068	
>= 10 points	0/311 (0.0)	1/321 (0.3)	0.34 (0.01, 8.16)	0.5048	
OCS dose					0.8896
<10 mg/day	0/214 (0.0)	1/218 (0.5)	0.28 (0.01, 6.71)	0.4334	
>=10 mg/day	0/245 (0.0)	1/249 (0.4)	0.39 (0.02, 9.31)	0.5584	
Result of type I IFN gene signature test					NE
LOW	0/ 86 (0.0)	0/ 90 (0.0)	NE		
HIGH	0/373 (0.0)	2/377 (0.5)	0.20 (0.01, 4.10)	0.2962	
Age (years)					NE
<= 65	0/447 (0.0)	2/463 (0.4)	0.20 (0.01, 4.20)	0.3028	
> 65	0/ 12 (0.0)	0/ 4 (0.0)	NE		
Sex					NE
male	0/ 33 (0.0)	0/ 34 (0.0)	NE		
female	0/426 (0.0)	2/433 (0.5)	0.20 (0.01, 4.07)	0.2935	
Race					0.7936
White	0/270 (0.0)	0/285 (0.0)	NE		
Black	0/ 65 (0.0)	1/ 59 (1.7)	0.20 (0.01, 4.53)	0.3119	
Other	0/116 (0.0)	1/115 (0.9)	0.36 (0.02, 8.67)	0.5309	
Ethnicity					NE
Hispanic/Latino	0/132 (0.0)	0/131 (0.0)	NE		
Non-hispanic/Latino	0/319 (0.0)	2/328 (0.6)	0.22 (0.01, 4.53)	0.3280	
Geographic region					NE
EU	0/135 (0.0)	0/147 (0.0)	NE		
non-EU	0/324 (0.0)	2/320 (0.6)	0.19 (0.01, 3.95)	0.2850	
Onset of disease					NE
Paediatric	0/ 36 (0.0)	0/ 35 (0.0)	NE		
Adult	0/423 (0.0)	2/432 (0.5)	0.20 (0.01, 4.15)	0.3000	
ADA result					NE
Negative	0/427 (0.0)	2/428 (0.5)	0.21 (0.01, 4.29)	0.3094	
Positive (At any time)	0/ 31 (0.0)	0/ 39 (0.0)	NE		
BMI (kg/m2)					NE
< 30	0/309 (0.0)	2/339 (0.6)	0.21 (0.01, 4.21)	0.3040	
>= 30	0/150 (0.0)	0/128 (0.0)	NE		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Vasculitis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=459)	Placebo (N=467)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Vasculitis - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=467) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI) p-Value	Interaction p-Value
SLEDAI-2K score				NE
< 10 points	0/148 (0.0)	0/146 (0.0)	NE	
>= 10 points	0/311 (0.0)	0/321 (0.0)	NE	
OCS dose				NE
<10 mg/day	0/214 (0.0)	0/218 (0.0)	NE	
>=10 mg/day	0/245 (0.0)	0/249 (0.0)	NE	
Result of type I IFN gene signature test				NE
LOW	0/ 86 (0.0)	0/ 90 (0.0)	NE	
HIGH	0/373 (0.0)	0/377 (0.0)	NE	
Age (years)				NE
<= 65	0/447 (0.0)	0/463 (0.0)	NE	
> 65	0/ 12 (0.0)	0/ 4 (0.0)	NE	
Sex				NE
male	0/ 33 (0.0)	0/ 34 (0.0)	NE	
female	0/426 (0.0)	0/433 (0.0)	NE	
Race				NE
White	0/270 (0.0)	0/285 (0.0)	NE	
Black	0/ 65 (0.0)	0/ 59 (0.0)	NE	
Other	0/116 (0.0)	0/115 (0.0)	NE	
Ethnicity				NE
Hispanic/Latino	0/132 (0.0)	0/131 (0.0)	NE	
Non-hispanic/Latino	0/319 (0.0)	0/328 (0.0)	NE	
Geographic region				NE
EU	0/135 (0.0)	0/147 (0.0)	NE	
non-EU	0/324 (0.0)	0/320 (0.0)	NE	
Onset of disease				NE
Paediatric	0/ 36 (0.0)	0/ 35 (0.0)	NE	
Adult	0/423 (0.0)	0/432 (0.0)	NE	
ADA result				NE
Negative	0/427 (0.0)	0/428 (0.0)	NE	
Positive (At any time)	0/ 31 (0.0)	0/ 39 (0.0)	NE	
BMI (kg/m2)				NE
< 30	0/309 (0.0)	0/339 (0.0)	NE	
>= 30	0/150 (0.0)	0/128 (0.0)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Vasculitis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=459)	Placebo (N=467)
Number of subjects with events, n (%)	0 (0.0)	3 (0.6)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.15 (0.01, 2.78)	
p-value	0.2007	
Odds Ratio (95% CI)	0.14 (0.01, 2.77)	
p-value	0.1977	
Risk Difference (95% CI)	-0.64 (-1.37, 0.08)	
p-value	0.0825	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Vasculitis - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=467) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.8161
< 10 points	0/148 (0.0)	1/146 (0.7)	0.34 (0.01, 8.14)	0.5068	
>= 10 points	0/311 (0.0)	2/321 (0.6)	0.20 (0.01, 4.15)	0.3005	
OCS dose					0.9312
<10 mg/day	0/214 (0.0)	1/218 (0.5)	0.28 (0.01, 6.71)	0.4334	
>=10 mg/day	0/245 (0.0)	2/249 (0.8)	0.23 (0.01, 4.73)	0.3425	
Result of type I IFN gene signature test					NE
LOW	0/ 86 (0.0)	0/ 90 (0.0)	NE		
HIGH	0/373 (0.0)	3/377 (0.8)	0.14 (0.01, 2.72)	0.1955	
Age (years)					NE
<= 65	0/447 (0.0)	3/463 (0.6)	0.15 (0.01, 2.78)	0.2007	
> 65	0/ 12 (0.0)	0/ 4 (0.0)	NE		
Sex					NE
male	0/ 33 (0.0)	0/ 34 (0.0)	NE		
female	0/426 (0.0)	3/433 (0.7)	0.14 (0.01, 2.70)	0.1935	
Race					0.9699
White	0/270 (0.0)	0/285 (0.0)	NE		
Black	0/ 65 (0.0)	1/ 59 (1.7)	0.20 (0.01, 4.53)	0.3119	
Other	0/116 (0.0)	2/115 (1.7)	0.22 (0.01, 4.41)	0.3203	
Ethnicity					0.8873
Hispanic/Latino	0/132 (0.0)	1/131 (0.8)	0.30 (0.01, 7.29)	0.4633	
Non-hispanic/Latino	0/319 (0.0)	2/328 (0.6)	0.22 (0.01, 4.53)	0.3280	
Geographic region					NE
EU	0/135 (0.0)	0/147 (0.0)	NE		
non-EU	0/324 (0.0)	3/320 (0.9)	0.14 (0.01, 2.62)	0.1869	
Onset of disease					0.7903
Paediatric	0/ 36 (0.0)	1/ 35 (2.9)	0.36 (0.02, 8.03)	0.5217	
Adult	0/423 (0.0)	2/432 (0.5)	0.20 (0.01, 4.15)	0.3000	
ADA result					0.9512
Negative	0/427 (0.0)	2/428 (0.5)	0.21 (0.01, 4.29)	0.3094	
Positive (At any time)	0/ 31 (0.0)	1/ 39 (2.6)	0.24 (0.01, 4.72)	0.3465	
BMI (kg/m2)					NE
< 30	0/309 (0.0)	3/339 (0.9)	0.15 (0.01, 2.79)	0.2015	
>= 30	0/150 (0.0)	0/128 (0.0)	NE		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Malignancy
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=459)	Placebo (N=467)
Number of subjects with events, n (%)	4 (0.9)	2 (0.4)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.77 (0.36, 8.71)	
p-value	0.4839	
Odds Ratio (95% CI)	1.77 (0.36, 8.84)	
p-value	0.4842	
Risk Difference (95% CI)	0.44 (-0.59, 1.48)	
p-value	0.4005	
p-Value for test for heterogenity between studies	0.5022	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Malignancy - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=467) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.4996
< 10 points	2/148 (1.4)	0/146 (0.0)	3.01 (0.32, 28.42)	0.3360	
>= 10 points	2/311 (0.6)	2/321 (0.6)	1.09 (0.16, 7.38)	0.9295	
OCS dose					0.2392
<10 mg/day	3/214 (1.4)	0/218 (0.0)	3.74 (0.42, 33.31)	0.2374	
>=10 mg/day	1/245 (0.4)	2/249 (0.8)	0.61 (0.08, 4.90)	0.6411	
Result of type I IFN gene signature test					0.4688
LOW	2/ 86 (2.3)	0/ 90 (0.0)	3.16 (0.34, 29.55)	0.3121	
HIGH	2/373 (0.5)	2/377 (0.5)	1.07 (0.16, 7.23)	0.9469	
Age (years)					NE
<= 65	4/447 (0.9)	2/463 (0.4)	1.80 (0.37, 8.86)	0.4707	
> 65	0/ 12 (0.0)	0/ 4 (0.0)	NE		
Sex					NE
male	0/ 33 (0.0)	0/ 34 (0.0)	NE		
female	4/426 (0.9)	2/433 (0.5)	1.77 (0.36, 8.70)	0.4841	
Race					NE
White	4/270 (1.5)	2/285 (0.7)	1.88 (0.38, 9.21)	0.4374	
Black	0/ 65 (0.0)	0/ 59 (0.0)	NE		
Other	0/116 (0.0)	0/115 (0.0)	NE		
Ethnicity					NE
Hispanic/Latino	0/132 (0.0)	0/131 (0.0)	NE		
Non-hispanic/Latino	4/319 (1.3)	2/328 (0.6)	1.80 (0.37, 8.83)	0.4713	
Geographic region					0.5408
EU	2/135 (1.5)	2/147 (1.4)	1.13 (0.17, 7.59)	0.8987	
non-EU	2/324 (0.6)	0/320 (0.0)	2.84 (0.30, 27.06)	0.3639	
Onset of disease					NE
Paediatric	0/ 36 (0.0)	0/ 35 (0.0)	NE		
Adult	4/423 (0.9)	2/432 (0.5)	1.77 (0.36, 8.72)	0.4823	
ADA result					NE
Negative	4/427 (0.9)	2/428 (0.5)	1.76 (0.36, 8.69)	0.4851	
Positive (At any time)	0/ 31 (0.0)	0/ 39 (0.0)	NE		
BMI (kg/m2)					0.7481
< 30	3/309 (1.0)	2/339 (0.6)	1.65 (0.26, 10.37)	0.5933	
>= 30	1/150 (0.7)	0/128 (0.0)	3.00 (0.13, 70.02)	0.4943	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Malignancy
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=459)	Placebo (N=467)
Number of subjects with events, n (%)	2 (0.4)	1 (0.2)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.47 (0.23, 9.28)	
p-value	0.6826	
Odds Ratio (95% CI)	1.47 (0.23, 9.38)	
p-value	0.6827	
Risk Difference (95% CI)	0.22 (-0.51, 0.96)	
p-value	0.5549	
p-Value for test for heterogenity between studies	0.5424	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Serious Malignancy - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=467) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.2758
< 10 points	2/148 (1.4)	0/146 (0.0)	3.01 (0.32, 28.42)	0.3360	
>= 10 points	0/311 (0.0)	1/321 (0.3)	0.34 (0.01, 8.36)	0.5120	
OCS dose					0.6292
<10 mg/day	1/214 (0.5)	0/218 (0.0)	2.53 (0.11, 60.39)	0.5656	
>=10 mg/day	1/245 (0.4)	1/249 (0.4)	0.97 (0.10, 9.26)	0.9799	
Result of type I IFN gene signature test					0.5570
LOW	1/ 86 (1.2)	0/ 90 (0.0)	3.24 (0.14, 75.91)	0.4651	
HIGH	1/373 (0.3)	1/377 (0.3)	1.01 (0.11, 9.69)	0.9908	
Age (years)					NE
<= 65	2/447 (0.4)	1/463 (0.2)	1.49 (0.24, 9.42)	0.6707	
> 65	0/ 12 (0.0)	0/ 4 (0.0)	NE		
Sex					NE
male	0/ 33 (0.0)	0/ 34 (0.0)	NE		
female	2/426 (0.5)	1/433 (0.2)	1.46 (0.23, 9.23)	0.6867	
Race					NE
White	2/270 (0.7)	1/285 (0.4)	1.56 (0.25, 9.78)	0.6375	
Black	0/ 65 (0.0)	0/ 59 (0.0)	NE		
Other	0/116 (0.0)	0/115 (0.0)	NE		
Ethnicity					NE
Hispanic/Latino	0/132 (0.0)	0/131 (0.0)	NE		
Non-hispanic/Latino	2/319 (0.6)	1/328 (0.3)	1.51 (0.24, 9.50)	0.6618	
Geographic region					0.6049
EU	1/135 (0.7)	1/147 (0.7)	1.03 (0.11, 9.77)	0.9782	
non-EU	1/324 (0.3)	0/320 (0.0)	2.89 (0.12, 69.80)	0.5141	
Onset of disease					NE
Paediatric	0/ 36 (0.0)	0/ 35 (0.0)	NE		
Adult	2/423 (0.5)	1/432 (0.2)	1.47 (0.23, 9.29)	0.6810	
ADA result					NE
Negative	2/427 (0.5)	1/428 (0.2)	1.46 (0.23, 9.19)	0.6899	
Positive (At any time)	0/ 31 (0.0)	0/ 39 (0.0)	NE		
BMI (kg/m2)					0.6189
< 30	1/309 (0.3)	1/339 (0.3)	1.12 (0.12, 10.71)	0.9203	
>= 30	1/150 (0.7)	0/128 (0.0)	3.00 (0.13, 70.02)	0.4943	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Malignancy
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=459)	Placebo (N=467)
Number of subjects with events, n (%)	1 (0.2)	0 (0.0)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	3.06 (0.13, 74.23)	
p-value	0.4918	
Odds Ratio (95% CI)	3.09 (0.12, 76.80)	
p-value	0.4911	
Risk Difference (95% CI)	0.22 (-0.21, 0.64)	
p-value	0.3165	
p-Value for test for heterogenity between studies	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Severe Malignancy - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=467) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					NE
< 10 points	1/148 (0.7)	0/146 (0.0)	3.08 (0.13, 73.27)	0.4875	
>= 10 points	0/311 (0.0)	0/321 (0.0)	NE		
OCS dose					NE
<10 mg/day	1/214 (0.5)	0/218 (0.0)	2.53 (0.11, 60.39)	0.5656	
>=10 mg/day	0/245 (0.0)	0/249 (0.0)	NE		
Result of type I IFN gene signature test					NE
LOW	1/ 86 (1.2)	0/ 90 (0.0)	3.24 (0.14, 75.91)	0.4651	
HIGH	0/373 (0.0)	0/377 (0.0)	NE		
Age (years)					NE
<= 65	1/447 (0.2)	0/463 (0.0)	3.06 (0.13, 74.23)	0.4918	
> 65	0/ 12 (0.0)	0/ 4 (0.0)	NE		
Sex					NE
male	0/ 33 (0.0)	0/ 34 (0.0)	NE		
female	1/426 (0.2)	0/433 (0.0)	2.97 (0.12, 71.93)	0.5036	
Race					NE
White	1/270 (0.4)	0/285 (0.0)	3.50 (0.15, 83.28)	0.4385	
Black	0/ 65 (0.0)	0/ 59 (0.0)	NE		
Other	0/116 (0.0)	0/115 (0.0)	NE		
Ethnicity					NE
Hispanic/Latino	0/132 (0.0)	0/131 (0.0)	NE		
Non-hispanic/Latino	1/319 (0.3)	0/328 (0.0)	3.33 (0.14, 80.11)	0.4580	
Geographic region					NE
EU	0/135 (0.0)	0/147 (0.0)	NE		
non-EU	1/324 (0.3)	0/320 (0.0)	2.89 (0.12, 69.80)	0.5141	
Onset of disease					NE
Paediatric	0/ 36 (0.0)	0/ 35 (0.0)	NE		
Adult	1/423 (0.2)	0/432 (0.0)	3.03 (0.13, 73.48)	0.4950	
ADA result					NE
Negative	1/427 (0.2)	0/428 (0.0)	3.13 (0.13, 75.82)	0.4833	
Positive (At any time)	0/ 31 (0.0)	0/ 39 (0.0)	NE		
BMI (kg/m2)					NE
< 30	0/309 (0.0)	0/339 (0.0)	NE		
>= 30	1/150 (0.7)	0/128 (0.0)	3.00 (0.13, 70.02)	0.4943	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Malignancy
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=459)	Placebo (N=467)
Number of subjects with events, n (%)	3 (0.7)	2 (0.4)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	1.47 (0.23, 9.28)	
p-value	0.6808	
Odds Ratio (95% CI)	1.47 (0.23, 9.42)	
p-value	0.6816	
Risk Difference (95% CI)	0.23 (-0.72, 1.17)	
p-value	0.6385	
p-Value for test for heterogenity between studies	0.2682	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of Special Interest (AESI) - Non-Severe Malignancy - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=467) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.5994
< 10 points	1/148 (0.7)	0/146 (0.0)	2.95 (0.12, 70.77)	0.5053	
>= 10 points	2/311 (0.6)	2/321 (0.6)	1.09 (0.16, 7.38)	0.9295	
OCS dose					0.2471
<10 mg/day	2/214 (0.9)	0/218 (0.0)	5.32 (0.26, 109.09)	0.2781	
>=10 mg/day	1/245 (0.4)	2/249 (0.8)	0.61 (0.08, 4.90)	0.6411	
Result of type I IFN gene signature test					0.5730
LOW	1/ 86 (1.2)	0/ 90 (0.0)	3.09 (0.13, 73.19)	0.4846	
HIGH	2/373 (0.5)	2/377 (0.5)	1.07 (0.16, 7.23)	0.9469	
Age (years)					NE
<= 65	3/447 (0.7)	2/463 (0.4)	1.51 (0.24, 9.50)	0.6628	
> 65	0/ 12 (0.0)	0/ 4 (0.0)	NE		
Sex					NE
male	0/ 33 (0.0)	0/ 34 (0.0)	NE		
female	3/426 (0.7)	2/433 (0.5)	1.49 (0.24, 9.37)	0.6732	
Race					NE
White	3/270 (1.1)	2/285 (0.7)	1.52 (0.24, 9.58)	0.6539	
Black	0/ 65 (0.0)	0/ 59 (0.0)	NE		
Other	0/116 (0.0)	0/115 (0.0)	NE		
Ethnicity					NE
Hispanic/Latino	0/132 (0.0)	0/131 (0.0)	NE		
Non-hispanic/Latino	3/319 (0.9)	2/328 (0.6)	1.46 (0.23, 9.19)	0.6871	
Geographic region					0.6333
EU	2/135 (1.5)	2/147 (1.4)	1.13 (0.17, 7.59)	0.8987	
non-EU	1/324 (0.3)	0/320 (0.0)	2.79 (0.12, 67.88)	0.5277	
Onset of disease					NE
Paediatric	0/ 36 (0.0)	0/ 35 (0.0)	NE		
Adult	3/423 (0.7)	2/432 (0.5)	1.48 (0.23, 9.33)	0.6765	
ADA result					NE
Negative	3/427 (0.7)	2/428 (0.5)	1.46 (0.23, 9.19)	0.6882	
Positive (At any time)	0/ 31 (0.0)	0/ 39 (0.0)	NE		
BMI (kg/m2)					NE
< 30	3/309 (1.0)	2/339 (0.6)	1.65 (0.26, 10.37)	0.5933	
>= 30	0/150 (0.0)	0/128 (0.0)	NE		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of SOCs Cardiac disorders and/or Vascular disorders
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

	Anifrolumab 300mg (N=459)	Placebo (N=467)
Number of subjects with events, n (%)	22 (4.8)	43 (9.2)
Analysis Anifrolumab 300mg vs. Placebo		
Relative Risk (95% CI)	0.54 (0.32, 0.90)	
p-value	0.0188	
Odds Ratio (95% CI)	0.51 (0.29, 0.89)	
p-value	0.0179	
Risk Difference (95% CI)	-4.41 (-7.67, -1.14)	
p-value	0.0082	
p-Value for test for heterogenity between studies	0.0774	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochrane>s Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one Adverse Event of SOCs Cardiac disorders and/or Vascular disorders - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=467) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score					0.9111
< 10 points	5/148 (3.4)	10/146 (6.8)	0.50 (0.18, 1.44)	0.2018	
>= 10 points	17/311 (5.5)	33/321 (10.3)	0.54 (0.30, 0.98)	0.0435	
OCS dose					0.1808
<10 mg/day	12/214 (5.6)	16/218 (7.3)	0.80 (0.37, 1.72)	0.5701	
>=10 mg/day	10/245 (4.1)	27/249 (10.8)	0.39 (0.19, 0.80)	0.0108	
Result of type I IFN gene signature test					0.4622
LOW	2/ 86 (2.3)	8/ 90 (8.9)	0.33 (0.08, 1.41)	0.1354	
HIGH	20/373 (5.4)	35/377 (9.3)	0.59 (0.34, 1.03)	0.0643	
Age (years)					0.8508
<= 65	21/447 (4.7)	42/463 (9.1)	0.53 (0.31, 0.89)	0.0175	
> 65	1/ 12 (8.3)	1/ 4 (25.0)	0.43 (0.06, 3.29)	0.4191	
Sex					0.4632
male	2/ 33 (6.1)	2/ 34 (5.9)	1.09 (0.18, 6.78)	0.9261	
female	20/426 (4.7)	41/433 (9.5)	0.53 (0.31, 0.92)	0.0248	
Race					0.8860
White	13/270 (4.8)	29/285 (10.2)	0.60 (0.29, 1.23)	0.1631	
Black	3/ 65 (4.6)	6/ 59 (10.2)	0.52 (0.14, 1.87)	0.3141	
Other	5/116 (4.3)	8/115 (7.0)	0.78 (0.25, 2.42)	0.6643	
Ethnicity					0.1237
Hispanic/Latino	8/132 (6.1)	10/131 (7.6)	1.07 (0.39, 2.95)	0.8971	
Non-hispanic/Latino	13/319 (4.1)	33/328 (10.1)	0.42 (0.22, 0.79)	0.0069	
Geographic region					0.5825
EU	7/135 (5.2)	17/147 (11.6)	0.42 (0.15, 1.20)	0.1042	
non-EU	15/324 (4.6)	26/320 (8.1)	0.59 (0.32, 1.10)	0.0970	
Onset of disease					0.8068
Paediatric	1/ 36 (2.8)	2/ 35 (5.7)	0.68 (0.11, 4.07)	0.6711	
Adult	21/423 (5.0)	41/432 (9.5)	0.54 (0.32, 0.91)	0.0201	
ADA result					0.5376
Negative	21/427 (4.9)	41/428 (9.6)	0.53 (0.31, 0.90)	0.0193	
Positive (At any time)	1/ 31 (3.2)	2/ 39 (5.1)	1.03 (0.14, 7.75)	0.9796	
BMI (kg/m2)					0.5546
< 30	12/309 (3.9)	30/339 (8.8)	0.49 (0.23, 1.02)	0.0565	
>= 30	10/150 (6.7)	13/128 (10.2)	0.68 (0.31, 1.48)	0.3268	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochrane>s Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Blood and lymphatic system disorders	Number of subjects with events, n (%)	19 (4.1)	28 (6.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.69 (0.39, 1.22)	
	p-value	0.2011	
	Odds Ratio (95% CI)	0.68 (0.37, 1.23)	
	p-value	0.2011	
	Risk Difference (95% CI)	-1.85 (-4.67, 0.96)	
	p-value	0.1972	
	p-Value for test for heterogenity between studies	0.9823	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Cardiac disorders	Number of subjects with events, n (%)	8 (1.7)	17 (3.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.49 (0.21, 1.15)	
	p-value	0.1005	
	Odds Ratio (95% CI)	0.48 (0.20, 1.14)	
	p-value	0.0982	
	Risk Difference (95% CI)	-1.90 (-3.97, 0.18)	
	p-value	0.0736	
	p-Value for test for heterogenity between studies	0.6777	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Ear and labyrinth disorders	Number of subjects with events, n (%)	12 (2.6)	21 (4.5)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.67 (0.33, 1.37)	
	p-value	0.2770	
	Odds Ratio (95% CI)	0.66 (0.31, 1.38)	
	p-value	0.2677	
	Risk Difference (95% CI)	-1.89 (-4.27, 0.49)	
	p-value	0.1200	
	p-Value for test for heterogenity between studies	0.3260	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Eye disorders	Number of subjects with events, n (%)	34 (7.4)	18 (3.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.84 (1.04, 3.23)	
	p-value	0.0350	
	Odds Ratio (95% CI)	1.92 (1.06, 3.50)	
	p-value	0.0323	
	Risk Difference (95% CI)	3.55 (0.59, 6.51)	
	p-value	0.0189	
	p-Value for test for heterogenity between studies	0.4134	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Gastrointestinal disorders	Number of subjects with events, n (%)	101 (22.0)	111 (23.8)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.93 (0.73, 1.18)	
	p-value	0.5309	
	Odds Ratio (95% CI)	0.91 (0.67, 1.23)	
	p-value	0.5332	
	Risk Difference (95% CI)	-1.77 (-7.19, 3.65)	
	p-value	0.5228	
	p-Value for test for heterogenity between studies	0.1498	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Gastrointestinal disorders, PT: Abdominal pain upper	Number of subjects with events, n (%)	8 (1.7)	11 (2.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.74 (0.30, 1.83)	
	p-value	0.5149	
	Odds Ratio (95% CI)	0.74 (0.29, 1.87)	
	p-value	0.5192	
	Risk Difference (95% CI)	-0.61 (-2.43, 1.21)	
	p-value	0.5110	
	p-Value for test for heterogenity between studies	0.5257	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Gastrointestinal disorders, PT: Diarrhoea	Number of subjects with events, n (%)	16 (3.5)	25 (5.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.67 (0.36, 1.25)	
	p-value	0.2061	
	Odds Ratio (95% CI)	0.65 (0.34, 1.26)	
	p-value	0.2033	
	Risk Difference (95% CI)	-1.87 (-4.51, 0.78)	
	p-value	0.1667	
	p-Value for test for heterogenity between studies	0.4195	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Gastrointestinal disorders, PT: Gastritis	Number of subjects with events, n (%)	5 (1.1)	11 (2.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.50 (0.17, 1.49)	
	p-value	0.2120	
	Odds Ratio (95% CI)	0.49 (0.16, 1.49)	
	p-value	0.2089	
	Risk Difference (95% CI)	-1.27 (-2.94, 0.41)	
	p-value	0.1378	
	p-Value for test for heterogenity between studies	0.5511	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Gastrointestinal disorders, PT: Gastrooesophageal reflux disease	Number of subjects with events, n (%)	11 (2.4)	12 (2.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.93 (0.40, 2.17)	
	p-value	0.8643	
	Odds Ratio (95% CI)	0.93 (0.39, 2.22)	
	p-value	0.8627	
	Risk Difference (95% CI)	-0.17 (-2.18, 1.83)	
	p-value	0.8676	
	p-Value for test for heterogenity between studies	0.3474	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Gastrointestinal disorders, PT: Nausea	Number of subjects with events, n (%)	17 (3.7)	26 (5.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.68 (0.37, 1.25)	
	p-value	0.2127	
	Odds Ratio (95% CI)	0.67 (0.35, 1.26)	
	p-value	0.2087	
	Risk Difference (95% CI)	-1.86 (-4.56, 0.84)	
	p-value	0.1763	
	p-Value for test for heterogenity between studies	0.6448	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Gastrointestinal disorders, PT: Vomiting	Number of subjects with events, n (%)	18 (3.9)	12 (2.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.59 (0.76, 3.34)	
	p-value	0.2169	
	Odds Ratio (95% CI)	1.62 (0.75, 3.48)	
	p-value	0.2184	
	Risk Difference (95% CI)	1.35 (-0.93, 3.63)	
	p-value	0.2463	
	p-Value for test for heterogenity between studies	0.3381	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: General disorders and administration site conditions	Number of subjects with events, n (%)	58 (12.6)	49 (10.5)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.21 (0.84, 1.74)	
	p-value	0.2989	
	Odds Ratio (95% CI)	1.24 (0.82, 1.86)	
	p-value	0.3058	
	Risk Difference (95% CI)	2.15 (-1.97, 6.27)	
	p-value	0.3070	
	p-Value for test for heterogenity between studies	0.3321	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: General disorders and administration site conditions, PT: Fatigue	Number of subjects with events, n (%)	10 (2.2)	10 (2.1)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.02 (0.41, 2.52)	
	p-value	0.9734	
	Odds Ratio (95% CI)	1.02 (0.40, 2.60)	
	p-value	0.9605	
	Risk Difference (95% CI)	0.04 (-1.83, 1.91)	
	p-value	0.9668	
	p-Value for test for heterogenity between studies	0.3973	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: General disorders and administration site conditions, PT: Oedema peripheral	Number of subjects with events, n (%)	10 (2.2)	4 (0.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	2.04 (0.59, 7.03)	
	p-value	0.2609	
	Odds Ratio (95% CI)	2.07 (0.59, 7.24)	
	p-value	0.2562	
	Risk Difference (95% CI)	1.32 (-0.26, 2.90)	
	p-value	0.1007	
	p-Value for test for heterogenity between studies	0.2414	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: General disorders and administration site conditions, PT: Pyrexia	Number of subjects with events, n (%)	7 (1.5)	13 (2.8)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.70 (0.27, 1.84)	
	p-value	0.4691	
	Odds Ratio (95% CI)	0.69 (0.26, 1.85)	
	p-value	0.4592	
	Risk Difference (95% CI)	-1.26 (-3.13, 0.61)	
	p-value	0.1879	
	p-Value for test for heterogenity between studies	0.2395	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Immune system disorders	Number of subjects with events, n (%)	24 (5.2)	11 (2.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	2.20 (1.08, 4.46)	
	p-value	0.0292	
	Odds Ratio (95% CI)	2.27 (1.09, 4.73)	
	p-value	0.0286	
	Risk Difference (95% CI)	2.87 (0.42, 5.33)	
	p-value	0.0216	
	p-Value for test for heterogenity between studies	0.7104	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Immune system disorders, PT: Hypersensitivity	Number of subjects with events, n (%)	13 (2.8)	3 (0.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	4.22 (1.19, 14.97)	
	p-value	0.0258	
	Odds Ratio (95% CI)	4.37 (1.21, 15.81)	
	p-value	0.0247	
	Risk Difference (95% CI)	2.19 (0.52, 3.87)	
	p-value	0.0104	
	p-Value for test for heterogenity between studies	0.4771	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Infections and infestations	Number of subjects with events, n (%)	322 (70.2)	263 (56.3)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.25 (1.13, 1.38)	
	p-value	<.0001	
	Odds Ratio (95% CI)	1.82 (1.39, 2.39)	
	p-value	<.0001	
	Risk Difference (95% CI)	13.84 (7.70, 19.97)	
	p-value	<.0001	
	p-Value for test for heterogenity between studies	0.5342	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Infections and infestations, PT: Bronchitis	Number of subjects with events, n (%)	45 (9.8)	21 (4.5)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	2.14 (1.29, 3.55)	
	p-value	0.0034	
	Odds Ratio (95% CI)	2.26 (1.32, 3.89)	
	p-value	0.0030	
	Risk Difference (95% CI)	5.30 (2.00, 8.61)	
	p-value	0.0017	
	p-Value for test for heterogenity between studies	0.4851	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Infections and infestations, PT: Gastroenteritis	Number of subjects with events, n (%)	13 (2.8)	14 (3.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.94 (0.44, 2.02)	
	p-value	0.8841	
	Odds Ratio (95% CI)	0.94 (0.43, 2.07)	
	p-value	0.8858	
	Risk Difference (95% CI)	-0.17 (-2.33, 2.00)	
	p-value	0.8802	
	p-Value for test for heterogenity between studies	0.5191	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Infections and infestations, PT: Gastroenteritis viral	Number of subjects with events, n (%)	11 (2.4)	8 (1.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.44 (0.54, 3.85)	
	p-value	0.4726	
	Odds Ratio (95% CI)	1.44 (0.53, 3.94)	
	p-value	0.4769	
	Risk Difference (95% CI)	0.68 (-1.15, 2.51)	
	p-value	0.4669	
	p-Value for test for heterogenity between studies	0.1681	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Infections and infestations, PT: Herpes zoster	Number of subjects with events, n (%)	28 (6.1)	7 (1.5)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	3.88 (1.70, 8.89)	
	p-value	0.0013	
	Odds Ratio (95% CI)	4.08 (1.75, 9.53)	
	p-value	0.0012	
	Risk Difference (95% CI)	4.60 (2.15, 7.05)	
	p-value	0.0002	
	p-Value for test for heterogenity between studies	0.6738	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Infections and infestations, PT: Influenza	Number of subjects with events, n (%)	12 (2.6)	10 (2.1)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.17 (0.49, 2.80)	
	p-value	0.7279	
	Odds Ratio (95% CI)	1.17 (0.48, 2.88)	
	p-value	0.7269	
	Risk Difference (95% CI)	0.47 (-1.49, 2.43)	
	p-value	0.6383	
	p-Value for test for heterogenity between studies	0.3332	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Infections and infestations, PT: Nasopharyngitis	Number of subjects with events, n (%)	76 (16.6)	46 (9.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.66 (1.18, 2.34)	
	p-value	0.0039	
	Odds Ratio (95% CI)	1.81 (1.22, 2.68)	
	p-value	0.0034	
	Risk Difference (95% CI)	6.71 (2.38, 11.04)	
	p-value	0.0024	
	p-Value for test for heterogenity between studies	0.4641	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Infections and infestations, PT: Oral herpes	Number of subjects with events, n (%)	17 (3.7)	12 (2.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.43 (0.69, 2.98)	
	p-value	0.3414	
	Odds Ratio (95% CI)	1.45 (0.68, 3.09)	
	p-value	0.3403	
	Risk Difference (95% CI)	1.13 (-1.11, 3.38)	
	p-value	0.3229	
	p-Value for test for heterogenity between studies	0.7440	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Infections and infestations, PT: Pharyngitis	Number of subjects with events, n (%)	21 (4.6)	17 (3.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.11 (0.57, 2.14)	
	p-value	0.7663	
	Odds Ratio (95% CI)	1.12 (0.56, 2.26)	
	p-value	0.7460	
	Risk Difference (95% CI)	0.95 (-1.60, 3.49)	
	p-value	0.4659	
	p-Value for test for heterogenity between studies	0.1682	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Infections and infestations, PT: Pneumonia	Number of subjects with events, n (%)	15 (3.3)	14 (3.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.06 (0.50, 2.24)	
	p-value	0.8760	
	Odds Ratio (95% CI)	1.07 (0.49, 2.31)	
	p-value	0.8661	
	Risk Difference (95% CI)	0.27 (-1.98, 2.51)	
	p-value	0.8162	
	p-Value for test for heterogenity between studies	0.3356	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Infections and infestations, PT: Respiratory tract infection	Number of subjects with events, n (%)	14 (3.1)	2 (0.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	3.90 (1.07, 14.18)	
	p-value	0.0389	
	Odds Ratio (95% CI)	4.01 (1.08, 14.81)	
	p-value	0.0374	
	Risk Difference (95% CI)	2.62 (0.94, 4.30)	
	p-value	0.0022	
	p-Value for test for heterogenity between studies	0.5153	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Infections and infestations, PT: Sinusitis	Number of subjects with events, n (%)	26 (5.7)	25 (5.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.06 (0.61, 1.83)	
	p-value	0.8476	
	Odds Ratio (95% CI)	1.06 (0.59, 1.89)	
	p-value	0.8435	
	Risk Difference (95% CI)	0.31 (-2.63, 3.25)	
	p-value	0.8362	
	p-Value for test for heterogenity between studies	0.2679	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Infections and infestations, PT: Upper respiratory tract infection	Number of subjects with events, n (%)	74 (16.1)	46 (9.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.63 (1.15, 2.30)	
	p-value	0.0061	
	Odds Ratio (95% CI)	1.74 (1.17, 2.59)	
	p-value	0.0059	
	Risk Difference (95% CI)	6.26 (1.95, 10.58)	
	p-value	0.0045	
	p-Value for test for heterogenity between studies	0.3162	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Infections and infestations, PT: Urinary tract infection	Number of subjects with events, n (%)	57 (12.4)	63 (13.5)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.92 (0.66, 1.29)	
	p-value	0.6254	
	Odds Ratio (95% CI)	0.91 (0.62, 1.34)	
	p-value	0.6256	
	Risk Difference (95% CI)	-1.07 (-5.40, 3.26)	
	p-value	0.6281	
	p-Value for test for heterogenity between studies	0.4513	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Infections and infestations, PT: Vaginal infection	Number of subjects with events, n (%)	7 (1.5)	10 (2.1)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.72 (0.27, 1.89)	
	p-value	0.5031	
	Odds Ratio (95% CI)	0.71 (0.27, 1.91)	
	p-value	0.5000	
	Risk Difference (95% CI)	-0.62 (-2.34, 1.11)	
	p-value	0.4840	
	p-Value for test for heterogenity between studies	0.8350	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Injury, poisoning and procedural complications	Number of subjects with events, n (%)	92 (20.0)	80 (17.1)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.17 (0.90, 1.54)	
	p-value	0.2451	
	Odds Ratio (95% CI)	1.21 (0.87, 1.70)	
	p-value	0.2550	
	Risk Difference (95% CI)	2.90 (-2.08, 7.89)	
	p-value	0.2537	
	p-Value for test for heterogenity between studies	0.7682	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Injury, poisoning and procedural complications, PT: Infusion related reaction	Number of subjects with events, n (%)	43 (9.4)	33 (7.1)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.37 (0.87, 2.13)	
	p-value	0.1715	
	Odds Ratio (95% CI)	1.39 (0.86, 2.27)	
	p-value	0.1827	
	Risk Difference (95% CI)	2.29 (-1.24, 5.82)	
	p-value	0.2029	
	p-Value for test for heterogenity between studies	0.1482	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Investigations	Number of subjects with events, n (%)	26 (5.7)	28 (6.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.95 (0.56, 1.59)	
	p-value	0.8354	
	Odds Ratio (95% CI)	0.94 (0.54, 1.64)	
	p-value	0.8320	
	Risk Difference (95% CI)	-0.33 (-3.34, 2.69)	
	p-value	0.8316	
	p-Value for test for heterogenity between studies	0.8817	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Metabolism and nutrition disorders	Number of subjects with events, n (%)	30 (6.5)	40 (8.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.77 (0.49, 1.22)	
	p-value	0.2642	
	Odds Ratio (95% CI)	0.75 (0.45, 1.23)	
	p-value	0.2530	
	Risk Difference (95% CI)	-2.03 (-5.43, 1.37)	
	p-value	0.2419	
	p-Value for test for heterogenity between studies	0.3976	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Musculoskeletal and connective tissue disorders	Number of subjects with events, n (%)	105 (22.9)	104 (22.3)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.03 (0.81, 1.30)	
	p-value	0.8344	
	Odds Ratio (95% CI)	1.04 (0.76, 1.41)	
	p-value	0.8239	
	Risk Difference (95% CI)	0.61 (-4.77, 6.00)	
	p-value	0.8234	
	p-Value for test for heterogenity between studies	0.7709	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Musculoskeletal and connective tissue disorders, PT: Arthralgia	Number of subjects with events, n (%)	22 (4.8)	10 (2.1)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	2.18 (1.04, 4.59)	
	p-value	0.0396	
	Odds Ratio (95% CI)	2.25 (1.05, 4.86)	
	p-value	0.0382	
	Risk Difference (95% CI)	2.65 (0.30, 5.00)	
	p-value	0.0273	
	p-Value for test for heterogenity between studies	0.6926	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Musculoskeletal and connective tissue disorders, PT: Back pain	Number of subjects with events, n (%)	23 (5.0)	21 (4.5)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.05 (0.57, 1.93)	
	p-value	0.8832	
	Odds Ratio (95% CI)	1.06 (0.56, 2.01)	
	p-value	0.8595	
	Risk Difference (95% CI)	0.52 (-2.22, 3.26)	
	p-value	0.7104	
	p-Value for test for heterogenity between studies	0.1170	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Musculoskeletal and connective tissue disorders, PT: Myalgia	Number of subjects with events, n (%)	5 (1.1)	10 (2.1)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.51 (0.18, 1.51)	
	p-value	0.2245	
	Odds Ratio (95% CI)	0.51 (0.17, 1.52)	
	p-value	0.2242	
	Risk Difference (95% CI)	-1.05 (-2.66, 0.57)	
	p-value	0.2038	
	p-Value for test for heterogenity between studies	0.8580	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Musculoskeletal and connective tissue disorders, PT: Pain in extremity	Number of subjects with events, n (%)	12 (2.6)	3 (0.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	3.75 (1.03, 13.59)	
	p-value	0.0443	
	Odds Ratio (95% CI)	3.83 (1.04, 14.08)	
	p-value	0.0432	
	Risk Difference (95% CI)	1.97 (0.34, 3.60)	
	p-value	0.0178	
	p-Value for test for heterogenity between studies	0.7279	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Musculoskeletal and connective tissue disorders, PT: Systemic lupus erythematosus	Number of subjects with events, n (%)	11 (2.4)	16 (3.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.70 (0.33, 1.50)	
	p-value	0.3645	
	Odds Ratio (95% CI)	0.69 (0.32, 1.53)	
	p-value	0.3637	
	Risk Difference (95% CI)	-1.03 (-3.18, 1.12)	
	p-value	0.3490	
	p-Value for test for heterogenity between studies	0.8025	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Number of subjects with events, n (%)	16 (3.5)	7 (1.5)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	2.11 (0.81, 5.48)	
	p-value	0.1260	
	Odds Ratio (95% CI)	2.15 (0.81, 5.70)	
	p-value	0.1224	
	Risk Difference (95% CI)	1.99 (-0.02, 4.00)	
	p-value	0.0526	
	p-Value for test for heterogenity between studies	0.1955	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Nervous system disorders	Number of subjects with events, n (%)	90 (19.6)	78 (16.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.17 (0.89, 1.54)	
	p-value	0.2620	
	Odds Ratio (95% CI)	1.22 (0.87, 1.71)	
	p-value	0.2535	
	Risk Difference (95% CI)	2.92 (-2.03, 7.87)	
	p-value	0.2479	
	p-Value for test for heterogenity between studies	0.3167	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Nervous system disorders, PT: Dizziness	Number of subjects with events, n (%)	10 (2.2)	12 (2.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.85 (0.37, 1.98)	
	p-value	0.7081	
	Odds Ratio (95% CI)	0.85 (0.36, 2.02)	
	p-value	0.7095	
	Risk Difference (95% CI)	-0.39 (-2.35, 1.57)	
	p-value	0.6980	
	p-Value for test for heterogenity between studies	0.6572	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Nervous system disorders, PT: Headache	Number of subjects with events, n (%)	38 (8.3)	45 (9.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.87 (0.57, 1.31)	
	p-value	0.5051	
	Odds Ratio (95% CI)	0.85 (0.54, 1.35)	
	p-value	0.4902	
	Risk Difference (95% CI)	-1.35 (-5.02, 2.32)	
	p-value	0.4709	
	p-Value for test for heterogenity between studies	0.4488	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Nervous system disorders, PT: Migraine	Number of subjects with events, n (%)	8 (1.7)	10 (2.1)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.94 (0.36, 2.43)	
	p-value	0.8993	
	Odds Ratio (95% CI)	0.93 (0.35, 2.47)	
	p-value	0.8915	
	Risk Difference (95% CI)	-0.39 (-2.17, 1.38)	
	p-value	0.6634	
	p-Value for test for heterogenity between studies	0.4133	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Psychiatric disorders	Number of subjects with events, n (%)	34 (7.4)	42 (9.0)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.82 (0.53, 1.27)	
	p-value	0.3785	
	Odds Ratio (95% CI)	0.81 (0.50, 1.30)	
	p-value	0.3807	
	Risk Difference (95% CI)	-1.58 (-5.12, 1.95)	
	p-value	0.3800	
	p-Value for test for heterogenity between studies	0.3926	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Psychiatric disorders, PT: Anxiety	Number of subjects with events, n (%)	11 (2.4)	8 (1.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.39 (0.56, 3.45)	
	p-value	0.4785	
	Odds Ratio (95% CI)	1.40 (0.55, 3.55)	
	p-value	0.4772	
	Risk Difference (95% CI)	0.68 (-1.14, 2.51)	
	p-value	0.4640	
	p-Value for test for heterogenity between studies	0.8337	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Psychiatric disorders, PT: Depression	Number of subjects with events, n (%)	13 (2.8)	9 (1.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.44 (0.61, 3.38)	
	p-value	0.4050	
	Odds Ratio (95% CI)	1.45 (0.61, 3.49)	
	p-value	0.4018	
	Risk Difference (95% CI)	0.91 (-1.06, 2.87)	
	p-value	0.3660	
	p-Value for test for heterogenity between studies	0.6764	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Psychiatric disorders, PT: Insomnia	Number of subjects with events, n (%)	9 (2.0)	20 (4.3)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.49 (0.22, 1.08)	
	p-value	0.0781	
	Odds Ratio (95% CI)	0.47 (0.21, 1.08)	
	p-value	0.0754	
	Risk Difference (95% CI)	-2.32 (-4.56, -0.09)	
	p-value	0.0417	
	p-Value for test for heterogenity between studies	0.3967	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Renal and urinary disorders	Number of subjects with events, n (%)	18 (3.9)	16 (3.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.13 (0.58, 2.22)	
	p-value	0.7194	
	Odds Ratio (95% CI)	1.14 (0.56, 2.30)	
	p-value	0.7204	
	Risk Difference (95% CI)	0.50 (-1.92, 2.92)	
	p-value	0.6853	
	p-Value for test for heterogenity between studies	0.4803	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Reproductive system and breast disorders	Number of subjects with events, n (%)	24 (5.2)	21 (4.5)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.16 (0.65, 2.08)	
	p-value	0.6117	
	Odds Ratio (95% CI)	1.17 (0.64, 2.16)	
	p-value	0.6120	
	Risk Difference (95% CI)	0.73 (-2.04, 3.50)	
	p-value	0.6052	
	p-Value for test for heterogenity between studies	0.4394	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with events, n (%)	64 (13.9)	59 (12.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.11 (0.79, 1.54)	
	p-value	0.5502	
	Odds Ratio (95% CI)	1.12 (0.77, 1.64)	
	p-value	0.5581	
	Risk Difference (95% CI)	1.31 (-3.05, 5.68)	
	p-value	0.5558	
	p-Value for test for heterogenity between studies	0.5746	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Respiratory, thoracic and mediastinal disorders, PT: Cough	Number of subjects with events, n (%)	24 (5.2)	15 (3.2)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.63 (0.87, 3.06)	
	p-value	0.1305	
	Odds Ratio (95% CI)	1.66 (0.86, 3.22)	
	p-value	0.1300	
	Risk Difference (95% CI)	2.02 (-0.57, 4.60)	
	p-value	0.1265	
	p-Value for test for heterogenity between studies	0.9949	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Skin and subcutaneous tissue disorders	Number of subjects with events, n (%)	63 (13.7)	50 (10.7)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.27 (0.90, 1.81)	
	p-value	0.1783	
	Odds Ratio (95% CI)	1.32 (0.88, 1.97)	
	p-value	0.1737	
	Risk Difference (95% CI)	3.01 (-1.20, 7.22)	
	p-value	0.1614	
	p-Value for test for heterogenity between studies	0.2672	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Vascular disorders	Number of subjects with events, n (%)	14 (3.1)	29 (6.2)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.49 (0.25, 0.97)	
	p-value	0.0402	
	Odds Ratio (95% CI)	0.48 (0.24, 0.97)	
	p-value	0.0398	
	Risk Difference (95% CI)	-3.15 (-5.85, -0.46)	
	p-value	0.0218	
	p-Value for test for heterogenity between studies	0.0673	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Vascular disorders, PT: Hypertension	Number of subjects with events, n (%)	7 (1.5)	18 (3.9)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.41 (0.17, 0.98)	
	p-value	0.0442	
	Odds Ratio (95% CI)	0.40 (0.16, 0.97)	
	p-value	0.0431	
	Risk Difference (95% CI)	-2.32 (-4.39, -0.26)	
	p-value	0.0277	
	p-Value for test for heterogenity between studies	0.7141	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=467) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SOC: Eye disorders	SLEDAI-2K score					0.8165
	< 10 points	11/148 (7.4)	6/146 (4.1)	1.66 (0.65, 4.21)	0.2870	
	>= 10 points	23/311 (7.4)	12/321 (3.7)	1.90 (0.95, 3.80)	0.0689	
	OCS dose					0.1187
	<10 mg/day	11/214 (5.1)	10/218 (4.6)	0.91 (0.38, 2.21)	0.8423	
	>=10 mg/day	23/245 (9.4)	8/249 (3.2)	2.43 (1.04, 5.73)	0.0415	
	Result of type I IFN gene signature test					0.9861
	LOW	4/ 86 (4.7)	2/ 90 (2.2)	1.73 (0.35, 8.52)	0.4975	
	HIGH	30/373 (8.0)	16/377 (4.2)	1.76 (0.97, 3.21)	0.0649	
	Age (years)					0.9019
	<= 65	33/447 (7.4)	18/463 (3.9)	1.81 (1.03, 3.20)	0.0399	
	> 65	1/ 12 (8.3)	0/ 4 (0.0)	1.50 (0.08, 29.15)	0.7888	
	Sex					0.3999
	male	3/ 33 (9.1)	0/ 34 (0.0)	4.33 (0.52, 36.13)	0.1755	
	female	31/426 (7.3)	18/433 (4.2)	1.69 (0.95, 2.99)	0.0734	
	Race					0.4491
	White	16/270 (5.9)	12/285 (4.2)	1.38 (0.66, 2.86)	0.3900	
	Black	6/ 65 (9.2)	0/ 59 (0.0)	4.35 (0.77, 24.59)	0.0960	
	Other	11/116 (9.5)	6/115 (5.2)	1.28 (0.46, 3.51)	0.6349	
	Ethnicity					0.6504
	Hispanic/Latino	11/132 (8.3)	6/131 (4.6)	1.39 (0.50, 3.86)	0.5234	
	Non-hispanic/Latino	22/319 (6.9)	12/328 (3.7)	1.85 (0.93, 3.68)	0.0789	
	Geographic region					0.7557
	EU	9/135 (6.7)	6/147 (4.1)	1.56 (0.55, 4.40)	0.4024	
	non-EU	25/324 (7.7)	12/320 (3.8)	1.90 (0.95, 3.81)	0.0709	
	Onset of disease					0.5651
	Paediatric	3/ 36 (8.3)	0/ 35 (0.0)	2.95 (0.49, 17.69)	0.2375	
	Adult	31/423 (7.3)	18/432 (4.2)	1.70 (0.96, 3.01)	0.0707	
	ADA result					0.5821
	Negative	29/427 (6.8)	16/428 (3.7)	1.73 (0.95, 3.16)	0.0732	
	Positive (At any time)	5/ 31 (16.1)	2/ 39 (5.1)	2.71 (0.62, 11.79)	0.1847	
	BMI (kg/m2)					0.5974
	< 30	24/309 (7.8)	13/339 (3.8)	1.99 (1.02, 3.85)	0.0422	
	>= 30	10/150 (6.7)	5/128 (3.9)	1.40 (0.46, 4.26)	0.5514	

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Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=467) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SOC: Immune system disorders	SLEDAI-2K score					0.2242
	< 10 points	13/148 (8.8)	3/146 (2.1)	3.91 (1.07, 14.34)	0.0395	
	>= 10 points	11/311 (3.5)	8/321 (2.5)	1.44 (0.56, 3.73)	0.4496	
	OCS dose					0.9538
	<10 mg/day	15/214 (7.0)	7/218 (3.2)	2.15 (0.92, 5.04)	0.0770	
	>=10 mg/day	9/245 (3.7)	4/249 (1.6)	2.06 (0.61, 6.95)	0.2430	
	Result of type I IFN gene signature test					0.0753
	LOW	9/ 86 (10.5)	0/ 90 (0.0)	9.93 (1.30, 75.98)	0.0271	
	HIGH	15/373 (4.0)	11/377 (2.9)	1.38 (0.64, 2.97)	0.4101	
	Age (years)					0.7810
	<= 65	19/447 (4.3)	11/463 (2.4)	1.78 (0.85, 3.72)	0.1231	
	> 65	5/ 12 (41.7)	0/ 4 (0.0)	2.37 (0.37, 15.37)	0.3649	
	Sex					0.4897
	male	1/ 33 (3.0)	1/ 34 (2.9)	0.87 (0.06, 12.52)	0.9164	
	female	23/426 (5.4)	10/433 (2.3)	2.30 (1.10, 4.82)	0.0272	
	Race					0.5740
	White	18/270 (6.7)	7/285 (2.5)	2.54 (1.04, 6.17)	0.0402	
	Black	2/ 65 (3.1)	1/ 59 (1.7)	1.28 (0.21, 7.86)	0.7871	
	Other	2/116 (1.7)	2/115 (1.7)	0.93 (0.13, 6.39)	0.9396	
	Ethnicity					0.9139
	Hispanic/Latino	4/132 (3.0)	2/131 (1.5)	2.00 (0.36, 11.27)	0.4308	
	Non-hispanic/Latino	18/319 (5.6)	8/328 (2.4)	2.23 (0.96, 5.15)	0.0613	
	Geographic region					0.9091
	EU	6/135 (4.4)	2/147 (1.4)	2.11 (0.43, 10.29)	0.3564	
	non-EU	18/324 (5.6)	9/320 (2.8)	1.90 (0.89, 4.09)	0.0992	
	Onset of disease					0.7856
	Paediatric	2/ 36 (5.6)	0/ 35 (0.0)	2.79 (0.31, 25.19)	0.3599	
	Adult	22/423 (5.2)	11/432 (2.5)	2.03 (0.99, 4.15)	0.0536	
	ADA result					0.1547
	Negative	24/427 (5.6)	9/428 (2.1)	2.62 (1.22, 5.62)	0.0133	
	Positive (At any time)	0/ 31 (0.0)	2/ 39 (5.1)	0.48 (0.05, 4.36)	0.5162	
	BMI (kg/m2)					0.9226
	< 30	12/309 (3.9)	6/339 (1.8)	2.12 (0.78, 5.74)	0.1398	
	>= 30	12/150 (8.0)	5/128 (3.9)	1.98 (0.72, 5.43)	0.1868	

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Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=467) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SOC: Immune system disorders, PT: Hypersensitivity	SLEDAI-2K score					0.8348
	< 10 points	6/148 (4.1)	1/146 (0.7)	4.17 (0.72, 24.26)	0.1116	
	>= 10 points	7/311 (2.3)	2/321 (0.6)	3.22 (0.61, 17.17)	0.1703	
	OCS dose					0.9695
	<10 mg/day	8/214 (3.7)	2/218 (0.9)	3.35 (0.60, 18.85)	0.1702	
	>=10 mg/day	5/245 (2.0)	1/249 (0.4)	3.52 (0.58, 21.34)	0.1716	
	Result of type I IFN gene signature test					0.2791
	LOW	6/ 86 (7.0)	0/ 90 (0.0)	13.39 (0.79, 228.40)	0.0730	
	HIGH	7/373 (1.9)	3/377 (0.8)	2.37 (0.62, 9.07)	0.2087	
	Age (years)					0.9860
	<= 65	10/447 (2.2)	3/463 (0.6)	3.41 (0.94, 12.40)	0.0630	
	> 65	3/ 12 (25.0)	0/ 4 (0.0)	3.50 (0.23, 52.56)	0.3648	
	Sex					0.2557
	male	1/ 33 (3.0)	1/ 34 (2.9)	0.87 (0.06, 12.52)	0.9164	
	female	12/426 (2.8)	2/433 (0.5)	5.20 (1.10, 24.59)	0.0376	
	Race					0.2157
	White	11/270 (4.1)	2/285 (0.7)	4.89 (1.26, 18.98)	0.0218	
	Black	0/ 65 (0.0)	0/ 59 (0.0)	NE		
	Other	1/116 (0.9)	1/115 (0.9)	0.94 (0.10, 8.77)	0.9543	
	Ethnicity					0.9910
	Hispanic/Latino	2/132 (1.5)	0/131 (0.0)	3.13 (0.33, 29.53)	0.3182	
	Non-hispanic/Latino	10/319 (3.1)	3/328 (0.9)	3.09 (0.79, 12.01)	0.1038	
	Geographic region					0.6548
	EU	4/135 (3.0)	0/147 (0.0)	4.95 (0.57, 42.87)	0.1468	
	non-EU	9/324 (2.8)	3/320 (0.9)	2.77 (0.73, 10.54)	0.1350	
	Onset of disease					0.8555
	Paediatric	2/ 36 (5.6)	0/ 35 (0.0)	2.79 (0.31, 25.19)	0.3599	
	Adult	11/423 (2.6)	3/432 (0.7)	3.55 (0.95, 13.28)	0.0603	
	ADA result					NE
	Negative	13/427 (3.0)	3/428 (0.7)	4.20 (1.19, 14.89)	0.0262	
	Positive (At any time)	0/ 31 (0.0)	0/ 39 (0.0)	NE		
	BMI (kg/m2)					0.4732
	< 30	4/309 (1.3)	2/339 (0.6)	2.08 (0.34, 12.53)	0.4261	
	>= 30	9/150 (6.0)	1/128 (0.8)	5.14 (0.93, 28.23)	0.0598	

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Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

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Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=467) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations	SLEDAI-2K score					0.4058
	< 10 points	106/148 (71.6)	88/146 (60.3)	1.17 (1.00, 1.38)	0.0558	
	>= 10 points	216/311 (69.5)	175/321 (54.5)	1.28 (1.13, 1.45)	0.0001	
	OCS dose					0.1772
	<10 mg/day	152/214 (71.0)	134/218 (61.5)	1.17 (1.03, 1.34)	0.0201	
	>=10 mg/day	170/245 (69.4)	129/249 (51.8)	1.34 (1.16, 1.55)	<.0001	
	Result of type I IFN gene signature test					0.5349
	LOW	63/ 86 (73.3)	49/ 90 (54.4)	1.33 (1.06, 1.67)	0.0140	
	HIGH	259/373 (69.4)	214/377 (56.8)	1.23 (1.10, 1.37)	0.0003	
	Age (years)					0.7557
	<= 65	312/447 (69.8)	261/463 (56.4)	1.24 (1.12, 1.37)	<.0001	
	> 65	10/ 12 (83.3)	2/ 4 (50.0)	1.41 (0.63, 3.16)	0.4040	
	Sex					0.7373
	male	21/ 33 (63.6)	17/ 34 (50.0)	1.35 (0.86, 2.12)	0.1939	
	female	301/426 (70.7)	246/433 (56.8)	1.25 (1.12, 1.38)	<.0001	
	Race					0.8844
	White	185/270 (68.5)	155/285 (54.4)	1.27 (1.11, 1.45)	0.0005	
	Black	43/ 65 (66.2)	33/ 59 (55.9)	1.17 (0.88, 1.55)	0.2709	
	Other	88/116 (75.9)	68/115 (59.1)	1.24 (1.04, 1.48)	0.0149	
	Ethnicity					0.8053
	Hispanic/Latino	93/132 (70.5)	74/131 (56.5)	1.23 (1.02, 1.47)	0.0275	
	Non-hispanic/Latino	223/319 (69.9)	182/328 (55.5)	1.26 (1.12, 1.43)	0.0002	
	Geographic region					0.2272
	EU	87/135 (64.4)	69/147 (46.9)	1.38 (1.12, 1.71)	0.0030	
	non-EU	235/324 (72.5)	194/320 (60.6)	1.19 (1.07, 1.33)	0.0016	
	Onset of disease					0.7457
	Paediatric	29/ 36 (80.6)	22/ 35 (62.9)	1.18 (0.87, 1.59)	0.2822	
	Adult	293/423 (69.3)	241/432 (55.8)	1.24 (1.12, 1.38)	<.0001	
	ADA result					0.9393
	Negative	300/427 (70.3)	240/428 (56.1)	1.26 (1.13, 1.39)	<.0001	
	Positive (At any time)	22/ 31 (71.0)	23/ 39 (59.0)	1.27 (0.92, 1.76)	0.1457	
	BMI (kg/m2)					0.0206
	< 30	216/309 (69.9)	177/339 (52.2)	1.34 (1.18, 1.52)	<.0001	
	>= 30	106/150 (70.7)	86/128 (67.2)	1.06 (0.91, 1.24)	0.4742	

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Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

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Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=467) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Bronchitis	SLEDAI-2K score					0.0316
	< 10 points	13/148 (8.8)	12/146 (8.2)	1.04 (0.48, 2.25)	0.9227	
	>= 10 points	32/311 (10.3)	9/321 (2.8)	3.39 (1.60, 7.19)	0.0014	
	OCS dose					0.1399
	<10 mg/day	26/214 (12.1)	8/218 (3.7)	3.21 (1.47, 7.01)	0.0034	
	>=10 mg/day	19/245 (7.8)	13/249 (5.2)	1.47 (0.74, 2.92)	0.2762	
	Result of type I IFN gene signature test					0.7463
	LOW	11/ 86 (12.8)	5/ 90 (5.6)	1.73 (0.58, 5.15)	0.3256	
	HIGH	34/373 (9.1)	16/377 (4.2)	2.12 (1.17, 3.84)	0.0129	
	Age (years)					0.3190
	<= 65	42/447 (9.4)	20/463 (4.3)	2.14 (1.27, 3.60)	0.0043	
	> 65	3/ 12 (25.0)	1/ 4 (25.0)	0.90 (0.18, 4.53)	0.9014	
	Sex					0.8862
	male	1/ 33 (3.0)	0/ 34 (0.0)	2.63 (0.12, 59.40)	0.5442	
	female	44/426 (10.3)	21/433 (4.8)	2.08 (1.25, 3.47)	0.0047	
	Race					0.5134
	White	30/270 (11.1)	12/285 (4.2)	2.48 (1.25, 4.91)	0.0092	
	Black	5/ 65 (7.7)	4/ 59 (6.8)	1.15 (0.31, 4.19)	0.8348	
	Other	9/116 (7.8)	5/115 (4.3)	1.47 (0.44, 4.85)	0.5311	
	Ethnicity					0.2509
	Hispanic/Latino	15/132 (11.4)	4/131 (3.1)	3.59 (1.21, 10.66)	0.0215	
	Non-hispanic/Latino	29/319 (9.1)	17/328 (5.2)	1.73 (0.94, 3.17)	0.0785	
	Geographic region					0.3335
	EU	14/135 (10.4)	4/147 (2.7)	3.24 (1.04, 10.16)	0.0433	
	non-EU	31/324 (9.6)	17/320 (5.3)	1.72 (0.96, 3.10)	0.0705	
	Onset of disease					0.3943
	Paediatric	5/ 36 (13.9)	0/ 35 (0.0)	4.17 (0.74, 23.44)	0.1048	
	Adult	40/423 (9.5)	21/432 (4.9)	1.91 (1.14, 3.20)	0.0146	
	ADA result					0.0766
	Negative	44/427 (10.3)	17/428 (4.0)	2.49 (1.43, 4.33)	0.0012	
	Positive (At any time)	1/ 31 (3.2)	4/ 39 (10.3)	0.45 (0.07, 2.75)	0.3879	
	BMI (kg/m2)					0.1002
	< 30	32/309 (10.4)	12/339 (3.5)	2.91 (1.52, 5.56)	0.0013	
	>= 30	13/150 (8.7)	9/128 (7.0)	1.20 (0.52, 2.75)	0.6640	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=467) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Herpes zoster	SLEDAI-2K score					0.0755
	< 10 points	4/148 (2.7)	3/146 (2.1)	1.23 (0.30, 5.03)	0.7748	
	>= 10 points	24/311 (7.7)	4/321 (1.2)	6.05 (2.12, 17.29)	0.0008	
	OCS dose					0.9748
	<10 mg/day	12/214 (5.6)	3/218 (1.4)	3.74 (1.01, 13.88)	0.0483	
	>=10 mg/day	16/245 (6.5)	4/249 (1.6)	3.85 (1.28, 11.54)	0.0162	
	Result of type I IFN gene signature test					0.8637
	LOW	4/ 86 (4.7)	1/ 90 (1.1)	2.92 (0.46, 18.57)	0.2552	
	HIGH	24/373 (6.4)	6/377 (1.6)	3.50 (1.41, 8.68)	0.0068	
	Age (years)					NE
	<= 65	28/447 (6.3)	7/463 (1.5)	3.95 (1.73, 9.04)	0.0011	
	> 65	0/ 12 (0.0)	0/ 4 (0.0)	NE		
	Sex					0.8709
	male	4/ 33 (12.1)	0/ 34 (0.0)	3.85 (0.67, 22.22)	0.1312	
	female	24/426 (5.6)	7/433 (1.6)	3.28 (1.41, 7.65)	0.0059	
	Race					0.5169
	White	15/270 (5.6)	5/285 (1.8)	3.15 (1.15, 8.60)	0.0256	
	Black	1/ 65 (1.5)	1/ 59 (1.7)	0.94 (0.10, 8.57)	0.9531	
	Other	10/116 (8.6)	1/115 (0.9)	4.46 (0.94, 21.09)	0.0594	
	Ethnicity					0.6083
	Hispanic/Latino	10/132 (7.6)	1/131 (0.8)	4.40 (0.93, 20.84)	0.0621	
	Non-hispanic/Latino	16/319 (5.0)	6/328 (1.8)	2.74 (1.08, 6.91)	0.0330	
	Geographic region					0.3527
	EU	7/135 (5.2)	3/147 (2.0)	2.33 (0.65, 8.30)	0.1930	
	non-EU	21/324 (6.5)	4/320 (1.3)	5.11 (1.76, 14.81)	0.0027	
	Onset of disease					0.6570
	Paediatric	5/ 36 (13.9)	1/ 35 (2.9)	2.41 (0.44, 13.34)	0.3128	
	Adult	23/423 (5.4)	6/432 (1.4)	3.74 (1.52, 9.21)	0.0041	
	ADA result					0.5635
	Negative	24/427 (5.6)	7/428 (1.6)	3.29 (1.41, 7.69)	0.0060	
	Positive (At any time)	4/ 31 (12.9)	0/ 39 (0.0)	6.29 (0.83, 47.91)	0.0757	
	BMI (kg/m2)					0.7903
	< 30	19/309 (6.1)	5/339 (1.5)	3.90 (1.45, 10.51)	0.0071	
	>= 30	9/150 (6.0)	2/128 (1.6)	3.09 (0.76, 12.56)	0.1145	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=467) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Nasopharyngitis	SLEDAI-2K score					0.8988
	< 10 points	19/148 (12.8)	11/146 (7.5)	1.59 (0.77, 3.27)	0.2076	
	>= 10 points	57/311 (18.3)	35/321 (10.9)	1.68 (1.14, 2.48)	0.0094	
	OCS dose					0.8838
	<10 mg/day	30/214 (14.0)	19/218 (8.7)	1.59 (0.92, 2.75)	0.0990	
	>=10 mg/day	46/245 (18.8)	27/249 (10.8)	1.67 (1.08, 2.59)	0.0212	
	Result of type I IFN gene signature test					0.2460
	LOW	12/ 86 (14.0)	4/ 90 (4.4)	3.04 (1.01, 9.17)	0.0485	
	HIGH	64/373 (17.2)	42/377 (11.1)	1.53 (1.06, 2.19)	0.0216	
	Age (years)					0.7682
	<= 65	74/447 (16.6)	46/463 (9.9)	1.65 (1.17, 2.32)	0.0046	
	> 65	2/ 12 (16.7)	0/ 4 (0.0)	1.21 (0.16, 9.16)	0.8549	
	Sex					0.1511
	male	4/ 33 (12.1)	6/ 34 (17.6)	0.71 (0.22, 2.33)	0.5771	
	female	72/426 (16.9)	40/433 (9.2)	1.77 (1.23, 2.55)	0.0021	
	Race					0.4849
	White	34/270 (12.6)	26/285 (9.1)	1.40 (0.86, 2.27)	0.1760	
	Black	6/ 65 (9.2)	4/ 59 (6.8)	1.39 (0.39, 4.86)	0.6110	
	Other	36/116 (31.0)	15/115 (13.0)	2.13 (1.26, 3.59)	0.0045	
	Ethnicity					0.2428
	Hispanic/Latino	22/132 (16.7)	8/131 (6.1)	2.44 (1.17, 5.09)	0.0174	
	Non-hispanic/Latino	54/319 (16.9)	37/328 (11.3)	1.49 (1.01, 2.19)	0.0454	
	Geographic region					0.5451
	EU	26/135 (19.3)	20/147 (13.6)	1.45 (0.84, 2.48)	0.1801	
	non-EU	50/324 (15.4)	26/320 (8.1)	1.80 (1.14, 2.82)	0.0110	
	Onset of disease					0.6799
	Paediatric	5/ 36 (13.9)	3/ 35 (8.6)	1.22 (0.27, 5.42)	0.7972	
	Adult	71/423 (16.8)	43/432 (10.0)	1.68 (1.18, 2.39)	0.0039	
	ADA result					0.1518
	Negative	66/427 (15.5)	44/428 (10.3)	1.47 (1.03, 2.11)	0.0333	
	Positive (At any time)	10/ 31 (32.3)	2/ 39 (5.1)	3.61 (1.12, 11.61)	0.0316	
	BMI (kg/m2)					0.6252
	< 30	56/309 (18.1)	35/339 (10.3)	1.75 (1.18, 2.59)	0.0053	
	>= 30	20/150 (13.3)	11/128 (8.6)	1.41 (0.66, 3.02)	0.3701	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=467) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Respiratory tract infection	SLEDAI-2K score					0.6822
	< 10 points	4/148 (2.7)	0/146 (0.0)	4.86 (0.58, 40.96)	0.1456	
	>= 10 points	10/311 (3.2)	2/321 (0.6)	2.87 (0.73, 11.20)	0.1296	
	OCS dose					0.8287
	<10 mg/day	9/214 (4.2)	2/218 (0.9)	3.27 (0.77, 13.84)	0.1081	
	>=10 mg/day	5/245 (2.0)	0/249 (0.0)	4.21 (0.70, 25.21)	0.1153	
	Result of type I IFN gene signature test					0.9103
	LOW	1/ 86 (1.2)	0/ 90 (0.0)	3.10 (0.13, 73.16)	0.4836	
	HIGH	13/373 (3.5)	2/377 (0.5)	3.77 (1.04, 13.70)	0.0439	
	Age (years)					NE
	<= 65	14/447 (3.1)	2/463 (0.4)	3.97 (1.09, 14.45)	0.0362	
	> 65	0/ 12 (0.0)	0/ 4 (0.0)	NE		
	Sex					0.2600
	male	2/ 33 (6.1)	1/ 34 (2.9)	1.32 (0.15, 11.16)	0.8018	
	female	12/426 (2.8)	1/433 (0.2)	5.92 (1.31, 26.77)	0.0209	
	Race					0.8541
	White	12/270 (4.4)	2/285 (0.7)	3.56 (0.95, 13.28)	0.0587	
	Black	0/ 65 (0.0)	0/ 59 (0.0)	NE		
	Other	2/116 (1.7)	0/115 (0.0)	2.79 (0.30, 26.14)	0.3685	
	Ethnicity					0.1071
	Hispanic/Latino	0/132 (0.0)	1/131 (0.8)	0.36 (0.02, 8.62)	0.5311	
	Non-hispanic/Latino	14/319 (4.4)	1/328 (0.3)	6.49 (1.44, 29.18)	0.0148	
	Geographic region					0.2401
	EU	9/135 (6.7)	0/147 (0.0)	7.08 (1.27, 39.46)	0.0255	
	non-EU	5/324 (1.5)	2/320 (0.6)	1.56 (0.25, 9.89)	0.6355	
	Onset of disease					0.8256
	Paediatric	1/ 36 (2.8)	0/ 35 (0.0)	2.60 (0.12, 58.48)	0.5475	
	Adult	13/423 (3.1)	2/432 (0.5)	3.80 (1.04, 13.82)	0.0429	
	ADA result					NE
	Negative	14/427 (3.3)	2/428 (0.5)	3.90 (1.07, 14.19)	0.0386	
	Positive (At any time)	0/ 31 (0.0)	0/ 39 (0.0)	NE		
	BMI (kg/m2)					0.7517
	< 30	9/309 (2.9)	1/339 (0.3)	4.35 (0.89, 21.30)	0.0700	
	>= 30	5/150 (3.3)	1/128 (0.8)	2.95 (0.49, 17.77)	0.2375	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=467) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Upper respiratory tract infection	SLEDAI-2K score					0.7974
	< 10 points	26/148 (17.6)	14/146 (9.6)	1.70 (0.91, 3.16)	0.0951	
	>= 10 points	48/311 (15.4)	32/321 (10.0)	1.54 (1.01, 2.34)	0.0450	
	OCS dose					0.5275
	<10 mg/day	39/214 (18.2)	27/218 (12.4)	1.45 (0.92, 2.30)	0.1120	
	>=10 mg/day	35/245 (14.3)	19/249 (7.6)	1.82 (1.07, 3.12)	0.0282	
	Result of type I IFN gene signature test					0.7969
	LOW	16/ 86 (18.6)	7/ 90 (7.8)	1.71 (0.71, 4.10)	0.2331	
	HIGH	58/373 (15.5)	39/377 (10.3)	1.50 (1.03, 2.20)	0.0355	
	Age (years)					0.9931
	<= 65	71/447 (15.9)	46/463 (9.9)	1.59 (1.12, 2.26)	0.0096	
	> 65	3/ 12 (25.0)	0/ 4 (0.0)	1.58 (0.22, 11.26)	0.6499	
	Sex					0.7078
	male	4/ 33 (12.1)	3/ 34 (8.8)	1.27 (0.33, 4.82)	0.7300	
	female	70/426 (16.4)	43/433 (9.9)	1.65 (1.15, 2.36)	0.0061	
	Race					0.5035
	White	47/270 (17.4)	31/285 (10.9)	1.56 (1.01, 2.41)	0.0438	
	Black	9/ 65 (13.8)	1/ 59 (1.7)	3.34 (0.62, 18.14)	0.1617	
	Other	18/116 (15.5)	14/115 (12.2)	1.20 (0.64, 2.25)	0.5685	
	Ethnicity					0.2255
	Hispanic/Latino	22/132 (16.7)	9/131 (6.9)	2.43 (1.16, 5.09)	0.0184	
	Non-hispanic/Latino	52/319 (16.3)	37/328 (11.3)	1.45 (0.97, 2.15)	0.0692	
	Geographic region					0.9975
	EU	10/135 (7.4)	7/147 (4.8)	1.63 (0.64, 4.14)	0.3067	
	non-EU	64/324 (19.8)	39/320 (12.2)	1.63 (1.13, 2.36)	0.0096	
	Onset of disease					0.8492
	Paediatric	6/ 36 (16.7)	4/ 35 (11.4)	1.46 (0.45, 4.72)	0.5255	
	Adult	68/423 (16.1)	42/432 (9.7)	1.65 (1.14, 2.37)	0.0072	
	ADA result					0.4078
	Negative	73/427 (17.1)	43/428 (10.0)	1.68 (1.18, 2.40)	0.0044	
	Positive (At any time)	1/ 31 (3.2)	3/ 39 (7.7)	0.76 (0.12, 4.76)	0.7731	
	BMI (kg/m2)					0.4971
	< 30	45/309 (14.6)	28/339 (8.3)	1.74 (1.11, 2.72)	0.0153	
	>= 30	29/150 (19.3)	18/128 (14.1)	1.34 (0.72, 2.47)	0.3524	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=467) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SOC: Musculoskeletal and connective tissue disorders, PT: Arthralgia	SLEDAI-2K score					0.0480
	< 10 points	6/148 (4.1)	7/146 (4.8)	0.92 (0.31, 2.72)	0.8795	
	>= 10 points	16/311 (5.1)	3/321 (0.9)	4.88 (1.40, 17.02)	0.0130	
	OCS dose					0.4359
	<10 mg/day	9/214 (4.2)	6/218 (2.8)	1.55 (0.55, 4.32)	0.4049	
	>=10 mg/day	13/245 (5.3)	4/249 (1.6)	2.79 (0.96, 8.11)	0.0598	
	Result of type I IFN gene signature test					0.0908
	LOW	4/ 86 (4.7)	5/ 90 (5.6)	0.85 (0.24, 3.04)	0.8073	
	HIGH	18/373 (4.8)	5/377 (1.3)	3.35 (1.30, 8.60)	0.0122	
	Age (years)					0.0900
	<= 65	22/447 (4.9)	9/463 (1.9)	2.37 (1.08, 5.18)	0.0305	
	> 65	0/ 12 (0.0)	1/ 4 (25.0)	0.17 (0.01, 3.24)	0.2366	
	Sex					0.7729
	male	2/ 33 (6.1)	0/ 34 (0.0)	2.81 (0.31, 25.36)	0.3581	
	female	20/426 (4.7)	10/433 (2.3)	1.99 (0.94, 4.24)	0.0733	
	Race					0.1050
	White	15/270 (5.6)	4/285 (1.4)	3.84 (1.29, 11.43)	0.0158	
	Black	0/ 65 (0.0)	3/ 59 (5.1)	0.28 (0.03, 2.42)	0.2468	
	Other	7/116 (6.0)	3/115 (2.6)	2.07 (0.60, 7.17)	0.2503	
	Ethnicity					0.9646
	Hispanic/Latino	3/132 (2.3)	1/131 (0.8)	2.00 (0.26, 15.17)	0.5042	
	Non-hispanic/Latino	19/319 (6.0)	9/328 (2.7)	2.10 (0.95, 4.62)	0.0661	
	Geographic region					0.2562
	EU	5/135 (3.7)	0/147 (0.0)	6.16 (0.75, 50.59)	0.0904	
	non-EU	17/324 (5.2)	10/320 (3.1)	1.68 (0.78, 3.63)	0.1857	
	Onset of disease					0.7789
	Paediatric	2/ 36 (5.6)	0/ 35 (0.0)	2.79 (0.31, 25.19)	0.3599	
	Adult	20/423 (4.7)	10/432 (2.3)	2.00 (0.94, 4.26)	0.0713	
	ADA result					0.0951
	Negative	21/427 (4.9)	6/428 (1.4)	2.93 (1.15, 7.47)	0.0245	
	Positive (At any time)	1/ 31 (3.2)	4/ 39 (10.3)	0.56 (0.10, 3.08)	0.5024	
	BMI (kg/m2)					0.1423
	< 30	13/309 (4.2)	3/339 (0.9)	3.30 (1.07, 10.22)	0.0382	
	>= 30	9/150 (6.0)	7/128 (5.5)	1.09 (0.41, 2.85)	0.8686	

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Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=467) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SOC: Musculoskeletal and connective tissue disorders, PT: Pain in extremity	SLEDAI-2K score					0.4977
	< 10 points	4/148 (2.7)	2/146 (1.4)	1.88 (0.33, 10.63)	0.4745	
	>= 10 points	8/311 (2.6)	1/321 (0.3)	4.20 (0.89, 19.80)	0.0694	
	OCS dose					0.9497
	<10 mg/day	8/214 (3.7)	2/218 (0.9)	2.83 (0.66, 12.10)	0.1598	
	>=10 mg/day	4/245 (1.6)	1/249 (0.4)	3.05 (0.49, 19.10)	0.2325	
	Result of type I IFN gene signature test					0.4343
	LOW	2/ 86 (2.3)	1/ 90 (1.1)	1.51 (0.24, 9.34)	0.6600	
	HIGH	10/373 (2.7)	2/377 (0.5)	3.82 (0.89, 16.38)	0.0710	
	Age (years)					NE
	<= 65	12/447 (2.7)	3/463 (0.6)	3.81 (1.05, 13.80)	0.0419	
	> 65	0/ 12 (0.0)	0/ 4 (0.0)	NE		
	Sex					0.7929
	male	2/ 33 (6.1)	0/ 34 (0.0)	5.00 (0.27, 94.34)	0.2829	
	female	10/426 (2.3)	3/433 (0.7)	3.25 (0.89, 11.92)	0.0753	
	Race					0.9037
	White	7/270 (2.6)	2/285 (0.7)	2.96 (0.67, 13.17)	0.1538	
	Black	4/ 65 (6.2)	0/ 59 (0.0)	5.23 (0.62, 44.28)	0.1289	
	Other	1/116 (0.9)	0/115 (0.0)	2.80 (0.12, 67.00)	0.5242	
	Ethnicity					0.2983
	Hispanic/Latino	1/132 (0.8)	1/131 (0.8)	0.91 (0.06, 14.14)	0.9481	
	Non-hispanic/Latino	11/319 (3.4)	1/328 (0.3)	4.87 (1.02, 23.31)	0.0474	
	Geographic region					0.9136
	EU	4/135 (3.0)	1/147 (0.7)	2.51 (0.46, 13.80)	0.2903	
	non-EU	8/324 (2.5)	2/320 (0.6)	2.20 (0.44, 11.04)	0.3367	
	Onset of disease					0.7086
	Paediatric	2/ 36 (5.6)	0/ 35 (0.0)	5.45 (0.29, 101.55)	0.2555	
	Adult	10/423 (2.4)	3/432 (0.7)	2.95 (0.75, 11.54)	0.1206	
	ADA result					0.8823
	Negative	10/427 (2.3)	3/428 (0.7)	2.88 (0.74, 11.29)	0.1280	
	Positive (At any time)	2/ 31 (6.5)	0/ 39 (0.0)	2.38 (0.27, 20.64)	0.4319	
	BMI (kg/m2)					0.2454
	< 30	8/309 (2.6)	1/339 (0.3)	4.71 (1.02, 21.88)	0.0478	
	>= 30	4/150 (2.7)	2/128 (1.6)	1.22 (0.22, 6.61)	0.8206	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=467) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SOC: Vascular disorders	SLEDAI-2K score					0.3577
	< 10 points	5/148 (3.4)	6/146 (4.1)	0.82 (0.24, 2.76)	0.7500	
	>= 10 points	9/311 (2.9)	23/321 (7.2)	0.41 (0.18, 0.95)	0.0364	
	OCS dose					0.4758
	<10 mg/day	7/214 (3.3)	10/218 (4.6)	0.65 (0.20, 2.08)	0.4658	
	>=10 mg/day	7/245 (2.9)	19/249 (7.6)	0.38 (0.16, 0.90)	0.0270	
	Result of type I IFN gene signature test					0.8568
	LOW	1/ 86 (1.2)	4/ 90 (4.4)	0.43 (0.06, 3.11)	0.3997	
	HIGH	13/373 (3.5)	25/377 (6.6)	0.52 (0.25, 1.05)	0.0669	
	Age (years)					0.6039
	<= 65	13/447 (2.9)	29/463 (6.3)	0.47 (0.24, 0.93)	0.0292	
	> 65	1/ 12 (8.3)	0/ 4 (0.0)	1.00 (0.06, 15.99)	1.0000	
	Sex					0.4853
	male	1/ 33 (3.0)	1/ 34 (2.9)	1.10 (0.12, 9.72)	0.9335	
	female	13/426 (3.1)	28/433 (6.5)	0.49 (0.24, 0.98)	0.0444	
	Race					0.9616
	White	8/270 (3.0)	21/285 (7.4)	0.55 (0.22, 1.34)	0.1856	
	Black	2/ 65 (3.1)	2/ 59 (3.4)	0.70 (0.11, 4.44)	0.7045	
	Other	3/116 (2.6)	6/115 (5.2)	0.65 (0.16, 2.60)	0.5430	
	Ethnicity					0.2372
	Hispanic/Latino	5/132 (3.8)	7/131 (5.3)	0.98 (0.28, 3.46)	0.9733	
	Non-hispanic/Latino	8/319 (2.5)	22/328 (6.7)	0.39 (0.17, 0.91)	0.0288	
	Geographic region					0.6516
	EU	5/135 (3.7)	14/147 (9.5)	0.48 (0.16, 1.42)	0.1856	
	non-EU	9/324 (2.8)	15/320 (4.7)	0.66 (0.28, 1.56)	0.3432	
	Onset of disease					0.7939
	Paediatric	0/ 36 (0.0)	1/ 35 (2.9)	0.33 (0.01, 7.45)	0.4883	
	Adult	14/423 (3.3)	28/432 (6.5)	0.51 (0.26, 1.00)	0.0500	
	ADA result					0.7741
	Negative	14/427 (3.3)	28/428 (6.5)	0.49 (0.24, 0.98)	0.0430	
	Positive (At any time)	0/ 31 (0.0)	1/ 39 (2.6)	0.78 (0.03, 17.33)	0.8739	
	BMI (kg/m2)					0.6841
	< 30	10/309 (3.2)	22/339 (6.5)	0.37 (0.15, 0.92)	0.0323	
	>= 30	4/150 (2.7)	7/128 (5.5)	0.51 (0.15, 1.76)	0.2876	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Adverse Events by SOC, PT (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT	Subgroup Level	Anifrolumab 300mg (N=459) n/ N (%)	Placebo (N=467) n/ N (%)	Analysis Anifrolumab 300mg vs. Placebo Relative Risk (95% CI)	p-Value	Interaction p-Value
SOC: Vascular disorders, PT: Hypertension	SLEDAI-2K score					0.2311
	< 10 points	3/148 (2.0)	3/146 (2.1)	1.04 (0.22, 4.92)	0.9654	
	>= 10 points	4/311 (1.3)	15/321 (4.7)	0.31 (0.10, 1.02)	0.0532	
	OCS dose					0.3130
	<10 mg/day	3/214 (1.4)	4/218 (1.8)	0.87 (0.19, 4.06)	0.8565	
	>=10 mg/day	4/245 (1.6)	14/249 (5.6)	0.33 (0.12, 0.94)	0.0381	
	Result of type I IFN gene signature test					0.6100
	LOW	0/ 86 (0.0)	3/ 90 (3.3)	0.27 (0.03, 2.36)	0.2360	
	HIGH	7/373 (1.9)	15/377 (4.0)	0.50 (0.20, 1.24)	0.1324	
	Age (years)					0.4811
	<= 65	6/447 (1.3)	18/463 (3.9)	0.35 (0.14, 0.88)	0.0247	
	> 65	1/ 12 (8.3)	0/ 4 (0.0)	1.00 (0.06, 15.99)	1.0000	
	Sex					0.4137
	male	1/ 33 (3.0)	1/ 34 (2.9)	1.10 (0.12, 9.72)	0.9335	
	female	6/426 (1.4)	17/433 (3.9)	0.41 (0.16, 1.06)	0.0648	
	Race					0.4546
	White	4/270 (1.5)	14/285 (4.9)	0.41 (0.13, 1.26)	0.1180	
	Black	2/ 65 (3.1)	0/ 59 (0.0)	3.00 (0.16, 57.36)	0.4656	
	Other	1/116 (0.9)	4/115 (3.5)	0.43 (0.08, 2.34)	0.3270	
	Ethnicity					0.9918
	Hispanic/Latino	2/132 (1.5)	6/131 (4.6)	0.44 (0.10, 2.02)	0.2907	
	Non-hispanic/Latino	5/319 (1.6)	12/328 (3.7)	0.44 (0.16, 1.25)	0.1251	
	Geographic region					0.2233
	EU	1/135 (0.7)	9/147 (6.1)	0.20 (0.04, 1.08)	0.0608	
	non-EU	6/324 (1.9)	9/320 (2.8)	0.68 (0.24, 1.92)	0.4632	
	Onset of disease					0.8800
	Paediatric	0/ 36 (0.0)	1/ 35 (2.9)	0.33 (0.01, 7.45)	0.4883	
	Adult	7/423 (1.7)	17/432 (3.9)	0.43 (0.18, 1.03)	0.0572	
	ADA result					0.7250
	Negative	7/427 (1.6)	17/428 (4.0)	0.44 (0.18, 1.06)	0.0675	
	Positive (At any time)	0/ 31 (0.0)	1/ 39 (2.6)	0.78 (0.03, 17.33)	0.8739	
	BMI (kg/m2)					0.9055
	< 30	4/309 (1.3)	12/339 (3.5)	0.41 (0.13, 1.33)	0.1371	
	>= 30	3/150 (2.0)	6/128 (4.7)	0.46 (0.11, 1.83)	0.2676	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Serious Adverse Events by SOC, PT (incidence in either arm >= 5% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Infections and infestations	Number of subjects with events, n (%)	23 (5.0)	30 (6.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.78 (0.46, 1.33)	
	p-value	0.3681	
	Odds Ratio (95% CI)	0.77 (0.44, 1.35)	
	p-value	0.3648	
	Risk Difference (95% CI)	-1.41 (-4.40, 1.57)	
	p-value	0.3542	
	p-Value for test for heterogenity between studies	0.7511	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Serious Adverse Events by SOC, PT (incidence in either arm >= 5% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Infections and infestations, PT: Pneumonia	Number of subjects with events, n (%)	8 (1.7)	10 (2.1)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.79 (0.29, 2.12)	
	p-value	0.6388	
	Odds Ratio (95% CI)	0.79 (0.29, 2.16)	
	p-value	0.6435	
	Risk Difference (95% CI)	-0.40 (-2.18, 1.38)	
	p-value	0.6577	
	p-Value for test for heterogenity between studies	0.3274	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Serious Adverse Events by SOC, PT (incidence in either arm >= 5% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Musculoskeletal and connective tissue disorders	Number of subjects with events, n (%)	10 (2.2)	16 (3.4)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.66 (0.29, 1.51)	
	p-value	0.3203	
	Odds Ratio (95% CI)	0.65 (0.28, 1.52)	
	p-value	0.3188	
	Risk Difference (95% CI)	-1.25 (-3.37, 0.88)	
	p-value	0.2499	
	p-Value for test for heterogenity between studies	0.2299	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Serious Adverse Events by SOC, PT (incidence in either arm >= 5% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Musculoskeletal and connective tissue disorders, PT: Systemic lupus erythematosus	Number of subjects with events, n (%)	7 (1.5)	15 (3.2)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.52 (0.21, 1.32)	
	p-value	0.1689	
	Odds Ratio (95% CI)	0.51 (0.20, 1.32)	
	p-value	0.1661	
	Risk Difference (95% CI)	-1.69 (-3.64, 0.26)	
	p-value	0.0902	
	p-Value for test for heterogenity between studies	0.4074	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Serious Adverse Events by SOC, PT (incidence in either arm >= 5% or >=10 patients) - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

- NO OBSERVATIONS FOR THIS ANALYSIS -

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Severe (Grade >=3) by SOC, PT (incidence in either arm >= 5% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Infections and infestations	Number of subjects with events, n (%)	23 (5.0)	12 (2.6)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	1.93 (0.97, 3.87)	
	p-value	0.0623	
	Odds Ratio (95% CI)	1.99 (0.96, 4.10)	
	p-value	0.0628	
	Risk Difference (95% CI)	2.45 (0.00, 4.90)	
	p-value	0.0500	
	p-Value for test for heterogenity between studies	0.5824	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Severe (Grade >=3) by SOC, PT (incidence in either arm >= 5% or >=10 patients)
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

SOC / PT		Anifrolumab 300mg (N=459)	Placebo (N=467)
SOC: Musculoskeletal and connective tissue disorders	Number of subjects with events, n (%)	4 (0.9)	10 (2.1)
	Analysis Anifrolumab 300mg vs. Placebo		
	Relative Risk (95% CI)	0.52 (0.16, 1.71)	
	p-value	0.2825	
	Odds Ratio (95% CI)	0.51 (0.15, 1.71)	
	p-value	0.2774	
	Risk Difference (95% CI)	-1.27 (-2.83, 0.30)	
	p-value	0.1126	
	p-Value for test for heterogenity between studies	0.3881	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for heterogenity between studies from test for heterogeneity of the relative risks in the studies using Cochranes Q statistic.
Analysis of Relative Risks, Odds Ratios and Risk Differences includes factor for study.

Anifrolumab (MEDI-546)
D3461C00005 (TULIP SLE Study 1) + D3461C00004 (TULIP SLE Study 2) + D3461C00001 (MUSE) Meta-Analysis - Anifrolumab 300mg vs. Placebo population
Proportion of patients with at least one frequent Severe (Grade >=3) by SOC, PT (incidence in either arm >= 5% or >=10 patients) - Subgroup analysis
Full analysis set (Tulip1,Tulip2) & Safety analysis set (MUSE)

- NO OBSERVATIONS FOR THIS ANALYSIS -

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= date of last dose of investigational product + 28 days.
Relative Risk estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)
p-Value for interaction from test for heterogeneity of the relative risks in the subgroups using Cochranes Q statistic.
Analysis of Relative Risks includes factor for study.

Anhang 4-G3: Zusatzanalysen, TULIP SLE LTE, ITT-Population, nur in Deutschland zugelassene Medikamente

Contents

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Subject disposition and summary of treatment exposure (TULIP + LTE)
Full analysis set

		Randomised Anifrolumab 300mg (N=246)	Randomised Placebo (N=246)
Patients who completed the study		40 (16.3)	117 (47.6)
Patients ongoing		134 (54.5)	41 (16.7)
Patients withdrawn from the study		72 (29.3)	88 (35.8)
WITHDRAWAL BY SUBJECT		34 (13.8)	42 (17.1)
ADVERSE EVENT		17 (6.9)	10 (4.1)
LACK OF EFFICACY		10 (4.1)	14 (5.7)
OTHER		6 (2.4)	9 (3.7)
LOST TO FOLLOW-UP		3 (1.2)	7 (2.8)
CONDITION UNDER INVESTIGATION WORSENED		2 (0.8)	2 (0.8)
SEVERE NON-COMPLIANCE TO PROTOCOL		0	2 (0.8)
DEATH		0	1 (0.4)
MISSING		0	1 (0.4)
Duration of study (weeks)	n (missing)	246 (0)	246 (0)
	Mean (SD)	129.7 (63.55)	80.5 (56.44)
	Median	150.2	53.2
	Min, Max	0, 241	3, 241
Patients who completed IP		36 (14.6)	108 (43.9)
Patients ongoing on IP		118 (48.0)	40 (16.3)
Patients discontinued IP		92 (37.4)	98 (39.8)
Withdrawal By Subject		29 (11.8)	36 (14.6)
Adverse Event		23 (9.3)	18 (7.3)
Lack Of Efficacy		13 (5.3)	19 (7.7)
Other		17 (6.9)	10 (4.1)
Lost To Follow-Up		4 (1.6)	6 (2.4)
Condition Under Investigation Worsened		4 (1.6)	5 (2.0)
Progressive Disease		2 (0.8)	1 (0.4)
Severe Non-Compliance To Protocol		0	3 (1.2)
Duration of exposure (weeks)	n (missing)	246 (0)	246 (0)
	Mean (SD)	123.3 (66.43)	74.0 (56.75)
	Median	145.1	52.1
	Min, Max	0, 213	3, 215

Completion of study 09 is based upon the number of patients completing up to and including Week 208.
Completion of IP in study 09 is based upon the number of patients completing treatment with IP up to and including Week 204.
23 patients were incorrectly counted as having discontinued treatment.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Subject disposition and summary of treatment exposure (study 09)
Full analysis set

		Anifrolumab 300mg (N=173)	Placebo Feeder + Placebo LTE (N=72)
Patients who completed the study		6 (3.5)	4 (5.6)
Patients ongoing		134 (77.5)	41 (56.9)
Patients withdrawn from the study		33 (19.1)	27 (37.5)
WITHDRAWAL BY SUBJECT		15 (8.7)	13 (18.1)
LACK OF EFFICACY		6 (3.5)	4 (5.6)
ADVERSE EVENT		8 (4.6)	1 (1.4)
LOST TO FOLLOW-UP		3 (1.7)	3 (4.2)
OTHER		1 (0.6)	4 (5.6)
DEATH		0	1 (1.4)
SEVERE NON-COMPLIANCE TO PROTOCOL		0	1 (1.4)
Duration of study (weeks)	n (missing)	173 (0)	72 (0)
	Mean (SD)	164.9 (37.46)	158.5 (42.42)
	Median	168.0	162.3
	Min, Max	59, 241	70, 241
Patients who completed IP		4 (2.3)	0
Patients ongoing on IP		118 (68.2)	40 (55.6)
Patients discontinued IP		51 (29.5)	32 (44.4)
Withdrawal By Subject		14 (8.1)	12 (16.7)
Other		10 (5.8)	8 (11.1)
Lack Of Efficacy		9 (5.2)	6 (8.3)
Adverse Event		12 (6.9)	1 (1.4)
Lost To Follow-Up		3 (1.7)	3 (4.2)
Progressive Disease		2 (1.2)	1 (1.4)
Condition Under Investigation Worsened		1 (0.6)	0
Severe Non-Compliance To Protocol		0	1 (1.4)
Duration of exposure (weeks)	n (missing)	173 (0)	72 (0)
	Mean (SD)	160.2 (39.36)	151.2 (44.32)
	Median	164.6	153.6
	Min, Max	56, 213	57, 215

Completion of study 09 is based upon the number of patients completing up to and including Week 208.
Completion of IP in study 09 is based upon the number of patients completing treatment with IP up to and including Week 204.
29 patients were incorrectly counted as having discontinued treatment.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Demographic and baseline characteristics
Full analysis set

		Randomised Anifrolumab 300mg (N=246)	Randomised Placebo (N=246)	Total (N=492)
Age	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	42.8 (11.73)	40.8 (11.53)	41.8 (11.66)
	Median	42.0	41.0	41.5
	Min, Max	18, 68	19, 69	18, 69
Age subgroups (%)	<= 65	239 (97.2)	243 (98.8)	482 (98.0)
	> 65	7 (2.8)	3 (1.2)	10 (2.0)
Sex (%)	female	223 (90.7)	226 (91.9)	449 (91.3)
	male	23 (9.3)	20 (8.1)	43 (8.7)
Race (%)	American Indian or Alaska Native	0	1 (0.4)	1 (0.2)
	Asian	24 (9.8)	19 (7.7)	43 (8.7)
	Black or African American	33 (13.4)	32 (13.0)	65 (13.2)
	Other	21 (8.5)	17 (6.9)	38 (7.7)
	White	160 (65.0)	174 (70.7)	334 (67.9)
	Missing	8 (3.3)	3 (1.2)	11 (2.2)
Ethnicity (%)	Hispanic/Latino	50 (20.3)	56 (22.8)	106 (21.5)
	Non-hispanic/Latino	188 (76.4)	187 (76.0)	375 (76.2)
	Missing	8 (3.3)	3 (1.2)	11 (2.2)
Geographic region (%)	Asia Pacific	21 (8.5)	16 (6.5)	37 (7.5)
	Europe	92 (37.4)	89 (36.2)	181 (36.8)
	Latin America	33 (13.4)	32 (13.0)	65 (13.2)
	North America	95 (38.6)	100 (40.7)	195 (39.6)
	Rest Of World	5 (2.0)	9 (3.7)	14 (2.8)
Geographic region subgroup (%)	EU	92 (37.4)	89 (36.2)	181 (36.8)
	non-EU	154 (62.6)	157 (63.8)	311 (63.2)
Height (cm)	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	163.20 (8.167)	163.38 (7.996)	163.29 (8.074)
	Median	162.60	163.00	163.00
	Min, Max	145.0, 198.0	140.0, 195.0	140.0, 198.0
Weight (cm)	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	74.56 (20.129)	73.16 (18.263)	73.86 (19.212)
	Median	70.60	68.90	69.90
	Min, Max	42.0, 132.7	42.2, 138.0	42.0, 138.0
BMI (kg/m^2)	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	27.92 (6.999)	27.46 (6.887)	27.69 (6.940)
	Median	25.91	25.67	25.79
	Min, Max	16.0, 49.8	17.2, 57.5	16.0, 57.5
BMI (%)	<=28 kg/m2	142 (57.7)	150 (61.0)	292 (59.3)
	>28 kg/m2	104 (42.3)	96 (39.0)	200 (40.7)

[a] Asia Pacific: Australia, New Zealand, South Korea, Taiwan. Europe: Germany, Hungary, Italy, Poland, Romania, Ukraine, United Kingdom. Latin America: Argentinia, Brazil, Chile, Colombia, Peru. Rest of World: Israel.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SLE disease characteristics
Full analysis set

		Randomised Anifrolumab 300mg (N=246)	Randomised Placebo (N=246)	Total (N=492)
SLEDAI-2K score at screening	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	11.4 (3.89)	11.1 (3.39)	11.3 (3.64)
	Median	10.0	10.0	10.0
	Min, Max	6, 25	6, 24	6, 25
SLEDAI-2K score at screening, categorisation (%)	< 10 points	80 (32.5)	69 (28.0)	149 (30.3)
	>= 10 points	166 (67.5)	177 (72.0)	343 (69.7)
Clinical SLEDAI-2K score at screening	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	8.7 (3.03)	8.6 (2.63)	8.6 (2.83)
	Median	8.0	8.0	8.0
	Min, Max	4, 20	4, 18	4, 20
SLEDAI-2K score at baseline	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	11.3 (3.77)	11.4 (3.65)	11.3 (3.71)
	Median	10.0	10.0	10.0
	Min, Max	4, 32	4, 26	4, 32
SLEDAI-2K score at baseline, categorisation (%)	< 10 points	78 (31.7)	69 (28.0)	147 (29.9)
	>= 10 points	168 (68.3)	177 (72.0)	345 (70.1)
Clinical SLEDAI-2K score at baseline	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	8.8 (2.95)	8.9 (2.68)	8.8 (2.82)
	Median	8.0	8.0	8.0
	Min, Max	4, 20	4, 18	4, 20
Total Organ Score CNS	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	0.0 (0.51)	0.1 (0.72)	0.0 (0.62)
	Median	0.0	0.0	0.0
	Min, Max	0, 8	0, 8	0, 8
Total Organ Score CVS and Respiratory	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	0.1 (0.49)	0.1 (0.55)	0.1 (0.52)
	Median	0.0	0.0	0.0
	Min, Max	0, 2	0, 4	0, 4
Total Organ Score Hematological	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	0.2 (0.37)	0.1 (0.36)	0.1 (0.36)
	Median	0.0	0.0	0.0
	Min, Max	0, 2	0, 2	0, 2
Total Organ Score Immunology	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	2.0 (1.61)	1.9 (1.64)	1.9 (1.62)
	Median	2.0	2.0	2.0
	Min, Max	0, 4	0, 4	0, 4
Total Organ Score Mucocutaneous	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	4.0 (1.59)	4.0 (1.61)	4.0 (1.60)
	Median	4.0	4.0	4.0
	Min, Max	0, 6	0, 6	0, 6
Total Organ Score Musculoskeletal	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	3.7 (1.16)	3.9 (1.05)	3.8 (1.11)
	Median	4.0	4.0	4.0
	Min, Max	0, 8	0, 8	0, 8
Total Organ Score Renal	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	0.4 (1.45)	0.5 (1.74)	0.4 (1.60)
	Median	0.0	0.0	0.0
	Min, Max	0, 12	0, 12	0, 12

Baseline is defined as the last measurement prior to randomisation and dose administration on Day 1.
Only subjects with baseline positive anti-dsDNA and abnormal complement level, respectively, are included in the summary statistics for the respective variables.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SLE disease characteristics
Full analysis set

		Randomised Anifrolumab 300mg (N=246)	Randomised Placebo (N=246)	Total (N=492)
Total Organ Score Vascular	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	0.9 (2.55)	0.8 (2.46)	0.9 (2.50)
	Median	0.0	0.0	0.0
	Min, Max	0, 8	0, 8	0, 8
Adjudication Scoring (BILAG) at baseline Overall (%)	At least one A	107 (43.5)	123 (50.0)	230 (46.7)
	No A and <2Bs	11 (4.5)	17 (6.9)	28 (5.7)
	No A and at least 2 Bs	128 (52.0)	106 (43.1)	234 (47.6)
Adjudication Scoring (BILAG) at baseline Constitutional (%)	A	1 (0.4)	0	1 (0.2)
	B	14 (5.7)	11 (4.5)	25 (5.1)
	C, D or E	231 (93.9)	235 (95.5)	466 (94.7)
Adjudication Scoring (BILAG) at baseline Mucocutaneous (%)	A	53 (21.5)	56 (22.8)	109 (22.2)
	B	163 (66.3)	151 (61.4)	314 (63.8)
	C, D or E	30 (12.2)	39 (15.9)	69 (14.0)
Adjudication Scoring (BILAG) at baseline Neuropsychiatric (%)	B	5 (2.0)	4 (1.6)	9 (1.8)
	C, D or E	241 (98.0)	242 (98.4)	483 (98.2)
Adjudication Scoring (BILAG) at baseline Musculoskeletal (%)	A	68 (27.6)	77 (31.3)	145 (29.5)
	B	146 (59.3)	146 (59.3)	292 (59.3)
	C, D or E	32 (13.0)	23 (9.3)	55 (11.2)
Adjudication Scoring (BILAG) at baseline Cardiorespiratory (%)	A	2 (0.8)	2 (0.8)	4 (0.8)
	B	13 (5.3)	13 (5.3)	26 (5.3)
	C, D or E	231 (93.9)	231 (93.9)	462 (93.9)
Adjudication Scoring (BILAG) at baseline Gastrointestinal (%)	B	0	2 (0.8)	2 (0.4)
	C, D or E	246 (100.0)	244 (99.2)	490 (99.6)
Adjudication Scoring (BILAG) at baseline Ophthalmic (%)	A	1 (0.4)	0	1 (0.2)
	B	0	1 (0.4)	1 (0.2)
	C, D or E	245 (99.6)	245 (99.6)	490 (99.6)
Adjudication Scoring (BILAG) at baseline Renal (%)	A	1 (0.4)	4 (1.6)	5 (1.0)
	B	16 (6.5)	16 (6.5)	32 (6.5)
	C, D or E	229 (93.1)	226 (91.9)	455 (92.5)
Adjudication Scoring (BILAG) at baseline Haematological (%)	B	1 (0.4)	1 (0.4)	2 (0.4)
	C, D or E	245 (99.6)	245 (99.6)	490 (99.6)
BILAG-2004 global score at baseline	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	18.6 (5.28)	18.8 (5.17)	18.7 (5.22)
	Median	17.0	18.0	17.0
	Min, Max	2, 40	4, 33	2, 40
Physician Global Assessment (PGA) score at baseline	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	1.8 (0.42)	1.8 (0.38)	1.8 (0.40)
	Median	1.7	1.8	1.8
	Min, Max	1, 3	1, 3	1, 3
CLASI activity score at baseline	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	8.0 (7.46)	8.0 (7.42)	8.0 (7.43)
	Median	6.0	6.0	6.0
	Min, Max	0, 51	0, 52	0, 52
CLASI activity score at baseline, categorisation 1 (%)	0	8 (3.3)	14 (5.7)	22 (4.5)
	> 0	238 (96.7)	232 (94.3)	470 (95.5)

Baseline is defined as the last measurement prior to randomisation and dose administration on Day 1.
Only subjects with baseline positive anti-dsDNA and abnormal complement level, respectively, are included in the summary statistics for the respective variables.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SLE disease characteristics
Full analysis set

		Randomised Anifrolumab 300mg (N=246)	Randomised Placebo (N=246)	Total (N=492)
CLASI activity score at baseline, categorisation 2 (%)	<10	181 (73.6)	176 (71.5)	357 (72.6)
	>=10	65 (26.4)	70 (28.5)	135 (27.4)
CLASI damage score at baseline	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	1.7 (3.61)	1.9 (4.55)	1.8 (4.10)
	Median	0.0	0.0	0.0
	Min, Max	0, 23	0, 35	0, 35
CLASI damage score at baseline, categorisation 1 (%)	0	164 (66.7)	163 (66.3)	327 (66.5)
	> 0	82 (33.3)	83 (33.7)	165 (33.5)
CLASI damage score at baseline, categorisation 2 (%)	<10	233 (94.7)	234 (95.1)	467 (94.9)
	>=10	13 (5.3)	12 (4.9)	25 (5.1)
Tender Joint Count at Baseline	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	10.0 (7.47)	10.9 (7.48)	10.4 (7.48)
	Median	8.0	10.0	9.0
	Min, Max	0, 28	0, 28	0, 28
Tender Joint Count at Baseline, categorisation (%)	0	20 (8.1)	10 (4.1)	30 (6.1)
	> 0	226 (91.9)	236 (95.9)	462 (93.9)
Swollen Joint Count at Baseline	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	6.7 (5.78)	7.1 (5.70)	6.9 (5.74)
	Median	5.0	6.0	6.0
	Min, Max	0, 28	0, 25	0, 28
Swollen Joint Count at Baseline, categorisation (%)	0	26 (10.6)	22 (8.9)	48 (9.8)
	> 0	220 (89.4)	224 (91.1)	444 (90.2)
Active Joint Count at Baseline	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	6.2 (5.77)	6.6 (5.50)	6.4 (5.63)
	Median	5.0	5.0	5.0
	Min, Max	0, 28	0, 25	0, 28
Active Joint Count at Baseline, categorisation (%)	0	29 (11.8)	23 (9.3)	52 (10.6)
	> 0	217 (88.2)	223 (90.7)	440 (89.4)
SDI global score at baseline	n (missing)	245 (1)	244 (2)	489 (3)
	Mean (SD)	0.5 (0.97)	0.6 (0.91)	0.6 (0.94)
	Median	0.0	0.0	0.0
	Min, Max	0, 5	0, 5	0, 5
SDI global score at baseline, categorisation (%)	0 (no damage)	170 (69.1)	152 (61.8)	322 (65.4)
	>=1 (damage)	75 (30.5)	92 (37.4)	167 (33.9)
	Missing	1 (0.4)	2 (0.8)	3 (0.6)
Time from initial SLE diagnosis to randomisation (months)	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	125.0 (105.56)	101.9 (91.51)	113.4 (99.36)
	Median	98.0	75.0	85.5
	Min, Max	0, 493	4, 503	0, 503
Cushingoid features (%)	Any Cushingoid Feature	74 (30.1)	82 (33.3)	156 (31.7)
	Moon Face	42 (17.1)	47 (19.1)	89 (18.1)
	Buffalo Hump	19 (7.7)	12 (4.9)	31 (6.3)
	Purple or Violaceous Striae	21 (8.5)	17 (6.9)	38 (7.7)
	Central Obesity	33 (13.4)	35 (14.2)	68 (13.8)
	Hirsutisim	14 (5.7)	7 (2.8)	21 (4.3)
	Acne	14 (5.7)	10 (4.1)	24 (4.9)
	Easy Bruising	36 (14.6)	28 (11.4)	64 (13.0)
	Fragile Skin	22 (8.9)	25 (10.2)	47 (9.6)

Baseline is defined as the last measurement prior to randomisation and dose administration on Day 1.
Only subjects with baseline positive anti-dsDNA and abnormal complement level, respectively, are included in the summary statistics for the respective variables.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
SLE disease characteristics
Full analysis set

		Randomised Anifrolumab 300mg (N=246)	Randomised Placebo (N=246)	Total (N=492)
Results of 4-gene Type 1 Interferon (IFN) test (%)	High	201 (81.7)	198 (80.5)	399 (81.1)
	Low	45 (18.3)	48 (19.5)	93 (18.9)
Anti-dsDNA levels at baseline	n (missing)	229 (17)	219 (27)	448 (44)
	Mean (SD)	66.0 (190.83)	109.1 (425.60)	87.0 (327.69)
	Median	15.0	12.6	14.0
	Min, Max	1, 1808	1, 3790	1, 3790
Anti-dsDNA levels at baseline, categorisation (%)	Negative	131 (53.3)	144 (58.5)	275 (55.9)
	Positive	115 (46.7)	102 (41.5)	217 (44.1)
ANA (%)	Abnormal (titre >= 1:80)	216 (87.8)	222 (90.2)	438 (89.0)
	Normal (titre < 1:80)	18 (7.3)	16 (6.5)	34 (6.9)
	Missing	12 (4.9)	8 (3.3)	20 (4.1)
Complement C3 level at baseline	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	1.01 (0.316)	1.01 (0.320)	1.01 (0.318)
	Median	1.02	1.00	1.01
	Min, Max	0.2, 1.9	0.4, 2.0	0.2, 2.0
Complement C3 level at baseline, categorisation (%)	Abnormal	92 (37.4)	91 (37.0)	183 (37.2)
	Normal	154 (62.6)	155 (63.0)	309 (62.8)
Complement C4 level at baseline	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	0.17 (0.084)	0.17 (0.084)	0.17 (0.084)
	Median	0.16	0.17	0.16
	Min, Max	0.1, 0.5	0.1, 0.4	0.1, 0.5
Complement C4 level at baseline, categorisation (%)	Abnormal	54 (22.0)	56 (22.8)	110 (22.4)
	Normal	192 (78.0)	190 (77.2)	382 (77.6)
Complement CH50 level at baseline	n (missing)	246 (0)	246 (0)	492 (0)
	Mean (SD)	231.02 (108.651)	249.13 (106.383)	240.07 (107.795)
	Median	219.00	250.00	237.00
	Min, Max	5.0, 420.0	5.0, 420.0	5.0, 420.0
Complement CH50 level at baseline, categorisation (%)	Abnormal	23 (9.3)	21 (8.5)	44 (8.9)
	Normal	223 (90.7)	225 (91.5)	448 (91.1)

Baseline is defined as the last measurement prior to randomisation and dose administration on Day 1.
Only subjects with baseline positive anti-dsDNA and abnormal complement level, respectively, are included in the summary statistics for the respective variables.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Observation times for Efficacy endpoints
Full analysis set

		Anifrolumab 300mg (N=246)	Placebo (N=246)
SLEDAI-2K Total Score: Observation time (weeks)	n (missing)	246 (0)	246 (0)
	Mean (SD)	115.2 (64.32)	70.7 (53.52)
	Median	129.0	52.3
	Min, Max	0, 223	0, 218
PGA: Observation time (weeks)	n (missing)	246 (0)	246 (0)
	Mean (SD)	117.6 (64.75)	71.5 (53.98)
	Median	130.1	52.3
	Min, Max	0, 223	0, 218
SDI Global Score: Observation time (weeks)	n (missing)	246 (0)	246 (0)
	Mean (SD)	107.7 (61.94)	67.0 (49.69)
	Median	107.1	52.3
	Min, Max	0, 219	0, 211

Observation duration defined as time from randomization until last non-missing assessment after randomization. Subjects without assessment are censored at day 1.

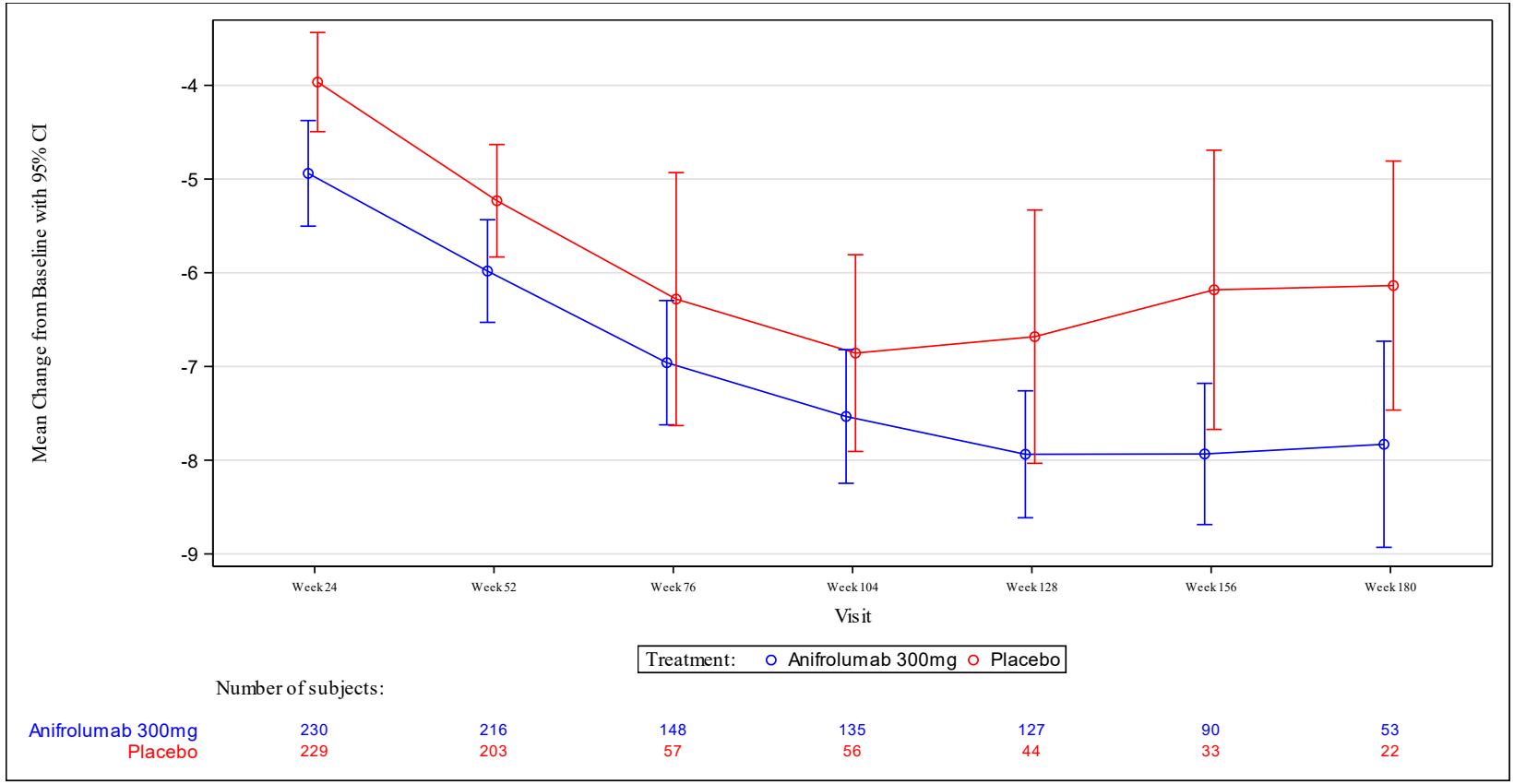
Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - SLEDAI-2K Total Score
Full analysis set

	Ramdomised ANI300 (N=246)				Randomised Placebo (N=246)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	246	11.29 (3.76)	0	-	246	11.42 (3.71)	0	-
Week 24	230	6.35 (4.03)	230	-4.94 (4.34)	229	7.40 (3.86)	229	-3.97 (4.06)
Week 52	216	5.29 (3.79)	216	-5.98 (4.08)	203	6.02 (3.91)	203	-5.23 (4.34)
Week 56	1	8.00 (-)	1	0.00 (-)	0	-	0	-
Week 60	1	0.00 (-)	1	-8.00 (-)	1	2.00 (-)	1	-14.00 (-)
Week 64	151	4.25 (3.06)	151	-6.99 (4.50)	62	4.95 (3.84)	62	-6.15 (4.60)
Week 68	2	4.50 (6.36)	2	-4.50 (4.95)	3	5.33 (4.16)	3	-7.00 (1.00)
Week 72	4	5.50 (4.43)	4	-3.75 (5.56)	3	5.00 (5.00)	3	-7.33 (0.58)
Week 76	148	4.14 (3.28)	148	-6.96 (4.08)	57	4.84 (4.01)	57	-6.28 (5.09)
Week 80	6	4.83 (3.13)	6	-7.50 (2.95)	3	10.00 (7.21)	3	0.67 (8.33)
Week 84	4	5.00 (3.83)	4	-6.00 (4.90)	1	6.00 (-)	1	-2.00 (-)
Week 88	137	3.74 (3.14)	137	-7.34 (4.17)	52	4.69 (3.53)	52	-6.52 (3.85)
Week 92	8	5.25 (4.27)	8	-6.25 (4.80)	3	3.33 (3.06)	3	-10.00 (6.56)
Week 96	0	-	0	-	2	3.00 (1.41)	2	-12.00 (4.24)
Week 100	1	0.00 (-)	1	-8.00 (-)	0	-	0	-
Week 104	135	3.46 (2.90)	135	-7.53 (4.19)	56	4.23 (3.14)	56	-6.86 (3.92)
Week 108	6	3.67 (2.34)	6	-6.67 (3.27)	2	3.00 (1.41)	2	-7.00 (1.41)
Week 112	2	4.00 (2.83)	2	-5.00 (4.24)	2	5.00 (1.41)	2	-6.50 (0.71)
Week 120	0	-	0	-	2	2.00 (0.00)	2	-9.00 (1.41)
Week 124	1	8.00 (-)	1	-2.00 (-)	0	-	0	-
Week 128	127	3.13 (2.82)	127	-7.94 (3.86)	44	4.14 (3.18)	44	-6.68 (4.44)
Week 132	4	6.50 (5.74)	4	-4.50 (5.26)	1	2.00 (-)	1	-18.00 (-)
Week 136	3	6.67 (4.16)	3	-4.00 (5.29)	2	6.00 (5.66)	2	-9.00 (12.73)
Week 140	1	2.00 (-)	1	-6.00 (-)	1	10.00 (-)	1	0.00 (-)
Week 144	0	-	0	-	1	8.00 (-)	1	-2.00 (-)
Week 148	0	-	0	-	1	10.00 (-)	1	-2.00 (-)
Week 152	0	-	0	-	1	8.00 (-)	1	-4.00 (-)
Week 156	90	2.70 (2.46)	90	-7.93 (3.60)	33	4.30 (2.70)	33	-6.18 (4.20)
Week 160	3	3.00 (2.65)	3	-8.67 (4.16)	0	-	0	-
Week 164	1	6.00 (-)	1	-2.00 (-)	0	-	0	-
Week 176	1	9.00 (-)	1	3.00 (-)	0	-	0	-
Week 180	53	2.79 (3.04)	53	-7.83 (3.99)	22	3.91 (2.79)	22	-6.14 (3.00)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - SLEDAI-2K Total Score
Full analysis set

	Ramdomised ANI300 (N=246)				Randomised Placebo (N=246)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Week 184	2	1.00 (1.41)	2	-10.00 (5.66)	0	-	0	-
Week 192	1	0.00 (-)	1	-8.00 (-)	0	-	0	-
Week 196	1	0.00 (-)	1	-8.00 (-)	0	-	0	-
Week 200	1	6.00 (-)	1	-2.00 (-)	0	-	0	-
Week 208	17	2.76 (3.53)	17	-7.59 (4.54)	7	4.86 (2.54)	7	-4.86 (3.02)
Week 212	6	4.67 (2.73)	6	-3.17 (2.99)	3	6.00 (2.00)	3	-4.00 (2.00)
Week 216	5	4.40 (3.21)	5	-5.00 (4.00)	5	8.00 (4.47)	5	-1.60 (4.34)
Week 220	4	5.00 (2.00)	4	-4.50 (1.91)	0	-	0	-

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - SLEDAI-2K Total Score
Full analysis set



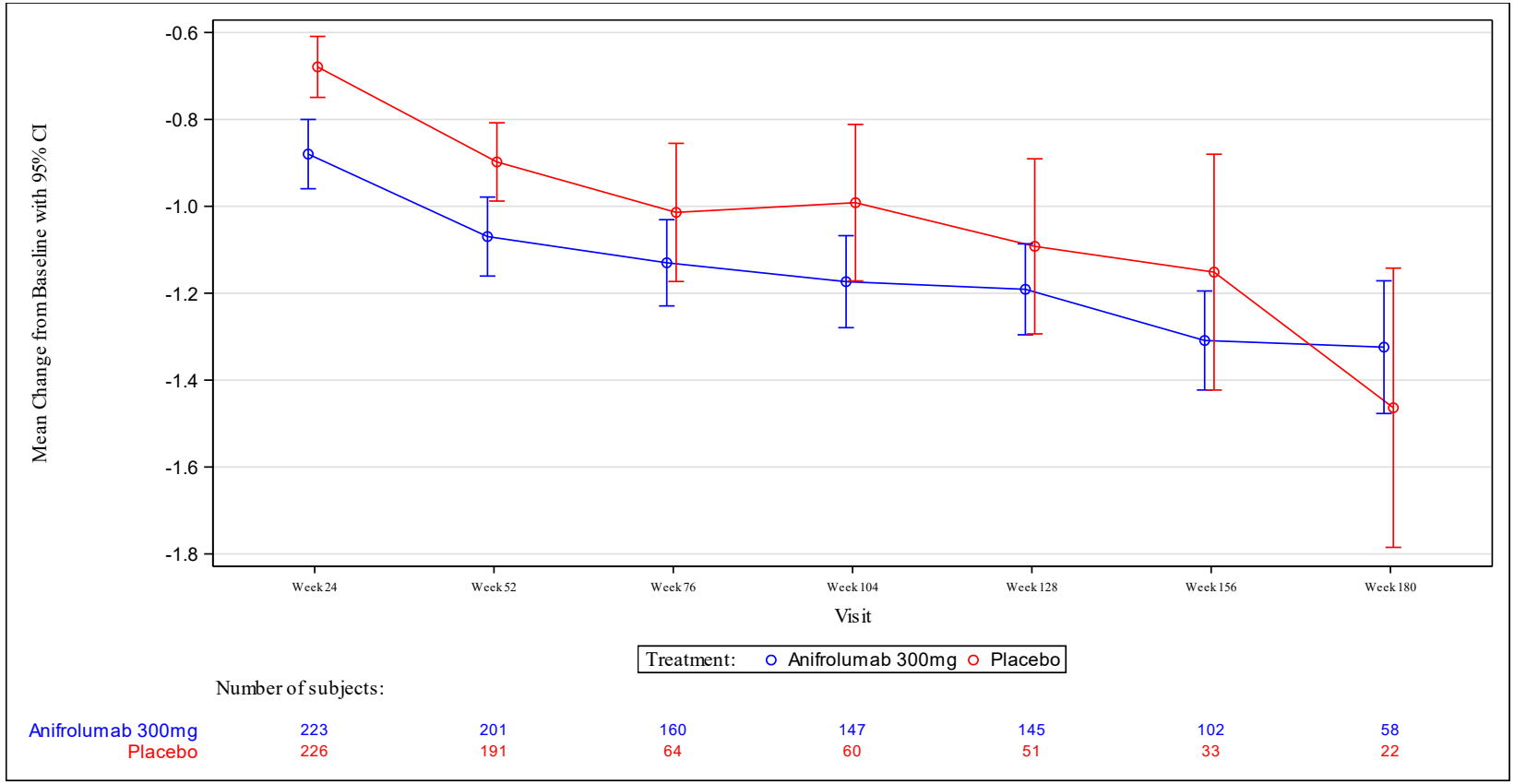
Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - PGA
Full analysis set

	Ramdomised ANI300 (N=246)				Randomised Placebo (N=246)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	246	1.77 (0.42)	0	-	246	1.80 (0.38)	0	-
Week 24	223	0.88 (0.59)	223	-0.88 (0.60)	226	1.12 (0.52)	226	-0.68 (0.54)
Week 52	201	0.67 (0.55)	201	-1.07 (0.65)	191	0.90 (0.57)	191	-0.90 (0.63)
Week 56	1	1.70 (-)	1	-0.60 (-)	0	-	0	-
Week 60	1	0.00 (-)	1	-1.60 (-)	1	0.80 (-)	1	-1.10 (-)
Week 64	162	0.66 (0.53)	162	-1.10 (0.64)	68	0.89 (0.56)	68	-0.90 (0.63)
Week 68	4	1.00 (0.83)	4	-1.15 (0.85)	3	1.07 (0.85)	3	-0.53 (1.12)
Week 72	3	1.70 (0.53)	3	0.10 (0.35)	3	1.53 (0.49)	3	0.07 (0.25)
Week 76	160	0.63 (0.54)	160	-1.13 (0.64)	64	0.80 (0.54)	64	-1.01 (0.64)
Week 80	5	0.70 (0.39)	5	-1.26 (0.74)	3	1.37 (1.32)	3	-0.23 (1.25)
Week 84	3	0.53 (0.75)	3	-1.60 (0.87)	0	-	0	-
Week 88	153	0.61 (0.52)	153	-1.13 (0.62)	62	0.72 (0.47)	62	-1.10 (0.58)
Week 92	8	0.93 (0.66)	8	-1.23 (0.82)	3	1.00 (0.70)	3	-0.63 (1.04)
Week 96	1	2.00 (-)	1	0.30 (-)	2	1.05 (0.49)	2	-0.85 (0.92)
Week 100	2	0.65 (0.64)	2	-1.05 (1.34)	1	0.60 (-)	1	-1.60 (-)
Week 104	147	0.57 (0.53)	147	-1.17 (0.65)	60	0.83 (0.60)	60	-0.99 (0.70)
Week 108	4	0.85 (0.93)	4	-1.15 (1.26)	3	0.27 (0.12)	3	-1.53 (0.59)
Week 112	2	1.45 (0.64)	2	-0.55 (0.07)	2	0.15 (0.21)	2	-1.40 (0.14)
Week 120	1	1.50 (-)	1	-1.00 (-)	2	0.80 (0.42)	2	-1.05 (0.21)
Week 124	2	1.60 (0.57)	2	-0.05 (0.07)	0	-	0	-
Week 128	145	0.55 (0.56)	145	-1.19 (0.64)	51	0.73 (0.57)	51	-1.09 (0.72)
Week 132	4	0.85 (0.93)	4	-0.65 (0.54)	1	0.10 (-)	1	-1.30 (-)
Week 136	3	1.13 (0.99)	3	-0.57 (0.65)	2	0.85 (1.06)	2	-0.45 (1.20)
Week 140	2	1.30 (0.28)	2	-0.40 (0.28)	1	1.50 (-)	1	0.30 (-)
Week 144	0	-	0	-	1	1.40 (-)	1	0.20 (-)
Week 148	0	-	0	-	1	1.20 (-)	1	-0.30 (-)
Week 152	1	1.10 (-)	1	-0.10 (-)	1	1.30 (-)	1	-0.20 (-)
Week 156	102	0.46 (0.46)	102	-1.31 (0.58)	33	0.76 (0.63)	33	-1.15 (0.77)
Week 160	2	0.80 (0.42)	2	-0.85 (0.64)	1	0.00 (-)	1	-1.90 (-)
Week 164	1	0.70 (-)	1	-0.80 (-)	0	-	0	-
Week 168	1	0.00 (-)	1	-1.20 (-)	0	-	0	-
Week 176	1	1.00 (-)	1	-0.20 (-)	0	-	0	-

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - PGA
Full analysis set

	Ramdomised ANI300 (N=246)				Randomised Placebo (N=246)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Week 180	58	0.48 (0.47)	58	-1.32 (0.58)	22	0.52 (0.61)	22	-1.46 (0.72)
Week 184	1	1.30 (-)	1	-0.20 (-)	0	-	0	-
Week 192	1	0.00 (-)	1	-1.20 (-)	0	-	0	-
Week 196	1	0.20 (-)	1	-1.00 (-)	0	-	0	-
Week 200	1	1.80 (-)	1	0.60 (-)	0	-	0	-
Week 208	19	0.66 (0.55)	19	-1.00 (0.71)	7	0.93 (0.92)	7	-0.67 (0.68)
Week 212	5	0.66 (0.73)	5	-0.82 (0.82)	3	0.67 (0.98)	3	-0.77 (0.78)
Week 216	6	0.87 (0.52)	6	-0.78 (0.79)	5	1.44 (0.60)	5	-0.22 (0.59)
Week 220	4	0.98 (0.39)	4	-0.85 (0.93)	0	-	0	-

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - PGA
Full analysis set



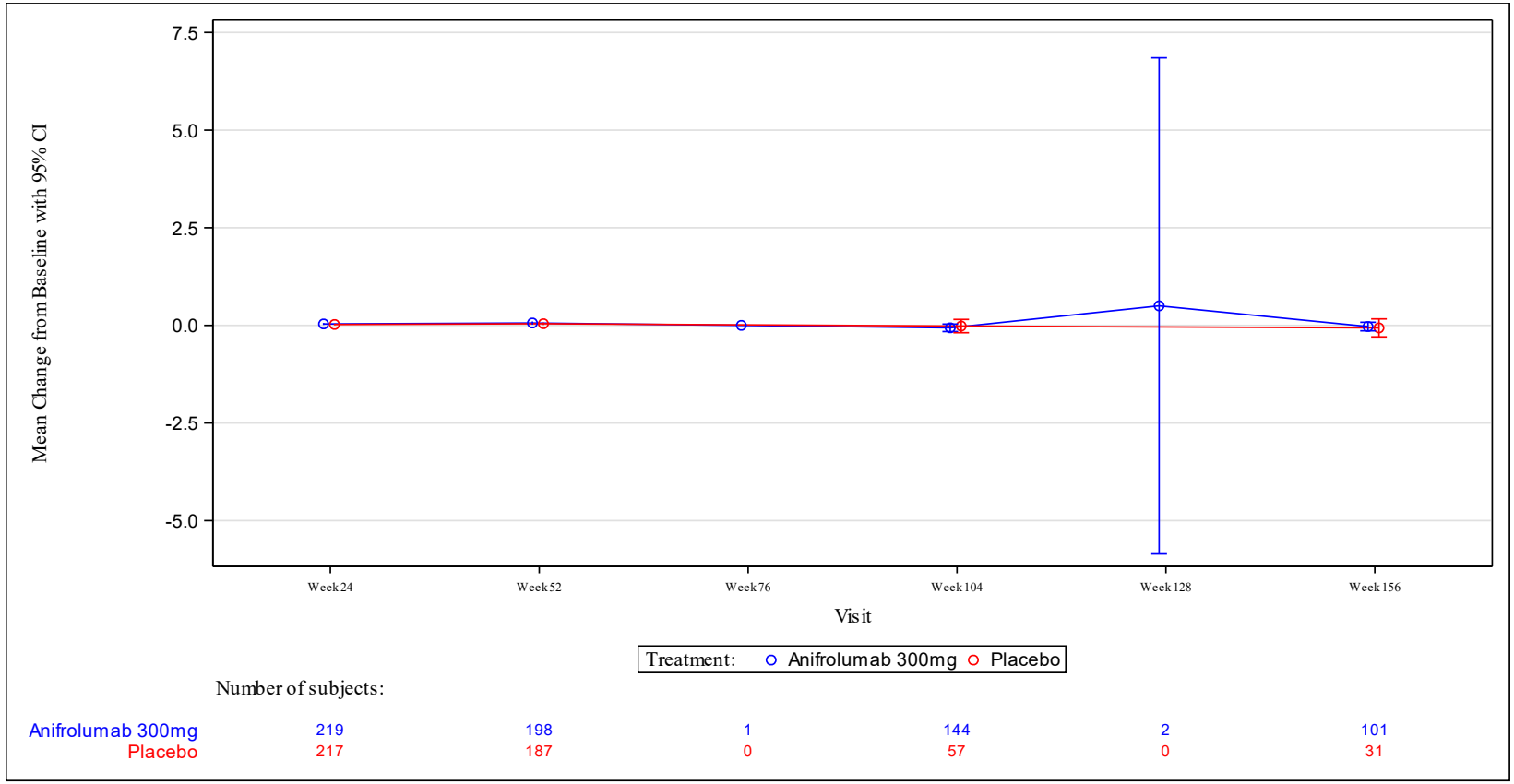
Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - SDI Global Score
Full analysis set

	Ramdomised ANI300 (N=246)				Randomised Placebo (N=246)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	245	0.52 (0.97)	0	-	244	0.58 (0.91)	0	-
Week 24	220	0.56 (0.98)	219	0.04 (0.19)	219	0.61 (0.99)	217	0.02 (0.15)
Week 52	199	0.60 (0.98)	198	0.06 (0.28)	189	0.58 (0.92)	187	0.04 (0.23)
Week 56	1	0.00 (-)	1	0.00 (-)	0	-	0	-
Week 60	1	0.00 (-)	1	0.00 (-)	1	4.00 (-)	1	3.00 (-)
Week 64	1	2.00 (-)	1	0.00 (-)	1	0.00 (-)	1	-1.00 (-)
Week 68	0	-	0	-	2	0.50 (0.71)	2	0.50 (0.71)
Week 72	1	0.00 (-)	1	0.00 (-)	0	-	0	-
Week 76	1	1.00 (-)	1	0.00 (-)	0	-	0	-
Week 80	0	-	0	-	1	2.00 (-)	1	0.00 (-)
Week 84	2	0.00 (0.00)	2	-0.50 (0.71)	0	-	0	-
Week 88	0	-	0	-	1	0.00 (-)	1	0.00 (-)
Week 92	2	1.50 (0.71)	2	0.00 (0.00)	0	-	0	-
Week 96	1	0.00 (-)	1	0.00 (-)	1	1.00 (-)	1	1.00 (-)
Week 100	2	0.00 (0.00)	2	0.00 (0.00)	0	-	0	-
Week 104	144	0.42 (0.79)	144	-0.06 (0.58)	58	0.59 (0.82)	57	-0.02 (0.64)
Week 108	3	0.33 (0.58)	3	0.00 (0.00)	2	0.50 (0.71)	2	0.00 (0.00)
Week 112	1	0.00 (-)	1	0.00 (-)	2	1.50 (2.12)	2	0.50 (0.71)
Week 116	0	-	0	-	1	0.00 (-)	1	-1.00 (-)
Week 120	0	-	0	-	1	0.00 (-)	1	-1.00 (-)
Week 124	1	0.00 (-)	1	0.00 (-)	0	-	0	-
Week 128	2	2.50 (0.71)	2	0.50 (0.71)	0	-	0	-
Week 132	2	0.00 (0.00)	2	0.00 (0.00)	1	0.00 (-)	1	0.00 (-)
Week 136	0	-	0	-	1	0.00 (-)	1	0.00 (-)
Week 140	1	0.00 (-)	1	0.00 (-)	0	-	0	-
Week 148	0	-	0	-	1	0.00 (-)	1	0.00 (-)
Week 152	1	0.00 (-)	1	0.00 (-)	0	-	0	-
Week 156	101	0.51 (0.91)	101	-0.03 (0.56)	32	0.44 (0.67)	31	-0.06 (0.63)
Week 160	1	2.00 (-)	1	2.00 (-)	1	0.00 (-)	1	0.00 (-)
Week 168	1	2.00 (-)	1	0.00 (-)	0	-	0	-
Week 192	1	0.00 (-)	1	0.00 (-)	0	-	0	-
Week 208	18	0.50 (0.92)	18	0.00 (0.59)	7	0.86 (0.90)	7	0.00 (0.58)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary statistics of mean values and change from baseline by timepoint - SDI Global Score
Full analysis set

	Ramdomised ANI300 (N=246)				Randomised Placebo (N=246)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Week 212	2	0.00 (0.00)	2	-0.50 (0.71)	0	-	0	-

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Graphical Summary of change from baseline by timepoint - SDI Global Score
Full analysis set



Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SLEDAI-2K Total Score
Full analysis set

Visit	Ramdomised ANI300 (N=246) N	Ramdomised ANI300 (N=246) LSMean (SE)	Randomised Placebo (N=246) N	Randomised Placebo (N=246) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 24		-4.82 (0.24)		-3.82 (0.24)	-1.00 (0.34)	(-1.66, -0.33)	0.0034			
Week 52		-5.87 (0.24)		-5.06 (0.25)	-0.81 (0.35)	(-1.49, -0.13)	0.0194			
Week 76		-6.86 (0.26)		-5.92 (0.37)	-0.95 (0.45)	(-1.84, -0.05)	0.0376			
Week 104		-7.59 (0.24)		-6.65 (0.35)	-0.94 (0.42)	(-1.78, -0.10)	0.0277			
Week 128		-7.85 (0.24)		-6.72 (0.38)	-1.13 (0.45)	(-2.01, -0.24)	0.0128			
Week 156		-8.09 (0.24)		-6.39 (0.37)	-1.71 (0.44)	(-2.58, -0.83)	0.0002			
Week 180		-8.11 (0.31)		-6.64 (0.47)	-1.47 (0.57)	(-2.59, -0.35)	0.0108			
OVERALL	230	-7.03 (0.18)	233	-5.89 (0.24)	-1.14 (0.30)	(-1.73, -0.55)	0.0002	-0.35 (0.09)	(-0.54, -0.17)	0.0002

A repeated measures model with fixed effects for baseline value, treatment group, visit and treatment*visit interaction was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SLEDAI-2K Total Score - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=246) N	LSMean (SE)	Randomised Placebo (N=246) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.1463
< 10 points	74	-5.27 (0.26)	65	-4.75 (0.35)	-0.52 (0.44)	(-1.39, 0.35)	0.2419	-0.20 (0.17)	(-0.54, 0.13)	0.2363	
>= 10 points	156	-7.87 (0.24)	168	-6.50 (0.30)	-1.36 (0.38)	(-2.12, -0.61)	0.0004	-0.39 (0.11)	(-0.61, -0.17)	0.0005	
Age (years)											NE
<= 65	225	-7.06 (0.19)	230	-5.88 (0.24)	-1.18 (0.30)	(-1.77, -0.59)	0.0001	-0.37 (0.09)	(-0.55, -0.18)	0.0001	
> 65	5	NE	3	NE	NE	NE		NE	NE		
Sex											0.1322
male	22	-7.67 (0.56)	20	-5.17 (0.71)	-2.50 (0.90)	(-4.33, -0.67)	0.0089	-0.85 (0.32)	(-1.48, -0.21)	0.0089	
female	208	-6.96 (0.20)	213	-5.90 (0.25)	-1.06 (0.32)	(-1.70, -0.43)	0.0011	-0.32 (0.10)	(-0.51, -0.13)	0.0011	
Geographic region											0.4531
EU	87	-7.89 (0.26)	83	-6.99 (0.33)	-0.90 (0.42)	(-1.73, -0.07)	0.0342	-0.33 (0.15)	(-0.63, -0.03)	0.0336	
non-EU	143	-6.49 (0.25)	150	-5.15 (0.33)	-1.34 (0.41)	(-2.15, -0.53)	0.0013	-0.38 (0.12)	(-0.61, -0.15)	0.0014	

A repeated measures model with fixed effects for baseline value, treatment group, visit and treatment*visit interaction was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - PGA
Full analysis set

	Ramdomised ANI300 (N=246)		Randomised Placebo (N=246)		Difference of					
Visit	N	LSMean (SE)	N	LSMean (SE)	LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 24		-0.90 (0.04)		-0.67 (0.04)	-0.23 (0.05)	(-0.33, -0.14)	<.0001			
Week 52		-1.09 (0.04)		-0.86 (0.04)	-0.23 (0.06)	(-0.34, -0.12)	<.0001			
Week 76		-1.11 (0.04)		-0.94 (0.05)	-0.17 (0.07)	(-0.30, -0.04)	0.0130			
Week 104		-1.16 (0.04)		-0.89 (0.06)	-0.27 (0.08)	(-0.42, -0.11)	0.0007			
Week 128		-1.17 (0.04)		-0.98 (0.07)	-0.20 (0.08)	(-0.36, -0.03)	0.0187			
Week 156		-1.23 (0.05)		-0.97 (0.07)	-0.26 (0.09)	(-0.43, -0.09)	0.0027			
Week 180		-1.27 (0.05)		-1.17 (0.08)	-0.10 (0.09)	(-0.27, 0.08)	0.2894			
OVERALL	228	-1.13 (0.03)	230	-0.93 (0.04)	-0.21 (0.05)	(-0.31, -0.10)	0.0001	-0.36 (0.09)	(-0.55, -0.18)	0.0001

A repeated measures model with fixed effects for baseline value, treatment group, visit and treatment*visit interaction was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - PGA - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=246) N	LSMean (SE)	Randomised Placebo (N=246) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.7378
< 10 points	73	-1.09 (0.06)	63	-0.87 (0.08)	-0.22 (0.10)	(-0.41, -0.03)	0.0235	-0.40 (0.17)	(-0.74, -0.06)	0.0214	
>= 10 points	155	-1.14 (0.04)	167	-0.96 (0.05)	-0.18 (0.06)	(-0.31, -0.06)	0.0049	-0.31 (0.11)	(-0.53, -0.09)	0.0053	
Age (years)											NE
<= 65	223	-1.13 (0.03)	227	-0.92 (0.04)	-0.21 (0.05)	(-0.31, -0.10)	0.0001	-0.37 (0.10)	(-0.56, -0.18)	0.0001	
> 65	5	NE	3	NE	NE	NE		NE	NE		
Sex											0.9722
male	22	-1.24 (0.10)	20	-1.03 (0.13)	-0.22 (0.16)	(-0.55, 0.12)	0.1957	-0.41 (0.31)	(-1.02, 0.20)	0.1920	
female	206	-1.12 (0.03)	210	-0.91 (0.04)	-0.21 (0.06)	(-0.32, -0.10)	0.0003	-0.36 (0.10)	(-0.55, -0.17)	0.0003	
Geographic region											0.0860
EU	87	-1.24 (0.04)	82	-1.15 (0.05)	-0.10 (0.07)	(-0.23, 0.03)	0.1434	-0.23 (0.15)	(-0.53, 0.07)	0.1398	
non-EU	141	-1.06 (0.05)	148	-0.79 (0.06)	-0.27 (0.07)	(-0.41, -0.12)	0.0004	-0.42 (0.12)	(-0.65, -0.19)	0.0004	

A repeated measures model with fixed effects for baseline value, treatment group, visit and treatment*visit interaction was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SDI Global Score
Full analysis set

Visit	Ramdomised ANI300 (N=246) N	Ramdomised ANI300 (N=246) LSMean (SE)	Randomised Placebo (N=246) N	Randomised Placebo (N=246) LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 24		0.04 (0.01)		0.02 (0.01)	0.02 (0.02)	(-0.02, 0.05)	0.3456			
Week 52		0.07 (0.02)		0.04 (0.02)	0.02 (0.03)	(-0.03, 0.07)	0.3522			
Week 104		-0.07 (0.05)		-0.03 (0.08)	-0.04 (0.09)	(-0.23, 0.14)	0.6486			
Week 156		0.00 (0.06)		-0.12 (0.09)	0.12 (0.11)	(-0.10, 0.34)	0.2702			
OVERALL	225	0.01 (0.03)	223	-0.02 (0.04)	0.03 (0.05)	(-0.06, 0.12)	0.5398	0.06 (0.09)	(-0.13, 0.24)	0.5392

A repeated measures model with fixed effects for baseline value, treatment group, visit and treatment*visit interaction was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Repeated measures model analysis - SDI Global Score - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=246) N	LSMean (SE)	Randomised Placebo (N=246) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.6920
< 10 points	73	0.03 (0.04)	60	0.05 (0.06)	-0.03 (0.07)	(-0.17, 0.12)	0.7362	-0.06 (0.17)	(-0.40, 0.28)	0.7254	
>= 10 points	152	-0.02 (0.03)	163	-0.04 (0.05)	0.01 (0.06)	(-0.11, 0.14)	0.8318	0.02 (0.11)	(-0.20, 0.24)	0.8342	
Age (years)											NE
<= 65	220	0.01 (0.03)	220	-0.02 (0.04)	0.03 (0.05)	(-0.06, 0.13)	0.4857	0.07 (0.10)	(-0.12, 0.25)	0.4858	
> 65	5	NE	3	NE	NE	NE		NE	NE		
Sex											NE
male	22	NE	20	NE	NE	NE		NE	NE		
female	203	0.03 (0.03)	203	-0.03 (0.04)	0.06 (0.05)	(-0.03, 0.16)	0.2060	0.13 (0.10)	(-0.07, 0.32)	0.2057	
Geographic region											0.7609
EU	86	-0.03 (0.04)	81	-0.04 (0.06)	0.01 (0.07)	(-0.13, 0.16)	0.8574	0.03 (0.15)	(-0.28, 0.33)	0.8559	
non-EU	139	0.06 (0.04)	142	0.02 (0.06)	0.04 (0.07)	(-0.09, 0.18)	0.5271	0.08 (0.12)	(-0.16, 0.31)	0.5285	

A repeated measures model with fixed effects for baseline value, treatment group, visit and treatment*visit interaction was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Incidence of Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=246) n (%)	Randomised Placebo (N=246) n (%)
Subjects with events	227 (92.3)	211 (85.8)
Infections and infestations	191 (77.6)	159 (64.6)
Nasopharyngitis	63 (25.6)	31 (12.6)
Upper respiratory tract infection	59 (24.0)	29 (11.8)
Urinary tract infection	47 (19.1)	37 (15.0)
Bronchitis	46 (18.7)	16 (6.5)
Sinusitis	23 (9.3)	13 (5.3)
Pharyngitis	20 (8.1)	15 (6.1)
Herpes zoster	25 (10.2)	7 (2.8)
Oral herpes	12 (4.9)	8 (3.3)
Gastroenteritis	9 (3.7)	7 (2.8)
Influenza	12 (4.9)	9 (3.7)
Pneumonia	11 (4.5)	10 (4.1)
Respiratory tract infection	12 (4.9)	1 (0.4)
Vaginal infection	9 (3.7)	7 (2.8)
Cystitis	7 (2.8)	5 (2.0)
Conjunctivitis	11 (4.5)	4 (1.6)
Viral upper respiratory tract infection	11 (4.5)	2 (0.8)
Gastroenteritis viral	6 (2.4)	4 (1.6)
Latent tuberculosis	9 (3.7)	3 (1.2)
Cellulitis	4 (1.6)	6 (2.4)
Otitis media	8 (3.3)	0
Tooth abscess	7 (2.8)	2 (0.8)
Onychomycosis	4 (1.6)	3 (1.2)
Oral candidiasis	3 (1.2)	5 (2.0)
Tooth infection	4 (1.6)	3 (1.2)
Vulvovaginal mycotic infection	6 (2.4)	2 (0.8)
Folliculitis	4 (1.6)	1 (0.4)
Fungal skin infection	3 (1.2)	2 (0.8)
Furuncle	2 (0.8)	2 (0.8)
Paronychia	3 (1.2)	3 (1.2)
Rhinitis	3 (1.2)	3 (1.2)
Tonsillitis	5 (2.0)	1 (0.4)
Viral infection	4 (1.6)	2 (0.8)
Bacterial vaginosis	1 (0.4)	3 (1.2)
Gastrointestinal viral infection	1 (0.4)	2 (0.8)
Herpes simplex	1 (0.4)	2 (0.8)
Lower respiratory tract infection	3 (1.2)	0
Respiratory tract infection viral	2 (0.8)	2 (0.8)
Vulvovaginitis	3 (1.2)	0
Cervicitis	3 (1.2)	0
Diverticulitis	2 (0.8)	0
Tinea versicolour	2 (0.8)	1 (0.4)
Vulvovaginal candidiasis	2 (0.8)	2 (0.8)
Acute sinusitis	2 (0.8)	1 (0.4)
Appendicitis	3 (1.2)	0
Ear infection	2 (0.8)	1 (0.4)
Fungal infection	2 (0.8)	1 (0.4)
Hordeolum	1 (0.4)	2 (0.8)
Laryngitis	1 (0.4)	1 (0.4)
Subcutaneous abscess	2 (0.8)	1 (0.4)
Tinea pedis	2 (0.8)	1 (0.4)
Tracheitis	3 (1.2)	0
Tracheobronchitis	2 (0.8)	1 (0.4)
Viral pharyngitis	3 (1.2)	0
Wound infection	1 (0.4)	2 (0.8)
Candida infection	2 (0.8)	0
Escherichia urinary tract infection	2 (0.8)	0
Gastrointestinal infection	0	2 (0.8)

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Incidence of Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=246) n (%)	Randomised Placebo (N=246) n (%)
Genital herpes	1 (0.4)	0
Genital herpes simplex	1 (0.4)	1 (0.4)
Otitis externa	1 (0.4)	1 (0.4)
Otitis media acute	2 (0.8)	0
Parotitis	2 (0.8)	0
Periodontitis	0	2 (0.8)
Pharyngitis streptococcal	0	2 (0.8)
Rotavirus infection	2 (0.8)	0
Sepsis	0	2 (0.8)
Sialoadenitis	2 (0.8)	0
Superinfection	1 (0.4)	1 (0.4)
Abscess	0	1 (0.4)
Abscess limb	1 (0.4)	0
Acarodermatitis	0	1 (0.4)
Alveolar osteitis	1 (0.4)	0
Bacterial vulvovaginitis	1 (0.4)	0
Bartholinitis	1 (0.4)	0
Chronic sinusitis	1 (0.4)	0
Chronic tonsillitis	1 (0.4)	0
Cystitis escherichia	0	1 (0.4)
Dacryocystitis	1 (0.4)	0
Epididymitis	0	1 (0.4)
Erysipelas	0	1 (0.4)
Escherichia infection	1 (0.4)	0
Eyelid infection	1 (0.4)	0
Gastroenteritis bacterial	0	1 (0.4)
Giardiasis	0	1 (0.4)
Gingivitis	1 (0.4)	0
Herpes zoster disseminated	1 (0.4)	0
Human ehrlichiosis	1 (0.4)	0
Labyrinthitis	1 (0.4)	0
Large intestine infection	1 (0.4)	0
Laryngitis viral	1 (0.4)	0
Localised infection	1 (0.4)	0
Meningitis	0	1 (0.4)
Molluscum contagiosum	0	1 (0.4)
Mumps	1 (0.4)	0
Mycobacterium avium complex infection	1 (0.4)	0
Nail infection	1 (0.4)	0
Otitis media bacterial	1 (0.4)	0
Otitis media chronic	0	1 (0.4)
Pelvic inflammatory disease	1 (0.4)	0
Pharyngitis bacterial	0	1 (0.4)
Pneumonia bacterial	1 (0.4)	0
Pneumonia staphylococcal	0	1 (0.4)
Pneumonia viral	1 (0.4)	0
Postoperative wound infection	0	1 (0.4)
Proteus infection	0	1 (0.4)
Pulpitis dental	0	1 (0.4)
Pyelonephritis	1 (0.4)	0
Rash pustular	0	1 (0.4)
Respiratory moniliasis	0	1 (0.4)
Root canal infection	0	1 (0.4)
Septic shock	0	1 (0.4)
Skin candida	0	1 (0.4)
Soft tissue infection	1 (0.4)	0
Streptococcal urinary tract infection	1 (0.4)	0
Tinea cruris	1 (0.4)	0
Tonsillitis bacterial	0	1 (0.4)
Ureaplasma infection	0	1 (0.4)
Viral sinusitis	1 (0.4)	0

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Incidence of Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=246) n (%)	Randomised Placebo (N=246) n (%)
Vulval abscess	0	1 (0.4)
Vulvovaginitis trichomonal	0	1 (0.4)
Musculoskeletal and connective tissue disorders	98 (39.8)	60 (24.4)
Back pain	24 (9.8)	12 (4.9)
Arthralgia	20 (8.1)	9 (3.7)
Systemic lupus erythematosus	7 (2.8)	10 (4.1)
Bursitis	8 (3.3)	2 (0.8)
Pain in extremity	9 (3.7)	1 (0.4)
Musculoskeletal pain	6 (2.4)	5 (2.0)
Osteonecrosis	3 (1.2)	4 (1.6)
Neck pain	7 (2.8)	1 (0.4)
Osteoarthritis	7 (2.8)	0
Tendonitis	6 (2.4)	3 (1.2)
Muscle spasms	4 (1.6)	3 (1.2)
Musculoskeletal chest pain	4 (1.6)	3 (1.2)
Costochondritis	4 (1.6)	2 (0.8)
Myalgia	2 (0.8)	4 (1.6)
Arthritis	4 (1.6)	1 (0.4)
Fibromyalgia	2 (0.8)	3 (1.2)
Intervertebral disc protrusion	5 (2.0)	0
Rotator cuff syndrome	2 (0.8)	3 (1.2)
Flank pain	2 (0.8)	2 (0.8)
Joint swelling	3 (1.2)	1 (0.4)
Osteoporosis	1 (0.4)	3 (1.2)
Synovial cyst	2 (0.8)	1 (0.4)
Tenosynovitis	2 (0.8)	1 (0.4)
Plantar fasciitis	0	3 (1.2)
Spinal osteoarthritis	2 (0.8)	1 (0.4)
Tenosynovitis stenosans	3 (1.2)	0
Musculoskeletal stiffness	1 (0.4)	1 (0.4)
Spinal pain	1 (0.4)	0
Synovitis	1 (0.4)	1 (0.4)
Chondritis	1 (0.4)	0
Groin pain	0	1 (0.4)
Intervertebral disc disorder	1 (0.4)	0
Joint instability	1 (0.4)	0
Ligamentitis	1 (0.4)	0
Metatarsalgia	1 (0.4)	0
Muscular weakness	0	1 (0.4)
Osteochondritis	0	1 (0.4)
Osteochondrosis	1 (0.4)	0
Osteopenia	1 (0.4)	0
Periarthritis	1 (0.4)	0
Polychondritis	1 (0.4)	0
SLE arthritis	0	1 (0.4)
Sacroiliitis	1 (0.4)	0
Sjogren's syndrome	1 (0.4)	0
Temporomandibular joint syndrome	0	1 (0.4)
Tendon pain	0	1 (0.4)
Gastrointestinal disorders	75 (30.5)	69 (28.0)
Nausea	15 (6.1)	17 (6.9)
Diarrhoea	10 (4.1)	16 (6.5)
Vomiting	13 (5.3)	5 (2.0)
Gastrooesophageal reflux disease	8 (3.3)	10 (4.1)
Abdominal pain upper	10 (4.1)	6 (2.4)
Constipation	6 (2.4)	5 (2.0)
Abdominal pain	5 (2.0)	6 (2.4)
Dental caries	7 (2.8)	3 (1.2)
Gastritis	2 (0.8)	8 (3.3)

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Incidence of Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=246) n (%)	Randomised Placebo (N=246) n (%)
Dyspepsia	2 (0.8)	6 (2.4)
Abdominal discomfort	4 (1.6)	1 (0.4)
Haemorrhoids	5 (2.0)	1 (0.4)
Hiatus hernia	0	4 (1.6)
Abdominal distension	2 (0.8)	1 (0.4)
Irritable bowel syndrome	2 (0.8)	1 (0.4)
Mouth ulceration	2 (0.8)	1 (0.4)
Toothache	2 (0.8)	1 (0.4)
Cheilitis	0	2 (0.8)
Colitis	2 (0.8)	0
Diverticulum	2 (0.8)	0
Duodenitis	1 (0.4)	1 (0.4)
Flatulence	0	2 (0.8)
Food poisoning	0	2 (0.8)
Haematochezia	1 (0.4)	1 (0.4)
Loose tooth	1 (0.4)	0
Oesophageal stenosis	0	1 (0.4)
Abdominal pain lower	1 (0.4)	0
Abdominal tenderness	1 (0.4)	0
Aphthous ulcer	1 (0.4)	0
Barrett's oesophagus	1 (0.4)	0
Chilaiditi's syndrome	1 (0.4)	0
Chronic gastritis	1 (0.4)	0
Dental cyst	1 (0.4)	0
Dry mouth	0	1 (0.4)
Dysphagia	1 (0.4)	0
Enterocolitis	0	1 (0.4)
Gastric mucosa erythema	1 (0.4)	0
Gastritis erosive	1 (0.4)	0
Gastrointestinal inflammation	1 (0.4)	0
Gastrointestinal pain	0	1 (0.4)
Gastrointestinal wall thickening	1 (0.4)	0
Gingival recession	1 (0.4)	0
Glossodynia	0	1 (0.4)
Impaired gastric emptying	1 (0.4)	0
Intra-abdominal haematoma	0	1 (0.4)
Large intestine polyp	0	1 (0.4)
Lip swelling	1 (0.4)	0
Oesophageal hypomotility	1 (0.4)	0
Oral mucosal eruption	1 (0.4)	0
Oral pain	0	1 (0.4)
Palatal disorder	1 (0.4)	0
Pancreatic steatosis	0	1 (0.4)
Paraesthesia oral	1 (0.4)	0
Peptic ulcer	0	1 (0.4)
Rectal haemorrhage	1 (0.4)	0
Salivary hypersecretion	0	1 (0.4)
Stomatitis	0	1 (0.4)
Tongue blistering	0	1 (0.4)
Tooth disorder	0	1 (0.4)
Tooth impacted	1 (0.4)	0
Injury, poisoning and procedural complications	78 (31.7)	51 (20.7)
Infusion related reaction	31 (12.6)	20 (8.1)
Fall	8 (3.3)	8 (3.3)
Contusion	10 (4.1)	5 (2.0)
Arthropod bite	7 (2.8)	2 (0.8)
Limb injury	2 (0.8)	3 (1.2)
Ligament sprain	4 (1.6)	1 (0.4)
Muscle strain	3 (1.2)	2 (0.8)
Road traffic accident	1 (0.4)	3 (1.2)

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Incidence of Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=246) n (%)	Randomised Placebo (N=246) n (%)
Ankle fracture	1 (0.4)	3 (1.2)
Epicondylitis	2 (0.8)	2 (0.8)
Foot fracture	1 (0.4)	3 (1.2)
Joint injury	2 (0.8)	2 (0.8)
Rib fracture	2 (0.8)	2 (0.8)
Skin abrasion	2 (0.8)	2 (0.8)
Animal bite	1 (0.4)	2 (0.8)
Arthropod sting	2 (0.8)	1 (0.4)
Meniscus injury	2 (0.8)	1 (0.4)
Animal scratch	2 (0.8)	0
Humerus fracture	1 (0.4)	1 (0.4)
Ligament rupture	2 (0.8)	0
Skin laceration	2 (0.8)	0
Thermal burn	2 (0.8)	0
Thoracic vertebral fracture	1 (0.4)	1 (0.4)
Tooth fracture	1 (0.4)	1 (0.4)
Wound	0	2 (0.8)
Accident	1 (0.4)	0
Anaemia postoperative	0	1 (0.4)
Concussion	1 (0.4)	0
Dental restoration failure	0	1 (0.4)
Facial bones fracture	1 (0.4)	0
Fibula fracture	0	1 (0.4)
Foreign body in respiratory tract	1 (0.4)	0
Hand fracture	1 (0.4)	0
Hypobarism	1 (0.4)	0
Incisional hernia	1 (0.4)	0
Injury	1 (0.4)	0
Joint dislocation	1 (0.4)	0
Limb crushing injury	0	1 (0.4)
Lower limb fracture	1 (0.4)	0
Mouth injury	1 (0.4)	0
Muscle contusion	1 (0.4)	0
Post procedural complication	1 (0.4)	0
Post procedural haematoma	0	1 (0.4)
Post procedural haemorrhage	0	1 (0.4)
Post-traumatic neck syndrome	0	1 (0.4)
Post-traumatic pain	1 (0.4)	0
Pubis fracture	0	1 (0.4)
Reactive gastropathy	1 (0.4)	0
Skin injury	0	1 (0.4)
Spinal fracture	1 (0.4)	0
Stress fracture	1 (0.4)	0
Sunburn	1 (0.4)	0
Tendon rupture	0	1 (0.4)
Tibia fracture	1 (0.4)	0
Toxicity to various agents	1 (0.4)	0
Traumatic fracture	1 (0.4)	0
Vaccination complication	1 (0.4)	0
Wound complication	1 (0.4)	0
Nervous system disorders	71 (28.9)	43 (17.5)
Headache	28 (11.4)	26 (10.6)
Dizziness	7 (2.8)	5 (2.0)
Migraine	3 (1.2)	5 (2.0)
Hypoaesthesia	6 (2.4)	1 (0.4)
Neuralgia	4 (1.6)	2 (0.8)
Paraesthesia	6 (2.4)	0
Sciatica	5 (2.0)	0
Syncope	4 (1.6)	2 (0.8)
Carpal tunnel syndrome	4 (1.6)	1 (0.4)

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Incidence of Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=246) n (%)	Randomised Placebo (N=246) n (%)
Cervicobrachial syndrome	3 (1.2)	1 (0.4)
Post herpetic neuralgia	4 (1.6)	0
Restless legs syndrome	2 (0.8)	2 (0.8)
Tremor	1 (0.4)	2 (0.8)
Migraine with aura	3 (1.2)	0
Presyncope	2 (0.8)	1 (0.4)
Tension headache	1 (0.4)	2 (0.8)
Amnesia	2 (0.8)	0
Facial paralysis	1 (0.4)	1 (0.4)
Myoclonus	1 (0.4)	1 (0.4)
Neuropathy peripheral	1 (0.4)	1 (0.4)
Peroneal nerve palsy	2 (0.8)	0
Radiculopathy	2 (0.8)	0
Cervical radiculopathy	0	1 (0.4)
Cognitive disorder	1 (0.4)	0
Dizziness postural	0	1 (0.4)
Dysarthria	1 (0.4)	0
Epilepsy	1 (0.4)	0
Hyperaesthesia	0	1 (0.4)
Intention tremor	0	1 (0.4)
Lumbar radiculopathy	1 (0.4)	0
Myasthenia gravis	1 (0.4)	0
Occipital neuralgia	1 (0.4)	0
Parkinson's disease	1 (0.4)	0
Parkinsonian gait	1 (0.4)	0
Sensory disturbance	0	1 (0.4)
Spinal cord compression	0	1 (0.4)
Tunnel vision	0	1 (0.4)
Skin and subcutaneous tissue disorders	52 (21.1)	36 (14.6)
Rash	7 (2.8)	8 (3.3)
Urticaria	6 (2.4)	2 (0.8)
Pruritus	4 (1.6)	4 (1.6)
Hidradenitis	4 (1.6)	1 (0.4)
Ecchymosis	4 (1.6)	2 (0.8)
Acne	4 (1.6)	0
Dermatitis contact	3 (1.2)	2 (0.8)
Eczema	4 (1.6)	1 (0.4)
Skin ulcer	3 (1.2)	2 (0.8)
Angioedema	2 (0.8)	2 (0.8)
Dermatitis allergic	2 (0.8)	1 (0.4)
Ingrowing nail	4 (1.6)	0
Dermatitis	0	3 (1.2)
Erythema	1 (0.4)	2 (0.8)
Night sweats	2 (0.8)	0
Purpura	2 (0.8)	1 (0.4)
Dermal cyst	1 (0.4)	1 (0.4)
Dermatitis atopic	2 (0.8)	0
Erythema nodosum	0	1 (0.4)
Hyperhidrosis	0	2 (0.8)
Perioral dermatitis	1 (0.4)	0
Psoriasis	1 (0.4)	1 (0.4)
Rash pruritic	1 (0.4)	1 (0.4)
Rosacea	2 (0.8)	0
Skin hyperpigmentation	1 (0.4)	1 (0.4)
Skin lesion	1 (0.4)	1 (0.4)
Alopecia	0	1 (0.4)
Blister	1 (0.4)	0
Cold urticaria	0	1 (0.4)
Decubitus ulcer	0	1 (0.4)
Dermatitis acneiform	0	1 (0.4)

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Incidence of Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=246) n (%)	Randomised Placebo (N=246) n (%)
Drug eruption	0	1 (0.4)
Dry skin	1 (0.4)	0
Guttate psoriasis	1 (0.4)	0
Haemorrhage subcutaneous	0	1 (0.4)
Keloid scar	1 (0.4)	0
Lichen sclerosus	1 (0.4)	0
Lipoatrophy	1 (0.4)	0
Nail bed bleeding	0	1 (0.4)
Nail disorder	1 (0.4)	0
Nail dystrophy	1 (0.4)	0
Pigmentation disorder	1 (0.4)	0
Post inflammatory pigmentation change	0	1 (0.4)
Rash follicular	1 (0.4)	0
Rash papular	0	1 (0.4)
Rash vesicular	1 (0.4)	0
Scab	1 (0.4)	0
Seborrhoeic dermatitis	1 (0.4)	0
Skin fissures	0	1 (0.4)
Systemic lupus erythematosus rash	0	1 (0.4)
Urticaria chronic	1 (0.4)	0
Vasculitic ulcer	1 (0.4)	0
Venous ulcer pain	0	1 (0.4)
Vitiligo	0	1 (0.4)
Xanthelasma	0	1 (0.4)
Respiratory, thoracic and mediastinal disorders	**56 (22.8)**	**38 (15.4)**
Cough	26 (10.6)	8 (3.3)
Asthma	5 (2.0)	6 (2.4)
Epistaxis	4 (1.6)	5 (2.0)
Nasal congestion	3 (1.2)	4 (1.6)
Oropharyngeal pain	5 (2.0)	3 (1.2)
Rhinitis allergic	4 (1.6)	2 (0.8)
Dyspnoea	2 (0.8)	3 (1.2)
Pleural effusion	3 (1.2)	2 (0.8)
Rhinorrhoea	3 (1.2)	1 (0.4)
Chronic obstructive pulmonary disease	2 (0.8)	1 (0.4)
Productive cough	3 (1.2)	1 (0.4)
Nasal obstruction	1 (0.4)	2 (0.8)
Upper respiratory tract inflammation	2 (0.8)	0
Acute respiratory failure	2 (0.8)	0
Pulmonary mass	1 (0.4)	1 (0.4)
Respiratory disorder	1 (0.4)	1 (0.4)
Sinus congestion	2 (0.8)	0
Atelectasis	1 (0.4)	0
Catarrh	0	1 (0.4)
Interstitial lung disease	1 (0.4)	0
Lung disorder	1 (0.4)	0
Paranasal sinus discomfort	0	1 (0.4)
Pulmonary alveolar haemorrhage	0	1 (0.4)
Pulmonary embolism	0	1 (0.4)
Respiratory distress	0	1 (0.4)
Respiratory failure	0	1 (0.4)
Sleep apnoea syndrome	0	1 (0.4)
Throat irritation	1 (0.4)	0
Tracheal stenosis	1 (0.4)	0
Upper-airway cough syndrome	1 (0.4)	0
Wheezing	1 (0.4)	0
General disorders and administration site conditions	**44 (17.9)**	**27 (11.0)**
Pyrexia	9 (3.7)	5 (2.0)
Non-cardiac chest pain	6 (2.4)	8 (3.3)

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Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Incidence of Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=246) n (%)	Randomised Placebo (N=246) n (%)
Oedema peripheral	8 (3.3)	3 (1.2)
Fatigue	7 (2.8)	2 (0.8)
Influenza like illness	2 (0.8)	1 (0.4)
Asthenia	3 (1.2)	2 (0.8)
Adverse drug reaction	2 (0.8)	2 (0.8)
Chest discomfort	3 (1.2)	1 (0.4)
Chest pain	4 (1.6)	0
Pain	2 (0.8)	1 (0.4)
Swelling face	0	3 (1.2)
Face oedema	2 (0.8)	0
Peripheral swelling	1 (0.4)	1 (0.4)
Chills	0	1 (0.4)
Gravitational oedema	0	1 (0.4)
Malaise	1 (0.4)	0
Nodule	1 (0.4)	0
Vaccination site reaction	1 (0.4)	0
Psychiatric disorders	27 (11.0)	30 (12.2)
Insomnia	8 (3.3)	15 (6.1)
Depression	14 (5.7)	6 (2.4)
Anxiety	11 (4.5)	6 (2.4)
Suicidal ideation	1 (0.4)	1 (0.4)
Adjustment disorder	0	1 (0.4)
Anxiety disorder	1 (0.4)	0
Depressed mood	0	1 (0.4)
Drug use disorder	1 (0.4)	0
Loss of libido	0	1 (0.4)
Mixed anxiety and depressive disorder	1 (0.4)	0
Panic attack	1 (0.4)	0
Persistent depressive disorder	0	1 (0.4)
Psychotic disorder	0	1 (0.4)
Substance-induced psychotic disorder	0	1 (0.4)
Metabolism and nutrition disorders	26 (10.6)	27 (11.0)
Hypokalaemia	4 (1.6)	5 (2.0)
Dehydration	0	7 (2.8)
Vitamin D deficiency	5 (2.0)	3 (1.2)
Hypercholesterolaemia	6 (2.4)	0
Hyperglycaemia	2 (0.8)	2 (0.8)
Vitamin B12 deficiency	3 (1.2)	1 (0.4)
Diabetes mellitus	3 (1.2)	0
Dyslipidaemia	1 (0.4)	2 (0.8)
Type 2 diabetes mellitus	1 (0.4)	2 (0.8)
Glucose tolerance impaired	1 (0.4)	1 (0.4)
Hyperlipidaemia	2 (0.8)	0
Hypertriglyceridaemia	2 (0.8)	0
Hypomagnesaemia	1 (0.4)	1 (0.4)
Vitamin B complex deficiency	2 (0.8)	0
Fluid overload	0	1 (0.4)
Hypercalcaemia	1 (0.4)	0
Hyperkalaemia	0	1 (0.4)
Hyperuricaemia	1 (0.4)	0
Hypocalcaemia	0	1 (0.4)
Hyponatraemia	0	1 (0.4)
Increased appetite	1 (0.4)	0
Iron deficiency	1 (0.4)	0
Lactic acidosis	0	1 (0.4)
Lipoedema	0	1 (0.4)
Overweight	1 (0.4)	0
Steroid diabetes	1 (0.4)	0

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Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Incidence of Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=246) n (%)	Randomised Placebo (N=246) n (%)
Eye disorders	29 (11.8)	15 (6.1)
Cataract	5 (2.0)	2 (0.8)
Blepharitis	3 (1.2)	3 (1.2)
Dry eye	4 (1.6)	1 (0.4)
Chalazion	1 (0.4)	2 (0.8)
Conjunctival haemorrhage	1 (0.4)	2 (0.8)
Episcleritis	3 (1.2)	0
Glaucoma	1 (0.4)	0
Keratitis	1 (0.4)	1 (0.4)
Retinopathy	2 (0.8)	0
Vision blurred	2 (0.8)	0
Vitreous floaters	2 (0.8)	0
Accommodation disorder	1 (0.4)	0
Asthenopia	1 (0.4)	0
Chorioretinopathy	1 (0.4)	0
Conjunctival erosion	0	1 (0.4)
Conjunctivitis allergic	1 (0.4)	0
Corneal erosion	0	1 (0.4)
Diplopia	0	1 (0.4)
Eye discharge	1 (0.4)	0
Eye inflammation	1 (0.4)	0
Eye pruritus	1 (0.4)	0
Lacrimation decreased	1 (0.4)	0
Lacrimation increased	1 (0.4)	0
Macular degeneration	1 (0.4)	0
Maculopathy	0	1 (0.4)
Periorbital oedema	1 (0.4)	0
Photophobia	0	1 (0.4)
Trichiasis	0	1 (0.4)
Visual impairment	0	1 (0.4)
Reproductive system and breast disorders	27 (11.0)	15 (6.1)
Menorrhagia	4 (1.6)	2 (0.8)
Dysmenorrhoea	5 (2.0)	0
Ovarian cyst	3 (1.2)	2 (0.8)
Uterine haemorrhage	3 (1.2)	0
Breast cyst	2 (0.8)	1 (0.4)
Cervical dysplasia	1 (0.4)	1 (0.4)
Fibrocystic breast disease	2 (0.8)	0
Menometrorrhagia	2 (0.8)	0
Menstruation irregular	1 (0.4)	1 (0.4)
Uterine polyp	2 (0.8)	0
Vulvovaginal pruritus	2 (0.8)	0
Adenomyosis	0	1 (0.4)
Adnexa uteri cyst	0	1 (0.4)
Amenorrhoea	1 (0.4)	0
Atrophic vulvovaginitis	1 (0.4)	0
Balanoposthitis	1 (0.4)	0
Breast calcifications	0	1 (0.4)
Breast mass	1 (0.4)	0
Cervical cyst	1 (0.4)	0
Cervical polyp	1 (0.4)	0
Cervix disorder	1 (0.4)	0
Dyspareunia	1 (0.4)	0
Endometrial hyperplasia	0	1 (0.4)
Menopausal symptoms	0	1 (0.4)
Metrorrhagia	1 (0.4)	0
Perineal rash	1 (0.4)	0
Polycystic ovaries	1 (0.4)	0
Premenstrual syndrome	1 (0.4)	0
Scrotal ulcer	0	1 (0.4)

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Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Incidence of Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=246) n (%)	Randomised Placebo (N=246) n (%)
Vaginal discharge	1 (0.4)	0
Vaginal haemorrhage	0	1 (0.4)
Vaginal ulceration	0	1 (0.4)
Renal and urinary disorders	23 (9.3)	13 (5.3)
Dysuria	1 (0.4)	6 (2.4)
Nephrolithiasis	4 (1.6)	1 (0.4)
Acute kidney injury	2 (0.8)	3 (1.2)
Lupus nephritis	2 (0.8)	1 (0.4)
Haematuria	2 (0.8)	0
Renal impairment	1 (0.4)	0
Renal colic	1 (0.4)	1 (0.4)
Bladder spasm	1 (0.4)	0
Chronic kidney disease	1 (0.4)	0
Glomerulonephritis	1 (0.4)	0
Hydronephrosis	1 (0.4)	0
Leukocyturia	1 (0.4)	0
Nephritis	1 (0.4)	0
Polyuria	1 (0.4)	0
Renal cyst	1 (0.4)	0
Renal failure	0	1 (0.4)
Stress urinary incontinence	1 (0.4)	0
Ureteric obstruction	1 (0.4)	0
Urethral meatus stenosis	1 (0.4)	0
Urinary incontinence	1 (0.4)	0
Urinary retention	1 (0.4)	0
Investigations	19 (7.7)	19 (7.7)
Weight increased	3 (1.2)	5 (2.0)
Alanine aminotransferase increased	2 (0.8)	2 (0.8)
Liver function test increased	0	4 (1.6)
Blood potassium decreased	2 (0.8)	1 (0.4)
Gamma-glutamyltransferase increased	1 (0.4)	2 (0.8)
Aspartate aminotransferase increased	1 (0.4)	1 (0.4)
Blood creatine phosphokinase increased	2 (0.8)	0
Cardiac murmur	1 (0.4)	1 (0.4)
Anticoagulation drug level below therapeutic	1 (0.4)	0
Blood alkaline phosphatase increased	1 (0.4)	0
Blood corticotrophin decreased	1 (0.4)	0
Blood creatinine increased	1 (0.4)	0
Blood immunoglobulin A decreased	0	1 (0.4)
Blood pressure increased	1 (0.4)	0
Heart rate increased	0	1 (0.4)
Hepatic enzyme increased	0	1 (0.4)
Human papilloma virus test positive	1 (0.4)	0
Influenza B virus test positive	1 (0.4)	0
International normalised ratio abnormal	1 (0.4)	0
International normalised ratio increased	0	1 (0.4)
Intraocular pressure increased	1 (0.4)	0
Transaminases increased	0	1 (0.4)
Urine protein/creatinine ratio increased	1 (0.4)	0
Vitamin D decreased	1 (0.4)	0
Weight decreased	1 (0.4)	0
Blood and lymphatic system disorders	17 (6.9)	17 (6.9)
Anaemia	4 (1.6)	8 (3.3)
Iron deficiency anaemia	7 (2.8)	4 (1.6)
Lymphadenopathy	3 (1.2)	2 (0.8)
Thrombocytopenia	2 (0.8)	1 (0.4)
Leukopenia	0	2 (0.8)
Lymphopenia	1 (0.4)	0

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Anifrolumab (MEDI-546)
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System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=246) n (%)	Randomised Placebo (N=246) n (%)
Microcytic anaemia	0	2 (0.8)
Autoimmune haemolytic anaemia	0	1 (0.4)
Leukocytosis	1 (0.4)	0
Neutropenia	1 (0.4)	0
Vascular disorders	15 (6.1)	18 (7.3)
Hypertension	8 (3.3)	13 (5.3)
Haematoma	2 (0.8)	1 (0.4)
Orthostatic hypotension	1 (0.4)	1 (0.4)
Phlebitis	2 (0.8)	0
Essential hypertension	1 (0.4)	0
Hypotension	0	1 (0.4)
Internal haemorrhage	0	1 (0.4)
Malignant hypertension	1 (0.4)	0
Raynaud's phenomenon	1 (0.4)	0
Varicophlebitis	0	1 (0.4)
Vasodilatation	0	1 (0.4)
Venous thrombosis limb	0	1 (0.4)
Cardiac disorders	12 (4.9)	15 (6.1)
Cardiac failure congestive	1 (0.4)	3 (1.2)
Atrial fibrillation	0	3 (1.2)
Palpitations	1 (0.4)	2 (0.8)
Supraventricular tachycardia	0	3 (1.2)
Acute myocardial infarction	0	2 (0.8)
Coronary artery disease	2 (0.8)	0
Myocardial infarction	1 (0.4)	1 (0.4)
Pericarditis	0	2 (0.8)
Sinus bradycardia	1 (0.4)	1 (0.4)
Tachycardia	1 (0.4)	1 (0.4)
Acute coronary syndrome	1 (0.4)	0
Angina pectoris	0	1 (0.4)
Angina unstable	1 (0.4)	0
Arrhythmia	1 (0.4)	0
Bundle branch block left	1 (0.4)	0
Bundle branch block right	1 (0.4)	0
Cardiac failure	0	1 (0.4)
Cardiac failure chronic	1 (0.4)	0
Cardiomegaly	0	1 (0.4)
Cardiomyopathy	0	1 (0.4)
Left ventricular dilatation	1 (0.4)	0
Myocardial ischaemia	1 (0.4)	0
Tachycardia paroxysmal	1 (0.4)	0
Ventricular arrhythmia	0	1 (0.4)
Ear and labyrinth disorders	16 (6.5)	12 (4.9)
Vertigo	8 (3.3)	2 (0.8)
Ear pain	4 (1.6)	3 (1.2)
Vertigo positional	3 (1.2)	2 (0.8)
Cerumen impaction	2 (0.8)	0
Ear congestion	1 (0.4)	1 (0.4)
Tinnitus	0	2 (0.8)
Deafness bilateral	1 (0.4)	0
Ear discomfort	0	1 (0.4)
Hyperacusis	1 (0.4)	0
Motion sickness	0	1 (0.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	17 (6.9)	9 (3.7)
Skin papilloma	5 (2.0)	1 (0.4)
Uterine leiomyoma	4 (1.6)	1 (0.4)
Anogenital warts	2 (0.8)	0

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Anifrolumab (MEDI-546)
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Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=246) n (%)	Randomised Placebo (N=246) n (%)
Colon adenoma	0	1 (0.4)
Haemangioma of liver	1 (0.4)	1 (0.4)
B-cell lymphoma	1 (0.4)	0
Benign breast neoplasm	1 (0.4)	0
Carcinoid tumour	0	1 (0.4)
Fibrous histiocytoma	1 (0.4)	0
Hepatic adenoma	1 (0.4)	0
Lipoma	0	1 (0.4)
Seborrhoeic keratosis	0	1 (0.4)
Squamous cell carcinoma of the cervix	0	1 (0.4)
Uterine cancer	0	1 (0.4)
Vulvovaginal warts	1 (0.4)	0
Immune system disorders	20 (8.1)	9 (3.7)
Hypersensitivity	10 (4.1)	3 (1.2)
Seasonal allergy	5 (2.0)	3 (1.2)
Allergy to animal	1 (0.4)	2 (0.8)
Drug hypersensitivity	0	2 (0.8)
Allergy to arthropod bite	1 (0.4)	0
Allergy to arthropod sting	1 (0.4)	0
Contrast media reaction	1 (0.4)	0
Reaction to preservatives	1 (0.4)	0
Endocrine disorders	8 (3.3)	3 (1.2)
Steroid withdrawal syndrome	3 (1.2)	0
Goitre	2 (0.8)	0
Hyperprolactinaemia	2 (0.8)	0
Hyperthyroidism	1 (0.4)	1 (0.4)
Adrenal insufficiency	0	1 (0.4)
Basedow's disease	1 (0.4)	0
Cushing's syndrome	1 (0.4)	0
Hyperparathyroidism	0	1 (0.4)
Hepatobiliary disorders	5 (2.0)	4 (1.6)
Hepatic steatosis	1 (0.4)	2 (0.8)
Biliary colic	1 (0.4)	0
Cholecystitis	0	1 (0.4)
Cholelithiasis	1 (0.4)	0
Drug-induced liver injury	1 (0.4)	0
Hepatic lesion	0	1 (0.4)
Hepatic mass	1 (0.4)	0
Social circumstances	1 (0.4)	1 (0.4)
Menopause	1 (0.4)	1 (0.4)
Pregnancy, puerperium and perinatal conditions	1 (0.4)	0
Abortion spontaneous	1 (0.4)	0

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Anifrolumab (MEDI-546)
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Incidence of Serious Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=246) n (%)	Randomised Placebo (N=246) n (%)
Subjects with events	45 (18.3)	55 (22.4)
Infections and infestations	18 (7.3)	19 (7.7)
Pneumonia	4 (1.6)	7 (2.8)
Gastroenteritis	1 (0.4)	2 (0.8)
Herpes zoster	4 (1.6)	0
Diverticulitis	2 (0.8)	0
Urinary tract infection	2 (0.8)	1 (0.4)
Appendicitis	2 (0.8)	0
Influenza	1 (0.4)	1 (0.4)
Sepsis	0	2 (0.8)
Abscess	0	1 (0.4)
Bronchitis	0	1 (0.4)
Epididymitis	0	1 (0.4)
Erysipelas	0	1 (0.4)
Gastroenteritis viral	1 (0.4)	0
Herpes zoster disseminated	1 (0.4)	0
Meningitis	0	1 (0.4)
Otitis media chronic	0	1 (0.4)
Pelvic inflammatory disease	1 (0.4)	0
Periodontitis	0	1 (0.4)
Pneumonia bacterial	1 (0.4)	0
Pneumonia staphylococcal	0	1 (0.4)
Postoperative wound infection	0	1 (0.4)
Pyelonephritis	1 (0.4)	0
Septic shock	0	1 (0.4)
Streptococcal urinary tract infection	1 (0.4)	0
Upper respiratory tract infection	0	1 (0.4)
Musculoskeletal and connective tissue disorders	7 (2.8)	11 (4.5)
Systemic lupus erythematosus	2 (0.8)	10 (4.1)
Osteonecrosis	1 (0.4)	1 (0.4)
Arthritis	1 (0.4)	0
Pain in extremity	1 (0.4)	0
Synovial cyst	1 (0.4)	0
Tenosynovitis	1 (0.4)	0
Cardiac disorders	5 (2.0)	6 (2.4)
Cardiac failure congestive	1 (0.4)	1 (0.4)
Coronary artery disease	2 (0.8)	0
Myocardial infarction	1 (0.4)	1 (0.4)
Supraventricular tachycardia	0	2 (0.8)
Acute coronary syndrome	1 (0.4)	0
Acute myocardial infarction	0	1 (0.4)
Atrial fibrillation	0	1 (0.4)
Bundle branch block left	1 (0.4)	0
Cardiac failure	0	1 (0.4)
Myocardial ischaemia	1 (0.4)	0
Ventricular arrhythmia	0	1 (0.4)
Respiratory, thoracic and mediastinal disorders	5 (2.0)	6 (2.4)
Asthma	3 (1.2)	1 (0.4)
Acute respiratory failure	2 (0.8)	0
Chronic obstructive pulmonary disease	0	1 (0.4)
Pleural effusion	1 (0.4)	0
Pulmonary alveolar haemorrhage	0	1 (0.4)
Pulmonary embolism	0	1 (0.4)
Respiratory distress	0	1 (0.4)
Respiratory failure	0	1 (0.4)

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Incidence of Serious Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=246) n (%)	Randomised Placebo (N=246) n (%)
Injury, poisoning and procedural complications	4 (1.6)	4 (1.6)
Ankle fracture	0	1 (0.4)
Facial bones fracture	1 (0.4)	0
Fall	1 (0.4)	0
Humerus fracture	1 (0.4)	0
Post procedural complication	1 (0.4)	0
Post procedural haematoma	0	1 (0.4)
Rib fracture	0	1 (0.4)
Tendon rupture	0	1 (0.4)
Traumatic fracture	1 (0.4)	0
Renal and urinary disorders	4 (1.6)	4 (1.6)
Acute kidney injury	1 (0.4)	1 (0.4)
Lupus nephritis	1 (0.4)	1 (0.4)
Renal impairment	1 (0.4)	0
Dysuria	0	1 (0.4)
Nephritis	1 (0.4)	0
Renal failure	0	1 (0.4)
General disorders and administration site conditions	3 (1.2)	4 (1.6)
Non-cardiac chest pain	2 (0.8)	1 (0.4)
Chest pain	1 (0.4)	0
Influenza like illness	0	1 (0.4)
Pain	0	1 (0.4)
Swelling face	0	1 (0.4)
Blood and lymphatic system disorders	2 (0.8)	4 (1.6)
Anaemia	0	3 (1.2)
Thrombocytopenia	2 (0.8)	0
Iron deficiency anaemia	0	1 (0.4)
Gastrointestinal disorders	2 (0.8)	2 (0.8)
Chilaiditi's syndrome	1 (0.4)	0
Colitis	1 (0.4)	0
Intra-abdominal haematoma	0	1 (0.4)
Oesophageal stenosis	0	1 (0.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.8)	2 (0.8)
B-cell lymphoma	1 (0.4)	0
Haemangioma of liver	0	1 (0.4)
Uterine cancer	0	1 (0.4)
Uterine leiomyoma	1 (0.4)	0
Nervous system disorders	3 (1.2)	1 (0.4)
Hypoaesthesia	1 (0.4)	0
Myasthenia gravis	1 (0.4)	0
Post herpetic neuralgia	1 (0.4)	0
Syncope	0	1 (0.4)
Skin and subcutaneous tissue disorders	1 (0.4)	3 (1.2)
Urticaria	0	2 (0.8)
Angioedema	1 (0.4)	0
Drug eruption	0	1 (0.4)
Vascular disorders	1 (0.4)	3 (1.2)
Hypotension	0	1 (0.4)
Malignant hypertension	1 (0.4)	0
Orthostatic hypotension	0	1 (0.4)
Venous thrombosis limb	0	1 (0.4)
Investigations	1 (0.4)	2 (0.8)

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Incidence of Serious Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=246) n (%)	Randomised Placebo (N=246) n (%)
Blood creatinine increased	1 (0.4)	0
International normalised ratio increased	0	1 (0.4)
Liver function test increased	0	1 (0.4)
Reproductive system and breast disorders	1 (0.4)	2 (0.8)
Menorrhagia	0	1 (0.4)
Uterine haemorrhage	1 (0.4)	0
Vaginal ulceration	0	1 (0.4)
Ear and labyrinth disorders	1 (0.4)	0
Vertigo	1 (0.4)	0
Hepatobiliary disorders	1 (0.4)	0
Cholelithiasis	1 (0.4)	0
Immune system disorders	1 (0.4)	0
Hypersensitivity	1 (0.4)	0
Metabolism and nutrition disorders	1 (0.4)	0
Hypercalcaemia	1 (0.4)	0
Pregnancy, puerperium and perinatal conditions	1 (0.4)	0
Abortion spontaneous	1 (0.4)	0
Psychiatric disorders	0	1 (0.4)
Psychotic disorder	0	1 (0.4)

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Incidence of Severe Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=246) n (%)	Randomised Placebo (N=246) n (%)
Subjects with events	31 (12.6)	27 (11.0)
Infections and infestations	12 (4.9)	7 (2.8)
Pneumonia	2 (0.8)	2 (0.8)
Bronchitis	1 (0.4)	2 (0.8)
Herpes zoster	2 (0.8)	0
Influenza	1 (0.4)	1 (0.4)
Sepsis	0	2 (0.8)
Acute sinusitis	1 (0.4)	0
Diverticulitis	1 (0.4)	0
Gastroenteritis	1 (0.4)	0
Herpes zoster disseminated	1 (0.4)	0
Meningitis	0	1 (0.4)
Pelvic inflammatory disease	1 (0.4)	0
Pneumonia bacterial	1 (0.4)	0
Pneumonia staphylococcal	0	1 (0.4)
Postoperative wound infection	0	1 (0.4)
Pyelonephritis	1 (0.4)	0
Septic shock	0	1 (0.4)
Streptococcal urinary tract infection	1 (0.4)	0
Urinary tract infection	1 (0.4)	0
Musculoskeletal and connective tissue disorders	4 (1.6)	6 (2.4)
Systemic lupus erythematosus	2 (0.8)	3 (1.2)
Arthralgia	0	1 (0.4)
Back pain	0	1 (0.4)
Pain in extremity	1 (0.4)	0
Rotator cuff syndrome	0	1 (0.4)
SLE arthritis	0	1 (0.4)
Tendonitis	1 (0.4)	0
Respiratory, thoracic and mediastinal disorders	4 (1.6)	5 (2.0)
Asthma	1 (0.4)	1 (0.4)
Acute respiratory failure	1 (0.4)	0
Cough	1 (0.4)	0
Dyspnoea	1 (0.4)	0
Epistaxis	1 (0.4)	0
Interstitial lung disease	1 (0.4)	0
Pulmonary alveolar haemorrhage	0	1 (0.4)
Pulmonary embolism	0	1 (0.4)
Respiratory distress	0	1 (0.4)
Respiratory failure	0	1 (0.4)
Cardiac disorders	4 (1.6)	4 (1.6)
Myocardial infarction	1 (0.4)	1 (0.4)
Acute coronary syndrome	1 (0.4)	0
Atrial fibrillation	0	1 (0.4)
Cardiac failure	0	1 (0.4)
Cardiac failure congestive	1 (0.4)	0
Cardiomyopathy	0	1 (0.4)
Coronary artery disease	1 (0.4)	0
Myocardial ischaemia	1 (0.4)	0
Supraventricular tachycardia	0	1 (0.4)
Nervous system disorders	5 (2.0)	1 (0.4)
Migraine	1 (0.4)	1 (0.4)
Hypoaesthesia	1 (0.4)	0
Peroneal nerve palsy	1 (0.4)	0
Post herpetic neuralgia	1 (0.4)	0
Radiculopathy	1 (0.4)	0

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Incidence of Severe Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=246) n (%)	Randomised Placebo (N=246) n (%)
Blood and lymphatic system disorders	3 (1.2)	2 (0.8)
Anaemia	1 (0.4)	1 (0.4)
Thrombocytopenia	2 (0.8)	0
Iron deficiency anaemia	0	1 (0.4)
Injury, poisoning and procedural complications	3 (1.2)	2 (0.8)
Facial bones fracture	1 (0.4)	0
Humerus fracture	1 (0.4)	0
Incisional hernia	1 (0.4)	0
Post procedural haematoma	0	1 (0.4)
Tendon rupture	0	1 (0.4)
Renal and urinary disorders	2 (0.8)	3 (1.2)
Lupus nephritis	1 (0.4)	1 (0.4)
Acute kidney injury	1 (0.4)	0
Dysuria	0	1 (0.4)
Renal failure	0	1 (0.4)
Gastrointestinal disorders	1 (0.4)	1 (0.4)
Abdominal pain	1 (0.4)	0
Colitis	1 (0.4)	0
Oesophageal stenosis	0	1 (0.4)
General disorders and administration site conditions	1 (0.4)	1 (0.4)
Influenza like illness	1 (0.4)	0
Pain	0	1 (0.4)
Vascular disorders	0	2 (0.8)
Hypertension	0	1 (0.4)
Venous thrombosis limb	0	1 (0.4)
Immune system disorders	0	1 (0.4)
Drug hypersensitivity	0	1 (0.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	1 (0.4)
Haemangioma of liver	0	1 (0.4)
Psychiatric disorders	1 (0.4)	0
Suicidal ideation	1 (0.4)	0

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Incidence of Non-Severe Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=246) n (%)	Randomised Placebo (N=246) n (%)
Subjects with events	225 (91.5)	208 (84.6)
Infections and infestations	188 (76.4)	158 (64.2)
Nasopharyngitis	63 (25.6)	31 (12.6)
Upper respiratory tract infection	59 (24.0)	29 (11.8)
Urinary tract infection	46 (18.7)	37 (15.0)
Bronchitis	45 (18.3)	14 (5.7)
Sinusitis	23 (9.3)	13 (5.3)
Pharyngitis	20 (8.1)	15 (6.1)
Herpes zoster	23 (9.3)	7 (2.8)
Oral herpes	12 (4.9)	8 (3.3)
Gastroenteritis	9 (3.7)	7 (2.8)
Respiratory tract infection	12 (4.9)	1 (0.4)
Influenza	11 (4.5)	9 (3.7)
Vaginal infection	9 (3.7)	7 (2.8)
Cystitis	7 (2.8)	5 (2.0)
Pneumonia	9 (3.7)	8 (3.3)
Conjunctivitis	11 (4.5)	4 (1.6)
Viral upper respiratory tract infection	11 (4.5)	2 (0.8)
Gastroenteritis viral	6 (2.4)	4 (1.6)
Latent tuberculosis	9 (3.7)	3 (1.2)
Cellulitis	4 (1.6)	6 (2.4)
Otitis media	8 (3.3)	0
Tooth abscess	7 (2.8)	2 (0.8)
Onychomycosis	4 (1.6)	3 (1.2)
Oral candidiasis	3 (1.2)	5 (2.0)
Tooth infection	4 (1.6)	3 (1.2)
Vulvovaginal mycotic infection	6 (2.4)	2 (0.8)
Folliculitis	4 (1.6)	1 (0.4)
Fungal skin infection	3 (1.2)	2 (0.8)
Furuncle	2 (0.8)	2 (0.8)
Paronychia	3 (1.2)	3 (1.2)
Rhinitis	3 (1.2)	3 (1.2)
Tonsillitis	5 (2.0)	1 (0.4)
Viral infection	4 (1.6)	2 (0.8)
Bacterial vaginosis	1 (0.4)	3 (1.2)
Gastrointestinal viral infection	1 (0.4)	2 (0.8)
Herpes simplex	1 (0.4)	2 (0.8)
Lower respiratory tract infection	3 (1.2)	0
Respiratory tract infection viral	2 (0.8)	2 (0.8)
Vulvovaginitis	3 (1.2)	0
Cervicitis	3 (1.2)	0
Tinea versicolour	2 (0.8)	1 (0.4)
Vulvovaginal candidiasis	2 (0.8)	2 (0.8)
Appendicitis	3 (1.2)	0
Diverticulitis	2 (0.8)	0
Ear infection	2 (0.8)	1 (0.4)
Fungal infection	2 (0.8)	1 (0.4)
Hordeolum	1 (0.4)	2 (0.8)
Laryngitis	1 (0.4)	1 (0.4)
Subcutaneous abscess	2 (0.8)	1 (0.4)
Tinea pedis	2 (0.8)	1 (0.4)
Tracheitis	3 (1.2)	0
Tracheobronchitis	2 (0.8)	1 (0.4)
Viral pharyngitis	3 (1.2)	0
Wound infection	1 (0.4)	2 (0.8)
Acute sinusitis	1 (0.4)	1 (0.4)
Candida infection	2 (0.8)	0
Escherichia urinary tract infection	2 (0.8)	0
Gastrointestinal infection	0	2 (0.8)

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Incidence of Non-Severe Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=246) n (%)	Randomised Placebo (N=246) n (%)
Genital herpes	1 (0.4)	0
Genital herpes simplex	1 (0.4)	1 (0.4)
Otitis externa	1 (0.4)	1 (0.4)
Otitis media acute	2 (0.8)	0
Parotitis	2 (0.8)	0
Periodontitis	0	2 (0.8)
Pharyngitis streptococcal	0	2 (0.8)
Rotavirus infection	2 (0.8)	0
Sialoadenitis	2 (0.8)	0
Superinfection	1 (0.4)	1 (0.4)
Abscess	0	1 (0.4)
Abscess limb	1 (0.4)	0
Acarodermatitis	0	1 (0.4)
Alveolar osteitis	1 (0.4)	0
Bacterial vulvovaginitis	1 (0.4)	0
Bartholinitis	1 (0.4)	0
Chronic sinusitis	1 (0.4)	0
Chronic tonsillitis	1 (0.4)	0
Cystitis escherichia	0	1 (0.4)
Dacryocystitis	1 (0.4)	0
Epididymitis	0	1 (0.4)
Erysipelas	0	1 (0.4)
Escherichia infection	1 (0.4)	0
Eyelid infection	1 (0.4)	0
Gastroenteritis bacterial	0	1 (0.4)
Giardiasis	0	1 (0.4)
Gingivitis	1 (0.4)	0
Human ehrlichiosis	1 (0.4)	0
Labyrinthitis	1 (0.4)	0
Large intestine infection	1 (0.4)	0
Laryngitis viral	1 (0.4)	0
Localised infection	1 (0.4)	0
Molluscum contagiosum	0	1 (0.4)
Mumps	1 (0.4)	0
Mycobacterium avium complex infection	1 (0.4)	0
Nail infection	1 (0.4)	0
Otitis media bacterial	1 (0.4)	0
Otitis media chronic	0	1 (0.4)
Pharyngitis bacterial	0	1 (0.4)
Pneumonia viral	1 (0.4)	0
Proteus infection	0	1 (0.4)
Pulpitis dental	0	1 (0.4)
Rash pustular	0	1 (0.4)
Respiratory moniliasis	0	1 (0.4)
Root canal infection	0	1 (0.4)
Skin candida	0	1 (0.4)
Soft tissue infection	1 (0.4)	0
Tinea cruris	1 (0.4)	0
Tonsillitis bacterial	0	1 (0.4)
Ureaplasma infection	0	1 (0.4)
Viral sinusitis	1 (0.4)	0
Vulval abscess	0	1 (0.4)
Vulvovaginitis trichomonal	0	1 (0.4)
Gastrointestinal disorders	75 (30.5)	69 (28.0)
Nausea	15 (6.1)	17 (6.9)
Diarrhoea	10 (4.1)	16 (6.5)
Vomiting	13 (5.3)	5 (2.0)
Gastrooesophageal reflux disease	8 (3.3)	10 (4.1)
Abdominal pain upper	10 (4.1)	6 (2.4)
Constipation	6 (2.4)	5 (2.0)

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Incidence of Non-Severe Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=246) n (%)	Randomised Placebo (N=246) n (%)
Dental caries	7 (2.8)	3 (1.2)
Abdominal pain	5 (2.0)	6 (2.4)
Gastritis	2 (0.8)	8 (3.3)
Dyspepsia	2 (0.8)	6 (2.4)
Abdominal discomfort	4 (1.6)	1 (0.4)
Haemorrhoids	5 (2.0)	1 (0.4)
Hiatus hernia	0	4 (1.6)
Abdominal distension	2 (0.8)	1 (0.4)
Irritable bowel syndrome	2 (0.8)	1 (0.4)
Mouth ulceration	2 (0.8)	1 (0.4)
Toothache	2 (0.8)	1 (0.4)
Cheilitis	0	2 (0.8)
Diverticulum	2 (0.8)	0
Duodenitis	1 (0.4)	1 (0.4)
Flatulence	0	2 (0.8)
Food poisoning	0	2 (0.8)
Haematochezia	1 (0.4)	1 (0.4)
Loose tooth	1 (0.4)	0
Abdominal pain lower	1 (0.4)	0
Abdominal tenderness	1 (0.4)	0
Aphthous ulcer	1 (0.4)	0
Barrett's oesophagus	1 (0.4)	0
Chilaiditi's syndrome	1 (0.4)	0
Chronic gastritis	1 (0.4)	0
Colitis	1 (0.4)	0
Dental cyst	1 (0.4)	0
Dry mouth	0	1 (0.4)
Dysphagia	1 (0.4)	0
Enterocolitis	0	1 (0.4)
Gastric mucosa erythema	1 (0.4)	0
Gastritis erosive	1 (0.4)	0
Gastrointestinal inflammation	1 (0.4)	0
Gastrointestinal pain	0	1 (0.4)
Gastrointestinal wall thickening	1 (0.4)	0
Gingival recession	1 (0.4)	0
Glossodynia	0	1 (0.4)
Impaired gastric emptying	1 (0.4)	0
Intra-abdominal haematoma	0	1 (0.4)
Large intestine polyp	0	1 (0.4)
Lip swelling	1 (0.4)	0
Oesophageal hypomotility	1 (0.4)	0
Oesophageal stenosis	0	1 (0.4)
Oral mucosal eruption	1 (0.4)	0
Oral pain	0	1 (0.4)
Palatal disorder	1 (0.4)	0
Pancreatic steatosis	0	1 (0.4)
Paraesthesia oral	1 (0.4)	0
Peptic ulcer	0	1 (0.4)
Rectal haemorrhage	1 (0.4)	0
Salivary hypersecretion	0	1 (0.4)
Stomatitis	0	1 (0.4)
Tongue blistering	0	1 (0.4)
Tooth disorder	0	1 (0.4)
Tooth impacted	1 (0.4)	0
Musculoskeletal and connective tissue disorders	97 (39.4)	57 (23.2)
Back pain	24 (9.8)	11 (4.5)
Arthralgia	20 (8.1)	9 (3.7)
Systemic lupus erythematosus	6 (2.4)	7 (2.8)
Bursitis	8 (3.3)	2 (0.8)
Musculoskeletal pain	6 (2.4)	5 (2.0)

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Incidence of Non-Severe Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=246) n (%)	Randomised Placebo (N=246) n (%)
Pain in extremity	8 (3.3)	1 (0.4)
Osteonecrosis	3 (1.2)	4 (1.6)
Neck pain	7 (2.8)	1 (0.4)
Osteoarthritis	7 (2.8)	0
Muscle spasms	4 (1.6)	3 (1.2)
Tendonitis	5 (2.0)	3 (1.2)
Musculoskeletal chest pain	4 (1.6)	3 (1.2)
Costochondritis	4 (1.6)	2 (0.8)
Myalgia	2 (0.8)	4 (1.6)
Arthritis	4 (1.6)	1 (0.4)
Fibromyalgia	2 (0.8)	3 (1.2)
Intervertebral disc protrusion	5 (2.0)	0
Flank pain	2 (0.8)	2 (0.8)
Joint swelling	3 (1.2)	1 (0.4)
Osteoporosis	1 (0.4)	3 (1.2)
Rotator cuff syndrome	2 (0.8)	2 (0.8)
Synovial cyst	2 (0.8)	1 (0.4)
Tenosynovitis	2 (0.8)	1 (0.4)
Plantar fasciitis	0	3 (1.2)
Spinal osteoarthritis	2 (0.8)	1 (0.4)
Tenosynovitis stenosans	3 (1.2)	0
Musculoskeletal stiffness	1 (0.4)	1 (0.4)
Spinal pain	1 (0.4)	0
Synovitis	1 (0.4)	1 (0.4)
Chondritis	1 (0.4)	0
Groin pain	0	1 (0.4)
Intervertebral disc disorder	1 (0.4)	0
Joint instability	1 (0.4)	0
Ligamentitis	1 (0.4)	0
Metatarsalgia	1 (0.4)	0
Muscular weakness	0	1 (0.4)
Osteochondritis	0	1 (0.4)
Osteochondrosis	1 (0.4)	0
Osteopenia	1 (0.4)	0
Periarthritis	1 (0.4)	0
Polychondritis	1 (0.4)	0
Sacroiliitis	1 (0.4)	0
Sjogren's syndrome	1 (0.4)	0
Temporomandibular joint syndrome	0	1 (0.4)
Tendon pain	0	1 (0.4)
Injury, poisoning and procedural complications	76 (30.9)	51 (20.7)
Infusion related reaction	31 (12.6)	20 (8.1)
Fall	8 (3.3)	8 (3.3)
Contusion	10 (4.1)	5 (2.0)
Arthropod bite	7 (2.8)	2 (0.8)
Limb injury	2 (0.8)	3 (1.2)
Ligament sprain	4 (1.6)	1 (0.4)
Muscle strain	3 (1.2)	2 (0.8)
Road traffic accident	1 (0.4)	3 (1.2)
Ankle fracture	1 (0.4)	3 (1.2)
Epicondylitis	2 (0.8)	2 (0.8)
Foot fracture	1 (0.4)	3 (1.2)
Joint injury	2 (0.8)	2 (0.8)
Rib fracture	2 (0.8)	2 (0.8)
Skin abrasion	2 (0.8)	2 (0.8)
Animal bite	1 (0.4)	2 (0.8)
Arthropod sting	2 (0.8)	1 (0.4)
Meniscus injury	2 (0.8)	1 (0.4)
Animal scratch	2 (0.8)	0
Ligament rupture	2 (0.8)	0

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Incidence of Non-Severe Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=246) n (%)	Randomised Placebo (N=246) n (%)
Skin laceration	2 (0.8)	0
Thermal burn	2 (0.8)	0
Thoracic vertebral fracture	1 (0.4)	1 (0.4)
Tooth fracture	1 (0.4)	1 (0.4)
Wound	0	2 (0.8)
Accident	1 (0.4)	0
Anaemia postoperative	0	1 (0.4)
Concussion	1 (0.4)	0
Dental restoration failure	0	1 (0.4)
Fibula fracture	0	1 (0.4)
Foreign body in respiratory tract	1 (0.4)	0
Hand fracture	1 (0.4)	0
Humerus fracture	0	1 (0.4)
Hypobarism	1 (0.4)	0
Injury	1 (0.4)	0
Joint dislocation	1 (0.4)	0
Limb crushing injury	0	1 (0.4)
Lower limb fracture	1 (0.4)	0
Mouth injury	1 (0.4)	0
Muscle contusion	1 (0.4)	0
Post procedural complication	1 (0.4)	0
Post procedural haemorrhage	0	1 (0.4)
Post-traumatic neck syndrome	0	1 (0.4)
Post-traumatic pain	1 (0.4)	0
Pubis fracture	0	1 (0.4)
Reactive gastropathy	1 (0.4)	0
Skin injury	0	1 (0.4)
Spinal fracture	1 (0.4)	0
Stress fracture	1 (0.4)	0
Sunburn	1 (0.4)	0
Tibia fracture	1 (0.4)	0
Toxicity to various agents	1 (0.4)	0
Traumatic fracture	1 (0.4)	0
Vaccination complication	1 (0.4)	0
Wound complication	1 (0.4)	0
Nervous system disorders	67 (27.2)	42 (17.1)
Headache	28 (11.4)	26 (10.6)
Dizziness	7 (2.8)	5 (2.0)
Hypoaesthesia	5 (2.0)	1 (0.4)
Migraine	2 (0.8)	4 (1.6)
Neuralgia	4 (1.6)	2 (0.8)
Paraesthesia	6 (2.4)	0
Sciatica	5 (2.0)	0
Syncope	4 (1.6)	2 (0.8)
Carpal tunnel syndrome	4 (1.6)	1 (0.4)
Cervicobrachial syndrome	3 (1.2)	1 (0.4)
Restless legs syndrome	2 (0.8)	2 (0.8)
Tremor	1 (0.4)	2 (0.8)
Migraine with aura	3 (1.2)	0
Post herpetic neuralgia	3 (1.2)	0
Presyncope	2 (0.8)	1 (0.4)
Tension headache	1 (0.4)	2 (0.8)
Amnesia	2 (0.8)	0
Facial paralysis	1 (0.4)	1 (0.4)
Myoclonus	1 (0.4)	1 (0.4)
Neuropathy peripheral	1 (0.4)	1 (0.4)
Cervical radiculopathy	0	1 (0.4)
Cognitive disorder	1 (0.4)	0
Dizziness postural	0	1 (0.4)
Dysarthria	1 (0.4)	0

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Incidence of Non-Severe Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=246) n (%)	Randomised Placebo (N=246) n (%)
Epilepsy	1 (0.4)	0
Hyperaesthesia	0	1 (0.4)
Intention tremor	0	1 (0.4)
Lumbar radiculopathy	1 (0.4)	0
Myasthenia gravis	1 (0.4)	0
Occipital neuralgia	1 (0.4)	0
Parkinson's disease	1 (0.4)	0
Parkinsonian gait	1 (0.4)	0
Peroneal nerve palsy	1 (0.4)	0
Radiculopathy	1 (0.4)	0
Sensory disturbance	0	1 (0.4)
Spinal cord compression	0	1 (0.4)
Tunnel vision	0	1 (0.4)
Skin and subcutaneous tissue disorders	52 (21.1)	36 (14.6)
Rash	7 (2.8)	8 (3.3)
Urticaria	6 (2.4)	2 (0.8)
Pruritus	4 (1.6)	4 (1.6)
Hidradenitis	4 (1.6)	1 (0.4)
Ecchymosis	4 (1.6)	2 (0.8)
Acne	4 (1.6)	0
Dermatitis contact	3 (1.2)	2 (0.8)
Eczema	4 (1.6)	1 (0.4)
Skin ulcer	3 (1.2)	2 (0.8)
Angioedema	2 (0.8)	2 (0.8)
Dermatitis allergic	2 (0.8)	1 (0.4)
Ingrowing nail	4 (1.6)	0
Dermatitis	0	3 (1.2)
Erythema	1 (0.4)	2 (0.8)
Night sweats	2 (0.8)	0
Purpura	2 (0.8)	1 (0.4)
Dermal cyst	1 (0.4)	1 (0.4)
Dermatitis atopic	2 (0.8)	0
Erythema nodosum	0	1 (0.4)
Hyperhidrosis	0	2 (0.8)
Perioral dermatitis	1 (0.4)	0
Psoriasis	1 (0.4)	1 (0.4)
Rash pruritic	1 (0.4)	1 (0.4)
Rosacea	2 (0.8)	0
Skin hyperpigmentation	1 (0.4)	1 (0.4)
Skin lesion	1 (0.4)	1 (0.4)
Alopecia	0	1 (0.4)
Blister	1 (0.4)	0
Cold urticaria	0	1 (0.4)
Decubitus ulcer	0	1 (0.4)
Dermatitis acneiform	0	1 (0.4)
Drug eruption	0	1 (0.4)
Dry skin	1 (0.4)	0
Guttate psoriasis	1 (0.4)	0
Haemorrhage subcutaneous	0	1 (0.4)
Keloid scar	1 (0.4)	0
Lichen sclerosus	1 (0.4)	0
Lipoatrophy	1 (0.4)	0
Nail bed bleeding	0	1 (0.4)
Nail disorder	1 (0.4)	0
Nail dystrophy	1 (0.4)	0
Pigmentation disorder	1 (0.4)	0
Post inflammatory pigmentation change	0	1 (0.4)
Rash follicular	1 (0.4)	0
Rash papular	0	1 (0.4)
Rash vesicular	1 (0.4)	0

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Incidence of Non-Severe Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=246) n (%)	Randomised Placebo (N=246) n (%)
Scab	1 (0.4)	0
Seborrhoeic dermatitis	1 (0.4)	0
Skin fissures	0	1 (0.4)
Systemic lupus erythematosus rash	0	1 (0.4)
Urticaria chronic	1 (0.4)	0
Vasculitic ulcer	1 (0.4)	0
Venous ulcer pain	0	1 (0.4)
Vitiligo	0	1 (0.4)
Xanthelasma	0	1 (0.4)
Respiratory, thoracic and mediastinal disorders	54 (22.0)	35 (14.2)
Cough	25 (10.2)	8 (3.3)
Asthma	4 (1.6)	6 (2.4)
Epistaxis	3 (1.2)	5 (2.0)
Nasal congestion	3 (1.2)	4 (1.6)
Oropharyngeal pain	5 (2.0)	3 (1.2)
Rhinitis allergic	4 (1.6)	2 (0.8)
Pleural effusion	3 (1.2)	2 (0.8)
Rhinorrhoea	3 (1.2)	1 (0.4)
Chronic obstructive pulmonary disease	2 (0.8)	1 (0.4)
Dyspnoea	1 (0.4)	3 (1.2)
Productive cough	3 (1.2)	1 (0.4)
Nasal obstruction	1 (0.4)	2 (0.8)
Upper respiratory tract inflammation	2 (0.8)	0
Pulmonary mass	1 (0.4)	1 (0.4)
Respiratory disorder	1 (0.4)	1 (0.4)
Sinus congestion	2 (0.8)	0
Acute respiratory failure	1 (0.4)	0
Atelectasis	1 (0.4)	0
Catarrh	0	1 (0.4)
Lung disorder	1 (0.4)	0
Paranasal sinus discomfort	0	1 (0.4)
Sleep apnoea syndrome	0	1 (0.4)
Throat irritation	1 (0.4)	0
Tracheal stenosis	1 (0.4)	0
Upper-airway cough syndrome	1 (0.4)	0
Wheezing	1 (0.4)	0
General disorders and administration site conditions	44 (17.9)	27 (11.0)
Pyrexia	9 (3.7)	5 (2.0)
Non-cardiac chest pain	6 (2.4)	8 (3.3)
Oedema peripheral	8 (3.3)	3 (1.2)
Fatigue	7 (2.8)	2 (0.8)
Influenza like illness	2 (0.8)	1 (0.4)
Asthenia	3 (1.2)	2 (0.8)
Adverse drug reaction	2 (0.8)	2 (0.8)
Chest discomfort	3 (1.2)	1 (0.4)
Chest pain	4 (1.6)	0
Pain	2 (0.8)	1 (0.4)
Swelling face	0	3 (1.2)
Face oedema	2 (0.8)	0
Peripheral swelling	1 (0.4)	1 (0.4)
Chills	0	1 (0.4)
Gravitational oedema	0	1 (0.4)
Malaise	1 (0.4)	0
Nodule	1 (0.4)	0
Vaccination site reaction	1 (0.4)	0
Psychiatric disorders	27 (11.0)	30 (12.2)
Insomnia	8 (3.3)	15 (6.1)
Depression	14 (5.7)	6 (2.4)

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Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Incidence of Non-Severe Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=246) n (%)	Randomised Placebo (N=246) n (%)
Anxiety	11 (4.5)	6 (2.4)
Adjustment disorder	0	1 (0.4)
Anxiety disorder	1 (0.4)	0
Depressed mood	0	1 (0.4)
Drug use disorder	1 (0.4)	0
Loss of libido	0	1 (0.4)
Mixed anxiety and depressive disorder	1 (0.4)	0
Panic attack	1 (0.4)	0
Persistent depressive disorder	0	1 (0.4)
Psychotic disorder	0	1 (0.4)
Substance-induced psychotic disorder	0	1 (0.4)
Suicidal ideation	0	1 (0.4)
Metabolism and nutrition disorders	26 (10.6)	27 (11.0)
Hypokalaemia	4 (1.6)	5 (2.0)
Dehydration	0	7 (2.8)
Vitamin D deficiency	5 (2.0)	3 (1.2)
Hypercholesterolaemia	6 (2.4)	0
Hyperglycaemia	2 (0.8)	2 (0.8)
Vitamin B12 deficiency	3 (1.2)	1 (0.4)
Diabetes mellitus	3 (1.2)	0
Dyslipidaemia	1 (0.4)	2 (0.8)
Type 2 diabetes mellitus	1 (0.4)	2 (0.8)
Glucose tolerance impaired	1 (0.4)	1 (0.4)
Hyperlipidaemia	2 (0.8)	0
Hypertriglyceridaemia	2 (0.8)	0
Hypomagnesaemia	1 (0.4)	1 (0.4)
Vitamin B complex deficiency	2 (0.8)	0
Fluid overload	0	1 (0.4)
Hypercalcaemia	1 (0.4)	0
Hyperkalaemia	0	1 (0.4)
Hyperuricaemia	1 (0.4)	0
Hypocalcaemia	0	1 (0.4)
Hyponatraemia	0	1 (0.4)
Increased appetite	1 (0.4)	0
Iron deficiency	1 (0.4)	0
Lactic acidosis	0	1 (0.4)
Lipoedema	0	1 (0.4)
Overweight	1 (0.4)	0
Steroid diabetes	1 (0.4)	0
Eye disorders	29 (11.8)	15 (6.1)
Cataract	5 (2.0)	2 (0.8)
Blepharitis	3 (1.2)	3 (1.2)
Dry eye	4 (1.6)	1 (0.4)
Chalazion	1 (0.4)	2 (0.8)
Conjunctival haemorrhage	1 (0.4)	2 (0.8)
Episcleritis	3 (1.2)	0
Glaucoma	1 (0.4)	0
Keratitis	1 (0.4)	1 (0.4)
Retinopathy	2 (0.8)	0
Vision blurred	2 (0.8)	0
Vitreous floaters	2 (0.8)	0
Accommodation disorder	1 (0.4)	0
Asthenopia	1 (0.4)	0
Chorioretinopathy	1 (0.4)	0
Conjunctival erosion	0	1 (0.4)
Conjunctivitis allergic	1 (0.4)	0
Corneal erosion	0	1 (0.4)
Diplopia	0	1 (0.4)
Eye discharge	1 (0.4)	0

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Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Incidence of Non-Severe Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=246) n (%)	Randomised Placebo (N=246) n (%)
Eye inflammation	1 (0.4)	0
Eye pruritus	1 (0.4)	0
Lacrimation decreased	1 (0.4)	0
Lacrimation increased	1 (0.4)	0
Macular degeneration	1 (0.4)	0
Maculopathy	0	1 (0.4)
Periorbital oedema	1 (0.4)	0
Photophobia	0	1 (0.4)
Trichiasis	0	1 (0.4)
Visual impairment	0	1 (0.4)
Reproductive system and breast disorders	27 (11.0)	15 (6.1)
Menorrhagia	4 (1.6)	2 (0.8)
Dysmenorrhoea	5 (2.0)	0
Ovarian cyst	3 (1.2)	2 (0.8)
Uterine haemorrhage	3 (1.2)	0
Breast cyst	2 (0.8)	1 (0.4)
Cervical dysplasia	1 (0.4)	1 (0.4)
Fibrocystic breast disease	2 (0.8)	0
Menometrorrhagia	2 (0.8)	0
Menstruation irregular	1 (0.4)	1 (0.4)
Uterine polyp	2 (0.8)	0
Vulvovaginal pruritus	2 (0.8)	0
Adenomyosis	0	1 (0.4)
Adnexa uteri cyst	0	1 (0.4)
Amenorrhoea	1 (0.4)	0
Atrophic vulvovaginitis	1 (0.4)	0
Balanoposthitis	1 (0.4)	0
Breast calcifications	0	1 (0.4)
Breast mass	1 (0.4)	0
Cervical cyst	1 (0.4)	0
Cervical polyp	1 (0.4)	0
Cervix disorder	1 (0.4)	0
Dyspareunia	1 (0.4)	0
Endometrial hyperplasia	0	1 (0.4)
Menopausal symptoms	0	1 (0.4)
Metrorrhagia	1 (0.4)	0
Perineal rash	1 (0.4)	0
Polycystic ovaries	1 (0.4)	0
Premenstrual syndrome	1 (0.4)	0
Scrotal ulcer	0	1 (0.4)
Vaginal discharge	1 (0.4)	0
Vaginal haemorrhage	0	1 (0.4)
Vaginal ulceration	0	1 (0.4)
Investigations	19 (7.7)	19 (7.7)
Weight increased	3 (1.2)	5 (2.0)
Alanine aminotransferase increased	2 (0.8)	2 (0.8)
Liver function test increased	0	4 (1.6)
Blood potassium decreased	2 (0.8)	1 (0.4)
Gamma-glutamyltransferase increased	1 (0.4)	2 (0.8)
Aspartate aminotransferase increased	1 (0.4)	1 (0.4)
Blood creatine phosphokinase increased	2 (0.8)	0
Cardiac murmur	1 (0.4)	1 (0.4)
Anticoagulation drug level below therapeutic	1 (0.4)	0
Blood alkaline phosphatase increased	1 (0.4)	0
Blood corticotrophin decreased	1 (0.4)	0
Blood creatinine increased	1 (0.4)	0
Blood immunoglobulin A decreased	0	1 (0.4)
Blood pressure increased	1 (0.4)	0
Heart rate increased	0	1 (0.4)

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Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Incidence of Non-Severe Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=246) n (%)	Randomised Placebo (N=246) n (%)
Hepatic enzyme increased	0	1 (0.4)
Human papilloma virus test positive	1 (0.4)	0
Influenza B virus test positive	1 (0.4)	0
International normalised ratio abnormal	1 (0.4)	0
International normalised ratio increased	0	1 (0.4)
Intraocular pressure increased	1 (0.4)	0
Transaminases increased	0	1 (0.4)
Urine protein/creatinine ratio increased	1 (0.4)	0
Vitamin D decreased	1 (0.4)	0
Weight decreased	1 (0.4)	0
Renal and urinary disorders	23 (9.3)	10 (4.1)
Dysuria	1 (0.4)	5 (2.0)
Nephrolithiasis	4 (1.6)	1 (0.4)
Acute kidney injury	1 (0.4)	3 (1.2)
Haematuria	2 (0.8)	0
Renal impairment	1 (0.4)	0
Lupus nephritis	2 (0.8)	0
Renal colic	1 (0.4)	1 (0.4)
Bladder spasm	1 (0.4)	0
Chronic kidney disease	1 (0.4)	0
Glomerulonephritis	1 (0.4)	0
Hydronephrosis	1 (0.4)	0
Leukocyturia	1 (0.4)	0
Nephritis	1 (0.4)	0
Polyuria	1 (0.4)	0
Renal cyst	1 (0.4)	0
Stress urinary incontinence	1 (0.4)	0
Ureteric obstruction	1 (0.4)	0
Urethral meatus stenosis	1 (0.4)	0
Urinary incontinence	1 (0.4)	0
Urinary retention	1 (0.4)	0
Ear and labyrinth disorders	16 (6.5)	12 (4.9)
Vertigo	8 (3.3)	2 (0.8)
Ear pain	4 (1.6)	3 (1.2)
Vertigo positional	3 (1.2)	2 (0.8)
Cerumen impaction	2 (0.8)	0
Ear congestion	1 (0.4)	1 (0.4)
Tinnitus	0	2 (0.8)
Deafness bilateral	1 (0.4)	0
Ear discomfort	0	1 (0.4)
Hyperacusis	1 (0.4)	0
Motion sickness	0	1 (0.4)
Vascular disorders	15 (6.1)	16 (6.5)
Hypertension	8 (3.3)	12 (4.9)
Haematoma	2 (0.8)	1 (0.4)
Orthostatic hypotension	1 (0.4)	1 (0.4)
Phlebitis	2 (0.8)	0
Essential hypertension	1 (0.4)	0
Hypotension	0	1 (0.4)
Internal haemorrhage	0	1 (0.4)
Malignant hypertension	1 (0.4)	0
Raynaud's phenomenon	1 (0.4)	0
Varicophlebitis	0	1 (0.4)
Vasodilatation	0	1 (0.4)
Blood and lymphatic system disorders	15 (6.1)	16 (6.5)
Anaemia	3 (1.2)	7 (2.8)
Iron deficiency anaemia	7 (2.8)	3 (1.2)

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Incidence of Non-Severe Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=246) n (%)	Randomised Placebo (N=246) n (%)
Lymphadenopathy	3 (1.2)	2 (0.8)
Leukopenia	0	2 (0.8)
Lymphopenia	1 (0.4)	0
Microcytic anaemia	0	2 (0.8)
Thrombocytopenia	1 (0.4)	1 (0.4)
Autoimmune haemolytic anaemia	0	1 (0.4)
Leukocytosis	1 (0.4)	0
Neutropenia	1 (0.4)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**17 (6.9)**	**8 (3.3)**
Skin papilloma	5 (2.0)	1 (0.4)
Uterine leiomyoma	4 (1.6)	1 (0.4)
Anogenital warts	2 (0.8)	0
Colon adenoma	0	1 (0.4)
B-cell lymphoma	1 (0.4)	0
Benign breast neoplasm	1 (0.4)	0
Carcinoid tumour	0	1 (0.4)
Fibrous histiocytoma	1 (0.4)	0
Haemangioma of liver	1 (0.4)	0
Hepatic adenoma	1 (0.4)	0
Lipoma	0	1 (0.4)
Seborrhoeic keratosis	0	1 (0.4)
Squamous cell carcinoma of the cervix	0	1 (0.4)
Uterine cancer	0	1 (0.4)
Vulvovaginal warts	1 (0.4)	0
Immune system disorders	**20 (8.1)**	**8 (3.3)**
Hypersensitivity	10 (4.1)	3 (1.2)
Seasonal allergy	5 (2.0)	3 (1.2)
Allergy to animal	1 (0.4)	2 (0.8)
Allergy to arthropod bite	1 (0.4)	0
Allergy to arthropod sting	1 (0.4)	0
Contrast media reaction	1 (0.4)	0
Drug hypersensitivity	0	1 (0.4)
Reaction to preservatives	1 (0.4)	0
Cardiac disorders	**10 (4.1)**	**13 (5.3)**
Cardiac failure congestive	0	3 (1.2)
Palpitations	1 (0.4)	2 (0.8)
Acute myocardial infarction	0	2 (0.8)
Atrial fibrillation	0	2 (0.8)
Pericarditis	0	2 (0.8)
Sinus bradycardia	1 (0.4)	1 (0.4)
Supraventricular tachycardia	0	2 (0.8)
Tachycardia	1 (0.4)	1 (0.4)
Angina pectoris	0	1 (0.4)
Angina unstable	1 (0.4)	0
Arrhythmia	1 (0.4)	0
Bundle branch block left	1 (0.4)	0
Bundle branch block right	1 (0.4)	0
Cardiac failure chronic	1 (0.4)	0
Cardiomegaly	0	1 (0.4)
Coronary artery disease	1 (0.4)	0
Left ventricular dilatation	1 (0.4)	0
Tachycardia paroxysmal	1 (0.4)	0
Ventricular arrhythmia	0	1 (0.4)
Endocrine disorders	**8 (3.3)**	**3 (1.2)**
Steroid withdrawal syndrome	3 (1.2)	0
Goitre	2 (0.8)	0
Hyperprolactinaemia	2 (0.8)	0

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Incidence of Non-Severe Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=246) n (%)	Randomised Placebo (N=246) n (%)
Hyperthyroidism	1 (0.4)	1 (0.4)
Adrenal insufficiency	0	1 (0.4)
Basedow's disease	1 (0.4)	0
Cushing's syndrome	1 (0.4)	0
Hyperparathyroidism	0	1 (0.4)
Hepatobiliary disorders	5 (2.0)	4 (1.6)
Hepatic steatosis	1 (0.4)	2 (0.8)
Biliary colic	1 (0.4)	0
Cholecystitis	0	1 (0.4)
Cholelithiasis	1 (0.4)	0
Drug-induced liver injury	1 (0.4)	0
Hepatic lesion	0	1 (0.4)
Hepatic mass	1 (0.4)	0
Social circumstances	1 (0.4)	1 (0.4)
Menopause	1 (0.4)	1 (0.4)
Pregnancy, puerperium and perinatal conditions	1 (0.4)	0
Abortion spontaneous	1 (0.4)	0

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

	Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
Number of subjects with events, n (%)	227 (92.3)	211 (85.8)
Number of censored subjects, n (%)	19 (7.7)	35 (14.2)
Exposure years	103.4	106.7
EAIR per 100 PY	219.5	197.8
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	3.57 (2.14, 4.14)	4.14 (3.00, 6.43)
Median (95% CI)	8.43 (7.14, 11.71)	11.86 (9.43, 16.29)
75%-ile (95% CI)	25.29 (20.00, 32.71)	34.00 (26.14, 40.29)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	1.20 (1.00, 1.45)	
p-value	0.0554	
Relative Risk (95% CI)	1.08 (1.01, 1.15)	
p-value	0.0217	
Odds Ratio (95% CI)	1.98 (1.10, 3.57)	
p-value	0.0229	
Risk Difference (95% CI)	6.50 (1.01, 12.00)	
p-value	0.0203	

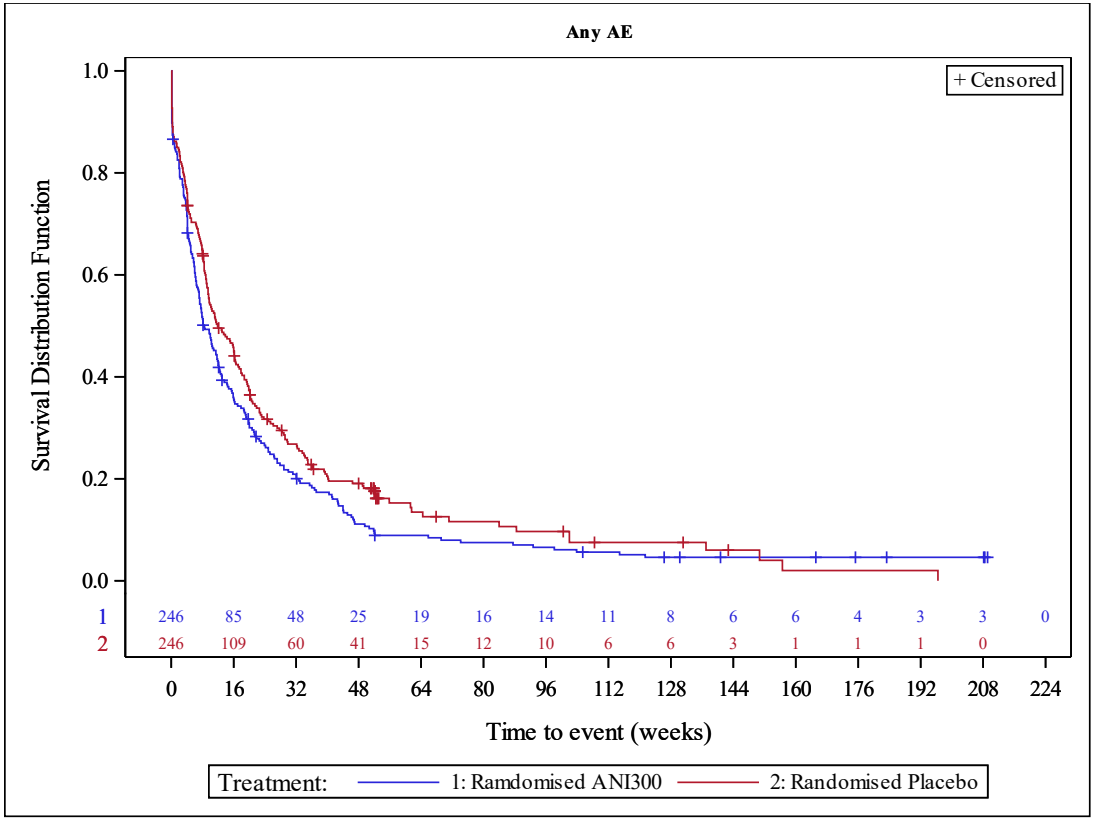
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%)	Ramdomised ANI300 (N=246) Median (95% CI)	Randomised Placebo (N=246) n/ N (%)	Randomised Placebo (N=246) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
Age (years)							0.2522
<= 65	222/239 (92.9)	8.14 (7.00, 11.71)	208/243 (85.6)	11.86 (9.43, 16.14)	1.22 (1.01, 1.48)	0.0361	
> 65	5/ 7 (71.4)	12.14 (0.14, NE)	3/ 3 (100.0)	17.43 (8.43, 17.86)	0.64 (0.14, 2.88)	0.5578	
Sex							0.1215
male	18/ 23 (78.3)	19.00 (9.71, 23.00)	17/ 20 (85.0)	8.86 (4.14, 35.00)	0.77 (0.40, 1.51)	0.4471	
female	209/223 (93.7)	7.86 (6.29, 10.43)	194/226 (85.8)	12.86 (9.57, 16.29)	1.27 (1.04, 1.55)	0.0163	
Geographic region							0.2055
EU	82/ 92 (89.1)	11.71 (7.57, 19.29)	67/ 89 (75.3)	27.14 (18.14, 39.14)	1.40 (1.01, 1.94)	0.0436	
non-EU	145/154 (94.2)	7.29 (5.71, 10.57)	144/157 (91.7)	8.71 (7.43, 9.71)	1.09 (0.87, 1.38)	0.4560	
SLEDAI-2K score at screening							0.9566
< 10 points	75/ 80 (93.8)	8.14 (5.86, 12.14)	60/ 69 (87.0)	11.29 (7.71, 18.71)	1.22 (0.87, 1.71)	0.2588	
>= 10 points	152/166 (91.6)	8.57 (6.86, 12.29)	151/177 (85.3)	12.86 (9.43, 17.14)	1.19 (0.95, 1.49)	0.1332	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of time to first Adverse Event during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Serious Adverse Event during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

	Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
Number of subjects with events, n (%)	45 (18.3)	55 (22.4)
Number of censored subjects, n (%)	201 (81.7)	191 (77.6)
Exposure years	523.7	314.4
EAIR per 100 PY	8.6	17.5
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (128.3, NE)	87.43 (49.57, 154.9)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	0.57 (0.38, 0.86)	
p-value	0.0059	
Relative Risk (95% CI)	0.82 (0.58, 1.16)	
p-value	0.2640	
Odds Ratio (95% CI)	0.78 (0.50, 1.21)	
p-value	0.2632	
Risk Difference (95% CI)	-4.07 (-11.17, 3.04)	
p-value	0.2620	

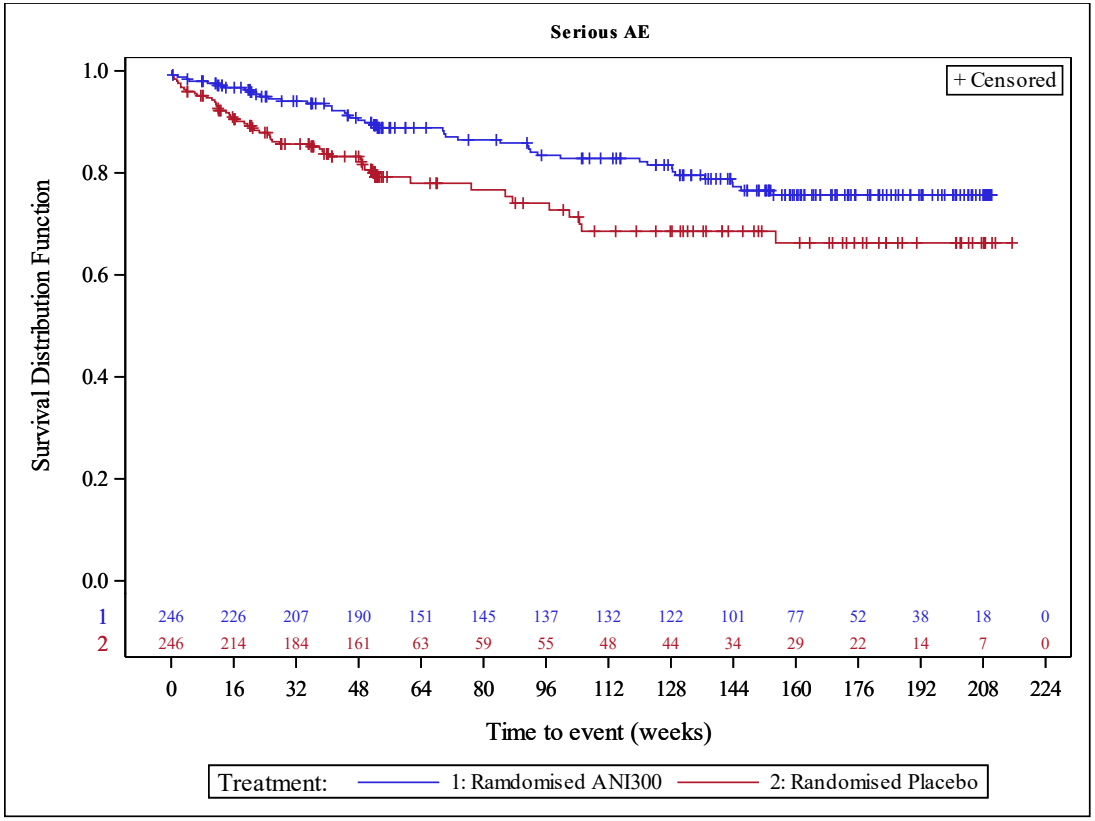
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Serious Adverse Event during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%)	 Median (95% CI)	Randomised Placebo (N=246) n/ N (%)	 Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	 p-Value	Interaction p-Value
Age (years)							0.9824
<= 65	43/239 (18.0)	NE (NE, NE)	55/243 (22.6)	NE (NE, NE)	0.55 (0.37, 0.83)	0.0036	
> 65	2/ 7 (28.6)	NE (19.00, NE)	0/ 3 (0.0)	NE (NE, NE)	NE		
Sex							0.6283
male	5/ 23 (21.7)	NE (122.00, NE)	4/ 20 (20.0)	NE (NE, NE)	0.80 (0.21, 3.03)	0.7462	
female	40/223 (17.9)	NE (NE, NE)	51/226 (22.6)	NE (NE, NE)	0.55 (0.36, 0.84)	0.0053	
Geographic region							0.6075
EU	16/ 92 (17.4)	NE (NE, NE)	16/ 89 (18.0)	NE (NE, NE)	0.70 (0.34, 1.42)	0.3191	
non-EU	29/154 (18.8)	NE (NE, NE)	39/157 (24.8)	NE (154.86, NE)	0.52 (0.32, 0.86)	0.0089	
SLEDAI-2K score at screening							0.4904
< 10 points	14/ 80 (17.5)	NE (NE, NE)	12/ 69 (17.4)	NE (96.86, NE)	0.60 (0.27, 1.31)	0.1944	
>= 10 points	31/166 (18.7)	NE (NE, NE)	43/177 (24.3)	NE (NE, NE)	0.57 (0.36, 0.91)	0.0171	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of time to first Serious Adverse Event during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Severe Adverse Event during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

	Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
Number of subjects with events, n (%)	31 (12.6)	27 (11.0)
Number of censored subjects, n (%)	215 (87.4)	219 (89.0)
Exposure years	546.7	331.7
EAIR per 100 PY	5.7	8.1
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (205.3, NE)	NE (154.9, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	0.80 (0.47, 1.35)	
p-value	0.3997	
Relative Risk (95% CI)	1.15 (0.71, 1.86)	
p-value	0.5764	
Odds Ratio (95% CI)	1.17 (0.68, 2.03)	
p-value	0.5763	
Risk Difference (95% CI)	1.63 (-4.07, 7.32)	
p-value	0.5759	

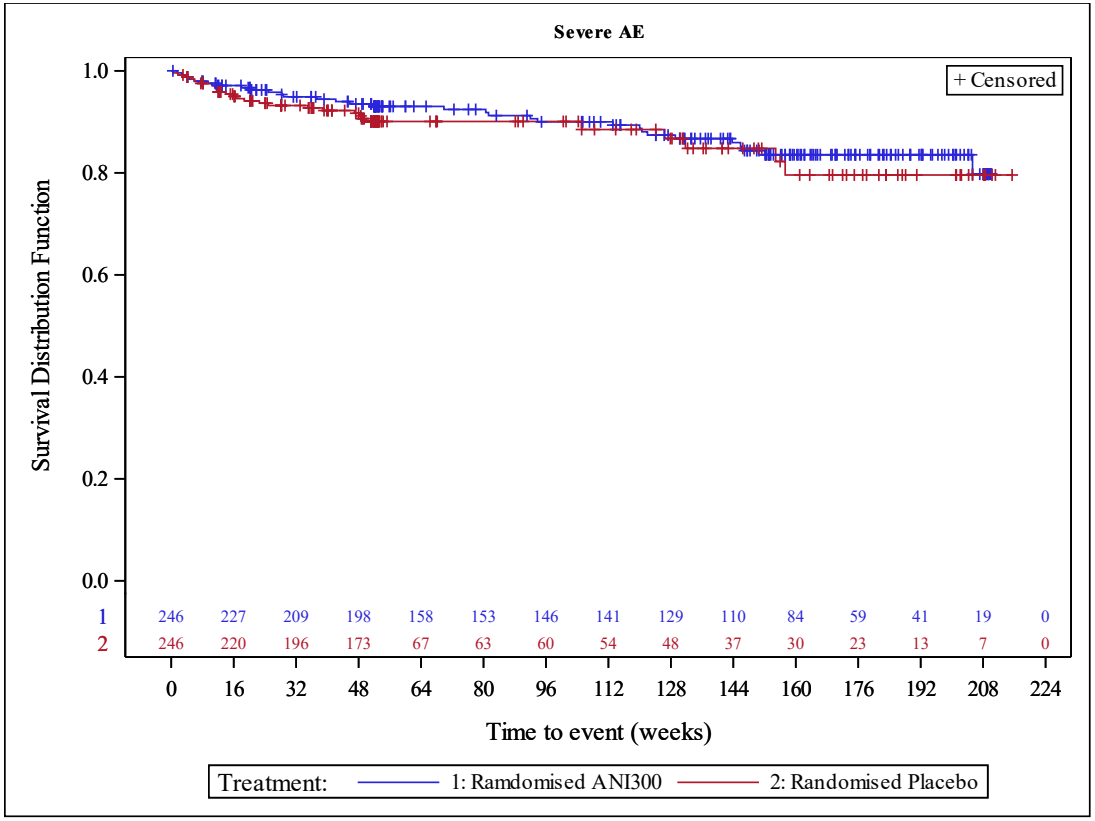
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Severe Adverse Event during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%)	Ramdomised ANI300 (N=246) Median (95% CI)	Randomised Placebo (N=246) n/ N (%)	Randomised Placebo (N=246) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
Age (years)							0.9999
<= 65	31/239 (13.0)	NE (NE, NE)	27/243 (11.1)	NE (NE, NE)	0.81 (0.48, 1.38)	0.4432	
> 65	0/ 7 (0.0)	NE (NE, NE)	0/ 3 (0.0)	NE (NE, NE)	NE		
Sex							0.5927
male	4/ 23 (17.4)	NE (NE, NE)	2/ 20 (10.0)	NE (NE, NE)	1.18 (0.21, 6.55)	0.8533	
female	27/223 (12.1)	NE (NE, NE)	25/226 (11.1)	NE (NE, NE)	0.76 (0.44, 1.34)	0.3434	
Geographic region							0.2152
EU	11/ 92 (12.0)	NE (NE, NE)	5/ 89 (5.6)	NE (NE, NE)	1.48 (0.50, 4.36)	0.4709	
non-EU	20/154 (13.0)	NE (NE, NE)	22/157 (14.0)	NE (NE, NE)	0.64 (0.35, 1.19)	0.1576	
SLEDAI-2K score at screening							0.9779
< 10 points	9/ 80 (11.3)	NE (NE, NE)	7/ 69 (10.1)	NE (NE, NE)	0.80 (0.29, 2.20)	0.6675	
>= 10 points	22/166 (13.3)	NE (NE, NE)	20/177 (11.3)	NE (NE, NE)	0.80 (0.43, 1.49)	0.4777	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of time to first Severe Adverse Event during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Non-Severe Adverse Event during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

	Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
Number of subjects with events, n (%)	225 (91.5)	208 (84.6)
Number of censored subjects, n (%)	21 (8.5)	38 (15.4)
Exposure years	105.0	108.1
EAIR per 100 PY	214.3	192.5
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	3.57 (2.14, 4.14)	4.14 (3.00, 6.57)
Median (95% CI)	9.71 (7.29, 12.00)	12.86 (9.57, 16.57)
75%-ile (95% CI)	26.43 (20.71, 35.43)	34.86 (28.43, 49.00)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	1.21 (1.00, 1.46)	
p-value	0.0526	
Relative Risk (95% CI)	1.08 (1.01, 1.16)	
p-value	0.0190	
Odds Ratio (95% CI)	1.96 (1.11, 3.44)	
p-value	0.0199	
Risk Difference (95% CI)	6.91 (1.20, 12.62)	
p-value	0.0177	

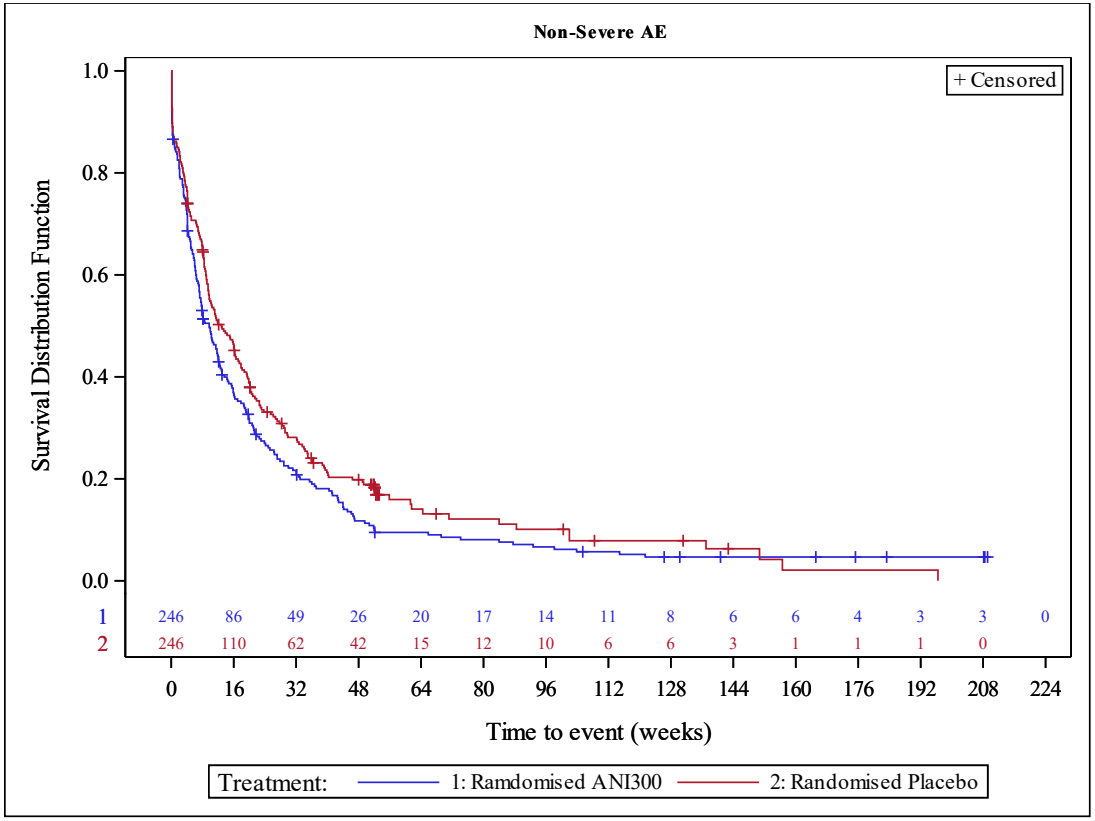
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Non-Severe Adverse Event during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%)	Ramdomised ANI300 (N=246) Median (95% CI)	Randomised Placebo (N=246) n/ N (%)	Randomised Placebo (N=246) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
Age (years)							0.2450
<= 65	220/239 (92.1)	8.57 (7.14, 12.00)	205/243 (84.4)	12.86 (9.57, 16.43)	1.23 (1.02, 1.49)	0.0344	
> 65	5/ 7 (71.4)	12.14 (0.14, NE)	3/ 3 (100.0)	17.43 (8.43, 17.86)	0.64 (0.14, 2.88)	0.5578	
Sex							0.1175
male	18/ 23 (78.3)	19.00 (9.71, 23.00)	17/ 20 (85.0)	8.86 (4.14, 35.00)	0.77 (0.40, 1.51)	0.4471	
female	207/223 (92.8)	8.14 (6.57, 11.43)	191/226 (84.5)	13.00 (9.57, 16.57)	1.27 (1.05, 1.55)	0.0158	
Geographic region							0.1486
EU	82/ 92 (89.1)	11.86 (7.71, 20.00)	65/ 89 (73.0)	29.14 (19.86, 39.86)	1.43 (1.03, 1.99)	0.0322	
non-EU	143/154 (92.9)	7.86 (5.71, 11.43)	143/157 (91.1)	8.86 (7.71, 9.71)	1.08 (0.86, 1.36)	0.5049	
SLEDAI-2K score at screening							0.9384
< 10 points	73/ 80 (91.3)	9.71 (6.00, 13.57)	60/ 69 (87.0)	11.86 (7.86, 19.86)	1.20 (0.86, 1.70)	0.2900	
>= 10 points	152/166 (91.6)	9.71 (7.00, 12.43)	148/177 (83.6)	13.43 (9.43, 17.86)	1.20 (0.96, 1.51)	0.1099	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of time to first Non-Severe Adverse Event during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event leading to discontinuation of study drug during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

	Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
Number of subjects with events, n (%)	16 (6.5)	14 (5.7)
Number of censored subjects, n (%)	230 (93.5)	232 (94.3)
Exposure years	580.3	347.7
EAIR per 100 PY	2.8	4.0
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	0.95 (0.46, 1.97)	
p-value	0.8896	
Relative Risk (95% CI)	1.14 (0.57, 2.29)	
p-value	0.7066	
Odds Ratio (95% CI)	1.15 (0.55, 2.42)	
p-value	0.7065	
Risk Difference (95% CI)	0.81 (-3.42, 5.04)	
p-value	0.7063	

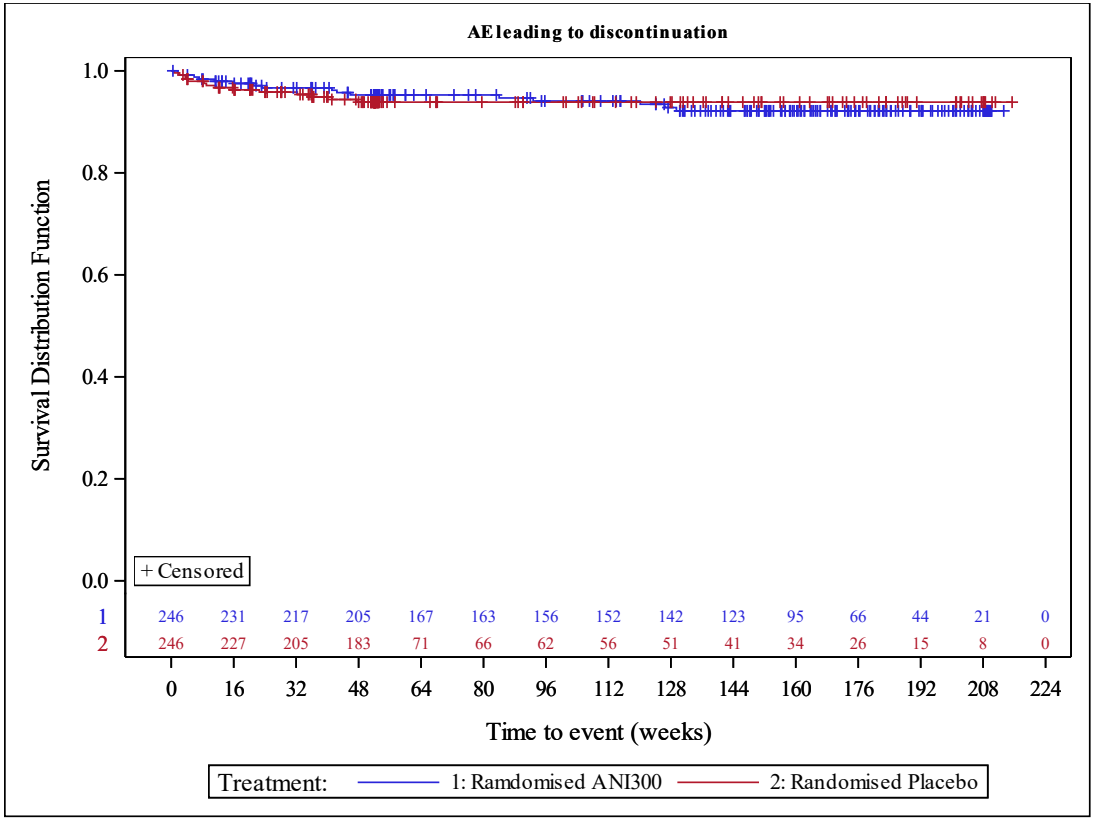
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event leading to discontinuation of study drug during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%) Median (95% CI)	Randomised Placebo (N=246) n/ N (%) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI) p-Value	Interaction p-Value
Age (years)				0.9897
<= 65	15/239 (6.3) NE (NE, NE)	14/243 (5.8) NE (NE, NE)	0.90 (0.43, 1.88) 0.7749	
> 65	1/ 7 (14.3) NE (21.00, NE)	0/ 3 (0.0) NE (NE, NE)	NE	
Sex				0.9886
male	2/ 23 (8.7) NE (NE, NE)	0/ 20 (0.0) NE (NE, NE)	NE	
female	14/223 (6.3) NE (NE, NE)	14/226 (6.2) NE (NE, NE)	0.88 (0.42, 1.87) 0.7487	
Geographic region				0.1382
EU	8/ 92 (8.7) NE (NE, NE)	3/ 89 (3.4) NE (NE, NE)	1.87 (0.49, 7.22) 0.3546	
non-EU	8/154 (5.2) NE (NE, NE)	11/157 (7.0) NE (NE, NE)	0.67 (0.27, 1.68) 0.3945	
SLEDAI-2K score at screening				0.7086
< 10 points	5/ 80 (6.3) NE (NE, NE)	3/ 69 (4.3) NE (NE, NE)	1.27 (0.30, 5.39) 0.7438	
>= 10 points	11/166 (6.6) NE (NE, NE)	11/177 (6.2) NE (NE, NE)	0.86 (0.37, 2.02) 0.7381	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of time to first Adverse Event leading to discontinuation of study drug during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to Adverse Event leading to death during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

	Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
Number of subjects with events, n (%)	2 (0.8)	0 (0.0)
Number of censored subjects, n (%)	244 (99.2)	246 (100.0)
Exposure years	581.4	348.7
EAIR per 100 PY	0.3	0.0
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	NE	
p-value		
Relative Risk (95% CI)	5.00 (0.24, 103.61)	
p-value	0.2980	
Odds Ratio (95% CI)	5.04 (0.24, 105.54)	
p-value	0.2972	
Risk Difference (95% CI)	0.81 (-0.31, 1.94)	
p-value	0.1556	

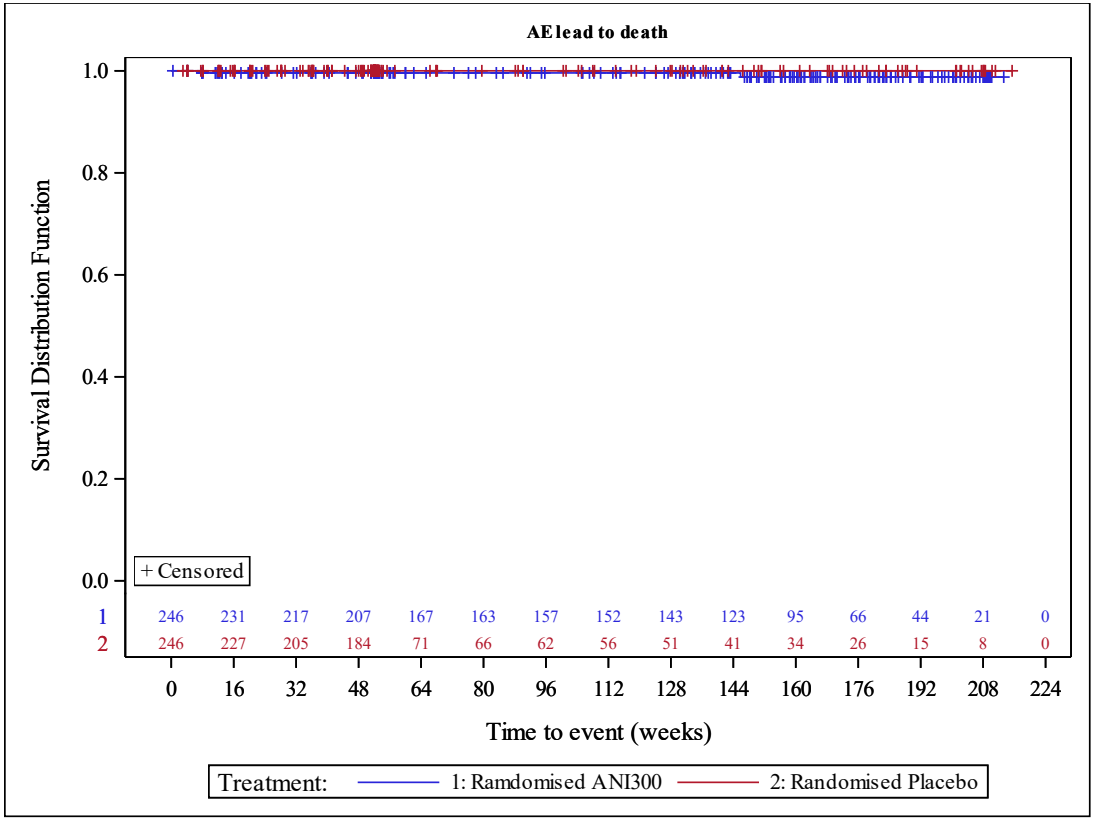
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to Adverse Event leading to death during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%) Median (95% CI)	Randomised Placebo (N=246) n/ N (%) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI) p-Value	Interaction p-Value
Age (years)				0.9997
<= 65	2/239 (0.8) NE (NE, NE)	0/243 (0.0) NE (NE, NE)	NE	
> 65	0/ 7 (0.0) NE (NE, NE)	0/ 3 (0.0) NE (NE, NE)	NE	
Sex				0.9992
male	0/ 23 (0.0) NE (NE, NE)	0/ 20 (0.0) NE (NE, NE)	NE	
female	2/223 (0.9) NE (NE, NE)	0/226 (0.0) NE (NE, NE)	NE	
Geographic region				1.0000
EU	1/ 92 (1.1) NE (NE, NE)	0/ 89 (0.0) NE (NE, NE)	NE	
non-EU	1/154 (0.6) NE (NE, NE)	0/157 (0.0) NE (NE, NE)	NE	
SLEDAI-2K score at screening				0.9999
< 10 points	1/ 80 (1.3) NE (NE, NE)	0/ 69 (0.0) NE (NE, NE)	NE	
>= 10 points	1/166 (0.6) NE (NE, NE)	0/177 (0.0) NE (NE, NE)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of time to Adverse Event leading to death during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Anaphylaxis
Full analysis set

	Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	246 (100.0)	246 (100.0)
Exposure years	581.5	348.7
EAIR per 100 PY	0.0	0.0
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	NE	
p-value		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

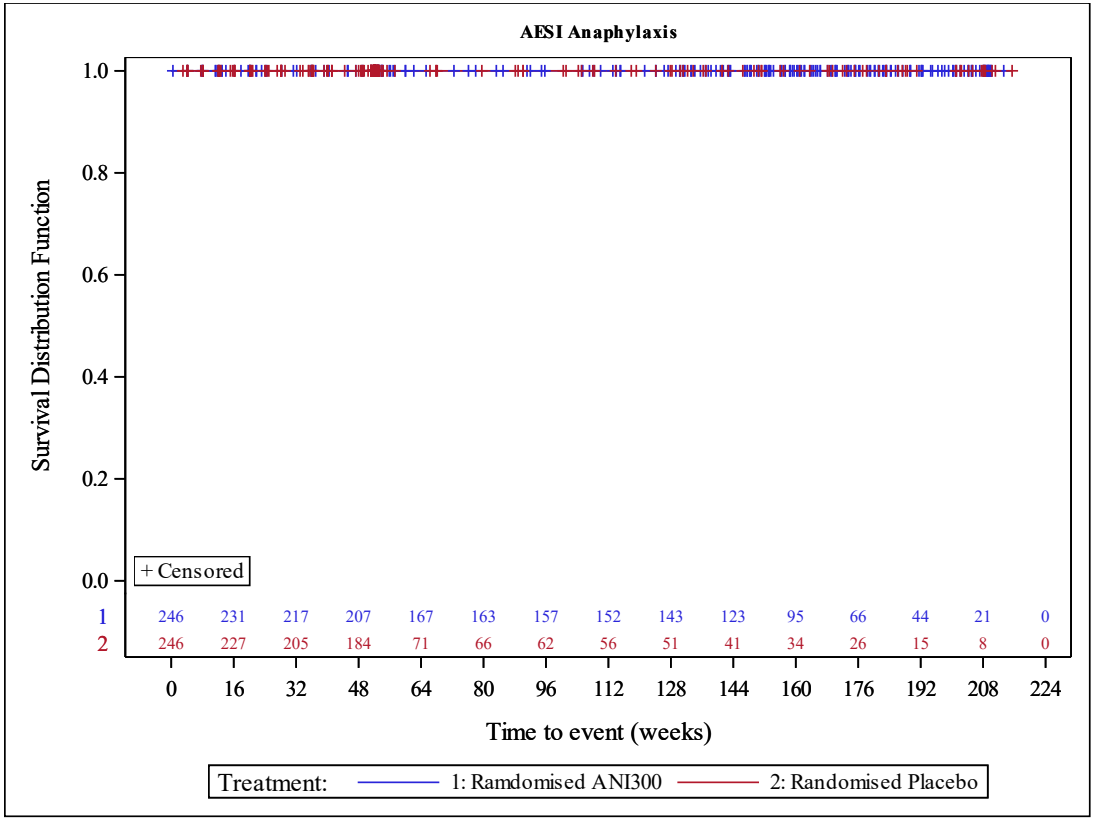
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Anaphylaxis - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%) Median (95% CI)	Randomised Placebo (N=246) n/ N (%) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI) p-Value	Interaction p-Value
Age (years)				NE
<= 65	0/239 (0.0) NE (NE, NE)	0/243 (0.0) NE (NE, NE)	NE	
> 65	0/ 7 (0.0) NE (NE, NE)	0/ 3 (0.0) NE (NE, NE)	NE	
Sex				NE
male	0/ 23 (0.0) NE (NE, NE)	0/ 20 (0.0) NE (NE, NE)	NE	
female	0/223 (0.0) NE (NE, NE)	0/226 (0.0) NE (NE, NE)	NE	
Geographic region				NE
EU	0/ 92 (0.0) NE (NE, NE)	0/ 89 (0.0) NE (NE, NE)	NE	
non-EU	0/154 (0.0) NE (NE, NE)	0/157 (0.0) NE (NE, NE)	NE	
SLEDAI-2K score at screening				NE
< 10 points	0/ 80 (0.0) NE (NE, NE)	0/ 69 (0.0) NE (NE, NE)	NE	
>= 10 points	0/166 (0.0) NE (NE, NE)	0/177 (0.0) NE (NE, NE)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Anaphylaxis
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Anaphylaxis
Full analysis set

	Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	246 (100.0)	246 (100.0)
Exposure years	581.5	348.7
EAIR per 100 PY	0.0	0.0
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	NE	
p-value		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

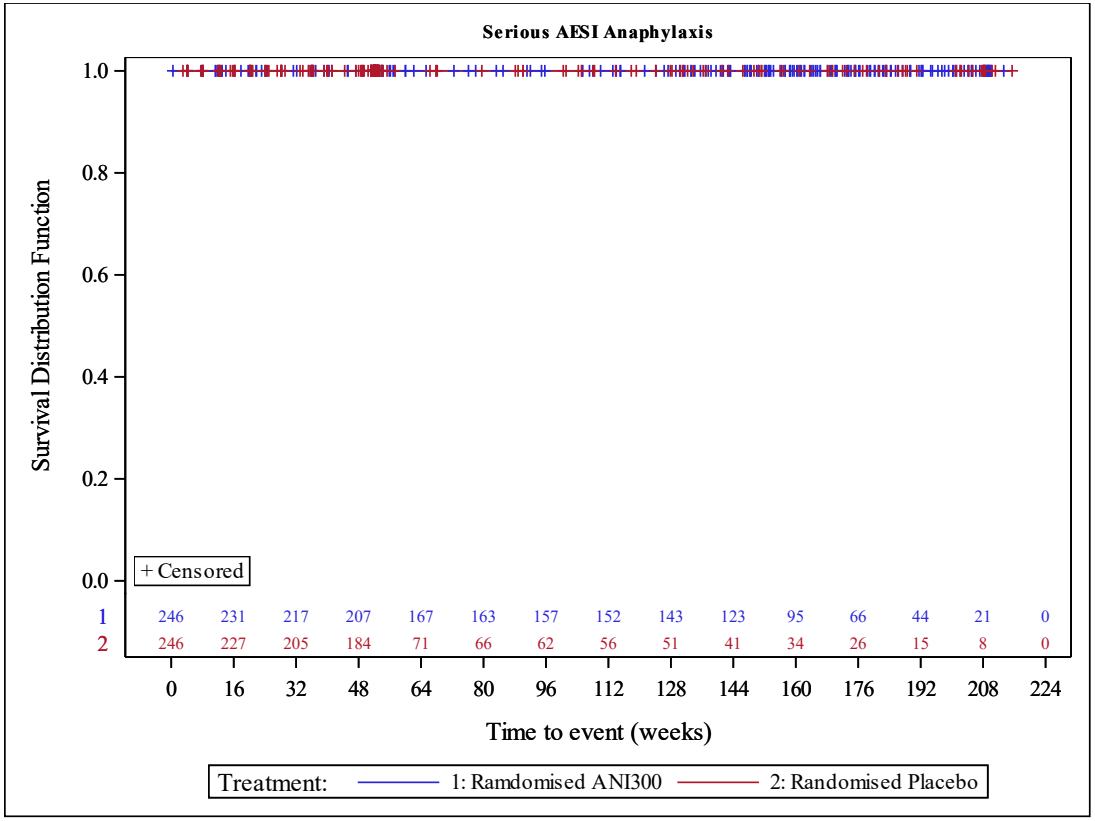
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Anaphylaxis - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%) Median (95% CI)	Randomised Placebo (N=246) n/ N (%) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI) p-Value	Interaction p-Value
Age (years)				NE
<= 65	0/239 (0.0) NE (NE, NE)	0/243 (0.0) NE (NE, NE)	NE	
> 65	0/ 7 (0.0) NE (NE, NE)	0/ 3 (0.0) NE (NE, NE)	NE	
Sex				NE
male	0/ 23 (0.0) NE (NE, NE)	0/ 20 (0.0) NE (NE, NE)	NE	
female	0/223 (0.0) NE (NE, NE)	0/226 (0.0) NE (NE, NE)	NE	
Geographic region				NE
EU	0/ 92 (0.0) NE (NE, NE)	0/ 89 (0.0) NE (NE, NE)	NE	
non-EU	0/154 (0.0) NE (NE, NE)	0/157 (0.0) NE (NE, NE)	NE	
SLEDAI-2K score at screening				NE
< 10 points	0/ 80 (0.0) NE (NE, NE)	0/ 69 (0.0) NE (NE, NE)	NE	
>= 10 points	0/166 (0.0) NE (NE, NE)	0/177 (0.0) NE (NE, NE)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Anaphylaxis
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Anaphylaxis
Full analysis set

	Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	246 (100.0)	246 (100.0)
Exposure years	581.5	348.7
EAIR per 100 PY	0.0	0.0
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	NE	
p-value		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

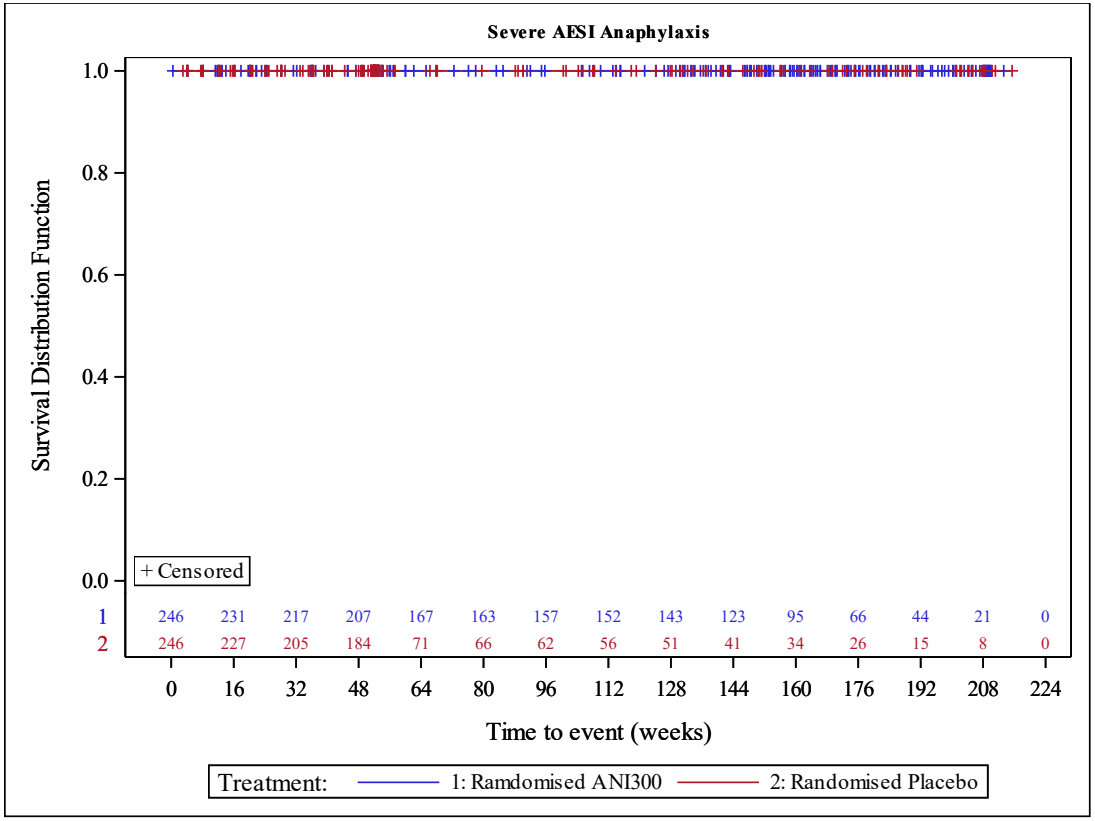
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Anaphylaxis - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%) Median (95% CI)	Randomised Placebo (N=246) n/ N (%) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI) p-Value	Interaction p-Value
Age (years)				NE
<= 65	0/239 (0.0) NE (NE, NE)	0/243 (0.0) NE (NE, NE)	NE	
> 65	0/ 7 (0.0) NE (NE, NE)	0/ 3 (0.0) NE (NE, NE)	NE	
Sex				NE
male	0/ 23 (0.0) NE (NE, NE)	0/ 20 (0.0) NE (NE, NE)	NE	
female	0/223 (0.0) NE (NE, NE)	0/226 (0.0) NE (NE, NE)	NE	
Geographic region				NE
EU	0/ 92 (0.0) NE (NE, NE)	0/ 89 (0.0) NE (NE, NE)	NE	
non-EU	0/154 (0.0) NE (NE, NE)	0/157 (0.0) NE (NE, NE)	NE	
SLEDAI-2K score at screening				NE
< 10 points	0/ 80 (0.0) NE (NE, NE)	0/ 69 (0.0) NE (NE, NE)	NE	
>= 10 points	0/166 (0.0) NE (NE, NE)	0/177 (0.0) NE (NE, NE)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Anaphylaxis
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Anaphylaxis
Full analysis set

	Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	246 (100.0)	246 (100.0)
Exposure years	581.5	348.7
EAIR per 100 PY	0.0	0.0
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	NE	
p-value		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

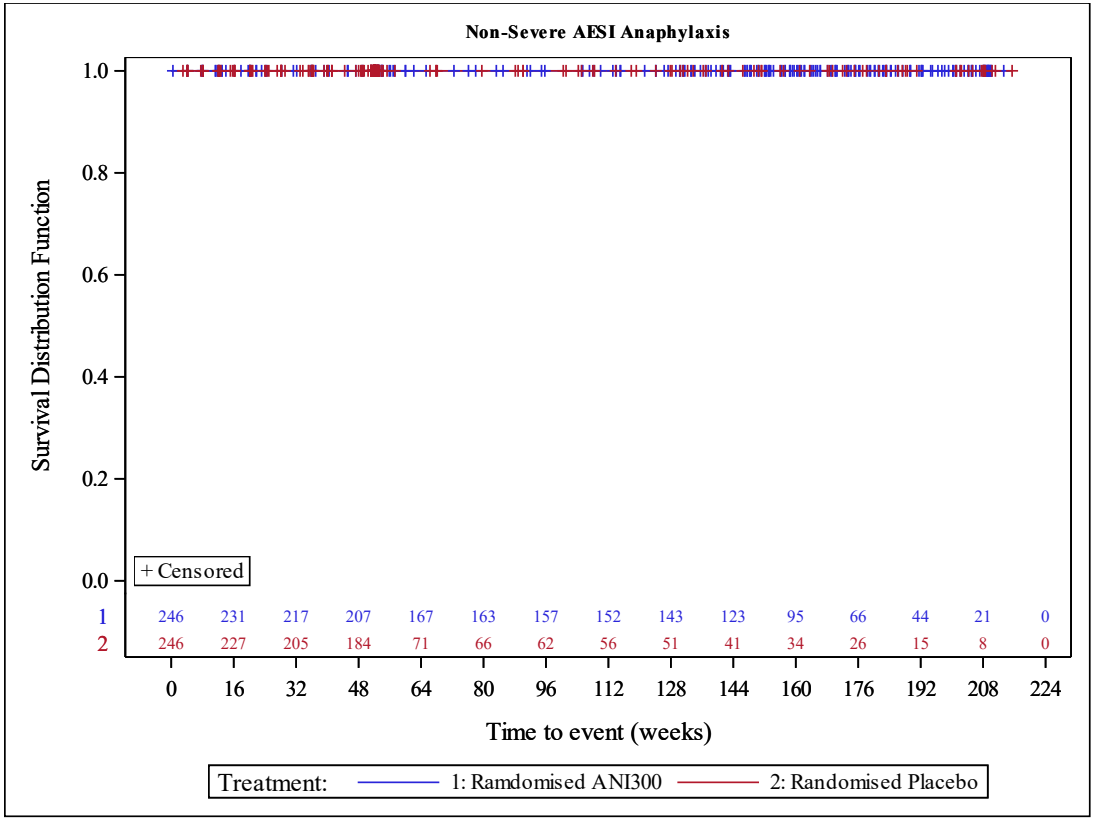
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Anaphylaxis - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%) Median (95% CI)	Randomised Placebo (N=246) n/ N (%) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI) p-Value	Interaction p-Value
Age (years)				NE
<= 65	0/239 (0.0) NE (NE, NE)	0/243 (0.0) NE (NE, NE)	NE	
> 65	0/ 7 (0.0) NE (NE, NE)	0/ 3 (0.0) NE (NE, NE)	NE	
Sex				NE
male	0/ 23 (0.0) NE (NE, NE)	0/ 20 (0.0) NE (NE, NE)	NE	
female	0/223 (0.0) NE (NE, NE)	0/226 (0.0) NE (NE, NE)	NE	
Geographic region				NE
EU	0/ 92 (0.0) NE (NE, NE)	0/ 89 (0.0) NE (NE, NE)	NE	
non-EU	0/154 (0.0) NE (NE, NE)	0/157 (0.0) NE (NE, NE)	NE	
SLEDAI-2K score at screening				NE
< 10 points	0/ 80 (0.0) NE (NE, NE)	0/ 69 (0.0) NE (NE, NE)	NE	
>= 10 points	0/166 (0.0) NE (NE, NE)	0/177 (0.0) NE (NE, NE)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Anaphylaxis
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Herpes Zoster
Full analysis set

	Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
Number of subjects with events, n (%)	26 (10.6)	7 (2.8)
Number of censored subjects, n (%)	220 (89.4)	239 (97.2)
Exposure years	545.5	336.7
EAIR per 100 PY	4.8	2.1
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	2.45 (1.05, 5.73)	
p-value	0.0328	
Relative Risk (95% CI)	3.71 (1.64, 8.40)	
p-value	0.0016	
Odds Ratio (95% CI)	4.04 (1.72, 9.48)	
p-value	0.0014	
Risk Difference (95% CI)	7.72 (3.36, 12.09)	
p-value	0.0005	

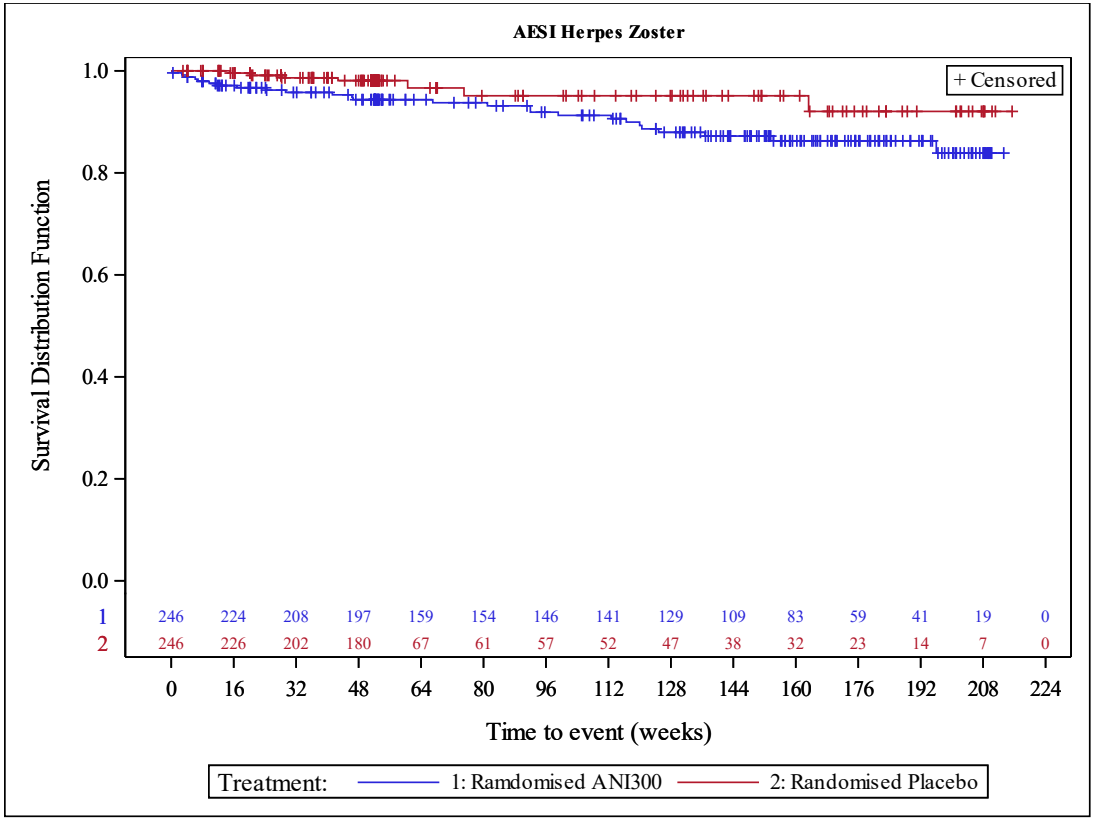
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%) Median (95% CI)	Randomised Placebo (N=246) n/ N (%) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI) p-Value	Interaction p-Value
Age (years)				0.9997
<= 65	26/239 (10.9) NE (NE, NE)	7/243 (2.9) NE (NE, NE)	2.50 (1.07, 5.85) 0.0287	
> 65	0/ 7 (0.0) NE (NE, NE)	0/ 3 (0.0) NE (NE, NE)	NE	
Sex				0.9818
male	4/ 23 (17.4) NE (NE, NE)	1/ 20 (5.0) NE (60.57, NE)	2.65 (0.29, 24.22) 0.3702	
female	22/223 (9.9) NE (NE, NE)	6/226 (2.7) NE (NE, NE)	2.38 (0.95, 5.98) 0.0572	
Geographic region				0.4521
EU	8/ 92 (8.7) NE (NE, NE)	3/ 89 (3.4) NE (NE, NE)	1.55 (0.40, 6.03) 0.5221	
non-EU	18/154 (11.7) NE (NE, NE)	4/157 (2.5) NE (NE, NE)	3.18 (1.06, 9.56) 0.0301	
SLEDAI-2K score at screening				0.4090
< 10 points	9/ 80 (11.3) NE (NE, NE)	1/ 69 (1.4) NE (NE, NE)	4.34 (0.54, 34.81) 0.1332	
>= 10 points	17/166 (10.2) NE (NE, NE)	6/177 (3.4) NE (NE, NE)	2.17 (0.84, 5.60) 0.1008	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Herpes Zoster
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Herpes Zoster
Full analysis set

	Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
Number of subjects with events, n (%)	5 (2.0)	0 (0.0)
Number of censored subjects, n (%)	241 (98.0)	246 (100.0)
Exposure years	578.8	348.7
EAIR per 100 PY	0.9	0.0
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	NE	
p-value		
Relative Risk (95% CI)	11.00 (0.61, 197.86)	
p-value	0.1039	
Odds Ratio (95% CI)	11.23 (0.62, 204.16)	
p-value	0.1022	
Risk Difference (95% CI)	2.03 (0.27, 3.80)	
p-value	0.0239	

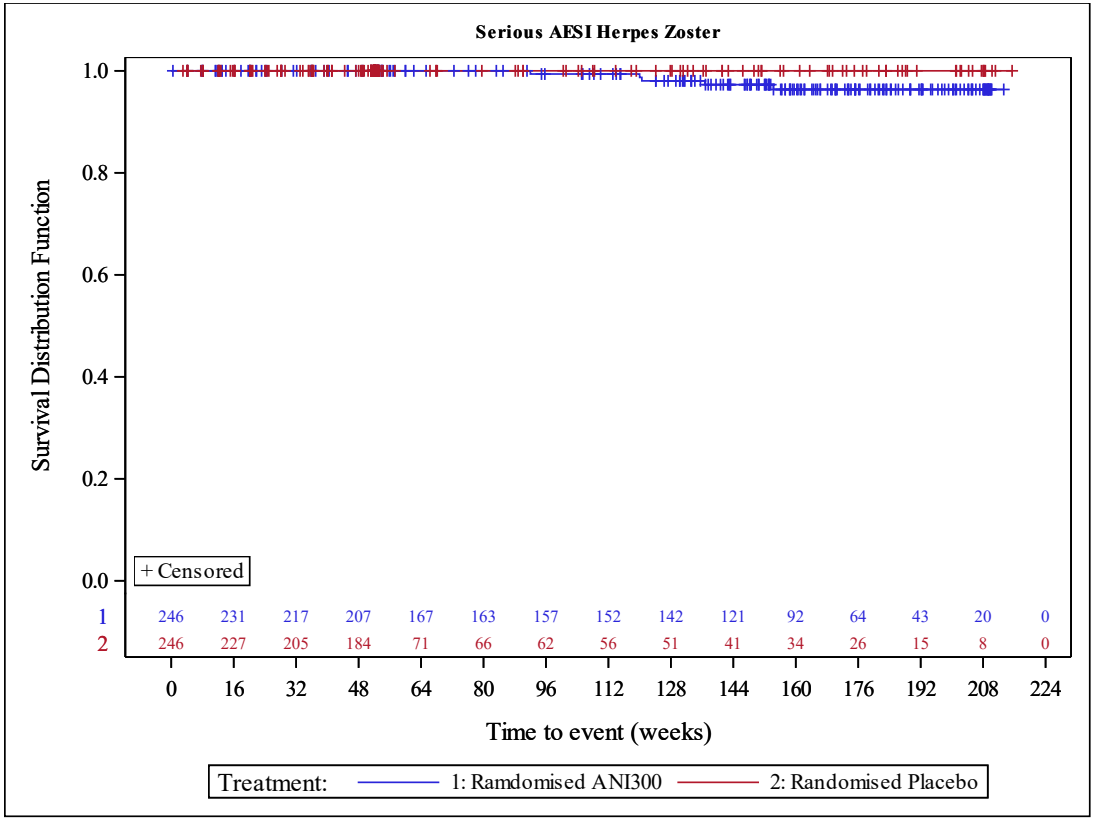
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%) Median (95% CI)	Randomised Placebo (N=246) n/ N (%) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI) p-Value	Interaction p-Value
Age (years)				NE
<= 65	5/239 (2.1) NE (NE, NE)	0/243 (0.0) NE (NE, NE)	NE	
> 65	0/ 7 (0.0) NE (NE, NE)	0/ 3 (0.0) NE (NE, NE)	NE	
Sex				0.9999
male	1/ 23 (4.3) NE (NE, NE)	0/ 20 (0.0) NE (NE, NE)	NE	
female	4/223 (1.8) NE (NE, NE)	0/226 (0.0) NE (NE, NE)	NE	
Geographic region				0.9999
EU	3/ 92 (3.3) NE (NE, NE)	0/ 89 (0.0) NE (NE, NE)	NE	
non-EU	2/154 (1.3) NE (NE, NE)	0/157 (0.0) NE (NE, NE)	NE	
SLEDAI-2K score at screening				0.9997
< 10 points	4/ 80 (5.0) NE (NE, NE)	0/ 69 (0.0) NE (NE, NE)	NE	
>= 10 points	1/166 (0.6) NE (NE, NE)	0/177 (0.0) NE (NE, NE)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Herpes Zoster
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Herpes Zoster
Full analysis set

	Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
Number of subjects with events, n (%)	3 (1.2)	0 (0.0)
Number of censored subjects, n (%)	243 (98.8)	246 (100.0)
Exposure years	580.3	348.7
EAIR per 100 PY	0.5	0.0
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	NE	
p-value		
Relative Risk (95% CI)	7.00 (0.36, 134.81)	
p-value	0.1973	
Odds Ratio (95% CI)	7.09 (0.36, 137.91)	
p-value	0.1960	
Risk Difference (95% CI)	1.22 (-0.15, 2.59)	
p-value	0.0814	

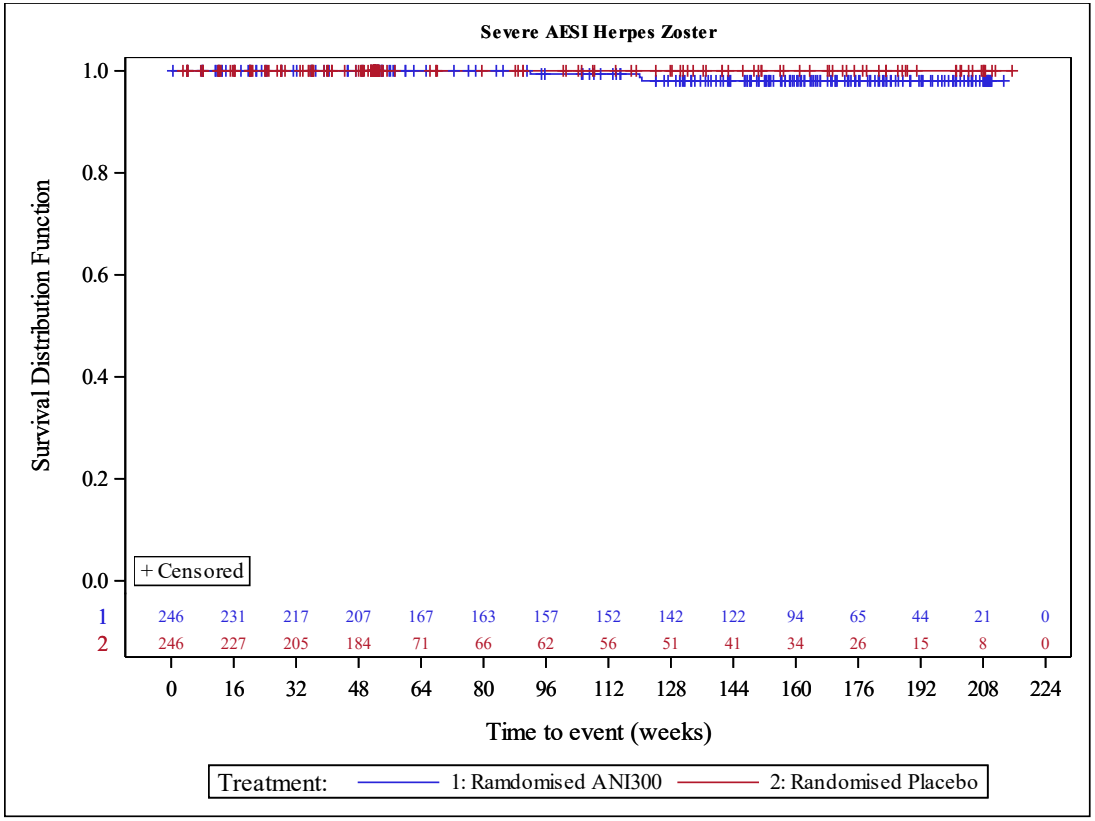
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%) Median (95% CI)	Randomised Placebo (N=246) n/ N (%) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI) p-Value	Interaction p-Value
Age (years)				NE
<= 65	3/239 (1.3) NE (NE, NE)	0/243 (0.0) NE (NE, NE)	NE	
> 65	0/ 7 (0.0) NE (NE, NE)	0/ 3 (0.0) NE (NE, NE)	NE	
Sex				0.9999
male	1/ 23 (4.3) NE (NE, NE)	0/ 20 (0.0) NE (NE, NE)	NE	
female	2/223 (0.9) NE (NE, NE)	0/226 (0.0) NE (NE, NE)	NE	
Geographic region				0.9999
EU	2/ 92 (2.2) NE (NE, NE)	0/ 89 (0.0) NE (NE, NE)	NE	
non-EU	1/154 (0.6) NE (NE, NE)	0/157 (0.0) NE (NE, NE)	NE	
SLEDAI-2K score at screening				0.9998
< 10 points	2/ 80 (2.5) NE (NE, NE)	0/ 69 (0.0) NE (NE, NE)	NE	
>= 10 points	1/166 (0.6) NE (NE, NE)	0/177 (0.0) NE (NE, NE)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Herpes Zoster
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Herpes Zoster
Full analysis set

	Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
Number of subjects with events, n (%)	23 (9.3)	7 (2.8)
Number of censored subjects, n (%)	223 (90.7)	239 (97.2)
Exposure years	546.6	336.7
EAIR per 100 PY	4.2	2.1
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	2.27 (0.96, 5.36)	
p-value	0.0558	
Relative Risk (95% CI)	3.29 (1.44, 7.52)	
p-value	0.0048	
Odds Ratio (95% CI)	3.52 (1.48, 8.37)	
p-value	0.0044	
Risk Difference (95% CI)	6.50 (2.31, 10.69)	
p-value	0.0023	

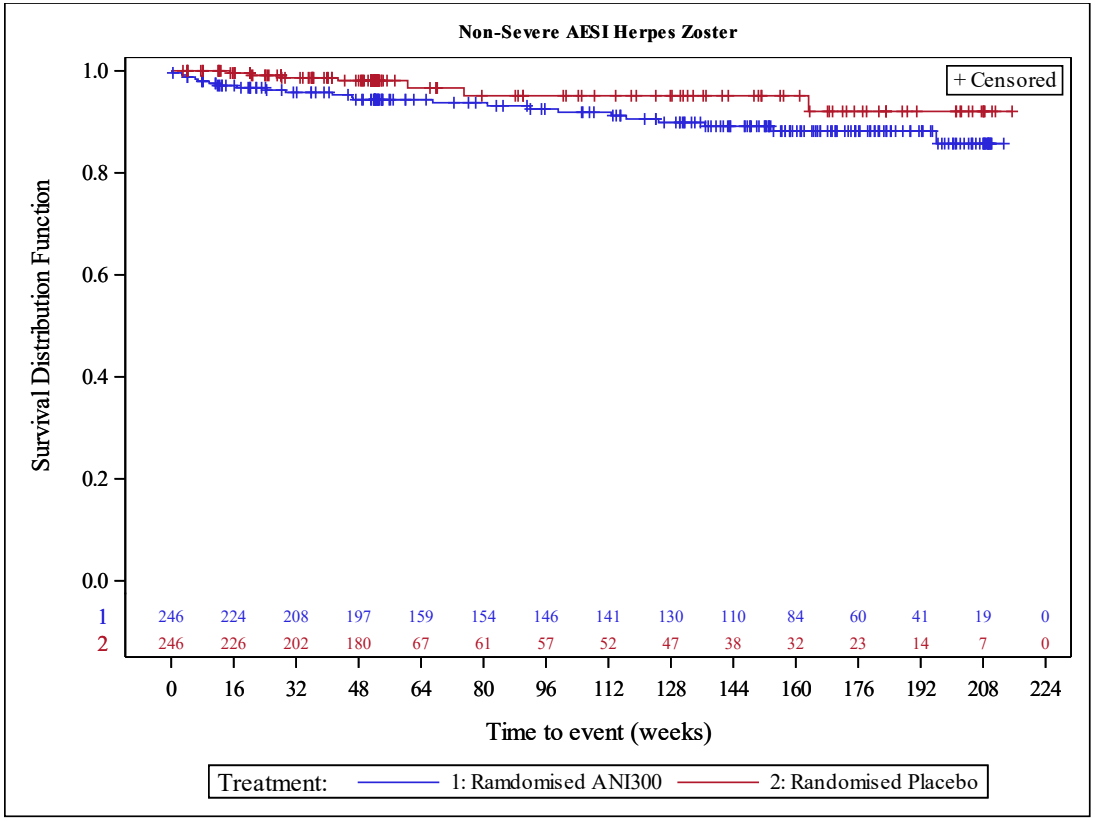
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%)	Ramdomised ANI300 (N=246) Median (95% CI)	Randomised Placebo (N=246) n/ N (%)	Randomised Placebo (N=246) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
Age (years)							0.9997
<= 65	23/239 (9.6)	NE (NE, NE)	7/243 (2.9)	NE (NE, NE)	2.31 (0.98, 5.47)	0.0497	
> 65	0/ 7 (0.0)	NE (NE, NE)	0/ 3 (0.0)	NE (NE, NE)	NE		
Sex							0.8886
male	3/ 23 (13.0)	NE (NE, NE)	1/ 20 (5.0)	NE (60.57, NE)	2.22 (0.23, 21.71)	0.4803	
female	20/223 (9.0)	NE (NE, NE)	6/226 (2.7)	NE (NE, NE)	2.24 (0.88, 5.69)	0.0812	
Geographic region							0.3202
EU	6/ 92 (6.5)	NE (NE, NE)	3/ 89 (3.4)	NE (NE, NE)	1.26 (0.30, 5.21)	0.7504	
non-EU	17/154 (11.0)	NE (NE, NE)	4/157 (2.5)	NE (NE, NE)	3.08 (1.02, 9.30)	0.0366	
SLEDAI-2K score at screening							0.5158
< 10 points	7/ 80 (8.8)	NE (NE, NE)	1/ 69 (1.4)	NE (NE, NE)	3.63 (0.44, 30.04)	0.2027	
>= 10 points	16/166 (9.6)	NE (NE, NE)	6/177 (3.4)	NE (NE, NE)	2.09 (0.80, 5.43)	0.1224	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Herpes Zoster
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Malignancy
Full analysis set

	Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
Number of subjects with events, n (%)	1 (0.4)	3 (1.2)
Number of censored subjects, n (%)	245 (99.6)	243 (98.8)
Exposure years	581.4	348.6
EAIR per 100 PY	0.2	0.9
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	0.32 (0.03, 3.06)	
p-value	0.2954	
Relative Risk (95% CI)	0.33 (0.03, 3.18)	
p-value	0.3399	
Odds Ratio (95% CI)	0.33 (0.03, 3.20)	
p-value	0.3393	
Risk Difference (95% CI)	-0.81 (-2.40, 0.77)	
p-value	0.3148	

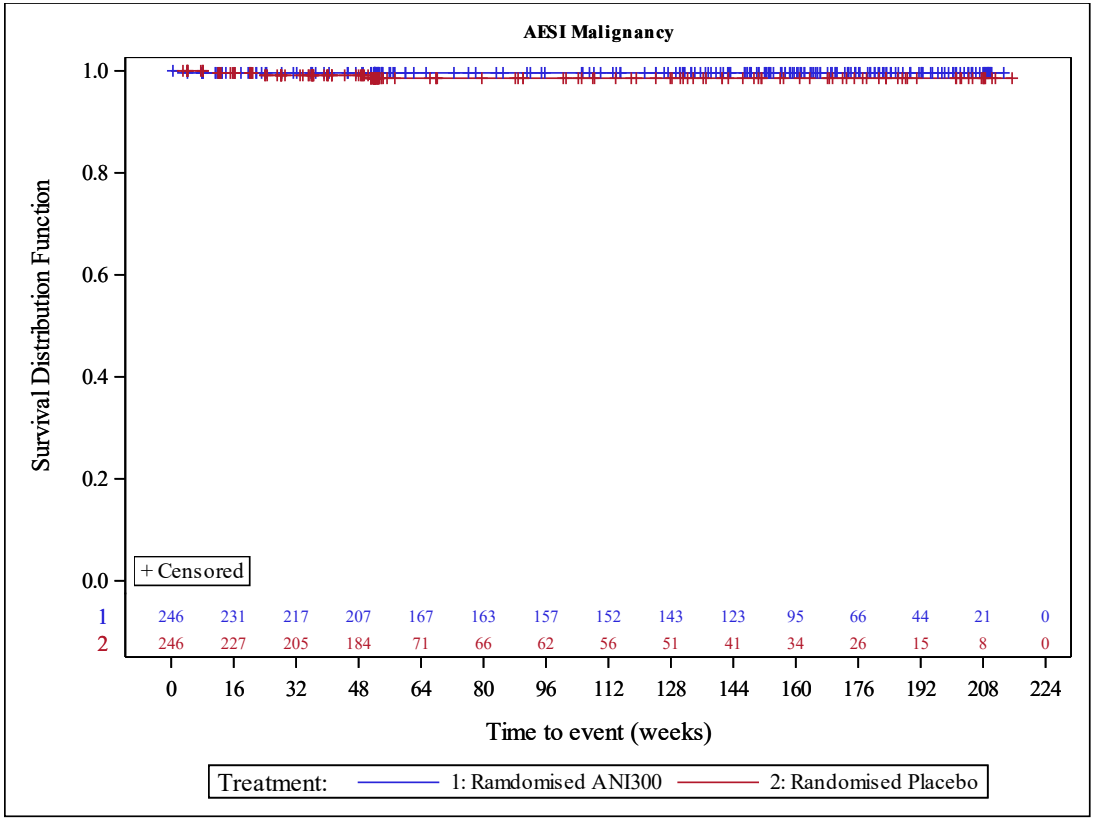
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%) Median (95% CI)	Randomised Placebo (N=246) n/ N (%) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	 p-Value	Interaction p-Value
Age (years)					0.9998
<= 65	1/239 (0.4) NE (NE, NE)	3/243 (1.2) NE (NE, NE)	0.32 (0.03, 3.10)	0.3013	
> 65	0/ 7 (0.0) NE (NE, NE)	0/ 3 (0.0) NE (NE, NE)	NE		
Sex					0.9999
male	0/ 23 (0.0) NE (NE, NE)	0/ 20 (0.0) NE (NE, NE)	NE		
female	1/223 (0.4) NE (NE, NE)	3/226 (1.3) NE (NE, NE)	0.32 (0.03, 3.11)	0.3034	
Geographic region					0.9948
EU	1/ 92 (1.1) NE (NE, NE)	2/ 89 (2.2) NE (NE, NE)	0.46 (0.04, 5.04)	0.5120	
non-EU	0/154 (0.0) NE (NE, NE)	1/157 (0.6) NE (NE, NE)	NE		
SLEDAI-2K score at screening					0.9956
< 10 points	1/ 80 (1.3) NE (NE, NE)	0/ 69 (0.0) NE (NE, NE)	NE		
>= 10 points	0/166 (0.0) NE (NE, NE)	3/177 (1.7) NE (NE, NE)	NE		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Malignancy
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Malignancy
Full analysis set

	Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
Number of subjects with events, n (%)	1 (0.4)	1 (0.4)
Number of censored subjects, n (%)	245 (99.6)	245 (99.6)
Exposure years	581.4	348.7
EAIR per 100 PY	0.2	0.3
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	0.99 (0.06, 15.89)	
p-value	0.9964	
Relative Risk (95% CI)	1.00 (0.06, 15.90)	
p-value	1.0000	
Odds Ratio (95% CI)	1.00 (0.06, 16.08)	
p-value	1.0000	
Risk Difference (95% CI)	0.00 (-1.12, 1.12)	
p-value	1.0000	

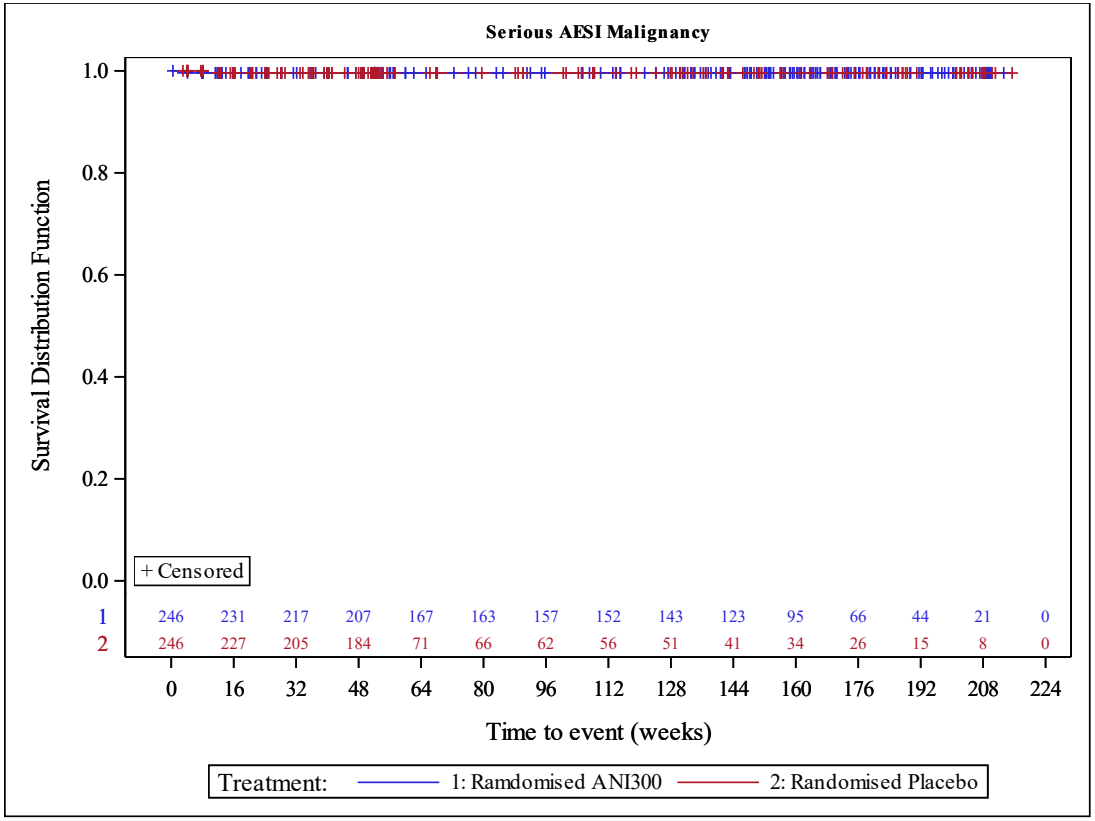
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%) Median (95% CI)	Randomised Placebo (N=246) n/ N (%) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI) p-Value	Interaction p-Value
Age (years)				1.0000
<= 65	1/239 (0.4) NE (NE, NE)	1/243 (0.4) NE (NE, NE)	1.01 (0.06, 16.16) 0.9941	
> 65	0/ 7 (0.0) NE (NE, NE)	0/ 3 (0.0) NE (NE, NE)	NE	
Sex				1.0000
male	0/ 23 (0.0) NE (NE, NE)	0/ 20 (0.0) NE (NE, NE)	NE	
female	1/223 (0.4) NE (NE, NE)	1/226 (0.4) NE (NE, NE)	1.01 (0.06, 16.13) 0.9950	
Geographic region				1.0000
EU	1/ 92 (1.1) NE (NE, NE)	1/ 89 (1.1) NE (NE, NE)	0.94 (0.06, 15.02) 0.9647	
non-EU	0/154 (0.0) NE (NE, NE)	0/157 (0.0) NE (NE, NE)	NE	
SLEDAI-2K score at screening				0.9973
< 10 points	1/ 80 (1.3) NE (NE, NE)	0/ 69 (0.0) NE (NE, NE)	NE	
>= 10 points	0/166 (0.0) NE (NE, NE)	1/177 (0.6) NE (NE, NE)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Malignancy
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Malignancy
Full analysis set

	Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	246 (100.0)	246 (100.0)
Exposure years	581.5	348.7
EAIR per 100 PY	0.0	0.0
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	NE	
p-value		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

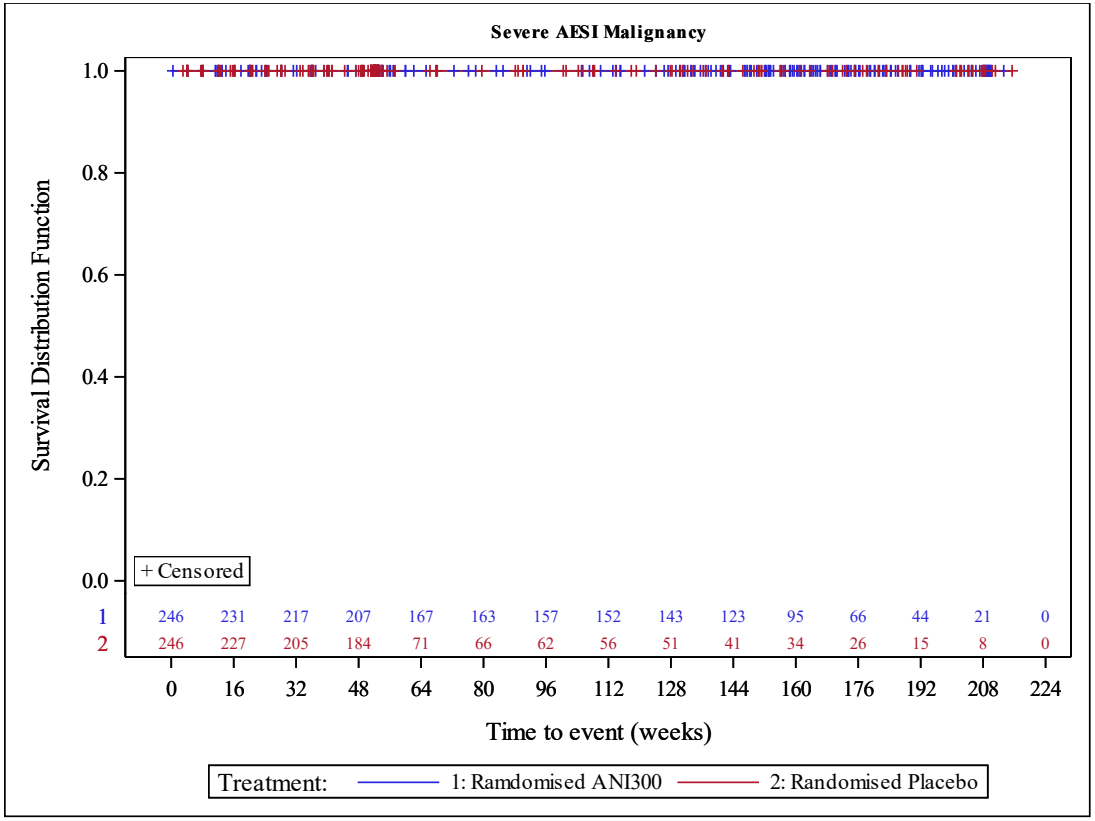
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%) Median (95% CI)	Randomised Placebo (N=246) n/ N (%) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI) p-Value	Interaction p-Value
Age (years)				NE
<= 65	0/239 (0.0) NE (NE, NE)	0/243 (0.0) NE (NE, NE)	NE	
> 65	0/ 7 (0.0) NE (NE, NE)	0/ 3 (0.0) NE (NE, NE)	NE	
Sex				NE
male	0/ 23 (0.0) NE (NE, NE)	0/ 20 (0.0) NE (NE, NE)	NE	
female	0/223 (0.0) NE (NE, NE)	0/226 (0.0) NE (NE, NE)	NE	
Geographic region				NE
EU	0/ 92 (0.0) NE (NE, NE)	0/ 89 (0.0) NE (NE, NE)	NE	
non-EU	0/154 (0.0) NE (NE, NE)	0/157 (0.0) NE (NE, NE)	NE	
SLEDAI-2K score at screening				NE
< 10 points	0/ 80 (0.0) NE (NE, NE)	0/ 69 (0.0) NE (NE, NE)	NE	
>= 10 points	0/166 (0.0) NE (NE, NE)	0/177 (0.0) NE (NE, NE)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Malignancy
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Malignancy
Full analysis set

	Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
Number of subjects with events, n (%)	1 (0.4)	3 (1.2)
Number of censored subjects, n (%)	245 (99.6)	243 (98.8)
Exposure years	581.4	348.6
EAIR per 100 PY	0.2	0.9
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	0.32 (0.03, 3.06)	
p-value	0.2954	
Relative Risk (95% CI)	0.33 (0.03, 3.18)	
p-value	0.3399	
Odds Ratio (95% CI)	0.33 (0.03, 3.20)	
p-value	0.3393	
Risk Difference (95% CI)	-0.81 (-2.40, 0.77)	
p-value	0.3148	

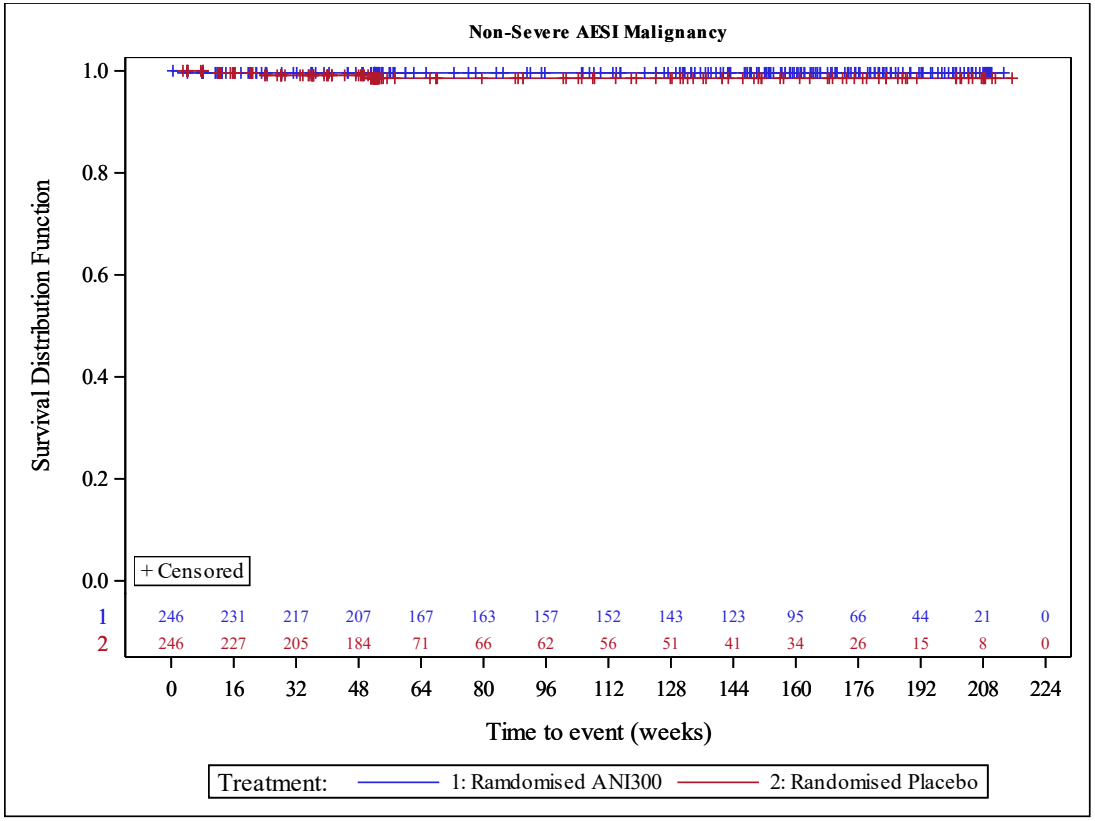
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%) Median (95% CI)	Randomised Placebo (N=246) n/ N (%) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI) p-Value	Interaction p-Value
Age (years)				0.9998
<= 65	1/239 (0.4) NE (NE, NE)	3/243 (1.2) NE (NE, NE)	0.32 (0.03, 3.10) 0.3013	
> 65	0/ 7 (0.0) NE (NE, NE)	0/ 3 (0.0) NE (NE, NE)	NE	
Sex				0.9999
male	0/ 23 (0.0) NE (NE, NE)	0/ 20 (0.0) NE (NE, NE)	NE	
female	1/223 (0.4) NE (NE, NE)	3/226 (1.3) NE (NE, NE)	0.32 (0.03, 3.11) 0.3034	
Geographic region				0.9948
EU	1/ 92 (1.1) NE (NE, NE)	2/ 89 (2.2) NE (NE, NE)	0.46 (0.04, 5.04) 0.5120	
non-EU	0/154 (0.0) NE (NE, NE)	1/157 (0.6) NE (NE, NE)	NE	
SLEDAI-2K score at screening				0.9956
< 10 points	1/ 80 (1.3) NE (NE, NE)	0/ 69 (0.0) NE (NE, NE)	NE	
>= 10 points	0/166 (0.0) NE (NE, NE)	3/177 (1.7) NE (NE, NE)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Malignancy
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Influenza
Full analysis set

	Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
Number of subjects with events, n (%)	12 (4.9)	9 (3.7)
Number of censored subjects, n (%)	234 (95.1)	237 (96.3)
Exposure years	566.9	342.9
EAIR per 100 PY	2.1	2.6
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	0.81 (0.33, 1.97)	
p-value	0.6447	
Relative Risk (95% CI)	1.33 (0.57, 3.11)	
p-value	0.5051	
Odds Ratio (95% CI)	1.35 (0.56, 3.27)	
p-value	0.5048	
Risk Difference (95% CI)	1.22 (-2.35, 4.79)	
p-value	0.5032	

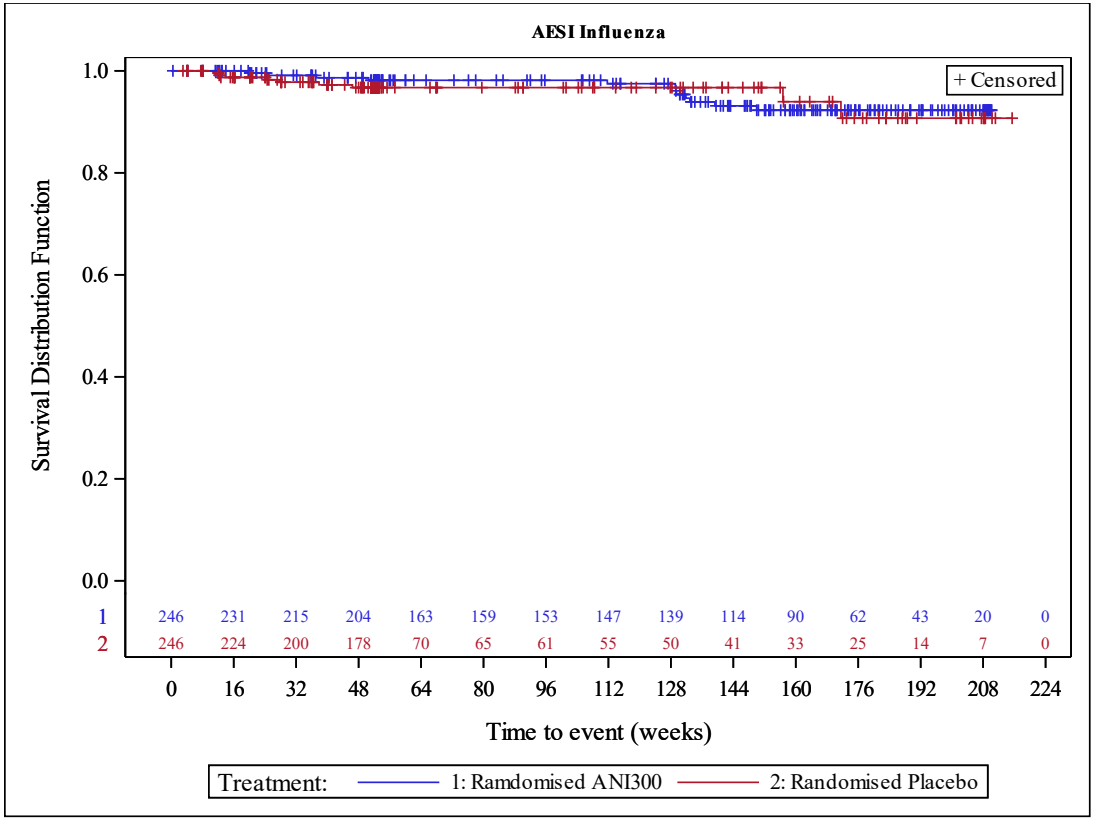
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%)	Ramdomised ANI300 (N=246) Median (95% CI)	Randomised Placebo (N=246) n/ N (%)	Randomised Placebo (N=246) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
Age (years)							1.0000
<= 65	12/239 (5.0)	NE (NE, NE)	9/243 (3.7)	NE (NE, NE)	0.83 (0.34, 2.01)	0.6777	
> 65	0/ 7 (0.0)	NE (NE, NE)	0/ 3 (0.0)	NE (NE, NE)	NE		
Sex							0.7856
male	1/ 23 (4.3)	NE (NE, NE)	1/ 20 (5.0)	NE (NE, NE)	0.60 (0.04, 9.90)	0.7170	
female	11/223 (4.9)	NE (NE, NE)	8/226 (3.5)	NE (NE, NE)	0.84 (0.33, 2.14)	0.7124	
Geographic region							0.6771
EU	4/ 92 (4.3)	NE (NE, NE)	2/ 89 (2.2)	NE (NE, NE)	1.32 (0.23, 7.48)	0.7498	
non-EU	8/154 (5.2)	NE (NE, NE)	7/157 (4.5)	NE (NE, NE)	0.70 (0.25, 1.97)	0.4935	
SLEDAI-2K score at screening							0.4094
< 10 points	5/ 80 (6.3)	NE (NE, NE)	2/ 69 (2.9)	NE (NE, NE)	1.49 (0.28, 7.90)	0.6368	
>= 10 points	7/166 (4.2)	NE (NE, NE)	7/177 (4.0)	NE (NE, NE)	0.59 (0.20, 1.75)	0.3395	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Influenza
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Influenza
Full analysis set

	Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
Number of subjects with events, n (%)	1 (0.4)	1 (0.4)
Number of censored subjects, n (%)	245 (99.6)	245 (99.6)
Exposure years	580.5	348.0
EAIR per 100 PY	0.2	0.3
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	0.59 (0.03, 10.35)	
p-value	0.7147	
Relative Risk (95% CI)	1.00 (0.06, 15.90)	
p-value	1.0000	
Odds Ratio (95% CI)	1.00 (0.06, 16.08)	
p-value	1.0000	
Risk Difference (95% CI)	0.00 (-1.12, 1.12)	
p-value	1.0000	

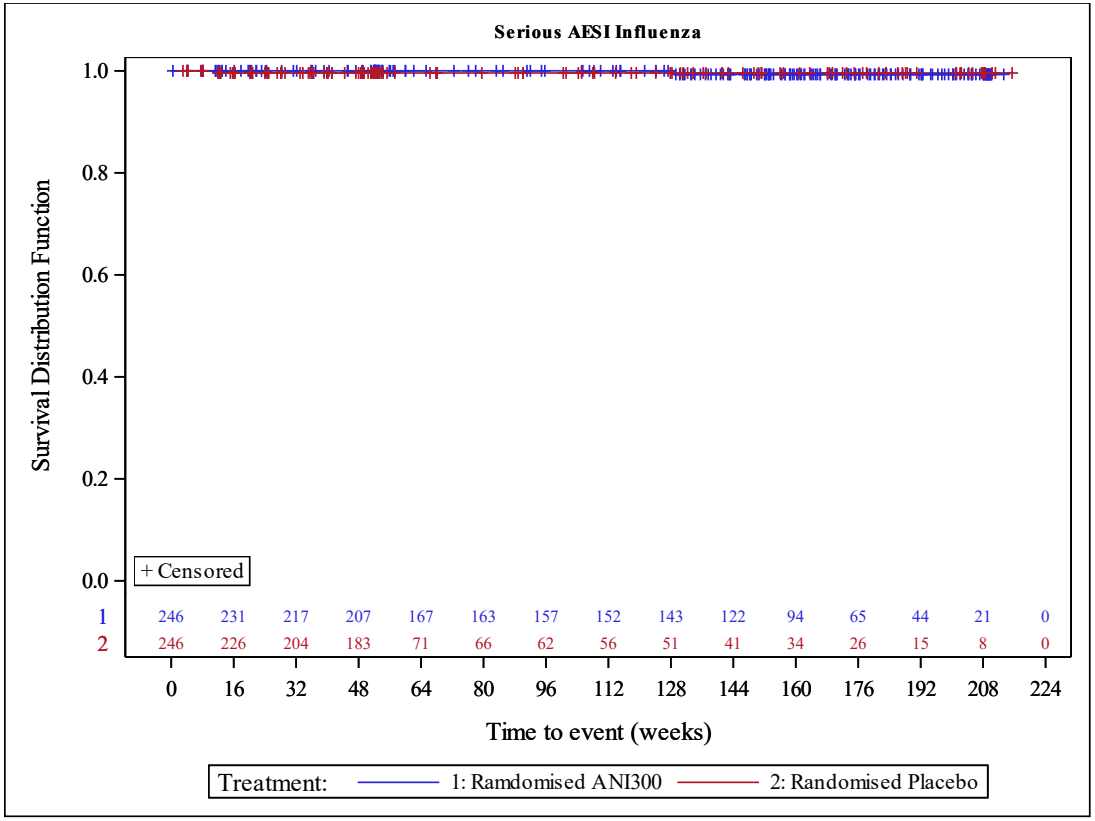
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%) Median (95% CI)	Randomised Placebo (N=246) n/ N (%) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI) p-Value	Interaction p-Value
Age (years)				1.0000
<= 65	1/239 (0.4) NE (NE, NE)	1/243 (0.4) NE (NE, NE)	0.60 (0.03, 10.56) 0.7264	
> 65	0/ 7 (0.0) NE (NE, NE)	0/ 3 (0.0) NE (NE, NE)	NE	
Sex				1.0000
male	0/ 23 (0.0) NE (NE, NE)	0/ 20 (0.0) NE (NE, NE)	NE	
female	1/223 (0.4) NE (NE, NE)	1/226 (0.4) NE (NE, NE)	0.59 (0.03, 10.40) 0.7138	
Geographic region				1.0000
EU	0/ 92 (0.0) NE (NE, NE)	0/ 89 (0.0) NE (NE, NE)	NE	
non-EU	1/154 (0.6) NE (NE, NE)	1/157 (0.6) NE (NE, NE)	0.62 (0.04, 10.84) 0.7387	
SLEDAI-2K score at screening				0.9971
< 10 points	1/ 80 (1.3) NE (NE, NE)	0/ 69 (0.0) NE (NE, NE)	NE	
>= 10 points	0/166 (0.0) NE (NE, NE)	1/177 (0.6) NE (NE, NE)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Influenza
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Influenza
Full analysis set

	Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
Number of subjects with events, n (%)	1 (0.4)	1 (0.4)
Number of censored subjects, n (%)	245 (99.6)	245 (99.6)
Exposure years	580.5	348.0
EAIR per 100 PY	0.2	0.3
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	0.59 (0.03, 10.35)	
p-value	0.7147	
Relative Risk (95% CI)	1.00 (0.06, 15.90)	
p-value	1.0000	
Odds Ratio (95% CI)	1.00 (0.06, 16.08)	
p-value	1.0000	
Risk Difference (95% CI)	0.00 (-1.12, 1.12)	
p-value	1.0000	

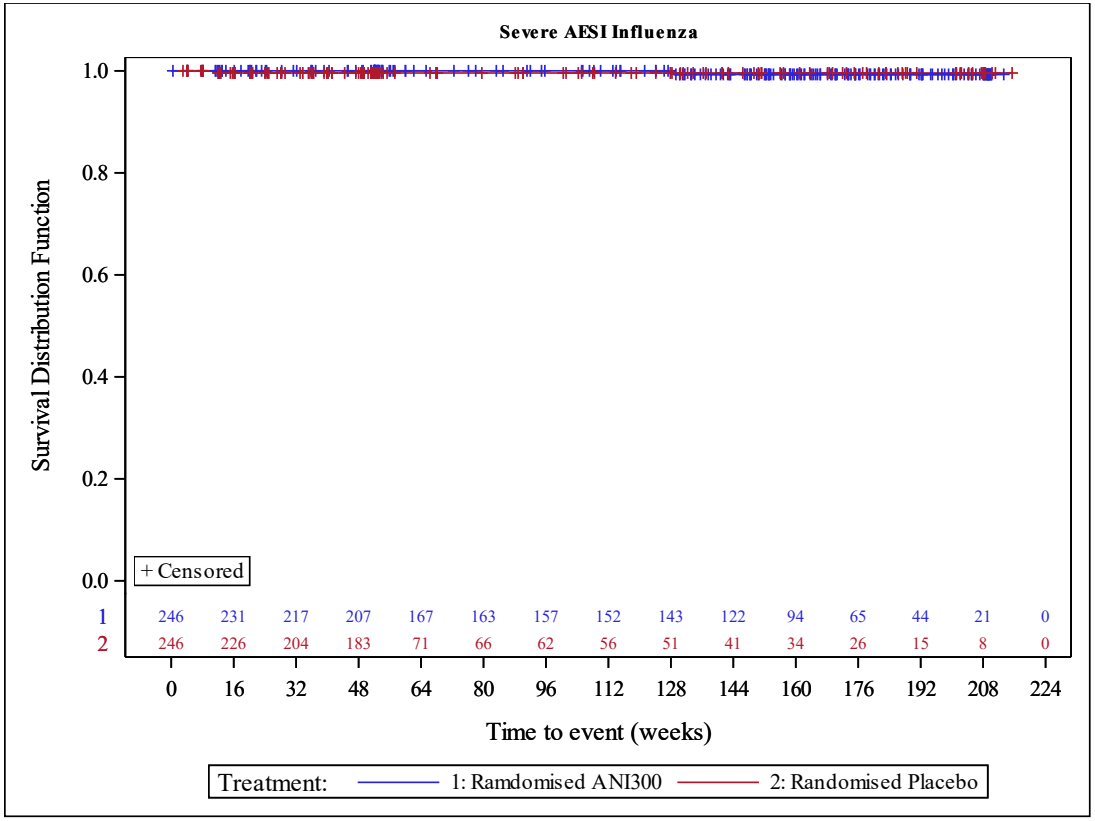
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%)	Ramdomised ANI300 (N=246) Median (95% CI)	Randomised Placebo (N=246) n/ N (%)	Randomised Placebo (N=246) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
Age (years)							1.0000
<= 65	1/239 (0.4)	NE (NE, NE)	1/243 (0.4)	NE (NE, NE)	0.60 (0.03, 10.56)	0.7264	
> 65	0/ 7 (0.0)	NE (NE, NE)	0/ 3 (0.0)	NE (NE, NE)	NE		
Sex							1.0000
male	0/ 23 (0.0)	NE (NE, NE)	0/ 20 (0.0)	NE (NE, NE)	NE		
female	1/223 (0.4)	NE (NE, NE)	1/226 (0.4)	NE (NE, NE)	0.59 (0.03, 10.40)	0.7138	
Geographic region							1.0000
EU	0/ 92 (0.0)	NE (NE, NE)	0/ 89 (0.0)	NE (NE, NE)	NE		
non-EU	1/154 (0.6)	NE (NE, NE)	1/157 (0.6)	NE (NE, NE)	0.62 (0.04, 10.84)	0.7387	
SLEDAI-2K score at screening							0.9971
< 10 points	1/ 80 (1.3)	NE (NE, NE)	0/ 69 (0.0)	NE (NE, NE)	NE		
>= 10 points	0/166 (0.0)	NE (NE, NE)	1/177 (0.6)	NE (NE, NE)	NE		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Influenza
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Influenza
Full analysis set

	Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
Number of subjects with events, n (%)	11 (4.5)	9 (3.7)
Number of censored subjects, n (%)	235 (95.5)	237 (96.3)
Exposure years	567.9	342.9
EAIR per 100 PY	1.9	2.6
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	0.76 (0.31, 1.87)	
p-value	0.5481	
Relative Risk (95% CI)	1.22 (0.52, 2.90)	
p-value	0.6486	
Odds Ratio (95% CI)	1.23 (0.50, 3.03)	
p-value	0.6485	
Risk Difference (95% CI)	0.81 (-2.68, 4.30)	
p-value	0.6479	

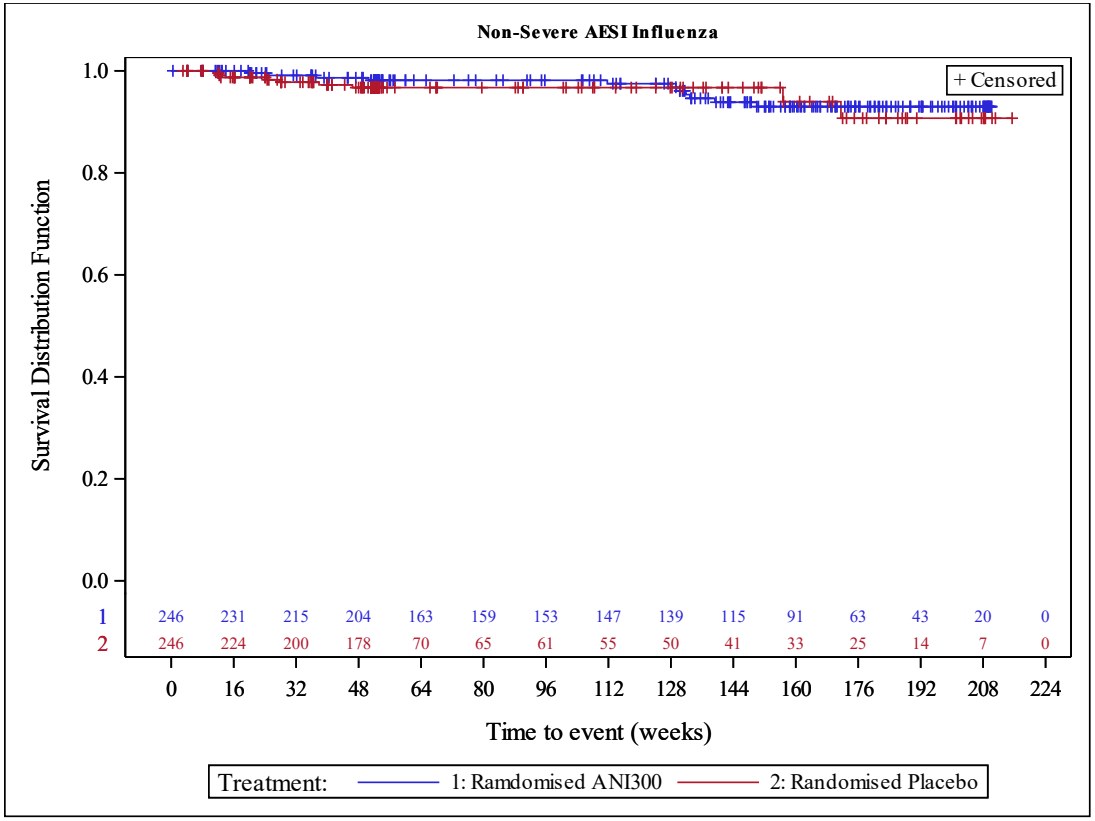
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%) Median (95% CI)	Randomised Placebo (N=246) n/ N (%) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI) p-Value	Interaction p-Value
Age (years)				0.9999
<= 65	11/239 (4.6) NE (NE, NE)	9/243 (3.7) NE (NE, NE)	0.77 (0.31, 1.91) 0.5776	
> 65	0/ 7 (0.0) NE (NE, NE)	0/ 3 (0.0) NE (NE, NE)	NE	
Sex				0.8342
male	1/ 23 (4.3) NE (NE, NE)	1/ 20 (5.0) NE (NE, NE)	0.60 (0.04, 9.90) 0.7170	
female	10/223 (4.5) NE (NE, NE)	8/226 (3.5) NE (NE, NE)	0.78 (0.30, 2.03) 0.6087	
Geographic region				0.5810
EU	4/ 92 (4.3) NE (NE, NE)	2/ 89 (2.2) NE (NE, NE)	1.32 (0.23, 7.48) 0.7498	
non-EU	7/154 (4.5) NE (NE, NE)	7/157 (4.5) NE (NE, NE)	0.62 (0.21, 1.83) 0.3831	
SLEDAI-2K score at screening				0.5695
< 10 points	4/ 80 (5.0) NE (NE, NE)	2/ 69 (2.9) NE (NE, NE)	1.28 (0.23, 7.16) 0.7817	
>= 10 points	7/166 (4.2) NE (NE, NE)	7/177 (4.0) NE (NE, NE)	0.59 (0.20, 1.75) 0.3395	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Influenza
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - MACE
Full analysis set

	Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
Number of subjects with events, n (%)	1 (0.4)	0 (0.0)
Number of censored subjects, n (%)	245 (99.6)	246 (100.0)
Exposure years	579.1	348.7
EAIR per 100 PY	0.2	0.0
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	NE	
p-value		
Relative Risk (95% CI)	3.00 (0.12, 73.29)	
p-value	0.5004	
Odds Ratio (95% CI)	3.01 (0.12, 74.30)	
p-value	0.5002	
Risk Difference (95% CI)	0.41 (-0.39, 1.20)	
p-value	0.3163	

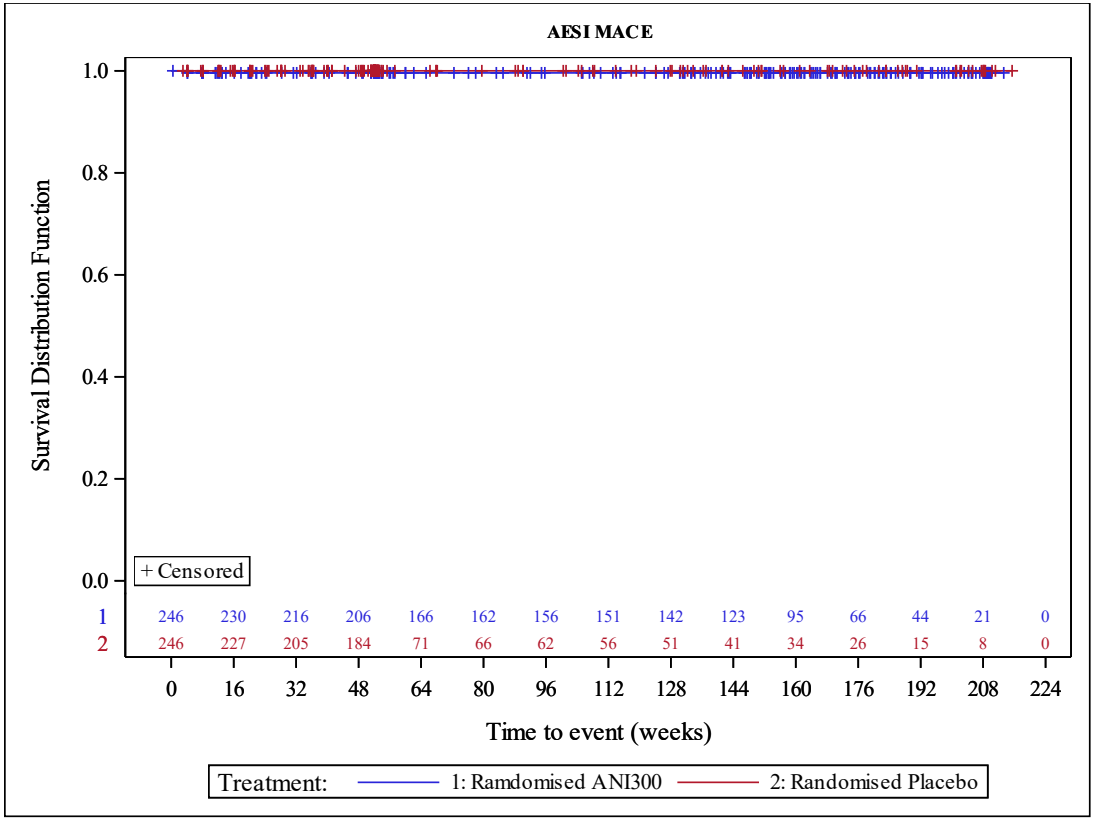
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - MACE - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%) Median (95% CI)	Randomised Placebo (N=246) n/ N (%) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI) p-Value	Interaction p-Value
Age (years)				0.9998
<= 65	1/239 (0.4) NE (NE, NE)	0/243 (0.0) NE (NE, NE)	NE	
> 65	0/ 7 (0.0) NE (NE, NE)	0/ 3 (0.0) NE (NE, NE)	NE	
Sex				0.9995
male	0/ 23 (0.0) NE (NE, NE)	0/ 20 (0.0) NE (NE, NE)	NE	
female	1/223 (0.4) NE (NE, NE)	0/226 (0.0) NE (NE, NE)	NE	
Geographic region				0.9994
EU	1/ 92 (1.1) NE (NE, NE)	0/ 89 (0.0) NE (NE, NE)	NE	
non-EU	0/154 (0.0) NE (NE, NE)	0/157 (0.0) NE (NE, NE)	NE	
SLEDAI-2K score at screening				0.9993
< 10 points	0/ 80 (0.0) NE (NE, NE)	0/ 69 (0.0) NE (NE, NE)	NE	
>= 10 points	1/166 (0.6) NE (NE, NE)	0/177 (0.0) NE (NE, NE)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - MACE
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious MACE
Full analysis set

	Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
Number of subjects with events, n (%)	1 (0.4)	0 (0.0)
Number of censored subjects, n (%)	245 (99.6)	246 (100.0)
Exposure years	579.1	348.7
EAIR per 100 PY	0.2	0.0
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	NE	
p-value		
Relative Risk (95% CI)	3.00 (0.12, 73.29)	
p-value	0.5004	
Odds Ratio (95% CI)	3.01 (0.12, 74.30)	
p-value	0.5002	
Risk Difference (95% CI)	0.41 (-0.39, 1.20)	
p-value	0.3163	

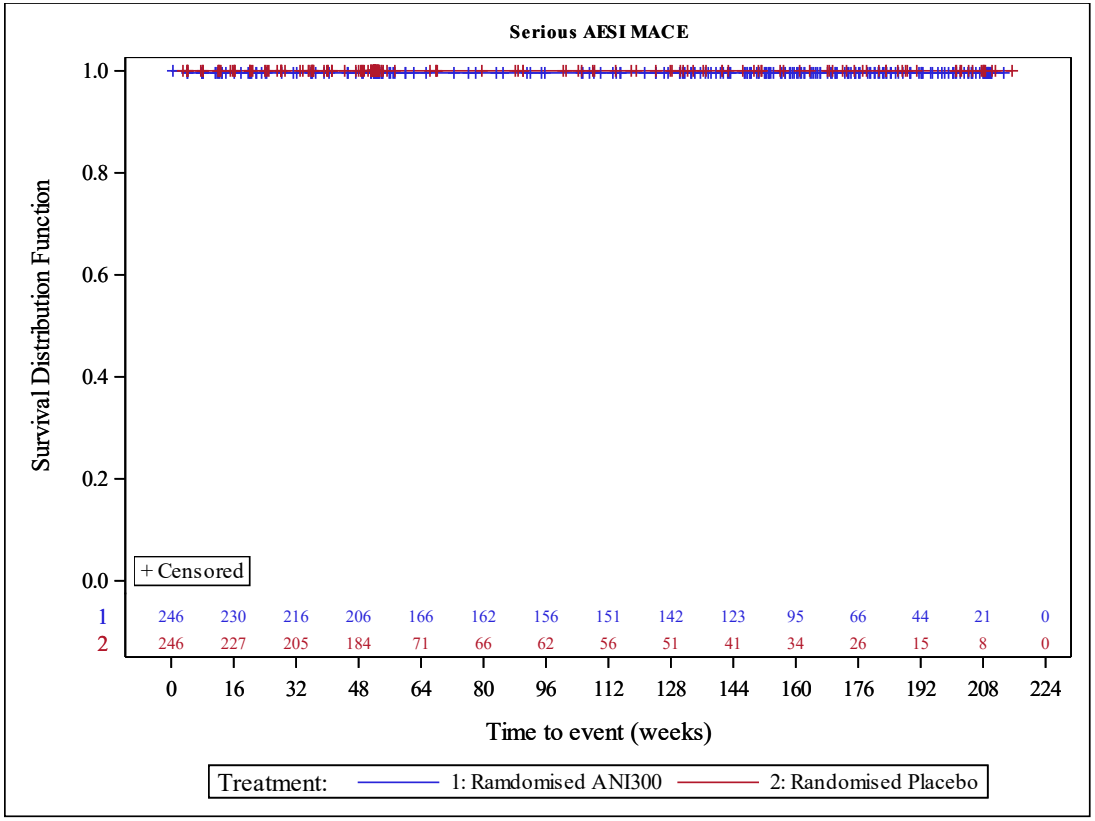
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious MACE - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%) Median (95% CI)	Randomised Placebo (N=246) n/ N (%) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI) p-Value	Interaction p-Value
Age (years)				0.9998
<= 65	1/239 (0.4) NE (NE, NE)	0/243 (0.0) NE (NE, NE)	NE	
> 65	0/ 7 (0.0) NE (NE, NE)	0/ 3 (0.0) NE (NE, NE)	NE	
Sex				0.9995
male	0/ 23 (0.0) NE (NE, NE)	0/ 20 (0.0) NE (NE, NE)	NE	
female	1/223 (0.4) NE (NE, NE)	0/226 (0.0) NE (NE, NE)	NE	
Geographic region				0.9994
EU	1/ 92 (1.1) NE (NE, NE)	0/ 89 (0.0) NE (NE, NE)	NE	
non-EU	0/154 (0.0) NE (NE, NE)	0/157 (0.0) NE (NE, NE)	NE	
SLEDAI-2K score at screening				0.9993
< 10 points	0/ 80 (0.0) NE (NE, NE)	0/ 69 (0.0) NE (NE, NE)	NE	
>= 10 points	1/166 (0.6) NE (NE, NE)	0/177 (0.0) NE (NE, NE)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious MACE
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe MACE
Full analysis set

	Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
Number of subjects with events, n (%)	1 (0.4)	0 (0.0)
Number of censored subjects, n (%)	245 (99.6)	246 (100.0)
Exposure years	579.1	348.7
EAIR per 100 PY	0.2	0.0
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	NE	
p-value		
Relative Risk (95% CI)	3.00 (0.12, 73.29)	
p-value	0.5004	
Odds Ratio (95% CI)	3.01 (0.12, 74.30)	
p-value	0.5002	
Risk Difference (95% CI)	0.41 (-0.39, 1.20)	
p-value	0.3163	

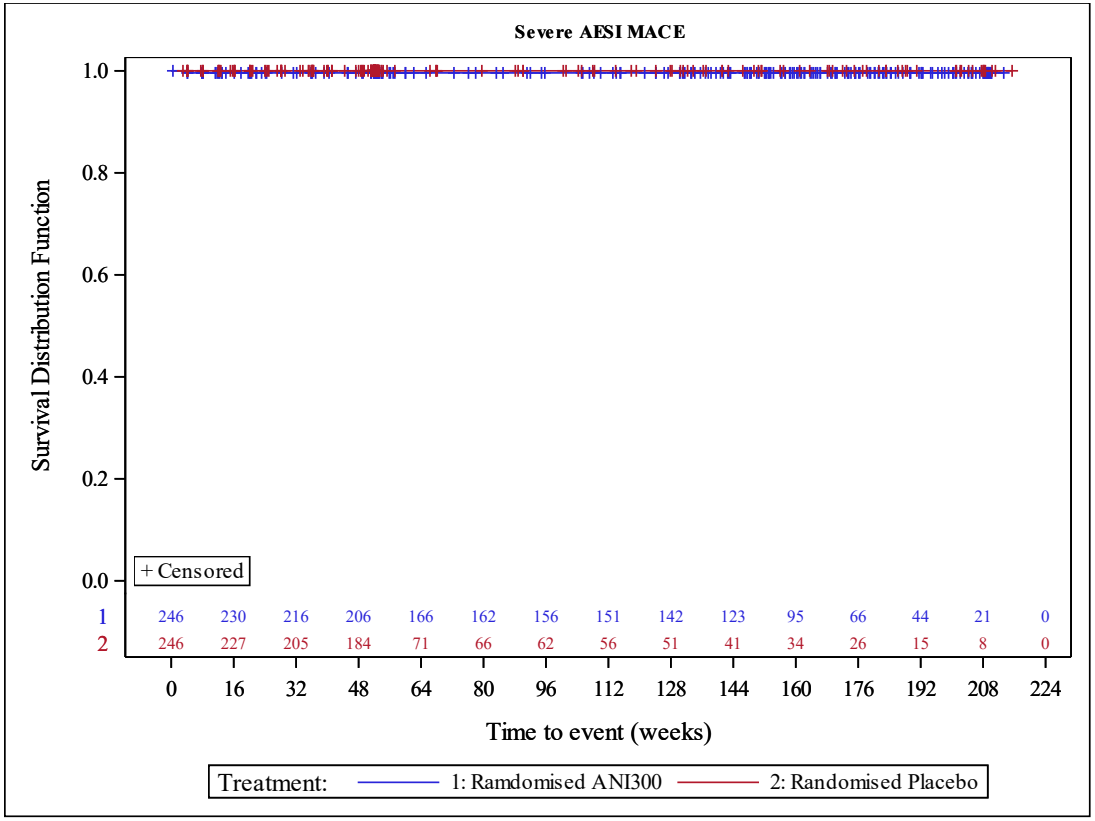
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe MACE - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%) Median (95% CI)	Randomised Placebo (N=246) n/ N (%) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI) p-Value	Interaction p-Value
Age (years)				0.9998
<= 65	1/239 (0.4) NE (NE, NE)	0/243 (0.0) NE (NE, NE)	NE	
> 65	0/ 7 (0.0) NE (NE, NE)	0/ 3 (0.0) NE (NE, NE)	NE	
Sex				0.9995
male	0/ 23 (0.0) NE (NE, NE)	0/ 20 (0.0) NE (NE, NE)	NE	
female	1/223 (0.4) NE (NE, NE)	0/226 (0.0) NE (NE, NE)	NE	
Geographic region				0.9994
EU	1/ 92 (1.1) NE (NE, NE)	0/ 89 (0.0) NE (NE, NE)	NE	
non-EU	0/154 (0.0) NE (NE, NE)	0/157 (0.0) NE (NE, NE)	NE	
SLEDAI-2K score at screening				0.9993
< 10 points	0/ 80 (0.0) NE (NE, NE)	0/ 69 (0.0) NE (NE, NE)	NE	
>= 10 points	1/166 (0.6) NE (NE, NE)	0/177 (0.0) NE (NE, NE)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe MACE
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe MACE
Full analysis set

	Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	246 (100.0)	246 (100.0)
Exposure years	581.5	348.7
EAIR per 100 PY	0.0	0.0
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	NE	
p-value		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

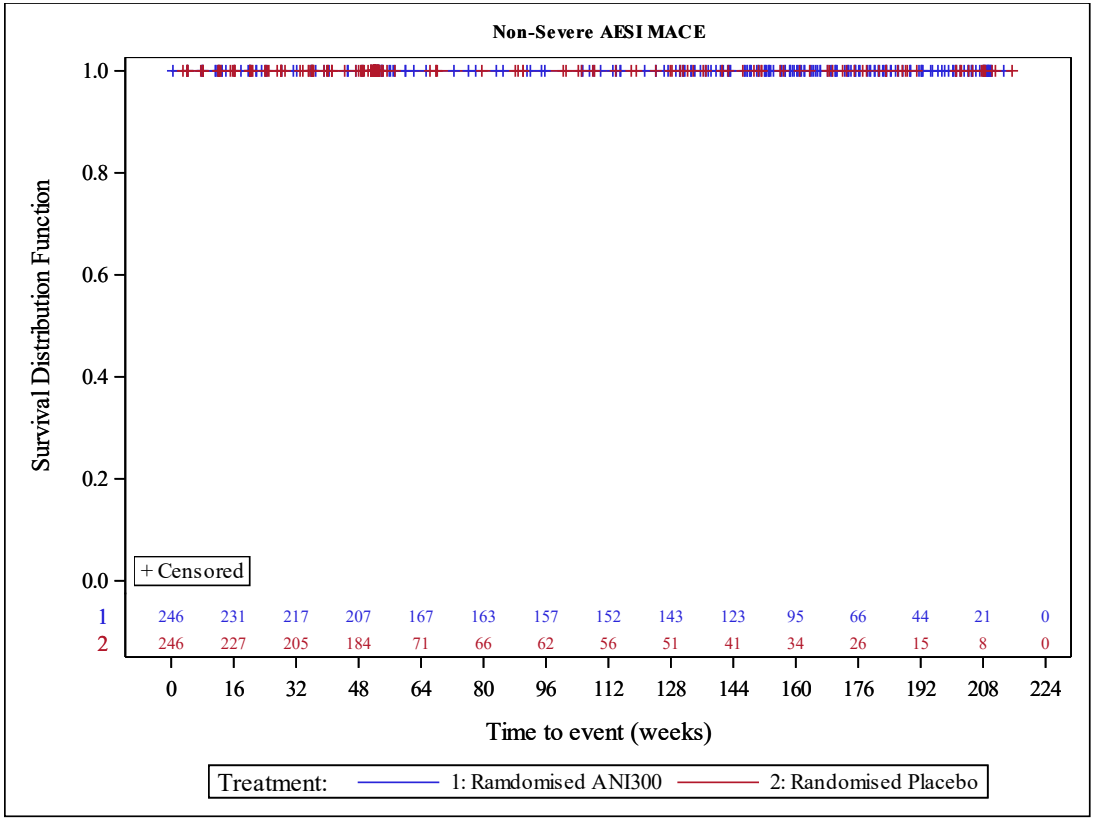
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe MACE - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%) Median (95% CI)	Randomised Placebo (N=246) n/ N (%) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI) p-Value	Interaction p-Value
Age (years)				NE
<= 65	0/239 (0.0) NE (NE, NE)	0/243 (0.0) NE (NE, NE)	NE	
> 65	0/ 7 (0.0) NE (NE, NE)	0/ 3 (0.0) NE (NE, NE)	NE	
Sex				NE
male	0/ 23 (0.0) NE (NE, NE)	0/ 20 (0.0) NE (NE, NE)	NE	
female	0/223 (0.0) NE (NE, NE)	0/226 (0.0) NE (NE, NE)	NE	
Geographic region				NE
EU	0/ 92 (0.0) NE (NE, NE)	0/ 89 (0.0) NE (NE, NE)	NE	
non-EU	0/154 (0.0) NE (NE, NE)	0/157 (0.0) NE (NE, NE)	NE	
SLEDAI-2K score at screening				NE
< 10 points	0/ 80 (0.0) NE (NE, NE)	0/ 69 (0.0) NE (NE, NE)	NE	
>= 10 points	0/166 (0.0) NE (NE, NE)	0/177 (0.0) NE (NE, NE)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe MACE
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-opportunistic infection
Full analysis set

	Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
Number of subjects with events, n (%)	190 (77.2)	158 (64.2)
Number of censored subjects, n (%)	56 (22.8)	88 (35.8)
Exposure years	188.2	175.1
EAIR per 100 PY	101.0	90.2
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	7.86 (6.29, 11.71)	11.57 (8.86, 16.00)
Median (95% CI)	24.43 (18.14, 32.71)	32.71 (24.86, 42.71)
75%-ile (95% CI)	62.14 (45.00, 111.9)	102.0 (64.43, 163.3)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	1.26 (1.02, 1.55)	
p-value	0.0340	
Relative Risk (95% CI)	1.20 (1.07, 1.35)	
p-value	0.0017	
Odds Ratio (95% CI)	1.89 (1.27, 2.81)	
p-value	0.0016	
Risk Difference (95% CI)	13.01 (5.05, 20.97)	
p-value	0.0014	

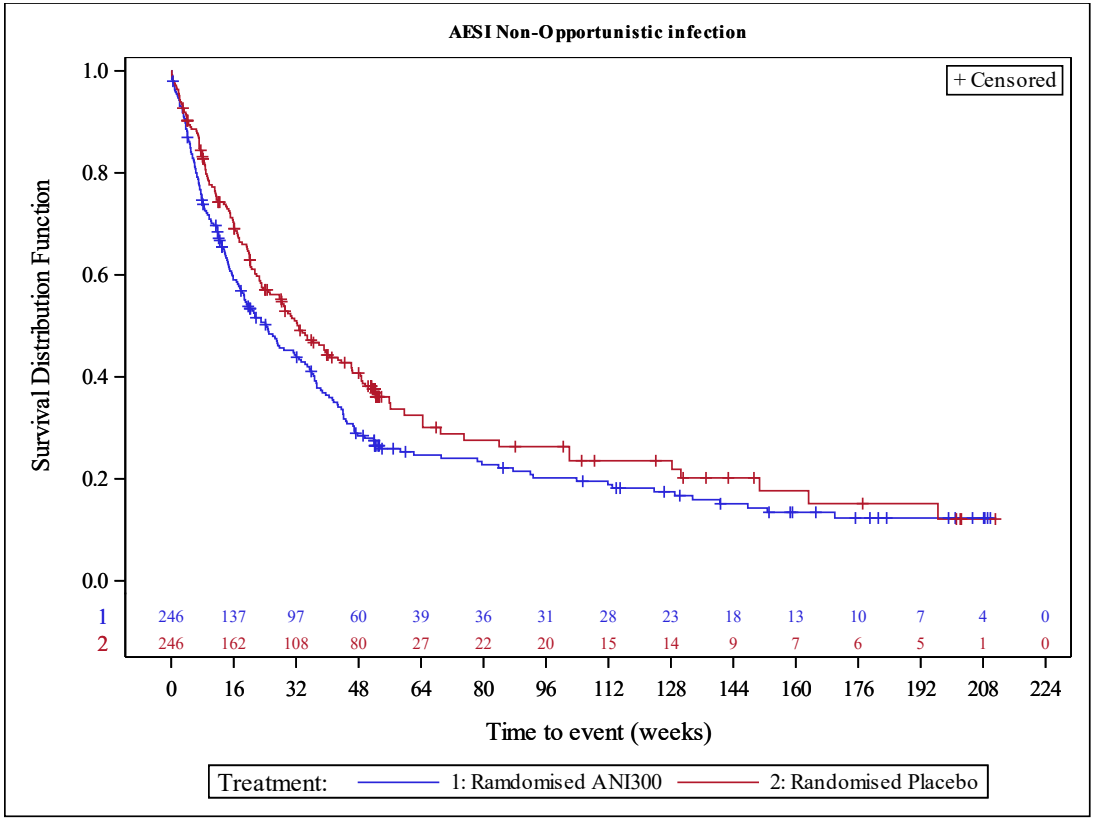
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%)	 Median (95% CI)	Randomised Placebo (N=246) n/ N (%)	 Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	 p-Value	Interaction p-Value
Age (years)							0.3991
<= 65	185/239 (77.4)	24.43 (18.57, 32.71)	157/243 (64.6)	32.29 (24.86, 40.57)	1.24 (1.00, 1.54)	0.0453	
> 65	5/ 7 (71.4)	15.57 (4.86, NE)	1/ 3 (33.3)	NE (21.43, NE)	3.51 (0.40, 30.46)	0.2265	
Sex							0.5601
male	15/ 23 (65.2)	41.57 (19.00, NE)	10/ 20 (50.0)	39.14 (7.14, NE)	1.04 (0.46, 2.32)	0.9311	
female	175/223 (78.5)	21.43 (15.86, 32.00)	148/226 (65.5)	32.29 (24.86, 42.71)	1.29 (1.04, 1.61)	0.0224	
Geographic region							0.8053
EU	66/ 92 (71.7)	37.14 (24.14, 51.86)	48/ 89 (53.9)	52.43 (39.14, 84.00)	1.30 (0.90, 1.90)	0.1642	
non-EU	124/154 (80.5)	18.14 (13.86, 25.00)	110/157 (70.1)	23.14 (19.57, 32.29)	1.25 (0.96, 1.61)	0.0924	
SLEDAI-2K score at screening							0.7129
< 10 points	66/ 80 (82.5)	23.00 (15.57, 35.43)	50/ 69 (72.5)	23.14 (20.14, 37.86)	1.19 (0.82, 1.72)	0.3528	
>= 10 points	124/166 (74.7)	24.71 (15.86, 36.00)	108/177 (61.0)	36.14 (28.29, 48.71)	1.27 (0.98, 1.65)	0.0703	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-opportunistic infection
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Non-opportunistic infection
Full analysis set

	Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
Number of subjects with events, n (%)	18 (7.3)	19 (7.7)
Number of censored subjects, n (%)	228 (92.7)	227 (92.3)
Exposure years	564.2	336.4
EAIR per 100 PY	3.2	5.6
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	0.63 (0.33, 1.22)	
p-value	0.1687	
Relative Risk (95% CI)	0.95 (0.51, 1.76)	
p-value	0.8643	
Odds Ratio (95% CI)	0.94 (0.48, 1.84)	
p-value	0.8643	
Risk Difference (95% CI)	-0.41 (-5.07, 4.25)	
p-value	0.8643	

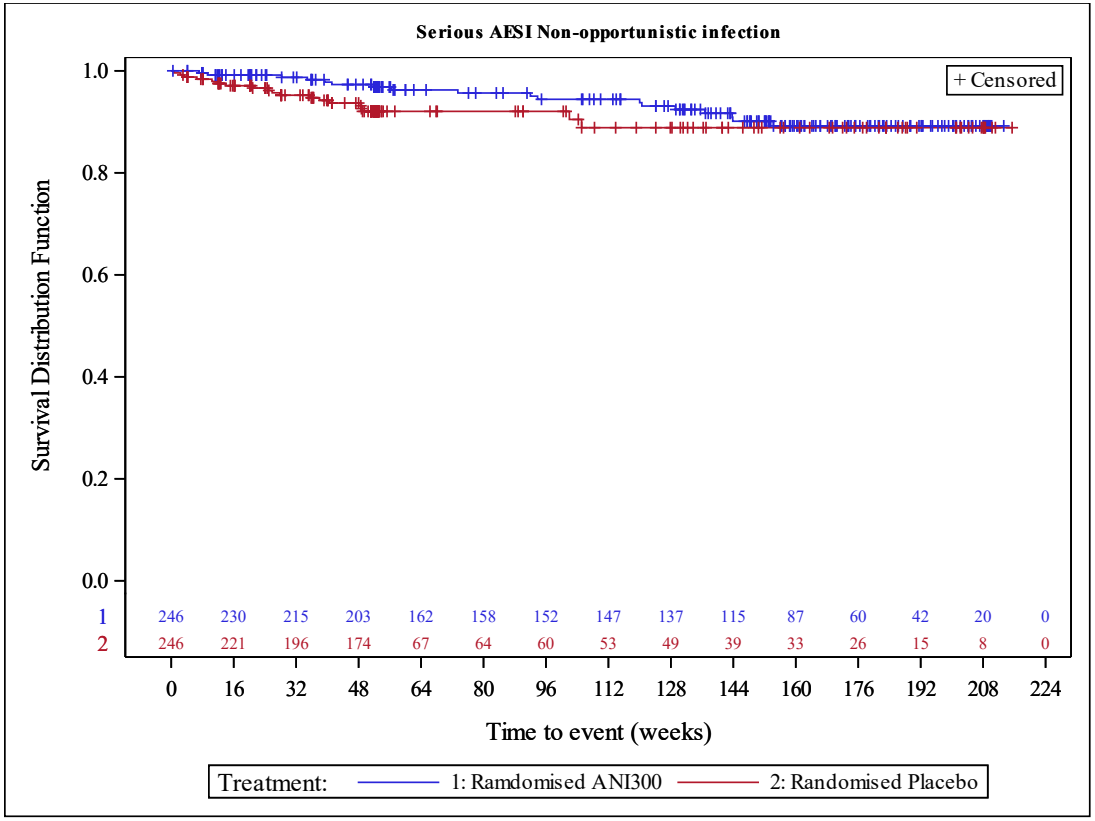
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Non-opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%) Median (95% CI)	Randomised Placebo (N=246) n/ N (%) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	 p-Value	Interaction p-Value
Age (years)					0.9998
<= 65	18/239 (7.5) NE (NE, NE)	19/243 (7.8) NE (NE, NE)	0.64 (0.33, 1.24)	0.1857	
> 65	0/ 7 (0.0) NE (NE, NE)	0/ 3 (0.0) NE (NE, NE)	NE		
Sex					0.5020
male	1/ 23 (4.3) NE (NE, NE)	2/ 20 (10.0) NE (NE, NE)	0.31 (0.03, 3.59)	0.3255	
female	17/223 (7.6) NE (NE, NE)	17/226 (7.5) NE (NE, NE)	0.67 (0.34, 1.34)	0.2544	
Geographic region					0.7044
EU	5/ 92 (5.4) NE (NE, NE)	6/ 89 (6.7) NE (NE, NE)	0.40 (0.12, 1.37)	0.1334	
non-EU	13/154 (8.4) NE (NE, NE)	13/157 (8.3) NE (NE, NE)	0.76 (0.35, 1.67)	0.4962	
SLEDAI-2K score at screening					0.1460
< 10 points	6/ 80 (7.5) NE (NE, NE)	2/ 69 (2.9) NE (NE, NE)	1.51 (0.30, 7.70)	0.6143	
>= 10 points	12/166 (7.2) NE (NE, NE)	17/177 (9.6) NE (NE, NE)	0.52 (0.25, 1.12)	0.0890	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Non-opportunistic infection
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Non-opportunistic infection
Full analysis set

	Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
Number of subjects with events, n (%)	12 (4.9)	7 (2.8)
Number of censored subjects, n (%)	234 (95.1)	239 (97.2)
Exposure years	570.4	343.8
EAIR per 100 PY	2.1	2.0
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	1.12 (0.43, 2.91)	
p-value	0.8153	
Relative Risk (95% CI)	1.71 (0.69, 4.28)	
p-value	0.2484	
Odds Ratio (95% CI)	1.75 (0.68, 4.52)	
p-value	0.2475	
Risk Difference (95% CI)	2.03 (-1.37, 5.43)	
p-value	0.2414	

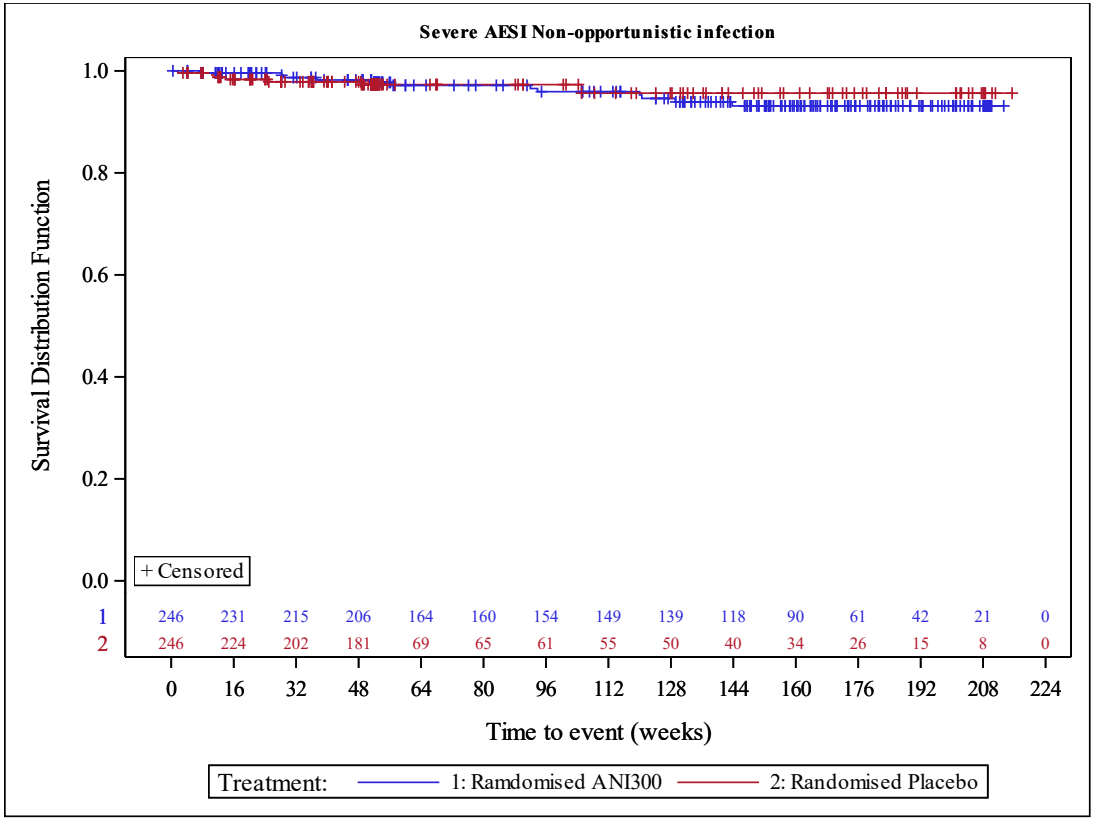
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Non-opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%)	Ramdomised ANI300 (N=246) Median (95% CI)	Randomised Placebo (N=246) n/ N (%)	Randomised Placebo (N=246) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
Age (years)							1.0000
<= 65	12/239 (5.0)	NE (NE, NE)	7/243 (2.9)	NE (NE, NE)	1.14 (0.44, 2.96)	0.7867	
> 65	0/ 7 (0.0)	NE (NE, NE)	0/ 3 (0.0)	NE (NE, NE)	NE		
Sex							0.9915
male	1/ 23 (4.3)	NE (NE, NE)	0/ 20 (0.0)	NE (NE, NE)	NE		
female	11/223 (4.9)	NE (NE, NE)	7/226 (3.1)	NE (NE, NE)	1.06 (0.40, 2.79)	0.9101	
Geographic region							0.6301
EU	3/ 92 (3.3)	NE (NE, NE)	1/ 89 (1.1)	NE (NE, NE)	1.43 (0.14, 14.19)	0.7604	
non-EU	9/154 (5.8)	NE (NE, NE)	6/157 (3.8)	NE (NE, NE)	1.08 (0.38, 3.10)	0.8874	
SLEDAI-2K score at screening							0.4525
< 10 points	4/ 80 (5.0)	NE (NE, NE)	1/ 69 (1.4)	NE (NE, NE)	2.10 (0.23, 19.59)	0.5055	
>= 10 points	8/166 (4.8)	NE (NE, NE)	6/177 (3.4)	NE (NE, NE)	0.96 (0.32, 2.82)	0.9363	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Non-opportunistic infection
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Non-opportunistic infection
Full analysis set

	Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
Number of subjects with events, n (%)	187 (76.0)	157 (63.8)
Number of censored subjects, n (%)	59 (24.0)	89 (36.2)
Exposure years	191.4	175.2
EAIR per 100 PY	97.7	89.6
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	8.00 (6.29, 11.71)	11.57 (8.86, 16.00)
Median (95% CI)	24.71 (18.57, 32.71)	32.71 (25.29, 42.71)
75%-ile (95% CI)	69.14 (46.86, 123.7)	102.0 (64.43, 163.3)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	1.24 (1.00, 1.53)	
p-value	0.0482	
Relative Risk (95% CI)	1.19 (1.06, 1.34)	
p-value	0.0035	
Odds Ratio (95% CI)	1.80 (1.21, 2.66)	
p-value	0.0034	
Risk Difference (95% CI)	12.20 (4.16, 20.23)	
p-value	0.0029	

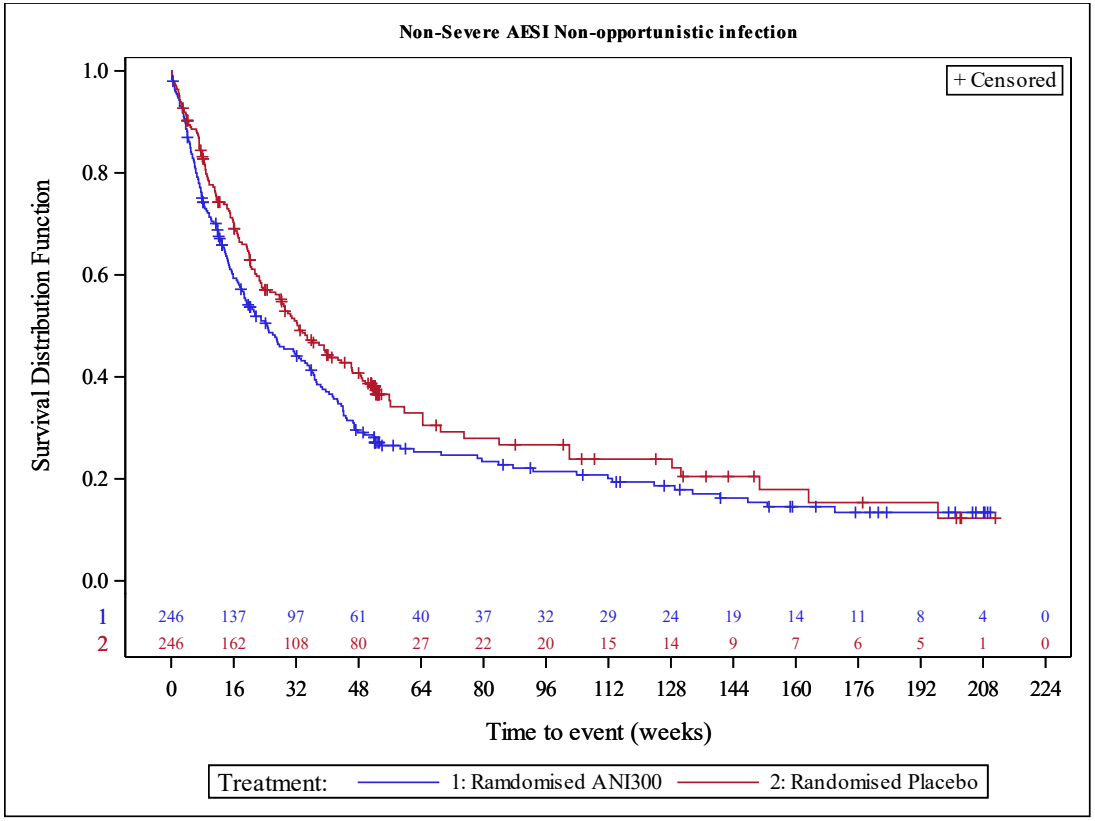
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Non-opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%)	 Median (95% CI)	Randomised Placebo (N=246) n/ N (%)	 Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	 p-Value	Interaction p-Value
Age (years)							0.3902
<= 65	182/239 (76.2)	24.71 (18.71, 33.29)	156/243 (64.2)	32.29 (25.29, 40.57)	1.22 (0.99, 1.52)	0.0639	
> 65	5/ 7 (71.4)	15.57 (4.86, NE)	1/ 3 (33.3)	NE (21.43, NE)	3.51 (0.40, 30.46)	0.2265	
Sex							0.4826
male	14/ 23 (60.9)	41.57 (19.00, NE)	10/ 20 (50.0)	39.14 (7.14, NE)	0.99 (0.44, 2.23)	0.9797	
female	173/223 (77.6)	21.43 (16.71, 32.71)	147/226 (65.0)	32.29 (25.29, 42.71)	1.27 (1.02, 1.59)	0.0313	
Geographic region							0.9599
EU	64/ 92 (69.6)	37.14 (24.14, 52.14)	48/ 89 (53.9)	52.43 (39.14, 84.00)	1.25 (0.86, 1.83)	0.2415	
non-EU	123/154 (79.9)	18.71 (14.00, 26.00)	109/157 (69.4)	23.14 (19.57, 32.29)	1.25 (0.96, 1.62)	0.0936	
SLEDAI-2K score at screening							0.7096
< 10 points	65/ 80 (81.3)	24.14 (17.00, 35.57)	50/ 69 (72.5)	23.14 (20.14, 37.86)	1.17 (0.81, 1.69)	0.4021	
>= 10 points	122/166 (73.5)	24.71 (15.86, 36.00)	107/177 (60.5)	36.14 (28.29, 51.43)	1.25 (0.96, 1.63)	0.0890	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Non-opportunistic infection
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Opportunistic infection
Full analysis set

	Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
Number of subjects with events, n (%)	1 (0.4)	1 (0.4)
Number of censored subjects, n (%)	245 (99.6)	245 (99.6)
Exposure years	581.4	347.7
EAIR per 100 PY	0.2	0.3
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	0.58 (0.03, 9.83)	
p-value	0.7007	
Relative Risk (95% CI)	1.00 (0.06, 15.90)	
p-value	1.0000	
Odds Ratio (95% CI)	1.00 (0.06, 16.08)	
p-value	1.0000	
Risk Difference (95% CI)	0.00 (-1.12, 1.12)	
p-value	1.0000	

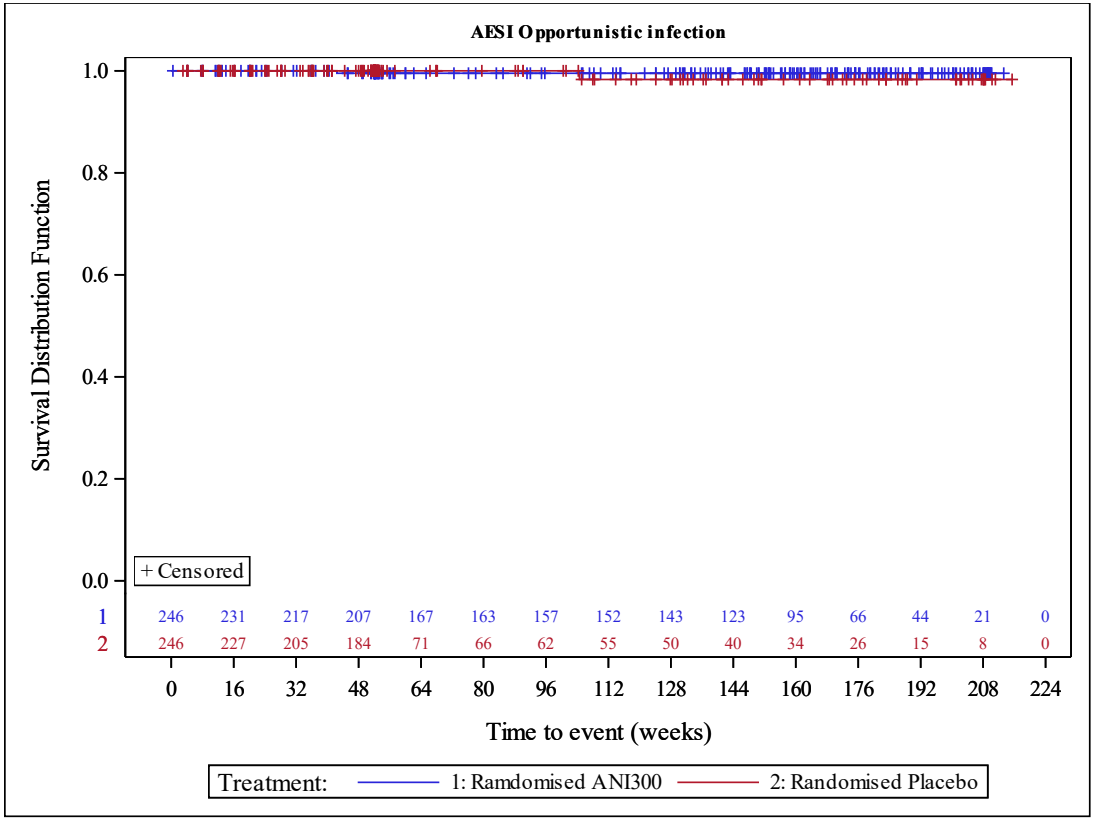
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%) Median (95% CI)	Randomised Placebo (N=246) n/ N (%) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	 p-Value	Interaction p-Value
Age (years)					1.0000
<= 65	1/239 (0.4) NE (NE, NE)	1/243 (0.4) NE (NE, NE)	0.59 (0.03, 9.97)	0.7093	
> 65	0/ 7 (0.0) NE (NE, NE)	0/ 3 (0.0) NE (NE, NE)	NE		
Sex					1.0000
male	0/ 23 (0.0) NE (NE, NE)	0/ 20 (0.0) NE (NE, NE)	NE		
female	1/223 (0.4) NE (NE, NE)	1/226 (0.4) NE (NE, NE)	0.58 (0.03, 9.88)	0.7023	
Geographic region					1.0000
EU	0/ 92 (0.0) NE (NE, NE)	0/ 89 (0.0) NE (NE, NE)	NE		
non-EU	1/154 (0.6) NE (NE, NE)	1/157 (0.6) NE (NE, NE)	0.59 (0.03, 9.98)	0.7105	
SLEDAI-2K score at screening					0.9966
< 10 points	0/ 80 (0.0) NE (NE, NE)	1/ 69 (1.4) NE (NE, NE)	NE		
>= 10 points	1/166 (0.6) NE (NE, NE)	0/177 (0.0) NE (NE, NE)	NE		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Opportunistic infection
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Opportunistic infection
Full analysis set

	Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	246 (100.0)	246 (100.0)
Exposure years	581.5	348.7
EAIR per 100 PY	0.0	0.0
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	NE	
p-value		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

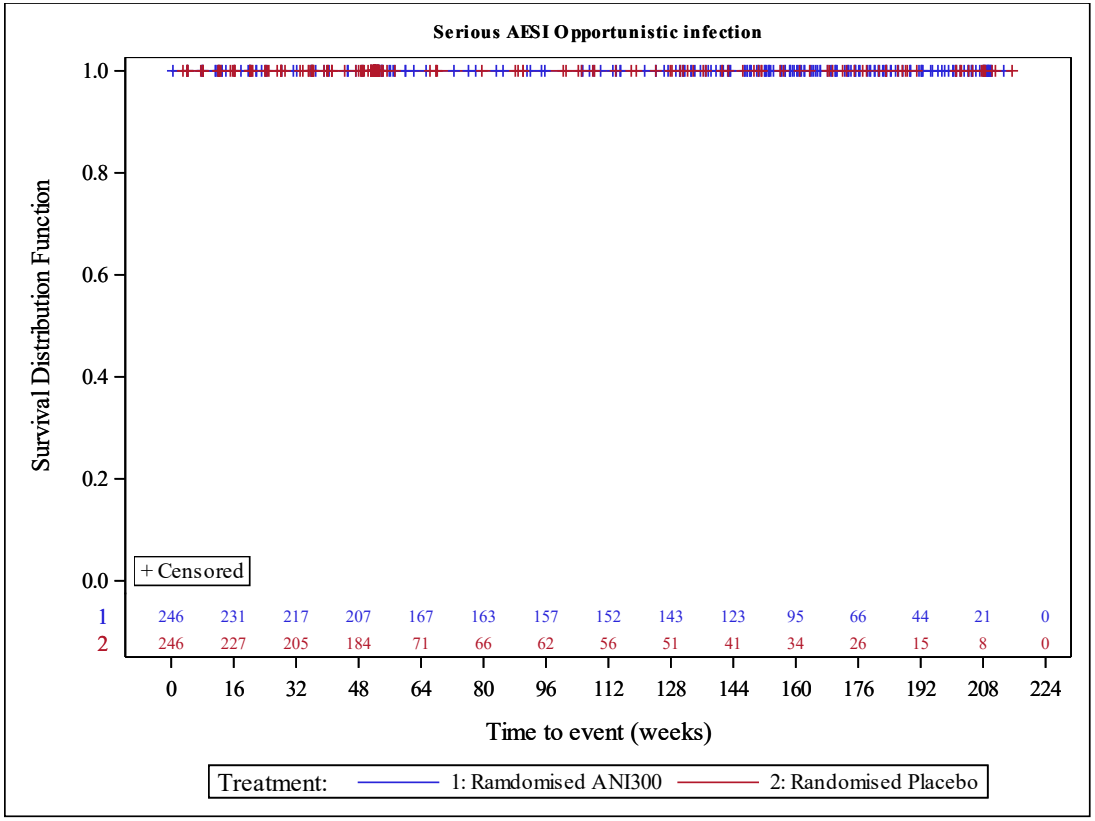
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%) Median (95% CI)	Randomised Placebo (N=246) n/ N (%) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI) p-Value	Interaction p-Value
Age (years)				NE
<= 65	0/239 (0.0) NE (NE, NE)	0/243 (0.0) NE (NE, NE)	NE	
> 65	0/ 7 (0.0) NE (NE, NE)	0/ 3 (0.0) NE (NE, NE)	NE	
Sex				NE
male	0/ 23 (0.0) NE (NE, NE)	0/ 20 (0.0) NE (NE, NE)	NE	
female	0/223 (0.0) NE (NE, NE)	0/226 (0.0) NE (NE, NE)	NE	
Geographic region				NE
EU	0/ 92 (0.0) NE (NE, NE)	0/ 89 (0.0) NE (NE, NE)	NE	
non-EU	0/154 (0.0) NE (NE, NE)	0/157 (0.0) NE (NE, NE)	NE	
SLEDAI-2K score at screening				NE
< 10 points	0/ 80 (0.0) NE (NE, NE)	0/ 69 (0.0) NE (NE, NE)	NE	
>= 10 points	0/166 (0.0) NE (NE, NE)	0/177 (0.0) NE (NE, NE)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Opportunistic infection
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Opportunistic infection
Full analysis set

	Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	246 (100.0)	246 (100.0)
Exposure years	581.5	348.7
EAIR per 100 PY	0.0	0.0
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	NE	
p-value		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

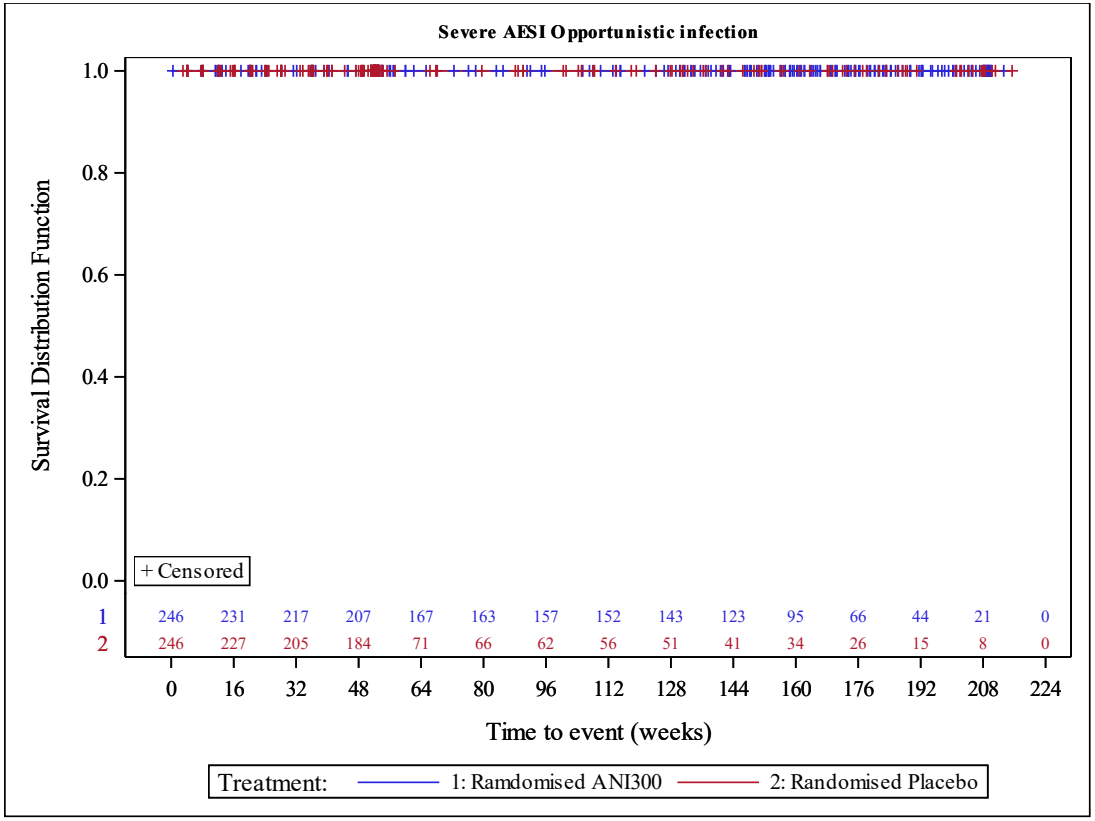
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%) Median (95% CI)	Randomised Placebo (N=246) n/ N (%) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI) p-Value	Interaction p-Value
Age (years)				NE
<= 65	0/239 (0.0) NE (NE, NE)	0/243 (0.0) NE (NE, NE)	NE	
> 65	0/ 7 (0.0) NE (NE, NE)	0/ 3 (0.0) NE (NE, NE)	NE	
Sex				NE
male	0/ 23 (0.0) NE (NE, NE)	0/ 20 (0.0) NE (NE, NE)	NE	
female	0/223 (0.0) NE (NE, NE)	0/226 (0.0) NE (NE, NE)	NE	
Geographic region				NE
EU	0/ 92 (0.0) NE (NE, NE)	0/ 89 (0.0) NE (NE, NE)	NE	
non-EU	0/154 (0.0) NE (NE, NE)	0/157 (0.0) NE (NE, NE)	NE	
SLEDAI-2K score at screening				NE
< 10 points	0/ 80 (0.0) NE (NE, NE)	0/ 69 (0.0) NE (NE, NE)	NE	
>= 10 points	0/166 (0.0) NE (NE, NE)	0/177 (0.0) NE (NE, NE)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Opportunistic infection
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Opportunistic infection
Full analysis set

	Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
Number of subjects with events, n (%)	1 (0.4)	1 (0.4)
Number of censored subjects, n (%)	245 (99.6)	245 (99.6)
Exposure years	581.4	347.7
EAIR per 100 PY	0.2	0.3
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	0.58 (0.03, 9.83)	
p-value	0.7007	
Relative Risk (95% CI)	1.00 (0.06, 15.90)	
p-value	1.0000	
Odds Ratio (95% CI)	1.00 (0.06, 16.08)	
p-value	1.0000	
Risk Difference (95% CI)	0.00 (-1.12, 1.12)	
p-value	1.0000	

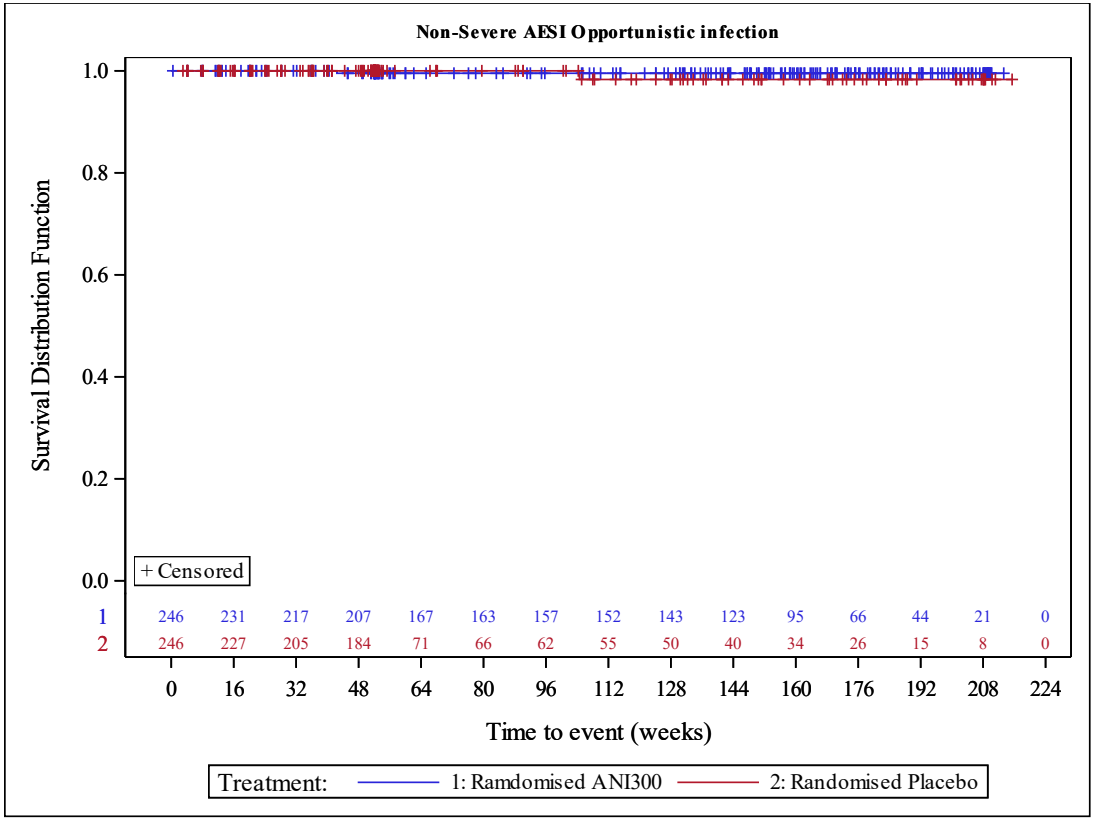
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%) Median (95% CI)	Randomised Placebo (N=246) n/ N (%) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	 p-Value	Interaction p-Value
Age (years)					1.0000
<= 65	1/239 (0.4) NE (NE, NE)	1/243 (0.4) NE (NE, NE)	0.59 (0.03, 9.97)	0.7093	
> 65	0/ 7 (0.0) NE (NE, NE)	0/ 3 (0.0) NE (NE, NE)	NE		
Sex					1.0000
male	0/ 23 (0.0) NE (NE, NE)	0/ 20 (0.0) NE (NE, NE)	NE		
female	1/223 (0.4) NE (NE, NE)	1/226 (0.4) NE (NE, NE)	0.58 (0.03, 9.88)	0.7023	
Geographic region					1.0000
EU	0/ 92 (0.0) NE (NE, NE)	0/ 89 (0.0) NE (NE, NE)	NE		
non-EU	1/154 (0.6) NE (NE, NE)	1/157 (0.6) NE (NE, NE)	0.59 (0.03, 9.98)	0.7105	
SLEDAI-2K score at screening					0.9966
< 10 points	0/ 80 (0.0) NE (NE, NE)	1/ 69 (1.4) NE (NE, NE)	NE		
>= 10 points	1/166 (0.6) NE (NE, NE)	0/177 (0.0) NE (NE, NE)	NE		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Opportunistic infection
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Tuberculosis (including latent TB)
Full analysis set

	Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
Number of subjects with events, n (%)	9 (3.7)	3 (1.2)
Number of censored subjects, n (%)	237 (96.3)	243 (98.8)
Exposure years	575.2	345.6
EAIR per 100 PY	1.6	0.9
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	1.34 (0.36, 4.99)	
p-value	0.6655	
Relative Risk (95% CI)	3.00 (0.82, 10.95)	
p-value	0.0963	
Odds Ratio (95% CI)	3.08 (0.82, 11.50)	
p-value	0.0950	
Risk Difference (95% CI)	2.44 (-0.28, 5.16)	
p-value	0.0786	

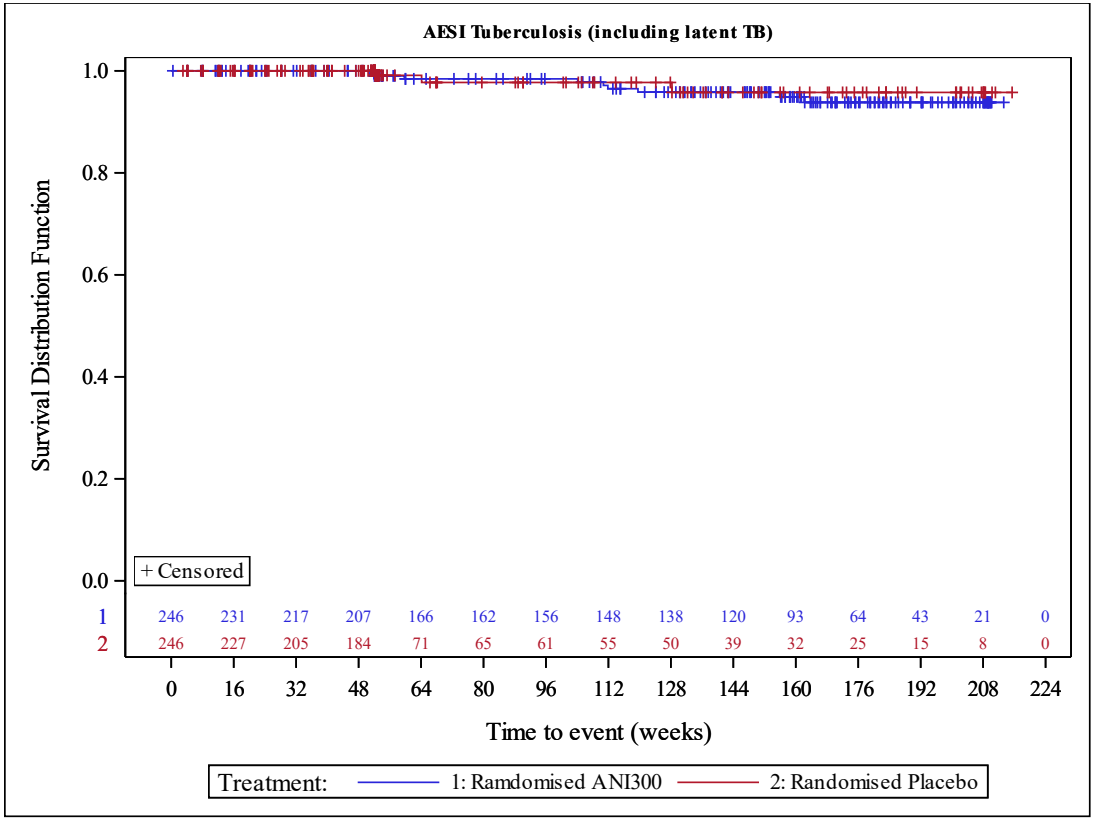
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%)	Ramdomised ANI300 (N=246) Median (95% CI)	Randomised Placebo (N=246) n/ N (%)	Randomised Placebo (N=246) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
Age (years)							1.0000
<= 65	9/239 (3.8)	NE (NE, NE)	3/243 (1.2)	NE (NE, NE)	1.37 (0.37, 5.10)	0.6406	
> 65	0/ 7 (0.0)	NE (NE, NE)	0/ 3 (0.0)	NE (NE, NE)	NE		
Sex							0.9999
male	0/ 23 (0.0)	NE (NE, NE)	0/ 20 (0.0)	NE (NE, NE)	NE		
female	9/223 (4.0)	NE (NE, NE)	3/226 (1.3)	NE (NE, NE)	1.33 (0.36, 4.98)	0.6688	
Geographic region							0.3377
EU	6/ 92 (6.5)	NE (NE, NE)	1/ 89 (1.1)	NE (NE, NE)	2.96 (0.35, 25.07)	0.2974	
non-EU	3/154 (1.9)	NE (NE, NE)	2/157 (1.3)	NE (NE, NE)	0.59 (0.10, 3.55)	0.5615	
SLEDAI-2K score at screening							0.9180
< 10 points	3/ 80 (3.8)	NE (NE, NE)	1/ 69 (1.4)	NE (NE, NE)	1.22 (0.12, 11.94)	0.8633	
>= 10 points	6/166 (3.6)	NE (NE, NE)	2/177 (1.1)	NE (NE, NE)	1.40 (0.28, 7.06)	0.6797	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Tuberculosis (including latent TB)
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Tuberculosis (including latent TB)
Full analysis set

	Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	246 (100.0)	246 (100.0)
Exposure years	581.5	348.7
EAIR per 100 PY	0.0	0.0
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	NE	
p-value		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

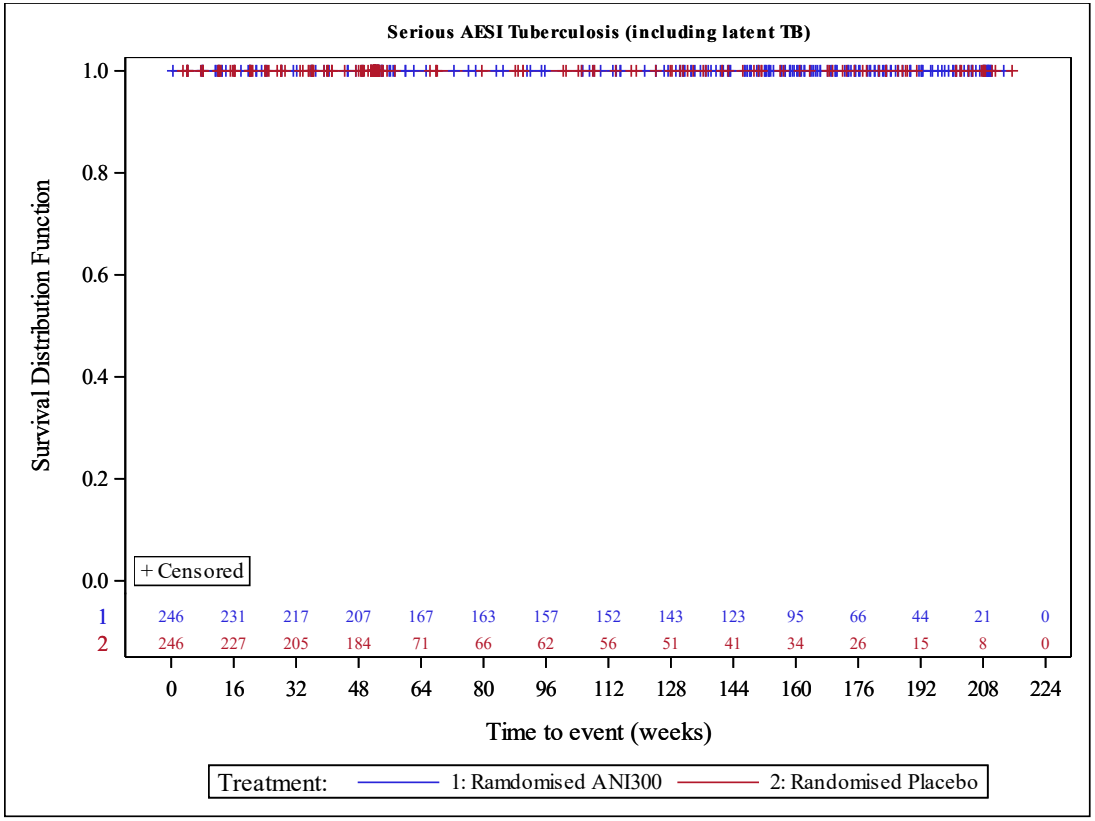
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%) Median (95% CI)	Randomised Placebo (N=246) n/ N (%) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI) p-Value	Interaction p-Value
Age (years)				NE
<= 65	0/239 (0.0) NE (NE, NE)	0/243 (0.0) NE (NE, NE)	NE	
> 65	0/ 7 (0.0) NE (NE, NE)	0/ 3 (0.0) NE (NE, NE)	NE	
Sex				NE
male	0/ 23 (0.0) NE (NE, NE)	0/ 20 (0.0) NE (NE, NE)	NE	
female	0/223 (0.0) NE (NE, NE)	0/226 (0.0) NE (NE, NE)	NE	
Geographic region				NE
EU	0/ 92 (0.0) NE (NE, NE)	0/ 89 (0.0) NE (NE, NE)	NE	
non-EU	0/154 (0.0) NE (NE, NE)	0/157 (0.0) NE (NE, NE)	NE	
SLEDAI-2K score at screening				NE
< 10 points	0/ 80 (0.0) NE (NE, NE)	0/ 69 (0.0) NE (NE, NE)	NE	
>= 10 points	0/166 (0.0) NE (NE, NE)	0/177 (0.0) NE (NE, NE)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Tuberculosis (including latent TB)
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Tuberculosis (including latent TB)
Full analysis set

	Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	246 (100.0)	246 (100.0)
Exposure years	581.5	348.7
EAIR per 100 PY	0.0	0.0
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	NE	
p-value		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

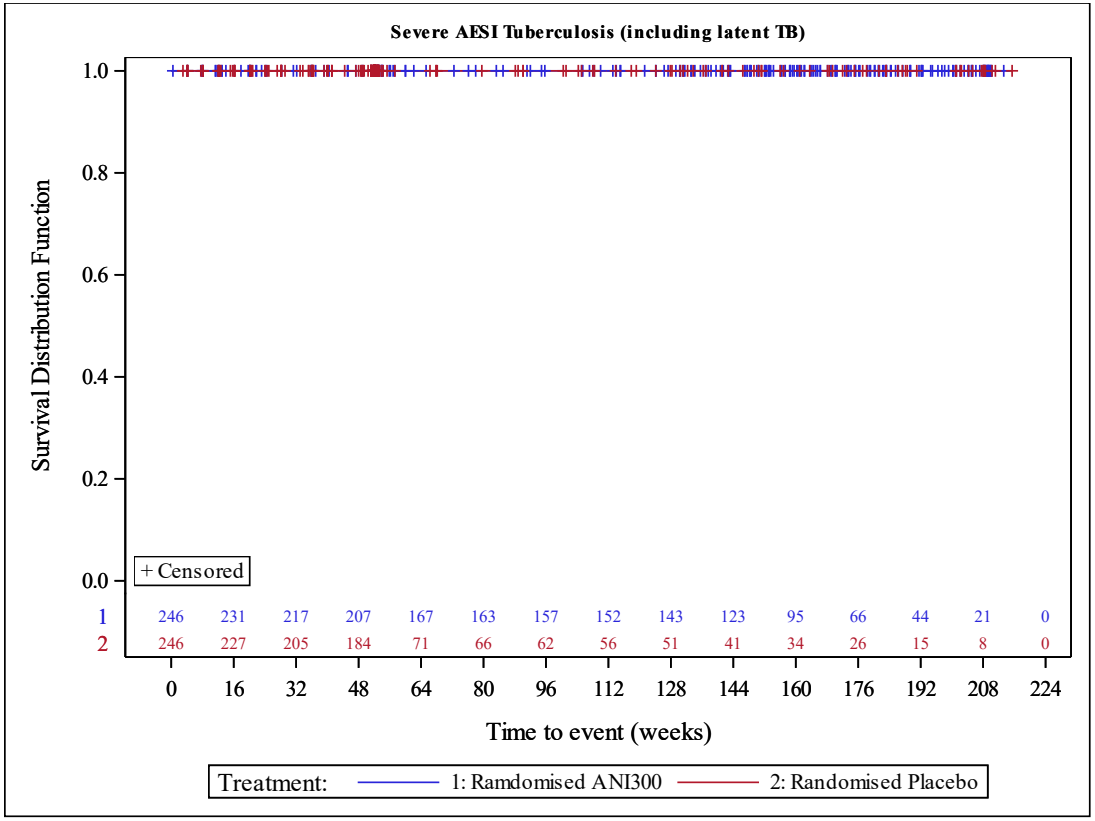
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%) Median (95% CI)	Randomised Placebo (N=246) n/ N (%) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI) p-Value	Interaction p-Value
Age (years)				NE
<= 65	0/239 (0.0) NE (NE, NE)	0/243 (0.0) NE (NE, NE)	NE	
> 65	0/ 7 (0.0) NE (NE, NE)	0/ 3 (0.0) NE (NE, NE)	NE	
Sex				NE
male	0/ 23 (0.0) NE (NE, NE)	0/ 20 (0.0) NE (NE, NE)	NE	
female	0/223 (0.0) NE (NE, NE)	0/226 (0.0) NE (NE, NE)	NE	
Geographic region				NE
EU	0/ 92 (0.0) NE (NE, NE)	0/ 89 (0.0) NE (NE, NE)	NE	
non-EU	0/154 (0.0) NE (NE, NE)	0/157 (0.0) NE (NE, NE)	NE	
SLEDAI-2K score at screening				NE
< 10 points	0/ 80 (0.0) NE (NE, NE)	0/ 69 (0.0) NE (NE, NE)	NE	
>= 10 points	0/166 (0.0) NE (NE, NE)	0/177 (0.0) NE (NE, NE)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Tuberculosis (including latent TB)
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Tuberculosis (including latent TB)
Full analysis set

	Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
Number of subjects with events, n (%)	9 (3.7)	3 (1.2)
Number of censored subjects, n (%)	237 (96.3)	243 (98.8)
Exposure years	575.2	345.6
EAIR per 100 PY	1.6	0.9
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	1.34 (0.36, 4.99)	
p-value	0.6655	
Relative Risk (95% CI)	3.00 (0.82, 10.95)	
p-value	0.0963	
Odds Ratio (95% CI)	3.08 (0.82, 11.50)	
p-value	0.0950	
Risk Difference (95% CI)	2.44 (-0.28, 5.16)	
p-value	0.0786	

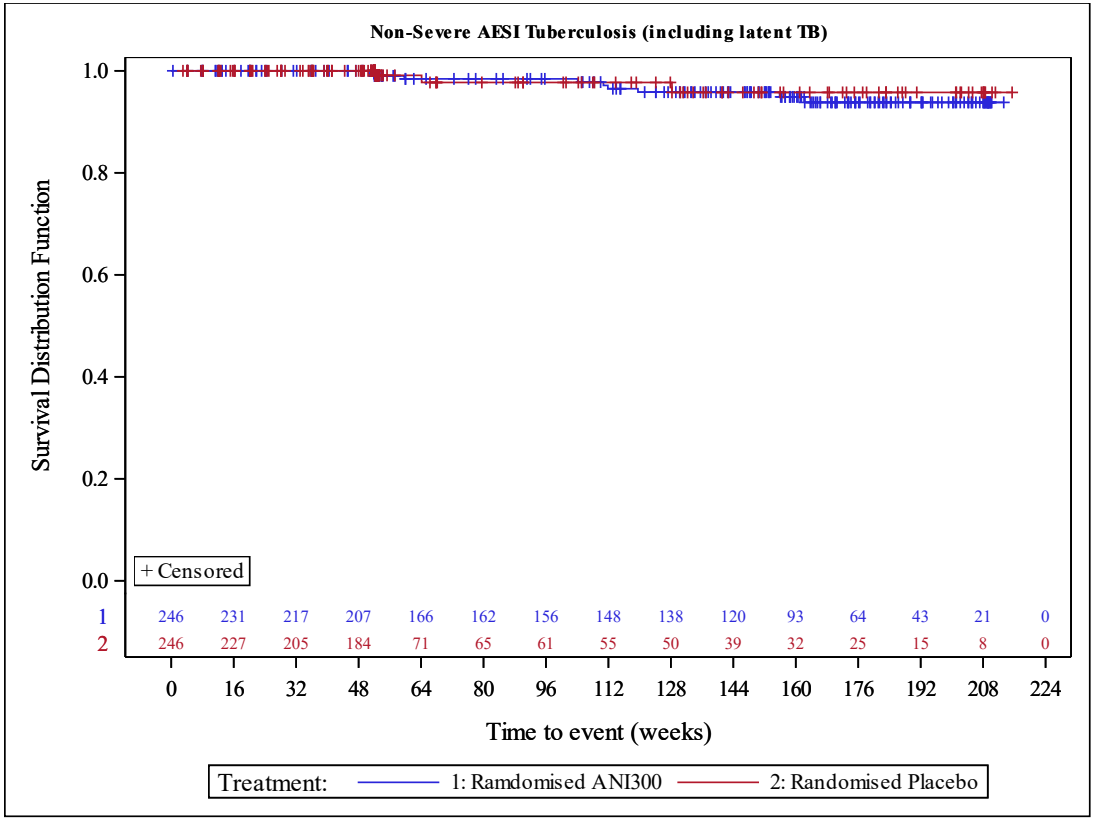
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%) Median (95% CI)	Randomised Placebo (N=246) n/ N (%) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	 p-Value	Interaction p-Value
Age (years)					1.0000
<= 65	9/239 (3.8) NE (NE, NE)	3/243 (1.2) NE (NE, NE)	1.37 (0.37, 5.10)	0.6406	
> 65	0/ 7 (0.0) NE (NE, NE)	0/ 3 (0.0) NE (NE, NE)	NE		
Sex					0.9999
male	0/ 23 (0.0) NE (NE, NE)	0/ 20 (0.0) NE (NE, NE)	NE		
female	9/223 (4.0) NE (NE, NE)	3/226 (1.3) NE (NE, NE)	1.33 (0.36, 4.98)	0.6688	
Geographic region					0.3377
EU	6/ 92 (6.5) NE (NE, NE)	1/ 89 (1.1) NE (NE, NE)	2.96 (0.35, 25.07)	0.2974	
non-EU	3/154 (1.9) NE (NE, NE)	2/157 (1.3) NE (NE, NE)	0.59 (0.10, 3.55)	0.5615	
SLEDAI-2K score at screening					0.9180
< 10 points	3/ 80 (3.8) NE (NE, NE)	1/ 69 (1.4) NE (NE, NE)	1.22 (0.12, 11.94)	0.8633	
>= 10 points	6/166 (3.6) NE (NE, NE)	2/177 (1.1) NE (NE, NE)	1.40 (0.28, 7.06)	0.6797	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Tuberculosis (including latent TB)
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Vasculitis
Full analysis set

	Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	246 (100.0)	246 (100.0)
Exposure years	581.5	348.7
EAIR per 100 PY	0.0	0.0
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	NE	
p-value		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

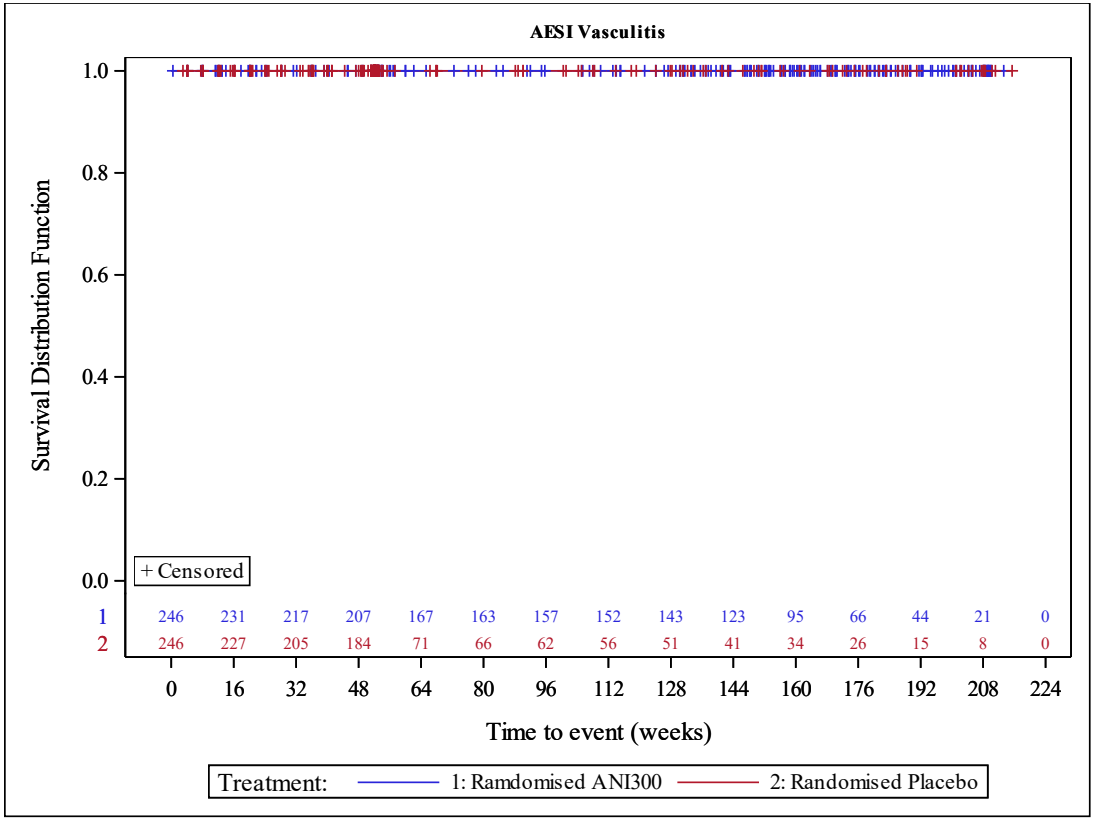
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%) Median (95% CI)	Randomised Placebo (N=246) n/ N (%) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI) p-Value	Interaction p-Value
Age (years)				NE
<= 65	0/239 (0.0) NE (NE, NE)	0/243 (0.0) NE (NE, NE)	NE	
> 65	0/ 7 (0.0) NE (NE, NE)	0/ 3 (0.0) NE (NE, NE)	NE	
Sex				NE
male	0/ 23 (0.0) NE (NE, NE)	0/ 20 (0.0) NE (NE, NE)	NE	
female	0/223 (0.0) NE (NE, NE)	0/226 (0.0) NE (NE, NE)	NE	
Geographic region				NE
EU	0/ 92 (0.0) NE (NE, NE)	0/ 89 (0.0) NE (NE, NE)	NE	
non-EU	0/154 (0.0) NE (NE, NE)	0/157 (0.0) NE (NE, NE)	NE	
SLEDAI-2K score at screening				NE
< 10 points	0/ 80 (0.0) NE (NE, NE)	0/ 69 (0.0) NE (NE, NE)	NE	
>= 10 points	0/166 (0.0) NE (NE, NE)	0/177 (0.0) NE (NE, NE)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Vasculitis
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Vasculitis
Full analysis set

	Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	246 (100.0)	246 (100.0)
Exposure years	581.5	348.7
EAIR per 100 PY	0.0	0.0
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	NE	
p-value		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

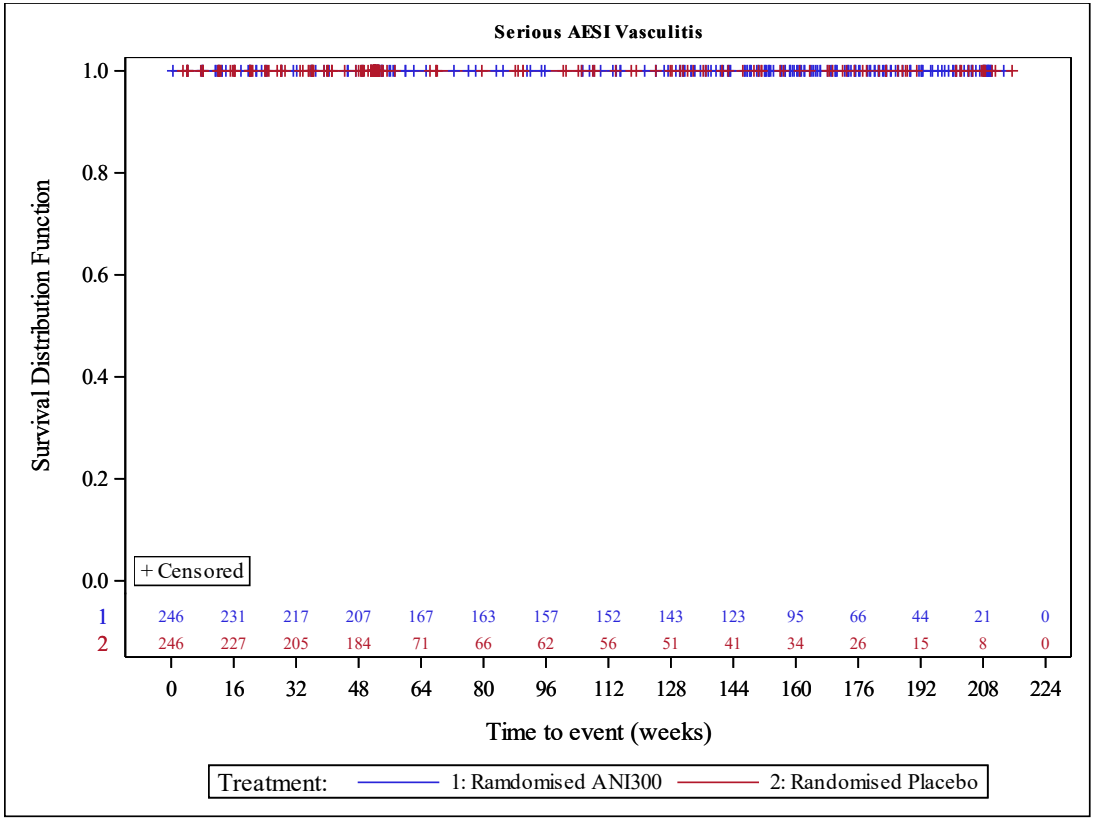
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%) Median (95% CI)	Randomised Placebo (N=246) n/ N (%) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI) p-Value	Interaction p-Value
Age (years)				NE
<= 65	0/239 (0.0) NE (NE, NE)	0/243 (0.0) NE (NE, NE)	NE	
> 65	0/ 7 (0.0) NE (NE, NE)	0/ 3 (0.0) NE (NE, NE)	NE	
Sex				NE
male	0/ 23 (0.0) NE (NE, NE)	0/ 20 (0.0) NE (NE, NE)	NE	
female	0/223 (0.0) NE (NE, NE)	0/226 (0.0) NE (NE, NE)	NE	
Geographic region				NE
EU	0/ 92 (0.0) NE (NE, NE)	0/ 89 (0.0) NE (NE, NE)	NE	
non-EU	0/154 (0.0) NE (NE, NE)	0/157 (0.0) NE (NE, NE)	NE	
SLEDAI-2K score at screening				NE
< 10 points	0/ 80 (0.0) NE (NE, NE)	0/ 69 (0.0) NE (NE, NE)	NE	
>= 10 points	0/166 (0.0) NE (NE, NE)	0/177 (0.0) NE (NE, NE)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Vasculitis
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Vasculitis
Full analysis set

	Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	246 (100.0)	246 (100.0)
Exposure years	581.5	348.7
EAIR per 100 PY	0.0	0.0
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	NE	
p-value		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

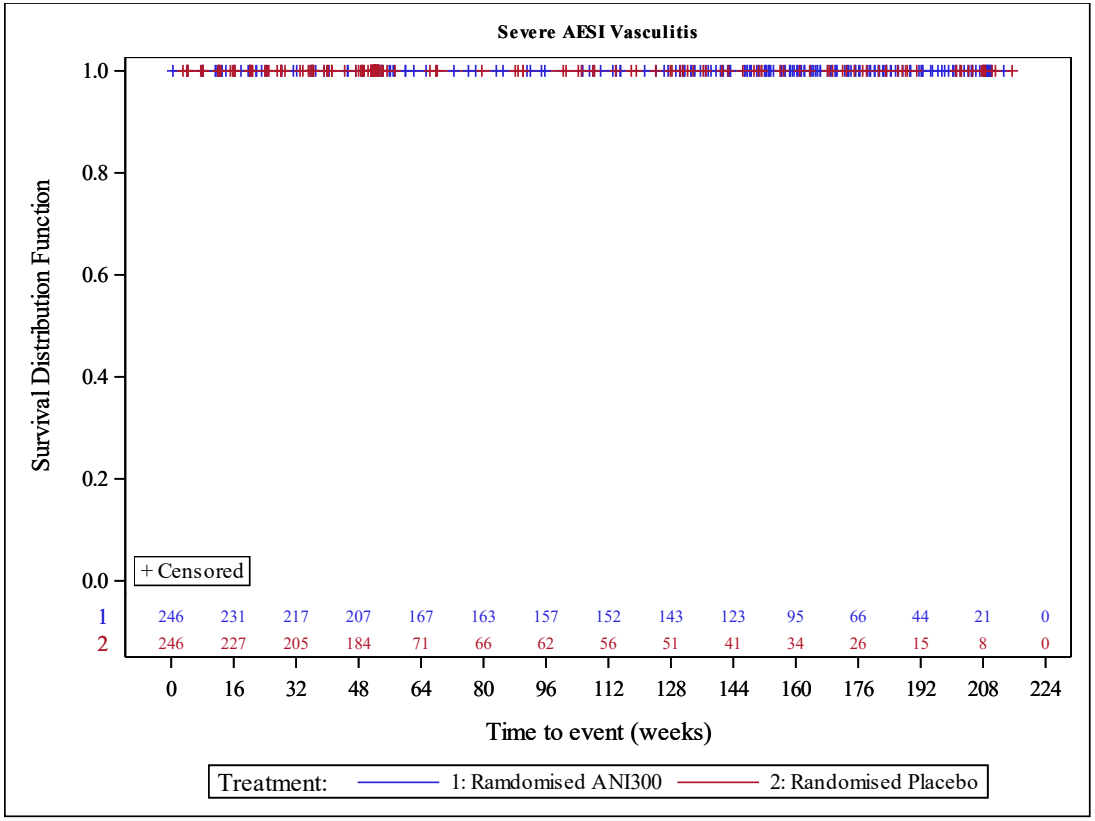
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%) Median (95% CI)	Randomised Placebo (N=246) n/ N (%) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI) p-Value	Interaction p-Value
Age (years)				NE
<= 65	0/239 (0.0) NE (NE, NE)	0/243 (0.0) NE (NE, NE)	NE	
> 65	0/ 7 (0.0) NE (NE, NE)	0/ 3 (0.0) NE (NE, NE)	NE	
Sex				NE
male	0/ 23 (0.0) NE (NE, NE)	0/ 20 (0.0) NE (NE, NE)	NE	
female	0/223 (0.0) NE (NE, NE)	0/226 (0.0) NE (NE, NE)	NE	
Geographic region				NE
EU	0/ 92 (0.0) NE (NE, NE)	0/ 89 (0.0) NE (NE, NE)	NE	
non-EU	0/154 (0.0) NE (NE, NE)	0/157 (0.0) NE (NE, NE)	NE	
SLEDAI-2K score at screening				NE
< 10 points	0/ 80 (0.0) NE (NE, NE)	0/ 69 (0.0) NE (NE, NE)	NE	
>= 10 points	0/166 (0.0) NE (NE, NE)	0/177 (0.0) NE (NE, NE)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Vasculitis
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Vasculitis
Full analysis set

	Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	246 (100.0)	246 (100.0)
Exposure years	581.5	348.7
EAIR per 100 PY	0.0	0.0
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	NE	
p-value		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

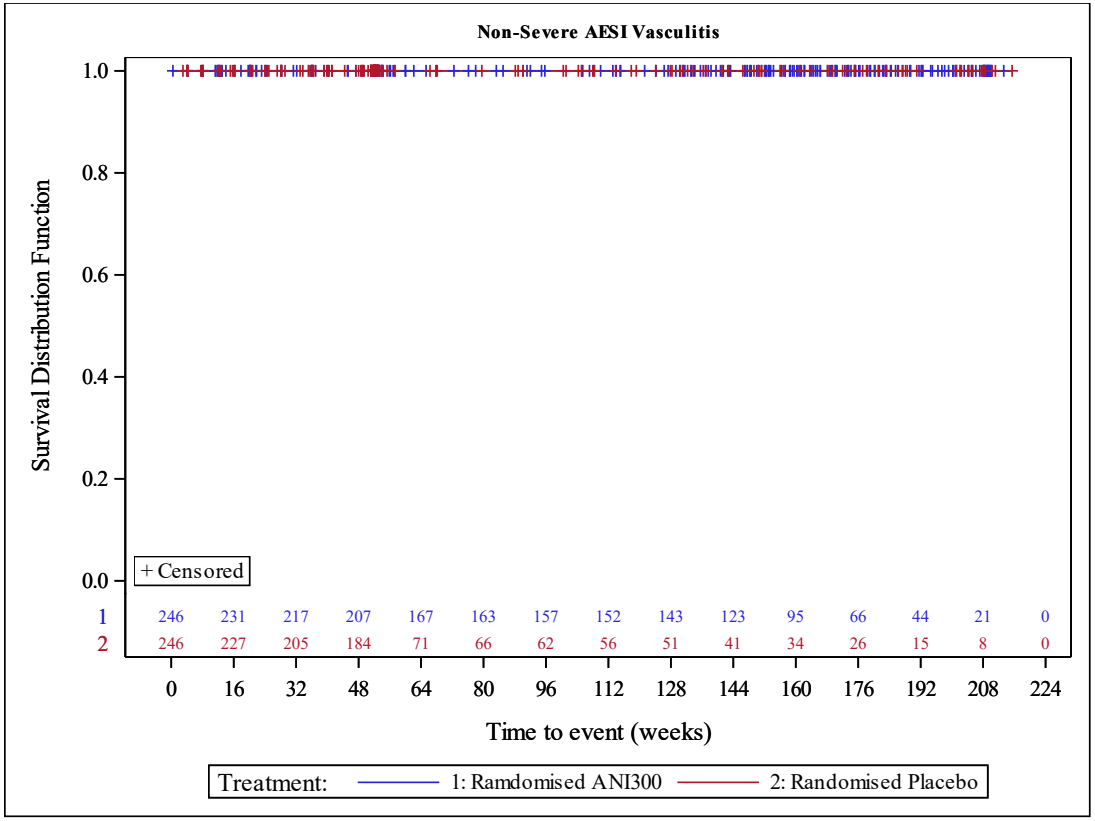
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%) Median (95% CI)	Randomised Placebo (N=246) n/ N (%) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI) p-Value	Interaction p-Value
Age (years)				NE
<= 65	0/239 (0.0) NE (NE, NE)	0/243 (0.0) NE (NE, NE)	NE	
> 65	0/ 7 (0.0) NE (NE, NE)	0/ 3 (0.0) NE (NE, NE)	NE	
Sex				NE
male	0/ 23 (0.0) NE (NE, NE)	0/ 20 (0.0) NE (NE, NE)	NE	
female	0/223 (0.0) NE (NE, NE)	0/226 (0.0) NE (NE, NE)	NE	
Geographic region				NE
EU	0/ 92 (0.0) NE (NE, NE)	0/ 89 (0.0) NE (NE, NE)	NE	
non-EU	0/154 (0.0) NE (NE, NE)	0/157 (0.0) NE (NE, NE)	NE	
SLEDAI-2K score at screening				NE
< 10 points	0/ 80 (0.0) NE (NE, NE)	0/ 69 (0.0) NE (NE, NE)	NE	
>= 10 points	0/166 (0.0) NE (NE, NE)	0/177 (0.0) NE (NE, NE)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Vasculitis
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Blood and lymphatic system disorders	Number of subjects with events, n (%)	17 (6.9)	17 (6.9)
	Number of censored subjects, n (%)	229 (93.1)	229 (93.1)
	Exposure years	550.0	329.9
	EAIR per 100 PY	3.1	5.2
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.72 (0.36, 1.43)	
	p-value	0.3485	
	Relative Risk (95% CI)	1.00 (0.52, 1.91)	
	p-value	1.0000	
	Odds Ratio (95% CI)	1.00 (0.50, 2.01)	
	p-value	1.0000	
	Risk Difference (95% CI)	0.00 (-4.48, 4.48)	
	p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Cardiac disorders	Number of subjects with events, n (%)	12 (4.9)	15 (6.1)
	Number of censored subjects, n (%)	234 (95.1)	231 (93.9)
	Exposure years	565.1	339.8
	EAIR per 100 PY	2.1	4.4
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.49 (0.22, 1.06)	
	p-value	0.0660	
	Relative Risk (95% CI)	0.80 (0.38, 1.67)	
	p-value	0.5536	
	Odds Ratio (95% CI)	0.79 (0.36, 1.72)	
	p-value	0.5534	
	Risk Difference (95% CI)	-1.22 (-5.24, 2.80)	
	p-value	0.5525	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Ear and labyrinth disorders	Number of subjects with events, n (%)	16 (6.5)	12 (4.9)
	Number of censored subjects, n (%)	230 (93.5)	234 (95.1)
	Exposure years	549.2	336.6
	EAIR per 100 PY	2.9	3.6
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.93 (0.43, 1.99)	
	p-value	0.8457	
	Relative Risk (95% CI)	1.33 (0.64, 2.76)	
	p-value	0.4382	
	Odds Ratio (95% CI)	1.36 (0.63, 2.93)	
	p-value	0.4378	
	Risk Difference (95% CI)	1.63 (-2.47, 5.72)	
	p-value	0.4360	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Eye disorders	Number of subjects with events, n (%)	29 (11.8)	15 (6.1)
	Number of censored subjects, n (%)	217 (88.2)	231 (93.9)
	Exposure years	528.5	338.7
	EAIR per 100 PY	5.5	4.4
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (149.3, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.38 (0.73, 2.61)	
	p-value	0.3163	
	Relative Risk (95% CI)	1.93 (1.06, 3.51)	
	p-value	0.0307	
	Odds Ratio (95% CI)	2.06 (1.07, 3.94)	
	p-value	0.0296	
	Risk Difference (95% CI)	5.69 (0.67, 10.71)	
	p-value	0.0262	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Gastrointestinal disorders	Number of subjects with events, n (%)	75 (30.5)	69 (28.0)
	Number of censored subjects, n (%)	171 (69.5)	177 (72.0)
	Exposure years	452.2	287.3
	EAIR per 100 PY	16.6	24.0
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	70.86 (43.29, 115.1)	48.86 (29.71, 92.14)
	Median (95% CI)	NE (NE, NE)	204.4 (165.3, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (204.4, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.85 (0.61, 1.19)	
	p-value	0.3454	
	Relative Risk (95% CI)	1.09 (0.83, 1.43)	
	p-value	0.5524	
	Odds Ratio (95% CI)	1.13 (0.76, 1.66)	
	p-value	0.5523	
	Risk Difference (95% CI)	2.44 (-5.60, 10.48)	
	p-value	0.5520	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Gastrointestinal disorders, PT: Abdominal pain upper	Number of subjects with events, n (%)	10 (4.1)	6 (2.4)
	Number of censored subjects, n (%)	236 (95.9)	240 (97.6)
	Exposure years	565.4	341.0
	EAIR per 100 PY	1.8	1.8
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.26 (0.45, 3.52)	
	p-value	0.6615	
	Relative Risk (95% CI)	1.67 (0.62, 4.51)	
	p-value	0.3151	
	Odds Ratio (95% CI)	1.69 (0.61, 4.74)	
	p-value	0.3144	
	Risk Difference (95% CI)	1.63 (-1.51, 4.76)	
	p-value	0.3088	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Gastrointestinal disorders, PT: Diarrhoea	Number of subjects with events, n (%)	10 (4.1)	16 (6.5)
	Number of censored subjects, n (%)	236 (95.9)	230 (93.5)
	Exposure years	565.2	338.0
	EAIR per 100 PY	1.8	4.7
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.48 (0.21, 1.06)	
	p-value	0.0651	
	Relative Risk (95% CI)	0.63 (0.29, 1.35)	
	p-value	0.2316	
	Odds Ratio (95% CI)	0.61 (0.27, 1.37)	
	p-value	0.2307	
	Risk Difference (95% CI)	-2.44 (-6.39, 1.51)	
	p-value	0.2259	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Gastrointestinal disorders, PT: Gastrooesophageal reflux disease	Number of subjects with events, n (%)	8 (3.3)	10 (4.1)
	Number of censored subjects, n (%)	238 (96.7)	236 (95.9)
	Exposure years	565.5	341.1
	EAIR per 100 PY	1.4	2.9
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.66 (0.26, 1.69)	
	p-value	0.3851	
	Relative Risk (95% CI)	0.80 (0.32, 1.99)	
	p-value	0.6318	
	Odds Ratio (95% CI)	0.79 (0.31, 2.04)	
	p-value	0.6317	
	Risk Difference (95% CI)	-0.81 (-4.13, 2.50)	
	p-value	0.6310	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Gastrointestinal disorders, PT: Nausea	Number of subjects with events, n (%)	15 (6.1)	17 (6.9)
	Number of censored subjects, n (%)	231 (93.9)	229 (93.1)
	Exposure years	562.1	334.2
	EAIR per 100 PY	2.7	5.1
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (204.4, NE)
	Median (95% CI)	NE (NE, NE)	NE (204.4, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.67 (0.33, 1.37)	
	p-value	0.2702	
	Relative Risk (95% CI)	0.88 (0.45, 1.73)	
	p-value	0.7148	
	Odds Ratio (95% CI)	0.87 (0.43, 1.79)	
	p-value	0.7148	
	Risk Difference (95% CI)	-0.81 (-5.17, 3.54)	
	p-value	0.7146	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Gastrointestinal disorders, PT: Vomiting	Number of subjects with events, n (%)	13 (5.3)	5 (2.0)
	Number of censored subjects, n (%)	233 (94.7)	241 (98.0)
	Exposure years	563.7	345.7
	EAIR per 100 PY	2.3	1.4
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	2.22 (0.79, 6.29)	
	p-value	0.1223	
	Relative Risk (95% CI)	2.60 (0.94, 7.18)	
	p-value	0.0653	
	Odds Ratio (95% CI)	2.69 (0.94, 7.66)	
	p-value	0.0640	
	Risk Difference (95% CI)	3.25 (-0.05, 6.56)	
	p-value	0.0538	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: General disorders and administration site conditions	Number of subjects with events, n (%)	44 (17.9)	27 (11.0)
	Number of censored subjects, n (%)	202 (82.1)	219 (89.0)
	Exposure years	504.5	332.1
	EAIR per 100 PY	8.7	8.1
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (140.0, NE)	204.4 (193.1, NE)
	Median (95% CI)	NE (NE, NE)	NE (204.4, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.29 (0.80, 2.10)	
	p-value	0.2983	
	Relative Risk (95% CI)	1.63 (1.04, 2.54)	
	p-value	0.0316	
	Odds Ratio (95% CI)	1.77 (1.05, 2.96)	
	p-value	0.0306	
	Risk Difference (95% CI)	6.91 (0.73, 13.09)	
	p-value	0.0284	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Immune system disorders	Number of subjects with events, n (%)	20 (8.1)	9 (3.7)
	Number of censored subjects, n (%)	226 (91.9)	237 (96.3)
	Exposure years	539.8	339.8
	EAIR per 100 PY	3.7	2.6
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.99 (0.90, 4.40)	
	p-value	0.0833	
	Relative Risk (95% CI)	2.22 (1.03, 4.78)	
	p-value	0.0412	
	Odds Ratio (95% CI)	2.33 (1.04, 5.23)	
	p-value	0.0400	
	Risk Difference (95% CI)	4.47 (0.33, 8.61)	
	p-value	0.0344	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Immune system disorders, PT: Hypersensitivity	Number of subjects with events, n (%)	10 (4.1)	3 (1.2)
	Number of censored subjects, n (%)	236 (95.9)	243 (98.8)
	Exposure years	561.1	344.5
	EAIR per 100 PY	1.8	0.9
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	3.37 (0.93, 12.23)	
	p-value	0.0504	
	Relative Risk (95% CI)	3.33 (0.93, 11.97)	
	p-value	0.0648	
	Odds Ratio (95% CI)	3.43 (0.93, 12.63)	
	p-value	0.0635	
	Risk Difference (95% CI)	2.85 (0.02, 5.67)	
	p-value	0.0482	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Infections and infestations	Number of subjects with events, n (%)	191 (77.6)	159 (64.6)
	Number of censored subjects, n (%)	55 (22.4)	87 (35.4)
	Exposure years	188.1	174.5
	EAIR per 100 PY	101.5	91.1
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	7.86 (6.29, 11.71)	11.57 (8.86, 16.00)
	Median (95% CI)	24.43 (18.14, 32.71)	32.29 (23.57, 40.57)
	75%-ile (95% CI)	58.71 (44.71, 103.9)	102.0 (64.43, 163.3)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.25 (1.01, 1.55)	
	p-value	0.0359	
	Relative Risk (95% CI)	1.20 (1.07, 1.35)	
	p-value	0.0016	
	Odds Ratio (95% CI)	1.90 (1.28, 2.83)	
	p-value	0.0016	
	Risk Difference (95% CI)	13.01 (5.08, 20.93)	
	p-value	0.0013	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Infections and infestations, PT: Bronchitis	Number of subjects with events, n (%)	46 (18.7)	16 (6.5)
	Number of censored subjects, n (%)	200 (81.3)	230 (93.5)
	Exposure years	493.0	336.6
	EAIR per 100 PY	9.3	4.8
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (93.00, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	2.18 (1.23, 3.88)	
	p-value	0.0066	
	Relative Risk (95% CI)	2.88 (1.67, 4.94)	
	p-value	0.0001	
	Odds Ratio (95% CI)	3.31 (1.82, 6.02)	
	p-value	<.0001	
	Risk Difference (95% CI)	12.20 (6.43, 17.96)	
	p-value	<.0001	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Infections and infestations, PT: Conjunctivitis	Number of subjects with events, n (%)	11 (4.5)	4 (1.6)
	Number of censored subjects, n (%)	235 (95.5)	242 (98.4)
	Exposure years	558.9	343.5
	EAIR per 100 PY	2.0	1.2
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.97 (0.62, 6.29)	
	p-value	0.2435	
	Relative Risk (95% CI)	2.75 (0.89, 8.52)	
	p-value	0.0795	
	Odds Ratio (95% CI)	2.83 (0.89, 9.02)	
	p-value	0.0782	
	Risk Difference (95% CI)	2.85 (-0.18, 5.87)	
	p-value	0.0655	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Infections and infestations, PT: Herpes zoster	Number of subjects with events, n (%)	25 (10.2)	7 (2.8)
	Number of censored subjects, n (%)	221 (89.8)	239 (97.2)
	Exposure years	545.5	336.7
	EAIR per 100 PY	4.6	2.1
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	2.39 (1.02, 5.61)	
	p-value	0.0391	
	Relative Risk (95% CI)	3.57 (1.57, 8.10)	
	p-value	0.0023	
	Odds Ratio (95% CI)	3.86 (1.64, 9.11)	
	p-value	0.0020	
	Risk Difference (95% CI)	7.32 (3.01, 11.63)	
	p-value	0.0009	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Infections and infestations, PT: Influenza	Number of subjects with events, n (%)	12 (4.9)	9 (3.7)
	Number of censored subjects, n (%)	234 (95.1)	237 (96.3)
	Exposure years	566.9	342.9
	EAIR per 100 PY	2.1	2.6
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.81 (0.33, 1.97)	
	p-value	0.6447	
	Relative Risk (95% CI)	1.33 (0.57, 3.11)	
	p-value	0.5051	
	Odds Ratio (95% CI)	1.35 (0.56, 3.27)	
	p-value	0.5048	
	Risk Difference (95% CI)	1.22 (-2.35, 4.79)	
	p-value	0.5032	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Infections and infestations, PT: Nasopharyngitis	Number of subjects with events, n (%)	63 (25.6)	31 (12.6)
	Number of censored subjects, n (%)	183 (74.4)	215 (87.4)
	Exposure years	463.8	316.9
	EAIR per 100 PY	13.6	9.8
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	87.57 (49.57, 172.9)	NE (145.7, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.71 (1.11, 2.64)	
	p-value	0.0146	
	Relative Risk (95% CI)	2.03 (1.37, 3.01)	
	p-value	0.0004	
	Odds Ratio (95% CI)	2.39 (1.49, 3.83)	
	p-value	0.0003	
	Risk Difference (95% CI)	13.01 (6.16, 19.86)	
	p-value	0.0002	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Infections and infestations, PT: Oral herpes	Number of subjects with events, n (%)	12 (4.9)	8 (3.3)
	Number of censored subjects, n (%)	234 (95.1)	238 (96.7)
	Exposure years	558.0	341.0
	EAIR per 100 PY	2.2	2.3
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.09 (0.44, 2.70)	
	p-value	0.8602	
	Relative Risk (95% CI)	1.50 (0.62, 3.61)	
	p-value	0.3648	
	Odds Ratio (95% CI)	1.53 (0.61, 3.80)	
	p-value	0.3643	
	Risk Difference (95% CI)	1.63 (-1.86, 5.11)	
	p-value	0.3607	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Infections and infestations, PT: Pharyngitis	Number of subjects with events, n (%)	20 (8.1)	15 (6.1)
	Number of censored subjects, n (%)	226 (91.9)	231 (93.9)
	Exposure years	546.6	332.0
	EAIR per 100 PY	3.7	4.5
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.92 (0.47, 1.83)	
	p-value	0.8209	
	Relative Risk (95% CI)	1.33 (0.70, 2.54)	
	p-value	0.3825	
	Odds Ratio (95% CI)	1.36 (0.68, 2.73)	
	p-value	0.3821	
	Risk Difference (95% CI)	2.03 (-2.51, 6.57)	
	p-value	0.3802	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Infections and infestations, PT: Pneumonia	Number of subjects with events, n (%)	11 (4.5)	10 (4.1)
	Number of censored subjects, n (%)	235 (95.5)	236 (95.9)
	Exposure years	571.2	339.2
	EAIR per 100 PY	1.9	2.9
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.82 (0.34, 1.98)	
	p-value	0.6655	
	Relative Risk (95% CI)	1.10 (0.48, 2.54)	
	p-value	0.8236	
	Odds Ratio (95% CI)	1.10 (0.46, 2.65)	
	p-value	0.8236	
	Risk Difference (95% CI)	0.41 (-3.17, 3.98)	
	p-value	0.8235	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Infections and infestations, PT: Respiratory tract infection	Number of subjects with events, n (%)	12 (4.9)	1 (0.4)
	Number of censored subjects, n (%)	234 (95.1)	245 (99.6)
	Exposure years	553.8	348.0
	EAIR per 100 PY	2.2	0.3
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	11.09 (1.44, 85.48)	
	p-value	0.0037	
	Relative Risk (95% CI)	12.00 (1.57, 91.58)	
	p-value	0.0166	
	Odds Ratio (95% CI)	12.56 (1.62, 97.39)	
	p-value	0.0154	
	Risk Difference (95% CI)	4.47 (1.66, 7.28)	
	p-value	0.0018	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Infections and infestations, PT: Sinusitis	Number of subjects with events, n (%)	23 (9.3)	13 (5.3)
	Number of censored subjects, n (%)	223 (90.7)	233 (94.7)
	Exposure years	531.1	337.5
	EAIR per 100 PY	4.3	3.9
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.45 (0.73, 2.89)	
	p-value	0.2853	
	Relative Risk (95% CI)	1.77 (0.92, 3.41)	
	p-value	0.0886	
	Odds Ratio (95% CI)	1.85 (0.91, 3.74)	
	p-value	0.0874	
	Risk Difference (95% CI)	4.07 (-0.52, 8.65)	
	p-value	0.0825	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Infections and infestations, PT: Upper respiratory tract infection	Number of subjects with events, n (%)	59 (24.0)	29 (11.8)
	Number of censored subjects, n (%)	187 (76.0)	217 (88.2)
	Exposure years	463.6	314.4
	EAIR per 100 PY	12.7	9.2
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	103.6 (75.57, NE)	NE (104.1, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.61 (1.03, 2.53)	
	p-value	0.0369	
	Relative Risk (95% CI)	2.03 (1.35, 3.06)	
	p-value	0.0006	
	Odds Ratio (95% CI)	2.36 (1.45, 3.84)	
	p-value	0.0005	
	Risk Difference (95% CI)	12.20 (5.51, 18.88)	
	p-value	0.0004	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Infections and infestations, PT: Urinary tract infection	Number of subjects with events, n (%)	47 (19.1)	37 (15.0)
	Number of censored subjects, n (%)	199 (80.9)	209 (85.0)
	Exposure years	513.7	314.5
	EAIR per 100 PY	9.1	11.8
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	195.9 (104.7, NE)	NE (75.14, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.94 (0.60, 1.45)	
	p-value	0.7693	
	Relative Risk (95% CI)	1.27 (0.86, 1.88)	
	p-value	0.2326	
	Odds Ratio (95% CI)	1.33 (0.83, 2.14)	
	p-value	0.2318	
	Risk Difference (95% CI)	4.07 (-2.57, 10.71)	
	p-value	0.2302	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Infections and infestations, PT: Viral upper respiratory tract infection	Number of subjects with events, n (%)	11 (4.5)	2 (0.8)
	Number of censored subjects, n (%)	235 (95.5)	244 (99.2)
	Exposure years	573.6	345.6
	EAIR per 100 PY	1.9	0.6
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	3.39 (0.74, 15.65)	
	p-value	0.0978	
	Relative Risk (95% CI)	5.50 (1.23, 24.56)	
	p-value	0.0255	
	Odds Ratio (95% CI)	5.71 (1.25, 26.04)	
	p-value	0.0244	
	Risk Difference (95% CI)	3.66 (0.84, 6.47)	
	p-value	0.0109	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Injury, poisoning and procedural complications	Number of subjects with events, n (%)	78 (31.7)	51 (20.7)
	Number of censored subjects, n (%)	168 (68.3)	195 (79.3)
	Exposure years	453.7	284.2
	EAIR per 100 PY	17.2	17.9
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	54.29 (29.57, 85.86)	123.9 (50.86, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.26 (0.88, 1.80)	
	p-value	0.2116	
	Relative Risk (95% CI)	1.53 (1.13, 2.08)	
	p-value	0.0064	
	Odds Ratio (95% CI)	1.78 (1.18, 2.67)	
	p-value	0.0059	
	Risk Difference (95% CI)	10.98 (3.26, 18.69)	
	p-value	0.0053	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Injury, poisoning and procedural complications, PT: Contusion	Number of subjects with events, n (%)	10 (4.1)	5 (2.0)
	Number of censored subjects, n (%)	236 (95.9)	241 (98.0)
	Exposure years	568.4	343.9
	EAIR per 100 PY	1.8	1.5
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.39 (0.47, 4.15)	
	p-value	0.5541	
	Relative Risk (95% CI)	2.00 (0.69, 5.77)	
	p-value	0.1995	
	Odds Ratio (95% CI)	2.04 (0.69, 6.06)	
	p-value	0.1985	
	Risk Difference (95% CI)	2.03 (-1.00, 5.07)	
	p-value	0.1890	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Injury, poisoning and procedural complications, PT: Infusion related reaction	Number of subjects with events, n (%)	31 (12.6)	20 (8.1)
	Number of censored subjects, n (%)	215 (87.4)	226 (91.9)
	Exposure years	522.7	314.3
	EAIR per 100 PY	5.9	6.4
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.39 (0.79, 2.45)	
	p-value	0.2593	
	Relative Risk (95% CI)	1.55 (0.91, 2.64)	
	p-value	0.1075	
	Odds Ratio (95% CI)	1.63 (0.90, 2.95)	
	p-value	0.1063	
	Risk Difference (95% CI)	4.47 (-0.90, 9.84)	
	p-value	0.1028	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Investigations	Number of subjects with events, n (%)	19 (7.7)	19 (7.7)
	Number of censored subjects, n (%)	227 (92.3)	227 (92.3)
	Exposure years	550.6	338.7
	EAIR per 100 PY	3.5	5.6
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.71 (0.37, 1.36)	
	p-value	0.2988	
	Relative Risk (95% CI)	1.00 (0.54, 1.84)	
	p-value	1.0000	
	Odds Ratio (95% CI)	1.00 (0.52, 1.94)	
	p-value	1.0000	
	Risk Difference (95% CI)	0.00 (-4.72, 4.72)	
	p-value	1.0000	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Metabolism and nutrition disorders	Number of subjects with events, n (%)	26 (10.6)	27 (11.0)
	Number of censored subjects, n (%)	220 (89.4)	219 (89.0)
	Exposure years	534.7	328.1
	EAIR per 100 PY	4.9	8.2
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (137.0, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.65 (0.37, 1.13)	
	p-value	0.1251	
	Relative Risk (95% CI)	0.96 (0.58, 1.60)	
	p-value	0.8844	
	Odds Ratio (95% CI)	0.96 (0.54, 1.70)	
	p-value	0.8844	
	Risk Difference (95% CI)	-0.41 (-5.89, 5.07)	
	p-value	0.8844	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Musculoskeletal and connective tissue disorders	Number of subjects with events, n (%)	98 (39.8)	60 (24.4)
	Number of censored subjects, n (%)	148 (60.2)	186 (75.6)
	Exposure years	419.2	293.3
	EAIR per 100 PY	23.4	20.5
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	52.00 (39.43, 75.29)	61.57 (39.00, 106.1)
	Median (95% CI)	164.3 (114.1, NE)	NE (156.9, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.27 (0.92, 1.76)	
	p-value	0.1441	
	Relative Risk (95% CI)	1.63 (1.25, 2.14)	
	p-value	0.0003	
	Odds Ratio (95% CI)	2.05 (1.39, 3.02)	
	p-value	0.0003	
	Risk Difference (95% CI)	15.45 (7.31, 23.58)	
	p-value	0.0002	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Musculoskeletal and connective tissue disorders, PT: Arthralgia	Number of subjects with events, n (%)	20 (8.1)	9 (3.7)
	Number of censored subjects, n (%)	226 (91.9)	237 (96.3)
	Exposure years	552.5	338.7
	EAIR per 100 PY	3.6	2.7
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.61 (0.72, 3.58)	
	p-value	0.2432	
	Relative Risk (95% CI)	2.22 (1.03, 4.78)	
	p-value	0.0412	
	Odds Ratio (95% CI)	2.33 (1.04, 5.23)	
	p-value	0.0400	
	Risk Difference (95% CI)	4.47 (0.33, 8.61)	
	p-value	0.0344	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Musculoskeletal and connective tissue disorders, PT: Back pain	Number of subjects with events, n (%)	24 (9.8)	12 (4.9)
	Number of censored subjects, n (%)	222 (90.2)	234 (95.1)
	Exposure years	544.6	330.8
	EAIR per 100 PY	4.4	3.6
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.44 (0.71, 2.92)	
	p-value	0.3089	
	Relative Risk (95% CI)	2.00 (1.02, 3.91)	
	p-value	0.0426	
	Odds Ratio (95% CI)	2.11 (1.03, 4.32)	
	p-value	0.0414	
	Risk Difference (95% CI)	4.88 (0.30, 9.46)	
	p-value	0.0369	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Musculoskeletal and connective tissue disorders, PT: Systemic lupus erythematosus	Number of subjects with events, n (%)	7 (2.8)	10 (4.1)
	Number of censored subjects, n (%)	239 (97.2)	236 (95.9)
	Exposure years	574.1	344.2
	EAIR per 100 PY	1.2	2.9
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.44 (0.16, 1.17)	
	p-value	0.0914	
	Relative Risk (95% CI)	0.70 (0.27, 1.81)	
	p-value	0.4616	
	Odds Ratio (95% CI)	0.69 (0.26, 1.85)	
	p-value	0.4613	
	Risk Difference (95% CI)	-1.22 (-4.45, 2.01)	
	p-value	0.4587	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Number of subjects with events, n (%)	17 (6.9)	9 (3.7)
	Number of censored subjects, n (%)	229 (93.1)	237 (96.3)
	Exposure years	549.9	346.1
	EAIR per 100 PY	3.1	2.6
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.31 (0.58, 2.98)	
	p-value	0.5205	
	Relative Risk (95% CI)	1.89 (0.86, 4.16)	
	p-value	0.1139	
	Odds Ratio (95% CI)	1.95 (0.85, 4.47)	
	p-value	0.1126	
	Risk Difference (95% CI)	3.25 (-0.69, 7.20)	
	p-value	0.1060	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Nervous system disorders	Number of subjects with events, n (%)	71 (28.9)	43 (17.5)
	Number of censored subjects, n (%)	175 (71.1)	203 (82.5)
	Exposure years	459.5	301.2
	EAIR per 100 PY	15.5	14.3
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	93.86 (52.29, 114.9)	156.6 (60.57, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.28 (0.87, 1.88)	
	p-value	0.2046	
	Relative Risk (95% CI)	1.65 (1.18, 2.31)	
	p-value	0.0033	
	Odds Ratio (95% CI)	1.92 (1.25, 2.94)	
	p-value	0.0030	
	Risk Difference (95% CI)	11.38 (3.99, 18.77)	
	p-value	0.0025	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Nervous system disorders, PT: Headache	Number of subjects with events, n (%)	28 (11.4)	26 (10.6)
	Number of censored subjects, n (%)	218 (88.6)	220 (89.4)
	Exposure years	534.1	317.6
	EAIR per 100 PY	5.2	8.2
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (156.6, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.80 (0.46, 1.38)	
	p-value	0.4173	
	Relative Risk (95% CI)	1.08 (0.65, 1.78)	
	p-value	0.7731	
	Odds Ratio (95% CI)	1.09 (0.62, 1.91)	
	p-value	0.7730	
	Risk Difference (95% CI)	0.81 (-4.71, 6.34)	
	p-value	0.7730	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Psychiatric disorders	Number of subjects with events, n (%)	27 (11.0)	30 (12.2)
	Number of censored subjects, n (%)	219 (89.0)	216 (87.8)
	Exposure years	531.8	322.8
	EAIR per 100 PY	5.1	9.3
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (91.14, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.72 (0.43, 1.23)	
	p-value	0.2288	
	Relative Risk (95% CI)	0.90 (0.55, 1.47)	
	p-value	0.6728	
	Odds Ratio (95% CI)	0.89 (0.51, 1.54)	
	p-value	0.6727	
	Risk Difference (95% CI)	-1.22 (-6.87, 4.44)	
	p-value	0.6725	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Psychiatric disorders, PT: Anxiety	Number of subjects with events, n (%)	11 (4.5)	6 (2.4)
	Number of censored subjects, n (%)	235 (95.5)	240 (97.6)
	Exposure years	559.6	343.5
	EAIR per 100 PY	2.0	1.7
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.59 (0.58, 4.34)	
	p-value	0.3582	
	Relative Risk (95% CI)	1.83 (0.69, 4.88)	
	p-value	0.2249	
	Odds Ratio (95% CI)	1.87 (0.68, 5.15)	
	p-value	0.2240	
	Risk Difference (95% CI)	2.03 (-1.19, 5.26)	
	p-value	0.2164	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Psychiatric disorders, PT: Depression	Number of subjects with events, n (%)	14 (5.7)	6 (2.4)
	Number of censored subjects, n (%)	232 (94.3)	240 (97.6)
	Exposure years	558.8	342.6
	EAIR per 100 PY	2.5	1.8
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.68 (0.64, 4.44)	
	p-value	0.2899	
	Relative Risk (95% CI)	2.33 (0.91, 5.97)	
	p-value	0.0772	
	Odds Ratio (95% CI)	2.41 (0.91, 6.39)	
	p-value	0.0760	
	Risk Difference (95% CI)	3.25 (-0.23, 6.73)	
	p-value	0.0669	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Psychiatric disorders, PT: Insomnia	Number of subjects with events, n (%)	8 (3.3)	15 (6.1)
	Number of censored subjects, n (%)	238 (96.7)	231 (93.9)
	Exposure years	569.3	338.6
	EAIR per 100 PY	1.4	4.4
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.44 (0.18, 1.05)	
	p-value	0.0573	
	Relative Risk (95% CI)	0.53 (0.23, 1.23)	
	p-value	0.1423	
	Odds Ratio (95% CI)	0.52 (0.22, 1.24)	
	p-value	0.1411	
	Risk Difference (95% CI)	-2.85 (-6.57, 0.88)	
	p-value	0.1340	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Renal and urinary disorders	Number of subjects with events, n (%)	23 (9.3)	13 (5.3)
	Number of censored subjects, n (%)	223 (90.7)	233 (94.7)
	Exposure years	555.0	340.7
	EAIR per 100 PY	4.1	3.8
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (205.3, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.21 (0.60, 2.42)	
	p-value	0.5904	
	Relative Risk (95% CI)	1.77 (0.92, 3.41)	
	p-value	0.0886	
	Odds Ratio (95% CI)	1.85 (0.91, 3.74)	
	p-value	0.0874	
	Risk Difference (95% CI)	4.07 (-0.52, 8.65)	
	p-value	0.0825	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Reproductive system and breast disorders	Number of subjects with events, n (%)	27 (11.0)	15 (6.1)
	Number of censored subjects, n (%)	219 (89.0)	231 (93.9)
	Exposure years	539.3	333.3
	EAIR per 100 PY	5.0	4.5
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.20 (0.63, 2.28)	
	p-value	0.5807	
	Relative Risk (95% CI)	1.80 (0.98, 3.30)	
	p-value	0.0573	
	Odds Ratio (95% CI)	1.90 (0.98, 3.66)	
	p-value	0.0560	
	Risk Difference (95% CI)	4.88 (-0.04, 9.80)	
	p-value	0.0520	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with events, n (%)	56 (22.8)	38 (15.4)
	Number of censored subjects, n (%)	190 (77.2)	208 (84.6)
	Exposure years	495.2	316.4
	EAIR per 100 PY	11.3	12.0
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	136.7 (76.71, NE)	182.9 (66.00, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.21 (0.80, 1.85)	
	p-value	0.3633	
	Relative Risk (95% CI)	1.47 (1.02, 2.14)	
	p-value	0.0411	
	Odds Ratio (95% CI)	1.61 (1.02, 2.55)	
	p-value	0.0400	
	Risk Difference (95% CI)	7.32 (0.40, 14.23)	
	p-value	0.0382	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Respiratory, thoracic and mediastinal disorders, PT: Cough	Number of subjects with events, n (%)	26 (10.6)	8 (3.3)
	Number of censored subjects, n (%)	220 (89.4)	238 (96.7)
	Exposure years	535.2	343.4
	EAIR per 100 PY	4.9	2.3
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	2.66 (1.19, 5.91)	
	p-value	0.0131	
	Relative Risk (95% CI)	3.25 (1.50, 7.04)	
	p-value	0.0028	
	Odds Ratio (95% CI)	3.52 (1.56, 7.93)	
	p-value	0.0024	
	Risk Difference (95% CI)	7.32 (2.88, 11.75)	
	p-value	0.0012	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Skin and subcutaneous tissue disorders	Number of subjects with events, n (%)	52 (21.1)	36 (14.6)
	Number of censored subjects, n (%)	194 (78.9)	210 (85.4)
	Exposure years	502.4	315.7
	EAIR per 100 PY	10.4	11.4
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	188.7 (92.57, NE)	152.6 (94.00, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.11 (0.72, 1.72)	
	p-value	0.6235	
	Relative Risk (95% CI)	1.44 (0.98, 2.13)	
	p-value	0.0622	
	Odds Ratio (95% CI)	1.56 (0.98, 2.50)	
	p-value	0.0610	
	Risk Difference (95% CI)	6.50 (-0.24, 13.25)	
	p-value	0.0589	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Vascular disorders	Number of subjects with events, n (%)	15 (6.1)	18 (7.3)
	Number of censored subjects, n (%)	231 (93.9)	228 (92.7)
	Exposure years	560.1	330.1
	EAIR per 100 PY	2.7	5.5
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (129.1, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.48 (0.24, 0.97)	
	p-value	0.0364	
	Relative Risk (95% CI)	0.83 (0.43, 1.62)	
	p-value	0.5894	
	Odds Ratio (95% CI)	0.82 (0.40, 1.67)	
	p-value	0.5892	
	Risk Difference (95% CI)	-1.22 (-5.64, 3.20)	
	p-value	0.5886	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Vascular disorders, PT: Hypertension	Number of subjects with events, n (%)	8 (3.3)	13 (5.3)
	Number of censored subjects, n (%)	238 (96.7)	233 (94.7)
	Exposure years	570.9	338.7
	EAIR per 100 PY	1.4	3.8
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.34 (0.14, 0.85)	
	p-value	0.0157	
	Relative Risk (95% CI)	0.62 (0.26, 1.46)	
	p-value	0.2701	
	Odds Ratio (95% CI)	0.60 (0.25, 1.48)	
	p-value	0.2693	
	Risk Difference (95% CI)	-2.03 (-5.60, 1.54)	
	p-value	0.2642	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%)	Ramdomised ANI300 (N=246) Median (95% CI)	Randomised Placebo (N=246) n/ N (%)	Randomised Placebo (N=246) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
SOC: Infections and infestations	Age (years)							0.3954
	<= 65	186/239 (77.8)	24.43 (18.57, 32.71)	158/243 (65.0)	32.14 (23.57, 39.86)	1.24 (1.00, 1.53)	0.0476	
	> 65	5/ 7 (71.4)	15.57 (4.86, NE)	1/ 3 (33.3)	NE (21.43, NE)	3.51 (0.40, 30.46)	0.2265	
	Sex							0.5658
	male	15/ 23 (65.2)	41.57 (19.00, NE)	10/ 20 (50.0)	39.14 (7.14, NE)	1.04 (0.46, 2.32)	0.9311	
	female	176/223 (78.9)	21.43 (15.86, 32.00)	149/226 (65.9)	32.14 (23.57, 40.57)	1.29 (1.03, 1.60)	0.0236	
	Geographic region							0.7846
	EU	66/ 92 (71.7)	37.14 (24.14, 51.86)	48/ 89 (53.9)	52.43 (39.14, 84.00)	1.30 (0.90, 1.90)	0.1642	
	non-EU	125/154 (81.2)	18.14 (13.86, 25.00)	111/157 (70.7)	22.57 (19.57, 30.86)	1.24 (0.96, 1.61)	0.0971	
	SLEDAI-2K score at screening							0.7247
	< 10 points	66/ 80 (82.5)	23.00 (15.57, 35.43)	50/ 69 (72.5)	23.14 (20.14, 37.86)	1.19 (0.82, 1.72)	0.3528	
	>= 10 points	125/166 (75.3)	24.71 (15.86, 36.00)	109/177 (61.6)	34.86 (27.71, 48.71)	1.27 (0.98, 1.64)	0.0728	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%)	Ramdomised ANI300 (N=246) Median (95% CI)	Randomised Placebo (N=246) n/ N (%)	Randomised Placebo (N=246) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Bronchitis	Age (years)							0.9879
	<= 65	44/239 (18.4)	NE (NE, NE)	16/243 (6.6)	NE (NE, NE)	2.11 (1.18, 3.77)	0.0096	
	> 65	2/ 7 (28.6)	NE (10.57, NE)	0/ 3 (0.0)	NE (NE, NE)	NE		
	Sex							0.9860
	male	2/ 23 (8.7)	NE (NE, NE)	0/ 20 (0.0)	NE (NE, NE)	NE		
	female	44/223 (19.7)	NE (NE, NE)	16/226 (7.1)	NE (NE, NE)	2.12 (1.19, 3.79)	0.0092	
	Geographic region							0.3043
	EU	16/ 92 (17.4)	NE (NE, NE)	3/ 89 (3.4)	NE (NE, NE)	4.08 (1.18, 14.11)	0.0165	
	non-EU	30/154 (19.5)	NE (NE, NE)	13/157 (8.3)	NE (NE, NE)	1.75 (0.90, 3.38)	0.0940	
	SLEDAI-2K score at screening							0.0043
	< 10 points	15/ 80 (18.8)	NE (NE, NE)	11/ 69 (15.9)	NE (NE, NE)	0.83 (0.38, 1.84)	0.6514	
	>= 10 points	31/166 (18.7)	NE (NE, NE)	5/177 (2.8)	NE (NE, NE)	5.14 (1.99, 13.30)	0.0002	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%)	Ramdomised ANI300 (N=246) Median (95% CI)	Randomised Placebo (N=246) n/ N (%)	Randomised Placebo (N=246) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Herpes zoster	Age (years)							0.9997
	<= 65	25/239 (10.5)	NE (NE, NE)	7/243 (2.9)	NE (NE, NE)	2.44 (1.04, 5.73)	0.0344	
	> 65	0/ 7 (0.0)	NE (NE, NE)	0/ 3 (0.0)	NE (NE, NE)	NE		
	Sex							0.9543
	male	4/ 23 (17.4)	NE (NE, NE)	1/ 20 (5.0)	NE (60.57, NE)	2.65 (0.29, 24.22)	0.3702	
	female	21/223 (9.4)	NE (NE, NE)	6/226 (2.7)	NE (NE, NE)	2.31 (0.92, 5.84)	0.0680	
	Geographic region							0.3685
	EU	7/ 92 (7.6)	NE (NE, NE)	3/ 89 (3.4)	NE (NE, NE)	1.41 (0.35, 5.62)	0.6278	
	non-EU	18/154 (11.7)	NE (NE, NE)	4/157 (2.5)	NE (NE, NE)	3.18 (1.06, 9.56)	0.0301	
	SLEDAI-2K score at screening							0.4715
	< 10 points	8/ 80 (10.0)	NE (NE, NE)	1/ 69 (1.4)	NE (NE, NE)	3.99 (0.49, 32.51)	0.1631	
	>= 10 points	17/166 (10.2)	NE (NE, NE)	6/177 (3.4)	NE (NE, NE)	2.17 (0.84, 5.60)	0.1008	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%)	Ramdomised ANI300 (N=246) Median (95% CI)	Randomised Placebo (N=246) n/ N (%)	Randomised Placebo (N=246) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Nasopharyngitis	Age (years)							0.9832
	<= 65	61/239 (25.5)	NE (NE, NE)	31/243 (12.8)	NE (NE, NE)	1.69 (1.09, 2.61)	0.0179	
	> 65	2/ 7 (28.6)	198.29 (11.86, NE)	0/ 3 (0.0)	NE (NE, NE)	NE		
	Sex							0.3287
	male	4/ 23 (17.4)	NE (NE, NE)	3/ 20 (15.0)	NE (145.71, NE)	0.85 (0.18, 3.95)	0.8343	
	female	59/223 (26.5)	NE (NE, NE)	28/226 (12.4)	NE (NE, NE)	1.82 (1.16, 2.87)	0.0085	
	Geographic region							0.2889
	EU	24/ 92 (26.1)	NE (NE, NE)	14/ 89 (15.7)	NE (NE, NE)	1.27 (0.65, 2.48)	0.4865	
	non-EU	39/154 (25.3)	NE (198.29, NE)	17/157 (10.8)	NE (NE, NE)	2.08 (1.17, 3.69)	0.0108	
	SLEDAI-2K score at screening							0.7147
	< 10 points	15/ 80 (18.8)	NE (198.29, NE)	7/ 69 (10.1)	NE (NE, NE)	1.46 (0.59, 3.61)	0.4160	
	>= 10 points	48/166 (28.9)	NE (NE, NE)	24/177 (13.6)	NE (NE, NE)	1.84 (1.12, 3.02)	0.0144	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%)	Ramdomised ANI300 (N=246) Median (95% CI)	Randomised Placebo (N=246) n/ N (%)	Randomised Placebo (N=246) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Respiratory tract infection	Age (years)							0.9994
	<= 65	12/239 (5.0)	NE (NE, NE)	1/243 (0.4)	NE (NE, NE)	11.24 (1.46, 86.63)	0.0035	
	> 65	0/ 7 (0.0)	NE (NE, NE)	0/ 3 (0.0)	NE (NE, NE)	NE		
	Sex							0.9920
	male	2/ 23 (8.7)	NE (NE, NE)	1/ 20 (5.0)	NE (NE, NE)	1.72 (0.16, 18.99)	0.6536	
	female	10/223 (4.5)	NE (NE, NE)	0/226 (0.0)	NE (NE, NE)	NE		
	Geographic region							0.9912
	EU	9/ 92 (9.8)	NE (NE, NE)	0/ 89 (0.0)	NE (NE, NE)	NE		
	non-EU	3/154 (1.9)	NE (NE, NE)	1/157 (0.6)	NE (NE, NE)	3.06 (0.32, 29.40)	0.3080	
	SLEDAI-2K score at screening							0.9931
	< 10 points	5/ 80 (6.3)	NE (NE, NE)	0/ 69 (0.0)	NE (NE, NE)	NE		
	>= 10 points	7/166 (4.2)	NE (NE, NE)	1/177 (0.6)	NE (NE, NE)	7.31 (0.90, 59.40)	0.0291	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%)	Ramdomised ANI300 (N=246) Median (95% CI)	Randomised Placebo (N=246) n/ N (%)	Randomised Placebo (N=246) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Upper respiratory tract infection	Age (years)							0.9843
	<= 65	57/239 (23.8)	NE (NE, NE)	29/243 (11.9)	NE (NE, NE)	1.56 (0.99, 2.46)	0.0517	
	> 65	2/ 7 (28.6)	NE (6.29, NE)	0/ 3 (0.0)	NE (NE, NE)	NE		
	Sex							0.5828
	male	5/ 23 (21.7)	NE (165.71, NE)	3/ 20 (15.0)	NE (82.86, NE)	1.08 (0.25, 4.62)	0.9136	
	female	54/223 (24.2)	NE (NE, NE)	26/226 (11.5)	NE (NE, NE)	1.68 (1.04, 2.69)	0.0312	
	Geographic region							0.9202
	EU	10/ 92 (10.9)	NE (NE, NE)	4/ 89 (4.5)	NE (NE, NE)	1.61 (0.49, 5.24)	0.4271	
	non-EU	49/154 (31.8)	NE (152.71, NE)	25/157 (15.9)	NE (NE, NE)	1.67 (1.03, 2.72)	0.0367	
	SLEDAI-2K score at screening							0.4891
	< 10 points	23/ 80 (28.8)	NE (NE, NE)	8/ 69 (11.6)	NE (NE, NE)	2.01 (0.89, 4.53)	0.0862	
	>= 10 points	36/166 (21.7)	NE (NE, NE)	21/177 (11.9)	NE (NE, NE)	1.41 (0.82, 2.44)	0.2142	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%)	Ramdomised ANI300 (N=246) Median (95% CI)	Randomised Placebo (N=246) n/ N (%)	Randomised Placebo (N=246) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
SOC: Respiratory, thoracic and mediastinal disorders, PT: Cough	Age (years)							0.9906
	<= 65	25/239 (10.5)	NE (NE, NE)	8/243 (3.3)	NE (NE, NE)	2.63 (1.18, 5.88)	0.0143	
	> 65	1/ 7 (14.3)	NE (83.43, NE)	0/ 3 (0.0)	NE (NE, NE)	NE		
	Sex							0.9887
	male	4/ 23 (17.4)	NE (NE, NE)	0/ 20 (0.0)	NE (NE, NE)	NE		
	female	22/223 (9.9)	NE (NE, NE)	8/226 (3.5)	NE (NE, NE)	2.31 (1.02, 5.22)	0.0395	
	Geographic region							0.9862
	EU	7/ 92 (7.6)	NE (NE, NE)	0/ 89 (0.0)	NE (NE, NE)	NE		
	non-EU	19/154 (12.3)	NE (NE, NE)	8/157 (5.1)	NE (NE, NE)	2.00 (0.87, 4.61)	0.0971	
	SLEDAI-2K score at screening							0.0771
	< 10 points	11/ 80 (13.8)	NE (NE, NE)	6/ 69 (8.7)	NE (NE, NE)	1.32 (0.48, 3.61)	0.5888	
	>= 10 points	15/166 (9.0)	NE (NE, NE)	2/177 (1.1)	NE (NE, NE)	6.37 (1.44, 28.12)	0.0052	

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Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%)	Ramdomised ANI300 (N=246) Median (95% CI)	Randomised Placebo (N=246) n/ N (%)	Randomised Placebo (N=246) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
SOC: Vascular disorders	Age (years)							0.9998
	<= 65	15/239 (6.3)	NE (NE, NE)	18/243 (7.4)	NE (NE, NE)	0.49 (0.24, 0.99)	0.0425	
	> 65	0/ 7 (0.0)	NE (NE, NE)	0/ 3 (0.0)	NE (NE, NE)	NE		
	Sex							0.9892
	male	1/ 23 (4.3)	NE (NE, NE)	0/ 20 (0.0)	NE (NE, NE)	NE		
	female	14/223 (6.3)	NE (NE, NE)	18/226 (8.0)	NE (NE, NE)	0.45 (0.22, 0.93)	0.0265	
	Geographic region							0.9795
	EU	7/ 92 (7.6)	NE (NE, NE)	8/ 89 (9.0)	NE (NE, NE)	0.49 (0.17, 1.41)	0.1790	
	non-EU	8/154 (5.2)	NE (NE, NE)	10/157 (6.4)	NE (NE, NE)	0.45 (0.17, 1.18)	0.0986	
	SLEDAI-2K score at screening							0.1619
	< 10 points	5/ 80 (6.3)	NE (NE, NE)	2/ 69 (2.9)	NE (NE, NE)	1.33 (0.25, 7.03)	0.7375	
	>= 10 points	10/166 (6.0)	NE (NE, NE)	16/177 (9.0)	NE (NE, NE)	0.36 (0.16, 0.81)	0.0108	

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Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%)	Ramdomised ANI300 (N=246) Median (95% CI)	Randomised Placebo (N=246) n/ N (%)	Randomised Placebo (N=246) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
SOC: Vascular disorders, PT: Hypertension	Age (years)							0.9998
	<= 65	8/239 (3.3)	NE (NE, NE)	13/243 (5.3)	NE (NE, NE)	0.35 (0.14, 0.86)	0.0181	
	> 65	0/ 7 (0.0)	NE (NE, NE)	0/ 3 (0.0)	NE (NE, NE)	NE		
	Sex							0.9912
	male	1/ 23 (4.3)	NE (NE, NE)	0/ 20 (0.0)	NE (NE, NE)	NE		
	female	7/223 (3.1)	NE (NE, NE)	13/226 (5.8)	NE (NE, NE)	0.30 (0.12, 0.78)	0.0094	
	Geographic region							0.7369
	EU	4/ 92 (4.3)	NE (NE, NE)	7/ 89 (7.9)	NE (NE, NE)	0.25 (0.07, 0.89)	0.0224	
	non-EU	4/154 (2.6)	NE (NE, NE)	6/157 (3.8)	NE (NE, NE)	0.45 (0.12, 1.65)	0.2174	
	SLEDAI-2K score at screening							0.2972
	< 10 points	3/ 80 (3.8)	NE (NE, NE)	2/ 69 (2.9)	NE (NE, NE)	0.75 (0.12, 4.60)	0.7520	
	>= 10 points	5/166 (3.0)	NE (NE, NE)	11/177 (6.2)	NE (NE, NE)	0.25 (0.08, 0.76)	0.0088	

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Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
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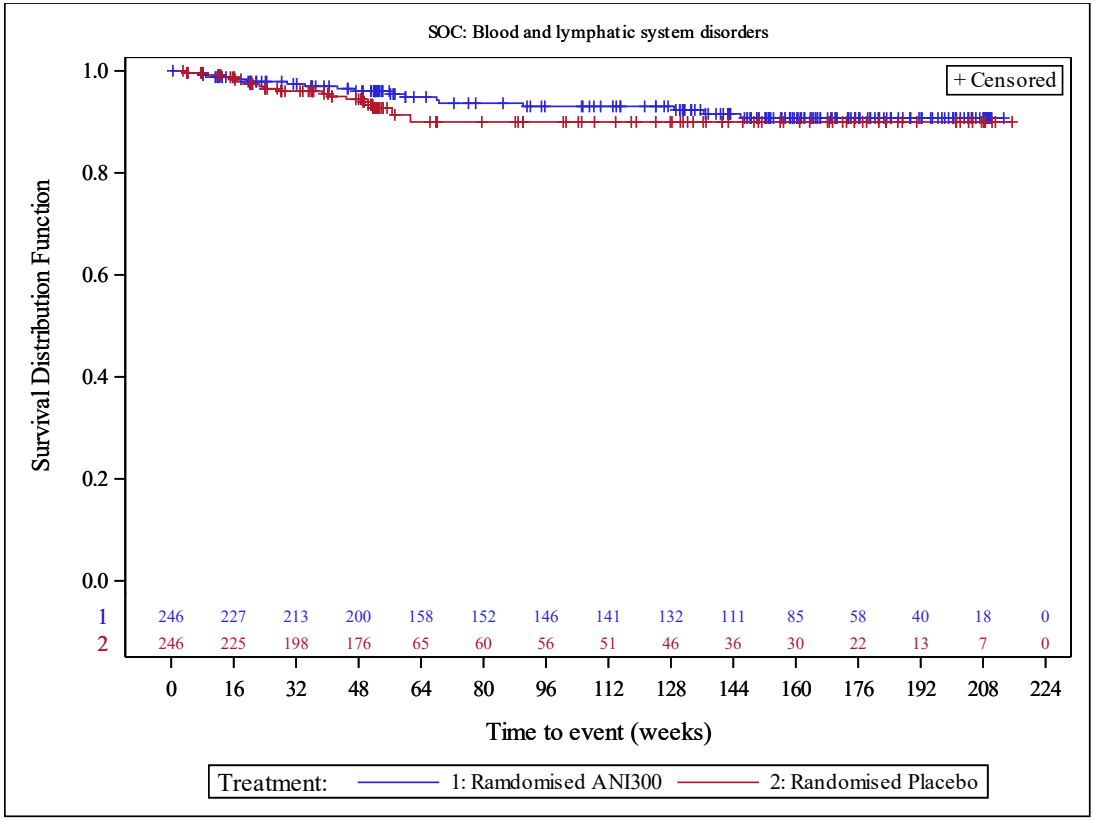
Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set



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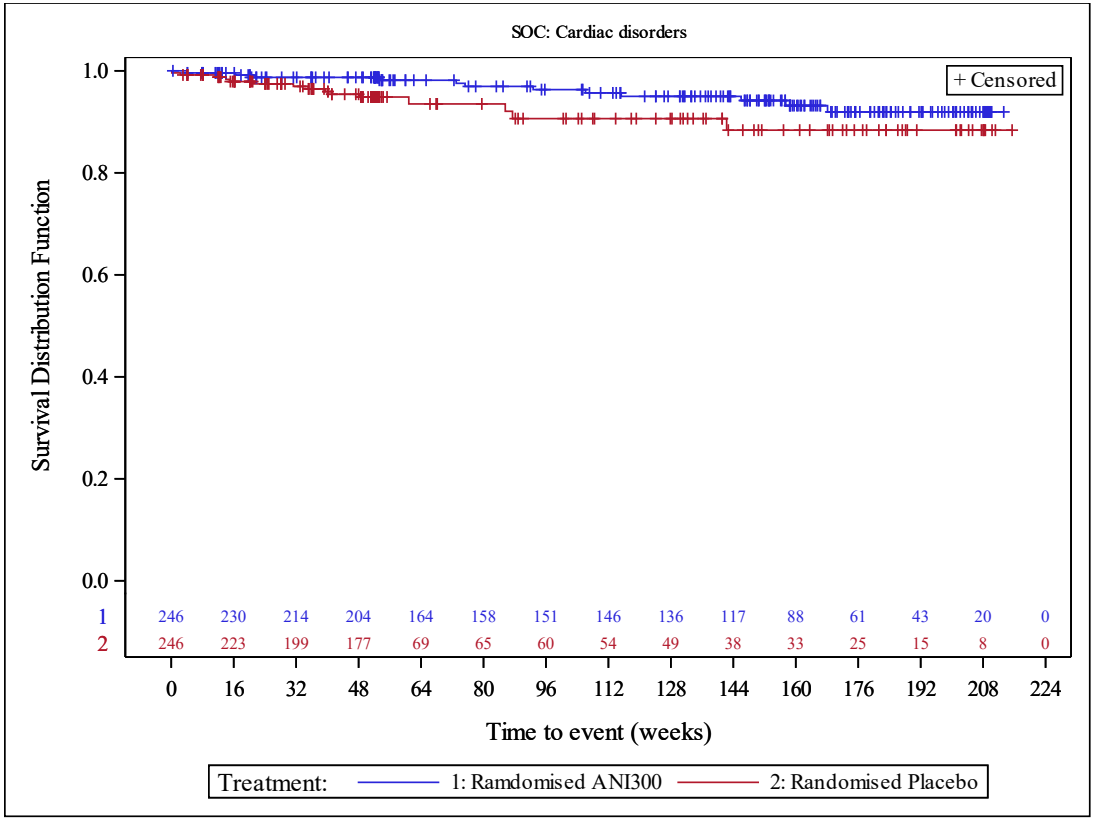

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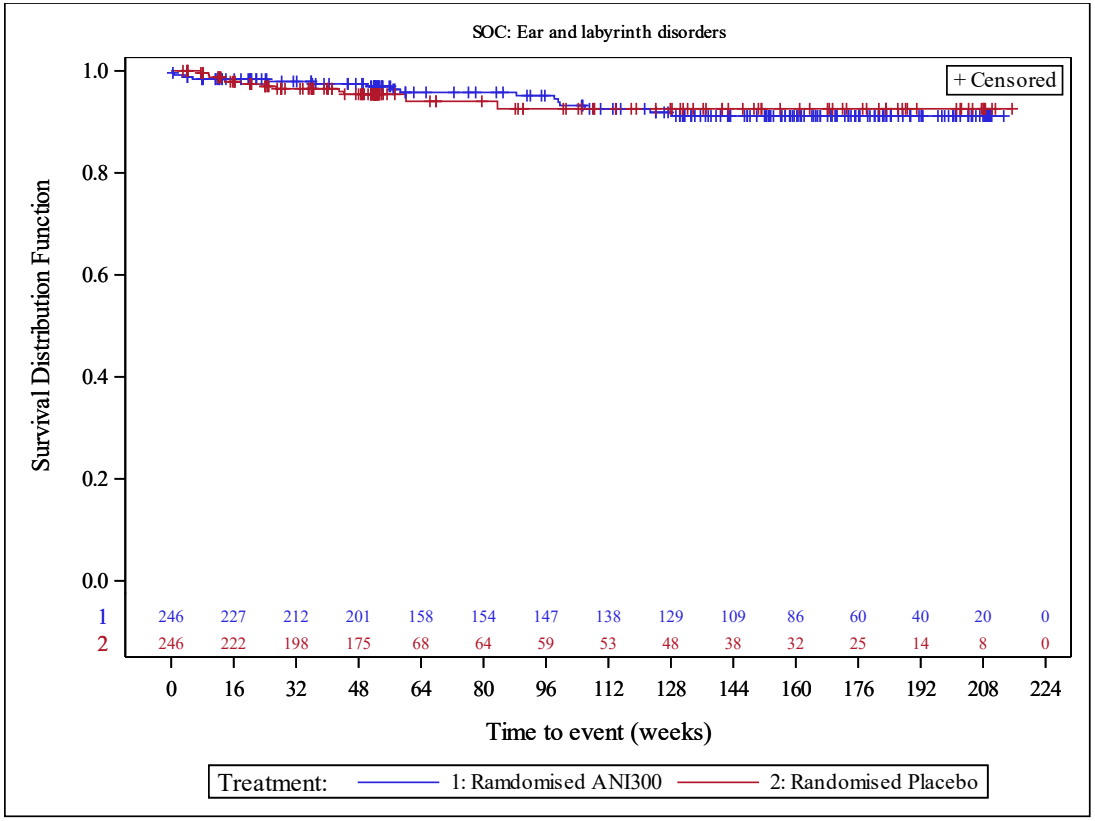

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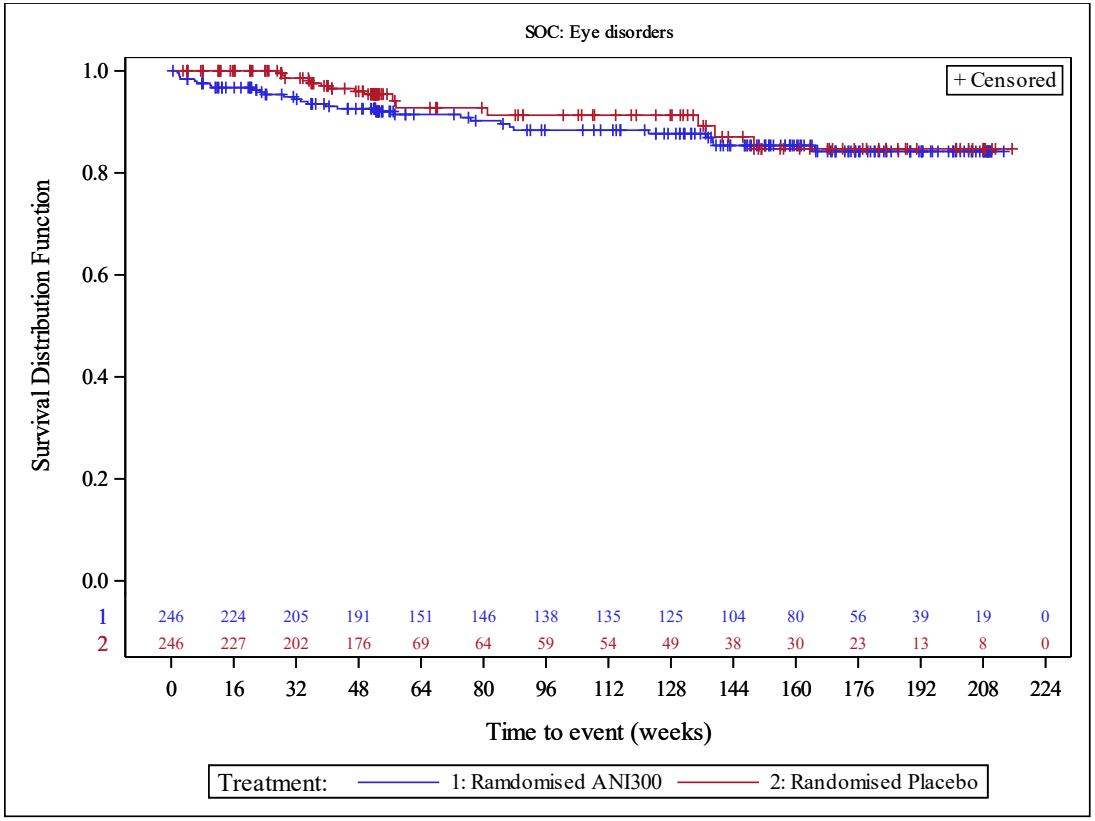

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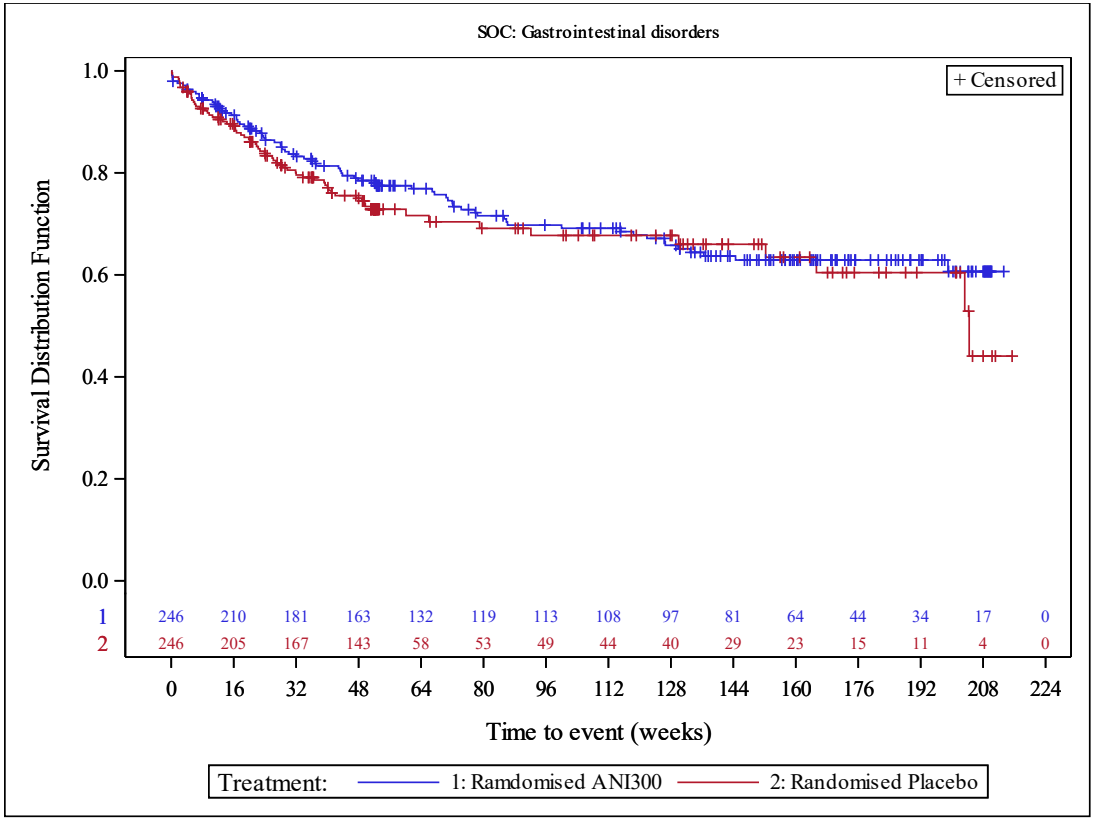

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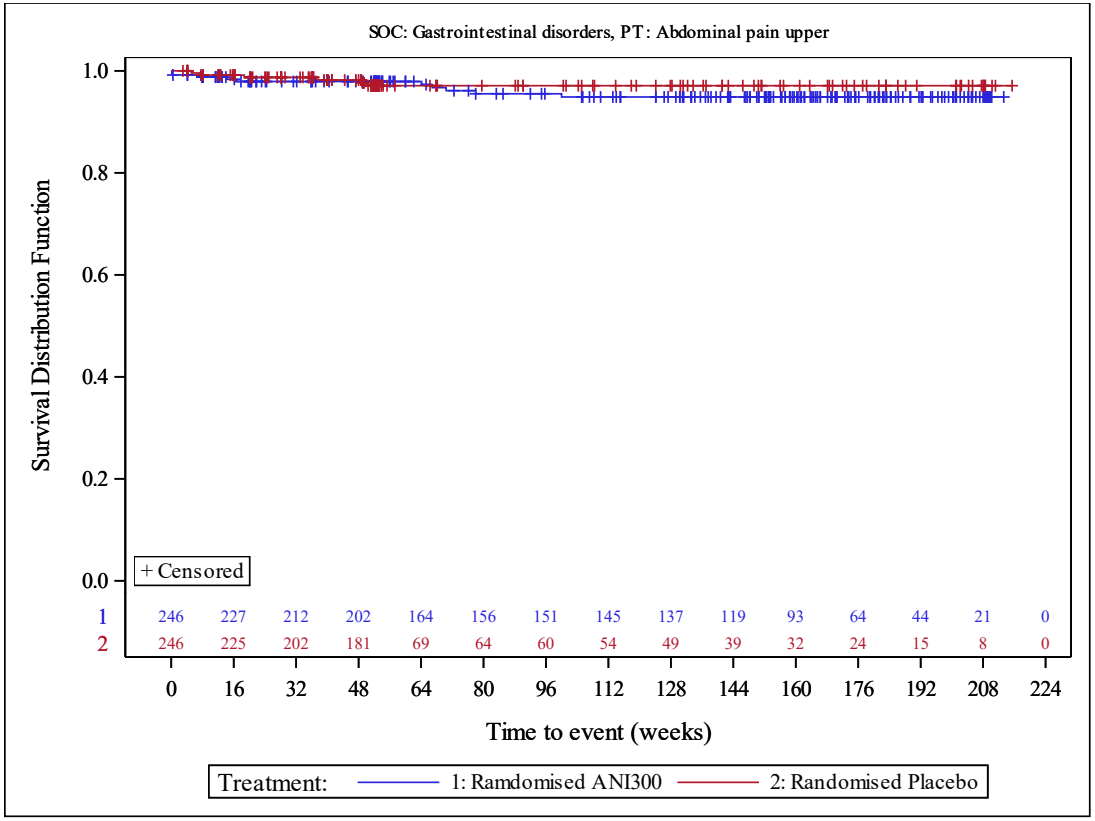

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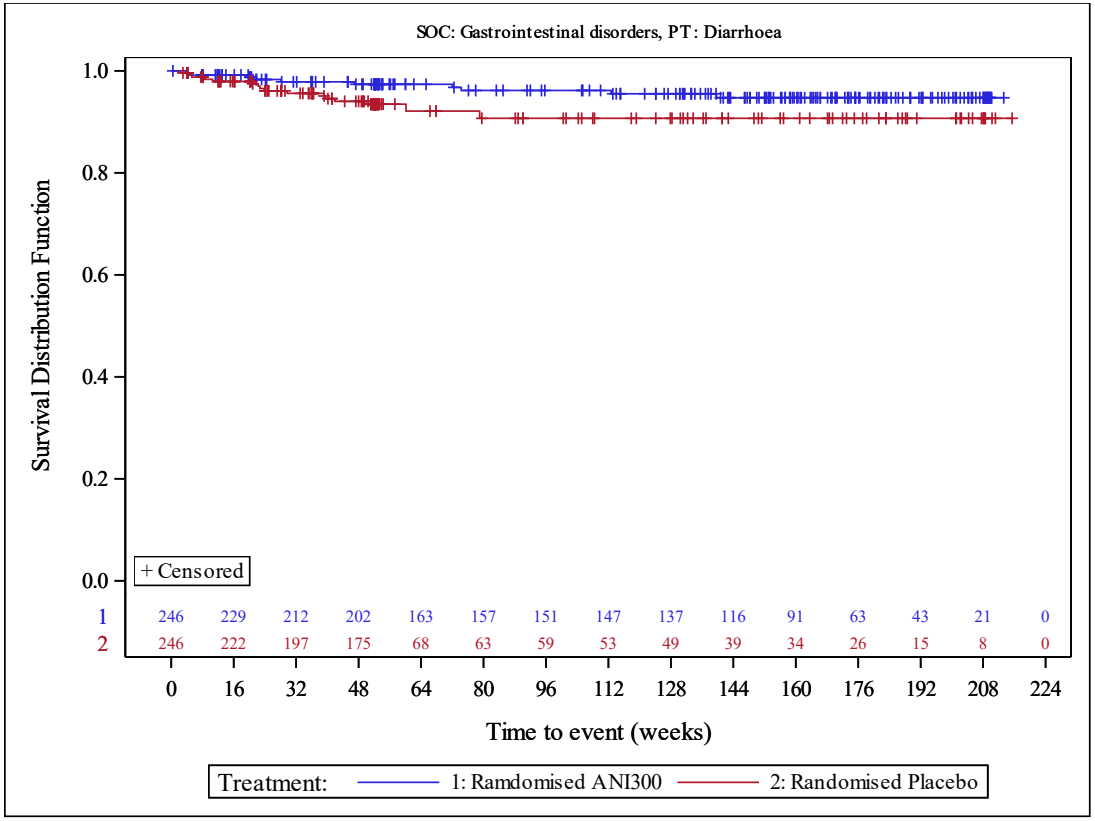

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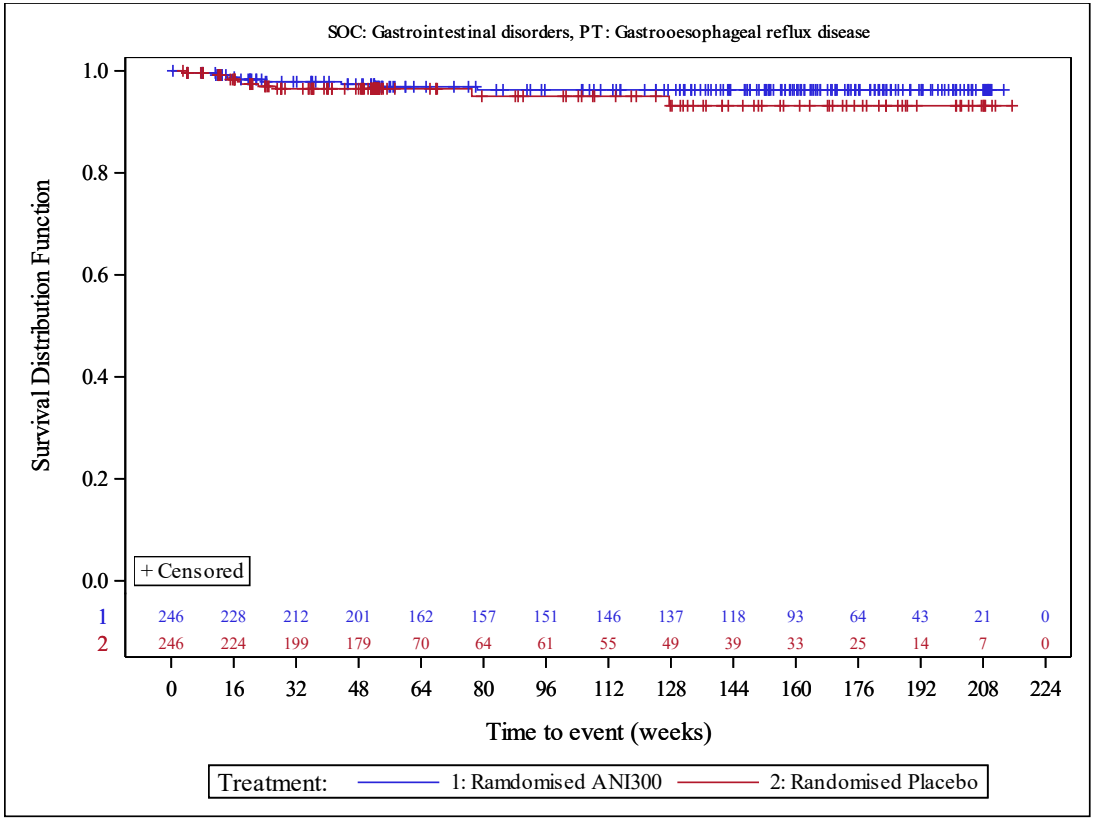

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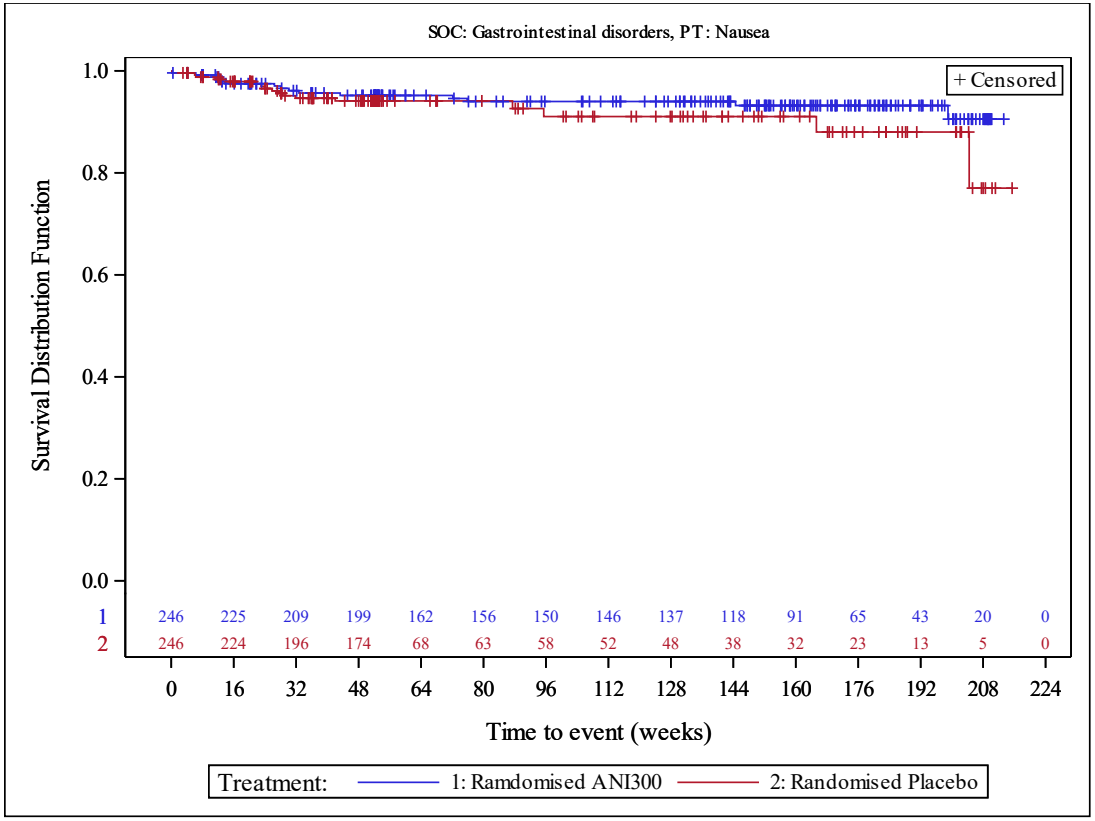

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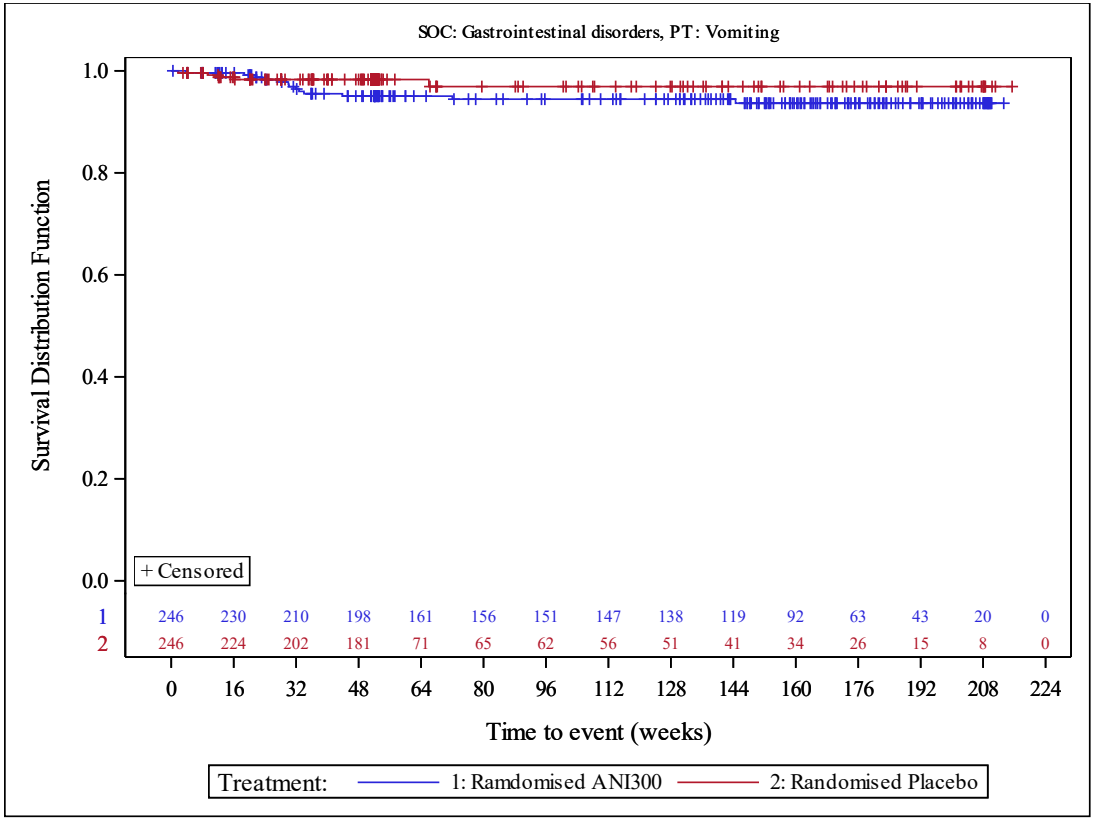

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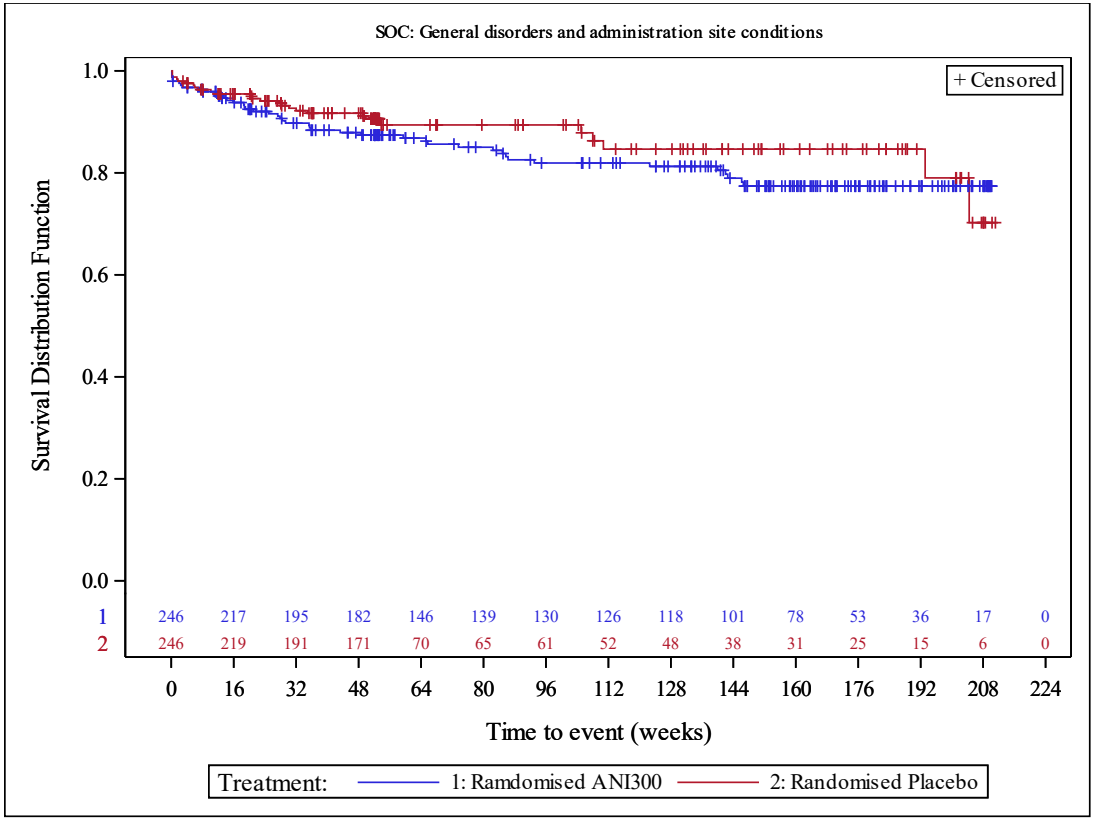

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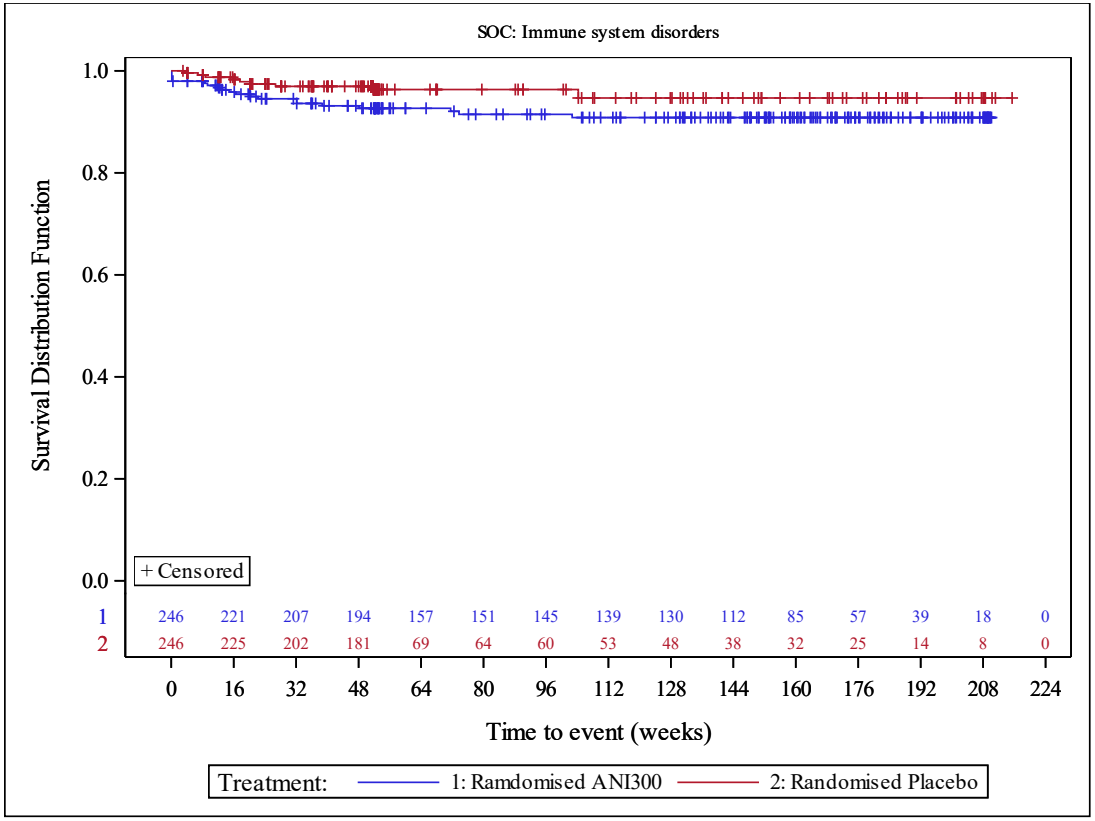

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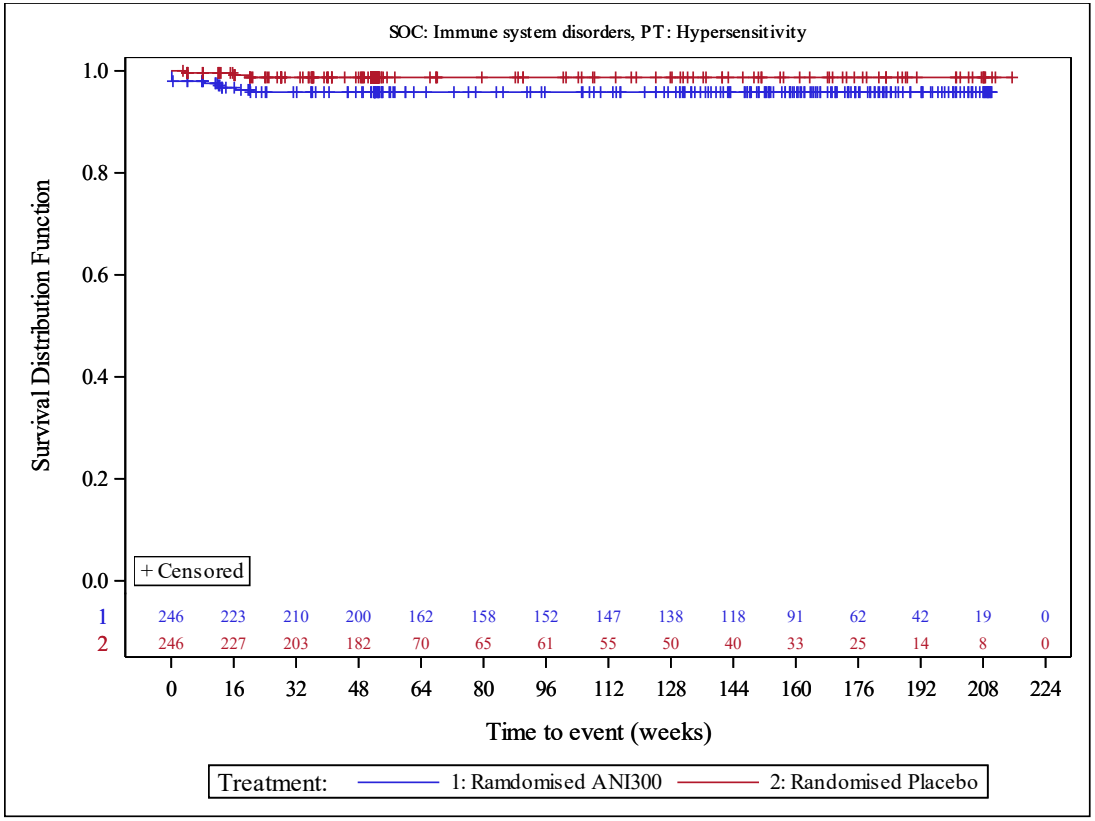

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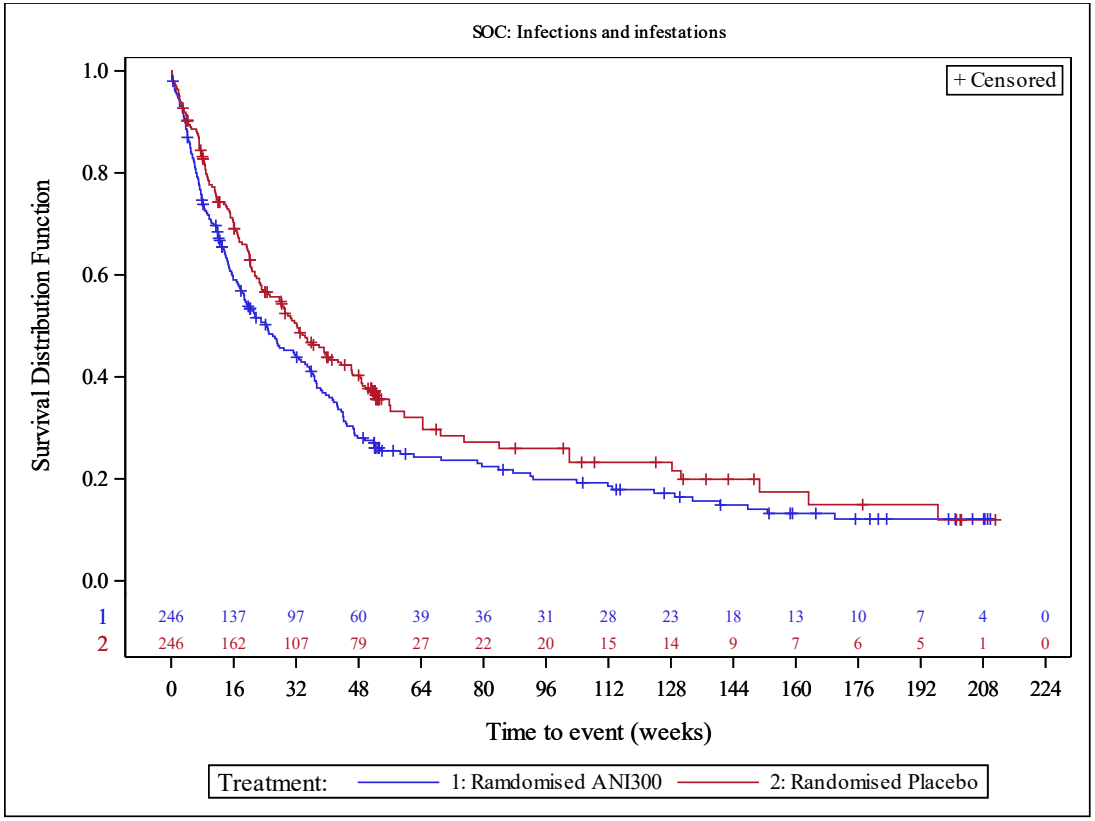

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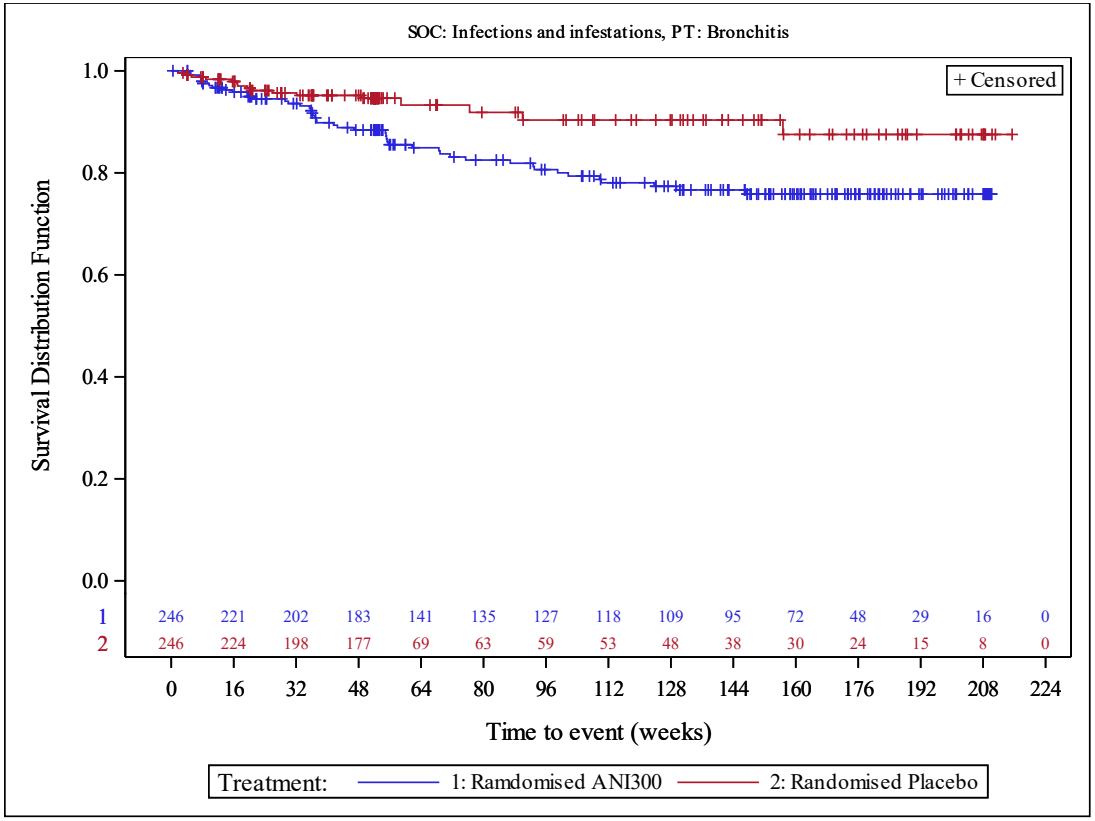

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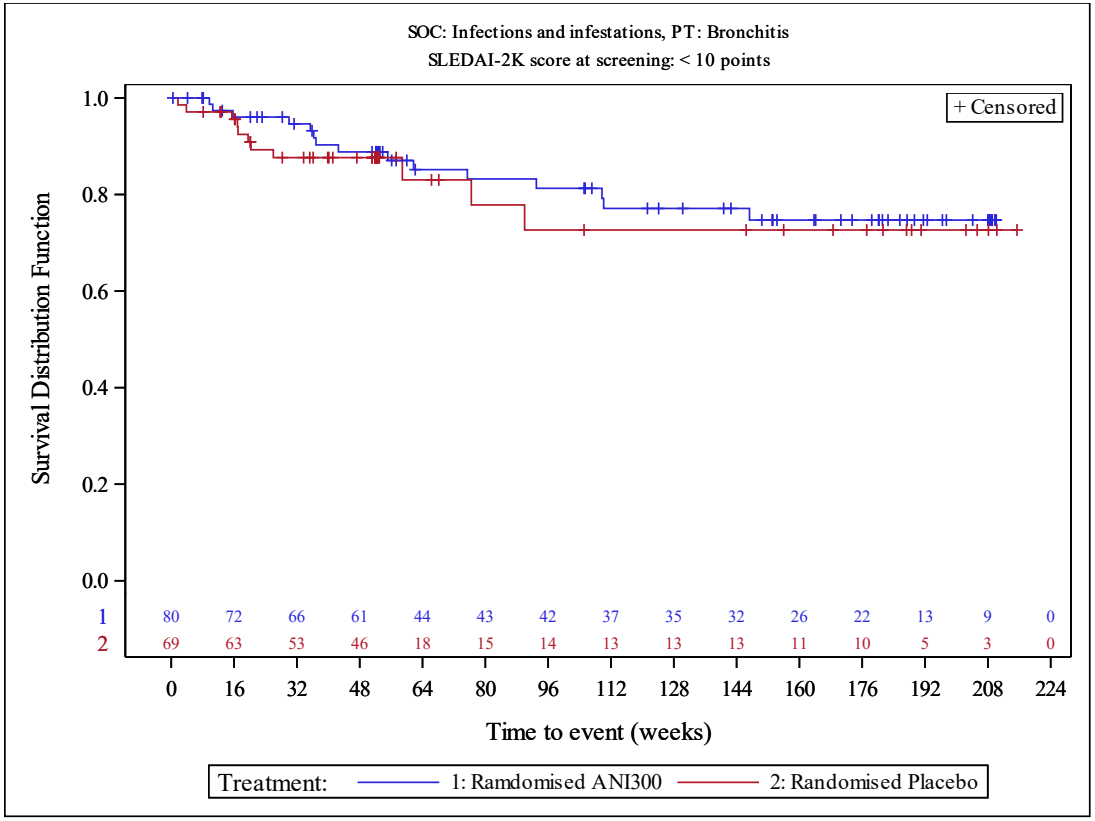

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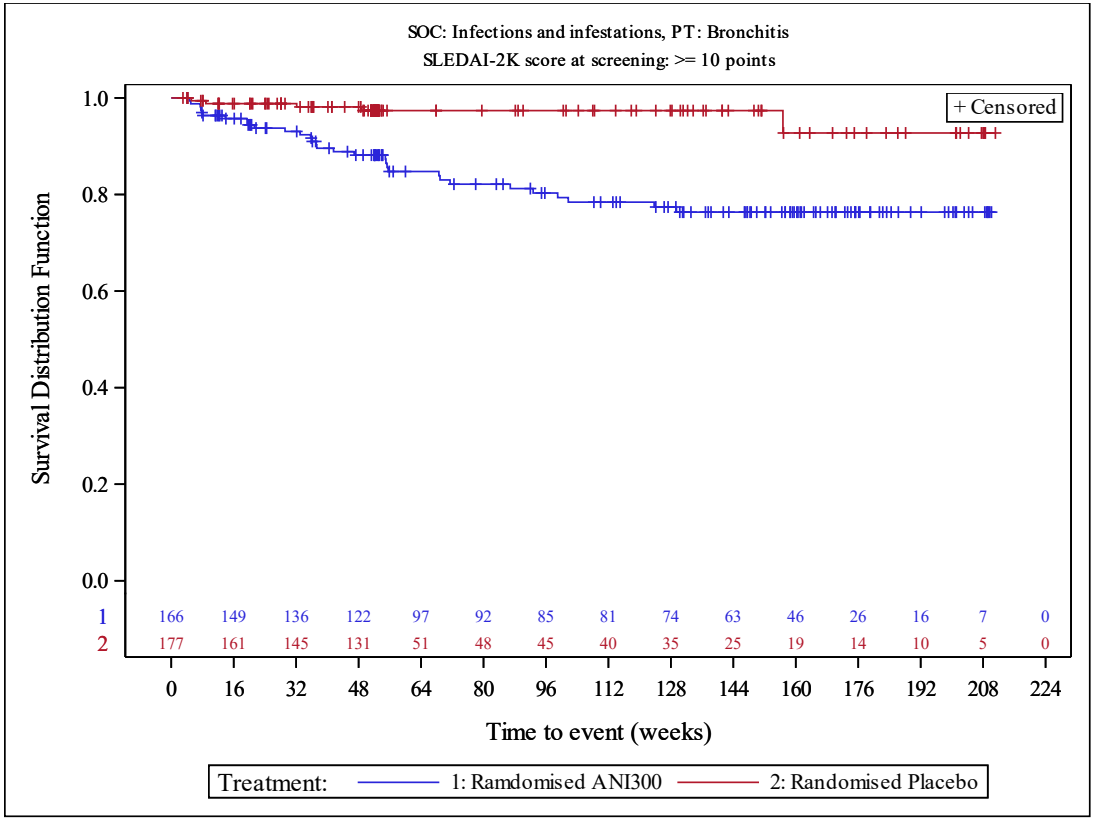

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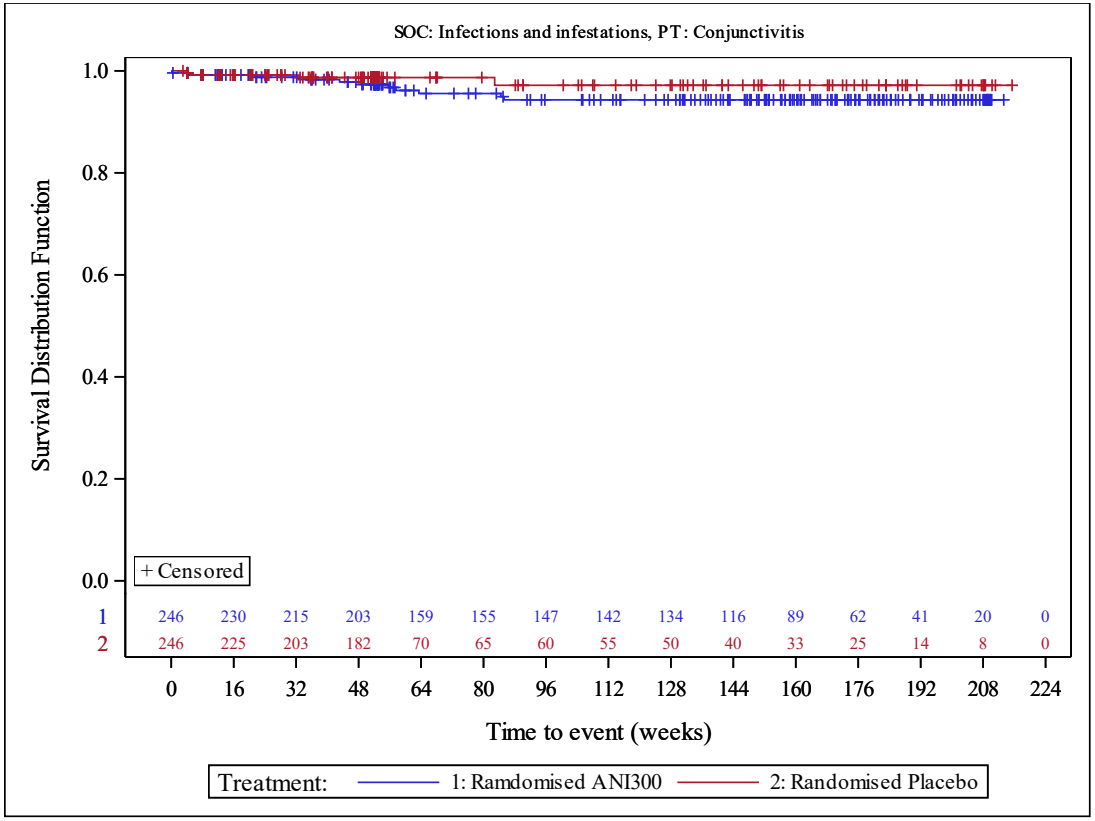

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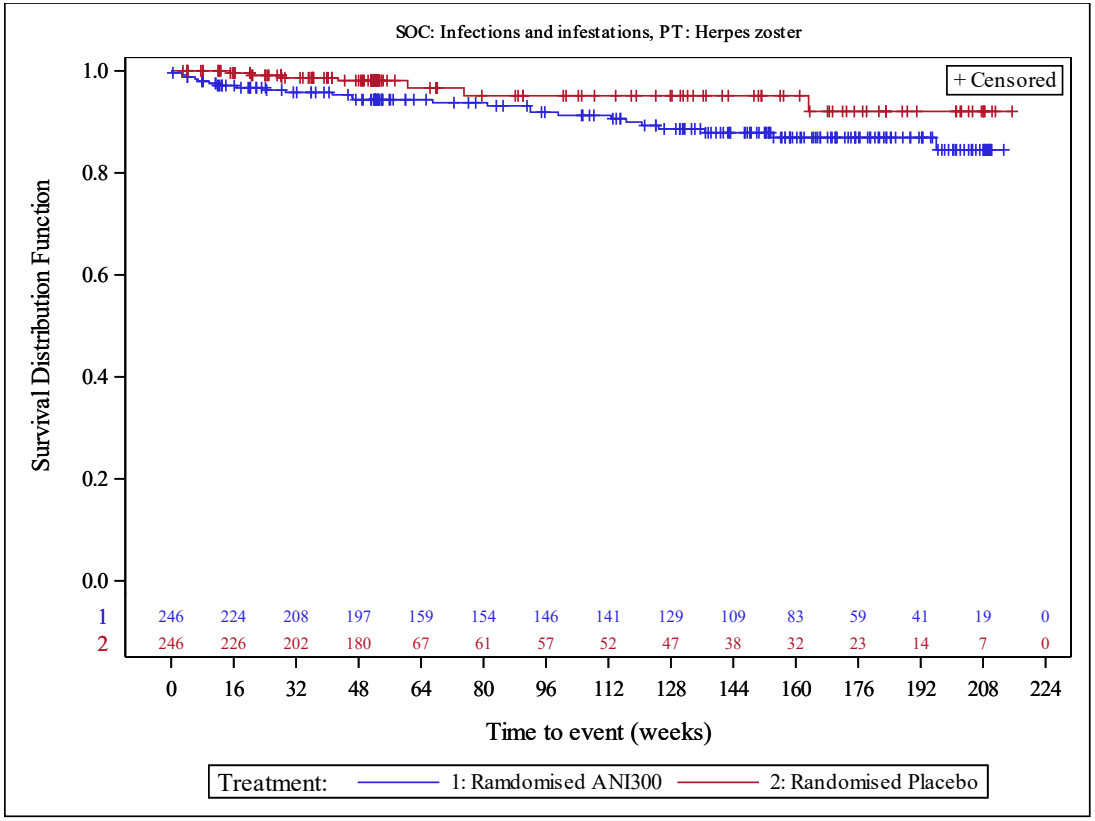

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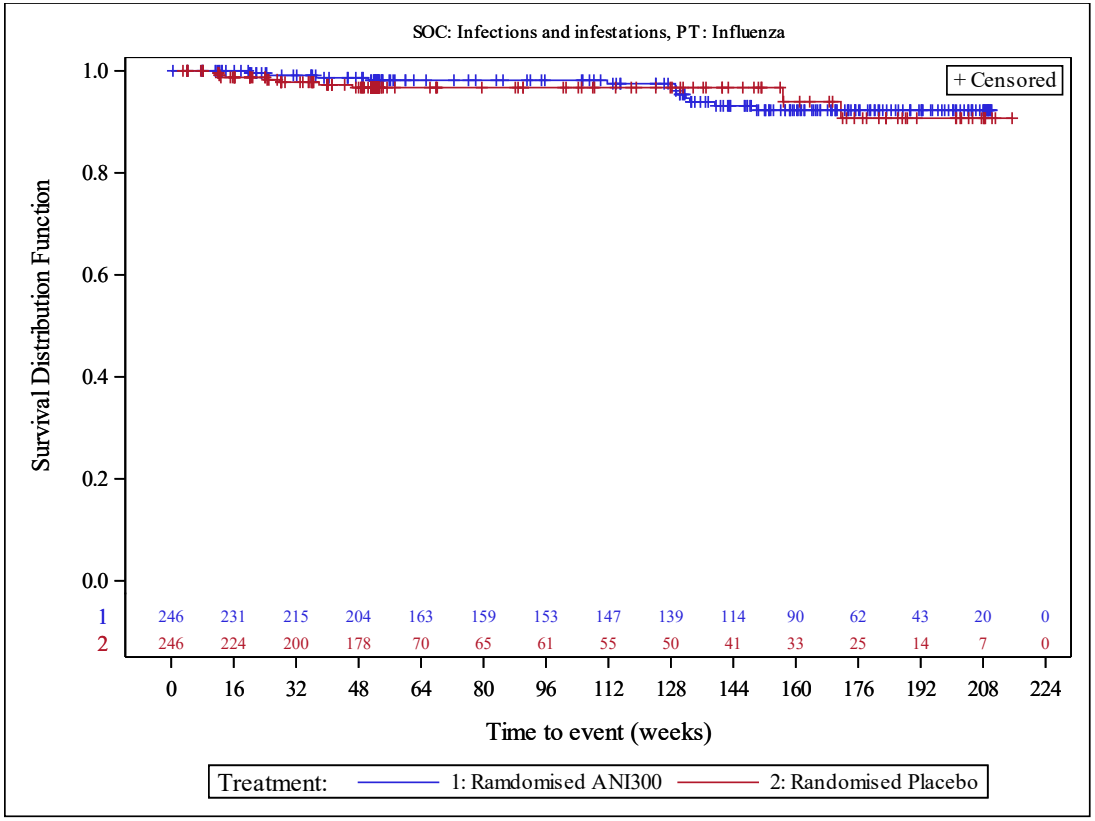

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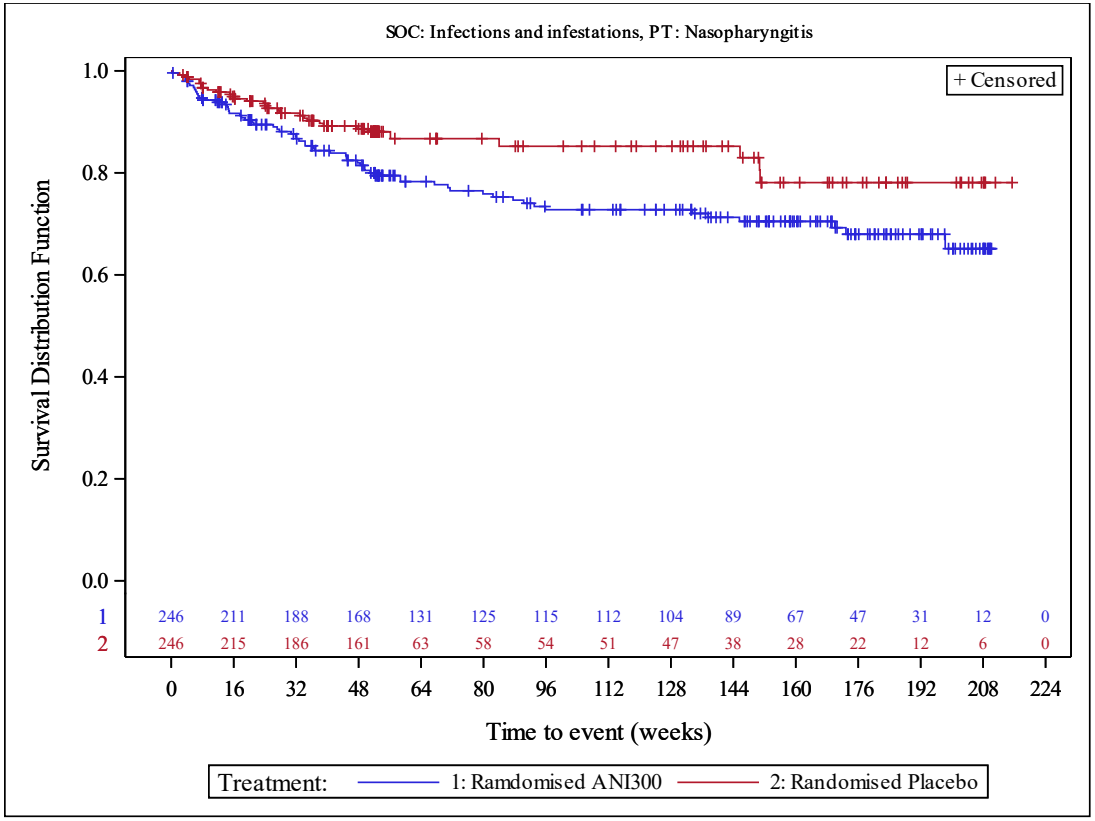

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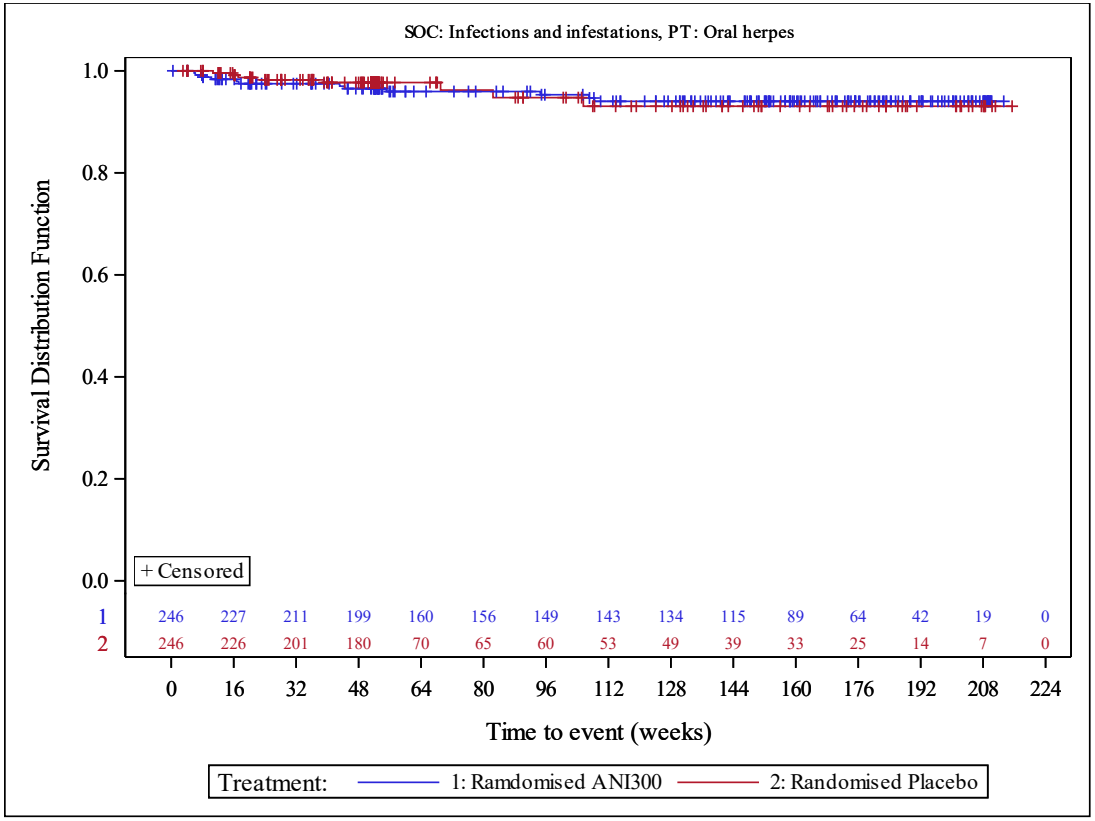

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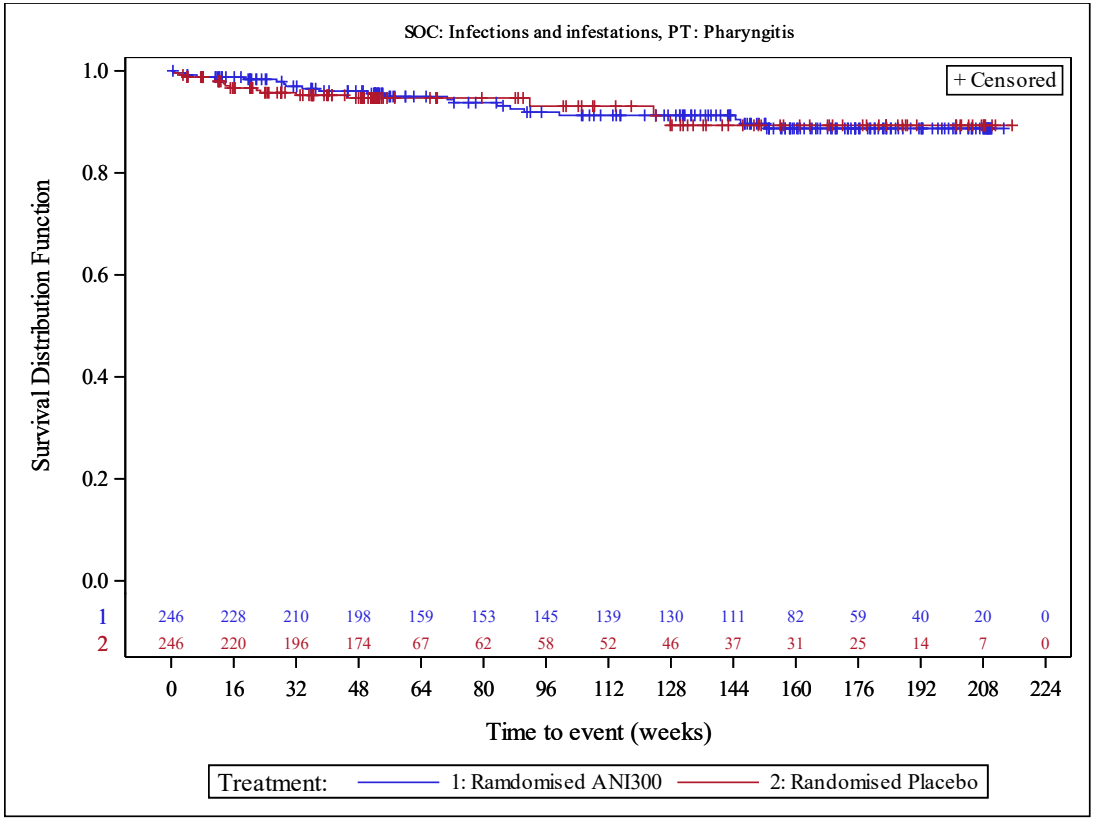

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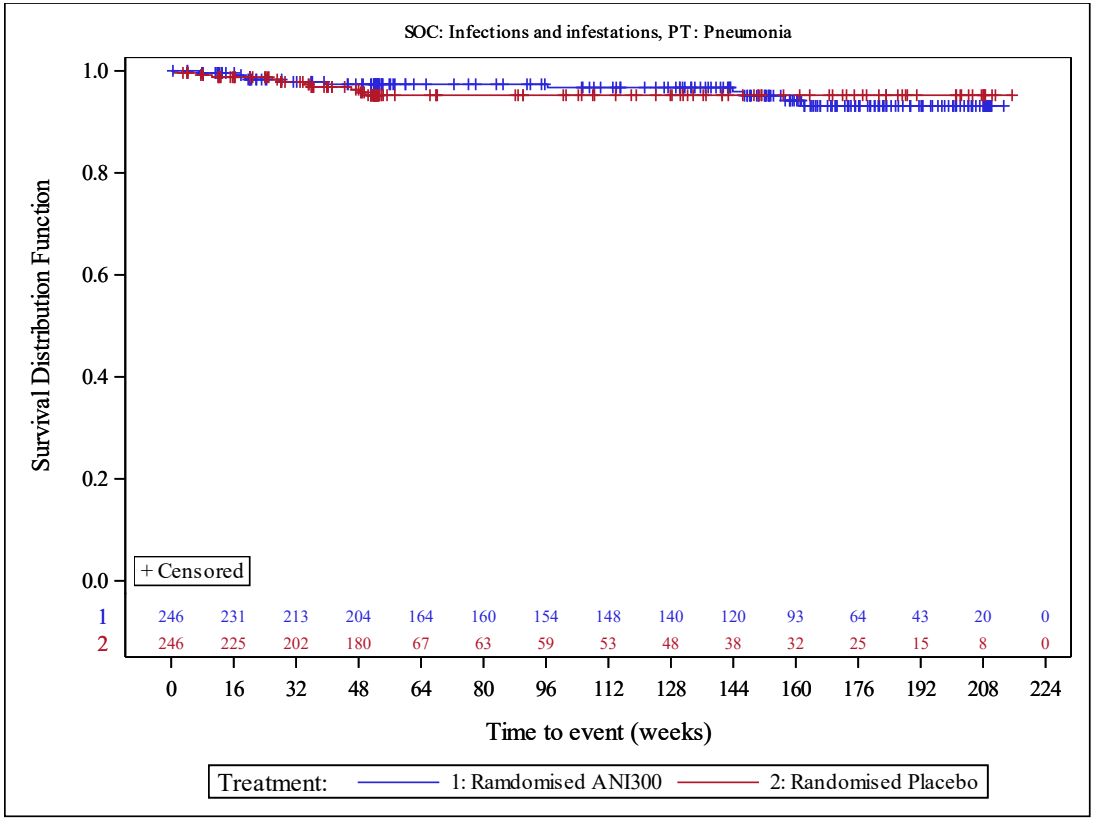

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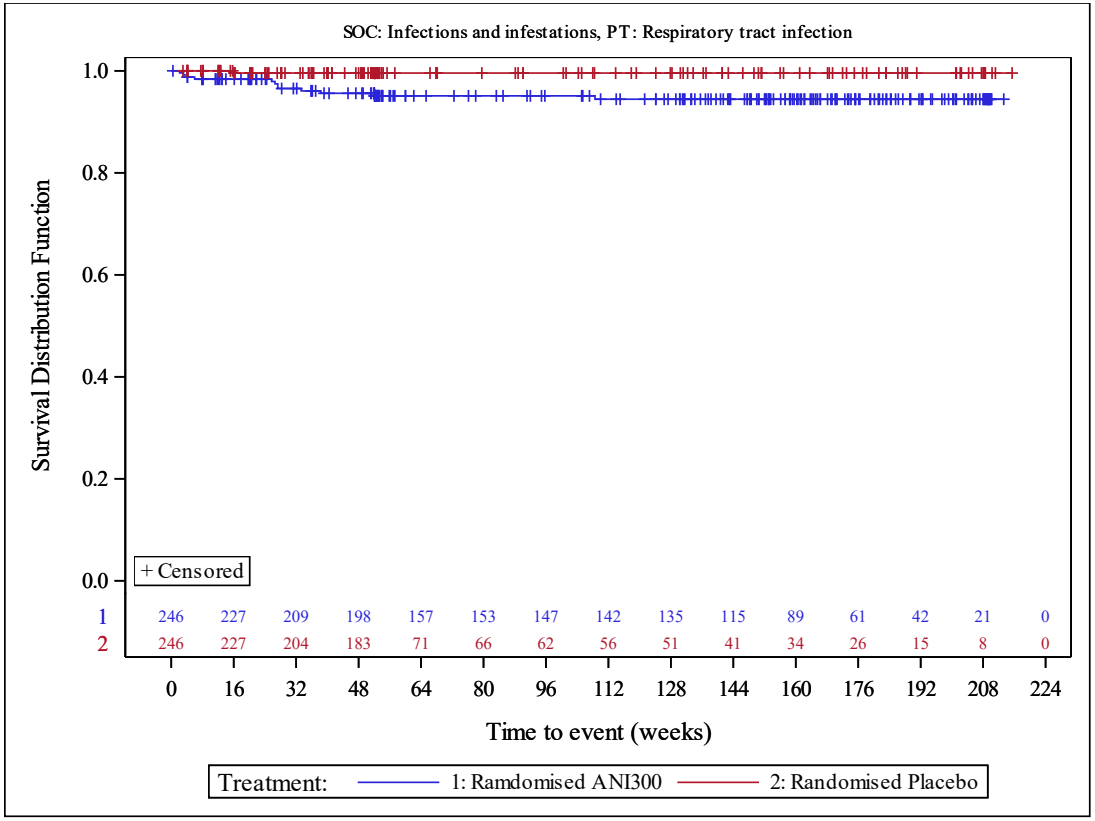

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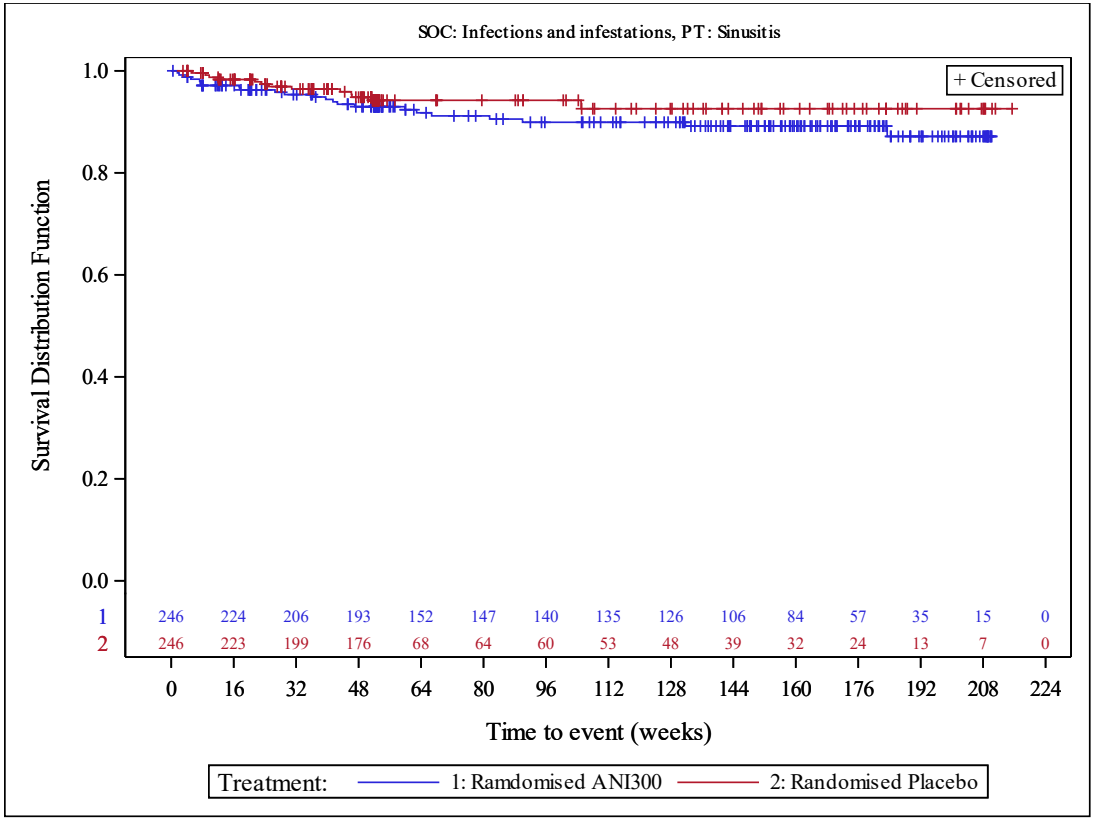

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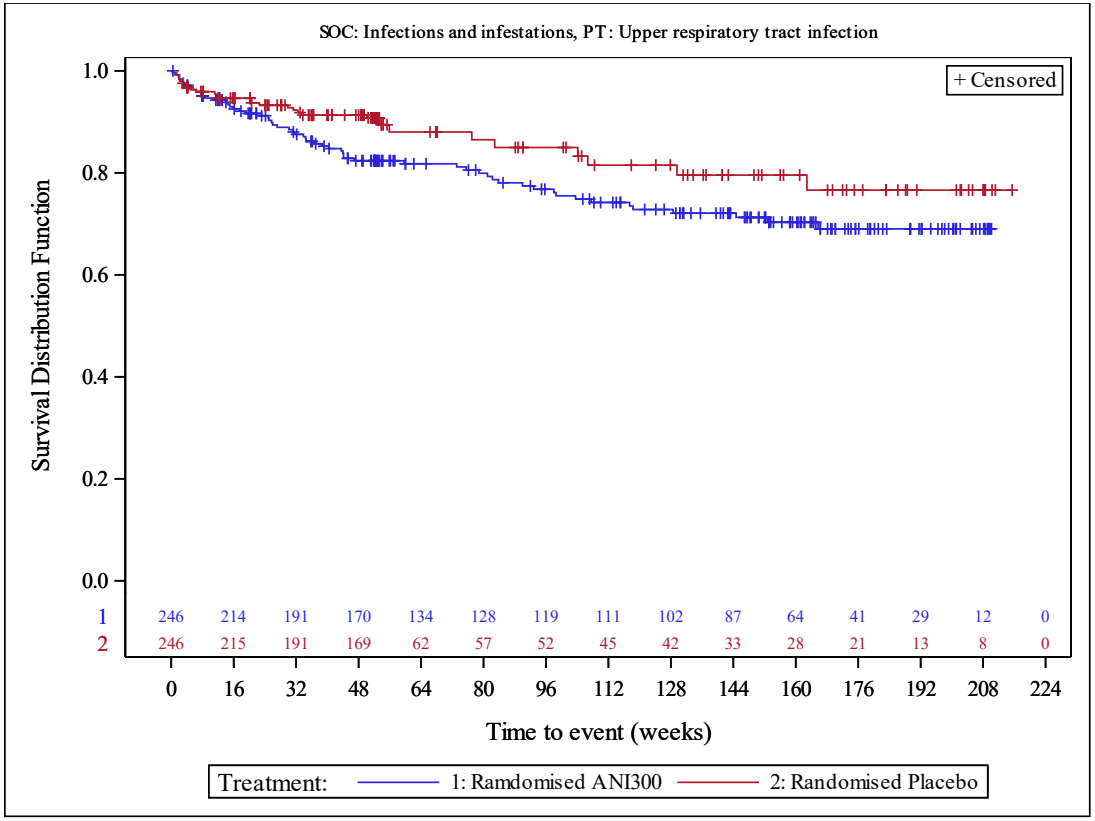

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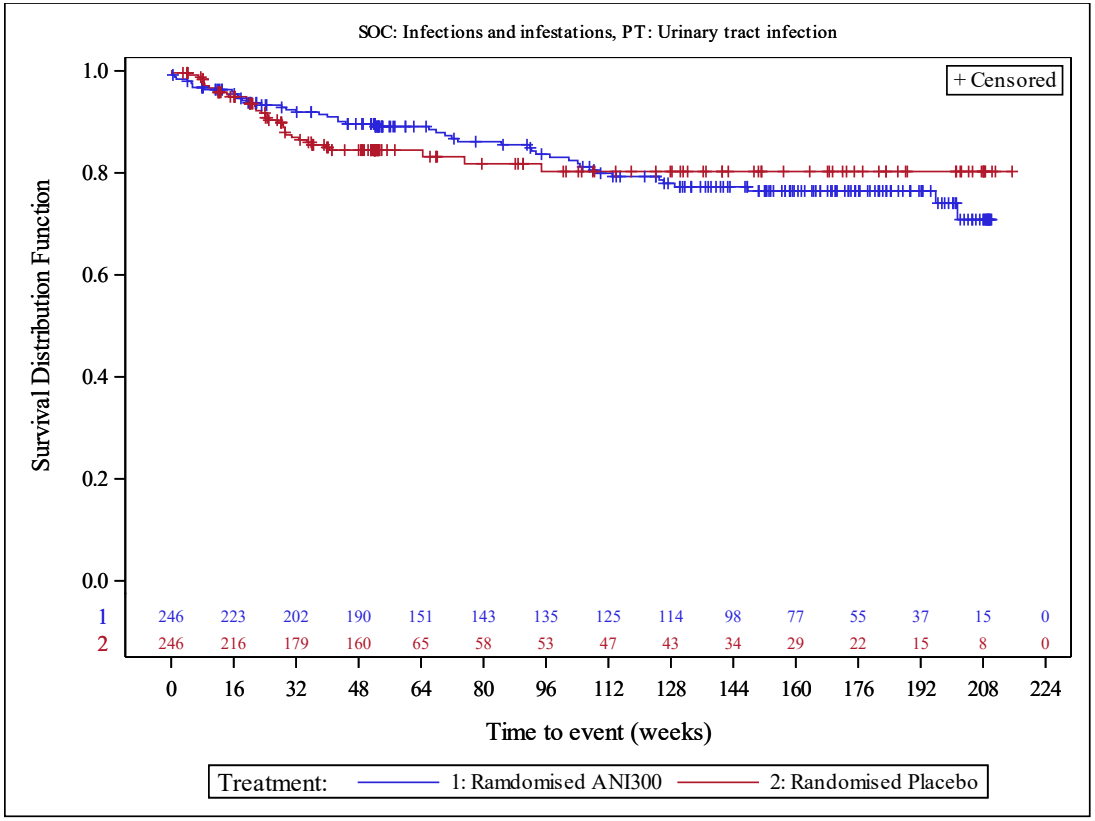

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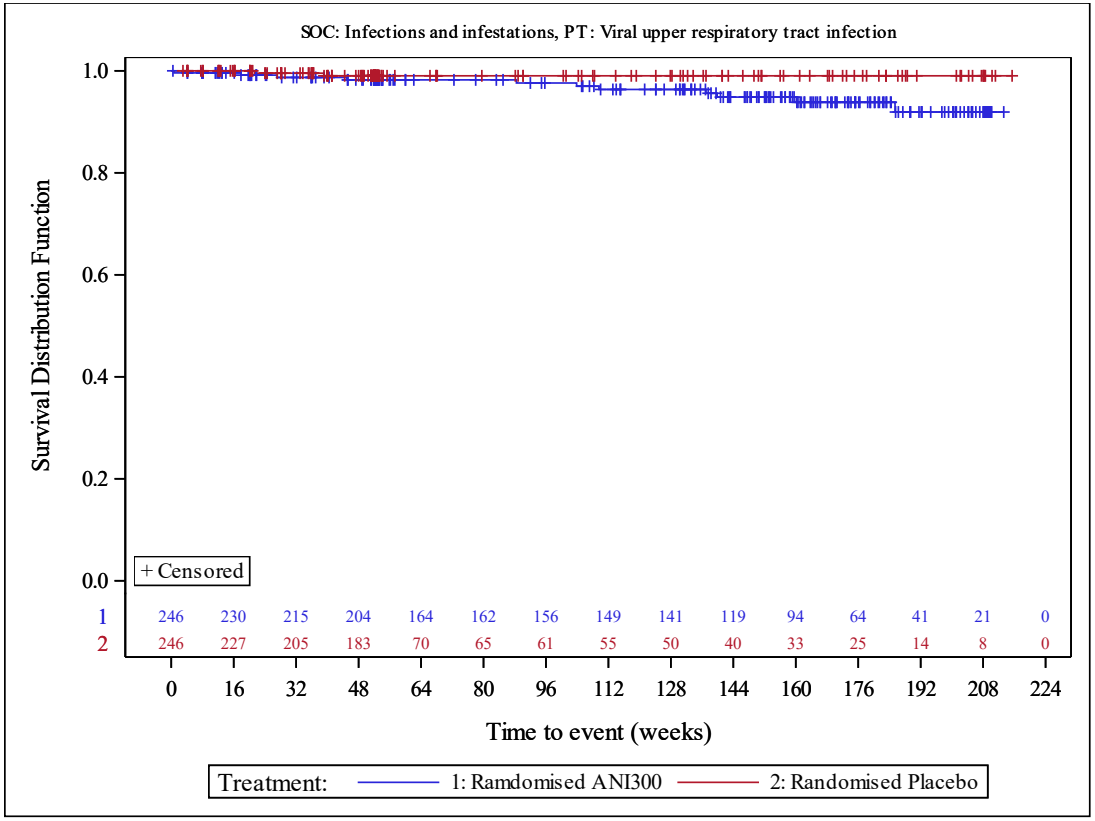

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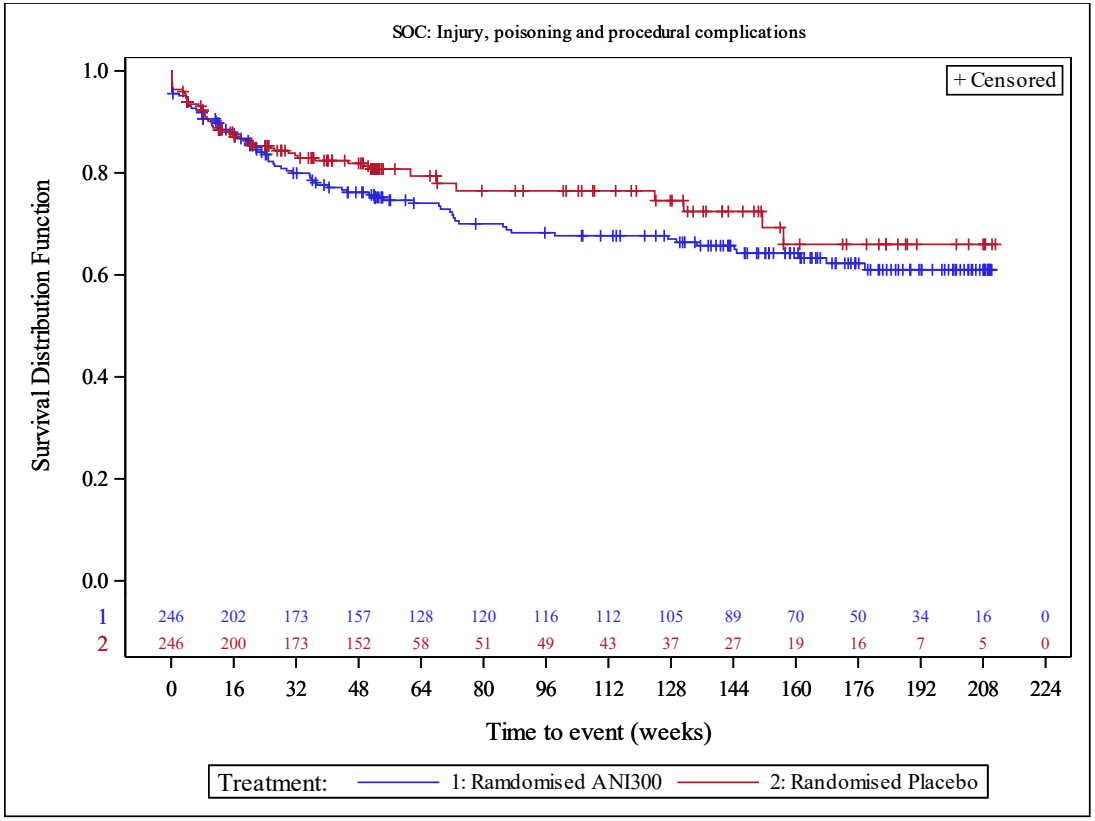

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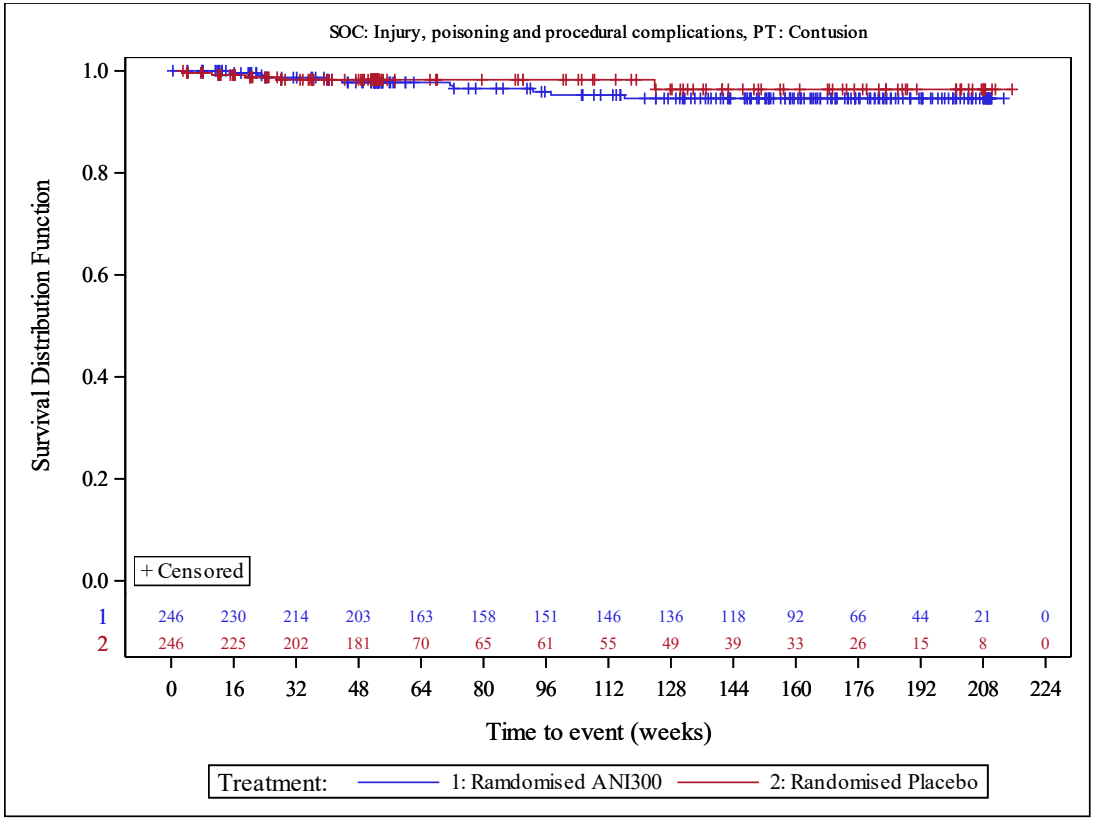

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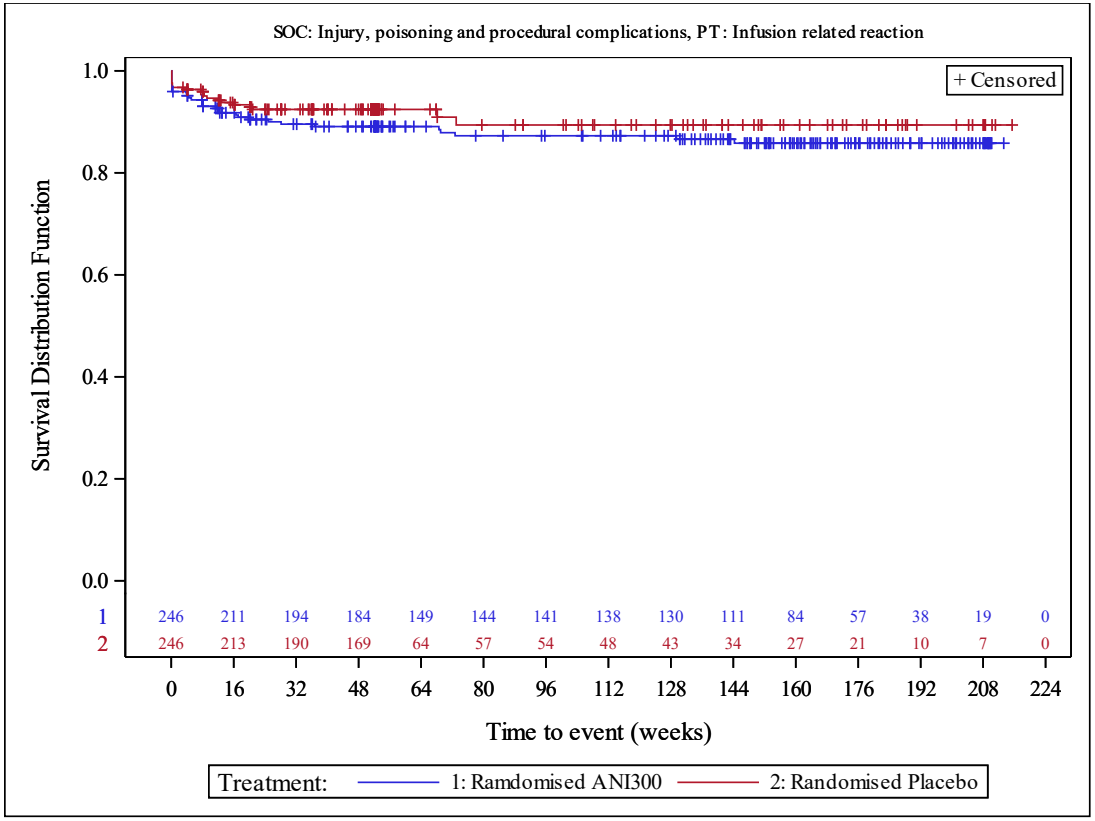

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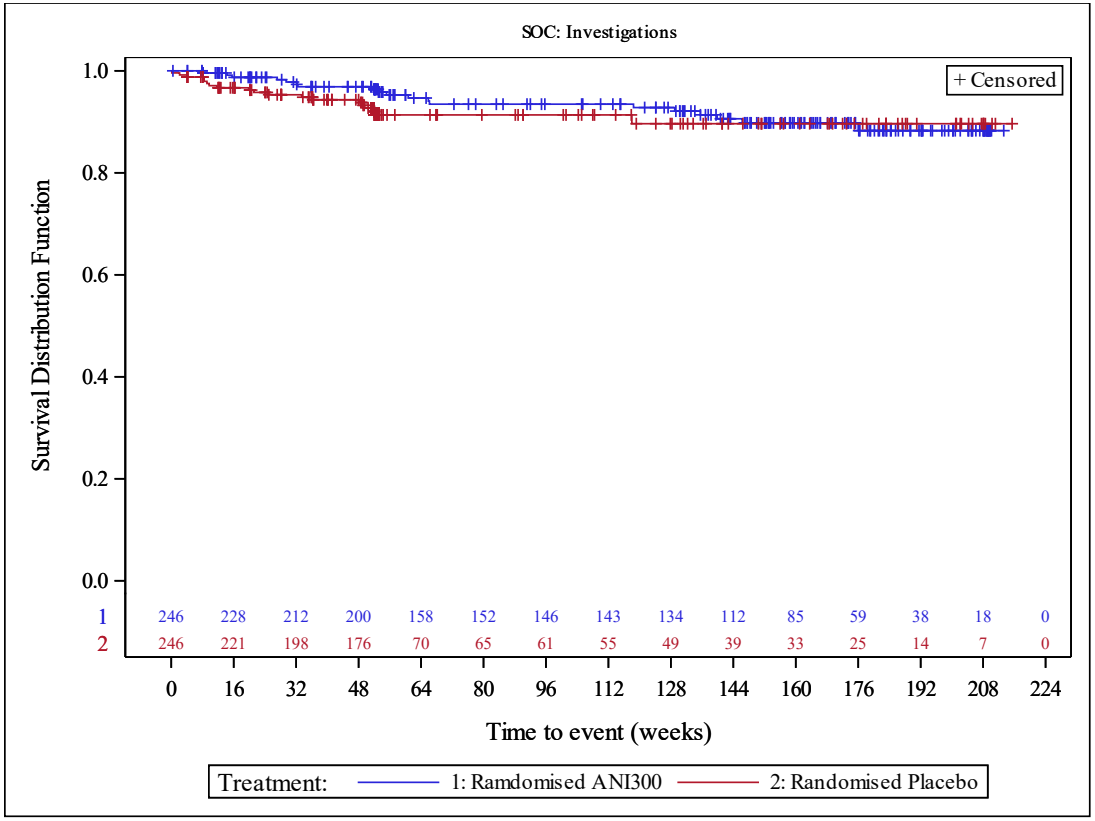

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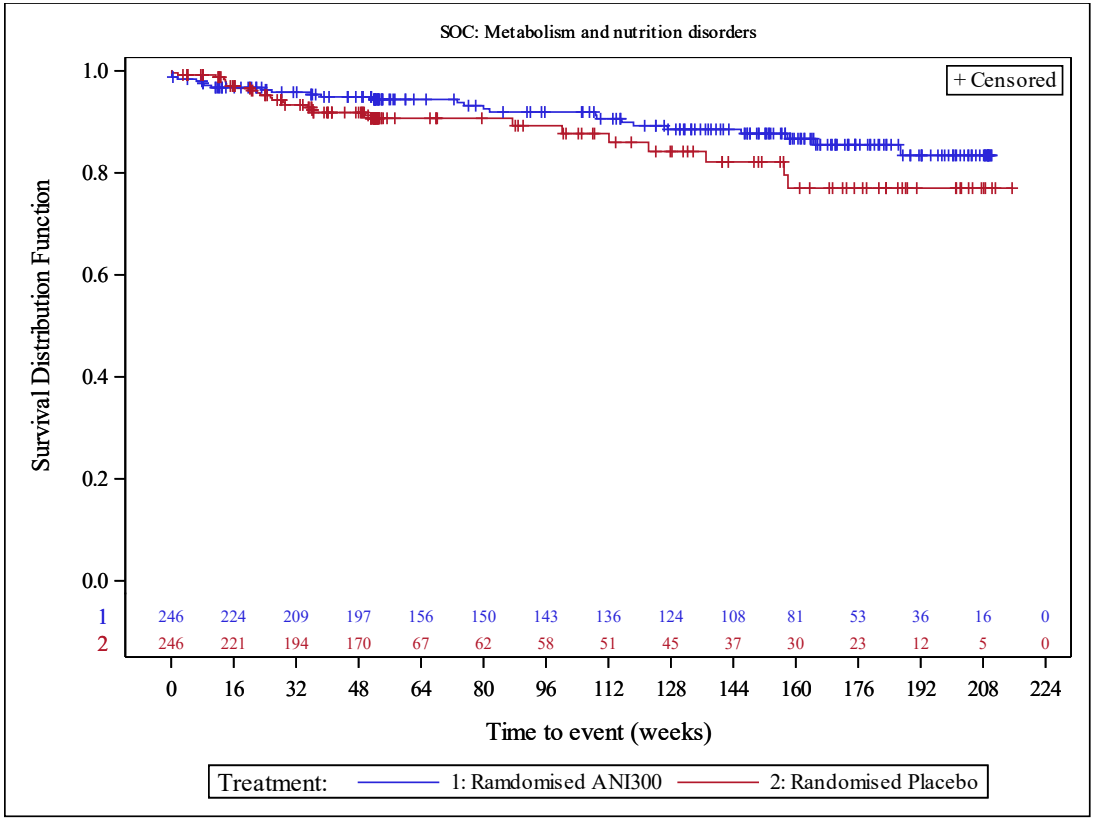

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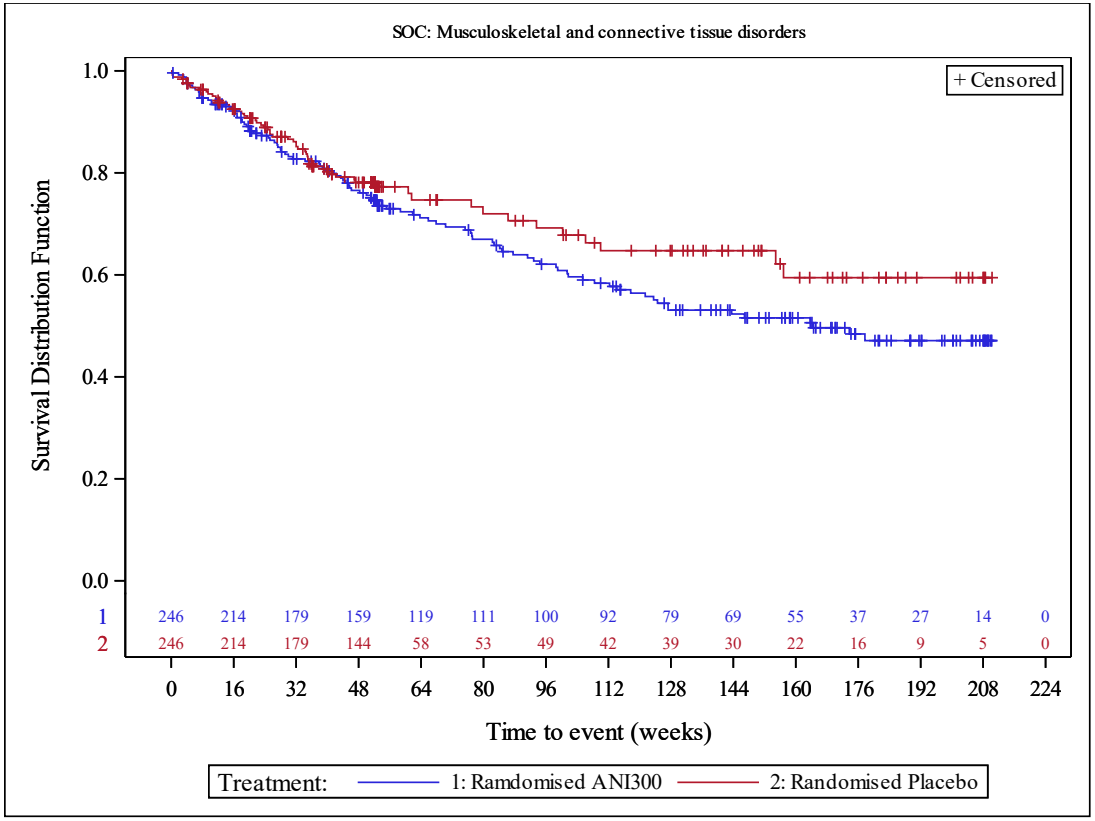

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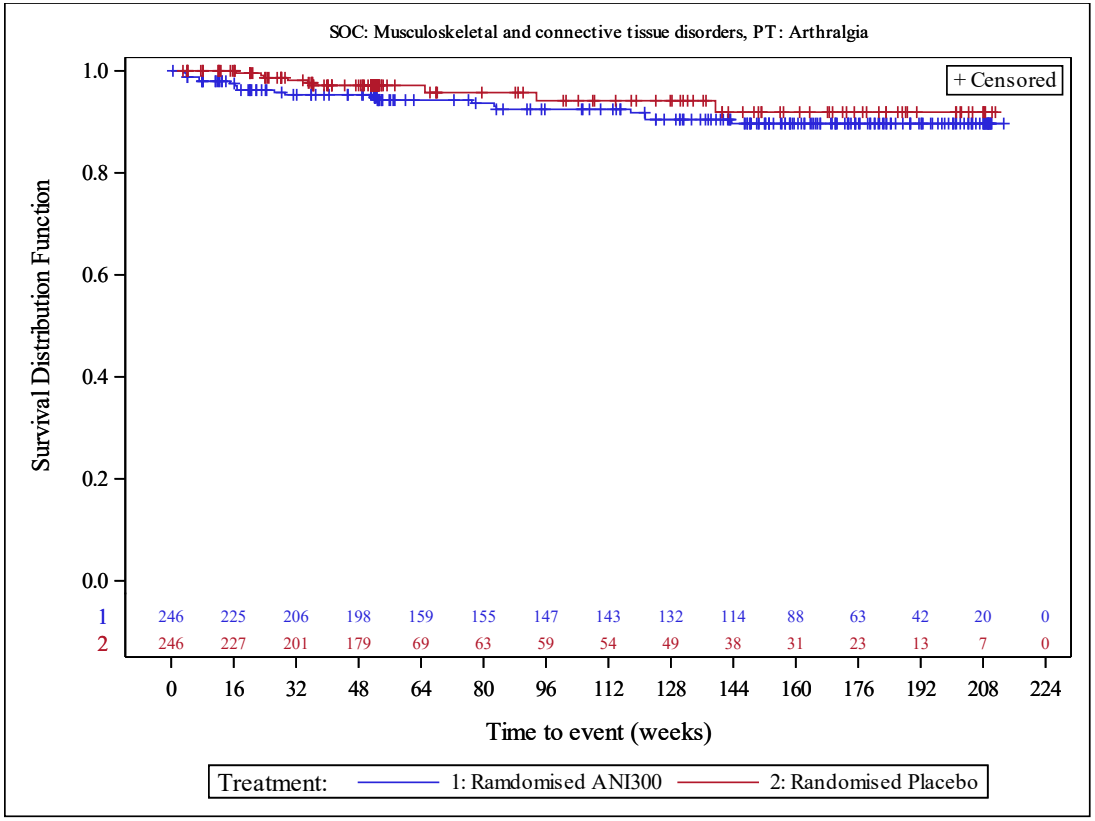

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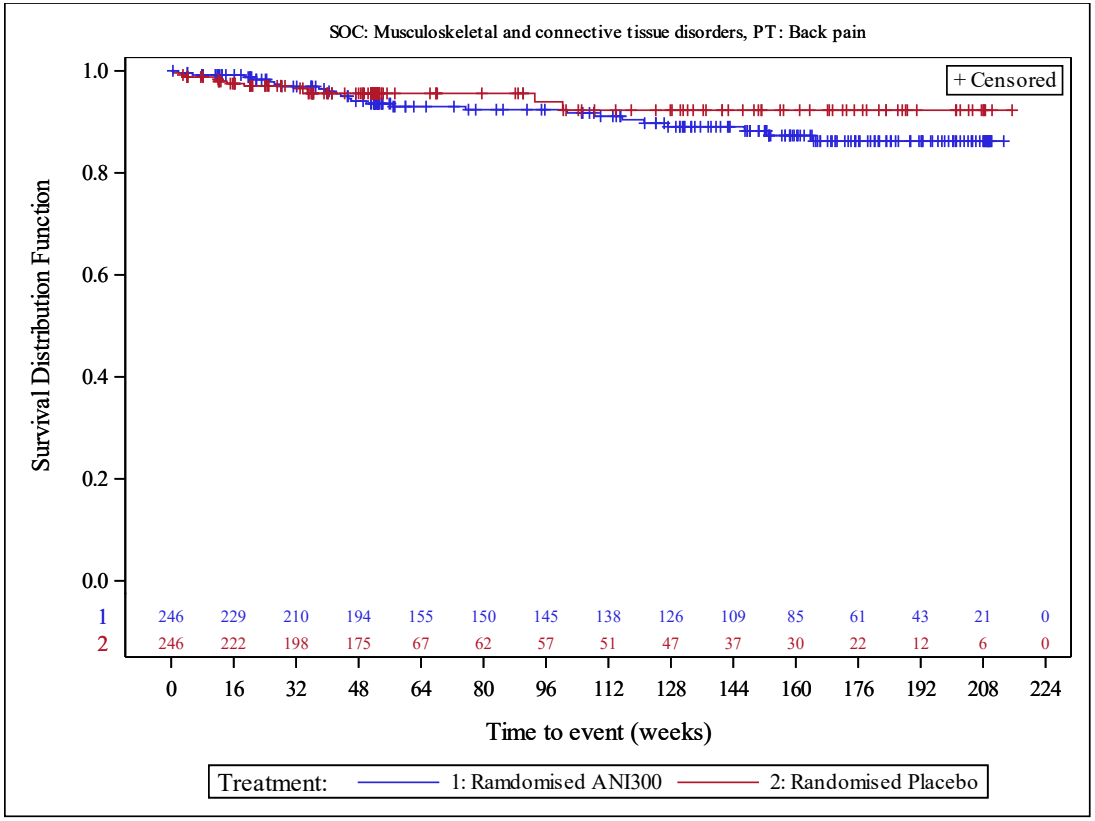

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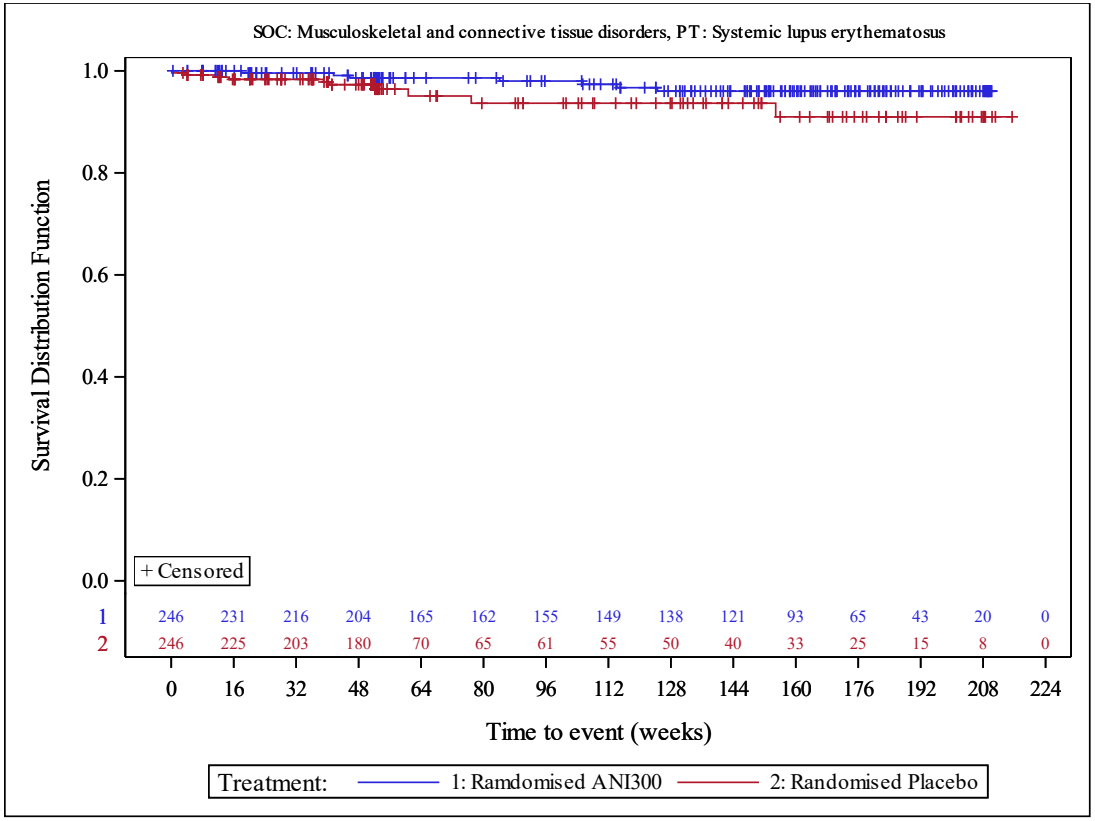

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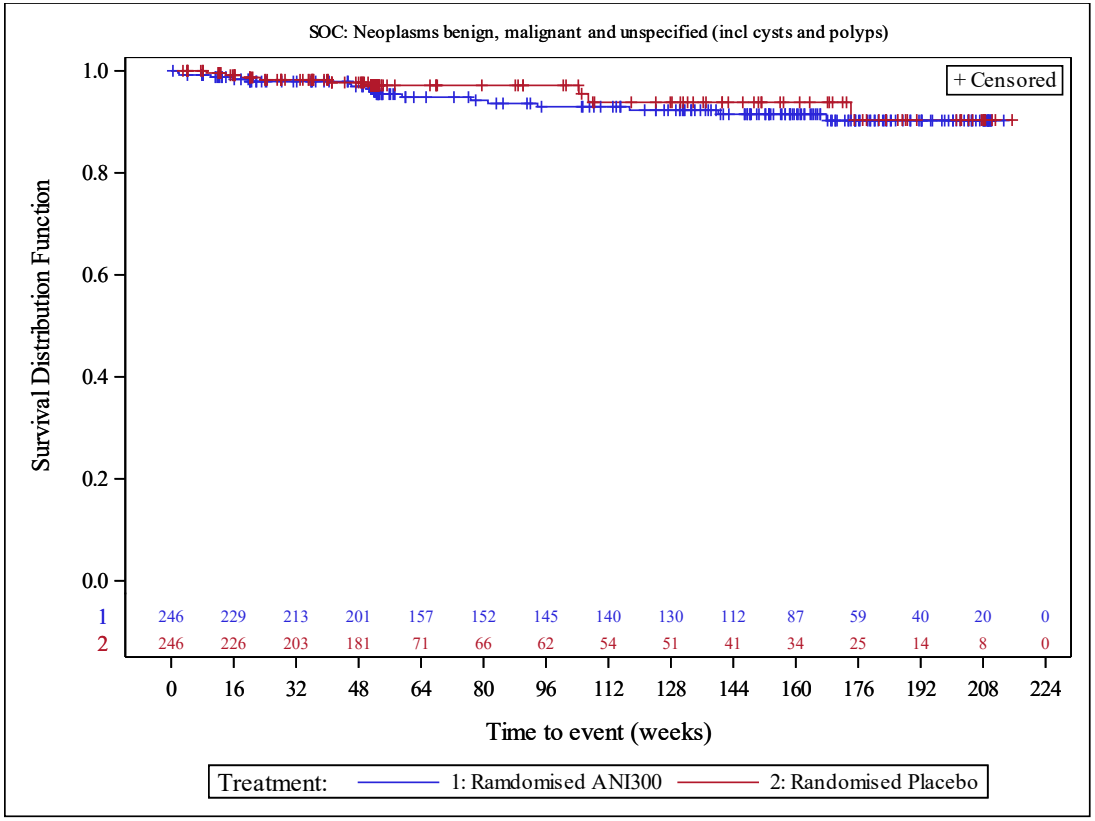

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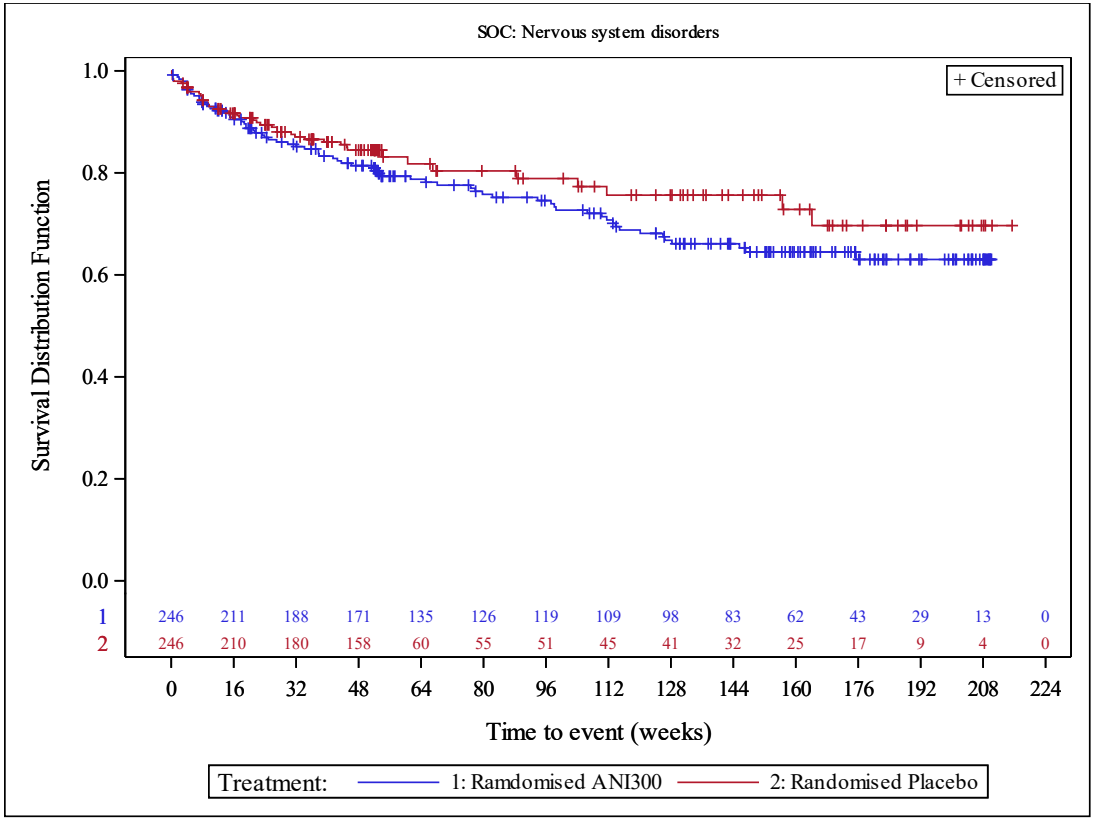

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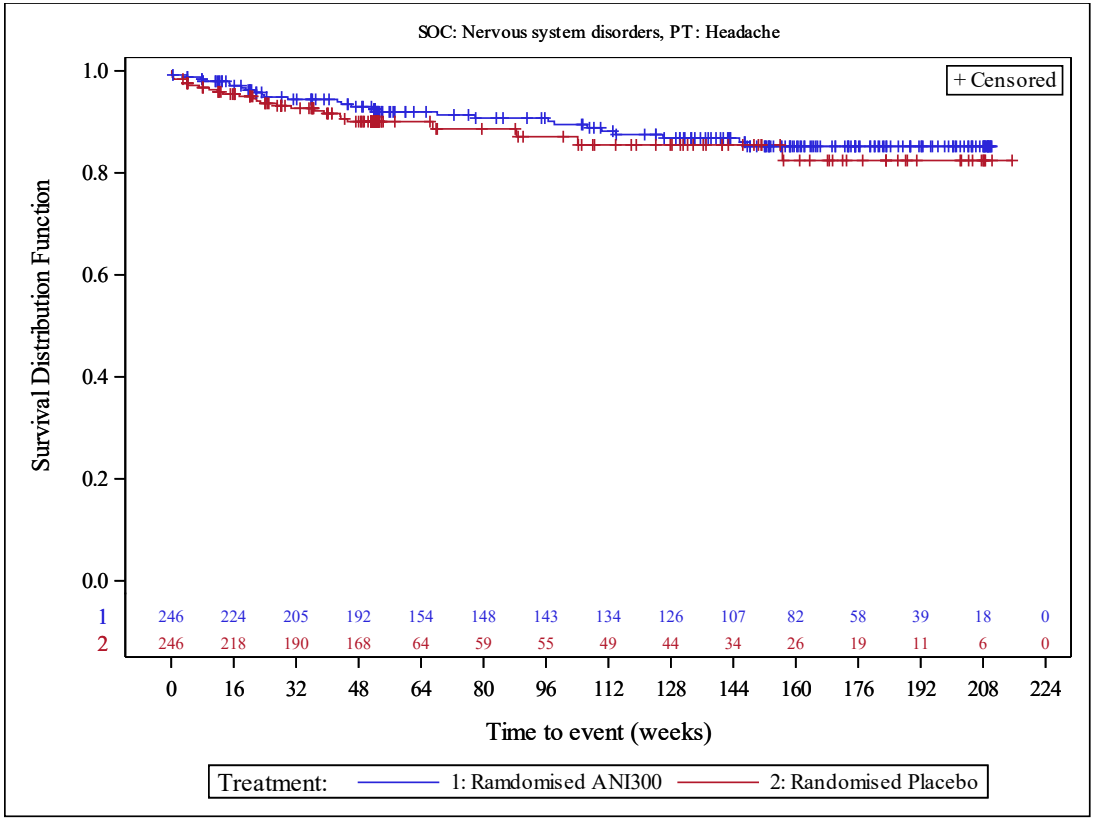

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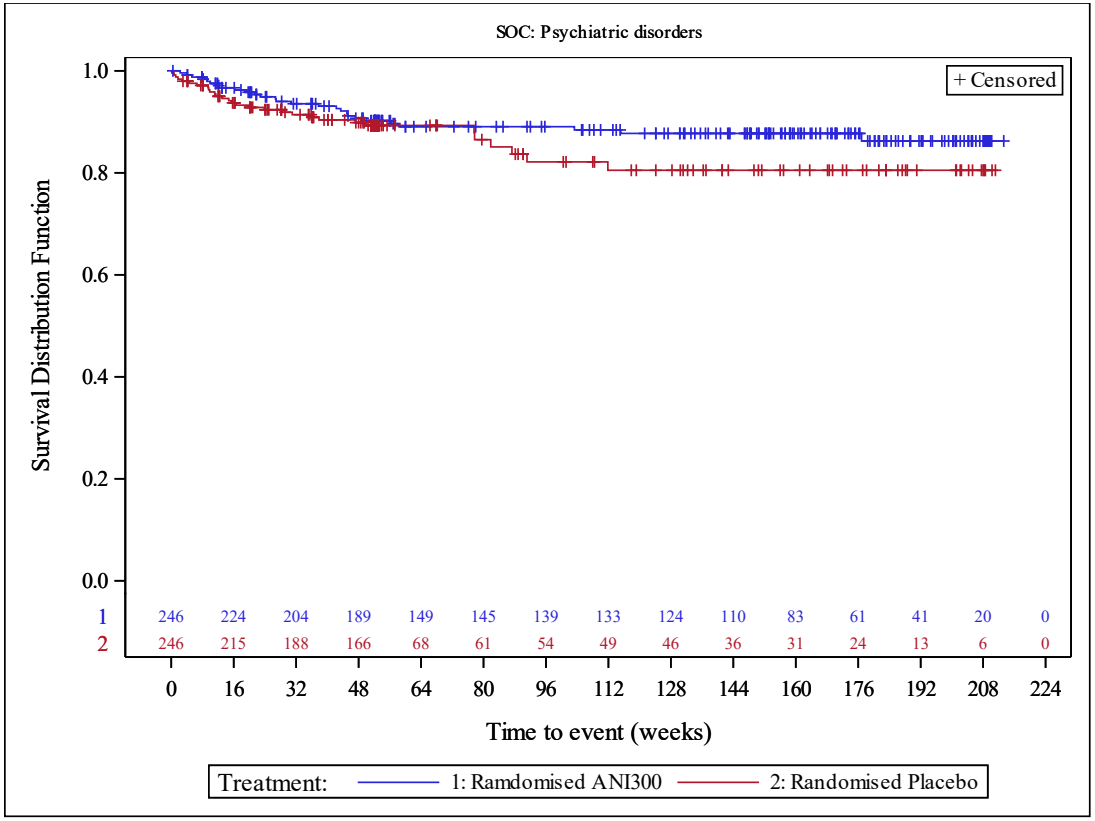

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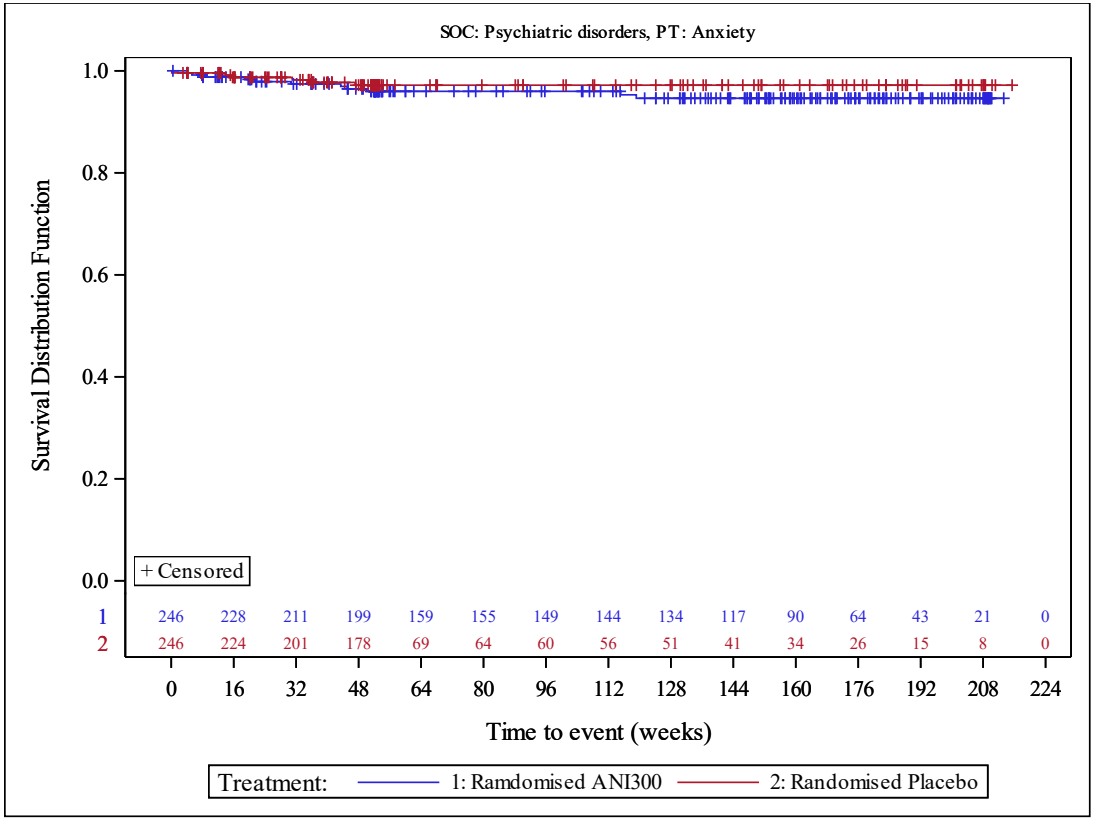

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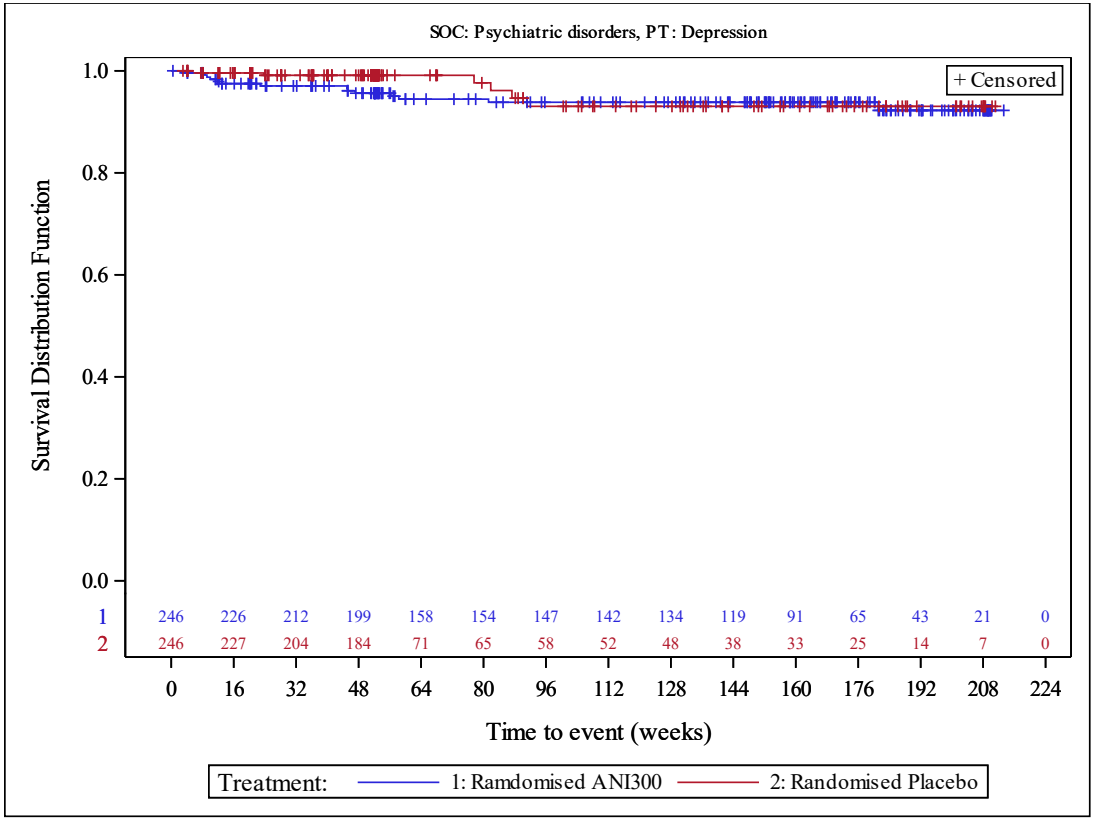

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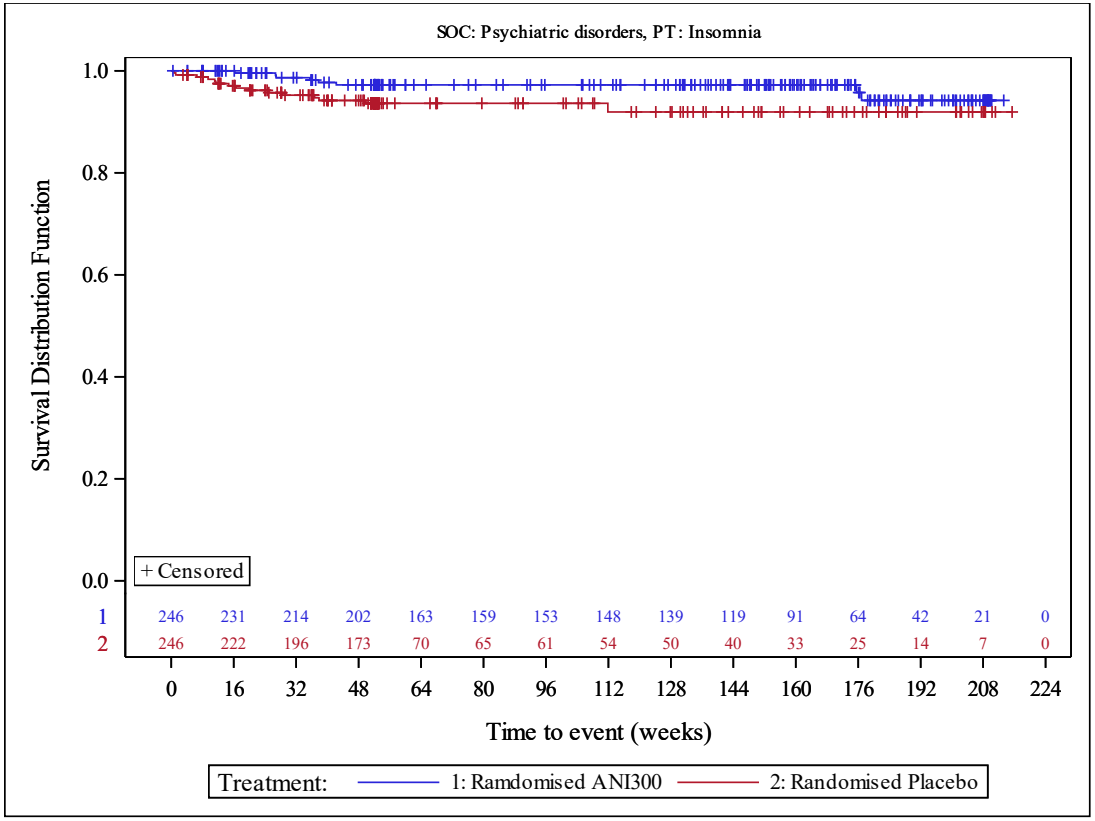

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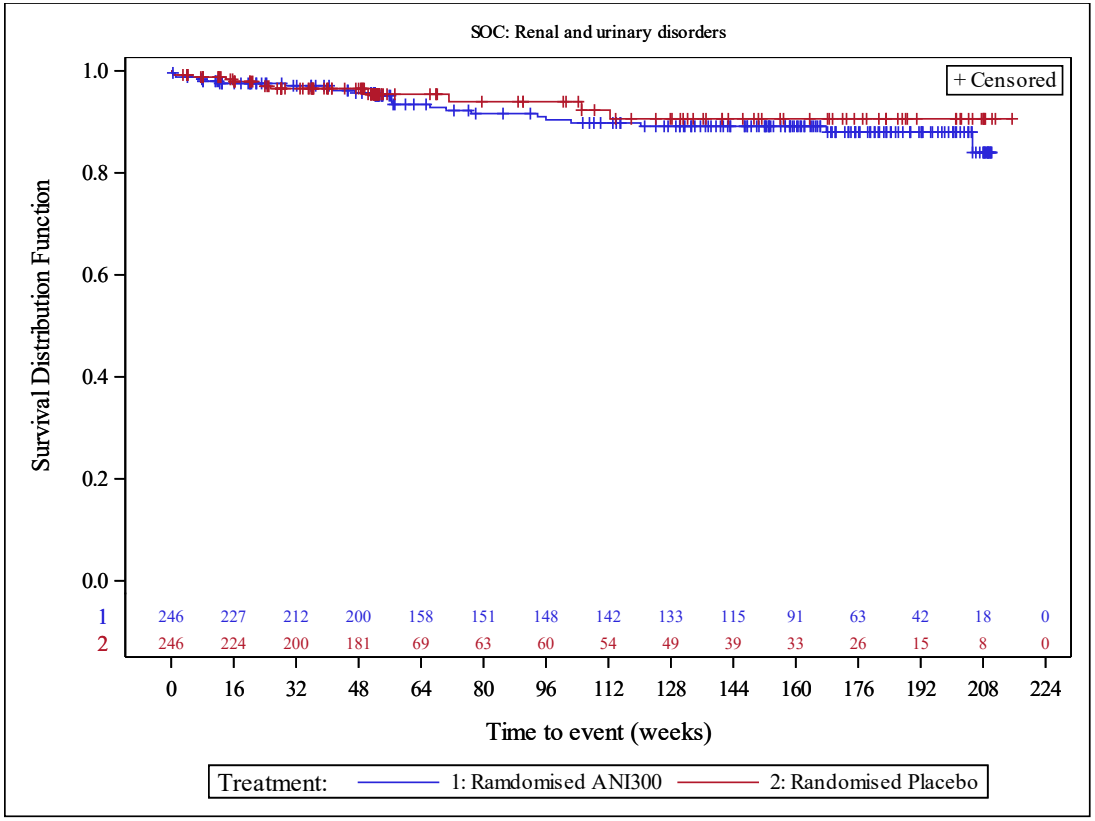

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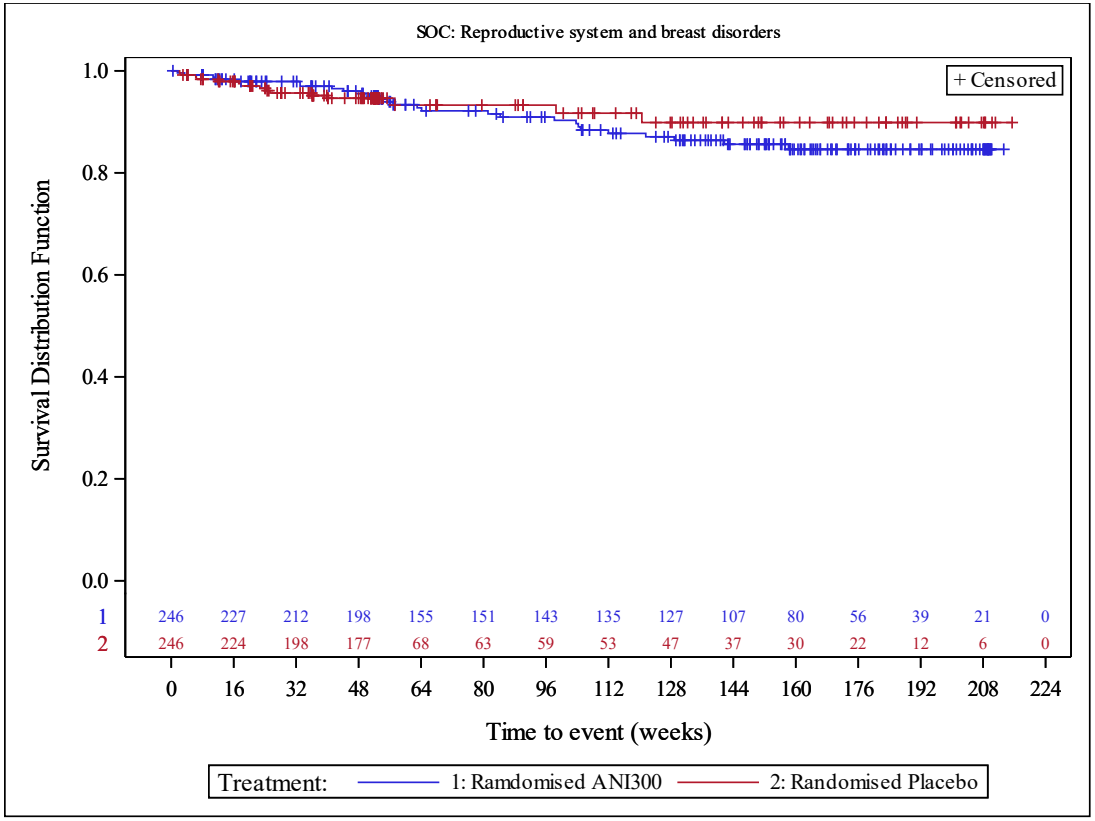

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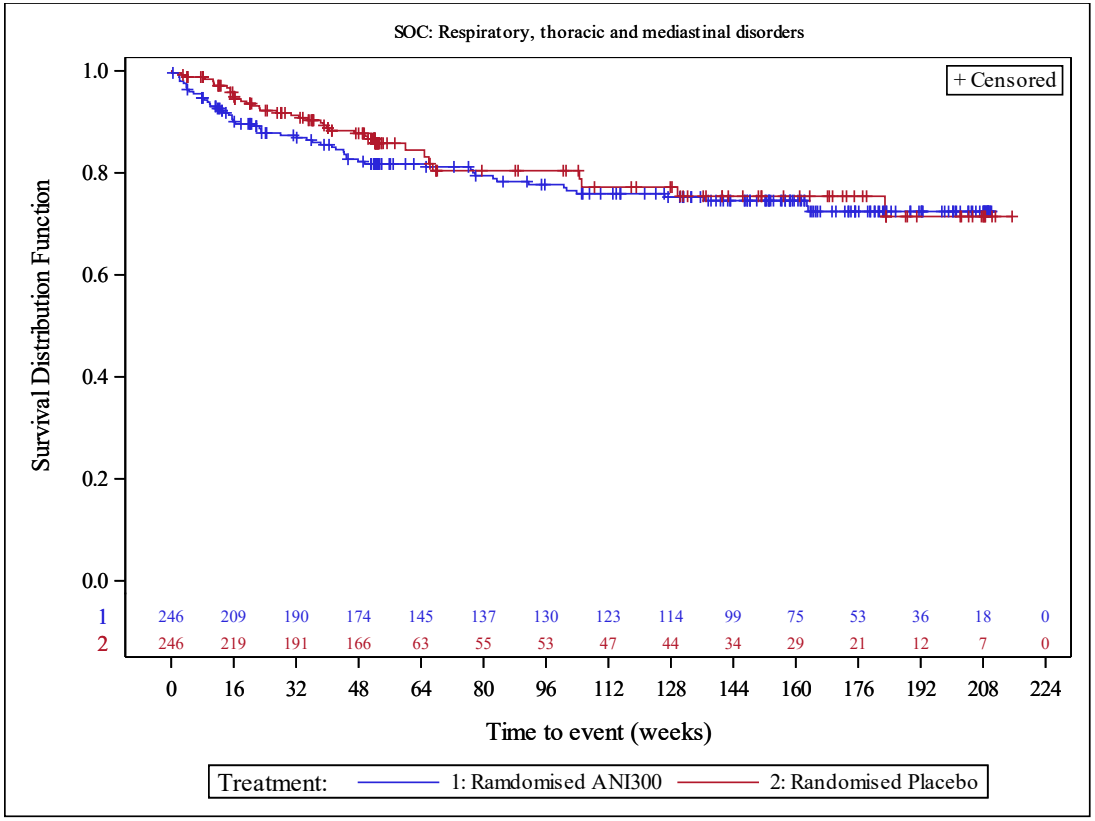

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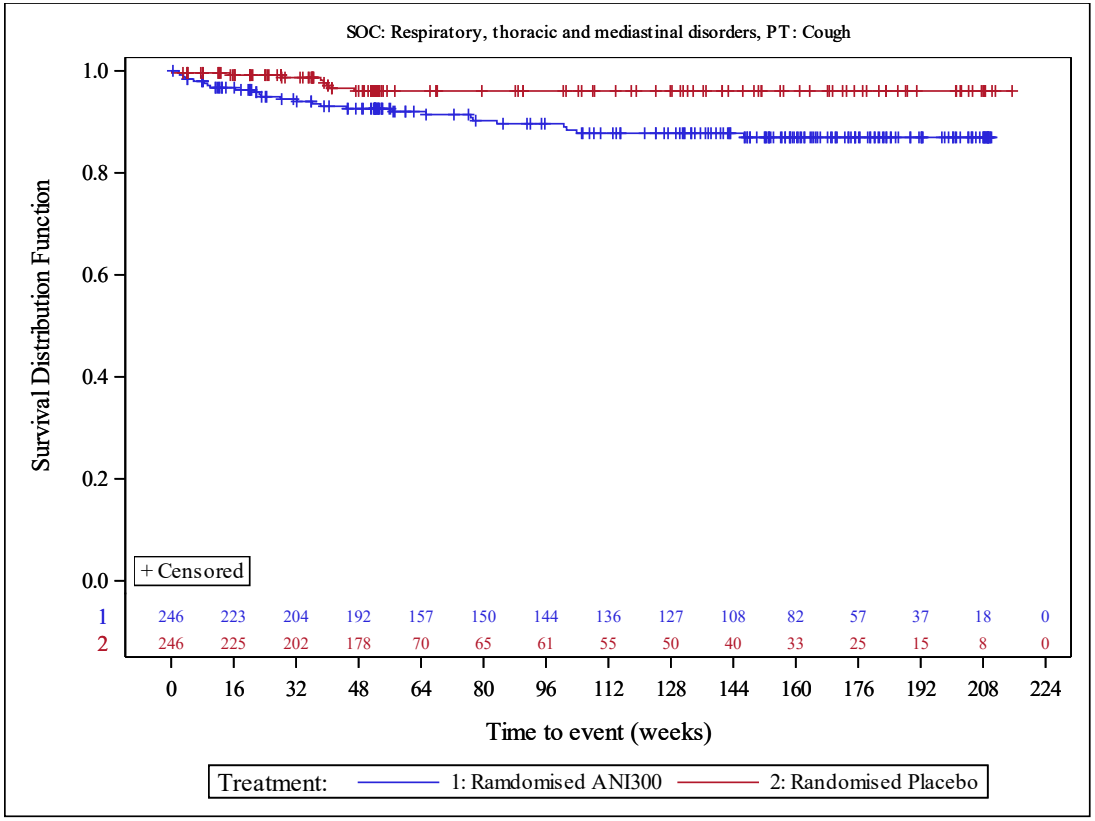
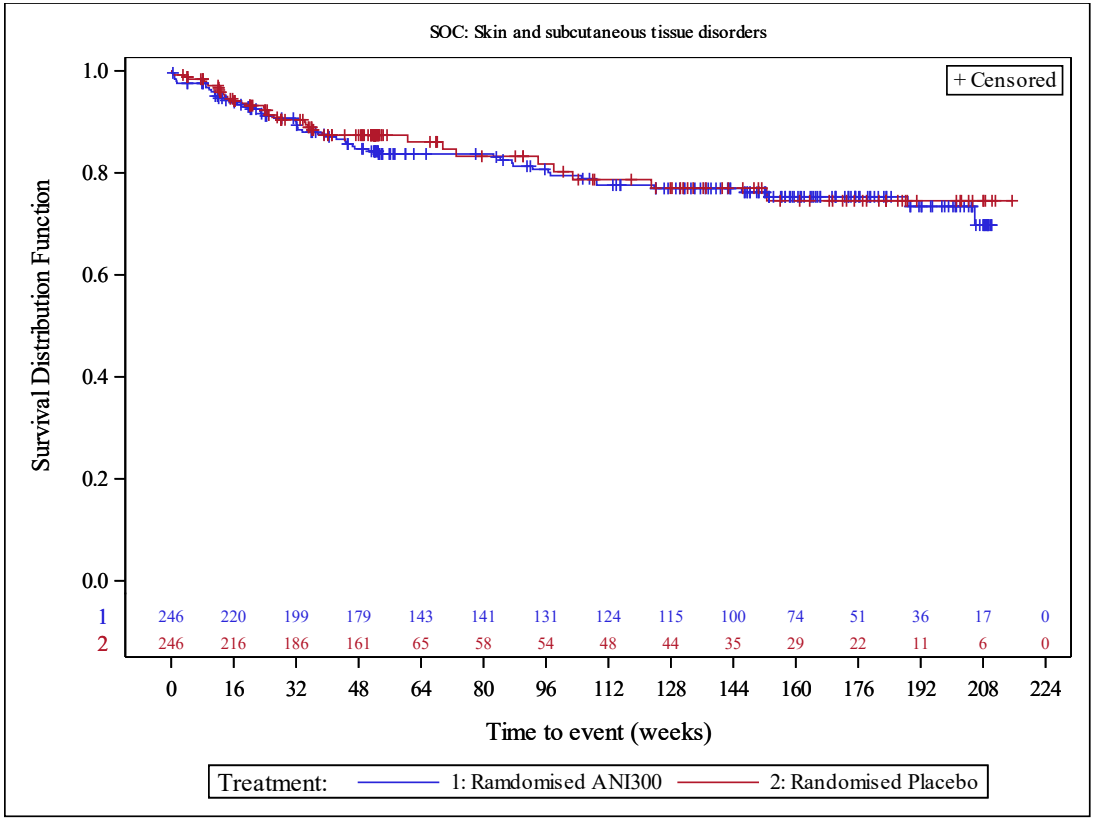


Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
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Anifrolumab (MEDI-546)
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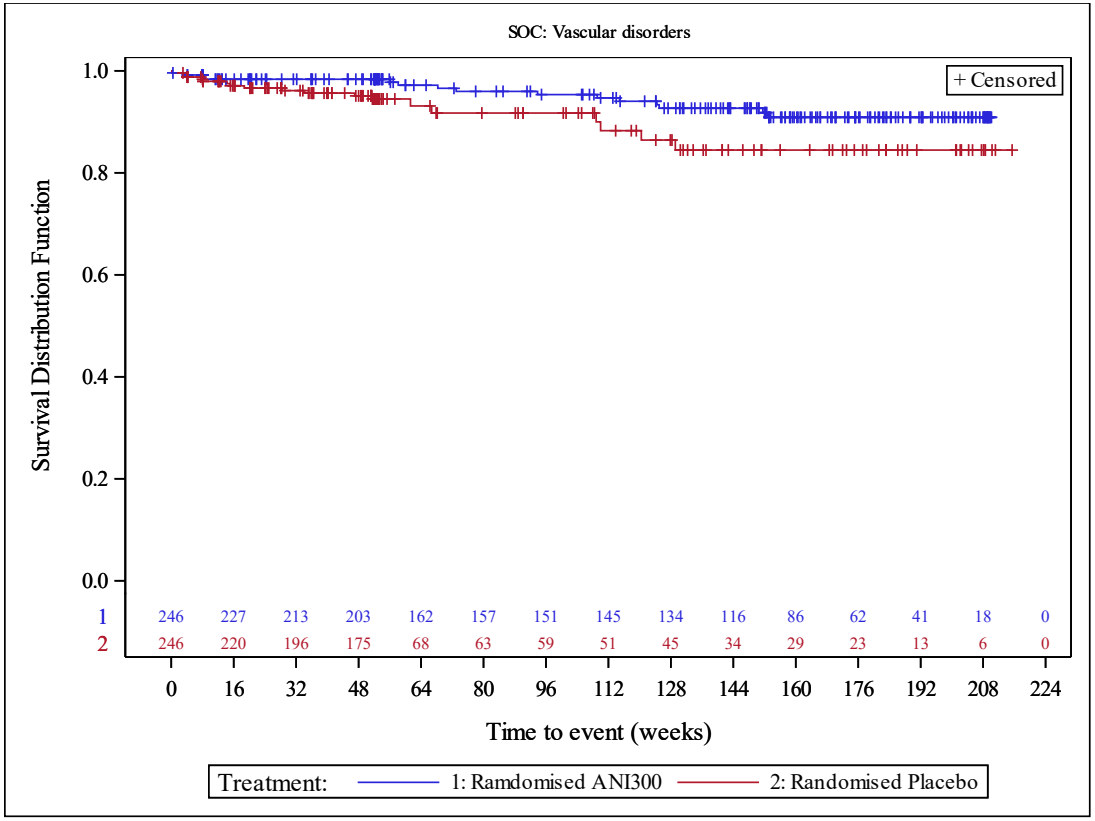
Full analysis set



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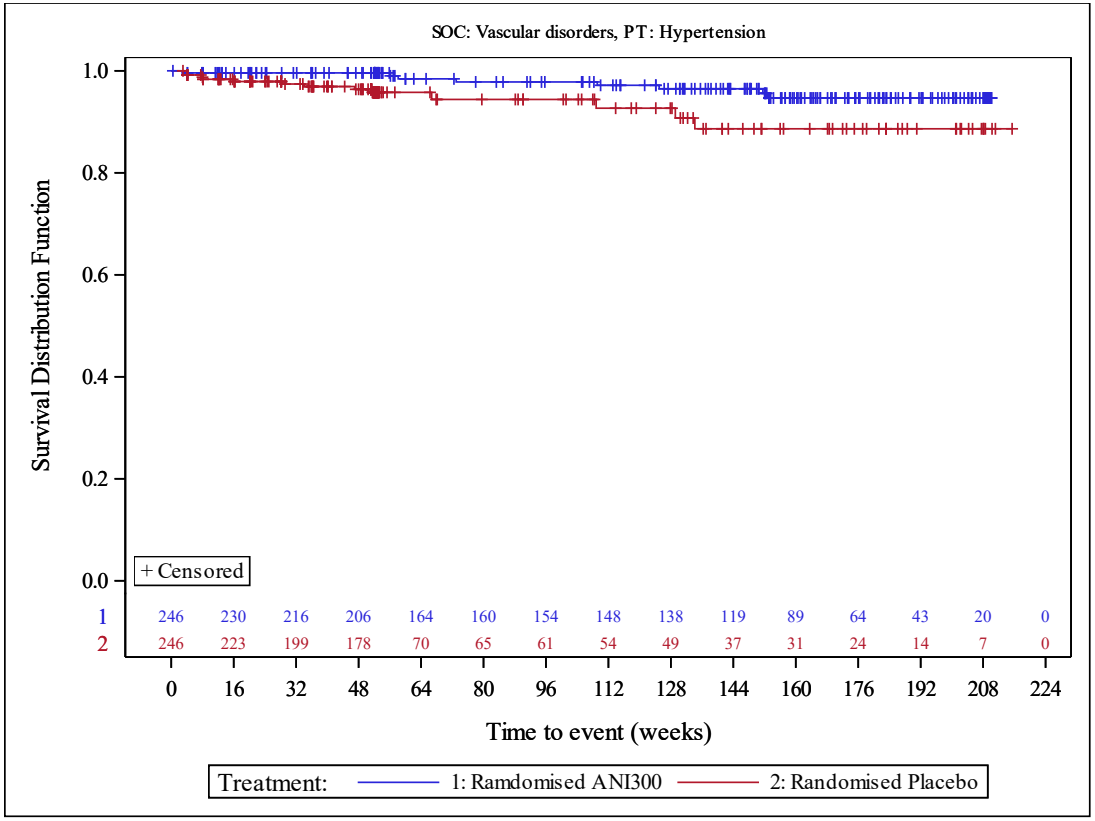
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Serious Adverse Events by SOC, PT during treatment (incidence in either arm >= 5% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Infections and infestations	Number of subjects with events, n (%)	18 (7.3)	19 (7.7)
	Number of censored subjects, n (%)	228 (92.7)	227 (92.3)
	Exposure years	564.2	336.4
	EAIR per 100 PY	3.2	5.6
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.63 (0.33, 1.22)	
	p-value	0.1687	
	Relative Risk (95% CI)	0.95 (0.51, 1.76)	
	p-value	0.8643	
	Odds Ratio (95% CI)	0.94 (0.48, 1.84)	
	p-value	0.8643	
	Risk Difference (95% CI)	-0.41 (-5.07, 4.25)	
	p-value	0.8643	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Serious Adverse Events by SOC, PT during treatment (incidence in either arm >= 5% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Musculoskeletal and connective tissue disorders	Number of subjects with events, n (%)	7 (2.8)	11 (4.5)
	Number of censored subjects, n (%)	239 (97.2)	235 (95.5)
	Exposure years	571.6	343.7
	EAIR per 100 PY	1.2	3.2
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.42 (0.16, 1.09)	
	p-value	0.0670	
	Relative Risk (95% CI)	0.64 (0.25, 1.61)	
	p-value	0.3413	
	Odds Ratio (95% CI)	0.63 (0.24, 1.64)	
	p-value	0.3407	
	Risk Difference (95% CI)	-1.63 (-4.94, 1.69)	
	p-value	0.3363	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Serious Adverse Events by SOC, PT during treatment (incidence in either arm >= 5% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Musculoskeletal and connective tissue disorders, PT: Systemic lupus erythematosus	Number of subjects with events, n (%)	2 (0.8)	10 (4.1)
	Number of censored subjects, n (%)	244 (99.2)	236 (95.9)
	Exposure years	579.0	344.2
	EAIR per 100 PY	0.3	2.9
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.14 (0.03, 0.64)	
	p-value	0.0035	
	Relative Risk (95% CI)	0.20 (0.04, 0.90)	
	p-value	0.0364	
	Odds Ratio (95% CI)	0.19 (0.04, 0.89)	
	p-value	0.0352	
	Risk Difference (95% CI)	-3.25 (-5.96, -0.54)	
	p-value	0.0187	

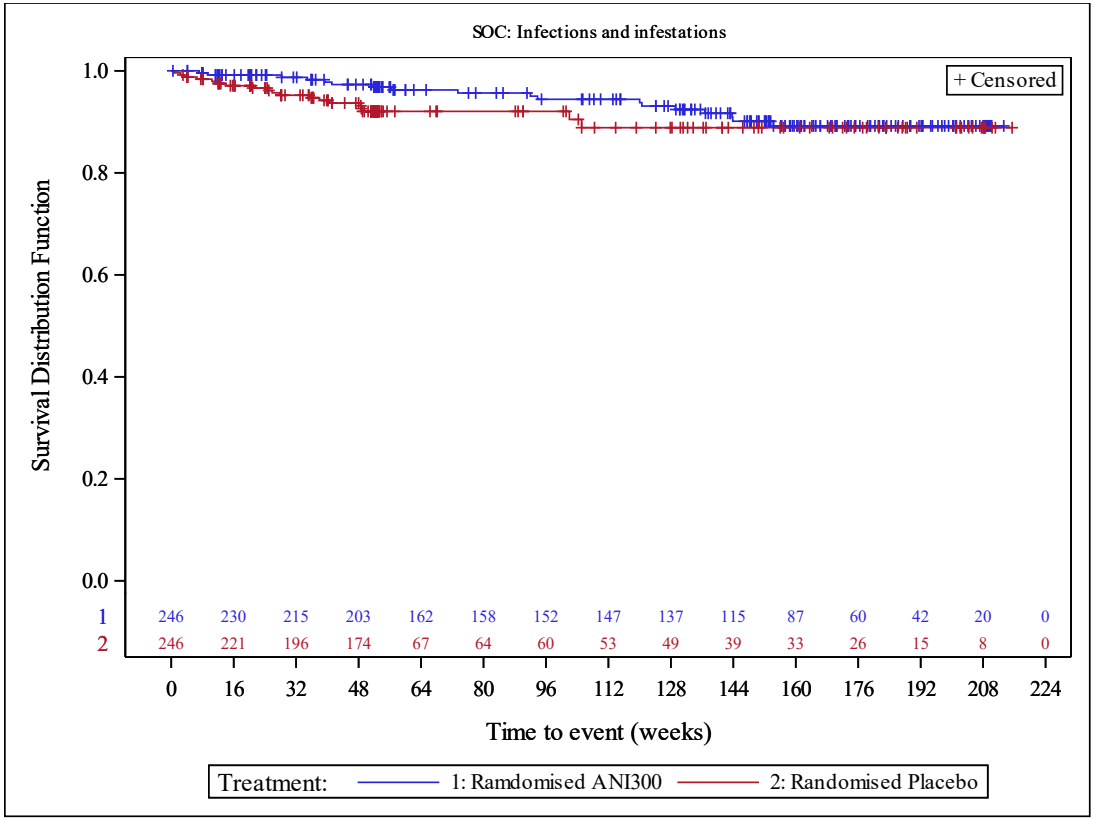
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Serious Adverse Events by SOC, PT during treatment (incidence in either arm >= 5% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Ramdomised ANI300 (N=246) n/ N (%)	Ramdomised ANI300 (N=246) Median (95% CI)	Randomised Placebo (N=246) n/ N (%)	Randomised Placebo (N=246) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
SOC: Musculoskeletal and connective tissue disorders, PT: Systemic lupus erythematosus	Age (years)							0.9996
	<= 65	2/239 (0.8)	NE (NE, NE)	10/243 (4.1)	NE (NE, NE)	0.14 (0.03, 0.65)	0.0038	
	> 65	0/ 7 (0.0)	NE (NE, NE)	0/ 3 (0.0)	NE (NE, NE)	NE		
	Sex							0.9930
	male	0/ 23 (0.0)	NE (NE, NE)	1/ 20 (5.0)	NE (NE, NE)	NE		
	female	2/223 (0.9)	NE (NE, NE)	9/226 (4.0)	NE (NE, NE)	0.15 (0.03, 0.71)	0.0064	
	Geographic region							0.9923
	EU	0/ 92 (0.0)	NE (NE, NE)	2/ 89 (2.2)	NE (NE, NE)	NE		
	non-EU	2/154 (1.3)	NE (NE, NE)	8/157 (5.1)	NE (NE, NE)	0.19 (0.04, 0.92)	0.0227	
	SLEDAI-2K score at screening							0.9924
	< 10 points	0/ 80 (0.0)	NE (NE, NE)	2/ 69 (2.9)	NE (NE, NE)	NE		
	>= 10 points	2/166 (1.2)	NE (NE, NE)	8/177 (4.5)	NE (NE, NE)	0.19 (0.04, 0.91)	0.0212	

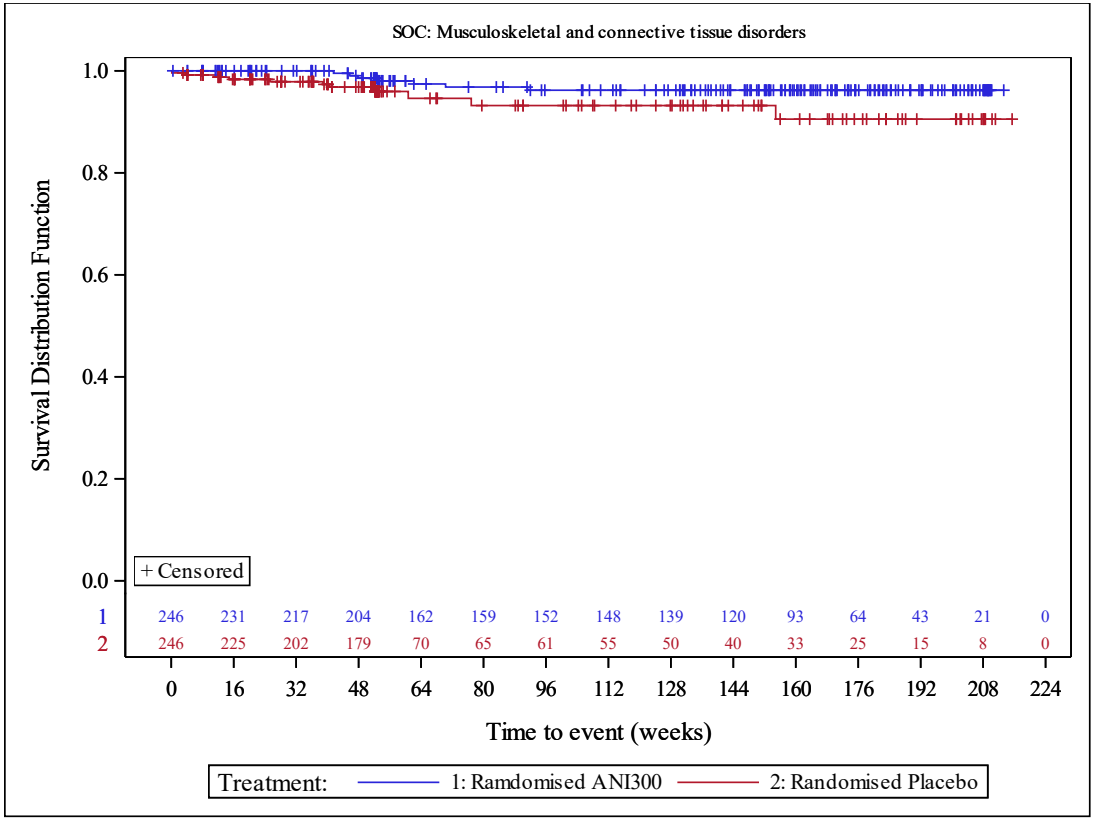
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of Incidence and time to first frequent Serious Adverse Events by SOC, PT during treatment (incidence in either arm >= 5% or >=10 patients)
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of Incidence and time to first frequent Serious Adverse Events by SOC, PT during treatment (incidence in either arm >= 5% or >=10 patients)
Full analysis set



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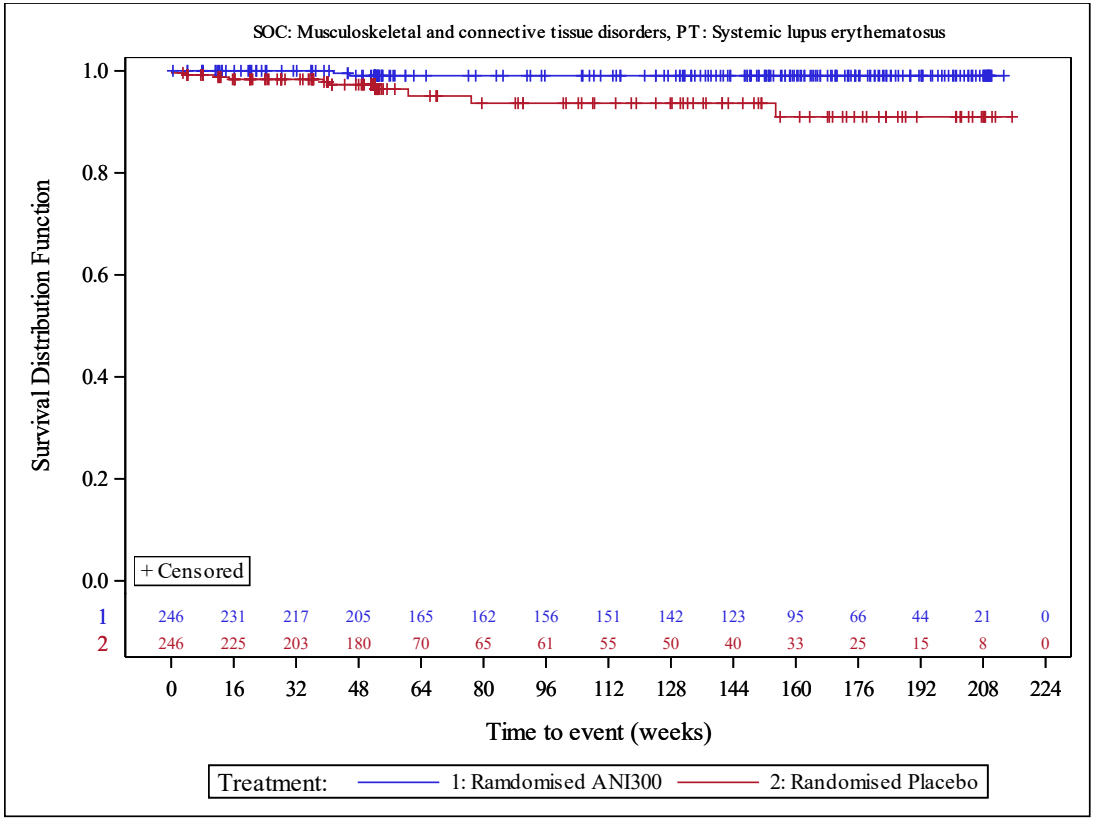
Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of Incidence and time to first frequent Serious Adverse Events by SOC, PT during treatment (incidence in either arm >= 5% or >=10 patients)
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Severe (Grade >=3) by SOC, PT during treatment (incidence in either arm >= 5% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=246)	Randomised Placebo (N=246)
SOC: Infections and infestations	Number of subjects with events, n (%)	12 (4.9)	7 (2.8)
	Number of censored subjects, n (%)	234 (95.1)	239 (97.2)
	Exposure years	570.4	343.8
	EAIR per 100 PY	2.1	2.0
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.12 (0.43, 2.91)	
	p-value	0.8153	
	Relative Risk (95% CI)	1.71 (0.69, 4.28)	
	p-value	0.2484	
	Odds Ratio (95% CI)	1.75 (0.68, 4.52)	
	p-value	0.2475	
	Risk Difference (95% CI)	2.03 (-1.37, 5.43)	
	p-value	0.2414	

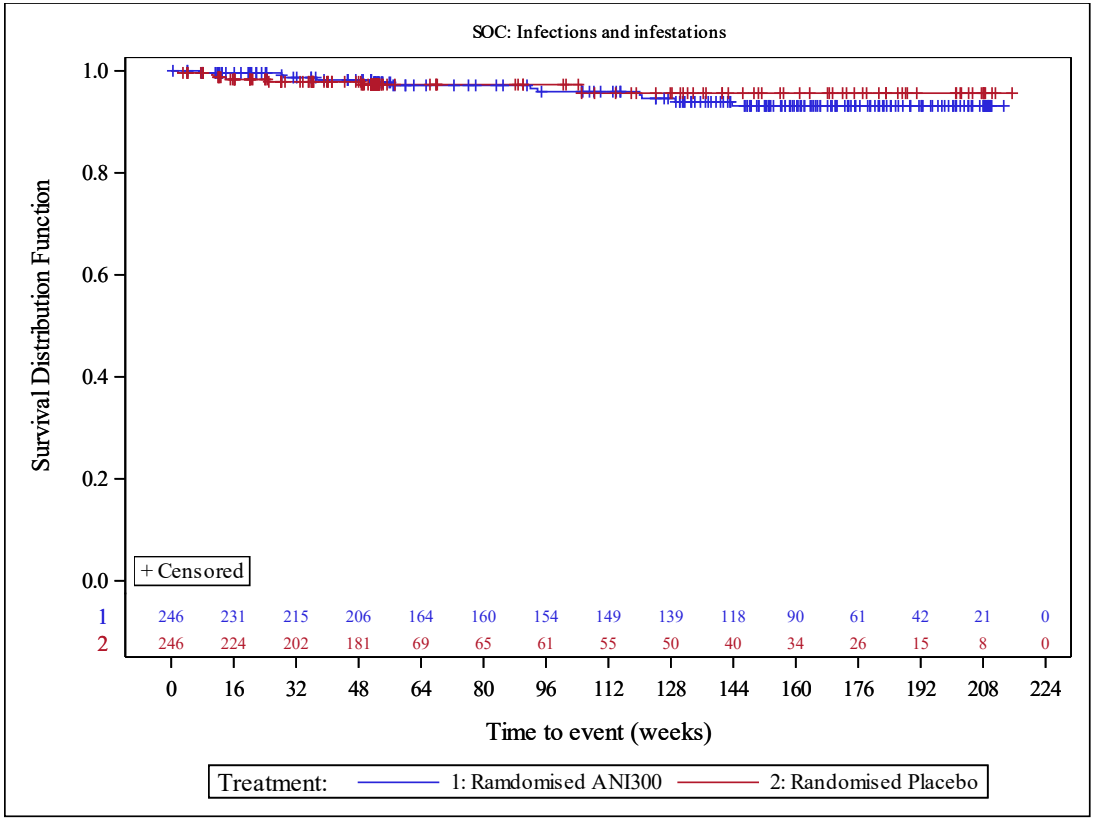
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of Incidence and time to first frequent Severe (Grade >=3) by SOC, PT during treatment (incidence in either arm >= 5% or >=10 patients) - Subgroup analysis
Full analysis set

- NO OBSERVATIONS FOR THIS ANALYSIS -

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Kaplan-Meier Plot of Incidence and time to first frequent Severe (Grade >=3) by SOC, PT during treatment (incidence in either arm >= 5% or >=10 patients)
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Incidence of Adverse Events by SOC, PT during treatment (Study 09)
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Anifrolumab 300mg (N=173) n (%)	Placebo Feeder + Placebo LTE (N=72) n (%)	Placebo Feeder + Anifrolumab 300mg (N=73) n (%)	Anifrolumab 150mg + Anifrolumab 300mg (N=52) n (%)
Subjects with events	142 (82.1)	54 (75.0)	54 (74.0)	44 (84.6)
Infections and infestations	122 (70.5)	40 (55.6)	44 (60.3)	36 (69.2)
Nasopharyngitis	38 (22.0)	7 (9.7)	15 (20.5)	9 (17.3)
Upper respiratory tract infection	31 (17.9)	10 (13.9)	14 (19.2)	7 (13.5)
Bronchitis	23 (13.3)	5 (6.9)	12 (16.4)	12 (23.1)
Pharyngitis	13 (7.5)	3 (4.2)	11 (15.1)	7 (13.5)
Urinary tract infection	28 (16.2)	5 (6.9)	9 (12.3)	5 (9.6)
Herpes zoster	12 (6.9)	3 (4.2)	8 (11.0)	9 (17.3)
Gastroenteritis	3 (1.7)	3 (4.2)	7 (9.6)	2 (3.8)
Influenza	8 (4.6)	2 (2.8)	4 (5.5)	4 (7.7)
Oral herpes	7 (4.0)	3 (4.2)	4 (5.5)	1 (1.9)
Sinusitis	12 (6.9)	2 (2.8)	4 (5.5)	3 (5.8)
Viral upper respiratory tract infection	7 (4.0)	1 (1.4)	4 (5.5)	0
Conjunctivitis	6 (3.5)	1 (1.4)	3 (4.1)	0
Cystitis	5 (2.9)	0	3 (4.1)	0
Pneumonia	5 (2.9)	0	3 (4.1)	2 (3.8)
Gastroenteritis viral	1 (0.6)	0	2 (2.7)	1 (1.9)
Impetigo	0	0	2 (2.7)	0
Latent tuberculosis	9 (5.2)	2 (2.8)	2 (2.7)	0
Lower respiratory tract infection	2 (1.2)	0	2 (2.7)	0
Oral candidiasis	3 (1.7)	1 (1.4)	2 (2.7)	1 (1.9)
Otitis externa	0	0	2 (2.7)	0
Rhinitis	0	0	2 (2.7)	3 (5.8)
Vaginal infection	9 (5.2)	2 (2.8)	2 (2.7)	0
Viral infection	2 (1.2)	1 (1.4)	2 (2.7)	0
Vulvovaginal mycotic infection	3 (1.7)	0	2 (2.7)	0
Abdominal infection	0	0	1 (1.4)	0
Acute sinusitis	1 (0.6)	1 (1.4)	1 (1.4)	0
Bacterial vaginosis	1 (0.6)	0	1 (1.4)	0
Ear infection	1 (0.6)	0	1 (1.4)	1 (1.9)
Folliculitis	1 (0.6)	0	1 (1.4)	1 (1.9)
Fungal skin infection	2 (1.2)	0	1 (1.4)	0
Genital herpes simplex	1 (0.6)	0	1 (1.4)	0
Herpes simplex	0	1 (1.4)	1 (1.4)	0
Nail infection	0	0	1 (1.4)	0
Otosalpingitis	0	0	1 (1.4)	0
Pelvic inflammatory disease	1 (0.6)	0	1 (1.4)	1 (1.9)
Postoperative wound infection	0	0	1 (1.4)	0
Pyelonephritis	1 (0.6)	0	1 (1.4)	0
Sepsis	0	0	1 (1.4)	0
Subcutaneous abscess	2 (1.2)	0	1 (1.4)	0
Tonsillitis	1 (0.6)	0	1 (1.4)	0
Tooth abscess	4 (2.3)	0	1 (1.4)	0
Tooth infection	0	0	1 (1.4)	0
Tracheobronchitis	0	0	1 (1.4)	1 (1.9)
Alveolar osteitis	1 (0.6)	0	0	0
Appendicitis	1 (0.6)	0	0	0
Bacterial sepsis	0	0	0	1 (1.9)
Cellulitis	1 (0.6)	2 (2.8)	0	2 (3.8)
Cellulitis staphylococcal	0	0	0	1 (1.9)
Cervicitis	2 (1.2)	0	0	0
Diverticulitis	1 (0.6)	0	0	0
Erysipelas	0	1 (1.4)	0	0
Fungal infection	2 (1.2)	0	0	0
Furuncle	0	1 (1.4)	0	0
Gastroenteritis bacterial	0	0	0	1 (1.9)
Gastrointestinal infection	0	1 (1.4)	0	0
Gastrointestinal viral infection	0	0	0	1 (1.9)

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Incidence of Adverse Events by SOC, PT during treatment (Study 09)
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Anifrolumab 300mg (N=173) n (%)	Placebo Feeder + Placebo LTE (N=72) n (%)	Placebo Feeder + Anifrolumab 300mg (N=73) n (%)	Anifrolumab 150mg + Anifrolumab 300mg (N=52) n (%)
Gingivitis	1 (0.6)	0	0	0
Herpes zoster disseminated	1 (0.6)	0	0	0
Hordeolum	1 (0.6)	0	0	0
Human ehrlichiosis	1 (0.6)	0	0	0
Labyrinthitis	1 (0.6)	0	0	0
Large intestine infection	1 (0.6)	0	0	0
Laryngitis	1 (0.6)	1 (1.4)	0	0
Mumps	1 (0.6)	0	0	0
Nasal vestibulitis	0	0	0	1 (1.9)
Onychomycosis	0	1 (1.4)	0	0
Otitis media	5 (2.9)	0	0	0
Otitis media acute	1 (0.6)	0	0	0
Otitis media bacterial	1 (0.6)	0	0	0
Paronychia	2 (1.2)	1 (1.4)	0	0
Parotitis	1 (0.6)	0	0	0
Periodontitis	0	0	0	1 (1.9)
Pneumocystis jirovecii pneumonia	0	0	0	1 (1.9)
Pneumonia bacterial	1 (0.6)	0	0	0
Pneumonia influenzal	0	0	0	1 (1.9)
Pneumonia staphylococcal	0	1 (1.4)	0	0
Pneumonia viral	1 (0.6)	0	0	0
Postoperative abscess	0	0	0	1 (1.9)
Pulpitis dental	0	0	0	1 (1.9)
Pyoderma	0	0	0	1 (1.9)
Respiratory moniliasis	0	1 (1.4)	0	0
Respiratory tract infection	3 (1.7)	0	0	1 (1.9)
Respiratory tract infection viral	2 (1.2)	0	0	1 (1.9)
Rotavirus infection	1 (0.6)	0	0	0
Sialoadenitis	1 (0.6)	0	0	0
Soft tissue infection	1 (0.6)	0	0	0
Streptococcal urinary tract infection	1 (0.6)	0	0	0
Superinfection	1 (0.6)	0	0	0
Tinea pedis	1 (0.6)	0	0	0
Tracheitis	2 (1.2)	0	0	1 (1.9)
Tungiasis	0	0	0	1 (1.9)
Viral pharyngitis	2 (1.2)	0	0	0
Vulvovaginal candidiasis	0	1 (1.4)	0	0
Vulvovaginitis	3 (1.7)	0	0	0
Vulvovaginitis trichomonal	0	1 (1.4)	0	0
Wound infection	1 (0.6)	0	0	0
Musculoskeletal and connective tissue disorders	59 (34.1)	15 (20.8)	20 (27.4)	12 (23.1)
Back pain	12 (6.9)	2 (2.8)	7 (9.6)	7 (13.5)
Arthralgia	8 (4.6)	3 (4.2)	3 (4.1)	3 (5.8)
Musculoskeletal pain	3 (1.7)	2 (2.8)	3 (4.1)	1 (1.9)
Systemic lupus erythematosus	6 (3.5)	3 (4.2)	3 (4.1)	2 (3.8)
Arthritis	3 (1.7)	1 (1.4)	2 (2.7)	1 (1.9)
Costochondritis	1 (0.6)	1 (1.4)	2 (2.7)	1 (1.9)
Foot deformity	0	0	2 (2.7)	0
Myalgia	1 (0.6)	0	2 (2.7)	1 (1.9)
Fibromyalgia	2 (1.2)	0	1 (1.4)	1 (1.9)
Intervertebral disc protrusion	2 (1.2)	0	1 (1.4)	0
Muscle spasms	1 (0.6)	0	1 (1.4)	1 (1.9)
Musculoskeletal chest pain	2 (1.2)	0	1 (1.4)	1 (1.9)
Neck pain	5 (2.9)	0	1 (1.4)	1 (1.9)
Osteoarthritis	4 (2.3)	0	1 (1.4)	2 (3.8)
Pain in extremity	4 (2.3)	1 (1.4)	1 (1.4)	2 (3.8)
Pain in jaw	0	0	1 (1.4)	0
Polyarthritis	0	0	1 (1.4)	0
Rotator cuff syndrome	0	1 (1.4)	1 (1.4)	1 (1.9)

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Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
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Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Anifrolumab 300mg (N=173) n (%)	Placebo Feeder + Placebo LTE (N=72) n (%)	Placebo Feeder + Anifrolumab 300mg (N=73) n (%)	Anifrolumab 150mg + Anifrolumab 300mg (N=52) n (%)
Spinal pain	0	0	1 (1.4)	0
Tendonitis	3 (1.7)	1 (1.4)	1 (1.4)	0
Bursitis	6 (3.5)	1 (1.4)	0	0
Flank pain	1 (0.6)	0	0	0
Groin pain	0	1 (1.4)	0	0
Joint instability	1 (0.6)	0	0	0
Joint swelling	1 (0.6)	0	0	0
Ligamentitis	1 (0.6)	0	0	0
Metatarsalgia	1 (0.6)	0	0	0
Musculoskeletal stiffness	1 (0.6)	0	0	0
Osteonecrosis	0	1 (1.4)	0	0
Osteoporosis	1 (0.6)	0	0	0
Periarthritis	1 (0.6)	0	0	0
Plantar fasciitis	0	1 (1.4)	0	0
Polychondritis	1 (0.6)	0	0	0
SLE arthritis	0	1 (1.4)	0	0
Sacroiliitis	1 (0.6)	0	0	0
Sjogren's syndrome	1 (0.6)	0	0	0
Spinal osteoarthritis	2 (1.2)	0	0	0
Synovial cyst	2 (1.2)	0	0	0
Synovitis	0	0	0	1 (1.9)
Tenosynovitis	1 (0.6)	0	0	0
Tenosynovitis stenosans	2 (1.2)	0	0	1 (1.9)
Injury, poisoning and procedural complications	31 (17.9)	13 (18.1)	17 (23.3)	14 (26.9)
Infusion related reaction	7 (4.0)	5 (6.9)	6 (8.2)	1 (1.9)
Contusion	5 (2.9)	1 (1.4)	2 (2.7)	6 (11.5)
Epicondylitis	1 (0.6)	0	2 (2.7)	0
Limb injury	1 (0.6)	1 (1.4)	2 (2.7)	0
Tooth fracture	0	1 (1.4)	2 (2.7)	0
Fall	5 (2.9)	3 (4.2)	1 (1.4)	3 (5.8)
Foot fracture	0	1 (1.4)	1 (1.4)	1 (1.9)
Joint dislocation	1 (0.6)	0	1 (1.4)	0
Ligament sprain	0	0	1 (1.4)	1 (1.9)
Periprocedural myocardial infarction	0	0	1 (1.4)	0
Procedural dizziness	0	0	1 (1.4)	0
Procedural pain	0	0	1 (1.4)	0
Radius fracture	0	0	1 (1.4)	1 (1.9)
Rib fracture	1 (0.6)	0	1 (1.4)	2 (3.8)
Road traffic accident	0	1 (1.4)	1 (1.4)	0
Skin injury	0	1 (1.4)	1 (1.4)	0
Skin laceration	0	0	1 (1.4)	0
Spinal fracture	1 (0.6)	0	1 (1.4)	0
Subcutaneous haematoma	0	0	1 (1.4)	0
Tibia fracture	1 (0.6)	0	1 (1.4)	0
Wrist fracture	0	0	1 (1.4)	0
Animal bite	0	1 (1.4)	0	0
Animal scratch	2 (1.2)	0	0	0
Ankle fracture	0	1 (1.4)	0	1 (1.9)
Arthropod bite	3 (1.7)	1 (1.4)	0	1 (1.9)
Arthropod sting	1 (0.6)	0	0	0
Brachial plexus injury	0	0	0	1 (1.9)
Dental restoration failure	0	1 (1.4)	0	0
Facial bones fracture	0	0	0	1 (1.9)
Foreign body in respiratory tract	1 (0.6)	0	0	0
Hand fracture	1 (0.6)	0	0	0
Humerus fracture	1 (0.6)	0	0	0
Hypobarism	1 (0.6)	0	0	0
Incision site pain	0	0	0	1 (1.9)
Incisional hernia	1 (0.6)	0	0	0

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Full analysis set

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Ligament rupture	1 (0.6)	0	0	0
Limb crushing injury	0	1 (1.4)	0	0
Lower limb fracture	1 (0.6)	0	0	0
Muscle strain	1 (0.6)	1 (1.4)	0	1 (1.9)
Post-traumatic pain	1 (0.6)	0	0	0
Pubis fracture	0	1 (1.4)	0	0
Respiratory fume inhalation disorder	0	0	0	1 (1.9)
Skin abrasion	1 (0.6)	0	0	0
Tendon rupture	0	1 (1.4)	0	0
Toxicity to various agents	1 (0.6)	0	0	0
Wound complication	1 (0.6)	0	0	0
Gastrointestinal disorders	34 (19.7)	12 (16.7)	16 (21.9)	12 (23.1)
Diarrhoea	4 (2.3)	3 (4.2)	5 (6.8)	4 (7.7)
Nausea	4 (2.3)	5 (6.9)	5 (6.8)	3 (5.8)
Abdominal pain upper	5 (2.9)	0	3 (4.1)	2 (3.8)
Constipation	2 (1.2)	2 (2.8)	3 (4.1)	0
Abdominal pain	2 (1.2)	2 (2.8)	2 (2.7)	3 (5.8)
Enteritis	0	0	2 (2.7)	0
Gastrooesophageal reflux disease	3 (1.7)	2 (2.8)	2 (2.7)	0
Toothache	1 (0.6)	0	2 (2.7)	0
Abdominal distension	1 (0.6)	0	1 (1.4)	0
Colitis	1 (0.6)	0	1 (1.4)	0
Dental caries	4 (2.3)	0	1 (1.4)	1 (1.9)
Dyspepsia	0	2 (2.8)	1 (1.4)	1 (1.9)
Enterocolitis	0	0	1 (1.4)	0
Erosive oesophagitis	0	0	1 (1.4)	0
Food poisoning	0	1 (1.4)	1 (1.4)	0
Gastritis	1 (0.6)	1 (1.4)	1 (1.4)	0
Lip oedema	0	0	1 (1.4)	0
Mouth ulceration	2 (1.2)	0	1 (1.4)	1 (1.9)
Tongue disorder	0	0	1 (1.4)	0
Tooth impacted	1 (0.6)	0	1 (1.4)	0
Vomiting	3 (1.7)	1 (1.4)	1 (1.4)	1 (1.9)
Abdominal discomfort	3 (1.7)	0	0	1 (1.9)
Anal pruritus	0	0	0	1 (1.9)
Aphthous ulcer	1 (0.6)	0	0	0
Barrett's oesophagus	1 (0.6)	0	0	0
Diverticulum	1 (0.6)	0	0	0
Gastric mucosa erythema	1 (0.6)	0	0	0
Gastrointestinal inflammation	1 (0.6)	0	0	0
Gastrointestinal pain	0	1 (1.4)	0	0
Gastrointestinal wall thickening	1 (0.6)	0	0	0
Gingival recession	1 (0.6)	0	0	0
Glossodynia	0	1 (1.4)	0	0
Haematochezia	1 (0.6)	1 (1.4)	0	0
Haemorrhoids	3 (1.7)	1 (1.4)	0	0
Impaired gastric emptying	1 (0.6)	0	0	0
Irritable bowel syndrome	1 (0.6)	0	0	0
Large intestine polyp	0	1 (1.4)	0	0
Lip swelling	1 (0.6)	0	0	0
Loose tooth	1 (0.6)	0	0	0
Oesophageal hypomotility	1 (0.6)	0	0	0
Oral mucosal eruption	1 (0.6)	0	0	0
Palatal disorder	1 (0.6)	0	0	0
Paraesthesia oral	1 (0.6)	0	0	0
Peritoneal haemorrhage	0	0	0	1 (1.9)
Proctalgia	0	0	0	1 (1.9)
Rectal haemorrhage	1 (0.6)	0	0	0
Stomatitis	0	1 (1.4)	0	0

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Tooth disorder	0	1 (1.4)	0	0
General disorders and administration site conditions	19 (11.0)	6 (8.3)	15 (20.5)	9 (17.3)
Oedema peripheral	3 (1.7)	0	3 (4.1)	2 (3.8)
Chest pain	1 (0.6)	0	2 (2.7)	1 (1.9)
Non-cardiac chest pain	2 (1.2)	1 (1.4)	2 (2.7)	0
Pain	1 (0.6)	0	2 (2.7)	1 (1.9)
Peripheral swelling	1 (0.6)	0	2 (2.7)	1 (1.9)
Pyrexia	3 (1.7)	2 (2.8)	2 (2.7)	0
Adverse drug reaction	2 (1.2)	1 (1.4)	1 (1.4)	0
Chest discomfort	2 (1.2)	0	1 (1.4)	1 (1.9)
Cyst	0	0	1 (1.4)	0
Fatigue	3 (1.7)	0	1 (1.4)	1 (1.9)
Feeling cold	0	0	1 (1.4)	0
Mucosal haemorrhage	0	0	1 (1.4)	0
Soft tissue inflammation	0	0	1 (1.4)	0
Asthenia	1 (0.6)	2 (2.8)	0	0
Discomfort	0	0	0	1 (1.9)
Influenza like illness	1 (0.6)	0	0	3 (5.8)
Swelling face	0	1 (1.4)	0	0
Vaccination site reaction	1 (0.6)	0	0	0
Withdrawal syndrome	0	0	0	1 (1.9)
Skin and subcutaneous tissue disorders	25 (14.5)	9 (12.5)	15 (20.5)	5 (9.6)
Dermal cyst	0	0	2 (2.7)	0
Dermatitis contact	1 (0.6)	0	2 (2.7)	0
Rash	5 (2.9)	3 (4.2)	2 (2.7)	0
Rash pruritic	0	0	2 (2.7)	0
Urticaria	3 (1.7)	1 (1.4)	2 (2.7)	2 (3.8)
Acne	3 (1.7)	0	1 (1.4)	0
Angioedema	1 (0.6)	0	1 (1.4)	0
Dermatitis	0	1 (1.4)	1 (1.4)	0
Ecchymosis	1 (0.6)	0	1 (1.4)	0
Erythema nodosum	0	0	1 (1.4)	0
Hidradenitis	2 (1.2)	0	1 (1.4)	0
Hyperkeratosis	0	0	1 (1.4)	0
Intertrigo	0	0	1 (1.4)	0
Night sweats	1 (0.6)	0	1 (1.4)	0
Photosensitivity reaction	0	0	1 (1.4)	0
Pruritus	0	1 (1.4)	1 (1.4)	0
Skin fissures	0	1 (1.4)	1 (1.4)	0
Skin hyperpigmentation	1 (0.6)	1 (1.4)	1 (1.4)	0
Actinic keratosis	0	0	0	1 (1.9)
Alopecia	0	1 (1.4)	0	0
Blood blister	0	0	0	1 (1.9)
Dermatitis atopic	1 (0.6)	0	0	0
Eczema	2 (1.2)	0	0	0
Guttate psoriasis	1 (0.6)	0	0	0
Ingrowing nail	1 (0.6)	0	0	0
Lipoatrophy	1 (0.6)	0	0	0
Nail bed bleeding	0	1 (1.4)	0	0
Nail dystrophy	1 (0.6)	0	0	0
Perioral dermatitis	1 (0.6)	0	0	0
Pigmentation disorder	1 (0.6)	0	0	0
Post inflammatory pigmentation change	0	1 (1.4)	0	0
Purpura	1 (0.6)	1 (1.4)	0	1 (1.9)
Seborrhoeic dermatitis	1 (0.6)	0	0	0
Skin discolouration	0	0	0	1 (1.9)
Skin lesion	1 (0.6)	0	0	1 (1.9)
Skin ulcer	1 (0.6)	1 (1.4)	0	0

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Systemic lupus erythematosus rash	0	1 (1.4)	0	0
Urticaria chronic	1 (0.6)	0	0	0
Nervous system disorders	39 (22.5)	13 (18.1)	10 (13.7)	15 (28.8)
Headache	13 (7.5)	6 (8.3)	4 (5.5)	6 (11.5)
Dizziness	4 (2.3)	1 (1.4)	2 (2.7)	1 (1.9)
Neuralgia	3 (1.7)	0	2 (2.7)	0
Neuropathy peripheral	0	0	2 (2.7)	2 (3.8)
Post herpetic neuralgia	3 (1.7)	0	2 (2.7)	1 (1.9)
Syncope	1 (0.6)	1 (1.4)	2 (2.7)	0
Carpal tunnel syndrome	2 (1.2)	1 (1.4)	1 (1.4)	0
Migraine	0	3 (4.2)	1 (1.4)	2 (3.8)
Migraine with aura	3 (1.7)	0	1 (1.4)	0
Burning sensation	0	0	0	1 (1.9)
Cerebrovascular accident	0	0	0	1 (1.9)
Cervical radiculopathy	0	0	0	1 (1.9)
Cognitive disorder	1 (0.6)	0	0	0
Dysarthria	1 (0.6)	0	0	0
Epilepsy	1 (0.6)	0	0	1 (1.9)
Hypoaesthesia	2 (1.2)	0	0	1 (1.9)
Lumbar radiculopathy	1 (0.6)	0	0	0
Myoclonus	1 (0.6)	0	0	0
Occipital neuralgia	1 (0.6)	0	0	0
Orthostatic intolerance	0	0	0	1 (1.9)
Paraesthesia	2 (1.2)	0	0	1 (1.9)
Parkinson's disease	1 (0.6)	0	0	0
Parkinsonian gait	1 (0.6)	0	0	0
Peroneal nerve palsy	1 (0.6)	0	0	0
Presyncope	2 (1.2)	0	0	0
Radiculopathy	2 (1.2)	0	0	0
Restless legs syndrome	0	2 (2.8)	0	0
Sciatica	2 (1.2)	0	0	0
Sensory disturbance	0	1 (1.4)	0	0
Psychiatric disorders	10 (5.8)	6 (8.3)	10 (13.7)	5 (9.6)
Insomnia	2 (1.2)	1 (1.4)	4 (5.5)	4 (7.7)
Depression	4 (2.3)	4 (5.6)	2 (2.7)	2 (3.8)
Affect lability	0	0	1 (1.4)	0
Anxiety	2 (1.2)	0	1 (1.4)	0
Anxiety disorder	1 (0.6)	0	1 (1.4)	0
Depressed mood	0	0	1 (1.4)	0
Persistent depressive disorder	0	0	1 (1.4)	0
Stress	0	0	1 (1.4)	0
Drug use disorder	1 (0.6)	0	0	0
Loss of libido	0	1 (1.4)	0	0
Panic attack	1 (0.6)	0	0	0
Suicidal ideation	1 (0.6)	0	0	0
Respiratory, thoracic and mediastinal disorders	23 (13.3)	10 (13.9)	10 (13.7)	9 (17.3)
Asthma	1 (0.6)	1 (1.4)	3 (4.1)	0
Rhinitis allergic	0	0	3 (4.1)	0
Dyspnoea	2 (1.2)	1 (1.4)	2 (2.7)	1 (1.9)
Nasal congestion	0	3 (4.2)	2 (2.7)	0
Pleural effusion	1 (0.6)	1 (1.4)	2 (2.7)	0
Cough	11 (6.4)	1 (1.4)	1 (1.4)	6 (11.5)
Oropharyngeal pain	3 (1.7)	1 (1.4)	1 (1.4)	0
Sinus congestion	1 (0.6)	0	1 (1.4)	0
Acute respiratory failure	1 (0.6)	0	0	0
Atelectasis	1 (0.6)	0	0	0
Catarrh	0	1 (1.4)	0	0

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Chronic obstructive pulmonary disease	2 (1.2)	1 (1.4)	0	0
Dyspnoea exertional	0	0	0	2 (3.8)
Epistaxis	1 (0.6)	1 (1.4)	0	1 (1.9)
Interstitial lung disease	0	0	0	1 (1.9)
Nasal obstruction	0	0	0	1 (1.9)
Productive cough	1 (0.6)	1 (1.4)	0	0
Pulmonary mass	1 (0.6)	0	0	0
Respiratory disorder	1 (0.6)	1 (1.4)	0	0
Respiratory distress	0	1 (1.4)	0	0
Upper respiratory tract inflammation	1 (0.6)	0	0	0
Wheezing	1 (0.6)	0	0	0
Investigations	11 (6.4)	1 (1.4)	7 (9.6)	4 (7.7)
Weight increased	1 (0.6)	0	3 (4.1)	0
Blood creatinine increased	0	0	1 (1.4)	0
Blood immunoglobulin A decreased	0	0	1 (1.4)	0
Ejection fraction decreased	0	0	1 (1.4)	0
International normalised ratio increased	0	0	1 (1.4)	0
Alanine aminotransferase increased	2 (1.2)	0	0	0
Aspartate aminotransferase increased	1 (0.6)	0	0	0
Blood alkaline phosphatase increased	1 (0.6)	0	0	0
Blood corticotrophin decreased	1 (0.6)	0	0	0
Blood creatine increased	0	0	0	1 (1.9)
Blood creatine phosphokinase increased	2 (1.2)	0	0	0
Blood pressure increased	0	0	0	3 (5.8)
Gamma-glutamyltransferase increased	1 (0.6)	0	0	0
Influenza B virus test positive	1 (0.6)	0	0	0
International normalised ratio abnormal	1 (0.6)	0	0	0
Intraocular pressure increased	1 (0.6)	0	0	0
Transaminases increased	0	1 (1.4)	0	0
Urine protein/creatinine ratio increased	1 (0.6)	0	0	0
Vitamin D decreased	1 (0.6)	0	0	0
Weight decreased	1 (0.6)	0	0	0
Cardiac disorders	10 (5.8)	4 (5.6)	6 (8.2)	3 (5.8)
Palpitations	1 (0.6)	1 (1.4)	2 (2.7)	1 (1.9)
Angina pectoris	0	1 (1.4)	1 (1.4)	0
Atrial fibrillation	0	1 (1.4)	1 (1.4)	0
Pericarditis	0	0	1 (1.4)	0
Ventricular hypokinesia	0	0	1 (1.4)	0
Acute myocardial infarction	0	2 (2.8)	0	0
Angina unstable	1 (0.6)	0	0	0
Arrhythmia	1 (0.6)	0	0	0
Bundle branch block left	1 (0.6)	0	0	0
Bundle branch block right	1 (0.6)	0	0	0
Cardiac failure chronic	1 (0.6)	0	0	0
Cardiac failure congestive	1 (0.6)	3 (4.2)	0	0
Cardiomegaly	0	1 (1.4)	0	0
Coronary artery disease	1 (0.6)	0	0	0
Cyanosis	0	0	0	1 (1.9)
Left ventricular dilatation	1 (0.6)	0	0	0
Myocardial infarction	0	1 (1.4)	0	0
Myocardial ischaemia	1 (0.6)	0	0	0
Sinus bradycardia	1 (0.6)	0	0	0
Supraventricular tachycardia	0	1 (1.4)	0	0
Tachycardia paroxysmal	1 (0.6)	0	0	0
Ventricular extrasystoles	0	0	0	1 (1.9)
Reproductive system and breast disorders	17 (9.8)	3 (4.2)	6 (8.2)	6 (11.5)
Breast mass	1 (0.6)	0	1 (1.4)	0

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Incidence of Adverse Events by SOC, PT during treatment (Study 09)
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Anifrolumab 300mg (N=173) n (%)	Placebo Feeder + Placebo LTE (N=72) n (%)	Placebo Feeder + Anifrolumab 300mg (N=73) n (%)	Anifrolumab 150mg + Anifrolumab 300mg (N=52) n (%)
Cervical dysplasia	0	0	1 (1.4)	0
Menopausal symptoms	0	1 (1.4)	1 (1.4)	0
Menorrhagia	1 (0.6)	1 (1.4)	1 (1.4)	0
Metrorrhagia	0	0	1 (1.4)	1 (1.9)
Pelvic pain	0	0	1 (1.4)	0
Uterine cervical erosion	0	0	1 (1.4)	0
Vaginal haemorrhage	0	0	1 (1.4)	0
Atrophic vulvovaginitis	1 (0.6)	0	0	0
Breast calcifications	0	1 (1.4)	0	0
Breast cyst	2 (1.2)	0	0	0
Cervical cyst	1 (0.6)	0	0	0
Cervical polyp	1 (0.6)	0	0	0
Cervix disorder	1 (0.6)	0	0	0
Dysmenorrhoea	4 (2.3)	0	0	1 (1.9)
Dyspareunia	1 (0.6)	0	0	0
Fibrocystic breast disease	2 (1.2)	0	0	0
Mammary duct ectasia	0	0	0	1 (1.9)
Menometrorrhagia	1 (0.6)	0	0	0
Menstruation irregular	1 (0.6)	0	0	0
Ovarian cyst	2 (1.2)	0	0	1 (1.9)
Ovarian cyst ruptured	0	0	0	1 (1.9)
Perineal rash	1 (0.6)	0	0	0
Polycystic ovaries	1 (0.6)	0	0	0
Premenstrual syndrome	1 (0.6)	0	0	0
Uterine haemorrhage	3 (1.7)	0	0	0
Uterine polyp	1 (0.6)	0	0	0
Vaginal discharge	0	0	0	1 (1.9)
Vascular disorders	12 (6.9)	6 (8.3)	6 (8.2)	5 (9.6)
Hypertension	8 (4.6)	4 (5.6)	2 (2.7)	2 (3.8)
Deep vein thrombosis	0	0	1 (1.4)	0
Hot flush	0	0	1 (1.4)	0
Thrombosis	0	0	1 (1.4)	0
Vasculitis	0	0	1 (1.4)	0
Essential hypertension	1 (0.6)	0	0	0
Haematoma	0	1 (1.4)	0	0
Lymphostasis	0	0	0	1 (1.9)
Malignant hypertension	1 (0.6)	0	0	0
Orthostatic hypotension	1 (0.6)	1 (1.4)	0	0
Raynaud's phenomenon	1 (0.6)	0	0	3 (5.8)
Varicophlebitis	0	1 (1.4)	0	0
Venous thrombosis	0	0	0	1 (1.9)
Eye disorders	15 (8.7)	5 (6.9)	5 (6.8)	4 (7.7)
Astigmatism	0	0	1 (1.4)	0
Chalazion	1 (0.6)	0	1 (1.4)	0
Conjunctival irritation	0	0	1 (1.4)	0
Conjunctivitis allergic	1 (0.6)	0	1 (1.4)	0
Hypermetropia	0	0	1 (1.4)	0
Vision blurred	0	0	1 (1.4)	0
Visual acuity reduced	0	0	1 (1.4)	0
Visual impairment	0	1 (1.4)	1 (1.4)	0
Blepharitis	2 (1.2)	0	0	0
Cataract	2 (1.2)	1 (1.4)	0	1 (1.9)
Conjunctival erosion	0	1 (1.4)	0	0
Conjunctival haemorrhage	1 (0.6)	0	0	1 (1.9)
Corneal erosion	0	1 (1.4)	0	0
Diplopia	0	1 (1.4)	0	0
Dry eye	3 (1.7)	0	0	0
Episcleritis	1 (0.6)	0	0	0

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Incidence of Adverse Events by SOC, PT during treatment (Study 09)
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Anifrolumab 300mg (N=173) n (%)	Placebo Feeder + Placebo LTE (N=72) n (%)	Placebo Feeder + Anifrolumab 300mg (N=73) n (%)	Anifrolumab 150mg + Anifrolumab 300mg (N=52) n (%)
Eye inflammation	1 (0.6)	0	0	0
Glaucoma	1 (0.6)	0	0	0
Keratitis	1 (0.6)	0	0	0
Lacrimation increased	1 (0.6)	0	0	0
Photophobia	0	1 (1.4)	0	0
Retinal detachment	0	0	0	1 (1.9)
Retinopathy	2 (1.2)	0	0	1 (1.9)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10 (5.8)	3 (4.2)	5 (6.8)	3 (5.8)
Skin papilloma	4 (2.3)	1 (1.4)	2 (2.7)	0
Fibrous histiocytoma	1 (0.6)	0	1 (1.4)	0
Haemangioma of bone	0	0	1 (1.4)	0
Uterine leiomyoma	3 (1.7)	0	1 (1.4)	1 (1.9)
Benign breast neoplasm	1 (0.6)	0	0	0
Colon adenoma	0	1 (1.4)	0	0
Haemangioma of liver	1 (0.6)	0	0	0
Lipoma	0	1 (1.4)	0	1 (1.9)
Squamous cell carcinoma	0	0	0	1 (1.9)
Blood and lymphatic system disorders	9 (5.2)	3 (4.2)	4 (5.5)	4 (7.7)
Iron deficiency anaemia	1 (0.6)	1 (1.4)	2 (2.7)	0
Anaemia	3 (1.7)	1 (1.4)	1 (1.4)	3 (5.8)
Lymphadenopathy	2 (1.2)	0	1 (1.4)	0
Autoimmune haemolytic anaemia	0	1 (1.4)	0	0
Leukopenia	0	0	0	1 (1.9)
Lymphopenia	1 (0.6)	0	0	0
Microcytic anaemia	0	1 (1.4)	0	0
Neutropenia	1 (0.6)	0	0	0
Thrombocytopenia	2 (1.2)	1 (1.4)	0	0
Renal and urinary disorders	14 (8.1)	3 (4.2)	4 (5.5)	1 (1.9)
Nephrolithiasis	1 (0.6)	0	3 (4.1)	0
Hydronephrosis	1 (0.6)	0	1 (1.4)	0
Acute kidney injury	1 (0.6)	1 (1.4)	0	0
Bladder spasm	1 (0.6)	0	0	0
Chronic kidney disease	1 (0.6)	0	0	0
Dysuria	1 (0.6)	2 (2.8)	0	0
Haematuria	2 (1.2)	0	0	0
Lupus nephritis	2 (1.2)	0	0	1 (1.9)
Renal cyst	1 (0.6)	0	0	0
Renal impairment	1 (0.6)	0	0	0
Stress urinary incontinence	1 (0.6)	0	0	0
Ureteric obstruction	1 (0.6)	0	0	0
Urethral meatus stenosis	1 (0.6)	0	0	0
Urinary incontinence	1 (0.6)	0	0	0
Ear and labyrinth disorders	11 (6.4)	2 (2.8)	3 (4.1)	0
Vertigo	7 (4.0)	0	2 (2.7)	0
Deafness bilateral	1 (0.6)	0	1 (1.4)	0
Cerumen impaction	1 (0.6)	0	0	0
Ear congestion	1 (0.6)	1 (1.4)	0	0
Ear pain	1 (0.6)	0	0	0
Motion sickness	0	1 (1.4)	0	0
Vertigo positional	2 (1.2)	0	0	0
Metabolism and nutrition disorders	14 (8.1)	8 (11.1)	3 (4.1)	4 (7.7)
Dehydration	0	1 (1.4)	1 (1.4)	1 (1.9)
Hyperglycaemia	0	1 (1.4)	1 (1.4)	0
Hypomagnesaemia	1 (0.6)	0	1 (1.4)	0
Type 2 diabetes mellitus	0	0	1 (1.4)	0

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Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Incidence of Adverse Events by SOC, PT during treatment (Study 09)
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Anifrolumab 300mg (N=173) n (%)	Placebo Feeder + Placebo LTE (N=72) n (%)	Placebo Feeder + Anifrolumab 300mg (N=73) n (%)	Anifrolumab 150mg + Anifrolumab 300mg (N=52) n (%)
Decreased appetite	0	0	0	2 (3.8)
Diabetes mellitus	2 (1.2)	0	0	1 (1.9)
Dyslipidaemia	1 (0.6)	1 (1.4)	0	0
Fluid overload	0	1 (1.4)	0	0
Hypercholesterolaemia	4 (2.3)	0	0	0
Hyperkalaemia	0	1 (1.4)	0	0
Hyperlipidaemia	1 (0.6)	0	0	0
Hypertriglyceridaemia	1 (0.6)	0	0	0
Hypokalaemia	2 (1.2)	1 (1.4)	0	0
Hyponatraemia	0	1 (1.4)	0	0
Iron deficiency	1 (0.6)	0	0	0
Vitamin B complex deficiency	2 (1.2)	0	0	0
Vitamin B12 deficiency	1 (0.6)	1 (1.4)	0	0
Vitamin D deficiency	4 (2.3)	1 (1.4)	0	0
Endocrine disorders	3 (1.7)	1 (1.4)	1 (1.4)	1 (1.9)
Hypothyroidism	0	0	1 (1.4)	0
Adrenal insufficiency	0	1 (1.4)	0	0
Basedow's disease	1 (0.6)	0	0	0
Goitre	1 (0.6)	0	0	0
Hyperprolactinaemia	1 (0.6)	0	0	0
Hyperthyroidism	1 (0.6)	0	0	0
Thyroid mass	0	0	0	1 (1.9)
Hepatobiliary disorders	3 (1.7)	1 (1.4)	1 (1.4)	0
Cholelithiasis	1 (0.6)	0	1 (1.4)	0
Biliary colic	1 (0.6)	0	0	0
Cholecystitis	0	1 (1.4)	0	0
Hepatic steatosis	1 (0.6)	0	0	0
Immune system disorders	3 (1.7)	2 (2.8)	1 (1.4)	2 (3.8)
Allergic oedema	0	0	1 (1.4)	0
Allergy to chemicals	0	0	1 (1.4)	0
Allergy to animal	1 (0.6)	1 (1.4)	0	0
Allergy to arthropod sting	1 (0.6)	0	0	0
Drug hypersensitivity	0	0	0	1 (1.9)
Seasonal allergy	1 (0.6)	1 (1.4)	0	1 (1.9)
Pregnancy, puerperium and perinatal conditions	1 (0.6)	0	0	0
Abortion spontaneous	1 (0.6)	0	0	0
Social circumstances	1 (0.6)	1 (1.4)	0	1 (1.9)
Menopause	1 (0.6)	1 (1.4)	0	1 (1.9)

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Incidence of Serious Adverse Events by SOC, PT during treatment (Study 09)
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Anifrolumab 300mg (N=173) n (%)	Placebo Feeder + Placebo LTE (N=72) n (%)	Placebo Feeder + Anifrolumab 300mg (N=73) n (%)	Anifrolumab 150mg + Anifrolumab 300mg (N=52) n (%)
Subjects with events	27 (15.6)	13 (18.1)	16 (21.9)	12 (23.1)
Infections and infestations	11 (6.4)	3 (4.2)	7 (9.6)	6 (11.5)
Bronchitis	0	0	2 (2.7)	0
Herpes zoster	4 (2.3)	0	2 (2.7)	1 (1.9)
Pneumonia	1 (0.6)	0	2 (2.7)	1 (1.9)
Gastroenteritis	0	1 (1.4)	1 (1.4)	0
Lower respiratory tract infection	0	0	1 (1.4)	0
Pelvic inflammatory disease	1 (0.6)	0	1 (1.4)	0
Pharyngitis	0	0	1 (1.4)	0
Postoperative wound infection	0	0	1 (1.4)	0
Sepsis	0	0	1 (1.4)	0
Bacterial sepsis	0	0	0	1 (1.9)
Cellulitis staphylococcal	0	0	0	1 (1.9)
Diverticulitis	1 (0.6)	0	0	0
Erysipelas	0	1 (1.4)	0	0
Herpes zoster disseminated	1 (0.6)	0	0	0
Influenza	1 (0.6)	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	1 (1.9)
Pneumonia bacterial	1 (0.6)	0	0	0
Pneumonia influenzal	0	0	0	1 (1.9)
Pneumonia staphylococcal	0	1 (1.4)	0	0
Postoperative abscess	0	0	0	1 (1.9)
Pyelonephritis	1 (0.6)	0	0	0
Streptococcal urinary tract infection	1 (0.6)	0	0	0
Urinary tract infection	1 (0.6)	0	0	0
Injury, poisoning and procedural complications	1 (0.6)	1 (1.4)	3 (4.1)	2 (3.8)
Joint dislocation	0	0	1 (1.4)	0
Periprocedural myocardial infarction	0	0	1 (1.4)	0
Spinal fracture	0	0	1 (1.4)	0
Arthropod bite	0	0	0	1 (1.9)
Humerus fracture	1 (0.6)	0	0	0
Rib fracture	0	0	0	1 (1.9)
Tendon rupture	0	1 (1.4)	0	0
Gastrointestinal disorders	0	0	2 (2.7)	1 (1.9)
Enterocolitis	0	0	1 (1.4)	0
Tooth impacted	0	0	1 (1.4)	0
Peritoneal haemorrhage	0	0	0	1 (1.9)
Nervous system disorders	1 (0.6)	1 (1.4)	2 (2.7)	1 (1.9)
Headache	0	0	1 (1.4)	1 (1.9)
Syncope	0	1 (1.4)	1 (1.4)	0
Cerebrovascular accident	0	0	0	1 (1.9)
Post herpetic neuralgia	1 (0.6)	0	0	0
Respiratory, thoracic and mediastinal disorders	2 (1.2)	2 (2.8)	2 (2.7)	1 (1.9)
Dyspnoea	0	0	1 (1.4)	0
Pleural effusion	1 (0.6)	0	1 (1.4)	0
Acute respiratory failure	1 (0.6)	0	0	0
Asthma	1 (0.6)	0	0	0
Chronic obstructive pulmonary disease	0	1 (1.4)	0	0
Dyspnoea exertional	0	0	0	1 (1.9)
Respiratory distress	0	1 (1.4)	0	0
Blood and lymphatic system disorders	2 (1.2)	2 (2.8)	1 (1.4)	0
Anaemia	0	1 (1.4)	1 (1.4)	0
Iron deficiency anaemia	0	1 (1.4)	0	0

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Incidence of Serious Adverse Events by SOC, PT during treatment (Study 09)
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Anifrolumab 300mg (N=173) n (%)	Placebo Feeder + Placebo LTE (N=72) n (%)	Placebo Feeder + Anifrolumab 300mg (N=73) n (%)	Anifrolumab 150mg + Anifrolumab 300mg (N=52) n (%)
Thrombocytopenia	2 (1.2)	0	0	0
Cardiac disorders	4 (2.3)	3 (4.2)	1 (1.4)	0
Pericarditis	0	0	1 (1.4)	0
Acute myocardial infarction	0	1 (1.4)	0	0
Bundle branch block left	1 (0.6)	0	0	0
Cardiac failure congestive	1 (0.6)	1 (1.4)	0	0
Coronary artery disease	1 (0.6)	0	0	0
Myocardial infarction	0	1 (1.4)	0	0
Myocardial ischaemia	1 (0.6)	0	0	0
Supraventricular tachycardia	0	1 (1.4)	0	0
Ear and labyrinth disorders	1 (0.6)	0	1 (1.4)	0
Vertigo	1 (0.6)	0	1 (1.4)	0
General disorders and administration site conditions	1 (0.6)	0	1 (1.4)	2 (3.8)
Mucosal haemorrhage	0	0	1 (1.4)	0
Chest discomfort	0	0	0	1 (1.9)
Influenza like illness	0	0	0	1 (1.9)
Non-cardiac chest pain	1 (0.6)	0	0	0
Investigations	0	0	1 (1.4)	0
International normalised ratio increased	0	0	1 (1.4)	0
Psychiatric disorders	0	0	1 (1.4)	0
Affect lability	0	0	1 (1.4)	0
Renal and urinary disorders	3 (1.7)	0	1 (1.4)	0
Hydronephrosis	0	0	1 (1.4)	0
Acute kidney injury	1 (0.6)	0	0	0
Lupus nephritis	1 (0.6)	0	0	0
Renal impairment	1 (0.6)	0	0	0
Skin and subcutaneous tissue disorders	0	1 (1.4)	1 (1.4)	0
Ecchymosis	0	0	1 (1.4)	0
Urticaria	0	1 (1.4)	0	0
Vascular disorders	1 (0.6)	1 (1.4)	1 (1.4)	1 (1.9)
Deep vein thrombosis	0	0	1 (1.4)	0
Malignant hypertension	1 (0.6)	0	0	0
Orthostatic hypotension	0	1 (1.4)	0	0
Venous thrombosis	0	0	0	1 (1.9)
Hepatobiliary disorders	1 (0.6)	0	0	0
Cholelithiasis	1 (0.6)	0	0	0
Metabolism and nutrition disorders	0	0	0	1 (1.9)
Dehydration	0	0	0	1 (1.9)
Musculoskeletal and connective tissue disorders	5 (2.9)	3 (4.2)	0	1 (1.9)
Arthritis	1 (0.6)	0	0	0
Back pain	0	0	0	1 (1.9)
Pain in extremity	1 (0.6)	0	0	0
Synovial cyst	1 (0.6)	0	0	0
Systemic lupus erythematosus	1 (0.6)	3 (4.2)	0	0
Tenosynovitis	1 (0.6)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.6)	0	0	0
Uterine leiomyoma	1 (0.6)	0	0	0

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Anifrolumab (MEDI-546)
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Incidence of Serious Adverse Events by SOC, PT during treatment (Study 09)
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Anifrolumab 300mg (N=173) n (%)	Placebo Feeder + Placebo LTE (N=72) n (%)	Placebo Feeder + Anifrolumab 300mg (N=73) n (%)	Anifrolumab 150mg + Anifrolumab 300mg (N=52) n (%)
Pregnancy, puerperium and perinatal conditions	1 (0.6)	0	0	0
Abortion spontaneous	1 (0.6)	0	0	0
Reproductive system and breast disorders	1 (0.6)	1 (1.4)	0	2 (3.8)
Menorrhagia	0	1 (1.4)	0	0
Ovarian cyst	0	0	0	1 (1.9)
Ovarian cyst ruptured	0	0	0	1 (1.9)
Uterine haemorrhage	1 (0.6)	0	0	0

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Anifrolumab (MEDI-546)
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Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Anifrolumab 300mg (N=173) n (%)	Placebo Feeder + Placebo LTE (N=72) n (%)	Placebo Feeder + Anifrolumab 300mg (N=73) n (%)	Anifrolumab 150mg + Anifrolumab 300mg (N=52) n (%)
Subjects with events	18 (10.4)	6 (8.3)	8 (11.0)	4 (7.7)
Injury, poisoning and procedural complications	2 (1.2)	1 (1.4)	4 (5.5)	1 (1.9)
Joint dislocation	0	0	1 (1.4)	0
Periprocedural myocardial infarction	0	0	1 (1.4)	0
Radius fracture	0	0	1 (1.4)	0
Spinal fracture	0	0	1 (1.4)	0
Humerus fracture	1 (0.6)	0	0	0
Incisional hernia	1 (0.6)	0	0	0
Muscle strain	0	0	0	1 (1.9)
Tendon rupture	0	1 (1.4)	0	0
Infections and infestations	7 (4.0)	1 (1.4)	2 (2.7)	3 (5.8)
Gastroenteritis	0	0	1 (1.4)	0
Pneumonia	0	0	1 (1.4)	1 (1.9)
Bacterial sepsis	0	0	0	1 (1.9)
Diverticulitis	1 (0.6)	0	0	0
Herpes zoster	2 (1.2)	0	0	1 (1.9)
Herpes zoster disseminated	1 (0.6)	0	0	0
Influenza	1 (0.6)	0	0	0
Pelvic inflammatory disease	1 (0.6)	0	0	0
Pneumonia bacterial	1 (0.6)	0	0	0
Pneumonia staphylococcal	0	1 (1.4)	0	0
Postoperative abscess	0	0	0	1 (1.9)
Pyelonephritis	1 (0.6)	0	0	0
Streptococcal urinary tract infection	1 (0.6)	0	0	0
Urinary tract infection	0	0	0	1 (1.9)
Ear and labyrinth disorders	0	0	1 (1.4)	0
Vertigo	0	0	1 (1.4)	0
Gastrointestinal disorders	0	0	1 (1.4)	0
Toothache	0	0	1 (1.4)	0
General disorders and administration site conditions	1 (0.6)	0	1 (1.4)	0
Chest pain	0	0	1 (1.4)	0
Influenza like illness	1 (0.6)	0	0	0
Blood and lymphatic system disorders	2 (1.2)	1 (1.4)	0	0
Iron deficiency anaemia	0	1 (1.4)	0	0
Thrombocytopenia	2 (1.2)	0	0	0
Cardiac disorders	2 (1.2)	1 (1.4)	0	0
Cardiac failure congestive	1 (0.6)	0	0	0
Myocardial infarction	0	1 (1.4)	0	0
Myocardial ischaemia	1 (0.6)	0	0	0
Supraventricular tachycardia	0	1 (1.4)	0	0
Musculoskeletal and connective tissue disorders	1 (0.6)	3 (4.2)	0	1 (1.9)
Back pain	0	0	0	1 (1.9)
Rotator cuff syndrome	0	1 (1.4)	0	0
SLE arthritis	0	1 (1.4)	0	0
Systemic lupus erythematosus	0	1 (1.4)	0	0
Tendonitis	1 (0.6)	0	0	0
Nervous system disorders	2 (1.2)	0	0	1 (1.9)
Cerebrovascular accident	0	0	0	1 (1.9)
Headache	0	0	0	1 (1.9)
Post herpetic neuralgia	1 (0.6)	0	0	0

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Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
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Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Anifrolumab 300mg (N=173) n (%)	Placebo Feeder + Placebo LTE (N=72) n (%)	Placebo Feeder + Anifrolumab 300mg (N=73) n (%)	Anifrolumab 150mg + Anifrolumab 300mg (N=52) n (%)
Radiculopathy	1 (0.6)	0	0	0
Psychiatric disorders	1 (0.6)	0	0	0
Suicidal ideation	1 (0.6)	0	0	0
Renal and urinary disorders	2 (1.2)	0	0	0
Acute kidney injury	1 (0.6)	0	0	0
Lupus nephritis	1 (0.6)	0	0	0
Respiratory, thoracic and mediastinal disorders	1 (0.6)	1 (1.4)	0	0
Cough	1 (0.6)	0	0	0
Dyspnoea	1 (0.6)	0	0	0
Respiratory distress	0	1 (1.4)	0	0

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Incidence of Non-Severe Adverse Events by SOC, PT during treatment (Study 09)
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Anifrolumab 300mg (N=173) n (%)	Placebo Feeder + Placebo LTE (N=72) n (%)	Placebo Feeder + Anifrolumab 300mg (N=73) n (%)	Anifrolumab 150mg + Anifrolumab 300mg (N=52) n (%)
Subjects with events	140 (80.9)	54 (75.0)	54 (74.0)	43 (82.7)
Infections and infestations	119 (68.8)	40 (55.6)	43 (58.9)	36 (69.2)
Nasopharyngitis	38 (22.0)	7 (9.7)	15 (20.5)	9 (17.3)
Upper respiratory tract infection	31 (17.9)	10 (13.9)	14 (19.2)	7 (13.5)
Bronchitis	23 (13.3)	5 (6.9)	12 (16.4)	12 (23.1)
Pharyngitis	13 (7.5)	3 (4.2)	11 (15.1)	7 (13.5)
Urinary tract infection	28 (16.2)	5 (6.9)	9 (12.3)	5 (9.6)
Herpes zoster	10 (5.8)	3 (4.2)	8 (11.0)	8 (15.4)
Gastroenteritis	3 (1.7)	3 (4.2)	6 (8.2)	2 (3.8)
Influenza	7 (4.0)	2 (2.8)	4 (5.5)	4 (7.7)
Oral herpes	7 (4.0)	3 (4.2)	4 (5.5)	1 (1.9)
Sinusitis	12 (6.9)	2 (2.8)	4 (5.5)	3 (5.8)
Viral upper respiratory tract infection	7 (4.0)	1 (1.4)	4 (5.5)	0
Conjunctivitis	6 (3.5)	1 (1.4)	3 (4.1)	0
Cystitis	5 (2.9)	0	3 (4.1)	0
Gastroenteritis viral	1 (0.6)	0	2 (2.7)	1 (1.9)
Impetigo	0	0	2 (2.7)	0
Latent tuberculosis	9 (5.2)	2 (2.8)	2 (2.7)	0
Lower respiratory tract infection	2 (1.2)	0	2 (2.7)	0
Oral candidiasis	3 (1.7)	1 (1.4)	2 (2.7)	1 (1.9)
Otitis externa	0	0	2 (2.7)	0
Pneumonia	5 (2.9)	0	2 (2.7)	1 (1.9)
Rhinitis	0	0	2 (2.7)	3 (5.8)
Vaginal infection	9 (5.2)	2 (2.8)	2 (2.7)	0
Viral infection	2 (1.2)	1 (1.4)	2 (2.7)	0
Vulvovaginal mycotic infection	3 (1.7)	0	2 (2.7)	0
Abdominal infection	0	0	1 (1.4)	0
Acute sinusitis	1 (0.6)	1 (1.4)	1 (1.4)	0
Bacterial vaginosis	1 (0.6)	0	1 (1.4)	0
Ear infection	1 (0.6)	0	1 (1.4)	1 (1.9)
Folliculitis	1 (0.6)	0	1 (1.4)	1 (1.9)
Fungal skin infection	2 (1.2)	0	1 (1.4)	0
Genital herpes simplex	1 (0.6)	0	1 (1.4)	0
Herpes simplex	0	1 (1.4)	1 (1.4)	0
Nail infection	0	0	1 (1.4)	0
Otosalpingitis	0	0	1 (1.4)	0
Pelvic inflammatory disease	0	0	1 (1.4)	1 (1.9)
Postoperative wound infection	0	0	1 (1.4)	0
Pyelonephritis	0	0	1 (1.4)	0
Sepsis	0	0	1 (1.4)	0
Subcutaneous abscess	2 (1.2)	0	1 (1.4)	0
Tonsillitis	1 (0.6)	0	1 (1.4)	0
Tooth abscess	4 (2.3)	0	1 (1.4)	0
Tooth infection	0	0	1 (1.4)	0
Tracheobronchitis	0	0	1 (1.4)	1 (1.9)
Alveolar osteitis	1 (0.6)	0	0	0
Appendicitis	1 (0.6)	0	0	0
Cellulitis	1 (0.6)	2 (2.8)	0	2 (3.8)
Cellulitis staphylococcal	0	0	0	1 (1.9)
Cervicitis	2 (1.2)	0	0	0
Diverticulitis	1 (0.6)	0	0	0
Erysipelas	0	1 (1.4)	0	0
Fungal infection	2 (1.2)	0	0	0
Furuncle	0	1 (1.4)	0	0
Gastroenteritis bacterial	0	0	0	1 (1.9)
Gastrointestinal infection	0	1 (1.4)	0	0
Gastrointestinal viral infection	0	0	0	1 (1.9)
Gingivitis	1 (0.6)	0	0	0

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Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Incidence of Non-Severe Adverse Events by SOC, PT during treatment (Study 09)
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Anifrolumab 300mg (N=173) n (%)	Placebo Feeder + Placebo LTE (N=72) n (%)	Placebo Feeder + Anifrolumab 300mg (N=73) n (%)	Anifrolumab 150mg + Anifrolumab 300mg (N=52) n (%)
Hordeolum	1 (0.6)	0	0	0
Human ehrlichiosis	1 (0.6)	0	0	0
Labyrinthitis	1 (0.6)	0	0	0
Large intestine infection	1 (0.6)	0	0	0
Laryngitis	1 (0.6)	1 (1.4)	0	0
Mumps	1 (0.6)	0	0	0
Nasal vestibulitis	0	0	0	1 (1.9)
Onychomycosis	0	1 (1.4)	0	0
Otitis media	5 (2.9)	0	0	0
Otitis media acute	1 (0.6)	0	0	0
Otitis media bacterial	1 (0.6)	0	0	0
Paronychia	2 (1.2)	1 (1.4)	0	0
Parotitis	1 (0.6)	0	0	0
Periodontitis	0	0	0	1 (1.9)
Pneumocystis jirovecii pneumonia	0	0	0	1 (1.9)
Pneumonia influenzal	0	0	0	1 (1.9)
Pneumonia viral	1 (0.6)	0	0	0
Pulpitis dental	0	0	0	1 (1.9)
Pyoderma	0	0	0	1 (1.9)
Respiratory moniliasis	0	1 (1.4)	0	0
Respiratory tract infection	3 (1.7)	0	0	1 (1.9)
Respiratory tract infection viral	2 (1.2)	0	0	1 (1.9)
Rotavirus infection	1 (0.6)	0	0	0
Sialoadenitis	1 (0.6)	0	0	0
Soft tissue infection	1 (0.6)	0	0	0
Superinfection	1 (0.6)	0	0	0
Tinea pedis	1 (0.6)	0	0	0
Tracheitis	2 (1.2)	0	0	1 (1.9)
Tungiasis	0	0	0	1 (1.9)
Viral pharyngitis	2 (1.2)	0	0	0
Vulvovaginal candidiasis	0	1 (1.4)	0	0
Vulvovaginitis	3 (1.7)	0	0	0
Vulvovaginitis trichomonal	0	1 (1.4)	0	0
Wound infection	1 (0.6)	0	0	0
Musculoskeletal and connective tissue disorders	59 (34.1)	14 (19.4)	20 (27.4)	12 (23.1)
Back pain	12 (6.9)	2 (2.8)	7 (9.6)	7 (13.5)
Arthralgia	8 (4.6)	3 (4.2)	3 (4.1)	3 (5.8)
Musculoskeletal pain	3 (1.7)	2 (2.8)	3 (4.1)	1 (1.9)
Systemic lupus erythematosus	6 (3.5)	2 (2.8)	3 (4.1)	2 (3.8)
Arthritis	3 (1.7)	1 (1.4)	2 (2.7)	1 (1.9)
Costochondritis	1 (0.6)	1 (1.4)	2 (2.7)	1 (1.9)
Foot deformity	0	0	2 (2.7)	0
Myalgia	1 (0.6)	0	2 (2.7)	1 (1.9)
Fibromyalgia	2 (1.2)	0	1 (1.4)	1 (1.9)
Intervertebral disc protrusion	2 (1.2)	0	1 (1.4)	0
Muscle spasms	1 (0.6)	0	1 (1.4)	1 (1.9)
Musculoskeletal chest pain	2 (1.2)	0	1 (1.4)	1 (1.9)
Neck pain	5 (2.9)	0	1 (1.4)	1 (1.9)
Osteoarthritis	4 (2.3)	0	1 (1.4)	2 (3.8)
Pain in extremity	4 (2.3)	1 (1.4)	1 (1.4)	2 (3.8)
Pain in jaw	0	0	1 (1.4)	0
Polyarthritis	0	0	1 (1.4)	0
Rotator cuff syndrome	0	0	1 (1.4)	1 (1.9)
Spinal pain	0	0	1 (1.4)	0
Tendonitis	2 (1.2)	1 (1.4)	1 (1.4)	0
Bursitis	6 (3.5)	1 (1.4)	0	0
Flank pain	1 (0.6)	0	0	0
Groin pain	0	1 (1.4)	0	0
Joint instability	1 (0.6)	0	0	0

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Anifrolumab (MEDI-546)
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Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Anifrolumab 300mg (N=173) n (%)	Placebo Feeder + Placebo LTE (N=72) n (%)	Placebo Feeder + Anifrolumab 300mg (N=73) n (%)	Anifrolumab 150mg + Anifrolumab 300mg (N=52) n (%)
Joint swelling	1 (0.6)	0	0	0
Ligamentitis	1 (0.6)	0	0	0
Metatarsalgia	1 (0.6)	0	0	0
Musculoskeletal stiffness	1 (0.6)	0	0	0
Osteonecrosis	0	1 (1.4)	0	0
Osteoporosis	1 (0.6)	0	0	0
Periarthritis	1 (0.6)	0	0	0
Plantar fasciitis	0	1 (1.4)	0	0
Polychondritis	1 (0.6)	0	0	0
Sacroiliitis	1 (0.6)	0	0	0
Sjogren's syndrome	1 (0.6)	0	0	0
Spinal osteoarthritis	2 (1.2)	0	0	0
Synovial cyst	2 (1.2)	0	0	0
Synovitis	0	0	0	1 (1.9)
Tenosynovitis	1 (0.6)	0	0	0
Tenosynovitis stenosans	2 (1.2)	0	0	1 (1.9)
Gastrointestinal disorders	34 (19.7)	12 (16.7)	16 (21.9)	12 (23.1)
Diarrhoea	4 (2.3)	3 (4.2)	5 (6.8)	4 (7.7)
Nausea	4 (2.3)	5 (6.9)	5 (6.8)	3 (5.8)
Abdominal pain upper	5 (2.9)	0	3 (4.1)	2 (3.8)
Constipation	2 (1.2)	2 (2.8)	3 (4.1)	0
Abdominal pain	2 (1.2)	2 (2.8)	2 (2.7)	3 (5.8)
Enteritis	0	0	2 (2.7)	0
Gastrooesophageal reflux disease	3 (1.7)	2 (2.8)	2 (2.7)	0
Abdominal distension	1 (0.6)	0	1 (1.4)	0
Colitis	1 (0.6)	0	1 (1.4)	0
Dental caries	4 (2.3)	0	1 (1.4)	1 (1.9)
Dyspepsia	0	2 (2.8)	1 (1.4)	1 (1.9)
Enterocolitis	0	0	1 (1.4)	0
Erosive oesophagitis	0	0	1 (1.4)	0
Food poisoning	0	1 (1.4)	1 (1.4)	0
Gastritis	1 (0.6)	1 (1.4)	1 (1.4)	0
Lip oedema	0	0	1 (1.4)	0
Mouth ulceration	2 (1.2)	0	1 (1.4)	1 (1.9)
Tongue disorder	0	0	1 (1.4)	0
Tooth impacted	1 (0.6)	0	1 (1.4)	0
Toothache	1 (0.6)	0	1 (1.4)	0
Vomiting	3 (1.7)	1 (1.4)	1 (1.4)	1 (1.9)
Abdominal discomfort	3 (1.7)	0	0	1 (1.9)
Anal pruritus	0	0	0	1 (1.9)
Aphthous ulcer	1 (0.6)	0	0	0
Barrett's oesophagus	1 (0.6)	0	0	0
Diverticulum	1 (0.6)	0	0	0
Gastric mucosa erythema	1 (0.6)	0	0	0
Gastrointestinal inflammation	1 (0.6)	0	0	0
Gastrointestinal pain	0	1 (1.4)	0	0
Gastrointestinal wall thickening	1 (0.6)	0	0	0
Gingival recession	1 (0.6)	0	0	0
Glossodynia	0	1 (1.4)	0	0
Haematochezia	1 (0.6)	1 (1.4)	0	0
Haemorrhoids	3 (1.7)	1 (1.4)	0	0
Impaired gastric emptying	1 (0.6)	0	0	0
Irritable bowel syndrome	1 (0.6)	0	0	0
Large intestine polyp	0	1 (1.4)	0	0
Lip swelling	1 (0.6)	0	0	0
Loose tooth	1 (0.6)	0	0	0
Oesophageal hypomotility	1 (0.6)	0	0	0
Oral mucosal eruption	1 (0.6)	0	0	0
Palatal disorder	1 (0.6)	0	0	0

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Full analysis set

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Paraesthesia oral	1 (0.6)	0	0	0
Peritoneal haemorrhage	0	0	0	1 (1.9)
Proctalgia	0	0	0	1 (1.9)
Rectal haemorrhage	1 (0.6)	0	0	0
Stomatitis	0	1 (1.4)	0	0
Tooth disorder	0	1 (1.4)	0	0
Injury, poisoning and procedural complications	29 (16.8)	13 (18.1)	16 (21.9)	13 (25.0)
Infusion related reaction	7 (4.0)	5 (6.9)	6 (8.2)	1 (1.9)
Contusion	5 (2.9)	1 (1.4)	2 (2.7)	6 (11.5)
Epicondylitis	1 (0.6)	0	2 (2.7)	0
Limb injury	1 (0.6)	1 (1.4)	2 (2.7)	0
Tooth fracture	0	1 (1.4)	2 (2.7)	0
Fall	5 (2.9)	3 (4.2)	1 (1.4)	3 (5.8)
Foot fracture	0	1 (1.4)	1 (1.4)	1 (1.9)
Ligament sprain	0	0	1 (1.4)	1 (1.9)
Procedural dizziness	0	0	1 (1.4)	0
Procedural pain	0	0	1 (1.4)	0
Rib fracture	1 (0.6)	0	1 (1.4)	2 (3.8)
Road traffic accident	0	1 (1.4)	1 (1.4)	0
Skin injury	0	1 (1.4)	1 (1.4)	0
Skin laceration	0	0	1 (1.4)	0
Subcutaneous haematoma	0	0	1 (1.4)	0
Tibia fracture	1 (0.6)	0	1 (1.4)	0
Wrist fracture	0	0	1 (1.4)	0
Animal bite	0	1 (1.4)	0	0
Animal scratch	2 (1.2)	0	0	0
Ankle fracture	0	1 (1.4)	0	1 (1.9)
Arthropod bite	3 (1.7)	1 (1.4)	0	1 (1.9)
Arthropod sting	1 (0.6)	0	0	0
Brachial plexus injury	0	0	0	1 (1.9)
Dental restoration failure	0	1 (1.4)	0	0
Facial bones fracture	0	0	0	1 (1.9)
Foreign body in respiratory tract	1 (0.6)	0	0	0
Hand fracture	1 (0.6)	0	0	0
Hypobarism	1 (0.6)	0	0	0
Incision site pain	0	0	0	1 (1.9)
Joint dislocation	1 (0.6)	0	0	0
Ligament rupture	1 (0.6)	0	0	0
Limb crushing injury	0	1 (1.4)	0	0
Lower limb fracture	1 (0.6)	0	0	0
Muscle strain	1 (0.6)	1 (1.4)	0	0
Post-traumatic pain	1 (0.6)	0	0	0
Pubis fracture	0	1 (1.4)	0	0
Radius fracture	0	0	0	1 (1.9)
Respiratory fume inhalation disorder	0	0	0	1 (1.9)
Skin abrasion	1 (0.6)	0	0	0
Spinal fracture	1 (0.6)	0	0	0
Toxicity to various agents	1 (0.6)	0	0	0
Wound complication	1 (0.6)	0	0	0
Skin and subcutaneous tissue disorders	25 (14.5)	9 (12.5)	15 (20.5)	5 (9.6)
Dermal cyst	0	0	2 (2.7)	0
Dermatitis contact	1 (0.6)	0	2 (2.7)	0
Rash	5 (2.9)	3 (4.2)	2 (2.7)	0
Rash pruritic	0	0	2 (2.7)	0
Urticaria	3 (1.7)	1 (1.4)	2 (2.7)	2 (3.8)
Acne	3 (1.7)	0	1 (1.4)	0
Angioedema	1 (0.6)	0	1 (1.4)	0
Dermatitis	0	1 (1.4)	1 (1.4)	0

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Full analysis set

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Ecchymosis	1 (0.6)	0	1 (1.4)	0
Erythema nodosum	0	0	1 (1.4)	0
Hidradenitis	2 (1.2)	0	1 (1.4)	0
Hyperkeratosis	0	0	1 (1.4)	0
Intertrigo	0	0	1 (1.4)	0
Night sweats	1 (0.6)	0	1 (1.4)	0
Photosensitivity reaction	0	0	1 (1.4)	0
Pruritus	0	1 (1.4)	1 (1.4)	0
Skin fissures	0	1 (1.4)	1 (1.4)	0
Skin hyperpigmentation	1 (0.6)	1 (1.4)	1 (1.4)	0
Actinic keratosis	0	0	0	1 (1.9)
Alopecia	0	1 (1.4)	0	0
Blood blister	0	0	0	1 (1.9)
Dermatitis atopic	1 (0.6)	0	0	0
Eczema	2 (1.2)	0	0	0
Guttate psoriasis	1 (0.6)	0	0	0
Ingrowing nail	1 (0.6)	0	0	0
Lipoatrophy	1 (0.6)	0	0	0
Nail bed bleeding	0	1 (1.4)	0	0
Nail dystrophy	1 (0.6)	0	0	0
Perioral dermatitis	1 (0.6)	0	0	0
Pigmentation disorder	1 (0.6)	0	0	0
Post inflammatory pigmentation change	0	1 (1.4)	0	0
Purpura	1 (0.6)	1 (1.4)	0	1 (1.9)
Seborrhoeic dermatitis	1 (0.6)	0	0	0
Skin discolouration	0	0	0	1 (1.9)
Skin lesion	1 (0.6)	0	0	1 (1.9)
Skin ulcer	1 (0.6)	1 (1.4)	0	0
Systemic lupus erythematosus rash	0	1 (1.4)	0	0
Urticaria chronic	1 (0.6)	0	0	0
General disorders and administration site conditions	19 (11.0)	6 (8.3)	14 (19.2)	9 (17.3)
Oedema peripheral	3 (1.7)	0	3 (4.1)	2 (3.8)
Non-cardiac chest pain	2 (1.2)	1 (1.4)	2 (2.7)	0
Pain	1 (0.6)	0	2 (2.7)	1 (1.9)
Peripheral swelling	1 (0.6)	0	2 (2.7)	1 (1.9)
Pyrexia	3 (1.7)	2 (2.8)	2 (2.7)	0
Adverse drug reaction	2 (1.2)	1 (1.4)	1 (1.4)	0
Chest discomfort	2 (1.2)	0	1 (1.4)	1 (1.9)
Chest pain	1 (0.6)	0	1 (1.4)	1 (1.9)
Cyst	0	0	1 (1.4)	0
Fatigue	3 (1.7)	0	1 (1.4)	1 (1.9)
Feeling cold	0	0	1 (1.4)	0
Mucosal haemorrhage	0	0	1 (1.4)	0
Soft tissue inflammation	0	0	1 (1.4)	0
Asthenia	1 (0.6)	2 (2.8)	0	0
Discomfort	0	0	0	1 (1.9)
Influenza like illness	1 (0.6)	0	0	3 (5.8)
Swelling face	0	1 (1.4)	0	0
Vaccination site reaction	1 (0.6)	0	0	0
Withdrawal syndrome	0	0	0	1 (1.9)
Nervous system disorders	37 (21.4)	13 (18.1)	10 (13.7)	14 (26.9)
Headache	13 (7.5)	6 (8.3)	4 (5.5)	5 (9.6)
Dizziness	4 (2.3)	1 (1.4)	2 (2.7)	1 (1.9)
Neuralgia	3 (1.7)	0	2 (2.7)	0
Neuropathy peripheral	0	0	2 (2.7)	2 (3.8)
Post herpetic neuralgia	2 (1.2)	0	2 (2.7)	1 (1.9)
Syncope	1 (0.6)	1 (1.4)	2 (2.7)	0
Carpal tunnel syndrome	2 (1.2)	1 (1.4)	1 (1.4)	0

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Migraine	0	3 (4.2)	1 (1.4)	2 (3.8)
Migraine with aura	3 (1.7)	0	1 (1.4)	0
Burning sensation	0	0	0	1 (1.9)
Cervical radiculopathy	0	0	0	1 (1.9)
Cognitive disorder	1 (0.6)	0	0	0
Dysarthria	1 (0.6)	0	0	0
Epilepsy	1 (0.6)	0	0	1 (1.9)
Hypoaesthesia	2 (1.2)	0	0	1 (1.9)
Lumbar radiculopathy	1 (0.6)	0	0	0
Myoclonus	1 (0.6)	0	0	0
Occipital neuralgia	1 (0.6)	0	0	0
Orthostatic intolerance	0	0	0	1 (1.9)
Paraesthesia	2 (1.2)	0	0	1 (1.9)
Parkinson's disease	1 (0.6)	0	0	0
Parkinsonian gait	1 (0.6)	0	0	0
Peroneal nerve palsy	1 (0.6)	0	0	0
Presyncope	2 (1.2)	0	0	0
Radiculopathy	1 (0.6)	0	0	0
Restless legs syndrome	0	2 (2.8)	0	0
Sciatica	2 (1.2)	0	0	0
Sensory disturbance	0	1 (1.4)	0	0
Psychiatric disorders	10 (5.8)	6 (8.3)	10 (13.7)	5 (9.6)
Insomnia	2 (1.2)	1 (1.4)	4 (5.5)	4 (7.7)
Depression	4 (2.3)	4 (5.6)	2 (2.7)	2 (3.8)
Affect lability	0	0	1 (1.4)	0
Anxiety	2 (1.2)	0	1 (1.4)	0
Anxiety disorder	1 (0.6)	0	1 (1.4)	0
Depressed mood	0	0	1 (1.4)	0
Persistent depressive disorder	0	0	1 (1.4)	0
Stress	0	0	1 (1.4)	0
Drug use disorder	1 (0.6)	0	0	0
Loss of libido	0	1 (1.4)	0	0
Panic attack	1 (0.6)	0	0	0
Respiratory, thoracic and mediastinal disorders	22 (12.7)	10 (13.9)	10 (13.7)	9 (17.3)
Asthma	1 (0.6)	1 (1.4)	3 (4.1)	0
Rhinitis allergic	0	0	3 (4.1)	0
Dyspnoea	1 (0.6)	1 (1.4)	2 (2.7)	1 (1.9)
Nasal congestion	0	3 (4.2)	2 (2.7)	0
Pleural effusion	1 (0.6)	1 (1.4)	2 (2.7)	0
Cough	10 (5.8)	1 (1.4)	1 (1.4)	6 (11.5)
Oropharyngeal pain	3 (1.7)	1 (1.4)	1 (1.4)	0
Sinus congestion	1 (0.6)	0	1 (1.4)	0
Acute respiratory failure	1 (0.6)	0	0	0
Atelectasis	1 (0.6)	0	0	0
Catarrh	0	1 (1.4)	0	0
Chronic obstructive pulmonary disease	2 (1.2)	1 (1.4)	0	0
Dyspnoea exertional	0	0	0	2 (3.8)
Epistaxis	1 (0.6)	1 (1.4)	0	1 (1.9)
Interstitial lung disease	0	0	0	1 (1.9)
Nasal obstruction	0	0	0	1 (1.9)
Productive cough	1 (0.6)	1 (1.4)	0	0
Pulmonary mass	1 (0.6)	0	0	0
Respiratory disorder	1 (0.6)	1 (1.4)	0	0
Upper respiratory tract inflammation	1 (0.6)	0	0	0
Wheezing	1 (0.6)	0	0	0
Investigations	11 (6.4)	1 (1.4)	7 (9.6)	4 (7.7)
Weight increased	1 (0.6)	0	3 (4.1)	0

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Incidence of Non-Severe Adverse Events by SOC, PT during treatment (Study 09)
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Anifrolumab 300mg (N=173) n (%)	Placebo Feeder + Placebo LTE (N=72) n (%)	Placebo Feeder + Anifrolumab 300mg (N=73) n (%)	Anifrolumab 150mg + Anifrolumab 300mg (N=52) n (%)
Blood creatinine increased	0	0	1 (1.4)	0
Blood immunoglobulin A decreased	0	0	1 (1.4)	0
Ejection fraction decreased	0	0	1 (1.4)	0
International normalised ratio increased	0	0	1 (1.4)	0
Alanine aminotransferase increased	2 (1.2)	0	0	0
Aspartate aminotransferase increased	1 (0.6)	0	0	0
Blood alkaline phosphatase increased	1 (0.6)	0	0	0
Blood corticotrophin decreased	1 (0.6)	0	0	0
Blood creatine increased	0	0	0	1 (1.9)
Blood creatine phosphokinase increased	2 (1.2)	0	0	0
Blood pressure increased	0	0	0	3 (5.8)
Gamma-glutamyltransferase increased	1 (0.6)	0	0	0
Influenza B virus test positive	1 (0.6)	0	0	0
International normalised ratio abnormal	1 (0.6)	0	0	0
Intraocular pressure increased	1 (0.6)	0	0	0
Transaminases increased	0	1 (1.4)	0	0
Urine protein/creatinine ratio increased	1 (0.6)	0	0	0
Vitamin D decreased	1 (0.6)	0	0	0
Weight decreased	1 (0.6)	0	0	0
Cardiac disorders	9 (5.2)	4 (5.6)	6 (8.2)	3 (5.8)
Palpitations	1 (0.6)	1 (1.4)	2 (2.7)	1 (1.9)
Angina pectoris	0	1 (1.4)	1 (1.4)	0
Atrial fibrillation	0	1 (1.4)	1 (1.4)	0
Pericarditis	0	0	1 (1.4)	0
Ventricular hypokinesia	0	0	1 (1.4)	0
Acute myocardial infarction	0	2 (2.8)	0	0
Angina unstable	1 (0.6)	0	0	0
Arrhythmia	1 (0.6)	0	0	0
Bundle branch block left	1 (0.6)	0	0	0
Bundle branch block right	1 (0.6)	0	0	0
Cardiac failure chronic	1 (0.6)	0	0	0
Cardiac failure congestive	0	3 (4.2)	0	0
Cardiomegaly	0	1 (1.4)	0	0
Coronary artery disease	1 (0.6)	0	0	0
Cyanosis	0	0	0	1 (1.9)
Left ventricular dilatation	1 (0.6)	0	0	0
Sinus bradycardia	1 (0.6)	0	0	0
Tachycardia paroxysmal	1 (0.6)	0	0	0
Ventricular extrasystoles	0	0	0	1 (1.9)
Reproductive system and breast disorders	17 (9.8)	3 (4.2)	6 (8.2)	6 (11.5)
Breast mass	1 (0.6)	0	1 (1.4)	0
Cervical dysplasia	0	0	1 (1.4)	0
Menopausal symptoms	0	1 (1.4)	1 (1.4)	0
Menorrhagia	1 (0.6)	1 (1.4)	1 (1.4)	0
Metrorrhagia	0	0	1 (1.4)	1 (1.9)
Pelvic pain	0	0	1 (1.4)	0
Uterine cervical erosion	0	0	1 (1.4)	0
Vaginal haemorrhage	0	0	1 (1.4)	0
Atrophic vulvovaginitis	1 (0.6)	0	0	0
Breast calcifications	0	1 (1.4)	0	0
Breast cyst	2 (1.2)	0	0	0
Cervical cyst	1 (0.6)	0	0	0
Cervical polyp	1 (0.6)	0	0	0
Cervix disorder	1 (0.6)	0	0	0
Dysmenorrhoea	4 (2.3)	0	0	1 (1.9)
Dyspareunia	1 (0.6)	0	0	0
Fibrocystic breast disease	2 (1.2)	0	0	0
Mammary duct ectasia	0	0	0	1 (1.9)

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Incidence of Non-Severe Adverse Events by SOC, PT during treatment (Study 09)
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Anifrolumab 300mg (N=173) n (%)	Placebo Feeder + Placebo LTE (N=72) n (%)	Placebo Feeder + Anifrolumab 300mg (N=73) n (%)	Anifrolumab 150mg + Anifrolumab 300mg (N=52) n (%)
Menometrorrhagia	1 (0.6)	0	0	0
Menstruation irregular	1 (0.6)	0	0	0
Ovarian cyst	2 (1.2)	0	0	1 (1.9)
Ovarian cyst ruptured	0	0	0	1 (1.9)
Perineal rash	1 (0.6)	0	0	0
Polycystic ovaries	1 (0.6)	0	0	0
Premenstrual syndrome	1 (0.6)	0	0	0
Uterine haemorrhage	3 (1.7)	0	0	0
Uterine polyp	1 (0.6)	0	0	0
Vaginal discharge	0	0	0	1 (1.9)
Vascular disorders	12 (6.9)	6 (8.3)	6 (8.2)	5 (9.6)
Hypertension	8 (4.6)	4 (5.6)	2 (2.7)	2 (3.8)
Deep vein thrombosis	0	0	1 (1.4)	0
Hot flush	0	0	1 (1.4)	0
Thrombosis	0	0	1 (1.4)	0
Vasculitis	0	0	1 (1.4)	0
Essential hypertension	1 (0.6)	0	0	0
Haematoma	0	1 (1.4)	0	0
Lymphostasis	0	0	0	1 (1.9)
Malignant hypertension	1 (0.6)	0	0	0
Orthostatic hypotension	1 (0.6)	1 (1.4)	0	0
Raynaud's phenomenon	1 (0.6)	0	0	3 (5.8)
Varicophlebitis	0	1 (1.4)	0	0
Venous thrombosis	0	0	0	1 (1.9)
Eye disorders	15 (8.7)	5 (6.9)	5 (6.8)	4 (7.7)
Astigmatism	0	0	1 (1.4)	0
Chalazion	1 (0.6)	0	1 (1.4)	0
Conjunctival irritation	0	0	1 (1.4)	0
Conjunctivitis allergic	1 (0.6)	0	1 (1.4)	0
Hypermetropia	0	0	1 (1.4)	0
Vision blurred	0	0	1 (1.4)	0
Visual acuity reduced	0	0	1 (1.4)	0
Visual impairment	0	1 (1.4)	1 (1.4)	0
Blepharitis	2 (1.2)	0	0	0
Cataract	2 (1.2)	1 (1.4)	0	1 (1.9)
Conjunctival erosion	0	1 (1.4)	0	0
Conjunctival haemorrhage	1 (0.6)	0	0	1 (1.9)
Corneal erosion	0	1 (1.4)	0	0
Diplopia	0	1 (1.4)	0	0
Dry eye	3 (1.7)	0	0	0
Episcleritis	1 (0.6)	0	0	0
Eye inflammation	1 (0.6)	0	0	0
Glaucoma	1 (0.6)	0	0	0
Keratitis	1 (0.6)	0	0	0
Lacrimation increased	1 (0.6)	0	0	0
Photophobia	0	1 (1.4)	0	0
Retinal detachment	0	0	0	1 (1.9)
Retinopathy	2 (1.2)	0	0	1 (1.9)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10 (5.8)	3 (4.2)	5 (6.8)	3 (5.8)
Skin papilloma	4 (2.3)	1 (1.4)	2 (2.7)	0
Fibrous histiocytoma	1 (0.6)	0	1 (1.4)	0
Haemangioma of bone	0	0	1 (1.4)	0
Uterine leiomyoma	3 (1.7)	0	1 (1.4)	1 (1.9)
Benign breast neoplasm	1 (0.6)	0	0	0
Colon adenoma	0	1 (1.4)	0	0
Haemangioma of liver	1 (0.6)	0	0	0
Lipoma	0	1 (1.4)	0	1 (1.9)

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Incidence of Non-Severe Adverse Events by SOC, PT during treatment (Study 09)
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Anifrolumab 300mg (N=173) n (%)	Placebo Feeder + Placebo LTE (N=72) n (%)	Placebo Feeder + Anifrolumab 300mg (N=73) n (%)	Anifrolumab 150mg + Anifrolumab 300mg (N=52) n (%)
Squamous cell carcinoma	0	0	0	1 (1.9)
Blood and lymphatic system disorders	8 (4.6)	3 (4.2)	4 (5.5)	4 (7.7)
Iron deficiency anaemia	1 (0.6)	0	2 (2.7)	0
Anaemia	3 (1.7)	1 (1.4)	1 (1.4)	3 (5.8)
Lymphadenopathy	2 (1.2)	0	1 (1.4)	0
Autoimmune haemolytic anaemia	0	1 (1.4)	0	0
Leukopenia	0	0	0	1 (1.9)
Lymphopenia	1 (0.6)	0	0	0
Microcytic anaemia	0	1 (1.4)	0	0
Neutropenia	1 (0.6)	0	0	0
Thrombocytopenia	1 (0.6)	1 (1.4)	0	0
Renal and urinary disorders	14 (8.1)	3 (4.2)	4 (5.5)	1 (1.9)
Nephrolithiasis	1 (0.6)	0	3 (4.1)	0
Hydronephrosis	1 (0.6)	0	1 (1.4)	0
Acute kidney injury	0	1 (1.4)	0	0
Bladder spasm	1 (0.6)	0	0	0
Chronic kidney disease	1 (0.6)	0	0	0
Dysuria	1 (0.6)	2 (2.8)	0	0
Haematuria	2 (1.2)	0	0	0
Lupus nephritis	2 (1.2)	0	0	1 (1.9)
Renal cyst	1 (0.6)	0	0	0
Renal impairment	1 (0.6)	0	0	0
Stress urinary incontinence	1 (0.6)	0	0	0
Ureteric obstruction	1 (0.6)	0	0	0
Urethral meatus stenosis	1 (0.6)	0	0	0
Urinary incontinence	1 (0.6)	0	0	0
Metabolism and nutrition disorders	14 (8.1)	8 (11.1)	3 (4.1)	4 (7.7)
Dehydration	0	1 (1.4)	1 (1.4)	1 (1.9)
Hyperglycaemia	0	1 (1.4)	1 (1.4)	0
Hypomagnesaemia	1 (0.6)	0	1 (1.4)	0
Type 2 diabetes mellitus	0	0	1 (1.4)	0
Decreased appetite	0	0	0	2 (3.8)
Diabetes mellitus	2 (1.2)	0	0	1 (1.9)
Dyslipidaemia	1 (0.6)	1 (1.4)	0	0
Fluid overload	0	1 (1.4)	0	0
Hypercholesterolaemia	4 (2.3)	0	0	0
Hyperkalaemia	0	1 (1.4)	0	0
Hyperlipidaemia	1 (0.6)	0	0	0
Hypertriglyceridaemia	1 (0.6)	0	0	0
Hypokalaemia	2 (1.2)	1 (1.4)	0	0
Hyponatraemia	0	1 (1.4)	0	0
Iron deficiency	1 (0.6)	0	0	0
Vitamin B complex deficiency	2 (1.2)	0	0	0
Vitamin B12 deficiency	1 (0.6)	1 (1.4)	0	0
Vitamin D deficiency	4 (2.3)	1 (1.4)	0	0
Ear and labyrinth disorders	11 (6.4)	2 (2.8)	2 (2.7)	0
Deafness bilateral	1 (0.6)	0	1 (1.4)	0
Vertigo	7 (4.0)	0	1 (1.4)	0
Cerumen impaction	1 (0.6)	0	0	0
Ear congestion	1 (0.6)	1 (1.4)	0	0
Ear pain	1 (0.6)	0	0	0
Motion sickness	0	1 (1.4)	0	0
Vertigo positional	2 (1.2)	0	0	0
Endocrine disorders	3 (1.7)	1 (1.4)	1 (1.4)	1 (1.9)
Hypothyroidism	0	0	1 (1.4)	0

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Incidence of Non-Severe Adverse Events by SOC, PT during treatment (Study 09)
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Anifrolumab 300mg (N=173) n (%)	Placebo Feeder + Placebo LTE (N=72) n (%)	Placebo Feeder + Anifrolumab 300mg (N=73) n (%)	Anifrolumab 150mg + Anifrolumab 300mg (N=52) n (%)
Adrenal insufficiency	0	1 (1.4)	0	0
Basedow's disease	1 (0.6)	0	0	0
Goitre	1 (0.6)	0	0	0
Hyperprolactinaemia	1 (0.6)	0	0	0
Hyperthyroidism	1 (0.6)	0	0	0
Thyroid mass	0	0	0	1 (1.9)
Hepatobiliary disorders	3 (1.7)	1 (1.4)	1 (1.4)	0
Cholelithiasis	1 (0.6)	0	1 (1.4)	0
Biliary colic	1 (0.6)	0	0	0
Cholecystitis	0	1 (1.4)	0	0
Hepatic steatosis	1 (0.6)	0	0	0
Immune system disorders	3 (1.7)	2 (2.8)	1 (1.4)	2 (3.8)
Allergic oedema	0	0	1 (1.4)	0
Allergy to chemicals	0	0	1 (1.4)	0
Allergy to animal	1 (0.6)	1 (1.4)	0	0
Allergy to arthropod sting	1 (0.6)	0	0	0
Drug hypersensitivity	0	0	0	1 (1.9)
Seasonal allergy	1 (0.6)	1 (1.4)	0	1 (1.9)
Pregnancy, puerperium and perinatal conditions	1 (0.6)	0	0	0
Abortion spontaneous	1 (0.6)	0	0	0
Social circumstances	1 (0.6)	1 (1.4)	0	1 (1.9)
Menopause	1 (0.6)	1 (1.4)	0	1 (1.9)

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event during study (Study 09)
Full analysis set

	Anifrolumab 300mg (N=173)	Placebo Feeder + Placebo LTE (N=72)	Placebo Feeder + Anifrolumab 300mg (N=73)	Anifrolumab 150mg + Anifrolumab 300mg (N=52)
Number of subjects with events, n (%)	144 (83.2)	56 (77.8)	54 (74.0)	45 (86.5)
Number of censored subjects, n (%)	29 (39.7)	16 (22.2)	19 (26.0)	7 (9.7)
Exposure years	125.2	48.8	59.0	35.8
EAIR per 100 PY	115.0	114.7	91.5	125.8

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Serious Adverse Event during study (Study 09)
Full analysis set

	Anifrolumab 300mg (N=173)	Placebo Feeder + Placebo LTE (N=72)	Placebo Feeder + Anifrolumab 300mg (N=73)	Anifrolumab 150mg + Anifrolumab 300mg (N=52)
Number of subjects with events, n (%)	28 (16.2)	13 (18.1)	18 (24.7)	15 (28.8)
Number of censored subjects, n (%)	145 (198.6)	59 (81.9)	55 (75.3)	37 (51.4)
Exposure years	341.1	131.4	137.5	97.1
EAIR per 100 PY	8.2	9.9	13.1	15.5

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Severe Adverse Event during study (Study 09)
Full analysis set

	Anifrolumab 300mg (N=173)	Placebo Feeder + Placebo LTE (N=72)	Placebo Feeder + Anifrolumab 300mg (N=73)	Anifrolumab 150mg + Anifrolumab 300mg (N=52)
Number of subjects with events, n (%)	18 (10.4)	7 (9.7)	12 (16.4)	7 (13.5)
Number of censored subjects, n (%)	155 (212.3)	65 (90.3)	61 (83.6)	45 (62.5)
Exposure years	351.0	140.6	152.0	106.8
EAIR per 100 PY	5.1	5.0	7.9	6.6

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Non-Severe Adverse Event during study (Study 09)
Full analysis set

	Anifrolumab 300mg (N=173)	Placebo Feeder + Placebo LTE (N=72)	Placebo Feeder + Anifrolumab 300mg (N=73)	Anifrolumab 150mg + Anifrolumab 300mg (N=52)
Number of subjects with events, n (%)	142 (82.1)	56 (77.8)	54 (74.0)	45 (86.5)
Number of censored subjects, n (%)	31 (42.5)	16 (22.2)	19 (26.0)	7 (9.7)
Exposure years	128.1	48.8	59.3	36.0
EAIR per 100 PY	110.9	114.7	91.0	125.1

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event leading to discontinuation of study drug during study (Study 09)
Full analysis set

	Anifrolumab 300mg (N=173)	Placebo Feeder + Placebo LTE (N=72)	Placebo Feeder + Anifrolumab 300mg (N=73)	Anifrolumab 150mg + Anifrolumab 300mg (N=52)
Number of subjects with events, n (%)	8 (4.6)	2 (2.8)	2 (2.7)	9 (17.3)
Number of censored subjects, n (%)	165 (226.0)	70 (97.2)	71 (97.3)	43 (59.7)
Exposure years	367.0	144.6	160.0	109.9
EAIR per 100 PY	2.2	1.4	1.3	8.2

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to Adverse Event leading to death during study (Study 09)
Full analysis set

	Anifrolumab 300mg (N=173)	Placebo Feeder + Placebo LTE (N=72)	Placebo Feeder + Anifrolumab 300mg (N=73)	Anifrolumab 150mg + Anifrolumab 300mg (N=52)
Number of subjects with events, n (%)	1 (0.6)	2 (2.8)	0 (0.0)	1 (1.9)
Number of censored subjects, n (%)	172 (235.6)	70 (97.2)	73 (100.0)	51 (70.8)
Exposure years	370.1	144.6	162.5	112.7
EAIR per 100 PY	0.3	1.4	0.0	0.9

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Anaphylaxis
Full analysis set

	Anifrolumab 300mg (N=173)	Placebo Feeder + Placebo LTE (N=72)	Placebo Feeder + Anifrolumab 300mg (N=73)	Anifrolumab 150mg + Anifrolumab 300mg (N=52)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	173 (237.0)	72 (100.0)	73 (100.0)	52 (72.2)
Exposure years	370.2	144.8	162.5	112.7
EAIR per 100 PY	0.0	0.0	0.0	0.0

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Serious Anaphylaxis
Full analysis set

	Anifrolumab 300mg (N=173)	Placebo Feeder + Placebo LTE (N=72)	Placebo Feeder + Anifrolumab 300mg (N=73)	Anifrolumab 150mg + Anifrolumab 300mg (N=52)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	173 (237.0)	72 (100.0)	73 (100.0)	52 (72.2)
Exposure years	370.2	144.8	162.5	112.7
EAIR per 100 PY	0.0	0.0	0.0	0.0

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Severe Anaphylaxis
Full analysis set

	Anifrolumab 300mg (N=173)	Placebo Feeder + Placebo LTE (N=72)	Placebo Feeder + Anifrolumab 300mg (N=73)	Anifrolumab 150mg + Anifrolumab 300mg (N=52)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	173 (237.0)	72 (100.0)	73 (100.0)	52 (72.2)
Exposure years	370.2	144.8	162.5	112.7
EAIR per 100 PY	0.0	0.0	0.0	0.0

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Non-Severe Anaphylaxis
Full analysis set

	Anifrolumab 300mg (N=173)	Placebo Feeder + Placebo LTE (N=72)	Placebo Feeder + Anifrolumab 300mg (N=73)	Anifrolumab 150mg + Anifrolumab 300mg (N=52)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	173 (237.0)	72 (100.0)	73 (100.0)	52 (72.2)
Exposure years	370.2	144.8	162.5	112.7
EAIR per 100 PY	0.0	0.0	0.0	0.0

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=173)	Placebo Feeder + Placebo LTE (N=72)	Placebo Feeder + Anifrolumab 300mg (N=73)	Anifrolumab 150mg + Anifrolumab 300mg (N=52)
Number of subjects with events, n (%)	13 (7.5)	3 (4.2)	8 (11.0)	9 (17.3)
Number of censored subjects, n (%)	160 (219.2)	69 (95.8)	65 (89.0)	43 (59.7)
Exposure years	356.2	140.6	152.3	104.6
EAIR per 100 PY	3.7	2.1	5.3	8.6

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Serious Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=173)	Placebo Feeder + Placebo LTE (N=72)	Placebo Feeder + Anifrolumab 300mg (N=73)	Anifrolumab 150mg + Anifrolumab 300mg (N=52)
Number of subjects with events, n (%)	5 (2.9)	0 (0.0)	2 (2.7)	1 (1.9)
Number of censored subjects, n (%)	168 (230.1)	72 (100.0)	71 (97.3)	51 (70.8)
Exposure years	365.2	144.8	160.2	112.5
EAIR per 100 PY	1.4	0.0	1.2	0.9

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Severe Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=173)	Placebo Feeder + Placebo LTE (N=72)	Placebo Feeder + Anifrolumab 300mg (N=73)	Anifrolumab 150mg + Anifrolumab 300mg (N=52)
Number of subjects with events, n (%)	3 (1.7)	0 (0.0)	0 (0.0)	1 (1.9)
Number of censored subjects, n (%)	170 (232.9)	72 (100.0)	73 (100.0)	51 (70.8)
Exposure years	366.9	144.8	162.5	112.5
EAIR per 100 PY	0.8	0.0	0.0	0.9

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Non-Severe Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=173)	Placebo Feeder + Placebo LTE (N=72)	Placebo Feeder + Anifrolumab 300mg (N=73)	Anifrolumab 150mg + Anifrolumab 300mg (N=52)
Number of subjects with events, n (%)	10 (5.8)	3 (4.2)	8 (11.0)	8 (15.4)
Number of censored subjects, n (%)	163 (223.3)	69 (95.8)	65 (89.0)	44 (61.1)
Exposure years	359.4	140.6	152.3	104.7
EAIR per 100 PY	2.8	2.1	5.3	7.6

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Malignancy
Full analysis set

	Anifrolumab 300mg (N=173)	Placebo Feeder + Placebo LTE (N=72)	Placebo Feeder + Anifrolumab 300mg (N=73)	Anifrolumab 150mg + Anifrolumab 300mg (N=52)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)
Number of censored subjects, n (%)	173 (237.0)	72 (100.0)	73 (100.0)	51 (70.8)
Exposure years	370.2	144.8	162.5	110.8
EAIR per 100 PY	0.0	0.0	0.0	0.9

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Serious Malignancy
Full analysis set

	Anifrolumab 300mg (N=173)	Placebo Feeder + Placebo LTE (N=72)	Placebo Feeder + Anifrolumab 300mg (N=73)	Anifrolumab 150mg + Anifrolumab 300mg (N=52)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	173 (237.0)	72 (100.0)	73 (100.0)	52 (72.2)
Exposure years	370.2	144.8	162.5	112.7
EAIR per 100 PY	0.0	0.0	0.0	0.0

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Severe Malignancy
Full analysis set

	Anifrolumab 300mg (N=173)	Placebo Feeder + Placebo LTE (N=72)	Placebo Feeder + Anifrolumab 300mg (N=73)	Anifrolumab 150mg + Anifrolumab 300mg (N=52)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	173 (237.0)	72 (100.0)	73 (100.0)	52 (72.2)
Exposure years	370.2	144.8	162.5	112.7
EAIR per 100 PY	0.0	0.0	0.0	0.0

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Non-Severe Malignancy
Full analysis set

	Anifrolumab 300mg (N=173)	Placebo Feeder + Placebo LTE (N=72)	Placebo Feeder + Anifrolumab 300mg (N=73)	Anifrolumab 150mg + Anifrolumab 300mg (N=52)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)
Number of censored subjects, n (%)	173 (237.0)	72 (100.0)	73 (100.0)	51 (70.8)
Exposure years	370.2	144.8	162.5	110.8
EAIR per 100 PY	0.0	0.0	0.0	0.9

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Influenza
Full analysis set

	Anifrolumab 300mg (N=173)	Placebo Feeder + Placebo LTE (N=72)	Placebo Feeder + Anifrolumab 300mg (N=73)	Anifrolumab 150mg + Anifrolumab 300mg (N=52)
Number of subjects with events, n (%)	8 (4.6)	3 (4.2)	4 (5.5)	5 (9.6)
Number of censored subjects, n (%)	165 (226.0)	69 (95.8)	69 (94.5)	47 (65.3)
Exposure years	364.6	143.6	158.6	108.2
EAIR per 100 PY	2.2	2.1	2.5	4.6

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Serious Influenza
Full analysis set

	Anifrolumab 300mg (N=173)	Placebo Feeder + Placebo LTE (N=72)	Placebo Feeder + Anifrolumab 300mg (N=73)	Anifrolumab 150mg + Anifrolumab 300mg (N=52)
Number of subjects with events, n (%)	1 (0.6)	0 (0.0)	0 (0.0)	1 (1.9)
Number of censored subjects, n (%)	172 (235.6)	72 (100.0)	73 (100.0)	51 (70.8)
Exposure years	369.1	144.8	162.5	112.2
EAIR per 100 PY	0.3	0.0	0.0	0.9

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Severe Influenza
Full analysis set

	Anifrolumab 300mg (N=173)	Placebo Feeder + Placebo LTE (N=72)	Placebo Feeder + Anifrolumab 300mg (N=73)	Anifrolumab 150mg + Anifrolumab 300mg (N=52)
Number of subjects with events, n (%)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	172 (235.6)	72 (100.0)	73 (100.0)	52 (72.2)
Exposure years	369.1	144.8	162.5	112.7
EAIR per 100 PY	0.3	0.0	0.0	0.0

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Non-Severe Influenza
Full analysis set

	Anifrolumab 300mg (N=173)	Placebo Feeder + Placebo LTE (N=72)	Placebo Feeder + Anifrolumab 300mg (N=73)	Anifrolumab 150mg + Anifrolumab 300mg (N=52)
Number of subjects with events, n (%)	7 (4.0)	3 (4.2)	4 (5.5)	5 (9.6)
Number of censored subjects, n (%)	166 (227.4)	69 (95.8)	69 (94.5)	47 (65.3)
Exposure years	365.7	143.6	158.6	108.2
EAIR per 100 PY	1.9	2.1	2.5	4.6

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - MACE
Full analysis set

	Anifrolumab 300mg (N=173)	Placebo Feeder + Placebo LTE (N=72)	Placebo Feeder + Anifrolumab 300mg (N=73)	Anifrolumab 150mg + Anifrolumab 300mg (N=52)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	173 (237.0)	72 (100.0)	73 (100.0)	52 (72.2)
Exposure years	370.2	144.8	162.5	112.7
EAIR per 100 PY	0.0	0.0	0.0	0.0

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Serious MACE
Full analysis set

	Anifrolumab 300mg (N=173)	Placebo Feeder + Placebo LTE (N=72)	Placebo Feeder + Anifrolumab 300mg (N=73)	Anifrolumab 150mg + Anifrolumab 300mg (N=52)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	173 (237.0)	72 (100.0)	73 (100.0)	52 (72.2)
Exposure years	370.2	144.8	162.5	112.7
EAIR per 100 PY	0.0	0.0	0.0	0.0

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Severe MACE
Full analysis set

	Anifrolumab 300mg (N=173)	Placebo Feeder + Placebo LTE (N=72)	Placebo Feeder + Anifrolumab 300mg (N=73)	Anifrolumab 150mg + Anifrolumab 300mg (N=52)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	173 (237.0)	72 (100.0)	73 (100.0)	52 (72.2)
Exposure years	370.2	144.8	162.5	112.7
EAIR per 100 PY	0.0	0.0	0.0	0.0

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Non-Severe MACE
Full analysis set

	Anifrolumab 300mg (N=173)	Placebo Feeder + Placebo LTE (N=72)	Placebo Feeder + Anifrolumab 300mg (N=73)	Anifrolumab 150mg + Anifrolumab 300mg (N=52)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	173 (237.0)	72 (100.0)	73 (100.0)	52 (72.2)
Exposure years	370.2	144.8	162.5	112.7
EAIR per 100 PY	0.0	0.0	0.0	0.0

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Non-opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=173)	Placebo Feeder + Placebo LTE (N=72)	Placebo Feeder + Anifrolumab 300mg (N=73)	Anifrolumab 150mg + Anifrolumab 300mg (N=52)
Number of subjects with events, n (%)	124 (71.7)	41 (56.9)	46 (63.0)	37 (71.2)
Number of censored subjects, n (%)	49 (67.1)	31 (43.1)	27 (37.0)	15 (20.8)
Exposure years	181.9	80.1	82.1	55.0
EAIR per 100 PY	68.2	51.2	56.0	67.3

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Serious Non-opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=173)	Placebo Feeder + Placebo LTE (N=72)	Placebo Feeder + Anifrolumab 300mg (N=73)	Anifrolumab 150mg + Anifrolumab 300mg (N=52)
Number of subjects with events, n (%)	11 (6.4)	3 (4.2)	7 (9.6)	5 (9.6)
Number of censored subjects, n (%)	162 (221.9)	69 (95.8)	66 (90.4)	47 (65.3)
Exposure years	359.0	143.3	152.7	107.3
EAIR per 100 PY	3.1	2.1	4.6	4.7

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Severe Non-opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=173)	Placebo Feeder + Placebo LTE (N=72)	Placebo Feeder + Anifrolumab 300mg (N=73)	Anifrolumab 150mg + Anifrolumab 300mg (N=52)
Number of subjects with events, n (%)	7 (4.0)	1 (1.4)	2 (2.7)	3 (5.8)
Number of censored subjects, n (%)	166 (227.4)	71 (98.6)	71 (97.3)	49 (68.1)
Exposure years	362.6	144.6	158.9	108.7
EAIR per 100 PY	1.9	0.7	1.3	2.8

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Non-Severe Non-opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=173)	Placebo Feeder + Placebo LTE (N=72)	Placebo Feeder + Anifrolumab 300mg (N=73)	Anifrolumab 150mg + Anifrolumab 300mg (N=52)
Number of subjects with events, n (%)	122 (70.5)	41 (56.9)	45 (61.6)	37 (71.2)
Number of censored subjects, n (%)	51 (69.9)	31 (43.1)	28 (38.4)	15 (20.8)
Exposure years	183.5	80.1	83.5	55.0
EAIR per 100 PY	66.5	51.2	53.9	67.3

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=173)	Placebo Feeder + Placebo LTE (N=72)	Placebo Feeder + Anifrolumab 300mg (N=73)	Anifrolumab 150mg + Anifrolumab 300mg (N=52)
Number of subjects with events, n (%)	0 (0.0)	1 (1.4)	0 (0.0)	1 (1.9)
Number of censored subjects, n (%)	173 (237.0)	71 (98.6)	73 (100.0)	51 (70.8)
Exposure years	370.2	143.8	162.5	112.3
EAIR per 100 PY	0.0	0.7	0.0	0.9

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Serious Opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=173)	Placebo Feeder + Placebo LTE (N=72)	Placebo Feeder + Anifrolumab 300mg (N=73)	Anifrolumab 150mg + Anifrolumab 300mg (N=52)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)
Number of censored subjects, n (%)	173 (237.0)	72 (100.0)	73 (100.0)	51 (70.8)
Exposure years	370.2	144.8	162.5	112.3
EAIR per 100 PY	0.0	0.0	0.0	0.9

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Severe Opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=173)	Placebo Feeder + Placebo LTE (N=72)	Placebo Feeder + Anifrolumab 300mg (N=73)	Anifrolumab 150mg + Anifrolumab 300mg (N=52)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	173 (237.0)	72 (100.0)	73 (100.0)	52 (72.2)
Exposure years	370.2	144.8	162.5	112.7
EAIR per 100 PY	0.0	0.0	0.0	0.0

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Non-Severe Opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=173)	Placebo Feeder + Placebo LTE (N=72)	Placebo Feeder + Anifrolumab 300mg (N=73)	Anifrolumab 150mg + Anifrolumab 300mg (N=52)
Number of subjects with events, n (%)	0 (0.0)	1 (1.4)	0 (0.0)	1 (1.9)
Number of censored subjects, n (%)	173 (237.0)	71 (98.6)	73 (100.0)	51 (70.8)
Exposure years	370.2	143.8	162.5	112.3
EAIR per 100 PY	0.0	0.7	0.0	0.9

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=173)	Placebo Feeder + Placebo LTE (N=72)	Placebo Feeder + Anifrolumab 300mg (N=73)	Anifrolumab 150mg + Anifrolumab 300mg (N=52)
Number of subjects with events, n (%)	10 (5.8)	2 (2.8)	2 (2.7)	0 (0.0)
Number of censored subjects, n (%)	163 (223.3)	70 (97.2)	71 (97.3)	52 (72.2)
Exposure years	363.6	141.1	160.4	112.7
EAIR per 100 PY	2.8	1.4	1.2	0.0

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Serious Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=173)	Placebo Feeder + Placebo LTE (N=72)	Placebo Feeder + Anifrolumab 300mg (N=73)	Anifrolumab 150mg + Anifrolumab 300mg (N=52)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	173 (237.0)	72 (100.0)	73 (100.0)	52 (72.2)
Exposure years	370.2	144.8	162.5	112.7
EAIR per 100 PY	0.0	0.0	0.0	0.0

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Severe Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=173)	Placebo Feeder + Placebo LTE (N=72)	Placebo Feeder + Anifrolumab 300mg (N=73)	Anifrolumab 150mg + Anifrolumab 300mg (N=52)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	173 (237.0)	72 (100.0)	73 (100.0)	52 (72.2)
Exposure years	370.2	144.8	162.5	112.7
EAIR per 100 PY	0.0	0.0	0.0	0.0

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Non-Severe Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=173)	Placebo Feeder + Placebo LTE (N=72)	Placebo Feeder + Anifrolumab 300mg (N=73)	Anifrolumab 150mg + Anifrolumab 300mg (N=52)
Number of subjects with events, n (%)	10 (5.8)	2 (2.8)	2 (2.7)	0 (0.0)
Number of censored subjects, n (%)	163 (223.3)	70 (97.2)	71 (97.3)	52 (72.2)
Exposure years	363.6	141.1	160.4	112.7
EAIR per 100 PY	2.8	1.4	1.2	0.0

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Vasculitis
Full analysis set

	Anifrolumab 300mg (N=173)	Placebo Feeder + Placebo LTE (N=72)	Placebo Feeder + Anifrolumab 300mg (N=73)	Anifrolumab 150mg + Anifrolumab 300mg (N=52)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)
Number of censored subjects, n (%)	173 (237.0)	72 (100.0)	72 (98.6)	52 (72.2)
Exposure years	370.2	144.8	161.7	112.7
EAIR per 100 PY	0.0	0.0	0.6	0.0

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Serious Vasculitis
Full analysis set

	Anifrolumab 300mg (N=173)	Placebo Feeder + Placebo LTE (N=72)	Placebo Feeder + Anifrolumab 300mg (N=73)	Anifrolumab 150mg + Anifrolumab 300mg (N=52)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	173 (237.0)	72 (100.0)	73 (100.0)	52 (72.2)
Exposure years	370.2	144.8	162.5	112.7
EAIR per 100 PY	0.0	0.0	0.0	0.0

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Severe Vasculitis
Full analysis set

	Anifrolumab 300mg (N=173)	Placebo Feeder + Placebo LTE (N=72)	Placebo Feeder + Anifrolumab 300mg (N=73)	Anifrolumab 150mg + Anifrolumab 300mg (N=52)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	173 (237.0)	72 (100.0)	73 (100.0)	52 (72.2)
Exposure years	370.2	144.8	162.5	112.7
EAIR per 100 PY	0.0	0.0	0.0	0.0

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population receiving standard of care treatment approved in Germany
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Non-Severe Vasculitis
Full analysis set

	Anifrolumab 300mg (N=173)	Placebo Feeder + Placebo LTE (N=72)	Placebo Feeder + Anifrolumab 300mg (N=73)	Anifrolumab 150mg + Anifrolumab 300mg (N=52)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)
Number of censored subjects, n (%)	173 (237.0)	72 (100.0)	72 (98.6)	52 (72.2)
Exposure years	370.2	144.8	161.7	112.7
EAIR per 100 PY	0.0	0.0	0.6	0.0

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anhang 4-G4: Zusatzanalysen, TULIP SLE LTE, ITT-Population

Contents

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Subject disposition and summary of treatment exposure (TULIP + LTE)
Full analysis set

		Randomised Anifrolumab 300mg (N=360)	Randomised Placebo (N=365)
Patients who completed the study		52 (14.4)	174 (47.7)
Patients ongoing		207 (57.5)	68 (18.6)
Patients withdrawn from the study		101 (28.1)	123 (33.7)
WITHDRAWAL BY SUBJECT		49 (13.6)	55 (15.1)
ADVERSE EVENT		23 (6.4)	14 (3.8)
LACK OF EFFICACY		14 (3.9)	20 (5.5)
OTHER		8 (2.2)	12 (3.3)
LOST TO FOLLOW-UP		4 (1.1)	10 (2.7)
CONDITION UNDER INVESTIGATION WORSENED		2 (0.6)	6 (1.6)
SEVERE NON-COMPLIANCE TO PROTOCOL		0	4 (1.1)
DEATH		0	1 (0.3)
DEVELOPMENT OF STUDY-SPECIFIC WITHDRAWAL CRITERIA		1 (0.3)	0
MISSING		0	1 (0.3)
Duration of study (weeks)	n (missing)	360 (0)	365 (0)
	Mean (SD)	133.1 (63.60)	82.0 (56.31)
	Median	153.1	53.3
	Min, Max	0, 241	3, 241
Patients who completed IP		44 (12.2)	162 (44.4)
Patients ongoing on IP		187 (51.9)	61 (16.7)
Patients discontinued IP		129 (35.8)	142 (38.9)
Withdrawal By Subject		42 (11.7)	48 (13.2)
Adverse Event		32 (8.9)	27 (7.4)
Lack Of Efficacy		19 (5.3)	29 (7.9)
Other		25 (6.9)	12 (3.3)
Lost To Follow-Up		5 (1.4)	10 (2.7)
Condition Under Investigation Worsened		4 (1.1)	10 (2.7)
Severe Non-Compliance To Protocol		0	5 (1.4)
Progressive Disease		2 (0.6)	1 (0.3)
Duration of exposure (weeks)	n (missing)	360 (0)	365 (0)
	Mean (SD)	126.5 (66.64)	75.2 (56.44)
	Median	148.4	52.1
	Min, Max	0, 216	3, 215

Completion of study 09 is based upon the number of patients completing up to and including Week 208.
Completion of IP in study 09 is based upon the number of patients completing treatment with IP up to and including Week 204.
23 patients were incorrectly counted as having discontinued treatment.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Subject disposition and summary of treatment exposure (study 09)
Full analysis set

		Anifrolumab 300mg (N=259)	Placebo Feeder + Placebo LTE (N=113)
Patients who completed the study		9 (3.5)	4 (3.5)
Patients ongoing		207 (79.9)	68 (60.2)
Patients withdrawn from the study		43 (16.6)	41 (36.3)
WITHDRAWAL BY SUBJECT		23 (8.9)	21 (18.6)
LACK OF EFFICACY		8 (3.1)	5 (4.4)
ADVERSE EVENT		8 (3.1)	2 (1.8)
LOST TO FOLLOW-UP		3 (1.2)	5 (4.4)
OTHER		1 (0.4)	4 (3.5)
SEVERE NON-COMPLIANCE TO PROTOCOL		0	2 (1.8)
CONDITION UNDER INVESTIGATION WORSENED		0	1 (0.9)
DEATH		0	1 (0.9)
Duration of study (weeks)	n (missing)	259 (0)	113 (0)
	Mean (SD)	167.4 (35.89)	156.6 (42.18)
	Median	170.3	157.1
	Min, Max	59, 241	58, 241
Patients who completed IP		5 (1.9)	0
Patients ongoing on IP		187 (72.2)	61 (54.0)
Patients discontinued IP		67 (25.9)	52 (46.0)
Withdrawal By Subject		20 (7.7)	19 (16.8)
Other		13 (5.0)	10 (8.8)
Lack Of Efficacy		14 (5.4)	8 (7.1)
Adverse Event		14 (5.4)	5 (4.4)
Lost To Follow-Up		3 (1.2)	5 (4.4)
Condition Under Investigation Worsened		1 (0.4)	2 (1.8)
Progressive Disease		2 (0.8)	1 (0.9)
Severe Non-Compliance To Protocol		0	2 (1.8)
Duration of exposure (weeks)	n (missing)	259 (0)	113 (0)
	Mean (SD)	162.4 (38.14)	147.9 (46.01)
	Median	166.3	151.3
	Min, Max	56, 216	56, 215

Completion of study 09 is based upon the number of patients completing up to and including Week 208.
Completion of IP in study 09 is based upon the number of patients completing treatment with IP up to and including Week 204.
29 patients were incorrectly counted as having discontinued treatment.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Demographic and baseline characteristics
Full analysis set

		Randomised Anifrolumab 300mg (N=360)	Randomised Placebo (N=365)	Total (N=725)
Age	n (missing)	360 (0)	365 (0)	725 (0)
	Mean (SD)	42.6 (11.97)	41.1 (11.85)	41.8 (11.92)
	Median	42.0	41.0	42.0
	Min, Max	18, 69	18, 69	18, 69
Age subgroups (%)	<= 65	348 (96.7)	361 (98.9)	709 (97.8)
	> 65	12 (3.3)	4 (1.1)	16 (2.2)
Sex (%)	female	333 (92.5)	340 (93.2)	673 (92.8)
	male	27 (7.5)	25 (6.8)	52 (7.2)
Race (%)	American Indian or Alaska Native	4 (1.1)	2 (0.5)	6 (0.8)
	Asian	41 (11.4)	35 (9.6)	76 (10.5)
	Black or African American	46 (12.8)	48 (13.2)	94 (13.0)
	Other	26 (7.2)	29 (7.9)	55 (7.6)
	White	235 (65.3)	243 (66.6)	478 (65.9)
	Missing	8 (2.2)	8 (2.2)	16 (2.2)
Ethnicity (%)	Hispanic/Latino	86 (23.9)	89 (24.4)	175 (24.1)
	Non-hispanic/Latino	266 (73.9)	268 (73.4)	534 (73.7)
	Missing	8 (2.2)	8 (2.2)	16 (2.2)
Geographic region (%)	Asia Pacific	38 (10.6)	32 (8.8)	70 (9.7)
	Europe	115 (31.9)	122 (33.4)	237 (32.7)
	Latin America	59 (16.4)	57 (15.6)	116 (16.0)
	North America	139 (38.6)	139 (38.1)	278 (38.3)
	Rest Of World	9 (2.5)	15 (4.1)	24 (3.3)
Geographic region subgroup (%)	EU	115 (31.9)	122 (33.4)	237 (32.7)
	non-EU	245 (68.1)	243 (66.6)	488 (67.3)
Height (cm)	n (missing)	360 (0)	365 (0)	725 (0)
	Mean (SD)	162.32 (8.405)	162.86 (8.042)	162.59 (8.223)
	Median	161.90	162.60	162.00
	Min, Max	138.0, 198.0	130.0, 195.0	130.0, 198.0
Weight (cm)	n (missing)	360 (0)	365 (0)	725 (0)
	Mean (SD)	73.47 (19.615)	72.78 (18.380)	73.12 (18.993)
	Median	69.90	67.80	68.90
	Min, Max	42.0, 132.7	42.2, 138.0	42.0, 138.0
BMI (kg/m^2)	n (missing)	360 (0)	365 (0)	725 (0)
	Mean (SD)	27.82 (6.870)	27.45 (6.760)	27.63 (6.812)
	Median	26.04	25.66	25.80
	Min, Max	16.0, 49.8	17.2, 57.5	16.0, 57.5
BMI (%)	<=28 kg/m2	205 (56.9)	223 (61.1)	428 (59.0)
	>28 kg/m2	155 (43.1)	142 (38.9)	297 (41.0)

[a] Asia Pacific: Australia, New Zealand, South Korea, Taiwan. Europe: Germany, Hungary, Italy, Poland, Romania, Ukraine, United Kingdom. Latin America: Argentinia, Brazil, Chile, Colombia, Peru. Rest of World: Israel.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
SLE disease characteristics
Full analysis set

		Randomised Anifrolumab 300mg (N=360)	Randomised Placebo (N=365)	Total (N=725)
SLEDAI-2K score at screening	n (missing)	360 (0)	365 (0)	725 (0)
	Mean (SD)	11.4 (3.87)	11.3 (3.62)	11.3 (3.74)
	Median	10.0	10.0	10.0
	Min, Max	6, 26	6, 26	6, 26
SLEDAI-2K score at screening, categorisation (%)	< 10 points	109 (30.3)	106 (29.0)	215 (29.7)
	>= 10 points	251 (69.7)	259 (71.0)	510 (70.3)
Clinical SLEDAI-2K score at screening	n (missing)	360 (0)	365 (0)	725 (0)
	Mean (SD)	8.8 (2.96)	8.7 (2.73)	8.8 (2.85)
	Median	8.0	8.0	8.0
	Min, Max	4, 20	4, 18	4, 20
SLEDAI-2K score at baseline	n (missing)	360 (0)	365 (0)	725 (0)
	Mean (SD)	11.4 (3.84)	11.5 (3.70)	11.4 (3.77)
	Median	10.0	10.0	10.0
	Min, Max	4, 32	4, 26	4, 32
SLEDAI-2K score at baseline, categorisation (%)	< 10 points	106 (29.4)	100 (27.4)	206 (28.4)
	>= 10 points	254 (70.6)	265 (72.6)	519 (71.6)
Clinical SLEDAI-2K score at baseline	n (missing)	360 (0)	365 (0)	725 (0)
	Mean (SD)	8.9 (2.93)	8.9 (2.73)	8.9 (2.83)
	Median	8.0	8.0	8.0
	Min, Max	4, 20	4, 18	4, 20
Total Organ Score CNS	n (missing)	360 (0)	365 (0)	725 (0)
	Mean (SD)	0.0 (0.60)	0.0 (0.59)	0.0 (0.59)
	Median	0.0	0.0	0.0
	Min, Max	0, 8	0, 8	0, 8
Total Organ Score CVS and Respiratory	n (missing)	360 (0)	365 (0)	725 (0)
	Mean (SD)	0.2 (0.55)	0.2 (0.57)	0.2 (0.56)
	Median	0.0	0.0	0.0
	Min, Max	0, 2	0, 4	0, 4
Total Organ Score Hematological	n (missing)	360 (0)	365 (0)	725 (0)
	Mean (SD)	0.2 (0.37)	0.1 (0.38)	0.1 (0.38)
	Median	0.0	0.0	0.0
	Min, Max	0, 2	0, 2	0, 2
Total Organ Score Immunology	n (missing)	360 (0)	365 (0)	725 (0)
	Mean (SD)	1.9 (1.61)	1.9 (1.66)	1.9 (1.63)
	Median	2.0	2.0	2.0
	Min, Max	0, 4	0, 4	0, 4
Total Organ Score Mucocutaneous	n (missing)	360 (0)	365 (0)	725 (0)
	Mean (SD)	4.2 (1.57)	4.0 (1.60)	4.1 (1.58)
	Median	4.0	4.0	4.0
	Min, Max	0, 6	0, 6	0, 6
Total Organ Score Musculoskeletal	n (missing)	360 (0)	365 (0)	725 (0)
	Mean (SD)	3.8 (1.09)	3.9 (1.04)	3.8 (1.07)
	Median	4.0	4.0	4.0
	Min, Max	0, 8	0, 8	0, 8
Total Organ Score Renal	n (missing)	360 (0)	365 (0)	725 (0)
	Mean (SD)	0.4 (1.42)	0.5 (1.70)	0.4 (1.56)
	Median	0.0	0.0	0.0
	Min, Max	0, 12	0, 12	0, 12

Baseline is defined as the last measurement prior to randomisation and dose administration on Day 1.
Only subjects with baseline positive anti-dsDNA and abnormal complement level, respectively, are included in the summary statistics for the respective variables.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
SLE disease characteristics
Full analysis set

		Randomised Anifrolumab 300mg (N=360)	Randomised Placebo (N=365)	Total (N=725)
Total Organ Score Vascular	n (missing)	360 (0)	365 (0)	725 (0)
	Mean (SD)	0.9 (2.49)	0.9 (2.50)	0.9 (2.49)
	Median	0.0	0.0	0.0
	Min, Max	0, 8	0, 8	0, 8
Adjudication Scoring (BILAG) at baseline Overall (%)	At least one A	174 (48.3)	179 (49.0)	353 (48.7)
	No A and <2Bs	16 (4.4)	25 (6.8)	41 (5.7)
	No A and at least 2 Bs	170 (47.2)	161 (44.1)	331 (45.7)
Adjudication Scoring (BILAG) at baseline Constitutional (%)	A	1 (0.3)	0	1 (0.1)
	B	24 (6.7)	17 (4.7)	41 (5.7)
	C, D or E	335 (93.1)	348 (95.3)	683 (94.2)
Adjudication Scoring (BILAG) at baseline Mucocutaneous (%)	A	84 (23.3)	75 (20.5)	159 (21.9)
	B	231 (64.2)	236 (64.7)	467 (64.4)
	C, D or E	45 (12.5)	54 (14.8)	99 (13.7)
Adjudication Scoring (BILAG) at baseline Neuropsychiatric (%)	A	1 (0.3)	1 (0.3)	2 (0.3)
	B	8 (2.2)	4 (1.1)	12 (1.7)
	C, D or E	351 (97.5)	360 (98.6)	711 (98.1)
Adjudication Scoring (BILAG) at baseline Musculoskeletal (%)	A	114 (31.7)	115 (31.5)	229 (31.6)
	B	203 (56.4)	212 (58.1)	415 (57.2)
	C, D or E	43 (11.9)	38 (10.4)	81 (11.2)
Adjudication Scoring (BILAG) at baseline Cardiorespiratory (%)	A	3 (0.8)	4 (1.1)	7 (1.0)
	B	27 (7.5)	23 (6.3)	50 (6.9)
	C, D or E	330 (91.7)	338 (92.6)	668 (92.1)
Adjudication Scoring (BILAG) at baseline Gastrointestinal (%)	A	0	1 (0.3)	1 (0.1)
	B	1 (0.3)	3 (0.8)	4 (0.6)
	C, D or E	359 (99.7)	361 (98.9)	720 (99.3)
Adjudication Scoring (BILAG) at baseline Ophthalmic (%)	A	1 (0.3)	0	1 (0.1)
	B	0	1 (0.3)	1 (0.1)
	C, D or E	359 (99.7)	364 (99.7)	723 (99.7)
Adjudication Scoring (BILAG) at baseline Renal (%)	A	2 (0.6)	7 (1.9)	9 (1.2)
	B	23 (6.4)	24 (6.6)	47 (6.5)
	C, D or E	335 (93.1)	334 (91.5)	669 (92.3)
Adjudication Scoring (BILAG) at baseline Haematological (%)	B	2 (0.6)	1 (0.3)	3 (0.4)
	C, D or E	358 (99.4)	364 (99.7)	722 (99.6)
BILAG-2004 global score at baseline	n (missing)	360 (0)	365 (0)	725 (0)
	Mean (SD)	19.2 (5.58)	18.9 (5.23)	19.1 (5.41)
	Median	17.0	18.0	18.0
	Min, Max	2, 40	4, 33	2, 40
Physician Global Assessment (PGA) score at baseline	n (missing)	360 (0)	365 (0)	725 (0)
	Mean (SD)	1.8 (0.41)	1.8 (0.39)	1.8 (0.40)
	Median	1.7	1.8	1.8
	Min, Max	1, 3	1, 3	1, 3
CLASI activity score at baseline	n (missing)	360 (0)	365 (0)	725 (0)
	Mean (SD)	8.4 (7.60)	7.8 (7.22)	8.1 (7.41)
	Median	6.0	6.0	6.0
	Min, Max	0, 51	0, 52	0, 52
CLASI activity score at baseline, categorisation 1 (%)	0	12 (3.3)	18 (4.9)	30 (4.1)

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Only subjects with baseline positive anti-dsDNA and abnormal complement level, respectively, are included in the summary statistics for the respective variables.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
SLE disease characteristics
Full analysis set

		Randomised Anifrolumab 300mg (N=360)	Randomised Placebo (N=365)	Total (N=725)
CLASI activity score at baseline, categorisation 1 (%)	> 0	348 (96.7)	347 (95.1)	695 (95.9)
CLASI activity score at baseline, categorisation 2 (%)	<10	253 (70.3)	271 (74.2)	524 (72.3)
	>=10	107 (29.7)	94 (25.8)	201 (27.7)
CLASI damage score at baseline	n (missing)	360 (0)	365 (0)	725 (0)
	Mean (SD)	2.1 (4.88)	1.9 (4.36)	2.0 (4.63)
	Median	0.0	0.0	0.0
	Min, Max	0, 30	0, 35	0, 35
CLASI damage score at baseline, categorisation 1 (%)	0	240 (66.7)	239 (65.5)	479 (66.1)
	> 0	120 (33.3)	126 (34.5)	246 (33.9)
CLASI damage score at baseline, categorisation 2 (%)	<10	333 (92.5)	349 (95.6)	682 (94.1)
	>=10	27 (7.5)	16 (4.4)	43 (5.9)
Tender Joint Count at Baseline	n (missing)	360 (0)	365 (0)	725 (0)
	Mean (SD)	10.3 (7.41)	10.8 (7.53)	10.5 (7.47)
	Median	9.0	10.0	9.0
	Min, Max	0, 28	0, 28	0, 28
Tender Joint Count at Baseline, categorisation (%)	0	23 (6.4)	18 (4.9)	41 (5.7)
	> 0	337 (93.6)	347 (95.1)	684 (94.3)
Swollen Joint Count at Baseline	n (missing)	360 (0)	365 (0)	725 (0)
	Mean (SD)	6.8 (5.75)	7.2 (5.73)	7.0 (5.74)
	Median	5.0	6.0	6.0
	Min, Max	0, 28	0, 28	0, 28
Swollen Joint Count at Baseline, categorisation (%)	0	36 (10.0)	32 (8.8)	68 (9.4)
	> 0	324 (90.0)	333 (91.2)	657 (90.6)
Active Joint Count at Baseline	n (missing)	360 (0)	365 (0)	725 (0)
	Mean (SD)	6.4 (5.70)	6.7 (5.58)	6.5 (5.64)
	Median	5.0	5.0	5.0
	Min, Max	0, 28	0, 28	0, 28
Active Joint Count at Baseline, categorisation (%)	0	40 (11.1)	34 (9.3)	74 (10.2)
	> 0	320 (88.9)	331 (90.7)	651 (89.8)
SDI global score at baseline	n (missing)	359 (1)	362 (3)	721 (4)
	Mean (SD)	0.6 (1.04)	0.6 (0.89)	0.6 (0.97)
	Median	0.0	0.0	0.0
	Min, Max	0, 5	0, 5	0, 5
SDI global score at baseline, categorisation (%)	0 (no damage)	245 (68.1)	231 (63.3)	476 (65.7)
	>=1 (damage)	114 (31.7)	131 (35.9)	245 (33.8)
	Missing	1 (0.3)	3 (0.8)	4 (0.6)
Time from initial SLE diagnosis to randomisation (months)	n (missing)	360 (0)	365 (0)	725 (0)
	Mean (SD)	123.2 (103.42)	105.7 (94.75)	114.4 (99.47)
	Median	91.0	79.0	85.0
	Min, Max	0, 555	4, 503	0, 555
Cushingoid features (%)	Any Cushingoid Feature	108 (30.0)	126 (34.5)	234 (32.3)
	Moon Face	57 (15.8)	65 (17.8)	122 (16.8)
	Buffalo Hump	28 (7.8)	24 (6.6)	52 (7.2)
	Purple or Violaceous Striae	27 (7.5)	28 (7.7)	55 (7.6)
	Central Obesity	50 (13.9)	54 (14.8)	104 (14.3)
	Hirsutisim	20 (5.6)	12 (3.3)	32 (4.4)
	Acne	24 (6.7)	16 (4.4)	40 (5.5)

Baseline is defined as the last measurement prior to randomisation and dose administration on Day 1.
Only subjects with baseline positive anti-dsDNA and abnormal complement level, respectively, are included in the summary statistics for the respective variables.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
SLE disease characteristics
Full analysis set

		Randomised Anifrolumab 300mg (N=360)	Randomised Placebo (N=365)	Total (N=725)
Cushingoid features (%)	Easy Bruising	53 (14.7)	52 (14.2)	105 (14.5)
	Fragile Skin	35 (9.7)	43 (11.8)	78 (10.8)
Results of 4-gene Type 1 Interferon (IFN) test (%)	High	298 (82.8)	301 (82.5)	599 (82.6)
	Low	62 (17.2)	64 (17.5)	126 (17.4)
Anti-dsDNA levels at baseline	n (missing)	331 (29)	326 (39)	657 (68)
	Mean (SD)	67.8 (195.59)	103.3 (392.31)	85.4 (309.53)
	Median	15.1	13.5	14.2
	Min, Max	1, 1897	1, 3790	1, 3790
Anti-dsDNA levels at baseline, categorisation (%)	Negative	193 (53.6)	210 (57.5)	403 (55.6)
	Positive	167 (46.4)	155 (42.5)	322 (44.4)
ANA (%)	Abnormal (titre >= 1:80)	324 (90.0)	329 (90.1)	653 (90.1)
	Normal (titre < 1:80)	23 (6.4)	26 (7.1)	49 (6.8)
	Missing	13 (3.6)	10 (2.7)	23 (3.2)
Complement C3 level at baseline	n (missing)	360 (0)	365 (0)	725 (0)
	Mean (SD)	1.01 (0.308)	1.01 (0.314)	1.01 (0.311)
	Median	1.01	0.99	1.00
	Min, Max	0.2, 1.9	0.4, 2.0	0.2, 2.0
Complement C3 level at baseline, categorisation (%)	Abnormal	130 (36.1)	137 (37.5)	267 (36.8)
	Normal	230 (63.9)	228 (62.5)	458 (63.2)
Complement C4 level at baseline	n (missing)	360 (0)	365 (0)	725 (0)
	Mean (SD)	0.17 (0.089)	0.17 (0.082)	0.17 (0.086)
	Median	0.15	0.16	0.16
	Min, Max	0.1, 0.6	0.1, 0.4	0.1, 0.6
Complement C4 level at baseline, categorisation (%)	Abnormal	84 (23.3)	85 (23.3)	169 (23.3)
	Normal	276 (76.7)	280 (76.7)	556 (76.7)
Complement CH50 level at baseline	n (missing)	360 (0)	365 (0)	725 (0)
	Mean (SD)	235.00 (108.867)	245.31 (105.458)	240.19 (107.214)
	Median	228.00	252.00	240.00
	Min, Max	5.0, 420.0	5.0, 420.0	5.0, 420.0
Complement CH50 level at baseline, categorisation (%)	Abnormal	35 (9.7)	31 (8.5)	66 (9.1)
	Normal	325 (90.3)	334 (91.5)	659 (90.9)

Baseline is defined as the last measurement prior to randomisation and dose administration on Day 1.
Only subjects with baseline positive anti-dsDNA and abnormal complement level, respectively, are included in the summary statistics for the respective variables.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Observation times for Efficacy endpoints
Full analysis set

		Anifrolumab 300mg (N=360)	Placebo (N=365)
SLEDAI-2K Total Score: Observation time (weeks)	n (missing)	360 (0)	365 (0)
	Mean (SD)	118.6 (64.04)	71.9 (53.71)
	Median	129.8	52.3
	Min, Max	0, 223	0, 218
PGA: Observation time (weeks)	n (missing)	360 (0)	365 (0)
	Mean (SD)	120.9 (64.30)	72.8 (54.28)
	Median	131.9	52.3
	Min, Max	0, 223	0, 218
SDI Global Score: Observation time (weeks)	n (missing)	360 (0)	365 (0)
	Mean (SD)	110.8 (61.30)	67.9 (49.75)
	Median	108.3	52.3
	Min, Max	0, 219	0, 211

Observation duration defined as time from randomization until last non-missing assessment after randomization. Subjects without assessment are censored at day 1.

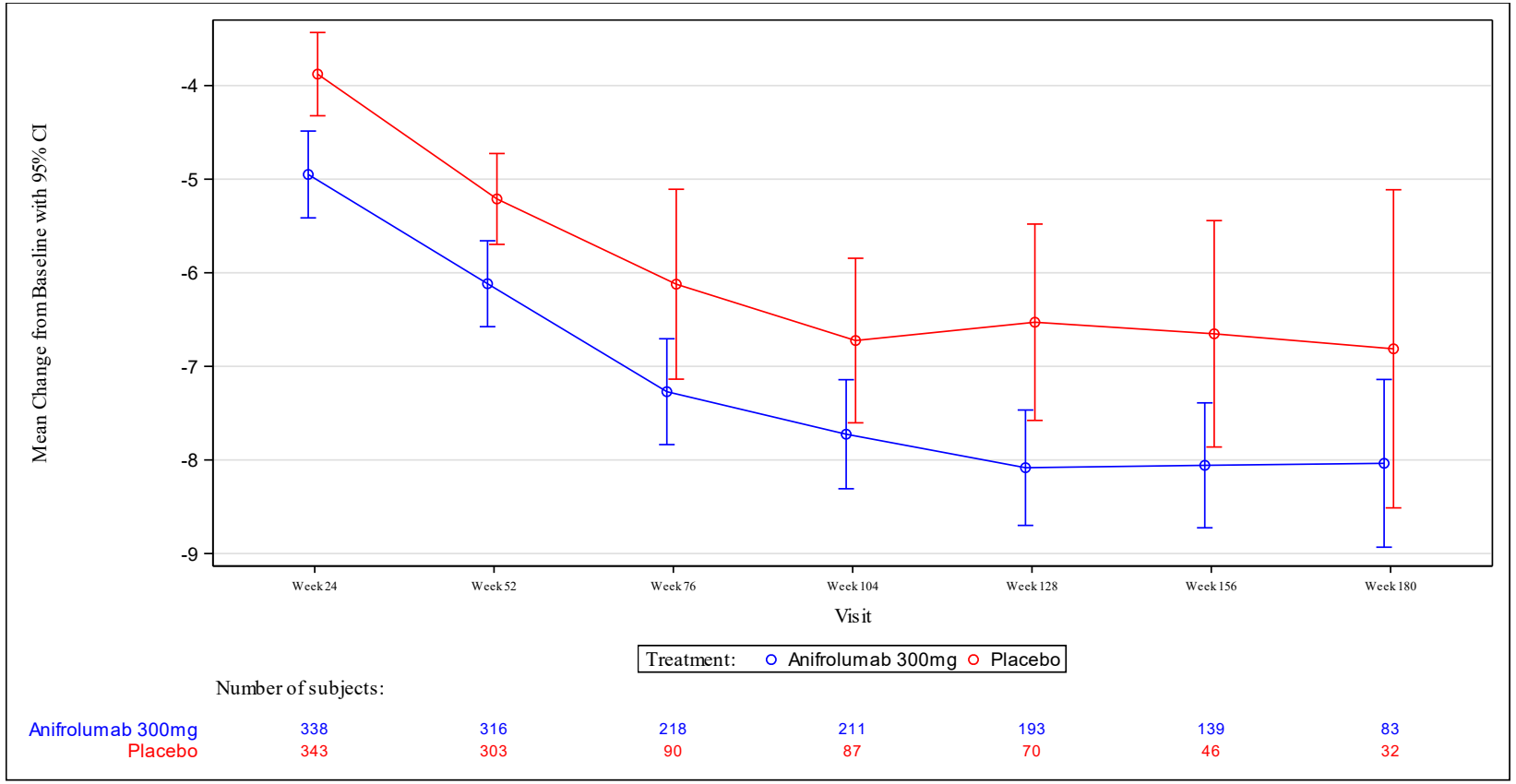
Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - SLEDAI-2K Total Score
Full analysis set

	Ramdomised ANI300 (N=360)				Randomised Placebo (N=365)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	360	11.42 (3.83)	0	-	365	11.51 (3.73)	0	-
Week 24	338	6.47 (4.12)	338	-4.95 (4.33)	343	7.57 (4.34)	343	-3.88 (4.19)
Week 52	316	5.25 (3.74)	316	-6.12 (4.15)	303	6.00 (3.92)	303	-5.21 (4.29)
Week 56	1	8.00 (-)	1	0.00 (-)	1	0.00 (-)	1	-10.00 (-)
Week 60	1	0.00 (-)	1	-8.00 (-)	2	6.00 (5.66)	2	-8.00 (8.49)
Week 64	228	4.17 (3.37)	228	-7.15 (4.53)	98	4.97 (3.88)	98	-6.17 (4.63)
Week 68	4	5.75 (4.03)	4	-5.25 (3.40)	5	5.20 (3.63)	5	-6.20 (2.49)
Week 72	7	6.57 (3.60)	7	-5.43 (4.89)	3	5.00 (5.00)	3	-7.33 (0.58)
Week 76	218	4.06 (3.39)	218	-7.27 (4.24)	90	4.92 (3.80)	90	-6.12 (4.84)
Week 80	7	5.00 (2.89)	7	-7.29 (2.75)	4	8.00 (7.12)	4	-2.00 (8.64)
Week 84	5	4.80 (3.35)	5	-5.20 (4.60)	1	6.00 (-)	1	-2.00 (-)
Week 88	205	3.79 (3.17)	205	-7.39 (4.24)	83	4.89 (3.81)	83	-6.40 (4.22)
Week 92	9	5.33 (4.00)	9	-6.44 (4.53)	4	3.00 (2.58)	4	-9.00 (5.72)
Week 96	1	6.00 (-)	1	-2.00 (-)	3	7.67 (8.14)	3	-7.00 (9.17)
Week 100	3	3.33 (3.06)	3	-4.00 (3.46)	0	-	0	-
Week 104	211	3.45 (2.85)	211	-7.73 (4.29)	87	4.41 (3.62)	87	-6.72 (4.13)
Week 108	7	4.29 (2.69)	7	-6.00 (3.46)	3	2.00 (2.00)	3	-7.33 (1.15)
Week 112	2	4.00 (2.83)	2	-5.00 (4.24)	4	5.50 (1.91)	4	-6.25 (0.50)
Week 116	0	-	0	-	2	4.00 (0.00)	2	-8.00 (2.83)
Week 120	0	-	0	-	2	2.00 (0.00)	2	-9.00 (1.41)
Week 124	2	6.00 (2.83)	2	-2.00 (0.00)	1	10.00 (-)	1	-4.00 (-)
Week 128	193	3.28 (3.41)	193	-8.08 (4.34)	70	4.31 (3.74)	70	-6.53 (4.40)
Week 132	8	5.75 (4.06)	8	-6.13 (7.06)	3	4.00 (5.29)	3	-11.33 (7.02)
Week 136	3	6.67 (4.16)	3	-4.00 (5.29)	2	6.00 (5.66)	2	-9.00 (12.73)
Week 140	2	4.00 (2.83)	2	-4.00 (2.83)	1	10.00 (-)	1	0.00 (-)
Week 144	0	-	0	-	3	5.33 (3.06)	3	-4.67 (4.62)
Week 148	1	8.00 (-)	1	-2.00 (-)	1	10.00 (-)	1	-2.00 (-)
Week 152	3	2.67 (4.62)	3	-6.00 (4.00)	2	8.00 (0.00)	2	-3.00 (1.41)
Week 156	139	2.84 (2.68)	139	-8.06 (3.98)	46	4.24 (3.06)	46	-6.65 (4.07)
Week 160	3	3.00 (2.65)	3	-8.67 (4.16)	2	6.00 (5.66)	2	-6.50 (9.19)
Week 164	1	6.00 (-)	1	-2.00 (-)	0	-	0	-
Week 168	1	10.00 (-)	1	0.00 (-)	0	-	0	-

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - SLEDAI-2K Total Score
Full analysis set

	Ramdomised ANI300 (N=360)				Randomised Placebo (N=365)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Week 172	0	-	0	-	1	0.00 (-)	1	-12.00 (-)
Week 176	2	4.50 (6.36)	2	-1.50 (6.36)	0	-	0	-
Week 180	83	3.11 (3.19)	83	-8.04 (4.10)	32	3.84 (4.54)	32	-6.81 (4.71)
Week 184	4	2.00 (2.83)	4	-9.50 (3.42)	0	-	0	-
Week 192	1	0.00 (-)	1	-8.00 (-)	0	-	0	-
Week 196	1	0.00 (-)	1	-8.00 (-)	0	-	0	-
Week 200	1	6.00 (-)	1	-2.00 (-)	0	-	0	-
Week 204	1	0.00 (-)	1	-6.00 (-)	0	-	0	-
Week 208	25	3.08 (3.21)	25	-7.48 (4.09)	9	3.78 (3.07)	9	-6.00 (3.61)
Week 212	11	4.36 (2.50)	11	-4.64 (4.25)	3	6.00 (2.00)	3	-4.00 (2.00)
Week 216	7	3.71 (2.87)	7	-7.00 (4.86)	5	8.00 (4.47)	5	-1.60 (4.34)
Week 220	5	4.00 (2.83)	5	-5.60 (2.97)	0	-	0	-

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - SLEDAI-2K Total Score
Full analysis set



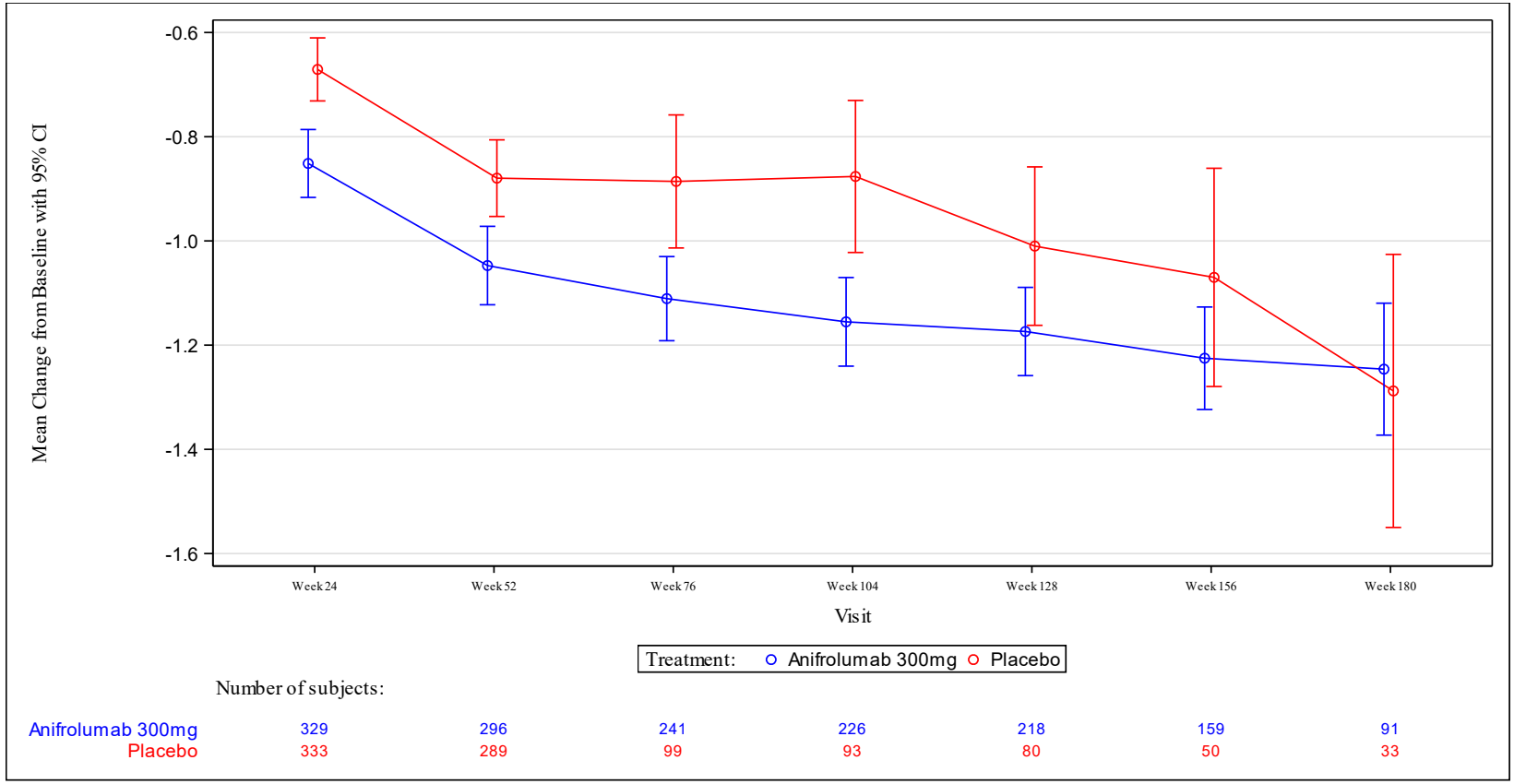
Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - PGA
Full analysis set

	Ramdomised ANI300 (N=360)				Randomised Placebo (N=365)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	360	1.77 (0.41)	0	-	365	1.80 (0.39)	0	-
Week 24	329	0.92 (0.60)	329	-0.85 (0.60)	333	1.12 (0.56)	333	-0.67 (0.56)
Week 52	296	0.70 (0.59)	296	-1.05 (0.66)	289	0.90 (0.59)	289	-0.88 (0.63)
Week 56	1	1.70 (-)	1	-0.60 (-)	1	0.00 (-)	1	-1.40 (-)
Week 60	2	0.50 (0.71)	2	-0.95 (0.92)	2	1.05 (0.35)	2	-0.70 (0.57)
Week 64	245	0.69 (0.55)	245	-1.07 (0.62)	105	0.92 (0.59)	105	-0.84 (0.62)
Week 68	6	1.03 (0.78)	6	-0.90 (0.89)	5	1.10 (0.61)	5	-0.44 (0.94)
Week 72	7	1.59 (0.46)	7	-0.03 (0.28)	3	1.53 (0.49)	3	0.07 (0.25)
Week 76	241	0.66 (0.56)	241	-1.11 (0.64)	99	0.89 (0.59)	99	-0.89 (0.64)
Week 80	6	0.87 (0.54)	6	-1.02 (0.89)	4	1.10 (1.20)	4	-0.48 (1.13)
Week 84	4	0.60 (0.63)	4	-1.33 (0.90)	0	-	0	-
Week 88	232	0.63 (0.56)	232	-1.12 (0.64)	96	0.79 (0.54)	96	-0.99 (0.61)
Week 92	9	0.90 (0.63)	9	-1.20 (0.77)	4	1.00 (0.57)	4	-0.63 (0.85)
Week 96	2	1.50 (0.71)	2	-0.05 (0.49)	3	1.17 (0.40)	3	-0.60 (0.78)
Week 100	5	1.06 (0.65)	5	-0.56 (0.83)	1	0.60 (-)	1	-1.60 (-)
Week 104	226	0.61 (0.54)	226	-1.16 (0.65)	93	0.90 (0.67)	93	-0.88 (0.71)
Week 108	5	0.82 (0.80)	5	-1.06 (1.11)	4	0.30 (0.12)	4	-1.60 (0.50)
Week 112	2	1.45 (0.64)	2	-0.55 (0.07)	4	0.95 (1.12)	4	-0.75 (1.17)
Week 116	0	-	0	-	2	1.45 (0.64)	2	-0.40 (1.13)
Week 120	1	1.50 (-)	1	-1.00 (-)	3	1.03 (0.50)	3	-0.70 (0.62)
Week 124	3	1.27 (0.70)	3	-0.27 (0.38)	1	1.50 (-)	1	0.00 (-)
Week 128	218	0.57 (0.57)	218	-1.17 (0.63)	80	0.77 (0.62)	80	-1.01 (0.68)
Week 132	8	0.94 (0.76)	8	-0.90 (0.65)	3	0.70 (0.87)	3	-0.77 (0.84)
Week 136	3	1.13 (0.99)	3	-0.57 (0.65)	2	0.85 (1.06)	2	-0.45 (1.20)
Week 140	4	1.33 (0.21)	4	-0.53 (0.25)	1	1.50 (-)	1	0.30 (-)
Week 144	0	-	0	-	3	1.57 (0.47)	3	0.00 (0.26)
Week 148	1	1.90 (-)	1	0.60 (-)	1	1.20 (-)	1	-0.30 (-)
Week 152	3	1.07 (1.05)	3	-0.20 (1.05)	2	1.20 (0.14)	2	-0.15 (0.07)
Week 156	159	0.54 (0.55)	159	-1.23 (0.63)	50	0.79 (0.68)	50	-1.07 (0.74)
Week 160	2	0.80 (0.42)	2	-0.85 (0.64)	2	0.75 (1.06)	2	-0.80 (1.56)
Week 164	1	0.70 (-)	1	-0.80 (-)	0	-	0	-
Week 168	2	0.40 (0.57)	2	-1.15 (0.07)	0	-	0	-

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - PGA
Full analysis set

	Ramdomised ANI300 (N=360)				Randomised Placebo (N=365)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Week 172	0	-	0	-	1	0.90 (-)	1	-0.60 (-)
Week 176	2	0.50 (0.71)	2	-0.75 (0.78)	0	-	0	-
Week 180	91	0.53 (0.54)	91	-1.25 (0.61)	33	0.57 (0.60)	33	-1.29 (0.74)
Week 184	1	1.30 (-)	1	-0.20 (-)	0	-	0	-
Week 192	1	0.00 (-)	1	-1.20 (-)	0	-	0	-
Week 196	1	0.20 (-)	1	-1.00 (-)	0	-	0	-
Week 200	1	1.80 (-)	1	0.60 (-)	0	-	0	-
Week 204	1	0.00 (-)	1	-1.30 (-)	0	-	0	-
Week 208	27	0.68 (0.69)	27	-0.99 (0.78)	9	0.79 (0.85)	9	-0.90 (0.74)
Week 212	10	0.86 (0.79)	10	-0.69 (0.93)	3	0.67 (0.98)	3	-0.77 (0.78)
Week 216	10	0.67 (0.52)	10	-1.08 (0.81)	5	1.44 (0.60)	5	-0.22 (0.59)
Week 220	5	0.84 (0.45)	5	-1.08 (0.95)	0	-	0	-

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - PGA
Full analysis set



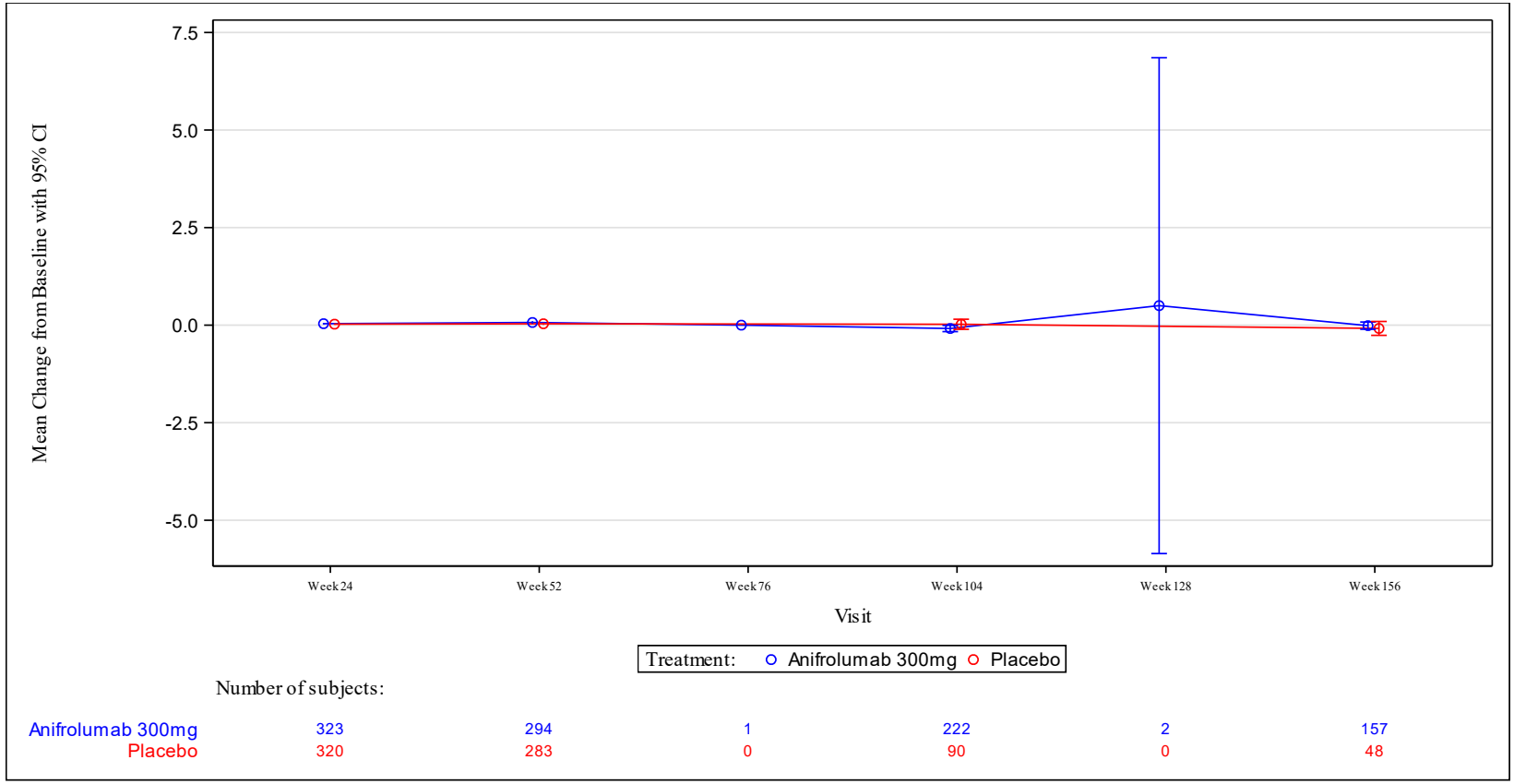
Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - SDI Global Score
Full analysis set

	Ramdomised ANI300 (N=360)				Randomised Placebo (N=365)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	359	0.58 (1.04)	0	-	362	0.56 (0.89)	0	-
Week 24	324	0.63 (1.08)	323	0.04 (0.19)	323	0.57 (0.93)	320	0.03 (0.16)
Week 52	295	0.66 (1.04)	294	0.07 (0.30)	286	0.54 (0.87)	283	0.04 (0.25)
Week 56	1	0.00 (-)	1	0.00 (-)	1	0.00 (-)	1	0.00 (-)
Week 60	1	0.00 (-)	1	0.00 (-)	2	2.00 (2.83)	2	1.00 (2.83)
Week 64	2	1.00 (1.41)	2	0.00 (0.00)	1	0.00 (-)	1	-1.00 (-)
Week 68	1	2.00 (-)	1	0.00 (-)	2	0.50 (0.71)	2	0.50 (0.71)
Week 72	2	1.50 (2.12)	2	-1.00 (1.41)	0	-	0	-
Week 76	1	1.00 (-)	1	0.00 (-)	0	-	0	-
Week 80	0	-	0	-	1	2.00 (-)	1	0.00 (-)
Week 84	2	0.00 (0.00)	2	-0.50 (0.71)	0	-	0	-
Week 88	1	0.00 (-)	1	0.00 (-)	1	0.00 (-)	1	0.00 (-)
Week 92	2	1.50 (0.71)	2	0.00 (0.00)	0	-	0	-
Week 96	2	1.00 (1.41)	2	0.00 (0.00)	2	0.50 (0.71)	2	0.50 (0.71)
Week 100	3	1.00 (1.73)	3	0.33 (0.58)	0	-	0	-
Week 104	222	0.45 (0.92)	222	-0.09 (0.61)	91	0.60 (0.79)	90	0.02 (0.62)
Week 108	4	0.25 (0.50)	4	-0.25 (0.50)	3	0.33 (0.58)	3	0.00 (0.00)
Week 112	1	0.00 (-)	1	0.00 (-)	3	1.33 (1.53)	3	0.33 (0.58)
Week 116	0	-	0	-	1	0.00 (-)	1	-1.00 (-)
Week 120	0	-	0	-	1	0.00 (-)	1	-1.00 (-)
Week 124	1	0.00 (-)	1	0.00 (-)	1	1.00 (-)	1	0.00 (-)
Week 128	2	2.50 (0.71)	2	0.50 (0.71)	0	-	0	-
Week 132	3	0.00 (0.00)	3	0.00 (0.00)	1	0.00 (-)	1	0.00 (-)
Week 136	0	-	0	-	1	0.00 (-)	1	0.00 (-)
Week 140	2	0.00 (0.00)	2	0.00 (0.00)	0	-	0	-
Week 144	0	-	0	-	2	1.00 (0.00)	2	0.00 (1.41)
Week 148	1	0.00 (-)	1	0.00 (-)	1	0.00 (-)	1	0.00 (-)
Week 152	2	1.50 (2.12)	2	0.50 (0.71)	1	1.00 (-)	1	1.00 (-)
Week 156	157	0.58 (1.03)	157	-0.01 (0.59)	49	0.45 (0.68)	48	-0.08 (0.61)
Week 160	1	2.00 (-)	1	2.00 (-)	2	0.50 (0.71)	2	-1.00 (1.41)
Week 168	2	1.00 (1.41)	2	0.00 (0.00)	0	-	0	-
Week 192	1	0.00 (-)	1	0.00 (-)	0	-	0	-

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary statistics of mean values and change from baseline by timepoint - SDI Global Score
Full analysis set

	Ramdomised ANI300 (N=360)				Randomised Placebo (N=365)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Week 204	1	3.00 (-)	1	1.00 (-)	0	-	0	-
Week 208	26	0.54 (0.95)	26	-0.04 (0.66)	9	0.67 (0.87)	9	0.00 (0.50)
Week 212	2	0.00 (0.00)	2	-0.50 (0.71)	0	-	0	-

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Graphical Summary of change from baseline by timepoint - SDI Global Score
Full analysis set



Number of subjects:

Anifrolumab 300mg	323	294	1	222	2	157
Placebo	320	283	0	90	0	48

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SLEDAI-2K Total Score
Full analysis set

Visit	Ramdomised ANI300 (N=360) N	LSMean (SE)	Randomised Placebo (N=365) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 24		-4.85 (0.21)		-3.78 (0.21)	-1.07 (0.29)	(-1.65, -0.50)	0.0003			
Week 52		-6.02 (0.20)		-5.08 (0.20)	-0.94 (0.29)	(-1.50, -0.38)	0.0011			
Week 76		-7.04 (0.22)		-5.97 (0.30)	-1.07 (0.37)	(-1.79, -0.34)	0.0041			
Week 104		-7.71 (0.21)		-6.60 (0.30)	-1.11 (0.36)	(-1.82, -0.39)	0.0025			
Week 128		-7.79 (0.23)		-6.65 (0.37)	-1.14 (0.43)	(-1.99, -0.28)	0.0093			
Week 156		-8.05 (0.21)		-6.70 (0.34)	-1.34 (0.40)	(-2.13, -0.56)	0.0009			
Week 180		-8.04 (0.31)		-6.87 (0.48)	-1.16 (0.57)	(-2.28, -0.05)	0.0415			
OVERALL	339	-7.07 (0.16)	347	-5.95 (0.22)	-1.12 (0.27)	(-1.65, -0.59)	<.0001	-0.31 (0.08)	(-0.46, -0.16)	<.0001

A repeated measures model with fixed effects for baseline value, treatment group, visit and treatment*visit interaction was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SLEDAI-2K Total Score - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=360) N	LSMean (SE)	Randomised Placebo (N=365) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.2724
< 10 points	102	-5.07 (0.24)	100	-4.38 (0.31)	-0.69 (0.39)	(-1.47, 0.09)	0.0811	-0.25 (0.14)	(-0.52, 0.03)	0.0808	
>= 10 points	237	-7.93 (0.21)	247	-6.66 (0.28)	-1.27 (0.35)	(-1.95, -0.59)	0.0003	-0.33 (0.09)	(-0.51, -0.15)	0.0003	
Age (years)											NE
<= 65	329	-7.10 (0.17)	343	-5.97 (0.22)	-1.13 (0.27)	(-1.67, -0.60)	<.0001	-0.32 (0.08)	(-0.47, -0.17)	<.0001	
> 65	10	NE	4	NE	NE	NE		NE	NE		
Sex											0.4274
male	26	-7.85 (0.52)	25	-6.10 (0.63)	-1.74 (0.82)	(-3.39, -0.09)	0.0391	-0.59 (0.29)	(-1.15, -0.03)	0.0392	
female	313	-6.99 (0.17)	322	-5.94 (0.23)	-1.06 (0.29)	(-1.62, -0.49)	0.0003	-0.29 (0.08)	(-0.45, -0.13)	0.0003	
Geographic region											0.4335
EU	109	-7.94 (0.30)	114	-6.53 (0.40)	-1.41 (0.50)	(-2.40, -0.43)	0.0053	-0.38 (0.14)	(-0.64, -0.11)	0.0054	
non-EU	230	-6.62 (0.20)	233	-5.67 (0.26)	-0.95 (0.33)	(-1.59, -0.30)	0.0042	-0.27 (0.09)	(-0.45, -0.08)	0.0042	

A repeated measures model with fixed effects for baseline value, treatment group, visit and treatment*visit interaction was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - PGA
Full analysis set

Visit	Ramdomised ANI300 (N=360) N	LSMean (SE)	Randomised Placebo (N=365) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 24		-0.86 (0.03)		-0.66 (0.03)	-0.20 (0.04)	(-0.28, -0.11)	<.0001			
Week 52		-1.05 (0.03)		-0.85 (0.03)	-0.20 (0.05)	(-0.29, -0.11)	<.0001			
Week 76		-1.06 (0.03)		-0.87 (0.05)	-0.19 (0.06)	(-0.31, -0.08)	0.0007			
Week 104		-1.11 (0.04)		-0.85 (0.05)	-0.26 (0.06)	(-0.39, -0.14)	<.0001			
Week 128		-1.12 (0.04)		-0.96 (0.06)	-0.17 (0.07)	(-0.30, -0.04)	0.0118			
Week 156		-1.15 (0.04)		-0.95 (0.06)	-0.19 (0.08)	(-0.34, -0.05)	0.0105			
Week 180		-1.19 (0.04)		-1.11 (0.07)	-0.08 (0.08)	(-0.24, 0.08)	0.3304			
OVERALL	337	-1.08 (0.03)	338	-0.89 (0.04)	-0.19 (0.05)	(-0.28, -0.10)	<.0001	-0.31 (0.08)	(-0.46, -0.16)	<.0001

A repeated measures model with fixed effects for baseline value, treatment group, visit and treatment*visit interaction was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - PGA - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=360) N	LSMean (SE)	Randomised Placebo (N=365) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.9265
< 10 points	101	-1.04 (0.05)	97	-0.86 (0.06)	-0.18 (0.08)	(-0.34, -0.01)	0.0354	-0.30 (0.14)	(-0.58, -0.02)	0.0346	
>= 10 points	236	-1.09 (0.03)	241	-0.91 (0.04)	-0.18 (0.06)	(-0.29, -0.08)	0.0010	-0.30 (0.09)	(-0.48, -0.12)	0.0010	
Age (years)											NE
<= 65	327	-1.08 (0.03)	334	-0.89 (0.04)	-0.19 (0.05)	(-0.28, -0.10)	<.0001	-0.32 (0.08)	(-0.47, -0.16)	<.0001	
> 65	10	NE	4	NE	NE	NE		NE	NE		
Sex											0.8076
male	26	-1.26 (0.10)	25	-1.04 (0.12)	-0.22 (0.15)	(-0.54, 0.09)	0.1624	-0.40 (0.28)	(-0.95, 0.16)	0.1587	
female	311	-1.06 (0.03)	313	-0.88 (0.04)	-0.18 (0.05)	(-0.28, -0.09)	0.0002	-0.30 (0.08)	(-0.46, -0.14)	0.0002	
Geographic region											0.9205
EU	110	-1.21 (0.04)	112	-1.03 (0.05)	-0.18 (0.06)	(-0.31, -0.05)	0.0062	-0.37 (0.14)	(-0.64, -0.11)	0.0062	
non-EU	227	-1.01 (0.04)	226	-0.82 (0.05)	-0.19 (0.06)	(-0.31, -0.07)	0.0017	-0.30 (0.09)	(-0.48, -0.11)	0.0017	

A repeated measures model with fixed effects for baseline value, treatment group, visit and treatment*visit interaction was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SDI Global Score
Full analysis set

Visit	Ramdomised ANI300 (N=360) N	LSMean (SE)	Randomised Placebo (N=365) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value
Week 24		0.04 (0.01)		0.02 (0.01)	0.01 (0.01)	(-0.01, 0.04)	0.3393			
Week 52		0.07 (0.02)		0.04 (0.02)	0.04 (0.02)	(-0.01, 0.08)	0.1208			
Week 104		-0.08 (0.04)		0.01 (0.06)	-0.10 (0.07)	(-0.24, 0.05)	0.2004			
Week 156		-0.00 (0.04)		-0.13 (0.08)	0.13 (0.09)	(-0.05, 0.30)	0.1528			
OVERALL	332	0.01 (0.02)	328	-0.01 (0.03)	0.02 (0.04)	(-0.05, 0.09)	0.5996	0.04 (0.08)	(-0.11, 0.19)	0.5989

A repeated measures model with fixed effects for baseline value, treatment group, visit and treatment*visit interaction was used.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Repeated measures model analysis - SDI Global Score - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=360) N	LSMean (SE)	Randomised Placebo (N=365) N	LSMean (SE)	Difference of LSMeans (SE)	(95% CI)	p-Value	Hedges'g (SE)	(95% CI)	p-Value	Interaction p-Value
SLEDAI-2K score at screening											0.7502
< 10 points	100	0.06 (0.03)	94	0.02 (0.05)	0.03 (0.06)	(-0.09, 0.15)	0.6037	0.08 (0.14)	(-0.21, 0.36)	0.5993	
>= 10 points	232	-0.02 (0.03)	234	-0.02 (0.04)	0.01 (0.05)	(-0.09, 0.10)	0.8799	0.01 (0.09)	(-0.17, 0.20)	0.8801	
Age (years)											NE
<= 65	322	0.00 (0.02)	325	-0.02 (0.03)	0.02 (0.04)	(-0.06, 0.10)	0.6067	0.04 (0.08)	(-0.11, 0.19)	0.6075	
> 65	10	NE	3	NE	NE	NE		NE	NE		
Sex											0.7583
male	26	0.02 (0.12)	25	0.04 (0.16)	-0.03 (0.20)	(-0.44, 0.38)	0.8855	-0.04 (0.28)	(-0.59, 0.51)	0.8853	
female	306	0.01 (0.02)	303	-0.02 (0.03)	0.03 (0.04)	(-0.04, 0.11)	0.3852	0.07 (0.08)	(-0.09, 0.23)	0.3844	
Geographic region											0.9281
EU	108	-0.05 (0.04)	109	-0.07 (0.05)	0.03 (0.06)	(-0.10, 0.15)	0.6788	0.06 (0.14)	(-0.21, 0.32)	0.6798	
non-EU	224	0.04 (0.03)	219	0.02 (0.04)	0.02 (0.05)	(-0.07, 0.11)	0.6823	0.04 (0.10)	(-0.15, 0.23)	0.6812	

A repeated measures model with fixed effects for baseline value, treatment group, visit and treatment*visit interaction was used.
Overall treatment estimates are displayed.
N defines number of subjects included in the repeated measures model.
An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges>g.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane>s Q statistic.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=360) n (%)	Randomised Placebo (N=365) n (%)
Subjects with events	336 (93.3)	316 (86.6)
Infections and infestations	288 (80.0)	235 (64.4)
Nasopharyngitis	95 (26.4)	51 (14.0)
Upper respiratory tract infection	94 (26.1)	48 (13.2)
Urinary tract infection	74 (20.6)	59 (16.2)
Bronchitis	67 (18.6)	24 (6.6)
Sinusitis	34 (9.4)	22 (6.0)
Oral herpes	26 (7.2)	14 (3.8)
Pharyngitis	25 (6.9)	20 (5.5)
Herpes zoster	40 (11.1)	11 (3.0)
Gastroenteritis	16 (4.4)	16 (4.4)
Pneumonia	21 (5.8)	15 (4.1)
Cystitis	9 (2.5)	9 (2.5)
Influenza	20 (5.6)	11 (3.0)
Viral upper respiratory tract infection	14 (3.9)	6 (1.6)
Gastroenteritis viral	14 (3.9)	5 (1.4)
Vaginal infection	11 (3.1)	10 (2.7)
Respiratory tract infection	14 (3.9)	3 (0.8)
Latent tuberculosis	18 (5.0)	3 (0.8)
Rhinitis	9 (2.5)	6 (1.6)
Conjunctivitis	14 (3.9)	5 (1.4)
Vulvovaginal mycotic infection	13 (3.6)	4 (1.1)
Cellulitis	10 (2.8)	6 (1.6)
Viral infection	8 (2.2)	4 (1.1)
Laryngitis	8 (2.2)	5 (1.4)
Tooth abscess	10 (2.8)	4 (1.1)
Otitis media	12 (3.3)	0
Acute sinusitis	7 (1.9)	3 (0.8)
Oral candidiasis	4 (1.1)	8 (2.2)
Tooth infection	7 (1.9)	4 (1.1)
Herpes simplex	5 (1.4)	2 (0.5)
Lower respiratory tract infection	5 (1.4)	2 (0.5)
Folliculitis	5 (1.4)	4 (1.1)
Bacterial vaginosis	4 (1.1)	3 (0.8)
Onychomycosis	5 (1.4)	3 (0.8)
Paronychia	5 (1.4)	4 (1.1)
Vulvovaginal candidiasis	4 (1.1)	4 (1.1)
Fungal skin infection	4 (1.1)	2 (0.5)
Tonsillitis	5 (1.4)	2 (0.5)
Cervicitis	3 (0.8)	1 (0.3)
Ear infection	5 (1.4)	1 (0.3)
Furuncle	2 (0.6)	2 (0.5)
Hordeolum	2 (0.6)	3 (0.8)
Pharyngotonsillitis	3 (0.8)	3 (0.8)
Tinea versicolour	4 (1.1)	1 (0.3)
Tracheitis	4 (1.1)	1 (0.3)
Vulvovaginitis	3 (0.8)	1 (0.3)
Wound infection	3 (0.8)	3 (0.8)
Diverticulitis	3 (0.8)	0
Fungal infection	3 (0.8)	2 (0.5)
Gastrointestinal viral infection	1 (0.3)	2 (0.5)
Otitis externa	4 (1.1)	1 (0.3)
Periodontitis	1 (0.3)	3 (0.8)
Respiratory tract infection viral	2 (0.6)	2 (0.5)
Viral pharyngitis	5 (1.4)	0
Abscess limb	3 (0.8)	1 (0.3)
Candida infection	3 (0.8)	1 (0.3)
Escherichia urinary tract infection	3 (0.8)	1 (0.3)
Gingivitis	2 (0.6)	2 (0.5)

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=360) n (%)	Randomised Placebo (N=365) n (%)
Pharyngitis streptococcal	1 (0.3)	2 (0.5)
Pyelonephritis	3 (0.8)	0
Subcutaneous abscess	2 (0.6)	2 (0.5)
Tracheobronchitis	3 (0.8)	1 (0.3)
Appendicitis	3 (0.8)	0
Asymptomatic bacteriuria	2 (0.6)	1 (0.3)
Bacterial vulvovaginitis	2 (0.6)	1 (0.3)
Dengue fever	2 (0.6)	0
Genital herpes	2 (0.6)	0
Localised infection	3 (0.8)	0
Otitis media acute	3 (0.8)	0
Sepsis	0	3 (0.8)
Sialoadenitis	2 (0.6)	1 (0.3)
Skin infection	3 (0.8)	0
Tinea pedis	2 (0.6)	1 (0.3)
Acarodermatitis	1 (0.3)	1 (0.3)
Alveolar osteitis	1 (0.3)	1 (0.3)
Bronchitis bacterial	2 (0.6)	0
Chronic sinusitis	1 (0.3)	1 (0.3)
Conjunctivitis viral	1 (0.3)	1 (0.3)
Erysipelas	1 (0.3)	1 (0.3)
Gastroenteritis bacterial	1 (0.3)	1 (0.3)
Gastrointestinal infection	0	2 (0.5)
Genital herpes simplex	1 (0.3)	1 (0.3)
Groin abscess	1 (0.3)	1 (0.3)
Helicobacter infection	1 (0.3)	1 (0.3)
Large intestine infection	1 (0.3)	1 (0.3)
Molluscum contagiosum	1 (0.3)	1 (0.3)
Oral fungal infection	2 (0.6)	0
Otitis externa fungal	0	1 (0.3)
Otitis media chronic	1 (0.3)	1 (0.3)
Parotitis	2 (0.6)	0
Pyelonephritis acute	1 (0.3)	1 (0.3)
Pyuria	1 (0.3)	0
Rotavirus infection	2 (0.6)	0
Skin candida	1 (0.3)	1 (0.3)
Superinfection	1 (0.3)	1 (0.3)
Tinea infection	1 (0.3)	1 (0.3)
Trichomoniasis	1 (0.3)	1 (0.3)
Abscess	0	1 (0.3)
Abscess oral	1 (0.3)	0
Arthritis bacterial	0	1 (0.3)
Arthritis infective	1 (0.3)	0
Atypical pneumonia	0	1 (0.3)
Bartholinitis	1 (0.3)	0
Body tinea	1 (0.3)	0
Bronchitis viral	1 (0.3)	0
Cervicitis human papilloma virus	0	1 (0.3)
Chronic tonsillitis	1 (0.3)	0
Cystitis bacterial	1 (0.3)	0
Cystitis escherichia	0	1 (0.3)
Dacryocystitis	1 (0.3)	0
Epididymitis	0	1 (0.3)
Escherichia infection	1 (0.3)	0
Eyelid infection	1 (0.3)	0
Genitourinary chlamydia infection	1 (0.3)	0
Giardiasis	0	1 (0.3)
Helicobacter gastritis	0	1 (0.3)
Herpes zoster cutaneous disseminated	1 (0.3)	0
Herpes zoster disseminated	1 (0.3)	0
Human ehrlichiosis	1 (0.3)	0

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=360) n (%)	Randomised Placebo (N=365) n (%)
Impetigo	0	1 (0.3)
Labyrinthitis	1 (0.3)	0
Laryngitis viral	1 (0.3)	0
Ludwig angina	0	1 (0.3)
Mediastinitis	0	1 (0.3)
Meningitis	0	1 (0.3)
Meningitis viral	1 (0.3)	0
Mumps	1 (0.3)	0
Mycobacterium avium complex infection	1 (0.3)	0
Nail infection	1 (0.3)	0
Nipple infection	1 (0.3)	0
Ophthalmic herpes simplex	1 (0.3)	0
Otitis media bacterial	1 (0.3)	0
Pelvic infection	0	1 (0.3)
Pelvic inflammatory disease	1 (0.3)	0
Pertussis	1 (0.3)	0
Pharyngitis bacterial	0	1 (0.3)
Pneumonia bacterial	1 (0.3)	0
Pneumonia staphylococcal	0	1 (0.3)
Pneumonia viral	1 (0.3)	0
Postoperative wound infection	0	1 (0.3)
Proteus infection	0	1 (0.3)
Pulpitis dental	0	1 (0.3)
Rash pustular	0	1 (0.3)
Respiratory moniliasis	0	1 (0.3)
Root canal infection	0	1 (0.3)
Septic shock	0	1 (0.3)
Skin bacterial infection	1 (0.3)	0
Soft tissue infection	1 (0.3)	0
Streptococcal urinary tract infection	1 (0.3)	0
Tinea cruris	1 (0.3)	0
Tinea manuum	1 (0.3)	0
Tonsillitis bacterial	0	1 (0.3)
Ureaplasma infection	0	1 (0.3)
Urethritis	0	1 (0.3)
Urinary tract infection bacterial	0	1 (0.3)
Urinary tract infection pseudomonal	1 (0.3)	0
Urosepsis	0	1 (0.3)
Viral sinusitis	1 (0.3)	0
Vulval abscess	0	1 (0.3)
Vulvovaginitis trichomonal	0	1 (0.3)
Wound infection staphylococcal	0	1 (0.3)
Musculoskeletal and connective tissue disorders	146 (40.6)	103 (28.2)
Back pain	35 (9.7)	24 (6.6)
Arthralgia	34 (9.4)	13 (3.6)
Systemic lupus erythematosus	14 (3.9)	15 (4.1)
Pain in extremity	14 (3.9)	7 (1.9)
Bursitis	14 (3.9)	5 (1.4)
Musculoskeletal pain	10 (2.8)	8 (2.2)
Osteoarthritis	12 (3.3)	0
Muscle spasms	5 (1.4)	8 (2.2)
Osteonecrosis	6 (1.7)	4 (1.1)
Myalgia	7 (1.9)	6 (1.6)
Joint swelling	5 (1.4)	6 (1.6)
Musculoskeletal chest pain	7 (1.9)	4 (1.1)
Tendonitis	8 (2.2)	3 (0.8)
Neck pain	8 (2.2)	1 (0.3)
Costochondritis	4 (1.1)	4 (1.1)
Fibromyalgia	4 (1.1)	5 (1.4)
Arthritis	6 (1.7)	1 (0.3)

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=360) n (%)	Randomised Placebo (N=365) n (%)
Flank pain	3 (0.8)	4 (1.1)
Intervertebral disc protrusion	7 (1.9)	0
Synovial cyst	4 (1.1)	2 (0.5)
Osteoporosis	2 (0.6)	4 (1.1)
Rotator cuff syndrome	2 (0.6)	3 (0.8)
Spinal osteoarthritis	3 (0.8)	2 (0.5)
Tenosynovitis	2 (0.6)	1 (0.3)
Muscular weakness	2 (0.6)	1 (0.3)
Musculoskeletal stiffness	2 (0.6)	1 (0.3)
Plantar fasciitis	0	3 (0.8)
Sjogren's syndrome	1 (0.3)	2 (0.5)
Spinal pain	2 (0.6)	0
Synovitis	2 (0.6)	1 (0.3)
Tenosynovitis stenosans	3 (0.8)	0
Arthropathy	2 (0.6)	0
Osteopenia	2 (0.6)	0
Periarthritis	1 (0.3)	1 (0.3)
Bone infarction	0	1 (0.3)
Bone loss	1 (0.3)	0
Chondritis	1 (0.3)	0
Enthesopathy	0	1 (0.3)
Exostosis	1 (0.3)	0
Foot deformity	0	1 (0.3)
Fracture pain	1 (0.3)	0
Groin pain	0	1 (0.3)
Intervertebral disc disorder	1 (0.3)	0
Joint contracture	1 (0.3)	0
Joint instability	1 (0.3)	0
Joint lock	1 (0.3)	0
Ligamentitis	1 (0.3)	0
Metatarsalgia	1 (0.3)	0
Muscle twitching	0	1 (0.3)
Osteochondritis	0	1 (0.3)
Osteochondrosis	1 (0.3)	0
Pain in jaw	0	1 (0.3)
Polychondritis	1 (0.3)	0
SLE arthritis	0	1 (0.3)
Sacroiliitis	1 (0.3)	0
Spinal stenosis	1 (0.3)	0
Temporomandibular joint syndrome	0	1 (0.3)
Tendon pain	0	1 (0.3)
Trigger finger	1 (0.3)	0
Gastrointestinal disorders	122 (33.9)	107 (29.3)
Nausea	25 (6.9)	27 (7.4)
Diarrhoea	24 (6.7)	25 (6.8)
Vomiting	25 (6.9)	11 (3.0)
Abdominal pain upper	13 (3.6)	13 (3.6)
Gastrooesophageal reflux disease	14 (3.9)	14 (3.8)
Constipation	12 (3.3)	13 (3.6)
Abdominal pain	9 (2.5)	11 (3.0)
Dyspepsia	4 (1.1)	10 (2.7)
Gastritis	5 (1.4)	11 (3.0)
Dental caries	9 (2.5)	4 (1.1)
Haemorrhoids	7 (1.9)	1 (0.3)
Abdominal discomfort	4 (1.1)	2 (0.5)
Colitis	4 (1.1)	1 (0.3)
Food poisoning	2 (0.6)	3 (0.8)
Hiatus hernia	2 (0.6)	4 (1.1)
Toothache	3 (0.8)	2 (0.5)
Abdominal distension	3 (0.8)	1 (0.3)

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Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=360) n (%)	Randomised Placebo (N=365) n (%)
Chronic gastritis	3 (0.8)	1 (0.3)
Gastric ulcer	2 (0.6)	1 (0.3)
Irritable bowel syndrome	2 (0.6)	2 (0.5)
Flatulence	1 (0.3)	2 (0.5)
Haemorrhoidal haemorrhage	3 (0.8)	0
Mouth ulceration	2 (0.6)	1 (0.3)
Abdominal pain lower	2 (0.6)	0
Cheilitis	0	2 (0.5)
Diverticulum	2 (0.6)	0
Duodenitis	1 (0.3)	1 (0.3)
Dysphagia	2 (0.6)	0
Enteritis	1 (0.3)	1 (0.3)
Gingival bleeding	2 (0.6)	0
Haematochezia	1 (0.3)	1 (0.3)
Impaired gastric emptying	2 (0.6)	0
Loose tooth	1 (0.3)	0
Oesophageal stenosis	0	1 (0.3)
Abdominal tenderness	1 (0.3)	0
Aphthous ulcer	1 (0.3)	0
Barrett's oesophagus	1 (0.3)	0
Chilaiditi's syndrome	1 (0.3)	0
Dental cyst	1 (0.3)	0
Dry mouth	0	1 (0.3)
Enterocolitis	0	1 (0.3)
Gastric mucosa erythema	1 (0.3)	0
Gastritis erosive	1 (0.3)	0
Gastrointestinal inflammation	1 (0.3)	0
Gastrointestinal pain	0	1 (0.3)
Gastrointestinal wall thickening	1 (0.3)	0
Gingival recession	1 (0.3)	0
Glossitis	0	1 (0.3)
Glossodynia	0	1 (0.3)
Intra-abdominal haematoma	0	1 (0.3)
Large intestine polyp	0	1 (0.3)
Lip swelling	1 (0.3)	0
Lip ulceration	1 (0.3)	0
Malabsorption	0	1 (0.3)
Odynophagia	0	1 (0.3)
Oesophageal hypomotility	1 (0.3)	0
Oesophagitis	1 (0.3)	0
Oral mucosal eruption	1 (0.3)	0
Oral pain	0	1 (0.3)
Palatal disorder	1 (0.3)	0
Pancreatic steatosis	0	1 (0.3)
Paraesthesia oral	1 (0.3)	0
Peptic ulcer	0	1 (0.3)
Rectal haemorrhage	1 (0.3)	0
Salivary hypersecretion	0	1 (0.3)
Stomatitis	0	1 (0.3)
Tongue blistering	0	1 (0.3)
Tooth disorder	0	1 (0.3)
Tooth impacted	1 (0.3)	0
Injury, poisoning and procedural complications	**119 (33.1)**	**81 (22.2)**
Infusion related reaction	52 (14.4)	30 (8.2)
Fall	14 (3.9)	11 (3.0)
Contusion	15 (4.2)	8 (2.2)
Arthropod bite	13 (3.6)	5 (1.4)
Ligament sprain	5 (1.4)	4 (1.1)
Foot fracture	5 (1.4)	4 (1.1)
Limb injury	2 (0.6)	5 (1.4)

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D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=360) n (%)	Randomised Placebo (N=365) n (%)
Animal bite	5 (1.4)	2 (0.5)
Muscle strain	4 (1.1)	4 (1.1)
Road traffic accident	2 (0.6)	3 (0.8)
Skin laceration	5 (1.4)	1 (0.3)
Injury	4 (1.1)	1 (0.3)
Rib fracture	4 (1.1)	3 (0.8)
Arthropod sting	4 (1.1)	1 (0.3)
Skin abrasion	2 (0.6)	4 (1.1)
Joint injury	2 (0.6)	3 (0.8)
Thermal burn	4 (1.1)	1 (0.3)
Ankle fracture	1 (0.3)	3 (0.8)
Epicondylitis	2 (0.6)	2 (0.5)
Ligament rupture	4 (1.1)	0
Meniscus injury	3 (0.8)	1 (0.3)
Radius fracture	2 (0.6)	2 (0.5)
Animal scratch	3 (0.8)	0
Thoracic vertebral fracture	2 (0.6)	1 (0.3)
Tooth fracture	1 (0.3)	2 (0.5)
Wound	1 (0.3)	2 (0.5)
Dental restoration failure	1 (0.3)	1 (0.3)
Hand fracture	1 (0.3)	1 (0.3)
Humerus fracture	1 (0.3)	1 (0.3)
Post-traumatic neck syndrome	0	2 (0.5)
Spinal compression fracture	1 (0.3)	1 (0.3)
Stress fracture	2 (0.6)	0
Tendon rupture	1 (0.3)	1 (0.3)
Toxicity to various agents	2 (0.6)	0
Traumatic haematoma	1 (0.3)	1 (0.3)
Upper limb fracture	1 (0.3)	0
Accident	1 (0.3)	0
Anaemia postoperative	0	1 (0.3)
Bite	1 (0.3)	0
Bone contusion	1 (0.3)	0
Chest injury	0	1 (0.3)
Concussion	1 (0.3)	0
Eye contusion	1 (0.3)	0
Facial bones fracture	1 (0.3)	0
Fibula fracture	0	1 (0.3)
Foreign body in respiratory tract	1 (0.3)	0
Hypobarism	1 (0.3)	0
Incisional hernia	1 (0.3)	0
Joint capsule rupture	1 (0.3)	0
Joint dislocation	1 (0.3)	0
Ligament injury	1 (0.3)	0
Limb crushing injury	0	1 (0.3)
Lower limb fracture	1 (0.3)	0
Mouth injury	1 (0.3)	0
Muscle contusion	1 (0.3)	0
Nail avulsion	1 (0.3)	0
Nail injury	0	1 (0.3)
Overdose	1 (0.3)	0
Perirenal haematoma	0	1 (0.3)
Post procedural complication	1 (0.3)	0
Post procedural haematoma	0	1 (0.3)
Post procedural haemorrhage	0	1 (0.3)
Post-traumatic pain	1 (0.3)	0
Pubis fracture	0	1 (0.3)
Reactive gastropathy	1 (0.3)	0
Scar	0	1 (0.3)
Skin injury	0	1 (0.3)
Spinal fracture	1 (0.3)	0

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=360) n (%)	Randomised Placebo (N=365) n (%)
Sunburn	1 (0.3)	0
Tendon injury	0	1 (0.3)
Tibia fracture	1 (0.3)	0
Traumatic fracture	1 (0.3)	0
Vaccination complication	1 (0.3)	0
Wound complication	1 (0.3)	0
Nervous system disorders	**112 (31.1)**	**66 (18.1)**
Headache	42 (11.7)	39 (10.7)
Dizziness	13 (3.6)	12 (3.3)
Migraine	6 (1.7)	9 (2.5)
Hypoaesthesia	6 (1.7)	3 (0.8)
Sciatica	9 (2.5)	0
Carpal tunnel syndrome	6 (1.7)	2 (0.5)
Post herpetic neuralgia	8 (2.2)	0
Syncope	6 (1.7)	2 (0.5)
Paraesthesia	7 (1.9)	0
Neuralgia	4 (1.1)	2 (0.5)
Restless legs syndrome	4 (1.1)	2 (0.5)
Amnesia	2 (0.6)	2 (0.5)
Cervicobrachial syndrome	3 (0.8)	1 (0.3)
Tremor	1 (0.3)	2 (0.5)
Lumbar radiculopathy	3 (0.8)	0
Migraine with aura	3 (0.8)	0
Neuropathy peripheral	2 (0.6)	1 (0.3)
Presyncope	2 (0.6)	1 (0.3)
Somnolence	3 (0.8)	0
Tension headache	1 (0.3)	2 (0.5)
Cervical radiculopathy	1 (0.3)	1 (0.3)
Dizziness postural	1 (0.3)	1 (0.3)
Dysgeusia	1 (0.3)	0
Facial paralysis	1 (0.3)	1 (0.3)
Ischaemic stroke	1 (0.3)	0
Myoclonus	1 (0.3)	1 (0.3)
Peroneal nerve palsy	2 (0.6)	0
Radiculopathy	2 (0.6)	0
Aphasia	1 (0.3)	0
Arachnoid cyst	0	1 (0.3)
Burning sensation	1 (0.3)	0
Cognitive disorder	1 (0.3)	0
Dysarthria	1 (0.3)	0
Epilepsy	1 (0.3)	0
Haemorrhagic cerebral infarction	0	1 (0.3)
Hemiparesis	1 (0.3)	0
Hyperaesthesia	0	1 (0.3)
Intention tremor	0	1 (0.3)
Intercostal neuralgia	1 (0.3)	0
Intracranial aneurysm	1 (0.3)	0
Meningism	1 (0.3)	0
Myasthenia gravis	1 (0.3)	0
Occipital neuralgia	1 (0.3)	0
Parkinson's disease	1 (0.3)	0
Parkinsonian gait	1 (0.3)	0
Peripheral sensory neuropathy	1 (0.3)	0
Sensory disturbance	0	1 (0.3)
Spinal cord compression	0	1 (0.3)
Trigeminal neuralgia	1 (0.3)	0
Tunnel vision	0	1 (0.3)
Vestibular migraine	1 (0.3)	0
Visual field defect	1 (0.3)	0

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=360) n (%)	Randomised Placebo (N=365) n (%)
Respiratory, thoracic and mediastinal disorders	81 (22.5)	63 (17.3)
Cough	32 (8.9)	14 (3.8)
Asthma	5 (1.4)	9 (2.5)
Epistaxis	6 (1.7)	8 (2.2)
Oropharyngeal pain	8 (2.2)	8 (2.2)
Dyspnoea	4 (1.1)	7 (1.9)
Rhinitis allergic	6 (1.7)	4 (1.1)
Nasal congestion	3 (0.8)	5 (1.4)
Productive cough	5 (1.4)	3 (0.8)
Rhinorrhoea	5 (1.4)	1 (0.3)
Pleural effusion	4 (1.1)	3 (0.8)
Sinus congestion	4 (1.1)	1 (0.3)
Chronic obstructive pulmonary disease	2 (0.6)	1 (0.3)
Upper respiratory tract inflammation	3 (0.8)	0
Lower respiratory tract congestion	2 (0.6)	0
Nasal obstruction	1 (0.3)	2 (0.5)
Pulmonary hypertension	0	1 (0.3)
Sleep apnoea syndrome	1 (0.3)	2 (0.5)
Acute respiratory failure	2 (0.6)	0
Pleuritic pain	1 (0.3)	0
Pulmonary embolism	1 (0.3)	1 (0.3)
Pulmonary mass	1 (0.3)	1 (0.3)
Respiratory disorder	1 (0.3)	1 (0.3)
Wheezing	1 (0.3)	1 (0.3)
Allergic sinusitis	0	1 (0.3)
Atelectasis	1 (0.3)	0
Bronchial hyperreactivity	1 (0.3)	0
Bronchitis chronic	1 (0.3)	0
Catarrh	0	1 (0.3)
Dysphonia	0	1 (0.3)
Dyspnoea exertional	0	1 (0.3)
Haemoptysis	1 (0.3)	0
Hypersensitivity pneumonitis	0	1 (0.3)
Interstitial lung disease	1 (0.3)	0
Lung disorder	1 (0.3)	0
Nasal polyps	1 (0.3)	0
Paranasal sinus discomfort	0	1 (0.3)
Pleurisy	1 (0.3)	0
Pulmonary alveolar haemorrhage	0	1 (0.3)
Rales	0	1 (0.3)
Respiratory distress	0	1 (0.3)
Respiratory failure	0	1 (0.3)
Throat irritation	1 (0.3)	0
Tracheal stenosis	1 (0.3)	0
Upper-airway cough syndrome	1 (0.3)	0
Vocal cord disorder	1 (0.3)	0
Skin and subcutaneous tissue disorders	83 (23.1)	51 (14.0)
Rash	8 (2.2)	10 (2.7)
Urticaria	7 (1.9)	7 (1.9)
Pruritus	7 (1.9)	6 (1.6)
Ecchymosis	6 (1.7)	2 (0.5)
Skin ulcer	4 (1.1)	2 (0.5)
Dermatitis contact	5 (1.4)	2 (0.5)
Eczema	5 (1.4)	2 (0.5)
Erythema	4 (1.1)	3 (0.8)
Hidradenitis	4 (1.1)	1 (0.3)
Acne	4 (1.1)	0
Angioedema	3 (0.8)	2 (0.5)
Dermatitis	1 (0.3)	4 (1.1)
Dermatitis allergic	3 (0.8)	1 (0.3)

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=360) n (%)	Randomised Placebo (N=365) n (%)
Ingrowing nail	4 (1.1)	0
Intertrigo	4 (1.1)	0
Perioral dermatitis	2 (0.6)	0
Skin hyperpigmentation	2 (0.6)	1 (0.3)
Dry skin	1 (0.3)	1 (0.3)
Hyperhidrosis	1 (0.3)	2 (0.5)
Miliaria	1 (0.3)	2 (0.5)
Night sweats	2 (0.6)	0
Purpura	2 (0.6)	1 (0.3)
Rash papular	0	2 (0.5)
Rash pruritic	2 (0.6)	1 (0.3)
Alopecia	1 (0.3)	1 (0.3)
Dermal cyst	1 (0.3)	1 (0.3)
Dermatitis atopic	2 (0.6)	0
Erythema nodosum	0	1 (0.3)
Nail dystrophy	1 (0.3)	1 (0.3)
Psoriasis	1 (0.3)	1 (0.3)
Rosacea	2 (0.6)	0
Seborrhoeic dermatitis	2 (0.6)	0
Skin fissures	1 (0.3)	1 (0.3)
Skin lesion	1 (0.3)	1 (0.3)
Actinic keratosis	1 (0.3)	0
Blister	1 (0.3)	0
Cold urticaria	0	1 (0.3)
Dandruff	1 (0.3)	0
Decubitus ulcer	0	1 (0.3)
Dermatitis acneiform	0	1 (0.3)
Drug eruption	0	1 (0.3)
Eczema asteatotic	0	1 (0.3)
Eczema nummular	0	1 (0.3)
Guttate psoriasis	1 (0.3)	0
Haemorrhage subcutaneous	0	1 (0.3)
Hyperkeratosis	0	1 (0.3)
Keloid scar	1 (0.3)	0
Keratosis pilaris	0	1 (0.3)
Leukonychia	1 (0.3)	0
Lichen sclerosus	1 (0.3)	0
Lipoatrophy	1 (0.3)	0
Livedo reticularis	0	1 (0.3)
Nail bed bleeding	0	1 (0.3)
Nail disorder	1 (0.3)	0
Onychoclasis	1 (0.3)	0
Papule	1 (0.3)	0
Petechiae	1 (0.3)	0
Photosensitivity reaction	1 (0.3)	0
Pigmentation disorder	1 (0.3)	0
Post inflammatory pigmentation change	0	1 (0.3)
Rash erythematous	1 (0.3)	0
Rash follicular	1 (0.3)	0
Rash maculo-papular	1 (0.3)	0
Rash vesicular	1 (0.3)	0
Scab	1 (0.3)	0
Skin discolouration	0	1 (0.3)
Solar dermatitis	0	1 (0.3)
Systemic lupus erythematosus rash	0	1 (0.3)
Urticaria chronic	1 (0.3)	0
Vasculitic ulcer	1 (0.3)	0
Venous ulcer pain	0	1 (0.3)
Vitiligo	0	1 (0.3)
Xanthelasma	0	1 (0.3)

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=360) n (%)	Randomised Placebo (N=365) n (%)
General disorders and administration site conditions	76 (21.1)	50 (13.7)
Pyrexia	11 (3.1)	11 (3.0)
Fatigue	13 (3.6)	5 (1.4)
Non-cardiac chest pain	9 (2.5)	10 (2.7)
Influenza like illness	8 (2.2)	5 (1.4)
Oedema peripheral	13 (3.6)	5 (1.4)
Chest pain	9 (2.5)	0
Asthenia	5 (1.4)	2 (0.5)
Adverse drug reaction	3 (0.8)	3 (0.8)
Pain	3 (0.8)	1 (0.3)
Peripheral swelling	4 (1.1)	2 (0.5)
Chest discomfort	4 (1.1)	1 (0.3)
Nodule	2 (0.6)	2 (0.5)
Swelling face	0	3 (0.8)
Chills	0	2 (0.5)
Drug intolerance	2 (0.6)	0
Face oedema	2 (0.6)	0
Facial pain	1 (0.3)	0
Feeling cold	0	1 (0.3)
Gait disturbance	1 (0.3)	0
Gravitational oedema	0	1 (0.3)
Injection site bruising	0	1 (0.3)
Injection site rash	0	1 (0.3)
Injection site reaction	0	1 (0.3)
Malaise	1 (0.3)	0
Thirst	0	1 (0.3)
Vaccination site reaction	1 (0.3)	0
Psychiatric disorders	39 (10.8)	43 (11.8)
Insomnia	12 (3.3)	18 (4.9)
Depression	17 (4.7)	12 (3.3)
Anxiety	12 (3.3)	8 (2.2)
Suicidal ideation	1 (0.3)	1 (0.3)
Adjustment disorder	0	1 (0.3)
Adjustment disorder with depressed mood	1 (0.3)	0
Affect lability	0	1 (0.3)
Anxiety disorder	1 (0.3)	0
Conversion disorder	1 (0.3)	0
Depressed mood	0	1 (0.3)
Drug use disorder	1 (0.3)	0
Libido decreased	0	1 (0.3)
Loss of libido	0	1 (0.3)
Mental disorder	1 (0.3)	0
Mixed anxiety and depressive disorder	1 (0.3)	0
Neurosis	1 (0.3)	0
Panic attack	1 (0.3)	0
Persistent depressive disorder	0	1 (0.3)
Psychotic disorder	0	1 (0.3)
Substance-induced psychotic disorder	0	1 (0.3)
Suicide attempt	0	1 (0.3)
Metabolism and nutrition disorders	38 (10.6)	40 (11.0)
Hypokalaemia	6 (1.7)	8 (2.2)
Dehydration	1 (0.3)	8 (2.2)
Vitamin D deficiency	5 (1.4)	4 (1.1)
Hypercholesterolaemia	7 (1.9)	1 (0.3)
Type 2 diabetes mellitus	2 (0.6)	3 (0.8)
Decreased appetite	2 (0.6)	2 (0.5)
Diabetes mellitus	4 (1.1)	0
Hyperglycaemia	2 (0.6)	2 (0.5)
Vitamin B12 deficiency	3 (0.8)	1 (0.3)

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Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=360) n (%)	Randomised Placebo (N=365) n (%)
Dyslipidaemia	1 (0.3)	2 (0.5)
Hyperlipidaemia	2 (0.6)	1 (0.3)
Hypocalcaemia	1 (0.3)	1 (0.3)
Glucose tolerance impaired	1 (0.3)	1 (0.3)
Hyperkalaemia	0	2 (0.5)
Hypertriglyceridaemia	2 (0.6)	0
Hyperuricaemia	1 (0.3)	1 (0.3)
Hypomagnesaemia	1 (0.3)	1 (0.3)
Iron deficiency	2 (0.6)	0
Obesity	1 (0.3)	1 (0.3)
Steroid diabetes	2 (0.6)	0
Vitamin B complex deficiency	2 (0.6)	0
Abnormal loss of weight	0	1 (0.3)
Diabetes mellitus inadequate control	1 (0.3)	0
Fluid overload	0	1 (0.3)
Hypercalcaemia	1 (0.3)	0
Hypoalbuminaemia	1 (0.3)	0
Hyponatraemia	0	1 (0.3)
Hypophosphataemia	1 (0.3)	0
Increased appetite	1 (0.3)	0
Lactic acidosis	0	1 (0.3)
Lipoedema	0	1 (0.3)
Overweight	1 (0.3)	0
Eye disorders	43 (11.9)	25 (6.8)
Cataract	7 (1.9)	3 (0.8)
Dry eye	6 (1.7)	3 (0.8)
Blepharitis	4 (1.1)	3 (0.8)
Conjunctival haemorrhage	3 (0.8)	3 (0.8)
Vision blurred	5 (1.4)	0
Chalazion	2 (0.6)	2 (0.5)
Episcleritis	3 (0.8)	0
Retinopathy	3 (0.8)	0
Swelling of eyelid	1 (0.3)	0
Corneal erosion	1 (0.3)	1 (0.3)
Erythema of eyelid	2 (0.6)	0
Glaucoma	1 (0.3)	0
Keratitis	1 (0.3)	1 (0.3)
Maculopathy	0	2 (0.5)
Vitreous floaters	2 (0.6)	0
Accommodation disorder	1 (0.3)	0
Asthenopia	1 (0.3)	0
Chorioretinopathy	1 (0.3)	0
Conjunctival erosion	0	1 (0.3)
Conjunctivitis allergic	1 (0.3)	0
Diplopia	0	1 (0.3)
Eczema eyelids	1 (0.3)	0
Eye discharge	1 (0.3)	0
Eye inflammation	1 (0.3)	0
Eye pruritus	1 (0.3)	0
Eyelid cyst	0	1 (0.3)
Eyelid oedema	0	1 (0.3)
Lacrimation decreased	1 (0.3)	0
Lacrimation increased	1 (0.3)	0
Macular degeneration	1 (0.3)	0
Meibomian gland dysfunction	1 (0.3)	0
Periorbital oedema	1 (0.3)	0
Photophobia	0	1 (0.3)
Punctate keratitis	0	1 (0.3)
Retinal exudates	0	1 (0.3)
Trichiasis	0	1 (0.3)

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Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=360) n (%)	Randomised Placebo (N=365) n (%)
Ulcerative keratitis	0	1 (0.3)
Visual impairment	0	1 (0.3)
Reproductive system and breast disorders	42 (11.7)	22 (6.0)
Ovarian cyst	8 (2.2)	2 (0.5)
Menorrhagia	5 (1.4)	3 (0.8)
Cervical dysplasia	4 (1.1)	2 (0.5)
Dysmenorrhoea	6 (1.7)	0
Uterine haemorrhage	4 (1.1)	0
Breast cyst	3 (0.8)	1 (0.3)
Amenorrhoea	2 (0.6)	1 (0.3)
Fibrocystic breast disease	3 (0.8)	0
Breast mass	2 (0.6)	0
Menometrorrhagia	2 (0.6)	0
Menstruation irregular	1 (0.3)	1 (0.3)
Uterine polyp	2 (0.6)	0
Vulvovaginal pruritus	2 (0.6)	0
Adenomyosis	0	1 (0.3)
Adnexa uteri cyst	0	1 (0.3)
Atrophic vulvovaginitis	1 (0.3)	0
Balanoposthitis	1 (0.3)	0
Breast calcifications	0	1 (0.3)
Breast disorder	1 (0.3)	0
Breast enlargement	1 (0.3)	0
Breast pain	1 (0.3)	0
Cervical cyst	1 (0.3)	0
Cervical polyp	1 (0.3)	0
Cervix disorder	1 (0.3)	0
Cystocele	0	1 (0.3)
Dysfunctional uterine bleeding	1 (0.3)	0
Dyspareunia	1 (0.3)	0
Ectropion of cervix	0	1 (0.3)
Endometrial hyperplasia	0	1 (0.3)
Endometrial hypertrophy	0	1 (0.3)
Endometriosis	0	1 (0.3)
Menopausal symptoms	0	1 (0.3)
Metrorrhagia	1 (0.3)	0
Perineal rash	1 (0.3)	0
Polycystic ovaries	1 (0.3)	0
Polymenorrhoea	1 (0.3)	0
Premenstrual syndrome	1 (0.3)	0
Pruritus genital	1 (0.3)	0
Scrotal ulcer	0	1 (0.3)
Uterine prolapse	0	1 (0.3)
Uterovaginal prolapse	0	1 (0.3)
Vaginal discharge	1 (0.3)	0
Vaginal haemorrhage	0	1 (0.3)
Vaginal ulceration	0	1 (0.3)
Investigations	34 (9.4)	26 (7.1)
Weight increased	7 (1.9)	6 (1.6)
Blood pressure increased	2 (0.6)	0
Alanine aminotransferase increased	3 (0.8)	3 (0.8)
Liver function test increased	0	5 (1.4)
Aspartate aminotransferase increased	1 (0.3)	2 (0.5)
Blood creatine phosphokinase increased	2 (0.6)	1 (0.3)
Blood potassium decreased	2 (0.6)	1 (0.3)
Gamma-glutamyltransferase increased	1 (0.3)	2 (0.5)
Urine protein/creatinine ratio increased	3 (0.8)	0
Weight decreased	3 (0.8)	0
Blood creatinine increased	2 (0.6)	0

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Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=360) n (%)	Randomised Placebo (N=365) n (%)
Cardiac murmur	1 (0.3)	1 (0.3)
Human papilloma virus test positive	1 (0.3)	1 (0.3)
Transaminases increased	1 (0.3)	1 (0.3)
Anticoagulation drug level below therapeutic	1 (0.3)	0
Bacterial test positive	1 (0.3)	0
Blood alkaline phosphatase increased	1 (0.3)	0
Blood corticotrophin decreased	1 (0.3)	0
Blood immunoglobulin A decreased	0	1 (0.3)
Blood pressure systolic increased	0	1 (0.3)
Cortisol decreased	1 (0.3)	0
Cytomegalovirus test positive	1 (0.3)	0
Electrocardiogram QT prolonged	1 (0.3)	0
Gardnerella test positive	0	1 (0.3)
Heart rate increased	0	1 (0.3)
Hepatic enzyme increased	0	1 (0.3)
Influenza B virus test positive	1 (0.3)	0
International normalised ratio abnormal	1 (0.3)	0
International normalised ratio increased	0	1 (0.3)
Intraocular pressure increased	1 (0.3)	0
Smear cervix abnormal	1 (0.3)	0
Vitamin D decreased	1 (0.3)	0
Renal and urinary disorders	33 (9.2)	20 (5.5)
Nephrolithiasis	6 (1.7)	2 (0.5)
Dysuria	1 (0.3)	8 (2.2)
Acute kidney injury	4 (1.1)	4 (1.1)
Renal colic	4 (1.1)	1 (0.3)
Lupus nephritis	3 (0.8)	2 (0.5)
Renal impairment	1 (0.3)	1 (0.3)
Haematuria	2 (0.6)	0
Chronic kidney disease	1 (0.3)	1 (0.3)
Hypertonic bladder	1 (0.3)	1 (0.3)
Urinary retention	2 (0.6)	0
Urinary tract discomfort	1 (0.3)	0
Bladder spasm	1 (0.3)	0
Chromaturia	1 (0.3)	0
Glomerulonephritis	1 (0.3)	0
Hydronephrosis	1 (0.3)	0
Leukocyturia	1 (0.3)	0
Nephritis	1 (0.3)	0
Polyuria	1 (0.3)	0
Renal cyst	1 (0.3)	0
Renal failure	0	1 (0.3)
Stress urinary incontinence	1 (0.3)	0
Ureteric obstruction	1 (0.3)	0
Urethral meatus stenosis	1 (0.3)	0
Urinary incontinence	1 (0.3)	0
Blood and lymphatic system disorders	28 (7.8)	28 (7.7)
Iron deficiency anaemia	12 (3.3)	8 (2.2)
Anaemia	5 (1.4)	10 (2.7)
Lymphadenopathy	4 (1.1)	2 (0.5)
Thrombocytopenia	2 (0.6)	2 (0.5)
Neutropenia	4 (1.1)	0
Leukopenia	0	3 (0.8)
Leukocytosis	1 (0.3)	1 (0.3)
Lymphopenia	1 (0.3)	0
Microcytic anaemia	0	2 (0.5)
Pancytopenia	0	1 (0.3)
Autoimmune haemolytic anaemia	0	1 (0.3)
Increased tendency to bruise	1 (0.3)	0

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Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=360) n (%)	Randomised Placebo (N=365) n (%)
Neutrophilia	0	1 (0.3)
Normocytic anaemia	0	1 (0.3)
Thrombocytosis	0	1 (0.3)
Vascular disorders	26 (7.2)	27 (7.4)
Hypertension	14 (3.9)	15 (4.1)
Haematoma	2 (0.6)	2 (0.5)
Deep vein thrombosis	1 (0.3)	1 (0.3)
Orthostatic hypotension	1 (0.3)	1 (0.3)
Phlebitis	2 (0.6)	0
Raynaud's phenomenon	1 (0.3)	1 (0.3)
Varicose vein	1 (0.3)	1 (0.3)
Essential hypertension	1 (0.3)	0
Hypotension	0	1 (0.3)
Internal haemorrhage	0	1 (0.3)
Lymphoedema	0	1 (0.3)
Malignant hypertension	1 (0.3)	0
Peripheral venous disease	1 (0.3)	0
Phlebitis superficial	1 (0.3)	0
Post thrombotic syndrome	0	1 (0.3)
Thrombophlebitis superficial	1 (0.3)	0
Varicophlebitis	0	1 (0.3)
Vasculitis	0	1 (0.3)
Vasodilatation	0	1 (0.3)
Venous thrombosis limb	0	1 (0.3)
Ear and labyrinth disorders	27 (7.5)	18 (4.9)
Vertigo	11 (3.1)	5 (1.4)
Ear pain	5 (1.4)	3 (0.8)
Vertigo positional	4 (1.1)	2 (0.5)
Tinnitus	1 (0.3)	4 (1.1)
Cerumen impaction	2 (0.6)	0
Deafness bilateral	2 (0.6)	0
Ear congestion	1 (0.3)	1 (0.3)
Hypoacusis	0	2 (0.5)
Deafness	1 (0.3)	0
Dysacusis	0	1 (0.3)
Ear discomfort	0	1 (0.3)
Ear pruritus	0	1 (0.3)
Hyperacusis	1 (0.3)	0
Inner ear inflammation	1 (0.3)	0
Meniere's disease	0	1 (0.3)
Motion sickness	0	1 (0.3)
Neurosensory hypoacusis	1 (0.3)	0
Otorrhoea	0	1 (0.3)
Tympanic membrane hyperaemia	1 (0.3)	0
Cardiac disorders	15 (4.2)	21 (5.8)
Palpitations	1 (0.3)	5 (1.4)
Atrial fibrillation	0	4 (1.1)
Cardiac failure congestive	1 (0.3)	3 (0.8)
Supraventricular tachycardia	0	3 (0.8)
Tachycardia	2 (0.6)	1 (0.3)
Acute myocardial infarction	0	2 (0.5)
Angina unstable	2 (0.6)	0
Bundle branch block right	2 (0.6)	0
Coronary artery disease	2 (0.6)	0
Myocardial infarction	1 (0.3)	1 (0.3)
Pericarditis	0	2 (0.5)
Sinus bradycardia	1 (0.3)	1 (0.3)
Acute coronary syndrome	1 (0.3)	0

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=360) n (%)	Randomised Placebo (N=365) n (%)
Angina pectoris	0	1 (0.3)
Aortic valve disease	1 (0.3)	0
Arrhythmia	1 (0.3)	0
Bradycardia	0	1 (0.3)
Bundle branch block left	1 (0.3)	0
Cardiac failure	0	1 (0.3)
Cardiac failure chronic	1 (0.3)	0
Cardiogenic shock	0	1 (0.3)
Cardiomegaly	0	1 (0.3)
Cardiomyopathy	0	1 (0.3)
Left ventricular dilatation	1 (0.3)	0
Myocardial ischaemia	1 (0.3)	0
Pericardial effusion	0	1 (0.3)
Tachycardia paroxysmal	1 (0.3)	0
Ventricular arrhythmia	0	1 (0.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	27 (7.5)	12 (3.3)
Skin papilloma	7 (1.9)	1 (0.3)
Uterine leiomyoma	5 (1.4)	2 (0.5)
Anogenital warts	3 (0.8)	0
Haemangioma of liver	1 (0.3)	2 (0.5)
Colon adenoma	0	1 (0.3)
Fibrous histiocytoma	2 (0.6)	0
Lipoma	1 (0.3)	1 (0.3)
Seborrhoeic keratosis	1 (0.3)	1 (0.3)
Squamous cell carcinoma	1 (0.3)	1 (0.3)
Acanthoma	1 (0.3)	0
B-cell lymphoma	1 (0.3)	0
Basal cell carcinoma	1 (0.3)	0
Benign breast neoplasm	1 (0.3)	0
Benign neoplasm of skin	1 (0.3)	0
Carcinoid tumour	0	1 (0.3)
Hepatic adenoma	1 (0.3)	0
Squamous cell carcinoma of skin	1 (0.3)	0
Squamous cell carcinoma of the cervix	0	1 (0.3)
Thyroid neoplasm	1 (0.3)	0
Uterine cancer	0	1 (0.3)
Vulvovaginal warts	1 (0.3)	0
Immune system disorders	31 (8.6)	12 (3.3)
Hypersensitivity	16 (4.4)	3 (0.8)
Seasonal allergy	8 (2.2)	6 (1.6)
Allergy to animal	1 (0.3)	2 (0.5)
Drug hypersensitivity	1 (0.3)	2 (0.5)
Allergy to arthropod bite	1 (0.3)	0
Allergy to arthropod sting	1 (0.3)	0
Allergy to vaccine	1 (0.3)	0
Contrast media reaction	1 (0.3)	0
Reaction to preservatives	1 (0.3)	0
Hepatobiliary disorders	11 (3.1)	9 (2.5)
Cholelithiasis	2 (0.6)	2 (0.5)
Hepatic steatosis	2 (0.6)	2 (0.5)
Hypertransaminasaemia	1 (0.3)	2 (0.5)
Drug-induced liver injury	1 (0.3)	1 (0.3)
Biliary colic	1 (0.3)	0
Cholecystitis	0	1 (0.3)
Cholecystitis acute	1 (0.3)	0
Hepatic function abnormal	1 (0.3)	0
Hepatic lesion	0	1 (0.3)
Hepatic mass	1 (0.3)	0

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=360) n (%)	Randomised Placebo (N=365) n (%)
Hepatomegaly	1 (0.3)	0
Liver disorder	0	1 (0.3)
Endocrine disorders	12 (3.3)	5 (1.4)
Steroid withdrawal syndrome	6 (1.7)	1 (0.3)
Goitre	2 (0.6)	0
Hyperprolactinaemia	2 (0.6)	0
Hyperthyroidism	1 (0.3)	1 (0.3)
Adrenal insufficiency	0	1 (0.3)
Basedow's disease	1 (0.3)	0
Cushing's syndrome	1 (0.3)	0
Hyperparathyroidism	0	1 (0.3)
Oestrogen deficiency	0	1 (0.3)
Thyroid mass	1 (0.3)	0
Social circumstances	1 (0.3)	1 (0.3)
Menopause	1 (0.3)	1 (0.3)
Pregnancy, puerperium and perinatal conditions	1 (0.3)	0
Abortion spontaneous	1 (0.3)	0
Product issues	0	1 (0.3)
Device connection issue	0	1 (0.3)

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Serious Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=360) n (%)	Randomised Placebo (N=365) n (%)
Subjects with events	78 (21.7)	81 (22.2)
Infections and infestations	35 (9.7)	30 (8.2)
Pneumonia	9 (2.5)	10 (2.7)
Herpes zoster	6 (1.7)	0
Gastroenteritis	2 (0.6)	2 (0.5)
Urinary tract infection	2 (0.6)	2 (0.5)
Diverticulitis	2 (0.6)	0
Influenza	2 (0.6)	1 (0.3)
Pyelonephritis	3 (0.8)	0
Appendicitis	2 (0.6)	0
Bronchitis	1 (0.3)	1 (0.3)
Gastroenteritis viral	2 (0.6)	0
Sepsis	0	2 (0.5)
Abscess	0	1 (0.3)
Abscess limb	1 (0.3)	0
Cellulitis	1 (0.3)	0
Dengue fever	1 (0.3)	0
Epididymitis	0	1 (0.3)
Erysipelas	0	1 (0.3)
Genital herpes	1 (0.3)	0
Herpes zoster cutaneous disseminated	1 (0.3)	0
Herpes zoster disseminated	1 (0.3)	0
Large intestine infection	0	1 (0.3)
Ludwig angina	0	1 (0.3)
Mediastinitis	0	1 (0.3)
Meningitis	0	1 (0.3)
Meningitis viral	1 (0.3)	0
Otitis media chronic	0	1 (0.3)
Pelvic infection	0	1 (0.3)
Pelvic inflammatory disease	1 (0.3)	0
Periodontitis	0	1 (0.3)
Pharyngitis streptococcal	1 (0.3)	0
Pneumonia bacterial	1 (0.3)	0
Pneumonia staphylococcal	0	1 (0.3)
Postoperative wound infection	0	1 (0.3)
Pyelonephritis acute	1 (0.3)	0
Septic shock	0	1 (0.3)
Sialoadenitis	0	1 (0.3)
Sinusitis	0	1 (0.3)
Streptococcal urinary tract infection	1 (0.3)	0
Upper respiratory tract infection	0	1 (0.3)
Urosepsis	0	1 (0.3)
Wound infection staphylococcal	0	1 (0.3)
Musculoskeletal and connective tissue disorders	14 (3.9)	16 (4.4)
Systemic lupus erythematosus	6 (1.7)	15 (4.1)
Osteonecrosis	1 (0.3)	1 (0.3)
Arthritis	1 (0.3)	0
Fracture pain	1 (0.3)	0
Musculoskeletal chest pain	1 (0.3)	0
Pain in extremity	1 (0.3)	0
Spinal stenosis	1 (0.3)	0
Synovial cyst	1 (0.3)	0
Tenosynovitis	1 (0.3)	0
Cardiac disorders	6 (1.7)	8 (2.2)
Atrial fibrillation	0	2 (0.5)
Cardiac failure congestive	1 (0.3)	1 (0.3)
Coronary artery disease	2 (0.6)	0

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Serious Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=360) n (%)	Randomised Placebo (N=365) n (%)
Myocardial infarction	1 (0.3)	1 (0.3)
Supraventricular tachycardia	0	2 (0.5)
Acute coronary syndrome	1 (0.3)	0
Acute myocardial infarction	0	1 (0.3)
Angina unstable	1 (0.3)	0
Aortic valve disease	1 (0.3)	0
Bundle branch block left	1 (0.3)	0
Cardiac failure	0	1 (0.3)
Cardiogenic shock	0	1 (0.3)
Myocardial ischaemia	1 (0.3)	0
Pericardial effusion	0	1 (0.3)
Ventricular arrhythmia	0	1 (0.3)
Respiratory, thoracic and mediastinal disorders	7 (1.9)	7 (1.9)
Asthma	3 (0.8)	1 (0.3)
Acute respiratory failure	2 (0.6)	0
Chronic obstructive pulmonary disease	0	1 (0.3)
Dyspnoea	1 (0.3)	1 (0.3)
Pleural effusion	1 (0.3)	1 (0.3)
Pulmonary embolism	1 (0.3)	1 (0.3)
Pulmonary hypertension	0	1 (0.3)
Pleurisy	1 (0.3)	0
Pulmonary alveolar haemorrhage	0	1 (0.3)
Respiratory distress	0	1 (0.3)
Respiratory failure	0	1 (0.3)
Injury, poisoning and procedural complications	8 (2.2)	7 (1.9)
Radius fracture	0	2 (0.5)
Ankle fracture	0	1 (0.3)
Facial bones fracture	1 (0.3)	0
Fall	1 (0.3)	0
Humerus fracture	1 (0.3)	0
Overdose	1 (0.3)	0
Perirenal haematoma	0	1 (0.3)
Post procedural complication	1 (0.3)	0
Post procedural haematoma	0	1 (0.3)
Rib fracture	0	1 (0.3)
Spinal compression fracture	1 (0.3)	0
Tendon rupture	0	1 (0.3)
Thoracic vertebral fracture	1 (0.3)	0
Traumatic fracture	1 (0.3)	0
Upper limb fracture	1 (0.3)	0
Renal and urinary disorders	6 (1.7)	7 (1.9)
Acute kidney injury	2 (0.6)	2 (0.5)
Lupus nephritis	1 (0.3)	2 (0.5)
Renal impairment	1 (0.3)	0
Chronic kidney disease	0	1 (0.3)
Dysuria	0	1 (0.3)
Nephritis	1 (0.3)	0
Nephrolithiasis	1 (0.3)	0
Renal failure	0	1 (0.3)
General disorders and administration site conditions	5 (1.4)	5 (1.4)
Non-cardiac chest pain	3 (0.8)	1 (0.3)
Chest pain	2 (0.6)	0
Influenza like illness	0	1 (0.3)
Pain	0	1 (0.3)
Pyrexia	0	1 (0.3)
Swelling face	0	1 (0.3)

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Serious Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=360) n (%)	Randomised Placebo (N=365) n (%)
Nervous system disorders	7 (1.9)	1 (0.3)
Ischaemic stroke	1 (0.3)	0
Post herpetic neuralgia	2 (0.6)	0
Syncope	1 (0.3)	1 (0.3)
Hypoaesthesia	1 (0.3)	0
Intracranial aneurysm	1 (0.3)	0
Myasthenia gravis	1 (0.3)	0
Blood and lymphatic system disorders	3 (0.8)	4 (1.1)
Anaemia	0	3 (0.8)
Thrombocytopenia	2 (0.6)	0
Iron deficiency anaemia	0	1 (0.3)
Neutropenia	1 (0.3)	0
Reproductive system and breast disorders	2 (0.6)	5 (1.4)
Cervical dysplasia	1 (0.3)	0
Endometrial hypertrophy	0	1 (0.3)
Menorrhagia	0	1 (0.3)
Uterine haemorrhage	1 (0.3)	0
Uterine prolapse	0	1 (0.3)
Uterovaginal prolapse	0	1 (0.3)
Vaginal ulceration	0	1 (0.3)
Gastrointestinal disorders	4 (1.1)	2 (0.5)
Chilaiditi's syndrome	1 (0.3)	0
Colitis	1 (0.3)	0
Gastrooesophageal reflux disease	1 (0.3)	0
Haemorrhoidal haemorrhage	1 (0.3)	0
Intra-abdominal haematoma	0	1 (0.3)
Oesophageal stenosis	0	1 (0.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (0.8)	3 (0.8)
Uterine leiomyoma	2 (0.6)	0
B-cell lymphoma	1 (0.3)	0
Haemangioma of liver	0	1 (0.3)
Squamous cell carcinoma	0	1 (0.3)
Uterine cancer	0	1 (0.3)
Skin and subcutaneous tissue disorders	2 (0.6)	3 (0.8)
Angioedema	2 (0.6)	0
Urticaria	0	2 (0.5)
Drug eruption	0	1 (0.3)
Vascular disorders	1 (0.3)	4 (1.1)
Deep vein thrombosis	0	1 (0.3)
Hypotension	0	1 (0.3)
Malignant hypertension	1 (0.3)	0
Orthostatic hypotension	0	1 (0.3)
Venous thrombosis limb	0	1 (0.3)
Investigations	2 (0.6)	2 (0.5)
Blood creatinine increased	1 (0.3)	0
International normalised ratio increased	0	1 (0.3)
Liver function test increased	0	1 (0.3)
Weight decreased	1 (0.3)	0
Psychiatric disorders	1 (0.3)	2 (0.5)
Conversion disorder	1 (0.3)	0
Psychotic disorder	0	1 (0.3)
Suicide attempt	0	1 (0.3)

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Serious Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=360) n (%)	Randomised Placebo (N=365) n (%)
Hepatobiliary disorders	2 (0.6)	0
Cholecystitis acute	1 (0.3)	0
Cholelithiasis	1 (0.3)	0
Ear and labyrinth disorders	1 (0.3)	0
Vertigo	1 (0.3)	0
Eye disorders	0	1 (0.3)
Ulcerative keratitis	0	1 (0.3)
Immune system disorders	1 (0.3)	0
Hypersensitivity	1 (0.3)	0
Metabolism and nutrition disorders	1 (0.3)	0
Hypercalcaemia	1 (0.3)	0
Pregnancy, puerperium and perinatal conditions	1 (0.3)	0
Abortion spontaneous	1 (0.3)	0

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Severe Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=360) n (%)	Randomised Placebo (N=365) n (%)
Subjects with events	55 (15.3)	34 (9.3)
Infections and infestations	27 (7.5)	10 (2.7)
Pneumonia	6 (1.7)	3 (0.8)
Bronchitis	2 (0.6)	2 (0.5)
Herpes zoster	4 (1.1)	0
Influenza	2 (0.6)	1 (0.3)
Pyelonephritis	3 (0.8)	0
Sepsis	0	2 (0.5)
Acute sinusitis	1 (0.3)	0
Dengue fever	1 (0.3)	0
Diverticulitis	1 (0.3)	0
Gastroenteritis	1 (0.3)	0
Herpes zoster disseminated	1 (0.3)	0
Laryngitis	1 (0.3)	0
Ludwig angina	0	1 (0.3)
Mediastinitis	0	1 (0.3)
Meningitis	0	1 (0.3)
Meningitis viral	1 (0.3)	0
Otitis media chronic	1 (0.3)	0
Pelvic inflammatory disease	1 (0.3)	0
Pharyngitis streptococcal	1 (0.3)	0
Pneumonia bacterial	1 (0.3)	0
Pneumonia staphylococcal	0	1 (0.3)
Postoperative wound infection	0	1 (0.3)
Septic shock	0	1 (0.3)
Sinusitis	0	1 (0.3)
Streptococcal urinary tract infection	1 (0.3)	0
Urinary tract infection	1 (0.3)	0
Musculoskeletal and connective tissue disorders	7 (1.9)	8 (2.2)
Systemic lupus erythematosus	5 (1.4)	5 (1.4)
Arthralgia	0	1 (0.3)
Back pain	0	1 (0.3)
Pain in extremity	1 (0.3)	0
Rotator cuff syndrome	0	1 (0.3)
SLE arthritis	0	1 (0.3)
Tendonitis	1 (0.3)	0
Respiratory, thoracic and mediastinal disorders	4 (1.1)	6 (1.6)
Asthma	1 (0.3)	1 (0.3)
Dyspnoea	1 (0.3)	1 (0.3)
Pulmonary hypertension	0	1 (0.3)
Acute respiratory failure	1 (0.3)	0
Cough	1 (0.3)	0
Epistaxis	1 (0.3)	0
Interstitial lung disease	1 (0.3)	0
Pulmonary alveolar haemorrhage	0	1 (0.3)
Pulmonary embolism	0	1 (0.3)
Respiratory distress	0	1 (0.3)
Respiratory failure	0	1 (0.3)
Cardiac disorders	4 (1.1)	5 (1.4)
Myocardial infarction	1 (0.3)	1 (0.3)
Acute coronary syndrome	1 (0.3)	0
Atrial fibrillation	0	1 (0.3)
Cardiac failure	0	1 (0.3)
Cardiac failure congestive	1 (0.3)	0
Cardiogenic shock	0	1 (0.3)
Cardiomyopathy	0	1 (0.3)

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Severe Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=360) n (%)	Randomised Placebo (N=365) n (%)
Coronary artery disease	1 (0.3)	0
Myocardial ischaemia	1 (0.3)	0
Supraventricular tachycardia	0	1 (0.3)
Nervous system disorders	8 (2.2)	1 (0.3)
Ischaemic stroke	1 (0.3)	0
Migraine	1 (0.3)	1 (0.3)
Post herpetic neuralgia	2 (0.6)	0
Hypoaesthesia	1 (0.3)	0
Intracranial aneurysm	1 (0.3)	0
Peroneal nerve palsy	1 (0.3)	0
Radiculopathy	1 (0.3)	0
Injury, poisoning and procedural complications	4 (1.1)	3 (0.8)
Facial bones fracture	1 (0.3)	0
Humerus fracture	1 (0.3)	0
Incisional hernia	1 (0.3)	0
Post procedural haematoma	0	1 (0.3)
Radius fracture	0	1 (0.3)
Tendon rupture	0	1 (0.3)
Upper limb fracture	1 (0.3)	0
Renal and urinary disorders	4 (1.1)	3 (0.8)
Acute kidney injury	2 (0.6)	0
Lupus nephritis	1 (0.3)	1 (0.3)
Dysuria	0	1 (0.3)
Nephrolithiasis	1 (0.3)	0
Renal failure	0	1 (0.3)
Blood and lymphatic system disorders	4 (1.1)	2 (0.5)
Anaemia	1 (0.3)	1 (0.3)
Thrombocytopenia	2 (0.6)	0
Iron deficiency anaemia	0	1 (0.3)
Neutropenia	1 (0.3)	0
Gastrointestinal disorders	3 (0.8)	1 (0.3)
Abdominal pain	1 (0.3)	0
Colitis	1 (0.3)	0
Dental caries	1 (0.3)	0
Gastrooesophageal reflux disease	1 (0.3)	0
Oesophageal stenosis	0	1 (0.3)
Vascular disorders	0	3 (0.8)
Hypertension	0	1 (0.3)
Vasculitis	0	1 (0.3)
Venous thrombosis limb	0	1 (0.3)
General disorders and administration site conditions	1 (0.3)	1 (0.3)
Influenza like illness	1 (0.3)	0
Pain	0	1 (0.3)
Psychiatric disorders	2 (0.6)	0
Conversion disorder	1 (0.3)	0
Suicidal ideation	1 (0.3)	0
Immune system disorders	0	1 (0.3)
Drug hypersensitivity	0	1 (0.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	1 (0.3)
Haemangioma of liver	0	1 (0.3)

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Severe Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=360) n (%)	Randomised Placebo (N=365) n (%)
Skin and subcutaneous tissue disorders	1 (0.3)	0
Angioedema	1 (0.3)	0

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Non-Severe Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=360) n (%)	Randomised Placebo (N=365) n (%)
Subjects with events	333 (92.5)	313 (85.8)
Infections and infestations	285 (79.2)	234 (64.1)
Nasopharyngitis	95 (26.4)	51 (14.0)
Upper respiratory tract infection	94 (26.1)	48 (13.2)
Urinary tract infection	73 (20.3)	59 (16.2)
Bronchitis	65 (18.1)	22 (6.0)
Sinusitis	34 (9.4)	21 (5.8)
Oral herpes	26 (7.2)	14 (3.8)
Pharyngitis	25 (6.9)	20 (5.5)
Herpes zoster	36 (10.0)	11 (3.0)
Gastroenteritis	16 (4.4)	16 (4.4)
Cystitis	9 (2.5)	9 (2.5)
Influenza	19 (5.3)	11 (3.0)
Viral upper respiratory tract infection	14 (3.9)	6 (1.6)
Gastroenteritis viral	14 (3.9)	5 (1.4)
Pneumonia	15 (4.2)	12 (3.3)
Vaginal infection	11 (3.1)	10 (2.7)
Respiratory tract infection	14 (3.9)	3 (0.8)
Latent tuberculosis	18 (5.0)	3 (0.8)
Rhinitis	9 (2.5)	6 (1.6)
Conjunctivitis	14 (3.9)	5 (1.4)
Vulvovaginal mycotic infection	13 (3.6)	4 (1.1)
Cellulitis	10 (2.8)	6 (1.6)
Viral infection	8 (2.2)	4 (1.1)
Tooth abscess	10 (2.8)	4 (1.1)
Laryngitis	7 (1.9)	5 (1.4)
Otitis media	12 (3.3)	0
Oral candidiasis	4 (1.1)	8 (2.2)
Tooth infection	7 (1.9)	4 (1.1)
Acute sinusitis	6 (1.7)	3 (0.8)
Herpes simplex	5 (1.4)	2 (0.5)
Lower respiratory tract infection	5 (1.4)	2 (0.5)
Folliculitis	5 (1.4)	4 (1.1)
Bacterial vaginosis	4 (1.1)	3 (0.8)
Onychomycosis	5 (1.4)	3 (0.8)
Paronychia	5 (1.4)	4 (1.1)
Vulvovaginal candidiasis	4 (1.1)	4 (1.1)
Fungal skin infection	4 (1.1)	2 (0.5)
Tonsillitis	5 (1.4)	2 (0.5)
Cervicitis	3 (0.8)	1 (0.3)
Ear infection	5 (1.4)	1 (0.3)
Furuncle	2 (0.6)	2 (0.5)
Hordeolum	2 (0.6)	3 (0.8)
Pharyngotonsillitis	3 (0.8)	3 (0.8)
Tinea versicolour	4 (1.1)	1 (0.3)
Tracheitis	4 (1.1)	1 (0.3)
Vulvovaginitis	3 (0.8)	1 (0.3)
Wound infection	3 (0.8)	3 (0.8)
Fungal infection	3 (0.8)	2 (0.5)
Gastrointestinal viral infection	1 (0.3)	2 (0.5)
Otitis externa	4 (1.1)	1 (0.3)
Periodontitis	1 (0.3)	3 (0.8)
Respiratory tract infection viral	2 (0.6)	2 (0.5)
Viral pharyngitis	5 (1.4)	0
Abscess limb	3 (0.8)	1 (0.3)
Candida infection	3 (0.8)	1 (0.3)
Diverticulitis	3 (0.8)	0
Escherichia urinary tract infection	3 (0.8)	1 (0.3)
Gingivitis	2 (0.6)	2 (0.5)

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Non-Severe Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=360) n (%)	Randomised Placebo (N=365) n (%)
Subcutaneous abscess	2 (0.6)	2 (0.5)
Tracheobronchitis	3 (0.8)	1 (0.3)
Appendicitis	3 (0.8)	0
Asymptomatic bacteriuria	2 (0.6)	1 (0.3)
Bacterial vulvovaginitis	2 (0.6)	1 (0.3)
Genital herpes	2 (0.6)	0
Localised infection	3 (0.8)	0
Otitis media acute	3 (0.8)	0
Pharyngitis streptococcal	1 (0.3)	2 (0.5)
Sialoadenitis	2 (0.6)	1 (0.3)
Skin infection	3 (0.8)	0
Tinea pedis	2 (0.6)	1 (0.3)
Acarodermatitis	1 (0.3)	1 (0.3)
Alveolar osteitis	1 (0.3)	1 (0.3)
Bronchitis bacterial	2 (0.6)	0
Chronic sinusitis	1 (0.3)	1 (0.3)
Conjunctivitis viral	1 (0.3)	1 (0.3)
Dengue fever	2 (0.6)	0
Erysipelas	1 (0.3)	1 (0.3)
Gastroenteritis bacterial	1 (0.3)	1 (0.3)
Gastrointestinal infection	0	2 (0.5)
Genital herpes simplex	1 (0.3)	1 (0.3)
Groin abscess	1 (0.3)	1 (0.3)
Helicobacter infection	1 (0.3)	1 (0.3)
Large intestine infection	1 (0.3)	1 (0.3)
Molluscum contagiosum	1 (0.3)	1 (0.3)
Oral fungal infection	2 (0.6)	0
Otitis externa fungal	0	1 (0.3)
Parotitis	2 (0.6)	0
Pyelonephritis acute	1 (0.3)	1 (0.3)
Pyuria	1 (0.3)	0
Rotavirus infection	2 (0.6)	0
Skin candida	1 (0.3)	1 (0.3)
Superinfection	1 (0.3)	1 (0.3)
Tinea infection	1 (0.3)	1 (0.3)
Trichomoniasis	1 (0.3)	1 (0.3)
Abscess	0	1 (0.3)
Abscess oral	1 (0.3)	0
Arthritis bacterial	0	1 (0.3)
Arthritis infective	1 (0.3)	0
Atypical pneumonia	0	1 (0.3)
Bartholinitis	1 (0.3)	0
Body tinea	1 (0.3)	0
Bronchitis viral	1 (0.3)	0
Cervicitis human papilloma virus	0	1 (0.3)
Chronic tonsillitis	1 (0.3)	0
Cystitis bacterial	1 (0.3)	0
Cystitis escherichia	0	1 (0.3)
Dacryocystitis	1 (0.3)	0
Epididymitis	0	1 (0.3)
Escherichia infection	1 (0.3)	0
Eyelid infection	1 (0.3)	0
Genitourinary chlamydia infection	1 (0.3)	0
Giardiasis	0	1 (0.3)
Helicobacter gastritis	0	1 (0.3)
Herpes zoster cutaneous disseminated	1 (0.3)	0
Human ehrlichiosis	1 (0.3)	0
Impetigo	0	1 (0.3)
Labyrinthitis	1 (0.3)	0
Laryngitis viral	1 (0.3)	0
Mumps	1 (0.3)	0

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Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Non-Severe Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=360) n (%)	Randomised Placebo (N=365) n (%)
Mycobacterium avium complex infection	1 (0.3)	0
Nail infection	1 (0.3)	0
Nipple infection	1 (0.3)	0
Ophthalmic herpes simplex	1 (0.3)	0
Otitis media bacterial	1 (0.3)	0
Otitis media chronic	0	1 (0.3)
Pelvic infection	0	1 (0.3)
Pertussis	1 (0.3)	0
Pharyngitis bacterial	0	1 (0.3)
Pneumonia viral	1 (0.3)	0
Proteus infection	0	1 (0.3)
Pulpitis dental	0	1 (0.3)
Pyelonephritis	1 (0.3)	0
Rash pustular	0	1 (0.3)
Respiratory moniliasis	0	1 (0.3)
Root canal infection	0	1 (0.3)
Sepsis	0	1 (0.3)
Skin bacterial infection	1 (0.3)	0
Soft tissue infection	1 (0.3)	0
Tinea cruris	1 (0.3)	0
Tinea manuum	1 (0.3)	0
Tonsillitis bacterial	0	1 (0.3)
Ureaplasma infection	0	1 (0.3)
Urethritis	0	1 (0.3)
Urinary tract infection bacterial	0	1 (0.3)
Urinary tract infection pseudomonal	1 (0.3)	0
Urosepsis	0	1 (0.3)
Viral sinusitis	1 (0.3)	0
Vulval abscess	0	1 (0.3)
Vulvovaginitis trichomonal	0	1 (0.3)
Wound infection staphylococcal	0	1 (0.3)
Gastrointestinal disorders	121 (33.6)	107 (29.3)
Nausea	25 (6.9)	27 (7.4)
Diarrhoea	24 (6.7)	25 (6.8)
Vomiting	25 (6.9)	11 (3.0)
Abdominal pain upper	13 (3.6)	13 (3.6)
Gastrooesophageal reflux disease	13 (3.6)	14 (3.8)
Constipation	12 (3.3)	13 (3.6)
Abdominal pain	9 (2.5)	11 (3.0)
Dyspepsia	4 (1.1)	10 (2.7)
Gastritis	5 (1.4)	11 (3.0)
Dental caries	8 (2.2)	4 (1.1)
Haemorrhoids	7 (1.9)	1 (0.3)
Abdominal discomfort	4 (1.1)	2 (0.5)
Food poisoning	2 (0.6)	3 (0.8)
Hiatus hernia	2 (0.6)	4 (1.1)
Colitis	3 (0.8)	1 (0.3)
Toothache	3 (0.8)	2 (0.5)
Abdominal distension	3 (0.8)	1 (0.3)
Chronic gastritis	3 (0.8)	1 (0.3)
Gastric ulcer	2 (0.6)	1 (0.3)
Irritable bowel syndrome	2 (0.6)	2 (0.5)
Flatulence	1 (0.3)	2 (0.5)
Haemorrhoidal haemorrhage	3 (0.8)	0
Mouth ulceration	2 (0.6)	1 (0.3)
Abdominal pain lower	2 (0.6)	0
Cheilitis	0	2 (0.5)
Diverticulum	2 (0.6)	0
Duodenitis	1 (0.3)	1 (0.3)
Dysphagia	2 (0.6)	0

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Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Non-Severe Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=360) n (%)	Randomised Placebo (N=365) n (%)
Enteritis	1 (0.3)	1 (0.3)
Gingival bleeding	2 (0.6)	0
Haematochezia	1 (0.3)	1 (0.3)
Impaired gastric emptying	2 (0.6)	0
Loose tooth	1 (0.3)	0
Abdominal tenderness	1 (0.3)	0
Aphthous ulcer	1 (0.3)	0
Barrett's oesophagus	1 (0.3)	0
Chilaiditi's syndrome	1 (0.3)	0
Dental cyst	1 (0.3)	0
Dry mouth	0	1 (0.3)
Enterocolitis	0	1 (0.3)
Gastric mucosa erythema	1 (0.3)	0
Gastritis erosive	1 (0.3)	0
Gastrointestinal inflammation	1 (0.3)	0
Gastrointestinal pain	0	1 (0.3)
Gastrointestinal wall thickening	1 (0.3)	0
Gingival recession	1 (0.3)	0
Glossitis	0	1 (0.3)
Glossodynia	0	1 (0.3)
Intra-abdominal haematoma	0	1 (0.3)
Large intestine polyp	0	1 (0.3)
Lip swelling	1 (0.3)	0
Lip ulceration	1 (0.3)	0
Malabsorption	0	1 (0.3)
Odynophagia	0	1 (0.3)
Oesophageal hypomotility	1 (0.3)	0
Oesophageal stenosis	0	1 (0.3)
Oesophagitis	1 (0.3)	0
Oral mucosal eruption	1 (0.3)	0
Oral pain	0	1 (0.3)
Palatal disorder	1 (0.3)	0
Pancreatic steatosis	0	1 (0.3)
Paraesthesia oral	1 (0.3)	0
Peptic ulcer	0	1 (0.3)
Rectal haemorrhage	1 (0.3)	0
Salivary hypersecretion	0	1 (0.3)
Stomatitis	0	1 (0.3)
Tongue blistering	0	1 (0.3)
Tooth disorder	0	1 (0.3)
Tooth impacted	1 (0.3)	0
Injury, poisoning and procedural complications	117 (32.5)	80 (21.9)
Infusion related reaction	52 (14.4)	30 (8.2)
Fall	14 (3.9)	11 (3.0)
Contusion	15 (4.2)	8 (2.2)
Arthropod bite	13 (3.6)	5 (1.4)
Ligament sprain	5 (1.4)	4 (1.1)
Foot fracture	5 (1.4)	4 (1.1)
Limb injury	2 (0.6)	5 (1.4)
Animal bite	5 (1.4)	2 (0.5)
Muscle strain	4 (1.1)	4 (1.1)
Road traffic accident	2 (0.6)	3 (0.8)
Skin laceration	5 (1.4)	1 (0.3)
Injury	4 (1.1)	1 (0.3)
Rib fracture	4 (1.1)	3 (0.8)
Arthropod sting	4 (1.1)	1 (0.3)
Skin abrasion	2 (0.6)	4 (1.1)
Joint injury	2 (0.6)	3 (0.8)
Thermal burn	4 (1.1)	1 (0.3)
Ankle fracture	1 (0.3)	3 (0.8)

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Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Non-Severe Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=360) n (%)	Randomised Placebo (N=365) n (%)
Epicondylitis	2 (0.6)	2 (0.5)
Ligament rupture	4 (1.1)	0
Meniscus injury	3 (0.8)	1 (0.3)
Animal scratch	3 (0.8)	0
Radius fracture	2 (0.6)	1 (0.3)
Thoracic vertebral fracture	2 (0.6)	1 (0.3)
Tooth fracture	1 (0.3)	2 (0.5)
Wound	1 (0.3)	2 (0.5)
Dental restoration failure	1 (0.3)	1 (0.3)
Hand fracture	1 (0.3)	1 (0.3)
Post-traumatic neck syndrome	0	2 (0.5)
Spinal compression fracture	1 (0.3)	1 (0.3)
Stress fracture	2 (0.6)	0
Toxicity to various agents	2 (0.6)	0
Traumatic haematoma	1 (0.3)	1 (0.3)
Accident	1 (0.3)	0
Anaemia postoperative	0	1 (0.3)
Bite	1 (0.3)	0
Bone contusion	1 (0.3)	0
Chest injury	0	1 (0.3)
Concussion	1 (0.3)	0
Eye contusion	1 (0.3)	0
Fibula fracture	0	1 (0.3)
Foreign body in respiratory tract	1 (0.3)	0
Humerus fracture	0	1 (0.3)
Hypobarism	1 (0.3)	0
Joint capsule rupture	1 (0.3)	0
Joint dislocation	1 (0.3)	0
Ligament injury	1 (0.3)	0
Limb crushing injury	0	1 (0.3)
Lower limb fracture	1 (0.3)	0
Mouth injury	1 (0.3)	0
Muscle contusion	1 (0.3)	0
Nail avulsion	1 (0.3)	0
Nail injury	0	1 (0.3)
Overdose	1 (0.3)	0
Perirenal haematoma	0	1 (0.3)
Post procedural complication	1 (0.3)	0
Post procedural haemorrhage	0	1 (0.3)
Post-traumatic pain	1 (0.3)	0
Pubis fracture	0	1 (0.3)
Reactive gastropathy	1 (0.3)	0
Scar	0	1 (0.3)
Skin injury	0	1 (0.3)
Spinal fracture	1 (0.3)	0
Sunburn	1 (0.3)	0
Tendon injury	0	1 (0.3)
Tendon rupture	1 (0.3)	0
Tibia fracture	1 (0.3)	0
Traumatic fracture	1 (0.3)	0
Upper limb fracture	1 (0.3)	0
Vaccination complication	1 (0.3)	0
Wound complication	1 (0.3)	0
Musculoskeletal and connective tissue disorders	143 (39.7)	98 (26.8)
Back pain	35 (9.7)	23 (6.3)
Arthralgia	34 (9.4)	13 (3.6)
Systemic lupus erythematosus	11 (3.1)	10 (2.7)
Pain in extremity	13 (3.6)	7 (1.9)
Bursitis	14 (3.9)	5 (1.4)
Musculoskeletal pain	10 (2.8)	8 (2.2)

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Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Non-Severe Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=360) n (%)	Randomised Placebo (N=365) n (%)
Osteoarthritis	12 (3.3)	0
Muscle spasms	5 (1.4)	8 (2.2)
Osteonecrosis	6 (1.7)	4 (1.1)
Myalgia	7 (1.9)	6 (1.6)
Joint swelling	5 (1.4)	6 (1.6)
Musculoskeletal chest pain	7 (1.9)	4 (1.1)
Neck pain	8 (2.2)	1 (0.3)
Tendonitis	7 (1.9)	3 (0.8)
Costochondritis	4 (1.1)	4 (1.1)
Fibromyalgia	4 (1.1)	5 (1.4)
Arthritis	6 (1.7)	1 (0.3)
Flank pain	3 (0.8)	4 (1.1)
Intervertebral disc protrusion	7 (1.9)	0
Synovial cyst	4 (1.1)	2 (0.5)
Osteoporosis	2 (0.6)	4 (1.1)
Spinal osteoarthritis	3 (0.8)	2 (0.5)
Rotator cuff syndrome	2 (0.6)	2 (0.5)
Tenosynovitis	2 (0.6)	1 (0.3)
Muscular weakness	2 (0.6)	1 (0.3)
Musculoskeletal stiffness	2 (0.6)	1 (0.3)
Plantar fasciitis	0	3 (0.8)
Sjogren's syndrome	1 (0.3)	2 (0.5)
Spinal pain	2 (0.6)	0
Synovitis	2 (0.6)	1 (0.3)
Tenosynovitis stenosans	3 (0.8)	0
Arthropathy	2 (0.6)	0
Osteopenia	2 (0.6)	0
Periarthritis	1 (0.3)	1 (0.3)
Bone infarction	0	1 (0.3)
Bone loss	1 (0.3)	0
Chondritis	1 (0.3)	0
Enthesopathy	0	1 (0.3)
Exostosis	1 (0.3)	0
Foot deformity	0	1 (0.3)
Fracture pain	1 (0.3)	0
Groin pain	0	1 (0.3)
Intervertebral disc disorder	1 (0.3)	0
Joint contracture	1 (0.3)	0
Joint instability	1 (0.3)	0
Joint lock	1 (0.3)	0
Ligamentitis	1 (0.3)	0
Metatarsalgia	1 (0.3)	0
Muscle twitching	0	1 (0.3)
Osteochondritis	0	1 (0.3)
Osteochondrosis	1 (0.3)	0
Pain in jaw	0	1 (0.3)
Polychondritis	1 (0.3)	0
Sacroiliitis	1 (0.3)	0
Spinal stenosis	1 (0.3)	0
Temporomandibular joint syndrome	0	1 (0.3)
Tendon pain	0	1 (0.3)
Trigger finger	1 (0.3)	0
Nervous system disorders	106 (29.4)	65 (17.8)
Headache	42 (11.7)	39 (10.7)
Dizziness	13 (3.6)	12 (3.3)
Migraine	5 (1.4)	8 (2.2)
Sciatica	9 (2.5)	0
Hypoaesthesia	5 (1.4)	3 (0.8)
Carpal tunnel syndrome	6 (1.7)	2 (0.5)
Syncope	6 (1.7)	2 (0.5)

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Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Non-Severe Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=360) n (%)	Randomised Placebo (N=365) n (%)
Paraesthesia	7 (1.9)	0
Neuralgia	4 (1.1)	2 (0.5)
Post herpetic neuralgia	6 (1.7)	0
Restless legs syndrome	4 (1.1)	2 (0.5)
Amnesia	2 (0.6)	2 (0.5)
Cervicobrachial syndrome	3 (0.8)	1 (0.3)
Tremor	1 (0.3)	2 (0.5)
Lumbar radiculopathy	3 (0.8)	0
Migraine with aura	3 (0.8)	0
Neuropathy peripheral	2 (0.6)	1 (0.3)
Presyncope	2 (0.6)	1 (0.3)
Somnolence	3 (0.8)	0
Tension headache	1 (0.3)	2 (0.5)
Cervical radiculopathy	1 (0.3)	1 (0.3)
Dizziness postural	1 (0.3)	1 (0.3)
Dysgeusia	1 (0.3)	0
Facial paralysis	1 (0.3)	1 (0.3)
Myoclonus	1 (0.3)	1 (0.3)
Aphasia	1 (0.3)	0
Arachnoid cyst	0	1 (0.3)
Burning sensation	1 (0.3)	0
Cognitive disorder	1 (0.3)	0
Dysarthria	1 (0.3)	0
Epilepsy	1 (0.3)	0
Haemorrhagic cerebral infarction	0	1 (0.3)
Hemiparesis	1 (0.3)	0
Hyperaesthesia	0	1 (0.3)
Intention tremor	0	1 (0.3)
Intercostal neuralgia	1 (0.3)	0
Meningism	1 (0.3)	0
Myasthenia gravis	1 (0.3)	0
Occipital neuralgia	1 (0.3)	0
Parkinson's disease	1 (0.3)	0
Parkinsonian gait	1 (0.3)	0
Peripheral sensory neuropathy	1 (0.3)	0
Peroneal nerve palsy	1 (0.3)	0
Radiculopathy	1 (0.3)	0
Sensory disturbance	0	1 (0.3)
Spinal cord compression	0	1 (0.3)
Trigeminal neuralgia	1 (0.3)	0
Tunnel vision	0	1 (0.3)
Vestibular migraine	1 (0.3)	0
Visual field defect	1 (0.3)	0
Skin and subcutaneous tissue disorders	82 (22.8)	51 (14.0)
Rash	8 (2.2)	10 (2.7)
Urticaria	7 (1.9)	7 (1.9)
Pruritus	7 (1.9)	6 (1.6)
Ecchymosis	6 (1.7)	2 (0.5)
Skin ulcer	4 (1.1)	2 (0.5)
Dermatitis contact	5 (1.4)	2 (0.5)
Eczema	5 (1.4)	2 (0.5)
Erythema	4 (1.1)	3 (0.8)
Hidradenitis	4 (1.1)	1 (0.3)
Acne	4 (1.1)	0
Dermatitis	1 (0.3)	4 (1.1)
Dermatitis allergic	3 (0.8)	1 (0.3)
Angioedema	2 (0.6)	2 (0.5)
Ingrowing nail	4 (1.1)	0
Intertrigo	4 (1.1)	0
Perioral dermatitis	2 (0.6)	0

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Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Non-Severe Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=360) n (%)	Randomised Placebo (N=365) n (%)
Skin hyperpigmentation	2 (0.6)	1 (0.3)
Dry skin	1 (0.3)	1 (0.3)
Hyperhidrosis	1 (0.3)	2 (0.5)
Miliaria	1 (0.3)	2 (0.5)
Night sweats	2 (0.6)	0
Purpura	2 (0.6)	1 (0.3)
Rash papular	0	2 (0.5)
Rash pruritic	2 (0.6)	1 (0.3)
Alopecia	1 (0.3)	1 (0.3)
Dermal cyst	1 (0.3)	1 (0.3)
Dermatitis atopic	2 (0.6)	0
Erythema nodosum	0	1 (0.3)
Nail dystrophy	1 (0.3)	1 (0.3)
Psoriasis	1 (0.3)	1 (0.3)
Rosacea	2 (0.6)	0
Seborrhoeic dermatitis	2 (0.6)	0
Skin fissures	1 (0.3)	1 (0.3)
Skin lesion	1 (0.3)	1 (0.3)
Actinic keratosis	1 (0.3)	0
Blister	1 (0.3)	0
Cold urticaria	0	1 (0.3)
Dandruff	1 (0.3)	0
Decubitus ulcer	0	1 (0.3)
Dermatitis acneiform	0	1 (0.3)
Drug eruption	0	1 (0.3)
Eczema asteatotic	0	1 (0.3)
Eczema nummular	0	1 (0.3)
Guttate psoriasis	1 (0.3)	0
Haemorrhage subcutaneous	0	1 (0.3)
Hyperkeratosis	0	1 (0.3)
Keloid scar	1 (0.3)	0
Keratosis pilaris	0	1 (0.3)
Leukonychia	1 (0.3)	0
Lichen sclerosus	1 (0.3)	0
Lipoatrophy	1 (0.3)	0
Livedo reticularis	0	1 (0.3)
Nail bed bleeding	0	1 (0.3)
Nail disorder	1 (0.3)	0
Onychoclasis	1 (0.3)	0
Papule	1 (0.3)	0
Petechiae	1 (0.3)	0
Photosensitivity reaction	1 (0.3)	0
Pigmentation disorder	1 (0.3)	0
Post inflammatory pigmentation change	0	1 (0.3)
Rash erythematous	1 (0.3)	0
Rash follicular	1 (0.3)	0
Rash maculo-papular	1 (0.3)	0
Rash vesicular	1 (0.3)	0
Scab	1 (0.3)	0
Skin discolouration	0	1 (0.3)
Solar dermatitis	0	1 (0.3)
Systemic lupus erythematosus rash	0	1 (0.3)
Urticaria chronic	1 (0.3)	0
Vasculitic ulcer	1 (0.3)	0
Venous ulcer pain	0	1 (0.3)
Vitiligo	0	1 (0.3)
Xanthelasma	0	1 (0.3)
Respiratory, thoracic and mediastinal disorders	79 (21.9)	60 (16.4)
Cough	31 (8.6)	14 (3.8)
Asthma	4 (1.1)	9 (2.5)

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Non-Severe Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=360) n (%)	Randomised Placebo (N=365) n (%)
Oropharyngeal pain	8 (2.2)	8 (2.2)
Epistaxis	5 (1.4)	8 (2.2)
Rhinitis allergic	6 (1.7)	4 (1.1)
Dyspnoea	3 (0.8)	7 (1.9)
Nasal congestion	3 (0.8)	5 (1.4)
Productive cough	5 (1.4)	3 (0.8)
Rhinorrhoea	5 (1.4)	1 (0.3)
Pleural effusion	4 (1.1)	3 (0.8)
Sinus congestion	4 (1.1)	1 (0.3)
Chronic obstructive pulmonary disease	2 (0.6)	1 (0.3)
Upper respiratory tract inflammation	3 (0.8)	0
Lower respiratory tract congestion	2 (0.6)	0
Nasal obstruction	1 (0.3)	2 (0.5)
Sleep apnoea syndrome	1 (0.3)	2 (0.5)
Pleuritic pain	1 (0.3)	0
Pulmonary mass	1 (0.3)	1 (0.3)
Respiratory disorder	1 (0.3)	1 (0.3)
Wheezing	1 (0.3)	1 (0.3)
Acute respiratory failure	1 (0.3)	0
Allergic sinusitis	0	1 (0.3)
Atelectasis	1 (0.3)	0
Bronchial hyperreactivity	1 (0.3)	0
Bronchitis chronic	1 (0.3)	0
Catarrh	0	1 (0.3)
Dysphonia	0	1 (0.3)
Dyspnoea exertional	0	1 (0.3)
Haemoptysis	1 (0.3)	0
Hypersensitivity pneumonitis	0	1 (0.3)
Lung disorder	1 (0.3)	0
Nasal polyps	1 (0.3)	0
Paranasal sinus discomfort	0	1 (0.3)
Pleurisy	1 (0.3)	0
Pulmonary embolism	1 (0.3)	0
Pulmonary hypertension	0	1 (0.3)
Rales	0	1 (0.3)
Throat irritation	1 (0.3)	0
Tracheal stenosis	1 (0.3)	0
Upper-airway cough syndrome	1 (0.3)	0
Vocal cord disorder	1 (0.3)	0
General disorders and administration site conditions	76 (21.1)	50 (13.7)
Pyrexia	11 (3.1)	11 (3.0)
Fatigue	13 (3.6)	5 (1.4)
Non-cardiac chest pain	9 (2.5)	10 (2.7)
Oedema peripheral	13 (3.6)	5 (1.4)
Influenza like illness	8 (2.2)	5 (1.4)
Chest pain	9 (2.5)	0
Asthenia	5 (1.4)	2 (0.5)
Adverse drug reaction	3 (0.8)	3 (0.8)
Peripheral swelling	4 (1.1)	2 (0.5)
Chest discomfort	4 (1.1)	1 (0.3)
Pain	3 (0.8)	1 (0.3)
Nodule	2 (0.6)	2 (0.5)
Swelling face	0	3 (0.8)
Chills	0	2 (0.5)
Drug intolerance	2 (0.6)	0
Face oedema	2 (0.6)	0
Facial pain	1 (0.3)	0
Feeling cold	0	1 (0.3)
Gait disturbance	1 (0.3)	0
Gravitational oedema	0	1 (0.3)

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Non-Severe Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=360) n (%)	Randomised Placebo (N=365) n (%)
Injection site bruising	0	1 (0.3)
Injection site rash	0	1 (0.3)
Injection site reaction	0	1 (0.3)
Malaise	1 (0.3)	0
Thirst	0	1 (0.3)
Vaccination site reaction	1 (0.3)	0
Metabolism and nutrition disorders	38 (10.6)	40 (11.0)
Hypokalaemia	6 (1.7)	8 (2.2)
Dehydration	1 (0.3)	8 (2.2)
Vitamin D deficiency	5 (1.4)	4 (1.1)
Hypercholesterolaemia	7 (1.9)	1 (0.3)
Type 2 diabetes mellitus	2 (0.6)	3 (0.8)
Decreased appetite	2 (0.6)	2 (0.5)
Diabetes mellitus	4 (1.1)	0
Hyperglycaemia	2 (0.6)	2 (0.5)
Vitamin B12 deficiency	3 (0.8)	1 (0.3)
Dyslipidaemia	1 (0.3)	2 (0.5)
Hyperlipidaemia	2 (0.6)	1 (0.3)
Hypocalcaemia	1 (0.3)	1 (0.3)
Glucose tolerance impaired	1 (0.3)	1 (0.3)
Hyperkalaemia	0	2 (0.5)
Hypertriglyceridaemia	2 (0.6)	0
Hyperuricaemia	1 (0.3)	1 (0.3)
Hypomagnesaemia	1 (0.3)	1 (0.3)
Iron deficiency	2 (0.6)	0
Obesity	1 (0.3)	1 (0.3)
Steroid diabetes	2 (0.6)	0
Vitamin B complex deficiency	2 (0.6)	0
Abnormal loss of weight	0	1 (0.3)
Diabetes mellitus inadequate control	1 (0.3)	0
Fluid overload	0	1 (0.3)
Hypercalcaemia	1 (0.3)	0
Hypoalbuminaemia	1 (0.3)	0
Hyponatraemia	0	1 (0.3)
Hypophosphataemia	1 (0.3)	0
Increased appetite	1 (0.3)	0
Lactic acidosis	0	1 (0.3)
Lipoedema	0	1 (0.3)
Overweight	1 (0.3)	0
Psychiatric disorders	38 (10.6)	43 (11.8)
Insomnia	12 (3.3)	18 (4.9)
Depression	17 (4.7)	12 (3.3)
Anxiety	12 (3.3)	8 (2.2)
Adjustment disorder	0	1 (0.3)
Adjustment disorder with depressed mood	1 (0.3)	0
Affect lability	0	1 (0.3)
Anxiety disorder	1 (0.3)	0
Depressed mood	0	1 (0.3)
Drug use disorder	1 (0.3)	0
Libido decreased	0	1 (0.3)
Loss of libido	0	1 (0.3)
Mental disorder	1 (0.3)	0
Mixed anxiety and depressive disorder	1 (0.3)	0
Neurosis	1 (0.3)	0
Panic attack	1 (0.3)	0
Persistent depressive disorder	0	1 (0.3)
Psychotic disorder	0	1 (0.3)
Substance-induced psychotic disorder	0	1 (0.3)
Suicidal ideation	0	1 (0.3)

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Non-Severe Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=360) n (%)	Randomised Placebo (N=365) n (%)
Suicide attempt	0	1 (0.3)
Eye disorders	43 (11.9)	25 (6.8)
Cataract	7 (1.9)	3 (0.8)
Dry eye	6 (1.7)	3 (0.8)
Blepharitis	4 (1.1)	3 (0.8)
Conjunctival haemorrhage	3 (0.8)	3 (0.8)
Vision blurred	5 (1.4)	0
Chalazion	2 (0.6)	2 (0.5)
Episcleritis	3 (0.8)	0
Retinopathy	3 (0.8)	0
Swelling of eyelid	1 (0.3)	0
Corneal erosion	1 (0.3)	1 (0.3)
Erythema of eyelid	2 (0.6)	0
Glaucoma	1 (0.3)	0
Keratitis	1 (0.3)	1 (0.3)
Maculopathy	0	2 (0.5)
Vitreous floaters	2 (0.6)	0
Accommodation disorder	1 (0.3)	0
Asthenopia	1 (0.3)	0
Chorioretinopathy	1 (0.3)	0
Conjunctival erosion	0	1 (0.3)
Conjunctivitis allergic	1 (0.3)	0
Diplopia	0	1 (0.3)
Eczema eyelids	1 (0.3)	0
Eye discharge	1 (0.3)	0
Eye inflammation	1 (0.3)	0
Eye pruritus	1 (0.3)	0
Eyelid cyst	0	1 (0.3)
Eyelid oedema	0	1 (0.3)
Lacrimation decreased	1 (0.3)	0
Lacrimation increased	1 (0.3)	0
Macular degeneration	1 (0.3)	0
Meibomian gland dysfunction	1 (0.3)	0
Periorbital oedema	1 (0.3)	0
Photophobia	0	1 (0.3)
Punctate keratitis	0	1 (0.3)
Retinal exudates	0	1 (0.3)
Trichiasis	0	1 (0.3)
Ulcerative keratitis	0	1 (0.3)
Visual impairment	0	1 (0.3)
Reproductive system and breast disorders	42 (11.7)	22 (6.0)
Ovarian cyst	8 (2.2)	2 (0.5)
Menorrhagia	5 (1.4)	3 (0.8)
Cervical dysplasia	4 (1.1)	2 (0.5)
Dysmenorrhoea	6 (1.7)	0
Uterine haemorrhage	4 (1.1)	0
Breast cyst	3 (0.8)	1 (0.3)
Amenorrhoea	2 (0.6)	1 (0.3)
Fibrocystic breast disease	3 (0.8)	0
Breast mass	2 (0.6)	0
Menometrorrhagia	2 (0.6)	0
Menstruation irregular	1 (0.3)	1 (0.3)
Uterine polyp	2 (0.6)	0
Vulvovaginal pruritus	2 (0.6)	0
Adenomyosis	0	1 (0.3)
Adnexa uteri cyst	0	1 (0.3)
Atrophic vulvovaginitis	1 (0.3)	0
Balanoposthitis	1 (0.3)	0
Breast calcifications	0	1 (0.3)

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Non-Severe Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=360) n (%)	Randomised Placebo (N=365) n (%)
Breast disorder	1 (0.3)	0
Breast enlargement	1 (0.3)	0
Breast pain	1 (0.3)	0
Cervical cyst	1 (0.3)	0
Cervical polyp	1 (0.3)	0
Cervix disorder	1 (0.3)	0
Cystocele	0	1 (0.3)
Dysfunctional uterine bleeding	1 (0.3)	0
Dyspareunia	1 (0.3)	0
Ectropion of cervix	0	1 (0.3)
Endometrial hyperplasia	0	1 (0.3)
Endometrial hypertrophy	0	1 (0.3)
Endometriosis	0	1 (0.3)
Menopausal symptoms	0	1 (0.3)
Metrorrhagia	1 (0.3)	0
Perineal rash	1 (0.3)	0
Polycystic ovaries	1 (0.3)	0
Polymenorrhoea	1 (0.3)	0
Premenstrual syndrome	1 (0.3)	0
Pruritus genital	1 (0.3)	0
Scrotal ulcer	0	1 (0.3)
Uterine prolapse	0	1 (0.3)
Uterovaginal prolapse	0	1 (0.3)
Vaginal discharge	1 (0.3)	0
Vaginal haemorrhage	0	1 (0.3)
Vaginal ulceration	0	1 (0.3)
Investigations	34 (9.4)	26 (7.1)
Weight increased	7 (1.9)	6 (1.6)
Blood pressure increased	2 (0.6)	0
Alanine aminotransferase increased	3 (0.8)	3 (0.8)
Liver function test increased	0	5 (1.4)
Aspartate aminotransferase increased	1 (0.3)	2 (0.5)
Blood creatine phosphokinase increased	2 (0.6)	1 (0.3)
Blood potassium decreased	2 (0.6)	1 (0.3)
Gamma-glutamyltransferase increased	1 (0.3)	2 (0.5)
Urine protein/creatinine ratio increased	3 (0.8)	0
Weight decreased	3 (0.8)	0
Blood creatinine increased	2 (0.6)	0
Cardiac murmur	1 (0.3)	1 (0.3)
Human papilloma virus test positive	1 (0.3)	1 (0.3)
Transaminases increased	1 (0.3)	1 (0.3)
Anticoagulation drug level below therapeutic	1 (0.3)	0
Bacterial test positive	1 (0.3)	0
Blood alkaline phosphatase increased	1 (0.3)	0
Blood corticotrophin decreased	1 (0.3)	0
Blood immunoglobulin A decreased	0	1 (0.3)
Blood pressure systolic increased	0	1 (0.3)
Cortisol decreased	1 (0.3)	0
Cytomegalovirus test positive	1 (0.3)	0
Electrocardiogram QT prolonged	1 (0.3)	0
Gardnerella test positive	0	1 (0.3)
Heart rate increased	0	1 (0.3)
Hepatic enzyme increased	0	1 (0.3)
Influenza B virus test positive	1 (0.3)	0
International normalised ratio abnormal	1 (0.3)	0
International normalised ratio increased	0	1 (0.3)
Intraocular pressure increased	1 (0.3)	0
Smear cervix abnormal	1 (0.3)	0
Vitamin D decreased	1 (0.3)	0

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Non-Severe Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=360) n (%)	Randomised Placebo (N=365) n (%)
Blood and lymphatic system disorders	25 (6.9)	27 (7.4)
Iron deficiency anaemia	12 (3.3)	7 (1.9)
Anaemia	4 (1.1)	9 (2.5)
Lymphadenopathy	4 (1.1)	2 (0.5)
Thrombocytopenia	1 (0.3)	2 (0.5)
Leukopenia	0	3 (0.8)
Neutropenia	3 (0.8)	0
Leukocytosis	1 (0.3)	1 (0.3)
Lymphopenia	1 (0.3)	0
Microcytic anaemia	0	2 (0.5)
Pancytopenia	0	1 (0.3)
Autoimmune haemolytic anaemia	0	1 (0.3)
Increased tendency to bruise	1 (0.3)	0
Neutrophilia	0	1 (0.3)
Normocytic anaemia	0	1 (0.3)
Thrombocytosis	0	1 (0.3)
Renal and urinary disorders	32 (8.9)	17 (4.7)
Nephrolithiasis	5 (1.4)	2 (0.5)
Dysuria	1 (0.3)	7 (1.9)
Acute kidney injury	2 (0.6)	4 (1.1)
Renal colic	4 (1.1)	1 (0.3)
Lupus nephritis	3 (0.8)	1 (0.3)
Renal impairment	1 (0.3)	1 (0.3)
Haematuria	2 (0.6)	0
Chronic kidney disease	1 (0.3)	1 (0.3)
Hypertonic bladder	1 (0.3)	1 (0.3)
Urinary retention	2 (0.6)	0
Urinary tract discomfort	1 (0.3)	0
Bladder spasm	1 (0.3)	0
Chromaturia	1 (0.3)	0
Glomerulonephritis	1 (0.3)	0
Hydronephrosis	1 (0.3)	0
Leukocyturia	1 (0.3)	0
Nephritis	1 (0.3)	0
Polyuria	1 (0.3)	0
Renal cyst	1 (0.3)	0
Stress urinary incontinence	1 (0.3)	0
Ureteric obstruction	1 (0.3)	0
Urethral meatus stenosis	1 (0.3)	0
Urinary incontinence	1 (0.3)	0
Ear and labyrinth disorders	27 (7.5)	18 (4.9)
Vertigo	11 (3.1)	5 (1.4)
Ear pain	5 (1.4)	3 (0.8)
Vertigo positional	4 (1.1)	2 (0.5)
Tinnitus	1 (0.3)	4 (1.1)
Cerumen impaction	2 (0.6)	0
Deafness bilateral	2 (0.6)	0
Ear congestion	1 (0.3)	1 (0.3)
Hypoacusis	0	2 (0.5)
Deafness	1 (0.3)	0
Dysacusis	0	1 (0.3)
Ear discomfort	0	1 (0.3)
Ear pruritus	0	1 (0.3)
Hyperacusis	1 (0.3)	0
Inner ear inflammation	1 (0.3)	0
Meniere's disease	0	1 (0.3)
Motion sickness	0	1 (0.3)
Neurosensory hypoacusis	1 (0.3)	0
Otorrhoea	0	1 (0.3)

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Non-Severe Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=360) n (%)	Randomised Placebo (N=365) n (%)
Tympanic membrane hyperaemia	1 (0.3)	0
Vascular disorders	26 (7.2)	24 (6.6)
Hypertension	14 (3.9)	14 (3.8)
Haematoma	2 (0.6)	2 (0.5)
Deep vein thrombosis	1 (0.3)	1 (0.3)
Orthostatic hypotension	1 (0.3)	1 (0.3)
Phlebitis	2 (0.6)	0
Raynaud's phenomenon	1 (0.3)	1 (0.3)
Varicose vein	1 (0.3)	1 (0.3)
Essential hypertension	1 (0.3)	0
Hypotension	0	1 (0.3)
Internal haemorrhage	0	1 (0.3)
Lymphoedema	0	1 (0.3)
Malignant hypertension	1 (0.3)	0
Peripheral venous disease	1 (0.3)	0
Phlebitis superficial	1 (0.3)	0
Post thrombotic syndrome	0	1 (0.3)
Thrombophlebitis superficial	1 (0.3)	0
Varicophlebitis	0	1 (0.3)
Vasodilatation	0	1 (0.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	27 (7.5)	11 (3.0)
Skin papilloma	7 (1.9)	1 (0.3)
Uterine leiomyoma	5 (1.4)	2 (0.5)
Anogenital warts	3 (0.8)	0
Colon adenoma	0	1 (0.3)
Fibrous histiocytoma	2 (0.6)	0
Haemangioma of liver	1 (0.3)	1 (0.3)
Lipoma	1 (0.3)	1 (0.3)
Seborrhoeic keratosis	1 (0.3)	1 (0.3)
Squamous cell carcinoma	1 (0.3)	1 (0.3)
Acanthoma	1 (0.3)	0
B-cell lymphoma	1 (0.3)	0
Basal cell carcinoma	1 (0.3)	0
Benign breast neoplasm	1 (0.3)	0
Benign neoplasm of skin	1 (0.3)	0
Carcinoid tumour	0	1 (0.3)
Hepatic adenoma	1 (0.3)	0
Squamous cell carcinoma of skin	1 (0.3)	0
Squamous cell carcinoma of the cervix	0	1 (0.3)
Thyroid neoplasm	1 (0.3)	0
Uterine cancer	0	1 (0.3)
Vulvovaginal warts	1 (0.3)	0
Immune system disorders	31 (8.6)	11 (3.0)
Hypersensitivity	16 (4.4)	3 (0.8)
Seasonal allergy	8 (2.2)	6 (1.6)
Allergy to animal	1 (0.3)	2 (0.5)
Drug hypersensitivity	1 (0.3)	1 (0.3)
Allergy to arthropod bite	1 (0.3)	0
Allergy to arthropod sting	1 (0.3)	0
Allergy to vaccine	1 (0.3)	0
Contrast media reaction	1 (0.3)	0
Reaction to preservatives	1 (0.3)	0
Cardiac disorders	13 (3.6)	19 (5.2)
Palpitations	1 (0.3)	5 (1.4)
Atrial fibrillation	0	3 (0.8)
Cardiac failure congestive	0	3 (0.8)
Tachycardia	2 (0.6)	1 (0.3)

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Non-Severe Adverse Events by SOC, PT during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Randomised Anifrolumab 300mg (N=360) n (%)	Randomised Placebo (N=365) n (%)
Acute myocardial infarction	0	2 (0.5)
Angina unstable	2 (0.6)	0
Bundle branch block right	2 (0.6)	0
Pericarditis	0	2 (0.5)
Sinus bradycardia	1 (0.3)	1 (0.3)
Supraventricular tachycardia	0	2 (0.5)
Angina pectoris	0	1 (0.3)
Aortic valve disease	1 (0.3)	0
Arrhythmia	1 (0.3)	0
Bradycardia	0	1 (0.3)
Bundle branch block left	1 (0.3)	0
Cardiac failure chronic	1 (0.3)	0
Cardiomegaly	0	1 (0.3)
Coronary artery disease	1 (0.3)	0
Left ventricular dilatation	1 (0.3)	0
Pericardial effusion	0	1 (0.3)
Tachycardia paroxysmal	1 (0.3)	0
Ventricular arrhythmia	0	1 (0.3)
Hepatobiliary disorders	11 (3.1)	9 (2.5)
Cholelithiasis	2 (0.6)	2 (0.5)
Hepatic steatosis	2 (0.6)	2 (0.5)
Hypertransaminasaemia	1 (0.3)	2 (0.5)
Drug-induced liver injury	1 (0.3)	1 (0.3)
Biliary colic	1 (0.3)	0
Cholecystitis	0	1 (0.3)
Cholecystitis acute	1 (0.3)	0
Hepatic function abnormal	1 (0.3)	0
Hepatic lesion	0	1 (0.3)
Hepatic mass	1 (0.3)	0
Hepatomegaly	1 (0.3)	0
Liver disorder	0	1 (0.3)
Endocrine disorders	12 (3.3)	5 (1.4)
Steroid withdrawal syndrome	6 (1.7)	1 (0.3)
Goitre	2 (0.6)	0
Hyperprolactinaemia	2 (0.6)	0
Hyperthyroidism	1 (0.3)	1 (0.3)
Adrenal insufficiency	0	1 (0.3)
Basedow's disease	1 (0.3)	0
Cushing's syndrome	1 (0.3)	0
Hyperparathyroidism	0	1 (0.3)
Oestrogen deficiency	0	1 (0.3)
Thyroid mass	1 (0.3)	0
Social circumstances	1 (0.3)	1 (0.3)
Menopause	1 (0.3)	1 (0.3)
Pregnancy, puerperium and perinatal conditions	1 (0.3)	0
Abortion spontaneous	1 (0.3)	0
Product issues	0	1 (0.3)
Device connection issue	0	1 (0.3)

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

	Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
Number of subjects with events, n (%)	336 (93.3)	316 (86.6)
Number of censored subjects, n (%)	24 (6.7)	49 (13.4)
Exposure years	144.4	151.4
EAIR per 100 PY	232.6	208.8
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	2.86 (2.00, 3.57)	4.14 (2.86, 4.86)
Median (95% CI)	7.71 (6.57, 10.00)	11.86 (9.57, 13.86)
75%-ile (95% CI)	23.00 (19.00, 27.14)	32.29 (26.14, 39.14)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	1.23 (1.05, 1.43)	
p-value	0.0091	
Relative Risk (95% CI)	1.08 (1.03, 1.13)	
p-value	0.0026	
Odds Ratio (95% CI)	2.17 (1.30, 3.62)	
p-value	0.0030	
Risk Difference (95% CI)	6.76 (2.41, 11.10)	
p-value	0.0023	

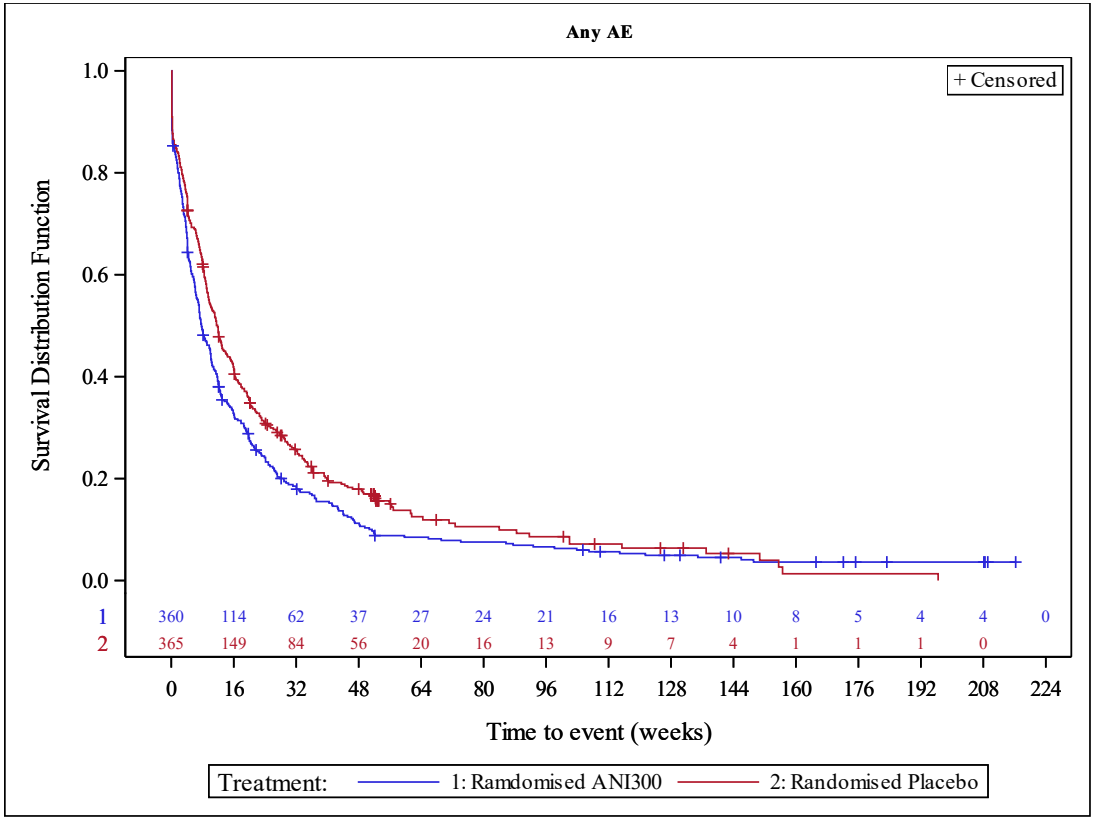
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Ramdomised ANI300 (N=360) Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Randomised Placebo (N=365) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
Age (years)							0.3818
<= 65	326/348 (93.7)	7.71 (6.43, 10.00)	312/361 (86.4)	11.86 (9.57, 13.86)	1.24 (1.06, 1.45)	0.0071	
> 65	10/ 12 (83.3)	9.29 (0.14, 29.43)	4/ 4 (100.0)	12.93 (6.43, 17.86)	0.83 (0.25, 2.76)	0.7238	
Sex							0.2269
male	22/ 27 (81.5)	18.71 (7.29, 21.86)	22/ 25 (88.0)	12.86 (6.57, 30.86)	0.91 (0.50, 1.66)	0.7437	
female	314/333 (94.3)	7.29 (6.14, 9.14)	294/340 (86.5)	11.57 (9.57, 13.86)	1.26 (1.08, 1.48)	0.0039	
Geographic region							0.6844
EU	104/115 (90.4)	10.14 (7.29, 14.29)	98/122 (80.3)	18.71 (13.00, 27.14)	1.27 (0.96, 1.67)	0.0994	
non-EU	232/245 (94.7)	7.14 (5.43, 9.14)	218/243 (89.7)	9.14 (8.14, 11.14)	1.19 (0.99, 1.44)	0.0593	
SLEDAI-2K score at screening							0.7204
< 10 points	100/109 (91.7)	7.57 (5.00, 10.29)	93/106 (87.7)	10.29 (7.29, 15.29)	1.19 (0.90, 1.58)	0.2295	
>= 10 points	236/251 (94.0)	7.86 (6.57, 10.14)	223/259 (86.1)	12.14 (9.57, 15.57)	1.24 (1.03, 1.49)	0.0207	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of time to first Adverse Event during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Serious Adverse Event during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

	Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
Number of subjects with events, n (%)	78 (21.7)	81 (22.2)
Number of censored subjects, n (%)	282 (78.3)	284 (77.8)
Exposure years	772.8	471.6
EAIR per 100 PY	10.1	17.2
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	136.7 (99.71, NE)	87.43 (61.29, 115.4)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	0.66 (0.48, 0.90)	
p-value	0.0091	
Relative Risk (95% CI)	0.98 (0.74, 1.29)	
p-value	0.8644	
Odds Ratio (95% CI)	0.97 (0.68, 1.38)	
p-value	0.8643	
Risk Difference (95% CI)	-0.53 (-6.55, 5.50)	
p-value	0.8643	

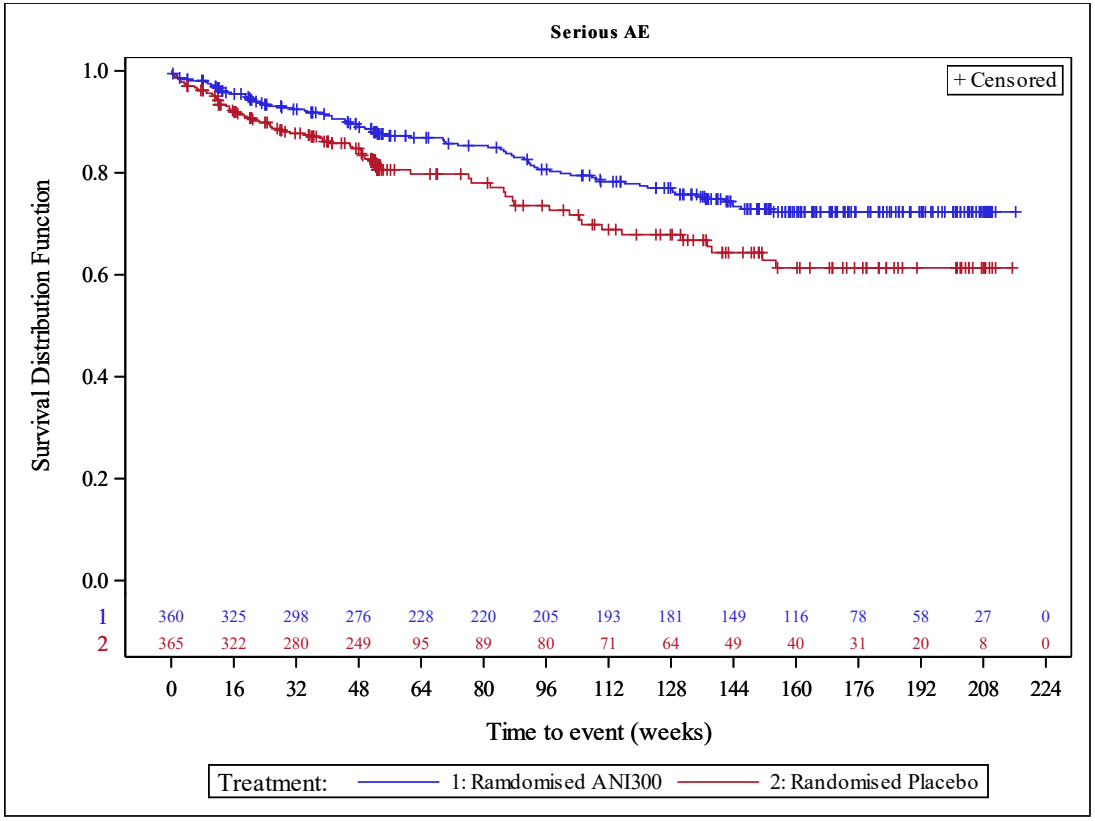
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Serious Adverse Event during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	 Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	 Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	 p-Value	Interaction p-Value
Age (years)							0.6702
<= 65	73/348 (21.0)	NE (NE, NE)	80/361 (22.2)	NE (NE, NE)	0.63 (0.46, 0.88)	0.0057	
> 65	5/ 12 (41.7)	NE (21.00, NE)	1/ 4 (25.0)	NE (48.71, NE)	1.22 (0.13, 11.82)	0.8616	
Sex							0.4743
male	7/ 27 (25.9)	NE (122.00, NE)	5/ 25 (20.0)	NE (115.43, NE)	1.04 (0.33, 3.30)	0.9526	
female	71/333 (21.3)	NE (NE, NE)	76/340 (22.4)	NE (NE, NE)	0.63 (0.45, 0.88)	0.0061	
Geographic region							0.3787
EU	23/115 (20.0)	NE (NE, NE)	29/122 (23.8)	NE (131.00, NE)	0.51 (0.29, 0.90)	0.0180	
non-EU	55/245 (22.4)	NE (NE, NE)	52/243 (21.4)	NE (NE, NE)	0.74 (0.50, 1.08)	0.1198	
SLEDAI-2K score at screening							0.9716
< 10 points	20/109 (18.3)	NE (NE, NE)	20/106 (18.9)	NE (104.57, NE)	0.55 (0.29, 1.04)	0.0616	
>= 10 points	58/251 (23.1)	NE (NE, NE)	61/259 (23.6)	NE (NE, NE)	0.69 (0.48, 1.00)	0.0498	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of time to first Serious Adverse Event during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Severe Adverse Event during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

	Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
Number of subjects with events, n (%)	55 (15.3)	34 (9.3)
Number of censored subjects, n (%)	305 (84.7)	331 (90.7)
Exposure years	810.3	506.2
EAIR per 100 PY	6.8	6.7
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (177.0, NE)	NE (157.3, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	1.13 (0.73, 1.76)	
p-value	0.5734	
Relative Risk (95% CI)	1.64 (1.10, 2.45)	
p-value	0.0159	
Odds Ratio (95% CI)	1.76 (1.11, 2.77)	
p-value	0.0153	
Risk Difference (95% CI)	5.96 (1.20, 10.73)	
p-value	0.0142	

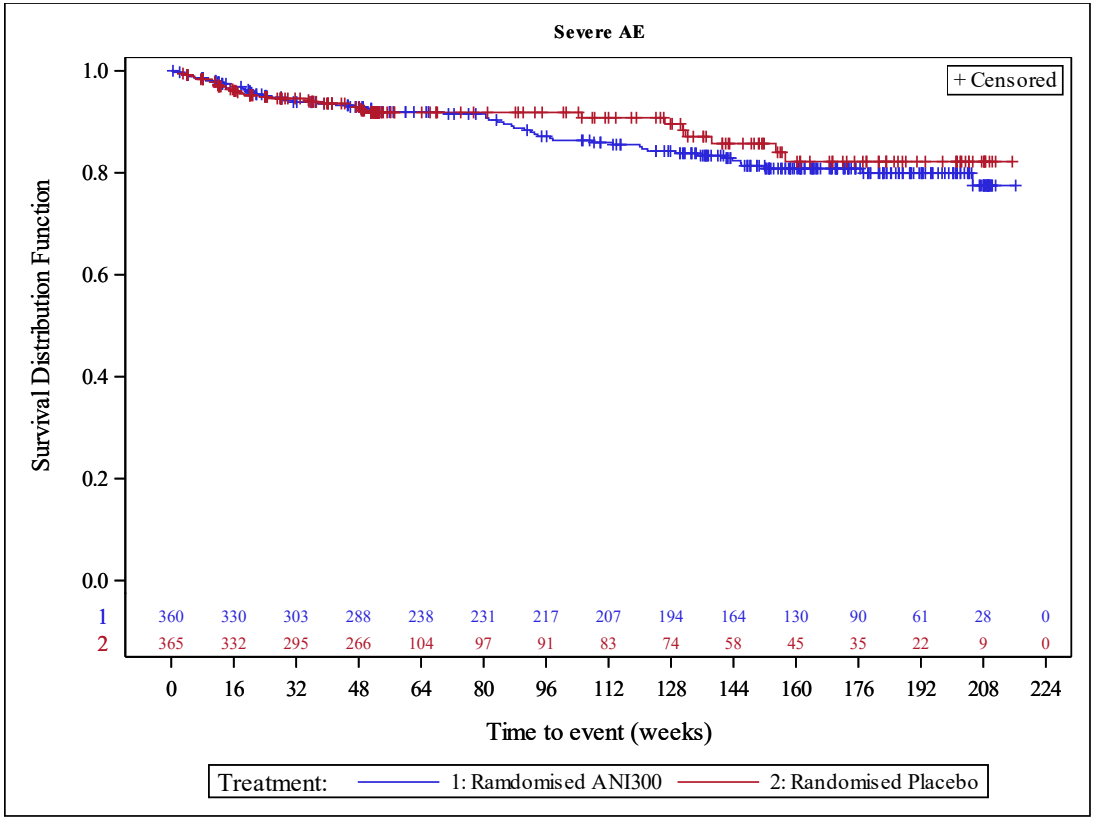
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Severe Adverse Event during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Ramdomised ANI300 (N=360) Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Randomised Placebo (N=365) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
Age (years)							0.9864
<= 65	53/348 (15.2)	NE (NE, NE)	34/361 (9.4)	NE (NE, NE)	1.14 (0.73, 1.76)	0.5715	
> 65	2/ 12 (16.7)	NE (93.00, NE)	0/ 4 (0.0)	NE (NE, NE)	NE		
Sex							0.6000
male	5/ 27 (18.5)	NE (NE, NE)	2/ 25 (8.0)	NE (NE, NE)	1.72 (0.33, 9.02)	0.5168	
female	50/333 (15.0)	NE (NE, NE)	32/340 (9.4)	NE (NE, NE)	1.09 (0.69, 1.72)	0.7000	
Geographic region							0.7754
EU	16/115 (13.9)	NE (NE, NE)	9/122 (7.4)	NE (NE, NE)	1.23 (0.53, 2.85)	0.6283	
non-EU	39/245 (15.9)	NE (NE, NE)	25/243 (10.3)	NE (NE, NE)	1.09 (0.65, 1.82)	0.7505	
SLEDAI-2K score at screening							0.5239
< 10 points	15/109 (13.8)	NE (NE, NE)	11/106 (10.4)	NE (NE, NE)	0.94 (0.42, 2.08)	0.8733	
>= 10 points	40/251 (15.9)	NE (NE, NE)	23/259 (8.9)	NE (NE, NE)	1.23 (0.73, 2.08)	0.4353	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of time to first Severe Adverse Event during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Non-Severe Adverse Event during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

	Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
Number of subjects with events, n (%)	333 (92.5)	313 (85.8)
Number of censored subjects, n (%)	27 (7.5)	52 (14.2)
Exposure years	147.0	152.8
EAIR per 100 PY	226.5	204.9
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	2.86 (2.00, 3.57)	4.14 (2.86, 4.86)
Median (95% CI)	8.00 (7.00, 10.14)	12.00 (9.71, 14.00)
75%-ile (95% CI)	23.00 (19.43, 27.86)	33.57 (27.71, 39.86)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	1.23 (1.05, 1.43)	
p-value	0.0099	
Relative Risk (95% CI)	1.08 (1.02, 1.14)	
p-value	0.0037	
Odds Ratio (95% CI)	2.05 (1.26, 3.34)	
p-value	0.0041	
Risk Difference (95% CI)	6.75 (2.25, 11.25)	
p-value	0.0033	

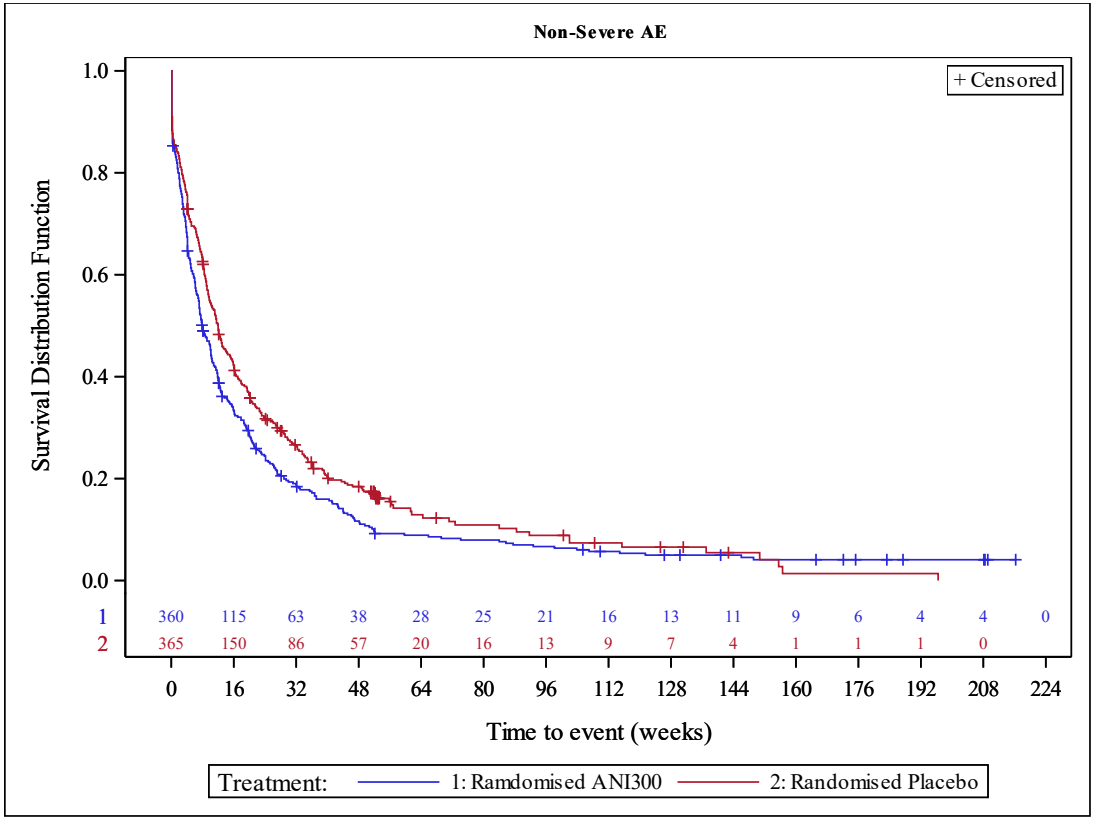
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Non-Severe Adverse Event during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Ramdomised ANI300 (N=360) Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Randomised Placebo (N=365) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
Age (years)							0.3863
<= 65	323/348 (92.8)	8.00 (6.86, 10.14)	309/361 (85.6)	12.00 (9.71, 14.00)	1.24 (1.06, 1.45)	0.0080	
> 65	10/ 12 (83.3)	9.29 (0.14, 29.43)	4/ 4 (100.0)	12.93 (6.43, 17.86)	0.83 (0.25, 2.76)	0.7238	
Sex							0.2330
male	22/ 27 (81.5)	18.71 (7.29, 21.86)	22/ 25 (88.0)	12.86 (6.57, 30.86)	0.91 (0.50, 1.66)	0.7437	
female	311/333 (93.4)	7.57 (6.29, 9.86)	291/340 (85.6)	12.00 (9.71, 14.00)	1.26 (1.07, 1.48)	0.0044	
Geographic region							0.5558
EU	104/115 (90.4)	10.14 (7.29, 16.00)	96/122 (78.7)	20.14 (14.29, 29.14)	1.29 (0.97, 1.70)	0.0806	
non-EU	229/245 (93.5)	7.14 (5.71, 9.71)	217/243 (89.3)	9.14 (8.14, 11.14)	1.19 (0.98, 1.43)	0.0716	
SLEDAI-2K score at screening							0.6588
< 10 points	98/109 (89.9)	8.14 (5.86, 11.14)	93/106 (87.7)	11.29 (7.29, 16.00)	1.18 (0.88, 1.56)	0.2682	
>= 10 points	235/251 (93.6)	8.00 (6.86, 10.43)	220/259 (84.9)	12.14 (9.86, 15.71)	1.25 (1.04, 1.50)	0.0192	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of time to first Non-Severe Adverse Event during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event leading to discontinuation of study drug during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

	Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
Number of subjects with events, n (%)	23 (6.4)	22 (6.0)
Number of censored subjects, n (%)	337 (93.6)	343 (94.0)
Exposure years	871.3	522.4
EAIR per 100 PY	2.6	4.2
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	0.84 (0.47, 1.53)	
p-value	0.5751	
Relative Risk (95% CI)	1.06 (0.60, 1.87)	
p-value	0.8402	
Odds Ratio (95% CI)	1.06 (0.58, 1.95)	
p-value	0.8402	
Risk Difference (95% CI)	0.36 (-3.15, 3.87)	
p-value	0.8402	

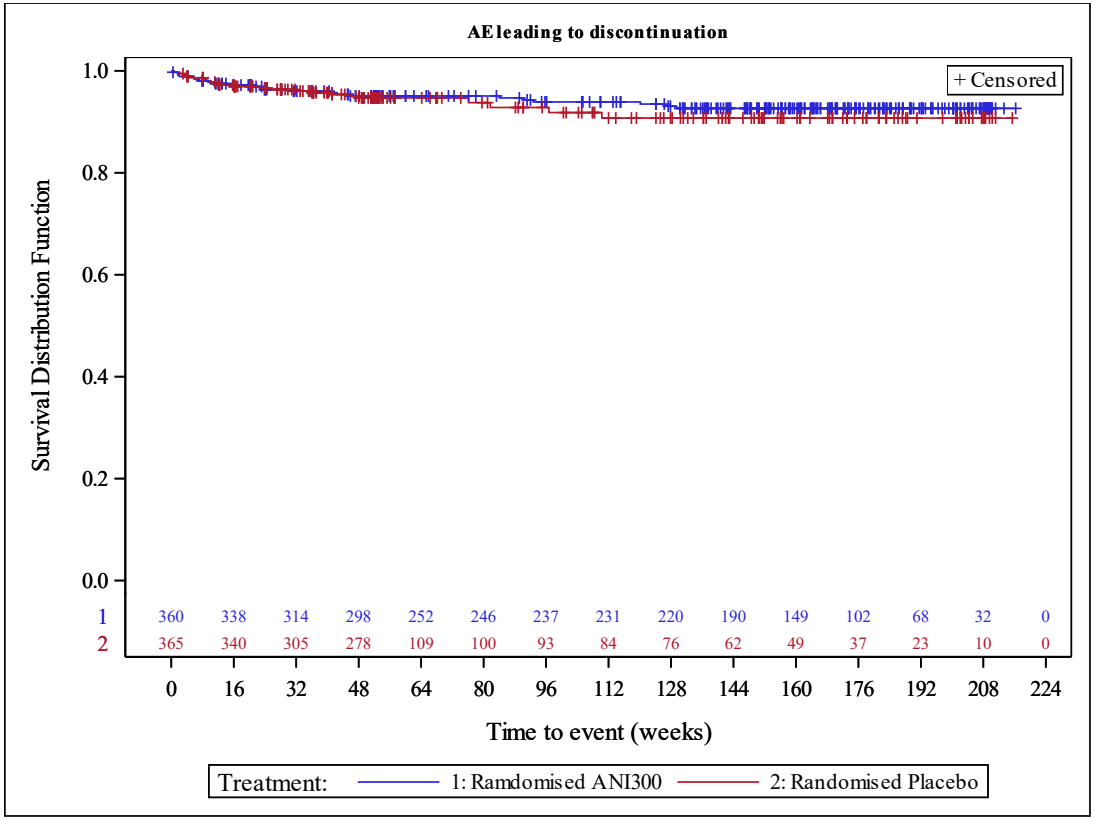
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event leading to discontinuation of study drug during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Ramdomised ANI300 (N=360) Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Randomised Placebo (N=365) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
Age (years)							0.9889
<= 65	22/348 (6.3)	NE (NE, NE)	22/361 (6.1)	NE (NE, NE)	0.82 (0.45, 1.50)	0.5233	
> 65	1/ 12 (8.3)	NE (NE, NE)	0/ 4 (0.0)	NE (NE, NE)	NE		
Sex							0.9874
male	2/ 27 (7.4)	NE (NE, NE)	0/ 25 (0.0)	NE (NE, NE)	NE		
female	21/333 (6.3)	NE (NE, NE)	22/340 (6.5)	NE (NE, NE)	0.80 (0.43, 1.47)	0.4681	
Geographic region							0.5707
EU	9/115 (7.8)	NE (NE, NE)	7/122 (5.7)	NE (NE, NE)	0.95 (0.35, 2.62)	0.9227	
non-EU	14/245 (5.7)	NE (NE, NE)	15/243 (6.2)	NE (NE, NE)	0.80 (0.38, 1.66)	0.5422	
SLEDAI-2K score at screening							0.8943
< 10 points	5/109 (4.6)	NE (NE, NE)	5/106 (4.7)	NE (NE, NE)	0.80 (0.23, 2.83)	0.7311	
>= 10 points	18/251 (7.2)	NE (NE, NE)	17/259 (6.6)	NE (NE, NE)	0.86 (0.44, 1.70)	0.6684	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of time to first Adverse Event leading to discontinuation of study drug during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to Adverse Event leading to death during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set

	Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
Number of subjects with events, n (%)	3 (0.8)	0 (0.0)
Number of censored subjects, n (%)	357 (99.2)	365 (100.0)
Exposure years	872.8	525.8
EAIR per 100 PY	0.3	0.0
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	NE	
p-value		
Relative Risk (95% CI)	7.10 (0.37, 136.90)	
p-value	0.1944	
Odds Ratio (95% CI)	7.16 (0.37, 139.05)	
p-value	0.1935	
Risk Difference (95% CI)	0.83 (-0.11, 1.77)	
p-value	0.0820	

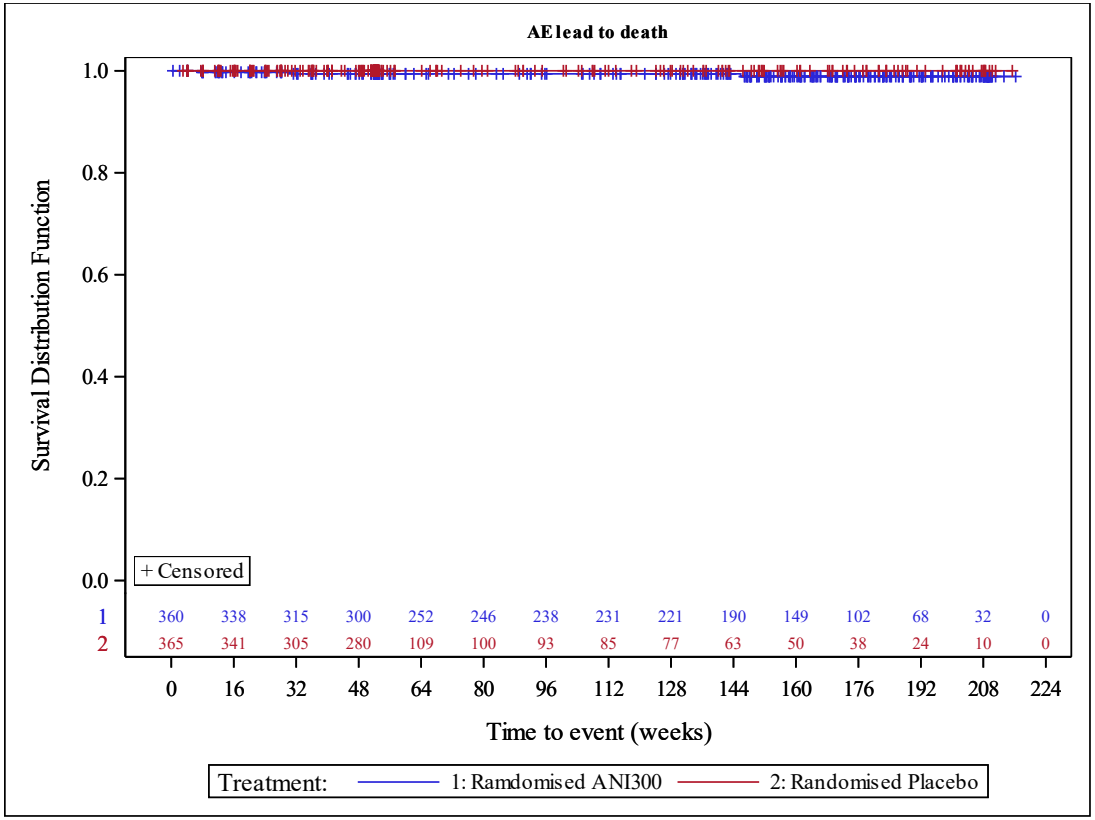
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to Adverse Event leading to death during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%) Median (95% CI)	Randomised Placebo (N=365) n/ N (%) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI) p-Value	Interaction p-Value
Age (years)				0.9996
<= 65	3/348 (0.9) NE (NE, NE)	0/361 (0.0) NE (NE, NE)	NE	
> 65	0/ 12 (0.0) NE (NE, NE)	0/ 4 (0.0) NE (NE, NE)	NE	
Sex				0.9992
male	0/ 27 (0.0) NE (NE, NE)	0/ 25 (0.0) NE (NE, NE)	NE	
female	3/333 (0.9) NE (NE, NE)	0/340 (0.0) NE (NE, NE)	NE	
Geographic region				1.0000
EU	1/115 (0.9) NE (NE, NE)	0/122 (0.0) NE (NE, NE)	NE	
non-EU	2/245 (0.8) NE (NE, NE)	0/243 (0.0) NE (NE, NE)	NE	
SLEDAI-2K score at screening				0.9999
< 10 points	2/109 (1.8) NE (NE, NE)	0/106 (0.0) NE (NE, NE)	NE	
>= 10 points	1/251 (0.4) NE (NE, NE)	0/259 (0.0) NE (NE, NE)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of time to Adverse Event leading to death during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Anaphylaxis
Full analysis set

	Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	360 (100.0)	365 (100.0)
Exposure years	872.8	525.8
EAIR per 100 PY	0.0	0.0
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	NE	
p-value		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

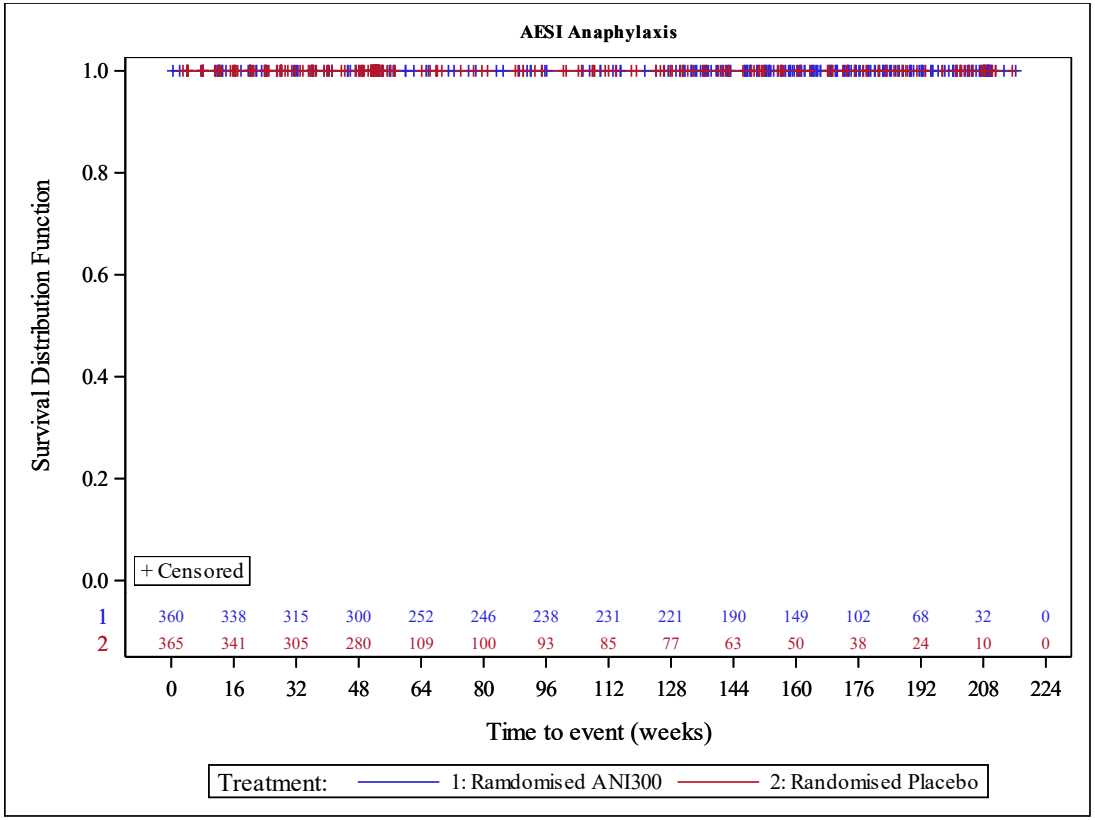
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Anaphylaxis - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%) Median (95% CI)	Randomised Placebo (N=365) n/ N (%) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI) p-Value	Interaction p-Value
Age (years)				NE
<= 65	0/348 (0.0) NE (NE, NE)	0/361 (0.0) NE (NE, NE)	NE	
> 65	0/ 12 (0.0) NE (NE, NE)	0/ 4 (0.0) NE (NE, NE)	NE	
Sex				NE
male	0/ 27 (0.0) NE (NE, NE)	0/ 25 (0.0) NE (NE, NE)	NE	
female	0/333 (0.0) NE (NE, NE)	0/340 (0.0) NE (NE, NE)	NE	
Geographic region				NE
EU	0/115 (0.0) NE (NE, NE)	0/122 (0.0) NE (NE, NE)	NE	
non-EU	0/245 (0.0) NE (NE, NE)	0/243 (0.0) NE (NE, NE)	NE	
SLEDAI-2K score at screening				NE
< 10 points	0/109 (0.0) NE (NE, NE)	0/106 (0.0) NE (NE, NE)	NE	
>= 10 points	0/251 (0.0) NE (NE, NE)	0/259 (0.0) NE (NE, NE)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Anaphylaxis
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Anaphylaxis
Full analysis set

	Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	360 (100.0)	365 (100.0)
Exposure years	872.8	525.8
EAIR per 100 PY	0.0	0.0
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	NE	
p-value		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

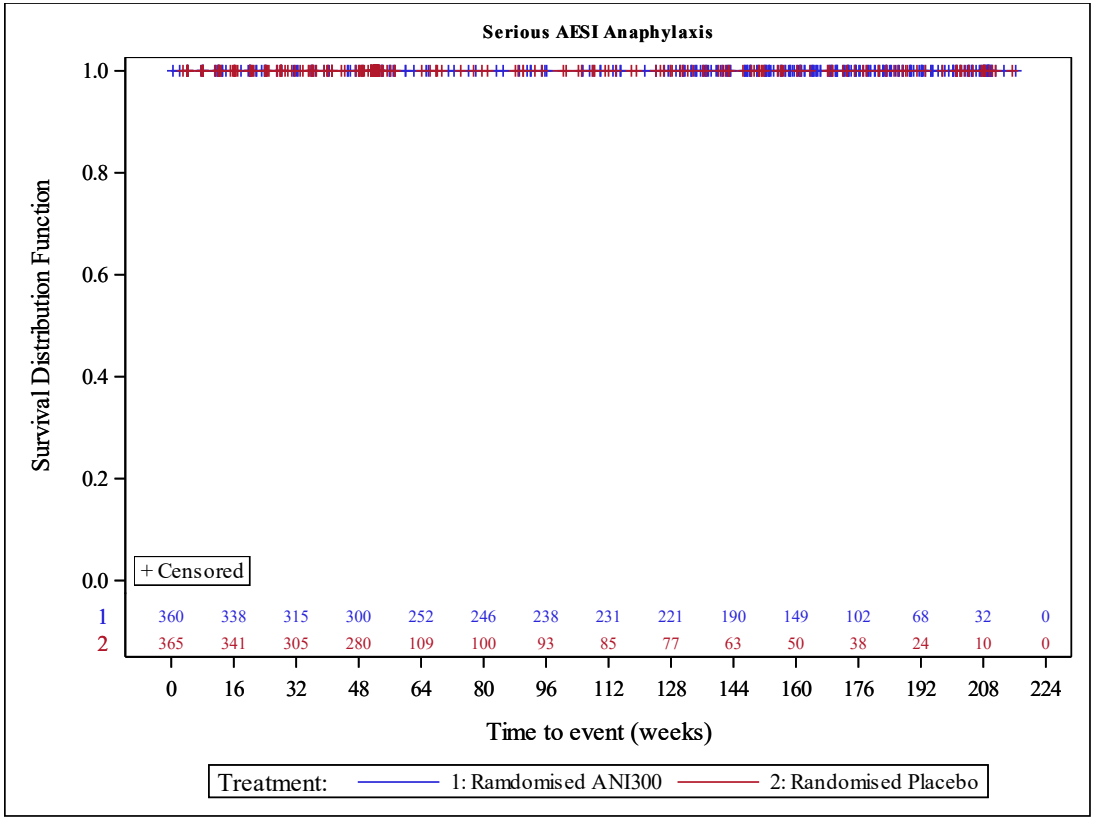
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Anaphylaxis - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Ramdomised ANI300 (N=360) Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Randomised Placebo (N=365) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
Age (years)							NE
<= 65	0/348 (0.0)	NE (NE, NE)	0/361 (0.0)	NE (NE, NE)	NE		
> 65	0/ 12 (0.0)	NE (NE, NE)	0/ 4 (0.0)	NE (NE, NE)	NE		
Sex							NE
male	0/ 27 (0.0)	NE (NE, NE)	0/ 25 (0.0)	NE (NE, NE)	NE		
female	0/333 (0.0)	NE (NE, NE)	0/340 (0.0)	NE (NE, NE)	NE		
Geographic region							NE
EU	0/115 (0.0)	NE (NE, NE)	0/122 (0.0)	NE (NE, NE)	NE		
non-EU	0/245 (0.0)	NE (NE, NE)	0/243 (0.0)	NE (NE, NE)	NE		
SLEDAI-2K score at screening							NE
< 10 points	0/109 (0.0)	NE (NE, NE)	0/106 (0.0)	NE (NE, NE)	NE		
>= 10 points	0/251 (0.0)	NE (NE, NE)	0/259 (0.0)	NE (NE, NE)	NE		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Anaphylaxis
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Anaphylaxis
Full analysis set

	Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	360 (100.0)	365 (100.0)
Exposure years	872.8	525.8
EAIR per 100 PY	0.0	0.0
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	NE	
p-value		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

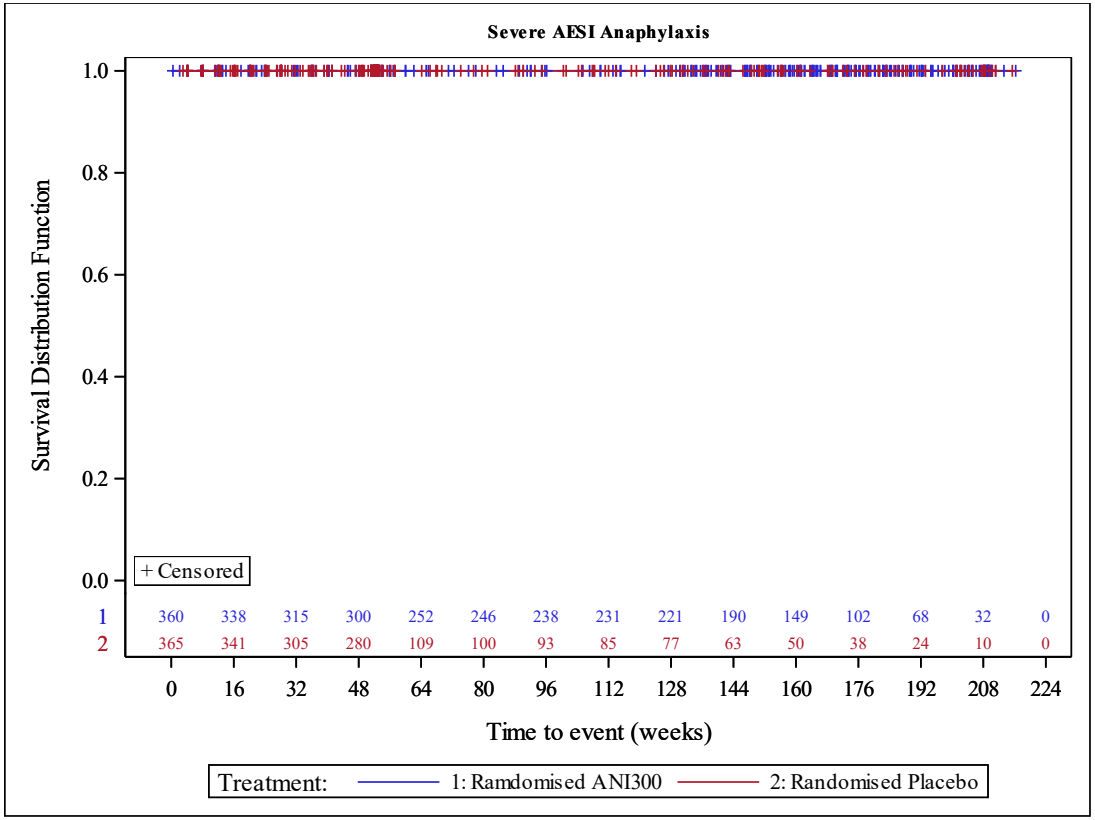
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Anaphylaxis - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Ramdomised ANI300 (N=360) Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Randomised Placebo (N=365) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
Age (years)							NE
<= 65	0/348 (0.0)	NE (NE, NE)	0/361 (0.0)	NE (NE, NE)	NE		
> 65	0/ 12 (0.0)	NE (NE, NE)	0/ 4 (0.0)	NE (NE, NE)	NE		
Sex							NE
male	0/ 27 (0.0)	NE (NE, NE)	0/ 25 (0.0)	NE (NE, NE)	NE		
female	0/333 (0.0)	NE (NE, NE)	0/340 (0.0)	NE (NE, NE)	NE		
Geographic region							NE
EU	0/115 (0.0)	NE (NE, NE)	0/122 (0.0)	NE (NE, NE)	NE		
non-EU	0/245 (0.0)	NE (NE, NE)	0/243 (0.0)	NE (NE, NE)	NE		
SLEDAI-2K score at screening							NE
< 10 points	0/109 (0.0)	NE (NE, NE)	0/106 (0.0)	NE (NE, NE)	NE		
>= 10 points	0/251 (0.0)	NE (NE, NE)	0/259 (0.0)	NE (NE, NE)	NE		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Anaphylaxis
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Anaphylaxis
Full analysis set

	Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	360 (100.0)	365 (100.0)
Exposure years	872.8	525.8
EAIR per 100 PY	0.0	0.0
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	NE	
p-value		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

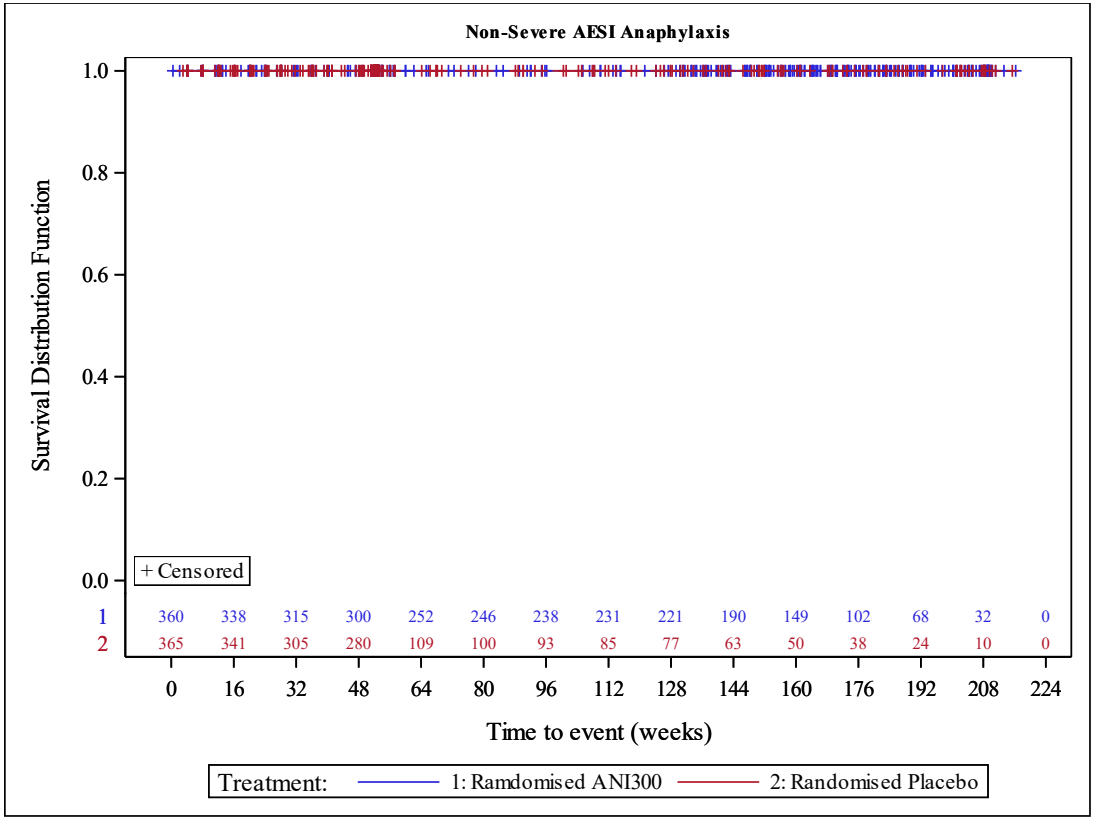
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Anaphylaxis - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%) Median (95% CI)	Randomised Placebo (N=365) n/ N (%) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI) p-Value	Interaction p-Value
Age (years)				NE
<= 65	0/348 (0.0) NE (NE, NE)	0/361 (0.0) NE (NE, NE)	NE	
> 65	0/ 12 (0.0) NE (NE, NE)	0/ 4 (0.0) NE (NE, NE)	NE	
Sex				NE
male	0/ 27 (0.0) NE (NE, NE)	0/ 25 (0.0) NE (NE, NE)	NE	
female	0/333 (0.0) NE (NE, NE)	0/340 (0.0) NE (NE, NE)	NE	
Geographic region				NE
EU	0/115 (0.0) NE (NE, NE)	0/122 (0.0) NE (NE, NE)	NE	
non-EU	0/245 (0.0) NE (NE, NE)	0/243 (0.0) NE (NE, NE)	NE	
SLEDAI-2K score at screening				NE
< 10 points	0/109 (0.0) NE (NE, NE)	0/106 (0.0) NE (NE, NE)	NE	
>= 10 points	0/251 (0.0) NE (NE, NE)	0/259 (0.0) NE (NE, NE)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Anaphylaxis
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Herpes Zoster
Full analysis set

	Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
Number of subjects with events, n (%)	42 (11.7)	11 (3.0)
Number of censored subjects, n (%)	318 (88.3)	354 (97.0)
Exposure years	814.1	511.5
EAIR per 100 PY	5.2	2.2
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	2.63 (1.34, 5.17)	
p-value	0.0036	
Relative Risk (95% CI)	3.87 (2.03, 7.40)	
p-value	<.0001	
Odds Ratio (95% CI)	4.25 (2.15, 8.40)	
p-value	<.0001	
Risk Difference (95% CI)	8.65 (4.90, 12.40)	
p-value	<.0001	

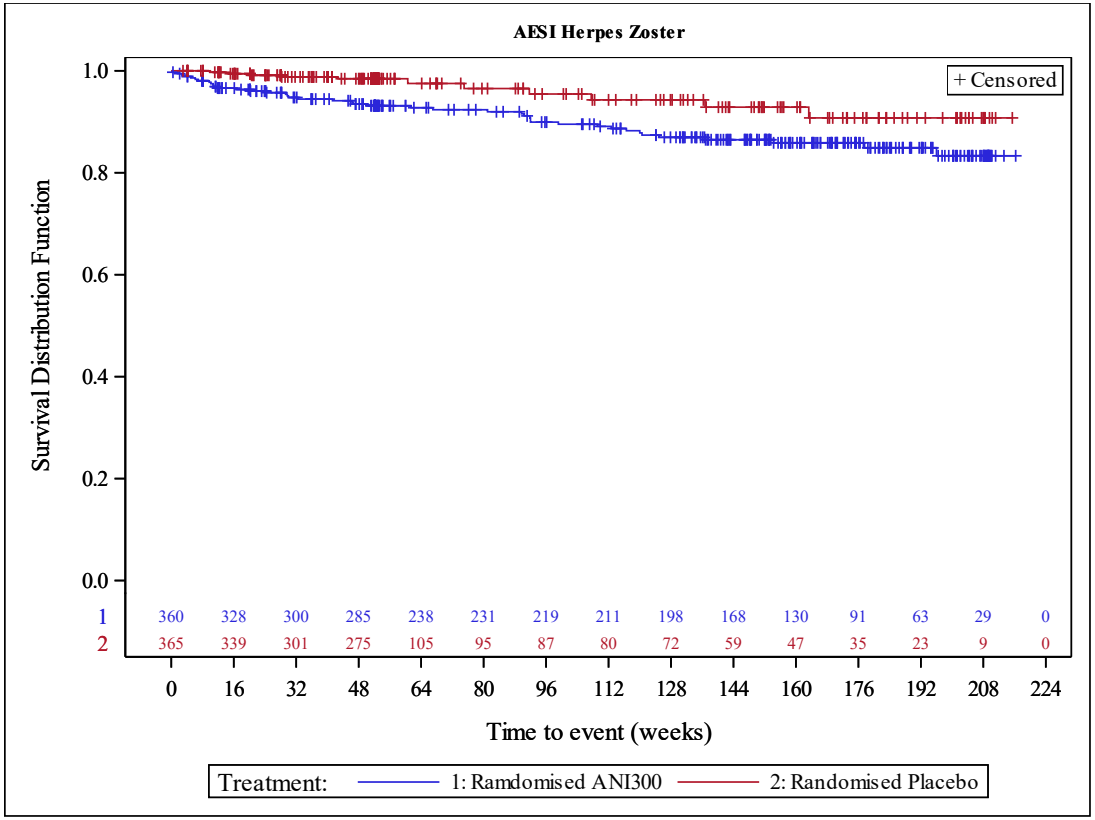
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Ramdomised ANI300 (N=360) Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Randomised Placebo (N=365) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
Age (years)							0.9996
<= 65	42/348 (12.1)	NE (NE, NE)	11/361 (3.0)	NE (NE, NE)	2.71 (1.38, 5.32)	0.0026	
> 65	0/ 12 (0.0)	NE (NE, NE)	0/ 4 (0.0)	NE (NE, NE)	NE		
Sex							0.9501
male	4/ 27 (14.8)	NE (NE, NE)	1/ 25 (4.0)	NE (60.57, NE)	2.91 (0.32, 26.64)	0.3225	
female	38/333 (11.4)	NE (NE, NE)	10/340 (2.9)	NE (NE, NE)	2.59 (1.27, 5.26)	0.0066	
Geographic region							0.1491
EU	10/115 (8.7)	NE (NE, NE)	5/122 (4.1)	NE (NE, NE)	1.28 (0.42, 3.85)	0.6620	
non-EU	32/245 (13.1)	NE (NE, NE)	6/243 (2.5)	NE (NE, NE)	3.80 (1.57, 9.19)	0.0015	
SLEDAI-2K score at screening							0.6465
< 10 points	11/109 (10.1)	NE (NE, NE)	2/106 (1.9)	NE (NE, NE)	3.14 (0.68, 14.50)	0.1239	
>= 10 points	31/251 (12.4)	NE (NE, NE)	9/259 (3.5)	NE (NE, NE)	2.52 (1.19, 5.37)	0.0130	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Herpes Zoster
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Herpes Zoster
Full analysis set

	Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
Number of subjects with events, n (%)	8 (2.2)	0 (0.0)
Number of censored subjects, n (%)	352 (97.8)	365 (100.0)
Exposure years	864.3	525.8
EAIR per 100 PY	0.9	0.0
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	NE	
p-value		
Relative Risk (95% CI)	17.24 (1.00, 297.50)	
p-value	0.0501	
Odds Ratio (95% CI)	17.63 (1.01, 306.54)	
p-value	0.0489	
Risk Difference (95% CI)	2.22 (0.70, 3.74)	
p-value	0.0042	

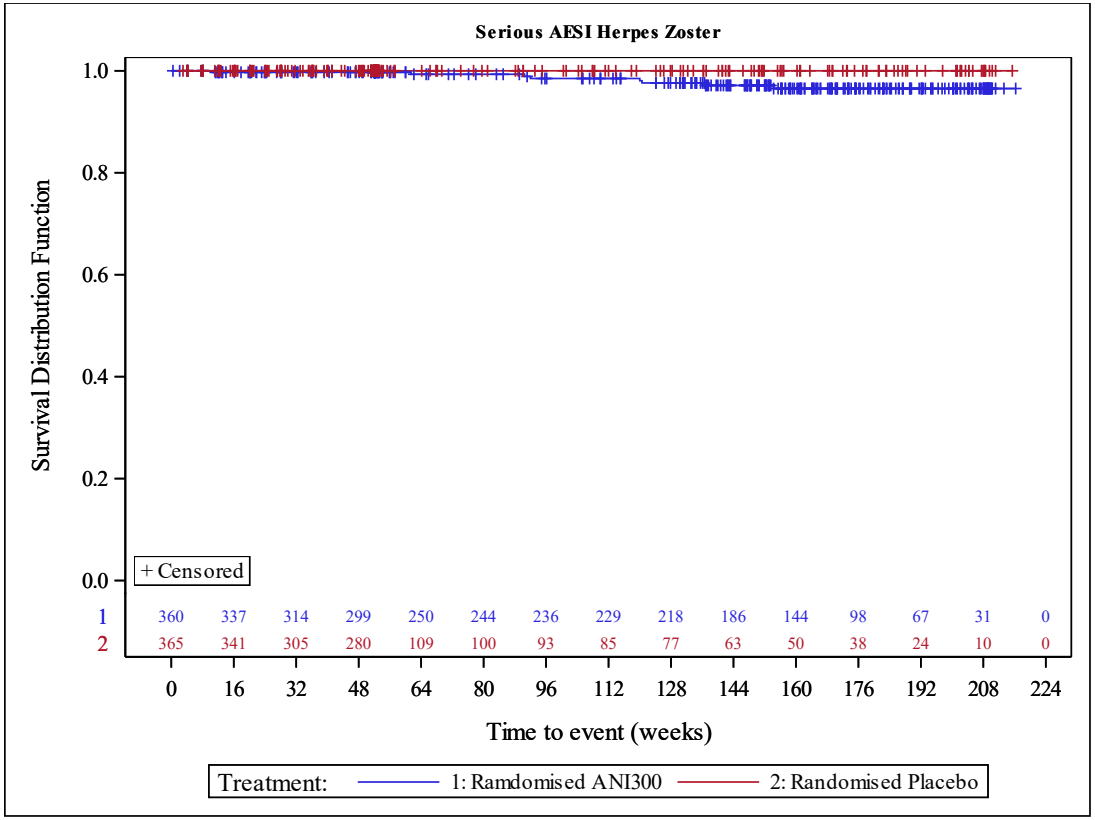
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Ramdomised ANI300 (N=360) Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Randomised Placebo (N=365) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
Age (years)							0.9997
<= 65	8/348 (2.3)	NE (NE, NE)	0/361 (0.0)	NE (NE, NE)	NE		
> 65	0/ 12 (0.0)	NE (NE, NE)	0/ 4 (0.0)	NE (NE, NE)	NE		
Sex							1.0000
male	1/ 27 (3.7)	NE (NE, NE)	0/ 25 (0.0)	NE (NE, NE)	NE		
female	7/333 (2.1)	NE (NE, NE)	0/340 (0.0)	NE (NE, NE)	NE		
Geographic region							1.0000
EU	3/115 (2.6)	NE (NE, NE)	0/122 (0.0)	NE (NE, NE)	NE		
non-EU	5/245 (2.0)	NE (NE, NE)	0/243 (0.0)	NE (NE, NE)	NE		
SLEDAI-2K score at screening							0.9999
< 10 points	4/109 (3.7)	NE (NE, NE)	0/106 (0.0)	NE (NE, NE)	NE		
>= 10 points	4/251 (1.6)	NE (NE, NE)	0/259 (0.0)	NE (NE, NE)	NE		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Herpes Zoster
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Herpes Zoster
Full analysis set

	Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
Number of subjects with events, n (%)	5 (1.4)	0 (0.0)
Number of censored subjects, n (%)	355 (98.6)	365 (100.0)
Exposure years	869.4	525.8
EAIR per 100 PY	0.6	0.0
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	NE	
p-value		
Relative Risk (95% CI)	11.15 (0.62, 200.95)	
p-value	0.1021	
Odds Ratio (95% CI)	11.31 (0.62, 205.28)	
p-value	0.1010	
Risk Difference (95% CI)	1.39 (0.18, 2.60)	
p-value	0.0243	

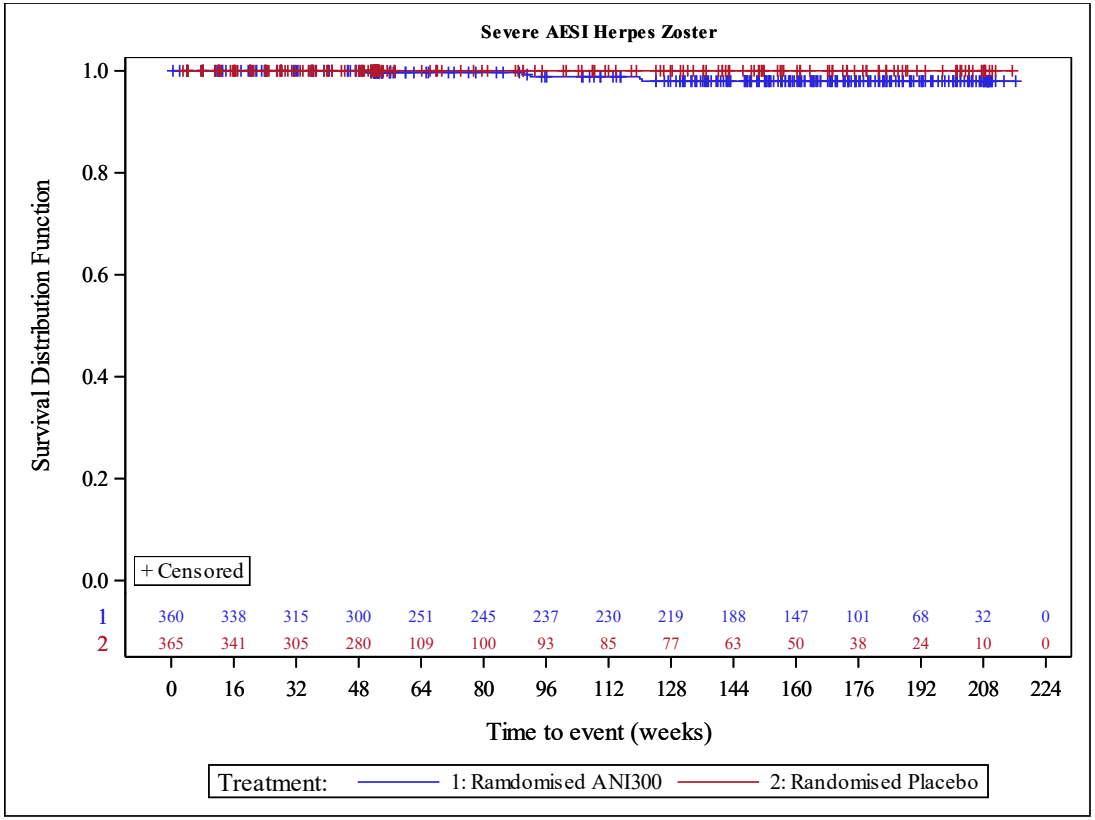
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%) Median (95% CI)	Randomised Placebo (N=365) n/ N (%) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI) p-Value	Interaction p-Value
Age (years)				0.9997
<= 65	5/348 (1.4) NE (NE, NE)	0/361 (0.0) NE (NE, NE)	NE	
> 65	0/ 12 (0.0) NE (NE, NE)	0/ 4 (0.0) NE (NE, NE)	NE	
Sex				0.9999
male	1/ 27 (3.7) NE (NE, NE)	0/ 25 (0.0) NE (NE, NE)	NE	
female	4/333 (1.2) NE (NE, NE)	0/340 (0.0) NE (NE, NE)	NE	
Geographic region				1.0000
EU	2/115 (1.7) NE (NE, NE)	0/122 (0.0) NE (NE, NE)	NE	
non-EU	3/245 (1.2) NE (NE, NE)	0/243 (0.0) NE (NE, NE)	NE	
SLEDAI-2K score at screening				0.9999
< 10 points	2/109 (1.8) NE (NE, NE)	0/106 (0.0) NE (NE, NE)	NE	
>= 10 points	3/251 (1.2) NE (NE, NE)	0/259 (0.0) NE (NE, NE)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Herpes Zoster
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Herpes Zoster
Full analysis set

	Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
Number of subjects with events, n (%)	37 (10.3)	11 (3.0)
Number of censored subjects, n (%)	323 (89.7)	354 (97.0)
Exposure years	817.6	511.5
EAIR per 100 PY	4.5	2.2
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	2.38 (1.20, 4.72)	
p-value	0.0107	
Relative Risk (95% CI)	3.41 (1.77, 6.58)	
p-value	0.0003	
Odds Ratio (95% CI)	3.69 (1.85, 7.35)	
p-value	0.0002	
Risk Difference (95% CI)	7.26 (3.67, 10.86)	
p-value	<.0001	

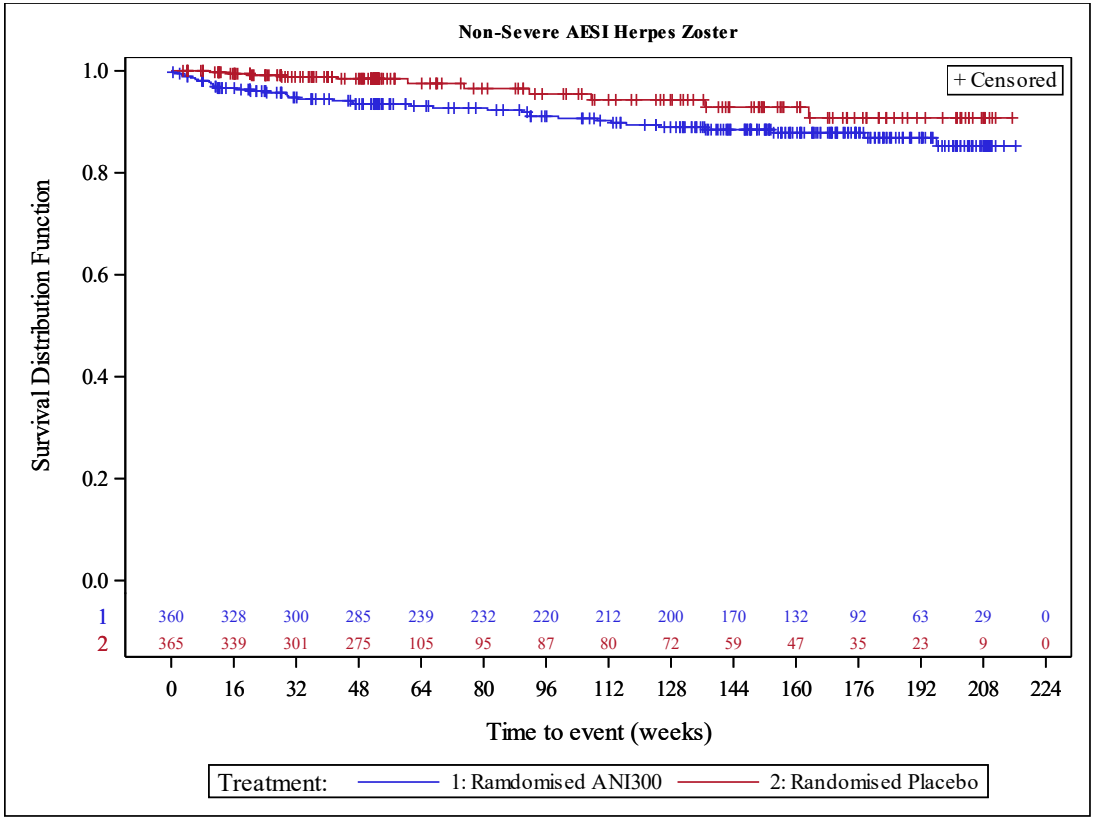
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Herpes Zoster - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Ramdomised ANI300 (N=360) Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Randomised Placebo (N=365) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
Age (years)							0.9997
<= 65	37/348 (10.6)	NE (NE, NE)	11/361 (3.0)	NE (NE, NE)	2.45 (1.24, 4.87)	0.0080	
> 65	0/ 12 (0.0)	NE (NE, NE)	0/ 4 (0.0)	NE (NE, NE)	NE		
Sex							0.9286
male	3/ 27 (11.1)	NE (NE, NE)	1/ 25 (4.0)	NE (60.57, NE)	2.44 (0.25, 23.89)	0.4276	
female	34/333 (10.2)	NE (NE, NE)	10/340 (2.9)	NE (NE, NE)	2.36 (1.15, 4.84)	0.0161	
Geographic region							0.1140
EU	8/115 (7.0)	NE (NE, NE)	5/122 (4.1)	NE (NE, NE)	1.08 (0.34, 3.40)	0.8974	
non-EU	29/245 (11.8)	NE (NE, NE)	6/243 (2.5)	NE (NE, NE)	3.50 (1.44, 8.53)	0.0034	
SLEDAI-2K score at screening							0.7358
< 10 points	9/109 (8.3)	NE (NE, NE)	2/106 (1.9)	NE (NE, NE)	2.73 (0.57, 12.98)	0.1896	
>= 10 points	28/251 (11.2)	NE (NE, NE)	9/259 (3.5)	NE (NE, NE)	2.31 (1.08, 4.96)	0.0276	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Herpes Zoster
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Malignancy
Full analysis set

	Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
Number of subjects with events, n (%)	4 (1.1)	4 (1.1)
Number of censored subjects, n (%)	356 (98.9)	361 (98.9)
Exposure years	866.8	525.7
EAIR per 100 PY	0.5	0.8
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	0.80 (0.20, 3.29)	
p-value	0.7589	
Relative Risk (95% CI)	1.01 (0.26, 4.02)	
p-value	0.9844	
Odds Ratio (95% CI)	1.01 (0.25, 4.09)	
p-value	0.9844	
Risk Difference (95% CI)	0.02 (-1.51, 1.54)	
p-value	0.9844	

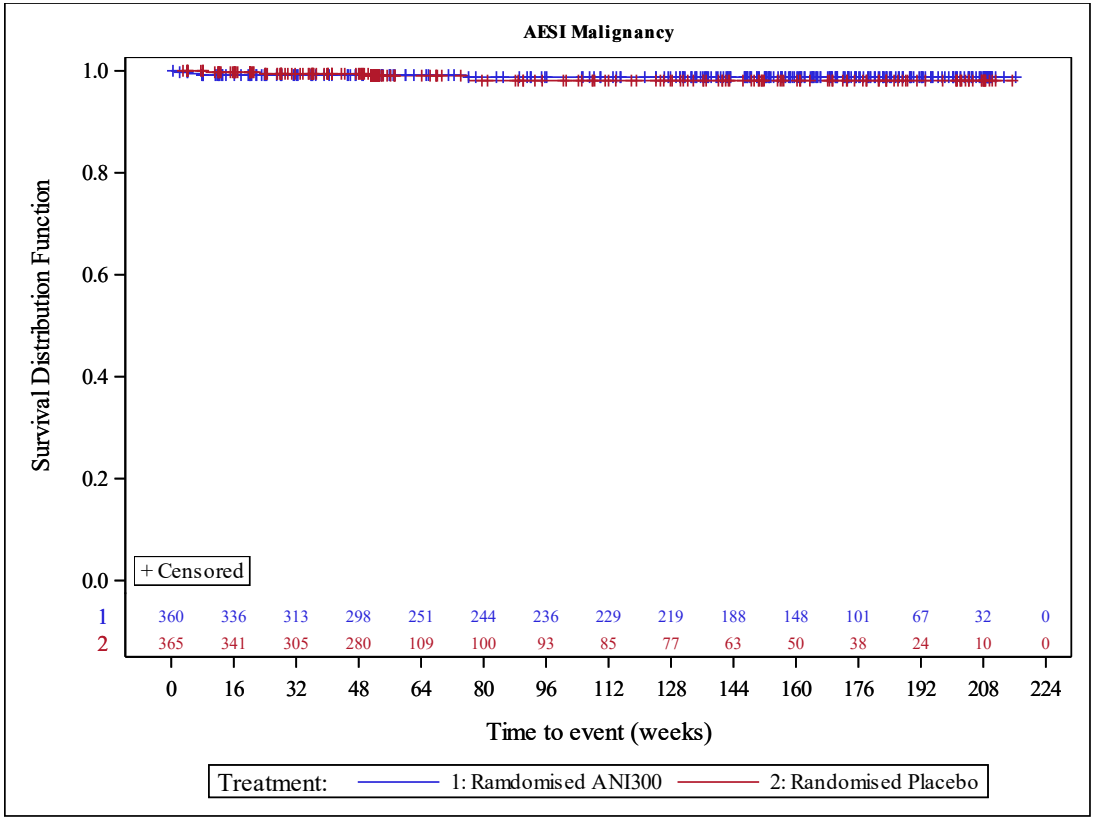
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Ramdomised ANI300 (N=360) Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Randomised Placebo (N=365) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
Age (years)							1.0000
<= 65	4/348 (1.1)	NE (NE, NE)	4/361 (1.1)	NE (NE, NE)	0.82 (0.20, 3.37)	0.7860	
> 65	0/ 12 (0.0)	NE (NE, NE)	0/ 4 (0.0)	NE (NE, NE)	NE		
Sex							0.9999
male	0/ 27 (0.0)	NE (NE, NE)	0/ 25 (0.0)	NE (NE, NE)	NE		
female	4/333 (1.2)	NE (NE, NE)	4/340 (1.2)	NE (NE, NE)	0.81 (0.20, 3.31)	0.7659	
Geographic region							0.9844
EU	2/115 (1.7)	NE (NE, NE)	2/122 (1.6)	NE (NE, NE)	1.03 (0.14, 7.29)	0.9789	
non-EU	2/245 (0.8)	NE (NE, NE)	2/243 (0.8)	NE (NE, NE)	0.63 (0.08, 4.72)	0.6529	
SLEDAI-2K score at screening							0.9936
< 10 points	1/109 (0.9)	NE (NE, NE)	0/106 (0.0)	NE (NE, NE)	NE		
>= 10 points	3/251 (1.2)	NE (NE, NE)	4/259 (1.5)	NE (NE, NE)	0.59 (0.13, 2.69)	0.4878	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Malignancy
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Malignancy
Full analysis set

	Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
Number of subjects with events, n (%)	1 (0.3)	2 (0.5)
Number of censored subjects, n (%)	359 (99.7)	363 (99.5)
Exposure years	872.8	525.7
EAIR per 100 PY	0.1	0.4
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	0.36 (0.03, 4.24)	
p-value	0.4034	
Relative Risk (95% CI)	0.51 (0.05, 5.57)	
p-value	0.5784	
Odds Ratio (95% CI)	0.51 (0.05, 5.60)	
p-value	0.5783	
Risk Difference (95% CI)	-0.27 (-1.20, 0.66)	
p-value	0.5700	

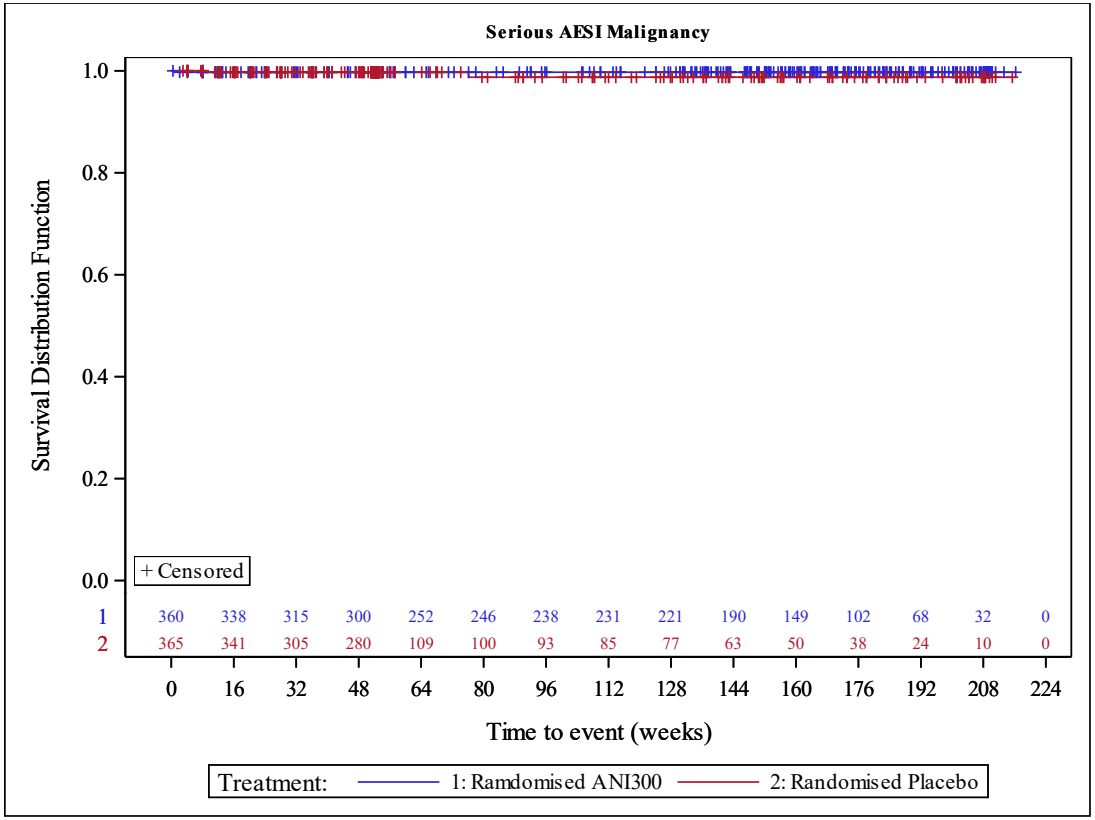
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Ramdomised ANI300 (N=360) Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Randomised Placebo (N=365) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
Age (years)							0.9999
<= 65	1/348 (0.3)	NE (NE, NE)	2/361 (0.6)	NE (NE, NE)	0.38 (0.03, 4.36)	0.4175	
> 65	0/ 12 (0.0)	NE (NE, NE)	0/ 4 (0.0)	NE (NE, NE)	NE		
Sex							0.9999
male	0/ 27 (0.0)	NE (NE, NE)	0/ 25 (0.0)	NE (NE, NE)	NE		
female	1/333 (0.3)	NE (NE, NE)	2/340 (0.6)	NE (NE, NE)	0.37 (0.03, 4.27)	0.4067	
Geographic region							0.9962
EU	1/115 (0.9)	NE (NE, NE)	1/122 (0.8)	NE (NE, NE)	1.05 (0.07, 16.76)	0.9734	
non-EU	0/245 (0.0)	NE (NE, NE)	1/243 (0.4)	NE (NE, NE)	NE		
SLEDAI-2K score at screening							0.9963
< 10 points	1/109 (0.9)	NE (NE, NE)	0/106 (0.0)	NE (NE, NE)	NE		
>= 10 points	0/251 (0.0)	NE (NE, NE)	2/259 (0.8)	NE (NE, NE)	NE		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Malignancy
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Malignancy
Full analysis set

	Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	360 (100.0)	365 (100.0)
Exposure years	872.8	525.8
EAIR per 100 PY	0.0	0.0
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	NE	
p-value		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

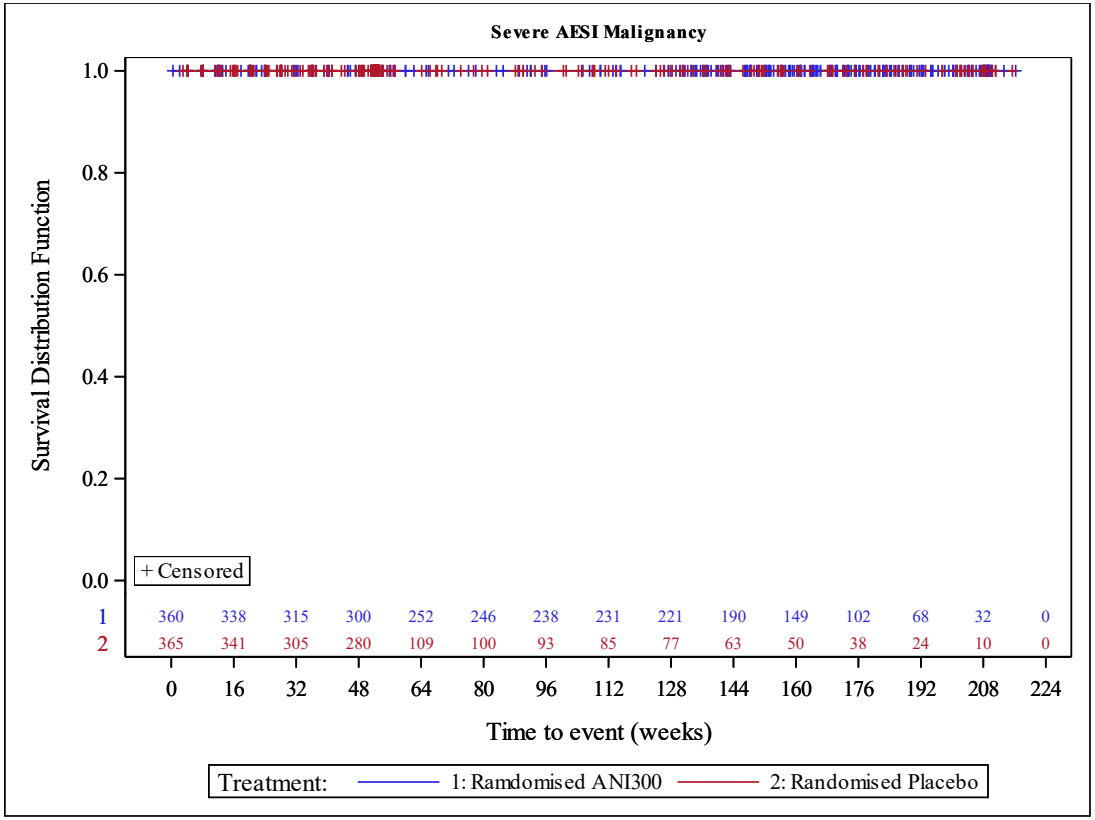
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Ramdomised ANI300 (N=360) Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Randomised Placebo (N=365) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
Age (years)							NE
<= 65	0/348 (0.0)	NE (NE, NE)	0/361 (0.0)	NE (NE, NE)	NE		
> 65	0/ 12 (0.0)	NE (NE, NE)	0/ 4 (0.0)	NE (NE, NE)	NE		
Sex							NE
male	0/ 27 (0.0)	NE (NE, NE)	0/ 25 (0.0)	NE (NE, NE)	NE		
female	0/333 (0.0)	NE (NE, NE)	0/340 (0.0)	NE (NE, NE)	NE		
Geographic region							NE
EU	0/115 (0.0)	NE (NE, NE)	0/122 (0.0)	NE (NE, NE)	NE		
non-EU	0/245 (0.0)	NE (NE, NE)	0/243 (0.0)	NE (NE, NE)	NE		
SLEDAI-2K score at screening							NE
< 10 points	0/109 (0.0)	NE (NE, NE)	0/106 (0.0)	NE (NE, NE)	NE		
>= 10 points	0/251 (0.0)	NE (NE, NE)	0/259 (0.0)	NE (NE, NE)	NE		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Malignancy
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Malignancy
Full analysis set

	Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
Number of subjects with events, n (%)	4 (1.1)	4 (1.1)
Number of censored subjects, n (%)	356 (98.9)	361 (98.9)
Exposure years	866.8	525.7
EAIR per 100 PY	0.5	0.8
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	0.80 (0.20, 3.29)	
p-value	0.7589	
Relative Risk (95% CI)	1.01 (0.26, 4.02)	
p-value	0.9844	
Odds Ratio (95% CI)	1.01 (0.25, 4.09)	
p-value	0.9844	
Risk Difference (95% CI)	0.02 (-1.51, 1.54)	
p-value	0.9844	

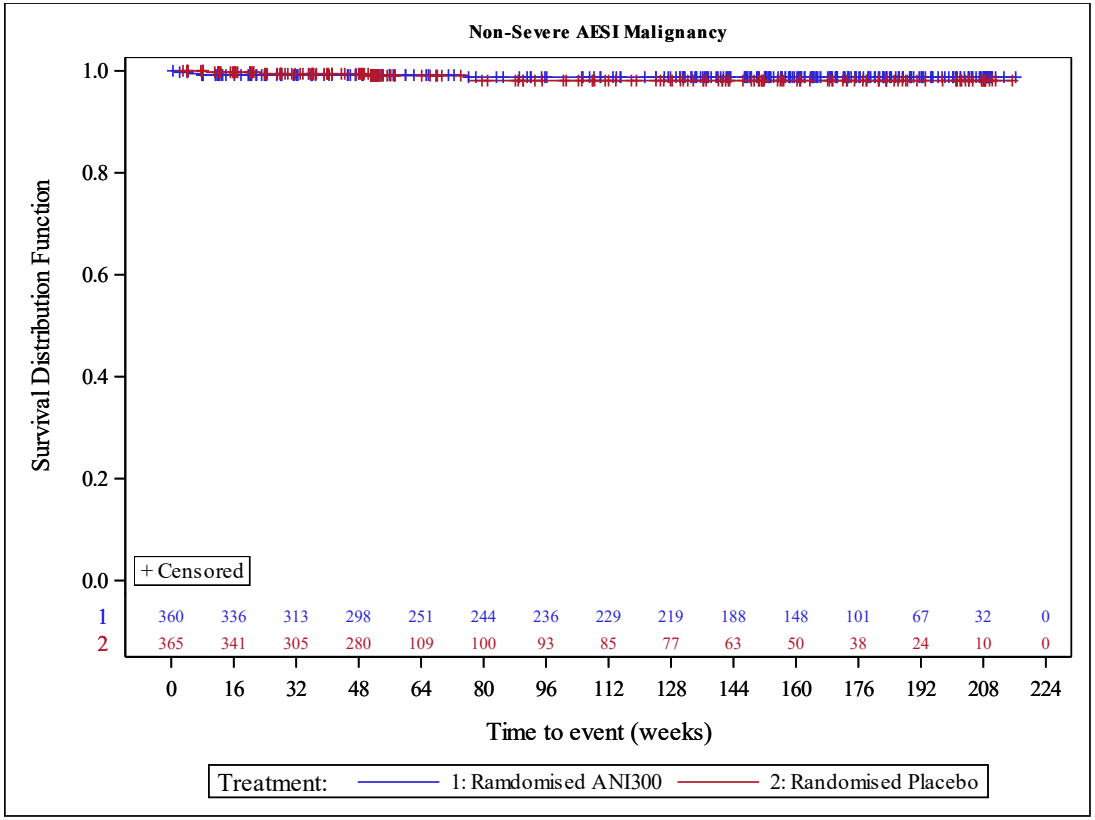
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Malignancy - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Ramdomised ANI300 (N=360) Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Randomised Placebo (N=365) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
Age (years)							1.0000
<= 65	4/348 (1.1)	NE (NE, NE)	4/361 (1.1)	NE (NE, NE)	0.82 (0.20, 3.37)	0.7860	
> 65	0/ 12 (0.0)	NE (NE, NE)	0/ 4 (0.0)	NE (NE, NE)	NE		
Sex							0.9999
male	0/ 27 (0.0)	NE (NE, NE)	0/ 25 (0.0)	NE (NE, NE)	NE		
female	4/333 (1.2)	NE (NE, NE)	4/340 (1.2)	NE (NE, NE)	0.81 (0.20, 3.31)	0.7659	
Geographic region							0.9844
EU	2/115 (1.7)	NE (NE, NE)	2/122 (1.6)	NE (NE, NE)	1.03 (0.14, 7.29)	0.9789	
non-EU	2/245 (0.8)	NE (NE, NE)	2/243 (0.8)	NE (NE, NE)	0.63 (0.08, 4.72)	0.6529	
SLEDAI-2K score at screening							0.9936
< 10 points	1/109 (0.9)	NE (NE, NE)	0/106 (0.0)	NE (NE, NE)	NE		
>= 10 points	3/251 (1.2)	NE (NE, NE)	4/259 (1.5)	NE (NE, NE)	0.59 (0.13, 2.69)	0.4878	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Malignancy
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Influenza
Full analysis set

	Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
Number of subjects with events, n (%)	20 (5.6)	11 (3.0)
Number of censored subjects, n (%)	340 (94.4)	354 (97.0)
Exposure years	846.8	517.7
EAIR per 100 PY	2.4	2.1
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (201.1, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	1.08 (0.51, 2.30)	
p-value	0.8411	
Relative Risk (95% CI)	1.84 (0.90, 3.79)	
p-value	0.0965	
Odds Ratio (95% CI)	1.89 (0.89, 4.01)	
p-value	0.0956	
Risk Difference (95% CI)	2.54 (-0.40, 5.49)	
p-value	0.0907	

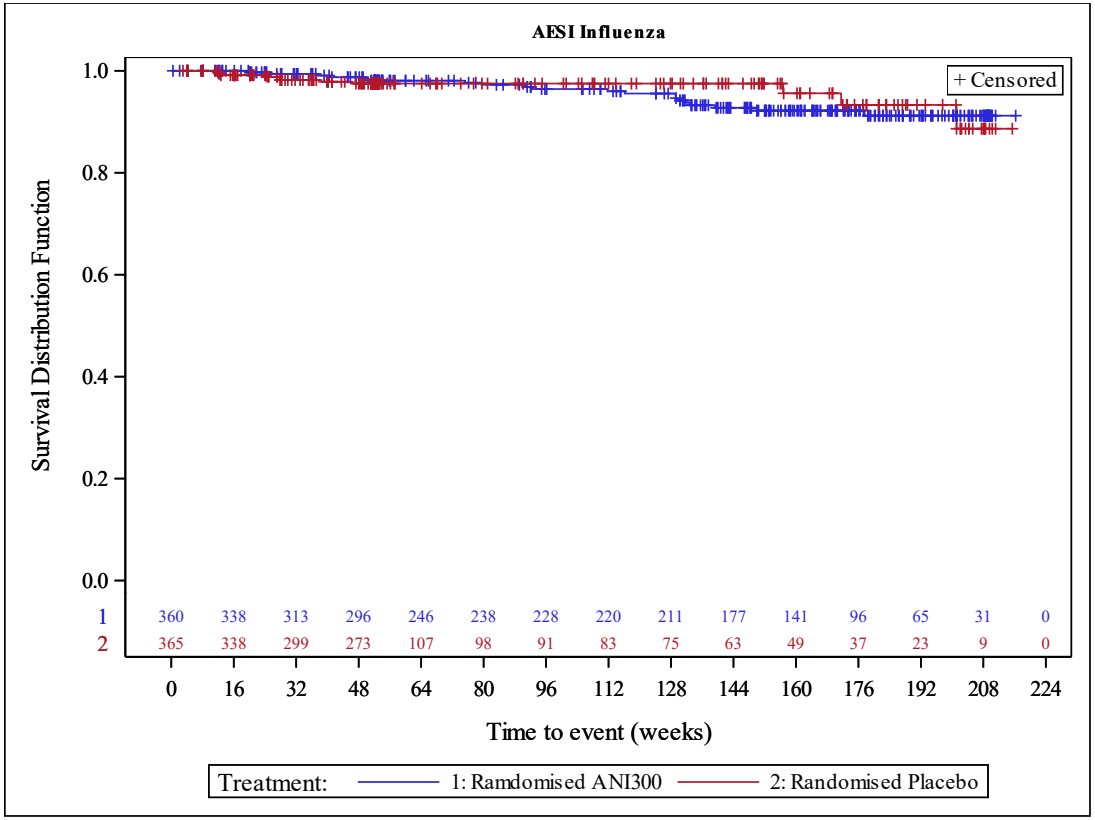
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%) Median (95% CI)	Randomised Placebo (N=365) n/ N (%) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	 p-Value	Interaction p-Value
Age (years)					0.9891
<= 65	19/348 (5.5) NE (NE, NE)	11/361 (3.0) NE (NE, NE)	1.07 (0.50, 2.30)	0.8557	
> 65	1/ 12 (8.3) NE (177.57, NE)	0/ 4 (0.0) NE (NE, NE)	NE		
Sex					0.6862
male	1/ 27 (3.7) NE (NE, NE)	1/ 25 (4.0) NE (NE, NE)	0.66 (0.04, 10.94)	0.7689	
female	19/333 (5.7) NE (NE, NE)	10/340 (2.9) NE (NE, NE)	1.12 (0.51, 2.45)	0.7819	
Geographic region					0.9408
EU	4/115 (3.5) NE (NE, NE)	2/122 (1.6) NE (NE, NE)	1.44 (0.26, 8.18)	0.6758	
non-EU	16/245 (6.5) NE (NE, NE)	9/243 (3.7) NE (NE, NE)	1.02 (0.44, 2.35)	0.9638	
SLEDAI-2K score at screening					0.5042
< 10 points	6/109 (5.5) NE (NE, NE)	2/106 (1.9) NE (NE, NE)	2.11 (0.41, 10.77)	0.3577	
>= 10 points	14/251 (5.6) NE (NE, NE)	9/259 (3.5) NE (NE, NE)	0.88 (0.37, 2.09)	0.7789	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Influenza
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Influenza
Full analysis set

	Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
Number of subjects with events, n (%)	2 (0.6)	1 (0.3)
Number of censored subjects, n (%)	358 (99.4)	364 (99.7)
Exposure years	870.9	525.1
EAIR per 100 PY	0.2	0.2
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	1.04 (0.09, 12.36)	
p-value	0.9726	
Relative Risk (95% CI)	2.03 (0.18, 22.26)	
p-value	0.5631	
Odds Ratio (95% CI)	2.03 (0.18, 22.53)	
p-value	0.5630	
Risk Difference (95% CI)	0.28 (-0.65, 1.22)	
p-value	0.5557	

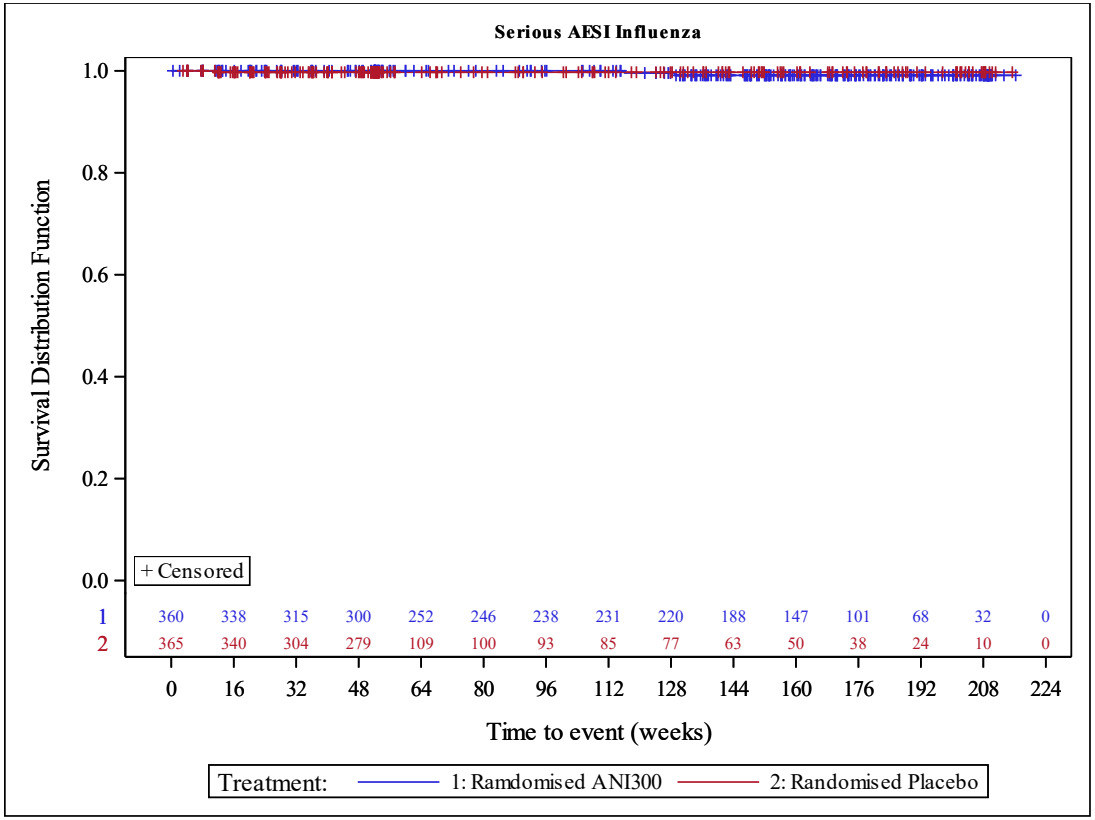
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Ramdomised ANI300 (N=360) Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Randomised Placebo (N=365) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
Age (years)							1.0000
<= 65	2/348 (0.6)	NE (NE, NE)	1/361 (0.3)	NE (NE, NE)	1.08 (0.09, 12.76)	0.9510	
> 65	0/ 12 (0.0)	NE (NE, NE)	0/ 4 (0.0)	NE (NE, NE)	NE		
Sex							1.0000
male	0/ 27 (0.0)	NE (NE, NE)	0/ 25 (0.0)	NE (NE, NE)	NE		
female	2/333 (0.6)	NE (NE, NE)	1/340 (0.3)	NE (NE, NE)	1.03 (0.09, 12.30)	0.9786	
Geographic region							1.0000
EU	0/115 (0.0)	NE (NE, NE)	0/122 (0.0)	NE (NE, NE)	NE		
non-EU	2/245 (0.8)	NE (NE, NE)	1/243 (0.4)	NE (NE, NE)	1.02 (0.09, 12.16)	0.9850	
SLEDAI-2K score at screening							0.9963
< 10 points	1/109 (0.9)	NE (NE, NE)	0/106 (0.0)	NE (NE, NE)	NE		
>= 10 points	1/251 (0.4)	NE (NE, NE)	1/259 (0.4)	NE (NE, NE)	0.62 (0.04, 10.79)	0.7386	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Influenza
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Influenza
Full analysis set

	Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
Number of subjects with events, n (%)	2 (0.6)	1 (0.3)
Number of censored subjects, n (%)	358 (99.4)	364 (99.7)
Exposure years	870.7	525.1
EAIR per 100 PY	0.2	0.2
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	1.07 (0.09, 12.58)	
p-value	0.9588	
Relative Risk (95% CI)	2.03 (0.18, 22.26)	
p-value	0.5631	
Odds Ratio (95% CI)	2.03 (0.18, 22.53)	
p-value	0.5630	
Risk Difference (95% CI)	0.28 (-0.65, 1.22)	
p-value	0.5557	

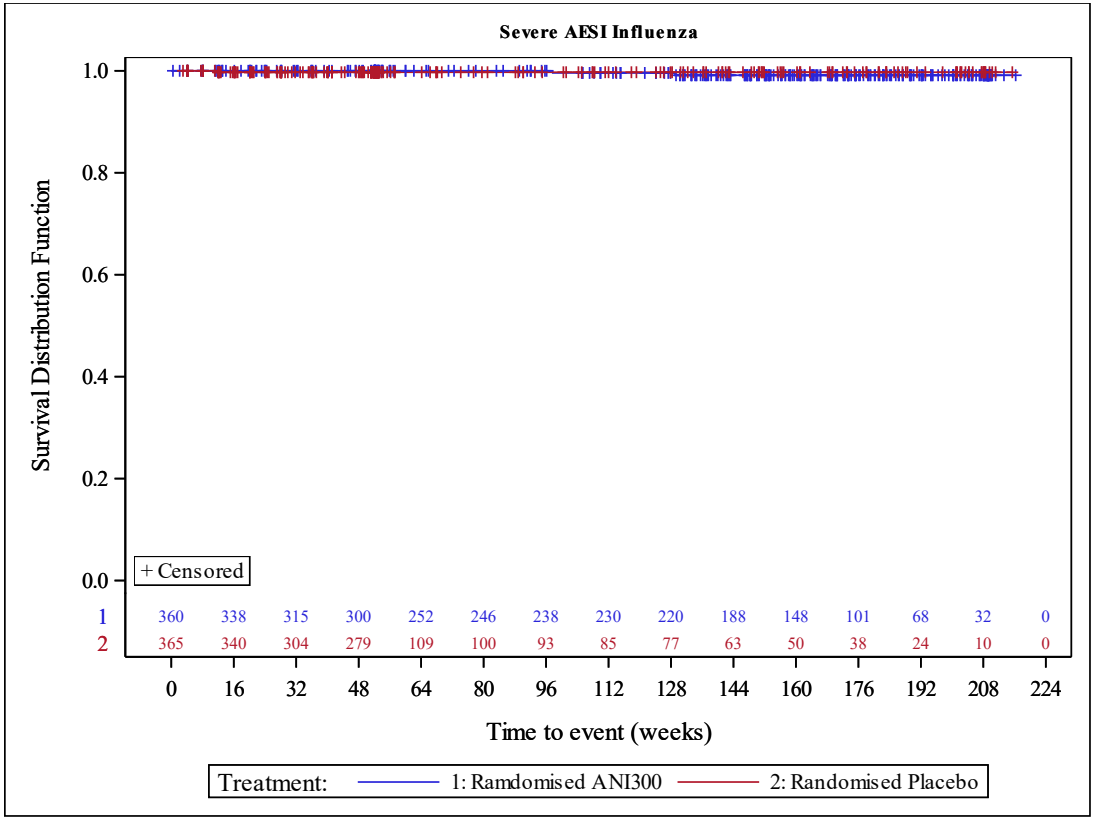
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Ramdomised ANI300 (N=360) Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Randomised Placebo (N=365) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
Age (years)							1.0000
<= 65	2/348 (0.6)	NE (NE, NE)	1/361 (0.3)	NE (NE, NE)	1.10 (0.09, 12.98)	0.9374	
> 65	0/ 12 (0.0)	NE (NE, NE)	0/ 4 (0.0)	NE (NE, NE)	NE		
Sex							1.0000
male	0/ 27 (0.0)	NE (NE, NE)	0/ 25 (0.0)	NE (NE, NE)	NE		
female	2/333 (0.6)	NE (NE, NE)	1/340 (0.3)	NE (NE, NE)	1.06 (0.09, 12.55)	0.9623	
Geographic region							1.0000
EU	0/115 (0.0)	NE (NE, NE)	0/122 (0.0)	NE (NE, NE)	NE		
non-EU	2/245 (0.8)	NE (NE, NE)	1/243 (0.4)	NE (NE, NE)	1.05 (0.09, 12.38)	0.9699	
SLEDAI-2K score at screening							0.9961
< 10 points	2/109 (1.8)	NE (NE, NE)	0/106 (0.0)	NE (NE, NE)	NE		
>= 10 points	0/251 (0.0)	NE (NE, NE)	1/259 (0.4)	NE (NE, NE)	NE		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Influenza
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Influenza
Full analysis set

	Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
Number of subjects with events, n (%)	19 (5.3)	11 (3.0)
Number of censored subjects, n (%)	341 (94.7)	354 (97.0)
Exposure years	847.8	517.7
EAIR per 100 PY	2.2	2.1
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (201.1, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	1.04 (0.48, 2.23)	
p-value	0.9214	
Relative Risk (95% CI)	1.75 (0.85, 3.63)	
p-value	0.1315	
Odds Ratio (95% CI)	1.79 (0.84, 3.82)	
p-value	0.1307	
Risk Difference (95% CI)	2.26 (-0.64, 5.16)	
p-value	0.1260	

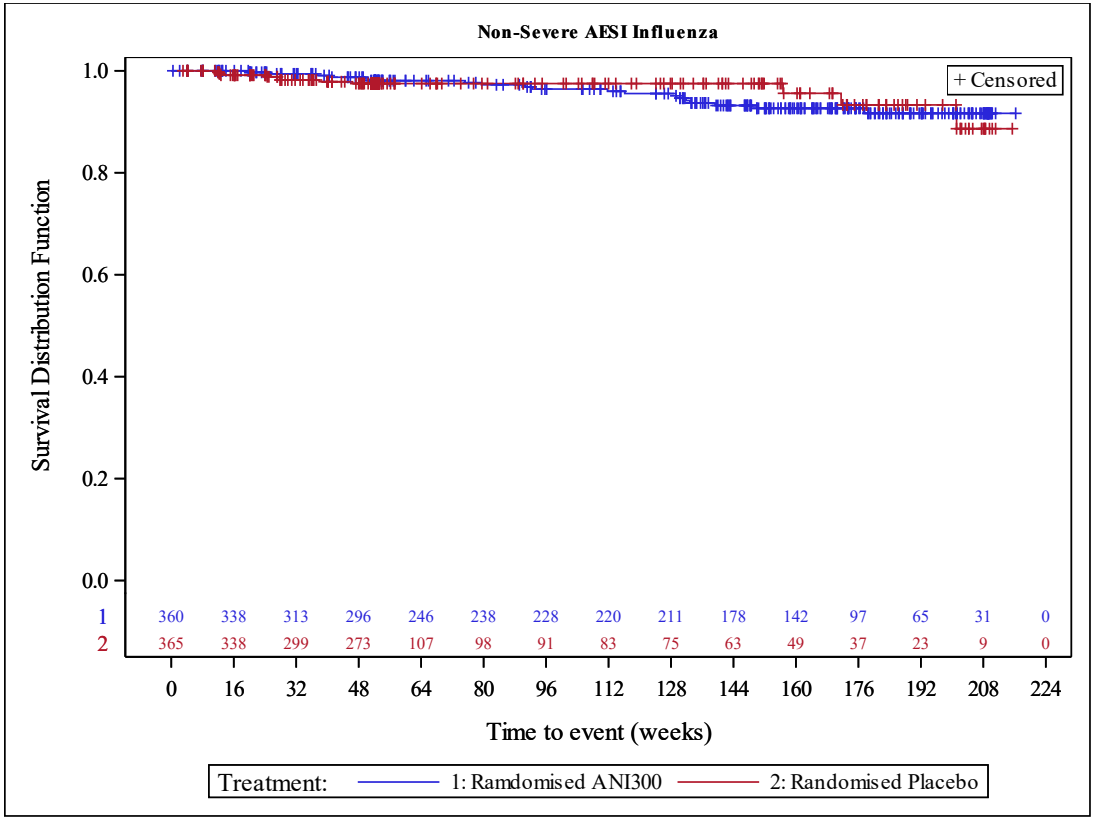
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Influenza - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%) Median (95% CI)	Randomised Placebo (N=365) n/ N (%) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI) p-Value	Interaction p-Value
Age (years)				0.9890
<= 65	18/348 (5.2) NE (NE, NE)	11/361 (3.0) NE (NE, NE)	1.03 (0.48, 2.22) 0.9394	
> 65	1/ 12 (8.3) NE (177.57, NE)	0/ 4 (0.0) NE (NE, NE)	NE	
Sex				0.7125
male	1/ 27 (3.7) NE (NE, NE)	1/ 25 (4.0) NE (NE, NE)	0.66 (0.04, 10.94) 0.7689	
female	18/333 (5.4) NE (NE, NE)	10/340 (2.9) NE (NE, NE)	1.07 (0.49, 2.37) 0.8616	
Geographic region				0.8855
EU	4/115 (3.5) NE (NE, NE)	2/122 (1.6) NE (NE, NE)	1.44 (0.26, 8.18) 0.6758	
non-EU	15/245 (6.1) NE (NE, NE)	9/243 (3.7) NE (NE, NE)	0.97 (0.42, 2.26) 0.9405	
SLEDAI-2K score at screening				0.6521
< 10 points	5/109 (4.6) NE (NE, NE)	2/106 (1.9) NE (NE, NE)	1.90 (0.36, 10.05) 0.4425	
>= 10 points	14/251 (5.6) NE (NE, NE)	9/259 (3.5) NE (NE, NE)	0.88 (0.37, 2.09) 0.7789	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Influenza
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - MACE
Full analysis set

	Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
Number of subjects with events, n (%)	1 (0.3)	0 (0.0)
Number of censored subjects, n (%)	359 (99.7)	365 (100.0)
Exposure years	870.4	525.8
EAIR per 100 PY	0.1	0.0
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	NE	
p-value		
Relative Risk (95% CI)	3.04 (0.12, 74.42)	
p-value	0.4953	
Odds Ratio (95% CI)	3.05 (0.12, 75.12)	
p-value	0.4951	
Risk Difference (95% CI)	0.28 (-0.27, 0.82)	
p-value	0.3166	

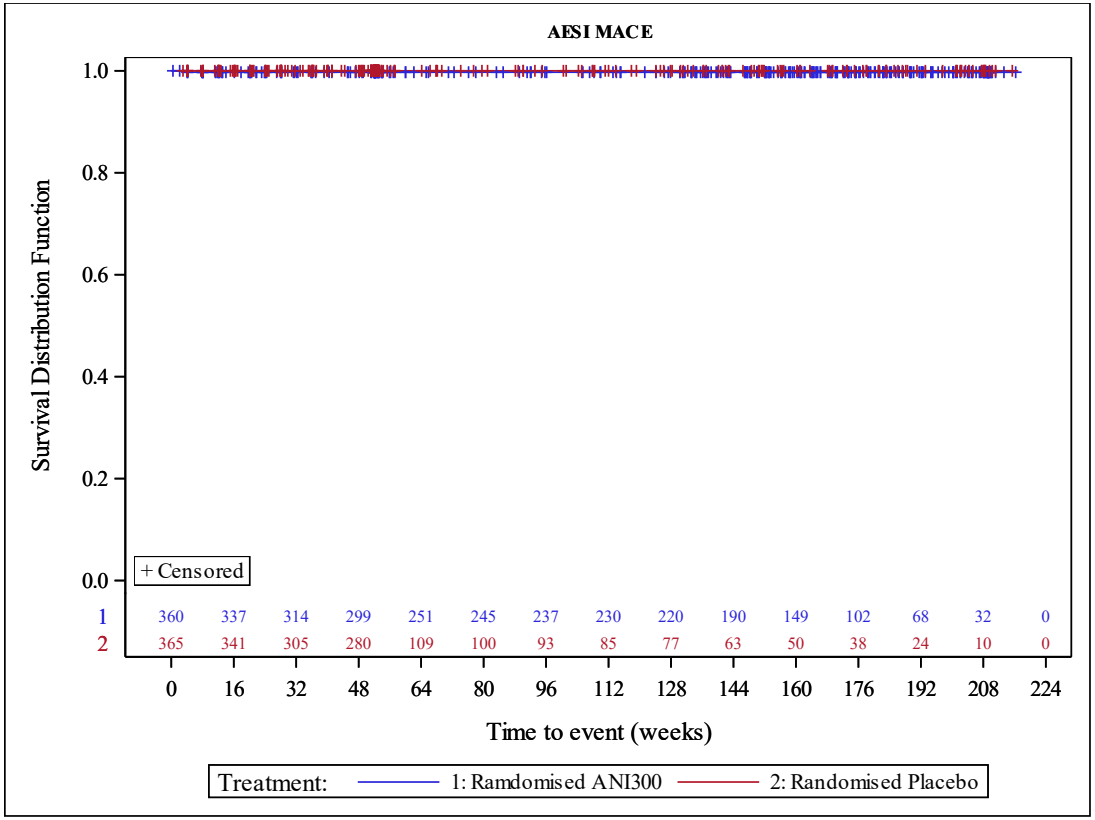
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - MACE - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Ramdomised ANI300 (N=360) Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Randomised Placebo (N=365) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
Age (years)							0.9998
<= 65	1/348 (0.3)	NE (NE, NE)	0/361 (0.0)	NE (NE, NE)	NE		
> 65	0/ 12 (0.0)	NE (NE, NE)	0/ 4 (0.0)	NE (NE, NE)	NE		
Sex							0.9995
male	0/ 27 (0.0)	NE (NE, NE)	0/ 25 (0.0)	NE (NE, NE)	NE		
female	1/333 (0.3)	NE (NE, NE)	0/340 (0.0)	NE (NE, NE)	NE		
Geographic region							0.9993
EU	1/115 (0.9)	NE (NE, NE)	0/122 (0.0)	NE (NE, NE)	NE		
non-EU	0/245 (0.0)	NE (NE, NE)	0/243 (0.0)	NE (NE, NE)	NE		
SLEDAI-2K score at screening							0.9993
< 10 points	0/109 (0.0)	NE (NE, NE)	0/106 (0.0)	NE (NE, NE)	NE		
>= 10 points	1/251 (0.4)	NE (NE, NE)	0/259 (0.0)	NE (NE, NE)	NE		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - MACE
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious MACE
Full analysis set

	Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
Number of subjects with events, n (%)	1 (0.3)	0 (0.0)
Number of censored subjects, n (%)	359 (99.7)	365 (100.0)
Exposure years	870.4	525.8
EAIR per 100 PY	0.1	0.0
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	NE	
p-value		
Relative Risk (95% CI)	3.04 (0.12, 74.42)	
p-value	0.4953	
Odds Ratio (95% CI)	3.05 (0.12, 75.12)	
p-value	0.4951	
Risk Difference (95% CI)	0.28 (-0.27, 0.82)	
p-value	0.3166	

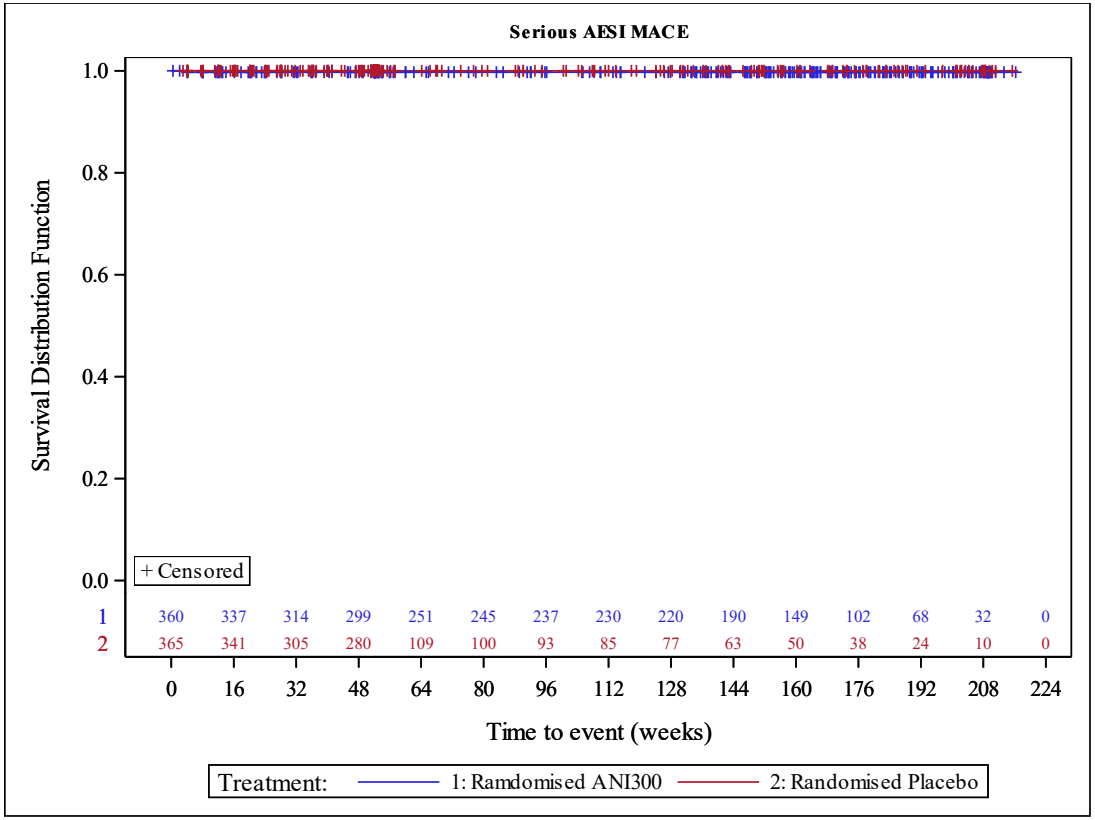
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious MACE - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Ramdomised ANI300 (N=360) Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Randomised Placebo (N=365) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
Age (years)							0.9998
<= 65	1/348 (0.3)	NE (NE, NE)	0/361 (0.0)	NE (NE, NE)	NE		
> 65	0/ 12 (0.0)	NE (NE, NE)	0/ 4 (0.0)	NE (NE, NE)	NE		
Sex							0.9995
male	0/ 27 (0.0)	NE (NE, NE)	0/ 25 (0.0)	NE (NE, NE)	NE		
female	1/333 (0.3)	NE (NE, NE)	0/340 (0.0)	NE (NE, NE)	NE		
Geographic region							0.9993
EU	1/115 (0.9)	NE (NE, NE)	0/122 (0.0)	NE (NE, NE)	NE		
non-EU	0/245 (0.0)	NE (NE, NE)	0/243 (0.0)	NE (NE, NE)	NE		
SLEDAI-2K score at screening							0.9993
< 10 points	0/109 (0.0)	NE (NE, NE)	0/106 (0.0)	NE (NE, NE)	NE		
>= 10 points	1/251 (0.4)	NE (NE, NE)	0/259 (0.0)	NE (NE, NE)	NE		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious MACE
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe MACE
Full analysis set

	Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
Number of subjects with events, n (%)	1 (0.3)	0 (0.0)
Number of censored subjects, n (%)	359 (99.7)	365 (100.0)
Exposure years	870.4	525.8
EAIR per 100 PY	0.1	0.0
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	NE	
p-value		
Relative Risk (95% CI)	3.04 (0.12, 74.42)	
p-value	0.4953	
Odds Ratio (95% CI)	3.05 (0.12, 75.12)	
p-value	0.4951	
Risk Difference (95% CI)	0.28 (-0.27, 0.82)	
p-value	0.3166	

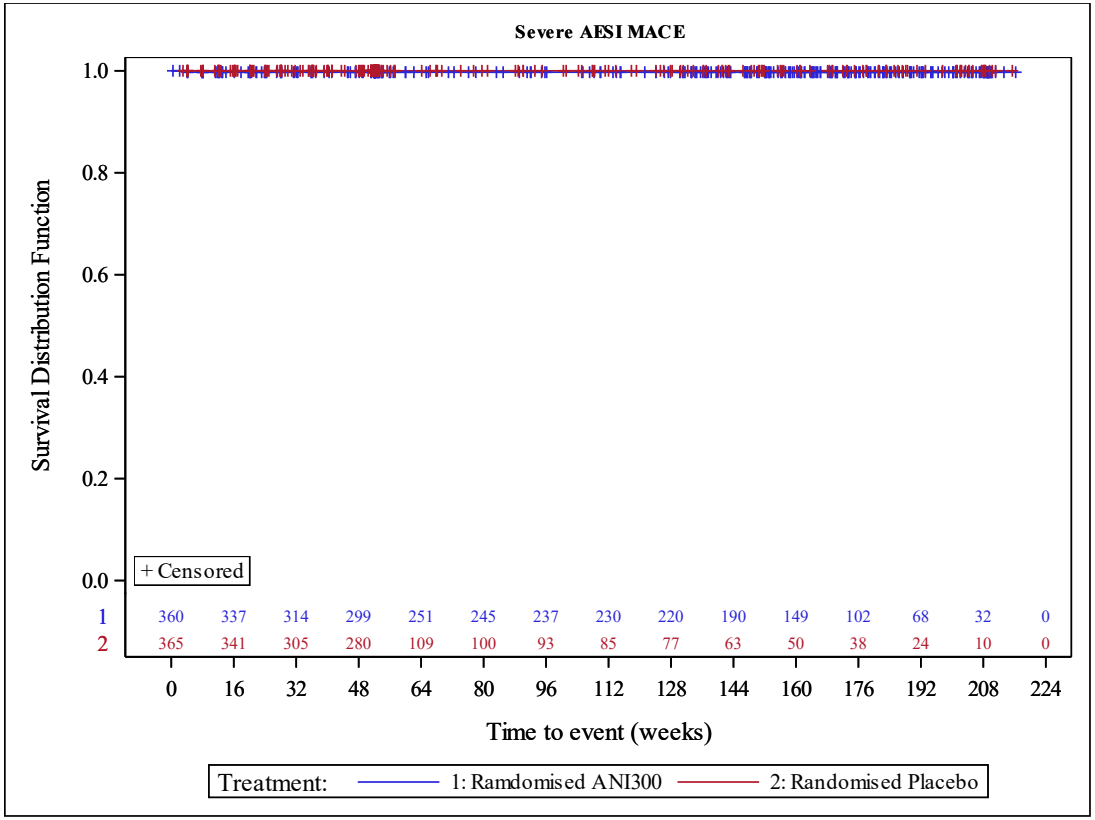
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe MACE - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Ramdomised ANI300 (N=360) Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Randomised Placebo (N=365) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
Age (years)							0.9998
<= 65	1/348 (0.3)	NE (NE, NE)	0/361 (0.0)	NE (NE, NE)	NE		
> 65	0/ 12 (0.0)	NE (NE, NE)	0/ 4 (0.0)	NE (NE, NE)	NE		
Sex							0.9995
male	0/ 27 (0.0)	NE (NE, NE)	0/ 25 (0.0)	NE (NE, NE)	NE		
female	1/333 (0.3)	NE (NE, NE)	0/340 (0.0)	NE (NE, NE)	NE		
Geographic region							0.9993
EU	1/115 (0.9)	NE (NE, NE)	0/122 (0.0)	NE (NE, NE)	NE		
non-EU	0/245 (0.0)	NE (NE, NE)	0/243 (0.0)	NE (NE, NE)	NE		
SLEDAI-2K score at screening							0.9993
< 10 points	0/109 (0.0)	NE (NE, NE)	0/106 (0.0)	NE (NE, NE)	NE		
>= 10 points	1/251 (0.4)	NE (NE, NE)	0/259 (0.0)	NE (NE, NE)	NE		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe MACE
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe MACE
Full analysis set

	Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	360 (100.0)	365 (100.0)
Exposure years	872.8	525.8
EAIR per 100 PY	0.0	0.0
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	NE	
p-value		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

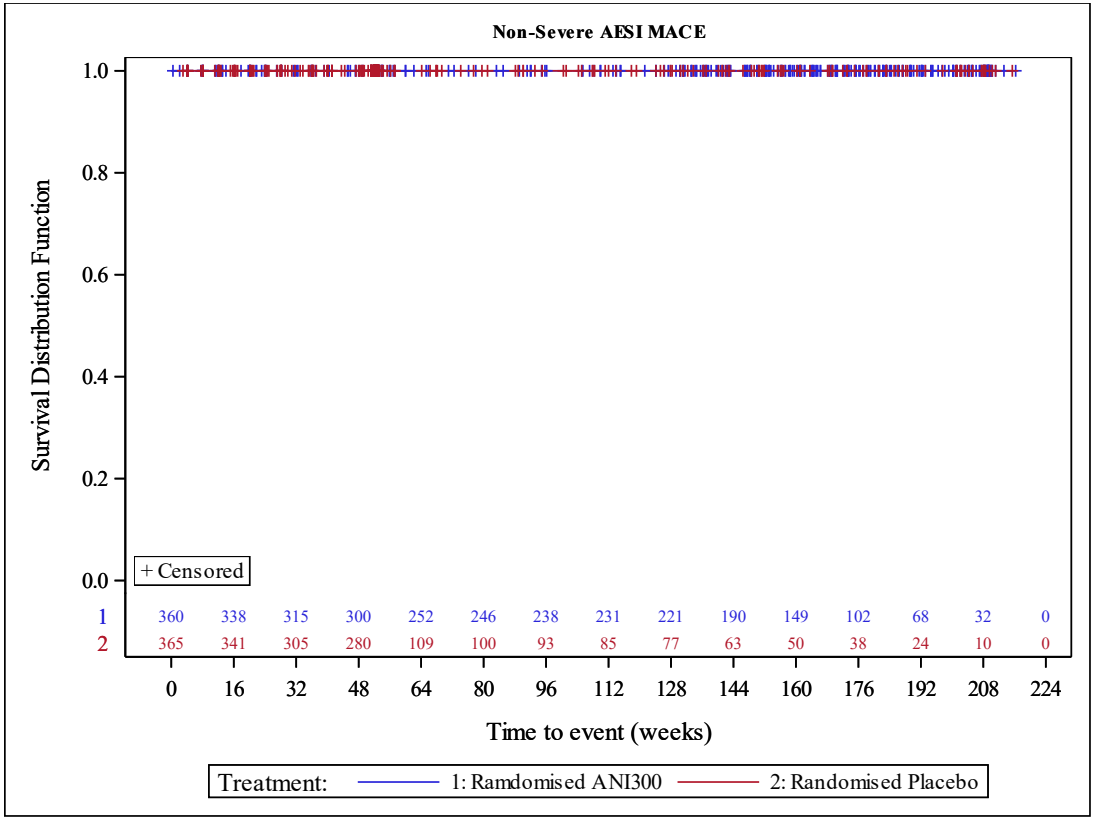
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe MACE - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Ramdomised ANI300 (N=360) Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Randomised Placebo (N=365) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
Age (years)							NE
<= 65	0/348 (0.0)	NE (NE, NE)	0/361 (0.0)	NE (NE, NE)	NE		
> 65	0/ 12 (0.0)	NE (NE, NE)	0/ 4 (0.0)	NE (NE, NE)	NE		
Sex							NE
male	0/ 27 (0.0)	NE (NE, NE)	0/ 25 (0.0)	NE (NE, NE)	NE		
female	0/333 (0.0)	NE (NE, NE)	0/340 (0.0)	NE (NE, NE)	NE		
Geographic region							NE
EU	0/115 (0.0)	NE (NE, NE)	0/122 (0.0)	NE (NE, NE)	NE		
non-EU	0/245 (0.0)	NE (NE, NE)	0/243 (0.0)	NE (NE, NE)	NE		
SLEDAI-2K score at screening							NE
< 10 points	0/109 (0.0)	NE (NE, NE)	0/106 (0.0)	NE (NE, NE)	NE		
>= 10 points	0/251 (0.0)	NE (NE, NE)	0/259 (0.0)	NE (NE, NE)	NE		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe MACE
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-opportunistic infection
Full analysis set

	Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
Number of subjects with events, n (%)	287 (79.7)	234 (64.1)
Number of censored subjects, n (%)	73 (20.3)	131 (35.9)
Exposure years	267.8	257.1
EAIR per 100 PY	107.2	91.0
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	7.29 (6.00, 9.00)	12.00 (8.86, 15.57)
Median (95% CI)	21.29 (17.86, 25.00)	31.86 (27.71, 39.43)
75%-ile (95% CI)	52.14 (44.00, 82.43)	102.0 (64.43, 150.7)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	1.33 (1.12, 1.59)	
p-value	0.0011	
Relative Risk (95% CI)	1.24 (1.13, 1.36)	
p-value	<.0001	
Odds Ratio (95% CI)	2.20 (1.58, 3.07)	
p-value	<.0001	
Risk Difference (95% CI)	15.61 (9.17, 22.05)	
p-value	<.0001	

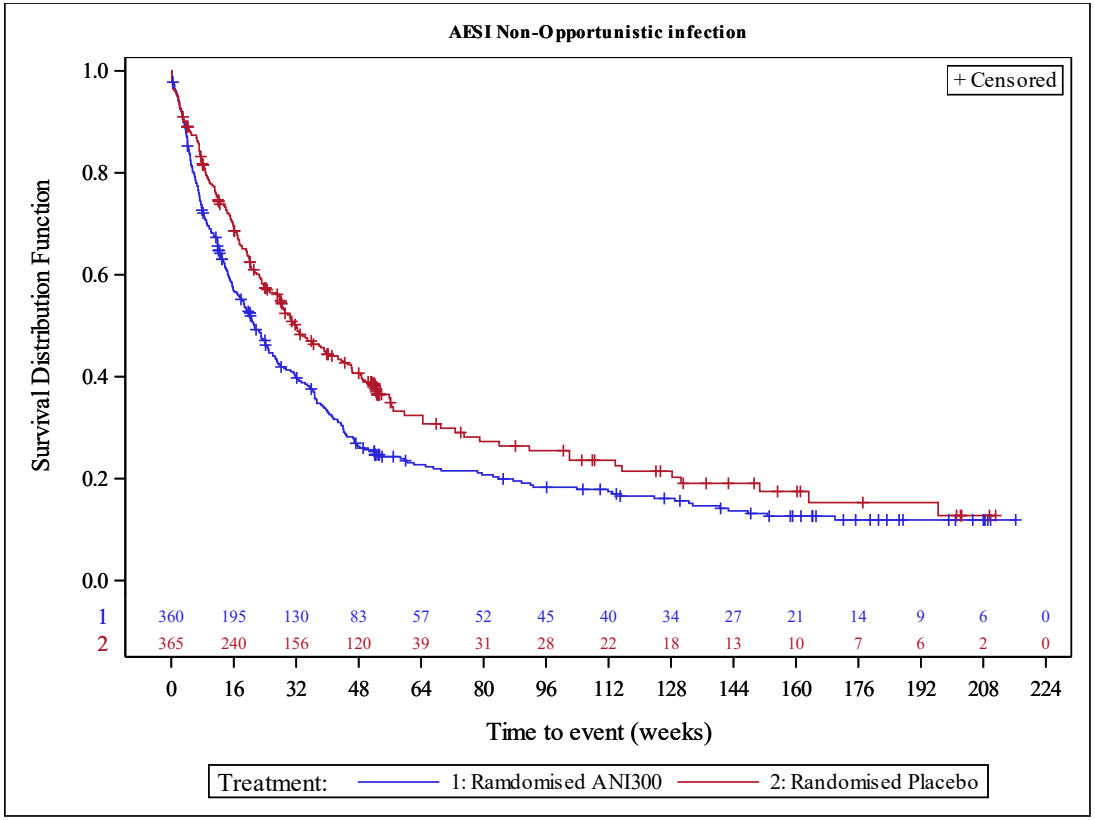
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Ramdomised ANI300 (N=360) Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Randomised Placebo (N=365) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
Age (years)							0.5329
<= 65	277/348 (79.6)	21.43 (17.86, 26.00)	232/361 (64.3)	31.86 (27.71, 39.43)	1.32 (1.11, 1.57)	0.0018	
> 65	10/ 12 (83.3)	18.07 (6.29, 29.43)	2/ 4 (50.0)	NE (6.43, NE)	2.46 (0.53, 11.39)	0.2381	
Sex							0.4022
male	18/ 27 (66.7)	39.14 (20.57, 92.00)	14/ 25 (56.0)	39.14 (16.14, NE)	1.02 (0.51, 2.06)	0.9451	
female	269/333 (80.8)	20.43 (15.71, 24.14)	220/340 (64.7)	31.86 (27.71, 39.86)	1.37 (1.14, 1.63)	0.0006	
Geographic region							0.8188
EU	87/115 (75.7)	27.71 (20.43, 37.29)	69/122 (56.6)	52.29 (34.86, 75.00)	1.35 (0.98, 1.86)	0.0618	
non-EU	200/245 (81.6)	19.00 (14.43, 23.14)	165/243 (67.9)	28.00 (20.57, 32.29)	1.32 (1.07, 1.63)	0.0083	
SLEDAI-2K score at screening							0.2901
< 10 points	88/109 (80.7)	20.71 (14.43, 27.71)	75/106 (70.8)	23.57 (20.00, 32.29)	1.18 (0.87, 1.61)	0.2893	
>= 10 points	199/251 (79.3)	22.57 (16.14, 27.00)	159/259 (61.4)	36.14 (28.57, 46.43)	1.41 (1.14, 1.74)	0.0013	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-opportunistic infection
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Non-opportunistic infection
Full analysis set

	Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
Number of subjects with events, n (%)	35 (9.7)	30 (8.2)
Number of censored subjects, n (%)	325 (90.3)	335 (91.8)
Exposure years	831.3	502.4
EAIR per 100 PY	4.2	6.0
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	0.77 (0.47, 1.27)	
p-value	0.3015	
Relative Risk (95% CI)	1.18 (0.74, 1.88)	
p-value	0.4794	
Odds Ratio (95% CI)	1.20 (0.72, 2.00)	
p-value	0.4792	
Risk Difference (95% CI)	1.50 (-2.66, 5.66)	
p-value	0.4788	

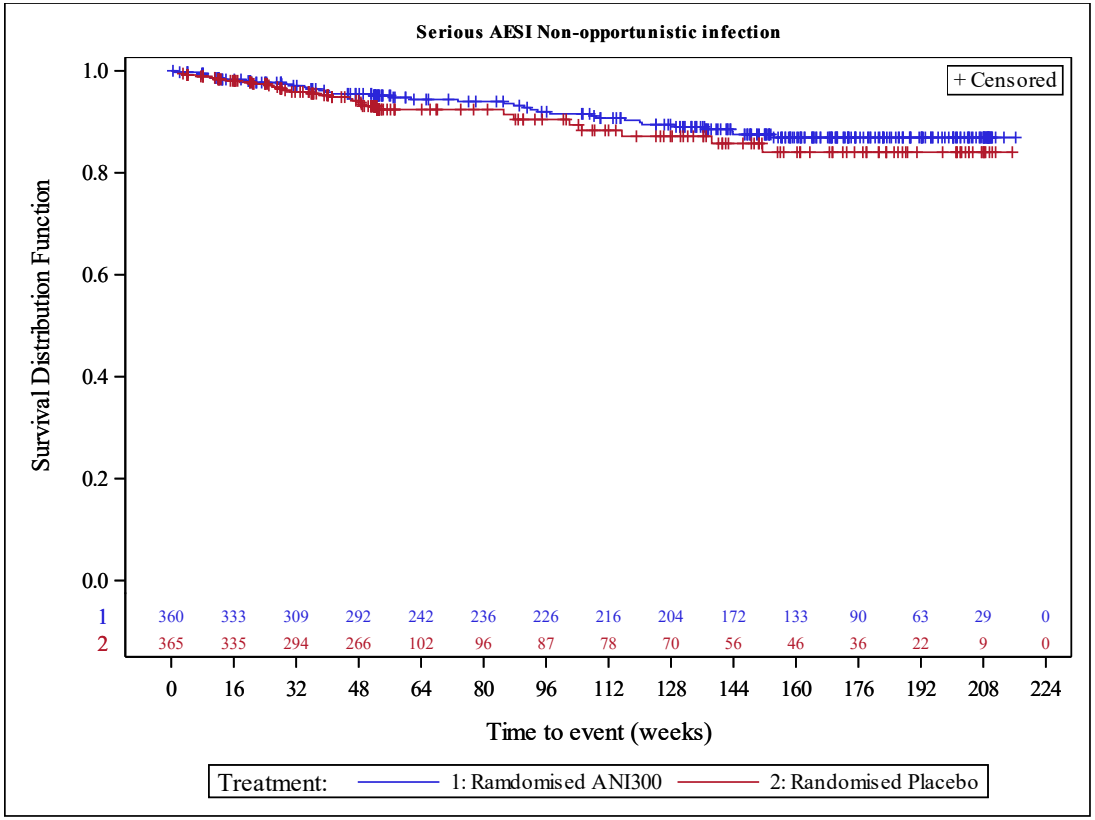
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Non-opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Ramdomised ANI300 (N=360) Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Randomised Placebo (N=365) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
Age (years)							0.9877
<= 65	33/348 (9.5)	NE (NE, NE)	30/361 (8.3)	NE (NE, NE)	0.74 (0.45, 1.24)	0.2523	
> 65	2/ 12 (16.7)	NE (39.14, NE)	0/ 4 (0.0)	NE (NE, NE)	NE		
Sex							0.4782
male	2/ 27 (7.4)	NE (NE, NE)	3/ 25 (12.0)	NE (115.43, NE)	0.44 (0.07, 2.72)	0.3649	
female	33/333 (9.9)	NE (NE, NE)	27/340 (7.9)	NE (NE, NE)	0.81 (0.48, 1.36)	0.4219	
Geographic region							0.1307
EU	7/115 (6.1)	NE (NE, NE)	11/122 (9.0)	NE (NE, NE)	0.32 (0.12, 0.84)	0.0151	
non-EU	28/245 (11.4)	NE (NE, NE)	19/243 (7.8)	NE (NE, NE)	1.07 (0.59, 1.93)	0.8340	
SLEDAI-2K score at screening							0.6772
< 10 points	10/109 (9.2)	NE (NE, NE)	7/106 (6.6)	NE (NE, NE)	0.81 (0.30, 2.19)	0.6775	
>= 10 points	25/251 (10.0)	NE (NE, NE)	23/259 (8.9)	NE (NE, NE)	0.75 (0.42, 1.35)	0.3403	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Non-opportunistic infection
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Non-opportunistic infection
Full analysis set

	Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
Number of subjects with events, n (%)	27 (7.5)	10 (2.7)
Number of censored subjects, n (%)	333 (92.5)	355 (97.3)
Exposure years	839.7	519.2
EAIR per 100 PY	3.2	1.9
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	1.83 (0.87, 3.82)	
p-value	0.1053	
Relative Risk (95% CI)	2.74 (1.34, 5.57)	
p-value	0.0055	
Odds Ratio (95% CI)	2.88 (1.37, 6.04)	
p-value	0.0052	
Risk Difference (95% CI)	4.76 (1.57, 7.96)	
p-value	0.0035	

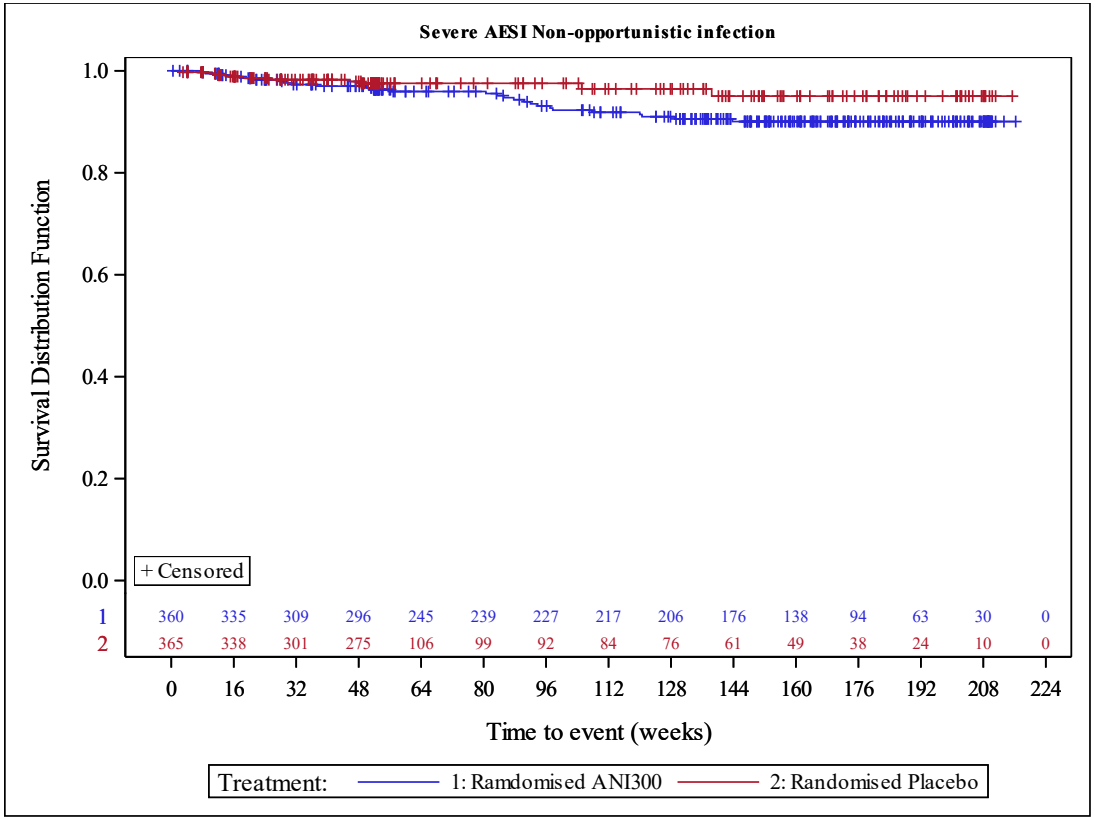
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Non-opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Ramdomised ANI300 (N=360) Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Randomised Placebo (N=365) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
Age (years)							0.9880
<= 65	26/348 (7.5)	NE (NE, NE)	10/361 (2.8)	NE (NE, NE)	1.83 (0.87, 3.85)	0.1053	
> 65	1/ 12 (8.3)	NE (107.71, NE)	0/ 4 (0.0)	NE (NE, NE)	NE		
Sex							0.9902
male	1/ 27 (3.7)	NE (NE, NE)	0/ 25 (0.0)	NE (NE, NE)	NE		
female	26/333 (7.8)	NE (NE, NE)	10/340 (2.9)	NE (NE, NE)	1.78 (0.85, 3.75)	0.1232	
Geographic region							0.6578
EU	6/115 (5.2)	NE (NE, NE)	3/122 (2.5)	NE (NE, NE)	1.27 (0.31, 5.23)	0.7427	
non-EU	21/245 (8.6)	NE (NE, NE)	7/243 (2.9)	NE (NE, NE)	2.04 (0.86, 4.88)	0.1009	
SLEDAI-2K score at screening							0.9324
< 10 points	8/109 (7.3)	NE (NE, NE)	3/106 (2.8)	NE (NE, NE)	1.60 (0.41, 6.21)	0.4941	
>= 10 points	19/251 (7.6)	NE (NE, NE)	7/259 (2.7)	NE (NE, NE)	1.93 (0.80, 4.65)	0.1377	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Non-opportunistic infection
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Non-opportunistic infection
Full analysis set

	Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
Number of subjects with events, n (%)	284 (78.9)	233 (63.8)
Number of censored subjects, n (%)	76 (21.1)	132 (36.2)
Exposure years	274.0	257.3
EAIR per 100 PY	103.7	90.6
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	7.29 (6.00, 9.00)	12.00 (8.86, 15.57)
Median (95% CI)	22.43 (18.57, 26.00)	31.86 (27.71, 39.43)
75%-ile (95% CI)	58.71 (44.43, 87.57)	102.0 (69.00, 150.7)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	1.31 (1.10, 1.56)	
p-value	0.0022	
Relative Risk (95% CI)	1.24 (1.13, 1.36)	
p-value	<.0001	
Odds Ratio (95% CI)	2.12 (1.52, 2.95)	
p-value	<.0001	
Risk Difference (95% CI)	15.05 (8.57, 21.54)	
p-value	<.0001	

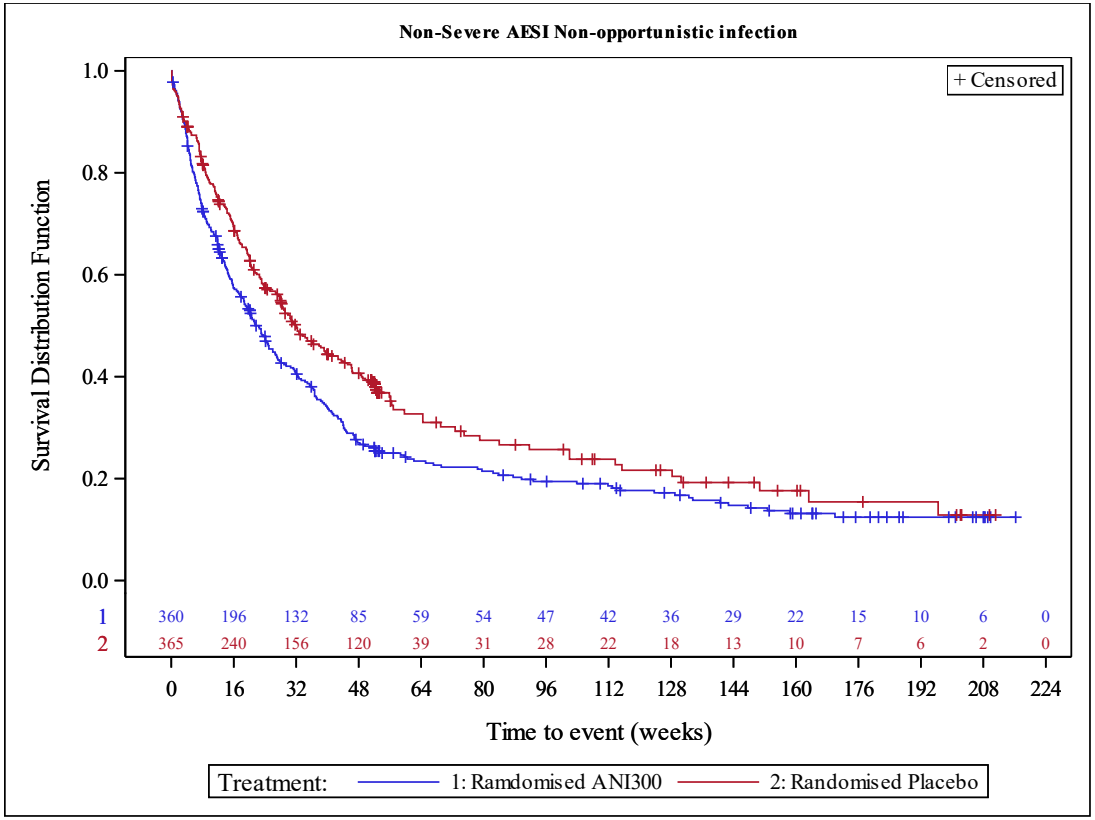
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Non-opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	 Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	 Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	 p-Value	Interaction p-Value
Age (years)							0.5202
<= 65	274/348 (78.7)	23.00 (18.57, 26.71)	231/361 (64.0)	31.86 (27.71, 39.43)	1.30 (1.09, 1.55)	0.0037	
> 65	10/ 12 (83.3)	18.07 (6.29, 29.43)	2/ 4 (50.0)	NE (6.43, NE)	2.46 (0.53, 11.39)	0.2381	
Sex							0.3478
male	17/ 27 (63.0)	39.14 (20.57, NE)	14/ 25 (56.0)	39.14 (16.14, NE)	0.98 (0.48, 1.99)	0.9593	
female	267/333 (80.2)	20.71 (15.86, 24.71)	219/340 (64.4)	31.86 (27.71, 39.86)	1.34 (1.12, 1.61)	0.0013	
Geographic region							0.9672
EU	85/115 (73.9)	28.86 (21.14, 44.71)	69/122 (56.6)	52.29 (34.86, 75.00)	1.28 (0.93, 1.77)	0.1238	
non-EU	199/245 (81.2)	19.00 (14.43, 23.14)	164/243 (67.5)	28.00 (20.57, 32.29)	1.32 (1.07, 1.63)	0.0085	
SLEDAI-2K score at screening							0.3127
< 10 points	87/109 (79.8)	20.71 (15.00, 28.86)	75/106 (70.8)	23.57 (20.14, 32.29)	1.17 (0.86, 1.59)	0.3237	
>= 10 points	197/251 (78.5)	23.00 (16.71, 28.14)	158/259 (61.0)	36.14 (28.57, 46.43)	1.38 (1.12, 1.70)	0.0026	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Non-opportunistic infection
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Opportunistic infection
Full analysis set

	Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
Number of subjects with events, n (%)	2 (0.6)	1 (0.3)
Number of censored subjects, n (%)	358 (99.4)	364 (99.7)
Exposure years	871.5	524.8
EAIR per 100 PY	0.2	0.2
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	1.04 (0.09, 12.07)	
p-value	0.9763	
Relative Risk (95% CI)	2.03 (0.18, 22.26)	
p-value	0.5631	
Odds Ratio (95% CI)	2.03 (0.18, 22.53)	
p-value	0.5630	
Risk Difference (95% CI)	0.28 (-0.65, 1.22)	
p-value	0.5557	

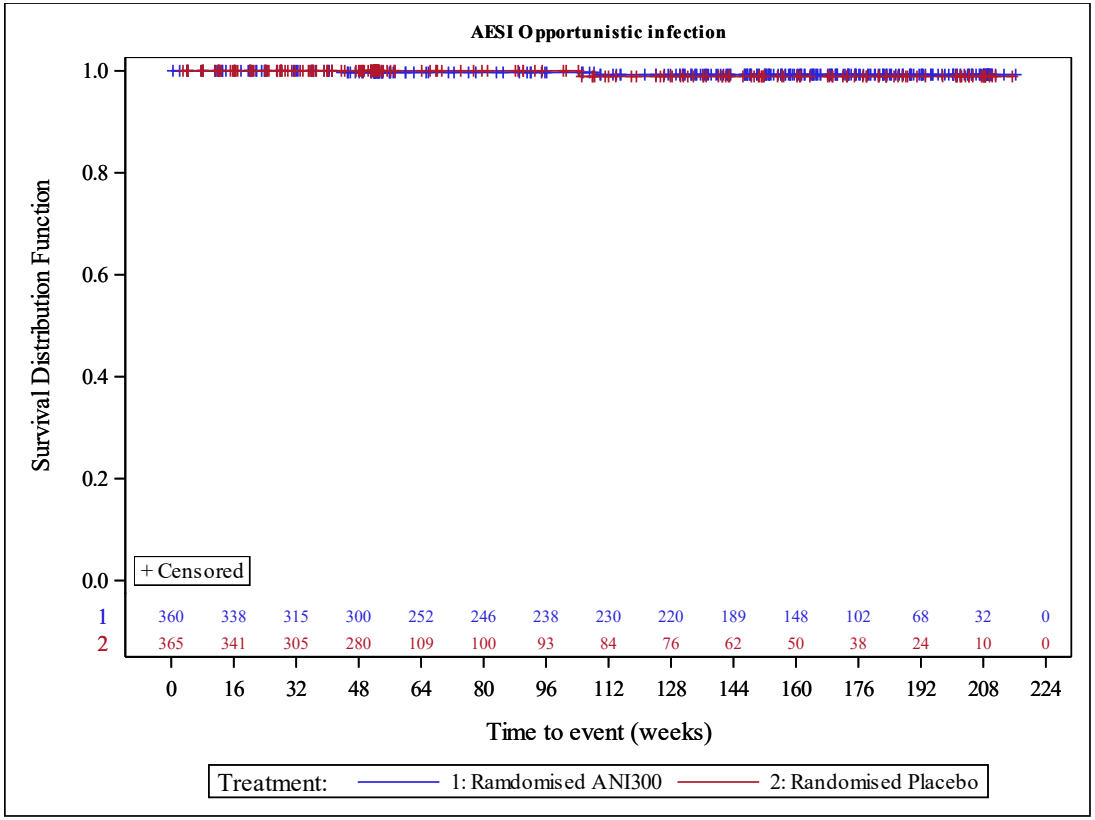
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Ramdomised ANI300 (N=360) Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Randomised Placebo (N=365) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
Age (years)							1.0000
<= 65	2/348 (0.6)	NE (NE, NE)	1/361 (0.3)	NE (NE, NE)	1.07 (0.09, 12.43)	0.9564	
> 65	0/ 12 (0.0)	NE (NE, NE)	0/ 4 (0.0)	NE (NE, NE)	NE		
Sex							1.0000
male	0/ 27 (0.0)	NE (NE, NE)	0/ 25 (0.0)	NE (NE, NE)	NE		
female	2/333 (0.6)	NE (NE, NE)	1/340 (0.3)	NE (NE, NE)	1.03 (0.09, 12.00)	0.9815	
Geographic region							0.9959
EU	1/115 (0.9)	NE (NE, NE)	0/122 (0.0)	NE (NE, NE)	NE		
non-EU	1/245 (0.4)	NE (NE, NE)	1/243 (0.4)	NE (NE, NE)	0.58 (0.03, 9.95)	0.7037	
SLEDAI-2K score at screening							0.9964
< 10 points	0/109 (0.0)	NE (NE, NE)	1/106 (0.9)	NE (NE, NE)	NE		
>= 10 points	2/251 (0.8)	NE (NE, NE)	0/259 (0.0)	NE (NE, NE)	NE		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Opportunistic infection
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Opportunistic infection
Full analysis set

	Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	360 (100.0)	365 (100.0)
Exposure years	872.8	525.8
EAIR per 100 PY	0.0	0.0
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	NE	
p-value		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

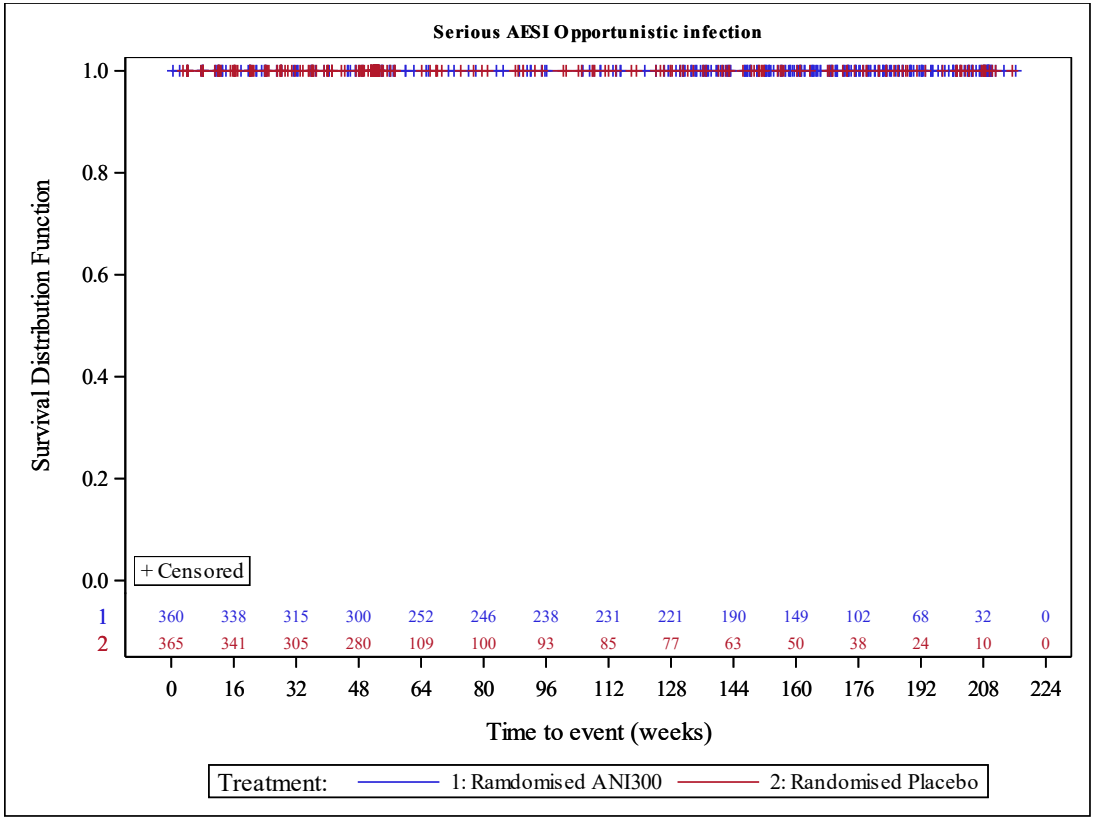
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Ramdomised ANI300 (N=360) Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Randomised Placebo (N=365) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
Age (years)							NE
<= 65	0/348 (0.0)	NE (NE, NE)	0/361 (0.0)	NE (NE, NE)	NE		
> 65	0/ 12 (0.0)	NE (NE, NE)	0/ 4 (0.0)	NE (NE, NE)	NE		
Sex							NE
male	0/ 27 (0.0)	NE (NE, NE)	0/ 25 (0.0)	NE (NE, NE)	NE		
female	0/333 (0.0)	NE (NE, NE)	0/340 (0.0)	NE (NE, NE)	NE		
Geographic region							NE
EU	0/115 (0.0)	NE (NE, NE)	0/122 (0.0)	NE (NE, NE)	NE		
non-EU	0/245 (0.0)	NE (NE, NE)	0/243 (0.0)	NE (NE, NE)	NE		
SLEDAI-2K score at screening							NE
< 10 points	0/109 (0.0)	NE (NE, NE)	0/106 (0.0)	NE (NE, NE)	NE		
>= 10 points	0/251 (0.0)	NE (NE, NE)	0/259 (0.0)	NE (NE, NE)	NE		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Opportunistic infection
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Opportunistic infection
Full analysis set

	Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	360 (100.0)	365 (100.0)
Exposure years	872.8	525.8
EAIR per 100 PY	0.0	0.0
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	NE	
p-value		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

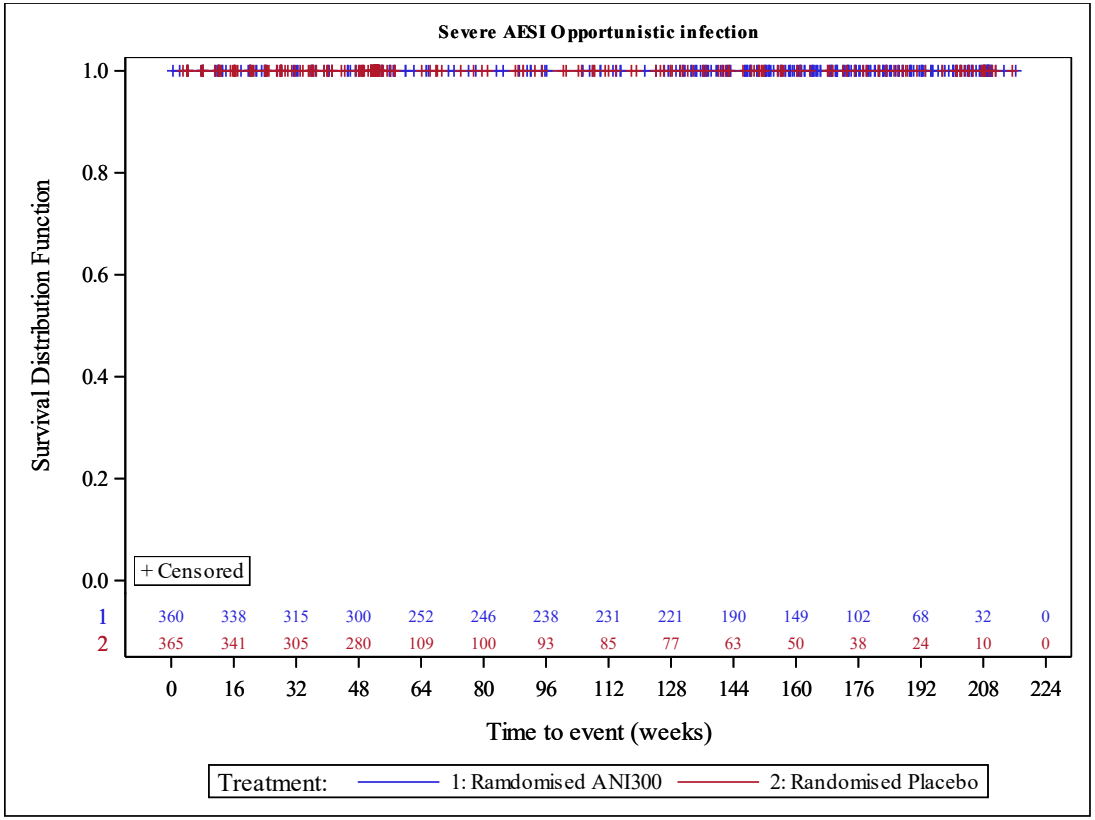
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Ramdomised ANI300 (N=360) Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Randomised Placebo (N=365) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
Age (years)							NE
<= 65	0/348 (0.0)	NE (NE, NE)	0/361 (0.0)	NE (NE, NE)	NE		
> 65	0/ 12 (0.0)	NE (NE, NE)	0/ 4 (0.0)	NE (NE, NE)	NE		
Sex							NE
male	0/ 27 (0.0)	NE (NE, NE)	0/ 25 (0.0)	NE (NE, NE)	NE		
female	0/333 (0.0)	NE (NE, NE)	0/340 (0.0)	NE (NE, NE)	NE		
Geographic region							NE
EU	0/115 (0.0)	NE (NE, NE)	0/122 (0.0)	NE (NE, NE)	NE		
non-EU	0/245 (0.0)	NE (NE, NE)	0/243 (0.0)	NE (NE, NE)	NE		
SLEDAI-2K score at screening							NE
< 10 points	0/109 (0.0)	NE (NE, NE)	0/106 (0.0)	NE (NE, NE)	NE		
>= 10 points	0/251 (0.0)	NE (NE, NE)	0/259 (0.0)	NE (NE, NE)	NE		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Opportunistic infection
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Opportunistic infection
Full analysis set

	Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
Number of subjects with events, n (%)	2 (0.6)	1 (0.3)
Number of censored subjects, n (%)	358 (99.4)	364 (99.7)
Exposure years	871.5	524.8
EAIR per 100 PY	0.2	0.2
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	1.04 (0.09, 12.07)	
p-value	0.9763	
Relative Risk (95% CI)	2.03 (0.18, 22.26)	
p-value	0.5631	
Odds Ratio (95% CI)	2.03 (0.18, 22.53)	
p-value	0.5630	
Risk Difference (95% CI)	0.28 (-0.65, 1.22)	
p-value	0.5557	

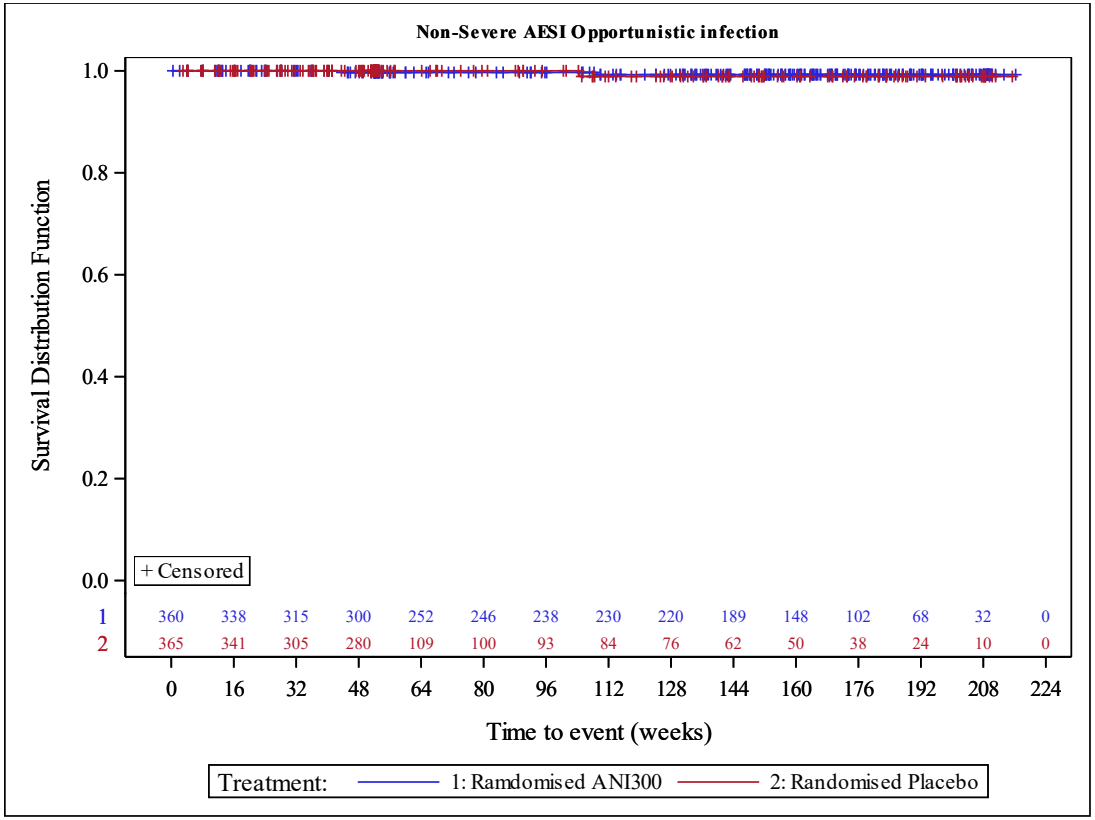
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Opportunistic infection - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Ramdomised ANI300 (N=360) Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Randomised Placebo (N=365) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
Age (years)							1.0000
<= 65	2/348 (0.6)	NE (NE, NE)	1/361 (0.3)	NE (NE, NE)	1.07 (0.09, 12.43)	0.9564	
> 65	0/ 12 (0.0)	NE (NE, NE)	0/ 4 (0.0)	NE (NE, NE)	NE		
Sex							1.0000
male	0/ 27 (0.0)	NE (NE, NE)	0/ 25 (0.0)	NE (NE, NE)	NE		
female	2/333 (0.6)	NE (NE, NE)	1/340 (0.3)	NE (NE, NE)	1.03 (0.09, 12.00)	0.9815	
Geographic region							0.9959
EU	1/115 (0.9)	NE (NE, NE)	0/122 (0.0)	NE (NE, NE)	NE		
non-EU	1/245 (0.4)	NE (NE, NE)	1/243 (0.4)	NE (NE, NE)	0.58 (0.03, 9.95)	0.7037	
SLEDAI-2K score at screening							0.9964
< 10 points	0/109 (0.0)	NE (NE, NE)	1/106 (0.9)	NE (NE, NE)	NE		
>= 10 points	2/251 (0.8)	NE (NE, NE)	0/259 (0.0)	NE (NE, NE)	NE		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Opportunistic infection
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Tuberculosis (including latent TB)
Full analysis set

	Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
Number of subjects with events, n (%)	18 (5.0)	3 (0.8)
Number of censored subjects, n (%)	342 (95.0)	362 (99.2)
Exposure years	848.9	522.6
EAIR per 100 PY	2.1	0.6
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	2.97 (0.86, 10.18)	
p-value	0.0703	
Relative Risk (95% CI)	6.08 (1.81, 20.47)	
p-value	0.0035	
Odds Ratio (95% CI)	6.35 (1.85, 21.75)	
p-value	0.0033	
Risk Difference (95% CI)	4.18 (1.74, 6.61)	
p-value	0.0008	

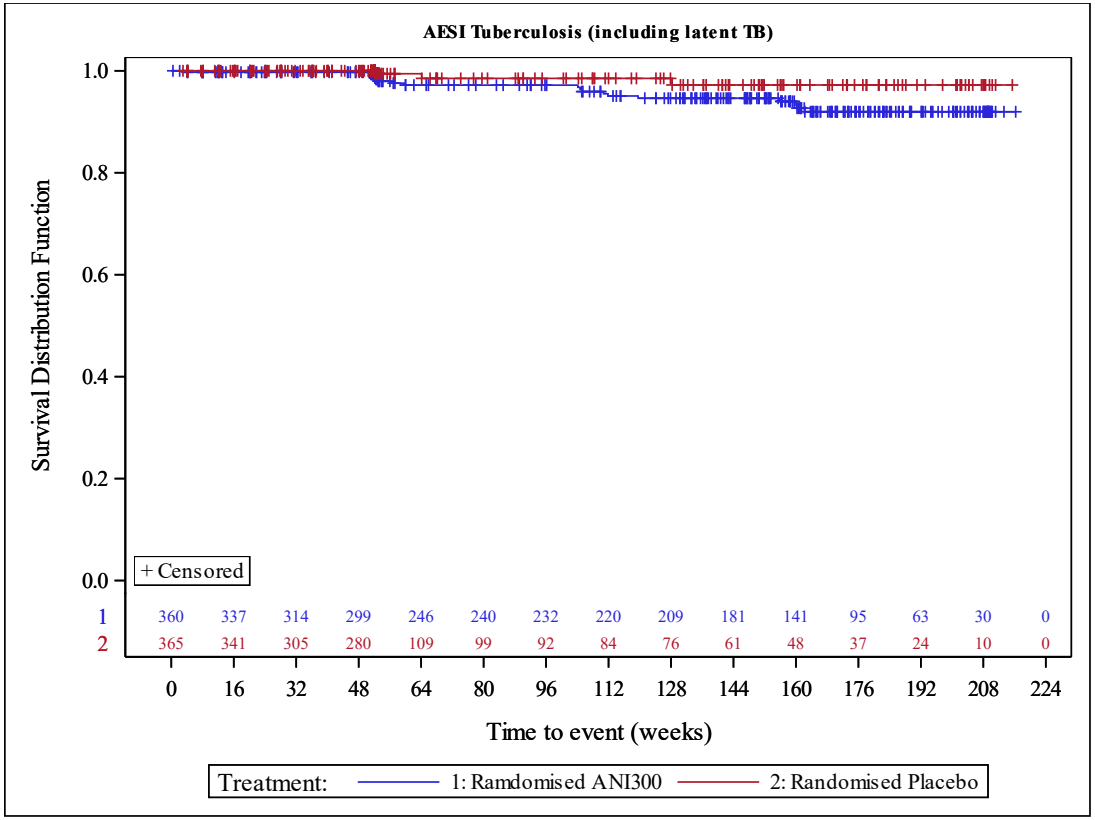
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Ramdomised ANI300 (N=360) Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Randomised Placebo (N=365) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
Age (years)							0.9941
<= 65	17/348 (4.9)	NE (NE, NE)	3/361 (0.8)	NE (NE, NE)	2.90 (0.84, 10.03)	0.0778	
> 65	1/ 12 (8.3)	NE (56.57, NE)	0/ 4 (0.0)	NE (NE, NE)	NE		
Sex							0.9997
male	0/ 27 (0.0)	NE (NE, NE)	0/ 25 (0.0)	NE (NE, NE)	NE		
female	18/333 (5.4)	NE (NE, NE)	3/340 (0.9)	NE (NE, NE)	2.94 (0.86, 10.09)	0.0732	
Geographic region							0.8347
EU	7/115 (6.1)	NE (NE, NE)	1/122 (0.8)	NE (NE, NE)	3.67 (0.44, 30.42)	0.1982	
non-EU	11/245 (4.5)	NE (NE, NE)	2/243 (0.8)	NE (NE, NE)	2.60 (0.57, 11.91)	0.2015	
SLEDAI-2K score at screening							0.4722
< 10 points	3/109 (2.8)	NE (NE, NE)	1/106 (0.9)	NE (NE, NE)	1.29 (0.13, 12.86)	0.8280	
>= 10 points	15/251 (6.0)	NE (NE, NE)	2/259 (0.8)	NE (NE, NE)	3.84 (0.87, 16.99)	0.0566	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Tuberculosis (including latent TB)
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Tuberculosis (including latent TB)
Full analysis set

	Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	360 (100.0)	365 (100.0)
Exposure years	872.8	525.8
EAIR per 100 PY	0.0	0.0
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	NE	
p-value		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

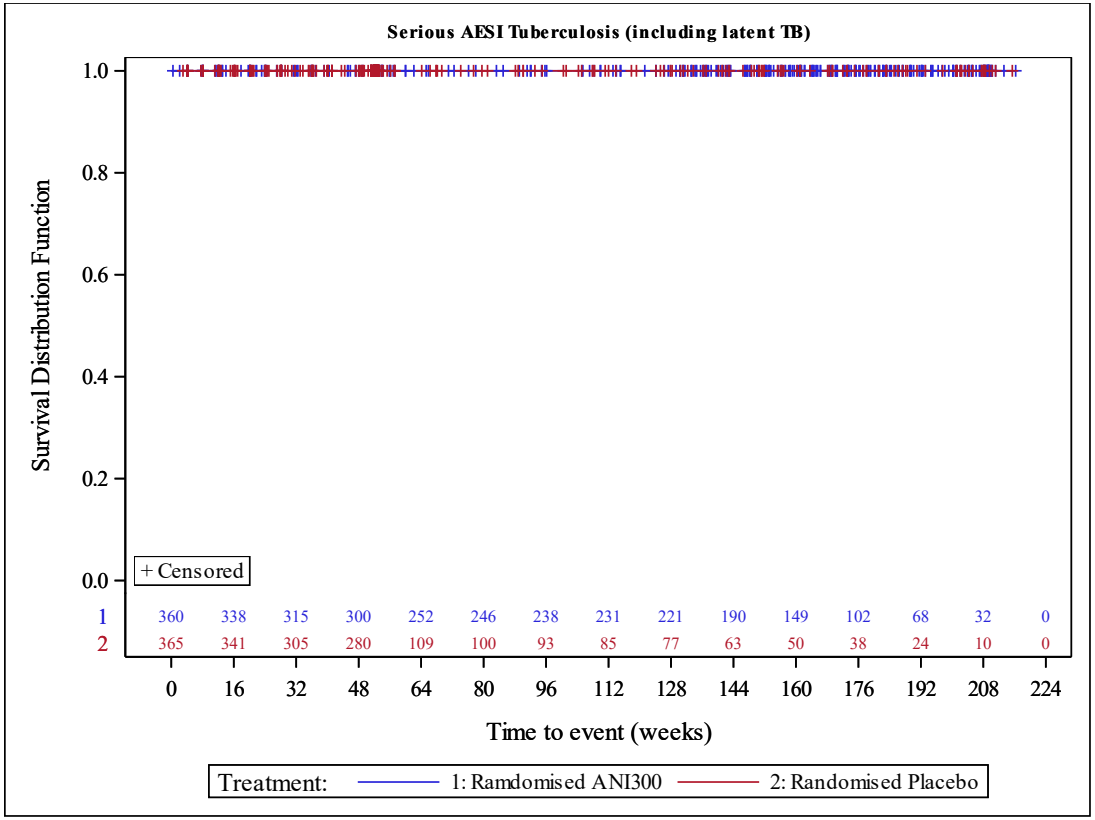
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Ramdomised ANI300 (N=360) Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Randomised Placebo (N=365) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
Age (years)							NE
<= 65	0/348 (0.0)	NE (NE, NE)	0/361 (0.0)	NE (NE, NE)	NE		
> 65	0/ 12 (0.0)	NE (NE, NE)	0/ 4 (0.0)	NE (NE, NE)	NE		
Sex							NE
male	0/ 27 (0.0)	NE (NE, NE)	0/ 25 (0.0)	NE (NE, NE)	NE		
female	0/333 (0.0)	NE (NE, NE)	0/340 (0.0)	NE (NE, NE)	NE		
Geographic region							NE
EU	0/115 (0.0)	NE (NE, NE)	0/122 (0.0)	NE (NE, NE)	NE		
non-EU	0/245 (0.0)	NE (NE, NE)	0/243 (0.0)	NE (NE, NE)	NE		
SLEDAI-2K score at screening							NE
< 10 points	0/109 (0.0)	NE (NE, NE)	0/106 (0.0)	NE (NE, NE)	NE		
>= 10 points	0/251 (0.0)	NE (NE, NE)	0/259 (0.0)	NE (NE, NE)	NE		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Tuberculosis (including latent TB)
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Tuberculosis (including latent TB)
Full analysis set

	Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	360 (100.0)	365 (100.0)
Exposure years	872.8	525.8
EAIR per 100 PY	0.0	0.0
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	NE	
p-value		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

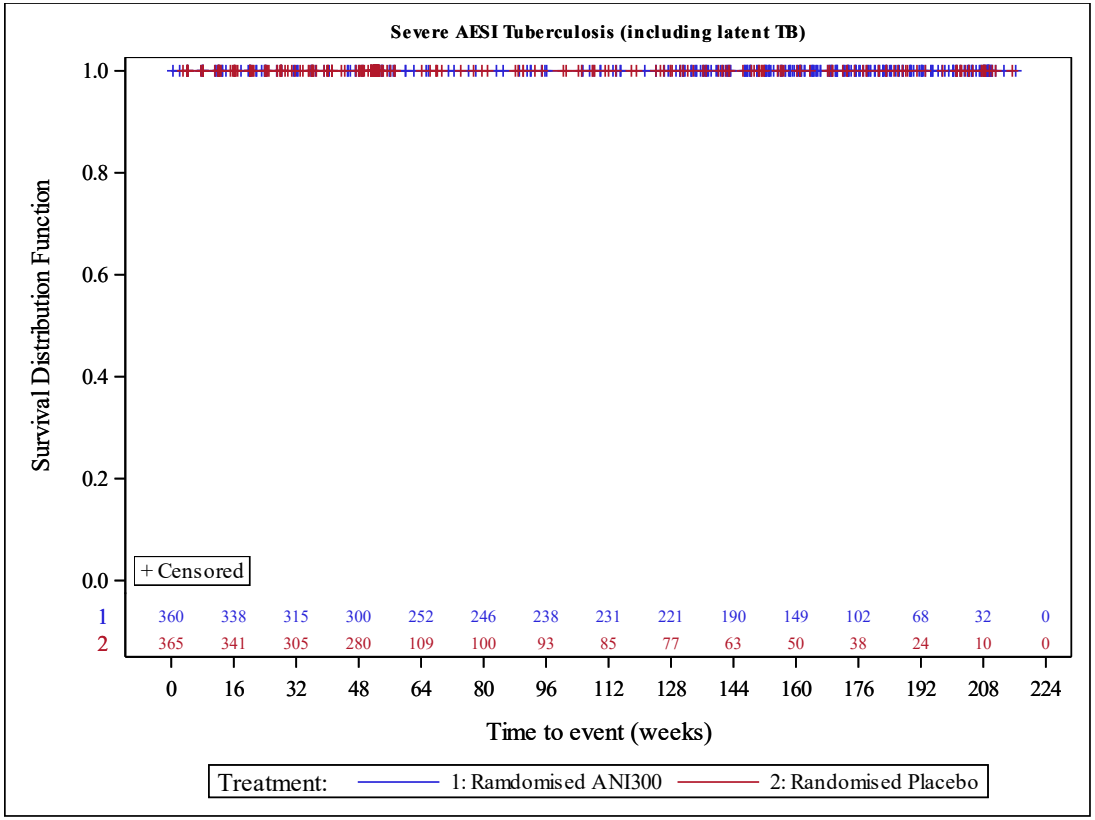
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%) Median (95% CI)	Randomised Placebo (N=365) n/ N (%) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI) p-Value	Interaction p-Value
Age (years)				NE
<= 65	0/348 (0.0) NE (NE, NE)	0/361 (0.0) NE (NE, NE)	NE	
> 65	0/ 12 (0.0) NE (NE, NE)	0/ 4 (0.0) NE (NE, NE)	NE	
Sex				NE
male	0/ 27 (0.0) NE (NE, NE)	0/ 25 (0.0) NE (NE, NE)	NE	
female	0/333 (0.0) NE (NE, NE)	0/340 (0.0) NE (NE, NE)	NE	
Geographic region				NE
EU	0/115 (0.0) NE (NE, NE)	0/122 (0.0) NE (NE, NE)	NE	
non-EU	0/245 (0.0) NE (NE, NE)	0/243 (0.0) NE (NE, NE)	NE	
SLEDAI-2K score at screening				NE
< 10 points	0/109 (0.0) NE (NE, NE)	0/106 (0.0) NE (NE, NE)	NE	
>= 10 points	0/251 (0.0) NE (NE, NE)	0/259 (0.0) NE (NE, NE)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Tuberculosis (including latent TB)
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Tuberculosis (including latent TB)
Full analysis set

	Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
Number of subjects with events, n (%)	18 (5.0)	3 (0.8)
Number of censored subjects, n (%)	342 (95.0)	362 (99.2)
Exposure years	848.9	522.6
EAIR per 100 PY	2.1	0.6
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	2.97 (0.86, 10.18)	
p-value	0.0703	
Relative Risk (95% CI)	6.08 (1.81, 20.47)	
p-value	0.0035	
Odds Ratio (95% CI)	6.35 (1.85, 21.75)	
p-value	0.0033	
Risk Difference (95% CI)	4.18 (1.74, 6.61)	
p-value	0.0008	

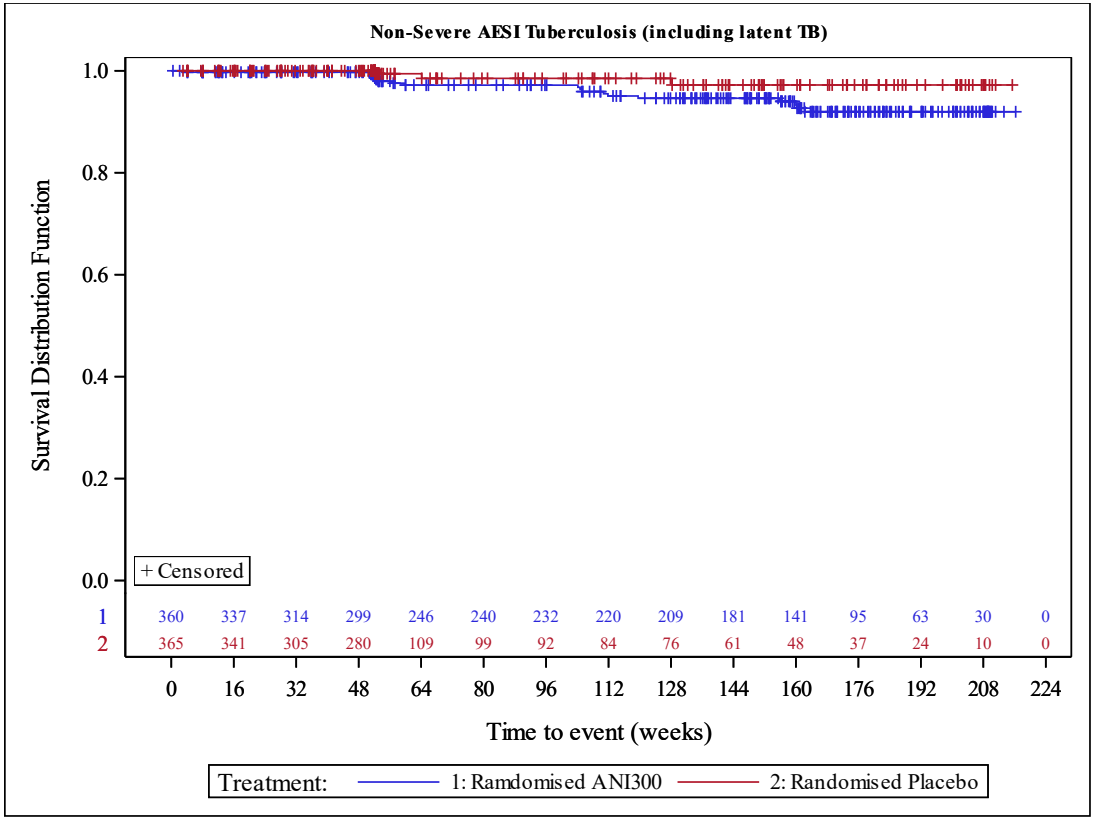
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Tuberculosis (including latent TB) - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Ramdomised ANI300 (N=360) Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Randomised Placebo (N=365) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
Age (years)							0.9941
<= 65	17/348 (4.9)	NE (NE, NE)	3/361 (0.8)	NE (NE, NE)	2.90 (0.84, 10.03)	0.0778	
> 65	1/ 12 (8.3)	NE (56.57, NE)	0/ 4 (0.0)	NE (NE, NE)	NE		
Sex							0.9997
male	0/ 27 (0.0)	NE (NE, NE)	0/ 25 (0.0)	NE (NE, NE)	NE		
female	18/333 (5.4)	NE (NE, NE)	3/340 (0.9)	NE (NE, NE)	2.94 (0.86, 10.09)	0.0732	
Geographic region							0.8347
EU	7/115 (6.1)	NE (NE, NE)	1/122 (0.8)	NE (NE, NE)	3.67 (0.44, 30.42)	0.1982	
non-EU	11/245 (4.5)	NE (NE, NE)	2/243 (0.8)	NE (NE, NE)	2.60 (0.57, 11.91)	0.2015	
SLEDAI-2K score at screening							0.4722
< 10 points	3/109 (2.8)	NE (NE, NE)	1/106 (0.9)	NE (NE, NE)	1.29 (0.13, 12.86)	0.8280	
>= 10 points	15/251 (6.0)	NE (NE, NE)	2/259 (0.8)	NE (NE, NE)	3.84 (0.87, 16.99)	0.0566	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Tuberculosis (including latent TB)
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Vasculitis
Full analysis set

	Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
Number of subjects with events, n (%)	0 (0.0)	1 (0.3)
Number of censored subjects, n (%)	360 (100.0)	364 (99.7)
Exposure years	872.8	525.6
EAIR per 100 PY	0.0	0.2
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	NE	
p-value		
Relative Risk (95% CI)	0.34 (0.01, 8.27)	
p-value	0.5060	
Odds Ratio (95% CI)	0.34 (0.01, 8.30)	
p-value	0.5058	
Risk Difference (95% CI)	-0.27 (-0.81, 0.26)	
p-value	0.3166	

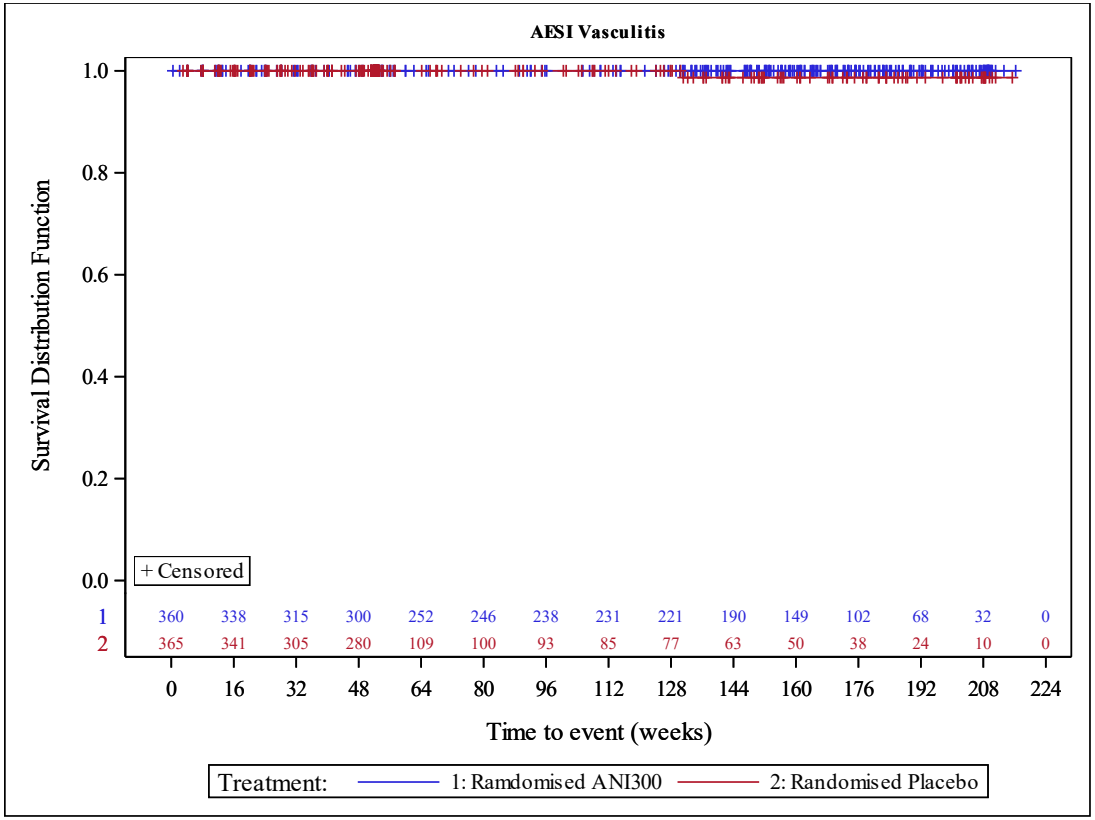
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Ramdomised ANI300 (N=360) Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Randomised Placebo (N=365) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
Age (years)							NE
<= 65	0/348 (0.0)	NE (NE, NE)	1/361 (0.3)	NE (NE, NE)	NE		
> 65	0/ 12 (0.0)	NE (NE, NE)	0/ 4 (0.0)	NE (NE, NE)	NE		
Sex							0.9996
male	0/ 27 (0.0)	NE (NE, NE)	0/ 25 (0.0)	NE (NE, NE)	NE		
female	0/333 (0.0)	NE (NE, NE)	1/340 (0.3)	NE (NE, NE)	NE		
Geographic region							0.9994
EU	0/115 (0.0)	NE (NE, NE)	1/122 (0.8)	NE (NE, NE)	NE		
non-EU	0/245 (0.0)	NE (NE, NE)	0/243 (0.0)	NE (NE, NE)	NE		
SLEDAI-2K score at screening							0.9993
< 10 points	0/109 (0.0)	NE (NE, NE)	1/106 (0.9)	NE (NE, NE)	NE		
>= 10 points	0/251 (0.0)	NE (NE, NE)	0/259 (0.0)	NE (NE, NE)	NE		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Vasculitis
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Vasculitis
Full analysis set

	Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	360 (100.0)	365 (100.0)
Exposure years	872.8	525.8
EAIR per 100 PY	0.0	0.0
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	NE	
p-value		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

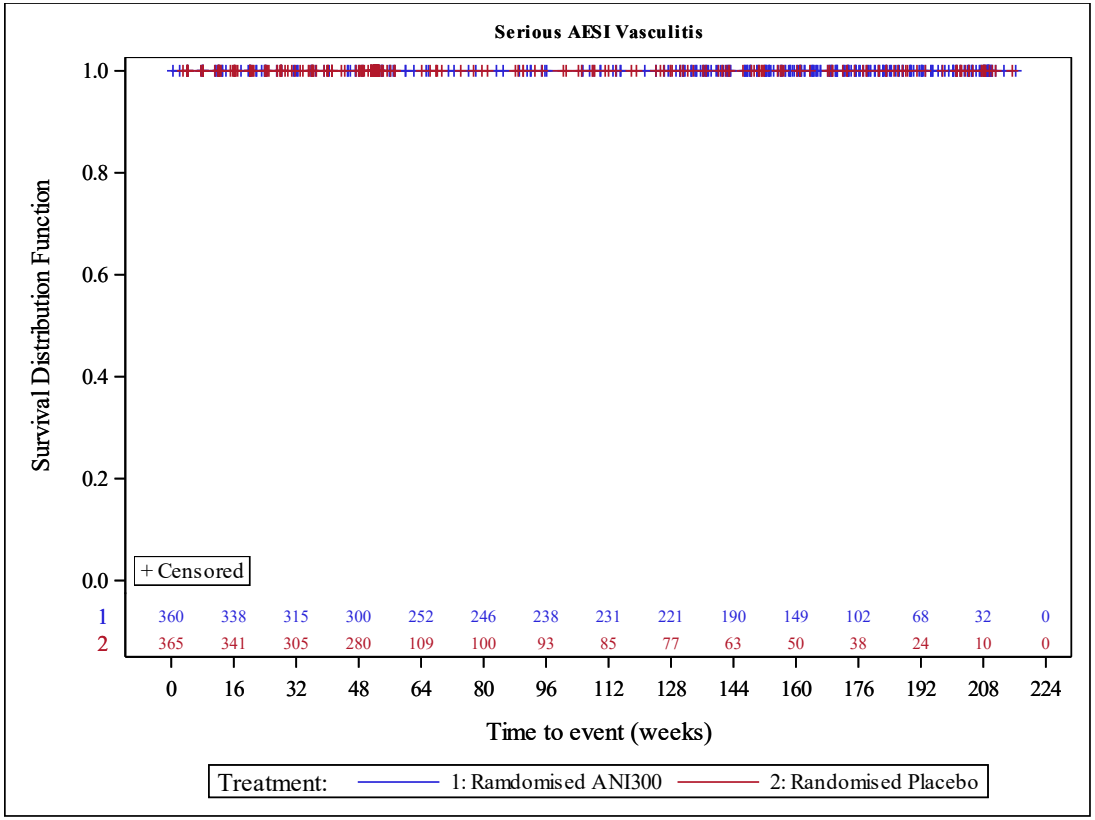
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Ramdomised ANI300 (N=360) Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Randomised Placebo (N=365) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
Age (years)							NE
<= 65	0/348 (0.0)	NE (NE, NE)	0/361 (0.0)	NE (NE, NE)	NE		
> 65	0/ 12 (0.0)	NE (NE, NE)	0/ 4 (0.0)	NE (NE, NE)	NE		
Sex							NE
male	0/ 27 (0.0)	NE (NE, NE)	0/ 25 (0.0)	NE (NE, NE)	NE		
female	0/333 (0.0)	NE (NE, NE)	0/340 (0.0)	NE (NE, NE)	NE		
Geographic region							NE
EU	0/115 (0.0)	NE (NE, NE)	0/122 (0.0)	NE (NE, NE)	NE		
non-EU	0/245 (0.0)	NE (NE, NE)	0/243 (0.0)	NE (NE, NE)	NE		
SLEDAI-2K score at screening							NE
< 10 points	0/109 (0.0)	NE (NE, NE)	0/106 (0.0)	NE (NE, NE)	NE		
>= 10 points	0/251 (0.0)	NE (NE, NE)	0/259 (0.0)	NE (NE, NE)	NE		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Serious Vasculitis
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Vasculitis
Full analysis set

	Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
Number of subjects with events, n (%)	0 (0.0)	1 (0.3)
Number of censored subjects, n (%)	360 (100.0)	364 (99.7)
Exposure years	872.8	525.6
EAIR per 100 PY	0.0	0.2
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	NE	
p-value		
Relative Risk (95% CI)	0.34 (0.01, 8.27)	
p-value	0.5060	
Odds Ratio (95% CI)	0.34 (0.01, 8.30)	
p-value	0.5058	
Risk Difference (95% CI)	-0.27 (-0.81, 0.26)	
p-value	0.3166	

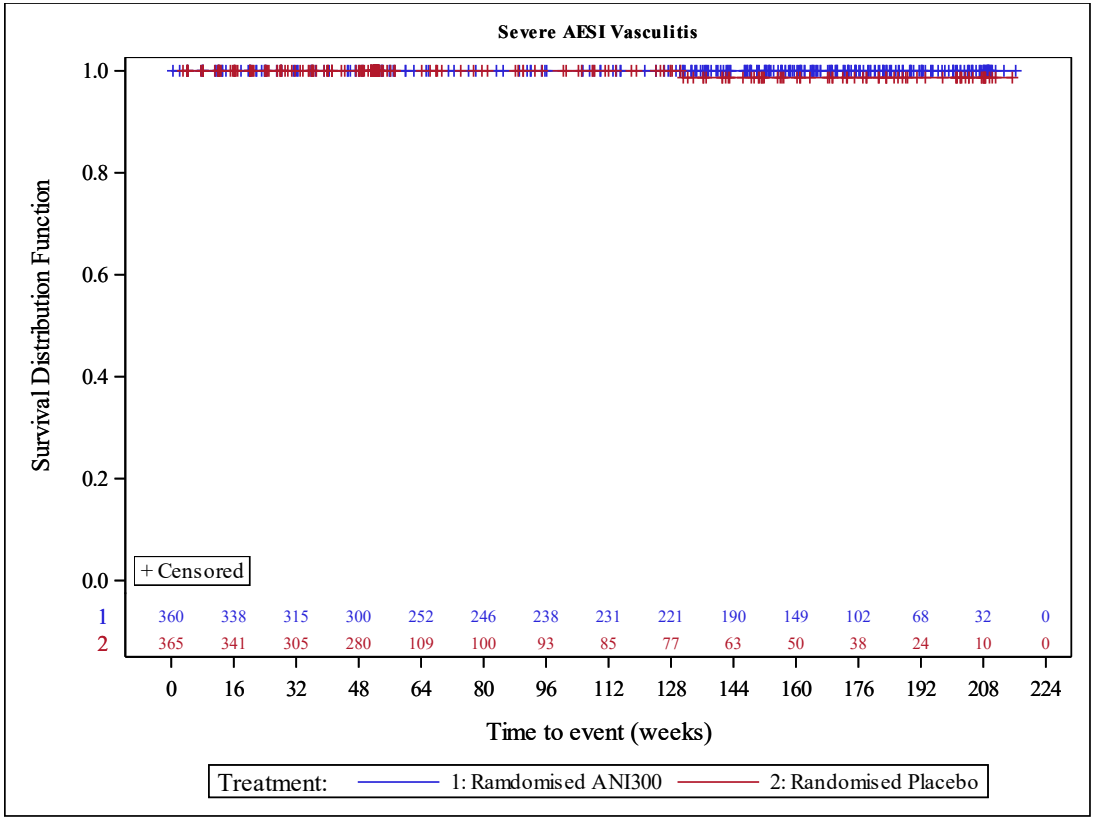
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Ramdomised ANI300 (N=360) Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Randomised Placebo (N=365) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
Age (years)							NE
<= 65	0/348 (0.0)	NE (NE, NE)	1/361 (0.3)	NE (NE, NE)	NE		
> 65	0/ 12 (0.0)	NE (NE, NE)	0/ 4 (0.0)	NE (NE, NE)	NE		
Sex							0.9996
male	0/ 27 (0.0)	NE (NE, NE)	0/ 25 (0.0)	NE (NE, NE)	NE		
female	0/333 (0.0)	NE (NE, NE)	1/340 (0.3)	NE (NE, NE)	NE		
Geographic region							0.9994
EU	0/115 (0.0)	NE (NE, NE)	1/122 (0.8)	NE (NE, NE)	NE		
non-EU	0/245 (0.0)	NE (NE, NE)	0/243 (0.0)	NE (NE, NE)	NE		
SLEDAI-2K score at screening							0.9993
< 10 points	0/109 (0.0)	NE (NE, NE)	1/106 (0.9)	NE (NE, NE)	NE		
>= 10 points	0/251 (0.0)	NE (NE, NE)	0/259 (0.0)	NE (NE, NE)	NE		

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Severe Vasculitis
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Vasculitis
Full analysis set

	Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	360 (100.0)	365 (100.0)
Exposure years	872.8	525.8
EAIR per 100 PY	0.0	0.0
Kaplan-Meier Quartiles of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Ramdomised ANI300 vs. Randomised Placebo		
Hazard Ratio (95% CI)	NE	
p-value		
Relative Risk (95% CI)	NE	
p-value		
Odds Ratio (95% CI)	NE	
p-value		
Risk Difference (95% CI)	NE	
p-value		

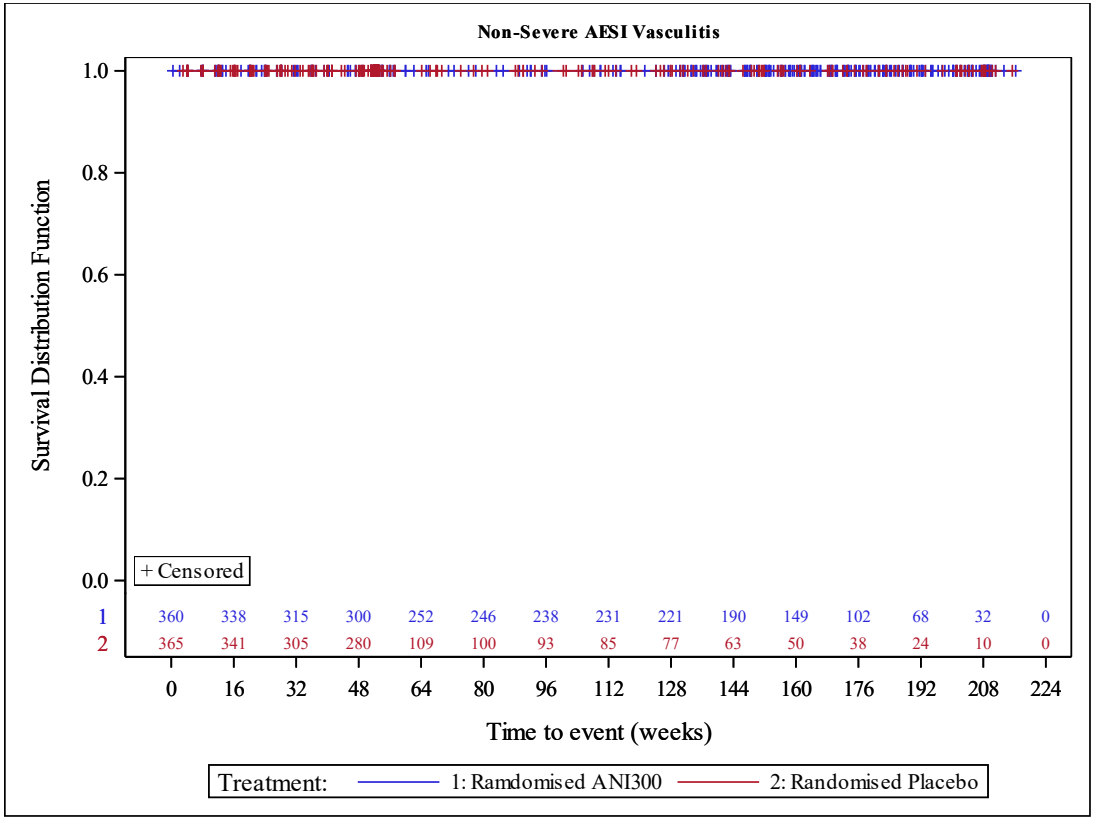
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Vasculitis - Subgroup analysis
Full analysis set

Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%) Median (95% CI)	Randomised Placebo (N=365) n/ N (%) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI) p-Value	Interaction p-Value
Age (years)				NE
<= 65	0/348 (0.0) NE (NE, NE)	0/361 (0.0) NE (NE, NE)	NE	
> 65	0/ 12 (0.0) NE (NE, NE)	0/ 4 (0.0) NE (NE, NE)	NE	
Sex				NE
male	0/ 27 (0.0) NE (NE, NE)	0/ 25 (0.0) NE (NE, NE)	NE	
female	0/333 (0.0) NE (NE, NE)	0/340 (0.0) NE (NE, NE)	NE	
Geographic region				NE
EU	0/115 (0.0) NE (NE, NE)	0/122 (0.0) NE (NE, NE)	NE	
non-EU	0/245 (0.0) NE (NE, NE)	0/243 (0.0) NE (NE, NE)	NE	
SLEDAI-2K score at screening				NE
< 10 points	0/109 (0.0) NE (NE, NE)	0/106 (0.0) NE (NE, NE)	NE	
>= 10 points	0/251 (0.0) NE (NE, NE)	0/259 (0.0) NE (NE, NE)	NE	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction .

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of time to first Adverse Event of Special Interest (AESI) during treatment - Randomised Anifrolumab 300mg vs. Randomised Placebo - Non-Severe Vasculitis
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Blood and lymphatic system disorders	Number of subjects with events, n (%)	28 (7.8)	28 (7.7)
	Number of censored subjects, n (%)	332 (92.2)	337 (92.3)
	Exposure years	818.3	493.2
	EAIR per 100 PY	3.4	5.7
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.74 (0.44, 1.27)	
	p-value	0.2777	
	Relative Risk (95% CI)	1.01 (0.61, 1.68)	
	p-value	0.9572	
	Odds Ratio (95% CI)	1.02 (0.59, 1.75)	
	p-value	0.9572	
	Risk Difference (95% CI)	0.11 (-3.78, 3.99)	
	p-value	0.9572	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Blood and lymphatic system disorders, PT: Anaemia	Number of subjects with events, n (%)	5 (1.4)	10 (2.7)
	Number of censored subjects, n (%)	355 (98.6)	355 (97.3)
	Exposure years	866.0	517.0
	EAIR per 100 PY	0.6	1.9
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.37 (0.12, 1.10)	
	p-value	0.0623	
	Relative Risk (95% CI)	0.51 (0.18, 1.47)	
	p-value	0.2106	
	Odds Ratio (95% CI)	0.50 (0.17, 1.48)	
	p-value	0.2099	
	Risk Difference (95% CI)	-1.35 (-3.42, 0.71)	
	p-value	0.1999	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Blood and lymphatic system disorders, PT: Iron deficiency anaemia	Number of subjects with events, n (%)	12 (3.3)	8 (2.2)
	Number of censored subjects, n (%)	348 (96.7)	357 (97.8)
	Exposure years	845.7	516.1
	EAIR per 100 PY	1.4	1.6
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.13 (0.46, 2.82)	
	p-value	0.7865	
	Relative Risk (95% CI)	1.52 (0.63, 3.68)	
	p-value	0.3519	
	Odds Ratio (95% CI)	1.54 (0.62, 3.81)	
	p-value	0.3515	
	Risk Difference (95% CI)	1.14 (-1.24, 3.53)	
	p-value	0.3485	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Cardiac disorders	Number of subjects with events, n (%)	15 (4.2)	21 (5.8)
	Number of censored subjects, n (%)	345 (95.8)	344 (94.2)
	Exposure years	849.4	507.9
	EAIR per 100 PY	1.8	4.1
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.42 (0.21, 0.83)	
	p-value	0.0106	
	Relative Risk (95% CI)	0.72 (0.38, 1.38)	
	p-value	0.3279	
	Odds Ratio (95% CI)	0.71 (0.36, 1.40)	
	p-value	0.3274	
	Risk Difference (95% CI)	-1.59 (-4.74, 1.57)	
	p-value	0.3246	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Ear and labyrinth disorders	Number of subjects with events, n (%)	27 (7.5)	18 (4.9)
	Number of censored subjects, n (%)	333 (92.5)	347 (95.1)
	Exposure years	825.4	505.5
	EAIR per 100 PY	3.3	3.6
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.04 (0.56, 1.92)	
	p-value	0.8988	
	Relative Risk (95% CI)	1.52 (0.85, 2.71)	
	p-value	0.1554	
	Odds Ratio (95% CI)	1.56 (0.85, 2.89)	
	p-value	0.1546	
	Risk Difference (95% CI)	2.57 (-0.94, 6.08)	
	p-value	0.1518	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Ear and labyrinth disorders, PT: Vertigo	Number of subjects with events, n (%)	11 (3.1)	5 (1.4)
	Number of censored subjects, n (%)	349 (96.9)	360 (98.6)
	Exposure years	856.2	521.3
	EAIR per 100 PY	1.3	1.0
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.47 (0.50, 4.34)	
	p-value	0.4793	
	Relative Risk (95% CI)	2.23 (0.78, 6.36)	
	p-value	0.1332	
	Odds Ratio (95% CI)	2.27 (0.78, 6.60)	
	p-value	0.1324	
	Risk Difference (95% CI)	1.69 (-0.46, 3.83)	
	p-value	0.1228	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Endocrine disorders	Number of subjects with events, n (%)	12 (3.3)	5 (1.4)
	Number of censored subjects, n (%)	348 (96.7)	360 (98.6)
	Exposure years	846.3	524.1
	EAIR per 100 PY	1.4	1.0
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.87 (0.65, 5.39)	
	p-value	0.2399	
	Relative Risk (95% CI)	2.43 (0.87, 6.84)	
	p-value	0.0916	
	Odds Ratio (95% CI)	2.48 (0.87, 7.12)	
	p-value	0.0907	
	Risk Difference (95% CI)	1.96 (-0.24, 4.17)	
	p-value	0.0809	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Eye disorders	Number of subjects with events, n (%)	43 (11.9)	25 (6.8)
	Number of censored subjects, n (%)	317 (88.1)	340 (93.2)
	Exposure years	788.0	500.8
	EAIR per 100 PY	5.5	5.0
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.25 (0.75, 2.06)	
	p-value	0.3894	
	Relative Risk (95% CI)	1.74 (1.09, 2.79)	
	p-value	0.0206	
	Odds Ratio (95% CI)	1.84 (1.10, 3.09)	
	p-value	0.0201	
	Risk Difference (95% CI)	5.10 (0.86, 9.33)	
	p-value	0.0184	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Gastrointestinal disorders	Number of subjects with events, n (%)	122 (33.9)	107 (29.3)
	Number of censored subjects, n (%)	238 (66.1)	258 (70.7)
	Exposure years	649.3	417.9
	EAIR per 100 PY	18.8	25.6
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	53.29 (37.14, 74.29)	43.29 (33.71, 63.86)
	Median (95% CI)	NE (199.0, NE)	204.4 (165.3, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (204.4, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.90 (0.69, 1.17)	
	p-value	0.4290	
	Relative Risk (95% CI)	1.16 (0.93, 1.43)	
	p-value	0.1861	
	Odds Ratio (95% CI)	1.24 (0.90, 1.69)	
	p-value	0.1856	
	Risk Difference (95% CI)	4.57 (-2.19, 11.34)	
	p-value	0.1849	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Gastrointestinal disorders, PT: Abdominal pain	Number of subjects with events, n (%)	9 (2.5)	11 (3.0)
	Number of censored subjects, n (%)	351 (97.5)	354 (97.0)
	Exposure years	858.6	514.9
	EAIR per 100 PY	1.0	2.1
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.57 (0.23, 1.42)	
	p-value	0.2251	
	Relative Risk (95% CI)	0.83 (0.35, 1.98)	
	p-value	0.6733	
	Odds Ratio (95% CI)	0.83 (0.34, 2.02)	
	p-value	0.6733	
	Risk Difference (95% CI)	-0.51 (-2.90, 1.87)	
	p-value	0.6726	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Gastrointestinal disorders, PT: Abdominal pain upper	Number of subjects with events, n (%)	13 (3.6)	13 (3.6)
	Number of censored subjects, n (%)	347 (96.4)	352 (96.4)
	Exposure years	852.3	506.3
	EAIR per 100 PY	1.5	2.6
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.76 (0.34, 1.66)	
	p-value	0.4818	
	Relative Risk (95% CI)	1.01 (0.48, 2.16)	
	p-value	0.9714	
	Odds Ratio (95% CI)	1.01 (0.46, 2.22)	
	p-value	0.9714	
	Risk Difference (95% CI)	0.05 (-2.66, 2.76)	
	p-value	0.9714	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Gastrointestinal disorders, PT: Constipation	Number of subjects with events, n (%)	12 (3.3)	13 (3.6)
	Number of censored subjects, n (%)	348 (96.7)	352 (96.4)
	Exposure years	851.3	518.6
	EAIR per 100 PY	1.4	2.5
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.59 (0.26, 1.31)	
	p-value	0.1897	
	Relative Risk (95% CI)	0.94 (0.43, 2.02)	
	p-value	0.8663	
	Odds Ratio (95% CI)	0.93 (0.42, 2.07)	
	p-value	0.8663	
	Risk Difference (95% CI)	-0.23 (-2.88, 2.43)	
	p-value	0.8662	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Gastrointestinal disorders, PT: Diarrhoea	Number of subjects with events, n (%)	24 (6.7)	25 (6.8)
	Number of censored subjects, n (%)	336 (93.3)	340 (93.2)
	Exposure years	828.7	504.4
	EAIR per 100 PY	2.9	5.0
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.69 (0.39, 1.23)	
	p-value	0.2056	
	Relative Risk (95% CI)	0.97 (0.57, 1.67)	
	p-value	0.9220	
	Odds Ratio (95% CI)	0.97 (0.54, 1.74)	
	p-value	0.9220	
	Risk Difference (95% CI)	-0.18 (-3.84, 3.47)	
	p-value	0.9220	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Gastrointestinal disorders, PT: Dyspepsia	Number of subjects with events, n (%)	4 (1.1)	10 (2.7)
	Number of censored subjects, n (%)	356 (98.9)	355 (97.3)
	Exposure years	869.7	516.5
	EAIR per 100 PY	0.5	1.9
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.27 (0.08, 0.89)	
	p-value	0.0229	
	Relative Risk (95% CI)	0.41 (0.13, 1.28)	
	p-value	0.1241	
	Odds Ratio (95% CI)	0.40 (0.12, 1.28)	
	p-value	0.1233	
	Risk Difference (95% CI)	-1.63 (-3.62, 0.37)	
	p-value	0.1095	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Gastrointestinal disorders, PT: Gastritis	Number of subjects with events, n (%)	5 (1.4)	11 (3.0)
	Number of censored subjects, n (%)	355 (98.6)	354 (97.0)
	Exposure years	863.2	513.3
	EAIR per 100 PY	0.6	2.1
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.33 (0.11, 0.96)	
	p-value	0.0338	
	Relative Risk (95% CI)	0.46 (0.16, 1.31)	
	p-value	0.1470	
	Odds Ratio (95% CI)	0.45 (0.16, 1.32)	
	p-value	0.1462	
	Risk Difference (95% CI)	-1.62 (-3.75, 0.51)	
	p-value	0.1349	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Gastrointestinal disorders, PT: Gastrooesophageal reflux disease	Number of subjects with events, n (%)	14 (3.9)	14 (3.8)
	Number of censored subjects, n (%)	346 (96.1)	351 (96.2)
	Exposure years	851.7	513.9
	EAIR per 100 PY	1.6	2.7
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.74 (0.35, 1.58)	
	p-value	0.4362	
	Relative Risk (95% CI)	1.01 (0.49, 2.10)	
	p-value	0.9703	
	Odds Ratio (95% CI)	1.01 (0.48, 2.16)	
	p-value	0.9703	
	Risk Difference (95% CI)	0.05 (-2.75, 2.86)	
	p-value	0.9703	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Gastrointestinal disorders, PT: Nausea	Number of subjects with events, n (%)	25 (6.9)	27 (7.4)
	Number of censored subjects, n (%)	335 (93.1)	338 (92.6)
	Exposure years	838.3	497.5
	EAIR per 100 PY	3.0	5.4
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (204.4, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.70 (0.40, 1.22)	
	p-value	0.2063	
	Relative Risk (95% CI)	0.94 (0.56, 1.59)	
	p-value	0.8133	
	Odds Ratio (95% CI)	0.93 (0.53, 1.64)	
	p-value	0.8133	
	Risk Difference (95% CI)	-0.45 (-4.21, 3.30)	
	p-value	0.8132	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Gastrointestinal disorders, PT: Vomiting	Number of subjects with events, n (%)	25 (6.9)	11 (3.0)
	Number of censored subjects, n (%)	335 (93.1)	354 (97.0)
	Exposure years	836.6	514.0
	EAIR per 100 PY	3.0	2.1
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.90 (0.93, 3.90)	
	p-value	0.0744	
	Relative Risk (95% CI)	2.30 (1.15, 4.61)	
	p-value	0.0184	
	Odds Ratio (95% CI)	2.40 (1.16, 4.96)	
	p-value	0.0178	
	Risk Difference (95% CI)	3.93 (0.77, 7.09)	
	p-value	0.0147	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: General disorders and administration site conditions	Number of subjects with events, n (%)	76 (21.1)	50 (13.7)
	Number of censored subjects, n (%)	284 (78.9)	315 (86.3)
	Exposure years	741.8	491.4
	EAIR per 100 PY	10.2	10.2
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	156.6 (93.00, NE)	193.1 (130.0, NE)
	Median (95% CI)	NE (NE, NE)	NE (204.4, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.22 (0.85, 1.75)	
	p-value	0.2828	
	Relative Risk (95% CI)	1.54 (1.11, 2.13)	
	p-value	0.0093	
	Odds Ratio (95% CI)	1.69 (1.14, 2.49)	
	p-value	0.0089	
	Risk Difference (95% CI)	7.41 (1.92, 12.91)	
	p-value	0.0082	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: General disorders and administration site conditions, PT: Fatigue	Number of subjects with events, n (%)	13 (3.6)	5 (1.4)
	Number of censored subjects, n (%)	347 (96.4)	360 (98.6)
	Exposure years	843.3	521.7
	EAIR per 100 PY	1.5	1.0
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.87 (0.65, 5.37)	
	p-value	0.2351	
	Relative Risk (95% CI)	2.64 (0.95, 7.32)	
	p-value	0.0628	
	Odds Ratio (95% CI)	2.70 (0.95, 7.65)	
	p-value	0.0619	
	Risk Difference (95% CI)	2.24 (-0.03, 4.51)	
	p-value	0.0526	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: General disorders and administration site conditions, PT: Non-cardiac chest pain	Number of subjects with events, n (%)	9 (2.5)	10 (2.7)
	Number of censored subjects, n (%)	351 (97.5)	355 (97.3)
	Exposure years	860.3	520.4
	EAIR per 100 PY	1.0	1.9
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.73 (0.29, 1.83)	
	p-value	0.5023	
	Relative Risk (95% CI)	0.91 (0.38, 2.22)	
	p-value	0.8400	
	Odds Ratio (95% CI)	0.91 (0.37, 2.27)	
	p-value	0.8400	
	Risk Difference (95% CI)	-0.24 (-2.56, 2.09)	
	p-value	0.8398	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: General disorders and administration site conditions, PT: Oedema peripheral	Number of subjects with events, n (%)	13 (3.6)	5 (1.4)
	Number of censored subjects, n (%)	347 (96.4)	360 (98.6)
	Exposure years	849.7	521.2
	EAIR per 100 PY	1.5	1.0
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.95 (0.68, 5.57)	
	p-value	0.2048	
	Relative Risk (95% CI)	2.64 (0.95, 7.32)	
	p-value	0.0628	
	Odds Ratio (95% CI)	2.70 (0.95, 7.65)	
	p-value	0.0619	
	Risk Difference (95% CI)	2.24 (-0.03, 4.51)	
	p-value	0.0526	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: General disorders and administration site conditions, PT: Pyrexia	Number of subjects with events, n (%)	11 (3.1)	11 (3.0)
	Number of censored subjects, n (%)	349 (96.9)	354 (97.0)
	Exposure years	857.0	519.3
	EAIR per 100 PY	1.3	2.1
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (204.4, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.73 (0.31, 1.72)	
	p-value	0.4738	
	Relative Risk (95% CI)	1.01 (0.45, 2.31)	
	p-value	0.9738	
	Odds Ratio (95% CI)	1.01 (0.43, 2.37)	
	p-value	0.9738	
	Risk Difference (95% CI)	0.04 (-2.46, 2.54)	
	p-value	0.9738	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Hepatobiliary disorders	Number of subjects with events, n (%)	11 (3.1)	9 (2.5)
	Number of censored subjects, n (%)	349 (96.9)	356 (97.5)
	Exposure years	858.4	512.7
	EAIR per 100 PY	1.3	1.8
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.87 (0.35, 2.15)	
	p-value	0.7684	
	Relative Risk (95% CI)	1.24 (0.52, 2.95)	
	p-value	0.6285	
	Odds Ratio (95% CI)	1.25 (0.51, 3.05)	
	p-value	0.6285	
	Risk Difference (95% CI)	0.59 (-1.80, 2.98)	
	p-value	0.6280	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Immune system disorders	Number of subjects with events, n (%)	31 (8.6)	12 (3.3)
	Number of censored subjects, n (%)	329 (91.4)	353 (96.7)
	Exposure years	811.9	513.2
	EAIR per 100 PY	3.8	2.3
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	2.18 (1.11, 4.27)	
	p-value	0.0208	
	Relative Risk (95% CI)	2.62 (1.37, 5.02)	
	p-value	0.0037	
	Odds Ratio (95% CI)	2.77 (1.40, 5.49)	
	p-value	0.0034	
	Risk Difference (95% CI)	5.32 (1.90, 8.75)	
	p-value	0.0023	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Immune system disorders, PT: Hypersensitivity	Number of subjects with events, n (%)	16 (4.4)	3 (0.8)
	Number of censored subjects, n (%)	344 (95.6)	362 (99.2)
	Exposure years	840.7	521.5
	EAIR per 100 PY	1.9	0.6
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	4.86 (1.41, 16.79)	
	p-value	0.0058	
	Relative Risk (95% CI)	5.41 (1.59, 18.40)	
	p-value	0.0069	
	Odds Ratio (95% CI)	5.61 (1.62, 19.43)	
	p-value	0.0065	
	Risk Difference (95% CI)	3.62 (1.30, 5.94)	
	p-value	0.0022	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Infections and infestations	Number of subjects with events, n (%)	288 (80.0)	235 (64.4)
	Number of censored subjects, n (%)	72 (20.0)	130 (35.6)
	Exposure years	267.7	256.5
	EAIR per 100 PY	107.6	91.6
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	7.29 (6.00, 9.00)	12.00 (8.86, 15.57)
	Median (95% CI)	21.29 (17.86, 25.00)	31.57 (27.71, 39.14)
	75%-ile (95% CI)	52.14 (44.00, 82.43)	102.0 (64.43, 150.7)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.33 (1.12, 1.58)	
	p-value	0.0011	
	Relative Risk (95% CI)	1.24 (1.13, 1.36)	
	p-value	<.0001	
	Odds Ratio (95% CI)	2.21 (1.58, 3.09)	
	p-value	<.0001	
	Risk Difference (95% CI)	15.62 (9.20, 22.04)	
	p-value	<.0001	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Infections and infestations, PT: Bronchitis	Number of subjects with events, n (%)	67 (18.6)	24 (6.6)
	Number of censored subjects, n (%)	293 (81.4)	341 (93.4)
	Exposure years	752.3	508.4
	EAIR per 100 PY	8.9	4.7
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (110.1, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	2.14 (1.33, 3.43)	
	p-value	0.0013	
	Relative Risk (95% CI)	2.83 (1.82, 4.41)	
	p-value	<.0001	
	Odds Ratio (95% CI)	3.25 (1.99, 5.31)	
	p-value	<.0001	
	Risk Difference (95% CI)	12.04 (7.28, 16.79)	
	p-value	<.0001	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Infections and infestations, PT: Cellulitis	Number of subjects with events, n (%)	10 (2.8)	6 (1.6)
	Number of censored subjects, n (%)	350 (97.2)	359 (98.4)
	Exposure years	859.3	519.7
	EAIR per 100 PY	1.2	1.2
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.21 (0.43, 3.42)	
	p-value	0.7130	
	Relative Risk (95% CI)	1.69 (0.62, 4.60)	
	p-value	0.3046	
	Odds Ratio (95% CI)	1.71 (0.61, 4.75)	
	p-value	0.3042	
	Risk Difference (95% CI)	1.13 (-1.01, 3.27)	
	p-value	0.2992	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Infections and infestations, PT: Conjunctivitis	Number of subjects with events, n (%)	14 (3.9)	5 (1.4)
	Number of censored subjects, n (%)	346 (96.1)	360 (98.6)
	Exposure years	845.7	519.7
	EAIR per 100 PY	1.7	1.0
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.83 (0.65, 5.16)	
	p-value	0.2490	
	Relative Risk (95% CI)	2.84 (1.03, 7.80)	
	p-value	0.0430	
	Odds Ratio (95% CI)	2.91 (1.04, 8.17)	
	p-value	0.0422	
	Risk Difference (95% CI)	2.52 (0.19, 4.85)	
	p-value	0.0338	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Infections and infestations, PT: Gastroenteritis	Number of subjects with events, n (%)	16 (4.4)	16 (4.4)
	Number of censored subjects, n (%)	344 (95.6)	349 (95.6)
	Exposure years	848.9	508.6
	EAIR per 100 PY	1.9	3.1
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.68 (0.33, 1.38)	
	p-value	0.2854	
	Relative Risk (95% CI)	1.01 (0.51, 2.00)	
	p-value	0.9682	
	Odds Ratio (95% CI)	1.01 (0.50, 2.06)	
	p-value	0.9682	
	Risk Difference (95% CI)	0.06 (-2.93, 3.05)	
	p-value	0.9682	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Infections and infestations, PT: Gastroenteritis viral	Number of subjects with events, n (%)	14 (3.9)	5 (1.4)
	Number of censored subjects, n (%)	346 (96.1)	360 (98.6)
	Exposure years	839.1	518.4
	EAIR per 100 PY	1.7	1.0
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	2.41 (0.86, 6.76)	
	p-value	0.0837	
	Relative Risk (95% CI)	2.84 (1.03, 7.80)	
	p-value	0.0430	
	Odds Ratio (95% CI)	2.91 (1.04, 8.17)	
	p-value	0.0422	
	Risk Difference (95% CI)	2.52 (0.19, 4.85)	
	p-value	0.0338	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Infections and infestations, PT: Herpes zoster	Number of subjects with events, n (%)	40 (11.1)	11 (3.0)
	Number of censored subjects, n (%)	320 (88.9)	354 (97.0)
	Exposure years	816.5	511.5
	EAIR per 100 PY	4.9	2.2
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	2.54 (1.29, 5.01)	
	p-value	0.0054	
	Relative Risk (95% CI)	3.69 (1.92, 7.07)	
	p-value	<.0001	
	Odds Ratio (95% CI)	4.02 (2.03, 7.97)	
	p-value	<.0001	
	Risk Difference (95% CI)	8.10 (4.41, 11.79)	
	p-value	<.0001	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Infections and infestations, PT: Influenza	Number of subjects with events, n (%)	20 (5.6)	11 (3.0)
	Number of censored subjects, n (%)	340 (94.4)	354 (97.0)
	Exposure years	846.8	517.7
	EAIR per 100 PY	2.4	2.1
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (201.1, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.08 (0.51, 2.30)	
	p-value	0.8411	
	Relative Risk (95% CI)	1.84 (0.90, 3.79)	
	p-value	0.0965	
	Odds Ratio (95% CI)	1.89 (0.89, 4.01)	
	p-value	0.0956	
	Risk Difference (95% CI)	2.54 (-0.40, 5.49)	
	p-value	0.0907	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Infections and infestations, PT: Latent tuberculosis	Number of subjects with events, n (%)	18 (5.0)	3 (0.8)
	Number of censored subjects, n (%)	342 (95.0)	362 (99.2)
	Exposure years	848.9	522.6
	EAIR per 100 PY	2.1	0.6
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	2.97 (0.86, 10.18)	
	p-value	0.0703	
	Relative Risk (95% CI)	6.08 (1.81, 20.47)	
	p-value	0.0035	
	Odds Ratio (95% CI)	6.35 (1.85, 21.75)	
	p-value	0.0033	
	Risk Difference (95% CI)	4.18 (1.74, 6.61)	
	p-value	0.0008	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Infections and infestations, PT: Nasopharyngitis	Number of subjects with events, n (%)	95 (26.4)	51 (14.0)
	Number of censored subjects, n (%)	265 (73.6)	314 (86.0)
	Exposure years	689.6	477.4
	EAIR per 100 PY	13.8	10.7
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	90.29 (56.29, 139.4)	NE (86.71, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.56 (1.11, 2.20)	
	p-value	0.0106	
	Relative Risk (95% CI)	1.89 (1.39, 2.57)	
	p-value	<.0001	
	Odds Ratio (95% CI)	2.21 (1.51, 3.22)	
	p-value	<.0001	
	Risk Difference (95% CI)	12.42 (6.64, 18.19)	
	p-value	<.0001	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Infections and infestations, PT: Oral herpes	Number of subjects with events, n (%)	26 (7.2)	14 (3.8)
	Number of censored subjects, n (%)	334 (92.8)	351 (96.2)
	Exposure years	820.4	508.1
	EAIR per 100 PY	3.2	2.8
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.36 (0.70, 2.64)	
	p-value	0.3605	
	Relative Risk (95% CI)	1.88 (1.00, 3.55)	
	p-value	0.0501	
	Odds Ratio (95% CI)	1.95 (1.00, 3.80)	
	p-value	0.0493	
	Risk Difference (95% CI)	3.39 (0.07, 6.71)	
	p-value	0.0457	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Infections and infestations, PT: Otitis media	Number of subjects with events, n (%)	12 (3.3)	0 (0.0)
	Number of censored subjects, n (%)	348 (96.7)	365 (100.0)
	Exposure years	856.1	525.8
	EAIR per 100 PY	1.4	0.0
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	NE	
	p-value		
	Relative Risk (95% CI)	25.35 (1.51, 426.49)	
	p-value	0.0248	
	Odds Ratio (95% CI)	26.22 (1.55, 444.53)	
	p-value	0.0237	
	Risk Difference (95% CI)	3.33 (1.48, 5.19)	
	p-value	0.0004	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Infections and infestations, PT: Pharyngitis	Number of subjects with events, n (%)	25 (6.9)	20 (5.5)
	Number of censored subjects, n (%)	335 (93.1)	345 (94.5)
	Exposure years	830.0	504.7
	EAIR per 100 PY	3.0	4.0
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.91 (0.50, 1.66)	
	p-value	0.7523	
	Relative Risk (95% CI)	1.27 (0.72, 2.24)	
	p-value	0.4150	
	Odds Ratio (95% CI)	1.29 (0.70, 2.36)	
	p-value	0.4147	
	Risk Difference (95% CI)	1.46 (-2.05, 4.98)	
	p-value	0.4138	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Infections and infestations, PT: Pneumonia	Number of subjects with events, n (%)	21 (5.8)	15 (4.1)
	Number of censored subjects, n (%)	339 (94.2)	350 (95.9)
	Exposure years	845.1	513.0
	EAIR per 100 PY	2.5	2.9
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.04 (0.53, 2.05)	
	p-value	0.9125	
	Relative Risk (95% CI)	1.42 (0.74, 2.71)	
	p-value	0.2882	
	Odds Ratio (95% CI)	1.45 (0.73, 2.85)	
	p-value	0.2877	
	Risk Difference (95% CI)	1.72 (-1.44, 4.89)	
	p-value	0.2856	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Infections and infestations, PT: Respiratory tract infection	Number of subjects with events, n (%)	14 (3.9)	3 (0.8)
	Number of censored subjects, n (%)	346 (96.1)	362 (99.2)
	Exposure years	839.6	524.0
	EAIR per 100 PY	1.7	0.6
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	4.28 (1.22, 14.96)	
	p-value	0.0134	
	Relative Risk (95% CI)	4.73 (1.37, 16.32)	
	p-value	0.0139	
	Odds Ratio (95% CI)	4.88 (1.39, 17.14)	
	p-value	0.0133	
	Risk Difference (95% CI)	3.07 (0.87, 5.27)	
	p-value	0.0063	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Infections and infestations, PT: Sinusitis	Number of subjects with events, n (%)	34 (9.4)	22 (6.0)
	Number of censored subjects, n (%)	326 (90.6)	343 (94.0)
	Exposure years	800.5	504.7
	EAIR per 100 PY	4.2	4.4
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.23 (0.71, 2.11)	
	p-value	0.4644	
	Relative Risk (95% CI)	1.57 (0.94, 2.63)	
	p-value	0.0881	
	Odds Ratio (95% CI)	1.63 (0.93, 2.84)	
	p-value	0.0873	
	Risk Difference (95% CI)	3.42 (-0.47, 7.30)	
	p-value	0.0847	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Infections and infestations, PT: Tooth abscess	Number of subjects with events, n (%)	10 (2.8)	4 (1.1)
	Number of censored subjects, n (%)	350 (97.2)	361 (98.9)
	Exposure years	859.9	520.8
	EAIR per 100 PY	1.2	0.8
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.63 (0.50, 5.32)	
	p-value	0.4179	
	Relative Risk (95% CI)	2.53 (0.80, 8.01)	
	p-value	0.1130	
	Odds Ratio (95% CI)	2.58 (0.80, 8.30)	
	p-value	0.1122	
	Risk Difference (95% CI)	1.68 (-0.32, 3.69)	
	p-value	0.1003	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Infections and infestations, PT: Upper respiratory tract infection	Number of subjects with events, n (%)	94 (26.1)	48 (13.2)
	Number of censored subjects, n (%)	266 (73.9)	317 (86.8)
	Exposure years	702.8	459.5
	EAIR per 100 PY	13.4	10.4
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	98.57 (75.57, 153.0)	168.4 (104.1, NE)
	Median (95% CI)	NE (208.6, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.53 (1.07, 2.18)	
	p-value	0.0176	
	Relative Risk (95% CI)	1.99 (1.45, 2.72)	
	p-value	<.0001	
	Odds Ratio (95% CI)	2.33 (1.59, 3.43)	
	p-value	<.0001	
	Risk Difference (95% CI)	12.96 (7.25, 18.67)	
	p-value	<.0001	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Infections and infestations, PT: Urinary tract infection	Number of subjects with events, n (%)	74 (20.6)	59 (16.2)
	Number of censored subjects, n (%)	286 (79.4)	306 (83.8)
	Exposure years	744.7	463.6
	EAIR per 100 PY	9.9	12.7
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	182.9 (104.7, NE)	NE (85.14, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.95 (0.67, 1.35)	
	p-value	0.7923	
	Relative Risk (95% CI)	1.27 (0.93, 1.73)	
	p-value	0.1281	
	Odds Ratio (95% CI)	1.34 (0.92, 1.96)	
	p-value	0.1274	
	Risk Difference (95% CI)	4.39 (-1.24, 10.02)	
	p-value	0.1263	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Infections and infestations, PT: Vaginal infection	Number of subjects with events, n (%)	11 (3.1)	10 (2.7)
	Number of censored subjects, n (%)	349 (96.9)	355 (97.3)
	Exposure years	855.1	510.6
	EAIR per 100 PY	1.3	2.0
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.71 (0.30, 1.71)	
	p-value	0.4435	
	Relative Risk (95% CI)	1.12 (0.48, 2.59)	
	p-value	0.8000	
	Odds Ratio (95% CI)	1.12 (0.47, 2.67)	
	p-value	0.8000	
	Risk Difference (95% CI)	0.32 (-2.13, 2.76)	
	p-value	0.7999	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Infections and infestations, PT: Viral upper respiratory tract infection	Number of subjects with events, n (%)	14 (3.9)	6 (1.6)
	Number of censored subjects, n (%)	346 (96.1)	359 (98.4)
	Exposure years	861.7	520.7
	EAIR per 100 PY	1.6	1.2
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.47 (0.55, 3.92)	
	p-value	0.4373	
	Relative Risk (95% CI)	2.37 (0.92, 6.09)	
	p-value	0.0742	
	Odds Ratio (95% CI)	2.42 (0.92, 6.37)	
	p-value	0.0733	
	Risk Difference (95% CI)	2.25 (-0.14, 4.63)	
	p-value	0.0651	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Infections and infestations, PT: Vulvovaginal mycotic infection	Number of subjects with events, n (%)	13 (3.6)	4 (1.1)
	Number of censored subjects, n (%)	347 (96.4)	361 (98.9)
	Exposure years	852.9	519.2
	EAIR per 100 PY	1.5	0.8
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	2.33 (0.74, 7.27)	
	p-value	0.1361	
	Relative Risk (95% CI)	3.30 (1.08, 10.01)	
	p-value	0.0354	
	Odds Ratio (95% CI)	3.38 (1.09, 10.47)	
	p-value	0.0347	
	Risk Difference (95% CI)	2.52 (0.31, 4.72)	
	p-value	0.0253	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Injury, poisoning and procedural complications	Number of subjects with events, n (%)	119 (33.1)	81 (22.2)
	Number of censored subjects, n (%)	241 (66.9)	284 (77.8)
	Exposure years	673.3	427.4
	EAIR per 100 PY	17.7	19.0
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	54.29 (35.57, 85.14)	73.00 (52.57, 156.1)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.20 (0.90, 1.60)	
	p-value	0.2152	
	Relative Risk (95% CI)	1.49 (1.17, 1.90)	
	p-value	0.0012	
	Odds Ratio (95% CI)	1.73 (1.24, 2.41)	
	p-value	0.0011	
	Risk Difference (95% CI)	10.86 (4.40, 17.33)	
	p-value	0.0010	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Injury, poisoning and procedural complications, PT: Arthropod bite	Number of subjects with events, n (%)	13 (3.6)	5 (1.4)
	Number of censored subjects, n (%)	347 (96.4)	360 (98.6)
	Exposure years	855.4	517.2
	EAIR per 100 PY	1.5	1.0
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.94 (0.68, 5.54)	
	p-value	0.2084	
	Relative Risk (95% CI)	2.64 (0.95, 7.32)	
	p-value	0.0628	
	Odds Ratio (95% CI)	2.70 (0.95, 7.65)	
	p-value	0.0619	
	Risk Difference (95% CI)	2.24 (-0.03, 4.51)	
	p-value	0.0526	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Injury, poisoning and procedural complications, PT: Contusion	Number of subjects with events, n (%)	15 (4.2)	8 (2.2)
	Number of censored subjects, n (%)	345 (95.8)	357 (97.8)
	Exposure years	850.6	517.5
	EAIR per 100 PY	1.8	1.5
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.29 (0.54, 3.09)	
	p-value	0.5735	
	Relative Risk (95% CI)	1.90 (0.82, 4.43)	
	p-value	0.1365	
	Odds Ratio (95% CI)	1.94 (0.81, 4.63)	
	p-value	0.1357	
	Risk Difference (95% CI)	1.97 (-0.58, 4.53)	
	p-value	0.1295	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Injury, poisoning and procedural complications, PT: Fall	Number of subjects with events, n (%)	14 (3.9)	11 (3.0)
	Number of censored subjects, n (%)	346 (96.1)	354 (97.0)
	Exposure years	852.7	515.3
	EAIR per 100 PY	1.6	2.1
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.81 (0.36, 1.81)	
	p-value	0.6019	
	Relative Risk (95% CI)	1.29 (0.59, 2.80)	
	p-value	0.5197	
	Odds Ratio (95% CI)	1.30 (0.58, 2.91)	
	p-value	0.5195	
	Risk Difference (95% CI)	0.88 (-1.78, 3.53)	
	p-value	0.5187	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Injury, poisoning and procedural complications, PT: Infusion related reaction	Number of subjects with events, n (%)	52 (14.4)	30 (8.2)
	Number of censored subjects, n (%)	308 (85.6)	335 (91.8)
	Exposure years	766.4	476.9
	EAIR per 100 PY	6.8	6.3
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.56 (0.99, 2.45)	
	p-value	0.0545	
	Relative Risk (95% CI)	1.76 (1.15, 2.69)	
	p-value	0.0093	
	Odds Ratio (95% CI)	1.89 (1.17, 3.03)	
	p-value	0.0089	
	Risk Difference (95% CI)	6.23 (1.63, 10.82)	
	p-value	0.0079	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Investigations	Number of subjects with events, n (%)	34 (9.4)	26 (7.1)
	Number of censored subjects, n (%)	326 (90.6)	339 (92.9)
	Exposure years	815.5	509.5
	EAIR per 100 PY	4.2	5.1
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.97 (0.57, 1.63)	
	p-value	0.9000	
	Relative Risk (95% CI)	1.33 (0.81, 2.16)	
	p-value	0.2587	
	Odds Ratio (95% CI)	1.36 (0.80, 2.32)	
	p-value	0.2582	
	Risk Difference (95% CI)	2.32 (-1.69, 6.33)	
	p-value	0.2567	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Metabolism and nutrition disorders	Number of subjects with events, n (%)	38 (10.6)	40 (11.0)
	Number of censored subjects, n (%)	322 (89.4)	325 (89.0)
	Exposure years	812.7	489.7
	EAIR per 100 PY	4.7	8.2
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (149.0, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.65 (0.41, 1.03)	
	p-value	0.0646	
	Relative Risk (95% CI)	0.96 (0.63, 1.47)	
	p-value	0.8609	
	Odds Ratio (95% CI)	0.96 (0.60, 1.53)	
	p-value	0.8609	
	Risk Difference (95% CI)	-0.40 (-4.91, 4.11)	
	p-value	0.8609	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Musculoskeletal and connective tissue disorders	Number of subjects with events, n (%)	146 (40.6)	103 (28.2)
	Number of censored subjects, n (%)	214 (59.4)	262 (71.8)
	Exposure years	618.9	434.8
	EAIR per 100 PY	23.6	23.7
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	52.00 (39.43, 62.57)	60.71 (36.14, 86.29)
	Median (95% CI)	164.3 (117.7, NE)	178.7 (137.3, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.10 (0.85, 1.42)	
	p-value	0.4598	
	Relative Risk (95% CI)	1.44 (1.17, 1.77)	
	p-value	0.0006	
	Odds Ratio (95% CI)	1.74 (1.27, 2.37)	
	p-value	0.0005	
	Risk Difference (95% CI)	12.34 (5.48, 19.20)	
	p-value	0.0004	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Musculoskeletal and connective tissue disorders, PT: Arthralgia	Number of subjects with events, n (%)	34 (9.4)	13 (3.6)
	Number of censored subjects, n (%)	326 (90.6)	352 (96.4)
	Exposure years	816.0	512.6
	EAIR per 100 PY	4.2	2.5
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.91 (1.00, 3.67)	
	p-value	0.0473	
	Relative Risk (95% CI)	2.65 (1.42, 4.94)	
	p-value	0.0021	
	Odds Ratio (95% CI)	2.82 (1.46, 5.45)	
	p-value	0.0019	
	Risk Difference (95% CI)	5.88 (2.31, 9.45)	
	p-value	0.0012	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Musculoskeletal and connective tissue disorders, PT: Back pain	Number of subjects with events, n (%)	35 (9.7)	24 (6.6)
	Number of censored subjects, n (%)	325 (90.3)	341 (93.4)
	Exposure years	810.4	501.2
	EAIR per 100 PY	4.3	4.8
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (178.7, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.04 (0.61, 1.76)	
	p-value	0.8975	
	Relative Risk (95% CI)	1.48 (0.90, 2.43)	
	p-value	0.1242	
	Odds Ratio (95% CI)	1.53 (0.89, 2.63)	
	p-value	0.1235	
	Risk Difference (95% CI)	3.15 (-0.83, 7.13)	
	p-value	0.1211	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Musculoskeletal and connective tissue disorders, PT: Bursitis	Number of subjects with events, n (%)	14 (3.9)	5 (1.4)
	Number of censored subjects, n (%)	346 (96.1)	360 (98.6)
	Exposure years	852.7	521.4
	EAIR per 100 PY	1.6	1.0
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.62 (0.57, 4.59)	
	p-value	0.3601	
	Relative Risk (95% CI)	2.84 (1.03, 7.80)	
	p-value	0.0430	
	Odds Ratio (95% CI)	2.91 (1.04, 8.17)	
	p-value	0.0422	
	Risk Difference (95% CI)	2.52 (0.19, 4.85)	
	p-value	0.0338	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Musculoskeletal and connective tissue disorders, PT: Musculoskeletal pain	Number of subjects with events, n (%)	10 (2.8)	8 (2.2)
	Number of censored subjects, n (%)	350 (97.2)	357 (97.8)
	Exposure years	858.3	518.6
	EAIR per 100 PY	1.2	1.5
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (206.3, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.87 (0.33, 2.25)	
	p-value	0.7705	
	Relative Risk (95% CI)	1.27 (0.51, 3.17)	
	p-value	0.6130	
	Odds Ratio (95% CI)	1.28 (0.50, 3.27)	
	p-value	0.6130	
	Risk Difference (95% CI)	0.59 (-1.68, 2.85)	
	p-value	0.6124	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Musculoskeletal and connective tissue disorders, PT: Osteoarthritis	Number of subjects with events, n (%)	12 (3.3)	0 (0.0)
	Number of censored subjects, n (%)	348 (96.7)	365 (100.0)
	Exposure years	853.3	525.8
	EAIR per 100 PY	1.4	0.0
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	NE	
	p-value		
	Relative Risk (95% CI)	25.35 (1.51, 426.49)	
	p-value	0.0248	
	Odds Ratio (95% CI)	26.22 (1.55, 444.53)	
	p-value	0.0237	
	Risk Difference (95% CI)	3.33 (1.48, 5.19)	
	p-value	0.0004	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Musculoskeletal and connective tissue disorders, PT: Pain in extremity	Number of subjects with events, n (%)	14 (3.9)	7 (1.9)
	Number of censored subjects, n (%)	346 (96.1)	358 (98.1)
	Exposure years	850.6	516.8
	EAIR per 100 PY	1.6	1.4
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.29 (0.51, 3.27)	
	p-value	0.5854	
	Relative Risk (95% CI)	2.03 (0.83, 4.97)	
	p-value	0.1218	
	Odds Ratio (95% CI)	2.07 (0.83, 5.19)	
	p-value	0.1210	
	Risk Difference (95% CI)	1.97 (-0.47, 4.41)	
	p-value	0.1138	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Musculoskeletal and connective tissue disorders, PT: Systemic lupus erythematosus	Number of subjects with events, n (%)	14 (3.9)	15 (4.1)
	Number of censored subjects, n (%)	346 (96.1)	350 (95.9)
	Exposure years	856.8	518.5
	EAIR per 100 PY	1.6	2.9
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.58 (0.27, 1.22)	
	p-value	0.1433	
	Relative Risk (95% CI)	0.95 (0.46, 1.93)	
	p-value	0.8795	
	Odds Ratio (95% CI)	0.94 (0.45, 1.99)	
	p-value	0.8795	
	Risk Difference (95% CI)	-0.22 (-3.07, 2.63)	
	p-value	0.8795	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Number of subjects with events, n (%)	27 (7.5)	12 (3.3)
	Number of censored subjects, n (%)	333 (92.5)	353 (96.7)
	Exposure years	823.1	522.6
	EAIR per 100 PY	3.3	2.3
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.52 (0.76, 3.04)	
	p-value	0.2317	
	Relative Risk (95% CI)	2.28 (1.17, 4.43)	
	p-value	0.0150	
	Odds Ratio (95% CI)	2.39 (1.19, 4.79)	
	p-value	0.0144	
	Risk Difference (95% CI)	4.21 (0.93, 7.49)	
	p-value	0.0118	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Nervous system disorders	Number of subjects with events, n (%)	112 (31.1)	66 (18.1)
	Number of censored subjects, n (%)	248 (68.9)	299 (81.9)
	Exposure years	673.3	455.0
	EAIR per 100 PY	16.6	14.5
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	77.86 (51.71, 110.3)	119.1 (73.57, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.35 (0.99, 1.84)	
	p-value	0.0555	
	Relative Risk (95% CI)	1.72 (1.32, 2.25)	
	p-value	<.0001	
	Odds Ratio (95% CI)	2.05 (1.45, 2.90)	
	p-value	<.0001	
	Risk Difference (95% CI)	13.03 (6.83, 19.23)	
	p-value	<.0001	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Nervous system disorders, PT: Dizziness	Number of subjects with events, n (%)	13 (3.6)	12 (3.3)
	Number of censored subjects, n (%)	347 (96.4)	353 (96.7)
	Exposure years	851.3	514.9
	EAIR per 100 PY	1.5	2.3
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.80 (0.36, 1.79)	
	p-value	0.5876	
	Relative Risk (95% CI)	1.10 (0.51, 2.37)	
	p-value	0.8115	
	Odds Ratio (95% CI)	1.10 (0.50, 2.45)	
	p-value	0.8115	
	Risk Difference (95% CI)	0.32 (-2.33, 2.98)	
	p-value	0.8114	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Nervous system disorders, PT: Headache	Number of subjects with events, n (%)	42 (11.7)	39 (10.7)
	Number of censored subjects, n (%)	318 (88.3)	326 (89.3)
	Exposure years	794.6	484.3
	EAIR per 100 PY	5.3	8.1
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (156.6, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.82 (0.53, 1.29)	
	p-value	0.3922	
	Relative Risk (95% CI)	1.09 (0.72, 1.65)	
	p-value	0.6749	
	Odds Ratio (95% CI)	1.10 (0.70, 1.75)	
	p-value	0.6749	
	Risk Difference (95% CI)	0.98 (-3.61, 5.57)	
	p-value	0.6749	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Psychiatric disorders	Number of subjects with events, n (%)	39 (10.8)	43 (11.8)
	Number of censored subjects, n (%)	321 (89.2)	322 (88.2)
	Exposure years	806.9	481.9
	EAIR per 100 PY	4.8	8.9
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (197.7, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.70 (0.45, 1.09)	
	p-value	0.1130	
	Relative Risk (95% CI)	0.92 (0.61, 1.38)	
	p-value	0.6873	
	Odds Ratio (95% CI)	0.91 (0.57, 1.44)	
	p-value	0.6872	
	Risk Difference (95% CI)	-0.95 (-5.56, 3.66)	
	p-value	0.6870	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Psychiatric disorders, PT: Anxiety	Number of subjects with events, n (%)	12 (3.3)	8 (2.2)
	Number of censored subjects, n (%)	348 (96.7)	357 (97.8)
	Exposure years	849.0	519.8
	EAIR per 100 PY	1.4	1.5
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.25 (0.50, 3.09)	
	p-value	0.6309	
	Relative Risk (95% CI)	1.52 (0.63, 3.68)	
	p-value	0.3519	
	Odds Ratio (95% CI)	1.54 (0.62, 3.81)	
	p-value	0.3515	
	Risk Difference (95% CI)	1.14 (-1.24, 3.53)	
	p-value	0.3485	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Psychiatric disorders, PT: Depression	Number of subjects with events, n (%)	17 (4.7)	12 (3.3)
	Number of censored subjects, n (%)	343 (95.3)	353 (96.7)
	Exposure years	846.7	508.1
	EAIR per 100 PY	2.0	2.4
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.05 (0.49, 2.23)	
	p-value	0.9018	
	Relative Risk (95% CI)	1.44 (0.70, 2.96)	
	p-value	0.3273	
	Odds Ratio (95% CI)	1.46 (0.69, 3.10)	
	p-value	0.3269	
	Risk Difference (95% CI)	1.43 (-1.42, 4.29)	
	p-value	0.3246	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Psychiatric disorders, PT: Insomnia	Number of subjects with events, n (%)	12 (3.3)	18 (4.9)
	Number of censored subjects, n (%)	348 (96.7)	347 (95.1)
	Exposure years	856.7	513.9
	EAIR per 100 PY	1.4	3.5
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.50 (0.24, 1.05)	
	p-value	0.0611	
	Relative Risk (95% CI)	0.68 (0.33, 1.38)	
	p-value	0.2835	
	Odds Ratio (95% CI)	0.66 (0.32, 1.40)	
	p-value	0.2830	
	Risk Difference (95% CI)	-1.60 (-4.49, 1.30)	
	p-value	0.2790	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Renal and urinary disorders	Number of subjects with events, n (%)	33 (9.2)	20 (5.5)
	Number of censored subjects, n (%)	327 (90.8)	345 (94.5)
	Exposure years	832.7	513.6
	EAIR per 100 PY	4.0	3.9
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.14 (0.64, 2.01)	
	p-value	0.6558	
	Relative Risk (95% CI)	1.67 (0.98, 2.86)	
	p-value	0.0599	
	Odds Ratio (95% CI)	1.74 (0.98, 3.10)	
	p-value	0.0591	
	Risk Difference (95% CI)	3.69 (-0.10, 7.47)	
	p-value	0.0563	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Reproductive system and breast disorders	Number of subjects with events, n (%)	42 (11.7)	22 (6.0)
	Number of censored subjects, n (%)	318 (88.3)	343 (94.0)
	Exposure years	807.5	503.4
	EAIR per 100 PY	5.2	4.4
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.31 (0.78, 2.22)	
	p-value	0.3076	
	Relative Risk (95% CI)	1.94 (1.18, 3.17)	
	p-value	0.0089	
	Odds Ratio (95% CI)	2.06 (1.20, 3.53)	
	p-value	0.0085	
	Risk Difference (95% CI)	5.64 (1.52, 9.76)	
	p-value	0.0073	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with events, n (%)	81 (22.5)	63 (17.3)
	Number of censored subjects, n (%)	279 (77.5)	302 (82.7)
	Exposure years	746.7	467.6
	EAIR per 100 PY	10.8	13.5
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	136.7 (83.86, NE)	155.6 (104.6, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.01 (0.72, 1.41)	
	p-value	0.9713	
	Relative Risk (95% CI)	1.30 (0.97, 1.75)	
	p-value	0.0785	
	Odds Ratio (95% CI)	1.39 (0.96, 2.01)	
	p-value	0.0778	
	Risk Difference (95% CI)	5.24 (-0.56, 11.04)	
	p-value	0.0766	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Respiratory, thoracic and mediastinal disorders, PT: Cough	Number of subjects with events, n (%)	32 (8.9)	14 (3.8)
	Number of censored subjects, n (%)	328 (91.1)	351 (96.2)
	Exposure years	809.5	514.5
	EAIR per 100 PY	4.0	2.7
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.89 (1.00, 3.57)	
	p-value	0.0465	
	Relative Risk (95% CI)	2.32 (1.26, 4.27)	
	p-value	0.0070	
	Odds Ratio (95% CI)	2.45 (1.28, 4.67)	
	p-value	0.0066	
	Risk Difference (95% CI)	5.05 (1.51, 8.59)	
	p-value	0.0051	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Skin and subcutaneous tissue disorders	Number of subjects with events, n (%)	83 (23.1)	51 (14.0)
	Number of censored subjects, n (%)	277 (76.9)	314 (86.0)
	Exposure years	740.2	474.1
	EAIR per 100 PY	11.2	10.8
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	146.1 (87.71, NE)	170.1 (102.9, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.27 (0.89, 1.81)	
	p-value	0.1906	
	Relative Risk (95% CI)	1.65 (1.20, 2.27)	
	p-value	0.0020	
	Odds Ratio (95% CI)	1.84 (1.26, 2.71)	
	p-value	0.0018	
	Risk Difference (95% CI)	9.08 (3.46, 14.70)	
	p-value	0.0015	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Skin and subcutaneous tissue disorders, PT: Rash	Number of subjects with events, n (%)	8 (2.2)	10 (2.7)
	Number of censored subjects, n (%)	352 (97.8)	355 (97.3)
	Exposure years	860.7	514.7
	EAIR per 100 PY	0.9	1.9
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.45 (0.17, 1.16)	
	p-value	0.0918	
	Relative Risk (95% CI)	0.81 (0.32, 2.03)	
	p-value	0.6550	
	Odds Ratio (95% CI)	0.81 (0.31, 2.07)	
	p-value	0.6549	
	Risk Difference (95% CI)	-0.52 (-2.78, 1.75)	
	p-value	0.6541	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Vascular disorders	Number of subjects with events, n (%)	26 (7.2)	27 (7.4)
	Number of censored subjects, n (%)	334 (92.8)	338 (92.6)
	Exposure years	833.8	496.1
	EAIR per 100 PY	3.1	5.4
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (172.0, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.58 (0.33, 1.01)	
	p-value	0.0516	
	Relative Risk (95% CI)	0.98 (0.58, 1.64)	
	p-value	0.9279	
	Odds Ratio (95% CI)	0.97 (0.56, 1.70)	
	p-value	0.9279	
	Risk Difference (95% CI)	-0.18 (-3.96, 3.61)	
	p-value	0.9279	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Vascular disorders, PT: Hypertension	Number of subjects with events, n (%)	14 (3.9)	15 (4.1)
	Number of censored subjects, n (%)	346 (96.1)	350 (95.9)
	Exposure years	852.0	511.6
	EAIR per 100 PY	1.6	2.9
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.57 (0.27, 1.20)	
	p-value	0.1324	
	Relative Risk (95% CI)	0.95 (0.46, 1.93)	
	p-value	0.8795	
	Odds Ratio (95% CI)	0.94 (0.45, 1.99)	
	p-value	0.8795	
	Risk Difference (95% CI)	-0.22 (-3.07, 2.63)	
	p-value	0.8795	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Ramdomised ANI300 (N=360) Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Randomised Placebo (N=365) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
SOC: Cardiac disorders	Age (years)							0.9879
	<= 65	15/348 (4.3)	NE (NE, NE)	20/361 (5.5)	NE (NE, NE)	0.45 (0.23, 0.90)	0.0209	
	> 65	0/ 12 (0.0)	NE (NE, NE)	1/ 4 (25.0)	NE (48.71, NE)	NE		
	Sex							0.1604
	male	4/ 27 (14.8)	NE (NE, NE)	2/ 25 (8.0)	NE (115.43, NE)	1.20 (0.22, 6.69)	0.8344	
	female	11/333 (3.3)	NE (NE, NE)	19/340 (5.6)	NE (NE, NE)	0.34 (0.16, 0.74)	0.0044	
	Geographic region							0.0641
	EU	8/115 (7.0)	NE (NE, NE)	5/122 (4.1)	NE (NE, NE)	0.92 (0.29, 2.89)	0.8814	
	non-EU	7/245 (2.9)	NE (NE, NE)	16/243 (6.6)	NE (NE, NE)	0.26 (0.10, 0.65)	0.0021	
	SLEDAI-2K score at screening							0.0356
	< 10 points	2/109 (1.8)	NE (NE, NE)	10/106 (9.4)	NE (NE, NE)	0.10 (0.02, 0.44)	0.0003	
	>= 10 points	13/251 (5.2)	NE (NE, NE)	11/259 (4.2)	NE (NE, NE)	0.77 (0.34, 1.76)	0.5392	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Ramdomised ANI300 (N=360) Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Randomised Placebo (N=365) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
SOC: Gastrointestinal disorders, PT: Dyspepsia	Age (years)							0.9930
	<= 65	2/348 (0.6)	NE (NE, NE)	10/361 (2.8)	NE (NE, NE)	0.14 (0.03, 0.66)	0.0042	
	> 65	2/ 12 (16.7)	NE (97.57, NE)	0/ 4 (0.0)	NE (NE, NE)	NE		
	Sex							0.9927
	male	0/ 27 (0.0)	NE (NE, NE)	1/ 25 (4.0)	NE (NE, NE)	NE		
	female	4/333 (1.2)	NE (NE, NE)	9/340 (2.6)	NE (NE, NE)	0.30 (0.09, 1.00)	0.0388	
	Geographic region							0.9921
	EU	0/115 (0.0)	NE (NE, NE)	1/122 (0.8)	NE (NE, NE)	NE		
	non-EU	4/245 (1.6)	NE (NE, NE)	9/243 (3.7)	NE (NE, NE)	0.29 (0.09, 0.97)	0.0336	
	SLEDAI-2K score at screening							0.9887
	< 10 points	0/109 (0.0)	NE (NE, NE)	7/106 (6.6)	NE (NE, NE)	NE		
	>= 10 points	4/251 (1.6)	NE (NE, NE)	3/259 (1.2)	NE (NE, NE)	1.06 (0.23, 4.89)	0.9384	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	p-Value	Interaction p-Value
SOC: Gastrointestinal disorders, PT: Gastritis	Age (years)							0.9997
	<= 65	5/348 (1.4)	NE (NE, NE)	11/361 (3.0)	NE (NE, NE)	0.34 (0.11, 0.99)	0.0387	
	> 65	0/ 12 (0.0)	NE (NE, NE)	0/ 4 (0.0)	NE (NE, NE)	NE		
	Sex							0.9928
	male	0/ 27 (0.0)	NE (NE, NE)	2/ 25 (8.0)	NE (NE, NE)	NE		
	female	5/333 (1.5)	NE (NE, NE)	9/340 (2.6)	NE (NE, NE)	0.39 (0.13, 1.18)	0.0856	
	Geographic region							0.9913
	EU	0/115 (0.0)	NE (NE, NE)	1/122 (0.8)	NE (NE, NE)	NE		
	non-EU	5/245 (2.0)	NE (NE, NE)	10/243 (4.1)	NE (NE, NE)	0.35 (0.12, 1.05)	0.0517	
	SLEDAI-2K score at screening							0.1970
	< 10 points	1/109 (0.9)	NE (NE, NE)	6/106 (5.7)	NE (NE, NE)	0.11 (0.01, 0.93)	0.0160	
	>= 10 points	4/251 (1.6)	NE (NE, NE)	5/259 (1.9)	NE (NE, NE)	0.61 (0.16, 2.34)	0.4663	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Ramdomised ANI300 (N=360) Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Randomised Placebo (N=365) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
SOC: Immune system disorders	Age (years)							0.9845
	<= 65	26/348 (7.5)	NE (NE, NE)	12/361 (3.3)	NE (NE, NE)	1.80 (0.90, 3.61)	0.0924	
	> 65	5/ 12 (41.7)	NE (4.00, NE)	0/ 4 (0.0)	NE (NE, NE)	NE		
	Sex							0.1401
	male	1/ 27 (3.7)	NE (NE, NE)	2/ 25 (8.0)	NE (104.29, NE)	0.34 (0.03, 3.96)	0.3703	
	female	30/333 (9.0)	NE (NE, NE)	10/340 (2.9)	NE (NE, NE)	2.56 (1.24, 5.29)	0.0084	
	Geographic region							0.8885
	EU	7/115 (6.1)	NE (NE, NE)	3/122 (2.5)	NE (NE, NE)	1.93 (0.49, 7.66)	0.3431	
	non-EU	24/245 (9.8)	NE (NE, NE)	9/243 (3.7)	NE (NE, NE)	2.25 (1.04, 4.87)	0.0356	
	SLEDAI-2K score at screening							0.3192
	< 10 points	13/109 (11.9)	NE (NE, NE)	3/106 (2.8)	NE (NE, NE)	4.02 (1.14, 14.19)	0.0197	
	>= 10 points	18/251 (7.2)	NE (NE, NE)	9/259 (3.5)	NE (NE, NE)	1.59 (0.71, 3.59)	0.2585	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Ramdomised ANI300 (N=360) Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Randomised Placebo (N=365) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
SOC: Immune system disorders, PT: Hypersensitivity	Age (years)							0.9925
	<= 65	13/348 (3.7)	NE (NE, NE)	3/361 (0.8)	NE (NE, NE)	3.93 (1.11, 13.89)	0.0225	
	> 65	3/ 12 (25.0)	NE (4.00, NE)	0/ 4 (0.0)	NE (NE, NE)	NE		
	Sex							0.1871
	male	1/ 27 (3.7)	NE (NE, NE)	1/ 25 (4.0)	NE (NE, NE)	0.94 (0.06, 15.05)	0.9659	
	female	15/333 (4.5)	NE (NE, NE)	2/340 (0.6)	NE (NE, NE)	6.80 (1.55, 29.92)	0.0034	
	Geographic region							0.9904
	EU	4/115 (3.5)	NE (NE, NE)	0/122 (0.0)	NE (NE, NE)	NE		
	non-EU	12/245 (4.9)	NE (NE, NE)	3/243 (1.2)	NE (NE, NE)	3.44 (0.96, 12.33)	0.0437	
	SLEDAI-2K score at screening							0.9139
	< 10 points	6/109 (5.5)	NE (NE, NE)	1/106 (0.9)	NE (NE, NE)	5.97 (0.72, 49.60)	0.0597	
	>= 10 points	10/251 (4.0)	NE (NE, NE)	2/259 (0.8)	NE (NE, NE)	4.27 (0.92, 19.74)	0.0435	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Ramdomised ANI300 (N=360) Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Randomised Placebo (N=365) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
SOC: Infections and infestations	Age (years)							0.5287
	<= 65	278/348 (79.9)	21.43 (17.86, 26.00)	233/361 (64.5)	31.57 (27.71, 39.14)	1.32 (1.11, 1.57)	0.0019	
	> 65	10/ 12 (83.3)	18.07 (6.29, 29.43)	2/ 4 (50.0)	NE (6.43, NE)	2.46 (0.53, 11.39)	0.2381	
	Sex							0.4059
	male	18/ 27 (66.7)	39.14 (20.57, 92.00)	14/ 25 (56.0)	39.14 (16.14, NE)	1.02 (0.51, 2.06)	0.9451	
	female	270/333 (81.1)	20.43 (15.71, 24.14)	221/340 (65.0)	31.57 (27.57, 39.43)	1.36 (1.14, 1.63)	0.0007	
	Geographic region							0.8015
	EU	87/115 (75.7)	27.71 (20.43, 37.29)	69/122 (56.6)	52.29 (34.86, 75.00)	1.35 (0.98, 1.86)	0.0618	
	non-EU	201/245 (82.0)	19.00 (14.43, 23.14)	166/243 (68.3)	27.71 (20.57, 32.29)	1.32 (1.07, 1.62)	0.0088	
	SLEDAI-2K score at screening							0.2977
	< 10 points	88/109 (80.7)	20.71 (14.43, 27.71)	75/106 (70.8)	23.57 (20.00, 32.29)	1.18 (0.87, 1.61)	0.2893	
	>= 10 points	200/251 (79.7)	22.57 (16.14, 27.00)	160/259 (61.8)	36.14 (28.43, 46.29)	1.40 (1.14, 1.73)	0.0014	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Ramdomised ANI300 (N=360) Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Randomised Placebo (N=365) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Bronchitis	Age (years)							0.4815
	<= 65	63/348 (18.1)	NE (NE, NE)	23/361 (6.4)	NE (NE, NE)	2.13 (1.31, 3.45)	0.0018	
	> 65	4/ 12 (33.3)	NE (29.43, NE)	1/ 4 (25.0)	NE (49.14, NE)	1.23 (0.13, 11.91)	0.8566	
	Sex							0.9846
	male	2/ 27 (7.4)	NE (NE, NE)	0/ 25 (0.0)	NE (NE, NE)	NE		
	female	65/333 (19.5)	NE (NE, NE)	24/340 (7.1)	NE (NE, NE)	2.09 (1.30, 3.36)	0.0019	
	Geographic region							0.0912
	EU	20/115 (17.4)	NE (NE, NE)	3/122 (2.5)	NE (NE, NE)	5.95 (1.76, 20.12)	0.0012	
	non-EU	47/245 (19.2)	NE (NE, NE)	21/243 (8.6)	NE (NE, NE)	1.59 (0.94, 2.69)	0.0783	
	SLEDAI-2K score at screening							0.0035
	< 10 points	18/109 (16.5)	NE (NE, NE)	14/106 (13.2)	NE (NE, NE)	0.85 (0.41, 1.73)	0.6476	
	>= 10 points	49/251 (19.5)	NE (NE, NE)	10/259 (3.9)	NE (NE, NE)	4.00 (2.01, 7.93)	<.0001	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Ramdomised ANI300 (N=360) Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Randomised Placebo (N=365) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Herpes zoster	Age (years)							0.9996
	<= 65	40/348 (11.5)	NE (NE, NE)	11/361 (3.0)	NE (NE, NE)	2.62 (1.33, 5.16)	0.0039	
	> 65	0/ 12 (0.0)	NE (NE, NE)	0/ 4 (0.0)	NE (NE, NE)	NE		
	Sex							0.9137
	male	4/ 27 (14.8)	NE (NE, NE)	1/ 25 (4.0)	NE (60.57, NE)	2.91 (0.32, 26.64)	0.3225	
	female	36/333 (10.8)	NE (NE, NE)	10/340 (2.9)	NE (NE, NE)	2.49 (1.22, 5.09)	0.0097	
	Geographic region							0.1259
	EU	9/115 (7.8)	NE (NE, NE)	5/122 (4.1)	NE (NE, NE)	1.18 (0.38, 3.63)	0.7722	
	non-EU	31/245 (12.7)	NE (NE, NE)	6/243 (2.5)	NE (NE, NE)	3.71 (1.53, 9.01)	0.0019	
	SLEDAI-2K score at screening							0.7000
	< 10 points	10/109 (9.2)	NE (NE, NE)	2/106 (1.9)	NE (NE, NE)	2.94 (0.63, 13.76)	0.1523	
	>= 10 points	30/251 (12.0)	NE (NE, NE)	9/259 (3.5)	NE (NE, NE)	2.46 (1.16, 5.25)	0.0162	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Ramdomised ANI300 (N=360) Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Randomised Placebo (N=365) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Nasopharyngitis	Age (years)							0.9804
	<= 65	91/348 (26.1)	NE (NE, NE)	51/361 (14.1)	NE (NE, NE)	1.54 (1.09, 2.18)	0.0142	
	> 65	4/ 12 (33.3)	198.29 (15.57, NE)	0/ 4 (0.0)	NE (NE, NE)	NE		
	Sex							0.1030
	male	4/ 27 (14.8)	NE (NE, NE)	5/ 25 (20.0)	NE (145.71, NE)	0.58 (0.15, 2.22)	0.4206	
	female	91/333 (27.3)	NE (NE, NE)	46/340 (13.5)	NE (NE, NE)	1.68 (1.17, 2.41)	0.0042	
	Geographic region							0.1661
	EU	31/115 (27.0)	NE (NE, NE)	22/122 (18.0)	NE (NE, NE)	1.16 (0.67, 2.03)	0.5922	
	non-EU	64/245 (26.1)	NE (NE, NE)	29/243 (11.9)	NE (NE, NE)	1.87 (1.20, 2.91)	0.0051	
	SLEDAI-2K score at screening							0.8859
	< 10 points	25/109 (22.9)	NE (NE, NE)	13/106 (12.3)	NE (NE, NE)	1.40 (0.71, 2.78)	0.3313	
	>= 10 points	70/251 (27.9)	NE (NE, NE)	38/259 (14.7)	NE (NE, NE)	1.62 (1.09, 2.42)	0.0166	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Ramdomised ANI300 (N=360) Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Randomised Placebo (N=365) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Respiratory tract infection	Age (years)							0.9996
	<= 65	14/348 (4.0)	NE (NE, NE)	3/361 (0.8)	NE (NE, NE)	4.38 (1.25, 15.31)	0.0117	
	> 65	0/ 12 (0.0)	NE (NE, NE)	0/ 4 (0.0)	NE (NE, NE)	NE		
	Sex							0.4277
	male	2/ 27 (7.4)	NE (NE, NE)	1/ 25 (4.0)	NE (NE, NE)	1.87 (0.17, 20.60)	0.6040	
	female	12/333 (3.6)	NE (NE, NE)	2/340 (0.6)	NE (NE, NE)	5.39 (1.20, 24.22)	0.0141	
	Geographic region							0.9920
	EU	9/115 (7.8)	NE (NE, NE)	0/122 (0.0)	NE (NE, NE)	NE		
	non-EU	5/245 (2.0)	NE (NE, NE)	3/243 (1.2)	NE (NE, NE)	1.51 (0.36, 6.40)	0.5710	
	SLEDAI-2K score at screening							0.9909
	< 10 points	5/109 (4.6)	NE (NE, NE)	0/106 (0.0)	NE (NE, NE)	NE		
	>= 10 points	9/251 (3.6)	NE (NE, NE)	3/259 (1.2)	NE (NE, NE)	2.86 (0.77, 10.64)	0.1002	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Ramdomised ANI300 (N=360) Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Randomised Placebo (N=365) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
SOC: Infections and infestations, PT: Upper respiratory tract infection	Age (years)							0.9813
	<= 65	90/348 (25.9)	NE (208.57, NE)	48/361 (13.3)	NE (NE, NE)	1.49 (1.05, 2.13)	0.0264	
	> 65	4/ 12 (33.3)	199.71 (27.57, NE)	0/ 4 (0.0)	NE (NE, NE)	NE		
	Sex							0.7566
	male	5/ 27 (18.5)	NE (165.71, NE)	3/ 25 (12.0)	NE (82.86, NE)	1.19 (0.28, 5.09)	0.8095	
	female	89/333 (26.7)	NE (208.57, NE)	45/340 (13.2)	NE (NE, NE)	1.56 (1.08, 2.24)	0.0170	
	Geographic region							0.9618
	EU	16/115 (13.9)	NE (208.57, NE)	8/122 (6.6)	NE (NE, NE)	1.29 (0.54, 3.08)	0.5696	
	non-EU	78/245 (31.8)	NE (199.71, NE)	40/243 (16.5)	NE (NE, NE)	1.58 (1.07, 2.33)	0.0194	
	SLEDAI-2K score at screening							0.8769
	< 10 points	33/109 (30.3)	NE (199.71, NE)	16/106 (15.1)	NE (NE, NE)	1.63 (0.89, 2.98)	0.1115	
	>= 10 points	61/251 (24.3)	NE (208.57, NE)	32/259 (12.4)	NE (NE, NE)	1.47 (0.95, 2.28)	0.0801	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Ramdomised ANI300 (N=360) Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Randomised Placebo (N=365) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
SOC: Musculoskeletal and connective tissue disorders, PT: Arthralgia	Age (years)							0.0813
	<= 65	33/348 (9.5)	NE (NE, NE)	12/361 (3.3)	NE (NE, NE)	2.08 (1.06, 4.07)	0.0296	
	> 65	1/ 12 (8.3)	NE (73.00, NE)	1/ 4 (25.0)	NE (23.71, NE)	0.00 (0.00,)	0.1138	
	Sex							0.9879
	male	3/ 27 (11.1)	NE (NE, NE)	0/ 25 (0.0)	NE (NE, NE)	NE		
	female	31/333 (9.3)	NE (NE, NE)	13/340 (3.8)	NE (NE, NE)	1.76 (0.91, 3.41)	0.0893	
	Geographic region							0.9849
	EU	6/115 (5.2)	NE (NE, NE)	0/122 (0.0)	NE (NE, NE)	NE		
	non-EU	28/245 (11.4)	NE (NE, NE)	13/243 (5.3)	NE (NE, NE)	1.52 (0.78, 2.98)	0.2185	
	SLEDAI-2K score at screening							0.0079
	< 10 points	9/109 (8.3)	NE (NE, NE)	9/106 (8.5)	NE (NE, NE)	0.68 (0.26, 1.75)	0.4226	
	>= 10 points	25/251 (10.0)	NE (NE, NE)	4/259 (1.5)	NE (NE, NE)	4.76 (1.64, 13.85)	0.0017	

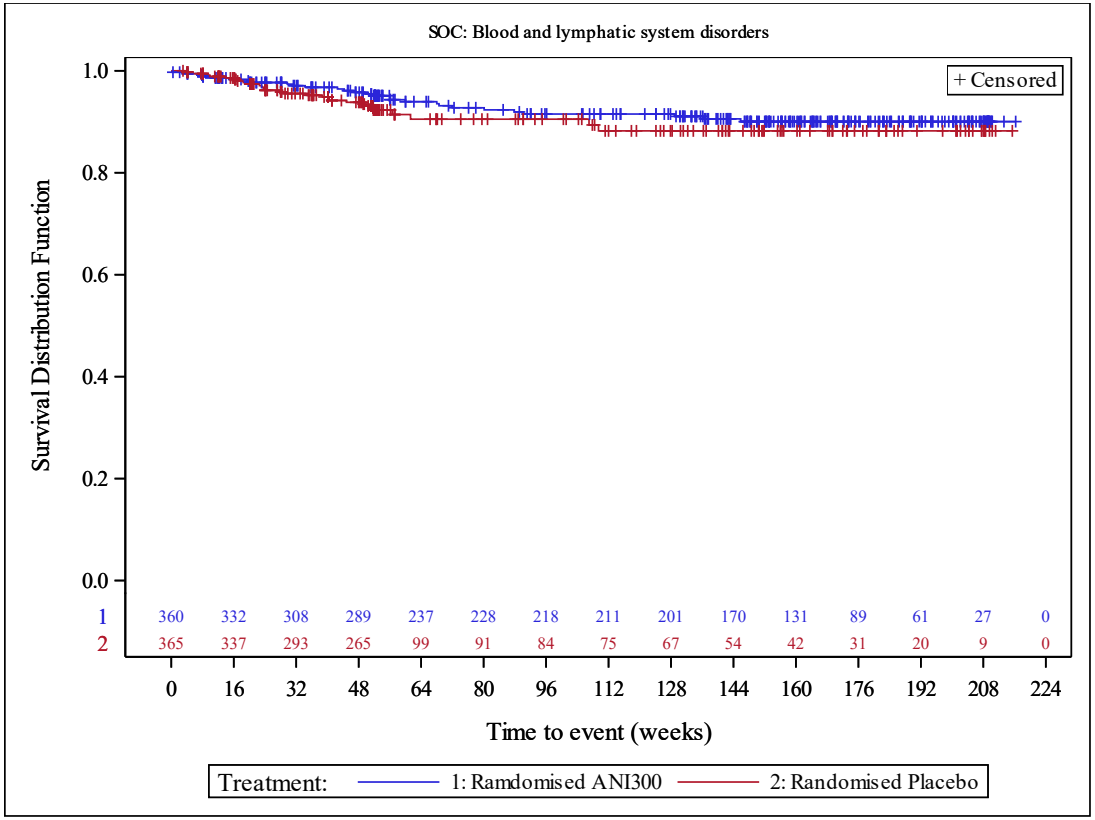
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Ramdomised ANI300 (N=360) Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Randomised Placebo (N=365) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
SOC: Respiratory, thoracic and mediastinal disorders, PT: Cough	Age (years)							0.9897
	<= 65	31/348 (8.9)	NE (NE, NE)	14/361 (3.9)	NE (NE, NE)	1.90 (1.00, 3.60)	0.0451	
	> 65	1/ 12 (8.3)	NE (83.43, NE)	0/ 4 (0.0)	NE (NE, NE)	NE		
	Sex							0.9874
	male	4/ 27 (14.8)	NE (NE, NE)	0/ 25 (0.0)	NE (NE, NE)	NE		
	female	28/333 (8.4)	NE (NE, NE)	14/340 (4.1)	NE (NE, NE)	1.68 (0.87, 3.21)	0.1159	
	Geographic region							0.1402
	EU	9/115 (7.8)	NE (NE, NE)	1/122 (0.8)	NE (NE, NE)	7.51 (0.94, 60.01)	0.0262	
	non-EU	23/245 (9.4)	NE (NE, NE)	13/243 (5.3)	NE (NE, NE)	1.45 (0.73, 2.89)	0.2881	
	SLEDAI-2K score at screening							0.3995
	< 10 points	12/109 (11.0)	NE (NE, NE)	7/106 (6.6)	NE (NE, NE)	1.44 (0.56, 3.71)	0.4446	
	>= 10 points	20/251 (8.0)	NE (NE, NE)	7/259 (2.7)	NE (NE, NE)	2.33 (0.98, 5.57)	0.0502	

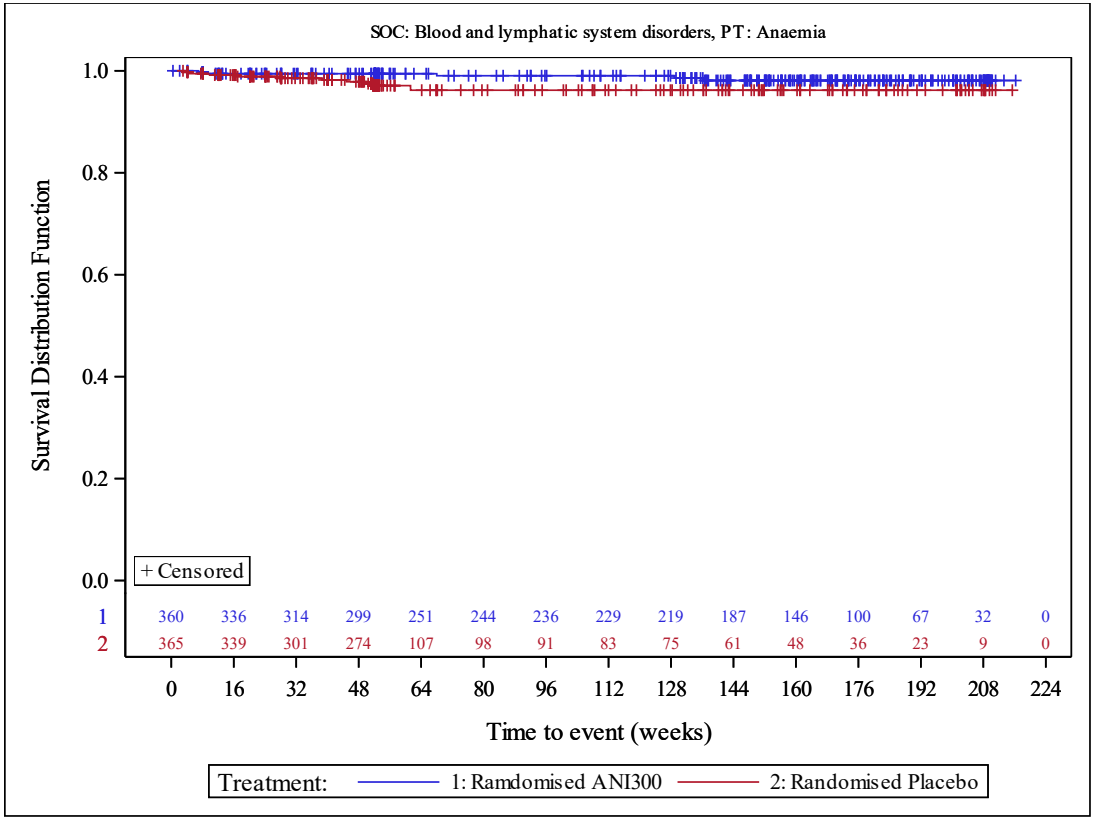
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
Full analysis set



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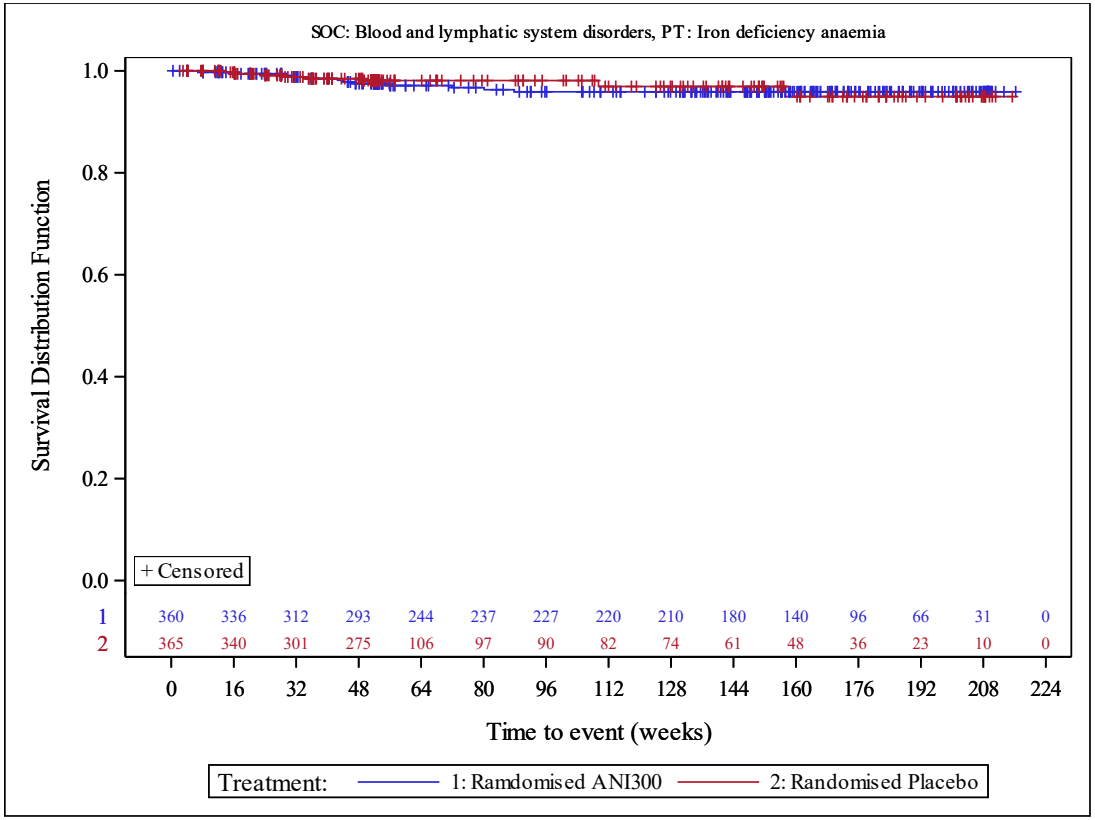

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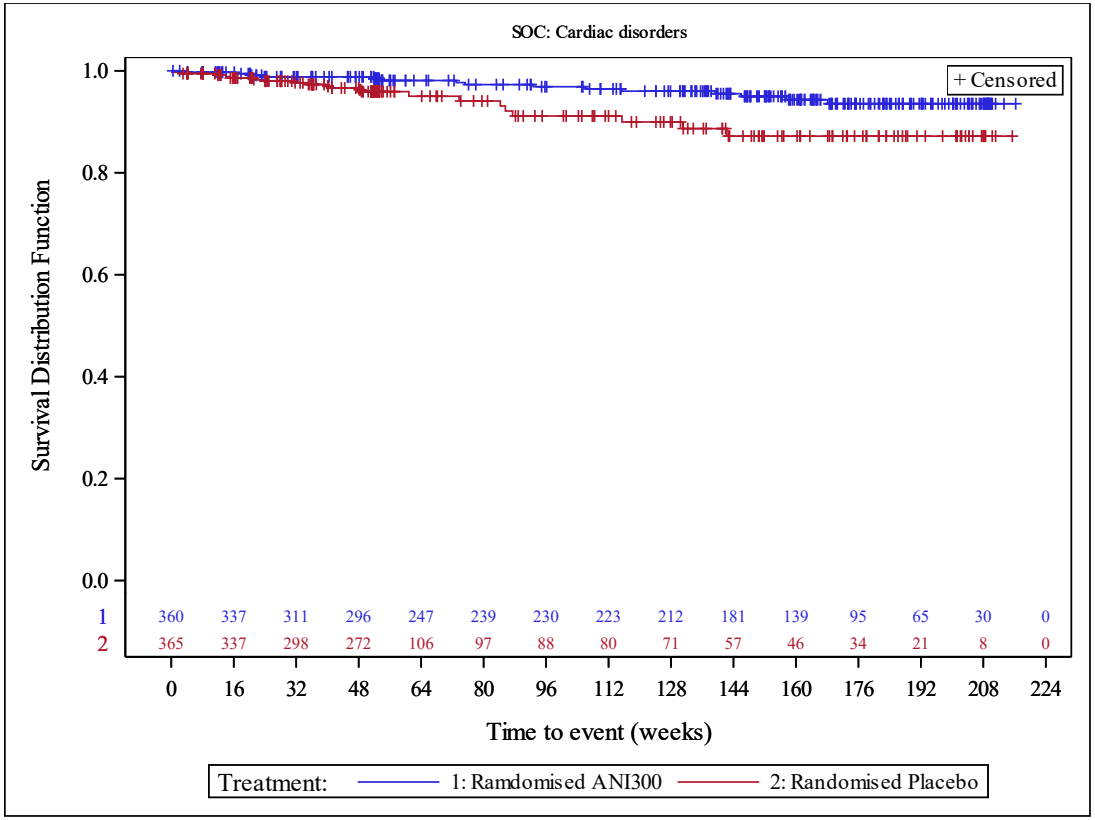

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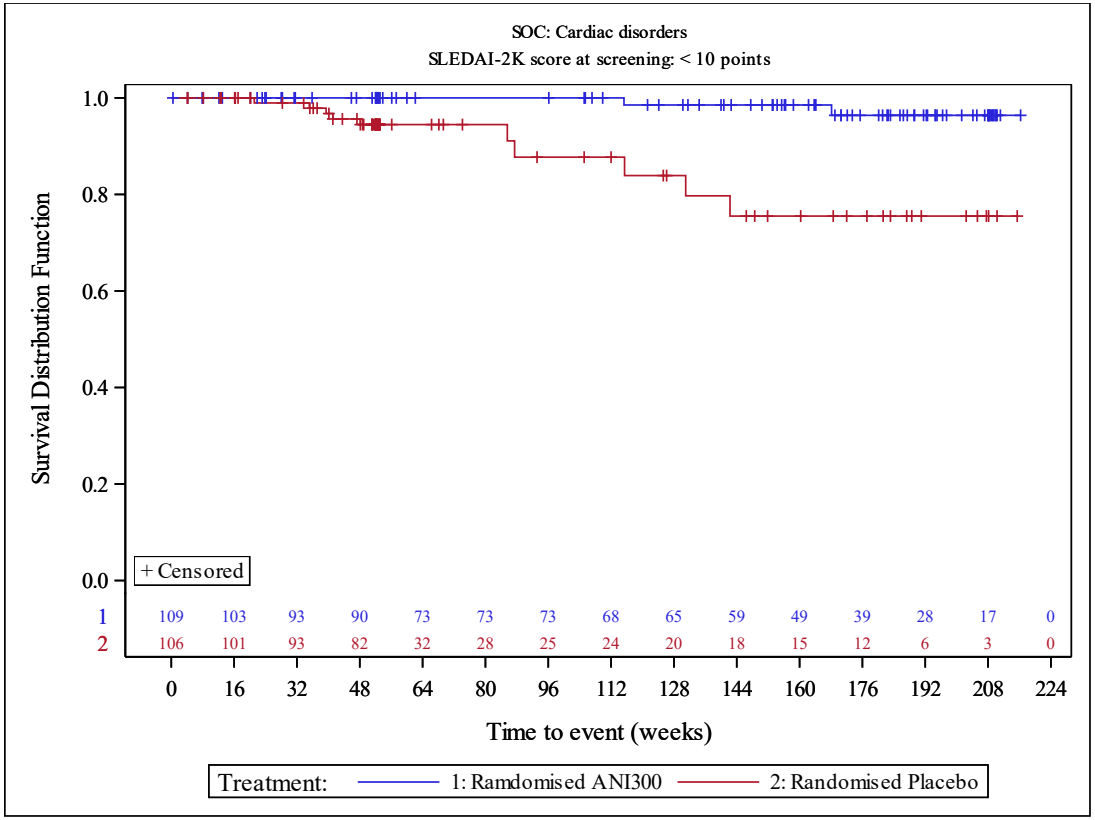

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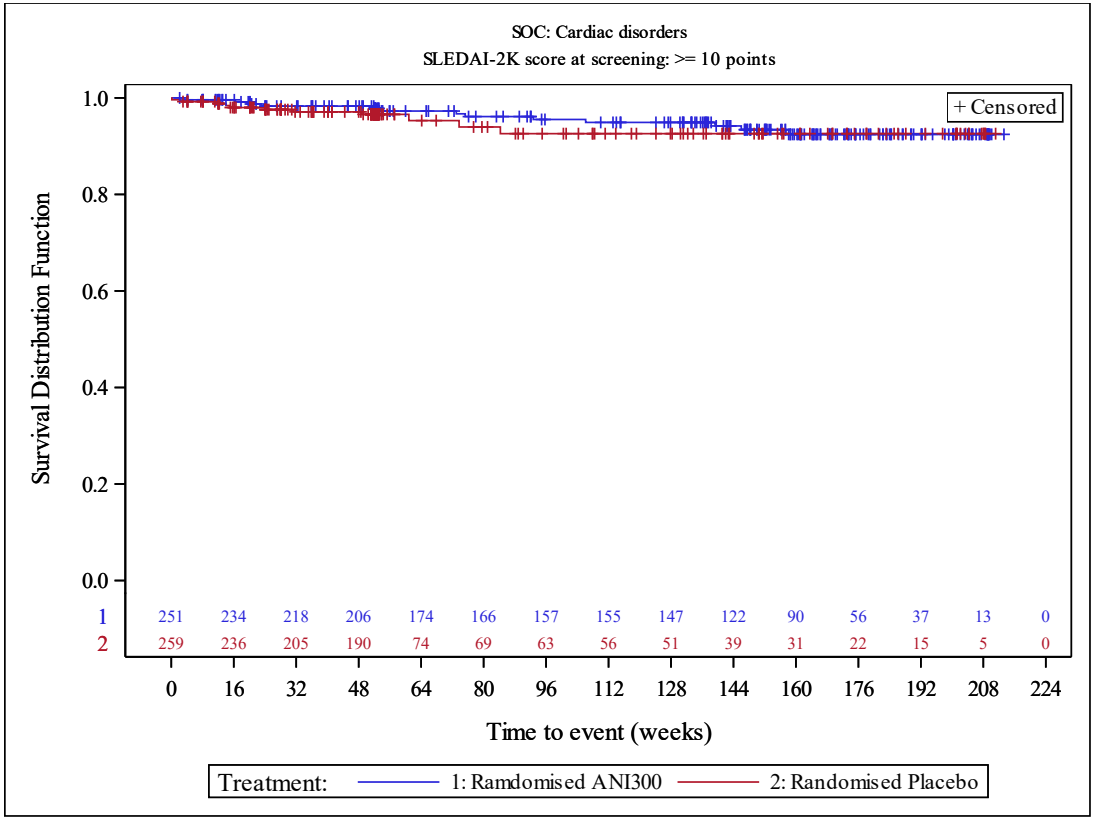

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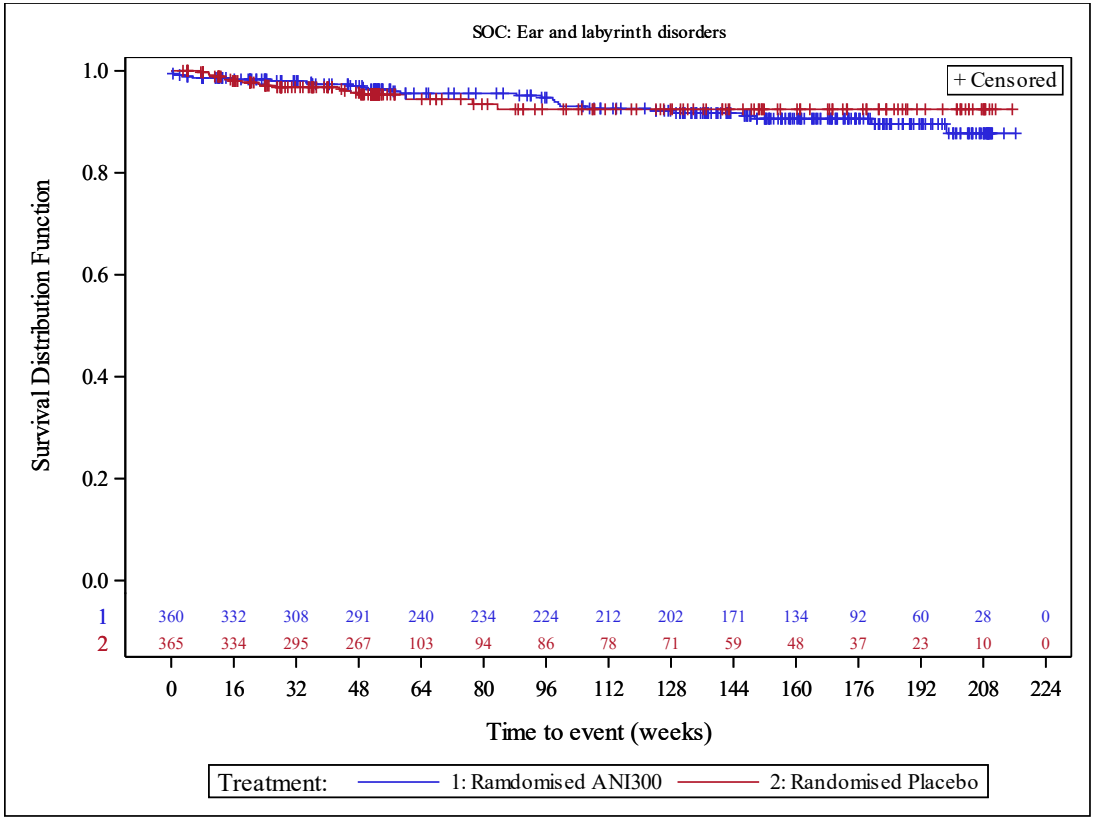

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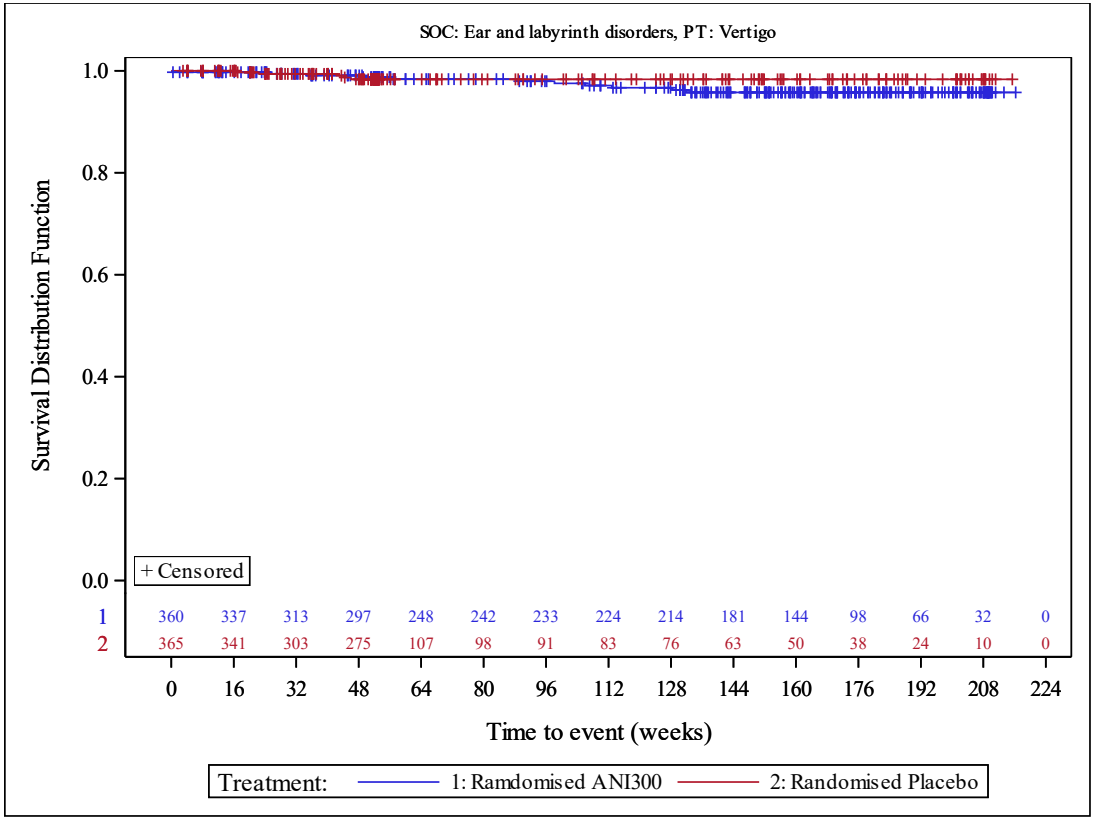

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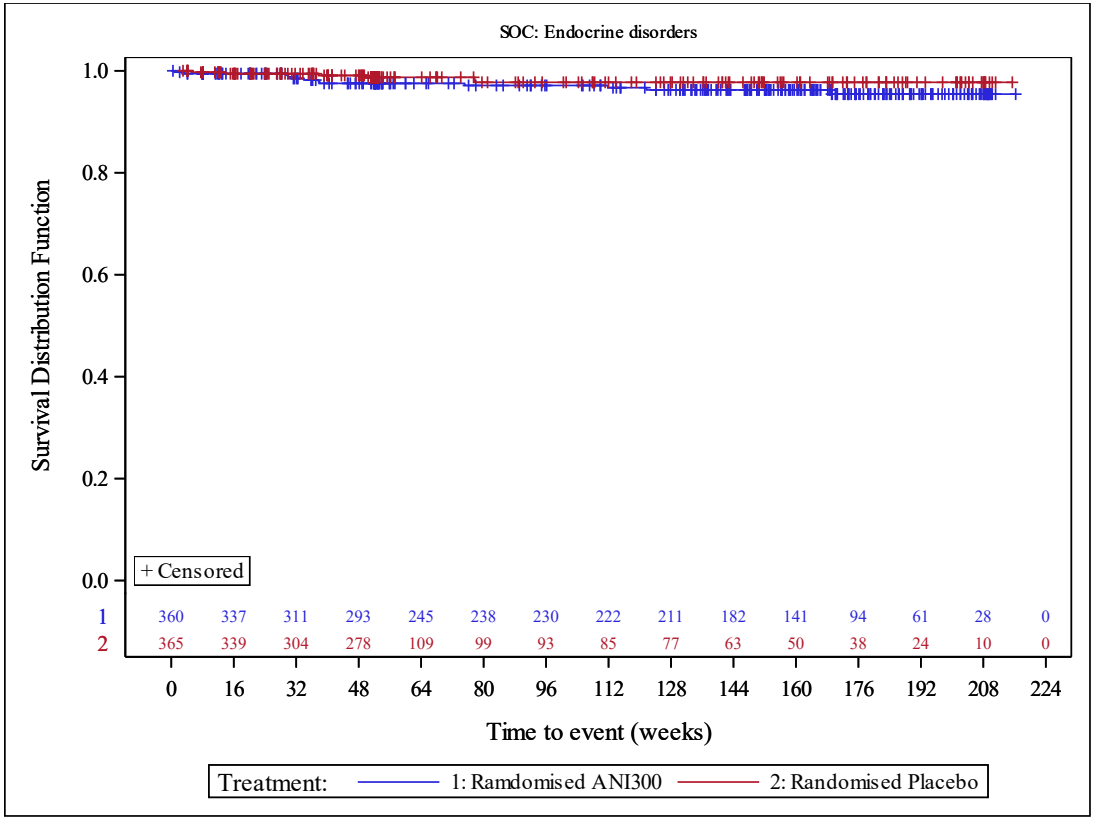

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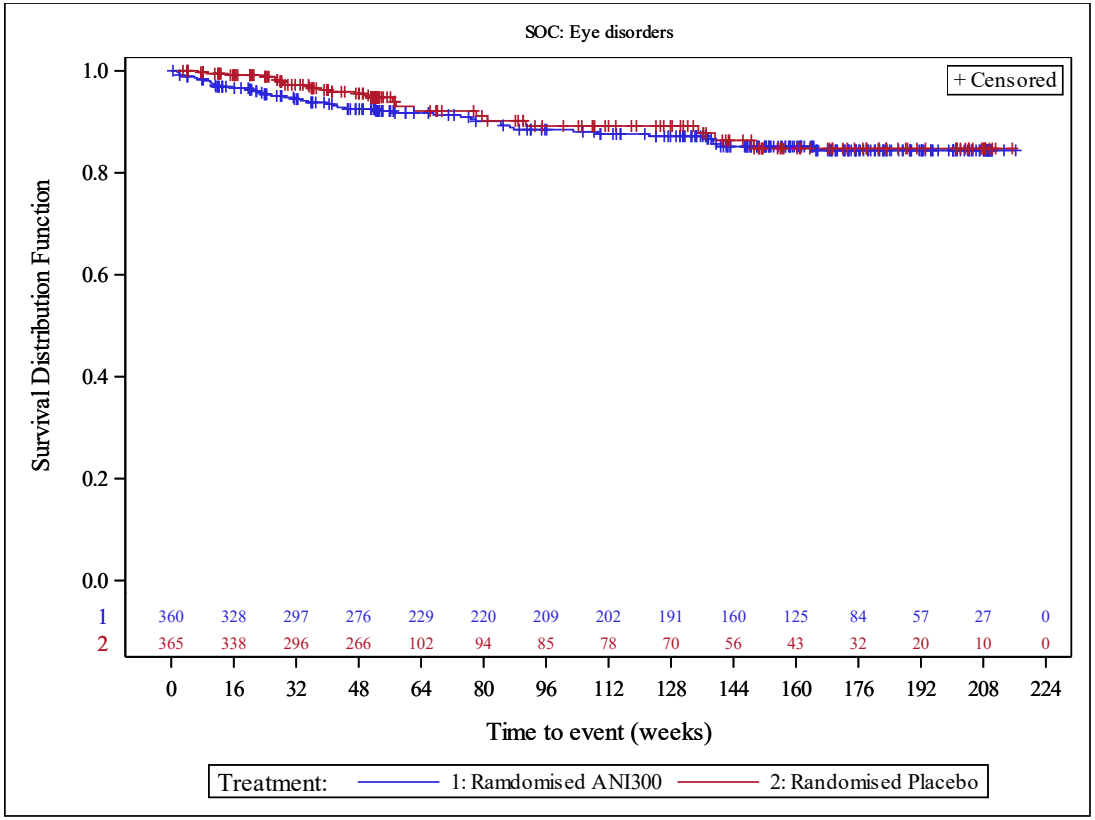

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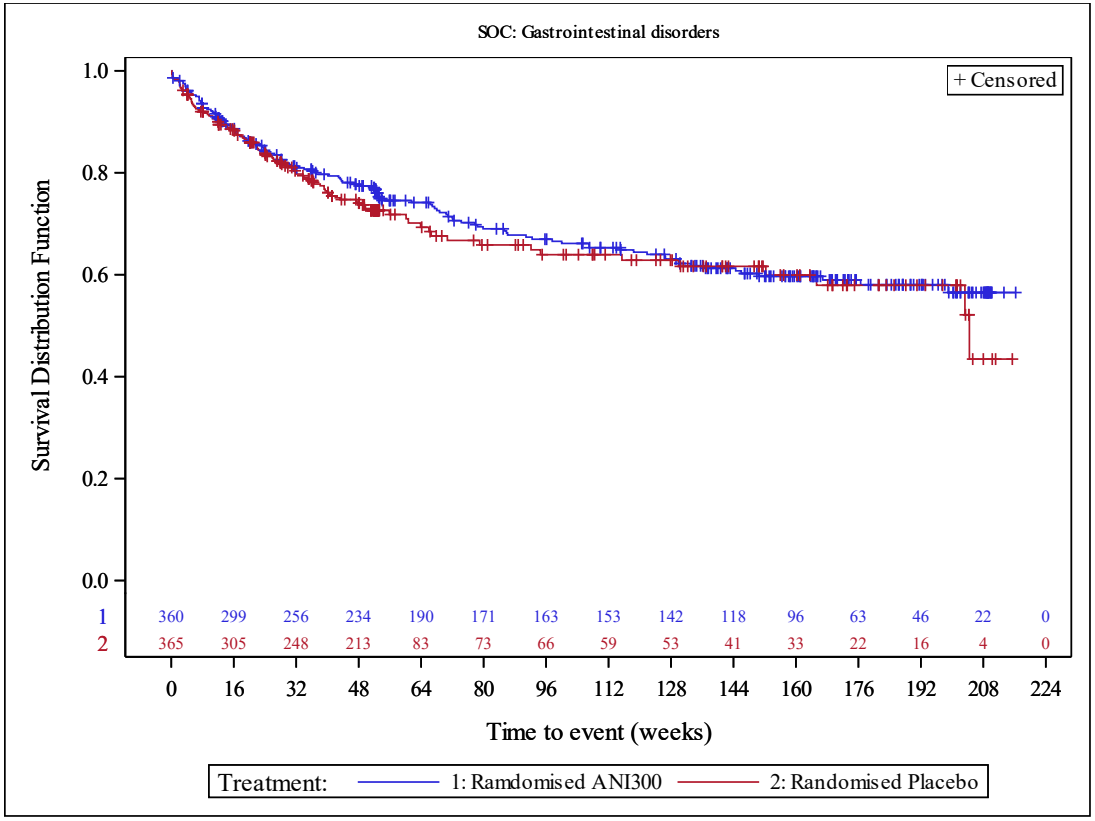

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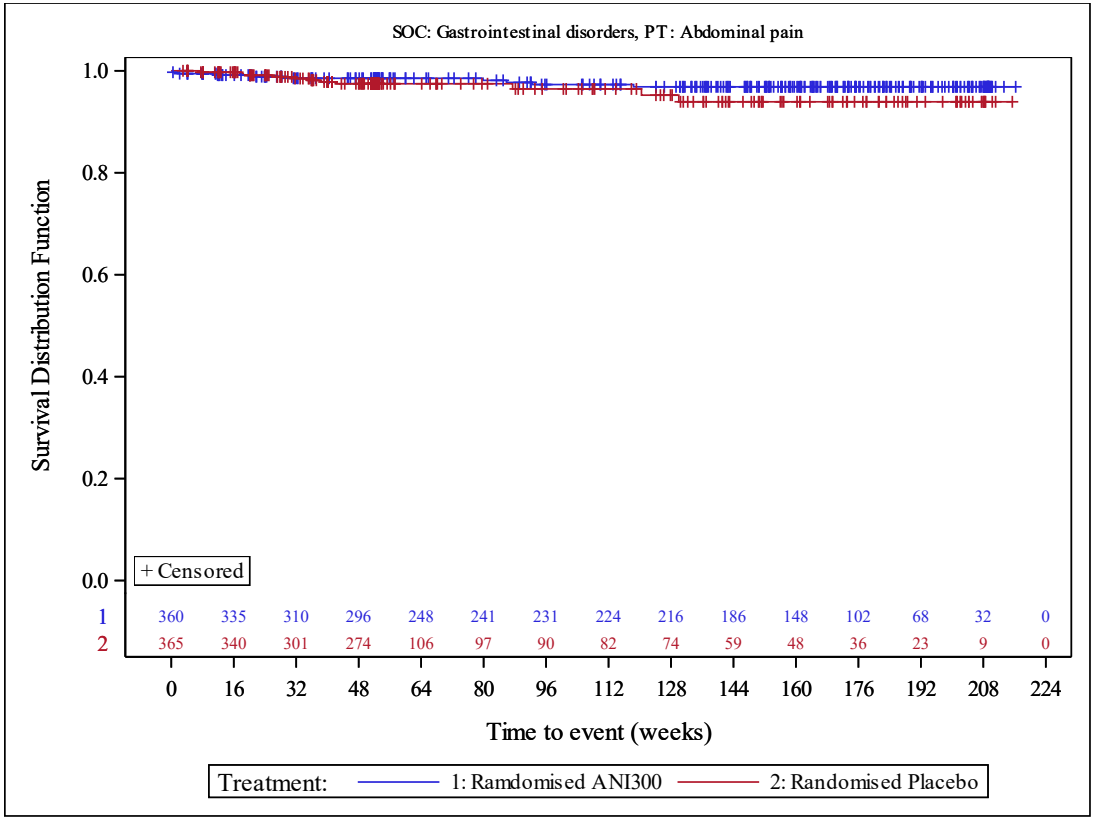

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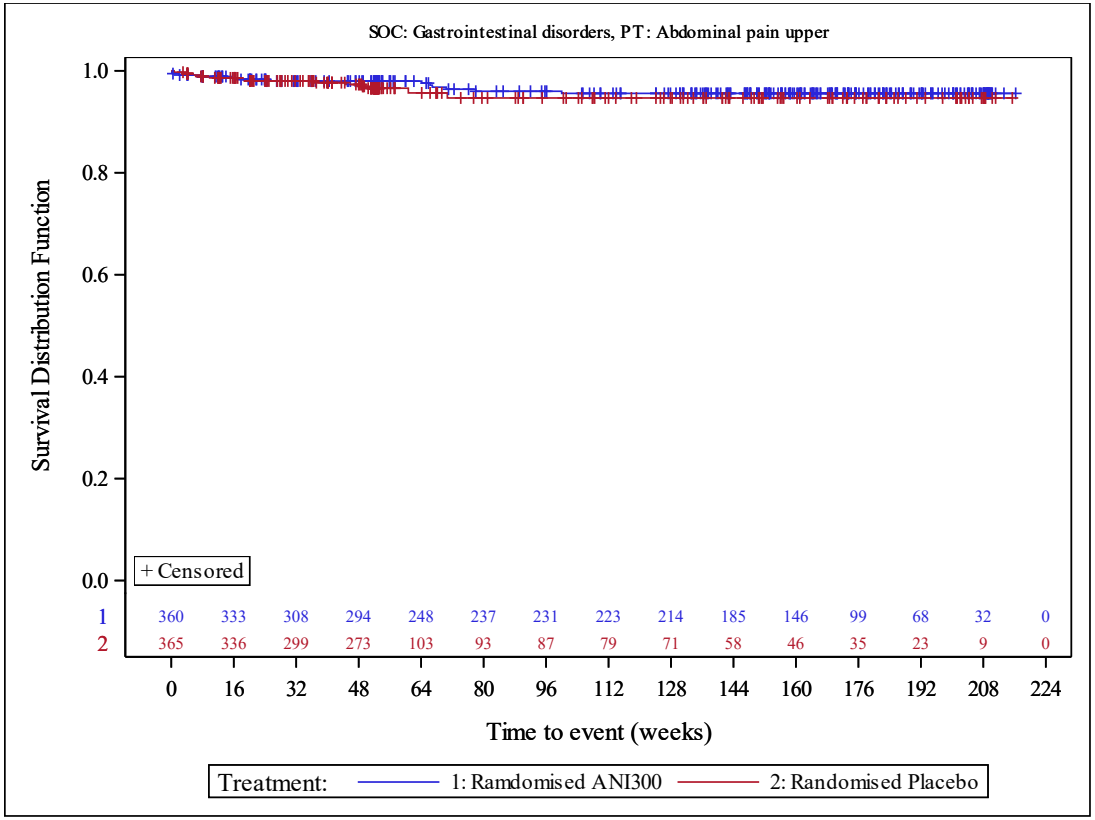

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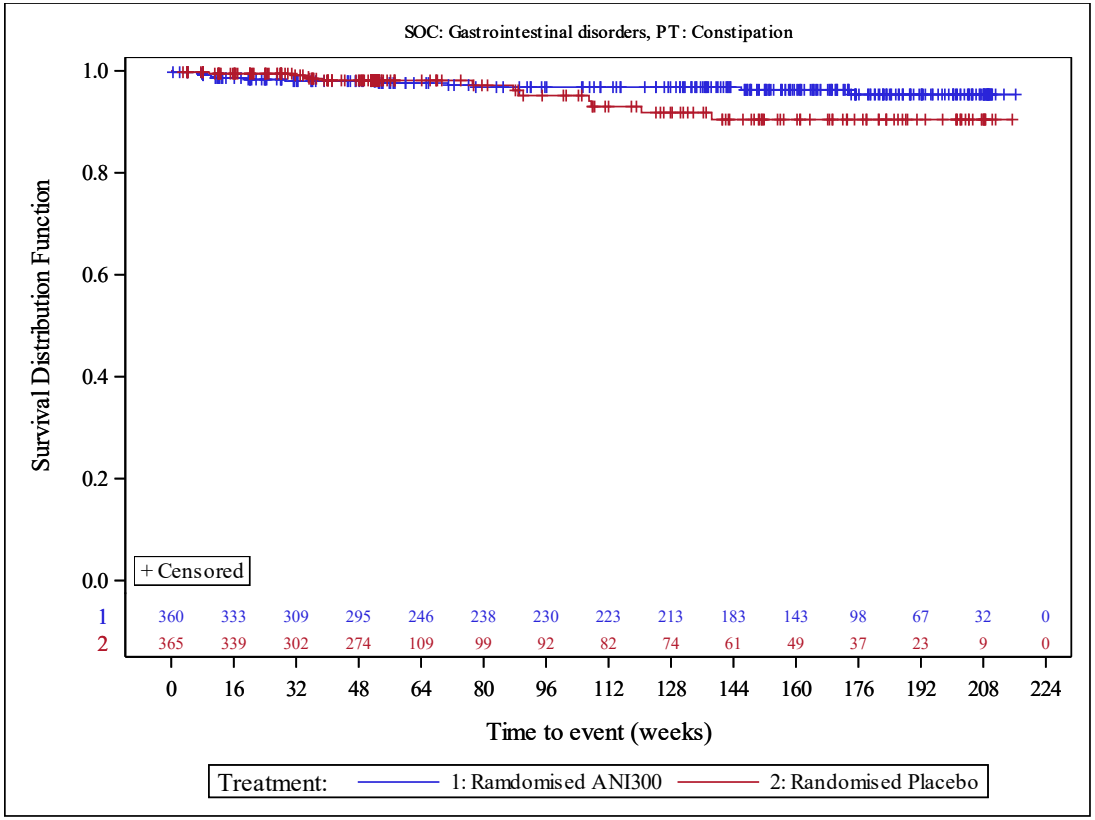

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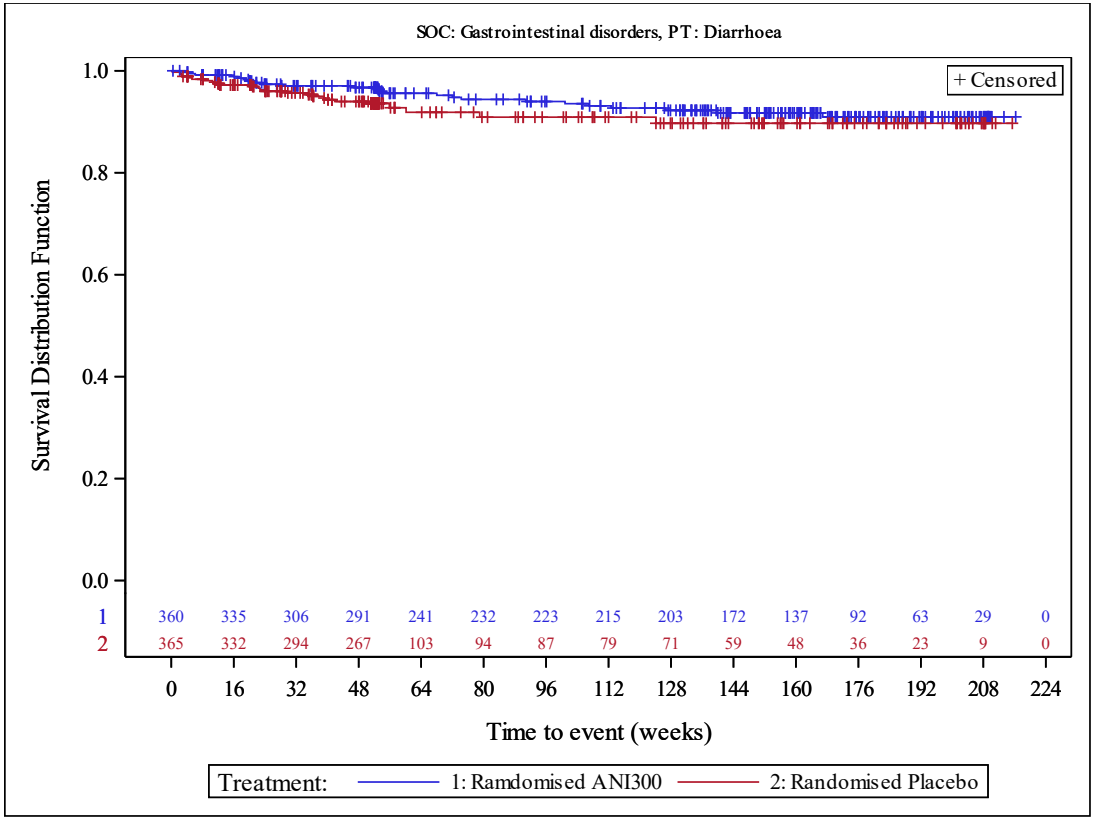

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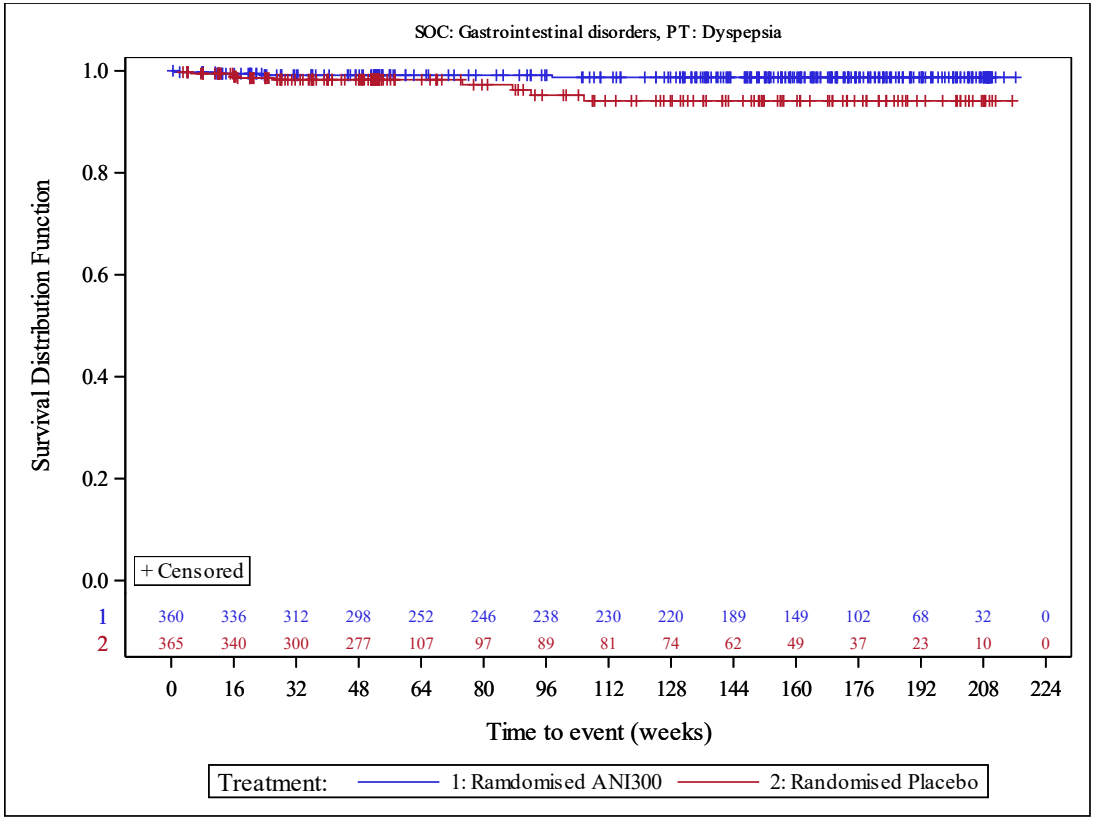

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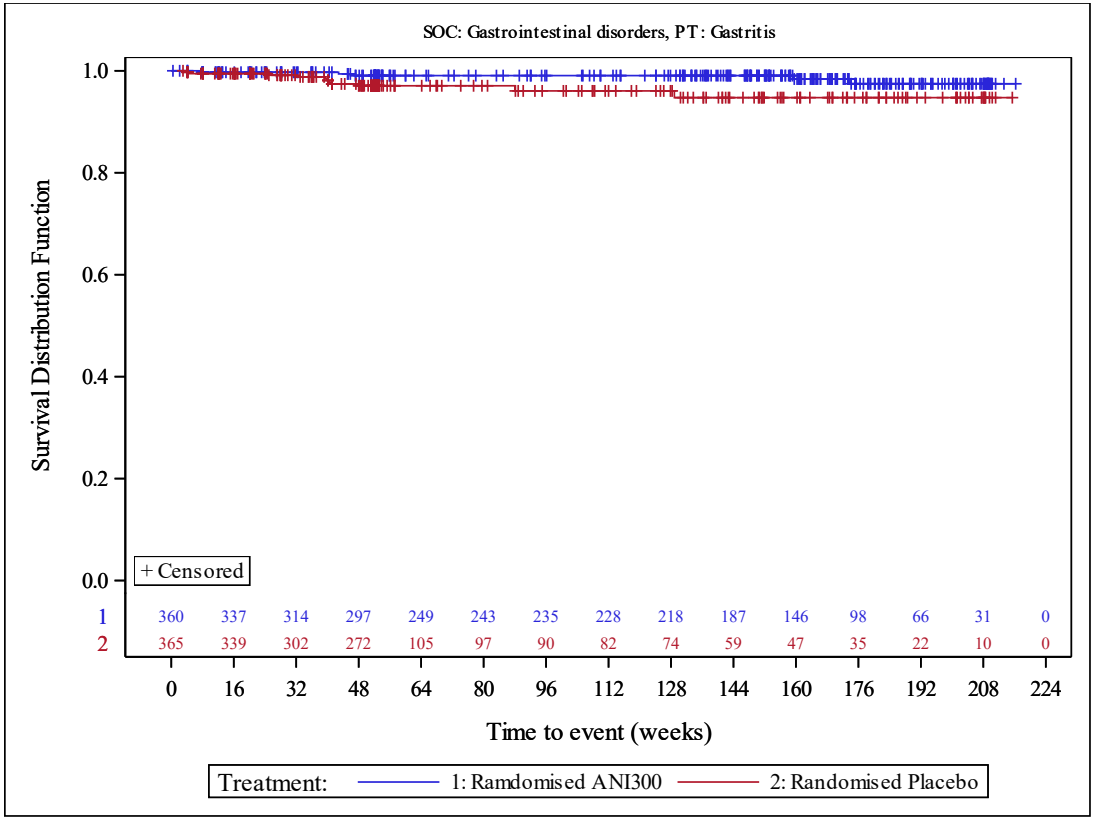

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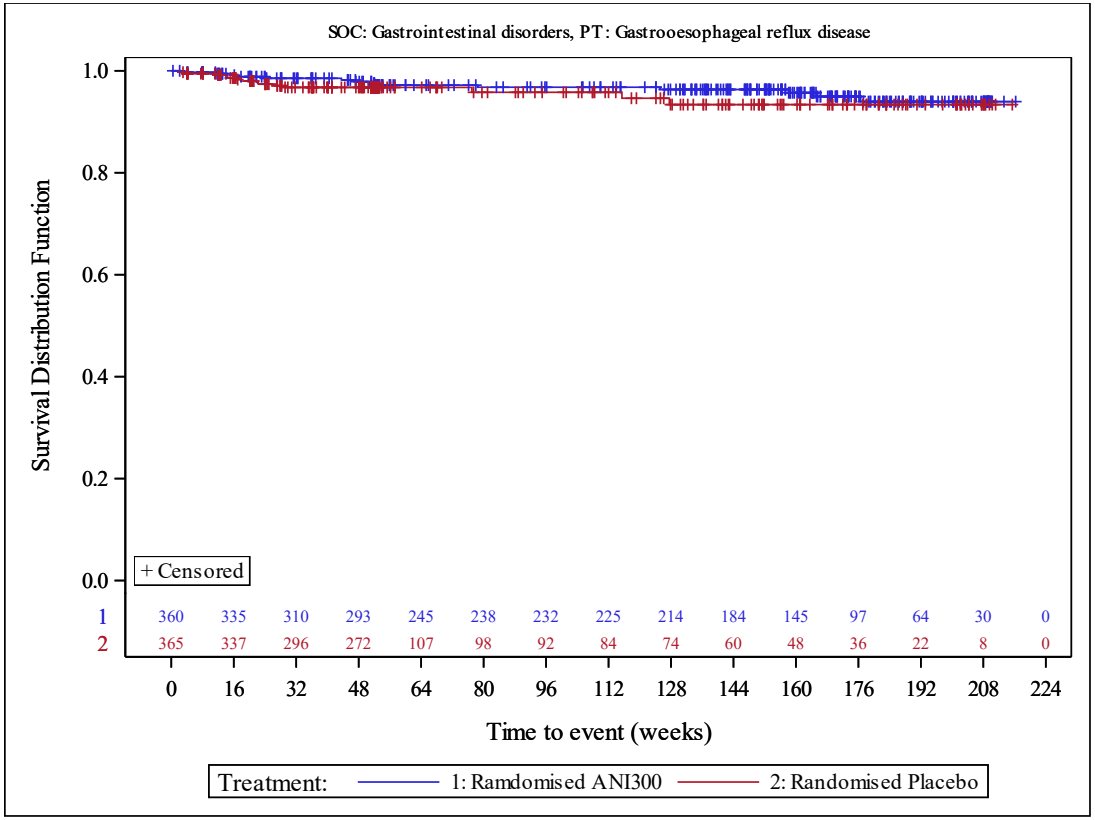

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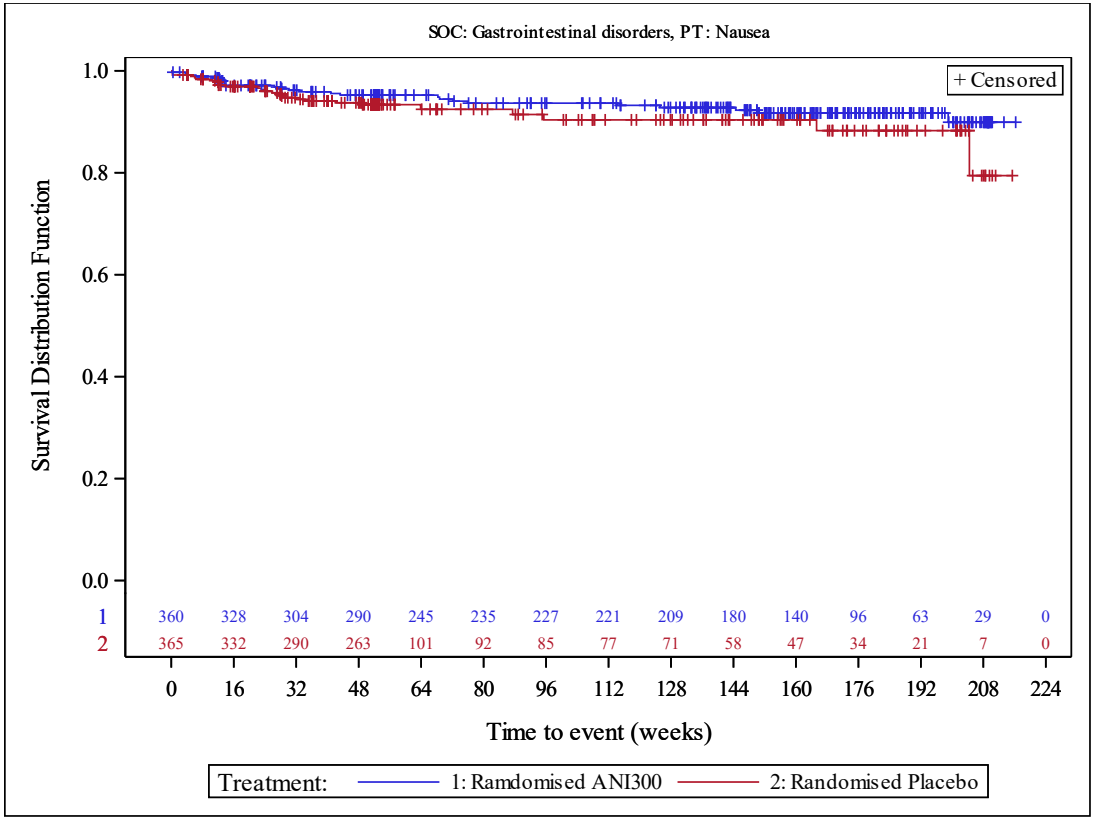

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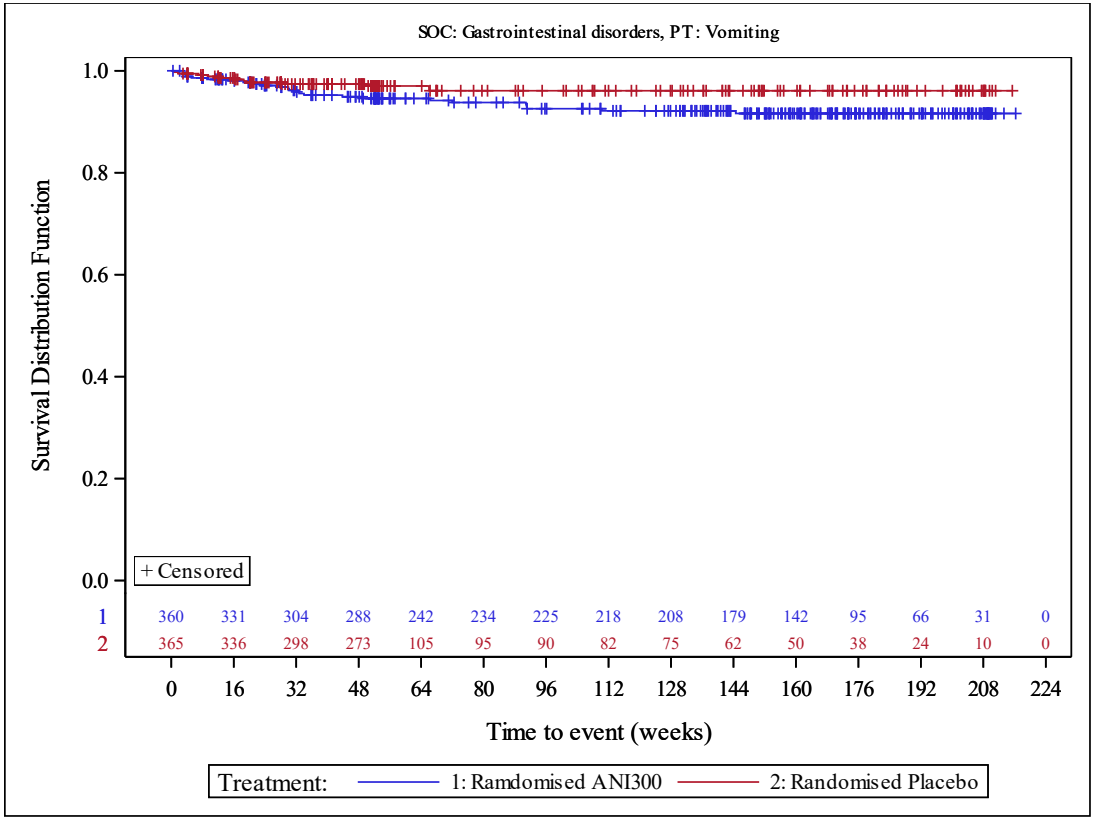

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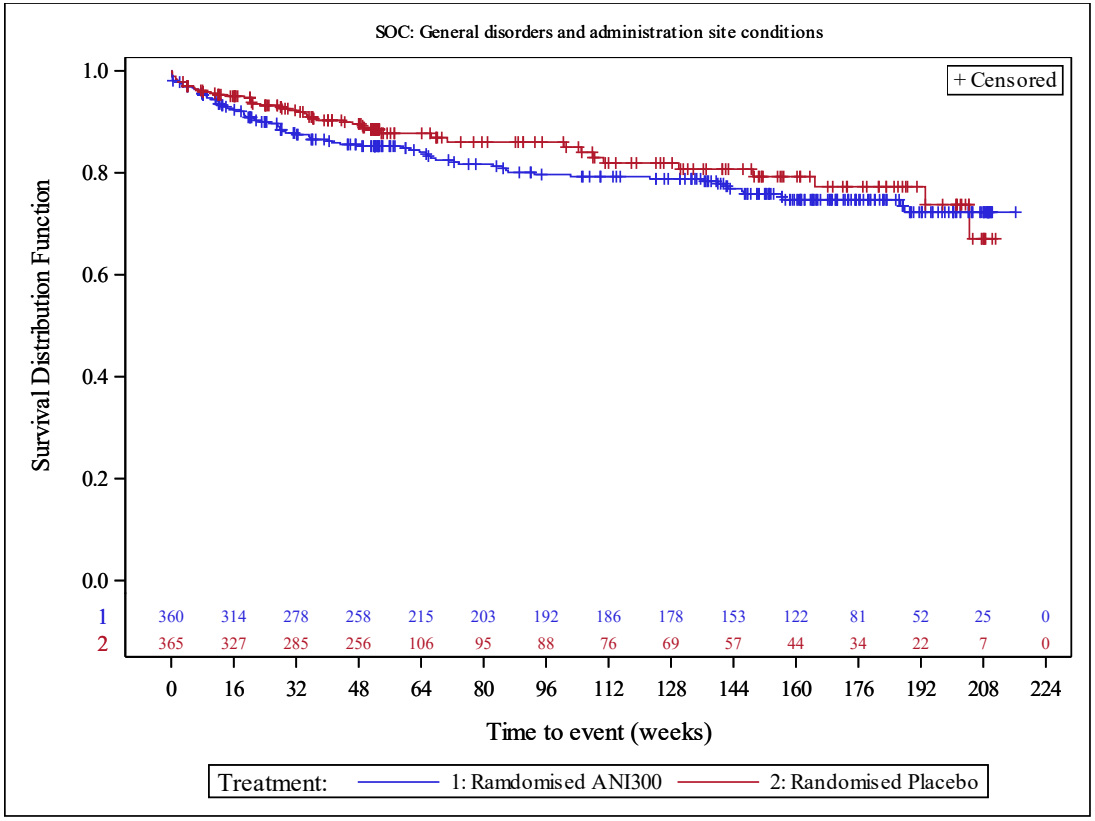

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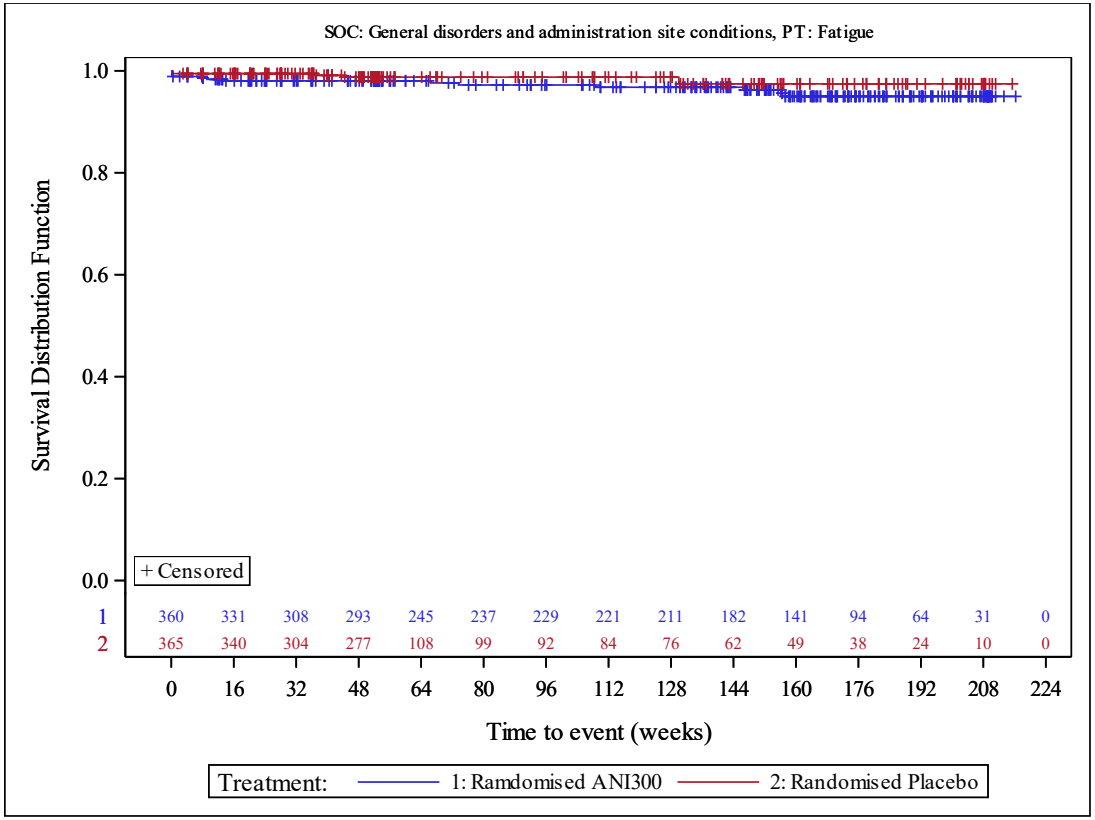

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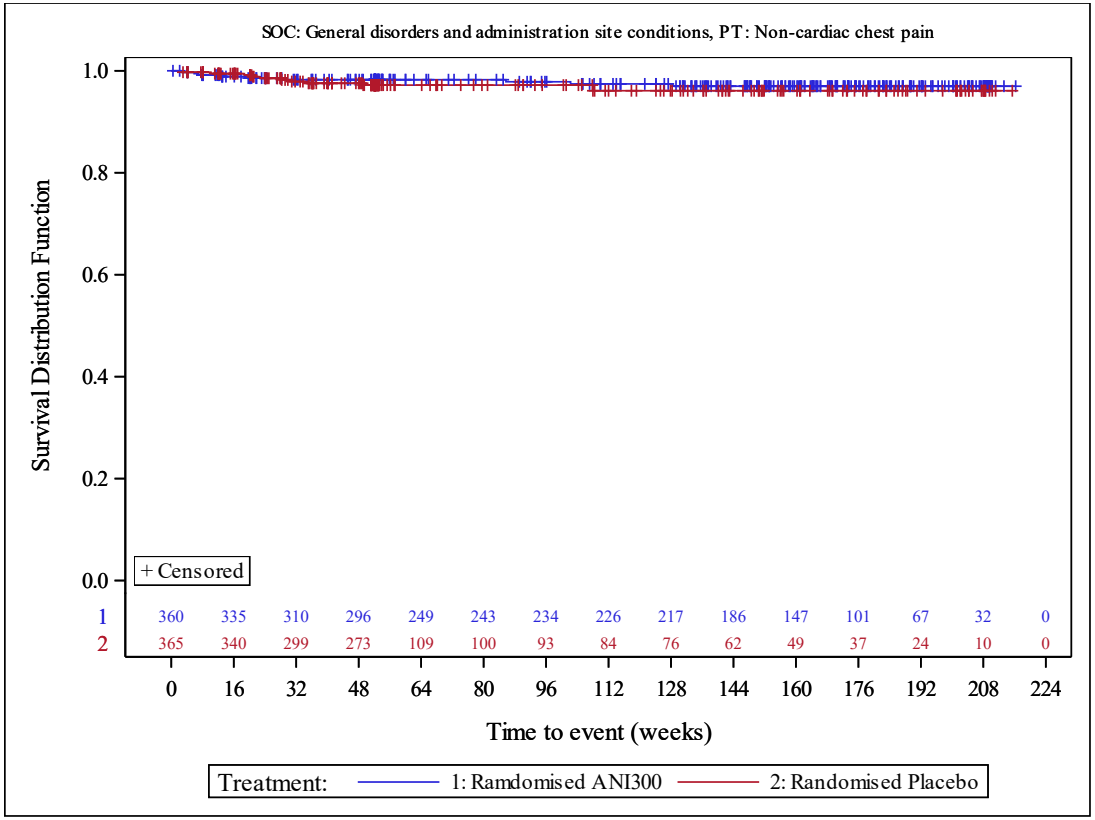

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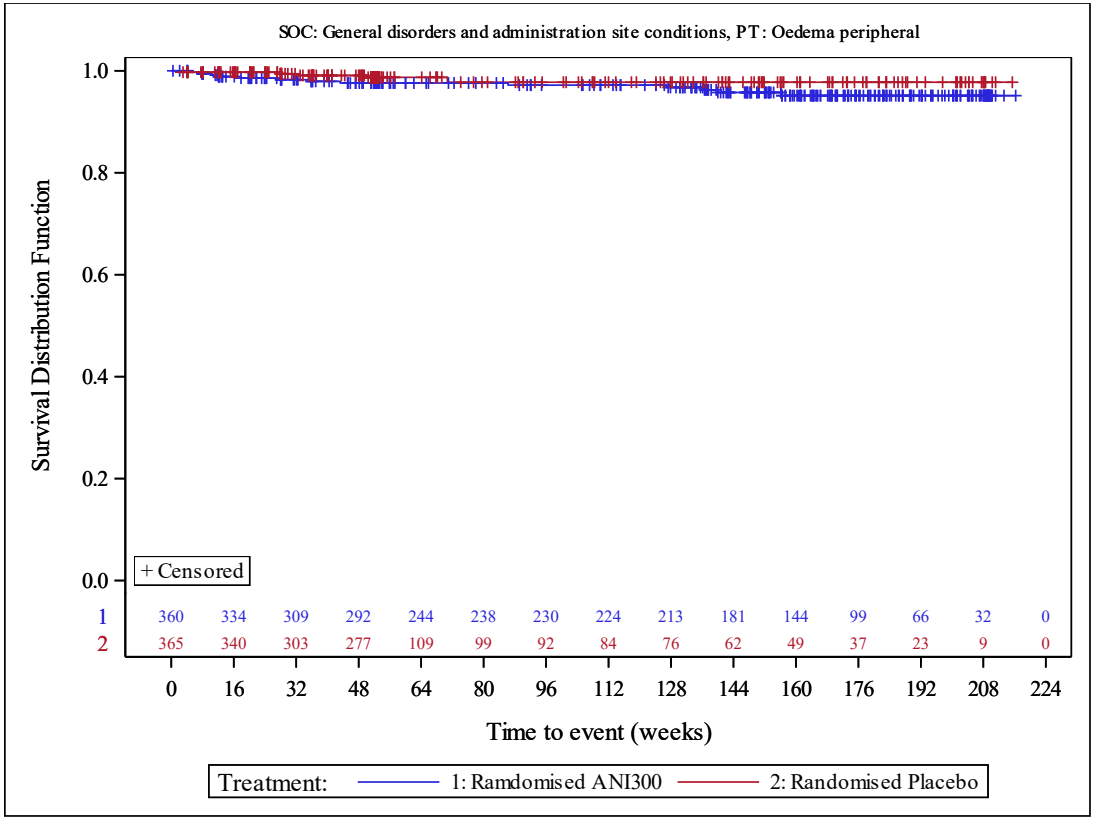

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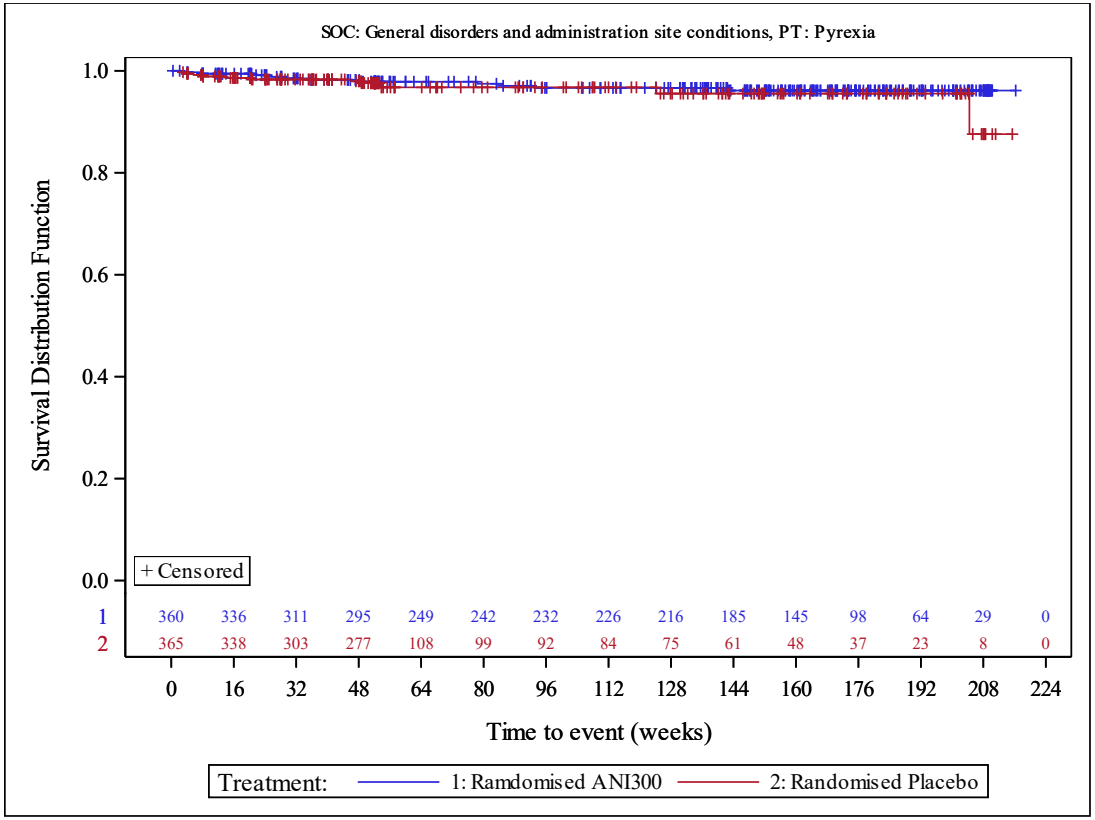

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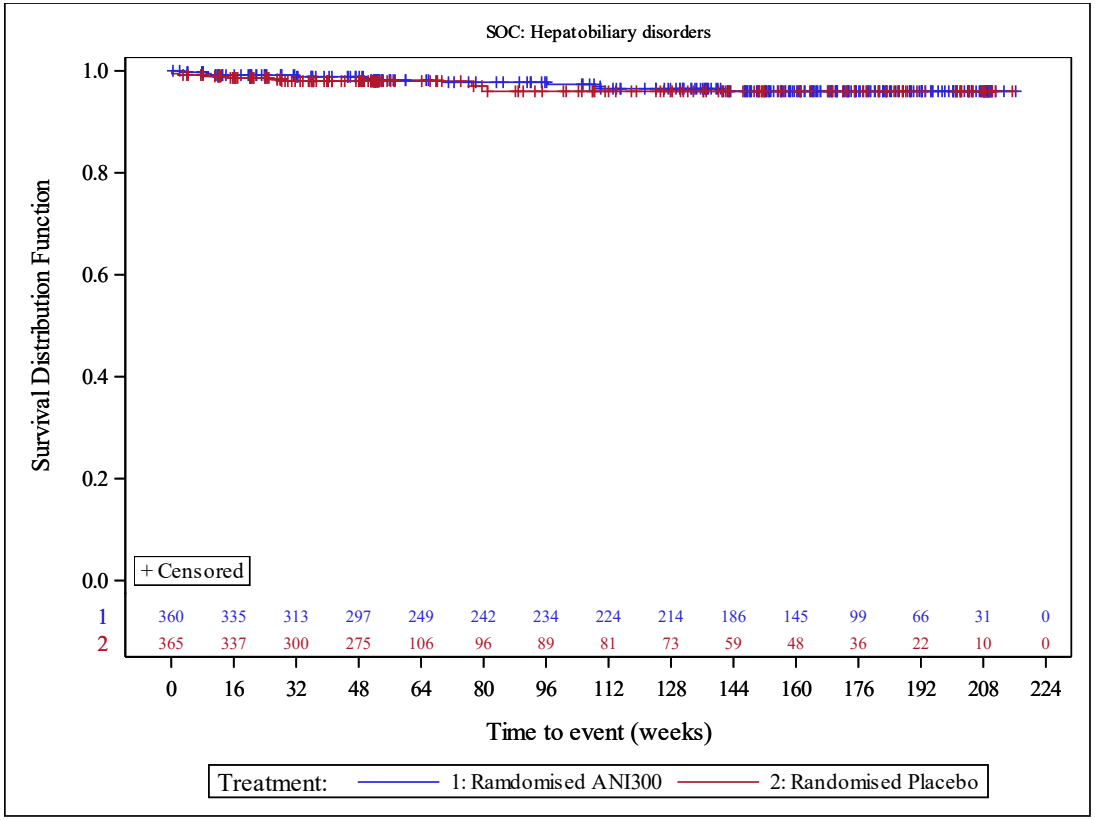

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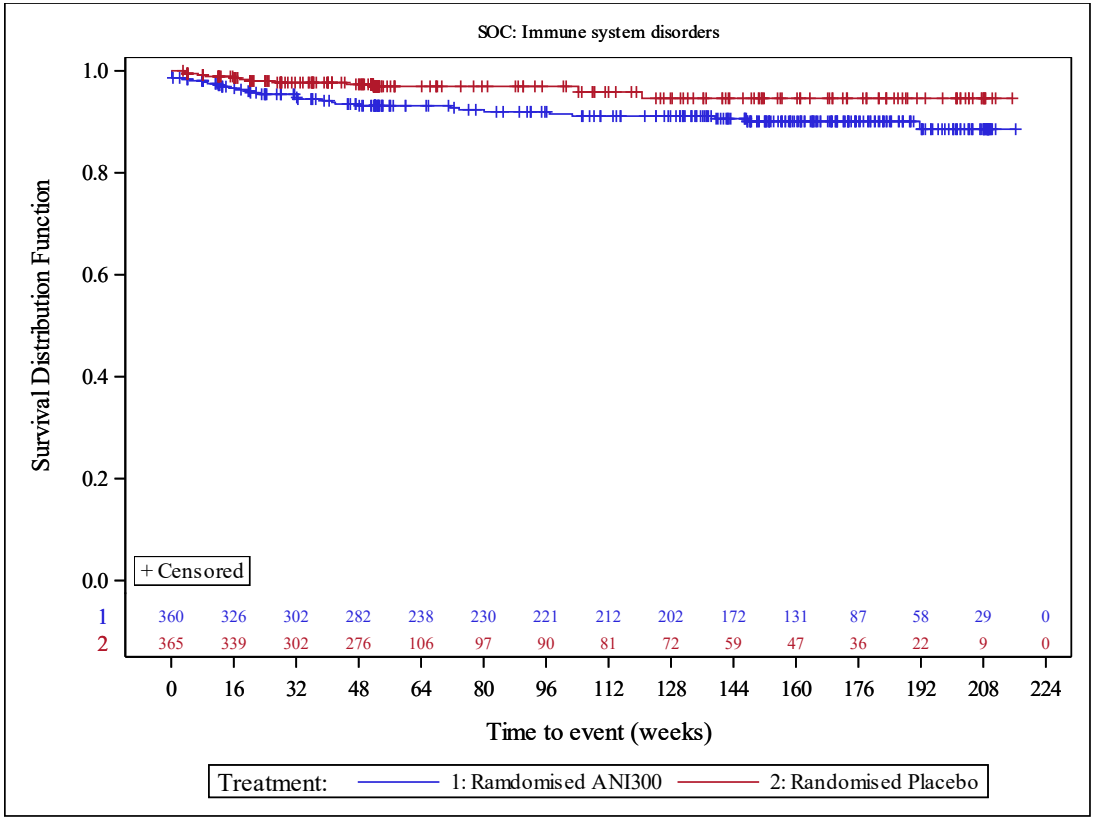

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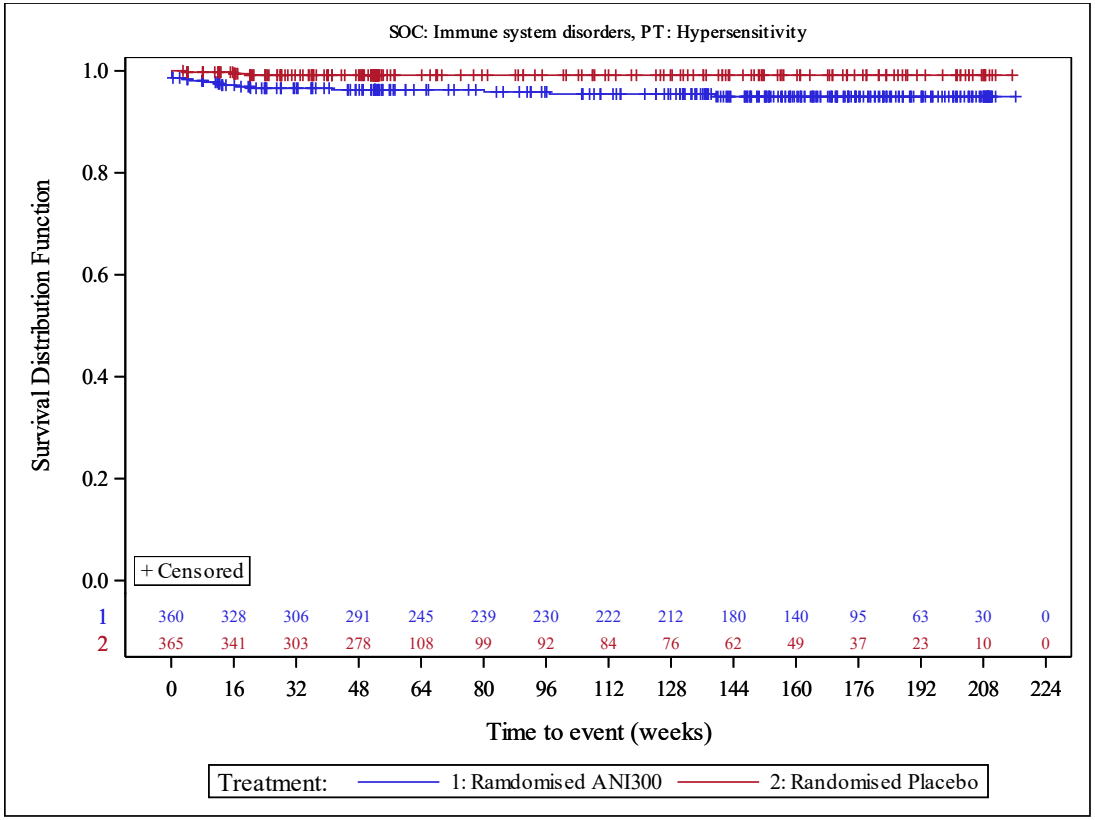

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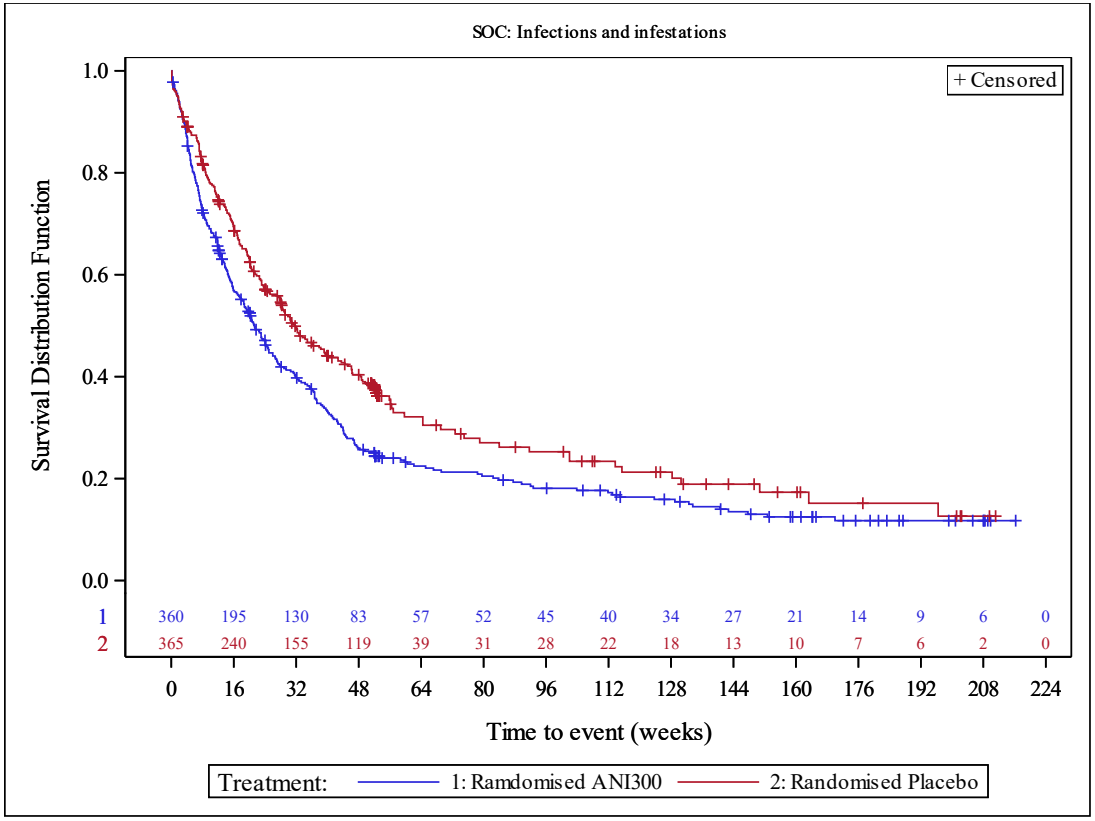

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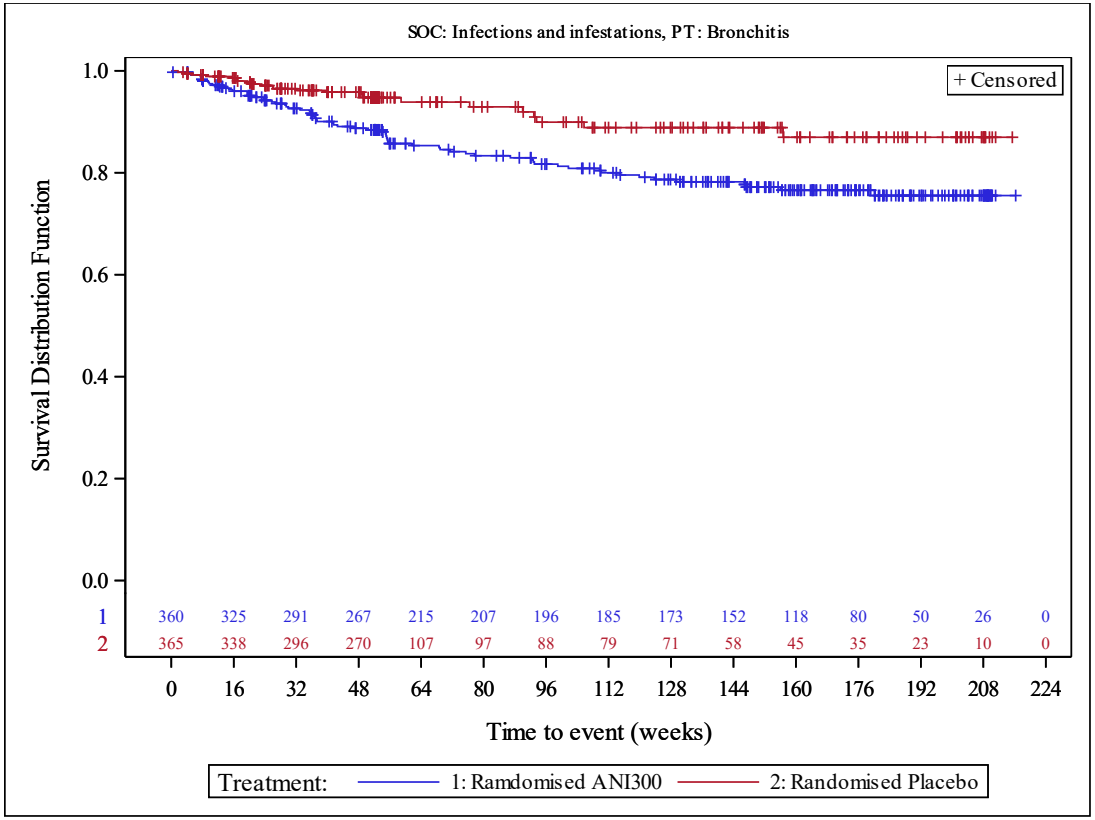

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Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
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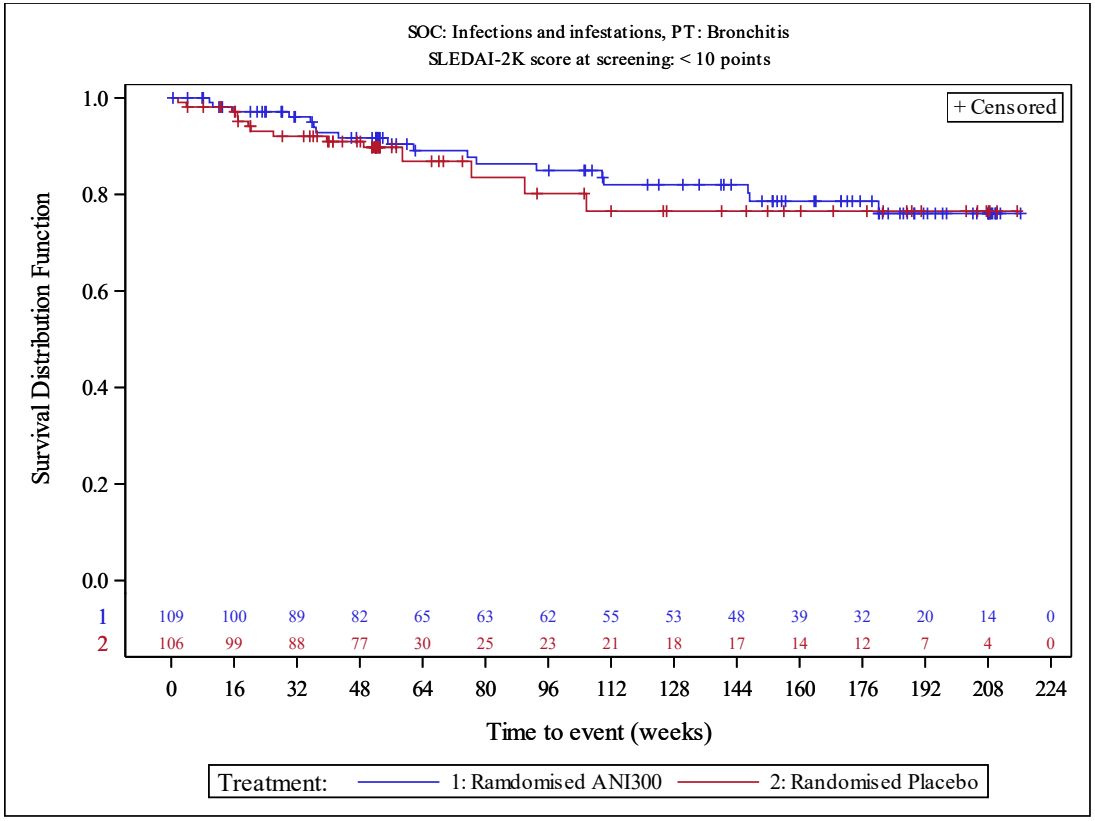

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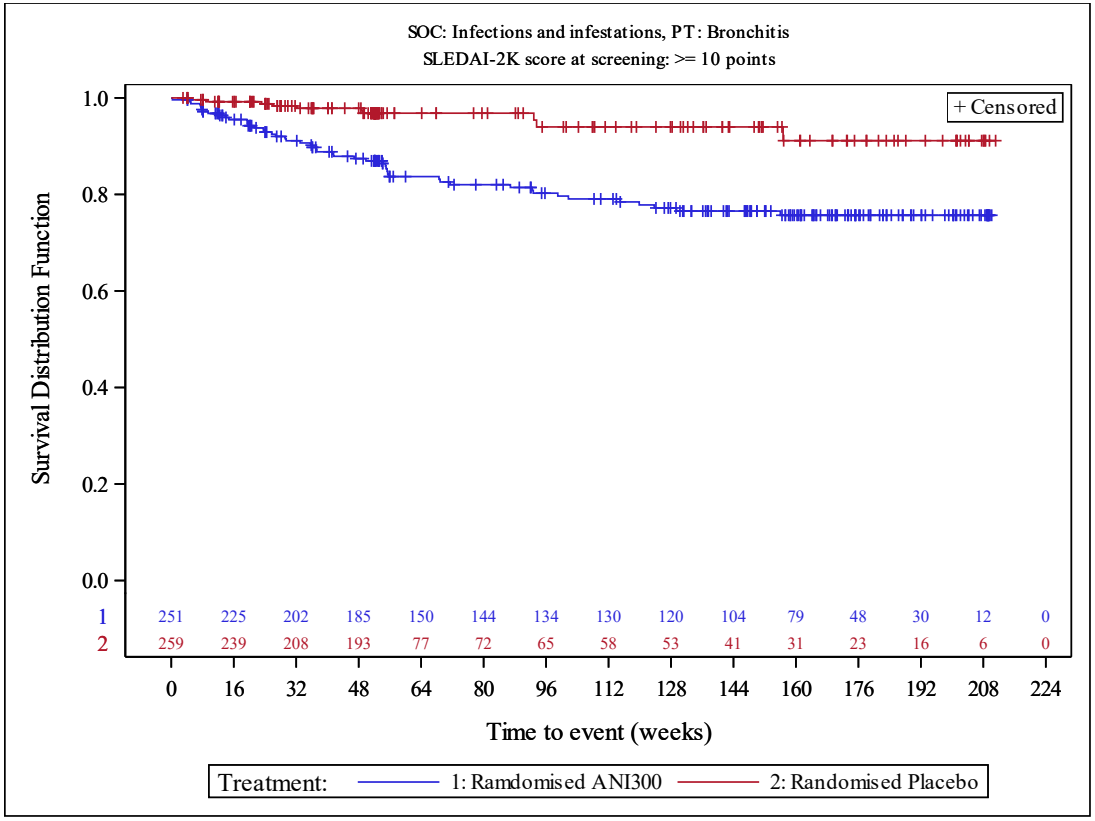

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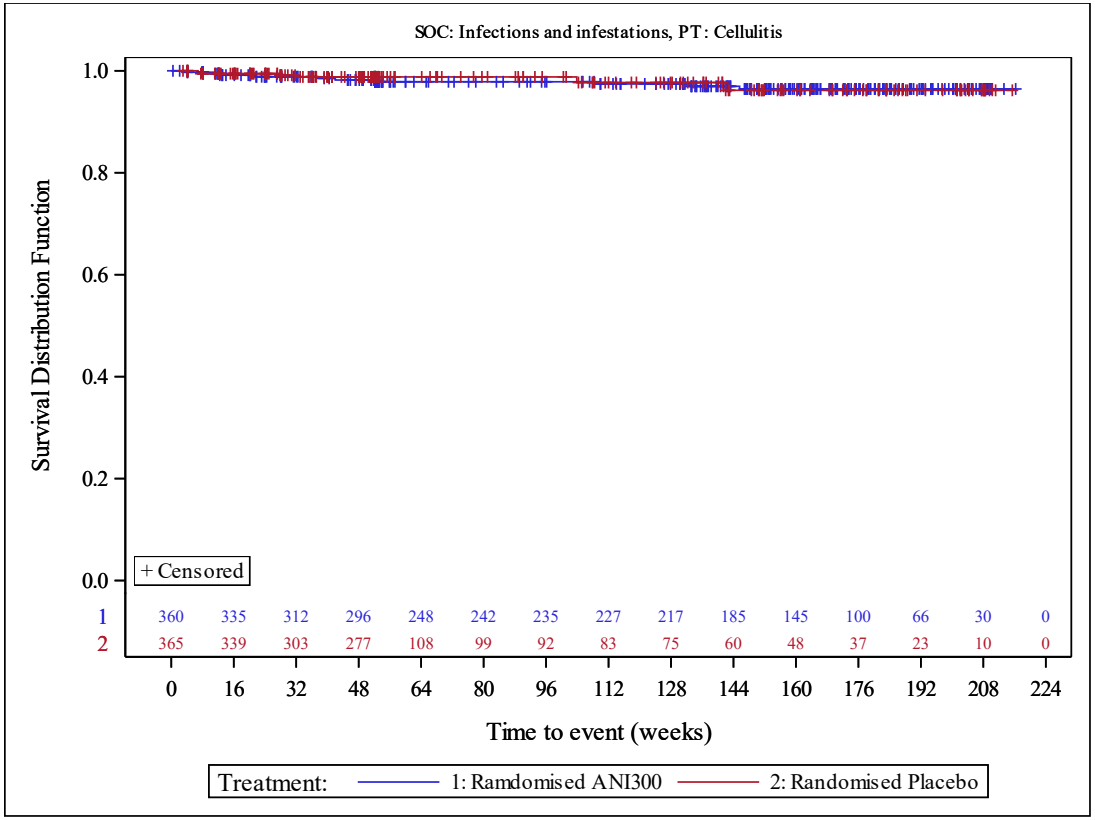

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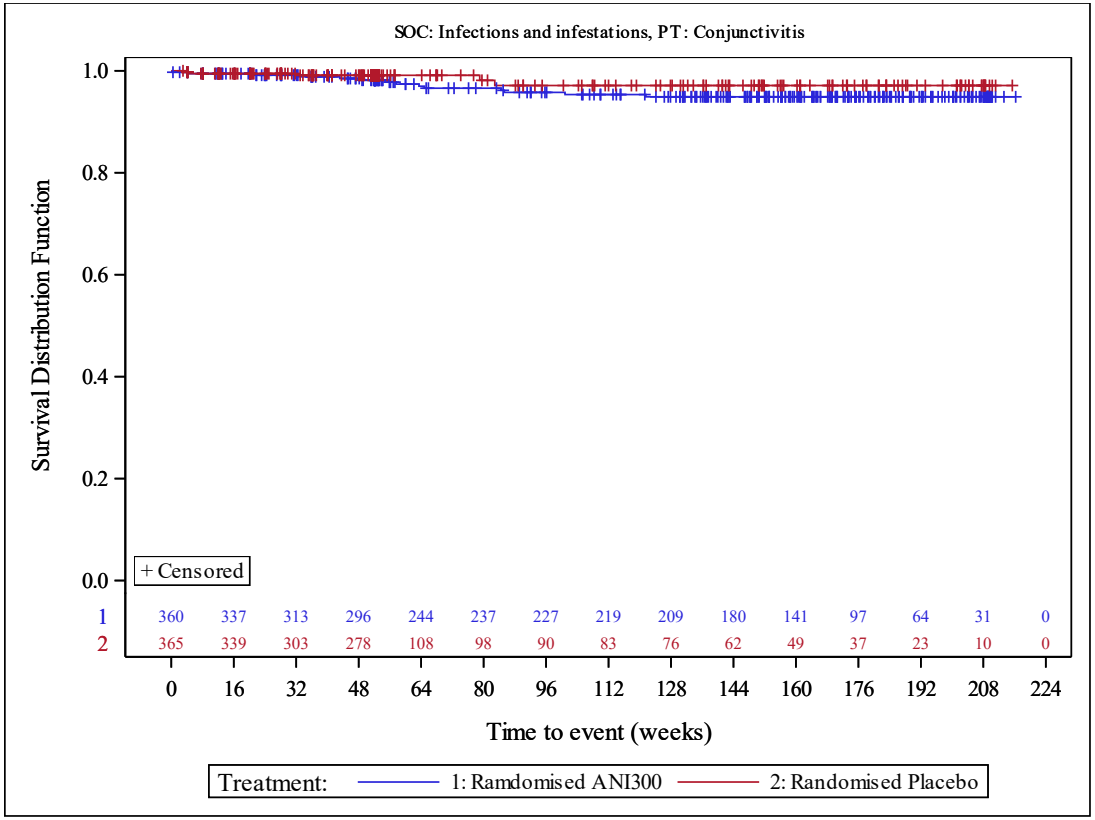

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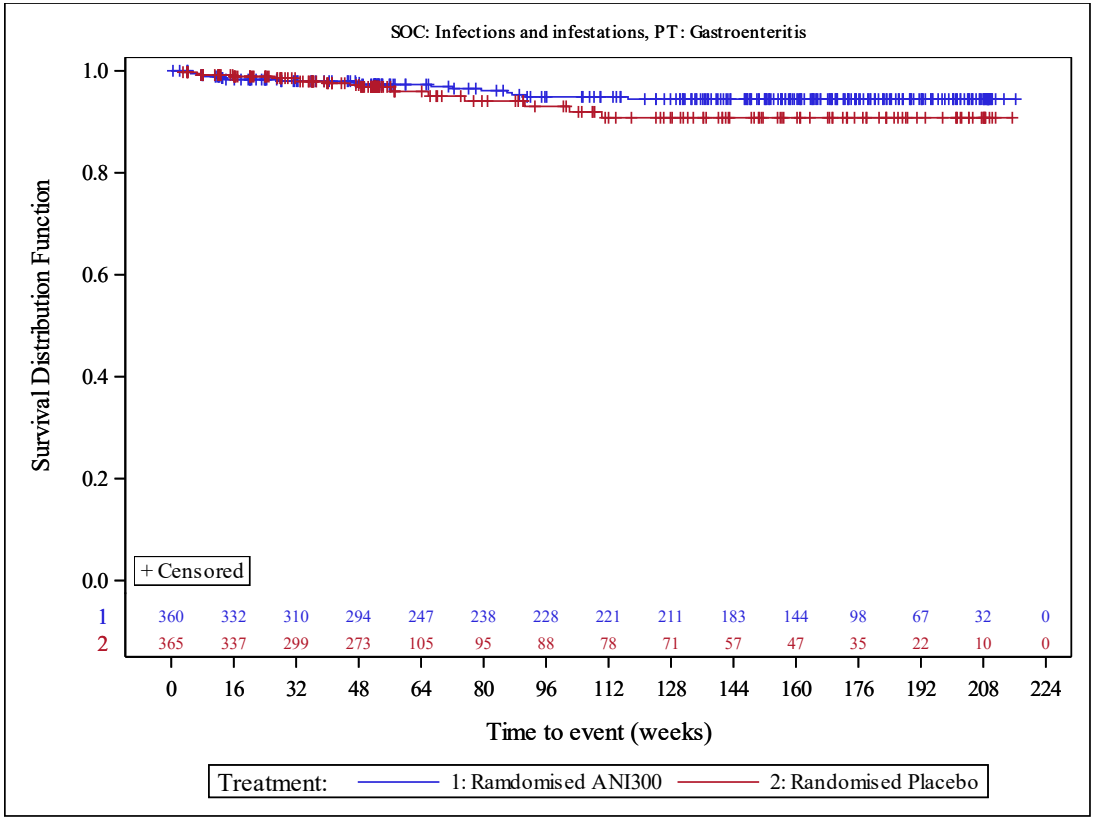

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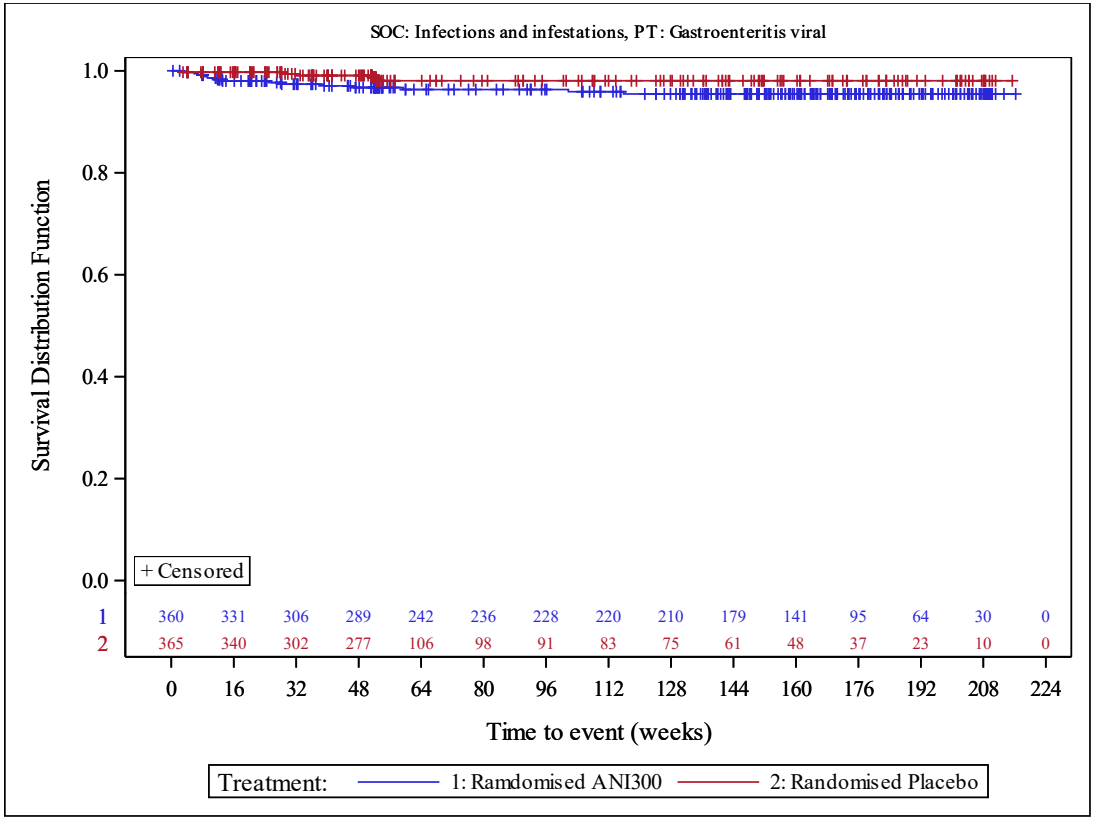

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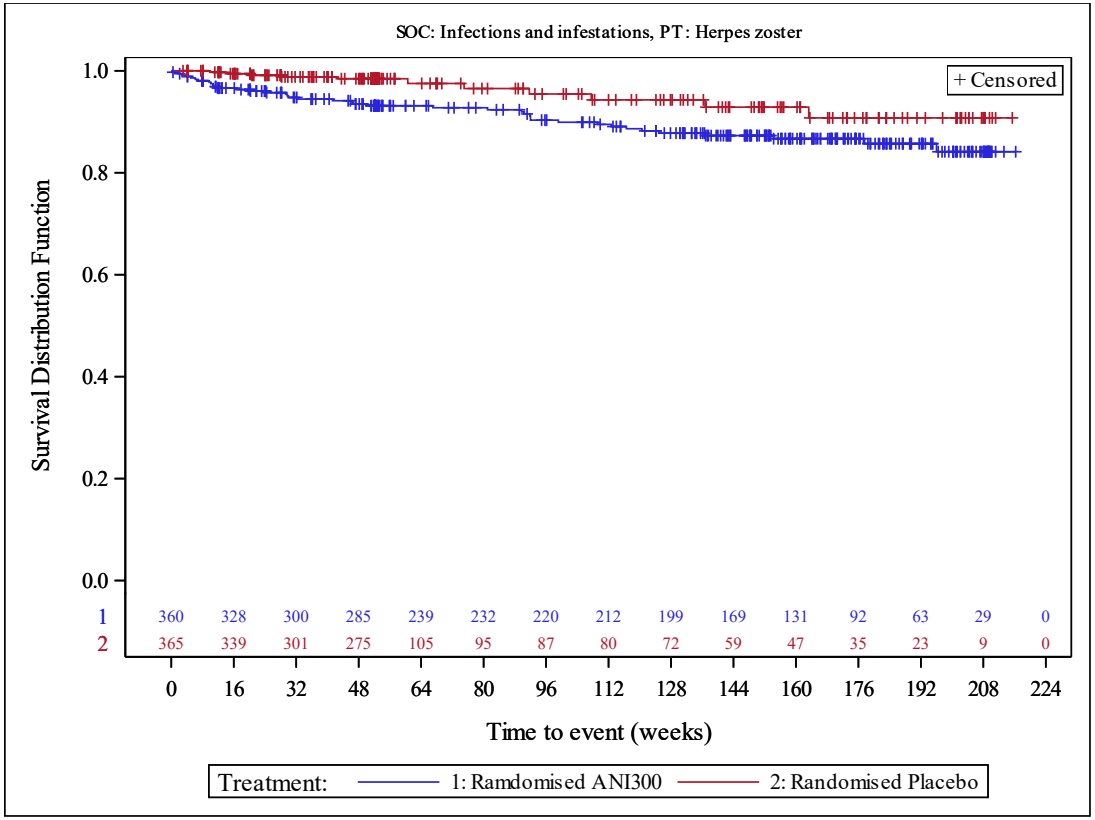

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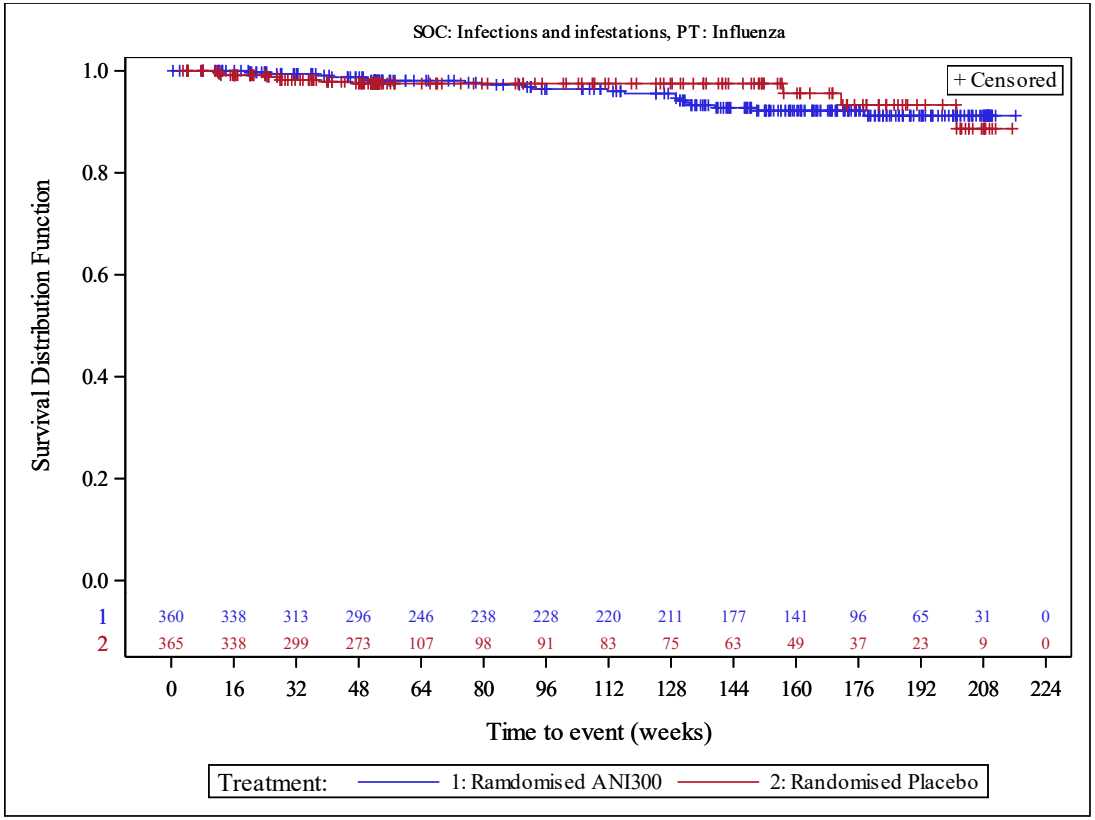

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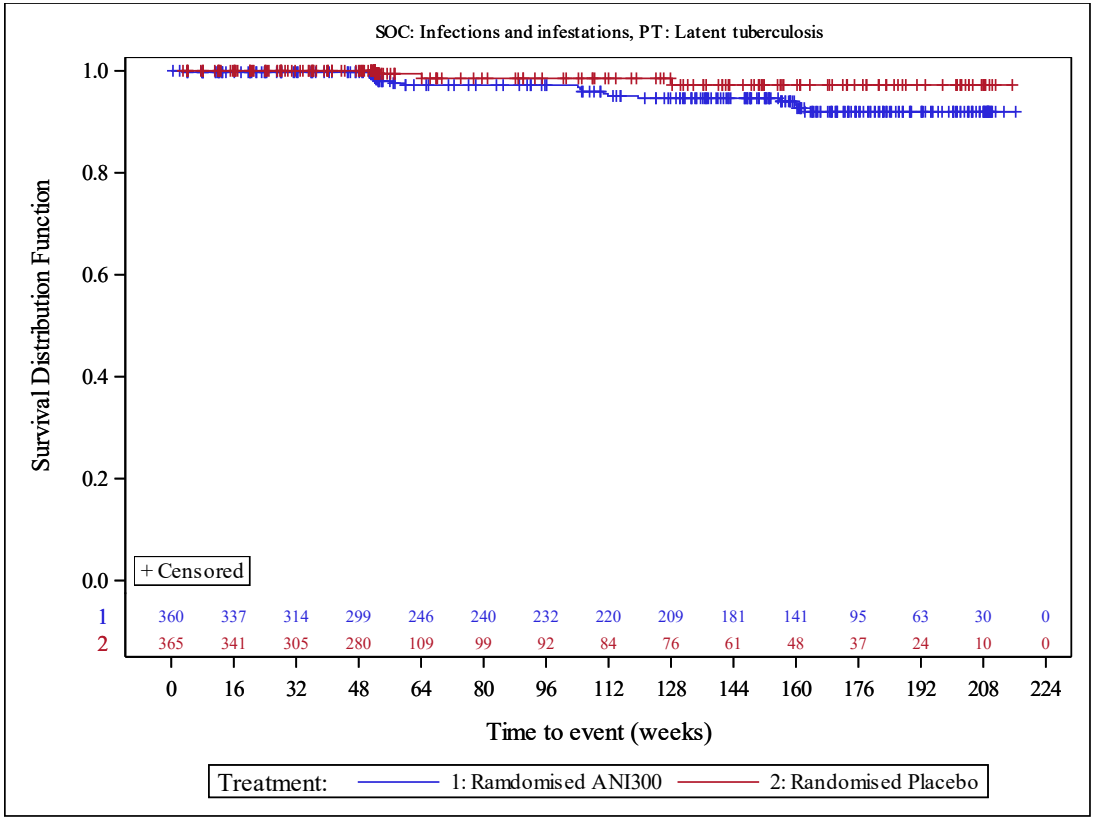

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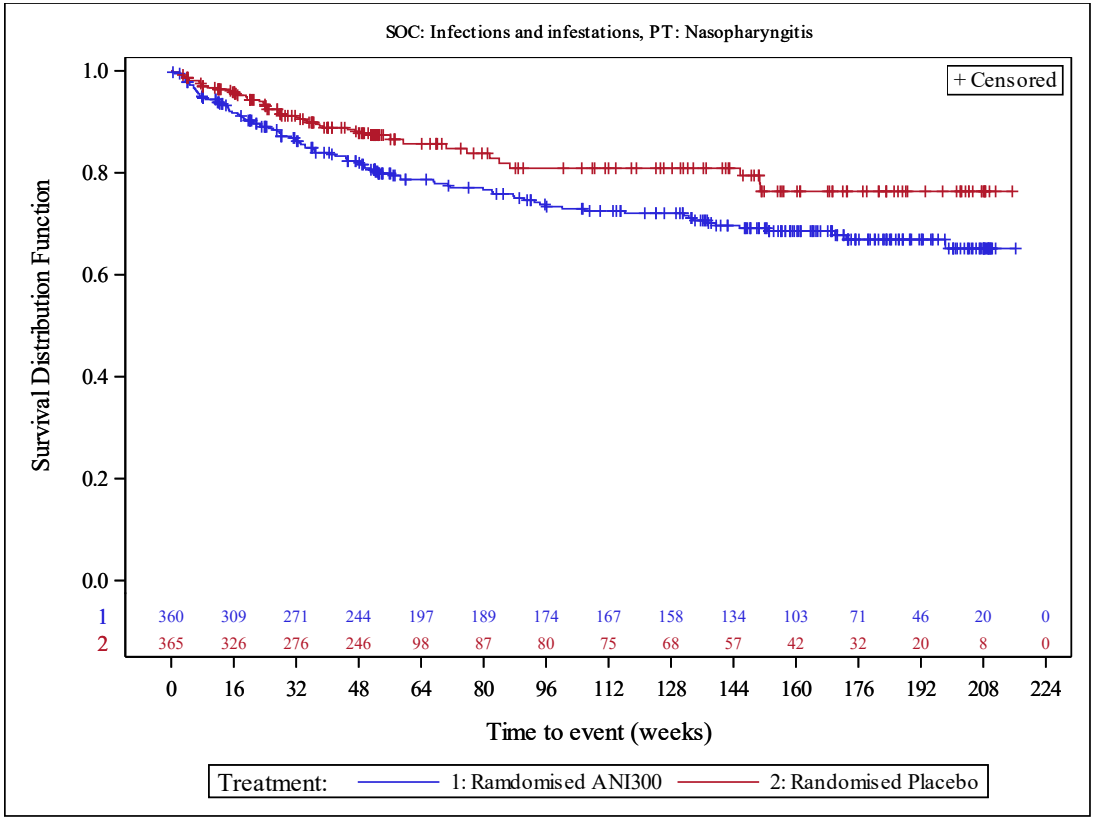

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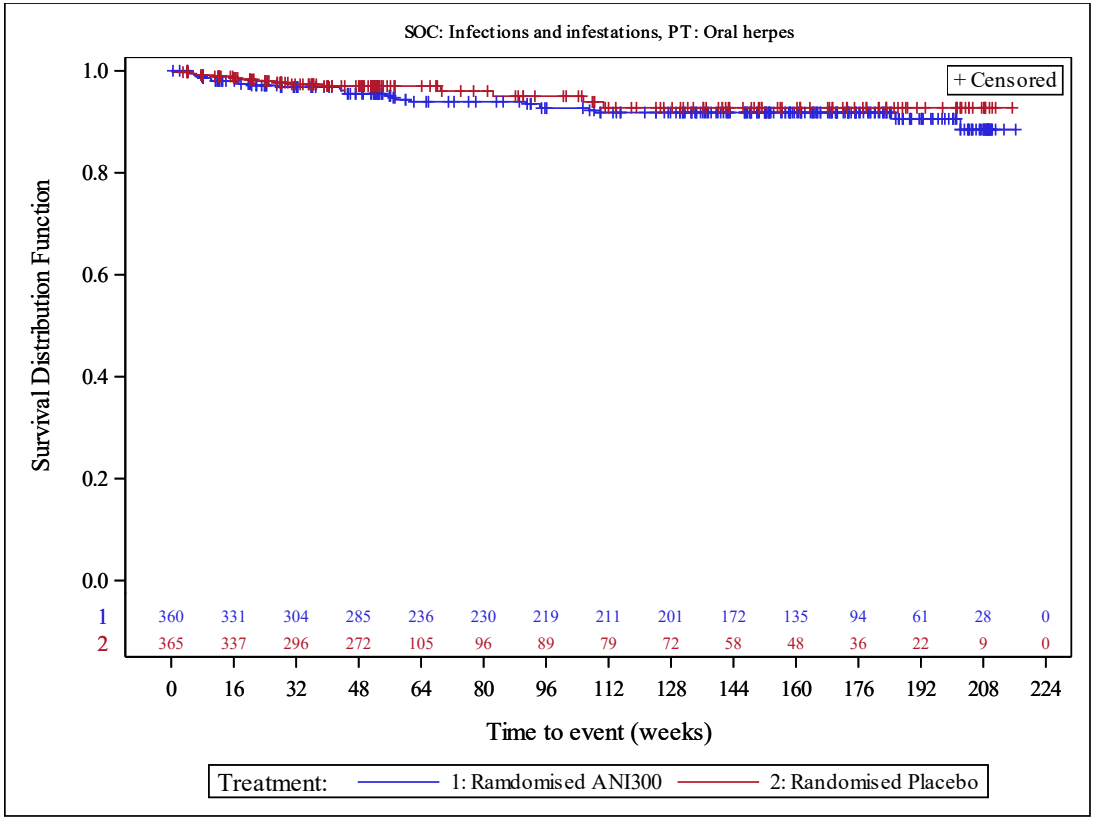

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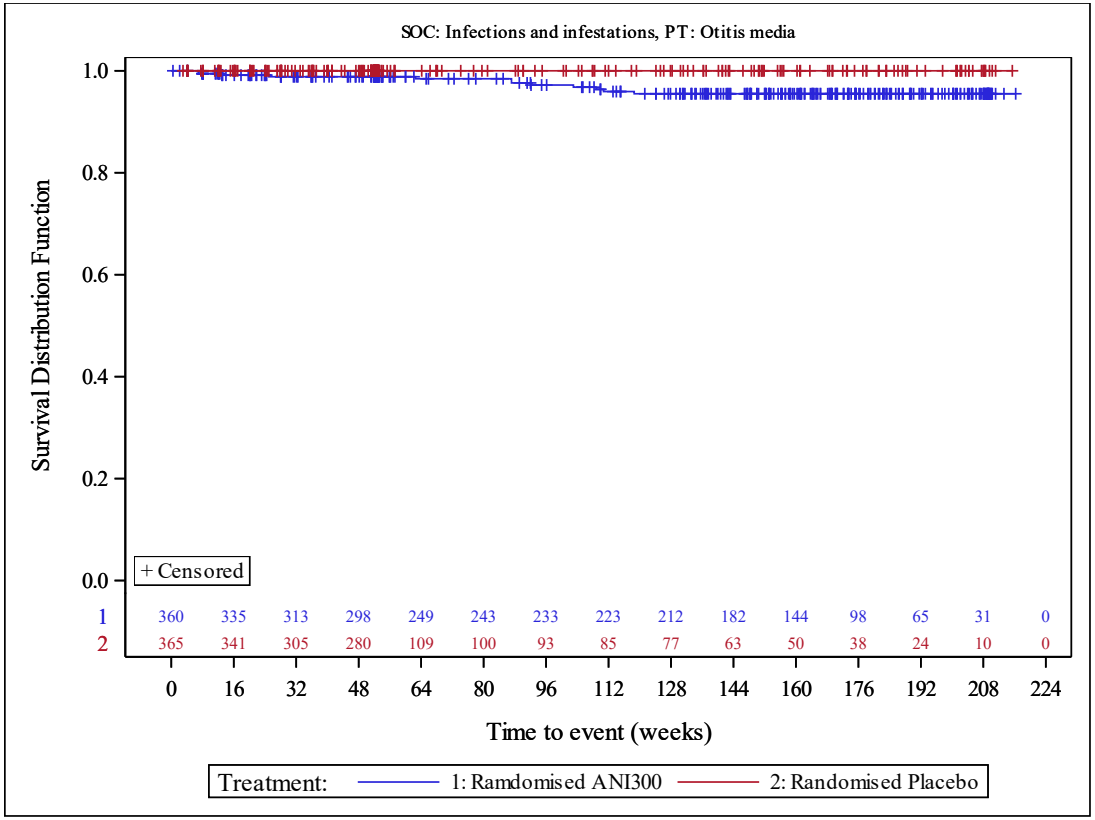

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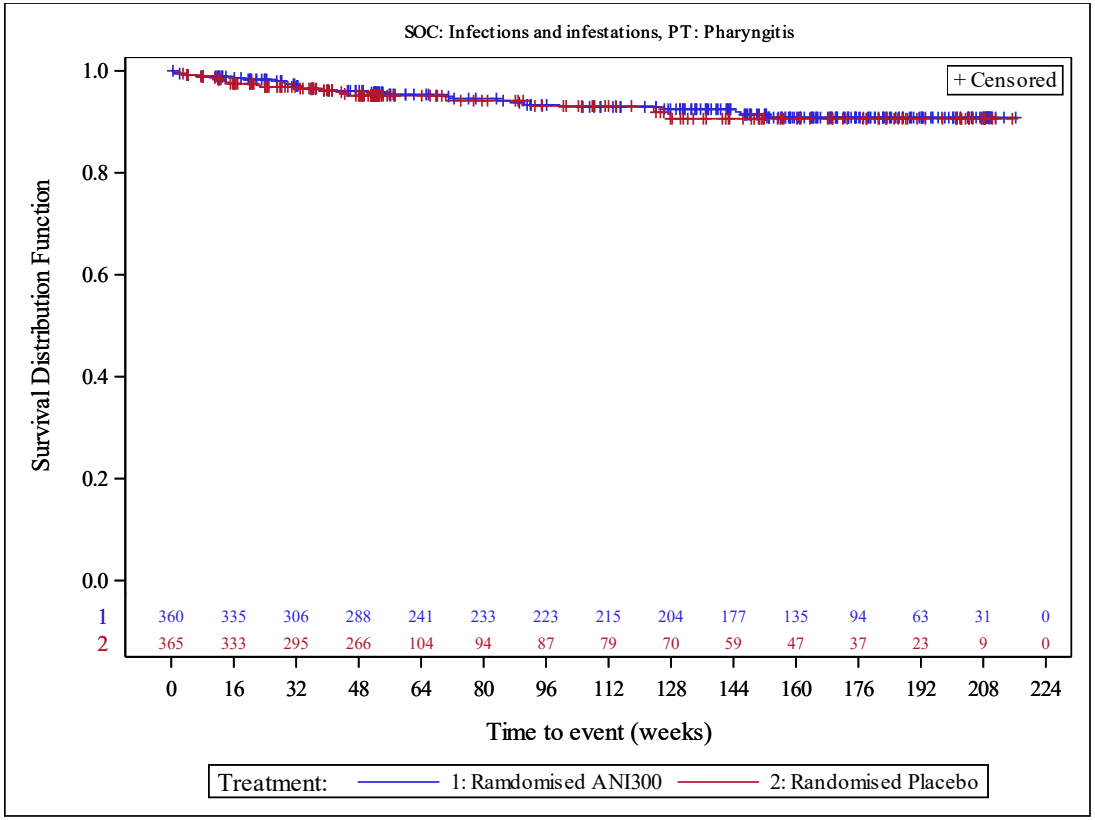

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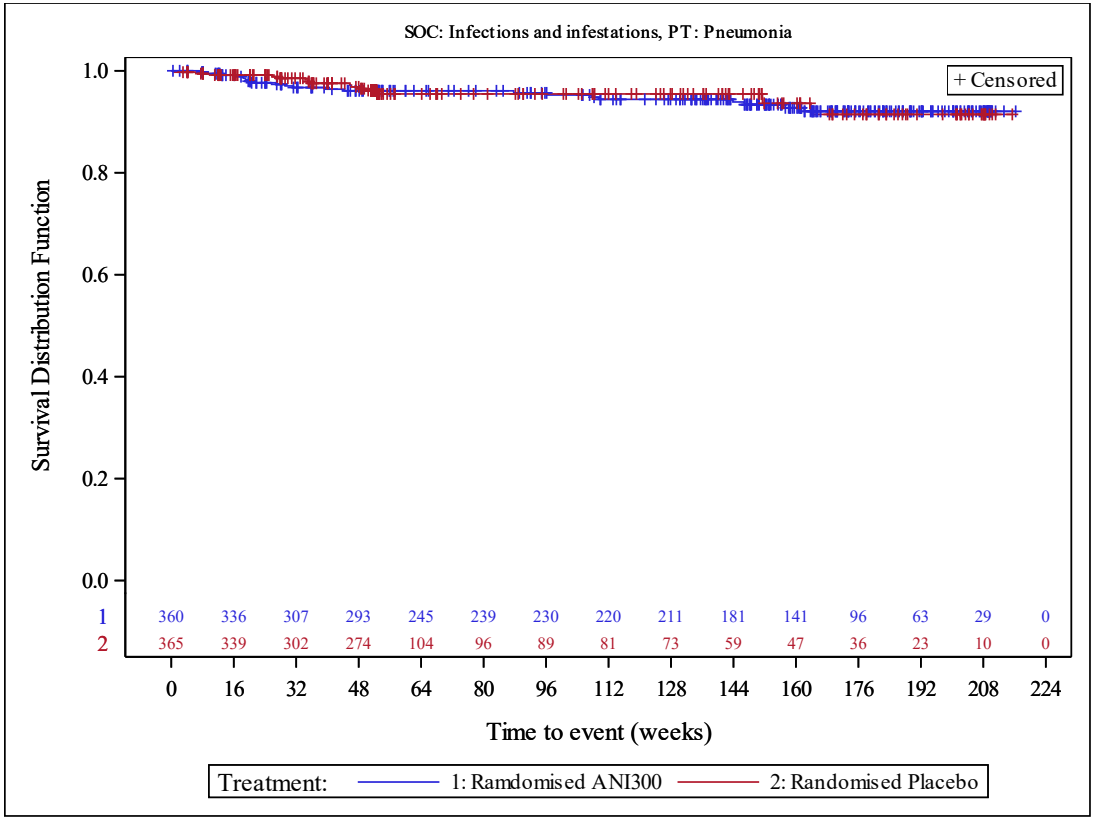

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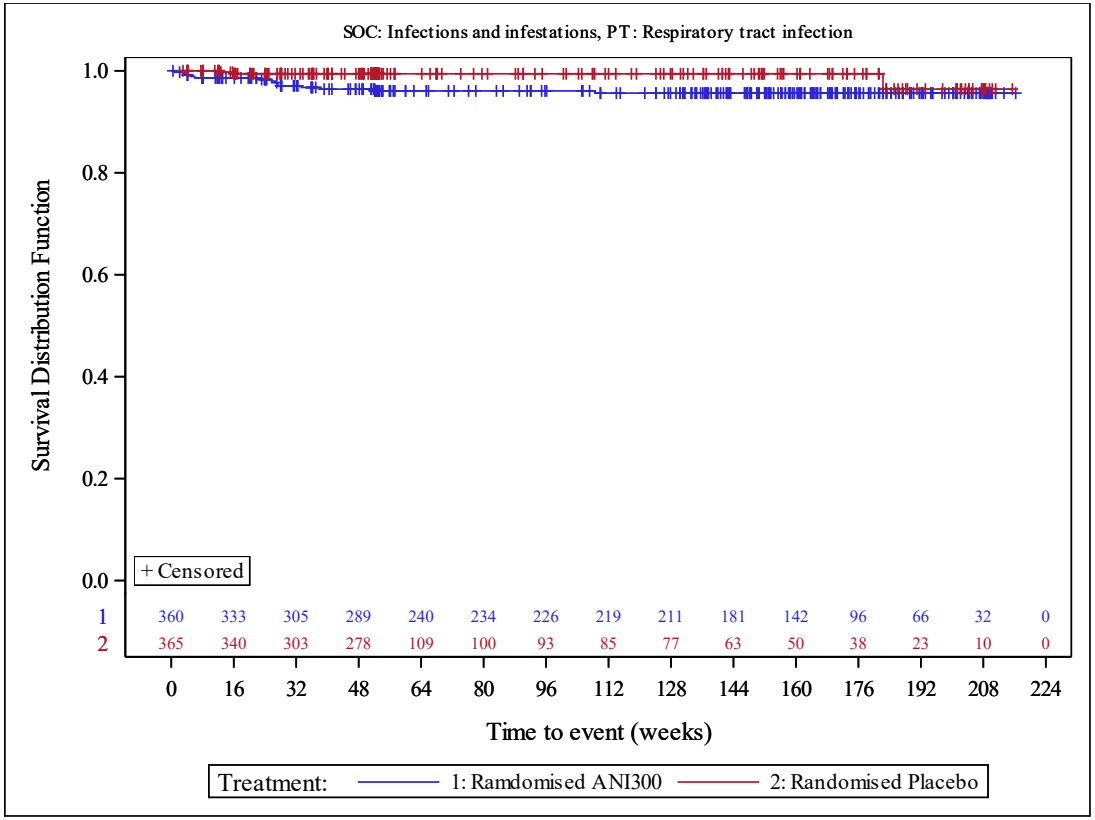

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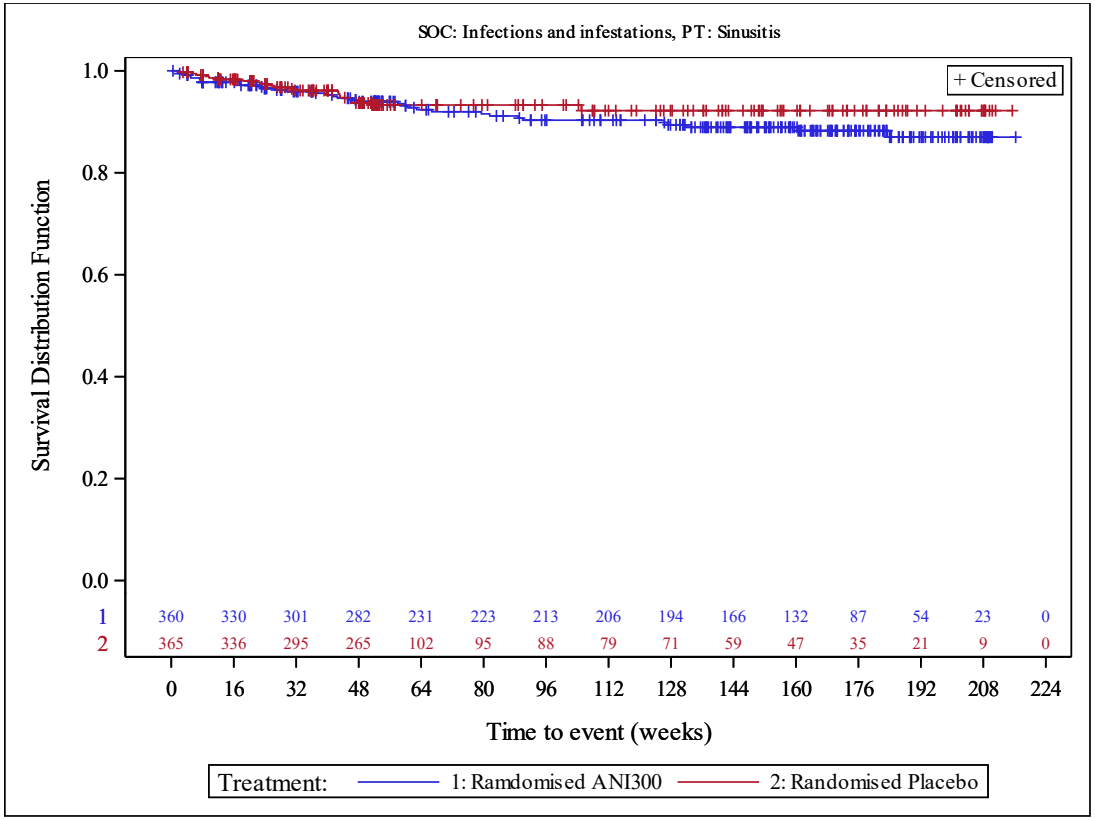

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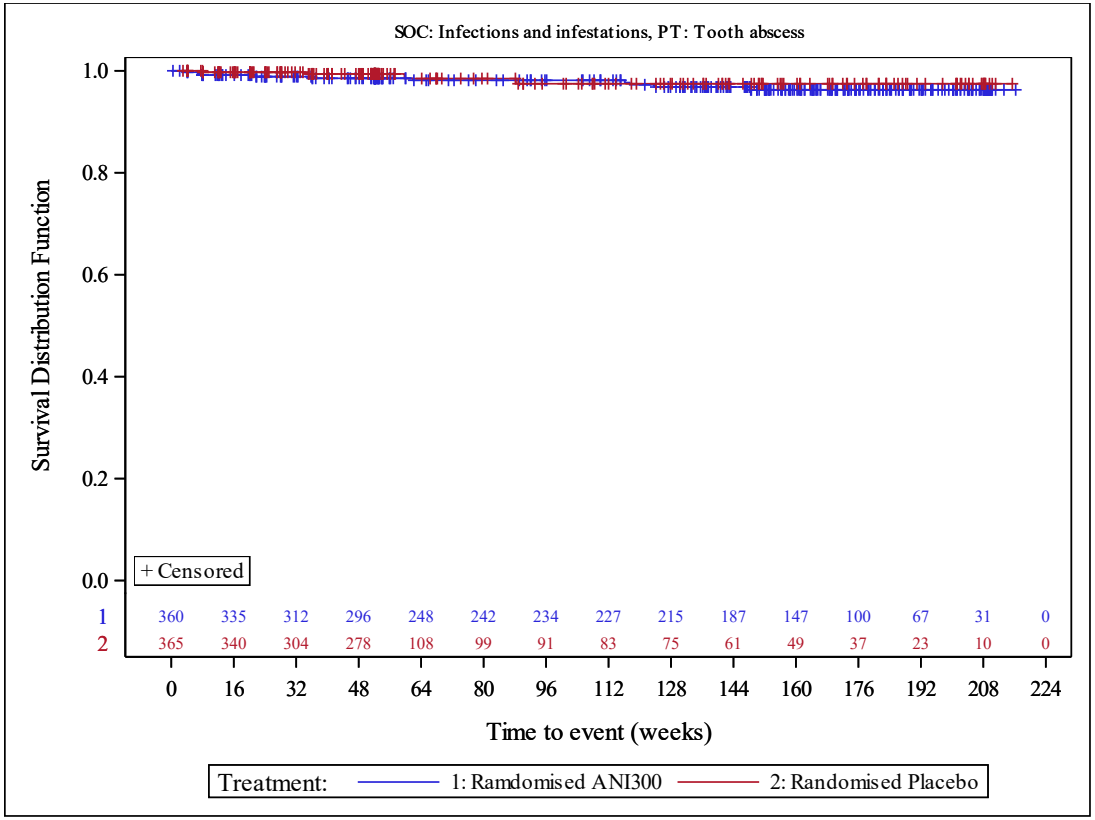

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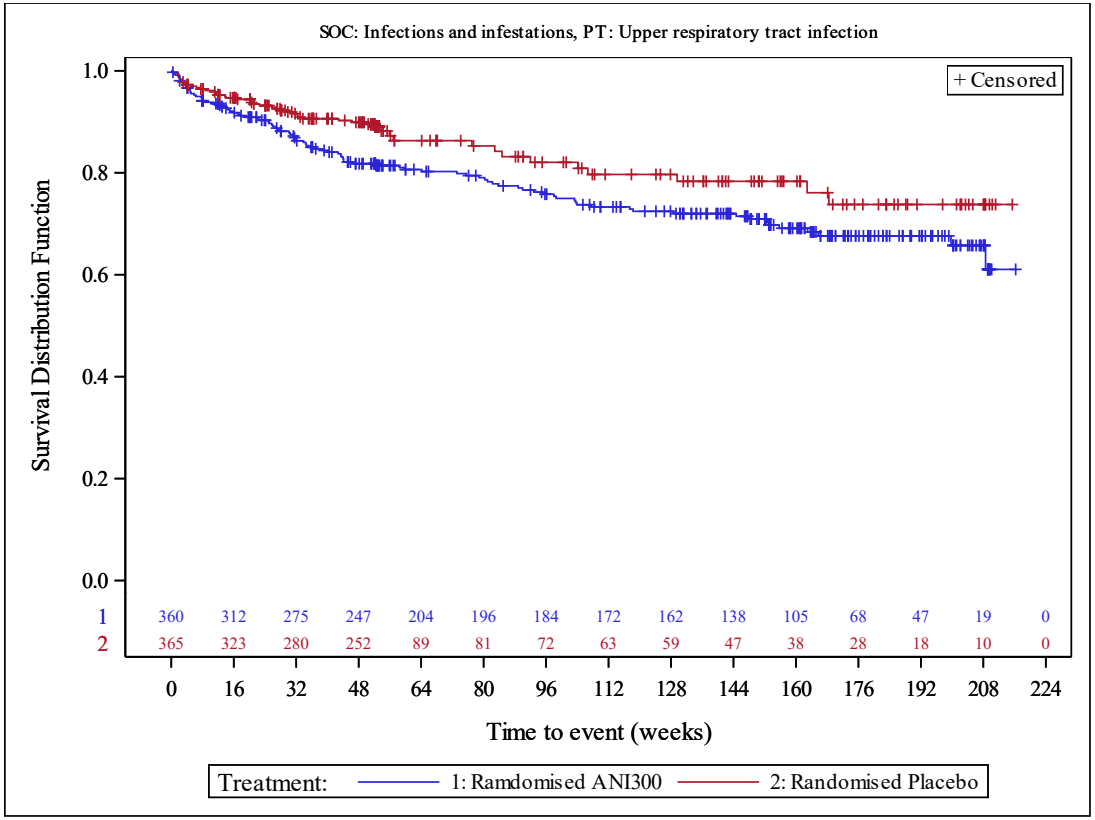

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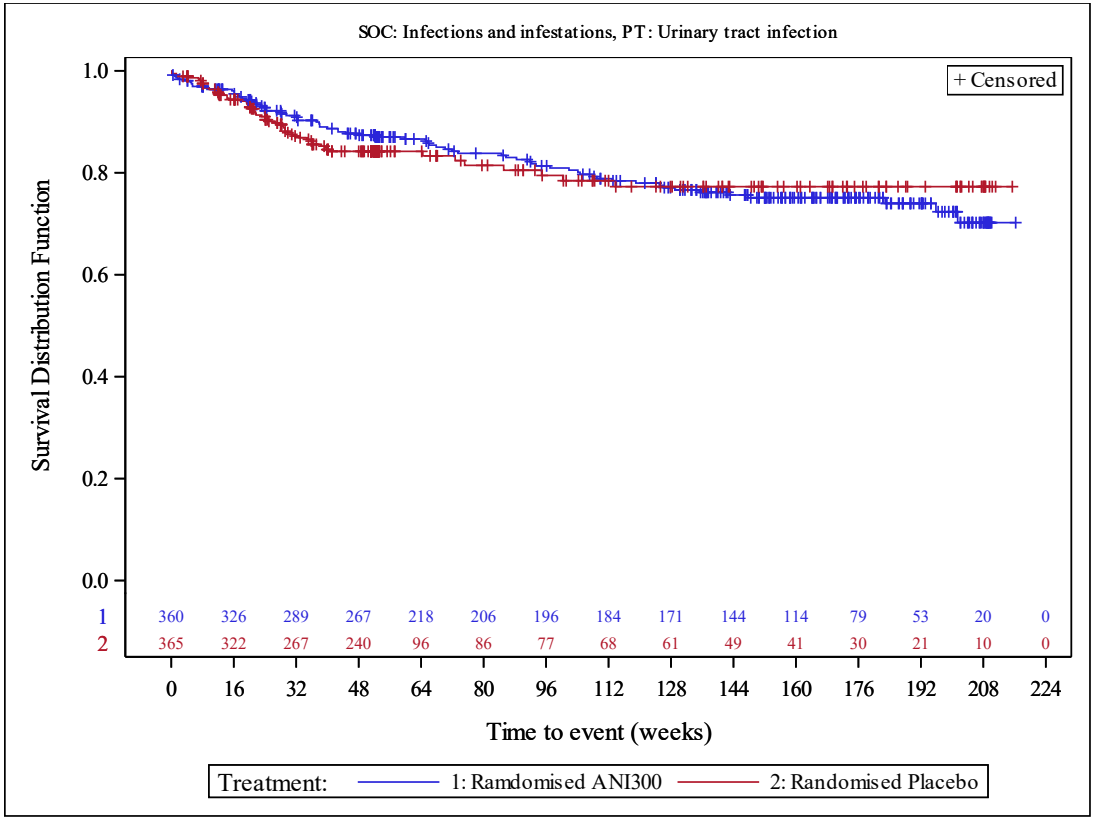

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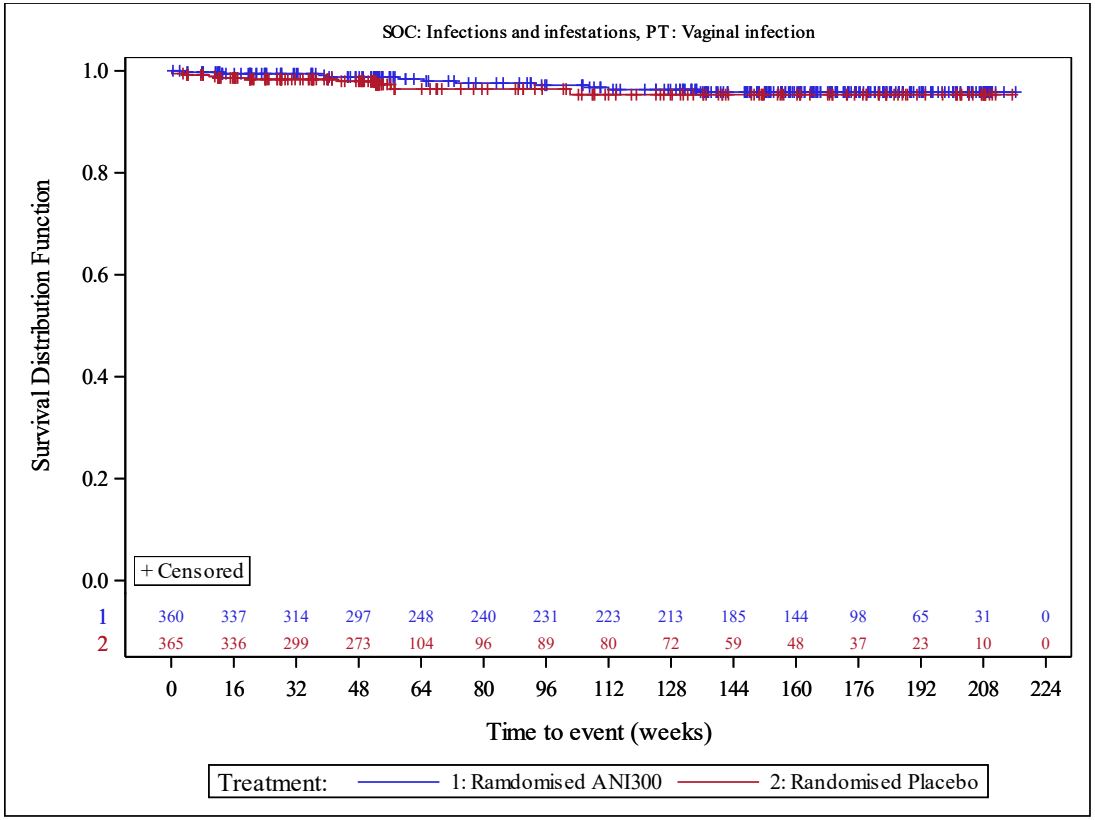

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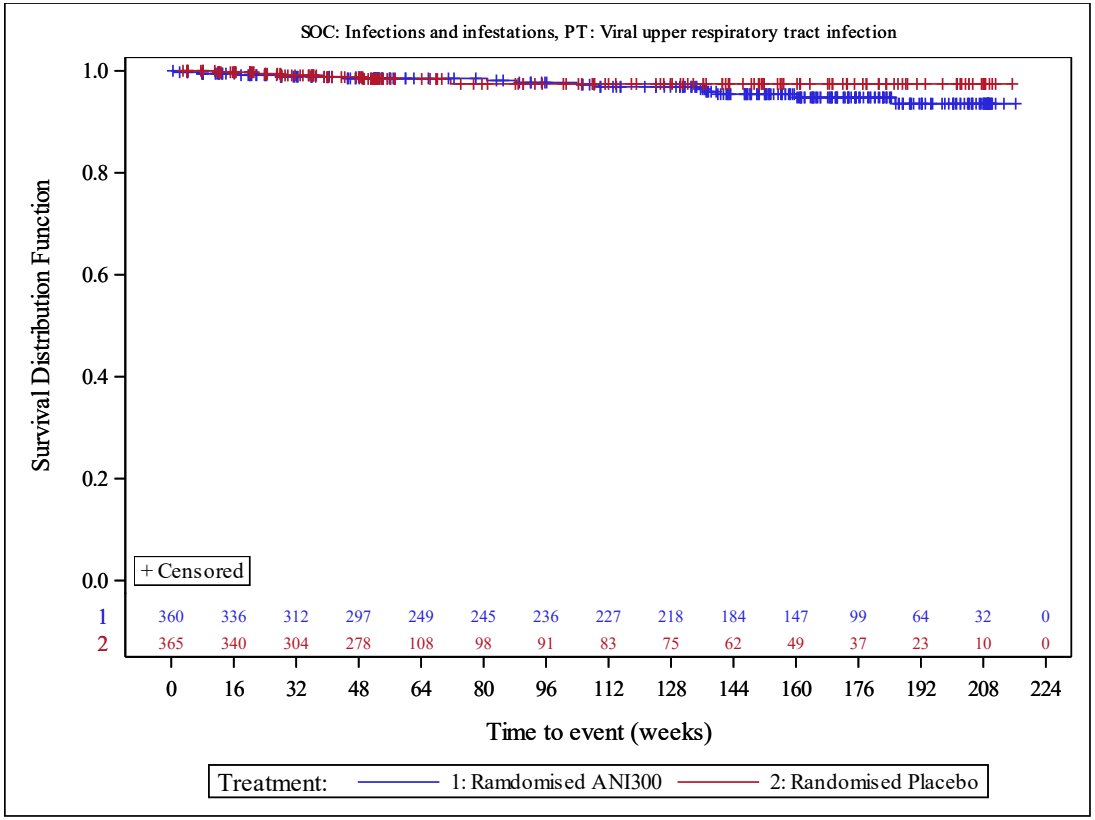

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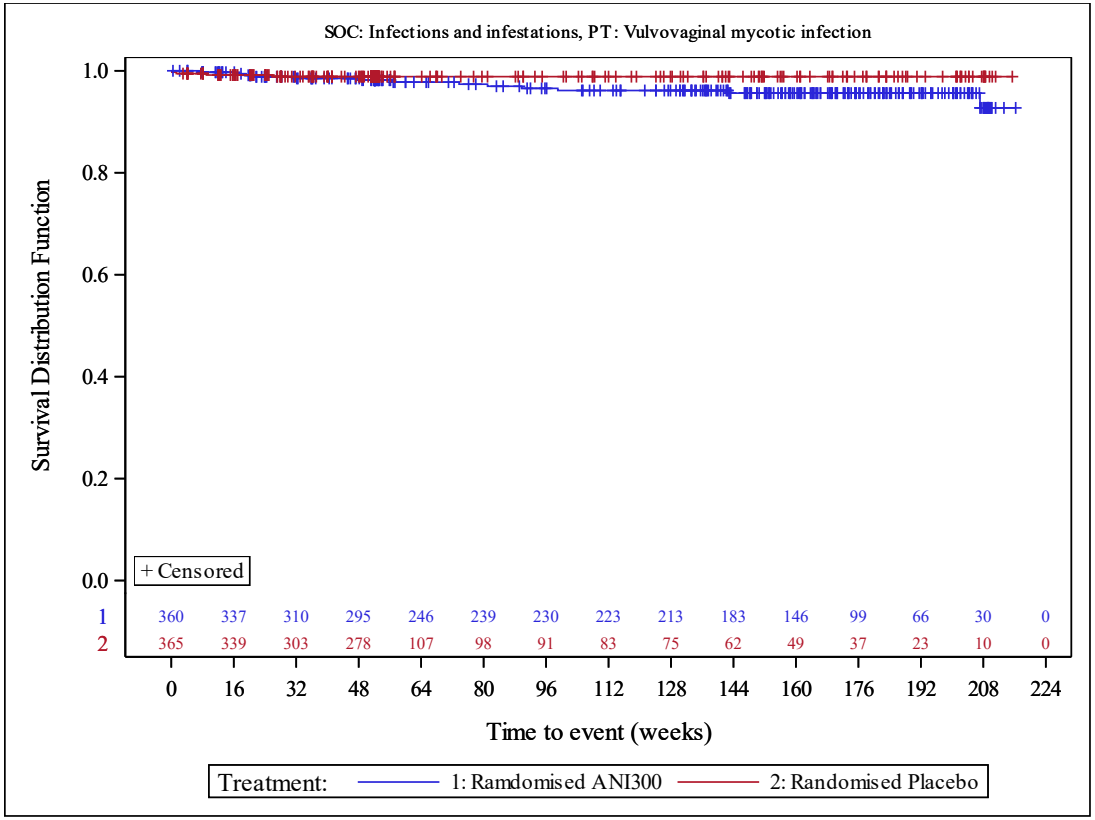

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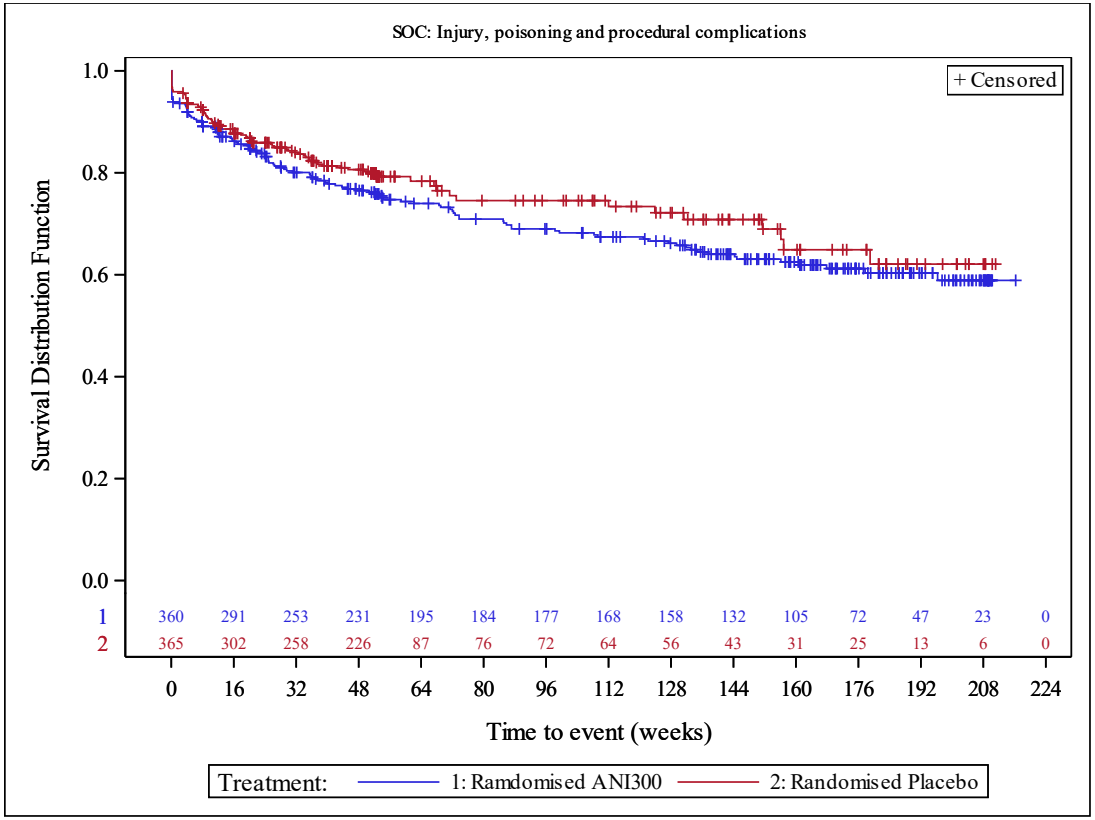

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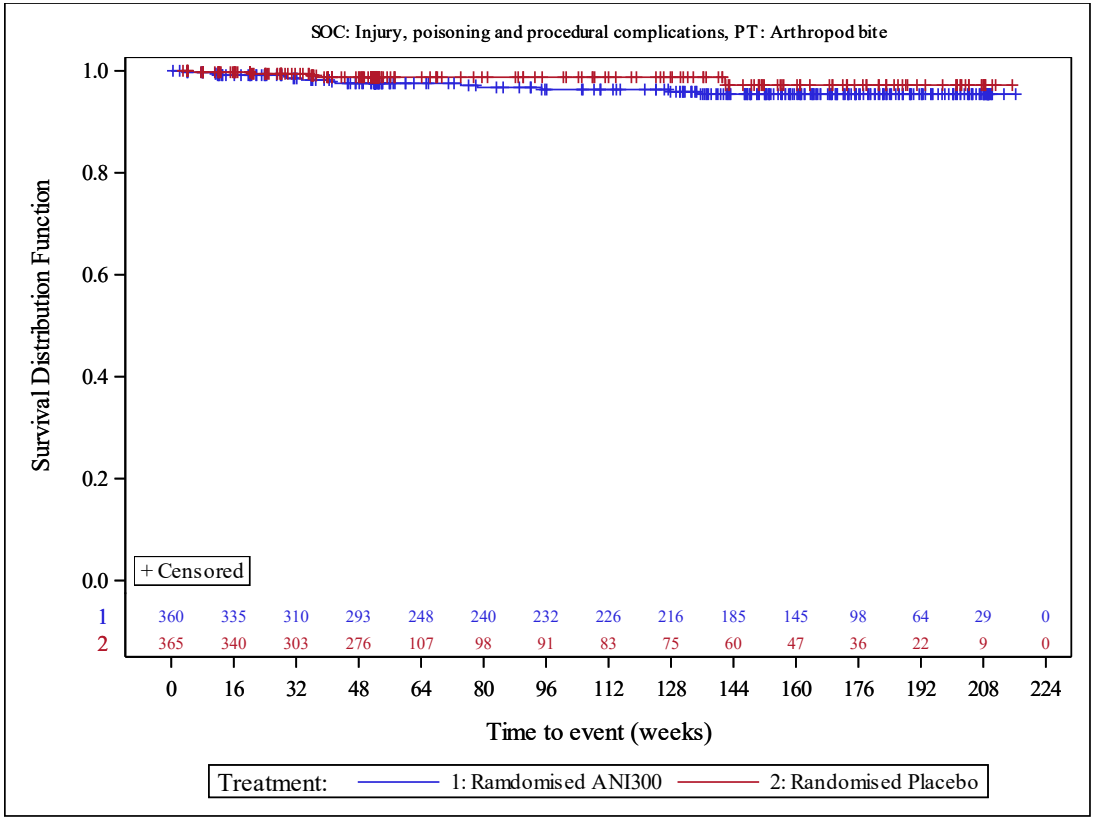

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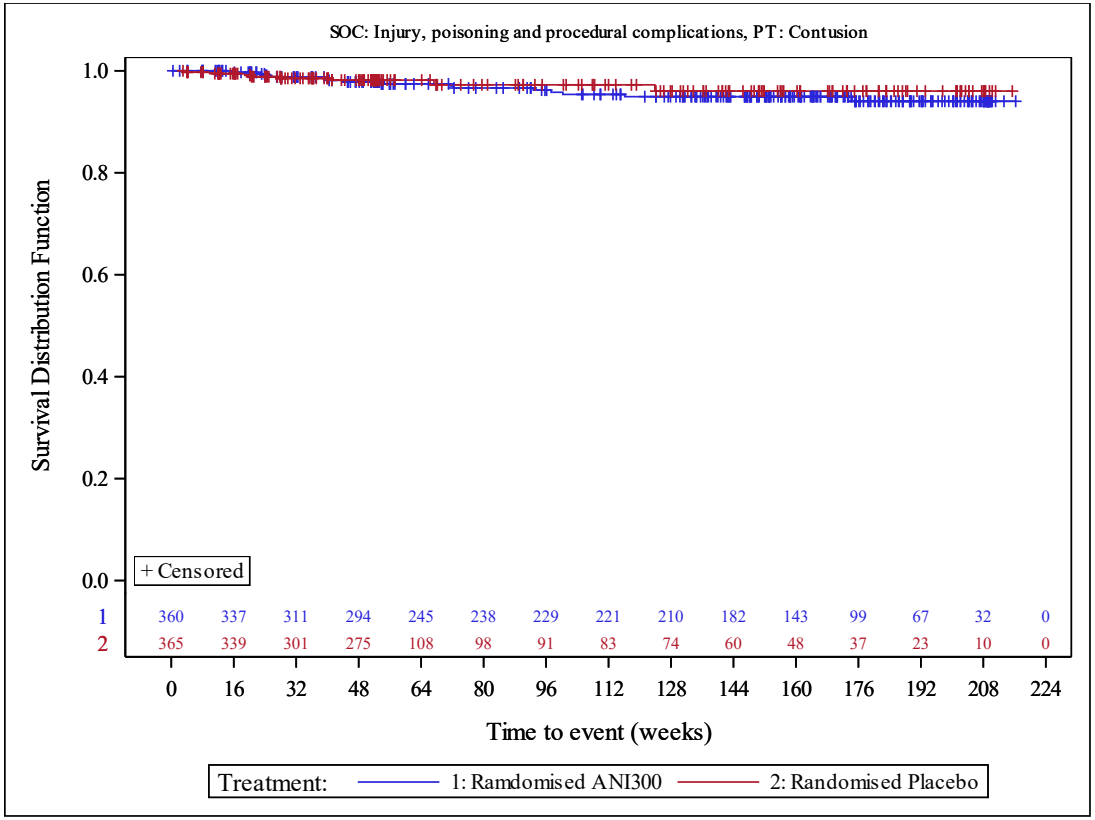

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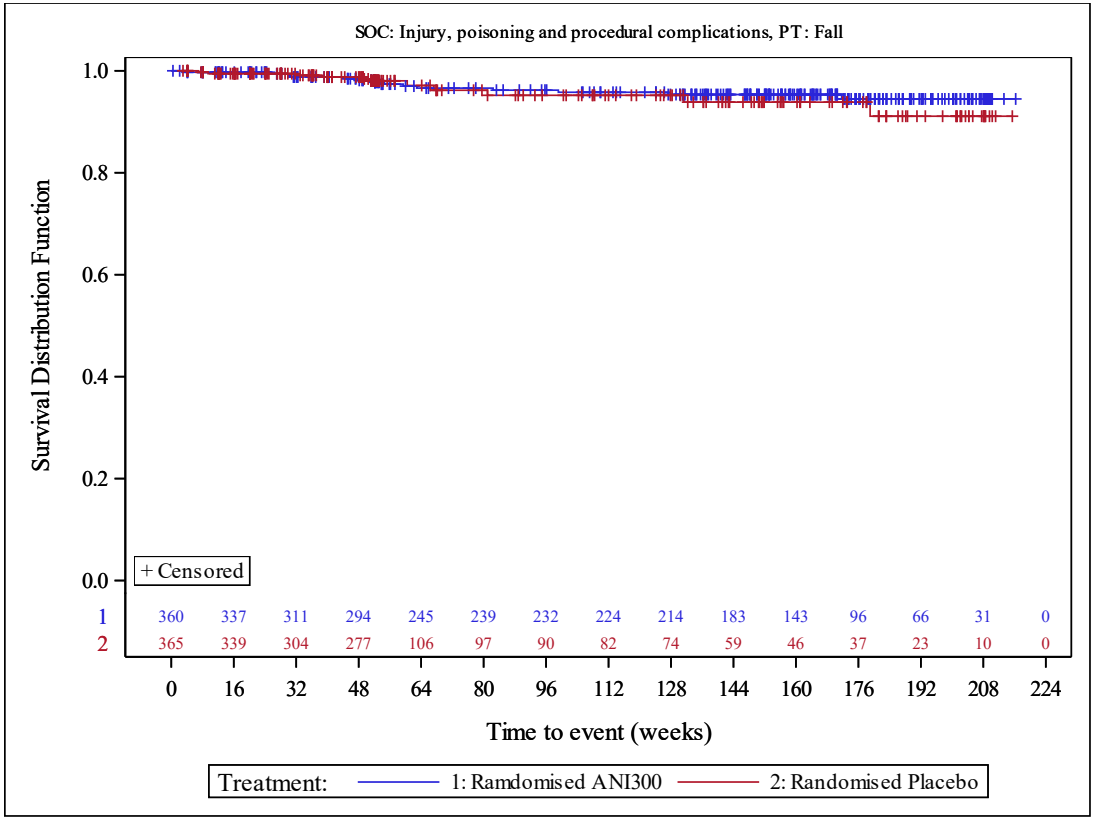

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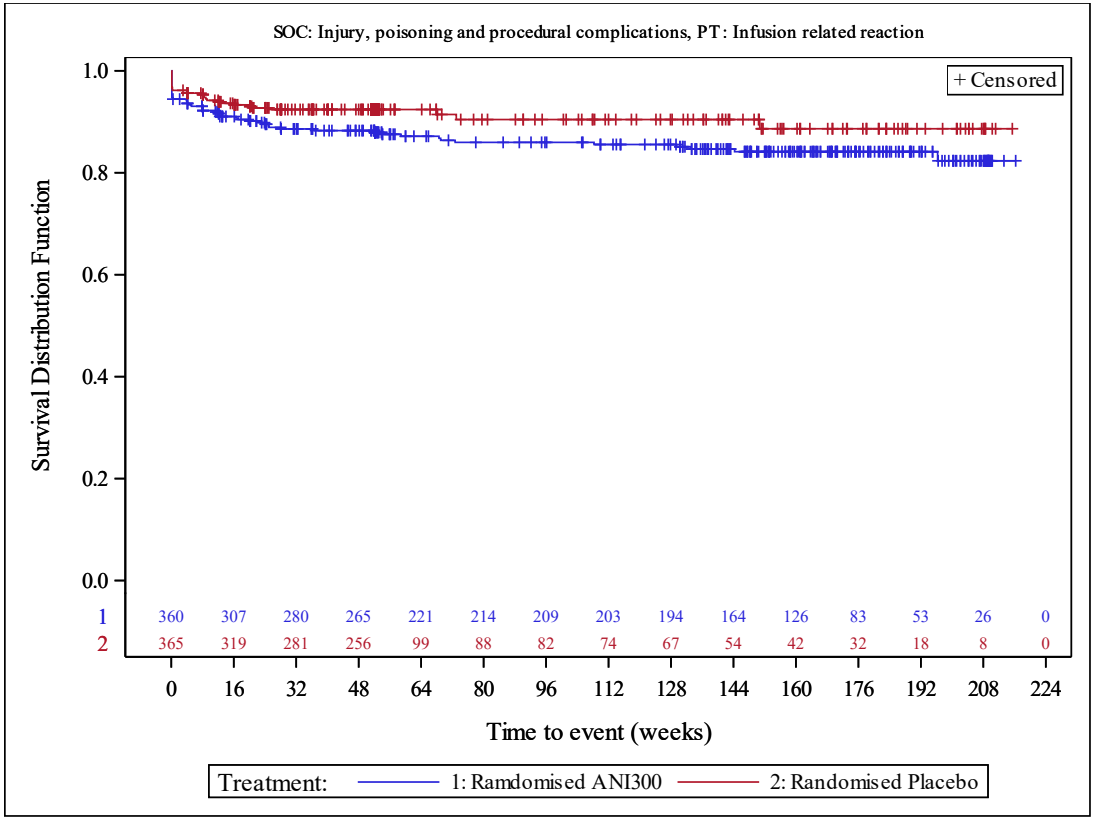

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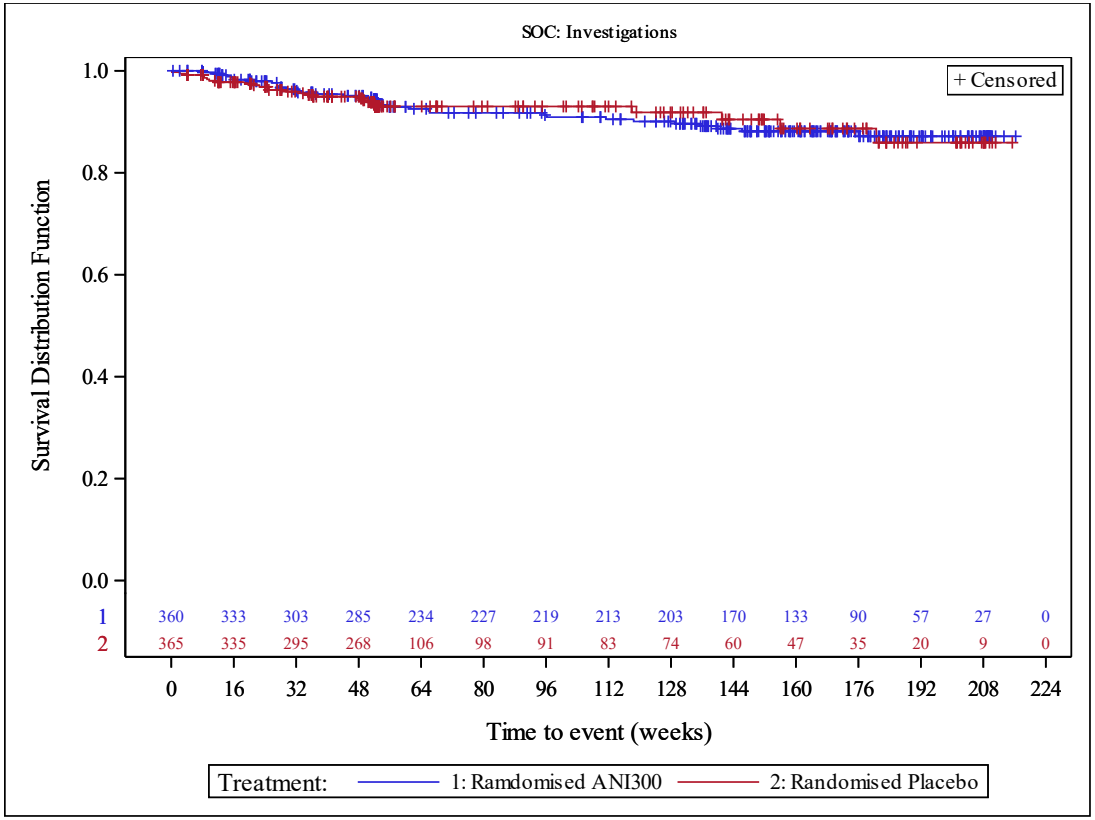

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Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Incidence and time to first frequent Adverse Event by SOC, PT during treatment (incidence in either arm >= 10% or >=10 patients)
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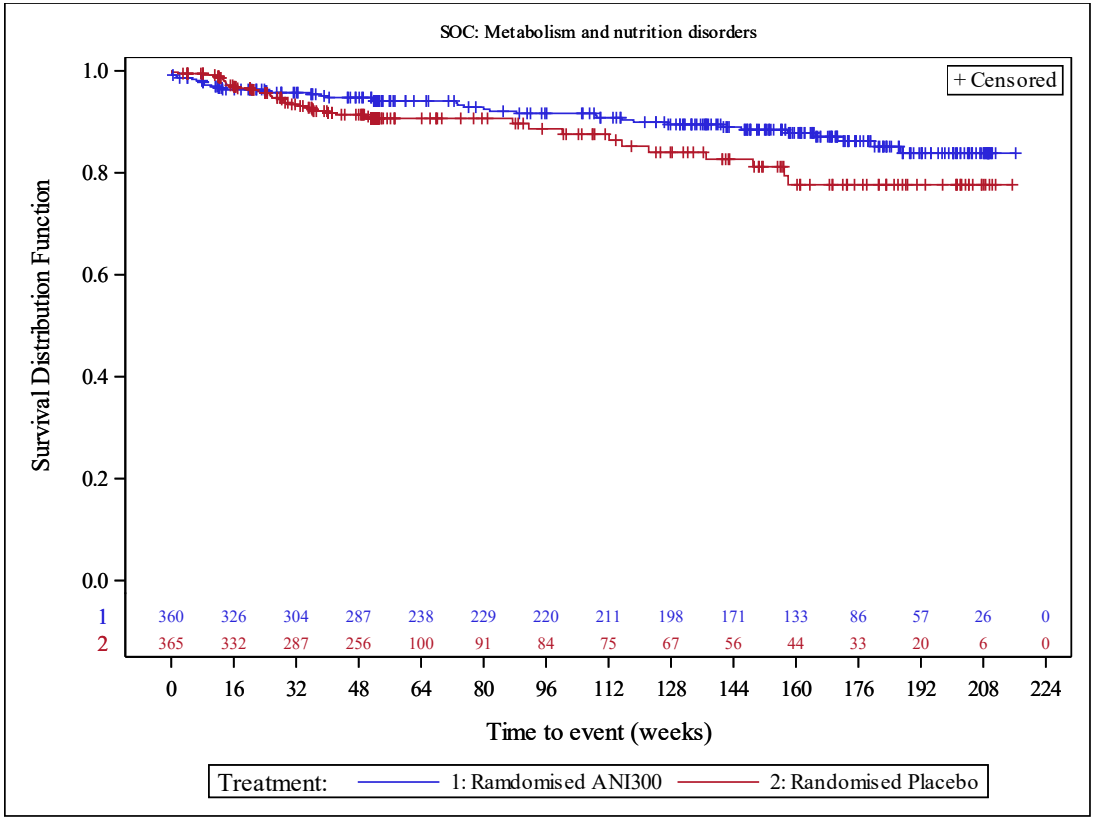

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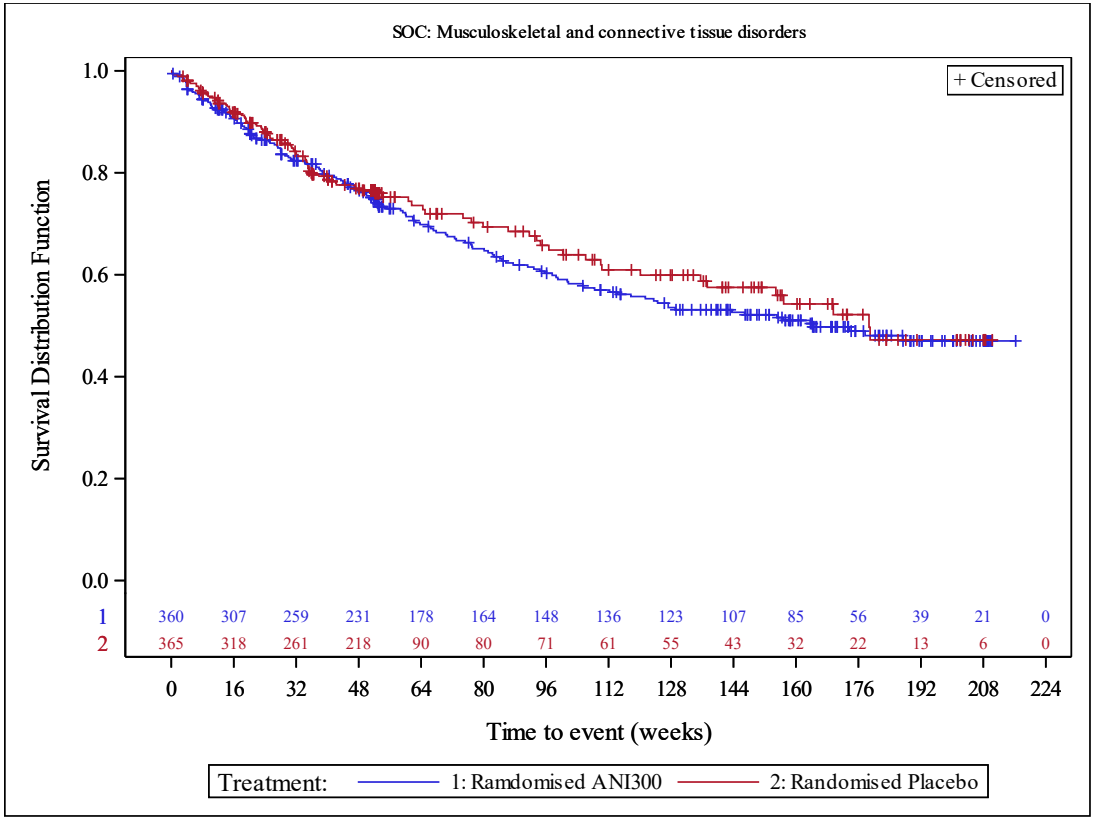

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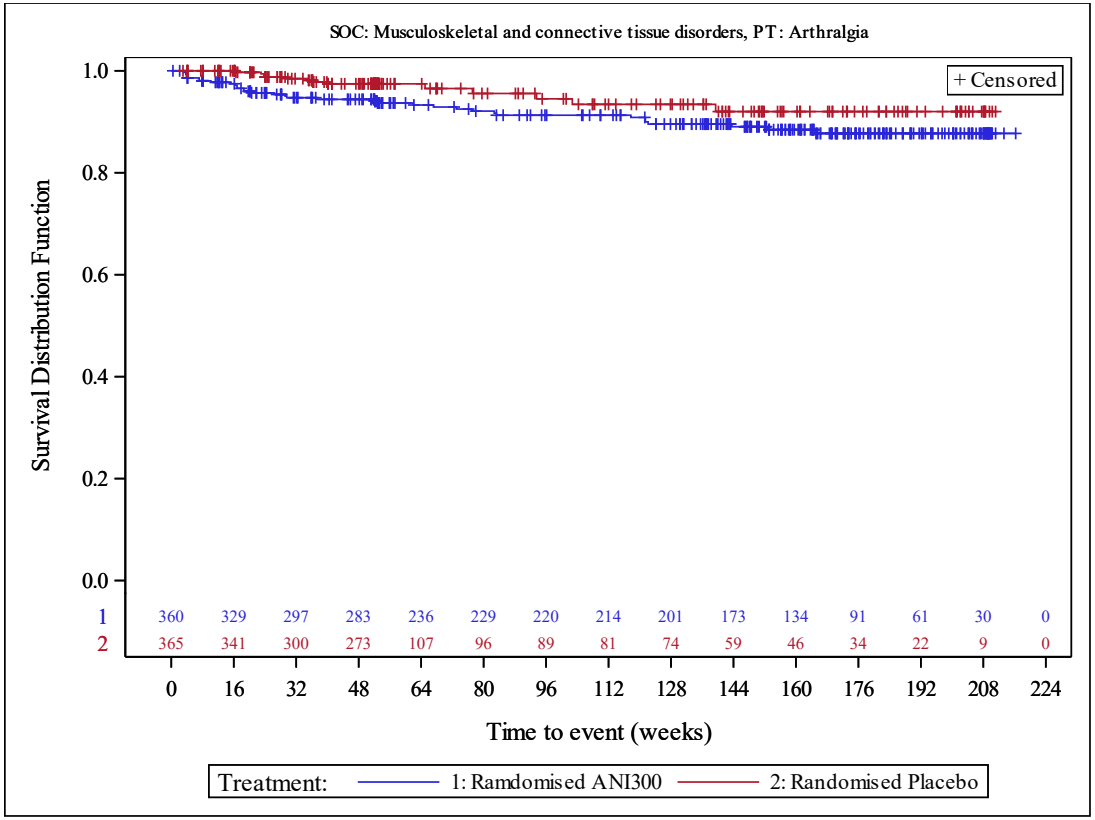

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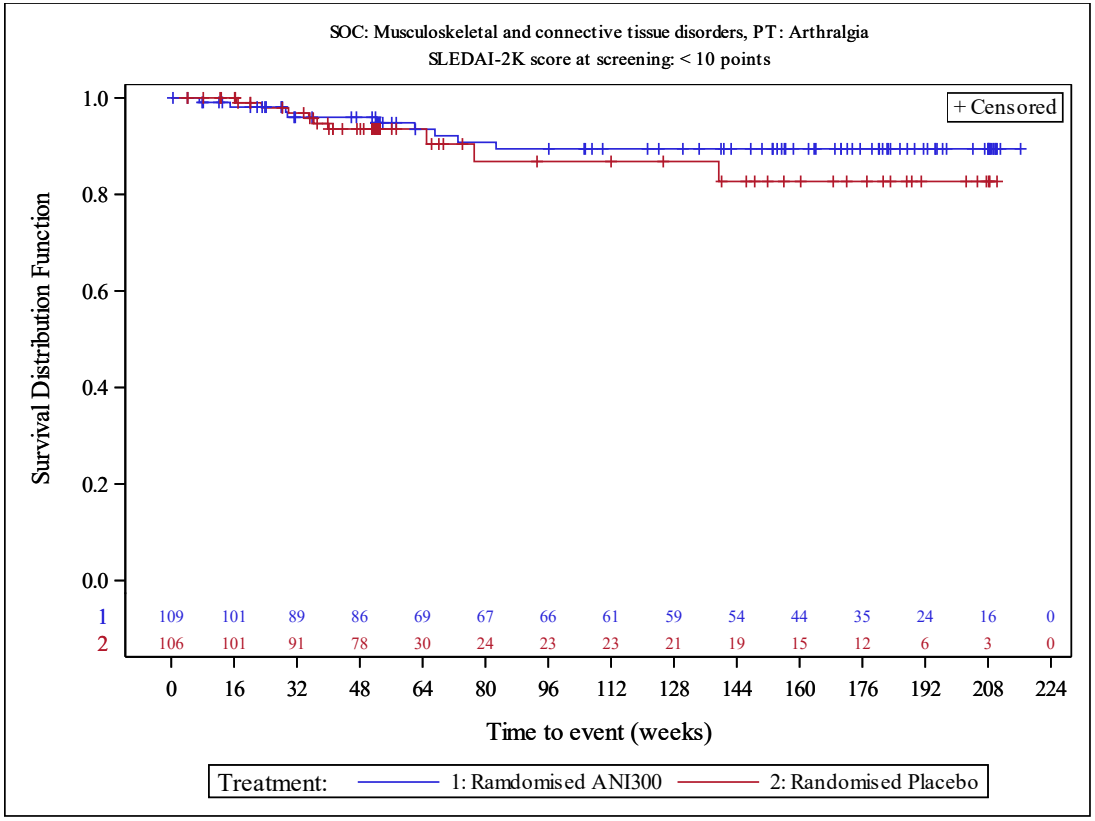

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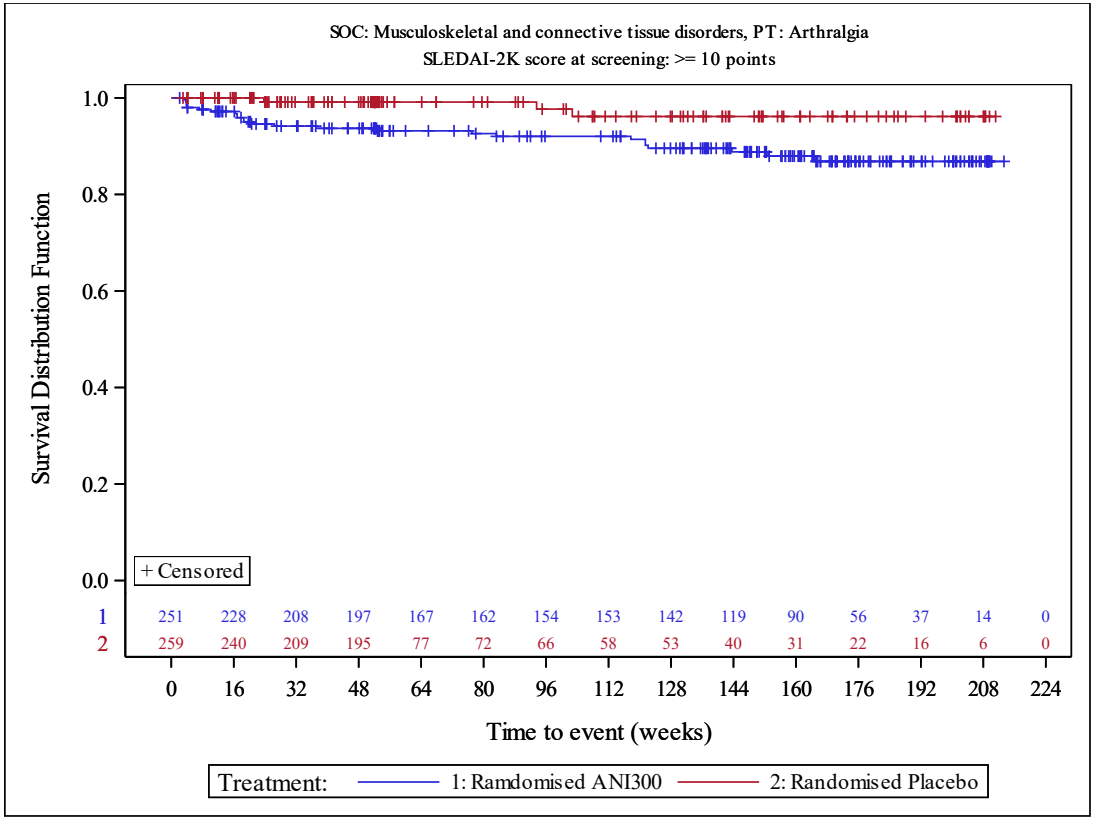

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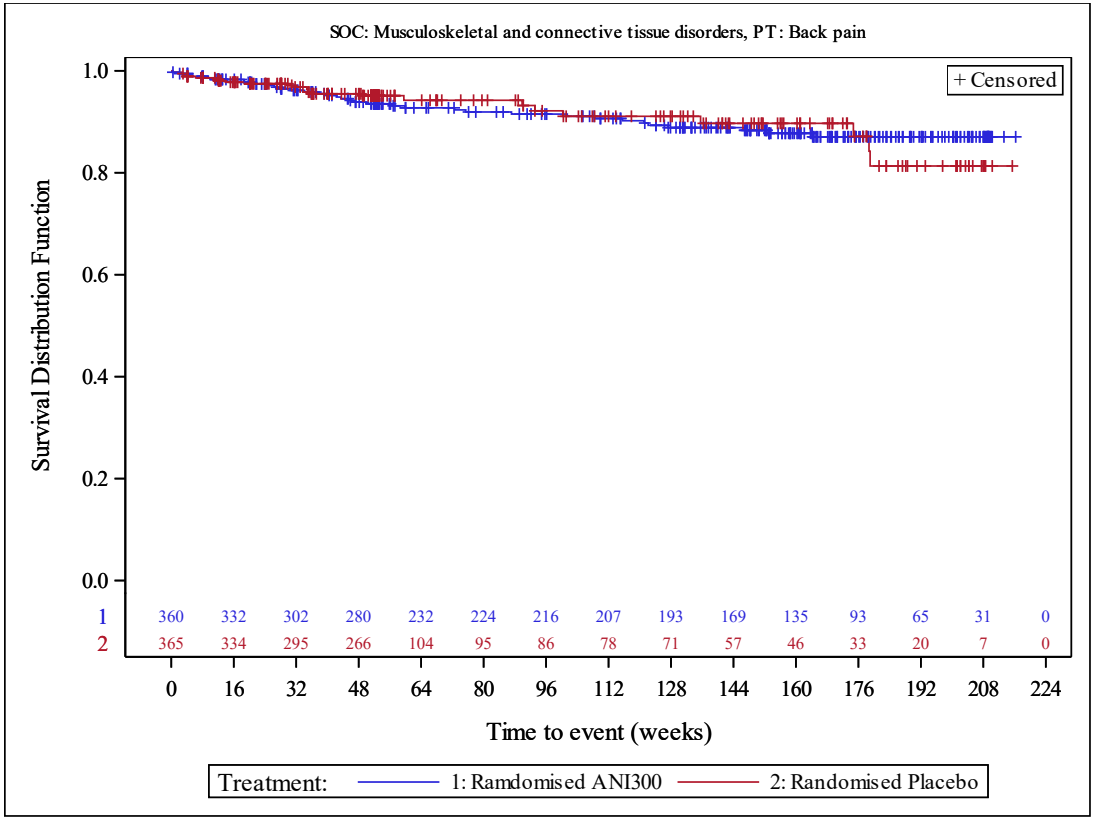

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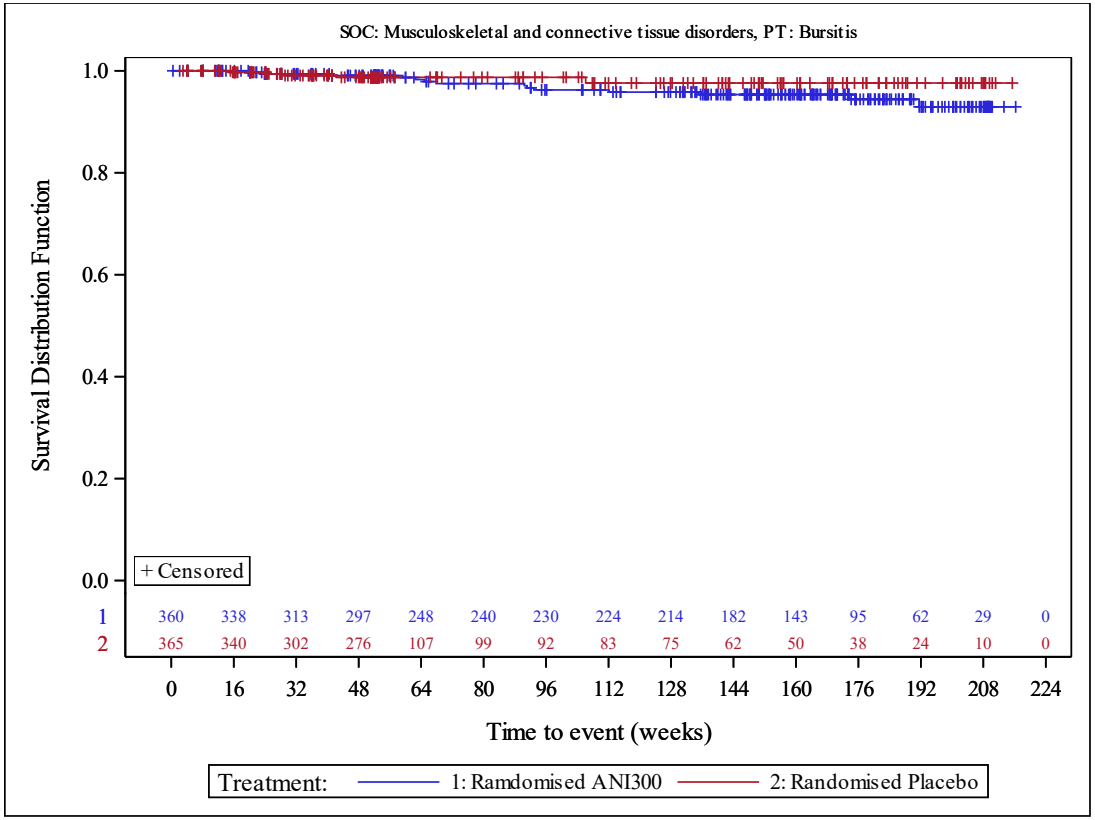

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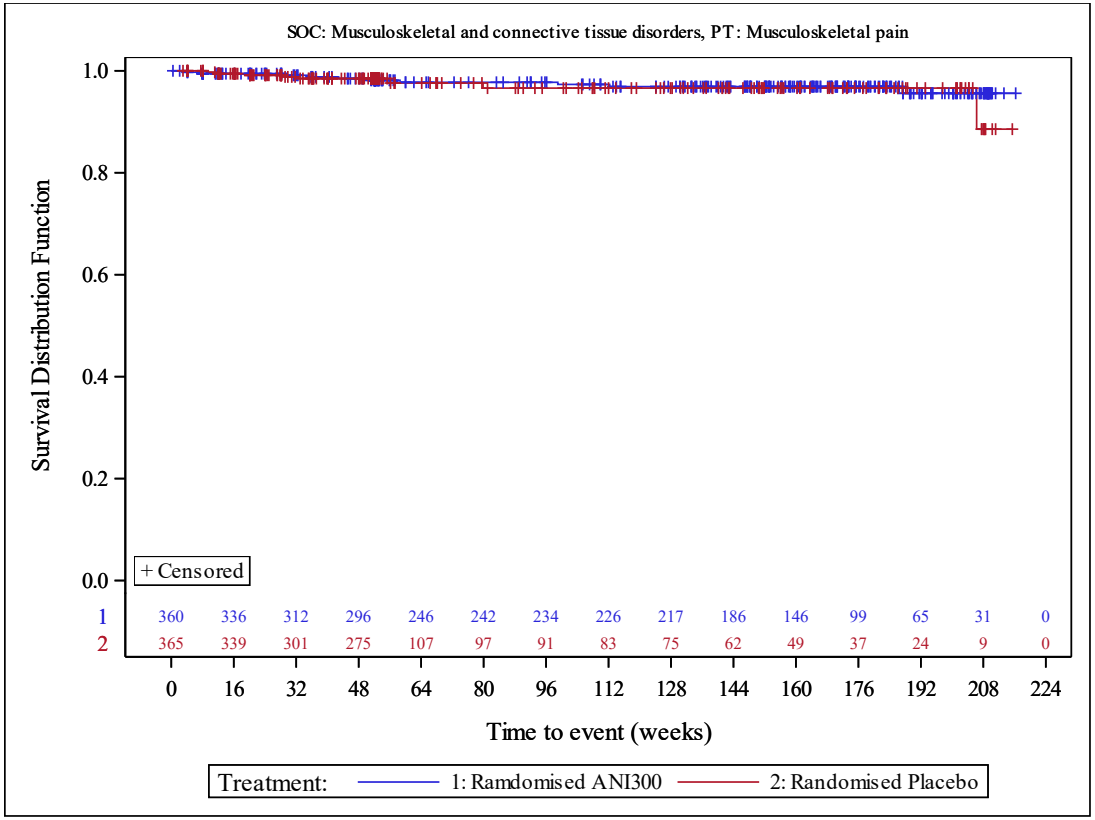

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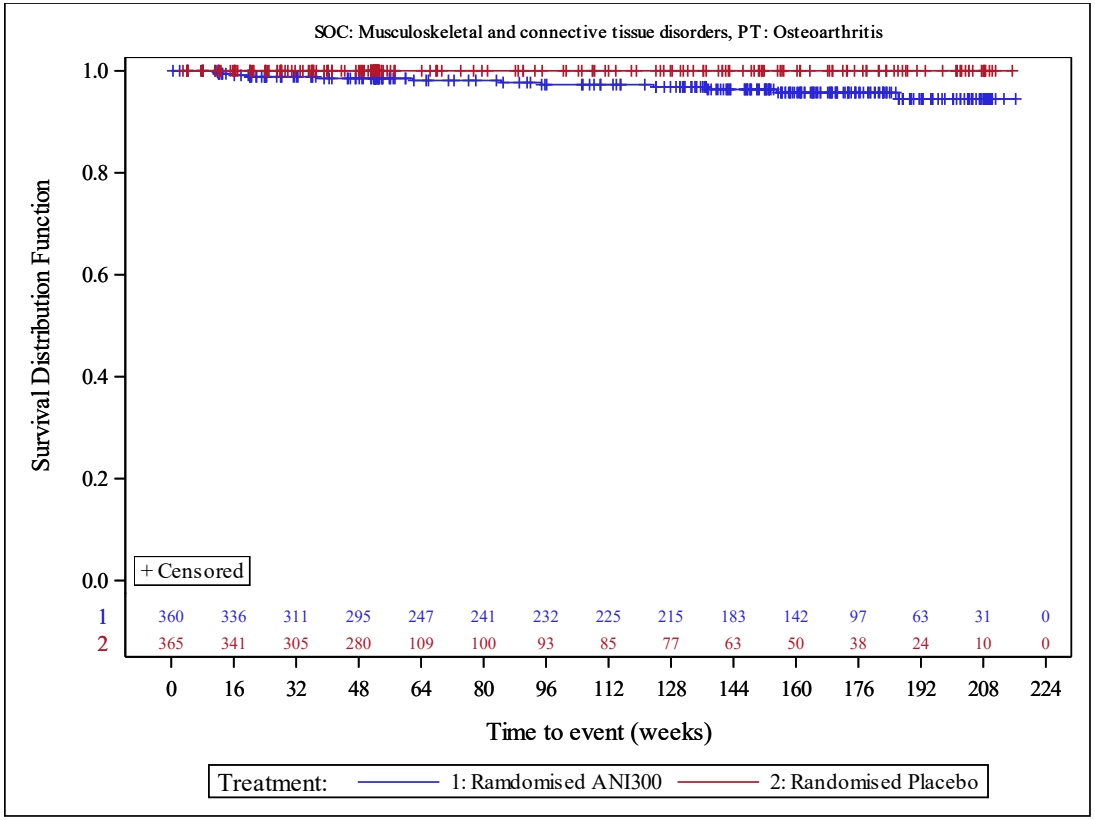

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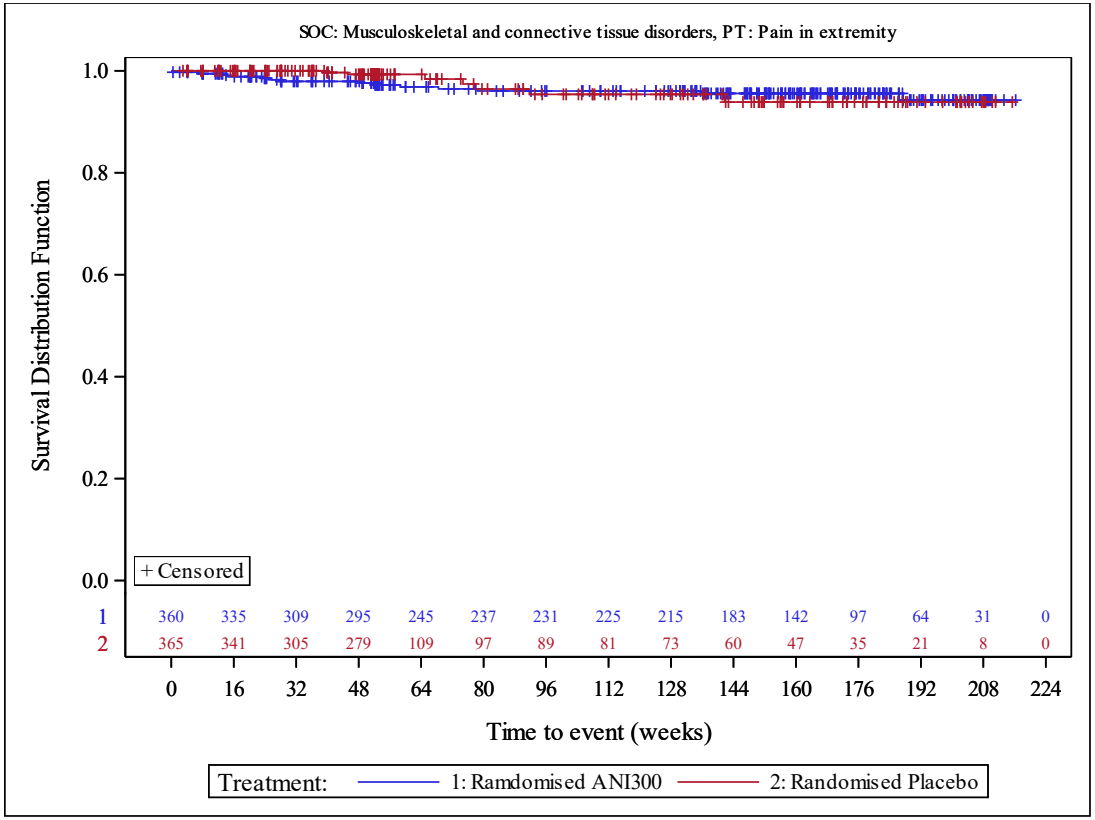

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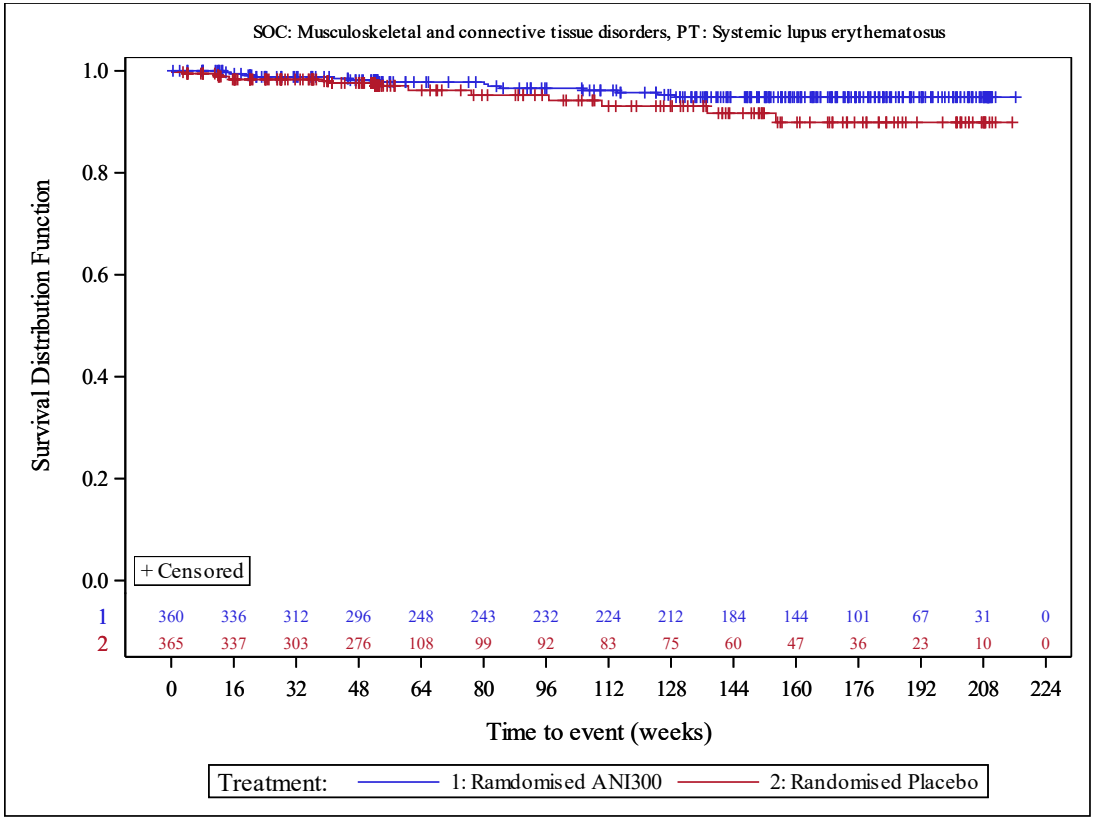

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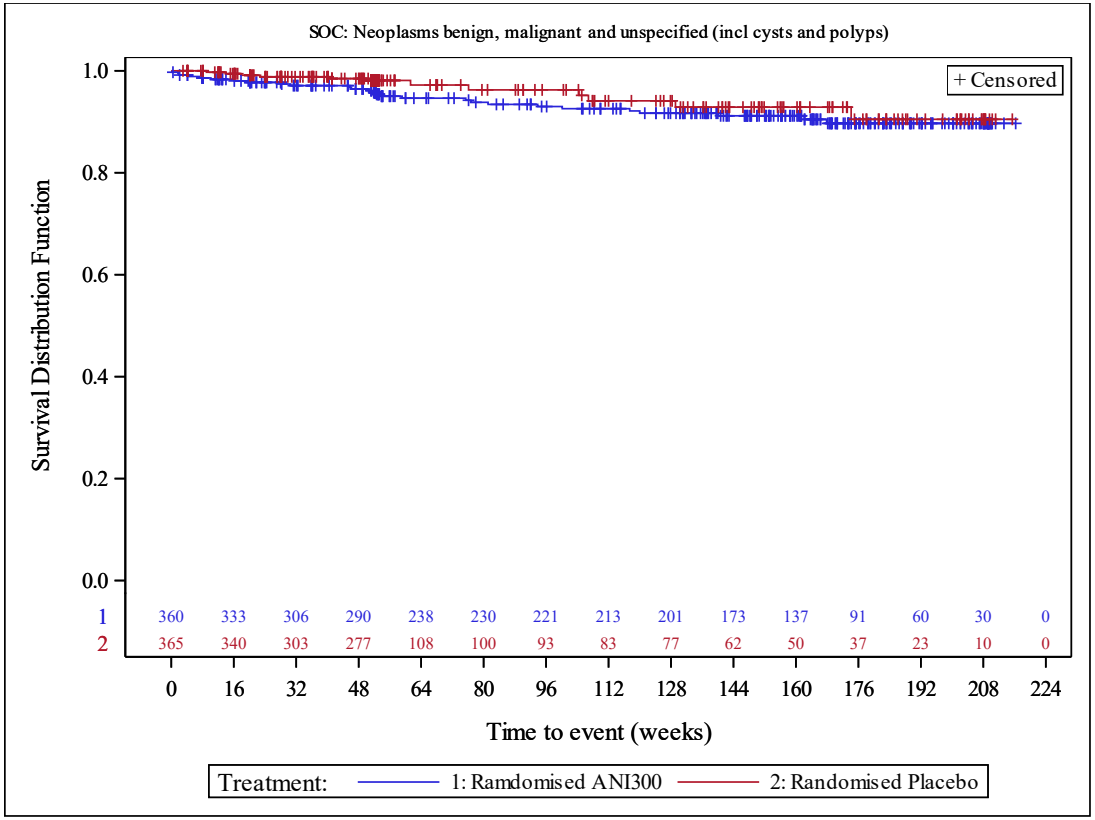

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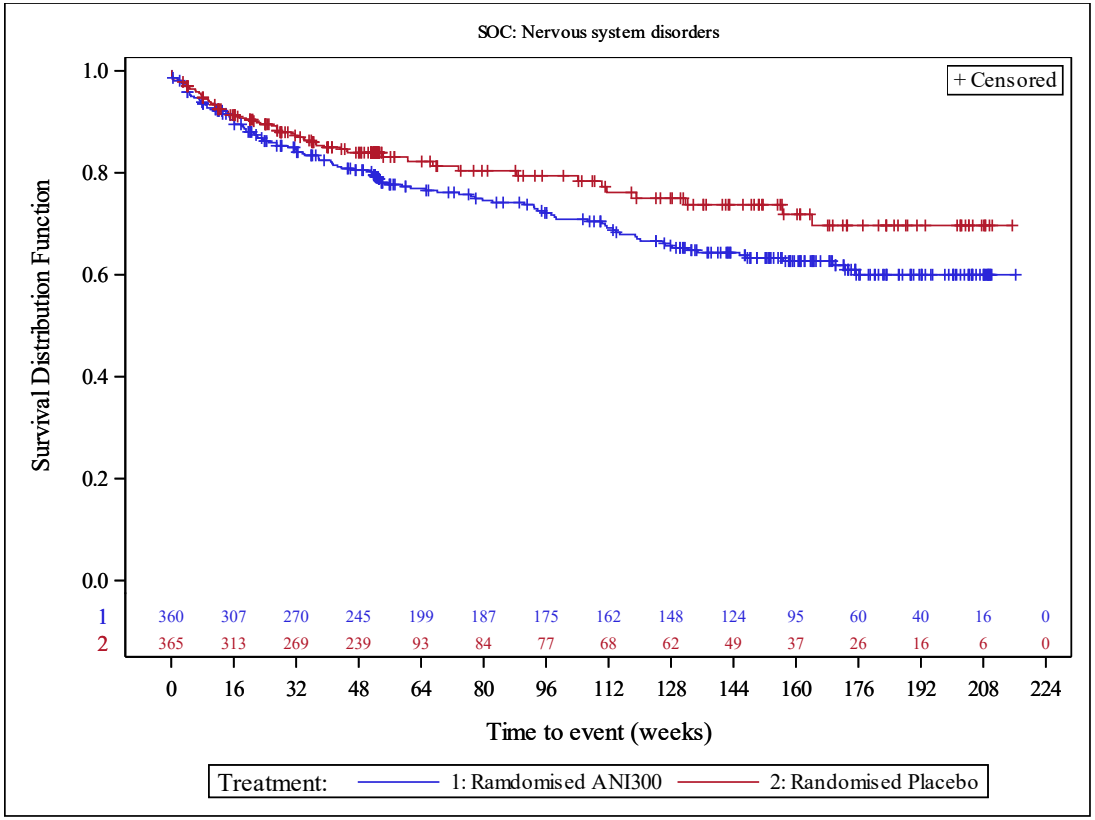

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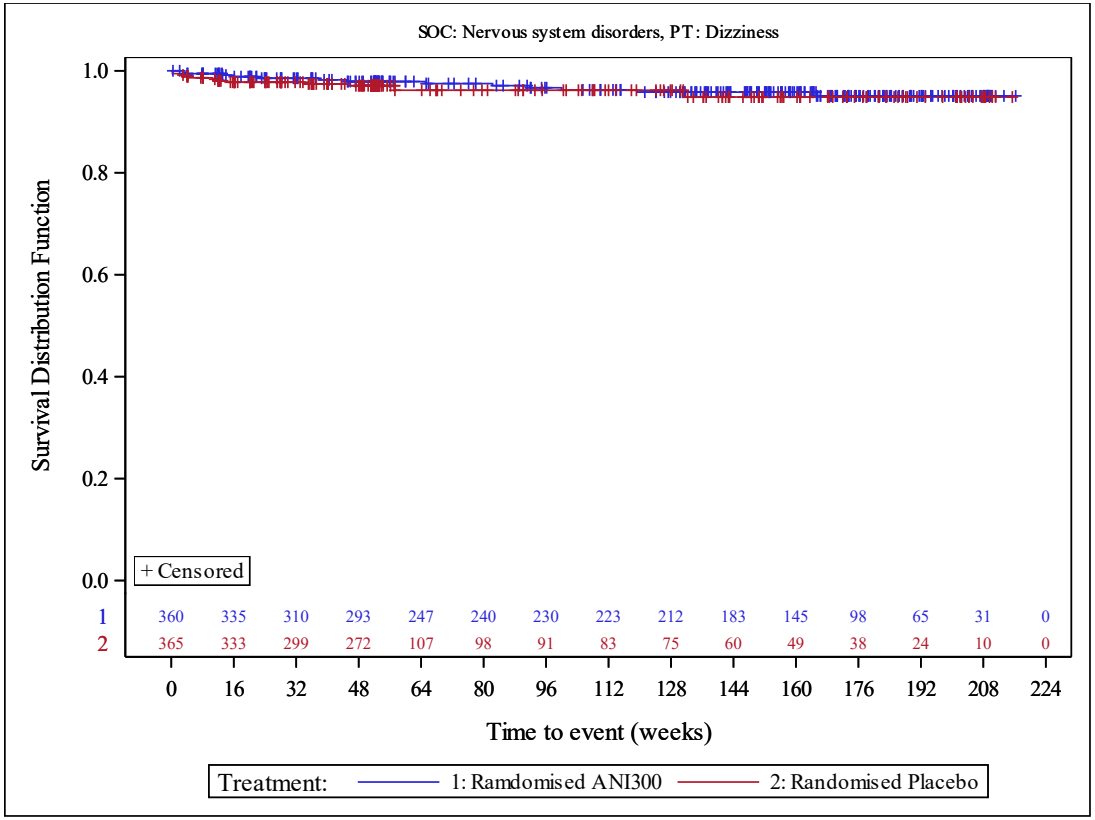

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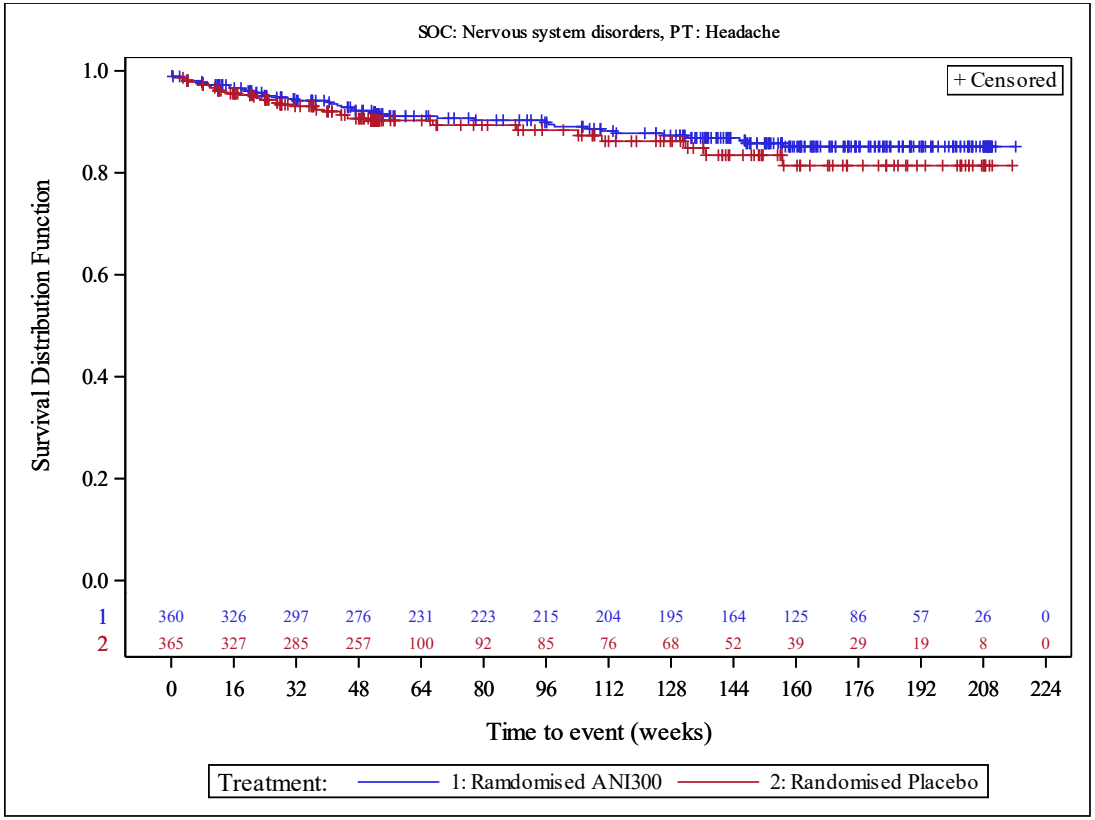

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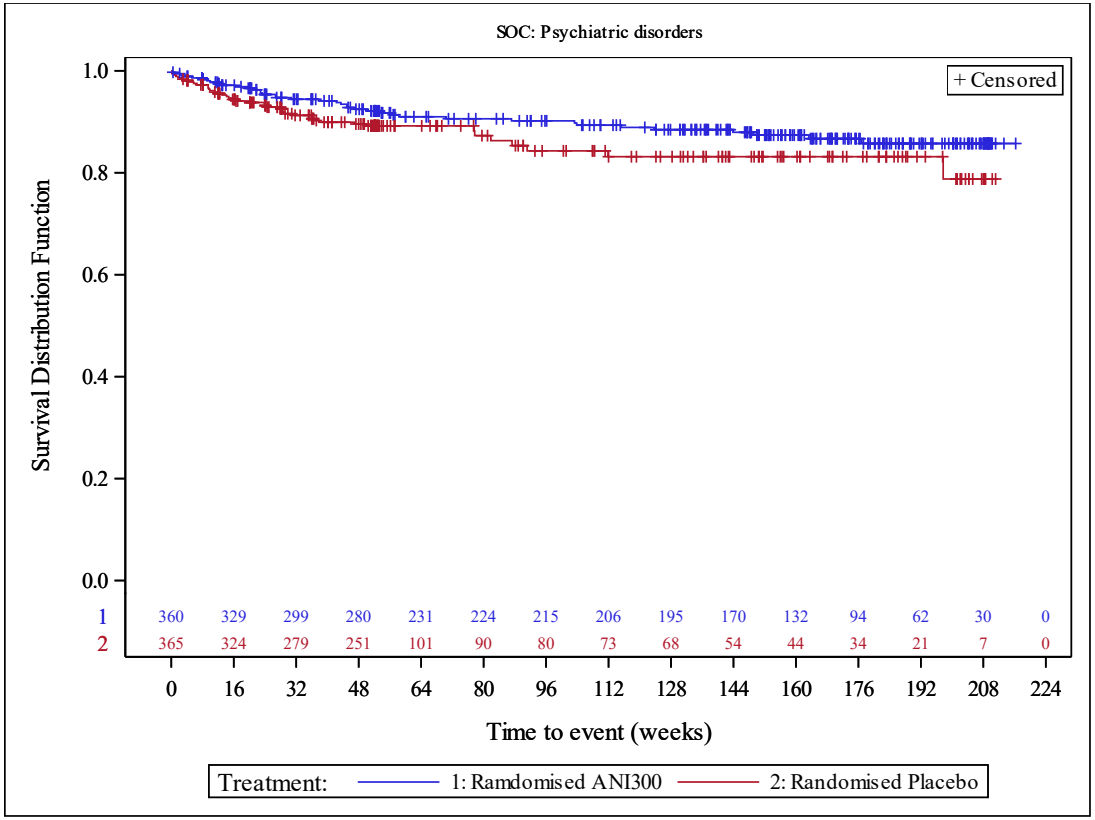

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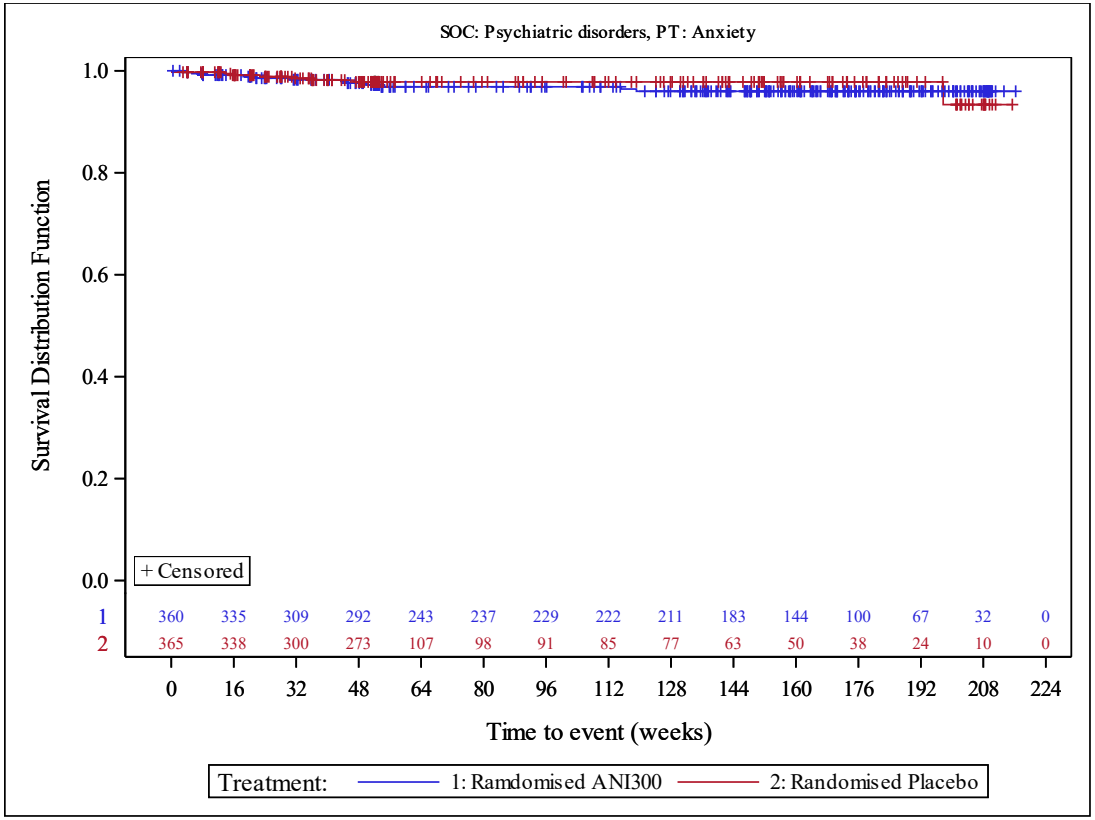

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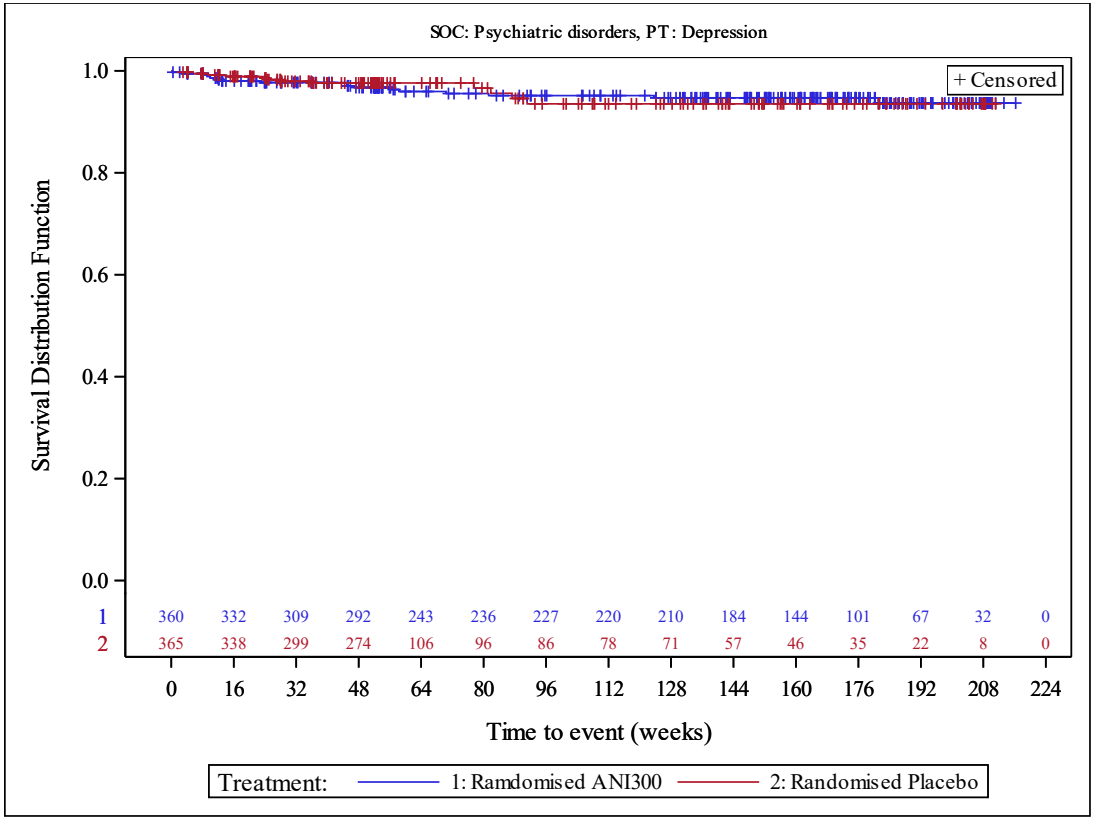

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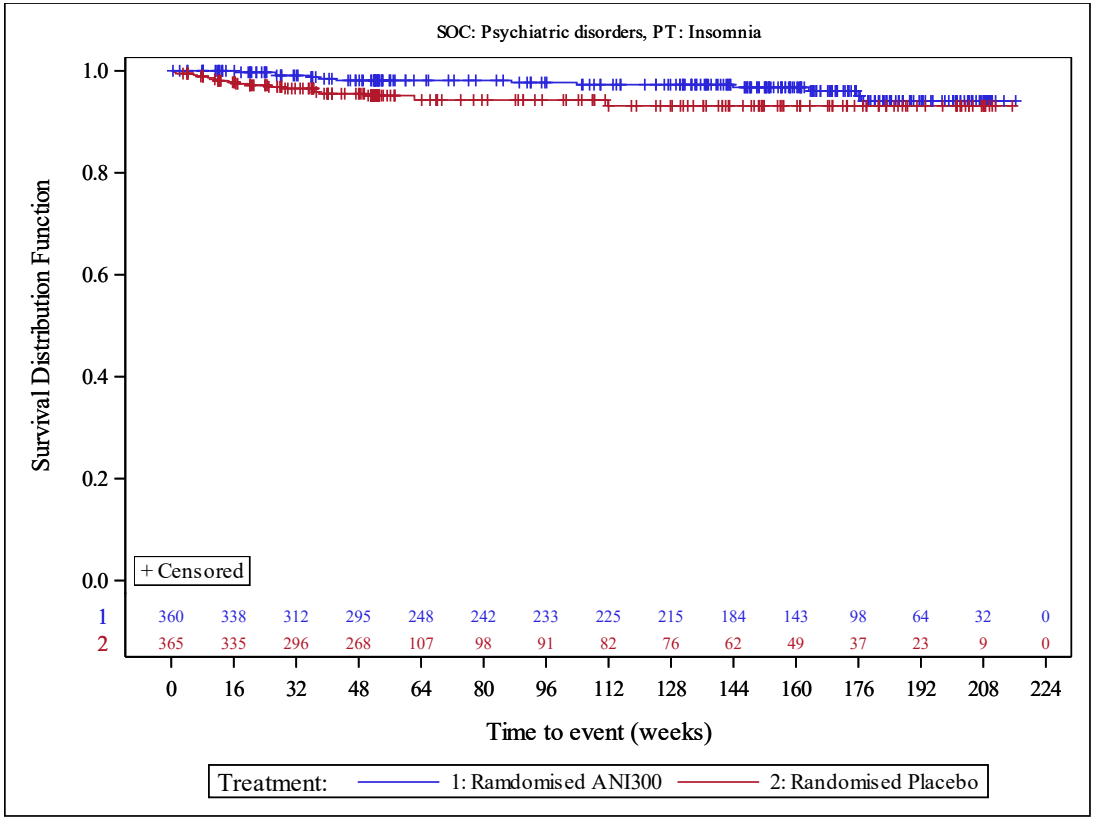

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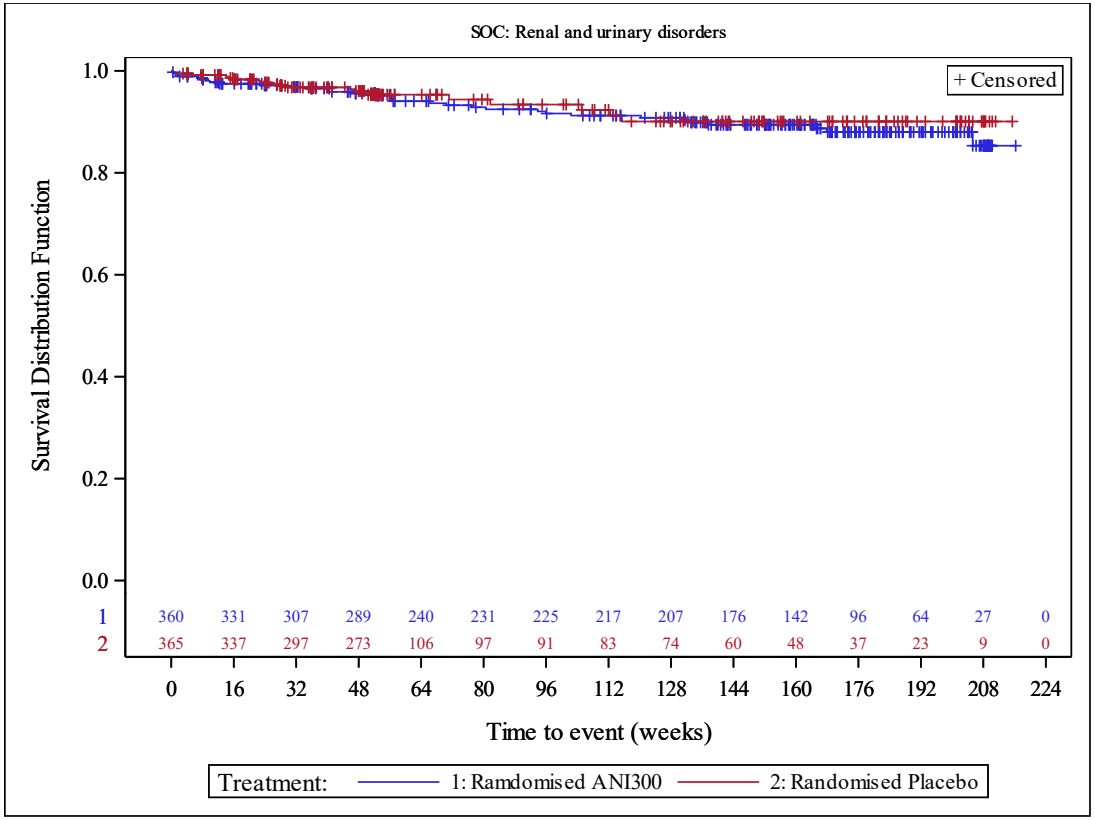

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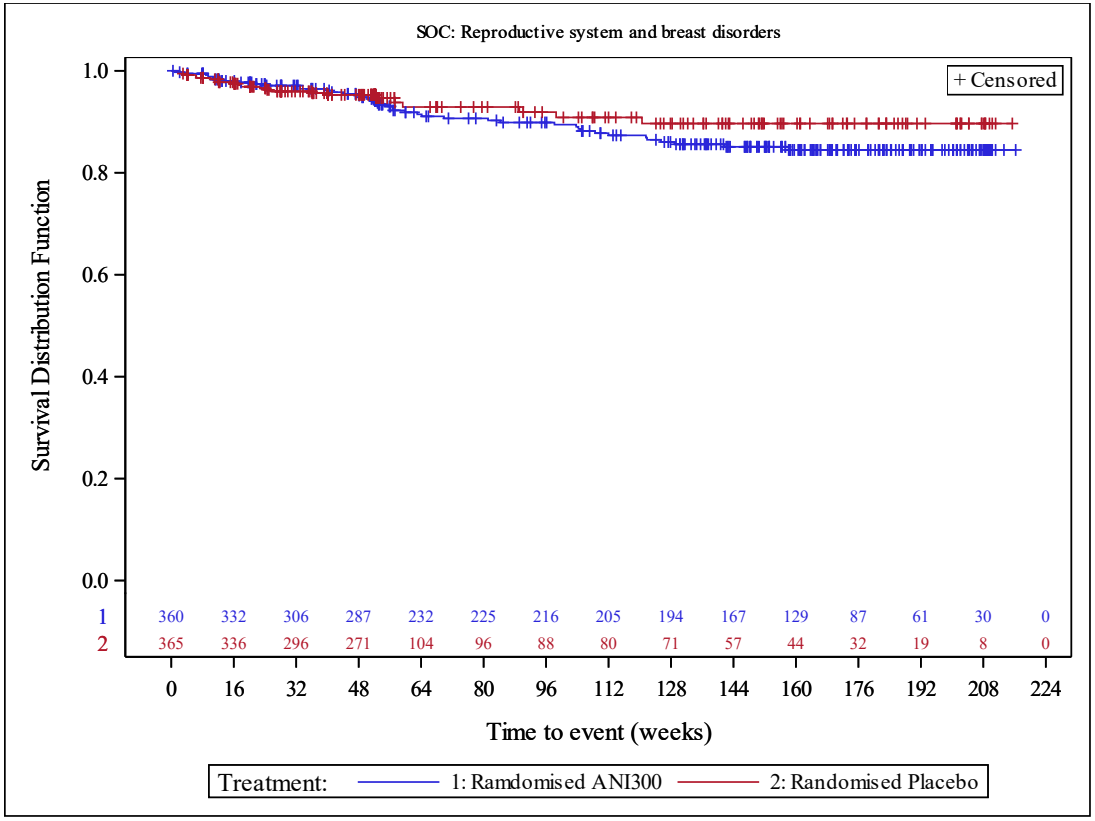

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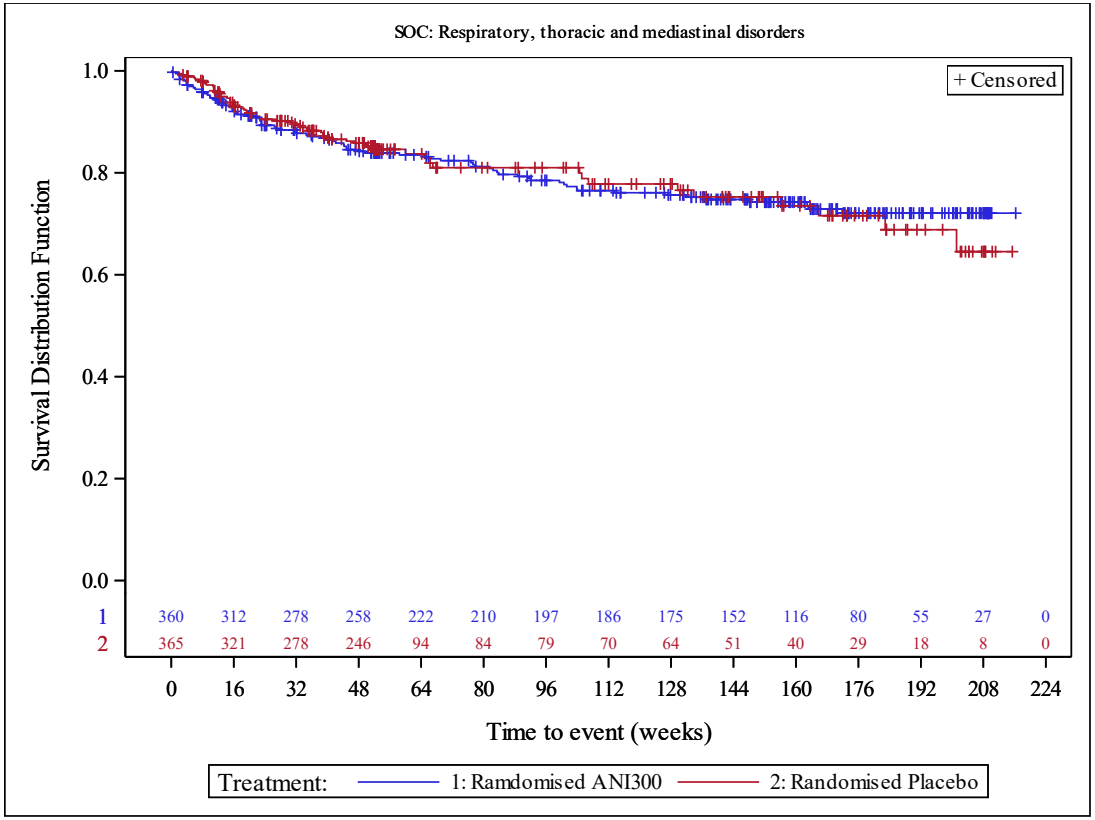

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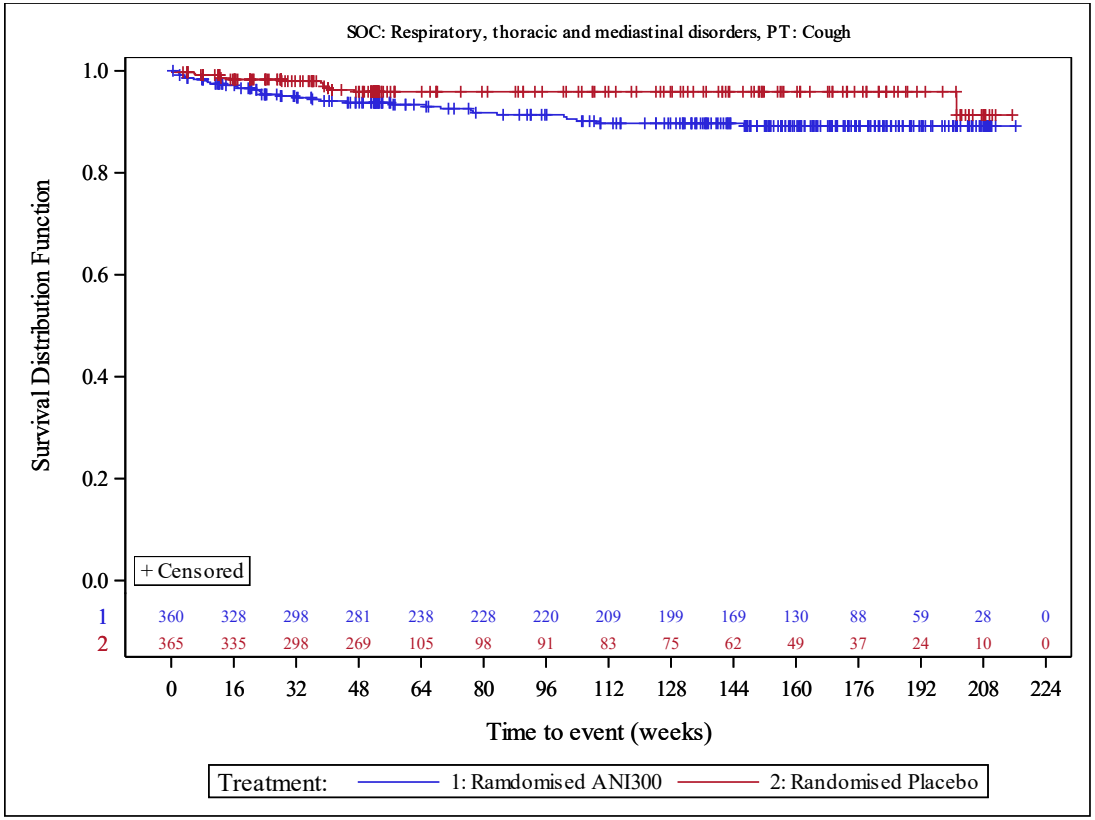

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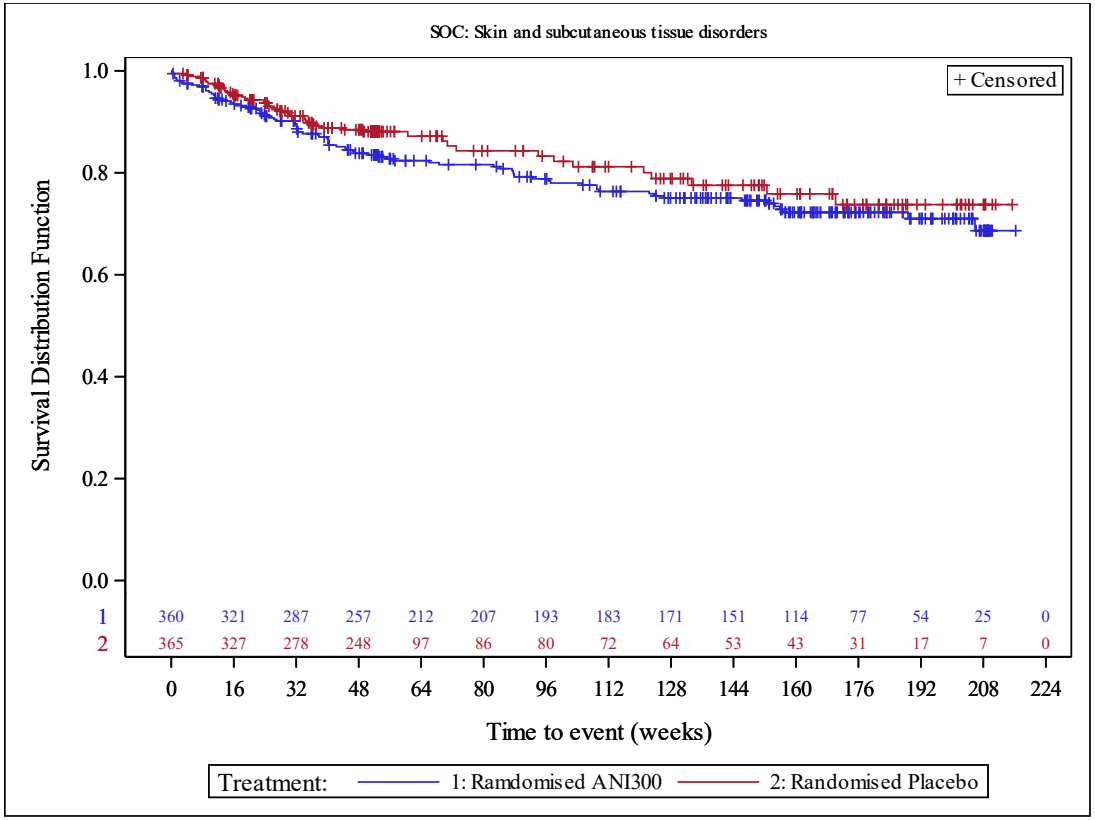

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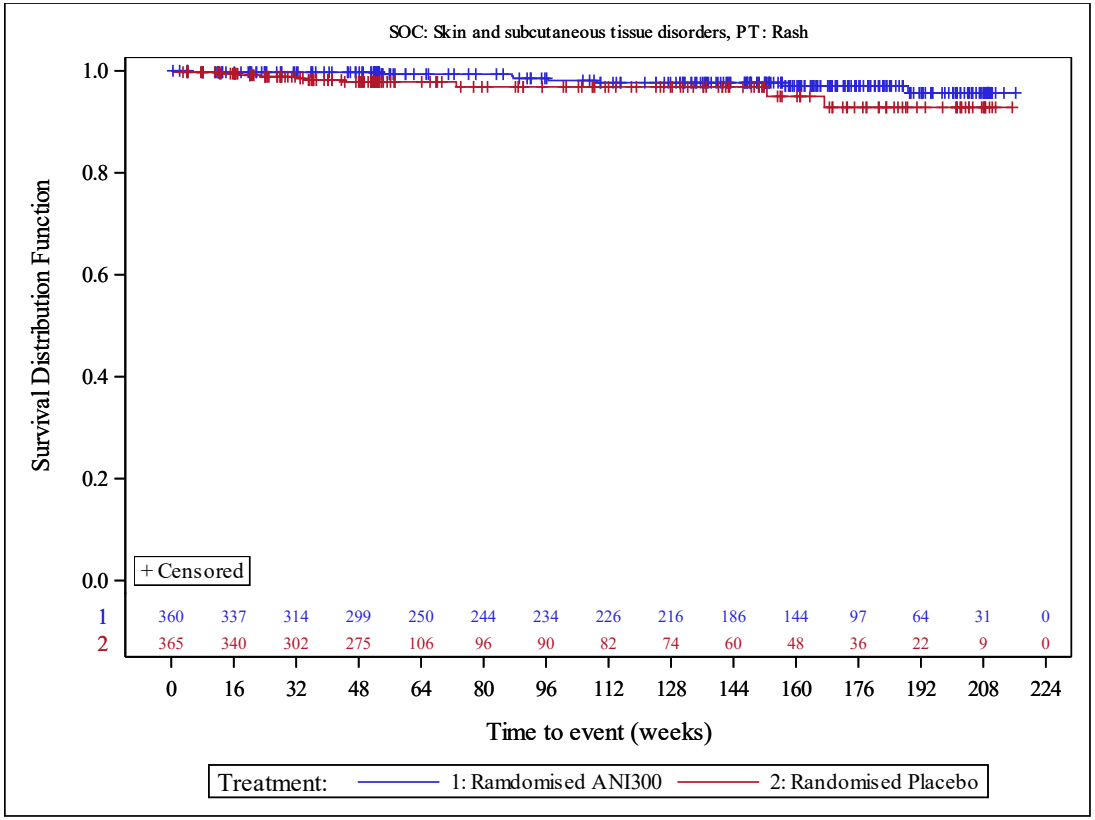

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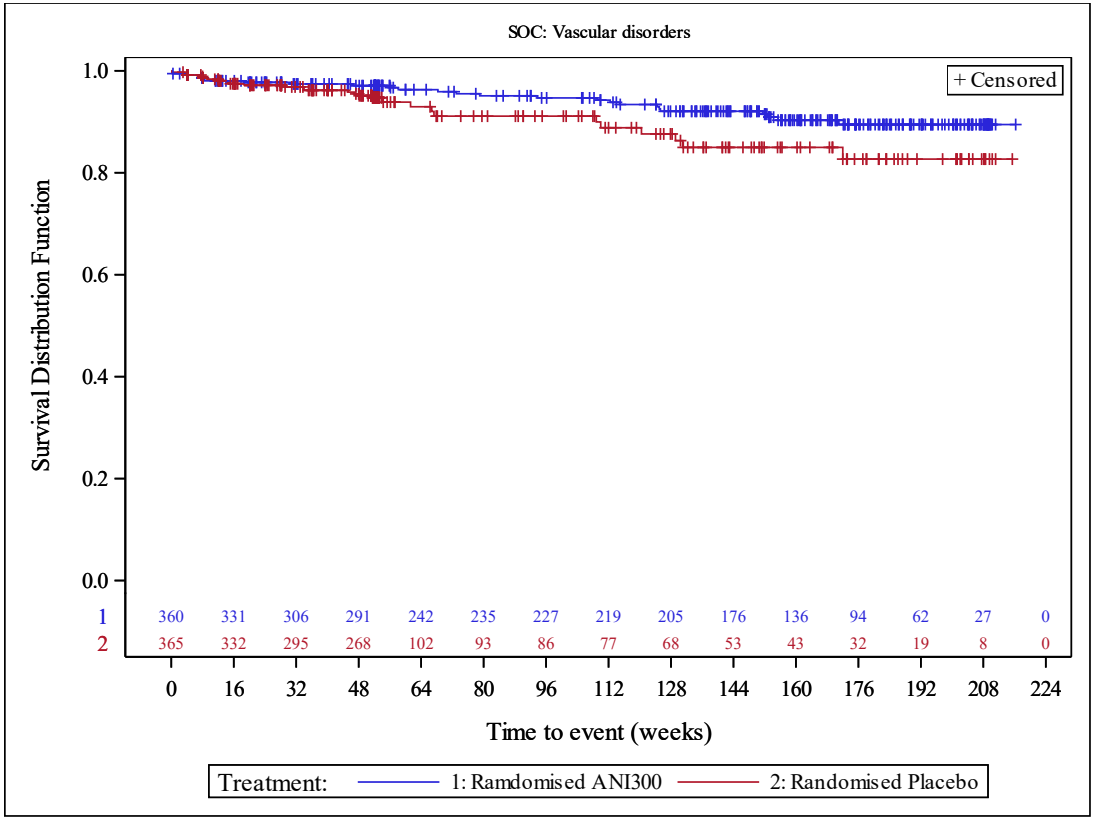

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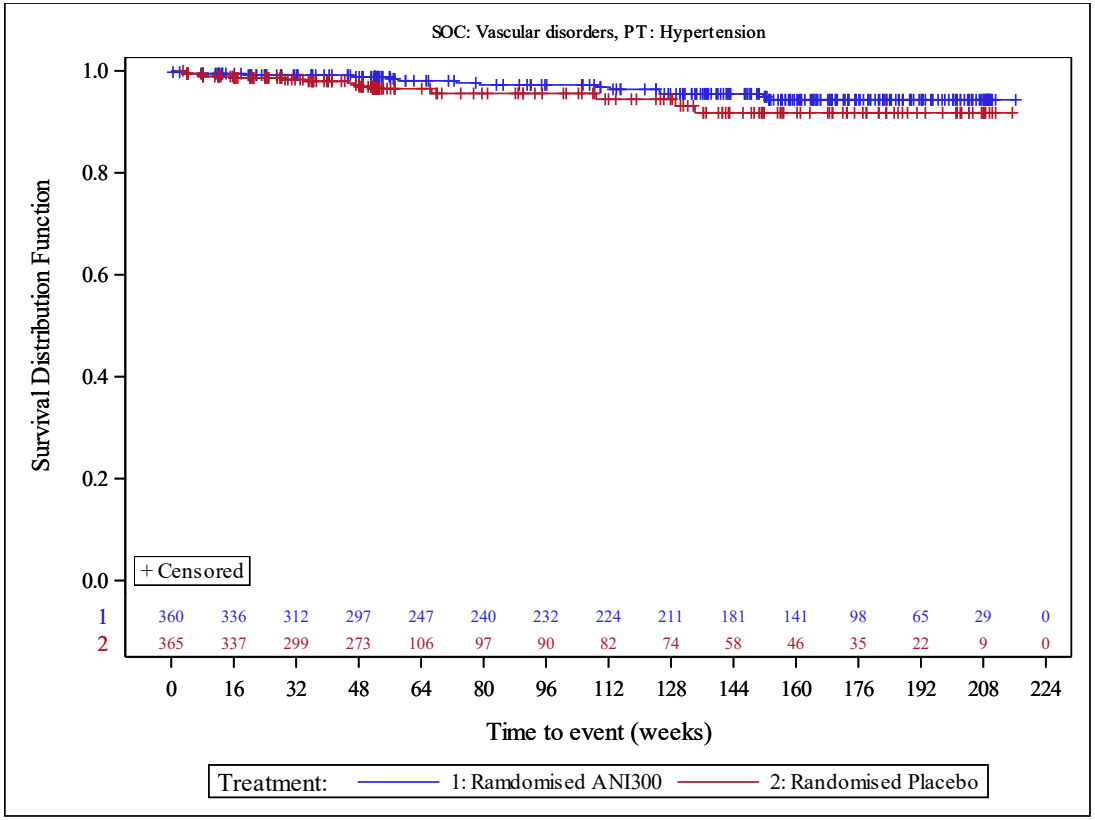

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Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Serious Adverse Events by SOC, PT during treatment (incidence in either arm >= 5% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Infections and infestations	Number of subjects with events, n (%)	35 (9.7)	30 (8.2)
	Number of censored subjects, n (%)	325 (90.3)	335 (91.8)
	Exposure years	831.3	502.4
	EAIR per 100 PY	4.2	6.0
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.77 (0.47, 1.27)	
	p-value	0.3015	
	Relative Risk (95% CI)	1.18 (0.74, 1.88)	
	p-value	0.4794	
	Odds Ratio (95% CI)	1.20 (0.72, 2.00)	
	p-value	0.4792	
	Risk Difference (95% CI)	1.50 (-2.66, 5.66)	
	p-value	0.4788	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Serious Adverse Events by SOC, PT during treatment (incidence in either arm >= 5% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Infections and infestations, PT: Pneumonia	Number of subjects with events, n (%)	9 (2.5)	10 (2.7)
	Number of censored subjects, n (%)	351 (97.5)	355 (97.3)
	Exposure years	863.8	518.7
	EAIR per 100 PY	1.0	1.9
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.69 (0.27, 1.73)	
	p-value	0.4222	
	Relative Risk (95% CI)	0.91 (0.38, 2.22)	
	p-value	0.8400	
	Odds Ratio (95% CI)	0.91 (0.37, 2.27)	
	p-value	0.8400	
	Risk Difference (95% CI)	-0.24 (-2.56, 2.09)	
	p-value	0.8398	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Serious Adverse Events by SOC, PT during treatment (incidence in either arm >= 5% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Musculoskeletal and connective tissue disorders	Number of subjects with events, n (%)	14 (3.9)	16 (4.4)
	Number of censored subjects, n (%)	346 (96.1)	349 (95.6)
	Exposure years	856.5	518.0
	EAIR per 100 PY	1.6	3.1
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.56 (0.27, 1.16)	
	p-value	0.1124	
	Relative Risk (95% CI)	0.89 (0.44, 1.79)	
	p-value	0.7383	
	Odds Ratio (95% CI)	0.88 (0.42, 1.84)	
	p-value	0.7382	
	Risk Difference (95% CI)	-0.49 (-3.39, 2.40)	
	p-value	0.7380	

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Serious Adverse Events by SOC, PT during treatment (incidence in either arm >= 5% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Musculoskeletal and connective tissue disorders, PT: Systemic lupus erythematosus	Number of subjects with events, n (%)	6 (1.7)	15 (4.1)
	Number of censored subjects, n (%)	354 (98.3)	350 (95.9)
	Exposure years	868.0	518.5
	EAIR per 100 PY	0.7	2.9
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	0.25 (0.10, 0.67)	
	p-value	0.0030	
	Relative Risk (95% CI)	0.41 (0.16, 1.03)	
	p-value	0.0586	
	Odds Ratio (95% CI)	0.40 (0.15, 1.03)	
	p-value	0.0578	
	Risk Difference (95% CI)	-2.44 (-4.87, -0.01)	
	p-value	0.0486	

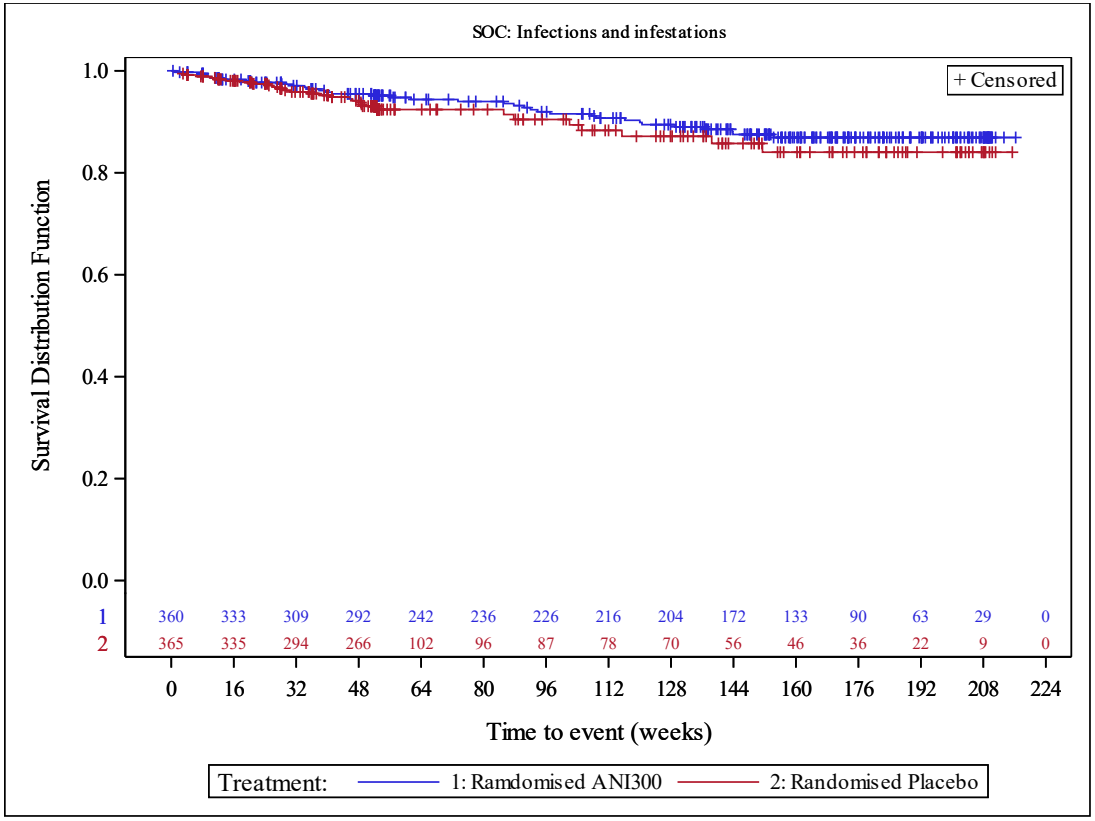
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Serious Adverse Events by SOC, PT during treatment (incidence in either arm >= 5% or >=10 patients) - Subgroup analysis
Full analysis set

SOC / PT	Subgroup Level	Ramdomised ANI300 (N=360) n/ N (%)	Ramdomised ANI300 (N=360) Median (95% CI)	Randomised Placebo (N=365) n/ N (%)	Randomised Placebo (N=365) Median (95% CI)	Treatment Comparison Hazard Ratio (95% CI)	Treatment Comparison p-Value	Interaction p-Value
SOC: Musculoskeletal and connective tissue disorders, PT: Systemic lupus erythematosus	Age (years)							0.9997
	<= 65	6/348 (1.7)	NE (NE, NE)	15/361 (4.2)	NE (NE, NE)	0.26 (0.10, 0.69)	0.0038	
	> 65	0/ 12 (0.0)	NE (NE, NE)	0/ 4 (0.0)	NE (NE, NE)	NE		
	Sex							0.9913
	male	0/ 27 (0.0)	NE (NE, NE)	1/ 25 (4.0)	NE (NE, NE)	NE		
	female	6/333 (1.8)	NE (NE, NE)	14/340 (4.1)	NE (NE, NE)	0.26 (0.10, 0.71)	0.0048	
	Geographic region							0.3236
	EU	1/115 (0.9)	NE (NE, NE)	6/122 (4.9)	NE (NE, NE)	0.07 (0.01, 0.62)	0.0021	
	non-EU	5/245 (2.0)	NE (NE, NE)	9/243 (3.7)	NE (NE, NE)	0.43 (0.14, 1.31)	0.1267	
	SLEDAI-2K score at screening							0.8681
	< 10 points	1/109 (0.9)	NE (NE, NE)	2/106 (1.9)	NE (NE, NE)	0.35 (0.03, 4.06)	0.3810	
	>= 10 points	5/251 (2.0)	NE (NE, NE)	13/259 (5.0)	NE (NE, NE)	0.24 (0.08, 0.69)	0.0046	

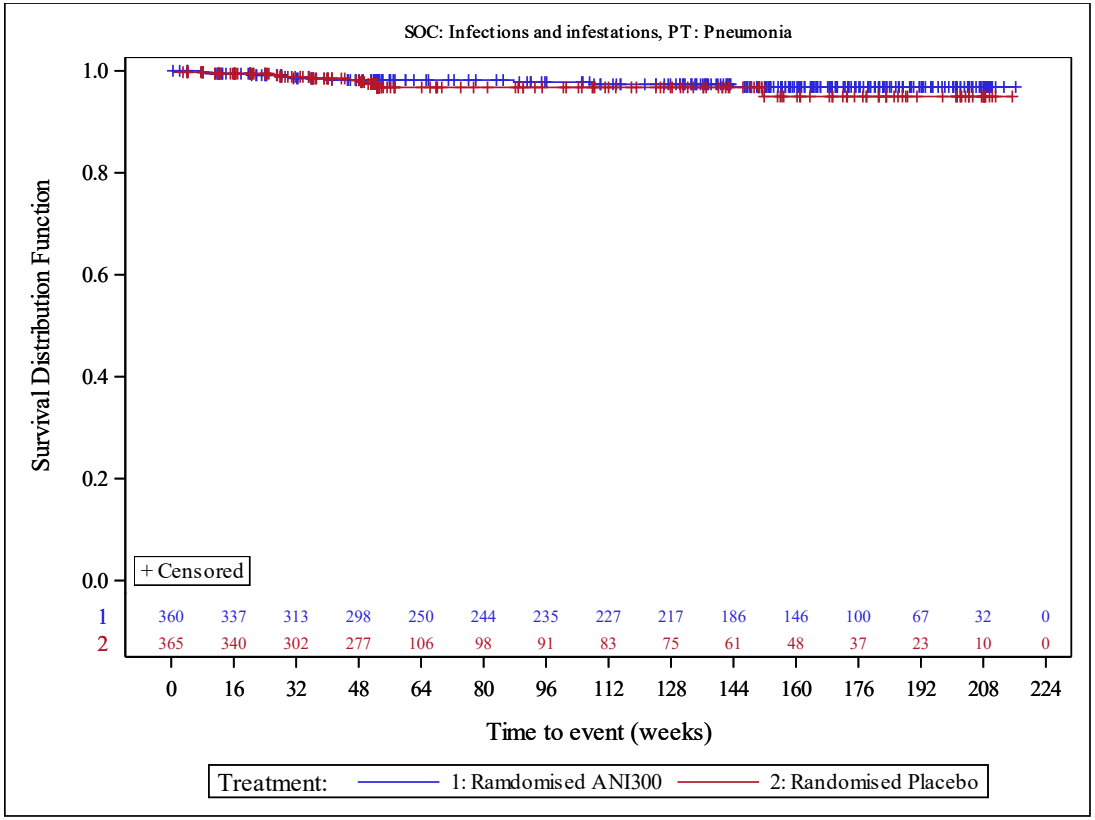
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Incidence and time to first frequent Serious Adverse Events by SOC, PT during treatment (incidence in either arm >= 5% or >=10 patients)
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Incidence and time to first frequent Serious Adverse Events by SOC, PT during treatment (incidence in either arm >= 5% or >=10 patients)
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
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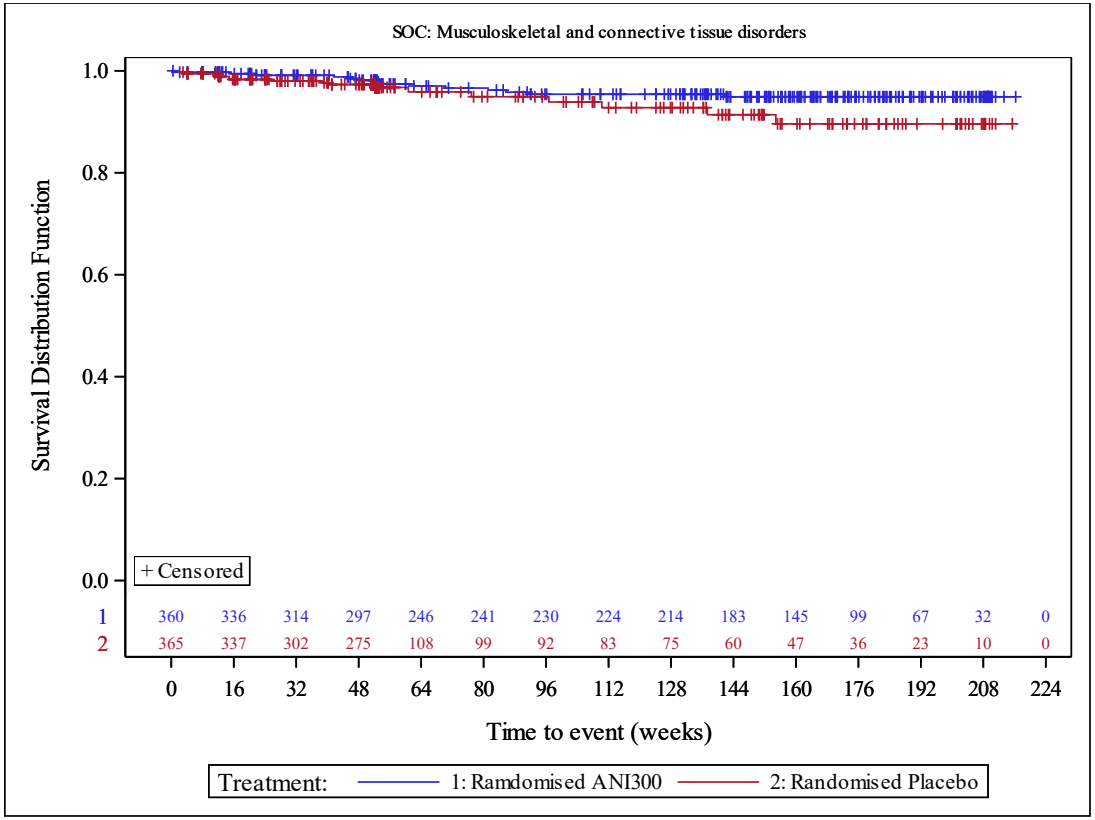
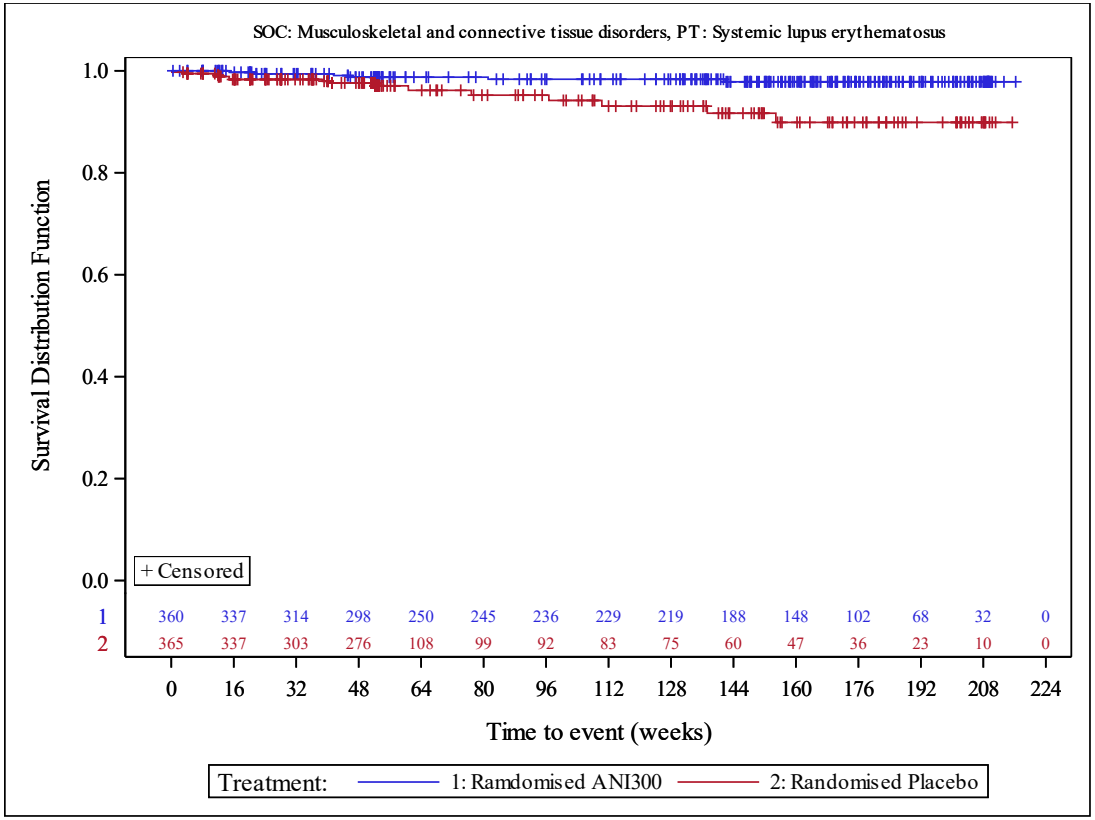
Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Incidence and time to first frequent Serious Adverse Events by SOC, PT during treatment (incidence in either arm >= 5% or >=10 patients)
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Incidence and time to first frequent Serious Adverse Events by SOC, PT during treatment (incidence in either arm >= 5% or >=10 patients)
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Severe (Grade >=3) by SOC, PT during treatment (incidence in either arm >= 5% or >=10 patients)
Full analysis set

SOC / PT		Ramdomised ANI300 (N=360)	Randomised Placebo (N=365)
SOC: Infections and infestations	Number of subjects with events, n (%)	27 (7.5)	10 (2.7)
	Number of censored subjects, n (%)	333 (92.5)	355 (97.3)
	Exposure years	839.7	519.2
	EAIR per 100 PY	3.2	1.9
	Kaplan-Meier Quartiles of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Ramdomised ANI300 vs. Randomised Placebo		
	Hazard Ratio (95% CI)	1.83 (0.87, 3.82)	
	p-value	0.1053	
	Relative Risk (95% CI)	2.74 (1.34, 5.57)	
	p-value	0.0055	
	Odds Ratio (95% CI)	2.88 (1.37, 6.04)	
	p-value	0.0052	
	Risk Difference (95% CI)	4.76 (1.57, 7.96)	
	p-value	0.0035	

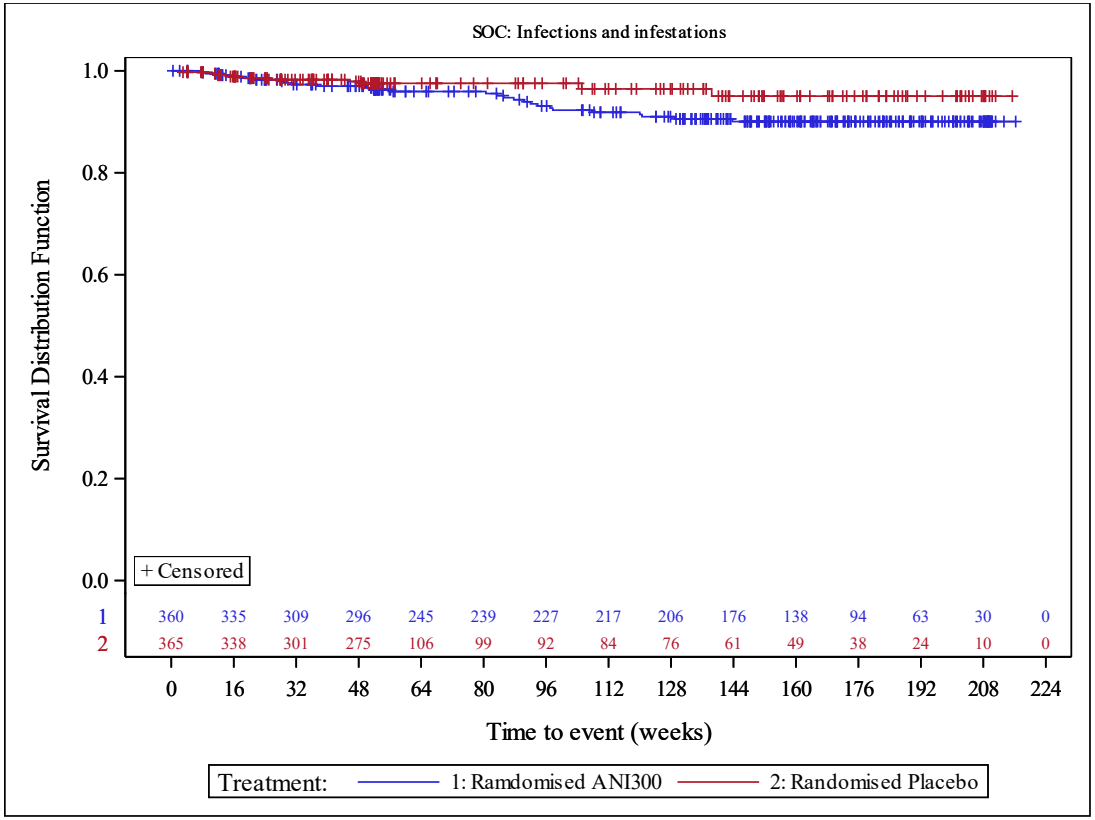
Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product to the minimum of date of first event, death, end of treatment + 28 days or end of study.
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
Two-sided log rank test used.
Relative Risks, Odds Ratios and Risk Differences estimated using Mantel-Haenszel method. Confidence limits and p-value calculated using normal approximation (Wald)

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of Incidence and time to first frequent Severe (Grade >=3) by SOC, PT during treatment (incidence in either arm >= 5% or >=10 patients) - Subgroup analysis
Full analysis set

- NO OBSERVATIONS FOR THIS ANALYSIS -

Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan-Meier estimate with 95% CI based on Brookmeyer-Crowley log(-log) transformation.
Hazard ratio and confidence interval are calculated from Cox proportional hazards model.
p-Value for interaction from Cox proportional hazards model with factors for treatment, subgroup and treatment*subgroup interaction.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Kaplan-Meier Plot of Incidence and time to first frequent Severe (Grade >=3) by SOC, PT during treatment (incidence in either arm >= 5% or >=10 patients)
Full analysis set



Analysis includes all AE with a date of onset >= day of first dose of investigational product and <= minimum (last dosing date + 28 days, end of study date, death date).
Kaplan Meier Plots are only generated if test for interaction is significant (alpha=0.05).

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Adverse Events by SOC, PT during treatment (Study 09)
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Anifrolumab 300mg (N=259) n (%)	Placebo Feeder + Placebo LTE (N=113) n (%)	Placebo Feeder + Anifrolumab 300mg (N=115) n (%)	Anifrolumab 150mg + Anifrolumab 300mg (N=69) n (%)
Subjects with events	218 (84.2)	87 (77.0)	92 (80.0)	60 (87.0)
Infections and infestations	187 (72.2)	66 (58.4)	75 (65.2)	48 (69.6)
Nasopharyngitis	61 (23.6)	13 (11.5)	29 (25.2)	14 (20.3)
Upper respiratory tract infection	47 (18.1)	17 (15.0)	21 (18.3)	8 (11.6)
Bronchitis	35 (13.5)	8 (7.1)	18 (15.7)	15 (21.7)
Pharyngitis	14 (5.4)	4 (3.5)	13 (11.3)	9 (13.0)
Gastroenteritis	7 (2.7)	7 (6.2)	12 (10.4)	3 (4.3)
Herpes zoster	18 (6.9)	6 (5.3)	11 (9.6)	9 (13.0)
Urinary tract infection	46 (17.8)	14 (12.4)	11 (9.6)	6 (8.7)
Influenza	15 (5.8)	3 (2.7)	9 (7.8)	5 (7.2)
Sinusitis	21 (8.1)	3 (2.7)	9 (7.8)	5 (7.2)
Oral herpes	16 (6.2)	5 (4.4)	6 (5.2)	1 (1.4)
Viral upper respiratory tract infection	9 (3.5)	2 (1.8)	5 (4.3)	1 (1.4)
Conjunctivitis	9 (3.5)	2 (1.8)	4 (3.5)	0
Cystitis	7 (2.7)	3 (2.7)	4 (3.5)	2 (2.9)
Gastroenteritis viral	4 (1.5)	0	4 (3.5)	1 (1.4)
Latent tuberculosis	15 (5.8)	2 (1.8)	4 (3.5)	0
Pneumonia	8 (3.1)	3 (2.7)	4 (3.5)	3 (4.3)
Bacterial vaginosis	4 (1.5)	0	3 (2.6)	0
Lower respiratory tract infection	4 (1.5)	1 (0.9)	3 (2.6)	0
Rhinitis	2 (0.8)	1 (0.9)	3 (2.6)	3 (4.3)
Vaginal infection	10 (3.9)	3 (2.7)	3 (2.6)	1 (1.4)
Vulvovaginal mycotic infection	8 (3.1)	0	3 (2.6)	2 (2.9)
Ear infection	2 (0.8)	0	2 (1.7)	2 (2.9)
Fungal skin infection	2 (0.8)	0	2 (1.7)	0
Gastrointestinal infection	0	1 (0.9)	2 (1.7)	0
Impetigo	0	0	2 (1.7)	0
Oral candidiasis	4 (1.5)	2 (1.8)	2 (1.7)	1 (1.4)
Otitis externa	1 (0.4)	0	2 (1.7)	0
Pharyngotonsillitis	1 (0.4)	0	2 (1.7)	0
Tooth infection	0	1 (0.9)	2 (1.7)	0
Tracheobronchitis	1 (0.4)	0	2 (1.7)	1 (1.4)
Viral infection	6 (2.3)	2 (1.8)	2 (1.7)	0
Abdominal infection	0	0	1 (0.9)	0
Acute sinusitis	4 (1.5)	2 (1.8)	1 (0.9)	1 (1.4)
Bartholinitis	0	0	1 (0.9)	0
Cellulitis	3 (1.2)	2 (1.8)	1 (0.9)	2 (2.9)
Cervicitis	2 (0.8)	1 (0.9)	1 (0.9)	0
Folliculitis	1 (0.4)	0	1 (0.9)	1 (1.4)
Genital herpes simplex	1 (0.4)	0	1 (0.9)	0
Herpes simplex	3 (1.2)	1 (0.9)	1 (0.9)	0
Herpes zoster meningitis	0	0	1 (0.9)	0
Molluscum contagiosum	1 (0.4)	0	1 (0.9)	0
Nail infection	0	0	1 (0.9)	1 (1.4)
Onychomycosis	0	1 (0.9)	1 (0.9)	0
Otitis media	8 (3.1)	0	1 (0.9)	0
Otosalpingitis	0	0	1 (0.9)	0
Pelvic inflammatory disease	1 (0.4)	0	1 (0.9)	1 (1.4)
Periodontitis	1 (0.4)	0	1 (0.9)	1 (1.4)
Postoperative wound infection	0	0	1 (0.9)	0
Pyelonephritis	3 (1.2)	0	1 (0.9)	0
Respiratory tract infection	3 (1.2)	1 (0.9)	1 (0.9)	1 (1.4)
Sepsis	0	1 (0.9)	1 (0.9)	0
Sialoadenitis	1 (0.4)	0	1 (0.9)	0
Subcutaneous abscess	2 (0.8)	0	1 (0.9)	0
Sweating fever	0	0	1 (0.9)	0
Tinea pedis	1 (0.4)	0	1 (0.9)	0
Tonsillitis	1 (0.4)	0	1 (0.9)	0

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Adverse Events by SOC, PT during treatment (Study 09)
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Anifrolumab 300mg (N=259) n (%)	Placebo Feeder + Placebo LTE (N=113) n (%)	Placebo Feeder + Anifrolumab 300mg (N=115) n (%)	Anifrolumab 150mg + Anifrolumab 300mg (N=69) n (%)
Tooth abscess	5 (1.9)	2 (1.8)	1 (0.9)	1 (1.4)
Urinary tract infection enterococcal	0	0	1 (0.9)	0
Vulvovaginitis	3 (1.2)	1 (0.9)	1 (0.9)	0
Abscess oral	1 (0.4)	0	0	0
Alveolar osteitis	1 (0.4)	1 (0.9)	0	0
Appendicitis	1 (0.4)	0	0	0
Arthritis infective	1 (0.4)	0	0	0
Asymptomatic bacteriuria	1 (0.4)	0	0	0
Bacterial sepsis	0	0	0	1 (1.4)
Bacterial vulvovaginitis	0	1 (0.9)	0	0
Bronchitis bacterial	2 (0.8)	0	0	0
Cellulitis staphylococcal	0	0	0	1 (1.4)
Cervicitis human papilloma virus	0	1 (0.9)	0	0
Chronic sinusitis	0	1 (0.9)	0	0
Conjunctivitis viral	1 (0.4)	0	0	0
Dengue fever	1 (0.4)	0	0	0
Diverticulitis	1 (0.4)	0	0	0
Erysipelas	0	1 (0.9)	0	0
Escherichia urinary tract infection	1 (0.4)	1 (0.9)	0	0
Fungal infection	2 (0.8)	0	0	0
Furuncle	0	1 (0.9)	0	0
Gastroenteritis bacterial	1 (0.4)	0	0	1 (1.4)
Gastrointestinal viral infection	0	0	0	1 (1.4)
Genitourinary chlamydia infection	1 (0.4)	0	0	0
Gingivitis	2 (0.8)	1 (0.9)	0	0
Groin abscess	1 (0.4)	0	0	0
Helicobacter infection	1 (0.4)	0	0	0
Herpes zoster cutaneous disseminated	1 (0.4)	0	0	0
Herpes zoster disseminated	1 (0.4)	0	0	0
Hordeolum	2 (0.8)	1 (0.9)	0	0
Human ehrlichiosis	1 (0.4)	0	0	0
Labyrinthitis	1 (0.4)	0	0	0
Large intestine infection	1 (0.4)	0	0	0
Laryngitis	5 (1.9)	2 (1.8)	0	0
Localised infection	1 (0.4)	0	0	0
Ludwig angina	0	1 (0.9)	0	0
Mediastinitis	0	1 (0.9)	0	0
Mumps	1 (0.4)	0	0	0
Nasal vestibulitis	0	0	0	1 (1.4)
Ophthalmic herpes simplex	1 (0.4)	0	0	0
Oral fungal infection	1 (0.4)	0	0	0
Otitis externa fungal	0	1 (0.9)	0	0
Otitis media acute	2 (0.8)	0	0	0
Otitis media bacterial	1 (0.4)	0	0	0
Otitis media chronic	1 (0.4)	0	0	0
Paronychia	3 (1.2)	1 (0.9)	0	1 (1.4)
Parotitis	1 (0.4)	0	0	0
Pertussis	1 (0.4)	0	0	0
Pharyngitis streptococcal	1 (0.4)	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	1 (1.4)
Pneumonia bacterial	1 (0.4)	0	0	0
Pneumonia influenzal	0	0	0	1 (1.4)
Pneumonia staphylococcal	0	1 (0.9)	0	0
Pneumonia viral	1 (0.4)	0	0	0
Postoperative abscess	0	0	0	1 (1.4)
Pulpitis dental	0	0	0	1 (1.4)
Pyelonephritis acute	0	1 (0.9)	0	0
Pyoderma	0	0	0	1 (1.4)
Pyuria	1 (0.4)	0	0	0
Respiratory moniliasis	0	1 (0.9)	0	0

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Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Adverse Events by SOC, PT during treatment (Study 09)
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Anifrolumab 300mg (N=259) n (%)	Placebo Feeder + Placebo LTE (N=113) n (%)	Placebo Feeder + Anifrolumab 300mg (N=115) n (%)	Anifrolumab 150mg + Anifrolumab 300mg (N=69) n (%)
Respiratory tract infection viral	2 (0.8)	0	0	1 (1.4)
Rotavirus infection	1 (0.4)	0	0	0
Skin infection	2 (0.8)	0	0	0
Soft tissue infection	1 (0.4)	0	0	0
Streptococcal urinary tract infection	1 (0.4)	0	0	0
Superinfection	1 (0.4)	0	0	0
Tinea manuum	1 (0.4)	0	0	0
Tinea versicolour	2 (0.8)	0	0	0
Tracheitis	3 (1.2)	0	0	1 (1.4)
Trichomoniasis	1 (0.4)	0	0	0
Tungiasis	0	0	0	1 (1.4)
Urinary tract infection bacterial	0	1 (0.9)	0	0
Urinary tract infection pseudomonal	1 (0.4)	0	0	0
Urosepsis	0	1 (0.9)	0	0
Viral pharyngitis	3 (1.2)	0	0	0
Vulvovaginal candidiasis	1 (0.4)	1 (0.9)	0	0
Vulvovaginitis trichomonal	0	1 (0.9)	0	0
Wound infection	3 (1.2)	1 (0.9)	0	0
Wound infection staphylococcal	0	1 (0.9)	0	0
Musculoskeletal and connective tissue disorders	89 (34.4)	33 (29.2)	31 (27.0)	17 (24.6)
Back pain	16 (6.2)	8 (7.1)	9 (7.8)	8 (11.6)
Arthralgia	15 (5.8)	5 (4.4)	4 (3.5)	3 (4.3)
Musculoskeletal pain	4 (1.5)	3 (2.7)	4 (3.5)	1 (1.4)
Systemic lupus erythematosus	10 (3.9)	6 (5.3)	4 (3.5)	3 (4.3)
Arthritis	4 (1.5)	1 (0.9)	3 (2.6)	1 (1.4)
Myalgia	4 (1.5)	0	3 (2.6)	1 (1.4)
Pain in extremity	6 (2.3)	5 (4.4)	3 (2.6)	3 (4.3)
Costochondritis	1 (0.4)	3 (2.7)	2 (1.7)	1 (1.4)
Foot deformity	0	0	2 (1.7)	0
Musculoskeletal chest pain	4 (1.5)	0	2 (1.7)	1 (1.4)
Osteoarthritis	7 (2.7)	0	2 (1.7)	2 (2.9)
Tendonitis	5 (1.9)	1 (0.9)	2 (1.7)	0
Fibromyalgia	2 (0.8)	0	1 (0.9)	3 (4.3)
Intervertebral disc protrusion	3 (1.2)	0	1 (0.9)	0
Muscle spasms	2 (0.8)	2 (1.8)	1 (0.9)	1 (1.4)
Neck pain	5 (1.9)	0	1 (0.9)	2 (2.9)
Pain in jaw	0	1 (0.9)	1 (0.9)	0
Polyarthritis	0	0	1 (0.9)	0
Rotator cuff syndrome	0	1 (0.9)	1 (0.9)	1 (1.4)
Spinal pain	1 (0.4)	0	1 (0.9)	0
Tenosynovitis stenosans	2 (0.8)	0	1 (0.9)	1 (1.4)
Torticollis	0	0	1 (0.9)	0
Arthropathy	1 (0.4)	0	0	0
Bursitis	11 (4.2)	1 (0.9)	0	0
Enthesopathy	0	1 (0.9)	0	0
Flank pain	1 (0.4)	1 (0.9)	0	0
Groin pain	0	1 (0.9)	0	0
Intervertebral disc degeneration	0	0	0	1 (1.4)
Joint instability	1 (0.4)	0	0	0
Joint lock	1 (0.4)	0	0	0
Joint swelling	2 (0.8)	2 (1.8)	0	0
Ligamentitis	1 (0.4)	0	0	0
Metatarsalgia	1 (0.4)	0	0	0
Muscular weakness	1 (0.4)	0	0	0
Musculoskeletal stiffness	2 (0.8)	0	0	0
Osteonecrosis	3 (1.2)	1 (0.9)	0	0
Osteopenia	1 (0.4)	0	0	0
Osteoporosis	2 (0.8)	0	0	0
Periarthritis	1 (0.4)	1 (0.9)	0	0

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Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Adverse Events by SOC, PT during treatment (Study 09)
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Anifrolumab 300mg (N=259) n (%)	Placebo Feeder + Placebo LTE (N=113) n (%)	Placebo Feeder + Anifrolumab 300mg (N=115) n (%)	Anifrolumab 150mg + Anifrolumab 300mg (N=69) n (%)
Plantar fasciitis	0	1 (0.9)	0	0
Polychondritis	1 (0.4)	0	0	0
SLE arthritis	0	1 (0.9)	0	0
Sacroiliitis	1 (0.4)	0	0	0
Sjogren's syndrome	1 (0.4)	1 (0.9)	0	0
Spinal osteoarthritis	2 (0.8)	0	0	0
Spinal stenosis	1 (0.4)	0	0	0
Synovial cyst	4 (1.5)	0	0	0
Synovitis	1 (0.4)	0	0	1 (1.4)
Tenosynovitis	1 (0.4)	0	0	0
Trigger finger	1 (0.4)	0	0	0
Injury, poisoning and procedural complications	59 (22.8)	21 (18.6)	29 (25.2)	18 (26.1)
Infusion related reaction	16 (6.2)	6 (5.3)	9 (7.8)	2 (2.9)
Contusion	8 (3.1)	2 (1.8)	4 (3.5)	6 (8.7)
Arthropod bite	5 (1.9)	1 (0.9)	2 (1.7)	1 (1.4)
Epicondylitis	1 (0.4)	0	2 (1.7)	0
Fall	9 (3.5)	6 (5.3)	2 (1.7)	3 (4.3)
Limb injury	1 (0.4)	2 (1.8)	2 (1.7)	0
Rib fracture	3 (1.2)	0	2 (1.7)	2 (2.9)
Tibia fracture	1 (0.4)	0	2 (1.7)	0
Tooth fracture	0	1 (0.9)	2 (1.7)	0
Animal bite	2 (0.8)	1 (0.9)	1 (0.9)	0
Arthropod sting	3 (1.2)	0	1 (0.9)	0
Foot fracture	3 (1.2)	2 (1.8)	1 (0.9)	1 (1.4)
Joint dislocation	1 (0.4)	0	1 (0.9)	0
Ligament rupture	1 (0.4)	0	1 (0.9)	0
Ligament sprain	0	0	1 (0.9)	1 (1.4)
Periprocedural myocardial infarction	0	0	1 (0.9)	0
Postoperative wound complication	0	0	1 (0.9)	0
Procedural dizziness	0	0	1 (0.9)	0
Procedural pain	0	0	1 (0.9)	0
Radius fracture	1 (0.4)	0	1 (0.9)	1 (1.4)
Road traffic accident	1 (0.4)	1 (0.9)	1 (0.9)	0
Skin abrasion	1 (0.4)	0	1 (0.9)	0
Skin injury	0	1 (0.9)	1 (0.9)	0
Skin laceration	2 (0.8)	1 (0.9)	1 (0.9)	0
Spinal fracture	1 (0.4)	0	1 (0.9)	0
Subcutaneous haematoma	0	0	1 (0.9)	0
Wrist fracture	0	0	1 (0.9)	0
Animal scratch	3 (1.2)	0	0	0
Ankle fracture	0	1 (0.9)	0	1 (1.4)
Bite	1 (0.4)	0	0	0
Brachial plexus injury	0	0	0	1 (1.4)
Dental restoration failure	1 (0.4)	1 (0.9)	0	0
Eye contusion	1 (0.4)	0	0	0
Facial bones fracture	0	0	0	1 (1.4)
Foreign body in respiratory tract	1 (0.4)	0	0	0
Hand fracture	1 (0.4)	0	0	0
Humerus fracture	1 (0.4)	0	0	0
Hypobarism	1 (0.4)	0	0	0
Incision site pain	0	0	0	1 (1.4)
Incisional hernia	1 (0.4)	0	0	0
Injury	3 (1.2)	1 (0.9)	0	0
Joint injury	0	1 (0.9)	0	0
Limb crushing injury	0	1 (0.9)	0	0
Lower limb fracture	1 (0.4)	0	0	0
Lumbar vertebral fracture	0	0	0	1 (1.4)
Muscle strain	1 (0.4)	1 (0.9)	0	1 (1.4)
Nail avulsion	1 (0.4)	0	0	0

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Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Adverse Events by SOC, PT during treatment (Study 09)
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Anifrolumab 300mg (N=259) n (%)	Placebo Feeder + Placebo LTE (N=113) n (%)	Placebo Feeder + Anifrolumab 300mg (N=115) n (%)	Anifrolumab 150mg + Anifrolumab 300mg (N=69) n (%)
Overdose	1 (0.4)	0	0	0
Post-traumatic pain	1 (0.4)	0	0	0
Pubis fracture	0	1 (0.9)	0	0
Respiratory fume inhalation disorder	0	0	0	1 (1.4)
Scar	0	1 (0.9)	0	0
Skin wound	0	0	0	1 (1.4)
Soft tissue injury	0	0	0	1 (1.4)
Spinal compression fracture	1 (0.4)	1 (0.9)	0	0
Tendon rupture	0	1 (0.9)	0	0
Thermal burn	2 (0.8)	0	0	0
Toxicity to various agents	2 (0.8)	0	0	0
Traumatic haematoma	1 (0.4)	1 (0.9)	0	0
Upper limb fracture	1 (0.4)	0	0	0
Wound	1 (0.4)	0	0	0
Wound complication	1 (0.4)	0	0	0
Gastrointestinal disorders	63 (24.3)	24 (21.2)	25 (21.7)	16 (23.2)
Nausea	10 (3.9)	6 (5.3)	6 (5.2)	3 (4.3)
Diarrhoea	14 (5.4)	5 (4.4)	5 (4.3)	5 (7.2)
Abdominal pain	4 (1.5)	4 (3.5)	4 (3.5)	3 (4.3)
Constipation	5 (1.9)	7 (6.2)	4 (3.5)	0
Abdominal pain upper	6 (2.3)	2 (1.8)	3 (2.6)	4 (5.8)
Dental caries	5 (1.9)	1 (0.9)	3 (2.6)	1 (1.4)
Dyspepsia	1 (0.4)	4 (3.5)	3 (2.6)	1 (1.4)
Enteritis	1 (0.4)	0	2 (1.7)	0
Gastritis	2 (0.8)	2 (1.8)	2 (1.7)	0
Gastrooesophageal reflux disease	7 (2.7)	3 (2.7)	2 (1.7)	1 (1.4)
Toothache	2 (0.8)	0	2 (1.7)	0
Abdominal distension	2 (0.8)	0	1 (0.9)	1 (1.4)
Chronic gastritis	2 (0.8)	1 (0.9)	1 (0.9)	0
Colitis	1 (0.4)	0	1 (0.9)	0
Dysphagia	1 (0.4)	0	1 (0.9)	1 (1.4)
Enterocolitis	0	0	1 (0.9)	0
Erosive oesophagitis	0	0	1 (0.9)	0
Faecaloma	0	0	1 (0.9)	0
Food poisoning	1 (0.4)	1 (0.9)	1 (0.9)	0
Gastritis erosive	0	0	1 (0.9)	0
Haematochezia	1 (0.4)	1 (0.9)	1 (0.9)	0
Inguinal hernia	0	0	1 (0.9)	0
Lip oedema	0	0	1 (0.9)	0
Mouth ulceration	2 (0.8)	0	1 (0.9)	1 (1.4)
Parotid gland enlargement	0	0	1 (0.9)	0
Tongue disorder	0	0	1 (0.9)	0
Tooth impacted	1 (0.4)	0	1 (0.9)	0
Umbilical hernia	0	0	1 (0.9)	0
Vomiting	9 (3.5)	2 (1.8)	1 (0.9)	1 (1.4)
Abdominal discomfort	3 (1.2)	0	0	1 (1.4)
Abdominal pain lower	1 (0.4)	0	0	0
Anal pruritus	0	0	0	1 (1.4)
Aphthous ulcer	1 (0.4)	0	0	0
Barrett's oesophagus	1 (0.4)	0	0	0
Diverticulum	1 (0.4)	0	0	0
Gastric mucosa erythema	1 (0.4)	0	0	0
Gastric ulcer	1 (0.4)	0	0	0
Gastrointestinal inflammation	1 (0.4)	0	0	0
Gastrointestinal pain	0	1 (0.9)	0	0
Gastrointestinal wall thickening	1 (0.4)	0	0	0
Gingival recession	1 (0.4)	0	0	0
Glossodynia	0	1 (0.9)	0	0
Haemorrhoids	4 (1.5)	1 (0.9)	0	0

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Hiatus hernia	2 (0.8)	0	0	1 (1.4)
Impaired gastric emptying	2 (0.8)	0	0	0
Irritable bowel syndrome	1 (0.4)	1 (0.9)	0	0
Large intestine polyp	0	1 (0.9)	0	0
Lip swelling	1 (0.4)	0	0	0
Lip ulceration	1 (0.4)	0	0	0
Loose tooth	1 (0.4)	0	0	0
Malabsorption	0	1 (0.9)	0	0
Oesophageal hypomotility	1 (0.4)	0	0	0
Oesophagitis	1 (0.4)	0	0	0
Oral mucosal eruption	1 (0.4)	0	0	0
Palatal disorder	1 (0.4)	0	0	0
Paraesthesia oral	1 (0.4)	0	0	0
Peritoneal haemorrhage	0	0	0	1 (1.4)
Proctalgia	0	0	0	1 (1.4)
Rectal haemorrhage	1 (0.4)	0	0	0
Stomatitis	0	1 (0.9)	0	0
Tooth disorder	0	1 (0.9)	0	0
Skin and subcutaneous tissue disorders	41 (15.8)	16 (14.2)	20 (17.4)	9 (13.0)
Urticaria	3 (1.2)	2 (1.8)	4 (3.5)	2 (2.9)
Dermal cyst	0	0	2 (1.7)	0
Dermatitis contact	2 (0.8)	0	2 (1.7)	0
Rash	6 (2.3)	3 (2.7)	2 (1.7)	1 (1.4)
Rash pruritic	0	0	2 (1.7)	0
Skin fissures	1 (0.4)	1 (0.9)	2 (1.7)	0
Acne	3 (1.2)	0	1 (0.9)	0
Actinic keratosis	1 (0.4)	0	1 (0.9)	1 (1.4)
Angioedema	1 (0.4)	0	1 (0.9)	0
Dermatitis	1 (0.4)	1 (0.9)	1 (0.9)	1 (1.4)
Ecchymosis	1 (0.4)	0	1 (0.9)	0
Eczema	3 (1.2)	1 (0.9)	1 (0.9)	1 (1.4)
Erythema nodosum	0	0	1 (0.9)	0
Hidradenitis	2 (0.8)	0	1 (0.9)	0
Hyperkeratosis	0	0	1 (0.9)	0
Intertrigo	2 (0.8)	0	1 (0.9)	0
Night sweats	1 (0.4)	0	1 (0.9)	0
Photosensitivity reaction	1 (0.4)	0	1 (0.9)	0
Pruritus	1 (0.4)	2 (1.8)	1 (0.9)	0
Skin hyperpigmentation	2 (0.8)	1 (0.9)	1 (0.9)	0
Skin lesion	1 (0.4)	0	1 (0.9)	1 (1.4)
Alopecia	1 (0.4)	1 (0.9)	0	0
Blood blister	0	0	0	1 (1.4)
Dandruff	1 (0.4)	0	0	0
Dermatitis atopic	1 (0.4)	0	0	0
Dry skin	0	1 (0.9)	0	0
Eczema asteatotic	0	1 (0.9)	0	0
Eczema nummular	0	1 (0.9)	0	0
Erythema	1 (0.4)	1 (0.9)	0	0
Guttate psoriasis	1 (0.4)	0	0	0
Ingrowing nail	1 (0.4)	0	0	0
Keratosis pilaris	0	1 (0.9)	0	0
Lipoatrophy	1 (0.4)	0	0	0
Miliaria	1 (0.4)	0	0	1 (1.4)
Nail bed bleeding	0	1 (0.9)	0	0
Nail dystrophy	1 (0.4)	1 (0.9)	0	0
Onychoclasis	1 (0.4)	0	0	0
Perioral dermatitis	2 (0.8)	0	0	0
Petechiae	1 (0.4)	0	0	0
Pigmentation disorder	1 (0.4)	0	0	0

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Post inflammatory pigmentation change	0	1 (0.9)	0	0
Purpura	1 (0.4)	1 (0.9)	0	1 (1.4)
Rash erythematous	1 (0.4)	0	0	0
Rash maculo-papular	0	0	0	1 (1.4)
Rash papular	0	1 (0.9)	0	0
Seborrhoeic dermatitis	2 (0.8)	0	0	0
Skin discolouration	0	1 (0.9)	0	1 (1.4)
Skin ulcer	2 (0.8)	1 (0.9)	0	0
Systemic lupus erythematosus rash	0	1 (0.9)	0	0
Urticaria chronic	1 (0.4)	0	0	0
General disorders and administration site conditions	34 (13.1)	12 (10.6)	18 (15.7)	12 (17.4)
Non-cardiac chest pain	3 (1.2)	1 (0.9)	4 (3.5)	1 (1.4)
Oedema peripheral	5 (1.9)	1 (0.9)	3 (2.6)	2 (2.9)
Chest pain	3 (1.2)	0	2 (1.7)	1 (1.4)
Pain	2 (0.8)	0	2 (1.7)	1 (1.4)
Peripheral swelling	2 (0.8)	1 (0.9)	2 (1.7)	1 (1.4)
Pyrexia	4 (1.5)	3 (2.7)	2 (1.7)	0
Adverse drug reaction	3 (1.2)	2 (1.8)	1 (0.9)	0
Chest discomfort	2 (0.8)	0	1 (0.9)	1 (1.4)
Cyst	0	0	1 (0.9)	0
Fatigue	6 (2.3)	1 (0.9)	1 (0.9)	2 (2.9)
Feeling cold	0	0	1 (0.9)	0
Incarcerated hernia	0	0	1 (0.9)	0
Mucosal haemorrhage	0	0	1 (0.9)	0
Soft tissue inflammation	0	0	1 (0.9)	0
Asthenia	1 (0.4)	2 (1.8)	0	0
Discomfort	0	0	0	1 (1.4)
Facial pain	1 (0.4)	0	0	0
Gait disturbance	1 (0.4)	0	0	0
Influenza like illness	2 (0.8)	2 (1.8)	0	3 (4.3)
Injection site reaction	0	1 (0.9)	0	0
Nodule	1 (0.4)	1 (0.9)	0	0
Oedema	0	0	0	1 (1.4)
Swelling face	0	1 (0.9)	0	0
Vaccination site reaction	1 (0.4)	0	0	0
Withdrawal syndrome	0	0	0	1 (1.4)
Respiratory, thoracic and mediastinal disorders	40 (15.4)	17 (15.0)	18 (15.7)	12 (17.4)
Cough	14 (5.4)	2 (1.8)	4 (3.5)	7 (10.1)
Asthma	1 (0.4)	4 (3.5)	3 (2.6)	1 (1.4)
Dyspnoea	3 (1.2)	2 (1.8)	3 (2.6)	1 (1.4)
Nasal congestion	0	3 (2.7)	3 (2.6)	0
Rhinitis allergic	2 (0.8)	1 (0.9)	3 (2.6)	0
Oropharyngeal pain	5 (1.9)	2 (1.8)	2 (1.7)	0
Pleural effusion	1 (0.4)	2 (1.8)	2 (1.7)	0
Pleuritic pain	1 (0.4)	0	1 (0.9)	0
Sinus congestion	3 (1.2)	1 (0.9)	1 (0.9)	1 (1.4)
Upper respiratory tract inflammation	2 (0.8)	0	1 (0.9)	0
Acute respiratory failure	1 (0.4)	0	0	0
Allergic sinusitis	0	1 (0.9)	0	0
Atelectasis	1 (0.4)	0	0	0
Bronchial hyperreactivity	1 (0.4)	0	0	0
Bronchitis chronic	1 (0.4)	0	0	0
Catarrh	0	1 (0.9)	0	0
Chronic obstructive pulmonary disease	2 (0.8)	1 (0.9)	0	1 (1.4)
Dyspnoea exertional	0	1 (0.9)	0	2 (2.9)
Epistaxis	2 (0.8)	1 (0.9)	0	2 (2.9)
Haemoptysis	1 (0.4)	0	0	0
Interstitial lung disease	0	0	0	1 (1.4)

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Adverse Events by SOC, PT during treatment (Study 09)
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Anifrolumab 300mg (N=259) n (%)	Placebo Feeder + Placebo LTE (N=113) n (%)	Placebo Feeder + Anifrolumab 300mg (N=115) n (%)	Anifrolumab 150mg + Anifrolumab 300mg (N=69) n (%)
Lower respiratory tract congestion	1 (0.4)	0	0	0
Nasal obstruction	0	0	0	1 (1.4)
Nasal polyps	1 (0.4)	0	0	0
Pleurisy	1 (0.4)	0	0	0
Productive cough	2 (0.8)	2 (1.8)	0	0
Pulmonary hypertension	0	1 (0.9)	0	0
Pulmonary mass	1 (0.4)	0	0	0
Rales	0	1 (0.9)	0	0
Respiratory disorder	1 (0.4)	1 (0.9)	0	0
Respiratory distress	0	1 (0.9)	0	0
Rhinorrhoea	1 (0.4)	0	0	0
Sleep apnoea syndrome	0	1 (0.9)	0	0
Vocal cord disorder	1 (0.4)	0	0	0
Wheezing	1 (0.4)	1 (0.9)	0	0
Nervous system disorders	60 (23.2)	20 (17.7)	15 (13.0)	20 (29.0)
Headache	19 (7.3)	9 (8.0)	5 (4.3)	10 (14.5)
Dizziness	7 (2.7)	2 (1.8)	3 (2.6)	4 (5.8)
Neuralgia	3 (1.2)	0	2 (1.7)	0
Neuropathy peripheral	0	0	2 (1.7)	2 (2.9)
Post herpetic neuralgia	6 (2.3)	0	2 (1.7)	1 (1.4)
Syncope	1 (0.4)	1 (0.9)	2 (1.7)	1 (1.4)
Carpal tunnel syndrome	2 (0.8)	2 (1.8)	1 (0.9)	0
Cerebrovascular accident	0	0	1 (0.9)	1 (1.4)
Migraine	1 (0.4)	3 (2.7)	1 (0.9)	2 (2.9)
Migraine with aura	3 (1.2)	0	1 (0.9)	0
Paraesthesia	2 (0.8)	0	1 (0.9)	1 (1.4)
Seizure	0	0	1 (0.9)	0
Thalamic infarction	0	0	1 (0.9)	0
Amnesia	0	1 (0.9)	0	0
Aphasia	1 (0.4)	0	0	0
Burning sensation	1 (0.4)	0	0	1 (1.4)
Cervical radiculopathy	1 (0.4)	0	0	1 (1.4)
Cognitive disorder	1 (0.4)	0	0	0
Dizziness postural	1 (0.4)	0	0	0
Dysarthria	1 (0.4)	0	0	0
Dysgeusia	1 (0.4)	0	0	0
Epilepsy	1 (0.4)	0	0	1 (1.4)
Haemorrhagic cerebral infarction	0	1 (0.9)	0	0
Hemiparesis	1 (0.4)	0	0	0
Hypersomnia	0	0	0	1 (1.4)
Hypoaesthesia	2 (0.8)	1 (0.9)	0	1 (1.4)
Intercostal neuralgia	1 (0.4)	0	0	0
Intracranial aneurysm	1 (0.4)	0	0	0
Ischaemic stroke	1 (0.4)	0	0	0
Lumbar radiculopathy	3 (1.2)	0	0	0
Meningism	1 (0.4)	0	0	0
Myoclonus	1 (0.4)	0	0	0
Nystagmus	0	0	0	1 (1.4)
Occipital neuralgia	1 (0.4)	0	0	0
Orthostatic intolerance	0	0	0	1 (1.4)
Parkinson's disease	1 (0.4)	0	0	0
Parkinsonian gait	1 (0.4)	0	0	0
Peroneal nerve palsy	1 (0.4)	0	0	0
Presyncope	2 (0.8)	0	0	0
Radiculopathy	2 (0.8)	0	0	0
Restless legs syndrome	1 (0.4)	2 (1.8)	0	1 (1.4)
Sciatica	5 (1.9)	0	0	0
Sensory disturbance	0	1 (0.9)	0	0
Somnolence	1 (0.4)	0	0	0

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Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Adverse Events by SOC, PT during treatment (Study 09)
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Anifrolumab 300mg (N=259) n (%)	Placebo Feeder + Placebo LTE (N=113) n (%)	Placebo Feeder + Anifrolumab 300mg (N=115) n (%)	Anifrolumab 150mg + Anifrolumab 300mg (N=69) n (%)
Vestibular migraine	1 (0.4)	0	0	0
Eye disorders	22 (8.5)	8 (7.1)	11 (9.6)	6 (8.7)
Dry eye	3 (1.2)	0	3 (2.6)	0
Vision blurred	1 (0.4)	0	2 (1.7)	0
Astigmatism	0	0	1 (0.9)	1 (1.4)
Cataract	2 (0.8)	1 (0.9)	1 (0.9)	2 (2.9)
Chalazion	2 (0.8)	0	1 (0.9)	0
Conjunctival irritation	0	0	1 (0.9)	0
Conjunctivitis allergic	1 (0.4)	0	1 (0.9)	0
Corneal infiltrates	0	0	1 (0.9)	0
Hypermetropia	0	0	1 (0.9)	0
Keratitis	1 (0.4)	0	1 (0.9)	0
Scleritis	0	0	1 (0.9)	0
Visual acuity reduced	0	0	1 (0.9)	0
Visual impairment	0	1 (0.9)	1 (0.9)	0
Blepharitis	2 (0.8)	0	0	0
Conjunctival erosion	0	1 (0.9)	0	0
Conjunctival haemorrhage	3 (1.2)	0	0	1 (1.4)
Corneal erosion	1 (0.4)	1 (0.9)	0	0
Diplopia	0	1 (0.9)	0	0
Episcleritis	1 (0.4)	0	0	0
Erythema of eyelid	1 (0.4)	0	0	0
Eye inflammation	1 (0.4)	0	0	0
Eyelid cyst	0	1 (0.9)	0	0
Glaucoma	1 (0.4)	0	0	0
Lacrimation increased	1 (0.4)	0	0	0
Maculopathy	0	1 (0.9)	0	0
Photophobia	0	1 (0.9)	0	0
Retinal detachment	0	0	0	1 (1.4)
Retinal exudates	0	1 (0.9)	0	0
Retinopathy	3 (1.2)	0	0	1 (1.4)
Swelling of eyelid	1 (0.4)	0	0	0
Psychiatric disorders	18 (6.9)	8 (7.1)	11 (9.6)	9 (13.0)
Insomnia	6 (2.3)	2 (1.8)	4 (3.5)	6 (8.7)
Depression	6 (2.3)	4 (3.5)	2 (1.7)	3 (4.3)
Affect lability	0	0	1 (0.9)	0
Anxiety	3 (1.2)	1 (0.9)	1 (0.9)	0
Anxiety disorder	1 (0.4)	0	1 (0.9)	0
Depressed mood	0	0	1 (0.9)	0
Nervousness	0	0	1 (0.9)	0
Neurosis	0	0	1 (0.9)	0
Persistent depressive disorder	0	0	1 (0.9)	0
Stress	0	0	1 (0.9)	0
Adjustment disorder with depressed mood	1 (0.4)	0	0	0
Drug use disorder	1 (0.4)	0	0	0
Generalised anxiety disorder	0	0	0	1 (1.4)
Loss of libido	0	1 (0.9)	0	0
Panic attack	1 (0.4)	0	0	0
Suicidal ideation	1 (0.4)	0	0	0
Reproductive system and breast disorders	26 (10.0)	6 (5.3)	11 (9.6)	8 (11.6)
Cervical dysplasia	1 (0.4)	0	3 (2.6)	0
Bartholin's cyst	0	0	1 (0.9)	0
Breast mass	2 (0.8)	0	1 (0.9)	1 (1.4)
Endometriosis	0	0	1 (0.9)	0
Menopausal symptoms	0	1 (0.9)	1 (0.9)	0
Menorrhagia	2 (0.8)	1 (0.9)	1 (0.9)	0
Metrorrhagia	0	0	1 (0.9)	1 (1.4)

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Anifrolumab (MEDI-546)
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Full analysis set

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Pelvic pain	0	0	1 (0.9)	0
Uterine cervical erosion	0	0	1 (0.9)	0
Vaginal haemorrhage	0	0	1 (0.9)	1 (1.4)
Vaginal ulceration	0	0	1 (0.9)	0
Adnexa uteri cyst	0	0	0	1 (1.4)
Amenorrhoea	1 (0.4)	1 (0.9)	0	0
Atrophic vulvovaginitis	1 (0.4)	0	0	0
Breast calcifications	0	1 (0.9)	0	0
Breast cyst	3 (1.2)	0	0	0
Breast disorder	1 (0.4)	0	0	0
Breast enlargement	1 (0.4)	0	0	0
Breast hyperplasia	0	0	0	1 (1.4)
Cervical cyst	1 (0.4)	0	0	0
Cervical polyp	1 (0.4)	0	0	0
Cervix disorder	1 (0.4)	0	0	0
Cervix inflammation	0	0	0	1 (1.4)
Coital bleeding	0	0	0	1 (1.4)
Cystocele	0	1 (0.9)	0	0
Dysmenorrhoea	5 (1.9)	0	0	1 (1.4)
Dyspareunia	1 (0.4)	0	0	0
Ectropion of cervix	0	1 (0.9)	0	0
Fibrocystic breast disease	3 (1.2)	0	0	0
Mammary duct ectasia	0	0	0	1 (1.4)
Menometrorrhagia	1 (0.4)	0	0	0
Menstruation irregular	1 (0.4)	0	0	0
Ovarian cyst	4 (1.5)	0	0	2 (2.9)
Ovarian cyst ruptured	0	0	0	1 (1.4)
Perineal rash	1 (0.4)	0	0	0
Polycystic ovaries	1 (0.4)	0	0	0
Polymenorrhoea	1 (0.4)	0	0	0
Premenstrual syndrome	1 (0.4)	0	0	0
Pruritus genital	1 (0.4)	0	0	0
Uterine haemorrhage	4 (1.5)	0	0	0
Uterine polyp	1 (0.4)	0	0	0
Uterine prolapse	0	1 (0.9)	0	0
Uterovaginal prolapse	0	1 (0.9)	0	0
Vaginal discharge	0	0	0	1 (1.4)
Investigations	16 (6.2)	4 (3.5)	10 (8.7)	5 (7.2)
Weight increased	3 (1.2)	1 (0.9)	3 (2.6)	1 (1.4)
Alanine aminotransferase increased	2 (0.8)	1 (0.9)	1 (0.9)	0
Blood creatine phosphokinase increased	2 (0.8)	1 (0.9)	1 (0.9)	0
Blood creatinine increased	0	0	1 (0.9)	0
Blood immunoglobulin A decreased	0	0	1 (0.9)	0
Ejection fraction decreased	0	0	1 (0.9)	0
Herpes simplex test positive	0	0	1 (0.9)	0
International normalised ratio increased	0	0	1 (0.9)	0
Liver function test increased	0	0	1 (0.9)	0
Aspartate aminotransferase increased	1 (0.4)	1 (0.9)	0	0
Bacterial test positive	1 (0.4)	0	0	0
Blood alkaline phosphatase increased	1 (0.4)	0	0	0
Blood corticotrophin decreased	1 (0.4)	0	0	0
Blood creatine increased	0	0	0	1 (1.4)
Blood pressure increased	1 (0.4)	0	0	3 (4.3)
Gamma-glutamyltransferase increased	1 (0.4)	0	0	0
Hepatic enzyme increased	0	0	0	1 (1.4)
Influenza B virus test positive	1 (0.4)	0	0	0
International normalised ratio abnormal	1 (0.4)	0	0	0
Intraocular pressure increased	1 (0.4)	0	0	0
Transaminases increased	0	1 (0.9)	0	0

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Urine protein/creatinine ratio increased	1 (0.4)	0	0	0
Vitamin D decreased	1 (0.4)	0	0	0
Weight decreased	2 (0.8)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	17 (6.6)	6 (5.3)	10 (8.7)	4 (5.8)
Skin papilloma	5 (1.9)	1 (0.9)	4 (3.5)	0
Basal cell carcinoma	1 (0.4)	0	1 (0.9)	0
Fibrous histiocytoma	2 (0.8)	0	1 (0.9)	0
Haemangioma of bone	0	0	1 (0.9)	0
Hygroma colli	0	0	1 (0.9)	0
Squamous cell carcinoma	0	1 (0.9)	1 (0.9)	1 (1.4)
Uterine leiomyoma	4 (1.5)	1 (0.9)	1 (0.9)	1 (1.4)
Acanthoma	1 (0.4)	0	0	0
Anogenital warts	1 (0.4)	0	0	0
Benign breast neoplasm	1 (0.4)	0	0	0
Colon adenoma	0	1 (0.9)	0	0
Haemangioma of liver	1 (0.4)	1 (0.9)	0	0
Intraductal papilloma of breast	0	0	0	1 (1.4)
Lipoma	0	1 (0.9)	0	1 (1.4)
Seborrhoeic keratosis	1 (0.4)	0	0	0
Thyroid neoplasm	1 (0.4)	0	0	0
Vascular disorders	18 (6.9)	10 (8.8)	8 (7.0)	5 (7.2)
Hypertension	12 (4.6)	4 (3.5)	3 (2.6)	2 (2.9)
Deep vein thrombosis	0	0	1 (0.9)	0
Hot flush	0	0	1 (0.9)	0
Raynaud's phenomenon	1 (0.4)	1 (0.9)	1 (0.9)	3 (4.3)
Thrombosis	0	0	1 (0.9)	0
Vasculitis	0	1 (0.9)	1 (0.9)	0
Essential hypertension	1 (0.4)	0	0	0
Haematoma	0	2 (1.8)	0	0
Lymphostasis	0	0	0	1 (1.4)
Malignant hypertension	1 (0.4)	0	0	0
Orthostatic hypotension	1 (0.4)	1 (0.9)	0	0
Peripheral venous disease	1 (0.4)	0	0	0
Post thrombotic syndrome	0	1 (0.9)	0	0
Varicophlebitis	0	1 (0.9)	0	0
Varicose vein	1 (0.4)	0	0	0
Venous thrombosis	0	0	0	1 (1.4)
Cardiac disorders	13 (5.0)	8 (7.1)	7 (6.1)	4 (5.8)
Palpitations	1 (0.4)	3 (2.7)	2 (1.7)	1 (1.4)
Angina pectoris	0	1 (0.9)	1 (0.9)	0
Arrhythmia	1 (0.4)	0	1 (0.9)	0
Atrial fibrillation	0	1 (0.9)	1 (0.9)	0
Pericarditis	0	0	1 (0.9)	0
Ventricular hypokinesia	0	0	1 (0.9)	0
Acute myocardial infarction	0	2 (1.8)	0	0
Angina unstable	1 (0.4)	0	0	0
Aortic valve disease	1 (0.4)	0	0	0
Bradycardia	0	1 (0.9)	0	0
Bundle branch block left	1 (0.4)	0	0	0
Bundle branch block right	2 (0.8)	0	0	0
Cardiac failure chronic	1 (0.4)	0	0	0
Cardiac failure congestive	1 (0.4)	3 (2.7)	0	0
Cardiogenic shock	0	1 (0.9)	0	0
Cardiomegaly	0	1 (0.9)	0	0
Coronary artery disease	1 (0.4)	0	0	0
Cyanosis	0	0	0	1 (1.4)
Left ventricular dilatation	1 (0.4)	0	0	0

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Myocardial infarction	0	1 (0.9)	0	0
Myocardial ischaemia	1 (0.4)	0	0	0
Pericardial effusion	0	1 (0.9)	0	0
Sinus bradycardia	1 (0.4)	0	0	0
Supraventricular tachycardia	0	1 (0.9)	0	0
Tachycardia	1 (0.4)	0	0	1 (1.4)
Tachycardia paroxysmal	1 (0.4)	0	0	0
Ventricular extrasystoles	0	0	0	1 (1.4)
Metabolism and nutrition disorders	20 (7.7)	11 (9.7)	7 (6.1)	5 (7.2)
Hypokalaemia	3 (1.2)	1 (0.9)	2 (1.7)	0
Dehydration	1 (0.4)	2 (1.8)	1 (0.9)	1 (1.4)
Hyperglycaemia	0	1 (0.9)	1 (0.9)	0
Hyperlipidaemia	1 (0.4)	0	1 (0.9)	0
Hypomagnesaemia	1 (0.4)	0	1 (0.9)	0
Hypophosphataemia	0	0	1 (0.9)	0
Iron deficiency	1 (0.4)	0	1 (0.9)	0
Type 2 diabetes mellitus	0	0	1 (0.9)	0
Abnormal loss of weight	0	1 (0.9)	0	1 (1.4)
Decreased appetite	1 (0.4)	0	0	2 (2.9)
Diabetes mellitus	3 (1.2)	0	0	1 (1.4)
Diabetes mellitus inadequate control	1 (0.4)	0	0	0
Dyslipidaemia	1 (0.4)	1 (0.9)	0	0
Fluid overload	0	1 (0.9)	0	0
Hypercholesterolaemia	5 (1.9)	0	0	0
Hyperkalaemia	0	2 (1.8)	0	0
Hypertriglyceridaemia	1 (0.4)	0	0	0
Hyperuricaemia	0	1 (0.9)	0	0
Hyponatraemia	0	1 (0.9)	0	1 (1.4)
Obesity	1 (0.4)	0	0	0
Vitamin B complex deficiency	2 (0.8)	0	0	0
Vitamin B12 deficiency	1 (0.4)	1 (0.9)	0	0
Vitamin D deficiency	4 (1.5)	1 (0.9)	0	0
Blood and lymphatic system disorders	13 (5.0)	7 (6.2)	6 (5.2)	4 (5.8)
Anaemia	3 (1.2)	1 (0.9)	2 (1.7)	3 (4.3)
Iron deficiency anaemia	4 (1.5)	2 (1.8)	2 (1.7)	0
Granulomatous lymphadenitis	0	0	1 (0.9)	0
Lymphadenopathy	2 (0.8)	0	1 (0.9)	0
Autoimmune haemolytic anaemia	0	1 (0.9)	0	0
Leukocytosis	0	1 (0.9)	0	0
Leukopenia	0	0	0	1 (1.4)
Lymphopenia	1 (0.4)	0	0	0
Microcytic anaemia	0	1 (0.9)	0	0
Neutropenia	2 (0.8)	0	0	0
Neutrophilia	0	1 (0.9)	0	0
Normocytic anaemia	0	1 (0.9)	0	0
Pancytopenia	0	1 (0.9)	0	0
Thrombocytopenia	2 (0.8)	2 (1.8)	0	0
Renal and urinary disorders	21 (8.1)	5 (4.4)	6 (5.2)	2 (2.9)
Nephrolithiasis	2 (0.8)	1 (0.9)	3 (2.6)	0
Haematuria	2 (0.8)	0	1 (0.9)	0
Hydronephrosis	1 (0.4)	0	1 (0.9)	0
Renal impairment	1 (0.4)	0	1 (0.9)	0
Acute kidney injury	3 (1.2)	2 (1.8)	0	0
Bladder spasm	1 (0.4)	0	0	0
Chromaturia	1 (0.4)	0	0	0
Chronic kidney disease	1 (0.4)	0	0	0
Cystitis haemorrhagic	0	0	0	1 (1.4)

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Dysuria	1 (0.4)	2 (1.8)	0	0
Hypertonic bladder	1 (0.4)	0	0	0
Lupus nephritis	3 (1.2)	1 (0.9)	0	1 (1.4)
Renal colic	1 (0.4)	0	0	0
Renal cyst	1 (0.4)	0	0	0
Stress urinary incontinence	1 (0.4)	0	0	0
Ureteric obstruction	1 (0.4)	0	0	0
Urethral meatus stenosis	1 (0.4)	0	0	0
Urinary incontinence	1 (0.4)	0	0	0
Urinary tract discomfort	1 (0.4)	0	0	0
Ear and labyrinth disorders	17 (6.6)	5 (4.4)	5 (4.3)	1 (1.4)
Hypoacusis	0	1 (0.9)	2 (1.7)	0
Vertigo	7 (2.7)	0	2 (1.7)	0
Deafness bilateral	2 (0.8)	0	1 (0.9)	0
Cerumen impaction	1 (0.4)	0	0	0
Deafness	1 (0.4)	0	0	0
Ear congestion	1 (0.4)	1 (0.9)	0	0
Ear discomfort	0	0	0	1 (1.4)
Ear pain	2 (0.8)	0	0	0
Ear pruritus	0	1 (0.9)	0	0
Inner ear inflammation	1 (0.4)	0	0	0
Motion sickness	0	1 (0.9)	0	0
Neurosensory hypoacusis	1 (0.4)	0	0	0
Tinnitus	1 (0.4)	2 (1.8)	0	0
Vertigo positional	2 (0.8)	0	0	0
Immune system disorders	8 (3.1)	3 (2.7)	4 (3.5)	2 (2.9)
Seasonal allergy	2 (0.8)	2 (1.8)	3 (2.6)	1 (1.4)
Allergic oedema	0	0	1 (0.9)	0
Allergy to chemicals	0	0	1 (0.9)	0
Hypersensitivity	3 (1.2)	0	1 (0.9)	0
Allergy to animal	1 (0.4)	1 (0.9)	0	0
Allergy to arthropod sting	1 (0.4)	0	0	0
Allergy to vaccine	1 (0.4)	0	0	0
Drug hypersensitivity	0	0	0	1 (1.4)
Endocrine disorders	4 (1.5)	1 (0.9)	2 (1.7)	1 (1.4)
Adrenal insufficiency	0	1 (0.9)	1 (0.9)	0
Hypothyroidism	0	0	1 (0.9)	0
Basedow's disease	1 (0.4)	0	0	0
Goitre	1 (0.4)	0	0	0
Hyperprolactinaemia	1 (0.4)	0	0	0
Hyperthyroidism	1 (0.4)	0	0	0
Thyroid mass	1 (0.4)	0	0	1 (1.4)
Hepatobiliary disorders	6 (2.3)	3 (2.7)	1 (0.9)	1 (1.4)
Cholelithiasis	1 (0.4)	0	1 (0.9)	1 (1.4)
Biliary colic	1 (0.4)	0	0	0
Cholecystitis	0	1 (0.9)	0	0
Cholecystitis acute	1 (0.4)	0	0	0
Drug-induced liver injury	0	1 (0.9)	0	0
Hepatic steatosis	2 (0.8)	0	0	0
Hypertransaminasaemia	1 (0.4)	0	0	0
Liver disorder	0	1 (0.9)	0	0
Pregnancy, puerperium and perinatal conditions	1 (0.4)	0	0	0
Abortion spontaneous	1 (0.4)	0	0	0
Product issues	0	1 (0.9)	0	0

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Adverse Events by SOC, PT during treatment (Study 09)
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Anifrolumab 300mg (N=259) n (%)	Placebo Feeder + Placebo LTE (N=113) n (%)	Placebo Feeder + Anifrolumab 300mg (N=115) n (%)	Anifrolumab 150mg + Anifrolumab 300mg (N=69) n (%)
Device connection issue	0	1 (0.9)	0	0
Social circumstances	1 (0.4)	1 (0.9)	0	1 (1.4)
Menopause	1 (0.4)	1 (0.9)	0	1 (1.4)
Surgical and medical procedures	0	0	0	1 (1.4)
Oesophageal dilation procedure	0	0	0	1 (1.4)

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Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Serious Adverse Events by SOC, PT during treatment (Study 09)
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Anifrolumab 300mg (N=259) n (%)	Placebo Feeder + Placebo LTE (N=113) n (%)	Placebo Feeder + Anifrolumab 300mg (N=115) n (%)	Anifrolumab 150mg + Anifrolumab 300mg (N=69) n (%)
Subjects with events	46 (17.8)	26 (23.0)	22 (19.1)	14 (20.3)
Infections and infestations	20 (7.7)	9 (8.0)	11 (9.6)	7 (10.1)
Herpes zoster	5 (1.9)	0	3 (2.6)	1 (1.4)
Pneumonia	3 (1.2)	2 (1.8)	3 (2.6)	2 (2.9)
Bronchitis	0	0	2 (1.7)	0
Gastroenteritis	1 (0.4)	1 (0.9)	2 (1.7)	0
Herpes zoster meningitis	0	0	1 (0.9)	0
Influenza	2 (0.8)	0	1 (0.9)	0
Lower respiratory tract infection	0	0	1 (0.9)	0
Pelvic inflammatory disease	1 (0.4)	0	1 (0.9)	0
Pharyngitis	0	0	1 (0.9)	0
Postoperative wound infection	0	0	1 (0.9)	0
Sepsis	0	0	1 (0.9)	0
Bacterial sepsis	0	0	0	1 (1.4)
Cellulitis staphylococcal	0	0	0	1 (1.4)
Dengue fever	1 (0.4)	0	0	0
Diverticulitis	1 (0.4)	0	0	0
Erysipelas	0	1 (0.9)	0	0
Herpes zoster cutaneous disseminated	1 (0.4)	0	0	0
Herpes zoster disseminated	1 (0.4)	0	0	0
Ludwig angina	0	1 (0.9)	0	0
Mediastinitis	0	1 (0.9)	0	0
Pharyngitis streptococcal	1 (0.4)	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	1 (1.4)
Pneumonia bacterial	1 (0.4)	0	0	0
Pneumonia influenzal	0	0	0	1 (1.4)
Pneumonia staphylococcal	0	1 (0.9)	0	0
Postoperative abscess	0	0	0	1 (1.4)
Pyelonephritis	3 (1.2)	0	0	0
Streptococcal urinary tract infection	1 (0.4)	0	0	0
Urinary tract infection	1 (0.4)	1 (0.9)	0	0
Urosepsis	0	1 (0.9)	0	0
Wound infection staphylococcal	0	1 (0.9)	0	0
Gastrointestinal disorders	0	0	4 (3.5)	1 (1.4)
Constipation	0	0	1 (0.9)	0
Enterocolitis	0	0	1 (0.9)	0
Inguinal hernia	0	0	1 (0.9)	0
Tooth impacted	0	0	1 (0.9)	0
Peritoneal haemorrhage	0	0	0	1 (1.4)
Injury, poisoning and procedural complications	4 (1.5)	1 (0.9)	3 (2.6)	2 (2.9)
Joint dislocation	0	0	1 (0.9)	0
Periprocedural myocardial infarction	0	0	1 (0.9)	0
Spinal fracture	0	0	1 (0.9)	0
Arthropod bite	0	0	0	1 (1.4)
Humerus fracture	1 (0.4)	0	0	0
Overdose	1 (0.4)	0	0	0
Rib fracture	0	0	0	1 (1.4)
Spinal compression fracture	1 (0.4)	0	0	0
Tendon rupture	0	1 (0.9)	0	0
Upper limb fracture	1 (0.4)	0	0	0
Nervous system disorders	4 (1.5)	1 (0.9)	3 (2.6)	1 (1.4)
Cerebrovascular accident	0	0	1 (0.9)	1 (1.4)
Headache	0	0	1 (0.9)	1 (1.4)
Syncope	0	1 (0.9)	1 (0.9)	0
Intracranial aneurysm	1 (0.4)	0	0	0

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Serious Adverse Events by SOC, PT during treatment (Study 09)
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Anifrolumab 300mg (N=259) n (%)	Placebo Feeder + Placebo LTE (N=113) n (%)	Placebo Feeder + Anifrolumab 300mg (N=115) n (%)	Anifrolumab 150mg + Anifrolumab 300mg (N=69) n (%)
Ischaemic stroke	1 (0.4)	0	0	0
Post herpetic neuralgia	2 (0.8)	0	0	0
General disorders and administration site conditions	2 (0.8)	0	2 (1.7)	2 (2.9)
Incarcerated hernia	0	0	1 (0.9)	0
Mucosal haemorrhage	0	0	1 (0.9)	0
Chest discomfort	0	0	0	1 (1.4)
Influenza like illness	0	0	0	1 (1.4)
Non-cardiac chest pain	2 (0.8)	0	0	0
Renal and urinary disorders	4 (1.5)	2 (1.8)	2 (1.7)	0
Hydronephrosis	0	0	1 (0.9)	0
Renal impairment	1 (0.4)	0	1 (0.9)	0
Acute kidney injury	2 (0.8)	1 (0.9)	0	0
Lupus nephritis	1 (0.4)	1 (0.9)	0	0
Respiratory, thoracic and mediastinal disorders	3 (1.2)	3 (2.7)	2 (1.7)	1 (1.4)
Dyspnoea	0	1 (0.9)	1 (0.9)	0
Pleural effusion	1 (0.4)	1 (0.9)	1 (0.9)	0
Acute respiratory failure	1 (0.4)	0	0	0
Asthma	1 (0.4)	0	0	0
Chronic obstructive pulmonary disease	0	1 (0.9)	0	0
Dyspnoea exertional	0	0	0	1 (1.4)
Pleurisy	1 (0.4)	0	0	0
Pulmonary hypertension	0	1 (0.9)	0	0
Respiratory distress	0	1 (0.9)	0	0
Blood and lymphatic system disorders	2 (0.8)	2 (1.8)	1 (0.9)	0
Anaemia	0	1 (0.9)	1 (0.9)	0
Iron deficiency anaemia	0	1 (0.9)	0	0
Thrombocytopenia	2 (0.8)	0	0	0
Cardiac disorders	5 (1.9)	4 (3.5)	1 (0.9)	0
Pericarditis	0	0	1 (0.9)	0
Acute myocardial infarction	0	1 (0.9)	0	0
Aortic valve disease	1 (0.4)	0	0	0
Bundle branch block left	1 (0.4)	0	0	0
Cardiac failure congestive	1 (0.4)	1 (0.9)	0	0
Cardiogenic shock	0	1 (0.9)	0	0
Coronary artery disease	1 (0.4)	0	0	0
Myocardial infarction	0	1 (0.9)	0	0
Myocardial ischaemia	1 (0.4)	0	0	0
Pericardial effusion	0	1 (0.9)	0	0
Supraventricular tachycardia	0	1 (0.9)	0	0
Ear and labyrinth disorders	1 (0.4)	0	1 (0.9)	0
Vertigo	1 (0.4)	0	1 (0.9)	0
Investigations	0	0	1 (0.9)	0
International normalised ratio increased	0	0	1 (0.9)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.8)	1 (0.9)	1 (0.9)	0
Basal cell carcinoma	0	0	1 (0.9)	0
Squamous cell carcinoma	0	1 (0.9)	0	0
Uterine leiomyoma	2 (0.8)	0	0	0
Psychiatric disorders	0	0	1 (0.9)	0
Affect lability	0	0	1 (0.9)	0
Reproductive system and breast disorders	1 (0.4)	3 (2.7)	1 (0.9)	2 (2.9)

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Serious Adverse Events by SOC, PT during treatment (Study 09)
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Anifrolumab 300mg (N=259) n (%)	Placebo Feeder + Placebo LTE (N=113) n (%)	Placebo Feeder + Anifrolumab 300mg (N=115) n (%)	Anifrolumab 150mg + Anifrolumab 300mg (N=69) n (%)
Cervical dysplasia	0	0	1 (0.9)	0
Menorrhagia	0	1 (0.9)	0	0
Ovarian cyst	0	0	0	1 (1.4)
Ovarian cyst ruptured	0	0	0	1 (1.4)
Uterine haemorrhage	1 (0.4)	0	0	0
Uterine prolapse	0	1 (0.9)	0	0
Uterovaginal prolapse	0	1 (0.9)	0	0
Skin and subcutaneous tissue disorders	0	1 (0.9)	1 (0.9)	0
Ecchymosis	0	0	1 (0.9)	0
Urticaria	0	1 (0.9)	0	0
Vascular disorders	1 (0.4)	1 (0.9)	1 (0.9)	1 (1.4)
Deep vein thrombosis	0	0	1 (0.9)	0
Malignant hypertension	1 (0.4)	0	0	0
Orthostatic hypotension	0	1 (0.9)	0	0
Venous thrombosis	0	0	0	1 (1.4)
Hepatobiliary disorders	2 (0.8)	0	0	0
Cholecystitis acute	1 (0.4)	0	0	0
Cholelithiasis	1 (0.4)	0	0	0
Metabolism and nutrition disorders	0	0	0	1 (1.4)
Dehydration	0	0	0	1 (1.4)
Musculoskeletal and connective tissue disorders	8 (3.1)	6 (5.3)	0	2 (2.9)
Arthritis	1 (0.4)	0	0	0
Back pain	0	0	0	1 (1.4)
Pain in extremity	1 (0.4)	0	0	0
Spinal stenosis	1 (0.4)	0	0	0
Synovial cyst	1 (0.4)	0	0	0
Systemic lupus erythematosus	3 (1.2)	6 (5.3)	0	1 (1.4)
Tenosynovitis	1 (0.4)	0	0	0
Pregnancy, puerperium and perinatal conditions	1 (0.4)	0	0	0
Abortion spontaneous	1 (0.4)	0	0	0

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Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Severe Adverse Events by SOC, PT during treatment (Study 09)
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Anifrolumab 300mg (N=259) n (%)	Placebo Feeder + Placebo LTE (N=113) n (%)	Placebo Feeder + Anifrolumab 300mg (N=115) n (%)	Anifrolumab 150mg + Anifrolumab 300mg (N=69) n (%)
Subjects with events	32 (12.4)	8 (7.1)	11 (9.6)	7 (10.1)
Infections and infestations	15 (5.8)	2 (1.8)	4 (3.5)	4 (5.8)
Gastroenteritis	0	0	2 (1.7)	0
Influenza	2 (0.8)	0	1 (0.9)	0
Pneumonia	2 (0.8)	0	1 (0.9)	2 (2.9)
Bacterial sepsis	0	0	0	1 (1.4)
Dengue fever	1 (0.4)	0	0	0
Diverticulitis	1 (0.4)	0	0	0
Herpes zoster	3 (1.2)	0	0	1 (1.4)
Herpes zoster disseminated	1 (0.4)	0	0	0
Ludwig angina	0	1 (0.9)	0	0
Mediastinitis	0	1 (0.9)	0	0
Otitis media chronic	1 (0.4)	0	0	0
Pelvic inflammatory disease	1 (0.4)	0	0	0
Pharyngitis streptococcal	1 (0.4)	0	0	0
Pneumonia bacterial	1 (0.4)	0	0	0
Pneumonia staphylococcal	0	1 (0.9)	0	0
Postoperative abscess	0	0	0	1 (1.4)
Pyelonephritis	2 (0.8)	0	0	0
Streptococcal urinary tract infection	1 (0.4)	0	0	0
Urinary tract infection	0	0	0	1 (1.4)
Injury, poisoning and procedural complications	3 (1.2)	1 (0.9)	4 (3.5)	1 (1.4)
Joint dislocation	0	0	1 (0.9)	0
Periprocedural myocardial infarction	0	0	1 (0.9)	0
Radius fracture	0	0	1 (0.9)	0
Spinal fracture	0	0	1 (0.9)	0
Humerus fracture	1 (0.4)	0	0	0
Incisional hernia	1 (0.4)	0	0	0
Muscle strain	0	0	0	1 (1.4)
Tendon rupture	0	1 (0.9)	0	0
Upper limb fracture	1 (0.4)	0	0	0
Gastrointestinal disorders	1 (0.4)	0	2 (1.7)	0
Constipation	0	0	1 (0.9)	0
Faecaloma	0	0	1 (0.9)	0
Toothache	0	0	1 (0.9)	0
Dental caries	1 (0.4)	0	0	0
General disorders and administration site conditions	1 (0.4)	0	2 (1.7)	0
Chest pain	0	0	1 (0.9)	0
Incarcerated hernia	0	0	1 (0.9)	0
Influenza like illness	1 (0.4)	0	0	0
Ear and labyrinth disorders	0	0	1 (0.9)	0
Vertigo	0	0	1 (0.9)	0
Nervous system disorders	5 (1.9)	0	1 (0.9)	2 (2.9)
Cerebrovascular accident	0	0	1 (0.9)	1 (1.4)
Headache	0	0	0	2 (2.9)
Intracranial aneurysm	1 (0.4)	0	0	0
Ischaemic stroke	1 (0.4)	0	0	0
Post herpetic neuralgia	2 (0.8)	0	0	0
Radiculopathy	1 (0.4)	0	0	0
Renal and urinary disorders	3 (1.2)	0	1 (0.9)	0
Renal impairment	0	0	1 (0.9)	0
Acute kidney injury	2 (0.8)	0	0	0

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Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Severe Adverse Events by SOC, PT during treatment (Study 09)
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Anifrolumab 300mg (N=259) n (%)	Placebo Feeder + Placebo LTE (N=113) n (%)	Placebo Feeder + Anifrolumab 300mg (N=115) n (%)	Anifrolumab 150mg + Anifrolumab 300mg (N=69) n (%)
Lupus nephritis	1 (0.4)	0	0	0
Blood and lymphatic system disorders	2 (0.8)	1 (0.9)	0	0
Iron deficiency anaemia	0	1 (0.9)	0	0
Thrombocytopenia	2 (0.8)	0	0	0
Cardiac disorders	2 (0.8)	2 (1.8)	0	0
Cardiac failure congestive	1 (0.4)	0	0	0
Cardiogenic shock	0	1 (0.9)	0	0
Myocardial infarction	0	1 (0.9)	0	0
Myocardial ischaemia	1 (0.4)	0	0	0
Supraventricular tachycardia	0	1 (0.9)	0	0
Musculoskeletal and connective tissue disorders	3 (1.2)	3 (2.7)	0	2 (2.9)
Back pain	0	0	0	1 (1.4)
Rotator cuff syndrome	0	1 (0.9)	0	0
SLE arthritis	0	1 (0.9)	0	0
Systemic lupus erythematosus	2 (0.8)	1 (0.9)	0	1 (1.4)
Tendonitis	1 (0.4)	0	0	0
Psychiatric disorders	1 (0.4)	0	0	0
Suicidal ideation	1 (0.4)	0	0	0
Respiratory, thoracic and mediastinal disorders	1 (0.4)	2 (1.8)	0	0
Cough	1 (0.4)	0	0	0
Dyspnoea	1 (0.4)	1 (0.9)	0	0
Pulmonary hypertension	0	1 (0.9)	0	0
Respiratory distress	0	1 (0.9)	0	0
Vascular disorders	0	1 (0.9)	0	0
Vasculitis	0	1 (0.9)	0	0

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Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Non-Severe Adverse Events by SOC, PT during treatment (Study 09)
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Anifrolumab 300mg (N=259) n (%)	Placebo Feeder + Placebo LTE (N=113) n (%)	Placebo Feeder + Anifrolumab 300mg (N=115) n (%)	Anifrolumab 150mg + Anifrolumab 300mg (N=69) n (%)
Subjects with events	215 (83.0)	87 (77.0)	92 (80.0)	59 (85.5)
Infections and infestations	183 (70.7)	66 (58.4)	74 (64.3)	48 (69.6)
Nasopharyngitis	61 (23.6)	13 (11.5)	29 (25.2)	14 (20.3)
Upper respiratory tract infection	47 (18.1)	17 (15.0)	21 (18.3)	8 (11.6)
Bronchitis	35 (13.5)	8 (7.1)	18 (15.7)	15 (21.7)
Pharyngitis	14 (5.4)	4 (3.5)	13 (11.3)	9 (13.0)
Gastroenteritis	7 (2.7)	7 (6.2)	11 (9.6)	3 (4.3)
Herpes zoster	15 (5.8)	6 (5.3)	11 (9.6)	8 (11.6)
Urinary tract infection	46 (17.8)	14 (12.4)	11 (9.6)	6 (8.7)
Sinusitis	21 (8.1)	3 (2.7)	9 (7.8)	5 (7.2)
Influenza	13 (5.0)	3 (2.7)	8 (7.0)	5 (7.2)
Oral herpes	16 (6.2)	5 (4.4)	6 (5.2)	1 (1.4)
Viral upper respiratory tract infection	9 (3.5)	2 (1.8)	5 (4.3)	1 (1.4)
Conjunctivitis	9 (3.5)	2 (1.8)	4 (3.5)	0
Cystitis	7 (2.7)	3 (2.7)	4 (3.5)	2 (2.9)
Gastroenteritis viral	4 (1.5)	0	4 (3.5)	1 (1.4)
Latent tuberculosis	15 (5.8)	2 (1.8)	4 (3.5)	0
Bacterial vaginosis	4 (1.5)	0	3 (2.6)	0
Lower respiratory tract infection	4 (1.5)	1 (0.9)	3 (2.6)	0
Pneumonia	6 (2.3)	3 (2.7)	3 (2.6)	1 (1.4)
Rhinitis	2 (0.8)	1 (0.9)	3 (2.6)	3 (4.3)
Vaginal infection	10 (3.9)	3 (2.7)	3 (2.6)	1 (1.4)
Vulvovaginal mycotic infection	8 (3.1)	0	3 (2.6)	2 (2.9)
Ear infection	2 (0.8)	0	2 (1.7)	2 (2.9)
Fungal skin infection	2 (0.8)	0	2 (1.7)	0
Gastrointestinal infection	0	1 (0.9)	2 (1.7)	0
Impetigo	0	0	2 (1.7)	0
Oral candidiasis	4 (1.5)	2 (1.8)	2 (1.7)	1 (1.4)
Otitis externa	1 (0.4)	0	2 (1.7)	0
Pharyngotonsillitis	1 (0.4)	0	2 (1.7)	0
Tooth infection	0	1 (0.9)	2 (1.7)	0
Tracheobronchitis	1 (0.4)	0	2 (1.7)	1 (1.4)
Viral infection	6 (2.3)	2 (1.8)	2 (1.7)	0
Abdominal infection	0	0	1 (0.9)	0
Acute sinusitis	4 (1.5)	2 (1.8)	1 (0.9)	1 (1.4)
Bartholinitis	0	0	1 (0.9)	0
Cellulitis	3 (1.2)	2 (1.8)	1 (0.9)	2 (2.9)
Cervicitis	2 (0.8)	1 (0.9)	1 (0.9)	0
Folliculitis	1 (0.4)	0	1 (0.9)	1 (1.4)
Genital herpes simplex	1 (0.4)	0	1 (0.9)	0
Herpes simplex	3 (1.2)	1 (0.9)	1 (0.9)	0
Herpes zoster meningitis	0	0	1 (0.9)	0
Molluscum contagiosum	1 (0.4)	0	1 (0.9)	0
Nail infection	0	0	1 (0.9)	1 (1.4)
Onychomycosis	0	1 (0.9)	1 (0.9)	0
Otitis media	8 (3.1)	0	1 (0.9)	0
Otosalpingitis	0	0	1 (0.9)	0
Pelvic inflammatory disease	0	0	1 (0.9)	1 (1.4)
Periodontitis	1 (0.4)	0	1 (0.9)	1 (1.4)
Postoperative wound infection	0	0	1 (0.9)	0
Pyelonephritis	1 (0.4)	0	1 (0.9)	0
Respiratory tract infection	3 (1.2)	1 (0.9)	1 (0.9)	1 (1.4)
Sepsis	0	1 (0.9)	1 (0.9)	0
Sialoadenitis	1 (0.4)	0	1 (0.9)	0
Subcutaneous abscess	2 (0.8)	0	1 (0.9)	0
Sweating fever	0	0	1 (0.9)	0
Tinea pedis	1 (0.4)	0	1 (0.9)	0
Tonsillitis	1 (0.4)	0	1 (0.9)	0

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Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Non-Severe Adverse Events by SOC, PT during treatment (Study 09)
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Anifrolumab 300mg (N=259) n (%)	Placebo Feeder + Placebo LTE (N=113) n (%)	Placebo Feeder + Anifrolumab 300mg (N=115) n (%)	Anifrolumab 150mg + Anifrolumab 300mg (N=69) n (%)
Tooth abscess	5 (1.9)	2 (1.8)	1 (0.9)	1 (1.4)
Urinary tract infection enterococcal	0	0	1 (0.9)	0
Vulvovaginitis	3 (1.2)	1 (0.9)	1 (0.9)	0
Abscess oral	1 (0.4)	0	0	0
Alveolar osteitis	1 (0.4)	1 (0.9)	0	0
Appendicitis	1 (0.4)	0	0	0
Arthritis infective	1 (0.4)	0	0	0
Asymptomatic bacteriuria	1 (0.4)	0	0	0
Bacterial vulvovaginitis	0	1 (0.9)	0	0
Bronchitis bacterial	2 (0.8)	0	0	0
Cellulitis staphylococcal	0	0	0	1 (1.4)
Cervicitis human papilloma virus	0	1 (0.9)	0	0
Chronic sinusitis	0	1 (0.9)	0	0
Conjunctivitis viral	1 (0.4)	0	0	0
Dengue fever	1 (0.4)	0	0	0
Diverticulitis	1 (0.4)	0	0	0
Erysipelas	0	1 (0.9)	0	0
Escherichia urinary tract infection	1 (0.4)	1 (0.9)	0	0
Fungal infection	2 (0.8)	0	0	0
Furuncle	0	1 (0.9)	0	0
Gastroenteritis bacterial	1 (0.4)	0	0	1 (1.4)
Gastrointestinal viral infection	0	0	0	1 (1.4)
Genitourinary chlamydia infection	1 (0.4)	0	0	0
Gingivitis	2 (0.8)	1 (0.9)	0	0
Groin abscess	1 (0.4)	0	0	0
Helicobacter infection	1 (0.4)	0	0	0
Herpes zoster cutaneous disseminated	1 (0.4)	0	0	0
Hordeolum	2 (0.8)	1 (0.9)	0	0
Human ehrlichiosis	1 (0.4)	0	0	0
Labyrinthitis	1 (0.4)	0	0	0
Large intestine infection	1 (0.4)	0	0	0
Laryngitis	5 (1.9)	2 (1.8)	0	0
Localised infection	1 (0.4)	0	0	0
Mumps	1 (0.4)	0	0	0
Nasal vestibulitis	0	0	0	1 (1.4)
Ophthalmic herpes simplex	1 (0.4)	0	0	0
Oral fungal infection	1 (0.4)	0	0	0
Otitis externa fungal	0	1 (0.9)	0	0
Otitis media acute	2 (0.8)	0	0	0
Otitis media bacterial	1 (0.4)	0	0	0
Paronychia	3 (1.2)	1 (0.9)	0	1 (1.4)
Parotitis	1 (0.4)	0	0	0
Pertussis	1 (0.4)	0	0	0
Pharyngitis streptococcal	1 (0.4)	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	1 (1.4)
Pneumonia influenzal	0	0	0	1 (1.4)
Pneumonia viral	1 (0.4)	0	0	0
Pulpitis dental	0	0	0	1 (1.4)
Pyelonephritis acute	0	1 (0.9)	0	0
Pyoderma	0	0	0	1 (1.4)
Pyuria	1 (0.4)	0	0	0
Respiratory moniliasis	0	1 (0.9)	0	0
Respiratory tract infection viral	2 (0.8)	0	0	1 (1.4)
Rotavirus infection	1 (0.4)	0	0	0
Skin infection	2 (0.8)	0	0	0
Soft tissue infection	1 (0.4)	0	0	0
Superinfection	1 (0.4)	0	0	0
Tinea manuum	1 (0.4)	0	0	0
Tinea versicolour	2 (0.8)	0	0	0
Tracheitis	3 (1.2)	0	0	1 (1.4)

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Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Non-Severe Adverse Events by SOC, PT during treatment (Study 09)
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Anifrolumab 300mg (N=259) n (%)	Placebo Feeder + Placebo LTE (N=113) n (%)	Placebo Feeder + Anifrolumab 300mg (N=115) n (%)	Anifrolumab 150mg + Anifrolumab 300mg (N=69) n (%)
Trichomoniasis	1 (0.4)	0	0	0
Tungiasis	0	0	0	1 (1.4)
Urinary tract infection bacterial	0	1 (0.9)	0	0
Urinary tract infection pseudomonal	1 (0.4)	0	0	0
Urosepsis	0	1 (0.9)	0	0
Viral pharyngitis	3 (1.2)	0	0	0
Vulvovaginal candidiasis	1 (0.4)	1 (0.9)	0	0
Vulvovaginitis trichomonal	0	1 (0.9)	0	0
Wound infection	3 (1.2)	1 (0.9)	0	0
Wound infection staphylococcal	0	1 (0.9)	0	0
Musculoskeletal and connective tissue disorders	88 (34.0)	32 (28.3)	31 (27.0)	16 (23.2)
Back pain	16 (6.2)	8 (7.1)	9 (7.8)	8 (11.6)
Arthralgia	15 (5.8)	5 (4.4)	4 (3.5)	3 (4.3)
Musculoskeletal pain	4 (1.5)	3 (2.7)	4 (3.5)	1 (1.4)
Systemic lupus erythematosus	9 (3.5)	5 (4.4)	4 (3.5)	2 (2.9)
Arthritis	4 (1.5)	1 (0.9)	3 (2.6)	1 (1.4)
Myalgia	4 (1.5)	0	3 (2.6)	1 (1.4)
Pain in extremity	6 (2.3)	5 (4.4)	3 (2.6)	3 (4.3)
Costochondritis	1 (0.4)	3 (2.7)	2 (1.7)	1 (1.4)
Foot deformity	0	0	2 (1.7)	0
Musculoskeletal chest pain	4 (1.5)	0	2 (1.7)	1 (1.4)
Osteoarthritis	7 (2.7)	0	2 (1.7)	2 (2.9)
Tendonitis	4 (1.5)	1 (0.9)	2 (1.7)	0
Fibromyalgia	2 (0.8)	0	1 (0.9)	3 (4.3)
Intervertebral disc protrusion	3 (1.2)	0	1 (0.9)	0
Muscle spasms	2 (0.8)	2 (1.8)	1 (0.9)	1 (1.4)
Neck pain	5 (1.9)	0	1 (0.9)	2 (2.9)
Pain in jaw	0	1 (0.9)	1 (0.9)	0
Polyarthritis	0	0	1 (0.9)	0
Rotator cuff syndrome	0	0	1 (0.9)	1 (1.4)
Spinal pain	1 (0.4)	0	1 (0.9)	0
Tenosynovitis stenosans	2 (0.8)	0	1 (0.9)	1 (1.4)
Torticollis	0	0	1 (0.9)	0
Arthropathy	1 (0.4)	0	0	0
Bursitis	11 (4.2)	1 (0.9)	0	0
Enthesopathy	0	1 (0.9)	0	0
Flank pain	1 (0.4)	1 (0.9)	0	0
Groin pain	0	1 (0.9)	0	0
Intervertebral disc degeneration	0	0	0	1 (1.4)
Joint instability	1 (0.4)	0	0	0
Joint lock	1 (0.4)	0	0	0
Joint swelling	2 (0.8)	2 (1.8)	0	0
Ligamentitis	1 (0.4)	0	0	0
Metatarsalgia	1 (0.4)	0	0	0
Muscular weakness	1 (0.4)	0	0	0
Musculoskeletal stiffness	2 (0.8)	0	0	0
Osteonecrosis	3 (1.2)	1 (0.9)	0	0
Osteopenia	1 (0.4)	0	0	0
Osteoporosis	2 (0.8)	0	0	0
Periarthritis	1 (0.4)	1 (0.9)	0	0
Plantar fasciitis	0	1 (0.9)	0	0
Polychondritis	1 (0.4)	0	0	0
Sacroiliitis	1 (0.4)	0	0	0
Sjogren's syndrome	1 (0.4)	1 (0.9)	0	0
Spinal osteoarthritis	2 (0.8)	0	0	0
Spinal stenosis	1 (0.4)	0	0	0
Synovial cyst	4 (1.5)	0	0	0
Synovitis	1 (0.4)	0	0	1 (1.4)
Tenosynovitis	1 (0.4)	0	0	0

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Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Non-Severe Adverse Events by SOC, PT during treatment (Study 09)
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Anifrolumab 300mg (N=259) n (%)	Placebo Feeder + Placebo LTE (N=113) n (%)	Placebo Feeder + Anifrolumab 300mg (N=115) n (%)	Anifrolumab 150mg + Anifrolumab 300mg (N=69) n (%)
Trigger finger	1 (0.4)	0	0	0
Injury, poisoning and procedural complications	57 (22.0)	21 (18.6)	28 (24.3)	17 (24.6)
Infusion related reaction	16 (6.2)	6 (5.3)	9 (7.8)	2 (2.9)
Contusion	8 (3.1)	2 (1.8)	4 (3.5)	6 (8.7)
Arthropod bite	5 (1.9)	1 (0.9)	2 (1.7)	1 (1.4)
Epicondylitis	1 (0.4)	0	2 (1.7)	0
Fall	9 (3.5)	6 (5.3)	2 (1.7)	3 (4.3)
Limb injury	1 (0.4)	2 (1.8)	2 (1.7)	0
Rib fracture	3 (1.2)	0	2 (1.7)	2 (2.9)
Tibia fracture	1 (0.4)	0	2 (1.7)	0
Tooth fracture	0	1 (0.9)	2 (1.7)	0
Animal bite	2 (0.8)	1 (0.9)	1 (0.9)	0
Arthropod sting	3 (1.2)	0	1 (0.9)	0
Foot fracture	3 (1.2)	2 (1.8)	1 (0.9)	1 (1.4)
Ligament rupture	1 (0.4)	0	1 (0.9)	0
Ligament sprain	0	0	1 (0.9)	1 (1.4)
Postoperative wound complication	0	0	1 (0.9)	0
Procedural dizziness	0	0	1 (0.9)	0
Procedural pain	0	0	1 (0.9)	0
Road traffic accident	1 (0.4)	1 (0.9)	1 (0.9)	0
Skin abrasion	1 (0.4)	0	1 (0.9)	0
Skin injury	0	1 (0.9)	1 (0.9)	0
Skin laceration	2 (0.8)	1 (0.9)	1 (0.9)	0
Subcutaneous haematoma	0	0	1 (0.9)	0
Wrist fracture	0	0	1 (0.9)	0
Animal scratch	3 (1.2)	0	0	0
Ankle fracture	0	1 (0.9)	0	1 (1.4)
Bite	1 (0.4)	0	0	0
Brachial plexus injury	0	0	0	1 (1.4)
Dental restoration failure	1 (0.4)	1 (0.9)	0	0
Eye contusion	1 (0.4)	0	0	0
Facial bones fracture	0	0	0	1 (1.4)
Foreign body in respiratory tract	1 (0.4)	0	0	0
Hand fracture	1 (0.4)	0	0	0
Hypobarism	1 (0.4)	0	0	0
Incision site pain	0	0	0	1 (1.4)
Injury	3 (1.2)	1 (0.9)	0	0
Joint dislocation	1 (0.4)	0	0	0
Joint injury	0	1 (0.9)	0	0
Limb crushing injury	0	1 (0.9)	0	0
Lower limb fracture	1 (0.4)	0	0	0
Lumbar vertebral fracture	0	0	0	1 (1.4)
Muscle strain	1 (0.4)	1 (0.9)	0	0
Nail avulsion	1 (0.4)	0	0	0
Overdose	1 (0.4)	0	0	0
Post-traumatic pain	1 (0.4)	0	0	0
Pubis fracture	0	1 (0.9)	0	0
Radius fracture	1 (0.4)	0	0	1 (1.4)
Respiratory fume inhalation disorder	0	0	0	1 (1.4)
Scar	0	1 (0.9)	0	0
Skin wound	0	0	0	1 (1.4)
Soft tissue injury	0	0	0	1 (1.4)
Spinal compression fracture	1 (0.4)	1 (0.9)	0	0
Spinal fracture	1 (0.4)	0	0	0
Thermal burn	2 (0.8)	0	0	0
Toxicity to various agents	2 (0.8)	0	0	0
Traumatic haematoma	1 (0.4)	1 (0.9)	0	0
Upper limb fracture	1 (0.4)	0	0	0
Wound	1 (0.4)	0	0	0

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Full analysis set

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Wound complication	1 (0.4)	0	0	0
Gastrointestinal disorders	63 (24.3)	24 (21.2)	25 (21.7)	16 (23.2)
Nausea	10 (3.9)	6 (5.3)	6 (5.2)	3 (4.3)
Diarrhoea	14 (5.4)	5 (4.4)	5 (4.3)	5 (7.2)
Abdominal pain	4 (1.5)	4 (3.5)	4 (3.5)	3 (4.3)
Abdominal pain upper	6 (2.3)	2 (1.8)	3 (2.6)	4 (5.8)
Constipation	5 (1.9)	7 (6.2)	3 (2.6)	0
Dental caries	4 (1.5)	1 (0.9)	3 (2.6)	1 (1.4)
Dyspepsia	1 (0.4)	4 (3.5)	3 (2.6)	1 (1.4)
Enteritis	1 (0.4)	0	2 (1.7)	0
Gastritis	2 (0.8)	2 (1.8)	2 (1.7)	0
Gastrooesophageal reflux disease	7 (2.7)	3 (2.7)	2 (1.7)	1 (1.4)
Abdominal distension	2 (0.8)	0	1 (0.9)	1 (1.4)
Chronic gastritis	2 (0.8)	1 (0.9)	1 (0.9)	0
Colitis	1 (0.4)	0	1 (0.9)	0
Dysphagia	1 (0.4)	0	1 (0.9)	1 (1.4)
Enterocolitis	0	0	1 (0.9)	0
Erosive oesophagitis	0	0	1 (0.9)	0
Food poisoning	1 (0.4)	1 (0.9)	1 (0.9)	0
Gastritis erosive	0	0	1 (0.9)	0
Haematochezia	1 (0.4)	1 (0.9)	1 (0.9)	0
Inguinal hernia	0	0	1 (0.9)	0
Lip oedema	0	0	1 (0.9)	0
Mouth ulceration	2 (0.8)	0	1 (0.9)	1 (1.4)
Parotid gland enlargement	0	0	1 (0.9)	0
Tongue disorder	0	0	1 (0.9)	0
Tooth impacted	1 (0.4)	0	1 (0.9)	0
Toothache	2 (0.8)	0	1 (0.9)	0
Umbilical hernia	0	0	1 (0.9)	0
Vomiting	9 (3.5)	2 (1.8)	1 (0.9)	1 (1.4)
Abdominal discomfort	3 (1.2)	0	0	1 (1.4)
Abdominal pain lower	1 (0.4)	0	0	0
Anal pruritus	0	0	0	1 (1.4)
Aphthous ulcer	1 (0.4)	0	0	0
Barrett's oesophagus	1 (0.4)	0	0	0
Diverticulum	1 (0.4)	0	0	0
Gastric mucosa erythema	1 (0.4)	0	0	0
Gastric ulcer	1 (0.4)	0	0	0
Gastrointestinal inflammation	1 (0.4)	0	0	0
Gastrointestinal pain	0	1 (0.9)	0	0
Gastrointestinal wall thickening	1 (0.4)	0	0	0
Gingival recession	1 (0.4)	0	0	0
Glossodynia	0	1 (0.9)	0	0
Haemorrhoids	4 (1.5)	1 (0.9)	0	0
Hiatus hernia	2 (0.8)	0	0	1 (1.4)
Impaired gastric emptying	2 (0.8)	0	0	0
Irritable bowel syndrome	1 (0.4)	1 (0.9)	0	0
Large intestine polyp	0	1 (0.9)	0	0
Lip swelling	1 (0.4)	0	0	0
Lip ulceration	1 (0.4)	0	0	0
Loose tooth	1 (0.4)	0	0	0
Malabsorption	0	1 (0.9)	0	0
Oesophageal hypomotility	1 (0.4)	0	0	0
Oesophagitis	1 (0.4)	0	0	0
Oral mucosal eruption	1 (0.4)	0	0	0
Palatal disorder	1 (0.4)	0	0	0
Paraesthesia oral	1 (0.4)	0	0	0
Peritoneal haemorrhage	0	0	0	1 (1.4)
Proctalgia	0	0	0	1 (1.4)

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Rectal haemorrhage	1 (0.4)	0	0	0
Stomatitis	0	1 (0.9)	0	0
Tooth disorder	0	1 (0.9)	0	0
Skin and subcutaneous tissue disorders	41 (15.8)	16 (14.2)	20 (17.4)	9 (13.0)
Urticaria	3 (1.2)	2 (1.8)	4 (3.5)	2 (2.9)
Dermal cyst	0	0	2 (1.7)	0
Dermatitis contact	2 (0.8)	0	2 (1.7)	0
Rash	6 (2.3)	3 (2.7)	2 (1.7)	1 (1.4)
Rash pruritic	0	0	2 (1.7)	0
Skin fissures	1 (0.4)	1 (0.9)	2 (1.7)	0
Acne	3 (1.2)	0	1 (0.9)	0
Actinic keratosis	1 (0.4)	0	1 (0.9)	1 (1.4)
Angioedema	1 (0.4)	0	1 (0.9)	0
Dermatitis	1 (0.4)	1 (0.9)	1 (0.9)	1 (1.4)
Ecchymosis	1 (0.4)	0	1 (0.9)	0
Eczema	3 (1.2)	1 (0.9)	1 (0.9)	1 (1.4)
Erythema nodosum	0	0	1 (0.9)	0
Hidradenitis	2 (0.8)	0	1 (0.9)	0
Hyperkeratosis	0	0	1 (0.9)	0
Intertrigo	2 (0.8)	0	1 (0.9)	0
Night sweats	1 (0.4)	0	1 (0.9)	0
Photosensitivity reaction	1 (0.4)	0	1 (0.9)	0
Pruritus	1 (0.4)	2 (1.8)	1 (0.9)	0
Skin hyperpigmentation	2 (0.8)	1 (0.9)	1 (0.9)	0
Skin lesion	1 (0.4)	0	1 (0.9)	1 (1.4)
Alopecia	1 (0.4)	1 (0.9)	0	0
Blood blister	0	0	0	1 (1.4)
Dandruff	1 (0.4)	0	0	0
Dermatitis atopic	1 (0.4)	0	0	0
Dry skin	0	1 (0.9)	0	0
Eczema asteatotic	0	1 (0.9)	0	0
Eczema nummular	0	1 (0.9)	0	0
Erythema	1 (0.4)	1 (0.9)	0	0
Guttate psoriasis	1 (0.4)	0	0	0
Ingrowing nail	1 (0.4)	0	0	0
Keratosis pilaris	0	1 (0.9)	0	0
Lipoatrophy	1 (0.4)	0	0	0
Miliaria	1 (0.4)	0	0	1 (1.4)
Nail bed bleeding	0	1 (0.9)	0	0
Nail dystrophy	1 (0.4)	1 (0.9)	0	0
Onychoclasis	1 (0.4)	0	0	0
Perioral dermatitis	2 (0.8)	0	0	0
Petechiae	1 (0.4)	0	0	0
Pigmentation disorder	1 (0.4)	0	0	0
Post inflammatory pigmentation change	0	1 (0.9)	0	0
Purpura	1 (0.4)	1 (0.9)	0	1 (1.4)
Rash erythematous	1 (0.4)	0	0	0
Rash maculo-papular	0	0	0	1 (1.4)
Rash papular	0	1 (0.9)	0	0
Seborrhoeic dermatitis	2 (0.8)	0	0	0
Skin discolouration	0	1 (0.9)	0	1 (1.4)
Skin ulcer	2 (0.8)	1 (0.9)	0	0
Systemic lupus erythematosus rash	0	1 (0.9)	0	0
Urticaria chronic	1 (0.4)	0	0	0
Respiratory, thoracic and mediastinal disorders	39 (15.1)	17 (15.0)	18 (15.7)	12 (17.4)
Cough	13 (5.0)	2 (1.8)	4 (3.5)	7 (10.1)
Asthma	1 (0.4)	4 (3.5)	3 (2.6)	1 (1.4)
Dyspnoea	2 (0.8)	2 (1.8)	3 (2.6)	1 (1.4)

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Nasal congestion	0	3 (2.7)	3 (2.6)	0
Rhinitis allergic	2 (0.8)	1 (0.9)	3 (2.6)	0
Oropharyngeal pain	5 (1.9)	2 (1.8)	2 (1.7)	0
Pleural effusion	1 (0.4)	2 (1.8)	2 (1.7)	0
Pleuritic pain	1 (0.4)	0	1 (0.9)	0
Sinus congestion	3 (1.2)	1 (0.9)	1 (0.9)	1 (1.4)
Upper respiratory tract inflammation	2 (0.8)	0	1 (0.9)	0
Acute respiratory failure	1 (0.4)	0	0	0
Allergic sinusitis	0	1 (0.9)	0	0
Atelectasis	1 (0.4)	0	0	0
Bronchial hyperreactivity	1 (0.4)	0	0	0
Bronchitis chronic	1 (0.4)	0	0	0
Catarrh	0	1 (0.9)	0	0
Chronic obstructive pulmonary disease	2 (0.8)	1 (0.9)	0	1 (1.4)
Dyspnoea exertional	0	1 (0.9)	0	2 (2.9)
Epistaxis	2 (0.8)	1 (0.9)	0	2 (2.9)
Haemoptysis	1 (0.4)	0	0	0
Interstitial lung disease	0	0	0	1 (1.4)
Lower respiratory tract congestion	1 (0.4)	0	0	0
Nasal obstruction	0	0	0	1 (1.4)
Nasal polyps	1 (0.4)	0	0	0
Pleurisy	1 (0.4)	0	0	0
Productive cough	2 (0.8)	2 (1.8)	0	0
Pulmonary hypertension	0	1 (0.9)	0	0
Pulmonary mass	1 (0.4)	0	0	0
Rales	0	1 (0.9)	0	0
Respiratory disorder	1 (0.4)	1 (0.9)	0	0
Rhinorrhoea	1 (0.4)	0	0	0
Sleep apnoea syndrome	0	1 (0.9)	0	0
Vocal cord disorder	1 (0.4)	0	0	0
Wheezing	1 (0.4)	1 (0.9)	0	0
General disorders and administration site conditions	34 (13.1)	12 (10.6)	16 (13.9)	12 (17.4)
Non-cardiac chest pain	3 (1.2)	1 (0.9)	4 (3.5)	1 (1.4)
Oedema peripheral	5 (1.9)	1 (0.9)	3 (2.6)	2 (2.9)
Pain	2 (0.8)	0	2 (1.7)	1 (1.4)
Peripheral swelling	2 (0.8)	1 (0.9)	2 (1.7)	1 (1.4)
Pyrexia	4 (1.5)	3 (2.7)	2 (1.7)	0
Adverse drug reaction	3 (1.2)	2 (1.8)	1 (0.9)	0
Chest discomfort	2 (0.8)	0	1 (0.9)	1 (1.4)
Chest pain	3 (1.2)	0	1 (0.9)	1 (1.4)
Cyst	0	0	1 (0.9)	0
Fatigue	6 (2.3)	1 (0.9)	1 (0.9)	2 (2.9)
Feeling cold	0	0	1 (0.9)	0
Mucosal haemorrhage	0	0	1 (0.9)	0
Soft tissue inflammation	0	0	1 (0.9)	0
Asthenia	1 (0.4)	2 (1.8)	0	0
Discomfort	0	0	0	1 (1.4)
Facial pain	1 (0.4)	0	0	0
Gait disturbance	1 (0.4)	0	0	0
Influenza like illness	2 (0.8)	2 (1.8)	0	3 (4.3)
Injection site reaction	0	1 (0.9)	0	0
Nodule	1 (0.4)	1 (0.9)	0	0
Oedema	0	0	0	1 (1.4)
Swelling face	0	1 (0.9)	0	0
Vaccination site reaction	1 (0.4)	0	0	0
Withdrawal syndrome	0	0	0	1 (1.4)
Nervous system disorders	56 (21.6)	20 (17.7)	14 (12.2)	19 (27.5)
Headache	19 (7.3)	9 (8.0)	5 (4.3)	8 (11.6)

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Non-Severe Adverse Events by SOC, PT during treatment (Study 09)
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Anifrolumab 300mg (N=259) n (%)	Placebo Feeder + Placebo LTE (N=113) n (%)	Placebo Feeder + Anifrolumab 300mg (N=115) n (%)	Anifrolumab 150mg + Anifrolumab 300mg (N=69) n (%)
Dizziness	7 (2.7)	2 (1.8)	3 (2.6)	4 (5.8)
Neuralgia	3 (1.2)	0	2 (1.7)	0
Neuropathy peripheral	0	0	2 (1.7)	2 (2.9)
Post herpetic neuralgia	4 (1.5)	0	2 (1.7)	1 (1.4)
Syncope	1 (0.4)	1 (0.9)	2 (1.7)	1 (1.4)
Carpal tunnel syndrome	2 (0.8)	2 (1.8)	1 (0.9)	0
Migraine	1 (0.4)	3 (2.7)	1 (0.9)	2 (2.9)
Migraine with aura	3 (1.2)	0	1 (0.9)	0
Paraesthesia	2 (0.8)	0	1 (0.9)	1 (1.4)
Seizure	0	0	1 (0.9)	0
Thalamic infarction	0	0	1 (0.9)	0
Amnesia	0	1 (0.9)	0	0
Aphasia	1 (0.4)	0	0	0
Burning sensation	1 (0.4)	0	0	1 (1.4)
Cervical radiculopathy	1 (0.4)	0	0	1 (1.4)
Cognitive disorder	1 (0.4)	0	0	0
Dizziness postural	1 (0.4)	0	0	0
Dysarthria	1 (0.4)	0	0	0
Dysgeusia	1 (0.4)	0	0	0
Epilepsy	1 (0.4)	0	0	1 (1.4)
Haemorrhagic cerebral infarction	0	1 (0.9)	0	0
Hemiparesis	1 (0.4)	0	0	0
Hypersomnia	0	0	0	1 (1.4)
Hypoaesthesia	2 (0.8)	1 (0.9)	0	1 (1.4)
Intercostal neuralgia	1 (0.4)	0	0	0
Lumbar radiculopathy	3 (1.2)	0	0	0
Meningism	1 (0.4)	0	0	0
Myoclonus	1 (0.4)	0	0	0
Nystagmus	0	0	0	1 (1.4)
Occipital neuralgia	1 (0.4)	0	0	0
Orthostatic intolerance	0	0	0	1 (1.4)
Parkinson's disease	1 (0.4)	0	0	0
Parkinsonian gait	1 (0.4)	0	0	0
Peroneal nerve palsy	1 (0.4)	0	0	0
Presyncope	2 (0.8)	0	0	0
Radiculopathy	1 (0.4)	0	0	0
Restless legs syndrome	1 (0.4)	2 (1.8)	0	1 (1.4)
Sciatica	5 (1.9)	0	0	0
Sensory disturbance	0	1 (0.9)	0	0
Somnolence	1 (0.4)	0	0	0
Vestibular migraine	1 (0.4)	0	0	0
Eye disorders	22 (8.5)	8 (7.1)	11 (9.6)	6 (8.7)
Dry eye	3 (1.2)	0	3 (2.6)	0
Vision blurred	1 (0.4)	0	2 (1.7)	0
Astigmatism	0	0	1 (0.9)	1 (1.4)
Cataract	2 (0.8)	1 (0.9)	1 (0.9)	2 (2.9)
Chalazion	2 (0.8)	0	1 (0.9)	0
Conjunctival irritation	0	0	1 (0.9)	0
Conjunctivitis allergic	1 (0.4)	0	1 (0.9)	0
Corneal infiltrates	0	0	1 (0.9)	0
Hypermetropia	0	0	1 (0.9)	0
Keratitis	1 (0.4)	0	1 (0.9)	0
Scleritis	0	0	1 (0.9)	0
Visual acuity reduced	0	0	1 (0.9)	0
Visual impairment	0	1 (0.9)	1 (0.9)	0
Blepharitis	2 (0.8)	0	0	0
Conjunctival erosion	0	1 (0.9)	0	0
Conjunctival haemorrhage	3 (1.2)	0	0	1 (1.4)
Corneal erosion	1 (0.4)	1 (0.9)	0	0

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Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Incidence of Non-Severe Adverse Events by SOC, PT during treatment (Study 09)
Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Anifrolumab 300mg (N=259) n (%)	Placebo Feeder + Placebo LTE (N=113) n (%)	Placebo Feeder + Anifrolumab 300mg (N=115) n (%)	Anifrolumab 150mg + Anifrolumab 300mg (N=69) n (%)
Diplopia	0	1 (0.9)	0	0
Episcleritis	1 (0.4)	0	0	0
Erythema of eyelid	1 (0.4)	0	0	0
Eye inflammation	1 (0.4)	0	0	0
Eyelid cyst	0	1 (0.9)	0	0
Glaucoma	1 (0.4)	0	0	0
Lacrimation increased	1 (0.4)	0	0	0
Maculopathy	0	1 (0.9)	0	0
Photophobia	0	1 (0.9)	0	0
Retinal detachment	0	0	0	1 (1.4)
Retinal exudates	0	1 (0.9)	0	0
Retinopathy	3 (1.2)	0	0	1 (1.4)
Swelling of eyelid	1 (0.4)	0	0	0
Psychiatric disorders	18 (6.9)	8 (7.1)	11 (9.6)	9 (13.0)
Insomnia	6 (2.3)	2 (1.8)	4 (3.5)	6 (8.7)
Depression	6 (2.3)	4 (3.5)	2 (1.7)	3 (4.3)
Affect lability	0	0	1 (0.9)	0
Anxiety	3 (1.2)	1 (0.9)	1 (0.9)	0
Anxiety disorder	1 (0.4)	0	1 (0.9)	0
Depressed mood	0	0	1 (0.9)	0
Nervousness	0	0	1 (0.9)	0
Neurosis	0	0	1 (0.9)	0
Persistent depressive disorder	0	0	1 (0.9)	0
Stress	0	0	1 (0.9)	0
Adjustment disorder with depressed mood	1 (0.4)	0	0	0
Drug use disorder	1 (0.4)	0	0	0
Generalised anxiety disorder	0	0	0	1 (1.4)
Loss of libido	0	1 (0.9)	0	0
Panic attack	1 (0.4)	0	0	0
Reproductive system and breast disorders	26 (10.0)	6 (5.3)	11 (9.6)	8 (11.6)
Cervical dysplasia	1 (0.4)	0	3 (2.6)	0
Bartholin's cyst	0	0	1 (0.9)	0
Breast mass	2 (0.8)	0	1 (0.9)	1 (1.4)
Endometriosis	0	0	1 (0.9)	0
Menopausal symptoms	0	1 (0.9)	1 (0.9)	0
Menorrhagia	2 (0.8)	1 (0.9)	1 (0.9)	0
Metrorrhagia	0	0	1 (0.9)	1 (1.4)
Pelvic pain	0	0	1 (0.9)	0
Uterine cervical erosion	0	0	1 (0.9)	0
Vaginal haemorrhage	0	0	1 (0.9)	1 (1.4)
Vaginal ulceration	0	0	1 (0.9)	0
Adnexa uteri cyst	0	0	0	1 (1.4)
Amenorrhoea	1 (0.4)	1 (0.9)	0	0
Atrophic vulvovaginitis	1 (0.4)	0	0	0
Breast calcifications	0	1 (0.9)	0	0
Breast cyst	3 (1.2)	0	0	0
Breast disorder	1 (0.4)	0	0	0
Breast enlargement	1 (0.4)	0	0	0
Breast hyperplasia	0	0	0	1 (1.4)
Cervical cyst	1 (0.4)	0	0	0
Cervical polyp	1 (0.4)	0	0	0
Cervix disorder	1 (0.4)	0	0	0
Cervix inflammation	0	0	0	1 (1.4)
Coital bleeding	0	0	0	1 (1.4)
Cystocele	0	1 (0.9)	0	0
Dysmenorrhoea	5 (1.9)	0	0	1 (1.4)
Dyspareunia	1 (0.4)	0	0	0
Ectropion of cervix	0	1 (0.9)	0	0

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Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
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Full analysis set

System Organ Class (SOC) Preferred Term (PT)	Anifrolumab 300mg (N=259) n (%)	Placebo Feeder + Placebo LTE (N=113) n (%)	Placebo Feeder + Anifrolumab 300mg (N=115) n (%)	Anifrolumab 150mg + Anifrolumab 300mg (N=69) n (%)
Fibrocystic breast disease	3 (1.2)	0	0	0
Mammary duct ectasia	0	0	0	1 (1.4)
Menometrorrhagia	1 (0.4)	0	0	0
Menstruation irregular	1 (0.4)	0	0	0
Ovarian cyst	4 (1.5)	0	0	2 (2.9)
Ovarian cyst ruptured	0	0	0	1 (1.4)
Perineal rash	1 (0.4)	0	0	0
Polycystic ovaries	1 (0.4)	0	0	0
Polymenorrhoea	1 (0.4)	0	0	0
Premenstrual syndrome	1 (0.4)	0	0	0
Pruritus genital	1 (0.4)	0	0	0
Uterine haemorrhage	4 (1.5)	0	0	0
Uterine polyp	1 (0.4)	0	0	0
Uterine prolapse	0	1 (0.9)	0	0
Uterovaginal prolapse	0	1 (0.9)	0	0
Vaginal discharge	0	0	0	1 (1.4)
Investigations	16 (6.2)	4 (3.5)	10 (8.7)	5 (7.2)
Weight increased	3 (1.2)	1 (0.9)	3 (2.6)	1 (1.4)
Alanine aminotransferase increased	2 (0.8)	1 (0.9)	1 (0.9)	0
Blood creatine phosphokinase increased	2 (0.8)	1 (0.9)	1 (0.9)	0
Blood creatinine increased	0	0	1 (0.9)	0
Blood immunoglobulin A decreased	0	0	1 (0.9)	0
Ejection fraction decreased	0	0	1 (0.9)	0
Herpes simplex test positive	0	0	1 (0.9)	0
International normalised ratio increased	0	0	1 (0.9)	0
Liver function test increased	0	0	1 (0.9)	0
Aspartate aminotransferase increased	1 (0.4)	1 (0.9)	0	0
Bacterial test positive	1 (0.4)	0	0	0
Blood alkaline phosphatase increased	1 (0.4)	0	0	0
Blood corticotrophin decreased	1 (0.4)	0	0	0
Blood creatine increased	0	0	0	1 (1.4)
Blood pressure increased	1 (0.4)	0	0	3 (4.3)
Gamma-glutamyltransferase increased	1 (0.4)	0	0	0
Hepatic enzyme increased	0	0	0	1 (1.4)
Influenza B virus test positive	1 (0.4)	0	0	0
International normalised ratio abnormal	1 (0.4)	0	0	0
Intraocular pressure increased	1 (0.4)	0	0	0
Transaminases increased	0	1 (0.9)	0	0
Urine protein/creatinine ratio increased	1 (0.4)	0	0	0
Vitamin D decreased	1 (0.4)	0	0	0
Weight decreased	2 (0.8)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	17 (6.6)	6 (5.3)	10 (8.7)	4 (5.8)
Skin papilloma	5 (1.9)	1 (0.9)	4 (3.5)	0
Basal cell carcinoma	1 (0.4)	0	1 (0.9)	0
Fibrous histiocytoma	2 (0.8)	0	1 (0.9)	0
Haemangioma of bone	0	0	1 (0.9)	0
Hygroma colli	0	0	1 (0.9)	0
Squamous cell carcinoma	0	1 (0.9)	1 (0.9)	1 (1.4)
Uterine leiomyoma	4 (1.5)	1 (0.9)	1 (0.9)	1 (1.4)
Acanthoma	1 (0.4)	0	0	0
Anogenital warts	1 (0.4)	0	0	0
Benign breast neoplasm	1 (0.4)	0	0	0
Colon adenoma	0	1 (0.9)	0	0
Haemangioma of liver	1 (0.4)	1 (0.9)	0	0
Intraductal papilloma of breast	0	0	0	1 (1.4)
Lipoma	0	1 (0.9)	0	1 (1.4)
Seborrhoeic keratosis	1 (0.4)	0	0	0
Thyroid neoplasm	1 (0.4)	0	0	0

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Anifrolumab (MEDI-546)
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Full analysis set

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Vascular disorders	18 (6.9)	9 (8.0)	8 (7.0)	5 (7.2)
Hypertension	12 (4.6)	4 (3.5)	3 (2.6)	2 (2.9)
Deep vein thrombosis	0	0	1 (0.9)	0
Hot flush	0	0	1 (0.9)	0
Raynaud's phenomenon	1 (0.4)	1 (0.9)	1 (0.9)	3 (4.3)
Thrombosis	0	0	1 (0.9)	0
Vasculitis	0	0	1 (0.9)	0
Essential hypertension	1 (0.4)	0	0	0
Haematoma	0	2 (1.8)	0	0
Lymphostasis	0	0	0	1 (1.4)
Malignant hypertension	1 (0.4)	0	0	0
Orthostatic hypotension	1 (0.4)	1 (0.9)	0	0
Peripheral venous disease	1 (0.4)	0	0	0
Post thrombotic syndrome	0	1 (0.9)	0	0
Varicophlebitis	0	1 (0.9)	0	0
Varicose vein	1 (0.4)	0	0	0
Venous thrombosis	0	0	0	1 (1.4)
Cardiac disorders	12 (4.6)	8 (7.1)	7 (6.1)	4 (5.8)
Palpitations	1 (0.4)	3 (2.7)	2 (1.7)	1 (1.4)
Angina pectoris	0	1 (0.9)	1 (0.9)	0
Arrhythmia	1 (0.4)	0	1 (0.9)	0
Atrial fibrillation	0	1 (0.9)	1 (0.9)	0
Pericarditis	0	0	1 (0.9)	0
Ventricular hypokinesia	0	0	1 (0.9)	0
Acute myocardial infarction	0	2 (1.8)	0	0
Angina unstable	1 (0.4)	0	0	0
Aortic valve disease	1 (0.4)	0	0	0
Bradycardia	0	1 (0.9)	0	0
Bundle branch block left	1 (0.4)	0	0	0
Bundle branch block right	2 (0.8)	0	0	0
Cardiac failure chronic	1 (0.4)	0	0	0
Cardiac failure congestive	0	3 (2.7)	0	0
Cardiomegaly	0	1 (0.9)	0	0
Coronary artery disease	1 (0.4)	0	0	0
Cyanosis	0	0	0	1 (1.4)
Left ventricular dilatation	1 (0.4)	0	0	0
Pericardial effusion	0	1 (0.9)	0	0
Sinus bradycardia	1 (0.4)	0	0	0
Tachycardia	1 (0.4)	0	0	1 (1.4)
Tachycardia paroxysmal	1 (0.4)	0	0	0
Ventricular extrasystoles	0	0	0	1 (1.4)
Metabolism and nutrition disorders	20 (7.7)	11 (9.7)	7 (6.1)	5 (7.2)
Hypokalaemia	3 (1.2)	1 (0.9)	2 (1.7)	0
Dehydration	1 (0.4)	2 (1.8)	1 (0.9)	1 (1.4)
Hyperglycaemia	0	1 (0.9)	1 (0.9)	0
Hyperlipidaemia	1 (0.4)	0	1 (0.9)	0
Hypomagnesaemia	1 (0.4)	0	1 (0.9)	0
Hypophosphataemia	0	0	1 (0.9)	0
Iron deficiency	1 (0.4)	0	1 (0.9)	0
Type 2 diabetes mellitus	0	0	1 (0.9)	0
Abnormal loss of weight	0	1 (0.9)	0	1 (1.4)
Decreased appetite	1 (0.4)	0	0	2 (2.9)
Diabetes mellitus	3 (1.2)	0	0	1 (1.4)
Diabetes mellitus inadequate control	1 (0.4)	0	0	0
Dyslipidaemia	1 (0.4)	1 (0.9)	0	0
Fluid overload	0	1 (0.9)	0	0
Hypercholesterolaemia	5 (1.9)	0	0	0

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Hyperkalaemia	0	2 (1.8)	0	0
Hypertriglyceridaemia	1 (0.4)	0	0	0
Hyperuricaemia	0	1 (0.9)	0	0
Hyponatraemia	0	1 (0.9)	0	1 (1.4)
Obesity	1 (0.4)	0	0	0
Vitamin B complex deficiency	2 (0.8)	0	0	0
Vitamin B12 deficiency	1 (0.4)	1 (0.9)	0	0
Vitamin D deficiency	4 (1.5)	1 (0.9)	0	0
Blood and lymphatic system disorders	12 (4.6)	7 (6.2)	6 (5.2)	4 (5.8)
Anaemia	3 (1.2)	1 (0.9)	2 (1.7)	3 (4.3)
Iron deficiency anaemia	4 (1.5)	1 (0.9)	2 (1.7)	0
Granulomatous lymphadenitis	0	0	1 (0.9)	0
Lymphadenopathy	2 (0.8)	0	1 (0.9)	0
Autoimmune haemolytic anaemia	0	1 (0.9)	0	0
Leukocytosis	0	1 (0.9)	0	0
Leukopenia	0	0	0	1 (1.4)
Lymphopenia	1 (0.4)	0	0	0
Microcytic anaemia	0	1 (0.9)	0	0
Neutropenia	2 (0.8)	0	0	0
Neutrophilia	0	1 (0.9)	0	0
Normocytic anaemia	0	1 (0.9)	0	0
Pancytopenia	0	1 (0.9)	0	0
Thrombocytopenia	1 (0.4)	2 (1.8)	0	0
Renal and urinary disorders	20 (7.7)	5 (4.4)	5 (4.3)	2 (2.9)
Nephrolithiasis	2 (0.8)	1 (0.9)	3 (2.6)	0
Haematuria	2 (0.8)	0	1 (0.9)	0
Hydronephrosis	1 (0.4)	0	1 (0.9)	0
Acute kidney injury	1 (0.4)	2 (1.8)	0	0
Bladder spasm	1 (0.4)	0	0	0
Chromaturia	1 (0.4)	0	0	0
Chronic kidney disease	1 (0.4)	0	0	0
Cystitis haemorrhagic	0	0	0	1 (1.4)
Dysuria	1 (0.4)	2 (1.8)	0	0
Hypertonic bladder	1 (0.4)	0	0	0
Lupus nephritis	3 (1.2)	1 (0.9)	0	1 (1.4)
Renal colic	1 (0.4)	0	0	0
Renal cyst	1 (0.4)	0	0	0
Renal impairment	1 (0.4)	0	0	0
Stress urinary incontinence	1 (0.4)	0	0	0
Ureteric obstruction	1 (0.4)	0	0	0
Urethral meatus stenosis	1 (0.4)	0	0	0
Urinary incontinence	1 (0.4)	0	0	0
Urinary tract discomfort	1 (0.4)	0	0	0
Ear and labyrinth disorders	17 (6.6)	5 (4.4)	4 (3.5)	1 (1.4)
Hypoacusis	0	1 (0.9)	2 (1.7)	0
Deafness bilateral	2 (0.8)	0	1 (0.9)	0
Vertigo	7 (2.7)	0	1 (0.9)	0
Cerumen impaction	1 (0.4)	0	0	0
Deafness	1 (0.4)	0	0	0
Ear congestion	1 (0.4)	1 (0.9)	0	0
Ear discomfort	0	0	0	1 (1.4)
Ear pain	2 (0.8)	0	0	0
Ear pruritus	0	1 (0.9)	0	0
Inner ear inflammation	1 (0.4)	0	0	0
Motion sickness	0	1 (0.9)	0	0
Neurosensory hypoacusis	1 (0.4)	0	0	0
Tinnitus	1 (0.4)	2 (1.8)	0	0

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Vertigo positional	2 (0.8)	0	0	0
Immune system disorders	8 (3.1)	3 (2.7)	4 (3.5)	2 (2.9)
Seasonal allergy	2 (0.8)	2 (1.8)	3 (2.6)	1 (1.4)
Allergic oedema	0	0	1 (0.9)	0
Allergy to chemicals	0	0	1 (0.9)	0
Hypersensitivity	3 (1.2)	0	1 (0.9)	0
Allergy to animal	1 (0.4)	1 (0.9)	0	0
Allergy to arthropod sting	1 (0.4)	0	0	0
Allergy to vaccine	1 (0.4)	0	0	0
Drug hypersensitivity	0	0	0	1 (1.4)
Endocrine disorders	4 (1.5)	1 (0.9)	2 (1.7)	1 (1.4)
Adrenal insufficiency	0	1 (0.9)	1 (0.9)	0
Hypothyroidism	0	0	1 (0.9)	0
Basedow's disease	1 (0.4)	0	0	0
Goitre	1 (0.4)	0	0	0
Hyperprolactinaemia	1 (0.4)	0	0	0
Hyperthyroidism	1 (0.4)	0	0	0
Thyroid mass	1 (0.4)	0	0	1 (1.4)
Hepatobiliary disorders	6 (2.3)	3 (2.7)	1 (0.9)	1 (1.4)
Cholelithiasis	1 (0.4)	0	1 (0.9)	1 (1.4)
Biliary colic	1 (0.4)	0	0	0
Cholecystitis	0	1 (0.9)	0	0
Cholecystitis acute	1 (0.4)	0	0	0
Drug-induced liver injury	0	1 (0.9)	0	0
Hepatic steatosis	2 (0.8)	0	0	0
Hypertransaminasaemia	1 (0.4)	0	0	0
Liver disorder	0	1 (0.9)	0	0
Pregnancy, puerperium and perinatal conditions	1 (0.4)	0	0	0
Abortion spontaneous	1 (0.4)	0	0	0
Product issues	0	1 (0.9)	0	0
Device connection issue	0	1 (0.9)	0	0
Social circumstances	1 (0.4)	1 (0.9)	0	1 (1.4)
Menopause	1 (0.4)	1 (0.9)	0	1 (1.4)
Surgical and medical procedures	0	0	0	1 (1.4)
Oesophageal dilation procedure	0	0	0	1 (1.4)

Coded using MedDRA version 22.1.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event during study (Study 09)
Full analysis set

	Anifrolumab 300mg (N=259)	Placebo Feeder + Placebo LTE (N=113)	Placebo Feeder + Anifrolumab 300mg (N=115)	Anifrolumab 150mg + Anifrolumab 300mg (N=69)
Number of subjects with events, n (%)	220 (84.9)	90 (79.6)	92 (80.0)	61 (88.4)
Number of censored subjects, n (%)	39 (33.9)	23 (20.4)	23 (20.0)	8 (7.1)
Exposure years	168.6	66.8	79.4	45.7
EAIR per 100 PY	130.5	134.6	115.9	133.5

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Serious Adverse Event during study (Study 09)
Full analysis set

	Anifrolumab 300mg (N=259)	Placebo Feeder + Placebo LTE (N=113)	Placebo Feeder + Anifrolumab 300mg (N=115)	Anifrolumab 150mg + Anifrolumab 300mg (N=69)
Number of subjects with events, n (%)	47 (18.1)	27 (23.9)	25 (21.7)	17 (24.6)
Number of censored subjects, n (%)	212 (184.3)	86 (76.1)	90 (78.3)	52 (46.0)
Exposure years	506.2	193.9	215.7	132.5
EAIR per 100 PY	9.3	13.9	11.6	12.8

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Severe Adverse Event during study (Study 09)
Full analysis set

	Anifrolumab 300mg (N=259)	Placebo Feeder + Placebo LTE (N=113)	Placebo Feeder + Anifrolumab 300mg (N=115)	Anifrolumab 150mg + Anifrolumab 300mg (N=69)
Number of subjects with events, n (%)	32 (12.4)	11 (9.7)	15 (13.0)	10 (14.5)
Number of censored subjects, n (%)	227 (197.4)	102 (90.3)	100 (87.0)	59 (52.2)
Exposure years	526.4	217.8	237.1	141.4
EAIR per 100 PY	6.1	5.1	6.3	7.1

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Non-Severe Adverse Event during study (Study 09)
Full analysis set

	Anifrolumab 300mg (N=259)	Placebo Feeder + Placebo LTE (N=113)	Placebo Feeder + Anifrolumab 300mg (N=115)	Anifrolumab 150mg + Anifrolumab 300mg (N=69)
Number of subjects with events, n (%)	217 (83.8)	90 (79.6)	92 (80.0)	61 (88.4)
Number of censored subjects, n (%)	42 (36.5)	23 (20.4)	23 (20.0)	8 (7.1)
Exposure years	172.5	66.8	79.7	46.7
EAIR per 100 PY	125.8	134.6	115.5	130.7

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event leading to discontinuation of study drug during study (Study 09)
Full analysis set

	Anifrolumab 300mg (N=259)	Placebo Feeder + Placebo LTE (N=113)	Placebo Feeder + Anifrolumab 300mg (N=115)	Anifrolumab 150mg + Anifrolumab 300mg (N=69)
Number of subjects with events, n (%)	10 (3.9)	6 (5.3)	6 (5.2)	9 (13.0)
Number of censored subjects, n (%)	249 (216.5)	107 (94.7)	109 (94.8)	60 (53.1)
Exposure years	559.1	217.8	246.6	148.4
EAIR per 100 PY	1.8	2.8	2.4	6.1

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to Adverse Event leading to death during study (Study 09)
Full analysis set

	Anifrolumab 300mg (N=259)	Placebo Feeder + Placebo LTE (N=113)	Placebo Feeder + Anifrolumab 300mg (N=115)	Anifrolumab 150mg + Anifrolumab 300mg (N=69)
Number of subjects with events, n (%)	1 (0.4)	2 (1.8)	0 (0.0)	1 (1.4)
Number of censored subjects, n (%)	258 (224.3)	111 (98.2)	115 (100.0)	68 (60.2)
Exposure years	565.1	223.2	249.7	151.1
EAIR per 100 PY	0.2	0.9	0.0	0.7

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Anaphylaxis
Full analysis set

	Anifrolumab 300mg (N=259)	Placebo Feeder + Placebo LTE (N=113)	Placebo Feeder + Anifrolumab 300mg (N=115)	Anifrolumab 150mg + Anifrolumab 300mg (N=69)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	259 (225.2)	113 (100.0)	115 (100.0)	69 (61.1)
Exposure years	565.2	223.4	249.7	151.2
EAIR per 100 PY	0.0	0.0	0.0	0.0

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Serious Anaphylaxis
Full analysis set

	Anifrolumab 300mg (N=259)	Placebo Feeder + Placebo LTE (N=113)	Placebo Feeder + Anifrolumab 300mg (N=115)	Anifrolumab 150mg + Anifrolumab 300mg (N=69)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	259 (225.2)	113 (100.0)	115 (100.0)	69 (61.1)
Exposure years	565.2	223.4	249.7	151.2
EAIR per 100 PY	0.0	0.0	0.0	0.0

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Severe Anaphylaxis
Full analysis set

	Anifrolumab 300mg (N=259)	Placebo Feeder + Placebo LTE (N=113)	Placebo Feeder + Anifrolumab 300mg (N=115)	Anifrolumab 150mg + Anifrolumab 300mg (N=69)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	259 (225.2)	113 (100.0)	115 (100.0)	69 (61.1)
Exposure years	565.2	223.4	249.7	151.2
EAIR per 100 PY	0.0	0.0	0.0	0.0

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Non-Severe Anaphylaxis
Full analysis set

	Anifrolumab 300mg (N=259)	Placebo Feeder + Placebo LTE (N=113)	Placebo Feeder + Anifrolumab 300mg (N=115)	Anifrolumab 150mg + Anifrolumab 300mg (N=69)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	259 (225.2)	113 (100.0)	115 (100.0)	69 (61.1)
Exposure years	565.2	223.4	249.7	151.2
EAIR per 100 PY	0.0	0.0	0.0	0.0

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=259)	Placebo Feeder + Placebo LTE (N=113)	Placebo Feeder + Anifrolumab 300mg (N=115)	Anifrolumab 150mg + Anifrolumab 300mg (N=69)
Number of subjects with events, n (%)	20 (7.7)	6 (5.3)	13 (11.3)	9 (13.0)
Number of censored subjects, n (%)	239 (207.8)	107 (94.7)	102 (88.7)	60 (53.1)
Exposure years	539.3	217.5	232.5	143.0
EAIR per 100 PY	3.7	2.8	5.6	6.3

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Serious Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=259)	Placebo Feeder + Placebo LTE (N=113)	Placebo Feeder + Anifrolumab 300mg (N=115)	Anifrolumab 150mg + Anifrolumab 300mg (N=69)
Number of subjects with events, n (%)	7 (2.7)	0 (0.0)	5 (4.3)	1 (1.4)
Number of censored subjects, n (%)	252 (219.1)	113 (100.0)	110 (95.7)	68 (60.2)
Exposure years	555.5	223.4	243.2	151.0
EAIR per 100 PY	1.3	0.0	2.1	0.7

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Severe Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=259)	Placebo Feeder + Placebo LTE (N=113)	Placebo Feeder + Anifrolumab 300mg (N=115)	Anifrolumab 150mg + Anifrolumab 300mg (N=69)
Number of subjects with events, n (%)	4 (1.5)	0 (0.0)	0 (0.0)	1 (1.4)
Number of censored subjects, n (%)	255 (221.7)	113 (100.0)	115 (100.0)	68 (60.2)
Exposure years	559.6	223.4	249.7	151.0
EAIR per 100 PY	0.7	0.0	0.0	0.7

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Non-Severe Herpes Zoster
Full analysis set

	Anifrolumab 300mg (N=259)	Placebo Feeder + Placebo LTE (N=113)	Placebo Feeder + Anifrolumab 300mg (N=115)	Anifrolumab 150mg + Anifrolumab 300mg (N=69)
Number of subjects with events, n (%)	16 (6.2)	6 (5.3)	13 (11.3)	8 (11.6)
Number of censored subjects, n (%)	243 (211.3)	107 (94.7)	102 (88.7)	61 (54.0)
Exposure years	544.9	217.5	232.5	143.2
EAIR per 100 PY	2.9	2.8	5.6	5.6

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Malignancy
Full analysis set

	Anifrolumab 300mg (N=259)	Placebo Feeder + Placebo LTE (N=113)	Placebo Feeder + Anifrolumab 300mg (N=115)	Anifrolumab 150mg + Anifrolumab 300mg (N=69)
Number of subjects with events, n (%)	1 (0.4)	2 (1.8)	2 (1.7)	1 (1.4)
Number of censored subjects, n (%)	258 (224.3)	111 (98.2)	113 (98.3)	68 (60.2)
Exposure years	562.7	220.9	247.6	149.3
EAIR per 100 PY	0.2	0.9	0.8	0.7

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Serious Malignancy
Full analysis set

	Anifrolumab 300mg (N=259)	Placebo Feeder + Placebo LTE (N=113)	Placebo Feeder + Anifrolumab 300mg (N=115)	Anifrolumab 150mg + Anifrolumab 300mg (N=69)
Number of subjects with events, n (%)	0 (0.0)	2 (1.8)	1 (0.9)	0 (0.0)
Number of censored subjects, n (%)	259 (225.2)	111 (98.2)	114 (99.1)	69 (61.1)
Exposure years	565.2	220.9	249.5	151.2
EAIR per 100 PY	0.0	0.9	0.4	0.0

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Severe Malignancy
Full analysis set

	Anifrolumab 300mg (N=259)	Placebo Feeder + Placebo LTE (N=113)	Placebo Feeder + Anifrolumab 300mg (N=115)	Anifrolumab 150mg + Anifrolumab 300mg (N=69)
Number of subjects with events, n (%)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	259 (225.2)	112 (99.1)	115 (100.0)	69 (61.1)
Exposure years	565.2	223.3	249.7	151.2
EAIR per 100 PY	0.0	0.4	0.0	0.0

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Non-Severe Malignancy
Full analysis set

	Anifrolumab 300mg (N=259)	Placebo Feeder + Placebo LTE (N=113)	Placebo Feeder + Anifrolumab 300mg (N=115)	Anifrolumab 150mg + Anifrolumab 300mg (N=69)
Number of subjects with events, n (%)	1 (0.4)	1 (0.9)	2 (1.7)	1 (1.4)
Number of censored subjects, n (%)	258 (224.3)	112 (99.1)	113 (98.3)	68 (60.2)
Exposure years	562.7	221.0	247.6	149.3
EAIR per 100 PY	0.2	0.5	0.8	0.7

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Influenza
Full analysis set

	Anifrolumab 300mg (N=259)	Placebo Feeder + Placebo LTE (N=113)	Placebo Feeder + Anifrolumab 300mg (N=115)	Anifrolumab 150mg + Anifrolumab 300mg (N=69)
Number of subjects with events, n (%)	15 (5.8)	4 (3.5)	9 (7.8)	6 (8.7)
Number of censored subjects, n (%)	244 (212.2)	109 (96.5)	106 (92.2)	63 (55.8)
Exposure years	550.7	222.1	239.6	146.4
EAIR per 100 PY	2.7	1.8	3.8	4.1

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Serious Influenza
Full analysis set

	Anifrolumab 300mg (N=259)	Placebo Feeder + Placebo LTE (N=113)	Placebo Feeder + Anifrolumab 300mg (N=115)	Anifrolumab 150mg + Anifrolumab 300mg (N=69)
Number of subjects with events, n (%)	2 (0.8)	0 (0.0)	1 (0.9)	1 (1.4)
Number of censored subjects, n (%)	257 (223.5)	113 (100.0)	114 (99.1)	68 (60.2)
Exposure years	563.3	223.4	248.2	150.6
EAIR per 100 PY	0.4	0.0	0.4	0.7

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Severe Influenza
Full analysis set

	Anifrolumab 300mg (N=259)	Placebo Feeder + Placebo LTE (N=113)	Placebo Feeder + Anifrolumab 300mg (N=115)	Anifrolumab 150mg + Anifrolumab 300mg (N=69)
Number of subjects with events, n (%)	2 (0.8)	0 (0.0)	1 (0.9)	0 (0.0)
Number of censored subjects, n (%)	257 (223.5)	113 (100.0)	114 (99.1)	69 (61.1)
Exposure years	563.0	223.4	248.2	151.2
EAIR per 100 PY	0.4	0.0	0.4	0.0

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Non-Severe Influenza
Full analysis set

	Anifrolumab 300mg (N=259)	Placebo Feeder + Placebo LTE (N=113)	Placebo Feeder + Anifrolumab 300mg (N=115)	Anifrolumab 150mg + Anifrolumab 300mg (N=69)
Number of subjects with events, n (%)	13 (5.0)	4 (3.5)	8 (7.0)	6 (8.7)
Number of censored subjects, n (%)	246 (213.9)	109 (96.5)	107 (93.0)	63 (55.8)
Exposure years	552.9	222.1	241.1	146.4
EAIR per 100 PY	2.4	1.8	3.3	4.1

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - MACE
Full analysis set

	Anifrolumab 300mg (N=259)	Placebo Feeder + Placebo LTE (N=113)	Placebo Feeder + Anifrolumab 300mg (N=115)	Anifrolumab 150mg + Anifrolumab 300mg (N=69)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	259 (225.2)	113 (100.0)	115 (100.0)	69 (61.1)
Exposure years	565.2	223.4	249.7	151.2
EAIR per 100 PY	0.0	0.0	0.0	0.0

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Serious MACE
Full analysis set

	Anifrolumab 300mg (N=259)	Placebo Feeder + Placebo LTE (N=113)	Placebo Feeder + Anifrolumab 300mg (N=115)	Anifrolumab 150mg + Anifrolumab 300mg (N=69)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	259 (225.2)	113 (100.0)	115 (100.0)	69 (61.1)
Exposure years	565.2	223.4	249.7	151.2
EAIR per 100 PY	0.0	0.0	0.0	0.0

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Severe MACE
Full analysis set

	Anifrolumab 300mg (N=259)	Placebo Feeder + Placebo LTE (N=113)	Placebo Feeder + Anifrolumab 300mg (N=115)	Anifrolumab 150mg + Anifrolumab 300mg (N=69)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	259 (225.2)	113 (100.0)	115 (100.0)	69 (61.1)
Exposure years	565.2	223.4	249.7	151.2
EAIR per 100 PY	0.0	0.0	0.0	0.0

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Non-Severe MACE
Full analysis set

	Anifrolumab 300mg (N=259)	Placebo Feeder + Placebo LTE (N=113)	Placebo Feeder + Anifrolumab 300mg (N=115)	Anifrolumab 150mg + Anifrolumab 300mg (N=69)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	259 (225.2)	113 (100.0)	115 (100.0)	69 (61.1)
Exposure years	565.2	223.4	249.7	151.2
EAIR per 100 PY	0.0	0.0	0.0	0.0

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Non-opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=259)	Placebo Feeder + Placebo LTE (N=113)	Placebo Feeder + Anifrolumab 300mg (N=115)	Anifrolumab 150mg + Anifrolumab 300mg (N=69)
Number of subjects with events, n (%)	190 (73.4)	68 (60.2)	77 (67.0)	49 (71.0)
Number of censored subjects, n (%)	69 (60.0)	45 (39.8)	38 (33.0)	20 (17.7)
Exposure years	259.4	113.9	114.1	73.4
EAIR per 100 PY	73.2	59.7	67.5	66.7

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Serious Non-opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=259)	Placebo Feeder + Placebo LTE (N=113)	Placebo Feeder + Anifrolumab 300mg (N=115)	Anifrolumab 150mg + Anifrolumab 300mg (N=69)
Number of subjects with events, n (%)	20 (7.7)	9 (8.0)	12 (10.4)	6 (8.7)
Number of censored subjects, n (%)	239 (207.8)	104 (92.0)	103 (89.6)	63 (55.8)
Exposure years	538.0	214.0	232.9	143.7
EAIR per 100 PY	3.7	4.2	5.2	4.2

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Severe Non-opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=259)	Placebo Feeder + Placebo LTE (N=113)	Placebo Feeder + Anifrolumab 300mg (N=115)	Anifrolumab 150mg + Anifrolumab 300mg (N=69)
Number of subjects with events, n (%)	15 (5.8)	2 (1.8)	4 (3.5)	4 (5.8)
Number of censored subjects, n (%)	244 (212.2)	111 (98.2)	111 (96.5)	65 (57.5)
Exposure years	544.8	222.5	244.2	145.1
EAIR per 100 PY	2.8	0.9	1.6	2.8

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Non-Severe Non-opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=259)	Placebo Feeder + Placebo LTE (N=113)	Placebo Feeder + Anifrolumab 300mg (N=115)	Anifrolumab 150mg + Anifrolumab 300mg (N=69)
Number of subjects with events, n (%)	188 (72.6)	68 (60.2)	76 (66.1)	49 (71.0)
Number of censored subjects, n (%)	71 (61.7)	45 (39.8)	39 (33.9)	20 (17.7)
Exposure years	261.2	113.9	115.5	74.2
EAIR per 100 PY	72.0	59.7	65.8	66.0

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=259)	Placebo Feeder + Placebo LTE (N=113)	Placebo Feeder + Anifrolumab 300mg (N=115)	Anifrolumab 150mg + Anifrolumab 300mg (N=69)
Number of subjects with events, n (%)	1 (0.4)	1 (0.9)	1 (0.9)	1 (1.4)
Number of censored subjects, n (%)	258 (224.3)	112 (99.1)	114 (99.1)	68 (60.2)
Exposure years	564.0	222.4	248.2	150.7
EAIR per 100 PY	0.2	0.4	0.4	0.7

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Serious Opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=259)	Placebo Feeder + Placebo LTE (N=113)	Placebo Feeder + Anifrolumab 300mg (N=115)	Anifrolumab 150mg + Anifrolumab 300mg (N=69)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)	1 (0.9)	1 (1.4)
Number of censored subjects, n (%)	259 (225.2)	113 (100.0)	114 (99.1)	68 (60.2)
Exposure years	565.2	223.4	248.2	150.7
EAIR per 100 PY	0.0	0.0	0.4	0.7

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Severe Opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=259)	Placebo Feeder + Placebo LTE (N=113)	Placebo Feeder + Anifrolumab 300mg (N=115)	Anifrolumab 150mg + Anifrolumab 300mg (N=69)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	259 (225.2)	113 (100.0)	115 (100.0)	69 (61.1)
Exposure years	565.2	223.4	249.7	151.2
EAIR per 100 PY	0.0	0.0	0.0	0.0

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Non-Severe Opportunistic infection
Full analysis set

	Anifrolumab 300mg (N=259)	Placebo Feeder + Placebo LTE (N=113)	Placebo Feeder + Anifrolumab 300mg (N=115)	Anifrolumab 150mg + Anifrolumab 300mg (N=69)
Number of subjects with events, n (%)	1 (0.4)	1 (0.9)	1 (0.9)	1 (1.4)
Number of censored subjects, n (%)	258 (224.3)	112 (99.1)	114 (99.1)	68 (60.2)
Exposure years	564.0	222.4	248.2	150.7
EAIR per 100 PY	0.2	0.4	0.4	0.7

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=259)	Placebo Feeder + Placebo LTE (N=113)	Placebo Feeder + Anifrolumab 300mg (N=115)	Anifrolumab 150mg + Anifrolumab 300mg (N=69)
Number of subjects with events, n (%)	16 (6.2)	2 (1.8)	4 (3.5)	0 (0.0)
Number of censored subjects, n (%)	243 (211.3)	111 (98.2)	111 (96.5)	69 (61.1)
Exposure years	549.4	219.7	246.3	151.2
EAIR per 100 PY	2.9	0.9	1.6	0.0

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Serious Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=259)	Placebo Feeder + Placebo LTE (N=113)	Placebo Feeder + Anifrolumab 300mg (N=115)	Anifrolumab 150mg + Anifrolumab 300mg (N=69)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	259 (225.2)	113 (100.0)	115 (100.0)	69 (61.1)
Exposure years	565.2	223.4	249.7	151.2
EAIR per 100 PY	0.0	0.0	0.0	0.0

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Severe Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=259)	Placebo Feeder + Placebo LTE (N=113)	Placebo Feeder + Anifrolumab 300mg (N=115)	Anifrolumab 150mg + Anifrolumab 300mg (N=69)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	259 (225.2)	113 (100.0)	115 (100.0)	69 (61.1)
Exposure years	565.2	223.4	249.7	151.2
EAIR per 100 PY	0.0	0.0	0.0	0.0

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Non-Severe Tuberculosis (including latent TB)
Full analysis set

	Anifrolumab 300mg (N=259)	Placebo Feeder + Placebo LTE (N=113)	Placebo Feeder + Anifrolumab 300mg (N=115)	Anifrolumab 150mg + Anifrolumab 300mg (N=69)
Number of subjects with events, n (%)	16 (6.2)	2 (1.8)	4 (3.5)	0 (0.0)
Number of censored subjects, n (%)	243 (211.3)	111 (98.2)	111 (96.5)	69 (61.1)
Exposure years	549.4	219.7	246.3	151.2
EAIR per 100 PY	2.9	0.9	1.6	0.0

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Vasculitis
Full analysis set

	Anifrolumab 300mg (N=259)	Placebo Feeder + Placebo LTE (N=113)	Placebo Feeder + Anifrolumab 300mg (N=115)	Anifrolumab 150mg + Anifrolumab 300mg (N=69)
Number of subjects with events, n (%)	0 (0.0)	1 (0.9)	1 (0.9)	0 (0.0)
Number of censored subjects, n (%)	259 (225.2)	112 (99.1)	114 (99.1)	69 (61.1)
Exposure years	565.2	222.8	249.0	151.2
EAIR per 100 PY	0.0	0.4	0.4	0.0

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Serious Vasculitis
Full analysis set

	Anifrolumab 300mg (N=259)	Placebo Feeder + Placebo LTE (N=113)	Placebo Feeder + Anifrolumab 300mg (N=115)	Anifrolumab 150mg + Anifrolumab 300mg (N=69)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	259 (225.2)	113 (100.0)	115 (100.0)	69 (61.1)
Exposure years	565.2	223.4	249.7	151.2
EAIR per 100 PY	0.0	0.0	0.0	0.0

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Severe Vasculitis
Full analysis set

	Anifrolumab 300mg (N=259)	Placebo Feeder + Placebo LTE (N=113)	Placebo Feeder + Anifrolumab 300mg (N=115)	Anifrolumab 150mg + Anifrolumab 300mg (N=69)
Number of subjects with events, n (%)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	259 (225.2)	112 (99.1)	115 (100.0)	69 (61.1)
Exposure years	565.2	222.8	249.7	151.2
EAIR per 100 PY	0.0	0.4	0.0	0.0

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.

Anifrolumab (MEDI-546)
D3461C00009 (LTE Study) - Anifrolumab 300mg vs. Placebo population
Summary of time to first Adverse Event of Special Interest (AESI) during study (Study 09) - Non-Severe Vasculitis
Full analysis set

	Anifrolumab 300mg (N=259)	Placebo Feeder + Placebo LTE (N=113)	Placebo Feeder + Anifrolumab 300mg (N=115)	Anifrolumab 150mg + Anifrolumab 300mg (N=69)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)
Number of censored subjects, n (%)	259 (225.2)	113 (100.0)	114 (99.1)	69 (61.1)
Exposure years	565.2	223.4	249.0	151.2
EAIR per 100 PY	0.0	0.0	0.4	0.0

Analysis includes all AE with a date of onset >= day of first dose of investigational in study 09 and <= end of study day in study 09.
The exposure-adjusted incidence rate (EAYR) per 100 patient-years is defined as the number of patients with the specific event divided by the total exposure time in years and then multiplied by 100.
The exposure time is defined as from the date of first administration of investigational product in study 09 to the minimum of date of first event or end of study.